



Wireless spinal cord stimulation - proposed algorithm before implantation

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General Note



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ABSTRACT

Background: We focus on interventional diagnostics and treatment by spinal cord stimulation (SCS) taking place in our workplace. SCS is a financially demanding therapy, so patient selection is considered important. **Methods:** We present a brief summary of the diagnostic interventions used on spinal cord structures that confirm or exclude pain generators in patients with complicated back pain. The indication process also includes psychological, psychiatric, neurological and neurosurgical examinations. **Results:** Our current algorithm is presented, which includes the use of current procedures in the diagnosis and treatment of back pain. In connection with positive diagnostic results, however, spinal therapeutic interventions are included. **Conclusions:** Our evaluation of data focused on patients with failed back surgery syndrome with implanted wireless spinal cord stimulator showed significant improvement of clinical state measured by numerical rating scale after 3, 6, and 9 months.

Key words: failed back surgery syndrome, spinal cord stimulation, neuromodulatory therapy.

1. INTRODUCTION

Spinal cord stimulation (SCS) is used in the treatment of chronic, unmanageable pain arising from various conditions. These include pain in the spine and lower limbs, most often after multiple spinal surgeries, otherwise unmanageable stomach and phantom pain, complex regional pain syndrome, pain syndrome after injury of peripheral nerves or plexus, severe postherpetic neuralgia, medically and operatively unresponsive refractory angina pectoris, and stages III and IV of ischaemic pain in the lower extremities, according to the Fontaine classification.

The method is based on stimulating the spinal cord by gentle electric discharge through electrodes implanted into the epidural space near the spinal cord. We are using wireless system, which differs from fully implanted system mainly in using injectable electrodes without implanted power source. A small, externally wearable rechargeable transmitter provides the energy to power the device wirelessly through the skin. It has been approved in the US by the Food and Drug Administration to deliver pulse rates of up to 10000 Hz (Perryman et al., 2012) but recently it has been restricted only up to 1500 Hz because of legal issue with Nevro company. The stimulation predominantly affects the dorsal roots of spinal cord, with a partial effect in the lateral horn (Rokyta et al., 2012) and prevent the transmission of pain from the point of origin to the brain.

2. INDICATION OF SPINAL CORD STIMULATION

The indication process for percutaneous spinal stimulation for a potential candidate is a medical and communicative challenge. The most common indication for SCS are patients who have undergone surgery or multiple spinal operations without the expected outcome and are not recommended for further surgical treatment due to unproven structural changes in the spine, a condition referred to as a failed back surgery syndrome (FBSS). The patients still suffers from pain, and from poor quality of life, feels handicapped and unable to perform normal activities, often consuming high doses of painkillers. In cases where the analgesic regimen includes opioids, this brings about the standard adverse effects of these drugs, such as constipation, urinary problems, cognitive impairment, sleep disturbance, and sexual function disorders. With the lack of movement due to pain, obesity is also common. The culmination of which is considerable frustration and mental disorders in most patients. After exhausting the possibilities of conservative therapy for their chronic pain, these patients are referred to specialists in neuromodulatory treatment. At this stage, chronic back and lower limb pain is already fully developed with a psychoactive disorder, depression. In such a patient, it is initially very important to distinguish the real proportion of neuropathic pain in the entire complex of symptoms. If this dominates throughout the FBSS complex, further steps must be taken to examine the patient in detail with respect to the pain itself, allowing a definitive determination of the suitability of indicating treatment with a spinal cord stimulator and percutaneous spinal cord stimulation.

An algorithm was developed within our workplace, whereby the patient is indicated for neuromodulatory treatment through spinal neurostimulation based on internationally recommended guidelines as well as guidelines within the Slovak Republic. The sequencing of this algorithm is the outcome of the collection of many years of work experience from neuromodulation centres over the world. At the same time, we implemented algorithms based on our own experience. These internal processes are structurally monitored in the framework of officially registered and ethical commission-approved studies.

The current algorithm of steps indicating neuromodulatory treatment for a patient is as follows:

1. The patient is closely examined by a clinician after surgery, or spinal cord surgery with insufficient outcome of surgical and conservative treatment, and thoroughly evaluated by magnetic resonance imaging. The aim is to determine the real proportion

- of pain and psychological superstructure while excluding the possibility of further surgical treatment. At this stage, we normally require a psychological and psychiatric examination of the patient and consultation with a spinal surgeon.
2. If pain is a dominant component for the patient, while complicated psychological superstructure, severe psychiatric illness, or inappropriate expectation from neuromodulatory treatment have been excluded, the patient is then referred for a detailed differentiation of the back pain itself with/without radiation to the extremities.
 3. The duration of pain in the patient is evaluated (the optimal duration for indication is no more than 2 years, acceptable within five years, and requiring an individual assessment for over 5 years). Furthermore, the percentage of back pain is evaluated along with pain in the limbs (generally pain in the limbs is more responsive to stimulation, although high frequency stimulators show promising results even in the case of axial back pain dominance). Other monitored parameters include pain intensity assessed by the scoring system Numerical Pain Scale (Numerical Rating Scale, NRS0-10). Furthermore, the Oswestry Disability Index.
 4. In the prevalence of an axial component to the pain in the area of the lumbar and sacral spine, facet joint testing (Figure 1) is normally performed in correlation with a clinical examination (Rapčan, 2009; Schwarzer, 1994). With a positive result according to the Spine Intervention Society (SIS) standards (Bogduk, 2004; 2009), we propose radiofrequency denervation of facet joints, which is performed with patient consent according to SIS standards (Bogduk, 2009).

Figure 1. Facet joints testing. Deposition of needles in "tunnel view" in "Scottie dog".

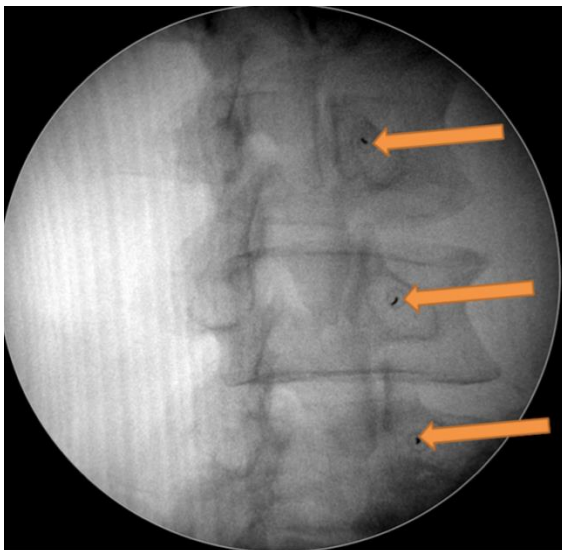
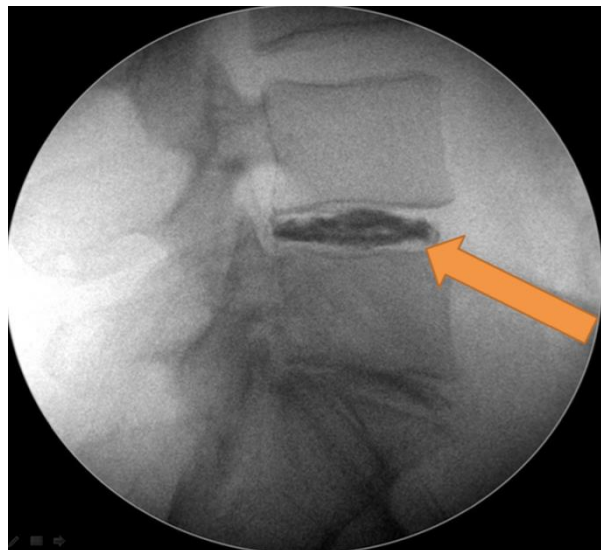


Figure 2. Discography (testing the disc for pain at increasing pressure of contrast medium, lateral projection - diffusion of the contrast medium in the L4/5 disc).



5. In cases of clinical suspicion of discogenic pain, we perform a discography (Figure 2). With a positive result and fulfilment of the indication criteria, treatment is carried out on the vertebral disc with a combination of radiofrequency treatment and manual decompression - Disc FX (Aprill and Bogduk, 2014; Hellinger, 2014).
6. In cases where a pathological process is suspected in the epidural space (such as postoperative fibrosis, inflammation, and lateral recession stenosis), the patient is referred for an epidural examination (Figure 3) with the possibility of peroperative treatment intervention in the epidural space (radiofrequency or laser disruption of adhesions, targeted drug delivery) (Bosscher et al., 2012; Di Donato et al., 2010; Ruetten et al., 2004). Dorsal ganglion pulse radiotherapy is indicated if radicular pain in the lower limbs persists despite epidural surgery. This can be performed transforaminally or, more frequently, with special navigable instruments, entering via the hiatus sacralis and navigating to the corresponding dorsal ganglia (Figure 4). Pulsed radiofrequency treatment may have a short- or long-term therapeutic effect on chronic radicular pain based on neuromodulatory action (Abejón et al., 2003). At the same time, in cases of a short-term yet significant positive effect of pulsed radiofrequency treatment, we believe it can provide positive information regarding the effect of neuromodulatory treatment on reducing the intensity of the patient's pain as well as the further planning of neuromodulatory treatment. In other words, a patient who responds to pulsed

radiofrequency treatment with a short-term pain-reduction effect should be a suitable candidate for indicating to a spinal cord stimulator. We would like to verify this hypothesis by an independent study.

7. If the patient does not experience effective improvement after the above-mentioned therapeutic interventions and the patient responds positively but only briefly to the application of pulsed radiofrequency treatment, the patient is considered to be a suitable candidate for the implantation of a trial spinal stimulator electrode (Figure 5, 6). In our workplace, a patient who does not have a radicular component of pain of at least 50% total pain is not a suitable candidate for implantation of the spinal stimulator. Controversial past results of spinal cord stimulation with respect to "low back pain" are also too inconsistent with our own clinical experience to be sufficiently persuasive for the indication of any type of pulse generator for spinal cord stimulation.

Figure 3. Epiduroscope in the sacral channel, lateral projection. Front epidural space, S1 channel. The arrow points to the tip of the catheter, from where the contrast increases.

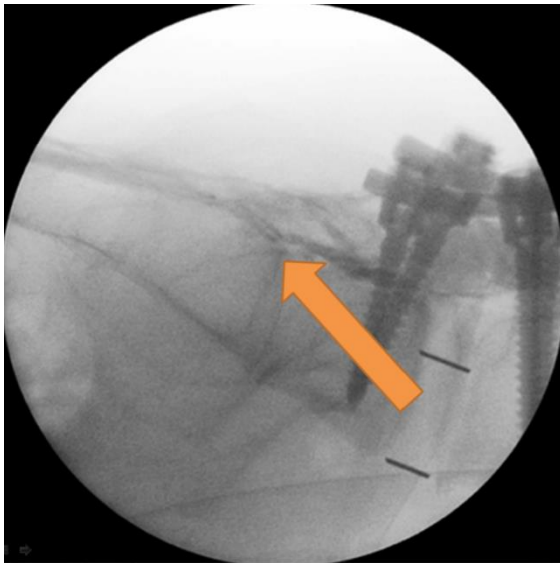


Figure 4. Epinavigator in the L5 dorsal root ganglion area on the right, foramen L5/S1.

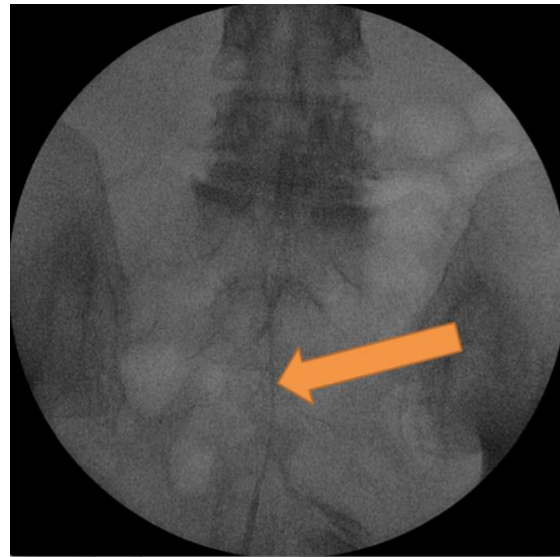


Figure 5. SCS electrode in the epidural space, AP projection, positioned paramedial on the right.

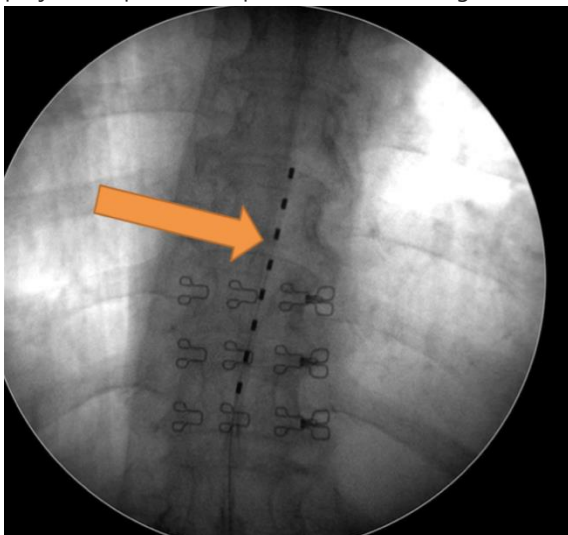
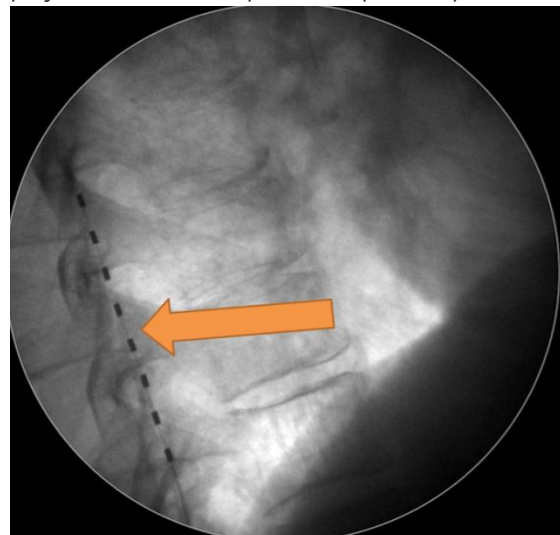


Figure 6. SCS electrode in the epidural space, lateral projection, location in posterior epidural space.



3. OUR EXPERIENCE FROM THE SPINAL CORD STIMULATION IMPLANTATION

Despite the high cost of wireless spinal cord stimulation implantation, from September 2017 to November 2019 this treatment was applied based on the pain sensation to 21 patients (10 males and 11 females) with FBSS. Patients had adjusted high frequency (7 patients) or burst stimulation (12 patients) program and their conditions were checked after six, nine and 12 months (Figure 7). Two patients were non-responders for stimulation treatment. The parameters of pain distribution in patients and SPS are given in Table 1. We had detected significant improvement of clinical state measured by numerical rating scale (or numerical pain scale) in 3, 6, and 9 months follow-up.

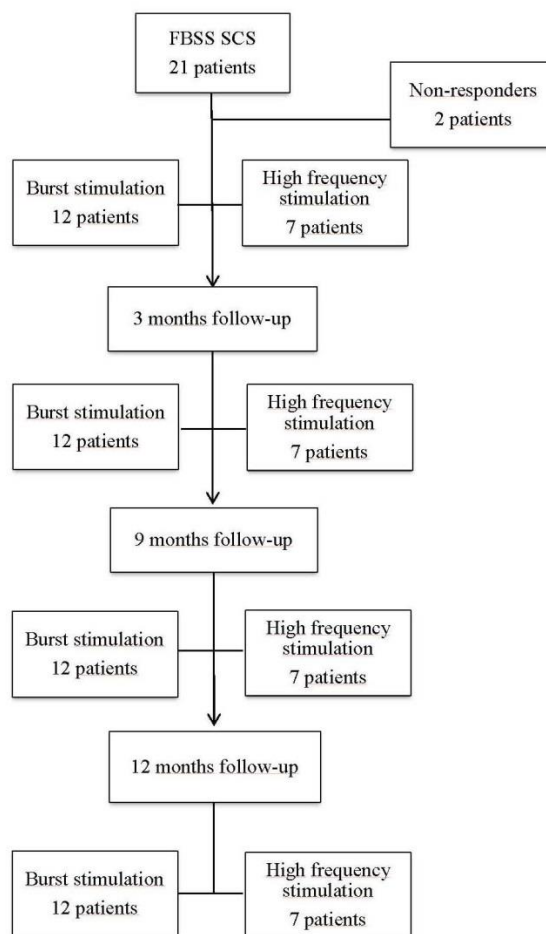


Figure 7: Flow chart of the patient enrolment and follow up.

Table 1: Data on spinal cord stimulation and pain distribution in patients.

Parameter	N	Parameter	N	Parameter	N
Frequency (Hz)		Amplitude (mA)		Pain distribution	
500	11	1	2	left leg	4
1000	4	2	3	right leg	4
10000	4	2.5	1	both legs	3
		3.5	3	non-responder	2
		4	2		
		5	3		
		5.7	1		
		8	1		

Table 2: Evaluation of pain intensity in patients before and 3-, 6- and 9-month after implementation SCS by the Numerical Pain Scale (NRS).

Time period	NRS (mean)	SD	CI 95%	p-value
before procedure	8.71	1.16	–	–
3 months	5.24	2.66	2.01 -4.93	0.001
6 months	5.59	2.58	1.7 -4.54	0.001
9 months	5.69	2.53	1.41 -4.62	0.001

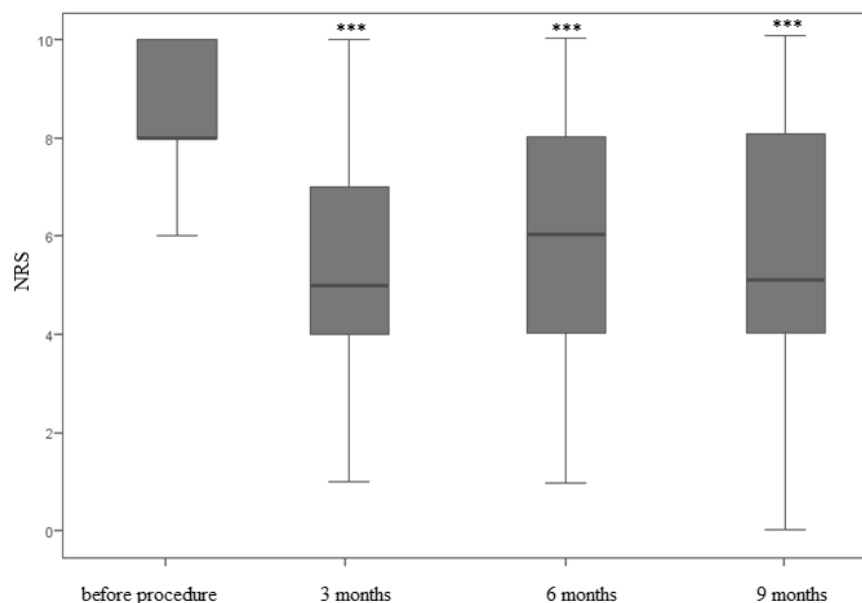


Figure 8: Graphical representation of statistical numerical pain scale evaluation in patients before and after implementation of SCS. Statistically significant differences compared to control (before treatment) at ***p < 0.001).

4. DISCUSSION

The long-term efficacy and low risk of the SCS treatment method has been confirmed (Cameron et al., 2004). This treatment method has had a positive effect on refractory angina pectoris, severe ischaemic pain of the lower limbs, severe peripheral vascular disease, peripheral neuropathic pain, chronic back pain with lumbosacral sciatica syndrome, and chronic neuropathic pain. In many cases, SCS therapy in the patients with chronic neuropathic pain after spinal surgery have shown a significant improvement in patients' clinical condition and their subsequent return to active life. Some studies also point to an improvement in axial pain in the spinal cord area, but these results are considered controversial, as the studies were sponsored by SCS manufacturers (Al-Kaisy et al., 2014). Success of SCS implantation is depended primarily on good patient selection and a good quality device with various programming options. Using wireless systems is bringing some differences in comparison with traditional implantable technologies. The advantage of wireless technology is less implanted material into the patient's body and a broad spectrum of programming options. The disadvantage is some technical instability of the product and more demanding type of the implantation technique. The total length of the wireless device including active leads and a receiver part is constant. When planning your implantation skin entry and epidural space entry with the aim to cover Th 9 and Th 10 vertebral levels with active leads you are restricted with your entries according to the length of the wireless system and the distance between the lead part and the receiver part. The receiver part has to be out of the epidural space, more or less subcutaneously, being able to receive signals from the external transmitter. In case of tall or obese patients system is difficult or impossible to implant for the functional use because the receiver part can be kinked or too deep. The

receiver part is very fragile and for example in case of caudal dislocation of the system, the receiver part can be easily damaged because of kinking and subsequently the system is permanently non-functional and requires reimplantation. Sometimes the subcutaneous receiver part can push itself through the skin and cause something similar to IPG pain. It is a nice and novel idea but in our opinion needs a significant technical improvement to become equally reliable as traditional IPG driven systems.

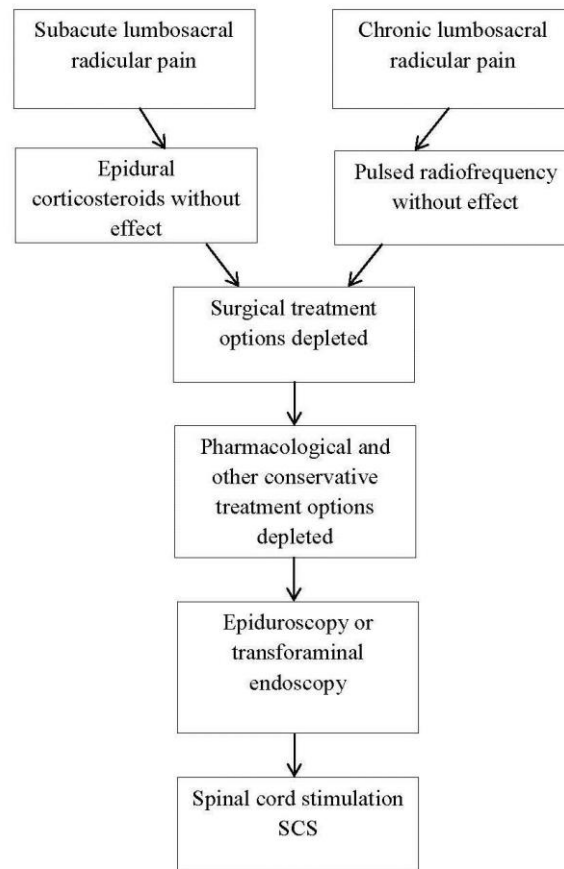


Figure 9: Schematic illustration of the algorithm for implantation of the spinal cord stimulator.

Using the algorithm described in scheme on Figure 9, we have succeeded in reducing the number of patients indicated for spinal cord stimulator, confirmed by counting the number of stimulators implanted over a one-year interval. We also believe that we have been able to significantly improve selection for spinal cord stimulators and thereby ensure their efficient use when compared to the past. This hypothesis is still in the hypothetical stage and requires a structured analysis of our patients' parameters from the introduction of the algorithm and comparison with patient parameters prior to its implementation.

The aim of SCS is to cover at least 80% (ideally 100%) of the painful area acting as the source of paraesthesia and achieve a reduction in pain of at least 50% together with a significant improvement in quality of life over 1-2 years of use (Buyten et al., 2010). The great advantage of stimulatory systems is their reversibility and the application of electrical currents with a limitation in the use of analgesics. Over time, this would ideally lead to the complete substitution of analgesic pharmacotherapy with neurostimulation therapy (Kozák et al., 2007).

5. CONCLUSION

Spinal cord stimulation is the most accepted method of choice for patients with FBSS. The expected effect of the spinal stimulator after implantation should be a significant reduction in pain, by at least half, with a simultaneous decrease in analgesic consumption. The optimal therapeutic effect should be achieved without complications over the course of 6 to 8 weeks. There is no dependence on SCS and no significant opioid-like side effects such as sedation, constipation, urinary disorders or hormonal disorders during use. SCS acts locally and has no undesirable effects on the body as a whole. Unfortunately, the number of patients who have a real benefit from this method is not sufficient in our own observations in the Slovak Republic. We see a great deal of redundancy in poorly-followed selection processes, where patients who do not meet the criteria for this method become candidates for a SCS.

Reserves can also be seen during the duration of the trial, which varies between 7 and 14 days in our country. We believe it would be better to extend the trial to 21 to 30 days in order to eliminate the "placebo" effect. The price could not be necessarily problematic as the available data show that, despite the relatively high initial cost, neuromodulation becomes cost effective over a period of 2 to 3 years (Kemler et al., 2008).

Informed Consent: Written and oral informed consent was obtained from all individual participants included in the study. Additional informed consent was obtained from all individual participants for whom identifying information is included in this manuscript.

Conflict of Interest: The authors declare that they have no conflict of interest.

Funding: This research received no external funding.

Ethical approval for human: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards (9N/2015).

Ethical approval

The study was approved by the Medical Ethics Committee of the Faculty of Medicine, Pavol Jozef Šafárik University in Košice (9N/2015).

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