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Case Report

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Outcomes of ECAP-controlled closed-loop spinal cord stimulation therapy in JAPAN: how to increase patient satisfaction with spinal cord stimulation

Abstract

Objective: Orthopedic surgeons commonly encounter patients with low back pain and leg pain. Despite conservative treatment, which may involve the use of weak opioids or NSAIDs, some patients do not experience improvement and may require increased dosages, contributing to concerns about opioid overuse overseas. Spinal cord stimulation (SCS) therapy, which can be trialed without surgical intervention, offers a potential treatment option. We evaluated Inceptiv (Medtronic), a generator that allows new stimulation settings using evoked compound action potentials (ECAPs)-controlled Closed-Loop technology.

Methods: We evaluated six patients (four females, two males) who underwent implantation of the Inceptiv generator for SCS therapy. The average walking time (seconds) during a 2.1-meter walk and pain assessment using the Numerical Rating Scale (NRS) were conducted. Patient satisfaction was assessed using a 5-point scale: very satisfied (5), somewhat satisfied (4), neutral (3), somewhat dissatisfied (2), very dissatisfied. (1).

Results: The average walking time improved from 11.8 seconds to 6.6 seconds, and the NRS score decreased from 7.6 to 4.2. Patient satisfaction was high, with four patients being very satisfied (5), one somewhat satisfied (4), and one neutral (3).

Discussion: SCS therapy with Closed-Loop technology using the Inceptiv generator offers the potential to adjust electrical stimulation to minimize discomfort in daily activities and provide pain relief. It is considered a new treatment option for patients with common orthopedic conditions such as thoracolumbar compression fractures and lumbar spinal stenosis who suffer from chronic refractory pain in routine clinical practice.

Keywords: spinal cord stimulation, closed-loop, ECAP (evoked compound action potentials), inceptive (Medtronic)

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Abbreviations: SCS, spinal cord stimulation; ECAPs, evoked compound action potentials; NRS, numerical rating scale; DTM, differential target multiplexed

Case presentation

An 81-year-old female presented with complaints of low back pain and bilateral leg pain. Her medical history included hypertension, and she previously managed her activities of daily living with the assistance of a cane. She had been diagnosed with lumbar spinal stenosis at a nearby orthopedic clinic and had undergone treatment with oral medications and physical therapy. She experienced intermittent claudication, requiring rest every 100 meters due to pain, and relied on a cane or handrail for mobility. At our clinic, she underwent a trial of spinal cord stimulation (SCS) therapy, followed by the implantation of the Inceptiv generator (Medtronic). During the trial, conventional stimulation settings were used, with one low-frequency stimulation (base signal: starting at 50Hz frequency and 200 µs pulse width, from 70% of the perception threshold) and three high-frequency stimulations (prime signal: starting at 300Hz frequency and 170µs pulse width, from 65% of the perception threshold), totaling four signals simultaneously delivered using the) Workflow. While the patient showed improvement in symptoms during the trial, she experienced discomfort with the electrical stimulation during changes in position, lying down, getting up, and raising her shoulders. During rehabilitation, there were instances where the electrical stimulation became uncomfortably intense depending on the movement; however, after the implantation using Closed-Loop with ECAP, uncomfortable sensations disappeared, and activities of daily living improved Figure 1. The Numerical Rating Scale (NRS) improved from 8 to 2, and the average walking time for a 2.1-meter walk improved from 9.74 seconds to 2.96 seconds. After the Inceptiv implantation, satisfaction was rated as very satisfied 5 out of 5).

Objective

SCS therapy has been utilized in orthopedic conservative treatment for the management of low back pain and leg pain. However, conventional SCS therapy settings have sometimes resulted in discomfort due to excessive stimulation during daily activities and rehabilitation, limiting the effectiveness of treatment. Therefore, achieving satisfactory stimulation levels for patients, especially when increasing the charge of stimulation, has been challenging, leading to activity restrictions and inadequate pain relief. In recent years, the concept of Closed-Loop, which allows real-time adjustment of electrical stimulation based on biofeedback signals generated by the spinal cord, has gained attention worldwide as a solution to this issue. With the introduction of the new rechargeable neurostimulation device, Inceptiv (Medtronic), incorporating Closed-Loop stimulation settings based on evoked compound action potentials (ECAPs) Figure 2, there is potential for improved clinical outcomes and patient satisfaction in SCS therapy. We examined what measures are necessary to enhance clinical outcomes and patient satisfaction in SCS therapy with Closed-Loop, which was treated in our facility.

Methods

We included six patients (four females, two males) with chronic refractory low back pain and leg pain who initially showed symptom improvement during a trial of SCS therapy but experienced symptom recurrence thereafter. These patients underwent implantation of the Inceptiv generator (Medtronic). Evaluation parameters included the average walking time (seconds) during a 2.1-meter walk and pain assessment using the Numerical Rating Scale (NRS). Patient satisfaction was rated on a 5-point scale: very satisfied (5), somewhat satisfied (4), neutral (3), somewhat dissatisfied (2), very dissatisfied (1). Patients with pain persisting for over two months and not responding to medication or nerve blocks were classified as having chronic refractory pain. A statistical t-test was performed, and $P < 0.01$ was considered a significant difference.

Results

The average walking time significant improved from 11.8 seconds to 6.6 seconds, and the NRS score significant decreased from 7.6 to 4.2 Figure 3. Patient satisfaction was high, with four patients being very satisfied (5), one somewhat satisfied (4), and one neutral (3). Following the implantation of Inceptiv, uncomfortable electrical stimulation did not occur in 5 out of 6 patients.

Discussion

Spinal cord stimulation (SCS) therapy involves delivering a low-level electrical current to the posterior columns of the spinal cord via electrodes called leads placed in the epidural space. This therapy aims to reduce pain and improve blood flow. SCS therapy requires collaboration among orthopedic surgeons for examination and appropriate diagnosis, anesthesiologists for procedural expertise, and rehabilitation physicians for specialized evaluation and training. Therefore, interdisciplinary coordination is crucial. While it is important to minimize procedural time, careful adjustment of stimulation settings post-implantation is necessary. It is essential to ensure proper electrode placement in the posterior columns and verify electrode alignment to optimize therapy effectiveness. Evaluation of SCS therapy often focuses on pain and daily activities, but comprehensive assessment may better capture patient satisfaction. Indeed, improvements in posture, walking time, and daily activities, even in the absence of pain relief, indicate successful outcomes. Therefore, a multifaceted approach to evaluation is recommended to fully assess patient satisfaction and treatment effectiveness.[1]

The surgical procedure is performed under local anesthesia with the patient in a prone position, while adjusting electrical stimulation from an external tablet device. During the procedure, the lead (electrode) is placed in the epidural space while confirming paresthesia, with the patient conversing to provide feedback. The new implantable device, Inceptiv by Medtronic, compared to the conventional Intellis, is MRI-compatible up to 3 Tesla and has an extended battery life from 9 to 15 years. With conventional stimulation settings, the distance between the lead and the spinal cord may vary with changes in posture and activity, leading to discomfort or unnecessary stimulation. Patients may fear uncomfortable stimulation, leading to treatment interruption or activity restriction. The new Inceptiv generator utilizes Closed-Loop technology, responding to electrical stimulation and measuring real-time biofeedback signals from the spinal cord to adjust stimulation levels. ECAPs are induced by stimulation electrodes and measured by recording electrodes after a certain period. ECAPs are generated with 50Hz stimulation, detected by electrodes, and used to adjust stimulation output. Using electrodes at both ends of the lead, one acts as the stimulation electrode, and the other as the sensing electrode, measuring the potential transmitted to the spinal cord. Neural responses to stimulation can be automatically adjusted within predefined thresholds. These thresholds can be customized for each patient Figure 1.

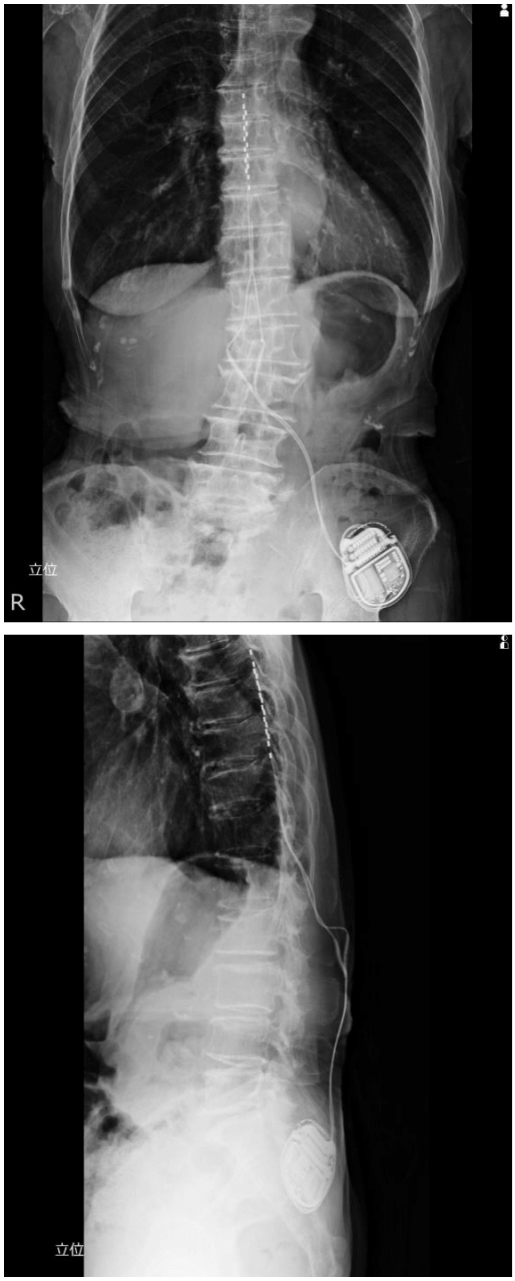

Figure 1 X-ray images (frontal and lateral views) after the implantation of Inceptiv.

Reports indicate that the pain relief effects for low back pain and leg pain persist for up to 12 months when using Closed-Loop technology.[2] Additionally, when compared to conventional Open-Loop technology, where stimulation settings are not adjusted in real-time, more participants experienced over 50% pain reduction with Closed-Loop. Furthermore, at 36 months, sustained pain relief was observed predominantly in the Closed-Loop group.[3] While SCS therapy has traditionally been applied to patients with chronic refractory pain, such as those with post-spinal surgery syndrome or peripheral vascular disorders, our facility actively employs it for patients with orthopedic

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conditions such as thoracolumbar compression fractures and lumbar spinal stenosis causing low back pain and leg pain. Compression fractures often lead to chronic and debilitating low back pain, significantly affecting daily life. Therefore, for patients with chronic refractory pain persisting for over two months without improvement from medication or nerve blocks, early intervention with SCS therapy is pursued. This intervention not only alleviates pain but also improves walking time, posture, and ease of movement, including turning over and getting up from bed. In addition to SCS therapy, rehabilitation is concurrently utilized, emphasizing the importance of mobility during hospitalization. At our clinic, patients are encouraged to engage in self-exercise, such as walking in the corridor and performing bending and stretching exercises while holding onto handrails (Figure 2-Figure 3).[4]

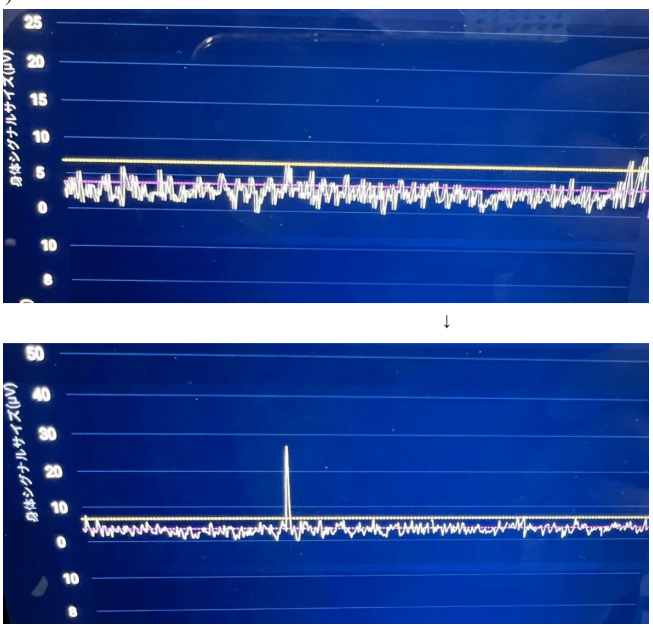

Figure 2 Stimulation by ECAPs during the implantation of Inceptiv. ECAPs increase when changing body positions such as raising the upper limbs and are adjusted to be within the threshold.

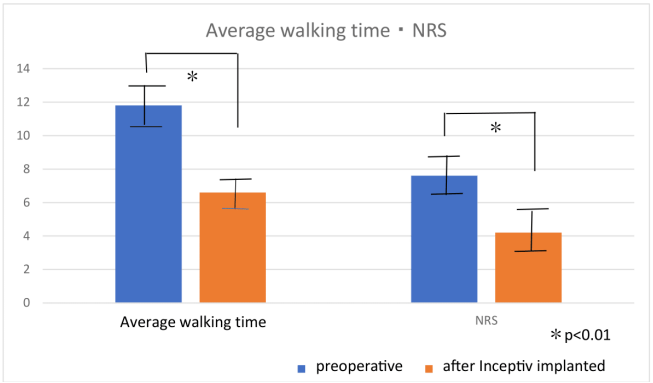

Figure 3 Average walking time and NRS before and after Inceptiv implantation.

Ahmed J Awad[5] reported in a retrospective study from 2013 to 2020 that SCS therapy for intermittent claudication due to lumbar spinal stenosis, regardless of whether spinal surgery was performed or not, as part of conservative therapy, resulted in sustained improvement of intermittent claudication for at least two years. SCS therapy has been increasingly utilized in the realm of orthopedic conservative management for low back pain and leg pain. Thermography showed an increase in body surface temperature of approximately 6°C in SCS.[6]

To enhance patient satisfaction, SCS therapy is considered a suitable option for patients who are unwilling or unable to undergo surgery due to risks, as well as those who do not respond to medication or nerve block therapy. It serves as a form of conservative treatment rather than spinal surgery. The ability to conduct a puncture trial is the greatest advantage, not available in other surgical treatments. Additionally, since it can be performed under local anesthesia, it is relatively safe with minimal invasiveness even in the presence of underlying conditions. Patients are required to stay in the hospital for at least one week and undergo thorough multidimensional evaluation and examination, followed by training by rehabilitation specialists. Also, it is important to confirm whether charging is possible during the implantation of the device. Therefore, at our clinic, a puncture trial is always conducted, and device implantation is not performed initially. In the future, the use of electrical stimulation with Closed-Loop technology in SCS therapy holds the promise of adjusting unpleasant stimuli in daily life. It is important to consider not only pain but also various symptoms that have improved and evaluate patient satisfaction from a multidimensional perspective. The use of Inceptiv with Closed-Loop technology in SCS therapy is considered a new treatment option for patients with chronic refractory pain from common orthopedic conditions seen in daily clinical practice, such as thoracolumbar compression fractures and lumbar spinal stenosis Figure 4-Figure 5.

Figure 4 The procedure during surgery. The patient is placed prone while the electrodes are placed under local anesthesia, guided by fluoroscopy (front and side views). Saline is used for subdural insertion using the resistance loss method, and the electrodes are placed on the dorsal column of the spinal cord. Electrical stimulation is applied from an external tablet to confirm paresthesia. Charging is cordless for ease of use.

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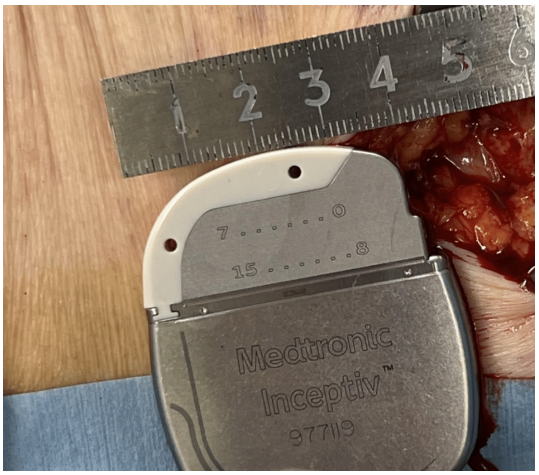

Figure 5 Implanting the Inceptiv generator during surgery.

Acknowledgments

None.

Conflicts of interest

The author declares that there is no conflicts of interest.

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