Interventional Pain Management Reports
ISSN 2575-9841 Volume 2, Number 5, pp167-171

Case Report

Wireless High Frequency Spinal Cord Stimulation for the Treatment of Post-Herpetic Ocular Neuralgia: A Case Report

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Background: High frequency wireless Spinal Cord Stimulation (SCS) at the C1-C2 vertebral levels provides analgesia for the treatment of refractory ocular pain on the left side secondary to post-herpetic neuralgia.

Objective: To assess analgesic effects of minimally invasive wireless neuromodulation in the treatment of chronic pain due to post-herpetic neuralgia.

Study Design: This observational, prospective case report was designed to illustrate the effectiveness of relieving chronic, intractable pain utilizing wireless spinal cord stimulation at multiple frequencies for the treatment of post-herpetic neuralgia.

Setting: Private Practice Interventional Pain Clinic.

Methods: This is a single case study of a 62-year-old patient who experienced an episode of shingles with rash over the left frontal and lateral ocular margin. After the rash subsided, the patient began suffering from severe pain in the left eye. The patient was placed on a 10-day course of valacyclovir, gabapentin, which was discontinued secondary to sedation intolerance, pregabalin titrated to 300 mg/day and oxycodone, all of which were ineffective in relieving the pain. The patient received a stellate ganglion block injection on 6 occasions, experiencing pain relief of only up to one-day after each injection. Stellate ganglion radiofrequency ablation was also unsuccessful. With original Visual Analog Scale (VAS) score of 9/10, inability to sleep and incapacity to perform activities of daily living (ADLs), the patient had Stimwave Freedom wireless stimulators placed sequentially at the C1-C2 vertebral levels.

Results: Programming at low frequencies from 40-120 Hz was unsuccessful in reducing left eye pain. Stimulation was increased to high frequency on the Stimwave SurgeTM adjustable waveform, and within 12 hours, the patient noted significant decrease in pain. At 3 days post-procedure, the patient's VAS score was 1/10. The patient had permanent placement of the devices, and at 8-month follow-up, VAS scores were 0-2/10, and the patient's mood, sleep and ability to perform ADLs all improved substantially.

Limitations: The study was limited by the novelty of the device. Although the doctor who implanted the device is very experienced, more cases of the use of the wireless Stimwave Freedom apparatus are necessary to establish its long-term effectiveness and safety. More clinical trials investigating the utilization of multiple frequencies are also required.

Conclusions: Epidural placement of 2, wireless sequentially placed octopolar stimulators with a minimally invasive technique at high frequency stimulation was safe and effective.

Key words: post-herpetic neuralgia, ocular, spinal cord stimulation, wireless, shingles, trigeminal nerve, high frequency

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For the last 4 decades, Spinal Cord Stimulation (SCS) has been used to treat several pain syndromes. Studies have proven that SCS has the ability to relieve pain, improve disability, and increase functionality (1-4). Conventional SCS, however, has limitations and many adverse effects associated with it, even though medical device companies have made remarkable progress in the technology of their SCS devices. Approximately 30-40% of patients who receive conventional SCS experience hardware-related or biologic complications, and essentially 80% of these require a revision in device placement (5). In this case report, it is demonstrated that the use of the Stimwave Freedom wireless, minimally invasive SCS stimulation system at higher frequencies and pulse rates, reduces pain intensity, decreases disability, and increases functionality.

STIMWAVE WIRELESS FREEDOM-8A SCS SYSTEM

The Stimwave wireless Freedom-8A SCS System reported here is a wireless neuromodulation technology that includes fully programmable octopolar stimulators, the electrodes of which are 3 mm in diameter with 4 mm in inter-electrode spacing. In addition to the electrodes, the stimulator contains embedded electronics, and a miniature receiver is mated into the inner lumen of the stimulator body to provide energy to the device. A small, external, rechargeable transmitter, worn by the subject over 1 layer of clothing is used to send wireless energy to the implanted receiver, thus eliminating the unnecessary implant components and the related complications of the traditional SCS apparatus, which utilizes an implanted pulse generator (IPG) and other bulky connectors and extension elements, which have been shown to cause up to 40% reoperation rate (5). Programmed by the medical professional to send the desired stimulation parameters through a wearable fabric RF transmitting antenna, the external pulse generator wirelessly transfers power and stimulation commands to the implanted stimulator with radiofrequency energy of 915 MHz.

This novel, minimally invasive technology has the capability to provide a wide spectrum of stimulation parameters for clinical applications which include amplitude: 1-24 mA, pulse width: 10-1000 μs, and frequency: 5-10,000 Hz. Importantly, the wireless system is implanted in one brief procedure with a very small incision and the use of a Touhy needle to place the electrode array attached to the stimulator into the epidural space. The shorter operating suite time and minimally invasive procedure performed with local anesthetic, results in less strain being placed on the patient, a decreased risk of infections, and less pain than that of going through the implantation of bulky materials used in conventional SCS devices. The healing time for the wireless SCS procedure is also considerably decreased relative to the implantation of conventional SCS devices.

CASE REPORT

The 62-year-old patient with no medical history of headache, migraine, glaucoma or immunodeficiency presented with the chief complaint of severe burning, lancinating chronic pain in the left eye following a case of shingles. On the Visual Analog Scale (VAS), the patient reported a pain intensity of 9 out of 10, and also stated that the pain was completely disabling, resulting in the inability to sleep or perform any activities of daily living (ADLs). The rash associated with the episode of shingles had previously covered the left frontal and lateral ocular margin.

Prior to seeking consultation for SCS treatment for the pain, the patient's Primary Care physician prescribed a 10-day course of oral valacyclovir. Ophthalmology evaluation revealed no intraocular abnormalities, no uveitis and the pressure was normal. The patient was also prescribed gabapentin, which was discontinued because the patient could not tolerate it secondary to sedation, pregabalin titrated to 300 mg/day and oxycodone, none of which gave the patient any relief from pain. Capsaicin cream was also ineffective, and the Qutenza patch is not indicated near the eye and was not prescribed. The patient was evaluated at the Mayo Clinic in Jacksonville, FL, USA, and underwent stellate ganglion block 6 times with minimal, short-term, up to one-day benefit after each injection. Finally, the patient endured a stellate ganglion radiofrequency ablation trial without success.

When the patient presented to the interventional pain management physician, an MRI of the cervical spine revealed only age-appropriate degenerative

disc disease and mild facet disease. In addition, no herniated nucleus pulposus, root compression or stenosis was noted. The patient was then deemed a viable candidate for a Stimwave SCS trial, especially due to the need for future recurring MRI examinations.

PROCEDURE

Under strict aseptic conditions, the patient was lightly sedated and injected with lignocaine. Two octopolar wireless stimulators were placed sequentially in the epidural space, one on the left side, 1-3 mm lateral and posterior to the midline and one distal, spanning the C1-C2 vertebral levels (Fig. 1). The position of the stimulators was confirmed on multiple fluoroscopic views, and the devices were subsequently anchored to the interspinous ligament to prevent migration. The patient tolerated the procedure well, and there were no surgical complications.

During the procedure, programming at low frequencies (tonic stimulation) from 40-120 Hz was unsuccessful in reducing the patient's left eye pain. The stimulation was then changed to high frequency, and within 12 hours, the patient reported significant reduction in pain. The procedure probably works by stimulating the C1-C3 afferents and the fifth cranial nerve, otherwise known as the trigeminal nerve. The trigeminal nerve senses pain in the facial area including ocular pain through the V1 branch (ophthalmic branch). The mechanism of action can be explained by the gate control theory of pain put forward by Melzack and Wall (6,7) in 1965, which involves the dorsal horns in the spinal cord that inhibit or facilitate transmission of pain signals from the body to the brain because of the diameter of the active nerves and the dynamic processes of the brain (6). According to the theory, the gates are open when substantia gelatinosa cells, which cap the apex of the posterior grey

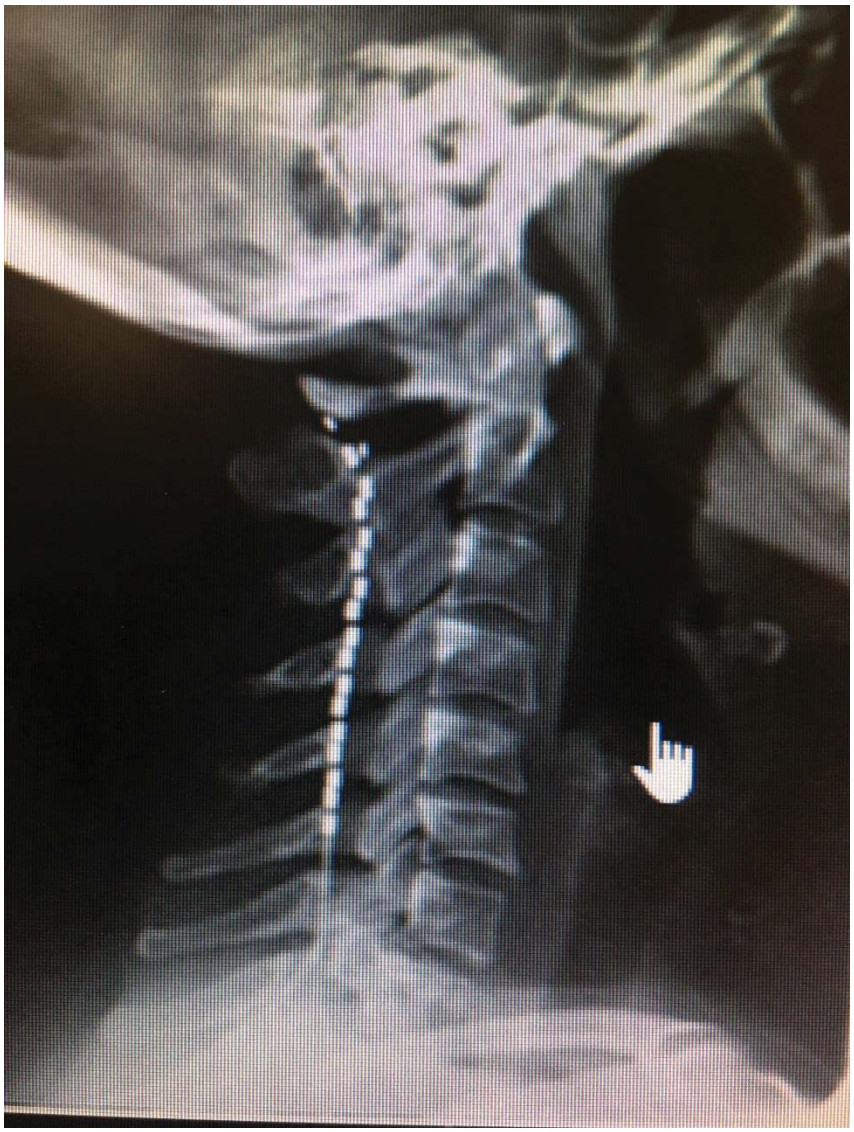

Fig. 1. Lateral view of stimulators placed near spinal cord in cervical area.

column (one of the 3 grey columns in the spinal cord), are inhibited as the cells allow nociceptive stimulation to be passed on to the central nervous system. The gates are closed when substantia gelatinosa cells are excited (7). When the gates are open, the perception of pain is amplified significantly (7). With stimulation of the C1-C3 afferents and the trigeminal complex, which includes the spinal nucleus of cranial nerve V, main sensory nucleus, trigeminal ganglion and the mesencephalic nucleus, the gates are closed and the ocular and/or facial pain is reduced.

POST-OPERATIVE EVALUATION

VAS score before stimulation was 9 out of 10. After 3 days, the patient's VAS score decreased to 1 out of 10, and it remained at this level throughout the 7-day trial period, indicating marked reduction in pain intensity. The patient then underwent permanent placement of the stimulators, which yielded similar results. Furthermore, the patient discontinued all opioid medications and pregabalin, and at 8-month follow-up, reported VAS scores of 0-2/10. The patient also stated that the ability to perform all ADLs increased greatly, and the patient's mood and quality of sleep had improved significantly. The patient did not experience any adverse events.

DISCUSSION

This case report demonstrates that the Stimwave wireless Freedom-8A SCS System has the capability to reduce pain, increase functionality, and decrease disability in post-herpetic neuralgia of the eye with no complications or side effects. Other clinical experience with HF SCS systems has shown that gaining analgesia in patients with neuropathic pain, especially chronic, refractory back and leg pain, is effective (3,8,9). Here, HF SCS stimulation provided paresthesia-free analgesia and seems to be paresthesia independent. Additionally, after 8 months, the patient still has sustainable analgesia. The wireless neuromodulation does not utilize an implantable pulse generator or additional wiring and extension cables, so the patient had no implant-related complications. The implantation procedure requires only a small incision because it is percutaneous and minimally invasive, to place the electrodes. No additional implant is needed for therapy, thus lowering costs of surgery. Furthermore, there is less post-operative pain than conventional SCS therapy with fewer adverse events, and it provides comfort as well as better cosmetic results.

SUMMARY AND PERSPECTIVE

Wireless HF SCS stimulation proves to be as good as or even better than conventional SCS for post-herpetic ocular neuralgia, and high frequency stimulation did not result in any adverse events. There is always capacity for improvement in the methods and technology applied to relieve chronic, refractory neuropathic pain, but wireless HF SCS stimulation and minimally invasive procedures are actions toward this goal. Additional, larger studies will be needed to establish the safety and efficacy of this wireless HF SCS neuromodulation method.

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