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Case Report

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A novel wireless minimally invasive neuromodulation device for the treatment of chronic intractable occipital neuralgia: case illustrations

Abstract

Background: Literature supports utilizing electrical stimulation of the occipital and trigeminal nerves (PNS) for treatment of neuralgic pain localized to the craniofacial and occipital areas. However, surgical factors like extensive lead tunneling, IPG implant locations and cosmetic events have limited a more widespread usage of peripheral nerve stimulation (PNS) for these conditions. Also, adverse events and complications like lead erosion and/or migration, and infection at the surgical site necessitates an alternate approach in the implant techniques with minimal invasive devices for this form of PNS.

Material and Methods: We describe a wireless neuromodulation device with percutaneous placement of electrode adjacent to the occipital nerves to treat refractory occipital neuralgia (ON) in two patients. Pre-procedure nerve blocks were effective in reducing pain by >50% VAS score. Both patients had follow up for 30 days.

Results: By the end of first week, at follow up there was complete relief from pain in both the cases. At 30 day follow up patients had demonstrated stable paresthesia intensity and comfort while pain control was total. The procedure was tolerated well and devoid of any complications.

Conclusion: The Percutaneous electrode with wireless neuromodulation provided complete pain relief in both patients from a refractory ON. Both patients had no device related complications or adverse events.

Keywords: peripheral nerve stimulation, neuromodulation, wireless implant, cranial nerve, occipital neuralgia, chronic neck pain, headache

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Introduction

Occipital neuralgia (ON) is a neuropathic disorder involving the greater, lesser, and/or third occipital nerve. This is characterized by sharp, electrical, paroxysmal pain, starting from the nape of the neck and spreads along the back of the head. PNS of the occipital nerves is a promising therapy for cases with medically refractory ON and is reversible with minimal side effects and has shown continued efficacy with long-term follow-up.[1-3] The ONS involves electrical stimulation of the occipital nerves by means of fixed electric discharges and the surgical technique is well established in practice.[3]

However, this surgical procedure remains invasive with placement of long stimulation leads, connecting wires and sizeable battery that requires to be placed inside the body. Also, this surgical PNS was limited by technological issues like cumbersome equipment and stimulation systems as well as complications. There are not only cosmetic concerns with the bulky battery and skin incisions, but high adverse events like lead erosion, fracture, infection also.[4,5] Technological nuances, today, have ensured a minimally invasive and yet effective neuromodulation as reported here in our pilot study. This utilizes percutaneous placement of a stimulation system adjacent to the target nerves which is controlled by a remote sensing antenna, (not implanted). The primary objective of the study was to determine the safety and efficacy in pain control in ON.

Material and methods

After Ethics committee approval was secured for this study, 2 patients were selected for recruitment.

Inclusion criteria

Adult patients of at least 22 years of age at the time of signing the informed consent without anatomical defects that would compromise or complicate the study were included. They were on stable doses of pain medications for at least 4 weeks prior to screening. Patients agreed to undergo the surgical procedure and comply with the study requirements. They were willing and able to operate the programmer, recharge the equipment and properly fill out the electronic diary during follow up duration. Subjects were good surgical candidates for the implant procedure and had a life expectancy greater than 12 months beyond the study period. Subjects had a decreased pain intensity of ≥ 50% VAS from baseline after local anesthetic block of the targeted nerves.

Exclusion criteria

People with migraine, cluster headache, trigeminal autonomic cephalgia, other headaches or other types of central origin pain and those who failed psychological evaluation were excluded. Subjects on anticoagulation therapy and/or unfit for surgical procedures were also excluded.

Device description

Subjects were implanted with one or more Stim Relieve ® stimulator systems (Stim Relieve LLC, Fort Lauderdale, FL, USA) each containing four or eight contacts (3 mm in diameter with 4 mm spacing). The stimulator system utilizes an implantable electrode contact array, microprocessor receiver and antenna embedded within the electrode wire that couples to an external transmitting antenna and

pulse generator (Figures 1 & 2). The implanted stimulator is 100% passive (i.e., no power source). The external transmitting antenna is worn in a baseball cap (Figure 3) and is wirelessly coupled to the implanted stimulator. The external pulse generator is programmed by the clinician to send desired stimulation parameters through a direct electric coupling RF transmitting antenna to the electrode receiver, thereby wirelessly transferring stimulation commands and power to the implanted stimulator. The system uses radiofrequency energy at 915 MHz to transfer power and selected parameters to the implanted stimulator. The implanted stimulator and power source are coupled at such a short distance that the energy emitted from the antenna is relatively low. Wavelengths and product specifications have been designed to decrease risk related to the wireless transmission of energy and reliably transfer the clinician's desired stimulation parameters. The stimulation parameter spectrum available for clinical use and evaluation include:

*Amplitude: 1 - 24 mA

*Pulse Width: 1 - 1000 micro Sec

*Frequency: 1 - 20,000 Hz

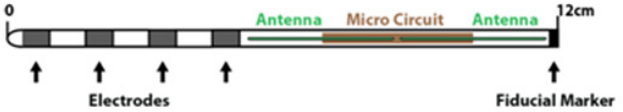

Figure 1 Neuro-stimulator electrode, MRI compatible, for both 1.5 and 3 Tesla.

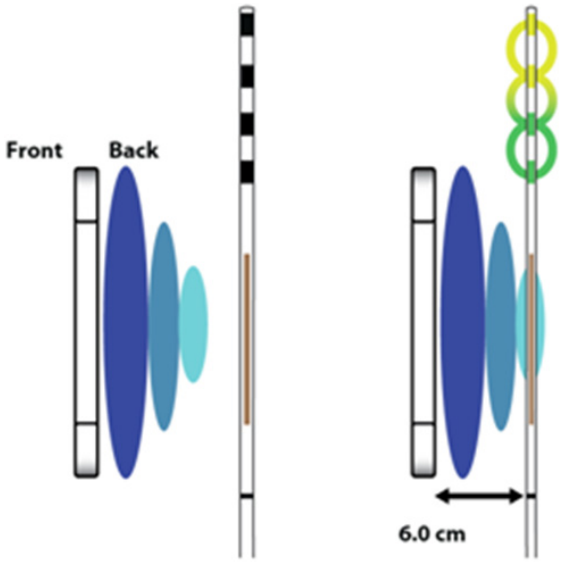

Figure 2 Neurostimulator receiver.

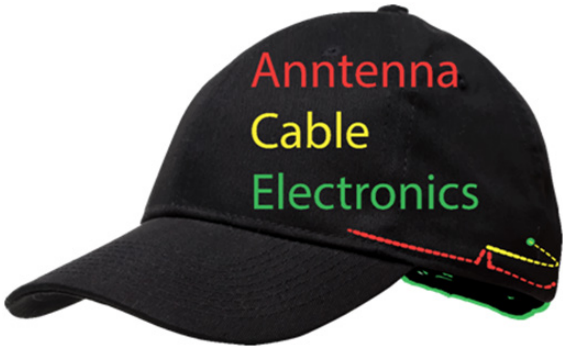

Figure 3 External pulse generator in a baseball cap.

Surgical procedure

Under strict aseptic precautions, the skin and subcutaneous tissues were infiltrated with local 1% lidocaine®. Doppler ultrasound was used to map out the vasculature around the target stimulator lead path. A small skin incision was made for needle insertion, which was shaped by hand to match the skull contour to achieve appropriate device placement. A 14-gauge Tuohy needle or angiocathether at occipital nerve targets was used for stimulator insertion. Doppler ultrasound was used to map out arterial vasculature around the target stimulator lead path and the devices were placed adjacent to nerves previously identified as pain generators by successful diagnostic nerve blocks using local anesthetic injections.

Bi-planar fluoroscopic images were applied to document final electrode positioning. The stimulator system was subsequently activated wirelessly to confirm electrode positioning with the patient reporting comfortable paresthesia along the distribution of the targeted nerve, after retraction of the needle tip exposing electrode contacts. The device was anchored via a sub-dermal suture located at the skin entry point. Distal tubing was cut at the insertion site and buried subcutaneously. The skin entry site was closed with suture or steristrips.

Stimulation protocol

Stimulation parameters were set at pulse widths of 100-200 microseconds and frequency of 60 Hz. (This is not to be confused with the device communication frequency between the external generator and electrode microprocessor of 915 mHz). A therapeutic stimulation regimen was applied for up to 30 days followed by removal of the trial leads utilizing fluoroscopy and a small incision at the electrode insertion site. During stimulation sessions, when therapy was needed to alleviate pain, patients wore a special baseball cap that housed the external pulse generator within the fabric lining (Figure 4).

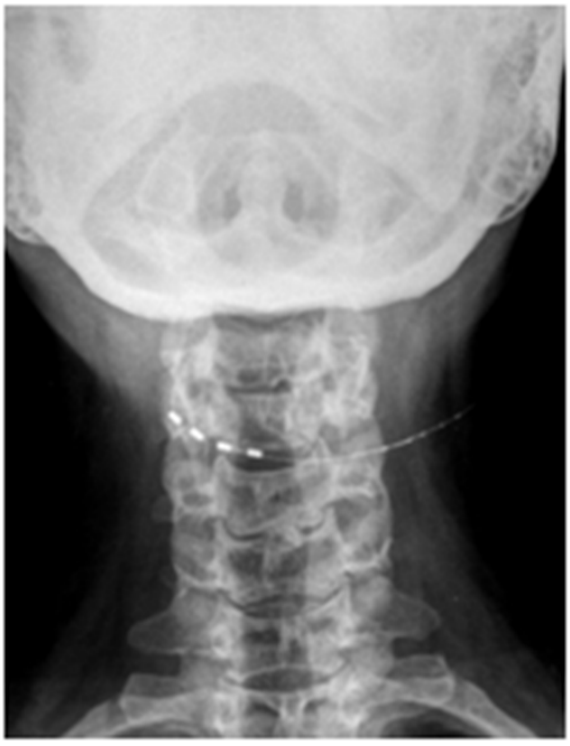

Figure 4 X-ray cervical spine AP view showing the electrode placed in the suboccipital region (case 1).

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Metrics for evaluating pain

Patients were monitored for ongoing pain relief and adverse events at 2 weeks and 4 weeks post-implant. Subjects were asked to describe their pain relief using the visual analog scale (VAS). Subjects were asked to report on medicaction usage at each assessment.

Case illustration 1(LM): A 58 year old female patient with an intractable neck pain for 1 year duration was enrolled in to the study after inclusion and exclusion criteria were met. She was receiving pain medication on regular basis and also received physical therapy prior to the intervention. Pain was predominantly located in the neck on the right side and aggravated by movement of neck as well as both arms. Following clearance from psychological evaluation and an informed consent, patient received electrode implantation. (Figure 4).

The procedure was uneventful. During the procedure the following parameters ensured effective stimulation: PW 200, Frequency 60. At 30-day follow up visit, the patient was completely relieved of her pain, from a VAS of 5, pre-procedure.

Case illustration 2 (JB): This 41 year old overweight male patient presented with neck pain and cranial pain not responding to pain medication and physical therapy over the past 6 months. His VAS at the time of enrolment was 5. Patient had the pain located predominantly on the left side. After psychological evaluation and clearance informed consent was obtained. Patient underwent electrode implantation without any adverse events (Figure 5). The settings for stimulation were as follows:

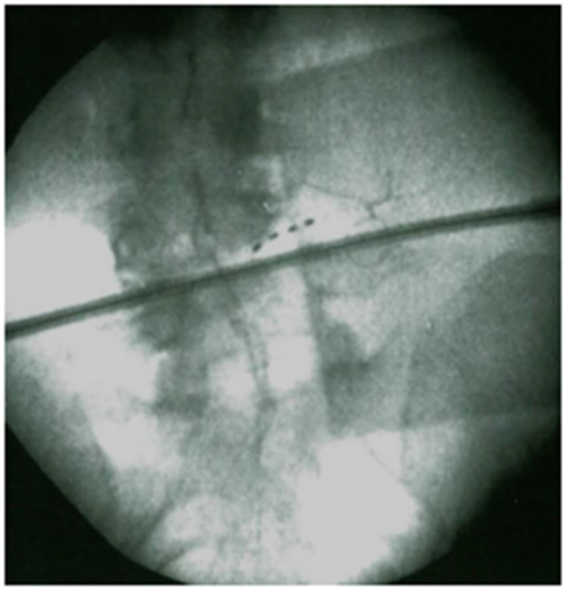

Figure 5 Fluoroscopic image of the electrode (case 2).

PW-100, Frequency 60 At 60-day follow up visit, he was comfortable with the stimulation parameters and completely relieved of his neck pain. The coverage of pain site was 100 percent.

The surgical procedure and the implant had no complications or adverse events.

Discussion

In a systematic review of occipital nerve stimulation for the treatment of chronic headaches, Jasper and Hayek concluded that ONS had at least Level IV (limited) evidence in the treatment of chronic severe headaches.[6]

Subsequently, based on the data derived from a systematic literature review of nine studies a Level III recommendation was offered by congress of neurological surgeons, for the use of ONS as a treatment option for patients with medically refractory ON (Occipital nerve stimulation for the treatment of patients with medically refractory occipital neuralgia: Congress of neurological surgeons systematic review and evidence based guideline.[7]

While ONS has been shown to be an effective modality, it stands at a disadvantage due to the technology related complications. Unfortunately, these systems are not designed for PNS and thus carry along the associated complications and side effects of the bulky design.[3,5,8] FDA approval and insurance coverage are lacking at this time.[9]

Minimally invasive placement of stimulation electrode and wireless neuromodulation shows promise. The device had a very low complication rate in our study while expanding the number of indications for the treatment of other chronic pain conditions. There is a significant reduction in side effects related to hardware components. Percutaneous electrode placement devoid of any implanted pulse generator or the long connective wires can be advantageous to the patient and the surgeon. They not only add to the comfort and cosmetic result but also provide reduced costs, less procedure time, low postoperative pain, and minimal adverse events while achieving the desired pain control.[10]

Future studies are required on larger patient populations with expanding pain metrics beyond the VAS, paresthesia coverage and medication log usage. Further evaluations with Short-Form McGill Pain Questionnaire (MPQ-SF), Quality of Life (SF-36), European Quality of Life - Five Dimensions (EQ-5D), Battery Health Inventory® (BHI2), Patient Global Impression of Change (PGIC) and long term adverse events will be helpful in increasing the utility of the technology.

Acknowledgments

None.

Conflicts of interest

None.

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None.

References

1. Weiner RL, Reed KL. Peripheral neurostimulation for the control of intractable occipital neuralgia. *Neuromodulation.* 1999;2(3):217-221.
2. Slavin KV, Nersesyan H, Wess C. Peripheral neurostimulation for treatment of intractable occipital neuralgia. *Neurosurgery*. 2006;58(1):112-119.
3. Trentman TL, Zimmerman RS. Occipital nerve stimulation: Technical and surgical aspects of implantation. *Headache*. 2008;48(2):319-327.
4. Schwedt TJ, Dodick DW, Hentz J, et al. Occipital nerve stimulation for chronic headache-long-term safety and efficacy. *Cephalalgia.* 2007;27(2):153-157.
5. Slavin KV. Technical aspects of peripheral nerve stimulation: hardware and complications. *Prog Neurol Surg*. 2011;24:189-202.
6. Jasper JF, Hayek SM. Implanted occipital nerve stimulators. *Pain Physician*. 2008;11(2):187-200.

7. Sweet JA, Mitchell LS, Norouze S, et al. Occipital Nerve Stimulation for the Treatment of Patients With Medically Refractory Occipital Neuralgia: Congress of Neurological Surgeons Systematic Review and Evidence-Based Guideline. *Neurosurgery*. 2015;77(3):332-341.
8. Parker JL, Cameron T. Technology for Peripheral Nerve Stimulation. *Prog Neurol Surg*. 2015;29:1-19.
9. Birk DM, Yin D, Slavin KV. Regulation of Peripheral Nerve Stimulation Technology. *Prog Neurol Surg*. 2015;29:225-237.
10. Yearwood TL, Perryman LT. Peripheral Neurostimulation with a Microsize Wireless Stimulator. *Prog Neurol Surg*. 2015;29:168-191.

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