

Occipital Nerve Stimulation for Treatment of Migraine

Minimally-invasive electrical nerve stimulation of the greater and/or lesser occipital nerves may be extremely effective in treating refractory migraine.



Those of us in the field of Pain Medicine know that some of the most difficult patients to help are those with intractable migraine headaches. As one by one, the accepted clinical treatments fail them, the depth of isolation these individuals experience is difficult for most of us to imagine. Many are labeled malingerers or emotionally disturbed, a slander that only augments the physical agony they feel. Finally, the most despairing of them take one last, worst action to escape the horror: suicide. For physicians who have experienced this loss, it is humbling and heartbreaking to know that the best efforts of science and compassion have failed to make a difference. Medicine desperately needs a solution for this subset of migraineurs. Drs. Hagen and Bennet are true pioneers in the field of neuroaugmentation. In this article, they provide us with a glimpse of a new technology that may offer relief for some of our patients who experience intractable migraines. Occipital nerve stimulation will not be the answer for all of them, but if it helps even a few, it could be called lifesaving.

—Lynn Webster, MD, FACPM, FASAM
Department Head



By James E. Hagen, MSc and Daniel S. Bennett, MD, DABPM

"If migraine patients have a common and legitimate complaint besides their migraines, it is that they have not been listened to by physicians. Looked at, investigated, drugged, charged, but not listened to."

—Dr. Oliver Sacks, *British Neurologist*¹

Migraine is a disabling primary headache that impacts millions. This disorder has been reported by 18% of women and 6% of men in the previous year.² In conjunction with pain, there are often other distressful symptoms such as nausea, vomiting, photophobia, phonophobia, osmophobia, and depression.³

A migraine headache can be unilateral or bilateral, often throbbing in nature, and usually aggravated by physical activity. Sometimes, when severe, the pain is expressed as, "band-like," or "tight." These headaches can occur at any time but seem to be most common upon arising.

The onset of migraine is usually gradual, but occasionally "stabbing" pain sensations that last only seconds are superimposed. Migraines can begin either with or without an aura, a transient visual or other sensory phenomenon (i.e., olfactory). Paresthesias occur with aura approximately one-third of the time. These typically start with numbness in the hands followed by symptoms in the lips, face and tongue.⁴

Pharmacologic treatment of migraine is currently the first-choice therapy for the majority of migraine classes; NSAIDs, triptans, ergot alkaloids, and steroids are commonly utilized. Most neurologists avoid opioids due to fear of opioid abuse, but also because of the rebound effect sometimes seen in opioid management of migraineurs. Avoiding triggers alone can prevent or diminish the severity or frequency of these headaches. Various other treatments include local nerve injections, botulinum toxin, acupuncture, physical therapy, herbal compounds, hypnosis, and dietary changes.

The economic costs of migraines in 1992 were estimated at \$17 billion.⁵ When considering the monetary outlay of ineffective treatment over time, the initial high cost of neuroaugmentation equipment appears justified.

Occipital neuralgia (ON), transformed migraine, and cluster headache are (3) three types of migraine that have been treated successfully with stimulation of the occipital nerves. All share the classification of trigeminal neuralgiform headache. Occipital nerve stimulation (ONS), a surgical intervention, is not new but has recently been under evaluation by the three major stimulation manufacturers in FDA trials:

- Advanced Bionics has completed enrollment of the PRISM study, which was designed to evaluate the safety and efficacy of ONS in certain migraine classes. This randomized, double-blind, crossover study has a total of 179 patients at 13 research sites (Unpublished data, Advanced Bionics, 2007).
- Medtronic, Inc., enrolled 68 subjects at 9 sites in their ONSTIM study for ONS for patients with intractable migraine. This feasibility study was also double blind and randomized to look at the safety and efficacy of ONS (Unpublished data, Medtronic, Inc., 2007).
- Advanced Neuromodulation Systems was not able to share clinical data at this time.

Migraine Treatment Through the Ages

Since early times, various forms of electrical current have been used for pain relief. The ancient Egyptians noted the electrical properties of the Nile catfish in hieroglyphics and described its use for the treatment of headaches and other conditions with

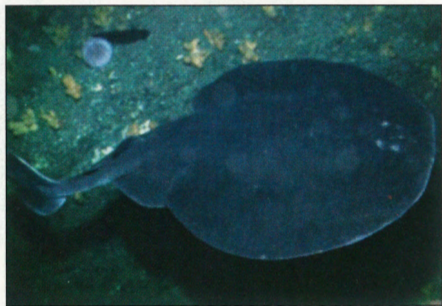


FIGURE 1. *Torpedo Nobliana*

painful symptoms.⁶ The first written document describing the medical use of electricity is believed to be from Roman physician Scribonius Largus in his *Compositiones Medicae*, which told of using the discharge of the torpedo fish (see Figure 1) to treat headache and gout.⁷ Many interventions, which now seem unsophisticated, have been used over time for headache relief.

During the 19th century, authorities proclaimed success in migraine treatment with Indian hemp preparations.⁸ Cannabis was a common treatment between 1842 and 1942 in the US and Europe.⁹ Cannabis and its components interact in a possibly effective manner with a number of the systems important to this disorder: effects on serotonergic, dopaminergic, opioid receptors, substance P, calcitonin gene-related peptide, and N-methyl-D-aspartic acid (NMDA) receptors have been studied.¹⁰ Clinical trials to evaluate migraine treatment are being carried out by a pharmaceutical company following successful trials for use of cannabis in neuropathic pain syndromes. (GW Pharmaceuticals, London, UK)

Picaza, et al. reported a case series of migraineurs with occipital neuralgia treated with peripheral nerve stimulation (PNS) in 1997.¹¹ Subcutaneous placement of different electrical contacts has shown excellent control of pain perception in a number of headache diagnoses.¹² With the development of newer surgical techniques utilizing both occipital and frontal subcutaneous (nerve) stimulation, improvements have been reported in pain relief with reduction in frequency of migraines and other global headache conditions.

Indications and Patient Selection

Choosing "the right patient for the right therapy" is critical for the most successful outcomes in any physiological disorder.

When considering patients for implantable therapies, spinal cord or nerve root stimulation, implantable drug delivery systems or peripheral nerve stimulation, consideration must be given to physical, psychological, and mental status issues. Having said this, the belief in many camps is that there are no prospective studies showing that current psychological testing has any impact on outcome over a range of modalities.

The correct headache type diagnosis must fall within the categories that demonstrate the highest positive outcomes. In ONS, the highest level of success follows work with highly trained neurologists who show an interest in treating migraines. Equally important, are the detection of other pathologies that can lead to migrainiform headache (i.e., arteriovenous malformation, tumors, etc.) In this regard, implanters are not usually specialists in the diagnosis of the myriad of headache varieties and subsets.

Implanting a medical device requires a good working relationship between the patient, staff, and pain surgeon. Interpersonal relationships need to be respected. While dysfunctional behavior by an implant candidate may jeopardize acceptable outcome, it is not predictive. The advice of an experienced behavioral pain psychologist is essential for a number of migraineurs. The existence of psychological disorders, depression, anxiety, or hostility must be co-managed. These patients do not always fall into exclusion criteria. With good support and possible psychological or psychiatric treatment, psychologically troubled implant candidates often become excellent patients who achieve successful post-operative outcomes. The exceptions, in our experience, are those patients with borderline or narcissistic personality disorders.

Methods

Weiner's initial protocol for ONS involved transverse placement of electrode arrays into the subcutaneous tissue at or near the level of C1 utilizing a vertical incision.¹³ Since the emerging occipital nerves become superficial to the fascia as they progress rostral to their emergence between C1-C2, with the greater occipital nerves on either side of midline, this was a good beginning. The lesser occipital nerves usually crossed the suboccipital region to the mastoid bone.¹⁴ Bescar, et al. performed an anatomical study of the pe-

ripheral nerves innervating the occipital region and found great variability in nerve topography both interindividually and intraindividually.¹⁵ At that time, new research techniques and devices began to be used successfully for treatment of headache. Wires with different numbers of electrical contacts, surgical stimulation paddle-type arrays, and a bipolar battery-powered microstimulator (Bion, Advanced Bionics, Valencia, CA) have all shown positive results in providing relief from certain headache pain conditions.¹⁶

Follow-up studies on greater than 150 implanted patients over the past 10 years have shown a 70-75% success rate defined as greater than 50% pain relief, reduction in medication usage, and reduction in visual analog scale (VAS) reported by the patients. The cohort contains an assortment of tension headaches, postherpetic neuralgia, cervicogenic headache, migraine with aura, and cluster headaches using intermittent stimulation programming. In the chronic daily headache (transformed migraine) and deafferentation post-traumatic pain populations, the use of continuous stimulation is more effective than intermittent therapy.¹⁷

Risks of Occipital Nerve Stimulation

As with any surgical intervention, associated adverse events may occur. The most common is lead migration. Lead migration, which descends downward from the original positioning, has been reported in approximately 15% of implants.¹⁸ Movement of the electrical contacts creates a programming issue as the electrodes have migrated away from the greater and/or lesser occipital nerves. A newly developed technique to address this issue has decreased the incidence of lead migration to approximately 1-2% (unpublished study data). In addition, the use of paddle-type electrode arrays virtually eliminates the migratory problem.

Lead fracture was problematic in early application of this technique. New methods of proximal wire 'redundancy' (where a loop of wire is left just proximal to the lead and at fulcrum points, i.e., nape of neck, thoracolumbar junction, and lumbosacral junction) have all but eliminated this problem. Other problems, although rare, include battery failure or depletion, hematoma at the battery site, loss of stimulation, allergic reaction to implanted material, and infections. Given the close proximity of the surgical field to the scalp

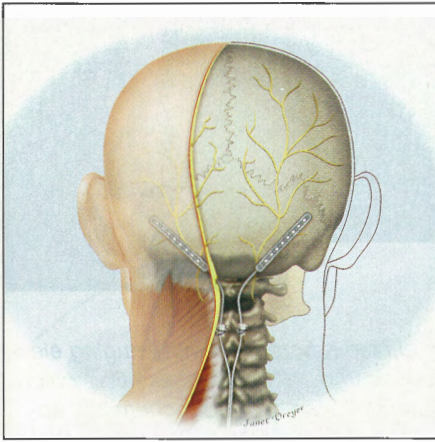


FIGURE 2. Occipital nerves with paddle placement. Courtesy of Advanced Bionics Corp. 2007.

(and hair), this is usually a problem of surgical technique – the incidence of infection can be minimized with shaving of the surgical area and good surgical skin preparation prior to incision.

Although rare, contamination of implanted materials can occur when proximal lead wires are not carefully maintained within the sterile surgical field. If wound dehiscence should occur, it is our opinion that the entire system should be explanted. After administering antibiotic therapy and obtaining clearance from an infectious disease specialist, reimplantation can be performed, while incorporating any pre- or postoperative antibiotic therapy recommendations. We have not seen recurrence of infection in our practice when utilizing this protocol.

Electrode Positioning and Programming

To obtain optimal pain relief and lowest headache frequency, correct electrode positioning is crucial. Sometimes needle localization or topical nerve stimulation is used to predict the mapping of the greater and/or lesser occipital nerves. We have found that the “point of maximal tenderness” on each affected side proves to provide the best location for maximal pain relief and largest spread of paresthesia¹⁹ (see Figures 2 and 3). Simply palpating the occiput in the area where the patient reports being the most “tender” has given superior pain relief outcome compared to previous methods. During examination, the occipital ridge is palpated starting at the occipital protuberance and proceeding laterally toward the styloid process. If a typical migraine pattern can be reproduced by applying moderate pressure over a localized area, this gives

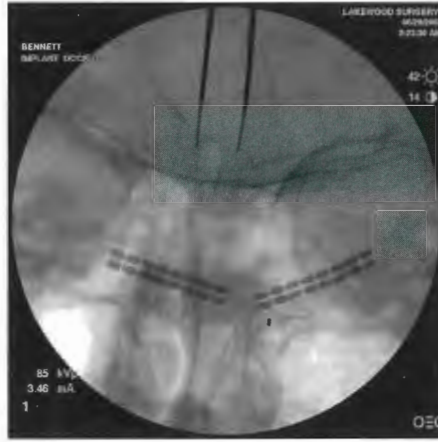


FIGURE 3. Radiograph of bilateral paddle placement for ONS.

the best mapping for location of the centromost electrical contact. Just prior to placement of the trial electrode string(s) or paddle, this procedure is again performed on the shaved area where the incision will be made. A single mark is made with an indelible marker to prevent this being scrubbed away during surgical skin preparation.

Programming of the system is often performed in the procedural suite by trialing various electrode configurations. This technique is utilized when percutaneous lead arrays have been positioned and the patient is awakened from conscious sedation anesthesia. Proper operative technique requires not allowing any local anesthetic to numb the targeted occipital nerve(s) because to do so prevents the patients from giving accurate feedback regarding the sensation and location of paresthesia during the implant trial and electrode positioning. If hemostasis is necessitated, 1:200,000 epinephrine solution can be placed along the tract where the lead is to be placed. Using the ‘point of maximal tenderness’ technique when implanting paddle leads, we have found that the array needs only to be centered over that point. Patients are routinely implanted under general anesthesia in our practice with excellent post-operative programming results. Using this protocol, intraoperative testing is not done.

While the common range of frequency of stimulation (Hz) ranges from 50 to 110, we see a preferred pulse width addressing a greater area of paresthesia to be from 100 to 400 milliseconds. Depending on the depth of the electrical contacts relative to the position of the greater and lesser occipital nerves, initial stimulation per-

ception can be as low as 0.3mA. Preferred current levels are usually within the 2.0 to 4.5mA range.

Post-operatively, more directed programming is performed to demarcate the best electrode parameters for maximal paresthesia spread and subsequent pain relief. As referenced above, headache scenarios dictate whether continuous or patient-controlled stimulation is recommended. In disorders without aura, it is our experience that continuous, low-level stimulation provides better outcomes. Headaches preceded by aura or a muscle spasm-type sensation seem to be better treated with patient-controlled stimulation at the first note of aura or tissue-tightening symptoms.

Conclusions

Electrical nerve stimulation of the greater and/or lesser occipital nerves has been extensively studied and has been shown to be extremely effective in the treatment of migraine. When utilizing techniques such as positioning the ONS electrodes at the “point of maximal tenderness” and understanding the parameters for programming, the healthcare professional treating migraine now has a proven, successful treatment. With newly developed anchoring and fixation methods, the problem of lead migration is barely a significant concern. For the tens of thousands of people living with migraines that have been unalleviated by medication treatments, ONS can be a minimally invasive, successful therapy and is worth trialing. ■

James Hagen, MSc, is a clinical neurophysiologist and Director, Clinical Services and Research for Integrative Treatment Centers in Denver, Colorado. His clinical and research interests include electrical neuromodulation for a variety of disorders, especially CRPS, migraines and visceral pain. He is Co-founder of the National Pain Foundation. He has authored articles addressing research, neuromodulation and care of persons living with pain. Mr. Hagen is the Director of Emerging Technologies for PRISM Healthcare Foundation, a 501(c)3 non-profit organization for education and research. Comments or questions can be sent to jhagen@denverpain.com.

Daniel S. Bennett, MD, DABPM is the Medical Director of Integrative treatment Centers in Denver, Colorado. Dr. Bennett has authored numerous articles and book chapters on many aspects of pain medicine, especially regarding electrical stimulation for a variety of

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