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Initial Experience With Implanted Peripheral Nerve Stimulation for the Treatment of Refractory Cephalgia

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ABSTRACT

Objective: To report 4 cases of improved pain control and function in patients with chronic cephalgia secondary to chronic headaches and/or trigeminal neuralgia.

Methods: Four patients with refractory cephalgia came to our clinic for interventional therapy after medications failure. Each patient underwent a trial with a temporary array of peripheral nerve stimulation depending on the distribution of their pain. Trials varied in duration from 1 to 3 days. Patients who received greater than 50% pain relief during trials were candidates for full implantation. All 4 patients went to full implantation of a permanent peripheral nerve stimulator lead array and generator battery.

Results: After implantation of the permanent lead array and generator, average pain relief among the 4 patients was 60%. Their function improved, and medication usage decreased along with side effects. Overall, all 4 patients reported that they would undergo implantation if given the choice again. Tolerance for medication decreases has varied widely, although all patients were on regimens that were stable and without side effects.

Conclusions: Initial experience suggests that refractory pain secondary to chronic migraines and trigeminal neuralgia may respond to peripheral nerve stimulation. Further studies are indicated to evaluate efficacy over the long term and to elucidate the optimal array and implantation technique.

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INTRODUCTION

Headaches are among the most common medical complaints. The overall prevalence of migraines is estimated to be 12% to 16% of the general population in North America and Europe.[1] Fewer population-based studies are available for other chronic headache syndromes, but tension-type headaches seem to be more prevalent than migraines.[2,3] Both migraines and tension-type headaches affect women more often than men, while cluster headaches are predominantly a disorder of men.[2]

Like many other chronic disorders, migraines not only affect the sufferer's quality of life but also cause an economic burden for society. A 1993 survey revealed migraines as the primary cause of 150 million lost workdays and 329,000 lost school days each year in the United States.[4,5]

Trigeminal neuralgia is the most common of the cranial neuralgias. The peak incidence is between the ages of 50 and 70 years.[6] Approximately 60% of patients with this condition are female. A large majority of classic trigeminal neuralgia (tic douloureux) cases are ultimately caused by mechanical compression of the trigeminal nerve as it leaves the pons and traverses the subarachnoid space toward Meckel's cave.[6]

MATERIALS AND METHODS

Three of four patients suffering from chronic migraine headaches refractory to medical management were referred to our clinic by experienced neurology headache specialists. These patients had well-documented histories of disabling chronic migraine headaches. Each had tried multiple medical regimens, discontinuing many of them because of a lack of efficacy or the presence of intolerable side effects. In each case, the amount of pain relief achieved with a medical regimen was insufficient for normal functioning.

A primary care physician referred the fourth patient, who suffered from trigeminal neuralgia in a V1 and V2 distribution that had been refractory to medical management largely because of the patient's inability to tolerate medications secondary to sedation. The facial pain was disabling and caused significant anxiety and depression, which his medical regimen worsened somewhat.

Case 1

A 45-year-old female with intractable migraine headaches with and without aura was referred by a neurologist specializing in headaches; she was on a stable regimen that was ineffective overall. Her headaches started 25 years ago, and she believed they were caused by birth control pills. Since then, recurrent retroorbital headaches had gradually increased in frequency and severity. The patient still experienced chronic daily headaches that negatively affected her daily functioning and quality of life. She continued to have daily attacks of level 3-4 out of 10 headaches, which intensified several times each week to a debilitating level of pain. The headaches were usually left sided but sometimes affected the right. Pain was diffuse and throbbing, burning, or stabbing. A visual aura of mosaic vision, photopsia, or polka dot vision sometimes preceded the headaches. Nausea, vomiting, photophobia, phonophobia, osmophobia, blurry vision, neck and shoulder tightness, cravings for chocolate, and scalp sensitivity were also present. Triggers included weather changes, changes in sleeping pattern, hunger, stress, changes in altitude, strong smells, and head trauma. Symptoms improved during 2 of her 3 pregnancies. Prior to trial and implant, the patient was averaging almost 1 visit per week to the Emergency Department for uncontrolled symptoms requiring parenteral medications. She did not have a significant history of medication overuse.

Bilateral occipital nerve blocks performed at the patient's initial clinic visit provided significant but temporary relief.

Case 2

A 40-year-old male with intractable migraine headaches with and without aura suffered from headaches since his teens but denied any inciting event. The headaches had worsened in duration, frequency, and intensity over the past 4 to 5 years. Frequency was constant. The pain affected the right frontal area and right occiput. Pain fluctuated between a 4/10 and a 10/10 in intensity, with more severe attacks occurring weekly. The patient described the headaches as sharp in character without aura or specific triggers. Associated symptoms included nausea, vomiting, photophobia, and osmophobia but not allodynia. Bright light and loud noise worsened the pain. He reported significant blood pressure elevations and low-grade fevers with severe attacks several times in the past.

The patient had treated his headaches with only acetaminophen, up to 8,500 mg in tablets per day, for the past several years. Multiple medications failed because of lack of efficacy or intolerable side effects. He preferred to rest and sleep in a dark room with a wet and cold cloth over his face. He made multiple and frequent Emergency Department visits for uncontrolled symptoms. Prophylactic treatment included verapamil 180 mg twice daily, propranolol 120 mg daily, and valproic acid 2,000 mg daily (also used for seizure prophylaxis). He reported that this regimen had been essentially ineffective since he began it, although he denied significant side effects.

Right-sided occipital and right supraorbital nerve blocks performed at the initial clinic visit provided significant but temporary relief.

Case 3

A 44-year-old female with chronic, intractable migraines with and without auras reported onset at age 11. Her headaches, described as pulsating, were primarily right sided and rarely left sided and primarily involved the parietal region. She denied any specific triggers and noted that they occurred daily and varied in intensity between a 5/10 and 10/10. Duration was from several hours up to 4 days, sometimes interrupting sleep. They were fairly abrupt and reached maximal intensity in about 15-30 minutes. Prodromes, if present, were characterized by blurry vision. Auras, described as flashing stars, occurred about 50% of the time. Associated symptoms included vomiting, nausea, allodynia, blurry vision, photophobia, phonophobia, osmophobia, and lightheadedness. Prodrome with allodynia was fairly common. Triggers included dietary factors (monosodium glutamate, chocolate, yogurt, artificial sweeteners, cheese, pizza, nuts, alcohol, and bananas), stress, weather changes, and menses. Opioids were somewhat effective for abortive therapy and pain control, but she made frequent visits to the Emergency Department for parenteral medication.

Right-sided occipital and right supraorbital nerve blocks at the initial clinic visit provided significant but temporary relief.

Case 4

A 67-year-old male suffered a stroke in May 2006 that left him with a residual gait disorder. In August 2009, he visited a neurologist with continual complaints of right eye pain, dry eyes, and some swallowing problems, reporting that the eye pain began after a fall out of his hospital bed in 2006. He first visited the clinic for his right eye pain and was presented with the option of peripheral nerve stimulation. He had had 2 prior unsuccessful nerve blocks and was taking gabapentin. The patient was unsure of the dose at the time: 800 mg 3 times a day had caused increased sleepiness, and 400 mg 3 times a day was ineffective. He tried carbamazepine, pregabalin, and baclofen without much symptom relief. On a visual analog scale, he rated the pain as 10/10, located in the right supraorbital and suborbital, lateral nasal, and right maxillary areas.

He initially underwent supraorbital and infraorbital nerve blocks with temporary relief of pain. He subsequently underwent a gasserian ganglion block that also provided short-term relief.

Trial Stimulation Procedure Technique

Each patient elected to undergo a peripheral nerve stimulation trial.

We made no significant changes to any of the patients' medications in the 4 to 6 weeks prior to the trial to avoid any concern regarding rebound headaches, opioid-induced hyperalgesia, or other issues that might affect the outcome of the trial.

A consultation between the patient and physician, and in some cases a neurologist, determined each patient's trial array. One patient's trial involved a combination of bilateral occipital leads, two had a combination of supraorbital and occipital leads, and the fourth a V1 and V2 lead.

We used fluoroscopy to assist in the placement of the temporary percutaneous lead and intravenous sedation and local anesthesia for the introducer needle and lead placement. We used Medtronic (Minneapolis, MN) Octrode (8 contacts) compact trial leads in all patients. To place the supraorbital and infraorbital leads, we made small stab incisions over the temporal area. With fluoroscopy, we placed the introducer needle along the projected path of the lead and then placed the lead through the needle to its tip. We removed the needle at that point, leaving the lead in the medial quarter of the margin of the orbit. We placed occipital leads using a similar technique, with either a midline or lateral approach from beneath the mastoid process and along the path of the greater occipital nerve.

Because of the inherent difficulty in securing the leads, all patients received the choice to have the leads removed prior to discharge that day. All patients opted to keep the leads overnight, for at least 1 day. Trials ranged in duration from 24 to 72 hours. No migration or accidental pulls of leads occurred during these trials.

A minimum criterion for a positive trial was 50% improvement in the patient's subjective pain reports during the trial. All 4 patients reported greater than 50% relief of pain during the trial period and elected full implantation.

We assessed the relative response to each area stimulated. In each case, the trial array and lead placement were optimal and later used for permanent implantation. The planned lead array in conjunction with patient feedback and surgical concerns determined the site for generator placement. Patients had a choice between 2 implantable pulse generators (IPGs), both by Medtronic: PrimeAdvanced, a nonrechargeable battery (average life of 5 years), and RestoreUltra, a rechargeable battery (maximum life of 9 years).

Permanent Implantation and Operative Technique

The surgical approach varied depending on the arrays being placed and the optimal positioning of the IPG battery. Patients received preoperative antimicrobial prophylaxis. We used general endotracheal anesthesia for the placement of all 4 devices. One patient received bilateral occipital leads while in the prone position. Two patients received a combination of occipital and supraorbital leads while in the lateral position. The final patient received 2 facial leads implanted while he was in the supine position.

Patients were prepped and draped in sterile fashion. We made small incisions to place introducer needles and anchor the leads. We then advanced the introducer needles along the planned path of the lead array, with x-rays from the patient's trial in the operating room so we could match as closely as possible the positioning of the leads from the successful trial. Permanent Medtronic 1 $\times$ 8 compact leads were anchored to the underlying fascia with nonabsorbable sutures in several places; a strain relief loop reduced the likelihood of lead migration. We made an incision over the gluteal region (3 patients) or the infraclavicular area (1 patient) and created a pocket to accommodate the IPG. We then tunneled the leads to the pocket and connected them to the IPG.

Afterward, we irrigated and closed the wounds and covered them with antimicrobial ointment, sterile dressing, and 4 $\times$ 4 bandages. After the patients woke from anesthesia, they were extubated and taken to the postanesthesia care unit. Initial programming of the device took place to optimize the patient's coverage and pain control, and the patient was discharged home with standard postoperative instructions and follow-up in 1 week. Thereafter, as-needed follow-up addressed any concerns and facilitated reprogramming of the device, if necessary.

RESULTS

Peripheral Stimulator Trial

As previously noted, all 4 patients reported greater than 50% improvement in their cephalgia. Overall, pain relief varied between 60% and 100% during the trials. Because the 4 patients had a positive response, all proceeded to full implantation.

Permanent Stimulator

One patient received bilateral occipital stimulation, 2 a combination of occipital and supraorbital stimulation, and 1 a combination of supraorbital and infraorbital stimulation. Depending on their individual needs, the patient received either a rechargeable or nonrechargeable programmable IPG.

Currently, patients are 6, 5, 4, and 2 months from implantation (mean 4 months). All 4 patients continue to use their stimulators and to report benefits similar to those obtained during the initial trial. Many have been able to decrease or discontinue other medications, thus decreasing their side effects. All described increased quality of life and function. All patients report that they would opt for the implantation again if given a choice.

Case 1

The 45-year-old female underwent the trial in July 2010, followed by full implantation of a bilateral occipital nervous system. Since that time, headaches have improved and are no longer constant; also, she may go up to 4 days without a headache. Breakthrough pain does occur, however, and appears to be largely related to hormonal changes associated with the patient's menstrual cycle. She continues to use medications for both prophylaxis and abortive therapy.

Case 2

Following implantation, the 40-year-old male patient has reported excellent efficacy (greater than 50%) overall and believes relief to be primarily related to the occipital lead because results with the supraorbital lead have been minimal.

Case 3

Following implantation, the 44-year-old female patient reported excellent efficacy (greater than 50%) overall, but still has breakthrough headaches requiring parenteral medications.

Case 4

The 67-year-old male patient required revision of his V2 stimulating lead, as the lead had advanced somewhat with tenting of the skin at the right infraorbital area.

DISCUSSION

Initial experience with these 4 patients confirms that peripheral nerve stimulation for cephalgia secondary to chronic migraine and trigeminal neuralgia may be effective. All patients reported significant benefit to their pain following implantation, but not all patients noted a substantial decrease in medication levels. One patient required revision of a lead due to migration, but no other complications were noted.

Multiple small studies have been performed on the efficacy of peripheral nerve stimulation for chronic migraines and other forms of cephalgia. Larger and more formalized studies are necessary to further evaluate the long-term benefit to patients with refractory cephalgia. Rigorous classification of the cephalgia will facilitate studying this modality and may eventually aid in patient selection for the therapy.

When considering patients for this invasive form of therapy, it is important to exhaust all conservative measures before proceeding to trial and implantation. A headache specialist should be consulted, and a thorough history of medications and failed therapy should be generated. Any definitive treatment for headache must be pursued. For patients with a refractory, well-evaluated cause of head and/or facial pain, peripheral nerve stimulation may be an effective therapeutic choice.

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