Occipital Nerve Stimulation (701125)

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<td>Individuals:</td>
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<td>• With migraine headache</td>
<td>• Occipital nerve stimulation</td>
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<pre><code>                                                                                   | • Medical management               | • Functional outcomes                |
                                                                                   |                                | • Quality of life                   |
                                                                                   |                                | • Treatment-related morbidity      |
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<p>| Individuals:                 | Interventions of interest are:             | Comparators of interest are:     | Relevant outcomes include:                     |
| • With non–migraine         | • Occipital nerve stimulation              | • Conservative treatment        | • Symptoms                                     |
| headache (e.g., hemicrania  |                                            | • Medical management             | • Functional outcomes                |
| continua, cluster)          |                                            |                                  | • Quality of life                   |
|                                | • Treatment-related morbidity      |</p>

Description

Occipital nerve stimulation delivers a small electrical charge to the occipital nerve intended to prevent migraines and other headaches in patients who have not responded to medications. The device consists of a subcutaneously implanted pulse generator (in the chest wall or abdomen) attached to extension leads that are tunneled to join electrodes placed across one or both occipital nerves at the base of the skull. Continuous or intermittent stimulation may be used.

Summary of Evidence

The evidence for occipital nerve stimulation in individuals who have migraine headaches includes randomized controlled trials (RCTs), systematic reviews of RCTs, and observational studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Systematic reviews identified five RCTs; one was judged to be at low risk of bias. Findings from pooled analyses of RCTs were mixed. For example, compared to placebo, response rates to occipital nerve stimulation did not differ significantly but did reduce the number of days with prolonged moderate-to-severe headache. Moreover, occipital nerve stimulation was associated with a substantial number of minor and serious adverse events. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for occipital nerve stimulation in individuals who have non-migraine headache (e.g., hemicrania continua, cluster) is investigational. If the physician feels this service is medically necessary, preauthorization is recommended.
continua, cluster) includes case series. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Most case series were small; many had 15 or fewer patients, with the largest having 22 patients. Moreover, RCTs are needed to compare outcomes between occipital nerve stimulation and controls to assess for the placebo effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy
Occipital nerve stimulation is considered investigational for all indications.

Background
Implanted peripheral nerve stimulators have been used to treat refractory pain for many years, but have only recently been proposed to manage craniofacial pain. Occipital, supraorbital, and infraorbital stimulation have been reported in the literature.

Headache
There are four types of headache: vascular, muscle contraction (tension), traction, and inflammatory. Primary (not the result of another condition) chronic headache is defined as headache occurring more than 15 days of the month for at least three consecutive months. An estimated 45 million Americans experience chronic headaches. For at least half of these people, the problem is severe and sometimes disabling. There are several types of primary headaches, including vascular. Herein, we will only discuss types of vascular headache, including migraine, hemicrania continua, and cluster.

Migraine
Migraine is the most common type of vascular headache. Migraine headaches are usually characterized by severe pain on one or both sides of the head, an upset stomach, and, at times, disturbed vision. One-year prevalence of migraine ranges from 6% to 15% in adult men and from 14% to 35% in adult women. Migraine headaches may last a day or more, and can strike as often as several times a week or as rarely as once every few years. Drug therapy for migraine is often combined with biofeedback and relaxation training. Sumatriptan is commonly used for relief of symptoms. Drugs used to prevent migraine include methysergide maleate, propranolol hydrochloride, ergotamine tartrate; amitriptyline, valproic acid, and verapamil.

Hemicrania Continua
Hemicrania continua causes moderate and occasionally severe pain on only one side of the head. At least one of the following symptoms must also occur: conjunctival injection and/or lacrimation, nasal congestion and/or rhinorrhea, or ptosis and/or miosis. Headache occurs daily and is continuous with no pain-free periods. Hemicrania continua occurs mainly in women, and its true prevalence is not known. Indomethacin usually provides rapid relief of symptoms. Other nonsteroidal anti-inflammatory drugs, including ibuprofen, celecoxib, and naproxen, can provide some relief of symptoms. Amitriptyline and other tricyclic antidepressants are effective in some patients.

Cluster Headache
Cluster headache occurs in cyclical patterns or clusters of severe or very severe unilateral orbital or supraorbital and/or temporal pain. The headache is accompanied by at least one of the following autonomic symptoms: ptosis (drooping eyelid), conjunctival injection, lacrimation, rhinorrhea, and, less commonly, facial blushing, swelling, or sweating. Bouts of one headache every other day to eight attacks per day may last from weeks to months, usually followed by remission periods when the headache attacks stop completely. The pattern varies
from person to person, but most people have one or two cluster periods a year. During remission, no headaches occur for months, and sometimes even years. The intense pain is caused by the dilation of blood vessels, which creates pressure on the trigeminal nerve. While this process is the immediate cause of the pain, the etiology is not fully understood. It is more common in men than in woman. One-year prevalence is estimated to be 0.5 to 1.0 in 1000. Management of cluster headache consists of abortive and preventive treatment. Abortive treatments include subcutaneous injection of sumatriptan, topical anesthetics sprayed into the nasal cavity, and strong coffee. Some patients respond to rapidly inhaled pure oxygen. A variety of other pharmacologic and behavioral methods of aborting and preventing attacks have been reported with wide variation in patient response.

**Regulatory Status**

To date, the U.S. Food and Drug Administration (FDA) has not cleared or approved any occipital nerve stimulation device for treatment of headache. In 1999, the Synergy™ IPG device (Medtronic), an implantable pulse generator, was approved by FDA through the premarket approval process for management of chronic, intractable pain of the trunk or limbs, and off-label use for headache is described in the literature. The Genesis™ neuromodulation system (St. Jude Medical) was approved by FDA for spinal cord stimulation and the Eon™ stimulator has received CE mark approval in Europe for the treatment of chronic migraines.

**Related Protocol**

Spinal Cord Stimulation

References

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


