



INFORMATION FOR HEALTH CARE PROFESSIONALS



Surgical Treatment of Headache

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Implantable stimulation devices and other surgical techniques have been used to treat headache disorders refractory to non-invasive therapies. The literature consists largely of case reports, small series and uncommonly randomized controlled trials (RCTs). The absence of a good clinical trial control limits our interpretation of outcomes to hypotheses only. Subjective outcomes like pain are extremely influenced by expectations and conditioning, which along with natural history contribute in a large way to outcomes and this must be kept in mind.

Occipital Nerve Stimulation (ONS)

Electrodes are inserted percutaneously to deliver electrical stimulation to one or both occipital nerves. Conditions that have been treated include posttraumatic headache, chronic migraine, chronic cluster, hemicrania continua, and new daily persistent headache. The physiology behind the purported benefits is poorly understood and paresthesias are often experienced. Prior to placement of permanent leads, a trial using temporary electrodes may be undertaken. Response to occipital nerve local anesthetic block is not predictive of benefit with ONS. Multiple unblinded studies have been performed on multiple headache types and RCTs are ongoing.

A 157 subject RCT of chronic migraine failed to reach primary end-point of more than 50% reduction of pain at 12 weeks. Multiple ONS unblinded trials on chronic cluster have been completed and a large randomized controlled trial is ongoing. Many subjects require surgical correction of complications which include migration or breakage of leads.

Vagal Nerve Stimulation (VNS)

Invasive VNS is used with both epilepsy and depression, comorbid with migraine, and iVNS has been shown to be effective in both conditions. Some patients with epilepsy treated with iVNS note an improvement in their headache frequency and/or severity. Small patient series with iVNS for refractory migraine and refractory chronic cluster headache have been performed with variable results. Implantation is low risk. Complications are related to placement of the device and include nausea, infection, transient voice change and equipment failure. A non-invasive, hand-held external vagal nerve stimulator was FDA approved in 2017 for the acute treatment of episodic cluster headache.

Sphenopalatine Ganglion Stimulation (SPG)

A small device is implanted (low risk) through the mouth (most common route of placement) adjacent this autonomic ganglion located in the midface. The stimulator is activated by a hand-held piece, used to abort attacks of cluster headache or migraine. A RCT for cluster episodes was positive with 67% of subjects achieving outcome compared to 7.4% of sham. The outcome was $\geq 50\%$ reduction in pain at 15 minutes. There is a suggestion that frequency of cluster headache attacks is reduced with SPG stimulation and RCTs are ongoing for both cluster and episodic migraine.

Deep Brain Stimulation (DBS)

DBS is a rare and considerably more risky procedure performed for chronic refractory cluster headache patients (and in refractory SUNCT-Short-lasting UNilateral headache with Conjunctival injection and Tearing). The Milan Group (Bussone/Leone) has the most experience. Functional and anatomic imaging show abnormalities in or near the posterior hypothalamic gray matter which is the site of electrode placement. Leone (2015) reported 79 patients treated and a mean follow up of 2.2 years, with 69.6% hypothalamic-stimulated patients showing a $\geq 50\%$ improvement. A small RCT of DBS for chronic cluster headache was negative. Risks include bleeding (1 death reported in Belgium), stroke and eye movement abnormalities.

Surgical ‘Trigger Site’ Deactivation

Surgical deactivation attempts to ‘release’ nerves or remove/dissect small facial/neck muscles. The trigger sites are identified based on the location of headache and may include frontal, temporal or occipital locations, corresponding to the muscles innervated by supraorbital and supratrochlear nerves, the zygomaticotemporal branch of the trigeminal nerve and the greater occipital nerve. One placebo-controlled surgical trial using sham surgery (Guyuron) was positive but significant methodological and other problems limit its value. Trigger sites are dubiously determined based upon response to onabotulinumtoxinA injections in that trial. The American Headache Society and the *Choosing Wisely* initiative of the American Board of Internal Medicine recommend that migraine surgery *should not* be performed in clinical practice, leaving open further study by way of clinical trials.

Other Procedures

Supraorbital nerve stimulation, high cervical spinal cord stimulation, surgical correction of nasal mucosal ‘contact points’, closure of patent foramen ovale (migraine with aura) and ligation of facial arteries have all been performed for a variety of headache disorders, with unclear benefit.

Summary

A significant minority of headache sufferers do not benefit from adequate trials of multiple acute and prophylactic drugs. Surgical treatments may offer such patients an improvement. These procedures are expensive (compared to medications), often not covered by insurance, and most published data allow only suggestions of what may work. Complications from implanted hardware are common. Better clarification is needed on what may be of benefit and fortunately clinical studies (including RCTs) are continuing.

References

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