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Neuromodulation Devices for Acute Headache Management

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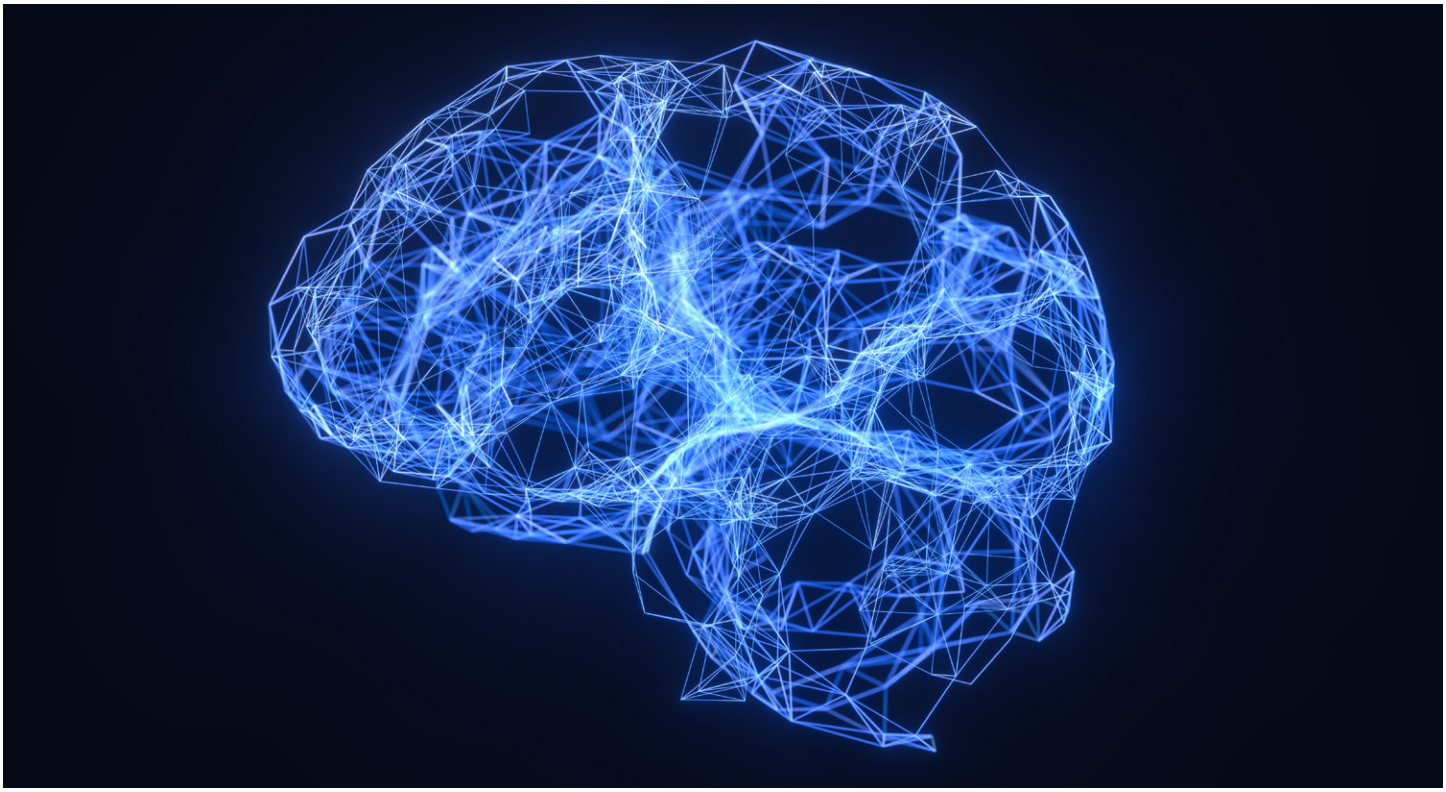

Migraine is a highly prevalent and disabling disease, affecting approximately 1 billion people, and is also the second leading cause of disability worldwide[1]. While there are numerous acute medications available to treat migraine, there are a variety of reasons that the available prescription and over-the-counter options may not be sufficient. These reasons may include lack of efficacy, existing comorbid conditions with medication contraindications or unwanted side effects. People with migraine seek out alternative and complementary medicine options, but until recently, these options have been limited. A new class of treatment options called neuromodulation devices have emerged with clinical data supporting use and potential efficacy along with a favorable side effect profile.

The following Q&A was designed to provide basic information for Primary Care Providers who wish to offer their migraine patients options for non-pharmaceutical pain management.

Sara is a 32 year old financial analyst who has 2 to 3 episodes per month of a moderate to severe headache associated with light sensitivity and nausea. She currently takes sumatriptan 100mg or ibuprofen 800mg as needed for headaches and she presents in clinic today to discuss other treatment options.

Q: I hate taking medications, is there anything out there I can do about my headaches that doesn't involve taking a pill or an injection?

A: Yes! There is a class of acute headache management options called neuromodulators. This class includes:

- E-TNS– an external trigeminal nerve stimulator (Cefaly)
- nVNS – a noninvasive vagal nerve stimulator (Gammacore)
- sTMS– a single-pulse transcranial magnetic stimulator (sTMS mini)
- REN – a remote electrical neuromodulator (Nerivio)

Q: How do they work?
A: There are currently four devices with differing mechanisms of action:

- The E-TNS device (on the acute setting) stimulates the trigeminal nerve, producing a sedative effect on the nervous system that may relieve headache pain[2].
- The nVNS device activates the vagus nerve with mild electrical stimulation, which is thought to modulate pain signals involved in migraine attacks[3].
- The sTMS device induces a current to the brain's cortex, disrupting cortical spreading depression (one of the steps in the migraine pathway) and thalamocortical connections[1].
- REN stimulates sensory fibers in the upper arm which then reach the brainstem and activates a pathway that ultimately inhibits incoming pain messaging[4].

Q: How do I use them?
A: Each device is slightly different.

- The E-TNS device is attached to an electrode which is applied to the forehead just above the eyebrows via temporary adhesive[2].
- The nVNS device is turned on and positioned on the neck near the vagus nerve with varying intensity[3].
- The sTMS device is positioned behind the head, cradling the skull, and a therapeutic pulse is delivered with the push of the button(s)[5].
- The REN device is applied to the upper arm and then controlled by an application on your personal phone. With the application, you can adjust the stimulation intensity as needed and automatically track usage into a migraine diary[4].

Q: In the past, I've had side effects with every medication I've tried. Are there side effects with these devices?
A: Side effects with these devices are extremely rare.

- E-TNS can cause irritation at the application site and fatigue during and after treatment[2].
- nVNS can also cause redness at the application site, facial twitching and nasopharyngitis[3].
- sTMS can cause lightheadedness, tingling and tinnitus[5].
- REN can cause redness at the application site, as well as a sensation of warmth or tingling, arm numbness or muscle spasm on the arm where the device is applied[4].

Q: I am thinking about getting pregnant within the next 1-2 years. If a device works for me, would I be able to use it during pregnancy?
A: While they have not been specifically studied during pregnancy, these devices could potentially be safe therapies. There has been a post-marketing study of the sTMS device that included 3 pregnant women, and all three reported benefit without any complications1. nVNS has also been used in patients for other indications without any evidence of harm to the fetus1. E-TNS is thought to be safe during pregnancy, but there has not been adequate data from clinical trials to support definitive use.

Q: How do I obtain a neuromodulation device?
A: Because the devices are considered durable medical equipment, they require a prescription that can be sent either electronically or by fax. The devices will be shipped to you upon receipt of the order and confirmation of payment.

Q: Is neuromodulation covered by my insurance?
A: No, these devices are not covered by most insurance plans. However, each company has a program to make the device somewhat more affordable/accessible to patients.

Q: Are there conditions in which neuromodulation devices cannot be used?
A: The prescribing information for each device contains a complete list of contraindications. Specifically,

- E-TNS should not be used if a patient had any brain or facial trauma within the last 3 months, a cardiac pacemaker or defibrillator, or implanted or metallic devices in the head[2].
- nVNS should not be used in patients with active implantable devices, metallic stents or screws at or near the neck. It cannot be used if using another device simultaneously. It is contraindicated in patients with active carotid or other atherosclerotic disease, cervical vagotomy, clinically significant hypertension, hypotension, bradycardia, tachycardia, seizure disorder, prolonged QT, cardiac arrhythmia, abnormal baseline EKG, abnormal cervical anatomy or brain tumor[3].
- sTMS should not be used in patients with aneurysm clips or coils, cochlear implants, cerebrospinal fluid shunts, metal implants in the skull, neck, shoulder, arm or hands, metallic heart valves, radioactive seeds or facial tattoos with metallic ink[5].
- REN cannot be used in individuals with a history of congestive heart failure, cardiac or cerebrovascular disease, uncontrolled epilepsy, implanted medical devices or metallic implants.[4].

References:

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