

The Present: Non-Invasive Neuromodulation for Headache

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Disclosures

- Dr. Schuster has documented that he has served over the past 24 months a consultant for Eli Lilly & Co, Averitas, Lundbeck, and Schedule 1 Therapeutics, as a speaker for Eli Lilly & Co and Averitas, and as an editorial board member for *Pain Medicine*, *Interventional Pain Medicine*, and *Annals of Headache Medicine*
- This presentation contains off-label or investigational use of drugs or products

Learning Objectives

- Attendees will learn about **5 devices** for portable non-invasive neuromodulation
- Attendees will learn about **indications** for these devices
- Attendees will learn about **barriers** patients may encounter to obtaining these devices (including insurance coverage and out-of-pocket costs)

Portable non-invasive neuromodulation devices

Cefaly		supraorbital peripheral nerve stimulation	migraine	acute and prevention	OTC	Cefaly.com	No insurance approval, \$379 x 1 time, Return by 90 days and get money back
gammaCore		vagus peripheral nerve stimulation	migraine and cluster headache	acute and prevention	Rx	Gammacore.com	May cost pt \$199+/month
sTMS mini		occipital cortex transcranial magnetic stimulation	migraine	acute (especially aura) and prevention	Rx	Eneura.com	Insurance approval, even with may cost pt \$250/month
Nerivio		arm band remote electrical neuromodulation	migraine	acute	Rx	Nerivio.com	\$99 for 12 treatments without insurance Can be \$10+ w/insurance

Population

Episodic Migraine

(<15 headache days/mo
or <8 migraine days/mo)

Chronic Migraine

(≥15 headache days/mo
and ≥ 8 migraine days/mo)

Treatments

**Acute/
Abortive**

APAP & NSAIDs
ASA/APAP/Caffeine
Triptans
D2 Antagonists
Ergots
Gepants
Lasmiditan
Timolol eye drops
Neuromodulation

?Medication Overuse
Gepants
D2 Antagonists
Timolol eye drops
Neuromodulation
APAP & NSAIDs
Triptans
Lasmiditan
Ergots

**Preventive/
Prophylactic**

AEDs (Topiramate esp.)
Beta-Blockers/ARBs
TCAs/Venlafaxine
CGRPs (mAbs/PO)
Memantine
Nutraceuticals (Mg, B2)
Neuromodulation
Lifestyle Treatments

OnabotulinumtoxinA
CGRPs (mAbs/PO)
AEDs (Topiramate esp.)
Beta-Blockers/ARBs
TCAs/Venlafaxine
Memantine
Nutraceuticals (Mg, B2)
Neuromodulation
Lifestyle Treatments

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Neuromodulation
Lifestyle Treatments

When to use

- American Headache Society: “Patients who prefer nondrug therapies and those who have failed to respond to, have contraindications to, or poor tolerability with pharmacotherapy may be candidates for neuromodulation”¹
- In tertiary referral clinic practice, most often as a complement to first- and second-line treatments (not monotherapy!)
 - Acute/Abortive and/or Preventive/Prophylactic
 - To avoid medication overuse (rebound) headache
 - Special populations: Adolescents, Pts w/Medical Comorbidities, ?Pregnancy

Supraorbital Nerve Stimulation



Cefaly FDA cleared for:

- Migraine Prevention: 20 min preferably QHS at 60 Hz
- Acute Migraine: 60 min preferably early in migraine attack at 100 Hz
 - Both pulse width 250 μ s, max 16 mA

Evidence

- Prevention: Positive sham-controlled RCT¹
- Acute: Positive sham-controlled RCT²
- In chronic migraine: more effective in patients with intermittent than continuous headache³
- BOLD-fMRI study suggested antinociceptive modulation in the anterior cingulate cortex (ACC)⁴

Single-Pulse TMS



stTMS mini (previously called Spring TMS) FDA cleared for:

- Migraine Prevention: 4 pulses (2 pulses, wait 15 min, 2 pulses) twice daily
- Acute Migraine: 3 pulses at migraine pain onset, can repeat after 15 minutes x 2 if needed

Evidence

- Acute: Positive sham-controlled RCT¹
- Prevention: Positive prospective open-label study²
- Adolescents: Open-label prevention study suggested feasible, well-tolerated³
- Frequency of KCl-induced cortical spreading depression waves reduced in rats treated with spTMS⁴

Vagus nerve stimulation



gammaCore FDA cleared for:

- Acute Migraine: 2 minutes at onset, can repeat after 15 minutes if needed
- Acute Cluster: 2 minutes on, 1 minute off, x 3
- Chronic Cluster Prevention: 2 minutes on, 5 minutes off, x 3, twice a day

Evidence

- Acute Cluster: 2 positive sham-controlled RCTs^{1,2}
- Acute Migraine: Positive sham-controlled RCT³
- Chronic Cluster Prevention: Positive open-label pragmatic RCT⁴
- Vestibular Migraine: Retrospective study suggests helpful⁵
- Decreases release of pro-inflammatory cytokines and chemokines⁶

Remote Electrical Neuromodulation



Nerivio FDA cleared for:

- Acute Migraine: 45 min within 60 min of onset of migraine
- Acute Migraine in Adolescents

Evidence

- Acute Migraine: 2 positive sham-controlled RCTs^{1,2}
- Acute Migraine in Adolescents: Prospective open-label single-arm study³
- Acute Migraine in patients with Chronic Migraine: Prospective open-label single-arm study⁴
- Conditioned Pain Modulation: activates descending inhibition pathways²

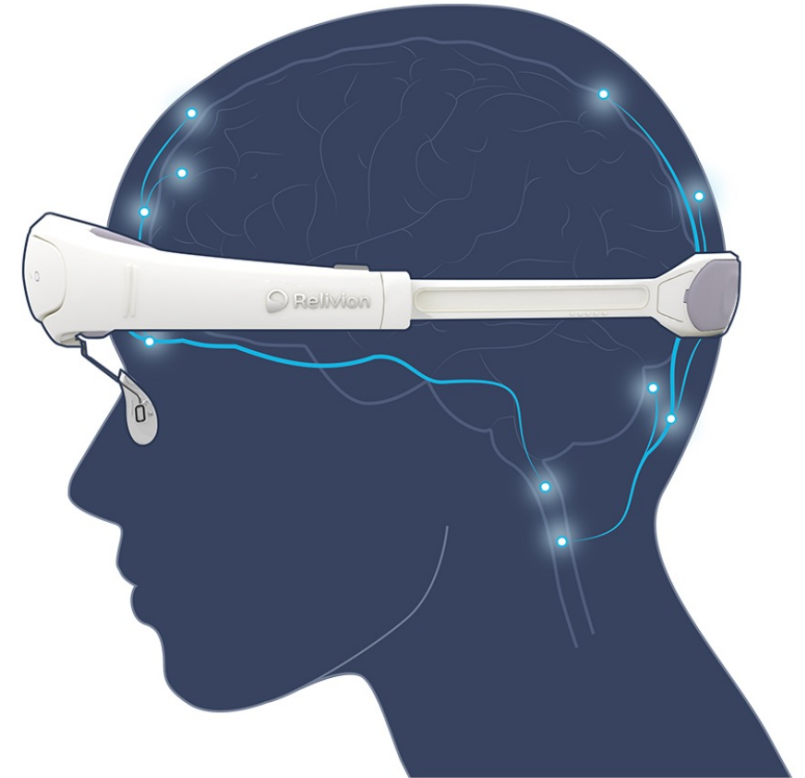
Occipital and Trigeminal Neuromodulation

Relivion FDA cleared (not yet commercially available):





- Acute Migraine

Evidence

- Acute Migraine: 1 positive sham-controlled RCT [Abstract Only]¹



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