Unmet Needs in the Treatment of Adolescent Migraine

Toolkit for Healthcare Professionals

This toolkit was developed by **SEI Healthcare** in collaboration with **Dr. Shannon Babineau** (Atlantic Health System, NJ, USA). This activity was supported by an independent medical grant by **Theranica Bio-Electronics Ltd**.

You can watch the **Adolescent Migraine** video case in full on-demand through our learning platform, www.IME.Healthcare.

BURDEN OF MIGRAINE IN ADOLESCENTS

- Headaches are a very common and disabling problem affecting millions of children and adolescents worldwide.^{1,2}
- Globally, 10% children and adolescents experience *migraine*, and 1-2% have *chronic migraine*.^{1,2}
- Migraine is the leading cause of disability worldwide for older adolescents and young adults.¹
- Adolescents with migraine miss more school than their peers and face **impairments in school performance**, leisure/social, family relationships, and overall quality of life.²
- Migraine is a silent disease, with no visible no outward findings, so a report of pain may be doubted, leading to shame and frustration.¹

TOP 3 BARRIERS TO ACCESSING CARE

Consulting an HCP Receiving a migraine diagnosis Prescribing appropriate treatment

GENERAL TREATMENT CONSIDERATIONS

At least 2/3 of adolescents will respond to currently available therapies, and those who benefit from preventive therapy are likely to maintain better headache control into adulthood.¹

Strategies for developing a treatment plan:³

- Use evidence-based preventive treatments.
- Start low and titrate.
- Reach a therapeutic dose.
- Give an adequate trial.
- Establish realistic expectations.
- Optimize agent selection.
- Maximize adherence.

| Lifestyle modifications and preventive therapies | Treating acute episodes |
|---|---|
| Lifestyle modifications Consistent lifestyle habits should be discussed with all patients and their families, including lifestyle modification, identifying and addressing migraine triggers/aggravating factors, and avoidance of medication overuse. ^{1,4} | All adolescents with migraine should receive an acute treatment plan to be used at the start of an episode that includes a school note permitting them to be excused from class at symptom onset to hydrate, take an acute medication, and rest before returning to class. ¹ |
| Preventive treatment Pharmacological options include topiramate, propranolol, or amitriptyline + CBT (remember to discuss safety profiles!).^{1,4} Neuromodulation devices.³ | Acute treatment options include NSAIDs, triptans, and/or antiemetics. ^{1,4} Neuromodulation devices are another possible option. ³ Opioids are <i>not recommended</i> for acute treatment of migraine in adolescents. ⁴ |

WHICH PATIENTS CAN BENEFIT FROM TREATMENT WITH A NEUROMODULATORY DEVICE?

- All patients with a confirmed diagnosis of migraine may be offered treatment with a neuromodulatory device, which modulates headache pain mechanisms by stimulating the nervous system centrally or peripherally with an electric current or a magnetic field.³
- Three devices are currently FDA-cleared for acute and/or preventive treatment of migraine treatment in adolescents 12 years and older (**REN**, **nVNS**, and **sTMS**).^{1,3}
- All FDA-cleared devices have good safety profiles. Device-related adverse events are generally mild and transient, and related to localized reactions (e.g. warmth, pain, redness).⁵⁻⁷
 - Neuromodulation may be an especially important alternative for patients who:³
 - **Prefer nonpharmacologic therapies**, and/or
 - Have failed to respond to, have contraindications to, or have poor tolerability with pharmacotherapy, and/or
 - Have frequent migraine attacks and are at higher risk of medication-overuse headache and/or chronic migraine.

| | Remote electrical neuromodulation (Nerivio®) ^{5,8} | Noninvasive vagus nerve stimulation (gammaCore Sapphire [™]) ^{6,9} | Single-pulse transcranial magnetic stimulation (SAVI Dual™) ^{7,10} |
|--|--|--|--|
| Mechanism of action | Electrical nerve stimulation through weak electrical pulses invokes CPM to inhibit migraine pain. | Mild electrical stimulation to the vagus nerve. | Brief, noninvasive, single pulse of magnetic energy creates a brief electrical current to stop/reduce migraine. |
| Administration | Self-administered (arm). | Self-administered (neck). | Self-administered (head) |
| Acute treatment | At onset of migraine headache or aura (45 min). | 2 x 2-min stimulations; repeat if needed. | 3 pulses > Wait 15 min > Repeat if needed. |
| Preventive treatment | Every other day (45 min). | 2 x 2-min stimulations BID. | 2 pulses > Wait 15 min > 2 pulses, BID. |
| Clinical data in adolescents (12–17 years) | Evaluated in 6 clinical studies, including a prospective, open-label study evaluating efficacy and safety in adolescents with migraine: Primary endpoints: favorable safety and tolerability (<i>N</i> =45 - largest adolescent data set compared with other devices). Secondary endpoints (efficacy): Pain relief at 2 hours: 71% Pain-free at 2 hours: 35% Improvement in functional ability at 2 hours: 69% | Label expansion to include adolescents based on previously reported RCT data for acute and preventive treatment of migraine, and supported by a small study in adolescents (N=9) with migraine with aura, in which 46.8% of 47 treated migraine attacks were successfully treated without the use of any acute rescue medication. | Pilot open-label study in adolescents to assess feasibility, tolerability, and patient acceptability of sTMS for acute and preventive treatment of migraine in adolescents (N=12): Overall, sTMS was a feasible, well-tolerated, and acceptable nonpharmacologic preventive treatment for migraine in adolescents. Key limitation: preventive treatment with a 15-min delay between pulse series was challenging, especially on school days, requiring administration without the 15-minute delay. |

Abbreviations: BID, twice a day; CBT, cognitive behavioral therapy; CPM, conditioned pain modulation; FDA, Food and Drug Administration; min, minute(s); NSAID, nonsteroidal anti-inflammatory drug; nVNS, noninvasive vagus nerve stimulation; RCT, randomized controlled trial; REN, remote electrical neuromodulation; sTMS, single-pulse transcranial magnetic stimulation.

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