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A Comprehensive Study on Nerivio Migra

Dr.Srinivas Pasula*, Ledo Thankachan, Dr. A. Srionivasa Rao, Dr.Beda Durga Prasad.

Department of Pharmacy Practice, Bhaskar College of Pharmacy, Amdapur X Road, Yenkapally, Moinabad, Ranga Reddy, Hyderabad, Telangana 500075

ABSTRACT

Migraine is one among the foremost prevalent and disabling disorders, characterized by recurrent headache attacks with nausea, vomiting, photophobia, and phonophobia. Nerivio Migra may be a breakthrough device for acute treatment of migraines. Attached to the patient's arm (below the shoulder), it's a clinically-tested wearable suited to be worn everywhere and at any time. Non steroidal anti inflammatory drugs (NSAIDs) and triptans, commonly used for acute migraine treatment[3], may be ineffective, poorly tolerated, contraindicated, and if used in excess, may lead to medication overuse headache there is a great unmet need for alternative acute migraine treatments that are both effective and well tolerated. Non-invasive neuromodulation is safe, well tolerated, and may have fewer adverse effects than drugs. Remote electrical neuromodulation (REN) may be a novel acute migraine treatment that stimulates upper arm peripheral nerves to induce conditioned pain modulation (CPM) -an endogenous analgesia mechanism during which conditioning stimulation inhibits pain in remote body regions.

Key words:
Migraine,
Phonophobia, photophobia
Remote electrical neuromodulation.

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*Corresponding Author
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Email:

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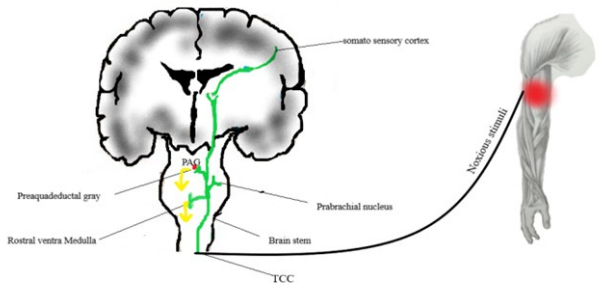
INTRODUCTION

Migraine is one among the foremost prevalent and disabling disorders, characterized by recurrent headache attacks with nausea, vomiting, photophobia, and phonophobia. Nerivio Migra may be a breakthrough device for the acute treatment of migraines. Attached to the patient's arm (below the shoulder), it is a clinically-tested wearable suited to be worn everywhere and at any time. NerivioMigra, also as other sorts of wearable's the corporate is planning, are controlled by intuitive smartphone applications to simply adapt therapy treatments to today's modern lifestyle. Which can be available in limited quantities for late 2019 and early 2020.

DISCUSSION

Migraine is one of the most prevalent and disabling disorders,[1] characterized by recurrent headache attacks with nausea, vomiting, photophobia, and phonophobia[2].Non-steroidal anti-inflammatory drugs (NSAIDs) and triptans, commonly used for acute migraine treatment[3], may be ineffective, poorly tolerated, contraindicated, and if used in excess, may lead to medication overuse headache [4,5] and migraine chronification[6] profound barriers to optimal migraine care[7,8]. Only 15.9% of the U.S. population with migraine use triptans, with an extremely high discontinuation prevalence of 55.2-81.5%[9] . Thus, there's an excellent unmet need for alternative acute migraine treatments that are both effective and well tolerated. Non-invasive neuromodulation is safe, well tolerated, and should have fewer adverse effects than drugs[10,11]. Remote electrical neuromodulation (REN) may be a novel acute migraine treatment that stimulates upper arm peripheral nerves to induce conditioned pain modulation (CPM) - an endogenous analgesia mechanism during which conditioning stimulation inhibits pain in remote body regions[12]. The mechanism of REN and its potential use in migraine are described in details during a recent pilot study[13].Presumably, REN activates descending inhibition pathways that originate within the periaqueductal gray (PAG) and within the rostral ventromedial medulla (RVM) which globally inhibit pain by the discharge of serotonin and noradrenalin (Fig. 1). the pilot study demonstrated that early treatment of migraine attacks with REN can significantly reduce headache[13]. During this paper, we report the results of a randomized, double-blind, sham - controlled, multicentre pivotal study designed to guage the efficacy and safety of REN for the acute treatment of migraine.

Figure 1. Migraine Head Ache



OPEN IN FIGURE VIEWER POWERPOINT

Schematic illustration of the principle of operation of REN. The device stimulates C and Aδnoxious sensory fibers of the upper arm above their depolarization thresholds but below the the perceived pain threshold. The noxious information reaches the brainstem through the ascending pain pathway

(black). This information activates the descending pain inhibitory pathway (green), involving the brainstem pain regulation centre (which includes the PAG, RVM, and sub nucleus reticularis dorsalis [SRD]), and therefore the release of serotonin and noradrenalin, which inhibit incoming messages of pain within the trigeminal cervical complex (TCC) that occur during a headache of a migraine attack. PAG = periaqueductal gray; RVM = rostral ventromedial medulla; SRD = sub nucleus reticularis dorsalis; TCC = trigeminal cervical complex.

STIMULATION DEVICE

The REN device (NerivioMigra®, Theranica Bio Electronics Ltd., Israel) may be a wireless wearable battery-operated stimulation unit controlled by a smartphone software application. The device is applied for 45 minutes on the lateral upper arm between the bellies of the lateral deltoid triceps, in order that it'll mainly stimulate small skin nerves. The rationale for exciting the arm and therefore the underlying mechanism of action are described in details elsewere13. The active device produces a proprietary electrical signal comprising a modulated symmetrical biphasic square pulse with a modulated frequency of 100120 Hz, pulse width of 400 μs, and output current up to 40 mA (adjusted by the participant). Although the heart beat stimulates C and Aδ noxious sensory fibers above their depolarization thresholds, the stimulation energy is low enough to take care of the general sensory experience below perceptual absolute threshold. The sham device differed from the active device within the pulse frequency which was ~0.083 Hz and therefore the pulse width which was 40-550 μs (modulated), aimed to induce a solid and perceptible sensation almost like the active device, but with a sufficient low frequency to stop any modulation of nociceptive processes.

The parameters of the sham and active devices were chosen following a pilot study which used several stimulation programs in a crossover design[13]. The stimulation intensity of both the active and sham devices was adjusted by the users using the app.

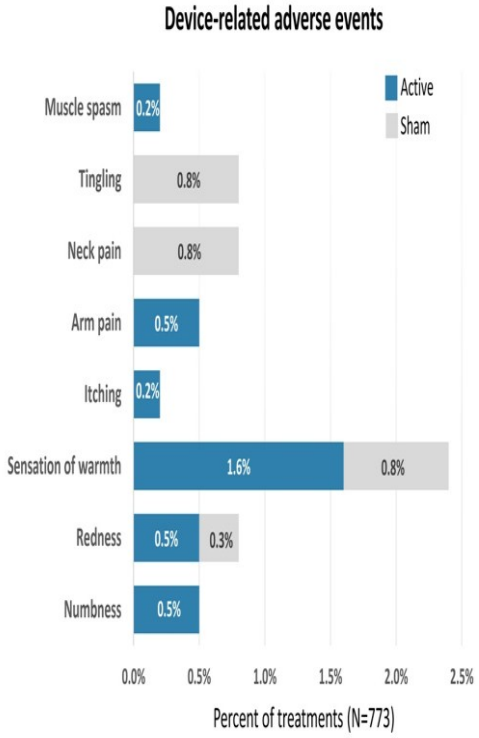
Working:1. Download and install the NerivioMigra app BLE wireless communication pairs the mobile app with NerivioMigra device to track your pain based on your personal data.

NerivioMigra is a breakthrough electronic device for acute treatment of migraines. Attached to the patient's arm (below the shoulder), it is a clinically-tested wearable suited to be worn everywhere and at any time. NerivioMigra, as well as other types of wearables the company is planning, are controlled by intuitive smartphone applications to easily adapt therapy treatments to today's modern lifestyle.2.Attach the NerivioMigradevice to your Migra arm NerivioMigra device contained ENS/NMES electrodes, a battery, and theranica'ssmart ship3. Keep your arm and relief your pain the electrical pulses, generate by the chip, the sensory nerves under the skin, resulting in pain relief.

RESEARCH FINDINGS

The pivotal study (TCH-003) was a prospective, randomized, double-blind, sham controlled multi-centre study aimed to demonstrate the security and efficacy of NerivioMigra remote electrical neuromodulation device for the acute treatment of migraine with or without aura. This study was conducted from December 2017 to October 2018 at 12 sites, 7 within the US and 5 inIsrael.296 participants with migraine with or without aura (in accordance with ICHD classification criteria) who had 2–8 attacks per month, ≤12 headache days per month, and were on either no or stable migraine preventive medications within the last two months before recruitment were enrolled. 252 participants were randomized to active (n=126) or sham stimulation (n=126). Headache pain levels were reported at baseline, 2 hours and 48 hours post-treatment. The analyses were performed on 202 participants (99 within the active group and 103 within the sham group) who treated an attack within one hour from symptoms onset and reported pain level at 2 hours post-treatment. At 2 hours post-treatment, active stimulation was significantly simpler than sham stimulation in reducing headache pain (66.7% vs. 38.8%, p

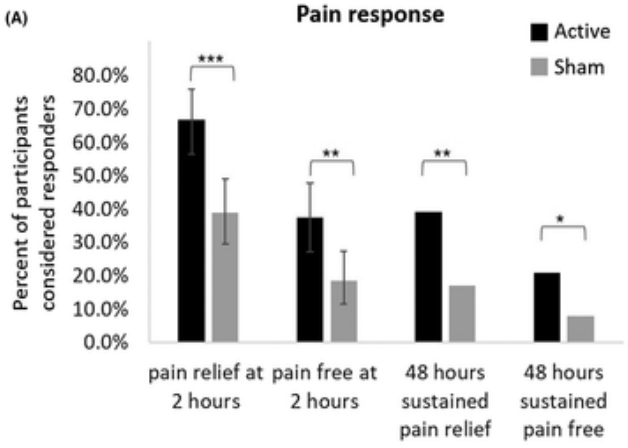
In conclusion, the results of the pivotal study indicate that Nerivio Migra is safe and effective for the acute treatment of migraine. The findings of this study were robust and clinically meaningful. Nerivio Migra, thus, offers a novel alternative for current pharmacological and non-pharmacological treatments that combines effective treatment with minimal side effects.

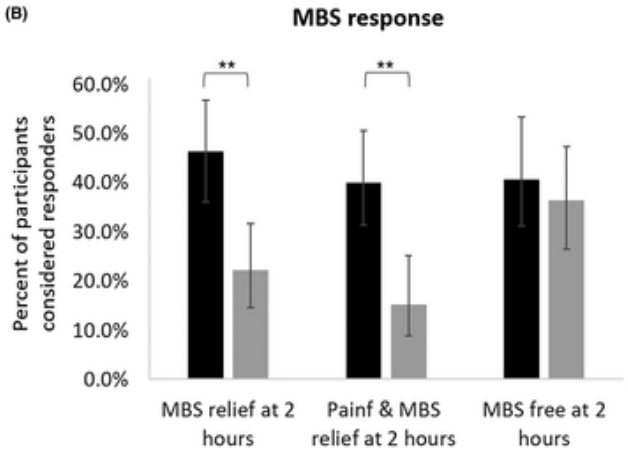


RESEARCH FINDING 2:

This was a randomized, double-blind, sham-controlled, multicenter study conducted at 7 sites within the us and 5 sites in Israel. 2 hundred and fifty-two adults meeting the International Classification of Headache Disorders criteria for migraine with 2-8 migraine headaches per month were randomized during a 1:1 ratio to active or sham stimulation. A smartphone-controlled wireless device was applied for 30-45 minutes on the upper arm within 1 hour of attack onset; electrical stimulation was at a perceptible but non-painful intensity. Migraine pain levels were

recorded at baseline, 2, and 48 hours post-treatment. Most bothersome symptoms (MBS) were also recorded. the first efficacy endpoint was the proportion of participants achieving pain relief at 2 hours post-treatment (improvement from severe or moderate pain to mild or none, or from mild pain to none). Relief of MBS and pain-free at 2 hours were key secondary endpoints. last active stimulation was simpler than sham stimulation in achieving pain relief (66.7% [66/99] vs 38.8% [40/103]; therapeutic gain of 27.9% [CI95%, 15.6-40.2]; P < .0001), pain-free (37.4% vs 18.4%, P = .003), and MBS relief (46.3% vs 22.2%, P = .0008) at 2 hours post-treatment. The pain relief and pain-free superiority of the active treatment was sustained 48 hours post-treatment. The incidence of device-related adverse events was low and similar between treatment groups (4.8% [6/126] vs 2.4% [3/126], P = .499).





CONCLUSION

In conclusion Nerivio Migrawhich is recently approved by the FDA is a safe non pharmacological treatment for acute migraine with minimal side effect and adverse effects

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