Acute Treatment of Migraine in Children aged 6-11: Real-World Analysis of Remote Electrical Neuromodulation (REN)

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BACKGROUND

Migraine is a prevalent neurological disorder severely impacting children and adolescents, yet only one pharmacological treatment is approved for ages 6-12 years. Remote Electrical Neuromodulation (REN) is nonpharmacological, prescribed, wearable-device, FDA-cleared for acute and/or preventive treatment of migraine with or without aura in patients 12 years and older. This study evaluates REN’s safety and efficacy in 6-11 years old.

METHODS

Prospective acute treatment of migraine data was collected through the REN device (Nerivio®) smartphone application. Endpoints were device safety (primary); consistent treatment efficacy [headache pain, functional disability, associated migraine symptoms] and REN-medication combinations 2-hours post-treatment.

REFERENCES

RESULTS

Children (n=293), median age 11 (IQR=9-11), 73.7% girls, conducted 5,493 REN treatments.

No adverse events and no device-related adverse events were reported. An additional analysis assessed the number of device-related customer support inquiries conducted by this patient cohort (usually through their parents), showing an average of 0.072 inquiries per child, which is similar to the inquiry rate of the entire population of REN users, in all ages (0.087).

REN was used standalone, with over-the-counter medications, with prescribed headache medications in 45.4%, 34.4%, 20.9% of treatments, respectively.

CONCLUSIONS

REN may serve as a safe and efficacious acute treatment of migraine for children. Providers and families seeking a safe, effective, pill- and needle-free treatment option for children suffering from migraine may consider REN.

Efficacy in at least 50% of REN treatments was calculated from all patients who voluntarily reported pain levels, symptoms, and/or disability at treatment-onset and at 2-hours post-treatment, with 72.2% (13/18) patients reporting pain relief, 36.0% (9/25) pain freedom, 83.3% (15/18) functional disability relief, 38.9% (7/18) functional disability freedom.

Migraine associated symptoms disappeared in at least 50% of REN treatments in 70.0% (7/10) patients for nausea/vomiting, 50.0% (4/8) phonophobia, 22.2% (2/9) photophobia; 63.6% (7/11) reported freedom from at least one associated symptom.