

Efficacy and Safety of Remote Electrical Neuromodulation (REN) for Migraine Treatment in Adolescents: A Cohort Real-World Evidence Study

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Received date: 01-Jun-2023, Manuscript No. IPJNN-23-13791; **Editor assigned:** 05-Jun-2023, PreQC No. IPJNN-23-13791 (PQ); **Reviewed:** 19-Jun-2023, QC No. IPJNN-23-13791; **Revised:** 26-Jun-2023, Manuscript No. IPJNN-23-13791 (R); **Published:** 03-Jul-2023, DOI: 10.4172/2171-6625.23.S6.005

Citation: Hershey AD, Inbar AS, Ironi A (2023) Efficacy and Safety of Remote Electrical Neuromodulation (REN) for Migraine Treatment in Adolescents: A Cohort Real-World Evidence Study. J Neurol Neurosci Vol.14 No.S6:005

Description

We recently reported the efficacy, treatment patterns, and safety of real-world usage of Remote Electrical Neuromodulation (REN) for the acute treatment of migraine attacks in a cohort of 1,629 adolescents aged 12-17, extending findings of prior clinical trials in adults and adolescents as well as real-world studies in adults [1].

Nearly 10% of children and adolescents in the United States experience headaches due to migraine, which negatively affect their quality of life, social activities, and school performance [2]. However, pharmacological treatment of attacks in adolescents is limited due to only few FDA approved medications, limited efficacy or lack of tolerability [3]. Remote Electrical Neuromodulation (REN) is a prescribed, drug-free, non-invasive, wearable device (Nerivio) controlled by a smartphone application. It is FDA-cleared for acute and/or preventive treatment of migraine with or without aura in patients 12 years of age or older. The device activates an intrinsic pain inhibition mechanism known as Conditioned Pain Modulation (CPM) by sub-painfully stimulating nociceptive nerve fibers in the upper arm, *via* a proprietary electrical signal (biphasic square pulse of 100-120 Hz, 400 μ s and up to 40 mA output current as adjusted by the user). Users are prompted to answer questions regarding their migraine attack at the beginning of treatments and 2 hours post-treatment.

Randomized, double-blind, sham-controlled trials in adults have shown that REN is safe and efficacious [4,5]. A large-scale real-world evidence study provided further data on the safety and efficacy of REN for the acute treatment of attacks of migraine in adults, also revealing that REN was mostly used as a standalone treatment [6]. REN was further shown to be highly effective, well-tolerated, and safe in a clinical trial evaluating the acute treatment of migraine attacks in adolescents and a post-hoc analysis comparing REN with standard care medications demonstrated that REN might be more efficacious for adolescents than some pharmacological medications [7,8].

This study evaluated a cohort of 1,629 adolescents aged 12-17

years who used the REN device to treat a total of 13,716 attacks of migraine. Average users age was 15.9 years (\pm 1.3) and 80.6% (1313) were female [1]. First, prospective data showed that a significant proportion of adolescents achieved consistent clinical benefit in at least 50% of their REN treatments at two hours post-treatment, with 60.3% achieving consistent pain relief, 26.3% achieving consistent pain freedom, 66.3% achieving relief from functional disability, and 41.2% achieving freedom from functional disability, further supporting the effectiveness of REN as a non-pharmacological treatment option for adolescents with migraine. Second, adolescents used REN as a standalone therapy in most treatments (64.4%). In remaining treatments, REN was combined with over-the-counter medications (18.6%) or prescription medications (17.0%). Efficacy rates were similar across these treatment categories, suggesting that REN can be effective either as a monotherapy or as an adjunct therapy, thus providing flexible treatment options which are important for addressing diverse needs and preferences of adolescents with migraine. Third, only three Device-Related Adverse Events (dAEs) were reported by adolescents' users. All three were minor and included tingling and local soreness during or after treatment, with no systemic side effects. The low incidence of adverse events further manifests the safety profile of REN in adolescent migraine treatment.

This analysis provides valuable insights into the use of REN for the acute treatment of migraine in adolescents, showing that REN is an efficacious, safe, and well-tolerated treatment for migraine attacks in adolescents in real-world settings, solidifying REN's importance as a valuable nonpharmacological treatment option for migraine management in adolescents.

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