The efficacy and safety of remote electric neuromodulation (REN), via neuromodulation device Nerivio™, for acute & preventive treatment of migraine: A Real World Evidence (RWE) study from India

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Aims & Objectives

Background: Remote electrical neuromodulation (REN) with the Nerivio[™] device has been introduced as a non-pharmacological option for migraine treatment. Evidence from real-world use in India remains scarce.

Objective:

To assess the efficacy and safety of Nerivio™ for both acute and preventive management of migraine in patients with chronic and episodic forms.

Methods:

- This retrospective, single-centre study included 141 patients (aged 12–75 years) diagnosed with migraine according to ICHD-3 criteria over a nine-month period.
- All patients were prescribed the Nerivio™ device for 60 days and evaluated at follow-up visits at 30, 60, and 90 days, with extended observation up to 180 days.
- Primary efficacy endpoints were changes in monthly migraine days (MMDs), attack frequency, and Migraine Disability Assessment (MIDAS) scores.
- Acute treatment response was defined as pain relief within 2 hours of device use, while preventive response was defined as a ≥50% reduction in MMDs. Safety outcomes were assessed by recording treatment-emergent adverse events.

Results:

- Among 141 patients, 98% had chronic migraine. At 60 days, mean monthly attacks declined from 9.16 to 2.40, and MMDs from 15.54 to 2.67 (both p<0.0001).
- MIDAS scores improved from 23.33 (severe disability) to 6.87 (mild disability).
- For acute use, 90% treated within 2 hours of onset; 80% achieved none/mild pain at 2 hours.
- Preventive benefits accrued over time, with ≥50% MMD reduction in ~20% at 30 days, ~60% at 60 days, ~80% at 90 days, and ~70% sustained at 180 days.
- Adverse events occurred in 2.8%, limited to mild transient local skin reactions. Overall, 70% achieved a clinically meaningful response, including 42% with excellent and 28% with moderate benefit.

Conclusion:

• REN with Nerivio™ is a safe and effective treatment for migraine in Indian clinical practice, offering both acute relief and sustained preventive benefit, with significant reduction in migraine burden and disability.