Efficacy and Safety of Combined Occipital and Supraorbital Transcutaneous Neurostimulation in Alleviating Migraine Headache Pain: A Prospective, Randomized, Single-blind, Parallel-group, Placebo Controlled Clinical Study

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Introduction

Combined occipital and supraorbital nerve stimulation (OS-TNS) has shown promising results in reducing migraine related pain, however, the intervention was only available with implanted neurostimulators[1,2].

This study is the first to assess a non-invasive OS-TNS device for treatment of migraine.

Purpose

To assess the safety and efficacy of a non-invasive combined occipital and supraorbital transcutaneous neurostimulation device (Relievion™, Neurolief Ltd. – Figure 1) for acute treatment of episodic migraine.

Methods

- A randomized, single-blind, parallel-group, sham-controlled study.
- 40 adults (age 21–62) suffering from episodic migraine were enrolled.
- Subjects were randomly allocated in 1:1 ratio to receive active or sham OS-TNS during 45 minutes with the Relievion™ headset.
- Treatment initiated at ≤90 minutes after onset of the migraine episode.
- Subjects were asked not to consume analgesic medications during two hours.
- The primary endpoint was a change (%) in VAS pain score from baseline to end of treatment.

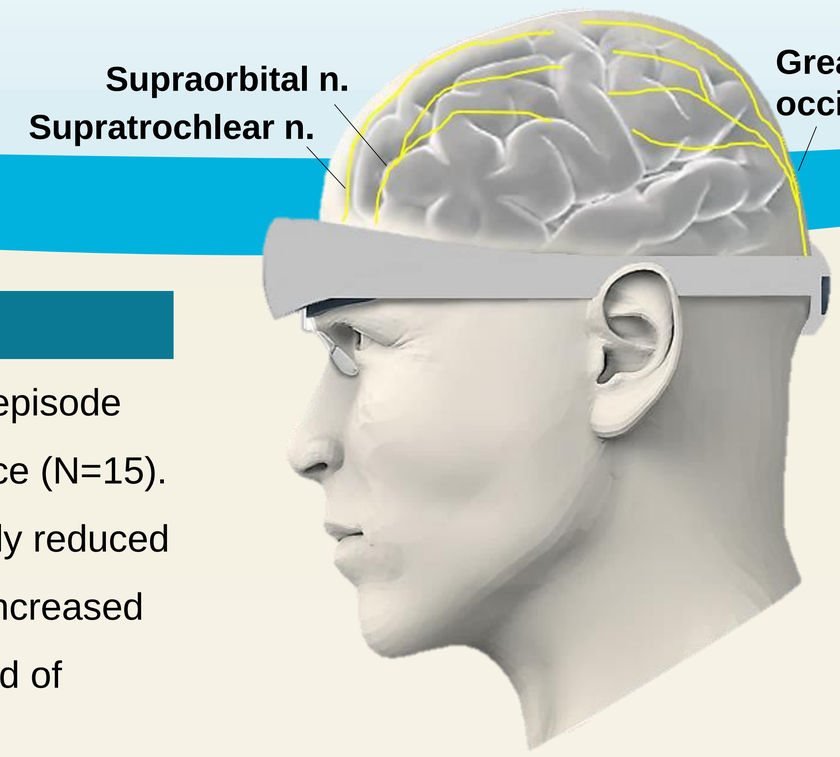

Figure 1: The device & target nerves

Results

- 30 patients treated one acute migraine episode with the active (N=15) or the sham device (N=15).
- The treatment group showed significantly reduced mean pain VAS score compared to an increased pain VAS score in the sham group at end of treatment.
  (-79.2% vs. +14.9%, respectively; P=0.0001) (*Figure 2*) and at two hours post treatment (-75.8% vs. +12.8%, respectively; P=0.0001)
- Pain-free rates at two hours where 53% in the treatment group compared to 0% in the sham group (P=0.0031).
- Responders* rates at 2 hours were 80% in the treatment group compared to 16.7% in the sham group and were mostly sustained at 24 hours.

Endpoint	Sham	Treatment	P
Change (%) in Pain VAS score at end of treatment	+14.9%	-79.2%	0.0001
Change (%) in Pain VAS score at 2 hours	+12.8%	-75.8%	0.0001
Pain Free at 2 hours (% subjects)	0%	53%	0.0031
Responders* at 2 hours (% subjects)	16.7%	80%	0.0018
Responders* at 24 hours (% subjects)	16.7%	60%	0.0357
Presence of photophobia at 2 hours (% subjects)	13%	75%	0.002

* Responders: Subjects reporting at least 50% pain reduction

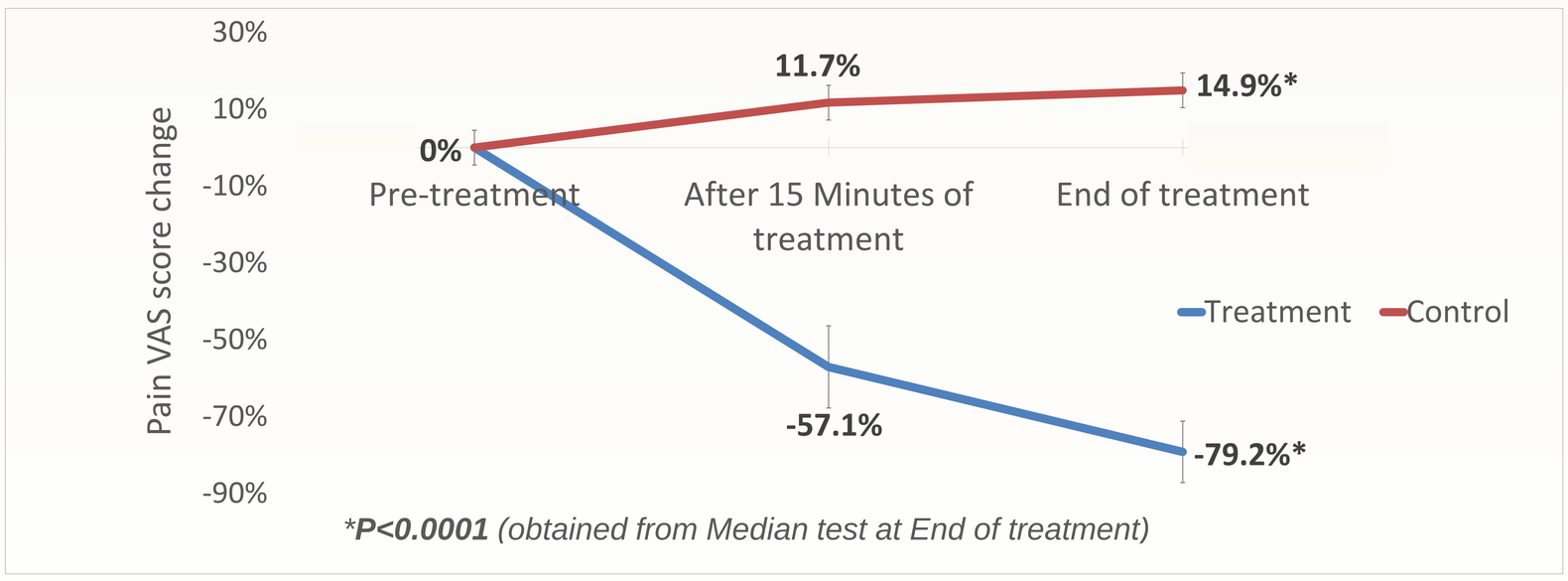

Figure 2: Effect on pain

Discussion & Conclusions

- Non-invasive combined occipital and supraorbital nerve stimulation is a safe and highly effective abortive treatment of episodic migraine.
- The therapeutic response was sustained for at least 24 hours post treatment for most of the patients.
- This treatment may be introduced as a fast acting, adverse effects free alternative to medications.

Acknowledgments

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1. Hann S, Sharan A; Dual occipital and supraorbital nerve stimulation for chronic migraine: a single-center experience, review of literature and surgical considerations. Neurosurg Focus. 2013 Sep;35(3):E9
2. Ken L. Reed; Peripheral Neuromodulation and Headaches: History, Clinical Approach, and Considerations on Underlying Mechanisms; Curr Pain Headache Rep. 2013; 17(1): 305.