

Combined Trigeminal & Occipital Nerve Stimulation (CTO-NS) Compared to Trigeminal Stimulation Alone for Treatment of Migraine Headache

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Introduction

Migraine is a prevalent and debilitating primary headache disorder. In the U.S population the prevalence of migraine is approximately 18% in women and 6% in men¹. Treatment of migraine headache by combined neurostimulation of both the trigeminal and occipital nerves (CTO-NS) has shown promising results²⁻³. Until recently, combined stimulation of these nerves was feasible by implanted devices only. We used a novel non-invasive CTO-NS device to assess the efficacy of concurrent Trigeminal and Occipital nerve stimulation compared to stimulation of the trigeminal nerve only in inhibiting migraine headache.

Method

Ten (10) subjects suffering from episodic migraine, eight (8) females and two (2) males aged 22–54 years, were treated. Treatment was initiated at no more than 120 minutes after the onset of the migraine episode. The CTO-NS neurostimulator (**Fig. 1**) consists of a head-mounted device which integrates six electrodes. Two (2) electrodes stimulate the greater occipital nerve branches and four (4) electrodes stimulate bilaterally the supraorbital and supratrochlear branches of the trigeminal nerve. Treatment was applied during 15 minutes to both the occipital and trigeminal nerves (both stimulation output channels of the device were activated) and then during additional 15 minutes to the trigeminal

nerve only (only one output channel activated), or started initially with trigeminal only and then applied to both nerves. The order was random. Before treatment and at the end of each 15 minutes session subjects were asked to mark their level of pain according to Visual Analogue Scale (VAS). Stimulation intensity was increased to the maximal level as long as it still felt comfortable to the subject.

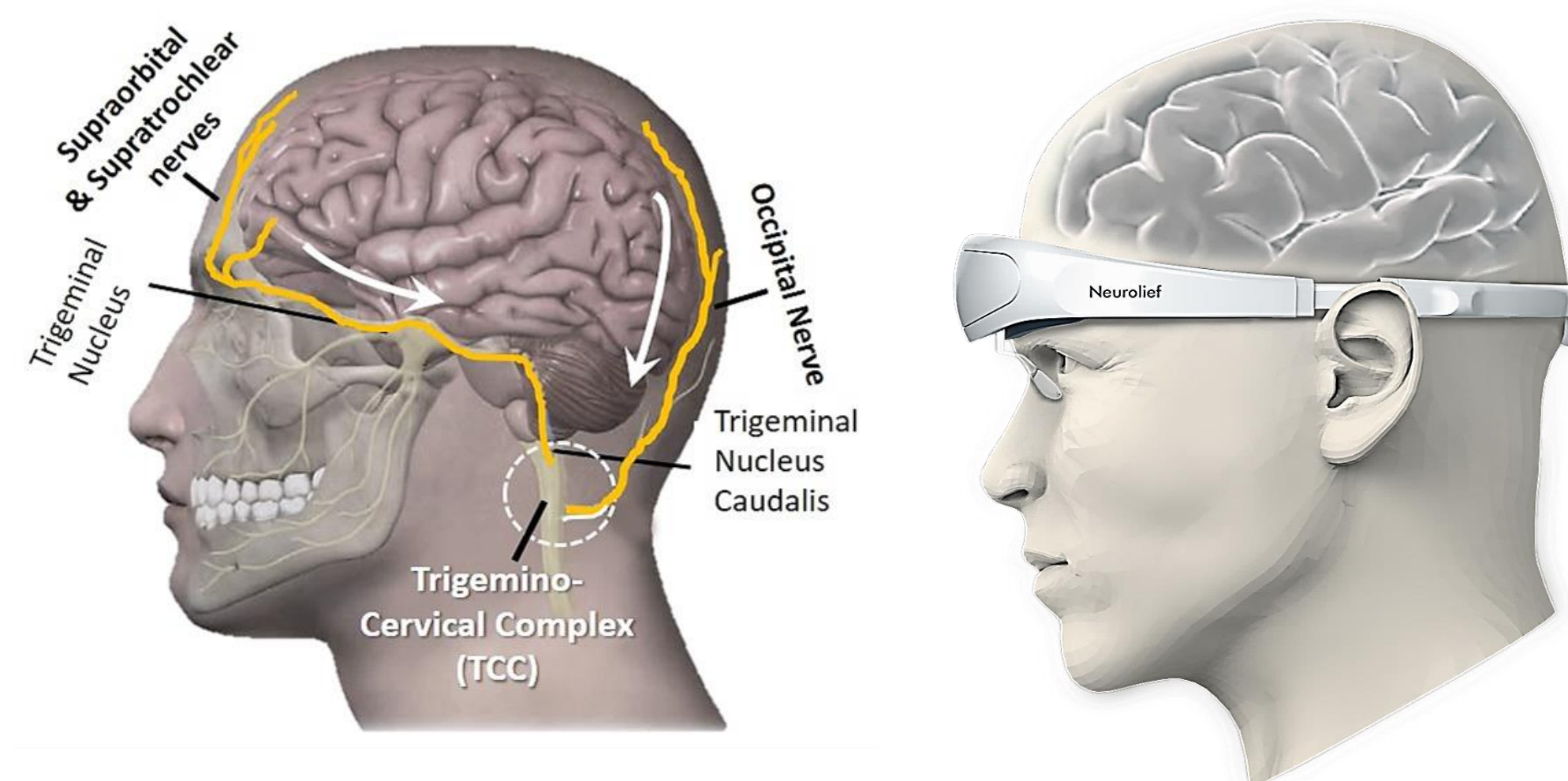


Fig. 1: The CTO-NS device and its target nerves

Results

The treatment was well tolerated by all subjects. Eight (8) out of Ten (10) subjects felt that stimulation of the trigeminal branches during concurrent stimulation was more pleasant compared to stimulation of these branches when the occipital stimulation was not active (conceivably due to modulation of the sensation by the occipital N. stimulation). Mean VAS pain score at baseline was 5.7 ± 2.2 . Mean VAS pain score reduced to 2.7 ± 1.8 (reduction of 56.3%) after combined occipital and trigeminal stimulation compared to only 4.1 ± 2.2 (reduction of 31%) after trigeminal stimulation alone (**Fig. 2**).

Trigeminal stimulation only Combined Occipital & Trigeminal stimulation

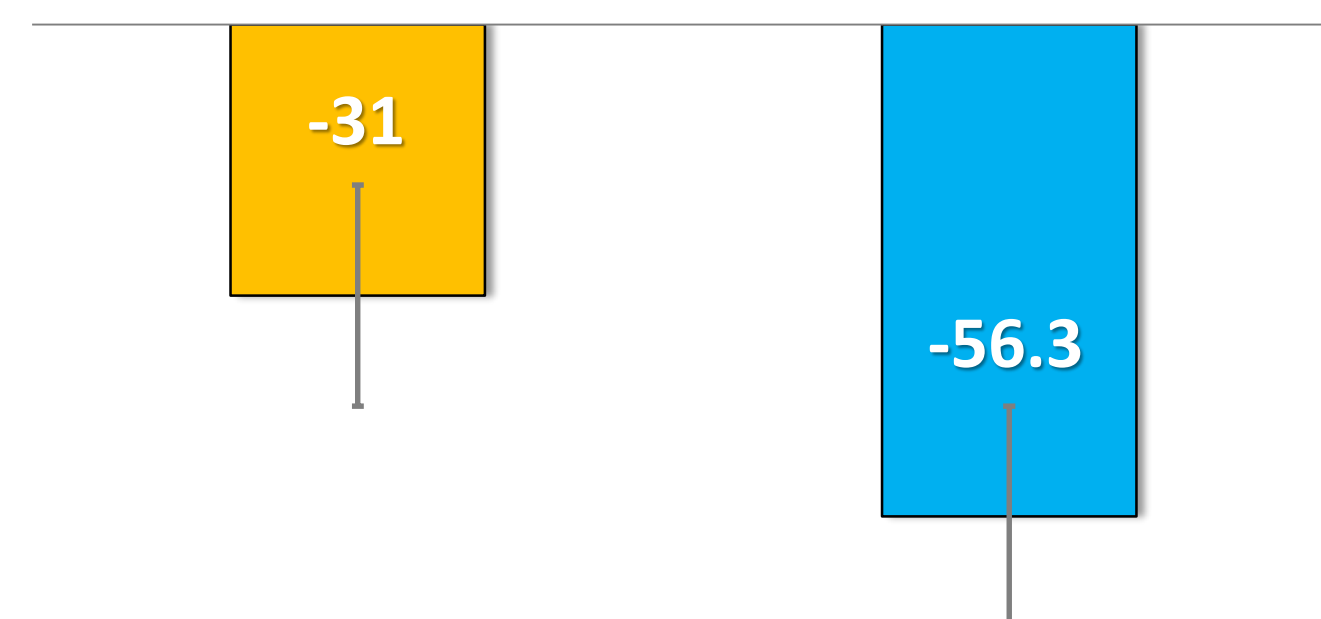


Fig. 2: Mean % pain reduction post trigeminal and post combined trigeminal & occipital stimulation

Conclusions

This proof of concept study suggests that combined trigeminal and occipital nerves stimulation applied by a non-invasive CTO-NS device is more effective compared to stimulation of the trigeminal nerve alone and may elicit rapid pain reduction when applied during migraine episode.

References

1. Lipton, R.B., et al., Migraine prevalence, disease burden, and the need for preventive therapy. *Neurology*, 2007. 68(5): p. 343-9
2. Reed KL. Peripheral neuromodulation and headaches: history, clinical approach, and considerations on underlying mechanisms. *Curr Pain Headache Rep* 2013; 17: 305.

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