Trigeminal and Occipital Neuromodulation for Rapid Pain Reduction in Occipital Migraine

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Introduction

In our soon to be published study, 67 percent of patients treated with an active Concurrent Trigeminal and Occipital Neurostimulation (CTO-NS) device for one acute migraine episode reported the occipital region as one of the four quadrants where they suffered pain (a small fraction of patients described a pain focus in the occipital region alone). Until recently, however, CTO-NS has been available only with use of surgically-implanted electrodes. This case study presents results of non-invasive CTO-NS treatment on a migraine patient whose pain always began in the occipital region..

Method

The subject was part of a randomized, single-blind, parallel-group, sham-controlled study. Forty (40) adults suffering from episodic migraine were enrolled. All individuals met the international criteria for migraine headache. Subjects were randomly allocated into either an active (N=20) or a sham occipital and supraorbital stimulation (N=20) group. Treatment or sham treatment was carried out for 45 minutes. The primary endpoint was defined based on relative change (percent change) in Visual Analogue Scale (VAS) pain score from baseline to end of treatment without using pain medication. No Rescue medication was allowed. Subjects had an average of six (6) migraine episodes monthly.

The CTO-NS neurostimulator (**Fig. 1**) consists of a headset with six integrated electrodes. Two electrodes stimulate the greater occipital nerve branches and four electrodes stimulate bilaterally the supraorbital and supratrochlear branches of the trigeminal nerve.

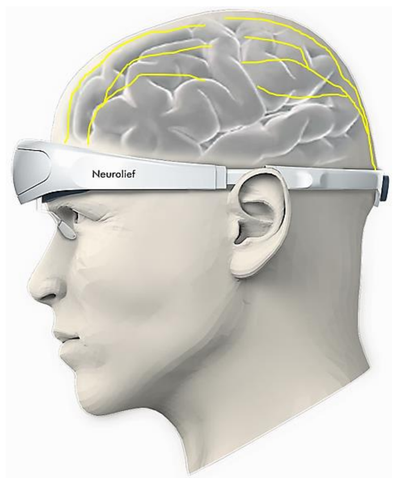

Fig. 1: The CTO-NS device and its target nerves

Results

The current study describes a case of a 42-year-old male who suffered four migraines per month for many years. The subject stated that the pain always began in the occipital region and extended to other regions as the migraine developed.

The baseline VAS pain score before the CTO-NS neuromodulation therapy was 5.5. This score declined sharply and rapidly to a value of 0.7 within 15 minutes of therapy. The subject was free of pain at 1 hour and 2 hours after initiation of treatment and remained pain-free for at least 24 hours.

The CTO-NS device was also evaluated for efficacy in mitigating functional disability, phonophobia, and photophobia, all of which disappeared after the treatment. No related adverse events were recorded.

Conclusions

Treatment with a wearable, non-invasive CTO-NS device had substantial benefit for the patient. Within 15 minutes of therapy initiation, subject's VAS pain score declined sharply and rapidly and he remained free of pain, functional disability, phonophobia, and photophobia for at least 24 hours.

This novel digital health CTO-NS device will enable real time remote monitoring of usage data and clinical outcome by the medical team, medical provider and the pharmaceutical industry.

References

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