

The Comparative Effectiveness of Vagal Nerve Stimulation and Occipital Nerve Stimulation in The Treatment of Chronic Migraine

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Abstract

Chronic migraine is a disorder that affects millions worldwide. Research indicates that people suffering from chronic migraine respond well to neurostimulation. Many studies have assessed migraine activity with a neurostimulator, but few have compared different treatments. A systematic review of a study that assessed the migraine activity using mean monthly migraine days for those implanted with an occipital nerve stimulator device was compared to the findings of another study which assessed the mean monthly migraine days for those implanted with a vagal nerve stimulator. The patients implanted with the occipital nerve stimulator had significantly decreased monthly migraine days when compared with other matched controls. Those who were implanted with the vagal nerve stimulator also had significantly decreased monthly migraine days when compared to controls. For this review, occipital nerve stimulation had a greater reduction in monthly migraine days when compared to those who were implanted with the vagal nerve stimulator. Further studies with greater sample sizes are needed to conclude which has greater efficacy.

Keywords: migraine; vagus nerve stimulation; occipital nerve stimulation; neuromodulation; headache; nerve stimulation

Introduction

Chronic Migraine (CM) is a highly disabling primary headache disorder affecting approximately two percent (2%) of the world's general population [1,2], and has a substantial impact on sufferers. Compared to episodic migraine, CM sufferers report higher levels of headache related disability and comorbid psychiatric disorders, as well as impaired health-related quality of life [3-6]. Despite significant advances in the pharmacological management of patients with CM, the CM remains intractable to medical treatment in many cases [7]. Pharmacologic treatment seems to be insufficient in the migraine management due to its unsatisfactory therapeutic effects, contraindications, and side effects [8]. Therefore, it is essential to find more effective and safe treatments [9]. Recent studies have demonstrated the safety and effectiveness of both Vagus nerve stimulation [10-12] and Occipital nerve stimulation [13-15]. This article will address the comparative effectiveness of Vagal Nerve Stimulation and Occipital Nerve Stimulation in the treatment of chronic Migraine (CN).

Methods

For the Occipital Nerve Stimulation Study (13):

The study was a randomized, blinded, and placebo-controlled study. A total of 110 test subjects were gathered for this study. No primary endpoint was prespecified, rather a range of efficacy measures were utilized at 3 months into the study and then compared to that of baseline. These measures included decrease in overall pain intensity (0-10 scale) and responder rate (percentage of patients with a 50% drop in headache pain intensity or a greater than or equal to 3-point drop in overall pain intensity from baseline). A headache day was defined as a headache intensity rated greater than or equal to 3. Chronic migraine was defined according to the second edition of the International Classification of Headache Disorders (ICHD-II). Subjects were then randomized into one of three treatment groups, adjustable stimulation (AS), preset stimulation (PS), and medical management (MM), using a randomization ratio of 2:1:1, respectively. The AS group was instructed to maintain the stimulator on the "on" position and adjust the device to minimize pain. There was also the control group which only received MM during the blinded phase of the study.

For the Vagal Nerve Stimulation Study [11]:

A total of 477 patients were enrolled in a double-blind study utilizing implanted non-invasive vagal nerve stimulation (nVNS) or sham stimulation. Patients

were 18 to 75 years of age with a diagnosis of migraine with or without aura according to International Classification of Headache Disorders, 3rd edition. Use of preventative migraine treatments at or within 30 days before baseline was not permitted. Patients were randomly assigned to receive nVNS or a sham control device and were trained accordingly. The primary efficacy outcome was the mean reduction in number of migraine days from baseline to the last 4 weeks of the 12-week double blind period. A migraine day was defined as any headache occurring in a single calendar day. Greater than or equal to 50% responder rates for migraine, headache, and acute medication days, with a “responder” defined as a patient who recorded a reduction of at least 50% from baseline to the last 3 weeks of the double-blind period, and migraine and headache day reductions in the open-label period were other secondary outcomes that were recorded.

Results

For the Occipital Nerve Stimulation Study (13)

After 3 months, the percent reduction in headache days per month was $27.0 \pm 44.8\%$ for AS, $8.8 \pm 28.6\%$ for PS, $4.4 \pm 19.1\%$ for MM and $39.9 \pm 51.0\%$ for the ancillary group. This corresponded to reductions in headache days per month of 6.7 ± 10.0 for AS, 1.5 ± 4.6 for PS, 1.0 ± 4.2 for MM and 9.1 ± 12.3 for the ancillary group. The reduction in overall pain intensity was 1.5 ± 1.6 , 0.5 ± 1.3 , 0.6 ± 1.0 and 1.9 ± 3.5 for AS, PS, MM and the ancillary group, respectively.

For the Vagal Nerve Stimulation Study (11)

Mean reductions in the number of headache days were -2.73 days (95% CI: -3.37 , -2.09 ; baseline: 8.9 headache days) for the nVNS group and -2.11 days (95% CI: -2.74 , -1.49 ; baseline: 9.1 headache days) for the sham group.

Table 1: Reduction in Monthly Migraine Days for Each Treatment.

Treatment Group	Reduction in Monthly Migraine Days
Occipital Nerve Stimulation (AS)	6.7
Occipital Nerve Stimulation (PS)	1.5
Vagal Nerve Stimulation	2.73

The above (Table 1) depicts the reduction in monthly migraine days that each treatment had.

Conclusion

Both studies suggest that both occipital nerve stimulation and vagal nerve stimulation have significant effects on reducing monthly migraine days. When participants were allowed to modify the frequency of their implantable occipital nerve stimulator, there was almost a three-fold reduction of monthly migraine days as compared to the participants using the vagal nerve stimulator. This likely correlates to the occipital nerve being more implicated in the pathogenesis of chronic episodic migraine than is the vagus nerve. Longitudinal studies conducted throughout longer periods of time need to be done in order to assess if these effects are longstanding and if there are any potential side effects that might be of concern with these treatments. Since implantable neurostimulation devices are expensive, additional efforts must also be pursued in order to lower the costs.

Conflict of Interest

No conflict of interest to be disclosed.

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Cite this article: Akbar S., Keane J., Goldstein L.B. (2025). The Comparative Effectiveness of Vagal Nerve Stimulation and Occipital Nerve Stimulation in The Treatment of Chronic Migraine, *Journal of Clinical Research and Clinical Trials*, BioRes Scientia Publishers. 4(2):1-3. DOI: 10.59657/2837-7184.brs.25.046

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Article History: Received: January 15, 2025 | Accepted: February 11, 2025 | Published: February 17, 2025