The Safety and Efficacy of Peripheral Nerve Stimulation of the Occipital Nerve for the Management of Chronic Migraine

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**Introduction**

Chronic migraine is a debilitating disorder with few treatment options. Peripheral nerve stimulation (PNS) of the occipital nerve is emerging as a potentially promising therapy for chronic migraine patients. We conducted a clinical trial to assess the safety and efficacy of PNS of the occipital nerve for the management of headache pain and disability associated with chronic migraine.

**Methods**

In this prospective, multi-center, open-label, controlled study, 157 patients were implanted with a neurostimulation system (St. Jude Medical Neuromodulation Division, Plano, TX) and randomized to an Active (n=105) or Control group (n=52) for 12 weeks. Patients then continued in an open-label phase with 24-, 48-, and 52-week evaluations. Outcome measures included headache days recorded through a patient diary, the Migraine Disability Assessment Scale, satisfaction, quality of life (QoL), patient-reported outcomes and adverse event rates.

**Results:**

**Inclusion/Exclusion**

- **Inclusion Criteria:**
  - A migraine headache that occurs 15 or more days per month for more than 3 months without medication overuse
  - Not attributable to any other disorder
  - Has at least two of the following diagnostic characteristics:
    - Duration of headache attacks of 4-72 hours
    - Character of headache pain:
      - Bilateral
      - Visceral
      - Pulsating
    - Sensitivity to noise or light
    - Aggravation by routine physical activity
    - Capability to be aggravated by routine physical activity
    - Sensitivity to noise or light
    - Aggravation by routine physical activity
    - Capability to be aggravated by routine physical activity
    - Sensitivity to noise or light
    - Aggravation by routine physical activity
    - Capability to be aggravated by routine physical activity
  - Has failed three or more preventive drugs
  - Has at least two of the following diagnostic characteristics:
    - A migraine headache that occurs 15 or more days per month
    - Duration of headache attacks of 4-72 hours
    - Character of headache pain:
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  - Has tried at least two migraine specific acute medication

- **Exclusion Criteria:**
  - Botox within 6 months prior to initial baseline
  - Headache Inhibits Daily Activity
  - Headache Episode Length
  - Headache Type
  - Patient Disability

**Results: 2-Week Controlled Phase**

**Results: 52-Week Open-Label Phase**

**Summary and Conclusions**

- **Most patients** (50.5%) completed the 12-week visit.
- **During the 12-week Control phase**, there were significant group differences in the reduction of headache days, as well as on the MIDAS, headache relief assessments and Cincinnati PAIN Scale.
- **In the Active group**, 35.2% of patients achieved a 30% reduction on the VAS, whereas only 17.3% of patients in the Control group achieved the same.
- **Statistical significance** was not observed on the primary endpoint established by the U.S. Food and Drug Administration. This was defined as a significant difference between patients in the Active and Control group who reported a 50% or greater reduction in pain as measured on the VAS.

- **Patients reported** 43.3% and 49.5% headache relief at 24 and 52 weeks post-implant, respectively, and the majority of patients rated their headache relief as excellent or good.
- **The majority of patients** were satisfied with the amount of headache relief and indicated improved quality of life at both 24 and 52 weeks post-implant. They also indicated that they would undergo the procedure again (83.0%), would recommend the procedure to someone else (88.7%), and were satisfied or very satisfied with the results of the procedure (68.0%).
- **Overall, the rate of serious device or procedure-related events was 1.0%**.
- **The results of this study provide** evidence to support safety and effectiveness of PNS of the occipital nerve for the management of headache pain and disability associated with chronic migraine.