

**O10****Efficacy of Occipital Nerve Stimulation for the Management of Intractable, Chronic Migraine: Results from a Prospective, Multicenter, Double-Blinded, Controlled Study**

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**Objectives:** Provide evidence to support efficacy of PNS for the management of intractable, chronic migraine.

**Background:** Intractable chronic migraine refers to the occurrence of headaches at least 15 or more days per month for more than three months in patients with migraine that have failed to respond to at least 3 preventative therapies and have been classified as moderately disabled using a validated disability instrument. Intractable chronic migraine is a debilitating disorder with few treatment options. Peripheral Nerve Stimulation (PNS) of the occipital nerves is a potentially promising therapy for chronic migraine patients.

**Methods:** In this IRB-approved, prospective, multicenter, double-blinded, controlled study, patients were implanted with a neurostimulation system (St. Jude Medical Neuromodulation Division, Plano, TX) and randomized to an Active or Control group for 12 weeks. Reduction in the number of headache days, scores for MIDAS, Zung Pain and Distress Scale (PAD), VAS, quality of life (QoL), and satisfaction are presented for patients that met the criteria for intractable, chronic migraine (defined as 15 or more days per month with headache of at least 4 hours of pain with peak intensity that is at least of moderate severity, failure of 3 or more preventative drugs, and at least moderate disability determined using a validated migraine disability instrument [e.g., MIDAS or HIT-6]).

**Results:** Most patients (122/125) completed the 12-week visit. Although there was not a significant group difference in the number of patients with a 50% reduction on the VAS (primary endpoint), there was a significant difference at 30% ( $p < 0.05$ ), which is considered clinically significant. Significant group differences for reduction in number of headache days, MIDAS, Zung PAD, VAS, quality of life and satisfaction at 12 weeks were observed ( $p < 0.05$ ). In the Active and Control groups respectively, number of headache days decreased by 7.0 and 2.7, total MIDAS scores improved by 72.9 and 27.2, PAD scores improved by 14.6 and 5.5, and a 30% reduction in VAS was achieved in 36.4% and 13.5% of patients, respectively. In addition, 64.8% of patients in the Active group reported improved quality of life whereas only 18.9% of patients in the control group reported the same. For satisfaction, 46.6% of patients in the Active group reported being satisfied whereas only 16.2% in the Control group reported being satisfied.

**Conclusions:** The results provide evidence to support efficacy of PNS of the occipital nerves for the management of headache pain and disability associated with intractable, chronic migraine. Further studies are warranted.