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Evidence for Long-Term Efficacy of Peripheral Nerve Stimulation of the Occipital Nerves in the Management of Chronic Migraine

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Objectives: Provide evidence to support long-term efficacy of PNS of the occipital nerves in the management of chronic migraine.

Background: Chronic migraine is a debilitating disorder with few treatment options. Recent studies have shown the utility of PNS of the occipital nerves in the management of chronic migraine.

Methods: In this IRB-approved, prospective, multicenter, double-blinded study, patients were implanted with a neurostimulation system (St. Jude Medical, Plano, TX) and randomized to an Active or Control group for 12 weeks. Patients continued in an open-label phase of the study which lasted an additional 40 weeks. Outcomes collected during this phase included headache day reduction (duration > four hours with moderate/severe peak intensity), migraine-related disability and distress as assessed by the migraine disability assessment (MIDAS) questionnaire and the Zung Pain and Distress (PAD) scale, headache pain relief, and satisfaction. All statistical testing was conducted to assess change from baseline to 1 year post-implant. Analyses were performed using paired *t*-tests. An intent-to-treat (ITT) analysis that included all patients (N=133) as well as an analysis of only patients that met the criteria for intractable, chronic migraine (ICM; N=105) was performed for all variables.

Results: For the ITT population, headache days were significantly reduced by 6.7 ($\pm$8.4) days ($p<0.001$), MIDAS scores were significantly reduced by 50.9 ($\pm$71.9) points to a mean score of 106.7 ($\pm$85.4) points ($p<0.001$), total PAD scores were significantly reduced by 10.3 ($\pm$14.8) points from a mean baseline score of 66.8 ($\pm$13.6) points ($p<0.001$). In addition, 65.4% of patients reported excellent or good headache relief and patient satisfaction was also high among this patient cohort. Slightly improved results were noted for the ICM population in which headache days were significantly reduced by 7.7 ($\pm$8.7) days ($p<0.001$), MIDAS scores were significantly reduced by 57.9 ($\pm$71.8) points from a baseline score of 169.7 ($\pm$70.6) points ($p<0.001$), total PAD scores were significantly reduced by 11.2 ($\pm$15.2) points to a score of 57.4 ($\pm$16.2) points. In addition, 67.9% of ICM patients reported excellent or good headache relief and patient satisfaction was also high among this patient cohort.

Conclusions: The results provide long-term evidence to support efficacy of PNS of the occipital nerves for the management of chronic migraine.