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The safety and efficacy of occipital nerve stimulation for the management of chronic migraine

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

Methods: In this prospective, multi-center, double-blind, controlled study, patients were implanted with a neurostimulation system (St. Jude Medical Neuromodulation) and randomized to an Active or Control group for 12 weeks. Patients then continued in an open-label phase with 24, 48, and 52 week evaluations. Scores for MIDAS, Zung Pain and Distress Scale (PAD), VAS, quality of life (QoL), satisfaction, and adverse events were reported.

Results: Most patients (153/157) completed the 12-week visit. There were significant group differences for all assessments at 12 weeks ($p < 0.01$). In the Active and Control groups respectively, MIDAS headache days decreased by 22.5 and 3.4, total MIDAS scores improved by 64.6 and 20.4, PAD scores improved by 13.3 and 5.5, VAS scores decreased by 14.1 and 7.0, 35.2% and 11.5% of patients achieved a 30% reduction in VAS, 66.7% and 17.2% of patients reported improved QoL, and 51.4% and 19.2% were satisfied. Overall, the rate of serious device- or procedure-related events was 1.0%. These events included 1 case of infection and 1 case of expected post-operative pain that required hospitalization.

Conclusion: The results provide evidence to support safety and effectiveness of ONS for the management of headache pain and disability associated with chronic migraine.