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Occipital Nerve Stimulation Via the BION Device for the Treatment of Medically Refractory Chronic Cluster Headache

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Objectives: To examine the effectiveness of occipital nerve stimulation (ONS) with the implantable BION stimulator on chronic cluster headache (CCH) frequency over a 3-month period.

Background: Preliminary results in small numbers of patients suggest that ONS may provide effective palliation for medically refractory CCH. Implantation of the device is invasive and requires at least 3 incisions to implant the device, wire leads, and impulse generator. The BION is a small (3.2mm diameter x 27.5mm length) cylindrical stimulator without wire leads or the need for a remotely implanted pulse generator effectively eliminating the potential for lead migration or fracture seen with previous ONS devices.

Methods: In a prospective non-randomized study, effectiveness of ONS with the BION stimulator was evaluated in five adult patients with CCH (defined by ICHD-2 criteria). Patients recorded cluster attack frequency using a headache diary at 1-month, 3-month (primary efficacy endpoint), 6-month, and 12-month intervals. Positive response to ONS was defined as a >50% reduction in headache frequency at 3 months.

Results: Four patients returned diaries for evaluation. Three (75.0%) showed a positive response at 3 months with a mean reduction of 65.2% (range 100.0-33.3, standard deviation 28.0). One patient did not use the stimulator or submit a diary. These results were sustained at 6 and 12-month follow-ups (one patient did not complete a 12-month diary, but reported no subjective change compared to their 3-month response). Adverse events were limited to two patients with neck pain and/or cramping with stimulation at high amplitudes and one patient requiring revision for a faulty battery.

Conclusions: This study supports the previously observed potential efficacy of ONS for medically refractory CCH and also demonstrates the potential for a wireless impulse generator to minimize morbidity as well as the short and long-term complications frequently associated with available technology.