

Real-world Use of Non-invasive Vagus Nerve Stimulation for Acute Treatment of Pain in Episodic Cluster Headache Attacks: Results From a Patient Registry

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Objective: The gammaCore[®] Patient Registry (GPR), a platform for patients to prospectively record experiences with non-invasive vagus nerve stimulation (nVNS), was created to expand understanding of the benefits and challenges of real-world nVNS use.

Background: Cluster headache (CH) has few safe, effective, and practical treatment options. nVNS (gammaCore) can relieve CH-associated pain within 15 minutes and has been cleared by the US Food and Drug Administration for acute treatment of episodic CH and migraine pain.

Design/Methods: At select US headache centers, adults diagnosed with episodic CH and prescribed nVNS were invited to participate in the GPR and asked to provide baseline information. Participants were trained on self-treatment with nVNS and the use of a tracker for collection of data on nVNS usage and the frequency, severity (0-4 scale; 0=no pain), and duration of their CH attacks.

Results: Between July 2017 and June 2018, 14 patients (50% women) provided data on nVNS use for 116 attacks, with a mean of 3.69 (standard error, 0.46) stimulations used per attack. Mean pain score was 2.68 (95% confidence interval [CI], 2.43-2.92) at attack onset and 1.30 (95% CI, 0.97-1.64) 30 minutes after initial treatment; mean reduction in pain score at that time was 1.38 (95% CI, 1.13-1.64). Patients subjectively self-reported that nVNS reduced pain in 82.0% of attacks (95% CI, 56.8%-94.1%); whereas their objective scores before and after treatment suggested that nVNS reduced pain in 86.9% of attacks (95% CI, 70.0%-95.0%). Of the 116 nVNS-treated attacks, 69.8% (95% CI, 53.0%-82.7%) had either mild or no pain at 30 minutes.

Conclusions: For the vast majority of attacks, nVNS reduced pain severity within 30 minutes. These real-world findings demonstrate the practical use of nVNS and complement evidence from clinical trials supporting its efficacy for acute treatment of episodic CH attacks.