

POSTER PRESENTATION

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Pathway ch-1 study: sphenopalatine ganglion (spg) stimulation for acute treatment of chronic cluster headache (CCH)

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Introduction

The pain and autonomic symptoms of cluster headache result from activation of the trigeminal parasympathetic reflex, mediated through the SPG [1,2]. We aimed to investigate the safety and efficacy of SPG stimulation for the acute treatment of CCH.

Methods

A multi-center, dose range finding, multiple headache attack (HA), acute treatment study with random insertion of placebo was initiated. All subjects met the ICHD-2 criteria for CCH with a minimum of 4 HA/week. Subjects were implanted with a miniaturized neurostimulator which, along with a controller, provides on-demand SPG stimulation. During the blinded experimental period (EXP), each HA was randomly treated with 1 of 3 therapies: full, sub-perception or placebo stimulation. Pain relief at 15 minutes (decrease from 'moderate' or 'severe' to 'none' or 'mild' on the 5-point scale) and HA frequency reduction were analyzed.

Results

Thirty-two subjects were enrolled, 27 completed the EXP. One subject remains in EXP, 1 skipped EXP, 2 were explanted due to early lead migration, and 1 did not complete the implant due to difficult anatomy. Pain relief was achieved in 67% of HA (n=190) treated with full compared to 8% (n=183) with sub-perception and 8% (n=189) with placebo stimulation. A clinically significant improvement occurred in 19 of 27 (70%) subjects: 7 (26%) achieved acute pain relief in $\geq 50\%$ of treated HAs, 10 (37%) a $\geq 50\%$ reduction in HA frequency compared to baseline and 2 (7%)

experienced both. Of the 12 frequency responders, HA frequency was reduced to ≤ 2 HA/week in 9 subjects. Eight (29%) of the 27 did not respond or did not provide sufficient data for evaluation. Most subjects (47%) experienced transient, mild to moderate numbness within the second division of the trigeminal nerve post implant with 62% resolving within the first three months.

Conclusions

Results suggest that acute, on-demand SPG stimulation using the ATI Neurostimulation System has acute and preventive effects and is an effective novel therapy for CCH. In this study, 70% of subjects responded to the therapy.

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