

LONG-TERM THERAPEUTIC RESPONSE OF SPHENOPALATINE GANGLION (SPG) STIMULATION FOR CLUSTER HEADACHE – PATHWAY CH-1 STUDY

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OBJECTIVE: The objective of this study is to investigate long-term therapeutic efficacy of SPG stimulation in chronic cluster headache patients.

BACKGROUND: This study is a continuation of the randomized, double-blind, multi-center study of an SPG neurostimulator (Pathway CH-1 study); 68% of patients experienced clinically significant improvements[1]. The aim of this interim long-term analysis is to evaluate therapeutic efficacy over 18 months.

DESIGN/METHODS: Therapeutic efficacy (acute pain response following SPG stimulation and/or attack frequency reduction) was analyzed during long-term follow up (12-18 months post-implant). Acute pain responders achieved relief from moderate or greater pain, or freedom from mild pain in ≥50% of attacks analyzed. Frequency responders achieved ≥50% attack frequency reduction for ≥2 months, versus baseline between 12-18 months.

RESULTS: **43 patients were enrolled in Pathway CH-1 and 24 completed follow-up through 18 months (556 days, range 483-620). 66% (16/24) were responders, experiencing a clinically significant long-term improvement with SPG stimulation.**

Of the 16 responders between 12-18 months, 8 (50%) were acute responders, treating 91% of attacks effectively (N=2011 attacks). 12 (75%) were frequency responders; attack frequency was reduced by 85% (from a baseline of 14.5 to 2.3 attacks/week).

CONCLUSIONS: Data through 18 months of follow-up indicates that on-demand SPG stimulation for CCH provides a continued therapeutic benefit in a majority of patients.

References:

[1] Schoenen J, Jensen RH, Lantéri-Minet M, Láinez MJ, Gaul C, Goodman AM, Caparso A, May A. Stimulation of the sphenopalatine ganglion (SPG) for cluster headache treatment.

Pathway CH-1: A randomized, sham-controlled study. *Cephalalgia* 2013.

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