

**EHMTC-0306
POSTER SESSION C**

**PATHWAY REGISTRY 12 MONTH INTERIM
RESULTS – LONG-TERM THERAPEUTIC
EFFECTIVENESS OF SPHENOPALATINE
GANGLION (SPG) STIMULATION FOR
CLUSTER HEADACHE (CH)**

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Background: The Pathway Registry evaluated sphenopalatine ganglion (SPG) stimulation for cluster headache (CH). Previously, in a randomized, double-blind, multicenter study (Pathway CH-1), 68% of patients experienced clinically significant improvements. We evaluated long-term therapeutic effectiveness of SPG stimulation.

Method: Acute pain response following SPG stimulation and attack frequency reduction were analyzed at 12 months following SPG microstimulator insertion. Acute effectiveness is relief/freedom from \geq moderate pain, or freedom from mild pain. Therapeutic responders achieved acute effectiveness in $\geq 50\%$ of attacks by end of stimulation, or $\geq 50\%$ attack frequency reduction versus baseline. Patients were similarly evaluated for ≥ 75 and $\geq 30\%$ therapeutic response.

Results: Through March 2016, 119 patients were enrolled. 80 patients (74 chronic CH, 6 episodic CH) had a microstimulator inserted and progressed through the 12 month study visit (374 ± 31 days post-insertion, range 322–475).

In these 80 patients (59 male, 21 female, age 46 ± 12 years), baseline attack frequency was 24.9 ± 20.8 attacks/week with severely CH impact (HIT-6: 64.0 ± 6.9). 66% (53/80) were therapeutic responders with a response of $\geq 50\%$. Frequency responders (43/80) reduced attack frequency by 86% (26.5 ± 23.2 to 3.6 ± 6.6 attacks/week, $p < 0.001$). Acute responders (25/80) achieved effective therapy in 87% of attacks (4212/4863) by end of stimulation.

46% (37/80) of patients experienced a very strong therapeutic response of at least 75%; 75% (61/80) experienced at therapeutic response of at least 30%.

Conclusion: Therapeutic effectiveness of SPG stimulation in chronic medically refractory cluster patients (Pathway CH-1 trial) is confirmed in an open label registry of a large series of cluster patients through 12 months.

Conflict of interest

Disclosure statement:

AG and AC are employees of Autonomic Technologies, Inc.