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EHMTI-0398. Long term safety of the ATI neurostimulation system for the treatment of cluster headache

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Introduction

At least two-thirds of cluster headache (CH) patients that received the ATI Neurostimulation System have achieved profound clinical improvements including acute headache pain relief and/or significant attack frequency reduction. The ATI Neurostimulator is inserted trans-orally using a minimally invasive technique.

Aim

This analysis aims to characterize the long term safety of the ATI Neurostimulation System in CH sufferers.

Method

Patients from the Pathway CH-1 and Pathway R-1 studies were included in the analysis. All adverse events (AEs) including transient swelling and pain, were documented and assessed for relationship to procedure and/or the presence of the neurostimulator.

Results

Ninety-eight (98) patients received the ATI Neurostimulator as of May 2014. Fifteen patients (15%) reported no AEs and 83 patients (85%) reported at least one related AE. In total, 341 AEs were reported (average 4.1 AEs/patient). Currently, 216 (63%) of all AEs have resolved; average time to resolution was 69 days (range 0-611). The majority of reported AEs (77.4%) occurred within 30 days of the insertion procedure (peri-op AEs). Of these AEs, 82% of patients experienced sensory disturbances. The large majority (72%) of these events had a mild to moderate impact on the patient's daily activities and were transient, with an average resolution of 110.3 days (range 20-313).

Conclusion

The majority of AEs were reported within 30 days of the Neurostimulator insertion procedure and the majority resolved within 3 months. These AEs are not different from standard sequelae reported for other trans-oral procedures and display a similar time course for healing.

Conflict of interest.

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