Non-invasive Vagus Nerve Stimulation for Chronic Migraine Prevention in a Prospective, Randomized, Sham-Controlled Pilot Study (the EVENT Study): Report From the Double-blind Phase

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Introduction
- Chronic migraine is characterized by recurrent episodes of headache that may be associated with visual or sensory symptoms (eg, aura)1
- Adult subjects (18-65 years of age) meeting the diagnostic criteria for chronic migraine were included
- The majority of subjects in both treatment arms were mild or moderate in intensity; no headache days per 28 days

Methods
- Subjects were randomized to receive nVNS or sham treatment for 8 weeks
- Prophylactic use of nVNS for 8 weeks was associated with a reduction of ~2 headache days per 28 days; no treatment effects were observed for pain intensity

Results
- Treatment with nVNS resulted in a 25% reduction in headache days per 28 days
- The majority of subjects in both treatment arms were mild or moderate in intensity; no headache days per 28 days

Conclusions
- nVNS may offer patients with chronic migraine a clinical benefit without exposure to additional pharmacologic treatment

References
- Headache days per 28 days

Use of Day Medication
- After 8 weeks, the proportion of subjects who experienced a >25% reduction in number of headache days per 28 days was higher in the nVNS group

Treatment Satisfaction and Ease of Use
- Subjects rated ease of use of the device as very easy, easy, difficult, or not at all satisfied
- The percentage of subjects who were satisfied with the device as extremely satisfied, somewhat satisfied, or not at all satisfied were 80% in the sham group and 95% in the nVNS group

Statistical Analyses
- No differences were observed between treatments in the use of abortive medications; 26 of 17

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