Non-invasive Vagus Nerve Stimulation (nVNS) for the Prevention of Menstrual/Menstrually Related Migraine: An Open-label Study

Licia Grazzi, MD1; Gabriella Egeo, MD, PhD2; Anne H. Calhoun, MD, FAHS3; Anna Maria Padovan4; Eric Liebler5; Piero Barbanti, MD, PhD5

1 Headache Center, Carlo Besta Neurological Institute and Foundation, Milan, Italy; 2Headache and Pain Unit, Istituti di Ricovero e Cura a Carattere Scientifico, San Raffaele Pisana, Rome, Italy; 3Carolina Headache Institute, Chapel Hill, North Carolina, USA; 4Kiara Association, Torino, Italy; 5electroCore, LLC, Basking Ridge, New Jersey, USA

Introduction

Challenges in the Treatment of Menstrual and Menstrually Related Migraine

- Menstrual migraines are more disabling, longer lasting, and less responsive to medications than non-menstrual attacks.
- Menstrual migraine attacks are more debilitating, longer lasting, and less responsive to medications (eg, triptans) than non-menstrual attacks.

Study Rationale

- Studies suggest that non-invasive vagus nerve stimulation (nVNS) gastrectomy, Figure 1, is effective, safe, and well tolerated in patients with refractory and/or drug intolerable migraine.
- The favorable tolerability, efficacy, and safety of nVNS may be particularly appealing for individuals with MMD who are at increased clinical outcomes and reduce the adverse event (AE) burden.

Study Objective

- To evaluate the efficacy, safety, and tolerability of nVNS for prophylaxis of MMD.

Methods

Study Design

- This is a 2x2, investigator-initiated, randomized, single-arm, open-label pilot trial comprised of 13-week study periods.
- Pain intensity was assessed after each study period on a scale from 0 to 10.
- Proportion of subjects with a ≥50% reduction in the mean number of MM/MRM days (ITT Population).

Subjects

- Women with regular menstrual cycles were included from 2 Italian sites (Table 1).
- Selected exclusion criteria included: International Classification of Headache Disorders, 3rd edition (beta version).
- A history of migraines or headaches for less than 1 year was exclusionary.
- A change in prophylactic medication type or dosage within 6 months before enrollment.
- A history of or current use of medications that are known to be effective against migraine.
- A history of or current use of medications that are known to be effective against migraine.

Intervention

- The nVNS device transcutaneously transfers electrical impulses to the submental region of the neck via the vagus nerve.
- During the 12-week nVNS period, patients used the device every day.
- Of all subjects, 39% (95% CI: 26%, 54%) had a ≥50% reduction in the mean number of MM/MRM days from baseline to week 12.

Results

Pain Intensity

- There was a significant reduction in mean analgesic use with nVNS (P < 0.001).
- Of all subjects, 39% (95% CI: 26%, 54%) (20/51) had a ≥50% reduction in the mean number of MM/MRM days from baseline to week 12.

Secondary End Points

- Analgesic use frequency was significantly reduced with nVNS (P < 0.001).
- Of all subjects, 39% (95% CI: 26%, 54%) had a ≥50% reduction in the mean number of MM/MRM days from baseline to week 12.

Migraine Disability

- The mean MMD score was significantly reduced with nVNS by 2.1 (P < 0.001).
- The mean MMD score was significantly reduced with nVNS by 2.1 (P < 0.001).

Table 1. Demographics and Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Total Population (n=56)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (y), mean ± SEM</td>
<td>40.2 ± 1.0</td>
</tr>
<tr>
<td>Sex, no. (%)</td>
<td>30 (54) male, 26 (46) female</td>
</tr>
<tr>
<td>Employment, no. (%)</td>
<td>52 (93) currently employed</td>
</tr>
<tr>
<td>Current employment, no. (%)</td>
<td>49 (88)</td>
</tr>
<tr>
<td>Number of MMD days, mean ± SEM</td>
<td>9.8 ± 1.0</td>
</tr>
<tr>
<td>Pain intensity, mean ± SEM</td>
<td>6.5 ± 0.6</td>
</tr>
<tr>
<td>Pain intensity range</td>
<td>0-10</td>
</tr>
<tr>
<td>Pain intensity severity</td>
<td>4.0</td>
</tr>
<tr>
<td>Pain intensity severity</td>
<td>6.5</td>
</tr>
<tr>
<td>Pain intensity severity</td>
<td>7.0</td>
</tr>
</tbody>
</table>

Acknowledgments and Funding

The authors disclose the following: Licia Grazzi, MD, has received consultancy and advisory fees from Allergan, Inc., and electroCore, LLC. Gabriella Egeo, MD, PhD, has no disclosures to disclose. Anne H. Calhoun, MD, FAHS, has received honoraria from Novo Nordisk, Inc. Among the disclosures for Erick Liebler are: speaker fees from Allergan, Inc., and Merck & Co., Inc.; and travel and accommodation expenses for the American Academy of Neurology, the American Migraine Foundation, the American Headache Society, the American Association of Neurology, and the American Neurological Association. Anna Maria Padovan has nothing to disclose. Piero Barbanti, MD, PhD, has received honoraria from Novo Nordisk, Inc., and travel and accommodation expenses for the American Academy of Neurology, the American Migraine Foundation, the American Headache Society, the American Association of Neurology, and the American Neurological Association. This study was investigator initiated. Devices for the study were supplied by electroCore, LLC. Statistical analyses for the study were conducted by Cardinale-Lawrence, Inc., Philadelphia, PA, USA. The study was supported by electroCore, LLC. Professional writing and editorial support was provided by Barbara Haughton, PhD, of Medical Economics Communications, LLC, Schenectady, NY, under the direction of the authors and was funded by electroCore, LLC.

Conclusions

- Menstrual migraines may be particularly appealing for individuals with MMD who are at increased clinical outcomes and reduce the adverse event burden.

References


Disclosures

The authors disclose the following: Licia Grazzi, MD, has received consultancy and advisory fees from Allergan, Inc., and electroCore, LLC. Gabriella Egeo, MD, PhD, has no disclosures to disclose. Anne H. Calhoun, MD, FAHS, has received honoraria from Novo Nordisk, Inc. Erick Liebler has received travel and accommodation expenses for the American Academy of Neurology, the American Migraine Foundation, the American Headache Society, the American Association of Neurology, and the American Neurological Association. Anna Maria Padovan has nothing to disclose. Piero Barbanti, MD, PhD, has received travel and accommodation expenses for the American Academy of Neurology, the American Migraine Foundation, and travel and accommodation expenses for the American Association of Neurology, and the American Neurological Association. This study was investigator initiated. Devices for the study were supplied by electroCore, LLC. Statistical analyses for the study were conducted by Cardinale-Lawrence, Inc., Philadelphia, PA, USA. The study was supported by electroCore, LLC. Professional writing and editorial support was provided by Barbara Haughton, PhD, of Medical Economics Communications, LLC, Schenectady, NY, under the direction of the authors and was funded by electroCore, LLC.

Prepared by the American Academy of Neurology: Abstract Editing Office, Vancouver, BC, Canada; April 30, 2016. The development of this poster, its content, and all images associated with it is the exclusive property of the author and is not available for distribution.

To obtain an electronic copy of this poster please visit:

http://www.euroheadache.org