MANAGEMENT OF CHRONIC MIGRAINE WITH QUARTERLY PERICRANIAL NERVE BLOCKS: A PROSPECTIVE 48-WEEK TRIAL

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Objectives

- To determine the efficacy and tolerability of a standardized protocol of repeated blocks of pericranial nerves in the management of chronic migraine.
Many patients with chronic migraine fail typical modalities.

Our clinical experience with pericranial blocks in the management of status migrainosus detected a subset of patients describing long-lasting results from their injections:
- Typically 3 months.
Pericranial nerve blocks have been used for decades to treat a variety of headache disorders.

Occipital nerve blocks have been shown to be effective in acute migraine and “chronic daily headache”, as well as cluster and cervicogenic headaches.

Prior work has involved heterogeneous populations and unstandardized protocols.
Methods

- Single-center, prospective, open-label study
- Subjects
  - Adult population, ages 18-65
  - Males or non-pregnant females
  - Diagnosis of chronic migraine (ICHD-IIIR criteria)
  - Failure of 3 adequate trials of preventive medications
  - Absence of opioid or butalbital use
  - Absence of prior reaction to local anesthetic agents
Methods

Protocol

- Administration of pericranial injections
  - 12-week intervals
  - 4 sets of injections over 48 weeks
- Fixed-dose (0.1 cc of 0.25% bupivacaine)
- Fixed-site (17 pericranial nerve injections each side)
  - 10 injections: Greater and lesser occipital
  - 5 injections: Auriculotemporal and zygomaticotemporal
  - 2 injections: Supraorbital and supratrochlear
Methods

- **Primary endpoint**
  - Mean change from baseline in the monthly frequency of headache days at week 48
    - Response defined as >50% reduction

- **Secondary endpoints**
  - Mean change in monthly severe headache days
  - Mean change in monthly acute medication days
  - Mean change in HIT-6 disability scores
Results

- 218 subjects enrolled and treated

<table>
<thead>
<tr>
<th>Baseline Characteristics (n=218)</th>
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<tbody>
<tr>
<td>Female (%)</td>
<td>87.1</td>
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<tr>
<td>Age (years)</td>
<td>40.4</td>
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<tr>
<td>History of migraine (years)</td>
<td>18.5</td>
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<tr>
<td>Headache days per 4 weeks</td>
<td>21.4</td>
</tr>
<tr>
<td>Severe headache days per 4 weeks</td>
<td>15.5</td>
</tr>
<tr>
<td>Acute treatment days per 4 weeks</td>
<td>18.3</td>
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<tr>
<td>HIT-6 score</td>
<td>66.2</td>
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</tbody>
</table>
Results

- 116 subjects (53.2%) met the primary endpoint with >50% reduction from baseline in monthly frequency of headache days at 48 weeks
  - 77 subjects (35.3%) with response < 4 weeks
  - 25 subjects (11.5%) with no response or lost to follow-up
Results

- Responder subgroup analysis (n=116)
  - Mean monthly headache days from 22.8 to 9.0
  - Mean monthly severe headache days from 15.9 to 6.1
  - Mean monthly acute treatment days from 18.1 to 7.9
  - Mean HIT-6 score from 66.7 to 59.2
  - No clinical or demographic differences versus the nonresponder subgroup
Results

- Monthly headache days
- Monthly severe headache days
- Monthly acute medication days

Comparisons between Baseline and 48 weeks.
Results

- Adverse events (n=585 sets of injections)
  - Local discomfort: 581
    - Immediate: 581 (99.3%)
    - Prolonged (>24 hours): 77 (13.2%)
  - Local numbness/paresthesias
    - Immediate: 502 (86.4%)
    - Prolonged (>24 hours): 5 (1%)
  - Nausea: 44 (7.5%)
  - Dizziness: 18 (3%)
    - Syncope: 1 (<.05%)
  - Worsening headache frequency: 3 (.05%)
A standardized program of pericranial nerve blocks performed at 12-week intervals was effective and well tolerated over the course of 48 weeks in adults with chronic migraine.