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

Impetus to Research

- 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

Background

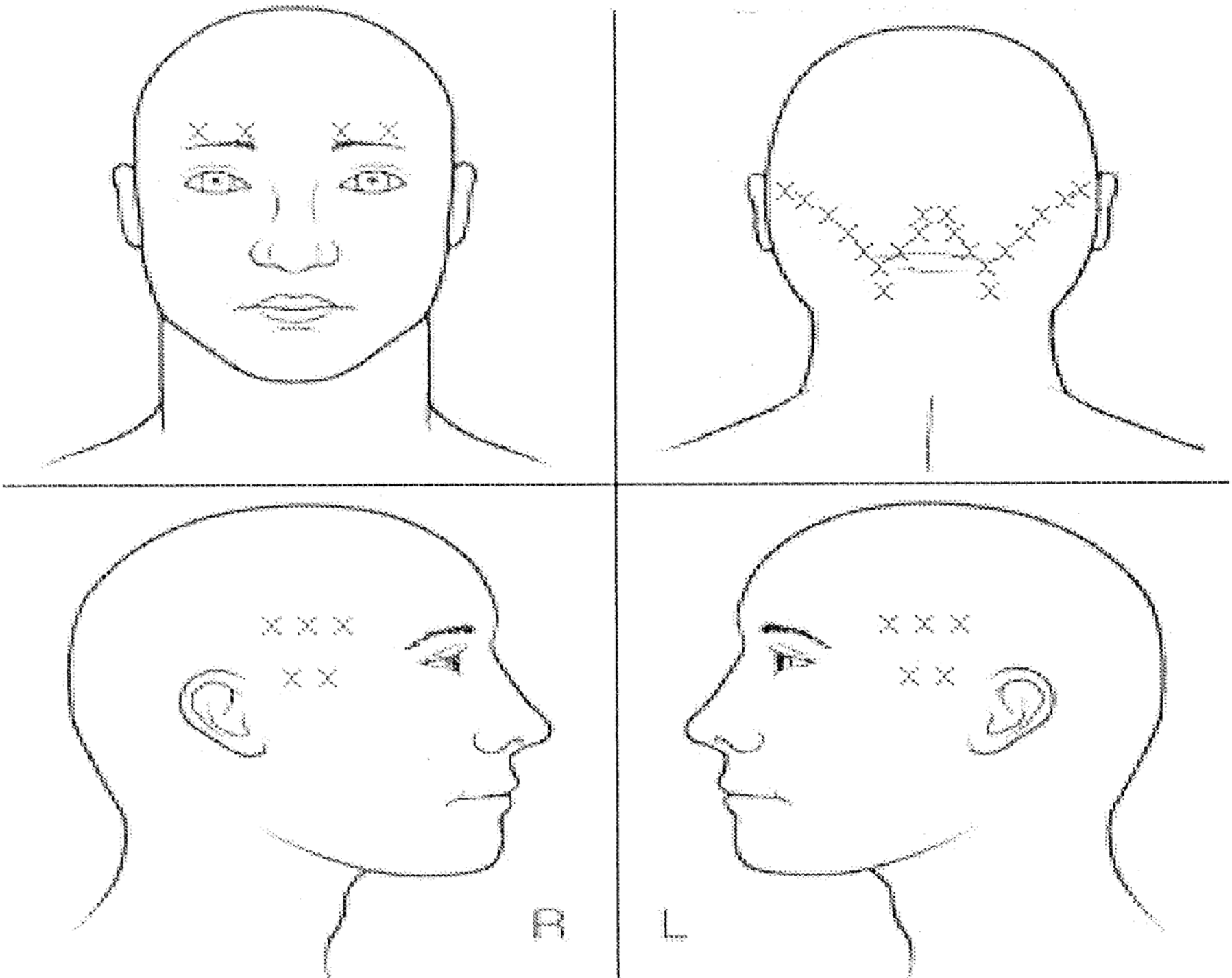
- Pericranial nerve blocks have been used for decades to treat a variety of headache disorders
- Occipital nerve blocks have been shown to be effective in acute migraine and “chronic daily headache”, as well as cluster and cervicogenic headaches
- Prior work has involved heterogeneous populations and 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-IIR 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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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

Baseline Characteristics (n=218)	
Female (%)	87.1
Age (years)	40.4
History of migraine (years)	18.5
Headache days per 4 weeks	21.4
Severe headache days per 4 weeks	15.5
Acute treatment days per 4 weeks	18.3
HIT-6 score	66.2

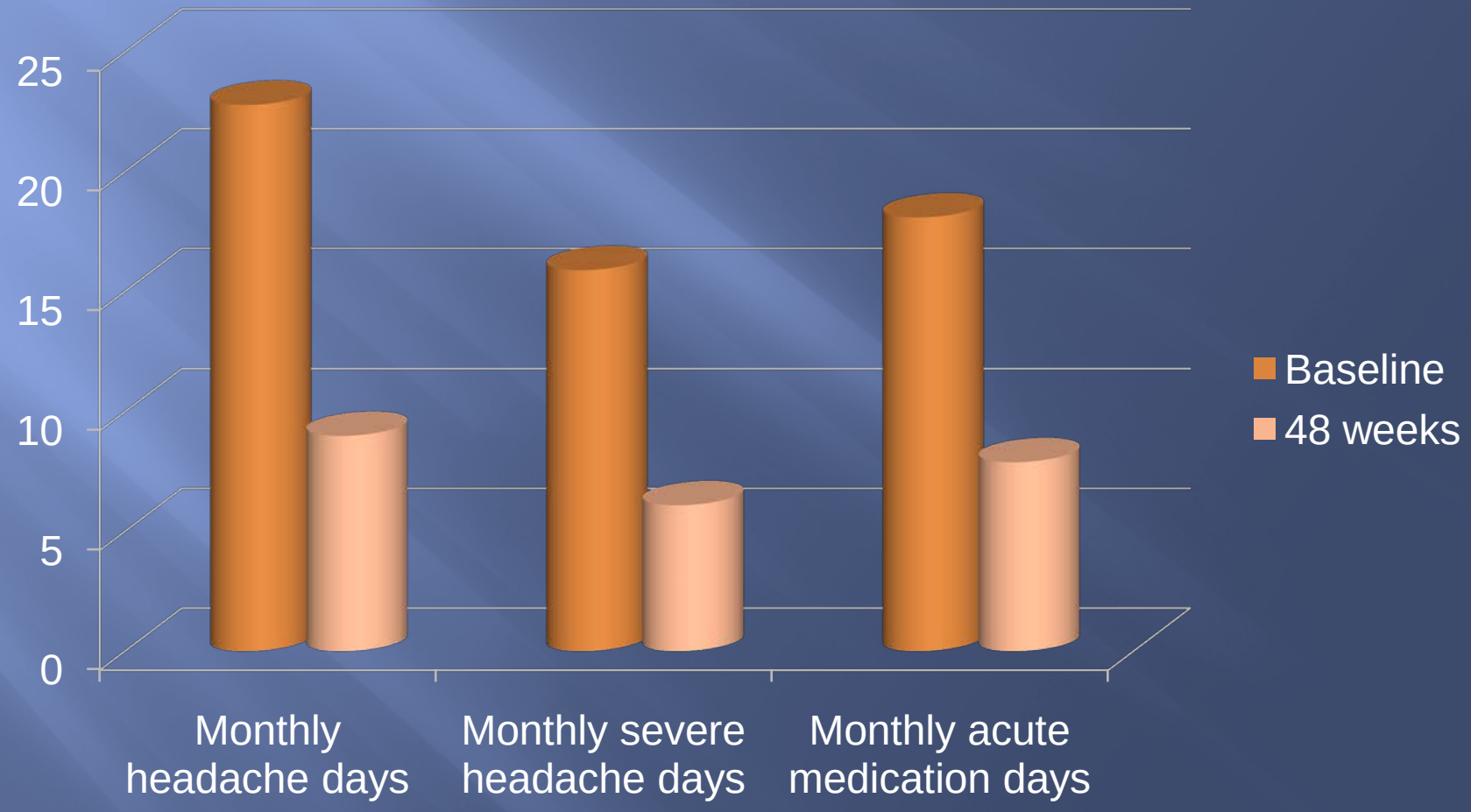
Results

- 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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20
15
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Monthly headache days
Monthly severe headache days
Monthly acute medication days
Baseline
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%)

Conclusions

- 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