After Market Analysis of Devices in Migraine: A Retrospective Observational Study

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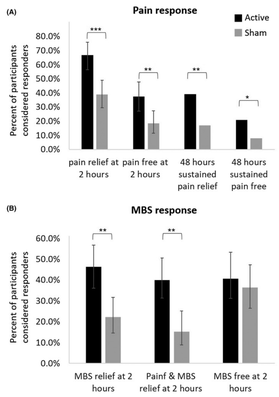
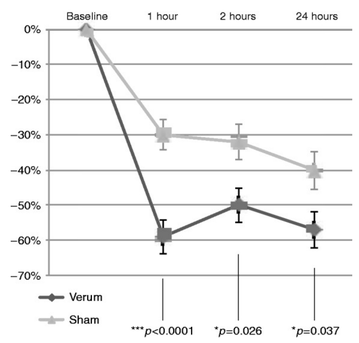
BACKGROUND

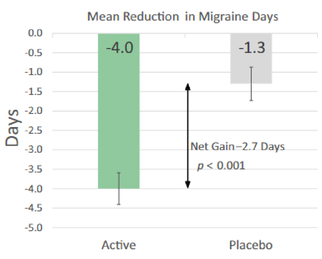
In addition to pharmacologic options for the prevention and acute treatment of migraine, the FDA has approved several devices to treat migraine. The Veterans Health Administration has started to cover these devices, with VA Medical Center in Lexington covering remote electrical neuromodulation devices (REN) and external trigeminal neurostimulation devices (ETN). These devices are new, and studies supporting their efficacy in the veteran population specifically is lacking.

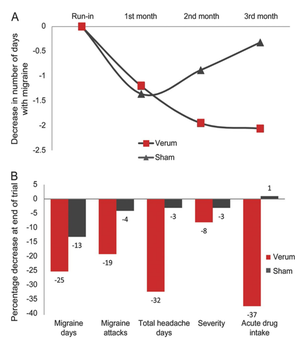
Devices have been evaluated in Randomized controlled trials against placebo for acute treatment and prevention (1-4). However, there are several aspects of the study design that limits its applicability to the VA population. Patients using parenteral medicatons such as galcanezumab, commonly used for migraine prevention, were excluded (1). More critically, botox, the standard of care for patients with chronic migraine, were excluded from the study. Different devices have also not been compared to one another per our literature review.

Electroceuticals have other issues with external validity with respect to the VA population. The devices most commonly used at the VA had a preponderance of female participants, was used in people who had a headache for 3 hours, and was not administered in those who had used a medication to treat the headache in the past 3 hours (3, 4).









OBJECTIVES

1. To examine the change in frequency of headaches, change in intensity of headaches, and potential side effects after starting devices approved for migraine.
2. To compare the relative effectiveness of different electroceuticals in treating migraine

DEVICES

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https://images.app.goo.gl/M49N4i8YEeVEg9gU6

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METHODS

Step1:
- Design- Retrospective observational study of VA patients to evaluate change in headache days per month before and after using a device.
- Data source- Chart review from documented frequency from patient headache calendar before and after.
- Outcome- Headache days before vs after starting. % change in headache days.
- Further studies can be based on information gathered here such as step 2.

Step 2:
- Subject to revision after step 1. Could change aspects such as power analysis.
- Randomized, pragmatic trial. Patients randomized between 2 devices.
- Patients will not be blinded but data will be analyzed in a blinded fashion.

Inclusion and exclusion criteria-
- Patients included will be adults at the Lexington VA neurology clinic who meet ICHD-3 criteria for migraine, and want a device to treat migraine
- Exclusion:
  - Patients already using a device.
  - Patients who would not be cleared to use the devices per manufacturer labelling.

REFERENCES

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