

PO-05-170 NON-INVASIVE STIMULATION OF THE MEDIAN NERVE: NEUROMODULATION TO REDUCE ATRIAL ARRHYTHMIAS IN PAROXYSMAL ATRIAL FIBRILLATION (BEAT-AF)

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Background

The autonomic nervous system is important in the initiation and maintenance of AF. Median nerve stimulation (MNS) is a non-invasive low-level electrical stimulation therapy which, in early studies, favorably affects atrial electrophysiology and reduces inflammation.

Objective

To assess if a novel wearable home-care neuromodulation and ECG monitoring device that performs MNS can reduce atrial arrhythmias (AA) and symptoms in AF.

Methods

BEAT-AF is a 2-center, sham-controlled, double-blind, 12-wk pilot RCT. Eligible PAF pts (AF burden 0.5% - 25% on 14d ECG patch) were randomized 1:1 to sham stimulation or MNS using a wristband-like device (CardiaCare): the physician-directed regimen was 20-min sessions performed 2-3 x per week, and up to once daily for symptoms verified by the device ECG monitor as being AA (AF/AT or PACs).

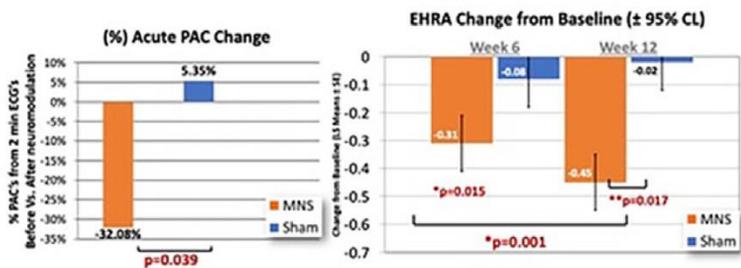
Results

For the 31-pt cohort (n=15 MNS / n=16 Sham; age 67.3±9.7 yrs; 8 F; CHADS-VASc 2.6±1.7; median baseline AF burden 4.9% [IQR 5.2%]), protocol adherence (performed/planned ratios) was good at 0.80 (MNS) & 0.78 (Sham). Based on the immediate pre-/post-treatment device ECG recordings, MNS significantly reduced the PAC burden by 32.1% (vs +5.4% with Sham, p=0.039). Comparing baseline to 12-wk ECG patches, there were also numeric, but non-significant reductions in 1) PAC burden by 21% (p=0.046; MNS) vs 2.7% (p=0.94; Sham) (between group p=0.46), 2) the adjusted median AF burden by 63% (MNS) vs 4.1% (Sham; p=0.42), and 3) the adjusted median composite AA burden (AF+PAC) by 43.9% (MNS) vs 2.3% (Sham; p=0.38). By EHRA class, symptoms significantly improved with MNS (0.45 vs 0.02 reduction; p=0.017). There were no device-related side effects.

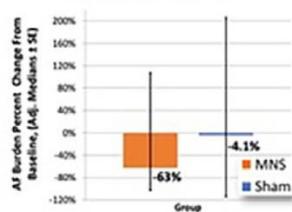
Conclusion

In paroxysmal AF, ambulatory non-invasive median nerve neuromodulation significantly reduced the PAC burden and improved symptomatology (and may reduce AF). Large multicenter powered studies of AF treatment with MNS are needed.

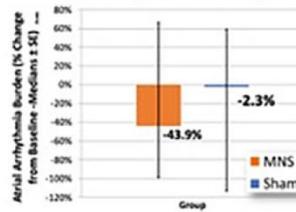
Closed-Loop Monitoring and Neuromodulation Wearable Device



Adjusted Median % AF Burden Change from baseline



Change in Arrhythmia Burden (AF+PAC) Between Groups



Baseline vs End Comparison of PAC Burden (from 14 Day ECG patch)

