

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



Ehud Chorin¹, Zaza Iakobishvili², Lorin A. Schwartz¹, Ariel Banai³, Raphael Rosso¹, Sami Viskin¹, Yitzhak Holand⁴, Amos Ziv⁴, Vivek Y. Reddy³ ⁽¹⁾Tel Aviv Medical Center, Tel Aviv, Israel. ⁽²⁾Community Cardiology Department, Clalit Health Services, Tel Aviv, Israel ⁽³⁾Mount Sinai Fuster Heart Hospital, New York, United States. ⁽⁴⁾CardiaCare Advanced Neuromodulation Technologies, Nes Zionna, Israel.

Background

The autonomic nervous system has an important role in the initiation and maintenance of AF. Median nerve stimulation (MNS) is a non-invasive electrical stimulation therapy which induces a low-level Vagus nerve effect and has demonstrated favorable effects on atrial electrophysiology and reduction of inflammation in early studies.

Objective

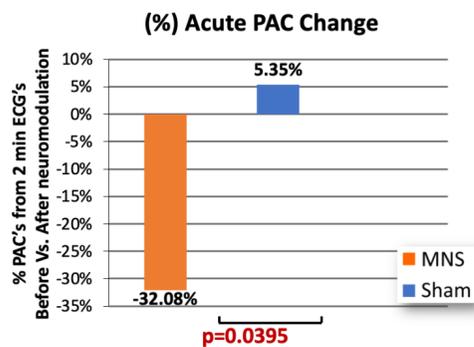
The BEAT-AF study (Breaking Ectopic Atrial Trends in AF) aimed to assess the effect of a novel wearable home-care neuromodulation and ECG monitoring device that performs Median Nerve stimulation in reducing atrial arrhythmias (AA) and symptoms in PAF patients.

Method

BEAT-AF was a 2-center, sham-controlled, double-blinded, 12-week pilot home-care RCT. Eligible PAF patients with AF burden of 0.5% - 25% as captured by a 14-day ECG patch, were randomized 1:1 to sham stimulation or MNS using a wristband-like wearable device (CardiaCare). The physician-directed regimen was 20-min of neuromodulation sessions performed 2-3 x per week, and up to once daily for symptoms or ECG findings detected and 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 was 4.9% [IQR 5.2%]), protocol adherence (performed/planned ratios) was good at 0.80 (MNS) & 0.78 (Sham).

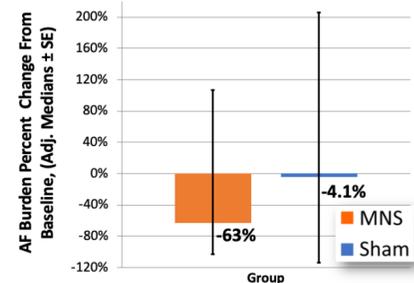


Based on the immediate pre-/post-treatment device ECG recordings, MNS significantly reduced the PAC burden by 32.1% (vs +5.4% with Sham, p=0.039, Fig 1).

Fig 1. Mean PAC change in 2 min ECG's Before Vs. Immediately after neuromodulation sessions as captured by CardiaCare single lead ECG

Results (Cont.)

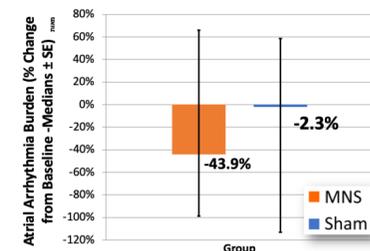
Adjusted Median % AF Burden Change from baseline



The adjusted median AF burden was reduced by 63% in the active MNS group vs 4.1% in sham group (p=0.42, Fig 2)

Fig 2. Median AF burden change from baseline measured by ambulatory 14-days ECG Patch (Bittium™)

Change in Arrhythmia Burden (AF+PAC) Between Groups



The adjusted median composite atrial arrhythmia burden (AF+PAC) was reduced by 43.9% in the active MNS group vs 2.3% in Sham (p=0.38, Fig 3)

Fig 3. Median composite Atrial arrhythmia burden change from baseline measured by ambulatory 14-day ECG Patch (Bittium™)

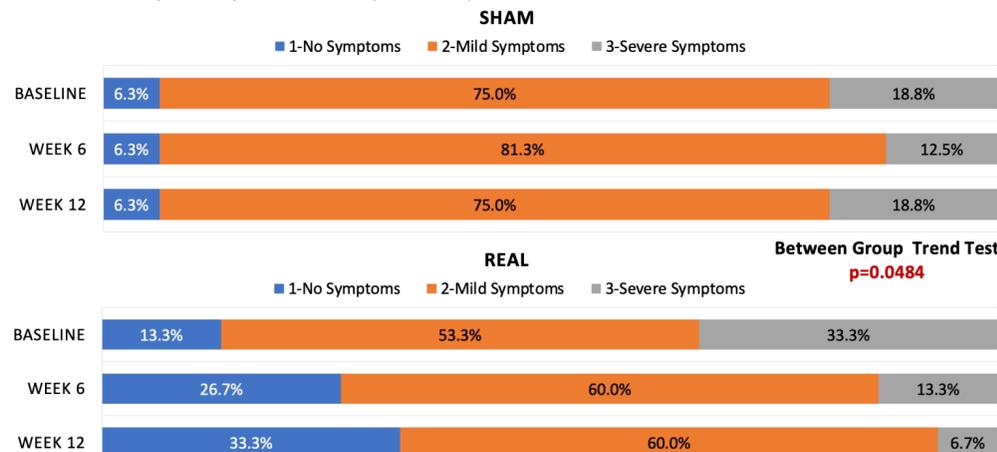
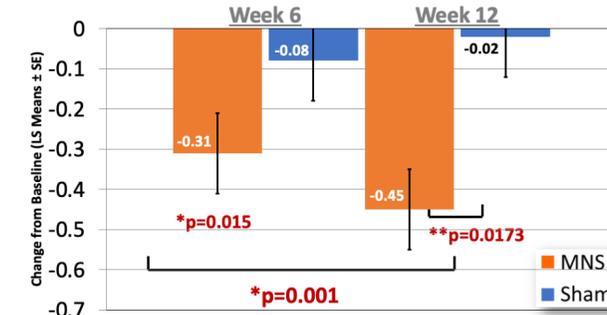


Fig 4. Change in symptom severity from baseline to week 12 by EHRA symptoms & life quality questionnaire (assessed by a blinded physician)

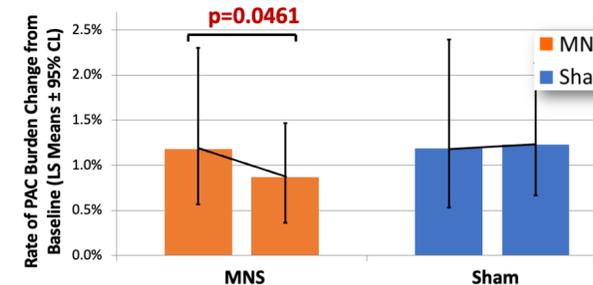
EHRA QOA Score improvements (± 95% CL)



By EHRA class, the active MNS group had a reduction of 80% in severe-class III symptoms (33% to 6.7%, p= 0.0484), no change was observed in the sham group (Fig 4). The MNS group only showed improvements in EHRA scores at wks 6 and 12 (0.45 vs 0.02 reduction; p=0.017 at wk 12, Fig 5).

Fig 5. Change in EHRA score from baseline to weeks 6 and 12

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



Comparing baseline to 12-wk ECG patches, there were also numeric, but non-significant reductions in PAC burden by 21% (p=0.046; MNS) vs 2.7% (p=0.94; Sham) (between group p=0.46; Fig 6)

Fig 6. Mean PAC burden change from baseline to week 12 measured by ambulatory 14-day ECG Patch (Bittium™)

Conclusion

In paroxysmal AF patients, ambulatory non-invasive median nerve neuromodulation with a novel wrist-band wearable significantly reduced PAC burden and improved symptomatology and quality of life (and possibly reduced AF). Large multicenter powered studies of AF treatment with MNS are therefore warranted.

