Journal of Cardiovascular Electrophysiology
THE OFFICIAL JOURNAL OF THE WORLD SOCIETY OF ARRHYTHMIAS
World Society of Arrhythmias
Editor-in-Chief
Bradley P. Knight

ABSTRACTS–AF SYMPOSIUM

Abstracts from the 27th Annual International Atrial Fibrillation Symposium

Safety and Feasibility of Home-Care Neuromodulation and Monitoring Wearable

Abstract Title: Safety and Feasibility of Home-Care Neuromodulation and Monitoring Wearable Device for Treatment of Atrial Fibrillation

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Introduction | Objectives: Autonomic modulation is an evolving field in arrhythmia management. tVNS Vagus nerve stimulation suppressed atrial fibrillation (AF) in humans. Median nerve neuromodulation was shown to reduce ventricular and atrial arrhythmias in pre-clinical models. We report the feasibility and safety of CardiaCare RR2, a wristband wearable device with neuromodulation and single lead ECG monitoring capabilities.

Methods: Patients arriving to the emergency room (ER) with symptomatic AF were recruited, underwent pharmacological or electrical cardioversion, received standard of care medication, and received a 24-hour ECG Holter monitor. They returned the next day for a supervised in-hospital first neuromodulation session and received the device and phone app for 8 weeks of home use. Patients were asked to conduct two neuromodulation sessions a week and three 30 sec ECG monitoring sessions daily.

Results: Eleven patients were recruited from the ER (age 66±12 yrs, 64% male). One dropped out prior to protocol initiation, ten completed the protocol. Usability rates were 94.7% for ECG monitoring (1675 recorded and analyzed) and 96.8% for neuromodulation (155 treatments, Avg 15.5 per patient). No Adverse Events were observed during the supervised in-hospital treatments or the follow up period. No unscheduled emergency department re-visits occurred. One patient reported minimal itching during use of the device, one patient reported feeling more tired, one patient had non-device related bradycardia and a patient with high AF burden received an ablation at week 6. A total of 289 ECG's were taken immediately before and immediately after neuromodulation. In 7 instances, multiple PACs (13.7±12.7 PACs/2 min) were observed. In all these cases we observed an acute reduction in the PAC burden following the neuromodulation (5.7±10/2 min, 58% reduction; p=0.0005). Two (20%) patients had AF recurrences during the 8-week follow-up period.

Conclusions: The use of CardiaCare neuromodulation and monitoring system is safe. Home-use compliance and usability in a real-world AF population is high. Acute PAC reductions and low AF recurrence rates show compelling early indications of possible AF burden reduction with use of the device.

Acute PAC reduction and 8 weeks AF reccurence