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#### The Application of Non-Invasive Methods for the Treatment of Cardiovascular Conditions

For the past two decades the scientists at the Heart Rhythm Institute at the University of Oklahoma Health Sciences Center have been developing a non-sentient, non-invasive method for preventing and treating atrial fibrillation (AF). We demonstrated in animals that low-level electrical stimulation of the auricular branch of the vagus nerve located in the anterior protuberance of the ear, known as the tragus, could prevent the occurrence and suppress the ongoing episodes of induced Atrial Fibrillation (AF). These studies culminated in the demonstration of this ability in humans. Dr. Stavros Stavrakis, a faculty member of our staff presented a seminal 6 month study of 1 hour of daily tragus stimulation in patients with abrupt onset of AF episodes (paroxysmal, PAF) at the recent Heart Rhythm Society meeting. Using continuous monitoring, his findings showed a 75-85% decrease in AF episodes over the 6 month study period.

Since 2004, we have also been studying in tandem, the effect of a different, even less (non-invasive) methodology for suppressing AF. An animal was placed in the center of a low-level electromagnetic field (LL-EMF) provided by a Helmholtz coil configuration (known as the Magnesphere). With the assistance of Dr. Jerry Jacobson and using the Jacobson Equation to determine the appropriate amplitude and frequency of the pulsed field (non-invasive and non-sentient) we were able to replicate the suppressive effects of tragus stimulation on AF.

Following those positive results, Dr. Daniel Sohinki, a second year cardiology fellow, completed his Master's Thesis thanks to the use of a Helmholtz coil (the mini Magnesphere) built to enclose the head and neck of PAF patients in the electrophysiology laboratory.

The study protocol determined to study the ability of LL-EMF in patients with PAF in the same way that Dr. Stavrakis showed using LL-tractus stimulation. Although the number of patients enrolled was relatively small, Dr. Sohinki just submitted an abstract of his Masters Thesis to the next meeting of the American Heart Association in November. He found that, compared to the sham group, pacing-induced AF duration in the LL-EMF group was  $7.73 \pm 3.03$  minutes shorter after 1-hour of stimulation (CI 0.98 - 14.47 minutes,  $p = 0.03$ ). A significantly smaller proportion of patients in the LL-EMF group experienced spontaneous firing initiating an episode of AF after 1-hour compared to sham (0/7 vs. 5/6,  $p = 0.0047$ ). In simpler terms, these results were statistically significant even though the study was small, and the measures of improvement in the treatment group are important endpoints for this disease.

Dr. Tarun Dasari, one of our faculty members whose specialty is heart failure (HF) has reviewed our study and noted that the key endpoints utilized in the AF study are also important endpoints utilized in his (HF) studies.

As a result of our successful AF study utilizing the "mini Magnesphere", Dr Dasari has been able to set aside a clinical space for the Magnesphere Halo unit so that we can study the effects of LL-EMF in patients with HF. We have established an acute and chronic protocol using various biomarkers, e.g., heart rate variability, blood levels of inflammatory substances, to determine efficacy of LL-EMF on ameliorating major symptoms of HF. The chronic study will involve the use of the Magnesphere Halo, home units, to measure the effects of LL-EMF for 1-1.5 hours of stimulation daily.

Future studies are planned for the Magnesphere's beneficial effect on heart failure, hypertension or many other cardiac and non-cardiac conditions whose common denominator is hyper-active sympathetic syndrome. After almost 20 years of pre-clinical and clinical research studies, it is in my opinion that the team at Magneceutical Health are on the cusp of demonstrating non-pharmacological, non-invasive treatment options for many other clinical conditions.

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