WASHINGTON, DC, May 8, 2020 — A new clinical trial effectively uses pulsed field (PF) energy to treat patients with persistent or paroxysmal atrial fibrillation (AF) and showcases a novel approach to performing point-by-point ablation to provide safe and effective patient outcomes. The first-in-human trial combines the effectiveness of radiofrequency (RF) energy with the safety of pulsed field energy for ablation procedures. The results of the multi-center trial were presented today as late-breaking clinical science as part of HRS 2020 Science and were published simultaneously in Circulation; Arrhythmia & Electrophysiology.

AF is the most common heart rhythm condition, impacting more than 33.5 million individuals around the world.1 Ablation is a known treatment for patients with persistent AF symptoms and is most commonly performed using a point-by-point approach to make multiple lesions to stop irregular heartbeats. This study looked to test a new point-by-point approach that leverages advancements in technology and attempts to increase patient safety and quality of care for this large arrhythmia patient population.

“As we see pulse field ablation take off as an influential technology for treating atrial fibrillation, we look forward to how our study can move adoption of this procedure forward,” said Dr. Vivek Y. Reddy, Director of Cardiac Arrhythmia Services for The Mount Sinai Hospital and the Mount Sinai Health System, and The Leona M. and Harry B. Helmsley Charitable Trust Professor of Medicine in Cardiac Electrophysiology at Icahn School of Medicine at Mount Sinai. “The streamlined efficacy and safety benefits of using this new pulse field ablation approach are a true advancement for electrophysiologists everywhere. We hope our findings will play a role in reducing the routine procedure time for this patient population.”

This trial sought to evaluate the use of a catheter capable of both RF and PF ablation to deliver efficient linear lesions and reduce ablation safety concerns, including damage to the esophagus and surrounding nerves. The trial examines the use of a novel lattice-tip ablation catheter able to deliver either focal RF or PF energy to treat PAF. The study took place across 3 centers with 11 operators. Patients included a 76-pt cohort (age 59 ± 9.9 yrs; M / F = 50 / 26; PAF / PerAF = 55 / 21) who underwent either RF/PF (40 pts; 47.4±16.2 lesions/pt) or PF/PF (36 pts; 53.1±14.4 lesions/pt) ablation. An 8Fr lattice with RF & PF generators (Sphere-9, Prism-1, HexaGen & HexaPulse, respectively; Affera Inc) was used to toggle between energy sources during ablation. Point-by-point PV encirclement was performed using biphasic PFA (2-5 sec; 24-32 Amp) posteriorly, and either temp-controlled irrigated RFA (Tmax 73°C; 5 sec) or PFA anteriorly. PVI was confirmed with bidirectional pacing, and adenosine or after a 20 min wait. Linear lesions were with PFA or RFA.

Results of the trial demonstrate a combined RF/PF energy approach or a PF-only approach during ablations can safely and efficiently perform pulmonary vein isolation (PVI) and linear lesions. Findings show that PVI therapy duration time (transpiring from first to last lesion) was 22.6±8.3 min/pt. Additionally, all lesion sets were acutely successful. Linear lesions included 13 mitral (4 RF / 1 RF+PF / 8 PF), 33 LA roof (12 RF / 21 PF) and 43 CTI (35 RF / 8 PF) lines, with therapy duration times of 5.1±3.6, 1.8±2.4 and 2.4±2.2 min/pt, respectively. The total fluoroscopy time was 4.7±3.5 min. There were no device complications; there were four vascular injuries. Post-procedure EGD revealed minor mucosal thermal injury in two of 36 RF/PF and zero of 24 PF/PF pts. Brain MRI revealed DWI+/FLAIR- and DWI+/FLAIR+ asymptomatic lesions in four and three of 52 pts, respectively; the initial ACT was lower in MRI-positive (255±26 sec) vs MRI-negative (349±84 sec) pts (p<0.00001). Only one pt (of 29; 3.4%) with ACT >300 had an MRI-positive lesion (DWI+/FLAIR-).

The authors of this study look to build upon their findings to determine the durability of the lesions created, and evaluate the one year outcomes of the patients in the study. As a next step, they are planning a large, multicenter FDA clinical trial in the U.S.

Sessions Details:
“Late-Breaking Clinical Trials II: Innovation Boulevard: Point-by-point Pulsed Field Ablation (+/- Radiofrequency Ablation) To Treat Atrial Fibrillation: A First-in-human Trial” [Friday, May 8, 2020 at 11:00 a.m. EST]

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About the Heart Rhythm Society
The Heart Rhythm Society is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients and is the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. Incorporated in 1979 and based in Washington, D.C., it has a membership of more than 7,000 heart rhythm professionals in more than 70 countries around the world. For more information, visit www.HRSonline.org.