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**LATE-BREAKING CLINICAL TRIAL RESULTS ANNOUNCED
AT HEART RHYTHM 2021:**

**EARLY CATHETER ABLATION OF VENTRICULAR TACHYCARDIA OUTPERFORMS
CONVENTIONAL MEDICAL THERAPY IN PATIENTS AT RISK FOR SUDDEN DEATH**

First randomized trial of its kind to enroll patients with nonischemic cardiomyopathy

BOSTON, MA, July 29, 2021 – Results from an international clinical trial show a significant reduction in risk of ventricular tachycardia (VT) recurrence, cardiovascular hospitalization, and death when catheter ablation is used as an early first-line treatment for patients with structural heart disease. Led by study coordinating center, the University of Chicago, The PAUSE-SCD trial is the first VT ablation trial to include patients with nonischemic cardiomyopathy and to be conducted across Asia. Findings of this landmark trial were presented today as late-breaking science during Heart Rhythm 2021.

Sudden cardiac death is one of the leading causes of death around the world,¹ occurring when blood flow to the brain is restricted due to a malfunctioning electrical system in the heart and is not treated within minutes. Patients with VT – a heart rhythm disorder that involves a dangerously fast heartbeat – and other structural heart diseases are at an increased risk of SCA.² As the study was conducted in Asia, the largest populous continent at risk of SCD, VT patients with nonischemic cardiomyopathy were included due to higher prevalence relative to ischemic cardiomyopathy. Nonischemic cardiomyopathy is a condition with decreased heart muscle function related to causes other than a prior heart attacks or coronary artery blockage.

The international, multi-center, randomized controlled trial was conducted in 11 sites across China, Japan, Korea, and Taiwan in collaboration with University of Chicago Medicine, who served as the study coordinating center. A total of 121 patients with structural heart disease or monomorphic VT indicated for implantable defibrillator (ICD) therapy were enrolled. Patients were randomized 1:1 to either ablation within 90 days of ICD implantation or medical therapy. Patients who refused ICD therapy were followed in a prospective registry after stand-alone ablation treatment. The primary outcome included a triple composite of VT recurrence, cardiovascular hospitalization, and death. The study was conducted over a six-year period with a median patient follow-up of 31 months.

Key findings of the trial reveal catheter ablation as a first-line treatment within 90 days of ICD therapy reduced the relative risk of VT recurrence, cardiovascular hospitalization, and death by 42% across varied etiologies of structural heart disease. Over the median follow-up period, the primary outcome occurred in 45% of patients who underwent ablation and 59% in those managed with conventional medical therapy (hazard ratio 0.58, 95% confidence interval, 0.35-0.96;

¹ Adabag AS, Luepker RV, Roger VL, Gersh BJ. Sudden cardiac death: epidemiology and risk factors. *Nat Rev Cardiol* 2010;7:216–25.

² Koplán, B. A., & Stevenson, W. G. (2009). Ventricular tachycardia and sudden cardiac death. *Mayo Clinic proceedings*, 84(3), 289–297. [https://doi.org/10.1016/S0025-6196\(11\)61149-X](https://doi.org/10.1016/S0025-6196(11)61149-X)

P=0.036). Ablation was performed a median of two days prior to ICD implantation (IQR 5 days prior-14 days after). There were 8% procedural-related complications in the ablation group.

“This is only one of three clinical trials to provide an in-depth look at catheter ablation as a preventive measure for patients at risk of life-threatening sudden cardiac events,” said Roderick Tung, MD, FHRS, University of Chicago and lead author. “Ablation has historically been viewed as a palliative, last-resort strategy and bringing it upfront as concurrent therapy with ICD implantation is a potentially meaningful paradigm shift. It is also the first to include patients with VT without prior myocardial infarction as well as the first to include more contemporary procedural strategies, such as high-resolution mapping and epicardial approaches. We hope that these results will influence future guidelines that are trending toward earlier use of catheter ablation over medical therapy in the course of patient treatment.”

Additionally, study results showed the ablation registry that enrolled patients who did not receive an ICD had higher freedom from recurrent VT compared to medical therapy with no significant differences in mortality. The authors express that this opens the door for scientific questioning as to whether ablation without defibrillator therapy may be acceptable in highly selected patients. Further, they note that defibrillator therapy is not affordable for many around the world, reinforcing the importance of a future studies that could potentially randomize patients with nonischemic cardiomyopathy, a group that has not shown consistent survival advantage with ICD implantation, to stand-alone ablation therapy.

Sessions Details:

“Late-Breaking Clinical Trials 1: *A Randomized Trial Of Early First-Line Catheter Ablation For Ventricular Tachycardia: Results From The Pan-Asia United States Prevention Of Sudden Cardiac Death Trial (PAUSE-SCD)*” [Thursday, July 29, 2021 at 9:15 a.m. EST]

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About Heart Rhythm 2021

The Heart Rhythm Society's annual meeting attracts thousands of the world's finest clinicians, scientists, researchers, and innovators in the field of cardiac pacing and electrophysiology. Heart Rhythm 2021 attendees were able to determine how to participate - virtually or in-person. More than 600 international experts in the field will serve as faculty for programming that includes Daily Plenary Sessions, Late-Breaking Clinical Trials, Recorded Cases, Debates, Rhythm Theater Presentations and more, while over 100 exhibitors will showcase innovative products and services.

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 90 countries around the world. For more information, visit www.HRSonline.org.