

EMBARGOED UNTIL SATURDAY, APRIL 30 AT 6:00 AM PST

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**LATE-BREAKING CLINICAL TRIAL RESULTS ANNOUNCED AT HEART RHYTHM
2022:**

**LARGEST ABLATION REGISTRY OF ITS KIND REVEALS POTENTIAL TREATMENT
OPTION FOR COMMON FAINTING CONDITION**

*Cardioneural ablation could replace need for pacemaker in young patients with
vasovagal syncope and episodes of slow heart rate*

SAN FRANCISCO, CA, April 30, 2022 – Today, findings of the largest multicenter cardioneural ablation (CNA) registry in the U.S. to date were announced, showing ablation can be a safe solution to address vasovagal syncope. The results build on international data around CNA and indicate the minimally invasive procedure to improve the brain-heart connection is a promising alternative to implanting a permanent pacemaker in young patients. The study was presented as late-breaking clinical science as part of Heart Rhythm 2022.

Vasovagal syncope is a type of recurrent fainting that occurs when there is a sudden drop in heart rate and blood pressure, impacting more than one third of the U.S. population ([John Hopkins Medicine](#)). It is often associated with standing upright for prolonged periods of time, dehydration, stress, or other emotional triggers. Vasovagal syncope can impact daily activity, especially since there are no established medical or pharmacological treatments for this condition other than behavioral modifications. Many patients will receive a pacemaker to target slow heartbeats that cause fainting. However, because vasovagal syncope often impacts a younger patient population, physicians are often hesitant to implant a permanent pacemaker in an individual under 50 years old.

CNA, a procedure to rewire the heart to prevent drops in heart rate and blood pressure that cause fainting, was first introduced as a treatment for vasovagal syncope in Brazil in 2004, China in 2012, and Turkey in 2015. This study is the first multicenter trial in the U.S. to evaluate the feasibility and safety of CNA procedures to treat recurrent fainting spells and slow heart rates.

Between 2016-2022, 76 CNA procedures were performed in 71 patients across 13 U.S. centers. Patients were treated on a compassionate basis based on their non-responsiveness to medical therapy and/or behavioral modification, and on their desire to not receive permanent pacing. Patients were between the age of 30 and 64 years old. Of the procedures, 63% were performed as concomitant with primary ablation (86% atrial fibrillation/atrial flutter ablation, 7% ventricular tachycardia or premature ventricular contraction, 7% supraventricular tachycardia).

Results showed a low rate of procedural complications with a reasonably high rate of efficacy in patients that received CNA. The majority of patients (82%) remained free from syncope after a single procedure at a median 8.5 months, showing a reduction of median episodes (6 to 0 episodes; $p < 0.001$) after CNA. A sympathetic response during ablation, or an increase in heart rate, (heart rate increase > 5 bpm) were observed 70% of cases (SVC-Ao [58%], RAGP [49%], LSGP [19%], LIGP [8%], RA septum [6%], PMLV [2%]).

“The benefits of ablation for patients with arrhythmias is well-established, and now we have the potential to apply this modified approach to a young patient population in desperate need of a solution. Some patients included had significant head and facial trauma as a result of their sudden fainting episodes. We believe our findings lay the groundwork for new indications for CNA, after seeing the significant impact ablation can make in rebalancing the autonomic nervous system,” said Roderick Tung, MD, Chief of Cardiology at the University of Arizona College of Medicine-Phoenix and study principal investigator. “We are encouraged that with a safe, efficient procedure, we may be able to revolutionize how we treat vasovagal patients and patients with functional bradycardia to allow them to resume their everyday lives without the fear and frustration of fainting recurrence.”

Dr. Tung was the first cardiologist to report this procedure in the U.S. and has performed 15 CNA procedures at the University of Chicago and five at the University of Arizona College of Medicine in Phoenix.

The authors express that these findings further validate the international data for the use of CNA in vasovagal syncope patients and support a potential expanded indication for catheter ablation for these patients. They express the importance of a prospective registry or randomized trial to further confirm the results and advance this promising new field and procedure.

Session Details:

“Late Breaking Clinical Trials: Clinical Innovations: *Feasibility and Safety of Catheter-Based Cardioneural Ablation: Results from the Multicenter US CNA Registry*” [Saturday, April 30, 2022 at 8:00 am PT]

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

About Heart Rhythm 2022

The Heart Rhythm Society's annual Heart Rhythm meeting convenes 5,500+ of the world's finest clinicians, scientists, researchers, and innovators in the field of cardiac pacing and electrophysiology. More than 600 international experts in the field will serve as faculty for the 250+ educational sessions, forums, symposia, and ceremonies, while 100+ exhibitors will showcase innovative products and services.