

EMBARGOED FOR RELEASE UNTIL THURSDAY JULY 29, 2021, 9:15 A.M.

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

**USE OF ORAL ANTICOAGULANTS FOLLOWING ABLATION SHOWN TO HELP REDUCE
RISK OF STROKE IN HIGH-RISK PATIENT POPULATION**

Results show use of blood thinners is more effective when compared to aspirin for patients undergoing left atrial catheter ablation

BOSTON, MA., July 29, 2021 – A new study shows direct oral anticoagulants (DOACS) are more effective than aspirin (ASA) in reducing cerebrovascular events (CVE), including transient ischemic attack and stroke in patients undergoing ventricular tachycardia using radiofrequency catheter ablation (RFA). Results of the STROKE-VT trial were presented as a late-breaking clinical trial as part of Heart Rhythm 2021.

Catheter ablation is an established treatment for patients with atrial fibrillation (AF), the most common heart rhythm disorder. However, stroke and thromboembolisms – a type of blood clot within heart vessels that can impact the brain and other organs – are known complications of left atrial (LA) catheter ablation, a procedure performed for those with symptomatic AF.¹ In fact, left LA catheter ablation has a stroke risk of approximately 0.5% to 1%.² Furthermore, it has been shown within the electrophysiology field that when ablation procedures are conducted without anticoagulants (AC), patients are at an increased risk of stroke³, but the effect on AC for left ventricle procedures is understudied.

The study enrolled a total of 246 patients across four centers scheduled for left ventricular arrhythmia (LVA) RFA. Patients were randomized to receive either DOAC or ASA following their procedure which was then administered three hours after hemostasis. A brain MRI was

¹ Forleo, G. B., Della Rocca, D. G., Lavalle, C., Mantica, M., Papavasileiou, L. P., Ribatti, V., Panattoni, G., Santini, L., Natale, A., & Biase, L. D. (2016, February 29). *A Patient With Asymptomatic Cerebral Lesions During AF Ablation: How Much Should We Worry?* Journal of atrial fibrillation. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5089485/>.

² Haeusler, K. G., Karl Georg Haeusler From the Department of Neurology (K.G.H., Kirchof, P., Paulus Kirchof From the Department of Neurology (K.G.H., Endres, M., Matthias Endres From the Department of Neurology (K.G.H., Davis, S. M., & Al., E. (2011, December 8). *Left Atrial Catheter Ablation and Ischemic Stroke*. Stroke. <https://www.ahajournals.org/doi/10.1161/STROKEAHA.111.627067>.

³ Freeman, J. V., James V. Freeman James V. Freeman, Shrader, P., Peter Shrader Duke Clinical Research Institute, Pieper, K. S., Karen S. Pieper Duke Clinical Research Institute, Allen, L. A., Larry A. Allen Division of Cardiology, Chan, P. S., Paul S. Chan Saint Luke's Mid America Heart Institute, Fonarow, G. C., Gregg C. Fonarow UCLA David Geffen School of Medicine, Gersh, B. J., Bernard J. Gersh Mayo Clinic, Kowey, P. R., Peter R. Kowey Lankenau Institute for Medical Research, Mahaffey, K. W., Kenneth W. Mahaffey Stanford University School of Medicine, Naccarelli, G., (2019, December 13). *Outcomes and Anticoagulation Use After Catheter Ablation for Atrial Fibrillation*. Circulation: Arrhythmia and Electrophysiology. <https://www.ahajournals.org/doi/10.1161/CIRCEP.119.007612>.

conducted within 24 hours and at 30 days and neurological changes were assessed before, after, and at 30 days follow-up based on the National Institutes of Health NIH stroke scale.

Findings show significantly lower procedure-related complications in the DOAC arm than the ASA arm (3.7% vs. 24%; $p < 0.001$). The rates of post-procedure CVE were lower in the DOAC arm compared to the ASA arm (4.5% vs. 19.6%, $p < 0.001$ and 0 vs. 7.1%, $p < 0.001$; respectively). At both 24 hours and 30 days, asymptomatic CVE on MRI were lower in the DOAC arm compared to the ASA arm (11.2% vs 25%, $p = 0.006$ and 6% vs 19.6%, $p = 0.001$; respectively).

“The STROKE-VT trial helps us answer a longstanding question around the best way to lower procedure-related risks for patients coming out of an ablation,” said Dhanunjaya R. Lakkireddy, MD, FHRS, Executive Medical Director of the Kansas City Heart Rhythm Institute and lead author of the STROKE-VT study. “Moving forward, we hope the findings encourage electrophysiologists to use anticoagulants after ablations to reduce cerebrovascular events in a patient population that is already very sick and at high-risk of stroke.”

Sessions Details:

“Late-Breaking Clinical Trials 1: *Safety And Efficacy Of Periprocedural Direct Oral Anticoagulant Versus Aspirin Use For Reduction Of The Risk Of Cerebrovascular Events In Patients Undergoing Ventricular Tachycardia Radiofrequency Catheter Ablation (STROKE-VT)*”
[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.