Mount Sinai first to use visually guided catheter ablation system to treat AFib patient

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For the first time in a new U.S. clinical trial, researchers at Mount Sinai School of Medicine have used the HeartLight Endoscopic Ablation System (EAS) to correct abnormal electrical signals inside the heart of a patient affected by atrial fibrillation (AFib), one of the nation's most common heart ailments. The device is the first catheter ablation system to incorporate a camera that allows doctors to see a direct, real-time image of the patient's heart tissue during ablation.

The HeartLight EAS national clinical trial is headed by Vivek Y. Reddy, MD, Professor of Cardiology, Mount Sinai School of Medicine, and Director of the Cardiac Arrhythmia Service at Mount Sinai Heart. Along with colleagues, he performed the successful procedure on the first patient on Valentine's Day last week. His colleagues include Srinivas R. Dukkipati, MD, Director of Mount Sinai's Experimental Electrophysiology Laboratory, and Andre d'Avila, MD, Co- Director of the Cardiac Arrhythmia Service.

"This new device has the potential to make AFib ablation more reliable, more reproducible, and more consistent for patients with paroxysmal [intermittent] atrial fibrillation," said Dr. Reddy. "The technology which is currently available leads to widely variable success rates, depending largely on physician skill and experience with the procedure. This visually-guided system with a rotating laser design has the potential to simplify AFib ablation and make it available to more patients than ever, before their paroxysmal AFib becomes chronic [continuous] AFib."

Estimates are that there are as many as six million U.S. adults with atrial fibrillation (AFib), a condition characterized by a rapid and irregular heart beat that can cause serious complications, including stroke, palpitations, fainting and early death. AFib diagnosis has increased over the past two decades and the condition now accounts for one-quarter of all strokes in the elderly.

Paroxysmal (intermittent) AFib is caused by irregular electrical signals that come from pulmonary veins that drain blood from the lungs to the heart. During a standard AFib ablation procedure, physicians use spot catheters to cauterize heart tissue in a point-by-point manner to encircle these pulmonary veins, creating a ring of scar tissue that electrically isolates the pulmonary veins, preventing the irregular electrical signals from causing AFib. But this is a technically complicated procedure since, unlike open heart surgery, physicians cannot directly see the tissue that is being cauterized. Despite using various cardiac mapping systems, problems often arise because the scar tissue that is created is not continuous, allowing the abnormal electrical signals to continue to pass into the heart and cause recurrence of AFib.

The new balloon catheter device used by the Mount Sinai Heart team features a built-in camera that allows the physicians to directly see the heart tissue that needs to be ablated. They can then guide an internal laser in a continuous arc around the origin of the vein, creating more uniform scar tissue. "By directly seeing the tissue that we are ablating, there is less chance of a gap in the encircling ablation line," said Dr. Dukkipati.

The trial is expected to eventually enroll an estimated 450 patients at up to 25 sites in the U.S. and follow them for up to 5 years post procedure. The Food and Drug Administration (FDA) granted Investigational Device Exemption approval for HeartLight EAS in December, and the device is already in use in Europe.

More information: More information about the clinical trial can be found at clinicaltrials.gov/show/NCT01456000

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