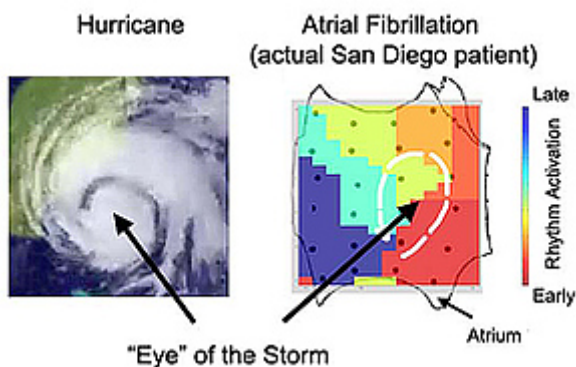


New Technology Improves Heart Rhythm Treatment

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CONFIRM study results point to a doubling of success in treating heart rhythm disorder. Researchers from UC San Diego, the University of California Los Angeles and Indiana University report having found, for the first time, that atrial fibrillation or irregular heart rhythms is caused by small electrical sources within the heart, in the form of electrical spinning tops ("rotors") or focal beats. Importantly, they found a way of detecting these key sources, then precisely targeting them for therapy that can shut them down in minutes with long lasting results.

The team, which included cardiologists, physicists and bioengineers, report the findings in the July issue of the *Journal of the American College of Cardiology* as the CONFIRM trial (**C**onventional Ablation for Atrial Fibrillation ^[SEP]With or Without **F**ocal **I**mpulse and **R**otor **M**odulation).



Left panel shows the eye of a hurricane. Right panel shows the striking similarity of the rotor or localized source of an arrhythmia in a patient with atrial fibrillation. Ablation targeted at these rotors or "eyes of the storm" successfully terminated and eliminated atrial fibrillation in the CONFIRM trial. Photo credit: UCSD/UCLA.

Currently, many patients treated for atrial fibrillation with standard therapies will experience a recurrence due to the difficulty of finding the source of the arrhythmia. The new findings will help cardiologists better target and treat arrhythmias.

The CONFIRM study examined 107 patients with atrial fibrillation referred for a non-surgical catheter ablation procedure. During this procedure, doctors thread a wire with a metal-tipped catheter inside the body, from a vein in the groin, to apply heat to the area of the heart that is producing the arrhythmia to stop it.

In one group of patients, the team used the new technique to help perform precise burns, called Focal Impulse and Rotor Modulation (FIRM) that

were aimed directly at the fundamental source of the arrhythmia – tiny electrical disturbances in the heart called rotors or focal sources that look like mini tornadoes or spinning tops.

Remarkably, this new procedure shut down atrial fibrillation or very significantly slowed it in 86 percent of patients in an average of only 2.5 minutes.

In comparison, conventional catheter procedures were performed in a second group of patients. Since this approach is less targeted, it involved hours of treatment over larger regions in the heart and often did not shut down the atrial fibrillation.

To track outcomes, patients received an implanted ECG monitor that very accurately assessed their heart rhythms over time. Researchers found that after two years, the FIRM-guided group had an 82.4 percent freedom from atrial fibrillation episodes, compared to only 44.9 percent freedom in the group that received standard therapy.

The new targeted method demonstrated an 86 percent improvement over the conventional method in the study.

"We are very excited by this trial, which for the first time shows that atrial fibrillation is maintained by small electrical hotspots, where brief FIRM guided ablation can shut down the arrhythmia and bring the heart back to a normal rhythm after only minutes of ablation," said lead author Sanjiv Narayan, MD, PhD, professor of medicine at UC San Diego Sulpizio Cardiovascular Center, director of Electrophysiology at the San Diego Veterans Affairs Medical Center and visiting professor at the UCLA Cardiac Arrhythmia Center.

"The results of this trial, with an 80 percent ablation success rate after a single procedure, are very gratifying. This is the dawn of a new phase of managing this common arrhythmia that is mechanism-based," said Kalyanam Shivkumar, MD, PhD, director of the UCLA Cardiac Arrhythmia Center, and professor of medicine and radiological sciences at UCLA.

This study also represents a successful example of technology transfer from U.S. researchers supported by U.S. research funding to a small U.S. enterprise. The science behind this work was funded by grants to Narayan from the National Institutes of Health, including a grant awarded as part of the American Recovery and Reinvestment Act, and by the Doris Duke Charitable Foundation.

These discoveries, owned by the Regents of the University of California, were then licensed to a local startup company, Topera Medical, which has recently obtained FDA clearance for the mapping system it developed (RhythmView™) from this early science. Narayan is a co-founder with equity interest in Topera. Wouter-Jan Rappel, PhD, holds equity interest in Topera. John Miller, MD, has received modest honoraria from Topera. Shivkumar is an unpaid advisor to Topera, and the other authors report no relationship with Topera.

Other authors included John Miller, MD, chief of electrophysiology at Indiana University; David Krummen, MD, associate professor of medicine with UC San Diego Sulpizio Cardiovascular Center and associate director of electrophysiology at the San Diego Veterans Affairs Medical Center; Wouter-Jan Rappel, PhD, University of California San Diego Department of Theoretical Biological Physics; and Paul Clopton from the San Diego Veterans Affairs Medical Center Department of Statistics.

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Media Contacts: Kim Edwards, UC San Diego, 619-543-6163, kedwards@ucsd.edu; Rachel Champeau, UCLA, 310-794-2270, rchampeau@mednet.ucla.edu

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