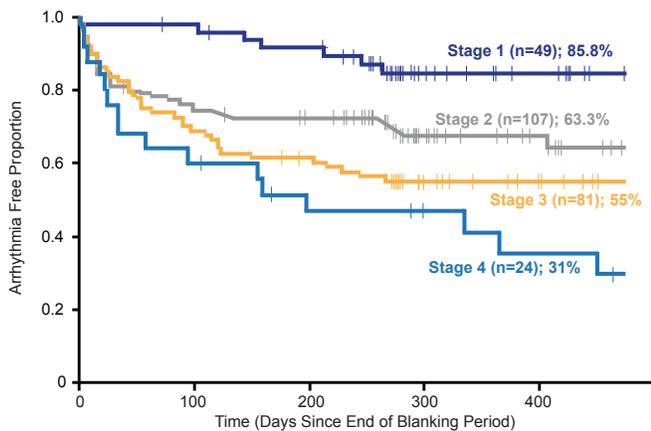


patients in the trial had posterior wall involvement, which accounted for about 57% of the total fibrotic tissue in the left atrium. The only predictor of atrial fibrosis was history of hypertension.

Atrial fibrosis and/or structural remodeling, as quantified by DE-MRI, was demonstrated in multivariate analysis to be the only independent predictor of ablation outcome (Figure 1).

**Figure 1. DE-MRI-Based Atrial Fibrillation Staging Is Associated With Ablation Procedure Outcome**



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Dr. Marrouche concluded that, in his opinion, the data from the DECAAF trial indicates that DE-MRI quantification of atrial fibrosis is a very strong predictor of AF ablation outcome and can be reproduced around the world. He added that DECAAF data would promote DE-MRI based individualized management of the AF and help triaging patients to the appropriate treatment option based on the amount of atrial disease. In the future this would not only help procedural success, but also avoid unnecessary ablation procedures.

## FIRM-Guided Ablation of Stable Rotors and Focal Sources Can Eliminate PAF Without PVI

Written by Mary Beth Nierengarten

In patients with paroxysmal atrial fibrillation (PAF), disease can be eliminated by targeting ablation to its primary sustaining mechanism alone without the need to ablate triggers. This is the conclusion of the Precise Rotor Elimination without Concomitant pulmonary vein Isolation for the Successful Elimination of Paroxysmal Atrial Fibrillation study [PRECISE-PAF; NCT01248156] presented in a late-breaking clinical trial session.

The study results also confirm recently published evidence that the primary sustaining mechanisms of PAF is by stable rotors and focal sources revealed by Focal Impulse and Rotor Map (FIRM) in patient-specific bi-atrial locations [Narayan SM et al. *J Am Coll Cardiol* 2012], and offers data that elimination of rotors or focal sources either directly by FIRM-guided ablation, or coincidentally when anatomical ablation passes through them, may explain the success of different AF ablation approaches [Narayan SM et al. *J Am Coll Cardiol* 2013. In press].

Sanjiv M. Narayan, MD, PhD, University of California, San Diego School of Medicine, Veterans Affairs Medical Center, San Diego, California, USA, and colleagues undertook the PRECISE-PAF trial to test their hypothesis that prospective targeted ablation of stable rotors and focal sources alone would eliminate PAF over the long term without the need for pulmonary vein isolation (PVI).

The study included 31 consecutive PAF patients undergoing FIRM-guided ablation in five centers in the United States. Patients included in the study were aged >21 years, had indications for PAF ablation, discontinued antiarrhythmics >5 half-lives, and amiodarone >30 days. The only patients excluded were those unable or unwilling to provide informed consent. The primary endpoint was single procedure freedom from AF.

Most of the study participants were male (n=28); the average age was 59 years; AF had been present for ~4 years; the average CHADS<sub>2</sub> score was 1.5; and 38.7% (n=12) had a CHADS<sub>2</sub> >2. Overall, 74.2% (n=23) had hypertension and 32.3% (n=10) had coronary disease.

The primary endpoints of the study were acute elimination of diagnosed AF rotors and focal sources based on repeated mapping, as well as long-term freedom of AF (ie, using standard criteria defined as <30 seconds on external intermittent monitors or <1% in patients with continuous monitoring). Monitoring was done quarterly and antiarrhythmic drugs were discontinued after a 90-day blanking period.

For each patient, the investigators delivered FIRM-guided ablation at each source to achieve termination of AF with noninducibility or to eliminate sources on repeat FIRM-maps. Residual tachycardias were also ablated. PVI was not done.

The study found that stable rotors and focal sources arose in all 31 patients, with 2.5 AF rotor/focal sources per patient. Overall, the sources arose in the left atrium in 66.3% of the patients and in the right atrium in 33.7%.

Median FIRM-guided ablation was 17.4±8.2 minutes, and total case ablation including typical atrial flutter ablation, was a median of 22.7±9.1 minutes. Although PVI showed potential in all patients, they were not isolated.

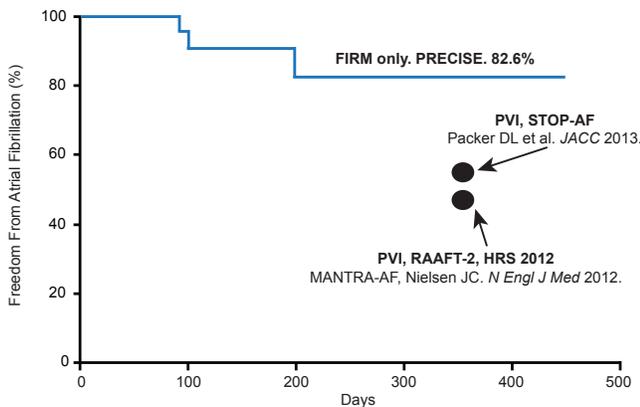
On follow-up for a median of 223 days, using more rigorous monitoring than typically used in AF trials, 82.6%



## CLINICAL TRIAL HIGHLIGHTS

of patients were free from AF after a single FIRM-guided ablation procedure. This compares favorably with the results from prior studies of PVI that provided 50% to 60% single procedure success rates (Figure 1).

**Figure 1. Single Procedure Freedom From Atrial Fibrillation in the PRECISE-PAF Trial**



Reproduced with permission from SM Narayan, MD, PhD.

Dr. Narayan concluded that the study confirms that PAF is a substrate-based disease. Accordingly, these results show that FIRM-guided ablation of stable rotors and focal sources can eliminate PAF without the need to eliminate triggers (PVI). This is in line with ablation for most other arrhythmias.

Limitations of the study highlighted by the investigators included the use of current mapping baskets that were suboptimal, the single-arm design of the study, the need for larger sample size and longer follow-up, and the focus only on PAF.

## Long AT/AF Episodes Associated With Adverse Clinical Events in ICD Patients

Written by Rita Buckley

Many patients utilizing pacemakers (PMs) and implantable cardiac defibrillators (ICDs) who have only short atrial tachycardia/atrial fibrillation (AT/AF) are not at higher risk of adverse events than those without AT/AF over the study period of approximately 24 months. However, long AT/AF episodes are associated with adverse clinical events, including hospitalization for clinical AT/AF and all-cause death in patients with ICDs. Michael Orlov, MD, PhD, Steward's St. Elizabeth's Medical Center/Tufts Medical School, Boston, Massachusetts, USA, presented the outcomes from the Registry of Atrial Tachycardia and Atrial Fibrillation Episodes in the Cardiac Rhythm Management Device Population [RATE; NCT00837798].

The RATE registry was a prospective, outcome-oriented registry designed to document the incidence of AT/AF, with associated clinical data, in a large group of patients with implanted cardiac rhythm management devices. The hypothesis was that short AT/AF episodes in the RATE population would be associated with prespecified adverse clinical events, including hospitalization for AT/AF, heart failure, stroke, and death. In addition, short AT/AF episodes would confer a high risk of subsequent longer AT/AF episodes.

Patients who received new PMs or ICDs with no documented AF in the prior 3 months were included in the study. They were followed-up every 6 months for up to 2 years. Adverse events included all hospitalizations, emergency room visits and short stays of <24 hours, and in-hospital deaths. These were adjudicated by two physicians blinded to electrogram data.

The study, which ran from 2007 to 2012, enrolled 5379 patients from 225 sites in the United States (3141 with PMs and 2238 with ICDs). The median follow-up was 23 months, with 2232 hospitalizations, 359 deaths, and 37,531 electrograms adjudicated.

- In the RATE Registry AT/AF was documented in half of the device population within 2 years
- Approximately 1 in 4 of these patients with implantable devices had short AT/AF only
- Patients with ONLY short AT/AF episodes were not at higher risk of adverse events than those without AT/AF over the study period
- Long AT/AF episodes were associated with adverse clinical events in the ICD group including
  - » Composite endpoint of adverse events
  - » Hospitalization for clinical AT/AF
  - » All-cause death
- Many patients with short AT/AF will not develop long AT/AF within a 24-month follow-up

## Novel Contact Force Catheters Are Effective and Safe for Paroxysmal AF Ablation

Written by Phil Vinal

Andrea Natale, MD, Texas Cardiac Arrhythmia Institute, Austin, Texas, USA, presented the 12-month findings from the Ablation of Symptomatic Paroxysmal Atrial Fibrillation Using Novel Contact Force Catheter trial [SMART-AF]. The study met its safety and effectiveness endpoints with no unanticipated device-related adverse events (AEs), and with 72% of the ablated patients free from atrial fibrillation (AF) recurrence. Furthermore,