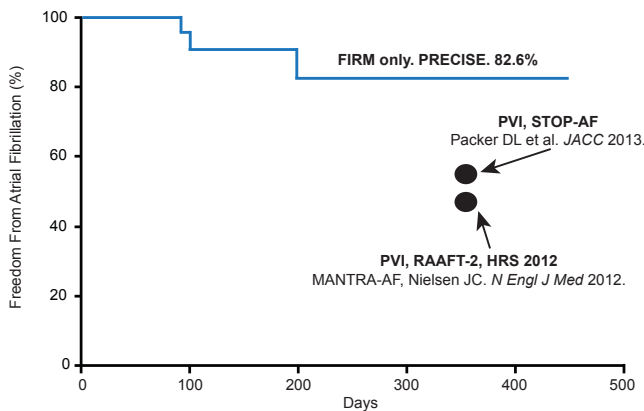




CLINICAL TRIAL HIGHLIGHTS

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



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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,