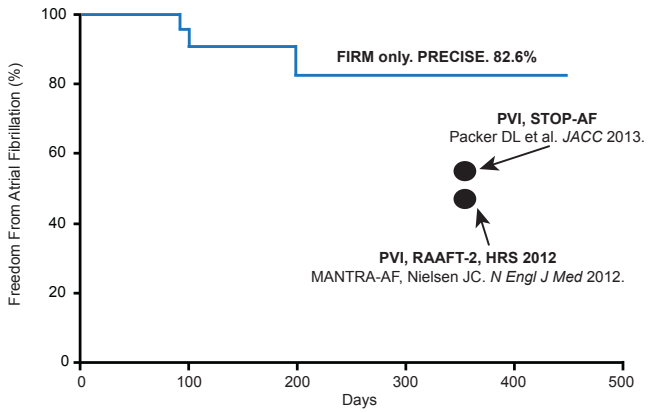
of patients were free from AF after a single FIRM-guided ablation procedure. This compares favorably with the results from prior studies of PVI that provided 50% to 60% single procedure success rates (Figure 1).

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 Vinall

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,

increased freedom from arrhythmia was correlated with increased percentage of time within physician-targeted contact force range.

The purpose of this study was to evaluate the safety and effectiveness of a new deflectable and irrigated tip catheter in treating drug-refractory symptomatic paroxysmal AF. The catheters have a sensor that measures the direct contact force between the heart tissue and the catheter tip. The devices were used with a navigation system that displayed integrated contact force and direction data. The ablation protocol included circumferential pulmonary vein isolation with confirmation of entrance block. This prospective, multicenter, single-arm study included 172 drug-refractory AF patients (aged ≥18 years) with left ventricular ejection fractions ≥40%.

The primary efficacy endpoint was freedom from documented symptomatic AF/atrial tachycardia (AT)/atrial flutter. Acute procedural failure, the introduction of a new antiarrhythmic drug for AF during the effectiveness period, repeat ablation beyond the 90-day blanking period, and >2 repeat ablation procedures in the blanking period were all considered efficacy failures. The primary safety endpoint was the incidence of early-onset primary AEs within 7 days of an AF ablation procedure. Assessments were made at 1, 3, 6, 9, and 12-month visits.

The majority of patients were male (72.1%) and Caucasian (96%), with a mean ±SD age of 58.8±11.0 years; 59.3% were hypertensive; mean ±SD AF duration was 5.4±5.1 years, and mean ±SD left atrial diameter was 38.6±6.1 mm.

The primary safety goal was met: the incidence of early-onset primary AEs was 9.9% (upper limit of confidence was 15.6%). There were no unanticipated device-related AEs: no deaths, and no incidence of stroke, transient ischemic attack, myocardial infarction, phrenic nerve palsy, atrio-esophageal fistula, thromboembolism, or pulmonary vein stenosis. Contact force had no effect on early primary AEs. There were four cases of cardiac tamponade and three vascular access complications.

Acute success was achieved in all subjects in the effectiveness cohort. At the end of the 12-month follow-up, 72% of patients were free from AF/AT/atrial flutter recurrences and 69% were deemed protocol-adjudicated successes ($p<0.001$).

Investigators selected their own contact force working range; 67% used a range of 5-40g. There was a significantly higher (15%; log-rank p value 0.03) success rate for primary effectiveness when contact force was within ≥80% of the investigator-selected range.

Post ablation, there were clinically meaningful improvements (≥3 points) in physical and mental quality of life measures; symptom frequency and severity scores also decreased.

The catheter has been approved by the FDA for use in the United States.

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