In conclusion, patients with paroxsymal AF were at a lower risk for stroke or SEE but had a similar risk of bleeding as patients with more sustained AF. Compared with patients with well-managed warfarin dosages (time in therapeutic range of 68.4%), edoxaban was associated with a reduced incidence of stroke or SEE, cardiovascular death, and bleeding, as well as more favorable net outcomes across all AF subtypes.

## Defibrillators Programmed With Longer Detection Intervals Safe for Secondary Prevention Patients

Written by Nicola Parry

Laurence D. Sterns, MD, Royal Jubilee Hospital, Victoria, British Columbia, Canada, presented results of the secondary prevention substudy of the Study to Evaluate System Safety and Clinical Performance of the Protecta Implantable Cardioverter Defibrillator (ICD) Plus Cardiac Resynchronization Therapy Defibrillator (CRT-D) trial [PainFree SST; NCT00982397]. This prospective, randomized, multicenter study demonstrated that defibrillators programmed with longer detection intervals are safe for secondary prevention in patients with ICDs.

Although previous studies have shown that extended ICD detection times for ventricular tachycardia or ventricular fibrillation (VF) reduce inappropriate therapies and mortality in primary prevention patients [Gasparini M et al. *JAMA* 2013; Moss AJ et al. *N Engl J Med* 2012; Wilkoff BL et al. *J Am Coll Cardiol* 2008], the effect of prolonged ICD detection in secondary prevention patients who have already experienced episodes of sudden cardiac arrest and are at increased risk for a deadly irregular heart rhythm had not been evaluated.

Prof. Sterns and colleagues conducted the PainFree SST trial to investigate the safety of prolonged detection for ventricular tachycardia or VF in secondary prevention patients. To be included in the study, patients were required to have secondary prevention indications for ICD.

Patients with mechanical tricuspid valves, those enrolled in concurrent drug or medical device studies, and those who were unwilling to provide written informed consent to participate in the study or who anticipated being unable to complete it were excluded from the trial.

The PainFree SST trial enrolled a total of 2790 patients receiving ICDs programmed with technology that enables the devices to discern whether an abnormal heart rhythm is life threatening. Of these participants, 705 were included in this substudy and were randomly assigned 1:1 to either standard interval detection (VF number of intervals to detect, 18 of 24; n=353) or extended interval detection (VF number of intervals to detect, 30 of 40; n=352) of ventricular tachycardia or VF ≥188 beats/minute.

The primary end point was freedom from arrhythmic syncope at 1 year. Secondary end points included time to first arrhythmic and all-cause syncope, appropriate therapy or inappropriate shock, and mortality.

At baseline, 35% of patients had atrial arrhythmias, and 33% had histories of syncope. At 1 year, 7 patients in the standard group and 11 in the prolonged group had arrhythmic syncope. The arrhythmic syncope–free rate was similar between the standard and prolonged groups (98.0% vs 96.9%; p=0.012 for noninferiority). There was no statistically significant increase in the time to first arrhythmic syncope (HR 1.52; 95% CI 0.66–3.52; p=0.32), incidence of all-cause syncope (HR, 1.17; 95% CI, 0.59–2.32; p=0.66), appropriate VF zone therapies (HR, 0.98; 95% CI, 0.67–1.43; p=0.91), time to first appropriate shock (HR, 1.04; 95% CI, 0.70–1.53; p=0.85), or incidence of inappropriate shocks (1.0% vs 1.3%, p=0.74). However, in the prolonged group, the VF therapy rate (1.5 vs 0.4, p=0.0001), VF shock rate (0.9 vs 0.27, p=0.0026), and VF antitachycardia pacing rate (0.57 vs 0.16; p=0.0019) were significantly lower.

The results of this substudy demonstrated that extended interval detections did not result in statistically increased risk for syncope in secondary prevention patients. Prof. Sterns concluded that the prolonged detection programming strategy may be considered as a strategy to reduce inappropriate shocks in patients with ICDs.

## Smartphone-Enabled ECG Devices Produce Diagnostic Tracings in Children

Written by Nicola Parry

Hoang H. Nguyen, MD, Washington University School of Medicine, St. Louis, Missouri, USA, presented results of the prospective, single-center Smartphone Pediatric Electrocardiogram trial [SPEAR] demonstrating that smartphone-enabled electrocardiogram (ECG) devices can produce accurate tracings of diagnostic and therapeutic quality in children in the remote setting.

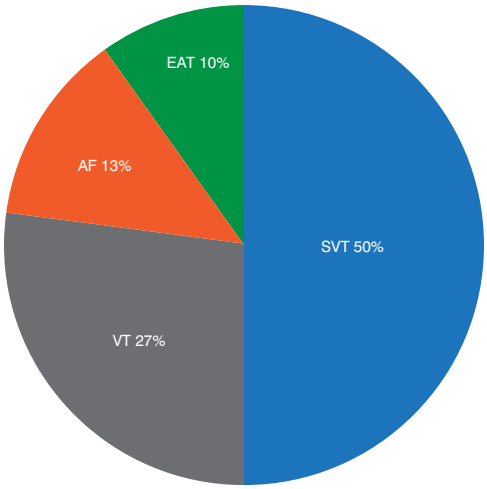
**S**martphone-enabled ECG recorders have the ability to enhance physician reach and patient care by facilitating ECG assessment in patients in remote areas. One such example is the AliveCor 1-lead ECG device, which consists of 2 exposed electrodes on the back of a smartphone case. This device generates an ECG when a finger of each hand is placed on each of the electrodes, and the electrical signal is processed and transmitted to the phone's AliveCor application.

Dr. Nguyen and colleagues are conducting a prospective trial throughout a 1-year period to investigate the usefulness of ECG tracings generated by the AliveCor device in pediatric patients, and to evaluate user satisfaction.

To be included in the trial, patients were required to be aged ≤21 years, have documented paroxysmal arrhythmia, and own an iPhone 4 or 5. Users were instructed to email ECG tracings of concern directly from the application for review by pediatric cardiac electrophysiologists. Following interpretation, patients were contacted with results and further care instructions. They were also required to complete online surveys regarding their experience and satisfaction with the device and cardiac care team.

In total, 30 patients (aged 2 months to 18 years; median age 12.5 years) were enrolled in the study. To date, 144 ECG tracings have been received from 20 patients, and the highest number of tracings received from a single patient during a 1-month period was 15. Users deemed ECGs as concerning 45% of the time. Signal quality allowed unequivocal rhythm diagnosis in 141 of 144 (98%) tracings; motion artifact prevented evaluation of the remaining three tracings. The most frequent diagnosis was supraventricular tachycardia (n=15; 50%), followed by ventricular tachycardia (n=8; 27%), atrial fibrillation (n=4; 13%), and ectopic atrial tachycardia (n=3; 10%; Figure 1).

Figure 1. Rhythm Diagnosis From Smartphone ECG Tracings




AF=atrial fibrillation; EAT=ectopic atrial tachycardia; SVT=supraventricular tachycardia; VT=ventricular tachycardia.

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Forty-four surveys have also been received to date, 68% of which are from parents. The results of the user survey thus far have been positive, with 98% of users indicating that the device is very easy to use and 93% indicating the ease at which it transmits tracings. Of users, 98% expressed a high level of comfort in using the device for arrhythmia management, and 99% indicated continued interest in using it after the study ends.

The parents of younger patients also provided feedback noting that the device can record their child's heart rhythm for prompt diagnosis without the need to visit the emergency room (ER) or pediatrician's office. They did, however, indicate the difficulty of device placement on small children. In addition, some noted that because the device was on the parental phone, it was not with the child at all times.

These preliminary data demonstrate that smartphone-enabled ECG devices can produce diagnostic tracings in children, with high use and user satisfaction. Such devices can help pediatric electrophysiologists better manage chronic arrhythmia by optimizing pediatric outpatient care, limiting ER use, and thereby reducing health care costs, concluded Dr. Nguyen.

## Ranolazine and Dronedarone in Combination Show Synergistic Effects on AF Suppression

Written by Nicola Parry

Peter R. Kowey, MD, Lankenau Medical Center, Wynnewood, Philadelphia, Pennsylvania, USA, presented results from the Phase 2 Study to Evaluate the Effect of Ranolazine and Dronedarone When Given Alone and in Combination in Patients With Paroxysmal Atrial Fibrillation trial [HARMONY; NCT01522651]. This randomized, double-blind, placebo-controlled trial demonstrated that a combination of ranolazine and low-dose dronedarone reduced the burden of paroxysmal atrial fibrillation (PAF) when compared with either drug alone.

Both ranolazine and dronedarone are drugs that block multiple ion channels. Dronedarone is approved for management of patients with PAF. Ranolazine not only is approved for chronic angina but also has been shown to have antiarrhythmic effects [Mason PK, DiMarco JP. *Circ Arrhythm Electrophysiol* 2009]. Neither of these drugs, however, has proved very effective for the treatment of PAF when used as monotherapy.

Dr. Kowey and colleagues conducted a study to determine if the combination of ranolazine and low-dose dronedarone is superior to individual drug therapy in reducing the burden of atrial fibrillation (AF) in patients with PAF.