Andrea Natale, MD, St David Medical Center, Austin, Texas, USA, stated that the VENTURE AF study was a phase IIIb, international study designed as an exploratory analysis of this issue since it was not feasible to enroll the large number of patients required to establish noninferiority or superiority of continued anticoagulation. Patients (n = 248) were randomized 1:1 to uninterrupted rivaroxaban 20 mg once daily or uninterrupted warfarin (international normalized ratio, 2.0 to 3.0) prior to catheter ablation and for 4 weeks following the procedure. There was independent, blinded adjudication of all prespecified thromboembolic and bleeding events.

The patient groups were well matched at baseline. The mean age was 59 years, 71% were men, and 91.9% were white. Most patients had paroxysmal AF: 95 (76.6%) in the rivaroxaban group and 87 (70.2%) in the warfarin group ($P = .25$). Eleven (8.9%) patients in each group had a previous catheter ablation ($P = .56$). Cardioversion had been performed previously in 47 patients (37.9%) in the rivaroxaban group and 54 (43.5%) in the warfarin group ($P = .37$).

The activated clotting time levels, according to per-protocol analysis, were significantly lower with rivaroxaban vs warfarin on the day the catheter ablation was performed (mean, 302 vs 332 seconds; $P < .001$), which has been seen with all of the NOACs, commented Dr Natale.

The total number of adjudicated events was 26 in the rivaroxaban group and 25 in the warfarin group, of which 21 and 18, respectively, were any bleeding event. The primary end point of major bleeding as measured by the GUSTO, ISTH, or TIMI definition of bleeding occurred in 1 patient in the warfarin group and none in the rivaroxaban group. Two thromboembolic events occurred in the warfarin group (1 ischemic stroke and 1 vascular death), and none in the rivaroxaban group. The most frequent minor bleeding event was hematoma or vessel puncture site hematoma, which occurred in 8 patients in the rivaroxaban arm and 10 patients in the warfarin group.

The study was limited by the low number of bleeding events, stated Dr Natale, who also noted that the sample size in this study is similar to that for the largest nonrandomized studies in this setting. Detailed data on the clinical outcomes will be published in the near future.

A prospective multicenter registry study was conducted at 4 centers in the United States and Europe, and it included consecutive patients taking apixaban (5 mg BID) for at least 30 days prior to undergoing radiofrequency catheter ablation. The last dose of apixaban was taken on the morning of the procedure. This analysis included 200 patients with uninterrupted apixaban and 200 patients with uninterrupted warfarin who were matched for age, sex, and type of AF. The patients were mostly men (71.5%), their average age was 65.9 years, and 334 (83.5%) had nonparoxysmal AF. The results were presented in a poster by Luigi Di Biase, MD, St David Medical Center, Austin, Texas, USA, and colleagues.

No differences were found between the apixaban and warfarin groups, respectively, for major bleeding (1% vs 0.5%; $P = 1.0$) or minor bleeding (3.5% vs 2.5%; $P = .56$). Total bleeding complications were also similar with apixaban (4.5%) and warfarin (3%, $P = .43$). The investigators stated there were no symptomatic thromboembolic complications. In a subset of 29 patients who had diagnostic magnetic resonance imaging following ablation, there were no cases of silent cerebral ischemia in the patients treated with apixaban.

The investigators for the VENTURE AF study and the multicenter registry stated that the results indicate that uninterrupted treatment with rivaroxaban and apixaban, respectively, had outcomes similar to that seen with warfarin. These data suggest that uninterrupted therapy with rivaroxaban and apixaban can be considered as a strategy to reduce periprocedural thromboembolic events and results in a risk of major bleeding in patients with nonvalvular atrial fibrillation undergoing catheter ablation similar to that seen with warfarin.

SELECT-LV: Direct, Wireless Endocardial LV Pacing Is Feasible for CRT

Written by Maria Vinall

Vivek Y. Reddy, MD, Mount Sinai Hospital, New York, New York, USA, presented results from the ongoing SELECT-LV study [NCT01905670], which showed that in patients with failed conventional cardiac resynchronization therapy (CRT; also called biventricular pacing), a wireless cardiac stimulation system provided synchronous left ventricular (LV) stimulation and significant reductions in QRS duration with no pericardial tamponade and few procedural adverse events.

SELECT-LV was designed to demonstrate the safe implantation of small receiver-electrodes into the endocardial surface of the left ventricle and to establish device utility in providing CRT in patients with heart failure. LV leadless pacing was performed via a 9-mm electrode implanted in the endocardial midlateral LV free wall. The electrode is activated by a submuscular ultrasonic transmitter synchronized to the right ventricular pacing pulse of a standard implantable cardioverter defibrillator pacemaker.

This was a nonrandomized, prospective, 6-center study in Europe in patients who met current guidelines for CRT but were considered CRT failures due to lead issues or nonresponse to CRT. The primary safety end point was safety during the 24-hour perioperative period, and the primary performance end point was safety and pacing at 1 month. Secondary end points at 6 months were safety, performance, and preliminary efficacy.

A total of 39 patients completed enrollment and screening. Implantation was attempted in 35 participants, 34 (97.1%) of which were successful. All implanted patients completed the 1-month follow-up; 26 patients completed the 6-month follow-up. Participants (88% men) were mean age 65.5 years with a mean ejection fraction (EF) of 26% and mean NYHA class of 2.6. At baseline, the mean intrinsic pre-implant QRS duration was 170 ms. About two-thirds of the patients were on anticoagulants prior to their implant. The most common reason for implantation was the inability to perform coronary sinus pacing.

There were a total of 4 procedure-related events in 4 patients (11.4%) during the <24-hour perioperative period: groin fistula, which was surgically repaired; groin pseudoaneurysm, which required no treatment; ventricular fibrillation during electrode implant; and electrode embolization to the lower leg during catheter/dilator exchange (judged both procedure and device related). Unlike an earlier terminated study that reported a 30% tamponade rate [Auricchio A et al. *Europace.* 2014], this study had no episodes of pericardial tamponade.

During the 1-month follow-up period, there were 8 events in 8 patients (22.9%), including 1 death following prolonged resuscitation. Among these, there were 6 procedure-related events, including pseudoaneurysm, hematoma at transmitter pocket, a suspected infection, and a death following prolonged resuscitation. Furthermore, there was 1 procedure- and device-related event as well as atrial fibrillation (AF) episodes in a patient with AF, although these episodes were unrelated to the procedure or device. During the 6-month follow-up, there were 3 device-related events (premature battery depletion in 3 patients [11.5%]); these events were subsequently resolved. There were also 10 comorbidity events in 5 patients (19.2%), although most were unrelated to the procedure.

At 1 month, the primary end point, consistent CRT, was met in 97.1% of evaluable patients. At 1 month, the mean QRS reductions were 50 and 37 ms, as compared with baseline right ventricular and intrinsic pacing, respectively.

At 1 month, the primary performance end point of biventricular pacing capture on 12-lead electrocardiogram was met in 33 of 34 evaluable patients (97.1%).

Table 1. Improved QRS Duration With Biventricular Pacing

	QRS Duration, ms		
Type of Pacing	**Baseline**	**1 wk**	**1 mo**
Right ventricular pacing	182	—	—
Intrinsic pacing	169	162	157
Biventricular pacing	—	133	132

Furthermore, mean QRS duration with biventricular pacing was 50 ms shorter vs baseline right ventricular pacing and 37 ms shorter than baseline intrinsic pacing (Table 1).

EF increased by ≥5% in 69.5% of patients with a mean 6-month difference from baseline of 6.7%. NYHA decreased from 2.6 at baseline to 1.8 at 6 months (61.5% of patients had a ≥1 class improvement), and 64.7% of patients had ≥15% improvement in LV end-systolic volume.

The results of the SELECT-LV study demonstrated the feasibility of direct, wireless endocardial LV pacing for CRT. Overall CRT efficacy improved with evidence of significant reductions in QRS duration, synchronous LV stimulation, electrical and structural remodeling, and improvement in LVEF. Safety results improved compared with previous studies, but more data are needed.

DECAAF: Balloon Cryoablation Results in More LA Scarring Than Other Ablation Techniques

Written by Maria Vinall

In a cohort study that used late gadolinium enhancement magnetic resonance imaging (LGE-MRI) to evaluate left atrial (LA) scarring, investigators showed that balloon cryoablation resulted in more scarring compared with point-by-point and multipolar radiofrequency (RF) ablation. These data from a cohort of the DECAAF study [Marrouche NF et al. *JAMA*. 2014] were presented in a poster by Nazem W. Akoum, MD, University of Washington, Seattle, Washington, USA.

The DECAAF study showed an independent association between atrial tissue fibrosis estimated by delayed enhancement MRI and the likelihood of recurrent arrhythmia among patients with AF undergoing catheter ablation [Marrouche NF et al. *JAMA*. 2014]. Pulmonary vein isolation (PVI) is commonly used for catheter ablation of atrial fibrillation (AF). The current cohort study used LGE-MRI to evaluate LA scarring resulting from the techniques used for PVI in the DECAAF study.