follow-up was 12 months, with a standard 3-month blanking period. Patients and electrocardiogram assessors were both blinded to treatment.

The primary outcome measure was recurrence of atrial tachyarrhythmia >30 seconds. Secondary outcomes included adverse events (AEs), effect on quality of life, procedural duration, and radiation exposure.

A total of 130 patients (mean age, 61.9 years; 68% men) were enrolled and randomized to PVI (n=64) or PVI plus lines (n=66). Successful PVI was achieved in 98% of patients across both treatment groups, with bidirectional block achieved in 81% of patients treated with PVI plus lines.

Recurrence of atrial tachyarrhythmia occurred in 32% of patients in the PVI group vs 38% in the PVI plus lines group within 12 months of a single procedure (RR, 0.87; 95% CI, 0.57 to 1.27; $P=.50$).

Procedure duration and radiation exposure were significantly higher in patients treated with PVI plus lines as compared with those receiving PVI alone. The rate of major procedural complications and other AEs was low and occurred at a similar rate between the groups. The quality of life was evaluated by 2 questionnaires and increased significantly in both groups; however, the difference between treatment groups was not significant.

Dr Wynn concluded that treatment with linear ablation in addition to PVI did not improve the rate of AF recurrence or the quality of life, while the additional treatment increased procedure duration and radiation exposure.

Vivek Y. Reddy, MD, Mount Sinai Hospital, New York, New York, USA, presented results of the HeartLight study [NCT01456000], demonstrating noninferiority of PVI with a visually guided laser balloon (VGLB) catheter compared with irrigated radiofrequency ablation (RFA), despite a significant difference in operator experience with these 2 technologies favoring the RFA group.

Technical difficulties with achieving PVI in patients with paroxysmal AF led to the development of novel catheter designs to facilitate the procedure [Dukkipati SR. *Circ Arrhythm Electrophysiol*. 2013]. A visually guided laser ablation catheter was designed to allow the operator to visualize target tissue directly for ablation, and single-center trials have demonstrated favorable safety and efficacy of this device.

HeartLight is a prospective randomized multicenter trial to determine the multicenter efficacy and safety of performing PVI with the VGLB catheter. The HeartLight system is an investigational device in the United States that has not yet been approved by the FDA.

The primary efficacy and safety outcomes were assessed by noninferiority analyses and were defined as freedom from symptomatic AF for 1 year while off AAD and the rate of primary AEs, respectively.

A total of 334 patients were evaluated in the trial (aged approximately 60 years; 66% men; n=167 in each treatment arm). The baseline characteristics were well matched between the groups.

Freedom from AF for 1 year was achieved in 61.1% of patients in the VGLB group vs 61.7% in the RFA group in the per-protocol analysis, meeting the criteria for noninferiority ($P=.003$). Similar results were seen when patients who could not stay off AAD were included in the analysis, with 65.3% of patients in the VGLB group vs 62.9% in the RFA group being free from AF for 1 year. The rate of patients who experienced primary AEs was 11.8% in the VGLB group vs 14.5% in the RFA group, meeting the end point of noninferiority ($P=.002$).

PVI was achieved on the first mapping attempt in 89.8% in the VGLB group vs 84.0% in the RFA group ($P=.02$). Pulmonary veins were reconnected after initial isolation in 2.7% and 5.7%, respectively ($P=.006$). A post hoc analysis revealed that operator experience did not play a significant role in the safety or efficacy of the VGLB PVI procedure.

Dr Reddy concluded that PVI could be achieved in virtually all patients using a single VGLB catheter with similar efficacy and safety to RFA.

Uninterrupted Anticoagulation With Catheter Ablation Feasible and Effective

Written by Mary Mosley

The optimal management of anticoagulation therapy during catheter ablation in patients with nonvalvular atrial fibrillation to minimize the risk of periprocedural thromboembolic and bleeding events remains unclear. The traditional approach has been to interrupt the use of an oral vitamin K antagonist (VKA) and to treat patients with a heparin-based regimen. However, the recent open-label, randomized COMPARE study [Di Biase L et al. *Circulation*. 2014] showed that continuing warfarin during catheter ablation reduced periprocedural stroke and minor bleeding compared with heparin bridging.

The benefit of uninterrupted anticoagulation therapy with a non-VKA oral anticoagulant (NOAC) compared with uninterrupted warfarin has now been shown with both rivaroxaban, in the open-label, randomized VENTURE AF [NCT01729871] study, and with apixaban, in a prospective multicenter registry of patients with nonvalvular atrial fibrillation.

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.