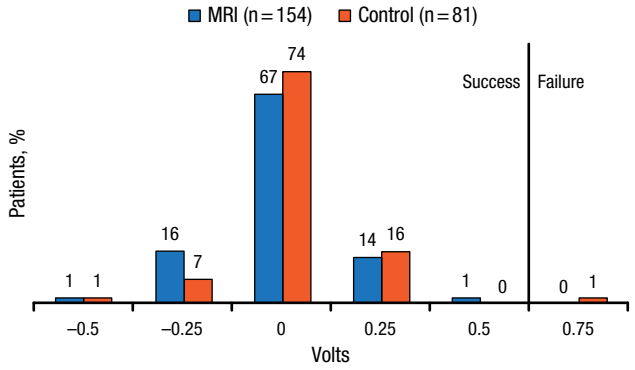
Figure 1. Change in Ventricular Pacing Capture Threshold in the Evera MRI Study



MRI, magnetic resonance imaging.

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< 2.0 W/kg with 20 minutes of active scan duration, and 50 minutes in the MRI bore.

The primary efficacy end points were ventricular pacing capture threshold (> 0.5 V) and ventricular sensing (> 50% decrease). The primary safety end points included complications related to the MRI, loss of capture, and treated ventricular arrhythmias during the scan. Success was defined as achievement of all 3 end points. Patients were excluded if they required device upgrades, generator changeouts, lead extractions, or lead or device revisions or if they had abandoned or capped leads or a non-MRI-compatible device or material implant.

The change in ventricular pacing capture threshold was noninferior between the 2 arms, with 100% and 98.8% success rates in the MRI and control arms, respectively ($P_{\text{Noninferiority}} < .0001$; Figure 1). In addition, there was no difference in ventricular sensing amplitude at 1 month post-MRI compared with patients who underwent a waiting period, with success achieved by 99.3% and 98.8% in the MRI and control arms, respectively ($P_{\text{Noninferiority}} = .0001$). The MRI arm achieved noninferiority for the secondary end points, including atrial pacing capture threshold, atrial sensing amplitude, right ventricular defibrillation impedance, and system-related complication-free rate > 80%.

The complication-free rate was 100% among all 147 patients who underwent MRI; however, 2 patients experienced implant site warmth, and 1 patient each experienced atrial tachycardia, back pain, and burning sensation of the forehead.

In the multicenter prospective nonrandomized single-arm ProMRI study, 154 patients received the Iforia ProMRI ICD system and underwent a thoracic spine or cardiac 1.5T closed-bore MRI. In addition, the maximum slew rate was ≤ 200 T/ms per axis, and the specific absorption rate was up to 2.0 W/kg for the entire body and 3.2 W/kg for the head. Patients were excluded from the study if they had planned cardiac surgery within 3 months, had a life expectancy < 3 months, had an abandoned ICD or pacemaker leads, were pregnant, or had any prostheses or devices that were non-MRI compatible. The end points of the ProMRI study included freedom from the following: serious adverse device events, ventricular capture threshold increase, and decrease in ventricular sensing.

Freedom from ventricular capture threshold > 0.5 V was achieved by 100% of patients (n = 153), with most patients experiencing no change in voltage ($P < .001$). Similarly, the freedom from decrease in ventricular sensing was achieved by 99.3% of patients at 1 month ($P < .001$). In addition, there were no significant changes in P wave amplitude, atrial pacing threshold, right ventricular pacing impedance, shock impedance, and batter capacity after MRI. In the study, 43 adverse events occurred that were deemed not related to the device; therefore, there were no serious adverse device events.

In conclusion, Dr Gold and Dr Awad indicated that the data from the Evera MRI and ProMRI studies demonstrated that the Evera MRI and Iforia ICD systems, respectively, were safe and effective in patients undergoing MRI, with no difference in pacing or sensing detected.

SMAN-PAF and HeartLight Trials Investigate Various PVI Methods

Written by Alla Zarifyan

Gareth Wynn, MBChB, Liverpool Heart and Chest Hospital, Liverpool, United Kingdom, presented results of the SMAN-PAF trial, demonstrating that treatment with linear ablation in addition to pulmonary vein isolation (PVI) did not decrease the rate of atrial fibrillation (AF) recurrence or improve the quality of life when compared with PVI alone.

Extensive ablation that goes beyond PVI may be beneficial in patients with substrate-based AF. Wide area circumferential ablation (WACA) may alter substrates, creating barriers to reentry, interrupting rotor activation, and modifying autonomic innervation. However, the evidence supporting extensive ablation is limited and based on nonrandomized studies.

SMAN-PAF is a randomized controlled trial of PVI with WACA or PVI with WACA plus biatrial linear lesion set (PVI plus lines). All patients followed a universal antiarrhythmic drug (AAD) regimen for at least 6 weeks prior to and exactly 6 weeks after the procedure. The average

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.