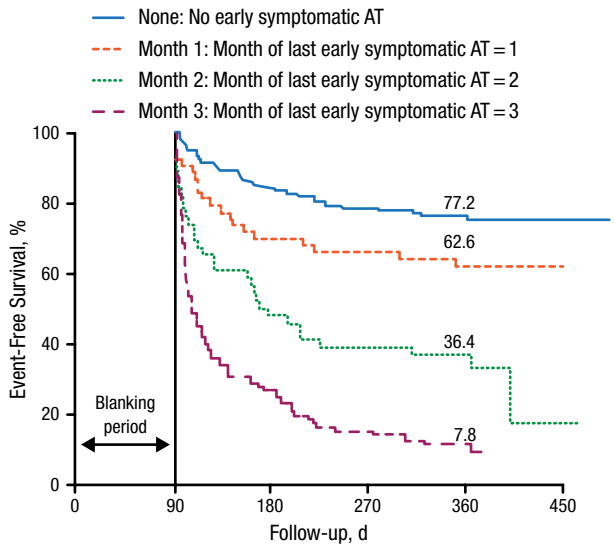
Figure 1. Freedom From Symptomatic AT After a Single Ablation Procedure



AT, atrial tachyarrhythmia.

Reproduced with permission from BA Hoffmann, MD.

$P < .0001$). Early recurrence persistence >2 months was associated with low long-term freedom from AF when compared with ER exclusively during the first month or the first 2 months (Figure 1). All comparisons were statistically significant ($P < .0001$).

A receiver operating characteristic analysis demonstrated that a blanking period of 50 days would be best for determining long-term success rates following ablation for paroxysmal AF (sensitivity, 0.75; specificity, 0.83; accuracy, 0.78), suggesting that the current recommendations regarding the duration of the blanking period should be revised.

The FreezeAF trial, presented by Dr Luik, was a prospective randomized controlled noninferiority study with a combined primary end point defined as absence of AT > 30 seconds (after the standard 3-month blanking period) and absence of persistent complications at 6 and 12 months after the procedure. Secondary end points included periprocedural complications, total procedure duration, and total x-ray exposure. The main inclusion criteria were age of 18 to 75 years, 2 episodes of paroxysmal AF within the previous 3 months (≥ 1 documented), and documented inefficacy of ≥ 1 antiarrhythmic drugs including a β-blocker.

A total of 291 patients (CB group, 144; RF group, 147) completed the study. All baseline characteristics were well matched between the groups. Freedom from AF without persistent complications was achieved in 65% of patients in the CB group vs 64% in the RF group after a single PVI at 6 months ($P_{\text{Noninferiority}} = .005$) and in 74% in the CB group vs 72% in the RF group after multiple PVI procedures at 12 months ($P_{\text{Noninferiority}} < .001$), as demonstrated by the per-protocol analysis. The intention-to-treat analysis produced similar results.

The mean total procedure time was significantly longer for the RF group compared with the CB group, at 189.1 vs 167.4 minutes, respectively ($P = .006$). However, the total x-ray dose was significantly higher for CB patients ($P = .012$), as higher x-ray doses were needed to demonstrate balloon occlusions in this procedure.

The rate of complications was significantly higher in the CB group at 12.2% vs 5.0% in the RF group ($P = .021$). The difference mainly resulted from a significantly higher rate of phrenic nerve palsy in the CB group compared with the RF group (5.8% vs 0%, respectively; $P = .002$).

Dr Luik concluded that PVI with CB is noninferior to open irrigated RF PVI in patients with paroxysmal AF.

New ICDs Safe, Effective After MRI in Evera MRI and ProMRI Studies

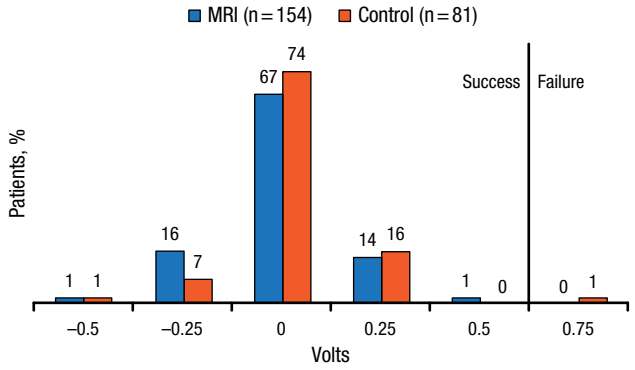
Written by Emma Hitt Nichols, PhD

Two new implantable cardioverter defibrillators (ICDs) have been demonstrated to be safe and effective in magnetic resonance imaging (MRI) scanning conditions. Michael R. Gold, MD, PhD, Medical University of South Carolina, Charleston, South Carolina, USA, presented data from the Evera MRI study [Gold MR et al. *J Am Coll Cardiol.* 2015], and Khaled A. Awad, MD, University of Alabama Birmingham School of Medicine, Birmingham, Alabama, USA, presented data from the ProMRI study [NCT02096692].

Due to the risks associated with devices during imaging, MRI is contraindicated in many patients with ICDs. Although MRI-safe pacemakers are available, there are currently no MRI-safe ICDs approved by the FDA. MRI has been used in some ICD patients in select centers; however, limitations must be imposed, such as restriction of imaging to particular body areas. The purpose of the Evera MRI and ProMRI studies was to evaluate the safety and efficacy of new ICD systems that were developed to be MRI compatible.

In the international open-label prospective Evera MRI study, 263 patients who had successful ICD implantation were randomly assigned 2:1 to undergo MRI scans of the chest, spine, and head or to enter a waiting period. Patients in the MRI arm received clinically relevant scans with a maximized gradient slew rate, a whole body

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



MRI, magnetic resonance imaging.

Reproduced with permission from MR Gold, MD, PhD.

< 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