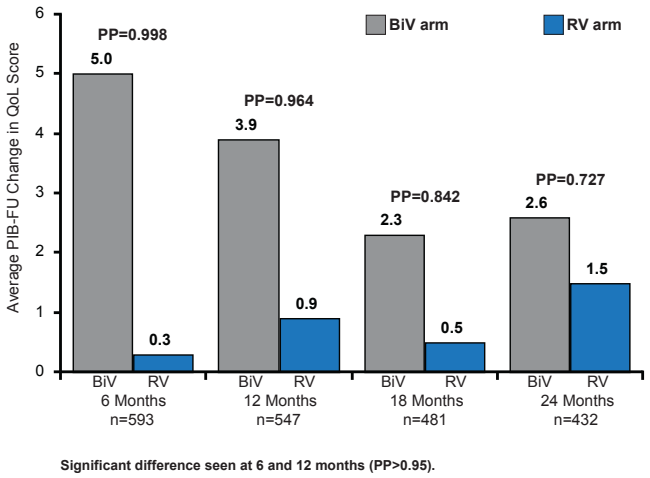
QoL was significantly improved at 6 and 12 months (PP=0998 and PP=0.964, respectively) in the BiV arm compared with the RV arm (Figure 3).

Figure 3. Improvement in QoL for Postimplant Baseline



BiV=biventricular; PIB-FU=postimplant baselne follow-up; PP=posterior probability; QoL=quality of life;RV=right ventricular.

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Current pacing guidelines recommend permanent RV pacing for patients who develop AV block; however, clinical studies such as the Mode Selection Trial in Sinus Node Dysfunction [MOST; Lamas GA et al. *N Engl J Med* 2002] and Dual Chamber and VVI Implantable Defibrillator [DAVID; Wilkoff BL et al. *JAMA* 2002] trials have shown that RV pacing may have long-term deleterious effects such as increased risk of HF hospitalization and LV systolic dysfunction.

Dr. Curtis concluded, "For patients with AV block and systolic dysfunction, biventricular pacing not only reduces the risk of mortality and morbidity, but also leads to better clinical outcomes and improved patient quality of life and heart failure status."

NOTE: The use of CRT devices for AV block and systolic dysfunction patients without ventricular dyssynchrony is not approved in the United States.

Catheter Ablation of Atrial Fibrillation Without Coumadin Discontinuation, Protects Against Thromboembolic Complications

Written by **Maria Vinall**

Evidence From the Role of Coumadin in Preventing Thromboembolism in Atrial Fibrillation (AF) Patients Undergoing Catheter Ablation trial [COMPARE; NCT01006876] confirms that the continuous use of warfarin while performing catheter ablation of AF significantly reduces the occurrence of periprocedural stroke/transient ischemic attack (TIA) and bleeding complications [Di Biase L et al. *Heart Rhythm* 2013]. The results, presented by Luigi Di Biase, MD, PhD, Texas Cardiac Arrhythmia Institute, St. David's Medical Center, Austin, Texas, and Albert Einstein College of Medicine, at Montefiore Hospital, Bronx, New York, USA, suggest that periprocedural anticoagulation management could play an important role in the occurrence of these complications.

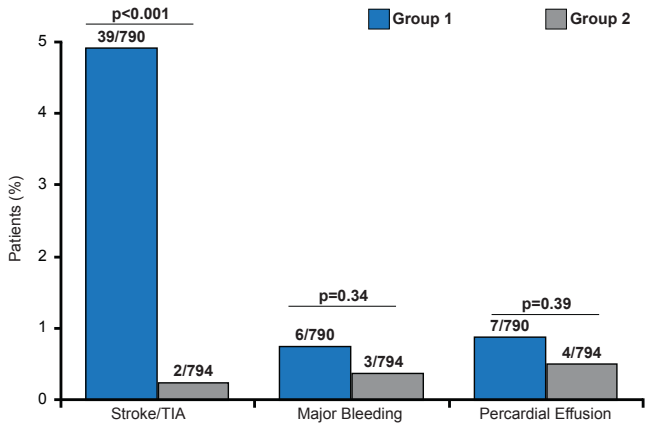
The open-label, randomized, parallel-group, multicenter study was conducted in 1560 patients, aged 18 to 75 years, undergoing radiofrequency catheter ablation for AF. Patients had paroxysmal, persistent, or long-standing persistent (LSP) AF; a $CHADS_2$ score ≥1; and an international normalized ratio (INR) in the range of 2.0 to 3.0 in the last 4 to 6 weeks prior to ablation.

Group 1 patients (off warfarin; n=790) discontinued warfarin 2 to 3 days prior to ablation and bridged with low weight molecular heparin (LWMH). Heparin was given during the procedure to maintain an activated clotting time (ACT) >250 seconds. Group 2 patients (on warfarin; n=794) received warfarin therapy throughout the study as well as heparin during the entire procedure to maintain the ACT >300 seconds. Neurological and bleeding complications were assessed 48 hours after ablation in both groups. The primary endpoint was the incidence of thromboembolic events 48 hours post ablation.

Baseline characteristics were similar in both groups. LSP was present in 49% of Group 1 and 51% of Group 2 patients. $CHADS_2$ scores ≥2 were present in 71% of Group 1 and 74% of Group 2 patients.

The incidence of periprocedural stroke was 3.7% (n=29) in Group 1: one patient with paroxysmal AF, two with persistent AF, and 26 with LSP AF. In Group 2, two (0.25%) patients experienced a stroke—both with LSP AF. The difference was significant (p<0.001). Both patients had a subtherapeutic INR the day of the procedure and no evidence of thrombus preprocedurally. When analyzing TIA and stroke together, event rates were 4.9% (n=39) in Group 1 and 0.25% (n=2) in Group 2 (p<0.001). There was no significant difference in major bleeding and pericardial effusion between the groups (Figure 1). However, significantly more Group 1 patients (22%; p<0.001) experienced minor bleeding complications compared with Group 2 (4.1%).

Figure 1. Periprocedural Events and Complications



TIA=transient ischemic attack.

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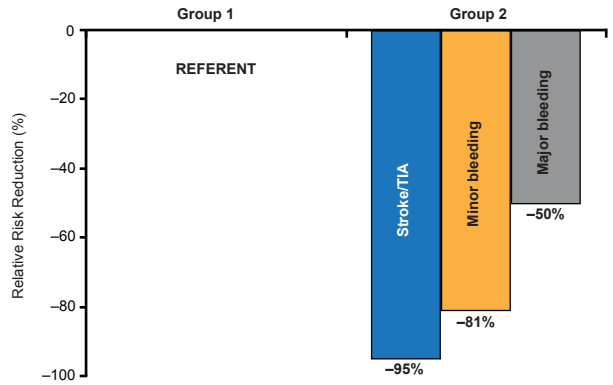
Warfarin use during ablation for AF was associated with relative risk reduction of 95% for stroke/TIA, 81% for minor bleeding, and 50% for major bleeding. Warfarin discontinuation, high $CHADS_2$ score, and AF type (nonparoxysmal) were significant predictors of thromboembolic events (Figure 2).

Figure 2. Relative Risk Reduction of Periprocedural Events



TIA=transient ischemic attack.

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Dr. Di Biase noted that periprocedural thromboembolic and hemorrhagic events are worrisome complications of catheter ablation for AF, particularly in patients with LSP AF, and with high $CHADS_2$ scores [Scherr D et al. *J Cardiovasc Electrophysiol* 2009]. These findings support other data suggesting that the combination of an open irrigation ablation catheter and periprocedural therapeutic anticoagulation with warfarin may reduce the risk of periprocedural stroke without increasing the risk of pericardial effusion or other bleeding complications [Di Biase L et al. *Circulation* 2010].

Dr. Di Biase concluded that the use of the newer anticoagulants during AF ablation procedures should be investigated in these high-risk patients and only compared with strategies that did not discontinue warfarin.

DE-MRI Quantification of Atrial Fibrosis Predicts Ablation Outcome in Patients With Atrial Fibrillation

Written by Emma Hitt, PhD

Nassir F. Marrouche, MD, University of Utah, Salt Lake City, Utah, USA, presented data from the Delayed-Enhancement Magnetic Resonance Imaging (DE-MRI) Determinant of Successful Radiofrequency Catheter Ablation for Atrial Fibrillation trial [DECAAF; NCT01150214].

Previous studies demonstrated that the structural changes to the heart that are associated with atrial fibrillation (AF) can be quantified using DE-MRI [Oakes RS et al. *Circulation* 2009]. The DECAAF trial tested the hypothesis that DE-MRI can be used to determine the amount of left atrial fibrosis and/or remodeling, which predicts the patient's response to AF ablation.

In the international, prospective, multicenter, blinded, follow-up DECAAF trial, 330 patients that were undergoing their first AF ablation procedure were enrolled. Data from 261 patients were analyzed, as 57 MRIs were of poor quality and could not be analyzed and 12 patients were lost to follow-up. Patients were excluded from the study if they had a prior left atrial catheter or surgical ablation, were contraindicated for the DE-MRI contrast agent, were morbidly obese, and/or were too large for the MRI structure.

The follow-up period consisted of electrocardiogram, or Holter or event monitoring at 3, 6, and 12 months, as well as any additional follow-ups after 12 months, following the ablation procedure. The MARREK DE-MRI software sequence was installed at each participating center, and the staff was trained on five patients prior to enrolling for the DECAAF study. The primary endpoint for the DECAAF trial was recurrence of atrial arrhythmias following a 90-day blanking period.

Quantification of atrial fibrosis by DE-MRI was categorized based on the Utah Classification System of Left Atrial Structural Remodeling, where stage 1 consists of <10% fibrosis/remodeling, stage 2 ≥10% to <20%, stage 3 ≥20% to <30%, and stage 4 ≥30% fibrosis/remodeling. The DECAAF trial results indicate that performing DE-MRI on patients prior to atrial ablation is feasible and produces reproducible data around the world. Interestingly, all