#### CLINICAL TRIAL HIGHLIGHTS

ICD therapy decisions. This bridge to therapeutic decisionmaking was shown to be safe and effective in several ways: (1) by safely terminating life-threatening arrhythmic events; (2) by avoiding unnecessary shock therapies for non-life-threatening ventricular tachyarrhythmias; and (3) by being associated with a very low rate of inappropriate therapies. As such, it opens the door to more targeted treatment for high-risk patients who suffer from congenital or acquired heart disease.

# Clinical Outcomes Better With Biventricular Versus Right Ventricular Pacing in Patients With Atrioventricular Block

### Written by Maria Vinall

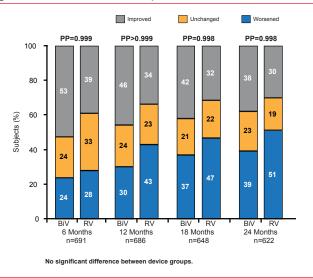
Anne B. Curtis, MD, University at Buffalo, Buffalo, New York, USA, presented new data from the Biventricular Versus Right Ventricular Pacing in Heart Failure Patients With Atrioventricular Block trial [BLOCK HF; NCT00267098], showing that biventricular (BiV) pacing is associated with better clinical outcomes, improved patient quality of life (QoL), and heart failure (HF) status. Previous reports from BLOCK HF showed that BiV pacing was superior to right ventricular (RV) pacing and led to a significant reduction in mortality, HF-related urgent care, and the risk of developing a significant increase in left ventricular (LV) end systolic volume index [Curtis AB et al. *N Engl J Med* 2013].

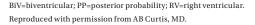
The current analysis assessed changes in three prespecified endpoints: Packer Clinical Composite response (determined using clinical outcomes, HF status, and patient symptoms); QoL (Minnesota Living With HF Questionnaire); and NYHA Class. The changes were measured at 6, 12, 18, and 24 months and compared with the same values measured at postimplant baseline (PIB)/ randomization between the BiV and RV arms. Patients were rated as "improved," "worsened," or "unchanged," and significant differences were determined by posterior probability (PP). PP values >0.95 were considered significant.

There were 349 patients in the BiV group and 342 in the RV group. Inclusion criteria included pacing indication for atrioventricular (AV) block; NYHA Class I, II, III; LV ejection fraction ≤50%; absence of a Class I indication for cardiac resynchronization therapy (CRT); and no previous pacemaker or implantable cardioverter defibrillator. Most patients were in their early 70s, had NYHA Class II or III, and second- or third-degree AV block. There were no significant differences in the results between patients implanted with CRT-P or CRT-D devices, thus these data were combined.

Compared with RV pacing, AV-block patients treated with BiV pacing had superior Packer Clinical Composite scores through 24 months, superior HF status as measured by NYHA class at 12 months, and superior QoL through 12 months. At every time point, significantly more patients were rated as improved on the Packer Clinical Composite score receiving BiV compared with those receiving RV pacing (Figure 1).

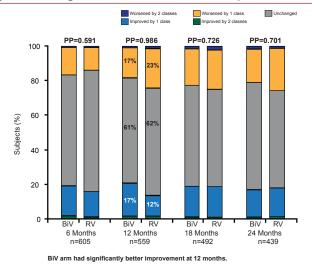






At 12 months patients in the BiV arm had significantly better improvement in NYHA class from PIB compared with RV (PP=0.986) but not at 18 or 24 months (Figure 2).





BiV=bientricular; PP=posterior probability; RV=right ventricular. Reproduced with permission from AB Curtis, MD.



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).

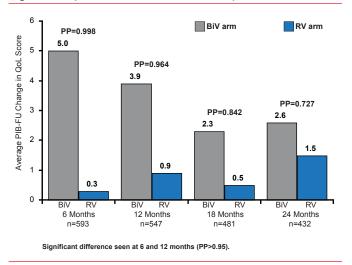


Figure 3. Improvement in QoL for Postimplant Baseline

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<sub>2</sub> score  $\geq$ 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<sub>2</sub> scores  $\geq$ 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%).

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