

# Biventricular Pacemaker/Defibrillators Versus Biventricular Pacemakers in Patients with Non-ischemic Cardiomyopathy



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## KEYWORDS

- Nonischemic cardiomyopathy • Biventricular pacemaker
- Biventricular implantable cardiac defibrillators • Arrhythmic death • Mortality
- Ventricular remodeling • VT/VF

## KEY POINTS

- Defibrillators have been shown to reduce arrhythmic death in patients with underlying cardiomyopathy.
- Biventricular pacing has been shown to result in ventricular remodeling, a reduction in rehospitalization rates, and reduced morbidity in select heart failure patients.
- Any reduction in arrhythmic death rates observed with biventricular pacing in nonischemic cardiomyopathy patients does not justify its stand-alone use.
- Initial device therapy in patients with nonischemic cardiomyopathy, bundle branch block, and heart failure symptoms should be with a biventricular pacemaker/implantable cardiac defibrillator.

## INTRODUCTION

The journey toward complete understanding of heart failure over the past century represents a long, gradual climb. There have been few advancements that represented a true leap in understanding ... vantage points of significant elevation along the way that allow one considerable retrospective. Heart failure therapy likewise has ranged from primary treatment with tourniquets and fasciotomy to modern day ventricular assist devices used as destination therapy. A more complete understanding of the progression of this disease and

the causes of mortality in the heart failure population has led to the development of implantable cardiac defibrillators (ICDs) and biventricular pacemakers (CRT-P). With modern technology, cardiac defibrillators are now available that incorporate biventricular pacing function, biventricular pacemaker/defibrillators (CRT-D). Biventricular pacing is the most effective device therapy currently available to treat heart failure, whereas ICDs are the most effective device therapy to prevent sudden death. Accordingly, it is logical that a CRT-D device will address the 2 leading causes of

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death among patients with heart failure with a reduced ejection fraction.

### **CONTROVERSY OVER UBIQUITOUS USE OF BIVENTRICULAR PACEMAKER/DEFIBRILLATOR DEVICES**

Although these devices have independently been shown to impact the natural progression of heart failure and survival,<sup>1,2</sup> controversy remains over the ubiquitous use of CRT-D devices owing primarily to the incremental cost of these devices, variations in mode of death, and reliability of pacemaker/defibrillator systems. Adding complexity to the analysis is the recent acknowledgment that inappropriate ICD shocks may contribute to mortality, and there is an incomplete response to CRT, with only approximately 70% of patients deriving clinical benefit. Furthermore, placement of biventricular pacing leads is a complex task that must be customized to the individual, and factors that affect the degree of response to CRT are incompletely understood.

At the core of this controversy is the understanding that morphologic changes in the ventricle and ventricular myocardium are responsible for the observed inexorable progression of diseases that lead the ventricle to fail. It is widely accepted that cardiac arrest secondary to ventricular arrhythmias is an important mode of death for patients with heart failure and that risk of death increases monotonically as the left ventricular ejection fraction falls below 40%. Multiple studies have documented a reversal of the morphologic changes found in diverse populations of heart failure patients with the use of biventricular pacing. Logic would dictate that this reversal would translate into a decrease in the risk for arrhythmic death. Although trends in reduction of arrhythmic death have been shown in large randomized trials of lone biventricular pacing,<sup>3</sup> a statistically significant reduction in arrhythmic death rates in all cohorts has not been shown. Similarly, many studies of CRT have failed to show a reduction in appropriate shocks or ICD therapy. Such a reduction has been demonstrated more recently in subgroups with great improvement in left ventricular systolic function.<sup>4-7</sup> Factors identified that affect overall mortality after CRT therapy in recent clinical trials include age, gender, QRS duration, right versus left bundle branch block, renal function, heart failure functional classification at implant, left ventricular end-systolic volume index, anterior left ventricular lead position, and ischemic etiology of cardiomyopathy (ICM).<sup>1-3,8-13</sup>

As the population of patients with non-ischemic cardiomyopathy (NICM) represents a diverse cohort in terms of etiology and, overall, represents

a smaller fraction in randomized, controlled clinical trials, less is known about the effect of CRT-P versus CRT-D therapy in this group. It is widely accepted that the risk for death over any defined period is lower in the NICM population; it is conjectured that the risk of death is increased because of recurrent ischemia/myocardial infarction (MI) in ischemic cardiomyopathy patients. Nevertheless, ICD therapy is proven to statistically improve survival in the NICM population and is commonly employed, even to the extent that it is included in ICD implantation guidelines.<sup>2</sup> Moreover, appropriate ICD therapy is similar among ischemic and non-ischemic cohorts. This was proven in the SCD HeFT (Sudden Cardiac Death in Heart Failure Trial), in which there was little difference in tachyarrhythmia occurrence or mortality reduction between ischemic and non-ischemic patients in the ICD arm.<sup>14</sup>

Likewise, CRT-P has been proven to improve heart failure functional classification, heart failure rehospitalization rates, and many measures of cardiac performance. CRT-P therapy, however, has not proven to date to have an antiarrhythmic effect that justifies its stand-alone use in the NICM population. Furthermore, medical guidelines and physician opinion have driven the use of CRT-D in patients with NICM and significant intraventricular conduction delay.

### **RANDOMIZED TRIALS OF BIVENTRICULAR PACEMAKERS AND BIVENTRICULAR PACEMAKER/DEFIBRILLATORS**

There are few data comparing CRT-P and D in randomized trials. COMPANION (Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure) is the only trial to randomize patients to these devices. As expected, there was no difference in heart failure hospitalizations, but mortality was lower with CRT-D devices. This was the only arm to show significant mortality difference compared with medical therapy. The trial was not powered to compare CRT-P and -D arms directly.<sup>3</sup> The results of several observational studies suggest improved survival with CRT-D devices. The European CRT Survey was a prospective, multinational, observational study. This study showed that CRT-P therapy, along with atrial fibrillation and advanced heart failure, was independently associated with higher mortality. There were trends for improved survival in women and in patients with longer QRS duration.<sup>15</sup> Auricchio and colleagues<sup>16</sup> performed a retrospective analysis of consecutive patients at several European centers with longer follow-up. CRT-D was associated with a 20% reduction in mortality,

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