

# Cardiac resynchronization therapy using pacemakers vs defibrillators in patients with nonischemic cardiomyopathy: The United States experience from 2007 to 2014



Samir Saba, MD, FACC, FHRS,<sup>\*</sup> Terence McLaughlin, MD,<sup>†</sup> Meiqi He, MS,<sup>‡</sup>  
Andrew Althouse, PhD,<sup>§</sup> Suresh Mulukutla, MD, FACC,<sup>\*</sup>  
Inmaculada Hernandez, PharmD, PhD<sup>‡</sup>

*From the <sup>\*</sup>Heart and Vascular Institute, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania,*

*<sup>†</sup>Department of Internal Medicine, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania,*

*<sup>‡</sup>Department of Pharmacy and Therapeutics, University of Pittsburgh School of Pharmacy, Pittsburgh,*

*Pennsylvania, and <sup>§</sup>Center for Clinical Trials and Data Coordination, University of Pittsburgh, Pittsburgh, Pennsylvania.*

**BACKGROUND** The impact of implantable defibrillator therapy on outcomes of patients with nonischemic cardiomyopathy (NICM) who receive a cardiac resynchronization therapy (CRT) device is controversial.

**OBJECTIVE** The purpose of this study was to examine the outcomes of NICM patients who receive a CRT-pacemaker (CRT-P) vs CRT-defibrillator (CRT-D).

**METHODS** Using 2007–2014 claims data for a 5% random sample of Medicare beneficiaries, we followed patients with NICM who received a CRT device (1236 CRT-P, 4359 CRT-D), excluding those with a prior history of ventricular arrhythmias with a primary outcome of all-cause mortality and secondary outcomes including time to first cardiac hospitalization and total medical costs. Propensity score matching and Cox proportional hazard models were used to balance patient characteristics between treatment groups.

**RESULTS** At 5 years, 2007 patients (36%) died and 3809 (68%) were hospitalized for any reason, whereas 2504 (45%) were hospitalized for cardiac causes. In the propensity score matched sample,

the time to all-cause mortality (hazard ratio [HR] 0.90; 95% confidence interval [CI] 0.74–1.09), any hospitalization (HR 1.13; 95% CI 0.98–1.30), and cardiac hospitalization (HR 0.98; 95% CI 0.83–1.17) did not differ between matched CRT-P and CRT-D recipients. However, CRT-P recipients had significantly lower medical costs (difference ~\$20,000) and cardiac-related medical costs at 12 and 24 months.

**CONCLUSION** Although more expensive, defibrillator therapy is not associated with prolonged survival or decreased risk of hospitalization in CRT recipients with NICM. These results suggest that in patients with NICM and no previous history of ventricular arrhythmias, CRT-P devices should be considered. These findings have important clinical and economic implications.

**KEYWORDS** Cardiac resynchronization therapy; Cost; Defibrillator; Mortality; Pacemaker

(Heart Rhythm 2019;16:1065–1071) © 2019 Heart Rhythm Society. All rights reserved.

## Introduction

Heart failure has grown to epidemic proportions in industrialized countries. In the United States, 5 million patients live with heart failure, and 400,000 new patients are diagnosed with this condition every year, leading to about 1 million hospital admissions and >\$50 billion in cost of care annually.<sup>1–5</sup> Nonischemic cardiomyopathy (NICM) is a

major cause of heart failure, associated with up to 20% 3-year mortality. Half of these deaths are due to pump failure; the other half is due to life-threatening ventricular arrhythmias. Based on current published guidelines,<sup>6</sup> implantable cardioverter-defibrillators are indicated for heart failure patients with severe NICM, but these guidelines are all based

Dr Saba reports research support from Boston Scientific and Medtronic. All other authors have reported that they have nothing to disclose. **Address reprint requests and correspondence:** Dr Samir Saba, University of Pittsburgh Medical Center, 200 Lothrop St, South Tower E352.6, Pittsburgh, PA 15213. E-mail address: [sabas@upmc.edu](mailto:sabas@upmc.edu).

### Attention HRS Members and Journal Subscribers

Visit the HRS Learning Center at [www.hrsonline.org/HRJ-CME](http://www.hrsonline.org/HRJ-CME) to earn Continuing Medical Education (CME) credit and Maintenance of Certification (MOC) points through an online activity related to this article.

on results of trials that preceded the use of cardiac resynchronization therapy (CRT). Therefore, whether defibrillator therapy still confers incremental survival advantages to NICM patients in the presence of CRT is questionable. The uncertainty about the incremental benefit of defibrillators over CRT on mortality in NICM patients has been brought to light by the results of the recent DANISH (DANish Randomized, Controlled, Multicenter Study to Assess the Efficacy of Implantable Cardioverter Defibrillator in Patients With Non-ischemic Systolic Heart Failure on Mortality) trial.<sup>7</sup>

CRT is an established therapy for patients with NICM, heart failure symptoms, and ventricular conduction abnormalities.<sup>8,9</sup> It has been shown to improve the endpoints of all-cause mortality and heart failure hospitalizations compared to optimal medical therapy. CRT can be delivered through a CRT-pacemaker (CRT-P) or a CRT-defibrillator (CRT-D). Both CRT-P and CRT-D provide resynchronization to the failing heart through low-energy pacing impulses, but CRT-D also can deliver high-energy shock therapy to terminate life-threatening ventricular arrhythmias. However, there are other major differences between these 2 types of implantable devices. CRT-P devices are smaller (ie, require a smaller surgical incision at implantation and protrude less under the skin), have longer battery life, have been involved in fewer Food and Drug Administration advisories and recalls over the past 2 decades, and cost a fraction of the price of CRT-D devices.<sup>10–13</sup> Despite these important differences, current published CRT guidelines do not distinguish between CRT-P and CRT-D indications.<sup>6</sup>

Because of these important considerations, we investigated the impact of the type of CRT device used on clinical outcomes and costs of care of NICM patients from real-world experience using Medicare datasets.

## Methods

### Study design and patient population

Patient data were obtained from a public database with deidentified patient information. Using 2006–2014 claims data from a 5% random sample of Medicare beneficiaries, we selected patients with a diagnosis of NICM between January 1, 2007, and December 31, 2014 ( $n = 128,751$ ) and identified those who had at least 1 claim with CPT codes for *de novo* left ventricular lead placement for CRT device implantation ( $n = 7727$ ) (Figure 1). Index date was defined as the date of the first claim with a CPT code for CRT device implantation. After excluding those who did not have CPT codes necessary to identify CRT-P or CRT-D and those who had a diagnosis of ventricular tachycardia, ventricular fibrillation, ventricular flutter, or cardiac arrest in the year before the index date, the final sample included 5595 beneficiaries. We followed them from index date until death or the end of the study period (December 31, 2014). Further details on the sample selection and the codes used to define diagnosis and procedures are delineated in Figure 1.

## Outcomes

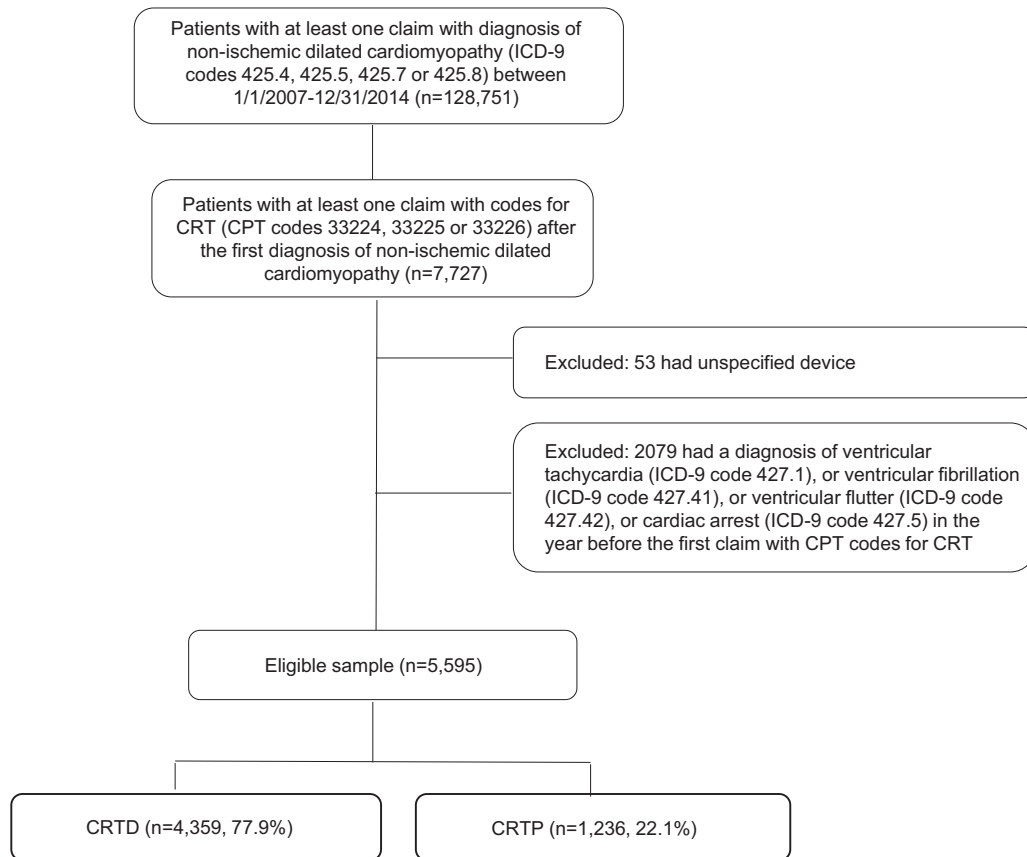
The primary outcome was all-cause mortality and was determined using the date of death provided in the Medicare Master Beneficiary File. Secondary outcomes included time to first hospitalization, time to first cardiac hospitalization, total medical costs, total cardiac-related medical costs, and inpatient cardiac-related costs. Hospitalizations were ascertained using the Medicare Provider Analysis and Review (MEDPAR) file and revenue center codes. Cardiac-related inpatient admissions were defined as those whose primary *International Classification of Diseases, Ninth Revision* (ICD-9) diagnosis code was cardiac related (first 3 digits of the primary ICD-9 diagnosis codes between 390 and 459). Cost outcomes were defined at 7 days and at 12 and 24 months after the index date. Because CRT devices may be implanted during an outpatient visit or a hospitalization that may last >1 day, in defining the inpatient admission outcomes, we applied a 7-day washout period after the index date. This enabled us to ensure that inpatient admissions represented a different episode of care than the implantation of CRT devices. Total medical costs were defined as the sum of the total payment amount for all inpatient, outpatient, emergency room, and provider claims in the 7 days and in the 12 or 24 months after index date. Costs incurred on index date were included in the calculations. Total cardiac-related medical costs were defined using claims whose primary ICD-9 diagnosis code was cardiac related.

## Covariates

We adjusted for demographic variables and clinical characteristics. Demographic variables included age, race, Medicaid eligibility, eligibility for low-income subsidy, and disability. Clinical characteristics included a diagnosis of ischemic cardiomyopathy in the year before index date and a comprehensive list of Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data Warehouse priority conditions, as listed in Table 1.

## Statistical analysis

We compared patient characteristics at baseline using analysis of variance for continuous variables and  $\chi^2$  tests for categorical variables. We constructed Kaplan-Meier time-to-event curves to calculate unadjusted cumulative incidence rates of mortality and hospitalization outcomes at 1, 2, and 5 years of follow-up. We also reported mean and median medical costs, cardiac-related medical costs, and inpatient cardiac costs for both treatment groups. To compare time-to-event outcomes across treatment groups while controlling for differences in patient characteristics, we constructed Cox proportional hazard models, which controlled for all the covariates listed in Table 1. To compare cost outcomes between treatment groups, we constructed generalized linear models with gamma distribution and log link, which also controlled for all the covariates listed in Table 1. We selected this model formulation



**Figure 1** Flow diagram detailing patient selection for this study. From January 2007 to December 2014, a total of 128,751 patients had at least 1 Medicare claim of nonischemic cardiomyopathy. After applying exclusion criteria, a total of 5595 patients received a cardiac resynchronization therapy (CRT) device and constituted the study population. CPT = Current Procedural Terminology; CRT-D = cardiac resynchronization therapy–defibrillator; CRT-P = cardiac resynchronization therapy–pacemaker; ICD = International Classification of Diseases.

because of the skewed distribution of costs and because outcome variables did not present a zero-mass problem, since all patients incurred costs.

Given the observational nature of our study, patients in each treatment group were not comparable. To reduce the influence of confounding, we performed propensity score matching and used the matched sample to construct the Cox proportional hazard models and generalized linear models, as described earlier. To compute the propensity score, we performed a logistic regression to predict the probability of receiving a CRT-P device, controlling for all the covariates listed in [Table 1](#). Using the propensity score, we used the nearest neighbor 1:1 matching approach with replacement to match treatment groups. The maximum propensity score distance allowed for matching was 0.001. The matched sample consisted of 1106 CRT-P and 1106 CRT-D recipients.

## Results

### Patient characteristics

[Table 1](#) lists the baseline characteristics of CRT-P and CRT-D recipients. Compared to CRT-D recipients, patients implanted with a CRT-P device were older, more likely to be women, and white. They also were more likely to have

comorbid conditions, including atrial fibrillation, prior history of stroke or transient ischemic attack, chronic kidney disease, chronic obstructive pulmonary disease, glaucoma, cataract, osteoporosis, rheumatoid arthritis, osteoarthritis, and prior history of hip or knee fracture. In the propensity score matched cohort, all baseline characteristics were balanced between treatment groups ([Table 1](#)).

### Time to all-cause mortality, any hospitalization, and cardiac hospitalization

Over 5 years of follow-up from the time of device implantation, 2007 patients (36%) died and 3809 patients (68%) were hospitalized for any reason, whereas 2504 (45%) were hospitalized for cardiac causes ([Supplementary Table 1](#)). After adjusting for unbalanced covariates using Cox proportional hazard models, there were minimal differences between CRT-P and CRT-D recipients in all-cause mortality (hazard ratio [HR] 1.12; 95% confidence interval [CI] 0.97–1.30), hospitalization (HR 1.09; 95% CI 1.00–1.18), or cardiac hospitalizations (HR 1.07; 95% CI 0.97–1.18) ([Figure 2](#)). Repeating the analyses in the propensity score matched cohort also showed no differences between the 2 groups in any outcomes, including all-cause mortality (HR 0.90; 95% CI 0.74–1.09), risk of hospitalization for any reason (HR

**Table 1** Baseline characteristics of CRT-P and CRT-D recipients

| Variable                               | Overall sample   |                  |         | Propensity score matched cohort |                  |         |
|--|------------------|------------------|---------|---------------------------------|------------------|---------|
|  | CRT-D (n = 4359) | CRT-P (n = 1236) | P value | CRT-D (n = 1106)                | CRT-P (n = 1106) | P value |
| Age (y)                                | 72.6 ± 9.2       | 77.9 ± 8.4       | <.001   | 76.9 ± 7.2                      | 77.1 ± 8.3       | .598    |
| Male                                   | 2828 (64.88)     | 743 (60.11)      | .002    | 689 (62.30)                     | 686 (62.03)      | .895    |
| Race                                   |                  |                  | <.001   |                                 |                  | .994    |
| White                                  | 3621 (83.30)     | 1103 (89.24)     |         | 976 (88.25)                     | 977 (88.34)      |         |
| Black                                  | 542 (12.47)      | 87 (7.04)        |         | 86 (7.78)                       | 86 (7.78)        |         |
| Other                                  | 184 (4.23)       | 46 (3.72)        |         | 44 (3.98)                       | 43 (3.89)        |         |
| Medicaid eligible                      | 838 (19.22)      | 192 (15.53)      | .003    | 175 (15.82)                     | 174 (15.73)      | .954    |
| Low-income subsidy                     | 2059 (47.24)     | 576 (46.60)      | .694    | 498 (45.03)                     | 519 (46.93)      | .370    |
| Disabled                               | 602 (13.81)      | 61 (4.94)        | <.001   | 56 (5.06)                       | 59 (5.33)        | .774    |
| Ischemic cardiomyopathy*               | 1291 (29.6)      | 281 (22.7)       | <.001   | 265 (23.96)                     | 277 (25.05)      | .553    |
| CMS priority conditions†               |                  |                  |         |                                 |                  |         |
| Acute myocardial infarction            | 763 (17.50)      | 196 (15.86)      | .175    | 168 (15.19)                     | 180 (16.27)      | .484    |
| Atrial fibrillation                    | 1965 (45.08)     | 845 (68.37)      | <.001   | 730 (66.00)                     | 721 (65.19)      | .687    |
| Cataract                               | 2632 (60.38)     | 934 (75.57)      | <.001   | 821 (74.23)                     | 819 (74.05)      | .923    |
| Chronic kidney disease                 | 2026 (46.48)     | 660 (53.40)      | <.001   | 565 (51.08)                     | 584 (52.80)      | .419    |
| Chronic obstructive pulmonary disease  | 1913 (43.89)     | 633 (51.21)      | <.001   | 556 (50.27)                     | 558 (50.45)      | .932    |
| Depression                             | 1328 (30.47)     | 400 (32.36)      | .203    | 372 (33.63)                     | 358 (32.37)      | .527    |
| Diabetes                               | 2377 (54.53)     | 665 (53.80)      | .650    | 596 (53.89)                     | 603 (54.52)      | .765    |
| Glaucoma                               | 783 (17.96)      | 331 (26.78)      | <.001   | 288 (26.04)                     | 286 (25.86)      | .923    |
| Hip or knee fracture                   | 112 (2.57)       | 49 (3.96)        | .010    | 40 (3.62)                       | 44 (3.98)        | .656    |
| History of stroke or TIA               | 824 (18.90)      | 323 (26.13)      | <.001   | 280 (25.32)                     | 275 (24.86)      | .806    |
| Osteoporosis                           | 680 (15.60)      | 276 (22.33)      | <.001   | 234 (21.16)                     | 230 (20.80)      | .835    |
| Rheumatoid arthritis or osteoarthritis | 2075 (47.60)     | 766 (61.97)      | <.001   | 450 (40.69)                     | 447 (40.42)      | .897    |

Values are given as mean ± SD or n (%) unless otherwise indicated.

CRT-D = cardiac resynchronization therapy–defibrillator; CRT-P = cardiac resynchronization therapy–pacemaker; TIA = transient ischemic attack.

\*Defined as having 1 medical claim with ICD-9 141.8 in the year before index date.

†Defined according to the Centers for Medicare and Medicaid Services (CMS) Chronic Condition Data Warehouse (<https://www.ccwdata.org/web/guest/condition-categories>).

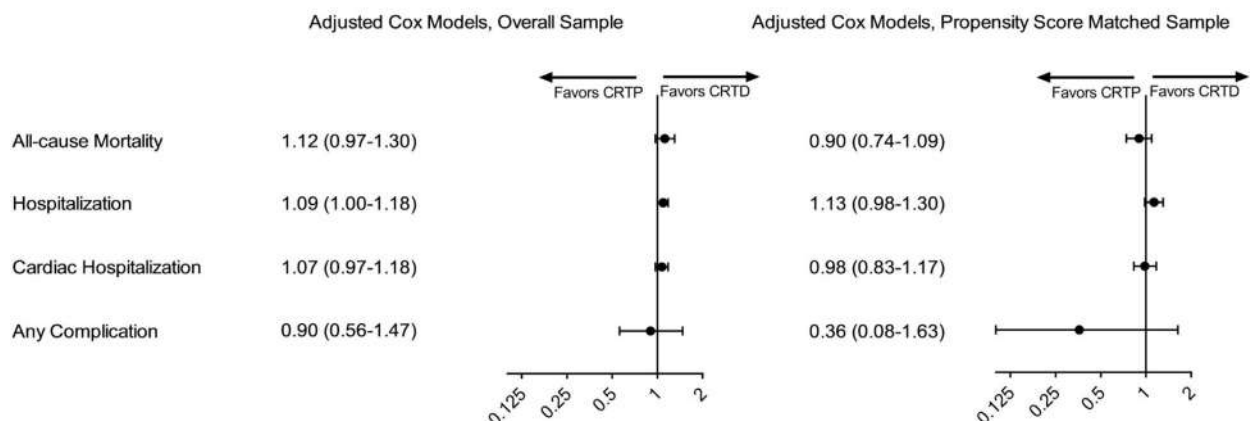
1.13; 95% CI 0.98–1.30), and risk of hospitalization for a cardiac reason (HR 0.98; 95% CI 0.83–1.17) (Figures 2 and 3).

### Cost outcomes

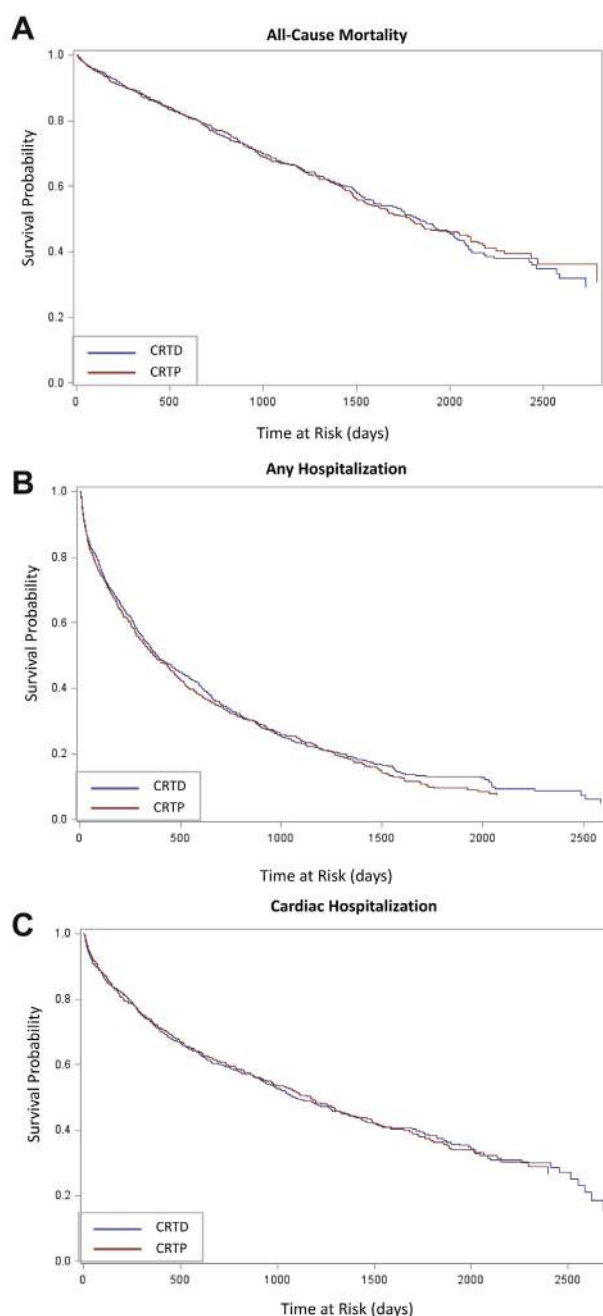
Mean (median) medical costs at 12 months of follow-up were estimated at \$109,560 (\$64,891) for CRT-D recipients and \$94,075 (\$52,020) for CRT-P recipients, with mean (median)

cardiac-related medical costs of \$73,884 (\$35,326) for CRT-D and \$55,092 (\$24,344) for CRT-P (Supplementary Table 2). As shown in Figure 4, medical costs, cardiac-related costs, and inpatient cardiac cost were all significantly lower in the CRT-P group compared to the CRT-D group at 7 days, 12 months, and 24 months. However, noncardiac medical costs were comparable between the 2 groups. The

Adjusted Hazard Ratio for CRTP vs. CRTD (95% CI)



**Figure 2** Adjusted hazard ratios were obtained from Cox proportional hazard models performed on the original sample and on the propensity score matched sample. Cox proportional hazard models controlled for all covariates listed in Table 1. CI = confidence interval; CRT-D = cardiac resynchronization therapy–defibrillator; CRT-P = cardiac resynchronization therapy–pacemaker.



**Figure 3** Adjusted survival curves, propensity score matched cohort. Survival curves for all-cause mortality (*top*), any hospitalization (*middle*), and cardiac hospitalization (*bottom*) were obtained from Cox proportional hazard models constructed on the propensity score matched sample and that controlled for all covariates listed in [Table 1](#). Part A (*top*) shows survival curves for all-cause mortality; Part B (*middle*) shows survival curves free from any hospitalization; and Part C (*bottom*) shows survival curves free from any cardiac hospitalization. CRT-D = cardiac resynchronization therapy–defibrillator; CRT-P = cardiac resynchronization therapy–pacemaker.

difference in medical costs and cardiac-related medical costs were consistently about \$20,000–\$25,000 lower for CRT-P compared to CRT-D patients. Because the difference in costs incurred in the first 7 days after index date was on the order of \$18,000, our results suggest that the difference in costs observed at 12 and 24 months is driven in large part by the

cost of the CRT device itself. Similar results were obtained when generalized linear models were constructed on the original sample (before propensity score matching), but estimates for differences in costs were slightly lower ([Supplementary Table 3](#)).

### Age-adjusted analyses

We divided the study cohort into a younger (<75 years) and an older ( $\geq 75$  years) group around the median for age to examine the impact of age on clinical outcomes ([Supplementary Table 4](#)), complications rates ([Figure 2](#) and [Supplementary Table 5](#)), and cost of care ([Supplementary Table 6](#)). In all these analyses, there were no differences in any clinical or cost analyses between CRT-P and CRT-D recipients in either age subgroup.

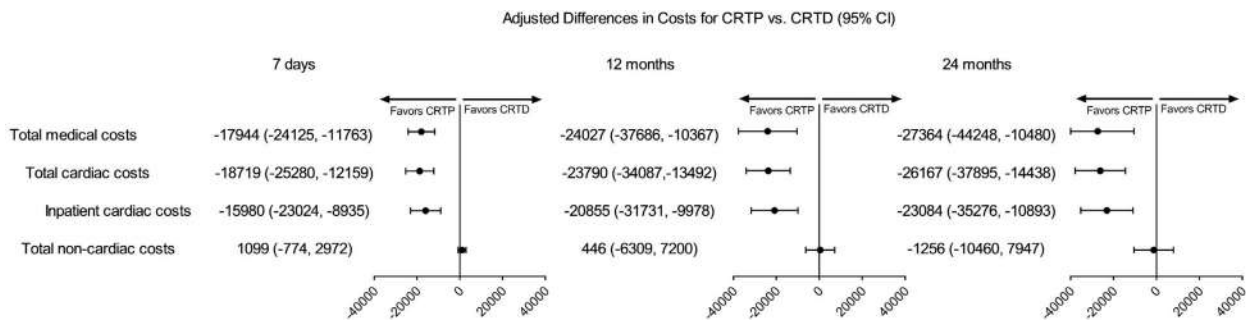
### Discussion

In this study, we showed that in patients with NICM and no prior history of ventricular arrhythmias or cardiac arrest, CRT-P device implantation is associated with a comparable risk of all-cause mortality and hospitalization as CRT-D implantation but at a significant lower cost of care, driven primarily by the lower cost of CRT-P devices. These real-world data from a nationally representative sample of Medicare beneficiaries from across the United States suggest that in this clinical setting, CRT-P devices should be strongly considered. Our findings have significant clinical and economic implications to our health care system.

Large randomized controlled trials have established the value of defibrillator therapy in reducing all-cause mortality in NICM patients with severe left ventricular dysfunction.<sup>6,14</sup> However, these trials preceded the use of CRT devices. In the presence of 2 distinct therapies that both improve survival (CRT and defibrillators), it is unclear whether their effects are additive, synergistic, or overlapping. That is, whether the benefits of 1 therapy enhance or dilute the effects of the other remains unclear. The only trial that randomized patients to CRT-P vs CRT-D therapy is the COMPANION (Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure),<sup>8</sup> which did not demonstrate a significant difference in all-cause mortality between these 2 therapies, except in 1 *post hoc* analysis.<sup>15</sup> The recently published DANISH trial further suggests that in the presence of CRT therapy, which was present in 58% of patients in that trial, defibrillator therapy does not further reduce mortality in NICM patients.<sup>7</sup> Our present findings are consistent with this evidence. Still, in the United States, CRT-D devices are overwhelmingly favored over CRT-P devices (4:1) in the majority of eligible heart failure patients,<sup>16</sup> absent any assistance from published guidelines<sup>6</sup> regarding the choice of type of CRT device.

Compared to CRT-D devices, CRT-P devices are smaller, have longer battery longevity, are less likely to be implicated in advisories or recalls,<sup>10,12,13,17</sup> and cost significantly less (by  $\sim$ \$20,000). In addition, CRT-P devices do not deliver painful shocks that are often inappropriate, that is, delivered





**Figure 4** Adjusted difference in costs, propensity score matched cohort. Adjusted differences in costs were obtained from generalized linear models with gamma distribution and log link constructed on the propensity score matched sample and that controlled for all covariates listed in Table 1. Adjusted differences in costs are expressed in US dollars. CI = confidence interval; CRT-D = cardiac resynchronization therapy–defibrillator; CRT-P = cardiac resynchronization therapy–pacemaker.

for the wrong reason such as for benign supraventricular arrhythmias or oversensing of noise. These shocks<sup>18</sup> drain the device battery, but more importantly they can lead to decreased patient quality of life<sup>19,20</sup> and increased cost of downstream care driven by device changeout for premature battery depletion, office or emergency department visits, or even hospitalizations secondary to shocks. This may all be well justified if there were any evidence that CRT-D recipients have better longevity than CRT-P recipients. However, this remains unproven, and the weight of the evidence available to date, including our present study, strongly indicates that patient outcomes are comparable for CRT-P and CRT-D recipients. Only a large prospective randomized controlled trial of CRT-P vs CRT-D therapy in eligible NICM patients can answer this question definitively.

### Study limitations

The present study must be interpreted in the context of its limitations. First, because of the observational nature of our study, treatment groups may be confounded due to patient factors and/or physician preference. In response, we used propensity score matching to minimize the impact of confounding. One may argue that the use of this technique and the subsequent loss of sample decreased the statistical power. This should not be of concern in this study because we demonstrated that our results from the propensity score matched sample were consistent with findings from the overall sample. Second, Medicare data are based on claims and diagnostic codes. We cannot rule out the possibility that some of the data may have been affected by wrong coding. Also, because Medicare data do not provide detailed clinical information, we could not ascertain whether the patients included in the present analysis all had severe cardiomyopathy with a low ejection fraction ( $\leq 35\%$ ), nor could we provide granular clinical information about them, including their QRS width and morphology on the surface electrocardiogram or their class of heart failure. However, given that CRT eligibility according to the guidelines throughout the study period (2007 through 2014) mandated that the ejection fraction be  $\leq 35\%$  and that the QRS width be  $> 120$  ms, we highly suspect that the overwhelming majority of patients

included in this analysis met this eligibility criteria. For this reason, our present analysis cannot provide information on the number of CRT-D recipients who received shocks during follow-up or on the nature of rhythms detected by the device. Lastly, our findings apply to a Medicare population; so our results may not be extrapolated to younger patients.

### Conclusion

Our findings demonstrate that despite significantly higher medical costs, NICM patients without a prior history of ventricular arrhythmias or cardiac arrest who received a CRT-D device did not experience prolonged life or fewer hospitalizations than patients who received CRT-P devices. Therefore, our data support greater use of CRT-P devices in these patients because they are associated with reduced costs and comparable outcomes. A pivotal randomized controlled trial of CRT-P vs CRT-D device therapy in eligible NICM patients is needed to conclusively answer this important question.

### Appendix Supplementary data

Supplementary data associated with this article can be found in the online version at <https://doi.org/10.1016/j.hrthm.2019.04.028>.

### References

- McKee PA, Castelli WP, McNamara PM, Kannel WB. The natural history of congestive heart failure: the Framingham study. *N Engl J Med* 1971; 285:1441–1446.
- Bart BA, Shaw LK, Cants CBMC, et al. Clinical determinants of mortality in patients with angiographically diagnosed ischemic or nonischemic cardiomyopathy. *J Am Coll Cardiol* 1997;30:1002–1008.
- Ho KK, Pinsky JL, Kannel WB, Levy D. The epidemiology of heart failure: the Framingham Study. *J Am Coll Cardiol* 1993;22(4 Suppl A):6A–13A.
- Schocken DD, Arrieta MI, Leaverton PE, Ross EA. Prevalence and mortality rate of congestive heart failure in the United States. *J Am Coll Cardiol* 1992; 20:301–306.
- Zannad F, Briancon S, Juilliere Y, et al. Incidence, clinical and etiologic features, and outcomes of advanced chronic heart failure: the EPICAL Study. *Epidémiologie de l'Insuffisance Cardiaque Avancée en Lorraine. J Am Coll Cardiol* 1999; 33:734–742.
- Al-Khatib SM, Ackerman MJ, Gillis AM, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death: executive summary. *Circulation* 2018;25:e210–e271.

7. Køber L, Thune JJ, Nielsen JC, et al. Defibrillator implantation in patients with nonischemic systolic heart failure. *N Engl J Med* 2016;375:1221–1230.
8. Bristow MR, Saxon LA, Boehmer J, et al. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. *N Engl J Med* 2004;350:2140–2150.
9. Cleland JGF, Daubert J-C, Erdmann E, et al. The effect of cardiac resynchronization on morbidity and mortality in heart failure. *N Engl J Med* 2005;352:1539–1549.
10. Liu J, Brumberg G, Rattan R, Jain S, Saba S. Class I recall of defibrillator leads: a comparison of the Sprint Fidelis and Riata families. *Heart Rhythm* 2012;9:1251–1255.
11. Brumberg GE, Kaseer B, Shah H, Saba S, Jain S. Biventricular defibrillator patients have higher complication rates after revision of recalled leads. *Pacing Clin Electrophysiol* 2012;35:665–671.
12. Liu J, Qin D, Rattan R, et al. Longitudinal follow-up of externalized Riata leads. *Am J Cardiol* 2013;112:1616–1618.
13. Liu J, Rattan R, Adelstein E, et al. Fluoroscopic screening of asymptomatic patients implanted with the recalled Riata lead family. *Circ Arrhythm Electrophysiol* 2012;5:809–814. <https://doi.org/10.1161/CIRCEP.112.973081>.
14. Bardy GH, Lee KL, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005;352:225–237.
15. Shun-Shin MJ, Zheng SL, Cole GD, Howard JP, Whinnett ZI, Francis DP. Implantable cardioverter defibrillators for primary prevention of death in left ventricular dysfunction with and without ischaemic heart disease: A meta-analysis of 8567 patients in the 11 trials. *Eur Heart J* 2017;38:1738–1746.
16. Epstein AE, Kay GN, Plumb VJ, et al. Implantable cardioverter-defibrillator prescription in the elderly. *Heart Rhythm* 2009;6:1136–1143.
17. Liu J, Brumberg G, Rattan R, et al. Longitudinal follow-up of implantable cardioverter defibrillator leads. *Am J Cardiol* 2014;113:103–106.
18. Daubert JP, Zareba W, Cannom DS, et al. Inappropriate implantable cardioverter-defibrillator shocks in MADIT II: frequency, mechanisms, predictors, and survival impact. *J Am Coll Cardiol* 2008;51:1357–1365.
19. Francis J, Johnson B, Niehaus M. Quality of life in patients with implantable cardioverter defibrillators. *Indian Pacing Electrophysiol J* 2006;6:173–181.
20. de Ornelas Maia ACC, Soares-Filho G, Pereira V, Nardi AE, Silva AC. Psychiatric disorders and quality of life in patients with implantable cardioverter defibrillators. *Prim Care Companion CNS Disord* 2013;15. PCC.12r01456.