

# Dual-Chamber Implantable Cardioverter-Defibrillator Selection Is Associated With Increased Complication Rates and Mortality Among Patients Enrolled in the NCDR Implantable Cardioverter-Defibrillator Registry

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- Objectives** The aim of this study was to compare single- versus dual-chamber implantable cardioverter-defibrillator (ICD) implantation and complication rates in a large, real-world population.
- Background** The majority of patients enrolled in ICD efficacy trials received single-chamber devices. Although dual-chamber ICDs offer theoretical advantages over single-chamber defibrillators, the clinical superiority of dual-chamber models has not been conclusively proven, and they may increase complications.
- Methods** The National Cardiovascular Data Registry ICD Registry was used to examine the association between baseline characteristics and device selection in 104,049 patients receiving single- and dual-chamber ICDs between January 1, 2006, and December 31, 2007. A longitudinal cohort design was then used to determine in-hospital complication rates.
- Results** Dual-chamber devices were implanted in 64,489 patients (62%). Adverse events were more frequent with dual-chamber than with single-chamber device implantation (3.17% vs. 2.11%,  $p < 0.001$ ), as was the rate of in-hospital mortality (0.40% vs. 0.23%,  $p < 0.001$ ). After adjusting for demographics, medical comorbidities, diagnostic test data, and ICD indication, the odds of any complication (odds ratio: 1.40; 95% confidence interval: 1.28 to 1.52;  $p < 0.001$ ) and in-hospital mortality (odds ratio: 1.45; 95% confidence interval: 1.20 to 1.74;  $p < 0.001$ ) were increased with dual-chamber versus single-chamber ICD implantation.
- Conclusions** In this large, multicenter cohort of patients, dual-chamber ICD use was common. Dual-chamber device implantation was associated with increases in periprocedural complications and in-hospital mortality compared with single-chamber defibrillator selection. (J Am Coll Cardiol 2011;58:1007-13) © 2011 by the American College of Cardiology Foundation

Although the majority of patients enrolled in implantable cardioverter-defibrillator (ICD) efficacy trials received single-chamber devices (1–3), subsequent reports have revealed high dual-chamber defibrillator implantation rates in real-world populations (4). The addition of an atrial lead provides theo-

retical advantages, although the clinical superiority of dual-chamber models has not been conclusively proven (5–9). Atrial lead placement has the potential to increase procedural complications, and a higher rate of adverse events was described in Canadian patients receiving dual- versus single-chamber defibrillators (10). To inform future device selection strategies, we examined the prevalence and procedural complication rates of single- versus dual-chamber ICD implantation in a cohort of patients enrolled in the National Cardiovascular Data Registry (NCDR) ICD Registry.

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## Methods

We studied the cross-sectional association between baseline characteristics and device selection in patients who received single- and dual-chamber devices in the NCDR ICD Registry.

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### Abbreviations and Acronyms

**ICD** = implantable cardioverter-defibrillator

**NCDR** = National Cardiovascular Data Registry

**SVT** = supraventricular tachycardia

In-hospital complication rates were then compared between device cohorts. Patient, device, and procedural information was obtained through a standardized form submitted to the NCDR by the implanting institution. Our analysis included all patients who underwent first-time ICD implantation between January 1, 2006, and December 31, 2007.

Patients receiving biventricular devices were excluded. A procedural complication was defined as any adverse event occurring between the time of ICD implantation and hospital discharge.

Indications for cardiac pacing were based on class I and IIa recommendations from the 2008 American College of Cardiology, American Heart Association, and Heart Rhythm Society Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities (11). Patients with the following indications were considered to be appropriate candidates for dual-chamber devices: second- or third-degree heart block, bradycardic cardiac arrest, abnormal sinus node function, and previous pacemaker implantation.

The NCDR Analysis Center at Yale University maintained the primary data and performed all statistical analyses. Differences in baseline characteristics were compared between the single- and dual-chamber ICD groups using F tests in analysis-of-variance models for continuous variables. Proportions were compared using chi-square or Fisher exact tests for categorical variables. Procedural complication rates were compared between cohorts using chi-square or Fisher exact tests. Multivariate hierarchical logistic regression models adjusting for potential confounders were used to determine whether dual-chamber ICD therapy was associated with increased risk for procedural complications compared with single-chamber ICD implantation. Random-effect terms for implanting center were included to address potential effects of clustering of patients among hospitals.

## Results

The NCDR ICD Registry recorded 104,049 first-time implantations of single- or dual-chamber ICDs during the study period (Fig. 1). Dual-chamber devices were implanted in 64,489 patients (62%). Baseline characteristics are described in Table 1. The proportion of patients who received dual-chamber devices with an indication for cardiac pacing is reported in Table 2. Abnormal sinus node function was relatively common, while comparatively few patients had a documented history of second- or third-degree atrioventricular block or previous pacemaker. Only 40.4% of dual-chamber ICD recipients fulfilled an indication for dual-chamber pacing.

Complications associated with ICD implantation were more frequent with dual-chamber than with single-chamber

models (Table 3). After adjusting for patient demographic characteristics, medical comorbidities, and diagnostic test results listed in Table 1, dual-chamber ICD selection was associated with 40% greater odds of a periprocedural complication (Table 4).

In-hospital mortality was significantly higher in dual-chamber ICD recipients (259 deaths [0.40%] with dual-chamber devices vs. 91 deaths [0.23%] with single-chamber devices). After adjusting for the same potential confounders, dual-chamber ICD selection remained associated with 45% greater odds of mortality compared with single-chamber device selection (Table 4).

## Discussion

In a large, multicenter population undergoing first-time ICD implantation, dual-chamber defibrillators were implanted nearly twice as often as single-chamber devices. Only 40% of dual-chamber ICD recipients demonstrated an indication for pacemaker therapy. Patients who received dual-chamber devices experienced greater odds of procedure-related complications and in-hospital mortality compared with single-chamber device recipients.

Appropriate ICD selection strategies remain controversial. Recent guidelines do not specifically address single-versus dual-chamber device selection, presumably because of continued disagreement between published studies (11). The use of dual-chamber ICDs in patients with a need for dual-chamber pacing is widely accepted as appropriate. In the NCDR population, fewer than one-half of patients receiving dual-chamber ICDs demonstrated such a pacing indication. Dual-chamber ICD selection for patients with histories of supraventricular tachycardia (SVT) is more contentious, as clinical trials in this area have yielded divergent results. Detection enhancements using dual-chamber technology have been shown to reduce inappropriate therapy due to SVT (5) and composite adverse clinical end points (6), although other investigations have failed to find an improvement in rhythm classification (7) or a difference in shocks with the use of dual-chamber algorithms (8,9). Notably, the prevalence of atrial fibrillation and flutter was significantly higher in the dual-chamber ICD cohort, suggesting that a history of SVT may have motivated atrial lead placement in a portion of these patients.

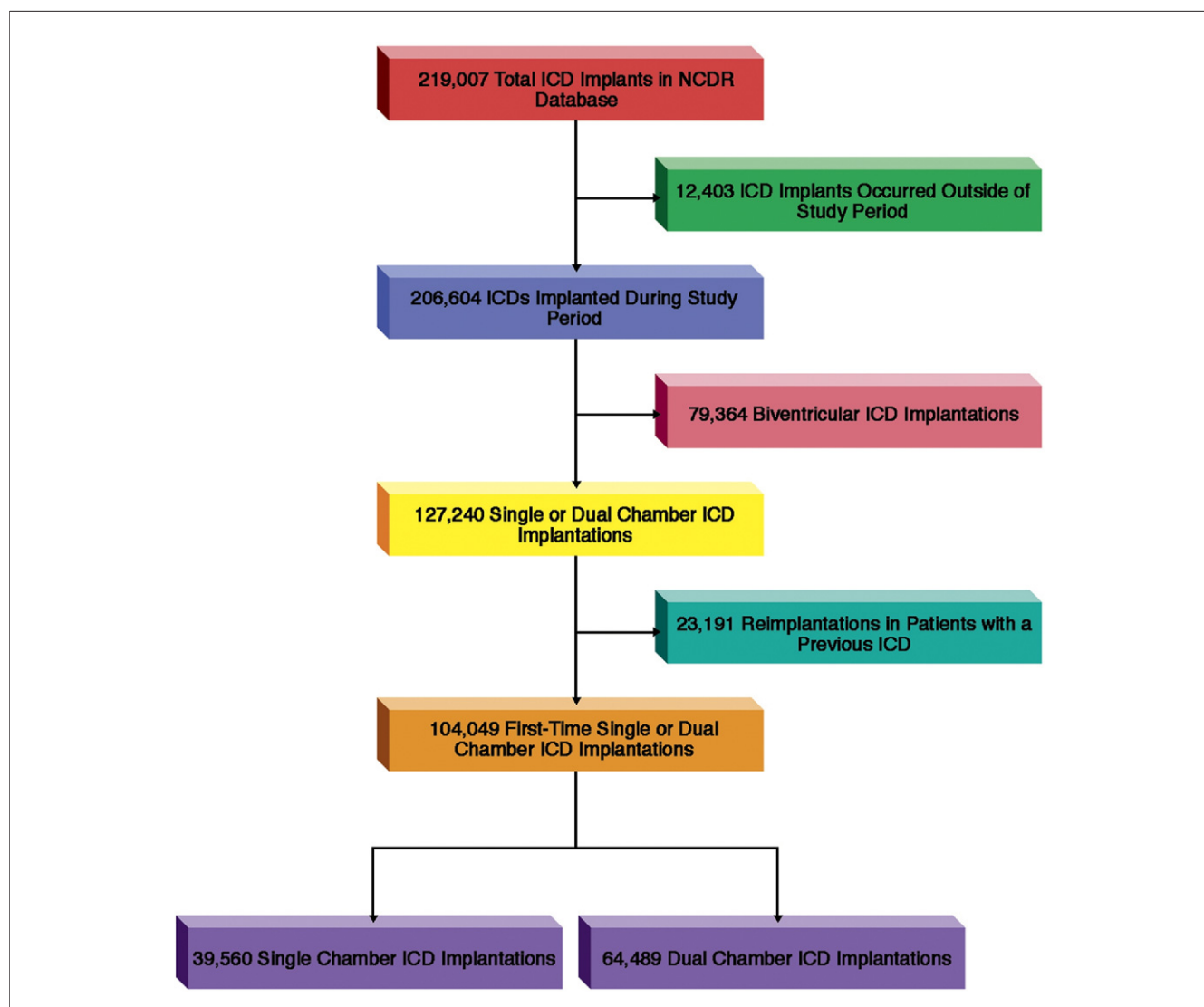
Detrimental effects of dual-chamber pacing modes in patients without an indication for pacemaker therapy have added to this debate. Among patients with heart failure receiving dual-chamber ICDs without a pacemaker indication, DDDR pacing was associated with an increased rate of death and heart failure hospitalization compared to a VVI algorithm (12). Advances in ICD programming, including dual-chamber algorithms to preferentially allow native atrioventricular conduction, can reduce the burden of ventricular pacing (13) and do not result in excess mortality or heart failure exacerbations compared with VVI strategies

(14). Nevertheless, no randomized trial has demonstrated improved clinical outcomes with dual-chamber ICD selection compared with an optimally programmed single-chamber defibrillator in patients without a pacing indication. Our study did not consider device programming but instead examined the upfront complications and mortality associated with device implantation. Without algorithms that can translate the additional information and therapies afforded by an atrial lead into demonstrable benefit, the frequent use of dual-chamber devices must be re-examined.

Concern for the development of a pacing indication after initial ICD implantation has occurred may also influence operators to choose dual-chamber devices. Goldberger *et al.* (15), citing cost-based decision analysis, argued that all ICD candidates should receive dual-chamber devices irrespective

of the need for a pacemaker or a history of SVT. Such a strategy would obviate a device upgrade should a patient subsequently develop an indication for dual-chamber therapy. Importantly, this prior analysis assumed equal complication rates for single- and dual-chamber device implantation. Future discussions regarding appropriate defibrillator selection must recognize the heightened incidence of adverse events associated with dual-chamber ICDs, as procedural complications come at a significant monetary cost, prolong hospital length of stay, and may expose patients to undue risk.

The higher complication and in-hospital mortality rates among patients receiving dual-chamber devices in our cohort persisted after controlling for potentially confounding variables. We hypothesized that acute com-



**Figure 1** Selection of Study Participants From the NCDR ICD Registry

All patients enrolled in the National Cardiovascular Data Registry (NCDR) Implantable Cardioverter-Defibrillator (ICD) Registry who underwent first-time ICD implantation between January 1, 2006, and December 31, 2007, were included in the analysis. Patients receiving biventricular devices and those with previous ICD implantation were excluded.

**Table 1** Baseline Characteristics of ICD Recipients

Characteristic	ICD Type		p Value
	Single Chamber (n = 39,560)	Dual Chamber (n = 64,489)	
<b>Admission characteristics</b>			
Age (yrs)	64.0 ± 13.9	67.1 ± 12.9	<0.0001
Female	10,273 (26.0%)	16,255 (25.2%)	0.006
Race			<0.0001
White	30,976 (78.3%)	52,991 (82.2%)	
Black	6,371 (16.1%)	8,055 (12.5%)	
Other	2,213 (5.6%)	3,443 (5.3%)	
Insurer			<0.0001
Medicare	23,140 (58.5%)	42,070 (65.2%)	
Medicaid	2,591 (6.5%)	2,853 (4.4%)	
Other government	475 (1.2%)	719 (1.1%)	
Commercial	8,637 (21.8%)	12,336 (19.1%)	
Health maintenance organization	3,116 (7.9%)	4,506 (7.0%)	
Other	1,601 (4.0%)	2,005 (3.1%)	
Hospitalized for ICD implantation	25,296 (63.9%)	35,951 (55.7%)	<0.0001
<b>History and risk factors</b>			
Syncope	6,970 (17.6%)	15,875 (24.6%)	<0.0001
Family history of sudden death	1,923 (4.9%)	3,207 (5.0%)	0.42
Congestive heart failure	28,171 (71.2%)	43,228 (67.0%)	<0.0001
NYHA functional class			<0.0001
I	6,841 (17.3%)	12,034 (18.7%)	
II	20,134 (50.9%)	30,009 (46.5%)	
III	11,494 (29.1%)	20,470 (31.7%)	
IV	1,091 (2.8%)	1,976 (3.1%)	
Cardiac arrest			<0.0001
No	35,207 (89.0%)	56,699 (87.9%)	
Bradycardic	202 (0.5%)	798 (1.2%)	
Tachycardic	4,151 (10.5%)	6,992 (10.8%)	
Atrial fibrillation/atrial flutter	10,734 (27.1%)	18,419 (28.6%)	<0.0001
History of VT			<0.0001
None	26,335 (66.6%)	36,751 (57.0%)	
Nonsustained VT	8,800 (22.2%)	17,437 (27.0%)	
Monomorphic sustained VT	3,289 (8.3%)	8,061 (12.5%)	
Polymorphic sustained VT	1,136 (2.9%)	2,240 (3.5%)	
Abnormal sinus node function	6,399 (16.2%)	17,743 (27.5%)	<0.0001
History of cardiac transplantation	95 (0.2%)	145 (0.2%)	0.62
Nonischemic dilated cardiomyopathy	12,197 (30.8%)	16,672 (25.9%)	<0.0001
Ischemic heart disease	25,803 (65.2%)	44,358 (68.8%)	<0.0001
Previous MI			<0.0001
No	17,399 (44.0%)	27,238 (42.2%)	
MI within 40 days of ICD implantation	2,601 (6.6%)	4,906 (7.6%)	
MI >40 days before ICD implantation	18,291 (46.2%)	29,800 (46.2%)	
MI within 40 days and >40 days	1,269 (3.2%)	2,545 (3.9%)	
Previous CABG surgery	12,369 (31.3%)	22,795 (35.3%)	<0.0001
Previous percutaneous coronary intervention	12,913 (32.6%)	22,597 (35.0%)	<0.0001
Previous valvular surgery	2,152 (5.4%)	4,075 (6.3%)	<0.0001
Previous pacemaker implantation	1,441 (3.6%)	5,290 (8.2%)	<0.0001
Cerebrovascular disease	5,382 (13.6%)	9,458 (14.7%)	<0.0001
Chronic lung disease	8,245 (20.8%)	13,943 (21.6%)	0.003
Diabetes	14,041 (35.5%)	22,751 (35.3%)	0.48
Hypertension	28,416 (71.8%)	48,353 (75.0%)	<0.0001
Renal failure on dialysis	1,766 (4.5%)	2,616 (4.1%)	0.002

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**Table 1** Continued

Characteristic	ICD Type		p Value
	Single Chamber (n = 39,560)	Dual Chamber (n = 64,489)	
<b>Diagnostics</b>			
Ejection fraction (%)	27.9 ± 10.8	29.9 ± 12.0	<0.0001
PR interval (ms)	172.8 ± 36.1	181.6 ± 43.2	<0.0001
QRS duration (ms)	108.8 ± 26.6	114.8 ± 30.2	<0.0001
Atrioventricular conduction			<0.0001
Normal	33,783 (85.4%)	46,065 (71.4%)	
First-degree heart block only	4,296 (10.9%)	12,243 (19.0%)	
Any second- or third-degree heart block	549 (1.4%)	2,811 (4.4%)	
Paced	932 (2.4%)	3,370 (5.2%)	
Intraventricular conduction			<0.0001
Normal	26,957 (68.1%)	37,958 (58.9%)	
LAFB or LPFB	1,412 (3.6%)	2,385 (3.7%)	
RBBB	2,285 (5.8%)	4,924 (7.6%)	
LBBB	3,932 (9.9%)	8,893 (13.8%)	
RBBB + LAFB or RBBB + LPFB	327 (0.8%)	991 (1.5%)	
Nonspecific	3,801 (9.6%)	6,291 (9.8%)	
Paced	846 (2.1%)	3,047 (4.7%)	
Creatinine (mg/dl)	1.4 ± 1.2	1.4 ± 1.1	0.67
BUN (mg/dl)	22.7 ± 13.1	23.0 ± 13.1	0.0001
Sodium (mmol/l)	138.6 ± 3.5	138.5 ± 3.5	0.017
BNP (pg/ml)	921.4 ± 1,089.2	929.2 ± 1,095.2	0.63
Systolic blood pressure (mm Hg)	129.3 ± 21.9	131.3 ± 22.6	<0.0001
<b>ICD indication</b>			
Primary prevention	32,413 (81.9%)	49,513 (76.8%)	<0.0001

Values are mean ± SD or n (%).

BNP = brain natriuretic peptide; BUN = blood urea nitrogen; CABG = coronary artery bypass graft; ICD = implantable cardioverter-defibrillator; LAFB = left anterior fascicular block; LBBB = left bundle branch block; LPFB = left posterior fascicular block; MI = myocardial infarction; NYHA = New York Heart Association; RBBB = right bundle branch block; VT = ventricular tachycardia.

plications would be higher in dual-chamber device recipients given that atrial lead implantation requires an additional electrode fixation and, depending on technique, a potential second venipuncture. A recent study in Canadian ICD recipients also demonstrated that periprocedural adverse events directly correlated with the number of implanted leads (10). The results of our study confirm and extend these findings in a large patient population receiving care across a wide spectrum of healthcare facilities in the United States. Because patients were followed only until hospital discharge, it is extremely unlikely that pacing mode or other differences in device programming could account for our findings. Similarly, the disparate use of antiarrhythmic drugs between cohorts would be unlikely to influence complications or mortality over this short time period. It is possible that the dual-chamber device group included a larger number of patients in whom left ventricular lead placement was attempted and aborted, thereby enriching the complication rate of this cohort. This is suggested by the significantly higher rate of coronary venous dissection (and pneumothorax) noted in the dual-chamber group. However, repeat analyses performed after censoring patients who experienced coronary venous dissection did not yield statistically different results, making it unlikely

that this misclassification accounts for the overall differences in complications and mortality between cohorts. Although patients receiving biventricular ICDs are likely to have more comorbidities than patients only eligible for standard defibrillator therapy, multivariate analysis controlling for baseline risk factors demonstrated increased odds of complication and death with dual-chamber device selection. Although absolute increases in complications and in-hospital mortality with the addition of an atrial lead are small, this should be understood amid the paucity of data supporting dual-chamber device superiority in the absence of a pacing indication. We believe that the excess mortality observed in dual-chamber ICD

**Table 2** Dual-Chamber ICD Recipients With an Indication for Pacemaker Therapy

Pacemaker Indication	Implantations Fulfilling Criteria
Abnormal sinus node function	17,743 (27.5%)
Bradycardic cardiac arrest	7,790 (12.1%)
Previous pacemaker implantation	4,806 (7.5%)
Second- or third-degree atrioventricular block	2,811 (4.4%)
Any 1 of the above indications	26,052 (40.4%)

Values are n (percent of total dual-chamber implants).  
ICD = implantable cardioverter-defibrillator.

**Table 3** Single- Versus Dual-Chamber ICD Implantation Complication Rates

Adverse Event	ICD Type		p Value
	Single Chamber	Dual Chamber	
Cardiac arrest	91 (0.23%)	203 (0.31%)	0.01
Drug reaction	33 (0.08%)	69 (0.11%)	0.24
Cardiac perforation	22 (0.06%)	42 (0.07%)	0.55
Cardiac valve injury	0 (0.00%)	1 (<0.01%)	0.43
Conduction block	7 (0.02%)	22 (0.03%)	0.12
Coronary venous dissection	4 (0.01%)	76 (0.12%)	<0.001
Hematoma	282 (0.71%)	593 (0.92%)	<0.001
Lead dislodgement	198 (0.50%)	565 (0.88%)	<0.001
Hemothorax	22 (0.06%)	52 (0.08%)	0.14
Pneumothorax	144 (0.36%)	339 (0.53%)	<0.001
Peripheral nerve injury	2 (0.01%)	3 (<0.01%)	0.93
Peripheral embolus	7 (0.02%)	21 (0.03%)	0.16
Phlebitis (superficial)	10 (0.03%)	40 (0.06%)	0.009
Phlebitis (deep)	6 (0.02%)	17 (0.03%)	0.24
Transient ischemic attack	3 (0.01%)	13 (0.02%)	0.11
Stroke	21 (0.05%)	41 (0.06%)	0.50
Myocardial infarction	6 (0.02%)	23 (0.04%)	0.05
Pericardial tamponade	19 (0.05%)	59 (0.09%)	0.01
Arteriovenous fistula	0 (0.00%)	5 (0.01%)	0.08
Infection related to device	12 (0.03%)	18 (0.03%)	0.82
Any adverse event	833 (2.11%)	2,047 (3.17%)	<0.001
All-cause mortality	91 (0.23%)	259 (0.40%)	<0.001
Cardiovascular cause	56 (0.14%)	181 (0.28%)	<0.001
Noncardiovascular cause	35 (0.09%)	78 (0.12%)	0.12
Death in laboratory	6 (0.02%)	17 (0.03%)	0.24

Values are n (%).  
ICD = implantable cardioverter-defibrillator.

recipients was due in part to the greater number of procedure-related complications in this cohort, although the observational nature of this study precludes a direct assessment of causality. The nearly 60% of dual-chamber device recipients in the NCDR ICD Registry who lacked a guideline-based indication for pacemaker therapy paid an infrequent but significant cost without promise of clinical benefit.

**Study limitations.** The NCDR ICD Registry was developed to record ICD implantation data in a Medicare primary prevention cohort. Data for patients meeting secondary prevention criteria or with private insurance were supplied electively. Although operators may have censored certain secondary prevention or private insurance payer implantations for unknowable reasons, it is reassuring that 88% of defibrillator implantations recorded in the NCDR database were performed at hospitals that registered data for all devices regardless of

insurance type or prevention indication (4). Although device selection was associated with increased complications and mortality in multivariate models, residual confounding due to unmeasured or imprecisely reported variables could potentially account for our findings. Finally, complication data were collected only through the time of hospital discharge. It is possible that long-term complication rates for these devices may diverge from in-hospital rates.

### Conclusions

Our study examined defibrillator implantation patterns in a large, national cohort of patients receiving care at both academic and community hospitals. Dual-chamber ICD implantation is common, and nearly 60% of these devices are used in patients without a pacing indication. Despite their unclear clinical benefit, dual-chamber ICDs are associated with increased odds of complications and in-hospital mortality after implantation compared with single-chamber devices. Given this heightened risk of periprocedural complications, the routine use of dual-chamber ICDs in patients without a pacing indication should be questioned.

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**Table 4** Odds of Adverse Events Associated With Dual-Chamber ICD Implantation

	Unadjusted OR	95% CI	p Value	Multivariate OR	95% CI	p Value
Any complication	1.49	1.37-1.61	<0.001	1.40	1.28-1.52	<0.001
In-hospital mortality	1.69	1.42-2.01	<0.001	1.45	1.20-1.74	<0.001

CI = confidence interval; ICD = implantable cardioverter-defibrillator; OR = odds ratio.

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**Key Words:** complication ■ defibrillator ■ dual-chamber ICD.