Association of Single- vs Dual-Chamber ICDs With Mortality, Readmissions, and Complications Among Patients Receiving an ICD for Primary Prevention

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Importance Randomized trials of implantable cardioverter-defibrillators (ICDs) for primary prevention predominantly used single-chamber devices. In clinical practice, patients often receive dual-chamber ICDs, even without clear indications for pacing. The outcomes of dual- vs single-chamber devices are uncertain.

Objective To compare outcomes of single- and dual-chamber ICDs for primary prevention of sudden cardiac death.

Design, Setting, and Participants Retrospective cohort study of admissions in the National Cardiovascular Data Registry's (NCDR) ICD registry from 2006-2009 that could be linked to Centers for Medicare & Medicaid Services fee-for-service Medicare claims data. Patients were included if they received an ICD for primary prevention and did not have a documented indication for pacing.

Main Outcomes and Measures Adjusted risks of 1-year mortality, all-cause readmission, heart failure readmission, and device-related complications within 90 days were estimated with propensity-score matching based on patient, clinician, and hospital factors.

Results Among 32 034 patients, 12 246 (38%) received a single-chamber device and 19 788 (62%) received a dual-chamber device. In a propensity-matched cohort, rates of complications were lower for single-chamber devices (3.51% vs 4.72%; $P<.001$; risk difference, −1.20 [95% CI, −1.72 to −0.69]), but device type was not significantly associated with 1-year mortality (unadjusted rate, 9.85% vs 9.77%; hazard ratio [HR], 0.99 [95% CI, 0.91 to 1.07]; $P=.79$), 1-year all-cause hospitalization (unadjusted rate, 43.86% vs 44.83%; HR, 1.00 [95% CI, 0.97-1.04]; $P=.82$), or hospitalization for heart failure (unadjusted rate, 14.73% vs 15.38%; HR, 1.05 [95% CI, 0.99-1.12]; $P=.19$).

Conclusions and Relevance Among patients receiving an ICD for primary prevention without indications for pacing, the use of a dual-chamber device compared with a single-chamber device was associated with a higher risk of device-related complications and similar 1-year mortality and hospitalization outcomes. Reasons for preferentially using dual-chamber ICDs in this setting remains unclear.

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A CENTRAL DECISION REGARDING implantable cardioverter-defibrillator (ICD) therapy is whether to use a single- or dual-chamber device. This question was not addressed by the randomized trials establishing the benefit of ICDs for primary prevention of sudden cardiac death because the majority of patients enrolled in these efficacy trials received single-chamber devices. More complex dual-chamber devices may offer theoretical benefits beyond single-chamber devices for patients without an indication for pacing, including clearer interpretability of electrograms for clinicians, enhanced device arrhythmia discrimination algorithms, possible reductions in inappropriate therapies, and the potential for a reduced risk of hospitalization and death.

In addition to possible benefits, dual-chamber devices may have greater risks. Because implanting a dual-

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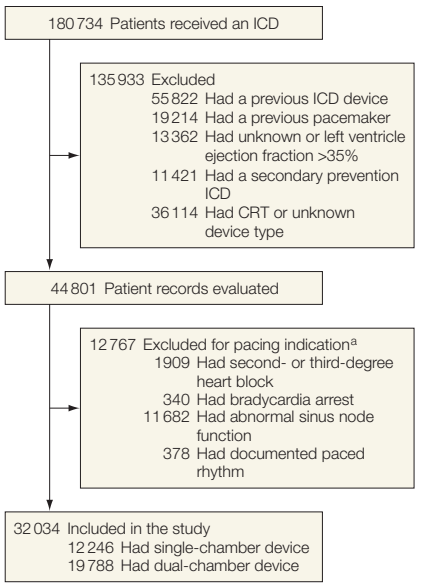
chamber ICD is a more complex and time-consuming procedure than implanting a single-chamber device, the possibility of device-related complications such as infection and lead displacement requiring reoperation is likely higher. However, the risk of longer-term complications, including mechanical complications requiring reoperation, is unknown.

In aggregate, the major primary prevention clinical trials of the efficacy of ICDs evaluated predominantly single-lead devices; thus, the Centers for Medicare & Medicaid Services (CMS) National Coverage Decision for ICDs states that "providers must be able to justify the medical necessity of devices other than single lead devices."[1] In contrast to the CMS guidance, current American College of Cardiology/American Heart Association/Heart Rhythm Society practice guidelines do not specify whether a single- or dual-chamber ICD should be used among patients receiving an ICD for primary prevention who do not have pacing indications.[2] In a national sample, more than two-thirds of patients receiving an ICD received a dual-chamber device; and among those receiving dual-chamber devices, 60% did not have a pacing indication.[3] Furthermore, marked geographic variation in the use of dual or single devices exists that is largely unrelated to patient characteristics.[4] This variation in use, presumably in part, reflects a lack of clarity regarding the long-term safety and outcomes of dual-chamber devices relative to single-chamber devices.

Thus, the aims of this study were to identify patients without an indication for pacing and compare outcomes, including mortality, hospitalizations, and longer-term implant-related complications between single- and dual-chamber devices.

Figure. Study Population



CRT indicates cardiac resynchronization therapy; ICD, implantable cardioverter-defibrillator.
[a]Patients may have had more than 1 indication.

METHODS

Data Source

Patients were enrolled from the National Cardiovascular Data Registry's (NCDR's) ICD registry. The ICD registry was established in 2005 through a partnership of the Heart Rhythm Society and the American College of Cardiology Foundation. On April 1, 2006, it became the sole repository of ICD implant data for Medicare beneficiaries. With a Coverage with Evidence Decision in January 2005, CMS mandated that hospitals enter Medicare patients receiving primary prevention ICDs into the database.[5] Nearly 80% of participating hospitals report data on all implants regardless of payer or indication.[6]

Clinical, demographic, and procedural information is collected in addition to information about adverse events until the time of discharge using standardized data elements and definitions. Data are submitted by participating hospitals using certified software. Data quality is examined using a formal Data Quality Reporting and audit process.[7,8] Longitudinal outcomes were obtained by linking NCDR registry files with Medicare inpatient fee-for-service claims using probabilistic matching, as previously described.[9]

Study Population

All admissions from 2006-2009 that could be matched to CMS Medicare fee-for-service claims data were identified. Patients were excluded if they

Table 1. Baseline Characteristics of Patients Receiving Single- or Dual-Chamber Implantable Cardioverter-Defibrillators in Overall Cohort

	Chamber ICD, %		
	Single (n = 12 246)	Dual (n = 19 788)	*P* Value
Age, mean (SD), y	73.5 (6.0)	73.9 (6.0)	<.001
Women	27.4	25.8	.001
Race/ethnicity			
White	80.7	82.5	<.001
Black	11.3	9.6	
Hispanic	5.3	5.1	
Payer			
Government	99.0	99.3	.01
Commercial	0.8	0.5	
HMO	0.1	0.1	
Reason for admission			
Admitted for ICD	72.6	66.0	<.001
Cardiac hospitalization	11.0	11.8	
Noncardiac hospitalization	13.4	18.7	
Unknown	3.0	3.6	
History and risk factors			
Syncope	10.6	14.9	<.001
Family history of sudden death	3.5	3.5	.85
NYHA class			
I	10.8	10.9	<.001
II	55.9	49.9	
III	31.7	36.9	
IV	1.6	2.3	
Cardiac arrest	1.9	2.1	.20
Atrial fibrillation/flutter	22.4	23.0	.19

(continued)

were not in the fee-for-service plan; had a previous ICD or pacemaker; had an ejection fraction of more than 35%; or if their ejection fraction was unknown, received an ICD for secondary prevention, received a biventricular device, or if device type was missing; or had a documented indication for pacing. Pacing indications were ascertained from the NCDR data collection form and included second- or third-degree heart block, previous bradycardic arrest, abnormal sinus node function, or a documented paced rhythm. Atrioventricular conduction is determined by electrocardiographic findings at the time of the decision to implant an ICD and is recorded in the registry as normal, first-degree heart block, or second- or third-degree heart block without pacing, and paced. Sinus node function is recorded in the registry as normal or abnormal prior to the date of implant. The Yale University human investigation committee approved the analysis and determined that informed consent was not applicable to the data collected by the registry (FIGURE).

Outcomes

Outcomes were ascertained from the time of implant through December 2010 from CMS claims data and included all-cause mortality, all-cause readmission, and readmission for heart failure at 1 year based on a primary discharge diagnosis of heart failure. Complications were evaluated using the definition used for a performance measure developed for CMS in partnership with the American College of Cardiology and endorsed by the National Quality Forum.[10] Because this measure was developed for public reporting purposes, only the most serious complications after implant (eg, pneumothorax requiring chest tube placement rather than any pneumothorax) are included.

Based on input from a technical expert panel convened as part of the metric development, the time frames used for the assessment of each complication varies depending on the extent to which the panel deemed it likely to have been attributable to the ICD implant. These measures have standard definitions and include (1) pneumothorax requiring chest tube at 30 days; (2) hematoma requiring blood transfusion or evacuation at 30 days; (3) cardiac tamponade at 30 days; (4) mechanical complications requiring reoperation for system, generator, or lead revision at 90 days; (5) device-related infection at 90 days; and (6) recurrent ICD implant at 90 days (defined as any *International Classification of Diseases, Ninth Revision, Clinical Modification* diagnosis code for subsequent ICD implant procedure within 90 days of the index procedure). The technical expert panel that developed the CMS measure agreed that

Table 1. Baseline Characteristics of Patients Receiving Single- or Dual-Chamber Implantable Cardioverter-Defibrillators in Overall Cohort (continued)

	Chamber ICD, %		
	Single (n = 12 246)	Dual (n = 19 788)	*P* Value
History and risk factors			
Ventricular tachycardia			
None	76.7	71.4	<.001
Nonsustained	20.5	24.1	
Sustained	2.8	4.5	
Nonischemic cardiomyopathy	23.9	22.4	.003
Ischemic heart disease	76.7	78.5	<.001
Previous			
MI	64.9	63.7	.03
CABG	41.3	42.9	.005
PCI	36.4	39.3	<.001
Valvular surgery	4.9	5.3	.11
Disease			
Cerebrovascular	16.5	17.0	.25
Chronic lung	24.5	23.9	.21
Diabetes	38.5	37.5	.07
Hypertension	78.3	79.9	<.001
Renal dysfunction	9.8	9.2	.08
Diagnostic studies			
EP study	8.6	10.9	<.001
Ejection fraction, %			
<25	33.9	31.3	<.001
25-<30	27.4	26.0	
≥30	38.7	42.8	
QRS duration, mean (SD), ms	110.2 (24.9)	114.1 (27.4)	<.001
First-degree AV block	13.3	20.6	<.001
Intraventricular conduction			
Normal	66.7	59.8	<.001
Left bundle-branch block	11.8	16.6	
Right bundle-branch block[a]	6.9	8.9	
Other	14.5	14.6	
Creatinine, mean (SD), mg/dL	1.4 (1.04)	1.38 (1.01)	.09
≥2.0	8.5	8.2	.21
BUN, mean (SD), mg/dL	24.9 (13.2)	24.7 (13.1)	.16
≥ 30	22.4	22.0	.39
Sodium, mean (SD), MEq/L	138.9 (3.4)	138.7 (3.6)	<.001
Systolic blood pressure, mean (SD), mm Hg	132.5 (22.1)	133.8 (22.8)	<.001
Discharge medications (not included in propensity score)			
ACE inhibitor	65.8	66.1	.52
ARB	18.7	18.5	.72
β-Blocker	88.1	87.6	.16

Abbreviation: ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blockers; AV, atrioventricular; BUN, blood urea nitrogen; CABG, coronary artery bypass graft; EP, electrophysiology; HMO, health maintenance organization; ICD, implantable cardioverter-defibrillator; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.
SI conversion factors: To convert creatinine from mg/dL to μmol/L, multiply by 88.4.
[a]With or without fascicular block.

a subsequent ICD implanted within 90 days of the index procedure would be an unplanned event.

Patient and Clinician Characteristics

Independent patient-level variables were obtained from the NCDR ICD registry and included: demographic characteristics (age, sex, race, insurance payer); reason for hospitalization; patient comorbidities and risk factors, including: syncope, family history of sudden death, history of heart failure, admission New York Heart Association classification, cardiac arrest, atrial fibrillation or flutter, ventricular tachycardia, etiology of cardiomyopathy (ischemic, nonischemic), myocardial infarction, coronary artery bypass graft surgery, percutaneous coronary intervention, valvular surgery, cerebrovascular disease, chronic lung disease, diabetes, hypertension, and renal failure (hemodialysis); diagnostic information: ejection fraction, whether an electrophysiology study was performed, QRS duration, whether the PR interval could be attained, presence of first-degree heart block, presence of an intraventricular conduction abnormality, serum creatinine, serum blood urea nitrogen, serum sodium level, and systolic blood pressure; and discharge medications: angiotensin-converting enzyme inhibitor, angiotensin II receptor blocker, and β-blocker. Physician characteristics included annual volume of ICD implants and level of training. Hospital characteristics included annual volume of ICD implants, geographic location, profit type (government, private or community, university), type of community (rural, suburban, urban), number of patient beds, teaching status, and presence of an electrophysiology laboratory in the hospital.

Missing data were rare for all variables (<1%). To avoid case-wise deletion of those observations with missing data points, missing values were imputed. For categorical variables, the missing variables were imputed as the most common value among those with the data present. For example, for the categorical variable New York Heart Association class, missing values were imputed as class II. For continuous variables, the missing values were imputed as the median.

Table 2. Baseline Physician and Hospital Characteristics Among Patients Receiving Single- or Dual-Chamber Implantable Cardioverter-Defibrillators in Overall Cohort

	ICD, %		
	Single (n = 12 246)	Dual (n = 19 788)	*P* Value
Physician characteristics			
Physician annual number of ICD implants, mean (SD)	68.8 (52.2)	68.8 (52.1)	.98
Physician annual ICD implants, No.			
≤25	20.7	22.3	<.001
>25 to ≤100	56.8	53.8	
>100	22.5	23.9	
Physician training			
Board-certified EP	73.1	70.3	<.001
EP fellowship only	6.4	6.2	
Surgery boards	2.1	2.7	
Pediatric cardiology boards	0.04	0.09	
HRS guidelines	11.2	12.7	
Other	7.2	8.1	
Hospital characteristics			
Hospital annual ICD implants, mean (SD), No.	203.5 (152.8)	196.6 (151.4)	<.001
Hospital annual ICD implants, No.			
<50	12.3	13.6	.003
≥50	12.3	13.6	
≥50 to ≤200	46.5	45.9	
>200	41.2	40.5	
Geographic location			
New England	6.5	3.1	<.001
Mid-Atlantic	19.2	11.2	
South-Atlantic	23.4	23.2	
Central			
East north	17.3	21.3	
East south	8.0	8.1	
West north	6.3	10.0	
West south	10.7	10.6	
Mountain	3.2	4.3	
Pacific	5.4	8.3	
Profit type			
Government	1.6	2.5	<.001
Private or community	83.3	87.0	
University	15.1	10.6	
Community type			
Rural	12.7	12.5	.22
Suburban	29.3	30.2	
Urban	57.9	57.3	
Patient beds, mean (SD), No.	493.9 (281.4)	463.7 (265)	<.001
Patient beds, No.			
≤100	3.6	4.2	<.001
>100-≤500	53.2	59.2	
>500	43.2	36.6	
Teaching hospital	57.8	51.6	<.001
EP laboratory present in hospital	67.4	68.8	.008

Abbreviations: EP, electrophysiology; HRS, Heart Rhythm Society; ICD, implantable cardioverter-defibrillator.

Statistical Analysis

Baseline characteristics were compared between patients who received a single-chamber device and patients who received a dual-chamber device using *t* tests for continuous variables and χ^2 tests for categorical variables. Unadjusted outcome rates were compared between patients who received a single-chamber device and patients who received a dual-chamber device using *t* tests. Power calculations were not performed because the study was retrospective with a fixed sample size. The

precision of the estimates for the hazard ratios between single- and dual-chamber ICDs is reflected in the confidence intervals for these estimates.

Because patients were not randomly assigned to receive single- or dual-chamber devices, we attempted to create more comparable treatment groups using propensity-score matching to adjust for differences in observed characteristics. The log odds of the probability that a patient received a dual-chamber ICD was modeled as a function of all of the available data about the patients, clinicians, and hospitals at the time of the implant. The distribution of predicted probabilities was compared between treatment groups to ensure enough overlap in predicted probabilities to permit comparison of outcomes.

A 1-to-1 matched analysis was then performed without replacement on the basis of the estimated propensity score of each patient in the study. Using the estimated logits, a patient who received a dual-chamber device was randomly selected and then matched to the closest patient with a single-chamber device. Patients with a single-chamber device who had an estimated logit within 0.6 SDs of selected patients with dual-chamber devices were eligible for matching. This matching interval has been shown to eliminate approximately 90% of the bias in observed confounders.[11] The success of matching was evaluated by examining standardized differences in the observed patient and clinician characteristics between single- and dual-chamber treatment groups. Small absolute differences in standardized differences (<10%) support the assumption of balance of observed variables between treatment groups.[12]

Using matched pairs, McNemar tests were performed to determine whether rates of subsequent complications, mortality, all-cause admission, and heart failure admission differed between recipients of single- and dual-chamber devices. Medications prescribed at discharge following ICD implant may affect longitudinal outcomes of hospitalization and mortality but were not known at the time of the decision of

Table 3. Rates of Outcomes Among Patients Receiving Single- vs Dual-Chamber Implantable Cardioverter-Defibrillator in the Overall Cohort

	No. (%) of Patients				
		Chamber ICD			
	Overall (n = 32 034)	Single (n = 12 246)	Dual (n = 19 788)	Difference (95% CI), %	*P* Value
30-Day outcome					
Pneumothroax requiring chest tube	173 (0.54)	53 (0.43)	120 (0.61)	−0.17 (−0.33 to −0.01)	.04
Hematoma requiring blood transfusion or evacuation	78 (0.24)	25 (0.20)	53 (0.27)	−0.06 (−0.17 to 0.04)	.26
Cardiac tamponade	225 (0.7)	54 (0.44)	171 (0.86)	−0.42 (−0.60 to −0.25)	<.001
90-Day outcome					
Mechanical complications requiring system revision	574 (1.79)	175 (1.43)	399 (2.02)	−0.59 (−0.87 to −0.30)	<.001
Device-related infection	215 (0.67)	74 (0.60)	141 (0.71)	−0.12 (−0.29 to 0.07)	.25
ICD replacement	252 (0.79)	91 (0.74)	161 (0.81)	−0.07 (− 0.27 to 0.13)	.49
Any complication	1374 (4.29)	432 (3.53)	942 (4.76)	−1.23 (−1.67 to −0.79)	<.001
1-Year outcome					
All-cause mortality	3208 (10.01)	1206 (9.85)	2002 (10.12)	−0.27 (−0.94 to 0.41)	.44
All-cause hospitalization	14241 (44.46)	5362 (43.79)	8879 (44.87)	−1.08 (−2.20 to 0.03)	.06
Heart failure hospitalization	4879 (15.23)	1803 (14.72)	3076 (15.54)	−0.82 (−1.62 to −0.02)	.047

Abbreviations: CI, confidence interval; ICD, implantable cardioverter-defibrillator.

Table 4. Characteristics of Propensity Score–Matched Patients Receiving Single- vs Dual-Chamber Implantable Cardioverter-Defibrillator

	ICD, No. (%) of Patients		
	Single (n = 11 619)	Dual (n = 11 619)	Standardized Difference, %
Age, mean (SD),y	73.5 (6.0)	73.6 (5.9)	−0.40
Women	3164 (27.2)	3143 (27.1)	0.41
Race/ethnicity			
White	9390 (80.8)	9442 (81.3)	−1.14
Black	1305 (11.2)	1242 (10.7)	1.74
Hispanic	613 (5.3)	620 (5.3)	−0.27
Payer			
Government	11 512 (99.1)	11 515 (99.1)	0.57
Commercial	81 (0.7)	72 (0.6)	0.96
HMO	12 (0.1)	13 (0.1)	−0.26
Reason for admission			
Admitted for ICD	8341 (71.8)	8258 (71.1)	1.58
Cardiac hospitalization	1308 (11.3)	1308 (11.3)	0.00
Noncardiac hospitalization	1620 (13.9)	1713 (14.7)	−2.28
Unknown	350 (3.0)	340 (2.9)	0.51
History and risk factors			
Syncope	1268 (10.9)	1350 (11.60)	−2.23
Family history of sudden death	404 (3.5)	415 (3.6)	−0.51
NYHA class			
I	1249 (10.8)	1244 (10.7)	0.14
II	6395 (55.0)	6322 (54.4)	1.26
III	3778 (32.5)	3854 (33.2)	−1.39
IV	197 (1.7)	199 (1.7)	−0.13
Cardiac arrest	222 (1.9)	203 (1.7)	1.22
Atrial fibrillation/flutter	2558 (22.0)	2503 (21.5)	1.15
Ventricular tachycardia			
None	8841 (76.1)	8827 (76.0)	0.28
Nonsustained	2434 (20.9)	2448 (21.1)	−0.30
Sustained	344 (3.0)	344 (3.0)	0.00
Nonischemic cardiomyopathy	2730 (23.5)	2686 (23.1)	0.90
Ischemic heart disease	8967 (77.2)	9016 (77.6)	−1.01

(continued)

which device type to implant and therefore were not included in the model determining the propensity to receive a dual-chamber device. Following propensity-score matching, multivariable survival models accounting for matched pairs were generated including discharge medications for the outcomes of mortality, all-cause hospitalization, and heart failure hospitalization at 1 year.

In secondary analyses, multivariable survival models accounting for clustering among hospitals were generated. The assumption of proportionality was tested and met for the Cox proportional hazards analyses. For 1-year mortality, the model was censored for patients who did not die within a year; for 1-year readmission, the model was censored for patients who did not get readmitted within a year, including death within a year; similar methods were applied to heart failure readmission within a year. The statistical significance of differences among strata was tested with a 2-way interaction term in survival models accounting for matched pairs.

The relationship between device type and outcomes was also explored in prespecified subgroups of the propensity-matched cohort. Analyses were stratified by age, sex, and renal dysfunction (defined as serum creatinine >2 mg/dL [to convert mg/dL to μmol/L, multiply by 88.4]) or undergoing dialysis. All statistical tests were 2-sided with a significance threshold of $P < .05$. All analyses were performed using the statistical packages of SAS version 9.3 (SAS Institute Inc) and STATA/SE 10.0 (StataCorp LP).

Table 4. Characteristics of Propensity Score-Matched Patients Receiving Single- vs Dual-Chamber Implantable Cardioverter-Defibrillator (continued)

	Chamber ICD, No. (%) of Patients		
	Single (n = 11 619)	Dual (n = 11 619)	Standardized Difference, %
History and risk factors			
Previous			
MI	7545 (64.9)	7566 (65.1)	−0.38
CABG	4836 (41.6)	4894 (42.1)	−1.01
PCI	4299 (37.0)	4406 (37.9)	−1.90
Valvular surgery	562 (4.80)	562 (4.80)	0.00
Cerebrovascular disease	1924 (16.6)	1925 (16.6)	−0.02
Chronic lung disease	2856 (24.6)	2859 (24.6)	−0.06
Diabetes	4472 (38.5)	4460 (38.4)	0.21
Hypertension	9129 (78.6)	9190 (79.1)	−1.29
Renal dysfunction	1125 (9.7)	1111 (9.6)	0.41
Diagnostics			
EP Study	1021 (8.8)	1082 (9.3)	−1.83
Ejection fraction, %			
<25	3881 (33.4)	3862 (33.2)	0.35
25-<30	3172 (27.4)	3090 (26.6)	1.73
≥30	4559 (39.2)	4667 (40.2)	−1.90
QRS duration, mean (SD), ms	110.6 (25.1)	111.1 (25.8)	−1.81
PR interval attainable	9594 (82.6)	9704 (83.5)	−1.74
Abnormal AV conduction	9996 (13.9)	9904 (14.8)	−2.26
Intraventricular conduction			
Normal	7669 (66.0)	7526 (64.8)	2.59
Bundle-branch block			
Left	1425 (12.3)	1489 (12.8)	−1.66
Right[a]	822 (7.1)	861 (7.4)	−1.29
Other	1703 (14.7)	1743 (15.0)	−0.97
Creatinine, mg/dL			
Mean (SD)	1.4 (1.0)	1.4 (1.0)	0.69
>2.0	982 (8.5)	970 (8.3)	0.37
BUN, mg/gL			
Mean (SD)	24.8 (13.1)	24.8 (13.3)	0.44
>30	2574 (22.1)	2561 (22.0)	0.27
Sodium, mean (SD), MEq/L	138.8 (3.4)	138.8 (3.5)	0.78
Systolic blood pressure, mean (SD), mm Hg	132.7 (22.1)	132.8 (22.4)	−0.42
Discharge medications (not included in propensity score)			
ACE inhibitor	7635 (65.7)	7716 (66.4)	−1.47
ARB	2177 (18.7)	2095 (18.0)	1.82
β-Blocker	10 226 (88.0)	10 165 (87.5)	1.60
β-Blocker and ACE inhibitor or ARB	8332 (71.7)	8289 (71.3)	0.82

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotensin II receptor blocker; BUN, blood urea nitrogen; CABG, coronary artery bypass grafting; EP, electrophysiology; HMO, health maintenance organization; ICD, implantable cardioverter-defibrillator; MI, myocardial infarction; NYHA, New York Heart Association; PCI, percutaneous coronary intervention.
SI conversion factor: To convert creatinine from mg/dL to μmol/L, multiply by 88.4.
[a] With or without fascicular block.

RESULTS

Between January 2006 and December 2009, 180 734 patients received an ICD that could be matched to CMS claims. Patients were excluded if they had a previous ICD (n = 55 822), previous pacemaker (n = 19 214), ejection fraction of more than 35% (n=12 000) or unknown ejection fraction (n = 1362), receipt of an ICD for secondary prevention (n = 11 421), receipt of a biventricular (n = 36 007) or unknown device type (n = 107), or a documented pacing indication (n = 12 767), resulting in a study cohort of 32 034 patients from 1270 hospitals (Figure). In this cohort, 19 788 patients (62%) = received a dual-chamber device and 12 246 (38%) received a single-chamber device. Patients who received a dual-chamber device were more likely to be men; have a history of syncope, sustained or nonsustained ventricular tachycardia, and ischemic heart disease; have an ejection fraction of at least 30%, a first-degree heart block, a right or left bundle-branch block; and a wider QRS duration (TABLES 1 and TABLE 2).

Unadjusted rates of any complication were higher for dual-chamber ICDs, with the largest absolute difference in mechanical complications requiring repeat operation for system revision (TABLE 3). Among the overall cohort, the unadjusted rate of hospitalization for heart failure within 1 year of receiving an implant was modestly lower for single-chamber devices (14.72% vs 15.54%; $P=.047$; risk difference, −0.82; 95% CI, −1.62 to −0.02). Unadjusted rates of all-cause hospitalization (43.79% vs 44.87%; $P=.06$; risk difference, −1.08; 95% CI, −2.20 to 0.03) and mortality (9.85% vs 10.12%; $P=.44$; risk difference, −0.27; 95% CI, −0.94 to 0.41) within 1 year did not differ by device type.

The propensity model included 41 variables (all variables in Tables 1 and Table 2 except discharge medications) and had an area under the receiver operating characteristic curve of 0.66 (95% CI 0.65-0.67). This suggests that the choice of a dual-chamber device is relatively random with respect to patient characteristics, which itself does not indicate a diminished capacity to reduce confounding. Sufficient overlap between the 2 groups existed to compare treatment effects (eFigure available at http://www.jama.com). In total, 11 619 patients (95%) with a single-chamber device were matched to 11 619 patients with dual-chamber devices. After propensity-score matching, standardized differences were less than 10% for all variables, indicating the 2 treatment groups were similar with respect to observed characteristics (TABLES 4 and TABLE 5).

In the propensity-matched cohort, rates of any of the assessed complications were significantly lower for single-chamber ICDs (3.51% vs 4.72%; $P<.001$; risk difference, −1.20; 95% CI, −1.72 to −0.69), with the largest absolute difference in mechanical complications requiring system revision (1.43% vs 1.98%; $P=.001$; risk difference, −0.55; 95% CI, −0.88 to −0.22; TABLE 6) Rates of all-cause hospitalization, heart failure hospitalization and mortality at 1 year did not differ between device types (Table 6). After further adjustment for discharge medications and accounting for matching, device type was still not significantly associated with mortality and hospitalization outcomes (9.85% vs 9.77%; HR, 0.99 [95% CI, 0.91-1.07]; $P=.792$ for 1-year mortality; 43.86% vs 44.83%; hazard ratio, 1.00 [95% CI, 0.97-1.04]; $P=.82$ for 1-year all-cause hospitalization; and 14.73% vs 15.38%; hazard ratio, 1.05 [95% CI, 0.98-1.12]; $P=.12$ for 1-year heart failure hospitalization). Results were similar in models

Table 5. Physician and Hospital Characteristics Among Propensity Score-Matched Patients Receiving Single- vs Dual-Chamber Implantable Cardioverter-Defibrillator

	Chamber ICD, No. (%)		
	Single (n = 11 619)	Dual (n = 11 619)	Standardized Difference, %
Physician characteristics			
Physician annual ICD implants, mean (SD), No.	69.1 (52.6)	68.7 (51.6)	0.82
Physician annual ICD implants, No.			
<25	2430 (20.9)	2562 (22.1)	−2.77
25 to ≤100	6522 (56.1)	6307 (54.3)	3.72
>100	2667 (22.9)	2750 (23.7)	−1.69
Physician training			
Board-certified EP	7728 (72.6)	7839 (72.5)	−2.03
EP fellowship only	664 (6.2)	670 (6.2)	−0.22
Surgery boards	229 (2.2)	248 (2.3)	−1.15
Pediatric cardiology boards	4 (0.04)	1 (0.01)	1.76
HRS guidelines	1216 (11.4)	1237 (11.4)	−0.59
Other	800 (7.5)	819 (7.6)	−0.64
Hospital characteristics			
Hospital annual ICD implants, mean (SD), No.	203.3 (154.1)	202.1 (150.5)	0.80
Hospital annual ICD implants, No.			
<50	1453 (12.5)	1478 (12.7)	−0.65
50 to ≤200	5389 (46.4)	5213 (44.9)	3.04
>200	4777 (41.1)	4928 (42.4)	−2.64
Geographic location			
New England	613 (5.3)	546 (4.7)	2.65
Mid-Atlantic	2042 (17.6)	1878 (16.2)	3.77
South-Atlantic	2793 (24.0)	2742 (23.6)	1.03
Central			
East north	2110 (18.2)	2203 (19.0)	−2.06
East south	961 (8.3)	981 (8.4)	−0.62
West north	771 (6.6)	858 (7.4)	−2.93
West south	1279 (11.0)	1299 (11.2)	−0.55
Mountain	394 (3.4)	390 (3.4)	0.19
Pacific	656 (5.7)	721 (6.2)	−2.37
Profit type			
Government	194 (1.7)	208 (1.7)	−0.92
Private/community	9786 (84.2)	9872 (85.0)	−2.05
University	1639 (14.1)	1539 (13.2)	2.50
Community type			
Rural	1487 (12.8)	1483 (12.8)	0.10
Suburban	3434 (29.6)	3453 (29.7)	−0.36
Urban	6698 (57.6)	6683 (57.5)	0.26
Patient beds, mean (SD), No.	486.9 (271.5)	485.9 (278.9)	0.35
<100	433 (3.7)	389 (3.4)	2.05
100 to ≤500	6310 (54.3)	6572 (56.6)	−4.54
>500	4876 (42.0)	4658 (40.1)	3.81
Teaching Hospital	6547 (56.3)	6478 (55.8)	1.20
EP Laboratory present in hospital	7866 (67.7)	7947 (68.4)	−1.50

Abbreviation: EP, electrophysiology; ICD, implantable cardioverter-defibrillator; HRS, Heart Rhythm Society.

also accounting for clustering among hospitals.

Rates of any complication were higher among patients receiving dual-chamber devices for all subgroups (age, sex, and presence of renal dysfunction). Women receiving dual-chamber devices had a particularly high rate of complications (6.43%; TABLE 7) However, no statistically significant interactions between these subgroup characteristics and device types were identified (all *P* values for interaction >.05). Furthermore, no significant differences in the association between device type and mortality, all-cause hospitalization, or heart failure hospitalization were observed for any of the subgroups evaluated (*P* values ≥.05 for interaction between stratification variable and device type for all outcomes).

DISCUSSION

The objective of this study was to compare mortality, hospitalizations, and complications among patients without a pacing indication who received single- or dual-chamber ICDs for primary prevention of sudden cardiac death. During the period studied, more than 60% of the Medicare fee-for-service primary prevention ICD recipients enrolled in the NCDR ICD registry received dual-chamber devices in the absence of pacing indications. No significant difference in mortality, all-cause hospitalization, or heart failure hospitalization was observed between single- and dual-chamber device types at 1 year. No difference in the association between device type and these outcomes was observed among prespecified subgroups of patients by age, sex, or presence of renal dysfunction. In contrast, dual-chamber devices were associated with a higher risk of complications in the overall cohort and in the prespecified patient subgroups, with the largest absolute difference in mechanical complications requiring reoperation for system revision.

This study expands the current understanding of the contemporary comparative outcomes of patients receiving ICDs for primary prevention. In this large national cohort of Medicare patients, dual-chamber devices did not have any observed advantage with regard to mortality or hospitalization compared with single-chamber ICDs. These results are consistent with 2 randomized trials, which demonstrated that atrial pacing with minimal ventricular pacing offers no advantage over a single-chamber ventricular back-up pacing mode with regard to hospitalization or death.[13,14]

Although randomized comparisons mitigate certain types of bias, clinical trials have limited applicability to everyday practice, which include a broader, sicker population and the delivery of the intervention under usual care circumstances and in the setting of contemporary medical therapy. Additionally, small numbers of women and elderly patients in prior clinical trials may have precluded the detection of differences in outcomes in these subgroups. This study addresses important gaps in the understanding of the real-world outcomes of ICDs by comparing the rates of mortality and hospitalization (both all-cause and for heart failure) among a community-based

Table 6. Rates of Outcomes in Propensity Score-Matched Patients Receiving Single vs Dual Chamber Implantable Cardioverter-Defibrillator

	No. (%) of Patients				
		Chamber ICD			
	Overall (n = 23 238)	Single (n = 11 619)	Dual (n = 11 619)	Difference (single-dual), % (95% CI)	*P* Value
30-Day results					
Pneumothroax requiring chest tube	122 (0.53)	51 (0.44)	71 (0.61)	−0.17 (−0.36 to 0.01)	.07
Hematoma requiring blood transfusion or evacuation	52 (0.22)	24 (0.21)	28 (0.24)	−0.03 (−0.16 to 0.09)	.58
Cardiac tamponade	158 (0.68)	51 (0.44)	107 (0.92)	−0.48 (−0.69 to −0.27)	<.001
90-Day results					
Mechanical complications requiring system revision	396 (1.70)	166 (1.43)	230 (1.98)	−0.55 (−0.88 to −0.22)	.001
Device-related infection	151 (0.65)	68 (0.59)	83 (0.71)	−0.13 (−0.34 to 0.08)	.22
ICD replacement	175 (0.75)	85 (0.73)	90 (0.77)	−0.04 (−0.27 to 0.18)	.70
Any complication	956 (4.11)	408 (3.51)	548 (4.72)	−1.20 (−1.72 to −0.69)	<.001
Outcomes at 1 y after implant					
All-cause mortality	2280 (9.81)	1145 (9.85)	1135 (9.77)	0.09 (−0.68 to 0.85)	.83
All-cause hospitalization	10189 (43.85)	5096 (43.86)	5093 (44.83)	0.03 (−1.25 to 1.30)	.97
Heart failure hospitalization	3498 (15.05)	1711 (14.73)	1787 (15.38)	−0.65 (−1.57 to 0.27)	.16

Abbreviation: CI, confidence interval; ICD, implantable cardioverter defibrillator.

Table 7. Rates of Any Complication Among Subgroups in the Matched Cohort

	Chamber ICD, No. (%)			
	Single	Dual	*P* Value	*P* Value for Interaction
Overall	408 (3.51)	548 (4.72)	<.001	
Age, y				
65-75	256 (3.45)	373 (5.03)	<.001	.06
>75	152 (3.63)	175 (4.16)	.21	
Sex				
Men	260 (3.08)	346 (4.08)	<.001	.79
Women	148 (4.68)	202 (6.43)	.002	
Presence of renal dysfunction				
No	366 (3.49)	486 (4.63)	<.001	.58
Yes	42 (3.73)	62 (5.58)	.04	

Abbreviation: ICD, implantable cardioverter defibrillator.

cohort of elderly patients receiving dual-chamber ICDs and a similar population of patients receiving single-chamber ICDs for primary prevention and among clinically important subgroups of patients who were underrepresented in clinical trials.

Our study also advances the understanding of the risks of dual-chamber devices. Because implanting a dual-chamber ICD is a more complex and time-consuming procedure than implanting a single-chamber device, the possibility of device-related complications such as infection and lead displacement requiring device revision is likely to increase. Indeed, we observed a greater risk of complications among patients receiving dual-chamber devices. Our findings are consistent with a prior study of community-based patients with implants that found a higher rate of in-hospital complications among those receiving a dual-chamber device.[3] However, this prior study did not evaluate complications that occurred after discharge after the device had been implanted, which may result in differential ascertainment as a function of length of stay. Prior studies of device complications beyond the index hospitalization have not differentiated between device types.[15,16] Our study found that in a real-world setting, rates of complications after implant were higher among those receiving dual-chamber devices. In particular, the rate of mechanical complication requiring reoperation for system revision was the most common complication and was higher among patients receiving dual-chamber devices.

Use of dual-chamber devices has cost implications as well. Cost-effectiveness analyses of the primary prevention trials assumed the use of single-chamber devices to provide estimates both for the costs and complications of ICD implants.[17,18] Dual-chamber devices are more costly for the initial implant and are associated with an increased risk of complications and have a greater risk of generator depletion,[3,19,20] both of which have associated costs. Thus, expert recommendations to improve the cost-benefit ratio of ICDs include careful selection of single- vs dual-chamber devices.[21] Despite the absence of compelling evidence to support these more costly devices, which are also associated with higher complication rates, current practice is highly variable.[22] Our study does not provide evidence that would support the more costly and more morbid device for patients receiving an ICD for primary prevention.

A theoretical benefit of dual chamber ICDs that we were unable to evaluate in this study is enhanced rhythm detection with a decrease in inappropriate shocks. It is intuitive that with an atrial lead, dual-chamber devices could substantially reduce inappropriate shocks because of their capacity to use atrial and ventricular information to recognize rhythms. However, a benefit of dual-chamber devices in decreasing inappropriate therapies has not been established.[23-26] A multicenter clinical trial found that although dual-chamber devices have decreased the odds of inappropriate rhythm diagnosis, it did not find any difference in risk of inappropriate shock.[27] A recent study found that device programming could improve outcomes.[28] Although only dual-chamber devices were included, the programming features evaluated did not require a dual-chamber device. Future studies are needed to determine whether the increased complications associated with dual-chamber devices are offset by a subsequent reduction in inappropriate therapies.

In addition to the inability to evaluate device therapies, several other issues should be considered in the interpretation of this study. First, we were unable to assess upgrades from single- to dual-chamber devices. Another rationale for implanting a dual-chamber device is potential progression of conduction disease requiring an upgrade from a single- to a dual-chamber device. One study found that initially implanting a dual-chamber device is the least costly approach when the rate of upgrades was 10%.[19] However, this is nearly double the rate of development of the need for dual-chamber pacing observed in clinical trials.[29,30] Second, device settings were not available. Although practice patterns have largely evolved to use programming strategies that minimize right ventricular pacing in patients with dual-chamber ICDs, we were unable to ascertain whether these strategies were used. Finally, we were not able to evaluate outcomes of quality of life or development of atrial fibrillation because data regarding these outcomes were not available. The strengths of the study include a large contemporary population-based cohort of patients receiving an ICD for primary prevention and the evaluation of hard clinical end points at long-term follow-up. However, the data are observational. Propensity-score matching was used to create comparable treatment groups according to measured confounders, but residual confounding by either unmeasured or incompletely measured factors cannot be excluded.

CONCLUSION

Many patients receiving primary prevention ICDs receive dual-chamber devices. Dual-chamber devices do not appear to offer any clinical benefit over single-chamber devices with regard to death, all-cause readmission, or heart failure readmission in the year following implant. However, dual-chamber ICDs are associated with higher rates of complications. Therefore, among patients without clear pacing indications, the decision to implant a dual-chamber ICD for primary prevention should be considered carefully.

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Study concept and design: Peterson, Varosy, Wang, Greenlee, Masoudi.
Acquisition of data: Varosy, Magid.
Analysis and interpretation of data: Varosy, Heidenreich, Wang, Dewland, Curtis, Go, Greenlee, Normand, Masoudi.
Drafting of the manuscript: Peterson, Masoudi.
Critical revision of the manuscript for important intellectual content: Varosy, Heidenreich, Wang, Dewland, Curtis, Go, Greenlee, Magid, Normand, Masoudi.

Statistical analysis: Wang, Dewland, Normand.
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