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## Original Investigation

# Implantable Cardioverter-Defibrillator Use Among Medicare Patients With Low Ejection Fraction After Acute Myocardial Infarction

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**IMPORTANCE** Implantable cardioverter-defibrillators (ICDs) are not recommended within 40 days of myocardial infarction (MI); thus, ICD implantation might not be considered during the post-MI care transition.

**OBJECTIVE** To examine ICD implantation rates and associated mortality among older MI patients with low ejection fraction (EF).

**DESIGN, SETTING, AND PARTICIPANTS** Retrospective observational study of Medicare beneficiaries with an EF of 35% or less after MI, treated at 441 US hospitals between 2007 and 2010, excluding patients with prior ICD implantation. Follow-up data were available through December 2010.

**EXPOSURES** ICD implantation within 1 year of MI vs no ICD implantation within 1 year of MI.

**MAIN OUTCOMES AND MEASURES** Patient characteristics associated with receiving an ICD within 1 year after discharge and 2-year mortality associated with ICD implantation.

**RESULTS** Among 10 318 MI patients with EF of 35% or lower, the cumulative 1-year ICD implantation rate was 8.1% (95% CI, 7.6%-8.7%). Patients with ICD implantation were more likely to have prior coronary artery bypass graft procedures, higher peak troponin levels, in-hospital cardiogenic shock, and cardiology follow-up within 2 weeks after discharge relative to patients who did not receive an ICD within 1 year. Implantation of ICD was associated with lower 2-year mortality (15.3 events per 100 patient-years [128 deaths in 838 patient-years] vs 26.4 events per 100 patient-years [3033 deaths in 11 479 patient-years]; adjusted HR, 0.64; 95% CI, 0.53-0.78).

	ICD Implanted Within 1 Year After MI (n = 785)	No ICD Implanted Within 1 Year After MI (n = 9533)	Adjusted HR (95% CI)
Prior CABG	31%	20%	1.49 (1.26-1.78)
Peak troponin levels, median, times the upper limit of normal	85	51	1.02 per 10-fold increase (1.01-1.03)
In-hospital cardiogenic shock	13%	8%	1.57 (1.25-1.97)
Cardiology follow-up within 2 weeks after discharge	30%	20%	1.64 (1.37-1.95)

**CONCLUSIONS AND RELEVANCE** In this large registry study of older patients who experienced MI from 2007-2010, fewer than 1 in 10 eligible patients with low EF received an ICD within 1 year after MI, although ICD implantation was associated with lower risk-adjusted mortality at 2 years. Additional research is needed to determine evidence-based approaches to increase ICD implantation among eligible patients.

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**M**ore than 350 000 people experience sudden cardiac death in the United States annually.<sup>1</sup> Randomized clinical trials established the benefit of primary prevention implantable cardioverter-defibrillators (ICDs) among patients with low ejection fraction (EF).<sup>2,3</sup> Timing of ICD implantation is critical as studies have not found a benefit to ICD implantation early after myocardial infarction (MI).<sup>4,5</sup> Guidelines recommend primary prevention ICD implantation in patients with an EF of 35% or lower despite being treated with optimal medical therapy for at least 40 days after an MI.<sup>6</sup>

Existing evidence suggests underutilization of ICDs in routine clinical practice,<sup>7</sup> especially after an MI.<sup>8</sup> Given the need to wait for at least 40 days, ICD consideration is susceptible to errors of omission during the transition of post-MI care between inpatient and outpatient care teams.<sup>9,10</sup> Although the incidence of MI and resultant ischemic cardiomyopathy increases with age,<sup>11,12</sup> the benefit of primary prevention ICDs remains controversial among older patients, as these patients were underrepresented in clinical trials.<sup>2,3,13</sup> Uncertainties regarding ICD effectiveness, along with other considerations of treatment goals and procedural risk, may discourage ICD implantation among older adults.<sup>14</sup>

Therefore, we examined a large, community-based sample of patients older than 65 years with acute MI and EF of 35% or less to (1) evaluate the incidence and hospital variation of 1-year ICD implantation after MI among potentially eligible patients, (2) describe factors associated with 1-year ICD implantation, and (3) compare 2-year mortality between patients with and without ICD implantation. We hypothesized that ICDs were significantly underused among older post-MI patients, but ICD use was associated with lower long-term mortality. The intent of this study was to identify opportunities to optimize ICD consideration and use in routine post-MI practice.

## Methods

### Study Population

The National Cardiovascular Data Registry Acute Coronary Treatment and Intervention Outcomes Network Registry-Get With the Guidelines (ACTION Registry-GWTG) is a quality improvement program in the United States that includes consecutive patients with ST-segment elevation MI (STEMI) or non-ST-segment elevation MI (NSTEMI).<sup>15,16</sup> Because patient information was collected without unique patient identifiers in ACTION Registry-GWTG, we used 5 indirect identifiers in combination (date of birth, sex, hospital identifier, date of admission, date of discharge) to link patients older than 65 years to Centers for Medicare & Medicaid Services claims data; linkage rates were consistent with prior studies using this methodology.<sup>17</sup> Included patients did not have an ICD in situ and had an EF of 35% or lower at the time of their MI. Because ICD implantation could be an inpatient or outpatient procedure, we focused on patients eligible for Medicare Part A and Part B fee-for-service plans: the linked dataset included patients who were eligible for

these plans during the index admission and received acute MI care at 484 hospitals between January 2, 2007, and September 30, 2010.

We excluded patients who were not eligible for Medicare benefits for at least 12 consecutive months prior to the index admission; these data allowed us to determine whether an ICD was previously implanted and to assess comorbid conditions not captured in ACTION Registry-GWTG for risk adjustment. Patients were excluded if they died, they did not have a left ventricular EF measurement, or their EF was greater than 35% during the index admission. Patients who had a same-day discharge, transferred to another hospital, were discharged to hospice, or left against medical advice were excluded.

We then excluded patients with prior ICD implantation or ICD implantation during the index admission using a combination of *Current Procedural Terminology* and *International Classification of Diseases, Ninth Revision*, codes indicative of ICD implantation or device monitoring in Medicare claims data (eAppendix 1 in the Supplement). In addition, for patients with multiple MI admissions during the study period, only the first ACTION Registry-GWTG admission was analyzed.

The Duke University Medical Center institutional review board granted a waiver of informed consent and study authorization.

### Statistical Analyses

Patients with billing codes for ICD insertion (eAppendix 1 in the Supplement) after index discharge were classified as having received an ICD. We assessed the cumulative incidence of 1-year ICD implantation after accounting for the competing risk of death. Descriptive baseline statistics were reported with categorical variables as frequencies with percentages and continuous variables as medians with interquartile ranges (IQRs).  $\chi^2$  and Wilcoxon rank-sum tests compared categorical and continuous variables, respectively, between patients with and without 1-year ICD implantation. We examined rates of ICD implantation among patients with very low EF ( $\leq 25\%$ ) and those with very high peak troponin levels (top tertile), as these patients were felt to have low likelihood of EF recovery. A multivariable Cox model, stratified by discharging hospital, was fit to determine factors associated with 1-year ICD implantation, censoring at time of death or at end of Medicare Part A and Part B fee-for-service eligibility. The list of covariates entered into the model was selected by clinical judgment (eAppendix 2 in the Supplement).

A Cox model, with adjustment for patient characteristics and a random effect for discharging hospital, tested for interhospital differences in 1-year ICD implantation rates. This analysis of hospital variation was limited to hospitals with more than 10 patients enrolled in the registry. Because interhospital variation was present, a multivariable hierarchical logistic regression model (eAppendix 3 in the Supplement) generated an estimated distribution of ICD implantation rates across hospitals among patients who were alive and eligible for fee-for-service at 1 year after discharge.

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We compared 2-year postdischarge mortality risk between patients with and without ICD implantation during the year after MI by fitting a time-to-death Cox model with ICD implantation as a time-dependent covariate, stratified by discharging hospital. Model covariates were adapted from a validated long-term post-MI mortality risk model<sup>18</sup> and supplemented with statistically significant variables from the univariable comparisons described here (eAppendix 4 in the Supplement). Prespecified subgroup analyses determined whether a differential relationship was observed between 1-year ICD implantation and mortality among patients 80 years and younger vs older than 80 years and among male vs female patients. For each subgroup, we tested the interaction between the subgroup and 1-year ICD implantation, using the covariates in eAppendix 4.

Several sensitivity analyses addressed the possibility that patients with certain comorbidities could be unlikely to receive ICDs. We repeated the multivariable mortality model after excluding patients with end-stage renal disease, prior stroke, and prior cancer, as clinicians may consider these potential contraindications to ICD use. In addition, we fit a propensity model for the probability of receiving an ICD vs not within 1 year after MI, using the covariates in eAppendix 2 in the Supplement. This identified patients with extreme propensity scores (below the 5th and above the 95th percentiles) who were very likely or very unlikely to receive an ICD. We repeated the multivariable model for mortality after excluding these patients. Then we conducted a landmark analysis, excluding patients who died within 40 days after MI.

Missing data were less than 1% for all variables, except body mass index (1.9%) and peak troponin (6.3%). Missing values in continuous covariates were imputed to MI type (STEMI vs NSTEMI) and sex-specific medians of the nonmissing values. Missing values for categorical variables were imputed to the most frequent group. All statistical analyses were performed using SAS software (version 9.3, SAS Institute). The Duke Clinical Research Institute conducted all analyses.

## Results

### Study Population

The linked data set included 72 439 patients eligible for Medicare Part A and Part B fee-for-service plans during the index MI admission at 484 hospitals between January 2, 2007, and September 30, 2010. We excluded patients who were not eligible for Medicare benefits for at least 12 consecutive months prior to the index admission (n = 4427); patients who died (n = 5065); those who did not have an EF measurement (n = 7748); patients whose EF was greater than 35% (n = 41 579) during the index admission; patients who had a same-day discharge, were transferred to another hospital, were discharged to hospice, or left against medical advice (n = 1476); patients who had prior ICD implantation or ICD implantation during the index admission (n = 1575); and those who had multiple MI admissions (n = 251).

The final study population included 10 318 post-MI patients older than 65 years with an EF of 35% or less who were

potentially eligible for primary prevention ICD implantation (Table). Last follow-up was December 31, 2010, and median follow-up was 718 days (IQR, 372-730 days).

### Rates of ICD Implantation

Median patient age was 78 years (IQR, 72-84 years). The majority of patients had an NSTEMI (n = 6675, 65%) and underwent in-hospital revascularization (n = 7749, 75%). Cumulative 1-year ICD implantation was 8.1% (95% CI, 7.6%-8.7%). Median time from index admission to ICD implantation was 137 days (IQR, 71-279 days) and 115 days (IQR, 52-261 days) among patients who had undergone revascularization. Cumulative incidence rates of 1-year ICD implantation for patients with baseline EF of 25% or less (n = 3560) and for patients in the highest tertile of peak troponin ( $\geq 130$  times upper limit of normal, n = 3292) were 11.4% (95% CI, 10.3%-12.5%) and 10.4% (95% CI, 9.4%-11.6%), respectively.

After adjusting for differences in patient case mix across hospitals, there was significant hospital variation (n = 242 hospitals) in ICD implantation rates (P = .02) with a median estimated 1-year ICD implantation rate of 7.4% (IQR, 5.9%-9.4%) (Figure 1). Patients at hospitals in the 90th percentile of 1-year ICD implantation (11.5%) were 2.4-fold more likely to receive an ICD than patients at hospitals in the 10th percentile (4.8%).

### Factors Associated With ICD Implantation

In univariable comparisons, patients who received an ICD within 1 year after MI were younger and were more likely to be male; to present with a STEMI; and to have larger infarcts (median peak troponin, 85 vs 51 times the upper limit of normal), prior coronary artery bypass graft procedures (31% vs 20%), and evidence of cardiogenic shock during index hospitalization (13% vs 8%), relative to patients who did not receive an ICD within 1 year (Table). The rate of early cardiology follow-up within 2 weeks after discharge was higher among patients who did vs did not receive an ICD within 1 year (30% vs 20%, P < .001).

Factors associated with 1-year ICD implantation within the multivariable model are shown in Figure 2. Among patient characteristics, older age, female sex, and end-stage renal disease were most strongly associated with lower likelihood of 1-year ICD implantation. Patients with ICD implantation were more likely to have prior coronary artery bypass graft procedures (adjusted hazard ratio [HR], 1.49; 95% CI, 1.26-1.78), higher peak troponin levels (adjusted HR, 1.02 per 10-fold increase; 95% CI, 1.01-1.03), in-hospital cardiogenic shock (adjusted HR, 1.57; 95% CI, 1.25-1.97), and cardiology follow-up within 2 weeks after discharge (adjusted HR, 1.64; 95% CI, 1.37-1.95), relative to patients who did not receive an ICD within 1 year. Readmission for heart failure or MI was also associated with higher likelihood of ICD implantation.

### Association Between 1-Year ICD Use and Mortality

In unadjusted analysis examining ICD implantation as a time-dependent variable, 1-year ICD implantation was associated with a lower risk of 2-year mortality (128 events in 838 patient-years, 15.3 events per 100 patient-years) relative to no ICD

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Table. Patient Characteristics<sup>a</sup>

Variable	ICD Implanted Within 1 Year After MI (n = 785)	No ICD Implanted Within 1 Year After MI (n = 9533)	P Value
<b>Demographic characteristics</b>			
Age, median (IQR), y	74 (69-79)	78 (72-84)	<.001
Female sex	237 (30)	4497 (47)	<.001
Nonwhite race	95 (12)	1000 (10)	.16
<b>Clinical variables</b>			
Body mass index, median (IQR) <sup>b</sup>	29 (25-31)	26 (23-30)	<.001
Current/recent smoker	161 (21)	1463 (15)	<.001
Diabetes mellitus	299 (38)	3481 (37)	.38
Hypertension	621 (79)	7535 (79)	.97
Hyperlipidemia	522 (67)	5665 (59)	<.001
Prior MI	316 (40)	2979 (31)	<.001
Prior PCI	243 (31)	2147 (23)	<.001
Prior CABG	240 (31)	1889 (20)	<.001
Prior heart failure	218 (28)	2356 (25)	.05
Prior stroke	74 (9)	1236 (13)	.005
Prior atrial fibrillation/flutter <sup>c</sup>	197 (25)	2251 (24)	.35
Peripheral arterial disease	122 (16)	1525 (16)	.73
Prior valvular disease <sup>c</sup>	136 (17)	1841 (19)	.17
Prior cancer history <sup>c</sup>	16 (2)	427 (4)	.001
End-stage renal disease <sup>d</sup>	68 (9)	1870 (20)	<.001
Charlson comorbidity index (>3)	203 (26)	2535 (27)	.66
<b>In-hospital characteristics</b>			
Transferred from another hospital	275 (35)	3126 (33)	.20
Treated at teaching hospital <sup>e</sup>	243 (31)	2682 (28)	.09
STEMI presentation	336 (43)	3307 (35)	<.001
Heart rate on presentation, median (IQR), beats/min	88 (74-104)	89 (75-105)	.73
Systolic BP on presentation, median (IQR), mm Hg	136 (117-155)	140 (120-160)	.01
Signs of heart failure on presentation	323 (41)	3688 (39)	.18
Creatinine level on presentation, median (IQR), mg/dL	1.2 (1.0-1.5)	1.2 (1.0-1.5)	.62
Hemoglobin level on presentation, median (IQR), g/dL	13 (12-15)	13 (12-14)	<.001
Peak troponin, median (IQR) <sup>f</sup>	85 (16-423)	51 (11-224)	<.001
Cardiogenic shock during index admission	104 (13)	898 (9)	<.001
VT/VF during index admission <sup>c</sup>	109 (14)	819 (9)	<.001
<b>In-hospital treatment</b>			
<b>During index admission</b>			
PCI	446 (57)	4439 (47)	<.001
CABG	96 (12)	930 (10)	.03
<b>Discharge</b>			
Aspirin use	734 (98)	8785 (97)	.55
Thienopyridine use	576 (74)	6455 (68)	<.001
β-Blocker use	712 (96)	8714 (97)	.33
ACE inhibitor/ARB use	607 (86)	6955 (83)	.04
Aldosterone antagonist use	99 (13)	879 (10)	.001
Statin use	669 (88)	7770 (85)	.04
<b>Postdischarge events</b>			
Cardiology follow-up within 2 wk of discharge <sup>c</sup>	235 (30)	1896 (20)	<.001
MI readmission within 1 y <sup>g</sup>	80 (10)	732 (8)	.01
Heart failure readmission within 1 y <sup>g</sup>	337 (43)	1597 (17)	<.001

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; BP, blood pressure; CABG, coronary artery bypass graft procedure; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; MI, myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; VF, ventricular fibrillation; VT, ventricular tachycardia.

<sup>a</sup> Data are No. (%) unless otherwise indicated.

<sup>b</sup> Calculated as weight in kilograms divided by height in meters squared.

<sup>c</sup> Data from Medicare.

<sup>d</sup> Dialysis or creatinine clearance <30 mL/min.

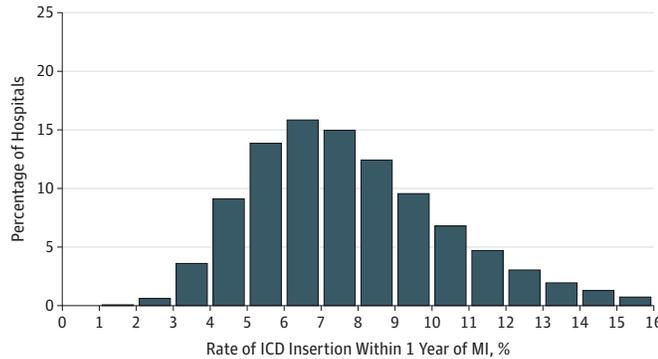
<sup>e</sup> Defined as membership in the Council of Teaching Hospitals and Health Systems.

<sup>f</sup> Troponin described as the ratio over institutional upper limit of normal.

<sup>g</sup> Presented as No. (rate per 100 patient-years).

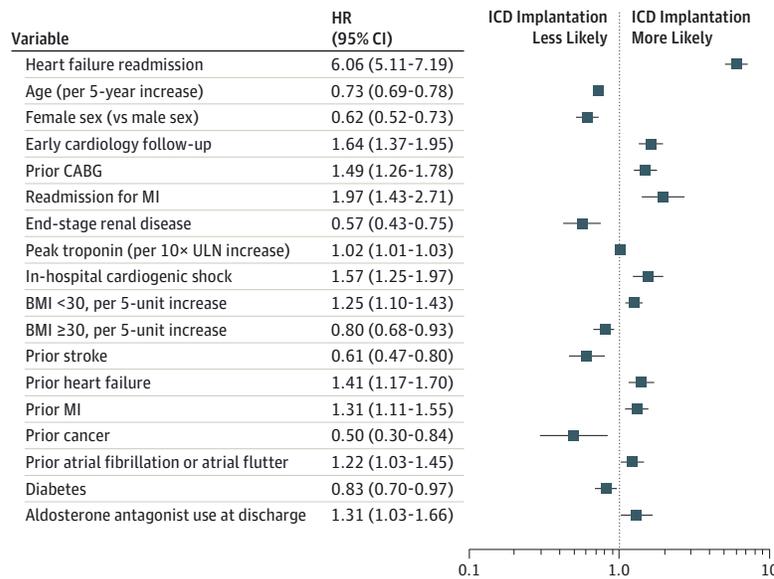
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Figure 1. Estimated Distribution of ICD Rates Across Hospitals Based on a Hierarchical Logistic Regression Model



This figure represents the 242 hospitals with at least 10 patients who underwent implantable cardioverter-defibrillator (ICD) implantation within 1 year of myocardial infarction (MI).

Figure 2. Forest Plot of the Association Between Patient Factors and ICD Implantation Within 1 Year After Myocardial Infarction



Cardiology follow-up was considered early if it occurred within 2 weeks of hospital discharge. HR indicates hazard ratio; ICD, implantable cardioverter-defibrillator; CABG, coronary artery bypass graft procedure; MI, myocardial infarction; ULN, upper limit of normal; BMI, body mass index.

implantation (3033 events in 11 479 patient-years, 26.4 events per 100 patient-years; unadjusted HR, 0.82; 95% CI, 0.68-0.98). After adjusting for patient characteristics and postdischarge time-dependent heart failure or MI readmissions, ICDs remained associated with significantly lower mortality (HR, 0.64; 95% CI, 0.53-0.78).

We conducted prespecified subgroup analyses by age and sex; 44% of our study population were 80 years or older (n = 4530), and 46% (n = 4734) were female. The relationship between ICD implantation and mortality was similar among patients 80 years or older (adjusted HR, 0.55; 95% CI, 0.39-0.76) and younger than 80 years (adjusted HR, 0.64; 95% CI, 0.51-0.80, P = .44 for interaction), as well as among male (adjusted HR, 0.64; 95% CI, 0.51-0.80) and female patients (adjusted HR, 0.65; 95% CI, 0.46-0.92, P = .92 for interaction).

**Sensitivity Analyses**

Several sensitivity analyses addressed the possibility that patients with certain comorbidities could be unlikely to receive ICDs. We first excluded patients with end-stage renal disease, prior stroke, or history of cancer within the last year (n = 3246), because clinicians may consider these to be potential contraindications to ICD use. The incidence of ICD implantation was 9.7% (95% CI, 9.0%-10.4%), and ICD use remained associated with lower mortality (adjusted HR, 0.62; 95% CI, 0.48-0.79).

The propensity scores for the patients who received and did not receive an ICD within 1 year largely overlapped (eAppendix 5 in the Supplement). When we excluded patients with propensity scores below the 5th percentile or above the 95th percentile, ICD use remained significantly associated

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with lower mortality (114 events, 15.1 events per 100 patient-years) compared with patients with no ICD (1915 events, 21.2 events per 100 patient-years; adjusted HR, 0.61; 95% CI, 0.49-0.76). In a sensitivity analysis limited to patients who survived 40 days after MI, ICD use again remained significantly associated with lower mortality (91 events, 12.5 events per 100 patient-years) relative to no ICD use (2263 events, 21.3 events per 100 patient-years; adjusted HR, 0.65; 95% CI, 0.53-0.79).

### Discussion

Fewer than 1 in 10 Medicare patients with low EF after acute MI received an ICD within 1 year after hospital discharge. In this older population, 1-year ICD implantation was associated with significantly lower 2-year mortality after adjustment for differences in baseline characteristics, in-hospital revascularization status, and postdischarge MI or heart failure readmissions. Increased patient contact with the health care system, via early cardiology follow-up or readmission for MI or heart failure, was associated with higher likelihood of ICD implantation.

Prior studies highlighted potential underuse of ICDs among eligible patients in routine clinical practice. Among patients who had sudden cardiac death, only 13% of those previously eligible for a primary prevention ICD had a device implanted prior to their arrest.<sup>7</sup> Medicare data from 2002 found that only 8% of hospitalized patients with ischemic cardiomyopathy underwent ICD implantation.<sup>19</sup> In a study of 533 acute MI patients with low EF, only 2% underwent ICD implantation in the next year.<sup>8</sup> By linking a large, national acute MI registry with Medicare data, our study is unique in its ability to evaluate the use and timing of ICD implantation in the post-MI setting, particularly in an understudied older-aged population who are at high risk of cardiac adverse outcomes yet are often undertreated. The detailed clinical data in ACTION Registry-GWTG permitted rigorous risk adjustment when examining outcomes and exclusion of patients who may not be eligible for ICD therapy (eg, patients discharged to end-of-life care).

In our study, less than 9% of eligible, older MI patients with an EF of 35% or less underwent ICD implantation within 1 year. Although there was site-level variation, rates of ICD implantation were low across all discharging hospitals. Older patients have been shown to have lower rates of ICD use relative to younger patients.<sup>14</sup> This may be due to a perception that older patients derive less benefit from ICDs. Our study population was significantly older (median age, 78 years) than the study populations in Multicenter Automatic Defibrillator Implantation Trial II (MADIT II) (median age, 64 years)<sup>2</sup> and Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) (median age, 60 years).<sup>3</sup> The unadjusted analysis found that patients who did not receive vs those who did receive an ICD within 1 year of MI had a 1.7-fold higher proportion of death (26.4 per 100 patient-years vs 15.3 per 100 patient-years). After multivariable adjustment, we found that ICD implantation within 1 year after discharge

remained associated with significantly lower 2-year mortality. This association persisted in sensitivity analyses aimed at ensuring good overlap in the propensity to receive ICD and after excluding a subset of patients at high risk of non-arrhythmic death. The magnitude of this association (36% lower risk of 2-year all-cause mortality) is consistent with the 31% relative risk reduction seen among prior MI patients in MADIT II.<sup>2</sup>

The clinical benefit of ICD implantation in patients of very advanced age is debated.<sup>20</sup> Older patients have similar rates of appropriate ICD shocks relative to younger patients, and these shocks are similarly successful in aborting sudden cardiac death.<sup>21</sup> However, the prevention of sudden cardiac death may have limited effect on overall mortality in patients older than 80 years. In our study, 4530 patients (44%) were 80 years or older, and we found a similar relationship between ICD implantation and mortality among patients aged 80 years or older and those younger than 80 years. These results are consistent with previous smaller observational studies.<sup>13,22,23</sup> Individualized shared decision making, taking into context the patient's quality of life, treatment goals, and preferences, is critical, because ICD therapy may shift death from a sudden event to a more gradual and comorbid process. Age alone should not be an exclusion for ICDs, and better risk prediction tools validated among older patients are needed.

Post-MI recovery of ventricular function may be a reason ICD implantation was not pursued, but postdischarge EF measurements were not available in our data. A previous study showed low EF recovery rates, so this is unlikely to fully explain the very low ICD implantation rate observed in our study.<sup>24</sup> High peak cardiac biomarkers and EF of 25% or less at the time of MI have both been associated with low rates of EF recovery,<sup>24,25</sup> but rates of ICD use after MI were similar among the overall study population (8.1%), the top tertile of peak troponin (10.4%), and patients with EF of 25% or less (11.4%). These findings support the theory that EF recovery may not be the major driver of the low observed rates of ICD use.

Patients at higher likelihood of ICD implantation within 1 year after MI appear to be those with more frequent postdischarge interactions with the cardiology care system due to early cardiology follow-up or readmissions for heart failure or MI. This message is familiar, as prior literature has shown lower ICD implantation rates in patients hospitalized on noncardiology services.<sup>26</sup> The inpatient-to-outpatient transition of care is important for ICD consideration after MI, because there is an obligate 40-day waiting period between the inpatient MI and when the patient is eligible for the therapy. Close clinical follow-up is necessary to optimize medical therapy prior to ICD implantation.<sup>27</sup> The post-MI care transition is a point of vulnerability amenable to potential quality improvement interventions. Health system interventions that encourage close outpatient follow-up, improve communication and implementation of longitudinal care plans, and educate patients should be studied to assess whether they can effectively optimize ICD consideration and use.

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Although this analysis represents the largest study of post-MI ICD implantation patterns and outcomes in an older patient population, several limitations need to be acknowledged. In the observational setting, we cannot infer a causal relationship between ICD use and mortality. Despite rigorous risk adjustment, the possibility of confounding by unmeasured covariates remains. However, the consistency of the association between ICD and mortality in sensitivity analyses is reassuring. Medicare claims data do not capture reasons for non-ICD implantation or EF levels if remeasured after MI. Recovery of EF may account for a small proportion of patients who did not undergo ICD implantation, as discussed earlier in this section. Some patients may have declined ICD implantation based on goals of care or preferences, but historical data would suggest this is the minority of patients.<sup>26</sup> Analyses of cardiovascular vs noncardiovascular death were not possible because cause of death could not be adjudicated in claims data.

We could not verify that ICD recipients met guideline criteria for implantation, although all patients had an EF of 35% or less at the time of MI and nearly 90% of patients were treated with optimal heart failure therapies at discharge. The findings in this older population may not be generalizable to a younger patient population.

## Conclusions

In this large registry study of older patients who experienced MI from 2007 to 2010, fewer than 1 in 10 eligible patients with low EF received an ICD within 1 year after MI, although ICD implantation was associated with lower risk-adjusted mortality at 2 years. Additional research is needed to determine evidence-based approaches to increase ICD implantation among eligible patients.

### ARTICLE INFORMATION

**Author Contributions:** Drs Pokorney and Wang had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

**Study concept and design:** Wang.

**Acquisition, analysis, or interpretation of data:** Pokorney, Miller, Chen, Thomas, Fonarow, de Lemos, Al-Khatib, Peterson, Wang.

**Drafting of the manuscript:** Pokorney, Chen, Thomas, Wang.

**Critical revision of the manuscript for important intellectual content:** Pokorney, Miller, Chen, Thomas, Fonarow, de Lemos, Al-Khatib, Peterson, Wang.

**Statistical analysis:** Chen, Thomas.

**Obtained funding:** Peterson, Wang.

**Administrative, technical, or material support:** Chen, Thomas, Wang.

**Study supervision:** Chen, Thomas, Peterson, Wang.

**Conflict of Interest Disclosures:** All authors have completed and submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Dr Pokorney reported having received grants or research support from AstraZeneca, Gilead, and Boston Scientific and having served on an advisory board for Janssen Pharmaceuticals. Dr Fonarow reported having served as a consultant or advisory board member for Ortho McNeil. Dr de Lemos reported having received honoraria from AstraZeneca and having served as a consultant or advisory board member for sanofi-aventis and Daiichi Sankyo. Dr Peterson reported having received grants or research support from Eli Lilly, Janssen Pharmaceuticals, and American Heart Association and having served as a consultant or advisory board member for Boehringer Ingelheim, Bristol-Myers Squibb, Janssen Pharmaceuticals, Pfizer, and Genentech. Dr Wang reported having received research grants or research support from Gilead, Eli Lilly, Daiichi Sankyo, AstraZeneca, Boston Scientific, Regeneron, and GlaxoSmithKline and having received honoraria from AstraZeneca and Eli Lilly. No other disclosures are reported.

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### REFERENCES

- Roger VL, Go AS, Lloyd-Jones DM, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics: 2012 update: a report from the American Heart Association. *Circulation*. 2012;125(1):e2-e220.
- Moss AJ, Zareba W, Hall WJ, et al; Multicenter Automatic Defibrillator Implantation Trial II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med*. 2002;346(12):877-883.
- Bardy GH, Lee KL, Mark DB, et al; Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med*. 2005;352(3):225-237.
- Hohnloser SH, Kuck KH, Dorian P, et al; DINAMIT Investigators. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. *N Engl J Med*. 2004;351(24):2481-2488.
- Steinbeck G, Andresen D, Seidl K, et al; IRIS Investigators. Defibrillator implantation early after myocardial infarction. *N Engl J Med*. 2009;361(15):1427-1436.
- Yancy CW, Jessup M, Bozkurt B, et al; Writing Committee Members; American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. 2013 ACCF/AHA guideline for the management of heart failure: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. 2013;128(16):e240-e327.
- Narayanan K, Reinier K, Uy-Evanado A, et al. Frequency and determinants of implantable cardioverter defibrillator deployment among primary prevention candidates with subsequent sudden cardiac arrest in the community. *Circulation*. 2013;128(16):1733-1738.
- Miller AL, Gosch K, Daugherty SL, et al. Failure to reassess ejection fraction after acute myocardial infarction in potential implantable cardioverter/defibrillator candidates: insights from the Translational Research Investigating Underlying Disparities in Acute Myocardial Infarction Patients' Health Status (TRIUMPH) registry. *Am Heart J*. 2013;166(4):737-743.
- Pham HH, Grossman JM, Cohen G, Bodenheimer T. Hospitalists and care transitions: the divorce of inpatient and outpatient care. *Health Aff (Millwood)*. 2008;27(5):1315-1327.
- Kripalani S, LeFevre F, Phillips CO, Williams MV, Basaviah P, Baker DW. Deficits in communication and information transfer between hospital-based and primary care physicians: implications for patient safety and continuity of care. *JAMA*. 2007;297(8):831-841.
- Go AS, Mozaffarian D, Roger VL, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics: 2014 update: a report from the American Heart Association. *Circulation*. 2014;129(3):e28-e292.
- Gardin JM, Siscovick D, Anton-Culver H, et al. Sex, age, and disease affect echocardiographic left ventricular mass and systolic function in the free-living elderly: the Cardiovascular Health Study. *Circulation*. 1995;91(6):1739-1748.
- Chan PS, Nallamothu BK, Spertus JA, et al. Impact of age and medical comorbidity on the effectiveness of implantable cardioverter-defibrillators for primary prevention. *Circ Cardiovasc Qual Outcomes*. 2009;2(1):16-24.
- Hess PL, Grau-Sepulveda MV, Hernandez AF, et al. Get With The Guidelines Steering Committee and Hospitals. Age differences in the use of implantable cardioverter-defibrillators among older

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patients hospitalized with heart failure. *J Cardiovasc Electrophysiol*. 2013;24(6):664-671.

15. Peterson ED, Roe MT, Rumsfeld JS, et al. A call to ACTION (acute coronary treatment and intervention outcomes network): a national effort to promote timely clinical feedback and support continuous quality improvement for acute myocardial infarction. *Circ Cardiovasc Qual Outcomes*. 2009;2(5):491-499.

16. Peterson ED, Roe MT, Chen AY, et al. The NCDR ACTION Registry-GWTG: transforming contemporary acute myocardial infarction clinical care. *Heart*. 2010;96(22):1798-1802.

17. Hammill BG, Hernandez AF, Peterson ED, Fonarow GC, Schulman KA, Curtis LH. Linking inpatient clinical registry data to Medicare claims data using indirect identifiers. *Am Heart J*. 2009;157(6):995-1000.

18. Roe MT, Chen AY, Thomas L, et al. Predicting long-term mortality in older patients after non-ST-segment elevation myocardial infarction: the CRUSADE long-term mortality model and risk score. *Am Heart J*. 2011;162(5):875-883.e1, e871.

19. Gauri AJ, Davis A, Hong T, Burke MC, Knight BP. Disparities in the use of primary prevention and defibrillator therapy among blacks and women. *Am J Med*. 2006;119(2):167.e17-167.e21.

20. Santangeli P, Di Biase L, Dello Russo A, et al. Meta-analysis: age and effectiveness of prophylactic implantable cardioverter-defibrillators. *Ann Intern Med*. 2010;153(9):592-599.

21. Yung D, Birnie D, Dorian P, et al. Survival after implantable cardioverter-defibrillator implantation in the elderly. *Circulation*. 2013;127(24):2383-2392.

22. Pellegrini CN, Lee K, Olgin JE, et al. Impact of advanced age on survival in patients with implantable cardioverter defibrillators. *Europace*. 2008;10(11):1296-1301.

23. Krahn AD, Connolly SJ, Roberts RS, Gent M; ATMA Investigators. Diminishing proportional risk of sudden death with advancing age: implications for prevention of sudden death. *Am Heart J*. 2004;147(5):837-840.

24. Solomon SD, Glynn RJ, Greaves S, et al. Recovery of ventricular function after myocardial

infarction in the reperfusion era: the healing and early afterload reducing therapy study. *Ann Intern Med*. 2001;134(6):451-458.

25. Sjöblom J, Muhrbeck J, Witt N, Alam M, Frykman-Kull V. Evolution of left ventricular ejection fraction after acute myocardial infarction: implications for implantable cardioverter-defibrillator eligibility. *Circulation*. 2014;130(9):743-748.

26. LaPointe NM, Al-Khatib SM, Piccini JP, et al. Extent of and reasons for nonuse of implantable cardioverter defibrillator devices in clinical practice among eligible patients with left ventricular systolic dysfunction. *Circ Cardiovasc Qual Outcomes*. 2011;4(2):146-151.

27. Miller AL, Wang Y, Curtis J, Masoudi FA, Buxton AE, Wang TY. Optimal medical therapy use among patients receiving implantable cardioverter/defibrillators: insights from the National Cardiovascular Data Registry. *Arch Intern Med*. 2012;172(1):64-67.