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Non–Evidence-Based ICD Implantations in the United States: Results from the NCDR-ICD Registry

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Abstract

Context—Practice guidelines do not recommend a primary prevention implantable cardioverter defibrillator (ICD) in patients recovering from a myocardial infarction (MI) or coronary artery bypass grafting (CABG) and those with severe heart failure symptoms or a recent diagnosis of heart failure.

Objective—To determine the number, characteristics, and in-hospital outcomes of patients who receive a non–evidence-based ICD and examine the distribution of these implants by site, physician specialty, and year of procedure.

Design, Setting, and Patients—Retrospective cohort study of cases submitted to the National Cardiovascular Data Registry-ICD Registry between 1/1/06 and 6/30/09.

Main Outcome Measure—In-hospital outcomes.

Results—The number of non–evidence-based ICD implants was 25,145 out of 111,707 (22.5%). The risk of in-hospital death and any post-procedure complication was significantly higher in patients who received a non–evidence-based ICD (0.6% [95% CI 0.5, 0.7] vs. 0.2% [95% CI 0.1, 0.2] and 3.2% [95% CI 3.0, 3.5] vs. 2.4% [95% CI 2.3, 2.5] respectively; $p < 0.0001$ for each comparison). There was substantial variation in non–evidence-based ICDs by site. The rate of non–evidence-based ICD implants was significantly lower for electrophysiologists (20.8% [95% CI 20.5, 21.1]) than non-electrophysiologists (24.8% [95% CI 24.2, 25.3] for non-electrophysiology cardiologists, 36.1% [95% CI 34.3, 38.0] for thoracic surgeons, 24.9% [95% CI 23.8, 25.9] for other specialties) ($p < 0.0001$). There was no clear decrease in the rate of non–

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Dr Al-Khatib had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

evidence-based ICDs over time (24.5% in 2006, 21.8% in 2007, 22.0% in 2008, 21.7% in 2009, $p<0.0001$ for a trend from 2006 to 2009 and $p=0.94$ for a trend from 2007 to 2009).

Conclusions—Among patients with ICD implants in this registry, 22.5% did not meet evidence-based criteria for implantation.

Keywords

implantable cardioverter defibrillator; indication; ICD Registry

Several randomized clinical trials have proven the efficacy of the implantable cardioverter defibrillator (ICD) at preventing sudden cardiac death in patients with advanced systolic heart failure.¹⁻³ These trials excluded patients who were in the acute phase of a myocardial infarction (MI), just had coronary revascularization, had New York Heart Association (NYHA) class IV symptoms, or had newly diagnosed heart failure. In other clinical trials, survival benefit from ICD therapy could not be demonstrated in patients recovering from an acute MI and patients who received an ICD at the time of coronary artery bypass grafting (CABG).⁴⁻⁶

The 2006 and 2008 practice guidelines for ICD therapy mandate at least a 40-day period following an MI before an ICD is implanted for a primary prevention indication. These guidelines also emphasize that ICD therapy is not indicated for NYHA class IV patients who are not candidates for a cardiac resynchronization therapy device. Finally, these guidelines specify that recommendations for primary prevention ICDs apply only to patients whose left ventricular ejection fraction is low (30% or 35%) despite receiving optimal medical therapy. Because this criterion is highly unlikely to be met by patients with newly diagnosed heart failure, these guidelines imply that ICD therapy is not recommended for patients with a new diagnosis of heart failure.^{7,8} The degree to which physicians in routine clinical practice follow these evidence-based recommendations is not clear.

We analyzed data from the National Cardiovascular Data Registry (NCDR)-ICD Registry, a national registry of ICD implantations, to determine the number and characteristics of patients recovering from an acute MI or CABG, patients with NYHA class IV symptoms, or patients with newly diagnosed heart failure who receive an ICD, to compare the characteristics and in-hospital outcomes of such patients with those of patients who receive an evidence-based ICD and to examine the distribution of these implants by site, physician specialty, and year of procedure.

METHODS

Data Source

When officials from the Centers for Medicare and Medicaid Services (CMS) announced their expanded coverage for ICD implantation for the primary prevention of sudden cardiac death in January 2005, they mandated that data on all such implants in Medicare beneficiaries be entered into a national ICD Registry. To respond to this mandate, the Heart Rhythm Society partnered with the ACC-NCDR to establish a national registry of ICD implantations that was launched on June 30, 2005. The Registry is being funded by hospital fees and grants from device companies and payers. Although CMS mandated submission of data only for primary prevention ICDs in Medicare beneficiaries, 78% of 1448 participating hospitals are submitting data on all ICD implants including procedures performed on non-Medicare patients and those performed for secondary prevention of sudden cardiac death. Because these hospitals are generally the larger participating hospitals, this accounts for 90% of the >520,000 ICD implants entered into the Registry as of April 2010.⁹

Details of the ICD Registry were published previously.¹⁰ After formal training on data collection and entry by NCDR, participating hospitals submit data directly to the NCDR via a secure Web site. Submitted data undergo rigorous electronic quality checks. If the data do not pass completeness criteria, participants can clean their data and resubmit as often as needed until the data pass. Annually, participants are randomly selected for an on-site audit (10%). Via quarterly reports, the NCDR shares data with sites on their rates of approved indications for primary prevention ICD implantations and in-hospital mortality and other adverse events. Their results are displayed in comparison with a national average for each of these endpoints.¹⁰

Because our study predates version 2.1 of the ICD Registry, all data analyzed in this study were collected using version 1 of the data collection form.

Patient Population

The ICD Registry was queried to identify adult patients (≥ 18 years) with ischemic or non-ischemic cardiomyopathy who underwent initial ICD implantation for a primary prevention indication between January 1, 2006 and June 30, 2009. Patients who had the ICD implanted for a secondary prevention indication or for inducible sustained ventricular tachycardia on electrophysiologic testing, patients who received an ICD with cardiac resynchronization therapy, and patients who received device replacements were excluded from this analysis.

Outcomes

All patients included in this analysis had a prior MI and ejection fraction < 30%, or prior congestive heart failure and ejection fraction < 35%. Patients were classified as receiving a non-evidence-based implant if they met any of the following criteria: 1) had an MI within 40 days before ICD implantation; 2) had CABG within 3 months before ICD implantation; 3) had NYHA class IV symptoms; or 4) had newly diagnosed heart failure at the time of ICD implantation (a patient could meet more than 1 criterion). Patients were classified as receiving an evidence-based implant if they met none of these criteria.

We determined the number and demographic and clinical characteristics of patients within each of the non-evidence-based implant subgroups. We compared the characteristics and in-hospital outcomes of patients receiving a non-evidence-based ICD implant with those of patients receiving an evidence-based ICD implant. In-hospital outcomes that were examined included death, any post-procedure complication, cardiac tamponade, pneumothorax, infection, hematoma, and length of hospital stay. We also examined the distribution of non-evidence-based ICD implants by site, physician specialty, and year of procedure.

Determination of Physician Certification

Details of this methodology were published previously.¹¹ In brief, the databases of the American Board of Internal Medicine, the Society for Thoracic Surgeons, and the American College of Surgery were manually searched to determine physician certification using a combination of physician name and either National Provider Identifier or Unique Physician Identification Number.¹¹ The categories included electrophysiologists, non-electrophysiology cardiologists, thoracic surgeons, and “other.” Physicians in the “other” category included internists and surgeons.

Statistical Analysis

This study was approved by the institutional review board of the Duke University Health System that determined that informed consent was not applicable to data collected by the ICD Registry. The authors had full access to the data and take responsibility for its integrity.

The baseline characteristics of the different subgroups of patients with a non-evidence-based ICD implant are presented as medians and 25th and 75th percentiles for continuous variables and as percentages for categorical variables. We compared the characteristics and in-hospital outcomes of patients receiving a non-evidence-based ICD implant with those of patients receiving an evidence-based implant using the Wilcoxon rank-sum test for continuous variables, due to non-normality of variable distributions (by the Kolmogorov-Smirnov test), and the chi-square test for categorical variables. Differences were declared to be statistically significant for a $p < 0.05$, and all statistical tests were 2-sided. A logistic regression model was used to adjust in-hospital outcomes for the following variables: age, gender, atrial fibrillation/flutter, prior ventricular tachycardia, cerebrovascular disease, chronic lung disease, diabetes, end-stage renal disease, and LVEF. We conducted a sensitivity analysis in which we excluded patients with NYHA class IV symptoms to determine the effect that these patients had on the main results.

Individual sites established the race and ethnicity of patients receiving an ICD and submitted these data to the ICD Registry. Race is included as a data element in all the NCDR registries because of the importance of assessing how access to medical care, selection of specific therapies, and procedural complications may be related to race.

All sites ($n=1227$) were included in this study. In the analysis of the distribution of non-evidence-based ICD implants by site, we excluded sites performing fewer than 20 implants ($n=315$, with 2786 patients) and an additional 7748 patients whose records were missing site identifiers.

In analyzing the distribution of non-evidence-based implants by physician specialty, we excluded 12,090 records with no data on physician specialty. We compared rates of non-evidence-based ICD implants between each physician specialty group and electrophysiologists, as the reference group, using the likelihood ratio chi-square tests. We examined temporal changes in non-evidence-based ICD implants from January 1, 2006 through June 30, 2009. A Mantel-Haenszel test was used to test for trends over time in the use of non-evidence-based implants as a proportion of all implants in each year (6 months for 2009). Proportions of each of the non-evidence-based implant subgroups were similarly tested. We used SAS version 8.2 for all analyses (SAS Institute Inc, Cary, NC).

RESULTS

Of the 112,678 patients who met our inclusion criteria, 971 were excluded for missing data. Of the remaining 111,707 initial primary prevention ICD implants that occurred between January 1, 2006 and June 30, 2009, 25,145 (22.5%) were for a non-evidence-based indication. Of these, 9257 (36.8%) were implanted in patients within 40 days from an MI, 814 (3.2%) were implanted in patients within 3 months from CABG, 3022 (12.0%) were implanted in patients with NYHA class IV symptoms, and 15,604 (62.1%) were implanted in patients with newly diagnosed heart failure.

The baseline characteristics of patients receiving any non-evidence-based ICD implant are presented in Table 1. The median age of these patients was 67 years (25th, 75th percentiles 57, 75 years). The majority were men (75.4%) and white (77.5%). Most patients had heart failure (91.8%) and ischemic heart disease (77.2%). The median ejection fraction was 25% (20%, 30%). The government was the primary insurance payer for 66% of these patients. In 63.3% of the patients, the ICD was a dual-chamber device.

As shown in Table 1, patients who received a non-evidence-based ICD were significantly older and sicker than patients who received an evidence-based ICD. Specifically, patients who received a non-evidence-based ICD were more likely to have heart failure, atrial

fibrillation/flutter, ischemic heart disease, cerebrovascular disease, chronic lung disease, diabetes, and end-stage renal disease. In addition, patients who received a non-evidence-based ICD were more likely to belong to a racial minority group (other than black) and to receive a dual-chamber ICD.

The demographic and clinical characteristics of the different subgroups are presented in Table 2. The median age ranged from 64.0 to 68.0 years. The majority of patients in all subgroups were male and white. The vast majority of patients had heart failure and ischemic heart disease in all subgroups except the subgroup of patients with NYHA class IV symptoms who were more likely to have non-ischemic dilated cardiomyopathy. The majority of patients received a dual-chamber ICD. Some patients (n=869) with NYHA class IV symptoms and a QRS duration of >120 ms who could have been potentially eligible for a cardiac resynchronization therapy device did not receive one.

As shown in Table 3, the risk of in-hospital death was significantly higher in patients who received a non-evidence-based device than patients who received an evidence-based device (0.6% [95% confidence interval (CI) 0.5, 0.7] vs. 0.2% [95% CI 0.1, 0.2]; $p<0.0001$). Likewise, the risk of any post-procedure complication was significantly higher in the non-evidence-based ICD group (3.2% [95% CI 3.0, 3.5] vs. 2.4% [95% CI 2.3, 2.5]; $p<0.0001$). Hematoma involving the ICD pocket was more common in patients receiving a non-evidence-based device (0.9% [95% CI 0.8, 1.0] vs. 0.7% [95% CI 0.7, 0.8]; $p=0.0093$). There was a trend toward a higher incidence of device-related infection in the non-evidence-based ICD group (0.04% [95% CI 0.02, 0.07] vs. 0.02% [95% CI 0.01, 0.03]; $p=0.056$). The risk of cardiac tamponade and pneumothorax was not significantly different between the 2 groups ($p=0.11$ and $p=0.56$, respectively). Adjusting for potential confounders, any adverse event and death were significantly higher in patients who received a non-evidence-based device ($p<0.0001$). There was a trend toward a higher risk of hematoma in the non-evidence-based ICD group ($p=0.066$). The median length of hospital stay was significantly longer for patients who received a non-evidence-based ICD compared with patients who received an evidence-based ICD (3 days vs. 1 day; $p<0.0001$). When these analyses were repeated after excluding patients with NYHA class IV symptoms, the rates of any post-procedure complication, death, and hematoma were significantly higher in patients who received a non-evidence-based ICD (Table 3).

As displayed in Figure 1, there was significant variation in the distribution of non-evidence-based ICD implants across sites with no clustering of such implants at a subset of sites. The proportion of ICD implants performed by the different types of physician specialty was as follows: 66,309 (66.6%) electrophysiologists, 24,706 (24.8%) non-electrophysiology cardiologists, 2561 (2.6%) thoracic surgeons, and 6041 (6.1%) other specialists. The rate of non-evidence-based ICD implants was significantly lower for electrophysiologists (20.8% [95% CI 20.5, 21.1]) than non-electrophysiologists (24.8% [95% CI 24.2, 25.3]) for non-electrophysiology cardiologists, 36.1% [95% CI 34.3, 38.0] for thoracic surgeons, 24.9% [95% CI 23.8, 25.9] for other specialties ($p<0.0001$ for all comparisons).

There was no clear decrease in the overall number of non-evidence-based ICD implants over time; 24.5% (6908/28,233) in 2006, 21.8% (7395/33,965) in 2007, 22.0% (7245/32,960) in 2008, and 21.7% (3597/16,549) in 2009 ($p<0.0001$ for a trend from 2006 to 2009 and $p=0.94$ for a trend from 2007 to 2009). The only subgroup that showed a significant decrease in non-evidence-based ICD implants over time as a proportion of all implants was patients within 40 days of an MI (10.5% in 2006, 7.7% in 2007, 7.9% in 2008, and 6.6% in 2009; $p<0.0001$ for a trend from 2006 to 2009 and $p=0.0003$ for a trend from 2007 to 2009). These results are displayed in Figure 2.

DISCUSSION

In a national sample of 111,707 recipients of an initial primary prevention ICD, we found an appreciable number (22.5%) of non-evidence-based ICD implants; i.e., patients who were either excluded from the major primary prevention clinical trials of ICD therapy or shown not to benefit from an ICD in other trials. Of great concern is that patients who received a non-evidence-based ICD were significantly sicker than patients who received an evidence-based device and were at a higher risk of post-procedural complications including death.

To our knowledge, our study is the first to examine in-hospital outcomes of patients receiving a non-evidence-based ICD nationally. Close examination of these outcomes shows there was 1 excess complication for every 121 non-evidence-based ICD implantations. Although the absolute difference in complications between the 2 groups is modest, these complications could have a significant impact on patient quality of life and health care utilization including length of hospital stay and costs. Importantly, these complications resulted from procedures that were not clearly indicated in the first place. While a small risk of complications is acceptable when a procedure has been shown to improve outcomes, no risk is acceptable if a procedure has no demonstrated benefit. It is noteworthy that the increased prevalence of comorbidities in recipients of non-evidence-based ICDs is undoubtedly associated with an increased risk of competing causes of death. As such, compared with patients who received an evidence-based ICD, these patients are likely to have worse intermediate and long-term outcomes including mortality. However, this needs to be confirmed by future studies.

In this time of limited resources and with the emphasis from CMS on quality improvement by promoting evidence-based care, it is increasingly important to assess hospital performance and to provide feedback to hospitals about their outcomes and their compliance with clinical guideline recommendations. Providing such feedback to hospitals has the potential to improve adherence to practice guidelines and eventually patient outcomes. In this study, we found substantial hospital variation in the use of non-evidence-based ICDs that at many sites constituted more than 40% of the overall number of implanted ICDs. Therefore, there is a great opportunity to educate sites and improve their adherence to guidelines. This highlights the significant role that the ICD Registry could play in quality improvement including the quality benchmarking reports provided to hospitals comparing their outcomes with a national aggregate.¹²

Unlike a previous analysis of the ICD Registry in which black and Hispanic patients were significantly more likely than white patients to meet all eligibility criteria for a cardiac resynchronization therapy device, patients who received a non-evidence-based ICD in our study were more likely to belong to a racial minority group other than black.¹³ Given that racial minorities have been shown to be less likely than white patients to receive evidence-based ICDs, it is concerning that some racial minority groups in this study were more likely to be recipients of a non-evidence-based device.¹⁴ Reasons for this finding need to be examined and addressed.

Importantly, the rate of non-evidence-based ICD implants was significantly higher for non-electrophysiologists than electrophysiologists. Potential reasons for this disparity include better knowledge of the data on primary prevention ICDs and increased commitment to adherence to practice guidelines by electrophysiologists. Future research should investigate real reasons behind this disparity and propose ways to decrease non-evidence-based ICD implants.

There was no clear decrease in the overall number of non-evidence-based ICD implants over time. Although these implants decreased significantly from 2006 to 2007, there was no

significant change from 2007 to 2009 to support a declining trend over time. These findings highlight the importance of continuing to enhance health care providers' knowledge of practice guidelines. The one subgroup that seemed to show a significant decrease in non-evidence-based ICD implants over time as a proportion of all implants was patients within 40 days of an MI. Although subgroup analyses should be viewed cautiously, potential reasons for this decline include wider dissemination of evidence-based practice guidelines, participation in the ICD Registry, and other quality improvement initiatives. Future accrual of data in the ICD Registry will allow a more robust examination of changes in non-evidence-based ICD implants over time.

Limitations

Our study has several limitations. First, the analysis of complications was limited to events occurring in the hospital. However, in a previous study, our group demonstrated that most ICD-related complications occur in the hospital.¹⁵ Second, hospitals are required to submit data on Medicare patients only, so this analysis may not reflect all cases. However, 78% of the hospitals entered data on all patients undergoing ICD implantation.⁹ Our results likely portray conservative estimates of non-evidence-based implants as submitting data on primary prevention ICDs in Medicare patients is mandatory, and to receive payment, hospitals have every incentive to ensure their procedures are performed for approved indications. It should be pointed out that some of these implants may have been clinically appropriate. The guidelines clarify that "the ultimate judgment regarding care of a particular patient must be made by the health care provider and the patient in light of all the circumstances presented by that patient. There are circumstances in which deviations from these guidelines are appropriate."^{7,8}

Conclusions

In this study, we found that a substantial number of ICDs are being implanted in patients who were either excluded from the major clinical trials of primary prevention ICDs or shown not to benefit from ICD therapy in other trials. Such patients are not only sicker than patients receiving an evidence-based device, but they are at a higher risk of in-hospital death and any post-procedure complication. We observed considerable variation in non-evidence-based ICD implants by site. The number of non-evidence-based ICD implants was significantly higher for non-electrophysiologists than electrophysiologists. There was no clear decrease in the overall number of non-evidence-based ICD implants over time. As such, more efforts should focus on enhancing adherence to evidence-based practice.

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Figure 1.
Rates of non-evidence-based ICD implants across sites.

Figure 2. Temporal changes in non-evidence-based ICD implants. The 2009 data are for the first 6 months only.

Table 1

Baseline Characteristics.

Characteristic	Non-Evidence- Based ICD Implant (N=25,145)	Evidence-Based ICD Implant (N=86,562)	P Value
Age, median (25th, 75th), yrs	67.0 (57.0, 75.0)	66.0 (57.0, 75.0)	0.0001
Male, No. (%)	18,965 (75.4)	64,464 (74.5)	0.0023
Race, No. (%)			<0.0001
White	19,463 (77.5)	66,730 (77.2)	
Black	3955 (15.7)	15,186 (17.6)	
Other	1695 (6.7)	4550 (5.3)	
Hispanic, No. (%)	1702 (6.8)	4893 (5.7)	<0.0001
Primary insurance payer, No. (%)			<0.0001
Government	16,589 (66.0)	57,209 (66.1)	
Commercial	5260 (20.9)	19,033 (22.0)	
HMO	2060 (8.2)	7604 (8.8)	
Other	1236 (4.9)	2716 (3.1)	
History of heart failure, No. (%)	23,092 (91.8)	75,700 (87.5)	<0.0001
Time since initial heart failure diagnosis, No. (%)			<0.0001
<3 months	15,604 (67.6)	0 (0.0)	
3 to 9 months	1558 (6.7)	15,770 (20.8)	
>9 months	5930 (25.7)	59,930 (79.2)	
NYHA class, No. (%)			<0.0001
I	1684 (6.7)	7490 (8.7)	
II	10,824 (43.0)	47,183 (54.5)	
III	9615 (38.2)	31,889 (36.8)	
IV	3022 (12.0)	0 (0.0)	
Atrial fibrillation/flutter, No. (%)	7166 (28.5)	23,445 (27.1)	<0.0001
Ischemic heart disease, No. (%)	19,415 (77.2)	60,826 (70.3)	<0.0001
Non-ischemic dilated cardiomyopathy, No. (%)	7052 (28.1)	29,425 (34.0)	<0.0001
Prior MI, No. (%)			<0.0001
None	8108 (32.2)	34,814 (40.2)	
Within 40 days of ICD implant	5601 (22.3)	0 (0.0)	
40 days prior to ICD implant	7780 (30.9)	51,748 (59.8)	
Within 40 days and >40 days prior to ICD implant	3656 (14.5)	0 (0.0)	
Prior CABG, No. (%)	9024 (35.9)	30,995 (35.8)	0.81
Cerebrovascular disease, No. (%)	3756 (14.9)	12,446 (14.4)	0.026
Chronic lung disease, No. (%)	6455 (25.7)	19,590 (22.6)	<0.0001
Diabetes, No. (%)	10,214 (40.6)	32,906 (38.0)	<0.0001
Hypertension, No. (%)	19,325 (76.9)	67,024 (77.4)	0.061
End-stage renal disease, No. (%)	1270 (5.1)	3349 (3.9)	<0.0001
LVEF, median (25th, 75th), %	25.0 (20.0, 30.0)	25.0 (20.0, 30.0)	<0.0001
QRS duration, median (25th, 75th), ms	104.0 (93.0, 120.0)	105.0 (94.0, 122.0)	<0.0001
Dual-chamber ICD, No. (%)	15,906 (63.3)	50,589 (58.4)	<0.0001

CABG indicates coronary artery bypass grafting; HMO, health maintenance organization; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association.

Table 2

Baseline Characteristics of the 4 Subgroups of Patients Who Received a Non-evidence-based ICD.

Characteristic	MI within 40 Days (N=9257)	CABG within 3 Months (N=814)	NYHA Class IV Symptoms (N=3022)	Newly Diagnosed Heart Failure (N=15,604)
Age, median (25th, 75th), yrs	68.0 (59.0, 75.0)	65.0 (57.0, 74.0)	64.0 (54.0, 74.0)	66.0 (56.0, 75.0)
Male, No. (%)	7185 (77.6)	663 (81.4)	2126 (70.4)	11,656 (74.7)
Race, No. (%)				
White	7485 (81.0)	682 (83.8)	2066 (68.4)	12,023 (77.1)
Black	1088 (11.8)	71 (8.7)	732 (24.2)	2533 (16.3)
Other	671 (7.2)	61 (7.5)	222 (7.4)	1029 (6.6)
Hispanic, No. (%)	678 (7.3)	58 (7.1)	247 (8.2)	977 (6.3)
Primary insurance payer, No. (%)				
Government	6341 (68.5)	490 (60.2)	2039 (67.5)	10,035 (64.3)
Commercial	1792 (19.4)	231 (28.4)	546 (18.1)	3447 (22.1)
HMO	725 (7.8)	67 (8.2)	230 (7.6)	1306 (8.4)
Other	399 (4.3)	26 (3.2)	207 (6.8)	816 (5.2)
History of heart failure, No. (%)	7395 (79.9)	677 (83.2)	2874 (95.1)	15,604 (100)
Time since initial heart failure diagnosis, No. (%)				
<3 months	2108 (28.5)	243 (35.9)	844 (29.4)	15,604 (100.0)
3 to 9 months	1087 (14.7)	173 (25.6)	355 (12.4)	0 (0.0)
>9 months	4200 (56.8)	261 (38.6)	1675 (58.3)	0 (0.0)
NYHA class, No. (%)				
I	893 (9.6)	88 (10.8)	0 (0.0)	832 (5.3)
II	4381 (47.3)	387 (47.5)	0 (0.0)	7102 (45.5)
III	3547 (38.3)	310 (38.1)	0 (0.0)	6826 (43.7)
IV	436 (4.7)	29 (3.6)	3022 (100.0)	844 (5.4)
Atrial fibrillation/flutter, No. (%)	2442 (26.4)	273 (33.5)	995 (32.9)	4486 (28.8)
Ischemic heart disease, No. (%)	8779 (94.8)	807 (99.1)	1954 (64.7)	10,989 (70.4)
Non-ischemic dilated cardiomyopathy, No. (%)	1026 (11.1)	38 (4.7)	1261 (41.8)	5373 (34.4)
Prior MI, No. (%)				
None	0 (0.0)	161 (19.8)	1439 (47.6)	6990 (44.8)
Within 40 days of ICD implant	5601 (60.5)	115 (14.1)	282 (9.3)	1518 (9.7)
40 days prior to ICD implant	0 (0.0)	510 (62.7)	1147 (38.0)	6506 (41.7)
Within 40 days and >40 days prior to ICD implant	3656 (39.5)	28 (3.4)	154 (5.1)	590 (3.8)
Prior CABG, No. (%)	3864 (41.7)	814 (100.0)	885 (29.3)	4755 (30.5)
Cerebrovascular disease, No. (%)	1534 (16.6)	122 (15.0)	483 (16.0)	2168 (13.9)
Chronic lung disease, No. (%)	2248 (24.3)	190 (23.3)	1025 (33.9)	3970 (25.5)
Diabetes, No. (%)	3989 (43.1)	366 (45.0)	1355 (44.8)	6078 (39.0)
Hypertension, No. (%)	7263 (78.5)	621 (76.5)	2324 (76.9)	11,852 (76.0)
End-stage renal disease, No. (%)	565 (6.1)	38 (4.7)	220 (7.3)	687 (4.4)
LVEF, median (25th, 75th), %	25.0 (20.0, 30.0)	25.0 (20.0, 30.0)	20.0 (15.0, 25.0)	25.0 (20.0, 30.0)

Characteristic	MI within 40 Days (N=9257)	CABG within 3 Months (N=814)	NYHA Class IV Symptoms (N=3022)	Newly Diagnosed Heart Failure (N=15,604)
QRS duration, median (25th, 75th), ms	106.0 (94.0, 121.0)	103.5 (93.0, 120.0)	106.0 (94.0, 126.0)	104.0 (92.0, 120.0)
Dual-chamber ICD, No. (%)	5915 (63.9)	532 (65.4)	1856 (61.4)	9898 (63.4)

CABG indicates coronary artery bypass grafting; HMO, health maintenance organization; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association.

Table 3

In-hospital outcomes.

Outcome	Non-Evidence- Based ICD Implant (N=25,145)	Evidence-Based ICD Implant (N=86,562)	P Value	Adjusted P Value *
Overall Population				
Any adverse event (including death)	813 (3.2 [3.0, 3.5])	2085 (2.4 [2.3, 2.5])	< 0.0001	< 0.0001
Hematoma	219 (0.9 [0.8, 1.0])	615 (0.7 [0.7, 0.8])	0.0093	0.066
Death	143 (0.6 [0.5, 0.7])	153 (0.2 [0.1, 0.2])	<0.0001	< 0.0001
Pneumothorax	111 (0.4 [0.4, 0.5])	359 (0.4 [0.4, 0.5])	0.56	0.64
Cardiac tamponade [†]	14 (0.1 [0.0, 0.1])	76 (0.1 [0.1, 0.1])	0.11	-
Device infection [†]	9 (0.04 [0.02, 0.07])	14 (0.02 [0.01, 0.03])	0.056	-
After excluding patients with NYHA class IV symptoms	(N=22,123)	(N=86,562)		
Any adverse event (including death)	659 (3.0 [2.8, 3.2])	2085 (2.4 [2.3, 2.5])	< 0.0001	0.0001
Hematoma	188 (0.8 [0.7, 1.0])	615 (0.7 [0.7, 0.8])	0.0308	0.12
Death	93 (0.4 [0.3, 0.5])	153 (0.2 [0.1, 0.2])	< 0.0001	< 0.0001

Values are presented as No. (% [95% CI]) unless otherwise indicated. ICD indicates implantable cardioverter defibrillator.

* Results were adjusted in a logistic regression model for the following variables: age, gender, atrial fibrillation/flutter, prior ventricular tachycardia, cerebrovascular disease, chronic lung disease, diabetes, end-stage renal disease, and LVEF.

[†] Pericardial tamponade and infection were too rare to provide a valid multivariable model fit.