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## Mortality Risk Following Replacement Implantable Cardioverter-Defibrillator Implantation at End of Battery Life: Results from the NCDR®

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### Abstract

**Background**—Implantable cardioverter-defibrillator (ICD) generator replacement at the end of expected battery life accounts for a substantial proportion of all ICD implant procedures. However, little is known about predictors of mortality following ICD generator replacement.

**Objective**—To identify clinical and procedural factors associated with death following ICD generator replacement.

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**Methods**—Patients from the National Cardiovascular Data Registry (NCDR<sup>®</sup>) ICD Registry™ receiving ICD generator replacements at the end of device battery life between January 1, 2005 and March 30, 2010 were eligible. Predictors of mortality were determined using multivariable Cox regression.

**Results**—Analysis of 111,826 patients (mean age 70.7 +12.4, 75.5% male) revealed 1-, 3-, and 5-year mortality of 9.8%, 27.0%, and 41.2%, respectively. After adjustment, atrial fibrillation (hazard ratio (HR) 1.23, 95% confidence interval (CI) 1.20 – 1.27) and congestive heart failure (HR 1.21, 95% CI 1.16 – 1.27) predicted worse survival. In addition to older age (HR 1.43 95% CI 1.41 – 1.45), several non-cardiac conditions were also associated with poorer survival, including: chronic lung disease (HR 1.53, 95% CI 1.49 – 1.57), cerebrovascular disease (HR 1.28, 95% CI 1.24 – 1.32), diabetes (HR 1.27, 95% CI 1.23 – 1.30), and lower glomerular filtration rate (HR 1.15 for each 10 unit (U) increment decline, 95% CI 1.14 – 1.16). In the absence of a non-ICD control group, risk reduction provided by ICD therapy in this cohort is not known.

**Conclusions**—In addition to age, atrial fibrillation, and congestive heart failure, non-cardiac comorbidities are associated with higher mortality following ICD replacement, which should be considered in the decision to undergo this procedure

## Keywords

Implantable cardioverter-defibrillators; outcomes research

## Introduction

Implantable cardioverter-defibrillator (ICD) implantation continues to attract intense scrutiny from clinicians, policy-makers, and the public.<sup>1</sup> Recent publication of appropriate use criteria (AUC) for ICD implantation further argues for refined decision-making for potential recipients of new devices.<sup>2</sup> The AUC draw in part from models derived from clinical trials,<sup>3, 4</sup> registries,<sup>5</sup> and academic centers<sup>6, 7</sup> describing survival following new ICD implantation, with the hope of identifying patients at particularly high risk for death despite the presence of an ICD. However, reports from nationwide data suggest that nearly 40% of all ICD implantations are replacements of existing devices.<sup>8</sup> Far less is known about the outcomes of these patients who are on average 3 years older than patients receiving new ICDs and have more arrhythmic comorbidities such as atrial fibrillation and ventricular tachycardia.<sup>9</sup> More than 20% of these patients will have received shocks from their ICD prior to replacement, with uncertain implications for long-term survival.<sup>8</sup>

Despite these important clinical complexities, survival following ICD generator replacement has only recently been evaluated in detail.<sup>9</sup> Prior analysis from the National Cardiovascular Data Registry – ICD Registry identified patients following generator replacement at the end of expected battery life to be at high risk for death compared to patients receiving new ICDs.<sup>9</sup> This hazard persisted with and without adjustment for key clinical variables, but the contribution of comorbidities and other factors to mortality in this group remain poorly understood.

Construction of prospective studies evaluating the management of patients eligible for ICD replacement will depend in part on a clearer picture of what contributes to post-replacement mortality.<sup>10</sup> Thus, the goals of this study were to identify clinical factors associated with mortality among patients following ICD generator replacement.

## Methods

### Data Source

This study analyzed data from the National Cardiovascular Data Registry (NCDR<sup>®</sup>) ICD Registry<sup>™</sup>, the details of which have been previously published.<sup>11–13</sup> In brief, the ICD Registry<sup>™</sup> was created in 2005 after the Centers for Medicare and Medicaid Services (CMS) national coverage decision for primary prevention ICD implantation, though most participating centers contribute data on all of their implants using data collected at the time of the procedure. Over 850,000 procedures have been captured as of December 2011, with over 12,000 new procedures entered each month.<sup>8</sup> All data entry for the current study was performed using the ICD Registry<sup>™</sup> Data Collection From v1.08.<sup>14</sup> Participating sites receive formal training on data collection and entry by the NCDR<sup>®</sup>. After submission, data are evaluated for quality and returned to sites if incomplete. Data from the ICD Registry<sup>™</sup> have been used to address key clinical research questions in prior studies<sup>12, 15</sup> including analysis of ICD generator replacement.<sup>9</sup>

Patient files are linked to the Social Security Death Index to determine patient vital status, which was available through 10/1/2011.

### Study Population

All patients receiving replacement ICDs between January 1, 2005 and March 30, 2010 were eligible for inclusion (Figure 1). Patients missing social security numbers were excluded as their vital status could not be determined. As the primary focus of this study was survival following routine replacement, subjects who did not have “end of expected battery life” as one of the reasons for replacement were also excluded. For patients with multiple entries (for initial and one or more replacement procedures) analysis of characteristics and survival focused on the first replacement procedure for which “end of expected battery life” pertained.

### Variables

The ICD Registry<sup>™</sup> collects over 130 standardized data elements describing demographic, clinical information and procedural information for each patient undergoing an ICD procedure. For this report, variables were selected *a priori* from the ICD Registry<sup>™</sup> that were felt to be necessary to describe and examine the characteristics and outcomes of patients receiving replacement ICDs based on American College of Cardiology / American Heart Association guidelines for device based therapy<sup>16</sup> as well as published literature regarding ICD outcomes (Table 1).<sup>3–6</sup>

Demographic variables included age, gender, race (white vs. other), and Hispanic ethnicity. Clinical information included data from clinical history and diagnostic studies. History of

the following cardiac conditions was collected: any ischemic heart disease, myocardial infarction, coronary artery bypass grafting, percutaneous coronary intervention, congestive heart failure, non-ischemic dilated cardiomyopathy (never, past 3 months, past 3–9 months, over 9 months), atrial fibrillation, ventricular tachycardia (none, nonsustained, monomorphic sustained, and polymorphic sustained), and abnormal sinus node function. Functional status was rated using the New York Heart Association levels I-IV. Finally, the presence of the following comorbid conditions were ascertained: cerebrovascular disease, chronic lung disease, diabetes, hypertension, and renal failure or dialysis.

The most recent information for the following were included; the left ventricular ejection fraction (%), QRS duration (ms), atrioventricular conduction pattern (normal, left bundle branch block (LBBB), right bundle branch block (LBBB), paced, or other), serum creatinine (mg/dl), and glomerular filtration rate (GFR) (ml/min) calculated using the Modification of Diet in Renal Disease Study Group (MDRD) Study equation.<sup>17</sup>

Procedure characteristics captured in the ICD registry included whether or not the procedure also involved an upgrade to a dual-chamber or biventricular system. The reason for hospitalization during which the device was placed was categorized as follows: ICD placement, congestive heart failure (CHF), cardiac but not for CHF, and non-cardiac. Type of device (single chamber, dual chamber, or biventricular) and whether the device was for primary or secondary prevention were also ascertained. In the ICD Registry, primary prevention indicates that the patient is at risk for but has not yet had an episode of sustained ventricular tachycardia, ventricular fibrillation, or resuscitated cardiac arrest. Thus, at the time of ICD replacement, a patient whose device was originally placed for primary prevention but subsequently experienced any of these events was coded as secondary prevention. Missing data were present <0.3% of the time for all data elements.

### Statistical Analysis

All baseline demographic data, clinical information, and procedural variables were described using frequencies for categorical variables and means/medians with SDs/interquartile ranges for continuous variables. Survival for the overall cohort was evaluated with the Kaplan-Meier method. For subjects who died, survival time was defined from the date of the ICD to replacement until the date of death. Subjects who did not die during the study observation period (ending 10/1/2011) were censored.

Predictors of survival were evaluated using Cox regression analysis. First, unadjusted hazard ratios and 95% confidence intervals were calculated for the following candidate variables: age (10 year increments); male gender; congestive heart failure (yes/no), NHYA heart failure class (using Class I as reference), atrial fibrillation, ventricular tachycardia (any), prior myocardial infarction, prior CABG, cerebrovascular disease, chronic lung disease, diabetes mellitus, hypertension, left ventricular ejection fraction (10 unit increments), QRS duration (5ms increments), GFR (10 unit increments), primary versus secondary prevention, and ICD type (single-chamber as reference). Next, a saturated model was created including all candidate variables, yielding adjusted hazard ratios and 95% confidence intervals. Complete case analysis was used to develop the model given the very low rate of missing variables.

## Results

### Baseline Patient Characteristics

From an initial pool of 533,817 procedures entered into the ICD Registry during the study period, 111,826 unique patients who received ICD replacements were eligible for analysis (see Figure 1). Only 3544 were excluded for lack of a usable social security number. The median follow-up time was 2.0 years (25–75% IQR 1.4–3.0), and the median time from initial ICD implantation was 4.6 years (25–75% IQR 3.6 – 5.8).

Table 1 presents the demographic, clinical and procedural characteristics of the study cohort at the time of their ICD replacement, which had a mean age of 70.7 +12.4 and was predominantly male (75.5%) and white (87.5%). In terms of the clinical substrate for ICD therapy, 67.6% of patients had coronary artery disease including 39.8% with a history of CABG, 31.3% prior PCI, and 55.5% prior MI. Congestive heart failure was present in 73.8% of patients, predominantly NYHA Class II (41.4%) or III (36.0%). Clinical arrhythmias were common including atrial fibrillation, any ventricular tachycardia, and sinus node dysfunction, as were diabetes and hypertension.

With regard to diagnostic studies at the time of ICD replacement, the mean left ventricular ejection fraction was 32.4 + 13.7%, mean serum creatinine was 1.3 + 0.9 mg/dL, and mean GFR was 63.7 ± 30.3 ml/min. Among patients without a paced rhythm (64,206, 57%), the median QRS was 120ms (25–75% IQR, 100–152).

### Procedural Characteristics

The vast majority of patients (92.6%) presented for their ICD replacement procedure specifically, and 65.6% received their devices for primary prevention of sudden cardiac death. For 6970 (6.2%) of all patients receiving replacement ICDs, an upgrade/lead addition was also performed. Device malfunction (1422, 1.3%), Recalls (1220, 1.1%), and infections (117, 0.1%) were uncommonly identified as additional reasons for replacement.

### Survival

One-, three-, and five-year mortality were 9.8%, 27.0%, and 41.2%, respectively (see Figure 2). Unadjusted and adjusted associations with mortality are detailed in Table 2. After multivariate adjustment, the cardiac conditions significantly associated with worse mortality included atrial fibrillation (HR 1.23, 95% CI 1.20 – 1.27) and the presence of congestive heart failure (HR 1.21, 95% CI 1.16 – 1.27), with NYHA Class III (HR 1.46, 95% CI 1.39 – 1.53) and Class IV (HR 2.24 95% CI 2.08--2.42) compared to Class I further worsening prognosis.

In addition to age (HR 1.43 95% CI 1.41 – 1.45), several non-cardiac comorbidities also were associated with worse mortality after multivariate adjustment. These included chronic lung disease (HR 1.53, 95% CI 1.49 – 1.57), cerebrovascular disease (HR 1.28, 95% CI 1.24 – 1.32), diabetes (HR 1.27, 95% CI 1.23 – 1.30), and renal function (HR 1.15 for each 10U decline in GFR, 95% CI 1.14 – 1.16).

With regard to device type, both dual-chamber and biventricular devices were associated with worse survival compared with single-chamber devices prior to adjustment, but after adjustment both were protective (dual chamber HR 0.86, 95% CI 0.83–0.90; biventricular HR 0.80, 95% CI 0.76 – 0.84).

## Discussion

This study reports, for the first time, the demographic, clinical, and procedural variables associated with survival in a nationwide sample of patients following routine replacement of ICD generators at the end of expected battery life. We found that atrial fibrillation, heart failure, and left ventricular ejection fraction were independently associated with poorer survival in this cohort. In addition, non-cardiac comorbidities including chronic lung disease, cerebrovascular disease, diabetes, and worse renal function were also independently associated with worse survival. Overall, over 40% of patients died within 5 years. These findings underscore the importance of evaluating patients' entire clinical history at the time of ICD generator replacement, with particular attention to accumulated comorbidities that may limit life expectancy and the potential of benefiting from ongoing treatment with an ICD.<sup>10</sup>

These results build upon prior attempts to characterize survival among recipients of ICDs, though nearly all of these studies excluded patients receiving replacement ICDs.<sup>1</sup> In agreement with our data, models derived from institutional cohorts<sup>6, 7</sup> identified cardiovascular comorbidities such as atrial fibrillation and heart failure severity as well as age and renal function as predictive of mortality after initial ICD implant, though not COPD or diabetes. Chronic lung disease and diabetes did emerge from the largest study of new ICD implants, however. Bilchik et al assessed survival among 45,884 ICD recipients using Medicare data to develop their SHOCKED algorithm incorporating age >75 years, NYHA Class III, AF, chronic kidney disease, left ventricular ejection fraction <20%, COPD and diabetes.<sup>5</sup> In this model, COPD (HR 1.70; 95% CI 1.61 – 1.80) and diabetes (HR 1.43; 95% CI 1.36 – 1.50) contributed to mortality out to 4 years. Similarly, Lee et al evaluated survival among 2467 new ICD implants in a Canadian cohort. In addition to age, heart failure, peripheral arterial disease, and renal disease, Lee et al found non-cardiac comorbidities including chronic lung disease, cancer, rheumatologic disease, and microvascular complications from diabetes (but not diabetes alone) retained predictive power after adjustment.<sup>18</sup> In a separate study drawing upon older data (devices implanted 2001–2004), Stein et al found diabetes to remain predictive in a multivariate model evaluating 1-year survival (HR 1.68, 95% CI 1.18–2.18, P=0.0004).<sup>19</sup>

Critically, accumulated comorbidities among ICD recipients influence not only survival but also benefit from the device in randomized trial populations. For example, short- and long-term evaluation of the MADIT-II study demonstrated that the subgroup with the highest number of clinical predictors (from a model including age, renal function, atrial fibrillation, heart failure class, and QRS width) had no survival advantage with ICD therapy.<sup>4, 20</sup> Levy et al found a similar pattern among patients from the SCD-HeFT study in which patients were grouped by risk using the Seattle Heart Failure Model.<sup>21</sup> Again, no benefit was seen in the highest risk group. These models, however, did not include many of the non-cardiac

conditions noted in observational studies of new implants – and now confirmed in our evaluation of ICD replacement. In addition, the MADIT-II and SCD-HeFT models evaluated only single-chamber systems, whereas our data include dual- and biventricular devices. Our finding of an excess hazard for each of these device types before adjustment that become protective after adjustment suggests that selection of both systems depends in part on comorbidities and may influence outcome substantially. Thus, prospective studies addressing both clinical and cost-effectiveness of ICD replacement should include variables including chronic lung disease, cerebrovascular disease, and diabetes as well as single-, dual-, and biventricular devices

Our study should be interpreted in context with potential limitations. Though this cohort was largely white and male, the ICD Registry™ represents a nationwide sample of ICD recipients in the United States, and thus reflects current implantation patterns. Our cohort included patients who necessarily survived to the point of ICD replacement, and thus description of their comorbidities and disease severity is conditional on their remaining healthy enough to arrive at this clinical decision. As battery life for generator models improves, the influence of this greater time to replacement on comorbidities may be uncertain. We did not have a control group of patients without ICDs, and could not identify cause of death (e.g. arrhythmic versus nonarrhythmic) from SSDI alone. Thus, we are unable to describe survival in our population in the absence of device-based therapy. Accordingly, our findings alone should not guide clinical decision-making for patients eligible for ICD replacement. However, these data may support discussions with potential ICD recipients about life expectancy and accumulated comorbidity, and will help inform prospective studies designed to refine clinical indications and outcomes following ICD replacement.

## Conclusion

Survival following ICD replacement is influenced by atrial fibrillation and heart failure severity, and also non-cardiac comorbidities including chronic lung disease, cerebrovascular disease, diabetes, and renal function.

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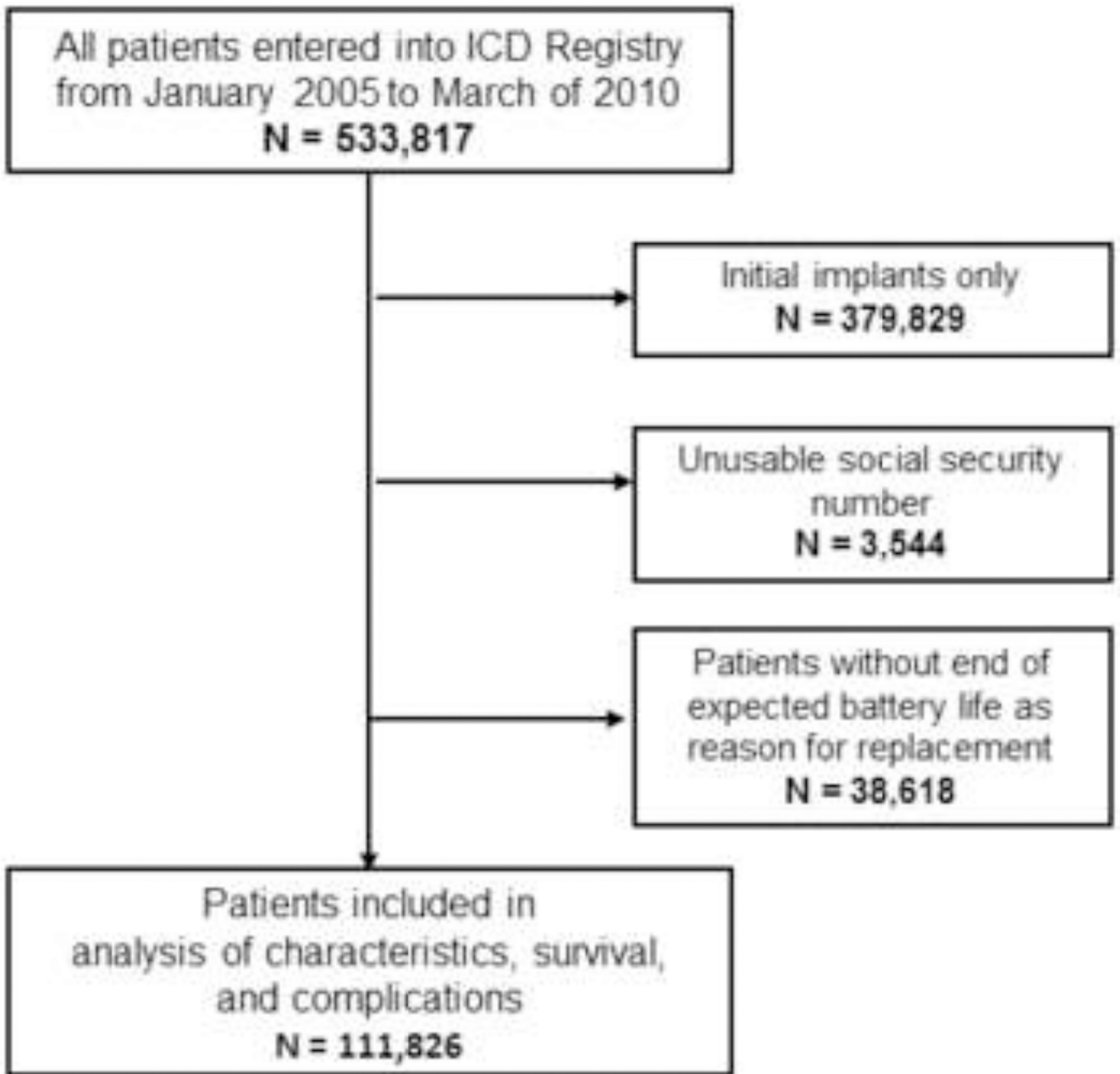
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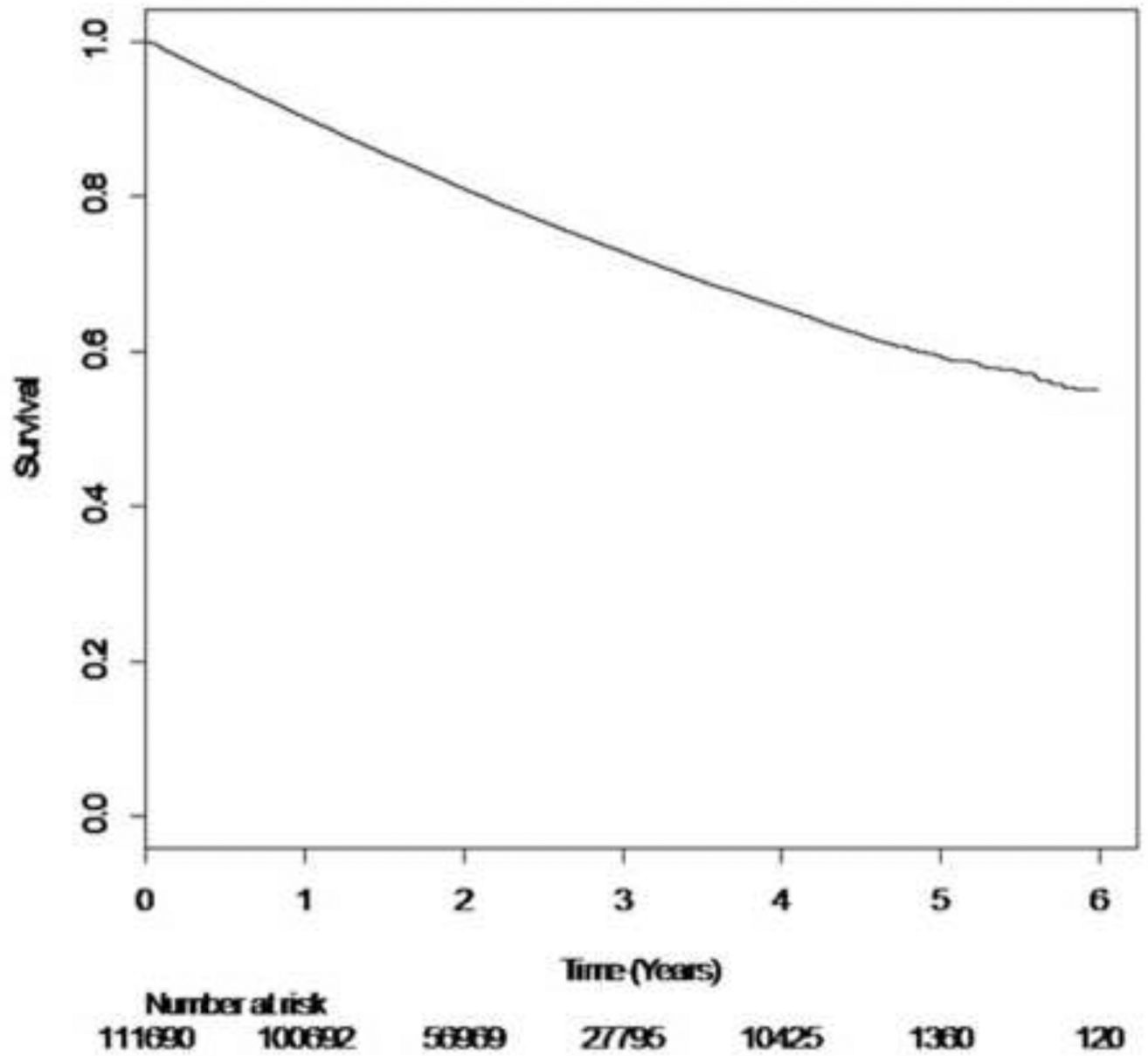


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**Figure 1.**

All patients entered into the ICD Registry from January 2005 – March 2010 were eligible. Those who only received initial ICD implants and those without usable social security numbers were excluded. For those patients receiving replacement ICDs, those whose reason(s) for replacement did not include end of expected battery life were also excluded.



**Figure 2.**

Unadjusted KM curve for survival for patients receiving replacement ICDs, with the number at risk at yearly intervals of follow-up provided.

**Table 1**

Characteristics of Patients Receiving Replacement ICDs.

Characteristic	Total n = 111,826
<b>Demographics</b>	
Age (years)	70.7 ± 12.4
Male	84439 (75.5%)
Caucasian	97842 (87.5%)
Hispanic	4112 (3.7%)
<b>Clinical History</b>	
Any Ischemic Heart Disease	75609 (67.6%)
Prior myocardial infarction	62015 (55.5%)
Previous CABG	44439 (39.8%)
Prior percutaneous coronary intervention	35006 (31.3%)
Congestive Heart Failure	82474 (73.8%)
Non-Ischemic Dilated Cardiomyopathy	
No	81066 (72.5%)
Yes Within the past 3 months	1025 (0.9%)
Yes 3 to 9 months	717 (0.6%)
Yes Greater than 9 months	28954 (25.9%)
NYHA Class	
Class I	22743 (20.4%)
Class II	46237 (41.4%)
Class III	40158 (36.0%)
Class IV	2481 (2.2%)
Atrial Fibrillation	47162 (42.2%)
Ventricular Tachycardia	
None	47052 (42.1%)
Yes VT, Non Sustained	32600 (29.2%)
Yes Monomorphic Sustained VT	26895 (24.1%)
Yes Polymorphic Sustained VT	5175 (4.6%)
Abnormal Sinus Node Function	35845 (32.1%)
Cerebrovascular Disease	17849 (16.0%)
Chronic Lung Disease	24089 (21.5%)

Characteristic	Total n = 111,826
Diabetes	38430 (34.4%)
Hypertension	81953 (73.3%)
Renal Failure-Dialysis	3101 (2.8%)
Left ventricular ejection fraction %	32.4 ± 13.7
QRS Duration (ms)	138.3 ± 37.3
Atrioventricular Conduction	
Normal	32924 (29.4%)
LBBB	16149 (14.4%)
RBBB	6307 (5.6%)
PACED	47620 (42.6%)
OTHER	8826 (7.9%)
Serum creatinine (mg/dL)	1.365 ± 0.906
Glomerular filtration rate (ml/min)	63.7 ± 30.3
<b>ICD Procedure</b>	
Reason for Admission	
Admitted for this Procedure	103494 (92.6%)
Cardiac CHF	2442 (2.2%)
Cardiac Other	4570 (4.1%)
Noncardiac	1212 (1.1%)
ICD Indication	
Primary Prevention	73394 (65.6%)
Secondary Prevention	38432 (34.4%)
ICD Type	
Single Chamber	18423 (16.5%)
Dual Chamber	43547 (39.0%)
Biventricular	49694 (44.5%)
<b>Discharge Medications</b>	
ACE-Inhibitor	58949 (53.9%)
Amiodarone	20227 (18.5%)
ARB	20065 (18.3%)
Aspirin	67293 (61.5%)
Beta Blocker	92381 (84.4%)

Characteristic	Total n = 111,826
Coumadin	39498 (36.1%)
Digoxin	36410 (33.3%)
Diuretic	70653 (64.6%)

**Table 2**

Unadjusted and adjusted predictors of death among patients following ICD replacement. NYHA = New York Heart Association; MI = myocardial infarction; CABG = coronary artery bypass grafting; PCI = percutaneous coronary intervention; LVEF = left ventricular ejection fraction; GFR = glomerular filtration rate.

	Unadjusted Associations		"Saturated" Adjusted Associations	
	HR (CI)	p-value	HR (CI)	p-value
Age (10 Yrs)	1.583(1.564, 1.602)	<.0001	1.429(1.408, 1.449)	<.0001
Male Gender	1.258(1.221, 1.296)	<.0001	1.176(1.137, 1.217)	<.0001
Congestive heart failure	2.237(2.164, 2.313)	<.0001	1.213(1.161, 1.267)	<.0001
NYHA Class1 Class2 Class3 Class4	Reference 1.638 (1.573, 1.706) 2.725 (2.620, 2.834) 5.130 (4.805, 5.477)	<.0001	Reference 1.125 (1.072, 1.18) 1.457 (1.386, 1.532) 2.244 (2.081, 2.42)	<.0001
Atrial fibrillation	1.685(1.645, 1.726)	<.0001	1.232(1.200, 1.266)	<.0001
Ventricular tachycardia	0.988(0.964, 1.013)	0.3512	1.073(1.043, 1.105)	<.0001
Prior MI	1.317(1.284, 1.35)	<.0001	0.986(0.957, 1.016)	0.3700
Prior CABG	1.503(1.467, 1.54)	<.0001	1.076(1.046, 1.107)	<.0001
Prior PCI	1.035(1.009, 1.062)	0.0093	0.938(0.911, 0.966)	<.0001
Cerebrovascular disease	1.603(1.557, 1.651)	<.0001	1.276(1.236, 1.318)	<.0001
Chronic lung disease	1.798(1.751, 1.846)	<.0001	1.529(1.486, 1.573)	<.0001
Diabetes mellitus	1.46(1.425, 1.497)	<.0001	1.269(1.234, 1.304)	<.0001
Hypertension	1.227(1.193, 1.262)	<.0001	0.986(0.956, 1.018)	0.3953
LVEF (decreasing 10 units)	0.746(0.738, 0.755)	<.0001	1.186 (1.172,1.202)	<.0001
QRS Duration (increasing 5 Units)	1.037(1.036, 1.039)	<.0001	1.007(1.005, 1.008)	<.0001
GFR (decreasing 10 Units)	0.795(0.79, 0.799)	<.0001	1.149 (1.141, 1.157)	<.0001
Primary Prevention	1.138(1.109, 1.167)	<.0001	0.945(0.917, 0.974)	0.0002
ICD Type Single Dual Biv	Reference 1.024 (.986, 1.064) 1.639 (1.580, 1.700)	<.0001	Reference .864 (.828, .902) .798 (.763, .835)	<.0001