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Primary Prevention Implantable Cardioverter-Defibrillators in Older Racial and Ethnic Minority Patients

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Abstract

Background—Racial and ethnic minorities are underrepresented in clinical trials of primary prevention implantable cardioverter-defibrillators (ICDs). This analysis investigates the association between primary prevention ICDs and mortality among Medicare, racial/ethnic minority patients.

Methods and Results—Data from Get With The Guidelines-Heart Failure Registry and National Cardiovascular Data Registry's-ICD Registry were used to perform an adjusted comparative effectiveness analysis of primary prevention ICDs in Medicare, racial/ethnic minority patients (non-white race or Hispanic ethnicity). Mortality data were obtained from the Medicare denominator file. The relationship of ICD to survival was compared between minority and white non-Hispanic patients. Our analysis included 852 minority patients, 426 ICD and 426 matched non-ICD patients, and 2,070 white non-Hispanic patients (1,035 ICD and 1,035 matched non-ICD patients). Median follow-up was 3.1 years. Median age was 73 years, and median ejection fraction was 23%. Adjusted 3-year mortality rates for minority ICD and non-ICD patients were 44.9% (95% CI: 44.2–45.7%) and 54.3% (95% CI: 53.4–55.1%), respectively (adjusted HR 0.79, CI: 0.63–0.98, p=0.034). White non-Hispanic patients receiving an ICD had lower adjusted 3-year

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mortality rates of 47.8% (95% CI: 47.3-48.3%) compared with 57.3% (95% CI: 56.8-57.9%) for those with no ICD (adjusted HR 0.75, 95% CI 0.67-0.83, $p < 0.0001$). There was no significant interaction between race/ethnicity and lower mortality risk with ICD ($p = 0.70$).

Conclusions—Primary prevention ICDs are associated with lower mortality in non-white and Hispanic patients, similar to that seen in white, non-Hispanic patients. These data support a similar approach to ICD patient selection, regardless of race or ethnicity.

Keywords

implantable cardioverter-defibrillator; implanted cardioverter defibrillator; primary prevention; sudden death; race; ethnicity; minority

Introduction

Randomized controlled clinical trials have established the survival benefit of primary prevention implantable cardioverter-defibrillators (ICD).¹⁻³ Racial and ethnic minority patients were underrepresented in those trials, with non-white patients ranging from 16% to 23% of all patients.^{1,2} Results from small, secondary analyses varied considerably with one study finding a trend towards harm with ICD use in racial and ethnic minorities⁴, while another showed improved outcomes with ICD use in minority patients.⁵ In light of these limited data, practice guidelines do not make specific recommendations about the use of ICDs in racial and ethnic minority patients.

While there has been a paucity of data regarding the efficacy and effectiveness of ICD use in minorities, racial and ethnic minority patients are at greater risk of heart failure⁶, cardiac arrest, and SCD relative to whites^{7,8}, but they are less likely than whites to receive ICDs.⁹⁻¹³ While these care differences appear to have lessened over time, they persist in contemporary practice.¹⁴ It is unclear whether these differences result from a lack of empirical data on long-term effectiveness of ICDs in minority patients. The objective of this analysis is to investigate the association between primary prevention ICDs and mortality among Medicare, racial/ethnic minority patients in clinical practice.

Methods

Data Sources

Data from the National Cardiovascular Data Registry's (NCDR[®]) ICD Registry[™], the Get with the Guidelines[®]-Heart Failure (GWTG-HF) database, and the Centers for Medicare & Medicaid Services (CMS) claims was used. Only variables that were identical in the NCDR[®] ICD Registry[™] and the GWTG[®]-HF database were used in this analysis. The NCDR[®] ICD Registry[™] and the GWTG[®]-HF database have been described previously.^{15,16} The ICD Registry[™] launched in 2005 in response to the CMS mandate that data on all Medicare beneficiaries who receive a primary prevention ICD be entered into a national registry. Most providers submit data on non-Medicare patients and for secondary prevention indications. Quality of data entered into the registry is ensured by data quality checks, outlier analysis, and audits.¹⁷

The GWTG® program was launched in 2000, as a voluntary quality improvement initiative that involves data collection on patients hospitalized with acute HF. The HF module evolved from the Organized Program to Initiate Lifesaving Treatment of Patients Hospitalized with Heart Failure (OPTIMIZE-HF) study.¹⁸ Data quality is ensured by automatic electronic data checks to prevent out-of-range or duplicate entries, and an audit found high concordance among a random sample of 5% of the first 10,000 patients. Quintiles (Cambridge, MA) serves as the data collection (through their Patient Management Tool – PMT) and coordination center for GWTG®. The Duke Clinical Research Institute (DCRI) (Durham, NC) serves as the data analysis center and has an agreement to analyze the aggregate de-identified data for research purposes. Available data include demographics, comorbidities, clinical characteristics, in-hospital outcomes, historical therapies and interventions, and contraindications to evidence-based therapies. Additional data are collected about the presence or absence of an ICD in-situ on admission, any ICD implantation during the index hospitalization, scheduled outpatient ICD implantation at the time of discharge, and contraindications that preclude an ICD implantation.

Inpatient and outpatient Medicare claims data and the corresponding denominator files for 2005 through 2011 were used. The registry was linked to Medicare claims data using combinations of indirect identifiers.¹⁹

Study Population

Patients were minorities if the patient/family considered themselves to be of Hispanic ethnicity, African American, Asian, American Indian/Alaska Native, Native Hawaiian/Pacific Islander, or other non-white race. The ICD group (from the ICD Registry™) consisted of all minority patients receiving a primary prevention ICD from 1/1/06 through 12/31/07, who were at least 65 years of age and whose primary insurance was Medicare (n=2,444). We excluded records of patients without a clear guideline-based indication for an ICD, including recent onset of HF, recent myocardial infarction or coronary artery bypass grafting (CABG), or class IV HF symptoms (n=925). We excluded patients who received an ICD with cardiac resynchronization therapy (CRT) (n=762), patients who received a secondary prevention ICD (n=57), patients with a left ventricular ejection fraction (LVEF) > 35% (n=23), patients who received device replacements (n=14), and patients without a documented LVEF (n=8). After these exclusions, 655 records remained from the ICD Registry™ group.

The initial non-ICD group (from GWTG®-HF) included records from minority patients in the GWTG®-HF database who were hospitalized for HF from 1/1/05 through 12/31/09, did not receive an ICD, were at least 65 years of age, and whose primary insurance was Medicare (n=9,507). We excluded records from the analysis where there was an LVEF >35% (n=4,508), no documented LVEF (n=1,428), or new-onset HF (n=785). Records were excluded if patients were discharged to hospice, a skilled nursing facility, or a rehabilitation center (n=525); were transferred to another acute care facility (n=48); or left against medical advice (n=26). Records were excluded if patients had a contraindication or other reason documented by a physician for not receiving an ICD including recent onset of HF, recent myocardial infarction or CABG, class IV HF symptoms, and no reasonable expectation of

survival for at least one year (n=415). After these exclusions, 1,772 records remained for analysis from the GWTG®-HF group.

After applying all exclusions, qualifying records were matched with CMS enrollment files and inpatient claims data to identify unique patients. The files included data on all fee-for-service Medicare beneficiaries aged 65 years or older who were hospitalized for a diagnosis of HF (International Classification of Diseases, Ninth Revision, Clinical Modification [ICD-9-CM] 428.x, 402.x1, 404.x1, and 404.x3). After matching by admission and discharge dates, date of birth, sex, and hospital, patient data in the registries were merged with Medicare Part A inpatient claims. Of the 2,427 hospitalizations of patients aged 65 years or older, we matched 2,053 to fee-for-service Medicare claims. Only the first hospitalization for each patient among matching records was selected; for patients who appeared in both registries, the ICD Registry™ record was retained. Our analysis included 1,893 unique Medicare patients, 453 in the ICD Registry™ and 1,440 in GWTG®-HF. The same process was repeated to acquire a study sample of white, non-Hispanic patients with 5,144 unique Medicare patients consisting of 1,103 in the ICD Registry and 4,041 in GWTG®-HF.

Outcomes

The outcome for this analysis was all-cause mortality. Vital status was determined from the Medicare denominator file through 12/31/2011. Patients with no record of death were considered alive as of 12/31/2011 or the date at which the patient was no longer enrolled in Part A & Part B fee-for-service Medicare, whichever came first.

Statistical Analysis

Baseline characteristics of minority patients in the ICD group and the non-ICD group were compared using the Pearson chi-square test for categorical variables and the Wilcoxon rank sum test for continuous variables. Summary statistics were reported as percentages (counts) for categorical variables and as medians (25th and 75th percentiles) for continuous variables. Variables with missing values in 15% or more of patients in either group were excluded from the analysis: QRS duration, blood urea nitrogen, creatinine, calcium channel blocker use in minority patients, and digoxin use in minority patients. The standardized difference between groups for each variable was calculated as the absolute value of the difference in means or proportions, divided by the average standard deviation and expressed as a percentage.

Baseline characteristics of ICD patients and non-ICD patients were quite different. A matching process was employed using the Rosenbaum and Rubin method to derive a set of non-ICD patients comparable to the sample of ICD patients.²⁰ First, for continuous variables, we excluded non-ICD patients whose value was below the minimum or above the maximum for ICD patients. Second, missing values were imputed using a Markov chain Monte Carlo method. Missing rates were generally quite low, <1% for all variables in the Registry and <3% for most variables in the GWTG®-HF. Third, a propensity model was built using logistic regression in which the dependent (outcome) variable was an indicator of whether each patient was an ICD or a non-ICD patient, and the independent (predictor)

variables were baseline characteristics deemed to be potentially clinically significant and available in both groups with very similar definitions. The variables included in the propensity model were race (white versus other), age, past medical history (prior atrial arrhythmia, ischemic heart disease, hypertension, diabetes), concomitant medications (beta blocker, calcium channel blocker, angiotensin converting enzyme inhibitor, angiotensin receptor blocker, statin, digoxin, and diuretic), clinical characteristics (systolic blood pressure and LVEF). New York Heart Association (NYHA) class and QRS duration were not available in the GWTG®-HF database. From the logistic regression model, an estimated propensity score (the probability – p – of being an ICD patient) and a corresponding logit for the propensity score ($\log_e[p/(1-p)]$) were calculated for each patient.

Fourth, 1:1 matching was used. A caliper width of $0.25 \times$ (standard deviation of the logit) was used. For a given ICD patient, all non-ICD patients were considered whose logit differed from the ICD patient's logit by less than the caliper width. Among these patients, the non-ICD patient with the shortest (Mahalanobis) distance from the ICD patient was selected as a match. Variables used in calculating the Mahalanobis distance were all significant predictors from the propensity model. ICD patients for whom there were no non-ICD patients within the caliper width were omitted from the analysis ($n=27$). Each non-ICD patient was matched only once. Creation of a matched cohort was repeated in the subgroup of white non-Hispanic patients.

Cox proportional hazards model evaluated the association of the presence of an ICD with the risk of all-cause mortality among the matched patients. The model included all non-minority and minority patients, a term for minority, and a term for the interaction between minority and presence of an ICD. The model contained all baseline variables listed above as covariates and was stratified by quartile of propensity score. A robust sandwich variance estimator was used in the Cox models to account for clustering within sites. The proportional hazards assumption for the ICD term was assessed and met. Risk relationships are expressed as hazard ratios with 95% confidence intervals (HR [CI]) within the subgroups of minorities and non-minorities. The interaction term tests whether these two hazard ratios are equal. Mortality rates at 1 and 3 years are presented as unadjusted Kaplan-Meier rates and as adjusted rates derived from the Cox model. Differences were declared to be statistically significant at $p < .05$. All statistical tests were 2-sided. For all analyses, SAS version 9.2 (SAS Institute, Cary, NC, USA) was used. The Duke University Health System institutional review board approved the study and determined that informed consent was not applicable to data collected by the ICD Registry.

Results

Patient Demographics

In GWTG®-HF database, there were 1,440 racial/ethnic minority patients eligible for but without an ICD. In the ICD registry™, there were 453 minority patients with a primary prevention ICD. The majority of the racial/ethnic minority patients were African American, and Hispanic patients were the second most common group of patients (Table 1). One-to-one matching produced minority patient cohorts of 426 patients with and without an ICD. Patients were similar with respect to age, gender, LVEF, systolic blood pressure, comorbid

conditions, and cardiac medications (Table 2, Supplement 1). One-to-one matching of 4,041 white non-Hispanic patients without an ICD and 1,103 white non-Hispanic patients with an ICD resulted in matched cohorts of 1,035 patients each (Supplement 2).

Mortality

There were 234 deaths during a median follow-up of 4.3 years among minority patients with an ICD and 239 deaths during a median follow-up of 2.9 years among minority patients without an ICD (Table 3). The median follow-up was 4.6 years and 3.1 years in the white non-Hispanic ICD and no ICD cohorts, respectively.

The unadjusted mortality rate at 3 years was 45.7% (95% CI: 40.8-50.9%) for minority patients with an ICD and 54.6% (95% CI: 49.6-59.8%) for minority patients without an ICD (Figure 1). The adjusted mortality rate at 3 years was 44.9% (95% CI: 44.2-45.7%) for the minority patients with an ICD, and 54.3% (95% CI: 53.4-55.1%) for minority patients without an ICD. At 1 year, the adjusted mortality rate among minority patients with ICDs was 6.0% lower than among minority patients without an ICD, and the separation in the survival curves increased over time (Figure 2). The adjusted hazard ratio for minority patients with an ICD compared to those without an ICD was 0.79 (95% CI: 0.63-0.98, $p=0.034$).

White non-Hispanic patients receiving an ICD had adjusted 3-year mortality rates of 47.8% (95% CI: 47.3-48.3%) compared with 57.3% (95% CI 56.8-57.9%) for those with no ICD (adjusted HR 0.75, 95% CI 0.67-0.83, $p<0.0001$). There was no significant interaction between race and the lower mortality risk associated with ICDs ($p=0.70$). The 3-year adjusted mortality rates of minority patients and white, non-Hispanic patients with ICDs were 9.4% and 9.5% lower than their paired non-ICD counterparts.

Discussion

It is important to understand the survival of minority patients who receive a primary prevention ICD in clinical practice. There are limited data on this topic. This study has nearly 3 times the number of minority patients with ICDs compared with the previously largest analysis. Our analysis found that ICD use was associated with lower mortality rates in minority patients, which were similar for minority and non-minority patients. There was no significant interaction between race and the lower mortality risk associated with ICDs.

Previously published analyses had small minority populations with ICDs and variable results. The Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) had 65 black patients who were randomized to an ICD. Although black patients in the trial with an ICD did not appear to have improvement in total mortality (HR 1.25, 95% CI: 0.42-3.6), cardiac death (HR 1.52, 95% CI: 0.47-4.96), or sudden death (HR 1.71, 95% CI: 0.33-8.84), these findings are likely due to the small number of racial/ethnic minority patients.⁴ This was not observed in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), which had a larger number of minority patients. Specifically, in SCD-HeFT, black patients appeared to have improved overall mortality with an ICD (HR 0.65, 95% CI: 0.43-0.99), and the increased survival with an ICD was similar to that seen in white non-Hispanic patients

(0.73, 95% CI: 0.58-0.90).⁵ The SCD-HeFT analysis was limited by the relatively small sample size of 153 African American patients with ICDs.

The Multicenter UnSustained Tachycardia Trial (MUSTT) had underrepresentation of non-white patients with only 14% minority patients enrolled in the trial;²¹ however, the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial had a higher percentage of non-white patients with 33% minority patients.²² Neither of these trials published secondary analyses of the outcomes of minority patients. The limited and conflicting available data may have created a perception that racial and ethnic minorities derive less benefit or an unknown benefit from ICD therapy, which could contribute to lower ICD use in minority patients.

Larger clinical studies are needed to validate the findings of our study. Additional data will become available with upcoming prospective observational studies of ICD patients with higher prevalence of minority patients than was seen in the randomized trials. One such study is the Longitudinal Study of ICDs, which is a prospective, cohort study designed to assess outcomes in primary prevention ICD patients. The study enrolled 2,621 patients with 32.7% minorities.²³ Another potentially important study is the Prospective Observational Study of the ICD in Sudden Cardiac Death Prevention (PROSE-ICD, NCT00733590) which is a multicenter, prospective cohort designed to evaluate the risk factors and mechanisms of arrhythmic death and ICD shocks. This study plans to enroll 1200 patients with 43% of those patients being minorities.²⁴

Limitations

Several limitations of this analysis should be noted. This analysis was based on observational, administrative claims data, so the findings are subject to coding and reporting bias. Although both registries required the patient's race and ethnicity to be patient/family reported, it is unknown how frequently race was truly self-reported. Despite propensity matching, residual measured or unmeasured confounding may influence these findings. Claims data do not include information about appropriate or inappropriate ICD shocks, and quality of life, which are important when discussing ICDs with patients. The results of this analysis may not apply to the overall population of minority patients especially patients without a clear guideline-based indication for an ICD as such patients were excluded from the analysis. This analysis is focused on Medicare patients, which may also limit the generalizability of the results. Although analyzing different race and ethnic groups individually is more informative, non-African American subgroups in our study were too small to analyze separately. Patients without an ICD in the GWTG®-HF cohort may not have been offered an ICD because of comorbidities that were not captured in the data. This would introduce bias by limiting our ability to fully adjust the data and match the patients.

In older racial/ethnic minority patients, a primary prevention ICD was associated with significant survival benefit that appeared to be similar to that seen in white non-Hispanic patients. Health care providers should continue to educate minority patients on the benefits of primary prevention ICDs in order to further reduce racial/ethnic disparities.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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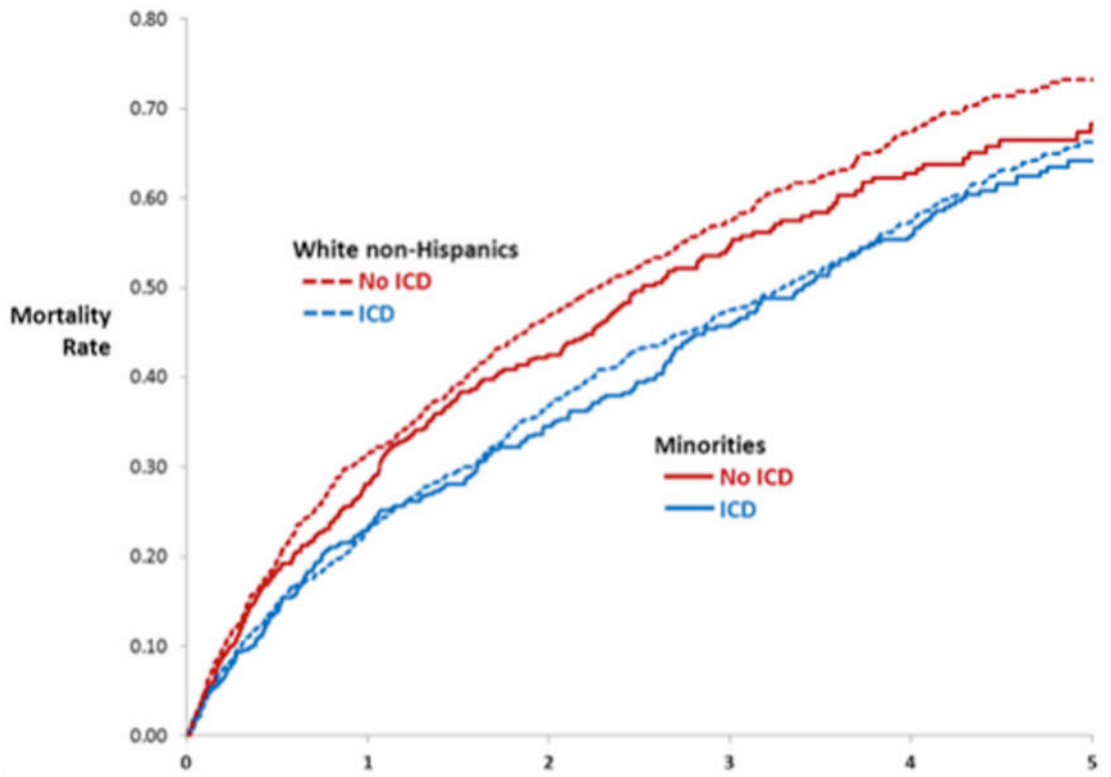
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Number at risk		Years of Follow-up					
		0	1	2	3	4	5
White non-Hispanics	No ICD	1035	663	491	303	161	84
	ICD	1035	766	605	490	385	130
Minorities	No ICD	433	279	207	121	73	33
	ICD	433	297	229	179	139	47

Figure 1. Unadjusted mortality for minority patients with and without an ICD.

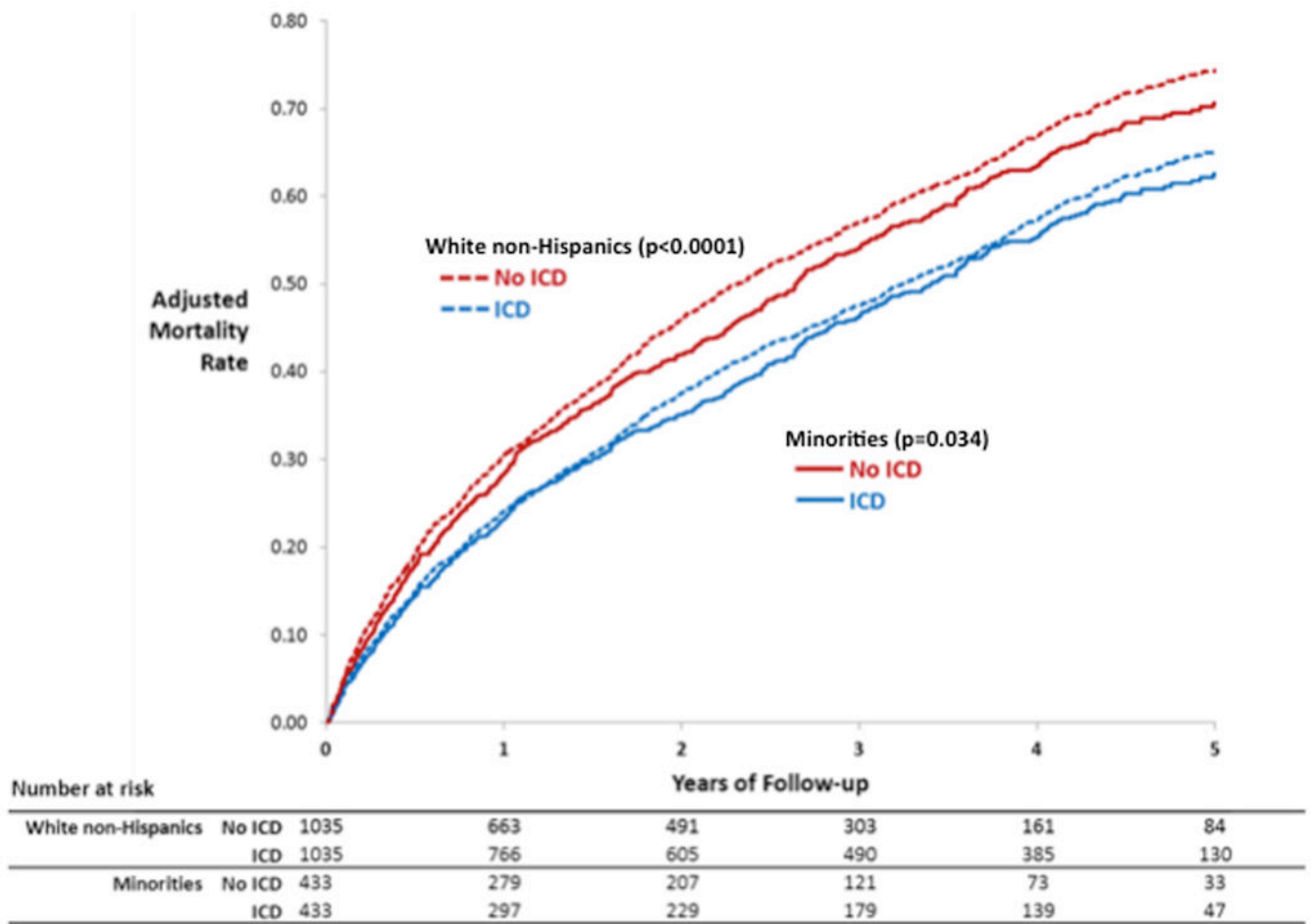


Figure 2.
Adjusted mortality for minority patients with and without an ICD.

Table 1
Racial and ethnic minorities - Prevalence of groups of racial and ethnic minority patients

	All eligible patients		Matched patients	
	GWTC® (N=1440)	ICD Registry™ (N=453)	GWTC® (N=426)	ICD Registry™ (N=426)
Hispanic	21% (302)	23% (103)	21% (90)	23% (99)
African American	63% (912)	67% (304)	64% (276)	67% (288)
Asian	4% (53)	4% (20)	3% (12)	5% (20)
American Indian/Alaska Native	2% (24)	1% (4)	2% (8)	1% (4)
Native Hawaiian/Pacific Islander	1% (13)	1% (4)	1% (5)	1% (4)
Other	9% (136)	4% (18)	10% (42)	4% (18)

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Table 2
Racial and ethnic minorities - Baseline characteristics for unmatched and matched patients from the ICD Registry™ and GWTG®-HF

Baseline characteristic	All minority patients qualifying for analysis				1:1 matched minority patients			
	GWTG®-HF N=1440	ICD Registry™ N=453	standardized difference (%)	P-value	GWTG®-HF N=426	ICD Registry™ N=426	standardized difference (%)	P-value
Age, years	76 (70, 82)	72 (69, 78)	44	<0.0001	73 (68, 78)	73 (69, 78)	2	0.96
Male	52% (744)	64% (290)	25	<0.0001	64% (275)	63% (273)	1	0.89
White race*	11% (160)	12% (56)	3	0.54	10% (43)	12% (53)	7	0.32
LVEF (%)	25 (20, 30)	22 (19, 29)	40	<0.0001	23 (20, 28)	23 (20, 29)	0	0.91
Ischemic heart disease	59% (852)	57% (256)	5	0.32	58% (252)	57% (246)	3	0.68
Prior atrial arrhythmia	23% (330)	33% (151)	23	<0.0001	30% (129)	31% (134)	3	0.71
Systolic BP	140 (122, 158)	128 (111, 144)	47	<0.0001	130 (116, 147)	129 (112, 145)	4	0.35
Diabetes	45% (653)	49% (221)	7	0.20	46% (201)	49% (211)	5	0.50
Hypertension	79% (1144)	90% (408)	30	<0.0001	89% (386)	90% (388)	1	0.83
ACE-inhibitor or ARB	75% (1078)	72% (323)	6	0.30	75% (326)	73% (312)	5	0.46
Beta blocker	85% (1226)	83% (370)	6	0.26	86% (373)	83% (355)	8	0.22
Diuretic	81% (1032)	80% (356)	2	0.69	82% (306)	81% (343)	3	0.64
Statin	38% (541)	53% (235)	29	<0.0001	49% (206)	52% (222)	6	0.37

* White race = white race and Hispanic ethnicity

Median (25th, 75th percentiles) for the continuous measures and % (n) for the categorical measures.

Table 3
Results of mortality analysis for minority and white non-Hispanic cohorts

	Minorities		White non-Hispanics	
	ICD (ICD Registry™)	No ICD (GWTG®-HF)	ICD (ICD Registry™)	No ICD (GWTG®-HF)
Number of patients	426	426	1035	1035
Follow-up duration among survivors (years)				
Median	4.3	2.9	4.6	3.1
25 th , 75 th percentiles	1.4, 4.9	1.5, 4.3	4.0, 5.1	2.1, 4.5
Min, max	0.049, 5.9	0.030, 6.7	0.014, 6.0	0.041, 6.8
Total deaths	234	239	637	646
Mortality rate at 1 year (95% CI)	23.1% (19.3, 27.4)	28.1% (24.0, 32.7)	23.1% (20.6, 25.8)	31.4% (28.6, 34.4)
Mortality rate at 3 years (95% CI)	45.7% (40.8, 50.9)	54.6% (49.6, 59.8)	47.4% (44.4, 50.6)	57.4% (54.2, 60.6)
Adjusted mortality rate at 1 year (95% CI)	22.4% (21.9, 22.9)	28.4% (27.9, 29.0)	24.2% (23.9, 24.5)	30.6% (30.2, 31.0)
Adjusted mortality rate at 3 years (95% CI)	44.9% (44.2, 45.7)	54.3% (53.4, 55.1)	47.8% (47.3, 48.3)	57.3% (56.8, 57.9)
Adjusted HR (95% CI) for ICD vs. no ICD	0.79 (0.63, 0.98)		0.75 (0.67, 0.83)	
P-value for HR	0.034		<0.0001	
P-value for interaction of minority status with ICD	0.70			