Sex and Racial Differences in the Use of Implantable Cardioverter-Defibrillators Among Patients Hospitalized With Heart Failure

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More than 350,000 people die annually as a result of sudden cardiac death, and a major risk factor for sudden cardiac death is heart failure with left ventricular systolic dysfunction.1,2 Half of all deaths from heart failure are sudden events thought to be attributable primarily to lethal arrhythmias. Several large randomized clinical trials have shown that implantable cardioverter-defibrillator (ICD) therapy reduces mortality in heart failure patients with left ventricular systolic dysfunction.4,6 Thus, evaluation of systolic function is recommended in all patients with heart failure, and ICD therapy is recommended for patients with systolic dysfunction who meet certain criteria.7,8

Previous studies have shown that disparities by sex and race often exist in the use of innovative or costly cardiovascular technologies as they emerge, and these disparities can persist for years.9,10 Recognition of disparities by sex and race has prompted the Institute of Medicine and the American Heart Association (AHA) to increase awareness throughout the public and among clinicians, payers, and policy makers, and to undertake efforts to reduce these disparities.11,12

In this study, we examined the overall use of ICD therapy in patients with heart failure who were at risk for sudden cardiac death. Second, we explored whether there were significant sex and racial disparities in ICD use among eligible patients.

Context Practice guidelines recommend implantable cardioverter-defibrillator (ICD) therapy for patients with heart failure and left ventricular ejection fraction of 30% or less. The influence of sex and race on ICD use among eligible patients is unknown.

Objective To examine sex and racial differences in the use of ICD therapy.

Design, Setting, and Patients Observational analysis of 13,034 patients admitted with heart failure and left ventricular ejection fraction of 30% or less and discharged alive from hospitals in the American Heart Association’s Get With The Guidelines—Heart Failure quality-improvement program. Patients were treated between January 2005 and June 2007 at 217 participating hospitals.

Main Outcome Measures Use of ICD therapy or planned ICD therapy at discharge.

Results Among patients eligible for ICD therapy, 4,615 (35.4%) had ICD therapy at discharge (1,614 with new ICDs, 527 with planned ICDs, and 2,474 with prior ICDs). ICDs were used in 375 of 1,329 eligible black women (28.2%), 754 of 2,531 white women (29.8%), 660 of 1,977 black men (33.4%), and 2,356 of 5,403 white men (43.6%) (P < .001). After adjustment for patient characteristics and hospital factors, the adjusted odds of ICD use were 0.73 (95% confidence interval, 0.60-0.88) for black men, 0.62 (95% confidence interval, 0.56-0.68) for white women, and 0.56 (95% confidence interval, 0.44-0.71) for black women, compared with white men. The differences were not attributable to the proportions of women and black patients at participating hospitals or to differences in the reporting of left ventricular ejection fraction.

Conclusions Less than 40% of potentially eligible patients hospitalized for heart failure received ICD therapy, and rates of use were lower among eligible women and black patients than among white men.

JAMA. 2007;298(13):1525-1532 www.jama.com

See also pp 1517 and 1564.

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SEX AND RACIAL DIFFERENCES IN ICD USE

an ongoing, voluntary, observational data collection and continuous quality-improvement initiative that began in 2000 and has been described previously.13-15 Participating hospitals use the point-of-service, interactive, Internet-based Patient Management Tool (Outcome Sciences, Inc, Cambridge, Massachusetts) and submit clinical information regarding in-hospital care and outcomes of patients hospitalized for coronary artery disease, stroke, or heart failure. The heart failure module, initiated from the Organized Program to Initiate Life-Saving Treatment in Hospitalized Patients With Heart Failure (OPTIMIZE-HF) in January 2005, serves as the main analysis data set and includes patients hospitalized with heart failure.16 Participating institutions are instructed to submit patient information on consecutive eligible patients into the Get With the Guidelines database.

All participating institutions were required to comply with local regulatory and privacy guidelines and to submit the program protocols for review and approval by their institutional review board. Because data were used primarily at the local site for quality improvement, sites were granted a waiver of informed consent under the common rule. The Duke Clinical Research Institute serves as the data analysis center and has an agreement to analyze the aggregate deidentified data for research purposes.

Trained personnel abstracted the data using standardized definitions. Admissions staff, medical staff, or both recorded self-reported race/ethnicity, usually as the patient was registered. Patients were assigned to race/ethnicity categories using options defined by the electronic case report form. Other variables included demographic and clinical characteristics, medical history, previous treatments, contraindications for evidence-based therapies, and in-hospital outcomes. Data collection regarding ICD therapy included prior implantation, new implantation, or planned implantation after hospital discharge; documented contraindications for ICD therapy, defined as any reason documented by a physician for not using ICD therapy or specific contraindications, such as the patient not receiving optimal medical therapy, has had an acute myocardial infarction within 40 days, has recent-onset heart failure, or has another life-threatening illness that would compromise 1-year survival with good functional status. Documentation of reasons for not placing an ICD were also collected, including economic, social, and religious reasons, nonadherence, and other reasons for refusal.

The Internet-based system performed edit checks to ensure the completeness of the reported data. In addition, data quality was monitored and reports were generated to confirm the completeness and accuracy of the submitted data. Only sites and variables with a high degree of completeness were used in the analyses.

Study Population
From January 2005 through June 2007, 59,965 patients with heart failure were discharged alive from participating hospitals. Our study was based on a final cohort of 13,034 patients eligible for ICD therapy from 217 hospitals. Among the excluded patients, 5,924 who had new-onset heart failure were excluded because they were not eligible for ICD therapy for primary prevention; 14,514 were excluded for the following reasons: 4,07 left against medical advice, 1,518 transferred to another acute care facility, 1,237 were discharged to hospice, 10,456 were discharged to a skilled nursing facility, and 896 were discharged to a rehabilitation center; 7,077 patients were excluded because there was no documentation of left ventricular ejection fraction (LVEF); 18,768 patients with LVEF of greater than 30% were excluded to confine the analysis to patients who met criteria for class I recommendations for ICD therapy based on current American College of Cardiology (ACC)/AHA heart failure guidelines;17; and 648 patients with a contraindication or other reason documented by a physician for not receiving ICD therapy were excluded.

Outcome Measures
The main outcome measure was the use of ICD therapy or documented plans for the placement of an ICD after hospital discharge among eligible patients with LVEF of 30% or less. For the purposes of the analysis, we also included patients in the numerator if they had prior ICD therapy. Performance measures assessed were the provision of discharge instructions, use of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker in patients with left ventricular systolic dysfunction, and smoking cessation counseling for eligible patients, which are the core measures of quality used by the Centers for Medicare & Medicaid Services.7,8 Additional indicators of evidence-based care included in the analysis were the use of β-blockers in left ventricular systolic dysfunction, anticoagulation for atrial fibrillation, and aldosterone antagonists for left ventricular dysfunction, which are class I therapies in the ACC/AHA heart failure guidelines.

Because documentation of LVEF is a national performance indicator for patients with heart failure and a prerequisite for ICD eligibility, we conducted a sensitivity analysis that included patients with no LVEF documentation.7,8 We also evaluated ICD use among eligible patients who did not have depression, stroke, or anemia and among eligible patients aged younger than 70 years.

Statistical Analyses
Using χ² tests for categorical variables and Wilcoxon rank sum tests for continuous variables, we compared the baseline characteristics of patients who received ICD therapy with the characteristics of patients who did not receive ICD therapy. We report medians and interquartile ranges for continuous variables and percentages for categorical variables. We also examined patient characteristics for the broader population of patients with and without documentation of LVEF.

We used multivariate logistic regression analysis to identify important factors associated with ICD use. We used...
the generalized estimating equations method to adjust for clustering within hospitals. The initial model included variables for age, sex, race (white vs black), geographic region where the data were collected, systolic blood pressure, and medical diagnoses including acute renal failure, anemia, atrial fibrillation, cerebrovascular accident or transient ischemic attack, chronic obstructive pulmonary disease, coronary artery disease, depression, diabetes mellitus, hyperlipidemia, hypertension, ischemic heart disease, peripheral vascular disease, renal insufficiency, and smoking. In addition, we tested for interactions between sex and race. Factors for which P was greater than or equal to .05 were removed from the logistic regression model.

We also performed analyses to determine if observed racial or sex differences in ICD use were attributable in part to the hospitals in which the patients received care. First, we examined differences in ICD use based on the proportion of black patients and women at each hospital. Second, we used a hierarchical model with hospital as a random effect and patient baseline characteristics as fixed effects. This hierarchical model takes into account the fact that ICD use for patients within the same hospital may be correlated, and allows us to examine differences in ICD use among patients within hospitals.

We performed sensitivity analyses to examine the robustness of the findings. We examined new or planned ICD use by sex and racial subgroups. We used the generalized estimating equations method to adjust for clustering within hospitals to determine adjusted odds ratios (ORs) for ICD use for sex and racial subgroups. We then examined frequency of ICD use in important patient subgroups based on lack of comorbid conditions, Medicare enrollment, symptoms of dyspnea, and predicted 1-year mortality using a previously validated model.

A P value of less than .05 was considered statistically significant for all tests. All analyses were performed using SAS software version 8.2 (SAS Institute, Cary, North Carolina).

RESULTS

Of the 13,034 patients eligible for ICD therapy, 4,615 (35.4%) received an ICD (1,614 patients with a new ICD, 527 with a planned ICD, and 2,474 with a prior ICD). TABLE 1 shows the baseline characteristics of the study population. Women represented 27.2% of patients who received ICD therapy and 37.8% of patients who did not (P < .001). Black patients represented 23.0% of patients with ICD therapy and 28.0% of patients without (P < .001). The frequency for ICD use was highest for white men, with 43.6% of those 5,403 eligible receiving an ICD (P < .001). The frequency for ICD use was 28.2% of 1,329 eligible black women, 33.4% of 1,977 eligible black men, and 29.8% of 2,531 eligible white women.

Contraindications to ICD therapy were documented for 648 (4.7%) otherwise potentially eligible patients. Documented reasons included 24 economic, 20 social, 44 nonadherence, 1 religious, 140 other reasons provided by patients, and 441 reasons provided by physicians, which included not receiving optimal medical therapy, acute myocardial infarction within the previous 40 days, and recent onset of heart failure. There were no significant differences for documented contraindications by sex or race (4.0% for white men, 5.2% for black men, 4.6% for white women, and 4.0% for black women; P = .12).

TABLE 2 shows other measures of heart failure quality of care. Provision of discharge instructions, use of an angiotensin-converting enzyme inhibitor or angiotensin receptor blocker, and smoking cessation counseling were similar between patients with and without ICD therapy. Use of β-blockers, anticoagulation for atrial fibrillation, and aldosterone antagonists was higher in patients with ICD therapy compared with those without ICD therapy.

TABLE 3 shows factors that were associated with ICD use among eligible heart failure patients in the generalized estimating equations model and the hierarchical model with site as a random effect. The 2 models had similar ORs, but with some variation in confidence intervals (CIs) between the models. In both models, women were approximately 40% less likely than men to receive ICD therapy and black patients were approximately 30% less likely than white patients to receive ICD therapy.

In generalized estimating equation models after adjustment for both patient and hospital factors including adjustment for age, insurance, systolic blood pressure, medical history variables (anemia, atrial fibrillation, chronic dialysis, hypertension, hyperlipidemia, ischemic heart disease, smoking), and geographic region, 3 groups of patients were significantly less likely than white men to receive ICD therapy: black men (OR, 0.73; 95% CI, 0.60-0.88; P = .001), white women (OR, 0.62; 95% CI, 0.56-0.68; P < .001), and black women (OR, 0.56; 95% CI, 0.44-0.71; P < .001).

Sensitivity Analyses

Because there may be differences in rates of new ICD placements vs prior ICD placements, we examined overall frequencies across sex and racial groups, and calculated adjusted ORs for new or planned ICDS. The frequency for new or planned ICD implantations after discharge was 25.8% of 4,109 eligible white men, 18.3% of 2,176 white women, 17.5% of 1,595 black men, and 13.0% of 1,096 black women (P < .001). After adjustment for patient characteristics (age, insurance, systolic blood pressure, anemia, chronic dialysis, hyperlipidemia, hypertension, renal insufficiency, pulmonary disease, and smoking status), the adjusted ORs for ICD use compared with white men were 0.59 (95% CI, 0.47-0.74; P < .001) for black men, 0.73 (95% CI, 0.64-0.82; P < .001) for white women, and 0.43 (95% CI, 0.33-0.56; P < .001) for black women.

To assess whether racial differences in ICD use were attributable to patient treatment site, hospitals were divided into tertiles of black patients hospital-
ized for heart failure (<5%, 5%-15%, and >15%), and differences in ICD use remained significant in hospitals with a higher proportion of black patients. In the lowest tertile, 30.7% of white patients (896 of 2922) received ICD therapy, compared with 21.6% of black patients (19 of 88; \( P = .07 \)). In the middle tertile, the rates were 43.2% of white patients (983 of 2274) and 32.7% of black patients (119 of 364; \( P < .001 \)). In the highest tertile, the rates were 44.6% (1266 of 2837) for white patients and 31.5% (907 of 2880) for black patients (\( P < .001 \)).

Similarly, sex differences in ICD use were not attributable to the proportion of women treated for heart failure at the hospital level. After dividing hospitals into tertiles of women hospitalized for heart failure (45%, 45%-55%, and >55%), differences in ICD use remained. In the lowest tertile, 33.6% of eligible women received ICD therapy (469 of 1398) compared with 46.0% of eligible men (1592 of 3464; \( P < .001 \)). In the highest tertile, 20.5% (74 of 361) of eligible women received ICD therapy compared with 29.3% (142 of 484) of eligible men (\( P = .004 \)).

We also examined ICD therapy for different groups of patients who physicians may consider are better candidates based on lack of comorbid conditions, similar insurance, or similar symptoms. Among patients aged younger than 70 years without anemia, cerebrovascular disease, or depression, the frequency of ICD therapy

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total (N = 13034)</th>
<th>ICD (n = 4615)</th>
<th>No ICD (n = 8419)</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, median (IQR), y</td>
<td>69 (57-78)</td>
<td>68 (58-76)</td>
<td>70 (57-80)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Women</td>
<td>34.1</td>
<td>27.2</td>
<td>37.8</td>
<td>&lt;.001</td>
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<tr>
<td>Race/ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Black</td>
<td>26.2</td>
<td>23.0</td>
<td>28.0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hispanic</td>
<td>6.1</td>
<td>4.1</td>
<td>7.3</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>63.1</td>
<td>69.1</td>
<td>59.8</td>
<td></td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicare</td>
<td>49.5</td>
<td>51.2</td>
<td>48.6</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Medicaid</td>
<td>7.5</td>
<td>7.0</td>
<td>7.8</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Other</td>
<td>37.2</td>
<td>38.8</td>
<td>36.3</td>
<td></td>
</tr>
<tr>
<td>No insurance</td>
<td>5.8</td>
<td>3.0</td>
<td>7.4</td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure, median (IQR), mm Hg</td>
<td>129 (112-148)</td>
<td>122 (108-140)</td>
<td>133 (115-153)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Body mass index, median (IQR)(^b)</td>
<td>27.3 (23.6-32.3)</td>
<td>27.4 (24.0-32.2)</td>
<td>27.2 (23.4-32.3)</td>
<td>.02</td>
</tr>
<tr>
<td>History</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anemia</td>
<td>9.8</td>
<td>9.2</td>
<td>10.1</td>
<td>.12</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>22.7</td>
<td>26.8</td>
<td>20.4</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Cerebrovascular disease</td>
<td>11.2</td>
<td>12.3</td>
<td>10.6</td>
<td>.03</td>
</tr>
<tr>
<td>Depression</td>
<td>6.9</td>
<td>7.8</td>
<td>6.4</td>
<td>.002</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insulin-dependent</td>
<td>20.9</td>
<td>20.4</td>
<td>21.2</td>
<td>.26</td>
</tr>
<tr>
<td>Non–insulin-dependent</td>
<td>14.7</td>
<td>16.6</td>
<td>13.7</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Chronic dialysis</td>
<td>2.8</td>
<td>2.0</td>
<td>3.2</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>35.4</td>
<td>44.4</td>
<td>30.5</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>61.1</td>
<td>61.8</td>
<td>60.7</td>
<td>.21</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>65.6</td>
<td>71.3</td>
<td>62.5</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Peripheral vascular disease</td>
<td>9.4</td>
<td>10.9</td>
<td>8.6</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td>22.6</td>
<td>24.2</td>
<td>21.8</td>
<td>.001</td>
</tr>
<tr>
<td>Renal insufficiency (creatinine &gt;2.0 mg/dL)</td>
<td>15.9</td>
<td>17.7</td>
<td>15.0</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Smoker</td>
<td>22.5</td>
<td>19.9</td>
<td>23.9</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Left ventricular ejection fraction, median (IQR), %</td>
<td>22 (18-27)</td>
<td>20 (16-25)</td>
<td>23 (20-28)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Geographic region</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Northeast</td>
<td>20.9</td>
<td>20.1</td>
<td>21.3</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>South</td>
<td>26.8</td>
<td>36.0</td>
<td>21.8</td>
<td></td>
</tr>
<tr>
<td>Midwest</td>
<td>34.8</td>
<td>32.3</td>
<td>36.2</td>
<td></td>
</tr>
<tr>
<td>West</td>
<td>17.5</td>
<td>11.7</td>
<td>20.7</td>
<td></td>
</tr>
<tr>
<td>Hospital bed size, median (IQR)</td>
<td>330 (251-553)</td>
<td>382 (274-590)</td>
<td>324 (232-449)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Abbreviations: ICD, implantable cardioverter-defibrillator; IQR, interquartile range.

\(^{a}\)SI conversion factor: to convert creatinine to \( \mu \)mol/L, multiply by 88.4.

\(^{b}\)Data are presented as percentages unless otherwise indicated. Data are based on patients with available data for each characteristic.

\(^{b}\)Body mass index is calculated as weight in kilograms divided by height in meters squared.
remained different across all groups: 44.3% of white men (801 of 1810), 33.1% of black men (411 of 1241), 38.1% of white women (248 of 651), and 29.8% of black women (200 of 672; \( P < .001 \)). For patients enrolled in Medicare, ICD use was significantly different across groups based on sex and race. ICD use among Medicare beneficiaries was 44.8% for white men (1532 of 3420), 36.5% for black men (271 of 742), 27.9% for white women (481 of 1724), and 28.4% for black women (154 of 542; \( P < .0001 \)). The overall rate of ICD use stratified by severity of heart failure symptoms based on dyspnea at rest or minimal exertion was 32.5%. In sex and racial subgroups, these rates were 40.3% for white men (1185 of 2942), 30.5% for black men (361 of 1183), 25.0% for white women (356 of 1424), and 25.7% for black women (211 of 820; \( P < .0001 \)).

Because prognosis may also influence ICD use, we examined ICD use based on predicted 1-year mortality using the EFFECT model. ICD use was 38.1% for low-risk patients, 37.7% for intermediate-risk patients, and 35.0% for high-risk patients (\( P = .26 \)). In low-risk patients, the rate of ICD use was 46.7% for white men, 32.9% for black men, 36.1% for white women, and 29.6% for black women (\( P < .0001 \)). In intermediate-risk patients, the ICD frequency was 46.7% for white men, 36.9% for black men, 26.4% for white women, and 30.1% for black women (\( P < .0001 \)). In high-risk patients, the rate of ICD use was 42.8% for white men, 41.4% for black men, 20.2% for white women, and 26.9% for black women (\( P < .0001 \)).

Racial and sex differences in ICD use did not appear attributable to differences in reporting of LVEF. The frequency of missing LVEF was 17.9% overall, 15.8% among white men, 10.8% among black men, 20.7% among white women, and 13.8% among black women. After exclusion of patients who were transferred, discharged to hospice, rehabilitation, or a skilled nursing facility, left against medical advice, or had documented contraindications for ICD therapy, there were 37873 patients with heart failure, including 13,034 patients with LVEF of 30% or less, 17,951 patients with LVEF of greater than 30%, and 6888 patients with no documented LVEF. If a broader performance measure is defined as either documentation of LVEF greater than 30% or an ICD present at discharge in eligible patients, then the failure rate or nonconformity rate was 74.1%. This nonconformity rate varied from 65.2% (4903 of 7519) among white men, 70.4% (1678 of 2384) among black men, 82.8% (4146 of 5008) among white women, and 85.1% (2888 of 3411) among black women.

Table 2. Quality-of-Care Measures for Patients With or Without ICD Therapy\(^a\)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Overall</th>
<th>ICD</th>
<th>No ICD</th>
<th>( P ) Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge instructions (n = 12,329)</td>
<td>81.7</td>
<td>82.2</td>
<td>81.4</td>
<td>.25</td>
</tr>
<tr>
<td>Angiotensin-converting enzyme inhibitor or angiotensin</td>
<td>85.9</td>
<td>86.6</td>
<td>85.6</td>
<td>.13</td>
</tr>
<tr>
<td>receptor blocker for left ventricular systolic dysfunction (n = 11,003)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking cessation counseling (n = 2773)</td>
<td>90.4</td>
<td>91.1</td>
<td>90.0</td>
<td>.38</td>
</tr>
<tr>
<td>( \beta )-Blocker for left ventricular systolic dysfunction (n = 12,435)</td>
<td>89.2</td>
<td>91.5</td>
<td>87.9</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Anticoagulation for atrial fibrillation (n = 2773)</td>
<td>66.9</td>
<td>73.5</td>
<td>62.1</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Aldosterone antagonist (n = 12,539)</td>
<td>28.6</td>
<td>36.3</td>
<td>24.4</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

Table 3. Factors Associated With Implantable Cardioverter-Defibrillator Use (or Planned Use) at Discharge Among Eligible Patients With Heart Failure\(^a\)

<table>
<thead>
<tr>
<th>Characteristic(^b)</th>
<th>Generalized Estimating Equations Model</th>
<th>Hierarchical Model With Site as a Random Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Odds Ratio (95% Confidence Interval)</td>
<td>( P ) Value</td>
</tr>
<tr>
<td>Age, per 10-y increase</td>
<td>0.83 (0.80-0.86)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Sex and race</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td>0.62 (0.56-0.68)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Black men vs white men</td>
<td>0.73 (0.60-0.88)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Other men vs white men</td>
<td>0.74 (0.63-0.87)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Black women interaction(^b)</td>
<td>1.25 (0.98-1.60)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Other women interaction(^b)</td>
<td>1.46 (1.14-1.86)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Location</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Midwest vs West</td>
<td>1.37 (1.04-2.24)</td>
<td>&lt;.21</td>
</tr>
<tr>
<td>Northeast vs West</td>
<td>1.13 (0.65-1.95)</td>
<td>&lt;.66</td>
</tr>
<tr>
<td>South vs West</td>
<td>1.70 (1.03-2.80)</td>
<td>&lt;.04</td>
</tr>
<tr>
<td>Insurance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other vs no insurance</td>
<td>1.92 (1.46-2.53)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Medicare vs no insurance</td>
<td>2.17 (1.65-2.85)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Medicaid vs no insurance</td>
<td>1.81 (1.33-2.47)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Systolic blood pressure, per 10-mm Hg increase</td>
<td>0.89 (0.88-0.91)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Anemia</td>
<td>0.76 (0.64-0.90)</td>
<td>&lt;.03</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>1.13 (1.01-1.27)</td>
<td>&lt;.03</td>
</tr>
<tr>
<td>Chronic dialysis</td>
<td>0.67 (0.53-0.85)</td>
<td>&lt;.01</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>0.91 (0.83-0.99)</td>
<td>&lt;.03</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>1.40 (1.26-1.55)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Hypertension</td>
<td>0.89 (0.81-0.99)</td>
<td>&lt;.03</td>
</tr>
<tr>
<td>Ischemic heart disease</td>
<td>1.35 (1.19-1.52)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Smoking</td>
<td>0.72 (0.65-0.80)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

\(a\) Data are presented as percentages unless otherwise indicated.

\(b\) Listed variables are significant factors in the final model that influenced implantable cardioverter-defibrillator use. Variables in the initial model included age, female sex, race, interaction of race and sex, systolic blood pressure, insurance (Medicare, Medicaid, other, and no insurance), medical history variables including anemia, atrial fibrillation, cerebrovascular accident/transient ischemic attack, depression, diabetes mellitus, dialysis, hypertension, hyperlipidemia, chronic obstructive pulmonary disease, peripheral vascular disease, renal insufficiency, smoker, and geographic region (West, Northeast, Midwest, South).
and 77.6% (1426 of 1837) among black women ($P < .001$).

**COMMENT**

This study is the first, to our knowledge, to examine ICD use among eligible patients with LVEF of 30% or less who were hospitalized with heart failure. There are 3 main findings: (1) the overall frequency of ICD use was low among potentially eligible patients; (2) women were significantly less likely than men to receive ICD therapy, independent of other characteristics; and (3) black patients were significantly less likely than white patients to receive ICD therapy independent of other characteristics. Consequently, the rate of ICD use was lowest among black women.

In the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), the relative risk reductions in all-cause mortality with ICD therapy were 31% and 23%, respectively, supporting the notion that physicians should carefully consider the potential benefit of ICD therapy in eligible patients. These and other studies led the 2005 ACC/AHA guidelines for heart failure to include ICD therapy for primary prevention of sudden cardiac death in patients with ischemic (class I, evidence A) and nonischemic heart disease (class I, evidence B) and LVEF of 30% or less who are receiving long-term optimal medical therapy and have a reasonable expectation of survival with good functional status of greater than 1 year. Furthermore, the Centers for Medicare & Medicaid Services agreed in 2005 to reimburse ICD therapy for patients with ischemic or nonischemic heart disease, LVEF of less than 35%, and New York Heart Association class II or III heart failure. Based on these criteria, our findings suggest that ICD therapy is significantly underused in patients hospitalized with heart failure, with approximately 35% of eligible patients receiving ICD therapy or planned ICD therapy at the time of hospital discharge.

The rate of ICD use observed in this study may over- or underestimate ICD use among all potentially eligible patients. LVEF measurement is an important quality metric among patients with heart failure because it helps to inform many treatment decisions, including the use of ICD therapy. We found that approximately 20% of patients with heart failure did not have an LVEF recorded. If one considers failure to meet the ICD performance measure to also include patients who do not have documentation of LVEF, then the nonconformity rate is over 70%. If a significant proportion of eligible patients who did not have a plan for ICD implantation documented, but then underwent ICD implantation after discharge, the nonconformity rates would be lower than reported in this study.

We found significant sex differences in ICD use. Cardiovascular disease is the leading cause of death for women, and survival among women with heart failure has not improved substantially over the last 2 decades. Nevertheless, ICD use among potentially eligible women lagged far behind ICD use among men, with women approximately 40% less likely to have an ICD. Although women are often underrepresented in clinical trials, and less than 30% of participants in the major ICD trials for primary prophylaxis were women, the ACC/AHA guidelines recommend equal treatment for men and women. Admittedly, published trials are underpowered to adequately assess the efficacy of ICDs specifically in subgroups of women, and future research should specifically target women with heart failure at risk for sudden death. To date, clinical trials have not shown major interactions based on sex for efficacy. For example, the MADIT-II trial had 192 women (16%) showing similar mortality and similar ICD effectiveness when compared with men. Therefore, until there is significant contrary evidence, eligible women with heart failure and LVEF of less than 30% should be considered for ICD therapy as primary prophylaxis per ACC/AHA guidelines.

Similarly, black patients are more likely than white patients to have heart failure and are at higher risk for sudden cardiac death. However, we found black patients were approximately 30% less likely than white patients to receive ICD therapy. In addition, disparities existed regardless of the proportion of black patients admitted at each hospital. For black patients, the available data on ICD efficacy comes from smaller subgroups than women. In a post hoc analysis of the 102 black patients in the Multicenter Unsustained Tachycardia Trial (MUSTT), survival for black patients randomly assigned to no electrophysiologically guided therapy was better than for black patients receiving electrophysiologically guided therapy. However, the difference was partially explained by a higher ICD implantation rate in white patients (50% vs 28%; $P = .03$). The SCD-HeFT trial did not report any significant sex or race interactions with the main results of mortality benefit with primary ICD placement, although women and non-white subgroups had hazard ratios with wide confidence intervals extending past unity.

The ACC/AHA heart failure guidelines acknowledge that certain patient cohorts have been underrepresented in randomized clinical trials, and subgroup analyses are limited with regard to whether benefit of therapies is uniform. However, the guidelines explicitly state that the recommendations should be followed in the absence of definitive evidence to the contrary and that black patients should receive equal treatment.

There are several potential factors that may explain the disparities observed in this study. System inequities may exist in the identification of eligible patients and delivery of ICD therapy. Physicians may consider certain subgroups more prominently due to a large number of white men in clinical trials. Patients may also differ in preferences for ICD therapy across sex and race subgroups, although Groeneveld et al found that black patients and white patients have similar prefer-
ences for innovative technologies such as implantable devices. In addition, another commonly proposed reason for ICD use disparity among black patients is that they tend to receive care at poorer quality centers. After adjusting for hospital characteristics in the hierarchical models, we found that race persisted as a significant predictor of lower ICD use.

Other studies have shown that ICDs are underused in women and black patients. Gauri et al examined Medicare claims for patients with ischemic cardiomyopathy and found that women were 60% less likely than men to receive ICD therapy for primary prevention. In the same study, black patients were 31% less likely than white patients to receive ICD therapy. These estimates are slightly higher than those in the present study, most likely because the analysis relied on Medicare claims data, which do not contain information about LVEF and thus did not allow for identification of patients with depressed LVEF who were truly eligible for ICD therapy.

In addition to eliminating sex and racial disparities, future research should improve knowledge about the cost-effectiveness and availability of ICD therapy. Several studies have shown ICD therapy to be cost-effective, but questions remain regarding the broad application of current evidence because of the total estimated costs to major payers and society. Future studies should help to further define the category of eligible heart failure patients who will derive a significant benefit from ICD therapy. In addition, greater attention should help guide the necessity and utility of added features to ensure that costs of ICD use do not escalate and possibly worsen disparities in care.

The analysis also found that ischemic heart disease was a major factor associated with ICD use. This finding may be due to the longer history of evidence for ICD therapy among patients with ischemic heart disease, or to other related factors that physicians recognize as signifying a high risk for sudden cardiac death. However, SCD-HeFT showed that ICD therapy conferred a survival advantage on patients with ischemic heart disease and patients with nonischemic heart disease. Factors associated with lower ICD use, such as age or comorbid diseases, may be related to the potential influence of comorbid disease on functional status and long-term life expectancy. As noted, guidelines suggest that physicians consider functional status and reasonable expected survival for at least 1 year. However, even among patients aged younger than 70 years without depression, anemia, or history of cerebrovascular disease, ICD use was suboptimal.

This study has several limitations. First, the data were from a voluntary, hospital-based quality-improvement program. Given that randomized trials of ICD therapy for primary prevention enrolled outpatients, assessment of ICD use among only patients hospitalized with heart failure can be questioned. However, we confined the analysis to patients who would have qualified for ICD therapy prior to hospitalization (ie, patients with a history of chronic heart failure and no documented contraindications to ICD therapy). Second, this program may include hospitals with a higher likelihood of following evidence-based recommendations. Thus, the results of this study may be conservative compared with overall community practice. Third, the data were reported through a standardized case report, but therapies or contraindications to therapies may have been underreported. Although we controlled for insurance status, we do not have data for out-of-pocket expenses which could affect patient decisions for ICD therapy. Also, documentation of LVEF was not available for all patients. However, by assuming that patients without a documented LVEF were eligible for ICD therapy, the disparities observed would be greater. Finally, because we did not have access to outpatient follow-up information, we were unable to delineate benefits of ICD use in reducing mortality risk or the adverse consequences of underuse and disparities in the use of ICD therapy for primary prevention of sudden cardiac death.

CONCLUSIONS

Eligible hospitalized patients with heart failure and LVEF of 30% or less are discharged frequently without ICD therapy or planned ICD therapy, and significant disparities exist for women and black patients. Further research is needed to understand the reasons for the disparities at the patient, physician, and hospital levels. Programs for awareness and promotion of evidence-based use of medical devices in heart failure are needed overall and for the important subgroups studied here. Publicly reported measures regarding ICD therapy should be considered.

Author Contributions: Dr Hernandez had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Hernandez, Fonarow, Peterson.

Acquisition of data: Fonarow, Peterson.

Analysis and interpretation of data: Hernandez, Fonarow, Liang, Al-Khatib, Curtis, LaBresh, Yancy, Albert, Peterson.

Drafting of the manuscript: Hernandez, Fonarow, Peterson.

Critical revision of the manuscript for important intellectual content: Hernandez, Fonarow, Liang, Al-Khatib, Curtis, LaBresh, Yancy, Albert, Peterson.

Statistical analysis: Hernandez, Fonarow, Liang, Peterson.

Obtained funding: Hernandez, Fonarow, Peterson.

Administrative, technical, or material support: Fonarow, Hernandez, Peterson.

Study supervision: Hernandez, Fonarow, Peterson.

Expertise in electrophysiology: Al-Khatib.

Financial Disclosures: Dr Hernandez reports receiving research grants from Scios, Medtronic, GlaxoSmithKline, and Roche Diagnostics; and serving on the speaker’s bureau or receiving honoraria in the past 5 years from Novartis. Dr Fonarow reports receiving research grants from Amgen, Biosite, Bristol-Myers Squibb, Boston Scientific/Guidant, GlaxoSmithKline, Medtronic, Merck, Pfizer, Sanofi-Aventis, and Scios Inc; serving on the speaker’s bureau or receiving honoraria in the past 5 years from Amgen, AstraZeneca, Biosite, Bristol-Myers Squibb, Boston Scientific/Guidant, GlaxoSmithKline, Ks, Medtronic, Merck, NitroMed, Novartis, Pfizer, Sanofi-Aventis, Schering Plough, Scios Inc, St Jude Medical, Takeda, and Wyeth; and serving as a consultant for Biosite, Bristol-Myers Squibb, Boston Scientific/Guidant, GlaxoSmithKline, Ks, Medtronic, NitroMed, Orasis Medical, Pfizer, Sanofi, Schering Plough, Scios Inc, and Wyeth. Dr Fonarow serves as chair of the American Heart Association’s Get With the Guidelines Steering Committee, and has received research funding from GlaxoSmithKline and Medtronic.

Dr Al-Khatib reports receiving research support from Medtronic and honoraria for presentations from Medtronic. Dr Curtis reports receiving research and salary support from Allergan Pharmaceuticals, GlaxoSmithKline, Lilly, Medtronic, Novartis, Ortho Bio-

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tech, OSI Eyetech, Pfizer, and Sanofi-Aventis. Dr Pe-
terson reports receiving research grants from Bristol-Myers Squibb, Schering-Plough, and Sanofi-Aventis. Drs Curtis and Peterson have made available a de-
tailed listing of disclosure information at http://www.
dci.duke.edu/research/coi.jsp. Dr Yancy reports re-
ceiving research grants from Cardiodynamics, GlaxoSmithKline, Scios Inc, Medtronic, and Ni-
troMed; serving as a consultant or on the speaker’s bureau for AstraZeneca, Cardiodynamics, GlaxoSmithKline, Medtronic, NitroMed, Novartis, and Scios Inc; serving on advisory boards for CHF Solu-
tions, a US Food and Drug Administration cardiovas-
cular device panel, and the National Institutes of Health; receiving honoraria from AstraZeneca, Cardiodynamics, GlaxoSmithKline, Medtronic, Novartis, and Scios Inc. Dr Albert reports serving as a consultant for GlaxoSmithKline and Medtronic and serving on the speaker’s bureau for GlaxoSmithKline, Medtronic, NitroMed, and Scios Inc. Drs Liang and LaBresh report that they have no conflicts of interest relevant to the subject matter discussed in the article.

Disclaimer: Dr Eric Peterson, a JAMA contributing edi-
tor, was not involved in the editorial review of or de-
cision to publish this article.

Funding/Support: The Get With the Guidelines–Heart Failure program is supported by an unre-
stricted educational grant from GlaxoSmithKline. Dr Hernandez is supported by an American Heart Asso-
ciation Pharmaceutical Roundtable grant 0675060N.

Role of the Sponsors: GlaxoSmithKline had no role in the design and conduct of the study; collection, man-
agement, analysis, and interpretation of the data; and pre-
paration, review, or approval of the manuscript.

Additional Contributions: We thank Damon M. Seils, MA, of Duke University for editorial assistance and manuscript preparation. Mr Seils did not receive com-
penation for his assistance apart from his employ-
ment at the institution where the study was con-
ducted.

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