Extent of and Reasons for Nonuse of Implantable Cardioverter Defibrillator Devices in Clinical Practice Among Eligible Patients With Left Ventricular Systolic Dysfunction

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Background—Several studies that used claims and registry data have reported that 40% to 80% of patients eligible for an implantable cardioverter defibrillator (ICD) fail to receive one in clinical practice, and the rates are especially high among women and blacks. The extent and documented reasons for nonuse of ICDs among patients with left ventricular systolic dysfunction are unknown.

Methods and Results—Using hospital claims and clinical data, we identified patients hospitalized with a heart failure diagnosis and left ventricular ejection fraction ≤30% between January 1, 2007, and August 30, 2007, at a tertiary-care center. Using claims data, we determined placement of an ICD or cardiac resynchronization therapy with defibrillation device at any time up to 1 year after hospitalization. Medical records for patients without an ICD were abstracted to determine reasons for nonuse. Patients with an ICD were compared with patients without an ICD and also with patients without an ICD who did not have any contraindication for an ICD as identified through chart abstraction. Of the 542 potentially eligible patients identified, 224 (41%) did not have an ICD. In the initial adjusted analysis, female sex (odds ratio 1.90; 95% CI, 1.28 to 2.81) and increasing age (odds ratio 1.07; 95% CI, 1.04 to 1.11) were associated with a higher likelihood of not having an ICD. After detailed chart review, of the 224 patients without an ICD, 117 (52%) were ineligible for the device and 38 (17%) patients refused the device, resulting in only 69 (13%) patients eligible for an ICD who failed to receive one. In this subsequent adjusted analysis, remaining factors associated with a higher likelihood of not having an ICD were absence of ventricular arrhythmias (odds ratio = 4.93; 95% CI, 2.56 to 9.50), noncardiology hospital service (odds ratio = 3.73; 95% CI, 1.98 to 7.04), and lack of health insurance (odds ratio = 3.10; 95% CI, 1.48 to 6.46).

Conclusions—On the basis of a detailed chart review, the true rate of ICD underuse may be substantially lower than previous estimates. In addition, after accounting for ICD eligibility criteria, patient sex and age disparities in ICD therapy were no longer present. (Circ Cardiovasc Qual Outcomes. 2011;4:00-00.)

Key Words: defibrillation ■ disparities ■ outcomes research
WHAT IS KNOWN

- The implantable cardioverter defibrillator (ICD) has been shown to be effective for both primary and secondary prevention of sudden cardiac death.
- Analyses of claims and registry data have found underuse and disparate use of ICDs in clinical practice.

WHAT THE STUDY ADDS

- Through detailed medical record abstraction, we found that a majority of heart failure patients who were seemingly eligible for an ICD had a contradiction to the ICD or had refused the ICD.
- After accounting for true ICD eligibility, the rate of underuse was only 13%.
- Unlike previous analyses of claims or registry data, we found that after accounting for true ICD eligibility, there was no association between female sex or advanced age and lack of ICD use.

Methods

Adult patients hospitalized from January 1, 2007, through August 30, 2007, with a primary or secondary diagnosis of heart failure at a single, academic, medical center were identified according to International Classification of Diseases, Revision 9 codes (398.91, 428.0, 428.1, 428.2x, 428.3x, 428.4x, 428.9). Patients who died during the index hospitalization were excluded from the study cohort. For patients with multiple hospitalizations with a primary or secondary diagnosis of heart failure during the study period, the first hospitalization during the study period was selected as the index hospitalization. Then, from data in the electronic health record and from the Duke Databank for Cardiovascular Disease, patients were selected for the study if their most recent left ventricular ejection fraction (EF) measurement by any modality (for example, echocardiogram, nuclear study, magnetic resonance imaging, or cardiac catheterization) obtained up to 1 year before discharge from the index hospitalization was ≤30%. The presence of an ICD or cardiac resynchronization therapy with defibrillation device up to 1 year after the index hospitalization was determined by using International Classification of Diseases, Revision 9, and Common Procedural Terminology codes (00.51, 00.54, 37.94, 37.95, 37.96, 37.97, 37.98, 37.99, 89.49, 996.04, V45.01, V45.02, V53.32) from all inpatient and outpatient encounters. In addition, American College of Cardiology National Cardiovascular Data Registry ICD registry data for the hospital were queried to identify any patients that might have been missed by using the claims data.

Medical records were abstracted for all patients without initial evidence for an ICD. Through abstraction, the absence of an ICD up to 1 year after the index hospitalization was confirmed. When the chart abstraction revealed that the patient had received an ICD, the date of implant, date of explant (if any), and type of defibrillator (ICD versus cardiac resynchronization therapy with defibrillation device) were collected. Abstractors used an electronic database (Microsoft Access) form to collect all data. This abstraction form was specifically designed to collect data on potential contraindications to an ICD inclusive of (1) immediate plans for heart transplantation; (2) New York Heart Association class IV heart failure during the index hospitalization; (3) nonoptimized medical therapy; (4) improvements in EF up to 1 year after the index hospitalization; (5) heart failure hospitalization within 40 days of the index hospitalization and follow-up assessment of EF; (6) percutaneous coronary intervention or coronary artery bypass grafting within 3 months after a qualifying EF measurement and follow-up EF measurements; (7) indicators of limited life expectancy, such as do-not-resuscitate orders, placement in hospice or palliative care, or ongoing active cancer diagnosis; (8) ongoing substance abuse; (9) ongoing serious infection; (10) severe cognitive or physical impairment; or (11) end-stage renal disease. Other factors collected included (1) duration of heart failure; (2) history of ventricular arrhythmias or sudden cardiac arrest with or without an ischemic event; (3) presence of a QRS interval >120 ms; (4) homelessness; and (5) residence in a long-term care facility before or after the index hospitalization. In addition, documentation within the medical record of any healthcare provider recommendation for an ICD implant and the cited reasons for not implanting an ICD were also collected. Because the study site is a tertiary-care center, abstractors also collected data on whether identified patients had any follow-up care (inpatient or outpatient) with a primary care provider or cardiologist anywhere within the Duke University Healthcare System. Patients without follow-up care, as described, were excluded from the analyses because subsequent placement of an ICD could not be determined.

The medical records of a randomly selected sample of patients with initial evidence of an ICD were also reviewed to confirm the presence of an ICD. If a patient who was thought to have an ICD was found (on chart review) not to have an ICD, then the International Classification of Diseases, Revision 9, code or the Common Procedural Terminology code initially identified that patient as an ICD recipient was determined. Then the medical records of all patients who were identified as ICD recipients (according to that same International Classification of Diseases, Revision 9, or Common Procedural Terminology code) were reviewed to verify ICD implantation. For purposes of quality control, a random sample consisting of ~5% of the abstracted medical records was selected for reabstraction by a different abstractor. Discrepancies in the 31 elements abstracted by 2 abstractors were then reviewed. This review identified 16 discrepancies of 403 abstracted elements, resulting in a discrepancy rate of 4%.

Patient demographics, comorbidities, health insurance, and inpatient hospital service during the index hospitalization were obtained from inpatient and outpatient claims data and the Duke Databank for Cardiovascular Disease for all patients with and without an ICD. Among patients without an ICD, abstracted data were reviewed to identify patients with a clinically acceptable reason for not receiving an ICD. Accepted reasons included (1) patient refusal of an ICD implant; (2) improvement in EF to >30% during the 1 year after the index hospitalization; (3) limited life expectancy, as determined by the presence of do-not-resuscitate orders, palliative or hospice care, or active cancer; (4) end-stage heart failure during the index hospitalization; and (5) anatomic barriers to ICD implant. The Duke University Health System institutional review board approved and reviewed this study.

Statistical Analysis

In this study, 2 analyses were performed. In both analyses, the outcome of interest was lack of an ICD implant up to 1 year after the index hospitalization. Both analyses included the same covariates and comparator group (all patients with an ICD implant). The difference between the analyses was the use of information abstracted from the medical record to exclude patients without an ICD who had an accepted reason for failure to implant an ICD (for example, contraindications and patient refusals). In the first analysis, no information from the abstracted medical records was considered. This analysis approximated the level of granularity available in claims data on determining the absence of an ICD implant. In the second analysis, patients with contraindications to an ICD implant or who refused an ICD were excluded from the analysis. This analysis compared all ICD recipients with only those nonrecipients who were considered ideal candidates for an ICD. Information on contraindications and patient preferences is frequently unavailable in claims or some registry data; therefore, this model provided a more granular
assessment than do prior analyses that have used only claims or some clinical registry data.

In both of our analyses, medians (and interquartile ranges) were reported for continuous variables, and percentages were reported for categorical variables. Continuous variables were compared by the Wilcoxon rank-sum test, and categorical variables were compared by $\chi^2$ tests, with the exception of categorical variables with a cell count of $<10$; in these cases, Fisher’s exact test was used.

To investigate the association between patient characteristics and lack of ICD use, 2 logistic-regression models were constructed. Candidate variables for inclusion in each model were selected from those variables that were found to be of statistical significance in univariate comparisons for 1 or both of the models. Based on prior published studies indicating disparities of age, race, and sex, these variables were included, even when the univariate comparisons were not found to be of statistical significance. Identical variables were included in both models to determine whether the additional detail obtained through chart abstraction resulted in differential factors associated with the lack of ICD use. To prevent overfitting of either model, the maximum number of variables in the smallest study group was 1 for every 10 patients.

Because some guideline recommendations have considered patients with an EF up to 35% to be eligible for ICD implant, a sensitivity analysis was conducted in which patients with a subsequent EF measurement $\leq 35\%$ were excluded (in previous analysis, patients with a subsequent EF measurement $>30\%$ were excluded). A probability value $<0.05$ was considered statistically significant for all tests, and all tests were 2 tailed. No adjustments were made for multiple comparisons. All analyses were performed with SAS software (version 8.2, SAS Institute, Cary, NC).

Results
A total of 576 patients hospitalized between January 1, 2007, and August 30, 2007, with a primary or secondary diagnosis of heart failure and an EF $\leq 30\%$ were identified. Of these patients, 34 (6%) did not have a qualifying follow-up encounter within the health system and were excluded, resulting in a final study population of 542 patients. Of these patients, a total of 318 (59%) had an ICD (206 ICD only and 112 cardiac resynchronization therapy with defibrillation device) within 1 year of their index hospitalization. This included 183 (58%) patients who had an ICD or cardiac resynchronization therapy with defibrillation device placed before their index hospitalization, 105 (33%) during their index hospitalization, and 30 (9%) in the 1 year after their index hospitalization.

Comparison of All ICD Recipients With All Nonrecipients
Of the 542 patients identified, 224 (41%) did not have an ICD up to 1 year after the index hospitalization. Differences in characteristics between patients with an ICD and those without an ICD are shown in Table 1. In the adjusted analysis, characteristics found to be significantly associated with not having an ICD were absence of ventricular arrhythmia or cardiac arrest (odds ratio [OR]=3.17; 95%
CI, 2.14 to 4.68), index hospitalization on a noncardiology service (OR; 95% CI, 1.65 to 4.21), female sex (OR; 95% CI, 1.28 to 2.81), advanced age (OR per 1 year; 95% CI, 1.04 to 1.11), or a higher-qualifying EF measurement (OR per 1% increase; 95% CI, 1.01 to 1.07) (the Figure).

Comparison of All ICD Recipients With Nonrecipients Without Contraindications

Through chart abstraction, a total of 155 (69%) of the 224 patients without an ICD were found to have a documented contraindication to ICD placement (117 patients) or refused ICD placement (38 patients). Contraindications included improvement in EF to ≤30% (n = 53), limited life expectancy (n = 54), class IV heart failure during the index hospitalization (n = 9), and an anatomic barrier to ICD implantation (n = 1). Thus, only 13% (n = 69) of the overall study population was truly eligible for an ICD but did not have one implanted within the year after the index hospitalization.

Differences in characteristics between those patients with an ICD and ideal candidates without an ICD are shown in Table 2. In the adjusted analysis, 2 characteristics that were found to be statistically significantly associated with lack of ICD use in the initial analysis were also found to be associated with the lack of ICD use in this secondary analysis. Those characteristics were absence of ventricular arrhythmias or cardiac arrest (OR = 4.93; 95% CI, 2.56 to 9.50) and index hospitalization on a noncardiology service (OR = 3.73; 95% CI, 1.98 to 7.04). Advanced age, female sex, and higher-qualifying EF measurement were not significantly associated with the lack of ICD use in this second analysis (OR = 3.10; 95% CI, 1.48 to 6.46), where it was not in the initial analysis. Results did not change in the sensitivity analysis when patients were excluded when their subsequent EF measurements were ≥35% instead of >30%.

Discussion

To date, several analyses of claims or registry data have indicated high rates of underutilization of this evidence-based therapy in clinical practice, as well as age, sex, and racial disparities in ICD use.10–17 Although we initially identified similar rates of ICD underutilization and disparities within our healthcare system, after detailed medical record abstraction, we discovered that a majority of those not receiving an ICD had an identified contraindication or patient refusal. After accounting for true ICD eligibility, the rate of nonuse was only 13%. Furthermore, there was no association between female sex or advanced age and the lack of ICD use.

The use of claims or registry data to assess utilization patterns is attractive, especially when examining patterns of care at multiple institutions. Two analyses of Medicare claims data identified patients with ischemic cardiomyopathy (by International Classification of Diseases, Revision 9 codes), determined the proportion with an ICD, and evaluated factors associated with nonuse.11,17 Gauri et al17 found that only 8% of those patients with a hospital admission for ischemic cardiomyopathy in 2002 received an ICD during the same year. Additionally, that study found that women and black patients were less likely than men and white patients, respectively, to receive an ICD implant. Nevertheless, the existence of an ICD at the time of hospitalization was not determined in that study, and no attempt to exclude patients with potential contraindications was made. Curtis et al11 found that only 2% of those patients age 65 or older with a diagnosis of ischemic
cardiomyopathy between 1999 and 2005 had received an ICD within 1 year of their index ischemic cardiomyopathy event. Additionally, that study found that women were found to have a significantly lower likelihood of receiving an ICD than were men. The proportion of patients receiving an ICD who also had a ventricular arrhythmia or cardiac arrest was 6%.

Three additional studies used clinical registry data to investigate ICD use. First, Thomas et al found that 40% of patients with a prior myocardial infarction and an EF ≤35% who were enrolled in a registry received an ICD up to 18 months after inclusion in the registry. Patients with ventricular arrhythmias were excluded from the analysis. Men, white patients, younger patients, and patients with lower EFs were more likely to receive an ICD. Second, Hernandez et al used data from the American Heart Association’s Get With the Guidelines–Heart Failure quality improvement project to assess ICD use in all patients included in the registry with an EF ≤35% and who had none of the contraindications identified by the registry data abstractors (for example, new heart failure; left hospital against medical advice; transfer to/from hospital; or discharged to hospice, rehabilitation program, or skilled nursing facility; missing EF measurement; or other physician documented contraindication). In that study, 35% of patients had either a prior ICD implant, received an ICD during hospitalization, or had a plan for a future ICD implant. Women and black patients were less likely than men and white patients, respectively, to either have or have a plan for an ICD. Finally, using the American Heart Association’s Get With the Guidelines–Heart Failure registry, Shah et al analyzed the same time period as Hernandez et al but used different criteria for contraindications. That study found that 20% of patients had an ICD or had a plan for an ICD in the future. Yet rates varied dramatically by type of hospital, with larger academic hospitals capable of transplant programs, percutaneous coronary intervention, and coronary artery bypass grafting reaching upwards of 60% to 70%. This estimate is closest to our initial analysis estimate (59%), and the hospital characteristics are consistent with those of our institution.

Although most of the analyses that have used claims or registry data have attempted to identify ideal candidates for ICD implant, medical record abstraction is likely to be a more robust methodology. Analyses limited to claims or registry data alone may also be limited owing to the fact that those analyses typically include only patients who were enrolled or agreed to participate in the study and seldom include patient follow-up assessments. Identifying patients who were offered an ICD, but refused the device, is also not possible from claims data and may not be possible from registry data. In our analysis, after accounting for patient refusals and contraindi-
cations, we found no association between advanced age or sex and ICD nonuse. We also found no association between black race and ICD nonuse in either model. This finding may be indicative of the higher overall quality performance level of this type of institution.

Limitations
There are several limitations to our study. First, our study was conducted at a single academic health system, so the results may not be generalizable to other hospitals or health systems. On the basis of the results of the study by Shah et al, our institution most likely represents 1 with the highest rates of ICD use. We do not know whether the same differences between the 2 models would be found at other institutions. Second, there is a risk of medical record abstraction errors, as well as variability in the quality of medical record abstraction among abstractors. To minimize these risks, a random sample of records was selected for rereview by a second abstractor; the rate of discrepancies was determined, as described. On the basis of a discrepancy rate of 4%, we believe that the risk of error was minimized. Third, the number of patients in each group was relatively small, so our study may have lacked statistical power to show an association between certain factors, such as race, and underutilization of ICD therapy.

Conclusions
Previously reported rates of ICD underutilization from claims or registry data may have been overestimated. After detailed record review, the underutilization rate declined from 41% to only 13%. In addition, after accounting for ICD eligibility criteria, sex and age were no longer associated with nonuse of an ICD. Additional research at other institutions is needed to confirm these results.

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