Hospice Use Following Implantable Cardioverter-Defibrillator Implantation in Older Patients: Results From the National Cardiovascular Data Registry

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More than 50,000 implantable cardioverter-defibrillators (ICDs) are inserted annually in patients aged ≥65, with >40% of ICDs placed in patients aged ≥70 years and >10% in patients ≥80. As guidelines and systematic reviews explicitly discourage use of age alone as an exclusion for ICD implantation, demographic trends and the growing burden of heart disease will make millions more older patients eligible for these devices in the coming years. Moreover, older patients receiving ICDs are at higher risk for short-term death, in comparison with younger patients, and face other important uncertainties regarding their clinical course and healthcare needs after implantation.

Background—Older recipients of implantable cardioverter-defibrillators (ICDs) are at increased risk for short-term mortality in comparison with younger patients. Although hospice use is common among decedents aged ≥65, its use among older ICD recipients is unknown.

Methods and Results—Medicare patients aged ≥65 matched to data in the National Cardiovascular Data Registry – ICD Registry from January 1, 2006 to March 31, 2010 were eligible for analysis (N=194,969). The proportion of ICD recipients enrolled in hospice, cumulative incidence of hospice admission, and factors associated with time to hospice enrollment were evaluated. Five years after device implantation, 50.9% of patients were either deceased or in hospice. Among decedents, 36.8% received hospice services. The cumulative incidence of hospice enrollment, accounting for the competing risk of death, was 4.7% (95% confidence interval [CI], 4.6%–4.8%) within 1 year and 21.3% (95% CI, 20.7%–21.8%) at 5 years. Factors most strongly associated with shorter time to hospice enrollment were older age (adjusted hazard ratio, 1.77; 95% CI, 1.73–1.81), class IV heart failure (versus class I; adjusted hazard ratio, 1.79; 95% CI, 1.66–1.94); ejection fraction <20 (adjusted hazard ratio, 1.57; 95% CI, 1.48–1.67), and greater hospice use among decedents in the patients’ health referral region.

Conclusions—More than one-third of older patients dying with ICDs receive hospice care. Five years after implantation, half of older ICD recipients are either dead or in hospice. Hospice providers should be prepared for ICD patients, whose clinical trajectories and broader palliative care needs require greater focus. (Circulation. 2016;133:2030-2037. DOI: 10.1161/CIRCULATIONAHA.115.020677.)

Key Words: defibrillators, implantable □ health services research □ heart failure □ patient outcome assessment

Clinical Perspective on p 2037

One of the most challenging healthcare transitions for older patients is hospice enrollment, because this represents a shift in the primary goal of care from survival to comfort and generally signifies that the end of life is approaching. Although
hospice is the main provider of end-of-life care in the United States, its use among patients with ICDs is unknown. Early work suggests that hospice providers may be ill prepared to address the unique end-of-life care needs of these patients. For example, 1 study found that only 10% of hospice providers have a device deactivation policy. At the same time, a limited number of small studies involving retrospective postdeath family interviews and patient and provider surveys suggest that unwanted shocks, particularly near the end of life, contribute to pain, decreased quality of life, and patient and family distress.

Despite the high mortality rate of older ICD patients, very little is known about the extent to which they currently access hospice services. Such information may help hospice providers better understand and prepare for their role in caring for these patients, assist in targeting patients who have the greatest need for hospice care earlier in their clinical course, further inform patients and their families about their future care needs, and support shared decision making regarding initial implantation. To address these knowledge gaps, we leveraged data from National Cardiovascular Data Registry (NCDR) ICD Registry linked to Medicare claims to describe the incidence and features of hospice use in a large, nationally representative sample of older patients following ICD implantation, and to identify factors associated with hospice enrollment in this cohort.

**Methods**

### Data Sources

This study analyzed data from the NCDR ICD Registry, the details of which have been previously published. In brief, this registry was established in 2005 in concert with the Centers for Medicare and Medicaid Services expansion of coverage for primary prevention ICD implantation, with the goal of prospectively enrolling all Medicare beneficiaries receiving ICDs for primary prevention of sudden cardiac death as a condition of payment. Participating sites are trained on data collection, including the use of standardized definitions, and submitted data are subject to audit for errors and completeness. In practice, the majority of the >1500 participating hospitals enter data for all ICD recipients regardless of insurance status or indication. To ascertain hospice enrollment among ICD recipients, ICD Registry data for patients receiving implants between January 1, 2006 and March 31, 2010 were combined with Medicare fee-for-service claims from January 1, 2006 to December 31, 2010, ensuring at least 9 months follow-up after device insertion. Indirect patient linkage was accomplished via a previously established algorithm by using the following identifiers: age, sex, admission date or procedure date, and hospital Medicare provider number to achieve a 63% match rate. Death dates were derived from Centers for Medicare and Medicaid Services enrollment files and validated with data from the Social Security Administration. To assess regional variation in hospice referral after ICD placement, 2010 data from the Dartmouth Atlas were linked to the analytic file to characterize hospice use among decedents in the ICD patients’ hospital referral region (HRR). This year was selected because it was the only one corresponding to our study period for which these data were available.

The Yale University Human Investigation Committee and Institutional Review Boards at Beth Israel Deaconess Medical Center and Hebrew SeniorLife Institute for Aging Research approved the conduct of this study.

### Study Population

Patients >65 years who had ICDs inserted between January 1, 2006 through March 31, 2010 were eligible (Figure 1), aligned with use of the ICD Registry Version 1.0 collection form. Patients who were not fee-for-service Medicare patients were excluded because claims data for health maintenance organization enrollees were not available in the data files. There was no requirement for continuous fee-for-service enrollment before the index procedure. Patients enrolled in hospice before device placement were also excluded. For patients with multiple procedures during the study period, the first entry into the registry was taken as the index procedure for analytic purposes. Thus, baseline characteristics and time-to-event analyses are anchored to the index procedure, which may have been either a new or replacement ICD insertion.

### Patient Characteristics

Patient characteristics were derived from ICD Registry Data Collection Form v1.08 at the time of device placement unless otherwise stated. Demographic variables included age, sex, and race (white, black, or other). Clinical information included cardiac conditions, noncardiac conditions, diagnostic studies, and procedural details. Cardiac conditions, as documented in the standard ICD Registry form, included congestive heart failure, functional status (New York Heart Association class I–IV), atrial fibrillation/flutter, ventricular tachycardia, nonischemic cardiomyopathy, any ischemic heart disease, myocardial infarction, coronary artery bypass grafting, percutaneous coronary intervention, previous ICD implantation, and cerebrovascular disease. We also included type of device (single chamber, dual chamber, or biventricular) and whether the device was for primary or secondary prevention. In the ICD Registry, secondary-prevention indicates patients who have previously experienced sustained ventricular arrhythmias or, for those with an ICD implant before their index procedure in this cohort, appropriate ICD therapy. We also ascertained the most recent estimates of left ventricular ejection fraction (%) and glomerular filtration rate (mL/min), calculated using the Modification of Diet in Renal Disease Study Group (MDRD) Study. Noncardiac comorbidities abstracted from the ICD registry form included chronic lung disease, diabetes mellitus, and hypertension.

We postulated that dementia and cancer would be associated with hospice referral. Because these diagnoses are not included in the ICD Registry, these were obtained from International Classification of...
Diseases, Ninth Revision codes on the Medicare claim associated with the index procedure. To construct the cancer and dementia variables, we used a modified version of the Hierarchical Condition Categories.21,22

Finally, Medicare claims data were used to determine whether subjects were admitted to a skilled nursing facility in the 6 months before the index ICD procedure.

Hospice Use
Whether or not a subject was enrolled in hospice following ICD placement was determined by using Medicare hospice claims. If the subject was enrolled, we determined the dates of admission and discharge, length of stay, site of care (hospital versus home-based), and primary admitting diagnosis.

Hospice Use in HRR
Previous research has shown that regional penetration of hospice is highly associated with whether or not individual patients are enrolled in hospice. To account for this observation, the percentage of decedents who were enrolled in hospice during the last 6 months of life in the HRRs in which the subjects had their ICD inserted was ascertained from the Dartmouth Atlas by using 2010 data. Based on its distribution, this variable was categorized into quartiles as follows: 19.3% to <41.0%, 41.0% to <47.8%, 47.8% to <54.3%, 54.3% to 70.3%.

Statistical Analysis
All baseline demographic data, clinical information, and procedural variables were described using frequencies for categorical variables and means (standard deviations) and medians (first to third quartiles) for continuous variables.

The proportion of subjects who enrolled in hospice and the median time from index procedure to hospice enrollment were calculated. For subjects admitted to hospice, length of stay was evaluated in days and other characteristics of the hospice admission were presented as proportions. Time from ICD implantation and time from hospice admission to death were calculated in years. Cumulative incidence was calculated accounting for the competing risk of death for the time to hospice admission outcome.

Our primary analysis used time to hospice enrollment as measured from the date of ICD placement to date of first hospice enrollment as the outcome. Subjects who were never enrolled in hospice or were disenrolled from Medicare fee-for-service were censored at the end of the follow-up period (December 31, 2010). Missing data for each independent variable was iteratively imputed by using the Fully Conditional Specification method of multiple imputation to create 10 imputed data sets.23 For each data set, a proportional subdistribution hazards model that accounted for the competing risk of death was used to examine the association between the independent variables and time to hospice enrollment.24 Hazard ratios and their associated confidence intervals (CIs) were generated from these analyses again using the average of the estimates across 10 imputed datasets.

Replacement ICD was considered a priori to be an independent variable that might introduce survivorship bias and interactions with other independent variables based on previous studies.25 Thus, a second model was fit evaluating replacement ICD combined with prespecified interaction terms including age, atrial fibrillation, ventricular tachycardia, congestive heart failure, and left ventricular ejection fraction. This second model did not impact the observed relationships, and thus we present only the results of the main model.

All analyses were performed using SAS v9.4 (SAS Institute, Cary, NC).

Results
Baseline Characteristics
From the 516,147 patients entered into the ICD Registry during the study period, 312,801 were eligible for probabilistic matching after exclusions for age <65, discharge date outside of the study period, duplicates or missing hospital information (Figure 1). Only 624 (0.3%) patients were excluded because of previous hospice enrollment. Probabilistic matching to Medicare data yielded a final analytic cohort of 194,969. Comparisons between matched and unmatched patients according to demographic and clinical characteristics showed no significant differences. The median follow-up time for the final analytic cohort was 1.92 years (first to third quartile, 1.13–2.97). During the 5-year follow-up period, a total of 52,990 (27.1%) patient deaths were observed. The 1-year and 5-year incidences of mortality were 12.1% and 48.8%, respectively.

The demographic, cardiovascular, and noncardiovascular characteristics of the total cohort and stratified according to hospice enrollment are shown in Table 1. The overall cohort’s mean age was 75.5±6.4 years, 25.7% were female, and 89.6% were white. In terms of cardiovascular disease, the majority of patients had congestive heart failure (80.0%) and ischemic heart disease (73.5%), including previous coronary artery bypass grafting (42.6%) or percutaneous coronary intervention (34.5%). Clinical arrhythmias were common, including atrial fibrillation (42%) and ventricular tachycardia (41%). A total of 29.7% had received a previous ICD, 46.6% had cardiac resynchronization therapy devices, and 79.0% of all implant devices were placed for primary prevention. Among noncardiac conditions, only 1.1% of patients had a diagnosis of dementia, and only 1.7% had a previous diagnosis of cancer.

Hospice Enrollment
A total of 22,336 patients (11.5%) were enrolled in hospice during the 5-year follow-up period. The cumulative incidence of hospice admission, accounting for the competing risk of death, was 4.7% (95% CI, 4.6%–4.8%) at 1 year and 21.3% (95% CI, 20.7%–21.8%) at 5 years (Figure 2). For those enrolled in hospice, the median time from ICD implantation to hospice enrollment was 1.3 years (first to third quartiles, 0.57–2.3 years). A total of 36.8% of decedents received hospice services. At 5 years follow-up, 50.9% patients had either died or been enrolled in hospice.

For subjects who were admitted to hospice, the median length of stay for their first hospice admission was 10 days (first to third quartiles, 4–36 days). Death was documented
for 87.7% of hospice enrollees, and 84.3% of hospice services were provided at home (versus inpatient). The most common primary admitting diagnoses were congestive heart failure or cardiomyopathy (38.5%) and other heart disease (15.2%). Among noncardiac conditions, cancer diagnoses (17.5%), chronic kidney disease or renal failure (6.3%), chronic obstructive pulmonary disease and bronchiectasis (4.6%), and acute cerebrovascular disease (2.6%) were most common.

Factors Associated With Time to Hospice Enrollment
Unadjusted and adjusted associations between baseline characteristics and time to first hospice enrollment are shown in Table 2. In unadjusted analysis, all independent variables were associated with time to hospice enrollment and were entered into the multivariable model. All independent variables in the adjusted model remained significantly associated with the outcome, with the following factors being most strongly associated with a shorter time to hospice enrollment: cancer (adjusted hazard ratio [AHR], 2.04; 95% CI, 1.88–2.20), dementia (AHR, 1.93; 95% CI, 1.76–2.12), older age (AHR, 1.77; 95% CI, 1.73–1.81), class IV heart failure (versus class I [referent]; AHR, 1.79; 95% CI, 1.66–1.94); left ventricular ejection fraction <20 (AHR, 1.57; 95% CI, 1.48–1.67), chronic lung disease (AHR, 1.40; 95% CI, 1.36–1.44), and greater regional hospice penetration.
Discussion

This report from a nationwide sample provides the first comprehensive assessment of hospice use in older patients following ICD implantation. After accounting for the competing risk of death, the cumulative incidence rate of hospice admission in the 5 years following ICD placement was 21%. This finding underscores the need for hospice providers to prepare to care for dying ICD patients, including establishing protocols for turning off such devices and avoiding shocks at the end of life. At the same time, 63% of decedents did not receive hospice care. This finding, coupled with the fact that, at 5 years post-implantation, 51% of older ICD patients were either dead or in hospice, calls for a much greater understanding of the broader palliative care needs of older ICD patients and improved strategies to deliver that care.

Hospice is the main provider of end-of-life care for older Americans, with nearly half of all Medicare decedents making use of hospice services in 2012. In 2007, it was estimated that 43% of Medicare decedents with cancer and 34% of those with severe cognitive impairment received at least 3 days of hospice services. Thus, based on our findings, patients dying with ICDs are relatively common users of hospice, with 37% of decedents receiving such services and a cumulative incidence rate of enrollment over 5 years of 21% among those who had not already died. Nonetheless, hospices may be ill prepared to manage ICD patients, as indicated in a 2010 nationwide survey of 900 hospice providers indicating that, although 97% admitted patients with ICDs, only 10% had an ICD deactivation policy. Development and use of such policies, including routinely querying new hospice enrollees about the presence of an ICD, could be a potential quality metric for hospice providers.

The observation that half of older ICD recipients were either in hospice or deceased by 5 years postinsertion signals a critical need to better understand the palliative care needs of this vulnerable population. Very little is currently known about the clinical course of older ICD patients with respect to prognosis, communication, participation in advance care–planning discussions, sources of suffering, family member burden, and quality of end-of-life care. One concerning study found 65% of ICD patients (n=125, only 3% in hospice) had shock therapies active at the time of death, with 31% receiving shocks in the hours before death. Given that hospice has been shown to improve several key outcomes among dying patients, including those with cardiac disease, it is reasonable to assume that the 63% of ICD decedents who did not receive hospice may have benefited from such services. Moreover, given that the median length of stay was only 10 days, in comparison with 17 days for all hospice recipients nationwide in 2014, ICD patients who were enrolled in hospice may have benefited from earlier referral.

More broadly, the high mortality rate observed in our older ICD cohort, and the fact that the majority of decedents were never enrolled in hospice, suggests the need for greater integration of palliative care principles farther upstream in their clinical course. For example, general cardiologists and electrophysiologists should ensure that decision making at the time of device insertion is informed and aligned with patient preferences, and that such discussions are revisited in follow-up as the patient’s clinical status evolves. Primary care providers should also actively address such issues, as well as the broader palliative care needs of older ICD patients and improved strategies to deliver that care.

Figure 2. Cumulative incidence (solid line) with 95% confidence intervals (dashed lines) of hospice admission following implantable cardioverter-defibrillator implantation.
These findings are consistent with other studies of hospice use suggesting that the availability of providers and local clinical practice play important roles in the provision of hospice care, independent of clinical necessity or patient preferences.37

Our study has several potential limitations. Only ICD recipients in the ICD Registry who were matched to fee-for-service Medicare claims were eligible for our analyses, and thus our findings may not extend simply to patients who are younger or those in managed care plans. Although our probabilistic match strategy showed similar patient characteristics between matched and unmatched subjects, it is possible that residual differences remain between these groups. Follow-up ended in December 2010, and it is possible that hospice use among ICD recipients has evolved in the intervening years, although patient and market factors associated with hospice use have remained generally stable over time.18,38 Notably, access to palliative care more broadly has expanded markedly in the years including and extending beyond our study period.39 Thus, it is possible that referral of ICD patients toward hospice care may in fact be even more common than what we identified. In evaluating factors associated with hospice use, we were limited to variables ascertained from the

Table 2. Unadjusted and Adjusted Associations Between Baseline Characteristics and Time to First Hospice Enrollment Following Implantable Cardioverter-Defibrillator Implantation

| Variable                                                                 | Unadjusted Hazard Ratio (95% Confidence Interval) | P Value* | Adjusted† Hazard Ratio (95% Confidence Interval) | P Value* |
|--------------------------------------------------------------------------|---------------------------------------------------|---------|-------------------------------------------------|---------|
| Age (per 10 y)                                                          | 1.87 (1.83–1.92)                                   | <0.0001 | 1.77 (1.73–1.81)                                 | <0.0001 |
| Female sex                                                               | 0.94 (0.91–0.97)                                   | <0.001  | 0.93 (0.90–0.96)                                 | <0.0001 |
| Race (white vs nonwhite)                                                | 1.08 (1.01–1.15)                                   | .02     | 0.94 (0.89–1.00)                                 | .05     |
| Congestive heart failure                                                | 1.65 (1.59–1.72)                                   | <0.0001 | 1.21 (1.16–1.26)                                 | <0.0001 |
| New York Heart Association class                                         |                                                   |         |                                                 |         |
| Class I                                                                 | 1.00                                              |         |                                                 |         |
| Class II                                                                | 1.32 (1.25–1.39)                                   | <0.0001 | 1.09 (1.03–1.15)                                 | <0.001  |
| Class III                                                               | 1.83 (1.74–1.93)                                   | <0.0001 | 1.34 (1.26–1.43)                                 | <0.0001 |
| Class IV                                                                | 2.68 (2.49–2.88)                                   | <0.0001 | 1.79 (1.66–1.94)                                 | <0.0001 |
| History of atrial fibrillation/flutter                                   | 1.39 (1.35–1.43)                                   | <0.0001 | 1.17 (1.14–1.21)                                 | <0.0001 |
| History of ventricular tachycardia                                       | 1.09 (1.06–1.12)                                   | <0.0001 | 1.09 (1.06–1.12)                                 | <0.0001 |
| Ischemic heart disease                                                  | 1.24 (1.20–1.29)                                   | <0.0001 | 1.11 (1.04–1.15)                                 | <0.0001 |
| Cerebrovascular disease                                                 | 1.41 (1.36–1.46)                                   | <0.0001 | 1.23 (1.19–1.28)                                 | <0.0001 |
| Previous implantable cardioverter-defibrillator                         | 1.20 (1.16–1.24)                                   | <0.0001 | 1.13 (1.09–1.17)                                 | <0.0001 |
| Cardiac resynchronization therapy (CRT) vs non-CRT device               | 1.29 (1.26–1.33)                                   | <0.0001 | 0.94 (0.91–0.97)                                 | <0.001  |
| Chronic lung disease                                                    | 1.46 (1.41–1.50)                                   | <0.0001 | 1.40 (1.36–1.44)                                 | <0.0001 |
| Diabetes mellitus                                                       | 1.15 (1.12–1.19)                                   | <0.0001 | 1.14 (1.11–1.18)                                 | <0.0001 |
| Dementia                                                                | 2.33 (2.12–2.56)                                   | <0.0001 | 1.93 (1.76–2.12)                                 | <0.0001 |
| History of cancer                                                       | 2.04 (1.89–2.20)                                   | <0.0001 | 2.04 (1.88–2.20)                                 | <0.0001 |
| Skilled nursing facility claim in previous 6 mo                         | 1.88(1.78–1.98)                                    | <0.0001 | 1.45(1.36–1.53)                                  | <0.0001 |
| Left ventricular ejection fraction                                       |                                                   |         |                                                 |         |
| <20                                                                     | 1.80 (1.70–1.91)                                   | <0.0001 | 1.57 (1.48–1.67)                                 | <0.0001 |
| ≥20 to <40                                                              | 1.30 (1.24–1.36)                                   | <0.0001 | 1.18 (1.12–1.24)                                 | <0.0001 |
| ≥40                                                                     | 1.00                                              |         |                                                 |         |
| Glomerular filtration rate (per 10 U increment)                         | 0.86 (0.86–0.87)                                   | <0.0001 | 0.91 (0.90–0.91)                                 | <0.0001 |
| Quartile of % decedents in health referral region enrolled in hospice in last 6 mo of life | | |
| Quartile I (19.3% to <41.0%)                                            | 1.00                                              |         |                                                 |         |
| Quartile II (41.0% to <47.8%)                                           | 1.22 (1.14–1.30)                                   | <0.0001 | 1.25 (1.15–1.35)                                 | <0.0001 |
| Quartile III (47.8% to <54.3%)                                          | 1.46 (1.36–1.56)                                   | <0.0001 | 1.49 (1.38–1.62)                                 | <0.0001 |
| Quartile IV (54.3% to 70.3%)                                            | 1.78 (1.65–1.91)                                   | <0.0001 | 1.84 (1.70–1.99)                                 | <0.0001 |

*P values are 2-sided.†Factors with unadjusted hazard ratios with P<0.2 were entered into the adjusted model.
ICD Registry and Medicare claims. Factors potentially influencing hospice use, such as patient preference and severity of comorbid conditions (eg, dementia), were not available. In addition, we characterized variables at the time of ICD implantation, and were not able to account for interval development of conditions, such as cerebrovascular disease, progression of heart failure severity, or the incidence of ICD shocks. Characterizing these specific elements of patients’ evolution from healthy enough to receive an ICD to sick enough to merit hospice enrollment therefore remains a critical target of further study. This is particularly urgent given the influence of ICDs themselves on patients’ likelihood of dying either suddenly or from a more progressive process, outcomes that may not align well with many older patients’ preferences.40

In summary, substantial numbers of ICD recipients use hospice services, yet with relatively short lengths of stay. Hospice providers should be prepared to manage the unique needs of these patients. In addition, the large portion of ICD patients who either died or were in hospice within 5 years of device implantation argues strongly that these patients, particularly those with advanced heart failure, may benefit from a palliative care approach earlier in their clinical course, including earlier hospice referral. Finally, our study demonstrates a need for a clearer understanding of patients’ clinical trajectories following ICD implantation, including the ways in which these patients die, to provide the highest-quality care throughout the entire experience of living and dying with an ICD.

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