**Heart Failure and Heart Rhythm Disorders**

# Impact of Baseline Heart Failure Burden on Post-Implantable Cardioverter-Defibrillator Mortality Among Medicare Beneficiaries

Chih-Ying Chen, PhD,*† Lynne Warner Stevenson, MD,†‡ Garrick C. Stewart, MD,†‡
John D. Seeger, PharmD, DrPH,*† Lauren Williams, BA,* Jessica J. Jalbert, PhD,*†
Soko Setoguchi, MD, DrPH*†§

*Boston, Massachusetts; and Durham, North Carolina*

| | |
|---|---|
| **Objectives** | This study sought to assess the impact of baseline heart failure (HF) burden on survival with primary implantable cardioverter-defibrillator (ICD) among Medicare recipients. |
| **Background** | Survival after primary ICD implantation may differ between trial and Medicare populations. |
| **Methods** | Linking data from the CMS (Centers for Medicare and Medicaid Services) ICD registry and the Medicare files (2005 to 2009), we identified primary ICD recipients age ≥66 years with ejection fraction ≤35%. Number of previous HF hospitalizations (prev-HF-hosp) and length of hospitalization prior to implantation were used to define HF burden. Crude all-cause mortality was estimated. Adjusted hazard ratios (HR) were derived from Cox models. |
| **Results** | Of 66,974 ICD recipients (73% men, 88% white, mean age 75 years), 11,876 died (average follow-up = 1.4 years), with 3-year mortality of 31%. Among patients with no prev-HF-hosp, 3-year mortality was 27% compared with 63% in those with ≥3 prev-HF-hosp (adjusted HR: 1.8). Among patients with same-day implantation, 3-year mortality was 25% compared with 53% in those with >1-week hospitalization days prior to implantation (adjusted HR: 1.9). Mortality at 3-year follow-up among the 31,685 ICD recipients with no prev-HF-hosp and same-day implantation (low HF burden) was similar to that in trials (22%). |
| **Conclusions** | Nearly one-third of Medicare ICD recipients died within 3 years, reflecting a population with more advanced age and disease than seen in trial populations for primary prevention ICD. Nearly one-half of Medicare recipients had a low HF burden and had a survival similar to trial ICD recipients. Future research is warranted to understand the effectiveness of primary ICD implantation among Medicare beneficiaries with heavy HF burdens. (J Am Coll Cardiol 2013;61:2142–50) © 2013 by the American College of Cardiology Foundation |

Several landmark trials have demonstrated the efficacy of implantable cardioverter-defibrillators (ICD) in systolic heart failure (HF) (1–3). As a result, the Centers for Medicare and Medicaid Services (CMS) issued a national coverage determination in 2005 that expanded the ICD indication to include primary prevention of sudden cardiac death (SCD) among Medicare beneficiaries with previous myocardial infarction or

chronic HF and left ventricular ejection fraction (EF) ≤35% despite receipt of medical therapy (4). Data from the

IMPROVE-HF (Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting) and

Get With The Guidelines-Heart Failure Registries had been extrapolated to project that ICD may be indicated to prolong survival for as many as 800,000 additional HF patients, most of whom are over 65 years old (5).

The demographics of patients currently receiving ICD indicate that they are older with a higher prevalence of noncardiac comorbidities than their counterparts who are enrolled in the landmark clinical trials (6). The survival benefit of ICD is likely to attenuate with age (7–9), because increasing age has been associated with a decreased risk of SCD among HF populations (7,8) and noncardiac death is more common in older ICD recipients (10). The survival benefit of ICD also diminishes among patients with noncardiac comorbidities, such as chronic kidney disease (9,11,12).

The efficacy of ICD implantation for primary prevention (primary ICD) has been demonstrated among outpatient trial participants with stable mild-moderate HF symptoms, which have informed long-term cost-effectiveness estimates (1,13,14). It is not known how these benefits might translate to older patients with differing HF burdens, as reflected by multiple previous HF hospitalizations or prolonged current hospitalization for acute decompensation of chronic HF. In this study, we aimed to: 1) describe long-term survival with primary ICD in the Medicare population; and 2) evaluate the impact of HF and comorbidity burden on survival with ICD, using the number of previous HF hospitalizations and the length of hospitalization prior to ICD implantation as proxies for chronic and acute HF burden, respectively.

## Methods

**Data sources.** We conducted a retrospective cohort study using the CMS-ICD registry and MedPAR (Medicare Provider Analysis and Review) files from January 1, 2005, through December 31, 2009.

CMS-ICD REGISTRY. The CMS-ICD registry is a subset of the ACC-NCDR (American College of Cardiology–National Cardiovascular Data Registry) ICD registry, which is the sole repository for ICD implantation data for Medicare beneficiaries (15–19). The registry was developed through a partnership of the Heart Rhythm Society and the American College of Cardiology Foundation, using the expertise of the NCDR. The data are entered by hospital personnel and are only included in the analytic file if hospitals achieve certain completeness on specific data elements (20). In addition, a subset of hospitals is randomly selected for quality control review to evaluate data accuracy. Currently, over 400,000 patients are included in the CMS-ICD registry, which contains 37 of 170 data elements that the ACC-NCDR collects. These 37 elements include a patient's identifying information, history and clinical characteristics, medications, facility information, provider information, ICD indications, device information, and in-hospital complications.

MEDPAR FILE. The MedPAR file contains data from claims for services provided to fee-for-service beneficiaries admitted to Medicare-certified inpatient hospitals. It includes information on beneficiary demographics, diagnoses, procedures, and health resource use from hospitals or skilled nursing facilities, as well as detailed data on accommodation and departmental charges, days of care, and entitlement.

We linked the ICD registry to MedPAR files by 4 nonunique identifiers: sex, date of birth, admission date for ICD implantation, and provider identification number, similarly to previously described methods (21,22). We validated this linkage by comparing it with a linkage using a personal identifier (social security number cross-linked to beneficiary identification number) among the subset of the data that had this identifier. We found that our linkage method had 95% specificity, 98% sensitivity, and 98% positive predictive value compared with the linkage method using personal identifiers.

**Study population.** The study population consisted of Medicare fee-for-service beneficiaries who had a reduced (≤35%) EF and received an ICD for the primary prevention of SCD (Table 1). Patients who had a history of cardiac arrest or sustained ventricular tachycardia were excluded. We also required patients to be eligible for Medicare for at least 1 year prior to the index procedure and to be at least 66 years of age at the time of implantation. We censored patients in the analyses at the earliest occurrence of the following: death; or the end of the study period.

**Outcome.** The study outcome was all-cause mortality. The date of death was obtained from the MedPAR file.

**Measures of acute and chronic HF burden and subgroups.** We used the number of previous HF hospitalizations and the length of hospitalization prior to ICD implantation as indicators of chronic and acute HF burden. We followed a previously validated algorithm with a positive predictive value of 94% to identify HF hospitalizations within 1 year prior to ICD implantation from MedPAR data (23), and then categorized the number of previous HF hospitalizations into 4 levels (Table 2). We also classified the interval from admission to ICD implantation into 4 levels (Table 3). Patients who had no previous HF hospitalization and received ICD on the admission date were considered to have low burden of HF.

**Statistical analysis.** Baseline characteristics of the overall study population and each subgroup were characterized by percentages for categorical variables and using medians and

| Table 1 | Main Characteristics and Outcomes Among Medicare Beneficiaries Receiving Primary ICD Implantations (n = 66,974) |
|---|---|
| **Characteristics** | |
| Median age, yrs | 75 (71–80) |
| Male | 48,853 (73) |
| White | 58,916 (88) |
| Median EF, % | 25 (20–30) |
| **HF duration** | |
| New HF | 7,965 (12) |
| 0–3 months | 9,389 (14) |
| 3–9 months | 8,652 (13) |
| >9 months | 40,175 (61) |
| Missing | 793 |
| **NYHA functional class** | |
| I | 3,926 (6) |
| II | 20,647 (31) |
| III | 38,667 (58) |
| IV | 3,384 (5) |
| Missing | 350 |
| QRS interval ≥120 ms | 42,269 (63) |
| Ischemic cause HF | 53,232 (79) |
| ≥1 previous hospitalization for any cause | 18,752 (28) |
| ≥5 previous hospitalizations for any cause | 2,624 (4) |
| Cardiac resynchronization therapy–defibrillators | 32,201 (48) |
| **Outcomes** | |
| Death | 11,876 |
| In-hospital death | 327 |
| In-hospital death risk, % | 0.49 (0.45–0.55) |
| Average follow-up, yrs (days–yrs) | 1.4 (0–4) |
| Mortality rate, per 1,000 person-yrs | >128 |
| 1-yr mortality risk, % | 12 (12–13) |
| 2-yr mortality risk, % | 22 (22–23) |
| 3-yr mortality risk, % | 31 (30–32) |

Values are median (interquartile range), n (%), n, or hazard ratio (HR) (95% confidence interval [CI]).
EF = ejection fraction; HF = heart failure; ICD = implantable cardioverter-defibrillator(s); NYHA = New York Heart Association.

interquartile ranges or means and standard deviations for continuous variables.

We graphed cumulative mortality over time using Kaplan-Meier estimates for the entire study population and for each subgroup. Differences among subgroups were tested using log-rank tests. We used proportional hazards regression models to derive crude, demographic (age, sex, and race), and multivariable-adjusted hazard ratios (HR) among the subgroups. We attempted to account for the impact of other measures of HF severity (such as HF duration and New York Heart Association [NYHA] class) and of comorbidities (such as coronary artery disease, unsustained ventricular tachycardia, nondilated cardiomyopathy, cerebrovascular disease, diabetes, chronic kidney disease, chronic obstructive pulmonary disease, osteoporosis, mental disorders, metastatic cancer) on post-implantation mortality in the multivariable-adjusted model (see notes for Tables 2 and 3 for the complete list of covariates in the model).

All analyses were conducted using SAS for Windows (release 9.2, SAS Institute Inc., Cary, North Carolina). The study was approved by the institutional review board of Brigham and Women's Hospital.

## Results

**Characteristics and survival of overall Medicare patients with ICD.** The final study cohort consisted of 66,974 Medicare HF patients who underwent ICD implantation for primary prevention of SCD (see the Online Appendix for the description of the final study patients). The median age was 75 years and the majority were men (73%) and white (88%) (Table 1). More than one-half of the patients (61%) had known HF for more than 9 months, with 79% having HF due to an ischemic cause. The median EF was 25%. Over one-quarter (28%) of the patients were hospitalized at least once for any cause within 1 year prior to implantation, among whom 14% had more than 5 hospitalizations. During the average follow-up of 1.4 years, 11,876 patients died. One-, 2-, and 3-year mortality rates after ICD implantation were 12%, 22%, and 31%, respectively (Table 1).

**Chronic HF burden: number of previous HF hospitalizations.** At least 1 previous hospitalization for HF had occurred in the year preceding ICD implantation for 14,011 patients (21%). Of these, 27% had 2 or more hospitalizations attributed to HF (Table 2). A higher number of previous HF hospitalizations were associated with lower EF: 31% had EF ≤20% among patients with no previous HF hospitalization versus 48% among patients with 3 or more previous HF hospitalizations). Previous HF hospitalization was also associated with higher NYHA class at time of implantation: 59% of patients with no previous HF hospitalization had NYHA class III/IV symptoms at implantation compared with 84% among patients with 3 or more previous HF hospitalizations. Chronic HF burden was also associated with more frequent comorbidities, as reflected by the number of previous all-cause hospitalizations and the Charlson comorbidity score (Table 2).

**Mortality by the number of previous HF hospitalizations.** After ICD placement, mortality at 3 years increased from 27% in patients without previous HF hospitalization to 63% in those with 3 or more previous HF hospitalizations (Table 2, Fig. 1). Among patients who had more than 3 previous HF hospitalizations, more than one-half died within 2 years of implantation (Fig. 1). Compared with patients without a previous hospitalization, the crude HR for mortality ranged from 1.7 for patients with 1 previous HF hospitalization to 3.4 for patients with 3 or more previous HF hospitalizations. The pattern of HR across levels of chronic HF burden remained similar after adjusting for demographics. The impact of number of hospitalizations on all-cause mortality suggests that the number of hospitalizations may serve as a surrogate for HF severity and comorbidities, because its effect diminished substantially after adjusting for these variables in multivariable analy-

| Table 2 | Characteristics and Outcomes by the Number of Previous HF Hospitalizations | | | |
|---|---|---|---|---|
| | 0 Hospitalizations n = 52,963 (79) | 1 Hospitalization n = 10,247 (15) | 2 Hospitalizations n = 2,501 (4) | ≥3 Hospitalizations n = 1,263 (1) |
| **Characteristics** | | | | |
| Age, yrs | 75 (71–80) | 76 (71–80) | 76 (71–81) | 76 (71–80) |
| ≤70 | 13,005 (25) | 2,357 (23) | 564 (23) | 309 (24) |
| ≥80 | 14,025 (26) | 3,016 (29) | 733 (29) | 346 (27) |
| Male | 39,620 (75) | 6,906 (67) | 1,566 (63) | 761 (60) |
| White | 47,332 (89) | 8,682 (85) | 1,968 (79) | 934 (74) |
| EF, % | 25 (20–30) | 25 (20–30) | 25 (20–30) | 23 (20–30) |
| ≤20% | 16,418 (31) | 4,406 (43) | 1,075 (43) | 610 (48) |
| HF duration | 52,705 | 9,816 | 2,422 | 1,238 |
| New HF | 7,965 (15) | 0 (0) | 0 (0) | 0 (0) |
| 0–3 months | 7,297 (14) | 1,587 (16) | 348 (14) | 157 (12) |
| 3–9 months | 6,317 (12) | 1,771 (18) | 398 (16) | 166 (13) |
| >9 months | 31,126 (59) | 6,458 (66) | 1,676 (69) | 915 (74) |
| NYHA functional class | 52,663 | 10,211 | 2,489 | 1,261 |
| I | 3,617 (7) | 253 (2) | 44 (2) | 12 (1) |
| II | 17,597 (33) | 2,386 (23) | 474 (19) | 189 (15) |
| III | 29,239 (56) | 6,824 (67) | 1,716 (69) | 882 (70) |
| IV | 2,210 (4) | 748 (7) | 255 (10) | 178 (14) |
| QRS interval ≥120 ms | 32,949 (62) | 6,817 (67) | 1,651 (66) | 852 (67) |
| Ischemic cause HF | 42,168 (80) | 7,995 (78) | 2,020 (81) | 1,049 (83) |
| Unsustained VT | 12,382 (23) | 2,273 (22) | 590 (24) | 309 (24) |
| Previous hospitalization for any cause | 0.6 ± 1 | 2 ± 1.3 | 3.2 ± 1.4 | 5.5 ± 2.6 |
| ≥5 | 506 ± 1 | 498 ± 5 | 402 ± 16 | 720 ± 57 |
| LOS of implantation | 3.9 ± 5.2 | 4.2 ± 5.5 | 5 ± 6 | 5.9 ± 6.2 |
| Charlson score* | 0.6 ± 1.2 | 1.8 ± 1.6 | 2.5 ± 1.7 | 3.1 ± 1.8 |
| **Outcomes** | | | | |
| Death | 8,135 | 2,449 | 769 | 523 |
| Average follow-up, yrs (range: days–yrs) | 1.4 (0–4) | 1.3 (0–4) | 1.3 (0–4) | 1.1 (0–4) |
| Median survival, yrs | † | † | 3 (2.9–3.4) | 2.9 (1.7–2.1) |
| 1-yr mortality risk, % | 10 (10–11) | 17 (16–18) | 24 (23–26) | 33 (30–36) |
| 2-yr mortality risk, % | 19 (19–20) | 30 (29–31) | 37 (35–40) | 51 (48–55) |
| 3-yr mortality risk, % | 27 (27–28) | 40 (38–43) | 52 (46–57) | 63 (57–68)‡ |
| HR for death | — | 1.7 (1.6–1.7) | 2.2 (2.1–2.4) | 3.4 (3.2–3.8) |
| Age-, sex-, race-adjusted HR | — | 1.6 (1.6–1.7) | 2.2 (2.0–2.3) | 3.3 (3.0–3.6) |
| Multivariable adjusted HR§ | — | 1.2 (1.1–1.2) | 1.3 (1.2–1.5) | 1.8 (1.6–2.0) |

Values are median (IQR), n (%), mean ± SD, or HR (95% CI). Dashes indicate that data were unavailable. *Without counting cardiac conditions (myocardial infarction and heart failure). †The marked survival times are censored observations. ‡Follow-up was not long enough to observe median survival time. §Adjusted for: age; sex; race; year of implantation; device type; time from admission to implantation; time from implantation to discharge; EF; ischemic HF; QRS interval duration; NYHA class; HF duration; presence of unsustained ventricular tachycardia (VT), nondilated cardiomyopathy, cerebrovascular disease, diabetes, chronic kidney disease, chronic obstructive pulmonary disease (COPD), osteoporosis, dementia, depression, mania, anxiety, psychotic disorder, delirium, or metastatic cancer; myocardial infarction (MI) in 40 days; coronary artery bypass graft (CABG)/percutaneous coronary intervention (PCI) in 90 days; previous use of flu vaccine or pneumococcal vaccine; pacemaker; number of previous hospitalizations for any cause, MI, or other cardiac disease; Charlson comorbidity score without counting MI and HF.

LOS = length of stay; other abbreviations as in Table 1.

ses (Table 2). Although close to one-half (48%) (Table 1) of the patients received a CRT-defibrillator device, the impact of the number of previous HF hospitalization on post-implantation mortality did not vary by device type (data available upon request).

**Acute HF burden: number of days from admission to ICD implantation.** Of 27,398 patients who had at least 1 hospital day between the admission day and ICD implantation, 62% had been hospitalized for 2 to 7 days prior to the procedure. Similar to the impact of the number of previous HF hospitalizations, a longer duration from admission to

ICD implantation was associated with lower EF, higher NYHA class, and higher comorbidity burden. It was also associated with greater proportion of HF of ischemic origin (79% in the same-day implantation patients versus 83% in those who hospitalized for 8 or more days before implantation) (Table 3).

**Mortality by the number of days from admission to ICD implantation.** Mortality at 3 years was more than twice as high, from 25% in patients with same-day implantation to 53% in the patients hospitalized for 8 or more days before implantation (Table 3, Fig. 2). Among patients who had

| Table 3 | **Characteristics and Outcomes by the Number of Days From Admission to ICD Implantation** | | | |
|---|---|---|---|---|
| | 0 Days<br>n = 39,576 (59) | 1 Day<br>n = 5,636 (8) | 2–7 Days<br>n = 16,959 (25) | ≥8 Days<br>n = 4,803 (6) |
| **Characteristics** | | | | |
| Age, yrs | 75 (70–80) | 76 (71–80) | 76 (71–81) | 76 (71–81) |
| ≤70 | 10,005 (25) | 1,260 (22) | 3,877 (23) | 1,093 (23) |
| ≥80 | 9,982 (25) | 1,553 (28) | 5,151 (30) | 1,434 (30) |
| Male | 29,145 (74) | 4,269 (76) | 12,027 (71) | 3,412 (71) |
| White | 35,815 (91) | 5,023 (89) | 14,198 (84) | 3,880 (81) |
| EF, % | 25 (20–30) | 25 (20–30) | 25 (20–30) | 25 (20–30) |
| ≤20% | 11,845 (30) | 2,034 (36) | 6,743 (40) | 2,156 (45) |
| HF duration | 39,071 | 5,570 | 16,766 | 4,774 |
| New HF | 4,919 (13) | 748 (13) | 1,898 (11) | 400 (8) |
| 0–3 months | 4,007 (10) | 793 (14) | 3,379 (20) | 1,210 (25) |
| 3–9 months | 5,533 (14) | 658 (12) | 1,928 (12) | 533 (11) |
| >9 months | 24,612 (63) | 3,371 (61) | 9,561 (57) | 2,631 (55) |
| NYHA functional class | 39,398 | 5,605 | 16,852 | 4,769 |
| I | 2,555 (6) | 348 (6) | 866 (5) | 157 (3) |
| II | 13,510 (34) | 1,662 (30) | 4,449 (26) | 1,026 (21) |
| III | 22,286 (57) | 3,321 (59) | 10,089 (60) | 2,971 (62) |
| IV | 1,047 (3) | 274 (5) | 1,448 (9) | 615 (13) |
| QRS interval ≥120 ms | 25,363 (64) | 3,752 (67) | 10,365 (61) | 2,789 (58) |
| Ischemic cause HF | 31,111 (79) | 4,452 (79) | 13,662 (81) | 4,007 (83) |
| Unsustained VT | 6,384 (16) | 1,436 (26) | 5,578 (33) | 2,156 (45) |
| Previous hospitalization for any cause | 0.9 ± 1.3 | 1.1 ± 1.5 | 1.1 ± 1.6 | 1.4 ± 1.8 |
| ≥5 | 919 ± 2 | 202 ± 4 | 738 ± 4 | 267 ± 6 |
| Time from implantation to discharge, days | 1.4 ± 1.7 | 2.1 ± 2.7 | 2.8 ± 3.2 | 4.4 ± 5 |
| Charlson score* | 0.8 ± 1.3 | 1 ± 1.4 | 1.1 ± 1.6 | 1.3 ± 1.7 |
| **Outcomes** | | | | |
| Death | 5,245 | 972 | 3,999 | 1,660 |
| Average follow-up, yrs (range: days–yrs) | 1.5 (0–4) | 1.4 (0–4) | 1.3 (0–4) | 1.2 (0–4) |
| Median survival, yrs | † | † | 3.8 (3.8–3.8) | 2.7 (2.6–3.3) |
| 1-yr mortality risk, % | 8 (8–8) | 12 (11–13) | 18 (18–19) | 29 (28–31) |
| 2-yr mortality risk, % | 16 (16–17) | 22 (21–23) | 30 (29–31) | 43 (41–44) |
| 3-yr mortality risk, % | 25 (24–25) | 32 (29–35) | 41 (39–42) | 53 (50–57) |
| HR for death | — | 1.4 (1.3–1.5) | 2.1 (2.0–2.2) | 3.4 (3.2–3.6) |
| Age-, sex-, race-adjusted HR | — | 1.4 (1.3–1.5) | 2.0 (1.9–2.1) | 3.2 (3.1–3.4) |
| Multivariable adjusted HR‡ | — | 1.1 (1.0–1.2) | 1.4 (1.4–1.5) | 1.9 (1.8–2.0) |

Values are median (IQR), n (%), or HR (95% CI). Dashes indicate data were not available. *Without cardiac conditions: MI and HF. †Follow-up was not long enough to observe median survival time. ‡Adjusted for: age; sex; race; year of implantation; device type; time from implantation to discharge; EF; ischemic HF; QRS interval duration; NYHA class; HF duration; presence of unsustained VT, nondilated cardiomyopathy, cerebrovascular disease, diabetes, chronic kidney disease, COPD, osteoporosis, dementia, depression, mania, anxiety, psychotic disorder, delirium, or metastatic cancer; MI in 40 days; CABG/PCI in 90 days; previous use of flu vaccine or pneumococcal vaccine or pacemaker; number of previous hospitalizations for any cause, HF, MI, or other cardiac disease; Charlson comorbidity score without counting MI and HF. Abbreviations as in Tables 1 and 2.

more than 8 hospitalization days before implantation, more than one-half died by 3 years (Fig. 2). Compared with the same-day implantation group, the crude HR for mortality ranged from 1.4 in the same-day implantation group to 3.4 in the 8-or-more-days group. The pattern of elevated HR remained similar after adjusting for demographics. After adjusting for HF severity and comorbidities, the impact of the hospitalization duration on mortality was attenuated, indicating that duration of hospitalization, as with number of HF hospitalizations, likely serves as a surrogate for overall disease severity (Table 3). The impact of the hospitalization

duration on post-implantation mortality was also the same between patients who received CRT-defibrillator and simple ICD (data available upon request).

**A subgroup with low HF burden.** Accumulating acute and chronic HF burden is associated with escalating mortality risk. Conversely, patients who had no HF hospitalization in the year before ICD implantation and who received the device on the admission day (47%, n = 31,685) had the lowest risk of mortality (Table 4). In fact, these patients without a high burden of HF had similar mortality after ICD implantation as did those in the major trials (Fig. 3). By contrast, a higher
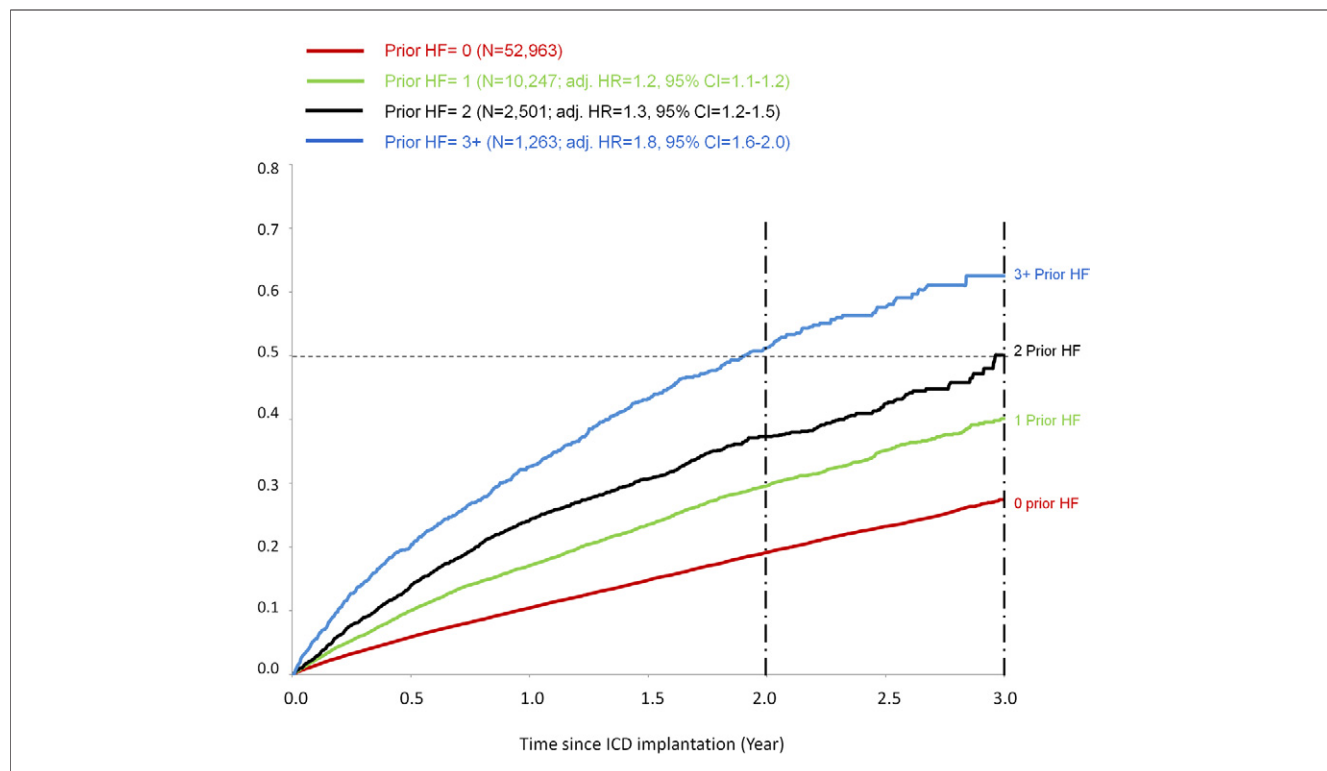
**Figure 1**    **Kaplan-Meier Cumulative Crude Mortality by the Number of Previous HF Hospitalizations**

After implantable cardioverter-defibrillator (ICD) placement, mortality at 3 years increased from 27% in patients without previous heart failure (HF) hospitalization to 63% in those with 3 or more previous HF hospitalizations. Among patients who had 3 or more previous HF hospitalizations, more than one-half died within 2 years of implantation. Adj. HR = adjusted hazard ratio; CI = confidence interval.

mortality was seen for primary ICD recipients with both chronic and acute burdens of HF at the time of implantation (n = 6,120, 3-year mortality: 50% to 69%) (Table 4).

## Discussion

We assessed mortality after ICD implantation in a large population of Medicare beneficiaries using a national ICD registry linked to Medicare inpatient claims data. Approximately 1 in 3 Medicare patients died within 3 years of implantation in our study. We observed higher mortality among patients with a higher number of previous HF hospitalizations (measure of chronic HF burden) and a longer duration between admission and ICD implantation (measure of acute HF burden). Both measures may be surrogates not only for HF severity but also for other comorbidities, and they have additive effects on post-ICD mortality. Although our analyses did not include a comparison group of non-ICD recipients and could not estimate the relative effect of ICD in these subgroups, they provided insights on the subpopulations that are less likely to experience a competing risk of mortality that cannot be prevented by ICD therapy. Specifically, we observed nearly one-half of the Medicare ICD recipients had low burden of HF at the time of implantation, and their survival was

similar to what had been demonstrated in the landmark trials.

Saxon et al. (24) assessed the long-term mortality after ICD implantation for primary and secondary prevention during the post-ICD coverage expansion period: 21% died at 3 years for patients receiving an ICD (n = 108,027) and 29% for those receiving CRT-defibrillator (n = 77,751). The overall survival after primary ICD implantation appears to be shorter among our Medicare population, given that mortality in the Saxon study is likely to have been elevated by including patients receiving the devices for secondary prevention. The shorter survival after ICD implantation among our Medicare patients could reflect more severe HF or comorbidities associated with older age. Compared with primary ICD recipients in a nationwide ICD registry (25), which includes patients younger than 66 years of age, our Medicare ICD recipients had worse HF symptoms by NYHA class.

We attempted to quantify the chronic burden of HF by the number of previous HF hospitalizations, which has been shown to be an independent predictor of mortality among HF patients (26–28). Patients with repeated HF hospitalizations are more likely to die from nonarrhythmic causes of death such as pump failure or noncardiac causes (29,30). Moreover, previous HF hospitalization has been shown to predict early HF death and lower ICD efficacy in MADIT-II (Multicenter
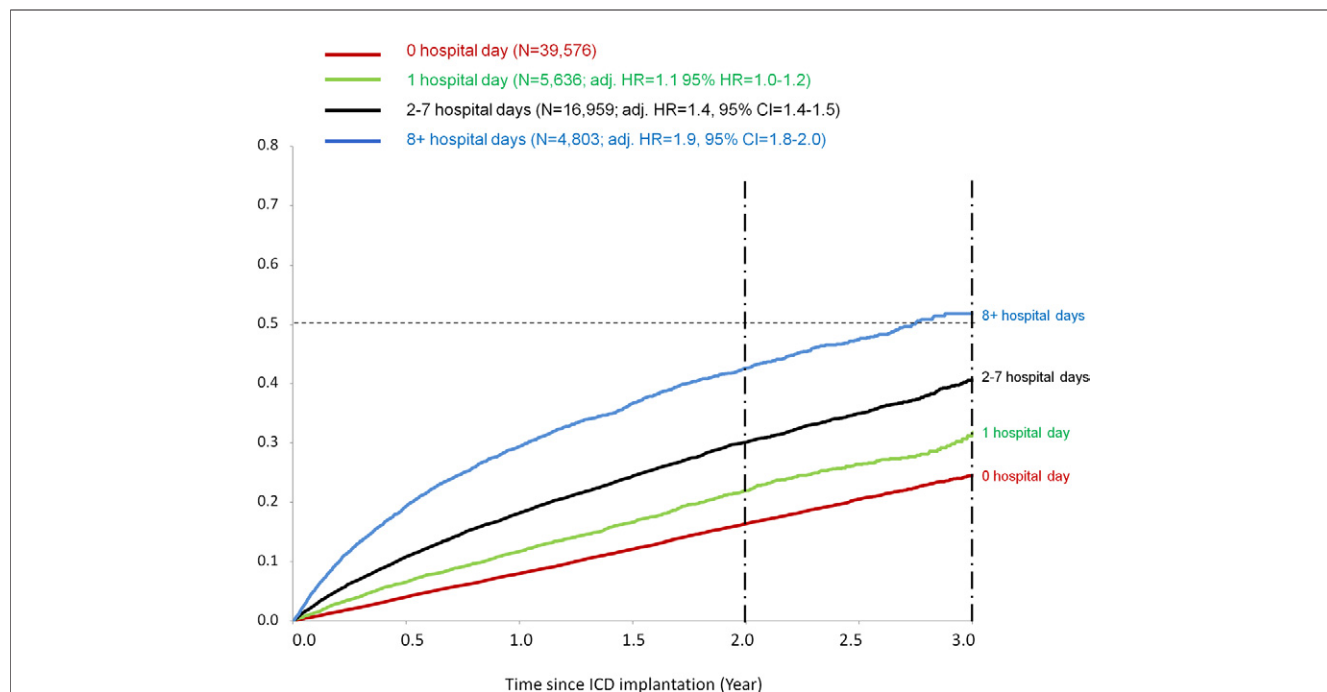
**Figure 2    Kaplan-Meier Cumulative Crude Mortality by the Number of Days From Admission to ICD Implantation**

Mortality at 3 years was more than twice as high, from 25% in patients with same-day implantation to 53% in the patients hospitalized for 8 or more days before implantation. Among patients who had more than 8 hospitalization days before implantation, more than one-half died within 3 years. Abbreviations as in Figure 1.

Automatic Defibrillator Implantation Trial II) (31). The decision to implant an ICD in patients with previous HF hospitalizations should be made cautiously and with appropriately calibrated expectations of HF survival.

To describe the burden of a prolonged exacerbation of HF, we used the duration from admission to ICD implantation, assuming that prior to implantation patients were likely undergoing evaluation or treatment either for HF or for other serious comorbidities. Increasing the number of days during a HF hospitalization suggests that decompensation is more complicated, more severe, or more refractory to interventions. Although we were not able to investigate what happened during the prolonged hospitalization before the procedure in our study population, our assumption was supported by the observation that those who received an elective ICD procedure had shorter times from admission to implantation ($0.3 \pm 1$ days) than did those who received ICD during an admission for HF, other cardiac conditions, or noncardiac conditions ($5 \pm 4$ days). Indications for HF

admission generally include symptoms at rest, which meet the definition of class IV HF, for which ICD are generally considered to be contraindicated. Evidence to support ICD use among patients with ongoing class IV symptoms is limited, as these patients were not included in pivotal trials of ICD efficacy among HF populations (1,3), although the use of ICD with CRT has been shown to be beneficial in ongoing class IV patients in the COMPANION (Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure) study (2). Prevention of SCD would be expected to have less impact on overall mortality than on preventing death due to HF after HF decompensation because the major cause of death among trial patients hospitalized for worsening HF is progressive HF rather than SCD (32), and HF hospitalization is a major risk factor for death in ICD recipients (31). Our findings indicate research is needed on whether ICD implantation during an admission for HF decompensation will have a survival benefit due to competing mortality. This may be particularly important for patients requiring a prolonged hospitalization given

**Table 4    Mortality at 3 Years After ICD Implantation Among Subgroups Categorized by Acute and Chronic HF Burdens**

| Chronic HF Burden \ Acute HF Burden | 0 Hospital Days From Admission to Implantation | 1–7 Hospital Days From Admission to Implantation | 8+ Hospital Days From Admission to Implantation |
|---|---|---|---|
| 0 Previous HF Hospitalizations | 22 (31,685) | 34 (17,581) | 50 (3,697) |
| 1–2 Previous HF Hospitalizations | 35 (7,332) | 50 (4,459) | 59 (957) |
| 3+ Previous HF Hospitalizations | 54 (559) | 69 (555) | 61 (149)* |

Values are % (n). *The survival times are censored observations.
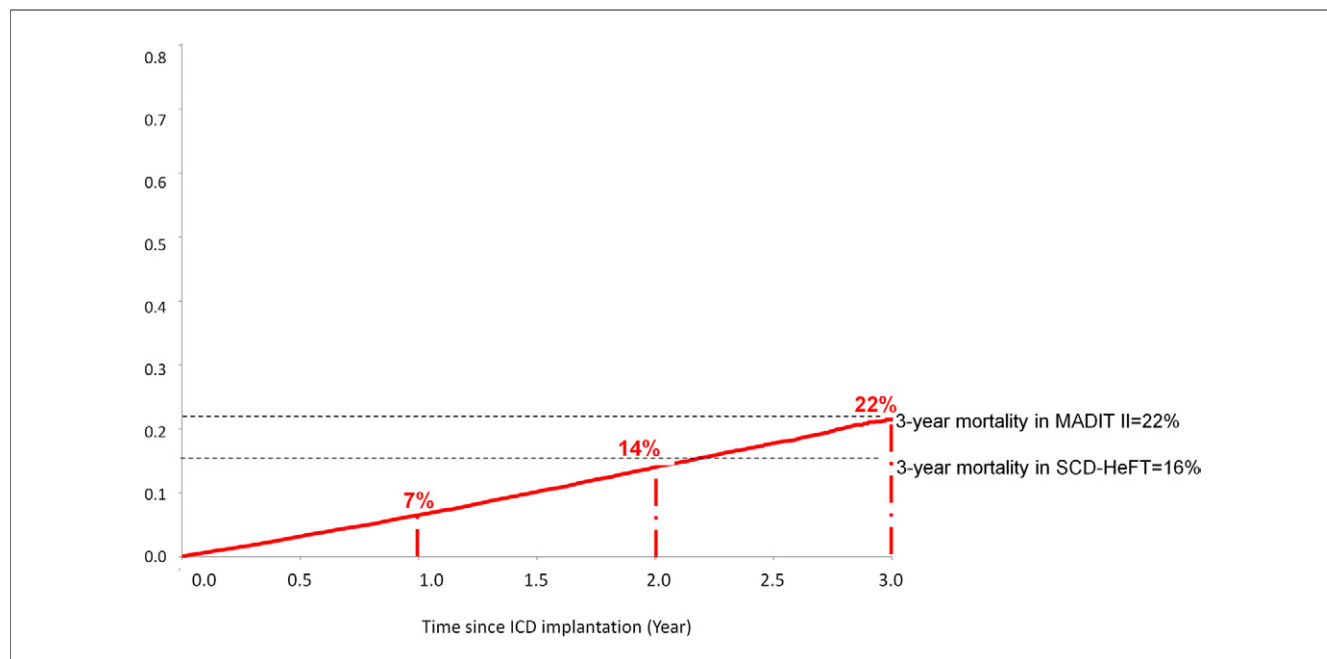Abbreviations as in Table 1.

**Figure 3**  **Post-Implantation Mortality Among Medicare Populations With Low Burden of HF (n = 31,685)**

Patients who had no HF hospitalization in the year before ICD implantation and received the device on the admission day (47%, n = 31,685) had similar mortality after ICD implantation as those in the major trials did (mortality at 3-year follow-up in patients with low HF burden = 22% vs. 16% to 22% in SCD-HeFT [Sudden Cardiac Death in Heart Failure Trial] and MADIT-II [Multicenter Automatic Defibrillator Implantation Trial II]). Abbreviations as in Figure 1.

our finding that length of hospitalization prior to implantation was associated with shorter survival.

Lastly, the post-implantation mortality among our Medicare primary ICD recipients is higher than that of the patients included in the major primary ICD trials (1,3): 16% in SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) and 22% in MADIT-II (at three-year follow-up). However, we observed the mortality was similar to that of the landmark trials (1,3) when ICD were implanted among Medicare patients who had no previous HF hospitalizations and who could receive ICD on the admission day (Table 4), despite the underlying age difference. It is encouraging that we identified this subpopulation by using the rough proxies of HF burdens. It is also worth noting that a substantial proportion of the Medicare ICD recipients were in the "low HF burden" category at the time of implantation, which reflects an appropriate selection of Medicare ICD recipients in the current practice. Nevertheless, future research is warranted to refine our measures of baseline HF burden to support clinical decisions on who should receive the device. **Study limitations.** Our results should be interpreted in light of inherent limitations. As mentioned earlier, our analyses did not include a comparison group of non-ICD recipients and could not estimate the relative effect of ICD by underlying HF burdens. The registry and Medicare data were not always in agreement. For example, 6% of patients who received ICD with a primary prevention indication were also noted in the registry to have sustained ventricular tachycardia noted (suggesting secondary prevention). We excluded these patients in

order to avoid mixing primary and secondary ICD. A review of a tertiary care center's ICD registry found incomplete coding for indication, further supporting our decision to exclude patients with discrepant indication data (33).

We linked 64% (n = 122,562) of registry records to MedPAR files. The MedPAR files do not contain claims for the majority of non-fee-for-service Medicare beneficiaries, unless those beneficiaries enrolled in a cost-based managed care plan and the plan elects to have CMS process and pay for the service provided (34). Given the prevalence of Medicare beneficiaries under a non-cost-based managed care arrangement, which ranged from 14% to 22% during the study time frame (34), our matched records represent approximately 79% of the implantations recorded in the registry that would be for fee-for-service Medicare beneficiaries. Incomplete linkage may have also been due to data entry errors or inconsistencies in the information collection policy between the registry and Medicare files on the fields that were used for linkage. For example, when sex is unknown to Medicare, "female" value is automatically assigned for that claim (35). Also, if arrival to the emergency department is recorded as the patient's admission date in the registry, it will differ from the date recorded in the claims data. Nevertheless, these errors are likely to be random and unlikely to compromise the validity of our findings.

## Conclusions

Approximately 1 in 3 Medicare primary ICD recipients died within 3 years of implantation. Medicare patients with a low

cumulative burden of HF had similar mortality to those in the landmark trials. Further studies are needed to assess effectiveness of primary ICD implantation among patients with heavy burdens of HF and other comorbidities to guide clinical strategies and policy decisions among Medicare beneficiaries.

**Reprint requests and correspondence:** Dr. Soko Setoguchi, Duke Clinical Research Institute, 2400 Pratt Street, Durham, North Carolina 27705. E-mail: soko.setoguchi@duke.edu.

## REFERENCES

1. Bardy GH, Lee KL, Mark DB, et al., for the SCD-HeFT Investigators. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. N Engl J Med 2005;352:225–37.
2. Bristow MR, Saxon LA, Boehmer J, et al., for the COMPANION Investigators. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med 2004;350:2140–50.
3. Moss AJ, Zareba W, Hall WJ, et al., for the MADIT-II Investigators. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. N Engl J Med 2002;346:877–83.
4. CMS National Coverage Determination for ICD. 2005. Available at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110&ncdver=3&IsPopup=y&NCAId=102&NcaName=Implantable+Defibrillators+-+Clinical+Trials&bc=AAAAAAAAIAAA&. Accessed April 8, 2013.
5. Fonarow GC, Yancy CW, Hernandez AF, Peterson ED, Spertus JA, Heidenreich PA. Potential impact of optimal implementation of evidence-based heart failure therapies on mortality. Am Heart J 2011;161:1024-30.e3.
6. Hammill SC, Kremers MS, Stevenson LW, et al. Review of the registry's fourth year, incorporating lead data and pediatric ICD procedures, and use as a national performance measure. Heart Rhythm 2010;7:1340–5.
7. Lindenfeld J, Shakar S, Zolty R, et al. Abstract 1880: increasing age decreases the risk of sudden death compared to progressive heart failure in patient with advance heart failure (abstr). Circulation 2006;114:II373.
8. Mehta PA, Dubrey SW, McIntyre HF, et al. Mode of death in patients with newly diagnosed heart failure in the general population. Eur J Heart Fail 2008;10:1108–16.
9. Setoguchi S, Nohria A, Rassen JA, Stevenson LW, Schneeweiss S. Maximum potential benefit of implantable defibrillators in preventing sudden death after hospital admission because of heart failure. CMAJ 2009;180:611–6.
10. Epstein AE, Kay GN, Plumb VJ, et al., for the ACT Investigators. Implantable cardioverter-defibrillator prescription in the elderly. Heart Rhythm 2009;6:1136–43.
11. Koplan BA, Epstein LM, Albert CM, Stevenson WG. Survival in octogenarians receiving implantable defibrillators. Am Heart J 2006;152:714–9.
12. Goldenberg I, Moss AJ, McNitt S, et al., for the MADIT-II Investigators. Relations among renal function, risk of sudden cardiac death, and benefit of the implanted cardiac defibrillator in patients with ischemic left ventricular dysfunction. Am J Cardiol 2006;98:485–90.
13. Mark DB, Nelson CL, Anstrom KJ, et al., for the SCD-HeFT Investigators. Cost-effectiveness of defibrillator therapy or amiodarone in chronic stable heart failure: results from the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT). Circulation 2006;114:135–42.
14. Sanders GD, Hlatky MA, Owens DK. Cost-effectiveness of implantable cardioverter-defibrillators. N Engl J Med 2005;353:1471–80.
15. Hammill S, Phurrough S, Brindis R. The National ICD Registry: now and into the future. Heart Rhythm 2006;3:470–3.
16. Hammill SC, Kremers MS, Kadish AH, et al. Review of the ICD registry's third year, expansion to include lead data and pediatric ICD procedures, and role for measuring performance. Heart Rhythm 2009;6:1397–401.

17. Hammill SC, Kremers MS, Stevenson LW, et al. Review of the registry's fourth year, incorporating lead data and pediatric ICD procedures, and use as a national performance measure. Heart Rhythm 2010;7:1340–5.
18. Hammill SC, Kremers MS, Stevenson LW, et al. Review of the registry's second year, data collected, and plans to add lead and pediatric ICD procedures. Heart Rhythm 2008;5:1359–63.
19. Hammill SC, Stevenson LW, Kadish AH, et al. Review of the registry's first year, data collected, and future plans. Heart Rhythm 2007;4:1260–3.
20. Messenger JC, Ho KKL, Young CH, et al. The National Cardiovascular Data Registry (NCDR) data quality brief: the NCDR data quality program in 2012. J Am Coll Cardiol 2012;60:1484–8.
21. Hammill BG, Hernandez AF, Peterson ED, Fonarow GC, Schulman KA, Curtis LH. Linking inpatient clinical registry data to Medicare claims data using indirect identifiers. Am Heart J 2009;157:995–1000.
22. Li Q, Glynn RJ, Dreyer NA, Liu J, Mogun H, Setoguchi S. Validity of claims-based definitions of left ventricular systolic dysfunction in Medicare patients. Pharmacoepidemiol Drug Saf 2011;20:700–8.
23. Lee DS, Donovan L, Austin PC, et al. Comparison of coding of heart failure and comorbidities in administrative and clinical data for use in outcomes research. Med Care 2005;43:182–8.
24. Saxon LA, Hayes DL, Gilliam FR, et al. Long-term outcome after ICD and CRT implantation and influence of remote device follow-up: the ALTITUDE survival study. Circulation 2010;122:2359–67.
25. Al-Khatib SM, Hellkamp A, Curtis J, et al. Non-evidence-based ICD implantations in the United States. JAMA 2011;305:43–9.
26. Pocock SJ, Wang D, Pfeffer MA, et al. Predictors of mortality and morbidity in patients with chronic heart failure. Eur Heart J 2006;27:65–75.
27. Setoguchi S, Stevenson LW, Schneeweiss S. Repeated hospitalizations predict mortality in the community population with heart failure. Am Heart J 2007;154:260–6.
28. Solomon SD, Dobson J, Pocock S, et al., for the CHARM Investigators. Influence of nonfatal hospitalization for heart failure on subsequent mortality in patients with chronic heart failure. Circulation 2007;116:1482–7.
29. Setoguchi S, Stevenson LW. Hospitalizations in patients with heart failure: who and why. J Am Coll Cardiol 2009;54:1703–5.
30. Wang NC, Piccini JP, Konstam MA, et al., for the EVEREST Investigators. Implantable cardioverter-defibrillators in patients hospitalized for heart failure with chronically reduced left ventricular ejection fraction. Am J Ther 2010;17:e78–87.
31. Goldenberg I, Moss AJ, Hall WJ, et al., for the MADIT-II Investigators. Causes and consequences of heart failure after prophylactic implantation of a defibrillator in the Multicenter Automatic Defibrillator Implantation Trial II. Circulation 2006;113:2810–7.
32. O'Connor CM, Miller AB, Blair JE, et al., for the EVEREST Investigators. Causes of death and rehospitalization in patients hospitalized with worsening heart failure and reduced left ventricular ejection fraction: results from Efficacy of Vasopressin Antagonism in Heart Failure Outcome Study with Tolvaptan (EVEREST) program. Am Heart J 2010;159:841-9.e1.
33. Zweibel S, Clyne C, Crespo E. ICD implantation and evidence-based patient selection. JAMA 2011;305:1538–9.
34. Research Data Assistance Center University of Minnesota. Medicare Managed Care Enrollees and the Medicare Utilization Files. Available at: http://www.resdac.org/resconnect/articles/114. Accessed April 8, 2013.
35. van Rees JB, de Bie MK, Thijssen J, Borleffs CJ, Schalij MJ, van Erven L. Implantation-related complications of implantable cardioverter-defibrillators and cardiac resynchronization therapy devices: a systematic review of randomized clinical trials. J Am Coll Cardiol 2011;58:995–1000.

---

**Key Words:** heart failure ■ implantable cardioverter-defibrillator ■ mortality ■ primary prevention.

▶ APPENDIX

---