Clinical Effectiveness of Implantable Cardioverter-Defibrillators Among Medicare Beneficiaries With Heart Failure

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Background—The clinical effectiveness of implantable cardioverter-defibrillators (ICDs) in older patients with heart failure has not been established, and older patients have been underrepresented in previous studies.

Methods and Results—We identified patients with heart failure who were aged 65 years or older and were eligible for an ICD, had left ventricular ejection fraction of 35% or less, and were discharged alive from hospitals participating in the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients With Heart Failure and the Get With the Guidelines–Heart Failure quality-improvement programs during the period January 1, 2003, through December 31, 2006. We matched the patients to Medicare claims to examine long-term outcomes. The main outcome measure was all-cause mortality over 3 years. The study population included 4685 patients who were discharged alive and were eligible for an ICD. Mean age was 75.2 years, 60% of the patients were women, mean ejection fraction was 25%, and 376 (8.0%) patients received an ICD before discharge. Mortality was significantly lower among patients who received an ICD compared with those who did not (19.8% versus 27.6% at 1 year, 30.9% versus 41.9% at 2 years, and 38.1% versus 52.3% at 3 years; \( P < 0.001 \) for all comparisons). The inverse probability-weighted adjusted hazard of mortality at 3 years for patients receiving an ICD was 0.71 (95% CI, 0.56 to 0.91).

Conclusions—Medicare beneficiaries hospitalized with heart failure and left ventricular ejection fraction of 35% or less who were selected for ICD therapy had lower risk-adjusted long-term mortality compared with those who did not receive an ICD.

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Key Words: defibrillation ■ heart failure ■ mortality

Large randomized clinical trials have shown that implantable cardioverter-defibrillators (ICDs) reduce mortality in patients with reduced left ventricular ejection fraction (LVEF) either with heart failure or after myocardial infarction.\(^1\)\(^-\)\(^3\) Reflecting this evidence, professional guidelines recommend evaluation of systolic function in all patients with heart failure and ICD therapy for patients with systolic dysfunction who meet certain criteria.\(^4\)\(^-\)\(^5\) Although patients aged 65 years or older make up >70% of the heart failure population, they have been underrepresented in pivotal clinical trials.\(^6\)

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Policy makers and government agencies have initiated major programs to examine the comparative effectiveness of therapies for which evidence is conflicting or lacking for groups of patients that are underrepresented in clinical trials or when substantial questions on the effectiveness of a therapy exist. Studying the use of ICDs in older patients and women is a high priority because of the size of the potential population at risk, continuing questions regarding effectiveness, and the low probability for randomized clinical trials to provide further evidence.\(^7\) Thus, there is a need to establish the clinical effectiveness of ICD therapy in older patients and women to address the potential risks and benefits.

We conducted a retrospective cohort study of the clinical effectiveness of ICD therapy in older patients with heart failure by using data from the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients With Heart Failure (OPTIMIZE-HF) registry, the Get With the Guidelines–Heart Failure (GWTG-HF) registry, and long-term outcome data from Medicare claims files.
Methods

Data Sources
We merged data from the OPTIMIZE-HF and GWTG-HF registries with enrollment files and inpatient claims from the Centers for Medicare and Medicaid Services (CMS) for the period January 1, 2003, through December 31, 2006. We followed up patients through the end of 2006 to examine mortality over 3 years. OPTIMIZE-HF and GWTG-HF had the same design, inclusion criteria, and data collection methods. In 2005, OPTIMIZE-HF was transitioned to GWTG-HF under the sponsorship of the American Heart Association. Patients were eligible for inclusion in the registries if they were admitted for an episode of worsening heart failure or had developed significant heart failure symptoms during a hospitalization for which heart failure was the primary discharge diagnosis. Hospital teams used heart failure case-ascertainment methods similar to those used by the Joint Commission. Data on medical history, signs and symptoms, medications, contraindications for or intolerance to medications, and diagnostic test results were collected by a Web-based registry. Unique identifiers and postdischarge outcomes were not collected in OPTIMIZE-HF or GWTG-HF. All regions of the United States were represented and a variety of centers participated, from community hospitals to large tertiary centers.

All participating institutions were required to comply with local regulatory and privacy guidelines and, if applicable, to obtain institutional review board approval. Because the data were used primarily at the local site for quality improvement, sites were granted a waiver of informed consent under the Common Rule. Outcome Sciences, Inc (Cambridge, Mass) served as the registry coordinating center. The Duke Clinical Research Institute (Durham, NC) served as the data analysis center.

The CMS files included data for all fee-for-service Medicare beneficiaries aged 65 years or older who were hospitalized with a diagnosis of heart failure (International Classification of Diseases, 9th Revision, Clinical Modification 428.x, 402.x1, 404.x1, and 404.x3). We merged patient data in the registries with Medicare Part A inpatient claims, matching by admission and discharge dates, hospital, date of birth, and sex. Of the 76,824 hospitalizations of patients aged 65 years or older, we matched 59,859 (78%) to fee-for-service Medicare claims representing 50,454 patients who were not enrolled in managed care plans, which account for 15% to 20% of the US population. We excluded 2431 patients who died before discharge, of whom 18 had received an ICD. We also excluded 88 sites that limited their participation in quality-improvement reporting to performance measures only.

Analysis Population
The merged data set included 41,210 patients aged 65 years or older who were discharged alive and for whom Medicare data were available. For patients with multiple hospitalizations recorded in the registry, we used information from the earliest hospitalization. We excluded patients who presented with new-onset heart failure (n=1,457) and patients who were missing quantitative information on LVEF (n=9,564) or had an LVEF of >35% (n=18,136), in accordance with current American College of Cardiology/American Heart Association clinical recommendations. We also excluded patients who were transferred to another acute care hospital (n=165), were discharged to a skilled nursing facility (n=1,697), left against medical advice (n=36), were discharged to hospice (n=342), or had an unknown discharge status (n=6). In studies of comparative effectiveness using observational data, persons included in the analysis must be eligible for the index hospitalization for heart failure. As with other studies of Medicare beneficiaries, we obtained dates of death from the CMS enrollment files, which are reported to CMS by the Social Security Administration.

Statistical Analysis
We summarized baseline characteristics by treatment group using percentages for categorical variables and means and SDs for continuous variables. For comparisons by treatment group, we used χ² tests for categorical variables and Wilcoxon rank-sum tests for continuous variables. We summarized observed mortality using a Kaplan–Meier estimator and tested for differences using a log-rank test.

We estimated adjusted relationships between treatment and outcome using a Cox proportional hazards model with treatment group as the only variable. We estimated adjusted relationships between treatment and outcome using an inverse probability-weighted Cox proportional hazards model. The weights were based on the probability of receiving an ICD. We used logistic regression models to estimate the propensity to receive ICD therapy versus no ICD therapy. The model included age, sex, race, ethnicity, cause of ischemic heart failure, number of previous heart failure hospitalizations, LVEF, diabetes mellitus, hyperlipidemia, atrial arrhythmia, depression, chronic obstructive pulmonary disease, anemia, peripheral vascular disease, cerebrovascular accident, systolic blood pressure, smoking in the past year, chronic renal insufficiency, serum sodium level, serum creatinine level, hemoglobin level, angiography during hospitalization, mechanical ventilation during hospitalization, and medications at admission based on previous work. The Cox model included medical therapies at discharge and a variable denoting whether the patient received an ICD. We used robust standard errors in all models to account for clustering by hospital.

We performed several sensitivity analyses. First, we assessed the effect of ICD therapy in 2 important subgroups—patients discharged with both an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB) and a β-blocker and patients with LVEF of 30% or less. Second, we assessed the heterogeneity of the effect by subgroup by including treatment-by-subgroup interactions in separate inverse probability-weighted Cox proportional hazards models. Because this approach resulted in additional statistical comparisons, we required P<0.01 for the interactions to be considered statistically significant. Subgroups included age (65 to 74 years versus 75 to 84 years), sex, and ischemic versus nonischemic cause of heart failure.

We used SAS software version 9.1.3 (SAS Institute, Inc, Cary, NC) for all analyses. The institutional review board of the Duke University Health System approved the study.

Results
Among the 4685 older patients with heart failure who were eligible for ICD therapy and were discharged alive with LVEF of 35% or less, 376 patients (8.0%) received an ICD during the hospitalization (Table 1). Patients who received an ICD tended to be younger, male, and white compared with those who did not receive an ICD. Almost two thirds of the patients had ischemic heart failure. The median LVEF was <30% for both groups but was significantly lower in patients receiving an ICD. Comorbid...
conditions were common, and there were significant differences between the groups in rates of diabetes mellitus, anemia, hyperlipidemia, and prior stroke or transient ischemic attack.

Table 2 shows the rates of discharge medications and inpatient procedures in the study population. The rates of ACE inhibitor or ARB and \(-\)blocker prescriptions were \(70\%\) in both groups and were higher in patients who received an ICD. Cardiac catheterization and associated percutaneous coronary interventions performed during the index hospitalization were more frequent in the ICD group. The median length of stay was 4 days (interquartile range, 3 to 7) for patients without an ICD and 7 days (interquartile range, 3 to 10) for patients with an ICD.

Mortality rates during the follow-up period were \(27.0\%\) \([n=1167]\) at 1 year, \(41.1\%\) \([n=1640]\) at 2 years, and \(51.4\%\) \([n=1872]\) at 3 years. Observed mortality was significantly lower for patients with an ICD compared with eligible patients without an ICD \(19.8\%\) \([n=65]\) versus \(27.6\%\) \([n=1102]\) at 1 year, \(30.9\%\) \([n=90]\) versus \(41.9\%\) \([n=1550]\) at 2 years, and \(38.1\%\) \([n=101]\) versus \(52.3\%\) \([n=1771]\) at 3 years; \(P<0.001\) for all comparisons). The unadjusted hazard ratio was 0.67 (95% CI, 0.52 to 0.87).

After weighting by the inverse probability of treatment, patients were well matched and had no significant differences on 25 of 26 characteristics (Table 1). The adjusted hazard ratio suggests that patients with heart failure who received an ICD had a significantly lower risk of mortality over 3 years \((0.72; 95\% \text{ CI}, 0.57 to 0.92; \text{Figure})\). Because of the potential influence of discharge medications on outcomes, we also examined the risk of mortality with different discharge medications in the model and found similar results (hazard ratio, 0.71; 95% CI, 0.56 to 0.91). We also observed the beneficial effect of ICD therapy on mortality among patients who had very low LVEF (30% or less) and among patients discharged with both ACE inhibitors or ARBs and \(-\)blockers (Table 3).

As shown in Table 4, the lower unadjusted risk of mortality was relatively consistent across subgroups. We found no significant differences based on ACE inhibitor or ARB and
β-blocker use, LVEF of 30% or less, age, sex, and cause of heart failure using α=0.01 to denote significant interactions in the adjusted analysis.

We also examined how many patients in the comparison group received an ICD after discharge. Among the 4309 patients who were classified as “no ICD,” 40 received an ICD within 30 days of discharge (0.9%) and 60 received an ICD within 60 days (1.4%).

### Discussion

In this study of the clinical effectiveness of ICDs among older Medicare beneficiaries hospitalized with heart failure, ICD therapy was associated with a significantly lower relative risk of mortality over 3 years compared with no ICD therapy, after adjustment for the probability of treatment, other prognostic variables, and medical therapy at discharge. The patients in the study cohort received usual care in the community at hospitals in all regions of the United States. The magnitude of the mortality risk reduction among patients who received an ICD was similar to findings from randomized clinical trials. Although ICDs were clinically effective, the mortality rates remained substantial.

Although the need remains for randomized trials of ICD therapy to include adequate numbers of older patients with heart failure, no new trials are underway or in development to address the problem we examined in this study. Older persons make up the majority of people at risk for sudden cardiac death but were underrepresented in the pivotal trials of ICDs. Participants in the Multicenter Automatic Defibrillator Implantation Trial II had a mean age of 64 years, and participants in the Sudden Cardiac Death in Heart Failure Trial had a median age of 60 years. Thus, the results of these trials may not be generalizable to older patients, who tend to have more comorbid conditions.1,3 Although analyses of subgroups in clinical trials are difficult and prone to error, opinion leaders, payers, and other stakeholders

### Table 2. Discharge Medications and Inpatient Procedures in the Study Population

<table>
<thead>
<tr>
<th>Medication or Procedure</th>
<th>Unweighted</th>
<th>ICD</th>
<th>P</th>
<th>Inverse Weighted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discharge medications</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>ACE inhibitor or angiotensin receptor blocker</td>
<td>3103 (72.0)</td>
<td>293 (77.9)</td>
<td>0.01</td>
<td>72.5 73.0 0.84</td>
</tr>
<tr>
<td>Aldosterone antagonist</td>
<td>885 (20.5)</td>
<td>86 (22.9)</td>
<td>0.28</td>
<td>20.7 20.9 0.91</td>
</tr>
<tr>
<td>Antiplatelet agent</td>
<td>2592 (60.2)</td>
<td>227 (60.4)</td>
<td>0.93</td>
<td>60.3 61.9 0.55</td>
</tr>
<tr>
<td>β-blocker</td>
<td>3363 (78.0)</td>
<td>315 (83.8)</td>
<td>0.009</td>
<td>78.2 79.3 0.64</td>
</tr>
<tr>
<td>Calcium channel blocker</td>
<td>270 (6.3)</td>
<td>18 (4.8)</td>
<td>0.25</td>
<td>6.2  7.0  0.55</td>
</tr>
<tr>
<td>Digoxin</td>
<td>1524 (35.4)</td>
<td>143 (38.0)</td>
<td>0.30</td>
<td>35.6 37.6 0.44</td>
</tr>
<tr>
<td>Diuretic</td>
<td>3606 (83.7)</td>
<td>298 (79.3)</td>
<td>0.03</td>
<td>83.7 78.7 0.01</td>
</tr>
<tr>
<td>Hydralazine</td>
<td>253 (5.9)</td>
<td>17 (4.5)</td>
<td>0.28</td>
<td>5.7  6.7  0.46</td>
</tr>
<tr>
<td>Lipid-lowering agent</td>
<td>2038 (47.3)</td>
<td>206 (54.8)</td>
<td>0.005</td>
<td>47.9 49.0 0.66</td>
</tr>
<tr>
<td>In-hospital procedures</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Coronary angiography</td>
<td>597 (13.9)</td>
<td>87 (23.1)</td>
<td>&lt;0.001</td>
<td>14.6 14.8 0.90</td>
</tr>
<tr>
<td>Coronary artery bypass graft surgery</td>
<td>42 (1.5)</td>
<td>4 (2.0)</td>
<td>0.57</td>
<td>1.5  0.9  0.45</td>
</tr>
<tr>
<td>Mechanical ventilation</td>
<td>82 (1.9)</td>
<td>13 (3.5)</td>
<td>0.04</td>
<td>2.0  1.6  0.55</td>
</tr>
<tr>
<td>Percutaneous coronary intervention</td>
<td>103 (2.4)</td>
<td>14 (3.7)</td>
<td>0.11</td>
<td>2.5  3.0  0.54</td>
</tr>
</tbody>
</table>

### Table 3. ICD Use and 3-Year Mortality, Overall and for Patient Subsets

<table>
<thead>
<tr>
<th>Patients</th>
<th>Unadjusted HR (95% CI)*</th>
<th>Inverse-Weighted HR (95% CI)*</th>
</tr>
</thead>
<tbody>
<tr>
<td>All patients (n=4685 [376 with ICD])</td>
<td>0.67 (0.52 to 0.87)</td>
<td>0.71 (0.56 to 0.91)</td>
</tr>
<tr>
<td>Patients discharged with ACE inhibitor/ARB and β-blocker (n=2765 [254 with ICD])</td>
<td>0.64 (0.48 to 0.87)</td>
<td>0.62 (0.45 to 0.84)</td>
</tr>
<tr>
<td>Patients with left ventricular ejection fraction ≤30% (n=3784 [343 with ICD])</td>
<td>0.69 (0.53 to 0.89)</td>
<td>0.76 (0.59 to 0.98)</td>
</tr>
</tbody>
</table>

HR indicates hazard ratio.

*Hazard ratios for ICD versus no ICD. The inverse-weighted model also controls for discharge medications.
There is growing evidence that ICD therapy is effective in reducing mortality among selected high-risk patients with heart failure. Studies such as the Multicenter Automatic Defibrillator Implantation Trial II found a 31% reduction in mortality, the Multicenter Automatic Defibrillator Implantation Trial I found a 23% reduction, and the Sudden Cardiac Death in Heart Failure Trial found a 26% reduction in mortality compared with those who did not receive ICD therapy. However, questions remain regarding the effects of ICDs in older patients. A recent meta-analysis by Ezekowitz et al demonstrated the efficacy of ICDs. In another study, Chan et al examined outcomes of ICD use from 2001 through 2005. Our findings, which reflect the experiences of a mix of patients with ischemic and nonischemic heart failure in the community, suggest that ICDs are clinically effective in older patients with heart failure up to 84 years of age.

Consistent with clinical trials of ICDs, we observed a 29% lower risk of mortality among patients who received an ICD compared with those who did not. Moreover, in a meta-analysis by Ezekowitz et al, the relative risk of all-cause mortality derived from 12 trials of ICD therapy for primary and secondary prevention was 0.80. The Multicenter Automatic Defibrillator Implantation Trial II found a 31% reduction in mortality, and the Sudden Cardiac Death in Heart Failure Trial found a 23% reduction. The consistency of findings across studies supports the current guideline recommendations for ICD therapy in selected high-risk patients with heart failure and LVEF of 35% or less who are receiving optimal medical therapy and are expected to survive at least 1 year with a reasonable quality of life.

In addition, our findings extend previous studies of the clinical effectiveness of ICDs and address the overall mortality risk-benefit ratio for ICD therapy in clinical practice. A study by Curtis et al examining sex differences in the use of ICDs was accompanied by questions about clinical effectiveness. Our study addresses this concern by including patients’ preferences and clinical status, and in the absence of significant heterogeneity, the clinical benefit should be considered for all eligible patients.

Clinical care often differs for the broad cohort of patients observed in clinical registries compared with the selected patients enrolled in randomized clinical trials. Although data on long-term adherence to medications were not available, patients discharged from participating hospitals had similar or greater evidence-based therapies at discharge when we compared eligible patients who received an ICD with those who did not. Also, the clinical effectiveness of ICD therapy was observed in patients discharged on both an ACE inhibitor or an ARB and a β-blocker.

Health status and quality of life are important factors to consider in ICD therapy and in analyses of clinical effectiveness. Although our study excluded patients with contraindications documented in the medical record, there may have been reasons not documented that influenced the decision regarding ICD therapy. ICD therapy has been shown to have a neutral effect on health status and quality of life in subjects

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### Table 4. Subgroup Analysis of ICD Use and 3-Year Mortality

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Unadjusted HR (95% CI)*</th>
<th>P for Interaction</th>
<th>Inverse-Weighted HR (95% CI)*</th>
<th>P for Interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>65 to 74 years (n = 2039 [188 with ICD])</td>
<td>0.60 (0.44 to 0.83)</td>
<td>0.26</td>
<td>0.65 (0.47 to 0.89)</td>
<td>0.31</td>
</tr>
<tr>
<td>75 to 84 years (n = 2646 [188 with ICD])</td>
<td>0.76 (0.59 to 0.98)</td>
<td></td>
<td>0.80 (0.62 to 1.03)</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women (n = 1896 [99 with ICD])</td>
<td>0.68 (0.45 to 1.01)</td>
<td></td>
<td>0.58 (0.41 to 0.83)</td>
<td>0.15</td>
</tr>
<tr>
<td>Men (n = 2789 [277 with ICD])</td>
<td>0.66 (0.52 to 0.84)</td>
<td></td>
<td>0.80 (0.63 to 1.01)</td>
<td></td>
</tr>
<tr>
<td>Cause of heart failure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nonischemic (n = 1800 [120 with ICD])</td>
<td>0.68 (0.48 to 0.98)</td>
<td></td>
<td>0.81 (0.59 to 1.12)</td>
<td>0.36</td>
</tr>
<tr>
<td>Ischemic (n = 2885 [256 with ICD])</td>
<td>0.66 (0.52 to 0.84)</td>
<td></td>
<td>0.67 (0.52 to 0.86)</td>
<td></td>
</tr>
</tbody>
</table>

HR indicates hazard ratio.
*Hazard ratios for ICD versus no ICD. The inverse-weighted model also controls for discharge medications.

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have raised questions about the effects of ICDs in older patients. The Multicenter Automatic Defibrillator Implantation Trial II showed consistent effects in patients aged 70 years and older. However, in the Sudden Cardiac Death in Heart Failure Trial, the CIs for the hazard of mortality included 1.0 for patients aged 65 years or older (0.86; 95% CI, 0.62 to 1.18). Our findings, which reflect the experiences of a mix of patients with ischemic and nonischemic heart failure in the community, suggest that ICDs are clinically effective in older patients with heart failure up to 84 years of age.

Consistent with clinical trials of ICDs, we observed a 29% lower risk of mortality among patients who received an ICD compared with those who did not. Moreover, in a meta-analysis by Ezekowitz et al the relative risk of all-cause mortality derived from 12 trials of ICD therapy for primary and secondary prevention was 0.80. The Multicenter Automatic Defibrillator Implantation Trial II found a 31% reduction in mortality, and the Sudden Cardiac Death in Heart Failure Trial found a 23% reduction. The consistency of findings across studies supports the current guideline recommendations for ICD therapy in selected high-risk patients with heart failure and LVEF of 35% or less who are receiving optimal medical therapy and are expected to survive at least 1 year with a reasonable quality of life.

In addition, our findings extend previous studies of the clinical effectiveness of ICDs and address the overall mortality risk-benefit ratio for ICD therapy in clinical practice. A study by Curtis et al examining sex differences in the use of ICDs was accompanied by questions about clinical effectiveness. Our study addresses this concern by including patients’ preferences and clinical status, and in the absence of significant heterogeneity, the clinical benefit should be considered for all eligible patients.

Clinical care often differs for the broad cohort of patients observed in clinical registries compared with the selected patients enrolled in randomized clinical trials. Although data on long-term adherence to medications were not available, patients discharged from participating hospitals had similar or greater evidence-based therapies at discharge when we compared eligible patients who received an ICD with those who did not. Also, the clinical effectiveness of ICD therapy was observed in patients discharged on both an ACE inhibitor or an ARB and a β-blocker.

Health status and quality of life are important factors to consider in ICD therapy and in analyses of clinical effectiveness. Although our study excluded patients with contraindications documented in the medical record, there may have been reasons not documented that influenced the decision regarding ICD therapy. ICD therapy has been shown to have a neutral effect on health status and quality of life in subjects.
enrolled in clinical trials; however, there are circumstances in which ICD therapy may decrease quality of life in older populations; hence, it is important to evaluate health status, psychological distress, and quality of life in older patients with heart failure after ICD therapy. Given that data on health status and quality of life are not routinely collected in usual care settings, prospective studies are needed to evaluate the effects of health status on the decision to use ICD therapy and in analyses of the clinical effectiveness of ICDs.

Limitations
This study has limitations. First, the analysis is observational; there may be residual measured and unmeasured confounders that would strengthen or weaken the relationships we observed. Although we used inverse-weighted propensity methods to balance characteristics between the groups, there were expected imbalances. In addition, these expected imbalances and unmeasured confounders may have caused our estimates of clinical effectiveness to be imprecise. Second, the analysis included only fee-for-service Medicare beneficiaries who were included in the clinical registries. We also excluded patients aged 85 years or older, patients discharged to a skilled nursing facility, and elective admissions. Thus, our findings may not be generalizable to these populations. However, these exclusions were defined to limit potential bias and likely resulted in a more conservative estimate of the effectiveness of ICD use. Third, given their primary use as tools for quality-of-care initiatives, registries may disproportionately include hospitals that are more likely to follow evidence-based recommendations, which in turn may influence long-term outcomes. Fourth, we did not include patients with prior ICD implantations because implantation dates were not available, and we could not estimate long-term survival accurately. Fifth, we did not have data on doses of medications such as ACE inhibitors, β-blockers, and diuretics or follow-up data on changes in medications after discharge. We also did not account for the small number of patients who crossed over from the comparison group to the ICD group after the index hospitalization. Finally, complications of device implantation, measures of appropriate and inappropriate device discharges, New York Heart Association functional class, quality of life, socioeconomic factors, and postdischarge health status were not available, although all are important considerations in evaluating the use of ICD therapy.

Conclusions
Medicare beneficiaries hospitalized with heart failure and LVEF of 35% or less who were eligible for ICD therapy had significantly lower adjusted risk of death over 3 years compared with patients discharged without an ICD. These findings are consistent with the results of randomized clinical trials of ICD therapy.

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References
Although large, randomized, clinical trials have shown that implantable cardioverter-defibrillators (ICDs) reduce mortality in patients with reduced left ventricular ejection fraction either with heart failure or after myocardial infarction, substantial questions about the effectiveness of ICD therapy exist for patients who were underrepresented in clinical trials, such as those aged 65 years or older. Therefore, we examined the clinical effectiveness of ICD therapy using data from the Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients With Heart Failure registry and the Get With The Guidelines–Heart Failure registry, linked to long-term outcome data from Medicare claims files. The study population included 4685 patients aged 65 years or older with left ventricular ejection fraction of 35% or less who were discharged alive and were eligible for an ICD during the period of January 1, 2003, through December 31, 2006. Mortality was significantly lower among patients who received an ICD compared with those who did not (19.8% versus 27.6% at 1 year, 30.9% versus 41.9% at 2 years, and 38.1% versus 52.3% at 3 years; P<.001 for all comparisons). The inverse probability-weighted adjusted hazard of mortality over 3 years for patients receiving an ICD was 0.71 (95% CI, 0.56 to 0.91). Based on these results, ICD therapy appears to be clinically effective in Medicare beneficiaries aged 65 years or older hospitalized with heart failure and left ventricular ejection fraction of 35% or less and who are eligible for treatment. Additional studies including those that assess health status and quality of life are needed.
Clinical Effectiveness of Implantable Cardioverter-Defibrillators Among Medicare Beneficiaries With Heart Failure

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