Influence of Age on Perioperative Complications Among Patients Undergoing Implantable Cardioverter-Defibrillators for Primary Prevention in the United States

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Background—The majority of current implantable cardioverter-defibrillator (ICD) recipients are significantly older than those in the ICD trials. Data on periprocedural complications among the elderly are insufficient. We evaluated the influence of age on perioperative complications among primary prevention ICD recipients in the United States.

Methods and Results—Using the National Cardiovascular Data’s ICD Registry, we identified 150,264 primary prevention patients who received ICDs from January 2006 to December 2008. The primary end point was any adverse event or in-hospital mortality. Secondary end points included major adverse events, minor adverse events, and length of stay. Of 150,264 patients, 61% (n=91,863) were 65 years and older. A higher proportion of patients ≥65 years had diabetes, congestive heart failure, atrial fibrillation, renal disease, and coronary artery disease. Approximately 3.4% of the entire cohort had any complication, including death, after ICD implant. Any adverse event or death occurred in 2.8% of patients under 65 years old; 3.1% of 65- to 69-year-olds; 3.5% of 70- to 74-year-olds; 3.9% of 75- to 79-year-olds, 4.5% of 80- to 84-year-olds; and 4.5% of patients 85 years and older. After adjustment for clinical covariates, multivariate analysis found an increased odds of any adverse event or death among 75- to 79-year-olds (1.14 [95% confidence interval, 1.01 to 1.25]), 80-to 84-year-olds (1.22 [95% confidence interval, 1.10 to 1.36]), and patients 85 years and older (1.15 [95% confidence interval, 1.01 to 1.32]), compared with patients under 65 years old.

Conclusions—Older patients had a modestly increased—but acceptably safe—risk of periprocedural complications and in-hospital mortality, driven mostly by increased comorbidity. (Circ Cardiovasc Qual Outcomes. 2011;4:549-556.)

Key Words: aging ■ implantable cardioverter-defibrillator ■ complications ■ registries

Although prior studies were mixed about the benefits of implantable cardioverter-defibrillator (ICD) therapy among the elderly,1-4 recent studies have found that ICDs are effective in reducing total mortality in all age groups.5-7 With the number of US individuals over age 65 projected to reach 72 million by 2030,8,9 the number of elderly patients eligible for ICD therapy will increase severalfold over the next 2 decades. Already, the average age of the ICD recipient is 68 years,10-11 with approximately 40% of recipients being 70 years and older at implant.12

Data on complication rates are needed to help older patients make an informed decision about the risks and benefits with ICD implantation. However, few studies have adequately examined the question. Patients of advanced age were underrepresented in the large primary prevention ICD trials (mean age, 60 to 65 years),4,13-15 and cohort studies of elderly recipients have been limited to single centers,16-23 outdated databases,7,16-18,20-22 or patients outside of the United States.16-19 With the advent of newer and smaller ICDs,23 the complication rates associated with ICD implantation reported from the older databases7,16-18 may be inaccurate. In addition, the influence of age on implantation complications may be continuous across the age groups. Past studies used only one age cut-off to define elderly pa-

Methods

We obtained the data from the National Cardiovascular Data Registry’s (NCDR) ICD Registry. Initiated in 2006, the registry was...
WHAT IS KNOWN

- Although approximately 40% of recipients are 70 years or older at implant, implantable cardioverter-defibrillator complication rates among advanced-aged patients are unknown.

WHAT THE STUDY ADDS

- Differences in complication rates among older patients were found.
- In unadjusted analyses, the occurrence of any adverse event or in-hospital death increased from 2.8% in the youngest age group (under 65 years of age) to 4.5% in the oldest age groups (80 years and older).
- After multivariate adjustment, advanced age was associated with only a modestly increased risk of periprocedural complications and in-hospital death.
- Comorbid conditions were as important, of even more so, than age in determining complication risks.

Study Population

All patients within the NCDR-ICD Registry who had undergone ICD implantation between January 2006 to December 2008 were included if they received an ICD implantation for primary prevention. This study excluded patients who had received ICDs for secondary prevention (history of syncope, cardiac arrest, or sustained ventricular tachycardia) to avoid potential underreporting by institutions, or had received a prior ICD.

Independent Variables

The primary independent variable was age, categorized into 5 groups: <65, 65 to 69, 70 to 74, 75 to 79, 80 to 84, and at least 85 years old. We categorized age because it was not linearly associated with outcomes. We also examined the following clinical variables in the multivariate model: (1) clinical data (sex, diabetes, hypertension, atrial fibrillation, renal failure, ischemic versus nonischemic cardiomyopathy, New York Heart Association (NYHA) class heart failure, LVEF at the time of ICD implant, QRS duration, atrioventricular (AV) block, bundle-branch block, timing of myocardial infarction (MI) to ICD implant (implant ≤40 days versus >40 days after MI), and reason for admission); (2) device data (type of ICD implanted); and (3) physician and hospital characteristics (including physician certification, community versus university versus government hospitals, hospital size, and geographic location).

Dependent Variables

The occurrence of any adverse event (major or minor adverse event) or death was considered the primary end point. Secondary end points included major adverse events, minor adverse events, and length of hospital stay. Adverse events were reported by implanting centers using standard definitions (online-only Supplement Appendix) and were defined as any major or minor event that occurred during or after ICD implant up until the time of discharge. Major adverse events were defined as cardiac arrest, cardiac perforation, cardiac valve injury, coronary venous dissection, hemotorax, pneumothorax, deep phlebitis, transient ischemic attack, stroke, MI, pericardial tamponade, lead dislodgment, and arterial-venous fistula. Minor adverse events were defined as drug reaction, conduction block, hematoma, peripheral embolus, superficial phlebitis, peripheral nerve injury, and infection related to device.

Statistical Analysis

To identify significant patient, physician, and hospital factors associated with our primary and secondary end points, we used hierarchical logistic regression models or multilevel models—which adjust for patient clustering within hospitals—to evaluate the relationship between age and any adverse event or death. Our initial analysis was unadjusted for other characteristics. We repeated the analysis after sequentially adjusting for patient clinical characteristics, physician certification, and hospital characteristics. Confounding factors included in the model were demographic, clinical, procedure, and physician characteristics listed in Tables 1 and 2. We used Markov chain Monte Carlo multiple imputation procedure to impute missing values with assumptions that the data were missing at random, and the parameters of the data model and of the missing data indicators were distinct. The statistical level of 0.05 was used for significance. All analyses were performed using the SAS statistical package version 9.2 (SAS Institute, Cary, NC). All analyses were approved by the Yale University Human Investigation Committee.

Results

Study Population

We identified 333,993 patients who underwent ICD implantation from January 2006 to December 2008. We excluded 32,767 patients who had received a prior ICD; 119,435 patients who had received ICDs for secondary prevention; and 31,527 patients from hospitals that had submitted data only on Medicare beneficiaries. The final study group consisted of 150,264 patients.

Clinical Characteristics of the Study Group

Figure 1 illustrates the distribution of ICD implantations among the age groups. Of 150,264 patients, 61% (n = 191,863) were 65 years and older. The average age of the cohort was 67±13 years. Among patients 65 years and older, patients 70 to 79 years made up the largest age subgroups (15.1%, 70 to 74 years and 15.4%, 75 to 79 years); 65- to 69-year-old patients represented 14.5% of the total ICD population, 80- to 84-year-olds represented 11.3%, and ≥85-year-olds represented 4.8%.

Table 1 describes the characteristics of the ICD recipients. As expected, the proportion of patients with more advanced NYHA heart failure class and ischemic cardiomyopathy increased with age. Patients ≥65 years old had a higher frequency of diabetes, atrial fibrillation, and renal disease. Approximately one-quarter (27%) of recipients were women, a proportion that only modestly changed with age. The majority of patients were hospitalized electively for device implantation, whereas the remainder of patients received ICDs after being hospitalized for other cardiac or noncardiac issues; the latter occurred more frequently with age.

Otherwise, only clinically modest differences were observed among the age groups in measures of timing of MI to...
ICD implant, QRS duration, type of physician performing the ICD implant, hospital type, and geographic location. Tables 1 and 2 summarize the clinical, physician, and hospital characteristics of the study population by age group.

**Perioperative Complications**

Figure 2 shows the crude adverse event and mortality rates for each age group; 5068 patients (3.4%) had any adverse event or death. Of the total events (n=5359), minor events comprised 61% (n=3244). The rates of any adverse or death varied across the age groups. Patients under 65 years old had the lowest rates of any events, including death, (2.8%), followed by 65- to 69-year-olds (3.1%), then 70- to 74-year-olds (3.5%), and then 75- to 79-year-olds (3.9%). Once patients reached 80 years of age, the rate of any events, including mortality, reached a plateau (4.5%, 80- to 84-years and 4.5%, ≥85 years). In-hospital mortality rates only modestly increased with age.

Exclusive of death, the frequencies of major and minor adverse events varied with age, with minor events comprising the majority of events. Among all the complications, hematoma was the most common. A higher frequency of pneumothorax, MI, pericardial tamponade, hemothorax, and hematoma were observed with age. Otherwise, the rates of drug reaction, cardiac valve injury, lead dislodgment, peripheral nerve injury, peripheral embolus, transient ischemic attack, stroke, AV fistula, and device-related infections appeared similar across ages. Table 3 describes the adverse event rates in each age group.

Using patients under 65 years old as the reference group, in the hierarchical model, which adjusted only for clustering and

### Table 1. Characteristics of ICD Recipients

<table>
<thead>
<tr>
<th>Clinical Characteristics</th>
<th>Age Groups, Years</th>
<th>&lt;65 (n=58 401)</th>
<th>65–69 (n=21 805)</th>
<th>70–74 (n=22 680)</th>
<th>75–79 (n=23 132)</th>
<th>80–84 (n=16 937)</th>
<th>≥85 (n=7309)</th>
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<tbody>
<tr>
<td>Female, %</td>
<td></td>
<td>27</td>
<td>28</td>
<td>26</td>
<td>27</td>
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<td>White, %</td>
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<td>71</td>
<td>82</td>
<td>84</td>
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<td>90</td>
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<td>NYHA class, %</td>
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<td>II</td>
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<td>LVEF, mean, % (SD)</td>
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<td>25 (9)</td>
<td>25 (8)</td>
<td>26 (8)</td>
<td>26 (7)</td>
<td>26 (8)</td>
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<td>QRS duration, mean (SD)</td>
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<td>118 (32)</td>
<td>127 (33)</td>
<td>130 (34)</td>
<td>135 (35)</td>
<td>138 (35)</td>
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<td>1st-Degree</td>
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<td>Left bundle-branch block, %</td>
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<td>Other medical conditions, %</td>
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<td>Renal disease*</td>
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<td>Elective†</td>
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<td>Cardiac</td>
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<td>Noncardiac</td>
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<tr>
<td>ICD type, %</td>
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<td>Dual</td>
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<td>30</td>
<td>39</td>
<td>44</td>
<td>49</td>
<td>53</td>
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</tbody>
</table>

ICD indicates implantable cardioverter-defibrillator; NYHA, New York Heart Association; LVEF, left ventricular ejection fraction; and AV, atrioventricular.

*Glomerular filtration rate <60 mL/min per 1.73 m².
†Elective admission for ICD implantation.
no other characteristics, the odds ratios for the combined outcome of any adverse event or mortality were 1.12 (95% confidence interval [CI], 1.03 to 1.22) for 65- to 69-year-olds, 1.27 (95% CI, 1.17 to 1.38) for 70- to 74-year-olds, 1.42 (95% CI, 1.31 to 1.54) for 75- to 79-year-olds, 1.63 (95% CI, 1.49 to 1.77) for 80- to 84-year-olds, and 1.61 (95% CI, 1.43 to 1.81) for patients 85 years and older.

After adjustment for clinical characteristics (including comorbidities and type of ICD implanted), physician certification, and hospital characteristics, multivariate analysis found an increased odds of any adverse event or death among 75- to 79-year-olds (1.14 [95% CI, 1.03 to 1.25], 80-to 84-year-olds (1.22 [95% CI, 1.21 to 1.79]), and patients 85 years and older (1.15 [95% CI, 1.01 to 1.32]), compared with patients under 65 years old. However, age was a weaker predictor of complications, compared with sex, renal failure, stage IV heart failure, 2nd or 3rd-degree AV block, atrial fibrillation, biventricular ICD placement, hospitalizations not primarily for device implant, and physician certification. Besides device type, the strongest predictor for periprocedural complications was ICD implantation by a thoracic surgeon (odds ratio, 1.49 [95% CI 1.24 to 1.79]), compared with board-certified electrophysiologists. Table 4 describes the predictors of any adverse events or death after ICD implantation.

Impact on Length of Hospital Stay

The overall median length of stay was 1 [1, 4] days. Although median length of stay was different among the age groups, clinically significant differences were modest (Table 3). Among patients electively admitted for device implantation, the median length of stay was 1 [1, 4] days for patients under 65 years of age, 1 [1, 3] 65 to 69 years of age, 1 [1, 4] 70 to 74 years of age, 1 [1, 4] 75 to 79 years of age, 1 [1, 5] 80 to 84 years of age, and 1 [1, 6] for patients 85 years and older.
Similarly, for urgent cardiac and noncardiac admissions, despite variations in length of stay with age, clinically significant differences were modest.

**Discussion**

We evaluated the rate of ICD implantation-related complications, using a national registry of the largest population of older patients to date, and found differences in complication rates among older patients. In analyses without adjustment for clinical characteristics, the occurrence of any adverse event or in-hospital death increased from 2.8% in the youngest age group (under 65 years of age) to 4.5% in the oldest age groups (80 years and older). After multivariate adjustment, advanced age was associated with only a modestly increased risk of periprocedural complications and in-hospital death. Comorbidity conditions were as important, or even more so, than age in determining complication risks.

With the aging population, it is not surprising that the average age of the current ICD recipient is above 65 years of age. However, other comorbidities may also increase with age and predispose patients to procedural complications. Prior studies have reported ICD complication rates as high as 10% to 40%, making some physicians wary of referring their elderly patients for ICD implantation. In our study, we found low complication rates—fewer than 5%—even for individuals older than 80 years of age. Despite the older average age of these patients (age, 67 years), and their multiple risk variables, these patients performed similarly to patients in the ICD trials, who were on average 5 to 10 years younger, and had fewer comorbidities. The patients probably benefitted from having received ICDs in recent years—when operators had already gained significant experience with ICD implantation and that the majority of these patients were implanted by electrophysiologists.

Notably, despite trends in underreferral of older patients for ICD implantation, we still found that a significant proportion of current ICD recipients were older. Almost half (46%) of the patients were 70 years and older, and more than 15% were 80 years and older, confirming the rapidly expanding demographic of elderly ICD recipients. Such observations are consistent with reports from the ACT Registry, a national registry of patients with St Jude devices. Our study extends the observations from the ACT study by including all patients who received an ICD in the US and providing a real-world evaluation in a large cohort. The numbers of elderly ICD recipients will only to continue to grow in the coming years, and they probably will require more biventricular devices than the standard ICDs. Given the technical challenge associated with biventricular devices, the trend of decreasing ICD complications is unlikely to continue.

We observed that for all age groups, the majority of complications were minor. These minor complications did not appear to meaningfully impact length of stay, or significantly increase in-hospital mortality. However, the effect on quality of life could not be measured in our study and perhaps can be addressed in future studies.

### Table 3. Select Perioperative Adverse Events and Length of Stay by Age Group

<table>
<thead>
<tr>
<th>Adverse Events</th>
<th>Total (n=150,264)</th>
<th>&lt;65 (n=58,401)</th>
<th>65–69 (n=21,805)</th>
<th>70–74 (n=22,680)</th>
<th>75–79 (n=23,132)</th>
<th>80–84 (n=16,937)</th>
<th>≥85 (n=7,309)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Major adverse events, n (%)</strong></td>
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<tr>
<td>Cardiac arrest</td>
<td>393 (0.26)</td>
<td>165 (0.28)</td>
<td>50 (0.23)</td>
<td>48 (0.21)</td>
<td>47 (0.20)</td>
<td>65 (0.38)</td>
<td>18 (0.25)</td>
</tr>
<tr>
<td>Cardiac perforation</td>
<td>110 (0.07)</td>
<td>23 (0.04)</td>
<td>18 (0.08)</td>
<td>17 (0.07)</td>
<td>29 (0.13)</td>
<td>19 (0.11)</td>
<td>4 (0.05)</td>
</tr>
<tr>
<td>Hemotorax</td>
<td>142 (0.09)</td>
<td>38 (0.07)</td>
<td>20 (0.09)</td>
<td>19 (0.08)</td>
<td>28 (0.12)</td>
<td>26 (0.15)</td>
<td>11 (0.15)</td>
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<tr>
<td>Pneumotorax</td>
<td>676 (0.45)</td>
<td>186 (0.32)</td>
<td>91 (0.42)</td>
<td>104 (0.46)</td>
<td>127 (0.55)</td>
<td>116 (0.68)</td>
<td>52 (0.71)</td>
</tr>
<tr>
<td>TIA</td>
<td>38 (0.03)</td>
<td>9 (0.02)</td>
<td>4 (0.02)</td>
<td>11 (0.05)</td>
<td>7 (0.03)</td>
<td>6 (0.04)</td>
<td>1 (0.01)</td>
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<td>Stroke</td>
<td>75 (0.05)</td>
<td>24 (0.04)</td>
<td>7 (0.03)</td>
<td>10 (0.04)</td>
<td>12 (0.05)</td>
<td>15 (0.09)</td>
<td>7 (0.10)</td>
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<tr>
<td>MI</td>
<td>39 (0.03)</td>
<td>6 (0.01)</td>
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<td>Tamponade</td>
<td>149 (0.10)</td>
<td>39 (0.07)</td>
<td>22 (0.10)</td>
<td>28 (0.12)</td>
<td>21 (0.09)</td>
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<td>AV fistula</td>
<td>3 (0.00)</td>
<td>1 (0.00)</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>0 (0.00)</td>
<td>2 (0.01)</td>
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<td><strong>Minor adverse events, n (%)</strong></td>
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<tr>
<td>Conduction block</td>
<td>65 (0.04)</td>
<td>22 (0.04)</td>
<td>9 (0.04)</td>
<td>5 (0.02)</td>
<td>9 (0.04)</td>
<td>15 (0.09)</td>
<td>5 (0.07)</td>
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<td>Hemorrhage</td>
<td>1410 (0.94)</td>
<td>369 (0.63)</td>
<td>170 (0.78)</td>
<td>243 (1.07)</td>
<td>288 (1.25)</td>
<td>229 (1.35)</td>
<td>111 (1.52)</td>
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<td>Any major or minor adverse event</td>
<td>4897 (3.26)</td>
<td>1575 (2.70)</td>
<td>658 (3.02)</td>
<td>758 (3.34)</td>
<td>871 (3.77)</td>
<td>725 (4.28)</td>
<td>310 (4.24)</td>
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<td>Any adverse event (major or minor) or death</td>
<td>5068 (3.37)</td>
<td>1614 (2.76)</td>
<td>671 (3.08)</td>
<td>792 (3.49)</td>
<td>904 (3.91)</td>
<td>756 (4.46)</td>
<td>331 (4.53)</td>
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<td>In-hospital mortality</td>
<td>462 (0.31)</td>
<td>141 (0.24)</td>
<td>48 (0.22)</td>
<td>71 (0.31)</td>
<td>75 (0.32)</td>
<td>91 (0.54)</td>
<td>36 (0.49)</td>
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<td>LOS, elective admissions, median d*</td>
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TIA indicates transient ischemic attack; MI, myocardial infarction; AV, atrioventricular; and LOS, length of stay.

*Median days [1st quartile, 3rd quartile].
One important finding of our study was the identification of multiple cardiac and noncardiac conditions, besides age, that increase perioperative complications. Consistent with prior investigations, we found that female sex, those who received ICDs with cardiac resynchronization therapy, and device implantation by nonelectrophysiologists were associated with higher perioperative complications, and were even stronger predictors of complications than age. Comorbidities, including end-stage renal disease, stage IV heart failure, atrial fibrillation, and advanced heart block, were also stronger predictors of complications than advanced age. Consistent with clinical experience, we found that patients who received ICDs in the latter portion of a hospitalization precipitated by cardiac and noncardiac reasons were more likely to have complications than patients hospitalized primarily for device implant, an observation reflecting the higher morbidity of the former group of patients. These findings confirm clinical experience that patients should not be excluded from ICD consideration, based on age alone. Clinicians must weigh the number and severity of comorbid conditions—both observed here and perhaps, some not captured in our dataset—even more so than age when deciding the potential complication risks in older patients.

Interestingly, although women tend to live longer and their risk of coronary heart disease increases with age, the proportion of female ICD recipients did not increase with age. This observation appears to support observations of ICD underutilization among women and probably are multifactorial. Potential explanations include more stringent application of ICD guidelines to women, higher complication rates among women, or presentation of women with coronary disease at an older age (and with more comorbidities), leading to a higher threshold for referral.

Finally, few data are available on the impact of age on length of stay after ICD implant. Similar to other types of procedures, we found that age was associated with a longer length of stay. However, the differences were clinically modest. Among patients electively hospitalized for device implantation—which was a more meaningful representation of device-related morbidity—these differences were clinically insignificant. The lack of clinically meaningful variations in hospital stay likely reflected the low rates of major events and deaths overall, and in each of the age groups.

Our study had several limitations. First, the data were obtained from a national database that required mandatory enrollment only of Medicare beneficiaries. Therefore, to generate a study cohort representative of the community, we confined analysis to hospitals who submitted data on both Medicare and non-Medicare beneficiaries. Second, we examined only in-hospital complications and mortality. We were unable to capture complications, such as infection or lead failure, which develop after hospital discharge. However, evaluating this early time window allowed us to evaluate complication rates related to implantation, which are important for decision-making. Third, we did not include lead complications (except lead dislodgment), given the short follow-up, but instead a comprehensive list of other implantation-related adverse events was evaluated. Finally, our database consisted only of patients who had received ICD implants. Potentially, not all the preselection factors may have been captured by the covariates in the dataset. Complication rates depend on patient case selection, and we cannot exclude the possibility that complication rates were decreased in practice because ICD use was restricted to seemingly healthier, older adults. Nevertheless, our dataset has broad representativeness for actual ICD use in older adults. It includes near-complete data on the large number of ICD recipients over age 65 nationally, and rates are probably up to date and accurate, since these rates are not publicly reported and centers had little incentive to underreport adverse events.

**Conclusions**

Our study offers a real-world evaluation of ICD implantation-related complications among the US elderly. After adjusting for various clinical, device-related, and operator characteristics, patients 75 years and older have an increased, but
acceptably safe, risk of periprocedural complications, including in-hospital mortality, some of which is explained by observed comorbidity and some perhaps by unobserved comorbidity. Nevertheless, these results should not preclude elderly patients from receiving ICDs, but provide much needed information for elderly patients who are eligible for ICD therapy, so that an individualized decision can be reached.

Acknowledgments

The views expressed are those of the authors. They do not necessarily represent those of the Department of Veterans Affairs, or the official views of the NCDR or its associated professional societies identified at www.ncdr.com.

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Disclosures

Dr Heidenreich has served as a consultant (<$5000) to Boston Scientific. Dr Hsia’s conflicts of interest are Medtronic: advisory board, research support; Biosense Webster: research support, speaker; Voyage Medical: scientific advisory board; and St Jude Medical: speaker.

References


Influence of Age on Perioperative Complications Among Patients Undergoing Implantable Cardioverter-Defibrillators for Primary Prevention in the United States

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Appendix – Definitions of Adverse Events

ICD Registry™

Cardiac Arrest: Sudden cessation of cardiac activity so that the patient became unresponsive, with no normal breathing and no signs of circulation.

Drug Reaction: Anaphylaxis, rash, etc.

Cardiac Perforation: Migration of pacing or defibrillator lead to epicardial surface, resulting in pain, pericardial effusion, failure to capture, capture of diaphragm, phrenic nerve, or intercostals muscle of sufficient magnitude to require repositioning.

Cardiac Valve Injury: Manipulation of pacing or defibrillating leads that may tear a valve leaflet or chordae tendinae (usually manifests as a new regurgitant murmur appearing after the procedure).

Conduction Block: Injury parts of the specialized cardiac conducting system from manipulation of pacing or defibrillating leads. (Usually manifest as a new RBBB or new on set of complete heart block in a person with preexisting LBBB).

Coronary Venous Dissection: Manipulation of pacing or defibrillating leads in the coronary sinus (CS) leading to tear of the CS endothelium, with dissection into the CS wall. Occasionally result in perforation of the CS.

Hematoma: Hematoma resulting in re-operation or transfusion.

Lead Dislodgement: Movement of lead sufficient to require repositioning.

Hemothorax: As documented by accumulation of blood in thorax.

Pneumothorax: Air in thorax sufficient to require chest tube.
Peripheral Nerve Injury: Sensory or motor loss of peripheral nerve function. This may result from external nerve compression as a result of positioning during an implantation procedure, internal compression (e.g. secondary to hematoma formation) or direct nerve injury.

Peripheral Embolus: Acute occlusion of an artery resulting from embolization of a cardiac or proximal arterial thrombus.

Phlebitis – Superficial: As documented by signs of superficial venous inflammation, such as local erythema, tenderness or swelling.

Phlebitis – Deep: As documented by occlusion of deep vein resulting in extremity swelling, plus or minus signs of inflammation.

TIA: Loss of neurological function that was abrupt in onset but with complete return of function within 24 hours.

CVA/Stroke: Central neurologic deficit persisting > 72 hours after onset.

Pericardial Tamponade: Fluid in the pericardial space compromising cardiac filling, and requiring intervention as documented by either: 1) Echo showing pericardial fluid and signs of tamponade such as right heart compromise, or 2) Systemic hypotension due to pericardial fluid compromising cardiac function.

AV Fistula: A connection between the access artery and the accompanying vein that is demonstrated by arteriography or ultrasound and often characterized by a continuous bruit.

Infection Related to Device: Infection related to the device.

MI: MI during the EP lab visit or after lab visit until discharge (or before any subsequent lab visits) as documented by:
NON ST ELEVATION MYOCARDIAL INFARCTION (NSTEMI)

AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present:

1) Troponin T or I: Maximal concentration of troponin T or I > the MI decision limit on at least one occasion during the first 24 hours after the index clinical event.

2) CK-MB: Maximal value of CK-MB > 2 x the upper limit of normal on one occasion during the first hours after the index clinical event. OR Maximal value of CK-MB, preferable CK-MB mass, > upper limit of normal on two successive samples.

3) Total CK: In the absence of availability of a troponin or CK-MB assay, total CK > 2 x the upper limit of normal, or the B fraction of CK may be employed, but these last two biomarkers are considerably less satisfactory than CK-MB.

AND ONE OF THE FOLLOWING:

1) Either ST segment depression or T wave abnormalities; or

2) Ischemic symptoms in the presence or absence of chest discomfort. Ischemic symptoms may include:
   a) unexplained nausea and vomiting; or
   b) persistent shortness of breath secondary to left ventricular failure; or
   c) unexplained weakness, dizziness, lightheadedness, or syncope.

ST ELEVATION MYOCARDIAL INFARCTION (STEMI)

AT LEAST ONE OF THE FOLLOWING BIOCHEMICAL INDICATORS for detecting myocardial necrosis must be present (Reference Control Limits as above):

1) Troponin T or I

2) CK-MB

3) Total CK
AND ONE OF THE FOLLOWING ECG CHANGES:

1) ST-segment elevation: New or presumed new ST segment elevation at the J point in two
or more contiguous leads with the cut-off points >=0.2 mV in leads V1, V2, or V3, or
>=0.1 mV in other leads; OR

2) Development of any Q wave in leads V1 through V3, or the development of a Q-wave > or
= to 30 ms (0.03s) in leads I, II, aVL, aVF, V4, V5, or V6. (Q wave changes must be
present in any two contiguous leads, and be > or = to 1mm in depth.)