Implantable Cardiac Device Procedures in Older Patients

Use and In-Hospital Outcomes

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Background: Although the effectiveness of implantable cardioverter defibrillators (ICDs) and cardiac resynchronization therapy (CRT) alone or in combination is well established, limited data are available on device use and short-term outcomes in older patients. We sought to characterize age-specific practices and outcomes among patients with heart failure undergoing device implantation using a large nationally representative administrative database.

Methods: The cohort comprised patients older than 18 years with a diagnosis of heart failure who underwent implantation of an ICD or CRT between January 1, 2004, and December 31, 2005. Data included patient demographics, comorbidities, type of device, procedural complications, length of stay, total cost of hospitalization, and hospital characteristics. Multivariate stepwise logistic regression analysis was used to identify risk factors for in-hospital mortality.

Results: We identified 26,887 patients who received an implantable device. The median age was 70.0 years (17.5% were ≥80 years), 72.6% were male, and 31.3% were of nonwhite race/ethnicity. Compared with younger patients, those 80 years or older were more likely to receive CRT alone. In-hospital mortality increased from 0.7% among patients younger than 80 years to 1.2% among those aged 80 to 85 years and 2.2% among those older than 85 years (P < .001). Independent predictors of in-hospital mortality included age 80 years or older, elevated comorbidity score, inotrope use, and procedure-related complications.

Conclusions: Despite the fact that most device trials have excluded patients 80 years or older, more than one-fifth of ICD and CRT devices are implanted in this age group. Advanced age is an independent predictor of in-hospital mortality following device implantation, suggesting that additional study is needed to define criteria for appropriate device use in older patients.

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See Invited Commentary at end of article
placement of ICDs and CRT among patients admitted to acute care hospitals with a diagnosis of heart failure. We were particularly interested in assessing the importance of advanced age, complications related to device procedures, and other risk factors for in-hospital mortality following implantation or revision of a cardiac device.

METHODS

STUDY DESIGN

We used PREMIER's Perspective Comparative Database to evaluate the relationship between age, treatment use, and outcomes during admission to an acute care hospital that included an ICD or CRT device implantation or revision. PREMIER is a hospital performance improvement alliance created and owned by several hundred hospitals and health care systems.11 The database incorporates detailed patient-level data in a large national sample organized by discharge month. Data validation and audits are performed by PREMIER to ensure quality. Variables within PREMIER include patient demographic information (based on UB-92 health claim form coding; age is censored at 89 years because of privacy regulations), admission and discharge dates by month and year, length of stay, in-hospital mortality, procedure and diagnosis codes according to the International Classification of Diseases, Ninth Revision (ICD-9),12 and hospital characteristics (size, location, and teaching status). The database also includes itemized billing records for costs associated with care such as drug therapy and surgery.13 These records reflect actual provider expenses.

Inclusion criteria for this study were the following: (1) inpatient admission between January 1, 2004, and December 31, 2005; (2) primary or secondary ICD-9 diagnosis code for heart failure; (3) ICD-9 procedure code for implantation or replacement of a complete cardiac device or generator (excluding pacemaker);14 and (4) age older than 18 years. Patients were organized into 3 exclusive device type groups of (1) CRT-D, (2) ICD, or (3) CRT-P; patients receiving sequential procedures during any given hospitalization were assigned in the order listed. Patients who received both ICD and CRT-P devices but on separate days were assigned to the CRT-D group, but the first day of intervention served as the day of procedure. Hospitalizations were excluded if records could not be found in the billing data that validated the ICD-9 procedure codes (eg, no billing record for device) (n=832), the sum of costs for individual billing records did not match the total cost as calculated by PREMIER (n=549), the exact date for device procedure was not coded (n=518), or sex was unknown (n=2). Excluding these subjects did not result in statistically significant differences in patient demographics or hospital characteristics across the device groups.

We identified device complications according to ICD-9 diagnosis and procedure code algorithms described by Reynolds et al.14 Complications included but were not limited to the following: pneumothorax, cardiac perforation with pericardial effusion or tamponade, mechanical complication of device, infection related to the implant, hematoma or hemorrhage, and acute renal failure requiring new hemodialysis.

We also identified concomitant cardiac procedures that could confound device-related outcomes such as mortality and complications.15 Concomitant procedures were identified using ICD-9 procedure codes and included diagnostic cardiac catheterization, percutaneous coronary intervention, coronary artery bypass grafting surgery, catheter ablation, and heart valve surgery (eAppendix 1, http://www.archinternmed.com). In an attempt to find evidence of a preexisting device, the presence of an ICD-9 procedure code for monitoring of implantable cardiac devices (eAppendix 2) on any day before the date of device procedure was used. These cases likely represent a device upgrade or replacement (eg, CRT-D for ICD).

Coexisting illnesses were identified using ICD-9 diagnosis codes (algorithm by Quan et al16) and were compiled into a comorbidity score as structured under the Charlson Comorbidity Index (sum of 17 coexisting conditions scored according to their relative effects on mortality).16 As defined, the Charlson Comorbidity Index includes heart failure as a comorbid condition. Because all admissions in this study required a diagnosis of heart failure, comorbidity scores were reduced by a value of 1.

Costs presented represent the actual cost to treat the patient as reported by the individual hospital to PREMIER. This includes all supplies, labor, depreciation of equipment, and other expenses (essentially all direct and overhead costs) incurred during the care of the patient.

Our research team previously demonstrated that inotropic therapy is a risk factor for in-hospital mortality among patients undergoing device procedures.1 Therefore, standardized charge codes within the billing records were used to identify inotropic drugs (dopamine hydrochloride, dopamine hydrochloride, or milrinone) administered during the hospitalization.

STATISTICAL ANALYSIS

χ² Tests were used to evaluate potential relationships between patient age and hospital characteristics. Among patients who did not undergo a concomitant cardiac procedure, χ² tests were used to evaluate potential relationships among key variables during the hospitalization. Variables included patient age, sex, race/ethnicity, device type, comorbidity score (including underlying comorbid conditions), evidence of intravenous inotropic therapy, in-hospital mortality, and frequency of device complications. Bonferroni adjustment was used appropriately for multiple comparisons. Kruskal-Wallis tests were used to analyze differences in length of stay and total cost of hospitalization across age groups, with stratification by device type, frequency of complication, and comorbidity score. All costs were converted to December 2005 US dollars according to the consumer price index for medical care.17

Logistic regression analysis with stepwise selection was performed to model in-hospital mortality among patients without concomitant cardiac procedures. Covariates included age (19-79 or ≥80 years), sex, race/ethnicity (white, black, or nonwhite other), comorbidity score (0, 1-2, or ≥3), device type (CRT-D, ICD, or CRT-P), hospital location (rural or urban), hospital teaching status, and hospital bed count (0-400, 401-600, or ≥601). In addition, a covariate was included to capture the interaction of inotropic use and acute procedural complication. The age groups were chosen to directly evaluate mortality risk among patients 80 years or older relative to younger patients, as this cohort was excluded from randomized clinical trials or was markedly underrepresented.

Data management and analyses were performed using commercially available statistical software (SAS version 9.2; SAS Institute Inc, Cary, North Carolina). Differences were considered statistically significant at 2-sided P < .05 unless otherwise noted. The study was approved by the Saint Louis University Institutional Review Board, St Louis, Missouri.

RESULTS

There were 26 887 adult hospitalizations with a primary or secondary ICD-9 diagnosis code for heart failure and an ICD-9 procedure code for an implantable cardiac device. Key demographic variables are given in
**Table 1.** Patients were predominantly male and white; the median age was 70.0 years. The median length of hospital stay was 5.0 days. Most patients received CRT-D (43.9%) or ICD (49.4%) therapy. More than one-third (33.8%) (n=9083) of admissions involved at least 1 concomitant cardiac procedure; the most frequent was diagnostic cardiac catheterization (n=7020). Among 15 869 patients (59.0%) who received a device after day 1, a total of 58 had a device monitoring code before the procedure.

### Advanced Age

Patients 80 years or older accounted for 17.5% (n=4694) of the cohort; 21.1% (n=992) of these patients were older than 85 years, and 6.6% (n=309) were 89 years or older. **Table 2** compares older patients (80-85 years and >85 years) with younger patients based on device type, medical therapy administered in hospital, and comorbidity score. Sex did not differ significantly across these age groups; however, the percentage of black patients decreased as age increased (5.7% for 80-85 years and 4.8% for >85 years vs 14.5% for <80 years, P<.001). In addition, chronic renal failure among patients not undergoing a concomitant cardiac procedure was more common in the older age groups: 24.0% of patients with renal insufficiency were 80 years or older compared with 18.6% of patients without renal insufficiency.

Increased CRT-P use was observed with advanced age. Among patients older than 85 years, 21.1% received CRT-P compared with 5.1% for those 19 to 79 years and 12.7% for those 80 to 85 years. Furthermore, older patients (⩾80 years) had fewer concomitant cardiac procedures and slightly lower comorbidity scores. In addition, the percentage of patients receiving inotropic therapy was lower in older patients (80-85 and >85 years, P<.001).

### Device Complications

Most patients (66.2%) (n=17 804) did not have an additional cardiac procedure that might have led to an in-hospital complication. For this subgroup, the frequencies of acute device complications based on patient demographics, device type, comorbidity score, and evidence of inotropic therapy are given in Table 3. Female sex, black race/ethnicity, high comorbidity score, and use of intravenous inotropic therapy were significantly associated with higher complication rates (P<.001 for all comparisons). The frequency of complication did not differ based on device type, although it was slightly lower for younger patients (P=.03). Among patients having a mechanical complication directly attributable to the device (n=242), 85.9% were coded as due to the ICD, and the remainder were related to complications of the lead implant. Specific comorbid conditions associated with higher frequency of complication were cerebrovascular disease, chronic pulmonary disease, and renal disease (P<.001 for all comorbidities).

### In-hospital Mortality

Overall in-hospital mortality was 1.0%. Admissions without any concomitant cardiac procedures (n=17 804) were associated with an in-hospital mortality rate of 0.9% (1.3% for admissions with a code for a procedure). Bivariate analysis revealed that patients aged 80 to 85 years (1.2%) and older than 85 years (2.2%) had higher mortality rates compared with younger patients (0.7%) (P<.001). Hospital and patient characteristics associated with inhospital mortality based on multivariate analysis are given in Table 4 according to device procedure. Although age was significant, the most potent variable was inotrope use, particularly when a device-related complication occurred. For example, among patients undergoing CRT-D procedure, the odds ratio for death among patients with inotrope use and at least 1 complication was 35.51 (95% confidence interval, 14.44-87.32; P<.001) compared with those with no inotrope use and no complications.

### Length of Stay and Total Cost of Hospitalization

Among admissions without any concomitant cardiac procedures, the presence of a device complication or an elevated comorbidity score resulted in increased length of stay and total cost of hospitalization (Table 5). Advanced age was associated with increased length of stay and total cost of hospitalization but only consistently among patients undergoing a CRT-D procedure (n=8371). Elective admissions, defined by UB-92 coding or by implantation of the device on day 1 or 2, were associated with shorter lengths of stay (median, 2.0 vs 6.0 days), lower mortality (by 80.0%), and lower total cost of hospitalization of between $5127 and $7811 compared with nonelective admissions.
Implantable cardiac devices have been increasingly used in primary prevention of sudden cardiac death among patients with systolic heart failure, largely on the basis of favorable results from large multicenter clinical trials. Current clinical practice guidelines emphasize duration of heart failure, New York Heart Association class, and ejection fraction. Table 2 and Table 3 provide detailed information on the distribution of patient risk factors and the frequency of acute device complications, respectively, among patients not undergoing a concomitant cardiac procedure.
tion fraction in the selection of patients for cardiac devices. However, it has become increasingly apparent that certain patient subgroups may not benefit from device implantation; for example, use of ICDs in patients with renal failure and in those with advanced heart failure symptoms has not been associated with a survival benefit. In addition, the usefulness of device therapy in the expanding subgroup of older patients with systolic heart failure has not been critically examined. The mean age in major clinical trials has ranged from 58 to 67 years; some trials specified an upper age limit (80 years) in the inclusion criteria. As described by Heiat et al, pa-

### Table 4. Stepwise Logistic Regression Results Modeling In-Hospital Mortality Among 17 804 Patients Not Undergoing a Concomitant Cardiac Procedure

<table>
<thead>
<tr>
<th>Variable</th>
<th>CRT-D Group ((n=8371))</th>
<th>ICD Group ((n=8095))</th>
<th>CRT-P Group ((n=1338))</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>OR (95% CI)</td>
<td>(P) Value</td>
<td>OR (95% CI)</td>
</tr>
<tr>
<td>Age, y</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(\geq 80) vs 19-79</td>
<td>NS</td>
<td></td>
<td>2.12 (1.19-3.79)</td>
</tr>
<tr>
<td>Comorbidity score</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-2 vs 0</td>
<td>NS</td>
<td></td>
<td>2.44 (1.47-4.05)</td>
</tr>
<tr>
<td>(\geq 3) vs 0</td>
<td>2.74 (1.62-4.65)</td>
<td>&lt;.001</td>
<td>2.59 (1.77-15.79)</td>
</tr>
<tr>
<td>Any inotropic therapy or complication</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No inotrope, (\geq 1) complications vs no inotrope, no complication</td>
<td>4.24 (1.22-14.75)</td>
<td>.02</td>
<td>20.61 (11.41-37.23)</td>
</tr>
<tr>
<td>Inotrope, no complications vs no inotrope, no complication</td>
<td>20.65 (11.12-38.36)</td>
<td>&lt;.001</td>
<td>24.69 (7.78-78.39)</td>
</tr>
<tr>
<td>Inotrope, (\geq 1) complications vs no inotrope, no complication</td>
<td>35.51 (14.44-87.32)</td>
<td>.001</td>
<td>24.69 (7.78-78.39)</td>
</tr>
<tr>
<td>Hospital location</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urban vs rural</td>
<td>0.36 (0.16-0.82)</td>
<td>.02</td>
<td>NS</td>
</tr>
</tbody>
</table>

**Abbreviations:** CI, confidence interval; CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy without defibrillator; ICD, implantable cardioverter defibrillator; NS, not significant; OR, odds ratio.

### Table 5. Length of Stay and Total Cost of Hospitalization by Age Among 17 804 Patients Not Undergoing a Concomitant Cardiac Procedure

<table>
<thead>
<tr>
<th>Variable</th>
<th>19-79 y</th>
<th>80-85 y</th>
<th>&gt;85 y</th>
<th>Length of Stay</th>
<th>Cost of Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comorbidity score</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>2 (39 734)</td>
<td>2 (42 193)</td>
<td>3 (41 390)</td>
<td>.09</td>
<td>.04</td>
</tr>
<tr>
<td>1-2</td>
<td>3 (41 014)</td>
<td>3 (43 469)</td>
<td>5 (45 485)</td>
<td>&lt;.001</td>
<td>.01</td>
</tr>
<tr>
<td>(\geq 3)</td>
<td>6 (44 958)</td>
<td>6 (47 395)</td>
<td>10 (49 577)</td>
<td>&lt;.001</td>
<td>.02</td>
</tr>
<tr>
<td>No. of complications</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>2 (40 771)</td>
<td>3 (43 112)</td>
<td>3 (43 112)</td>
<td>&lt;.001</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>(\geq 1)</td>
<td>9 (49 120)</td>
<td>8 (53 284)</td>
<td>8 (56 659)</td>
<td>.78</td>
<td>.09</td>
</tr>
</tbody>
</table>

**CRT-D Group**

| Comorbidity score              |         |         |       |                |                         |
| 0                               | 2 (32 834) | 3 (31 518) | 4 (33 308) | <.001 | .61          |
| 1-2                             | 3 (34 122) | 4 (35 298) | 6 (33 898) | <.001 | .32          |
| \(\geq 3\)                      | 6 (37 174) | 8 (38 126) | 10 (38 462) | .03 | .38          |
| No. of complications            |         |         |       |                |                         |
| 0                               | 3 (34 018) | 4 (34 705) | 6 (33 748) | <.001 | .60          |
| \(\geq 1\)                      | 9 (43 582) | 9 (41 485) | 11 (40 918) | .87 | .30          |

**ICD Group**

| Comorbidity score              |         |         |       |                |                         |
| 0                               | 2 (21 108) | 2 (20 200) | 3 (21 394) | .01 | .12          |
| 1-2                             | 3 (24 267) | 4 (21 615) | 7 (25 490) | <.001 | .05          |
| \(\geq 3\)                      | 7 (30 015) | 8 (33 400) | 8 (32 572) | .44 | .56          |
| No. of complications            |         |         |       |                |                         |
| 0                               | 3 (23 150) | 3 (21 688) | 5 (23 117) | <.001 | .03          |
| \(\geq 1\)                      | 9 (35 383) | 8 (27 331) | 14 (34 394) | .25 | .18          |

**CRT-P Group**

**Abbreviations:** CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy without defibrillator; ICD, implantable cardioverter defibrillator.
tients in clinical trials often do not represent the typical patient with heart failure. The mean age of patients with heart failure was 61 years in randomized trials from 1985 to 1999 compared with an estimated mean age of 77 years in the community setting. This is important because older patients may be more susceptible to competing mortality risks. Perhaps as a consequence, a definite survival benefit could not be demonstrated in a retrospective study of Medicare beneficiaries with heart failure undergoing placement of ICDs, although this result may reflect methodological limitations more than a real finding. Similarly, results from a study of Canadian patients with heart failure suggested that long-term survival benefit attributable to ICD placement was limited among older patients.

In this study, we used PREMIER’s Perspective Comparative Database, a well-established administrative claims system, to compare the characteristics of a large cohort of patients undergoing device procedures. These patients seem to be representative of patients receiving devices. For example, when subjects with concomitant cardiac procedures were removed from these analyses, the observed mortality rate (0.9%) compared favorably with findings by Reynolds et al (0.9%) in the Medicare population.

Almost one-fifth (17.5%) of 26,887 patients were 80 years or older; 3.7% were older than 85 years. The proportion of patients receiving CRT-P increased with age. This finding may reflect the fact that physicians value symptom relief to a greater degree among older (as opposed to younger) patients, as CRT improves symptoms and functional status. In addition, patient preferences may be driving decision making among older patients. We found that older patients were less likely to have a concomitant cardiac procedure or a high comorbidity score, suggesting that these patients may be, in fact, somewhat more carefully selected than the younger cohort. However, older patients had slightly more complications related to the device procedure. In addition, advanced age (≥80 years) was associated in multivariate analysis with increased risk of in-hospital mortality. In a substudy of MADIT-II subjects, older patients (≥75 years) had a reduction in mortality risk proportional to that of patients 75 years and younger, but 1-year mortality remained markedly higher in the older group.

In an analysis limited to patients who did not undergo a concomitant cardiac procedure, we did not find a noticeable difference in total cost of hospitalization based on age except among patients who received CRT-D. In this cohort, comorbidity score and number of complications were each associated with increased total cost of hospitalization.

Our analyses used administrative data, which have known limitations. Diagnoses were limited to those that were recorded during the index hospitalization. Furthermore, the potential for inaccurate coding could have resulted in underreporting of comorbidities and complications; however, our particular data set included as many as 49 diagnosis codes per hospitalization, which should lessen concern about underreporting of comorbidities. Some risk factors for mortality such as New York Heart Association class and left ventricular ejection fraction are unavailable in this database; therefore, we may not have sufficiently characterized severity of illness and risk for death. However, results of a study by Panotopoulos et al suggested that, despite matching for functional class and ejection fraction, mortality remained markedly higher among ICD recipients with advanced age (≥75 years) relative to younger patients. Differentiation within the ICD cohort on the basis of indication (primary or secondary prevention of sudden death) cannot be reliably determined using diagnostic coding, especially as we do not have information on antecedent hospitalizations or outpatient care.

For many procedures, there is an association between procedure volume and reduced adverse events within hospitals. Because surgical volume for specific devices was unavailable, we used hospital bed count as a surrogate for hospital volume in multivariate analysis. In addition, we did not have data on subspecialty of the implanting physician, which has been shown to affect outcomes; PREMIER physician specialty is limited to the categories of cardiologist, thoracic surgeon, and other.

Finally, the outcomes in these analyses were limited to the index hospitalization when a device procedure was performed. Follow-up complications and mortality cannot be assessed, and we are unable to capture other important outcomes such as readmission rate and quality of life. However, a recent study of Medicare patients receiving devices found that almost 70% of complications following placement of ICDs occur during the index hospitalization.

In conclusion, our findings indicate that procedure-related complication rates and in-hospital mortality are elevated in patients with advanced age. Older patients are more likely to receive CRT alone rather than a defibrillator or combination defibrillator and CRT device. The degree to which patient preferences have a role in device selection has not been evaluated, but the importance of physician-patient dialogue about the potential survival benefit and the effect of device therapy on quality of life and functional status has been emphasized. Given trends in the demographics of heart failure and the costs of device therapy, additional studies are required to clarify the appropriateness of device implantation in older patients with heart failure, as well as the merits of less invasive options.

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REFERENCES


