Over the past decade, implantable cardioverter-defibrillators (ICDs) have played an increasingly important role in the care of patients at high risk of sudden cardiac death. Randomized clinical trials have demonstrated that ICDs improve survival in patients with evidence of high risk of sudden cardiac death because of prior myocardial infarction or heart failure. In response to this evidence, payers expanded their coverage of these devices to include primary prevention ICD implantation.

As part of this coverage expansion, the ICD Registry was developed by the American College of Cardiology’s National Cardiovascular Data Registry (NCDR) in partnership with the Heart Rhythm Society to collect information from US hospitals about the characteristics and in-hospital outcomes of patients undergoing ICD implantation. Participating hospitals are required to submit data to the registry for all Medicare patients receiving primary prevention ICDs, and 79% of participating hospitals submit data for all patients receiving ICDs regardless of indication. Thus, the registry represents a significant investment by hospitals, physicians, and professional societies in monitoring the care of patients undergoing ICD implantation.

A major goal of the registry is to provide feedback to sites that can be used for quality improvement efforts, and studies using data from the ICD Registry have identified potential areas for improvement, including procedural safety, concomitant medical therapy, and use of cardiac resynchronization therapy (CRT) in eligible patients; however, it is not known whether the quality of care for patients has changed over time. Having collected data about implants since 2006, the registry provides an excellent opportunity to address this question.

**Background**—The ICD Registry was established in 2006 in part to measure quality of care in patients undergoing implantation of implantable cardioverter-defibrillators (ICDs); however, whether outcomes have improved since initiation of the registry is unknown. Our objective was to examine changes over time in 3 quality metrics available from the registry.

**Methods and Results**—We performed an observational study of 367,153 patients who received new ICD implants from April 2006 to March 2010. Three quality metrics were selected: Adverse events (in-hospital complications or mortality), optimal medical therapy (OMT), and cardiac resynchronization therapy (CRT). OMT was defined as prescription of β-blocker and either angiotensin-converting enzyme inhibitor or angiotensin receptor blocker in eligible patients. CRT eligibility was determined by QRS ≥120 ms, left ventricular ejection fraction ≤35%, and New York Heart Association class III/IV. Observation periods were divided into four 12-month intervals. We analyzed changes over time and used hierarchical logistic regression to adjust for potential confounders. Adverse events decreased over time (3.7% to 2.8%, P<0.001). Among eligible patients, rates of OMT and CRT increased over time (OMT: 69.0% to 74.3%, P<0.001; CRT: 80.5% to 84.2%, P<0.001). After adjustment for potential confounders, patients were significantly less likely to experience adverse events in year 4 than in year 1 (odds ratio, 0.75; 95% confidence interval, 0.71–0.79) and significantly more likely to receive OMT (odds ratio, 1.29; 95% confidence interval, 1.26–1.32) and CRT (odds ratio, 1.42; 95% confidence interval, 1.35–1.49).

**Conclusions**—Since initiation of the ICD Registry, adverse events have been decreasing, and rates of OMT and CRT among eligible patients have been increasing, although there is still significant room for improvement.

**Key Words:** cardioverter-defibrillators, implantable, electrophysiology, quality of health care, registries

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**Temporal Trends in Quality of Care Among Recipients of Implantable Cardioverter-Defibrillators**

**Insights From the National Cardiovascular Data Registry**

John A. Dodson, MD; Rachel Lampert, MD; Yongfei Wang, MS; Stephen C. Hammill, MD; Paul Varosy, MD; Jeptha P. Curtis, MD

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**O**ver the past decade, implantable cardioverter-defibrillators (ICDs) have played an increasingly important role in the care of patients at high risk of sudden cardiac death. Randomized clinical trials have demonstrated that ICDs improve survival in patients with evidence of high risk of sudden cardiac death because of prior myocardial infarction or heart failure. In response to this evidence, payers expanded their coverage of these devices to include primary prevention ICD implantation. Participating hospitals are required to submit data to the registry for all Medicare patients receiving primary prevention ICDs, and 79% of participating hospitals submit data for all patients receiving ICDs regardless of indication. Thus, the registry represents a significant investment by hospitals, physicians, and professional societies in monitoring the care of patients undergoing ICD implantation.

A major goal of the registry is to provide feedback to sites that can be used for quality improvement efforts, and studies using data from the ICD Registry have identified potential areas for improvement, including procedural safety, concomitant medical therapy, and use of cardiac resynchronization therapy (CRT) in eligible patients; however, it is not known whether the quality of care for patients has changed over time. Having collected data about implants since 2006, the registry provides an excellent opportunity to address this question.
gap in knowledge by evaluating trends in the care of patients undergoing ICD implantation. To accomplish this, we evaluated 3 quality metrics that are known to be meaningfully associated with long-term outcomes: Adverse events (procedural complications or mortality), prescription of optimal medical therapy (OMT) among eligible patients, and implantation of a CRT device among eligible patients.

Furthermore, we performed analyses examining whether changes in quality of care varied across hospitals and whether individual performance metrics were correlated.

Methods

Data Source

Details of the ICD Registry have been described previously. In brief, information about patients undergoing ICD implantation are collected using standardized definitions and submitted by participating hospitals to the ICD Registry via a secure Web site. For the purposes of training, new NCDR sites participate in a quarterly conference call in which data entry practices are reviewed, and the NCDR maintains a Web site with a list of frequently asked questions, as well as a call center where individuals and centers can receive direction about proper abstraction strategies. Participating sites may also participate in quarterly conference calls and an annual in-person meeting at which NCDR leaders answer questions and review cases that represent common challenges faced by data abstractors.

Once data are submitted, they undergo quality checks to ensure data completeness, consistency, and accuracy. Before they are entered into the Enterprise Data Warehouse, submissions receive 1 of 3 color-coded scores based on data quality. Data are given a green light if they have passed all quality and integrity checks and are suitable for analysis. A yellow light means that data have passed integrity checks but are incomplete; these data are loaded into the Enterprise Data Warehouse, and sites are given the opportunity to resubmit their data. A red light denotes a failed submission because of either extensive missing data or data that are internally inconsistent. These data are neither processed nor loaded into the Enterprise Data Warehouse. Data accuracy is also evaluated with chart audits, which consisted in 2% of patient records in 2010 and 4% in 2011 (F. Pourhamidi, NCDR staff, e-mail correspondence dated July 8, 2013).

For the present study, we used version 1 data, which include procedures between April 1, 2006, and March 31, 2010. Full elements are available at the NCDR Web site. We analyzed data for patients undergoing first-time transvenous ICD implantation and divided periods of analysis into 12-month intervals (year 1: April 1, 2006, to March 31, 2007; year 2: April 1, 2007, to March 31, 2008; year 3: April 1, 2008, to March 31, 2009; year 4: April 1, 2009, to March 31, 2010). Because the focus was on change in our metrics over time, we restricted our analysis to hospitals reporting to the ICD Registry for at least 12 of the total of 16 quarters. If a patient had multiple procedures within a given 12-month interval, only the initial procedure was counted.

Institutional review board approval was obtained through the Yale University Human Investigation Committee, and the requirement for informed consent was waived on the basis of the nature of the study.

Outcomes

We defined 3 quality metrics that were available from registry data: (1) Adverse in-hospital events (including complications or death), (2) receipt of OMT, and (3) receipt of CRT among eligible patients.

Using definitions similar to prior studies from the ICD Registry, we divided complications into major (cardiac arrest, cardiac perforation, valve injury, stroke, myocardial infarction, tamponade, device infection, peripheral embolus, lead dislodgement, hemothorax, pneumothorax, arteriovenous fistula) and minor (drug reaction, hematoma, phlebitis, conduction block, peripheral nerve injury) complications. Complications were only available for analysis if they occurred during the index hospitalization. OMT was determined according to American Heart Association/American College of Cardiology consensus guidelines for patients with heart failure and systolic dysfunction and included discharge with a prescription for a β-blocker and angiotensin-converting enzyme inhibitor/angiotensin receptor blocker for patients with left ventricular ejection fraction ≤35% and no recorded contraindications to OMT recorded by sites at the time of procedure. For CRT, eligible patients were defined by left ventricular ejection fraction ≤35%, QRS duration ≥120 ms, and New York Heart Association class III or IV heart failure, in accordance with consensus guidelines available during the study period and as used in prior ICD Registry analyses. We did not include patients with New York Heart Association class II heart failure because our period of analysis was before the publication of data that showed a definitive benefit of CRT therapy in these patients. Because new data were emerging during this period that patients with a QRS duration ≥120 ms had a greater benefit than those with QRS 120 to 150 ms, we also performed a sensitivity analysis for CRT using a QRS duration of ≥150 ms rather than ≥120 ms.

Statistical Analysis

Patient characteristics and outcomes were compared among different years by 1-way ANOVA or nonparametric test for continuous variables where appropriate and the Pearson χ² test for categorical variables. For each year of data, we calculated the proportion of patients experiencing adverse events and the proportions of eligible patients receiving OMT and CRT. Trends in outcomes for the study cohort over the 4-year period of analysis were examined with the Cochran-Armitage test. To evaluate the independent effect of different time periods, we used hierarchical logistic regression models with and without adjustment for potential confounders. Odds ratios and 95% confidence intervals were reported for outcomes in year 4 versus year 1 (reference group). We then performed several exploratory hospital-level analyses for each quality metric (adverse events, OMT among those eligible, CRT among those eligible), excluding hospitals that performed <50 procedures in each year to ensure stable estimates. We first analyzed the distribution of absolute change in each quality metric among hospitals between year 1 and year 4. Subsequently, we examined the correlation between quality metrics among hospitals in the aggregate time period (ie, combining data from year 1 through year 4). A 2-tailed P value <0.05 was considered statistically significant for all tests. All statistical analyses were performed with the use of SAS software, version 9.2 (SAS Institute, Cary, NC).

Results

Study Sample

From an initial sample of 538670 patients, we excluded 8843 who received an epicardial lead, 142484 who had a previous ICD, and 20190 who underwent ICD implantation in hospitals reporting data for <12 quarters, which left an analytic sample of 367153 patients. Patient and hospital characteristics over time are shown in Table 1. Overall, there were only modest changes in these characteristics during the 4-year study period.

Unadjusted Outcomes

There were significant declines in adverse events over the study period (Table 2), which decreased from 3.7% to 2.8% overall (trend P<0.001). Major complications decreased from 2.3% to 2.0% (P for trend <0.001), and minor complications decreased from 1.4% to 0.8% (P for trend <0.001). In-hospital death declined only slightly from 0.4% to 0.3% (P for trend <0.05). The proportion of eligible patients receiving OMT increased steadily from 55.316 of 80120 (69.0%) in year 1 to 53.805 of 72416 (74.3%) in year 4 (P for trend <0.001). Similarly, the proportion of patients receiving CRT among those eligible increased from 23.897 of 29687 (80.5%) in year...
Using a QRS cutoff of 150 ms instead of 120 ms for CRT eligibility, this trend was similar: 14183 of 16579 (85.5%) in year 1 and 13384 of 15186 (88.1%) in year 4 ($P < 0.001$).

**Table 1.** Patient Characteristics Over Time

<table>
<thead>
<tr>
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<tr>
<td>Demographics</td>
<td></td>
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<tr>
<td>Age, y</td>
<td>67.7±12.8</td>
<td>67.5±13.1</td>
<td>67.1±13.2</td>
<td>66.9±13.3</td>
<td>&lt;0.01</td>
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<tr>
<td>Female</td>
<td>26.7</td>
<td>27.1</td>
<td>27.2</td>
<td>27.7</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Nonwhite race</td>
<td>18.0</td>
<td>18.7</td>
<td>19.6</td>
<td>20.0</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Medical history</td>
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<tr>
<td>Cerebrovascular disease</td>
<td>14.4</td>
<td>14.4</td>
<td>14.2</td>
<td>14.3</td>
<td>0.32</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>21.7</td>
<td>23.1</td>
<td>23.3</td>
<td>23.0</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>36.6</td>
<td>37.3</td>
<td>37.5</td>
<td>37.8</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Hypertension</td>
<td>73.3</td>
<td>76.0</td>
<td>77.5</td>
<td>78.7</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Renal failure: dialysis</td>
<td>4.2</td>
<td>4.2</td>
<td>4.2</td>
<td>4.0</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>77.8</td>
<td>77.2</td>
<td>77.3</td>
<td>77.1</td>
<td>&lt;0.01</td>
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<tr>
<td>Previous myocardial infarction</td>
<td>54.7</td>
<td>53.0</td>
<td>51.0</td>
<td>49.0</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>NYHA class III/IV</td>
<td>51.6</td>
<td>51.4</td>
<td>51.2</td>
<td>51.4</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Sustained ventricular tachycardia</td>
<td>10.7</td>
<td>11.3</td>
<td>11.9</td>
<td>12.2</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Prior pacemaker</td>
<td>11.3</td>
<td>10.8</td>
<td>10.4</td>
<td>10.1</td>
<td>&lt;0.01</td>
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<tr>
<td>Diagnostics</td>
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<tr>
<td>%EF, when assessed</td>
<td>27.0±10.4</td>
<td>27.7±10.8</td>
<td>28.1±11.1</td>
<td>28.5±11.4</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Creatinine level, mg/dL</td>
<td>1.40±1.18</td>
<td>1.39±1.15</td>
<td>1.36±1.14</td>
<td>1.35±1.14</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Sodium level, mmol/L</td>
<td>138.5±3.6</td>
<td>138.5±3.5</td>
<td>138.4±3.5</td>
<td>138.4±3.4</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Systolic blood pressure, mmHg</td>
<td>129.8±12.9</td>
<td>130.2±22.3</td>
<td>130.5±22.3</td>
<td>130.8±22.5</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>QRS width, ms</td>
<td>125.7±34.2</td>
<td>124.8±34.0</td>
<td>124.3±33.5</td>
<td>124.4±33.3</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Hospital characteristics</td>
<td></td>
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</tr>
<tr>
<td>Private/community</td>
<td>84.7</td>
<td>84.4</td>
<td>84.0</td>
<td>83.3</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Teaching</td>
<td>55.5</td>
<td>54.7</td>
<td>54.5</td>
<td>54.3</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Number of beds</td>
<td>489.8±259.7</td>
<td>479.9±253.4</td>
<td>479.8±252.3</td>
<td>479.8±253.2</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Hospital volume</td>
<td>599.2±386.8</td>
<td>589.1±383.3</td>
<td>585.0±384.6</td>
<td>585.8±383.9</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

Values are percentages or mean±SD.

%EF indicates percent ejection fraction; and NYHA, New York Heart Association.

1 to 23040 of 27367 (84.2%) in year 4 ($P$ for trend <0.001). Using a QRS cutoff of 150 ms instead of 120 ms for CRT eligibility, this trend was similar: 14183 of 16579 (85.5%) in year 1 and 13384 of 15186 (88.1%) in year 4 ($P$ for trend <0.001).

**Adjusted Outcomes**

The unadjusted and adjusted odds ratios (year 4 versus year 1) for adverse events, OMT, and CRT are shown in Table 3. After adjustment for potential confounders, patients were...
significantly less likely to experience adverse events in year 4 than in year 1 (odds ratio, 0.75; 95% confidence interval, 0.71–0.79) and significantly more likely to receive OMT (odds ratio, 1.29; 95% confidence interval, 1.26–1.32) and CRT (odds ratio, 1.42; 95% confidence interval, 1.35–1.49).

Hospital-Level Analyses

For hospitals that performed >50 procedures in each year of observation, the median rate of in-hospital adverse events decreased by 0.79% (interquartile range −2.72% to 0.92%), the median proportion of patients receiving OMT increased by 4.83% (interquartile range −1.77% to 12.86%), and the median proportion of patients receiving CRT increased by 3.73% (interquartile range −1.70% to 9.91%). As shown in Figure 1, although the majority of hospitals improved their metrics, in some hospitals metric performance declined. There was no correlation between in-hospital adverse events and either CRT (r=0.03, P=0.46) or OMT (r=0.04, P=0.27) among eligible patients (Figure 2). There was a weak positive correlation between CRT and OMT among eligible patients (r=0.17, P<0.001).

Discussion

In a large sample of US patients undergoing new ICD implantation over a 4-year period, we found a significant improvement in quality of care as evidenced by a decrease in adverse events and significant increases in the proportions of eligible patients receiving OMT and CRT. Because each of these quality metrics has been independently associated with survival, the observed improvements are likely to benefit both the short- and long-term outcomes of new ICD recipients.

Although these findings are encouraging, there remains significant room for improvement. Among eligible patients in year 4, 26% did not receive OMT and 16% did not receive CRT. In addition, there was considerable variation in change for quality metrics among hospitals such that many hospitals had worse outcomes in year 4 than in year 1. Although this may reflect the play of chance, it raises some concern that
not all hospitals are improving at the same rate. Similarly, we found that there was very little correlation among different quality metrics (ie, fewer in-hospital adverse events were not at all correlated with increasing rates of OMT or CRT), which suggests the factors that allow a hospital to perform well in one area may not carry over to other domains. This is consistent with prior research that has shown high correlation among process measures (for example, β-blocker and aspirin at discharge among survivors of acute myocardial infarction) but less correlation between process measures and outcomes such as mortality. Thus, efforts to improve care of patients undergoing ICD implantation may require a broad range of approaches targeting physicians, hospital processes, and staff education. Although there may be a “ceiling effect” (eg, we would not expect complications to ever reach 0%), evidence continues to evolve (eg, recent data support the continuance of periprocedural oral anticoagulation to reduce the incidence of device pocket hematoma), which suggests continued opportunities for improvement.

The factors responsible for the observed improvements in quality of care are unknown. The observed trends may reflect changes in care related to improved technology and operator proficiency over time (in the case of complications) and more widespread adoption of evidence-based practices (in the case of OMT and CRT). It is also possible that the feedback provided by the NCDR to sites has facilitated quality improvement efforts by individual hospitals. This feedback includes quarterly outcome reports with benchmark comparison metrics, site audits, monthly site manager calls, and an annual educational conference. Although engagement with this process among sites may vary, quarterly ICD registry conference calls involve between 150 and 200 sites; ≈1200 sites access the ICD Registry’s outcomes dashboard (where the quality reports are contained); and 921 participants attended the annual in-person meeting in 2013 (F. Pourhamidi, NCDR staff, e-mail correspondence dated July 8, 2013). However, given the absence of an appropriate comparison group, we cannot empirically measure the impact of these efforts. Finally, we cannot exclude the possibility that the differences over time may reflect changes in the data abstraction processes of participating hospitals; however, as noted previously, the registry has a robust data quality program in place that includes chart review from selected sites to determine the accuracy of submitted data.

The present findings must be interpreted in the context of our study design. We cannot extend our results to hospitals that either did not submit data to the registry or whose data did not meet NCDR quality standards. In addition, like any large registry, we have limited information regarding clinical decision making and why a particular therapy was not used in a specific case. For example, it is possible that for CRT, the option to implant CRT may have been offered to and declined by patients, attempted and unsuccessful, or not offered because of other considerations (eg, imminent referral for mechanical circulatory support or transplantation). For OMT, we did not include data on other therapies that may have been beneficial (such as potassium-sparing diuretics) because these were not available from the registry. Furthermore, because doses...
are not recorded in the registry, we cannot determine whether the OMT medications were truly optimized. In addition, we do not know whether use of OMT medications increased because of conditions other than heart failure (eg, hypertension, which increased in prevalence over time). Both the OMT and CRT metrics were process measures; we were unable to evaluate in our data set whether increasing rates of OMT and CRT were actually associated with reduced long-term mortality, although our selection of these metrics was based on efficacy data from randomized trials. Furthermore, because the present study was observational in nature, practice patterns may have changed over time on the basis of data that emerged before the revision of guidelines. Finally, we were not able to use version 2 registry data to capture in-hospital outcomes beyond March 2010, and we do not have information on important outcomes that may have occurred after hospital discharge (such as device-related infections, or OMT at 6 months). The investigation of in-hospital trends beyond March 2010 and the linking of registry data with other sources that capture outcomes beyond the initial hospitalization are worthwhile directions for future investigations.

In conclusion, since initiation of the ICD Registry in 2006, adverse events among ICD recipients have decreased, and rates of OMT and CRT among eligible patients have increased. Although these trends are encouraging, there remains significant variation among hospitals, which highlights the importance of continued quality improvement efforts. Determining factors that promote improvements in quality of care is an important avenue of further research.

Acknowledgments

The ICD Registry is an initiative of the American College of Cardiology Foundation and the Heart Rhythm Society.

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Disclosures

Yongfei Wang is under contract with the American College of Cardiology to provide statistical analysis support. Dr Curtis receives salary support under contract with the NCDR to provide analytic services and with the Centers for Medicare & Medicaid Services to support development of quality measures in addition to equity interest in Medtronic. The other authors report no conflicts.

References

Implantable cardioverter-defibrillators (ICDs) improve survival in patients at high risk of sudden cardiac death, and their use has increased over time. In conjunction with a coverage expansion in 2006 to cover primary prevention, the ICD Registry was developed to capture the characteristics and in-hospital outcomes of ICD recipients. A major goal of the registry is to provide feedback to hospitals that can be used for quality improvement efforts, and as the largest database of US ICD recipients to date, it provides a unique opportunity to examine quality metrics. The purpose of our study was to examine trends in 3 quality metrics known to be associated with long-term outcomes in patients receiving ICDs: Adverse in-hospital events (procedural complications or mortality), prescription of optimal medical therapy as defined by receipt of angiotensin-converting enzyme inhibitor and β-blocker in eligible patients at discharge, and use of cardiac resynchronization therapy in eligible patients. We found that from April 2006 to March 2010, there was significant improvement in all 3 quality metrics: Adverse events declined (from 3.7% to 2.8%, \( P<0.0001 \)), and use of optimal medical therapy and cardiac resynchronization therapy increased (optimal medical therapy, from 69.0% to 74.3%, \( P<0.001 \); cardiac resynchronization therapy, from 80.5% to 84.2%, \( P<0.001 \)). After adjustment for patient characteristics in each year, these trends persisted. However, we found that among hospitals, there was little correlation in good performance between the 3 metrics. Our results show an encouraging trend in quality metrics among US ICD recipients over a 4-year period, although there remains room for improvement.
Temporal Trends in Quality of Care Among Recipients of Implantable Cardioverter-Defibrillators: Insights From the National Cardiovascular Data Registry

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