Variation in Use of Dual-Chamber Implantable Cardioverter-Defibrillators

Results From the National Cardiovascular Data Registry

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Background: Among patients without an indication for a pacemaker, current evidence is inconclusive whether a dual-chamber implantable cardioverter-defibrillator (ICD) is superior to a single-chamber ICD. The current use of dual-chamber ICDs is not well characterized.

Methods: We conducted a cross-sectional study exploring hospital-level variation in the use of dual-chamber ICDs across the United States. Patients receiving a primary prevention ICD from 2006 through 2009 without a documented indication for a pacemaker were included. Multivariate hierarchical logistic regression was used to explore patient, health care provider, and physician factors related to the use of a dual-chamber device.

Results: Dual-chamber devices were implanted in 58% of the 87,115 patients without a pacing indication among 1,293 hospitals, with hospital rates ranging from 0% in 33 centers to 100% in 109 centers. In multivariate analysis, geographic region was a strong independent predictor of dual-chamber device use, ranging from 36.4% in New England (reference region) to 66.4% in the Pacific region (odds ratio [OR], 5.25; 95% CI, 3.35-8.21). Hospital clustering was assessed using a median OR which was 3.96, meaning that 2 identical patients at different hospitals would have nearly a 4-fold difference in their chance of receiving a dual-chamber ICD.

Conclusions: Use of dual-chamber ICDs for the primary prevention of sudden cardiac death among patients without an indication for permanent pacing varies markedly at the hospital level in the United States. This is a clear example of how practice can vary independent of patient factors.

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out a documented indication for permanent pacing is not well characterized; furthermore, the influences of patient, health care provider, hospital, and regional factors on the use of dual-chamber devices in community settings across the United States have not been described. Accordingly, this study explored hospital and regional level variation in the use of dual-chamber ICDs among patients without documented indications for pacing and defined the patient and physician factors associated with dual-chamber ICD placement in the United States.

### METHODS

#### DATA SOURCES

Data from the National Cardiovascular Data Registry (NCDR) ICD Registry were used for this analysis. Participation in this registry is mandated by the CMS for reimbursement for all Medicare primary prevention ICDs, and implanting centers are required to enter complete data to receive Medicare reimbursement. However, more than 75% of hospitals report data on all ICD implantations (irrespective of indication and payer). The registry contains information on patient, health care provider, and hospital characteristics.

#### STUDY POPULATION

All patients receiving a first-time ICD for primary prevention from 2006 and 2009 were included. Patients receiving an ICD for secondary prevention, including those with a history of syncope, cardiac arrest, or sustained ventricular tachycardia, were excluded. We also excluded patients with an indication for permanent or biventricular pacing, specifically those with (1) a QRS interval duration of at least 120 milliseconds because these patients would be eligible for a biventricular pacemaker; (2) documented abnormal sinus node function; (3) second- or third-degree atrioventricular block; or (4) prior pacemaker implantation. To avoid the influence of low-volume outliers, patients treated at hospitals where fewer than 20 total ICDs received implants during the study period were also excluded.

#### GEOGRAPHIC REGIONS

Two types of regions were used for the analysis. For the multivariate model, the country was divided into 9 regions as defined by the US Census (New England, Mid Atlantic, South Atlantic, Northeast Central, Southeast Central, Northwest Central, Southwest Central, Mountain, and Pacific).

Hospital referral regions (HRRs) were used to explore smaller regional patterns of use of discretionary dual-chamber ICDs. A total of 306 different HRRs have been defined in the United States by the Dartmouth Atlas project and are based on referral patterns for tertiary care using major cardiovascular and neurosurgical procedures from the Medicare claims data. By using referral patterns to define regions, HRRs approximate a local culture of practice and are the standard in geographic variation research.

#### OUTCOME MEASURE AND PREDICTOR VARIABLES

The primary outcome measure was implantation of a dual-chamber ICD. Candidate predictor variables included patient (demographic and clinical), health care provider, and hospital characteristics, including the geographic region described in the previous subsection. The registry contains information on patient characteristics, including demographics and cardiovascular history; procedural characteristics, including indications, device details, diagnostic studies, and complications; and characteristics of the index hospitalization, including other cardiac procedures and discharge medications using standardized data elements and definitions. Hospital characteristics were obtained from the hospital profile managed by the NCDR and include address, financing, community area, bed number, teaching status, ICD volume, and presence of an EP laboratory. The registry has also been supplemented with information on health care provider volume, and certification. Health care provider certification was determined with the American Board of Internal Medicine, Society for Thoracic Surgeons, and American College of Surgeons databases to determine physician certification, categorized as electrophysiologist (EP), non-EP, cardiologist, thoracic surgeon, and other.

#### STATISTICAL ANALYSIS

Patients receiving single-chamber ICDs were compared with those receiving dual-chamber ICDs, using chi-square tests for dichotomous outcomes and t tests for continuous outcomes. Multivariate hierarchical logistic regression was used to determine the relationship between dual-chamber ICD and patient, health care provider, and hospital characteristics. Hierarchical models were used to account for the clustering of patients within physicians or hospitals. Physician and hospital clustering could not be accounted for in the same model because many physicians work in multiple hospitals. Therefore, 2 separate models were constructed, 1 accounting for clustering by physician and 1 for clustering by hospital. All variables in Table 1 were considered as candidates. Backward selection was used to determine which variables were retained in the final model (P < .05). Variables in the final model include age (<65, 65-75, or >75 years), sex, race/ethnicity (white, black, Hispanic, other), and select comorbidities (lung disease, atrial fibrillation, diabetes mellitus, and hemodialysis); health care provider variables included physician specialty (board-certified EP, fellowship-trained EP, surgeon, or credentialed other); hospital variables included American Heart Association region and profit type (government, university, or private).

To determine the proportion of total variance in outcomes attributable to clustering within physicians or hospitals, we calculated the intracluster correlation (ICC) coefficient before adjustment, after adjusting for patient factors, and after adjusting for patient, health care provider, and hospital factors in the 2 models. If variation could be explained by adjusting for any of these covariates, then the ICC should decrease as the covariates are added to the model. To further quantify the extent to which observed variation was due to clustering of patients within physicians or hospitals, the median odds ratio (MOR) was also calculated for the 2 models. The MORs are always greater than 1, do not have 95% CIs, and are more easily interpretable than ICCs for examining clustering effects from hierarchical models. For example, an MOR of 1.0 would signify no clustering effects, whereas an MOR of 2.0 would signify that a patient has 2-fold higher odds of receiving a dual-chamber ICD if he or she went to another randomly selected physician or hospital.

Many consider paroxysmal atrial fibrillation to be an indication for a dual-chamber ICD and permanent atrial fibrillation to be an indication for a single-chamber device. Because we could not distinguish permanent from paroxysmal atrial fibrillation in the registry, we repeated the analysis excluding all patients with atrial fibrillation. To further assess the robust-
ness of the findings, we repeated the analysis but restricted it to the Medicare population because this is the population for which there is complete enrollment in the registry.

Statistical analyses were performed using the SAS statistical package (version 9.2; SAS Institute, Cary, North Carolina) and STATA 10.0 (StataCorp LP, College Station, Texas). Use of the NCDR database was approved by the ICD Registry Research and Publications Committee and analysis was approved by the Yale University School of Medicine Human Investigation Committee, New Haven.

### RESULTS

From 2006 through 2009, 239,113 first-time primary prevention ICDs were entered in the ICD registry. After excluding 151,665 patients with an indication for a dual-chamber device (permanent or biventricular pacing indication) and 333 patients receiving their ICD at a low-volume hospital, a total of 87,115 patients were eligible for a single- or dual-chamber ICD (Figure 1).
The use of dual-chamber devices occurred in 58% of the patients (50,626) without pacing indications across 1,293 hospitals (Table 1). The proportion of dual-chamber devices increased steadily over the study period from 53% in the first quarter of 2006 to 62% in the fourth quarter of 2009 (P < .001). The hospital rate of dual-chamber ICD implantation ranged from 0% to 100%, with 33 hospitals (3%) exclusively implanting single-chamber ICDs, 109 hospitals (8%) exclusively implanting dual-chamber ICDs, and the remainder (89%) falling in between (Figure 2). The physician implantation rate ranged from 0% to 100% with 443 (11%) implanting single-chamber ICDs exclusively and 941 (23%) implanting dual-chamber ICDs exclusively, with the remainder falling in between (Figure 3). The lowest regional rate (by US Census region) of dual-chamber ICD implantation was 36.4% in New England compared with 66.4% in the Pacific region (odds ratio [OR], 5.25; 95% CI, 3.35-8.21). Patterns of variation by HRR are shown in Figure 4. While there seems to be lower use of dual-chamber ICDs in the Northeast region, there is otherwise no discernible pattern, with high-use regions appearing immediately adjacent to low-use regions.

Using multivariate hierarchical logistic regression, patients were more likely to receive a dual-chamber ICD if they were older (65.4% for age > 75 years vs 53.5% for age < 65 years; OR, 1.52; 95% CI, 1.46-1.60), had atrial fibrillation or flutter (66.4% vs 56.3%; OR, 1.66; 95% CI, 1.59-1.73), had hypertension (59.4% vs 54.2%; OR, 1.11; 95% CI, 1.07-1.15) or if their ICD was implanted by a surgeon (68.7% vs 57.3% for an EP; OR, 1.95; 95% CI, 1.67-2.27). Those less likely to receive a dual-chamber ICD were black patients (52.8% vs 59.5% for white; OR, 0.81; 95% CI, 0.78-0.85), patients receiving hemodialysis (56.0% vs 58.2%; OR, 0.85; 95% CI, 0.78-0.92), and patients at academic medical centers (49.0% vs 59.7% for private or community hospitals; OR, 0.65; 95% CI, 0.49-0.86) (Table 2).

In unadjusted analysis, the ICC was 0.41. This remained largely unchanged after adjusting for patient-level factors (ICC = 0.42) and after adjusting for physician- and hospital-level factors (ICC = 0.39). This signifies that 39% of the variance between hospitals was attributable to clustering within hospitals. The MOR was 3.96, signifying that a randomly selected patient receiving an ICD at one hospital would have a nearly 4-fold higher odds of receiving a dual-chamber ICD than an identical patient at a different randomly selected hospital in the sample. Similarly, when the analysis was repeated among only the Medicare population, the hospital-level MOR was 3.85. When patients with atrial fibrillation were excluded, the hospital-level MOR was 4.51. When the analysis was performed accounting for clustering of use among physicians (rather than hospitals), the MOR was 4.89, signifying that a randomly selected patient receiving an ICD from one physician would have a nearly 5-fold higher odds of receiving a dual-chamber ICD than an identical patient at a different randomly selected physician in the sample.

To our knowledge, this is the first study to document physician, hospital, and regional variation in the use of dual-chamber ICDs among those without a pacing indication. The degree of variation is particularly striking, with
some physicians and hospitals implanting a dual-chamber device in all of their patients and others implanting them in none. While some patient, health care provider, and hospital characteristics were associated with this “discretionary” dual-chamber device use, regional effects and clustering within hospitals accounted for substantially more variability than these factors. Even after adjustment for a wide range of patient, health care provider, and hospital characteristics, 39% of the variance was attributable to clustering within hospitals.

A particularly important contribution of this study is that it demonstrates that patient characteristics explain little of the marked regional variability in the use of dual-chamber ICDs observed in this study. Research on practice variation using administrative data is often criticized for the inability to account for all the pertinent patient-level factors. A unique strength of the ICD Registry is the availability of a broad range of clinical patient characteristics. Interestingly, we found that regional effects far outweighed the influence of the patient characteristics in influencing the use of dual-chamber ICDs, demonstrating that patient characteristics generally play a relatively small role in this decision. While patient-level variability may be important in explaining variation in some interventions, our data add to a larger body of literature demonstrating that practice varies markedly for reasons independent of patients’ clinical characteristics.

While physicians presumably drive the decision to place a single- or dual-chamber ICD, it is unclear why variability by physician is as great as it is. Our prior work has demonstrated that physicians’ attitudes and recommendations around primary prevention ICDs do not vary in relation to ICD use when patients clearly meet the guideline criteria. However, when the evidence is less clear and the procedure becomes more discretionary, as among patients who are frail or with a shortened life expectancy, physicians were more likely to recommend a primary prevention ICD in the higher-use regions. This is consistent with research demonstrating that regional variations are more pronounced when decisions are discretionary.

If clinical factors traditionally collected in a registry do not explain the variation in dual-chamber ICD use, other factors must be considered. The potential factors that could influence a physician’s behavior are many. In regard to financial incentives, while device manufacturers may benefit from the implantation of the more expensive dual-chamber devices, hospitals and physicians do not directly benefit because neither CPT nor DRG codes for ICD implantation distinguish between single- and dual-lead ICDs. For nearly half a century, social scientists have argued that opinion leaders and practice norms are the important contributors to the “diffusion of innovations” into a health care system. Perhaps the variation seen in the use of dual-chamber ICDs is a function of opinion leaders with strong opinions one way or another. In addition, implicit professional norms or the practice culture at the hospital level may be central drivers of practice variation. While the cause of this variation remains unknown, understanding why and how a procedure such as discretionary dual-chamber ICDs can vary from 0% to 100% at both the physician and hospital levels remains an important research endeavor.

The literature on the risks and benefits of single- vs dual-chamber devices is inconclusive. A theoretical benefit of dual-chamber devices is improved rhythm recognition, particularly among those with atrial arrhythmias, with the hope of reducing inappropriate device therapies. One study randomized patients with dual-chamber ICDs to either single- or dual-chamber rhythm detection and demonstrated that dual-chamber detection led to a reduction in inappropriate detection of atrial arrhythmias. However, while dual-chamber devices improve rhythm recognition, to our knowledge, no study has demonstrated that these devices reduce inappropriate...
An additional potential benefit of implanting a dual-chamber ICD is avoiding the need for revision if a patient develops an indication for permanent pacing. One analysis found that dual-chamber ICDs might be cost-effective at an upgrade rate as low as 5%. However, evidence suggests that dual-chamber devices could result in higher in-hospital complications and death. Finally, although trials demonstrated that dual-chamber ICDs can be safely programmed to pacing strategies that minimize ventricular pacing, dual-chamber devices offered no additional advantage with regard to incidence of hospitalization or mortality. The guidelines do not specify whether a single- or dual-chamber device should be implanted in patients without a pacing indication. In sum, there is little definitive evidence to guide clinicians as to whether they should implant a single- or a dual-chamber device.

We identified patient, clinician, and hospital factors associated with receipt of a dual-chamber ICD. The finding that older patients are more likely to receive a dual-chamber ICD may be directly related to a belief that older patients are more likely to develop conduction disease. The finding that black patients are less likely to receive a dual-chamber ICD may be due to the fact that they are often seen at hospitals that do fewer procedures in general. It is unclear why surgeons are more likely to implant dual-chamber ICDs and academic hospitals less likely. The marked variability found in the use of dual-chamber devices in this study demonstrates the need for research to define the population who will benefit from receiving an atrial lead. Furthermore, this analysis highlights how practice varies markedly when the evidence is inconclusive.

Several issues should be considered when interpreting these findings. First, data in the ICD Registry are self-reported by each of the participating hospitals. Second, while robust patient and clinical data are collected in the registry, the decision to implant a dual-chamber device may at times be justified by factors that were not collected. Third, patient preferences were not included in this analysis. However, while patient preferences vary from individual to individual, in aggregate, patient preferences do not vary meaningfully by location. Finally, we were not able to assess the long-term effectiveness of single- vs dual-chamber ICDs.

Use of dual-chamber ICDs in patients without pacing indications varies widely and seems to be unrelated to patient factors. Research to understand this variation is needed to produce a deeper understanding of the influences on decision making, including an exploration of the hospital culture and norms and the importance of opinion leaders. Given the lack of clear data to support the use of one device type over the other, comparative effectiveness studies designed to inform the real-world clinical decision making about whether to use a single- or a dual-chamber ICD accounting for differences in device programming are also essential.

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**EDITOR’S NOTE**

**Dual-Chamber Implantable Cardioverter-Defibrillators for Nonpacing Indications**

Despite the absence of data to support benefit for patients receiving a dual-chamber implantable cardioverter-defibrillator (ICD) compared with a single-chamber ICD for a nonpacing indication, most implants are of dual-chamber ICDs. In contrast to the lack of data for benefit, there are data from multiple randomized and observational trials suggesting increased harm. A recent National Cardiovascular Data Registry (NCDR) analysis found that procedural complications, including in-hospital mortality, were at least 40% greater for dual-chamber compared with single-chamber devices. In this issue, in an analysis of NCDR data from 2006 to 2009, Matlock et al found wide geographic variation with a 4-fold difference in the chance of receiving dual-chamber ICDs. This varied and widespread use of dual-chamber devices for nonpacing indications has no known benefit and definite harms, and is designated as Less Is More.

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