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The Relation Between Patients' Outcomes and the Volume of Cardioverter-Defibrillator Implantation Procedures Performed by Physicians Treating Medicare Beneficiaries

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OBJECTIVES The purpose of this study is to determine if implantable cardioverter-defibrillator (ICD) implantation should be limited to physicians with high procedural volume.

BACKGROUND Expanding indications for ICDs will result in an increasing number of physicians implanting these devices.

METHODS Using the 20% Part B Medicare files for 1999 through 2001, we identified new ICD implantations and the corresponding denominator files. We used Medicare Provider Analysis and Review hospital records and the appropriate International Classification of Diseases-9 diagnosis and procedure codes to define complications within 90 days. We defined physician volume categories by assigning one-quarter of the patients to each quartile. A logistic regression model was used to adjust outcomes for potential confounders.

RESULTS Ninety-day mortality did not differ between patients who had their ICD implanted by physicians with the highest volume of implants and those who had their ICD implanted by physicians with the lowest volume of implants (6.2% vs. 5.9%; odds ratio [OR] 0.99; 95% confidence interval [CI] 0.75 to 1.30). Within 90 days, mechanical complications were significantly higher in the lowest volume quartile (OR 1.47; 95% CI 1.09 to 1.99) but were comparable for physicians who implanted at least 11 ICDs per year. The risk of ICD infection was significantly higher in patients who had their ICD implanted by physicians with the lowest volume of implants (OR 2.47; 95% CI 1.18 to 5.17).

CONCLUSIONS We observed an association between a higher volume of ICD implants and a lower rate of mechanical complications and infections. This association suggests that ICD implantation should not be performed by physicians without regard to their procedural volume. (J Am Coll Cardiol 2005;46:1536–40) © 2005 by the American College of Cardiology Foundation

Today, the implantable cardioverter-defibrillator (ICD) is the most effective therapy at reducing the risk of sudden cardiac death in various patient populations (1–4). Patients with a history of myocardial infarction and left ventricular ejection fraction (LVEF) of 30% or less were shown, in the Multicenter Automatic Defibrillator Implantation Trial-II (MADIT-II) trial, to have a significantly better survival

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with an ICD (5). A similar improvement in survival was seen in the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) when patients with ischemic or non-ischemic cardiomyopathy, New York Heart Association functional class II or III congestive heart failure symptoms, and an LVEF of 35% or less were treated with an ICD (6). Thus, the number of patients who will require ICD therapy is expected to rise exponentially. Because the number of invasive electrophysiologists may not be enough to meet the rising need for ICD implants, it has been suggested that ICD implantation should be performed by other cardiologists and surgeons.

For many procedures, there is an association between a higher procedural volume and improved patient outcomes. This association has been consistently observed in relation to several cardiovascular procedures and cancer resections (7–19). Although a few studies have suggested that patients undergoing pacemaker implantation have better outcomes if their procedures are performed by high-volume physicians, little is known about the relation between patients' outcomes and physician and hospital volume of cardioverter-defibrillator implantations (20–23). The purpose of this study is to determine if ICD implantation should be limited to physicians with high procedural volume.

METHODS

Sources of data. We obtained the 20% Part B and 100% Medicare Provider Analysis and Review (MEDPAR) files and the corresponding denominator files from the Center

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Abbreviations and Acronyms

CI = confidence interval
ICD = implantable cardioverter-defibrillator
LVEF = left ventricular ejection fraction
MEDPAR = Medicare Provider Analysis and Review
OR = odds ratio

for Medicare and Medicaid Services for the years 1999 through 2001. The Part B files contained claims for services delivered by physicians to a random sample of 20% of Medicare beneficiaries; MEDPAR files contained a record for each hospitalization for all Medicare beneficiaries, and the denominator files contained demographic and eligibility information for each Medicare beneficiary and date of death.

Identifying ICD placement and the patient cohort. Using the 20% sample of Part B claims, we identified all claims with an appropriate current procedural terminology (CPT) code (see Appendix) for placement of a complete ICD for any indication, a valid physician identifier, and a procedure date between January 1, 1999 and September 30, 2001. These claims were collapsed into a set of unique patient identifiers that became our study cohort. Using the denominator file, we excluded patients if they were <65 years of age at the time of the procedure, not eligible for both Part B and Part A programs, or enrolled in a managed care plan. For patients with data suggestive of more than one complete ICD implant, we assessed outcomes for only the first procedure. Due to lack of data on indication for ICD implantation, we could not determine what percentage of ICD implantations in this study were for primary versus secondary prevention of sudden cardiac death.

Identification of covariates and outcomes. Part B claims for ICD placement were linked to all Part A claims with the same unique patient identifier. The Part A claims with dates of admission and discharge that included the date of implantation on the Part B claims were identified as the index hospitalization. Data from these Part A claims were used to identify whether the hospitalization was elective, urgent, or emergent and to assess patient comorbidities, summarized using a previously validated Charlson comorbidity score (24). This score includes cancer, liver disease, renal failure, diabetes mellitus, myocardial infarction, peripheral vascular disease, dementia, chronic obstructive pulmonary disease, rheumatic heart disease, and acquired immunodeficiency syndrome. Some patients had no evidence of a hospitalization at the time of ICD placement. These patients were assumed to be undergoing elective procedures. They were included in the multivariate analysis (see the following text) using a dummy variable for "missing data."

Outcomes were identified from information on the index Part A and Part B claims and from any claims available within 90 days of the index procedure. We looked for the presence of the specific codes for device-related infections or mechanical complications of the procedure during the index hospitalization and during subsequent hospitalizations within 90 days from the procedure. We assumed that disease codes for infection and inflammatory reaction to cardiac device, bacteremia, and staphylococcus septicemia represented a procedural complication. Mechanical complications refer to those resulting from a malfunction on the part of the device. Breakdown, displacement, perforation, and protrusion of the device and/or lead(s) are forms of mechanical complications (25).

Physician ICD volume and other characteristics. Using the number of Part B claims for ICD placement with a physician's unique identifier, the number of months between the first and last ICD claim, and a five-fold multiplier given our 20% national sample, we calculated an average annual volume of ICD placement. Because of the similarities between ICD and pacemaker implantation, we used the same method to calculate an annual rate of pacemaker implantation and controlled for this exposure in our multivariate analysis.

To examine the relationship between physician volume of ICD implantations and patient outcomes, we examined a frequency distribution of physician volumes. Using this information, we created cut points such that roughly a quarter of all patients were associated with physician's having a narrow range of average procedure rates.

Statistical analysis. Categorical variables are summarized as frequencies. Differences in patient characteristics by physician volume category were assessed using the chi-square test. Differences in outcomes across physician volume categories were assessed using the chi-square test of trend. Multiple logistic regression models were used to assess the effect of physician volume category on outcomes while adjusting for patient characteristics. Patient characteristics that we adjusted for included age, gender, race, urgency of admission (outpatient procedure, elective, urgent, emergency), admission for acute myocardial infarction, and Charlson comorbidity score. We also controlled for the volume of pacemaker implantations. In order to allow a departure from linearity, all variables were entered as dummy variables including physician volume. To account for clustering of patients within physician, we used over-dispersed binary logistic models (26). Results were considered significant at $p < 0.05$.

RESULTS

Baseline characteristics. Between 1999 to 2001, 1,672 physicians implanted ICDs in 9,854 patients meeting study criteria. The average annual volume ranged from 1 to 87 with a median of 7 procedures per year. Figure 1 shows the distribution of physicians across strata of physician volumes. A total of 62% of physicians performed 1 to 10 ICD implants per year on 24% of the

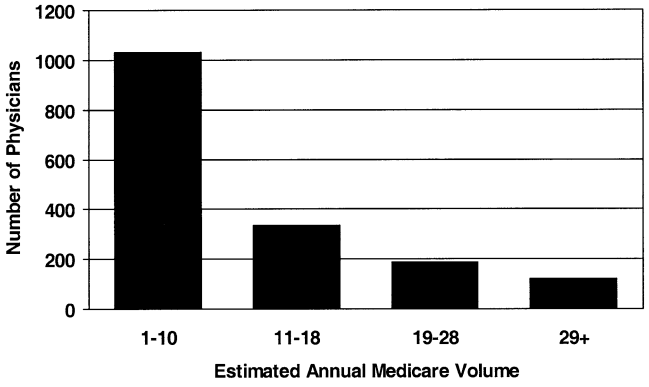

Figure 1. Distribution of physicians according to the annual volume of implantable cardioverter-defibrillator implantation procedures in Medicare beneficiaries during each year of the study period.

patient population while 7% of all physicians performed ≥29 implants per year on 25% of all patients.

Of 12,830 patients in the 20% Part B sample who underwent ICD implantation in the study period, 9,854 met the inclusion criteria. Of these patients, 51.8% were between 65 and 75 years of age, 19.3% were 80 years of age or older, 21.6% were women, and 92.4% were white. The Charlson comorbidity score was 0 in 46.1%, 1 in 33.8%, 2 in 14.6%, and 3 or more in 5.5% of the patients. Of all patients, 9.4% had their ICD implanted on outpatient basis, 29.6% were electively admitted for the procedure, and 61% had their ICD implanted during an urgent or emergency admission. Table 1 shows baseline characteristics of patients in the four physician volume quartiles. As can be seen, there were small differences in patient characteristics across quartiles. Patients treated by the lowest volume physicians were slightly more likely to be black and slightly less likely to have comorbid conditions.

Outcomes. Unadjusted outcomes by physician volume are shown in Table 2. Mortality rate averaged 2.4% within 30 days and 5.8% within 90 days. There was no difference in mortality rates by physician volume. Unadjusted 30-day mechanical complications increased significantly from 3.8% in patients who underwent ICD implantation by physicians with the highest volume of implants to 6.0% in patients who underwent ICD implantation by physicians with the lowest volume of implants ($p < 0.001$). There was a similar increase in mechanical complications within 90 days ($p < 0.001$). The unadjusted 30-day and 90-day ICD infection rates were significantly higher in patients who had the ICD implanted by physicians with the lowest volume of implants than in patients who had the ICD implanted by physicians with the highest volume of implants ($p = 0.01$).

In the adjusted comparison of 90-day outcomes, there remained no significant difference in mortality across quartiles of physician volume (odds ratio [OR] for the lowest vs. the highest quartile 0.99; 95% confidence interval [CI] 0.75 to 1.30). Mechanical complications were significantly higher in the lowest volume quartile than the highest (OR 1.47; 95% CI 1.09 to 1.99) but were comparable for physicians in the second and third volume quartiles. The risk of ICD infection was significantly higher in patients who had their ICD implanted by physicians in all but the highest volume quartile (OR for the lowest vs. the highest quartile 2.47; 95% CI 1.18 to 5.17) (Fig. 2).

Table 1. Baseline Characteristics of Patients According to Physician-Volume Quartile

ICD Annualized Volume	1–6 (n = 2,487)	7–11 (n = 2,559)	12–17 (n = 2,336)	18+ (n = 2,472)	p Value
Age (yrs)					
65–69	562 (22.6%)	593 (23.2%)	507 (21.7%)	564 (22.8%)	0.38
70–74	712 (28.6%)	748 (29.2%)	690 (29.5%)	727 (29.4%)	
75–79	734 (29.5%)	729 (28.5%)	707 (30.3%)	676 (27.4%)	
80–84	373 (15.0%)	384 (15.0%)	320 (13.7%)	403 (16.3%)	
85+	106 (4.3%)	105 (4.1%)	112 (4.8%)	102 (4.1%)	
Female	536 (21.6%)	569 (22.2%)	489 (20.9%)	536 (21.7%)	0.74
Race					
White	2,251 (90.5%)	2,386 (93.2%)	2,155 (92.3%)	2,313 (93.6%)	<0.01
Black	163 (6.6%)	117 (4.6%)	137 (5.9%)	121 (4.9%)	
Other	73 (2.9%)	56 (2.2%)	44 (1.9%)	38 (1.5%)	
Charlson comorbidity score					
0	1,197 (48.1%)	1,144 (44.7%)	1,104 (47.3%)	1,095 (44.3%)	0.18
1	800 (32.2%)	892 (34.9%)	785 (33.6%)	858 (34.7%)	
2	350 (14.1%)	388 (15.2%)	322 (13.8%)	376 (15.2%)	
3 or more	140 (5.6%)	135 (5.3%)	125 (5.4%)	143 (5.8%)	
Urgency of admission					
Outpatient	244 (9.8%)	233 (9.1%)	255 (10.9%)	196 (7.9%)	<0.01
Elective	726 (29.2%)	711 (27.8%)	708 (30.3%)	775 (31.4%)	
Urgent	710 (28.6%)	707 (27.6%)	710 (30.4%)	829 (33.5%)	
Emergency	807 (32.5%)	908 (35.5%)	663 (28.4%)	672 (27.2%)	
Pacemaker annualized volume					<0.01
1–3	1,309 (52.6%)	586 (22.9%)	349 (14.9%)	182 (7.4%)	
19+	145 (5.8%)	380 (14.9%)	754 (32.3%)	1,184 (47.9%)	

ICD = implantable cardioverter-defibrillator.

Table 2. Unadjusted Mortality and Morbidity Rates According to Physician-Volume Quartile

Outcome	1–10 (n = 2,487)	11–18 (n = 2,559)	19–28 (n = 2,336)	29+ (n = 2,472)	p Value (Trend)
30-day mortality	63 (2.5%)	59 (2.3%)	49 (2.1%)	66 (2.7%)	0.9
90-day mortality	147 (5.9%)	145 (5.7%)	128 (5.5%)	152 (6.1%)	0.8
30-day mechanical complications	149 (6.0%)	103 (4.0%)	98 (4.2%)	93 (3.8%)	<0.01
90-day mechanical complications	174 (7.0%)	126 (4.9%)	114 (4.9%)	109 (4.4%)	<0.01
30-day ICD infection	23 (0.9%)	28 (1.1%)	18 (0.8%)	9 (0.4%)	0.01
90-day ICD infection	32 (1.3%)	36 (1.4%)	28 (1.2%)	14 (0.6%)	0.01

ICD = implantable cardioverter-defibrillator.

DISCUSSION

The present study. Our study is the first study to show an inverse relationship between volume of ICD implantations and patients' outcomes. Compared with patients who had their ICD implanted by physicians with the highest volume of ICD implants, patients who had their ICD implanted by physicians with the lowest volume of ICD implants had a 47% higher odds of mechanical complications and a 147% higher odds of ICD infection within 90 days after ICD implantation. These findings are important both to the individual patient who is considering which physician to go to for ICD implantation and to the general public.

There are at least three possible explanations for the inverse relationship between volume of ICD implantations and patients' outcomes. The first possible explanation is referral bias. Physicians with the lowest volume of ICD implants may have had sicker patients than physicians with the highest ICD implants. Although this is not supported by the Charlson comorbidity score data in our study, patients who had their ICD implanted by physicians with the lowest ICD implants were more likely to be admitted to the hospital emergently. Even after we adjusted for this factor, however, the volume of ICD implants was still a significant, independent predictor of a better outcome.

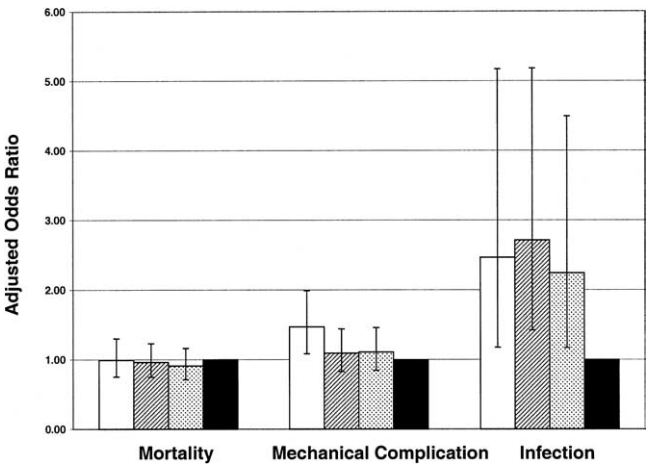

Figure 2. Adjusted odds ratios for 90-day complications among Medicare beneficiaries who underwent implantable cardioverter-defibrillator implantation from 1999 through 2001 by physician quartile. Odds ratios were adjusted for age, gender, race, urgency of admission, Charlson comorbidity score, acute myocardial infarction, and pacemaker implant volume. **Open bars** = 1 to 10; **ruled bars** = 11 to 18; **dotted bars** = 19 to 28; **solid bars** = 29+.

The second possible explanation is that high-volume physicians are more likely to have better operative skills that result from greater experience than low-volume physicians and usually practice at high-volume hospitals. Such hospitals are more likely to have experienced physicians and ancillary personnel. The third possible explanation is physicians' training. It is probable that high-volume physicians are trained in electrophysiology and that low-volume physicians are not.

Previous studies. Some investigators have reported on the relation between volume of procedures and the outcome of pacemaker implantation (20–23). Periodic surveys of cardiac pacing patterns have been conducted since 1969 in the U.S. (23). The most recent survey was done in 1997. It showed that low-volume implanters had a higher rate of early electrode problems with passive fixation, unipolar leads, and late electrode problems with atrial leads. Although that study targeted information concerning ICD practices, it did not report on the relation between volume of ICD implantation and patients' outcomes (23). Examining 632 consecutive pacemaker implantations at a single institution, Parsonnet et al. (21) showed an appreciably higher incidence of complications for implanters who performed fewer than 12 pacemaker implantations per year. Similarly, Tobin et al. (22) found an inverse relationship between complication rate and pacemaker implanters' volume and experience.

Training guidelines. To accommodate the large number of patients who could benefit from an ICD, the Heart Rhythm Society has issued a clinical competency statement on training pathways for ICD implantation by non-electrophysiologists (27). Training guidelines proposed in this document pertain only to ICD implantations in patients who have not experienced sustained ventricular tachycardia or fibrillation but who are at high risk for these life-threatening arrhythmias. Importantly, these guidelines only target experienced pacemaker implanters defined as physicians who implant a minimum of 35 pacemakers per year with a minimum of 100 implants over the preceding three years. Our results heighten the need for strict training guidelines for ICD implanters.

Study limitations. Our study has some limitations. First, we included only Medicare patients. Because Medicare

patients are older and are more prone to complications, our results may not be reproducible in non-Medicare patients. However, there is little reason to believe that volume would be less important in younger patients. Second, because we used administrative data, we may not have accounted adequately for differences in severity of illness of patients among the different quartiles. Third, the volume of ICD implants for each physician may not have been uniform during all three years of the study. Our analyses did not take this possible variation in volume of ICD implants into account. Fourth, because we used administrative data, we could not validate the coding data with chart review. Although it is possible that some outcomes, such as complications, were undercoded, it is unlikely that undercoding was not random.

Conclusions. We conclude that patients who have their ICD implanted by high-volume physicians have lower rates of mechanical complications and ICD infection than patients who have their ICD implanted by low-volume physicians. Our findings suggest that ICD implantation should be directed toward high-volume physicians.

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APPENDIX

Event	CPT Codes	International Classification of Diseases-9 Codes
ICD insertion	33249	
Pacemaker insertion	33200, 33201, 33206, 33207, 33208	
Mechanical complications		Diagnosis codes 996.00, 996.04
Infection		Diagnosis code 996.61

CPT = current procedural terminology; ICD = implantable cardioverter-defibrillator.