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ORIGINAL PAPER

Patient and Physician Determinants of Implantable Cardioverter Defibrillator Use in the Heart Failure Population

Recent studies report surprisingly low rates of implantable cardioverter defibrillator (ICD) placement for primary prevention against sudden cardiac death among patients with heart failure and left ventricular systolic dysfunction. Reasons for the low rates of utilization are not well understood. The authors examined ICD implantation rates at a university-based tertiary care center and used multivariable analysis to identify independent factors associated with ICD utilization. The ICD implantation rate for 850 eligible patients was 70%. Forty-seven (18%) patients refused implantation; women were twice as likely to refuse compared to men (8% vs 4%, P=.013). Race was not associated with utilization. On multivariable analysis, independent predictors of implantation included having a heart failure specialist (odds ratio [OR], 8.13; P<.001) or general cardiologist (OR, 2.23; P=.13) managing care, age range 70 to 79 (OR, 0.55; P<.001) or 80 and older (OR, 0.26; P<.001), female sex (OR, 0.49; P<.001), QRS interval (OR, 1.016; P<.001), diastolic blood pressure (OR, 0.979; P=.011), cerebrovascular disease (OR, 0.44; P=.007), and dementia (OR, 0.13; P=.002). Our registry of patients with cardiomyopathy and heart failure reveals that high rates of utilization are possible. Factors closely associated with ICD utilization include type of physician coordinating care, age, and comorbidities. Congest Heart Fail. *2010;16:141–146.*

Sanders H. Chae, MD; Todd M. Koelling, MD
From the Division of Cardiovascular Medicine, Department of Internal Medicine, University of Michigan, Ann Arbor, MI

Address for correspondence:
Todd M. Koelling, MD, 1500 East Medical Center Drive, SPC 5853, CVC Room 2167, Ann Arbor, MI 48109
E-mail: tkoellin@umich.edu
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Several multicenter randomized trials have demonstrated the benefit of implantable cardioverter defibrillators (ICDs) for the primary prevention of sudden cardiac death among patients with ischemic and nonischemic cardiomyopathy due to left ventricular systolic dysfunction.[1,2] However, sudden cardiac death due to lethal arrhythmia remains a frequent cause of mortality in this population of patients. The most recent 2008 guidelines establish ICD implantation for primary prevention against sudden cardiac death as a class I indication for patients with a left ventricular ejection fraction (LVEF) $\leq$35% due to nonischemic cardiomyopathy or ischemic cardiomyopathy at least 40 days post–myocardial infarction with New York Heart Association (NYHA) class II or III symptoms.[3] Ischemic cardiomyopathy patients with an LVEF of 30% and NYHA class I symptoms at least 40 days post-myocardial infarction also have a class I indication for ICD placement.[3]

Despite these recommendations, 2 major retrospective observational studies have documented the low level of ICD utilization among patients with congestive heart failure (CHF) and left ventricular systolic dysfunction. The Get With the Guidelines Registry examined inpatients at more than 217 participating centers and found an ICD implantation rate on discharge of 35%.[4] The Registry to Improve the Use of Evidence-Based Heart Failure Therapies in the Outpatient Setting (IMPROVE-HF), a large multicenter ambulatory registry, examined more than 150 outpatient centers and found a range of utilization rates from 0% to 100%, with a median utilization rate of 49%.[5] One notable finding has been that women and African Americans have utilization rates well below that of white men.[4,6] In this study, we examine the experience of utilization of ICDs in a single university-based tertiary care center to evaluate the claim of low utilization rates. In addition, we reviewed outpatient and inpatient records to evaluate data regarding patient and physician characteristics as well as patient preferences that may influence rates of ICD utilization.

Methods

This study was reviewed and approved by the University of Michigan Internal Review Board. The data were collected from the Physician Group Practice Incentive Program (PGIP) Heart Failure Registry at the University of Michigan Health System (UMHS). The Heart Failure Registry represents all ambulatory heart failure patients treated in UMHS. It was initiated in 2004 and is an ongoing quality improvement project promoted by Blue Cross Blue Shield of Michigan. Patients' data are entered into the registry after an encounter in which a diagnosis of CHF or systolic dysfunction is coded. The registry is updated in biannual snapshots of clinical care at UMHS. Our analysis examined patients included in the PGIP Heart Failure Registry through encounters from December 1, 2004, through

December 1, 2006. Patients with documentation of an LVEF ≤35% at any point in the study period were included in the analysis.

Demographic information regarding age, sex, race, insurance status, and treating physician were compiled into the registry, in addition to clinical data such as comorbidities, etiology of cardiomyopathy, medications, ejection fraction, QRS interval, blood pressure, and renal function through individual patient chart review through December 31, 2007. Race was self-reported and classified accordingly. For patients who did not undergo ICD implantation, documentation of patient refusal was also recorded through review of medical records. Patients who had documented improvement of their LVEF to >35% or documentation of NYHA class I symptoms with a nonischemic cardiomyopathy were excluded from the analysis because they do not fall under American College of Cardiology/American Heart Association (AHA/ACC) guidelines as candidates for an ICD for primary prevention.[3]

Statistical Analysis. Statistical analyses were performed using SPSS for Windows statistical software (version 17.0, Chicago, IL). We used chi-square tests for categorical variables and Student's *t*-tests for continuous variables to compare differences among patients who had undergone ICD implantation and those who did not undergo ICD implantation. We used multivariate stepwise logistic regression analysis to identify variables associated with ICD nonutilization. A *P* value <.05 was considered statistically significant.

Results

The UMHS Heart Failure Registry contained 4050 patients who were seen in a primary care or cardiology specialty clinic within the health system during the time period of the study. Of the patients in the registry, 3897 (96.2%) had an assessment of left ventricular function. The majority (87%) of left ventricular function assessments were performed using echocardiography. Of the patients with documentation of left ventricular function, 1932 (49.6%) had an LVEF >40% on all assessments of left ventricular systolic function, 830 (21.3%) had an LVEF >40% on the most recent assessment of left ventricular function but were previously found to have an LVEF <40%, and 247 (6.3%) had LVEF from 36% to 40%. Thirty-eight (1.0%) of the patients with documentation of left ventricular function had an LVEF ≤35% but did not have a class I indication for ICD implantation, as they had nonischemic cardiomyopathy and NYHA class I symptoms. The remaining 850 (21.8%) patients had a documented LVEF ≤35% and met level I AHA/ACC guidelines for implantation of an ICD for primary prevention. Of the ICD-eligible patients, 594 (70%) underwent ICD implantation. Forty-seven (18%) patients refused ICD implantation, but these patients were included in the primary analysis as patients in whom ICDs were not utilized. Women were twice as likely as men to refuse an ICD (8% vs 4%; *P*=.013). The baseline characteristics of the 850 eligible patients are presented in Table I.

Patients who underwent ICD implantation were more likely to be younger (mean age, 61.2±13.3 vs 71.1±14.5; *P*<.0001) and have a lower LVEF (22.4±7.7 vs 25.1±7.3; *P*<.0001), wider QRS interval (140±36 vs 122±33; *P*<.001), and lower systolic and diastolic blood pressures (113.3±18.8 vs 122.0±19.6 and 64.6±11.3 vs 67.4±11.7, respectively; *P*<.001 for both). Ages between 70 to 79 and 80 and older were highly predictive of refusal to undergo ICD implantation compared to patients younger than 60 (57% and 40% implanted, respectively, vs 81%; *P*<.0001). Women were less likely to undergo ICD implantation (58% vs 75% utilization in men; *P*<.001). In terms of comorbidity, univariate analysis revealed that patients with a history of dementia and history of cancer were substantially less likely to undergo ICD utilization (15%; *P*<.001 and 58%; *P*=.016, respectively). All other comorbidities, including coronary artery disease were not predictive of ICD utilization on univariate analysis, although there was a lower utilization rate among patients with a history of depression or selective serotonin reuptake inhibitors use that trended toward significance (62%, *P*=.059). Race and health insurance status were not predictive of ICD implantation (Table II).

Patients who had a cardiologist specializing in heart failure or a general cardiologist coordinating their care were more likely to receive an ICD than patients whose care was coordinated by a general practice physician (86% and 56% vs 26%, respectively; *P*<.0001). Patients followed by a heart failure specialist who were under evaluation for cardiac transplant had the highest rate of ICD utilization, with 94 of 96 (97.9%) eligible patients having an ICD placed. Of the 268 patients followed by a general cardiologist, 153 were followed jointly within UMHS by a primary care physician, and 115 had a primary care physician external to UMHS. Patients followed jointly with UMHS primary care had an ICD utilized in 82 (53.6%), while those followed by a general cardiologist and a primary care physician external to UMHS had an ICD utilized in 66 (57.4%) (*P*=NS). Of the 486 patients followed by a heart failure specialist, 99 were followed jointly by a UMHS primary care physician and 387 were followed by a primary care physician external to UMHS, 360 (93%) of whom were also previously seen by a general cardiologist external to UMHS. Patients followed by a UMHS heart failure specialist jointly with a UMHS primary care physician had an ICD in place in 71 (71.7%), and those followed concurrently with a primary care physician external to UMHS had an ICD in place in 350 (90.4%) (*P*<.001).

On multivariate logistic regression analysis, the strongest predictor of ICD utilization was the type of physician coordinating cardiac care. The treating physician was predictive of ICD utilization both when heart failure cardiologists were compared to primary care physicians and when heart failure cardiologists were compared to general cardiologists (odds ratio [OR], 8.13; 95% confidence interval [CI], 4.26–15.53;

$P<.001$ compared to primary care physicians and OR, 4.42; 95% CI, 3.08–6.33; $P<.001$ compared to general cardiologists). Age was a strong predictor of ICD utilization. Patients 70 to 79 years old and 80 and older years were much less likely to undergo implantation than patients younger than 60 (OR, 0.55; 95% CI, 0.32–0.95; $P=.032$ and OR, 0.26; 95% CI, 0.15–0.46; $P<.001$, respectively). Sex remained a predictor of ICD utilization on multivariate analysis (OR, 0.49; 95% CI, 0.33–0.73; $P<.001$). Race and health insurance status did not predict ICD utilization. Although QRS interval and diastolic blood pressure continued to predict ICD implantation, LVEF and systolic blood pressure were no longer predictors of ICD implantation on multivariable analysis. In terms of comorbidities, dementia and stroke predicted nonutilization of ICDs, while history of cancer did not predict ICD utilization on multivariate analysis. All other comorbidities, including coronary artery disease, were not predictive of ICD utilization (Table III). Area under the curve for this multivariable model was 0.824.

Table I. Baseline Characteristics of Patients

Variable	ICD Implanted	ICD Not Implanted	All Patients
No.	594	256	850
Age, y	61.2±13.3	71.1±14.5	64.2±14.4
Male, %	75.4	59.4	70.6
Race, %			
White	77.9	79.3	78.4
Black	14.5	15.2	14.7
Other	7.6	5.5	6.9
Insurance, %			
Medicare	54.9	71.5	59.9
Medicaid	8.4	6.3	7.8
Blue Cross	25.1	11.8	21.1
MCARE	3.9	4.6	4.1
Other	7.7	5.8	7.1
Ejection fraction, %	22.4±7.7	25.1±7.3	23.2±7.7
QRS, ms	140±36	122±33	135±36
NYHA class, %			
I	16.6	22.1	17.7
II	35.5	48.4	38.1
III	41.8	25.4	38.5
IV	6.1	4.1	5.7
Systolic BP, mm Hg	113.3±18.8	122.0±19.6	115.9±19.4
Diastolic BP, mm Hg	64.6±11.3	67.4±11.7	65.4±11.6
eGFR, mL/s	65.9±24.5	67.4±11.7	65.2±26.0
Comorbidities, %			
CAD	54.5	56.2	55.5
DM	33.2	29.7	32.1
PVD	10.4	14.8	11.8
CVD/CVA	15.0	11.3	13.9
Pulmonary disease	15.8	16.4	16.0
Renal disease	17.7	18.8	18.0
Cancer	7.1	12.1	8.6
Leukemia/lymphoma	1.3	1.6	1.4
Dementia	0.7	8.6	3.1
Depression	20.5	19.5	20.8
Physician coordinating care, %			
Heart failure cardiologist	70.7	25.8	57.2
General cardiologist	25.1	46.5	31.5
Primary care physician	4.2	27.7	11.3
Refusal			
Female, No.	N/A	21	
Male, No.	N/A	26	
Utilization of other therapies for CHF, %			
ACE inhibitor/ARB	86.2	82.0	84.9
β-Blocker	91.6	78.9	87.8
Aldosterone antagonist	57.2	27.7	48.3
Loop diuretic	89.6	81.3	87.1
Thiazide diuretic	37.0	35.9	36.7
Digoxin	66.2	47.6	60.6
Amiodarone	29.8	12.1	24.5

Abbreviations: ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blocker; BP, blood pressure; CAD, coronary artery disease; CHF, congestive heart failure; CVD, cerebrovascular disease; CVA, cerebrovascular accident; DM, diabetes mellitus; eGFR, estimated glomerular filtration rate; ICD, implantable cardioverter defibrillator; NYHA, New York Heart Association; PVD, peripheral vascular disease. Values are mean ± SD unless otherwise noted.

Discussion

Although ICDs have been shown to provide lifesaving benefit from sudden cardiac death for patients with left ventricular systolic dysfunction and CHF, many patients who might potentially benefit from this therapy do not receive the device. The IMPROVE-HF registry of 157 medical centers and practices showed a median ICD utilization rate of 49% nationwide. This retrospective review of our registry data provides a profile of utilization at a single academic, university-based, teaching health care system with divisions that specialize in heart transplantation and left ventricular assist devices (LVADs) as well as electrophysiology. Our data describe four findings.

First, we found that utilization of ICDs at our center under the most recent ACC/AHA guidelines is more than 70%. This would place our center in the 90th percentile of practices in the IMPROVE-HF registry. While our utilization rate can be improved upon, it confirms that high rates of utilization of ICDs are possible and that this utilization rate serves potentially as a realistic benchmark for utilization rates, especially when compared to the rates reported at other centers within IMPROVE-HF. As a retrospective registry, this study can not establish whether particular measures at our center enhanced ICD utilization or evaluate any degree of effect of any specific intervention on implantation rates. However, there have been several initiatives at our center over the last several

Table II. Utilization Rate by Subgroup

Variable	No. Implanted/Total	%	*P* Value
Age			
59 and younger	257/319	81	<.001
60–69	181/232	78	
70–79	99/157	57	
80 and older	57/142	40	
Sex			
Male	448/600	75	<.001
Female	146/250	58	
Race			
White	463/666	70	NS
Black	86/125	69	
Other	45/59	76	
Insurance			
Medicare	326/509	64	NS
Medicaid	50/66	76	
Blue Cross	149/179	83	
MCARE	23/35	66	
Other	46/61	75	
NYHA class			
I	79/106	75	NS
II	169/228	74	
III	199/230	87	
IV	29/34	85	
Comorbidity			
CAD	328/427	69	NS
DM	197/273	72	NS
PVD	62/100	62	NS
CVD/CVA	89/118	75	NS
Pulmonary disease	94/136	69	NS
Renal disease	105/153	69	NS
Cancer	42/73	58	.016
Leukemia/lymphoma	8/12	66	NS
Dementia	4/26	15	<.001
Depression	122/177	62	.059
Physician coordinating care			
Heart failure cardiologist	420/486	86	<.001
General cardiologist	149/268	56	
Primary care physician	25/97	26	

Abbreviations: CAD, coronary artery disease; CVD, cerebrovascular disease; CVA, cerebrovascular accident; DM, diabetes mellitus; NYHA, New York Heart Association; PVD, peripheral vascular disease.

Table III. Independent Predictors of Implantable Cardioverter Defibrillator Utilization

Variable	Odds Ratio (95% CI)	*P* Value
Heart failure cardiologist (vs PCP)	8.13 (4.26–15.53)	<.001
General cardiologist (vs PCP)	2.23 (1.19–4.18)	.013
Age 60–69 vs <60	0.79 (0.48–1.30)	NS
Age 70–79 vs <60	0.55 (0.32–0.95)	.032
Age ≥80 (vs age <60)	0.26 (0.15–0.046)	<.001
Female	0.49 (0.33–0.73)	<.001
QRS (per ms)	1.016 (1.010–1.022)	<.001
Diastolic BP (per mm Hg)	0.979 (0.964–0.995)	.011
CVD/CVA	0.44 (0.25, 0.80)	.007
Dementia	0.13 (0.04, .048)	.002

Abbreviations: BP, blood pressure; CI, confidence interval; CVD, cerebrovascular disease; CVA, cerebrovascular accident; PCP, primary care physician. Excluded variables: race, insurance status, systolic BP, ejection fraction, glomerular filtration rate, coronary artery disease, diabetes, peripheral vascular disease, renal disease, pulmonary disease, hematologic malignancy, other malignancy, depression, and New York Heart Association class.

decades that may have resulted in higher utilization of ICDs. The Guidelines Applied in Practice for Heart Failure (GAP-HF) initiative, developed through University of Michigan investigators, is a heart failure quality improvement program that employs the use of standard admission orders, clinical pathways, and discharge contracts that are designed to enhance adherence to evidence-based therapies for patients with heart failure treated in the hospital. This initiative had been in place for 3 years prior to the measurement period reported in this study. Although ICDs are not a formal element of the initiative, the program may have raised awareness of the mortality benefit of ICDs in the heart failure population, leading to more aggressive referral for ICD implantation.

Second, another factor that may explain the high level of utilization of ICDs at our center is our finding that the strongest predictor of ICD utilization was the type of physician coordinating cardiac care. Cardiologists who specialize in managing heart failure, transplantation, and LVADs have significantly higher rates of ICD utilization than other types of physicians. While we anticipated that heart failure specialists would refer for ICD implantation at higher rates than primary care physicians, the higher rate of utilization among heart failure specialists compared to general cardiologists was unexpected. This finding might result from referral bias, since the cardiomyopathy specialists at our center receive referrals for patients throughout the region for evaluation for cardiac transplant. Patients referred for cardiac transplant might be healthier than other heart failure patients and will receive an ICD as part of their transplant evaluation. Although our model attempted to control for age and comorbidities that impact the likelihood of undergoing transplant, the model might not have been adequate to capture all variables that ultimately result in ICD implantation or transplant evaluation. This particular result is similar to the recent report from the Get With the Guidelines Registry, which found that hospitals in which open heart surgery, percutaneous coronary interventions, and heart transplant are performed have higher implantation rates than centers in which those procedures are not offered.[7] However, our result seems to suggest that the particular type of physician coordinating care directly affects the likelihood of ICD utilization.

There are several other reasons ICD utilization rates among heart failure cardiologists might be higher than rates among other physicians. Implantation of an ICD is contraindicated for patients with end-stage NYHA class IV CHF unless they receive an LVAD or are listed for cardiac transplant. Thus, patients with class IV CHF at a transplant center have an indication for an ICD under ACC/AHA guidelines that is not enjoyed by patients with class IV CHF at other centers that do not offer LVADs or transplant. Our study period also coincides with publications of benefit from cardiac resynchronization therapy (CRT) from biventricular pacing such as the Cardiac Resynchronization in Heart Failure (CARE-HF) and the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trials.[8,9] Hence, the higher rates of utilization by heart failure specialists might have reflected early adoption of CRT, an effect that may diminish as CRT becomes more widespread. Finally, referral to heart failure specialists might itself be a practice measure that enhances ICD utilization rates. Comparison of utilization rates by managing physicians at other centers as well as prospective measurement of ICD referral patterns after referral to heart failure specialists would be needed to assess the impact of specialist care on ICD utilization rates. Our data demonstrate that patients referred by a general cardiologist external to UMHS are more likely to have an ICD implanted than patients referred from a UMHS primary care physician. This supports the argument that involvement of two cardiologists (an external referring general cardiologist and a UMHS heart failure specialist) achieves higher utilization rates than involvement of just one (either a UMHS general cardiologist or a UMHS heart failure specialist).

Third, age, in particular ages between 70 and 79 years old or 80 and older, strongly predicted ICD utilization. Of the 256 patients who did not undergo ICD implantation, one-third were older than 80. We suspect that the influence of age on ICD utilization is appropriate and reflects the complex nature of a decision to implant an ICD. Unlike other interventions such as catheterization or anticoagulation for atrial fibrillation in which elderly individuals might be less likely to receive aggressive therapy, the decision to pursue implantation of an ICD directly involves the trade-off between quantity and quality of life. The risk of complications from the procedure, discomfort from the implantation, and hospitalization may deter elderly individuals who are focused more on quality of life to defer implantation. In addition, many patients who benefit from an ICD do so only by receiving a painful shock. For the elderly, the mortality benefit of an ICD shock might not necessarily offset the pain of the shock. Although the guidelines attempt to incorporate this concern by giving a level I recommendation for ICD implantation only for patients expected to live longer than 1 year, there remains ambiguity about the optimal management of elderly patients for whom mortality is merely one of multiple considerations.

Finally, we found that sex predicted ICD implantation despite our high level of utilization. This finding remained even when we forced into the model variables associated with sex such as coronary artery disease (data not shown). Although many centers have demonstrated sex-based bias in ICD utilization, those centers also demonstrated low rates of utilization based on race and health insurance that were not replicated in our data. While preferential rates of utilization for white men at other centers suggests structural barriers resulting in systematic underprovision of health care to racial minorities, women, and the poor, our data, which demonstrate high implantation rates of ICDs and lack of bias on the basis of race and health insurance, raise the question of whether the relationship between sex and ICD utilization reflects a more complicated dynamic than simply institutional and clinician bias. One potential explanation for our finding is that the source of lower utilization rates among women lies with the patients themselves rather than structural factors if women elect to forego ICD implantation. When we reviewed our data to evaluate patient refusal to undergo ICD implantation, we found only a small number of refusals but discovered that women were statistically more likely to refuse device implantation than men (Table I). When we incorporated refusal into our multivariable regression model, sex remained a predictor of ICD implantation (Table III). However, our registry is likely underpowered to detect an interaction between sex and refusal since we documented only a small number of refusals. Because our registry did not contain a formal method of determining patient preferences and could only document patient preferences based on physician report, the low number of refusals probably undercounts the true number of refusals. In light of the persistent effect of sex on ICD utilization despite our high levels of utilization, this issue merits further evaluation in a more structured manner.

Our study suffers from a number of important limitations. The study is retrospective, so it faces the inherent methodological limitations of all retrospective analyses. Data on comorbidity, medications, and refusal of ICD implantation were obtained through review of individual patient charts and thus were limited to the documentation provided by the managing physicians and care providers. In addition, many of these patients also receive care at other institutions. We did not have access to those charts, so there may be additional data about these patients that were not captured in our database. For instance, some patients may have enjoyed an improvement in LVEF that was documented in records unavailable to us. While we identified many patients as individuals whom we did not analyze because their LVEF had improved, there may have been additional individuals with improvement in LVEF whom we classified as patients without appropriate ICD utilization. Improvements in documentation and record keeping would certainly enhance our understanding of ICD utilization.

We did not analyze implantation rates of ICDs on the basis of NYHA class for a number of reasons. First, NYHA class is part of the indication for an ICD in patients with a nonischemic cardiomyopathy, so assessment of utilization rates according to NYHA class is redundant for this population of patients. NYHA class is also highly subjective and variable, rendering its documentation and measurement unreliable. In fact, one-third of the patients in our data set were missing documentation of NYHA class. In addition, we did not limit our analysis of utilization rates only to patients with documented NYHA class because we sought to establish the most conservative assessment of utilization rates at our institution. While this may have resulted in lowering our utilization rate because it might have counted patients with undocumented NYHA class I nonischemic heart failure as patients for whom ICDs were not utilized, we consider it a strength of the research that the utilization rate at our institution remained high despite this decision. Finally, as mentioned earlier, the implantation of ICDs in patients with NYHA class IV CHF who receive an LVAD or are listed for transplant in our center makes it difficult to compare to utilization on the basis of NYHA class at other centers that do not offer assist devices or transplant.

Our data reflect the experience of an academic tertiary care center with divisions specializing in CHF and electrophysiology. While some of the practice measures that enhance ICD utilization here may provide insight into utilization in other clinical settings, some practice features here might not be applicable to other types of clinical centers.

Finally, we did not evaluate the impact of CRT on ICD utilization rates. Since landmark trials on CRT were published after the creation of the registry, the data set does not distinguish whether the device implanted was strictly an ICD or CRT device. Since CRT provides symptomatic benefit for some patients, the higher utilization rates at our center might reflect higher patient preferences for a CRT device over an ICD alone.

In conclusion, our single-center registry of ICD utilization rates at a university-based health system that offers cardiac transplant and LVADs demonstrated a high rate of utilization compared to rates at other centers. An implantation rate of 70% might be a reasonably high level of ICD utilization for centers attempting to adhere to best practice models based on evidence-based medicine. The type of physician coordinating cardiac care was the strongest predictor of utilization. Age was also a strong predictor of ICD implantation. Female sex, presence of dementia, and history of stroke/transient ischemic attack predicted ICD nonutilization, while race and all other comorbidities did not predict implantation.

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