CARDIOLOGY Rounds®

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The role of the ICD in the prevention of sudden death

By KAMRAN AHMAD, MD, FRCPC

Global cardiovascular (CV) mortality is accounted for by a limited set of causes, mainly, sudden death and pump failure. Most therapies for coronary artery disease (CAD), congestive heart failure (CHF), and nonischemic cardiomyopathy reduce mortality by reducing all causes of CV mortality. Defibrillator therapy is unique because, generally, it addresses only sudden cardiac death (SCD; arrhythmic mortality). Cardiac resynchronization devices also address SCD, but they may have an additional small impact on mortality due to reductions in pump failure. Yet, despite their narrow therapeutic focus (on fatal arrhythmias), implantable cardioverter defibrillators (ICDs) have been shown to drastically lower mortality due to coronary or nonischemic left ventricular (LV) dysfunction with or without HF. The relative reduction in mortality is approximately one-quarter to one-third, which rivals any pharmacological therapy for the same conditions. Defibrillator therapy differs in many ways from drug therapy, but for many reasons it is less utilized than drug therapy with similar or fewer therapeutic benefits. The reasons may include misperceptions of the magnitude of benefits, uncertainty about the patient populations where it may improve survival, or the effect on patient lifestyles and waiting times. This issue of *Cardiology Rounds* discusses the use of ICDs for primary prevention of SCD in patients with LV dysfunction and/or HF. The discussion is based on presentations by Chris Simpson, MD, and Anil Gupta, MD at a satellite symposium during the October 2008 Canadian Cardiovascular Congress.

SCD prevalence and the impact of ICDs

The magnitude of the problem of SCD and the public health challenge to reduce it are illustrated by the "Myerburg Paradox." In the United States, estimates of the number of deaths from SCD vary between 300 000 - 600 000 per year. When stratified by the most robust predictor of SCD – LV ejection fraction (EF) — the paradox emerges as follows: patients with the lowest LVEF are at the highest risk for sudden death, however, they constitute a small portion of the population as a whole. The largest absolute numbers of sudden deaths, therefore, are experienced by subjects with well-preserved or normal LVEF.[1] Since SCD victims comprise a very small proportion of the population at large, these patients are exceedingly difficult to identify.

At an LVEF between 30%-35%, however, the risk of SCD is sufficiently high (approximately 3%-5% per year and more) that prophylactic management with an ICD becomes justifiable based on LVEF alone.[2,3] In terms of reductions in mortality, several trials over the past 6 years have demonstrated an unequivocal reduction in mortality even when ICDs are added to best medical therapy in comparison with antiarrhythmic drugs. The relative risk reduction in mortality with primary prophylaxis ICD therapy ranges between 25% to 35% (Figure 1).[4]

The evidence for primary prevention with an ICD is sufficiently robust that implantation is a Class I recommendation with evidence level "A" for patients with ischemic cardiomyopathy and an LVEF ≤30%. This is reflected in the Canadian, American, and European guidelines.[5] For patients with ischemic cardiomyopathy and an LVEF between 30%-35%, ICD implantation is a class IIa recommendation with "B" level evidence by Canadian guidelines. The same guidelines recommend ICD implantation in nonischemic dilated cardiomyopathy with an LVEF <30% and "B" level evidence.[6] With compelling evidence and supportive guidelines, why are patients referred for ICDs in numbers that fall short of the total population eligible for ICDs?

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Figure 1: Meta-analysis of primary prevention ICD trials: Overall results show a relative risk of 0.81 in favour of ICDs for mortality reduction.[4]

Study, Year (Reference)	ICD n/n	Control n/n	RR (Random) (95% CI)	Weight, %	RR (Random) (95% CI)
Primary prevention programs					
MADIT, 1996	15/95	39/101		4.05	0.41 (0.24-0.69)
CABG Patch, 1997	101/446	95/454		10.85	1.08 (0.84-1.39)
CAT, 2002	13/50	17/54		3.15	0.83 (0.45-1.52)
MADIT II, 2002	105/42	97/490		10.70	0.71 (0.56-0.92)
AMIOVIRT, 2003	7/51	9/52		1.55	0.79 (0.32-1.97)
COMPANION, 2004	105/595	131/617		11.59	0.83 (0.66-1.05)
DEFINITE, 2004	28/227	40/229		5.22	0.71 (0.45-1.10)
DINAMIT, 2004	62/332	58/342		8.07	1.10 (0.80-1.52)
SCD-HeFT, 2005	182/529	244/847		14.74	0.76 (0.65-0.90)
Subtotal	3367	3186		69.93	0.81 (0.69-0.95)

ICD referral and utilization – lower than expected

In the province of Ontario, data from tracking ICD implants revealed that centres in the province cumulatively failed to meet the implantation target of 2000 ICDs for the fiscal year of April 2006 to May 2007. This resulted in financial clawbacks by the provincial government from hospitals due to ICD "underutilization".[7] The "underutilization" was not due to a lack of funding for device implant and follow-up, nor to a lack of implantation capacity. In fact, a review[8] of data from the echocardiography laboratory of one Ontario teaching centre revealed the following: 247 patients were screened for review based on receiving an echocardiogram for LV function >1-month post-myocardial infarction (MI); of these, 56 patients had an LVEF <30%, but only one (1.8%) was referred for an ICD. An additional 21 patients had an LVEF between 30%-35%, none of whom were referred for ICD implantation.[4]

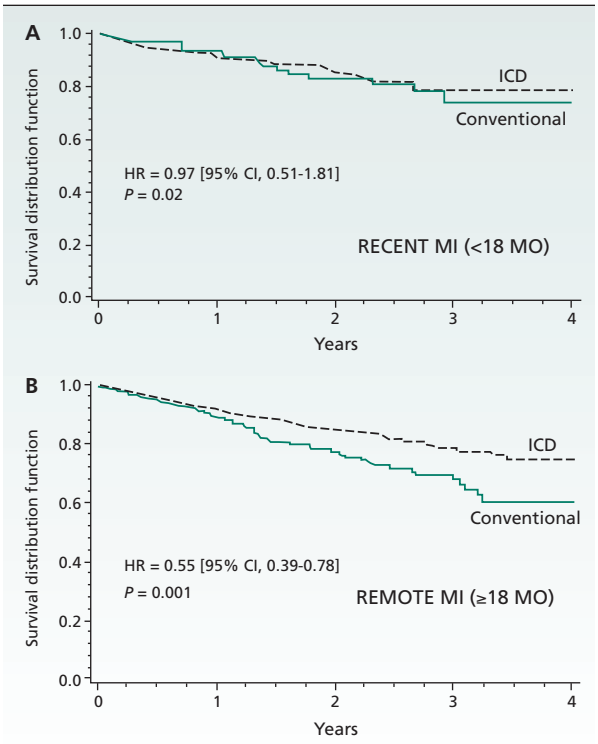
The identifiable reasons for the lower than expected ICD referral rate are related, for the most part, to perceptions of the referring physician about ICD therapy, and the evaluation and implantation process. Some physicians are uncertain about ICD effectiveness for preventing mortality in some patient subgroups; as well, they have concerns about the impact on patient lifestyles (especially driving), and a perception of excessive wait times for evaluation and implantation. These perceptions have negatively influenced referrals for ICDs (Simpson C; personal communication).[9,10] Considerable evidence exists to refute some of the major misperceptions concerning ICD therapy, as can be seen in the following case studies.

A stable patient with LV dysfunction and remote MI

A recently retired, 57-year-old female teacher suffered an ST-elevation MI 10 years ago and was treated with tissue plasminogen activator (tPA). At the time, angiography revealed single vessel disease of the left anterior descending (LAD) artery. Over the last 10 years, she has had excellent medical management with a beta blocker, a statin, an angiotensin-converting enzyme (ACE) inhibitor, and acetylsalicylic acid (ASA). She has stopped smoking and has New York Heart Association (NYHA) Class II heart failure symptoms and no anginal symptoms. Recently, her LVEF by multigated acquisition (MUGA) was found to be 27% with a large anterior scar.

Evidence-based guidelines would suggest that she is an appropriate candidate for an ICD that could significantly extend her lifespan by one year. In surveys of Ontario physicians, many expressed skepticism about the benefit of an ICD in such a patient due to the fact that she is doing well on current therapy; futher, they suggest that since she has survived for 10 years post-MI, this predicts a higher likelihood of freedom from all cause (including arrhythmic) mortality for the next several years, if not more. However, ample evidence exists to the contrary; in fact, most primary prophylaxis ICD trials involved a majority of patients with ischemic cardiomyopathy and this patient would meet the inclusion criteria. An appropriate waiting period (4-12 weeks) after the most recent MI and/or revascularization was part of the inclusion criteria. By the end of the follow-up period for these trials (which spanned at least 2 years), substantial survival benefits (approximately a one-quarter to one-third relative risk reduction of all cause mortality) were realized in patients treated with ICDs. The survival benefit was more pronounced the longer follow-up was pursued (survival curves diverged after 6-12 months and continued to diverge afterwards). In a *post hoc* analysis of the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-2),[11] the survival benefit with ICD implantation was considerably higher in patients whose last MI was more remote (>1.5 years before) as compared with those whose MI had occurred within 18 months prior to enrolment (Figure 2). The Defibrillator in Acute Myocardial Infarction Trial (DINAMIT)[12] could be considered a corollary, since patients with low LVEFs were enrolled within 40 days of the most recent MI, and ICDs conferred no survival benefit in this population. This suggests that in patients

Figure 2: MADIT-2 Trial: A more pronounced mortality reduction was observed in patients who had suffered an MI at least 18 months before ICD implantation. Stable patients with LV dysfunction years after an MI obtain significant survival benefit from ICD implantation.[11]



who have survived for at least 18 months post-MI, the risk of death from arrhythmia remains relatively constant, while the risk of nonarrhythmic death (eg, from pump failure) diminishes.

Ischemic vs nonischemic The issue of driving

A 51-year-old male truck driver originally presented 2 years ago with nonspecific symptoms of fatigue, exertional dyspnea, and with indications of functional NYHA Class III. He was found to have dilated cardiomyopathy with an LVEF of 19%, and was treated with an ACE inhibitor, furosemide, a beta-blocker, and spironolactone. Now he feels much better and is NYHA Class II, but his LVEF is still 27% with global hypokinesis.

Canadian guidelines support ICD implantation in this patient as a class IIA recommendation (ie, most physicians would agree with the recommendation) with a "B" level of evidence. In the surveyed Ontario physicians who would not refer similar patients for ICD implantation, some believed there was no benefit from ICDs in nonischemic cardiomyopathy, while others thought that ICD implantation would automatically disqualify a patient from driving.

Several trials[13] of ICD implantation in nonischemic cardiomyopathy have been conducted. Some included both ischemic and nonischemic cardiomyopathy patients, while others enrolled purely nonischemic cardiomyopathy patients. The point estimate for benefit is in favour of ICD therapy in all of these trials. For some of the smaller trials, the magnitude of benefit failed to reach statistical significance, but in the larger trials (eg, Sudden Cardiac Death in Heart Failure Trial [SCD-HeFT], Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure [COMPANION]), there was clear, statistically significant benefit in terms of survival with ICD therapy as compared with optimal medical therapy.[13] Guidelines limit the Class IIa recommendation to patients who have had a diagnosis of cardiomyopathy for at least 9 months on optimal medical therapy, in those with an LVEF of <30%. The guidelines also note that the average LVEF of patients with nonischemic cardiomyopathy was very low (21%-25%) in the larger trials and patients with higher LVEF measurements were under-represented.

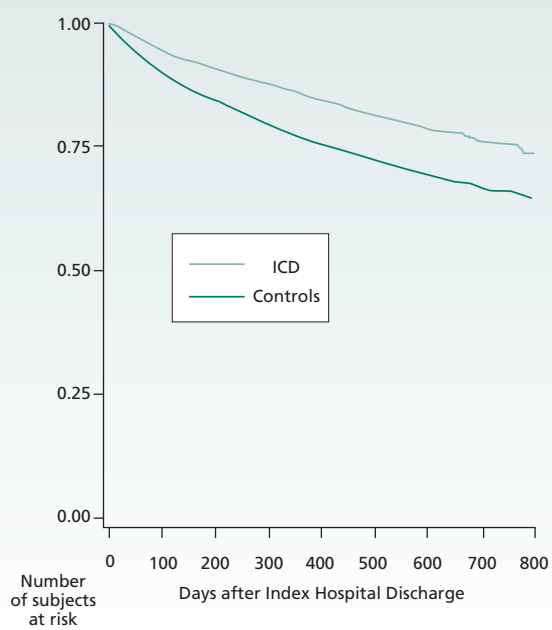
Restrictions on driving (both private and commercial) are based primarily on the patient's cardiac status. The presence of an ICD is a consideration, but only in a more restricted set of driving circumstances. Because this patient has never had a documented arrhythmia or syncopal event, driving fitness is based primarily upon LVEF and HF status. An NYHA class II patient with an LVEF <35% is automatically disqualified from commercial driving, but there is no restriction on private driving. After an ICD implant, private driving is restricted for 4 weeks, but then can resume as before. For patients with NYHA class I-III heart failure, implantation of an ICD is a disqualification from commercial driving.[14] Thus, having an LVEF that would qualify a patient for an ICD in the first place disqualifies them from commercial driving, but does not restrict them from private driving. For most primary prophylaxis patients, ICD implantation does not degrade their fitness to drive.

Benefits in elderly patients

An 84-year-old retired salesman has had multiple non-ST-segment elevation myocardial infarctions (STEMIs) and percutaneous coronary interventions (PCIs). Currently, his anatomy is not amenable to revascularization; his creatinine level is 250 µmol/L, he has controlled type 2 diabetes, and is in NYHA Class II congestive HF with Canadian Cardiovascular Society (CCS) Class I angina. He has an LVEF of 21% and is receiving treatment with a beta-blocker, furosemide, spironolactone, an ACE inhibitor, ASA, a statin, and clopidogrel. He is the sole caregiver for his wife, who has Alzheimer disease, thus his goal is to prolong his survival. Would an ICD accomplish this?

As with the previous cases, Canadian guidelines would support ICD implantation in this patient with level "A" evidence. The guidelines contain a proviso that "patients with significant comorbidities may not benefit from an ICD." However, multivariate analysis of the Multicenter Unsustained Tachycardia Trial (MUSTT) suggest that these comorbidities place patients at a higher risk for all-cause mortality, including arrhythmic mortality.[15] As a result, they may have a demonstrably higher chance of prolonged survival with an ICD implant.

Figure 3: A significant survival benefit from primary prophylaxis ICD implantation is found even in the elderly; observations from a retrospective case-control study of survival among 7125 elderly (age >65 yr), Medicare patients with LV dysfunction stratified by primary prophylaxis ICD implant vs no ICD implant and case matched for comorbidities.[18]



An upper limit of age for continued survival benefit from primary prophylaxis ICD has not been established and ICD trials did not specify an upper-age limit. While most patients in these trials were under age 65, many older patients were enrolled. Subgroup analysis of the MADIT-2 and SCD-HeFT trials revealed a higher likelihood of survival with ICD implantation in patients over age 65, but this failed to reach statistical significance.[16,17] A recent retrospective study of 7125 Medicare patients aged >65 years with HF and LV dysfunction, who received a primary prophylaxis ICD, demonstrated a higher likelihood of survival with ICD implantation in comparison with age and comorbidity-matched controls (Figure 3).[18] For the hypothetical patient above, the evidence to implant an ICD to prolong his life is more compelling than evidence to suggest he would not benefit from an ICD. As with all patients, the goals of implantation (in this case, prolongation of life, understanding that there will be no improvement in HF or CAD status) must be clearly understood by the patient and the physicians.

HF and cardiac resynchronization therapy (CRT)

Patients who have LV dysfunction, HF, and left bundle branch block (LBBB) have the potential not only to benefit from longer survival with an ICD, but also to have an improvement in their CHF symptoms. When LBBB is present in the context of LV dysfunction, contraction of the posterior and lateral LV walls are delayed in comparison with the LV septum, resulting in "dyssynchronous" contraction of the LV segments. By implanting a third lead via the right atrium in the coronary sinus branches against the epicardial posterolateral LV wall, synchronous contraction can be restored with biventricular pacing, ie, pacing at the right ventricular (RV) apex (and septum) and the posterolateral LV wall. CRT has been shown to produce consistent improvement in HF symptoms. CRT may improve survival, as well, but these data are variable. In the Cardiac Resynchronization in Heart Failure (CARE-HF) study,[19] biventricular pacemakers (not ICDs) were implanted in patients with LV dysfunction (LVEF <35%) and LBBB, and compared with best medical therapy in the control group. Even without ICD capability, the CRT group experienced a 10% absolute risk reduction in mortality and a 16% absolute risk reduction in the combined endpoint of mortality and HF hospitalization.[19] In the COMPANION study,[20] implantation of a CRT pacemaker (no ICD function) was associated with a nonsignificant 24% relative risk reduction in mortality compared with best medical therapy. Implantation of a CRT defibrillator was associated with a statistically significant 36% relative risk reduction in all-cause mortality.[14] CRT results in symptom improvement for approximately two-thirds of the patients who receive it. Currently, it is thought that for a reliable realization of mortality benefits from CRT, the device must be an ICD-CRT device as opposed to a pacemaker-CRT device.

Wait times
EF >30% and questions about ICD effectiveness

Another factor influencing Ontario physician decisions to refrain from referring patients for ICD implantation is the perception that wait times for implantation of an ICD are excessive (ie, approximately ≥1 year). Although this was the situation in the early part of the decade, since then comprehensive steps have been taken to define an appropriate waiting period for an ICD implant and to prevent excessive wait times for the implantation. Based on the MADIT-2 trial, for the medical therapy only group, the monthly mortality rate was 0.8%. Mortality due to causes that were not preventable with an ICD was 0.5% per month; therefore, the rate of deaths "preventable" with an ICD was 0.3% per month. To keep within an upper limit of waiting-list mortality of ≤0.5%, an acceptable wait time for ICD implantation is 7-8 weeks from the time of a decision to implant an ICD. The majority of Ontario centres have been able to meet this waiting time target through fast-tracking referrals (eg, ICD assessment clinics), increases in implant capacity, and waitlist monitoring and triaging.[21]

For patients with an LVEF between 30% and 40%, some uncertainty exists as to the magnitude of benefit

from ICD implantation. The average LVEF in ICD trials was considerably lower than the cutoff of 30% for most trials. In those trials where the cutoff was 35%, there were relatively fewer patients with an LVEF between 30%-35% and a subgroup analysis of the SCD-HeFT trial for patients with LVEFs in this range indicated no survival benefit from ICD implantation. There are no primary prevention ICD trials addressing patients with an LVEF between 35% and 40%, even though American and European guidelines suggest that it is justifiable to implant ICDs in these patients owing to imprecision in LVEF measurements obtained by echocardiographs or MUGA scans.[22] In Ontario, this question of the magnitude of benefit from ICDs in patients with an LVEF between 30%-40% and ischemic cardiomyopathy will be examined in the Selective Strategy to Manage Arrhythmia Risk and Therapy (SMART)-2 study. This will be a prospective cohort follow-up study of approximately 4000 patients identified as having poor LV function at a "baseline" outpatient echocardiogram, recorded in a community echocardiography laboratory. The primary objectives of this study are to determine the 5-year all-cause mortality, CV mortality and SCD (or presumed arrhythmic mortality) in a cohort of patients identified with poor LVEF (≤40%) in the community. Among the secondary endpoints are a comparison of the primary outcomes between patients with an LVEF between 30%-40% versus those with an LVEF <30%. The study will examine 12-lead ECG predictors of risk including the following: rhythm (sinus or other), heart rate, QRS duration, and presence of pathological Q-waves.[23]

Conclusions

Sudden cardiac death remains a leading cause of death in Canada. Primary prophylaxis with an ICD can reduce all-cause mortality by preventing SCD by a magnitude equal to and often greater than pharmacological therapies. Nevertheless, referrals for ICD implantation have not been as high as projected, in spite of available resources to implant them expediently. For patients with an LVEF <30%, ICD implantation is of clear benefit in patients with remote MIs, who are on the best medical therapy, and with varying degrees of HF. ICD implantation has no long-term impact on private driving status and, in the vast majority of cases, will not reduce the independence of patients. CRT-ICD implantation in patients with LBBB, LV dysfunction, and HF can not only increase survival, but also improve CHF symptoms. In Ontario, wait times for ICD implantations are on track to meet benchmarks of no more than 7-8 weeks from the time of assessment. In patients aged >65 years, survival data is more limited; nevertheless, there is a trend towards improved survival in several trials, but this trend did not meet statistical significance. Recent retrospective data suggest that there is a definite survival benefit, but randomized clinical trial evidence for a primary ICD is weighted heavily towards patients <65-years-old.

Referral to an ICD implant centre does not commit a patient to immediate implantation of a device. A careful review of objective data (EF assessments, revascularization status, medical therapy, etc.) is carried out, as well as the development of a clear description outlining the risks and benefits of ICD implantation. Patients are assessed for suitability to undergo CRT implantation or for ICD. In Ontario (as well as some other Canadian provinces), patients referred for ICD implant are entered into a comprehensive database, which includes demographic information as well as cardiac and noncardiac comorbidities. Studies and data collection initiatives such as these will help to refine indications for ICDs and establish clearer upper LVEF cutoffs for receiving benefits. Further data may emerge to clarify how comorbidities (eg, diabetes, renal failure, age >65 years, unrevascularized CAD) influence the risk of death and the benefit of defibrillators for primary prophylaxis in subsets of patients with low LVEFs.

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Abstracts of Interest

Hospital variation and characteristics of implantable cardioverter-defibrillator use in patients with heart failure: data from the GWTG-HF (Get With The Guidelines-Heart Failure) registry.

Shah B, Hernandez AF, Liang L, Al-Khatib SM, Yancy CW, Fonarow GC, Peterson ED; Get With The Guidelines Steering Committee. Durham, North Carolina.

OBJECTIVES: The aim of this study was to describe hospital variation and factors associated with adherence to guidelines for implantable cardioverter-defibrillator (ICD) therapy.

BACKGROUND: Studies have shown incomplete application of ICD therapy in eligible heart failure (HF) patients.

METHODS: New or discharge prescription rates for ICD therapy (ejection fraction <or=30% without documented ICD contraindications) for hospitals were calculated from participants in the GWTG-HF (Get With The Guidelines-Heart Failure) registry during January 2005 to June 2007. With hierarchical modeling, hospitals' patient case-mix adjusted ICD rate and hospital factors associated with ICD use were determined. The association of ICD rate and other quality of care indicators and procedure use was determined.

RESULTS: Overall use of ICD in-hospital or planned implantation rate was 20%. This rate ranged widely among hospitals, from 1% among the lowest tertile to 35% among the top tertile ($P < 0.01$). After adjusting for patient case mix, independent hospital characteristics associated with higher ICD use were percutaneous coronary intervention, coronary artery bypass grafting, and heart transplant capability as well as larger hospital bed size ($P < 0.01$). Hospital Centers for Medicare and Medicaid Services/Joint Commission on the Accreditation of Healthcare Organizations performance measures (discharge instructions, angiotensin-converting enzyme inhibitor/angiotensin II receptor blocker use, smoking cessation; $P \pm 0.05$) were similar across ICD, whereas higher ICD-rate hospitals had higher adherence to GWTG-HF performance measures (beta-blocker use, evidence-based beta-blocker use, aldosterone-antagonist, hydralazine/ nitrate; $P < 0.05$) except warfarin in patients with atrial fibrillation ($P = 0.18$).

CONCLUSIONS: There is significant unexplained hospital variation in the use of ICD therapy among potentially eligible HF patients. However, hospitals that use ICD therapy more often also have more rapidly adopted other newer evidence-based HF therapies.

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Gender Differences in Procedure-Related Adverse Events in Patients Receiving Implantable Cardioverter-Defibrillator Therapy.

Peterson PN, Daugherty SL, Wang Y, Vidaillet HJ, Heidenreich PA, Curtis JP, Masoudi FA; on behalf of the National Cardiovascular Data Registry.

BACKGROUND: Women are at higher risk than men for adverse events with certain invasive cardiac procedures. Our objective was to compare rates of in-hospital adverse events in men and women receiving implantable cardioverter defibrillator (ICD) therapy in community practice. Methods and Results-Using the National Cardiovascular Data Registry ICD Registry, we identified patients undergoing first-time ICD implantation between January 2006 and December 2007. Outcomes included in-hospital adverse events after ICD implantation. Multivariable analysis assessed the association between gender and in-hospital adverse events, with adjustment for demographic, clinical, procedural, physician, and hospital characteristics. Of 161 470 patients, 73% were male, and 27% were female. Women were more likely to have a history of heart failure (81% versus 77%, $P<0.01$), worse New York Heart Association functional status (57% versus 50% in class III and IV, $P<0.01$), and nonischemic cardiomyopathy (44% versus 27%, $P<0.01$) and were more likely to receive biventricular ICDs (39% versus 34%, $P<0.01$). In unadjusted analyses, women were more likely to experience any adverse event (4.4% versus 3.3%, $P<0.001$) and major adverse events (2.0% versus 1.1%, $P<0.001$). In multivariable models, women had a significantly higher risk of any adverse event (OR 1.32, 95% CI 1.24 to 1.39) and major adverse events (OR 1.71, 95% CI 1.57 to 1.86).

CONCLUSIONS: Women are more likely than men to have in-hospital adverse events related to ICD implantation. Efforts are needed to understand the reasons for higher ICD implantation-related adverse event rates in women and to develop strategies to reduce the risk of these events.

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