REVIEW

Implantable cardioverter defibrillators: state of the art

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Abstract: It has been estimated that 180,000–450,000 people die suddenly in the US every year. Currently, the most effective method for reducing the risk of sudden death in those patients at highest risk is implantation of an internal cardioverter defibrillator (ICD). The evidence base for the benefit of the ICD has matured over the last two decades, and large studies have consistently shown reduced mortality or sudden cardiac death (SCD) in selected patient populations. Since its initial application in the early 1980s in patients who had already suffered an episode of SCD (secondary prevention), ICD use has expanded dramatically and now includes patients who are at high risk for a first event of SCD (primary prevention). More recent studies have focused on new technology, optimal programming, and other gaps in our understanding of the use of ICDs.

Keywords: sudden cardiac death, primary prevention, secondary prevention, myocardial infarction, ventricular fibrillation, ventricular tachycardia, LVEF, subcutaneous implantable cardioverter-defibrillator

Introduction

It has been estimated that in the US, 180,000–450,000 patients per year will have an episode of sudden cardiac death (SCD), and SCD can also be the first manifestation of heart disease.[1] The Implantable cardioverter defibrillator (ICD) was invented as a novel method for the treatment of SCD. Prior to the development of ICDs, antiarrhythmic medications were used for treating patients at risk for SCD. Several landmark trials including the Cardiac Arrhythmia Suppression Trial (CAST) performed in the 1980s highlighted the inadequacy of medications for the treatment of patients at risk for SCD.[2,3] Since the first implant in 1980, ICDs have become more complex and sophisticated and are now considered an essential option for the treatment of SCD.

History and early studies

With the advent of the coronary care unit in the 1960s, mortality rates following myocardial infarction (MI) fell.[4] This reduction in mortality was multifactorial but in large part due to a dedicated nursing staff, intense patient monitoring, and early detection and defibrillation of malignant arrhythmias.[4–6] An implanted device that could defibrillate malignant ventricular arrhythmia was conceived and developed in the 1970s. A team of researchers led by Michel Mirowski, William Staewen, and Morton Mower from Sinai Hospital produced a prototype suitable for in vivo testing. In 1980, they successfully implanted ICDs in three patients suffering from ventricular fibrillation (VF).[7,8] Although met with initial skepticism, ICDs have now rapidly matured into an

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established therapy with consistent benefits including improved survival as identified in several landmark clinical trials.

Landmark studies for primary and secondary prevention

Patients who have survived SCD or sustained ventricular tachycardia (VT) are at particular risk for arrhythmia recurrence and cardiac death (secondary prevention). Several initial trials were instrumental in the establishment of the modern ICD for secondary prevention.[9–12] The Antiarrhythmics Versus Implantable Defibrillators (AVID) study evaluated patients who had survived near-fatal VF, or sustained VT with a left ventricular ejection fraction (LVEF) ≤40%. A group of 1,013 patients were randomized to ICD placement or antiarrhythmic therapy. At the 3-year follow-up, 75.4% compared to 64.1% ($P<0.02$) survived in the ICD group compared to the medically managed group, and a 31% reduction in mortality was seen in the ICD group.[11] During this period, the results from two smaller studies were also published: the Canadian Implantable Defibrillator Study (CIDS) and the Cardiac Arrest Study Hamburg (CASH).[10,12] Both CIDS and CASH trials failed to find benefit with ICDs but were relatively underpowered trials that were almost half the size of AVID. However, a subsequent meta-analysis of the AVID, CIDS, and CASH studies found a 50% relative risk reduction in arrhythmic death with ICD implantation.[13] Post hoc analysis suggested that recurrent ventricular arrhythmias were more likely in patients with poorer left ventricular function, who were not revascularized after the index event, presented with VT rather than VF, or had a history of cerebrovascular disease (Table 1).[14,15]

There is a large body of evidence in support of ICDs for patients at high risk for a first event of SCD (primary prevention), particularly in patients with ischemic heart disease. Seven large randomized trials have evaluated the use of ICDs for primary prevention (Table 1).[16–19] The two largest studies, the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II) and the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT), unequivocally established the ICD as an effective treatment for primary prevention in selected patients. MADIT-II enrolled 1,232 patients with reduced LVEF (≤30%) and prior MI who were randomized in a 3:2 ratio to ICD and no ICD. Researchers found a 31% risk reduction in mortality for the ICD implantation group.[16] The SCD-HeFT studied 2,521 patients with New York Heart Association Class II or Class III heart failure symptoms and reduced LVEF (≤35%) due to ischemic or nonischemic cardiomyopathy (NICM) who were divided into three therapy groups: placebo, amiodarone, or ICD implantation. The SCD-HeFT investigators found a 23% risk reduction in mortality in the ICD group when compared to the amiodarone or placebo groups and provided additional support for ICD use in primary prevention.[18]

Gaps in knowledge for ICD implantation

Since randomized clinical trials are designed to evaluate the superiority of a therapy or treatment strategy in a selected population, knowledge gaps become apparent when the clinician tries to apply study results to individual patient care. There are several patient groups where the benefits of ICD therapy are not as well defined because they were underrepresented or not included in clinical trials.[20]

Nonischemic cardiomyopathy

Initial secondary prevention randomized controlled trials included only a fraction of patients with NICM.[9–12] In the AVID trial, 67% of the ICD therapy group had a history of prior MI, and 81% had known coronary artery disease.[11] Similarly, in the CIDS and CASH trials, only 9% and 12% of patients, respectively, were diagnosed with NICM.[10,12] A meta-analysis of NICM patients from AVID, CASH, and CIDS found that ICD therapy reduced the risk of death due to ventricular arrhythmias and most patients with NICM who have experienced an episode of SCD should be considered for ICD implant.[13]

Our understanding of the benefits of ICD therapy for primary prevention in patients with NICM has been informed by several small randomized controlled trials and a sub-analysis of SCD-HeFT. The small underpowered Cardiomyopathy Trial (CAT) and Amiodarone Versus Implantable Cardioverter-Defibrillator Trial (AMIOVIRT) failed to show a benefit associated with ICD therapy for primary prevention.[21,22] The larger Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) enrolled 458 patients with NICM, LVEF <36%, and abnormal autonomic function to ICD or no ICD therapy and after almost 3-year follow-up, found that ICD therapy was associated with a nonsignificant trend toward improved mortality and a significant decrease in SCD.[23] In a prespecified sub-analysis of the 1,211 patients with NICM enrolled in SCD-HeFT (approximately 50% of the study population), ICD therapy was associated with a nonsignificant survival advantage (hazard ratio 0.73; 97.5% confidence interval [CI] 0.50–1.07; $P=0.06$).[18,24]

Table 1 A comparison of randomized secondary and primary ICD trials

Study name	Number of patients	Inclusion criteria	Patient characteristics (%)	Outcomes/comments
Secondary prevention trials				
AVID[11] (ICD vs amiodarone or sotolol)	1,016 (507 in defibrillator group and 509 in antiarrhythmic group)	Resuscitated from VF VT with syncope Sustained VT with EF ≤40% and hemodynamic compromise Excluded if within 72 hours of MI, electrolyte imbalance	Average age 65 years Average LVEF 32% 87% white 80% male 42% without CHF and 48% NYHA Class I–II at enrollment Beta blocker use 42% in ICD group compared to 17%	5-Year follow-up Improved survival at end of study in ICD group (P<0.02) 39%, 27%, and 31% decrease in death rate in ICD group at 1, 2, and 3 years ICD group had higher use of beta blockers
CIDS[10] (ICD vs amiodarone)	631 (310 in ICD group and 321 in amiodarone group)	Documented VF Out-of-hospital arrest requiring defibrillation Sustained VT causing syncope VT >150 bpm with presyncope and EF ≤35% Syncope with induced monomorphic VT	Average age 63 years 84% male Average LVEF 33.5% 50% with no CHF 40% NYHA Class I and II	3-Year follow-up 8.3% all-cause mortality rate in ICD group compared to 10.2% in amiodarone group (P=0.142) 3.7% arrhythmic death rate in ICD group compared to 4.5% (P=0.094) Used both thoracotomy–(3% mortality) and non-thoracotomy-placed ICDs
CASH[12] (ICD vs amiodarone or metoprolol)	288 (99 in ICD group, 92 in amiodarone group, and 97 in metoprolol group)	Resuscitated arrest from VT or VF Excluded if within 72 hours of MI, cardiac surgery, or electrolyte imbalance	Average age 58 years 80% male Average LEVF 46% 26% NYHA Class I 57% NYHA Class II	Mean follow-up of 57 months Nonsignificant death rate of 36.4% in ICD group compared to 44.4% in antiarrhythmic group (P=0.081) Significant sudden death rate reduction, 13% in the ICD group compared to 33% (P=0.005) Propafenone originally studied, however, stopped due to mortality risk
Primary prevention trials				
MADIT-II[16] (ICD vs conventional medical therapy)	1,232 (742 in ICD group and 490 in control group)	LVEF ≤30% ≥1 month post-MI	Average age 65 years 85% male 23% mean LVEF 53% history of CABG	Mean follow-up 20 months 14.2% mortality in ICD group compared to 19.8% HR 0.69 (P=0.016) 31% risk reduction of death 5% absolute mortality risk reduction
SCD-HeFT[18] (medical therapy plus either ICD, placebo, or amiodarone)	2,551 (829 in ICD group, 845 in amiodarone group, and 847 in placebo group)	LVEF ≤35% Chronic CHF with NYHA Class II or III	Median age 60 years 76% male Median LVEF 25%	Median follow-up 46 months Mortality relative risk reduction of 23% (HR 0.77; P=0.007) Absolute risk reduction of 7.2% Mortality between placebo and amiodarone similar (HR 1.06; P=0.53) (Continued)

Table I (*Continued*)

Study name	Number of patients	Inclusion criteria	Patient characteristics (%)	Outcomes/comments
DEFINITE[23] (NICM medical therapy ± ICD therapy)	458 (229 in ICD group and 229 standard medical therapy group)	NICM LVEF ≤35% Documented NSVT or ≥10 PVC on 24-hour Holter Symptomatic CHF	Mean age 58 years 71% male Mean LVEF 21% NYHA Class I (22), II (57), and III (21)	Mean follow-up 29 months Nonsignificant trend in survival benefit (HR 0.65; *P*=0.08) Significant reduction in arrhythmic deaths (HR 0.2; *P*=0.006)

Abbreviations: AVID, Antiarrhythmics Versus Implantable Defibrillators; bpm, beats per minute; CABG, coronary artery bypass graft; CASH, Cardiac Arrest Study Hamburg; CHF, congestive heart failure; CIDS, Canadian Implantable Defibrillator Study; DEFINITE, Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation; HR, hazard ratio; ICD, implantable cardioverter defibrillator; LVEF, left ventricular ejection fraction; MADIT-II, Multicenter Automatic Defibrillator Implantation Trial II; MI, myocardial infarction; NICM, nonischemic cardiomyopathy; NSVT, nonsustained ventricular tachycardia; NYHA, New York Heart Association; SCD-HeFT, Sudden Cardiac Death in Heart Failure Trial; VF, ventricular fibrillation; VT, ventricular tachycardia; EF, ejection fraction; PVC, premature ventricular contraction.

Collectively, the data from DEFINITE and SCD-HeFT are consistent. ICD therapy is beneficial for primary prevention in patients with NICM, LVEF 35% or less, and Class II or Class III heart failure symptoms, but the benefit is in part attenuated by an overall reduced rate of malignant ventricular arrhythmias when compared to a similar group of patients with ischemic cardiomyopathy.

Renal disease

It is well established that chronic kidney disease (CKD) greatly increases the risk of cardiovascular disease (CVD).[25,26] It has also been shown that the prevalence of CVD is 10–30 times higher in patients undergoing dialysis than the general population.[26] Large randomized trials often excluded those with CKD, and there is evidence that CKD may increase risk of ICD-related complications.[27–30] ICD implantation has been shown to reduce arrhythmic mortality in high-risk patients with CKD, but patients with CKD also have an increased risk of non-arrhythmic mortality.[31] At this juncture, the presence of CKD should not preclude ICD implant in high-risk patients, but both the provider and patient must understand that competing risks and an increased implant complication rate in patients with CKD will likely reduce the overall benefit of ICD therapy.

Age

ICDs have been implanted successfully in young children as early as an age of 1 year. Although ICD implantation has been shown to be effective in treating arrhythmias, inappropriate discharges and lead failure are more common in younger populations (age 1–30 years).[32] While there is no age limit restriction for ICD therapy, questions have been raised about the effects in older patients (>65 years). The literature has shown that patients of advanced age often live long enough to warrant ICD placement; however, other research has noted that age in conjunction with heart failure is likely a competing risk for mortality.[33,34] Not surprisingly, an analysis of the Canadian ICD registry data identified a significant decrease in 2-year survival in patients >80 years old (34%–53%) when compared to patients <65 years old (84%) emphasizing the importance of considering long-term survival when deciding whether to implant an ICD.[34] As it stands, no conclusive evidence has emerged, and ICD placement should be individualized to specific patient needs. Although frailty and the presence of accompanying conditions must always be considered when implanting an ICD, these issues are particularly relevant in the older patient.

Nonwhite patient population

As mentioned previously, the majority of the participants in the initial primary and secondary prevention trails were white men. The efficacy of ICD use in nonwhite racial populations has been studied using subset analysis from the large primary prevention trials.[35,36] Analysis of the SCD-HeFT found that enrolled black patients were younger but had higher mortality with more ischemic heart disease, worse heart failure, and lower LVEF. However, despite increased mortality risk, SCD-HeFT researchers found that compared to placebo, mortality reduction was equally reduced in both racial groups.[35] In contrast, subset analyses of MADIT-II and the DEFINITE trials found lower ICD efficacy in the black patient populations compared to equally matched white populations.[16,23] However, none of these studies were designed to compare racial disparities and are sufficient to make major conclusions about efficacy.

Several studies have noted a significant discrepancy in ICD implantation in different racial groups.[37–39] In an analysis of a large heart failure quality improvement database, investigators found that black men and women were, respectively, 27% and 44% less likely to receive an ICD at discharge after a heart failure hospitalization when compared to white men after adjusting for comorbidities.[38] Importantly, in a subsequent analysis of the same database, it appears that the quality improvement program was associated with an overall increase in ICD use that was greatest among blacks with resolution of the racial disparities. Collectively, the data suggest that ICDs are beneficial in all racial populations and that racial disparities can be decreased with implementation of quality improvement programs.[37–39]

Women

Women have been underrepresented in the large randomized trials evaluating ICD therapy, averaging approximately 18% of the study populations.[11,17,40] Using data pooled from five major primary prevention trials, a meta-analysis was unable to identify a mortality benefit in the 934 women (out of the 4,744 patients who received ICDs in the trials) enrolled in the trials.[40] In contrast, another comprehensive meta-analysis found that interaction tests did not show statistically significant differences and that the absence of benefit in women is most likely due to lack of statistical power.[41] More recently, data from the National Cardiovascular Data Registry were used to evaluate the effects of ICD placement in elderly women (outcomes were evaluated using Medicare data). Four hundred and ninety women >65 years old who underwent ICD placement were compared to a matched

group of 490 ICD-eligible women without an ICD who had been hospitalized for heart failure. The survival of women with an ICD compared to women without an ICD was significantly higher (hazard ratio 0.79; P=0.013) after 4 years, suggesting that women also benefit from ICD implantation in primary prevention.[42] Although therapy allocation was not randomized and acknowledging the study design issues with patient matching, the benefits of ICD therapy appeared to be similar in magnitude to men and provide support for the American College of Cardiology (ACC)/American Heart Association (AHA)/Heart Rhythm Society (HRS) guidelines for device-based therapy that do not make distinction about race or sex.[43–46]

Although indications for ICD therapy are not different between men and women, it should be noted that large database and registry studies have consistently shown a higher complication rate associated with ICD implant in women.[47–49] In an analysis of 3,340 patients who underwent ICD implantation in Ontario, Canada, women had a significantly higher risk for major complications compared to men (hazard ratio 1.49; 95% CI 1.02–2.16; P=0.037). Similarly, evaluation of 161,470 patients in the National Cardiovascular Database found that the in-hospital adverse event rate was higher in women when compared to men (women 4.4% vs men 3.3%; P<0.001) with women more likely to have a drug reaction, cardiac perforation, pericardial tamponade, lead dislodgement, hemothorax, and pneumothorax. Although the adverse event rate was higher, no sex differences in in-hospital mortality were detected.[47]

Multisociety guideline and consensus statements

The use of ICDs for the prevention of SCD has been endorsed by several major societies including the ACC, AHA, HRS, and the European Society of Cardiology (ESC). To date, four major guideline statements have been published and encompass the major expert opinion for ICD use.[43–46] The guidelines are issued with different classes of recommendations based on level and strength of evidence. Each of these guidelines provides insight into the use of ICDs from different clinical perspectives, heart failure, MI, arrhythmia, etc. Although each guideline offers a unique perspective in ICD use, the guidelines are similar but not identical in their recommendations. For example, the 2006 ACC/AHA/ESC guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death provided a range of LVEF from ≤30% to 40% for ICD eligibility, while the 2012 Update of the 2008

ACC/AHA/HRS guidelines for Device-Based Therapy and the 2013 ACCF/AHA Heart failure guidelines use an LVEF of ≤35% as a "cut-off", since this is the value chosen in the patient populations enrolled in SCD-HeFT. Although using a range of LVEF can be criticized because of the apparent lack of support from randomized clinical trials, it is important to acknowledge the variability in LVEF interpretation from different diagnostic studies. For example, one of the enrollment criteria for the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) was an LVEF <30%. When the echocardiograms were evaluated by a core laboratory, 48% of patients had an LVEF >30% with a range of 30%–45%.[50] In an attempt to provide some guidance to clinicians for patients who are not specifically covered by guidelines, in 2014, HRS/ACC/AHA published an expert consensus statement for ICD therapy in patients who were not enrolled or underrepresented in clinical trials.[20]

Considerations after ICD implantation
Quality of life

Patients often have frequent questions with regard to lifestyle restrictions after ICD placement. Several websites including a website from the National Heart, Lung, and Blood institute (http://heartdisease.about.com/od/palpitationsarrhythmias/a/ICD_lifestyle.htm) have been created to address specific concerns. The majority of patients will continue to benefit from ICD implantation without the sacrifice of quality of life (QOL).[51] Patients who have strong social support networks prior to implantation have shown to have decreased anxiety and depression.[52] Depression and anxiety have been reported in as many as 50% of ICD recipients in one study cohort, and patients with a history of anxiety and depression prior to implantation often have shown to have decreased QOL.[52–54] To maximize patients' QOL, particular sensitivity must take place to screen for depression and anxiety following implantation. Several depression- and QOL-screening tools, including the Florida Shock and Anxiety Scale, Patient Health Questionnaire-9, and the Implanted Device Adjustment Scale, have been studied to be effective.[51,55–57] Patients anxiety often stems from a lack of understanding about the device and their condition. Formal education before and following implantation improves physician–patient relationships and reduces patients' postimplantation anxiety.[51] Implanting physicians should be encouraged to incorporate standardized educational and emotional support techniques in efforts to improve patient support and reduce anxiety.[51,58–60] In addition, incorporation of support groups has also been shown to benefit and empower patients and should be considered.[51,52,61]

Programming

Currently, upon detection of arrhythmia, modern devices have one of three options; observation, antitachycardia pacing (ATP), or direct-current defibrillation (Figure 1). While defibrillation has traditionally been considered the primary therapy of ICDs, over the last decade, there has been the realization that ICDs generally should be considered as devices that primarily provide antitachycardia therapy with defibrillation as a "safety net". Direct-current shocks require much higher energy expenditure and are uncomfortable, and analysis of clinical trials and large registry data suggest that shocks are associated with increased risk of heart failure and increased mortality.[62–65] ATP is designed to provide rapid electrical bursts intended to disrupt a reentrant circuit.[65] It has been shown to be highly effective and safe and often can be employed to effectively terminate a tachycardia even as the ICD is charging in preparation for a shock.[62,64,66] More than a decade ago, investigators found that approximately 90% of rapid ventricular arrhythmias with rates >188 beats per minute (bpm) that would traditionally be categorized as rapid VT could be terminated by ATP.[66]

The importance of optimal programming has now been clearly demonstrated with the recent publication of two randomized controlled trials. In Multicenter Automatic Defibrillator Implantation Trial – Reduce Inappropriate Therapy (MADIT-RIT), three different ICD programming configurations were tested in 1,500 patients referred for ICD implant for primary prevention. One group (high-rate therapy) only received therapy for heart rates (HRs) ≥200 bpm. In the second group (delayed therapy), ICDs were programmed to a 60-second delay for HR 170–199 bpm, a 12-second delay for HR 200–249 bpm, and a 2.5-second delay for HR ≥250 bpm. The control group received a 2.5-second delay for HR 170–199 bpm and a 1-second delay for rates ≥200 bpm. After an average follow-up of 1.4 years, both the high-rate therapy and the delayed therapy groups showed a reduced likelihood of initial inappropriate therapy and all-cause mortality (hazard ratio with high-rate therapy vs controls, 0.45; 95% CI 0.24–0.85; P=0.01; hazard ratio with delayed therapy vs controls, 0.56; 95% CI 0.30–1.02; P=0.06).[67] The Avoid Delivering Therapies for Nonsustained Arrhythmias in ICD Patients III (ADVANCE III) trial confirmed the results of MADIT-RIT and also extended the findings to patients who received an ICD for secondary prevention. Researchers randomized 1,900 patients with ICDs for both primary and secondary prevention into standard vs long-detection
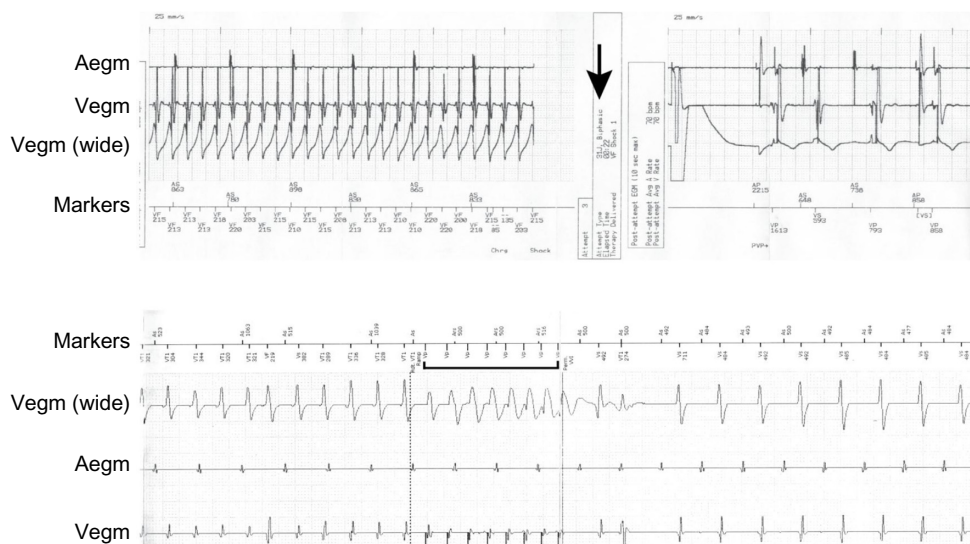
Figure 1 Example electrograms obtained from ICD devices

Notes: Top: Electrograms retrieved from an ICD after a shock. The ICD records an atrial electrogram (Aegm) from the electrodes of a lead placed in the right atrium, and a ventricular electrogram (Vegm) is recorded from two electrodes in the right ventricle. In addition, a ventricular electrogram is recorded from more widely spaced electrograms (Vegm [wide]), that is often recorded between a ventricular electrode and the ICD can, that records a signal that is more similar in appearance to a standard surface ECG recording. Finally, a marker channel is provided that notes what the device is "seeing". On the left portion of the recording, the patient is in a very rapid ventricular rhythm with dissociated atrial activity consistent with ventricular tachycardia. Although relatively regular, the tachycardia intervals are very short and defined by the device as VF and measure from 200 ms to 220 ms (the numbers listed on the marker channel). The patient receives a 31 J shock (arrow) that returns the patient to sinus rhythm. After the shock, the patient has spontaneous atrial signal at a normal rate (AS), and since the patient has atrioventricular block, the atrial signal is followed by VP. Bottom: Electrograms retrieved from another patient with a different manufacturer's ICD. Notice that although the format is different, the recordings and signals provided are the same. This patient also has a rapid ventricular rate that is consistent with ventricular tachycardia given the atrioventricular dissociation. Since the ventricular rate is slower (the electrograms are generally separated by 300–340 ms), the ICD interprets this arrhythmia as VT. Whether the ICD interprets a rhythm as VF or VT depends on how the physician has defined and programmed the therapy zones of the ICD. In this case, the tachycardia is terminated by a series of pacing stimuli (VP: the entire train noted by the horizontal bracket). In this case, the patient has atrioventricular conduction with first-degree AV block, so the ICD records an atrial electrogram (AS) followed by a ventricular electrogram (VS).

Abbreviations: AS, atrial sensed; AP, atrial pacing; AV, atrioventricular; ECG, electrocardiogram; ICD, internal cardioverter defibrillator; VF, ventricular fibrillation; VP, ventricular pacing; VS, ventricular sensed; VT, ventricular tachycardia.

groups. In the long-detection group, the ICD would only provide therapy if 30/40 cycle lengths were short enough to be classified as a ventricular tachyarrhythmia to allow for spontaneous resolution of transient arrhythmias. After a median follow-up of 12 months, the long-detection group had a 37% reduction in ATP and shocks for ventricular tachyarrhythmias confirming that many ventricular arrhythmias will terminate spontaneously.[68]

Device type (dual- vs single-chamber devices, single coil vs dual coil)

Studies comparing dual- and single-chamber devices have shown that both are equally effective in detection and treatment of malignant arrhythmias. The presence of an atrial lead may help discriminate VT from supraventricular tachycardia by identifying the presence of atrioventricular dissociation (Figure 1). Currently, there is conflicting data suggesting a definitive decrease in inappropriate therapies with the addition of an atrial lead.[69–72] While some older studies have found that the presence of an atrial lead can reduce the risk for inappropriate therapies, the current generation of ICDs uses sophisticated QRS morphology-matching criteria that

are very effective for differentiating VT from supraventricular tachycardia. The Reduction And Prevention of Tachyarrhythmias and Shocks Using Reduced Ventricular Pacing with Atrial Algorithms Study (The RAPTURE Study) randomized 100 patients to single- or dual-chamber ICDs and found that when employing modern programming configurations (delayed therapy as described in the "Programing" section, advanced morphology-matching criteria), the likelihood of an inappropriate shock was low whether or not an atrial lead was present (2%).[73] Not surprisingly, atrial leads are associated with an increased risk of procedural complications.[74] The recent 2014 HRS/ACC/AHA expert consensus statement addresses the use of dual-chamber devices noting that atrial leads should generally be reserved for patients with sinus node dysfunction or patients with atrioventricular block.[20]

In an ICD, defibrillation is performed by delivering a shock between a distal coil electrode located in the right ventricle (cathode) and the ICD can acting as a second electrode (anode). Some ICD lead designs have a second coil located more proximally in the superior vena cava (SVC) and innominate vein (Figure 2) that is usually configured to act as a second anode. The additional surface area
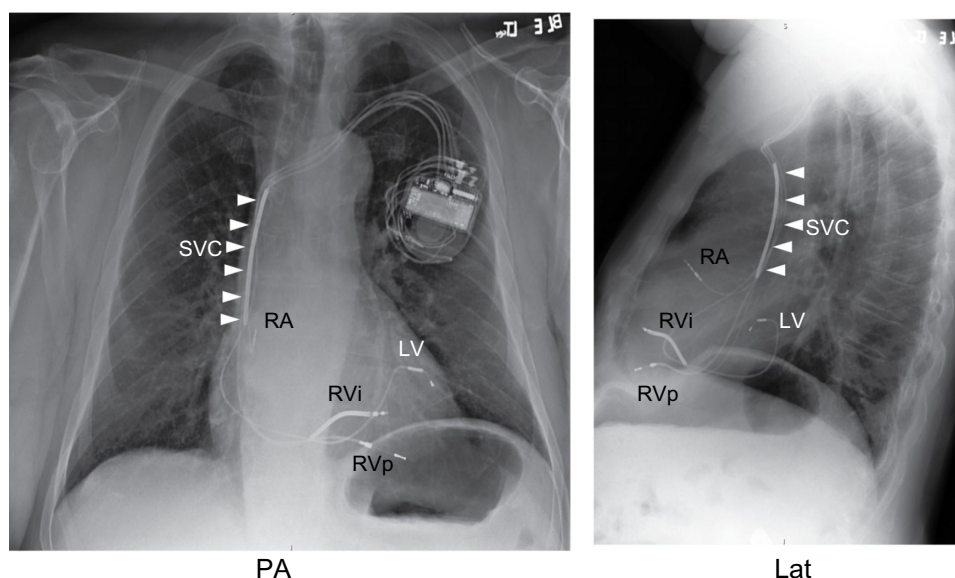
Figure 2 Posteroanterior and lateral chest radiographs of a patient with an ICD in place.
Notes: The implanted device provides both cardiac resynchronization therapy and defibrillator capabilities (CRT-D device). The device uses an ICD lead placed in the middle of the anteroseptal wall of the right ventricle (RVi), an atrial lead placed in the right atrial appendage (RA), and a lead placed in a venous branch of the coronary sinus (LV). There is also an abandoned pacemaker lead (RVp) that is not in use (the proximal end has been capped in the pocket). Notice the relatively posterior location of the left ventricle in comparison to the anterior right ventricle on the lateral view. The ICD lead can be identified by the presence of the larger coil electrodes (arrowheads). This ICD lead has a distal coil placed in the right ventricle and a proximal coil in the SVC.
Abbreviations: ICD, internal cardioverter defibrillator; Lat, lateral; PA, posteroanterior; SVC, superior vena cava.

provided by the addition of the SVC coil has the theoretical advantage of reducing impedance and the amount of energy required to defibrillate the heart (formally measured as the defibrillation threshold). The data from clinical studies are mixed. The presence of a dual-coil ICD lead was not associated with reduced defibrillation threshold in SCD-HeFT but did reduced thresholds slightly in MADIT-CRT.[75,76] In both analyses, the presence of a dual-coil ICD lead did not reduce mortality or improve clinical outcomes. However, dual-coil leads are associated with an increased risk of complications associated with lead extraction, and single-coil leads are preferred in younger patients who have a higher likelihood of requiring future lead extraction.[77]

Device failure

In patients implanted with ICDs, device failure is an important postimplant cause of morbidity and mortality. High-voltage lead failures and device malfunctions can cause inappropriate shocks and failure to detect malignant arrhythmias.[78,79] The ICD lead is the most likely component to fail because of the repetitive stress placed on leads from cardiac motion, respiration, and musculoskeletal motion. Lead failures can result from improper implantation and lead design defects but are frequently due to the stress from normal activity.[80] Between 1990 and 2000, safety alerts and recalls affected 114,645 ICD devices.[81] The Medtronic Sprint Fidelis and St Jude Riata and Riata ST are ICD lead

designs that were available for commercial use and widely implanted but then later withdrawn from the market when it was recognized that they were associated with a higher-than-expected failure rate. Close to half of a million leads were implanted before recognition of premature failure of the Spring Fidelis and Riata family leads.[80] As a historical comparison, in the AVID trial, 2.8% of leads failed, and 0.7% of generators failed during the course of the trial, while in MADIT-II, 1.8% of leads failed.[16,82] The failure rate of modern ICD leads is currently estimated to be 0.58% per year.[80] A method for early identification of ICD leads and devices is critical and has an important potential role for large registries.[83] It is important to note that even when an ICD component has been recalled due to a higher-than-expected failure rate, <1% of recalled ICD components have malfunctioned, and the overall additional mortality from recalled devices is low.[81]

Device monitoring and follow-up

Device follow-up and monitoring are essential to ensure optimal function, and improve clinical efficacy. Initially, face-to-face meetings were the only method for patient follow-up. More than 40 years ago, clinic visits were supplemented with transtelephonic checks. However, over the last decade, remote-monitoring capabilities of ICDs have expanded dramatically and allow more rapid identification of device failure, potential deterioration of a patient's clinical

Table 2 Randomized studies on remote monitoring and ICDs

Trial (sponsor)	Number (initially enrolled)	Follow-up	Findings
ICD			
TRUST[6] (Biotronik)	908 (1,339)	15 months	Remote monitoring reduced the time for arrhythmia identification, from 36 days to less than 2 days
EVATEL[36] (French Department of Health)	1,434 (1,501)	12 months	No difference in remote follow-up vs office visit follow-up in preventing major clinic adverse event
ECOST[14] (Biotronik)	433	24 months	Remote monitoring significantly lowered the number of appropriate and inappropriate shocks delivered and was associated with an 18% decrease in health care costs
ICD/CRT-D			
CONNECT[5] (Medtronic)	1,980 (1,997)	15 months	Remote monitoring reduced the time from clinical event to clinical decision from 22 days to 5 days
EVOLVO[11] (Medtronic)	200	16 months	Identification of worsening heart failure by remote monitoring was associated with rapid assessment of patient status (less than 2 days) with a 35% decrease in emergency department or urgent in-office evaluation

Abbreviations: CONNECT, Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision Trial; ICD, internal cardioverter defibrillator; TRUST, The Lumos-T Safely Reduces Routine Office Device Follow-up.

status, and better utilization of health care and patient resources.[84–88]

Several studies evaluating the effectiveness and safety of remote monitoring for ICD devices have been performed. Five large trials have evaluated the use of remote monitoring in patients with ICD or CRT-D implantation (Table 2).[84–88] The Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) investigators found a reduction in in-hospital device evaluations by 45% with no increase in morbidity. The researchers also found a reduced time to arrhythmia detection from 36 days to <2 days and a significant increase in the number of events leading to device reprogramming in the remote-monitoring population.[85] In the Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision Trial (CONNECT), under 2,000 patients were randomized to remote monitoring or standard clinical follow-up. The CONNECT found a significantly reduced time to clinical decision after clinical event from 22 days to 4.5 days, as well as noting a significant reduction in length of hospital stays for cardiovascular hospitalizations.[86] The MONITOR-ICD study is currently underway and is designed to evaluate the economic and clinical effects of ICD remote monitoring. The last patient was enrolled in January of 2013, and results from this analysis are pending.[89] Remote monitoring is now established as an essential part of ICD follow-up, and a multisociety document that will be published in 2015 will provide guidance on best practice.

New technologies
Subcutaneous ICDs

One of the important drawbacks of the current ICD technology is the requirement for an endovascular lead. As previously noted, the failure rate of ICD leads is not trivial, and if ICD lead removal is required for management of infection or is considered for eliminating extraneous hardware, extraction is associated with morbidity and mortality (Figure 3). Completely subcutaneous ICDs (S-ICDs) are now available worldwide for implantation. A specialized lead is placed vertically parallel to the sternum and then horizontally across the anterior chest where it is attached to an ICD can placed in the anterior axillary region (Figure 4). The lead has three electrodes, a distal sensing electrode at the lead tip, a proximal sensing electrode placed near the xyphoid process, and an intervening shocking electrode between the two sensing electrodes. The defibrillation energy is delivered between the shocking electrode and the ICD can. Major benefits include a reduced need for fluoroscopy at implantation, and elimination of an endovascular lead.[90] S-ICDs have been shown to have the lowest rate of inappropriate discharges of any ICD.[91] Despite the very appealing advantages, S-ICDs have some drawbacks. Current S-ICDs
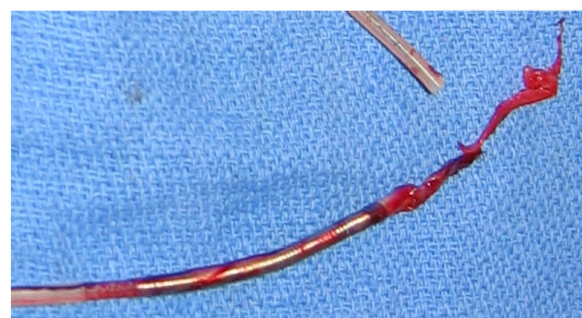

Figure 3 Gross anatomy of an ICD lead that has been removed due to infection.
Note: Notice the significant amount of adherent fibrotic tissue that is removed when the lead is extracted.
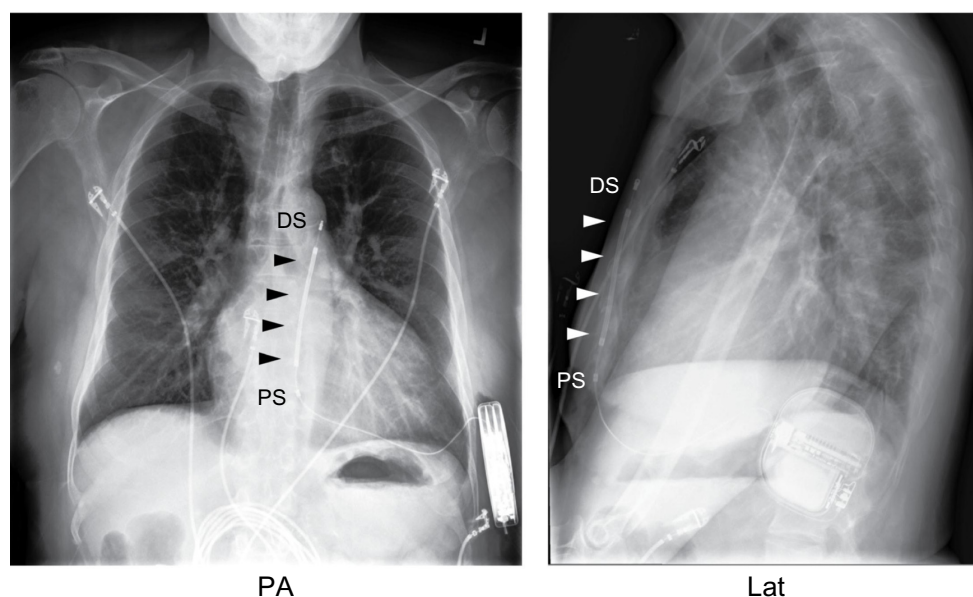**Abbreviation:** ICD, internal cardioverter defibrillator.

Figure 4 Posteroanterior and lateral chest radiographs of a patient with a subcutaneous ICD.
Notes: Notice that the lead travels anteriorly across the chest and has three electrodes that can be best seen in the posteroanterior image: A distal sensing electrode (DS), a proximal sensing electrode (PS), and an intervening coil electrode (arrowheads).
Abbreviation: ICD, internal cardioverter defibrillator.

have no programming options for long-term pacing or ATP for ventricular arrhythmias, although future generations of ICD will likely integrate leadless pacing technologies that will obviate this problem. Due to the distance between the leads and the heart, the device has to release higher energy discharges, and the current generation of S-ICD cans are 30% larger than their transvenous counterparts. Again, this problem will likely be overcome with continued improvements in battery chemistry and circuitry design. Even without these technologic advancements, the current generation of S-ICDs are particularly appealing for some patients. For example, an S-ICD is an intriguing option in the patient on hemodialysis with minimal intravascular options. Since younger patients are more likely to experience lead failure or require lead extraction over their lifetime, an S-ICD may be the best option for this patient population. The S-ICD could also be useful in patients with congenital heart disease where anatomy prevents placement of an endovascular lead in the ventricle. Although theoretically advantageous in these patient populations, supporting data are sparse limited to case reports or small case series.

Percutaneous ICD

Fully operational intravascular defibrillators have undergone testing in canine models, and may be a viable replacement for ICDs in future years. These defibrillators are anchored in the subclavian vein and descend down the vena cava via the right atrium. The device contains electrodes in the SVC

and inferior vena cava and a single-coil lead in the right ventricle.[92] Still in its infancy, the percutaneous ICD's efficacy remains untested, and many challenges surrounding generator exchange and explantation are foreseen.

Magnetic resonance imaging-compatible ICDs

Magnetic resonance imaging is often recommended for optimal imaging in a variety of settings.[93,94] Magnetic resonance imaging is generally not recommended in patients with ICDs, although it can be performed in selected patients with ICDs if clinically necessary.[95,96] All of the manufacturers have developed ICDs designed to function in the magnetic resonance imaging environment that are in varying stages of development and approval. Although none of these ICDs are approved for use in the US, ICDs from several manufacturers have received Conformite Europeenne Mark and can be implanted in Europe.

Conclusion

Over the last two decades, ICD technology has matured into an established and essential treatment option for patients at high risk for ventricular arrhythmias. The landmark trials, MADIT-II and SCD-HeFT, firmly established the additional benefit of the ICD over conventional therapies including the use of antiarrhythmic medication (amiodarone) for saving lives. Our knowledge of best use of ICD therapy has also expanded with a more nuanced understanding of the potential

benefits and problems with ICDs in individual patients, best programming algorithms to improve survival and QOL, and optimal follow-up recommendations.

Disclosure

The authors report no conflicts of interest in this work.

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