REVIEW ARTICLE

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Cardiac Implantable Electronic Devices

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Cardiac implantable electronic devices (CIEDs) constitute a major breakthrough in the management of heart rhythm disorders. These devices largely include bradycardia pacemakers, biventricular pacemakers, and implantable cardioverter–defibrillators (ICDs). In the United States, more than 400,000 CIEDs are implanted every year.[1,2] The increasing number of patients with a CIED has made it necessary for all clinicians to have a basic understanding of what these devices do, the evidence supporting their use, their possible contribution to the overall clinical presentation, and the consideration of how they should be managed when surgery, a nonsurgical procedure, magnetic resonance imaging (MRI), or radiation therapy is planned.

BRADYCARDIA PACEMAKERS

Of all the available CIEDs, bradycardia pacemakers have been around the longest. Indications for bradycardia pacemakers include sick sinus syndrome and type II second-degree, high-grade, and complete heart block.[3] Numerous randomized clinical trials have compared the outcomes of different pacing modes for management of sick sinus syndrome and advanced heart block[4-11] (Table 1). For patients with sick sinus syndrome, dual-chamber (atrial and ventricular) pacing has been shown to improve outcomes.[4-7,9] Although single-chamber ventricular pacing and dual-chamber pacing have a similar effect on outcomes in patients with high-grade atrioventricular block,[6,8,10] dual-chamber pacing is preferred for most patients in order to prevent the pacemaker syndrome.[3]

Although conventional bradycardia pacing is beneficial, insertion of such devices carries known risks. About 10% of patients have a complication within 5 years after implantation of a conventional pacemaker.[12,13] To avoid pacemaker pocket and lead-related complications, the leadless pacemaker was developed.[14-16] The initial leadless pacemaker was capable of right ventricular pacing only. However, newer versions of the pacemaker can sense and track mechanical activity in the right atrium and pace in the right ventricle (although atrioventricular synchrony is not consistently achieved at lower rates and is lost at rates >135 beats per minute). One of the newer versions is capable of pacing in the right atrium and the right ventricle. Data are needed to address the question of whether replacement or the addition of a new leadless device is preferable in managing a leadless pacemaker at the end of battery life.

To date, there is a dearth of randomized, controlled trial data on the outcomes of leadless pacing as compared with those of conventional transvenous pacing. Data from observational studies show a high success rate for implantation of leadless pacemakers in real-world settings (approximately 99%) and a low rate of major complications.[17,18] In observational studies using historical data or Medicare claims data on conventional transvenous pacemakers as controls, the risk of major complications with a leadless pacemaker was 31 to 63% lower than the risk with conven-

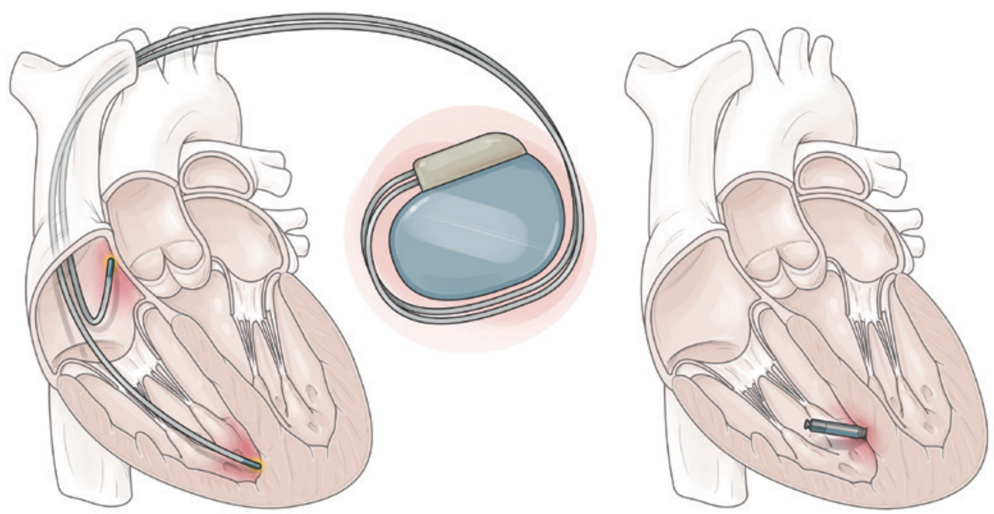
Table 1. Randomized Clinical Trials (RCTs) of Bradycardia Pacemakers.

RCT and Year	Sample Size	Follow-up	Patient Population	Primary End Point	Main Findings
	no. of patients	*yr*			
Atrial vs. ventricular pacing,[4] 1994	225	5	Sick sinus syndrome	Atrial fibrillation, thromboembolism, death	Atrial pacing resulted in significantly lower rates of atrial fibrillation and thromboembolic events but not death
Longer follow-up of atrial vs. ventricular pacing,[5] 1997	225	8	Sick sinus syndrome	Atrial fibrillation, thromboembolism, death, heart failure	Atrial pacing resulted in significantly less atrial fibrillation, fewer thromboembolic events, and lower rates of death and heart failure
Pacemaker Selection in the Elderly (PSE),[6] 1998	407	2.5	Age ≥65 yr, sinus rhythm, bradycardia pacing indication	Health-related quality of life per 36-item Medical Outcomes Study Short-Form General Health Survey	Patients with sinus-node dysfunction, but not those with atrioventricular block, had moderately better quality of life and cardiovascular functional status with dual-chamber pacing than with ventricular pacing
Mode Selection Trial in Sinus-Node Dysfunction (MOST),[7] 2002	2010	2.7	Sick sinus syndrome	Death from any cause or nonfatal stroke	Dual-chamber pacing did not improve stroke-free survival, as compared with ventricular pacing but reduced the risk of atrial fibrillation and signs and symptoms of heart failure and slightly improved quality of life
Canadian Trial of Physiological Pacing (CTOPP),[8] 2000	2568	3	Symptomatic bradycardia with no chronic atrial fibrillation	Stroke or death due to cardiovascular causes	The rate of stroke or cardiovascular death was similar with ventricular and physiologic pacing*
CTOPP,[9] 2004	2568	6	Symptomatic bradycardia with no chronic atrial fibrillation	Stroke or death due to cardiovascular causes	The rate of stroke or cardiovascular death was similar with ventricular and physiologic pacing, but the rate of atrial fibrillation was significantly lower with physiologic pacing*
United Kingdom Pacing and Cardiovascular Events (UKPACE),[10] 2005	2021	4.6	Age ≥70 yr; first pacemaker implantation for high-grade atrioventricular block	All-cause mortality	The effect on mortality was similar with single-chamber ventricular pacing and dual-chamber pacing; there were no significant between-group differences in secondary end points of atrial fibrillation, heart failure, stroke, or other thromboembolic events
Comparison of single-lead atrial pacing with dual-chamber pacing in sick sinus syndrome (DANPACE),[11] 2011	1415	5.4	Sick sinus syndrome	Death from any cause	There was no significant difference in death from any cause between single-chamber atrial pacing and dual-chamber pacing; atrial pacing was associated with a higher risk of paroxysmal atrial fibrillation and 2 times the risk of pacemaker reoperation

* Physiologic pacing refers to atrial-based pacing.

tional transvenous pacemakers during the first year after implantation.[15,16,18,19] The need for device-related reintervention has also been shown to be significantly lower (range, 38 to 41% lower during the first year after implantation) for leadless pacemakers than for conventional pacemakers.[15,16,19]

However, implantation of a leadless pacemaker has been associated with a higher risk of cardiac perforation than implantation of a conventional pacemaker (adjusted risk, 0.8% vs. 0.4%; difference, 0.4 percentage points; 95% confidence interval [CI], 0.1 to 0.7; P=0.004).[19] An analysis of the Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database showed that between June 2016 and July 2021, a total of 563 perforations were reported to have occurred within 30 days after implantation of a leadless pacemaker, leading to 150 deaths (27%) and 146 emergency surgeries (26%).[20] Within 2 to 3 years after implantation, the risks of death from any cause and death due to cardiovascular causes appear to be similar between leadless pacemakers and conventional pacemakers.[15,21] However, a 3-year comparison of the Micra pacemaker (leadless VVI) with a transvenous, single-chamber ventricular pacemaker (transvenous VVI) in the Micra Coverage with Evidence Development (CED) Study, which used Medicare administrative claims data, showed that patients with a leadless VVI had slightly lower rates of hospitalization for heart failure (hazard ratio, 0.90; 95% CI, 0.84 to 0.97).[16]



Conventional Transvenous Pacemaker

Pros:
- Longer duration of use
- Better at ensuring atrioventricular synchrony
- Ability to achieve conduction system pacing

Cons:
- Higher risk of infection
- Higher risk of lead-related complications

Leadless Pacemaker

Pros:
- Lower risk of infection
- No lead-related complications
- Lower need for device-related reintervention

Cons:
- Suboptimal degree of atrioventricular synchrony in many patients
- Higher risk of cardiac perforation
- Inability to achieve conduction system pacing
- Lack of experience with long-term device extraction

Figure 1. Pros and Cons of Various Pacemaker Types.
Adapted from Reynolds et al.[24]

An important advantage of the leadless pacemakers is the significantly lower risk of infection. In the 3-year analysis of the Micra CED Study, the risk of infection was less than 0.2%.[16] Among 720 patients who received a leadless pacemaker in the Micra investigational device exemption trial, 21 serious infections, defined as bacteremia or endocarditis, occurred in 16 patients. None of the infections were deemed to be due to the leadless pacemaker, and no cases of persistent bacteremia after cessation of antibiotic therapy were observed during 13 months of follow-up.[22] The low risk of infection makes leadless pacemakers a particularly good option for patients on hemodialysis. In a study involving 201 patients on hemodialysis, with a mean follow-up of 6 months, no patient had a device-related infection or required device removal due to bacteremia.[23] A comparison of transvenous conventional pacemakers with leadless pacemakers is shown in Figure 1.[24] A dual-chamber leadless pacemaker was investigated in a prospective, multicenter, single-group study[25] involving 300 patients. The primary safety end point, freedom from device and procedure-related complications at 90 days, was met for 271 patients (90.3%), an outcome that surpassed the performance goal of 78% (P<0.001). However, more data are still needed on dual-chamber leadless pacemakers.

An important complication of right ventricular pacing is the development of pacing-induced cardiomyopathy. In studies of conventional transvenous pacing, the incidence of pacing-induced cardiomyopathy ranged from 6 to 25%.[26-28] The most widely accepted definition of pacing-induced cardiomyopathy is a left ventricular ejection fraction (LVEF) of 50% or less, coupled with an absolute reduction of 5 to 10 percentage points from the baseline LVEF. Risk factors for pacing-induced cardiomyopathy include older age, male sex, a history of atrial fibrillation, a wider-paced QRS duration, left ventricular dysfunction at baseline, and a high burden of right ventricular pacing.[26-29] Currently, there is no consensus on what constitutes a high right ventricular pacing burden. Although 40% is widely used, 20% right ventricular pacing can result in pacing-induced cardiomyopathy.[30] Therefore, when possible, right ventricular pacing should be minimized through proper pacemaker programming.[31,32] Although proper programming should be ensured at implantation, it is important to remember that pacemakers often need to be reprogrammed after implantation in order to satisfy the individual needs of patients.

For patients who are expected to have a right ventricular pacing burden that exceeds 20%, cardiac physiologic pacing is becoming the standard.[30] Cardiac physiologic pacing is defined as any form of cardiac pacing that restores or preserves the synchrony of ventricular contraction.[30] Cardiac physiologic pacing can be achieved through cardiac-resynchronization therapy (CRT), which usually involves biventricular pacing, in most cases with the use of a transvenous coronary sinus pacing lead, or with conduction system pacing, in which the right ventricular lead is positioned in the region of the His bundle or the left bundle-branch area.[30]

BIVENTRICULAR PACEMAKERS

Biventricular pacing has revolutionized the treatment and outcomes of heart failure and a reduced ejection fraction. Class I and class IIa indications for biventricular pacing are grouped as follows: an LVEF of 35% or lower, left bundle-branch block, a QRS duration of 150 msec or longer, and New York Heart Association (NYHA) class III or ambulatory class IV despite optimal medical therapy for heart failure; an LVEF of 35% or lower, left bundle-branch block with a QRS duration of 130 msec or longer, and NYHA class II, III, or ambulatory class IV despite optimal medical therapy for heart failure; and an LVEF of 35% or lower, no left bundle-branch block, a QRS duration of 150 msec or longer, and NYHA class II, III, or ambulatory class IV despite optimal medical therapy for heart failure.[33] The pivotal randomized trials supporting these recommendations are shown in Table 2.[34-37]

An important recommendation for cardiac physiologic pacing concerns patients with an indication for permanent pacing and an LVEF of 36 to 50% who are expected to have substantial right ventricular pacing (20 to 40%). For such patients, cardiac physiologic pacing is reasonable in order to reduce the risk of pacing-induced cardiomyopathy.[30] This recommendation is supported by the results of the BLOCK HF (Biventricular versus Right Ventricular Pacing in Heart Failure Patients with Atrioventricular Block) trial, which showed that in patients with heart failure and an LVEF of 50% or less who were expected to have a high right ventricular pacing burden,

Table 2. RCTs of Cardiac-Resynchronization Therapy (CRT) and an Implantable Cardioverter–Defibrillator (ICD).*

RCT and Year	Sample Size	Follow-up	Patient Population	Primary End Point	Main Findings
	no. of patients	*mo*			
CRT for heart failure with a reduced ejection fraction					
Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION),[34] 2004	1520	11.9–16.2	NYHA class III or IV due to ischemic or nonischemic cardiomyopathy, QRS duration ≥120 msec	Time to death from any cause or hospitalization for any cause	As compared with medical therapy, CRT with a pacemaker reduced the risk of the primary end point (HR, 0.81; P=0.02), as did CRT with a pacemaker–defibrillator (HR 0.80; P=0.01)
Cardiac Resynchronization — Heart Failure (CARE-HF),[35] 2005	813	29.4	NYHA class III or IV heart failure due to systolic dysfunction, cardiac dyssynchrony, on standard pharmacologic therapy	Time to death from any cause or an unplanned hospitalization for a major cardiovascular event	The primary end point occurred in 159 patients in the CRT group vs. 224 patients in the medical therapy group (39% vs. 55%; HR, 0.63; 95% CI, 0.51 to 0.77; P<0.001)
Multicenter Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT),[36] 2009	1820	28.8	NYHA class I or II symptoms due to ischemic or nonischemic cardiomyopathy, LVEF ≤30%, QRS duration ≥130 msec	Death from any cause or a nonfatal heart failure event	The primary end point was observed in 187 of 1089 patients in the CRT–ICD group (17%) and 185 of 731 patients in the ICD-only group (25%) (HR, 0.66; 95% CI, 0.52 to 0.84; P=0.001)
Resynchronization–Defibrillation for Ambulatory Heart Failure Trial (RAFT),[37] 2010	1798	40	NYHA class II or III heart failure, LVEF ≤30%, intrinsic QRS duration ≥120 msec or a paced QRS duration ≥200 msec	Death from any cause or hospitalization for heart failure	The primary outcome was observed in 297 of 894 patients (33%) in the ICD–CRT group and 364 of 904 patients (40%) in the ICD group (HR, 0.75; 95% CI, 0.64 to 0.87; P<0.001)
Transvenous ICDs					
Antiarrhythmics vs. Implantable Defibrillators (AVID) Trial,[38] 1997	1016	18.2	Resuscitated from near-fatal ventricular fibrillation, sustained ventricular tachycardia with syncope, or sustained ventricular tachycardia with LVEF ≤40% and hemodynamic compromise	All-cause mortality	Reductions in mortality with the ICD were 39±20% at 1 yr, 27±21% at 2 yr, and 31±21% at 3 yr

Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II),[39] 2002	1232	20	Prior myocardial infarction and LVEF ≤30%	All-cause mortality	The HR for death from any cause in the ICD group vs. the conventional medical therapy group was 0.69 (95% CI, 0.51 to 0.93; P=0.02)
Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE),[40] 2004	458	29	Nonischemic cardiomyopathy, LVEF ≤ 35%, premature ventricular complexes or nonsustained ventricular tachycardia	All-cause mortality	The HR for death from any cause in the ICD group vs. the medical therapy group was 0.65 (95% CI, 0.40 to 1.06; P=0.08)
Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT),[41] 2005	2521	45.5	NYHA class II or III, HF due to ischemic or nonischemic cardiomyopathy, and LVEF ≤35%	All-cause mortality	As compared with placebo, amiodarone resulted in a similar risk of death (HR, 1.06; 97.5% CI, 0.86 to 1.30; P=0.53); the ICD decreased the risk of death by 23% (HR, 0.77; 97.5% CI, 0.62 to 0.96; P=0.007)

* Plus–minus values are means ±SD. HR denotes hazard ratio, LVEF left ventricular ejection fraction, and NYHA New York Heart Association.

biventricular pacing was superior to right ventricular pacing in increasing the time to death, reducing the need for an urgent care visit for heart failure requiring intravenous therapy, and reducing the risk of a 15% or greater increase in the left ventricular end-systolic volume index.[42] However, these results were not replicated by BioPace (Biventricular Pacing for Atrio-Ventricular Block to Prevent Cardiac Desynchronization Study).[43] Since a report on the full results of the trial was never published, the BLOCK HF findings have had a larger impact on guidelines and clinical practice.[3,30,42,43]

Determinants of a benefit from biventricular pacing include patient characteristics, the location of the left ventricular lead (a nonapical lateral or posterolateral location is best), and optimal programming of the device to ensure more than 97% biventricular pacing.[44] Patient characteristics that portend a higher likelihood of a benefit from biventricular pacing include left bundle-branch block, nonischemic cardiomyopathy, and female sex.[45,46] Evidence that women derive a benefit from biventricular pacing at a shorter QRS duration than do men informed a new class I recommendation of biventricular pacing for women who have an LVEF of 35% or lower, sinus rhythm, left bundle-branch block with a QRS duration of 120 to 149 msec, and NYHA class II, III, or IV symptoms while receiving optimal medical therapy.[30] The cumulative evidence supports a role for biventricular pacing in patients with atrial fibrillation. Thus, biventricular pacing is recommended for improvements in the quality of life, functional capacity, and LVEF in patients with atrial fibrillation.[30]

CONDUCTION SYSTEM PACING

Although conduction system pacing started with His bundle pacing, left bundle-branch area pacing is quickly becoming the standard because of easier deployment and a lower risk of lead dislodgement during follow-up.[30] In a prospective, multicenter cohort study of left bundle-branch area pacing in 63 patients with nonischemic cardiomyopathy, the mean (±SD) QRS complex shortened from 169±16 msec to 118±12 msec (P<0.001), the LVEF increased from 33±8% to 55±10% (P<0.001), the left ventricular end-systolic volume decreased from 123±61 ml to 67±39 ml (P<0.001), and the NYHA class improved from 2.8±0.6 at baseline to 1.4±0.6 at 1 year.[47] An international, multicenter, collaborative study involving 325 patients showed that left bundle-branch area pacing was associated with a narrowing of the QRS complex, from 152±32 msec to 137±22 msec (P<0.01), and an increase in the LVEF, from 33±10% to 44±11% (P<0.01) during 6 months of follow-up.[48] Clinical improvements were seen in 72% of the patients, and echocardiographic improvements were seen in 73% of the patients.

In a randomized trial involving 40 patients with nonischemic cardiomyopathy and left bundle-branch block, after 6 months of follow-up, LVEF improvement was significantly greater with left bundle-branch area pacing than with biventricular pacing (mean difference, 5.6%; 95% CI, 0.3 to 10.9; P=0.04).[49] Left bundle-branch area pacing also resulted in greater reductions in left ventricular end-systolic volume and N-terminal pro–brain natriuretic peptide, with similar changes in NYHA class, 6-minute walk distance, QRS duration, and rates of CRT response.

A prospective, multicenter, nonrandomized study compared left bundle-branch area pacing with biventricular pacing in 371 patients.[50] During a median follow-up of 340 days, the composite end point of hospitalization for heart failure and all-cause mortality occurred in 24.2% of patients in the group assigned to left bundle-branch area pacing as compared with 42.4% of those in the biventricular pacing group (hazard ratio, 0.621; 95% CI, 0.415 to 0.93; P=0.02). Left bundle-branch area pacing was associated with a shorter QRS duration (123.7±18 msec vs. 149.3±29.1 msec, P<0.001) and a higher postprocedural LVEF (34.1±12.5% vs. 31.4±10.8%, P=0.04). In an observational study involving 1778 patients with an LVEF of 35% or less who received first-time biventricular pacing (981 patients) or left bundle-branch area pacing (797 patients) for a class I or II indication for CRT, the adjusted incidence of the primary outcome, death or hospitalization for heart failure in a time-to-event analysis, was significantly reduced with left bundle-branch area pacing than with biventricular pacing (20.8% vs. 28%; hazard ratio, 1.495; 95% CI, 1.213 to 1.842; P<0.001).[51] LVEF improvement was significantly greater with left bundle-branch area pacing than with biventricular pacing (13±12% vs. 10±12%, P<0.001). How to select the best pacemaker type for a given patient is summarized in Figure 2.

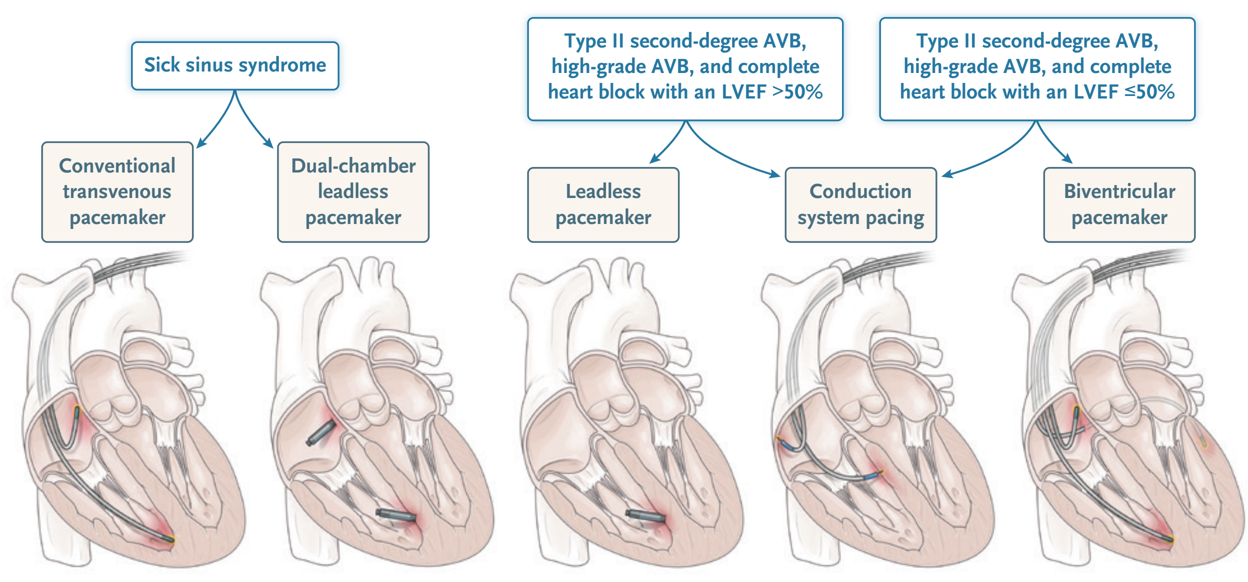


Figure 2. Selecting a Pacemaker Type for a Given Patient.

A conventional transvenous pacemaker has a right ventricular lead in an apical or septal position (and excludes conduction system pacing). Adapted from Jarcho,[52] Reynolds et al.,[24] and Knops et al.[25] AVB denotes atrioventricular block, and LVEF left ventricular ejection fraction.

IMPLANTABLE CARDIOVERTER–DEFIBRILLATORS

The ICD is one of the most effective therapies currently available for the prevention of sudden death from cardiac causes, the most common cause of death in developed countries.[53] Common indications for an ICD include sustained ventricular arrhythmias or sudden cardiac arrest not due to a reversible cause; chronic systolic heart failure due to ischemic or nonischemic cardiomyopathy, an LVEF of 35% or lower, and NYHA class II or III despite optimal medical therapy for heart failure; chronic systolic heart failure due to ischemic cardiomyopathy, an LVEF of 30% or lower, and NYHA class I despite optimal medical therapy for heart failure; and inherited cardiomyopathies (e.g., hypertrophic cardiomyopathy) and channelopathies (e.g., the long QT syndrome).[53] The pivotal randomized trials informing the first three sets of indications are shown in Table 2.[38-41] There is also real-world evidence of the effectiveness of ICDs for primary prevention in patients with heart failure (the second and third sets of indications above) overall and in important subgroups such as women, Black patients, and even patients with coexisting conditions.[54-58]

Prior study results supporting use of ICDs in patients with nonischemic cardiomyopathy were challenged by the findings of DANISH (Danish Study to Assess the Efficacy of ICDs in Patients with Non-Ischemic Systolic Heart Failure on Mortality), which showed that ICDs used for primary prevention did not improve survival.[59] Potential explanations for these disparate findings between DANISH and prior trials include selection of patients at higher risk for death from heart failure than for sudden death from cardiac causes, enrollment of a majority of patients who received a CRT device, and the salutary effects of improved medical therapy for heart failure on the risk of sudden death from cardiac causes. More data are needed on the outcomes of ICD use in patients with nonischemic cardiomyopathy.

An important advance in ICDs is an entirely subcutaneous ICD, which was introduced to prevent transvenous lead–related issues such as infection, fracture, dislodgement, and tricuspid regurgitation.[60] The subcutaneous ICD is a particularly attractive option for patients who have a high risk of infection and those with venous access issues.[53,61] Two randomized trials have compared the outcomes of subcutaneous ICDs with transvenous ICDs.[62,63] The PRAETORIAN (Prospective Randomized Comparison of Subcutaneous and Transvenous Implantable Cardioverter Defibrillator Therapy) trial, which randomly assigned 849 patients with guideline-recommended indications for an ICD to a transvenous ICD (423 patients) or a subcutaneous ICD (426 patients), showed that during a median follow-up of 49.1 months, the primary end point of device-related complications and inappropriate shocks (delivered for causes other than ventricular arrhythmias) was similar in the two groups (hazard ratio for subcutaneous ICDs, 0.99; 95% CI, 0.71 to 1.39; P=0.01 for noninferiority).[62]

The ATLAS (Avoid Transvenous Leads in Appropriate Subjects) trial compared subcutaneous ICDs with transvenous ICDs in 544 patients who had guideline-based indications for an ICD, were 60 years of age or younger, and had prespecified risk factors for lead complications.[63] During a mean follow-up of 2.5 years, perioperative, lead-related complications were significantly reduced in the group of patients who received subcutaneous ICDs as compared with the transvenous ICD group (1 of 251 patients [0.4%] vs. 12 of 252 [4.8%]; difference, −4.4 percentage points; 95% CI, −6.9 to −1.9; P=0.001). Data from registries have shown good outcomes with subcutaneous ICDs and a significant reduction in the risk of inappropriate shocks with the newer models.[64-67] Although the subcutaneous ICD does not provide pacing, studies are under way to determine whether this device can effectively and safely be paired with a leadless pacemaker.

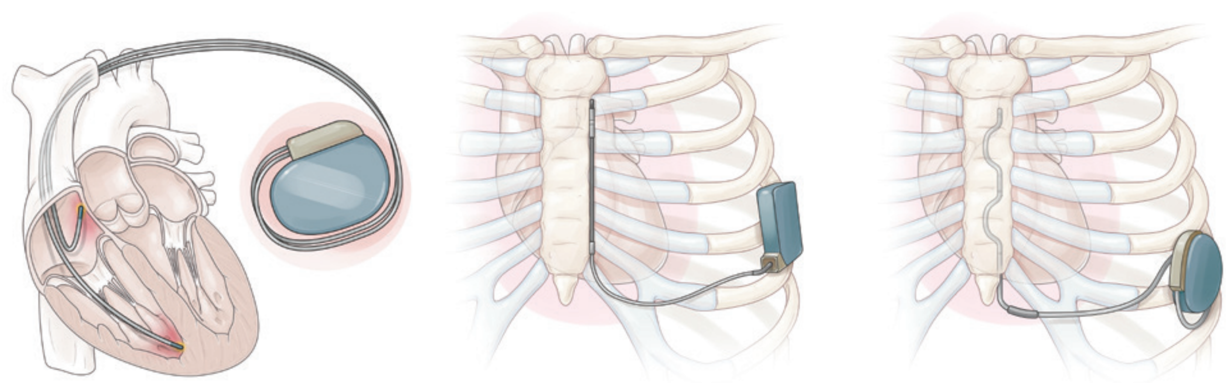
The pros and cons of each type of ICD should be included in shared decision-making discussions with patients. These discussions should cover not just the lower risk of complications with the subcutaneous ICD but also its larger size, shorter battery life, and inability to provide pacing, including antitachycardia pacing to terminate ventricular arrhythmias. In addition, patients who are candidates for a subcutaneous ICD should be informed about the need for screening with a special electrocardiogram (ECG) to reduce the risk of inappropriate shocks. About 10% of candidates do not pass the screening. Figure 3 shows the main differences among the transvenous ICD, the subcutaneous ICD, and the extravascular ICD.

To overcome some of the limitations of the subcutaneous ICD (e.g., size and inability to pace), the extravascular ICD was invented. In a prospective, nonrandomized, premarket global clinical trial, 316 patients with guideline indications for an ICD received an extravascular ICD system and underwent defibrillation threshold testing.[68] Defibrillation was successful in 98.7% of the patients (P<0.001 for the comparison with the performance goal of 88%). A total of 29 patients received 118 inappropriate shocks for 81 arrhythmic episodes.

All current ICDs are magnetic resonance imaging (MRI)–conditional (meaning that they are safe in an MRI environment provided that specific conditions are met) and are very effective at terminating ventricular arrhythmias. In addition, these devices can discriminate ventricular arrhythmias from supraventricular arrhythmias, a feature that has led to reduced rates of inappropriate shocks.[53,69] Implementation of optimal ICD programming by setting longer detection durations and higher rate cutoffs for ventricular arrhythmias has further reduced the risk of inappropriate shocks.[70,71]

POSSIBLE CONTRIBUTION OF CIEDS TO THE CLINICAL PRESENTATION

In patients with a CIED, it is critically important to consider whether and, if so, how the CIED may be contributing to the overall clinical presentation. Patients who have a CIED and present with any symptom or sign of a systemic infection should be evaluated for a device-related infection, which in some patients may be quite subtle.[72] It is also imperative for clinicians to realize that bacteremia may be an indication for device and lead extraction, even in the absence of signs of device pocket infection, and involving the electrophysiology team early in the care of



Conventional Transvenous ICD	Subcutaneous ICD	Extravascular ICD
Pros: • Longer duration of use • Supported by the strongest evidence • Capable of bradycardia, antitachycardia, and, in some, biventricular pacing • Longest battery life Cons: • Higher risk of infection • Higher risk of lead-related complications	Pros: • Lower risk of infection • Lower risk of lead-related complications Cons: • Largest size • Shorter battery life • Not capable of bradycardia, antitachycardia, or biventricular pacing	Pros: • Lower risk of lead-related complications • Capable of bradycardia and antitachycardia pacing Cons: • No clinical practice data (not FDA-approved for clinical use in the United States) • Higher risk of inappropriate shocks • Logistic difficulties in aligning electrophysiologist's availability with thoracic surgeon's availability

Figure 3. Pros and Cons of Various ICD Types.
Adapted from Bardy et al.[60] and Friedman et al.[68] ICD denotes implantable cardioverter–defibrillator.

such patients is advisable.[72] For patients presenting with cardiac symptoms, signs, or both, the CIED should be checked to assess the battery longevity and to rule out device or lead malfunction, inappropriate or suboptimal device programming, a high right ventricular pacing burden, and arrhythmias recorded by the device that may be responsible for the patient's presentation. Many ICDs and biventricular pacemakers provide data on the volume status that may inform the treatment of heart failure.[73,74] Many CIEDs are monitored remotely, and information about the integrity of the device or leads and the occurrence of arrhythmias can be retrieved from remote transmissions.

CIED MANAGEMENT FOR SURGERY, NONSURGICAL PROCEDURES, MRI, AND RADIATION THERAPY

Clinicians involved in procedures that use any sources of electromagnetic interference should be aware of best practices related to the perioperative management of CIEDs. Such practices tailor the management plan to the individual patient, the type of CIED, the type of surgery, and the location of the device in relation to the surgical site.[75] The surgical team should implement the management plan proposed by the CIED team, which can largely be derived from the CIED clinic records, which specifies when devices should be reprogrammed or when a magnet should be applied (to disable sensing) in order to prevent electromagnetic interference from inhibiting pacing in pacemaker-dependent patients and from causing inappropriate ICD shocks. Only a minority of patients require assessment by a CIED specialist perioperatively. It is recommended that patients with pacemakers who will be undergoing elective surgery have their device checked as part of routine care during the preceding 12 months, and patients with ICDs who will be undergoing elective surgery should have their ICD checked as part of routine care during the preceding 6 months.[75]

Newer-generation CIEDs are MRI-conditional. However, some patients have devices that are not MRI-conditional or have abandoned or epicardial leads that preclude MRI. If MRI is urgently needed, the electrophysiology team should be consulted regarding how to maximize the safety of MRI in these circumstances.

If a CIED is directly in the field of radiation therapy, it should be moved to another site. If a CIED is not directly in the field of radiation therapy, damage to the device is infrequent. Factors that warrant heightened monitoring during and after radiation therapy[76] include pacemaker dependency, the presence of an ICD, exposure to neutron contamination, and an increase in the absorbed radiation dose because of the proximity of the device to the radiation field. Generally, patients with any of these factors should undergo close monitoring and magnet application during radiation therapy and routine weekly device interrogations (in person or through remote monitoring). A multidisciplinary approach that involves radiation oncologists, cardio-oncologists, and electrophysiologists is necessary to ensure the safety of patients with CIEDs who are receiving radiation therapy.[76]

CONCLUSIONS AND FUTURE DIRECTIONS

The field of CIEDs has evolved substantially in the past two decades, and evidence is accumulating with respect to which patients benefit most from different methods of pacing and various types of ICD. Despite these major advances, several gaps in knowledge remain. In relation to pacing, we need to determine both how to optimize the effectiveness and safety of dual-chamber, leadless pacemakers and whether leadless pacemakers could be developed that would allow conduction system pacing. More data are needed on how the effectiveness and safety of His or left bundle-branch area pacing compare with those of biventricular pacing. This question is being assessed by the Left vs. Left pragmatic randomized trial, which is enrolling patients with an LVEF of 50% or less and either a wide QRS complex (≥130 msec) or anticipated pacing of 40% or more.[76]

More data are needed on the role of ICDs for primary prevention in patients with nonischemic cardiomyopathy; the outcomes of subcutaneous ICDs in patients not included or not well represented in prior studies, such as patients with hypertrophic cardiomyopathy; and the outcomes of extravascular ICDs. Other data gaps concern the identification of patients who are most likely to benefit from an ICD among all ICD-eligible patients and the development of methods to identify and treat patients at high personal risk for sudden death from cardiac causes who are not identified by current ICD guidelines.[53] Filling these gaps will enable clinicians to deliver personalized care, ensuring that patients receive the type of CIED that will provide the greatest benefit.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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