Wearable Cardioverter-Defibrillator Therapy for the Prevention of Sudden Cardiac Death

A Science Advisory From the American Heart Association

Endorsed by the Heart Rhythm Society

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Sudden cardiac death (SCD) accounts for >300 000 deaths in the United States annually.[1] Although the majority of these deaths occur in low-risk populations[2] in which aggressive interventions are not practical, some higher-risk populations have been established in whom intervention with an implantable cardioverter-defibrillator (ICD) has been shown in randomized trials to reduce mortality.[3–7] Additionally, there is a population of patients who may benefit from automatic emergency cardioversion-defibrillation but are not deemed appropriate candidates for ICD implantation at the time of presentation. This group is defined by 2 populations. The first subgroup comprises those who are at perceived risk but for whom there may be optimism for clinical improvement (eg, patients soon after revascularization or those with a recent diagnosis of myocardial infarction [MI] or cardiomyopathy). Alternatively stated, the optimal management of these patients at risk (or perceived risk) during the waiting period before an ICD is indicated remains unknown. The second subgroup includes those who have a clear indication for ICD but also have a contraindication to immediate ICD placement (eg, active infection or unknown prognosis).

The wearable cardioverter-defibrillator (WCD) is a device designed for patients at risk of SCD who are not immediate candidates for ICD therapy. By providing automatic therapy, the WCD does not depend on a second person to defibrillate, as required with a manual or automated external defibrillator (AED). Unlike the ICD (including both transvenous and subcutaneous devices), the WCD requires no surgical operation, can be provided for a short period of time, is temporary, and is easily removed. These characteristics of the WCD, along with safety and efficacy data presented to the US Food and Drug Administration (FDA), resulted in approval in the United States in 2002.[8]

Because of the increasing use of the WCD and uncertainty of indications among practicing cardiovascular health professionals, this science advisory was prepared by the American Heart Association. In this advisory, we describe the WCD in the context of its unique technology, clinical niche, and alternative therapies. We review the available literature to support the efficacy and safety of WCDs and explore the possible indications for use of this technology. Finally, on the basis of our analysis and pending definitive trials, we provide relative guidance for use of the WCD in clinical practice according to the American Heart Association methods of classifying the consensus on their certainty and level (quality) of evidence available (Table 1). Table 2 provides a summary of the key concepts presented in this science advisory.

Because there is a paucity of prospective data supporting the use of the WCD, particularly the absence of any published, randomized, clinical trials, the recommendations provided in this advisory are not intended to be prescriptive or to suggest an evidence-based approach to the management of patients with FDA-approved indications for use. Instead, these

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Table 1. Applying Classification of Recommendations and Level of Evidence

SIZE OF TREATMENT EFFECT

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT

	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* Procedure/Test / Treatment COR III: No benefit — Not Helpful / No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful / Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated; should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality; should not be performed/ administered/ other
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

recommendations are offered to provide clinicians direction when discussing this therapy with patients. It is our opinion that the final decision on the use of the WCD should be based on shared decision making, which would include a frank risk-benefit discussion between the clinician and the patient that acknowledges the uncertainty surrounding the efficacy and safety of the WCD.

Epidemiology and Prevention of SCD

One in 3 out-of-hospital cardiac arrests is attributable to ventricular tachycardia (VT) or ventricular fibrillation (VF).[1] Despite the efficacy of rapid defibrillation, most patients with VT/VF arrest do not receive timely defibrillation. Although outcomes vary widely between communities in North America, on average, survival from VT/VF arrest averages <1 in 5.[9] Thus, in recent years, efforts have become increasingly proactive and focused on protecting high-risk patient subgroups from arrhythmic death. The most obvious candidates are those with a history of cardiac arrest or sustained ventricular tachyarrhythmias, in whom ICDs are effective.[6] ICDs are also beneficial for the primary prevention of SCD in patients with certain forms of structural heart disease associated with risk of malignant arrhythmias (such as hypertrophic cardiomyopathy) or primary electric disease (such as long-QT syndrome)

Table 2. Key Concepts

SCD remains an important and preventable cause of death.
Despite their obvious benefits, current defibrillator technologies have limitations and risks.
Transient contraindications to implanted device therapy commonly arise in clinical practice.
WCDs can serve as a temporary means of preventing arrhythmic death without the need for bystander response to cardiac arrest.
WCDs use vector analysis of surface electrocardiographic signals to detect life-threatening ventricular arrhythmias.
Patient compliance is an integral part of successful WCD therapy.
Observational data suggest that the WCD can successfully identify and terminate ventricular arrhythmias.
WCD use is reasonable when there is a clear indication for an ICD in the presence of a transient contraindication to an ICD.
WCD use may be appropriate in clinical circumstances associated with transient increased arrhythmic risk.
Risk counseling and discussion of patient preferences are integral parts of patient care and WCD therapy.

ICD indicates implantable cardioverter-defibrillator; SCD, sudden cardiac death; and WCD, wearable cardioverter-defibrillator.

and in those with significantly impaired left ventricular systolic function.[10] The last group includes patients with ischemic or nonischemic heart disease and a persistently depressed left ventricular ejection fraction (LVEF) ≤0.35 combined with New York Heart Association (NYHA) functional class II to III heart failure despite long-term guideline-directed medical therapy or a prior MI and an ejection fraction ≤0.30 in the absence of severe (NYHA functional class IV) heart failure and who are >40 days from their MI.[3–5] These FDA-approved indications are based on and supported by pivotal trials that confirmed a survival benefit from an ICD in these populations.[3,4] Meta-analyses of the major trials suggest a net relative risk reduction of between 20% and 30%.[11,12] Although these indications for ICD placement are widely accepted, the optimal management of patients who are perceived to be at high risk during the waiting period (before definitive ICD implantation is known to be beneficial) remains controversial.[13,14] This waiting period is considered to be 90 days after diagnosis, while guideline-directed medical therapy is implemented and optimized.

At the forefront of the debate are the merits of sudden death prevention in high-risk patients who are in the early phase of recovery from an acute MI (AMI) or with a newly diagnosed nonischemic cardiomyopathy. The rationale for postponing ICD placement under these circumstances is that a substantial portion of patients will experience significant myocardial recovery and improved ventricular function. Additionally, many patients experience improvement after the institution of optimal medical therapies or interventional therapies such that the need for ICD prophylaxis is obviated. For example, partial or complete recovery of LVEF has been observed in more than half of patients at 3 months after AMI after institution of heart failure therapies or revascularization.[15–20] Guideline-directed medical therapy with β-blockade and renin-angiotensin-aldosterone system antagonism during the early period after diagnosis of nonischemic cardiomyopathy may result in improved ventricular function and decreased future risk of SCD; 50% of patients with newly diagnosed nonischemic cardiomyopathy will demonstrate a 10% improvement in LVEF with the initiation of medical therapy.[21,22]

Although the rationale and reasons for postponing ICD implantation are sensible, the current evidence base is incomplete. For example, the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT) excluded patients with a diagnosis of cardiomyopathy of <3 months and those who had not received guideline-directed medical therapy. No available randomized trials have compared early ICD implantation (ie, within 3 months) with standard medical therapy in nonischemic cardiomyopathy. Furthermore, although clinical trials of ICD implantation early after MI have shown no benefit, these trials recruited highly selected patients who often had additional risk factors for increased all-cause mortality. For example, the Immediate Risk Stratification Improves Survival (IRIS) trial mandated an LVEF ≤40% and a resting heart rate >90 bpm or nonsustained VT >150 bpm on Holter monitoring. IRIS screened 62 944 unselected post-MI patients to enroll 898 (1.4% of the total screened). Thus, the generalizability of these trial findings is in question.

An often-expressed concern about the current ICD criteria is the risk of fatal sustained VT/VF during the waiting period. In the Valsartan in Acute Myocardial Infarction Trial (VALIANT) trial, among patients with an ejection fraction of ≤0.30 after MI who were followed up for a median of 24.7 months, 21% of the sudden death or resuscitated cardiac arrest events occurred within the first 30 days after AMI.[23] Although autopsy findings demonstrated that many of the sudden deaths were not arrhythmic in nature, a substantial portion (51%) were arrhythmic.[24] Notably, the majority of the patients in VALIANT who died suddenly or were resuscitated within a month of AMI had also been judged to be in stable clinical condition on hospital discharge.

In the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) Trial,[25] a subgroup analysis of those with a recent diagnosis of cardiomyopathy, mortality was 48% lower in ICD recipients randomized within 9 months of initial diagnosis (9.2% versus 17.7%; P=0.058).[26] Taken together, these findings suggest that benefit from a primary prevention ICD is not time dependent either in nonischemic cardiomyopathy or after AMI and that a comparable risk for life-threatening arrhythmias may exist for these patients at virtually all windows of time after their index event or diagnosis. Admittedly, most trials of primary prevention ICD therapy compared with guideline-directed medical therapy demonstrate that the survival benefits do not really emerge until ≈1 year after implantation, rendering it more difficult to identify an effect from treatment that is confined to an earlier and shorter time interval.[3,4]

Although early ICD implantation appears to decrease SCD, the overall survival benefit from ICD placement early after MI or a new diagnosis of cardiomyopathy has not been substantiated. For example, the suggestion in DEFINITE of improved survival among ICD recipients with newly diagnosed cardiomyopathy was retrospective and statistically inconclusive. In the Cardiomyopathy Trial (CAT), patients with recently diagnosed dilated cardiomyopathy (LVEF

<0.30) derived no measureable benefit from the ICD.[27] The Defibrillator and Acute Myocardial Infarction (DINAMIT) and IRIS trials prospectively randomized patients with significantly impaired ventricular function (ejection fractions of <0.35 and <0.40, respectively), along with other risk factors, to receive an ICD shortly (mean, 18 and 13 days, respectively) after AMI.[28,29] In both trials, the lower rates of sudden death in the ICD arms were paralleled by concomitant increases in nonarrhythmic mortality such that total mortality was ultimately no different in the ICD-treated and medically treated groups. Taken together, these findings do not support a survival benefit from early implanted/permanent defibrillator placement for primary prevention in otherwise high-risk patients.

Defibrillator Technologies and Limitations

Time to defibrillation is crucial in the resuscitation of VT/VF arrest.[30] The probability of survival during VT/VF arrest decreases by 7% to 10% for every minute that defibrillation is delayed without cardiopulmonary resuscitation and 3%/min to 4%/min with cardiopulmonary resuscitation. The development of the AED has been important to improving survival in cases of witnessed VT/VF arrest.[31] An easily accessible AED obviates the need to wait for activation of the emergency medical response system and the arrival of advanced life support personnel (paramedics) with a manual defibrillator. The availability of an AED allows earlier defibrillation by first responder personnel or by laypeople if an AED is strategically located near the scene of the arrest (what has become known as public-access defibrillation).[32] External defibrillators are highly efficacious in treating cardiac arrest resulting from ventricular tachyarrhythmias.[33] However, their overall effectiveness in improving survival after cardiac arrest depends on the time required for their deployment on scene by emergency care providers or the availability of an AED and the presence of a bystander who is willing and able to administer the treatment when needed. A randomized, clinical trial of AED use in the home after AMI failed to identify a survival benefit.[34]

In the relatively small but important minority of patients in whom an increased risk of cardiac arrest is predictable on the basis of clinical risk factors, implantation of a prophylactic defibrillator offers distinct advantages. An ICD, which continuously monitors a patient's rhythm, affords the benefit of minimal delay between the onset of a potentially fatal tachyarrhythmia and its automatically instituted treatment. To their disadvantage, ICDs require surgical placement, including vascular access, and long-term retention of hardware. Adverse event rates associated with implantation range from 1.3% to 11.0%, including bleeding, lead dislodgement, pneumothorax, cardiac perforation, acute infection, and death (0.4%–1.2%).[35] ICDs also have potential for long-term morbidity resulting from component failure, lead dysfunction, inappropriate shocks, vascular occlusion, and infection. Lead longevity is ≈85% at 5 to 10 years after implantation, and removal often necessitates formal extraction with its attendant risks.[36–38] The subcutaneous ICD recently approved by the FDA allays some but not all of these potential concerns.[39] Although functionally analogous to a traditional ICD, the subcutaneous defibrillator system lacks intracardiac leads and thus avoids the need for vascular access and the potential long-term complications from indwelling intravascular hardware. Still, the subcutaneous ICD shares many of the same hazards as transvenous ICDs, including lead dislodgement (2.5%), skin erosion (1.7%), and infection (5.9%), along with a 13% incidence of inappropriate shocks during follow-up.[40] Although subcutaneous ICDs have been shown to effectively terminate electrically induced VF, the effectiveness of the subcutaneous ICD compared with the transvenous ICD in improving survival from spontaneous VF has yet to be established.[41]

External defibrillators and ICDs offer potential lifesaving therapy for malignant tachyarrhythmias. Determining whether and when to deploy such therapies in high-risk patients requires striking a critical balance among available clinical evidence, patient preference, and physician discretion.

Technical Considerations of the WCD

Sensing and Defibrillation

The WCD has several unique sensing and energy delivery mechanisms that distinguish it from other forms of defibrillation. The WCD device consists of 2 primary components, a wearable garment and a battery-powered monitor-defibrillator. The garment is sized to the patient's chest circumference and weight and is worn under clothes against the skin. The garment contains both sensing and defibrillation electrodes. A 4-electrode, 2-lead system, located in the belt of the garment, is used to record surface ECGs for morphology analysis and detection of arrhythmia. The monitor is usually worn on a belt or shoulder strap. WCD devices use analog and digital filters, as well as several algorithms to recognize electromagnetic interference and other sources of noise. The detection algorithms used by the WCD exhibit a sensitivity of 90% to 100% and a specificity of 98% to 99%.[42,43] Inappropriate shock rates in early studies were ≈1% to 2%.[43,44] WCD devices are programmable, with detection rates for both VT and VF zones.

When a WCD detects a potential arrhythmia, a detection and treatment algorithm is initiated. The process incorporates patient interaction. Once an arrhythmia has met the morphology and rate criteria, formal detection occurs, and the device initiates patient responsiveness testing. This testing incorporates vibratory, audible, and visual alerts. If the patient presses a response button, the episode is aborted. If no patient response is recorded, the defibrillation electrodes discharge gel onto the skin and ultimately deliver a shock via an apex-posterior vector. Depending on the type of arrhythmia (VT or VF) and the device programming, the overall response time (detection to shock) can take between 25 and 60 seconds.[45] WCD shock energies range between 75 and 150 J biphasic, and shock efficacy rates between 69% and 99% have been reported.[42,46–48] WCD devices are capable of delivering up to 5 shocks; however, once the device has treated an episode of arrhythmia, the garment and electrodes must be replaced. Although the vast majority of observational data are from adults, small series have reported WCD use in pediatric populations, including patients 9 to 17 years of age.[49,50] A key challenge in pediatric use is appropriate fitting given the smaller torso of children and adolescents.

Use of the WCD is approved by the FDA in selected patients at risk for sudden cardiac arrest. However, there are several important relative contraindications. Patients with unipolar pacing (atrial or ventricular) cannot use a WCD because the large-amplitude pacing stimuli can interfere with arrhythmia detection.[51] Additionally, patients who cannot detect or respond to patient responsiveness testing stimuli are not appropriate candidates for the WCD.

Beyond the contraindications to WCD therapy, there are also several important limitations. Again, it is important to note that there are no pacing capabilities with the WCD. Patient comfort remains a challenge with WCD therapy, particularly over longer periods of time. Additional patient characteristics make the WCD less than ideal, including extreme body habitus (eg, obesity) and open or healing chest wounds. Given the use of external shocks, patients may also experience adverse events, including but not limited to diminished quality of life secondary to pain and even cutaneous burns. Finally, at the time of this writing, there are no completed randomized trials of WCD therapy. Thus, no definitive data are available on comparative efficacy versus alternative (or no) treatment.

Patient Adherence

Compliance is an important component of effective WCD therapy. Patients are instructed to wear their device at all times except when showering or bathing. Discontinuation rates as high as 22% have been reported, resulting primarily from patient comfort and lifestyle concerns.[46] In the largest observational series to date, daily use was >90% in more than half of the cohort, and the device discontinuation rate was 14%.[48] Some concerns have been expressed about compliance rates in pediatric populations. However, data are limited. A cohort of 4 children with anthracycline-induced cardiomyopathy found limited compliance in half of the patients.[50] A second, larger study found that there was no difference in compliance between young adults (age, 19–21 years; n=103) and those ≤18 years of age (n=81); both groups had an average compliance of 19 h/d (80% compliance).[49]

Clinical Experience With WCDs

A summary of the available clinical studies of WCD therapy is shown in Table 3. After demonstration of shock efficacy in controlled settings,[42] the first systematic, clinical evaluation of the WCD occurred in the companion Wearable Defibrillator Investigative Trial (WEARIT) and Bridge to ICD in Patients at Risk of Arrhythmic Death (BIROAD) study.[46] The WEARIT study enrolled patients with symptomatic heart failure (NYHA class III–IV) and LVEF <0.30 who were considered high risk but did not meet eligibility requirements for an ICD. Similarly, the BIROAD study enrolled patients who were perceived to be at high risk for sudden death and within 4 months of an MI or surgical revascularization. Specific reasons for consideration of the WCD in the BIROAD cohort included but were not limited to ventricular arrhythmias within 48 hours of coronary artery bypass grafting (CABG), LVEF <0.30 after CABG, syncope after CABG, and patient refusal of an ICD. In these 2 prospective studies, which enrolled 289 patients, 6 of 8 WCD defibrillation attempts (75%) were successful.

Table 3. Clinical Studies of WCDs*

Reference	Patient Population	Sample Size, n	Adherence, h/d	Duration of Therapy, d	Appropriate Shock Rate, %	Inappropriate Shock Rate, %	Survival, %
Epstein et al,[52] 2013	Patients 0–3 mo after AMI	8453	21.8 (median)	69±61	1.6	1.3	93
Mitrani et al,[53] 2013	Newly diagnosed cardiomyopathy or recent revascularization	134	14±8	72±55	0	0	98
Zishiri et al,[54] 2013	Recent revascularization with left ventricular dysfunction	809	NR	79±69 (CABG) 81±183 (PCI)	1.3	1.6	98
Kao et al,[55] 2012	HF patients listed for transplantation, with a new diagnosis, or receiving inotropes	82	20±5	80±58	0	0	100
Saltzberg et al,[56] 2012	Peripartum Nonischemic cardiomyopathy	107 159	18±5 17±6	75±81 56±54	0 0.6	0 0	97 85
Rao et al,[57] 2011	Congenital structural heart disease Inherited arrhythmias	43 119	19 (12–21) 19 (10–22)	27 (10–55) 29 (7–68)	0 2.5	0 5.9	87 97
Chung et al,[48] 2010	Aggregate US experience	3569	20±5	53±70	1.7	1.9	99
Collins et al,[49] 2010	Age ≤18 y Age 19–21 y	81 103	20 (1–24) 19 (1–24)	29 (0–531) 35 (0–499)	0 1.9	1.2 0.9	89 91
Klein et al,[43] 2010	Nationwide experience in Germany	354	21	106	3.1	0.8	NR
Feldman et al,[46] 2004	WEARIT/BIROAD clinical studies (HF patients or bridge to ICD for other indications)	289	NR	93	1.0	2.1	96

Shock rates are given as percentages (n patients with shock/n WCD patients). AMI indicates acute myocardial infarction; BIROAD, Bridge to ICD in Patients at Risk of Arrhythmic Death; CABG, coronary artery bypass grafting; HF, heart failure; ICD, implantable cardioverter-defibrillator; NR, not relevant; PCI, percutaneous coronary intervention; WCD, wearable cardioverter-defibrillator; and WEARIT, Wearable Defibrillator Investigative Trial.

*Based on a Medline search on July 1, 2013, and updated on December 2, 2013. Studies with ≥50 subjects were included.

There were 12 deaths, half of which were sudden and occurred in patients who were not wearing the WCD as instructed. Approximately one quarter of the study population (n=68 of 289) discontinued the study as a result of device-related discomfort or adverse reactions. These studies were the first to demonstrate the feasibility of the WCD in patients at high risk for SCD. Moreover, they demonstrated reasonable efficacy in those patients who complied with wearing the device.

On the basis of data from a manufacturer registry, in the United States between 2002 and 2006, a total of 3569 patients wore a WCD for at least 1 day (mean duration, 53±70 days).[48] WCD discontinuation because of discomfort or adverse reactions occurred in 14%. Longer duration of use was associated with higher rates of compliance. Indications for WCD use included ICD explantation (23%), ventricular arrhythmia before planned ICD implantation (16%), recent MI (16%), post-CABG status (9%), and recent diagnosis of cardiomyopathy with an LVEF ≤0.35 (28%). During a total of 143 643 patient-years, there were 80 sustained VT/VF events in 59 patients (1.7%/patient-year). Most of these sustained VT/VF events occurred in patients with an explanted device (event rate, 5.2%). First-shock efficacy was 99% (n=79 of 80), and post-VT/VF survival was 90% (n=72 of 80). Consistent with other studies of sudden death events,[58] a substantial number of sudden cardiac arrests were attributable to non-VT/VF events (25%), including 23 asystole events.

Compared with a single-center cohort of patients receiving ICDs (1996–2004) for traditional indications, survival was similar in the WCD cohort (3.6% mortality rate versus 4.4% at 3 months; P=0.256).[48] However, the comparison of event rates between these WCD and ICD cohorts was complicated by limited demographic and clinical data. Overall, 2% of the WCD patients received an inappropriate shock (rate, 1.4%/mo), which was similar to the rate of appropriate shocks (Table 3). Reasons for inappropriate WCD shocks included signal noise (68%), supraventricular tachycardia (27%), nonsustained VT (6%), oversensing of normal cardiac signals (4%), ECG signal loss (4%), and failure to activate the response button. Other data suggest that the inappropriate shock rate in patients treated with the WCD can reach 1.9% to 5.9% within 2 to 3 months.[46,48,57] In contrast, ICD shock rates have been demonstrated to be 13% over 41 months.[59]

In addition to the overall published national experience,[48] several observational studies in selected patient groups and single centers have been reported. In a manufacturer's database of WCD use in 8453 patients within 90 days of MI (median time from AMI to WCD, 16 days; 62% of patients revascularized; 77% with LVEF ≤0.30), 1.6% of the patients received appropriate shocks.[52]

The WCD has been used as a bridge until either myocardial recovery or ICD implantation in patients with newly diagnosed cardiomyopathy, patients with NYHA functional class IV heart failure, and those listed for transplantation. In a multicenter prospective WCD registry of 89 patients with idiopathic dilated cardiomyopathy, 42% experienced myocardial recovery and did not develop an indication for permanent ICD.[55] Furthermore, none of the patients had SCD or required WCD therapy. Event rates appear to be lower in patients with newly diagnosed cardiomyopathy (<1%) compared with patients who meet current ICD guideline indications.[48,53] Event rates are also lower in patients with recent revascularization, although there appears to be greater variation in these event rates across WCD studies (0%–1.6%; Table 3) Although overall event rates are lower in patients with newly diagnosed cardiomyopathy or recent coronary revascularization, retrospective observational data suggest that the WCD may confer a survival benefit. In a comparison of 4149 patients with recent revascularization and LVEF ≤0.35 who did not receive an ICD at hospital discharge with 809 patients who received a WCD at discharge, propensity-adjusted survival was greater in those treated with a WCD after CABG (7% versus 3%; adjusted hazard ratio, 0.42; 95% confidence interval, 0.31–0.55) or percutaneous coronary intervention (PCI; 10% versus 2%; adjusted hazard ratio, 0.33; 95% confidence interval, 0.21–0.52). Consistent with prior data, however, only 1.3% of those treated with a WCD received appropriate therapy for VT/VF.[54] WCD therapy may also be a reasonable treatment option in appropriate pediatric patients at high risk of SCD.[44,50]

Although there is an accumulating series of observational data of WCD use in clinical practice, questions about device efficacy will ultimately require randomized studies. The Vest Prevention of Early Sudden Death Trial (VEST) and Registry[60] (NCT01446965) is currently evaluating the use of the WCD after MI. The study is randomizing patients within 7 days of an MI who have an LVEF ≤0.35. The study will test the hypothesis that WCD use improves 12-month survival after MI.

Potential Indications for WCD Therapy

With the recognition that a WCD might be advocated in a wide variety of clinical circumstances, the following recommendations are derived from the accrued clinical experience, available observational data, and prospective evidence. The recommendations are aggregated and summarized in Table 4.

Infection and Extraction

ICD implantation may be complicated by infection in ≈1% of patients and >2% of those receiving generator replacement,[62] typically requiring extraction of the entire system to eliminate the infection. Depending on physician practice and the nature of the infection, most of the time there is a delay between extraction and implantation of a new ICD system. If this interval is brief or the patient requires inpatient care for other reasons, monitoring and access to external defibrillation may be appropriate. On the other hand, if the delay is prolonged, the clinician is faced with the decision of whether to keep the patient as an inpatient, to discharge the patient without protection from SCD, or to provide a WCD until ICD implantation can be safely accomplished. The potential benefit and cost-effectiveness of bridging with a WCD pending reimplantation of an ICD after infection may also relate to the underlying risk. For example, patients with secondary prevention devices and those with prior ICD therapies may benefit more, on the basis of risk, than patients who have primary prevention devices and have never received appropriate ICD therapy.

Table 4. Indications and Recommendations for WCD Therapy

Indication	Class	Level of Evidence
Use of WCDs is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection.[46,48]	IIa	C
Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation.[46,55,61]	IIa	C
Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or with treatment of left ventricular dysfunction; for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in patients starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc) in which the underlying cause is potentially treatable.[53,54,56]	IIb	C
WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 d of MI.[48,52]	IIb	C
WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 mo.	III: No benefit	C

ICD indicates implantable cardioverter-defibrillator; MI, myocardial infarction; SCD, sudden cardiac death; and WCD, wearable cardioverter-defibrillator.

On occasion, an ICD is extracted for reasons other than infection (eg, venous obstruction). In these cases, the opportunity for reimplantation of an ICD or subcutaneous ICD should be available acutely such that WCD therapy should rarely be necessary after extraction.

Recommendation

1. **Use of wearable defibrillators is reasonable when there is a clear indication for an implanted/permanent device accompanied by a transient contraindication or interruption in ICD care such as infection (*Class IIa; Level of Evidence C*).[46,48]**

After MI

Despite the failure of clinical trials to demonstrate improved survival with ICD implantation early after MI, there is an increased risk of SCD in the immediate 40 days after AMI. In DINAMIT,[28] the hazard ratio for arrhythmic mortality was 0.42 (P=0.009) with ICD therapy, but this was offset by increased nonarrhythmic mortality. Similar findings were demonstrated in the IRIS trial.[29] The WCD may have a role as a bridge for prevention of SCD in the first 40 days after infarction in patients who are considered to have an increased risk of arrhythmic death. This very population is the subject of the aforementioned VEST, a randomized, clinical trial that should help to clarify the role of the WCD in this patient population.

Recommendation

1. **WCDs may be appropriate as bridging therapy in situations associated with increased risk of death in which ICDs have been shown to reduce SCD but not overall survival such as within 40 days of MI (*Class IIb; Level of Evidence C*).[48,52]**

After CABG or PCI

Patients with LVEF ≤0.35 have higher mortality after CABG than those with preserved LVEF, and of those who die in the postoperative period, half have an SCD.[63] On the other hand, up to 50% of patients will demonstrate significant improvement in LVEF after CABG.[64] Improved survival in the immediate post-CABG period has not been demonstrated with the ICD.[65] There are even fewer data on ICD placement after PCI, but the issues of potential improvement in LVEF are similar. Therefore, the Centers for Medicare & Medicaid Services mandated a 90-day waiting period for placement of a primary prevention ICD after revascularization with either CABG or PCI.[66] However, patients with multiple risk factors or high-risk features may ultimately require an ICD after 90 days. Given the presumed risk of SCD for these individuals during the waiting period, the WCD may provide a bridge of protection in patients within 90 days of CABG or PCI.[48,52,54]

Previously Qualified Patients Sustaining MI or Undergoing Revascularization (CABG or PCI)

Some patients may have already met the criteria for placement of a primary prevention ICD but for whatever reason have not yet received an ICD. If these patients then sustain an MI or undergo revascularization, it is not clear whether their risk is determined by the previous indication or is modified by the subsequent event. Several investigators advocate that the appropriate waiting period (40 days after MI or 90 days after CABG or PCI) must be allowed before placement of an ICD in patients who "previously qualified."[67] The Heart Rhythm Society/American College of Cardiology/American Heart Association expert consensus statement on the use of ICDs in patients who are not included or are not well represented in clinical trials states that in patients who are within 90 days of revascularization, who previously qualified for the implantation of an ICD for primary prevention, who have undergone revascularization that is unlikely to result in an improvement in LVEF, and who are not within 40 days after MI, implantation of an ICD can be useful.[68] Alternatively, placement of a WCD may also be appropriate during this waiting period in patients who have previously qualified for an ICD when revascularization has not necessarily addressed the previous risk. The WCD might be a useful bridging option if there is reason to believe that there will be improvement with revascularization as a result of either hibernating myocardium distal to a stenosis or subsequent ventricular remodeling.

Newly Diagnosed Nonischemic Dilated Cardiomyopathy

In the setting of newly diagnosed nonischemic cardiomyopathy, the benefit of ICD early after diagnosis remains controversial. In CAT, patients with recently diagnosed nonischemic dilated cardiomyopathy and LVEF ≤0.30 derived no benefit from ICD implantation.[27] Overall, the DEFINITE study[25] failed to demonstrate statistical benefit for patients with nonischemic dilated cardiomyopathy, NYHA class I to III heart failure, LVEF ≤0.35, and ventricular ectopy or nonsustained VT; however, there was a trend toward reduced mortality with the ICD (P=0.08). SCD-HeFT[3] demonstrated a significant reduction in mortality in patients with NYHA class II or II heart failure and LVEF ≤0.35 when an ICD was implanted >3 months from diagnosis. Of note, in SCD-HeFT, all patients were treated medically with β-blockers and angiotensin-converting enzyme inhibition before the determination of LVEF and randomization. The potential for improvement in myocardial function with guideline-directed medical therapy prompted the requirement by the Centers for Medicare & Medicaid Services that the decision to implant an ICD for a primary prevention indication in this category of patients be delayed for 3 months among patients enrolled in a registry and 9 months for other patients, after repeat determination of the LVEF after appropriate therapy.[66] However, current guidelines state that the period of time required to ascertain improvement of LV function with guideline-directed medical therapy is uncertain[69] and that timing of ICD implantation is a decision that requires careful consideration. Such patients with recent diagnosis of heart failure in whom the prospect of improvement in ventricular function is still unknown represent a population for consideration of WCD therapy. In this population, WCD therapy may be appropriate in those patients with additional risk markers for arrhythmic death, including high-grade ventricular ectopy or nonsustained VT.

Unknown Cardiac Prognosis

The WCD is ideal for shorter-term applications when the risk of SCD is changing or uncertain or the magnitude of SCD risk is unclear relative to the risk of nonarrhythmic death or total mortality. In addition to the common scenarios of patients with post-MI left ventricular systolic dysfunction or newly diagnosed nonischemic dilated cardiomyopathy, there are a number of other clinical situations in which prognosis is particularly uncertain and therefore may lead to consideration for WCD therapy in some patients. Peripartum cardiomyopathy is one such example. Cohort studies have reported highly variable mortality rates ranging from 2% to 56%, with half of these events occurring within 12 weeks of delivery. Recovery of ventricular function occurs in 30% to 50% of patients, often within 6 months of diagnosis.[70,71] Despite this early risk of death, the risk of SCD is not well described. One recent study suggested that SCD and ventricular arrhythmias requiring therapy were rare in women with peripartum cardiomyopathy.[56] Myocarditis, catecholamine-induced myocardial dysfunction (stress cardiomyopathy or Takotsubo cardiomyopathy), tachycardia-mediated cardiomyopathy, thyroid-mediated cardiomyopathy, and trastuzumab-related cardiomyopathy all provide potentially similar clinical scenarios in which recovery is relatively likely. In the setting of high likelihood of cardiac recovery, the role of WCDs may ultimately be limited to patients with particularly high-risk features or in secondary prevention.

Substance abuse–related (eg, alcohol, methamphetamine) cardiomyopathies also are unique because of the potential for ventricular recovery with discontinuation of abuse. WCDs for the prevention of SCD may be useful in providing time to assess adherence to medical recommendations.[72]

There may also be prognostic uncertainty on the severe end of the heart failure spectrum. Guidelines recommend against permanent ICD implantation in patients not "expected to survive >1 year with good functional status."[10] However, whether patients will have such a poor prognosis as to remain in NYHA functional class IV with a short survival or will stabilize into NYHA functional class III with reasonable long-term survival can be difficult to determine. Despite extensive literature on heart failure prognosis with numerous validated heart failure risk models, the confidence intervals around median estimates for survival are typically quite wide. Among patients in whom risk models predict a median survival of 1 year, ≈25% will be dead within 6 months and 25% will still be alive at 2 years.[73] In a another example of how such risk modeling can break down in practical application, when the widely used Seattle Heart Failure Model was applied to a cohort of 138 heart failure patients with NYHA class III and IV symptoms, the model identified 6 patients (4.3%) with a predicted life expectancy of ≤1 year; at the 12 month follow-up, 43 patients (31%) had died.[74] Thus, applying population estimates to individual patients can be highly problematic, and guidelines citing specific survival cutoffs are difficult to operationalize. Furthermore, almost no models include estimates for nonsurvival end points such as health-related quality of life.[75] Therefore, WCD therapy may be particularly helpful in relatively unstable patients with severe heart failure and high-risk features for SCD for whom some additional time may clarify expectations for future survival and quality of life.

Recommendation

1. **Use of WCDs may be reasonable when there is concern about a heightened risk of SCD that may resolve over time or treatment of left ventricular dysfunction, for example, in ischemic heart disease with recent revascularization, newly diagnosed nonischemic dilated cardiomyopathy in a patient starting guideline-directed medical therapy, or secondary cardiomyopathy (tachycardia mediated, thyroid mediated, etc) in which the underlying cause is potentially treatable (*Class IIb; Level of Evidence C*).[53,54,56]**

The intent of this recommendation is not to suggest that all patients with newly diagnosed nonischemic cardiomyopathy or left ventricular dysfunction require WCD therapy. In fact, blanket use of the WCD in this way would be neither appropriate nor consistent with the available clinical evidence. However, WCD treatment in certain patients with high-risk features may be useful.

Unknown Noncardiac Prognosis

Typical cardiac indications for permanent ICD placement can occur in the setting of noncardiac comorbidities that may be relative or transient contraindications to ICD placement. A WCD may allow additional time to better understand the severity and reversibility of such comorbidity. One example is the setting of SCD with clear indications for secondary prevention with an ICD but in which the events around the time of SCD have created acute noncardiac issues (eg, anoxic brain injury or acute kidney injury) for which recovery is unknown. A second example is the setting of primary prevention ICD in which competing illness (eg, cancer) can change the risk-benefit dynamic that guides decisions about ICD therapy. Because significant absolute benefits of primary prevention ICD therapy are seen over years, a WCD may allow time to assess cancer response to chemotherapy in a patient with relatively high-risk features for SCD. Another situation in which the WCD may present an important treatment alternative for select at-risk patients is the acute phase of recovery from an invasive procedure or surgery. However, when prognosis is known with certainty and the risks of nonarrhythmic death exceed those of life-threatening arrhythmia, a WCD is not indicated.

Recommendation

1. **WCDs should not be used when nonarrhythmic risk is expected to significantly exceed arrhythmic risk, particularly in patients who are not expected to survive >6 months (*Class III; Level of Evidence C*).**

Patients Awaiting Transplantation and on Mechanical Circulatory Support

Patients awaiting cardiac transplantation are generally at high risk of death, including SCD, because of the severity of their cardiac disease. The use of inotropes to bridge some patients to transplantation can further increase the short-term risk of ventricular arrhythmia. However, the duration of risk may be significantly truncated by procurement of an acceptable organ donation. Therefore, WCD therapy may be a useful approach in this setting. Unfortunately, wait times for patients listed for transplantation can be highly variable and generally long and, in the era of mechanical circulatory support, have grown progressively longer for patients not at status 1A.[76,77] Therefore, unless patients are expected to remain in status 1A or are at status 1B in an organ procurement region with relatively short wait times (ie, <90 days), permanent ICD implantation has generally been the approach of choice, which is consistent with the International Society for Heart and Lung Transplantation guidelines for the care of cardiac transplantation candidates.[61] A permanent ICD is also preferred when the patient meets the criteria for cardiac resynchronization therapy.

Mechanical circulatory support can also change the dynamic for considering therapy options for SCD. The risk of hemodynamic compromise from ventricular arrhythmia is variably reduced by a left ventricular assist device (LVAD); for patients reliant on right ventricular function, VT/VF may not be tolerated. Ventricular arrhythmias are also common in patients with an LVAD. Therefore, the general approach has been to pair LVAD therapy with permanent ICD therapy. For patients with bridge-to-transplantation LVAD who are listed at status 1A and have favorable blood type and low panel reactive antibodies,[77] WCD therapy may be an option. However, whether the efficacy of WCDs in the setting of LVAD equipment is altered remains poorly characterized.

Recommendation

1. **Use of WCDs is reasonable as a bridge to more definitive therapy such as cardiac transplantation (*Class IIa; Level of Evidence C*).[46.55.61]**

Allow Time for Patient Decision Making

Despite the clear survival benefit of ICD therapy in select populations, a patient's decision to undergo permanent implantation is a relatively complex process and may require time. Unlike cardiac resynchronization therapy, β-blockers, and renin-angiotensin-aldosterone antagonists, which improve survival and health-related quality of life, ICDs abort death without fundamentally changing cardiac remodeling (absent concomitant cardiac resynchronization therapy). ICDs also come with the risk of complications during implantation, infection, inappropriate shocks, need for monitoring, more hospitalizations, and the potential for greater suffering at the end of life. Thus, ICD placement is a preference-sensitive decision that requires consideration of tradeoffs for increased chance of survival at the risk of decreased quality of life. A WCD may offer patients temporary protection against SCD while they gain a better understanding of their cardiac disease, clarify their values, define overall goals of care, and then decide on their preference for permanent implantation of a defibrillator.[78]

Future Research Needs

Risk stratification remains a major challenge for patient selection for WCD therapy. Unlike most cardiovascular therapies, which are designed to reduce the long-term risk of events, WCDs are intended to decrease short-term or transient risk of sudden death. Therefore, extrapolation of benefit of WCDs from studies or methodologies of long-term risk reduction is inappropriate and potentially hazardous.

A related challenge is how to account for the competing risk of nonarrhythmic death harbored by patients with risk factors for arrhythmic death. In the DINAMIT trial, a randomized comparison of ICD and no ICD in patients with recent MI and LVEF <0.35, there was no difference in the risk of all-cause mortality.[28] However, the risk of arrhythmic death was lower in the ICD group (hazard ratio, 0.42; P=0.009), but overall survival was no different, largely because patients in the ICD group had a higher risk of cardiac, nonarrhythmic death (hazard ratio, 1.72; P=0.05). A likely explanation is that many prominent risk factors for SCD, including heart failure, left ventricular systolic dysfunction, conduction disease, and inducible VT with programmed stimulation, are also associated with death from nonarrhythmic and noncardiovascular causes.[79] Consequently, even estimations of

risk based on 30-day all-cause and cardiovascular mortality, which are common safety end points in clinical trials of heart failure and MI, may be inaccurate in determining the benefit of WCD therapy.

For these reasons, well-conducted randomized trials are greatly needed. The most promising study is the aforementioned VEST trial, which had enrolled >1700 patients in 2015, with completion expected by the end of 2016 (NCT01446965).[60] In situations where equipoise for randomization is not possible, carefully conducted observational studies may further clarify risk prediction. The Study of the Wearable Defibrillator in Heart-Failure Patients (SWIFT; NCT01326624) is an observational study to evaluate rates of defibrillation in 4 important subgroups: advanced heart failure, LVEF ≤0.35 with revascularization or heart failure diagnosis within 90 days, Killip class III to IV AMI, and those awaiting ICD reimplantation.[80]

In the absence of comparative data, the cost-effectiveness of therapy remains unclear but will be influenced largely by the number of patients needed to treat to prevent 1 arrhythmic event or death. Improved risk stratification to minimize use in low-risk patients would therefore dramatically improve the overall cost per life saved. Finally, simpler, more portable devices may increase healthcare efficiency as a result of improved patient compliance and tolerability, improved care delivery and access to technology, and lower cost.

Limitations

Although WCD therapy is increasingly used in clinical practice, at present, only preliminary data exist on the actual effectiveness of this intervention in improving survival among patients who are at risk for SCD. Accordingly, this science advisory provides a tentative interim framework to assist in decision making until more definitive studies are available.

Conclusions

SCD resulting from VT/VF remains an important and potentially preventable cause of death. Despite their obvious benefits, current defibrillator technologies have limitations and risks. WCDs can serve as a temporary means of aborting arrhythmic death in patients with transient risk of SCD or those with indications for ICD implantation who have a transient barrier to permanent device implantation. Providers need to keep many factors in mind and to continuously weigh the individual risks and benefits of ICD placement and WCDs in their patients. Furthermore, discussion of patient preferences is an integral part of patient care and WCD therapy. Further research, including randomized trials, is needed to better inform the optimal use of WCD therapy.

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*Modest.

†Significant.

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*Significant.

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Wearable Cardioverter-Defibrillator Therapy for the Prevention of Sudden Cardiac Death: A Science Advisory From the American Heart Association

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