

Wearable Cardioverter-Defibrillator Use in Patients Perceived to Be at High Risk Early Post-Myocardial Infarction

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- Objectives** The aim of this study was to describe usage of the wearable cardioverter-defibrillator (WCD) during mandated waiting periods following myocardial infarction (MI) for patients perceived to be at high risk for sudden cardiac arrest (SCA).
- Background** Current device guidelines and insurance coverage require waiting periods of either 40 days or 3 months before implanting a cardioverter-defibrillator post-myocardial infarction (MI), depending on whether or not acute revascularization was undertaken.
- Methods** We assessed characteristics of and outcomes for patients who had a WCD prescribed in the first 3 months post-MI. The WCD medical order registry was searched for patients who were coded as having had a “recent MI with ejection fraction $\leq 35\%$ ” or given an International Classification of Diseases, Ninth Revision 410.xx diagnostic code (acute MI), and then matched to device-recorded data.
- Results** Between September 2005 and July 2011, 8,453 unique patients (age 62.7 ± 12.7 years, 73% male) matched study criteria. A total of 133 patients (1.6%) received 309 appropriate shocks. Of these patients, 91% were resuscitated from a ventricular arrhythmia. For shocked patients, the left ventricular ejection fraction (LVEF) was $\leq 30\%$ in 106, 30% to 35% in 17, $>36\%$ in 8, and not reported in 2 patients. Of the 38% of patients not revascularized, 84% had a LVEF $\leq 30\%$; of the 62% of patients revascularized, 77% had a LVEF $\leq 30\%$. The median time from the index MI to WCD therapy was 16 days. Of the treated patients, 75% received treatment in the first month, and 96% within the first 3 months of use. Shock success resulting in survival was 84% in nonrevascularized and 95% in revascularized patients.
- Conclusions** During the 40-day and 3-month waiting periods in patients post-MI, the WCD successfully treated SCA in 1.4%, and the risk was highest in the first month of WCD use. The WCD may benefit individual patients selected for high risk of SCA early post-MI. (J Am Coll Cardiol 2013;62:2000–7) © 2013 by the American College of Cardiology Foundation

Sudden cardiac arrest (SCA) and sudden cardiac death (SCD) are feared events early post-myocardial infarction (MI) (1). Whereas implantable cardioverter-defibrillators (ICDs) have become the cornerstone for both primary and

secondary SCD prevention, current guidelines proscribe ICD therapy for 40 days or 3 months post-MI, depending

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on whether or not patients undergo acute revascularization (2,3). Nevertheless, although the risk of SCA and death early post-MI is large, clinical trials have failed to demonstrate a mortality benefit from the early use of ICDs. The DINAMIT (Defibrillator in Acute Myocardial Infarction Trial) (4) and the IRIS (Immediate Risk Stratification Improves Survival) studies (5) randomized patients early post-MI to continued optimized medical therapy (OMT) alone or with an ICD, and neither study showed a benefit from ICD therapy.

As a consequence of these clinical trial data, waiting periods of 40 days post-MI if no revascularization was undertaken, or 3 months when percutaneous or surgical intervention was done have become standard practice before ICD implantation, and are endorsed in the ACC/AHA/HRS device-based therapy guidelines (2). Furthermore, the Centers for Medicare & Medicaid Services accepted these waiting periods as being necessary for reimbursement as dictated by a National Coverage Determination on ICD implantation (3). However, there remain patients post-MI perceived to be at high risk for SCD within these waiting periods, and consideration for ICD treatment is complicated by tension between clinical judgment, clinical trial data, and reimbursement rules. The present study describes the characteristics and outcomes of patients who were prescribed a wearable cardioverter-defibrillator (WCD) (LifeVest, ZOLL, Pittsburgh, Pennsylvania) to treat potentially fatal ventricular arrhythmias during the 40-day and 3-month waiting periods in high-risk patients post-MI.

Methods

The WCD medical order database was searched for patients who were prescribed the device between September 27, 2005, and July 13, 2011. All patients prescribed a WCD after market release in the United States are entered into a database maintained by the manufacturer for regulatory, reimbursement, and tracking purposes. The database contains indications, baseline demographics (age and sex), compliance, end of use reasons, and events. All patients signed consent to use their data for quality monitoring, healthcare operation activities, and/or research, and all data were de-identified. The institutional review board at the University of Pennsylvania exempted this study from review.

Patient use and compliance were calculated using the patient-use data flags stored by the WCD monitor and downloaded to a secure server. Clinical data were extracted from the medical documents supplied to ZOLL for reimbursement purposes. To find recent MI patients, the database was searched for patients who were coded as having had a “recent MI with ejection fraction $\leq 35\%$ ” or given an International Classification of Diseases, Ninth Revision 410.XX diagnostic code (acute MI), and then matched to device-recorded data. Recordings of all treated arrhythmias from the WCD were individually overread to verify the arrhythmia diagnosis (A.E.E.). Each was classified as

monomorphic ventricular tachycardia (MVT), ventricular flutter (VFI), polymorphic VT (PMVT), or ventricular fibrillation (VF). Follow-up was through the database and the Social Security Death Master File (SSDMF), with the latter limited after 2012 when protected state death records were removed from the SSDMF database.

Wearable cardioverter-defibrillator.

The WCD consists of 3 defibrillation electrode pads, 4 sensing electrodes, a vibration box, and a defibrillation unit incorporated into a lightweight patient-worn vest. The vest holds monitoring electrodes against the chest by tension from an elastic belt. The defibrillation electrodes are positioned for apex-to-posterior defibrillation. The vest comes in multiple sizes, and the chest straps and elastic belt can be adjusted to accommodate the chest size and weight of the patient. Arrhythmia detection threshold rates are programmable, with a VF zone programmable between 120 and 250 beats/min, and a VT zone programmable between 120 beats/min and the VF detection rate. When an arrhythmia is detected and after a 10-s delay, an escalating alarm sequence starts with vibrational pulses against the skin and proceeds to add audible alerts and voice prompts. During the alarm sequence, if the response buttons are not pressed to withhold treatment, up to 5 150-J biphasic shocks are delivered and the electrocardiogram stored. The WCD description and arrhythmia algorithm have been described elsewhere in detail (6,7). Event data were reviewed and shocks deemed appropriate if they occurred during sustained (>30 s) VT/VF and inappropriate if not. Inappropriate shocks were further analyzed for the cause of inappropriate detection and the reason for lack of proper response button use.

Statistical analysis. Data are presented as means \pm SD, with medians, or range for skewed distributions. Actuarial event survival curves were generated according to Kaplan-Meier analysis. For analytical purposes, all appropriate shocks and arrhythmias occurring within 24 h of the index arrhythmia were considered 1 event (“shock event”). Inappropriate shock events were all shocks occurring within 24 h of the index inappropriate shock.

Results

Between September 27, 2005, and July 13, 2011, a WCD was prescribed for 8,678 patients post-MI. Of those, 225 were not fitted with the device or did not wear it due to death, a deteriorating condition, insurance noncoverage,

Abbreviations and Acronyms

AED = automated external defibrillator
ICD = implantable cardioverter-defibrillator
LVEF = left ventricular ejection fraction
MVT = monomorphic ventricular tachycardia
OMT = optimized medical therapy
PMVT = polymorphic ventricular tachycardia
SCA = sudden cardiac arrest
SCD = sudden cardiac death
SSDMF = Social Security Death Master File
VF = ventricular fibrillation
VFI = ventricular flutter
WCD = wearable cardioverter-defibrillator

Table 1	Recent MI Patients Prescribed a WCD		
	All Patients (N = 8,678)	Patients Fitted and Wearing WCD (n = 8,453)	Patients Treated for VT/VF (n = 133)
Male, %	73	73	83
Age, yrs	62.7 ± 12.7	62.6 ± 12.7	63.0 ± 12.2
Median WCD use	Not applicable	57 days	15 days
Average LVEF, %	Data not available	Data not available	23.8 ± 8.8
Revascularized post-MI, %	Data not available	Data not available	62

Values are % or mean ± SD.
LVEF = left ventricular ejection fraction; MI = myocardial infarction; VF = ventricular fibrillation; VT = ventricular tachycardia; WCD = wearable cardioverter-defibrillator.

implantation of an ICD, or for unknown reasons, leaving 8,453 patients who were fitted with a WCD and who wore it for at least 15 min. As shown in Table 1, the mean age was 62.7 ± 12.7 years, and 73% were men. The mean time from MI to WCD prescription was 9 ± 9 days. The mean length of use was 69 ± 61 days (median 57 days), and median daily use was 21.8 h.

Of these 8,453 patients, 133 (1.6%) patients received appropriate shocks during 146 shock events. Of the 309 appropriate shocks delivered during the 146 shock events as defined in the preceding text, 252 successfully terminated VT/VF, 9 led to asystole, 41 were unsuccessful, 1 each resulted in nonsustained VT and supraventricular tachycardia, and rhythm outcomes were unknown in 5. From an individual event perspective, 134 occurred in 121 patients that resulted in survival (conscious arrival to an emergency room, or did not go); 12 patients did not survive (92% survival per event, and 91% per patient). Of those initial survivors, 3 died within 2 days after shock delivery, and 41 died at a time remote from shock delivery (≥3 days). The average number of appropriate shocks per event was 2.1 ± 2.8 (range 1 to 18). VT was not consistently detected in 2 additional events, due to the rate falling below the VT threshold; neither patient survived. A third VT/VF event was not detected due to signal artifact obscuring the electrocardiogram signal, and this event also resulted in death. Bradycardia or asystole events not associated with VT/VF were responsible for 34 additional deaths (0.4% of patients) while wearing the WCD. For shocked patients, the left ventricular ejection fraction (LVEF) was ≤30% in 106, 30% to 35% in 17, >36% in 8, and not reported in 2 patients. Of the 38% patients not revascularized, 84% had a LVEF ≤30%. Of the 62% patients who were revascularized, 77% had a LVEF ≤30%.

Ninety-nine patients received 114 inappropriate shocks (shocks not associated with VT/VF). None of the inappropriate shocks induced arrhythmias, and there were no burns or other shock sequelae beyond the immediate pain. These occurred during 102 shock events and, in combination with a universal lack of proper response button use to prevent shock, were due to electrical oversensing [15], noise artifact [62], detection of supraventricular tachycardia [21], nonsustained VT [3], and other causes [1]. The inappropriate shock rate was 0.006 shocks per patient month of use.

For those patients who received an appropriate shock, the mean length of WCD use was 31 ± 37 days (median 15 days), and the length of use after appropriate shock was 8 ± 18 days (median 3 days). The average time from WCD prescription to first shock delivery was 22 ± 32 days (median 9 days) (Fig. 1), with 75% of first shocks occurring in the first 30 days and 96% occurring in the first 90 days. The average time from the index MI to first treatment was 30 ± 37 days (median 16 days), and from revascularization to first treatment 26 ± 37 days (median 14 days). The time from MI to WCD prescription was 7 days for both non-revascularized and revascularized patients.

When recordings were analyzed according to arrhythmia diagnosis at onset and treatment, 66 patients had MVT at onset and at treatment (Fig. 2), 28 had VF at onset and at treatment (Fig. 3), 17 had PMVT that degenerated to VF at treatment, 11 patients had PMVT that stabilized into a MVT or VFI at treatment, 10 had VT or VFI that degenerated into VF at treatment, and 1 had VF at onset that regularized into VFI at treatment. In 18 instances, the actual arrhythmia onset was not captured, with the recording starting during arrhythmia. Because all of the latter were VT, onset for these patients was classified as VT. For those with electrocardiogram recordings showing the actual onset of the first shocked arrhythmia (n = 115), the median time

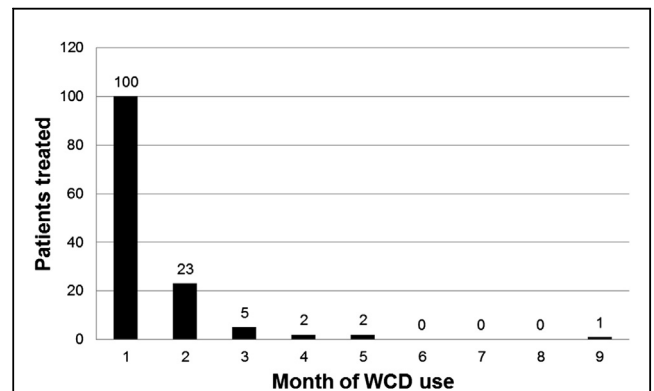


Figure 1 Timing of WCD Shock Events

The time by month after wearable cardioverter-defibrillator (WCD) treatment was initiated to time of shock events is shown. See text for discussion.

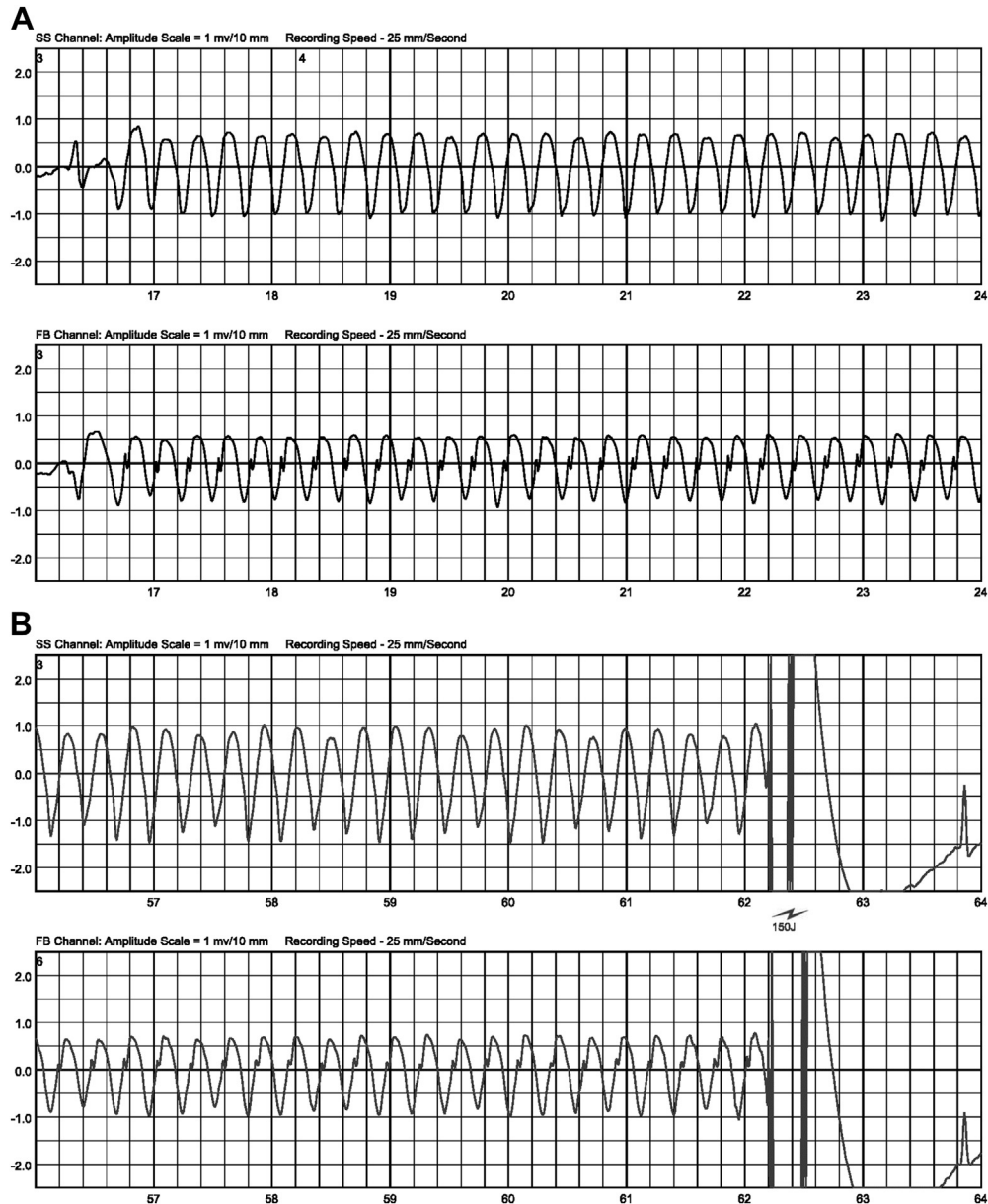


Figure 2 WCD Recording of Cardiac Arrest Due to MVT

Recordings from resuscitation of cardiac arrest from monomorphic ventricular tachycardia (MVT) showing arrhythmia onset (A) and cardioversion 45 s later (B). WCD = wearable cardioverter-defibrillator.

from onset to therapy was 47 s (25th percentile 44 s, 75th percentile 76 s). Reasons why arrhythmia onset was not available included noise artifact, removal of the battery by a conscious patient, and slow VT. There was a wide variation because some patients (who remained conscious) prevented therapy by holding the response buttons until they lost consciousness or halted the inhibition.

For those treated patients who died, the average time from WCD start to death was 202 ± 294 days (median 81 days), and average time from first treatment to death was 175 ± 297 days (median 29 days). Follow-up time to assess mortality for

those not dead was 900 ± 456 days. The actuarial survival analysis of all patients treated with a WCD showed that in the 3-, 6-, and 12-month intervals following the WCD application, cumulative survival was 96%, 94%, and 93%, respectively (Fig. 4A). The actuarial survival analysis of patients treated with appropriate shocks showed that in the same 3-, 6-, and 12-month intervals, cumulative survival was 73%, 70%, and 65%, respectively (Fig. 4B). For survival analysis stratified by rhythm, because the distinction between MVT and VFI and between PMVT and VF is somewhat arbitrary, they were grouped as VT/VFI and PMVT/VF,

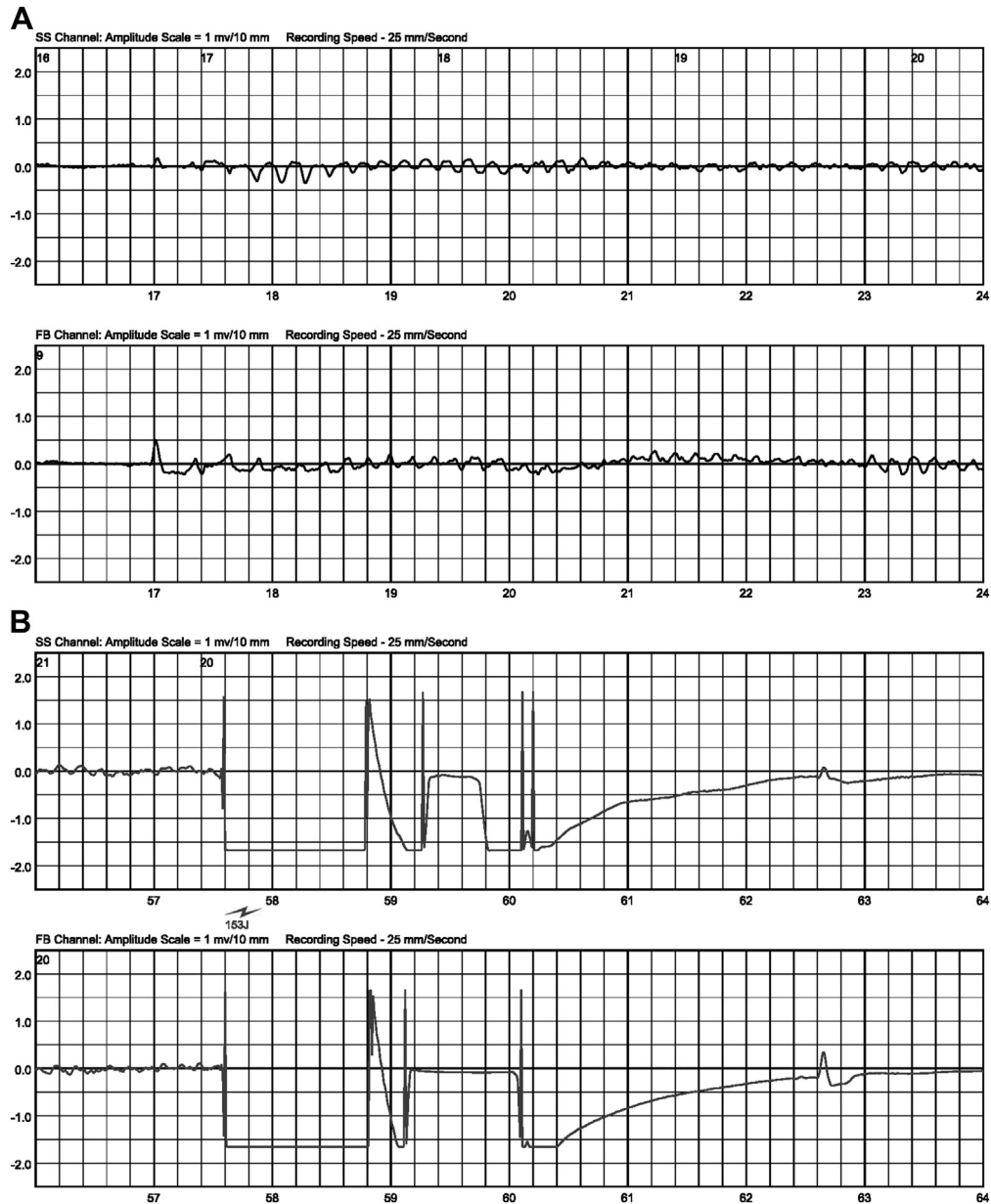


Figure 3 WCD Recording of Cardiac Arrest Due to VF

Recordings from resuscitation of cardiac arrest from ventricular fibrillation (VF) showing arrhythmia onset (A) and defibrillation 41 s later (B). WCD = wearable cardioverter-defibrillator.

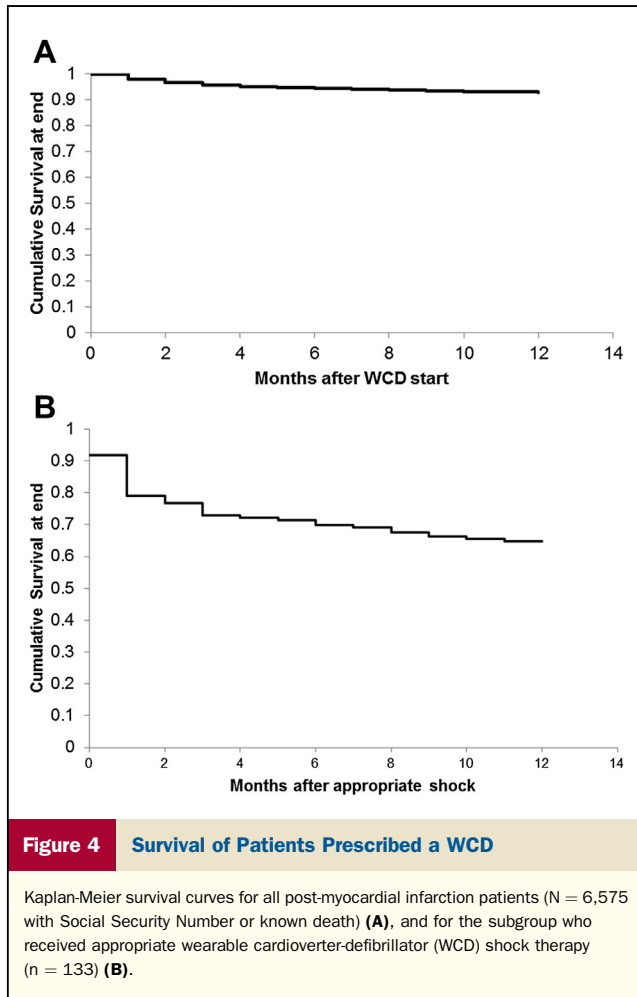
respectively. When analyzed according to the rhythm at onset, survival was 63% for those with VT/VF and 67% for those treated for PMVT/VF ($p = \text{NS}$). When analyzed according to the treated rhythm, survival was 67% for those with VT/VF and 62% for those treated for PMVT/VF ($p = \text{NS}$).

Discussion

This study shows that during mandatory ICD implantation waiting times (40 days or 3 months, depending on whether

or not revascularization was performed) in patients perceived to be at high risk for SCA post-MI, the WCD successfully treats VT/VF. The risk of VT/VF was highest in the first month of WCD use, with a median time until first treatment of 9 days, and 1.4% of patients were resuscitated by the WCD in the early weeks post-MI. Of treated patients, 75% received therapy in the first month of use, and 96% in the first 3 months of use.

To place these data in perspective, the current study may be compared with the VALIANT (Valsartan in Acute



Myocardial Infarction Trial) (1), DINAMIT (4), and the IRIS (5) studies. In VALIANT, 14,703 patients were randomized to receive valsartan, captopril, or both after MI complicated by heart failure, a low LVEF, or both (1). It was shown that 7% either died suddenly (6%) or were resuscitated from cardiac arrest (1%) at a median time of 180 days during a median follow-up of 24.7 months. The cumulative event rate was 1.4% (19% of the events in the trial) in the first 30 days, and 2.5% between 1 and 6 months. Of those resuscitated in the first month, 74% were alive 1 year later. For patients with heart failure, the risk of death was 4 to 6 times higher than those without heart failure (1,8). In our population, 1.6% of patients had events with a mean of 22 days to shock (30 days from MI), very similar to the event rate in VALIANT. Nevertheless, in VALIANT, sudden unexpected deaths were reported without verification that they were indeed arrhythmic, and autopsy findings from a substudy suggest that only about 50% of post-MI sudden deaths were likely arrhythmic (9). The present study may provide a more accurate assessment of true arrhythmic events. In the present study, and similar to VALIANT, shocked patients who survived the initial event had a 1-year survival of 71%.

Results from the DINAMIT and IRIS studies have led to the speculation that in patients early post-MI, defibrillation may not improve overall survival because they have a high risk of death from other cardiac causes. In DINAMIT, patients with a LVEF $\leq 35\%$ and abnormal autonomic function between 6 and 40 days post-MI were randomized to OMT with or without an ICD. Survival in both groups was identical (4). In the IRIS study, patients with a LVEF $\leq 40\%$ and a heart rate > 90 beats/min with or without nonsustained VT 5 to 31 days post-MI on OMT were randomized to receive an ICD or not. Identical to DINAMIT, the IRIS study showed no survival benefit with ICD therapy, and as in DINAMIT, the reduction in SCD by the ICD was offset by a parallel increase in nonsudden death (5).

To further place our data in perspective, the annual mortality rate in DINAMIT for both the control and ICD groups was approximately 7.2% or, assuming a linear mortality rate, 1.8% in the first 3 months (4). In the IRIS study, approximately 11.6% died during the first year of follow-up or, again assuming a linear mortality rate, 2.9% in the first 3 months (5). In DINAMIT, the mean time from index MI to randomization was 18 days, and an average of 6 more days to ICD implantation (4). In the IRIS study, however, 91.1% of the patients who received an ICD did so in the index hospitalization (5). The differences in proximity to the index MI when patients were enrolled in the 2 studies may partly explain differences in mortality in the first 3 months. Furthermore, because mortality risk is generally highest in the immediate post-MI period, these linear interpolations may underestimate the risk. Withstanding these limitations, the overall mortality of 4% at 3 months in our entire population is higher than the death rates in both the DINAMIT and IRIS studies, attesting to their having been selected for particularly high risk.

The failure of ICD therapy to provide benefit when implanted early after MI was foreshadowed by MADIT II (Multicenter Automatic Defibrillator Implantation Trial) (10). In the MADIT II trial, which required a waiting period of 1 month post-MI and 3 months if revascularization had been undertaken, ICD benefit only occurred 9 months after randomization in the trial. At 3 months following enrollment, about 4% of the patients had died in both the ICD and medical therapy groups. The survival curves only began to diverge at 9 months. Notably, in long-term follow-up, only if implantation occurred > 18 months from the last MI was ICD benefit apparent (11).

Because ICD trials were designed to address long-term mortality, interpretation of the results of this study, which address the short-term risk of SCA, in the context of ICD data is challenging. In both the DINAMIT and IRIS studies, the decrease in arrhythmic mortality was exactly counterbalanced by nonarrhythmic mortality in the ICD group (4,5). Furthermore, after appropriate shocks for VT/VF in DINAMIT, mortality was 30% at 1 year (4); similarly, in MADIT II, mortality was 20% 1 year after appropriate therapy (10). In the present study, mortality 1 year

after treatment was 29%. The true advantage of WCD therapy is that because the LVEF significantly improves with OMT over the initial 8 to 12 weeks after MI, for those surviving, it may improve to a point where an ICD is not indicated. In the HEART (Healing and Early Afterload Reducing Therapy) study (12), 66% of patients had improvement in the LVEF by day 90 (mean absolute improvement 4.5%), and the REFINE (Risk Estimation Following Infarction, Noninvasive Evaluation) study demonstrated the absolute improvement in the LVEF was 18% at 8 weeks (13). Although some may argue that prescription of a defibrillator, whether an ICD or WCD, is not appropriate during the waiting period post-MI, as LV function improves, our study suggests that a small, but not necessarily unimportant, group of patients may derive benefit from defibrillation early after MI.

It is important to note that access to rapid defibrillation does not necessarily ensure SCA survival, because 0.4% of the patients in the present study died from bradycardia or asystole. This is in keeping with the VALIANT substudy referenced earlier in the text in which Pouleur et al. (9) showed that of 105 SCDs, 51 of the patients had specific findings such that their deaths, without autopsy, would have been deemed arrhythmic, most commonly recurrent MI (31 patients) or cardiac rupture (13 patients). Although sudden death due to recurrent MI or rupture was highest in the first month in VALIANT, it then declined. Arrhythmic deaths, however, increased over time, from 20% in the first month to 75% later in the study (9). Finally, Chung et al. (7) reported the aggregate national experience with a WCD in 2010. Of 3,569 patients wearing the device, daily use was 19.9 ± 4.7 h per day, and >90% of the day in 52% of the patients. Although first-shock success was 100% for unconscious VT/VF, 8 patients died after successful shock therapy. In addition, asystole occurred in 23 patients (0.6%), of whom 17 died, pulseless electrical activity occurred in 2, and respiratory arrest occurred in 1, representing 24.5% of SCAs, in keeping with the data mentioned in the previous text, attesting to the fact that many apparently sudden deaths are either noncardiac or from nonshockable rhythms. These findings may help explain the results of DINAMIT, IRIS, and our study.

The automated external defibrillator (AED) also may be considered for the purpose of bridging therapy in a noninvasive manner during waiting periods (14-16). Although it has proven benefit in public areas (17,18), about 75% of cardiac arrests occur at home (19,20), and often in the absence of a witness who can deploy the device (21). In the HAT (Home Automated External Defibrillator Trial), for survivors of anterior-wall MI who were not candidates for ICD implantation, a home AED did not significantly improve overall survival compared with conventional care (16). Thus, having a wearable device that automatically provides monitoring and delivers electrical therapy without bystander intervention avoids some limitations of AED use and may be useful in that regard.

A unique aspect of this database gives insight into the arrhythmias that lead to SCA in the contemporary, ambulatory setting. Prior data obtained from Holter recordings varied in the distribution of terminal rhythms at the time of death. Bayés de Luna et al. (22) reported that VT degenerated into VF in 62% of the recordings, and 21% had VF or torsade de pointes VT as the initiating and treated arrhythmia. Pratt et al. (23) and Panidis and Morganroth (24) reported that VF was always preceded by VT or VFI. Our contemporary data show that MVT degenerated into VF in only 7.5% of the recordings, but that at onset and treatment, MVT was present in 50%, and PMVT or VF was present in 38% of the recordings. Interestingly, survival was not influenced by differences in the presenting or treated arrhythmia. The median time to therapy of 47 s is also notable. First, this suggests that therapy was not overly aggressive. Second, having a delay before therapy is in keeping with the excellent outcomes reported by the MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial-Reduction in Inappropriate Therapy) in which ICDs were programmed to have a delay in therapy (25), and a substudy of the DEFINITE (Defibrillators in Non-ischemic Cardiomyopathy Treatment Evaluation) study in which Ellenbogen et al. (26) proposed that the equal rates of syncope and ICD shocks in the control and ICD groups suggests that given time, many arrhythmias spontaneously terminate. Finally, the treatment rate of 1.6% is much lower than the appropriate shock rate in the DINAMIT and IRIS studies, also attesting to the absence of overtreatment.

Study limitations. Our study is purely observational, derived from the manufacturer's database. In addition to the absence of a control group who received medical care without a WCD, other limitations are present. First, the database for the WCD, by necessity, included only limited patient information. Specific information regarding the medical therapy provided, comorbidity, and clinical reasons why individuals may have been chosen for a WCD are unknown. Indeed, precise data regarding myocardial function beyond the LVEF are unknown. Furthermore, the LVEF was determined from chart review only for patients who were treated or died. To get information on the patients who survived and did not receive WCD treatment would require chart review, which is not feasible. In addition, the frequency of pre-existing LV dysfunction, prior MI, current functional class, and scar burden are unknown, all factors that influence outcome. Second, shock success, even though delivered to unconscious patients during a sustained ventricular arrhythmia, is an imperfect surrogate for resuscitation from certain arrhythmic death (27). Third, quality-of-life data are not available in our study, and the psychological impact of using a WCD post-MI was not assessed, especially important because depression and anxiety frequently occur during this time. Fourth, the management and outcomes of patients resuscitated by the WCD are unknown because this information

was not part of the manufacturer's database. Fifth, cost effectiveness could not be assessed due to the nature of the database. Finally, in 2012, protected state death records were removed from the SSDMF database, which diminished our ability to determine survival in patients.

Conclusions

To our knowledge, this is the only report that describes use of the WCD in patients early post-MI perceived to be at high risk for SCA, a population currently not covered for ICD implantation. That 1.4% of patients may be successfully treated in the first 3 months with a resuscitation survival rate of 91% implies that a select group of patients may benefit from defibrillation early after MI, particularly during the first 30 days following hospital discharge. These survivors may then receive an ICD. Further study of WCD use for the prevention of SCD is warranted in the critical period early post-MI. The ongoing Vest Prevention of Early Sudden Death Trial and VEST Registry (ClinicalTrials.gov identifier NCT01446965) will help to answer that question.

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REFERENCES

1. Solomon SD, Zelenkofske S, McMurray JVV, et al. Sudden death in patients with myocardial infarction and left ventricular dysfunction, heart failure, or both. *N Engl J Med* 2005;352:2581-8.
2. Epstein AE, DiMarco JP, Ellenbogen KA, et al. ACC/AHA/HRS 2008 guidelines for device-based therapy of cardiac rhythm abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmic Devices). *J Am Coll Cardiol* 2008;51:e1-62.
3. National Coverage Determination (NCD) for Implantable Automatic Defibrillators (20.4). Medicare National Coverage Determinations (NCD) Manual. Publication 100-103. January 1, 2005. Centers for Medicare & Medicaid Services. Available at: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=110&ncdver=3&NCAId=148&NcaName=Implantable+Defibrillators&IsPopup=y&bc=AAAAAAAAEAAA&c>. Accessed January 29, 2013.
4. Hohnloser SH, Kuck KH, Dorian P, et al. Prophylactic use of an implantable cardioverter-defibrillator after acute myocardial infarction. *N Engl J Med* 2004;351:2481-8.
5. Steinbeck G, Andresen D, Seidl K, et al. Defibrillator implantation early after myocardial infarction. *N Engl J Med* 2009;361:1427-36.
6. Klein HU, Meltendorf U, Reek S, et al. Bridging a temporary high risk of sudden arrhythmic death. Experience with the wearable cardioverter defibrillator (WCD). *Pacing Clin Electrophysiol* 2010;33:353-67.
7. Chung MK, Szymkiewicz SJ, Shao M, et al. Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. *J Am Coll Cardiol* 2010;56:194-203.
8. Adabag AS, Therneau TM, Gersh BJ, Weston SA, Roger VL. Sudden death after myocardial infarction. *JAMA* 2008;300:2022-9.
9. Pouleur AC, Barkoudah E, Uno H, et al. Pathogenesis of sudden unexpected death in a clinical trial of patients with myocardial infarction and left ventricular dysfunction, heart failure, or both. *Circulation* 2010;122:597-602.
10. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002;346:877-83.
11. Wilber DJ, Zareba W, Hall WJ, et al. Time dependence of mortality risk and defibrillator benefit after myocardial infarction. *Circulation* 2004;109:1082-4.
12. Solomon SD, Glynn RJ, Greaves S, et al. Recovery of ventricular function after myocardial infarction in the reperfusion era: the Healing and Early Afterload Reducing Therapy Study. *Ann Intern Med* 2001;134:451-8.
13. Exner DV, Kavanagh KM, Slawnych MP, et al. Noninvasive risk stratification early after a myocardial infarction: the REFINE Study. *J Am Coll Cardiol* 2007;50:2275-84.
14. Caffrey SL, Willoughby PJ, Pepe PE, Becker LB. Public use of automated external defibrillators. *N Engl J Med* 2002;347:1242-7.
15. Public Access Defibrillation Trial Investigators. Public-access defibrillation and survival after out-of-hospital cardiac arrest. *N Engl J Med* 2004;351:637-46.
16. Bardy GH, Lee KL, Mark DB, et al. Home use of automated defibrillators for sudden cardiac arrest. *N Engl J Med* 2008;358:1793-804.
17. Valenzuela TD, Roe DJ, Nichol G, Clark LL, Spaite DW, Hardman RG. Outcomes of rapid defibrillation by security officers after cardiac arrest in casinos. *N Engl J Med* 2000;343:1206-9.
18. Page RL, Joglar JA, Kowal RC, et al. Use of automated external defibrillators by a U.S. Airline. *N Engl J Med* 2000;343:1210-6.
19. Eisenberg MS, Mengert TJ. Cardiac resuscitation. *N Engl J Med* 2001;344:1304-13.
20. Pell JP, Sirel JM, Marsden AK, Ford I, Walker NL, Cobbe SM. Potential impact of public access defibrillators on survival after out of hospital cardiopulmonary arrest: retrospective cohort study. *BMJ* 2002;325:515-9.
21. Ye S, Grunnert M, Thune JJ, et al. Circumstances and outcomes of sudden unexpected death in patient with high-risk myocardial infarction: implications for prevention. *Circulation* 2011;123:2674-80.
22. Bayés de Luna A, Coumel P, Leclercq JF. Ambulatory sudden cardiac death: mechanisms of production of fatal arrhythmia of the basis of data from 157 cases. *Am Heart J* 1989;117:151-9.
23. Pratt CM, Francis MJ, Luck JC, Wyndham CR, Miller RR, Quinones MA. Analysis of ambulatory electrocardiograms in 15 patients during spontaneous ventricular fibrillation with special reference to preceding arrhythmic events. *J Am Coll Cardiol* 1983;2:789-97.
24. Panidis IP, Morganroth J. Sudden death in hospitalized patients: cardiac rhythm disturbances detected by ambulatory electrocardiographic monitoring. *J Am Coll Cardiol* 1983;2:798-805.
25. Moss AJ, Schuger C, Beck CA, et al. Reduction in inappropriate therapy and mortality through ICD programming. *N Engl J Med* 2012;367:2275-83.
26. Ellenbogen KA, Levine JH, Berger RD, et al. Are implantable cardioverter defibrillator shocks a surrogate for sudden cardiac death in patients with nonischemic cardiomyopathy? *Circulation* 2006;113:776-82.
27. Kim SG, Fogoros RN, Furman S, Connolly SJ, Kuck KH, Moss AJ. Standardized reporting of ICD patient outcome: the report of a North American Society of Pacing and Electrophysiology Policy Conference, February 9-10, 1993. *Pacing Clin Electrophysiol* 1993;16:1358-62.

Key Words: defibrillation ■ implantable cardioverter-defibrillator ■ resuscitation ■ sudden cardiac arrest ■ wearable cardioverter-defibrillator.