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NEW RESEARCH PAPERS

Benefit of the Wearable Cardioverter-Defibrillator in Protecting Patients After Implantable-Cardioverter Defibrillator Explant

Results From the National Registry

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ABSTRACT

OBJECTIVES This study reports on the time course of reimplantation and benefits of the wearable cardioverter-defibrillator (WCD) in patients post implantable cardioverter-defibrillator (ICD) explantation.

BACKGROUND The WCD is used to treat patients at high risk for ventricular tachycardia (VT) and ventricular fibrillation (VF), including patients with ICD-related infections who undergo device removal and cannot be immediately reimplanted.

METHODS This retrospective study included consecutive patients from 2002 to 2014 who underwent ICD removal because of device-related infection and were prescribed a WCD. WCD-stored electrocardiograms were reviewed. Event outcome was assessed through either the manufacturer WCD registry or the Social Security death index search.

RESULTS A total of 8,058 patients (mean age 62 ± 14 years, 75% male) were included in the analysis. Median time to reimplantation of an ICD was 50 days (interquartile range: 24 to 83 days). While wearing the WCD, 334 patients (4%) experienced 406 VT/VF events, of which 348 events were treated. Shocks were averted in 54 events by conscious patients. The overall 24-h survival, both treated and nontreated, was 93% (312 of 334). VT/VF occurrence was the highest in the initial weeks after ICD removal (0.9%, 0.7%, and 0.7% per week for weeks 1, 2, and 3, respectively). The 12-month cumulative event rate was 10%. For all patients, the 30-day post-event survival was 81%. An ICD was reimplanted in 80% of patients.

CONCLUSIONS The risk of VT/VF reaches 4% during the first 2 months and 10% at 1 year after ICD removal. WCD demonstrated a high efficacy for protecting patients from VT/VF. Clinicians may use the WCD as an ICD alternative when reimplantation is medically delayed. (J Am Coll Cardiol EP 2017;3:243–50) © 2017 by the American College of Cardiology Foundation.

The implantable cardioverter-defibrillator (ICD) has become the standard of care for patients who have survived a previous sudden cardiac arrest (SCA) or who demonstrate persistent left ventricular dysfunction and are at a significant risk for SCA. The incidence of cardiac device infections (CDIs) has increased out of proportion to the increase in cardiac device implantations. Medicare

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ABBREVIATIONS AND ACRONYMS

CDI = cardiac device infection

CE = cost-effectiveness

CI = confidence interval

ICD = implantable cardioverter-defibrillator

SCA = sudden cardiac arrest

VF = ventricular fibrillation

VT = ventricular tachycardia

WCD = wearable cardioverter-defibrillator

beneficiaries had a 42% increase in cardiac device implantation rate from 1990 to 1999, whereas there was a simultaneous 124% increase in device infections (1). Voigt et al. (2) reported a 210% increase in CDIs between 1996 and 2003, compared with a 49% increase in device implantation rates. Another study examined a 16-year period (1993 to 2008) and reported that the incidence of such infections had increased by 210%, whereas the actual device implantation went up by 96% (3). Current

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guidelines advocate removal of the entire implanted system with administration of intravenous antibiotics, which can last from 10 days to 6 weeks depending on the nature of the infection (4). Thus, ICD reimplantation may be postponed for extended periods of time. Patients with an ICD lose protection against lethal ventricular tachyarrhythmias after device explantation. Although inpatient monitoring is an obvious alternative, this is neither desirable nor economically feasible.

In non-pacemaker-dependent patients, a wearable cardioverter-defibrillator (WCD) allows outpatient management until implantation is possible. The WCD has been approved for commercial use in the United States since 2002 (5). Since its approval, the WCD has been a therapeutic option for those who undergo ICD explant secondary to device infection. The Heart Rhythm Society recommends the WCD as an alternative to early reimplantation of an ICD when there is a concern for ongoing infection (6). Previous studies have reported favorable results for the WCD for multiple indications (7,8). Most recently, Tanawuttiwat et al. (9) did a single-site study on 97 patients who were prescribed a WCD after ICD removal. The WCD was found to be effective and safe in their study cohort (9).

The current study was designed to evaluate WCD use among ICD explant patients from the U.S. national commercial experience. Our goals were to: 1) assess the ventricular tachycardia (VT)/ventricular fibrillation (VF) risk after ICD explant; 2) define the VT/VF risk trend over time; and 3) report the clinical strategy after WCD use.

TABLE 1 ICD Explant Patients Using the WCD

	All Patients (N = 8,058)	Patients Who Received Reimplantation After WCD Use (n = 4,505)	Patients With VT/VF (n = 334)
Age (yrs)	62 ± 14	62 ± 13	62 ± 13
Male (%)	75	76	76
Median length of wear (days)	53 (25-94)	50 (24-83)	58 (28-123)
Ejection fraction (%)	NA	NA	27 ± 12
Indication for ICD			
Secondary prevention	NA	NA	77 (23%)
Primary prevention—NICM	NA	NA	86 (26%)
Primary prevention—ICM	NA	NA	52 (16%)
Congenital/inherited	NA	NA	5 (1%)
Other	NA	NA	4 (1%)
Unknown	NA	NA	109 (33%)

Values are mean ± SD, n, median (interquartile range), or n (%).

ICD = implantable cardioverter-defibrillator; ICM = ischemic cardiomyopathy; NA = not available; NICM = nonischemic cardiomyopathy; VF = ventricular fibrillation; VT = ventricular tachycardia; WCD = wearable cardioverter-defibrillator.

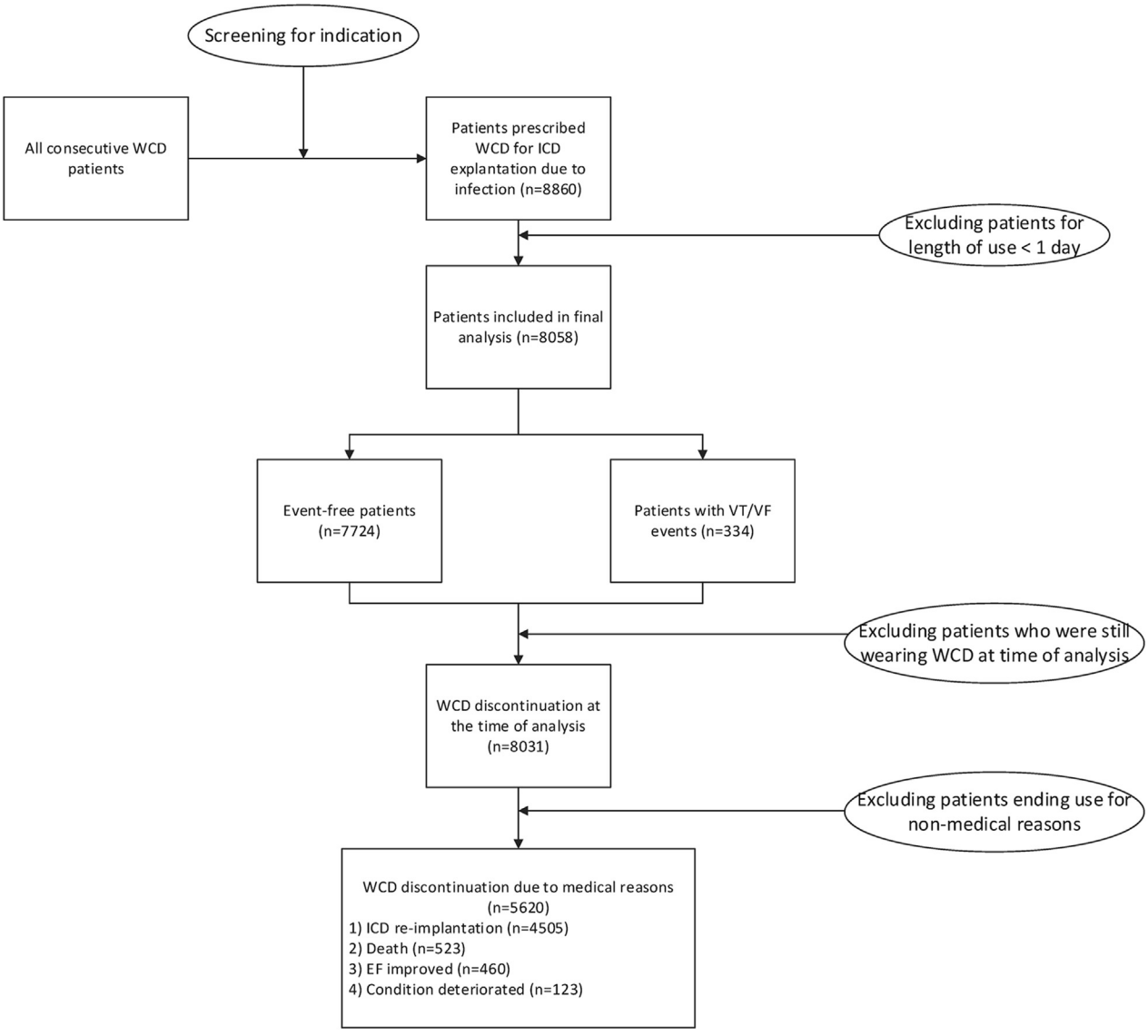
METHODS

PATIENT SELECTION. This was a retrospective study conducted on consecutive patients who underwent ICD removal because of CDIs and were prescribed a WCD. WCD prescriptions between 2002 and 2014 were reviewed from the manufacturer-maintained U.S. registry. Patients were excluded from final analysis if ICD removal was not due to device-related infection or if the patient wore the device for <1 day. All study subjects signed consent to use their data for quality monitoring and research. All data used for this study were de-identified. This registry contains demographic data, clinical indication for a WCD prescription, device-recorded electrocardiogram, and device usage information including length of use and daily wear time. The registry contained limited information on time of initial ICD or lead(s) insertion, indication for ICD (primary prevention vs. secondary prevention), underlying cardiac pathology, or whether a complete system extraction was performed.

DEFINITIONS. In this study, all electrocardiograms were reviewed for sustained ventricular arrhythmias, which included VT with duration >30 s or VF. A single event was defined as all sustained VT/VF episodes occurring within 24 h of the index arrhythmia. If a patient remained conscious or hemodynamically stable during an event, he or she could use the WCD response buttons to avoid or delay a shock. For either shocked or nonshocked VT/VF events, a 24-h post-event survival was recorded to assess acute outcome. Patients were followed up by call at the time of WCD discontinuation or by a mortality search from the Social Security death index if the patient was alive when he or she stopped wearing the device.

All shocks delivered for rhythms other than sustained VT or VF were considered inappropriate. Presenting arrhythmias were adjudicated by consensus from 2 reviewing physicians and were classified as: 1) monomorphic VT (heart rate ≤250 beats/min); 2) high-rate monomorphic VT including ventricular flutter (heart rate >250 beats/min); or 3) polymorphic VT and VF.

FIGURE 1 Patient Selection Flow Chart



EF = ejection fraction; ICD = implantable cardioverter-defibrillator; VF = ventricular fibrillation; VT = ventricular tachycardia; WCD = wearable cardioverter-defibrillator.

The time interval from ICD explant to reimplantation was approximated as days between WCD prescription and the last day of WCD use when ICD placement was documented as the discontinuation reason.

STATISTICAL ANALYSIS. Continuous variables are presented as mean ± SD when normally distributed or as median with interquartile range (IQR) when skewed. Categorical variables were presented as frequencies and percentages.

VT/VF event rate was calculated as total number of VT/VF events divided by total number of patients at risk during a specified period. The cumulative probability of sustained VT/VF was displayed according to Kaplan-Meier method through the WCD use. Patients were censored when they stopped wearing the WCD. The cumulative survival of patients who experienced at least one VT/VF event was also analyzed through Kaplan-Meier method; and patients were censored if mortality status was unknown at the time of analyses. A 2-sided p value of <0.05 was considered statistically significant. All statistical analyses were conducted using SPSS version 23 (IBM Corp., Armonk, New York).

TABLE 2 VT/VF Events and Presenting Arrhythmias

	Monomorphic VT (HR ≤250 beats/min)	High-Rate Monomorphic VT (HR >250 beats/min or Ventricular Flutter)	Polymorphic VT/VF	Total
Treated VT/VF	140 (40%)	25 (7%)	183 (53%)	348 (86%)
Nontreated VT/VF	49 (84%)	2 (3%)	7 (12%)	58 (14%)
Total	189 (47%)	27 (7%)	190 (47%)	406 (100%)

Values are n (%).
HR= heart rate. Other abbreviations as in Table 1.

RESULTS

A total of 8,058 patients met the study inclusion criteria and were included in the final analysis (Table 1). Mean age was 62 ± 14 years (range 8 to 100 years). Men comprised 75% of the study cohort. The mean duration of follow-up was 88 ± 148 days. Figure 1 summarizes the patient selection and clinical course flow chart.

VENTRICULAR ARRHYTHMIAS AND MORTALITY. A total of 334 patients experienced 406 VT/VF events. The majority of patients (n = 283, 85%) experienced only 1 event; 51 (15%) had more than 1 event, and 12 of the 51 experienced more than 2 events. Among the 406 VT/VF events, 348 (86%) were hemodynamically unstable (i.e., patient lost consciousness and did not use the response buttons during an event) and were shocked by the WCD. In 54 VT/VF events, patients did not lose consciousness and used the response buttons to avert shocks, and in all cases the arrhythmias spontaneously terminated. When analyzing the presenting rhythm, monomorphic VT (<250 beats/min) was the predominant rhythm (84%) during conscious arrhythmia events, while monomorphic VT (<250 beats/min) was the presenting arrhythmia in 40% of all episodes treated. (Table 2). Four other nontreated VT/VF episodes were due to heart rate falling below the programmed detection threshold after initial detection (n = 2), low amplitude VF (n = 1), and capacitor damage (n = 1).

Median time from ICD explant to first VT/VF event was 29 days (IQR: 11 to 65 days). VT/VF more commonly presented early after ICD explant, with a weekly event rate of 0.9% (95% confidence interval [CI]: 0.7% to 1.1%) during the first week, then 0.7% (95% CI: 0.5% to 0.9%), and 0.7% (95% CI: 0.6% to 1.0%), respectively, during the next 2 weeks. The VT/VF event rate decreased slightly to 0.4% (95% CI: 0.3% to 0.7%) per week starting from the fourth week through the end of month 2, except for the fifth week, when it was 0.6% (95% CI: 0.5% to 0.9%). During the first 2 months, 74% of events occurred, making the 2-month event rate 4.2% (95% CI: 3.6% to 4.9%) (Figure 2A).

Although the event rate incidence decreased over time, the risk continued throughout the duration of follow-up. There were 52 episodes that occurred between 3 months and 1 year and 20 episodes that occurred after 1 year. The longest time to event was a little more than 4 years (1,475 days) from ICD removal. The cumulative 1-year VT/VF rate was 10% (95% CI: 9% to 12%) (Figure 2B).

Overall, 93% of patients (312 of 334) were alive for at least 24 h after the first VT/VF event, whether or not treated by the WCD, with 94% survival in those who experienced shocked VT/VF events. In Kaplan-Meier survival analysis, 81% (95% CI: 77% to 86%) survived the first month, and 75% (95% CI: 70% to 80%) survived 90 days. The 1-year survival rate was 66% (95% CI: 60% to 71%) (Figure 3). In the nontreated VT/VF group, 1-year survival was 76% (95% CI: 63% to 89%).

POST-WCD STRATEGY. At the time of analysis, 8,031 patients finished wearing the WCD. The remaining 27 patients (0.3%) still using the WCD were censored from analysis. A total of 2,411 patients discontinued WCD for nonmedical reasons. The majority of the cohort (n = 4,505 [80%]) underwent ICD reimplantation after ending WCD use. Other reasons for discontinuation of WCD use included ejection fraction improvement (n = 460 [8%]) and condition deteriorated requiring immediate hospitalization (n = 132 [2%]). Death was the reason for WCD discontinuation in 523 patients (9%). Fifty-seven patients had fatal asystole with the WCD being active at that time and 7 died of VT/VF. The remaining 459 deaths were considered unknown because the death occurred in the hospital with the WCD turned off or removed before death.

Figure 4 summarizes the distribution of WCD use duration before reimplantation. Among those who received an ICD, median time of WCD use was 50 days (IQR: 24 to 83 days). Notably, the longest length of WCD use was 1,475 days, or a little more than 4 years, before receipt of another ICD. In this example, a male patient presented with a pocket infection involving the ICD and was prescribed a WCD. During WCD use, the patient underwent coronary artery bypass graft and valve surgery while continuing to use the WCD. He experienced 2 VT events, and both were successfully shocked by the WCD. The patient was eventually reimplanted with an ICD.

INAPPROPRIATE WCD SHOCKS. Of the 8,058 total patients, 159 (2%) received inappropriate shocks. No death was caused by inappropriate shocks.

DISCUSSION

Lead-associated endocarditis is the most common indication for ICD explant (6). Unlike lead fracture or ICD mechanical malfunction, device-related infection often requires delayed reimplantation after complete ICD system removal because of prolonged antibiotic therapy. Patients are generally discharged from the hospital until reimplantation is warranted.

Efficacy and safety of the WCD have been reported favorably in previous studies (7,8,10). However, the description of arrhythmia risk and outcomes among WCD patients with explanted ICDs have been limited. Chung et al. (7) reported on the aggregate national experience with the WCD, which showed the ICD explant group presented with the highest number of events. They found that 45 of 638 patients (8%) had VT/VF episodes post-explant, which was almost 8-fold higher than the risk for all other indications (7). Tanawuttiwat et al. (9) did a single-site study on WCD use after ICD removal among 97 patients and observed a 4% SCA rate within the first 40 days. Compared with patients using a WCD for secondary prevention (previous VT/VF with delayed first ICD placement) and primary prevention indications, patient having an ICD explanted demonstrated the highest VT/VF risk.

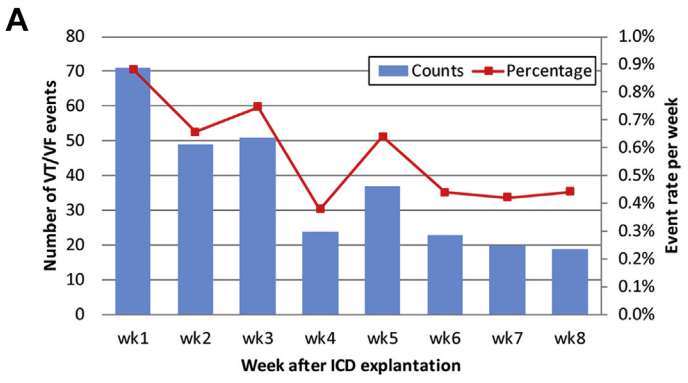
Our study found the incidence of VT/VF is time dependent. The highest occurrence was noted in the initial weeks after ICD explantation, with a first-week event rate of 0.9%, followed by 0.7% for the second and third weeks, respectively. We further observed that the 2-month event rate (4%) was consistent with the previous much smaller single-site study by Tanawuttiwat et al. (9).

Although the incidence of VT/VF decreased by 2-fold by 4 weeks post-ICD explant, VT/VF episodes continued to occur, resulting in a cumulative event rate at the end of 1 year of 10%.

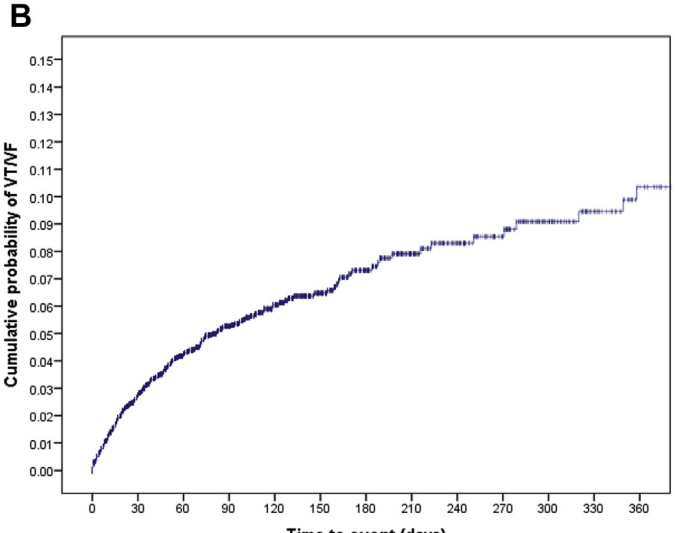
We found the overall VT/VF occurrence rate to be high in the acute period after ICD removal compared with event rates in outpatient ICD follow-up reports (11). Several factors may be at play. First, comorbidities such as endocarditis, associated valvular involvement, or cardiac emboli could exacerbate ventricular arrhythmias in patients at known increased risk (4,12). Second, the ICD explant procedure itself may lead to an acute increase in VT/VF.

Unlike an ICD, the WCD allows conscious patients to avoid unnecessary shocks. Shocks delivered to conscious patients are painful and may cause long-term psychological stress. In addition, ICD shocks are associated with higher mortality. The MADIT-RIT (Multicenter Automatic Defibrillator Implantation Trial-Reduce Inappropriate Therapy) investigators reported that reducing total therapy by 70% in the delayed therapy group and by 83% in the high-rate therapy group, the observed mortality reduction was 44% and 55%, respectively (13). The study concluded

FIGURE 2 VT/VF Risk Over Time



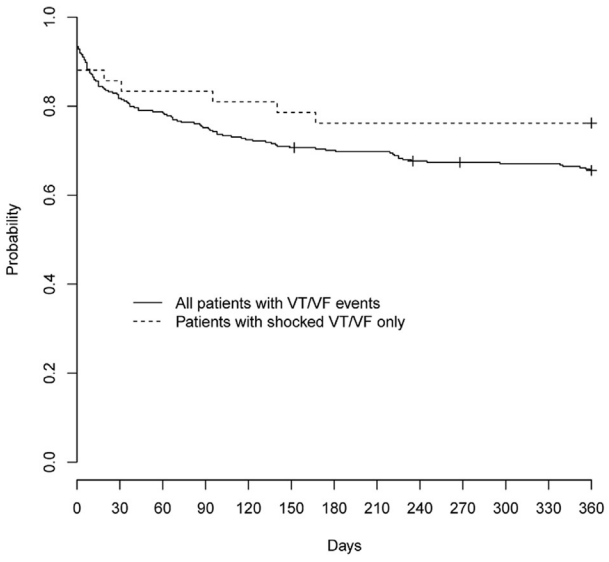
Week	1st	2nd	3rd	4th	5th	6th	7th	8th
VT/VF events	71	49	51	24	37	23	20	19
Patients at risk	8,058	7,460	6,835	6,330	5,786	5,230	4,747	4,297



Days	30	60	90	120	150	180	210	240	270	300	330	360
VT/VF events	190	69	28	13	5	7	4	2	1	2	1	2
Patients at risk	8,058	5,488	3,413	2,080	1,335	956	722	548	450	379	305	250

(A) VT/VF event occurrence during the first 8 weeks. **(B)** One-year cumulative probability of VT/VF events. Abbreviations as in Figure 1.

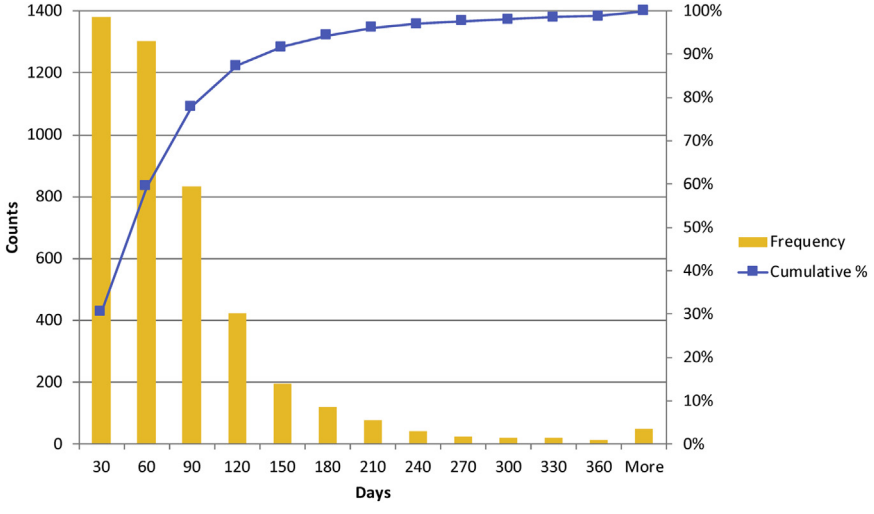
FIGURE 3 One-Year Kaplan-Meier Survival Curve for Patients With VT/VF Events



	Days	60	120	180	240	300	360
Patients at risk	All patients with VT/VF events (n=344)	263	243	234	226	222	217
	Patients with self-terminated VT/VF only (n=42)	36	35	33	33	33	33

Abbreviations as in Figure 1.

FIGURE 4 Distribution of Time From Implantable Cardioverter-Defibrillator Explant to Reimplantation (n = 4,505)



that defibrillator shocks, whether appropriate or inappropriate, cause myocardial damage.

In our study, 54 sustained VT/VF events were detected by the device but were not treated because conscious patients used the response buttons to avert a shock. When the presenting rhythm was analyzed, monomorphic VT made up the majority of conscious arrhythmia events. All arrhythmias during these nonshocked VT/VF events spontaneously resolved.

The inappropriate shock rate was low in our study. The 2% inappropriate shock rate was comparable to the 1% reported by the WEARIT-II (Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator) investigators (8).

After excluding patients who discontinued the WCD for nonmedical reasons, the majority of the cohort (81%) underwent ICD reimplantation. Timing of ICD reimplantation varied widely. This likely reflects careful assessment to determine whether the infection has been completely treated and, possibly, whether the patient still required or agreed to reimplantation. Antibiotic treatment of ICD infections usually lasts 10 to 14 days, with therapy course extension as long as 4 to 6 weeks if infection is complicated (4). Once the infection is cleared, patients may undergo ICD reimplant. In our study, the median time from explant to reimplant was 50 days (IQR: 24 to 83 days), which is somewhat longer than previously reported (9).

After ICD explant, 78% of patients used the WCD for up to 3 months. Of the 22% who continued wearing the device after 3 months, 6% continued beyond 6 months, and 1% continued to use the WCD for more than 1 year. The reasons for longer-term WCD use were not clearly reflected in the registry database. However, such findings indicated that the WCD can be safely used over prolonged periods of time.

In the current cost-sensitive health care system, treatment modalities must be compared on the basis of whether they are clinically effective as well as economically favorable. Previously published articles reported a mean length of use in all WCD patients of about 2 months (7,10). Although the majority of the study cohort fell within that range, many exceeded that number. In light of our findings, future studies should address questions related to whether using the device for a prolonged time in explant patients is cost effective. In our study, we found that 5% of the VT/VF events occurred after 1 year of WCD use, and 1 event occurred as long as after 4 years of use. The device remained effective in terminating VT regardless of the length of use. Healy and Carrillo (14) performed a cost-effectiveness (CE) analysis of WCD use among ICD explant patients and reported that the WCD was economically favorable when it was used for at least 2 weeks after explant. They found it cost, on average, $26,436 to earn another quality-adjusted life-year (QALY), and the dollar amount per QALY remained below the societal willingness-to-pay threshold of $100,000/QALY, even as length of wear increased after the second week (15). They concluded that the CE ratio is time sensitive and positively related to SCA risk. Clinicians should be aware that Healy's model only explored the fluctuation of CE ratio up to 2 months. Thus, although the statement that the CE ratio is associated with time and SCA risk may remain true, the actual number is unknown. Importantly, the VT/VF incidence, as stated earlier, is higher in the post-extraction population, making the cost per life year saved lower than for the majority of ICD patients.

Eight percent of patients did not receive an ICD at the time of ending use of a WCD. Although the number is fairly small, our findings suggest that not every patient will require or agree to reimplantation. In these patients, the WCD can provide protection from fatal VT/VF episodes while the reimplantation decision unfolds.

STUDY LIMITATIONS. This was a retrospective study that relied on information stored in the manufacturer's registry. A comprehensive clinical profile was not available for most patients, including underlying cardiac disease, indication for ICD, duration of ICD insertion before extraction, type of infection, type of ICD extraction procedure, rationale for prolonged WCD use, and long-term follow-up after the end of WCD use. The limitations of the current database have precluded a detailed long-term survival benefits analysis. A prospective study may be warranted.

CONCLUSIONS

Patients who underwent ICD explant were at elevated risk for VT/VF after hospital discharge. The WCD provided effective protection against VT/VF mortality, with a low incidence of unnecessary shocks, while patients were receiving antibiotic therapy. Clinicians used the device as a short-term (up to 12 weeks) solution for SCA protection in the majority of patients. In 22% of patients, the WCD was used as a longer-term (>3 months) solution. Our study suggests that this noninvasive device can offer clinician flexibility in managing post-ICD explant patients during a vulnerable period until a long-term risk management strategy can be implemented.

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PERSPECTIVES

COMPETENCY IN MEDICAL KNOWLEDGE: In a retrospective analysis of patients who underwent ICD device removal for a device-related infection and were prescribed a WCD, the risk of VT/VF was 10% at 1 year, and the WCD was highly effective for preventing sudden cardiac death.

TRANSLATIONAL OUTLOOK: The WCD is a safe alternative to immediate device implantation in patients with device-related infections. Patients can wear the WCD for long periods of time while appropriate clinical evaluation and treatment of infection and underlying heart disease proceed. Better characterization of patients receiving a WCD will be useful to further risk-stratify benefit and risk of sudden cardiac death.

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KEY WORDS **cardiac device infection, implantable cardioverter-defibrillator, sudden cardiac arrest, ventricular arrhythmia, wearable cardioverter-defibrillator**