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Real world utilization and impact of the wearable cardioverter-defibrillator in a community setting



Aditi Naniwadekar^{a,*,1}, Talal Alnabelsi^b, Kamal Joshi^{a,1}, Edinrin Obasare^{a,1}, Allan Greenspan^{a,1}, Sumeet Mainigi^{a,1}

^a The Institute for Heart and Vascular Health, Einstein Medical Center, Philadelphia, PA, United States

^b Department of Internal Medicine, Einstein Medical Center, Philadelphia, PA, United States

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ABSTRACT

Introduction: The wearable cardioverter-defibrillator (WCD) is used in patients at risk for sudden cardiac death (SCD) but not immediate candidates for intracardiac defibrillator (ICD) implantation.

Methods: We performed a single center retrospective study of patients prescribed WCD upon hospital discharge from January 2002 to October 2015. Clinical characteristics were obtained from the hospital electronic database and device data from Zoll LifeVest database.

Results: Of 140 patients, 62% were men, 85.9% were African-American and mean age was 58.2 ± 15.5 years. Ischemic cardiomyopathy was present in 45 (32%) and non-ischemic cardiomyopathy in 64 patients (46%). Mean left ventricular ejection fraction (EF) was 0.28 ± 0.4 . WCD was worn for 7657 patient-days (21 patient-years), with each patient using WCD for median of 43 days (IQR: 7–83 days), and daily mean use 17.3 ± 7.5 h. There were a total of 6 (4.2%) WCD shocks of which 2 (1.4%) were appropriate (one for VT, one for VF) and 4 (2.8%) were inappropriate (2 had supraventricular tachycardia, 2 had artifact). Two patients who received appropriate shocks were African-American with non-ischemic cardiomyopathy (EF < 20%), non-sustained VT and wide QRS duration. Upon termination of WCD use, 45 (32%) received ICD while EF improved in 34 patients (32%).

Conclusions: In a predominantly minority, community setting, WCD compliance is high and use is effective in aborting SCD. However, inappropriate shocks do occur. A significant proportion of patients did not ultimately require ICD implantation suggesting this may be a cost-effective strategy in patients at risk of SCD.

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1. Introduction

The wearable cardioverter-defibrillator (WCD) is an external device capable of recognizing and defibrillating life-threatening tachyarrhythmias. It has been available since 2002 and serves as a prophylactic strategy for patients at risk of sudden cardiac death (SCD) who are not immediate candidates for the Implantable Cardiac Defibrillator (ICD). ICD implantation is commonly deferred due to a patient's comorbid factors, the presence of an infection or when the risk of SCD is undetermined (genetic abnormalities,

syncope of unknown cause) [1]. This could also occur when the indication for ICD implantation has not yet been established: within 3 months of diagnosis of non-ischemic cardiomyopathy (NICM) with left ventricular (LV) ejection fraction $\leq 35\%$, 40 days after an acute myocardial infarction with LV dysfunction without revascularization or 90 days after revascularization [2,3].

While the risk of SCD remains the highest in the first 30 days after an acute myocardial infarction and LV dysfunction, results of the DINAMIT study revealed no survival benefit for implanting an ICD in those 30 days [4,5]. Physicians in the meantime have adopted the practice of using the WCD as a prophylactic measure in this time period based on non-randomized trials [1,6,7]. Patients with NICM on the other hand are also prescribed the WCD in the 3 months of goal directed medical therapy (GDMT), albeit in the absence of supportive evidence [8]. The patient population who is likely to derive benefit from the WCD has yet to be defined. We

* Corresponding author. 5501 Old York Rd., Philadelphia, PA, 19141, United States.

E-mail address: aditinaniwadekar@gmail.com (A. Naniwadekar).

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hereby report our own experience with the WCD at a large academic institution in an African-American predominant population, using independently derived data.

2. Methods

We conducted a single center retrospective study of 140 consecutive patients prescribed a WCD between January 2002 and October 2015. Indications for WCD were based on Medicare Durable Medical Equipment Regional Carrier local coverage policies for use, but in some cases it was prescribed at the discretion of the individual physician. WCD indications included patients with recent MI, post-revascularization with EF < 35%, newly diagnosed NICM, VT/VF while awaiting ICD implantation, following ICD explant or genetic predisposition to SCD. Patients with these conditions were prescribed a WCD at the discretion of the treating physician. Patient demographics and past medical history including medications used were obtained from the electronic medical records. Patients were categorized as NICM if they had no evidence of significant coronary artery disease (major coronary artery stenosis >70%) on cardiac catheterization or if nuclear imaging data revealed no evidence of myocardial scar. Approval for the study was obtained from the institutional review board at Einstein Medical Center, Philadelphia.

2.1. WCD description

The WCD is a 1.7-lbs defibrillator unit with 3 non-adhesive defibrillation electrodes and 4 non-adhesive capacitive electrodes for monitoring 2 surface leads incorporated into a chest strap. The defibrillation electrodes are positioned for apex-posterior defibrillation. On detection of an arrhythmia, there is vibration against the skin, audible tones, and a voice cautioning bystanders of an impending shock. Patients are trained to hold a pair of response buttons during these alarms. If no response occurs, the device presumes that the patient is unconscious and as a result charges, extrudes gel from the defibrillation electrodes, and delivers up to 5 biphasic shocks of pre-programmable energy levels with maximum output of 150 J. The WCD did not have pacing capability in this version, it recorded asystole events and broadcast “device disabled, call ambulance” to enlist bystander help once asystole was detected.

Patients were fitted with the device prior to their discharge and instructed on how to use the WCD by the providing physician and a device representative. Patient WCD shock data were obtained from electronic medical records and from the manufacturer. Patient compliance was defined as the time during a day that a WCD user had the device on, the belt connected, and at least one electrocardiogram lead contacting the skin and was assessed by real-time monitoring. Days were determined as any day with at least some WCD use. All potentially lethal arrhythmias (sustained VT/VF or asystole) occurring within 24 h were considered a single SCA event. A cardiologist and cardiac electrophysiologist independently determined WCD shocks to be appropriate if they occurred on sustained VT/VF and inappropriate if not. Inappropriate shocks were further analyzed for inappropriate detection cause from electrocardiogram recordings and lack of response button use from patient call reports. Two-lead electrocardiograms from all shocks and baseline tracings were reviewed by the two physicians and differences adjudicated by consensus with the first author. Patient call reports and the electronic database at Einstein Medical center were reviewed for reports of deaths while wearing a WCD.

3. Statistical analysis

The chi-square or Fisher exact tests were used to compare discrete variables which are listed as absolute numbers and percentages. Normally distributed continuous variables are listed as mean \pm SD and were compared using Student t tests. The Mann-Whitney *U* test was used to compare nonparametric continuous variables which are listed as medians with interquartile ranges (IQRs). A *p* value < 0.05 was considered statistically significant. All *p* values are 2-sided. All statistical analyses were performed using SPSS version 22.0 (IBM, Armonk, New York).

4. Results

A total of 140 patients were included in the study. Baseline characteristics of the patients are depicted in Table 1. Notably, 85.9% of the subjects were of African American race. The mean age was 58.2 \pm 15.5 years. Mean age for the African American patients was 57.5 years, and 62.1 years for non-African American race. The mean QRS duration was 102.7 ms Mean serum creatinine level and eGFR were 1.17 mg/dl and 81 respectively. Non-sustained ventricular tachycardia (NSVT) was detected before WCD prescription during telemetry monitoring in 50 (37%) patients. Ischemic cardiomyopathy (ICM) was present in 45 patients (32%) and non-ischemic cardiomyopathy (NICM) in 64 patients (46%).

Specific clinical indications for prescription of the WCD are depicted in Fig. 1.

4.1. WCD utilization

The WCD was worn for a total of 7657 patient-days (21 patient-years), with each.

patient using the WCD for a median of 43 days (IQR: 7–83 days), and a daily mean use of 17.3 \pm 7.5 h. The mean ejection fraction on 2D echocardiography was 28% \pm 40%.

The percentage of compliance for the total wear time was 62%. Patients with NICM wore the WCD for a longer duration (median duration 59 days vs. 38 days in the ICM group). Daily compliance was greater in patients with ICM (median duration 22 h vs 20 h in the NICM group).

Table 1
Demographics.

Characteristics	Number of patients	Percentage (%)
Race		
African American	116	85.9
Caucasian	15	11.1
History of VT	32	23.7
History of VF	7	5.2
History of NSVT	50	37
Acute Myocardial Infarction	31	23
STEMI	15	11.1
NSTEMI	16	11.9
Revascularization	41	30.4
Stenting	38	28.1
CABG	4	2.3
Cardiomyopathy	109	82
ICM	45	33.8
NICM	64	48.2
Medications		
Beta Blockers	122	90.4
Amiodarone	11	8.1
CCB	22	16.3
ACEI/ARBs	95	70.4

Clinical Indications for WCD

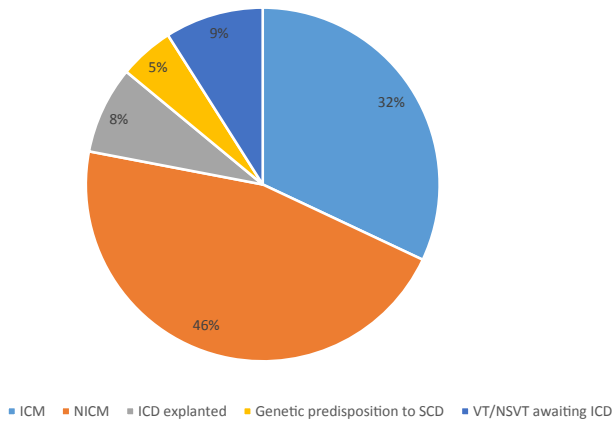


Fig. 1. Clinical indications for WCD.

4.2. WCD shocks

There were a total of 6 (4.2%) WCD shocks out of which 2 (1.4%) were appropriate (one for VT, one for VF) and 4 (2.8%) were inappropriate (2 had supraventricular tachycardia, 2 had artifact). Distribution of WCD shocks is presented in Fig. 2. No patient with ICM (0 of 45; 0%) received an appropriate shock from the WCD during the wear time. Among NICM patients, 2 of 64 (3.1%) received appropriate shocks. Their left ventricular ejection fraction on echocardiography was 10% and 15% respectively and both had sustained VT as an indication for the WCD. Of note, both patients were of African-American ethnicity and had QRS duration of 118 ms and 128 ms respectively.

One of these patients went on to have an ICD implanted for secondary prevention. The other patient had sustained ventricular tachycardia in the setting of hyperkalemia and acute renal failure and subsequently recovered her EF obviating the need for an ICD. One episode of sustained VT occurred in a 35-year-old male with idiopathic VT, which terminated after external defibrillation in the emergency department because the patient intentionally withheld shock therapy.

On the other hand, 1 of 64 (1.6%) NICM patients received an inappropriate shock due to artifact. Two ICM patients (4.4%) received inappropriate shocks, both due to rapidly conducted supraventricular tachycardia. One patient with recurrent syncope and NSVT received an inappropriate shock due to artifact.

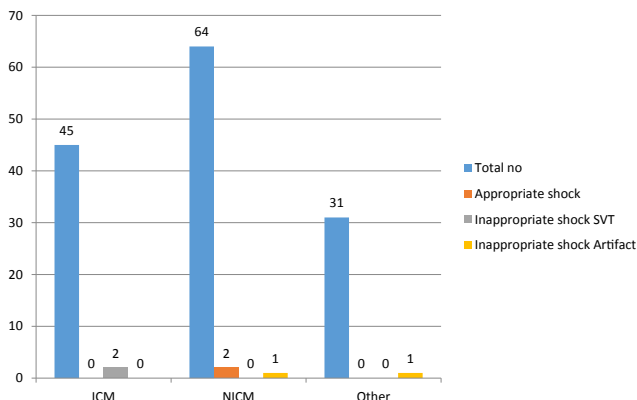


Fig. 2. Distribution of WCD shocks.

4.3. Follow-up and patient outcomes

During follow-up, LVEF improved in 34 patients (32%) obviating the need for a prophylactic ICD (Fig. 3). Twenty one patients (33%) had LVEF improvement > 35% in patients with NICM. Twenty five patients (56%) ultimately underwent ICD implantation for primary prevention because of a persistently low EF. On the other hand, 14 patients (31%) with ICM received an ICD. Thirteen patients (29%) with ICM recovered their LV function to > 35%, obviating the need for an ICD.

Upon termination of WCD use, a total of 45 patients (32%) received an intracardiac defibrillator. Seven patients decided not to pursue device implantation. Other outcomes include: lack of follow up (n = 32), death (n = 7) and clinical worsening/poor prognosis (n = 2). Four people are currently awaiting reassessment of LVEF to determine a need for ICD implantation.

Seven patients died during follow up whilst wearing the WCD. Five patients had ICM while 2 patients had NICM. Four patients had WCD removed prior to death because of hospice or comfort care and 3 patients had PEA/asystole.

5. Discussion

Our study is a single-center experience of predominantly minority race patients discharged with a WCD from a large academic community hospital. There were more WCD prescriptions for NICM compared to ICM which is likely due to higher prevalence of NICM in our setting. The rate of appropriate shocks was 1.4% during a median wear time of 73 days, with no appropriate shocks delivered for patients with ICM. The rate of inappropriate shocks was 2.8% during the same median wear time. Two appropriate shocks were delivered by the WCD among newly diagnosed NICM patients, both of whom were African-American patients (1 male and 1 female) and had intraventricular conduction delay on ECG with evidence of NSVT on telemetry.

In patients with NICM, the DEFINITE (Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation) trial demonstrated that in patients implanted with an ICD after NICM diagnosis, there was reduced arrhythmic death compared to patients without an ICD. However, this benefit was not observed early after implantation, and patient numbers were small [9]. Data from previous studies investigating outcomes in patients with NICM suggest that the impact of defibrillators on reduction of SCD in patients during the first 90 days on GDMT is low [10,11]. The VALIANT trial has demonstrated that early risk of SCD is not insignificant in patients

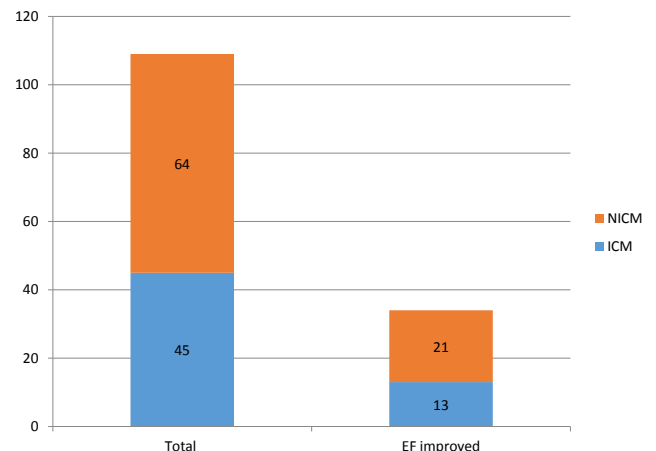


Fig. 3. Improvement in left ventricular ejection fraction.

with newly diagnosed ICM. [12].

A recent study by Singh et al. demonstrates that the rates of appropriate shocks in patients with ICM are greater than those with NICM and emphasizes that the benefit of WCDs in reduction of SCD in patients with NICM is not insignificant [8]. They concluded that the number of lives saved by the WCD were 4 of 271 (1.5%) which draws a parallel to the DINAMIT (Defibrillator in Acute Myocardial Infarction Trial) and IRIS (Immediate Risk-Stratification Improves Survival) studies, demonstrating that ICDs decrease sudden, arrhythmic death, but do not diminish overall mortality [5,13].

Prior studies have demonstrated that heart failure is more prevalent in African Americans than in whites with earlier onset, higher rates of death and morbidity and a more malignant course. When hospitalized for heart failure, African Americans have a 45% greater risk of death or decline in functional status than whites. Hypertension is the main culprit for subsequent heart failure in African Americans along with diabetes, obesity and chronic kidney disease. There is also evidence of more target-organ damage due to higher likelihood of poorer control of hypertension. As compared with whites, African Americans are also significantly younger (mean age >10 years younger) at presentation and are more likely to have nonischemic cardiomyopathy [14,15]. In addition, there are also racial differences in the incidence of SCD that are not well understood. It seems that the African American population appears to experience out-of-hospital cardiac arrest several years earlier than whites and with lower survival rates after cardiac arrest [16]. Racial differences in the baseline characteristics of patients admitted for acute heart failure have been described from both the Outcomes of a Prospective Trial of Intravenous Milrinone for Exacerbations of Chronic Heart Failure (OPTIME-CHF) study and the 2001–2004 Acute Decompensated Heart Failure National Registry (ADHERE) [17,18].

Paradoxically, based on our center's experience, the rates of prescription for NICM exceeded those with ICM. Unlike the experience of Singh et al., patients with NICM at our center experienced a higher incidence of appropriate shocks. Though the demographic breakdown of their patient population based on race has not been specified in the study, the reason for this might be linked to the ethnic composition of our patient population of which 85.9% were of African-American ethnicity. Due to differences in genetic composition, presentation of HF and risk of sudden cardiac death, similar risk-stratification for prescription of WCD between ethnic minorities and the general population cannot be made.

Unfortunately, there have been no randomized clinical trials assessing the utility of the WCD in newly diagnosed cardiomyopathy, particularly NICM or its role in preventing early SCD compared to GDMT alone. The WEARIT-I/BIROAD registry enrolled 289 patients at high risk of SCD but who were not able to receive an ICD. In the study, the risk of appropriate WCD shocks was 2.8% while that of the risk of inappropriate WCD shocks was 2.1%. However, the exact proportions of patients within pre-specified categories of SCD risk were not specified [19].

The WEARIT-II Registry enrolled 2000 patients with ischemic (40%), or non-ischemic cardiomyopathy (46%), or congenital/ inherited heart disease (n = 268) prescribed WCD between August 2011 and February 2014. There were a total of 22 (1.1%) appropriate shocks while the inappropriate shock rate was 0.5% [20].

In a manufacturer-sponsored nationwide WCD registry comprising of 3569 patients that included primary prevention patients, secondary prevention patients, and patients with an explanted ICD, Chung et al. reported an overall incidence of 1.7% for appropriate shocks and 1.9% for inappropriate shocks. There were 80 sustained VT or VF events in 59 patients. The overall survival rate was 99.2% and long-term mortality was not significantly different from first ICD implant patients during WCD use. The long-term

mortality was highest among patients with traditional ICD indications.

We reported 4 (2.8%) inappropriate shocks in our study. Two of these patients had supraventricular tachycardia and 2 had artifact misinterpreted as ventricular tachyarrhythmias. High incidence of inappropriate shocks can produce acute pain, anxiety, depression and even patient reluctance to wear the WCD. Patients are educated to suppress the shock if they are awake and thus hemodynamically stable; however, this only occurred in one patient who had recurrent VT episodes but was otherwise asymptomatic. Our center serves predominantly an ethnic minority and an underserved population which could explain the lack of literacy in some of our patient groups and thus poor understanding of device function. Another reason could be reluctance to abort a shock in fear of interfering with the device.

We need to develop better predictors of early SCD in ethnic minorities patients with newly diagnosed cardiomyopathy with larger randomized trials. As 32% of the patients in our study experienced LVEF improvement and were spared an ICD, it seems that WCD may prevent this costly and invasive therapy. However, the incidence of inappropriate shocks is not negligible and the side-effects of inappropriate shocks should be considered before prescribing a WCD.

6. Study limitations

Our study is a small and single-center analysis, thus our results may not be generalizable to the whole population. Due to its retrospective design, we are unable to determine whether WCD use improves mortality or not.

7. Conclusion

In a predominantly minority population in a community setting, the WCD compliance is high and use is effective in aborting SCD due to ventricular tachyarrhythmias. However, inappropriate shocks do occur. While a large number of WCD were prescribed to prevent a small number of ventricular arrhythmias, a significant proportion of patients did not ultimately require ICD implantation suggesting this may be a cost-effective strategy in patients at concerning risk of SCD. Further trials and better risk stratification should be undertaken before this practice becomes the standard of care.

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