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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.

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 ≤ 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 ± 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 ± 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 ± 7.5 h. The mean ejection fraction on 2D echocardiography was 28% ± 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