Use of the Wearable Cardioverter Defibrillator in High-Risk Cardiac Patients: Data from the Prospective Registry of Patients Using the Wearable Cardioverter Defibrillator (WEARIT-II Registry)

Running title: Kutyifa et al.; WEARIT-II

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Journal Subject Term: Arrhythmias, clinical electrophysiology, drugs
Abstract

Background—Prospective data on the safety and efficacy of the wearable cardioverter defibrillator (WCD) in a real world setting are lacking. The Prospective Registry of Patients Using the Wearable Defibrillator (WEARIT-II) Registry was designed to provide real world data on the WCD as a strategy during a period of risk stratification.

Methods and Results—The WEARIT-II Registry enrolled 2000 patients with ischemic (n=805, 40%), or non-ischemic cardiomyopathy (n=927, 46%), or congenital/inherited heart disease (n=268) prescribed WCD between August 2011 and February 2014. Clinical data, arrhythmia events, implantable cardioverter defibrillator (ICD) implantation, or improvement in ejection fraction (EF) were captured. The median age was 62 years, median EF was 25%. Median WCD wear-time was 90 days, with median daily use of 22.5 hours. There were a total of 120 sustained ventricular tachyarrhythmias (VT/VF) in 41 patients, of whom 54% received appropriate WCD shock. Only 10 patients (0.5%) received inappropriate WCD therapy. The rate of sustained VT/VF by 3 months was 3% among patients with ischemic cardiomyopathy and congenital/inherited heart disease, and 1% among non-ischemic patients (p=0.02). At the end of WCD use, 840 patients (42%) were implanted with ICD. The most frequent reason not to implant ICD following WCD use was improvement in EF.

Conclusions—The WEARIT-II prospective Registry demonstrate a high rate of sustained VT/VF at 3 months in at-risk patients who are not eligible for an ICD, and suggest that the WCD can be safely used to protect patients during this time period of risk assessment.

Key words: implantable cardioverter-defibrillator; ventricular fibrillation; ventricular tachycardia; sudden cardiac death; Wearable Cardioverter Defibrillator; Risk Stratification
Background

Sudden cardiac death (SCD) due to ventricular tachyarrhythmias is a significant contributor to mortality in heart disease patients accounting for approximately 300,000 deaths per year in the United States. Defibrillation therapy, if delivered within minutes of the patient’s collapse, provides the highest probability of surviving life-threatening ventricular tachyarrhythmias.\(^2\)

Implantation of an implantable cardioverter defibrillator (ICD) is associated with a significant reduction in all-cause mortality in at-risk cardiac patients.\(^2-4\) However, appropriate selection prior to a decision for ICD implantation may be essential in several patient subsets, including patients with a transient risk for SCD; patients who do not meet current guideline indications for an ICD due to restrictions based on time from specific clinical events (e.g., myocardial infarction);\(^5\) patients who previously have had an ICD removed because of complications or malfunction, patients who refuse an ICD, and patients with a suspected arrhythmic disorder who are still undergoing evaluation.

The Wearable Cardioverter Defibrillator (WCD) provides continuous arrhythmia monitoring, detection of arrhythmic cardiac arrest and automatic defibrillation with rapid detection of the potentially fatal ventricular tachyarrhythmia. The safety and effectiveness of the WCD in saving lives has been documented in publications including the first testing reported in 1998,\(^6\) the WEARIT/BIROAD study in 2004,\(^7\) and the first retrospective report in 2010.\(^8\)

The aim of the WEARIT-II Registry, the first prospective, observational registry on the WCD, was 1) to characterize the patients currently prescribed with a wearable cardioverter defibrillator, 2) to assess the risk for sustained ventricular tachyarrhythmic events among at-risk cardiac patients during the WCD use by the etiology of the disease, and 3) to identify the rate of ejection fraction improvement and the need for subsequent ICD implantation in high-risk cardiac patients.
Methods

Study population

All patients who wore a medically prescribed Wearable Cardioverter Defibrillator (LifeVest® system, ZOLL, Pittsburgh, USA) were offered participation in the Registry through a letter included at the time of dispensing the WCD. Current indication for use of the WCD has been outlined earlier. In short, patients with low ejection fraction and a high risk for sudden cardiac death after myocardial infarction, following coronary revascularization, with a new onset dilated non-ischemic cardiomyopathy, with high risk for sudden cardiac death until stabilization, or with inherited or congenital heart disease patients are prescribed WCD. Patients who agreed to participate were entered into the Registry after written informed consent. Patients were expected to receive uniform, current guideline indicated care including medical therapy and management, and the Registry physicians were not involved in any medical care of the subjects. The University of Rochester was the Coordination and Data Center (CDC) for the WEARIT-II Registry, responsible for the overall study and data management of the Registry, independent from the manufacturer of the WCD. The study protocol was approved by the Research Subjects Review Board at the University of Rochester, Rochester, NY. Patients were divided into the following categories: 1) ischemic cardiomyopathy patients with prior MI or known coronary artery disease with a high risk for SCD, 2) non-ischemic cardiomyopathy with no known coronary artery disease, 3) congenital/inherited heart disease patients.

Wearable Cardioverter Defibrillator

The commercially available market-released WCD devices were used in the WEARIT-II Registry. The WCD is composed of a garment containing three self-gelling defibrillation patch
electrodes, two on the back and one in the front, and four non-adhesive ECG electrodes connecting to a monitoring unit that weighs about 0.77 kg.

The WCD continuously monitors the patient’s heart rhythm and can automatically deliver up to 5 posterior-anterior defibrillation shocks. Once an arrhythmia is detected, an alarm sequence starts with a silent vibration and is followed by an escalating audible siren alarms. The device detection algorithm incorporates three inputs: heart rate, template matching, and persistence of the event. The default VT and VF detection rate thresholds are 150 and 200 beats per minute (BPM), respectively. The algorithm also includes a pair of response buttons that allows a conscious patient to respond to the alarm, preventing an unnecessary WCD shock. In the absence of a patient response and the continuing detection of an arrhythmia through the responsiveness test, up to 5 shocks are delivered. The device uses a biphasic shock waveform with programmable energy levels of up to 150 J. The duration of the patient responsiveness test is at least 25 seconds but may last longer if the response buttons are activated or if ECG signal interference is detected. The WCD broadcasts an asystole alarm (including voice alerts to call for help and perform CPR) and starts ECG recording when there is a severe bradycardia detected (below 10 BPM). The device currently does not have any pacing capabilities. Further specific details have been previously published elsewhere.9

Data collection, follow-up

After enrollment, patients completed a baseline questionnaire collecting information on their medical history, comorbidities, and other baseline clinical characteristics. Baseline data on medical history and co-morbidities were collected from self-reports of the patients as well as from the Medical Order Forms completed by the physicians at the participating centers. Device data were collected, providing daily compliance data, using the actual WCD monitoring data.
Compliance was defined as hours per day of use. Electrocardiography data were transmitted on a weekly basis and recorded during arrhythmia and asystole alarms. Patients were sent follow-up questionnaires at 1-, 3-, and 12-months to evaluate interim clinical events. Physicians were sent follow-up questionnaires at 3-, and 12-month follow-up to assess the rate of ICD implantation, and clinical events in their patients. In the current manuscript, we report occurrence of clinical and arrhythmic events during WCD use. Additionally, at the end of the WCD use, typically at 3 months of follow-up, we assessed whether the patients were implanted with an ICD or they improved their ejection fraction. The WCD is typically prescribed and used for 3 months, and the decision of implanting an ICD is made at this 3 month time point, based on reassessment of ejection fraction, the occurrence of arrhythmias, and clinical status. Collection of long-term follow-up data on clinical outcome up to 12-months is currently ongoing.

**Arrhythmia events**

An arrhythmic episode included an onset and a conversion to a slower and regular rhythm. Any arrhythmia episode that was separated by 5 minutes from the previous one was considered a separate episode. Each individual arrhythmia episode was reviewed and adjudicated in the registry and classified into four major categories: 1. Sustained ventricular tachycardia (VT, lasting 30 seconds or longer) or ventricular fibrillation (VF) with WCD shock therapy, 2. Sustained VT with no WCD shock delivered, due to use of the response buttons, 3. Non-sustained VT of less than 30 seconds of duration, or 4. Atrial fibrillation (AF) or supraventricular tachycardia (SVT) properly detected by the device. Inappropriate WCD therapy was classified as non-VT/VF episodes detected and treated by a WCD shock.

**Statistical analysis**

Continuous variables are expressed as median (interquartile range). Categorical data are
summarized as frequencies and percentages. Baseline clinical characteristics were compared between patients with ischemic, non-ischemic cardiomyopathy, or congenital/inherited heart disease, using the Kruskal-Wallis test for continuous variables and the \( \chi^2 \) test or Fisher’s exact test for dichotomous variables, as appropriate. Differences in compliance among subgroups were assessed using non-parametric Kruskal-Wallis tests.

The cumulative probability of first treated VT or VF or sustained VT that spontaneously terminated during response button use or during extended detection time by disease etiology was displayed according to the Kaplan-Meier method through the first 3 months of the WCD use, with comparisons of cumulative event rates by the log-rank test.

Arrhythmic events were captured by calculating the number and percent of patients with specific event types as well as event rates per 100 patient follow-up years. These different measures were compared between different subgroups. The rates of arrhythmia events were analyzed using the total number of events and study follow-up and compared using bar graphs with statistical testing by the negative binomial regression model.

All statistical tests were two-sided, and a nominal p-value of < 0.05 was considered statistically significant. Analyses were carried out with SAS software (version 9.3, and version 9.4 SAS institute, Cary, North Carolina).

**Results**

From August 2011 until February 2014, a total of 2000 patients were enrolled in WEARIT-II Registry. Among enrolled patients, 805 patients (40%) had ischemic cardiomyopathy, 927 patients (46%) had non-ischemic cardiomyopathy, and 268 (14%) patients were diagnosed with congenital or inherited heart disease.
Baseline clinical characteristics

Clinical characteristics of the Registry patients by disease etiology are listed in Table 1. The median age of the study patients was 62 years (IQR: 16). Patients with ischemic etiology were older than patients with non-ischemic and congenital/inherited heart disease (p-value for the overall difference < 0.001). The proportion of women was highest among patients with non-ischemic cardiomyopathy (36%) and lowest among those with ischemic cardiomyopathy (23%). The median ejection fraction was 25%, with relatively lower EF in the non-ischemic group (20%) than in the ischemic (26%) or in the congenital/inherited sub-groups (23%, p-value for the overall difference < 0.001). About half of the study patients reported heart failure (HF) symptoms at baseline. Medical therapy was similar in patient sub-groups. Patients with congenital/inherited heart disease were more likely to have a history of atrial fibrillation, while those with ischemic heart disease were more likely to have a history of sudden cardiac arrest (SCA) (11%) or syncope (23%) prior to WCD use.

Among patients with congenital/inherited disease, the most common etiology was congenital heart disease reported in 61%, followed by inherited heart disease (53%), such as hypertrophic cardiomyopathy (25%), arrhythmogenic right ventricular dysplasia (23%), long QT syndrome (10%) and Brugada syndrome (1%), allowing for multiple diagnoses at initial assessment.

Compliance

Median duration of WCD use was 90 days (IQR: 65), and median daily use was 22.5 hours (IQR: 2.69) in the total patient population (Figure 1A). There was no significant difference in the daily use among the sub-groups of ischemic, non-ischemic or congenital/inherited heart disease (Supplemental Figure 1).
Arrhythmic events

A total number of 120 sustained VT/VF events occurred in 41 patients (Table 2), corresponding to a rate of 22 sustained episodes per 100 patient-years. Notably, most sustained VTs were not treated by the WCD because the patient used the response button to delay therapy and subsequently the VTs self-terminated. Specifically, 90 sustained VT events in 22 patients were withheld from therapy, whereas 30 events in 22 patients required WCD shock therapy due to hemodynamic instability (corresponding to 5 events per 100 patient years). All patients who required shock delivery had their VT/VF episodes successfully terminated with the first shock. The event rate for non-sustained ventricular tachycardia (NSVT) and atrial tachyarrhythmias (SVT/AF) was 30 per 100 patient-years and 101 per 100 patient-years respectively (Table 2).

The rate of inappropriate WCD therapy was very low; only 10 patients (0.5 %, 2 per 100 patient years) had inappropriate WCD therapy during the follow-up due to ECG artifacts. Inappropriate shocks did not induce ventricular tachycardia or ventricular fibrillation.

When the cumulative probability of sustained VT/VF was assessed by disease etiology, patients with ischemic and congenital/inherited heart disease were shown to have significantly higher probabilities of VT/VF than those with non-ischemic cardiomyopathy. In particular, at 3 months of follow-up, the rate of sustained VTs was 3% among patients with both ischemic cardiomyopathy and congenital/inherited heart disease, compared to 1% among those with non-ischemic cardiomyopathy (p=0.02 for the overall difference among the 3 groups; Figure 2A).

Figure 2B shows all atrial and ventricular tachyarrhythmias detected by the WCD during usage, adjusted for follow-up time. Consistent results among patients with ischemic cardiomyopathy and inherited/congenital disorders were shown when the total number of episodes was assessed. Similarly, the rate of all treated VT/VF episodes was higher among
patients with ischemic cardiomyopathy and inherited/congenital disorders compared with the non-ischemic group.

**Decision making after end of WCD use**

At the end of WCD use, an ICD was implanted in 36% of patients with non-ischemic cardiomyopathy, in 42% of the ischemic patients, and in 46% of patients with congenital/inherited heart disease (Figure 3A). The most frequent reason not to implant an ICD following the use of the WCD was improvement in ejection fraction (41%).

Arrhythmia and WCD therapy events during WCD use facilitated the decision of whether to implant an ICD at the end of use. Among patients who had appropriate therapy while using the WCD, 85% received an ICD (Figure 3B). Likewise, the majority of patients (65%) with sustained non-treated VT received an ICD, while less than half of the patients with atrial arrhythmias or without arrhythmias were implanted with an ICD.

Of the 2000 patients who had the WCD, three (0.2%) died during WCD wearing. All three patients demonstrated an asystole event. None of the patients with VT or VF episodes died while wearing the WCD.

**Discussion**

WEARIT-II is the first prospective registry of the WCD to evaluate the safety and efficacy of the WCD as for the prevention of SCD in a real world setting during a time-period of risk assessment. We enrolled and prospectively followed 2000 patients with ischemic cardiomyopathy, non-ischemic cardiomyopathy or congenital/inherited heart disease prescribed the WCD due to increased risk for SCD.

Our findings from the WEARIT-II Registry provide several important clinical implications on the use of the WCD as a bridging strategy in these high risk populations: 1)
compliance with the WCD is very high and independent of disease etiology; 2) the rate of sustained ventricular tachyarrhythmias in patients prescribed a WCD in a real world setting is high (120 sustained events during the median follow-up of 90 days); 3) the risk of VT/VF appears to be high among patients with ischemic cardiomyopathy and congenital/inherited heart disease; 4) usage of WCD appears to be safe, wherein only 10 patients (less than 1%) received an inappropriate WCD therapy and 3 patients died while wearing the WCD, all due to asystole; and 5) the use of WCD may improve risk-assessment prior to a decision regarding the need for ICD implantation. At the end of the WCD use, less than half of the patients needed an ICD implantation, while 40% of the patients improved their cardiac function so that an ICD implantation was no longer indicated.

The safety and effectiveness of the WCD was first documented by Auricchio et al. They prospectively assessed 15 patients and after inducing an episode of rapid VT or VF in 10 of the 15 patients, in 9 of 10 patients the WCD successfully terminated the arrhythmia. No post-shock supraventricular or ventricular arrhythmias occurred. The results were promising but needed confirmation in a larger cohort. The WEARIT/BIROAD was the first study to evaluate the safety and efficacy of the WCD in a larger cohort of patients with heart failure and an EF<0.30 (WEARIT), and in those with high risk for SCD immediately after an MI or bypass surgery (BIROAD Study). After a total of 289 patients had been enrolled in the trial (177 in WEARIT and 112 in BIROAD), pre-specified safety and effectiveness guidelines had been met. Six (75%) of eight defibrillation attempts were successful. These findings provided the basis for wider use of the WCD, however, prospectively assessed data from larger cohorts were still lacking.

The nationwide registry on the WCD published by Chung et al. suggested that compliance was satisfactory with 90% wear time in > 50% of the patients and survival was
comparable to those with an ICD. Asystole emerged as a rare cause of death among WCD users.

In our study, we extended these findings by collecting prospective data on a large cohort of patients. We had a detailed arrhythmia episodes report with the arrhythmia events reviewed and adjudicated in each case. Asystole was less frequent in our cohort, with only 3 patients developing it (0.2%). Furthermore, in our study, for the first time, we evaluated patient compliance, the risk of arrhythmic events, and end of use decisions by disease etiology. We found that disease etiology does not influence compliance, and patients with congenital/inherited heart disease who are younger have similar compliance. In addition, we found important differences in VT/VF risk by disease etiology.

In WEARIT-II, there were a total of 120 sustained VT/VF events corresponding to 22 events per patient year. However the majority of these VT/VF events were self-terminating during the extended detection time. In order to evaluate whether the rate of sustained ventricular tachyarrhythmias among patients currently prescribed a WCD is comparable to those implanted with an ICD, we performed an analysis to compare the rate of VT/VF in the first 3 months in WEARIT-II, to patients enrolled in Multicenter Automatic Defibrillator Implantation Trial – Reducing Inappropriate Therapy (MADIT-RIT). MADIT-RIT consisted of patients with an ICD indication who were randomized to either a high-rate cut-off (Arm B), or delayed VT therapy (Arm C of the trial), both similar to current WCD programming. We observed a 3-month, overall 2% cumulative probability of sustained treated or non-treated VT/VF in WEARIT-II, which was even higher than the 1% event rate of VT or VF rate in MADIT-RIT. This suggests that WEARIT-II enrolled patients were at a higher risk for SCD (Supplemental Figure 2A and B). Importantly, in WEARIT-II the episodes of VT/VF were evenly distributed during the first three months of WCD use.
Furthermore, in WEARIT-II, the majority of sustained VT episodes terminated spontaneously during the use of the response button. These findings have important clinical implications suggesting that the use of the response button may prevent ‘unnecessary therapies’ and improve outcome. Also, the fact, that long detection time in WEARIT-II delayed or alleviated shocks confirms the finding of MADIT-RIT that using long detection times is effective in reducing shock therapy.

Assessing the risk of VT/VF events by disease etiology, we found that VT/VF risk was high among patients with ischemic cardiomyopathy, and congenital/inherited heart disease. The rate of sustained VT/VF events in the non-ischemic population of WEARIT-II was lower compared to the ischemic population in the registry, but comparable to patients with non-ischemic cardiomyopathy and an implanted transvenous ICD enrolled in the Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation (DEFINITE) trial. Furthermore, the risk for the occurrence of life-threatening arrhythmic events in patients with non-ischemic cardiomyopathy is highly unpredictable. Therefore, there is a need for continuous monitoring and protection during the period of risk assessment for SCD in this patient population.

An important subset of the patients with ischemic cardiomyopathy, who showed a high rate of sustained VT/VFs, was prescribed the WCD following an acute MI. While a previous study on post-MI patients suggested that the risk of ventricular tachyarrhythmias is the highest in the first month, in our study, we found a similar risk of VT/VF during the 3 months of WCD use. This finding further stresses the importance of appropriate risk protection for SCD in the early post-MI period in patients with left ventricular dysfunction.

In WEARIT-II, we demonstrated an excellent compliance that was similar in patient subgroups. The use of WCD use was safe, there was no death related to the WCD use itself.
The strength of our analysis is that we have information on all patients until the end of their WCD use. We have received information on all patients who prematurely discontinued the use of WCD or died while wearing the WCD.

Our study has certain limitations. Participation in the Registry was on a voluntary basis, and more compliant patients may have been self-selected. Data on the number and characteristics of patients who declined enrollment in the study were not collected. Furthermore, the WCD detected atrial and ventricular arrhythmias only above the detection rate; thus arrhythmias below the detection rate are not available. However, slow VTs may be self-terminating and they may not carry clinical significance, as recently suggested by the MADIT-RIT trial.\textsuperscript{10} Arrhythmia events were analyzed independently however there may be patients with multiple type of arrhythmia events. Furthermore, we do not have long-term follow-up data available beyond the time period of WCD use (median of 90 days) at this point. Collection of long-term follow-up data on clinical outcome up to 12-months in WEARIT-II participants is currently ongoing.

In conclusion, this is the first prospective Registry on the Wearable Cardioverter Defibrillator, independent of the manufacturer, to demonstrate the safety and efficacy of the WCD in a large patient cohort with ischemic, non-ischemic and congenital/inherited heart disease. We found that the WCD successfully terminates ventricular tachyarrhythmias, and with the extended time to shock provided by the use of response buttons, many hemodynamically stable VTs spontaneously terminate. The compliance of wearing the WCD was very high, and unrelated to disease etiology. At the end of the WCD use, detected arrhythmias facilitated the decision whether to implant an ICD device. WCD could be used as a powerful risk prediction tool to identify patients with high-risk for SCD who benefit from implantation of an ICD.
Acknowledgments: We would like to acknowledge the support of Chingping Wan and Steve Szymkiewicz from ZOLL Lifecor Corporation that significantly helped our work. We also would like to acknowledge the work of Mark L. Andrews, MS, our programmer at Heart Research Follow-Up, and Jennifer Robinson, MS, from Heart Research Follow-Up for the study coordination. Further thanks to Joy Alex, Bonnie MacKecknie and Donna Anzalone for their work in the registry. Finally, we would like to thank the patients and their physicians for their participation in the trial.

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Conflict of Interest Disclosures: Valentina Kutyifa, Arthur J. Moss, Helmut Klein, Wojciech Zareba, and Ilan Goldenberg received an institutional research grant to conduct the WEARIT-II registry.

References:


Table 1. Baseline Clinical Characteristics of Patients by Disease Etiology.

<table>
<thead>
<tr>
<th></th>
<th>Total patient population</th>
<th>Ischemic cardiomyopathy (1)</th>
<th>Non-ischemic cardiomyopathy (2)</th>
<th>Congenital/Inherited (3)</th>
<th>p-value for comparison 1-2-3 continuous measures</th>
<th>p-value for comparison 1-2-3 categorical measures</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of patients</strong></td>
<td>2000</td>
<td>805</td>
<td>927</td>
<td>268</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Age, years</strong></td>
<td>62 (16)</td>
<td>65 (14)</td>
<td>59 (18)</td>
<td>59 (15)</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>598 (30)</td>
<td>182 (23)</td>
<td>337 (36)</td>
<td>79 (29)</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>EF, %</strong></td>
<td>25 (10)</td>
<td>26 (15)</td>
<td>20 (15)</td>
<td>23 (13)</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Heart failure</strong></td>
<td>1040 (52)</td>
<td>388 (48)</td>
<td>483 (52)</td>
<td>169 (63)</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Renal disease</strong></td>
<td>162 (8)</td>
<td>79 (10)</td>
<td>54 (6)</td>
<td>29 (11)</td>
<td>0.002</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td>551 (28)</td>
<td>280 (35)</td>
<td>190 (20)</td>
<td>81 (30)</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Atrial fibrillation</strong></td>
<td>557 (28)</td>
<td>242 (35)</td>
<td>211 (23)</td>
<td>104 (39)</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Prior SCA</strong></td>
<td>170 (9)</td>
<td>85 (11)</td>
<td>67 (7)</td>
<td>18 (7)</td>
<td>0.023</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Syncope</strong></td>
<td>348 (17)</td>
<td>182 (23)</td>
<td>116 (13)</td>
<td>50 (19)</td>
<td>&lt; 0.001</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Beta-blockers</strong></td>
<td>1730 (87)</td>
<td>710 (88)</td>
<td>798 (86)</td>
<td>222 (83)</td>
<td>0.074</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>ACE-I/ARBs</strong></td>
<td>1482 (74)</td>
<td>604 (75)</td>
<td>697 (75)</td>
<td>181 (68)</td>
<td>0.031</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td><strong>Amiodarone</strong></td>
<td>259 (13)</td>
<td>113 (14)</td>
<td>107 (12)</td>
<td>39 (15)</td>
<td>0.214</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

*Abbreviations: EF = ejection fraction, SCA = sudden cardiac arrest, ACE-I = ACE-Inhibitor, ARB = Angiotensin Receptor Blocker
Table 2. First and Recurrent Arrhythmic Events and the Range of Arrhythmic Events Per Patient.

<table>
<thead>
<tr>
<th>Event Description</th>
<th>Patients (%)</th>
<th>Events (mean events/patient) (range)</th>
<th>Event Rate Per 100 Pt-Years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any sustained VT/VF *</td>
<td>41 (2.1%)</td>
<td>120 (2.9) (1-18)</td>
<td>22</td>
</tr>
<tr>
<td>WCD therapy for VT/VF</td>
<td>22 (1.1%)</td>
<td>30 (1.4) (1-8)</td>
<td>5</td>
</tr>
<tr>
<td>Sustained VT, no therapy</td>
<td>22 (1.1%)</td>
<td>90 (4.1) (1-18)</td>
<td>16</td>
</tr>
<tr>
<td>Non-sustained VT</td>
<td>28 (1.4%)</td>
<td>164 (5.9) (1-18)</td>
<td>30</td>
</tr>
<tr>
<td>Atrial arrhythmias/SVT</td>
<td>72 (3.6%)</td>
<td>561 (7.8) (1-136)</td>
<td>101</td>
</tr>
<tr>
<td>Asystole</td>
<td>6 (0.3%)</td>
<td>9 (1.5) (1-3)</td>
<td>2</td>
</tr>
<tr>
<td>Inappropriate therapy</td>
<td>10 (0.5%)</td>
<td>11 (1.1) (1-2)</td>
<td>2</td>
</tr>
</tbody>
</table>

* Treated VT/VF and sustained VT that spontaneously terminated during response button use
† Abbreviations: WCD = Wearable Cardioverter Defibrillator, VT = ventricular tachycardia, NSVT = non-sustained ventricular tachycardia, SVT = supraventricular tachycardia.
¥ in patients with at least one event
γ this includes recurrent events and refers to the total patient population

Figure Legends:

Figure 1. A. Use of WCD (daily hours) in the Total Patient Population in the Registry, B. Use of WCD (daily hours) in the Registry by Disease Etiology.

Figure 2. The Rate of A. First Arrhythmic Events in WCD Patients By Disease Etiology, and B. Total Arrhythmic Events in WCD Patients By Disease Etiology. * denotes p-value < 0.05 for comparison between ischemic, non-ischemic and congenital heart disease patients. ¥ denotes p-value < 0.05 for comparison between ischemic and non-ischemic heart disease patients. ‡

Abbreviations: Asys_brady = asystole, bradyarrhythmia, VTVF_Rx = appropriate therapy, SustVT_NoRx = sustained VT with no treatment by WCD, NSVT = non-sustained ventricular tachycardia, AF = atrial fibrillation, SVT = supraventricular tachycardia.
Figure 3. A. End of use EF improvement and ICD Implantation Rates by Disease Etiology, B. Detected Arrhythmias During the Use of the WCD and Implantation of an ICD at the End of the WCD Use. Other = patient did not receive an ICD and did not improve ejection fraction. B. Detected Arrhythmias During the Use of the WCD and Implantation of an ICD at the End of the WCD Use.* Abbreviations: VTVF_trt = appropriate therapy by the WCD, SustVT_Notrt = sustained VT with no treatment by the WCD, other = arrhythmias other than sustained VT with or without treatment.
Figure 1
Figure 2A

Probability of VT/VF

logrank p=0.02

Patients at Risk
Ischemic 805
Non-ischemic 927
Congenital 268

<table>
<thead>
<tr>
<th>Months from First Wear Day</th>
<th>Ischemic</th>
<th>Non-ischemic</th>
<th>Congenital</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0</td>
<td>728 (0.01)</td>
<td>851 (0.01)</td>
<td>233 (0.02)</td>
</tr>
<tr>
<td>1.0</td>
<td>545 (0.02)</td>
<td>675 (0.01)</td>
<td>180 (0.02)</td>
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<tr>
<td>2.0</td>
<td></td>
<td></td>
<td>111 (0.03)</td>
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<tr>
<td>3.0</td>
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<tr>
<td>Condition</td>
<td>Rate per 100 Patient-years</td>
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<td>-----------------</td>
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<td></td>
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<tr>
<td>Ays_Brady*</td>
<td>3.24</td>
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</tr>
<tr>
<td>VTVF_Rx*</td>
<td>7.40</td>
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<tr>
<td>SustVT_NoRx</td>
<td>17.12</td>
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</tr>
<tr>
<td>VTVF Any*</td>
<td>24.53</td>
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<tr>
<td>NSVT</td>
<td>23.60</td>
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<td>AF_SVT</td>
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</tr>
<tr>
<td>Ischemic</td>
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<tr>
<td>Non-ischemic</td>
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<tr>
<td>Congenital</td>
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<td>128.85</td>
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</tbody>
</table>
Figure 3A

Bar chart showing the percentage of patients received ICD, EF improved, and other categories for different cardiac conditions. The conditions are ICM, NICM, and Congenital/Inherited.

- ICM
  - Received ICD: 42%
  - EF Improved: 41%
  - Other: 17%

- NICM
  - Received ICD: 36%
  - EF Improved: 42%
  - Other: 22%

- Congenital/Inherited
  - Received ICD: 46%
  - EF Improved: 31%
  - Other: 23%
Figure 3B

- VTVF_trt: 85%
- SustVT_notrt: 65%
- Other: 46%
- No Arrhythmias: 39%

% patients

Received ICD