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)

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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 nonischemic 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 implantation, and improvement in ejection fraction were captured. The median age was 62 years; the median ejection fraction was 25%. The median WCD wear time was 90 days, with median daily use of 22.5 hours. There was a total of 120 sustained ventricular tachyarrhythmias in 41 patients, of whom 54% received appropriate WCD shock. Only 10 patients (0.5%) received inappropriate WCD therapy. The rate of sustained ventricular tachyarrhythmias by 3 months was 3% among patients with ischemic cardiomyopathy and congenital/inherited heart disease, and 1% among nonischemic patients (P=0.02). At the end of WCD use, 840 patients (42%) were implanted with an implantable cardioverter defibrillator. The most frequent reason not to implant an implantable cardioverter defibrillator following WCD use was improvement in ejection fraction.

Conclusions—The WEARIT-II Registry demonstrates a high rate of sustained ventricular tachyarrhythmias at 3 months in at-risk patients who are not eligible for an implantable cardioverter defibrillator, and suggests that the WCD can be safely used to protect patients during this period of risk assessment. (Circulation. 2015;132:1613-1619. DOI: 10.1161/CIRCULATIONAHA.115.015677.)

Key words: death, sudden, cardiac • defibrillator, implantable • defibrillators • tachycardia, ventricular

Sudden cardiac death (SCD) attributable to ventricular tachyarrhythmias is a significant contributor to mortality in patients with heart disease, accounting for ≈300,000 deaths per year in the United States.1 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 before 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 because of restrictions based on the time from specific clinical events (eg, 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 Wearable Defibrillator Investigative Trial (WEARIT)/Bridge to ICD in Patients at Risk of Arrhythmic Death (BIROAD) study in 2004,7 and the first retrospective report in 2010.8

The aim of the Prospective Registry of Patients Using the Wearable Defibrillator (WEARIT-II Registry, the first prospective, observational registry on the WCD, was (1) to...
characterize the patients currently prescribed with a WCD, and to assess the risk for sustained ventricular tachyarrhythmic events among at-risk cardiac patients during 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 at the end of WCD use.

Methods

Study Population
All patients who wore a medically prescribed wearable cardioverter defibrillator (LifeVest system, ZOLL, Pittsburgh, PA) 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 before. In short, patients with low ejection fraction and a high risk for SCD after myocardial infarction, following coronary revascularization, with a new-onset dilated nonischemic cardiomyopathy, with high risk for SCD until stabilization, or with inherited or congenital heart disease 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 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 assigned to the following categories: (1) patients who had ischemic cardiomyopathy with previous myocardial infarction (MI) or known coronary artery disease with a high risk for SCD, (2) patients who had nonischemic cardiomyopathy with no known coronary artery disease, and (3) patients who had congenital/inherited heart disease.

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 3 self-gelling defibrillation patch electrodes, 2 on the back and 1 in the front, and 4 nonadhesive ECG electrodes connected to a monitoring unit that weighs 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 escalating audible siren alarms. The device detection algorithm incorporates 3 inputs: heart rate, template matching, and persistence of the event. The default ventricular tachycardia (VT) and ventricular fibrillation (VF) detection rate thresholds are 150 and 200 beats/min, 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 cardiopulmonary resuscitation) and starts ECG recording when there is a severe bradycardia detected (<10 beats/min). The device currently does not have any pacing capabilities. Further specific details have been previously published elsewhere.

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 comorbidities were collected from self-reports of the patients and from the Medical Order Forms completed by the physicians at the participating centers, as well. Device data were collected, providing daily compliance data by using the actual WCD monitoring data. Compliance was defined as hours per day of use. ECG 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 the 3- and 12-month follow-ups to assess the rate of ICD implantation and clinical events in their patients. In the current article, we report the 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 to implant an ICD is made at this 3-month time point, based on the 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 arrhythmia 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 4 major categories: (1) sustained VT (lasting 30 seconds or longer) or VF with WCD shock therapy, (2) sustained VT with no WCD shock delivered owing to the use of the response buttons, (3) nonsustained VT of <30 seconds of duration, or (4) atrial fibrillation or supraventricular tachycardia 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 cardiomyopathy, nonischemic cardiomyopathy, or congenital/inherited heart disease by using the Kruskal-Wallis test for continuous variables and the χ² test or Fisher exact test for dichotomous variables, as appropriate. Differences in compliance among subgroups were assessed using nonparametric 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 logrank test.

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

All statistical tests were 2-sided, and a nominal P value of <0.05 was considered statistically significant. Analyses were performed with SAS software (version 9.3, and version 9.4 SAS Institute, Cary, NC).

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 nonischemic 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 (interquartile range, 16). Patients with ischemic etiology were older than patients with nonischemic etiology and congenital/inherited heart disease (P value for the overall difference <0.001). The proportion of women was highest among patients with nonischemic cardiomyopathy (36%) and lowest among those with ischemic cardiomyopathy (23%). The median ejection fraction was 25%, with relatively lower EF in the nonischemic group (20%) than in the ischemic (26%) or in the congenital/inherited subgroups (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 subgroups. Patients with congenital/inherited heart disease were more likely to have a history of atrial fibrillation, whereas those with ischemic heart disease were more likely to have a history of sudden cardiac arrest (11%) or syncope (23%) before 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 (25%), long QT syndrome (10%), and Brugada syndrome (1%), allowing for multiple diagnoses at the initial assessment.

Compliance

Median duration of WCD use was 90 days (interquartile range, 65), and median daily use was 22.5 hours (interquartile range, 2.69) in the total patient population (Figure 1). There was no significant difference in the daily use among the subgroups of ischemic, nonischemic, or congenital/inherited heart disease (Figure I in the online-only Data Supplement).

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. It is noteworthy that 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 owing 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 nonsustained ventricular tachycardia and atrial tachyarrhythmias (supraventricular tachycardia/atrial fibrillation) 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 because of ECG artifacts. Inappropriate shocks did not induce VT or VF.

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 nonischemic 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, in comparison with 1% among those with nonischemic 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

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

ACE-I indicates angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; EF, ejection fraction; and SCA, sudden cardiac arrest.
rate of all treated VT/VF episodes was higher among patients with ischemic cardiomyopathy and inherited/congenital disorders in comparison with the nonischemic group.

**Decision Making After the End of WCD Use**

At the end of WCD use, an ICD was implanted in 36% of patients with nonischemic cardiomyopathy, in 42% of patients with ischemic cardiomyopathy, 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 following the use of the WCD was improvement in ejection fraction (41%).

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Of the 2000 patients who had the WCD, 3 (0.2%) died during WCD wearing. All 3 patients demonstrated an asystole event. None of the patients with VT or VF episodes died while wearing the WCD.

**Table 2. First and Recurrent Arrhythmia Events and the Range of Arrhythmia Events Per Patient**

<table>
<thead>
<tr>
<th>Event Type</th>
<th>Patients, n (%)</th>
<th>Events (Mean Events/Patient) (Range)</th>
<th>Event Rate Per 100 Patient-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>Nonsustained VT</td>
<td>28 (1.4)</td>
<td>164 (5.9) (1–48)</td>
<td>30</td>
</tr>
<tr>
<td>Atrial arrhythmias/VT</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>

NSVT indicates nonsustained ventricular tachycardia; SVT, supraventricular tachycardia; VT, ventricular fibrillation; WCD, wearable cardioverter defibrillator.

*In patients with at least 1 event.
†This includes recurrent events and refers to the total patient population.
‡Treated VT/VF and sustained VT that spontaneously terminated during response button use.

**Discussion**

WEARIT-II is the first prospective registry of the WCD to evaluate the safety and efficacy of the WCD 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, nonischemic cardiomyopathy, or congenital/inherited heart disease prescribed the WCD attributable to the 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 (<1%) received an inappropriate WCD therapy and 3 patients died while wearing the WCD, all because of asystole; and (5) the use of WCD may improve risk assessment before a decision regarding the need for ICD implantation. At the end of the WCD use, fewer than half of the patients needed an ICD implantation, whereas 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, the WCD successfully terminated the arrhythmia in 9 of 10 patients. No postshock 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 at 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), prespecified safety and effectiveness guidelines had been met. Six (75%) of 8 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 the survival of patients 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 the WEARIT-II Registry, 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. 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 with patients enrolled in Multicenter Automatic Defibrillator Implantation Trial – Reducing Inappropriate Therapy (MADIT-RIT). MADIT-RIT consisted of patients with an ICD indication who were randomly assigned to either conventional programming (arm A of the trial), or to a high-rate cutoff (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 nontreated 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 (Figure IIA and IIB in the online-only Data Supplement). Importantly, in WEARIT-II, the episodes of VT/VF were evenly distributed during the first 3 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 the 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 nonischemic population of WEARIT-II was lower than the rate of sustained VT/VF events in the ischemic population in the registry, but comparable to patients with nonischemic 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 nonischemic 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. Although 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 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. Arrhythmia events were analyzed independently, but there may be patients with multiple types 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, nonischemic 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 at high risk for SCD who would benefit from implantation of an ICD.

Acknowledgments
We acknowledge the support of Chingpin Wan and Steve Szymkiewicz from ZOLL LifeCorporation that significantly helped our work. We also 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, and Donna Anzalone for their work in the registry. Finally, we thank the patients and their physicians for their participation in the registry.

Sources of Funding
The WEARIT-II Registry was supported by a research grant from ZOLL, Pittsburgh, PA, to the University of Rochester Medical Center, Cardiology Division, Heart Research Follow-up Program, Rochester, NY.

Disclosures
Drs Kuttyifa, Moss, Klein, Zareba, and Goldenberg received an institutional research grant to conduct the WEARIT-II registry. The other authors report no conflicts.

References
The wearable cardioverter defibrillator (WCD) has been in use since 2002, and it is estimated that >100 000 patients have worn this device. Despite this, we lack prospective data on the safety and efficacy of the WCD in a real-world setting. The Prospective Registry of Patients Using the Wearable Defibrillator (WEARIT-II) Registry provided data on the WCD as a strategy during a period of risk stratification, enrolling 2000 patients with ischemic cardiomyopathy (40%), nonischemic cardiomyopathy (46%), or congenital/inherited heart disease (14%) between August 2011 and February 2014. We demonstrated high compliance to WCD (median daily use of 22.5 hours), with no differences by disease etiology. There were a total of 120 sustained ventricular tachyarrhythmias in 41 patients, and more than half of them received appropriate WCD therapy. The risk of ventricular tachyarrhythmia appeared to be high among patients with ischemic cardiomyopathy and congenital/inherited heart disease. Less than 1% received inappropriate WCD therapy. At the end of the WCD use, 840 patients (42%) were implanted with an implantable cardioverter defibrillator (ICD). The most frequent reason not to implant ICD following WCD use was improvement in the ejection fraction. Appropriate therapy delivered by the WCD was useful to facilitate the decision of subsequent ICD implantation. In summary, the WEARIT-II Registry demonstrated the safety and feasibility of using the WCD in at-risk cardiac patients who are not eligible for an ICD to protect them from sudden cardiac death, and to facilitate the decision regarding subsequent ICD implantation.

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_Circulation_. 2015;132:1613-1619; originally published online August 27, 2015; doi: 10.1161/CIRCULATIONAHA.115.015677

_Circulation_ is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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**Supplemental Figure 1.** 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
Supplemental Figure 2. The Rate of First Episodes of WCD therapy for VT/VF or Sustained VT in A. WEARIT-II, B. Rate of VT/VF ≥200 bpm in MADIT-RIT ICD patients in Arms B, and C A.