Evidence Table

Clinical Area: Wearable cardioverter defibrillators (WCDs) for adults.

Study Type: Case series.
Study Aim: To assess the safety and efficacy of a wearable cardioverter defibrillator device in treating ventricular tachyarrhythmias in adult patients at high risk of sudden cardiac death.

Outcomes
- **Primary endpoint:** Rate of delivering successful defibrillations.

Design
- **Number of subjects:** N=289 (n=177 in WEARIT, and 112 in BIROAD). WEARIT and BIROAD were begun as separate studies but were later combined based on a request from the FDA. The authors did not indicate at what stage they were grouped. The results were presented for each group as a subpopulation.
- **Description of study population:** The 2 studies enrolled patients from 18 centers in the US and one center in Germany. The mean age was 55 years (60 in BIROAD, and 52 in WEARIT), 82% were men, 66% were smoking, 59% (79% in BIROAD, and 12% in WEARIT) had a history of hypertension, 52% (71% in BIROAD, and 15% in WEARIT) non-sustained ventricular tachycardia, and 32% (42% in BIROAD, and 21% in WEARIT) ventricular tachycardia. The mean ejection fraction was 23% (30% in BIROAD, and 19% in WEARIT, and 57% (73% in BIROAD, and 27% in WEARIT) were on beta-blockers.
- **Inclusion criteria:** Age 18-75 years WEARIT: Ambulatory patients with NYHA functional class III or IV heart failure symptoms and an ejection fraction <30%. BIROAD: Patients in whom a wearable device could be used to bridge patients for a period of 4 months to the possible use of an ICD. Those included: 1. Patients with a recent MI complicated with by ventricular tachyarrhythmias within 48 hour of the infarct, EF <30% at least 3 days after the infarct, or an episode of syncope or sudden cardiac arrest (SCA) at least 48 hours after an MI but not a candidate for an ICD. 2. Patients who had ventricular arrhythmias within 48 hours of a CABG surgery, had a LVEF <30%, at least 3 days after CABG, had a sudden cardiac arrest or syncope at least 48 hours of the bypass and were unable to receive an ICD, or were ICD candidates who were at home, and not expected to receive an ICD for at least 4 months, or refused therapy with ICD.
- **Exclusion criteria:** Inability to use the device for any reason including body size (chest circumference <28 or >48 inches, had advanced directive prohibiting resuscitation, participating in another clinical trial, were not seen at last daily by a companion or caregiver, unable to provide an informed consent, or had a noncardiac terminal illness.

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• **Consecutive patients:** Not discussed.

• **Intervention:** Before receiving the wearable defibrillator (WCD, manufactured by LIFECOR, Inc., Pittsburgh, PA, USA), the patients were instructed on the use and the maintenance of the device. It consisted of 2 defibrillator electrodes, 4 sensing ECG electrodes, and a vibrator incorporated in a garment worn by the patient along with a monitor defibrillator worn at the waist containing the monitoring and defibrillating electronics. If an arrhythmia was detected by the ECG, an alarm was set off to warn the patient and bystanders of an impending shock. If the patient did not respond to the alarm, the device delivered up to five shocks using a monophasic wavelength with a maximum output of 285 J.

• **Source of outcome data (e.g. patient self-report, doctor report, lab results):** Patients were evaluated in follow-up visits biweekly for the first month, then monthly. The visits consisted of a physical exam, and an interrogation of the device.

• **Length of follow-up:** 4 months for the BIROAD population as a bridge to either receive an ICD or discontinue therapy. Patients in the WEARIT group continued in the study until they developed a terminal heart failure requiring bed confinement, became unable to interact with the device, or experienced a definitive event as ICD implant, heart transplantation, or hospitalization for terminal heart failure. Patients in both groups could discontinue participation at any time during therapy. Mean duration of use was 3.1 months (2.6 m for the BIROD, and 3.4 months for the WEARIT population).

**Validity**

• *Is the study type appropriate for the questions being asked?* No a study with a comparison group would be more appropriate.

• *Were patients similar with respect to baseline characteristics?* No, two studies with different inclusion criteria, and patient characteristics were combined.

• *Was the intervention and other aspects of patient care similar for all patients (or for all patients in a defined subgroup)?* Apparently.

• *Was the process of observation likely to affect the outcome?* Not for the objective outcomes.

• *Did an objective observer assess outcomes and were outcome measurements consistent?* All data were reviewed by an independent Data and Safety Monitoring Board.

• *Was follow-up duration appropriate?* Probably not.

• **Conclusions regarding validity of methods:**

The study was only observational, and had no control or comparison group to compare the efficacy of the device to an alternative or no therapy. It also had potential biases and confounding. Moreover, the study combined two case series with different inclusion criteria, population characteristics and implications.
Results:

Total patient months use = 901

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<tr>
<td>Defibrillation success rate</td>
<td>6/8 attempts*</td>
<td>69**</td>
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<tr>
<td>Unnecessary shock episodes</td>
<td>6/901 months of use</td>
<td>0.67/month of patient use</td>
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*Two in the WEARIT patients (both in the same patient six days apart).
Four in the BIROAD patients (two in the same patient nine days apart)
For the two unsuccessful attempts, the therapy electrodes were incorrectly placed with the defibrillating pads reversed (one was not fatal as the patient received an external defibrillation).

**Calculated by the author based on a prespecified sequential design.

Deaths**

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<tr>
<td></td>
<td>12/289</td>
<td>4.15%</td>
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**6 sudden deaths (5 in patients not wearing the device, and one in a patient who reversed the leads).
6 nonsudden deaths occurred in the WEARIT population due compliance issues or inappropriate use of the device.

Other device related adverse events

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<td>Premature withdrawal</td>
<td>65/289</td>
<td>22.5%</td>
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<td>Skin rashes and itching</td>
<td>17/289</td>
<td>5.9%</td>
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Causes of discontinued use

WEARIT population
- 30% due to discomfort or lifestyle issues
- 20% received an ICD*
- 16% had a heart transplant

BIROAD population
- 42% reaching 4 months study endpoint, or do not need the device
- 23% received an ICD*
- 11% due to discomfort or lifestyle issues

*Most important reasons for receiving an ICD: increased ventricular arrhythmias, BIROAD termination, eligibility for ICD, or tachyarrhythmias while wearing the device.

Authors’ Conclusions:

The authors concluded, "The results of the study suggest that a wearable defibrillator is beneficial in detecting and effectively treating ventricular tachyarrhythmias in patients at high risk for sudden death who are not clear candidates for an ICD and may be useful as a bridge to transplantation or ICD in some patients".
Reviewer’s conclusion:

These were two case series, with different inclusion criteria and different population characteristics, combined in one study. The WEARIT population were patients with NYHA class III or IV heart failure and an ejection fraction <30% while BIROAD included a more heterogeneous group of patients considered at high risk for sudden death after an MI or CABG surgery or were candidates of ICD but refused to receive the implant. This BIROAD population used the wearable defibrillator (WCD) for 4 months after which they discontinued therapy or received an ICD. There was no control or comparison group that compared the efficacy of the device to another therapy or to no treatment. Moreover, 16% of the patients received an ICD during the study period, which makes it hard to determine the efficacy of the WCD among these patients who prematurely withdrew from the study. One other limitation is the short follow-up period and the small number of events that occurred within that duration.