The wearable cardioverter-defibrillator (WCD) was approved by the US Food and Drug Administration in 2001. Since then, use of the WCD has grown steadily, and the device is now also available in Australia, Europe, Israel, Japan, and Singapore. Earlier this year, the American Heart Association published a science advisory that rated the use of the WCD as it is reasonable (Class IIa) or may be considered (Class IIb) in several specific patient categories. At this point, many clinicians worldwide wonder if the WCD has become standard of care. Are we delivering inadequate care if we do not offer the WCD to our patients?

The WCD received US Food and Drug Administration approval (as durable medical equipment) primarily on the basis of the demonstration of shock efficacy in controlled laboratory settings. The first systematic clinical evaluation was the WEARIT/BIROAD study (Wearable Defibrillator Investigative Trial and Bridge to ICD in Patients at Risk of Arrhythmic Death), a nonrandomized, noncontrolled series published in 2004. It followed up 289 patients at high risk for sudden cardiac death (SCD) who were given the WCD. In this population, 6 of 8 (75%) defibrillation attempts were successful. The 6 sudden deaths all occurred in patients not wearing the WCD as instructed. This was the first study to demonstrate the feasibility and reasonable efficacy of the WCD.

Since the WEARIT/BIROAD study, there has been a steady stream of observational research supporting the use of the WCD in a variety of clinical settings. It has been studied specifically in patients with recent myocardial infarction (MI), newly diagnosed cardiomyopathy, recent revascularization, peripartum cardiomyopathy, nonischemic cardiomyopathy, congenital structural heart disease, and inherited arrhythmias. Aggregate US nationwide data from the manufacturer (ZOLL, Pittsburg, PA) registry have also been reported. These data showed that between 2002 and 2006, 3569 patients wore a WCD at least 1 day (mean duration, 53±70 days). Mean daily use was 19.9±4.7 hours. Fourteen percent of the patients discontinued the WCD as a result of discomfort or adverse reactions. Indications for the WCD included implantable cardioverter-defibrillator (ICD) explantation (23%), ventricular arrhythmia before planned ICD implantation (16%), recent MI (16%), post–coronary artery bypass graft status (9%), and recent diagnosis of cardiomyopathy with an left ventricular ejection fraction (EF) ≤35% (28%). Shock efficacy was very high. There were 80 sustained ventricular tachycardia/ventricular fibrillation events in 59 patients (1.7%). First-shock efficacy was 99% (79 of 80), and post–ventricular tachycardia/ventricular fibrillation survival was 90% (72 of 80). Most of these ventricular tachyarrhythmias occurred in patients with an explanted device (event rate, 5.2%).

To date, almost all the published observational research on the WCD has been based on patients in the United States. In this issue of Circulation, Wässing et al report aggregate nationwide data on patients prescribed the WCD in Germany.
They studied 6043 patients representing all 16 German states who were prescribed the WCD from April 2010 through October 2013. Just like the study on the aggregate US data, clinical patient data were obtained from the manufacturer’s registry. In general, their findings are consistent with the nationwide data from the United States.

The authors grouped the patient population into 8 cardiovascular indications for the WCD based on billing in Germany. They found that 37% had newly diagnosed dilated cardiomyopathy, 27% had ischemic cardiomyopathy, 12% had recent ICD explantation, 12% had nonischemic cardiomyopathy, 10% had myocarditis, 2.5% had genetic disease, 1.4% were on the heart transplant waiting list, and 0.4% had long-term congestive heart failure. Of the patients with ischemic cardiomyopathy, 43% experienced MI within 40 days of WCD prescription, 44% had received a percutaneous coronary intervention within 3 months, and 13% had a coronary artery bypass graft within 3 months. Notably, there were more patients with myocarditis than in the US cohort.

The German cohort seemed to tolerate wearing the WCD better than the US cohort. The median WCD use was an impressive 23.1 hours (interquartile range, 21.0–23.7 hours) of daily use and 59 total days (interquartile range, 33–90 total days) of wear. Only 3% of the patient population had ≤3 total days of WCD wear. The shock efficacy was slightly lower than what was seen in the United States, however. This could have been due to different patient selection or alternative approaches to assessing treatment results. There were 120 patients treated with 163 shocks ranging from 1 to 5 shocks per episode. Ninety-four patients were shocked for ventricular tachyarrhythmias; 94% (88 of 94) of patients were converted successfully into a slower heart rhythm; and 93% (87 of 94) were alive at 24 hours after shock.

This analysis of the German nationwide data importantly shows that the WCD also can be effective outside the United States, however. This could have been due to different patient selection or alternative approaches to assessing treatment results. Treatment was an impressive 23.1 hours (interquartile range, 21.0–23.7 hours) of daily use and 59 total days (interquartile range, 33–90 total days) of wear. Only 3% of the patient population had ≤3 total days of WCD wear. The shock efficacy was slightly lower than what was seen in the United States, however. This could have been due to different patient selection or alternative approaches to assessing treatment results. There were 120 patients treated with 163 shocks ranging from 1 to 5 shocks per episode. Ninety-four patients were shocked for ventricular tachyarrhythmias; 94% (88 of 94) of patients were converted successfully into a slower heart rhythm; and 93% (87 of 94) were alive at 24 hours after shock.

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In the American Heart Association science advisory, WCD use was not rated Class I because there are no completed randomized, controlled trials (RCTs) supporting its use. The VEST trial (Vest Prevention of Early Sudden Death Trial) is an RCT that will finish enrollment in late 2016 or early 2017. This trial is evaluating the efficacy of the WCD to prevent sudden death in the first 90 days after MI in patients with an EF ≤35%. Until this and other RCTs with the WCD are finished, it is premature to call the WCD a lifesaving technology. Although it is true that the WCD effectively terminates life-threatening ventricular tachyarrhythmias, it is not yet proven to decrease SCD or mortality. What if the WCD actually increases SCD or mortality by constricting breathing or increasing patient anxiety or reinfarction from false alarms? The gold standard for determining efficacy of a therapy is an RCT. The medical literature is filled with examples of therapies considered standard of care on the basis of noncontrolled, nonrandomized observational studies that were later proven incorrect by RCTs (eg, the use of Class IC antiarrhythmics to suppress premature ventricular contractions after MI to prevent cardiovascular events in postmenopausal women). In 2 large randomized trials, DINAMIT (Defibrillator in Acute Myocardial Infarction Trial) and IRIS (Immediate Risk Stratification Improves Survival), early ICD implantation in post-MI patients with low EF led to less arrhythmic deaths but no overall survival benefit. This finding further calls into question the efficacy of the WCD in the immediate post-MI population. Notably, these studies were powered to determine long-term rather than short-term mortality benefit. These studies also used other factors (low heart rate variability in DINAMIT and high heart rate or presence of nonsustained ventricular tachycardia in IRIS) to select a presumed high-risk group. These characteristics may be risk factors for overall mortality but not necessarily SCD and thus may have inadvertently resulted in the selection of a group at high risk of nonarrhythmic death. In addition, although the EFs immediately after MI in these studies were low, it is possible that a significant portion of these patients recover their EF to >40% within 3 months, as recently shown in a report from the PREDICTS study (Prediction of SCD in Acute Myocardial Infarction Trial) and IRIS (Immediate Risk Stratification Improves Survival).
of ICD Treatment Study), and thus are not at long-term high risk of SCD. Therefore, although it is clear from DINAMIT and IRIS that early ICD implantation is not currently warranted, it is not clear whether using the WCD in the post-MI, low-EF population as a bridge to the 3-month time point (at which EF is reassessed and an ICD possibly is implanted) will have benefit. This is precisely the population and treatment strategy being studied in the ongoing VEST trial.

So, on the basis of the existing research on the WCD, what is the clinician to do? Shall we start using the WCD on the basis of the observational data that suggested benefit of the device, or shall we wait until the RCTs are done? Currently, there is no consistent approach in the United States. Use of the WCD varies widely by hospital and sometimes even among cardiologists in the same practice.

Perhaps the most reasonable approach is the one advocated by the American Heart Association science advisory. Acknowledging the lack of completed RCTs to prove efficacy, the advisory stops short of stating that the WCD is standard of care. Rather, it recommends that providers continuously weigh the individual risks and benefits of the device in their patients. The decision on the use of the WCD should be based on shared decision making, which would include a frank discussion between the clinician and the patient about its risks, benefits, and uncertain efficacy.

DISCLOSURES

Drs Lee and Olgin are the coprimary investigators of the VEST trial, an international, multicenter RCT of the WCD sponsored by the manufacturer (ZOLL, Pittsburg, PA).

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FOOTNOTES

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