Circulation

CARDIOLOGY NEWS

Wearable Defibrillator Trial Has Mixed Result

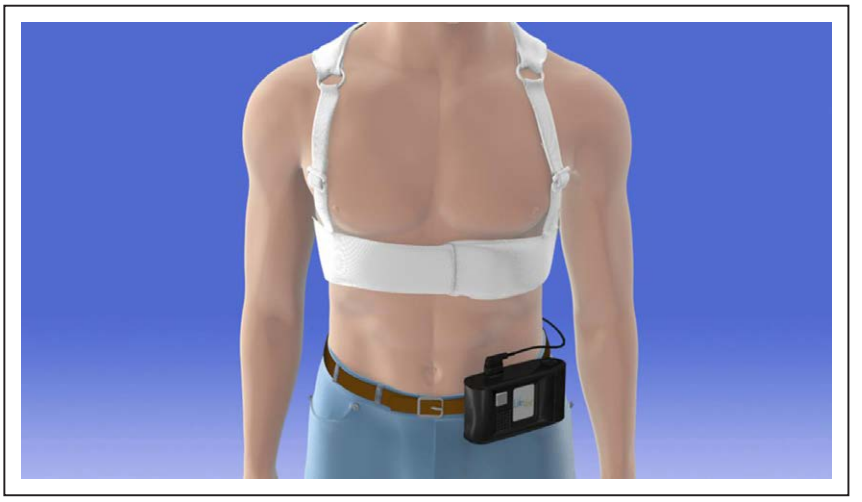
Bridget M. Kuehn

The much-awaited results of the VEST trial (Vest Prevention of Early Sudden Death Trial) failed to provide the definitive answer on the potential value of wearable cardioverter-defibrillators (WCDs) in reducing sudden death during the vulnerable period just after a myocardial infarction.

The VEST trial was the first multicenter, randomized controlled trial of WCDs in patients with an ejection fraction ≤35% after an acute myocardial infarction. In the trial, 2302 patients were randomly assigned in a 2:1 ratio to medical therapy plus a WCD or medical therapy alone at 108 sites in 4 countries. It failed to meet its primary end point of a reduction in sudden death during the first 90 days after a heart attack, but it did show a significant reduction in all-cause mortality, its secondary end point, according to data presented at the American College of Cardiology 2018 Scientific Session.

"This is a very important study," said Dhanunjaya Lakkireddy, MD, director of the Center for Excellence in AF and Complex Arrhythmias at the University of Kansas Medical Center. He noted that low compliance among a subgroup of patients may have contributed to the results and that subgroup analyses may help to determine whether this was true or if certain subgroups of patients benefited.

Valentina Kutyifa, MD, PhD, associate professor in the Department of Medicine at the University of Rochester in New York, agreed that further analysis is needed. "The results presented so far are interesting, but unclear and need further analysis," she said.



The major clinical trial of wearable cardioverter-defibrillators did not find a significant reduction in sudden death during the first 90 days after heart attack, but it did find reduction in overall mortality.
Reproduced from ZOLL LifeVest with permission. Copyright © 2018 ZOLL LifeVest.

FILLING THE GAP

There is great hope that WCDs might fill a gap in care during the immediate aftermath of a myocardial infarction. These vests are worn under clothing and continuously monitor the heart. If they detect a problem they may sound an alert to seek medical care or deliver a shock to restore a normal heart rhythm, explained VEST trial lead author Jeffrey Olgin, MD, professor and chief of cardiology, University of California, San Francisco in a press statement. This could be helpful during the first 3 months after a heart attack when patients with low ejection fraction are at elevated risk of death, even with optimal medical treatment, Olgin explained. The mortality rate is 5% during this vulnerable period.

Implantable cardioverter-defibrillators are not recommended before 40 to 90 days after a heart attack. Studies have shown implantable cardioverter-defibrillators do not reduce mortality when implanted this early. Some patients' ejection fractions will improve enough so that they no longer qualify for an implantable cardioverter-defibrillator after 3 months, Olgin said in a press briefing.

"There is a very high risk of death immediately after a heart attack that tails off after about 3 months," Olgin said in the press statement. "The

challenge is that we don't currently have a good way of preventing deaths during this very vulnerable period."

Previous studies had suggested that WCDs could be safe and effective in the initial post–myocardial infarction period, according to a 2013 review in *Circulation*. Data published in 2015 from the WEARIT-II registry (Prospective Registry of Patients Using the Wearable Defibrillator) showed that devices could be safely used in real-world high-risk patients. The registry enrolled 2000 patients with ischemic or nonischemic cardiomyopathy, or congenital or inherited heart disease with low ejection fractions (median 25%). Patients wore the devices on average 90 days with a median daily use of 22.5 hours. The devices delivered appropriate shocks to 54% of the 41 patients who experienced sustained ventricular tachyarrhythmias during the trial. Only 0.5% (10 patients) received an inappropriate shock.

The VEST trial had comparable results in terms of inappropriate shocks with 0.5% (8 participants) receiving an inappropriate shock. Participants also had the option of aborting shocks, and 2.3% (43 participants) did so. Of the 20 participants who received an appropriate shock, 14 survived at 90 days.

Many hoped that the VEST trial would show a definitive reduction in deaths, but the results were more complicated. The trial did show a 35% relative risk reduction in all causes of death in the WCD group in comparison with the control group in the first 90 days post–myocardial infarction. But there was not a significant difference in sudden deaths between the 2 groups. So, although the results are promising, and the devices appeared to perform as expected, they are not as clear as hoped.

"It's a secondary outcome; from a methodological standpoint it needs to be interpreted with caution," Olgin said.

COMPLIANCE CONCERNS

About 1 in 5 of the patients randomly assigned to the WCD did not wear the vest at all, Olgin noted, although those who did wear it averaged ≈21 hours a day.

The WEAR-IT II registry had better compliance with patients wearing their vests on average 22.5 hours per day, explained Kutyifa. It will be key to ensure good compliance with the WCD to see the benefits, she suggested.

Olgin, agreed that there is "room to make [WCDs] more comfortable and tolerable." He also suggested that shared decision making with patients may also help improve compliance.

"As we do with the decision around implantable cardioverter-defibrillators, the patient should be brought into the decision about whether they should have this therapy and whether they are going to take it home and wear it," he said.

The difficulties classifying sudden deaths might also have contributed to the lack of a significant reduction in sudden deaths, said Olgin. But he still believed the trial results would likely increase the use of WCDs after a heart attack.

"It is possible that sudden deaths were misclassified as it's difficult to define sudden death with accuracy when a death is unwitnessed and there is little documentation," Olgin said. "But the cause of death is irrelevant if we can prevent it. This study found that the device was associated with fewer deaths among people recovering from a heart attack with low ejection fraction. It's also the first therapy associated with a mortality benefit above and beyond standard medical therapy immediately after a heart attack."

At the American College of Cardiology 2018 Scientific Session, at the end of Olgin's presentation, 78% of physicians said in a digital survey that the results would not change their practice. Currently, the use of the WCDs varies by practice and physician, noted Lakkireddy. He explained that his practice uses them for a more limited group of high-risk patients than the VEST trial did.

"I would still use in high-risk patients," he said.

With the jury still out on the value of WCDs, many physicians await the publication of the full results, additional subgroup analyses, and perhaps even a sham-controlled trial for more definitive answers. ■

http://circ.ahajournals.org

Wearable Defibrillator Trial Has Mixed Result

Bridget M. Kuehn

Circulation. 2018;138:99-100
doi: 10.1161/CIRCULATIONAHA.118.035739
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231

Print ISSN: 0009-7322. Online ISSN: 1524-4539