

# The wearable cardioverter-defibrillator is needed for most high-risk patients



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Is there still a role for wearable cardioverter-defibrillators (WCDs)? The answer is a resounding yes. Since the WCD was approved by the US Food and Drug Administration in 2002, there has been a steady accumulation of research to support its use. Even before the VEST trial,<sup>1</sup> there were clinical studies, prospective case series reports, and registry data analyses all indicating that the WCD was well tolerated, accurate in sensing ventricular tachyarrhythmias, and highly successful at defibrillation.<sup>2-7</sup> This is indisputable. Unfortunately, VEST did not have a statistically significant positive primary endpoint, so detractors have seized this opportunity to criticize the WCD. However, careful and complete consideration of the VEST data shows it further supports the continued use of the WCD.

VEST<sup>1</sup> was the first randomized controlled trial of the WCD. It was a physician-initiated study involving more than 100 enrolling sites from 4 countries (United States [U.S.], Germany, Poland, and Hungary). A total of 2302 patients with an acute myocardial infarction and ejection fraction  $\leq 35\%$  were randomized in a 2:1 ratio to receive guideline-directed medical therapy with the WCD vs guideline-directed medical therapy alone. Among 1524 participants randomized to receive the WCD, appropriate shocks occurred in 20 participants, with 100% first shock success. The WCD led to nonsignificant decreases in arrhythmic and nonarrhythmic mortality (Figures 1 and 2) and a nominally significant 36% decrease in overall mortality (relative risk, 0.64; 95% confidence interval (CI), 0.43–0.98; uncorrected  $P = .04$ ) (Figure 3).

We acknowledge that interpreting the overall mortality outcome in VEST is not straightforward, since it was not the primary endpoint. Most approaches to correcting the  $P$  value of this secondary outcome for multiple comparisons make it no longer statistically significant. However, it is notable that overall mortality was the original primary endpoint of VEST.

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The primary endpoint was changed partway during the enrollment phase to arrhythmic mortality primarily owing to budgetary constraints of the study sponsor, Zoll Medical. The effect size for arrhythmic mortality was expected to be larger than that for overall mortality, giving a calculated target sample size that was allowable based on available funding from the study sponsor. When the trial results were revealed, it was clear that changing the primary endpoint was a fatefully bad decision. If the primary endpoint had not been changed from overall mortality, the  $P$  value for this outcome would not need to be corrected, and there would be no lingering controversy regarding the VEST results.

Given the failure of VEST to show a significant benefit in the primary endpoint, we interpret the trial as inconclusive for arrhythmic mortality; but that does not mean it provides evidence against the use of a WCD; in fact, point estimates for all 3 main outcomes (arrhythmic mortality, nonarrhythmic mortality, and overall mortality) were all in the favorable direction (Figure 4). In contrast, DINAMIT and IRIS studied implantable cardioverter-defibrillator (ICD) implantation in a similar patient population and found that all benefit in arrhythmic mortality was offset by an increase in nonarrhythmic mortality.<sup>8,9</sup> It is reassuring that this was not the case in VEST.

One reason that VEST did not find a greater difference between treatment groups was undoubtedly owing to crossovers, which biased the results to the null. Of participants randomized to the WCD group, 2.8% decided afterwards not to accept the WCD; and 2.6% of participants randomized to the control group opted out of the study so they could break protocol and get a WCD, which was commercially available in 2 of the enrolling countries (U.S. and Germany). Furthermore, the mean WCD wear time of participants in the treatment group was only  $14 \pm 9.3$  hours/day, even though all were asked to use the WCD continuously except when bathing. Notably, of the 48 participants who died in the WCD group, only 12 (25%) of them were wearing the WCD at time of death. Despite the frequent crossovers, all participants were analyzed based on their original treatment assignment, as required for an intention-to-treat analysis.

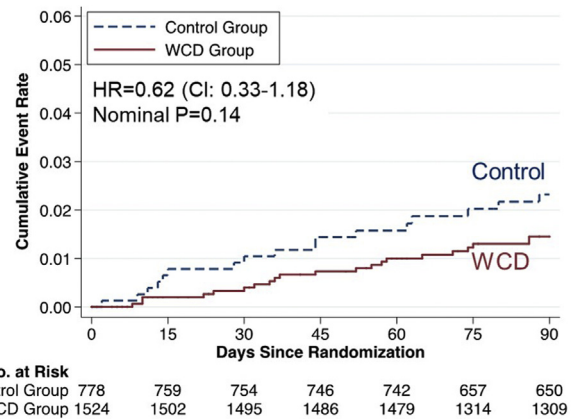
An as-treated analysis (prespecified) and an on-treatment analysis were performed on the VEST data to determine

**KEY FINDINGS**

- Even before the VEST trial, there were clinical studies, prospective case series reports, and registry data analyses all indicating that the wearable cardioverter-defibrillator (WCD) was well tolerated, accurate in sensing ventricular tachyarrhythmias, and highly successful at defibrillation.
- In VEST, post-myocardial infarction patients with low ejection fraction randomized to the WCD had nonsignificant decreases in arrhythmic and nonarrhythmic mortality and a nominally significant 36% decrease in overall mortality.
- When considering the WCD, we recommend shared decision making, which should include discussion of the nuances of the VEST findings, as well as the potential downsides of the WCD, such as alarms and discomfort.

the association of wearing the WCD to the mortality outcomes. The as-treated analysis showed a 57% decrease in arrhythmic mortality (rate ratio, 0.43; 95% CI, 0.21–0.91; uncorrected *P* = .03) and 74% decrease in overall mortality (rate ratio, 0.26; 95% CI, 0.14–0.48; uncorrected and Bonferroni-corrected *P* < .001).<sup>1</sup> Similarly, the on-treatment analysis showed 62% decrease in arrhythmic mortality (hazard ratio, 0.32; 95% CI, 0.17–0.86; *P* = .02) and 75% decrease in overall mortality (hazard ratio, 0.25; 95% CI, 0.13–0.48; *P* < .001).<sup>10</sup> Adjustment for baseline characteristics associated with WCD compliance did not substantively affect the results. Both analyses suggest that if participants in the treatment group wore the WCD more, the VEST trial would have had more robust positive results. Although both analyses are subject to confounding, it is hard to imagine how confounding alone could account for such a dramatic improvement of arrhythmic and overall mortality in the WCD group.

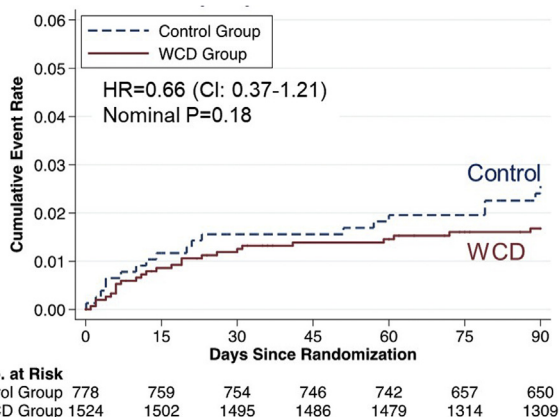
There is reason to believe that real-world usage of the WCD would be better than the mean 14 ± 9.3 hours/day



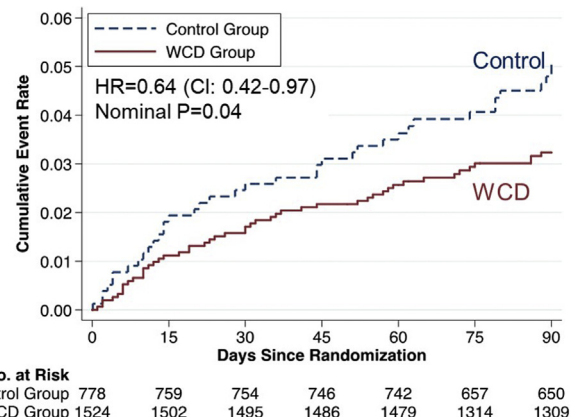
**Figure 2** Kaplan-Meier curves of time to event for nonarrhythmic mortality. WCD = wearable cardioverter-defibrillator.

seen in VEST. The knowledge that VEST was testing whether the WCD confers benefit may have inadvertently given participants the impression that the WCD was new, unproven technology that may be helpful or harmful. This may have contributed to the poor WCD wear times seen in VEST. An analysis of the U.S. registry of commercially prescribed WCDs showed the mean wear time of the WCD was 19.9 ± 4.7 hours/day on days it is worn.<sup>3</sup> A similar study of the German registry showed a median wear time of 23.1 hours/day.<sup>7</sup> Better real-world WCD compliance may mean greater benefit of the device in the post-myocardial infarction population.

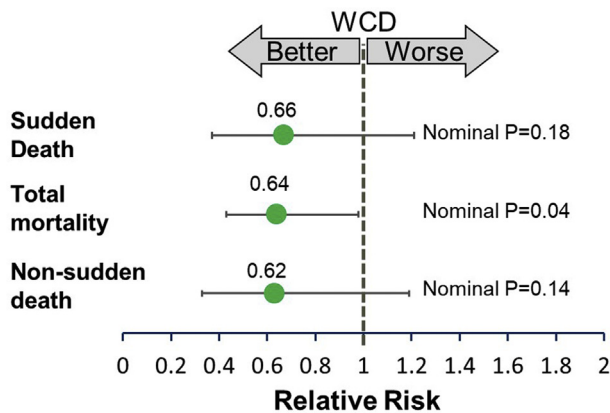
Finally, and perhaps the most compelling reason to believe that there is still a role for the WCD, is that we currently have no good alternatives. Without the WCD, inefficient and less proven approaches will probably be undertaken in certain clinical scenarios. Take for example a secondary-prevention ICD patient who has bacteremia and a vegetation on 1 of the device leads. Removal of the ICD, extraction of the leads, and several weeks of intravenous antibiotics are indicated. Since early reimplantation of an ICD would put the new device at risk for infection, how would you protect that patient from



**Figure 1** Kaplan-Meier curves of time to event for the arrhythmic mortality, the primary endpoint. WCD = wearable cardioverter-defibrillator.



**Figure 3** Kaplan-Meier curves of time to event for overall mortality. WCD = wearable cardioverter-defibrillator.



**Figure 4** Relative risk for arrhythmic, nonarrhythmic, and overall mortality outcomes. WCD = wearable cardioverter-defibrillator.

sudden cardiac death during treatment? Without the WCD as an option, you might choose to (1) keep the patient in the hospital on electrocardiogram monitoring until the antibiotics are done, (2) send the patient home for several weeks of antibiotics without protection from sudden cardiac death, or (3) implant the ICD before the antibiotic course is finished. It is clear that none of these options is optimal, as all involve greater cost, risk, or both. At the very least, the WCD should be still available as an option for patients who have a clear ICD indication but cannot have an ICD owing to transient circumstances like infection.

Based on the aforementioned evidence, we continue to offer the WCD to our high-risk patients, including the post-myocardial infarction, low ejection fraction population studied in VEST. We recommend shared decision making, which should include discussion of the nuances of the VEST findings, as well as the potential downsides of the WCD, such as alarms and discomfort. We emphasize to patients the importance of wear time to maximize benefit. Since VEST did not identify specific clinical or demographic factors associated with improved outcomes, we generally target patients based on their motivation to wear the WCD.

To contain costs, some insurance companies have called for the abandonment of therapies without randomized controlled trials unequivocally proving a therapy's efficacy. Regarding the WCD, this would be a major mistake. As

mentioned above, there is a large volume of nonrandomized clinical studies supporting the efficacy of the WCD. With VEST, we now have randomized controlled trial evidence suggesting, if not proving, the benefit of the WCD. Taking away the option of the WCD will lead to clinical scenarios where we must choose between suboptimal treatment plans, leading sometimes to poorer patient outcomes. This may ironically cost insurance companies more in the long run. Regarding the WCD, we should not take a shortsighted view and eliminate what has become an important option to protect our patients.

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## Disclosures

Dr. Lee was Co-PI of the VEST Trial.

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