

Late Breaking Trial Presented at the American College of Cardiology **Vest Prevention of Early Sudden Death Trial (VEST)**

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This trial was proposed because of the significant risk of sudden cardiac death after acute myocardial infarction in patients with left ventricular dysfunction.

The VEST trial asks whether a wearable cardioverter defibrillator (WCD) can reduce sudden death (SD) mortality in the immediate post-MI period (<90 days) in patients with reduced LVEF, as a bridge to evaluation for ICD. The VEST trial is the first randomized WCD trial in the world.

2302 patients were enrolled within 7 days of hospital discharge with acute myocardial infarction and EF \leq 35%.

Patients were randomized 2:1 to Wearable cardioverter defibrillator (WCD) + guideline directed therapy or Guideline-directed therapy alone.

The ejection fraction was assessed 8 hours after MI or PCI and 48 hours after coronary artery bypass graft surgery. Patients with existing ICD, significant valvular disease, unipolar pacing system, chronic dialysis, a chest too small or too large for the WCD, discharge to skilled nursing facility for more than 7 days, or pregnancy were excluded.

Screening and enrollment were performed between 2008 and 2017 in 108 enrolling sites internationally (76 US, 6 Germany, 24 Poland, 2 Hungary).

Follow-up in the study was performed at 1 month and 3 months. The primary endpoint was initially total mortality but during the course of the study was changed to sudden cardiac death and death due to ventricular arrhythmias.

Secondary endpoints included: 1) Total mortality and Non-sudden death; 2) Cause-specific death; 3) Non-fatal outcomes including Cardiovascular Hospitalizations, WCD compliance, and Adverse events. The analysis was intention-to-treat.

In the WCD plus guideline based therapy arm, there were 1524 patients, with 1481 patients receiving WCD, 43 never wore WCD, and 67 had an ICD implanted during follow-up. In the guideline based therapy arm, 758 patients were never given WCD, 20 were given WCD as a protocol violation and 44 patients had ICD implant during follow-up. ICD timing from randomization was 62 (24-81) days in the WCD group and 58 (25-77) days in the non WCD group. The follow-up was a mean 84.3 ± 15.6 days. The mean age was 60.9 ± 12.6 years in the WCD group and 61.4 ± 12.3 years in the non WCD group. The EF in the index MI was $28.2 \pm 6.1\%$ in the WCD group and $28.2 \pm 5.9\%$ in the non WCD group. 1272 (84.2%) patients in the WCD group had PCI compared to 650 (84.1%) patients in the non WCD group.

For the primary endpoint of sudden cardiac death and ventricular arrhythmia death there

was no statistically significant difference, 25 (1.6%) in the WCD group compared to 19 (2.4%) in the nonWCD group, $p=0.18$. There was no statistically significant difference in nonsudden death 10 (0.7%) in the WCD group and 5 (0.6%) in the nonWCD group, $p=0.14$. Deaths due to stroke were more frequent in the nonWCD group: 0 (0.0%) in the WCD group and 4 (0.5%) in the nonWCD group, $p=0.01$. However, all-cause mortality 48 (3.1%) was lower in the WCD group compared to 38 (4.9%) in the nonWCD group, $p=0.04$, a decrease of 36%.

One appropriate shock occurred in 13 (0.9%) patients in the WCD group and in 0 (0%) patients in the nonWCD group. There were 2 or more appropriate shocks in 7 (0.5%) patients in the WCD group compared to 1 (0.1%) patient in the nonWCD group. One inappropriate shock occurred in 8 (0.5%) WCD patients and two or more inappropriate shocks occurred in 2 (0.1%) WCD patients and there no inappropriate shocks in the nonWCD group. 1 aborted shock occurred in 43 (2.8%) patients; 2 or more aborted shocks occurred in 12 (0.8%) patients; and more than 5 shocks occurred in 15 (1.0%).

The study investigators proposed several important considerations in interpreting the sudden cardiac death outcomes. They noted that there is the possible misclassification of sudden deaths. Of note, 14 of 20 participants who received an appropriate shock survived to 90 days. The study investigators hypothesized that the WCD may confer additional protection beyond sudden death, such as earlier care for bradycardia, NSVT or aborted shocks and lower stroke death in WCD group. They also postulated that there might have been reduced anxiety or increased medication compliance in the WCD group. The WCD group had a lower incidence of reported shortness of breath.

The study investigators concluded that based on this trial that prescribing the WCD is reasonable to protect high-risk patients with a low LVEF post-MI until evaluation for an ICD at 40-90 days.