In the current issue of Circulation: Arrhythmia and Electrophysiology, Zishiri et al\(^1\) evaluate the risk of mortality after coronary artery revascularization in patients with left ventricular dysfunction. Patients with revascularization, including 2198 surgical and 1951 percutaneous intervention patients with left ventricular ejection fraction (LVEF) \(\leq 35\%\) from the Cleveland Clinic were compared with 809 patients in the wearable cardioverter defibrillator (WCD) postmarket US database. Early 90-day mortality was higher among the patients who did not receive a WCD at discharge, including coronary artery bypass graft and percutaneous transluminal coronary angioplasty (PCI) patients, compared with the WCD registry patients. Patients with WCD also had a lower risk of long-term mortality. However, as only 1.3% of the WCD patients received an appropriate therapy, the mortality differences between the 2 groups cannot be explained entirely by prevention of sudden arrhythmic death.

Approved by the US Food and Drug Administration in 2001, the WCD (ZOLL LifeCore Corp, Pittsburgh, PA) is a novel device that offers potentially life-saving therapy to a specific patient niche—patients who are at risk for sudden death from ventricular arrhythmias, who cannot or should not receive an implantable cardioverter defibrillator (ICD) for what is generally a brief period of time. Data from 3569 patients in the nationwide registry showed that the WCD is effective at treating ventricular tachycardia (VT) and ventricular fibrillation (VF), with 100% (76 of 76) first shock success for unconscious VT/VF and 99% (79 of 80) for all VT/VF.\(^2\) Importantly, patient compliance was high, with >50% of patients wearing the WCD 90% of the time. More than a decade has passed since initial approval, but the indications remain unclear.

One of the primary aims of this study was to determine whether survival was influenced by hospital discharge with a WCD in patients with LVEF \(\leq 35\%\) who underwent coronary artery bypass graft or PCI. In the landmark Coronary Artery Bypass Graft Patch Trial, randomization of 900 patients with coronary artery disease and a depressed LVEF showed no improved survival among patients who underwent prophylactic ICD implantation at the time of coronary bypass surgery.\(^3\) In 14 609 patients with acute myocardial infarction complicated by heart failure, left ventricular dysfunction, or both, the VALIANT study showed that the risk of sudden death is highest in the first 30 days after myocardial infarction.\(^4\) However, the DINAMIT trial, a randomized comparison of patients 6 to 40 days after myocardial infarction, did not show that prophylactic ICD implantation reduced overall mortality.\(^5\) The reduction in arrhythmic death attributed to ICD implantation was offset by a higher rate of nonarrhythmic death in the ICD group. In this study, 25 of 310 patients had a device-related complication, but no deaths were related to ICD implantation. Although the patients included in Zishiri’s study are a hodgepodge of patients with different risk factors for sudden cardiac death, the previous literature in this area does not support the hypothesis that a WCD would alter mortality in several of the subsets included. Although both an ICD and WCD will prevent death from VT or VF, the WCD avoids the risks associated with device implantation. A WCD would be expected to offer a mortality benefit where an implantable defibrillator does not only if the rate of device-related deaths (eg, deaths from device implantation or device pacing) is significant. A systematic literature review revealed in-hospital mortality rate of 0.2% for nonthoracotomy ICDs.\(^6\) The rational for the study design is thus somewhat suspect.

The authors are commended for their attempt to better define which patients are likely to benefit from WCD using large patient cohorts. However, the study design compares 2 groups whose characteristics are not fully defined, making interpretation of the findings challenging. More than one third of the patients in the national registry did not have revascularization type recorded and were excluded from subgroup analysis. Further complicating the comparison, the Cleveland Clinic is a tertiary care referral center specializing in delivery of complex cardiac and cardiothoracic care. In the non-WCD cohort, 25% of patients underwent concomitant aortic valve surgery and 35% underwent concomitant mitral valve surgery, with nearly 10% undergoing both aortic and mitral valve surgery.\(^7\) Nearly 7% of patients had simultaneous aortic surgery, and 5.9% received a left ventricular assist device. The patients in the nationwide WCD registry presumably included patients from academic and community hospitals, and the overall complexity of these patients is likely significantly less than the patients treated at the Cleveland Clinic, potentially leading to improved survival rates. The characteristics of the patient populations were not completely defined, and thus could not be entirely controlled for statistically.

The rate of appropriate WCD therapy in the current study was low, in line with previous findings.\(^7\) If the WCD does, in fact, reduce mortality, but not by preventing arrhythmic deaths from VT/VF, then what is the mechanism? If the WCD improves clinical outcomes via another mechanism, it is
critical to identify the mechanism so that the benefit to patients can be maximized in a cost-efficient manner. A WCD, if worn properly, is a 24-hour reminder to the patient that he or she is at an increased risk of sudden death. It serves as a similar reminder to a patient’s loved ones and caretakers. Perhaps, wearing a WCD increases a patient’s compliance with medications, either because of increased patient awareness or by prompting reminders from caretakers. Patients discharged with a WCD may have more frequent contact with their health care teams in cardiology and primary care. Close outpatient management of heart failure has been shown to reduce morbidity and mortality.8 The constant visual reminder provided by the WCD may impact a patient’s behaviors in ways that a 5-cm ICD incision does not. However, if this is the mechanism of improved survival, there may be more efficient, cost-effective ways to maximize the effect, perhaps using personal technology such as the ever-present smartphone. Zishiri’s study was not designed to evaluate the mode of survival benefit. Prospective well-controlled trials are needed, as a defibrillator, whether external or implantable, is certainly not the best way to prevent nonarrhythmic deaths.

The findings of the current study are thought provoking, but do not get at the heart of questions regarding the appropriate indications for WCD use. There are currently no guidelines available to instruct cardiologists in patient selection for WCD. The Zoll website lists the following conditions that are covered by most insurance plans in the United States: primary prevention with EF ≤35%, including after recent myocardial infarction, before and after coronary artery bypass graft or PTCA, awaiting cardiac transplantation, recently diagnosed nonischemic cardiomyopathy, New York Heart Association (NYHA) class IV heart failure, terminal disease with life expectancy of <1 year, ICD indications when ICD is delayed or prohibited, and ICD explantation (http://lifevest.zoll.com).9 Several indications, including secondary prevention when an ICD is contraindicated or has been explanted, are common sense. In other cases, such as class IV heart failure with no plans for left ventricular assist device (LVAD) or transplant, or terminal disease with limited life expectancy, the benefit of a WCD is much less clear. Without well-designed, prospective randomized trials, decision making is driven more by emotions than data. Our group commonly prescribes WCDs for patients in whom use would be supported by a consensus of electrophysiologists, such as secondary prevention in a patient who has undergone lead extraction because of device infection. However, we have also prescribed WCDs in less clear-cut cases, eg, women with peripartum cardiomyopathy. In such cases, the desire to prescribe a WCD may be impacted by the patient’s young age and the presence of a new child. In one small study, none of the 107 peripartum cardiomyopathy patients prescribed a WCD between 2003 and 2009 received an appropriate shock for VT or VF.10 Utilization of technology to prevent sudden arrhythmic death should be driven by data from large, well-designed trials, not based on the physician’s determination of the value of the life to be saved, however well intentioned. The national WCD database is likely affected by such bias, underscoring the need for controlled prospective trials.

Regarding which patients the WCD provides a significant survival benefit, the waters remain murky. Prospective trials need to be designed using well-defined treatment and control groups, not merely comparison with the diverse, poorly defined WCD database. Study end points, both arrhythmic and nonarrhythmic deaths, need to be defined. If WCDs are improving survival through a means other than termination of VT or VF, the mechanism(s) needs to be identified. Although we advocate use of WCD for secondary prevention of sudden cardiac death for patients who cannot have an ICD implanted or have had an ICD explanted, until clear benefit is shown, we cannot support routine use of WCDs for primary prevention in postrevascularization patients.

Disclosures
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References

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