Early Risk of Mortality After Coronary Artery Revascularization in Patients With Left Ventricular Dysfunction and Potential Role of the Wearable Cardioverter Defibrillator

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Background—Implantation of implantable cardioverter defibrillator for prevention of sudden cardiac death is deferred for 90 days after coronary revascularization, but mortality may be highest early after cardiac procedures in patients with ventricular dysfunction. We determined mortality risk in postrevascularization patients with left ventricular ejection fraction ≤35% and compared survival with those discharged with a wearable cardioverter defibrillator (WCD).

Methods and Results—Hospital survivors after surgical (coronary artery bypass graft surgery) or percutaneous (percutaneous coronary intervention [PCI]) revascularization with left ventricular ejection fraction ≤35% were included from Cleveland Clinic and national WCD registries. Kaplan–Meier, Cox proportional hazards, propensity score-matched survival, and hazard function analyses were performed. Early mortality hazard was higher among 4149 patients discharged without a defibrillator compared with 809 with WCDs (90-day mortality post–coronary artery bypass graft surgery 7% versus 3%, P=0.03; post-PCI 10% versus 2%, P<0.0001). WCD use was associated with adjusted lower risks of long-term mortality in the total cohort (39%, P<0.0001) and both post–coronary artery bypass graft surgery (38%, P=0.048) and post-PCI (57%, P<0.0001) cohorts (mean follow-up, 3.2 years). In propensity-score-matched analyses, WCD use remained associated with lower mortality (58% post–coronary artery bypass graft surgery, P=0.002; 67% post-PCI, P<0.0001). Mortality differences were not attributable solely to therapies for ventricular arrhythmia. Only 1.3% of the WCD group had a documented appropriate therapy.

Conclusions—Patients with left ventricular ejection fraction ≤35% have higher early compared to late mortality after coronary revascularization, particularly after PCI. As early hazard seemed less marked in WCD users, prospective studies in this high-risk population are indicated to confirm whether WCD use as a bridge to left ventricular ejection fraction improvement or implantable cardioverter defibrillator implantation can improve outcomes after coronary revascularization.

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Key Words: coronary revascularization • left ventricular dysfunction • percutaneous coronary intervention • survival • wearable defibrillator

Implantation of implantable cardioverter defibrillator (ICD) for primary prevention of sudden cardiac death (SCD) is typically deferred for 3 months after revascularization and 40 days after myocardial infarction (MI) based on primary prevention randomized studies that excluded such patients from randomization,1-3 randomized ICD trials that failed to show a total mortality benefit early after MI,4,5 and Medicare reimbursement restrictions. Nevertheless, SCD risk is higher early after major cardiac events.6 The Valsartan in Acute Myocardial Infarction Trial (VALIANT) study7 showed that patients with reduced systolic function were at highest risk for SCD in the first 30 days after MI. In preliminary data from our institution, we similarly observed higher early mortality after coronary artery bypass graft surgery (CABG).

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Despite this risk, ICDs do not improve overall survival early after MI; lower rates of arrhythmic deaths seem counterbalanced by more nonarrhythmic deaths, as in the DINAMIT (Defibrillator in Acute Myocardial Infarction) and IRIS (Immediate Risk Stratification Improves Survival) trials.4,5 Similar phenomena could be operative after coronary
revascularization. The only trial of ICD placement at time of CABG showed no survival benefit, although this early study (CABG-PATCH [Coronary Artery Bypass Graft Surgery with/without Simultaneous Epicardial Patch for Automatic Implantable Cardioverter Defibrillator Trial]) used currently obsolete epicardial abdominal ICD systems. However, as our preliminary data showed substantial early mortality, we sought to determine whether a noninvasive strategy that could ameliorate early SCD risk might improve overall survival.

The wearable cardioverter defibrillator (WCD) is an external device capable of automatic ventricular tachyarrhythmia detection and defibrillation. The device can improve sudden cardiac arrest survival over reliance on emergency medical services. Survival is comparable with that of patients with ICDs. The WCD is often used during transition periods as a bridge to left ventricular (LV) improvement or ICD implantation.11

We aimed to determine in patients with LV ejection fraction (LVEF) ≤35% whether (1) mortality risk is different early compared to late after discharge from CABG or percutaneous coronary intervention (PCI); and (2) survival is different in patients discharged with or without a WCD after CABG or PCI.

Methods

Patients for this retrospective observational parallel cohort study were obtained from prospectively collected registries of all patients who underwent cardiac surgery and PCI at the Cleveland Clinic and from a national database of all patients issued a WCD postmarket release in the United States. The study period for inclusion was August 1, 2002, to December 31, 2009.

Study Population

No WCD Revascularization Subjects

Patients were included if they underwent CABG or PCI at the Cleveland Clinic during the study period, had LVEF ≤35%, and survived to hospital discharge. Exclusion criteria included presence of a preexisting ICD, ICD implantation before discharge after CABG or PCI, WCD issued at discharge, or absence of a Social Security number to validate Medicare or Medicaid status. Subjects were not excluded for concomitant procedures at the time of CABG. Subjects were divided into specified CABG and PCI subgroups. Subjects were studied under PCI and cardiac surgery registries approved by the Cleveland Clinic Institutional Review Board.

WCD Revascularization Subjects

Data of all patients issued a WCD (LifeVest, ZOLL, Pittsburgh, PA) postmarket release in the United States are entered into a database maintained by the manufacturer for regulatory, reimbursement, and tracking purposes. The database includes indications, demographics, and events. Patients signed consent to use their data for quality monitoring, health care operation activities, or research. The study included patients who wore the WCD for any time during the study period with the indication being post-CABG or PCI with LVEF ≤35%.

Outcomes Follow-up

Mortality

The primary outcome was all-cause mortality, determined from the Social Security Death Index. A 6-month censor period was incorporated to adjust for lags in death reporting. Date of censoring for all observations was March 8, 2010. Social Security Death Index information was provided for WCD cohorts by ZOLL. The national WCD database also collected data on deaths during WCD use. ZOLL data were available for only 3 years, and cutoffs for graphical presentation are 3 years.

Events During WCD Use

WCD function, arrhythmia criteria, and event and outcome determination have been described previously.10 All potentially lethal arrhythmias (sustained ventricular tachycardia [VT]/ventricular fibrillation [VF] or asystole) occurring within 24 hours were considered a single sudden cardiac arrest event. Two-lead electrocardiograms from all shocks and asystole events were reviewed by 2 authors (S.J.S., E.T.Z.) and differences adjudicated by consensus with the senior author (M.K.C.). There was 100% concordance to logged events.

Statistical Analyses

Data were stratified by procedure (CABG, PCI) and WCD use. Data are expressed as mean±SD or median (15th, 85th percentile) unless otherwise indicated. These percentiles were used as they are similar to ±1 SD and encompassed 70% of the data. Wilcoxon rank-sum tests were used for continuous data. Categorical data are displayed as frequencies and percentages and analyzed with χ2 or Fisher exact tests. All analyses used SAS statistical software (SAS v9.1; SAS, Inc., Cary, NC). Results were considered statistically significant for 2-sided P<0.05.

Survival Analyses

Survival was assessed nonparametrically by the Kaplan-Meier method and parametrically by a multiphase hazard model. The parametric model was used to resolve various phases of instantaneous risk of death (hazard function) and to estimate shaping parameters.12 Cox proportional hazard models were used to adjust for covariates. Available baseline covariates common to the WCD and Cleveland Clinic databases included age, sex, hypertension, diabetes mellitus, and LVEF. To adjust for potential improvement in survival related to improved procedural techniques, we adjusted for the time interval since January 1, 2002, and index revascularization procedure. To better understand the differences in early versus late mortality, we also performed survival analysis with all outcomes censored at 90 days and another analysis where all events occurring within 90 days of revascularization were excluded and time zero was reset to 90 days after revascularization.

Propensity Score-Matched Analyses

To further reduce influences of potential selection bias on the outcome, we performed propensity score-matched survival analysis and comparison of the WCD and No WCD groups. A Markov Chain Monte Carlo multiple imputation technique11 was used to impute missing values with 5-fold multiple imputation using PROC MI (SAS v9.1). Based on each imputed complete dataset, propensity scores were estimated for each patient. The average of the propensity scores during the 5 imputed complete data sets yielded the final estimate of the propensity scores. Variables were excluded from analysis if >15% to 20% was missing.

Preoperative variables and multivariable logistic regression were used to identify factors associated with WCD use in the comparisons. As few variables were common to both databases, propensity models included all common variables (age, sex, hypertension, diabetes mellitus, LVEF, and procedure date years since January 1, 2002). A propensity score was calculated for each patient by solving the propensity model for probability of receiving a WCD. The C-statistic was calculated to assess the goodness-of-fit measurement of the logistic model. Ranging from 0.5 to 1.0, the C-statistic describes how well the model discriminates between dichotomous observations (WCD use versus no WCD use) with higher values indicating a better predictive model. Using only the propensity score, WCD cases were matched to No WCD cases using a greedy matching strategy.13,14 For the greedy matching algorithm, one at a time, propensity scores of the WCD are matched with the closest non-WCD propensity score within a distance of 0.1. After a match has been found, then that pair is removed from the patient list. This is continued until all cases are matched or there are no longer any candidate non-WCD scores that fall within the 0.1 distance parameter. WCD cases whose propensity scores deviated by more than 0.1 from those of non-WCD cases were considered unmatched. Separate propensity score-matched analyses were performed for
patients with CABG and PCI. The decomposition of time-varying hazard phase analyses has been previously published.12

Results

At the Cleveland Clinic 4149 patients who underwent CABG (N=2198) or PCI (N=1951) met entry criteria and were included into the No WCD group. In the national registry, 809 patients met criteria and were included into the WCD group. Of these, 514 patients had revascularization type recorded (226 CABG, 288 PCI). Patients without a record of method of revascularization were excluded from subgroup analyses.

Baseline Patient Characteristics

In the total cohort (N=4958) and in the CABG cohort (N=2424), patients with WCD were younger, more likely to be male, with diabetes mellitus, and lower LVEF than in No WCD patients (Table 1). Median and mean durations of WCD use after CABG were 72 (22, 113) and 79±69 days. In the PCI cohort (N=2239), WCD users were younger with lower LVEF but less diabetes mellitus. Median and mean durations of WCD use after PCI were 61 (2, 111) and 81±183 days. Across all cohorts, times since January 1, 2002, to index revascularization were excluded from subgroup analyses.

Survival Analyses

In the entire cohort, 1480 of 4958 subjects (30%) died (follow-up, 3.2±2.3 years; median, 2.8 years). In the No WCD group, 1399 of 4149 subjects (34%) died; 81 of 809 (10%) died in the WCD group. These data were not available for the WCD group. In the national registry, 809 (N=2198) or PCI (N=1951) met entry criteria and were included into the No WCD group. In the PCI cohorts, 763 of 1951 (39%) No WCD and 31 of 288 (11%) WCD patients died. In the total cohort (N=4958) and in the CABG cohort (N=226) WCD users were younger, more likely to be male, with diabetes mellitus, and lower LVEF than in No WCD.

Table 1. Baseline Characteristics

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<td>WCD No WCD</td>
<td>WCD No WCD</td>
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<tr>
<td><strong>N (%)</strong></td>
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<td>n=226 (%) n=2198 (%)</td>
<td>n=288 (%) n=1951 (%)</td>
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<tr>
<td>Age, y</td>
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<td>63.7±11.1 67.5±10.7</td>
<td>63.2±12.8 66.9±12.3</td>
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<tr>
<td>Sex, female</td>
<td>1234/4958 (25%) 156/809 (19%) 1078/4149 (26%)</td>
<td>30/226 (13) 527/2198 (24%)</td>
<td>67/288 (23) 551/1951 (28%)</td>
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<td>Hypertension</td>
<td>3761/4684 (80%) 431/536 (80%) 3330/4148 (80%)</td>
<td>125/156 (80) 1762/2198 (80)</td>
<td>162/212 (76) 1568/1950 (80)</td>
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<td>Diabetes mellitus</td>
<td>2089/4622 (45) 246/492 (50) 1843/4130 (45)</td>
<td>87/150 (58) 944/2198 (43)</td>
<td>74/192 (39) 899/1951 (46)</td>
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<tr>
<td>LVEF, %</td>
<td>26.8±7.6 24.7±8.3 27.2±7.4</td>
<td>23.5±7.7 27.2±8.0</td>
<td>26.3±8.1 27.3±8.8</td>
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<tr>
<td>Interval from January 1, 2002, to index revascularization, y</td>
<td>4.2±2.3 6.7±1.5 3.7±2.1</td>
<td>6.7±1.5 3.6±2.2</td>
<td>6.6±1.5 3.9±2.1</td>
</tr>
</tbody>
</table>

Continuous variables reported as mean±SD and median (15th, 85th percentiles).

CABG indicates coronary artery bypass graft surgery; LVEF, left ventricular ejection fraction; PCI, percutaneous coronary intervention; and WCD, wearable cardioverter defibrillator.
Other predictors of long-term mortality included older age, diabetes mellitus, female sex, and lower LVEF.

Hazard function curves in the CABG cohort stratified by WCD (Figure 2A inset) demonstrated higher risk of death in the early phase of the study for both WCD and No WCD groups, although the early risk seemed higher in the No WCD group. Survival analysis restricted to the first 90 days after CABG (Figure 2B left) showed better survival in the WCD group compared with the No WCD group (HR, 0.54; 95% CI, 0.39–0.68; p < 0.0001). Mortality in the WCD versus No WCD cohorts was 1% versus 3% at 1 month, 3% versus 7% at 3 months, 5% versus 9% at 6 months, and 7% versus 12% at 1 year, respectively. Analysis of survival after the first 90 days (Figure 2B right) showed no significant difference between WCD and No WCD groups (HR, 0.68; 95% CI, 0.38–1.21; P=0.19), suggesting the observed mortality difference was accrued within the first 90 days.

**PCI Cohort**

In the PCI cohort (follow-up, 3.1±2.3 years; median, 2.8 years), Kaplan–Meier survival analyses stratified by WCD use (Figure 3A) demonstrated better survival in the WCD cohort compared with the No WCD group with univariate HR, 0.405; 95% CI, 0.273 to 0.601; P<0.0001. Multivariable Cox proportional hazards analyses (Table 2) showed that after PCI WCD use was associated with a 57% lower risk of death (HR, 0.430; 95% CI, 0.290–0.638; P<0.0001). Other predictors of long-term mortality included age, diabetes mellitus, and lower LVEF.

Hazard function analysis stratified by WCD (Figure 3A inset) demonstrated higher risk of death in the early phase after PCI in both WCD and No WCD users, but early risk...
survival in the WCD group (HR, 0.412; 95% CI, 0.311–0.545; \( P<0.0001 \)). Survival analyses of the first 90 days after revascularization (Figure 4B left) showed better survival in the WCD group compared with the No WCD group (HR, 0.41; 95% CI, 0.31–0.55; \( P<0.0001 \)). Survival analyses after 90 days (Figure 4B right) showed continued survival differences with better survival in the WCD group (HR, 0.52; 95% CI, 0.37–0.72; \( P=0.0001 \)), suggesting continued survival differences extending beyond the first 3 months.

**Propensity Score-Matched CABG Cohort**

The C-statistic of the saturated propensity model for CABG was 0.89. Greedy matching using propensity scores yielded 198 (88% of CABG WCD patients) well-matched pairs (Figure II in the online-only Data Supplement) with no significant differences in patient characteristics between WCD and No WCD groups after propensity matching (Table III in the online-only Data Supplement).

Between the matched CABG cohorts (Figure 5A), a significant difference in survival remained with better survival in the WCD group (HR, 0.416; 95% CI, 0.232–0.743; \( P=0.002 \)). Survival analysis of the first 90 days after CABG in the matched groups (Figure 5B left) showed better survival in the WCD compared with the No WCD group (HR=0.002), but on univariate Cox proportional hazards modeling, differences were not significant (HR, 0.59; 95% CI, 0.32–1.103; \( P=0.42 \)). Analyses after the first 90 days (Figure 5B right) also showed no significant differences between WCD and No WCD groups (HR, 0.65; 95% CI, 0.28–1.48; \( P=0.3 \)). Thus in this analysis, WCD use was associated with significantly better overall long-term survival, but early and late mortality differences were not demonstrated.

**Propensity Score-Matched PCI Cohort**

The C-statistic of the saturated propensity model for PCI was 0.87.Greedy matching using propensity scores yielded 264 (92% of PCI WCD patients) well-matched pairs with no significant differences in patient characteristics between WCD and No WCD groups after matching (Figure III and Table III in the online-only Data Supplement).

Between the matched PCI cohorts (Figure 6A) a significant difference in survival was evident with better survival in the WCD group (HR, 0.334; 95% CI, 0.212–0.524; \( P<0.0001 \)). Survival analysis of the first 90 days after PCI showed significantly better survival in the WCD compared with the No WCD group (HR, 0.31; 95% CI, 0.19–0.48; \( P<0.0001 \)). Survival analysis after 90 days showed a persistent significant difference between groups (HR, 0.44; 95% CI, 0.26–0.75; \( P=0.003 \)), suggesting continued survival differences beyond the first 3 months.

**Arrhythmia Events During WCD Use and Subsequent ICD Implantation**

Throughout the entire period of WCD use, 18 appropriate defibrillations occurred in 11 patients (1.3% of the WCD group) for VT/VF. Defibrillations were successful in 12 to 18 shocks. One patient required 8 shocks for 2 separate VT episodes. Inappropriate shocks numbered 13 (42% of
total therapies): 3 for atrial fibrillation/flutter, 1 for sinus tachycardia at 180 beats per minute, and 9 for sensing channel noise. Of 3 asystolic events, 2 were fatal. The surviving patient had a transient self-terminating 10-second episode. The first patient who died had VT at 150 to 170 beats per minute, under the VT detection criterion programmed at 180 beats per minute, which degenerated into slow VF, still under the rate criterion, with eventual asystole. The second patient who died had an idioventricular rhythm at 55 beats per minute that gradually slowed to asystole; he was found dead wearing the WCD.

In the WCD database, 32% of the CABG cohort and 30% of the PCI cohort subsequently underwent ICD implantation. These data were not available for the No WCD group.

Discussion
This study of survival after CABG and PCI demonstrated significant risk of death, early after coronary revascularization procedures in patients with LV dysfunction, consistent with prior studies that suggested higher mortality risks early after cardiac events. This period likely carries risk of arrhythmic...
and nonarrhythmic death. Thus, a critical question is whether arrhythmic protection might improve early survival in high-risk groups. Early ICD implantation after MI for primary prevention of SCD has failed to show significant survival benefits; reductions in arrhythmic death were counterbalanced by nonarrhythmic mortality. Analogous situations may pertain to postrevascularization periods. We sought to determine whether a noninvasive method of arrhythmia protection might yield demonstrable survival benefits in this early period, as such a method might minimize device-related nonarrhythmic complications.

In both unmatched and propensity score-matched total, CABG, and PCI cohorts, findings were remarkably consistent with significantly better survival in WCD users. Although the study was a comparison of data from a single high-volume, high patient acuity center to national registry WCD data, we attempted to adjust for potential confounders using multivariable Cox proportional hazards modeling and propensity score-matched populations. Consistent significant differences in survival between WCD and non-WCD users remained demonstrable. Because of limitations in available patient characteristics in the national database, these methods could not fully account for all comorbid factors. However, although the WCD group was younger, this group had significantly lower LVEF than the No WCD group, and the propensity-matched CABG and PCI analyses were well balanced in all covariates used in matching, including age and LVEF.
Despite these limitations, a major outcome of this study should be a highlighting of the high early mortality hazard after coronary revascularization in patients with LVEF ≤ 35% who do not have an ICD (or WCD). Review of survival curves from prior studies of patients with risk markers, such as ventricular dysfunction, after CABG and PCI confirm similar higher early mortality as observed in our cohorts.\(^1\)\(^7\)\(^-\)\(^2\)\(^0\) Moreover, in 2 recent large national databases of survival after CABG and PCI, similar early mortality hazards were evident in patients with reduced LV function. In 348,341 isolated CABG patients ≥ 65 years of age from the Society of Thoracic Surgeons Adult Cardiac Surgery Database linked to Centers for Medicare and Medicaid Services (CMS) databases, mortality was 7.6% at 30 days and 18.5% at 1 year after CABG in patients with LVEF < 30% and 4.4% and 11.6% in patients with LVEF 30% to 45%, respectively.\(^2\)\(^1\) Survival curves from this study showed early mortality hazard similar to the current study (Figure V in the online-only Data Supplement). We report here comparable, if not better, 3% 1-month and 12% 1-year mortality in our No WCD CABG cohort, despite inclusion of concomitant procedures and mean LVEF of 23.2%. A recent large analysis of mortality after PCI in 343,466 patients from the National Cardiovascular Data Registry (NCDR) linked to CMS databases reported 3% overall mortality at 30 days and 6% at 6 months. Survival curves also demonstrated early mortality hazard, similar to our current study, that was most marked in patients with LVEF < 30%, where mortality seemed comparable to or exceeded the early mortality reported in our No WCD cohort with mean LVEF of 27.3% and in the WCD cohort with mean LVEF of 26.3% (Figure VI in the online-only Data Supplement).\(^2\)\(^2\)
The differences in early mortality hazard and long-term survival with early WCD use were most marked after PCI and less marked after CABG. Thus, early benefits of WCD use after revascularization may be potentially highest after PCI. The PCI cohort contained a proportion of patients who had recent MI. Whether the defibrillation testing typically performed with ICD implants, inflammatory reactions, or infectious complications associated with ICDs contribute to nonarrhythmic deaths or overall mortality early after MI or revascularization is unknown, but these would theoretically be avoided using a noninvasive bridging strategy.

Arrhythmic event analyses demonstrated that the observed mortality differences were not entirely due to defibrillation from the WCD, as only 1.3% of the WCD group were documented to have received appropriate defibrillation therapy during the period of WCD use. Inappropriate WCD therapies represented 41% of total therapies, but incidence remained low (1.6%/patient, or 0.6%/mo). The low incidence of asystole (0.4%) but high associated mortality was comparable with that previously reported in WCD users.10

Mean WCD use was <90 days, yet in total and PCI unmatched and matched cohorts, continued survival advantages occurred after >90 days, again suggesting that additional factors beyond actual WCD use may be important. WCD users may be more likely to maintain medical contact and follow-up, including earlier follow-up for symptoms short of arrhythmic events triggering shocks, or more consistent reassessment of their LVEF for subsequent ICD decisions after the 3-month period. The more marked long-term differences in survival benefit seen in the PCI cohorts compared with the CABG cohorts may be related to closer follow-up after CABG compared with the less invasive PCI procedures.

The early risk period with high mortality during the first 3 months after revascularization in patients with LVEF ≤35%
indicates a need for further studies to assess methods to improve survival outcomes in this high-risk group after CABG or PCI. At minimum, concerted efforts to assure follow-up and assessment for long-term SCD risk and ICD implantation for continued low LVEF after 3 months seem well indicated.

**Limitations**

The national WCD database was limited in the variables collected, including concomitant surgeries and other potential confounding variables, and revascularization mode was missing from 288 subjects, excluding these subjects from the propensity-matched analyses. The Cleveland Clinic No WCD group also lacked specific postdischarge tracking of ICD implantation, and we had no hospital length of stay data for the WCD group. The study is retrospective and despite use of multivariable Cox regression and propensity score-matched analyses, which have been shown to reduce potential bias and confounding in epidemiological association studies, unmeasured confounding variables could have accounted for observed differences. The Cox proportional hazards model was also limited by nonproportional hazards. Therefore, instantaneous hazard functions were calculated and presented. The comparison of No WCD group was derived from a high-volume center that performs complex procedures in patients with multiple comorbidities and high acuity and might have biased toward better survival in a national WCD registry. Nevertheless, using 2 methods of analysis, consistent differences in survival were observed. Moreover, large national databases of PCI or CABG in patients with LV dysfunction show similar, and perhaps even worse, early hazard and overall mortality compared with our No WCD cohorts (Figures V and VI in the online-only Data Supplement). The findings of

![Figure 6.](image-url)
WCD After Coronary Artery Revascularization

this study should be limited to hypothesis generation without attribution of causality to survival differences associated with WCD use, but rationalize further studies to evaluate the efficacy of the WCD and other therapies on reducing early and late phase mortality in postrevascularization patients with reduced LV function.

Conclusions

Patients with LVEF ≤35% have higher early compared with late mortality after coronary revascularization, particularly after PCI. Early hazard seemed less marked in WCD users, although differences in mortality were not attributable solely to therapies for ventricular arrhythmia. This study highlights the need for targeting measures to reduce early mortality in the first 3 months after coronary revascularization, including PCI, and the need for further studies to ascertain whether WCD use as a bridge to LVEF improvement or ICD implantation can improve survival outcomes after coronary revascularization. Until prospective randomized data becomes available, it is our opinion that it remains reasonable to risk stratify and identify highest risk groups so that there can be consideration of rational prescription of the WCD as a bridge to LV improvement or ICD implantation or at least planning for closer follow-up.

Disclosures

ZOLL provided WCD data, but no study funding. Study was designed at Cleveland Clinic and statistical analysis performed independently by Cleveland Clinic statisticians. All members of the Cleveland Clinic Section of Cardiac Electrophysiology and Pacing (E.M. Cronin and Drs Tchou and Chung) participate in industry-funded research with Boston Scientific, Medtronic, St. Jude Medical, and Biotronik. Dr Roselli consults for Medtronic. Dr Gillinov performs research with St. Jude Medical. Drs Glad and Szymkiewicz are employees of ZOLL. Dr Chung performs research funded by the National Institutes of Health (R01 HL090620), and ZOLL ($0), and has been a speaker ($0 compensation) for Medtronic, St. Jude Medical, Boston Scientific, and ZOLL. The other authors have no conflicts to report.

References

Implantable cardioverter defibrillators (ICDs) have been shown to reduce mortality in patients with ischemic cardiomyopathy and left ventricular dysfunction with left ventricular ejection fraction <35%, but ICD implantation is typically deferred for 3 months after coronary revascularization procedures, as ICD trials typically excluded this time period from study. This study shows that patients with left ventricular ejection fraction <35% are at particularly high risk for mortality early after percutaneous coronary intervention or coronary artery bypass graft surgery, a finding that was most marked after percutaneous coronary intervention. In contrast, this high early mortality was not observed in survival curves from a national database of patients with left ventricular dysfunction, although this apparent difference cannot be wholly attributed to successful appropriate therapy for ventricular arrhythmias. In this nonrandomized comparison, wearable cardioverter defibrillator use may have been associated with other confounding factors, including potential triggering of closer follow-up and reassessment for ICD implantation at subsequent follow-up. These findings emphasize the need to address the early mortality risk after coronary revascularization. Although results suggest consideration for use of a wearable cardioverter defibrillator in particularly high-risk patients during the period of recovery after percutaneous coronary intervention or coronary artery bypass graft surgery before reassessment of left ventricular function and indications for ICD implantation, whether wearable cardioverter defibrillator use would result in mortality reduction during this early period should be tested in a randomized clinical trial.
Early Risk of Mortality After Coronary Artery Revascularization in Patients With Left Ventricular Dysfunction and Potential Role of the Wearable Cardioverter Defibrillator


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http://circep.ahajournals.org/content/6/1/117

Data Supplement (unedited) at:
http://circep.ahajournals.org//subscriptions/
Supplemental Table 1. PCI Target Vessels and Prior MI History in the No WCD PCI Cohort.
In 1283 patients there were 1612 prior MI events (time prior to PCI 5.1 years, median 0.39 years).

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<td>Left circumflex artery</td>
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<td>2 days</td>
<td>195</td>
</tr>
<tr>
<td>1 day</td>
<td>132</td>
</tr>
</tbody>
</table>
Supplemental Table 2. Concomitant surgeries in the No WCD CABG Cohort.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aortic Valve Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repair</td>
<td>16</td>
<td>0.73</td>
</tr>
<tr>
<td>Replacement</td>
<td>537</td>
<td>24</td>
</tr>
<tr>
<td>Mitral Valve Surgery</td>
<td>771</td>
<td>35</td>
</tr>
<tr>
<td>Repair</td>
<td>646</td>
<td>29</td>
</tr>
<tr>
<td>Replacement</td>
<td>125</td>
<td>4.7</td>
</tr>
<tr>
<td>Tricuspid Valve Surgery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Repair</td>
<td>201</td>
<td>9.1</td>
</tr>
<tr>
<td>Replacement</td>
<td>197</td>
<td>9</td>
</tr>
<tr>
<td>Aortic and Mitral Valve Surgery</td>
<td>208</td>
<td>9.5</td>
</tr>
<tr>
<td>Aortic, Mitral, and Tricuspid Valve Surgery</td>
<td>56</td>
<td>2.5</td>
</tr>
<tr>
<td>Aortic Root, Ascending Aorta, Arch Replacement</td>
<td>151</td>
<td>6.9</td>
</tr>
<tr>
<td>Descending Aorta Grafting</td>
<td>2</td>
<td>0.09</td>
</tr>
<tr>
<td>Major Left Ventricular Procedure</td>
<td>176</td>
<td>8</td>
</tr>
<tr>
<td>Atrial Fibrillation Procedure</td>
<td>212</td>
<td>9.6</td>
</tr>
<tr>
<td>Carotid endarterectomy</td>
<td>15</td>
<td>0.68</td>
</tr>
<tr>
<td>Removal of atrial myxoma, cardiac tumor</td>
<td>3</td>
<td>0.14</td>
</tr>
<tr>
<td>Pericardiectomy</td>
<td>4</td>
<td>0.18</td>
</tr>
<tr>
<td>Transmyocardial laser revascularization</td>
<td>14</td>
<td>0.64</td>
</tr>
<tr>
<td>Congenital Heart Disease Procedure</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congenital atrial septal defect / patent foramen ovale suture closure</td>
<td>63</td>
<td>2.9</td>
</tr>
<tr>
<td>Insertion of assist device</td>
<td>129</td>
<td>5.9</td>
</tr>
<tr>
<td>Internal Thoracic Artery (ITA) Graft</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single ITA Grafting</td>
<td>1527</td>
<td>69</td>
</tr>
<tr>
<td>Bilateral ITA Grafting</td>
<td>1461</td>
<td>66</td>
</tr>
<tr>
<td></td>
<td>66</td>
<td>3</td>
</tr>
</tbody>
</table>
Supplemental Table 3: Patient characteristics of propensity-matched cohorts. Continuous variables reported as mean±standard deviation and median (15th, 85th percentiles).

<table>
<thead>
<tr>
<th></th>
<th>Entire Cohort</th>
<th>CABG</th>
<th>PCI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>WCD N=707(%)</td>
<td>No WCD N=707(%)</td>
<td>P value</td>
</tr>
<tr>
<td>Age, years</td>
<td>64.3±11.7</td>
<td>65.6±12.7</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>64.6 (51.7,77.1)</td>
<td>66.4 (52.1,79)</td>
<td></td>
</tr>
<tr>
<td>Female gender</td>
<td>138/707(20)</td>
<td>167/707(24)</td>
<td>0.061</td>
</tr>
<tr>
<td>Hypertension</td>
<td>381/476(80)</td>
<td>564/707(80)</td>
<td>0.91</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>212/439(48)</td>
<td>320/704(45)</td>
<td>0.35</td>
</tr>
<tr>
<td>LVEF, %</td>
<td>25.4±8.2</td>
<td>25.5±7.2</td>
<td>0.29</td>
</tr>
<tr>
<td></td>
<td>25 (17,35)</td>
<td>25 (20,35)</td>
<td></td>
</tr>
<tr>
<td>Interval from 1/1/2002 to index revascularization, years</td>
<td>6.7±0.9</td>
<td>6.7±0.9</td>
<td>0.077</td>
</tr>
<tr>
<td></td>
<td>6.8 (5.7,7.8)</td>
<td>7 (5.7,7.7)</td>
<td></td>
</tr>
</tbody>
</table>
Supplemental Figure 1. Propensity score matching in the Entire Cohort.
A. Density of propensity scores in the entire cohort stratified by WCD versus No WCD use groups.
B. Mirrored histogram of distribution of propensity scores for WCD groups in the entire cohort. Darkened area represents matched patients.
C. Covariate balance description before and after matching between WCD versus No WCD groups for the entire cohort.

A. Density of propensity scores in the entire study cohort stratified by WCD vs. no WCD use.
B. Mirrored histogram of distribution of propensity scores for WCD groups in the Entire Cohort. Darkened area represents matched patients.
C. Covariate balance description before and after matching between WCD versus no WCD groups for the Entire Cohort.
Supplemental Figure 2. Propensity score matching in the CABG Cohort.
A. Density of propensity scores in the CABG cohort stratified by WCD vs. no WCD use.
B. Mirrored histogram of distribution of propensity scores for WCD groups in the CABG cohort. Darkened area represents matched patients.
C. Covariate balance description before and after matching between WCD versus No WCD groups for the CABG cohort.

A. Density of propensity scores in the CABG cohort stratified by WCD vs. no WCD use.
B. Mirrored histogram of distribution of propensity scores for WCD groups in the CABG cohort. Darkened area represents matched patients.
C. Covariate balance description before and after matching between WCD versus No WCD groups for the CABG cohort.
Supplemental Figure 3. Propensity score matching in the PCI Cohort.
A. Density of propensity scores in the PCI cohort stratified by WCD versus No WCD use groups.
B. Mirrored histogram of distribution of propensity scores for WCD groups in the PCI cohort. Darkened area represents matched patients.
C. Covariate balance description before and after matching between WCD versus No WCD groups for the PCI cohort.

A. Density of propensity scores in the PCI cohort stratified by WCD versus No WCD use groups.
B. Mirrored histogram of distribution of propensity scores for WCD groups in the PCI cohort. Darkened area represents matched patients.
C. Covariate balance description before and after matching between WCD versus No WCD groups for the PCI cohort.
Supplemental Figure 4. Hazard function curves for propensity score matched groups. A. 1 year. B. 3 months

A.
**Supplemental Figure 5.** Superimposed survival curves from the CathPCI National Cardiovascular Data Registry (NCDR) linked to Centers for Medicare and Medicaid Services (CMS) databases (modified and re-drawn from Weintraub WS, et al. Circulation 2012;125:-1501-1510) and the PCI Cohorts stratified by WCD use from current study (from Figure 3). **A.** CathPCI NCDR CMS survival curves showing observed (solid line) mortality with 95% confidence intervals (dashed lines) stratified by EF in patients with ST-elevation MI (STEMI) with WCD (blue solid line) and No WCD curves (orange solid line) from Figure 3. **B.** CathPCI NCDR CMS survival curves showing observed (solid line) mortality with 95% confidence intervals (dashed lines) stratified by EF in patients with No ST-elevation MI (No STEMI) with WCD (blue solid line) and No WCD curves (orange solid line) from Figure 3.

**A. PCI Cohorts - NCDR STEMI vs. current study WCD and No WCD cohorts**

![Graph showing survival curves with different markers for different EF categories and WCD statuses.](image-url)
B. PCI Cohorts - NCDR No STEMI vs. current study WCD and No WCD cohorts

![Survival curve graph showing comparison between WCD and No WCD cohorts based on ejection fraction (EF) categories: EF ≥ 30, EF < 30, and EF missing.](image)

- **Survival (%)**
  - 100
  - 90
  - 80
  - 70
  - 60
  - 50

- **Years**
  - 0.0
  - 0.5
  - 1.0
  - 1.5
  - 2.0
  - 2.5
  - 3.0

- **Legend**
  - WCD
  - No WCD
  - EF ≥ 30
  - EF < 30
  - EF missing
Supplemental Figure 6. Superimposed survival curves from the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database linked to Centers for Medicare and Medicaid Services (CMS) databases (modified and re-drawn from Shahian DM, et al. Circulation 2012;125:-1491-1500) and the CABG Cohorts stratified by WCD use from current study (from Figure 2). STS CMS survival curves showing predicted (solid) and observed (dashed) mortality stratified by EF shown with WCD (blue solid line) and No WCD curves (orange solid line) from Figure 2.