The Journal of Innovations in Cardiac Rhythm Management, 6 (2015), 1929–1940

The Journal of Innovations in Cardiac Rhythm Management™

DOI: 10.19102/icrm.2015.060302

DEVICE THERAPY

RESEARCH ARTICLE

Potential Cost-effectiveness of Wearable Cardioverter-Defibrillator Early Post Myocardial Infarction

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ABSTRACT. *Patients who have had a recent myocardial infarction (MI) and have a reduced left ventricular ejection fraction (LVEF) are at increased risk of sudden cardiac death (SCD). Current guidelines recommend that implantable cardioverter-defibrillator (ICD) implantation should not occur within 40 days post MI or 3 months of revascularization. The wearable cardioverter-defibrillator (WCD) is a promising approach to reducing SCD post MI, but its cost-effectiveness is uncertain. We sought to determine the potential cost-effectiveness of the WCD. We developed a Markov model of the cost, quality-of-life, survival, and incremental cost-effectiveness of the WCD compared with usual care among patients who have had a recent MI with a reduced LVEF. Sudden cardiac event rates, efficacy of the WCD, ICD effectiveness, and long-term cost and health outcomes were derived from the literature. In our base-case analyses, the WCD strategy was more expensive than usual care (incremental cost of $11,503), but improved life expectancy by 0.261 life years or 0.190 quality-adjusted life years (QALYs). The incremental cost-effectiveness of the WCD was $44,100/LY or $60,600/QALY. Findings were sensitive to assumptions of sudden cardiac arrest rate. Use of the WCD cost <$100,000/QALY gained as long as the rate of cardiac arrest in the first month post MI was ⩾1.163%. Our analysis suggested that for patients who have had a recent MI and have reduced LVEF, use of a WCD could reduce the rate of SCD during the recovery period at a cost that appears to be economically attractive.*

KEYWORDS. *cost–benefit analysis, defibrillation, heart arrest, myocardial infarction, sudden death.*

ISSN 2156-3977 (print)
ISSN 2156-3993 (online)

Introduction

Patients who have had a recent myocardial infarction (MI), with or without coronary revascularization, and have a reduced left ventricular ejection fraction (LVEF) are at increased risk of sudden cardiac death (SCD). Implantable cardioverter-defibrillators (ICDs) have not reduced mortality in the setting of recent MI with reduced LVEF, even though they have proven effective[1–5] and cost-effective[6,7] for primary prevention in other clinical settings. The Defibrillator in Acute Myocardial Infarction (DINAMIT)[8] and the Immediate Risk Stratification Improves Survival (IRIS)[9] trials both randomized patients to receive an ICD early post MI, but neither trial showed that the ICD reduced mortality. As a result, current guidelines from the American College of Cardiology/

Dr. Sanders' contribution to this publication was as a paid consultant, and was not part of her Duke University duties or responsibilities. Dr. Hlatky's and Dr. Owens' contributions to this publication were as paid consultants, and were not part of their Stanford University duties or responsibilities.

This study was supported by ZOLL. The content is solely the responsibility of the authors and does not necessarily represent the official views of ZOLL. The authors had editorial control of content and access to all relevant data.

Manuscript received January 1, 2015, final version accepted February 1, 2015.

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American Heart Association/Heart Rhythm Society recommend that ICD implantation should not occur within 40 days post MI or within 3 months of coronary revascularization.[10]

The elevated risk for SCD in the early post-MI period, coupled with the lack of success of the ICD in this setting, have motivated the search for alternative approaches to reduce the risk of SCD. The wearable cardioverter-defibrillator (WCD, LifeVest®, ZOLL®, Pittsburgh, PA) is a non-invasive, ambulatory device that contains sensing electrodes, defibrillation electrodes, and a defibrillation unit that can automatically deliver a treatment shock when appropriate, without any bystander intervention.[11] The WEARIT/BIROAD non-randomized observational registry showed that the WCD effectively terminates sustained ventricular arrhythmias.[12] On the basis of these data, the US Food and Drug Administration in 2002 approved the WCD for use in patients who are at risk for SCD.[13] Subsequently, clinical guidelines suggest use of the WCD for post-MI patients at high risk for SCD.[10]

Recent observational studies have evaluated the use of the WCD.[11,14,15] Epstein and colleagues[11] evaluated outcomes with the WCD among 8,453 post-MI patients and found that 91% of the 133 patients who received appropriate shocks were resuscitated from ventricular arrhythmia. Survival at 1 year for patients who received appropriate shocks was 65%. The effectiveness of WCD in post-MI patients is currently being tested in the ongoing VEST randomized clinical trial (http://clinicaltrials.gov/ct2/show/NCT01446965?term=VEST+zoll&rank=1), which is due to be completed in late 2015. Although a definitive evaluation of effectiveness will await the results of the VEST trial, we used observational studies and data on the rates of SCD after MI from relevant randomized trials[16] to assess the potential cost-effectiveness of the WCD in early post-MI patients with reduced LVEF.

Methods

We developed a Markov model[18,19] to assess the cost-effectiveness of the WCD compared with the current standard of care for early post-MI patients (TreeAge Pro, v2011, Williamstown MA). The model tracked a cohort of patients during their lifetime who were considered at an increased risk for SCD but not yet eligible for prophylactic ICD implantation since they were within either 40 days from their MI or 90 days from coronary revascularization. Patients received either the WCD or current standard of care (no therapy) (**Figure 1**). Each month, all patients were at risk for sudden cardiac arrest (SCA). Patients who had an SCA event in the WCD strategy could be resuscitated by the WCD. Patients in the standard-of-care strategy who had a witnessed SCA event could be resuscitated by emergency medical services (EMS). Patients in either strategy who survived an SCA were considered to be a secondary prevention patient and thereby eligible for immediate ICD implantation.

After 3 months, patients who were alive and had not experienced an SCA were re-evaluated to determine their eligibility for a primary prevention ICD implantation. Patients whose LVEF had improved to >35% would be followed with optimal medical therapy. Patients with an LVEF ≤35% would have an ICD implanted for primary prevention. Each month, patients were at risk for dying and this risk was reduced based on ICD therapy. Patients who had an ICD implanted would be at risk for ICD infections and the need for generator replacements over time. The model assessed the patient's survival, quality-of-life, and the costs related to health states (**Table 1**). We followed the recommendations of the Panel on Cost-Effectiveness in Health and Medicine.[17]

Patient population

We assessed the cost-effectiveness of the WCD in patients who met the following criteria: MI within the past 40 days OR who have had coronary artery bypass graft (CABG) or percutaneous coronary intervention within the past 3 months; LVEF ≤35%; New York Heart Association (NYHA) class II or III. These patients are currently not considered eligible for ICD placement and therefore we evaluated alternative bridging strategies for these patients.

Mortality and efficacy of treatment strategies

We modeled the underlying mortality and available treatment strategies in two time periods: early post MI (0–3 months) and late post MI (month 4 onwards).

Early post MI

During the initial 3-month period early post MI we considered patients to be at risk for an arrhythmic event (and subsequent mortality), and non-arrhythmic mortality (either cardiac or non-cardiac).

Arrhythmic mortality

We assumed that the rate of arrhythmic events was 2.25% during the initial month of use and then 1.0% in subsequent months, based on data from 3,852 patients with EF ≤30% in the Valsartan in Acute Myocardial Infarction Trial (VALIANT) study.[16] VALIANT enrolled patients with an acute MI complicated by heart failure, left ventricular systolic dysfunction, or both and enrolled patients on average within 5 days from their MI, therefore representing the target population for the WCD. This underlying rate was varied extensively in sensitivity analyses. We assumed that the per-patient survival for these events in patients with a WCD was 90.9% (121/133 patients) based on data from the WCD medical order registry.[11] For patients in the standard-of-care strategy, we assumed that half of the arrhythmic events would be witnessed and lead to cardiac resuscitation, and that 9.6% of patients in whom resuscitation was attempted would survive to hospital discharge, based on data from the Cardiac Arrest Registry to Enhance

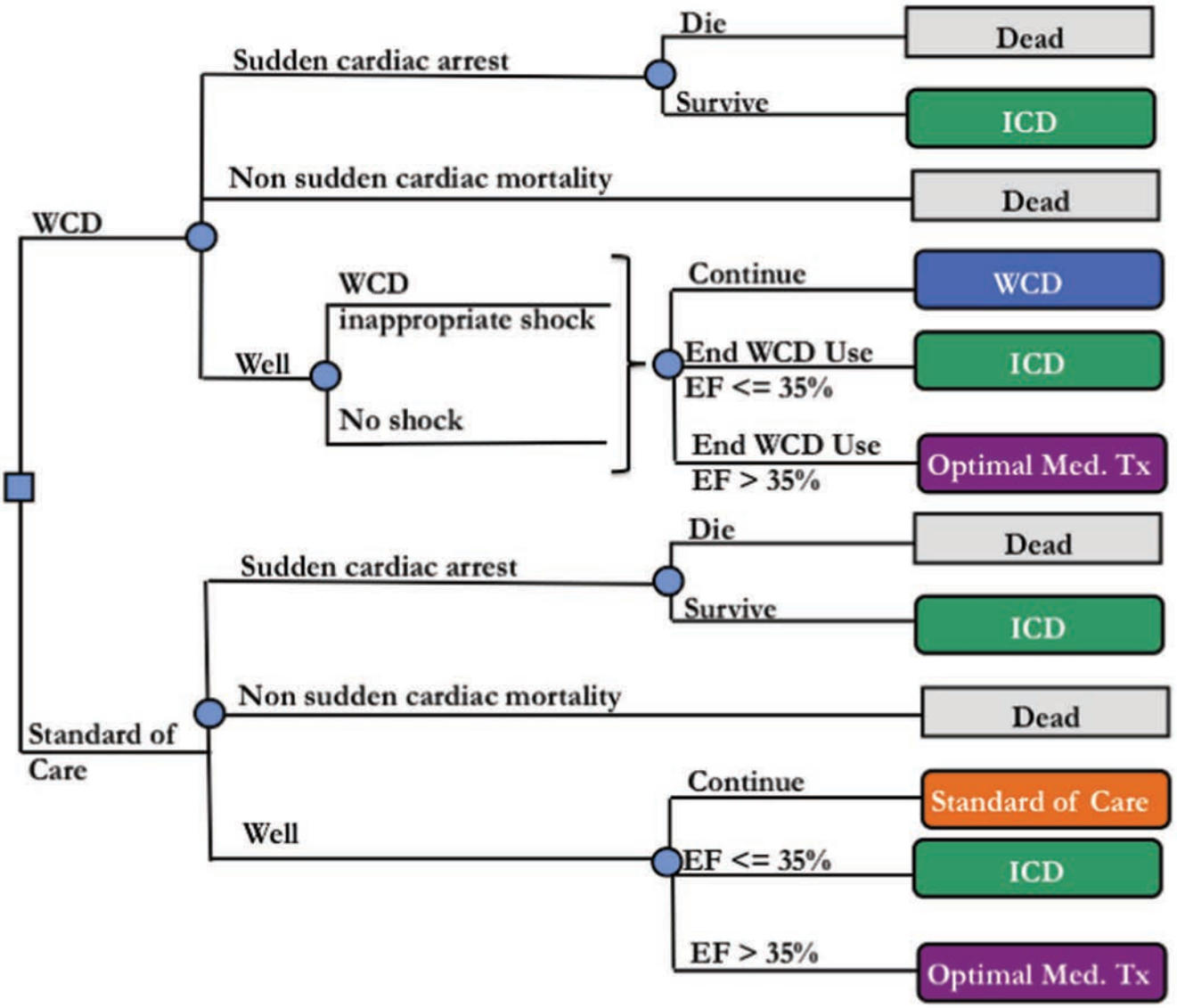

Figure 1: Decision model. The square on the left represents a choice between alternative treatments: WCD or standard of care. Circles represent chance nodes. During the early post-MI period (3 months), patients are at risk for arrhythmic events and death, as well as non-arrhythmic and non-cardiac death. Patients who experienced an arrhythmic event could be saved either from WCD or through the use of EMS. Patients who survived an arrhythmic event were considered eligible for ICD implantation. Patients using WCD could also experience inappropriate shocks while using the WCD. After 3 months, patients who had not experienced an arrhythmic event and had survived were eligible for a primary prevention ICD if their LVEF remained ≤35%. Patients were then followed for their remaining lifetime incorporating the potential benefit of an implanted ICD if appropriate.

Survival (CARES) (http://www.cdc.gov/mmwr/preview/mmwrhtml/ss6008a1.htm).

Patients who survived an arrhythmic event in either strategy were assumed to be at elevated risk for future SCD. These ''secondary prevention patients'' would have an ICD implanted on the basis of current ACC/AHA recommendations.[10]

Non-arrhythmic mortality

Non-arrhythmic mortality during the initial 3-month period was assumed to be 4.2% (1.42% per month) to reflect that half of total mortality within this population is expected to be arrhythmic and half is expected to be non-arrhythmic. This assumption is supported by data from the control groups of published ICD trials.[1–5,8] Non-arrhythmic mortality was assumed to be equal in both the WCD and standard-of-care strategies.

Late post MI

Following the initial 3-month period, surviving patients from either the WCD or standard-of-care strategy were assumed have different levels of SCD risk: 1) survivors of

Table 1: Input variables and sources

Input variable	Base-case estimate	Range	Source
Demographic variables			
Age, years	62.7	40–75	WCD registry[11]
Male, %	73	50–85	WCD registry[11]
Early post MI (0–3 months)			
Arrhythmic event			
Month 1, %	2.25	0.5–4	Ref. [16]
Month 2–3, %	1.0	0.22–1.78	Ref. [16]
Non arrhythmic cardiac and non cardiac mortality (3-month), %	4.20	0.9–7.5	Estimated and expert opinion that total mortality is 50% arrhythmic and 50% all other causes[1–5,8]
Late post MI (4+ months)			
Annual mortality, %			
Primary prevention patients	10	5–20	Refs. [1–5,25]
Secondary prevention patients	15	5–45	Refs. [20–24]
Patients with improved LVEF (>35%)	0.75 × primary prevention mortality	0.5–1	Estimated, expert opinion
Treatment variables			
Efficacy of WCD in successfully terminating sudden cardiac arrest, %	90.9	80–100	WCD registry[11]
Probability of inappropriate shocks using WCD (per month)	0.006	0.001–0.01	WCD registry[11]
Patients being recognized as having sudden cardiac arrest in the community, %	50	0–100	Ref. [32]
Efficacy of EMS in successfully terminating recognized sudden cardiac arrest and allowing survival to hospital discharge, %	9.6	0–30	Ref. [32]
Efficacy of ICD in reducing total mortality in secondary prevention patients, %	0.66	0.53–0.83	Ref. [21]
Efficacy of ICD in reducing total mortality in primary prevention patients, %	0.6	0.37–0.98	Ref. [25]
ICD operative death, %	0	0–1.5	Refs. [1–5,20,22–24]
Probability of ICD complications, %	0.12	0–0.3	Ref. [5]
Frequency of ICD generator replacement, years	5	2–9	Based on Refs. [3–34], Medtronic and Boston Scientific unpublished data, and on expert opinion
Duration of ICD benefit	Lifetime		Assumed

Table 1. Continued

Input variable	Base-case estimate	Range	Source
LVEF remaining ≤35% after 90-days, %	56	25–100	Based on preliminary findings of the WEARIT-II Registry presented at Heart Rhythm Society Meeting in 2013 (http://www.hrsonline.org/Education-Meetings/Scientific-Sessions/Expedited-Sessions#axzz2sIJlfu1L)
Compliance with ICD implantation following sudden cardiac arrest, %	100	50–100	Assumed
Compliance with ICD implantation recommendation after 90 days, %			
Standard of care	100	20–100	Assumed
WCD use	100	20–100	
Costs, $			
WCD (monthly)	2754	2000–3500	Cost of WCD is based on current Medicare reimbursement for HCPCS code K0606 for monthly WCD system as durable medical equipment
Follow up for inappropriate WCD shock	50	0–200	Assumed
ICD implantation	36,034	27,000–45,000	2014 Medicare Inpatient Prospective Hospital Payment system, weighted average of MS–DRGs 222–227 + Current Procedural Terminology code 33249
ICD lead replacement	15,595	11,000–20,000	2014 Medicare Inpatient Prospective Hospital Payment system MS-DRG 265 + Current Procedural Terminology code 33240
ICD generator replacement	27,271	20,000–35,000	2014 Medicare Inpatient Prospective Hospital Payment system MS-DRG 245 + Current Procedural Terminology code 33240
Monthly cardiac follow-up costs	50	0–200	Assumed
Monthly health-related costs	360	270–455	Based on current consumer expenditure survey for age-specific health related expenses (http://www.bls.gov/cex/2012/combined/age.pdf)
Emergency medical services (EMS) and hospitalization for sudden cardiac arrest	18,500	3,000–40,000	Ref. [35]
Utilities			
Baseline health state (optimal medical therapy)	0.88	0.6–1.0	Baseline utility reflects underlying heart failure and post-MI health state[26–28] note that this baseline health state utility is then multiplied by sex and age-specific utilities for current health from[30]
ICD therapy	1.0	0.6–1.0	Assumed to be equivalent to current health in the base case
ICD complications	3.5 days	1–5 days	We assume a small decrement in quality-of-life for patients who require hospitalization for ICD infection
WCD use	1	0.95–1.05	We assume in the base-case that WCD use is equivalent to current health in terms of quality-of-life utility
Shock, WCD	0.5 day	0–2 days	We assume a temporary decrement in quality-of-life for patients who receive a shock while using WCD
Other variables			
Discount rate, %	3	0–5	Ref. [17]

ICD: implantable cardioverter defibrillator; LVEF: left ventricular ejection fraction; MI: myocardial infarction; WCD: wearable cardioverter defibrillator.

Table 2: Health and economic outcomes

Strategy	Cost, $	Incremental cost, $	LE, y	Incremental LE, y	ICER ($/LY)	Quality-Adjusted Life Expectancy, y	Incremental QALE, y	ICER ($/QALY)
Standard of Care	101,232		9.203			6.688		
WCD	112,735	11,503	9.464	0.261	44,138	6.878	0.190	60,567

ICER: incremental cost-effectiveness ratio; LE: life expectancy; QALE: quality-adjusted life expectancy.

an arrhythmic event (secondary prevention patients); 2) no arrhythmic event, LVEF≤35% at 3 months (primary prevention patients); or 3) not having experienced an arrhythmic event, LVEF>35% at 3 months.

Patients in risk category 1 or 2 would be eligible for an ICD; we assume all patients in category 1 (secondary prevention patients) would receive an ICD. In our base-case analysis we also assume that all patients in risk category 2 would adhere to current recommendations and accept ICD implantation. Patients in risk category 3 would no longer meet recommendations for primary prevention ICD implantation and therefore would receive guideline-based medical therapy.

Patients in risk category 1 (secondary prevention patients) were assumed to have an annual total mortality of 15%. This estimate was based on the mortality observed in the control arms of secondary prevention trials.[20–24]

The relative risk for mortality of these secondary prevention patients treated with an ICD was 0.66 (95% CI 0.53–0.83), based on the meta-analysis of secondary prevention trials that enrolled patients with LVEF ≤35%.[21]

Note that in the WCD registry, 133 patients received appropriate WCD shock therapy, with a 12-month total survival of 65% (86/133).[11] Omitting the 12 patients who died during the original event, the 12-month survival was 71% (86/121). Patients in the WCD registry were eligible for ICD therapy, and 87/121 patients (72%) went

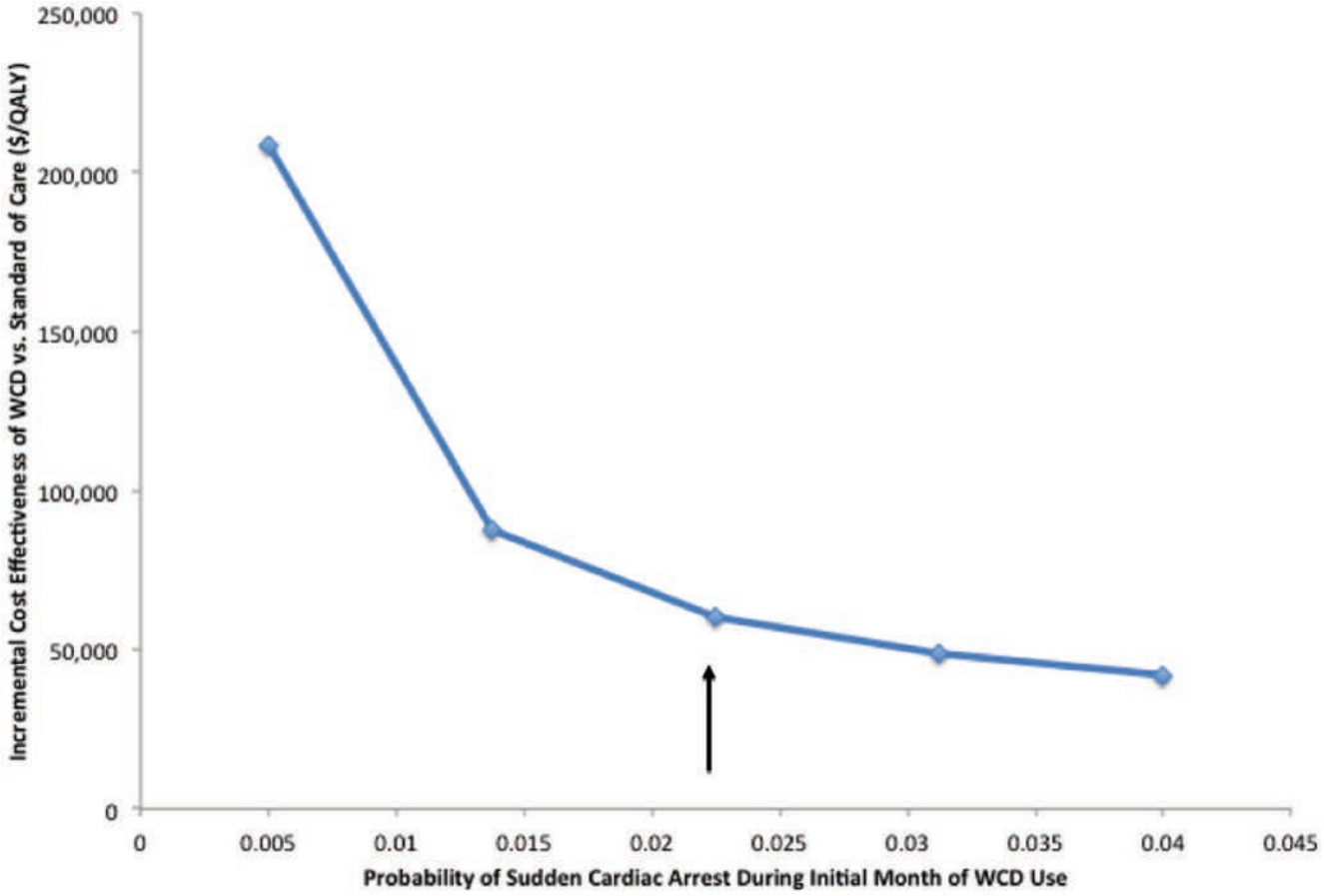

Figure 2: Sensitivity analysis: Probability of sudden cardiac arrhythmic event. The *x*-axis indicates the probability of sudden cardiac arrest during the initial month post myocardial infarction. The *y*-axis indicates the incremental cost-effectiveness ratio of wearable cardioverter-defibrillator compared with standard of care in dollars per quality-adjusted life year gained. The base-case assumption is a 2.25% probability of sudden cardiac arrest (arrow).

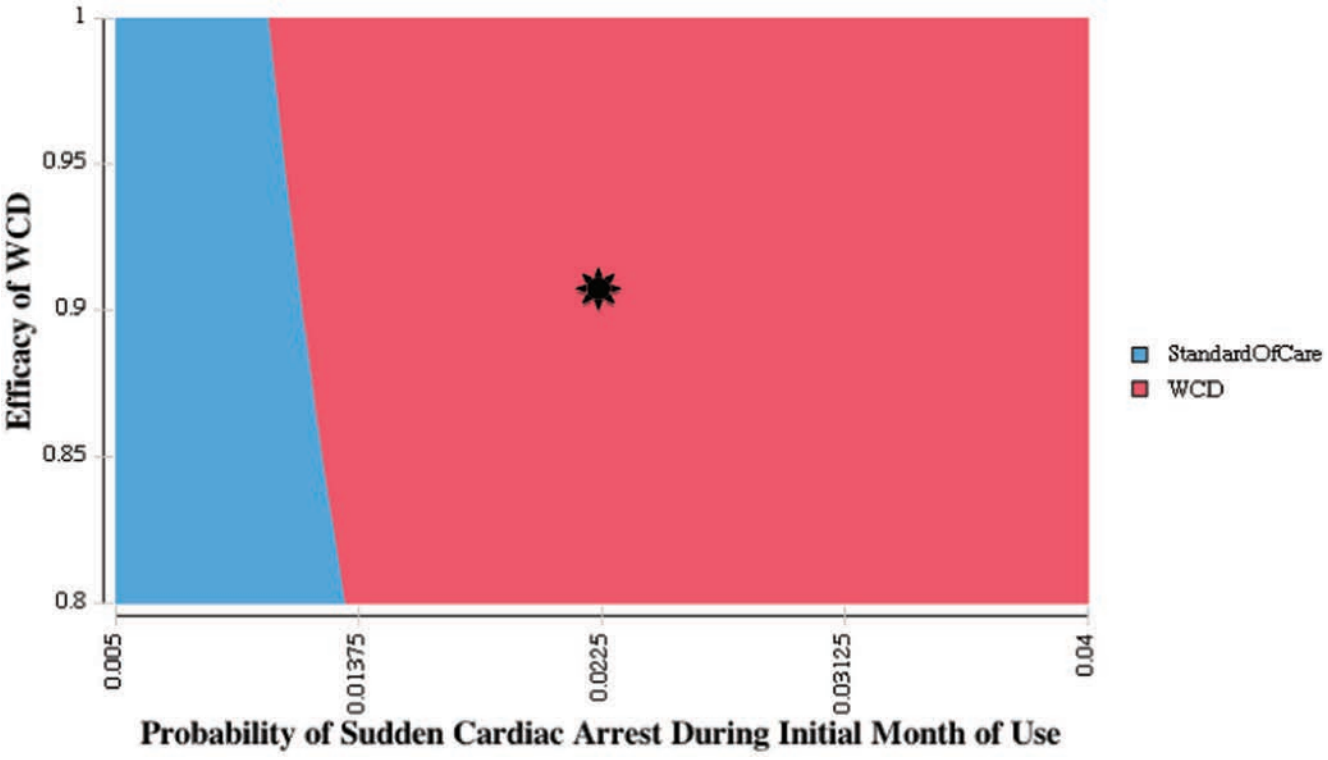

Figure 3: Sensitivity analysis: Probability of an arrhythmic event and survival with wearable cardioverter-defibrillator (WCD) (willingness-to-pay threshold = $100,000/QALY). Two-way sensitivity analysis where the *x*-axis indicates the probability of sudden cardiac arrest during the initial month post MI, the y-axis indicates the efficacy of the WCD in successfully terminating a sudden cardiac arrest. The area in red represents combinations of these two estimates where the WCD costs less than $100,000/QALY gained, the area in blue represents combinations where the WCD costs more than $100,000/QALY gained than the standard of care. The star represents the base-case assumptions of 2.25% probability of sudden cardiac arrest and 90.9% efficacy.

on to have an ICD implanted. The observed survival of 71% therefore incorporated these patients with a presumed reduction in their mortality based on ICD therapy. This translates to a ~38% mortality in patients in this risk category. We explored this underlying mortality in survivors of SCA in sensitivity analyses.

Patients in risk category 2 (primary prevention patients) were assumed to have an annual total mortality of 10% based on the annual mortality in the primary prevention trials of patients at least 40 days post MI.[25] The efficacy of the ICD in these patients was 0.60 (95% CI 0.37 to 0.98) on the basis of this same analysis.[25]

Patients in risk category 3 with an increased LVEF were assumed to have a reduced annual total mortality of 7.5%, which was estimated to be 75% of the rate in patients from risk category 2. We assumed, based on the 18-month results from the prospective registry and follow-up of patients using WCD in the WEARIT-II registry, that 44% of patients would have an improvement in their LVEF during the bridging period.

Treatment complications

We included a 0.6% monthly rate of an inappropriate shock from the WCD based on the WCD registry.[11] These shocks were not assumed to have associated mortality though they did impact quality of life and costs. Operative in-hospital complications and long-term ICD complications mimicked those observed in the trials.[1–5,20,22–24] We modeled the need for ICD generator replacement (and associated complications) every 5 years and varied all assumptions in sensitivity analyses.

Quality of life

The model incorporated adjustments for the quality of life associated with age-specific current health, WCD use, heart failure,[26–28] ICD implantation, inappropriate WCD/ICD shocks, ICD generator replacement, and ICD complications (**Table 1**). We assumed that use of a WCD did not impact a patient's quality of life, but explored this assumption in sensitivity analyses.[29] Similarly, we assumed that ICD implantation did not change a patient's quality of life, again varying this assumption. We multiplied utilities on the basis of ICD therapy and ventricular dysfunction by age-specific utility weights.[30]

Costs

We included the direct costs of medical care associated with WCD use, EMS, ICD implantation and follow-up, or

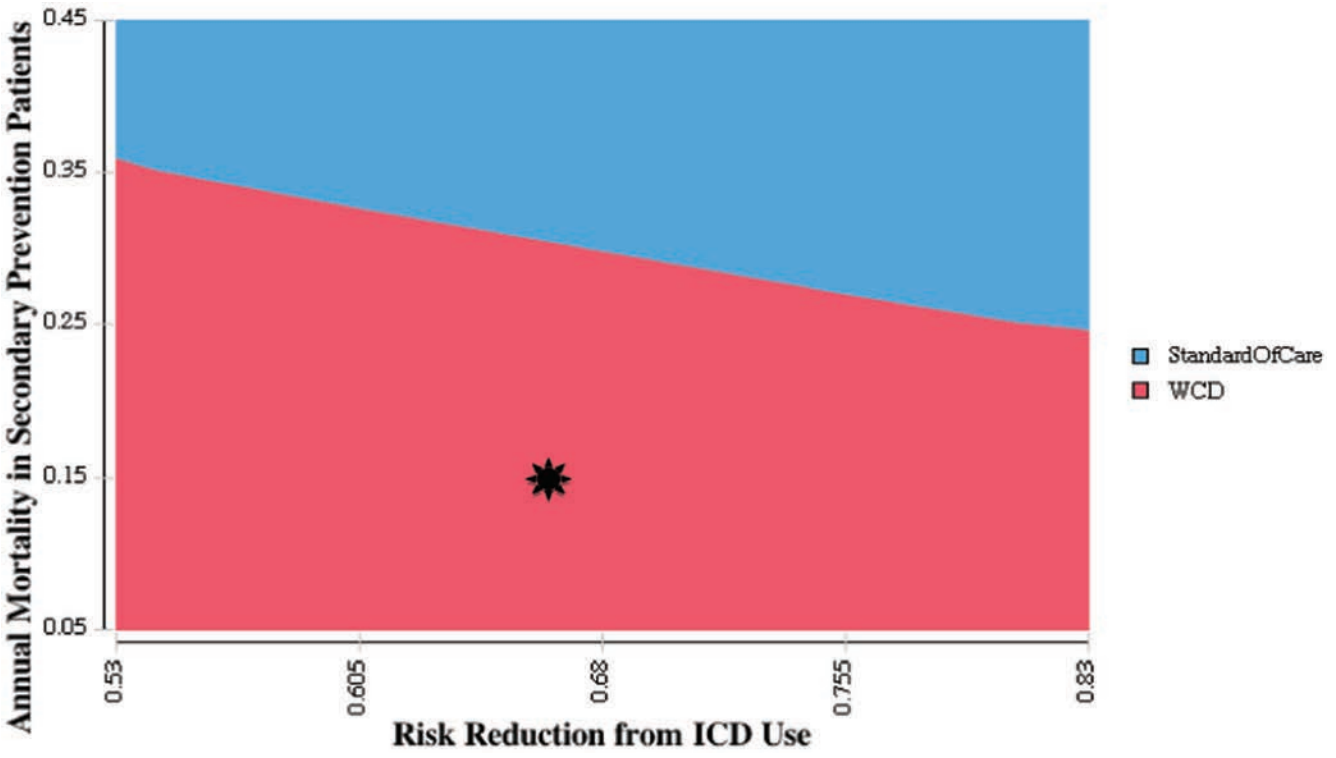

Figure 4: Sensitivity analysis: Underlying mortality and efficacy of the implantable cardioverter-defibrillator (ICD) in secondary prevention patients (willingness-to-pay threshold = $100,000/QALY). Two-way sensitivity analysis where the *x*-axis indicates the risk reduction in total mortality with ICD use in secondary prevention patients, the y-axis indicates the underlying annual mortality for secondary prevention patients on optimal medical therapy. The area in red represents combinations of these two estimates where the wearable cardioverter-defibrillator (WCD) costs less than $100,000/QALY gained, the area in blue represents combinations where WCD costs more than $100,000/QALY gained as compared to standard of care. The star represents the base-case assumptions of 0.66 hazard ration for the ICD on total mortality and 15% annual mortality.

treatment of patients with standard of care. For WCD patients, we included the cost of WCD use ($2754/month) and then an additional physician visit for patients who received an inappropriate shock. Patients within the standard-of-care strategy who received EMS cost $18,500 for the EMS service and subsequent hospitalization. Survivors of SCA in both strategies also received additional costs related to ICD implantation. For ICD patients, we included the cost of the initial ICD implantation, generator replacement, and lead replacement. All ICD and WCD costs were based on fiscal year 2014 Medicare Inpatient Prospective Hospital Payment system and professional fees (**Table 1**). Age-specific medical costs unrelated to the prevention of SCD were estimated based on data from the Bureau of Labor Statistics (http://www.bls.gov/cex/2012/combined/age.pdf). Costs were updated to 2014 US dollars using the gross domestic product deflator.[31]

Sensitivity analyses

We performed sensitivity analyses to account for important model assumptions and uncertainties. When possible, we used ranges for clinical inputs based on reported or calculated 95% confidence intervals from the original data source. Costs were varied by 25%. For other variables, ranges represented our judgment of the variation likely to be encountered in clinical practice (**Table 1**).

Results

In our base-case analysis, we assumed a 2.25% risk of SCA in the first month post MI and 1% in the subsequent 2 months prior to ICD implantation. Under these assumptions the WCD strategy was more expensive than the standard-of-care strategy, with estimated lifetime discounted costs higher by $11,503. The WCD strategy also had better clinical outcomes, with an improvement in life expectancy of 0.261 life years or 0.190 QALYs (**Table 2**). The incremental cost-effectiveness of the WCD compared with usual care was $44,100/LY or $60,600/QALY.

Sensitivity analyses

Our findings were sensitive to assumptions of SCA rate in the early post-MI period, such that the incremental cost-effectiveness of the WCD was more favorable in higher-risk patients. If the SCD rate were increased to 4%

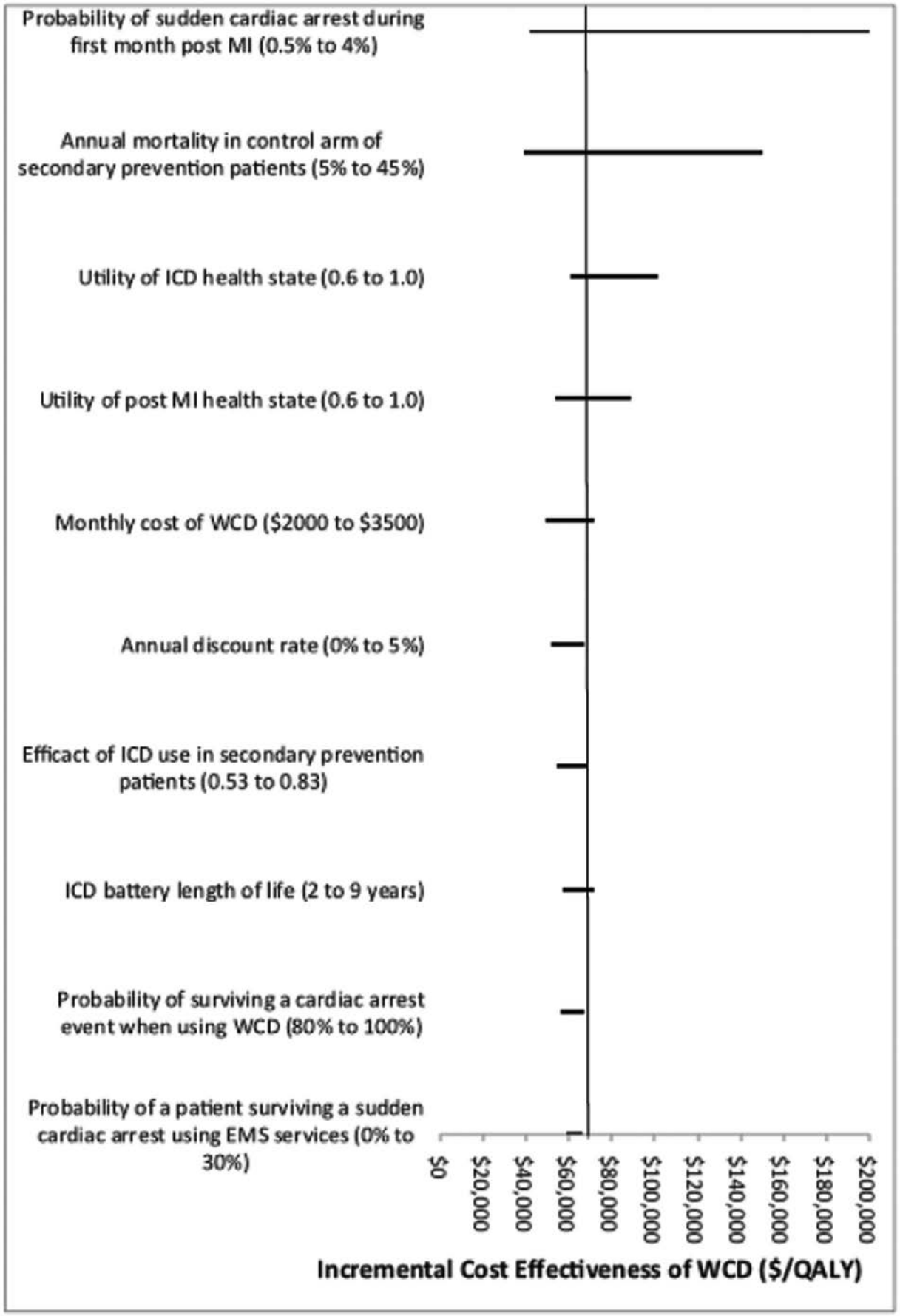
Probability of sudden cardiac arrest during first month post MI (0.5% to 4%)
Annual mortality in control arm of secondary prevention patients (5% to 45%)
Utility of ICD health state (0.6 to 1.0)
Utility of post MI health state (0.6 to 1.0)
Monthly cost of WCD ($2000 to $3500)
Annual discount rate (0% to 5%)
Efficact of ICD use in secondary prevention patients (0.53 to 0.83)
ICD battery length of life (2 to 9 years)
Probability of surviving a cardiac arrest event when using WCD (80% to 100%)
Probability of a patient surviving a sudden cardiac arrest using EMS services (0% to 30%)
$0
$20,000
$40,000
$60,000
$80,000
$100,000
$120,000
$140,000
$160,000
$180,000
$200,000
Incremental Cost Effectiveness of WCD ($/QALY)

Figure 5: Tornado diagram of incremental cost-effectiveness of wearable cardioverter-defibrillator (WCD) use. Tornado diagram representing the incremental cost-effectiveness ratios of one-way sensitivity analysis on the WCD strategy compared to current standard of care. The vertical line represents the incremental cost-effectiveness ratio under base-case conditions.

in the first month, the incremental cost-effectiveness of the WCD would improve to $42,100/QALY. Conversely, if the population was lower risk with a 0.5% probability of SCA then the WCD would be less favorable at $208,500/QALY than the standard-of-care strategy (**Figure 2**). In a sensitivity analysis in which we varied the modeled risk of sudden death, use of the WCD cost less than $100,000/QALY gained as long as the rate of cardiac arrest in the first month post MI was ⩾1.163%.

We assumed that the WCD successfully terminated 90.9% of SCA events. We explored how varying this assumption impacted our findings (**Figure 3**). At our base-case estimate of 2.25% SCA events in month 1, the use of the WCD cost less than $100,000/QALY even if the WCD was only successful in terminating 80% of events. At SCA rates <1.37%, reductions in efficacy of the WCD caused its incremental cost-effectiveness to rise and favor the standard-of-care strategy.

If the WCD successfully terminated SCA, surviving patients were considered eligible for ICD implantation as a secondary prevention patient. The benefit of the WCD therefore was impacted by the underlying mortality in these patients and the efficacy of the ICD in reducing this mortality. Any increase in this mortality or reduction in the ICD efficacy would lessen the benefit of the WCD and its incremental cost-effectiveness (**Figure 4**). At annual mortality rates >30%, the smaller reduction in mortality from the WCD would cause its incremental cost-effectiveness to rise above $100,000/QALY. Similarly, if ICD implantation or other related downstream costs (e.g., frequency or cost of ICD battery replacement) were increased, it would lessen the cost-effectiveness of the WCD. Because patients who survived the early post-MI period without an arrhythmic event were treated as primary prevention patients in both strategies, varying our assumptions related to the underlying mortality or efficacy of the ICD in these patients did not impact our findings.

We initially assumed that the WCD and the ICD would not further change the patients' quality of life. If the quality of life were decreased significantly by prophylactic ICD implantation to <0.62 or by use of the WCD to <0.5, the cost-effectiveness of the WCD strategy would be less favorable at over $100,000/QALY. If the WCD utility increased the baseline utility by 5%,[29] the cost-effectiveness of the WCD would improve to $58,300/QALY gained.

Lowering the cost of the WCD improved cost-effectiveness. If the monthly cost of the WCD was reduced to $2,000, the incremental cost-effectiveness of WCD use would improve to $49,100/QALY. Conversely, if the cost of the WCD increased to $3,500/month, the incremental cost-effectiveness of the WCD would be less favorable ($71,900/QALY).

Additional sensitivity analyses (**Table 1**) did not change our results substantially (**Figure 5**).

Discussion

Patients who have had a recent MI with a reduced LVEF are at considerable risk of SCD, particularly in the first several months after hospital discharge. An ICD is not effective in reducing mortality in this early, high-risk period after an MI, so alternative approaches to the prevention of SCD in this period are clearly needed. The WCD can effectively terminate life-threatening ventricular arrhythmias, and may be used to bridge the high-risk period between hospital discharge and eligibility for an ICD several weeks later. Our study suggests that using a WCD in this setting could be economically attractive, with an incremental cost-effectiveness ratio of $44,100/LY, or $60,600/QALY, which compares favorably to other interventions accepted as cost-effective.

This analysis is based on a simulation model of the outcomes expected from use of a WCD, which synthesizes the best available data on the risk of SCD in the target population, the effectiveness of the WCD, and the costs of treatment. The results of this analysis depend upon the specific assumptions made, most particularly on the underlying risk of SCD in patients early post MI. We used data from the VALIANT study, since it enrolled a large population of patients with a recent MI and reduced LVEF. When the risk of SCD in the first month post MI is 2.25%, as it was in VALIANT, we project that the WCD will prevent enough patient deaths to justify its use and expense. The incremental cost-effectiveness ratio (ICER) for the WCD is below $100,000/QALY gained as long as the rate of cardiac arrest in the first month is more than 1.163%. This suggests that patients at low risk of SCD would be unlikely to obtain sufficient benefits from the WCD to justify its use clinically and economically.

The other parameter in the model of key importance is the efficacy of the WCD in successfully converting a life-threatening ventricular arrhythmia. Data from the WCD registry show the WCD can successfully convert over 90% of events, and our model suggests that given our SCA rates (2.25% in the first month), the WCD will cost <$100,000/QALY as long as it can terminate >80% events.

The WCD is designed as a temporary bridge until the post-MI patient either has recovery of ventricular function (and hence reduced risk of SCD) or becomes eligible for definitive therapy with an ICD. In this model, we assumed that most patients (56%) would have an LVEF ≤35% at the end of the WCD treatment period, and hence would receive an ICD. Consequently, the cost-effectiveness of the WCD is constrained by the cost-effectiveness of the subsequent use of an ICD in secondary or primary prevention. Use of the ICD for these indications has an ICER in the range of $50,000–60,000/QALY, which is only modestly more favorable than the ICER we found for temporary use of the WCD ($60,600/QALY).

Data from clinical registries of the WCD show that adherence of patients is quite high, with an average daily use of 21.8 hours.[11] The estimated effectiveness of the WCD used in the model effectively incorporates this pattern of adherence. The cost-effectiveness of WCD in patients with lower adherence to the WCD can be estimated by reducing the efficacy (**Figure 3**).

There are a number of limitations to this analysis. As in any model, the results depend on using reliable estimates of real-world effectiveness of the WCD, and all the evidence to date is derived from prospective and retrospective observational studies. The results from randomized controlled trials will provide the most reliable data on the efficacy of the WCD in post-MI patients and will further inform the cost-effectiveness. All of the numerical estimates in the model are subject to uncertainty, which could affect the results, even though we varied them systematically in sensitivity analyses.

In conclusion, our analysis suggests that use of a WCD could reduce the rate of SCD during the recovery period of patients who have had a recent MI and have reduced left ventricular function at a cost that appears to be economically attractive when compared with other generally accepted treatments in the United States.

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