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STUDIE VEST

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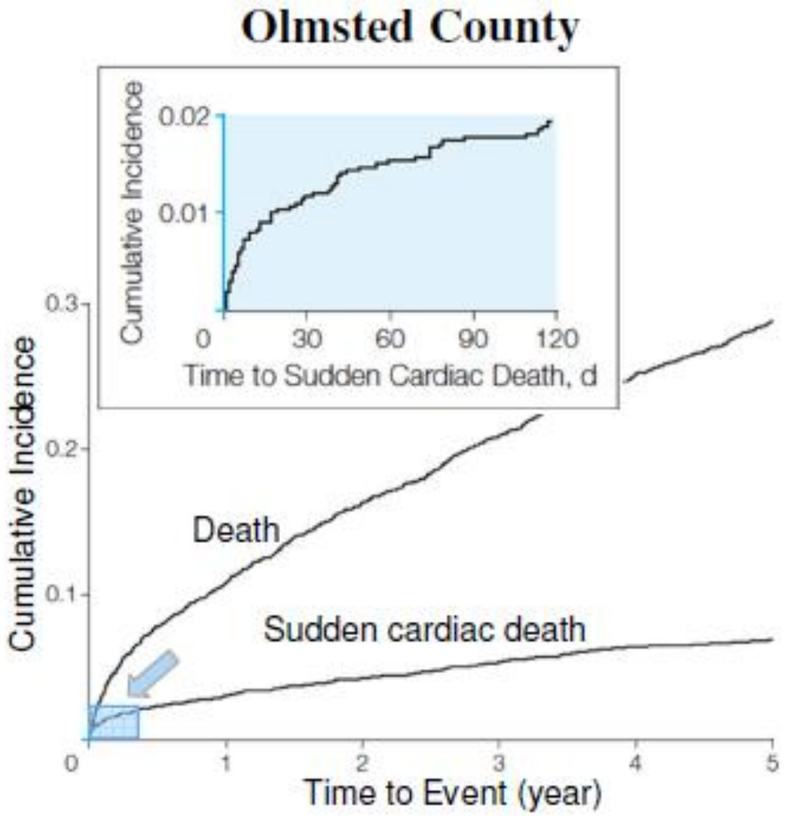
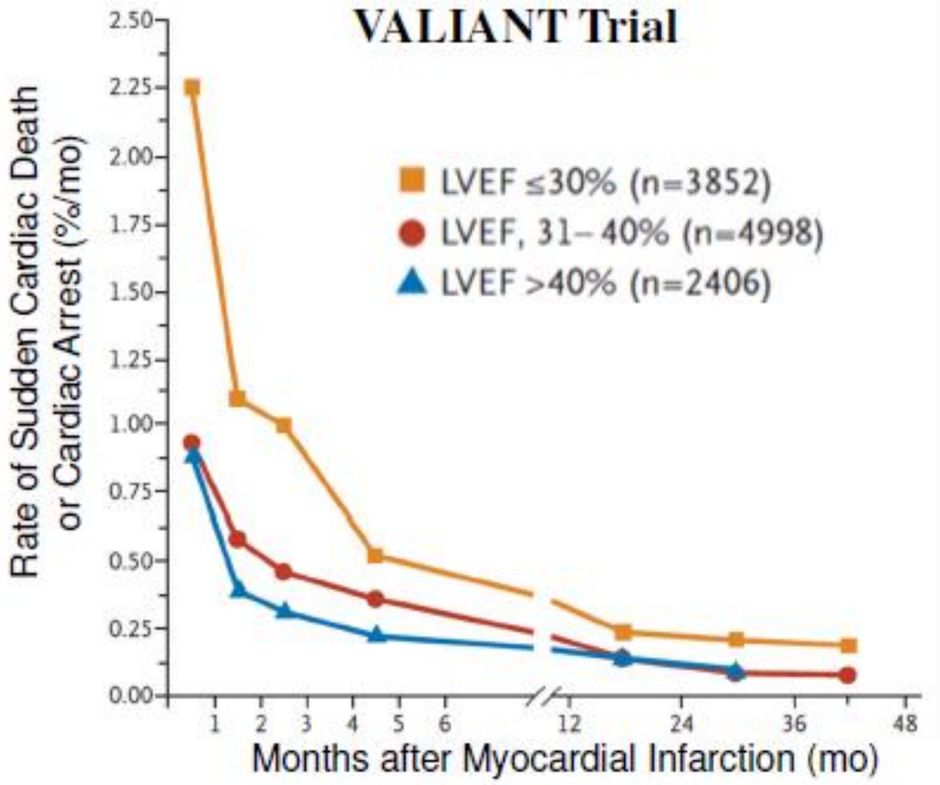
Background: SCD is high after MI

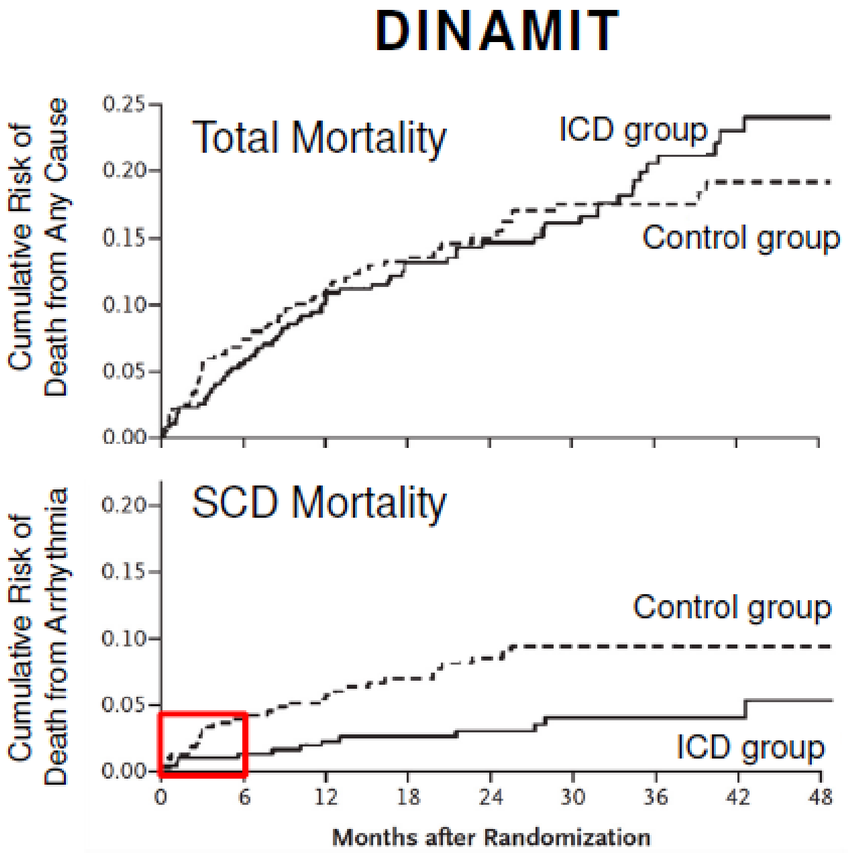


Adabag, *et al.* JAMA 2008

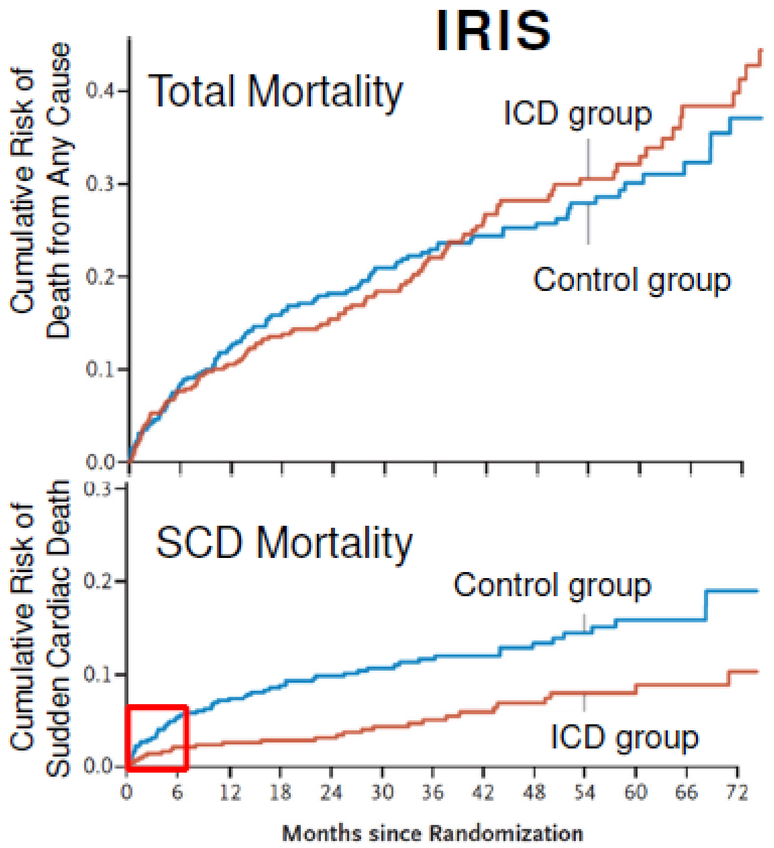


VALIANT—Solomon, *et al.* NEJM 2005

Background: No benefit from early ICD



DINAMIT: Hohnloser, *et al.* NEJM 2004



IRIS: Steinbeck, *et al.* NEJM 2009

Background: Guideline recommendations

JACC
JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY

Al-Khatib SM, et al.
2017 VA/SCD Guidelines

6.1.2. Primary Prevention of SCD in Patients with Ischemic Heart Disease

Recommendations for Primary Prevention of SCD in Patients With Ischemic Heart Disease		
COR	**LOE**	**Recommendations**
I	A	1. In patients with LVEF of 35% or less that is due to ischemic heart disease who are at least 40 days post-MI and at least 90 days post revascularization, and with NYHA class II or III HF despite GDMT, an ICD is recommended if meaningful survival of greater than 1 year is expected (1,2).

2017 ACC/AHA/HRS Guideline for Management of Patients With Ventricular Arrhythmias. JACC 2017

Background: VEST rationale

- ICD not indicated in immediate post-MI period
- Some early mortality not due to arrhythmias immediately post-MI, thus not preventable by ICD
- LVEF may recover over 3 months post-MI

Can a wearable cardioverter defibrillator (WCD) reduce SD mortality in the immediate post-MI period (<90 days) in patients with reduced LVEF, as a bridge to evaluation for ICD?

Methods: Study design

- **Multi-center, randomized, open-label trial**
- **Participants enrolled within 7 days of hospital d/c with acute MI and EF≤35%**
- **Randomized 2:1 to receive:**
  - Wearable cardioverter defibrillator (WCD) + guideline-directed therapy **or**
  - Guideline-directed medical therapy alone
- **MD's & sites blinded to detected arrhythmias**
- **Crossovers & ICDs prohibited (except for secondary prevention during follow-up)**

Methods: Inclusion & exclusion

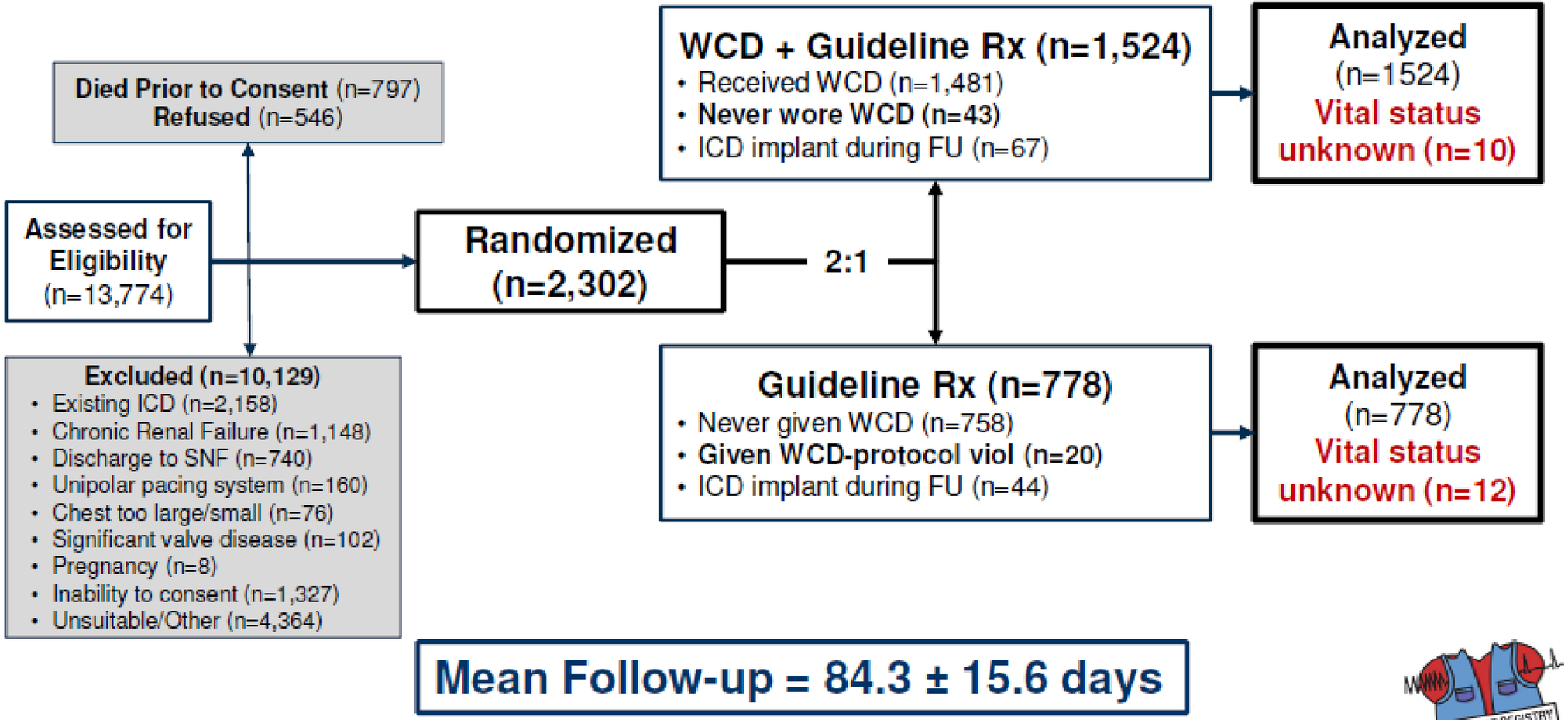
Inclusion Criteria

- ≤7 days of hospital discharge for acute MI
- EF ≤35% assessed:
  - ≥8 hrs after MI
  - ≥8 hrs after PCI
  - ≥48 hrs after CABG

Exclusion Criteria

- Existing ICD
- Significant valve disease
- Unipolar pacing system
- Chronic hemodialysis
- Chest too small/large for WCD
- Discharge to SNF for >7 days
- Pregnancy

Results: CONSORT diagram



Mean Follow-up = 84.3 ± 15.6 days

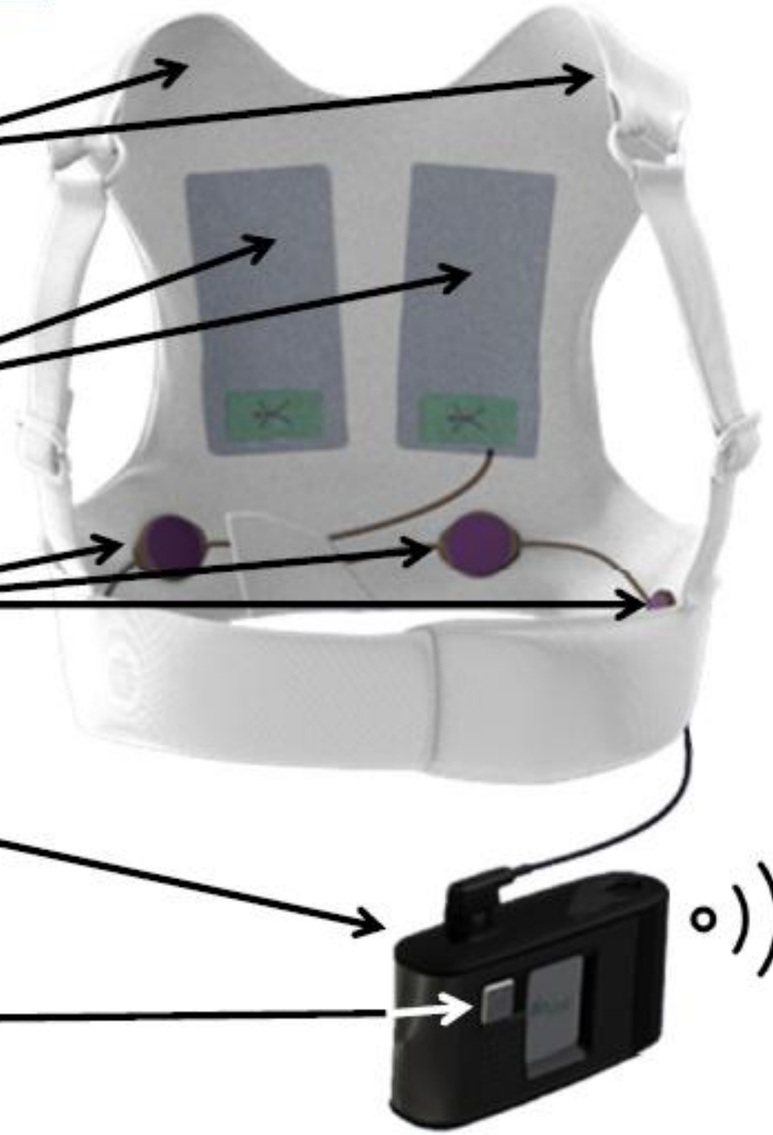
Washable-Interchangeable Garment

Self-Gelling Defibrillation Electrodes

Dry ECG Electrodes

Rechargeable Monitor & Battery Pack

Response Buttons



Monitors
- Wear-time
- Noise
- Device warning
- Asystole
- VT/VF

Treatment
- VT/VF

Investigators blinded to data

VEST & VEST REGISTRY

Methods: Outcomes

- **Follow-up at 1 month & 3 months**
- **Search NDI at end of study**
- **Primary Outcome: SCD & death due to ventricular arrhythmias**
- **Secondary outcomes**
  - Total mortality & Non-sudden death
  - Cause-specific death
  - Non-fatal outcomes
    - CV Hospitalizations
    - WCD compliance
    - Adverse events

Results: Participant characteristics

Characteristic	WCD Group (N=1524)	Control Group (N=778)
Age, mean ± SD	60.9 ± 12.6	61.4 ± 12.3
Men, n (%)	1107 (72.8%)	577 (74.7%)
Body mass index, Mean ± SD	28.4 ± 5.5	28.6 ± 6.6
Smoker, n(%)	561 (36.9%)	273 (35.5%)
Race n (%)		
White	1278 (84.1%)	636 (82.6%)
Black	143 (9.4%)	75 (9.7%)
Asian	23 (1.5%)	14 (1.8%)
Native American/Alaskan	25 (1.7%)	12 (1.6%)
Pacific Islander/Hawaiian	1 (0.1%)	0 (0%)
Mixed	20 (1.3%)	14 (1.8%)
Hispanic, n (%)	85 (5.6%)	34 (4.4%)

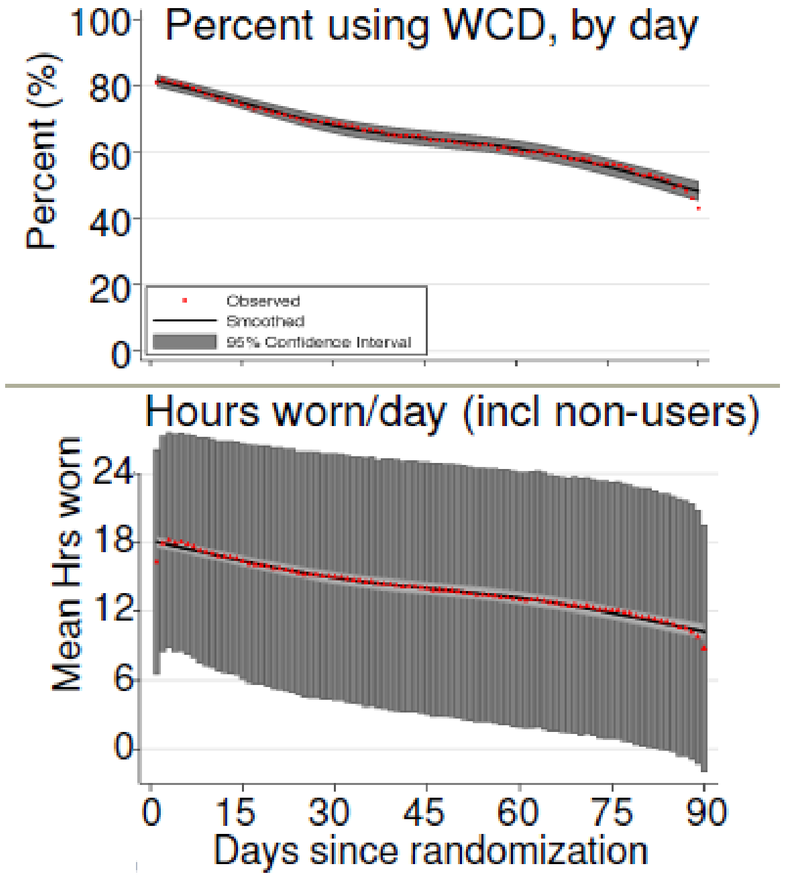
Results: Prior history

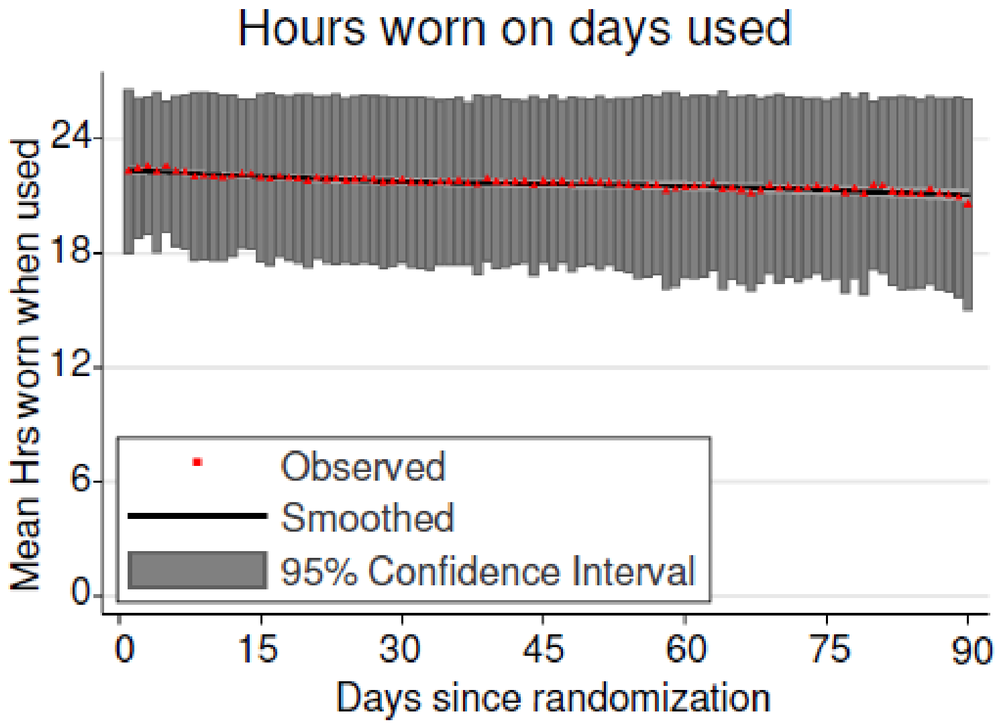
Characteristic	WCD Group (N=1524)	Control Group (N=778)
Diabetes Mellitus, n (%)	496 (32.6%)	246 (31.7%)
Hypertension, n(%)	993 (65.3%)	501 (64.6%)
Prior MI, n (%)	380 (25.1%)	193 (24.9%)
Prior CABG, n (%)	133 (8.8%)	70 (9.0%)
Prior PCI, n (%)	374 (24.6%)	202 (26.0%)
Prior CHF, n (%)	246 (16.2%)	146 (18.9%)
NYHA Classification, n (%)		
I	691 (45.5%)	326 (42.1%)
II	528 (34.8%)	286 (36.9%)
III	211 (13.9%)	116 (15.0%)
IV	46 (3.0%)	18 (2.3%)

Results: Characteristics of index MI

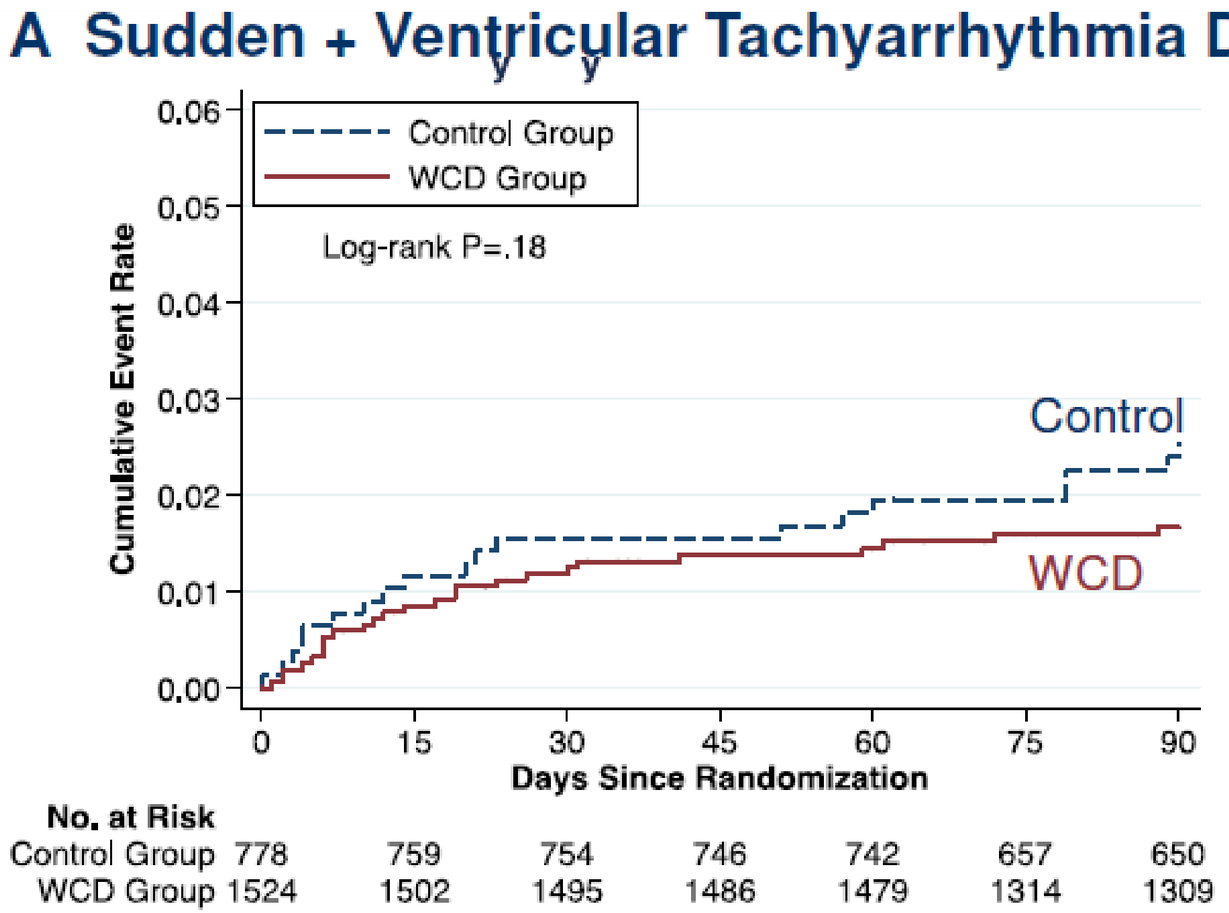
Characteristic	WCD Group (N=1524)	Control Group (N=778)
LVEF	28.2 ± 6.1%	28.2 ± 5.9%
PCI during MI hospitalization	1272 (84.2%)	650 (84.1%)
Thrombolytics during MI hospitalization	118 (7.8%)	71 (9.2%)
CABG during index hospitalization	14 (0.9%)	12 (1.5%)
Cardiac Arrest/VF	169 (11.2%)	70 (9.1%)
Pulmonary Edema requiring Intubation	162 (10. 7%)	88 (11.4%)
Intra-aortic Balloon Pump	173 (11.5%)	93 (12.0%)
Cardiogenic Shock	136 (9.0%)	79 (10.2%)

Results: WCD wear-time

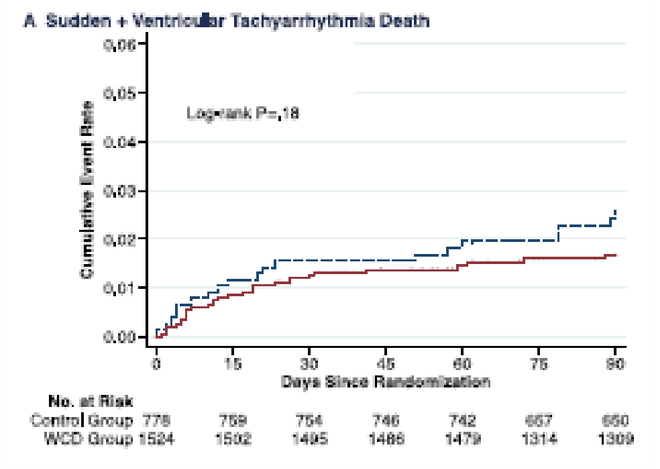




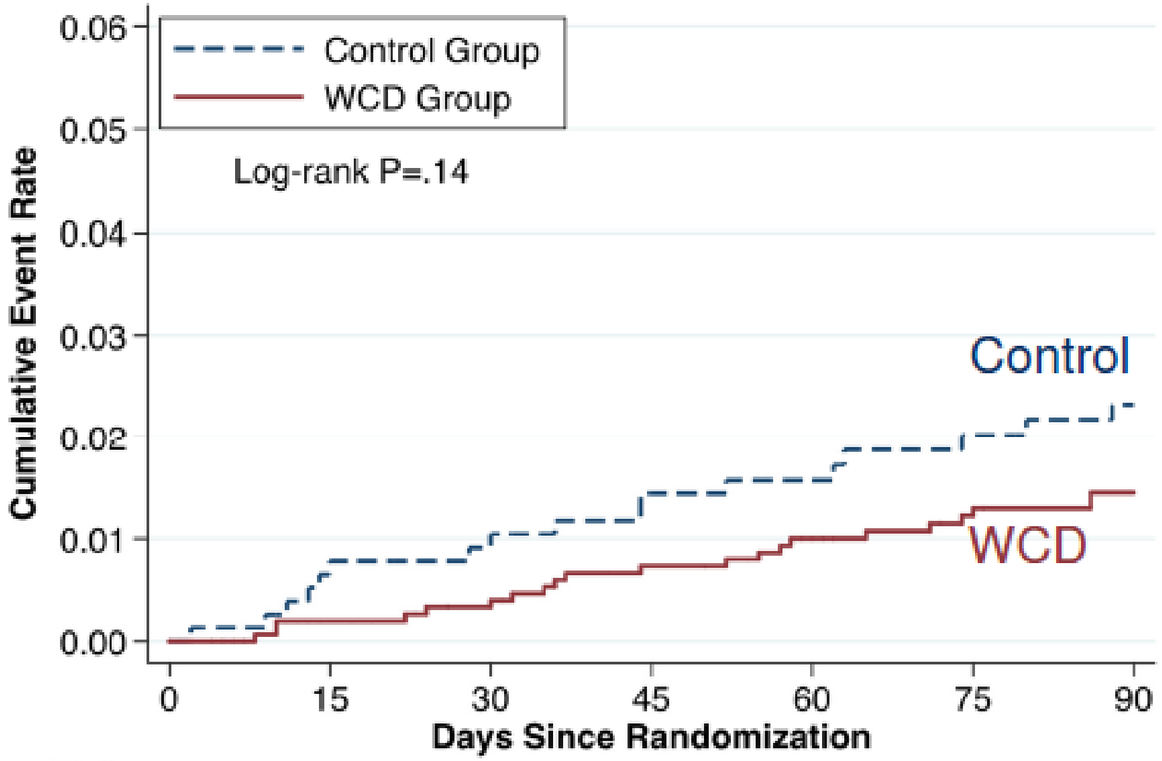
Results: Outcomes, intention-to-treat



Results: Outcomes, intention-to-treat



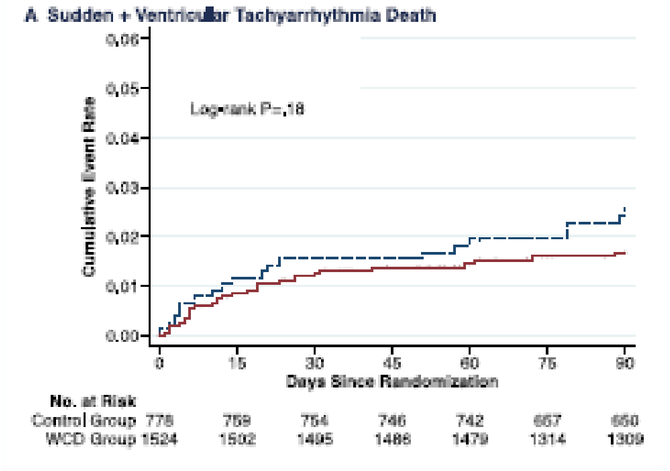
B Non-sudden Death

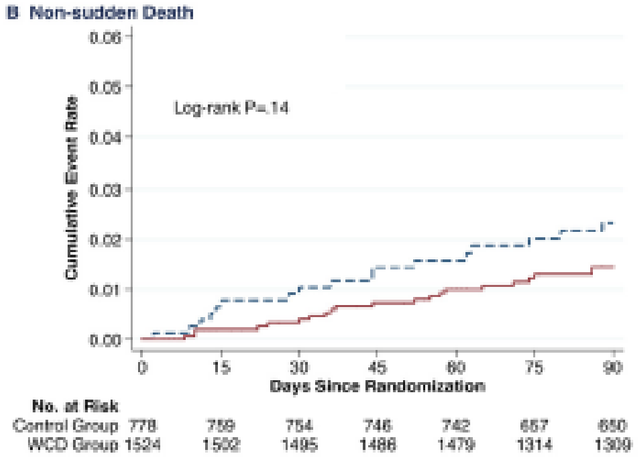


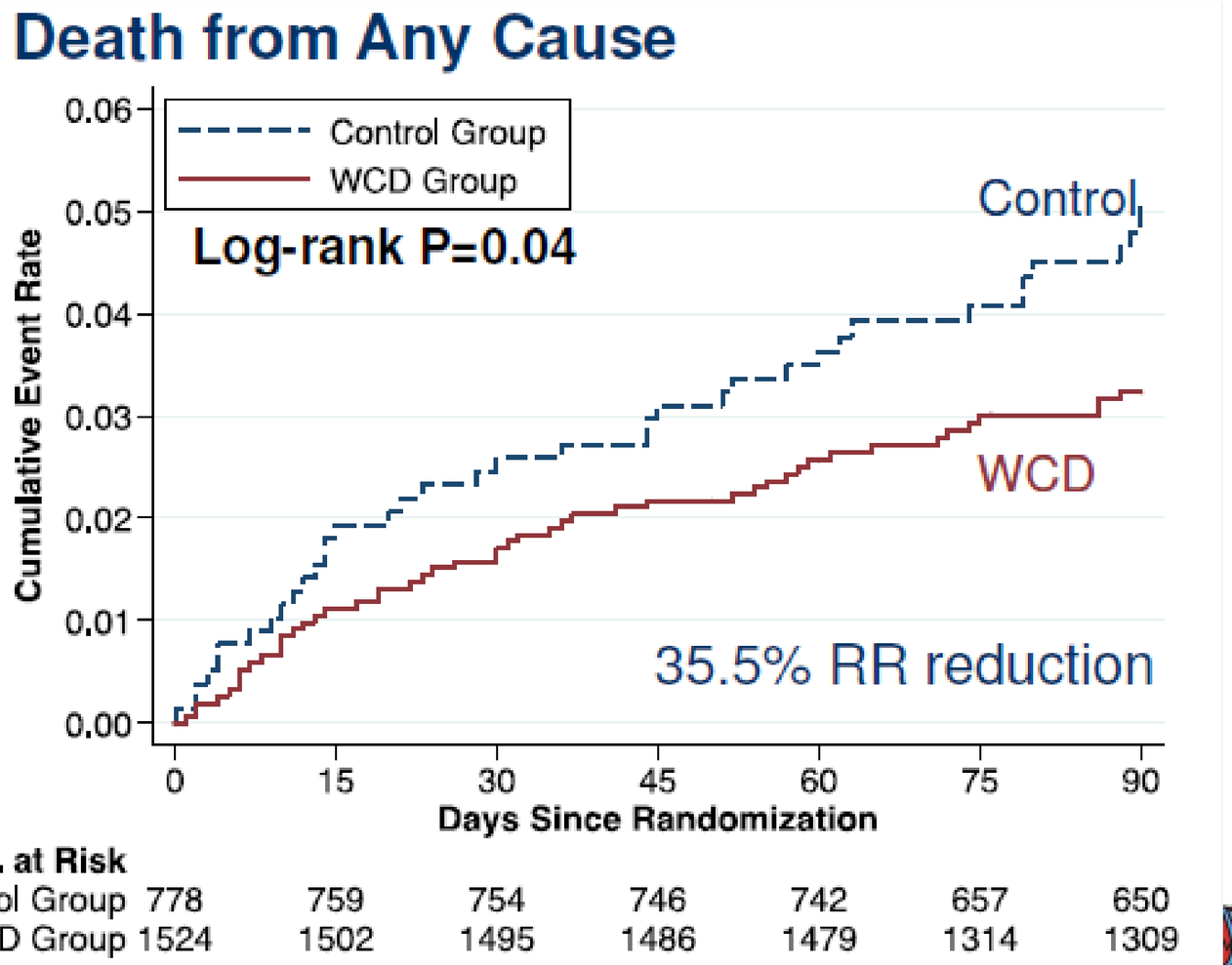
No. at Risk

Control Group	778	759	754	746	742	657	650
WCD Group	1524	1502	1495	1486	1479	1314	1309

Results: Outcomes, intention-to-treat







Results: Cause-specific death

Clinical event type	WCD (N=1524)	Control (N=778)	P value*
FATAL EVENTS, n (%)			
Sudden Death (1° outcome)	25 (1.6%)	19 (2.4%)	0.18
Non-sudden death	21 (1.4%)	17 (2.2%)	0.15
Congestive heart failure death	10 (0.7%)	5 (0.6%)	1.0
Recurrent MI death	1 (0.1%)	1 (0.1%)	1.0
Stroke death	0 (0.0%)	**4 (0.5%)**	**0.01**
Other cardiovascular death	5 (0.3%)	3 (0.4%)	1.0
Other death	5 (0.3%)	4 (0.5%)	0.72
Indeterminate death	2 (0.1%)	2 (0.3%)	0.83
Death, any cause	48 (3.1%)	**38 (4.9%)**	**0.04**
NON-FATAL EVENTS, n (%)			
Rehospitalization, cardiovascular	334 (22%)	174 (22%)	0.81
Rehospitalization, any cause	475 (31%)	253 (33%)	0.51

Results: WCD therapies & events

Theraples	WCD Group (N=1524)	Control Group (N=778)
Appropriate shocks (p=0.002)		
1 appropriate shock	13 (0.9%)	0 (0%)
≥2 appropriate shocks	7 (0.5%)	1 (0.1%)
Inappropriate shocks (p=0.05)		
1 inappropriate shock	8 (0.5%)	0 (0%)
≥2 inappropriate shocks	2 (0.1%)	0 (0%)
Aborted shocks (p<0.001)		
1 aborted shock	43 (2.8%)	0 (0%)
≥2 aborted shocks	12 (0.8%)	0 (0%)
>5 aborted shocks	15 (1.0%)	0 (0%)

Results: Pre-specified symptoms

Characteristics	WCD	Control	P value
Fatigue	36.0%	38.8%	0.21
Back pain	20.0%	19.4%	0.73
Trouble sleeping	39.0%	37.3%	0.47
Dizziness	24.3%	23.5%	0.66
Fainting	4.2%	5.1%	0.34
Nausea	9.4%	12.0%	0.06
Headache	18.3%	19.1%	0.66
Palpitations	23.1%	25.7%	0.18
Chest pain	18.7%	21.4%	0.14
Shortness of breath	38.7%	**45.4%**	**0.003**
Rash in any location	**15.2%**	7.1%	**<0.001**
Rash on torso	**12.9%**	3.8%	**<0.001**
Itch in any location	**17.2%**	6.4%	**<0.001**
Itch on torso	**14.5%**	3.1%	**<0.001**

Discussion: Sudden death outcome

- **Possible misclassification of sudden deaths**
  - Reducing power for SD outcome but not total mortality
  - 14 of 20 participants who received an appropriate shock survived to 90 days
- **WCD may confer additional protection beyond SD**
  - Earlier care for bradycardia, NSVT or aborted shocks
  - Lower stroke death in WCD group
- **Reduced anxiety or increased medication compliance**
  - More shortness of breath in controls

Discussion: Limitations

- **Participants and investigators not blinded**
  - Differences in shortness of breath between groups
  - No differences in prescribing guideline-directed Rx
- **Crossovers**
  - 20 participants in Control group received the WCD
  - 19% in WCD group did not use the WCD
  - Should bias results toward the null, but still found a difference in total mortality

Conclusions

- **The WCD did not statistically significantly reduce sudden death mortality**
- **The WCD did reduce total mortality in the first 90 days post-MI in patients with LVEF ≤35%**
  - Relative risk reduction of 35.5%
- **VEST represents the first randomized, controlled trial of the WCD**
- **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**

DĚKUJI ZA POZORNOST

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