Wearable Defibrillators

Alex Velasquez M.D.

Assistant Professor

University of Miami Miller School of Medicine

02-03-2023

- No Disclosures

Introduction

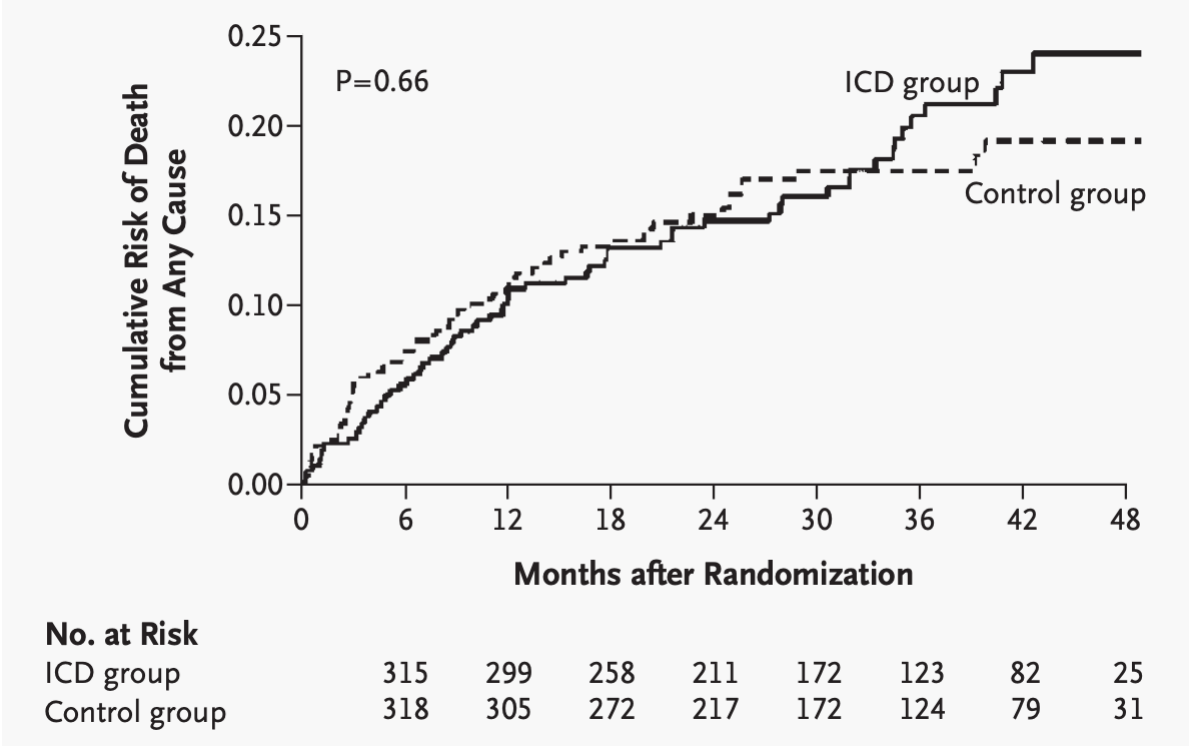
- Wearable defibrillators (WCDs), were first introduced into medical practice in the early 2000s.
- The goal was to provide an alternative for individuals who were at high risk for sudden cardiac arrest (SCA) but were not eligible for implantable cardioverter-defibrillators (ICDs).

2017 AHA/ACC/HRS Guideline for Management of Patients With Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death-Statement on Wearable Defibrillators

COR	LOE	Recommendations
IIa	B-NR	1. In patients with an ICD and a history of SCA or sustained VA in whom removal of the ICD is required (as with infection), the wearable cardioverter-defibrillator is reasonable for the prevention of SCD.[S11.2-1–S11.2-4]
IIb	B-NR	2. In patients at an increased risk of SCD but who are not ineligible for an ICD, such as awaiting cardiac transplant, having an LVEF of 35% or less and are within 40 days from an MI, or have newly diagnosed NICM, revascularization within the past 90 days, myocarditis or secondary cardiomyopathy or a systemic infection, the wearable cardioverter-defibrillator may be reasonable.[S11.2-1–S11.2-5]

DINAMIT Trial

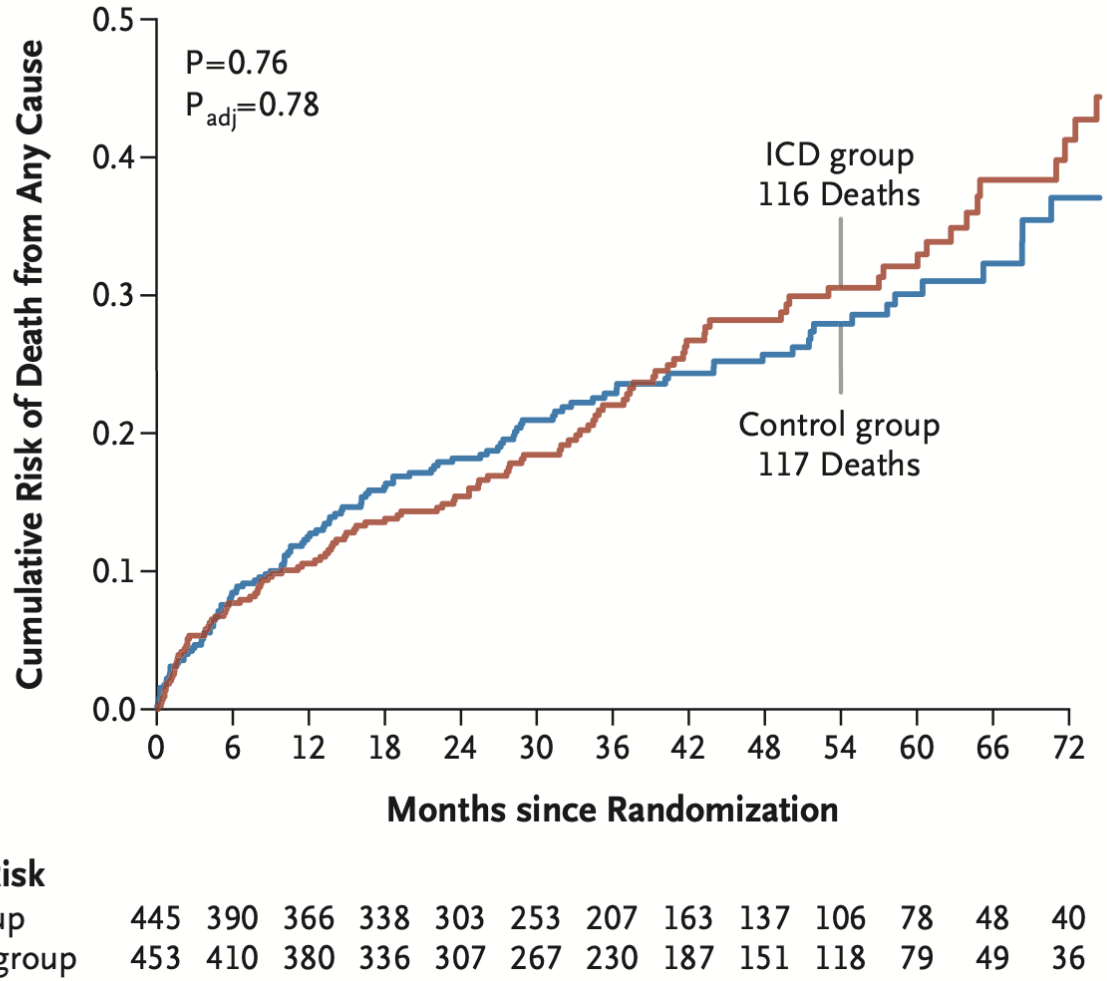
- 674 patients with recent MI < 40 Days and LVEF < 35%
  - 332 ICD group
  - 342 control group
- No difference in all cause mortality inpatients with LVEF <35-40% after an MI



Hohnloser, S. H., et al. (2004). "Prophylactic Use of an Implantable Cardioverter–Defibrillator after Acute Myocardial Infarction." New England Journal of Medicine **351**(24): 2481-2488.

IRIS TRIAL

- 898 patients enrolled within 5 to 31 days post MI if they had a reduced left ventricular ejection fraction (≤40%) +
  - a heart rate > 90 bpm by ECG
  - Non-sustained ventricular tachycardia (≥150 beats per minute) during Holter monitoring
- 445 to ICD
- 453 to medical therapy alone.
- Overall mortality was not reduced in the ICD group (hazard ratio, 1.04; 95% confidence interval [CI], 0.81 to 1.35; P=0.78).



No. at Risk

ICD group	445	390	366	338	303	253	207	163	137	106	78	48	40
Control group	453	410	380	336	307	267	230	187	151	118	79	49	36

MIAMI 2023 VALVES
MiamiValves.org

Steinbeck, G., et al. (2009). "Defibrillator Implantation Early after Myocardial Infarction." New England Journal of Medicine **361**(15): 1427-1436.

- In both DINAMIT and IRIS sudden cardiac death was lower in ICD implantation group
- Non-SCD rates were higher in those implanted with ICD
  - suggesting increased mortality associated with complications related to ICD implantation.
- As a result, ACC/AHA/HRS recommend ICD implantation for primary prevention of SCD in this population after a 40-day period of guideline-directed medical therapy (or 90 day period of guideline-directed medical therapy if revascularization is performed)

Approval Trial- WEARIT/BIROAD

- The authors hypothesized that the wearable cardioverter defibrillator device could successfully defibrillate lethal ventricular arrhythmias with an acceptable level of unnecessary shocks in various groups of high risk ambulatory patients.
- WEARIT and BIROAD were begun as separate studies at 18 centers in the United States and one center in Germany.

Feldman, A. M., H. Klein, P. Tchou, S. Murali, W. J. Hall, D. Mancini, J. Boehmer, M. Harvey, M. S. Heilman, S. J. Szymkiewicz and A. J. Moss (2004). "Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD." Pacing Clin Electrophysiol **27**(1): 4-9.

What does it look like?

- A chest garment with
  - two defibrillator pads positioned vertically along the back,
  - a frontal belt containing a horizontally positioned defibrillator pad with electrodes that detect the heart rhythm.
- A small monitor box that records the rhythms
- Once activated the life vest can provide three alarms
  - A gong alert-attention is required to the monitor box
  - A vibration alert- a lethal arrhythmia has been detected
  - A siren alert- a shock is imminent
- A blue gel is released from the defibrillation pads to improve contact for electrical conduction.
- The shock vector is between the pads on the back and the defibrillator pad on the frontal belt.

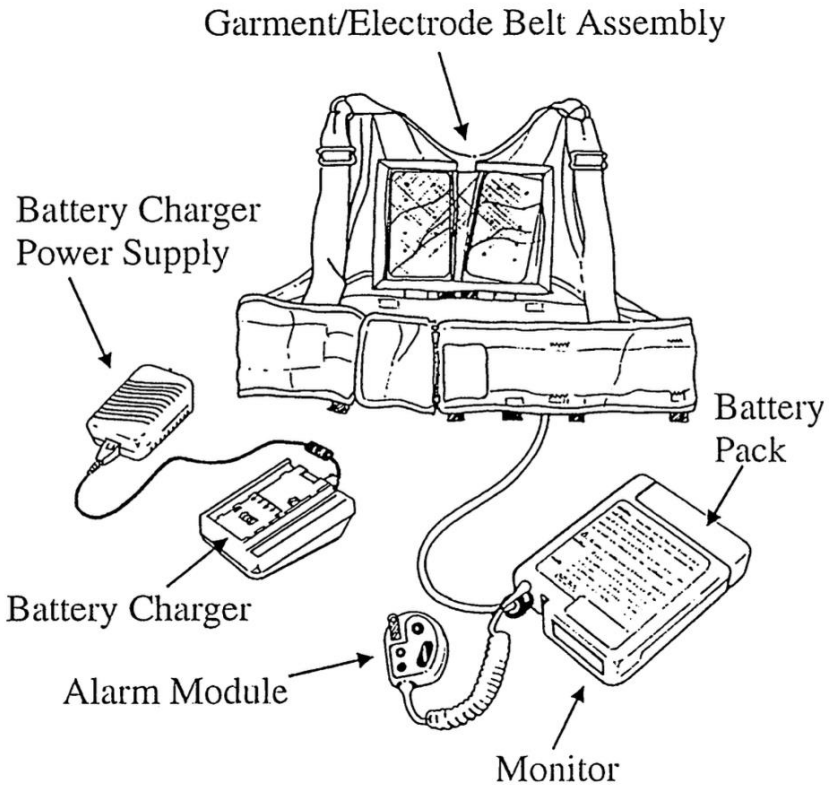


Figure 1. *Wearable defibrillator used in study.*

Feldman, A. M., H. Klein, P. Tchou, S. Murali, W. J. Hall, D. Mancini, J. Boehmer, M. Harvey, M. S. Heilman, S. J. Szymkiewicz and A. J. Moss (2004). "Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD." Pacing Clin Electrophysiol **27**(1): 4-9.

WEARIT

- ambulatory patients
  - New York Heart Association (NYHA) functional Class III or IV heart failure symptoms
  - an ejection fraction <0.30.

Feldman, A. M., H. Klein, P. Tchou, S. Murali, W. J. Hall, D. Mancini, J. Boehmer, M. Harvey, M. S. Heilman, S. J. Szymkiewicz and A. J. Moss (2004). "Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD." Pacing Clin Electrophysiol **27**(1): 4-9.

BIROAD

- used to bridge patients for a period of 4 months to the possible use of an ICD
- Patients who experienced a recent myocardial infarction that was complicated by any of the following:
  - ventricular tachyarrhythmias within 48 hours of the infarct
  - an ejection fraction <0.30 at least 3 days after the infarct
  - an episode of syncope or SCA at least 48 hours after a myocardial infarction but were not candidates for an ICD
- had a ventricular arrhythmia within 48 hours of coronary artery bypass grafting (CABG),
- had a left ventricular ejection fraction of <0.30 at least 3 days after CABG
- had SCA or syncope at least 48 hours after CABG but were unable to receive an ICD
- were ICD candidates who were at home and were not expected to receive a device for at least 4 months
- met criteria for an ICD but had refused therapy

Table I.

	Total Study	BIROAD	WEARIT
EF	23 ± 10	30 ± 10	19 ± 7
QRS	121 ± 33	109 ± 20	128 ± 38
Age	55 ± 12	60 ± 11	52 ± 11
Sex	0.82 male	0.83 male	0.79 male
Smoking	.66	.68	.62
HX BP	.59	.79	.12
NSVT	.52	.71	.15
VT	.32	.42	.21
β-Blockers	.57	.73	.27
AAD	.22	.13	.34
INOTROPES	.16	.04	.45

EF = ejection fraction; HX BP = history of hypertension; NSVT = nonsustained ventricular tachycardia; VT = ventricular tachycardia.

Feldman, A. M., H. Klein, P. Tchou, S. Murali, W. J. Hall, D. Mancini, J. Boehmer, M. Harvey, M. S. Heilman, S. J. Szymkiewicz and A. J. Moss (2004). "Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD." Pacing Clin Electrophysiol **27**(1): 4-9.

WEARIT/BIROAD RESULTS

- 289 patients enrolled
  - 177 in WEARIT
  - 112 in BIROAD
- 6/8 attempted defibrillations were successful
  - Both failed defibrillations were because of reversed electrodes
- 6 inappropriate shocks were observed during 901 months (8%/year)
- 65/289 (22%) withdrew from study prior to study endpoint
  - discomfort or lifestyle issues, with the size and weight of the monitor most frequently given as the reason

Feldman, A. M., H. Klein, P. Tchou, S. Murali, W. J. Hall, D. Mancini, J. Boehmer, M. Harvey, M. S. Heilman, S. J. Szymkiewicz and A. J. Moss (2004). "Use of a wearable defibrillator in terminating tachyarrhythmias in patients at high risk for sudden death: results of the WEARIT/BIROAD." Pacing Clin Electrophysiol **27**(1): 4-9.

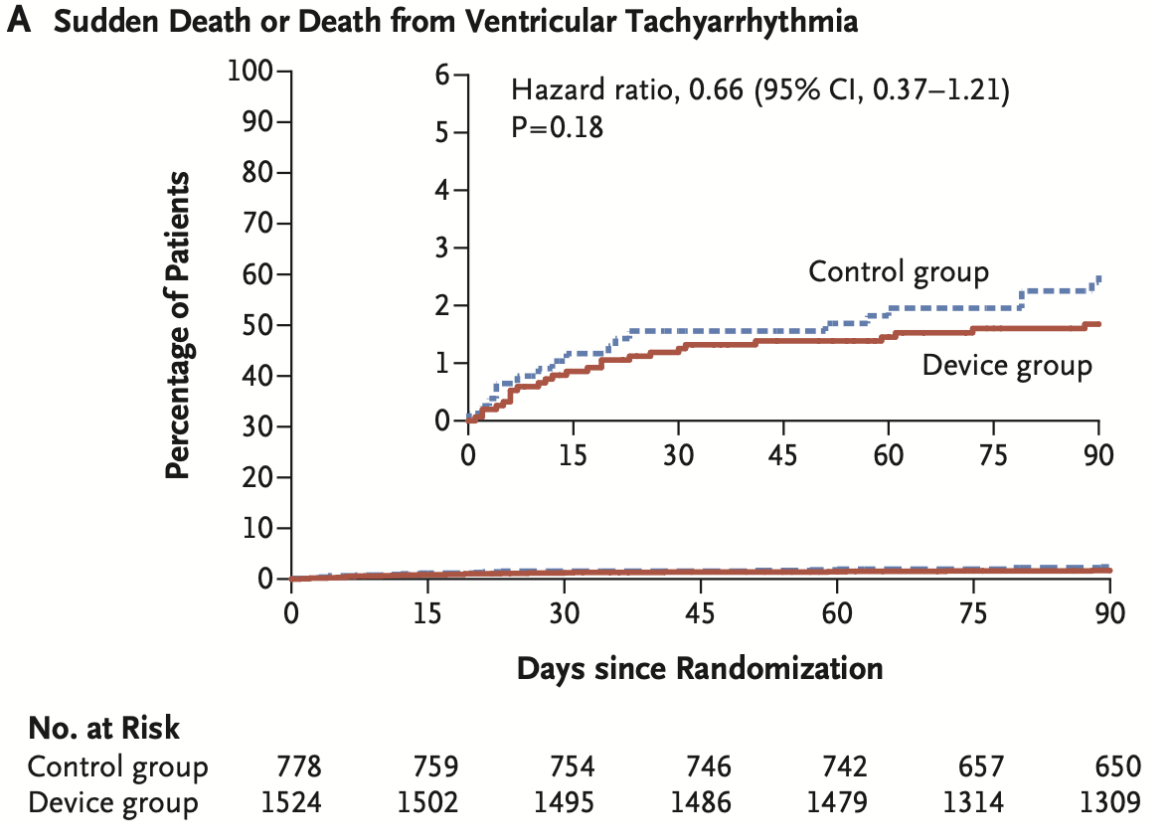
Vest Trial –Design

- 10 year enrollment
- 2302 patients were randomized after AMI with LVEF < 35% in a 2: 1 ratio.
- Analysis was in an intention-to-treat fashion
- Patients excluded:
  - an ICD or unipolar pacemaker
  - clinically significant valve disease
  - long-term hemodialysis
  - chest circumference that was too small or too large to accommodate the wearable cardioverter–defibrillator
  - pregnant
  - had been discharged to a nursing facility with an anticipated stay of more than 7 days
- Initially, the primary outcome of the trial was death from any cause at 60 days
- After the first 244 participants had been enrolled primary outcome changed to the combined 90-day incidence of sudden death and non -sudden death due to ventricular tachyarrhythmia

Olgin, J. E., et al. (2018). "Wearable Cardioverter–Defibrillator after Myocardial Infarction." New England Journal of Medicine **379**(13): 1205-1215.

Vest Trial- Outcomes

- Primary outcome of sudden death, death from VT/VF at 90 Days was not significantly different between WCD(1.6%) and 2.4% in Non-WCD group.
- Secondary outcome of death from any cause was lower for WCD (3.1%) than in non-WCD group (4.9%) HR 0.64; 95% CI, 0.43 to 0.98
- Non-arrhythmic deaths were not significantly different 1.4% vs 2.2%
- Wear time of 70% of the time was only achieved in the first 2weeks of trial.



Olgin, J. E., et al. (2018). "Wearable Cardioverter–Defibrillator after Myocardial Infarction." New England Journal of Medicine **379**(13): 1205-1215.

VEST TRIAL-Additional Outcomes

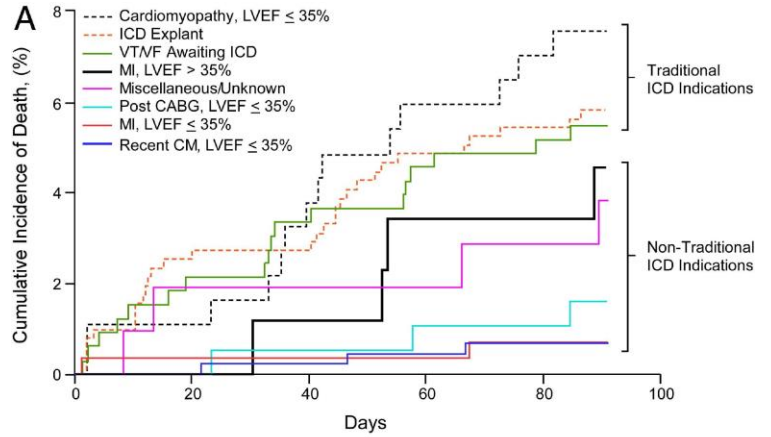
- 98 % of patients did not receive any shocks
- 29 total shocks
  - 19 appropriate shocks
  - 31% were inappropriate
  - 69 aborted shocks
- 1092 alarms indicating arrhythmia were detected. 146 patients had over 100 alarms.
- Median wear time 18 hours

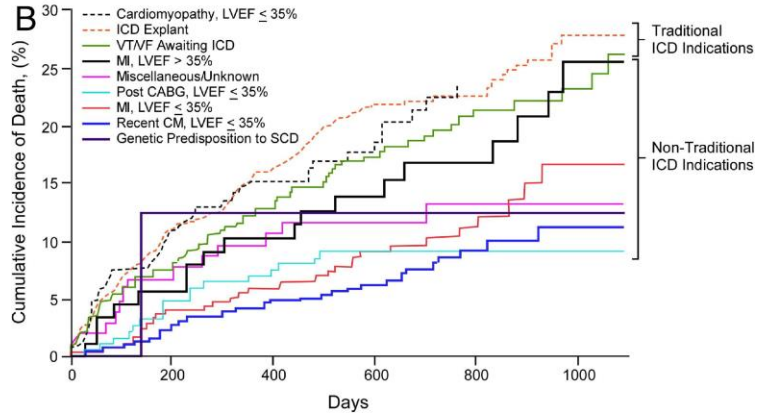
- Proportion of patients using the device decreased from
  - 81% at randomization
  - 41% at 90 days
- nearly a third of patients wore it for 0 hours
- only 25% of patients were even wearing the device at the time of their death
- Number needed to treat 125
- Cost for 3 months ~$10000 for 3 months
- $1.25 million per 1 life saved.

Variable	Device Group (N = 1524)	Control Group (N = 778)	P Value
	no. of participants with event (%)		
No. of total shocks			<0.001
0	1495 (98.1)	777 (99.9)	
1	20 (1.3)	0	
≥2	9 (0.6)	1 (0.1)	
No. of appropriate shocks			0.008
0	1504 (98.7)	777 (99.9)	
1	13 (0.9)	0	
≥2	7 (0.5)	1 (0.1)	
No. of inappropriate shocks			0.12
0	1515 (99.4)	778 (100)	
1	7 (0.5)	0	
≥2	2 (0.1)	0	
No. of shocks aborted by pressing response button†			<0.001
0	1455 (95.5)	777 (99.9)	
1	43 (2.8)	1 (0.1)	
2–5	11 (0.7)	0	
>5	15 (1.0)	0	
No. of alarms indicating arrhythmia			<0.001
0	432 (28.3)	762 (97.9)	
1	115 (7.5)	1 (0.1)	
2–5	252 (16.5)	2 (0.3)	
6–100	579 (38.0)	12 (1.5)	
>100	146 (9.6)	1 (0.1)	
No. of alarms indicating asystole			<0.001
0	1483 (97.3)	777 (99.9)	
1	22 (1.4)‡	0	
≥2	19 (1.2)‡	1 (0.1)	

Aggregate National Experience With the Wearable Cardioverter-Defibrillator

- Those with explanted ICD or prior VT/VF had highest risk of death in registry
- Lowest risk was seen post-CABG and recent diagnosis of NICM





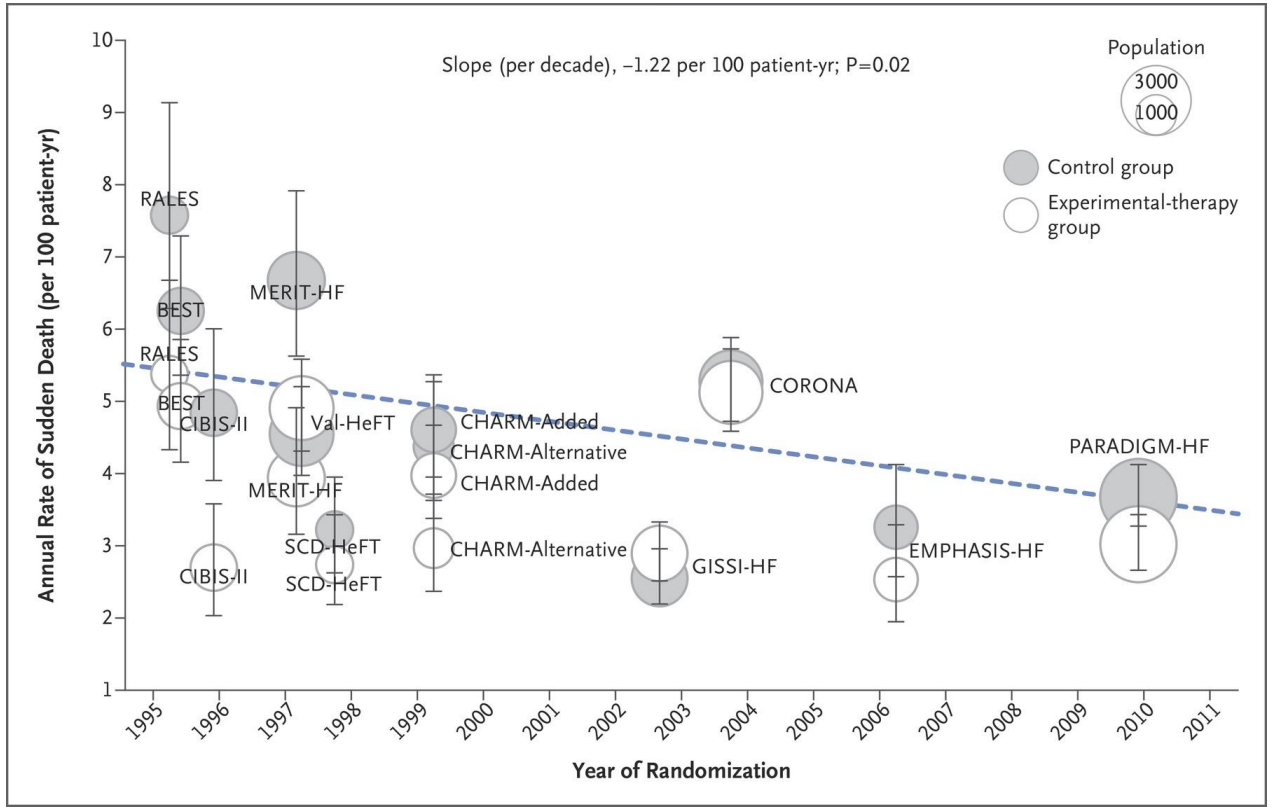
	n	Estimated Mortality Rate % (95% CI)	Hazard Ratio (95% CI)	p Value
Traditional ICD indications	1,029	26.8 (23.3–30.4)	—	—
LVEF ≤35%, recent MI	273	16.7 (10.1–23.3)	0.49 (0.33–0.71)	<0.001
LVEF ≤35%, post-CABG	184	9.3 (5.1–13.5)	0.40 (0.25–0.66)	<0.001
LVEF ≤35%, recent NICM	428	11.3 (7.0–15.5)	0.34 (0.24–0.49)	<0.001

MIAMI 2023 VALVES
MiamiValves.org

Chung, M. K., Szymkiewicz, S. J., Shao, M., Zishiri, E., Niebauer, M. J., Lindsay, B. D., & Tchou, P. J. (2010). Aggregate national experience with the wearable cardioverter-defibrillator: event rates, compliance, and survival. *J Am Coll Cardiol, 56(3), 194-203. doi:10.1016/j.jacc.2010.04.016*

Declining Risk of Sudden Death

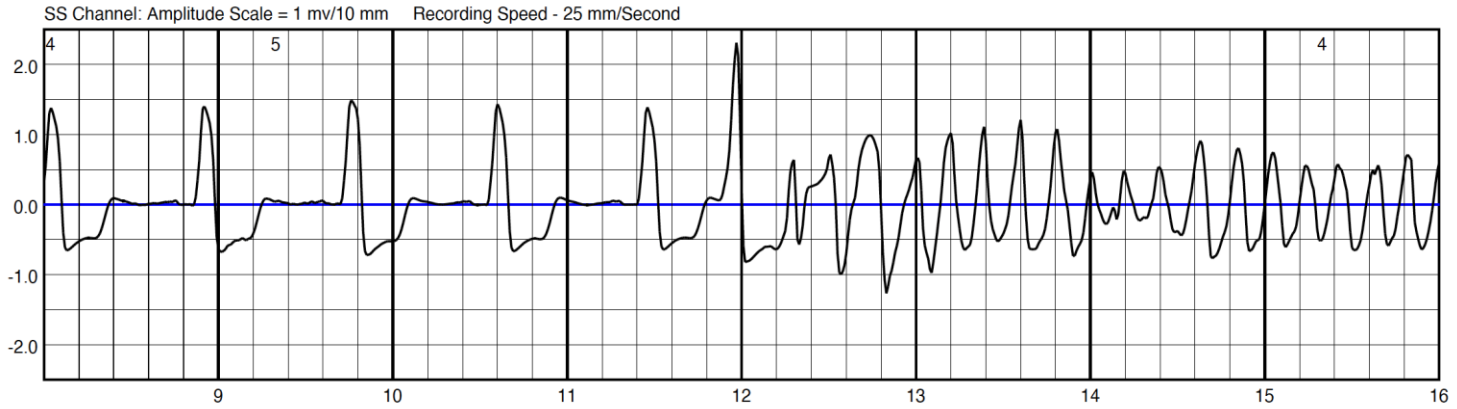
- Maybe WCD solves a problem from another era that no longer applies



Shen, L., Jhund, P. S., Petrie, M. C., Claggett, B. L., Barlera, S., Cleland, J. G. F., . . . Mcmurray, J. J. V. (2017). Declining Risk of Sudden Death in Heart Failure. *New England Journal of Medicine, 377(1), 41-51. doi:10.1056/nejmoa1609758*

Case

- 59 year old woman with non-ischemic cardiomyopathy (LVEF 15-20%) with left bundle branch block with a QRS 154ms referred 5 months after diagnosis
- The following rhythm was obtained from wearable defibrillator the night before BIV ICD implantation.



Narratives are Persuasive Because They are Easier to Understand: Examining Processing Fluency as a Mechanism of Narrative Persuasion

Olivia M. Bullock[1]*, Hillary C. Shulman[1] and Richard Huskey[2]

[1]School of Communication, The Ohio State University, Columbus, OH, United States, [2]Department of Communication, Center for Mind and Brain, University of California, Davis, Davis, CA, United States

- They found that "*narratives are processed more fluently (easily) than non-narratives, and when processing is eased, persuasion becomes more likely*"

Bullock, O. M., H. C. Shulman and R. Huskey (2021). "Narratives are Persuasive Because They are Easier to Understand: Examining Processing Fluency as a Mechanism of Narrative Persuasion." Frontiers in Communication **6**.

In Summary

- Wearable defibrillators are can defibrillate effectively
- They require adherence to work
- Their current design likely compromises efficacy as the main randomized controlled trial failed to show improvement in arrhythmic death in high risk individuals
- Anecdotal evidence is difficult to ignore

Thank you