The wearable cardioverter-defibrillator (WCD)

State of the art

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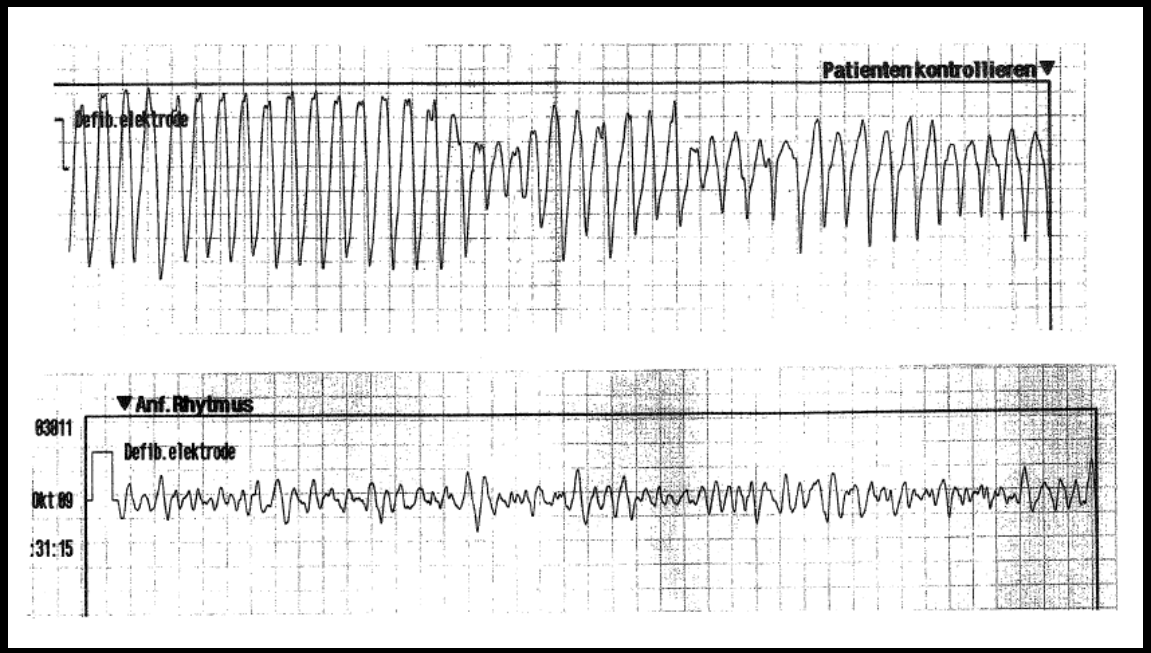
Presenter Disclosure Information

Helmut U. Klein

Lecture honoraria (LH,)
Research grants (RG)

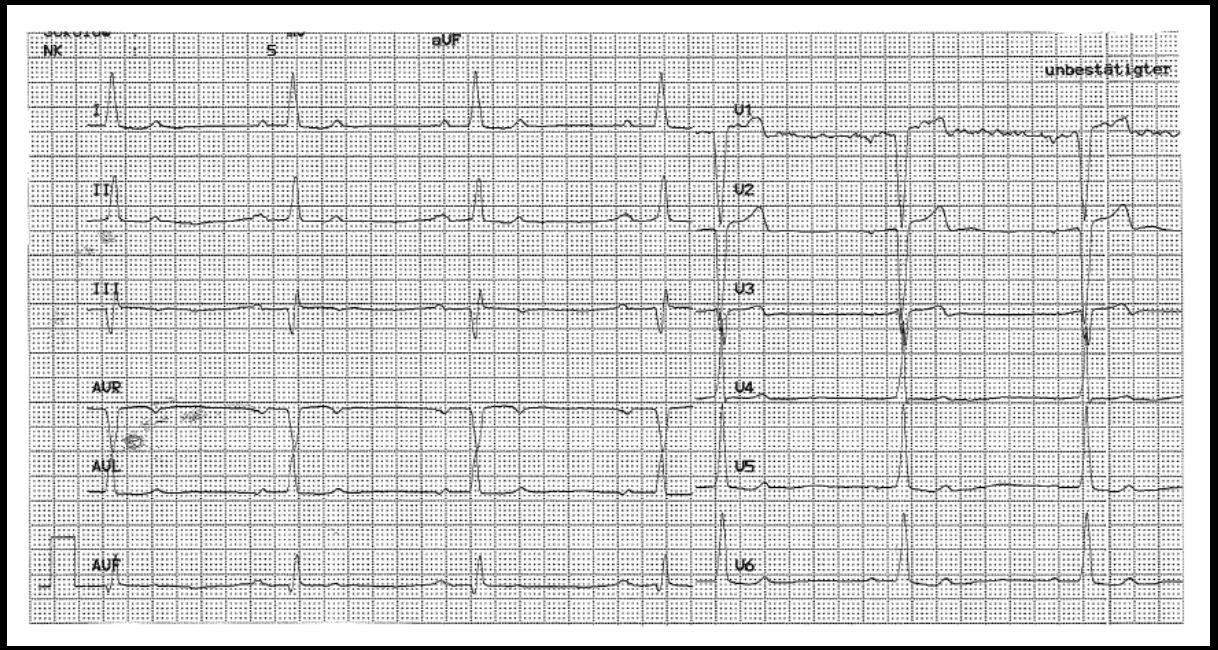
Boston Scientific, Inc. (RG,LH)
ZOLL-Lifecor Corp. (RG, LH)

Rhythm strip from the Paramedics at the time of cardiac arrest- during Marathon running



ECG after hospital admission

K.W.54 years

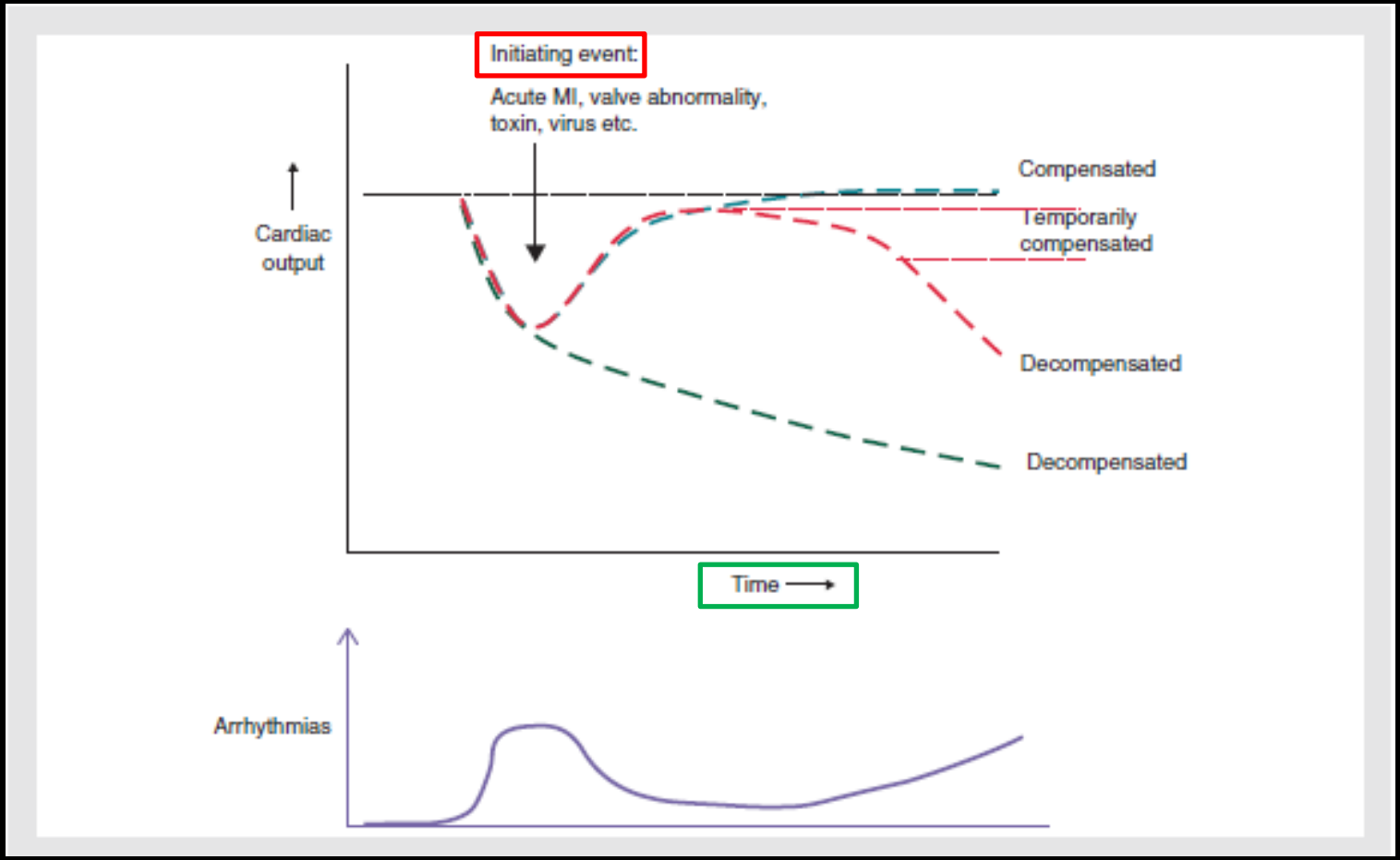


Coronary Angiography:
severe 3-vessel CAD;
LVEF 23%

Current ICD Therapy

- Guidelines are based mostly on LVEF.
  However, LVEF is not a fixed parameter
- VT/VF events occur mostly with higher LVEF values
  (only 10% VT/VF events/year with LVEF<35%)
- 5%-6% ICD complications / year
- 3%-6% implantation complications (recently: 9.6%)
- 15% complications with upgrading procedures
- 3%-5% ICD infection
  (more than twice as high after ICD replacement)
- 10%-15% inappropriate shocks
- 30% unnecessary shocks (MADIT-RIT)
- Device/Lead failure will always occur

Arrhythmias during the transition to chronic heart failure



GYH Lip et al. Euro J Heart Failure 2015
Consensus Arrhythmias in Heart Failure

What needs to be done?

- We have to face the "real world" problems with ICD therapy
- We have to improve risk stratification for potential arrhythmic events
- We have to accept the close relationship between heart failure and arrhythmic events
- During the time of risk analysis the patient needs to be protected from VT/VF events
- We need new RCTs for each underlying problem to evaluate the benefit of ICD therapy

Currently available risk parameters

- Functional Parameters:
  LV-EF; LVEED; LVESD
- Autonomic Tests: HRV; HRT; DC; BRS
- ECG Parameters:
  HR; QRS duration; Fragmented QRS; TWA; SAECG
- Arrhythmic Parameters: complex PVCs; NSVT; EPS (?)
- Clinical Parameters: NYHA Class
- Imaging Parameters: LGE-MRI

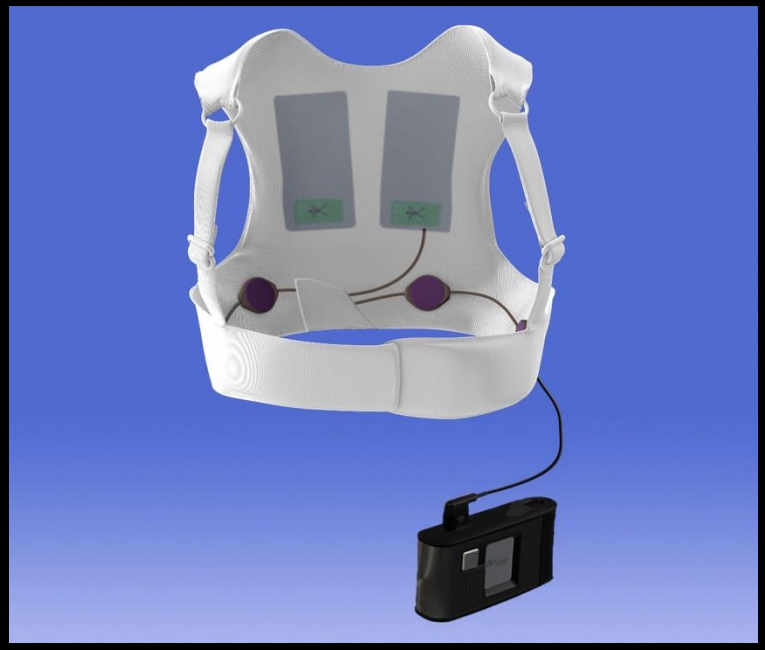
The problem with LV-EF

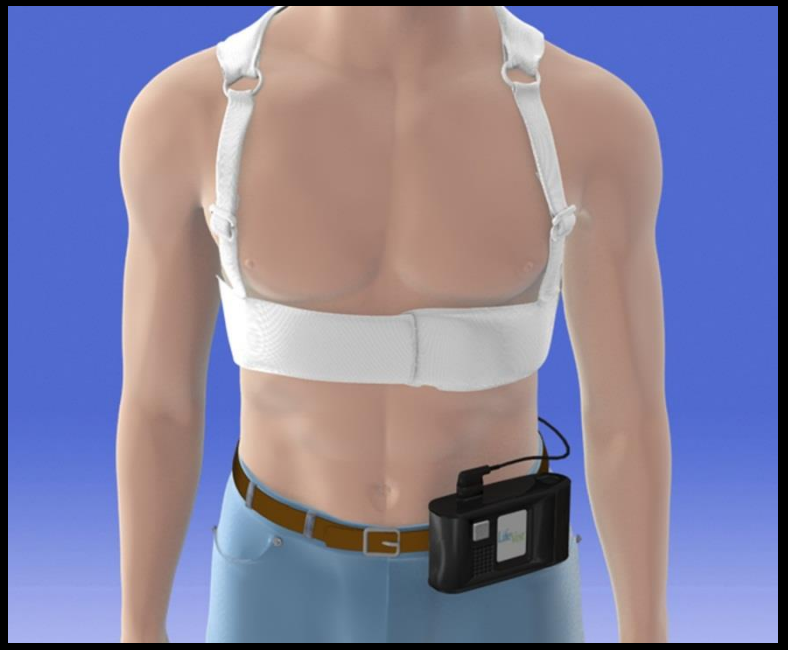
- Dynamic nature of LV function (recovery or impairment?)
- How long to wait for recovery?
- Does the risk remain after LV-EF recovery?
- SCD is more frequent with improved LV-EF
- “Magic” discriminator of LV-EF (30%,35%,40%)?
- LV-EF discriminator different between ICM and NICM?

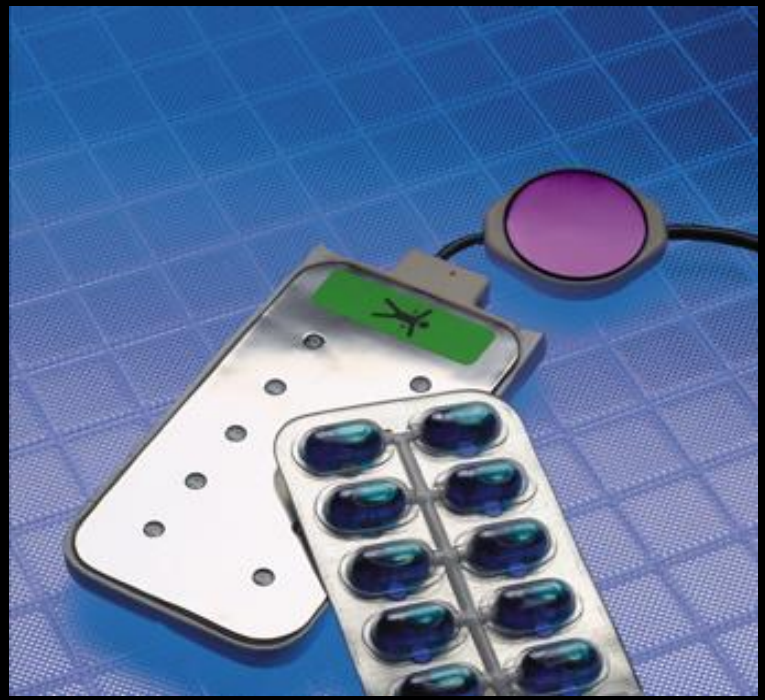
The concept of the WCD

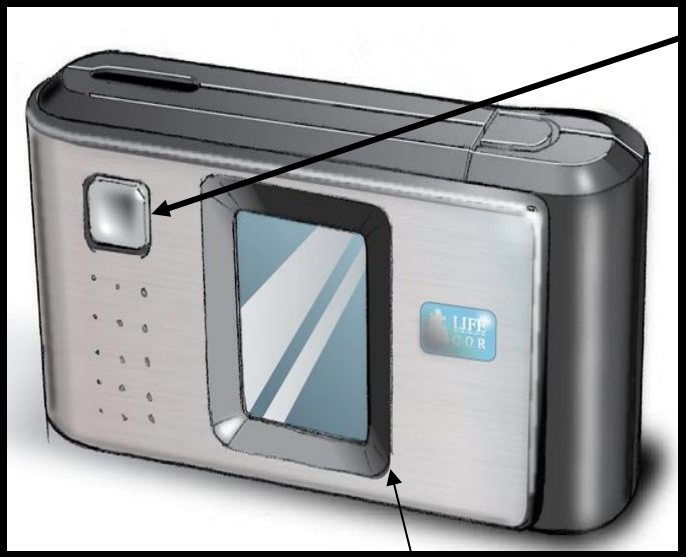
- The WCD is a tool to bridge a time period of risk assessment in order to confirm - or disregard- a permanent risk of SCD after WCD wearing

- During wearing time of the LifeVest® the patient is protected by a highly effective defibrillator,
- While wearing the LifeVest® the physician has time to monitor the clinical status, to assess structural and functional changes of the heart, and to analyze various risk parameters
- The WCD allows continuous monitoring of dangerous arrhythmias.







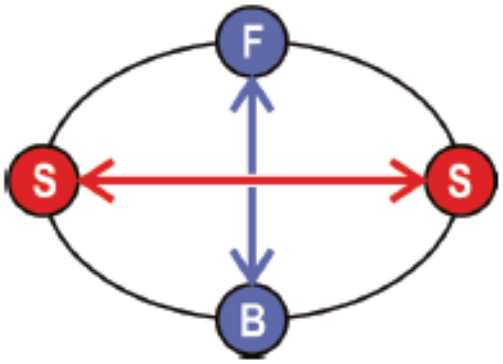


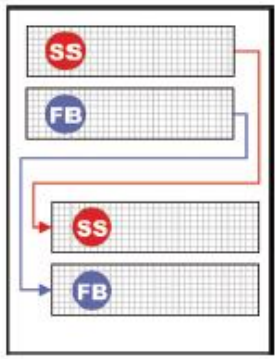
response button

LCD

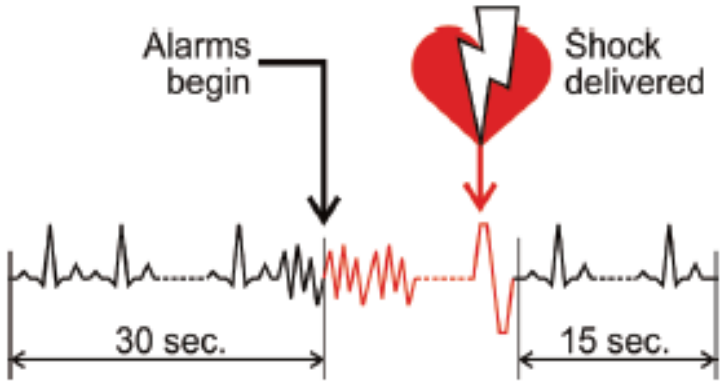
LifeVest 4000

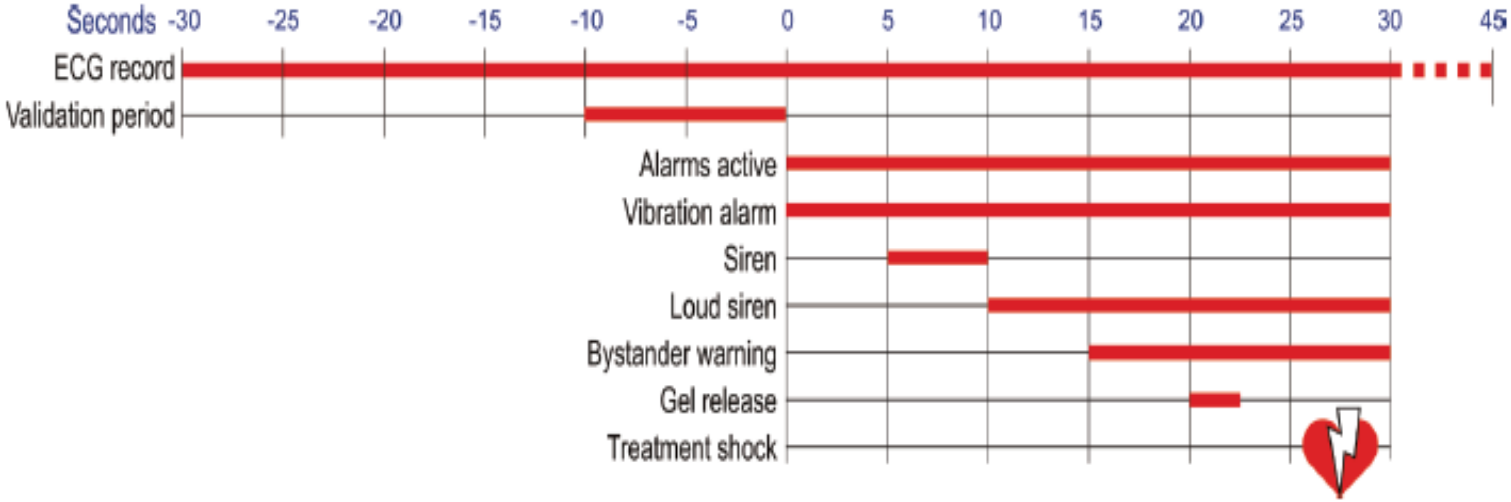
Two-channel ECG system



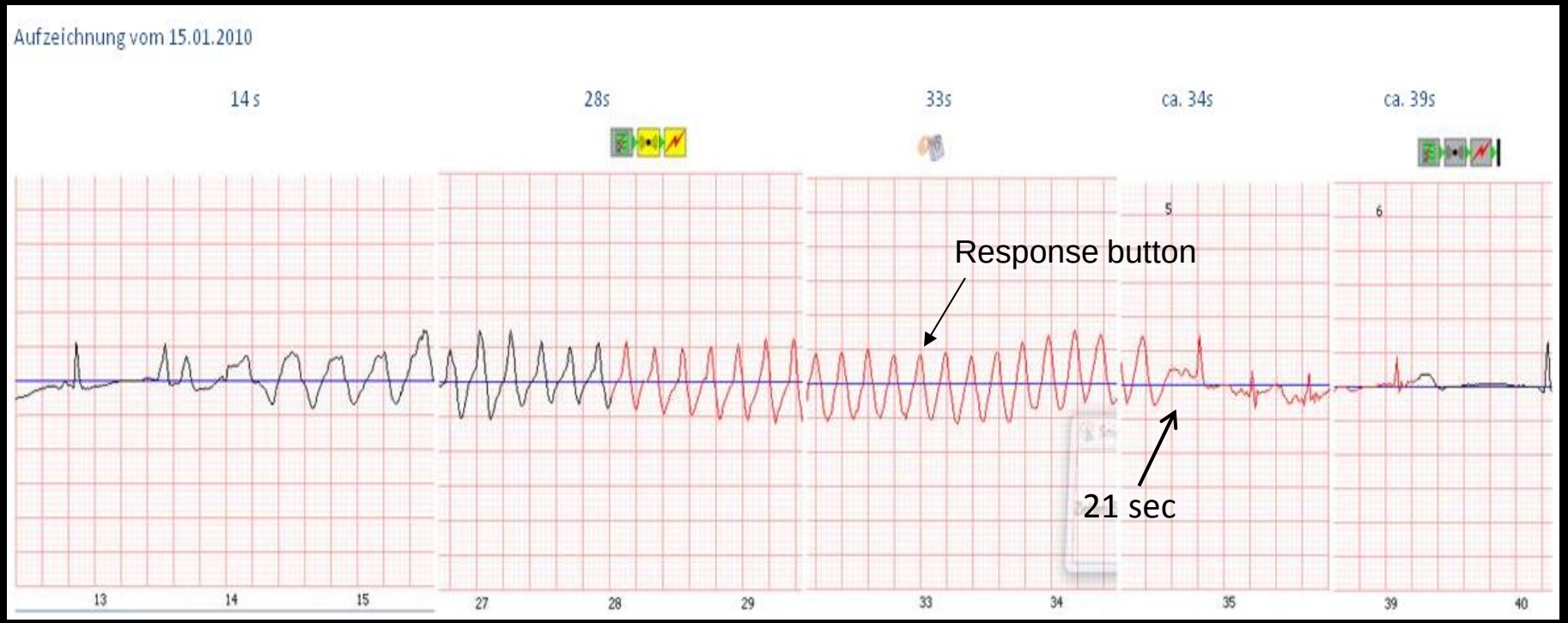


Detection and treatment





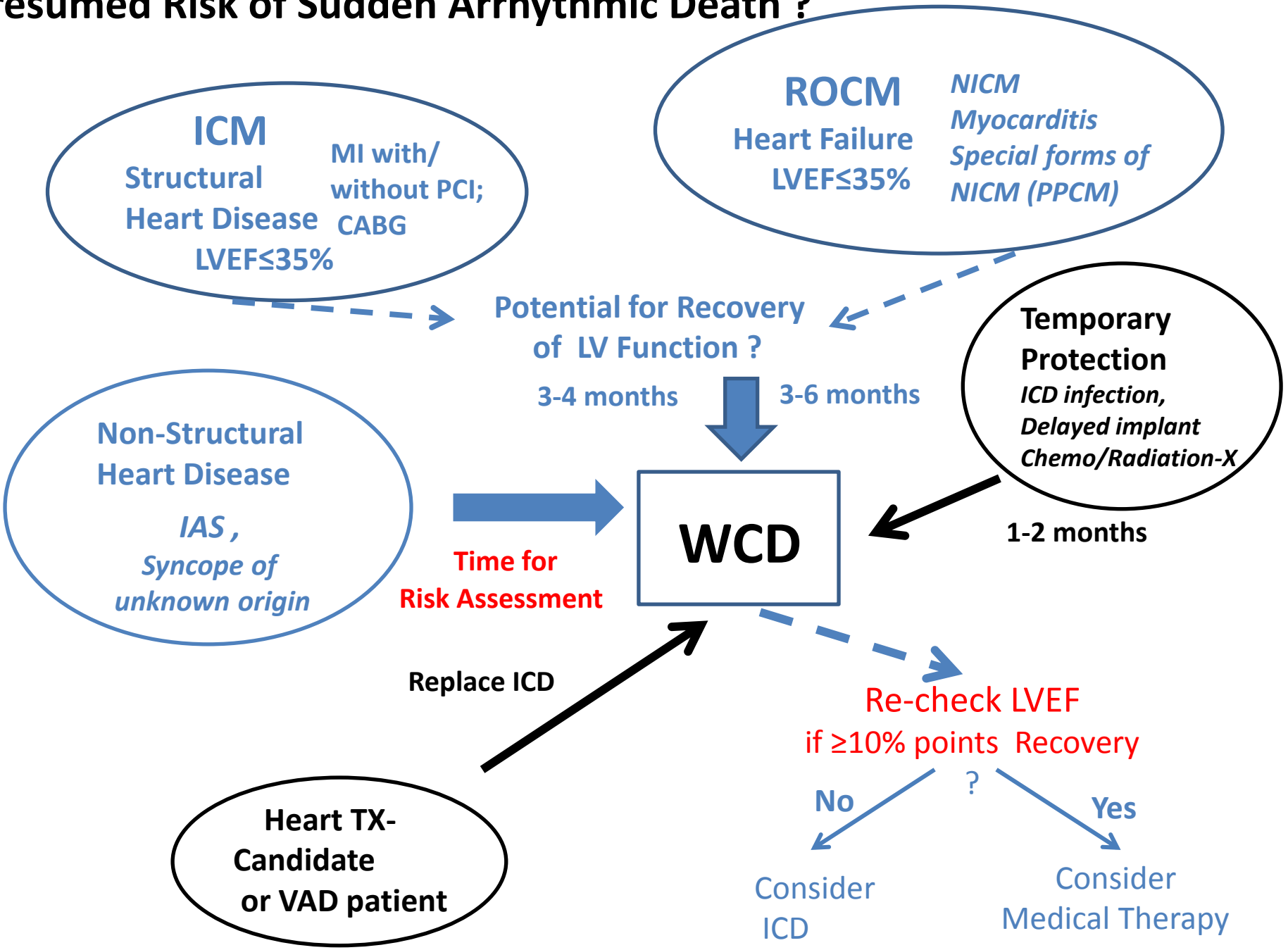
K.G. 38y, female LQT-Type 2



Characteristics of the WCD

- Detection of VT/VF events: 98%
- Bradycardia/ Asystole Detection: 100%
- Termination of VT/VF (1.shock): 93%-95%
- Inadequate shock delivery: 0.5%-0.7%
  Artefact/noise alarm: 2-8 min/day
- Compliance (wearing): 90%-95%
- Wearing compliance / day: 22h-23h
- Mean wearing time/ prescription: 100 days (depending upon WCD indication)

Presumed Risk of Sudden Arrhythmic Death ?



Wearable Cardioverter-Defibrillator Use in Patients Perceived to be at High Risk Early Post Myocardial Infarction

Andrew E. Epstein, MD, FAHA, FACC, FHRS*; William T. Abraham, MD[#]; Nicole Bianco, PhD[¶]; Karl B. Kern, MD**; Michael Mirro, MD[##]; Sunil V. Rao, MD[¶¶]; Edward K. Rhee, MD***; Scott D. Solomon, MD[###]; Steven Szymkiewicz, MD[¶]

JACC 2013; 62:200-07

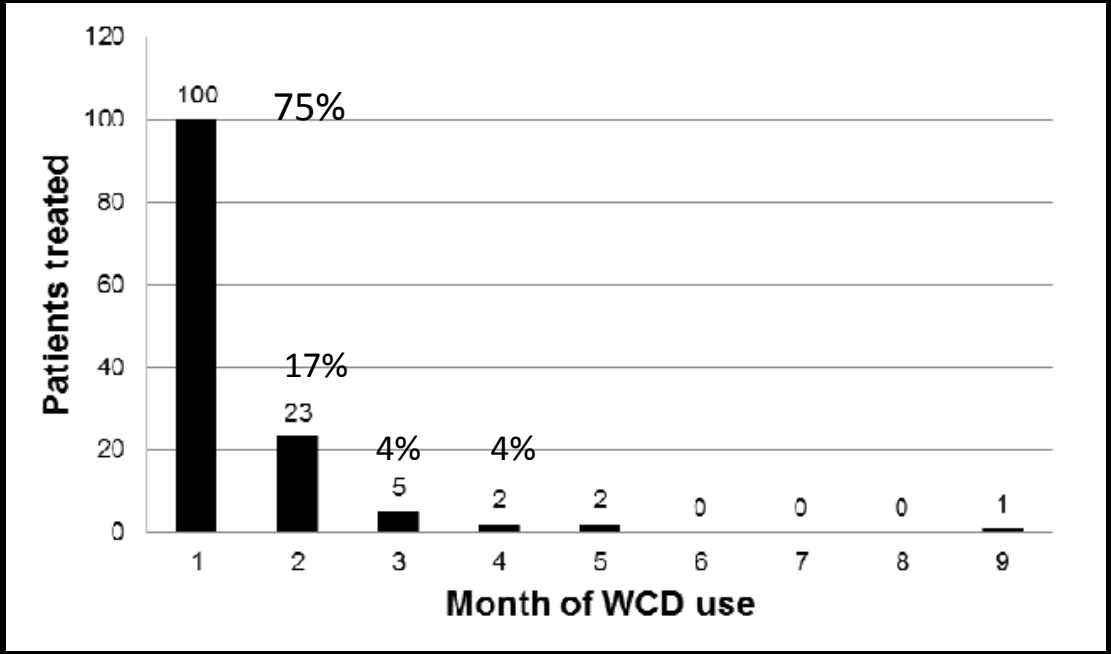
8453 pts for 3 mo with WCD after AMI; LV-EF≤35%

133 pts received 309 appropriate WCD shocks (1.6%)

mean time of first Shock: after 16 days post AMI

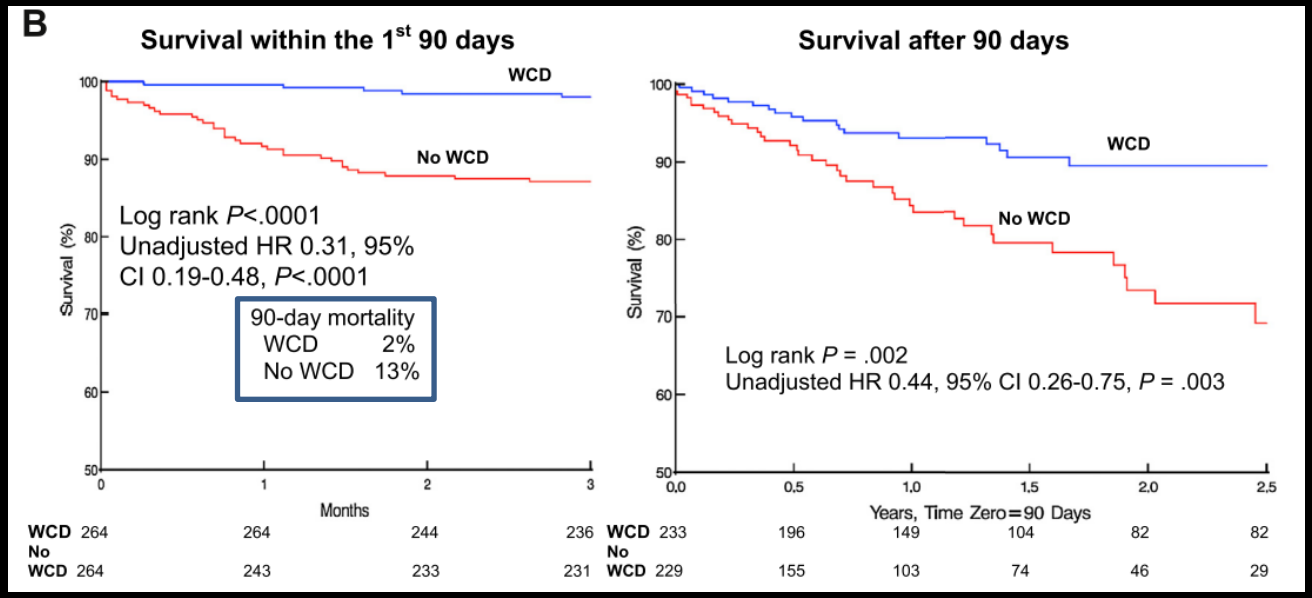
Long-term survival: 84% for non-revascularized pts

95% for revascularized pts



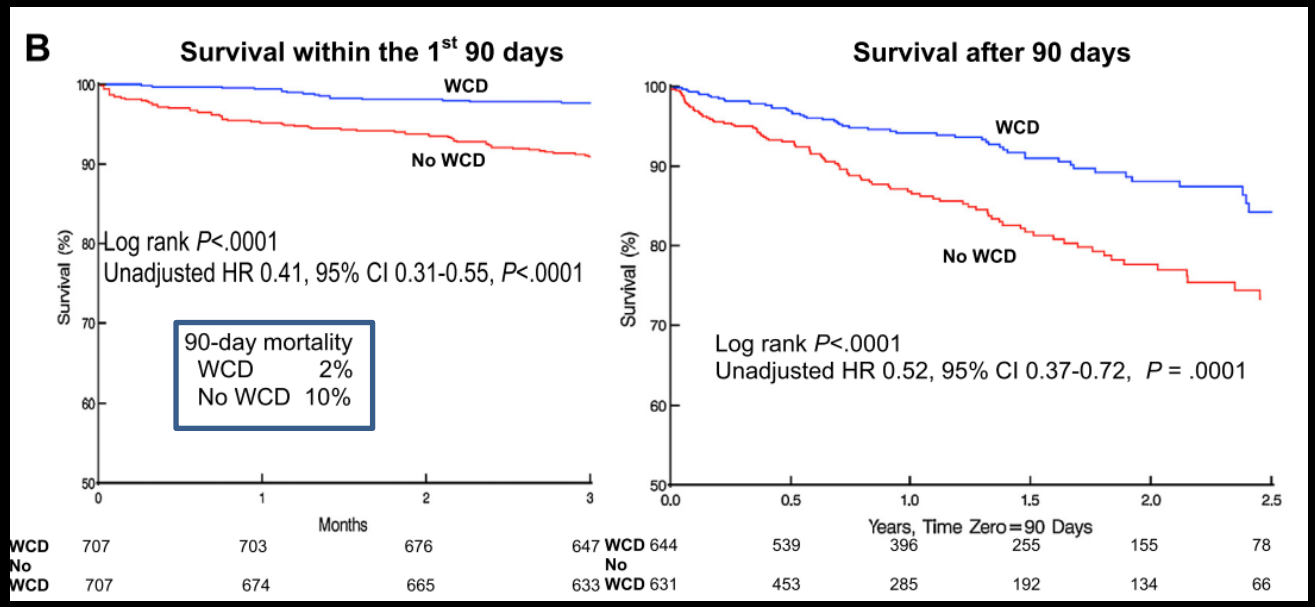
Survival after coronary artery revascularization; Role of WCD

PCI



Propensity score matched groups without WCD

CABG

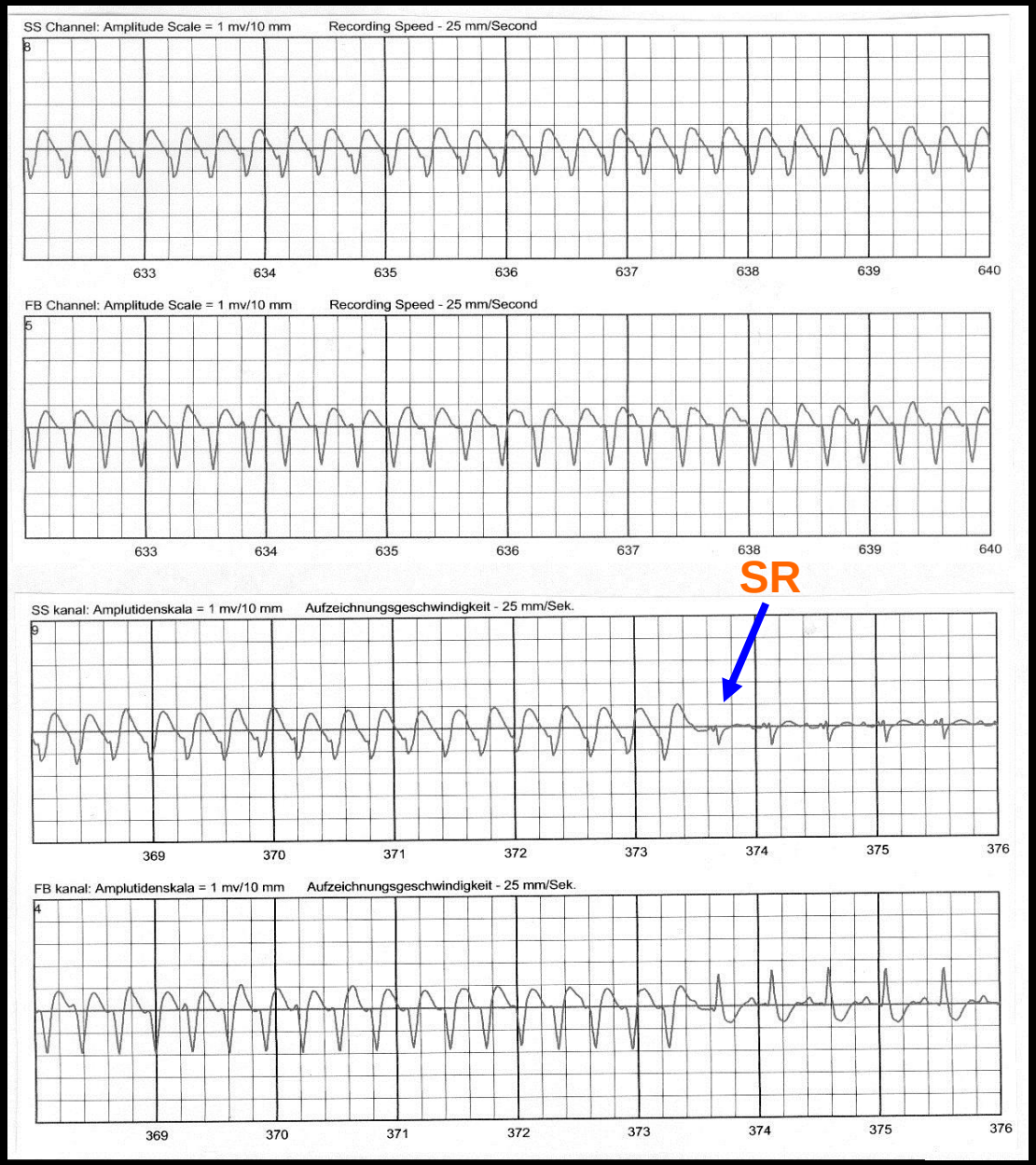


Propensity score matched groups without WCD

E. T. Zishiri et al. Circ Arrhythm 2013; 6: 124-31

spontaneous SR

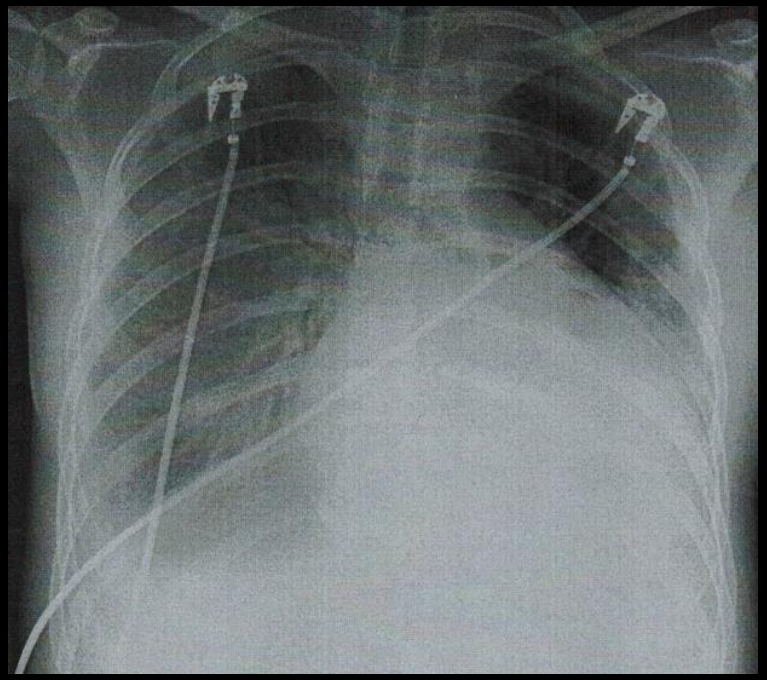
19.5 min after withholding shock with the response buttons

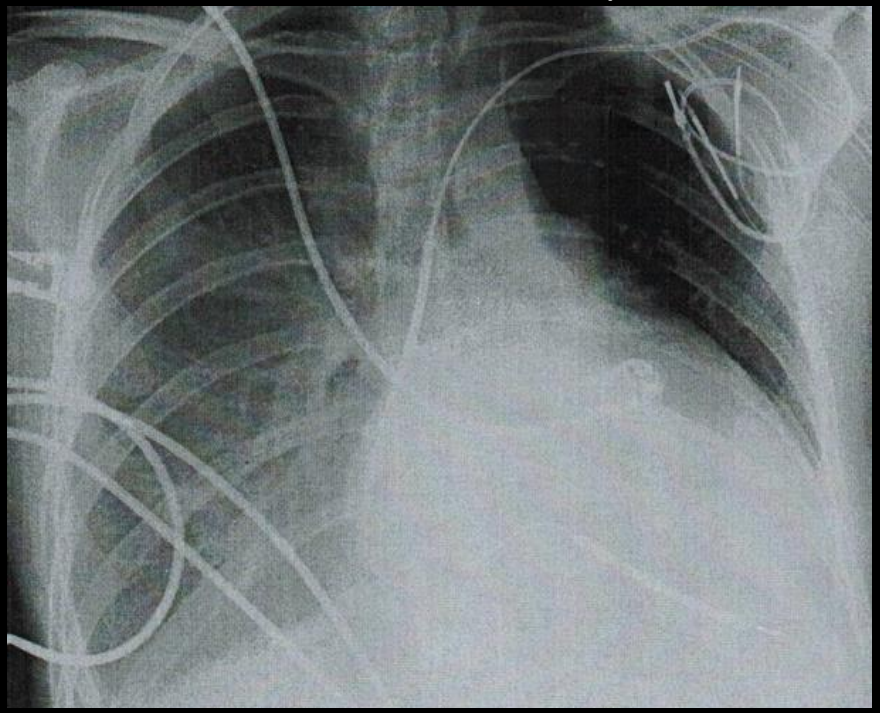


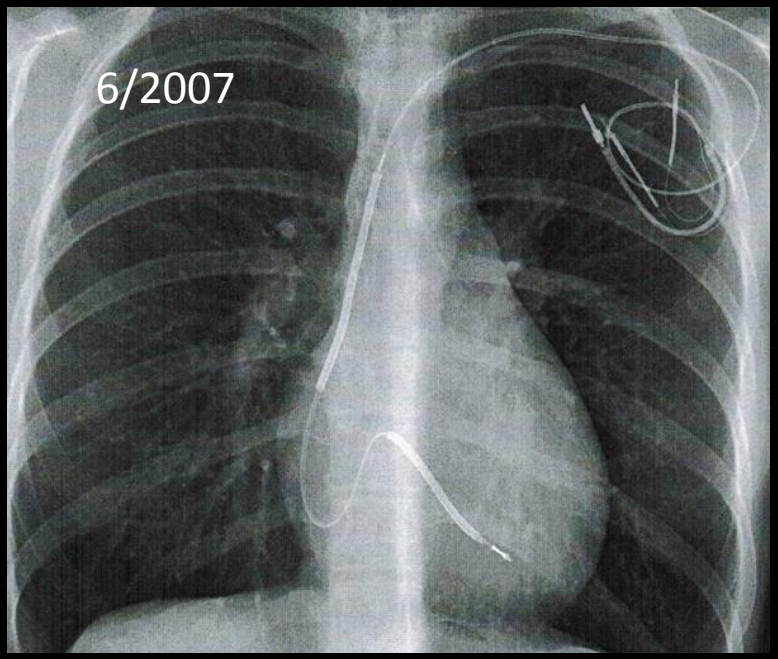
11:47 am

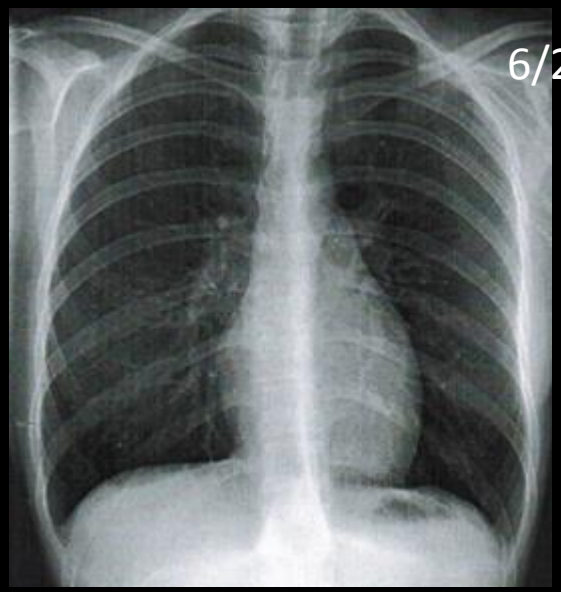
G.B. 58y, male; 7 weeks after AMI at home

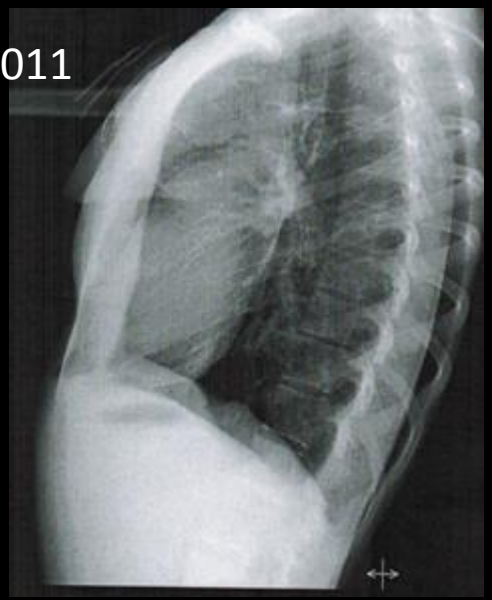
24 y old female









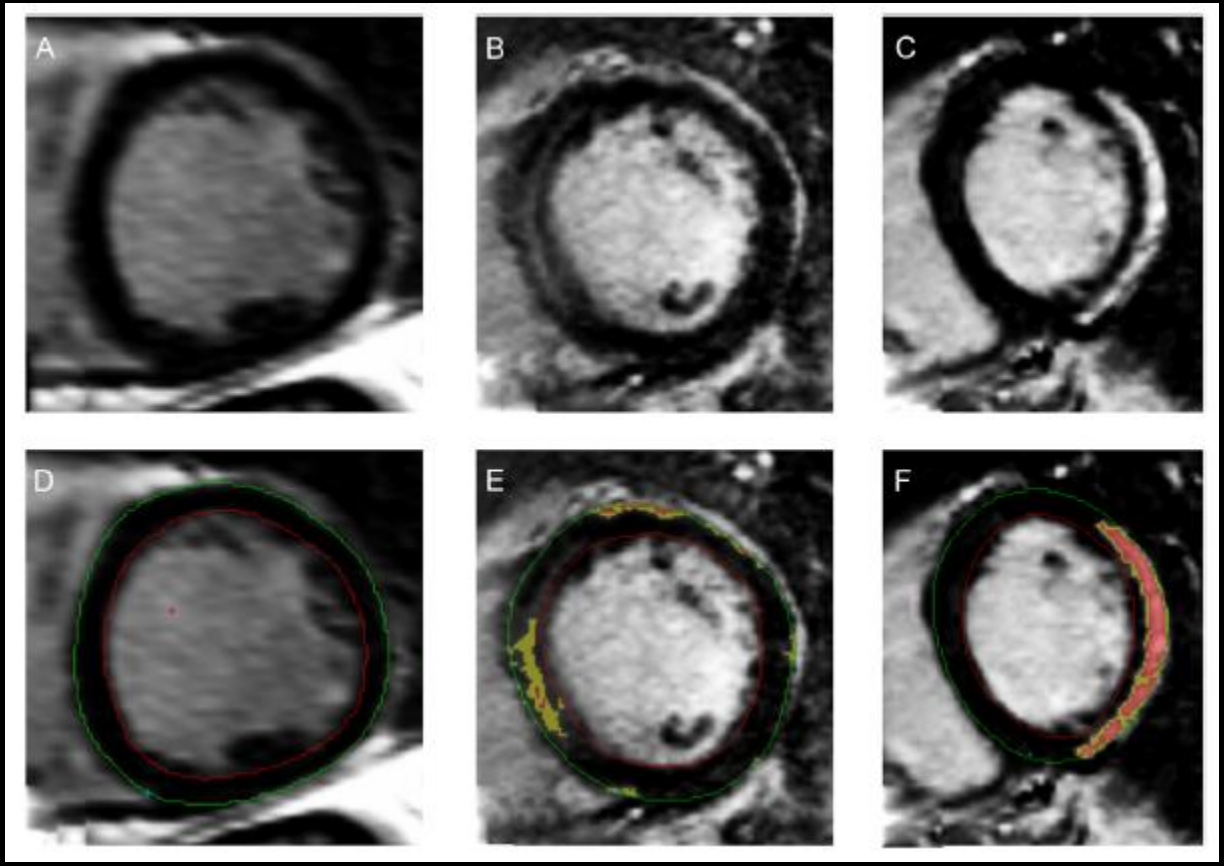


Courtesy by Prof. J. Winter

Effect of myocardial scar on occurrence and type of VAR in patients with non-ischemic cardiomyopathy

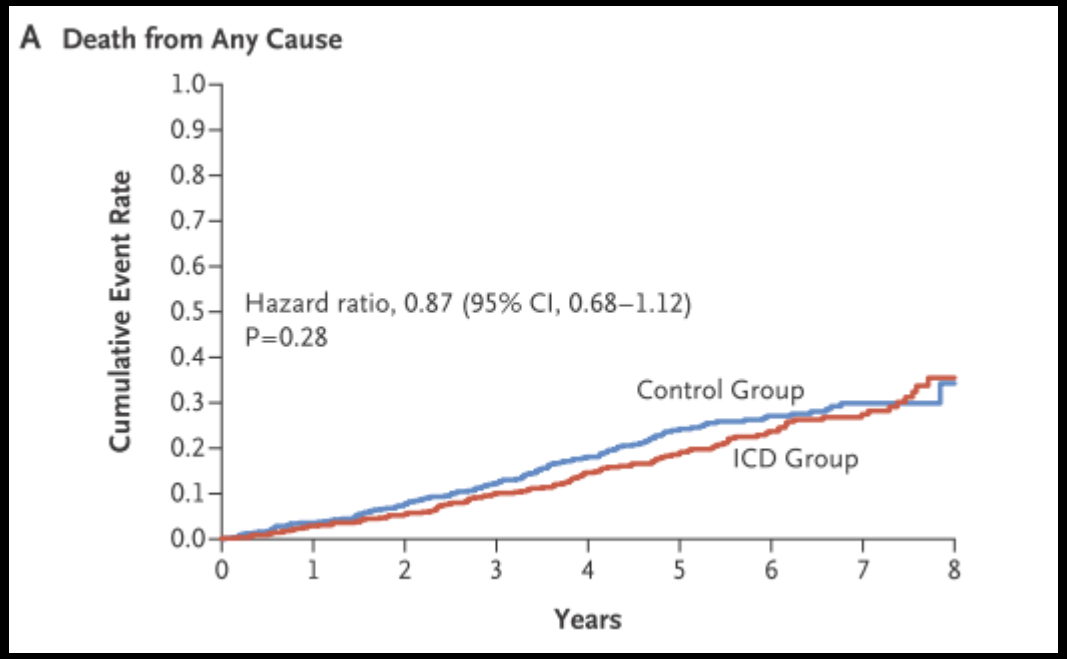
n=87 pts with ICDs
(64 with prim prevent.)

Mean LVEF = 29%,
F-up: 45 months
Mono VT: 18 pts (21%)
Poly VT/VF: 10 pts (11%)
Mean LGE: 6.3 g
Cut-off value: 7.2 g LGE
(no sarcoidosis or amyloidosis)



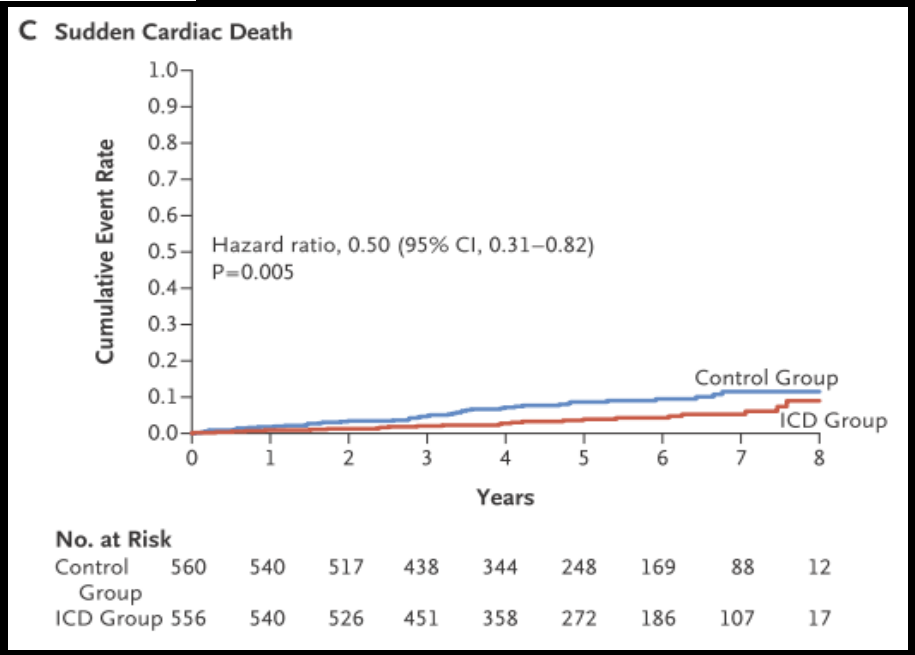
S.R.D. Piers et al. Heart Rhythm 2015; 122106-14

DANISH Trial



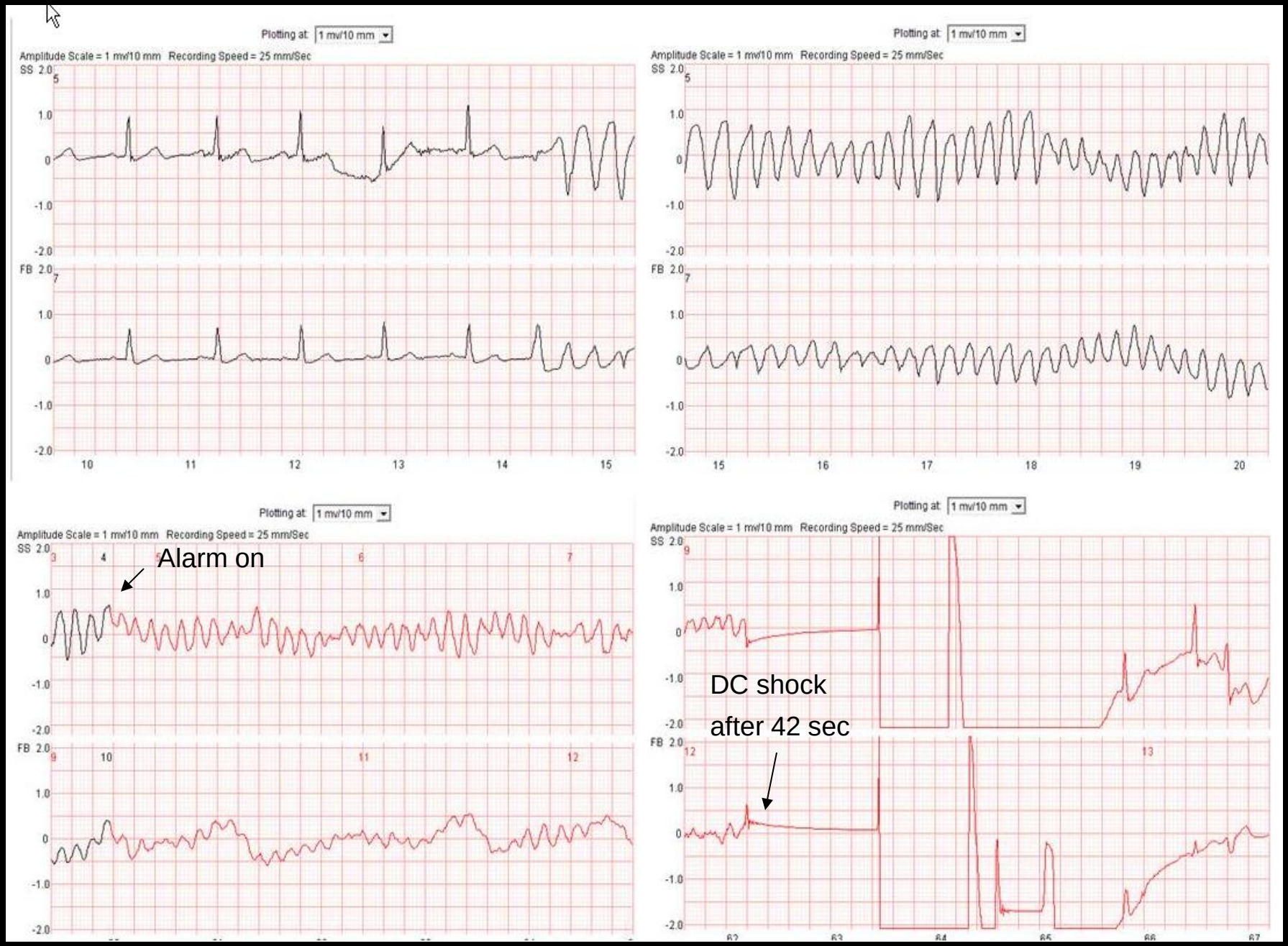
Overall mortality

SCD



SCD: 4.3% ICD
8.2% Control

L. Kober et al. N Engl. J Med 2016 ;
DOI: 10.1056/NEJMoa1608029



B.L. female, 57 Years

10/21/ 2008, 4:41 pm; sitting in a chair, unconscious

WEARIT-II: STUDY POPULATION

- **2000 patients enrolled in the US**

  - Currently enrolling patients in Europe, Israel -

  Data collection: August 2011 – February 2014

- **Ischemic cardiomyopathy: 805 pts, (40.3%)**
- **Non-ischemic CMP : 927 pts, (46.4%)**
- **Cong./inherited: 268 pts, (13.4%)**

V. Kutyifa et al. Circulation 2015;132:1613-19

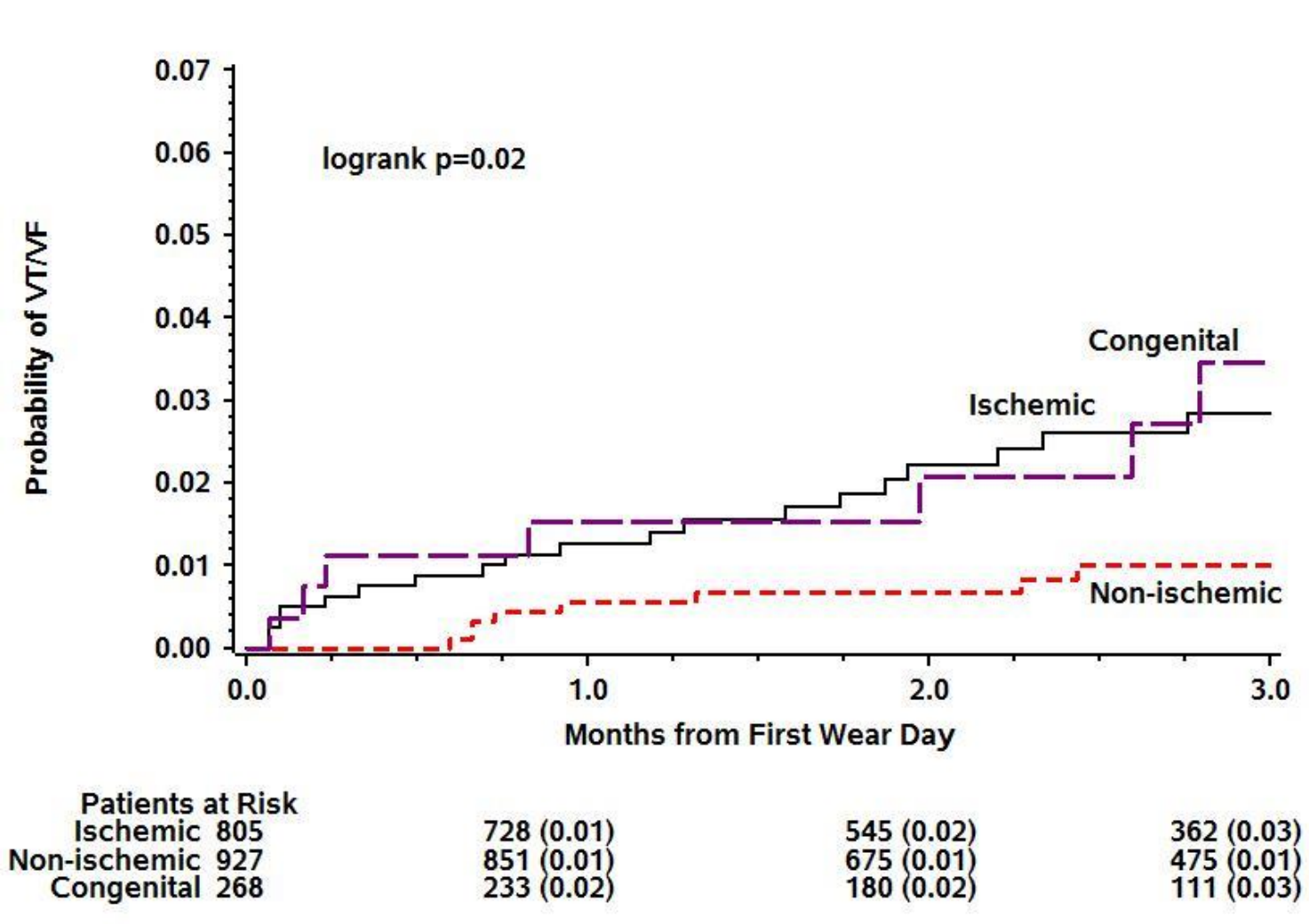
Arrhythmic events

median wearing time: 90 days, median wearing/day: 22,5 h

	Patients (%)	Events (events/pt)	Event Rate Per 100 Pt-Years
Any VT/VF *	41 (2.1%)	120 (2.9)	22
WCD Therapy for VT/VF	22 (1.1%)	30 (1.4)	5
Sustained VT	19 (1.0%)	90 (4.1)	15
Non-sustained VT	28 (1.4%)	164 (5.9)	30
Atrial arrhythmias/SVT	72 (3.6%)	561 (7.8)	101
Asystole	6 (0.3%)	9 (1.5)	2

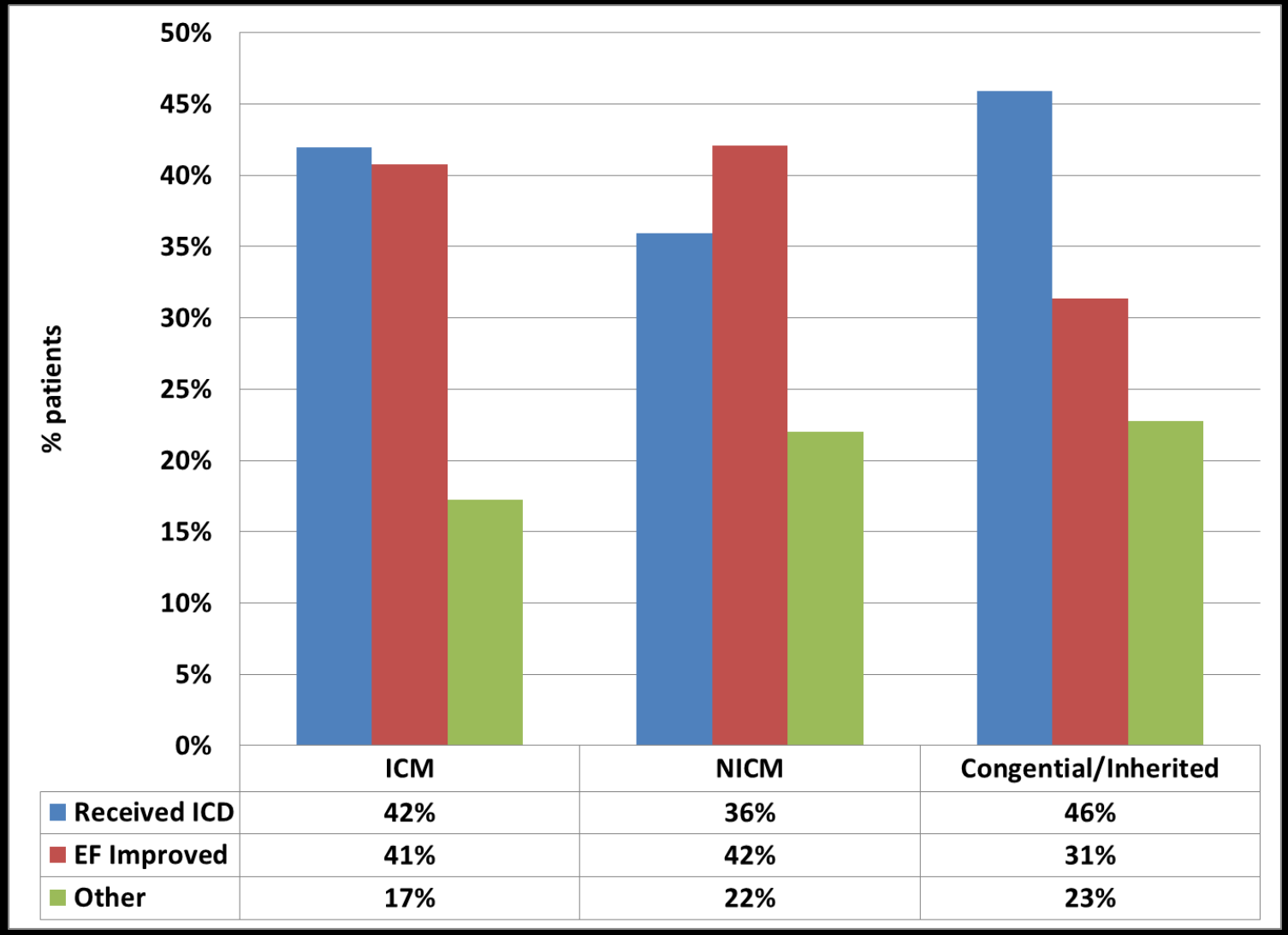
V. Kutyifa et al. Circulation 2015;132:1613-19

VT/VF BY DISEASE ETIOLOGY



V. Kutyifa et al. Circulation 2015;132:1613-19

ICD Implantation rate by disease etiology



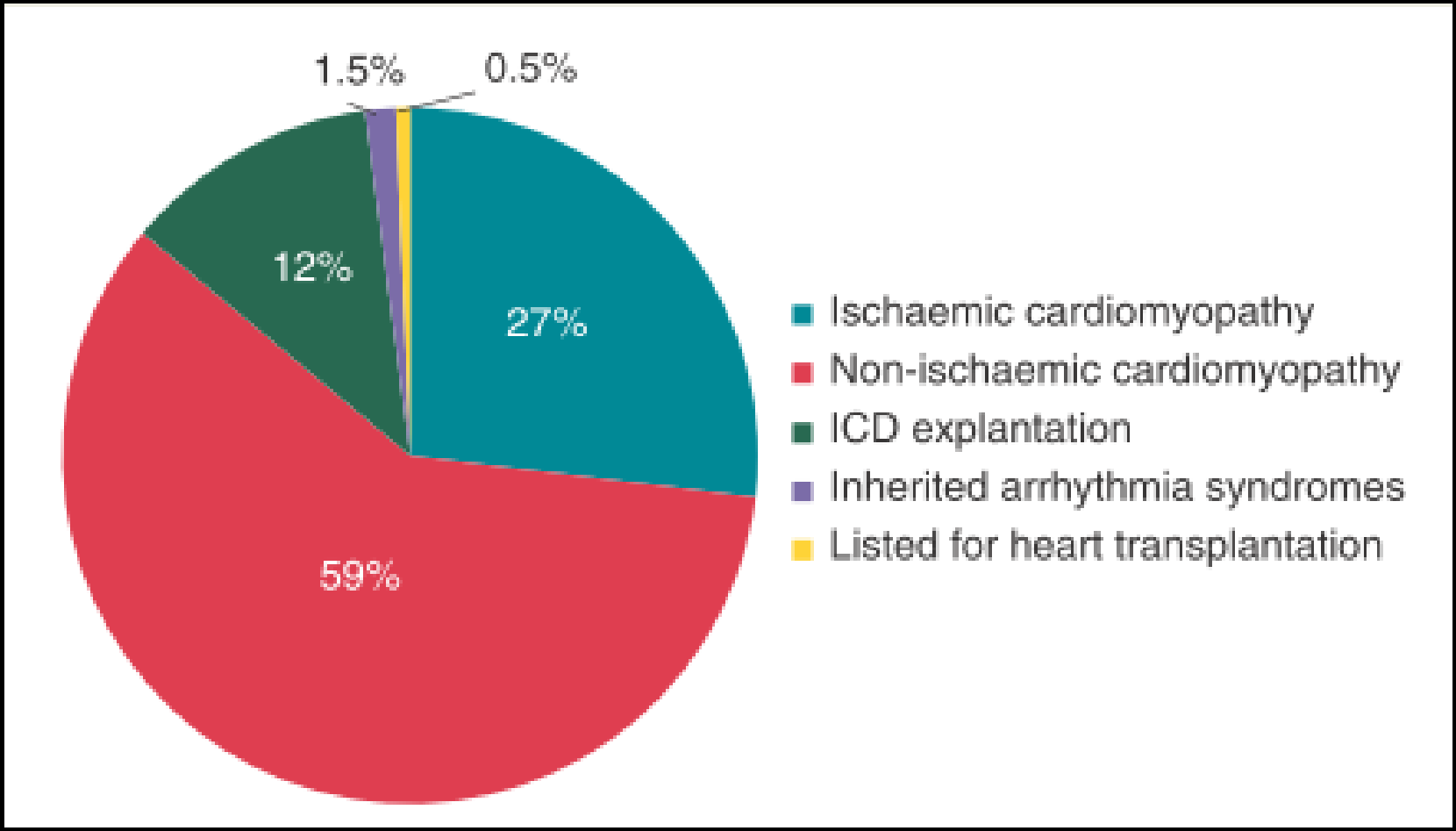
	ICM	NICM	Congential/Inherited
Received ICD	42%	36%	46%
EF Improved	41%	42%	31%
Other	17%	22%	23%

WEARIT-II Registry

V. Kutyifa et al. Circulation 2015;132:1613- 19

German Experience with the WCD (2010-2013)

(N.T. Waessnig et al. Circulation 2016)



6043 pts; mean age 57 y; 78 % males

Appropriate WCD treatment: 94 pts (1.6%)

Survival /24 h: 93%

Inapprop. Shocks: 26 pts (0.4%)

242 episodes of VT in 70 pts (response button)

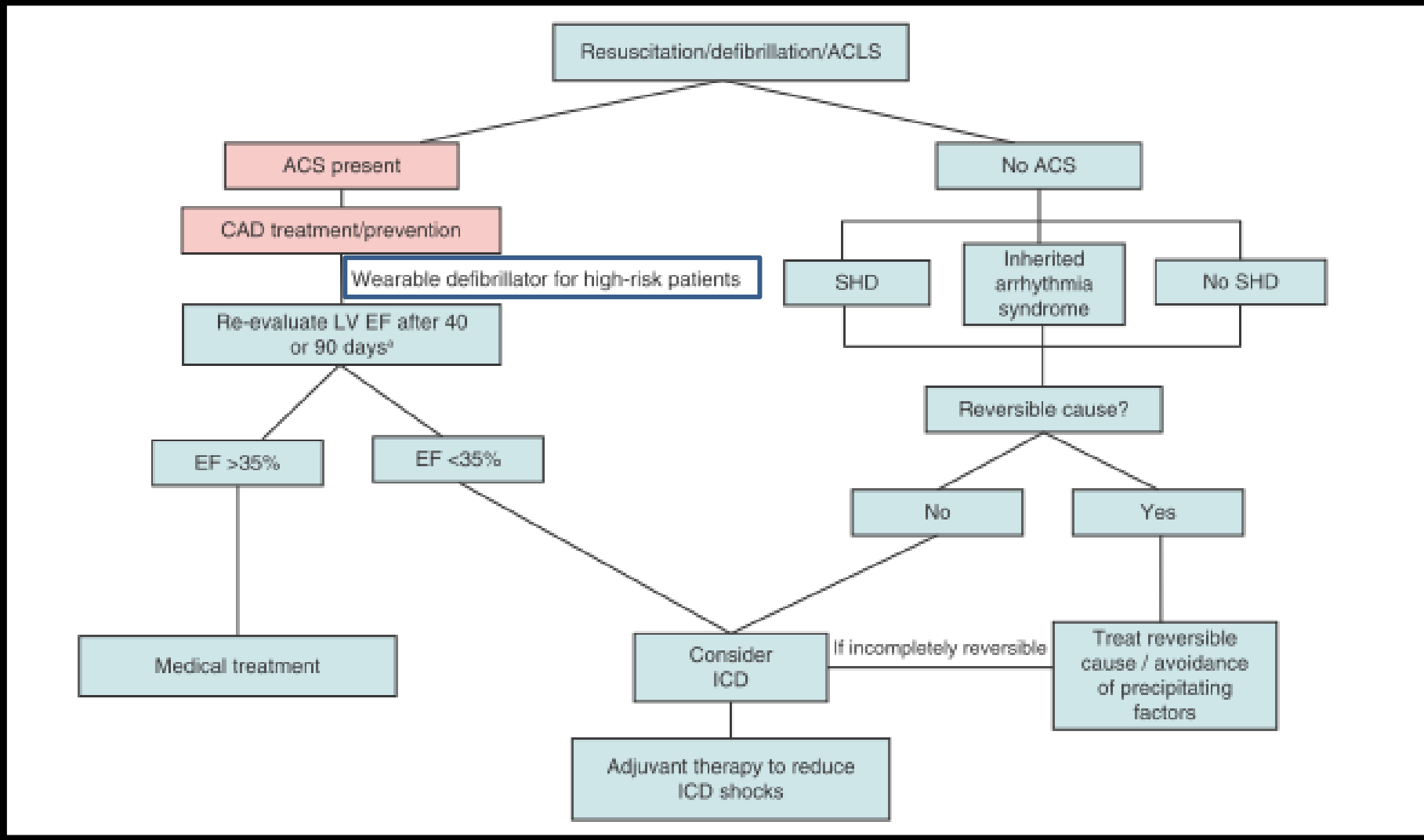
S. Reek et al. Europace 2016 doi 10.1093/europace/euw180

Summary of accepted and potential WCD indications

Clinical situation	Period of WCD wearing	End of WCD usage
Accepted indications[a]		
Acute myocardial infarction with LVEF ≤ 35%	40–90 days	LVEF improvement or indicated ICD implantation
Before/after revascularization procedures (CABG/PCI) with LVEF ≤ 35%	3–4 months	LVEF improvement or indicated ICD implantation
Recent onset cardiomyopathy NICM or presumed myocarditis with acute heart failure and/or LVEF ≤ 35%	3–6 months	LVEF improvement or indicated ICD implantation
Intermittent bridging after ICD removal (e.g. infection)	1–2 months	Completion of antibiotic therapy and ICD re-implantation
Delayed but indicated ICD implantation	2–3 months or longer	Resolution of cause of delay
Bridge to heart transplantation	Variable	Until heart transplantation
Potential indications		
Period of risk stratification in cases with syncope/cardiac arrest of unknown origin; cases with suspected inherited arrhythmia syndromes	Usually 1–3 months	Until risk has been defined
Protection in patients with LV assist device	Undetermined	Until heart transplantation, at the end of a risk stratification prior or until ICD implantation
Potentially dangerous ECG changes with drugs (e.g. QT prolongation)	Variable, depends on continuous drug administration or elimination kinetics	Withdrawal of the drug and normalization of ECG changes

Reek et al. Europace 2016 doi 10.1093/europace/euw180

EHRA/HRS/APHRS Expert Consensus on VAR



CT Pedersen et al. Heart Rhythm 2014 ; 11: e166-96

ESC Guidelines

for the management of pts with ventricular arrhythmias and the prevention of sudden cardiac death

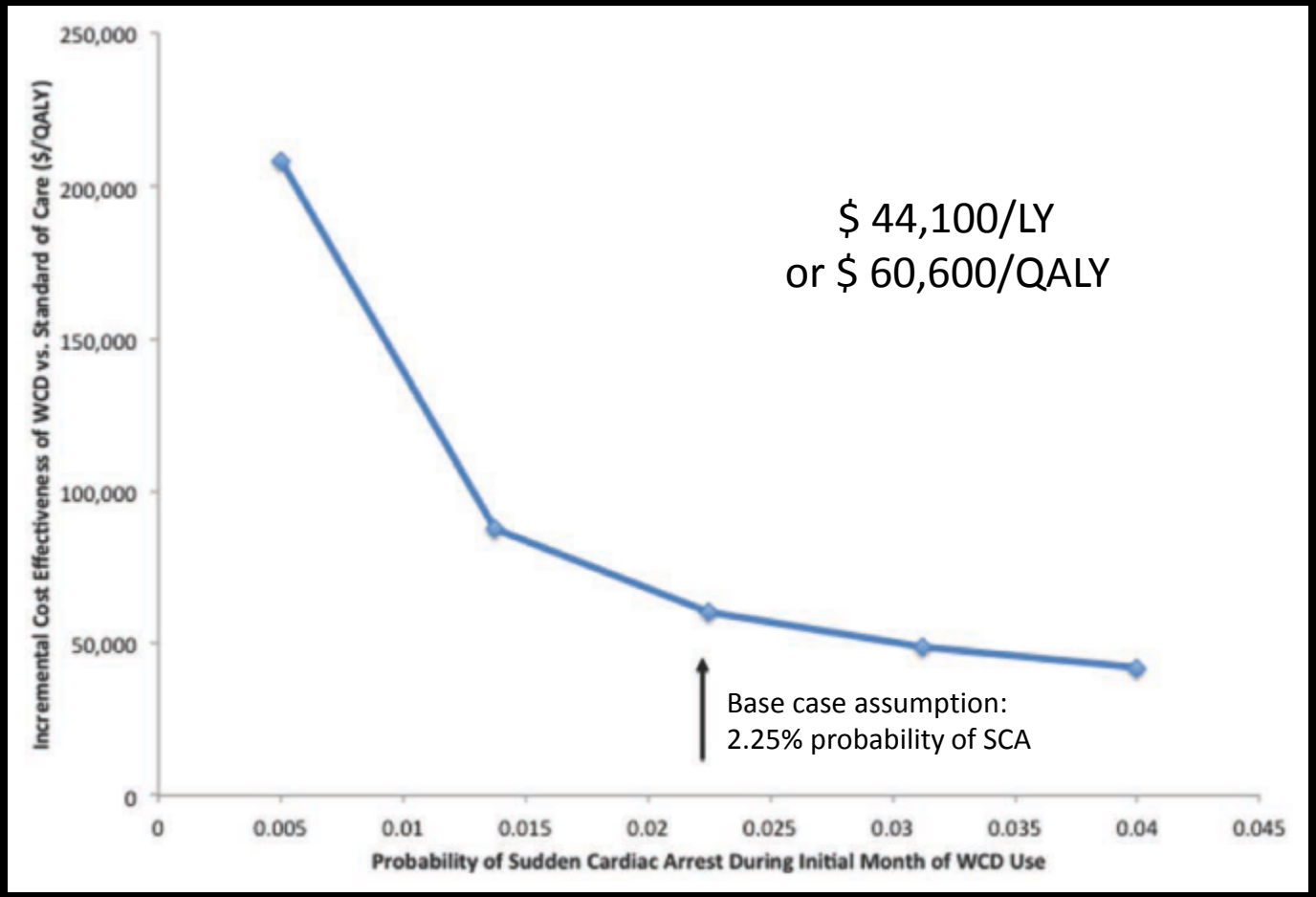
Wearable cardioverter defibrillator

Recommendation	Class[a]	Level[b]	Ref.[c]
The WCD may be considered for adult patients with poor LV systolic function who are at risk of sudden arrhythmic death for a limited period, but are not candidates for an implantable defibrillator (e.g. bridge to transplant, bridge to transvenous implant, peripartum cardiomyopathy, active myocarditis and arrhythmias in the early post-myocardial infarction phase).	IIb	C	167, 168

LV = left ventricular; WCD = wearable cardioverter defibrillator.
[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting recommendations.

S. G. Priori et al. EUROPACE 2015; 17: 1601-87

Incremental Cost-effectiveness ratio of the WCD compared with standard of care ($ per quality adjusted life year gained)



Sensitivity analysis: Probability of sudden arrhythmic event during the first month after AMI

GD Sanders et al. J Cardiac Rhythm Management 2015; 6:1929-40

Conclusion

- The WCD is not a therapy;
  it is a diagnostic tool to confirm ICD therapy when the permanent risk has been reliably assessed….
- or to defer ICD therapy when the assumed risk has diminished or disappeared
- During the time of risk assessment the patient is reliably protected from SCD
- The WCD is a reliable long-term ECG-monitoring device that provides valid information on arrhythmic events during risk assessment