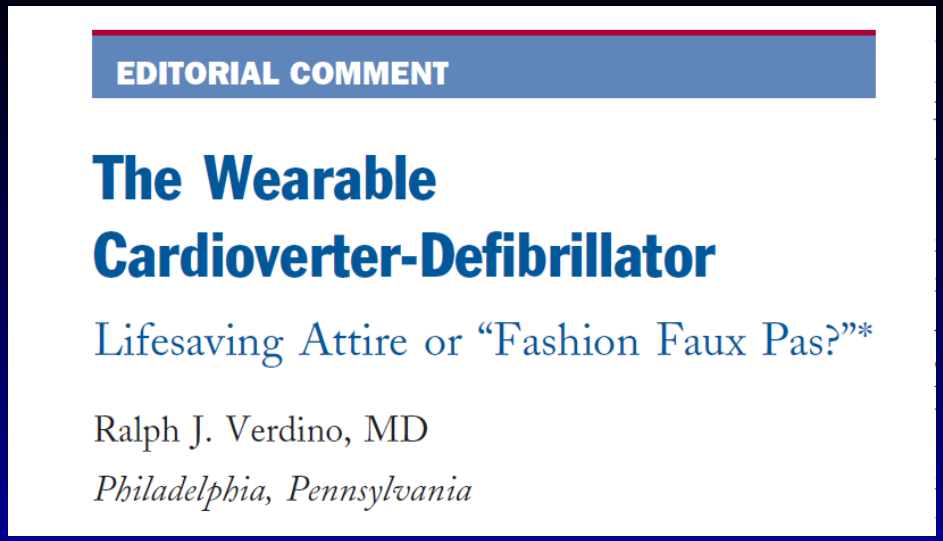
Welcher Patient benötigt eine life-vest?

Bernhard Zrenner

Medizinische Klinik I
Krankenhaus Landshut-Achdorf
Lehrkrankenhaus der Technischen Universität München

Editorials zum WCD



EDITORIAL COMMENT

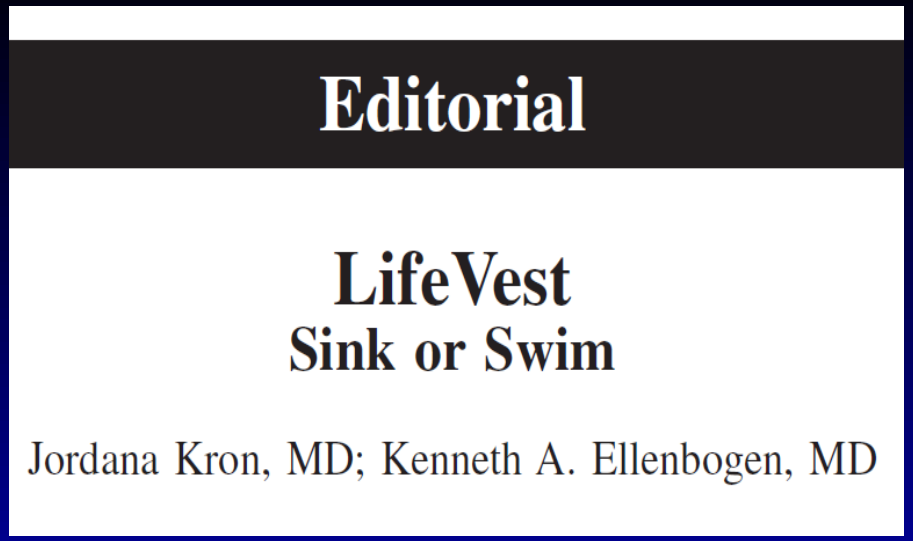
The Wearable Cardioverter-Defibrillator

Lifesaving Attire or "Fashion Faux Pas?"*

Ralph J. Verdino, MD

Philadelphia, Pennsylvania

Verdino, Journal of the American College of Cardiology 2010 Vol. 56, No. 3,



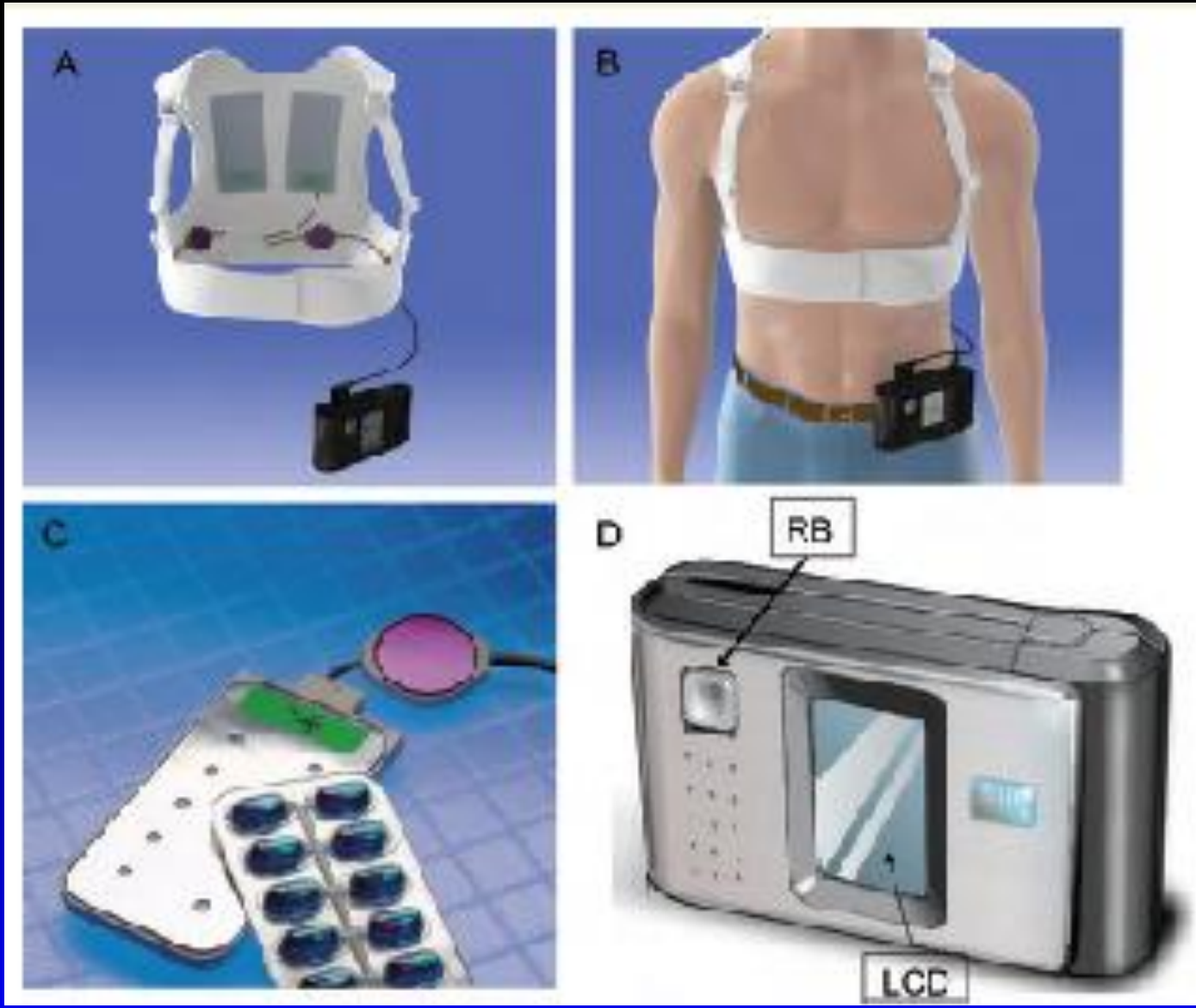
Editorial

LifeVest
Sink or Swim

Jordana Kron, MD; Kenneth A. Ellenbogen, MD

Kron et al, Circ Arrhythm Electrophysiol. 2013; 6:5-6

LifeVest w model 4000



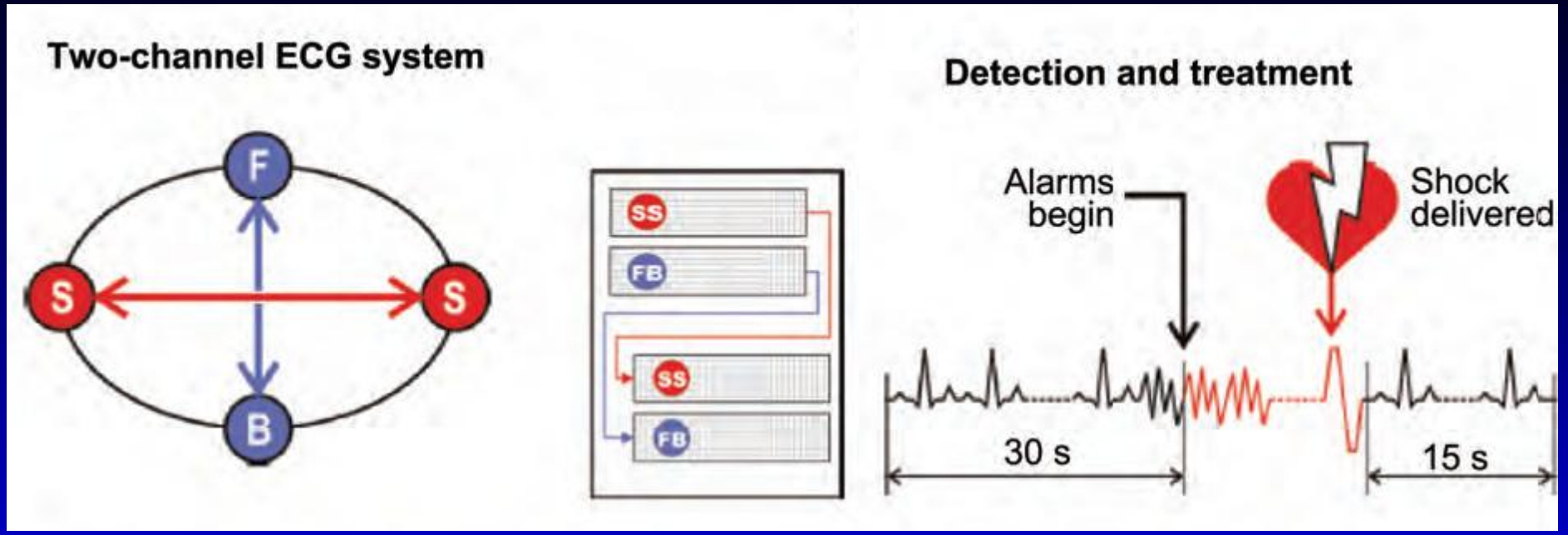
Klein et al, European Heart Journal (2013) 34, 2230–2242

LifeVest w model 4000

Klein et al, European Heart Journal (2013) 34, 2230–2242

LifeVest w model 4000

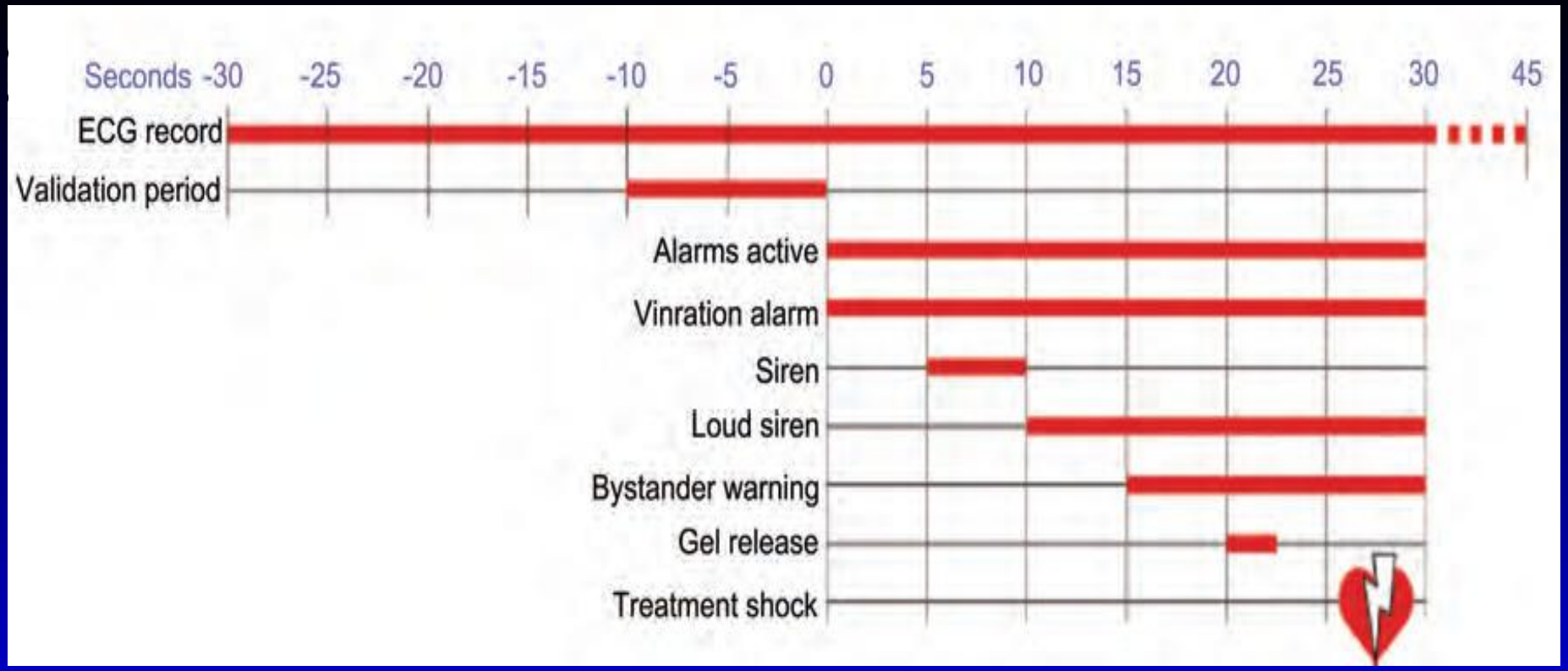
EKG Aufzeichnung und Therapieablauf



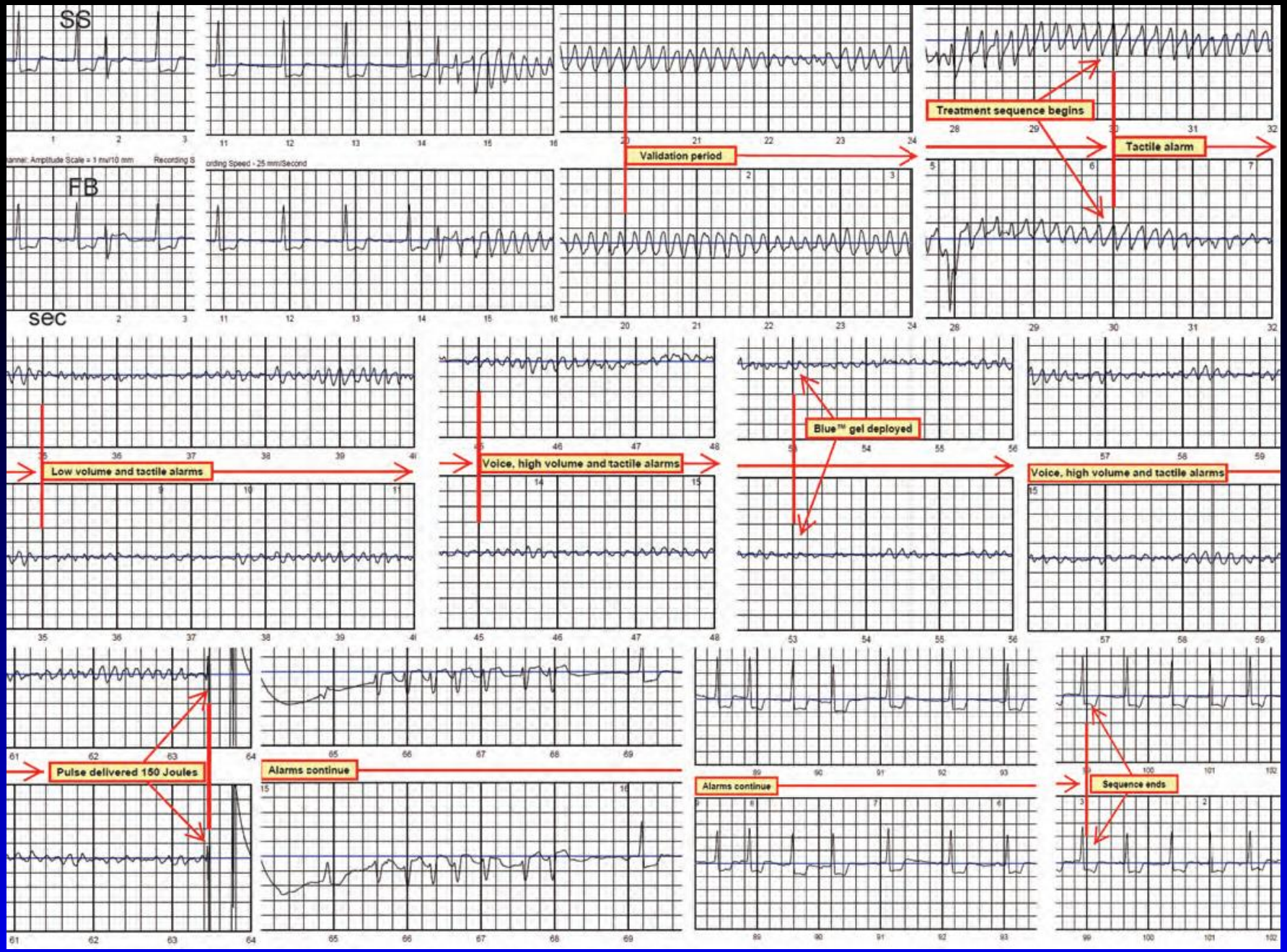
Klein et al, European Heart Journal (2013) 34, 2230–2242

LifeVest w model 4000

EKG Aufzeichnung und Therapieablauf



Klein et al, European Heart Journal (2013) 34, 2230–2242



Klein et al, European Heart Journal (2013) 34, 2230–2242

Programming Parameters of the WCD

Programming Ventricular Tachycardia (VT)

Programmable: 120 - VF cut-off
(default 150 b.p.m.)
Recommendation: 170–220 b.p.m.

Shock delay
Programmable 60–180 s
(default 60s - at night 0–30 s)

Recommendation: 60 s; - at night 90 s

Shock energy
Programmable: 75–150 J
Recommendation: 150 J

Programming Ventricular fibrillation (VF)

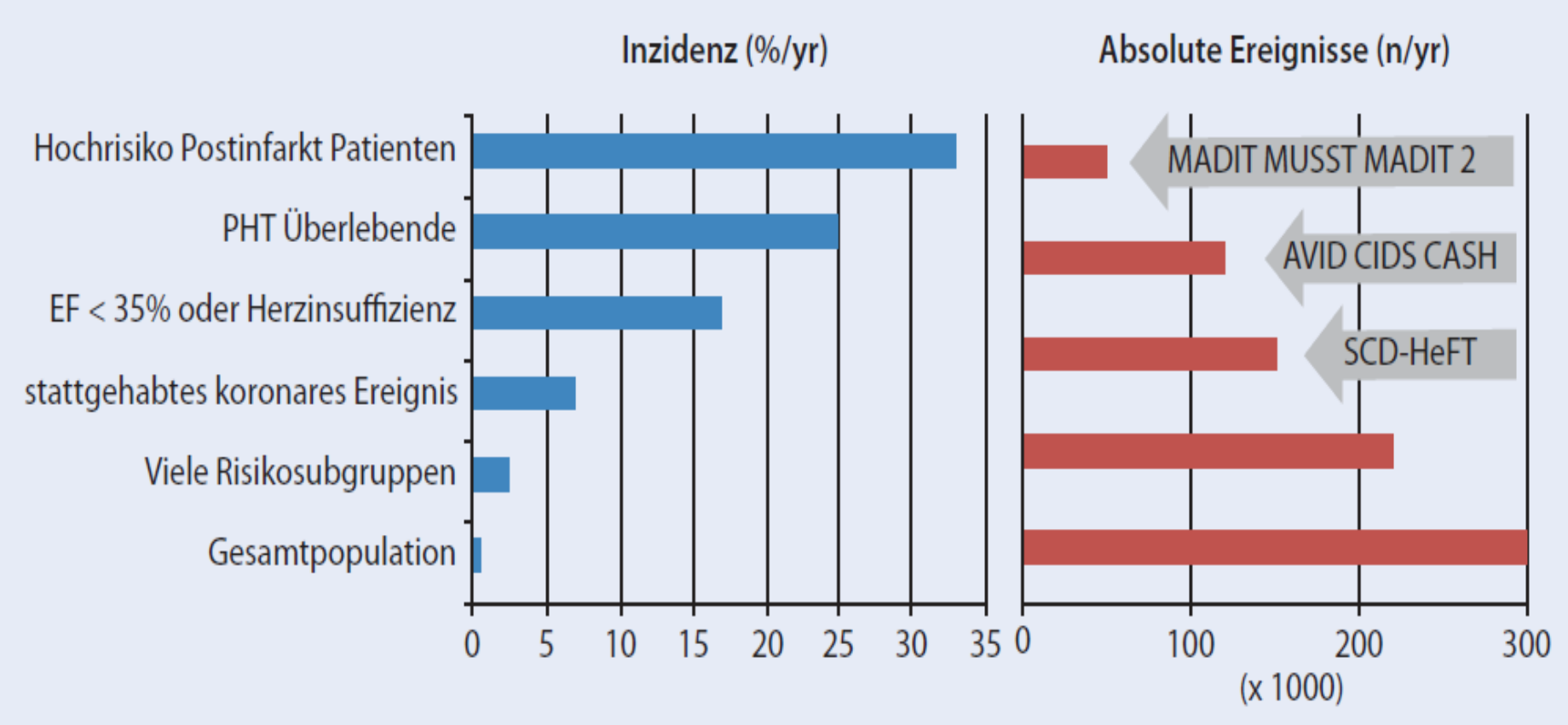
Programmable: 120–250 b.p.m.
(default 200 bpm)
Recommendation: .220 b.p.m.

Shock delay
Programmable 25–55 s
(default 25s)

Recommendation: 30 s; - no shock delay at night

Shock energy
Programmable: 75-150 J
Recommendation: 150 J

Population und Inzidenz des PHT



Cadillac Risk Score

Risikofaktor	Score
LVEF < 40 %	4
Niereninsuffizienz	3
Killip-Klassifikation 2 und 3	3
Finaler TIMI-Fluss 0–2	2
Alter > 65 Jahre	2
Anämie	2
Koronare 3-Gefäß-Erkrankung	2
Gesamtpunktzahl	0–18

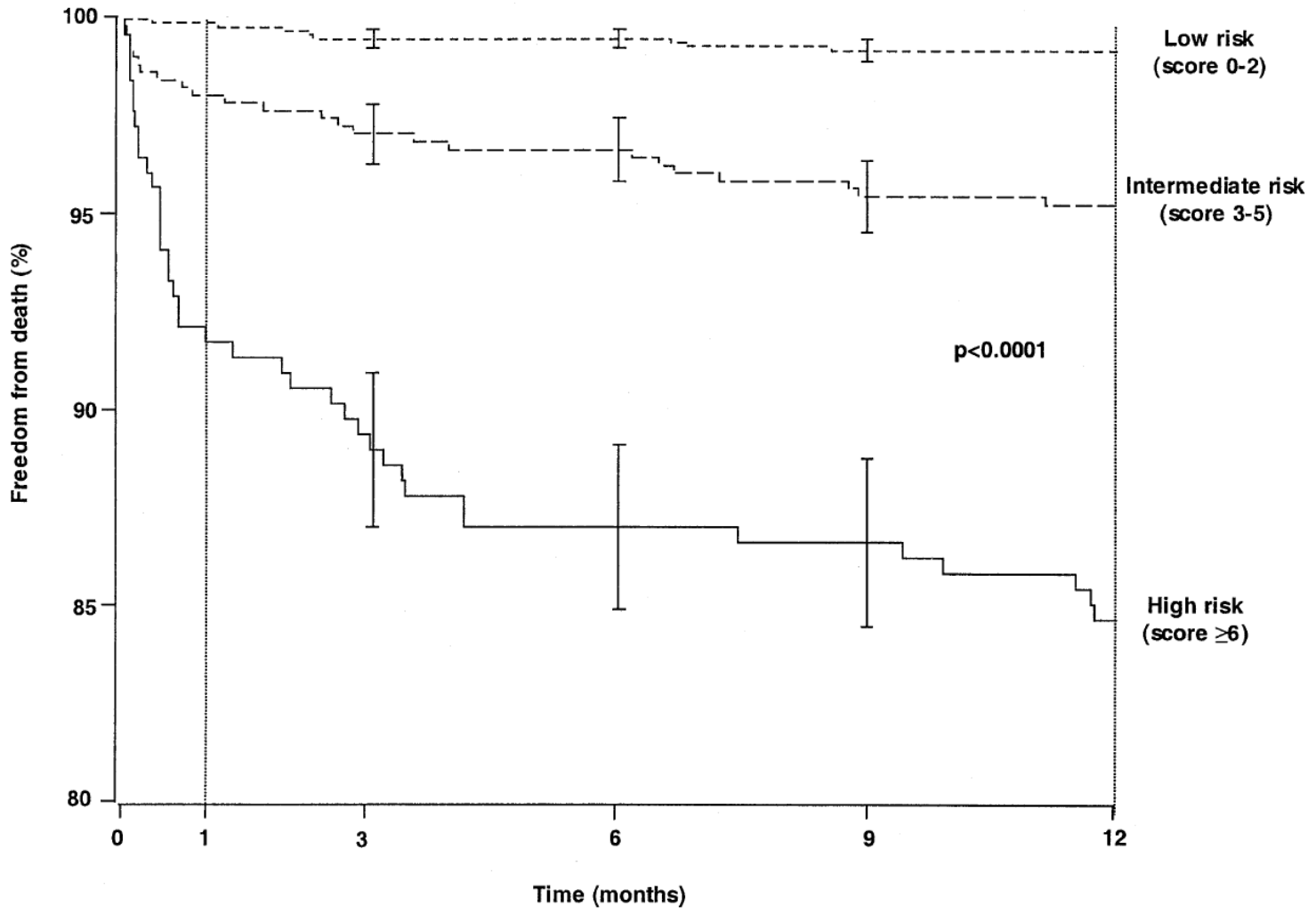
Tab. 2 Prognostische Bedeutung des CADILLAC-Scores

Risikoeinschätzung	Niedrig	Mittel	Hoch
Punktzahl	0–2 Punkte	3–5 Punkte	≥ 6 Punkte

Halkin A et al, J Am Coll Cardiol 2005 45(9):1397–1405
Wickenbrock et al, Herzschr Elektrophys 2014 25:47–52

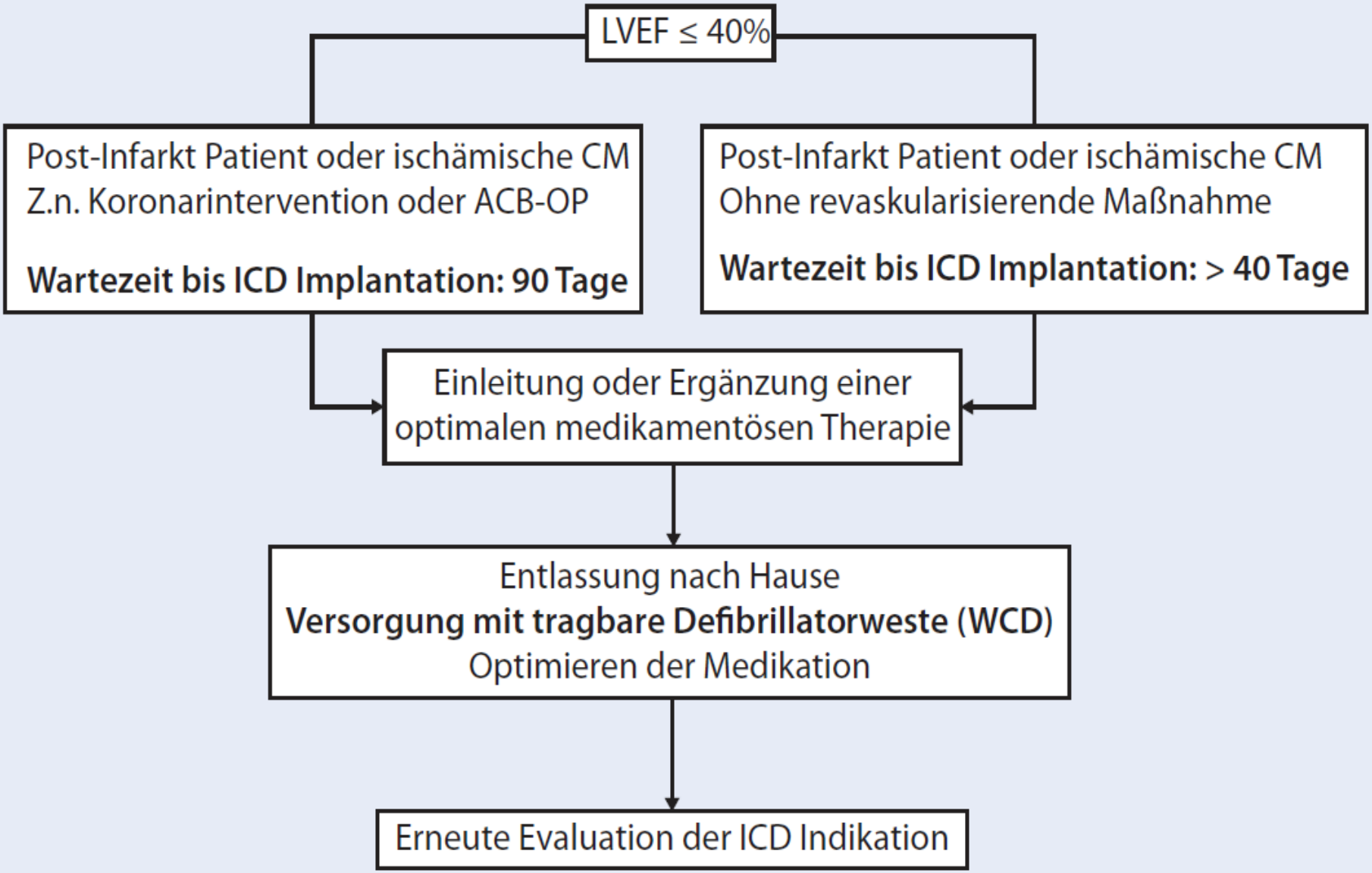
Freedom from all-cause mortality

among the CADILLAC trial patients stratified by risk class



Halkin A et al, J Am Coll Cardiol 2005 45(9):1397–1405

Neue Feststellung einer LV-EF<40%



WCD Clinical Trials and Registries

Authors	Inclusion Criteria	Patients, n	Mean WCD Use Time, d	Appropriate Shocks, No. VT or VF Events/No. Patients	First-Shock Success Rate, %	Inappropriate Shock, No. Events/No. Patients	Mortality,* %
Auricchio et al[3]	Patients undergoing EPS because of SCA†	9	...	...	100	...	...
Reek et al[4]	Patients undergoing EPS because of VT	12	...	...	100	...	...
Rao et al[9]	CSHD	43	27	0	...	0	**5**
	IA	119	29	3/2	100	7/4	**2**
Saltzberg et al[10]	PPCM	107	124	0	...	0	**0**
	NIDCM (women only)	159	96	2/1	100	0	**7**
Feldman et al[5] (WEARIT/BIROAD)	Symptomatic HF and EF ≤30% or high risk of sudden death after MI/CABG	289	93	8/6	75	6/6	**4**
Klein et al[6]	All comers	354	106	21/11	95	3/NA	NA
Chung et al[7]	All comers	3569	53	80/59	99	NA/67	**1**

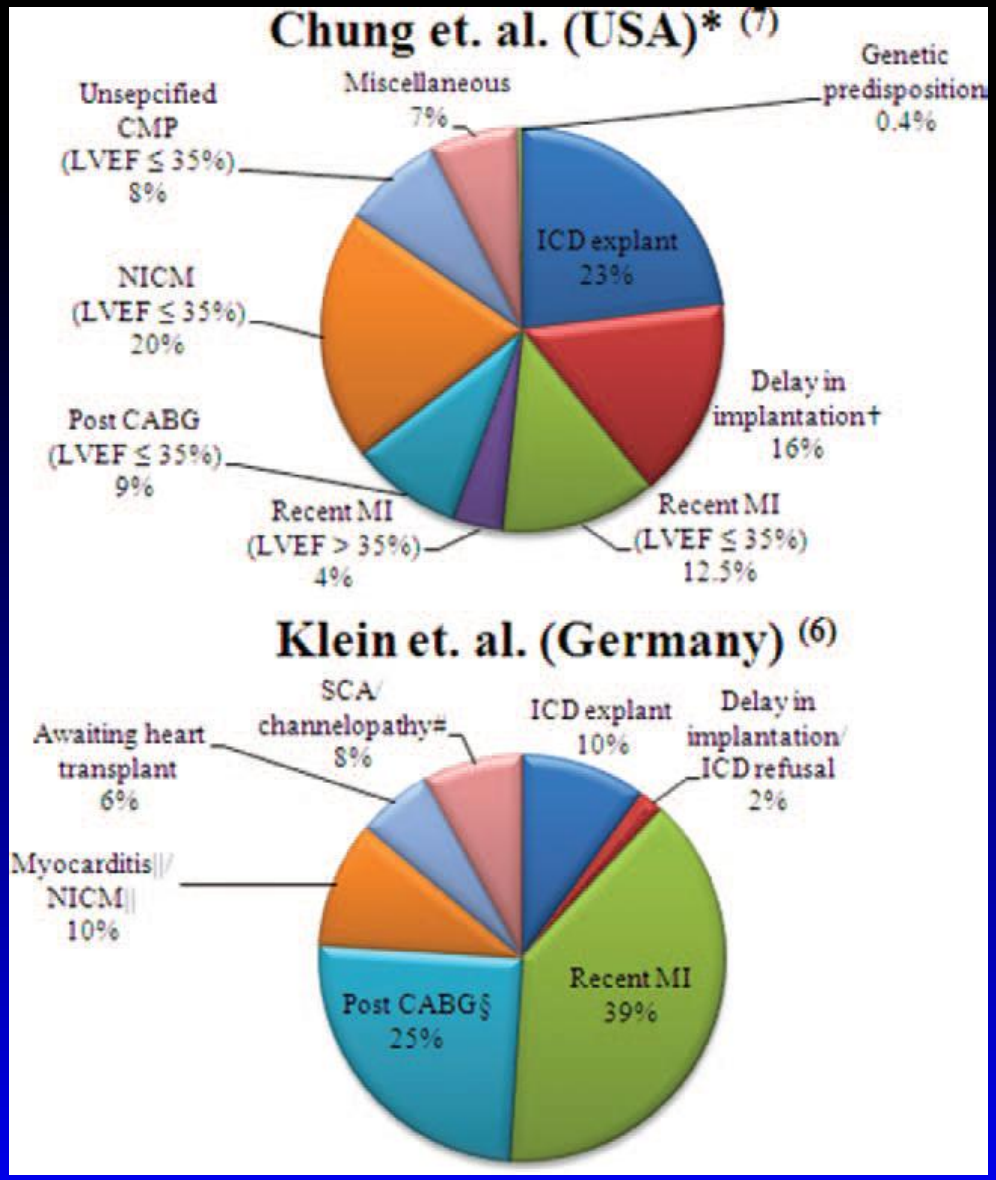
CABG, coronary artery bypass graft; CSHD, congenital structural heart disease; EF, ejection fraction; EPS, electrophysiological testing; HF, heart failure; IA, inheritable arrhythmia; MI, myocardial infarction; NIDCM, nonischemic dilated cardiomyopathy; PPCM, peripartum cardiomyopathy; VF,ventricular fibrillation; VT,ventricular tachycardia; WCD, wearable cardioverter-defibrillator; and WEARIT/BIROAD, Wearable Defibrillator Investigative Trial and Bridge to ICD in Patients at Risk of Arrhythmic Death.

* Mortality during wearable defibrillator use period.

†All episodes were VF induced during the EPS, and the WCD was used only during the EPS.

Adler et al, Circulation. 2013;127:854-860

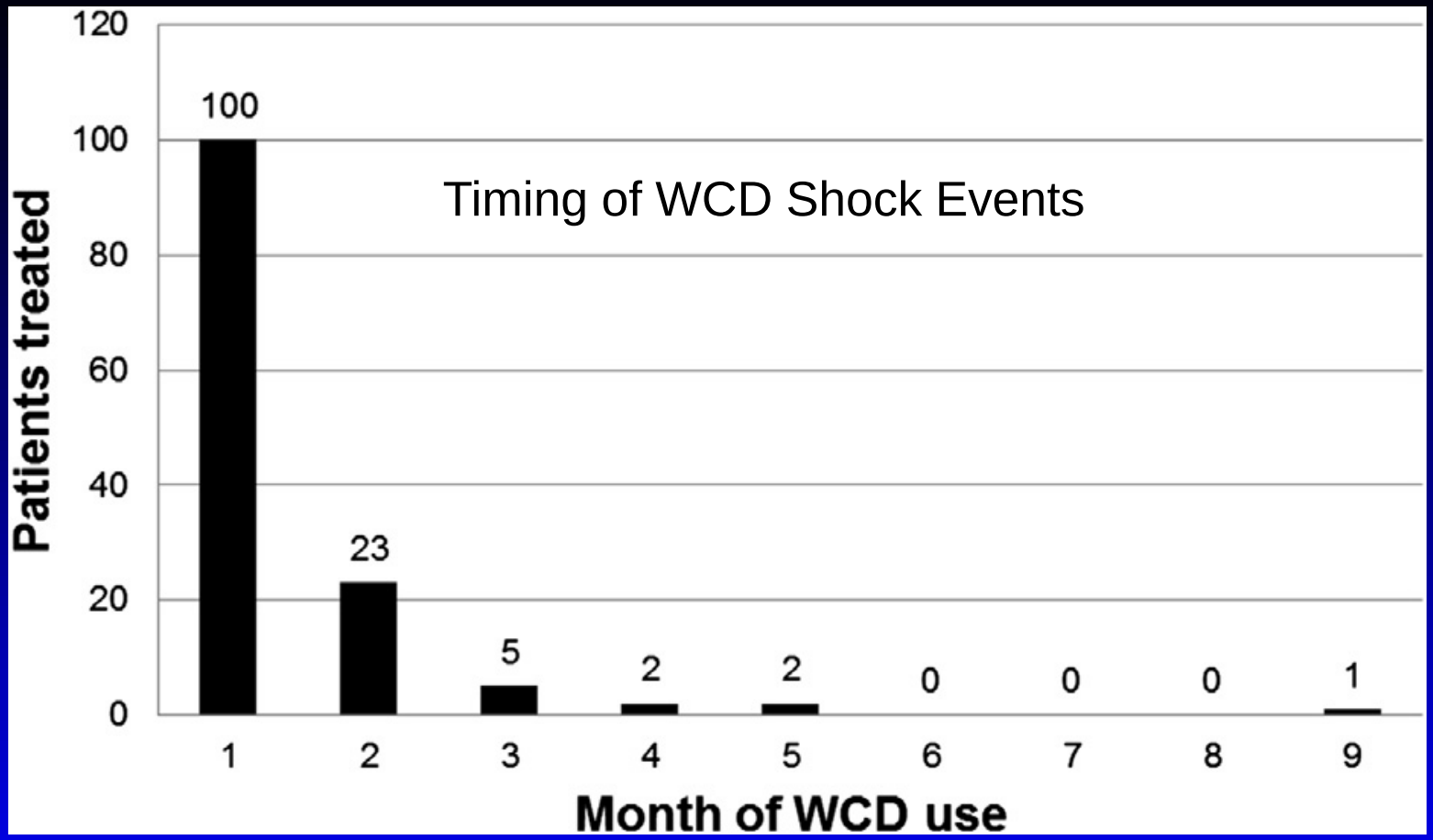
Indications for WCD therapy



Adler et al, Circulation. 2013;127:854-860

WCD Use

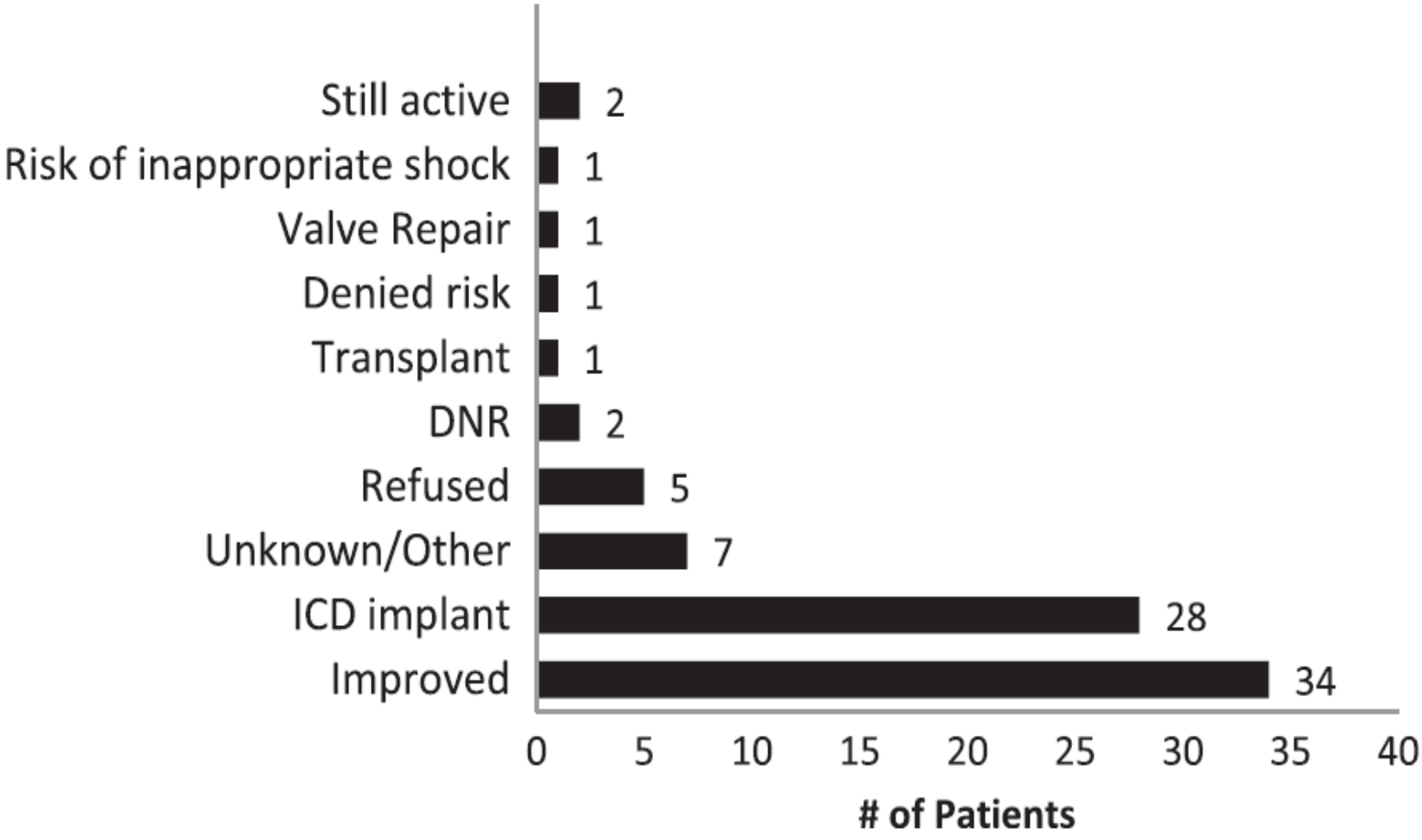
Patients Perceived to be at High Risk Early Post-Myocardial Infarction



Epstein et al, Journal of the American College of Cardiology, 2013 Vol. 62, No. 21

WCD

Reasons to end therapy

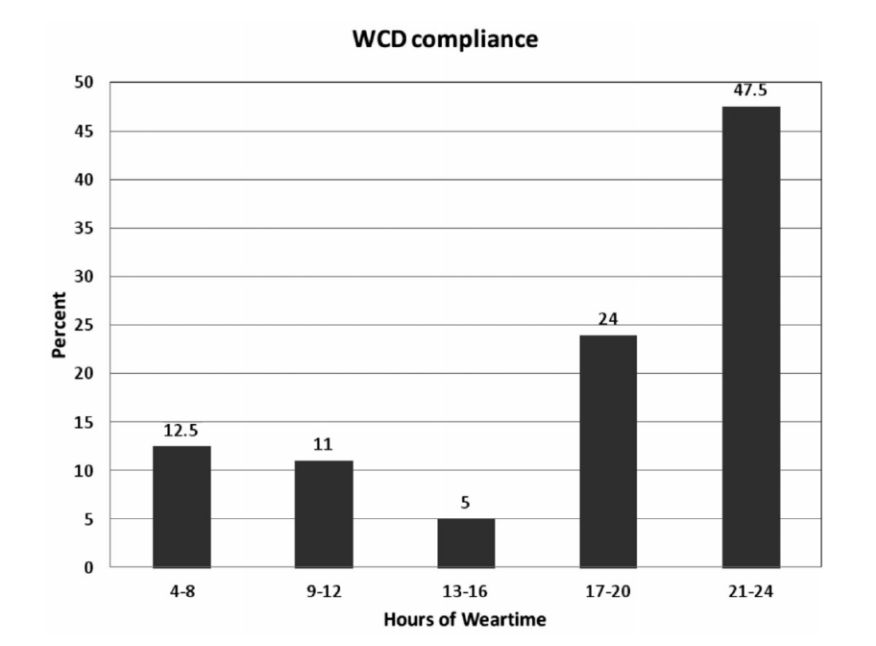


Kao et al, BMC Cardiovascular Disorders 2012, 12:123

Protection from Outpatient Sudden Cardiac Death following ICD Removal Using a Wearable Cardioverter Defibrillator

97 patients (mean age 62.8)
The median duration of antibiotic use was 14.7 days.
The median daily WCD use was 20 hours/day and the median length of use was 21 days.
3 patients were shocked by WCD. 2 patients for sustained VT, successfully terminated by theWCD. A third patient experienced two inappropriate treatments due to oversensitivity of the signal artifact.
3 patients experienced sudden death outside the hospital while not wearing the device.
5 patients died while hospitalized.

Compliance of patients (average hours of daily wear).



Tanawuttiwat et al, PACE 2014

Mögliche WCD Indikationen

Risk stratification	Bridging period for ICD or Heart transplantation	Future indication for WCD (?)
After AMI; LVEF ≤ 35% with or without PCI	ICD explantation for infection or lead problems	Haemodialysis patients
Revascularization with CABG or PCI with LVEF ≤35%	Delayed ICD implantation due to co-morbidities	Peri-partum cardiomyopathy
Non-ischaemic cardiomyopathy with acute heart failure; suspected myocarditis; LVEF ≤40%	Waiting list for Heart transplantation	Chemotherpy-induced cardiomyopathy
Syncope of unknown cause with structural heart disease	Patients on LV-assist devices	Drug-induced QT-prolongation
Suspected inherited arrhythmia syndrome		After VT-catheter ablation

Klein et al, European Heart Journal (2013) 34, 2230–2242

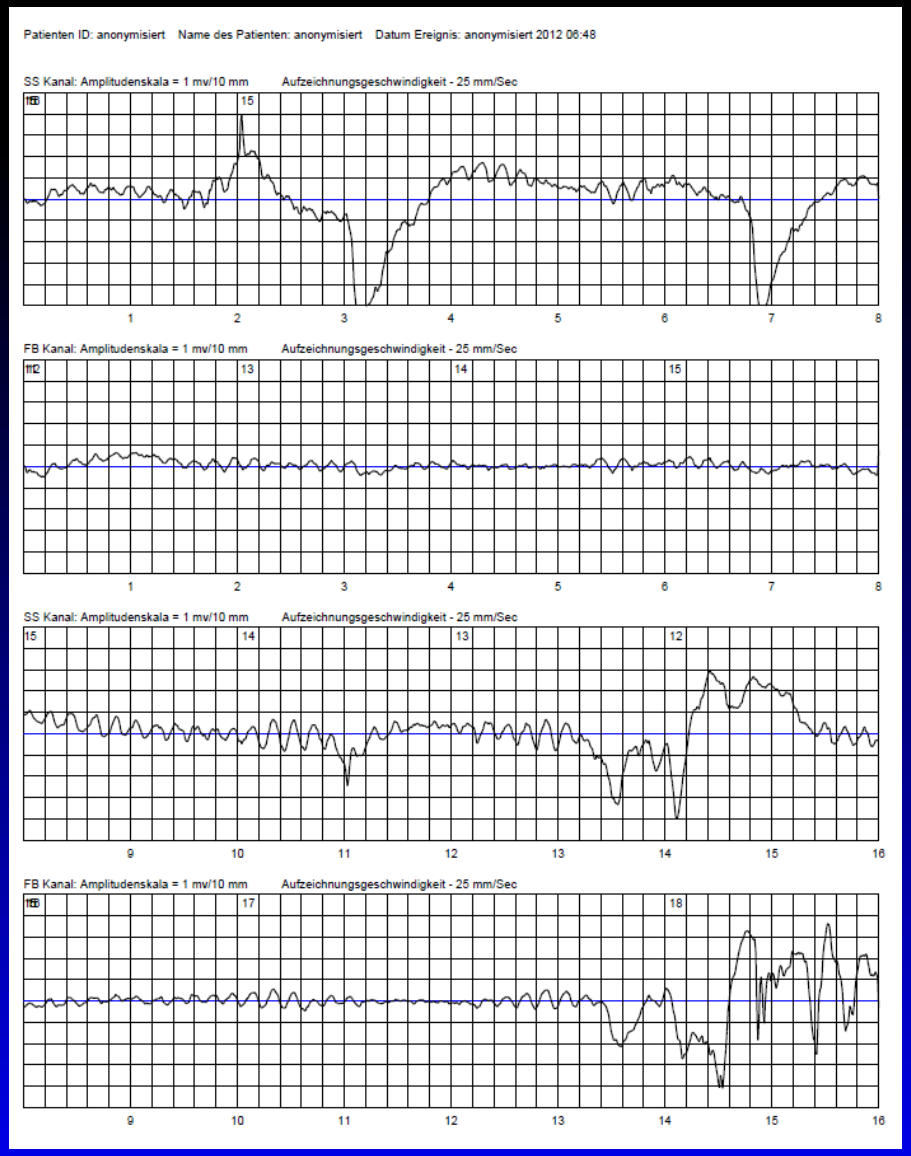
Kasuistik

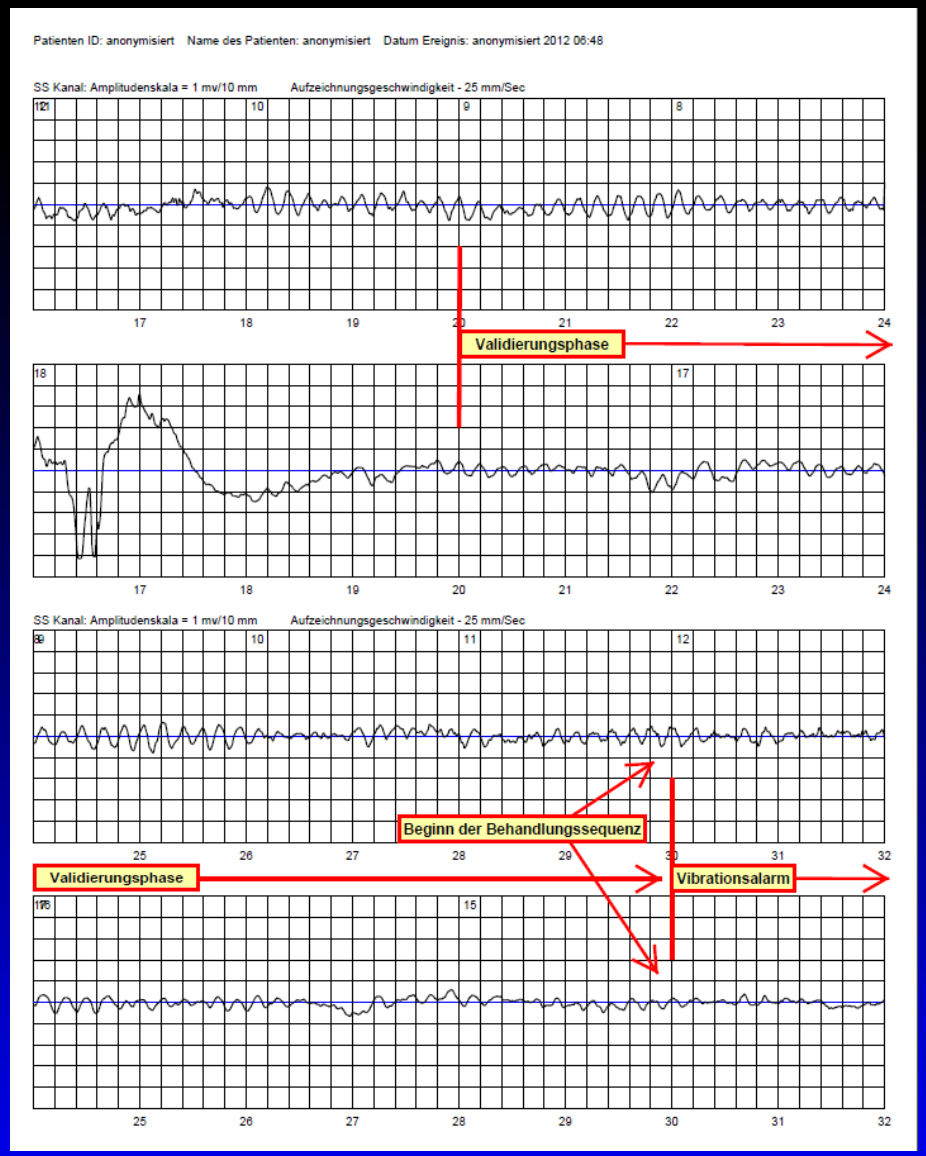
Der Patient erhielt wegen zwei separater VT/VF-Episoden zwei Behandlungsschocks. Die Arrhythmien wurden durch die 150 Joule-Schocks jeweils erfolgreich in einen langsameren, geordneten Rhythmus konvertiert.

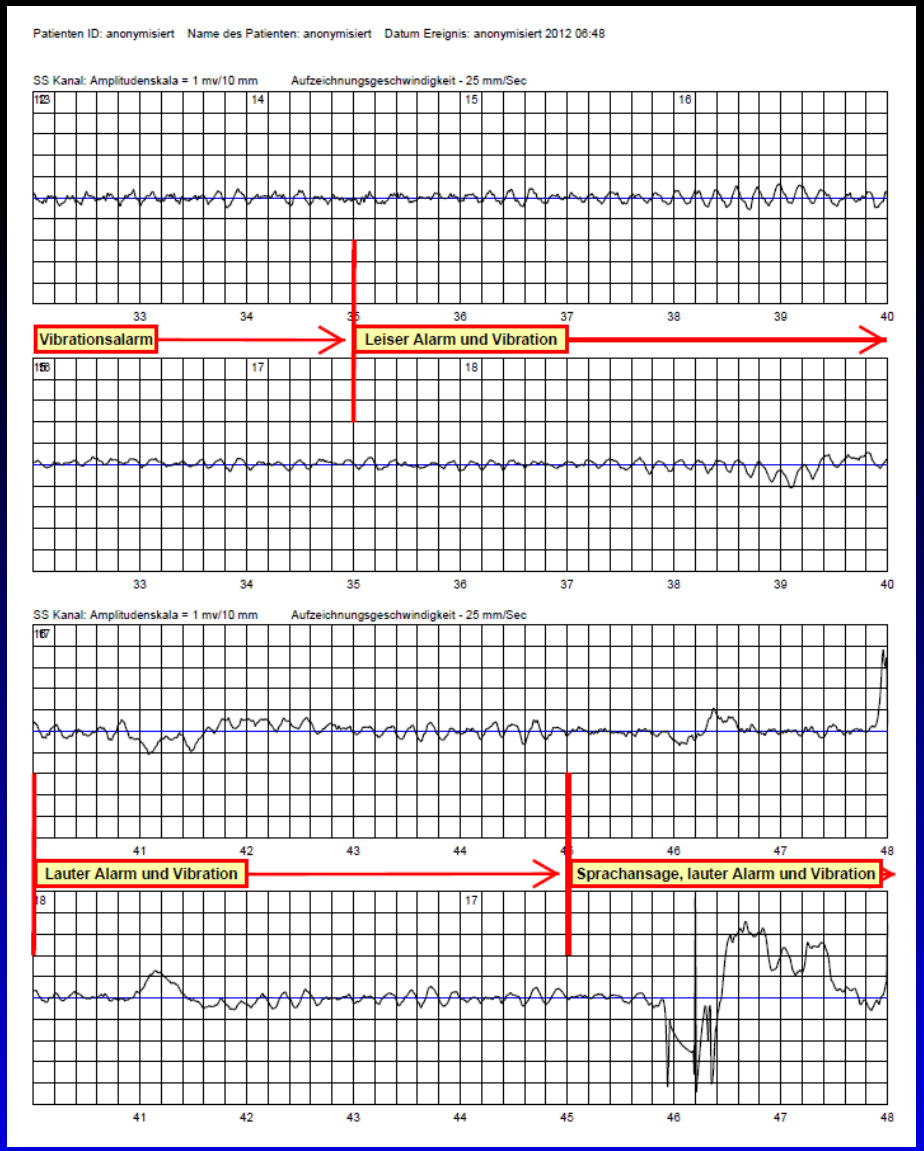
Der Patient war zu Hause und verließ gerade das Badezimmer, als er das Bewusstsein verlor und von der LifeVest behandelt wurde. Seine Familie beobachtete die Behandlung und rief den Rettungsdienst, der den Patienten ins Krankenhaus brachte.

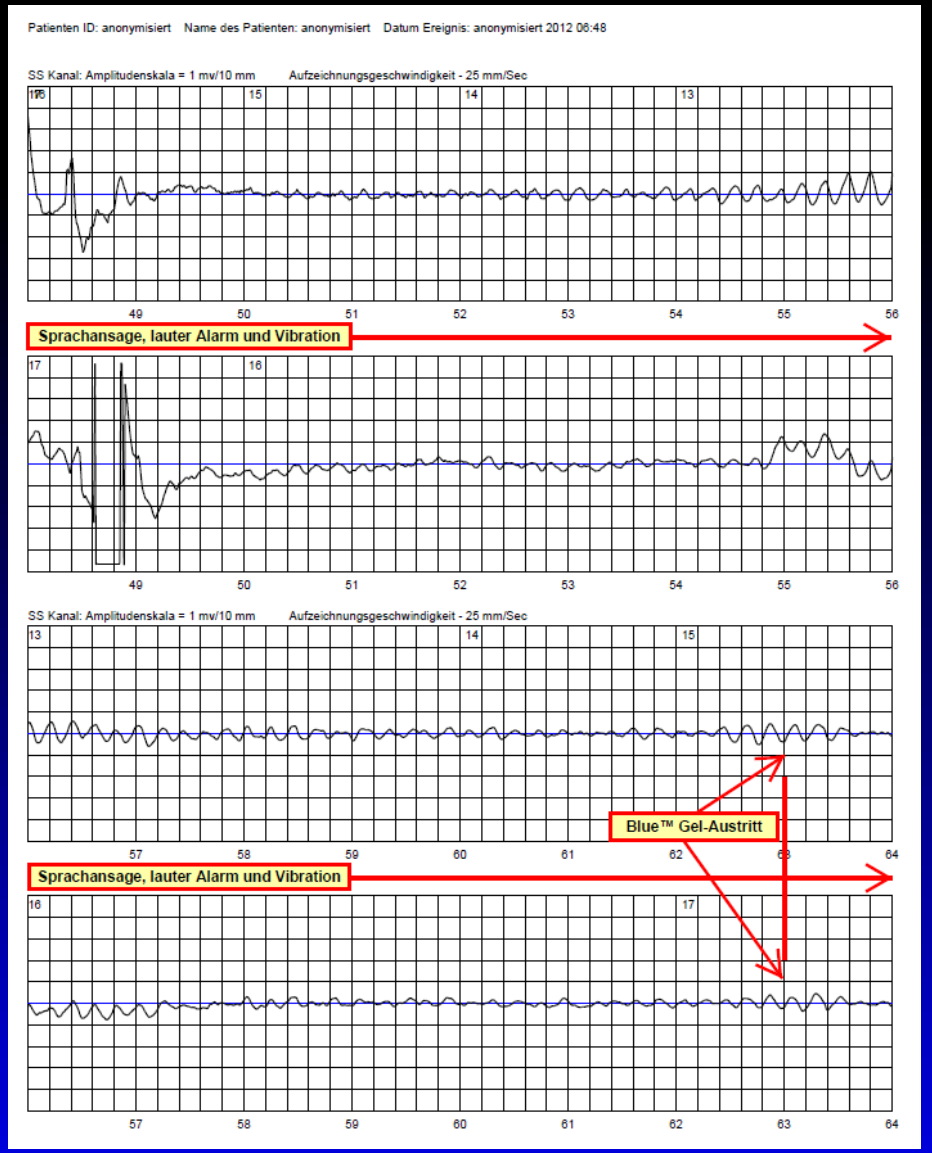
Der Patient lag auf der Intensivstation im Bett, als er ein zweites Mal von der LifeVest behandelt wurde. Medizinische Mitarbeiter beobachteten die Behandlung.

Der Patient erhielt einen ICD.

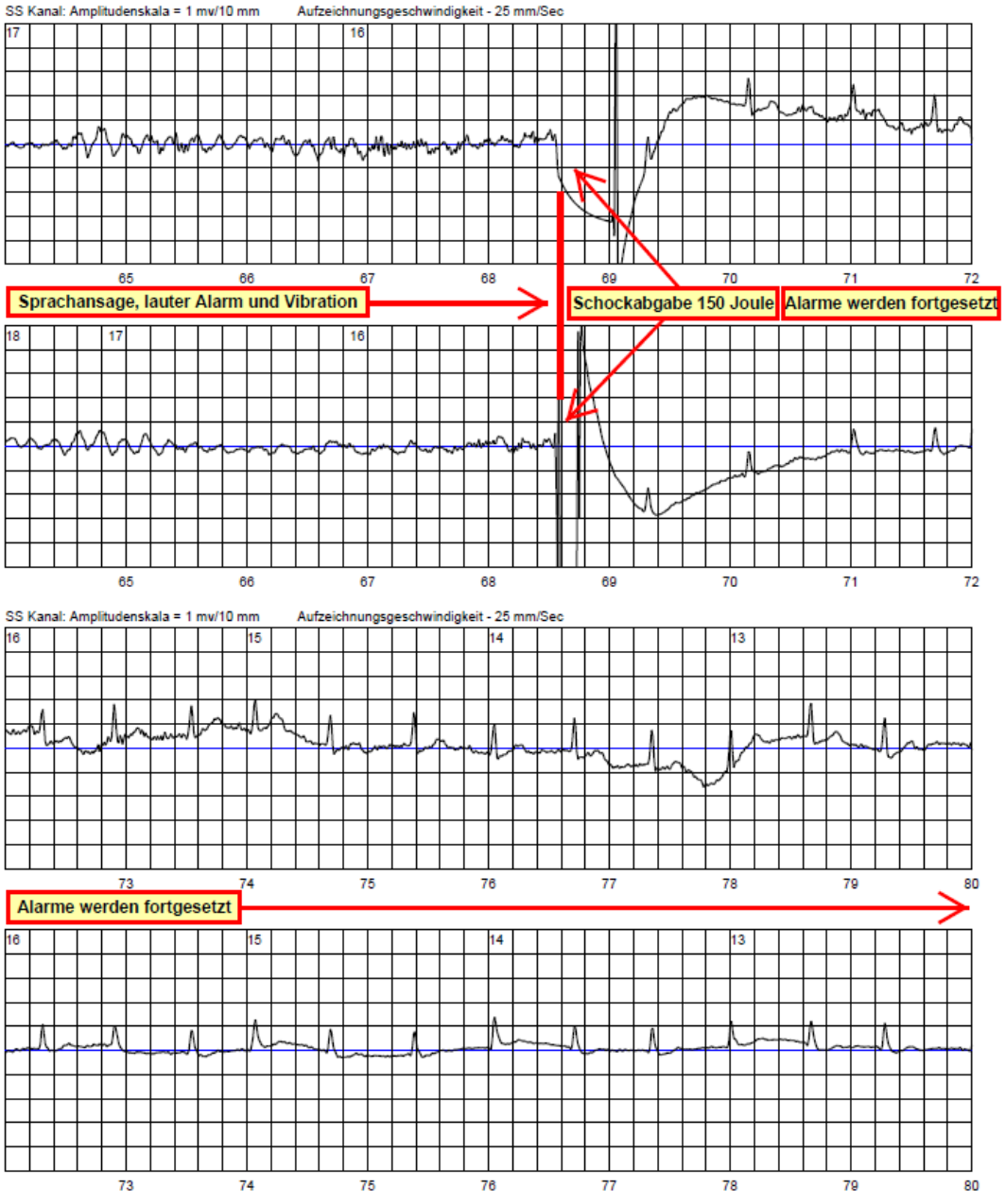

Patienten ID: anonymisiert Name des Patienten: anonymisiert Datum Ereignis: anonymisiert 2012 06:48
SS Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec
FB Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec
SS Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec
FB Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec


Patienten ID: anonymisiert Name des Patienten: anonymisiert Datum Ereignis: anonymisiert 2012 06:48
SS Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec
Validierungsphase
SS Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec
Beginn der Behandlungssequenz
Validierungsphase
Vibrationsalarm

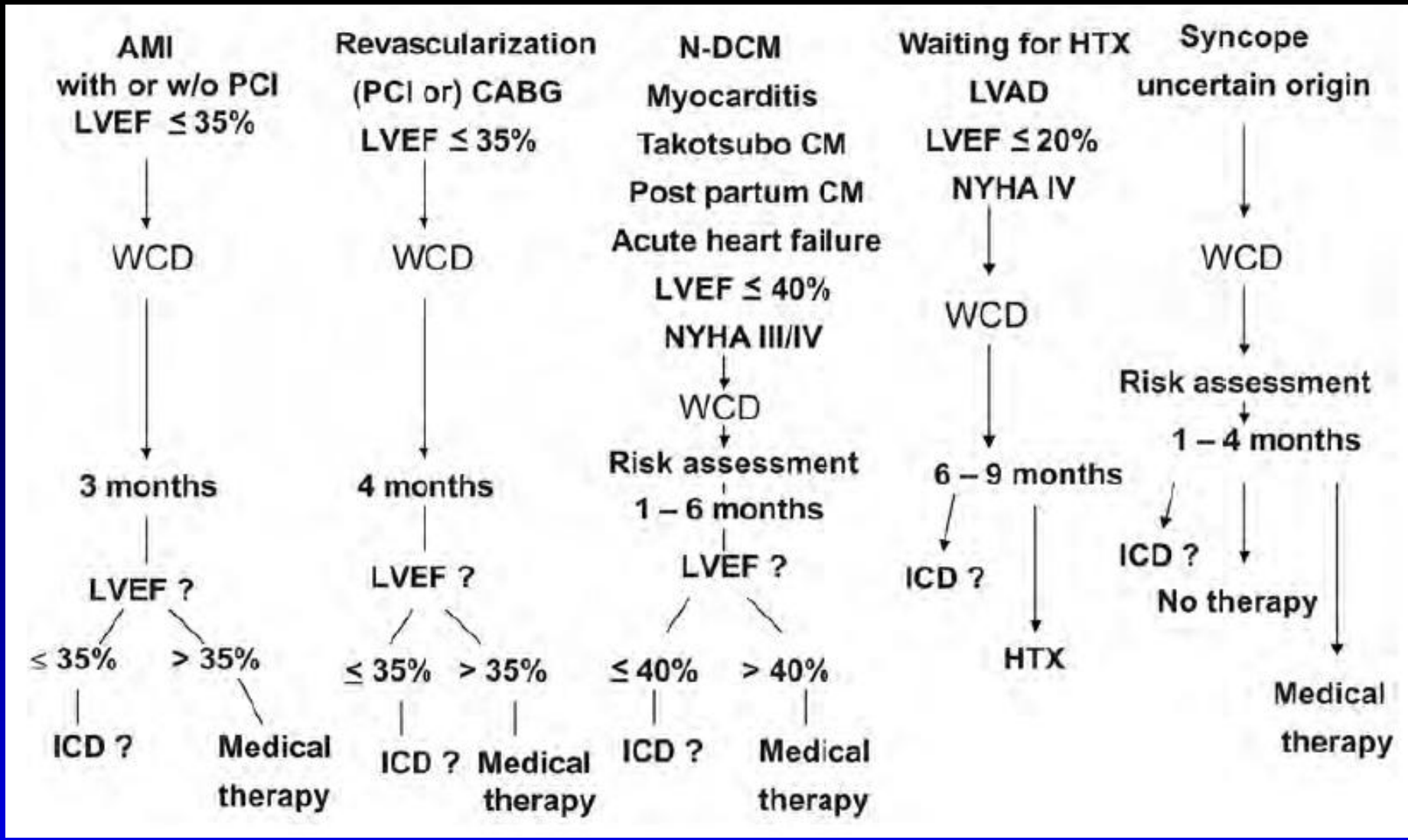

Patienten ID: anonymisiert Name des Patienten: anonymisiert Datum Ereignis: anonymisiert 2012 06:48
SS Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec
Vibrationsalarm
Leiser Alarm und Vibration
SS Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec
Lauter Alarm und Vibration
Sprachansage, lauter Alarm und Vibration


Patienten ID: anonymisiert Name des Patienten: anonymisiert Datum Ereignis: anonymisiert 2012 06:48
SS Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec
Sprachansage, lauter Alarm und Vibration
SS Kanal: Amplitudenskala = 1 mv/10 mm Aufzeichnungsgeschwindigkeit - 25 mm/Sec
Blue™ Gel-Austritt
Sprachansage, lauter Alarm und Vibration

Patienten ID: anonymisiert Name des Patienten: anonymisiert Datum Ereignis: anonymisiert 2012 06:48



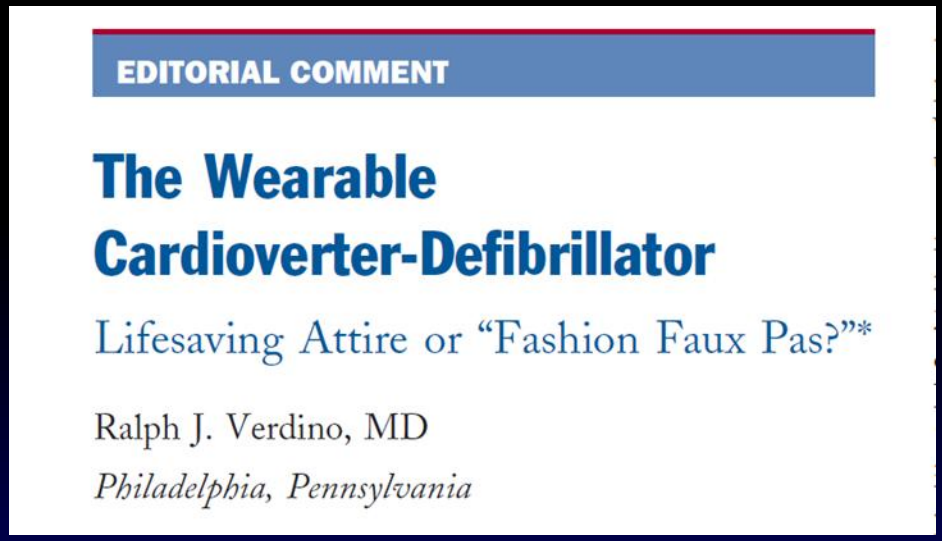
Risk assessment for ICD and WCD therapy



Klein et al, European Heart Journal (2013) 34, 2230–2242

Zusammenfassung

- ✓ Die „life vest“ gibt Schutz gegen Tachyarrhythmien
- ✓ Therapieadhärenz entscheidend
- ✓ Wird auf Antrag von den Kassen bezahlt
- ✓ Bradyarrhythmien derzeit nicht therapiebar
- ✓ Patientenselektion durch klinische Parameter



EDITORIAL COMMENT

The Wearable Cardioverter-Defibrillator

Lifesaving Attire or "Fashion Faux Pas?"*

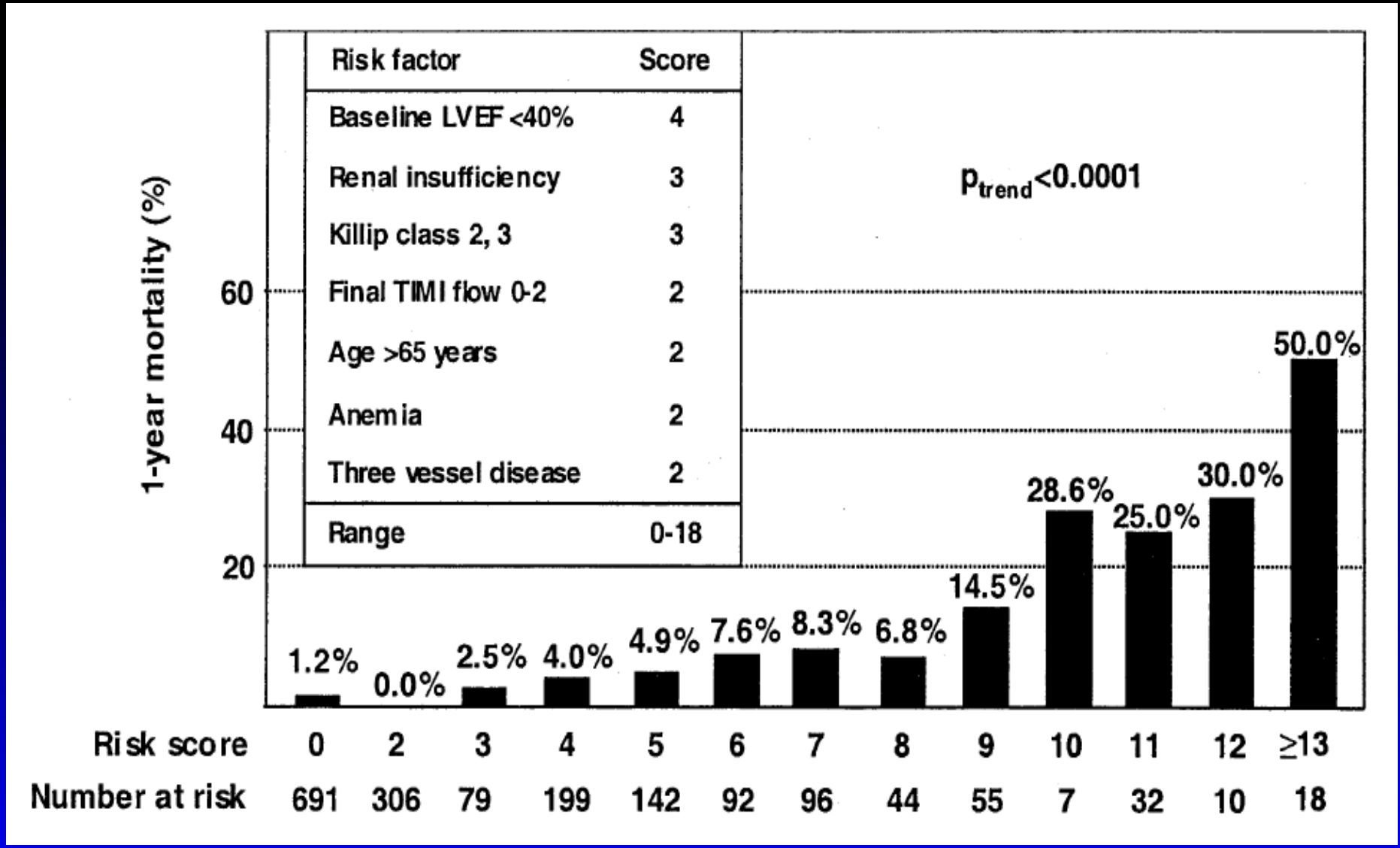
Ralph J. Verdino, MD

Philadelphia, Pennsylvania

Not prescribing this lifesaving attire to your high-risk patient awaiting ICD implantation or re-implantation is the real faux pas.

Verdino, Journal of the American College of Cardiology 2010 Vol. 56, No. 3,

Cadillac Risk Score and 1-Year Mortality



Halkin A et al, J Am Coll Cardiol 2005 45(9):1397–1405

Mögliche WCD Indikationen

1. Patients with accepted indications for ICD implantation (LVEF ≤35% and MI, NICM, or other DCM) who also usually have temporary or contraindications for ICD use

   [For example]

   - Patients waiting for re-implantation of ICD after extraction of an infected ICD
   - Patients in NYHA class IV heart failure
   - Terminal disease with life expectancy <1 year

2. Patients with a condition that temporarily places them at high risk of an arrhythmic death

   [For example]

   - ICM in the early period before and after CABG or PTCA
   - Recent MI before and after CABG or PTCA
   - Patients with low LVEF resulting from potentially reversible condition such as newly diagnosed DCM (tachycardia-induced cardiomyopathy, transient myocarditis

3. Patients under investigation for a disease with a high risk of arrhythmic death pending definitive diagnosis

   [For example]

   - Patients suspected of having an inheritable arrhythmic disorder who are awaiting results of confirmatory testing or survivors of a cardiac arrest of unclear origin

4. Patients listed for cardiac transplant

5. ICD explantation

CABG, coronary artery bypass grafting; DCM, dilated cardiomyopathy; ICD, implantable cardioverter-defibrillator; ICM, ischemic cardiomyopathy; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NICM, nonischemic cardiomyopathy; PTCA, percutaneous transluminal coronary angioplasty; WCD, wearable cardioverter-defibrillator.

Shimizu, **Circulation Journal 2014**

1) patients with a left ventricular ejection fraction 35% waiting for the reimbursement-mandated 30- to 90-day window from initial diagnosis or revascularization to elapse before ICD implantation;
2) patients who do not currently meet ICD implantation criteria due to New York Heart Association functional class IV heart failure;
3) patients who meet ICD implantation criteria but whose condition delays or prohibits implantation, usually coincident infection; and
4) patients who have undergone ICD explantation, usually for infection, who are receiving a course of antibiotics or other treatment before implantation of a new ICD.

Verdino, Journal of the American College of Cardiology 2010 Vol. 56, No. 3,

- 3,569 patients wore the WCDs for a total of 143,643 days (mean 50 days, range of 1 to 1,590 days)
- mean of almost 20 h/day
- Daily use was confirmed in 90% of patients
- 15% of patients stopped wearing the WCD prematurely because of comfort issues or adverse reactions.

Verdino, Journal of the American College of Cardiology 2010 Vol. 56, No. 3,

80 sustained ventricular tachycardia (VT)/ventricular fibrillation (VF) events were recorded in 59 patients (1.7% of the study cohort).
The first shock was successful in 79 of 80 patients.
The only patient who failed a WCD shock had hemodynamically tolerated VT that also failed several external shocks delivered by emergency medical service workers in the ambulance and hospital staff members in the emergency department. His VT was later terminated pharmacologically.

Although the shocks were effective, 8 of these patients died, all of recurrent arrhythmias:

- ✓ 4 after recovering consciousness at the arrival of professional medical care,
- ✓ 1 whose spouse prevented a second WCD shock,
- ✓ 2 due to electrocardiogram signal disruption presumably after a fall, and
- ✓ 1 who failed detection due to a pacemaker operating in a unipolar mode.

Verdino, Journal of the American College of Cardiology 2010 Vol. 56, No. 3,

Only 67 episodes of
inappropriate ICD discharges were logged in these 3,569 patients during 4,788 months of use. These results are not dissimilar to those of inappropriate shocks from ICDs (2).

Verdino, Journal of the American College of Cardiology 2010 Vol. 56, No. 3,

The authors divided the population into 2 groups: those who received the WCD for traditional ICD implantation criteria and those who received it for nontraditional ICD indications. The traditional group comprised 4 types of patients: 1) those who recently had an ICD explanted; 2) those with an episode of VT/VF awaiting ICD implantation; 3) those with a long-standing cardiomyopathy and left ventricular ejection fraction of 35%; and 4) those with a genetic predisposition to sudden cardiac death. Nontraditional indications mainly included 2 groups of patients: 1) those with a left ventricular ejection fraction 35% but who had only recently been diagnosed or had a recent myocardial infarction or recent coronary bypass surgery; and 2) those with a recent myocardial infarction and an ejection fraction 35%.

Verdino, Journal of the American College of Cardiology 2010 Vol. 56, No. 3,

Although the VALIANT (Valsartan in Acute Myocardial Infarction) study demonstrated a high incidence of sudden cardiac death in patients with early post-myocardial infarction with left ventricular ejection fractions 35% (3),

Solomon et al, N Engl J Med. 2005;352:2581–2588

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

Current device guidelines and insurance coverage require waiting periods of either 40 days or 3 months before implanting a cardioverter-defibrillator post-myocardial infarction (MI), depending on whether or not acute revascularization was undertaken.

Methods We assessed characteristics of and outcomes for patients who had a WCD prescribed in the first 3 months post-MI. The WCD medical order registry was searched for patients who were coded as having had a "recent MI with ejection fraction 35%" or given an International Classification of Diseases, Ninth Revision 410.xx diagnostic code (acute MI), and then matched to device-recorded data.

Results Between September 2005 and July 2011, 8,453 unique patients (age 62.7 12.7 years, 73% male) matched study criteria. A total of 133 patients (1.6%) received 309 appropriate shocks. Of these patients, 91% were resuscitated from a ventricular arrhythmia. For shocked patients, the left ventricular ejection fraction (LVEF) was 30% in 106, 30% to 35% in 17, >36% in 8, and not reported in 2 patients. Of the 38% of patients not revascularized, 84% had a LVEF 30%; of the 62% of patients revascularized, 77% had a LVEF 30%. The median
time from the index MI to WCD therapy was 16 days. Of the treated patients, 75% received treatment in the first month, and 96% within the first 3 months of use. Shock success resulting in survival was 84% in nonrevascularized and 95% in revascularized patients.

Epstein et al, Journal of the American College of Cardiology, 2013 Vol. 62, No. 21

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

To our knowledge, this is the only report that describes use of the WCD in patients early post-MI perceived to be at high risk for SCA, a population currently not covered for ICD implantation. That 1.4% of patients may be successfully treated in the first 3 months with a resuscitation survival rate of 91% implies that a select group of patients may benefit from defibrillation early after MI, particularly during the first 30 days following hospital discharge. These survivors may then receive an ICD.

Further study of WCD use for the prevention of SCD is warranted in the critical period early post-MI.

The ongoing Vest Prevention of Early Sudden Death Trial and VEST Registry (ClinicalTrials.gov identifier NCT01446965) will help to answer that question.

Epstein et al, Journal of the American College of Cardiology, 2013 Vol. 62, No. 21

There are currently no guidelines available to instruct cardiologists in patient selection for WCD.
The Zoll website lists the following conditions that are covered by most insurance plans in the United States:
Primary prevention with EF ≤35%, including after recent myocardial infarction,
before and after coronary artery bypass graft or PTCA,
awaiting cardiac transplantation,
recently diagnosed nonischemic cardiomyopathy, NYHA class IV heart failure, terminal disease with life expectancy of <1 year,
ICD indications when ICD is delayed or prohibited, and
ICD explantation