News der kardialen Device - Therapie

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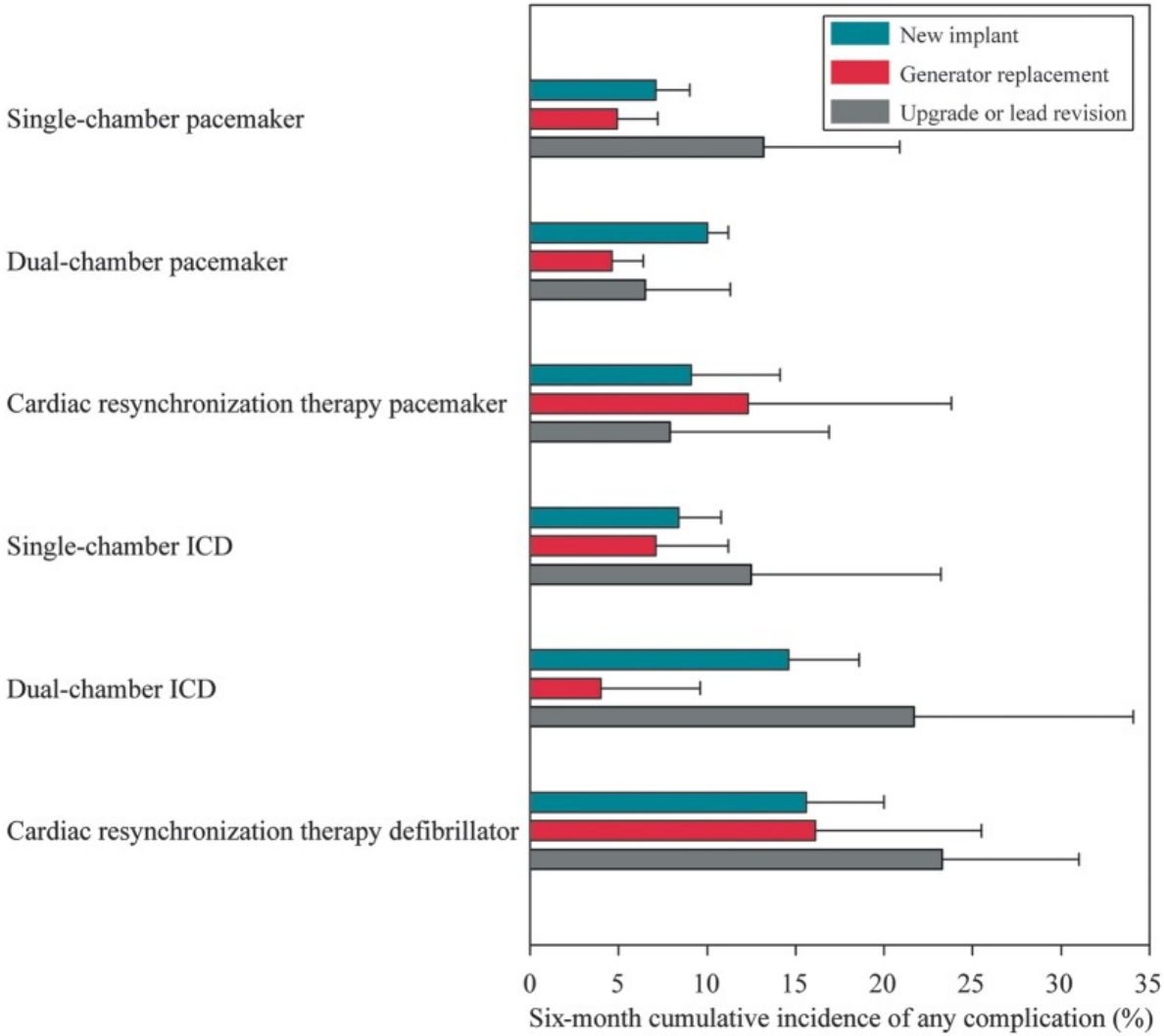
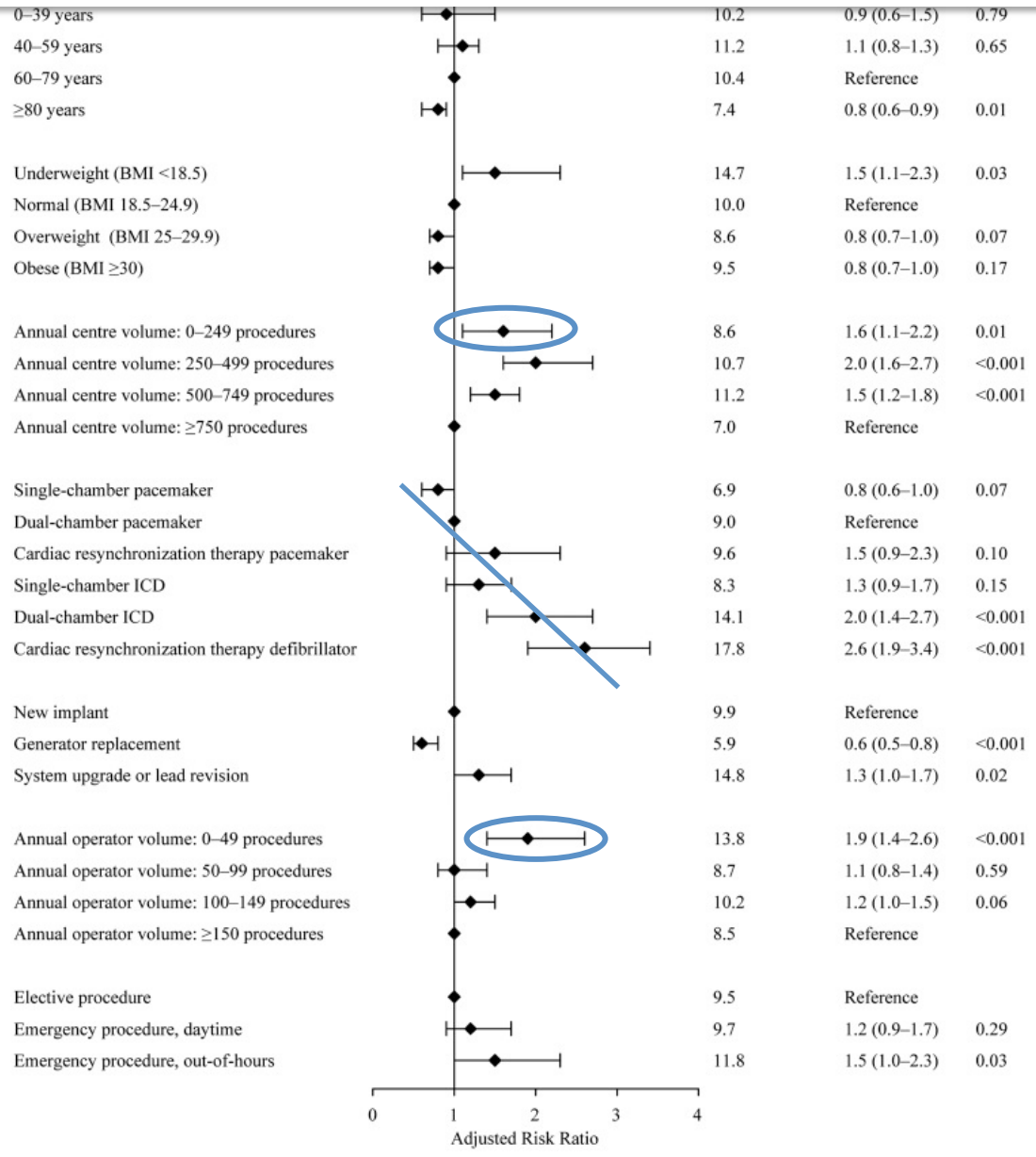
Complications after Implantation / Replacement / Upgrade or lead revision (transvenous Systems)



Kirkfeldt et al, Eur Heart J. 2014

Complications after Implantation / Replacement / Upgrade or lead revision (transvenous Systems)



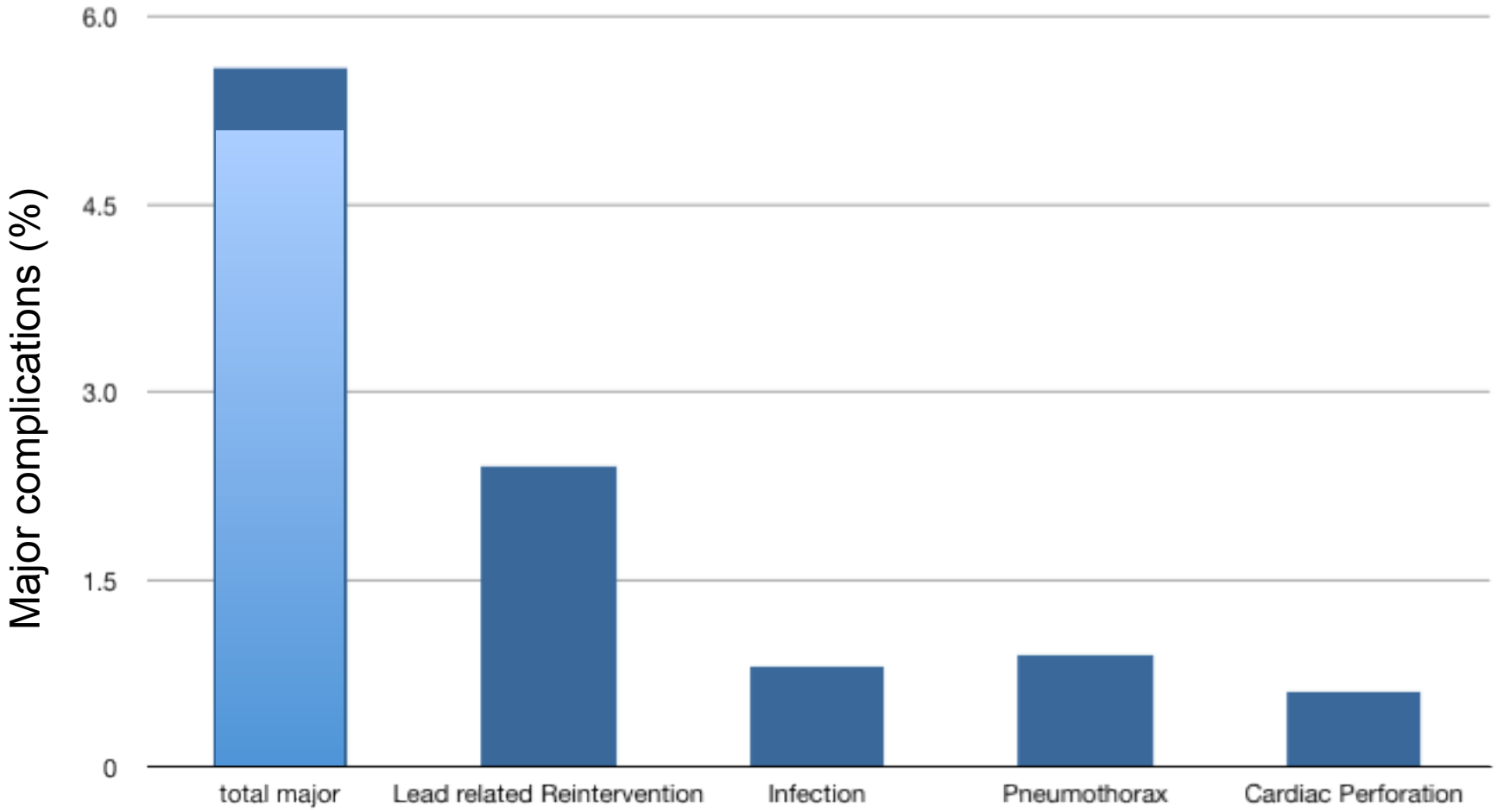
Complexity

Skills

Kirkfeldt et al, Eur Heart J. 2014

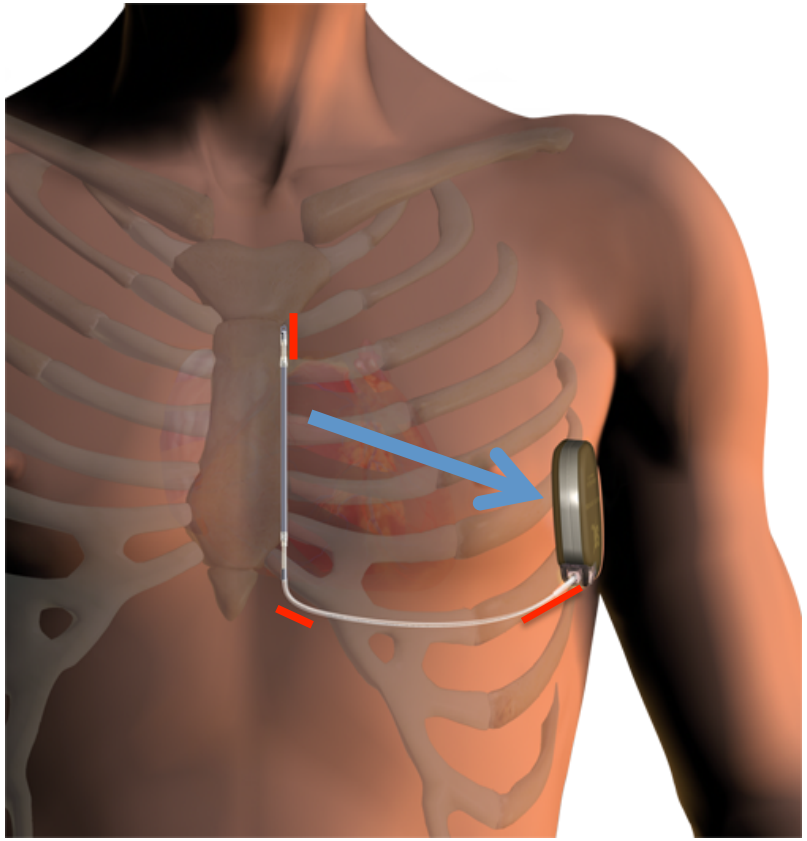
Complications after Implantation / Replacement / Upgrade or lead revision (transvenous Systems)

at 6 months



modified from Kirkfeldt et al, Eur Heart J. 2014

SICD



Subcutaneous System
Heart / Vasculature untouched

Therapies:
- Biphasic shock, 80 J
- Postshock pacing only
- Charge time < 10 s

SICD

- Volume: 59.5 cc
- Weight: 130 grams
- Thickness: 12.7 mm
- Battery Longevity: 7.3 y

SICD

Commercially distributed in some European countries since 2009

FDA approval 2012

Indications:
Same as ICD

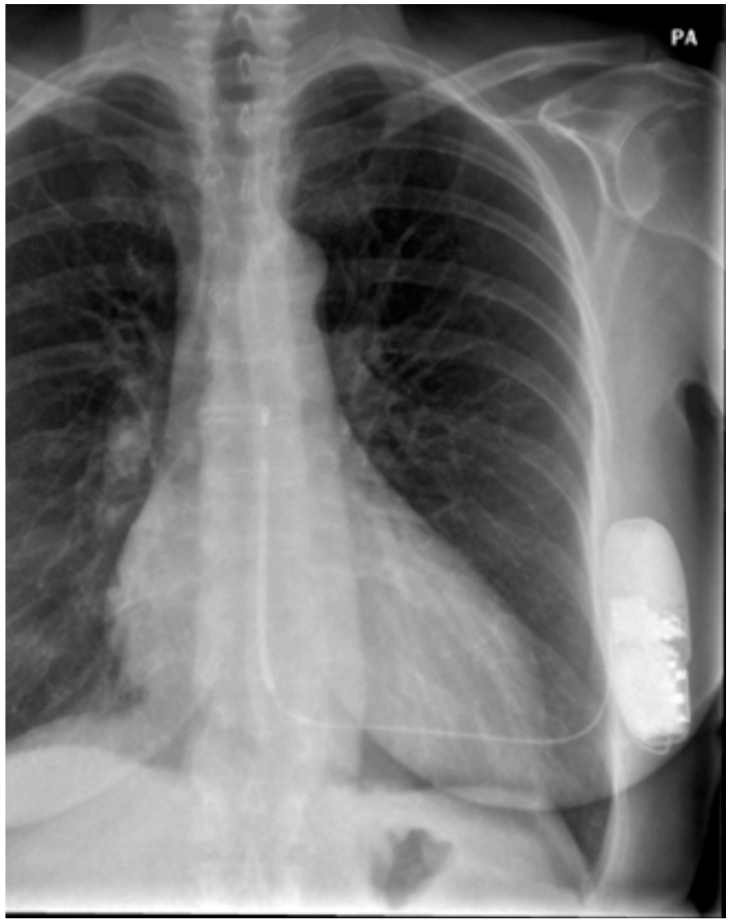
- no symptomatic bradycardia
- no frequent VTs that can be terminated with ATP

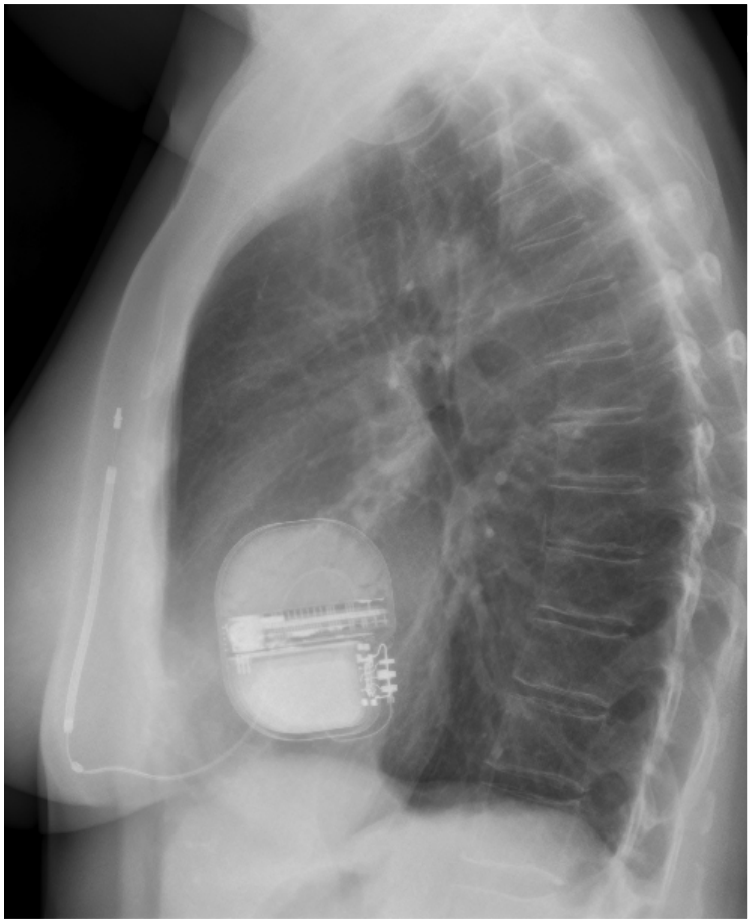
Contraindications

- Unipolar pacemaker

3-5% of patients not elegible (T-wave oversensing)

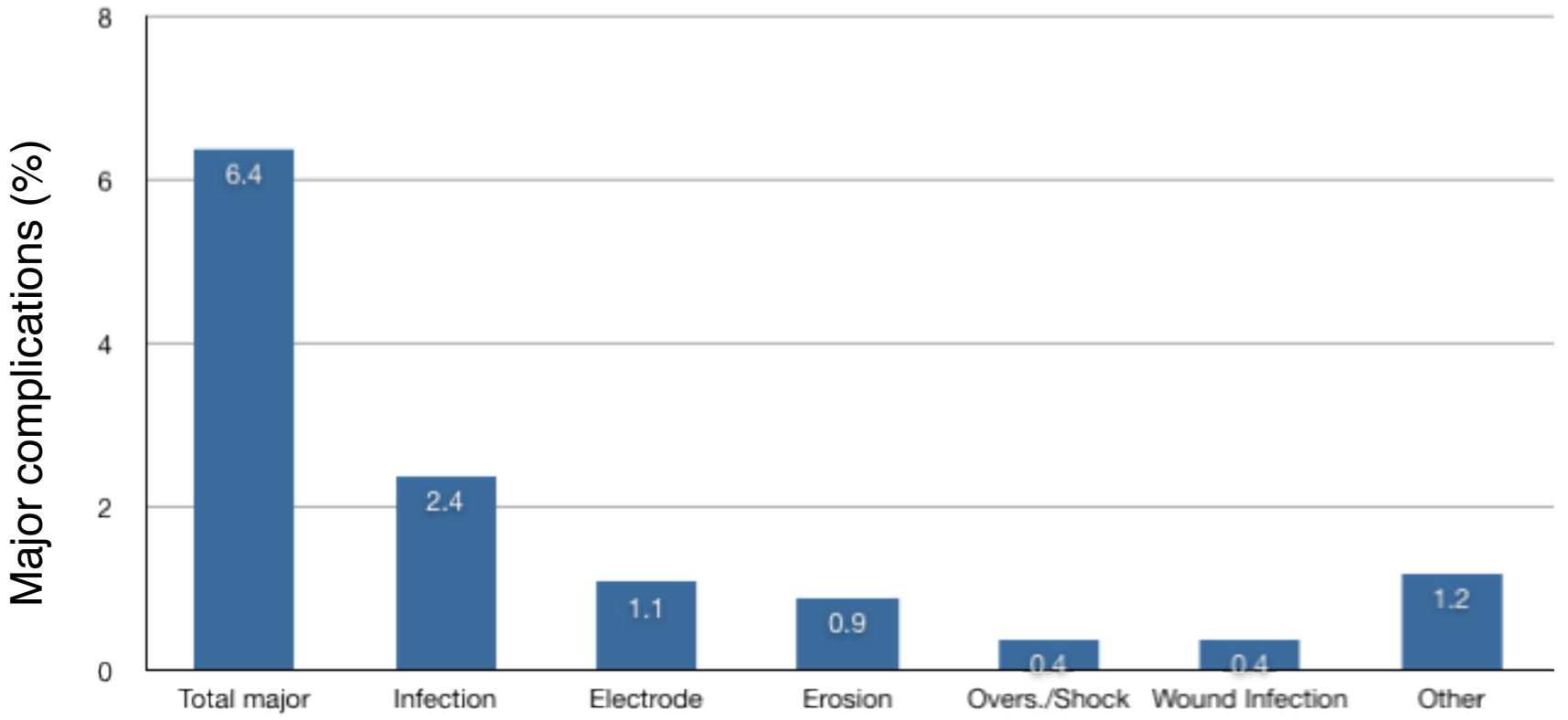
SICD





SICD

Effortless Registry: Major Complications requiring Intervention



modified from Lambiase et al, EHJ 2014

SICD
Effortless Registry

456 Patients, 317 Episodes in 85 Patients

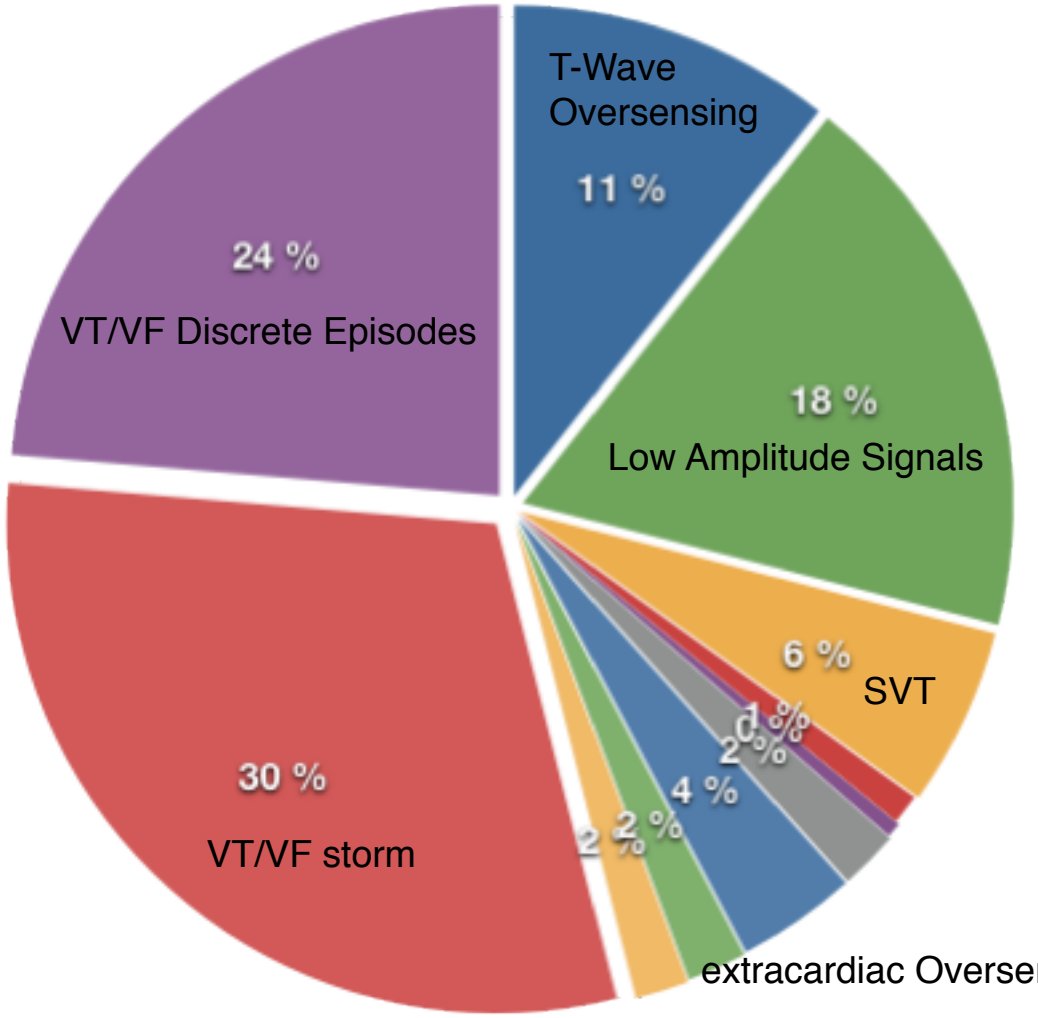
Conversion Efficacy in Testing	99.7 %
Overall shock conversion rate	96 %

Appropriate Therapies	7.2 % (Patients)
Inappropriate Therapies	7.0 % (Patients)

Lambiase et al, EHJ 2014

SICD

Effortless Registry: Appropriate and Inappropriate Shocks



modified from Lambiase et al, EHJ 2014

SICD

- Does what it is supposed to do
- Moderate Complication rate (beginning of learning curve ?)
- no Rx
- Shock Box

Leadless Pacemaker

J. ELECTROCARDIOLOGY, 3 (3-4) 325-331, 1970

Special Article

Totally Self-Contained Intracardiac Pacemaker*

J. WILLIAM SPICKLER, PH.D., NED S. RASOR, PH.D.†, PAUL KEZDI, M.D.
S. N. MISRA, M.D., K. E. ROBINS, P.E., AND CHARLES LeBOEUF, P.E.

SUMMARY

Recent developments in miniature long-life power sources and electronics, such as nuclear batteries and integrated circuits make feasible a new generation of pacemakers, the intracardiac pacemaker (IC), i.e., a completely self-contained pacemaker implanted inside the right ventricle by transvenous insertion. Since the IC pacemaker eliminates all leads, problems associated with the leads such

circuits have been improved substantia
addition, the development of the endo
catheter electrode has broadened the
of operative procedures to include a
portion of the patient population. Two
problems that still exist with conver
pacemakers are perforation or dislocat
the transvenous electrode and the short
the batteries that are presently used. Ir
tion, there is a certain physical and p
logical discomfort involved wit

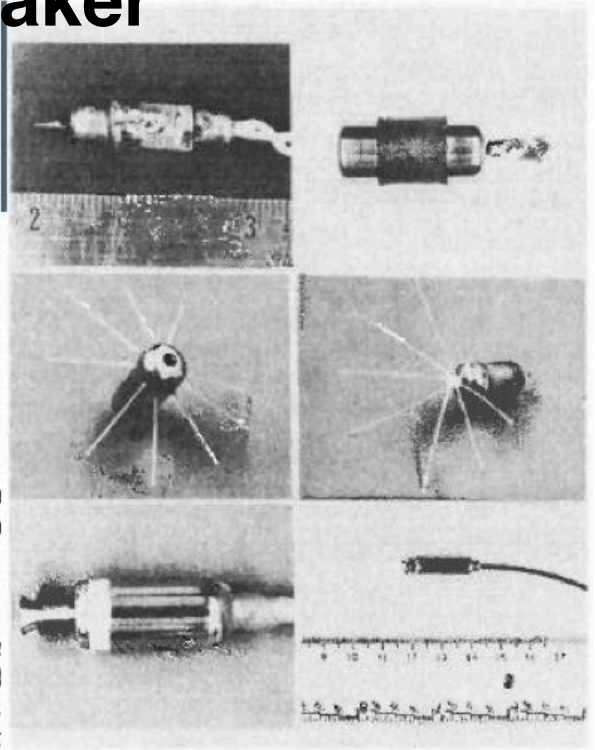


Fig. 2. Some early unsatisfactory dummy capsules

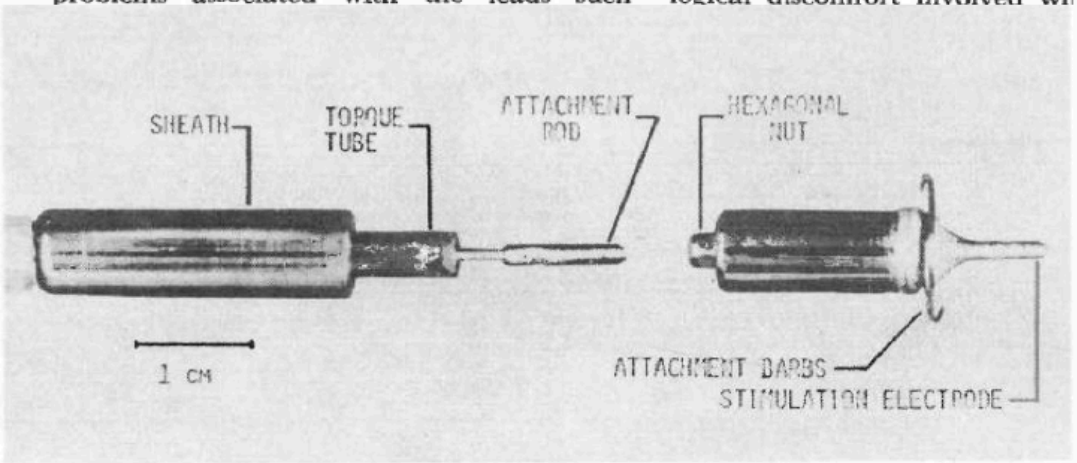


Fig. 4. Intracardiac pacemaker with catheter for transvenous insertion.

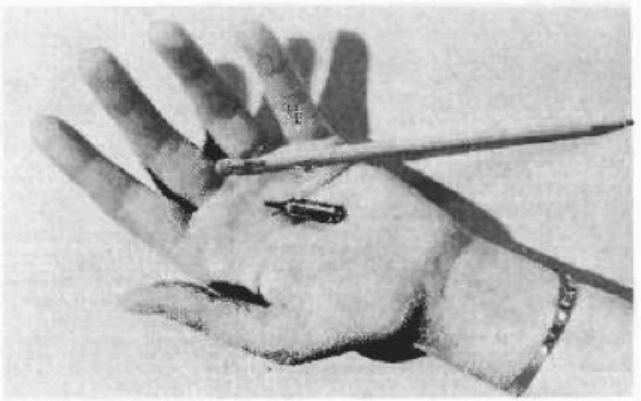
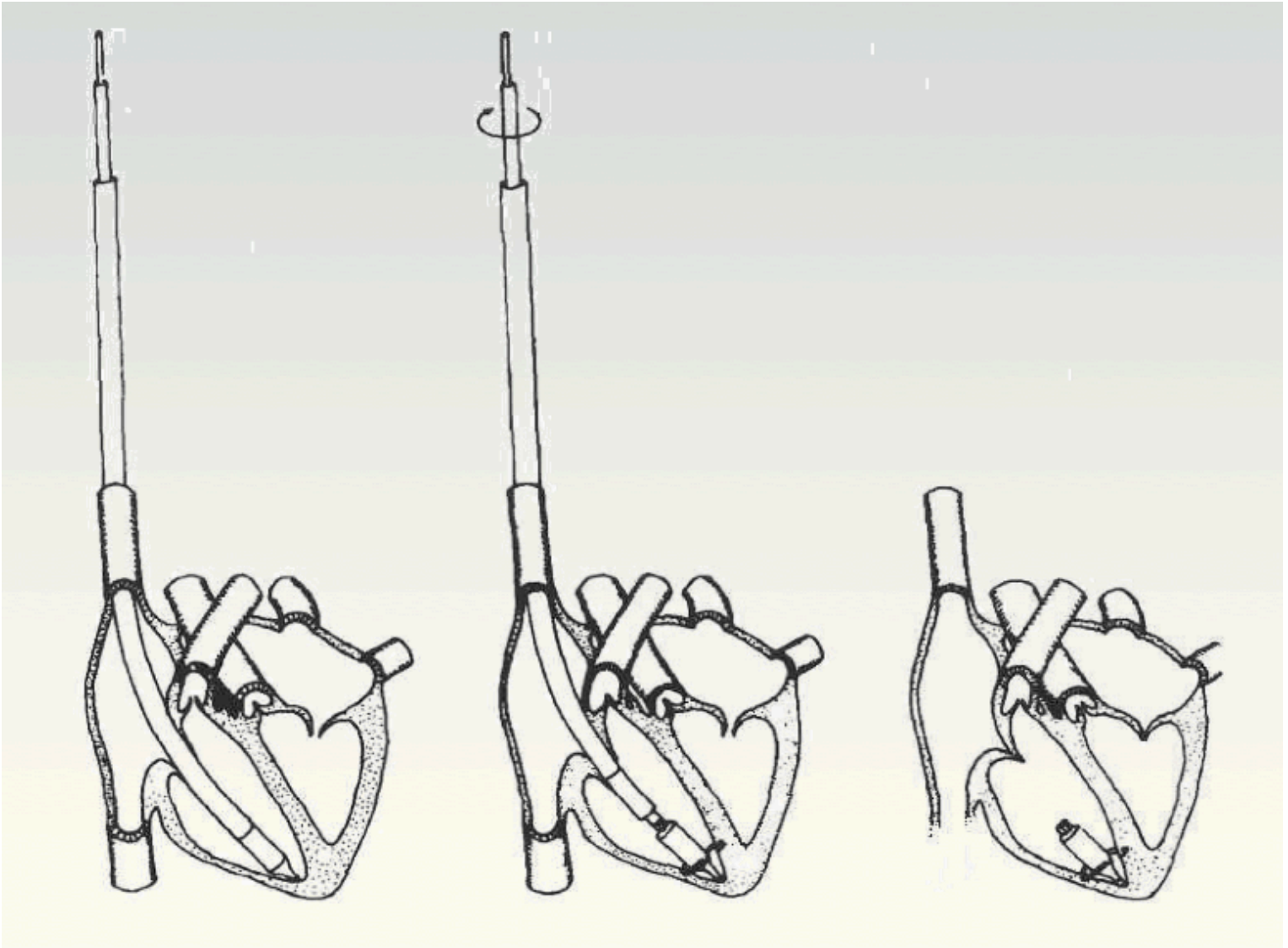


Fig. 8. Nuclear-powered intracardiac pacemaker.

Leadless Pacemaker

System proposed by Spickler in 1970



Leadless Pacemaker

5-7 mm diameter, 26 - 35 mm length

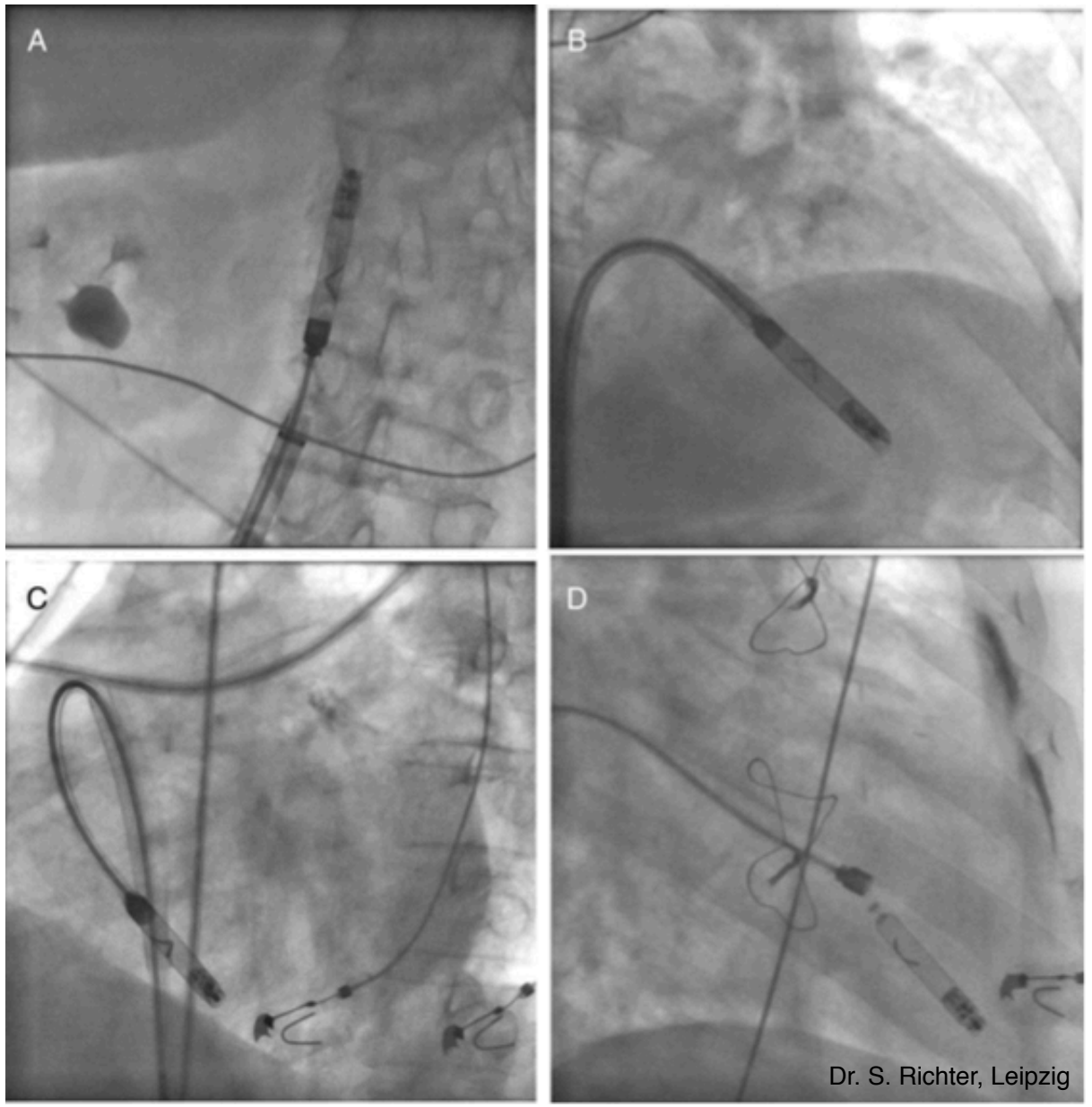
Bipolar Sensing

Battery 6.5 – 12 years

„retrievable“

VVIR

Leadless Pacemaker

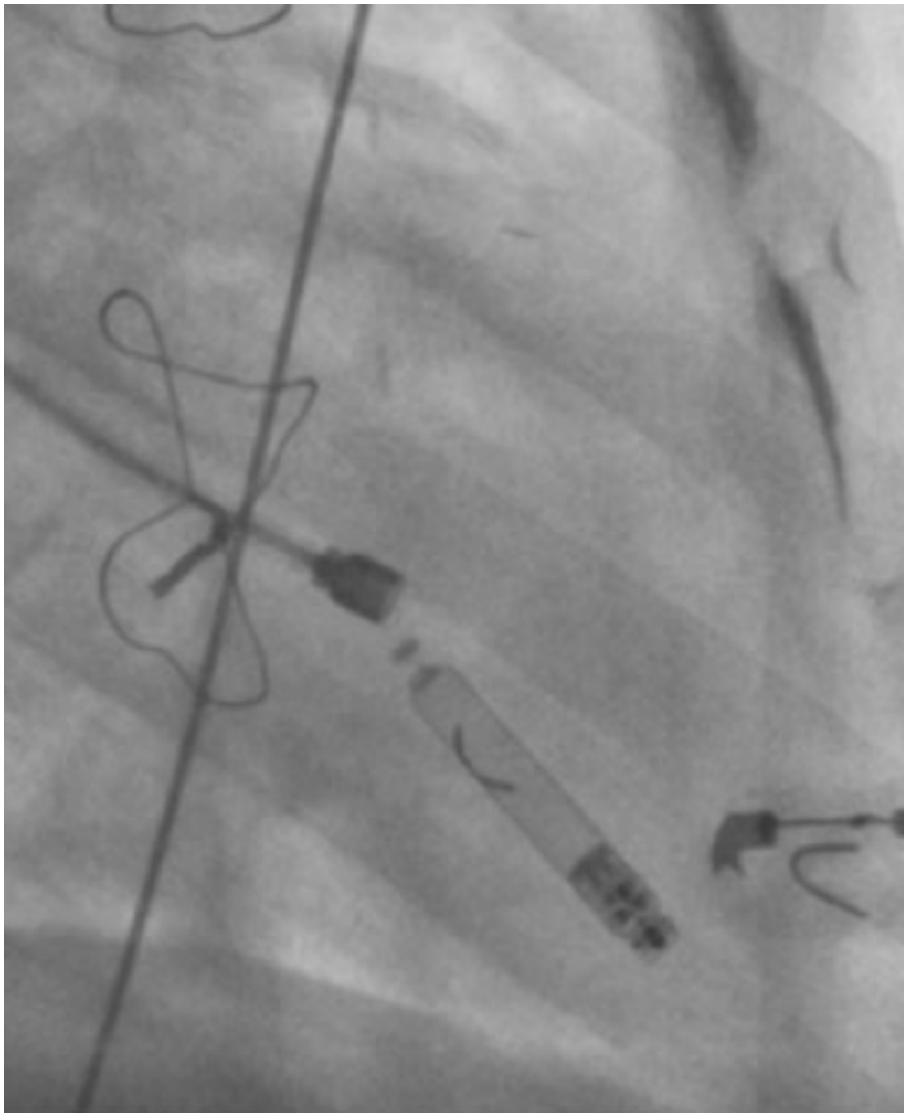


Leadless Pacemaker

Developments, Questions

Mechanical issues, perforations

- stiff device



Leadless Pacemaker
Developments, Questions

• Mechanical issues, perforations, embolization
(Nanostim > Micra ?)

• Only VVIR -> combine multiple communicating devices into a multi site pacing system ?

• Retrievability: might be different after a few months compared to elective battery replacement

• R-function (heat driven in Nanostim model) ?

ICD

• well established since > 3 decades in high risk patients

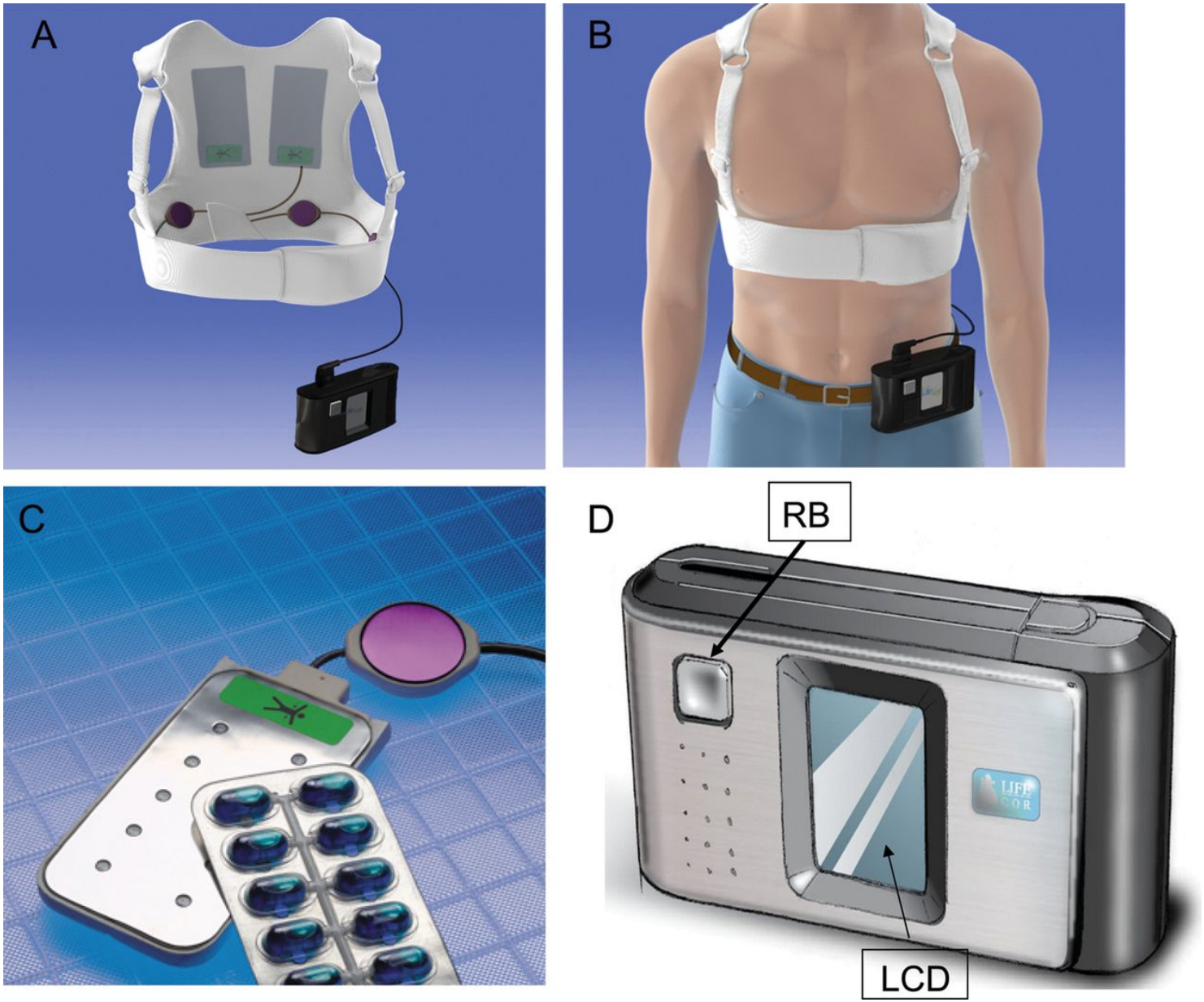
• secondary prophylaxis

• primary prophylaxis

but
-> patients with reversible causes for arrhythmias ?
-> patients awaiting ICD Implantation
-> patients after MI
Dinamit, Hohnloser et al, NEJM 2004
Valiant, Solomon et al, NEJM, 2005
-> patients with system infection

Wearable Cardiac Defibrillator

Life Vest



Wearable Cardiac Defibrillator

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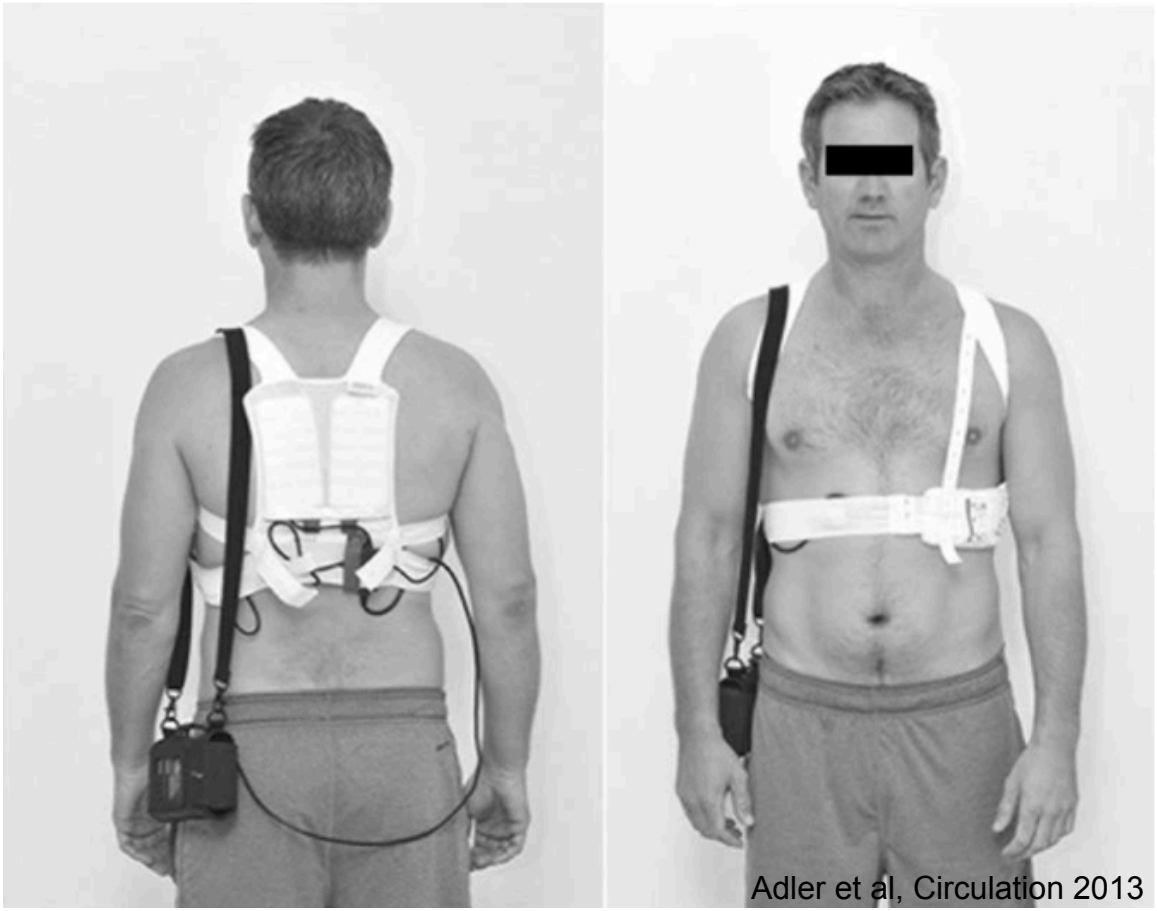


Adler et al, Circulation 2013

- Elastic belt and shoulder strap
  - 4 dry sensing electrodes
  - 3 defibrillation electrodes

- battery (24 h use, 2 h charge)

- 600 g

- loop recorder, no pacing

- vibration signal, 2 sound alarms

- button to withhold the shock

-Monophasic shock (230 J), biphasic shock (150 J)

Wearable Cardiac Defibrillator

WEARIT/BIROAD: 289 Patienten, 8 events in 6 patients, 901 pts months
Feldmann, Klein et al. Pacing Clin Electrophysiology, 2004

FDA approved 2002

Does what it is supposed to do, low shock incidence
Chung et al, JACC 2010
WEARIT-II, ESC 2014

No proarrhythmia published so far

No randomized study

VEST registry: ongoing, Life Vest randomized vs. standard care after MI
Primary Endpoint: sudden death 3 months after MI

Wearable Cardiac Defibrillator

Limitations and Gaps of Knowledge

- post MI patients did receive appropriate shocks for VT/VF in DINAMIT, which did not result in improved survival
-similar results in IRIS (Steinbeck et al, NEJM 2009)

• do appropriate therapies in this period translate into improved survival ?

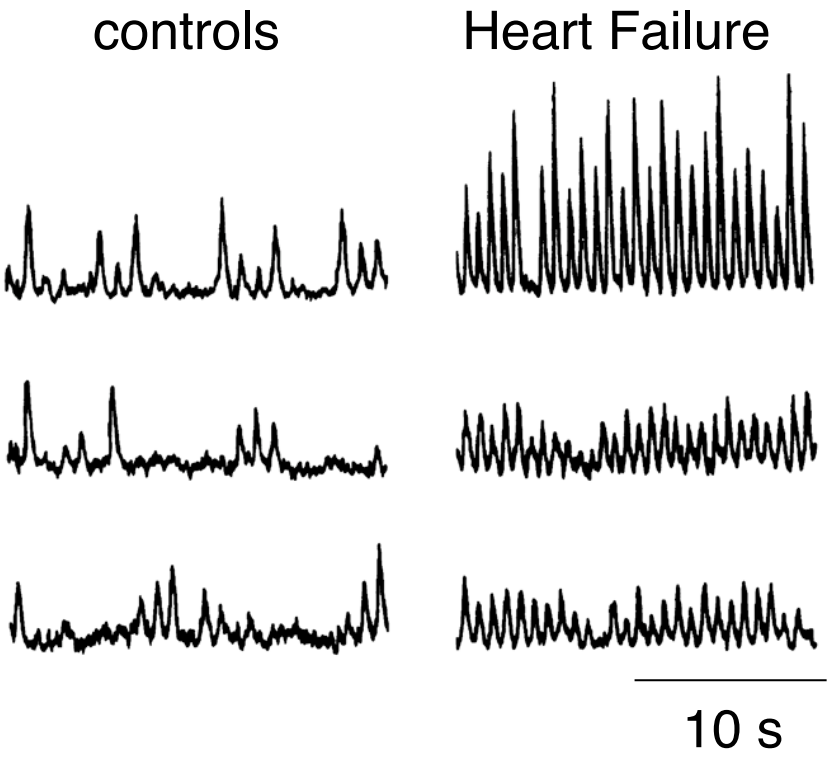
• same outcomes with shocks from transvenous lead vs. subcutaneous vs. skin leads ?

• Patient selection: Small subgroup of post MI patients at risk

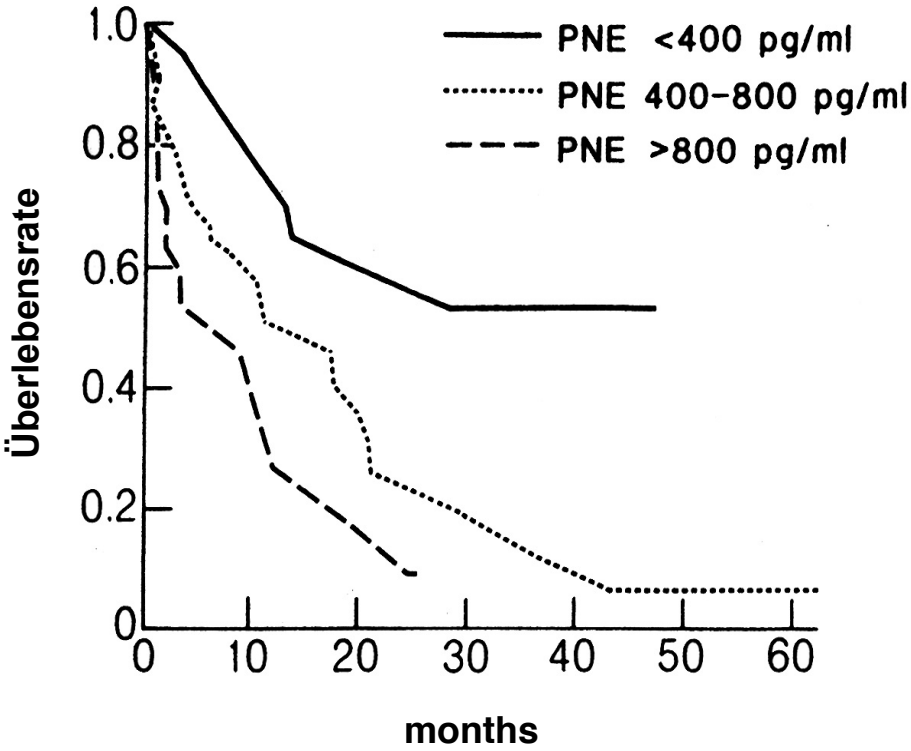
• ICDs prescribed by arrhythmia specialists, wearable defibrillators by physicians less experienced in the management of arrhythmias
-> more complications (programming, inappropriate shocks) ?

Sympathetic Nerve Activity and Survival In Heart Failure

Muscle Sympathetic Nerve Activity

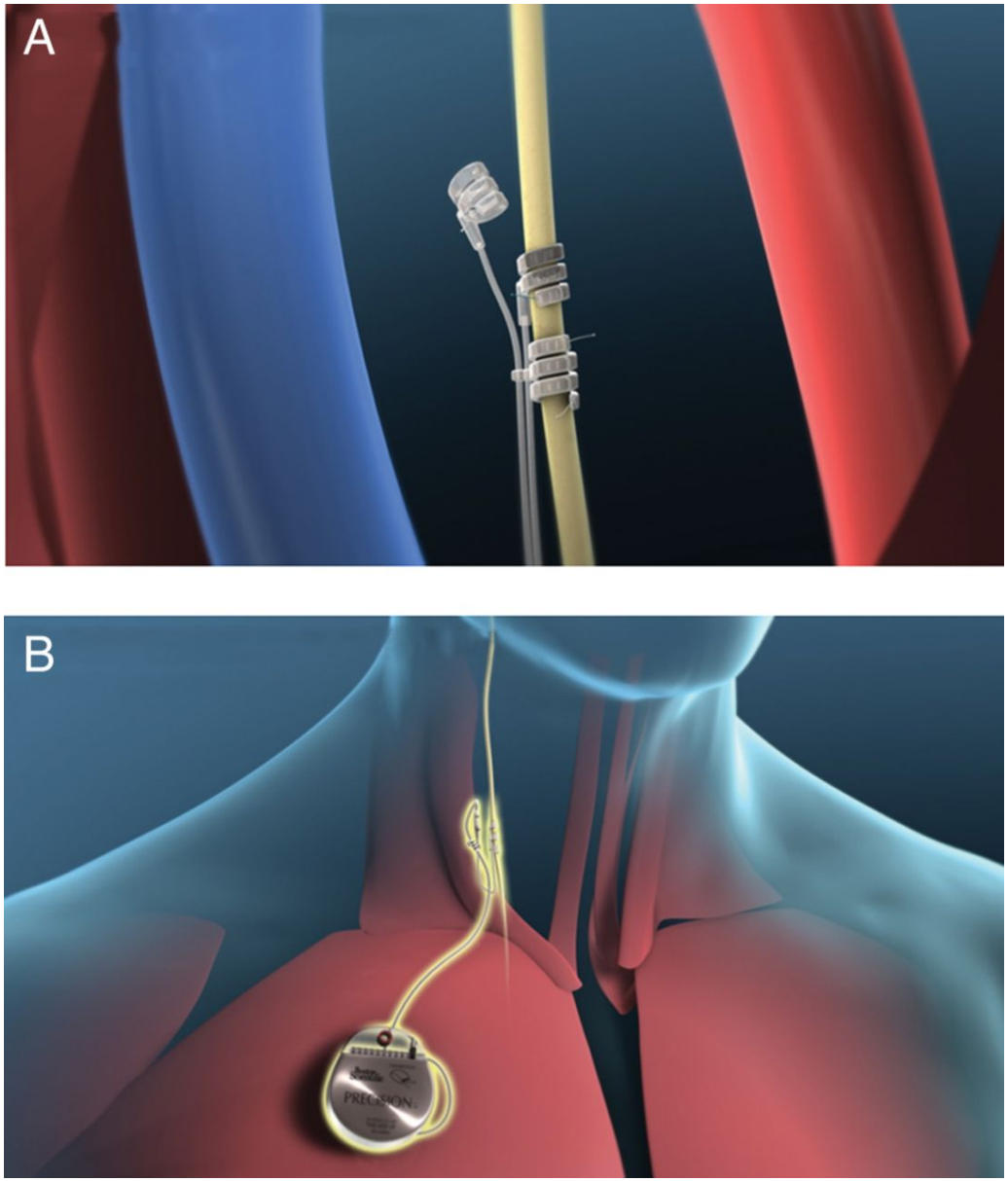


Plasma Norepinephrine



Cohn et al, NEJM, 1984

Vagus Stimulation in Heart Failure



Zannad et al, Eur Heart J, 2014

Vagus Stimulation in Heart Failure

ANTHEM – HF: randomized left vs right Vagal Nerve Stimulation
Pemchand et al, J Card Fail, 2014

- 60 patients
- significant improvement in LVEF
- no control group

NECTAR – HF: first sham controlled trial
Zannad et al, Eur Heart J, 2014

- 96 patients, 63 treated
- study negative

INNOVATE – HF: ongoing trial

- different device with additional sensor in the right ventricle
- first results expected in 2016