Implantable Cardioverter-Defibrillator (ICD)

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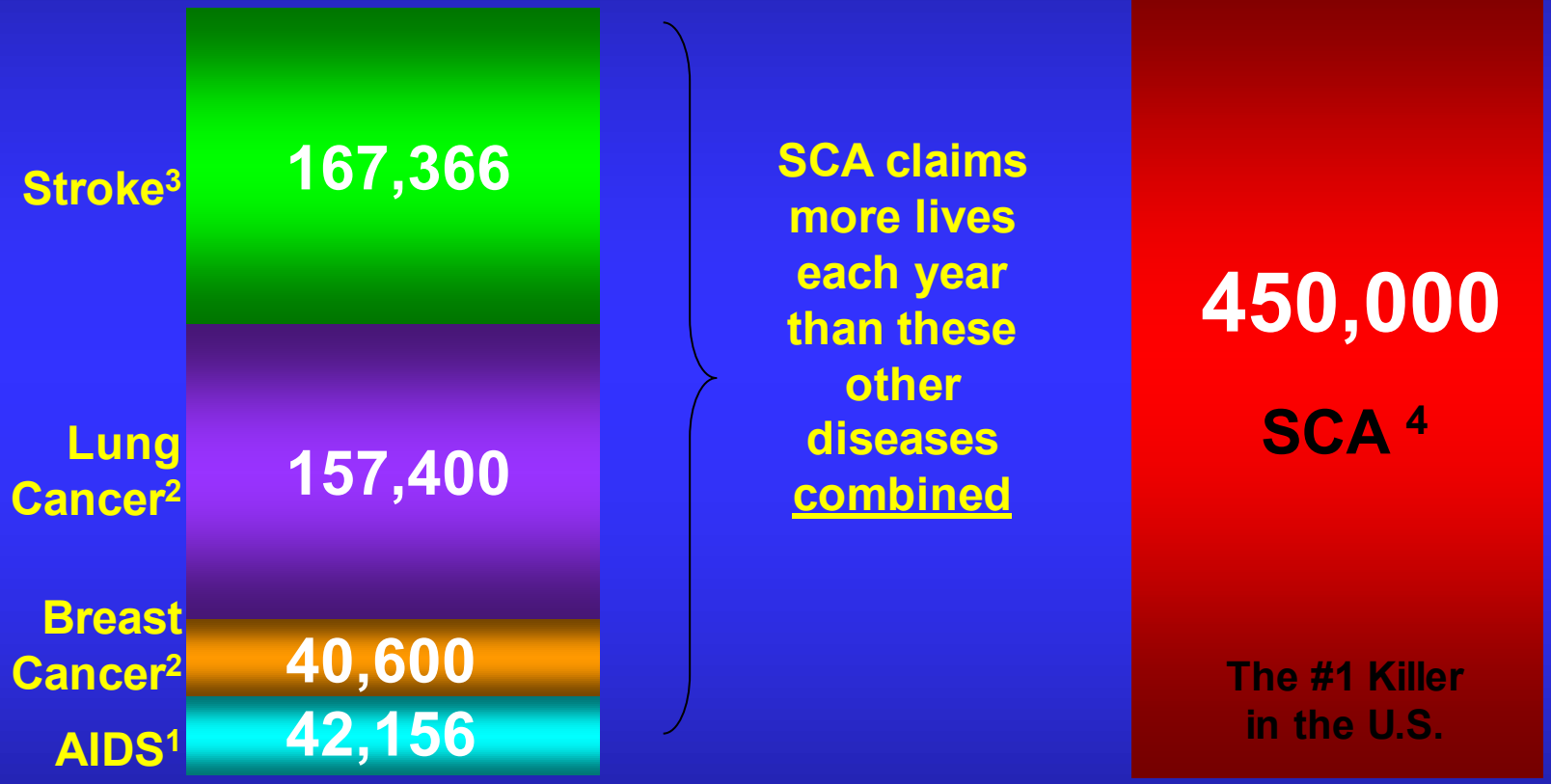
Implantable Cardioverter Defibrillator (ICD)

1. Overview
2. Technical aspects
3. Indications for secondary and primary prevention of SCD
4. Short- and long-term problems

Magnitude of SCA in the US



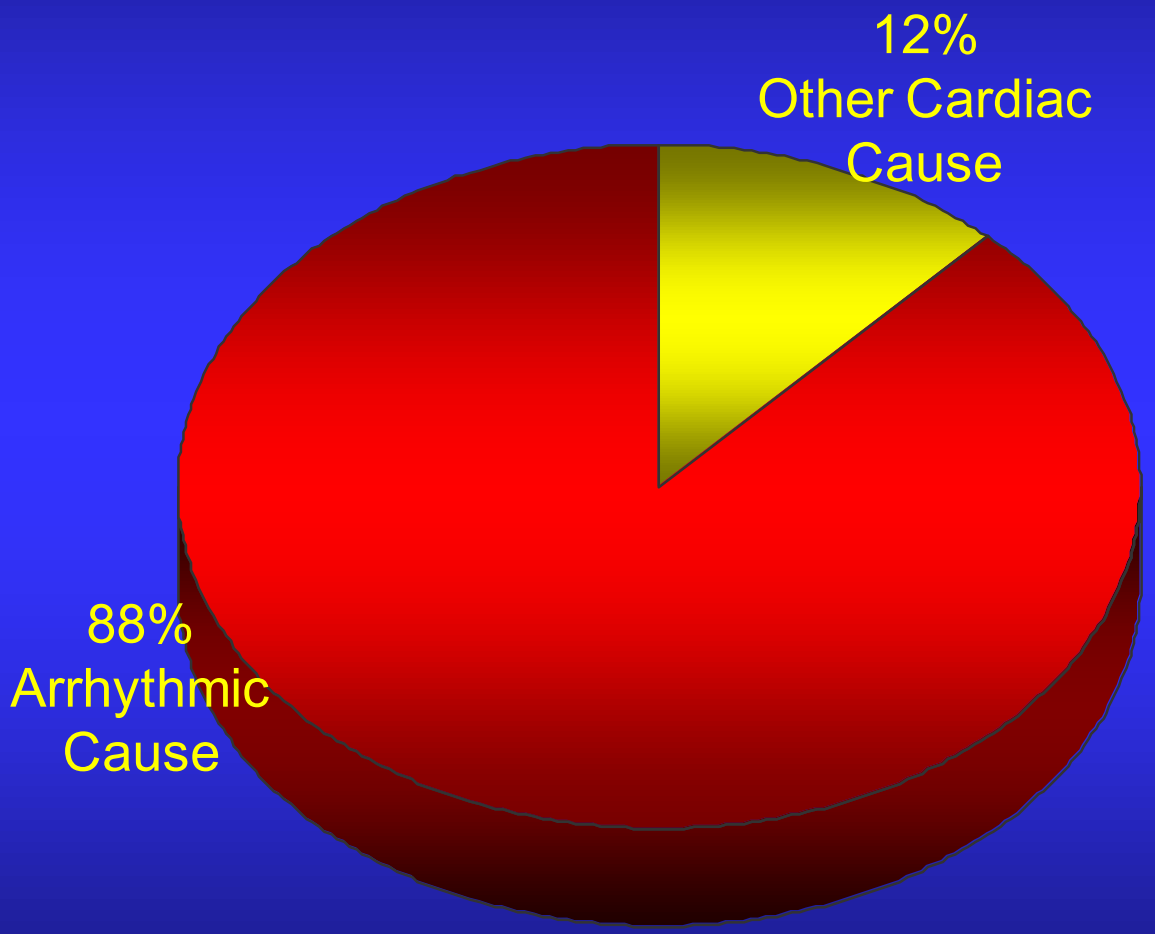
[1] U.S. Census Bureau, *Statistical Abstract of the United States: 2001*.

[2] American Cancer Society, Inc., *Surveillance Research, Cancer Facts and Figures 2001*.

[3] *2002 Heart and Stroke Statistical Update*, American Heart Association.

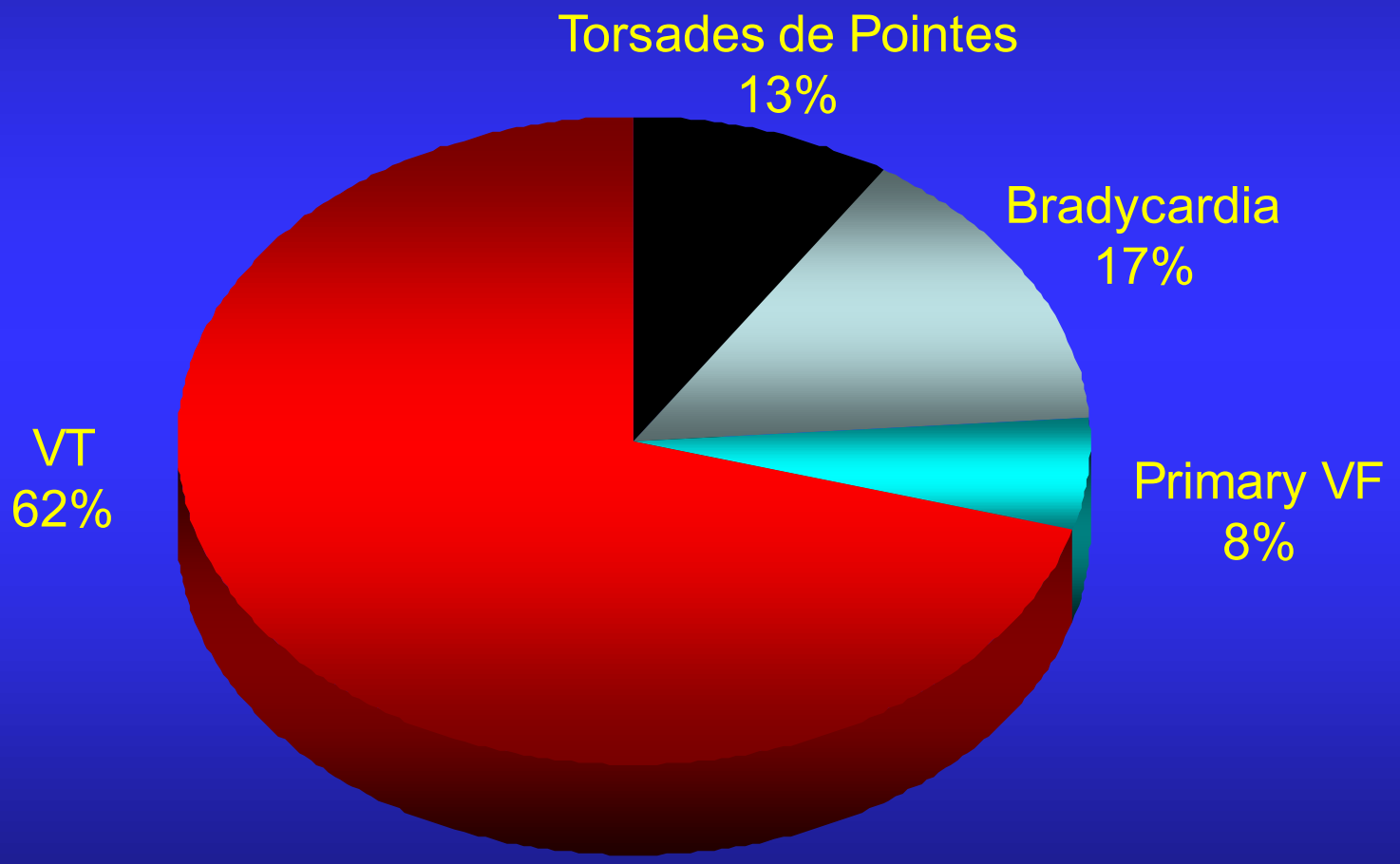
[4] *Circulation*. 2001;104:2158-2163.

Arrhythmic Cause of SCD



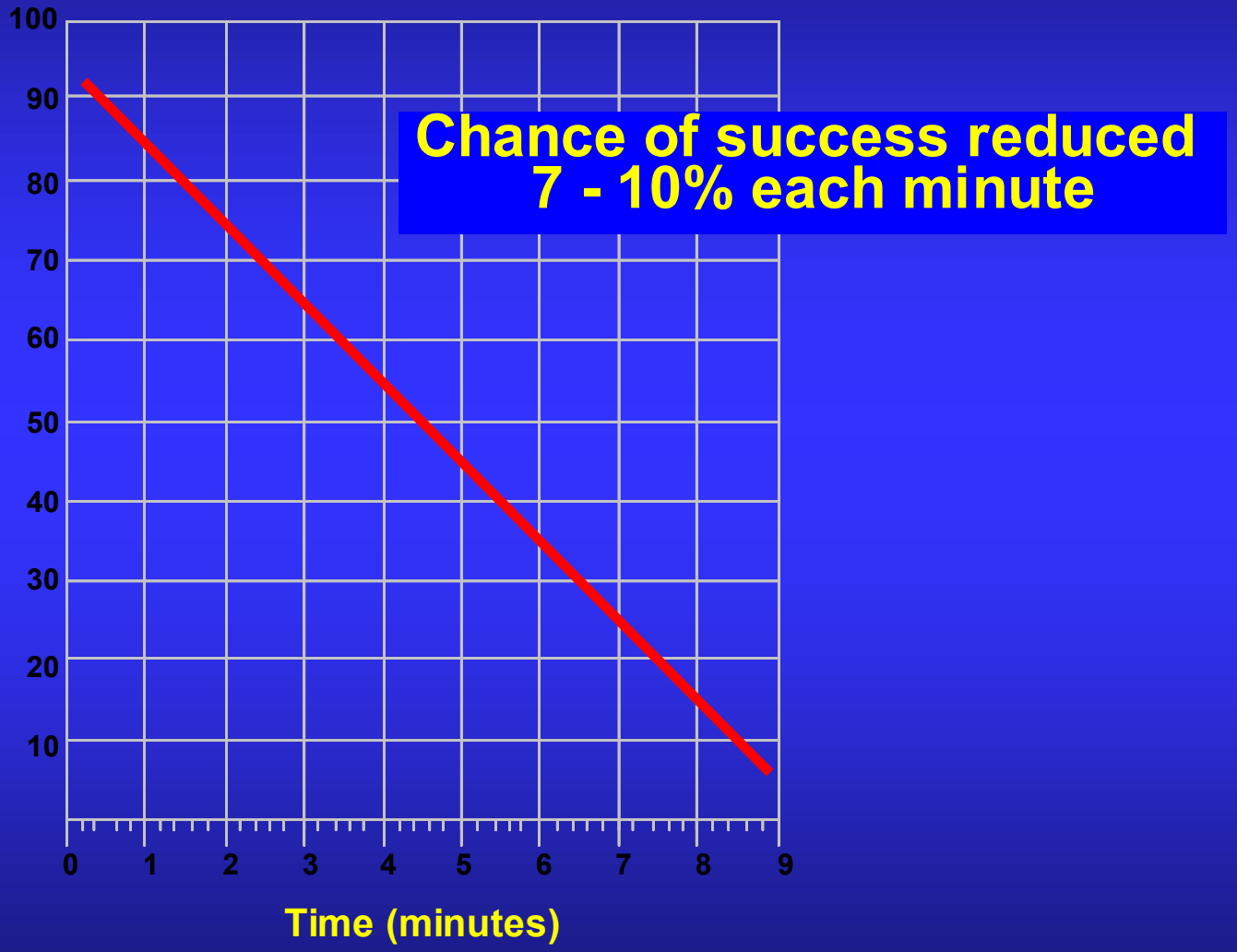
Albert CM. *Circulation*. 2003;107:2096-2101.

Underlying Arrhythmias of Sudden Cardiac Arrest



Bayés de Luna A. *Am Heart J.* 1989;117:151-159.

SCA Resuscitation Success vs. Time*



Cummins RO. *Annals Emerg Med.* 1989;18:1269-1275.

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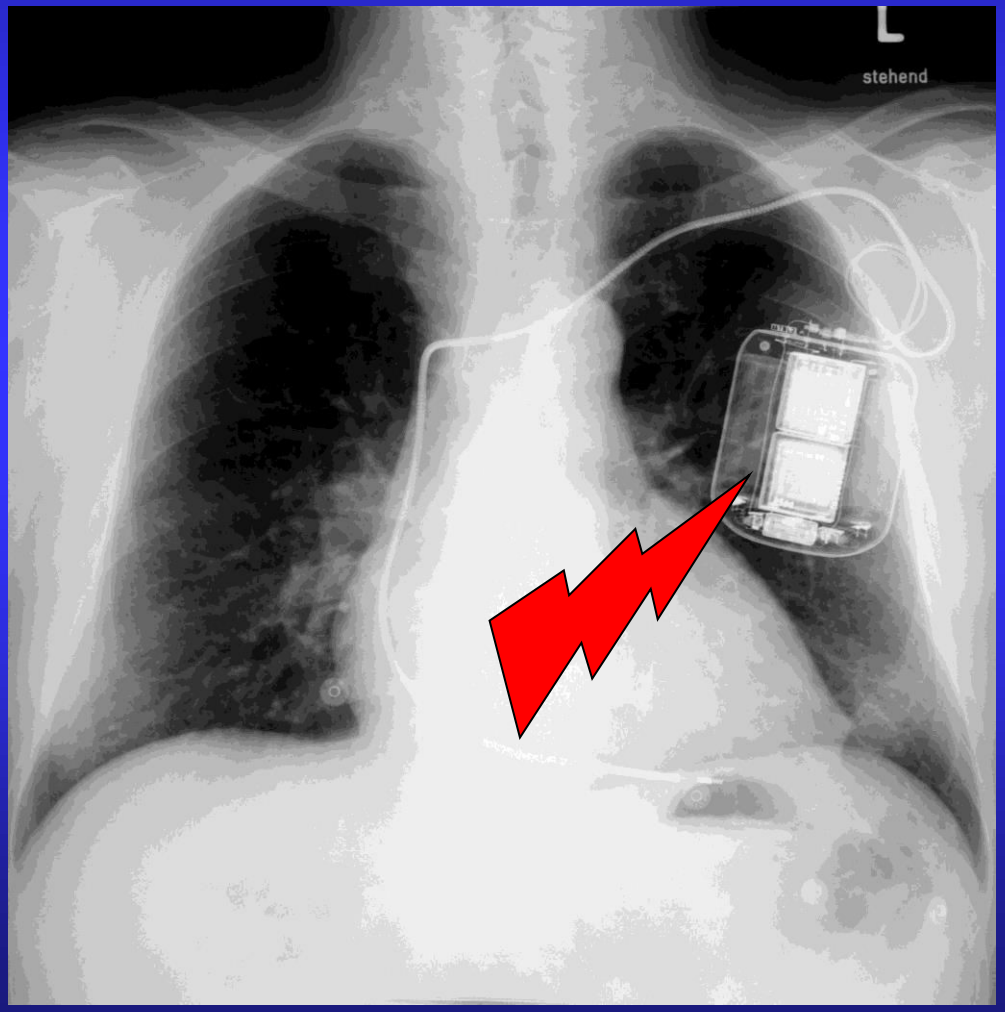
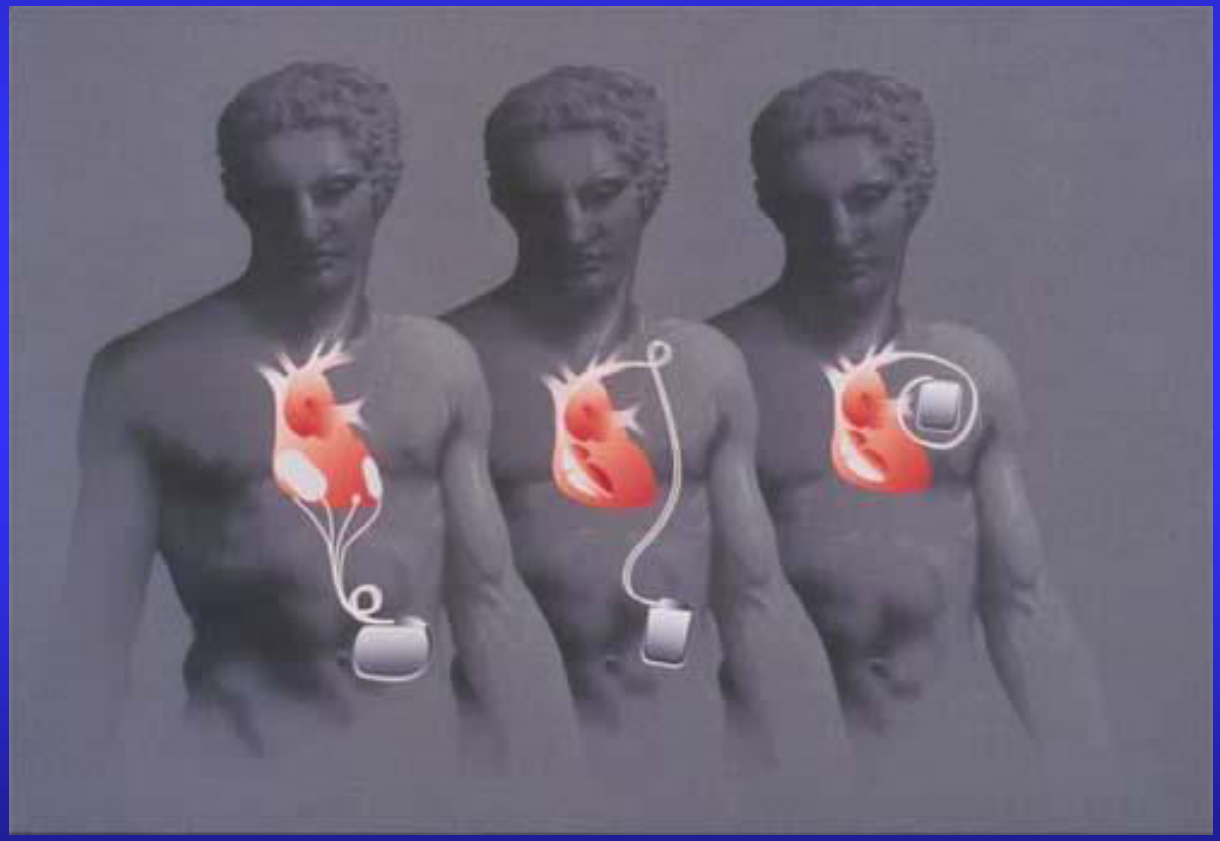


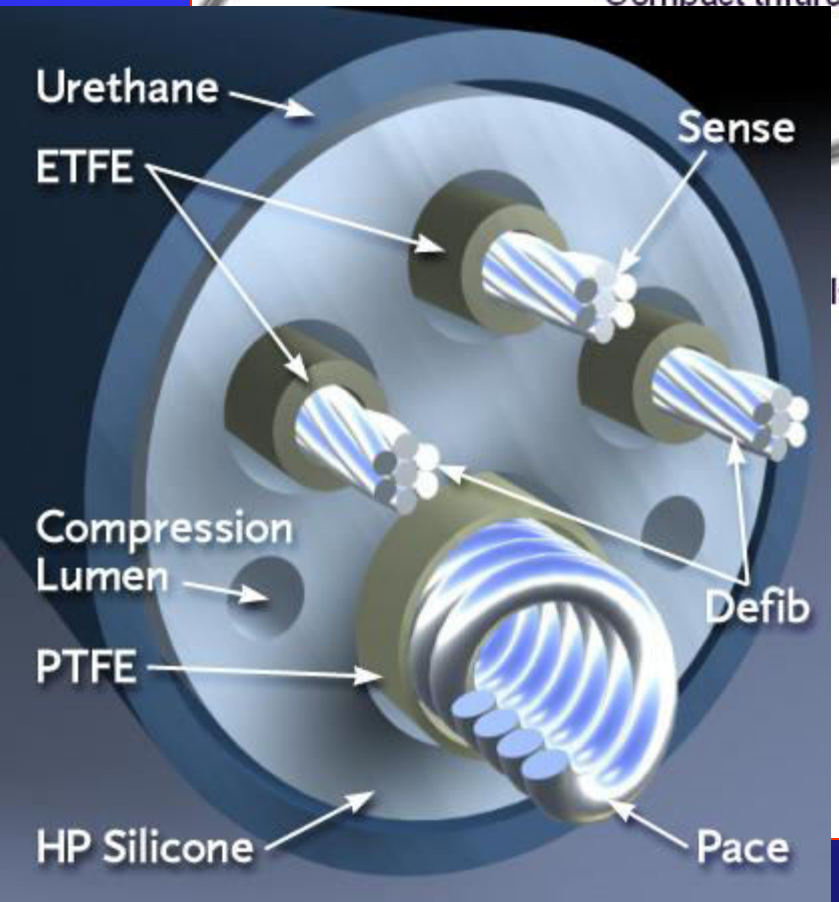
ICD-implantation sites

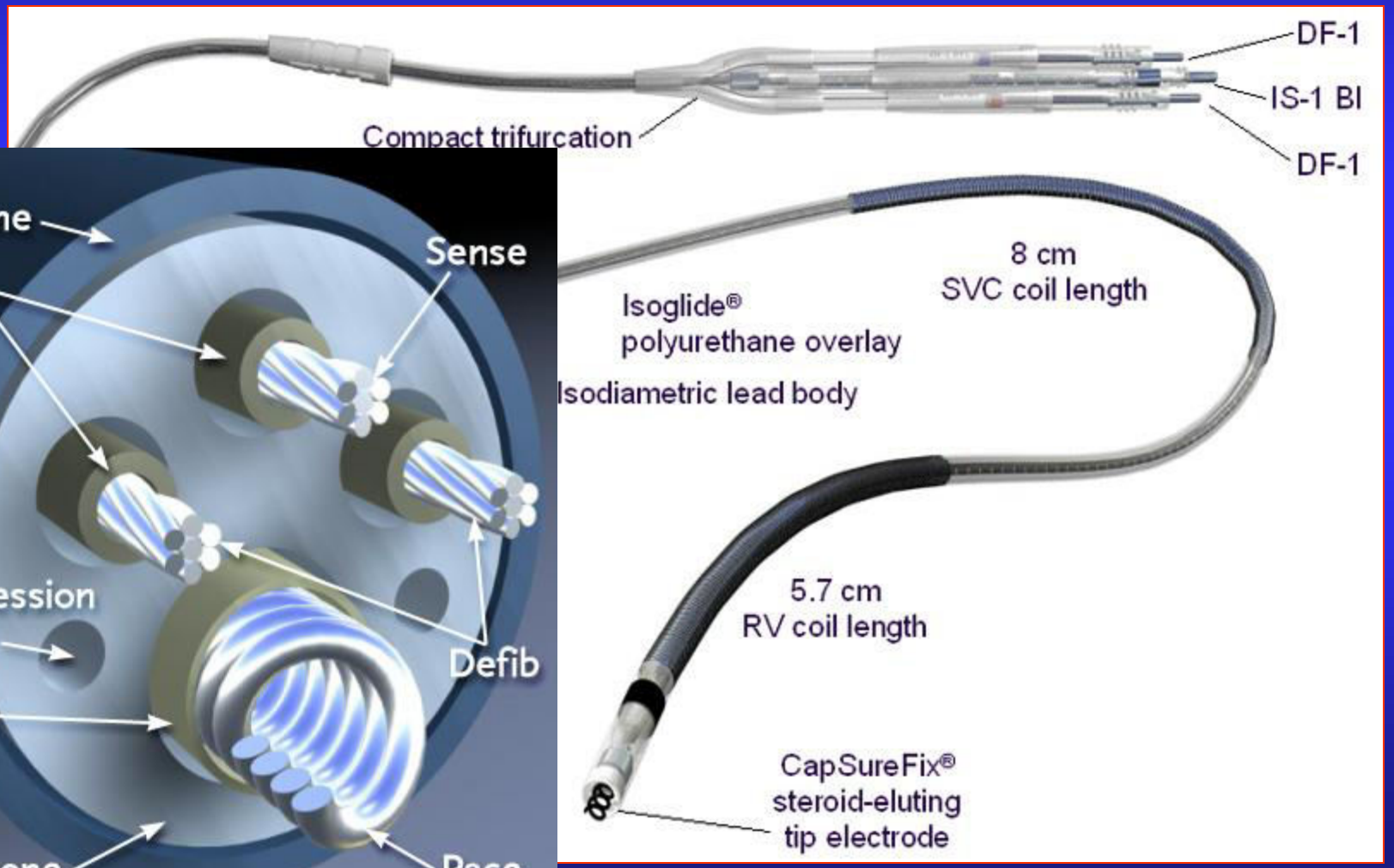


ICD-size


209 cc
113 cc
80 cc
80 cc
72 cc
54 cc
62 cc
49 cc
39.5 cc
39 cc
39.5 cc
39 cc

ICD-leads


Urethane
ETFE
Sense
Compression
Lumen
Defib
PTFE
HP Silicone
Pace


DF-1
IS-1 BI
DF-1
Compact trifurcation
8 cm
SVC coil length
Isoglide®
polyurethane overlay
Isodiametric lead body
5.7 cm
RV coil length
CapSureFix®
steroid-eluting
tip electrode

Functions of an ICD

An ICD is a „pacemaker that shocks" !

<u>3 main features</u>

1.) State- of-the-art pacemaker (VVIR,DDDR)
- > antibradycardia therapy

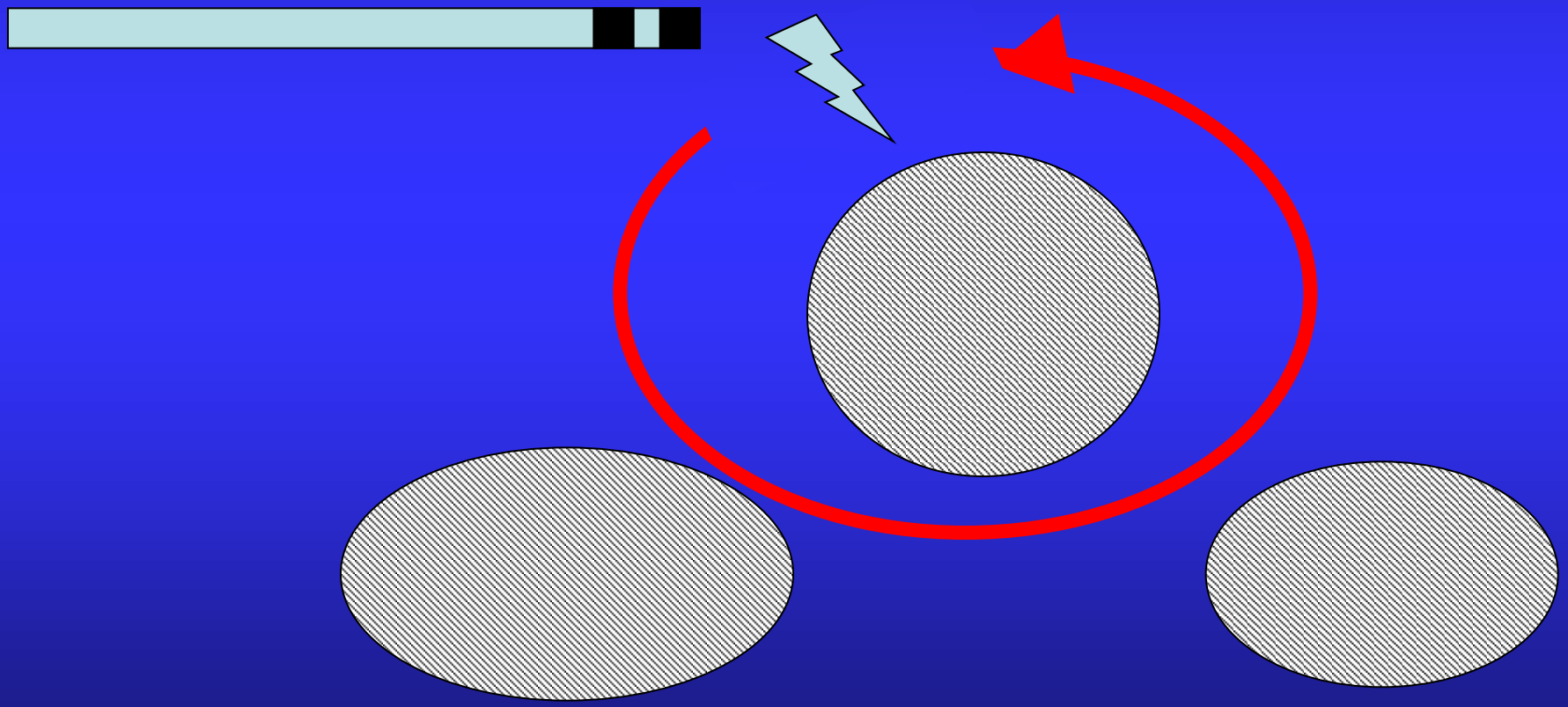
2.) Shock delivery Rx of ventricular fibrillation/tachycardia
-> most effective treatment of sudden cardiac death !

3.) Antitachycardia pacing (ATP) for Rx of monomorphic VT
-> „pain-free" treatment !

Antitachycardia Pacing (ATP)

„Pain-free“ therapy of monomorphic VT

ATP – „Excitable Gap“



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Groups at risk and incidence of SCD

Total population

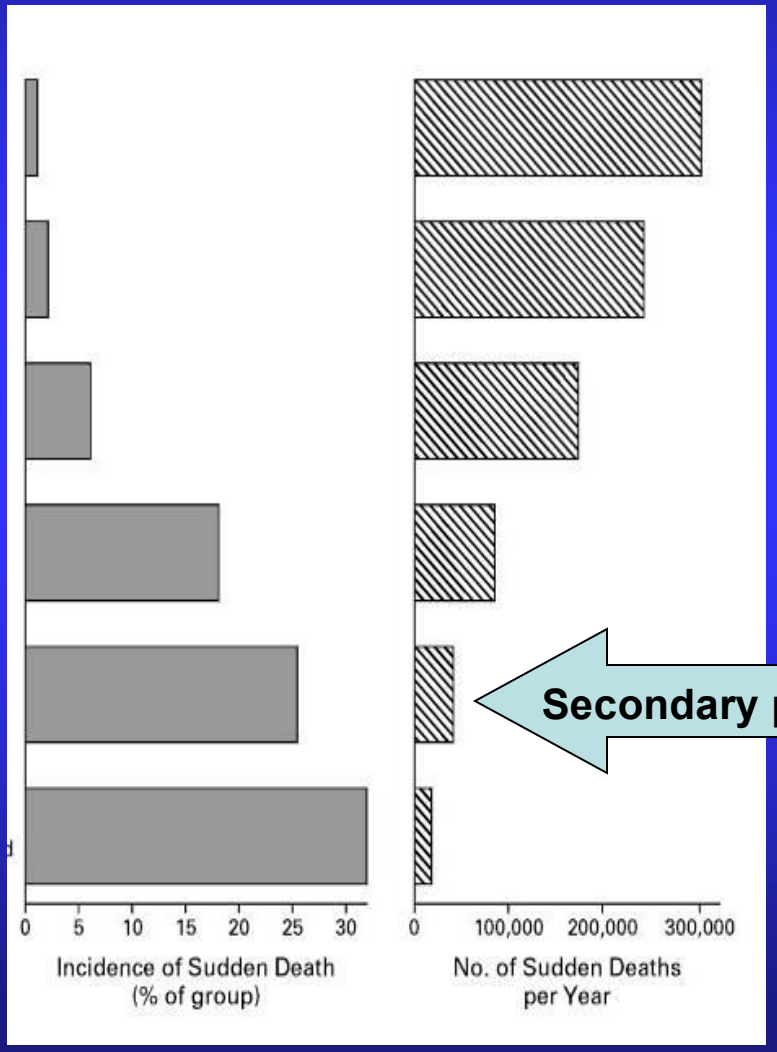
Pts with coronary risk factors

Pts after coronary event

Pts with EF < 35%

Pts with survived SCD

Pts post-MI with high risk



Secondary prophylaxis of SCD

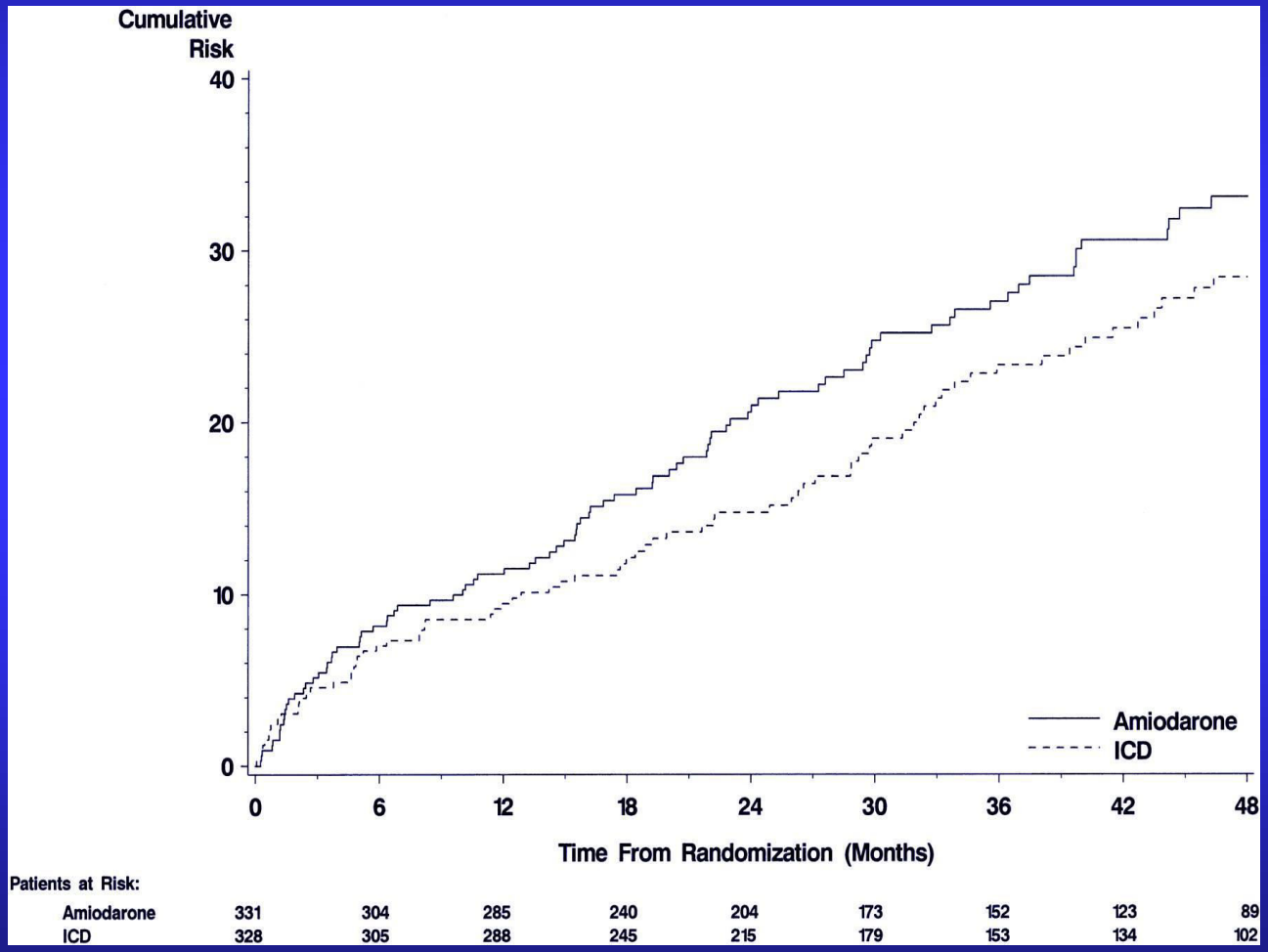
Comperative studies of ICD vs. AA post-VT/VF

	n	Indication	Follow-up (years)
AVID (NEJM 1997)	1016	VT/VF	1,5
CIDS (Circ 2000)	659	VT/VF/Syncope	3,0
CASH (Circ 2000)	288	VF/Rea	5,8

Connolly et al, Eur Heart J 2000

Secondary prophylaxis of SCD

Meta-Analysis of AVID, CIDS, CASH



Connolly et al, Circulation 2000

Secondary prophylaxis of SCD

Meta-Analysis of AVID, CIDS, CASH

Consistent results in all 3 primary prevention trials

Mortality reduction: 28% (12,3% -> 8,8%/yr)

Reduction of SCD: 50%

Connolly et al, Eur Heart J 2000

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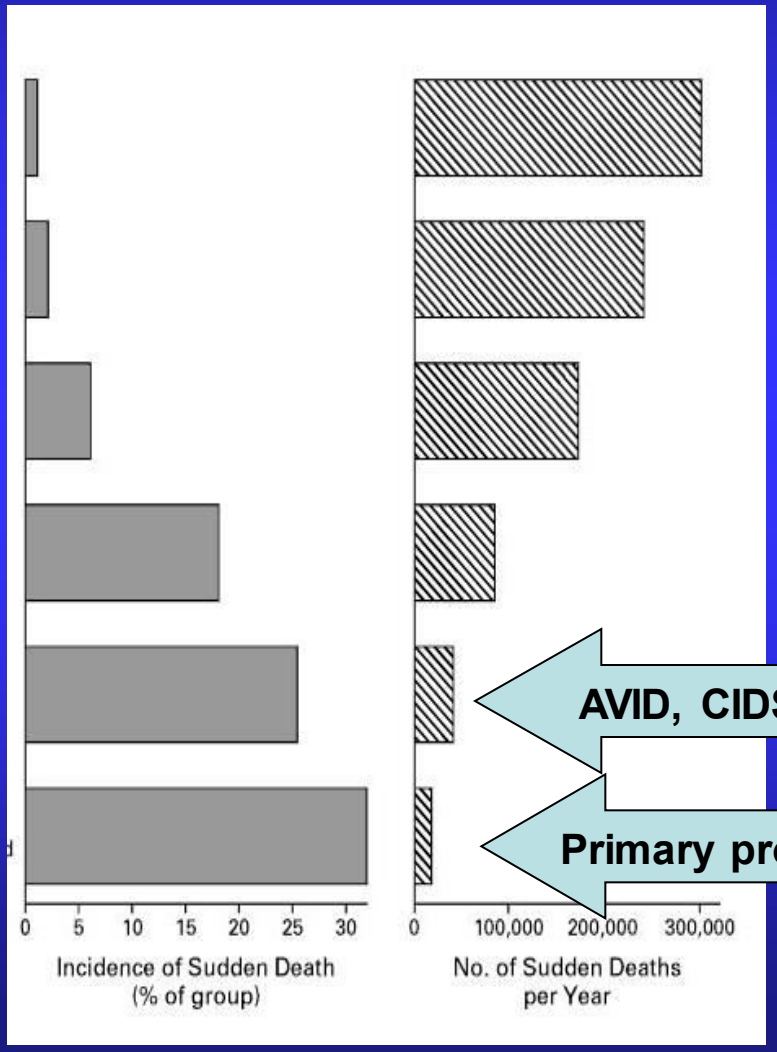
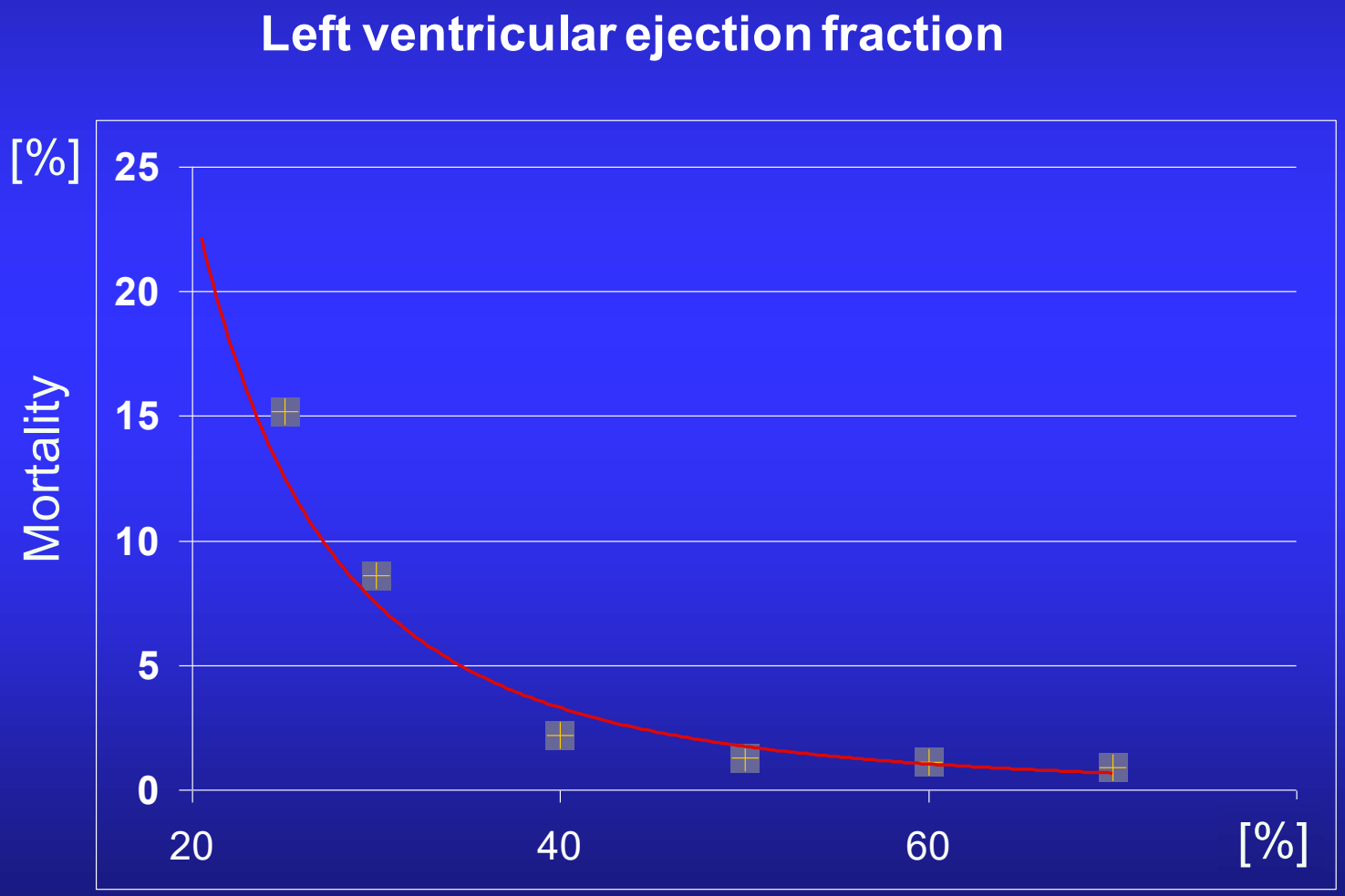
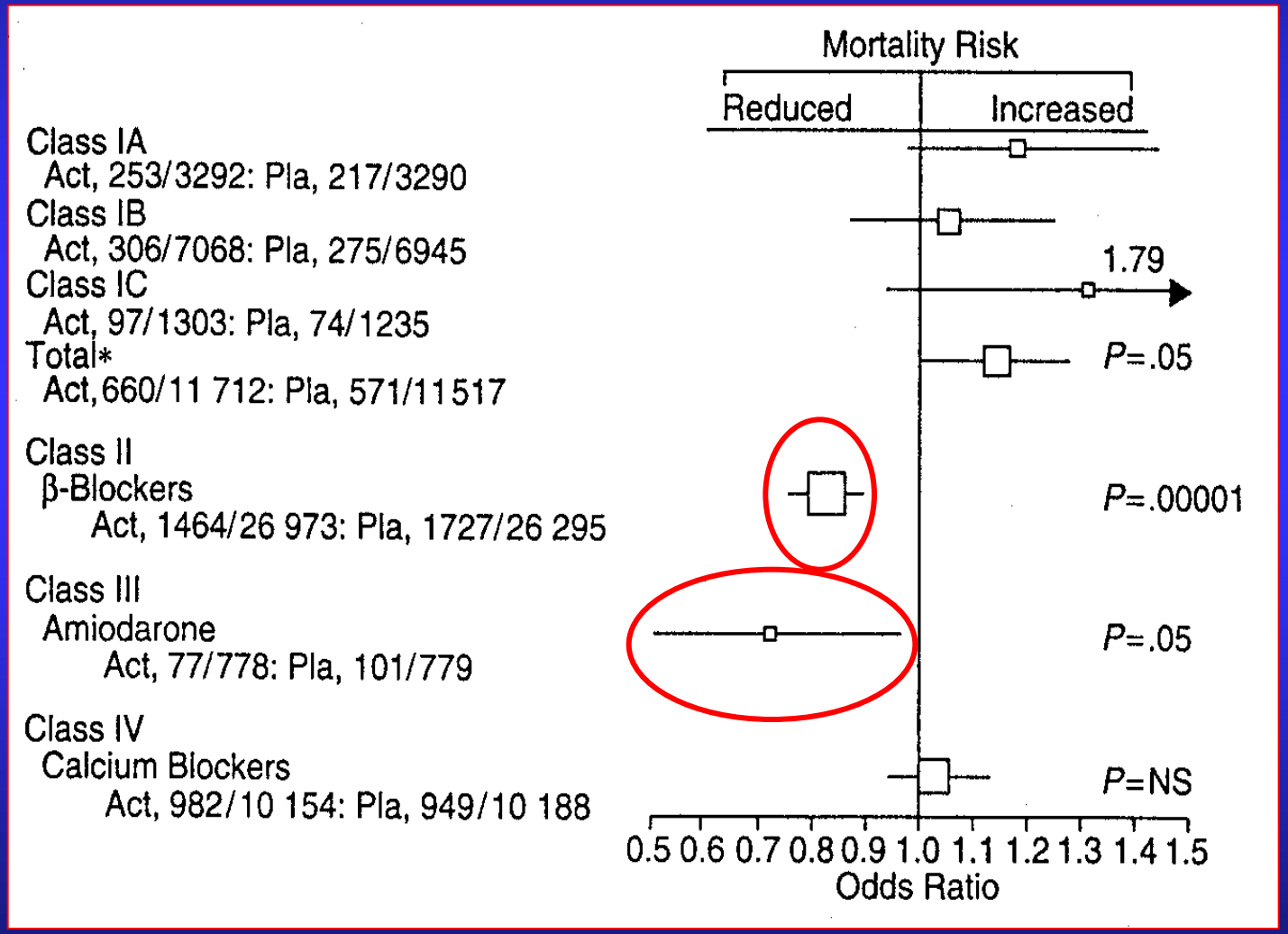


Primary prophylaxis of SCD - Post-MI risk stratification

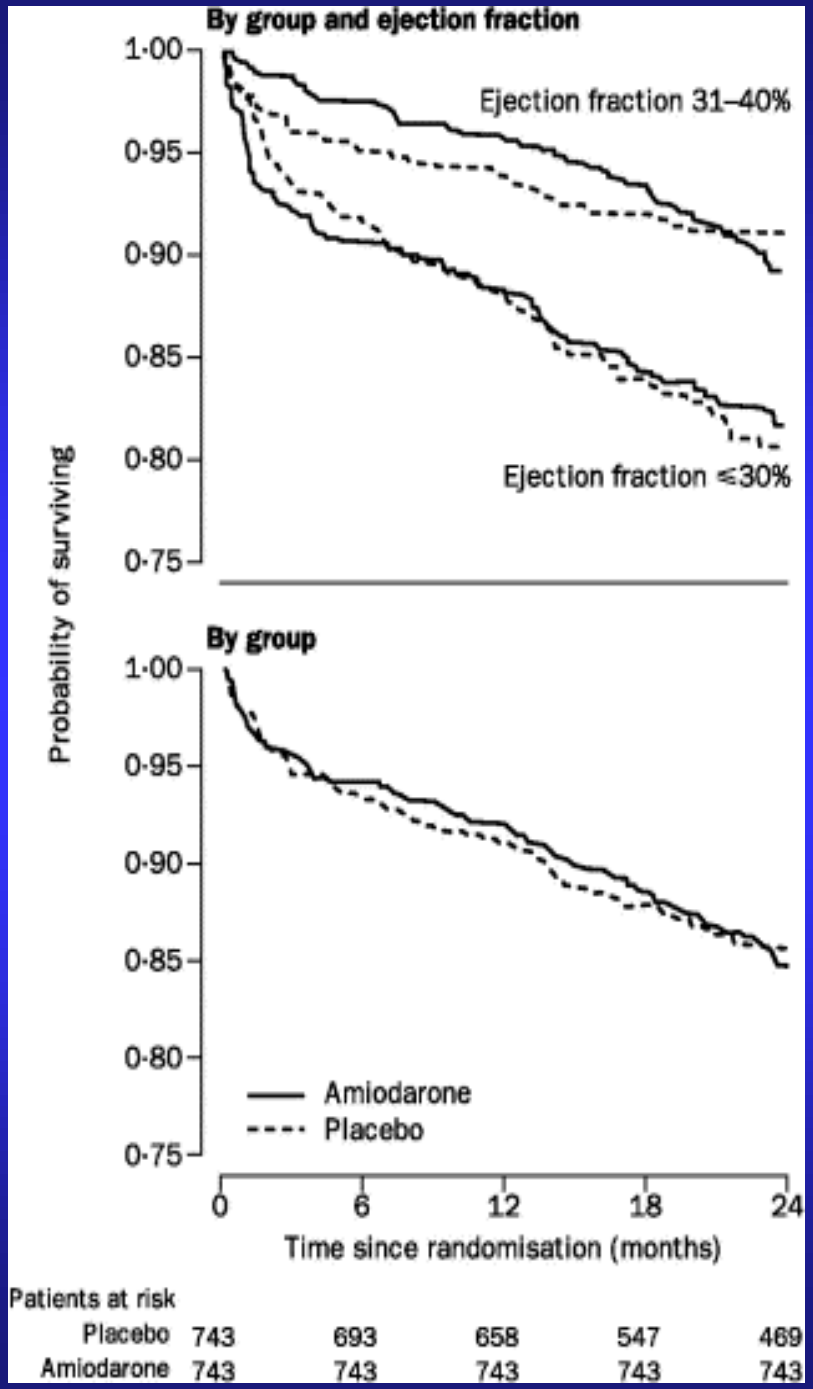


GISSI-Study, Circulation 1995

Primary prophylaxis of SCD – Drug therapy



Teo et al, JAMA 1993



Amiodaron for primary prevention of SCD (EMIAT-trial)

1486 Post-MI pts., EF < 40%

(743 pts Amio/Plac each)

Total mortality

Median FU 21 months

Julian et al, Lancet 1997

ICD Clinical Trials in Post-MI Patients

MADIT

- **M**ulticenter **A**utomatic **D**efibrillator **I**mplantation **T**rial

  Moss AJ. *N Engl J Med* 1996:335:1933-40.

MUSTT

- **M**ulticenter **U**nsustained **T**achycardia **T**rial

  Buxton AE. *N Engl J Med.* 1999;341:1882-90.

MADIT-II

- **M**ulticenter **A**utomatic **D**efibrillator **I**mplantation **T**rial-**II**

  Moss AJ. *N Engl J Med.* 2002;346:877-83.

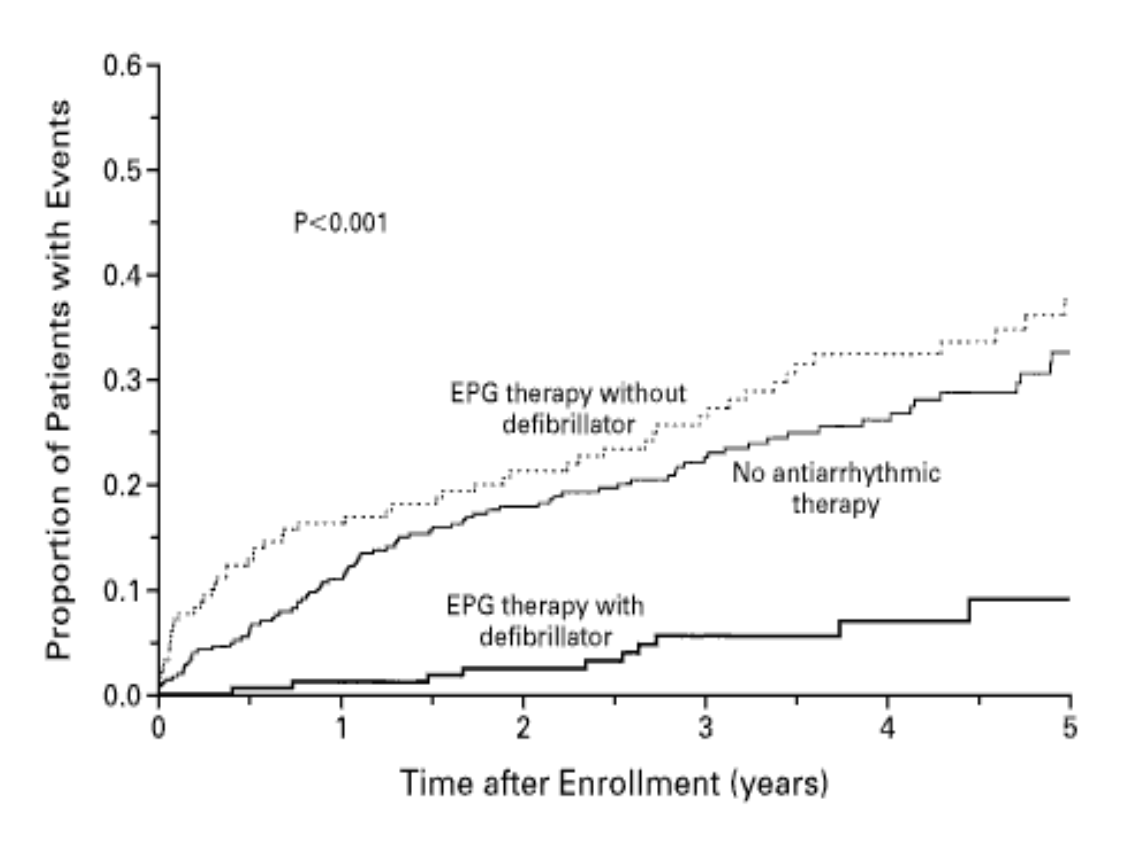
CAD-Primary Prevention: MUSST

Multicenter Unsustained Tachycardia Trial (MUSTT)

- n = 704 pts, EF ≤ 40 %, ischemic CMP,
  ns-VT in Holter recordings
- EPS: inducible sustained VT
- Randomisation: EPS-guided antiarrhythmic Rx vs. ICD

Buxton et al, N Engl J Med 1999

CAD-Primary Prevention: MUSST



Buxton et al, N Engl J Med 1999

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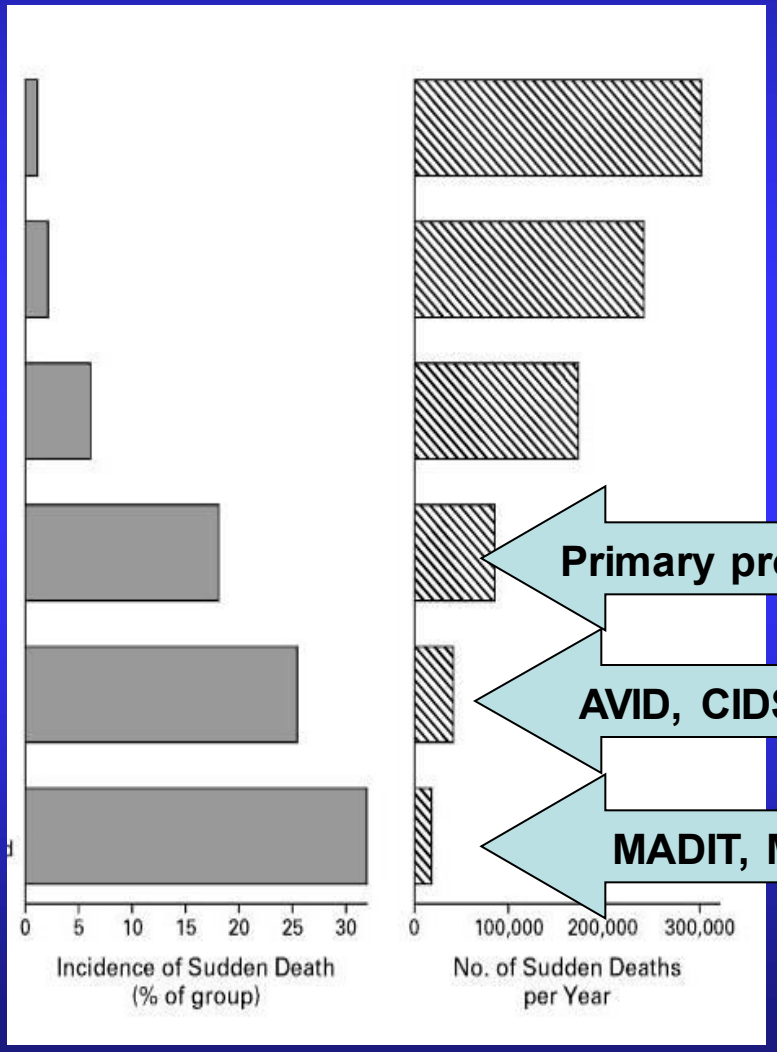


CAD-Primary Prevention: MADIT II

MADIT II (Moss et al. NEJM 2002)

Inclusion:

4 weeks post-MI, EF ≤ 30%

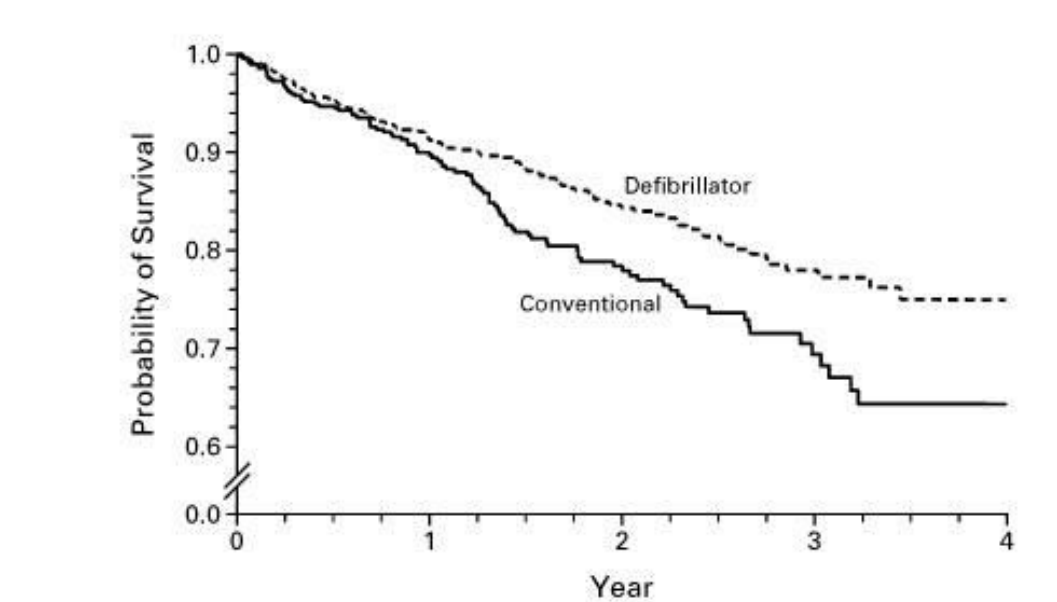
FU: 20 months, EF 0.23+0.05

Mortality:

Conventinal: 19.8%

ICD: 14.2% (Hazard Ratio 0.69)

RR: 31 %, NNT 17



No. at Risk					
Defibrillator	742	503 (0.91)	274 (0.84)	110 (0.78)	9
Conventional	490	329 (0.90)	170 (0.78)	65 (0.69)	3

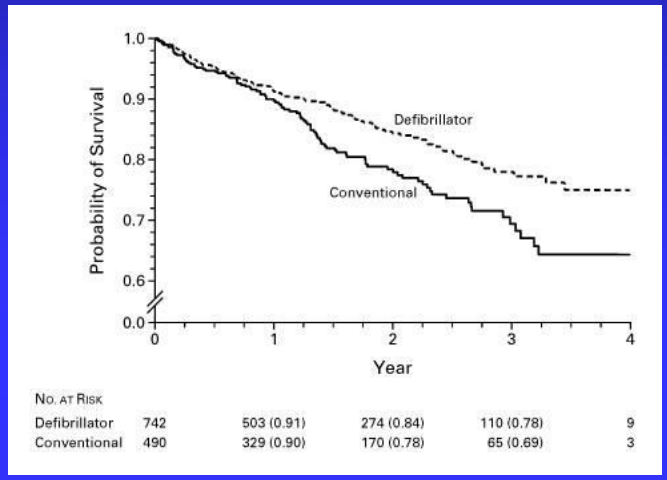
Mortality Differences – ischemic and non-ischemic

Mortality MADIT II

(FU: 20 months, EF 0.23+0.05)

Conventional: 19.8%

ICD: 14.2% (Hazard Ratio 0.69)

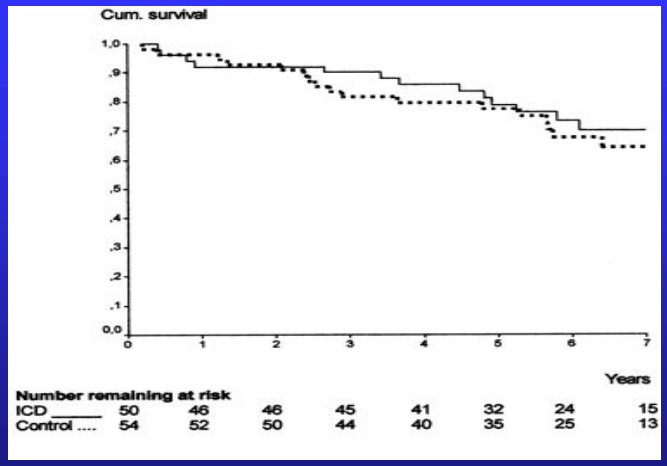


Mortality CAT

(FU: 24 months, EF 0.24+0.07)

Conventional: 7%

ICD: 8%



Non-ischemic CMP: Primary Prevention

DEFINITE

n=458

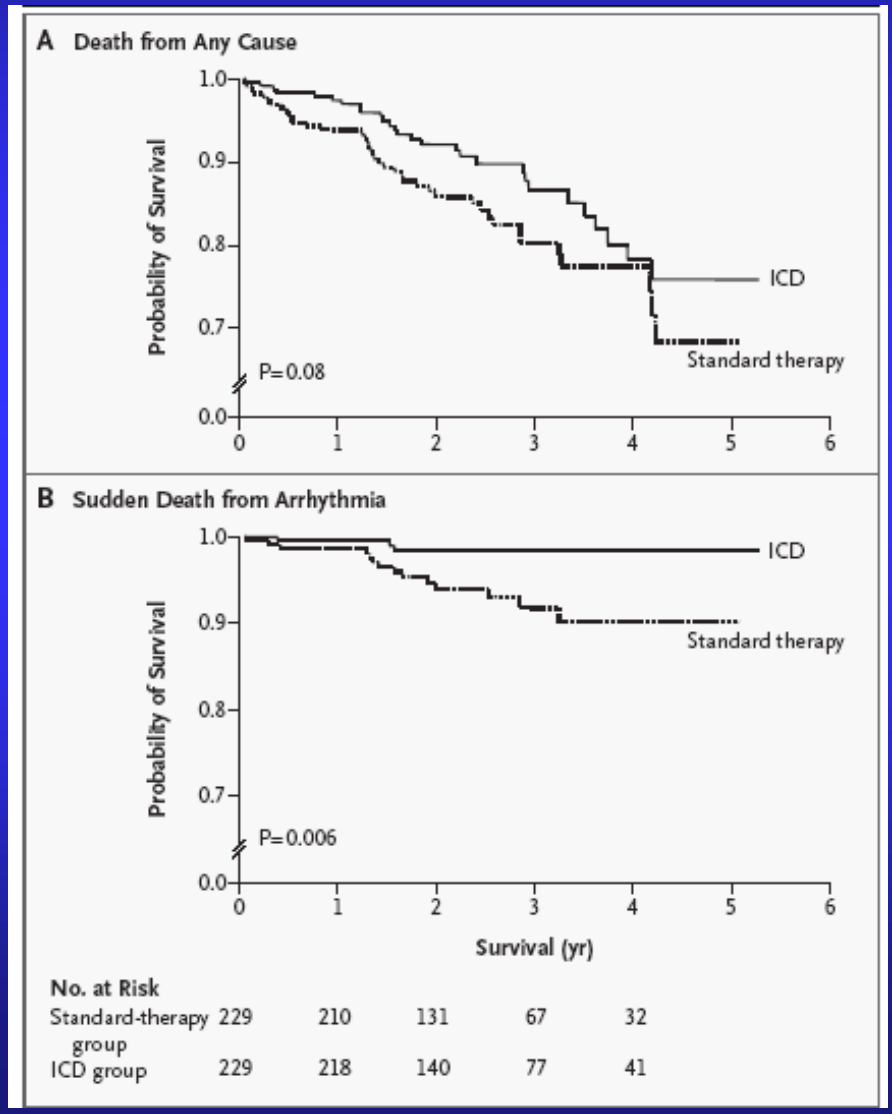
EF ≤ 35%, NSVT or > 10 VES/h

FU: 24 months

Mortality:

Conventional: 14.1 %

ICD: 7.9 % (P=0.08)

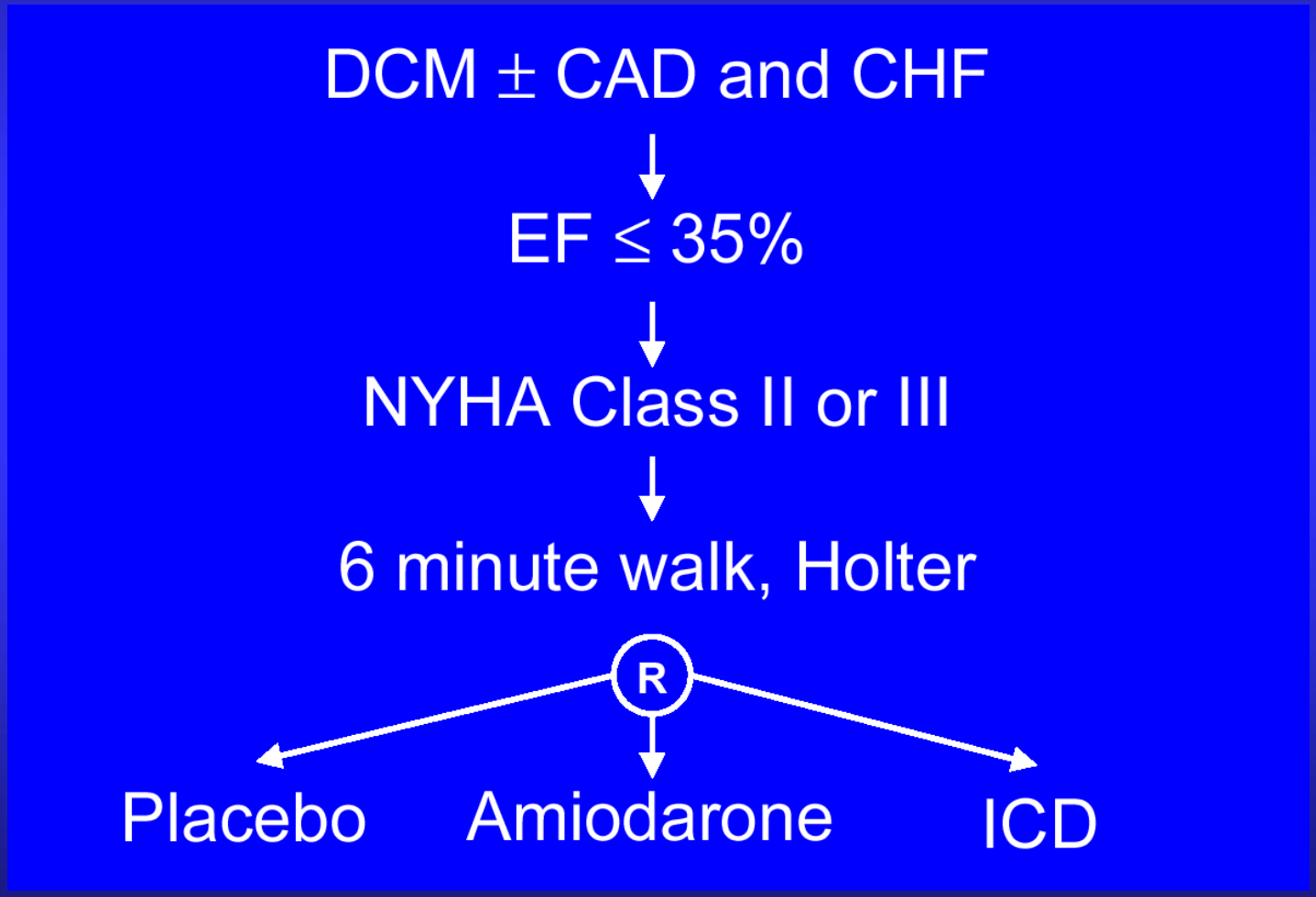


SCD-HeFT – Hypothesis and primary endpoint

- Intention-to-treat analysis:
  Do **Amiodaron** or a „shock-only“ **ICD reduce** the **all-cause mortality** compared to placebo* in patients with
  ischemic or **non-ischemic NYHA II or III** CHF and **EF ≤ 35%** ?

* Drugs double-blind

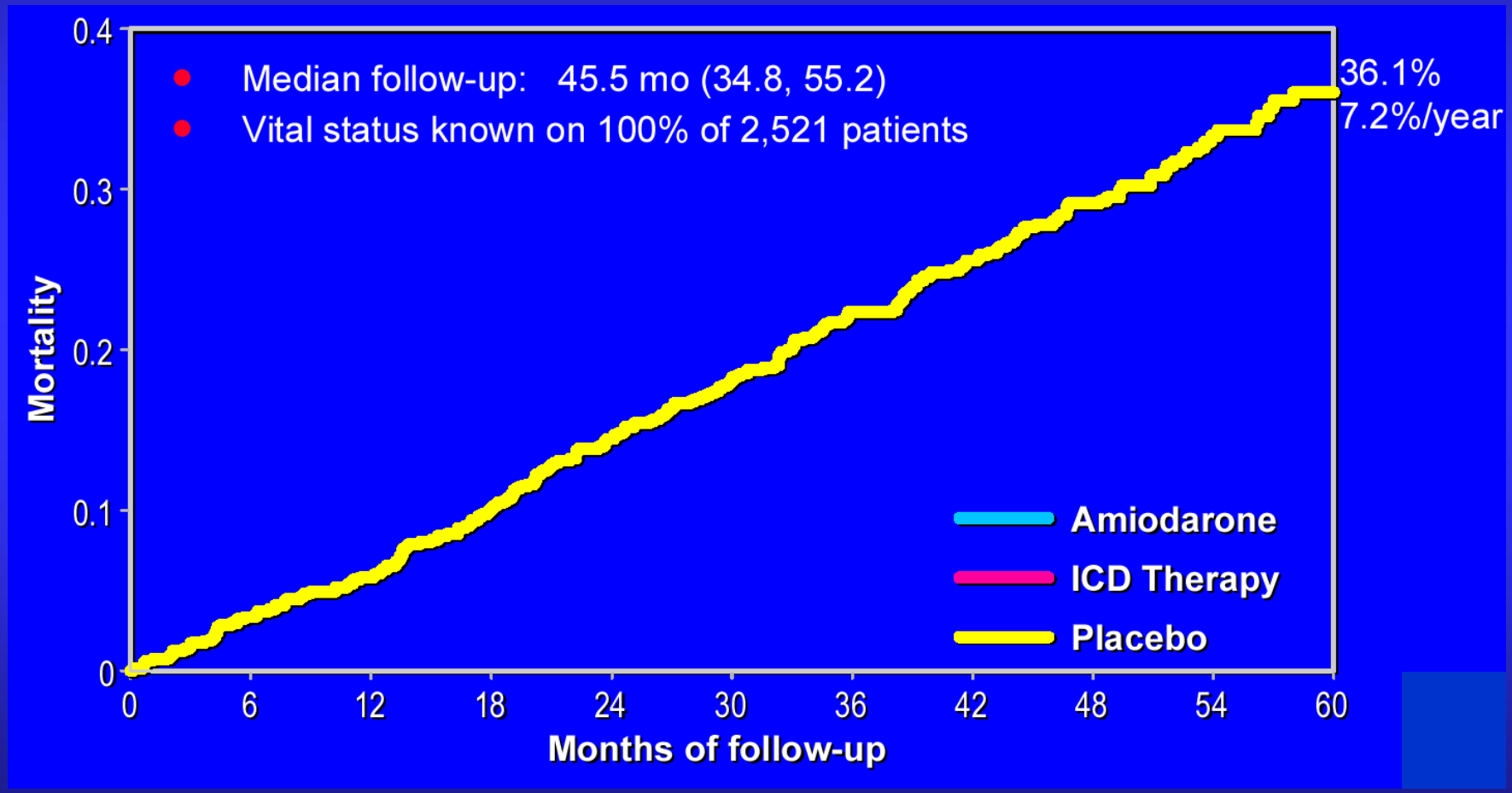
SCD-HeFT – Inclusion criteria



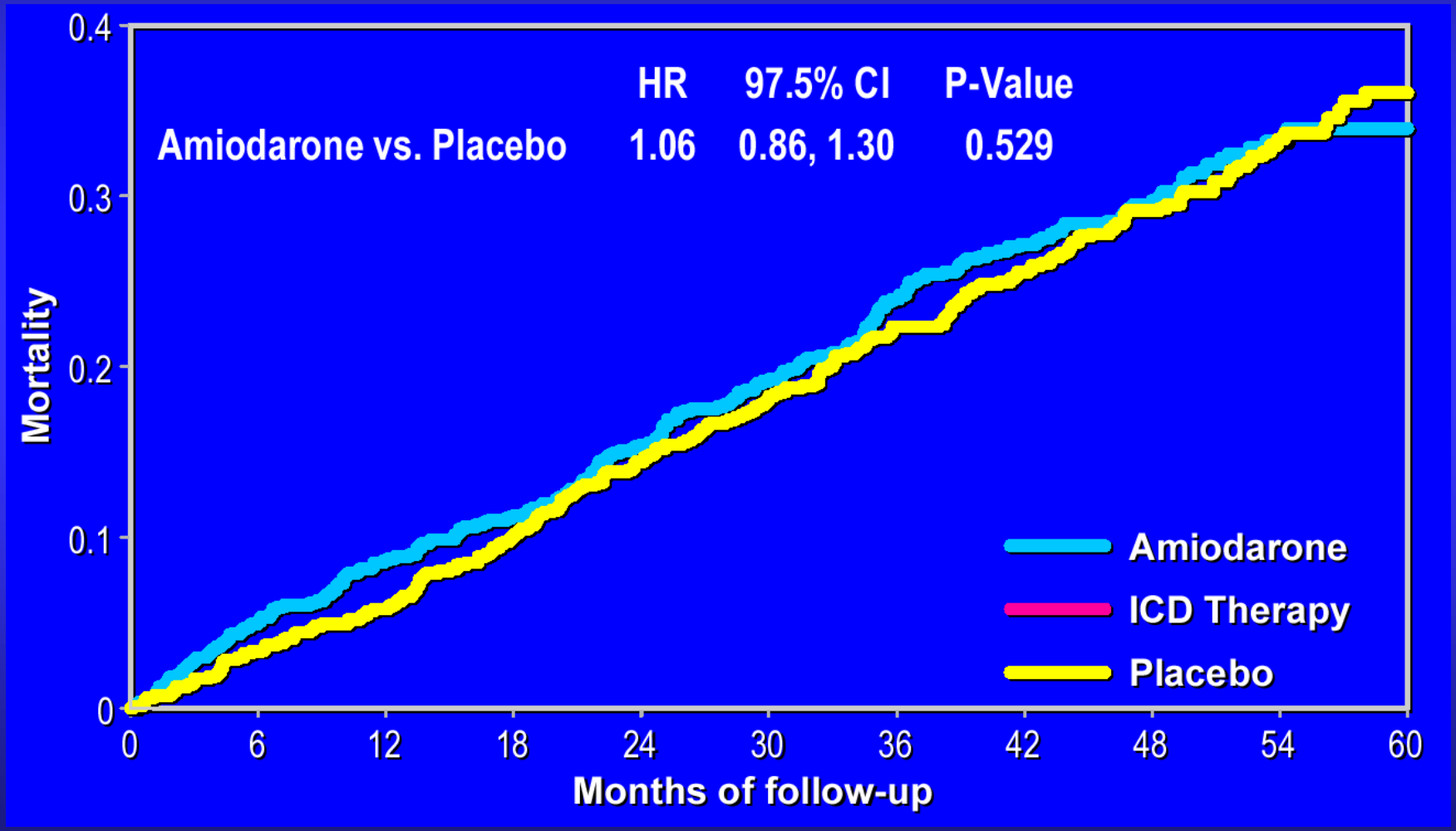
SCD-HeFT – patient characteristics

CHF duration	24.5 mo (8.1, 59.4)
LV EF	25.0 (20.0, 30.0)
NYHA II, III	70%, 30%
Ischemic, non-ischemic	52%, 48%
6 minute walk	1130 ft (840, 1360)
Diabetes	30%
CABG and/or Perc. Revasc.	37%
H/O Hypertension	56%
H/O Hyperlipidemia	53%
H/O AF	15%
H/O NSVT	23%
ECG QRS duration	112 ms (96, 140), 41% ≥ 120 ms

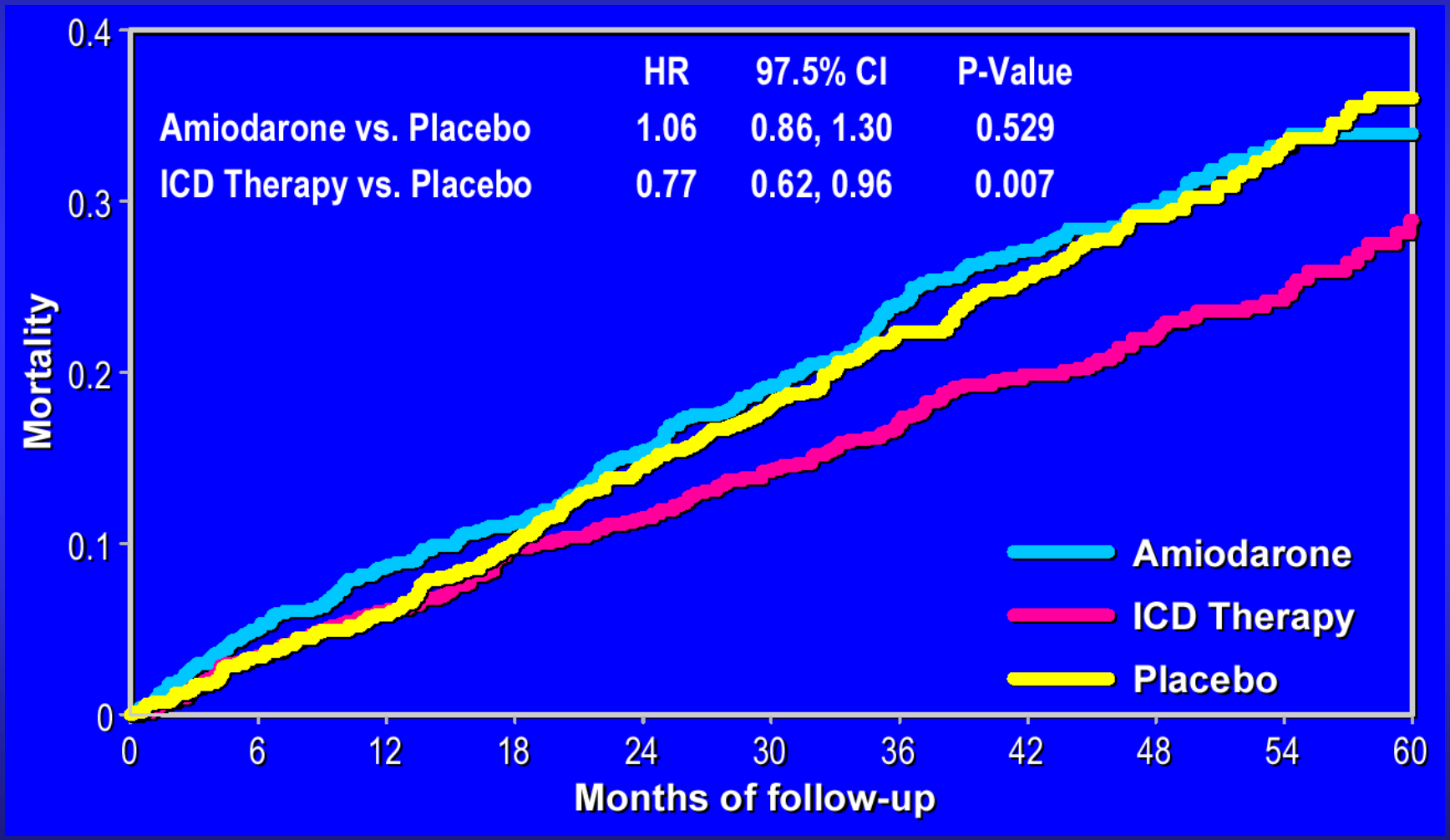
SCD-HeFT – Mortality (Intention-to-treat)



SCD-HeFT – Amiodaron vs. Placebo



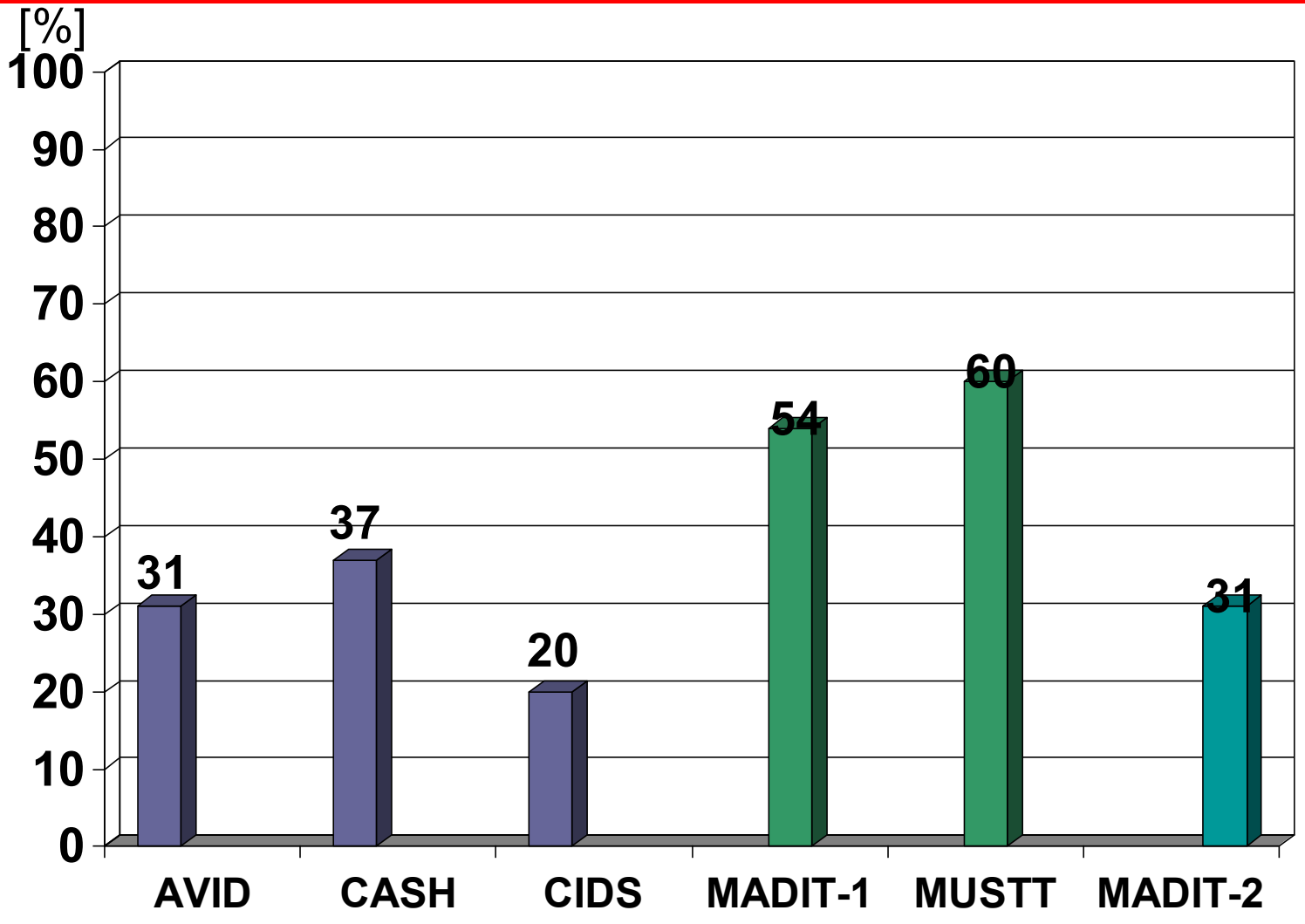
SCD-HeFT – ICD vs. Placebo



SCD-HeFT – Conclusion

- In pts with CHF NYHA II or III, EF ≤ 35%, and an optimized medical therapy, the annual mortality is 7.2 % over 5 years
- Simple, „shock only“ ICD reduces mortality by 23%
- Amiodaron does not improve survival

ICD-therapy - Mortality-Benefits (RR)



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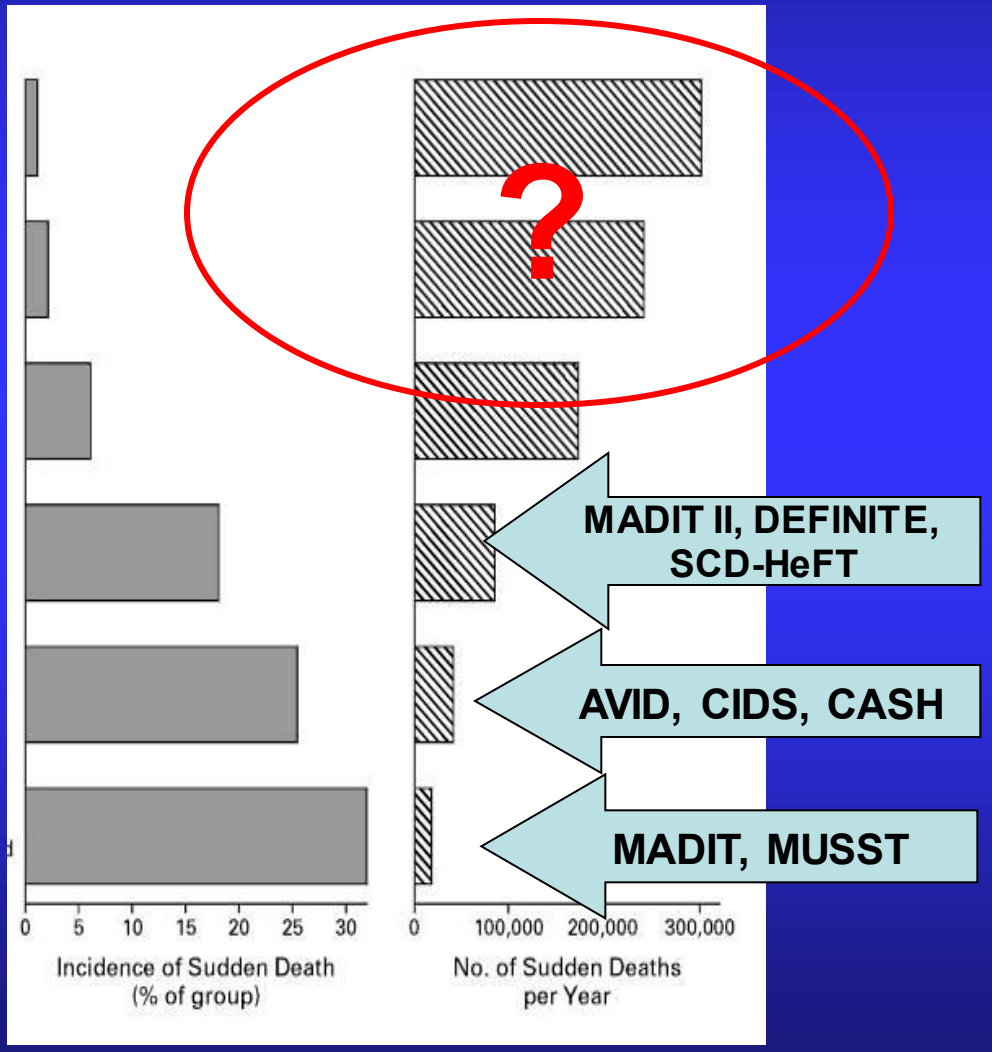

Summary: ICD-Indications

	Ischemic heart ds	Non-ischemic HD
Secondary Prophylaxis	AVID, CIDS, CASH	
Primary Prophylaxis	MADIT II (EF<30%), MUSST, MADIT	DEFINITE (EF<35%) ??
	SCD-HeFT (all pts with EF<35%) ?	

Chỉ định đặt ICD

Class I

- 1. Sống sót sau ngưng tim do VF hoặc VT có rối loạn huyết động, sau khi đã loại trừ tất cả các nguyên nhân có thể hồi phục được.
- 2. Bệnh tim cấu trúc có nhịp nhanh thất kéo dài, xuất hiện tự nhiên
- 3. Ngất không rõ nguồn gốc, tạo được VF hoặc VT gây rối loạn huyết động khi khảo sát điện sinh lý.
- 4. NMCT cũ trên 40 ngày, EF <35%, NYHA II hoặc III.

Chỉ định đặt ICD

- 5. Bệnh cơ tim dãn nở không do thiếu máu cục bộ, EF <35%, NYHA II or III.
- 6. NM cơ tim cũ trên 40 ngày, EF <30%, NYHA class I.
- 7. NMCT cũ, EF< 40%, nhịp nhanh thất không kéo dài, và tạo được VF or VT kéo dài khi khảo sát điện sinh lý.

Chỉ định đặt ICD

CLASS IIa

- 1. Ngất không rõ nguyên nhân, rối loạn chức năng thất trái đáng kể, Bệnh cơ tim dãn nở không do thiếu máu cục bộ.
- 2. Nhịp nhanh thất kéo dài, chức năng thất trái bình thường hoặc gần bình thường
- 3. Bệnh cơ tim phì đại có 1 hay nhiều yếu tố nguy cơ đột tử
- 4. Bệnh loạn sản thất phải sinh loạn nhịp (ARVD/C), có 1 hay nhiều yếu tố nguy cơ đột tử
- *YTNC đột tử: ngưng tim trước đó, nhịp nhanh thất tự nhiên, tiền sử gia đình đột tử, ngất, thất trái dày từ 30mm trở lên, đáp ứng huyết áp bất thường khi gắng sức*

Chỉ định đặt ICD

- 5. Hội chứng QT dài có ngất và/ hoặc nhịp nhanh thất khi đang uống ức chế bêta.
- 6. Bệnh nhân đang chờ ghép tim chưa được nhập viện
- 7. Hội chứng Brugada đã bị ngất
- 8. Hội chứng Brugada có nhịp nhanh thất không gây ngưng tim
- 9. Nhịp nhanh thất đa dạng do catecholamine, có ngất và/ hoặc có nhịp nhanh thất kéo dài khi đang dùng ức chế bêta
- 10. Bệnh sarcoidosis tim, viêm cơ tim tế bào lớn, bệnh Chagas.

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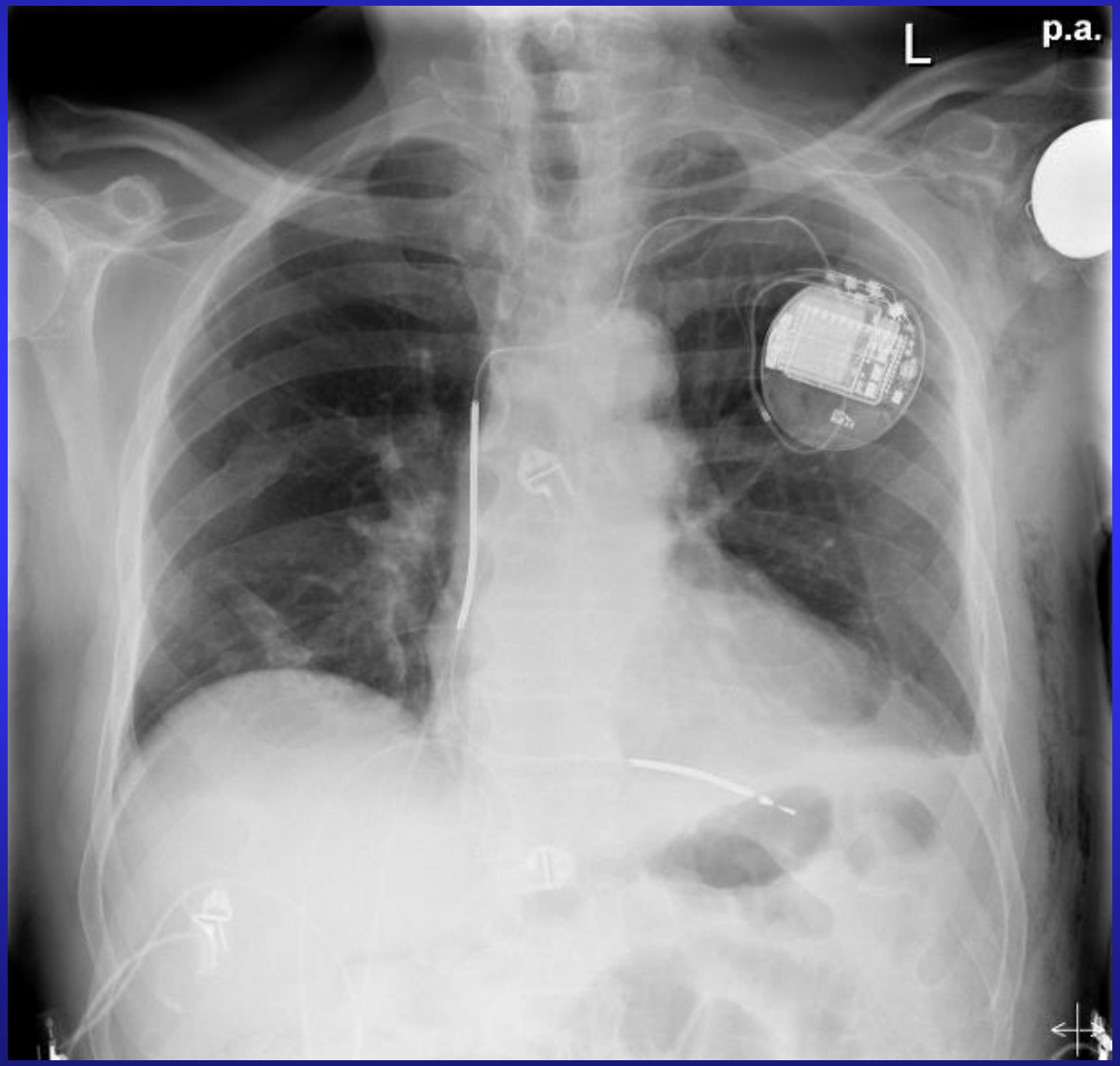
Complications in ICD pts

144 pts with 3rd generation ICD
F/U 21±15 months

Early complications:	- hematoma	3%
	- pneumothorax	1%
	- high DFT	1%
Late complications:	- lead related	4%
	- inappropriate shocks	16%

Grimm et al, PACE 1999

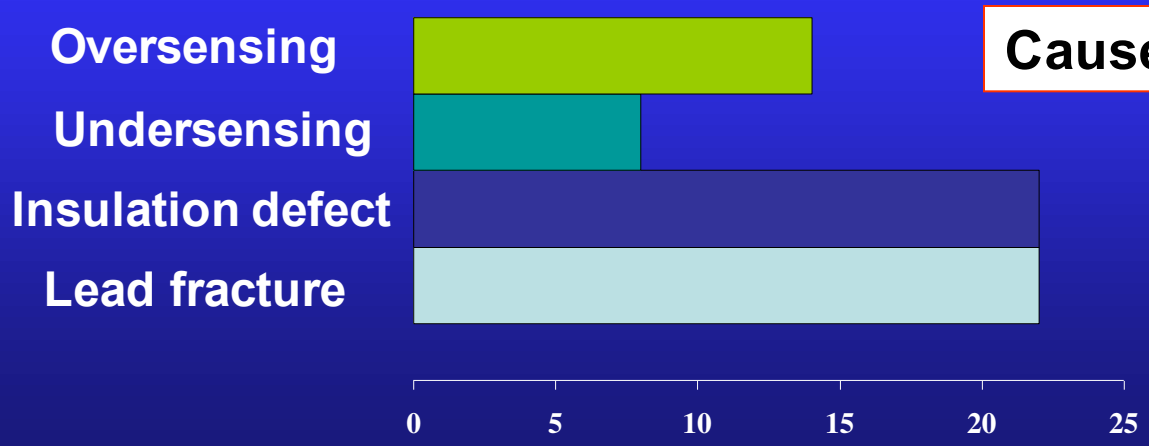
Perioperative complication: pneumothorax (1%)



Incidence of lead failure in chronically implanted ICD-leads

1657 consecutive ICD patients in 3 European centers
F/U 60 ± 31 months (5/1995 - 1/2004)

Lead related problems:	37 pts (2.2%)
Occurrence of lead problem:	23±17 months
Inappropriate shocks c/o lead problems:	21 pts (57%)



Cause of lead problem

Sticherling et al 2004 (abstr.)

Management of lead failure in chronically implanted ICD-leads

20/37 pts (54%) had problem in the P/S part only

-> all received an additional P/S lead

17/37 pts (46%) received a new ICD lead

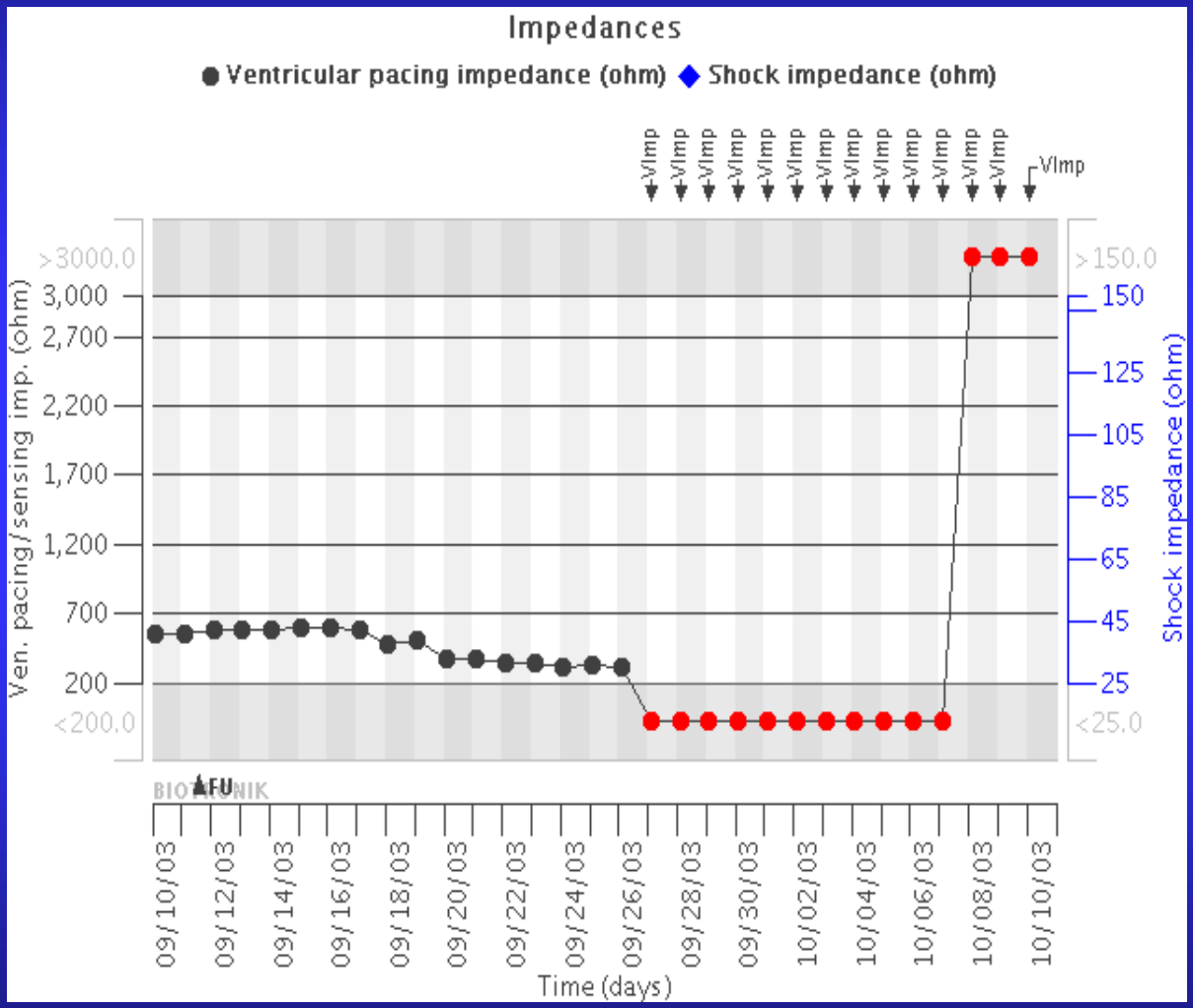
Incidence of further ICD-lead related problems:

2/37 (5%) after a F/U of 33 ± 31 months

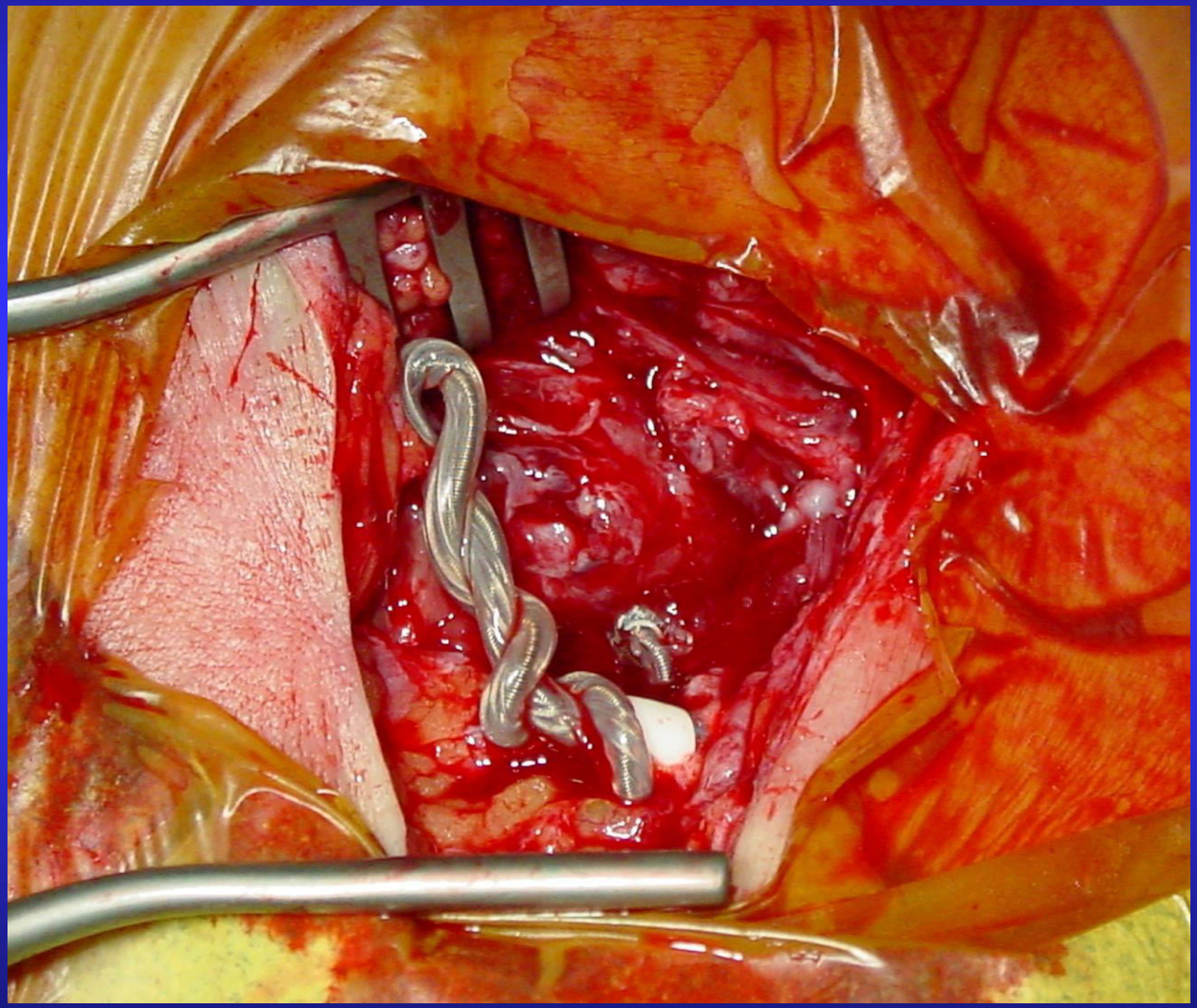
- LV lead placement (ICD lead)
- oversensing secondary to contact to old ICD lead

Sticherling et al 2004 (abstr.)

Early Recognition of “silent” lead dysfunction



Broken lead



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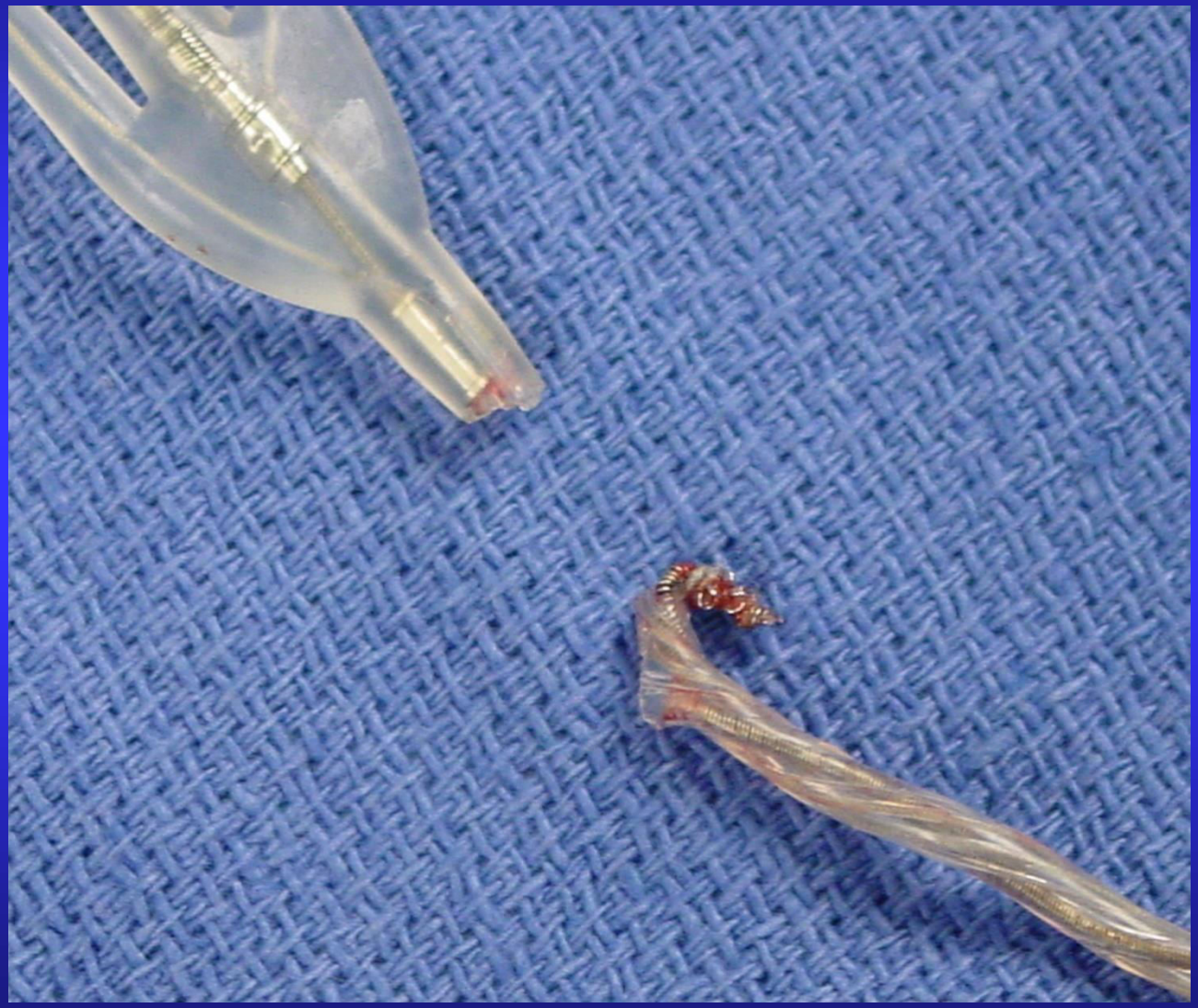
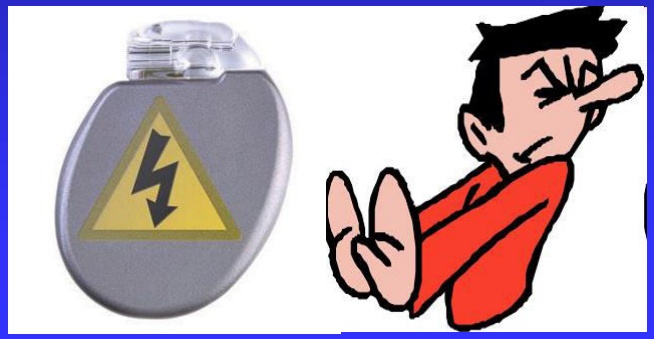


Totally Subcutaneous Lead System ("Leadless" ICD System)

- Placed strictly by anatomical landmarks without fluoroscopy
- TV lead exposed to > 30 million cardiac contractions/year
- Subcutaneous lead not exposed to heart stresses

Inappropriate shocks

Incidence: 16-28 % (of all shocks)

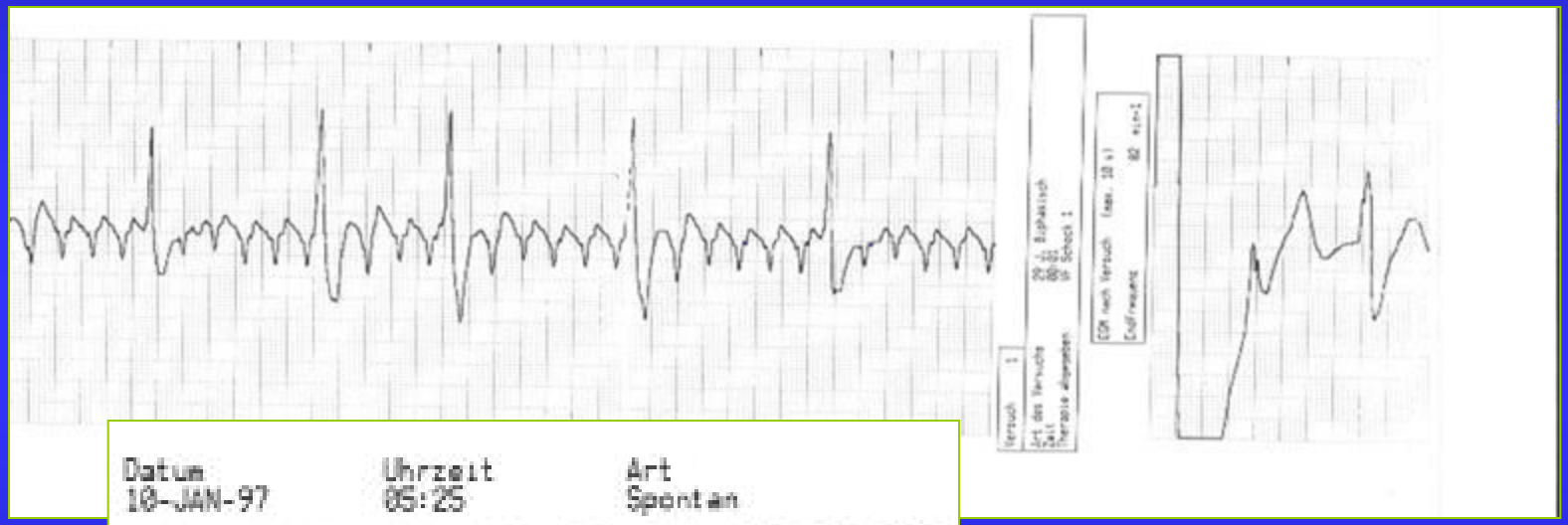


Causes of inappropriate shocks:

- Atrial fibrillation with rapid ventr. response	35%
- Sinus tachycardia/Atrial tachycardia	22%
- Oversensing	13%
- Non-sustained VT	30%

Schmitt et al.PACE 1994
Grimm et al, PACE 1999

Inappropriate shock: oversensing of atrial flutter

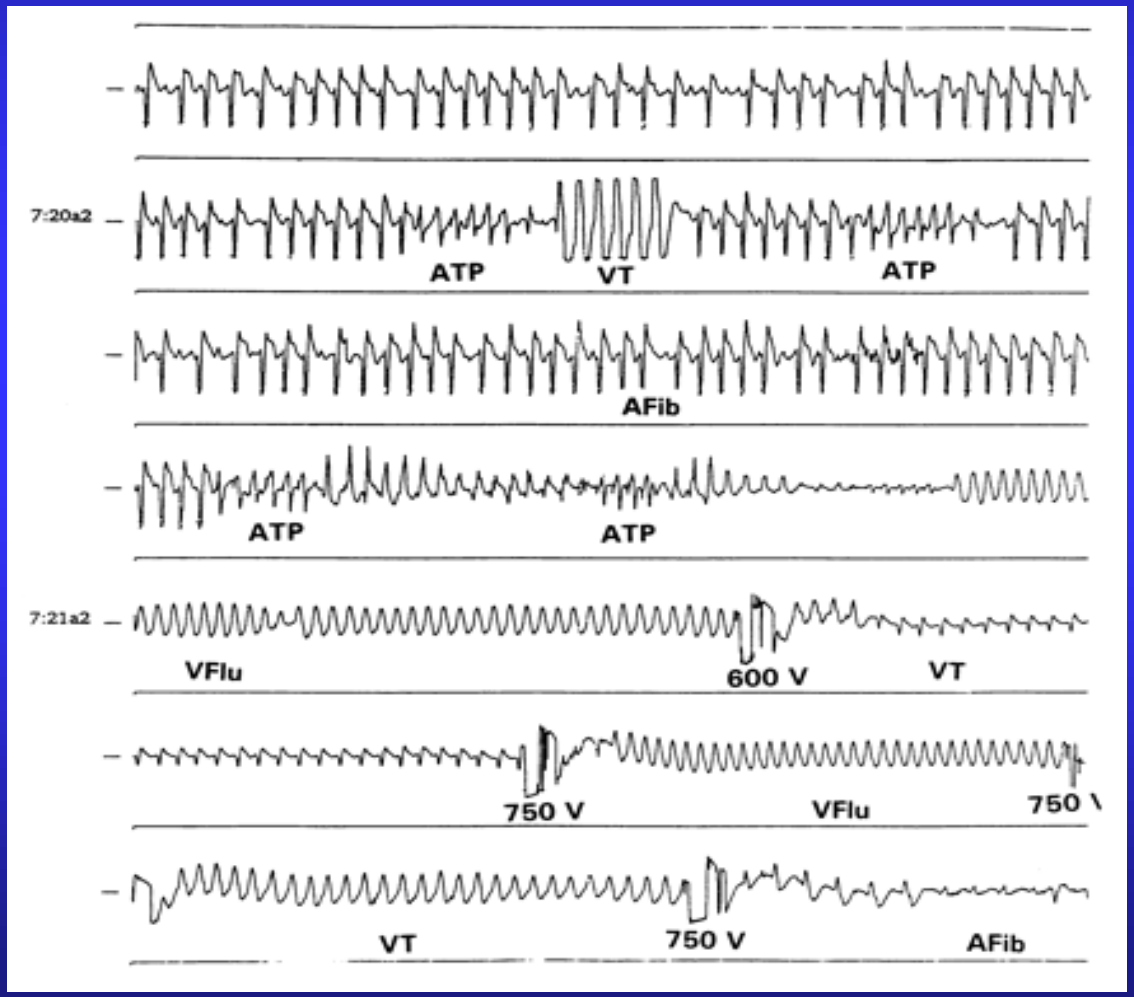


Datum	Uhrzeit	Art
10-JAN-97	05:25	Spontan

232 VF	758 VS	201 VF	746 VS	229 VF	188 VF	721 VS	236 VF	232 VF	750 VS
225 VF	725 VS	225 VF	246 VF	217 VF	693 VS	223 VF	141 VF	625 VS	488 VS
213 VF	719 VS	227 VF	244 VF	223 VF	730 VS	229 VF	260 VF	219 VF	680 VS
260 VF	223 VF								

Sticherling et al, PACE 1997

Inappropriate shock: proarrhythmic effect

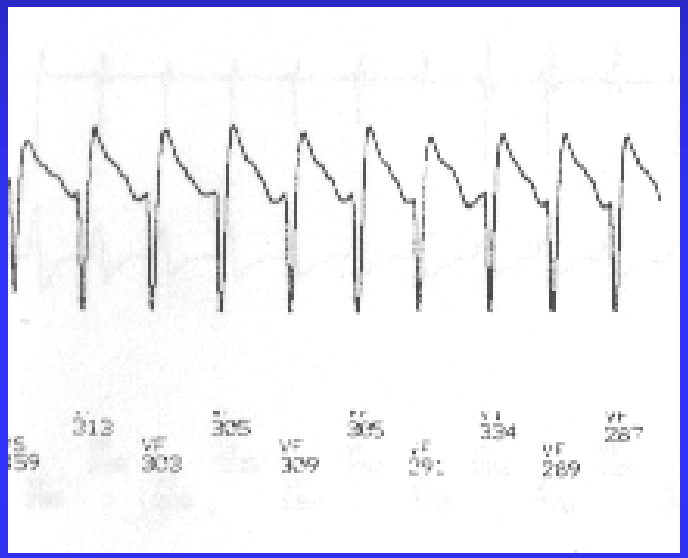


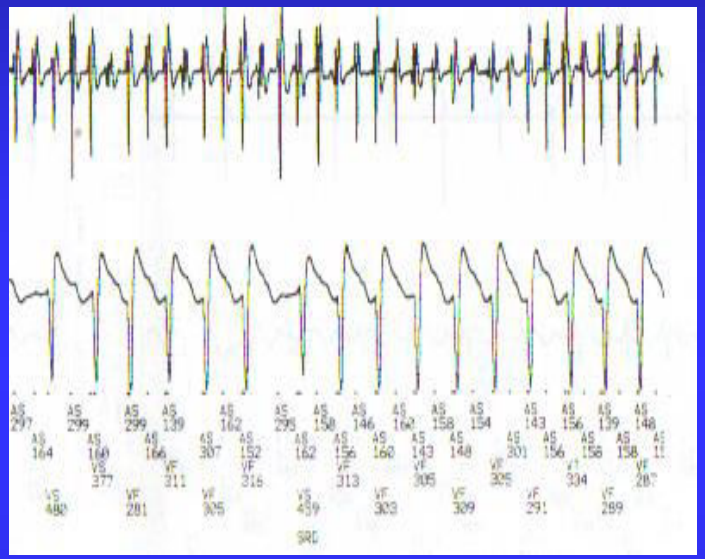
Antitachycardia Pacing 1-5%

Low energy CV shock 5%

Pinski, Circulation 1995

ICD- SVT/VT Differentiation





Single Chamber:

Onset
Stability
Morphology criteria

Dual Chamber:

Atrial stability
A vs. V intervals/rates
AV association
P:R pattern
A response to PVC

Impact of RV-pacing in the ICD population (DAVID Study)

Hypothesis:

Dual-chamber Pacing superior to VVI-Backup Pacing

Study Population:

506 Pat. with EF $\leq$ 40% and standard ICD-Indication without need for antibradycardia pacing

Design:

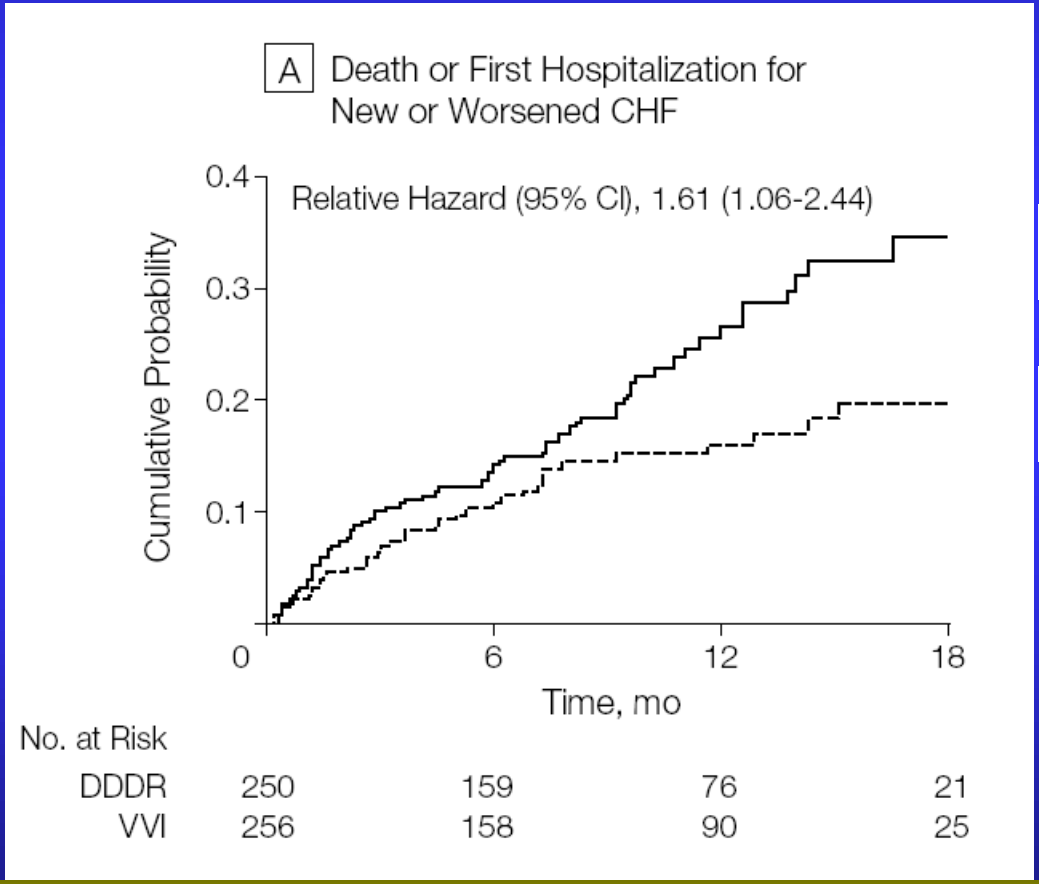
256 Pat. VVI, 40/min

250 Pat. DDDR, 70/min

David Investigators, JAMA 2002

DAVID-Study

David Investigators, JAMA 2002;288:3115-3123



DDD, 70/min

VVI, 40/min

RV-Stimulation = Cardiac Dyssynchronisation ?

Effects of concomitant antiarrhythmic medication on ICD function

- AA prolong VT cycle length (esp. class I agents)
  -> adaption of ICD VT-zone
- Class Ic agents increase capture threshold
- Sotalol and Dofetilide decrease DFT
- Amiodarone increases DFT

ICD-Summary

Highly effective in preventing SCD

Reliable long-term performance

Main issues:

- Economical aspects -> Costs

- Risk stratification for primary prevention

THANKS FOR YOUR ATTENTION!

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