

Sudden Cardiac Arrest

- Selecting Patients for ICD Implantation

Heart Teaching Day
Oct 15, 2009

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Objectives

- Define SCA
- Incidence of SCA
- SCA and Post-MI patients
- SCA and HF patients
- ICD Trials
- Identifying patients for referral – current guidelines

SCA

- Sudden and unexpected cessation of cardiac output – usually from arrhythmia
- Sudden Cardiac Arrest vs. Death
- Often confused with “heart attack” by the public and the press (often co-exist)
- Major public health problem which has received much less publicity than MI
- SCA from VT/VF always fatal unless defibrillation occurs within minutes

Ventricular Fibrillation

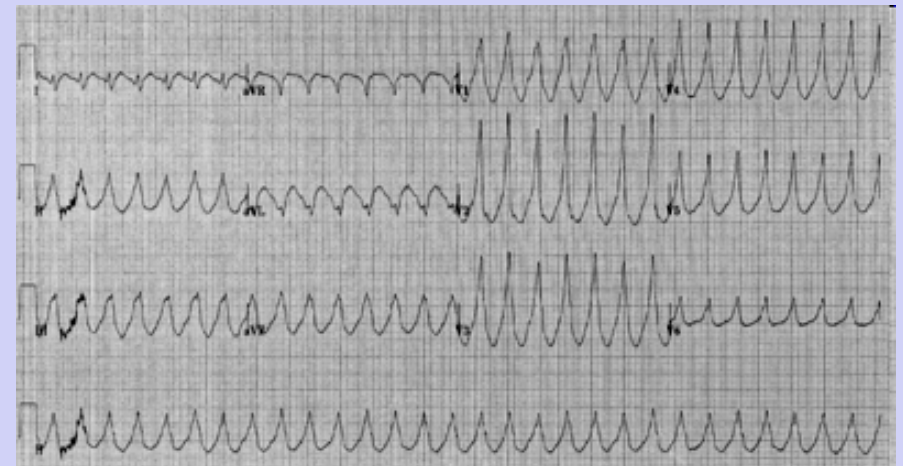
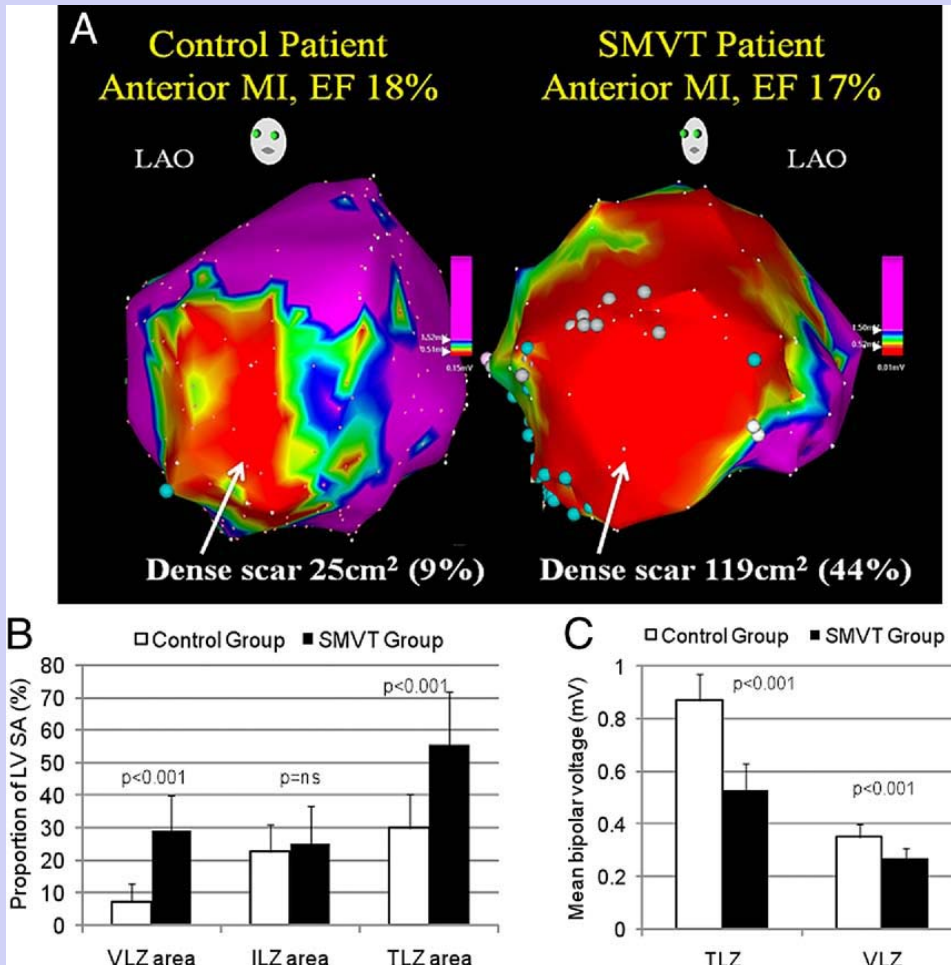
John A. MacWilliam, 1887



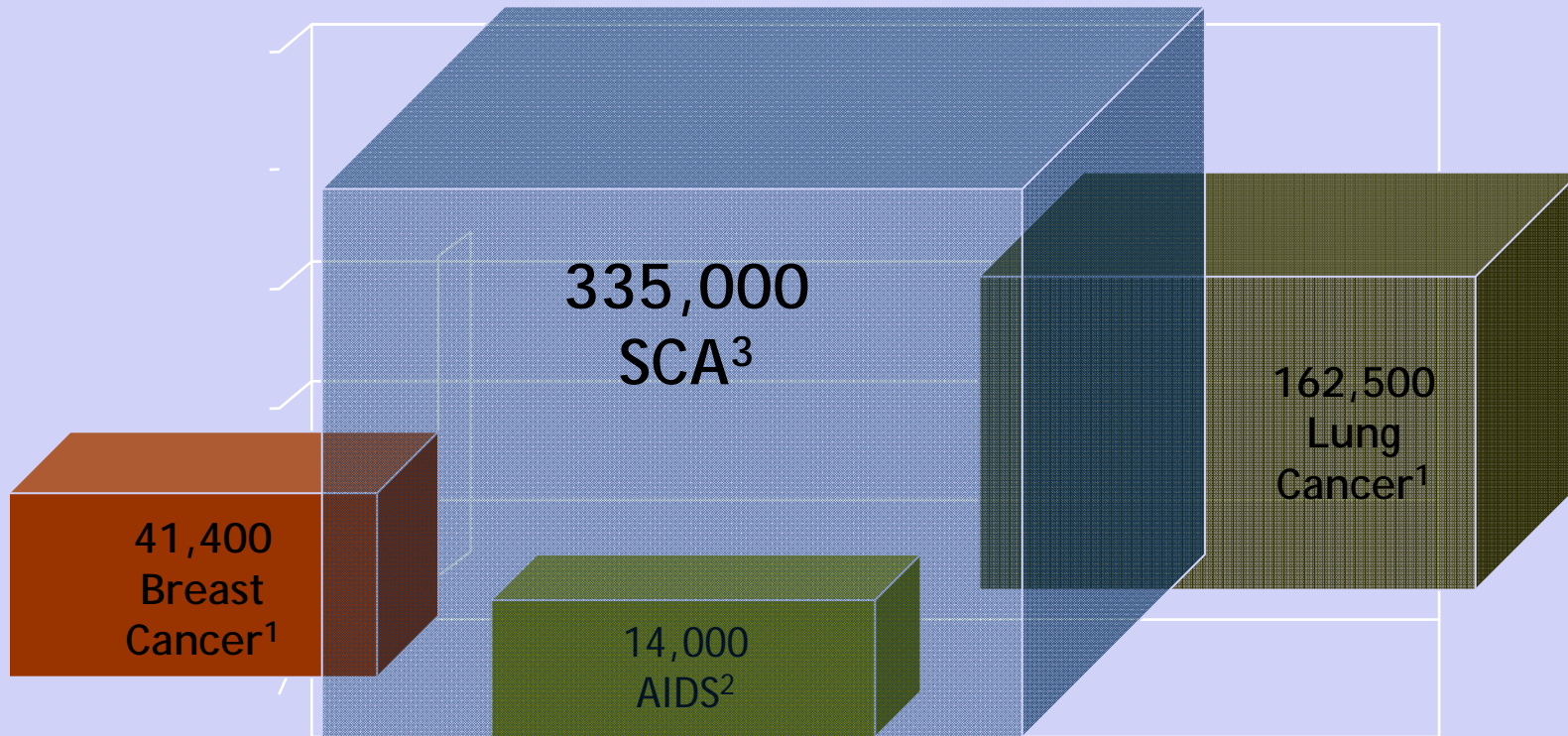
"The ventricular muscle is thrown into a state of irregular arrhythmic contraction, whilst there is a great fall in the arterial blood pressure, the ventricles become dilated with blood as the rapid quivering movement of their walls is insufficient to expel their contents; the muscular action partakes of the nature of a rapid incoordinate twitching of the muscular tissue ... The cardiac pump is thrown out of gear, and the last of its vital energy is dissipated in the violent and the prolonged turmoil of fruitless activity in the ventricular walls."

Ventricular Tachycardia

- Substrate
 - Scar density
 - Voltage characteristics
 - Residual “conducting channels”
- Trigger



Sudden Cardiac Arrest is one of the Leading Causes of Death in the U.S.¹⁻³



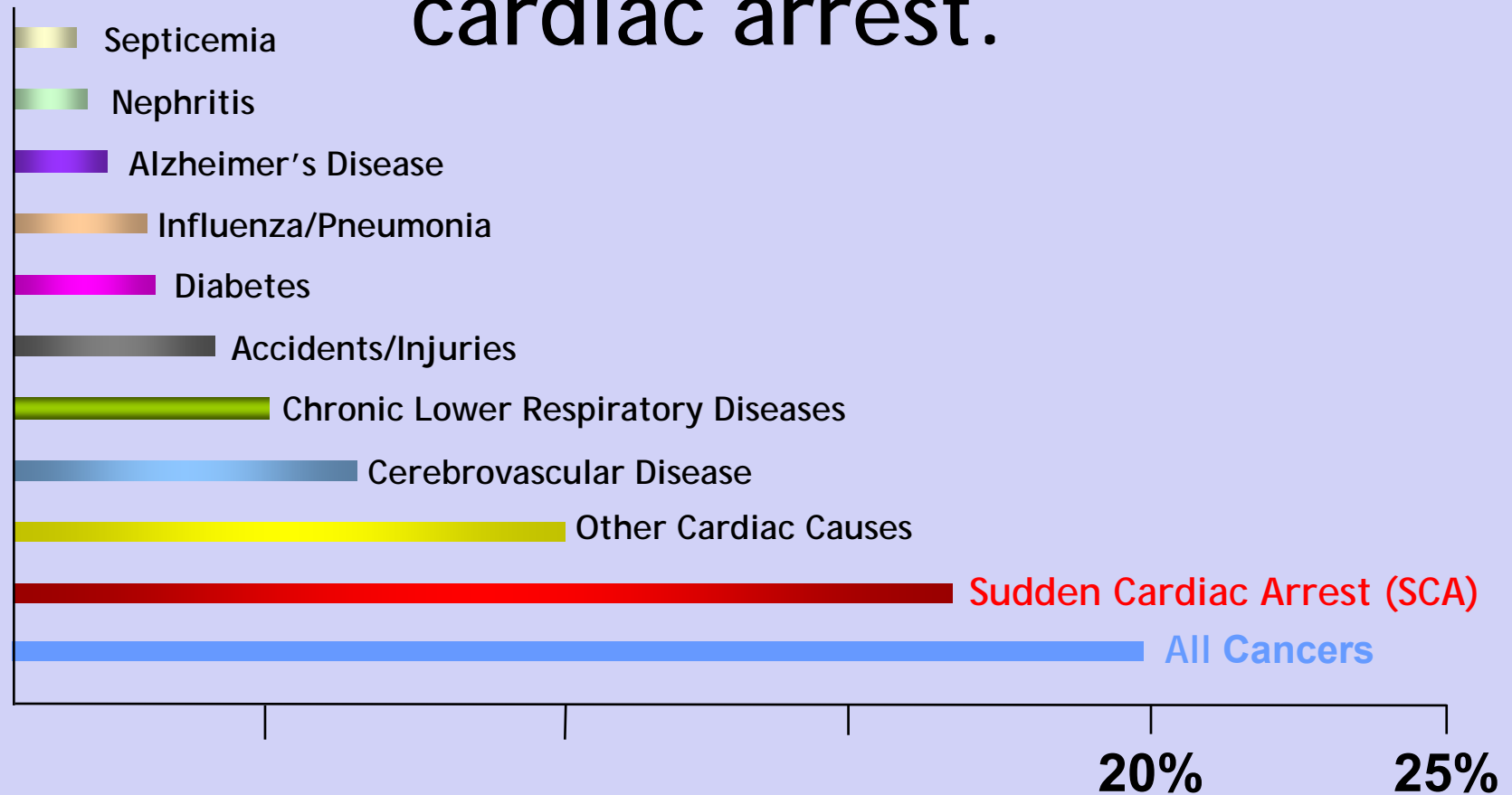
¹ American Cancer Society. Cancer Facts and Figures 2006.

² CIA. The World Factbook – rank Order – HIV/AIDS – deaths. Available at: <http://www.cia.gov>

³ American Heart Association. 2005 Heart and Stroke Statistics Update.

The State of New York will lose approximately 19,000 lives this year to Sudden Cardiac Arrest.

Only ALL cancers combined cause more deaths each year than sudden cardiac arrest.



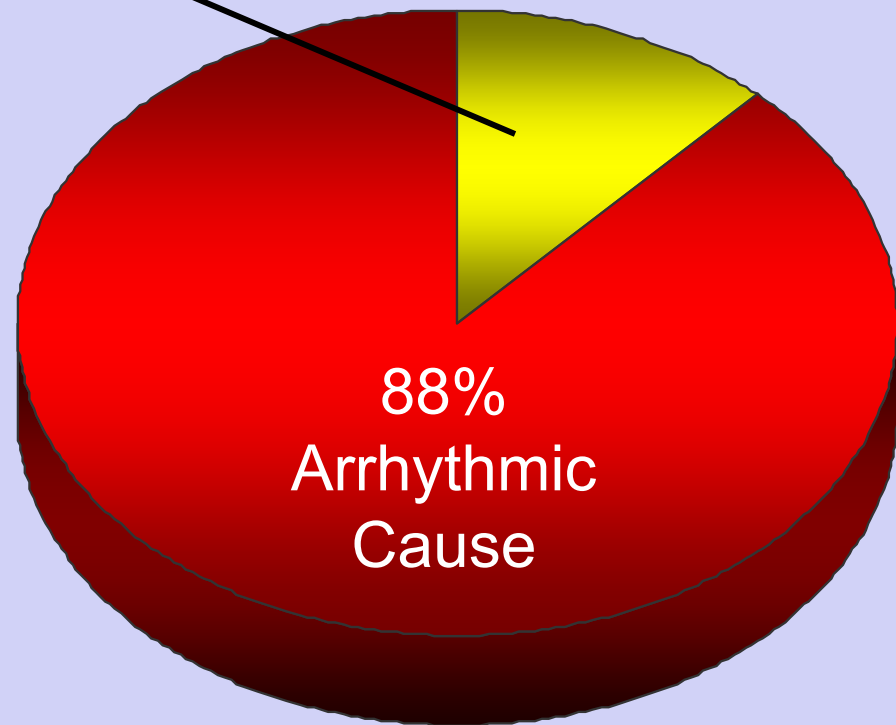
National Vital Statistics Report, Vol 49 (11), Oct. 12, 2001.

State-specific mortality from sudden cardiac death – United States 1999. *MMWR*. 2002;51:123-126.

Cause of SCA

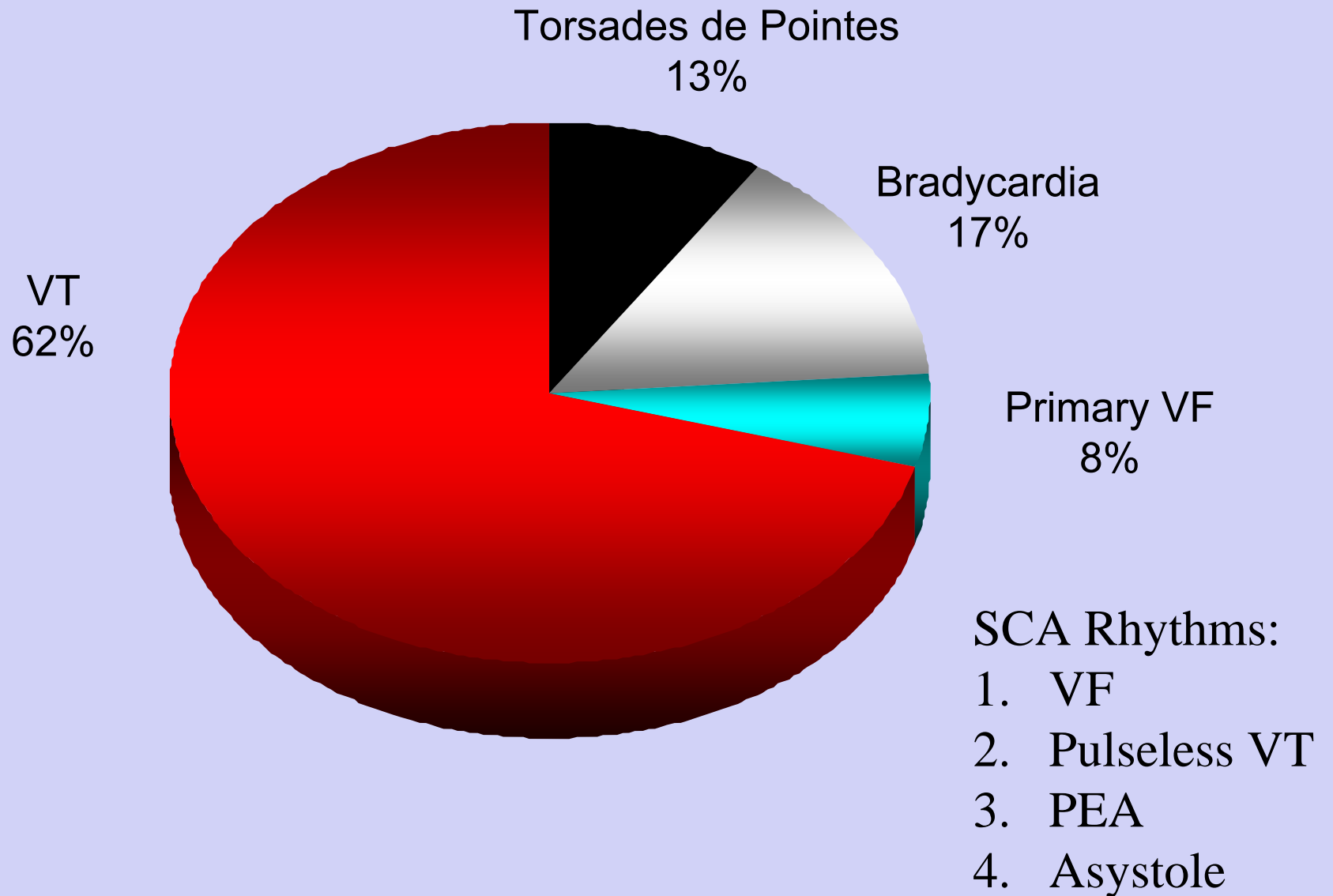
12% Other Causes:

- Cardiac rupture
- Aortic Dissection
- PE
- Cerebral Hemorrhage



1 hour definition per Hinkle and Thaler

Underlying Arrhythmias in SCA



Adapted from Bayes de Luna A. *Am Heart J.* 1989;117:151-159.

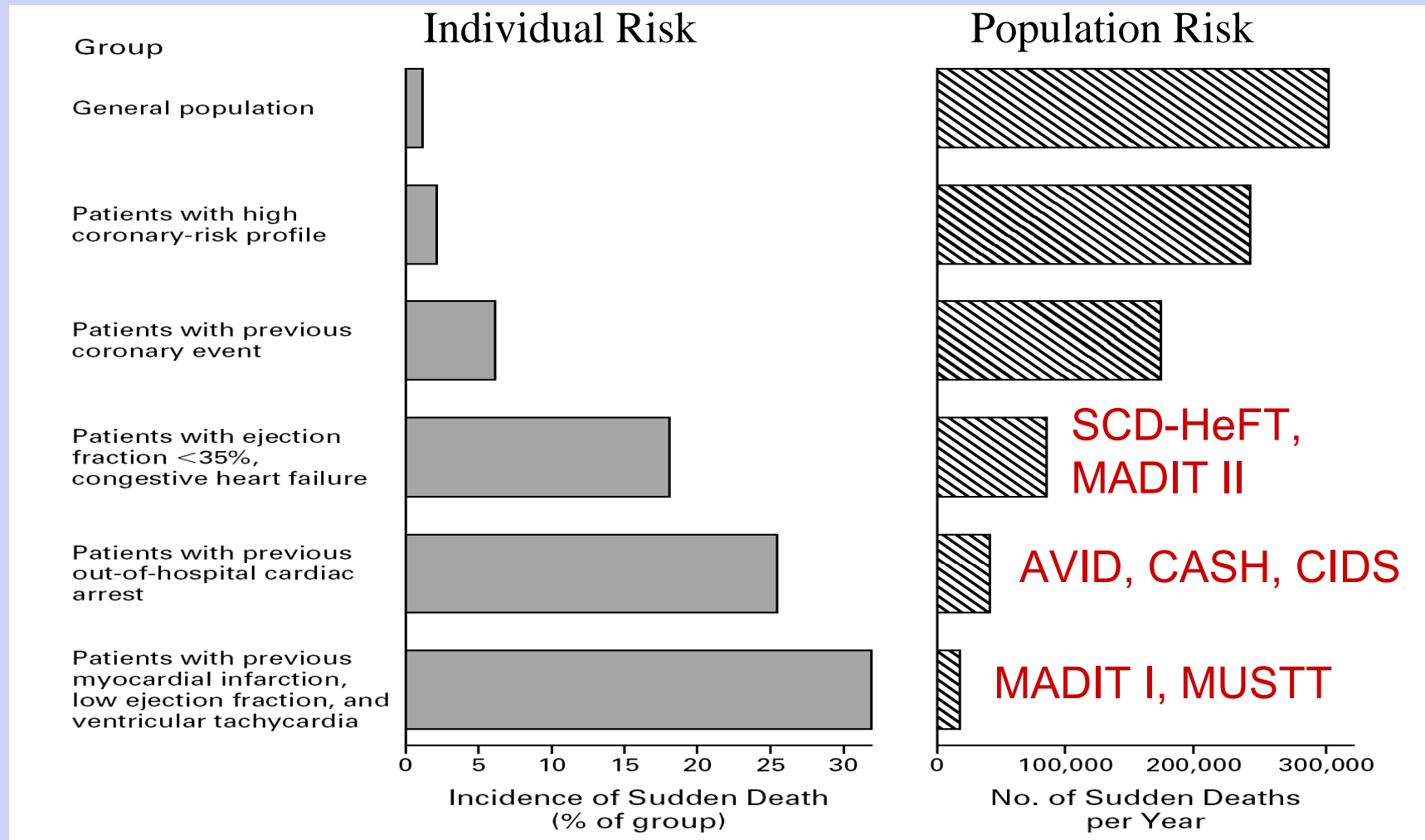
22 Month AED Program in Italy

	Overall	PPV	EMS
Shockable rhythms	67	34 (23.8%)	33 (15.6%)
Ventricular fibrillation	66	33	33
Ventricular tachycardia	1	1	0
Nonshockable rhythms	275	109 (76.2%)	166 (78.7%)
Asystole	247	98	149
Pulseless electrical activity	22	7	15
Atrioventricular block	6	4	2
No ECG recording	12	0	12 (5.7%)
Total	354	143	211

Who is at Risk for SCA?

- A prior SCA
- Family history of SCA
- Congestive Heart Failure (CHF)
- Having or had a Myocardial Infarction (MI)
- Reduced Ejection Fraction (35%)

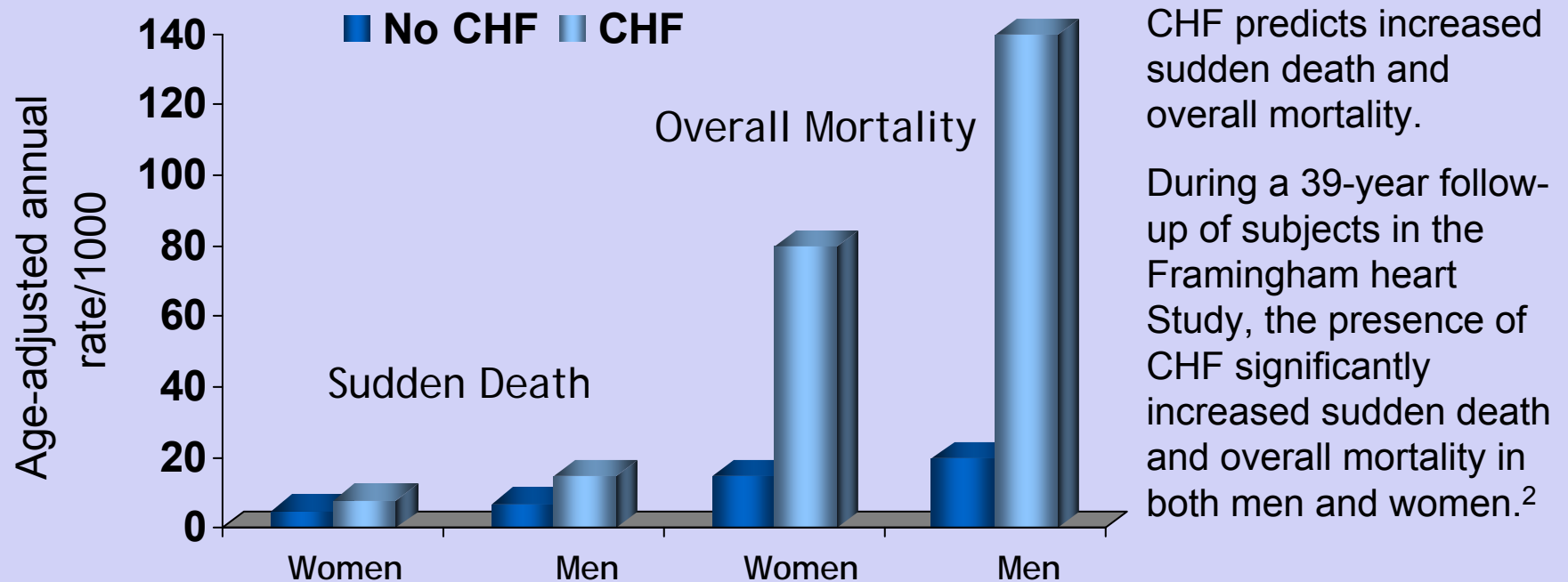
Patients with a previous cardiac arrest are at high risk for subsequent SCA events but account for a small percentage of annual sudden deaths



Myerburg RJ, et al. *Circulation*. 1998. 97:1514-1521.

5 year risk in MUSTT

In people diagnosed with CHF, sudden cardiac arrest occurs at **6-9** times the rate of the general population¹



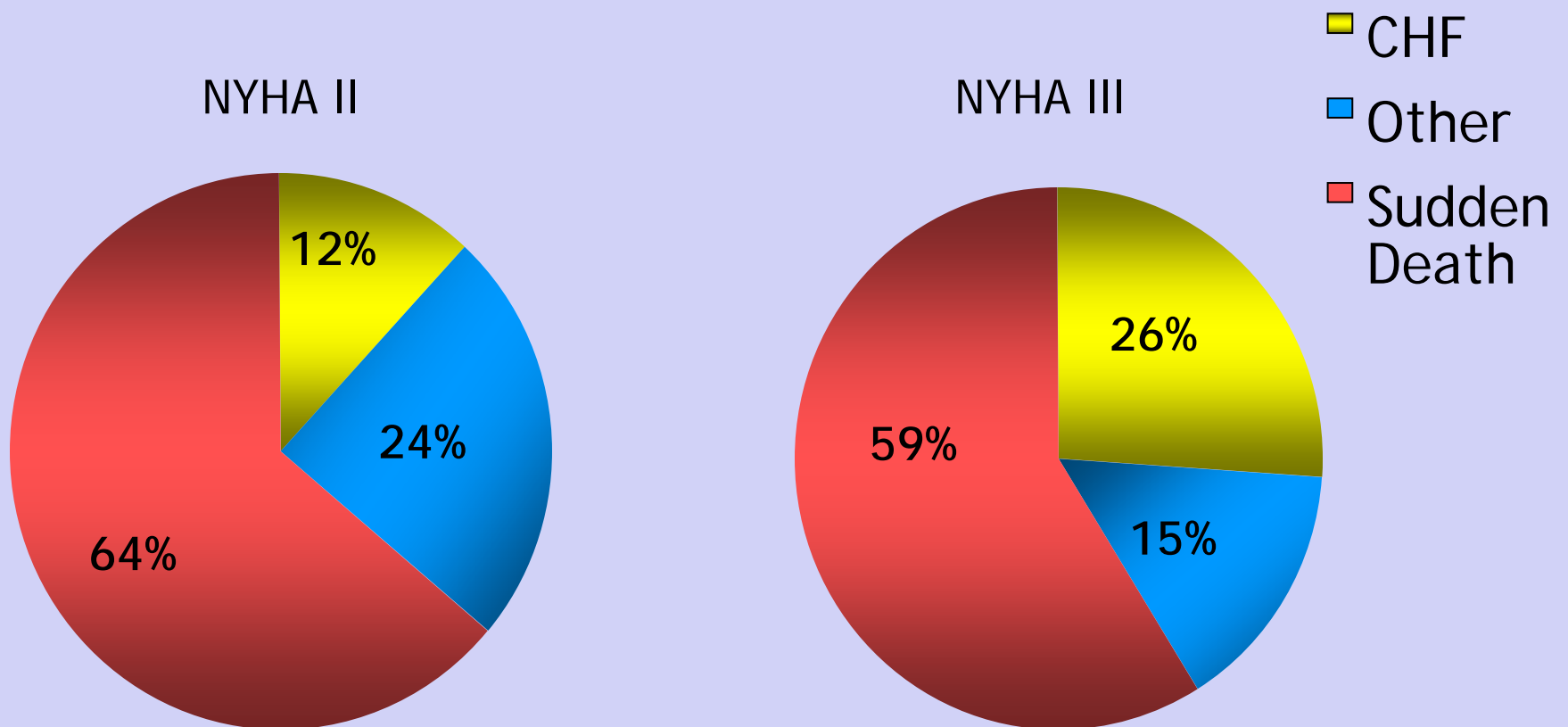
CHF predicts increased sudden death and overall mortality.

During a 39-year follow-up of subjects in the Framingham heart Study, the presence of CHF significantly increased sudden death and overall mortality in both men and women.²

¹American Heart Association. *Heart and Stroke Statistical –2003 Update*. Dallas, Tex.: American Heart Association: 2002. (Data from 2000).

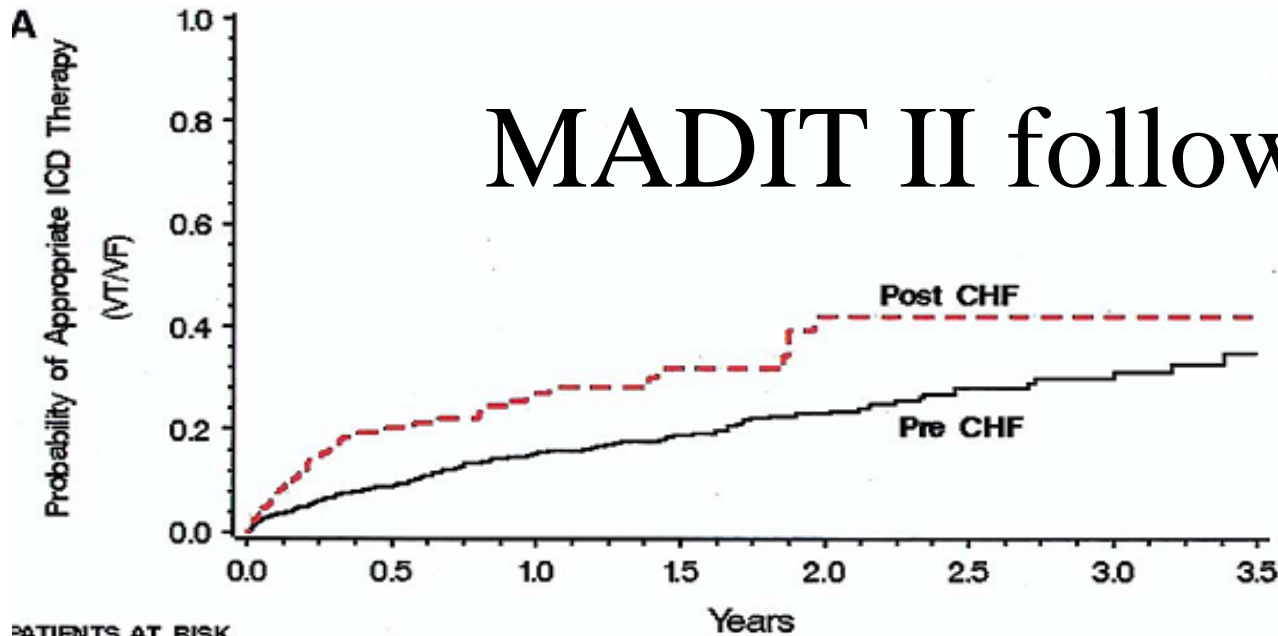
²Kannel WB, Wilson PWF, D'Agostino RB, Cobb J. Sudden coronary death in women. *Am Heart J*. 1998 Aug; 136: 205-212

The most common mode of death in mild to moderate HF is SCA



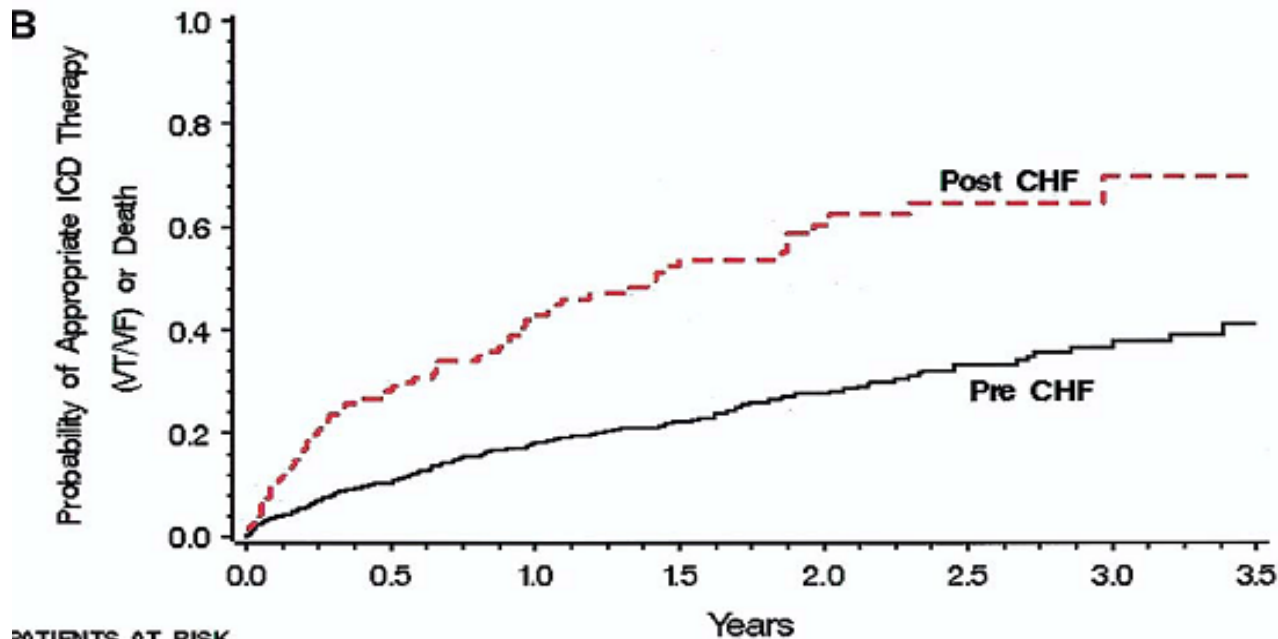
MERIT-HF Study Group. Effect of Metoprolol CR/XL in chronic heart failure: Metoprolol CR/XL randomized intervention trial in congestive heart failure (MERIT-HF). *LANCET*. 1999;353:2001-07.

MADIT II follow up



PATIENTS AT RISK

Post CHF	144	54 (0.27)	22 (0.42)	6 (0.42)
Pre CHF	718	344 (0.15)	165 (0.23)	53 (0.30)



PATIENTS AT RISK

Post CHF	144	54 (0.43)	22 (0.61)	6 (0.70)
Pre CHF	718	344 (0.18)	165 (0.28)	53 (0.37)

Factors Influencing Appropriate Firing of the Implanted Defibrillator for Ventricular Tachycardia/Fibrillation Findings From the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-II)
MADIT-II Investigators
Boston, Massachusetts; and Rochester, New York

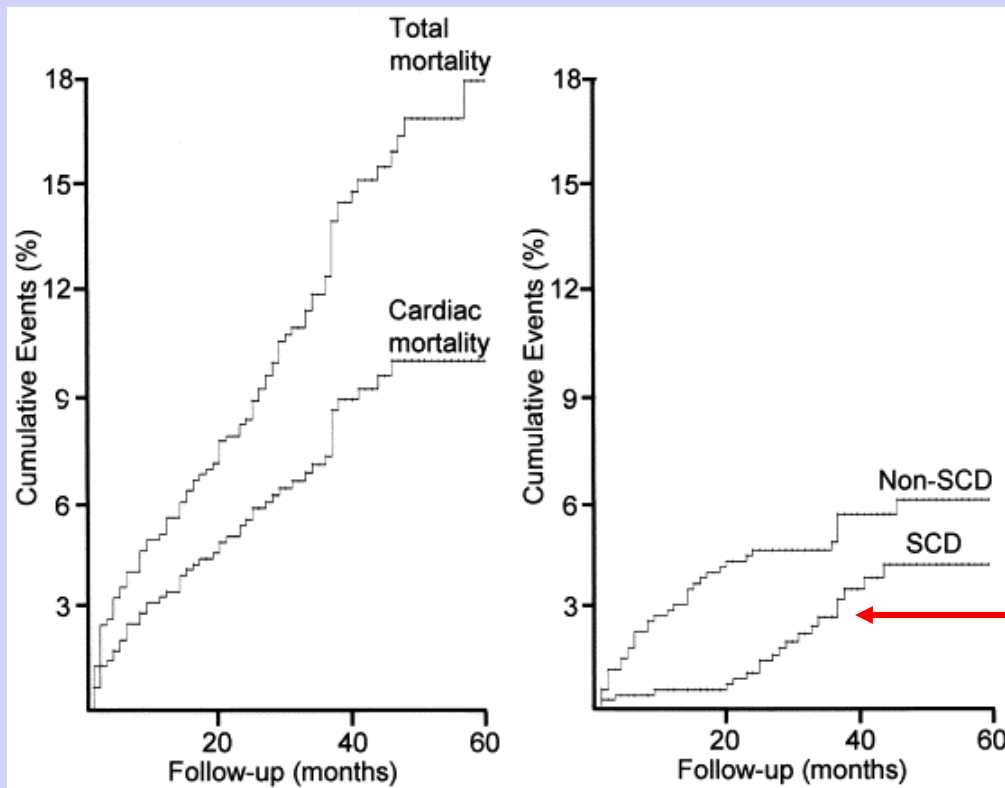
People who've had a heart attack have a sudden death rate that's **4-6** times that of the general population¹

- A previous MI can be identified in as many as 75% of SCA patients
- A previous MI raises the one-year risk of SCA by 5% as a single risk factor
- The five-year risk of SCA for patients with a previous MI, non-sustained, inducible, non-suppressible VT, and a LVEF \leq 40% is 32% (MUSTT)

¹American Heart Association. *Heart and Stroke Statistical –2003 Update*. Dallas, Tex.: American Heart Association: 2002. (Data from 2000).

Time Dependence of Mortality Risk Post-MI:

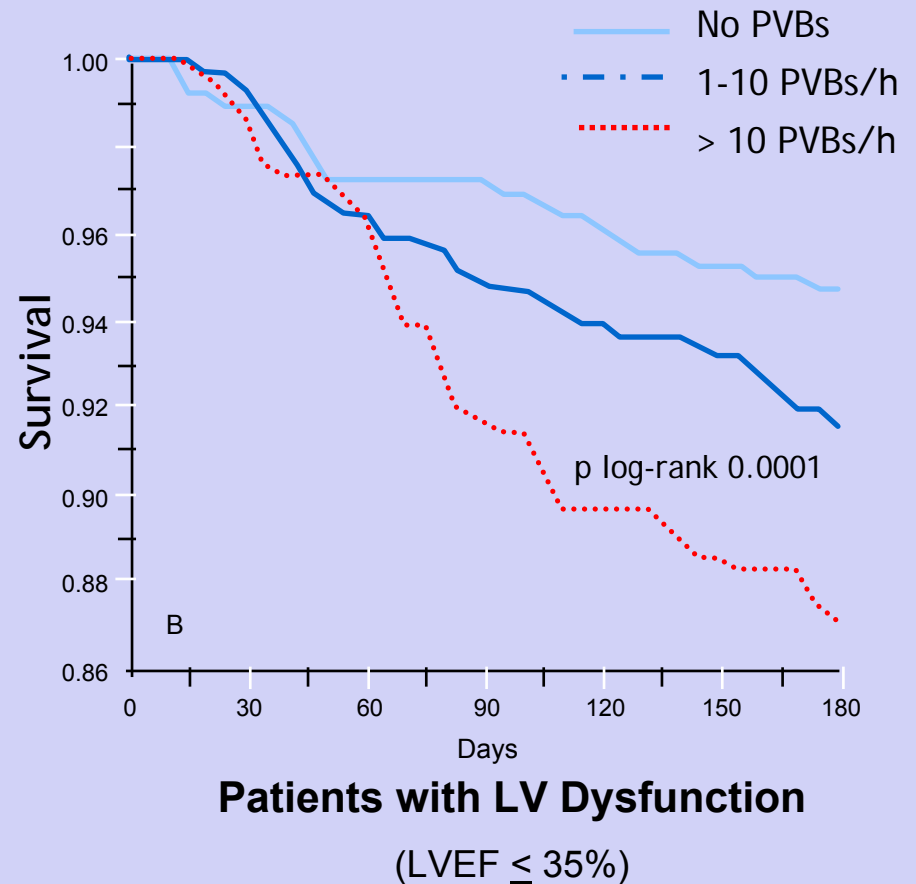
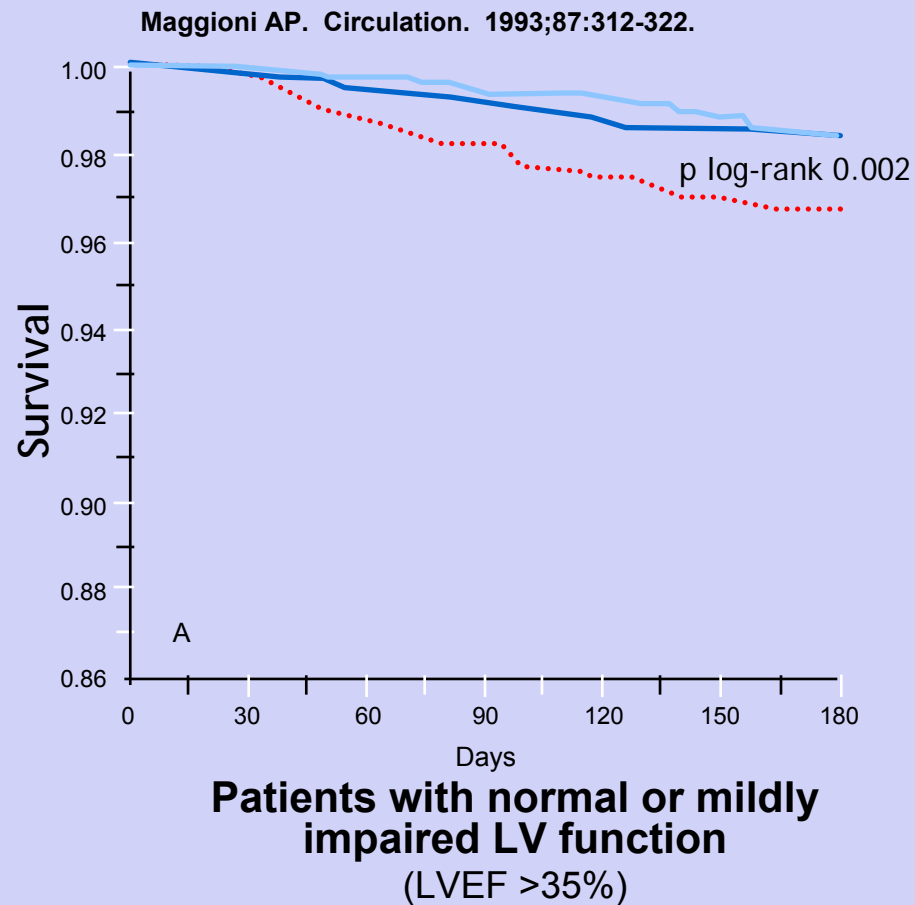
*Prediction of Sudden Cardiac Death After Myocardial Infarction
in the Beta-Blocking Era¹*



- 700 post-MI patients; ~95% on beta blockers 2 years after discharge.
- Arrhythmia events or SCDs did not concentrate early after the index event, but most of them occurred more than 18 months post-MI.

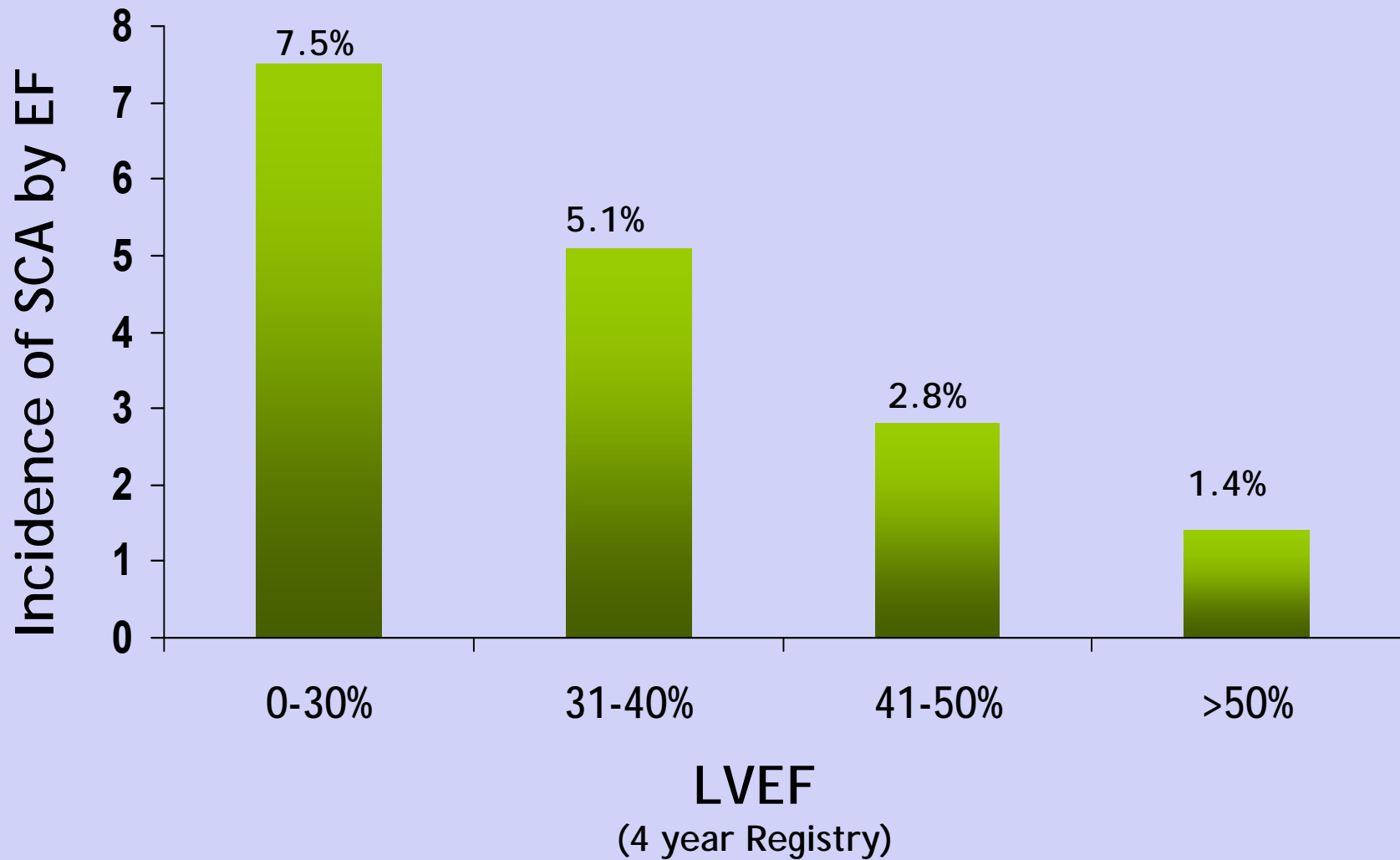
¹Huikuri H, et al. *J Am Coll Cardiol* 2003; 42: 652-8.

Reduced left ventricular ejection fraction (LVEF) remains the single most important risk factor for overall mortality and sudden cardiac arrest



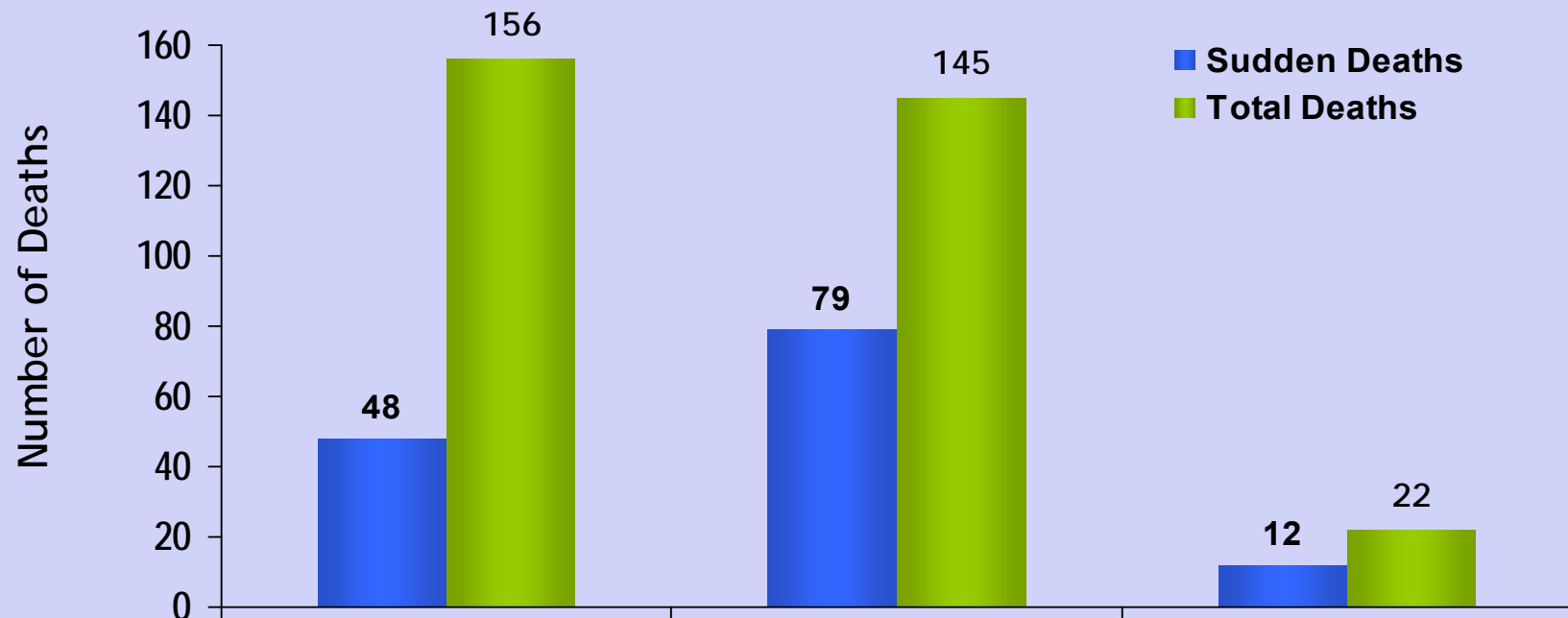
8700 post-MI pts from GISSI-2 – Lytic era

LVEF and SCA Incidence



Gorgels PMA. *European Heart Journal*. 2003;24:1204-1209.
Maastricht Circulatory Arrest Registry

Residual Risk of SCD in Treatment Arms of CHF Beta Blocker Trials



**% Sudden Death
of Total Death**

CIBIS-II (1999)¹

31%

MERIT-HF (1999)²

54%

USCHFT (1996)³

54%

No. Pts in Treatment Arm: N = 1327
Average Follow-Up: 16 months

N = 1990
12 months

N = 696
6.5 months

¹ CIBIS-II Investigators. *Lancet*. 1999;353:9-13.

² MERIT-HF Study Group. *Lancet*. 1999;353:2001-2007.

³ Packer M. *N Engl J Med*. 1996;334:349-355.

SCD in Heart Failure^{1,2}

- Despite improvements in medical therapy, symptomatic HF still confers a 20-25% risk of premature death in the first 2.5 yrs after diagnosis.
 - ≈ 50% of these premature deaths are SCD (VT/VF)

¹ Bardy G. The Sudden Cardiac Death-Heart Failure Trial (SCD-HeFT) in Woosley RL, Singh S. *Arrhythmia Treatment and Therapy*. Copyright 2000 by Marcel Dekker, Inc. , pp. 323-342,

² Sweeney MO. *PACE*. 2001;24:871-888.

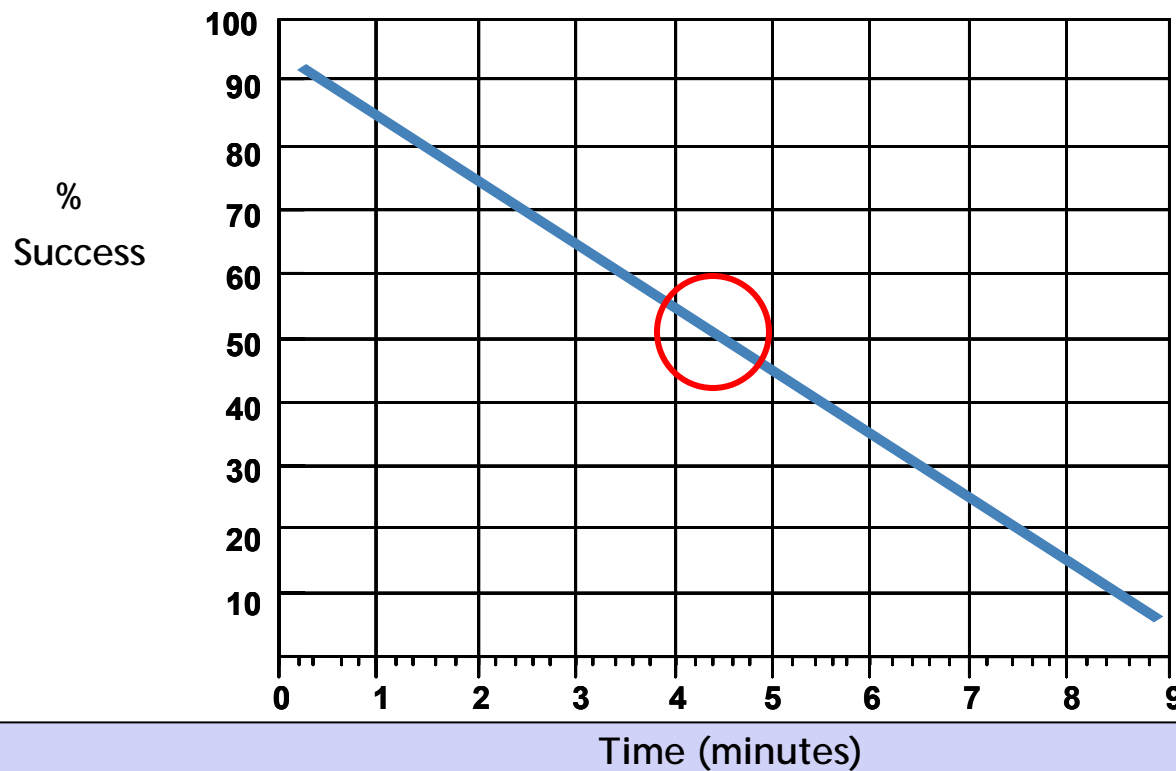
Surviving SCA

Physician guidelines recommend ICD therapy
as the standard of care for patients at risk for SCA

Urgency of Sudden Cardiac Arrest

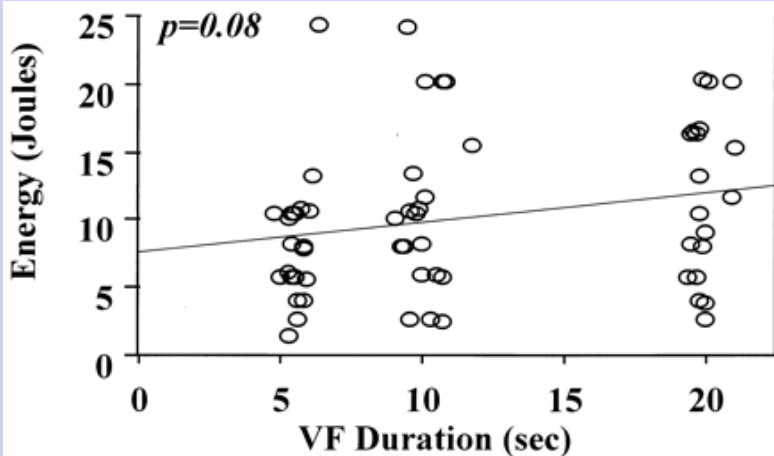
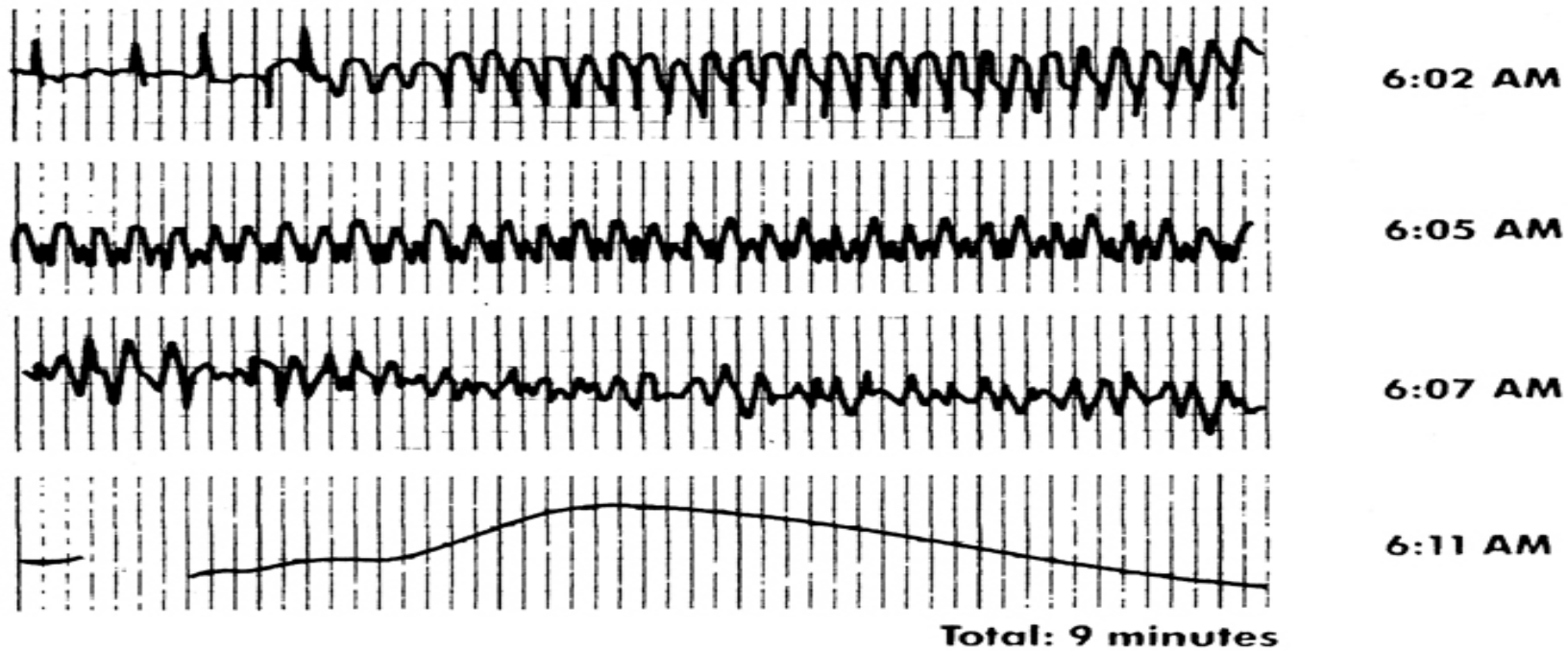
Resuscitation Success vs. Time

Chance of success reduced 7-10% every minute



Adapted from text: Cummins RO, 1998. *Annals of Emergency Medicine*. 18:1269-1275.

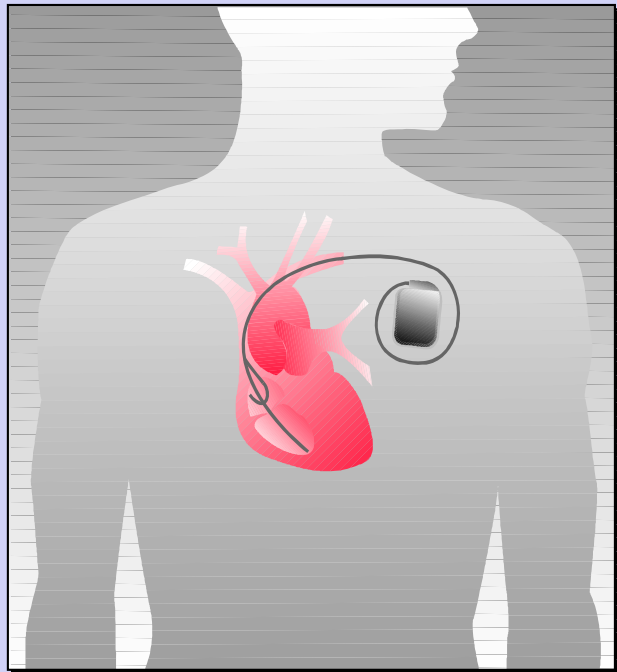
Sudden Cardiac Arrest



Only effective treatment for VF is an electrical shock delivered by:

- Automated external defibrillator (AED) or
- Implantable cardioverter-defibrillator (ICD)

Implantable Cardioverter Defibrillators (ICDs) Restore Heart Rhythm



First-line therapy for patients at risk for SCA

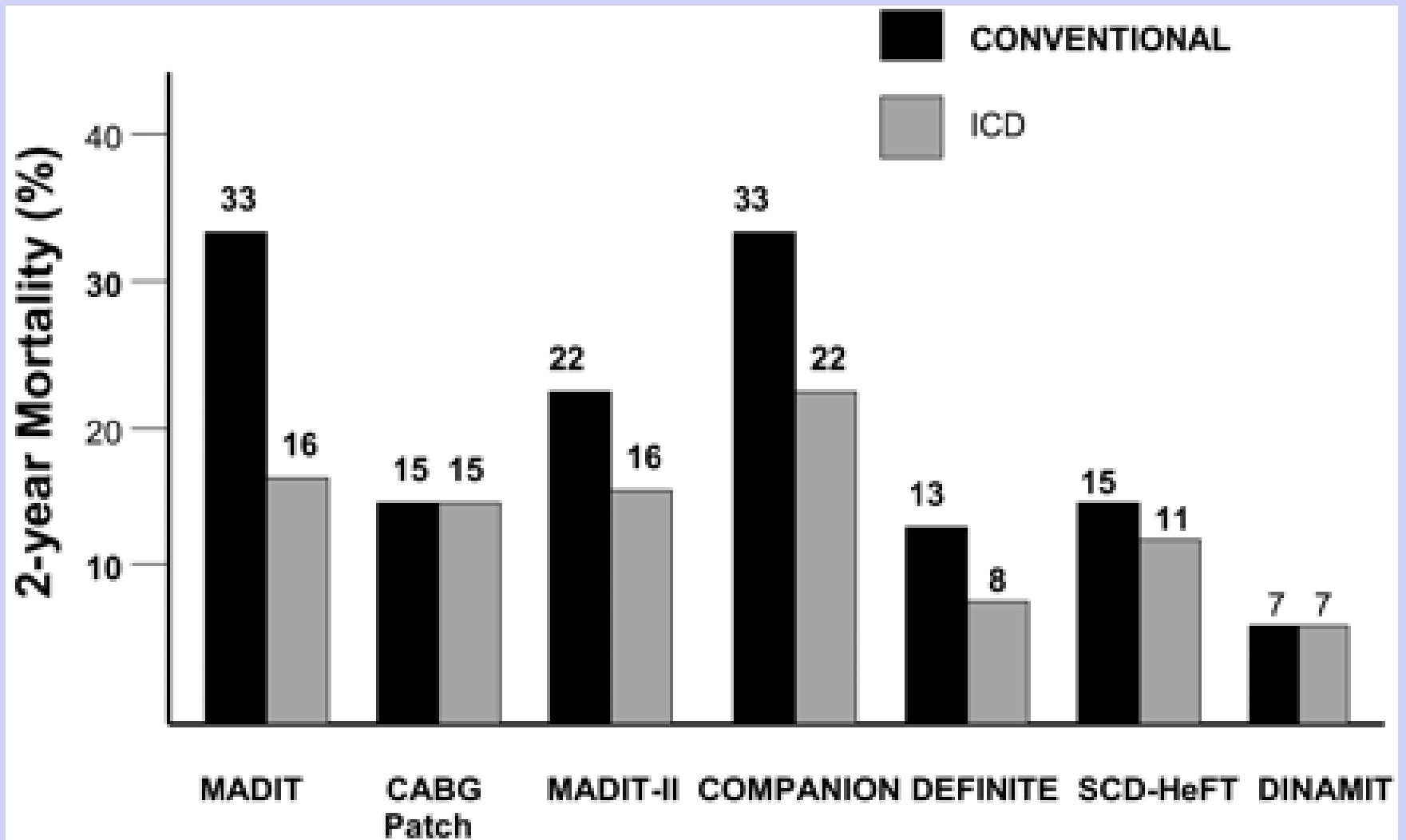
- ICD therapy consists of pacing, cardioversion, and defibrillation therapies to treat tachyarrhythmias. ICDs also have programmable diagnostic functions.
- An ICD system includes the device, and the pacing, sensing and defibrillation lead(s).

Overview of Clinical Trials of ICD Therapy in:

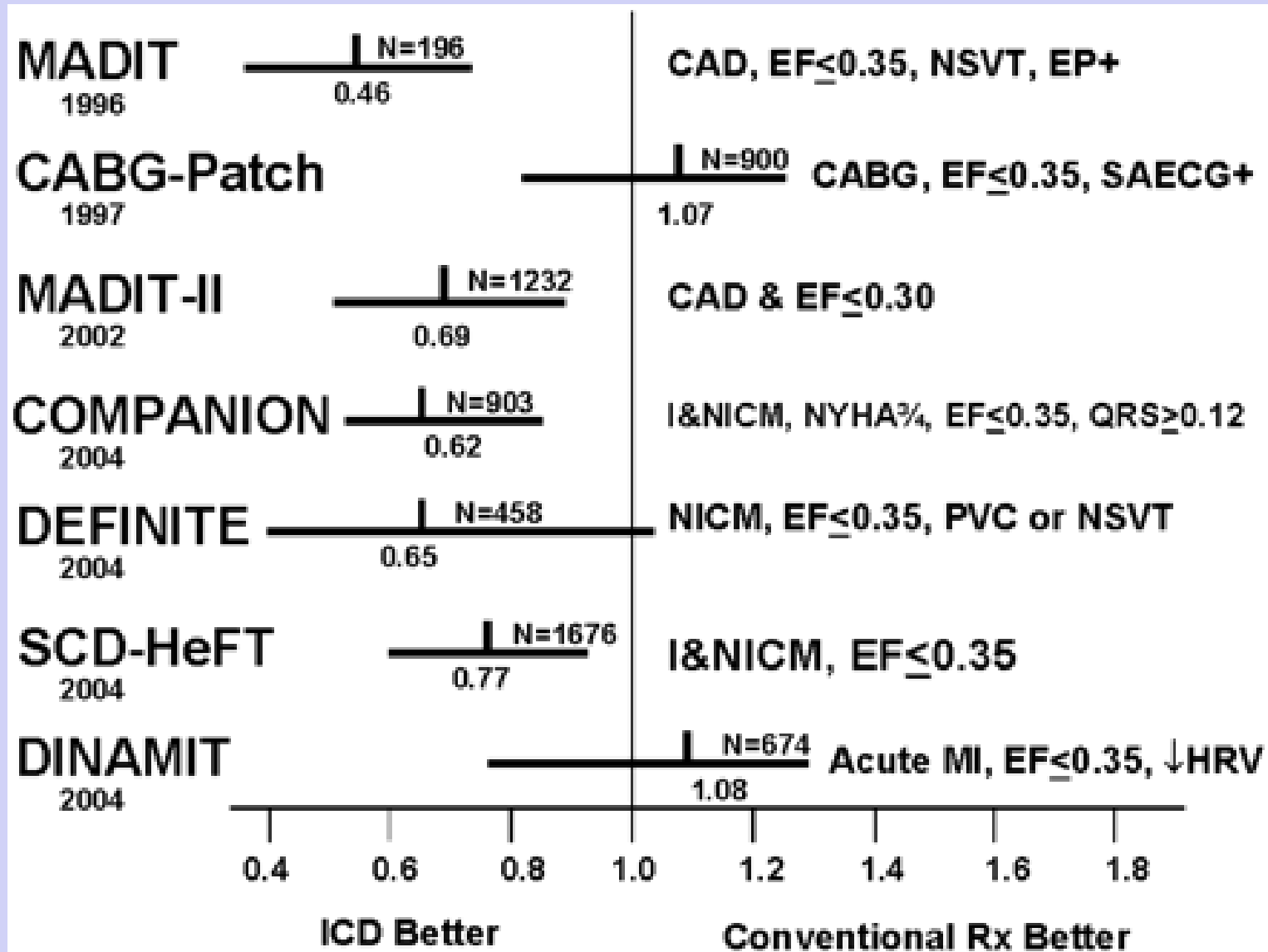
- 1) Post-MI Patients with LV Dysfunction
- 2) CHF Patients

Physician guidelines recommend ICD therapy
as the standard of care for patients at risk for SCA

Primary Prevention Trials



Prophylactic ICD Trials



ICD Clinical Trials in Post-MI/CAD Patients

MADIT

Multicenter **A**utomatic **D**efibrillator **I**mplantation **T**rial

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

MUSTT

Multicenter **U**nsustained **T**achycardia **T**rial

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

MADIT-II

Multicenter **A**utomatic **D**efibrillator **I**mplantation **T**rial-II

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

MADIT

Objective:

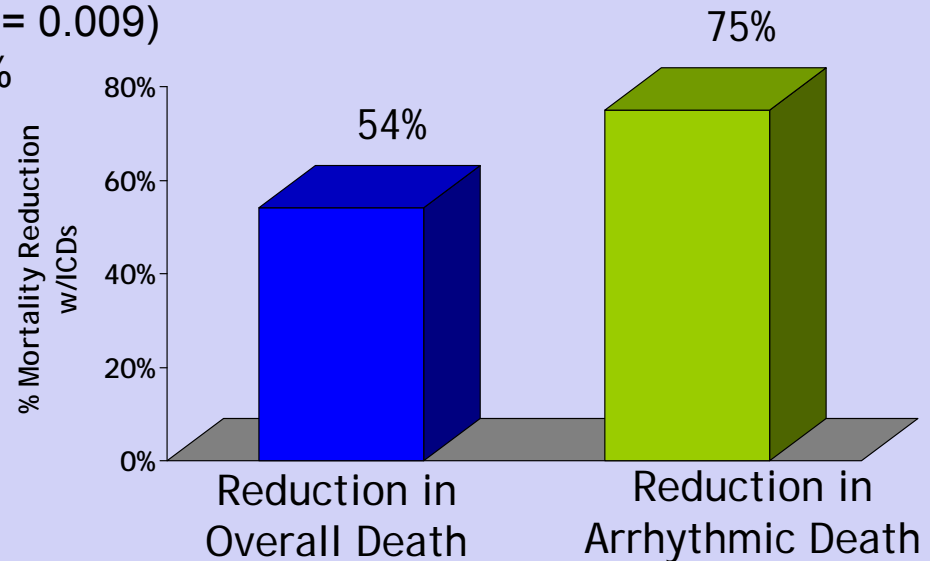
- Evaluate the effectiveness of ICD therapy (n = 99) versus conventional therapy (n = 101) in high risk MI patients

Inclusion Criteria:

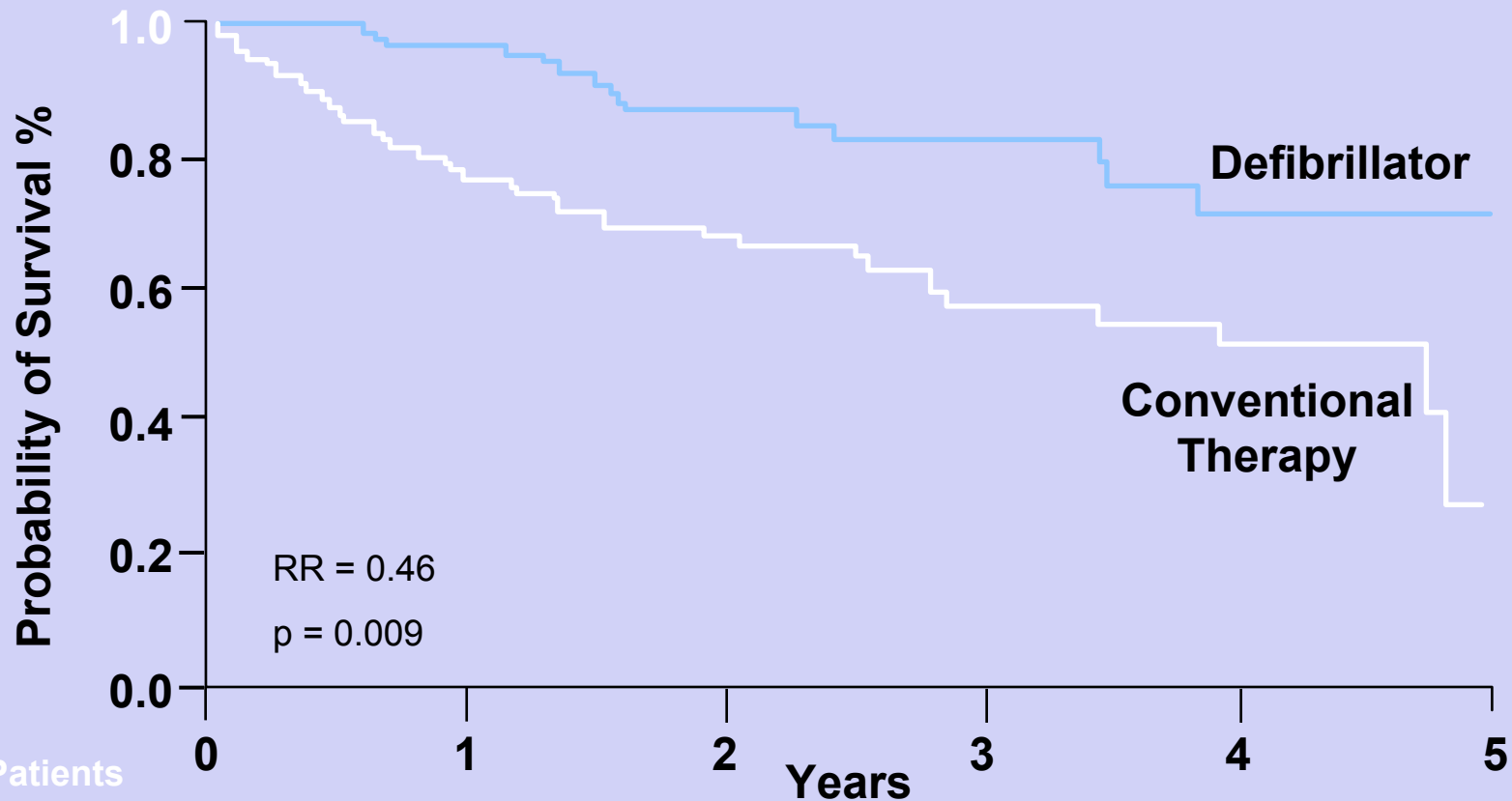
- Q-wave MI > 3 weeks, and
- Asymptomatic NSVT, and
- LVEF < 35%, and
- Inducible VT, but not suppressible on EPS, and
- NYHA Class I-III

ICD Results:

- Reduced overall mortality by 54% (p = 0.009)
- Reduced arrhythmic mortality by 75%



MADIT Survival Results



No. of Patients

	0	1	2	3	4	5
Defibrillator	95	80	53	31	17	3
Conventional therapy	101	67	48	29	17	0

Moss AJ. *N Engl J Med.* 1996;335:1933-1940.

MUSTT

Objective:

- Evaluate whether AA therapy guided by EP testing could reduce arrhythmic death and overall mortality in high-risk post-MI patients
- Positive EP study (inducible VT) randomized to ICD or AAD

Inclusion Criteria:

- CAD, and
- LVEF < 40%, and
- Asymptomatic NSVT, and
- Inducible VT on EP testing

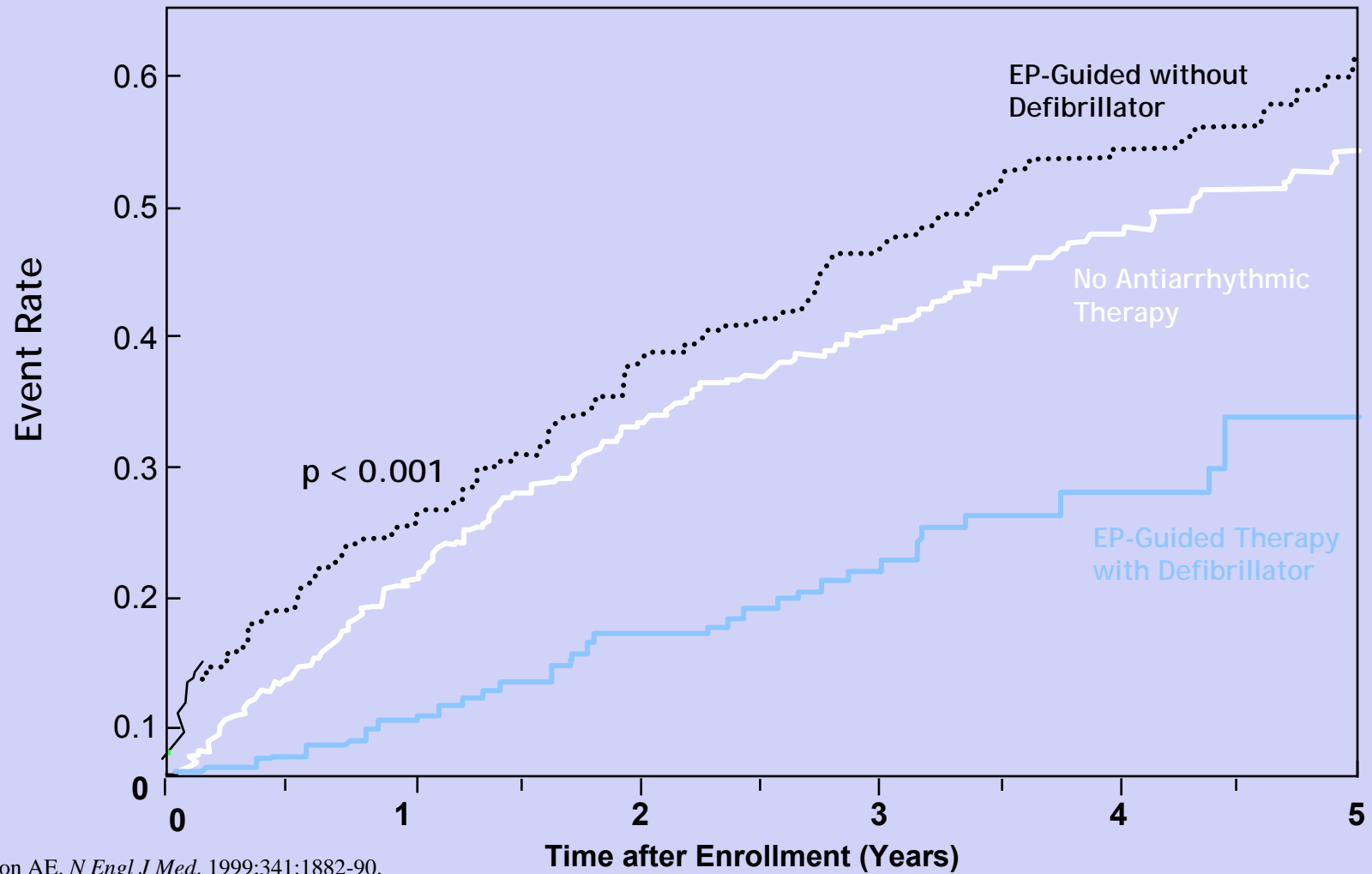
Results:

- EP guided Rx with AA therapy reduced arrhythmic death by 27% and overall mortality by 20% compared to non-EP guided therapy patients ($p = 0.04$)

The entire mortality benefit was due to the ICD therapy in the EP guided Rx arm:

- ICDs reduced arrhythmic death by 76% and overall mortality by 60% compared to EP guided patients receiving AA drugs ($p < 0.001$)
- ICDs reduced arrhythmic death by 73% and overall mortality by 55% compared to non-EP guided therapy patients ($p < 0.001$)

MUSTT Randomized Patient Results: Total Mortality



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

MADIT II

Objective:

Evaluate the effectiveness of ICD therapy (n = 742) compared to conventional therapy (n = 490) in high-risk post-MI patients

Inclusion Criteria:

Post-MI \geq 4 weeks, and

LVEF \leq 30%

No requirement for EPS or NSVT

ICD Results:

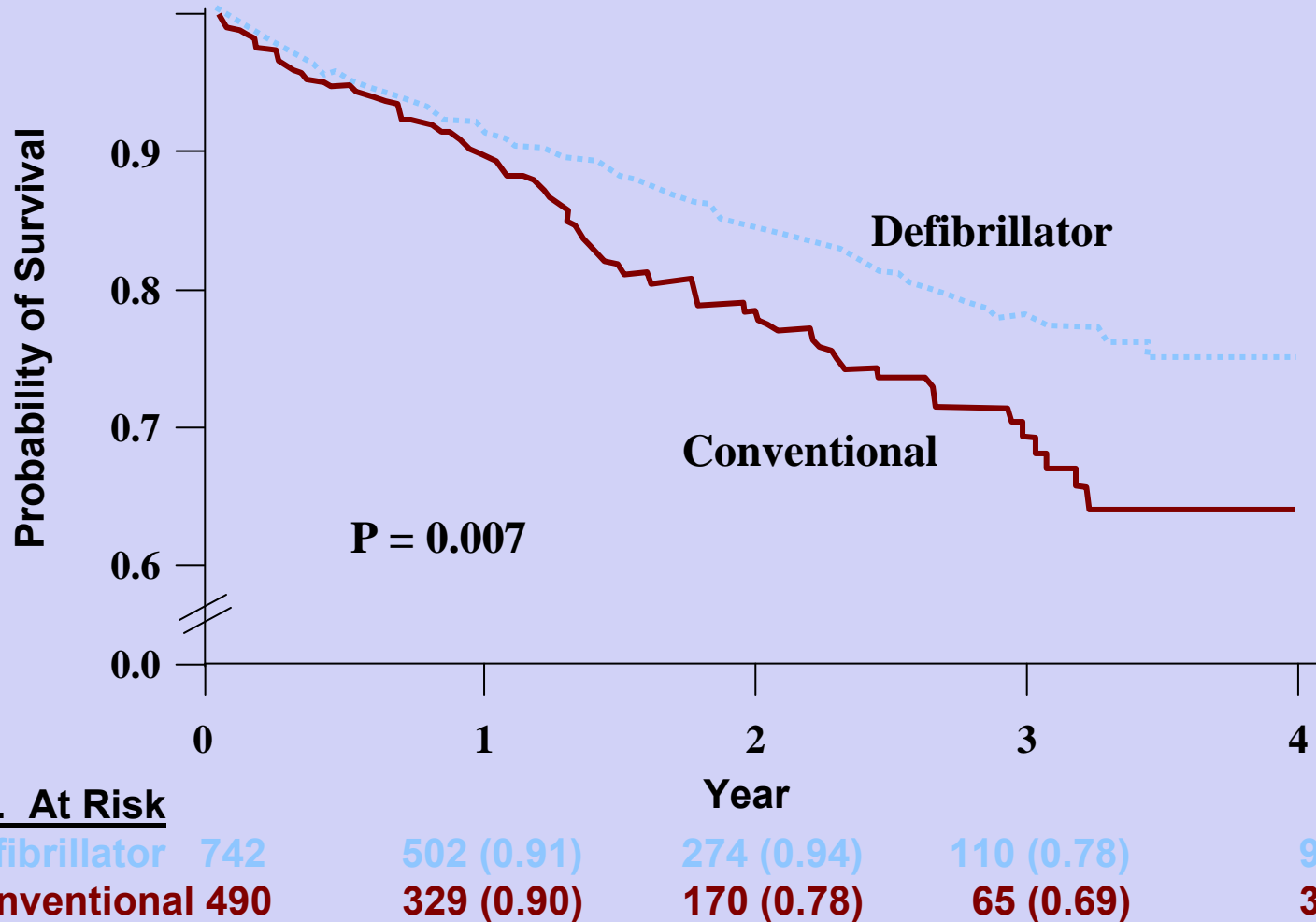
Reduced overall mortality by 31% (p = 0.007)¹

Reduced arrhythmic death by 61%²

¹ Moss AJ. *N Engl J Med.* 2002;346:877-883

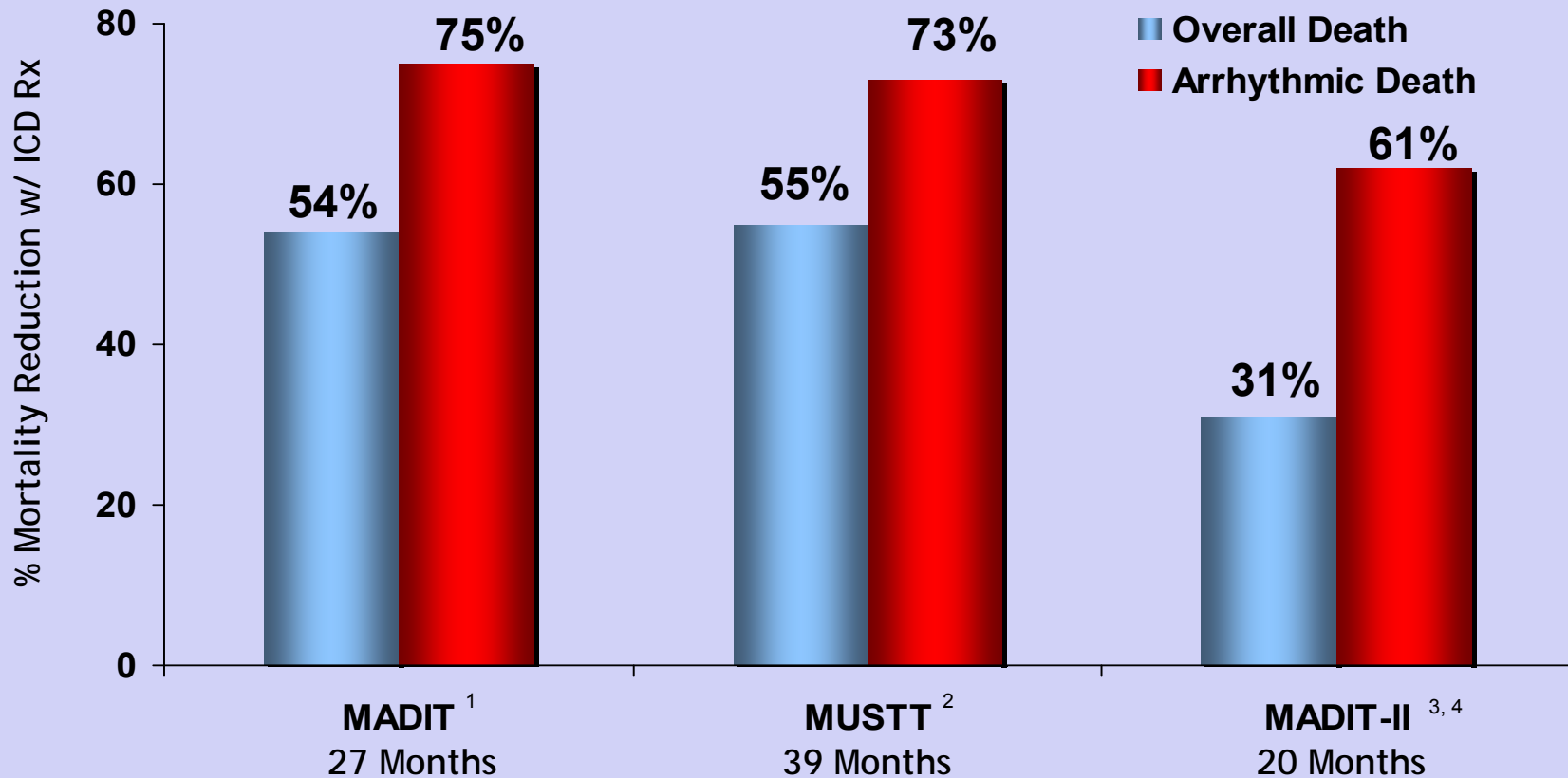
² Moss AJ. Presented before ACC 51st Annual Scientific Sessions, Late Breaking Clinical Trials, March 19, 2002.

MADIT-II Survival Results



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

ICD Mortality Reduction in Post-MI Patients with LV Dysfunction



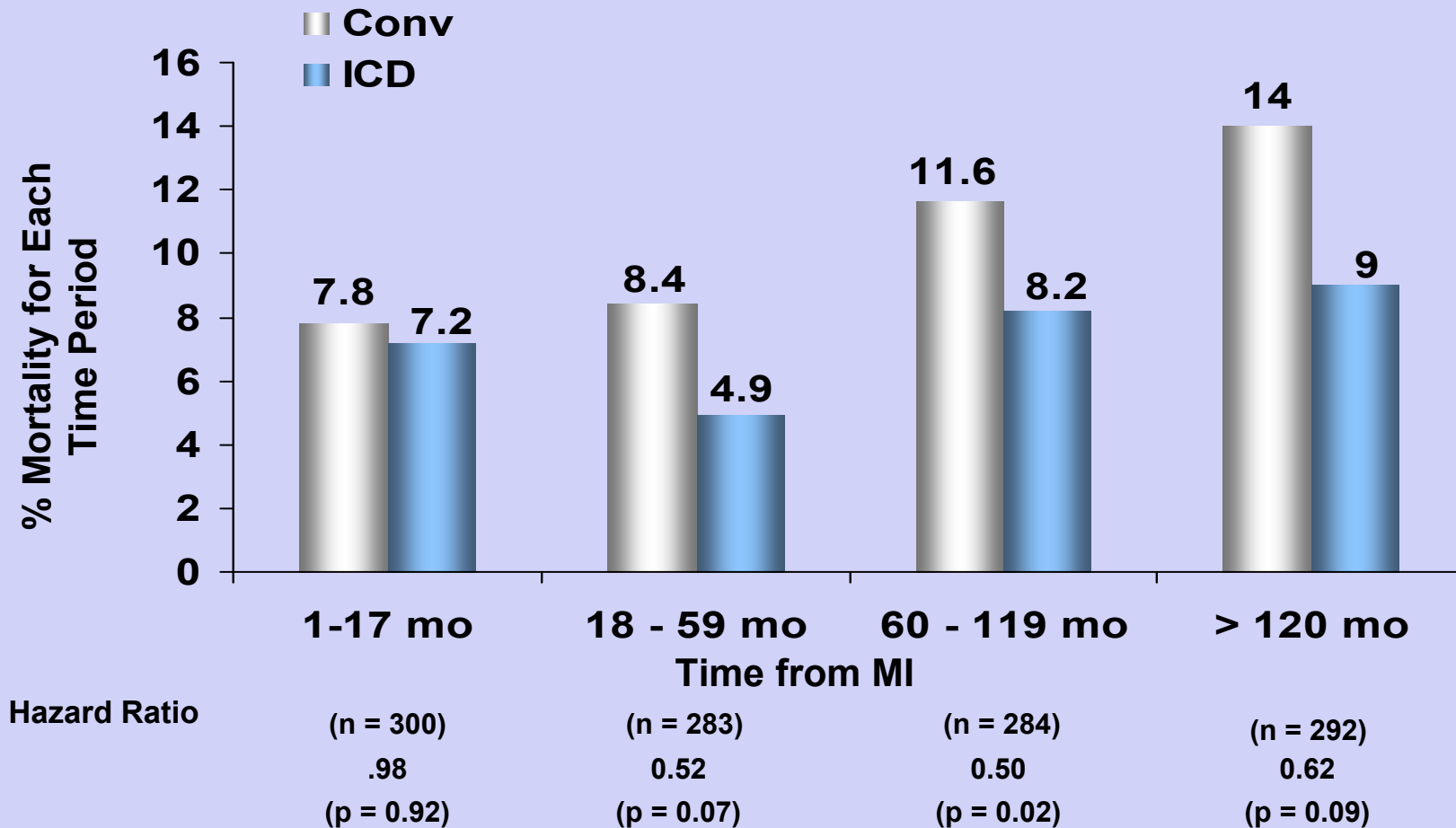
¹ Moss AJ. *N Engl J Med.* 1996;335:1933-40.

² Buxton AE. *N Engl J Med.* 1999;341:1882-90.

³ Moss AF. *N Engl J Med.* 2002;346:877-83.

⁴ Moss AJ. Presented before ACC 51st Annual Scientific Sessions, Late Breaking Clinical Trials, March 19, 2002.

Relation of Time from MI to ICD Benefit in the MADIT-II Trial



SCD-HeFT

- **Objective:**

- To determine, by intention-to-treat analysis, if amiodarone or an ICD reduces all-cause mortality compared to placebo* in patients with either ischemic or non-ischemic NYHA Class II and III CHF and $EF \leq 35\%$.

- **Inclusion Criteria:**

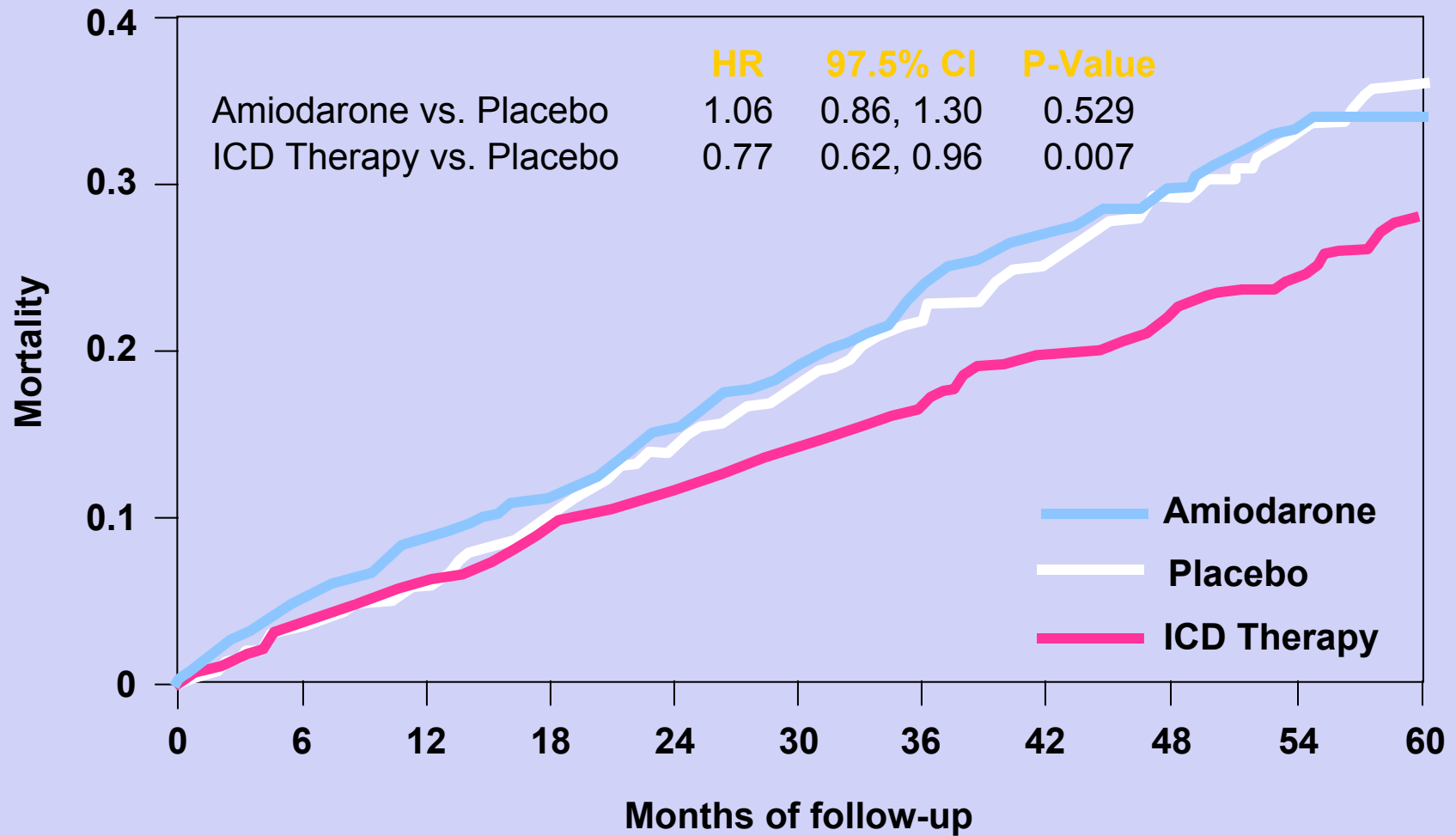
- NYHA Class II or III (ischemic or non-ischemic)
- $LVEF \leq 35\%$
- ≥ 18 years of age; no upper age limitation
- CHF ≥ 3 months
- ACE I and Beta Blocker therapy if tolerated

- **ICD Results:**

- In class II or III CHF patients with $EF \leq 35\%$ on good background drug therapy, the mortality rate for placebo-controlled patients is 7.2% per year over 5 years
- ICDs decrease mortality by 23%
- Amiodarone, when used as a primary preventive agent, does not improve survival

* Double-blind for drug therapy
Bardy G. *N Engl J Med.* 2005;352:225-37.

SCD-HeFT: Mortality by Intention-to-Treat



Summary - Key Randomized Trials

ICD therapy for the primary prevention of SCA

						Mortality (%)		
Trial	N	Age (yrs)	Mean LVEF (%)	Follow-up (mos)	Control Therapy	Control	ICD	P
SCD-HeFT	2521	60.1	25	45.5	Optimal Medical Therapy	36.1	28.9	.007
MADIT	196	63 ± 9	26	27	Conventional	38.6	15.7	.009
MADIT II	1232	64 ± 10	23	20	Optimal Medical Therapy	19.8	14.2	.007
MUSTT	704	67 ± 12	30	39	No EP-guided therapy	48	24	.06
DEFINITE	458	58	21	29.0±14.4	Optimal Medical Therapy	14.1	7.9	.08

DiMarco JP. *N Engl J Med*. 2003;349:1836-47.

Kadish A, et.al. *N Engl J Med* 2004;350:2151-8.

2006 ACC/AHA/ESC Guidelines

ICD Class I Recommendations:

- Secondary prevention for patients with a history of SCA, VF, or hemodynamically destabilizing VT, unexplained syncope
- Prevention of SCD in patients who are at least **40 days post-MI** with an **LVEF \leq 30-40%** and **NYHA functional class II or III**
- Prevention of SCD in **NYHA Class II-III CHF, LVEF \leq 30-35%, on OPT**
- Patients who are at high risk of SCA due to genetic disorders such as **long QT syndrome, Brugada syndrome, hypertrophic cardiomyopathy** and **arrhythmogenic right ventricular dysplasia (ARVD)**.

ICD Class II Recommendations:

- Ischemic and non-ischemic patients with **NYHA functional class I, LVEF \leq 30-35%**

Death from SCA Can Be Prevented...

- At-risk patients are those with:
 - Coronary artery disease, previous MI
 - Low left ventricular ejection fraction
 - Nonischemic cardiomyopathy and heart failure
- Defibrillation is the only effective treatment for SCA
- Multiple clinical trials have shown a mortality benefit associated with prophylactic ICD implantation

Example of SCA incidence in a typical clinic

CHF Patients only

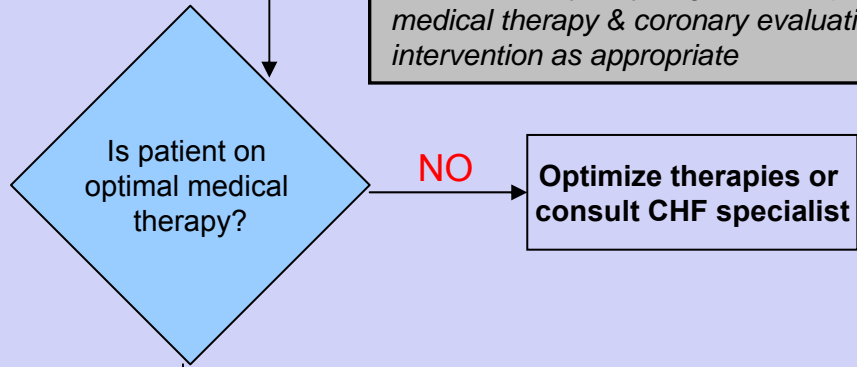
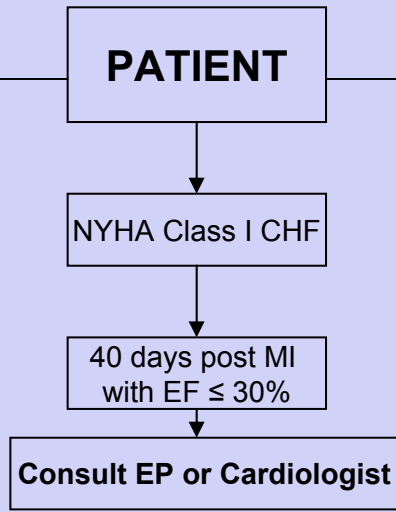
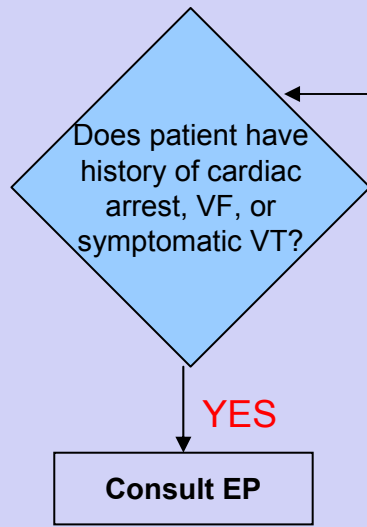
- **1000 CHF Patients**

26%¹⁻⁴ will be Class II/III with EF < 35%
(260)

– 7.2%⁵ of those will have an SCA
attack (19)

- 95%⁶ of those patients will die
without an ICD implant (18)

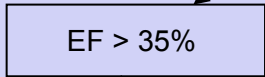
– **18 lives could be saved with
appropriate referral/treatment**



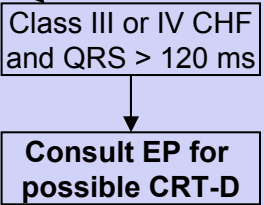
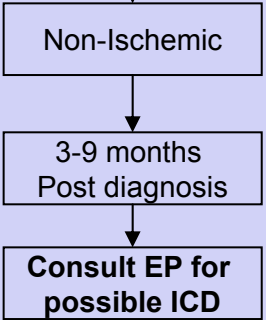
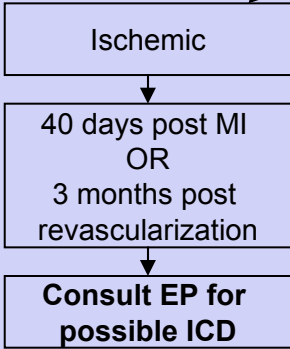
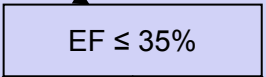
The Ohio Heart and Vascular Center in Cincinnati Patient Care Pathway

Note: Pathway only begins after optimal medical therapy & coronary evaluation/intervention as appropriate

Note: This is just a suggested pathway

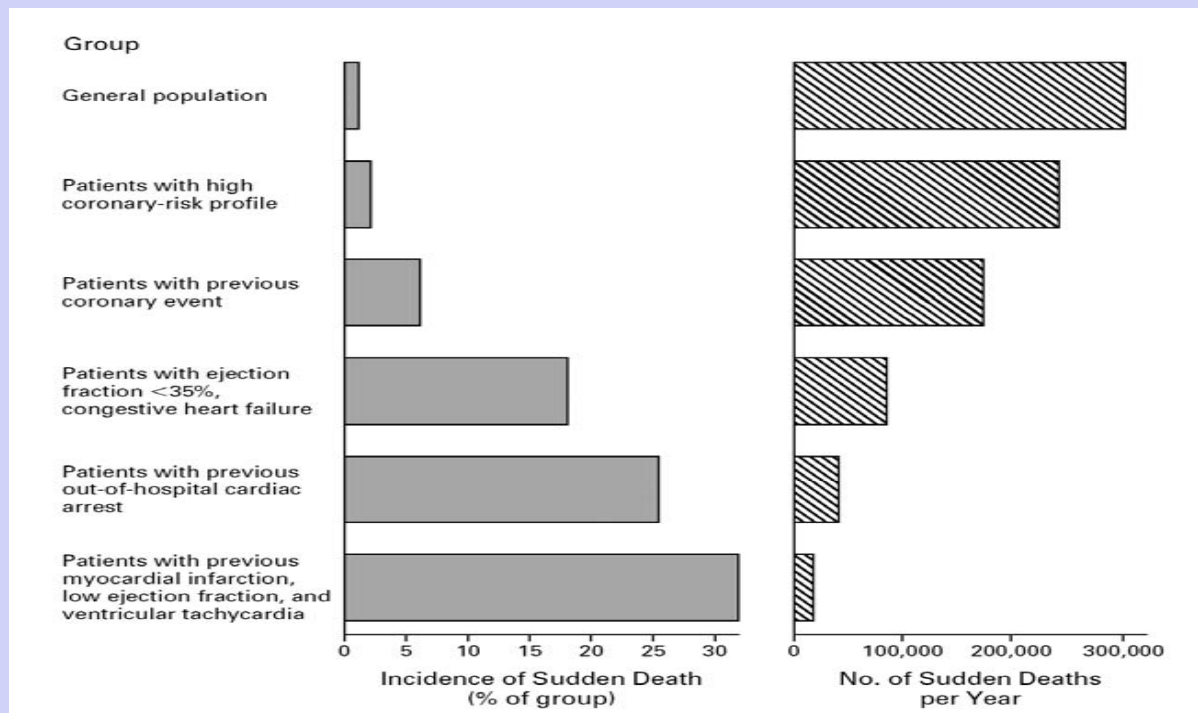


1. Consider referral to HF Specialist or HF Program.
2. Repeat diagnostics with change of symptoms AND consider annual testing.



Summary

The majority of patients who die of SCA in the United States come from the general population and have not been identified as being at high risk of SCA



Summary

Crucial to SCA prevention - identify high risk patients and refer them for consideration for ICD implant.

High risk patients often have one or more of:

- Previous MI
- Low ejection fraction
- Congestive heart failure
- Hx of aborted SCA