

**ICD Update:  
In Post-MADIT-II and SCD-HeFT Era in  
the USA**

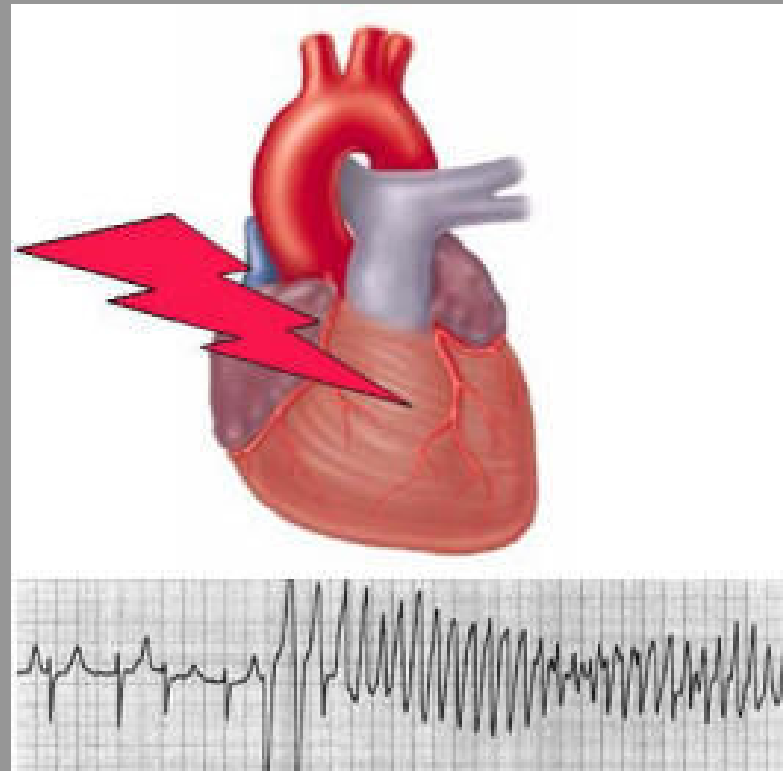
**Soo G. Kim, MD  
Professor of Medicine  
Director of Electrophysiology Laboratory  
Montefiore Medical Center  
Albert Einstein College of Medicine  
Bronx, New York**

**For the 50<sup>th</sup> Anniversary of the Korean  
Society of Circulation**

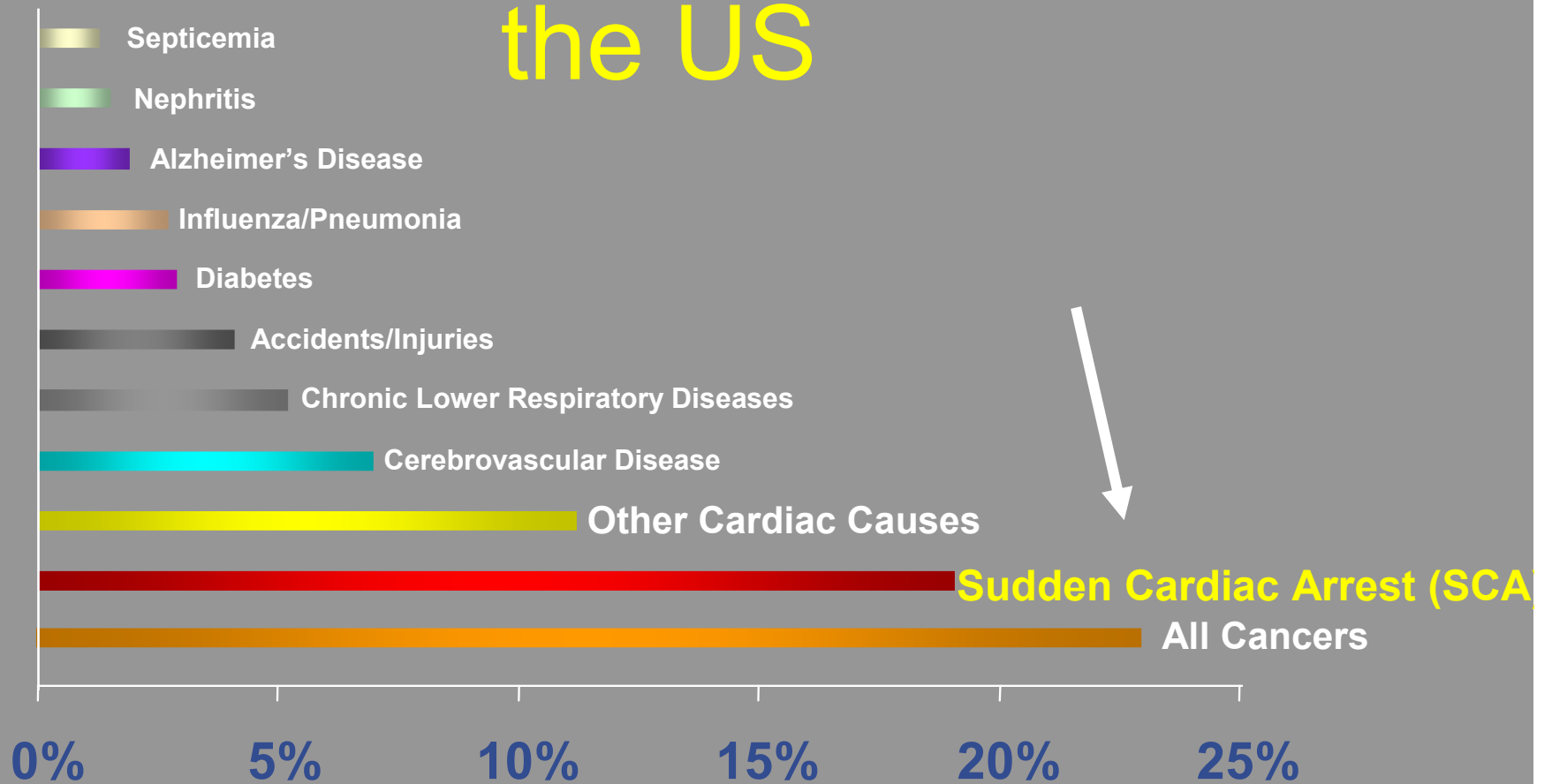
# **ICD Therapy for Sudden Cardiac Death Based on Evidences Developed by Prospective Studies**

- **Evidence for secondary prevention**
- **Evidence for primary prevention**
- **Current practice in the USA**

# Sudden Cardiac Arrest (SCA)



# Leading Causes of Death in the US

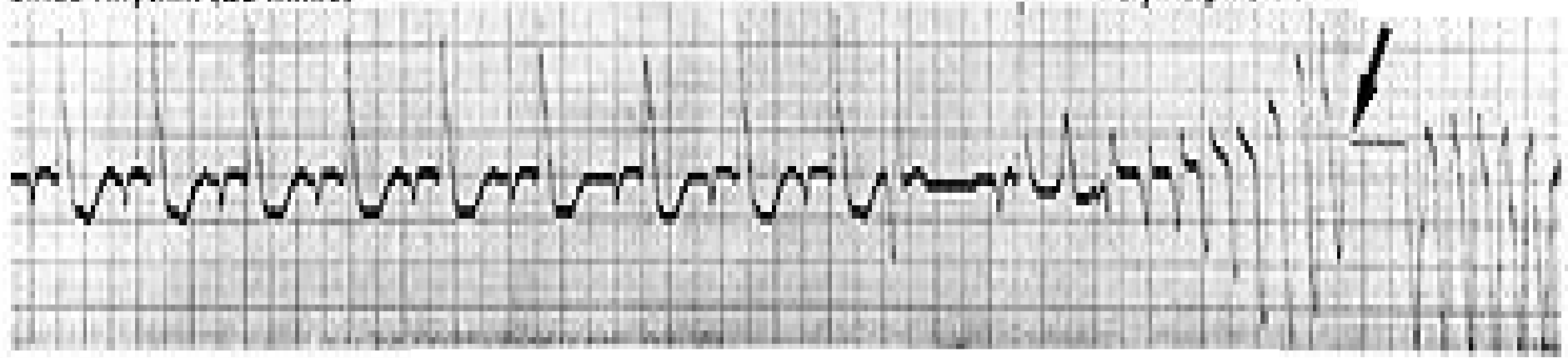


National Vital Statistics Report, Vol 49 (11), Oct. 12, 2001.

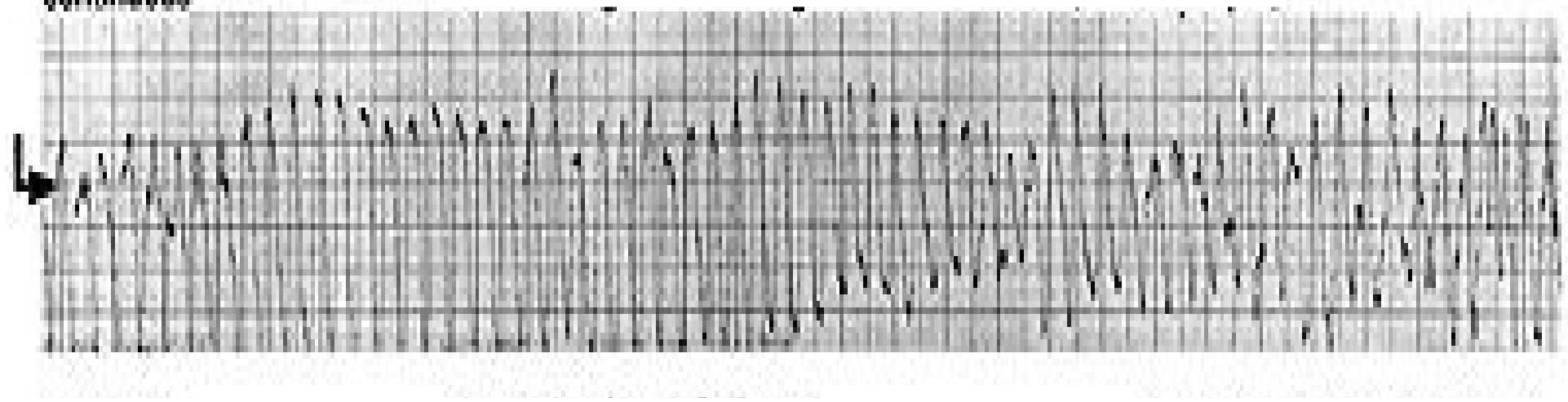
State-specific mortality from sudden cardiac death – United States 1999. *MMWR*. 2002;51:123-126.

Sinus Rhythm (25 mm/s)

Polymorphic VT



continuous

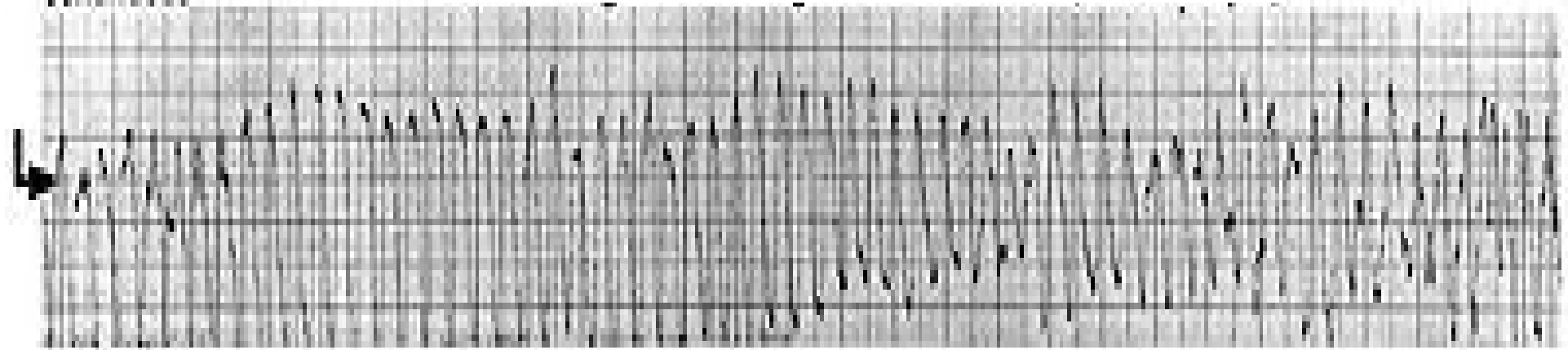


Sinus Rhythm (25 mm/s)

Polymorphic VT

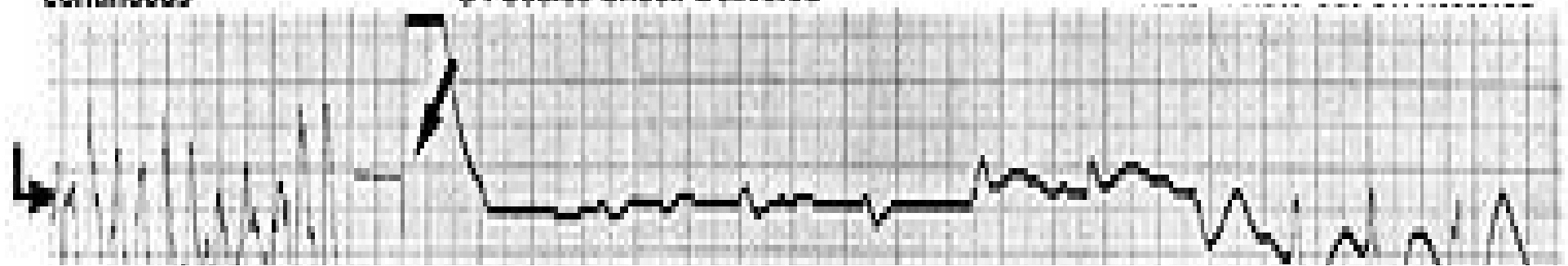


continuous



continuous

34 Joules Shock Delivered





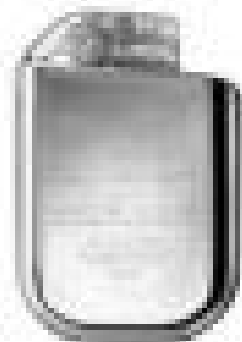




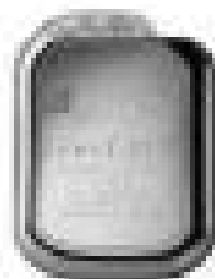
# Evolution of ICD



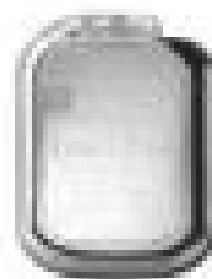
209 cc



113 cc



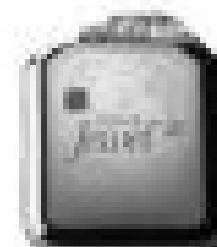
80 cc



80 cc



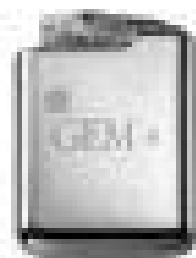
72 cc



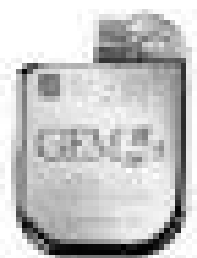
54 cc



62 cc



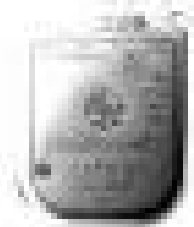
49 cc



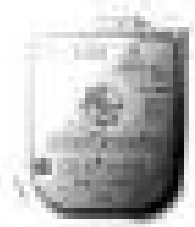
39.5 cc



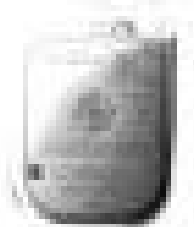
39 cc



39.5 cc



39 cc

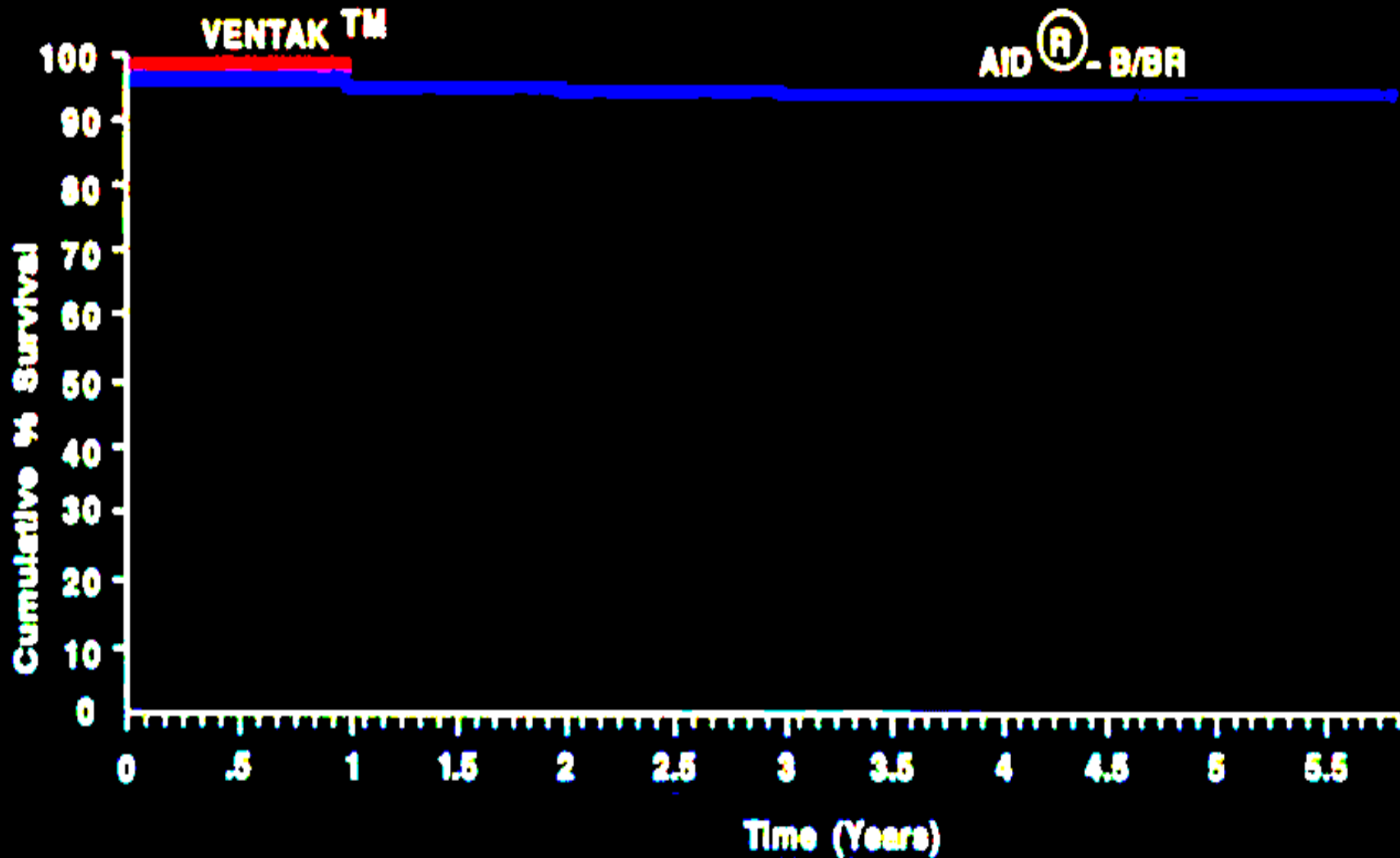


39.5 cc

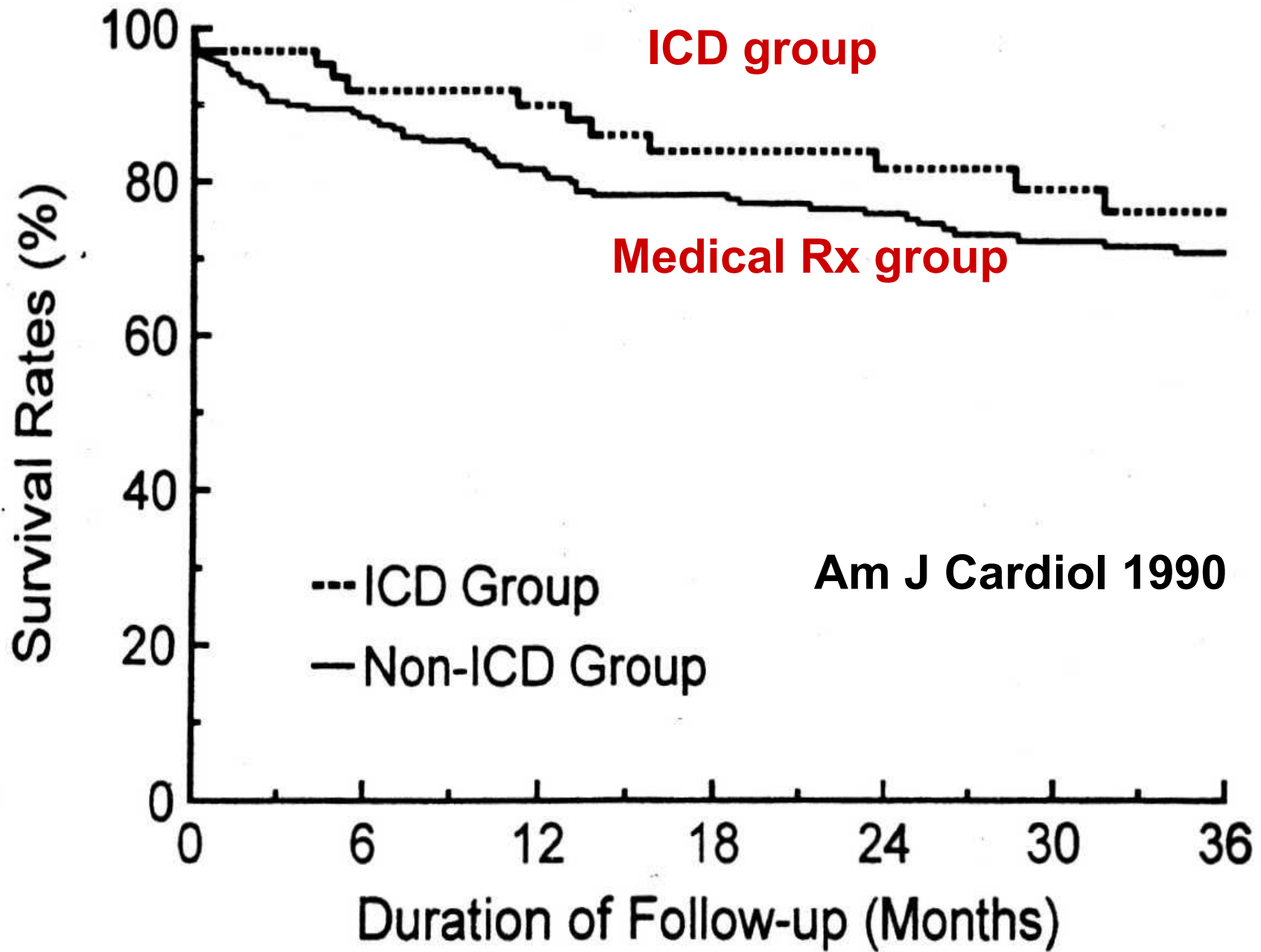


36 cc

# Sudden death rates of ICD patients



8/15/87



**EDITORIALS**

# **Implantable Defibrillator Therapy: Does It Really Prolong Life? How Can We Prove It?**

Soo G. Kim, MD

- **Total (all-cause) mortality**
- **Prospective studies**

**Since ICD was invented to prevent SCD, the benefit should be assessed by the reduction of SCD and not by total mortality.**

**ICDs cannot prevent deaths from CHF, MI, stroke or cancer.**

**Fogoros R. Am J Cardiol**

# **NASPE (North American Society of Pacing and Electrophysiology) Policy Conference, February 1992**

**Total mortality (all-cause mortality) rates, not sudden death rates, should be the primary endpoint of studies comparing antiarrhythmic therapies.**

**Prospective studies should be done to determine the benefits of ICD therapy over medical therapy.**

**Kim, Fogoros et al, PACE, 1992**

# **AVID (Antiarrhythmics Versus Implantable Defibrillators) Study**

- **ICDs versus drug therapy (for secondary prevention of SCD)**
- **Primary endpoint: total mortality**
- **Drug therapy: amiodarone or sotalol**

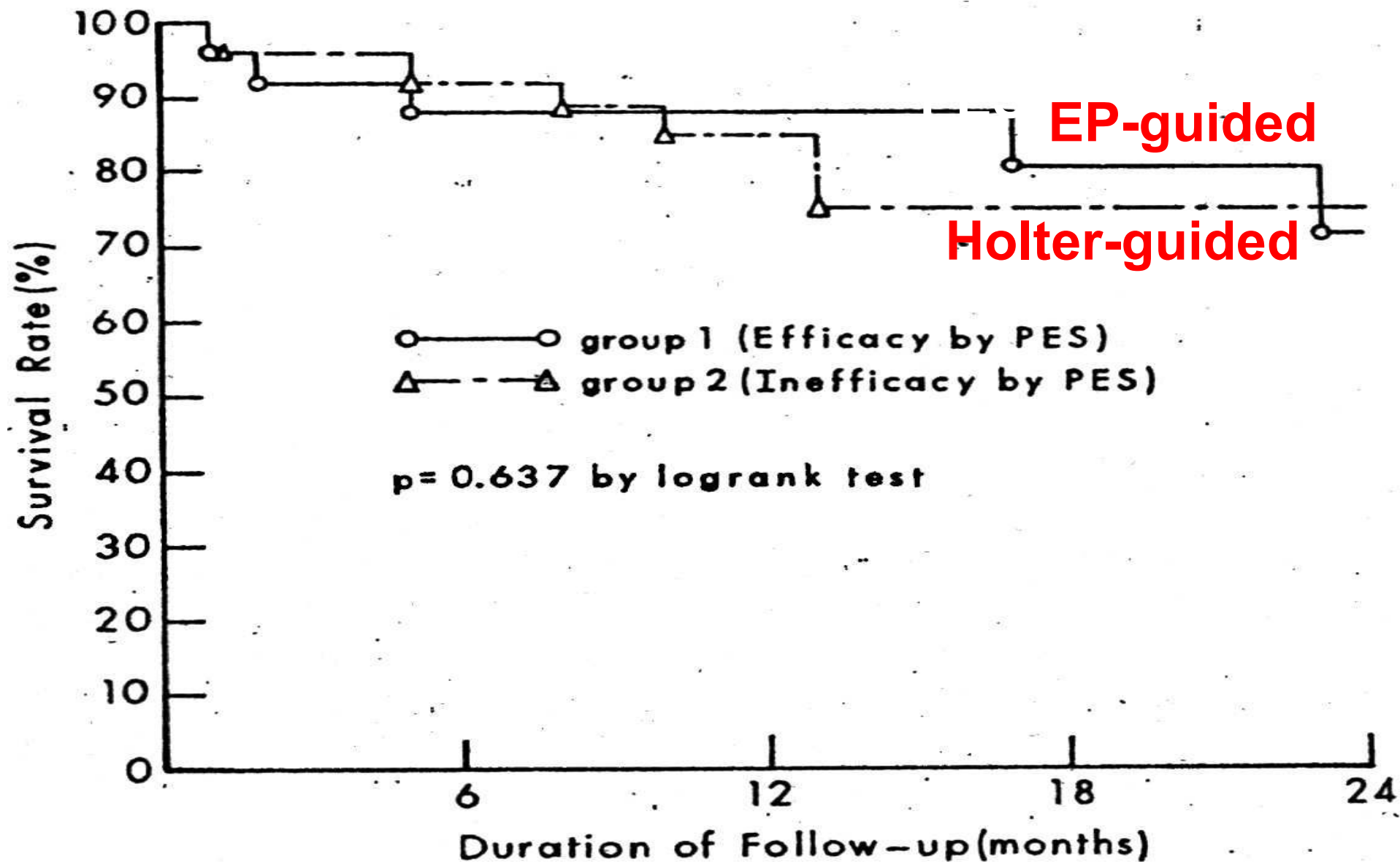


Figure 1. Rates of Arrhythmia-Free Survival in the Study Groups, According to the Method of Kaplan and Meier.



# *Circulation*

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*An Official Journal of the American Heart Association, Inc.<sup>®</sup>*

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## FEATURES

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**The management of patients with life-threatening ventricular tachyarrhythmias: programmed stimulation or Holter monitoring (either or both)?**

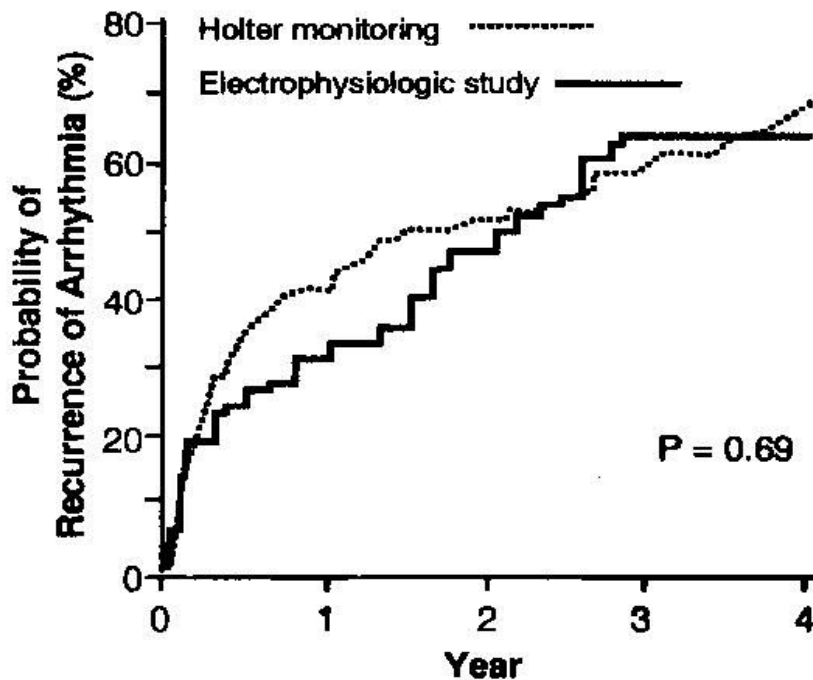
Soo G. Kim, M.D.

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# ESVEM Results

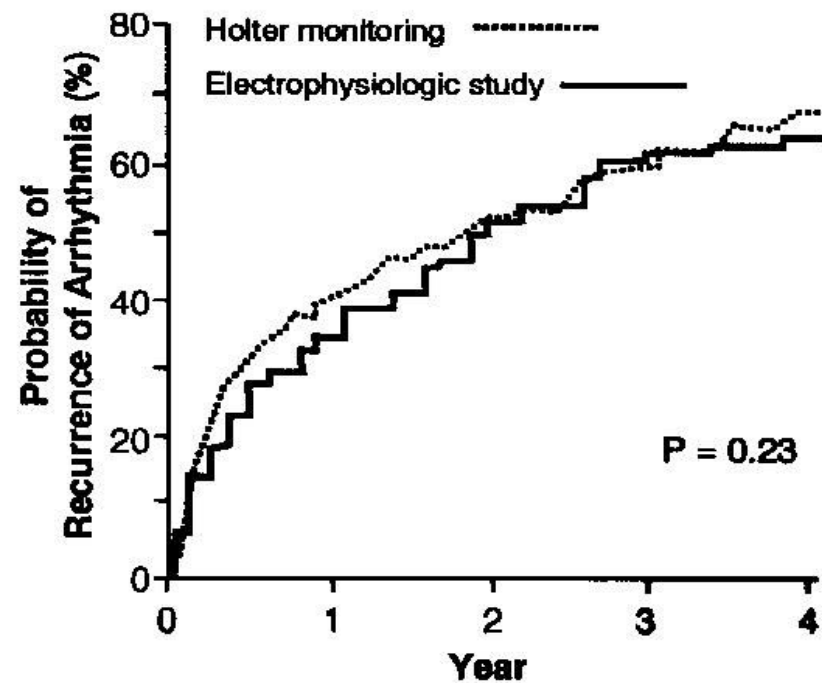
## On-treatment analysis

A. Patients receiving drug predicted to be effective



## Intention-to-treat analysis

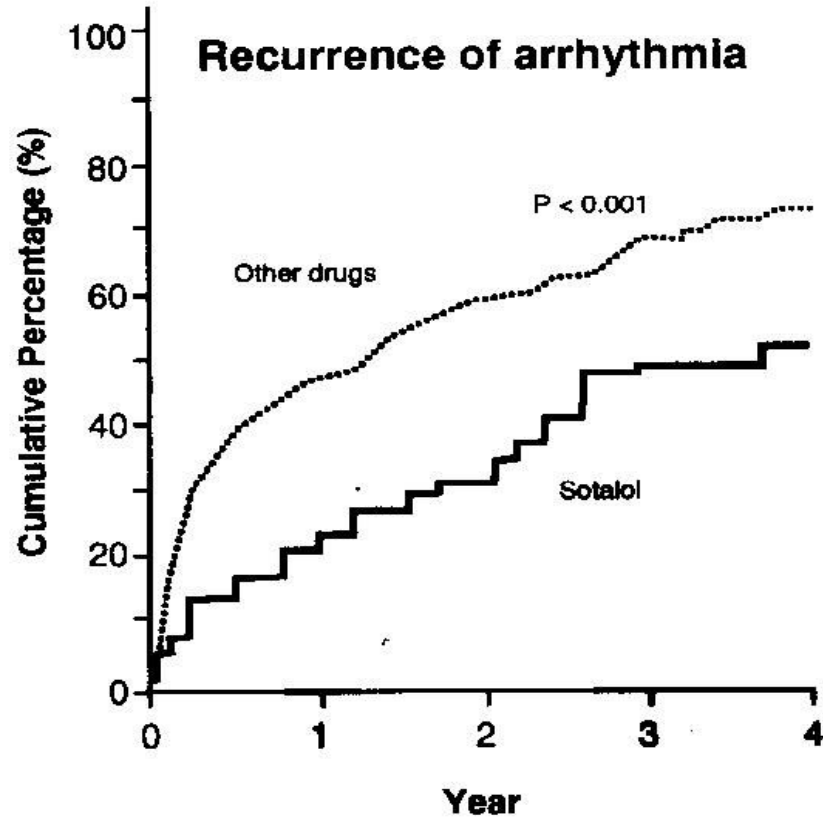
B. All randomized patients



Mason JW. N Engl J Med. 1993;329(7):445-451.

ESVEM study: EP versus Holter-guided Rx

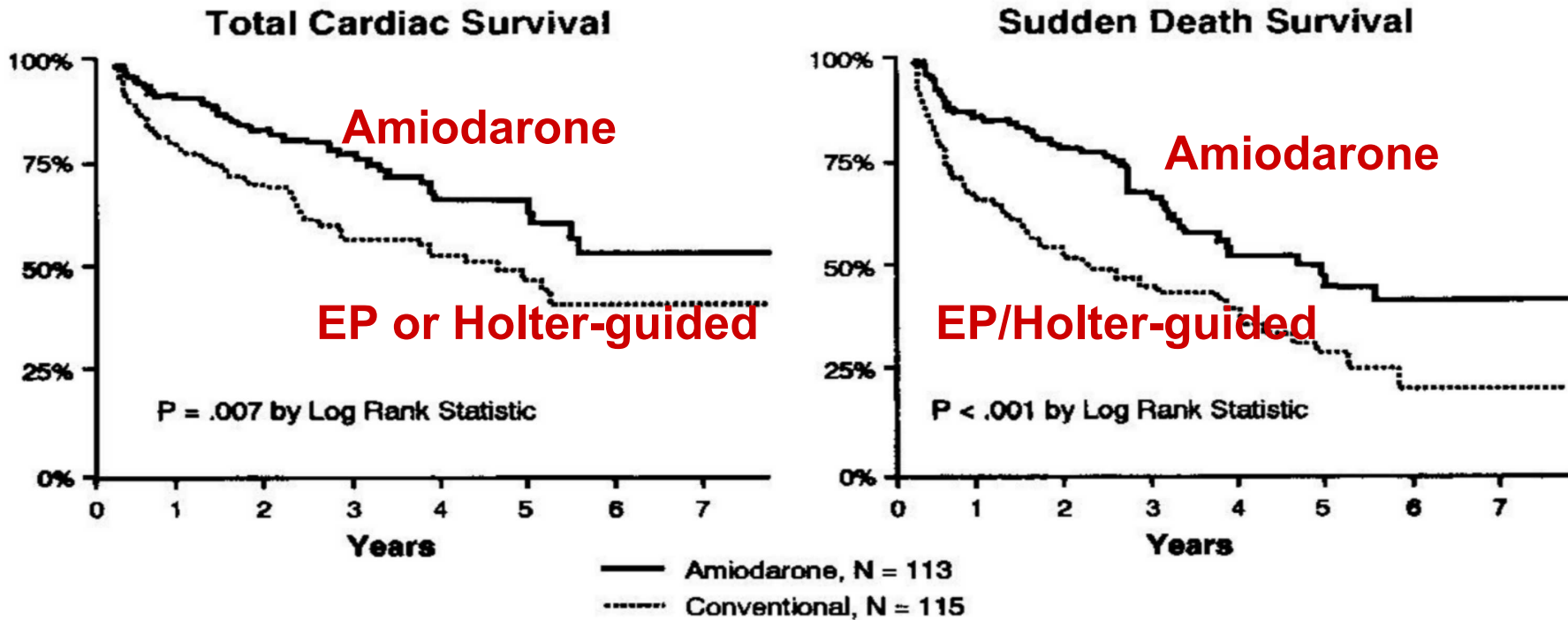
## ESVEM Results



Mason JW. N Engl J Med. 1993;329(7):452-458.

Sotalol was better than other drugs

# CASCADE Survival



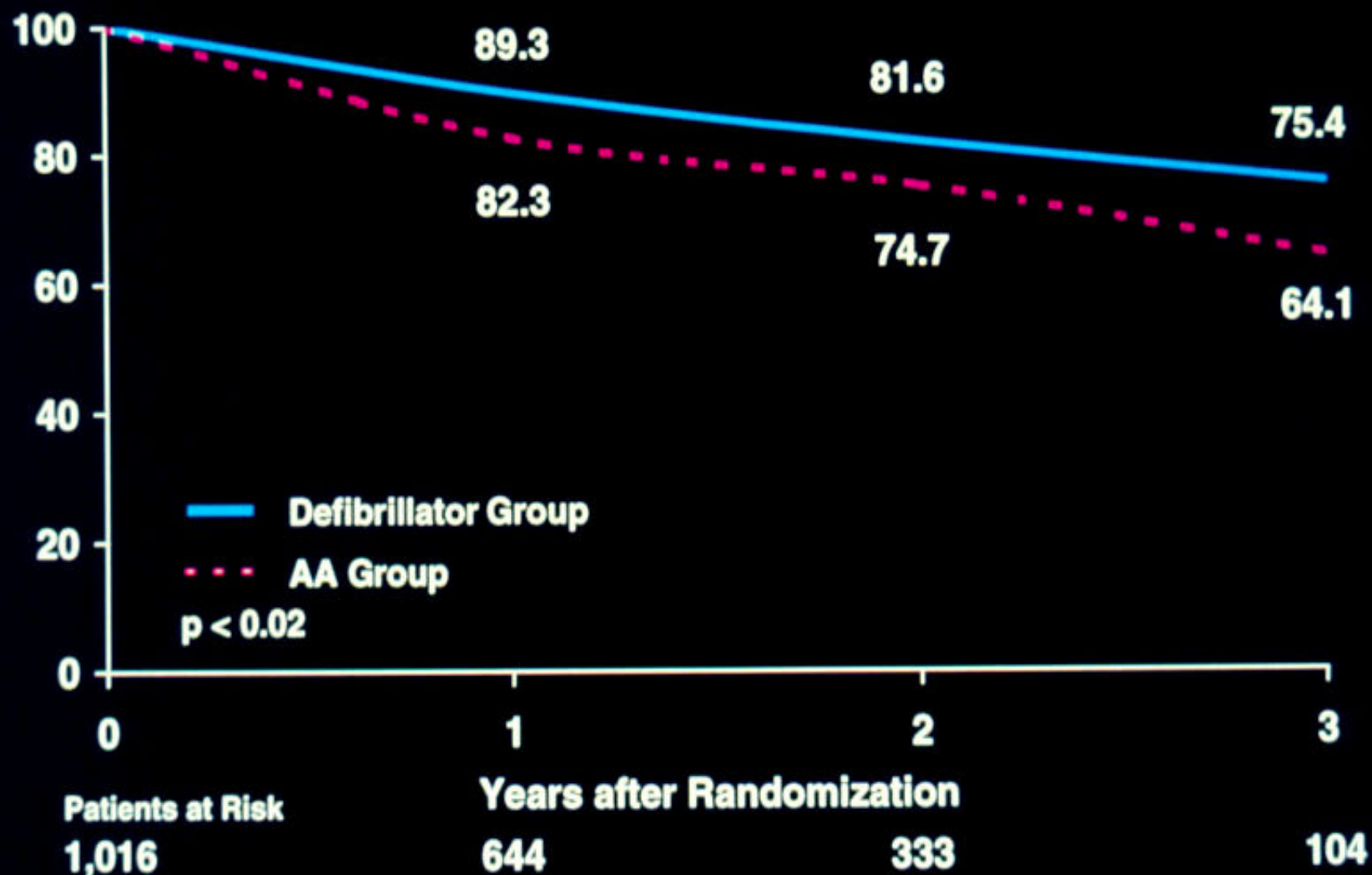
CASCADE Investigators. Am J Cardiol. 1993;72:280-287.

CASCADE study  
Amiodarone versus EP or Holter-guided Rx

# **AVID (Antiarrhythmics Versus Implantable Defibrillators) Study**

- **Drug therapy: amiodarone or sotalol**

# AVID Overall Survival



AVID Investigators. N Engl J Med. 1997;337(22):1576-1583.

## **Other Secondary ICD Trials**

- **CASH (Cardiac Arrest Study in Hamburg)**
- **CIDS (Canadian Implantable Defibrillator Study)**

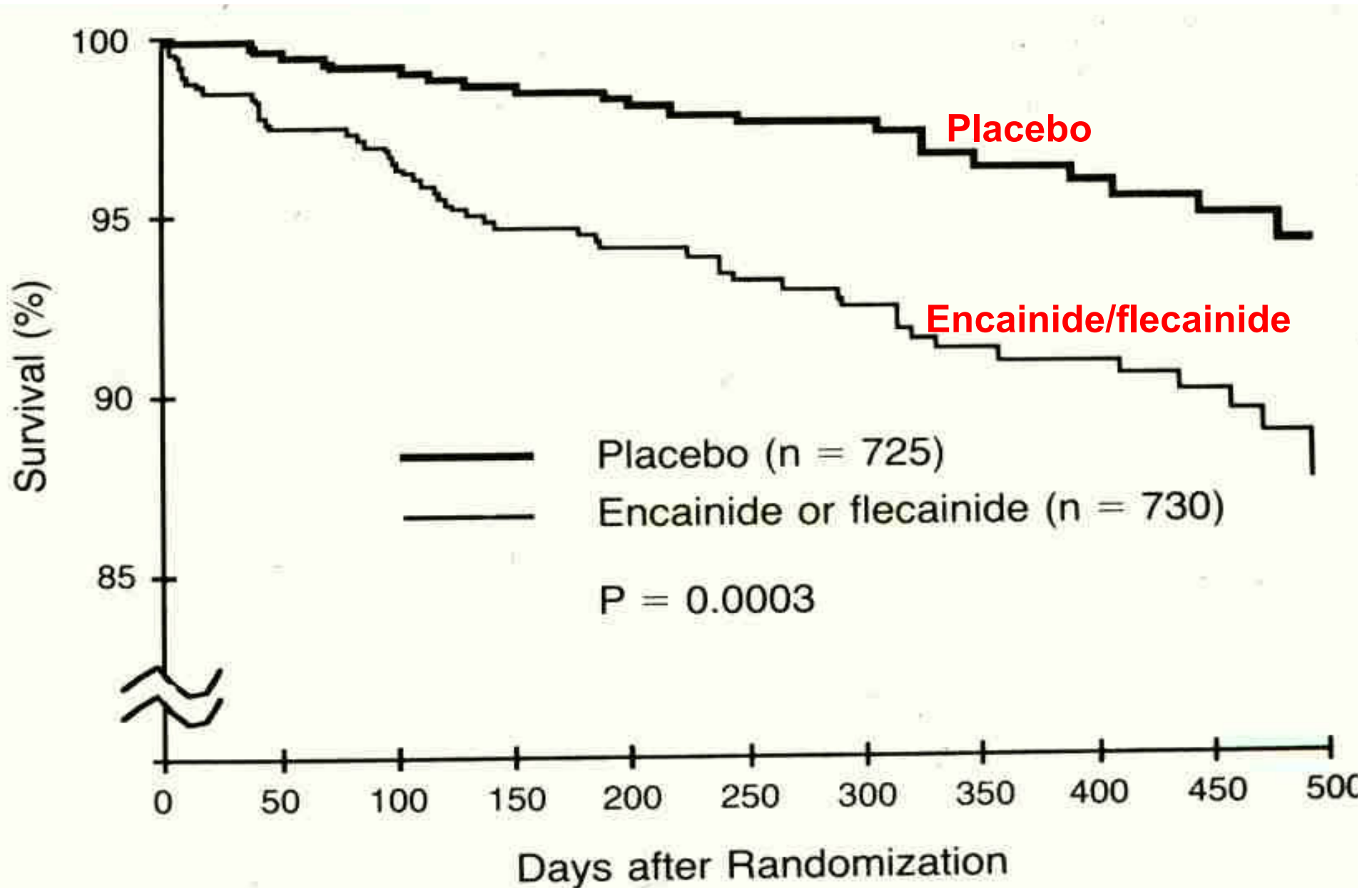
## Secondary Prevention of Sudden Death

- ICD therapy improves survival better than antiarrhythmic drug therapy.
- Antiarrhythmic drugs have very limited value and should be avoided (except for amiodarone and possibly sotalol in some clinical settings).



# **Primary Prevention of Sudden Death Multicenter Studies**

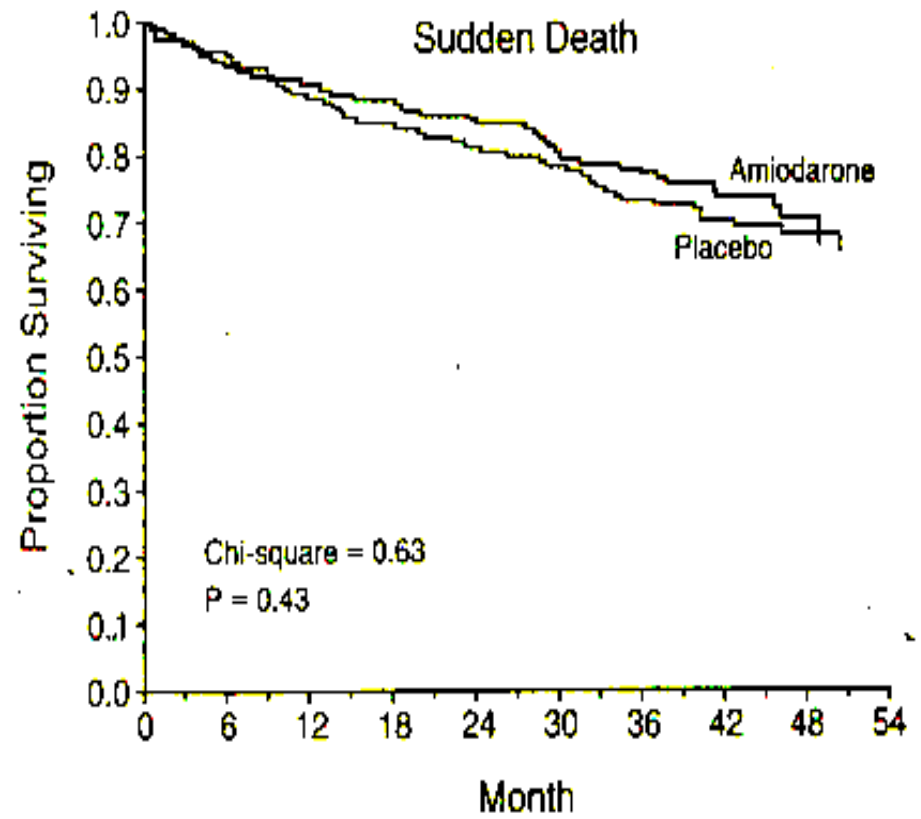
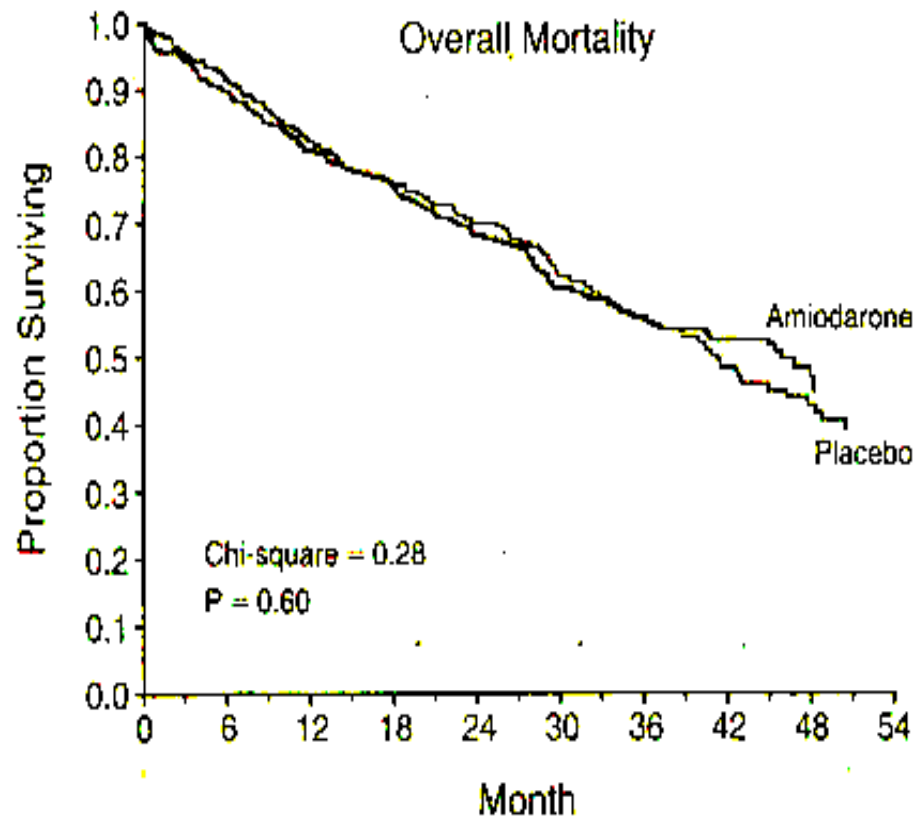
- **Drug therapy**
- **Device therapy**



**CAST (Cardiac Arrhythmia Suppression Trial): post-MI, EF < 40%, VPCs > 10/hour**

## **Amiodarone for primary prevention of sudden cardiac death**

- **EMIAT (European Myocardial Infarction Amiodarone Trial)**
- **CAMIAT (Canadian Amiodarone Myocardial Infarction Arrhythmia Trial)**
- **CHF-STAT (Congestive Heart Failure-Survival Trial of Amiodarone Therapy)**
- **GESICA**



Amiodarone	336	260	175	101	33
Placebo	338	263	178	95	39

Amiodarone	336	260	175	101	33
Placebo	338	263	178	95	39

Figure 1. Kaplan-Meier Estimates of Overall Mortality and Sudden Death from Cardiac Causes.

Amiodarone had no significant effect, as compared with placebo, on either overall mortality or the incidence of sudden death. The numbers below the figures are the numbers of patients at risk.

## CHF-STAT (VA study)

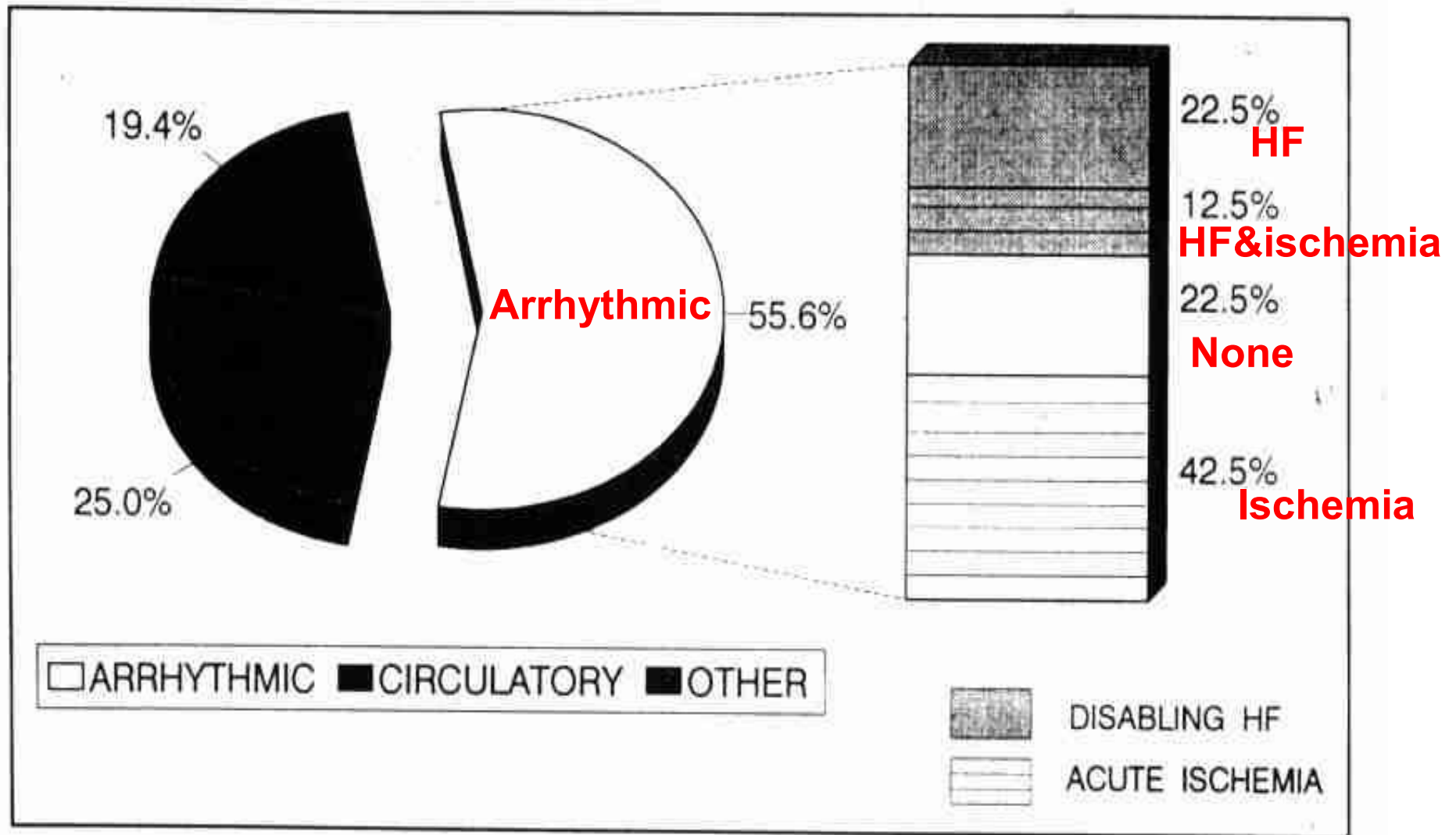
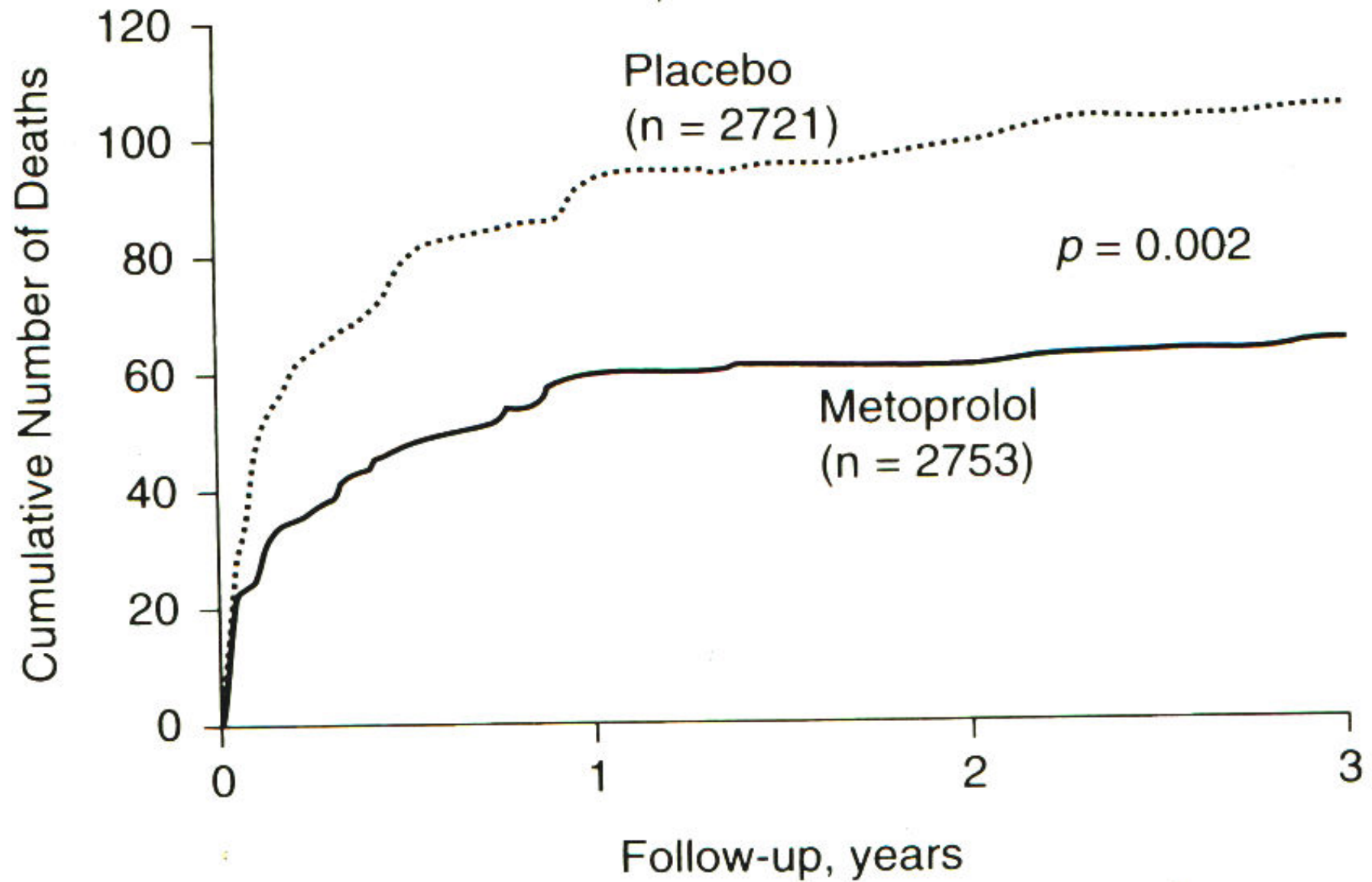


FIGURE 2. Circumstances of witnessed death in patients after MI. Deaths were classified by Hinkle-Thaler criteria. The bar graph at the right illustrates the proportion of deaths judged to be due to ventricular arrhythmias that were accompanied by disabling heart failure (shaded portion) or evidence of acute ischemia (horizontal lines).



Post-MI beta blocker study

Sinus Rhythm (25 mm/s)

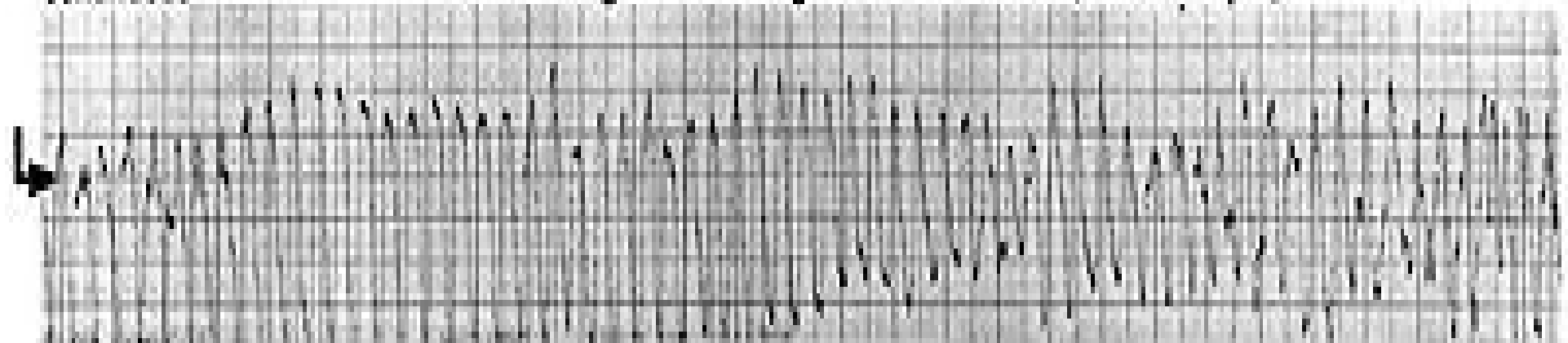
Polymorphic VT

Charge Begin



continuous

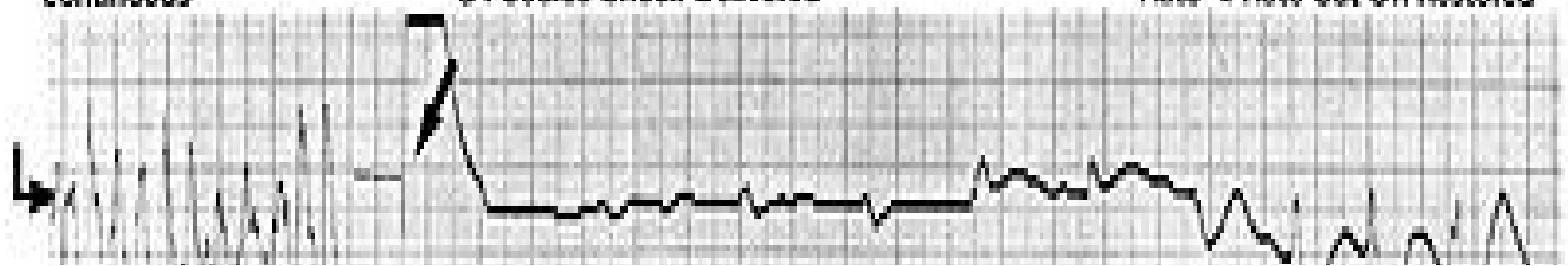
9.2 s Charge Time During Ventricular Flutter (300-350 bpm)



continuous

34 Joules Shock Delivered

Rate < Rate-Cut-Off Restored

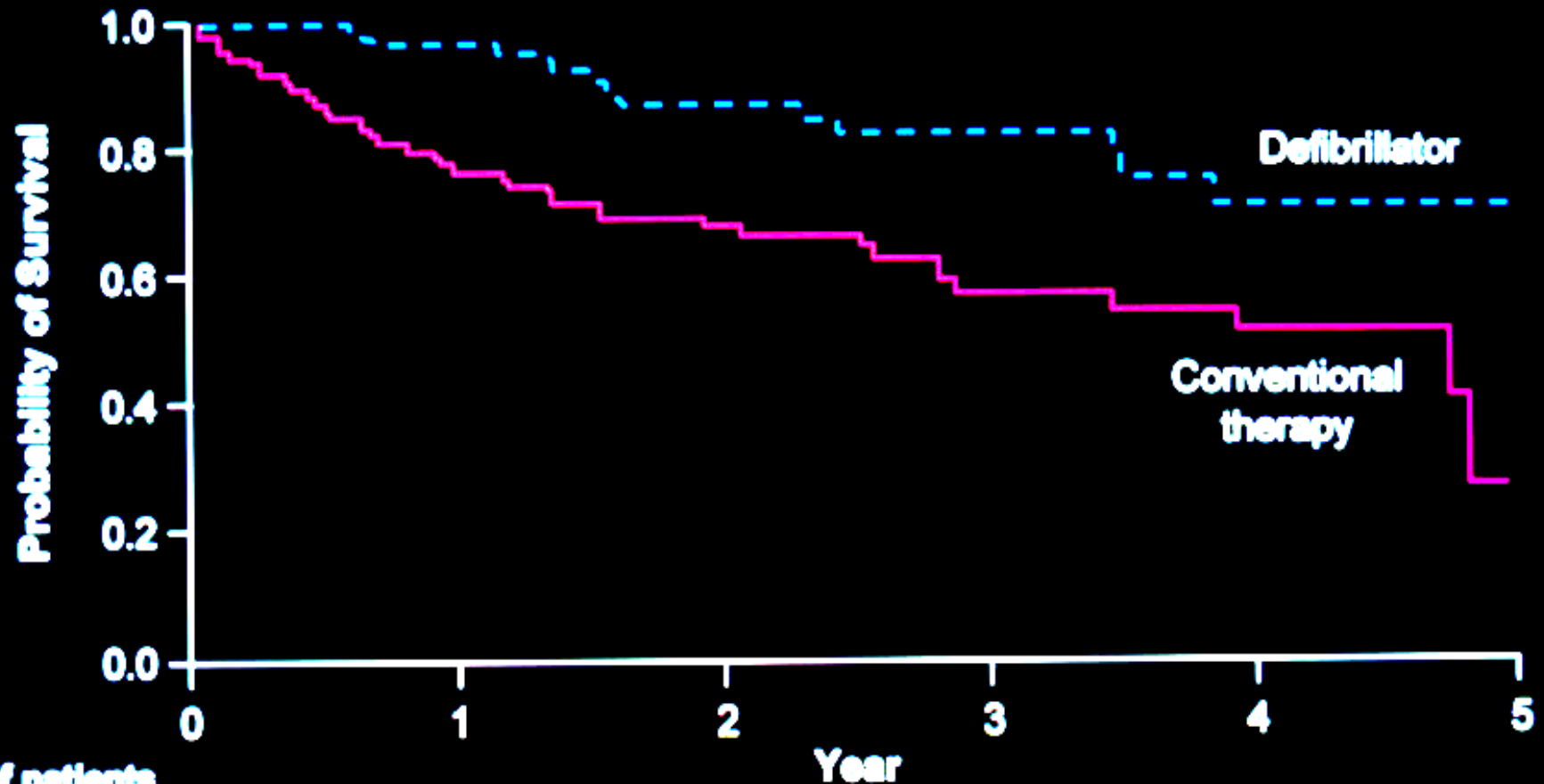


## **MADIT (Multicenter Automatic Defibrillator Implantation Trial)**

- **Post-MI patient with nonsustained VT and LV ejection fraction <35%.**
- **EP testing to induce ventricular tachycardia.**
- **Randomization: ICD versus medical therapy**



# MADIT Survival



No. of patients

Defibrillator	95	80	53	31	17	3
Conventional therapy	101	67	48	29	17	0

Moss AJ. *New Engl J Med.* 1998;338:1933-1940.

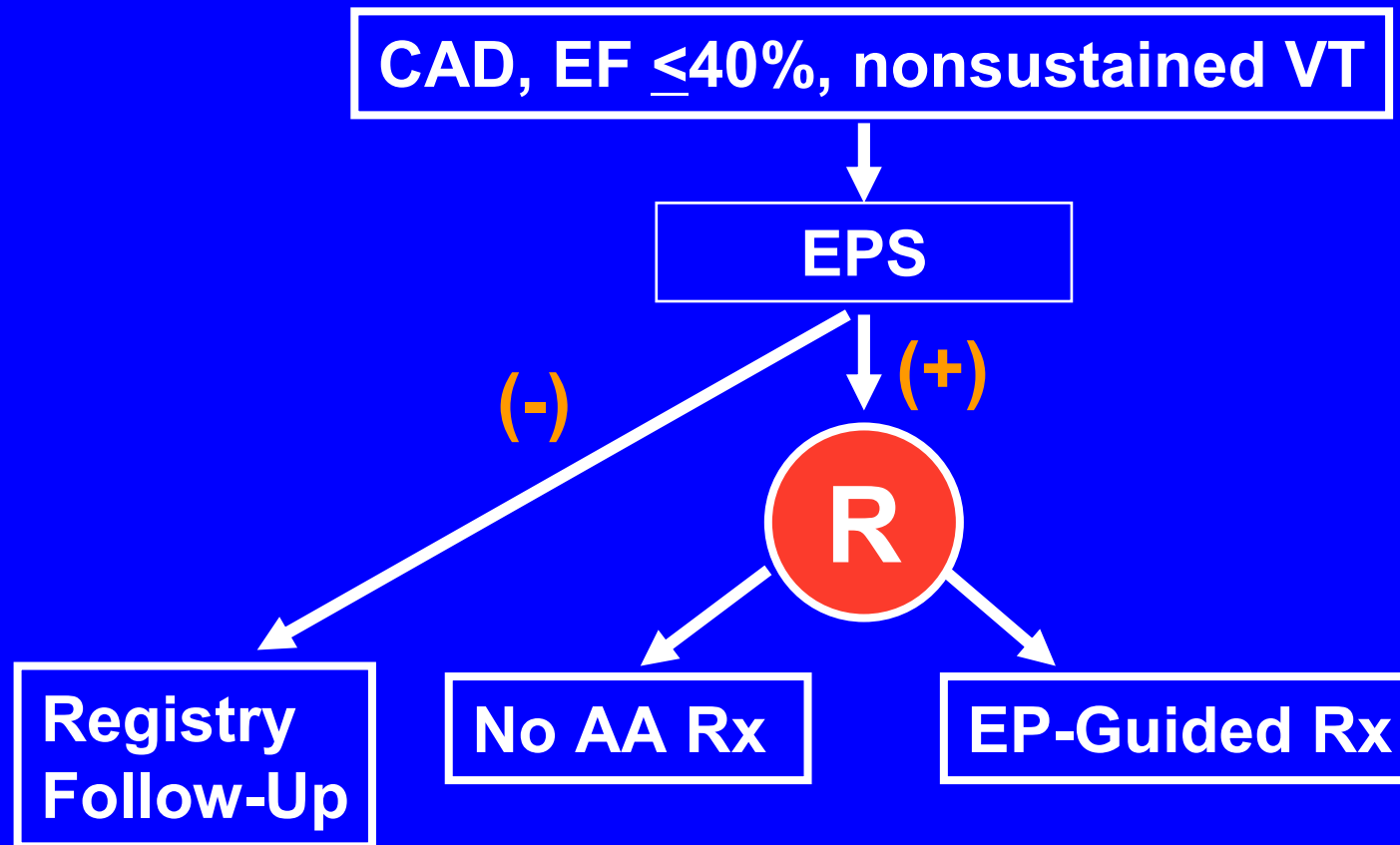
**Post-MI, NSVT, EF<35%, inducible VT by PES**

## **MUSTT (Multicenter UnSustained Tachycarida Trial)**

- **Hypothesis: EP-guided therapy will improve survival of post-MI patients with nonsustained VT.**

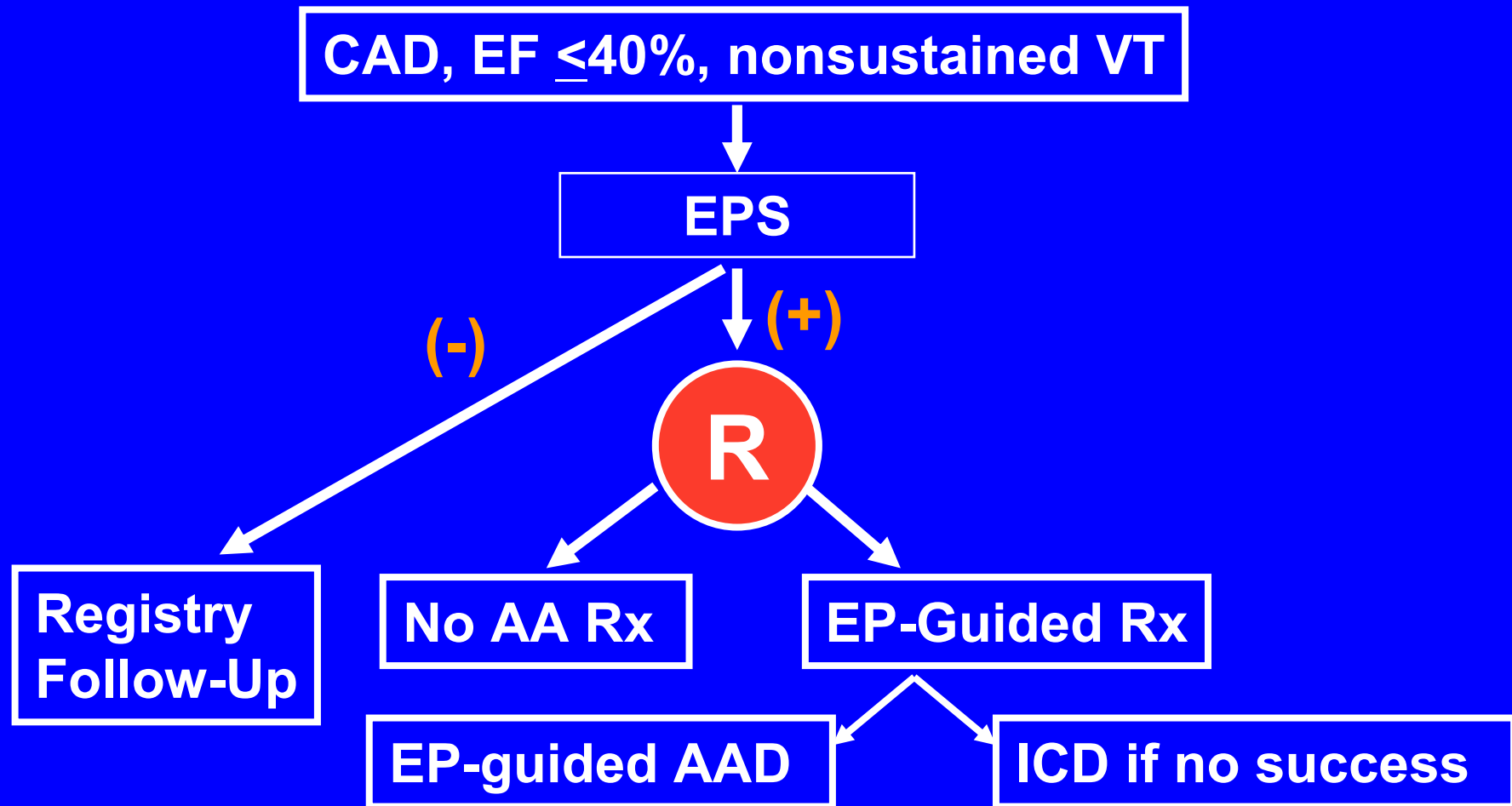
# MUSTT

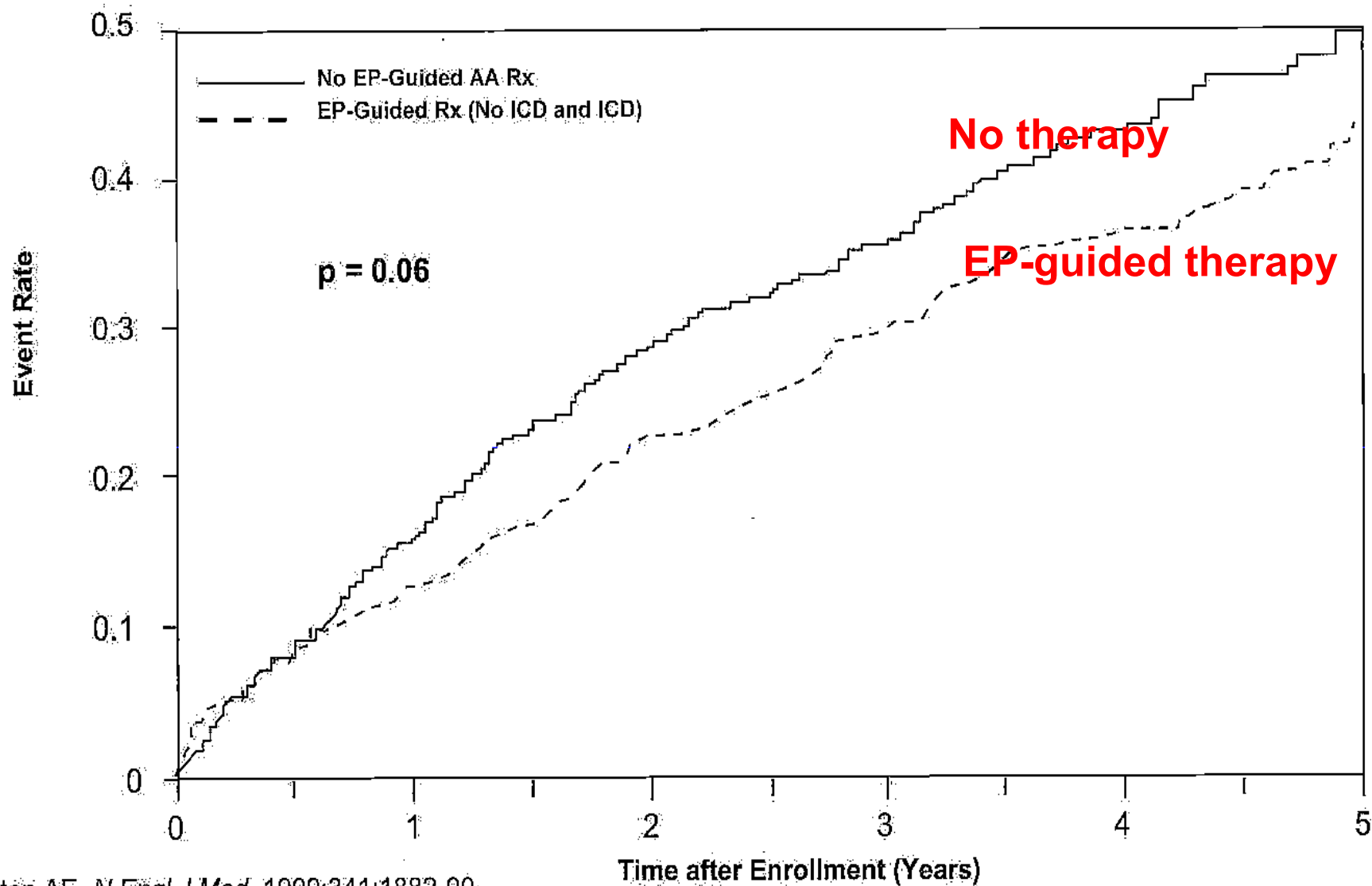
## Multicenter UnSustained Tachycardia Trial



# MUSTT

## Multicenter UnSustained Tachycardia Trial



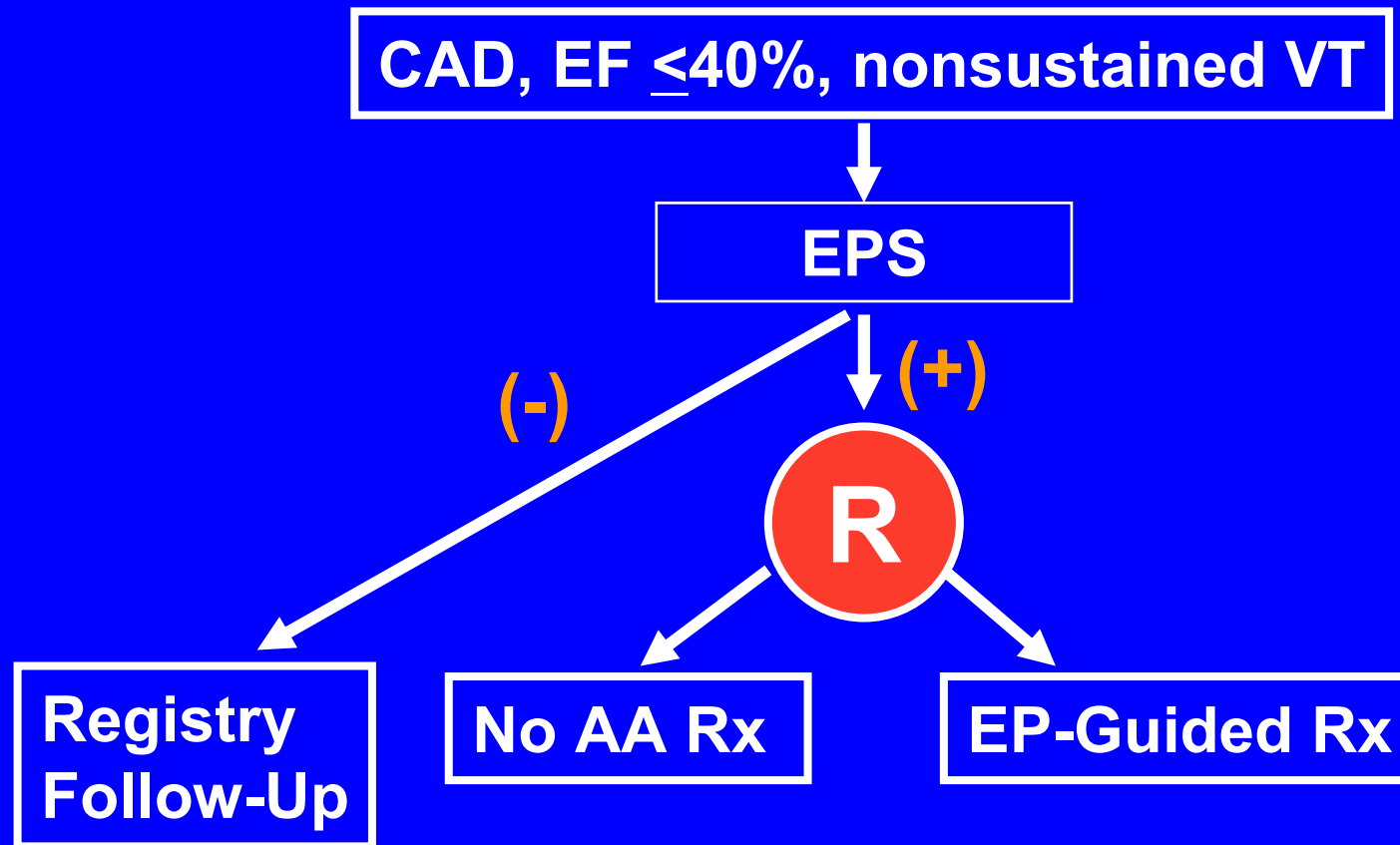


Buxton AE. *N Engl J Med*. 1999;341:1882-90.

**MUSTT: primary endpoint (EP-guided therapy vs no therapy)**

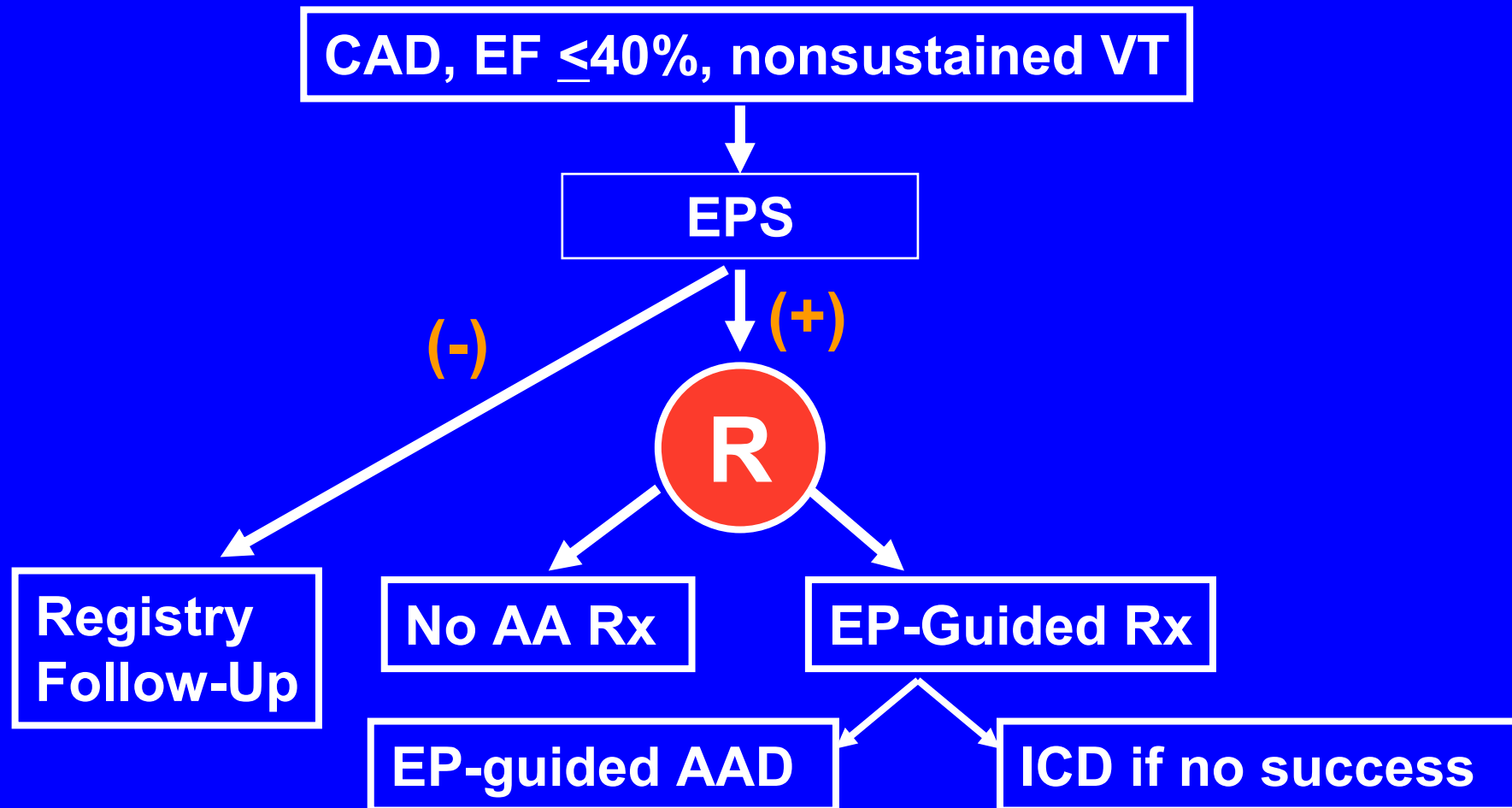
# MUSTT

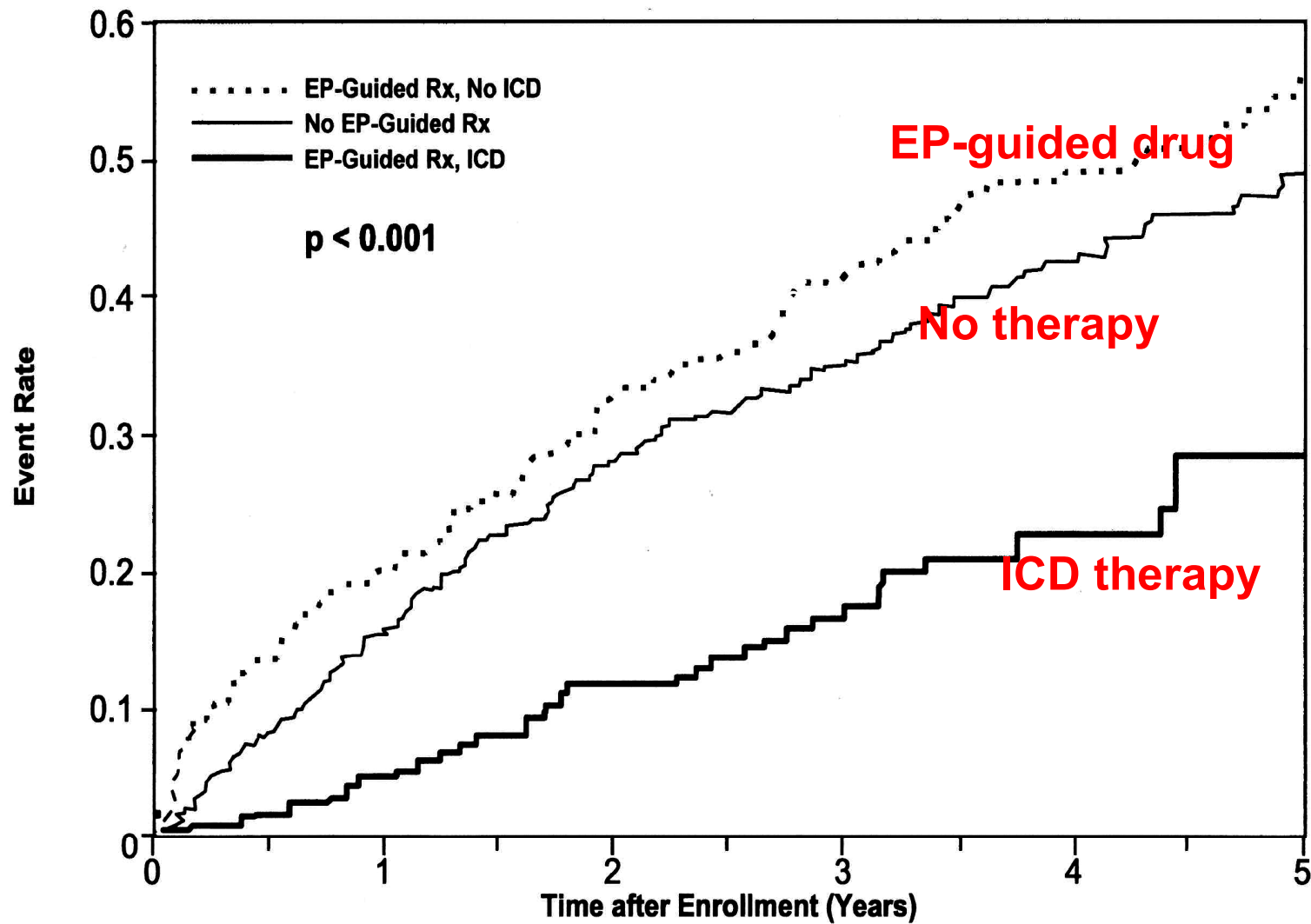
## Multicenter UnSustained Tachycardia Trial



# MUSTT

## Multicenter UnSustained Tachycardia Trial





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

MUSTT: subgroup analysis (not the study hypothesis)



## EDITORIAL REVIEWS

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# **Management of Survivors of Cardiac Arrest: Is Electrophysiologic Testing Obsolete in the Era of Implantable Defibrillators?**

SOO G. KIM, MD, FACC

*Bronx, New York*

## **MADIT II**

**No** requirement for electrophysiology studies or nonsustained VT

**Chronic coronary artery disease with prior MI**

**EF <30%**

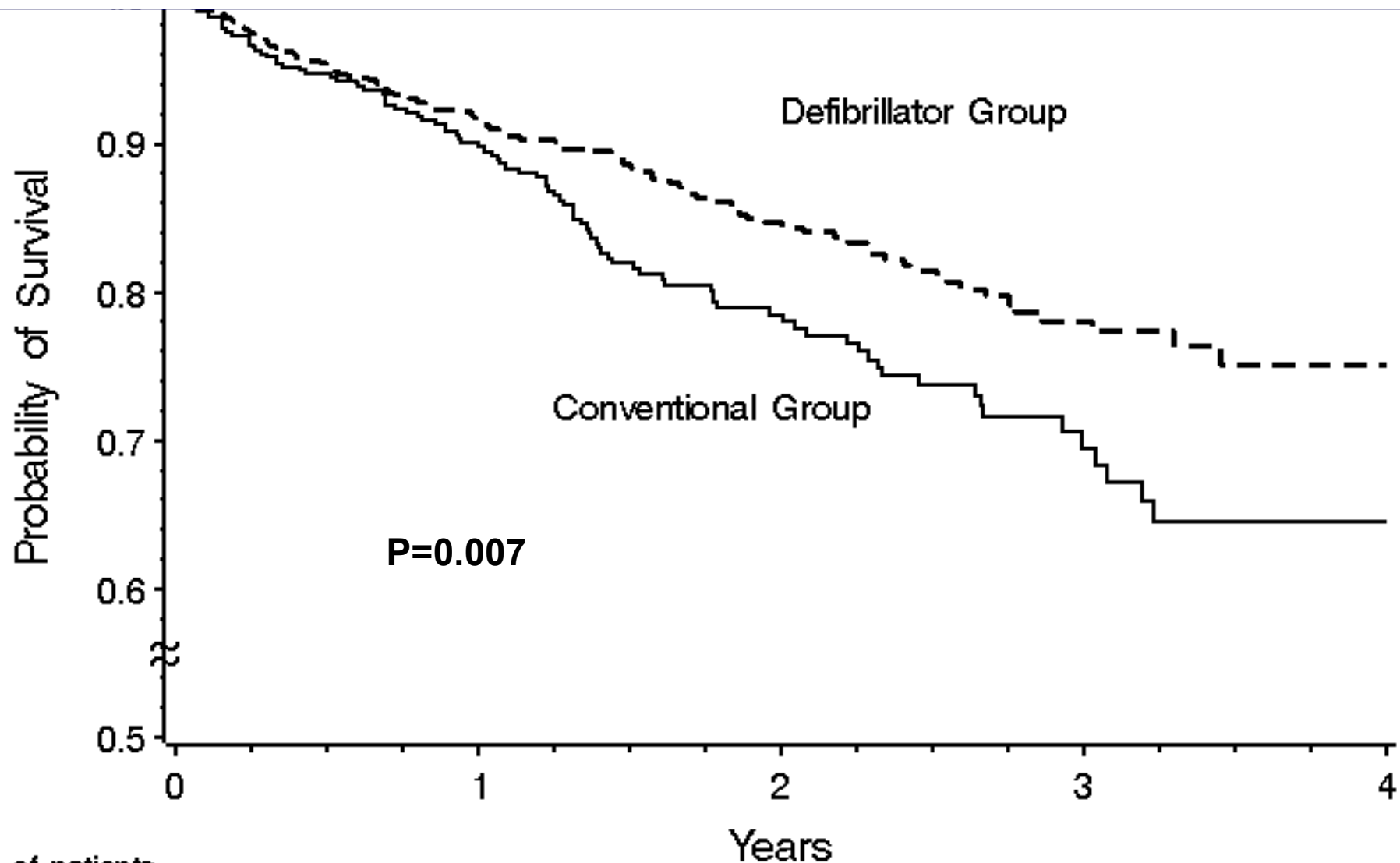
# MADIT II

## Exclusions

**NYHA functional class IV at enrollment**

**MI <1 month**

**Coronary artery bypass graft (CABG) <3 months**



No. of patients	Years	0	1	2	3	4
Defibrillator: 742		503 (0.91)	274 (0.84)	110 (0.78)	9	
Conventional: 490		329 (0.90)	170 (0.78)	65 (0.69)	3	

## MADIT-II

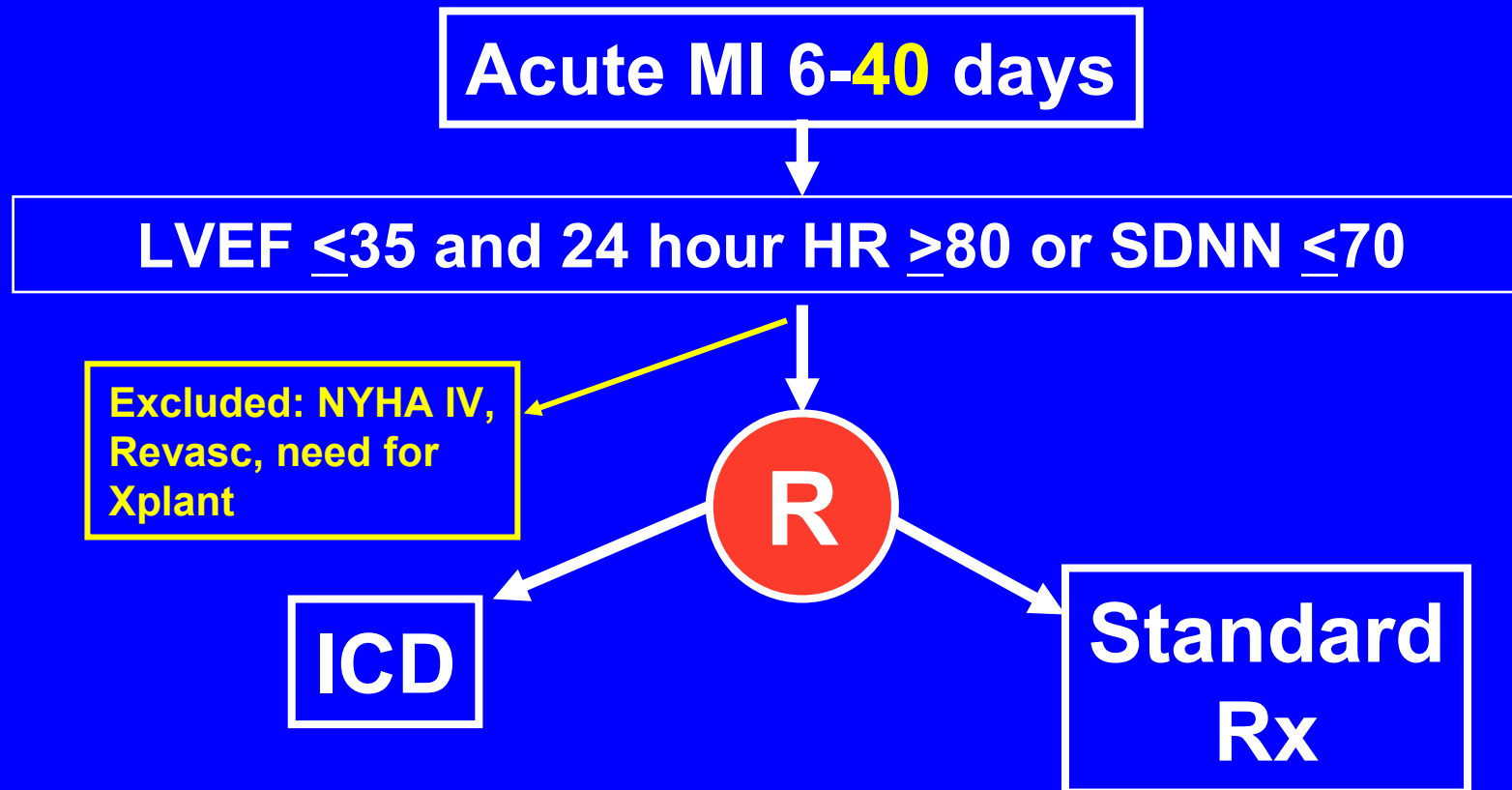
post-MI > 30 days, EF < 30%, no CABG < 3 months, no NYHA class IV

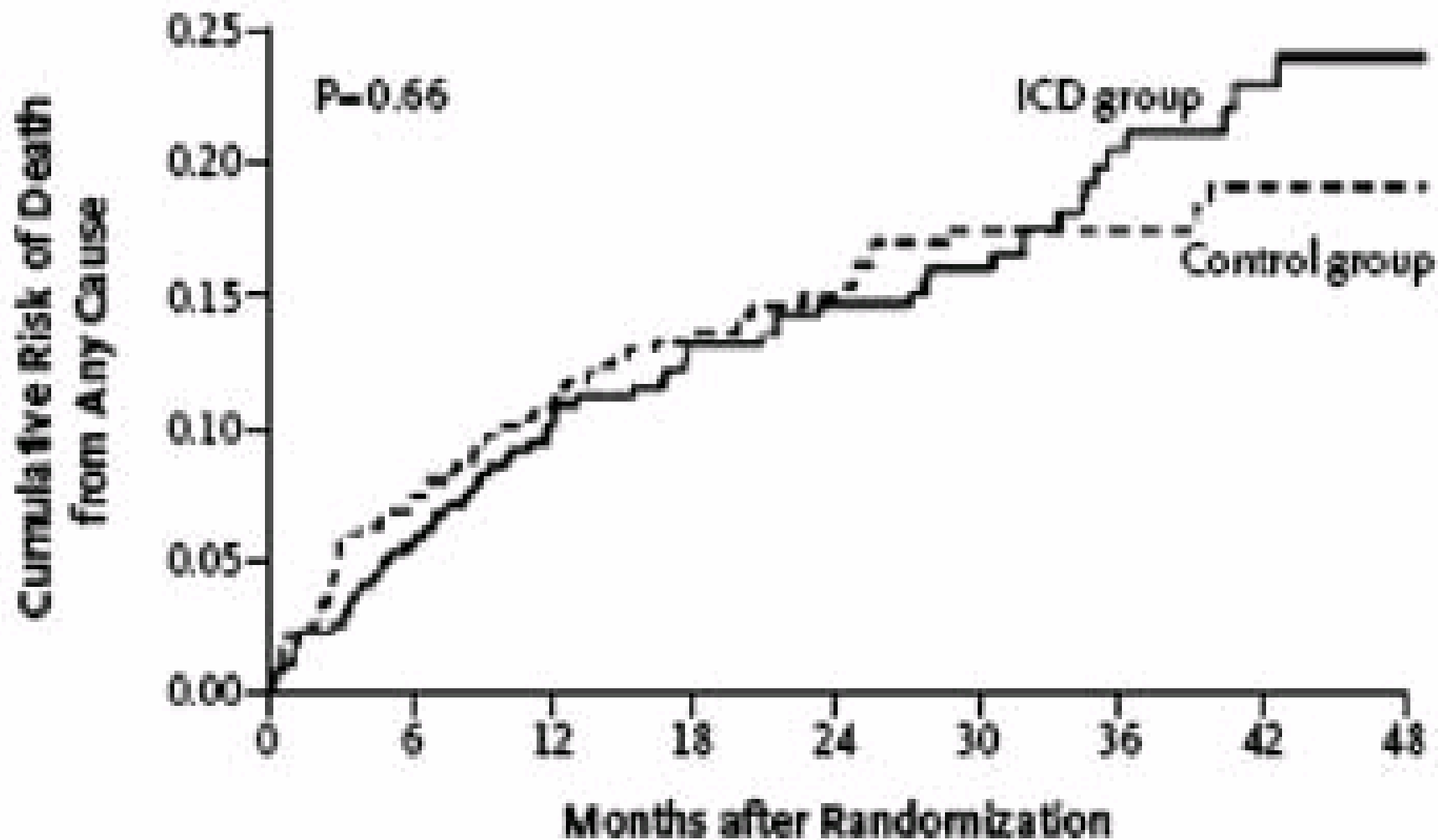
# **CMS (Center for Medicaid and Medicare Services) ICD Coverage Criteria after MADIT II and AVID**

- Documented CA due to VF not due to a reversible cause. (1991)
- Doc. Sustained VT not associated with acute MI or reversible cause(1999)
- Familial or inherited conditions with high risk of life-threatening VT “such as LQTS or HCM.” (1999)
- CAD + prior MI (>4wks) +EF  $\leq$  35% + inducible sustained VT. 1996, 2003 (MADIT-1)
- Prior MI + EF  $\leq$  30%, + QRS >120ms. 2003 (MADIT II).

# DINAMIT

## Defibrillator in Acute MI Trial (St J)





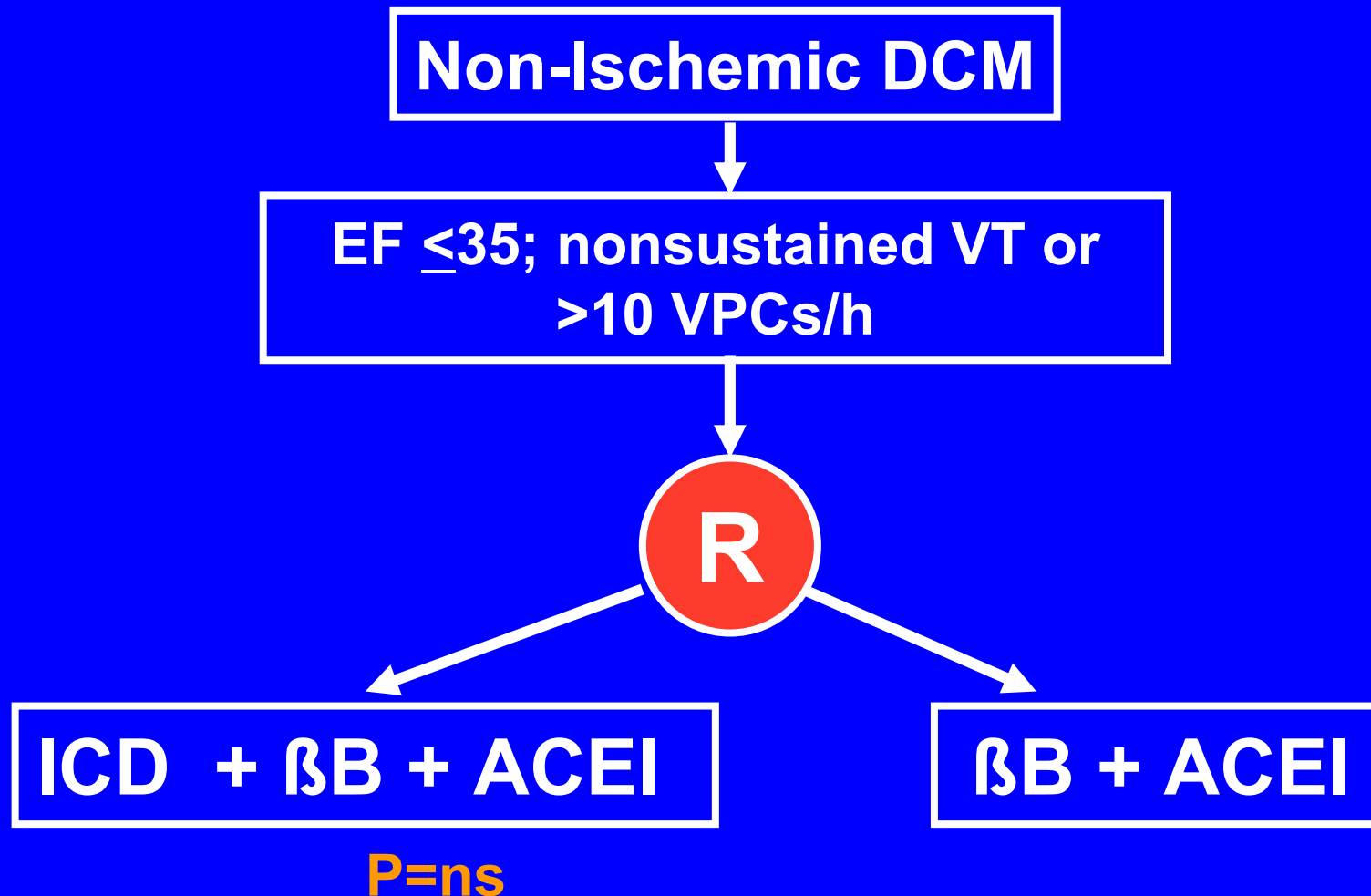
No. at Risk

ICD group	315	299	258	211	172	123	82	25
Control group	318	305	272	217	172	124	79	31

**DINAMIT**

# DEFINITE

## Defibrillators in Non-Ischemic Cardiomyopathy Treatment (St J)

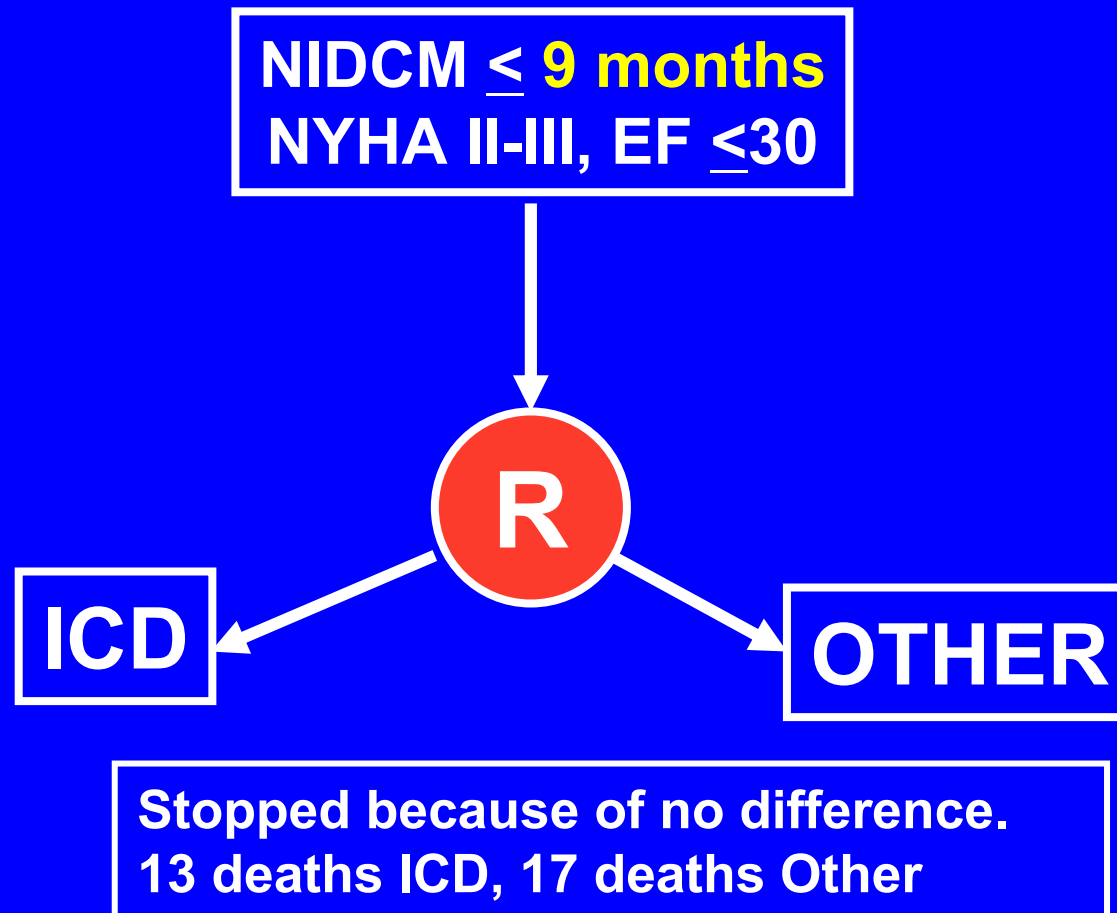




# Cardiomyopathy Trial (CAT)

## 1° Prevention Trial of Nonischemic Dilated Cardiomyopathy N = 104

Circ 2002;105:1453-1458



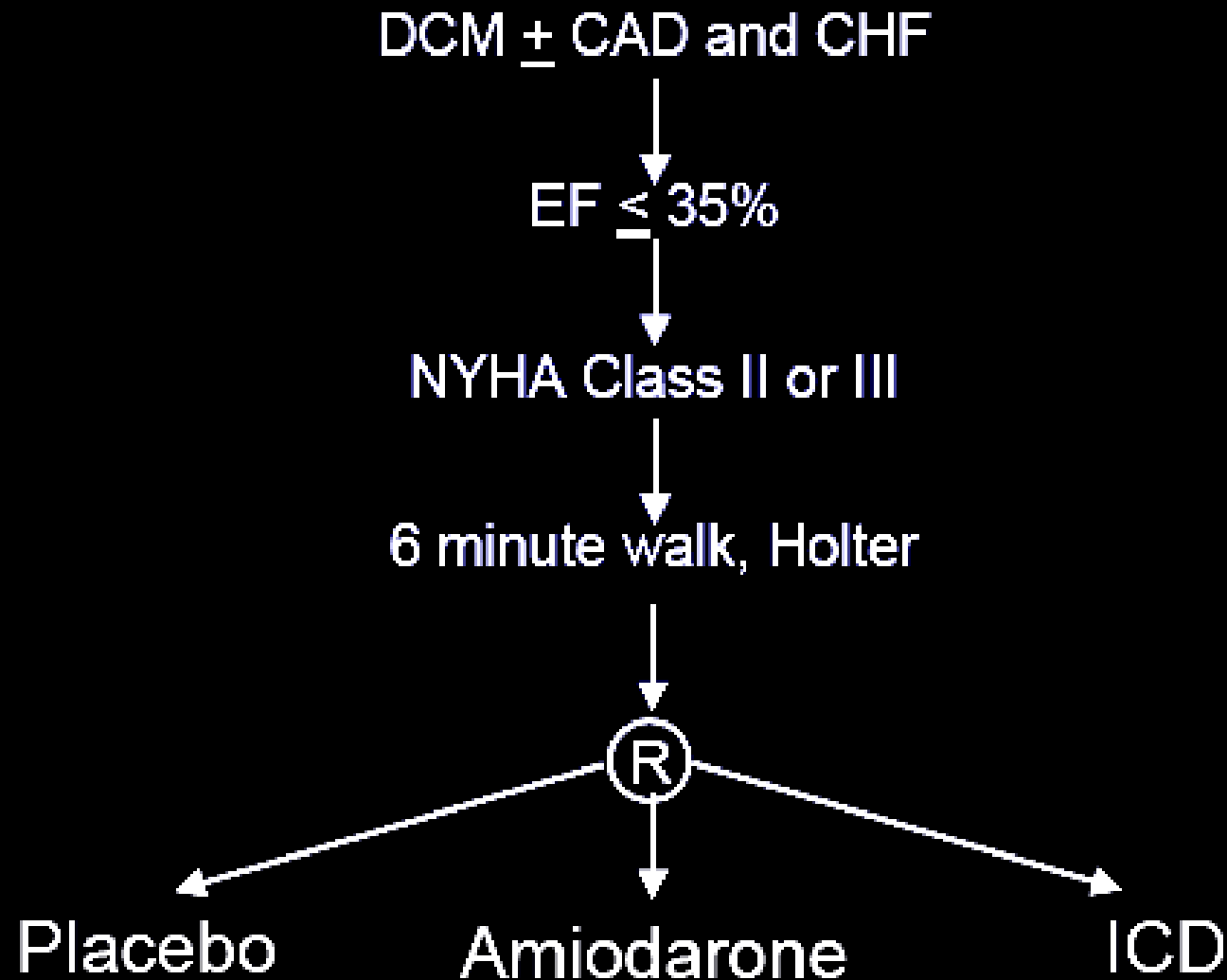
# **Sudden Cardiac Death-Heart Failure Trial (SCD-HeFT)**

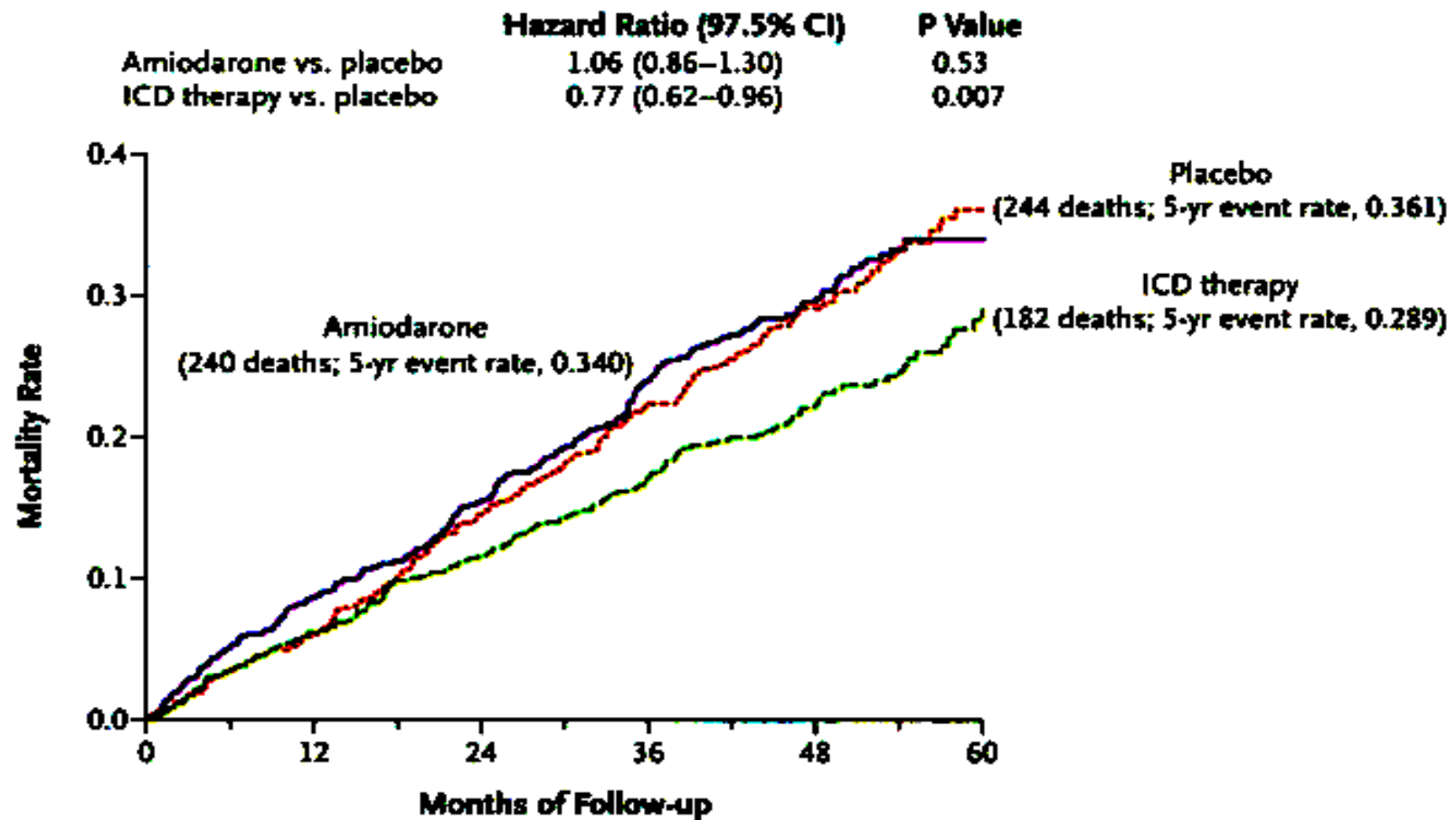
**Primary prevention trial (NIH-supported)**

**Coronary and noncoronary patients**

**Congestive heart failure**

# Enrollment Scheme



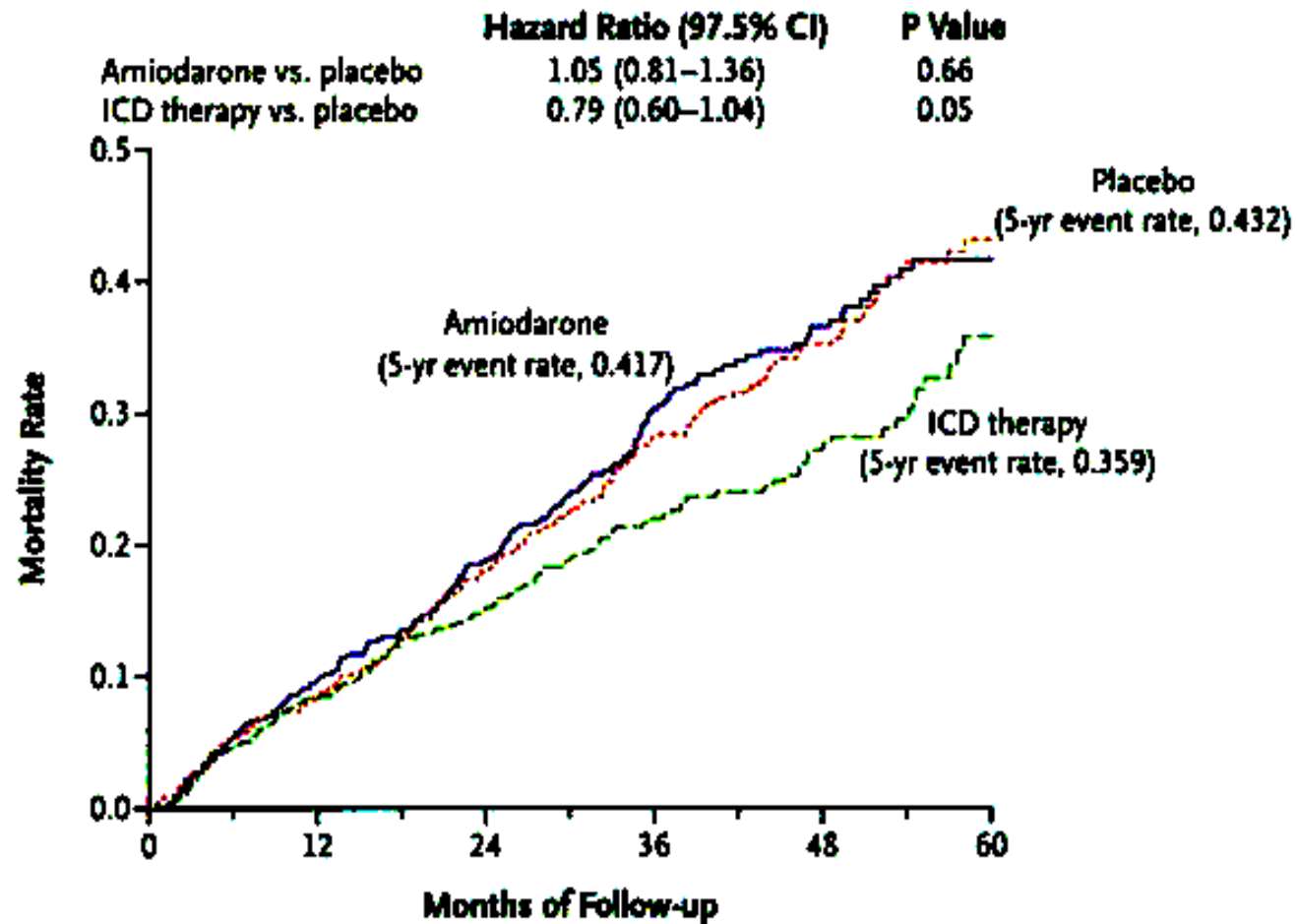


No. at Risk						
Amiodarone	845	772	715	484	280	97
Placebo	847	797	724	505	304	89
ICD therapy	829	778	733	501	304	103

**Figure 1.** Kaplan–Meier Estimates of Death from Any Cause.  
 CI denotes confidence interval.

**SCD-HeFT primary results: placebo, amiodarone and ICD**

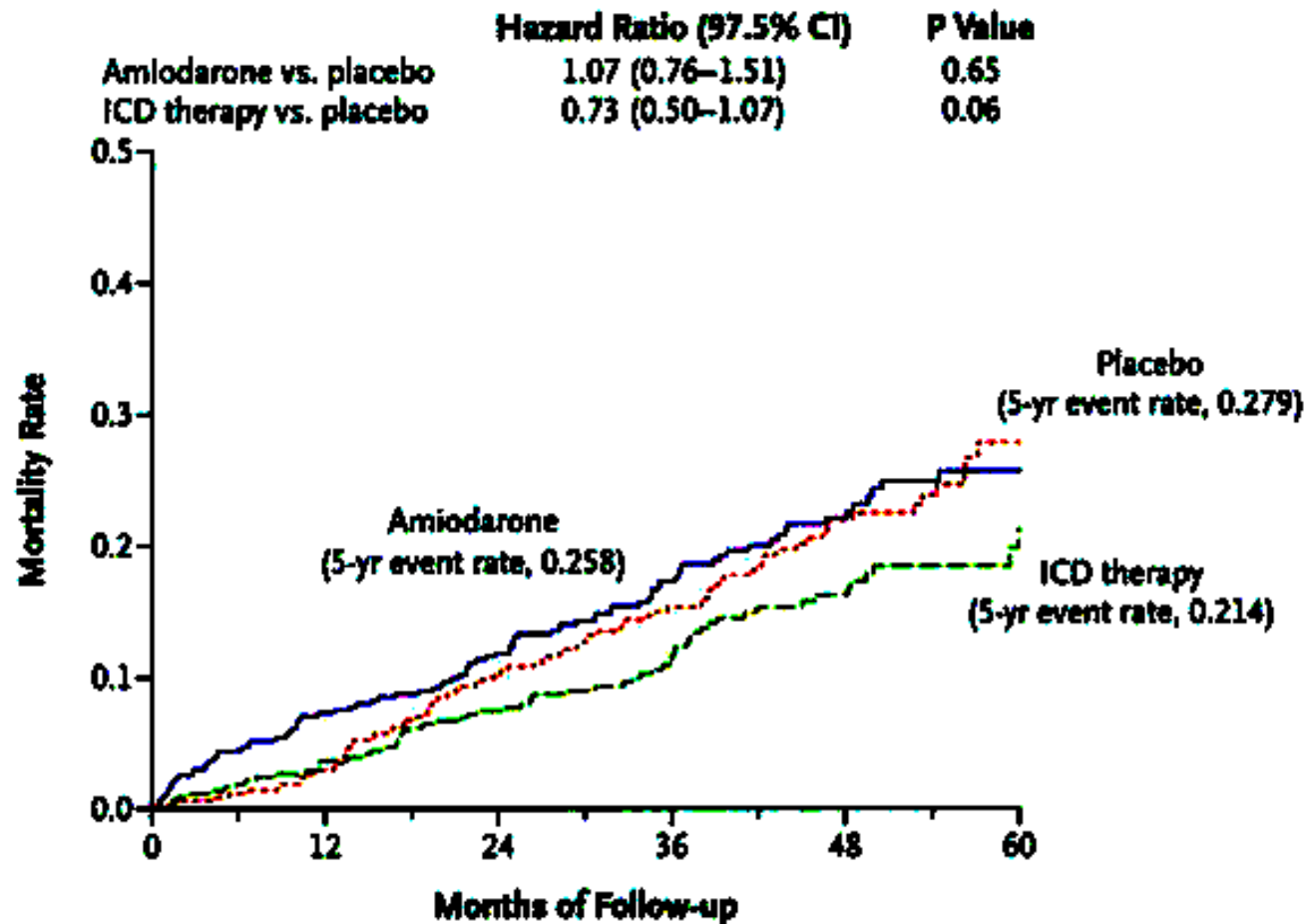
## A Ischemic CHF



No. at Risk						
Amiodarone	426	384	346	227	130	46
Placebo	453	415	370	244	152	48
ICD therapy	431	395	365	244	144	48

**SCD-HeFT: Ischemic patients  
(predefined subgroup and hypothesis)**

## B Nonischemic CHF



No. at Risk						
Amiodarone	419	388	369	257	150	51
Placebo	394	382	354	261	152	41
ICD therapy	398	383	368	257	160	55

**SCD-HeFT: Nonischemic patients  
(predefined subgroup and hypothesis)**

# **CMS ICD Coverage after SCD-HeFT**

## **1/27/05**

- Ischemic dilated cardiomyopathy with prior MI >40 days\*, CHF (class II-III), EF<35%**
  
- Nonischemic dilated cardiomyopathy >9 months\*\*, CHF (class II-III), EF<35%**

**\* DINAMIT**

**\*\* CAT**

# **CMS ICD Coverage after SCD-HeFT**

**1/27/05**

**CHF (NYHA IV) if the patient meets CRT criteria**



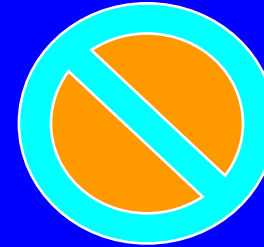
# **CMS ICD Coverage after SCD-HeFT**

## **1/27/05**

- **Additional Requirements.**
  - **Patient must be able to sign consent.**
  - **Enrollment in a CMS-approved registry.**
  - **a single lead device unless justified.**

# CMS ICD Coverage after SCD-HeFT

## 1/27/05



- ***Exclusions:***
  - Shock
  - Symptomatic hypotension when in a stable rhythm.
  - CABG or PTCA within 3 months\*
  - Acute MI within 40 days\*\*
  - Symptoms indicating need for revascularization.
  - Irreversible brain damage, OMS.
  - Any disease limiting life expectancy to <1y.

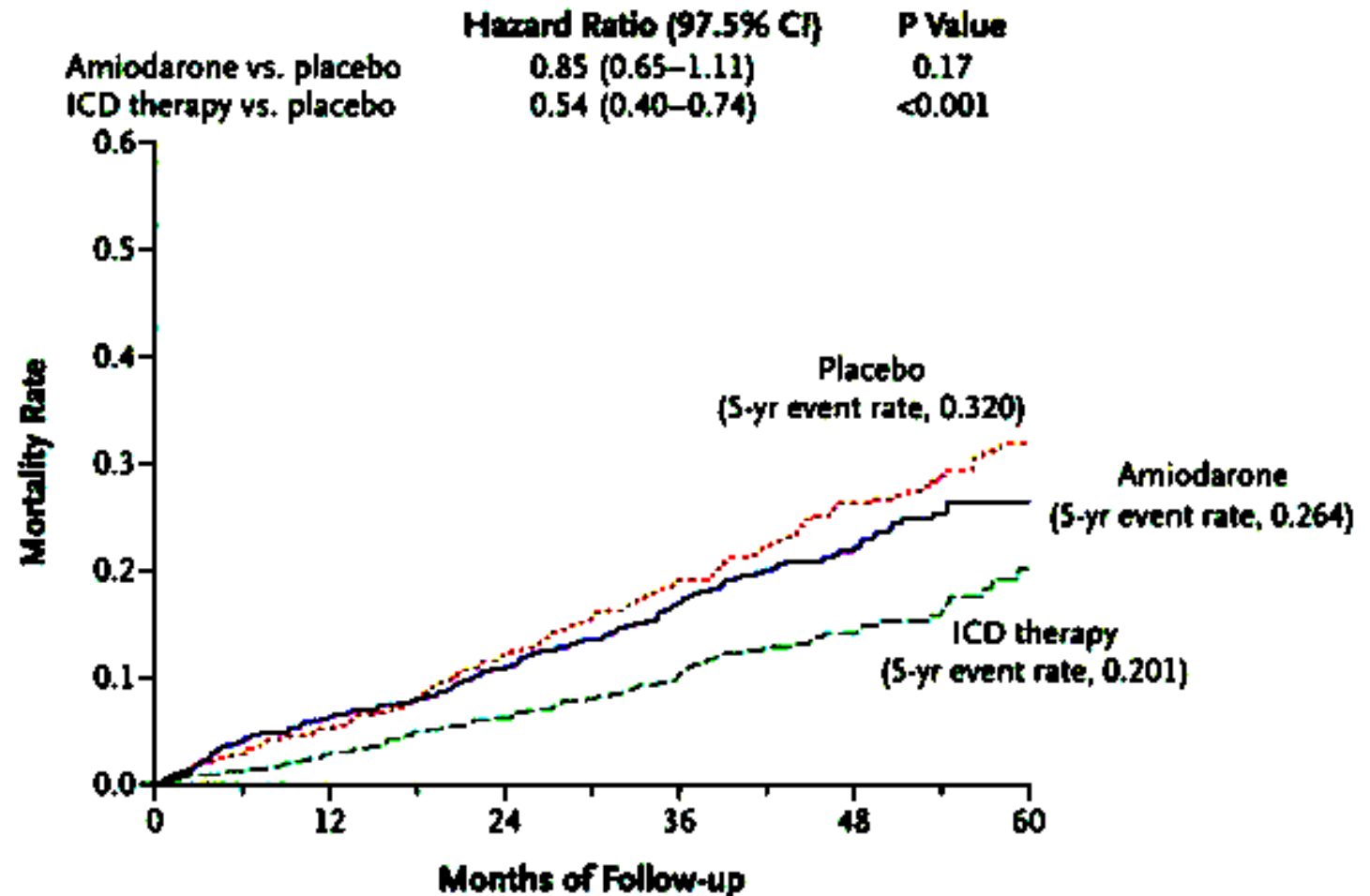
\*MADIT II

\*\*DINAMIT

## **CMS ICD Coverage previously approved before Jan 2005**

- Documented CA due to VF not due to a reversible cause. (1991)
- Doc. Sustained VT not associated with acute MI or reversible (1999)
- Familial or inherited conditions with high risk of life-threatening VT “such as LQTS or HCM.” 1999
- CAD + prior MI (>4wks) +EF  $\leq$  35% + inducible VT-S. 1996, 2003 (MADIT-1)
- Doc. Prior MI + EF  $\leq$  30%, (+ QRS >120ms). 2003 (MADIT II).

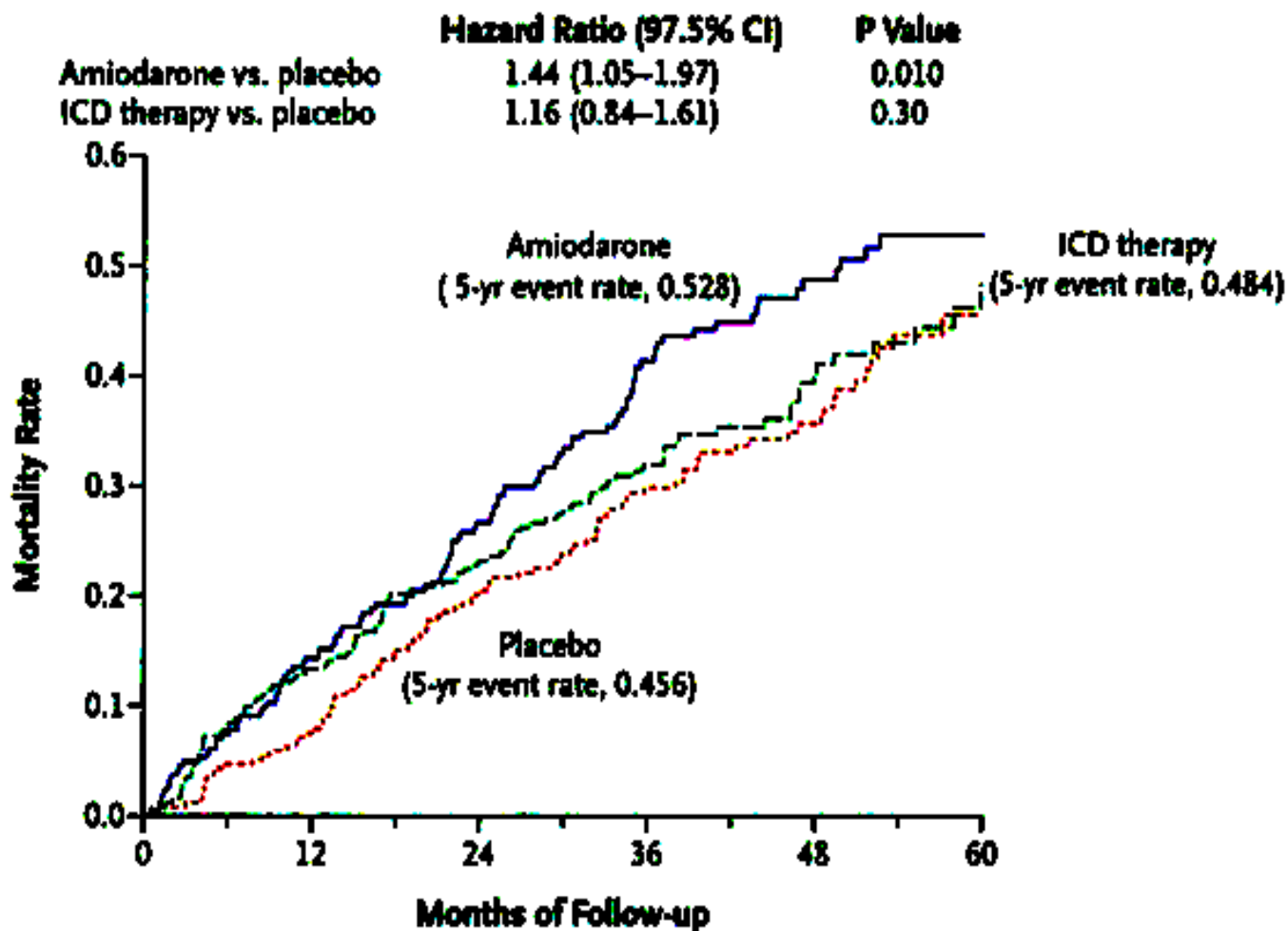
## A NYHA Class II



No. at Risk						
Amiodarone	601	563	536	378	222	76
Placebo	594	563	522	367	218	72
ICD therapy	566	550	531	371	236	80

SCD-HeFT: NYHA class II

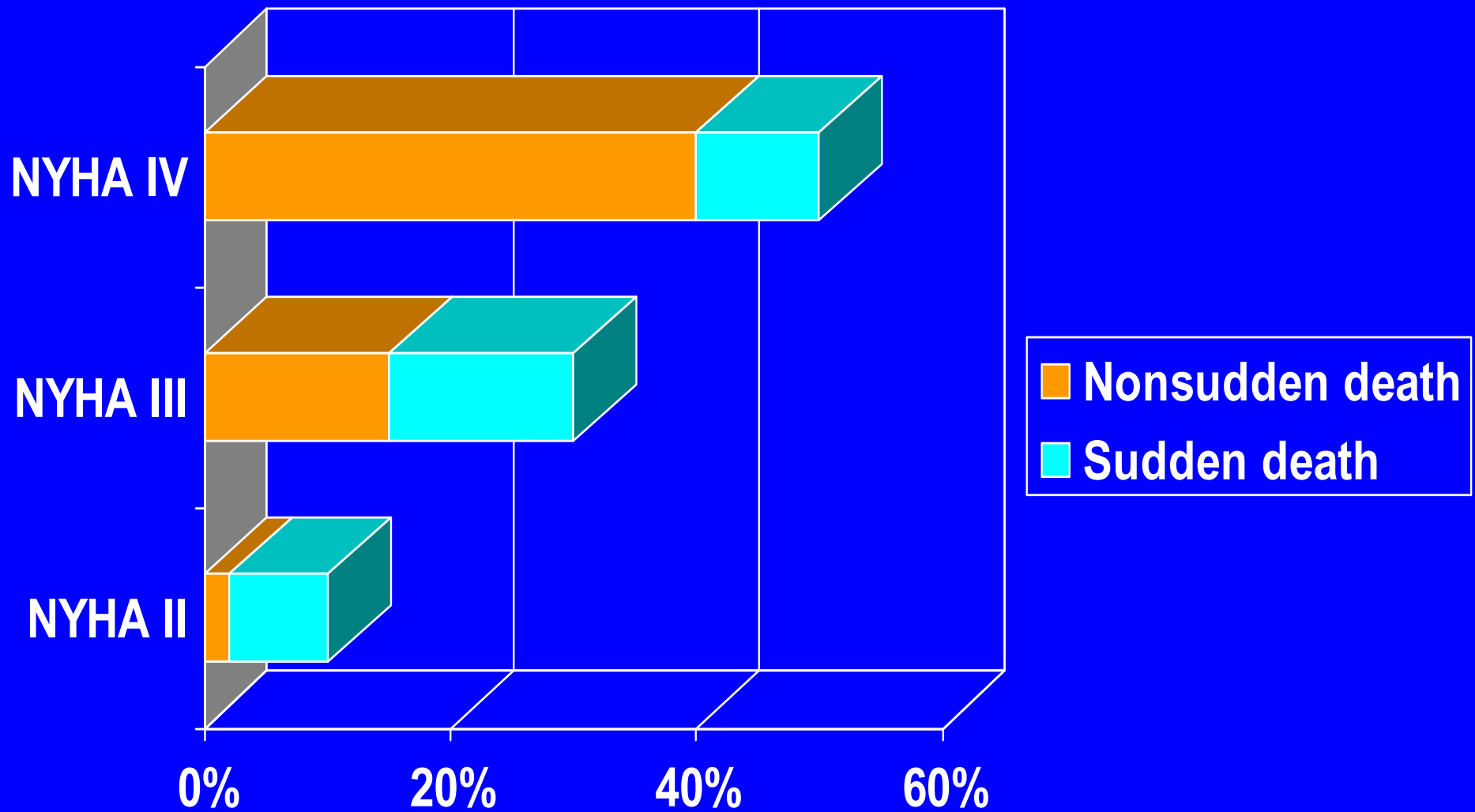
**B NYHA Class III**



No. at Risk						
Amiodarone	244	209	179	106	58	21
Placebo	253	234	202	138	86	17
ICD therapy	263	228	202	130	68	23

SCD-HeFT: NYHA class III

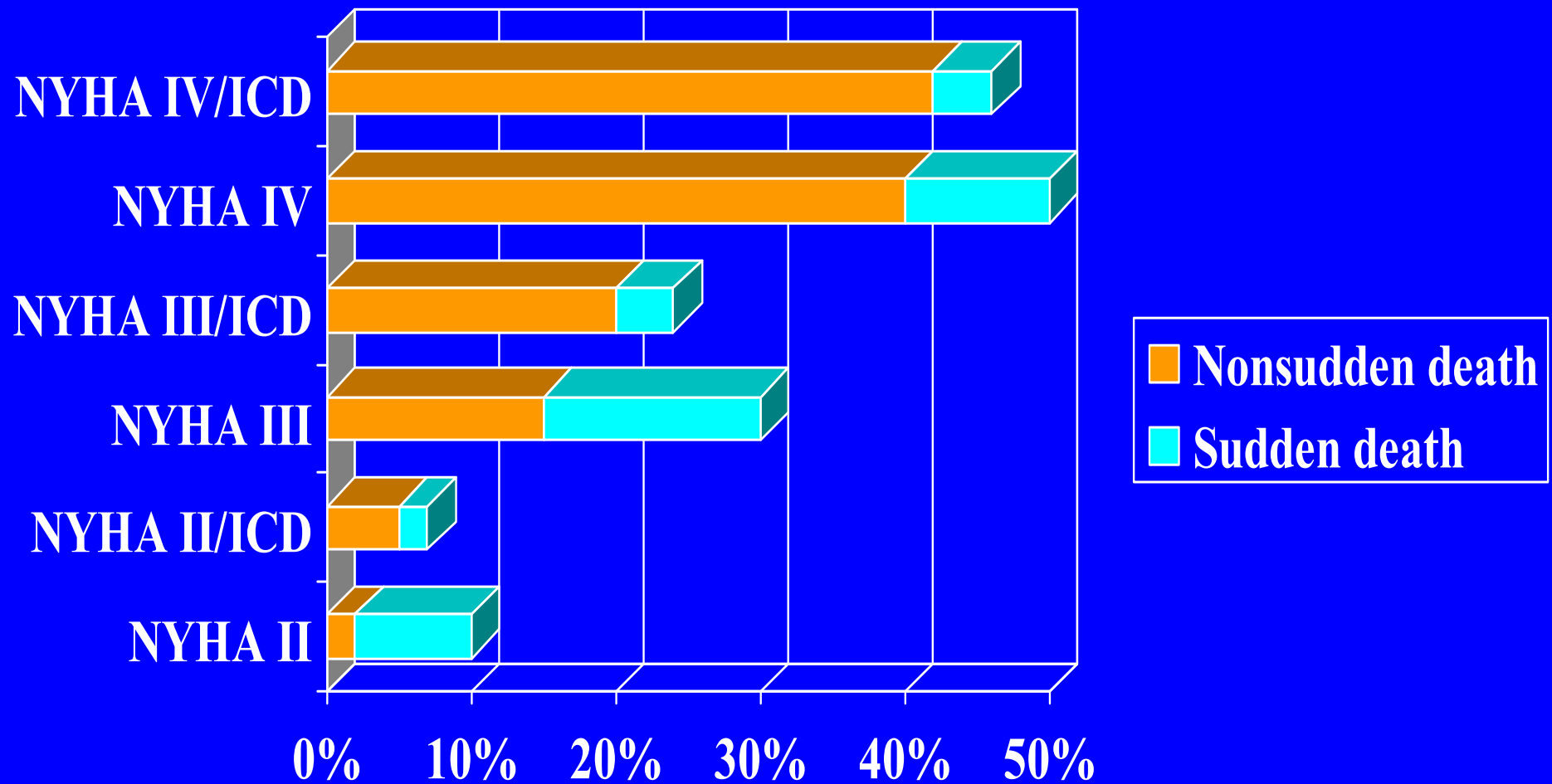
# Mortality/year and Mode of death in CHF patients



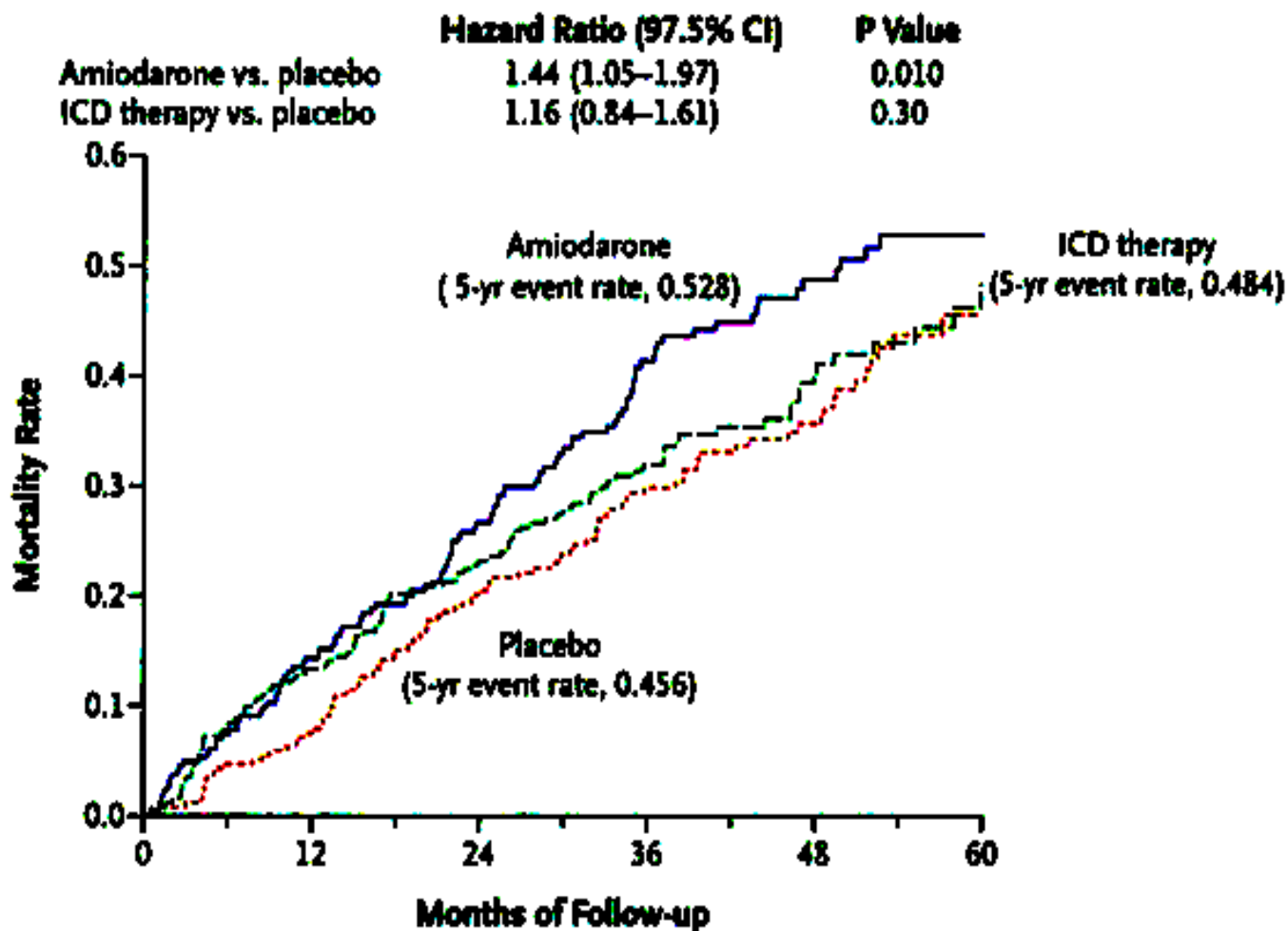
# Mode of death in CHF patients

## “Conversion of mode of death” by ICD

Kim SG. Am Heart J



**B NYHA Class III**



No. at Risk						
Amiodarone	244	209	179	106	58	21
Placebo	253	234	202	138	86	17
ICD therapy	263	228	202	130	68	23

SCD-HeFT: NYHA class III

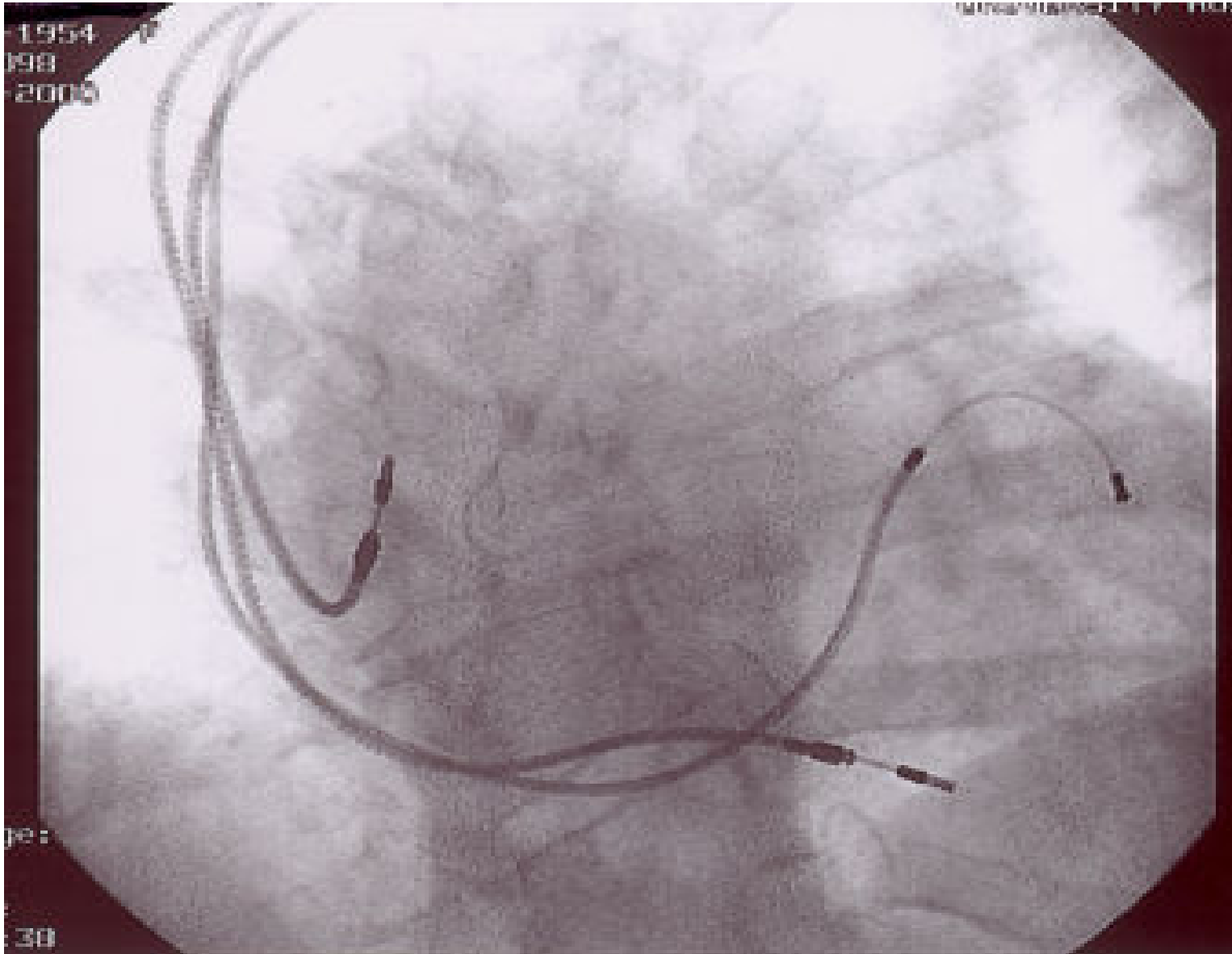


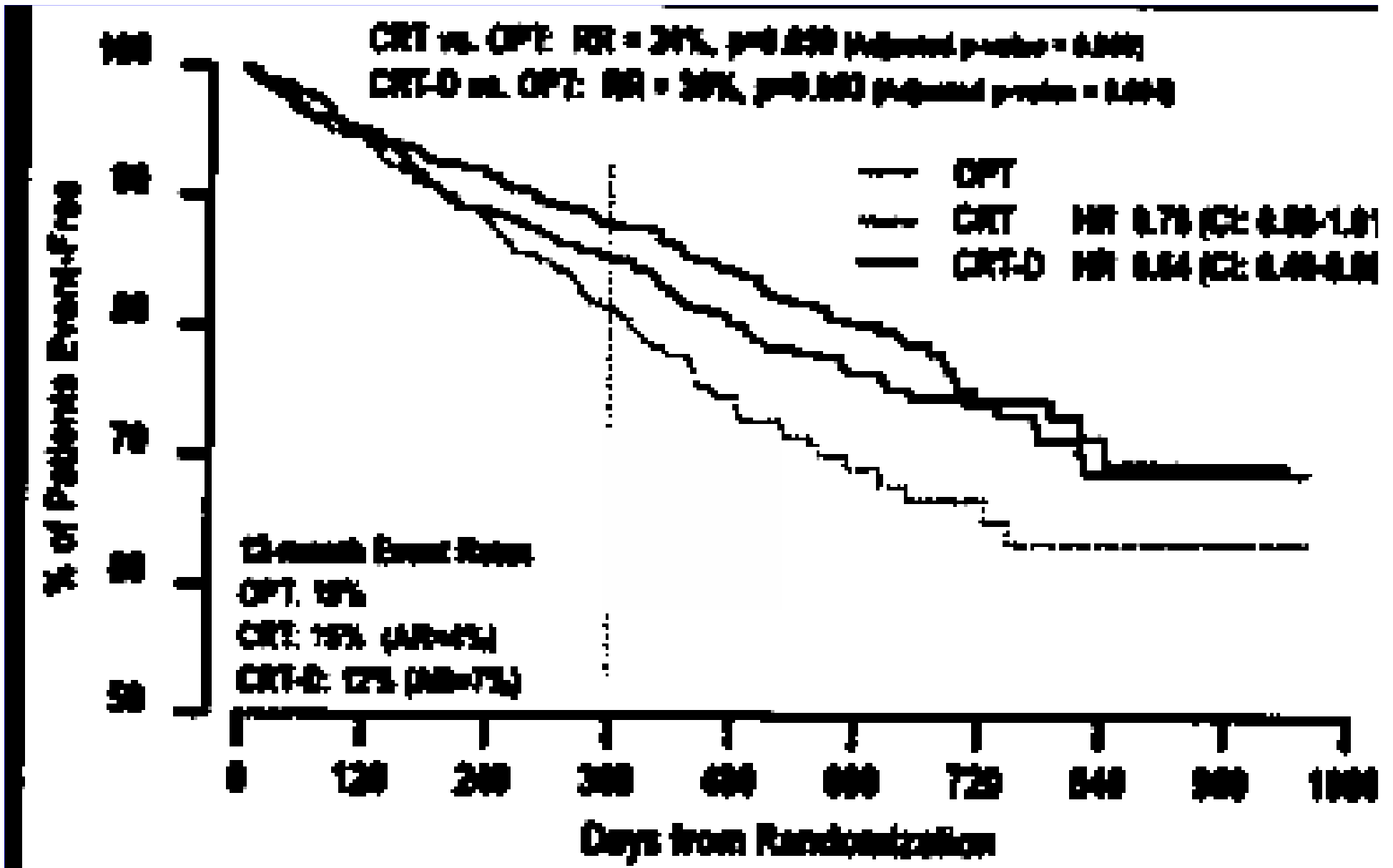
# **Primary prevention of sudden death**

## **Conclusions**

- Preventing sudden death (by ICD) improves survival of patients with severe heart disease.
- ICDs or antiarrhythmic drug therapy does not prevent progression of heart disease.
- Survival could be further improved by preventing progression of heart disease.
- Beta blockers, ACE inhibitors, statins, revascularization, etc.
- Cardiac resynchronization therapy (CRT)

# Cardiac Resynchronization Therapy (CRT)

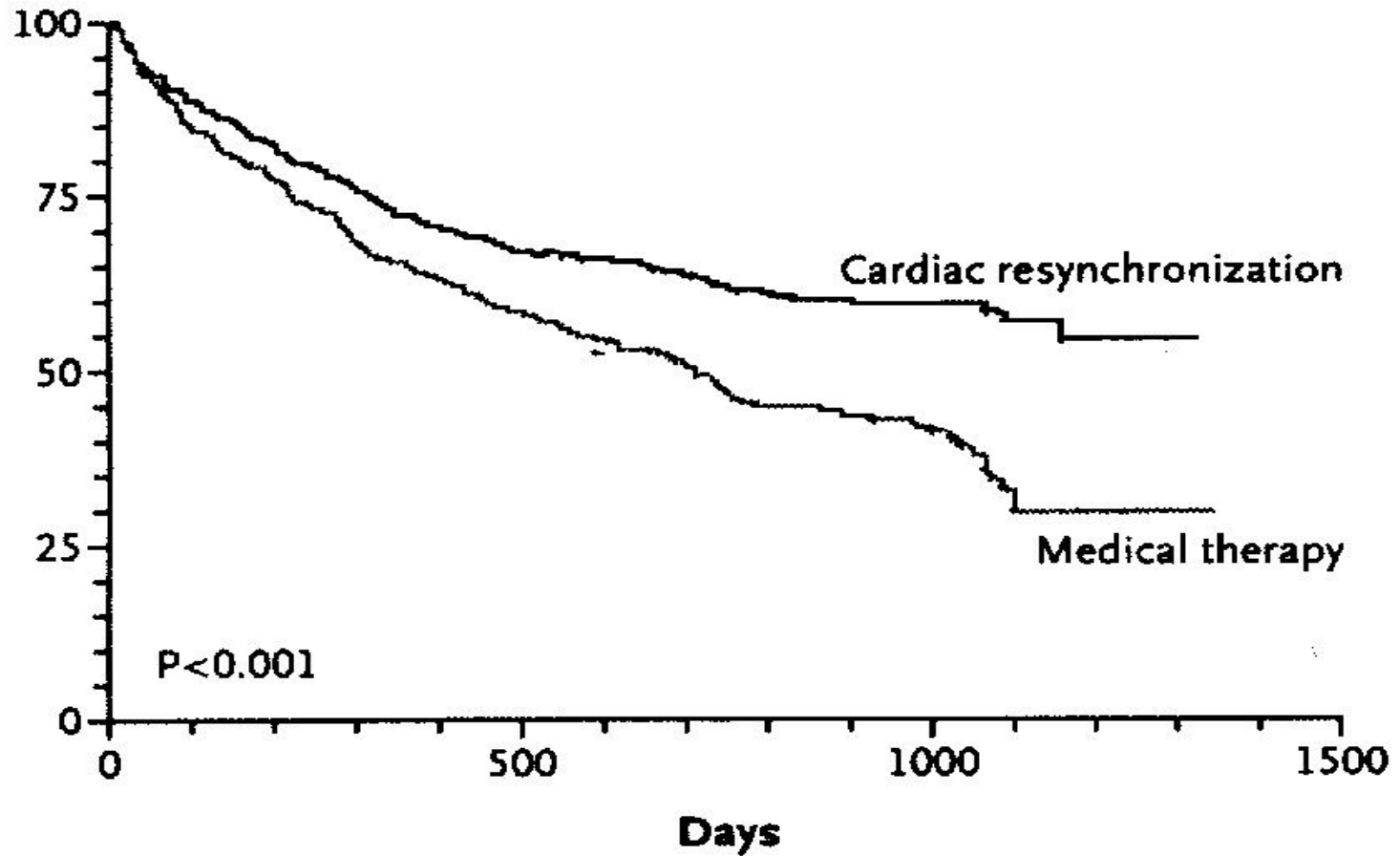




**COMPANION NYHA III-IV, EF<35%, QRS>120ms**  
**All-cause mortality**

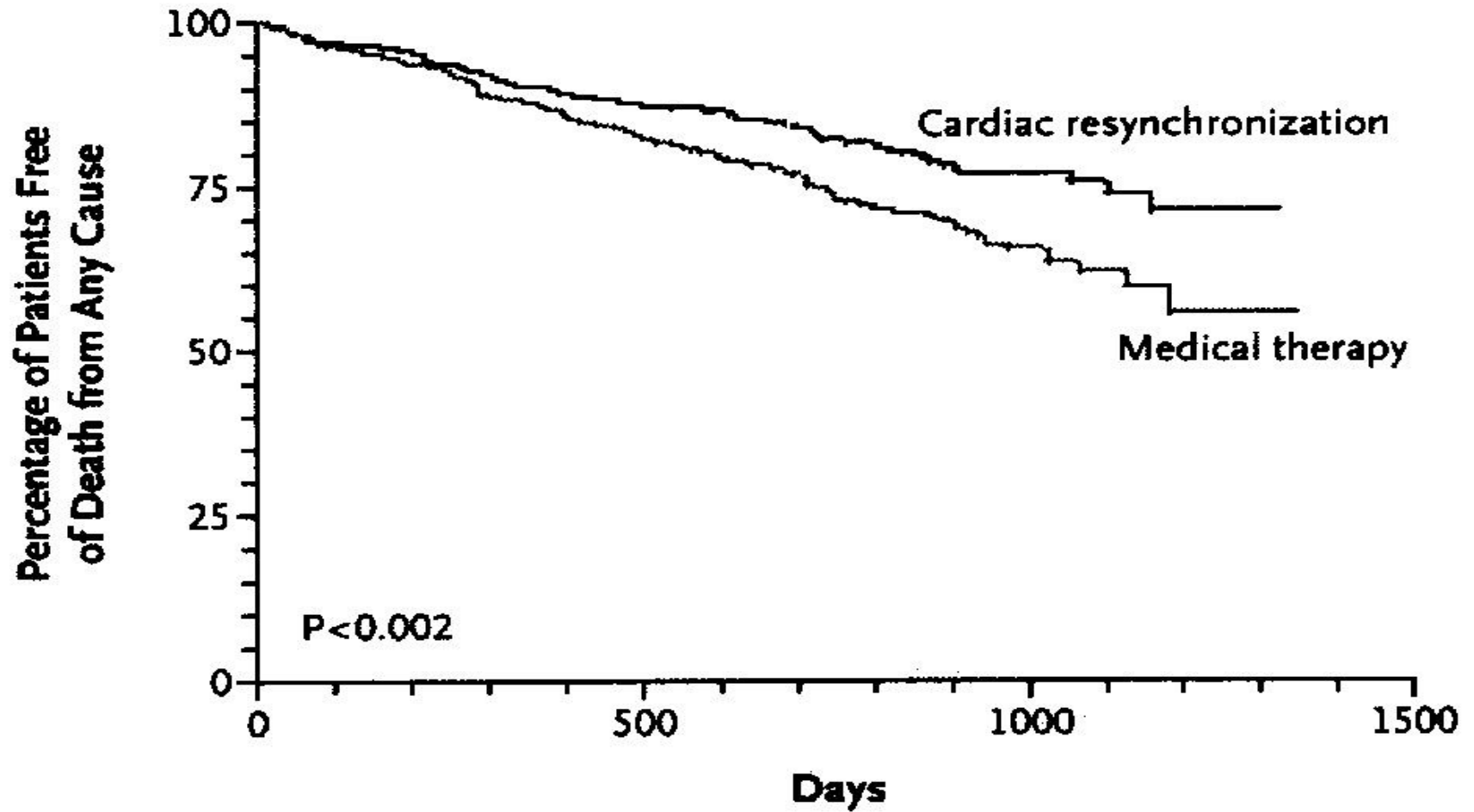
**A**

Percentage of Patients Free of Death  
from Any Cause or Unplanned  
Hospitalization for a Major  
Cardiovascular Event

**No. at Risk**

Cardiac resyn- chronization	409	323	273	166	68	7
Medical therapy	404	292	232	118	48	3

**CARE-HF** (Cardiac Resynchronization-Heart Failure)  
Primary endpoint (death or CV hospitalization)



**No. at Risk**

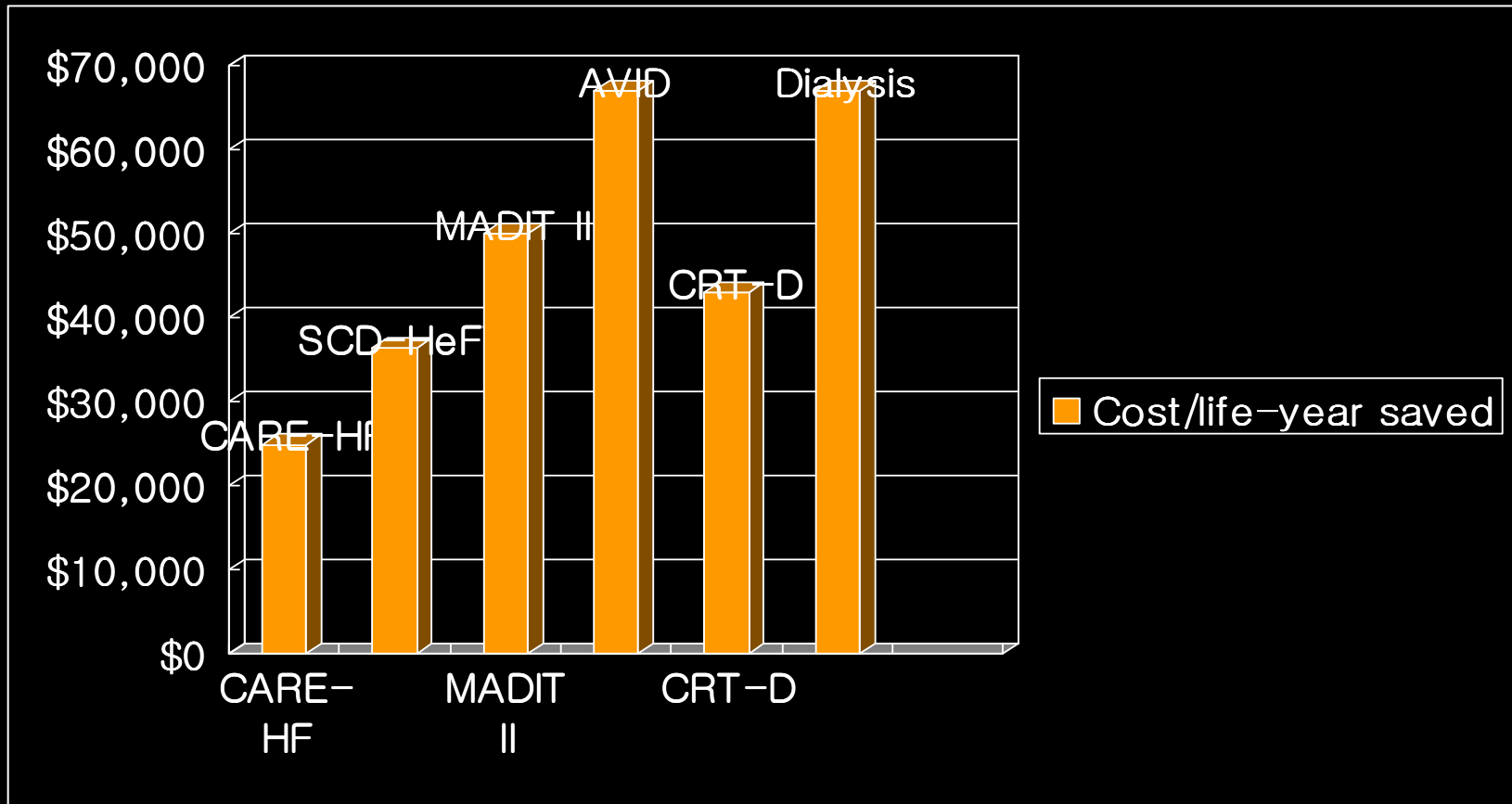
Cardiac resyn- chronization	409	376	351	213	89	8
Medical therapy	404	365	321	192	71	5

**CARE-HF study**  
All-cause mortality

# Questions on the ICD Therapy

- Is ICD therapy cost effective?
- Can a society afford such an expensive therapy?

# Cost-effectiveness of ICD and CRT Therapy



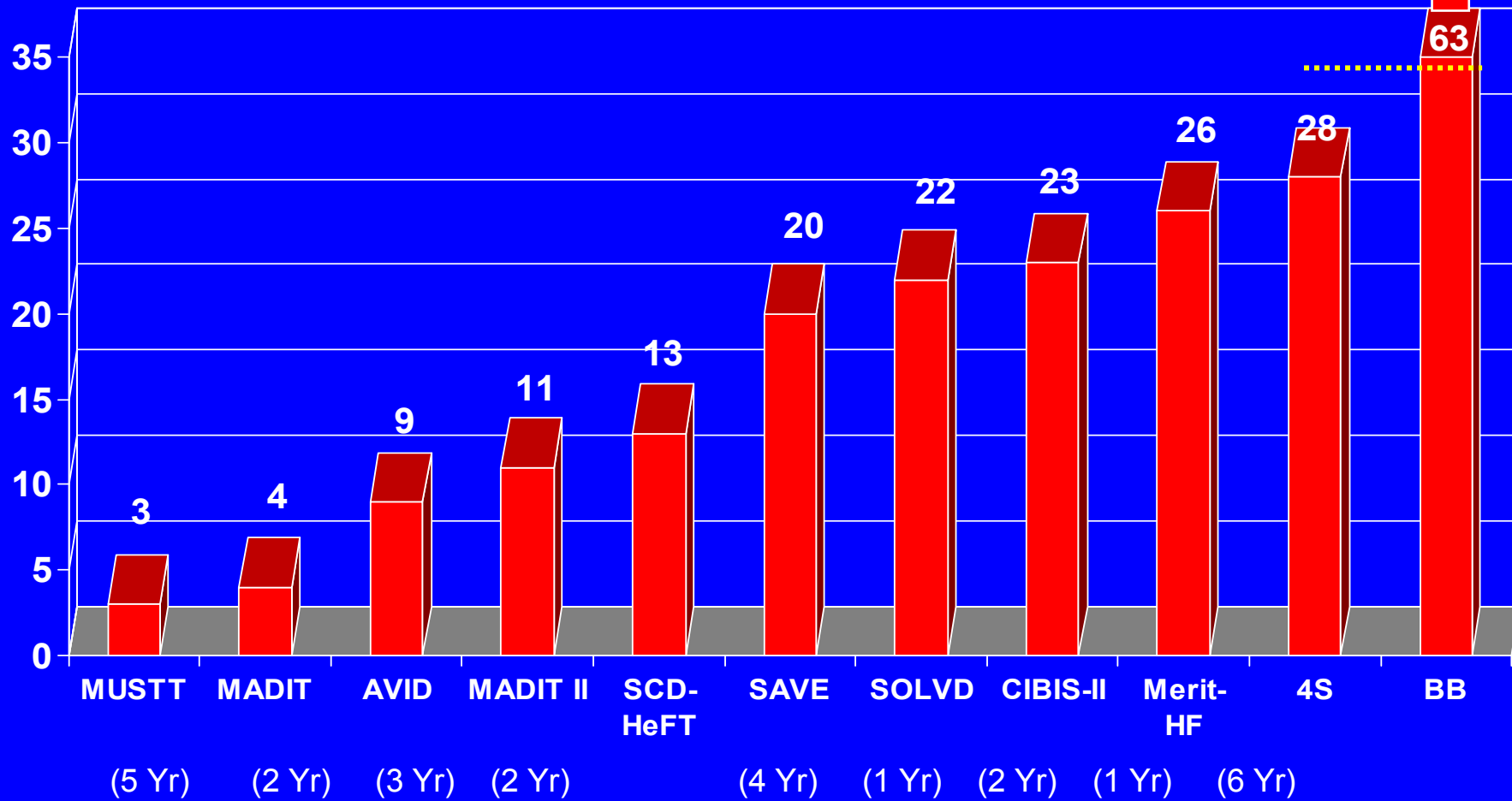
# Societal Spending on Other Life-Saving Interventions<sup>1</sup>

Intervention	Cost/Life-Year Saved in 1993
Flashing lights at railroad crossings	\$42,000
Flammability standard for upholstered furniture	\$68,000
Airbags (vs. manual lap belts) in cars	\$120,000
Annual mammography for women age 40-49	\$190,000
Smoke detectors in homes	\$210,000
Front disk (vs. drum) brakes in cars	\$240,000
Strengthen buildings in earthquake-prone areas	\$18,000,000
Ground fault circuit interrupters	\$1,200,000

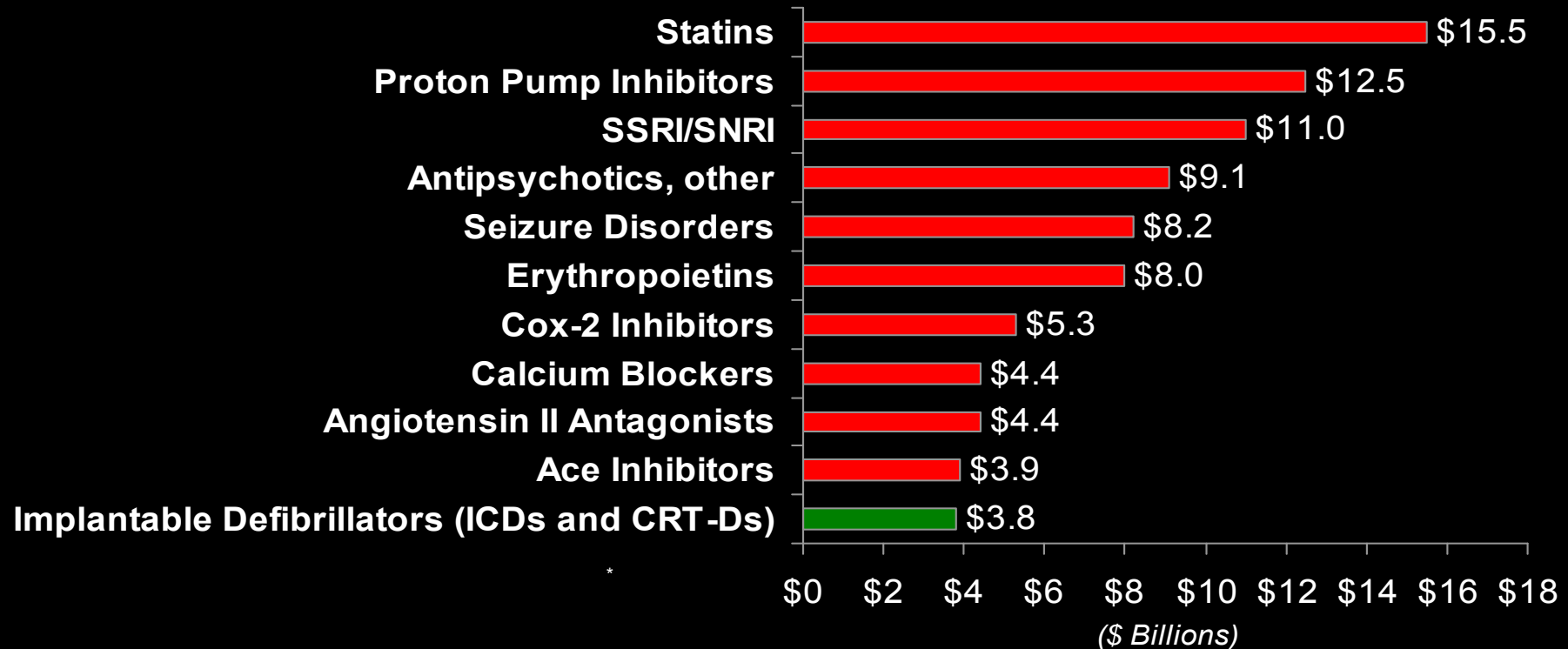
<sup>1</sup>Tengs TO, et al. Five-Hundred Life-Saving Interventions and Their Cost-Effectiveness. *Risk Analysis*, Vol. 15, No. 3, 1995.



# Number Needed to Treat To Save 1 Life



# Total United States Sales, 2004E



\* Implantable defibrillator sales estimates include initial implants and replacements

<sup>1</sup> IMS Health, IMS National Sales Perspectives™, 2005. Leading 20 Therapeutic Classes by U.S. Sales, 2004. Accessed March 7, 2005.

<sup>2</sup> JP Morgan Annual Market Model for Implantable Cardioverter Defibrillators. The MedTech Monitor. JP Morgan; New York: January 6, 2004.

# **CMS Registry for ICD Therapy**

- **Data collected for all patients undergoing ICD implant for primary prophylaxis.**
- **Implanting doctor, patient demographics, hospital admission, history and risk factors, diagnostic studies, ICD procedure, adverse events, discharge data, and discharge medications are reported on a 3 pages data form.**



Heart Rhythm Society

ACC-NCDR® ICD Registry™  
v1.08 Data Collection Form  
**IMPLANT**

**A. PARTICIPANT ADMINISTRATION:**

Participant ID<sup>1000</sup>/Name<sup>1010</sup>: \_\_\_\_\_ Medicare Provider #<sup>1015</sup>: \_\_\_\_\_ Participant NP1<sup>1015</sup>: \_\_\_\_\_

**B. DEMOGRAPHICS:**

Last Name<sup>2000</sup>: \_\_\_\_\_ First Name<sup>2010</sup>: \_\_\_\_\_ Middle Name<sup>2020</sup>: \_\_\_\_\_  
SSN<sup>2030</sup>: 096-24-8058 Unique Patient Id<sup>2040</sup>: 02975726 (automatic) Other ID<sup>2045</sup>: \_\_\_\_\_  
Date of Birth<sup>2050</sup>: 08/07/1992 Gender<sup>2060</sup>: Male Female  Spouse's Name<sup>2065</sup>: \_\_\_\_\_  
Race<sup>2070</sup>: White  Black  African American  Asian  American Indian/Alaska Native  Native Hawaiian  Other  \_\_\_\_\_  
Hispanic Ethnicity<sup>2075</sup>: No Yes   
Auxiliary 1<sup>2080</sup>: \_\_\_\_\_ Auxiliary 2<sup>2085</sup>: \_\_\_\_\_

**C. ADMISSION:**

Admission Date<sup>2000</sup>: 9/20/2007 Date of Implant<sup>2010</sup>: 10/04/2007  
Insurance Payer-Primary<sup>2020</sup>: Government Commercial: HMO Medicare: Medicare Medicaid: Medicaid Tricare: VA Health Plan Federal Employee Insurance  
→ If Government, Type-Primary: Medicare Medicaid: Medicaid Tricare: VA Health Plan Federal Employee Insurance  
Insurance Payer-Secondary<sup>2025</sup>: Government Commercial: HMO Non-U.S. Insurance: \_\_\_\_\_ Non-Mail Pay: \_\_\_\_\_  
→ If Government, Type-Secondary: Medicare Medicaid: Medicaid Tricare: VA Health Plan Federal Employee Insurance  
Reason for Admission<sup>2030</sup>: Admitted for this procedure Cardiac-CHF: Acute CHF Non-Cardiac: \_\_\_\_\_  
Auxiliary 3<sup>2035</sup>: \_\_\_\_\_ Auxiliary 4<sup>2040</sup>: \_\_\_\_\_

**D. HISTORY AND RISK FACTORS:**

Syncope<sup>2050</sup>: No Yes  Family Hx Sudden Death<sup>2055</sup>: No Yes   
CHF<sup>2060</sup>: No Yes  → If Yes, CHF Duration<sup>2065</sup>: Within the past 3 months 3 to 6 months: \_\_\_\_\_ Greater than 6 months: \_\_\_\_\_  
→ If Yes, Prior CHF Hospitalization<sup>2070</sup>: Not Hospitalized Yes-Within 6 months: \_\_\_\_\_ Yes-Greater than 6 months: \_\_\_\_\_  
NYHA Functional Class (Current Status)<sup>2075</sup>: Class I Class II: \_\_\_\_\_ Class III: \_\_\_\_\_ Class IV: \_\_\_\_\_  
Cardiac Arrest<sup>2080</sup>: Arrest Brady Arrest: \_\_\_\_\_ Tachy Arrest: \_\_\_\_\_  
→ If Brady Arrest, Brady Arrest Reason<sup>2085</sup>: (Check all that apply)  
 Acute MI  Severe Electrolyte Disturbance  Drug Induced Arrhythmia  Sinus Node Dysfunction/VV Block  
 Unknown Etiology  
→ If Tachy Arrest, Tachy Arrest Reason<sup>2090</sup>: (Check all that apply)  
 Acute MI  Severe Electrolyte Disturbance  Drug Induced Arrhythmia  Primary VTAF  
 Unknown Etiology  
Atrial Fibrillation or Flutter<sup>2095</sup>: No Yes   
Ventricular Tachycardia<sup>2100</sup>: No Yes-VT, Non-Sustained: \_\_\_\_\_ Yes-Monomorphic Sustained VT: \_\_\_\_\_ Yes-Polymorphic Sustained VT: \_\_\_\_\_  
Sinus Node Function<sup>2105</sup>: Abnormal  
Coronary Transplant<sup>2110</sup>: No Yes   
Non-Ischemic Dilated Cardiomyopathy<sup>2115</sup>: No Yes-Within the past 3 months: \_\_\_\_\_ Yes-3 to 6 months: \_\_\_\_\_ Yes-Greater than 6 months: \_\_\_\_\_  
Ischemic Heart Disease<sup>2120</sup>: No Yes-At Least One Epicardial Artery - 75%: \_\_\_\_\_ Yes-Other Diagnostic Tests: \_\_\_\_\_  
Previous MI<sup>2125</sup>: No Yes-Within 40 days: \_\_\_\_\_ Yes-Greater than 40 days: \_\_\_\_\_ Yes-Both Within 40 days/Greater than 40 days: \_\_\_\_\_  
Previous CABG<sup>2130</sup>: No Yes → If Yes, Date<sup>2135</sup>: \_\_\_\_\_  
Previous PCI<sup>2135</sup>: No Yes-Within the past 3 months: \_\_\_\_\_ Yes-Greater than 3 months: \_\_\_\_\_  
Previous Valvular Surgery<sup>2140</sup>: No Yes   
Permanent Pacemaker<sup>2145</sup>: No Yes-Atrial Chamber: \_\_\_\_\_ Yes-Ventricular Chamber: \_\_\_\_\_ Yes-Both Chamber: \_\_\_\_\_ Yes-Biventricular: \_\_\_\_\_  
Previous ICD<sup>2150</sup>: No Yes-Single Chamber: \_\_\_\_\_ Yes-Dual Chamber: \_\_\_\_\_ Yes-Biventricular: \_\_\_\_\_  
→ If Yes, Date<sup>2155</sup>: 08/09/2007  
→ If Yes, Previous ICD Reason<sup>2160</sup>: (Check all that apply)  Primary Prevention  Syncope with Inducible VT  
 Spontaneous Monomorphic Sustained VT  Spontaneous Polymorphic Sustained VT  Ventricular Fibrillation  
 Cardiac Arrest/Arrhythmic Etiology Unknown  Syncope and High Risk Characteristics  AFB  
→ If Yes, Previous ICD Implant Site<sup>2165</sup>: Thoracic Abdominal: \_\_\_\_\_  
Cerebrovascular Disease<sup>2170</sup>: No Yes  Chronic Lung Disease<sup>2175</sup>: No Yes   
Diabetes<sup>2180</sup>: No Yes  Hypertension<sup>2185</sup>: No Yes   
Renal Failure Dialysis<sup>2190</sup>: No Yes



Heart Rhythm Society

ACC-NCDR® ICD Registry™  
v1.08 Data Collection Form  
**IMPLANT**

**E. DIAGNOSTIC STUDIES:**

Ejection Fraction Assessed <sup>2000</sup>: No; Yes → If Yes, % <sup>2000</sup>: 55%

→ If Yes, EF Timeframe <sup>2000</sup>: 0-1 month; 1-2 months; 2-3 months; 3-6 months; 6-12 months; >12 months

Electrophysiology Study Done <sup>2000</sup>:  No;  Yes

→ If Yes, EPS Timeframe <sup>2000</sup>: 0-1 month; 1-2 months; 2-3 months; 3-6 months; 6-12 months; >12 months

→ If Yes, EPS Findings <sup>2000</sup>: (Check all that apply. "No Arrhythmias Induced" is mutually exclusive.)

No Arrhythmias Induced;  VT Induced;  Non-sustained VT;  Sustained Monomorphic VT;  Sustained Polymorphic VT;  Ventricular Fibrillation Induced;  Ventricular Fibrillation Induced;  Paced (any)

QRS Duration <sup>2000</sup>: 116 (msec); PR Interval Attainable <sup>2000</sup>: No; Yes → If Yes, PR Interval <sup>2000</sup>: 176 (msec)

AV Conduction <sup>2000</sup>:  Normal;  Abnormal-1<sup>st</sup> Degree Heart Block Only;  Abnormal-Heart Block 2<sup>nd</sup> or 3<sup>rd</sup> Degree (not paced);  Paced (any)

Intra-ventricular Conduction <sup>2000</sup>: Normal; Abnormal-Left Anterior Fascicular Block; Abnormal-Left Posterior Fascicular Block; Abnormal-LBBB; Abnormal-RBBB; Abnormal-Intra-ventricular Conduction Delay, Nonspecific; Abnormal-Bifascicular Block (RBBB Plus LAF); Abnormal-Bifascicular Block (RBBB Plus LPF)

Paced;  No;  Yes → If Yes, BUN <sup>2000</sup>: 9; Sodium <sup>2000</sup>: 12; BNP Drawn <sup>2000</sup>: No; Yes → If Yes, BNP <sup>2000</sup>: 12; Systolic BP <sup>2000</sup>: 128

**F. ICD PROCEDURES:**

ICD Indication <sup>2000</sup>:  Primary Prevention;  Secondary Prevention

Reason(s) for the implantation <sup>2000</sup>: (If Previous ICD, is Yes) (Check all that apply)

End of Battery Life;  Device Upgrade;  Device Malfunction;  Device Under Manufacture;  Adverse Event

Replace ICDs implanted during this admission <sup>2000</sup>:  No;  Yes

Implant Operator's UPIN <sup>2000</sup>: \_\_\_\_\_ Implant Operator's NPI <sup>2000</sup>: \_\_\_\_\_

Implant Operator's Last Name <sup>2000</sup>: FERRICK First Name <sup>2000</sup>: ESWEN Middle Name <sup>2000</sup>: \_\_\_\_\_

ICD Type <sup>2000</sup>: \_\_\_\_\_

If Electrically LV Lead Implant Method <sup>2000</sup>: \_\_\_\_\_

Implant: **ATLAS® HF** V-343  
SN 343078  
2007/10/31  
ST. JUDE MEDICAL

Explant: V-343 SN 343078 ST. JUDE MEDICAL

**G. ADVERSE EVENTS: (During or after the implant procedure until discharge)**

Cardiac Arrest <sup>2001</sup>	<input type="checkbox"/>	Phlebitis - Deep <sup>2001</sup>	<input type="checkbox"/>
Death <sup>2002</sup>	<input type="checkbox"/>	TIA <sup>2001</sup>	<input type="checkbox"/>
Device Malfunction <sup>2002</sup>	<input type="checkbox"/>	VA/AVN Block <sup>2001</sup>	<input type="checkbox"/>
Device Under Mfg <sup>2001</sup>	<input type="checkbox"/>	AVF Failure <sup>2001</sup>	<input type="checkbox"/>
Heart Block <sup>2001</sup>	<input type="checkbox"/>	Infection Related to Device <sup>2001</sup>	<input type="checkbox"/>
Coronary Vessel Dissect <sup>2002</sup>	<input type="checkbox"/>		
Hematoma <sup>2001</sup>	<input type="checkbox"/>		
Lead Dislodgement <sup>2001</sup>	<input type="checkbox"/>		
Hemothorax <sup>2001</sup>	<input type="checkbox"/>		
Pneumothorax <sup>2001</sup>	<input type="checkbox"/>		
Pericardial Nerve Injury <sup>2001</sup>	<input type="checkbox"/>		
Peripheral Embolism <sup>2001</sup>	<input type="checkbox"/>		
Phlebitis - Superficial <sup>2001</sup>	<input type="checkbox"/>		



H. DISCHARGE: (Complete this section at discharge)

CABG During this Admission<sup>2500</sup>: No; Yes → If Yes, Date<sup>2500</sup>  
PCI During this Admission<sup>2519</sup>: No; Yes → If Yes, Date<sup>2519</sup>  
Vital Status<sup>2525</sup>: Alive; Deceased-Cardiac Death; Deceased-Non-Cardiac Death  
→ If Deceased, Date<sup>2525</sup>; → If Deceased, Death in Lab<sup>2525</sup>: No; Yes

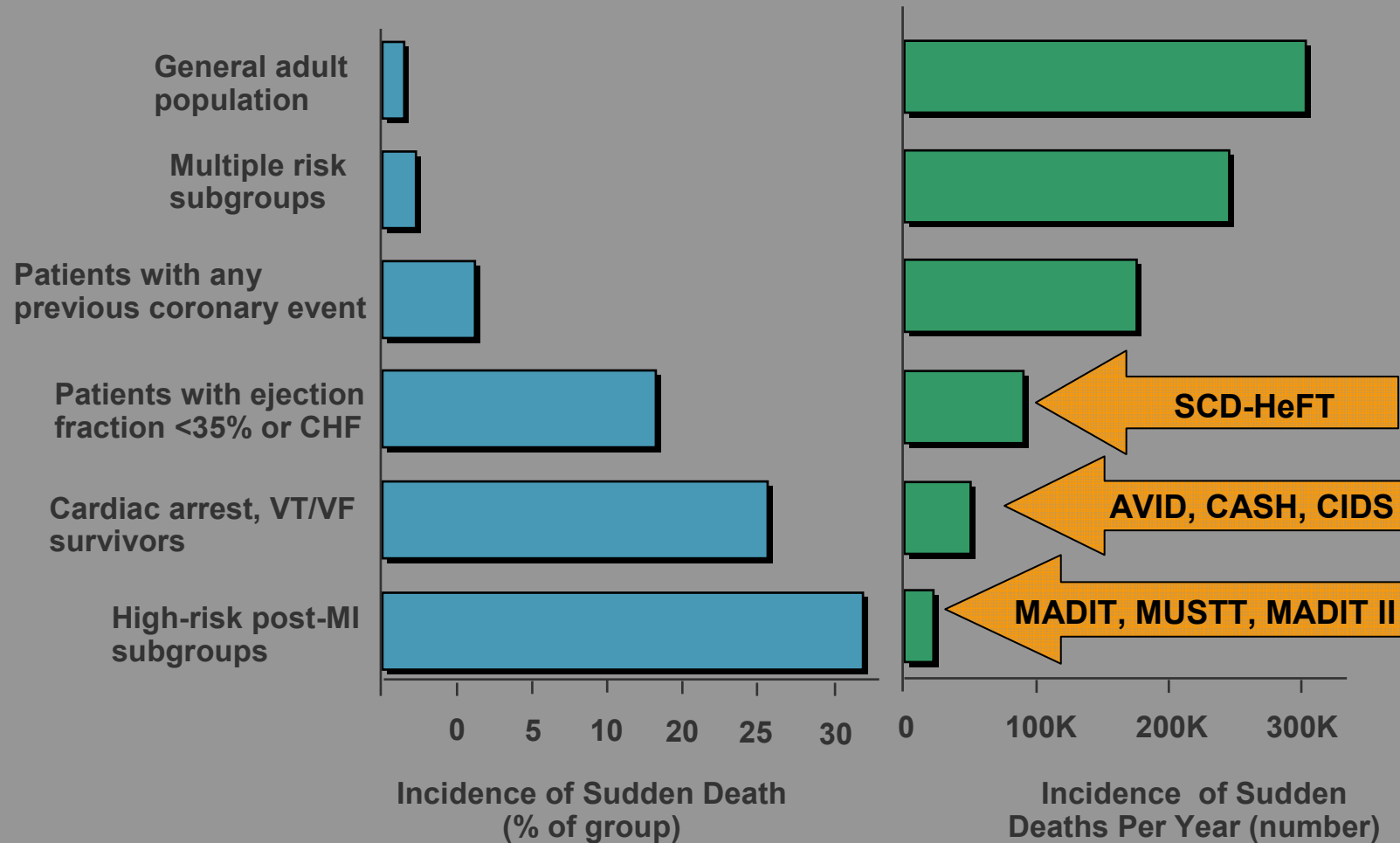
Discharge Date<sup>2526</sup>

I. Discharge Medications: (Medications prescribed at discharge)

If Vital Status<sup>2525</sup> is Alive then complete Discharge Medications below.

Medication Class	Medication	Yes	No	Other	Other	Other
Vase Inhibitor	ACE Inhibitor (any) <sup>2504</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Amiodarone <sup>2505</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Atorvastatin <sup>2506</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Beta-Blocker (any) <sup>2507</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Calcium Channel Blocker <sup>2508</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Antiarrhythmic Agent	Amiodarone <sup>2505</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Atorvastatin <sup>2506</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Calcium Channel Blocker <sup>2508</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Digoxin <sup>2509</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Digoxin <sup>2510</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Antihypertensive	ACE Inhibitor (any) <sup>2504</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Atorvastatin <sup>2506</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Beta-Blocker (any) <sup>2507</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Calcium Channel Blocker <sup>2508</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Diuretic <sup>2511</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
ARB	ARB (any) <sup>2512</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Atorvastatin <sup>2506</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Beta-Blocker (any) <sup>2507</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
Beta Blocker	Beta-Blocker (any) <sup>2507</sup>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
	Atorvastatin <sup>2506</sup>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

# Incidence of SCD: Specific Populations



Adapted from: Myerburg RJ. Sudden Cardiac Death: Exploring the Limits of Our Knowledge. *J Cardiovasc Electrophysiol* Vol. 12, pp. 369-381, March 2001.