

**ICD**

**The heart failure specialist's view**

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Update 2005

# ESC POCKET GUIDELINES

Committee for Practice Guidelines  
To improve the quality of clinical practice and patient care in Europe

## CHF

**GUIDELINES FOR THE DIAGNOSIS  
AND TREATMENT  
OF CHRONIC HEART FAILURE**

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- Task Force of ESC

- EHJ May 2005

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ESC Guidelines

## Guidelines for the diagnosis and treatment of chronic heart failure: executive summary (update 2005)

### The Task Force for the Diagnosis and Treatment of Chronic Heart Failure of the European Society of Cardiology

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ACC/AHA/ESC Guidelines

## ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death—executive summary

A report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death)

*Developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society*

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# ICD

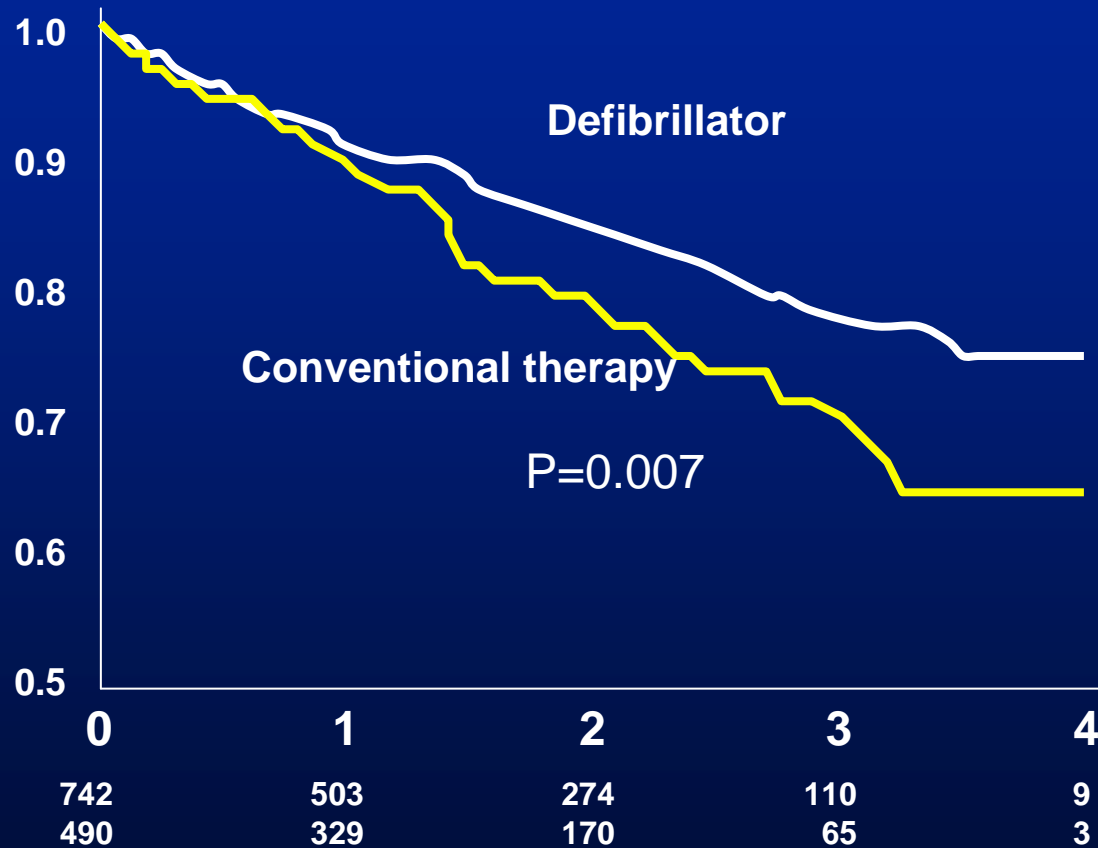
- Implantation of an ICD in combination with bi-ventricular pacing can be considered in patients who remain symptomatic with severe heart failure NYHA class III-IV with LVEF  $\leq 35\%$  and QRS duration  $> 120$  msec to improve mortality or morbidity (level of evidence B, class IIa)
- ICD therapy is recommended to improve survival in patients after cardiac arrest or who have sustained ventricular tachycardia, with reduced systolic left ventricular function (level of evidence A, class I)
- ICD implantation is reasonable in selected symptomatic patients with left ventricular ejection fraction  $< 30-35\%$ , not within 40 days of a myocardial infarction, on optimal background therapy including ACE-inhibitor, ARB, beta-blocker and an aldosterone antagonist, where appropriate, to reduce sudden death (level of evidence A, class I)

# **Why should we use ICDs?**

**Landmark trials have demonstrated efficacy**

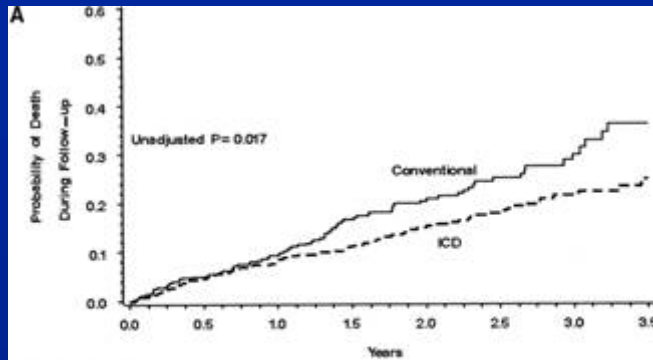
# MADIT II

1232 pts with prior MI and LVEF < 0,30



# MADIT II

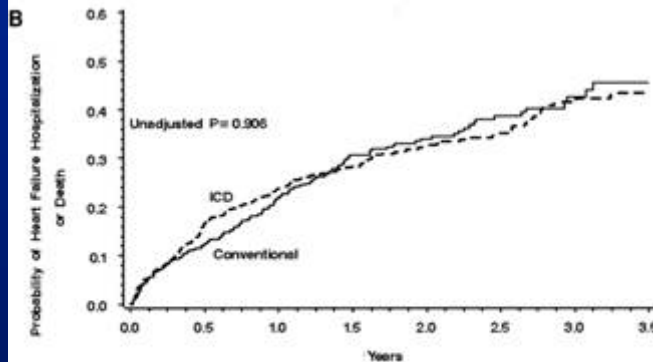
all-cause mortality



PATIENTS AT RISK

ICD	736	491 (0.09)	263 (0.15)	102 (0.22)
Conventional	482	314 (0.09)	159 (0.20)	55 (0.30)

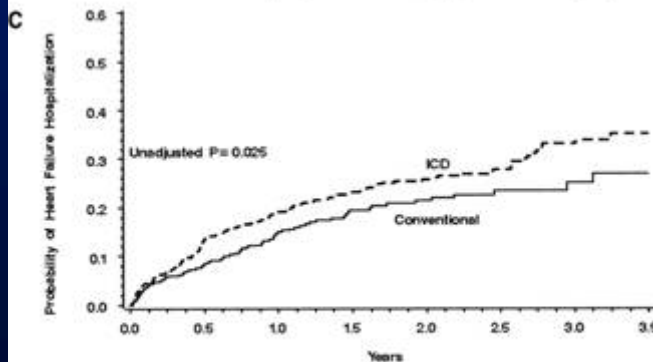
all-cause mortality or first hospitalization for HF



PATIENTS AT RISK

ICD	736	403 (0.24)	206 (0.33)	74 (0.42)
Conventional	482	272 (0.22)	137 (0.34)	49 (0.40)

first hospitalization for HF with censoring on death



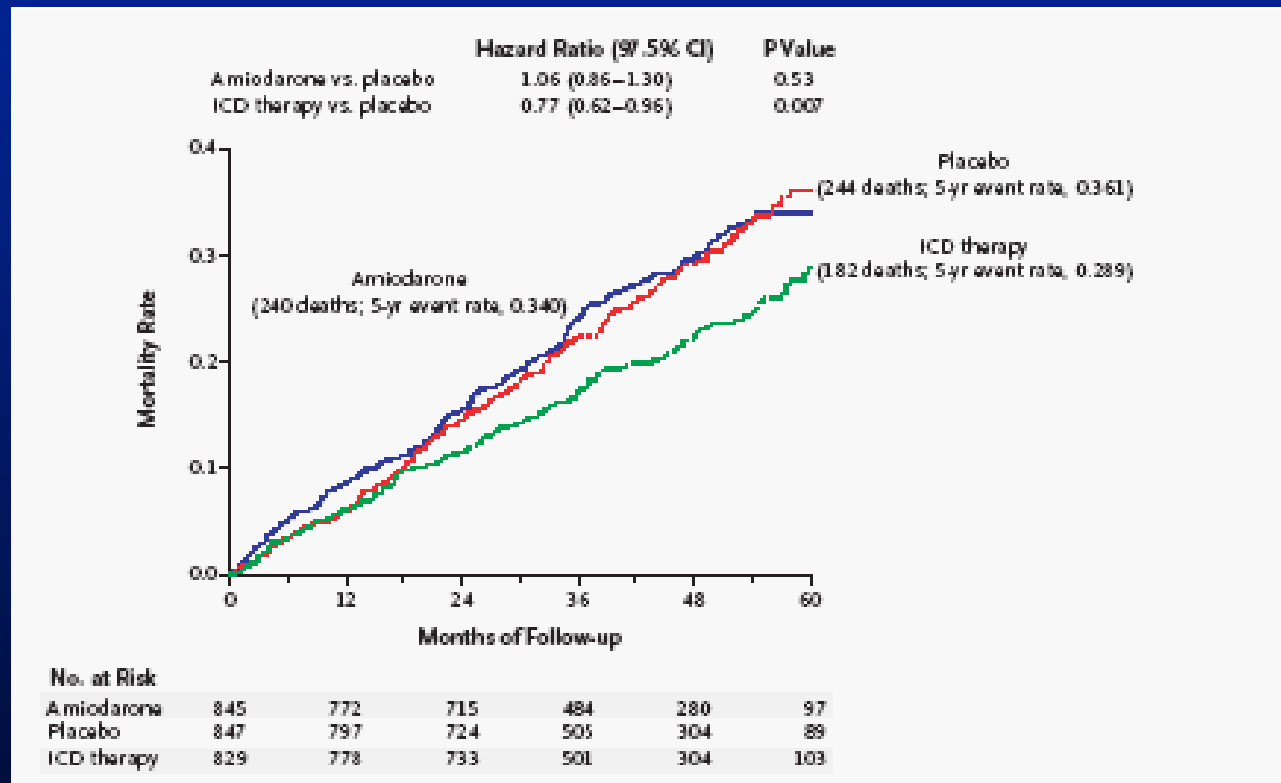
PATIENTS AT RISK

ICD	736	400 (0.15)	208 (0.26)	74 (0.33)
Conventional	482	272 (0.15)	137 (0.21)	49 (0.26)

# SCD-HeFT

2521 pts with CHF class II-III and LVEF<35%

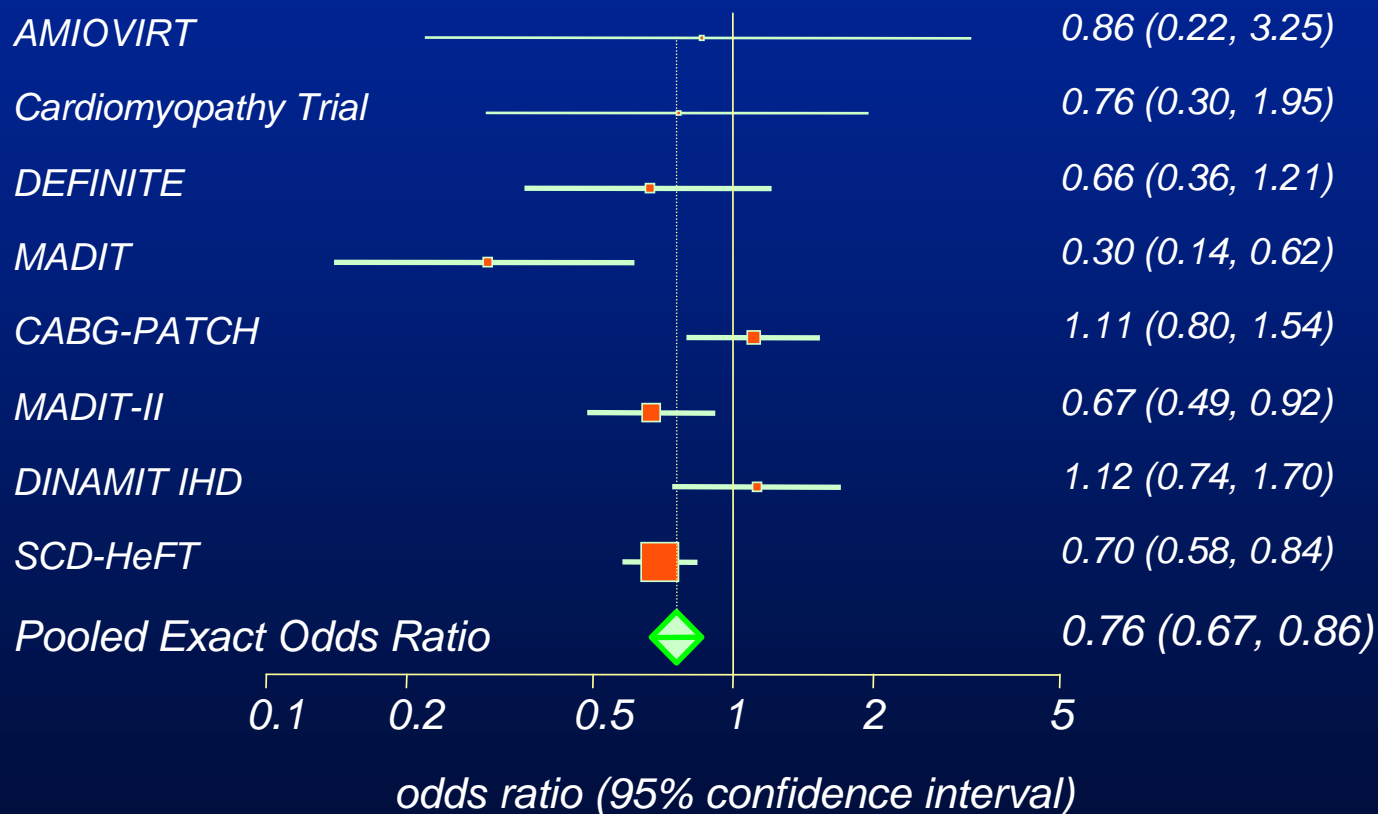
Randomized to placebo, amiodarone or single-lead, shock-only ICD



*Bardy et al NEJM Jan 20, 2005*

# Primary Prevention Studies with ICDs

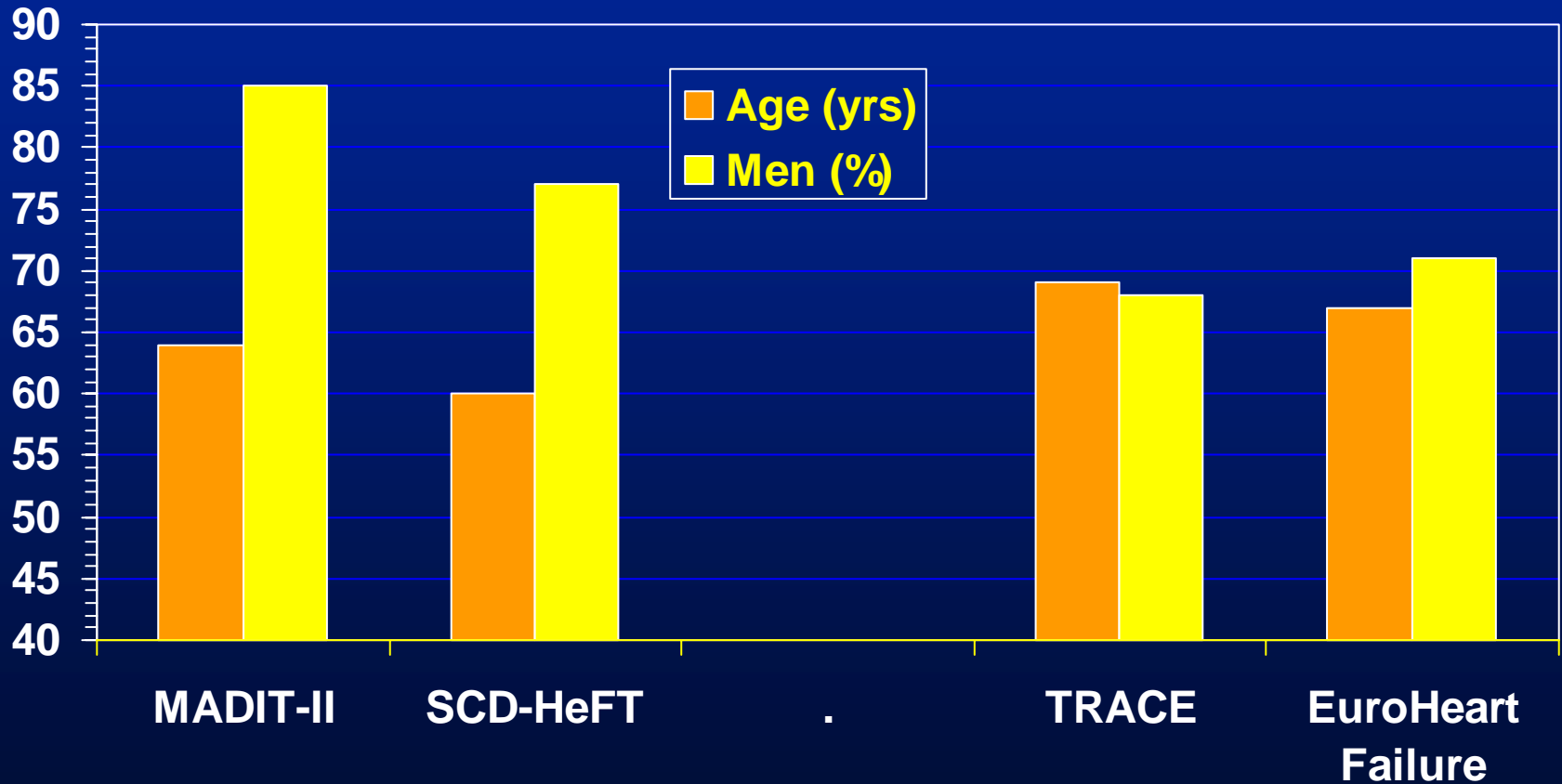
ICD Versus Control (Results < 1 favour ICD)



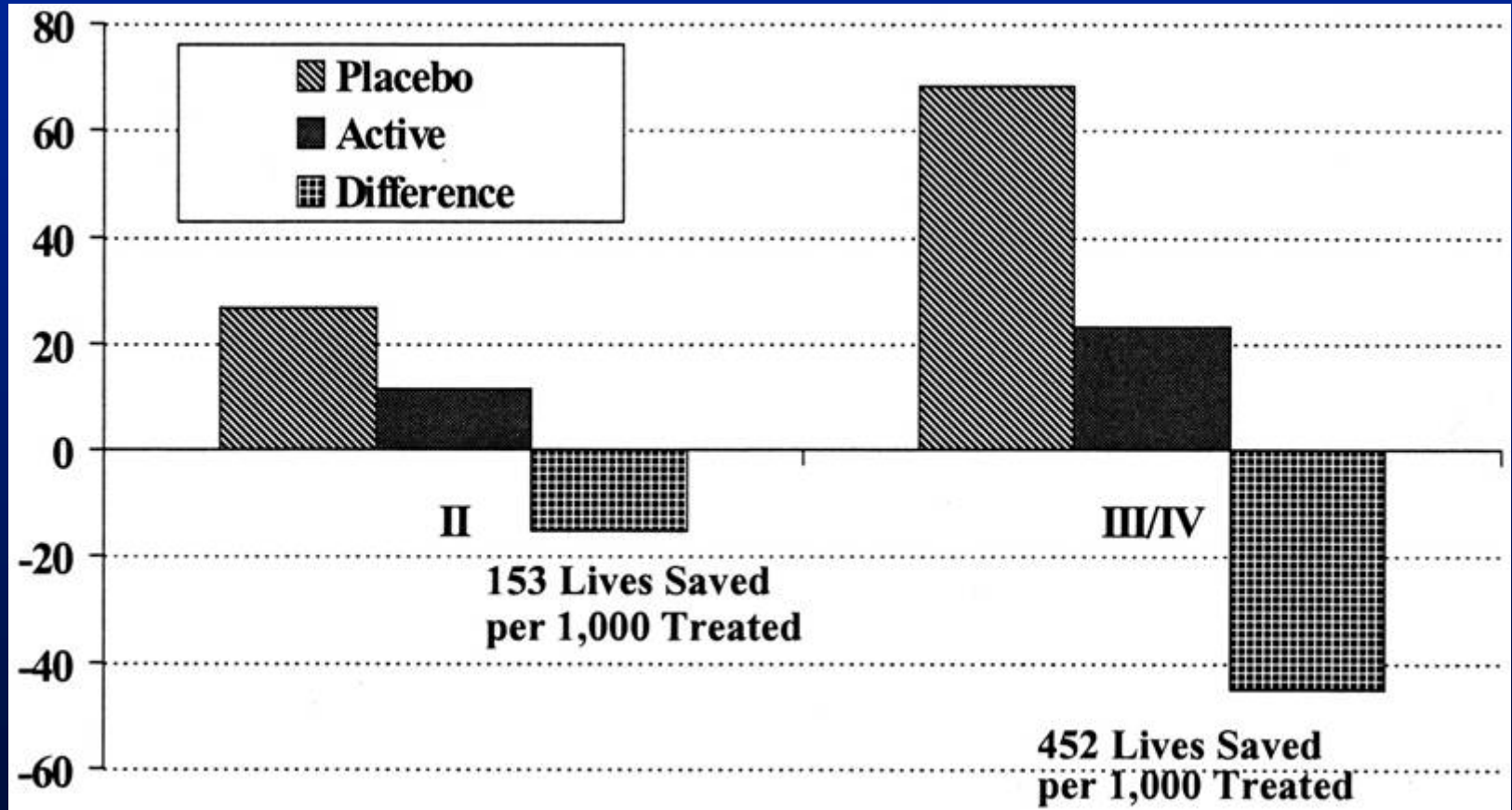
# ICD and CHF

- **Limitations in the evidence for ICD use in CHF**

# Age & Sex in MADIT-II and SCD-HeFT Not Reflected in Registries

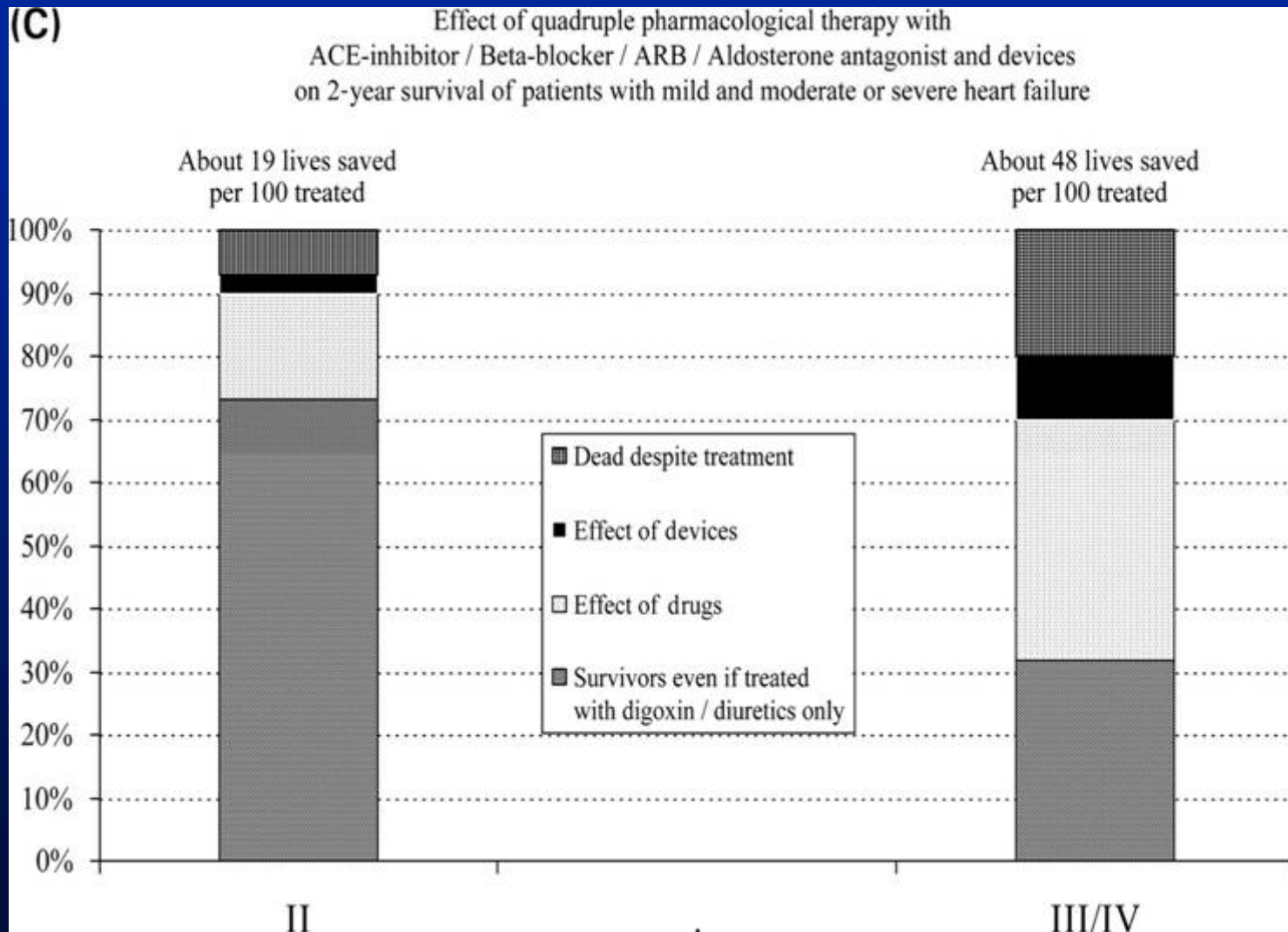


# The cumulative effects of triple therapy with angiotensin-converting enzyme inhibitors, beta-blockers, and aldosterone antagonists over two years showing



Cleland, J. G. F. et al. J Am Coll Cardiol 2003;42:1234-1237

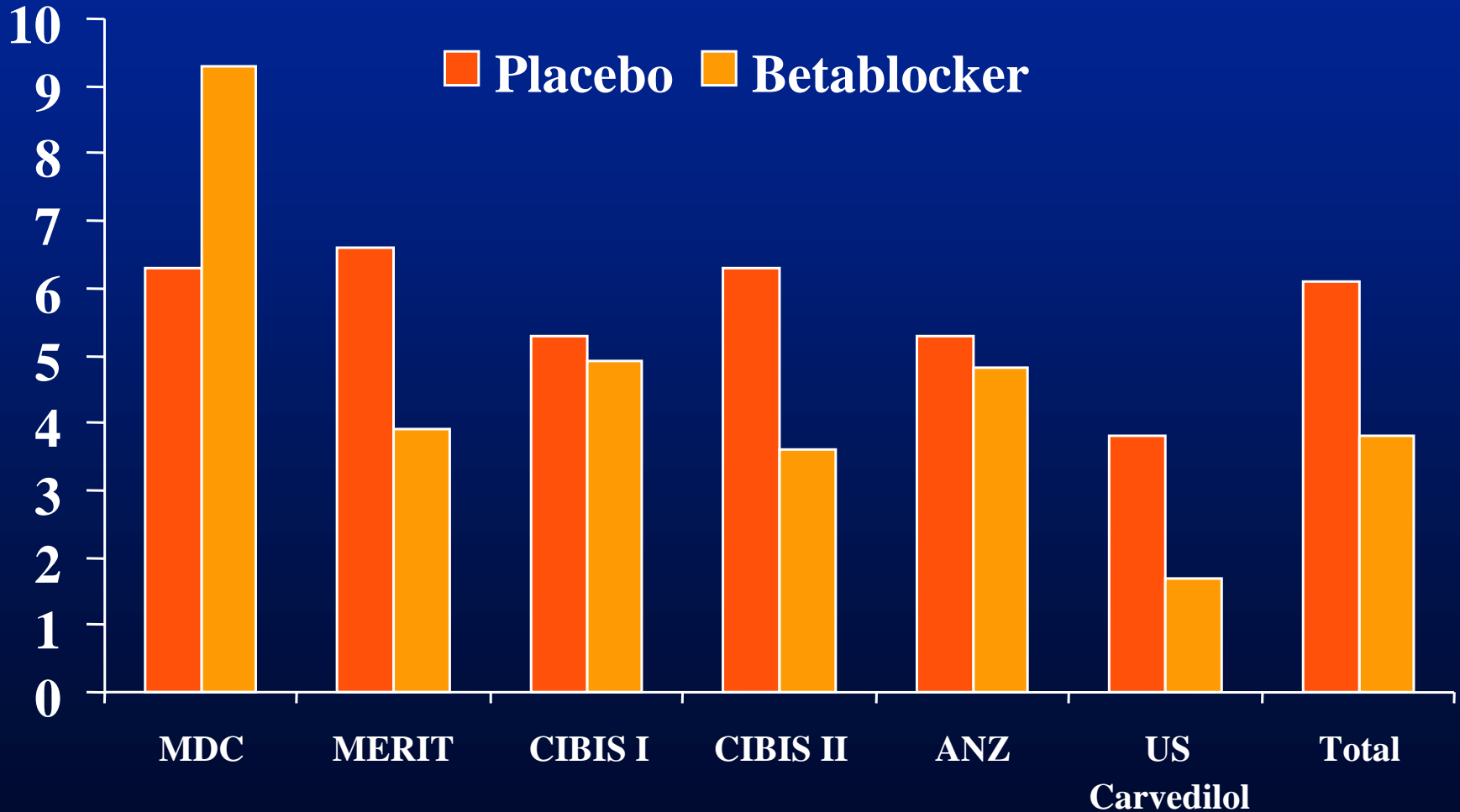
# Two year Survival on Therapy with Lifesaving Drugs and/or Devices



# Sudden Death in Selected Betablocker Trials in Heart Failure (N=9000)

Swedberg 2001

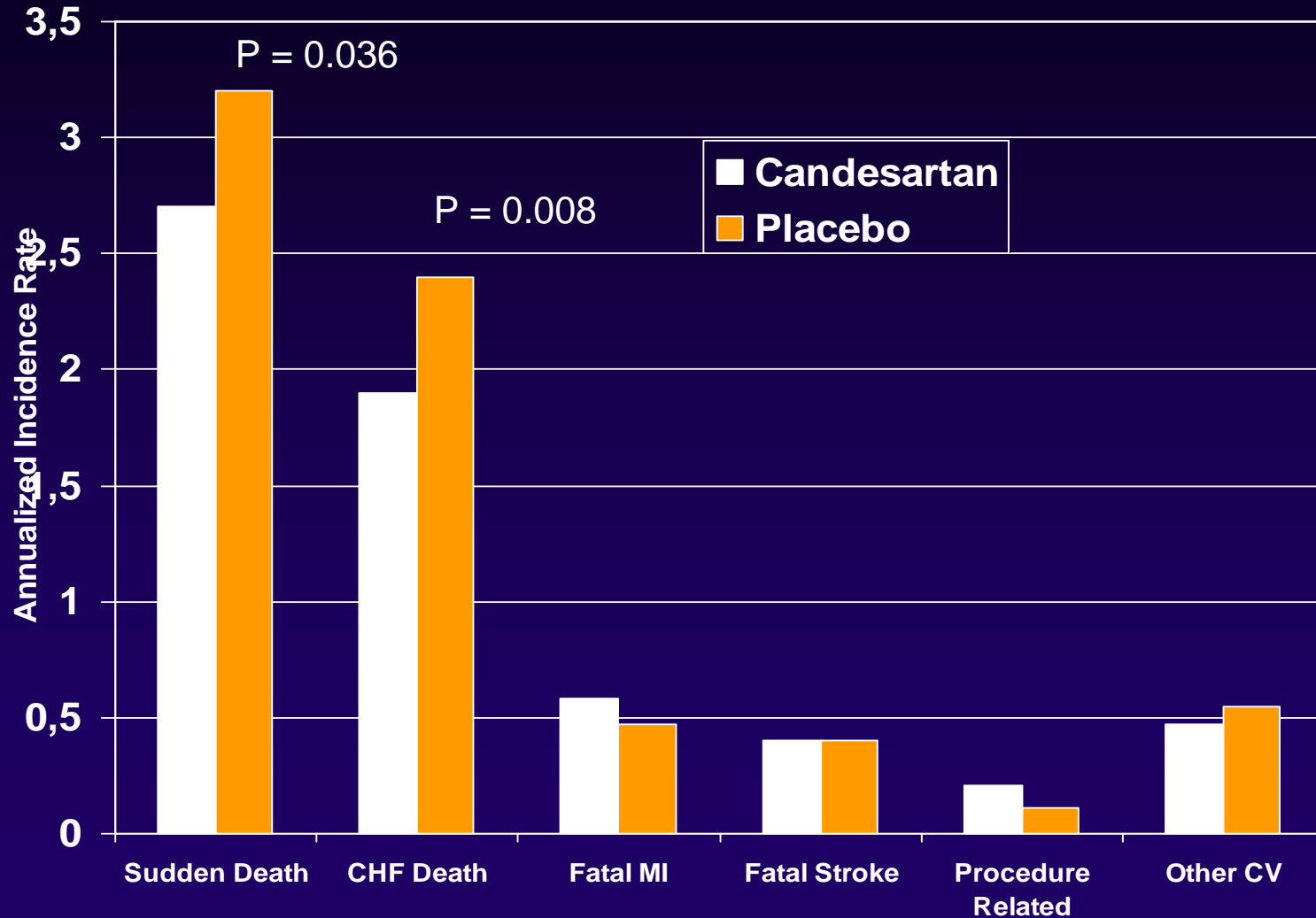
Sudden Death (%)





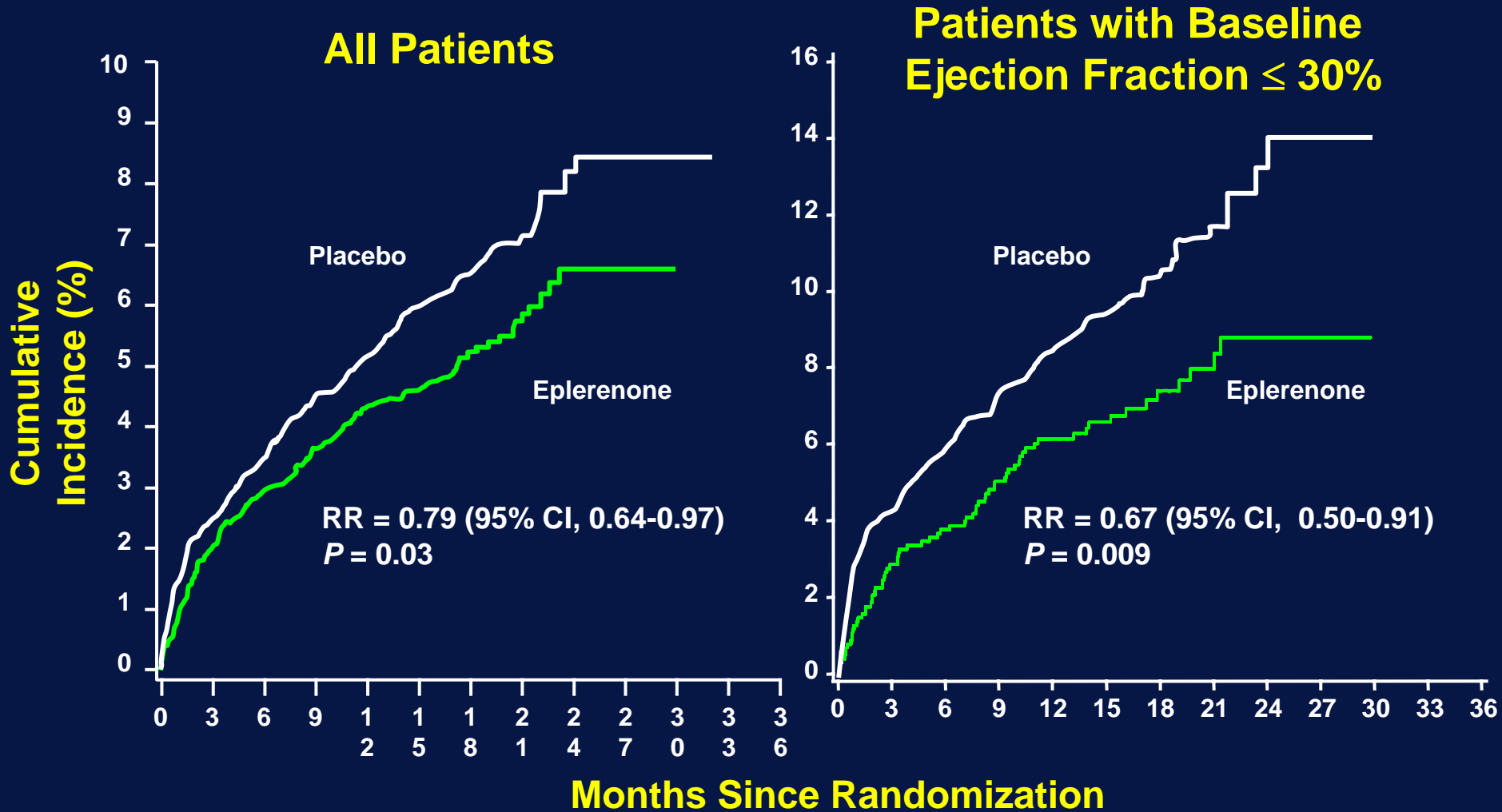
CHARM

# Effect of Candesartan on Cause of Death: The CHARM Program

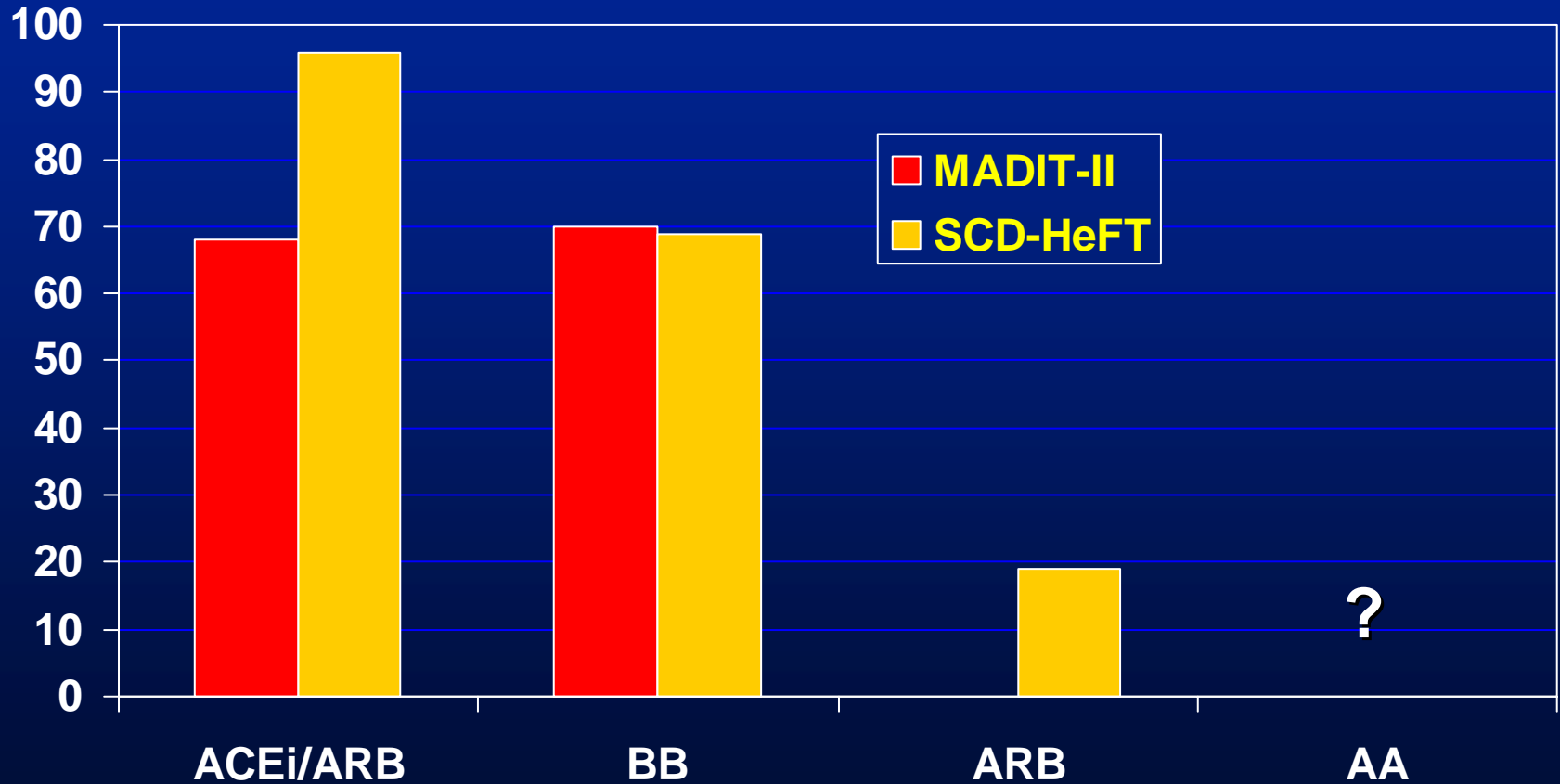


Solomon et al. Circulation 2004

# Relative Risk of Sudden Cardiac Death



# Uptake of Key Therapies in MADIT-II and SCD-HeFT

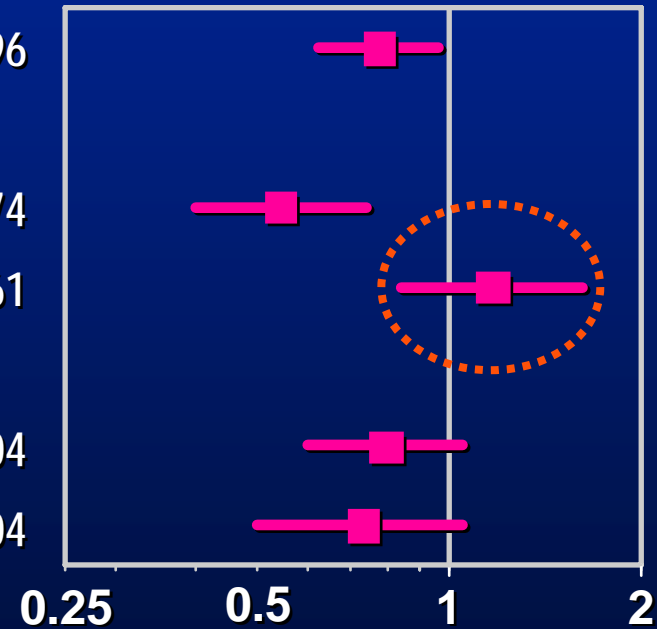


# ICD and advanced CHF

- **No ancillary benefit from ICD in very symptomatic patients**

# ICD vs. Control Hazard Ratios

Patient Group		N	HR	97.5% CI
All Patients		1676	0.77	0.62, 0.96
NYHA Class	Class II	1160	0.54	0.40, 0.74
	Class III	516	1.16	0.84, 1.61
CHF Etiology	Ischemic	884	0.79	0.60, 1.04
	Non-Ischemic	792	0.73	0.50, 1.04



# MADIT II

## Inclusion criteria

- MI > 4 weeks
- LVEF < 30%
- > 21 years

## Exclusion criteria

- **NYHA Class IV**
- Previous cardiac arrest
- Sustained VT
- CABG or PTCA  $\leq$  3 months
- CABG or PTCA planned
- Life-threatening diseases
- < 21 years

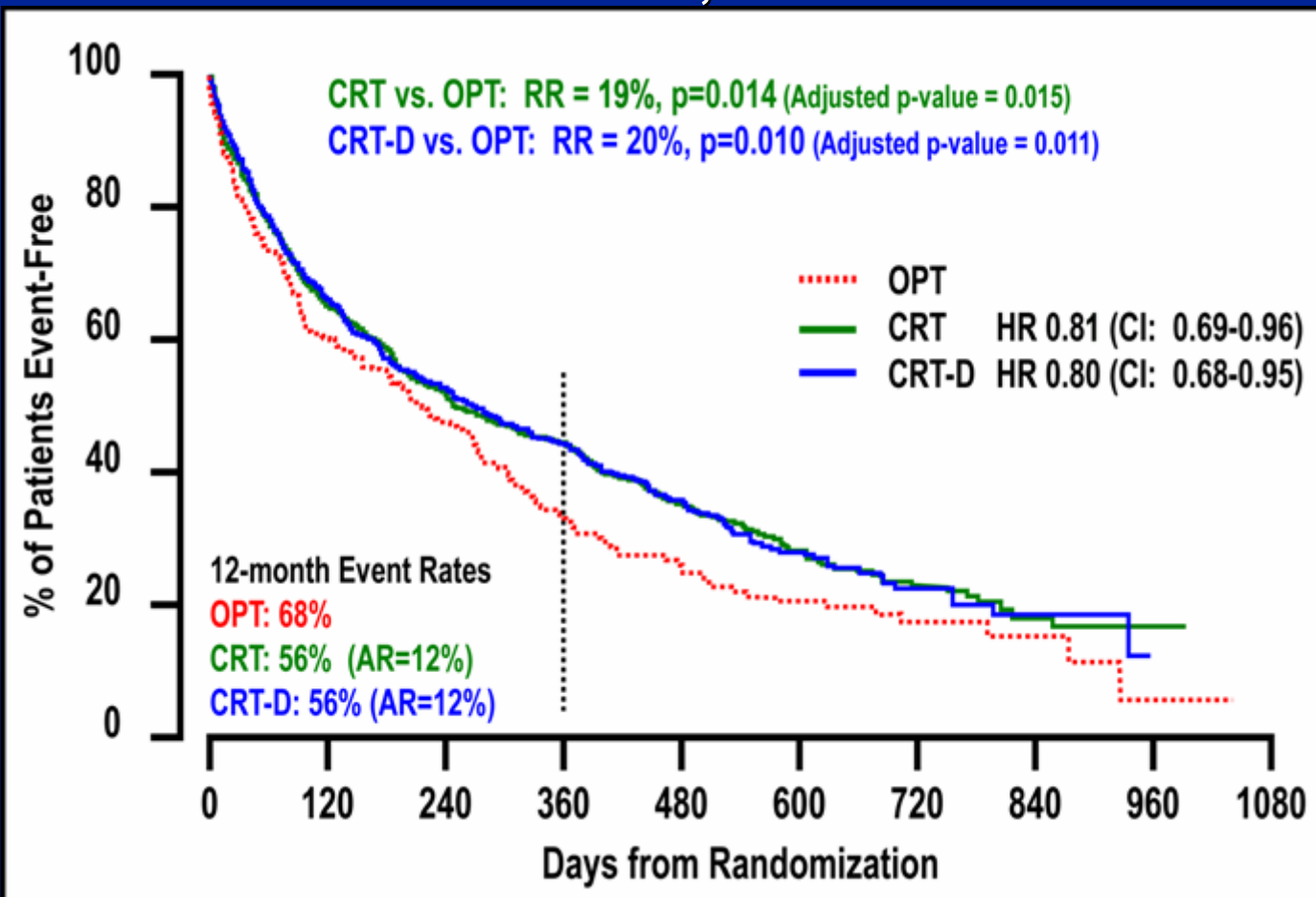
# ICD versus CRT

- **No clear additional benefit of ICD in symptomatic patients treated with CRT**

# COMPANION: *Primary Endpoint* *All-cause mortality or all-cause hospitalization*

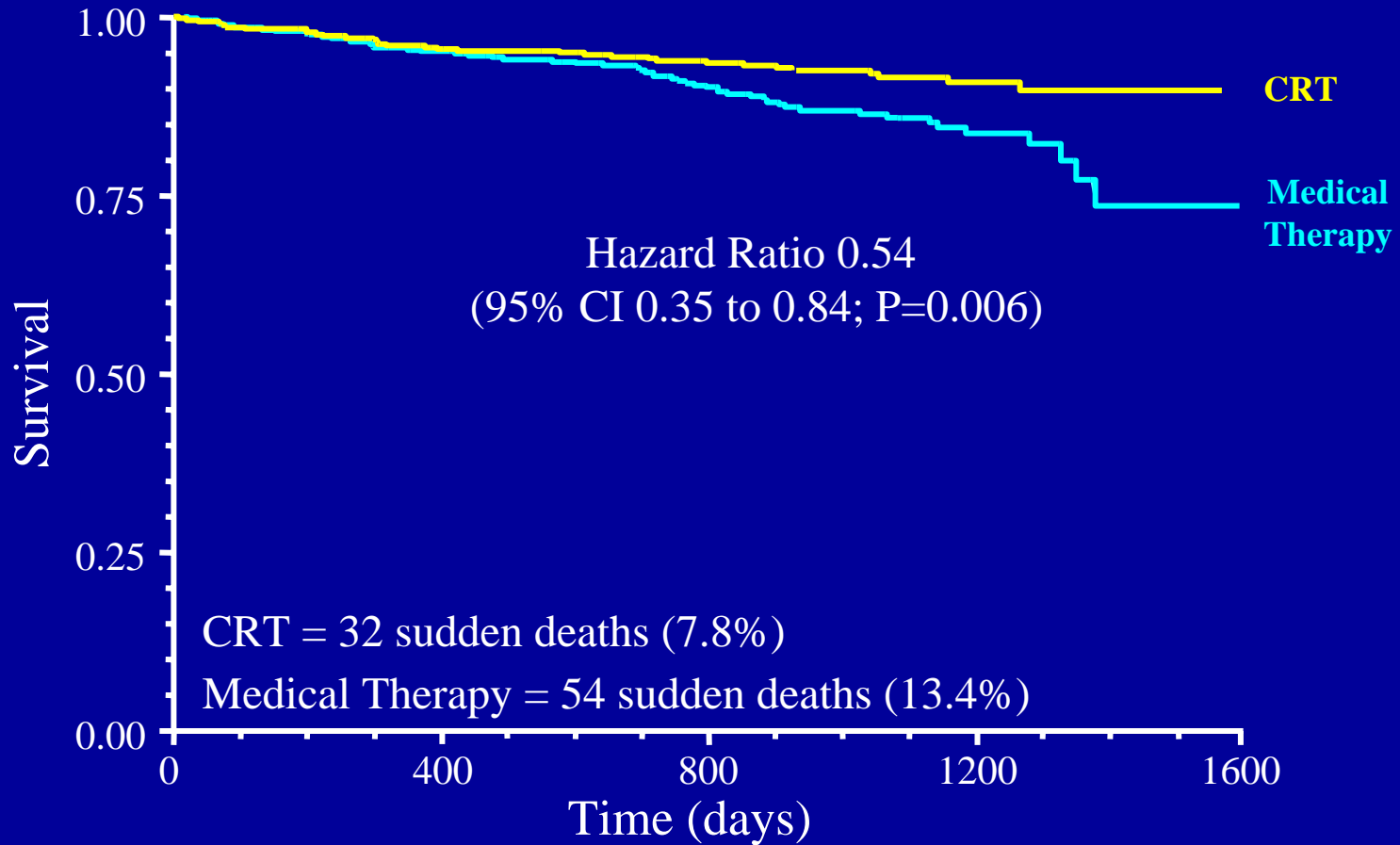
1520 pts in CHF NYHA class III-IV

randomized to conv. treatment, CRT or CRT+ICD



# CARE-HF Extension Study

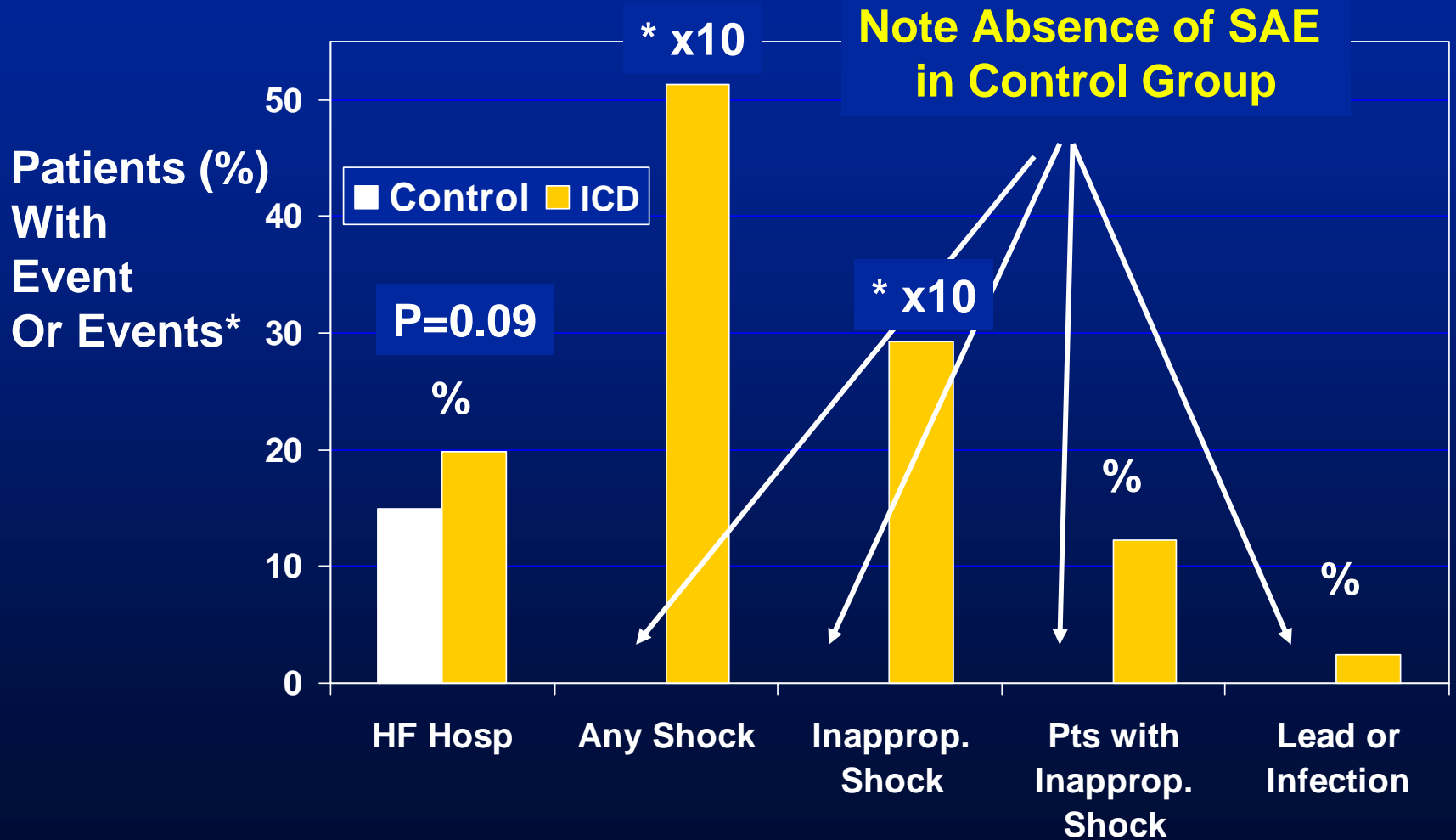
## Time to Sudden Cardiac Death



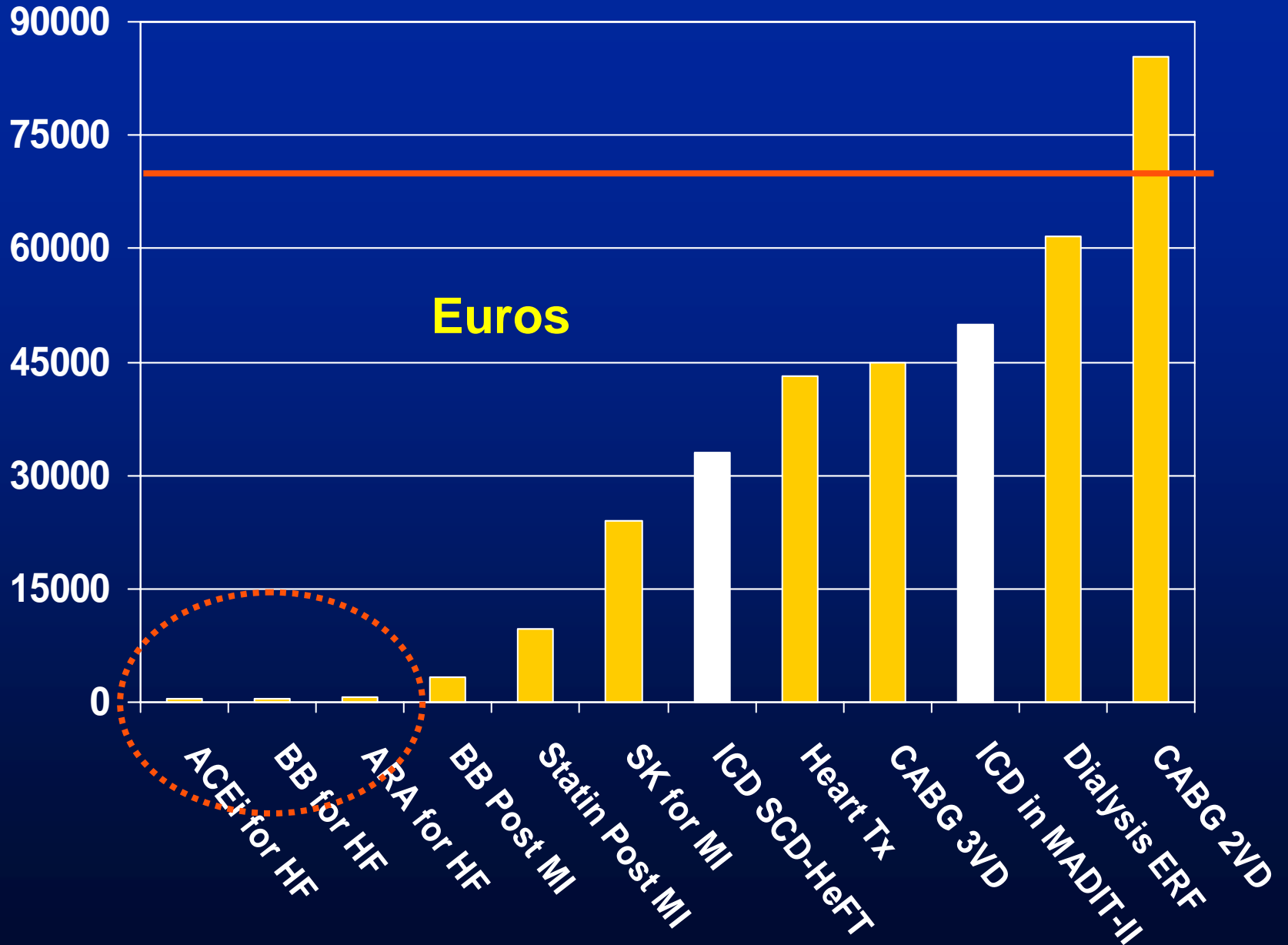
# ICDs and morbidity

- **Substantial morbidity with ICDs**

# Adverse Events in MADIT-II



# Are ICDs Cost Effective?



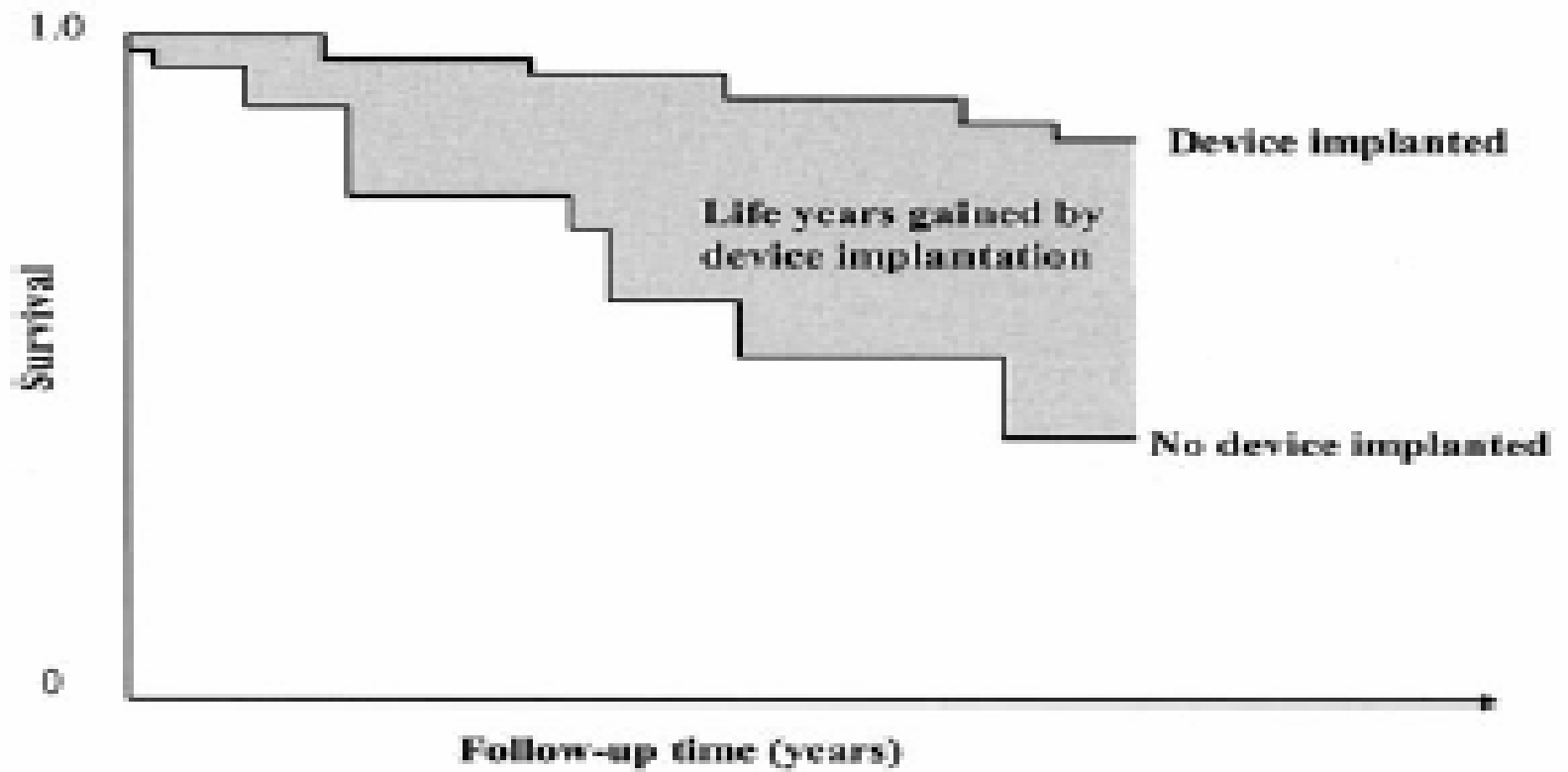
# ICD costs

## **Life-Years Gained From Defibrillator Implantation Markedly Nonlinear Increase During 3 Years of Follow-Up and Its Implications**

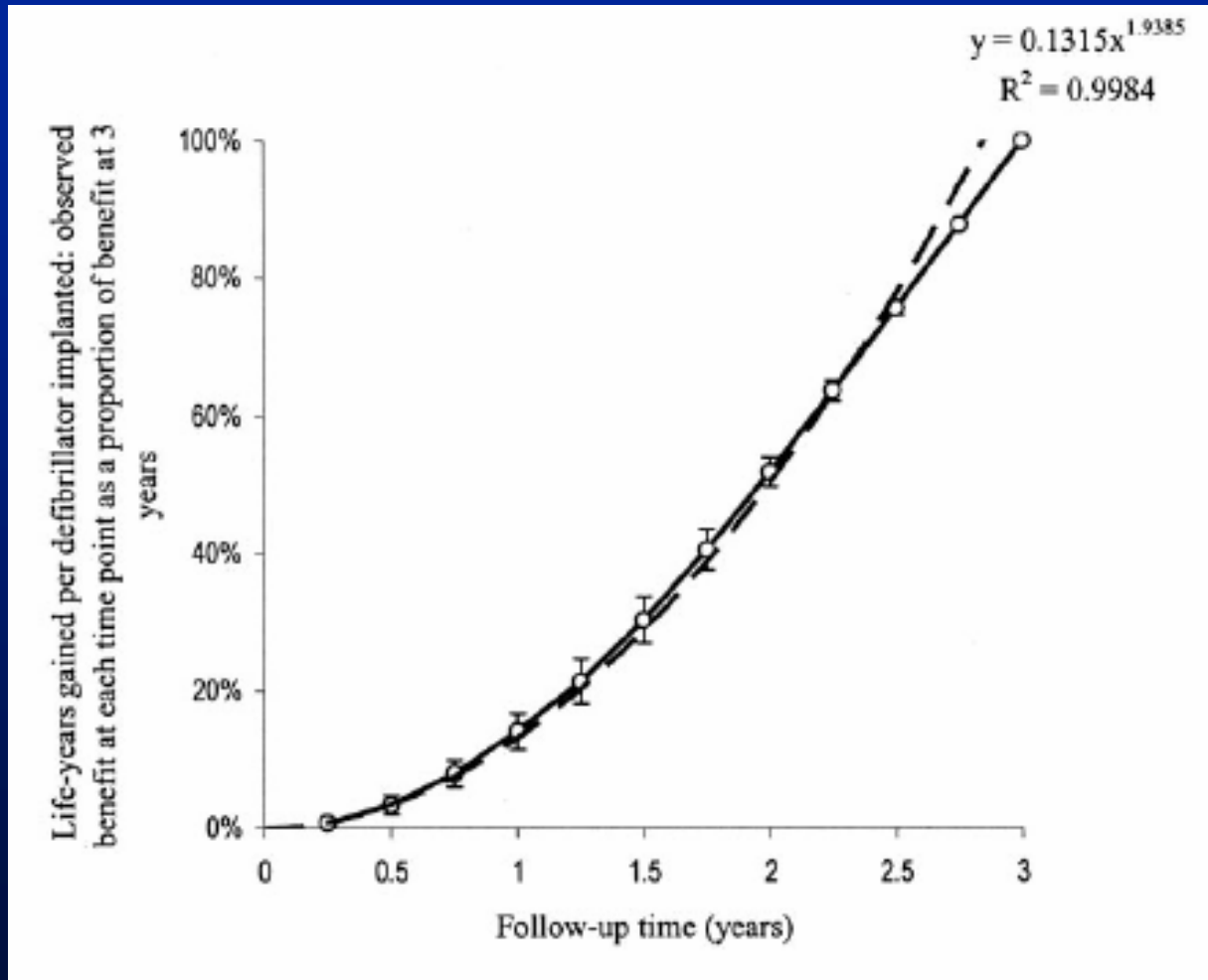
Tushar V. Salukhe, BSc, MRCP; Konstantinos Dimopoulos, MD; Richard Sutton, DMedSci;  
Andrew J. Coats, MA, DM; Massimo Piepoli, MD, PhD; Darrel P. Francis, MA, MRCP

***Circulation. 2004;109:1848-1853***

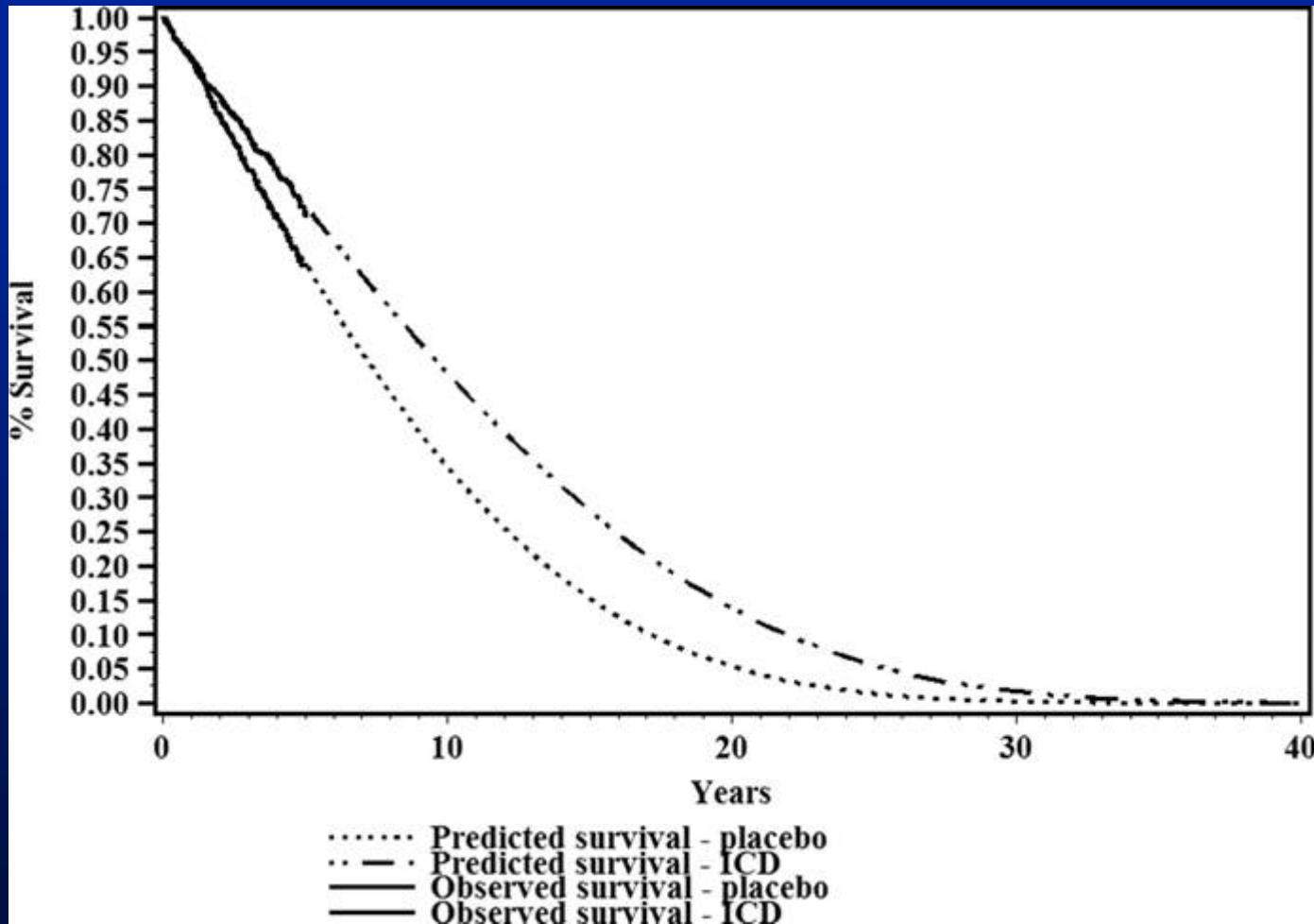
# ICDs



# Cost-effectiveness

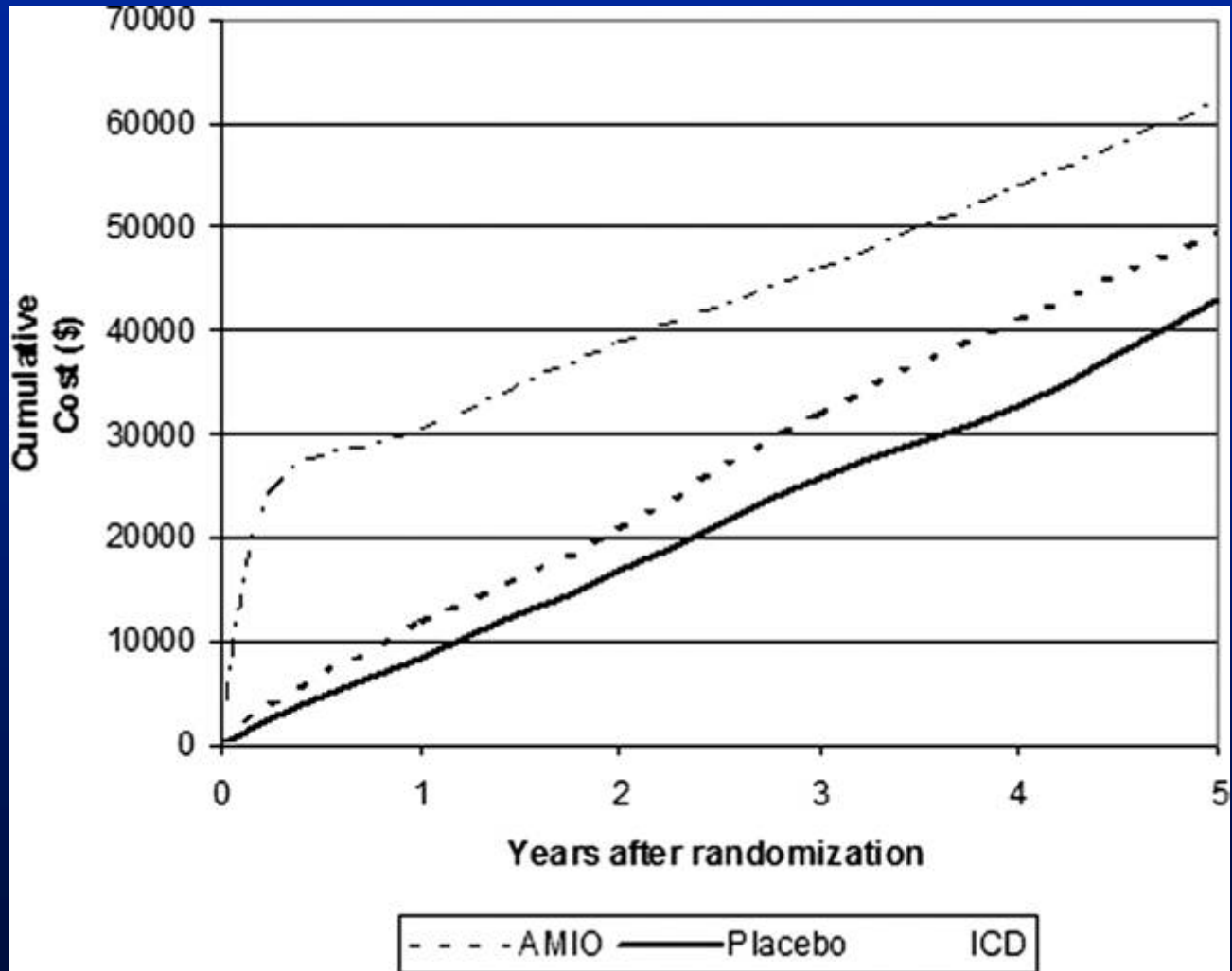


Empirical 5-year survival for the placebo and ICD groups in the SCD-HeFT (solid lines) superimposed on the modeled lifetime survival curves (dashed lines)



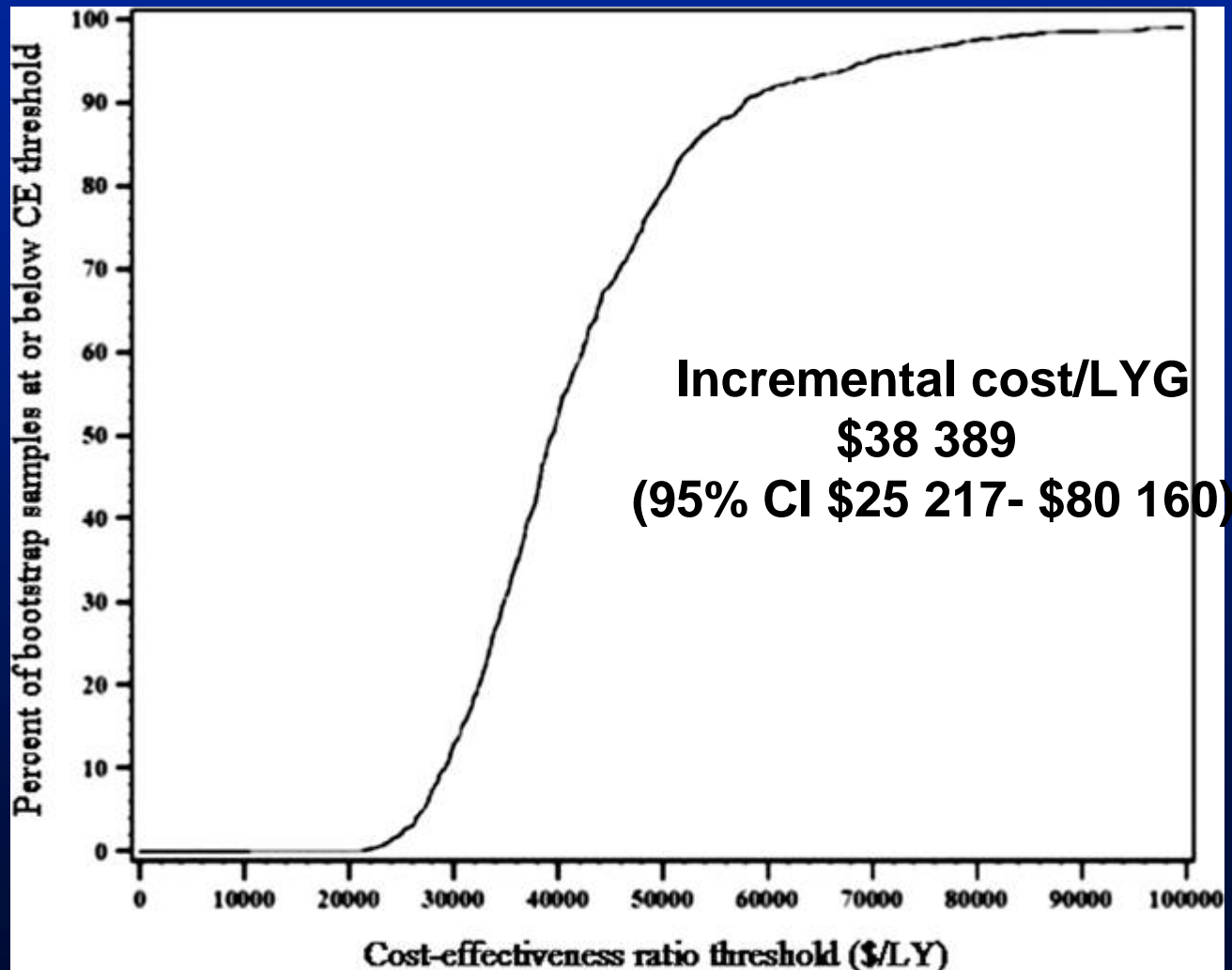
Mark, D. B. et al. Circulation 2006;114:135-142

## Cumulative 5-year costs for the 3 treatment arms



Mark, D. B. et al. *Circulation* 2006;114:135-142

# Willingness to pay for added health benefits in the form of added life-years, the probability that ICD therapy will be at or below that threshold based on the SCD-HeFT data



# **Cost-Effectiveness of Defibrillator Therapy or Amiodarone in Chronic Stable Heart Failure**

## **Results From the Sudden Cardiac Death in Heart Failure Trial (SCD-HeFT)**

Daniel B. Mark, MD, MPH; Charlotte L. Nelson, MS; Kevin J. Anstrom, PhD; Sana M. Al-Khatib, MD;  
Anastasios A. Tsiatis, PhD; Patricia A. Cowper, PhD; Nancy E. Clapp-Channing, RN, MPH;  
Linda Davidson-Ray, MA; Jeanne E. Poole, MD; George Johnson, BSEE; Jill Anderson, RN; Kerry L. Lee, PhD;  
Gust H. Bardy, MD; for the SCD-HeFT Investigators

**”Prophylactic use of single-lead, shock-only ICD therapy is economically attractive in patients with stable, moderately symptomatic heart failure with an ejection fraction <35%, particularly those in NYHA class II, as long as the benefits of ICD therapy observed in the SCD-HeFT persist for at least 8 years.”**

# Who Should NOT Receive an ICD?

When background pharmacological therapy has NOT been optimized including the combination of ACE-inhibitor/ARB, beta-blocker, aldosterone-antagonist as appropriate.

Neither in patients with:

- End stage heart failure
- Concomitant disease with limited survival probability e.g. cancer
- Severely reduced cognitive function

# Challenges

- **Integration of ICD to other lifesaving therapies in CHF including pharmacological therapy**
- **Need of team efforts and restructure of organisations. Heart failure clinics could be the core in this structure.**
- **In the management of patients with CHF, heart failure and arrhythmology are not separate entities.**

# Conclusions

- ICDs are proven to prolong life and to be cost-effective in patients with CHF and LV systolic dysfunction
- Fairly small survival benefit (vs drug therapy)
- Important morbidity
- There are patients with CHF and LV systolic dysfunction who should NOT receive an ICD but instead optimal therapy. These patients need to be identified.
- Integrated approach needed



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