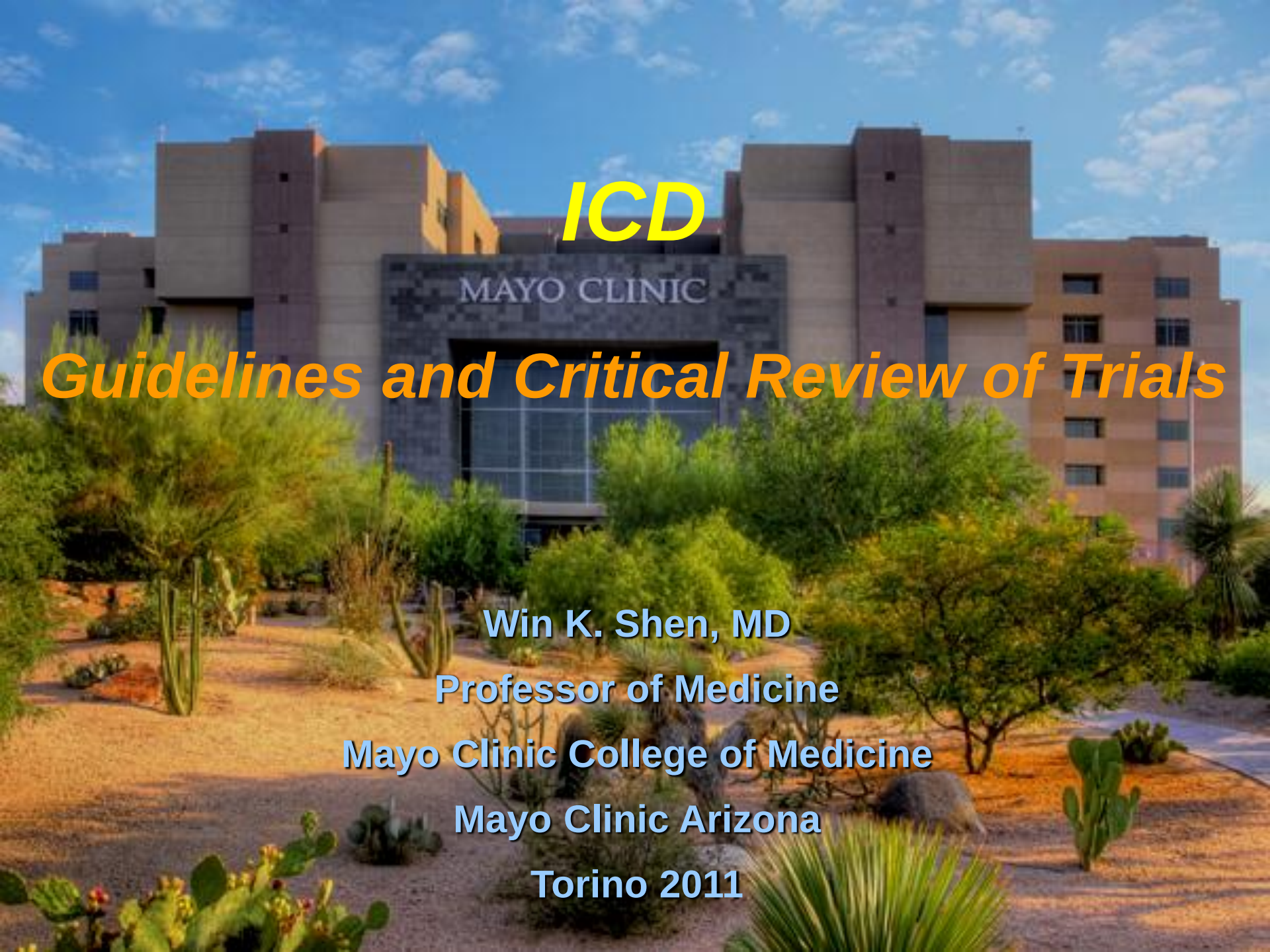

ICD

Guidelines and Critical Review of Trials

Win K. Shen, MD

Professor of Medicine

Mayo Clinic College of Medicine

Mayo Clinic Arizona

Torino 2011

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Disclosure

Relevant Financial Relationship(s)

None

Off Label Usage

None

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Objectives
ICD and SCD Prevention

- Prevalence and Pathophysiology
- Secondary Prevention
- Primary Prevention
  - Risk stratification
  - Role of antiarrhythmic drugs
  - Role of ICD
- Recommendations and Guidelines

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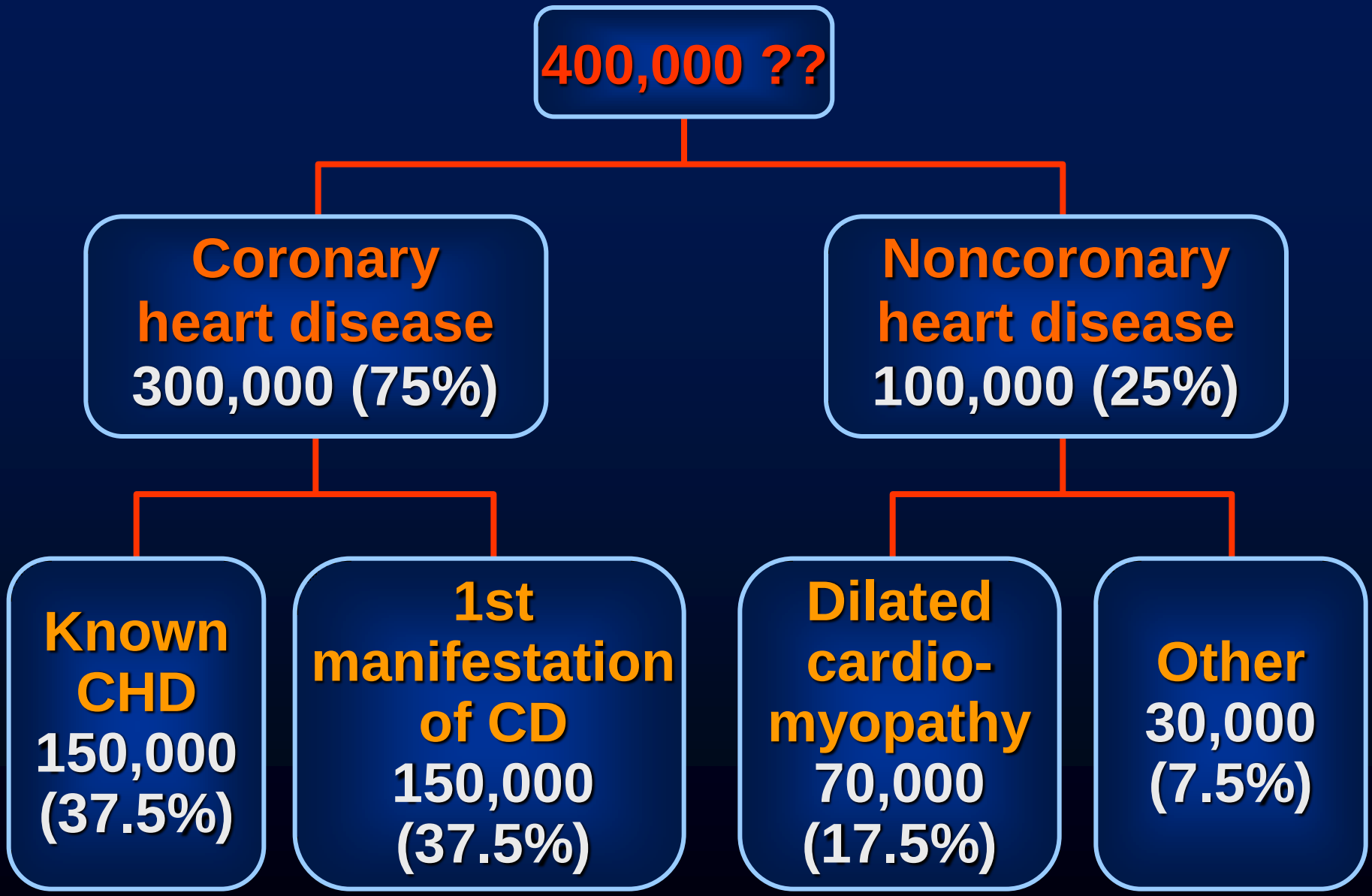
Sudden Cardiac Death



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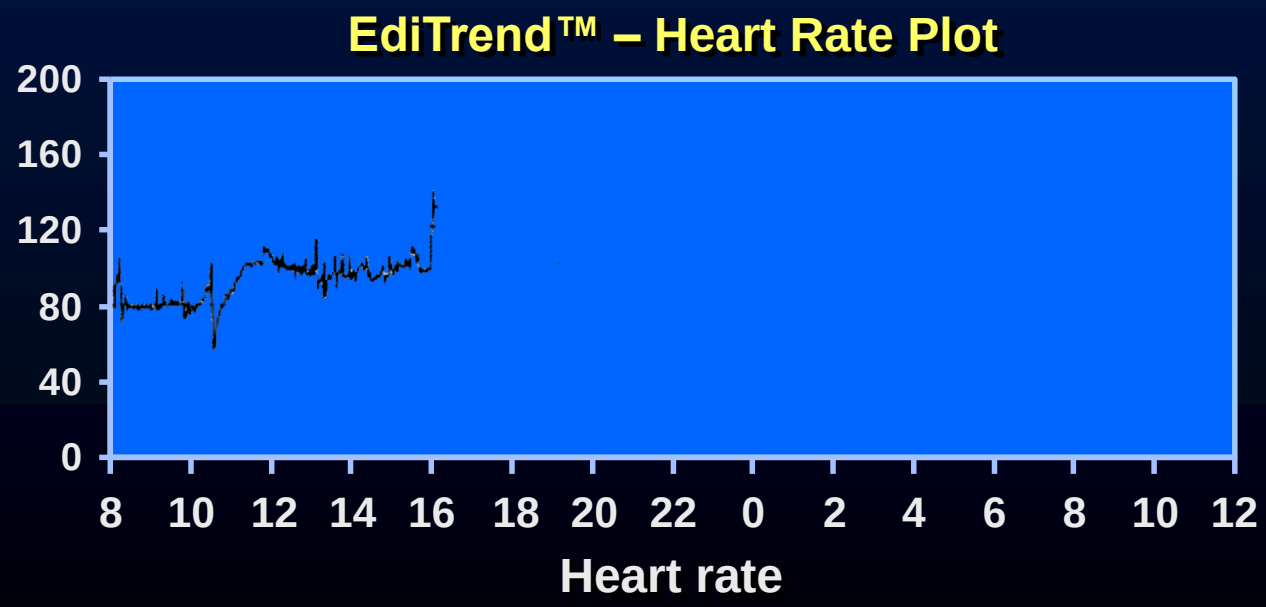
57-Year-Old Male with Palpitations and CAD

No Prior History of Syncope



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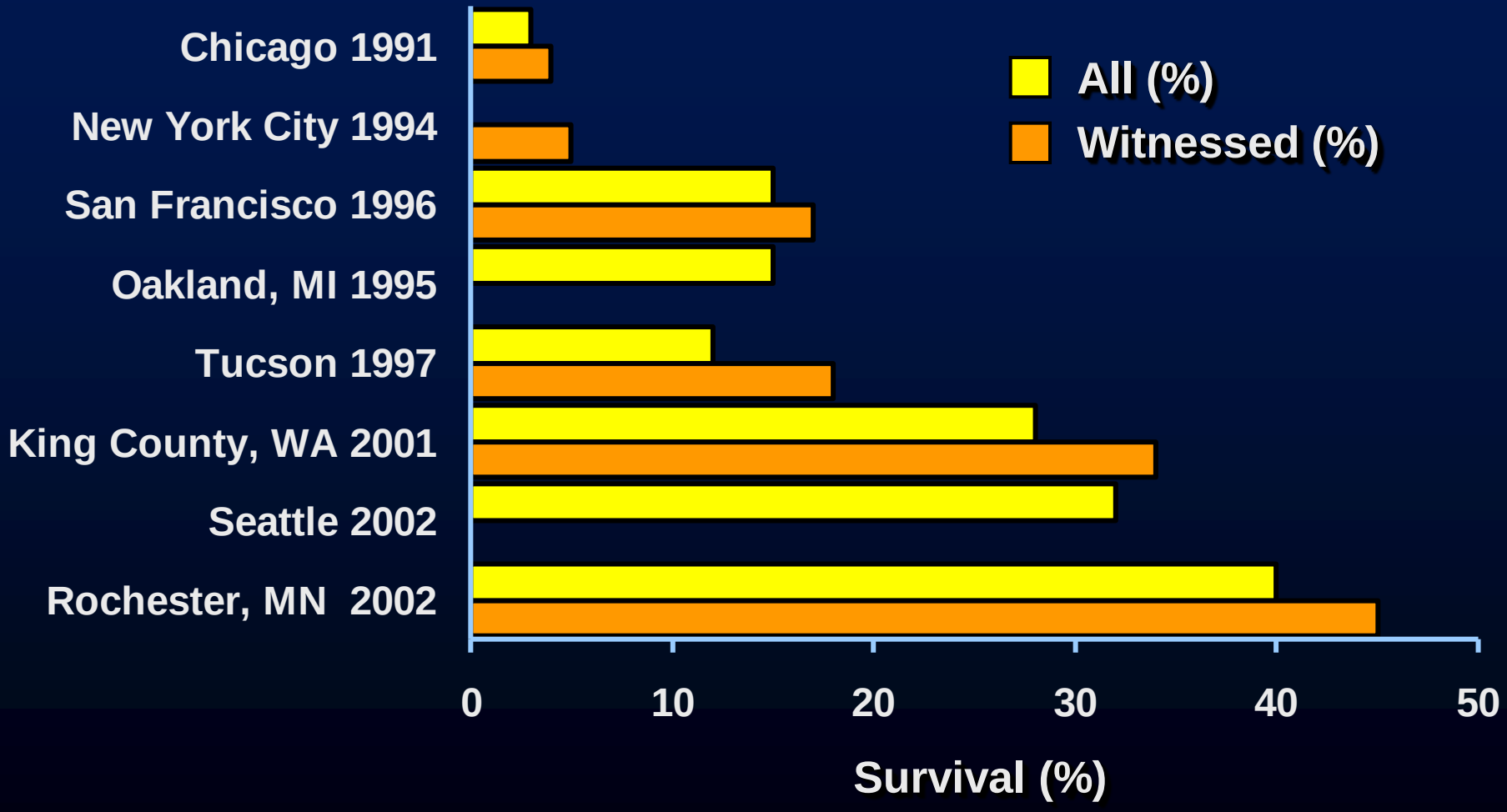
Survival After VF OHCA in USA



Bunch TJ and White RD: Mayo Proc, 2005

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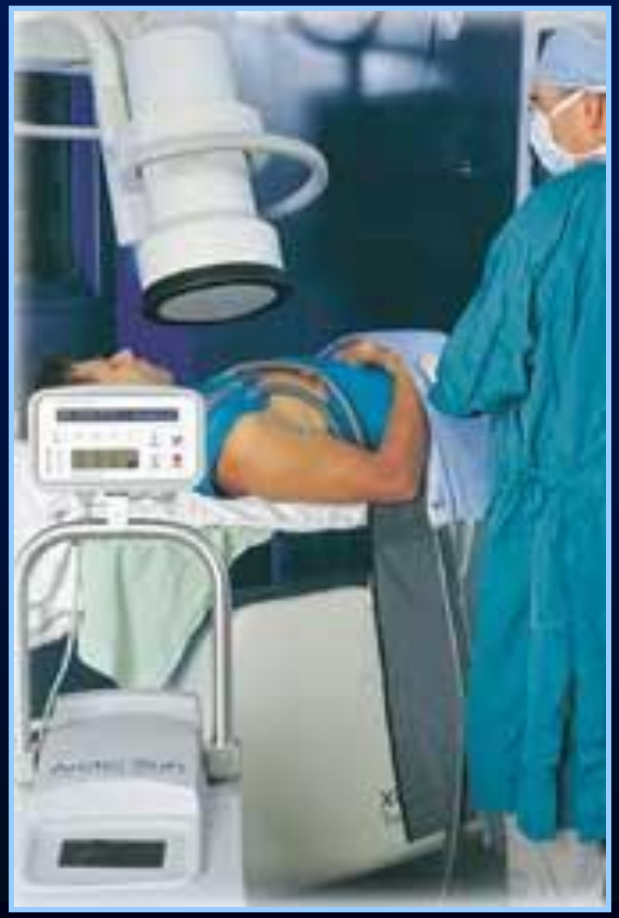
Arctic Sun 2000, Medivance

Gel pads placed on torso and limbs



Gel pads can be used with fluoroscopy

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Sudden Cardiac Death Prevention

Secondary SCD prevention

- SCD survivors, documented sustained VT/VF, syncope with inducible VT
- Recurrence 20-40% in 1 year

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Secondary SCD Prevention ICD Trials

Study	Pt No.	Underlying disease	Inclusion (exclusion criteria)	Age
AVID	6,035 screened 4,621 registry 1,885 eligible 1,016 randomized	CAD 81% EF 0.32±0.13	SCD survivors VT + syncope VT + EF ≤0.40	Mean 65±10 years
CASH	288* *58 propafenone	CAD 73% No HD 10% EF 0.46±0.19	SCD survivors VF 84%	Mean 58±11 years
CIDS	659	CAD 82% DCM 10% No HD 2% EF 0.34 ±0.14	VF; OHCA VT + syncope VT + EF ≤0.35	Mean 64±10 years

AVID Investigators: NEJM 1997; Kuck, Cappato, et al, Circ 2000; Connolly, Gent,, et al, Circ 2000

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Secondary SCD Prevention Trials

ICD vs Drugs

	AVID	CIDS	CASH
Patients (no.)	1,016	659	349
Therapy	ICD vs empiric amiodarone or guided satalol	ICD vs empiric amiodarone	ICD vs empiric amiodarone, metoprolol, or propafenone
Primary endpoint	TM	TM	TM
Drug event rate (%)	17.7	8.3	9.8
Principal finding	ICD ↓ TM by 39% (P<0.02) compared with amiodarone or sotalol group	ICD ↓ TM by 19.9% (P=0.072) compared with amiodarone group	ICD group ↓ TM by 30% (P=0.047) compared with metoprolol plus amiodarone group

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Recommendations for ICD Secondary Prevention

Class I

- Survivors of cardiac arrest due to VFib or hemodynamically unstable sustained VT after evaluation to define the cause of the event and to exclude any completely reversible causes *(level of evidence: A)*
- Structural HD and spontaneous sustained VT, whether hemodynamically stable or unstable *(level of evidence: B)*
- Syncope of undetermined origin with clinically relevant, hemodynamically significant sustained VT or VFib induced at electrophysiological study *(level of evidence: B)*

Modified from Epstein et al: JACC 51(21):2085, 2008

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Sudden Cardiac Death Prevention

Primary SCD prevention

- Patients with known underlying heart disease with increased risk of SCD
- Risks vary depending on the severity of myocardial dysfunction and other markers

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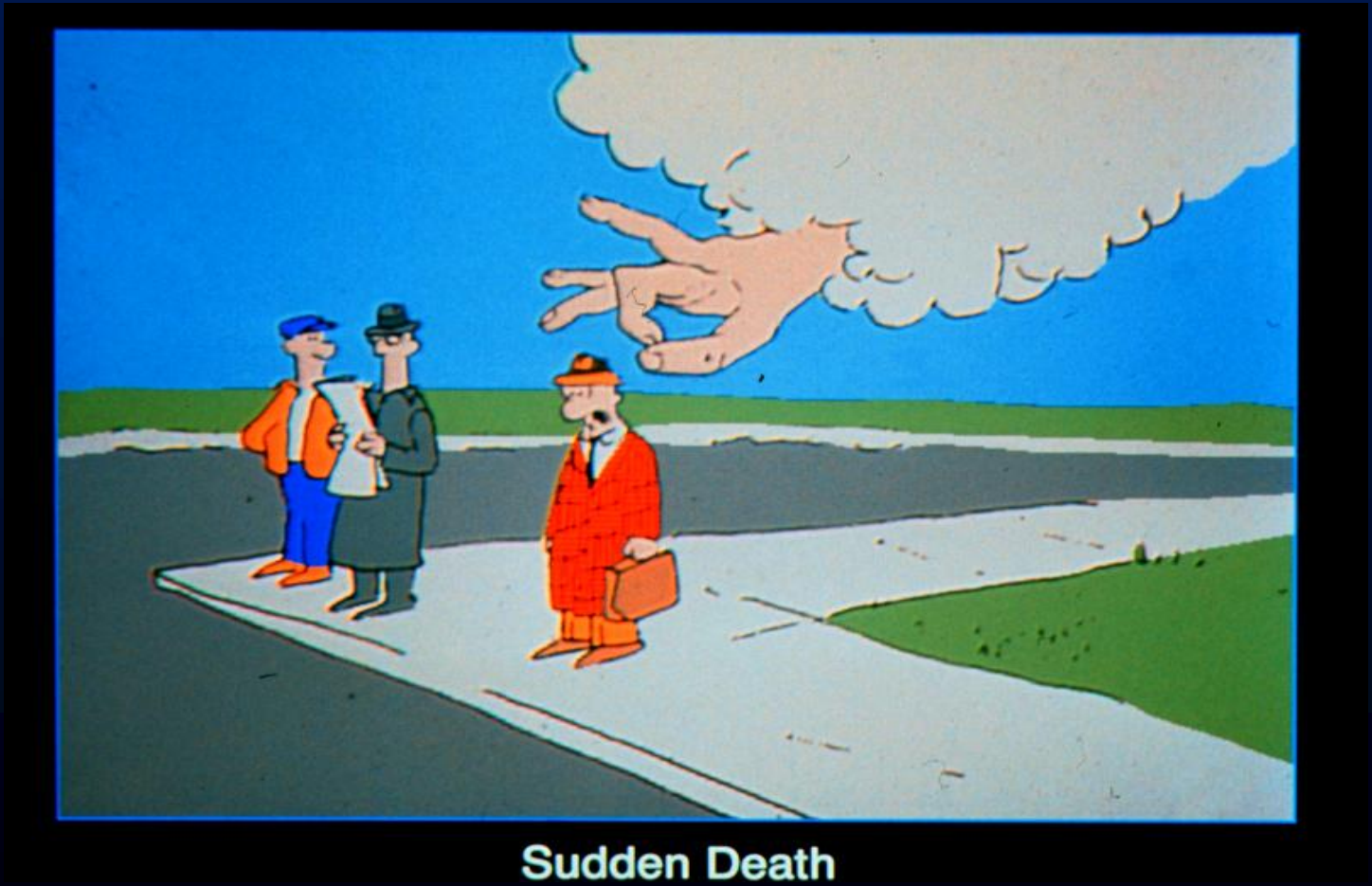
Sudden Cardiac Death
Risk Stratification and Prevention



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Risk Stratification in Patients with Heart Disease

Ventricular Arrhythmias and SCD

?

- Cardiac function
- Predictive value of NSVT on Holter
- Predictive value of EPS

Role of other methods of noninvasive risk stratification

- SAECG QRSD
- Heart rate variability (HRV)
- Baroreflex sensitivity (BRS)
- T-wave alternans QT

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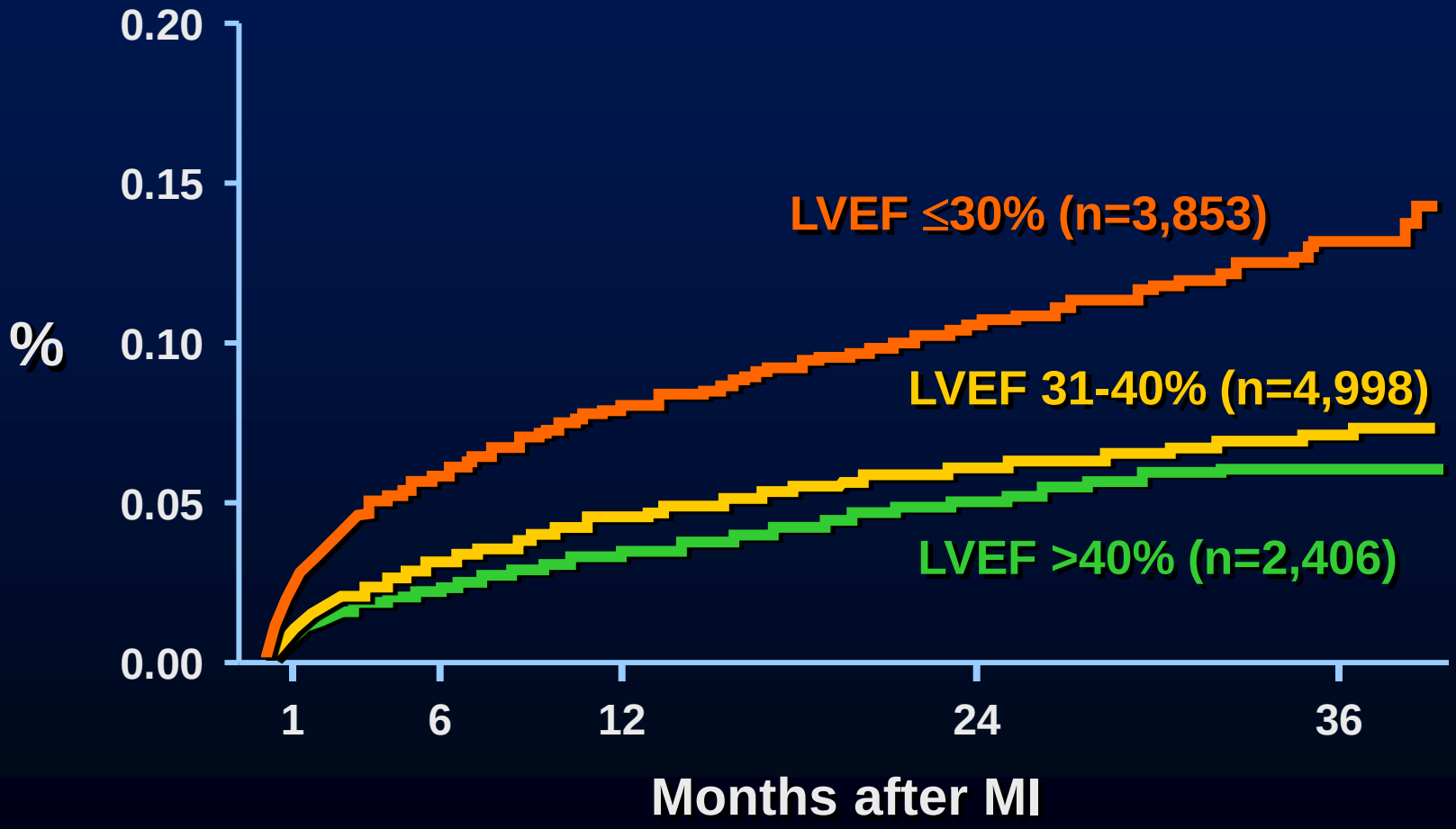
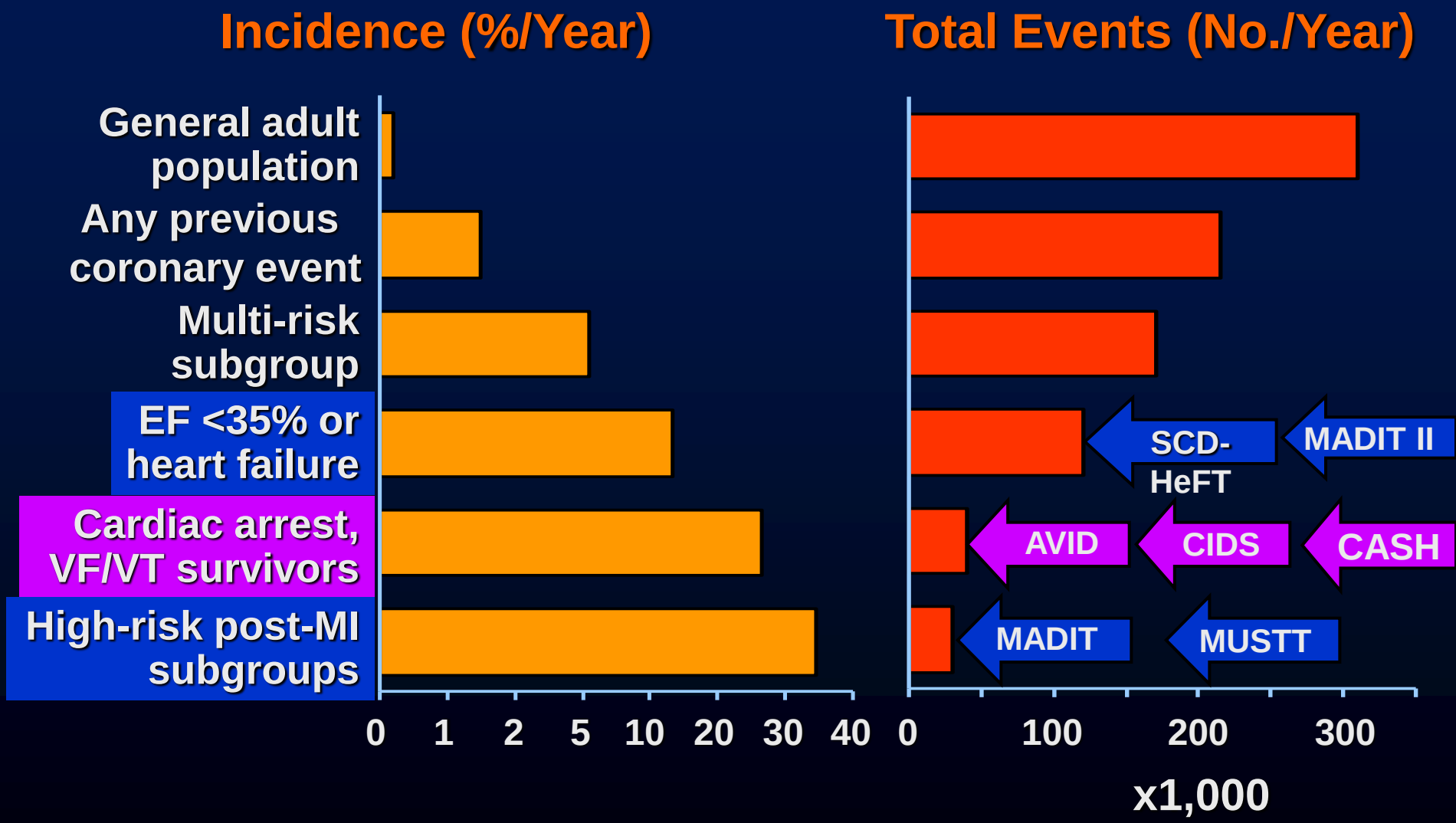
Sudden Death or Cardiac Arrest
Post MI (VALANT)



No. at risk	11,256	10,183	9,775	6,262	994

Solomon: NEJM, 2005

Risk of SCD and Populations of Patients with Cardiovascular Disease



Modified from Myerburg et al: Circ, 1998

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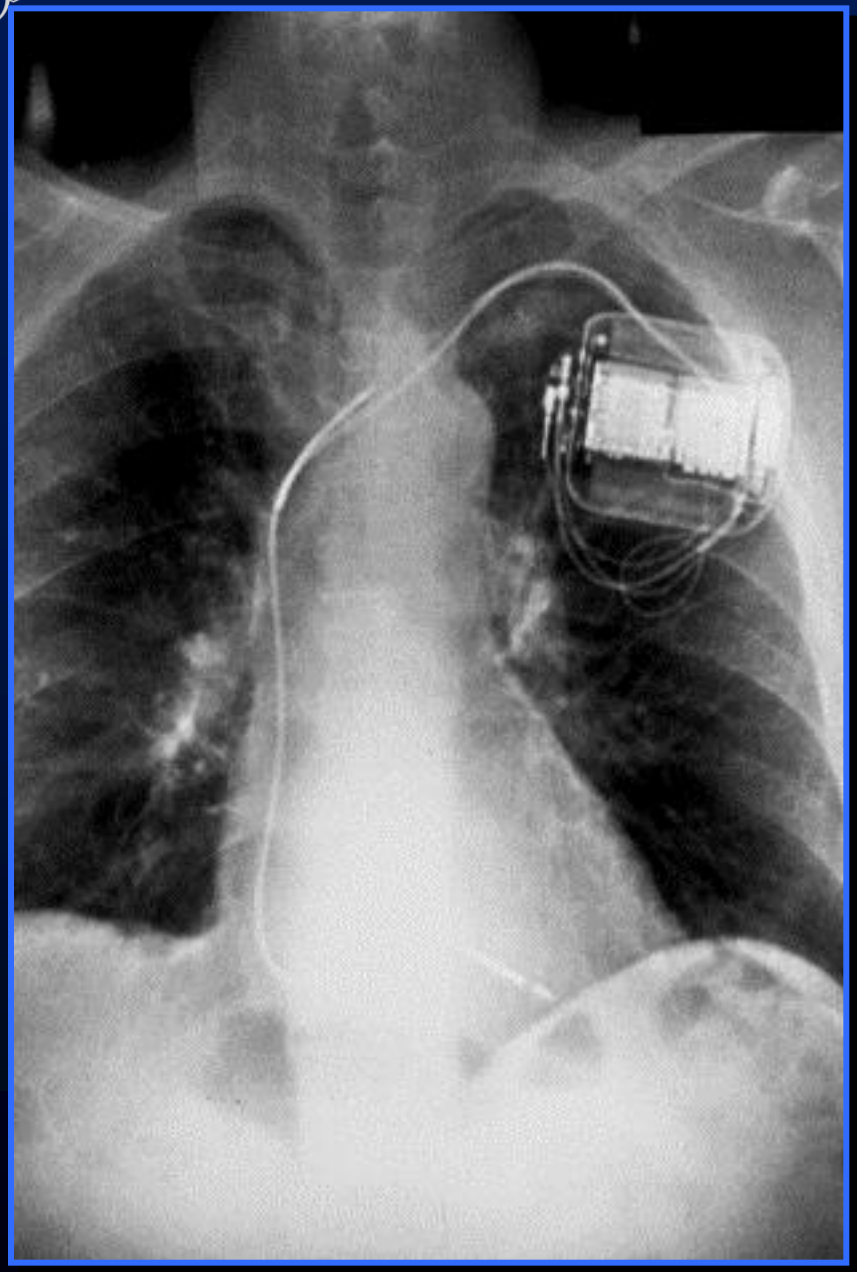


MODEL
7216A PCD™
VVICD
TACHYARRHYTHMIA
CONTROL DEVICE
PACER-
CARDIOVERTER-
DEFIBRILLATOR
GEM II DR

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ICD and Primary SCD Prevention

ICD for Primary Prevention (CAD)

- CABG-patch
- MUSTT
- MADIT 1
- MADIT 2
- SCD HeFT*
- DINAMIT
- IRIS

ICD for Primary Prevention (DCM)

- AMIOVERT
- CAT
- SCD HeFT*
- DEFINITE

Bi-V ICD for Primary Prevention (CHF)

- COMPANION (CAD and DCM)

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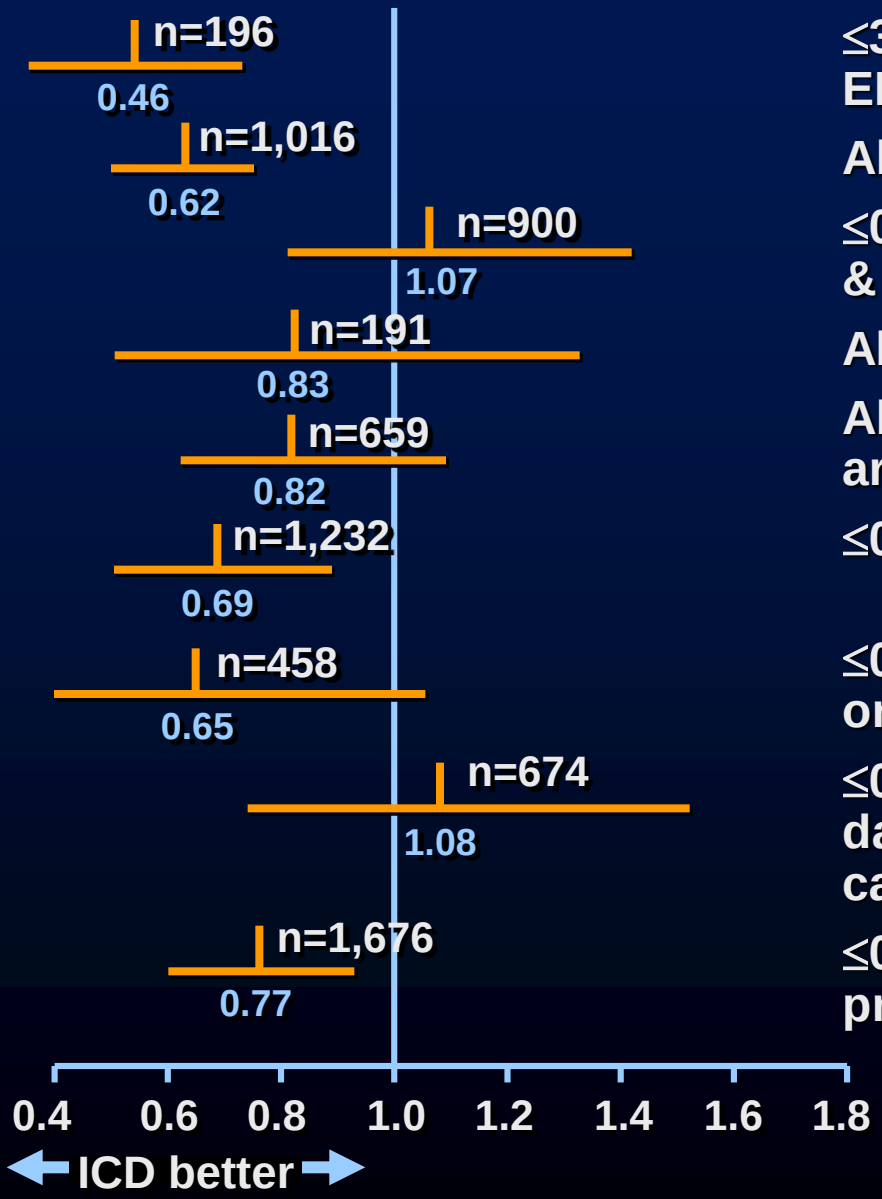
ICD Clinical Trials



Zipes et al: Circ, 2006

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Defibrillator IN Acute Myocardial Infarction Trial (DINAMIT)

- Recent MI (6-40 days)
- LVEF ≤35% and depressed HRV (SDNN ≤70 msec or 24-hr mean RR ≤750 msec
- Age 18-80 years

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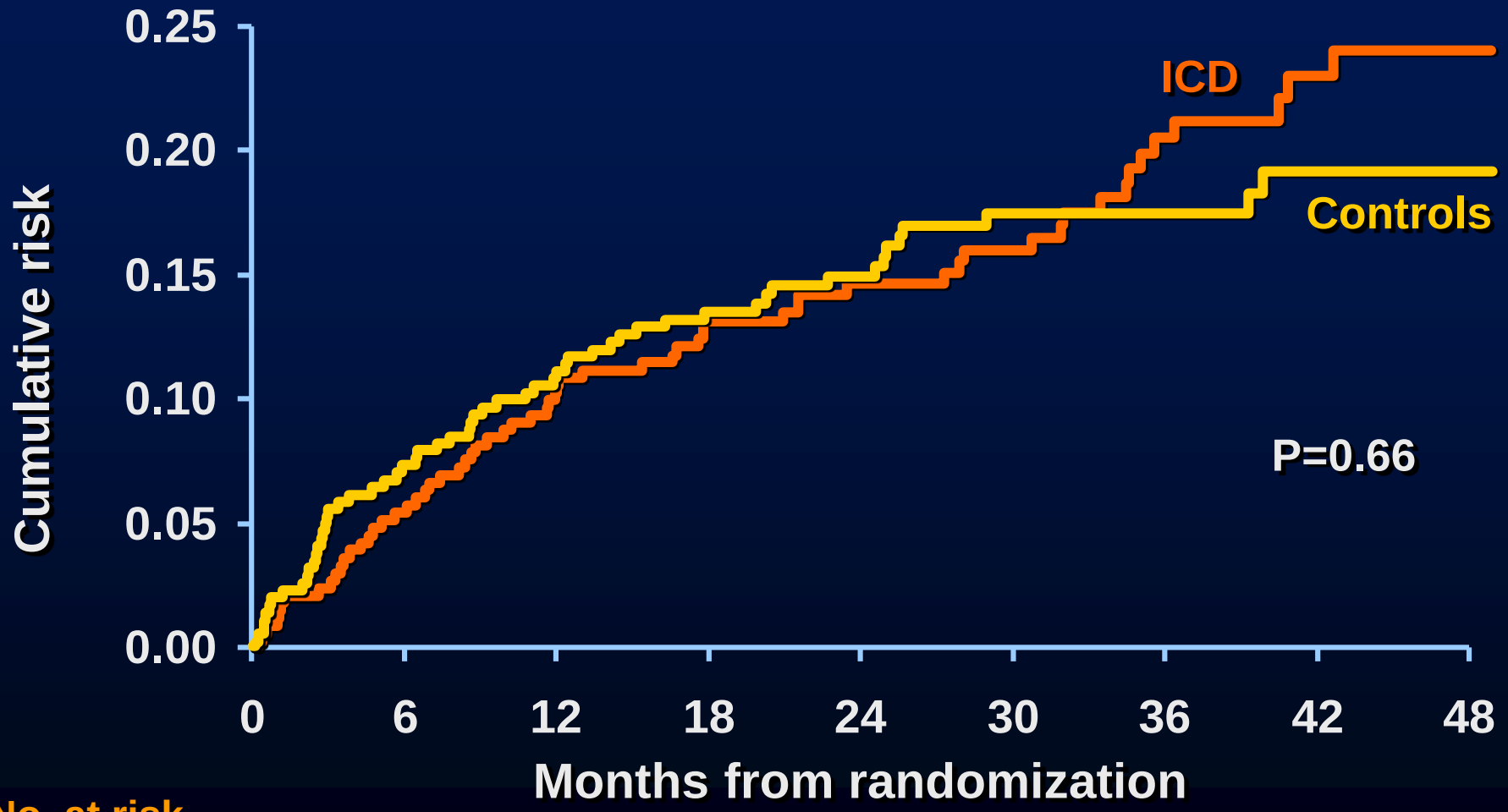
DINAMIT (All Cause Mortality)



No. at risk								
ICD	315	299	258	211	172	123	82	25
Controls	318	305	272	217	172	124	79	31

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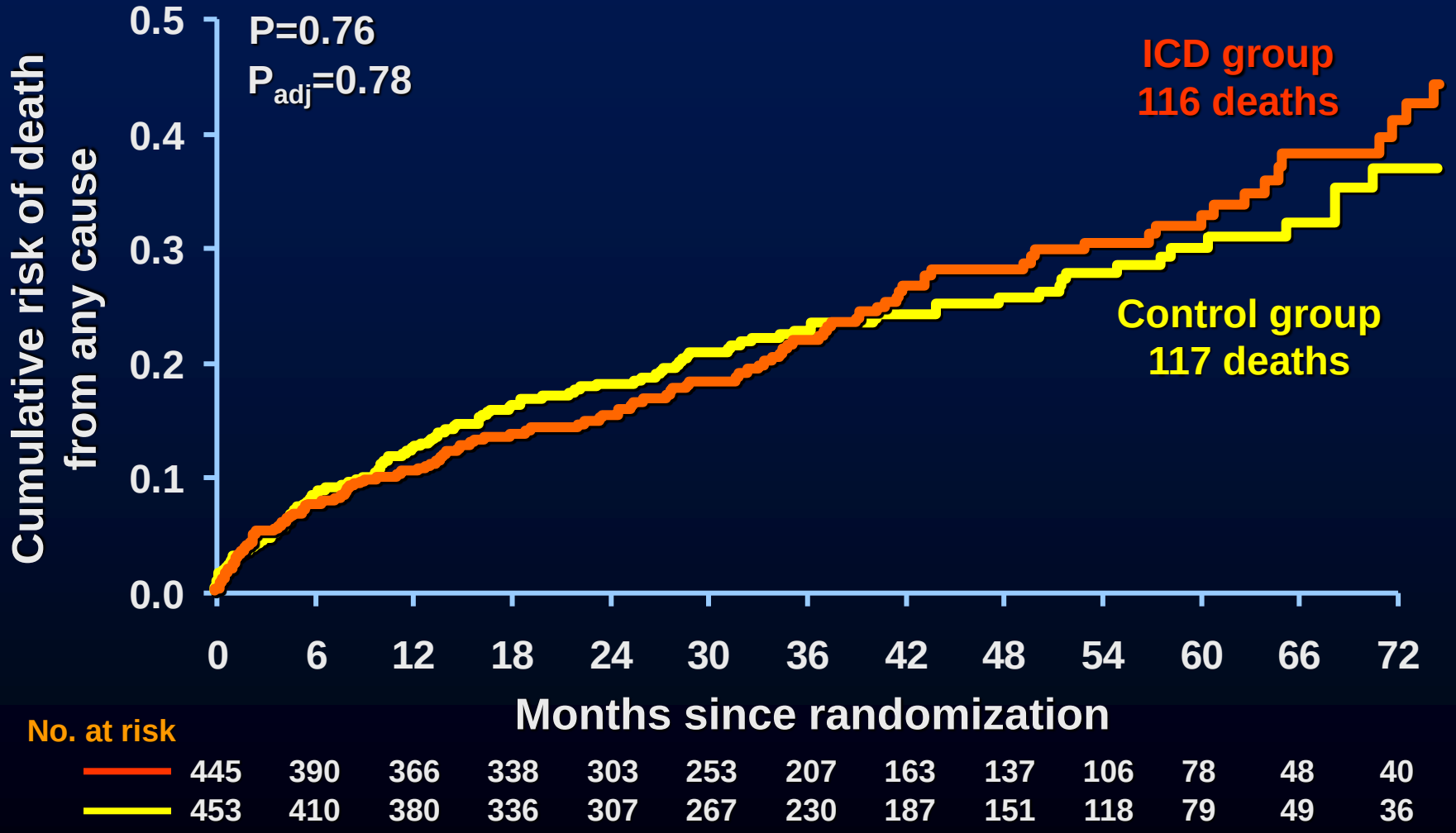
Immediate Risk Stratification Improves Survival (IRIS, Post MI 5 – 31 days, EF ≤ 40%)



Steinbeck et al: NEJM 361:1427, 2009

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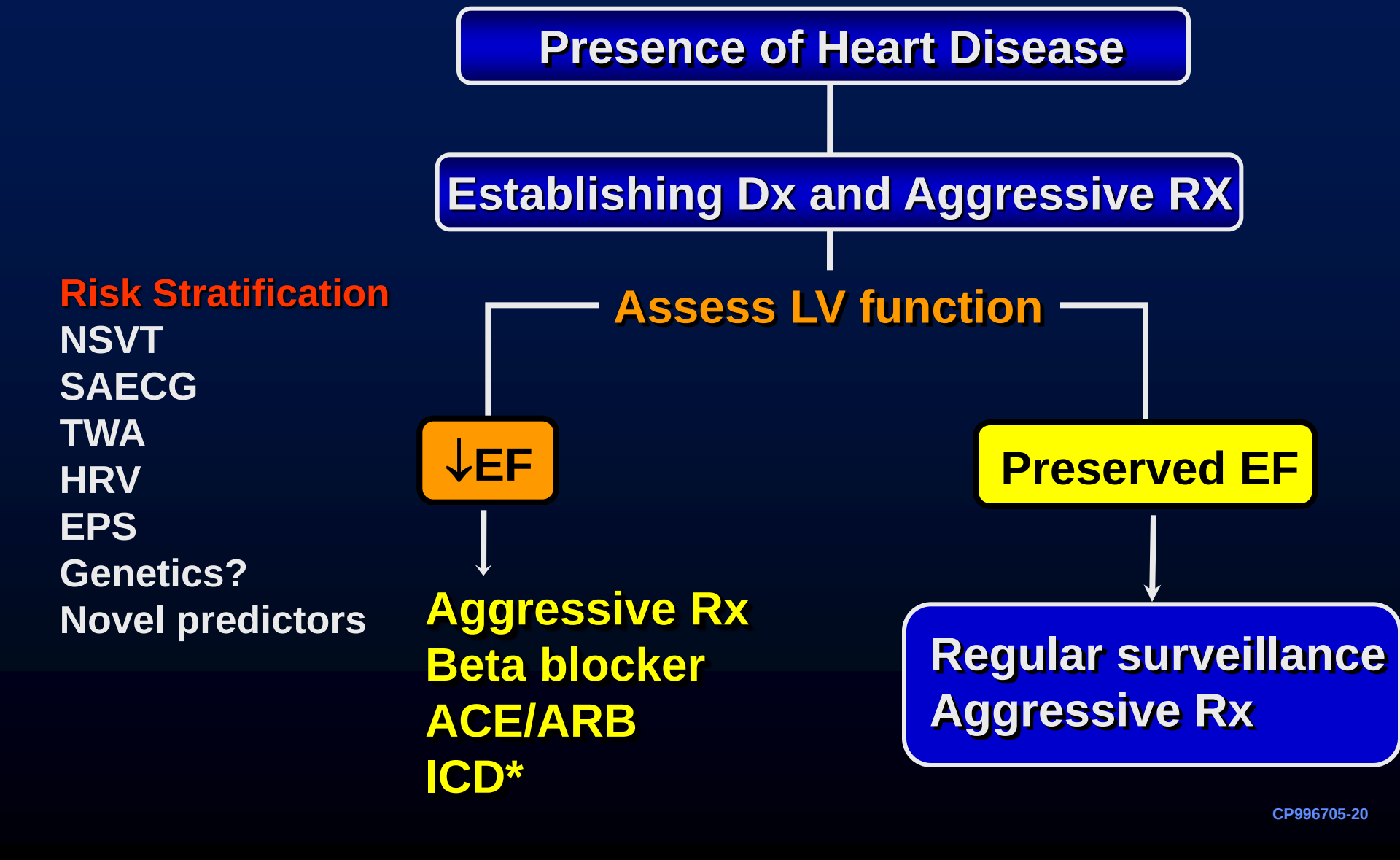
SCD Prevention in Patients with Heart Structural Disease

Practice in Evolution



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Journal of the American College of Cardiology
© 2006 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 48, No. 5, 2006
ISSN 0735-1097/06/$32.00
doi:10.1016/j.jacc.2006.07.008

ACC/AHA/ESC PRACTICE GUIDELINES—EXECUTIVE SUMMARY

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

Journal of the American College of Cardiology
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Published by Elsevier Inc.

Vol. 51, No. 21, 2008
ISSN 0735-1097/08/$34.00
doi:10.1016/j.jacc.2008.02.033

PRACTICE GUIDELINE: EXECUTIVE SUMMARY

ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: Executive Summary

A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices)

Developed in Collaboration With the American Association for Thoracic Surgery and Society of Thoracic Surgeons

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*Recused from voting on guideline recommendations (see Section 1.2, "Document Review and Approval," for more details); †American Association for Thoracic Surgery and Society of Thoracic Surgeons

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Recommendations for ICD Primary Prevention

Class I

- LVEF ≤35%, hx of MI >40 days, NYHA functional class II or III *(level of evidence: A)*
- Nonischemic dilated cardiomyopathy, LVEF ≤35%, NYHA functional class II or III *(level of evidence: B)*

Epstein et al: JACC 51(21):2085, 2008

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Recommendations for ICD Primary Prevention

Class I

- LVEF< 30%, > 40 days post MI, NYHA functional class I *(level of evidence: A)*
- Nonsustained VT, prior MI, LVEF <40%, and inducible VFib or sustained VT at electrophysiological study *(level of evidence: B)*

Epstein et al: JACC 51(21):2085, 2008

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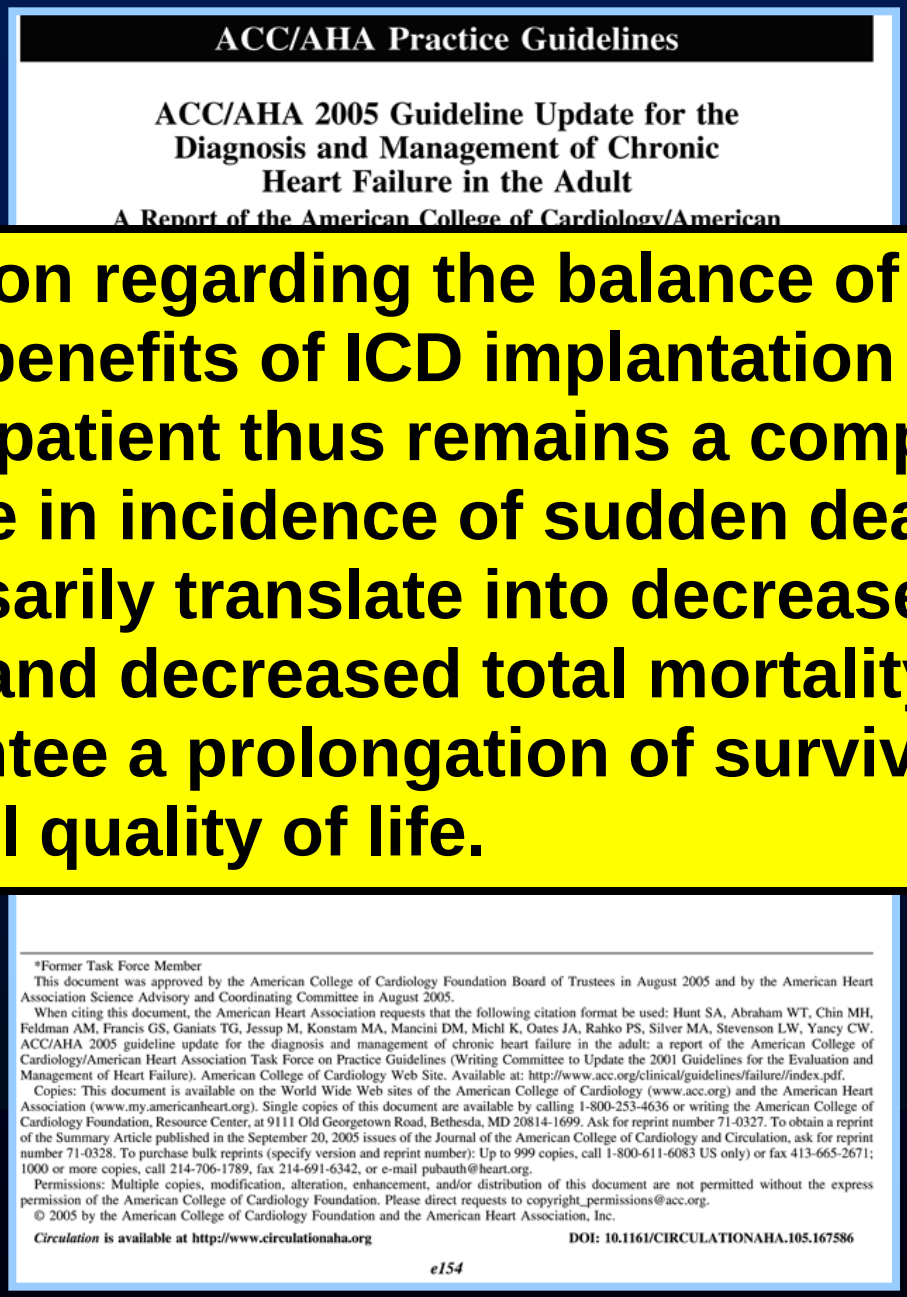

ACC/AHA Practice Guidelines

ACC/AHA 2005 Guideline Update for the Diagnosis and Management of Chronic Heart Failure in the Adult

A Report of the American College of Cardiology/American

The decision regarding the balance of potential risks and benefits of ICD implantation for an individual patient thus remains a complex one. A decrease in incidence of sudden death does not necessarily translate into decreased total mortality, and decreased total mortality does not guarantee a prolongation of survival with meaningful quality of life.

*Former Task Force Member

This document was approved by the American College of Cardiology Foundation Board of Trustees in August 2005 and by the American Heart Association Science Advisory and Coordinating Committee in August 2005.

When citing this document, the American Heart Association requests that the following citation format be used: Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG, Jessup M, Konstam MA, Mancini DM, Michl K, Oates JA, Rahko PS, Silver MA, Stevenson LW, Yancy CW. ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Update the 2001 Guidelines for the Evaluation and Management of Heart Failure). American College of Cardiology Web Site. Available at: http://www.acc.org/clinical/guidelines/failure//index.pdf.

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Circulation is available at http://www.circulationaha.org DOI: 10.1161/CIRCULATIONAHA.105.167586

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ICD & SCD Prevention

Torino 2011