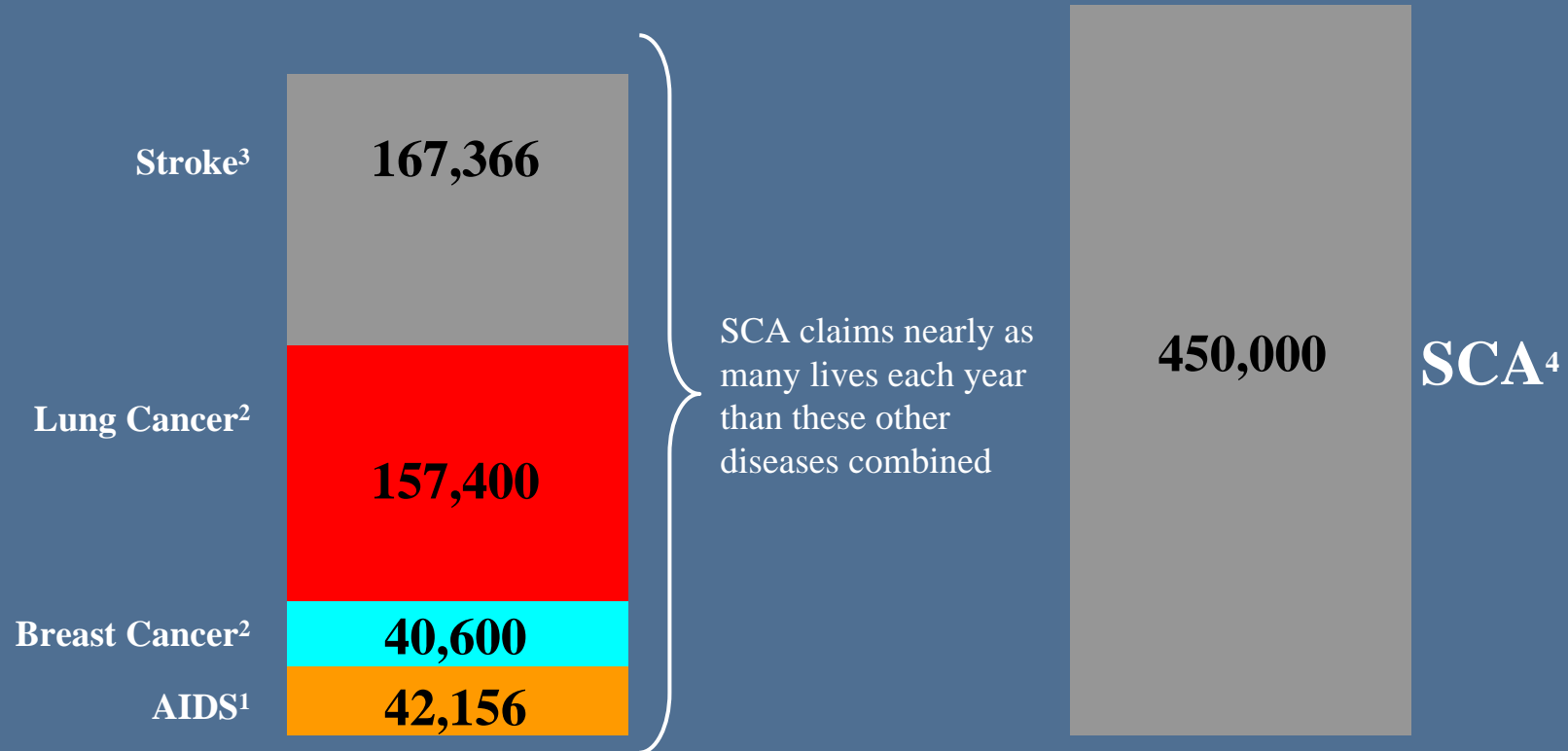


Implantable Defibrillators: Who Should Get One?

Malcolm Kirk, M.D., F.A.C.C.

Our Target:

Magnitude of Sudden Cardiac Arrest (SCA) in the U.S.



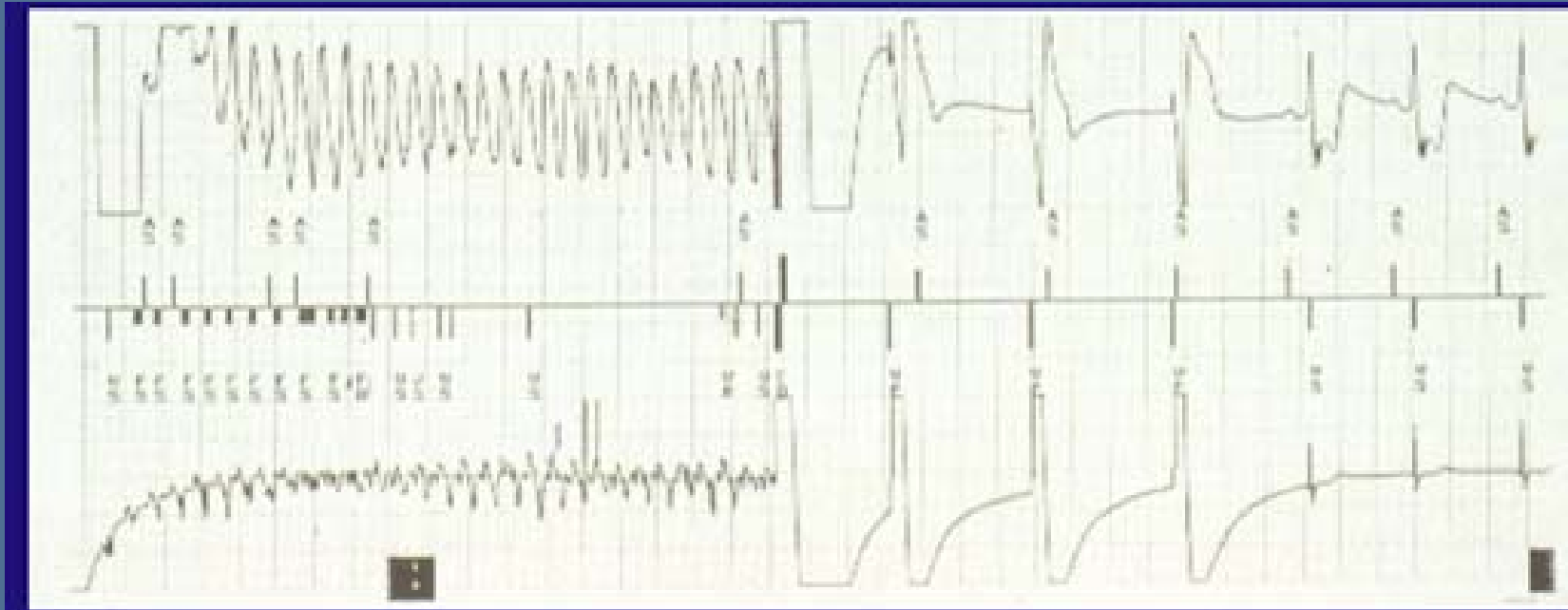
¹ U.S. Census Bureau, *Statistical Abstract of the United States: 2001*.

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

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

⁴ Zheng Z. *Circulation*. 2001;104:2158-2163.

Implanted Defibrillator (ICD) Therapy for Sudden Cardiac Death (SCD)



Defibrillator Indications

- Purpose of a Defibrillator (ICD):
 - Improve prognosis
- The vast majority of ICD implants now are for primary prevention.
 - Strictly guideline-driven
- Patient must be interested in therapy for prognosis



Applying Classification of Recommendations and Level of Evidence

Class I	Class IIa	Class IIb	Class III
<i>Benefit >>> Risk</i>	<i>Benefit >> Risk</i> <i>Additional studies with focused objectives needed</i>	<i>Benefit ≥ Risk</i> <i>Additional studies with broad objectives needed; Additional registry data would be helpful</i>	<i>Risk ≥ Benefit</i> <i>No additional studies needed</i>
Procedure/ Treatment SHOULD be performed/ administered	IT IS REASONABLE to perform procedure/administer treatment	Procedure/Treatment MAY BE CONSIDERED	Procedure/Treatment should NOT be performed/administered SINCE IT IS NOT HELPFUL AND MAY BE HARMFUL

Alternative Phrasing:

should is recommended is indicated is useful/effective/ beneficial	is reasonable can be useful/effective/ beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown /unclear/uncertain or not well established	is not recommended is not indicated should not is not useful/effective/beneficial may be harmful
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Implanted Defibrillators – Basis for recommendations

- Large Randomized Clinical Trials of Therapy:
 - Secondary Prevention – Cardiac Arrest ...The initial group
 - AVID
 - CIDS
 - CASH
 - Primary Prevention – Low EF ... Expanding indications
 - Low EF due to prior MI
 - MADIT
 - MUSTT
 - MADIT II
 - SCD HeFT
 - Low EF due to idiopathic Dilated Cardiomyopathy
 - SCD Heft
- Observational studies, uncontrolled trials, expert opinion
 - Primary prevention – other substrates
 - HOCM
 - Brugada
 - LQT



The Problem with current primary prevention: Incidence of SCD in Specific Populations and Annual SCD Numbers

GROUP

General population

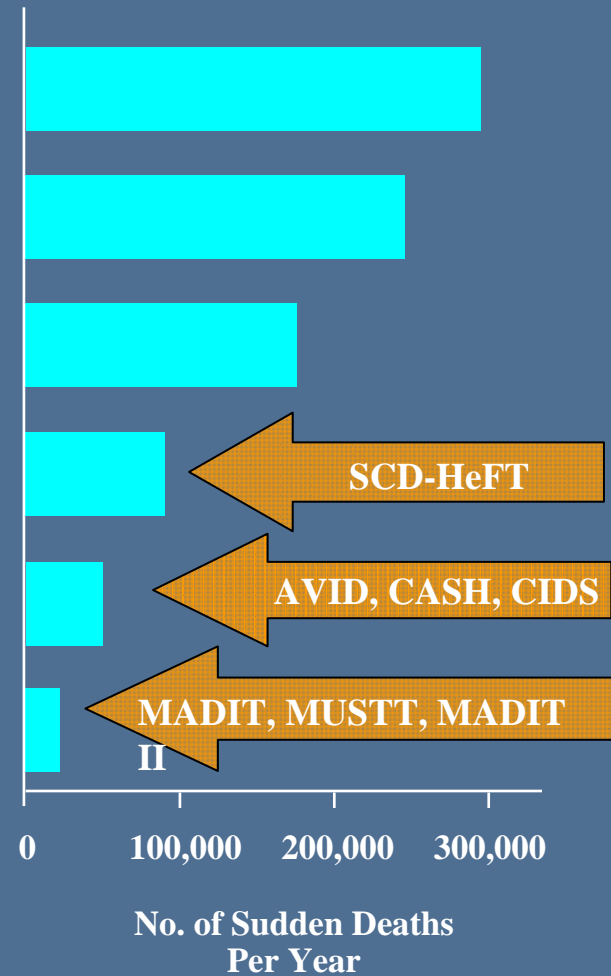
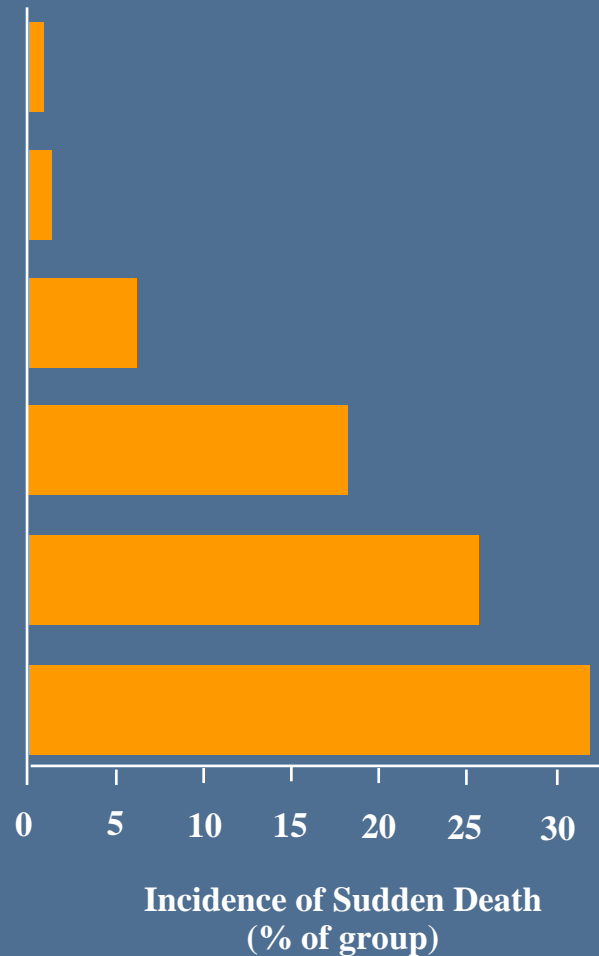
Patients with high coronary-risk profile

Patients with previous coronary event

Patients with EF < 35%, congestive heart failure

Patients with previous out-of-hospital cardiac arrest

Patients with previous MI, low EF and VT



Class I

Secondary Prevention

- Cardiac Arrest survivors -- due to ventricular fibrillation or hemodynamically unstable sustained VT
 - after evaluation to define the cause of the event
 - exclude any completely reversible causes.
 - exclude patients within 48 hours of an MI
- Spontaneous sustained VT.
 - Structural heart disease
 - “whether hemodynamically stable or unstable” [New:]
(AVID, CASH, CIDS cited)
- Syncope of undetermined origin
 - sustained VT or VF induced at electrophysiological study.
 - clinically relevant,
 - hemodynamically significant



Class I

Primary Prevention

- EF < 30%
 - Due to prior MI
- EF ≤ 35%
 - (Any Cause)
 - NYHA functional Class II or III
- EF < 40%
 - Due to prior MI
 - Spontaneous non-sustained VT
 - Inducible for sustained VT or VF at EP Study

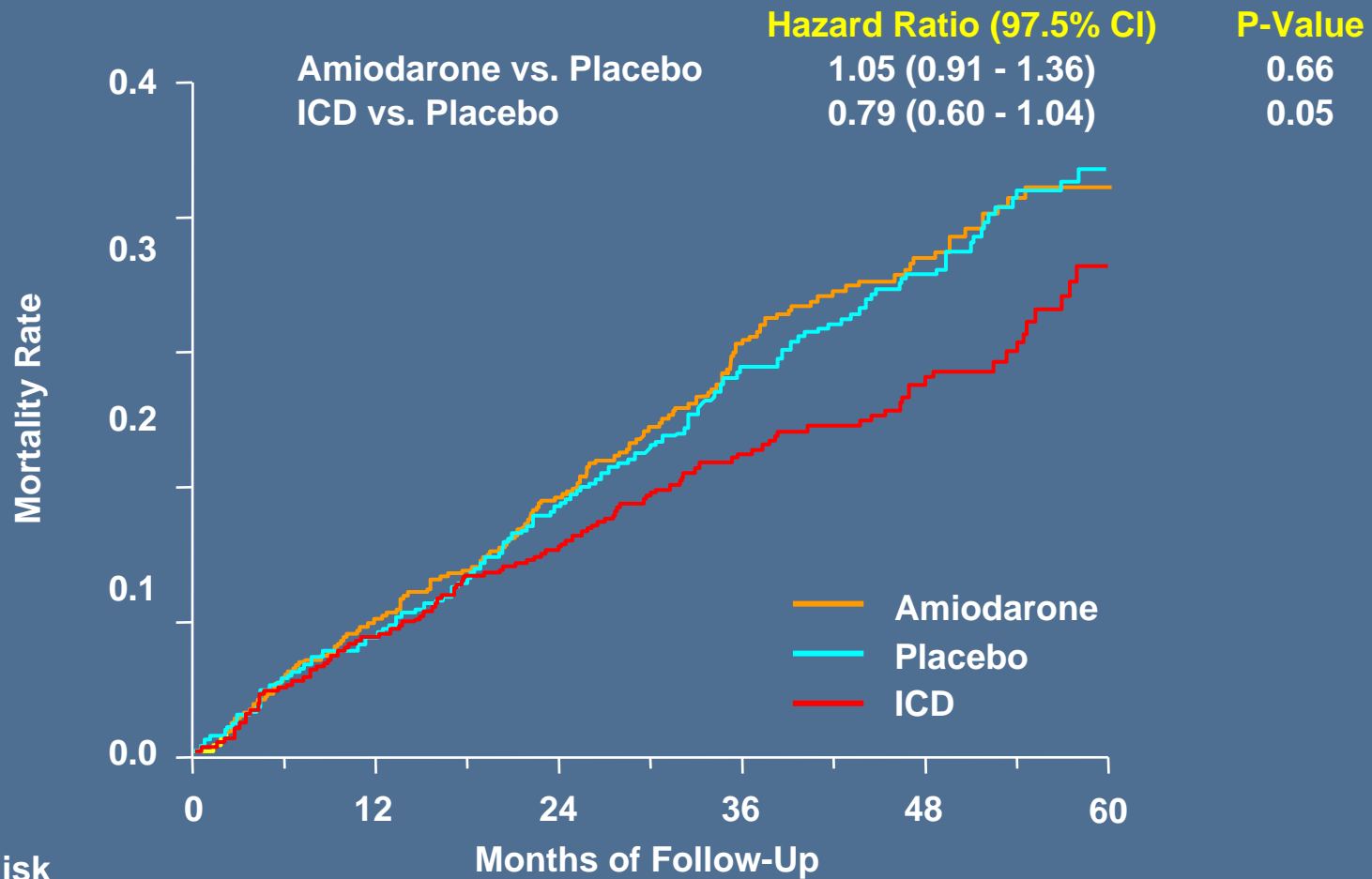


General requirements

- > 40 days post MI
- Receiving optimal medical therapy
- Expected survival > 1 year with good functional status



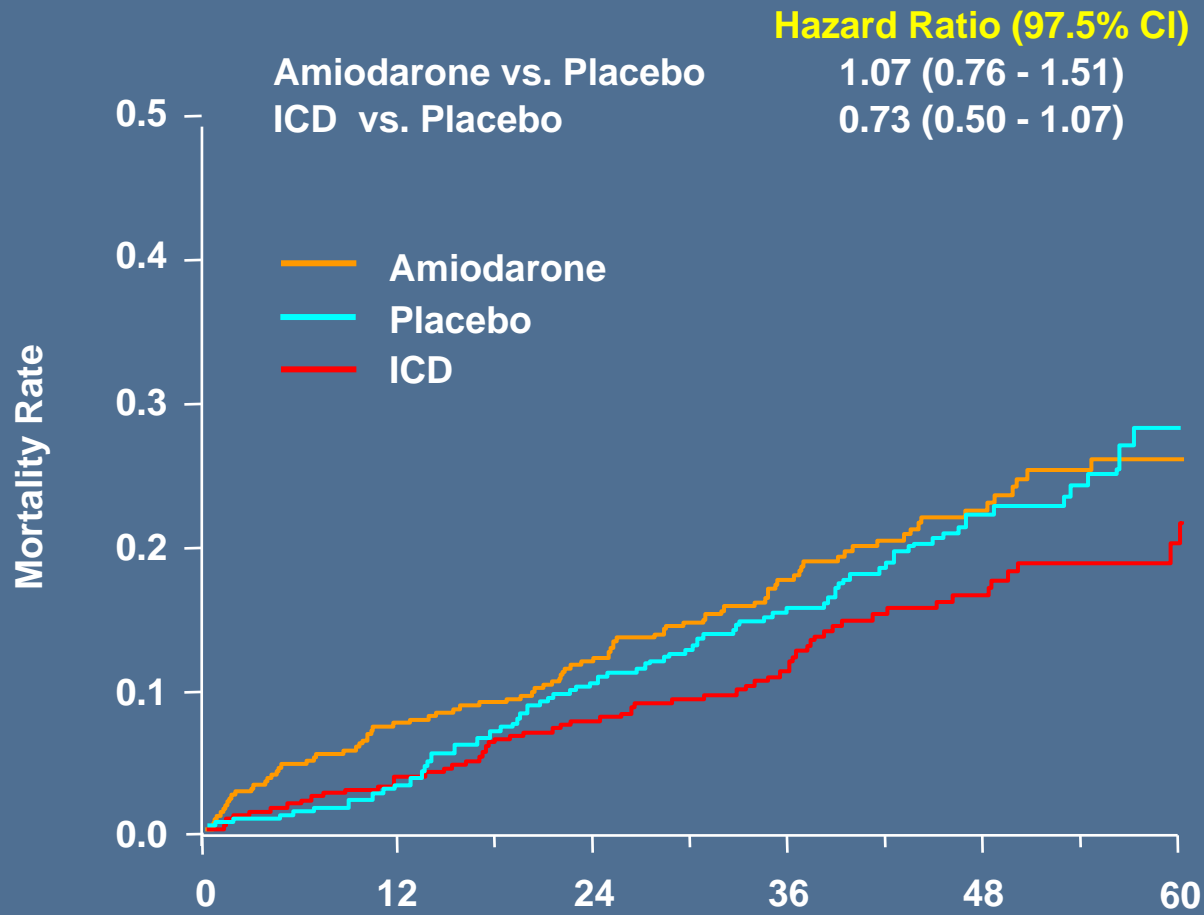
SCD-HeFT Mortality Rate Ischemic CHF Patients



No. at Risk

	0	12	24	36	48	60
Amiodarone	426	384	346	227	130	46
Placebo	453	415	370	244	152	48
ICD	431	395	365	244	144	48

SCD-HeFT Mortality Rate Non-Ischemic CHF Patients



No. at Risk	Months of Follow-Up					
	0	12	24	36	48	60
Amiodarone	419	388	369	257	150	51
Placebo	394	382	354	261	152	41
ICD	398	383	368	257	160	55

Bardy GH. *N Engl J Med.* 2005;352:225-237.

Class IIa

Primary Prevention

- Nonischemic DCM
 - Unexplained syncope
 - Significant LV dysfunction
- Sustained VT (not causing cardiac arrest) and
 - Normal or near-normal ventricular function.
- Hypertrophic Cardiomyopathy
 - Non-sustained VT
 - Syncope
 - Fam Hx SCD
 - LV thickness $\geq 30\text{mm}$
 - Paradoxical BP response to exercise
- Arrhythmogenic right ventricular dysplasia/cardiomyopathy (ARVD/C)
 - VT at EP Study
 - Severe RV dilation / extensive involvement / LV involvement
 - Unexplained syncope
 - High risk genotypes
- Long-QT syndrome
 - Syncope and/or VT while receiving beta blockers.

Class Ila

Primary Prevention

- Awaiting transplantation (at home).
- Brugada syndrome
 - syncope.
 - documented VT without cardiac arrest.
- Catecholaminergic polymorphic VT
 - syncope OR
 - documented sustained VT
 - while on beta blockers.
- Cardiac sarcoidosis,
- Giant cell myocarditis,
- Chagas disease



Class IIb

Primary Prevention

- EF \leq 35% -- Non-ischemic CM
 - NYHA functional Class I
- Long-QT syndrome
 - risk factors for SCD.
- Syncope AND
 - advanced structural heart disease
 - negative work-up
- Familial cardiomyopathy Fam Hx sudden death.
- LV Noncompaction



Class III

Contraindicated

- Patients who do not have a reasonable expectation of survival with an acceptable functional status for at least 1 year,
- Incessant VT or VF.
- Significant psychiatric illnesses
 - that may be aggravated by device implantation or
 - that may preclude systematic follow-up.
- NYHA Class IV patients
 - Drug-refractory congestive heart failure
 - Not candidates for
 - cardiac transplantation or
 - cardiac resynchronization therapy defibrillators (CRT-D).

Class III

Contraindicated

- Syncope of undetermined cause
 - without inducible ventricular tachyarrhythmias
 - without structural heart disease.
- VF or VT is amenable to surgical or catheter ablation
 - e.g.,
 - atrial arrhythmias associated with the Wolff-Parkinson-White syndrome,
 - RV or LV outflow tract VT,
 - idiopathic VT
 - fascicular VT in the absence of structural heart disease).
- Ventricular tachyarrhythmias due to a completely reversible disorder
 - in the absence of structural heart disease
 - (e.g., electrolyte imbalance, drugs, or trauma).

Primary Prevention ICD Summary

-- The Main Targets

- EF \leq 30%
+ prior MI
- EF \leq 35%
+ class II or III CHF
- EF \leq 40%
+ prior MI AND positive EP Study

