



The Role of ICD in Primary Prevention


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Topics Today

1. Important and impact of ICD in primary prevention
2. Risk stratification for ICD therapy
3. Appropriate use of ICD primary prevention therapy
4. Rarely appropriate co morbid for ICD primary prevention therapy
5. 1.5 ICD indication

Common think of ICD primary prevention therapy

ICD Therapy Practice in South Asia



Most of the ICD's implanted are for Secondary Prevention

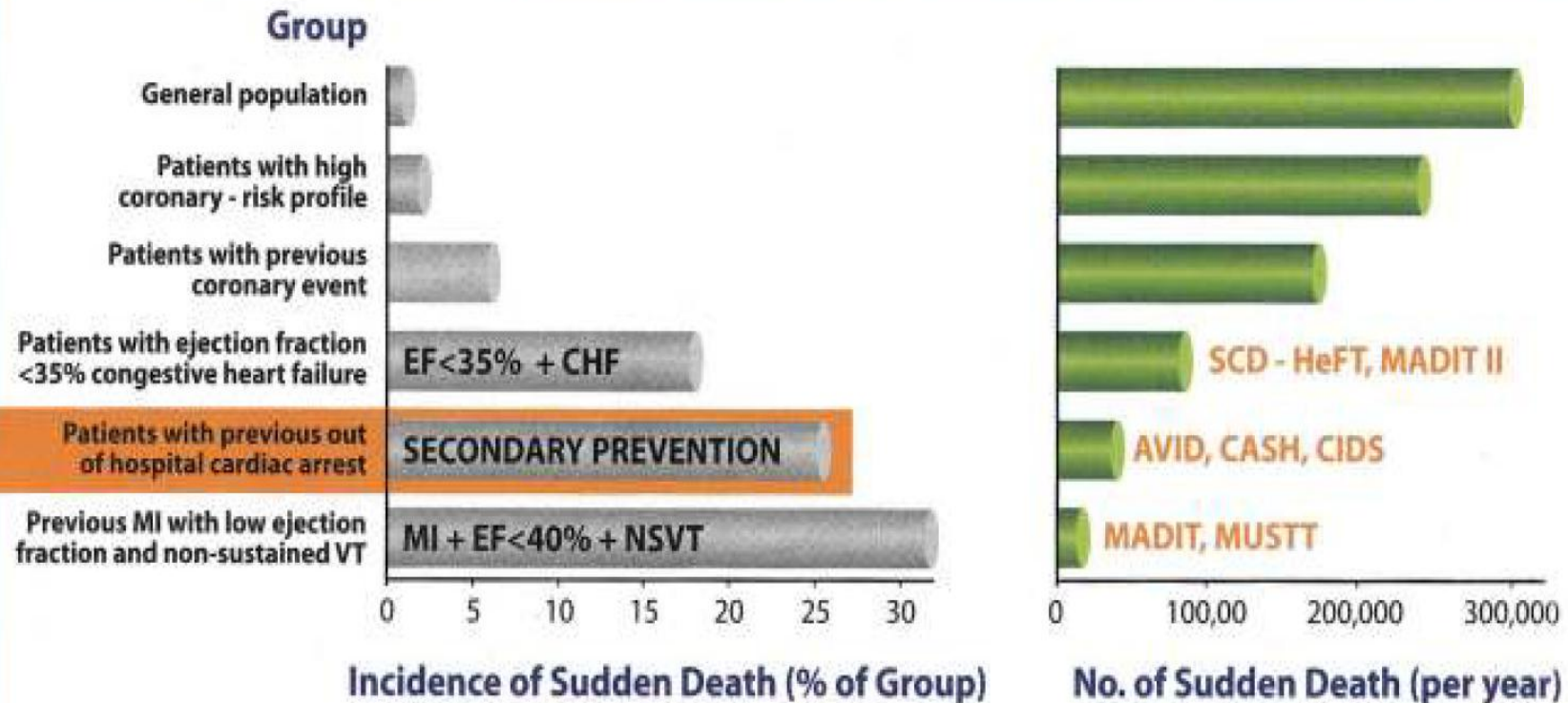
- SCA survivors and patients with VT and low EF
- Very few lives are saved

Primary Prevention is not Practiced

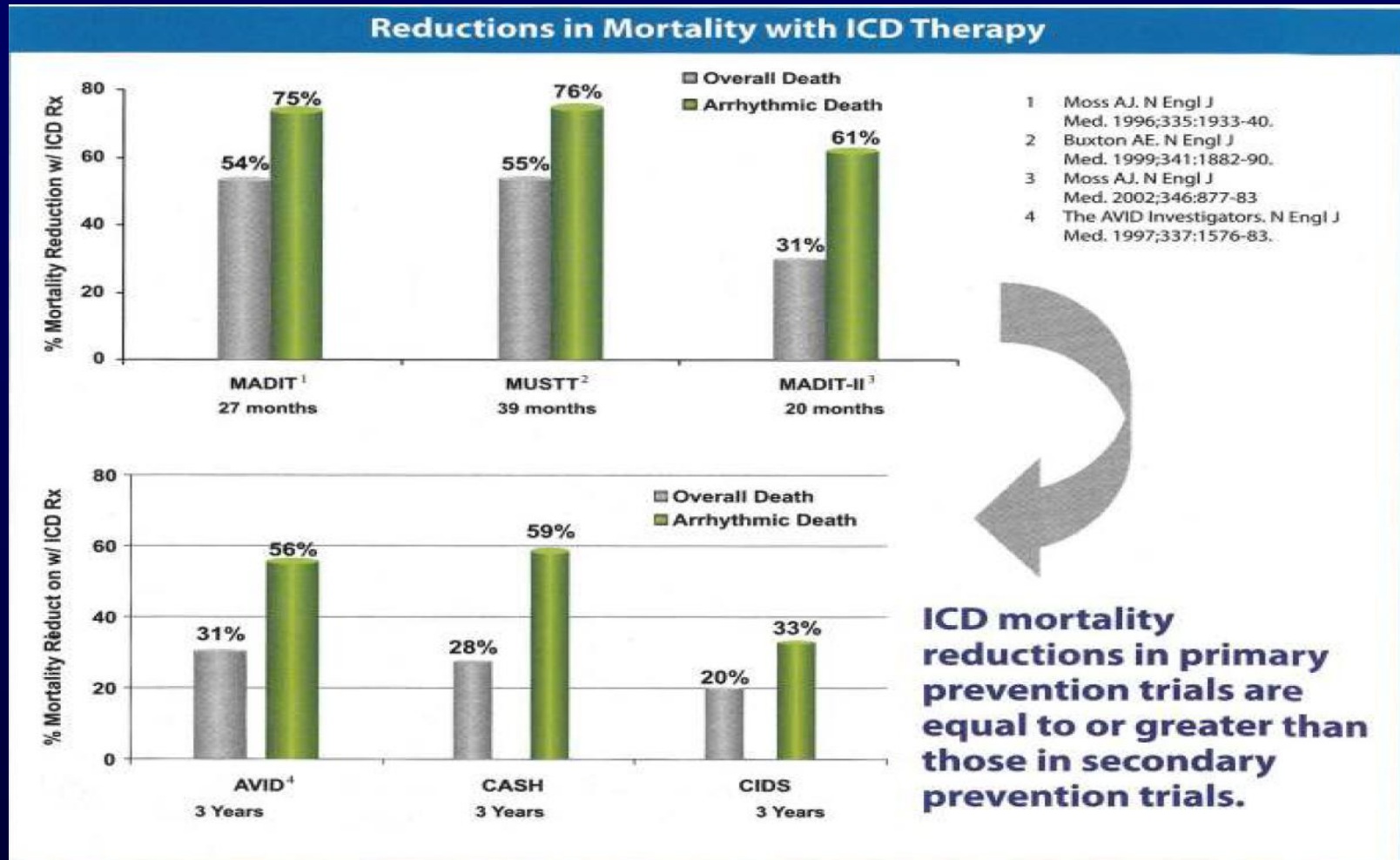
- Perception is that the primary prevention population's risk is not high enough to justify the cost and morbidity of ICD therapy

Important of Primary Prevention

Primary Prevention Patients have Similar Risk as Secondary Prevention Patients



Impact of ICD in mortality

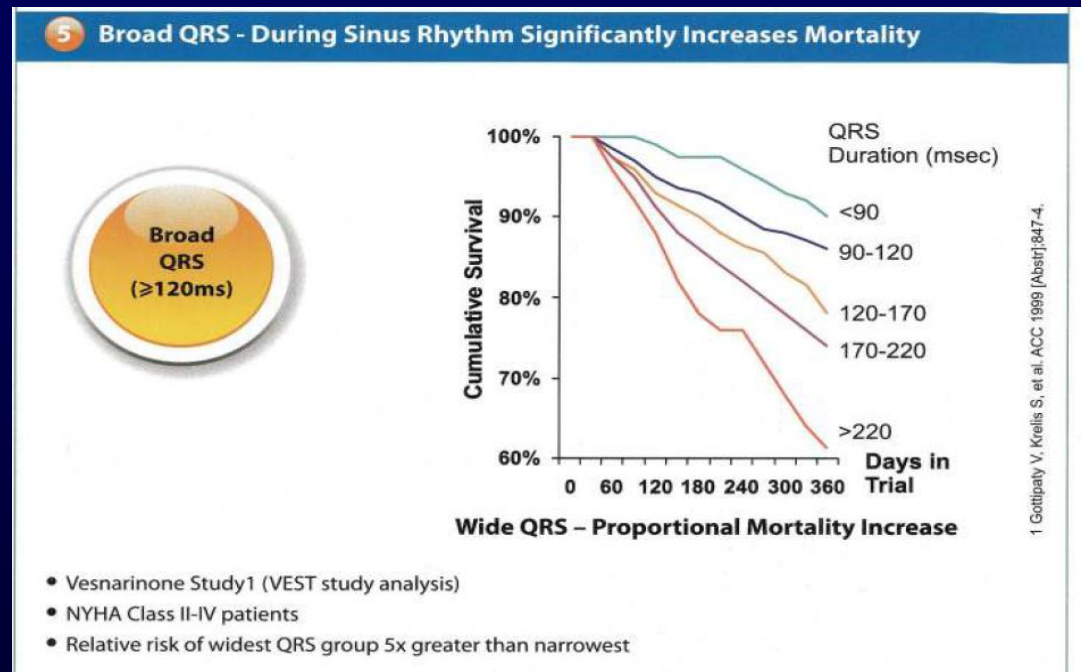


Risk stratification for ICD therapy

- Incidence of SCD in unselected adult population- only 2 per 1000 p/yr
- Currently : **LVEF**- 1^o factor for ICD
- **LVEF**- most consistent & powerful predictor of all-cause & cardiac mortality in IHD & DCM
- Others : SAECG, ventricular arrhythmia, T alternans, autonomic function, EP study

Standard ECG

- **Prolonged QRS duration** (usually ≥ 120 ms) is independent predictors of SCD
- **Prolonged QTc** (> 500 ms in long-QT synd) and familial short-QTc (≤ 300 ms) indicate an \uparrow risk of SCD



Invasive evaluation of SCD

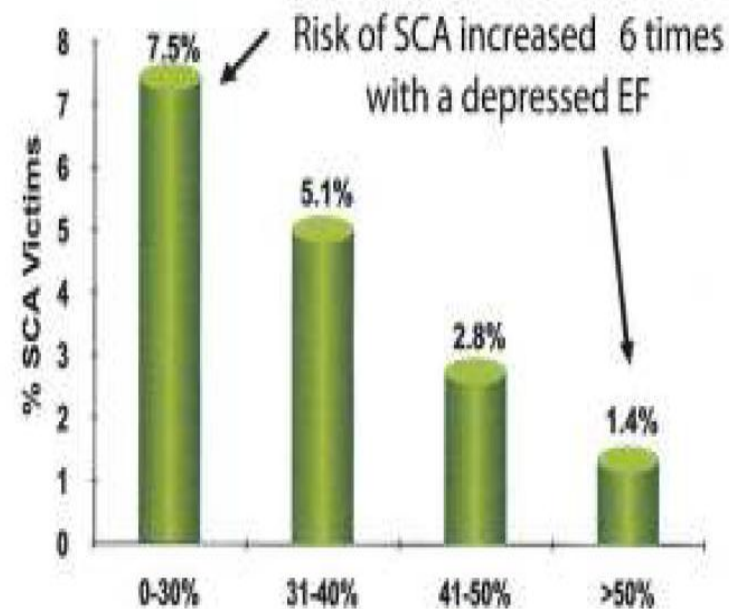
- IHD - inducibility of sustained VT during EPS
well-established marker of SCD
- Limitations-
 - Relatively high number of false negative
 - Non-inducibility of VT may not imply low risk
 - DCM-value of EPS- controversial

LVEF and NYHA

- LVEF- most consistent & powerful predictor of all-cause & cardiac mortality in IHD & DCMP
- NYHA- Despite subjective, imprecise- simple bedside potent risk-stratification tool
- Degree of NYHA class- Not linearly related
- **NYHA classes II & III** - much more likely arrhythmia than class IV
- Pts with NYHA IV - ↑mortality from progressive pump failure
- Primary prevention ICD trials have excluded pts with NYHA IV

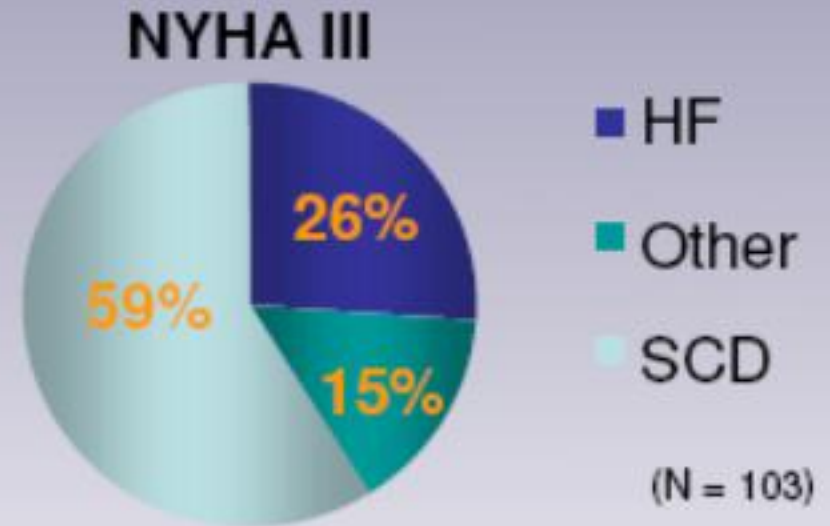
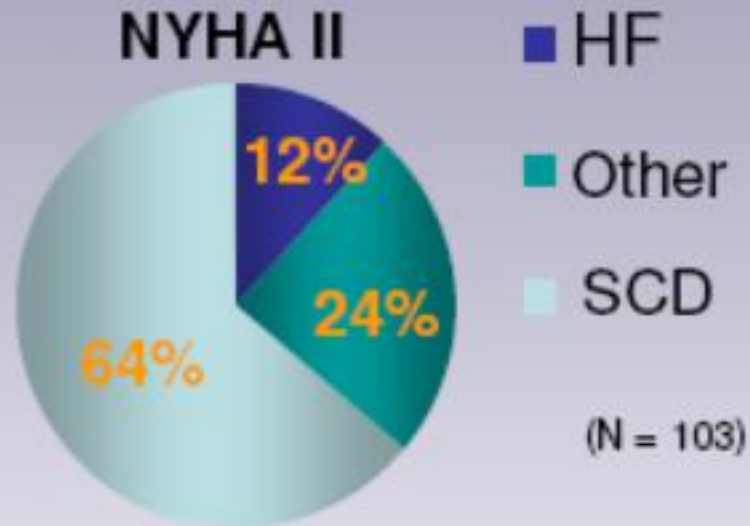
LVEF and SCA risk

2 Risk of SCA Increases 6 times with a Depressed EF



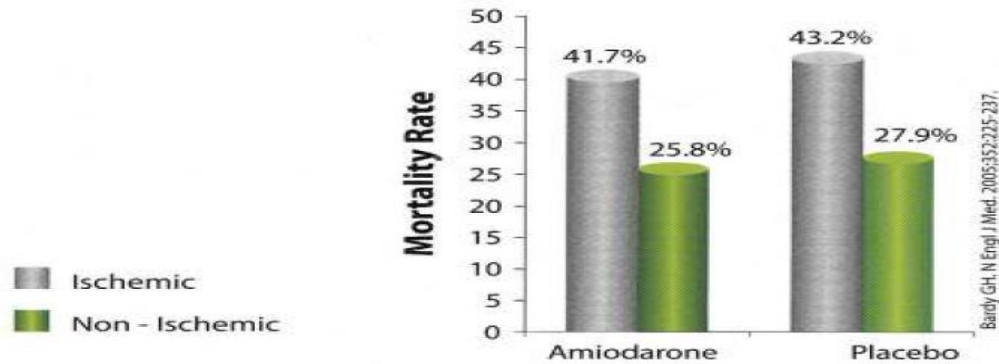
LVEF Gorgels, *European Heart Journal*. 2003;24:1204-1209.

Important of NYHA



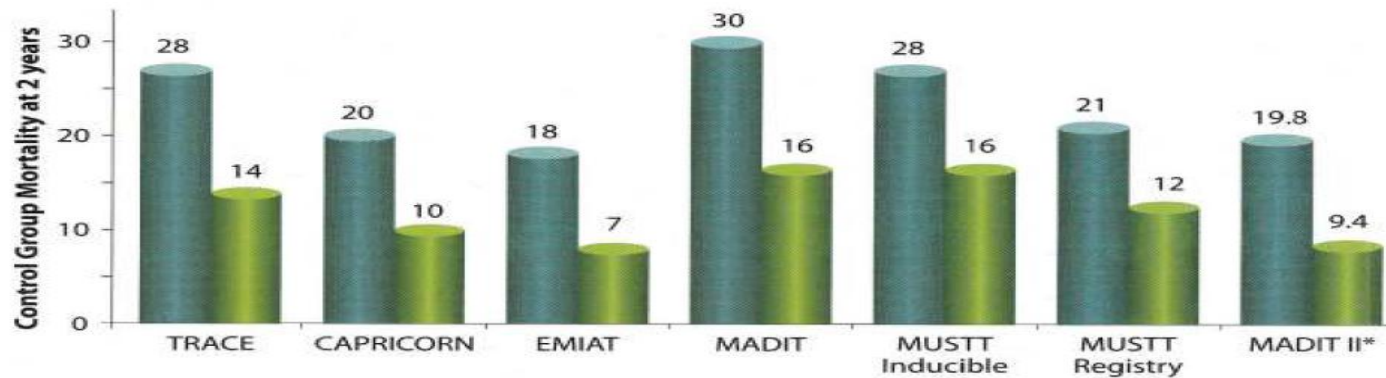
How High is the Risk for SCA in Primary Prevention Patients?

NYHA Class II/III patients with LV dysfunction have a 35% risk of SCA over 5 years



SCD-HeFT 5-Year Mortality Rate Ischemic vs. Non-Ischemic

Post MI, low EF patients have a 10-15% risk of SCA over 2 years



SCD Rates in Post-MI Patients with LV Dysfunction

■ Total Mortality ■ Arrhythmic Mortality

2013 ACC/AHA Device Therapy for Stage C HF/EF



ICD therapy is recommended for primary prevention of SCD to reduce total mortality in selected patients with nonischemic DCM or ischemic heart disease at least 40 days post-MI with LVEF of 35% or less, and NYHA class II or III symptoms on chronic GDMT, who have reasonable expectation of meaningful survival for more than 1 year.



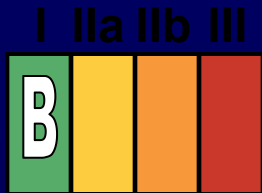
NYHA Class III/IV

CRT is indicated for patients who have LVEF of 35% or less, sinus rhythm, left bundle-branch block (LBBB) with a QRS duration of 150 ms or greater, and NYHA class II, III, or ambulatory IV symptoms on GDMT.



NYHA Class II

Device Therapy for Stage C HF/EF (cont.)



ICD therapy is recommended for primary prevention of SCD to reduce total mortality in selected patients at least 40 days post-MI with LVEF less than or equal to 30%, and NYHA class I symptoms while receiving GDMT, who have reasonable expectation of meaningful survival for more than 1 year.



CRT can be useful for patients who have LVEF of 35% or less, sinus rhythm, a non-LBBB pattern with a QRS duration of 150 ms or greater, and NYHA class III/ambulatory class IV symptoms on GDMT.

ESC 2016 CHF guideline

Recommendations for implantable cardioverter-defibrillator in patients with heart failure

Recommendations	Class ^a	Level ^b
<p>Secondary prevention</p> <p>An ICD is recommended to reduce the risk of sudden death and all-cause mortality in patients who have recovered from a ventricular arrhythmia causing haemodynamic instability, and who are expected to survive for >1 year with good functional status.</p>	I	A
<p>Primary prevention</p> <p>An ICD is recommended to reduce the risk of sudden death and all-cause mortality in patients with symptomatic HF (NYHA Class II–III), and an LVEF ≤35% despite ≥3 months of OMT, provided they are expected to survive substantially longer than one year with good functional status, and they have:</p> <ul style="list-style-type: none"> • IHD (unless they have had an MI in the prior 40 days – see below). • DCM. 	I	A
	I	B
ICD implantation is not recommended within 40 days of an MI as implantation at this time does not improve prognosis.	III	A
ICD therapy is not recommended in patients in NYHA Class IV with severe symptoms refractory to pharmacological therapy unless they are candidates for CRT, a ventricular assist device, or cardiac transplantation.	III	C
Patients should be carefully evaluated by an experienced cardiologist before generator replacement, because management goals and the patient's needs and clinical status may have changed.	IIa	B
A wearable ICD may be considered for patients with HF who are at risk of sudden cardiac death for a limited period or as a bridge to an implanted device.	IIIb	C

HRS 2013 : Appropriate criteria for ICD in ICM

Table 2.2. Post-Myocardial Infarction (>40 Days) With Ischemic Cardiomyopathy (Fig. 10)

Indication		Appropriate Use Score (1–9)			
		No Recent PCI or CABG (≤ 3 Months)			
		NYHA Class			
		I	II	III	IV
96.	<ul style="list-style-type: none"> LVEF $\leq 30\%$ 	A (8)	A (9)	A (9)	
97.	<ul style="list-style-type: none"> LVEF 31% to 35% 	A (7)	A (9)	A (9)	
98.	<ul style="list-style-type: none"> LVEF 36% to 40% Asymptomatic NSVT No EPS 				M (5)
99.	<ul style="list-style-type: none"> LVEF 36% to 40% Asymptomatic NSVT EPS without inducible VT/VF 				M (5)
100.	<ul style="list-style-type: none"> LVEF 36% to 40% Asymptomatic NSVT EPS with inducible sustained VT/VF 				A (8)
		Recent PCI or CABG (≤ 3 Months)			
101.	<ul style="list-style-type: none"> No known pre-existing cardiomyopathy LVEF $\leq 35\%$ 				M (6)
102.	<ul style="list-style-type: none"> Pre-existing documented cardiomyopathy LVEF $\leq 35\%$ on guideline-directed medical therapy > 3 months before PCI/CABG 				A (8)
103.	<ul style="list-style-type: none"> LVEF $\leq 35\%$ Need for ppm post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker) 				A (8)
104.	<ul style="list-style-type: none"> LVEF 36%–40% Need for ppm post-revascularization (e.g., SSS, CHB, or other guideline-directed indications for permanent pacemaker) 				M (6)

NOTE: grey shaded boxes indicate “not rated.”

A = Appropriate; CABG = coronary artery bypass graft surgery; CHB = complete heart block; EPS = electrophysiological study; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NSVT = nonsustained ventricular tachycardia; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; PPM = permanent pacemaker; SSS = sick sinus syndrome; VF = ventricular fibrillation; VT = ventricular tachycardia.

HRS 2013 : Appropriate criteria for ICD in ICM

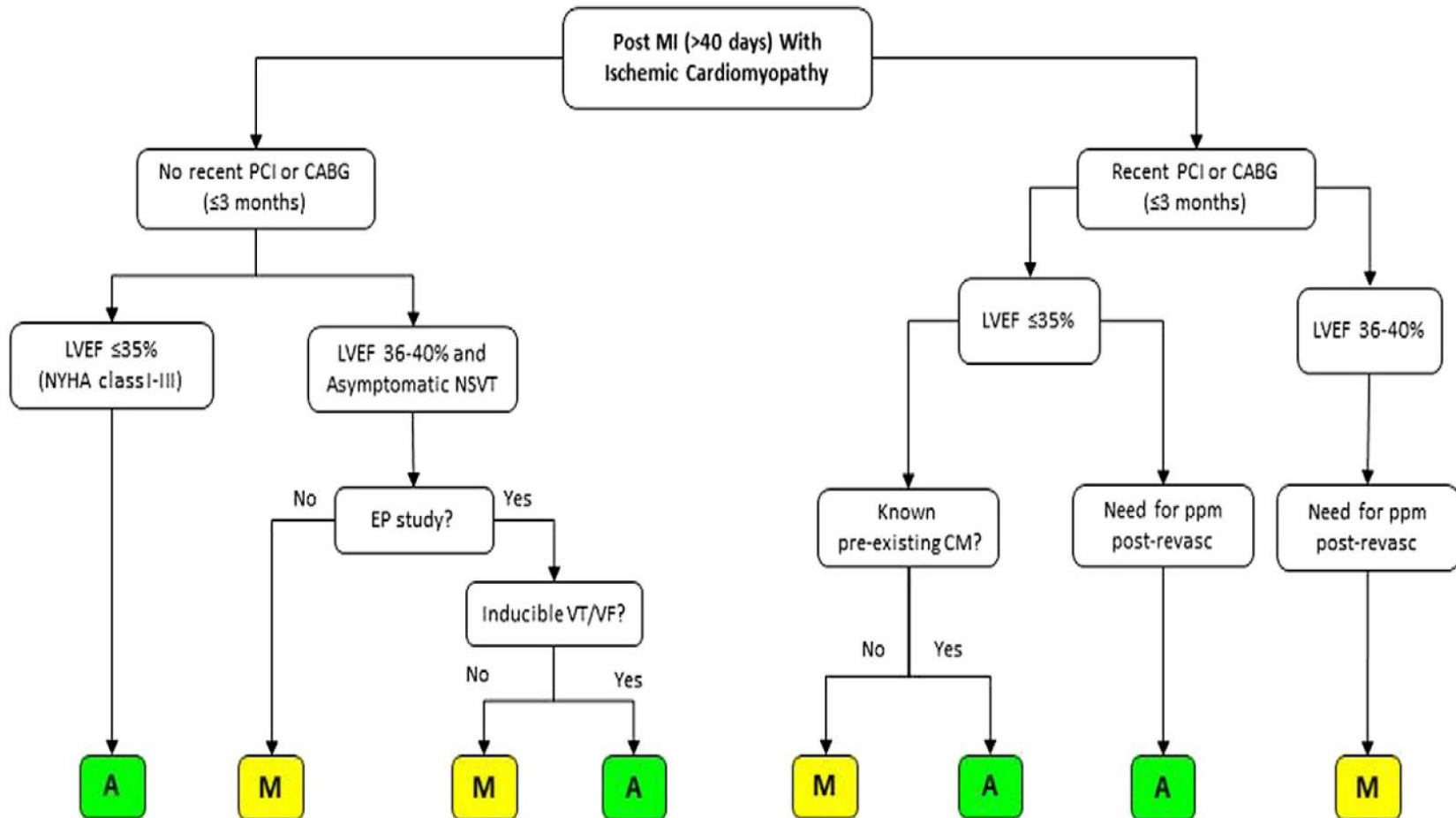


Figure 10. Primary Prevention: Coronary Artery Disease, Prior MI (>40 Days) With Ischemic Cardiomyopathy

HRS 2013 : Appropriate criteria for ICD in DCM

Table 2.4. Nonischemic Cardiomyopathy (Figs. 11 and 12)

Indication		Appropriate Use Score (1–9)		
Treatment Since Diagnosis <3 Months				
Newly Diagnosed Cardiomyopathy With Narrow QRS				
		NYHA Class		
		I	II–III	IV
108.	• LVEF ≤30%	R (3)	M (4)	
109.	• LVEF 31% to 35%	R (3)	R (3)	
At Least 3 Months on Guideline-Directed Medical Therapy				
		NYHA Class		
		I	II–III	IV
110.	• LVEF ≤30%	A (7)	A (9)	
111.	• LVEF 31% to 35%	A (7)	A (9)	
112.	• LVEF 36% to 40%	M (4)		
Recent Valve Surgery (i.e., Same Hospitalization or <3 Months) Which Included Incidental Bypass Graft				
113.	• LVEF ≤35% • Need for pacemaker and LV function not felt likely to improve	A (7)		
Specific Etiologies				
		LVEF		
		≤35%	>35%	
114.	• Sarcoid heart disease	A (8)	M (6)	
115.	• Myotonic dystrophy	A (8)	M (5)	
116.	• Chagas disease	A (8)	M (6)	
117.	• Amyloidosis with heart failure	M (6)	M (5)	
118.	• Acute lymphocytic myocarditis • Newly diagnosed (<3 months ago)	R (3)	R (3)	
119.	• Giant cell myocarditis	A (8)	A (7)	
120.	• Peripartum cardiomyopathy • Persists >3 months postpartum	A (8)	M (4)	

NOTE: grey shaded boxes indicate “not rated.”

A = Appropriate; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NYHA = New York Heart Association; R = Rarely Appropriate.

HRS 2013 : Appropriate criteria for ICD in DCM in DCM

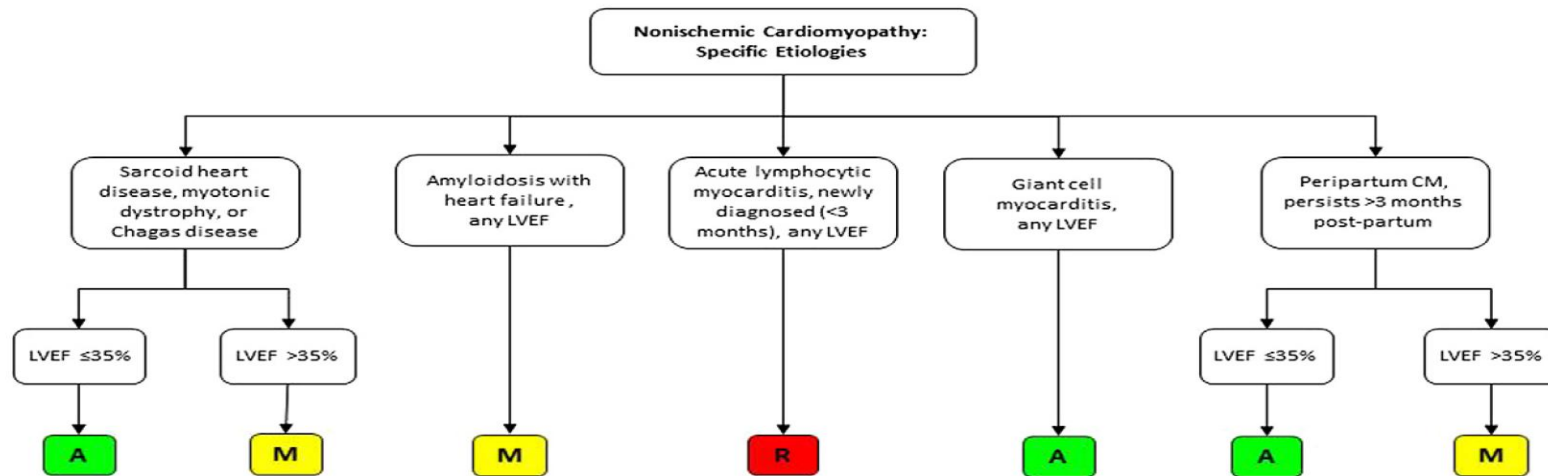


Figure 12. Primary Prevention: Nonischemic Cardiomyopathy, Specific Etiologies

A = Appropriate; CM = cardiomyopathy; LVEF = left ventricular ejection fraction; M = May Be Appropriate; R = Rarely Appropriate.

Original Article

Defibrillator Implantation in Patients with Nonischemic Systolic Heart Failure

Lars Køber, M.D., D.M.Sc., Jens J. Thune, M.D., Ph.D., Jens C. Nielsen, M.D.,
D.M.Sc., Jens Haarbo, M.D., D.M.Sc., Lars Videbæk, M.D., Ph.D., Eva Korup, M.D.,
Ph.D., Gunnar Jensen, M.D., Ph.D., Per Hildebrandt, M.D., D.M.Sc., Flemming H.
Steffensen, M.D., Niels E. Bruun, M.D., D.M.Sc., Hans Eiskjær, M.D., D.M.Sc., Axel
Brandes, M.D., Anna M. Thøgersen, M.D., Ph.D., Finn Gustafsson, M.D., D.M.Sc.,
Kenneth Egstrup, M.D., D.M.Sc., Regitze Videbæk, M.D., Christian Hassager, M.D.,
D.M.Sc., Jesper H. Svendsen, M.D., D.M.Sc., Dan E. Høfsten, M.D., Ph.D.,
Christian Torp-Pedersen, M.D., D.M.Sc., Steen Pehrson, M.D., D.M.Sc., for the
DANISH Investigators

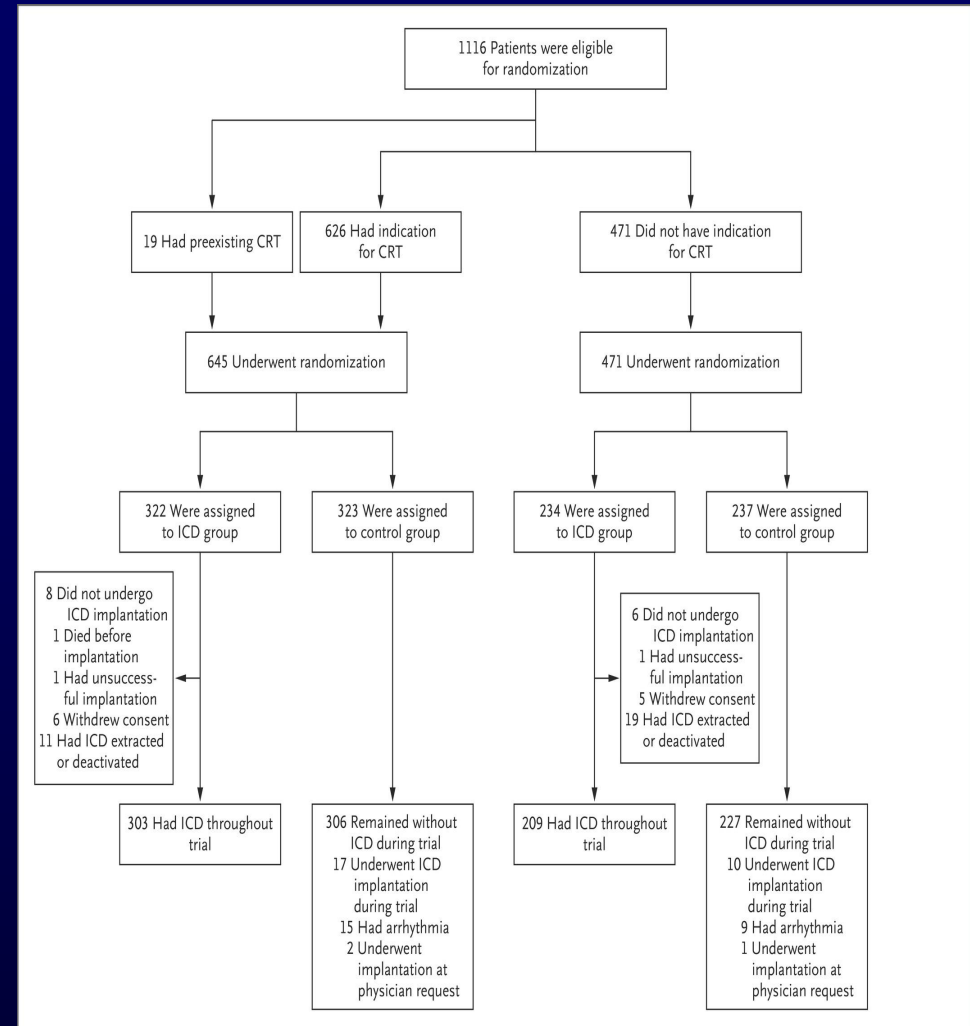
N Engl J Med
Volume 375(13):1221-1230
September 29, 2016



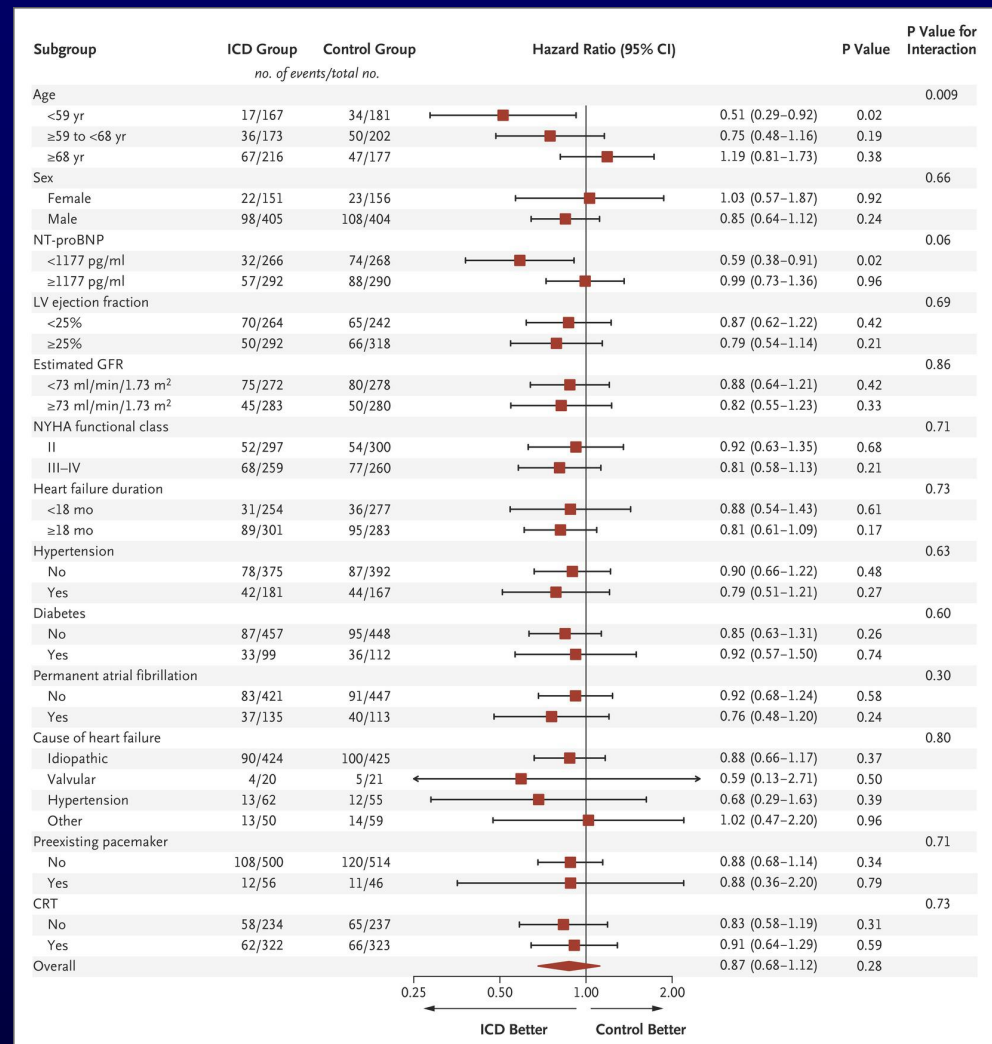
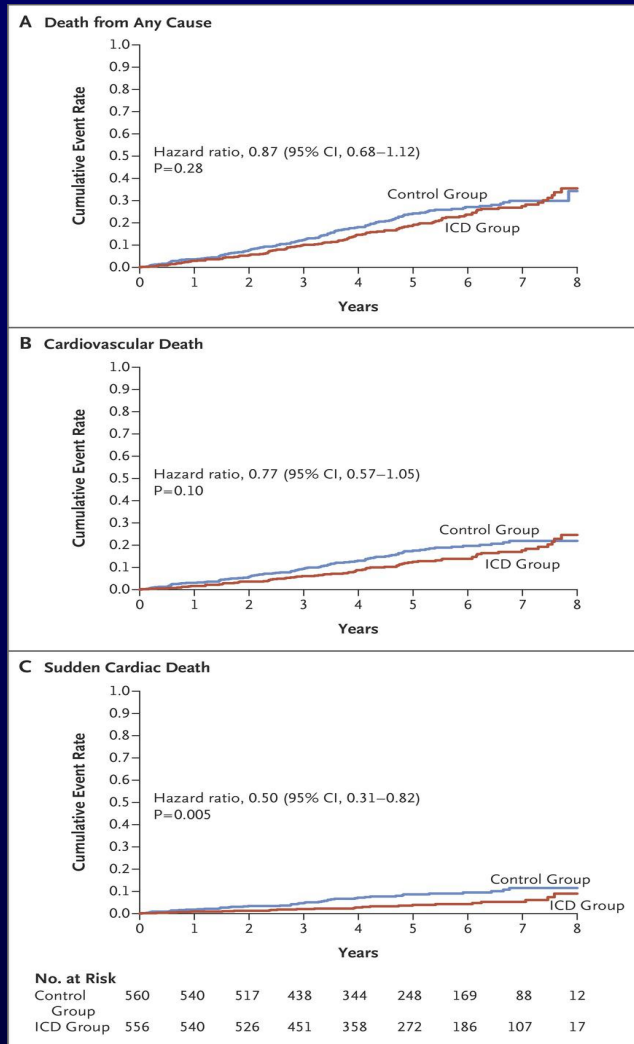
The NEW ENGLAND
JOURNAL of MEDICINE

DANISH : Study Overview

- In a randomized trial, more than 1100 patients with **nonischemic heart** failure (left ventricular ejection fraction $\leq 35\%$) were assigned either to receive or not to receive an ICD.
- At a median of 67.6 months, there was no significant difference in mortality between the two groups.



Time-to-Event Curves for Death from Any Cause, Cardiovascular Death, and Sudden Cardiac Death.



Køber L et al. N Engl J Med
2016;375:1221-1230



The NEW ENGLAND
JOURNAL OF MEDICINE

HRS 2013 : Appropriate criteria for ICD in genetic conditions

Indication		Appropriate Use Score (1-9)
121.	• Hypertrophic cardiomyopathy with 1 or more risk factors	A (7)
122.	• Arrhythmogenic right ventricular dysplasia/cardiomyopathy with no symptoms due to arrhythmia	A (7)
Congenital Long QT Syndrome With 1 or More Risk Factors		
123.	• Not receiving guideline-directed medical therapy	M (6)
124.	• Receiving guideline-directed medical therapy	A (7)
Catecholaminergic Polymorphic VT With Nonsustained VT (Without Syncope)		
125.	• Not receiving beta-blockers, flecainide, or propafenone	A (7)
126.	• Receiving beta-blockers	A (7)
127.	• Not tolerating or breakthrough nonsustained ventricular arrhythmias on beta-blockers	A (8)
Incidentally Discovered Brugada by ECG (Type I ECG Pattern) In the Absence of Symptoms or Family History of Sudden Cardiac Death		
128.	• No EPS	R (3)
129.	• Inducible VT or VF at EPS	A (7)
130.	• No inducible VT or VF at EPS	R (3)
Familial Dilated/Nonischemic Cardiomyopathy (RV/LV) Associated With Sudden Cardiac Death		
131.	• Evidence of structural cardiac disease but LVEF >35%	A (7)
132.	• Normal ECG and echo but carrying the implicated gene	M (6)
133.	• LV non-compaction with LVEF >35%	A (7)

HRS 2013 : Appropriate criteria for ICD in genetic conditions

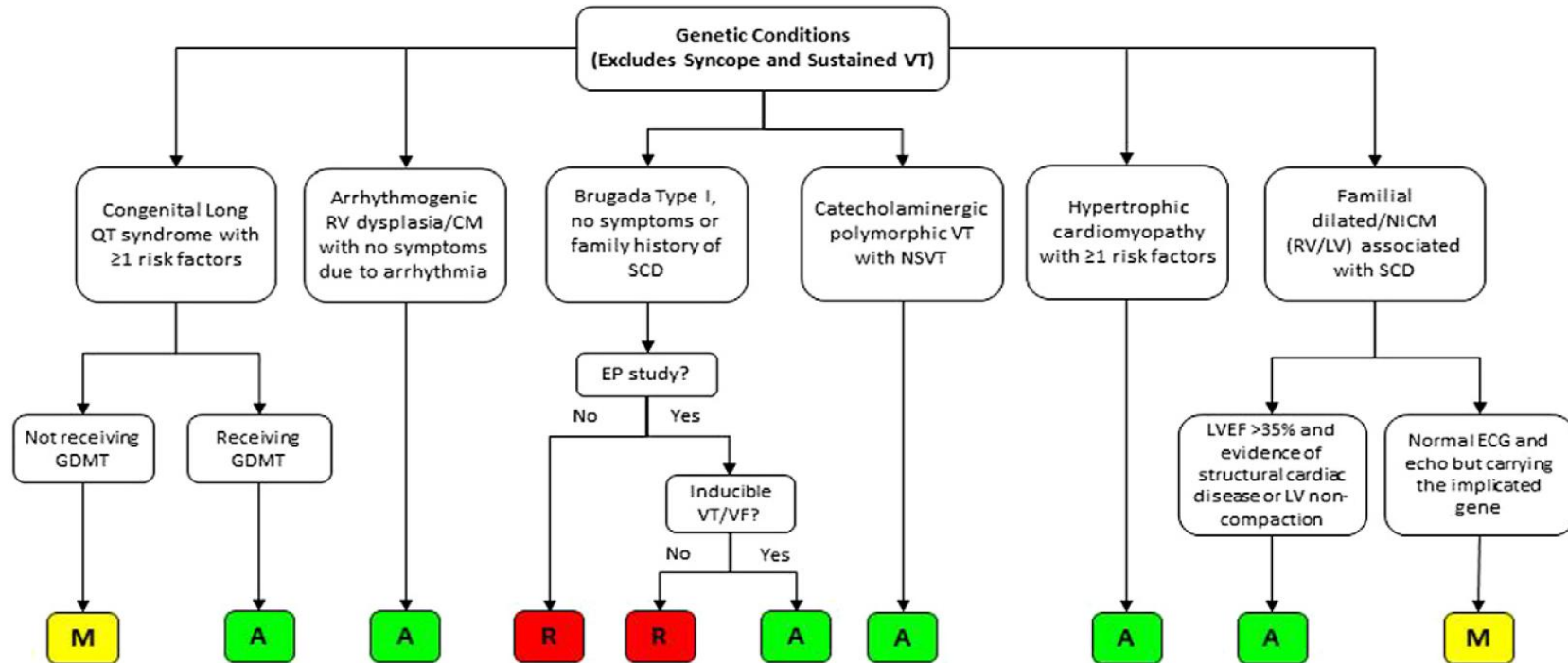


Figure 13. Primary Prevention: Genetic Conditions (Excludes Syncope and Sustained VT)

A = Appropriate; CM = cardiomyopathy; ECG = electrocardiogram; EPS = electrophysiological study; GDMT = guideline-directed medical therapy; LV = left ventricular; LVEF = left ventricular ejection fraction; M = May Be Appropriate; MI = myocardial infarction; NICM = nonischemic cardiomyopathy; NSVT = nonsustained ventricular tachycardia; R = Rarely Appropriate; RV = right ventricular; SCD = sudden cardiac death; VF = ventricular fibrillation; VT = ventricular tachycardia.

HRS 2013 : Rarely appropriate comorbidities for ICD

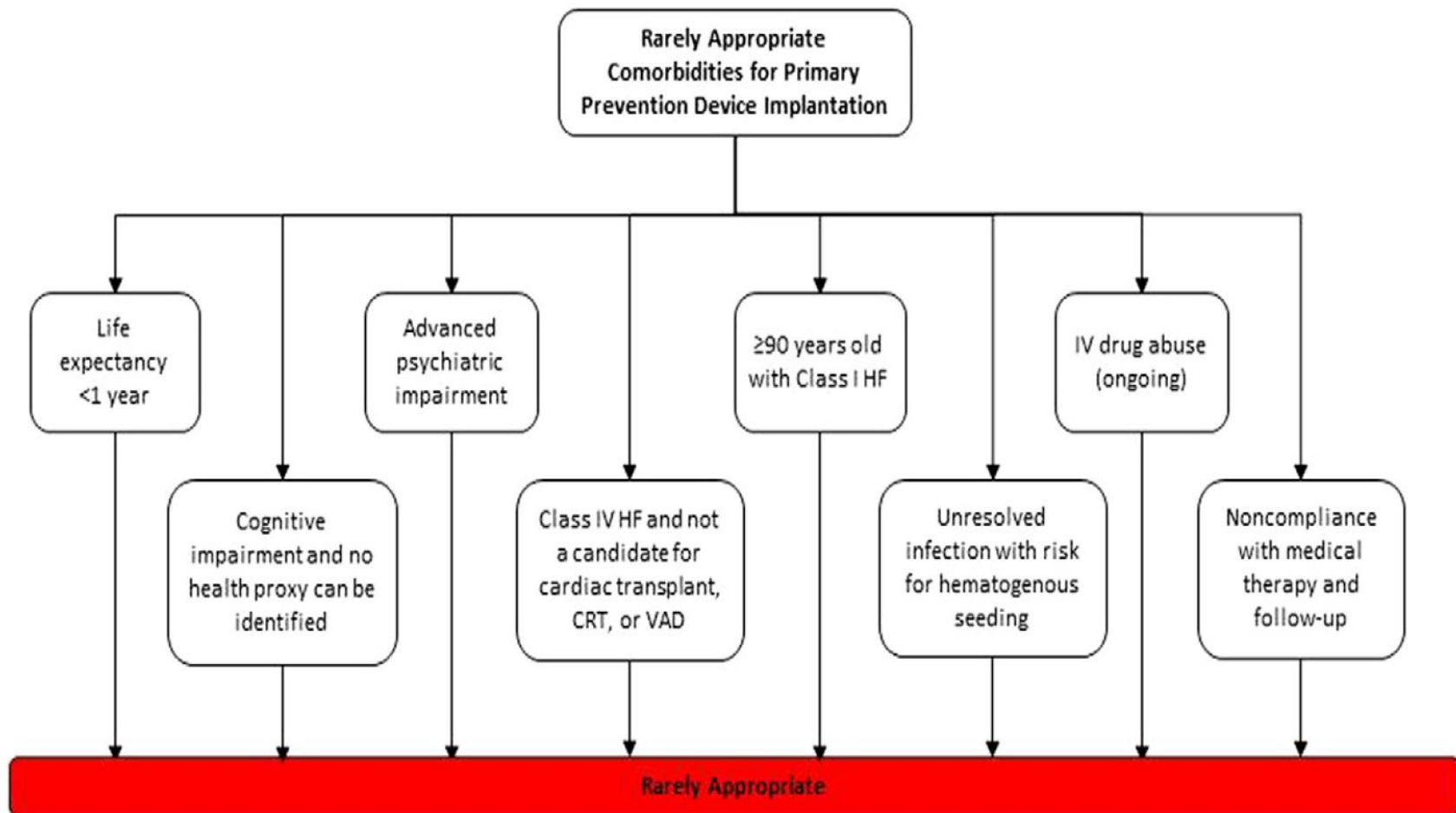


Figure 14. Primary Prevention: Comorbidities (Rarely Appropriate Indications)

1.5 Prevention

1.5 Definition



- A PP patient is considered to be in the 1.5 prevention subgroup if they meet one or more of the following conditions:
 - Pre-syncope/Syncope
 - Low LVEF (<25%)
 - Frequent PVCs
 - NSVT

1.5 Prevention

What is 1.5 Prevention?



1⁰



2⁰

1.5

Primary Prevention with Symptoms

- NSVT
- Frequent PVCs, especially with different morphologies
- EF < 25%
- Pre-syncope or syncope

1.5 Prevention

1.5 Criteria: Pre-Syncope/Syncope



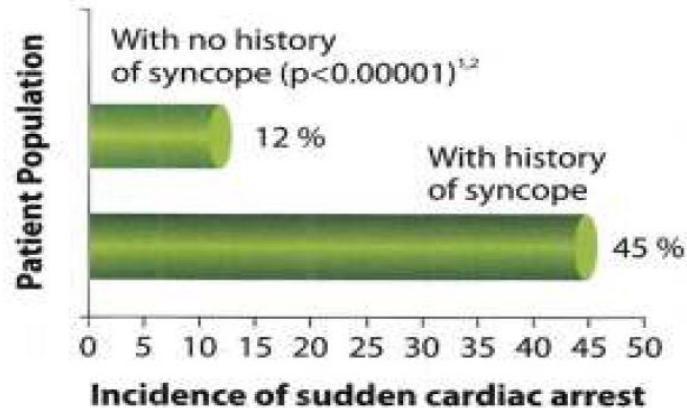
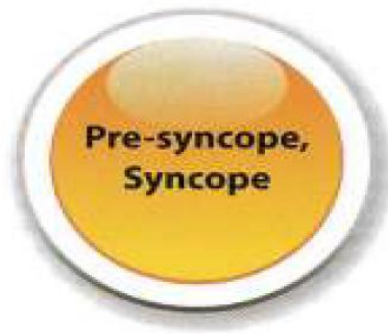
Within the past 12 months:

- Pre-syncope/ dizziness/ lightheadedness, due to suspected VT
- Syncope, due to suspected VT
- Unexplained syncope or pre-syncope, after ruling out these causes:
 - Syncope, due to carotid sinus hypersensitivity
 - Vasovagal syncope
 - Syncope, due to bradycardia
 - Syncope, due to SVT

syncope have high risk of SCA

- In syncope patients - incidence of SCD
- 45%, V/S incidence 12% in pts with no history of syncope ($p < 0.00001$)

1 Patients with Syncope have High Risk of SCA



1. Middlekauff HR, Stevenson WG, Stevenson LW, Saxon LA.
2. Syncope in advanced heart failure: high risk of sudden death regardless of origin of syncope. *J Am Coll Cardiol* 1992;21:1110-1116.

2017 ACC/AHA/HRS Guideline for the Evaluation and Management of Patients With Syncope

Developed in Collaboration with the American College of Emergency Physicians and
Society for Academic Emergency Medicine

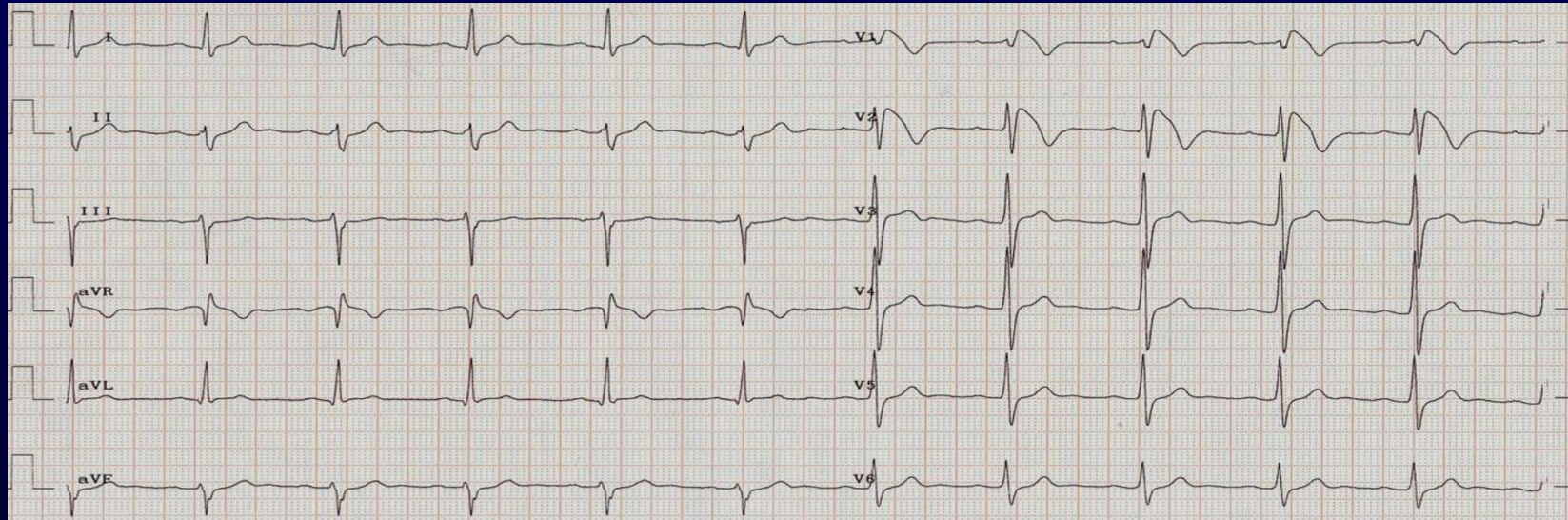
Endorsed by the Pediatric and Congenital Electrophysiology Society

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Inheritable Arrhythmic Conditions

Brugada Syndrome

COR	LOE	Recommendations
Ila	B-NR	ICD implantation is reasonable in patients with Brugada ECG pattern and syncope of suspected arrhythmic etiology.
Ilb	B-NR	Invasive EPS may be considered in patients with Brugada ECG pattern and syncope of suspected arrhythmic etiology.
III: No Benefit	B-NR	ICD implantation is not recommended in patients with Brugada ECG pattern and reflex-mediated syncope in the absence of other risk factors.





Clinical characteristics and treatment outcomes of patients with Brugada syndrome in northeastern Thailand

*Pattarapong Makarawate*¹, MD, *Narumol Chaosuwanakit*², MD, *Suda Vannaprasaht*³, MD, *Wichitra Tassaneeyakul*^{3,4}, PhD, *Kittisak Sawanyawisuth*^{1,5}, MD, PhD

Table II. Clinical characteristics of the 79 symptomatic patients with Brugada syndrome, according to their clinical presentations.

Characteristic	No. (%)		p-value
	Sudden cardiac arrest (n = 65)	Unexplained syncope (n = 14)	
Age* (yrs)	44.17 ± 8.80	46.00 ± 7.37	0.322
Male gender	64 (98.5)	13 (92.9)	0.325
Familial history of sudden death	17 (26.2)	6 (42.9)	0.330
Spontaneous type I ECG	48 (73.8)	12 (85.7)	0.498
Type 1 ECG with high intercostal leads	14 (21.5)	2 (14.3)	0.723
Type 1 ECG after sodium channel blockers	3 (4.6)	0 (0)	1.000
Residency region in Thailand			0.657
Northeastern	58 (89.2)	12 (85.7)	
Northern	4 (6.2)	2 (14.3)	
Southern	1 (1.5)	0 (0)	
Central	2 (3.1)	0 (0)	

*Data is presented as mean ± SD. ECG: electrocardiogram



Clinical characteristics and treatment outcomes of patients with Brugada syndrome in northeastern Thailand

Pattarapong *Makarawate*¹, MD, Narumol *Chaosuwannakit*², MD, Suda *Vannaprasaht*³, MD, Wichitra *Tassaneeyakul*^{3,4}, PhD, Kittisak *Sawanyawisuth*^{1,5}, MD, PhD

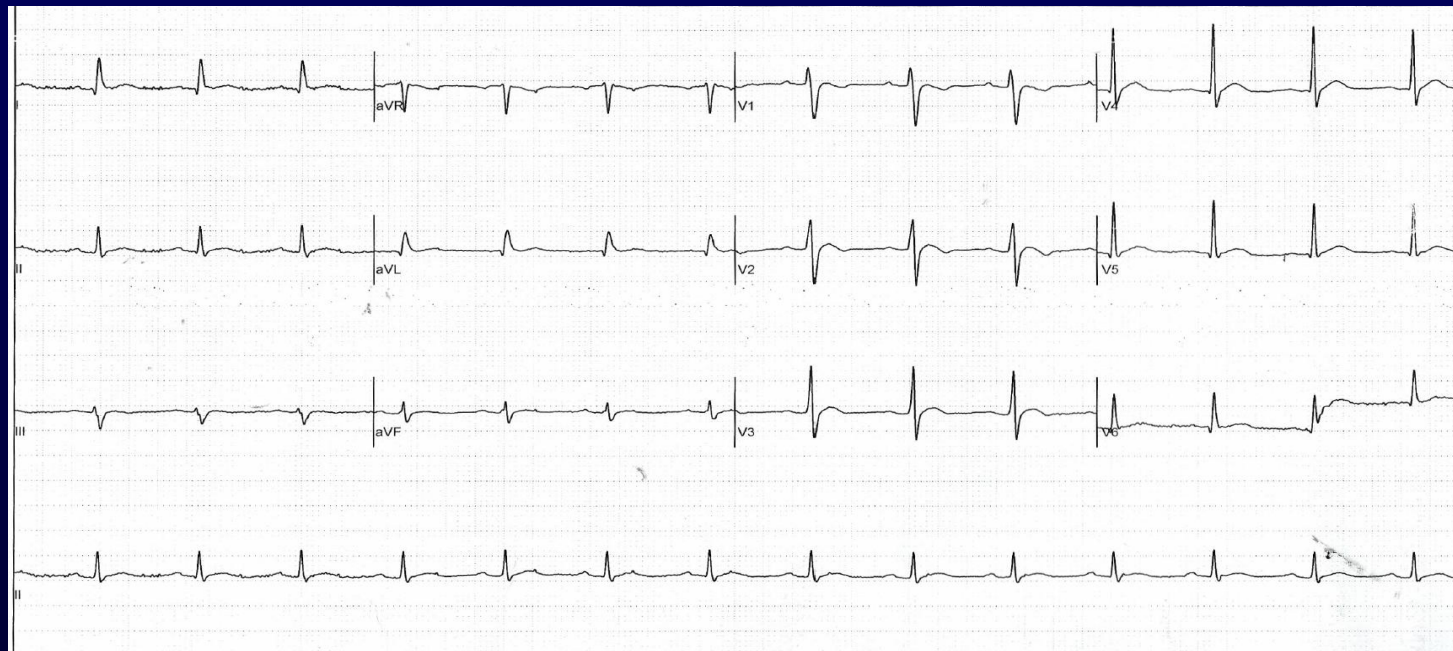
Table III. Treatment and treatment outcomes of the symptomatic patients with Brugada syndrome, according to their clinical presentations.

Characteristic	No. (%)		p-value
	Sudden cardiac arrest (n = 65)	Unexplained syncope (n = 14)	
Patients with ICD	64 (98.5)	12 (85.7)	0.079
Patients with appropriate ICD treatment	21 (32.3)	4 (28.6)	1.000
Patients with complication after ICD treatment	4 (6.2)	3 (21.4)	0.102
Death	0 (0)	0 (0)	1.000

ICD: implantable cardioverter defibrillator

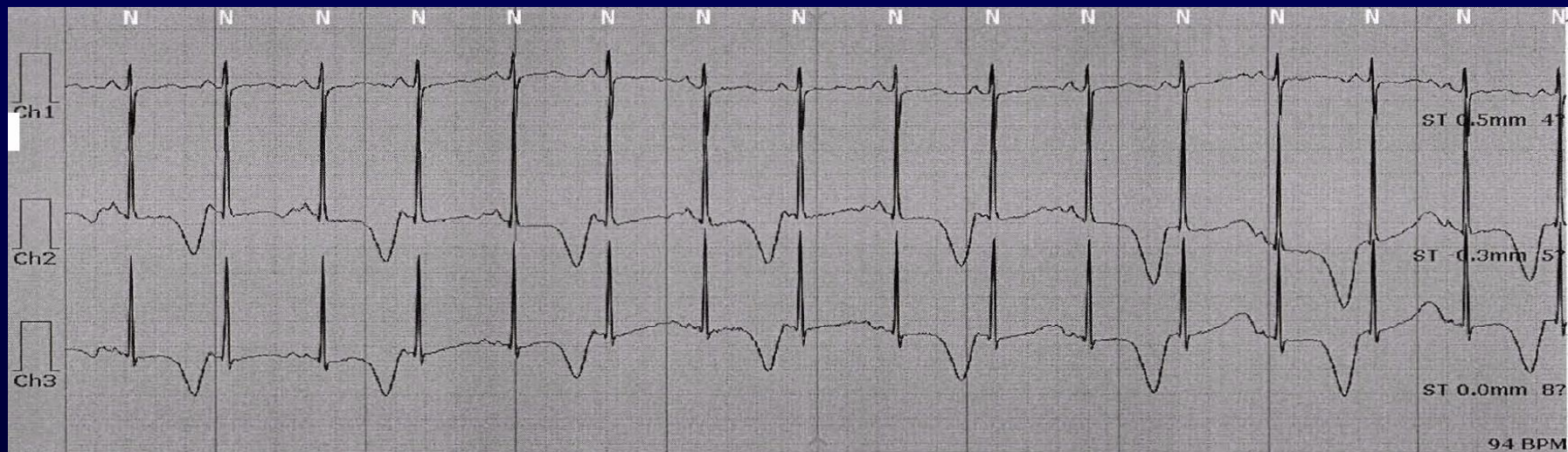
Short-QT Syndrome

COR	LOE	Recommendation
IIb	C-EO	ICD implantation may be considered in patients with short-QT pattern and syncope of suspected arrhythmic etiology.



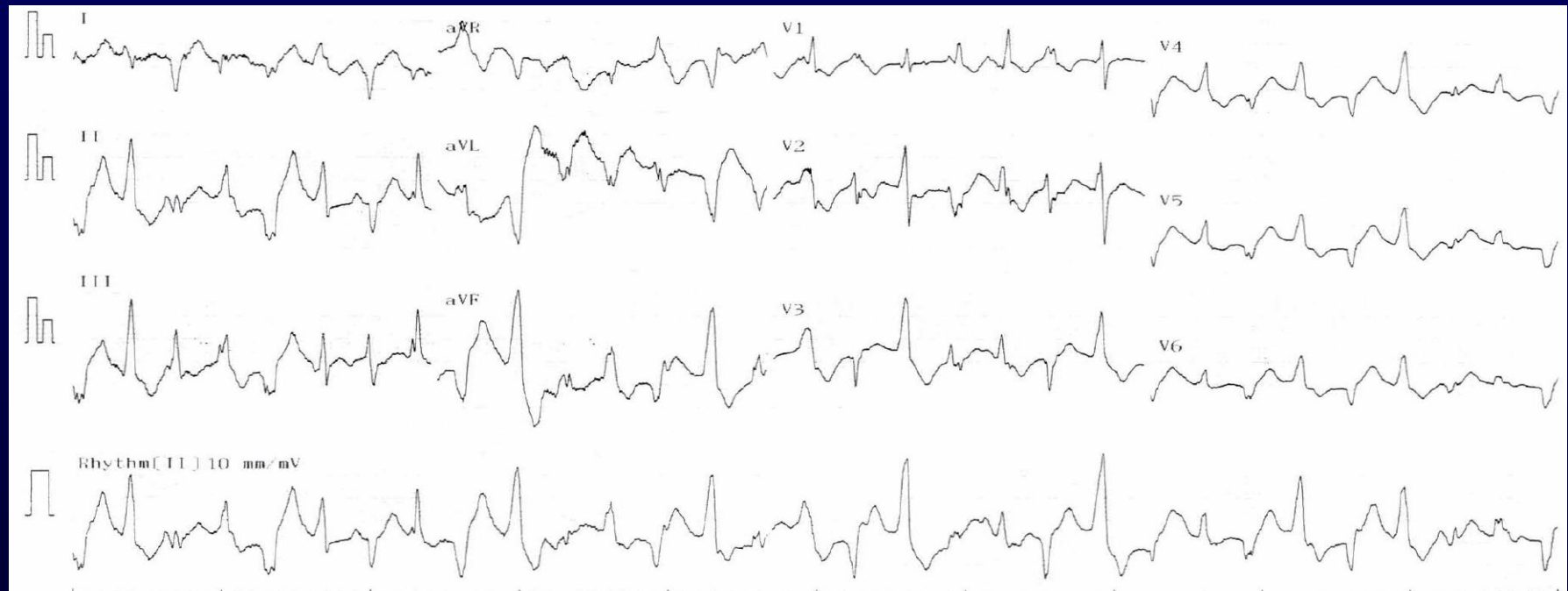
Long-QT Syndrome

COR	LOE	Recommendations
I	B-NR	Beta-blocker therapy, in the absence of contraindications, is indicated as a first-line therapy in patients with LQTS and suspected arrhythmic syncope.
Ila	B-NR	ICD implantation is reasonable in patients with LQTS and suspected arrhythmic syncope who are on beta-blocker therapy or are intolerant to beta-blocker therapy.



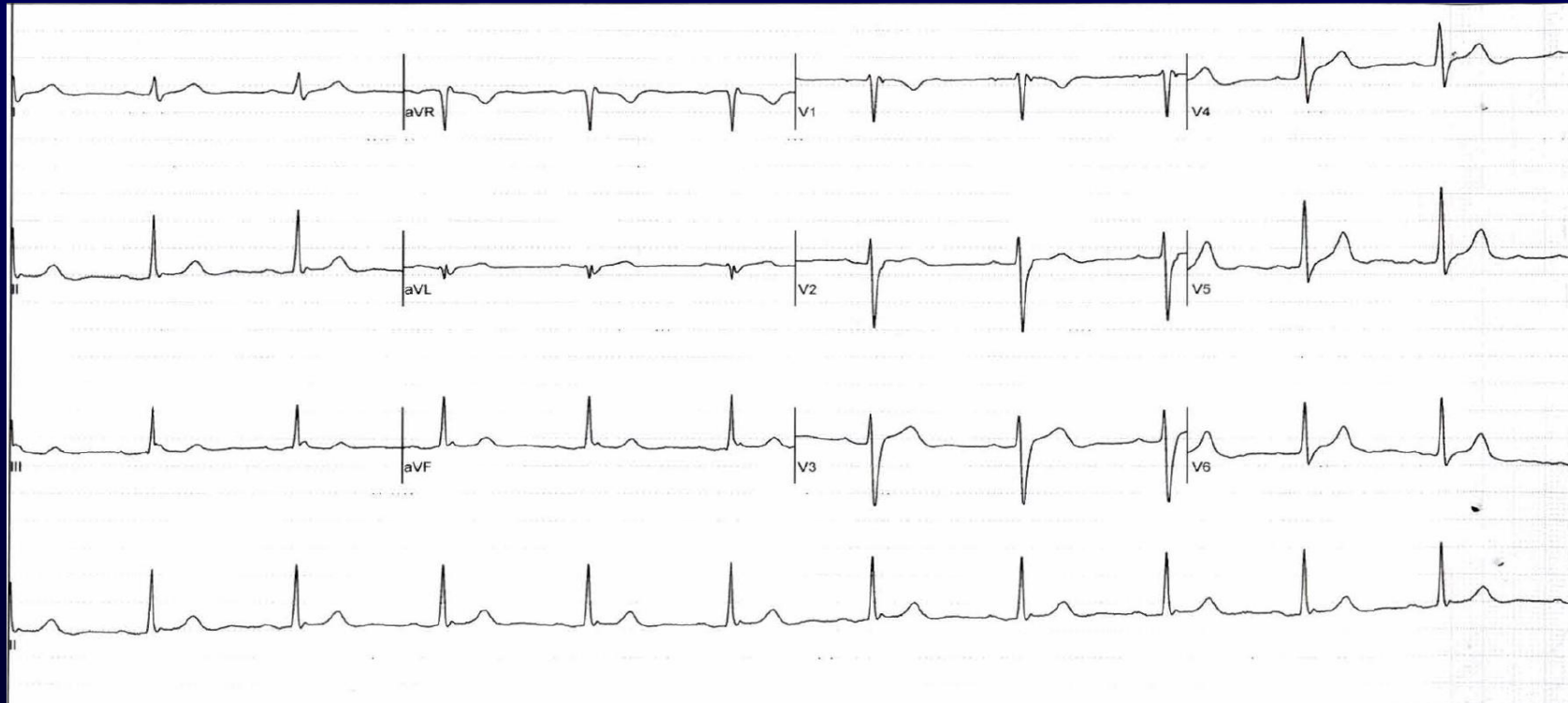
Catecholaminergic Polymorphic Ventricular Tachycardia

COR	LOE	Recommendations
Ila	C-LD	Flecainide is reasonable in patients with CPVT who continue to have syncope of suspected VA despite beta-blocker therapy.
Ila	B-NR	ICD therapy is reasonable in patients with CPVT and a history of exercise- or stress-induced syncope despite use of optimal medical therapy or LCSD.



Early Repolarization Pattern

COR	LOE	Recommendations
IIb	C-EO	ICD implantation may be considered in patients with early repolarization pattern and suspected arrhythmic syncope in the presence of a family history of early repolarization pattern with cardiac arrest.



1.5 Prevention

What is 1.5 Prevention?



1⁰



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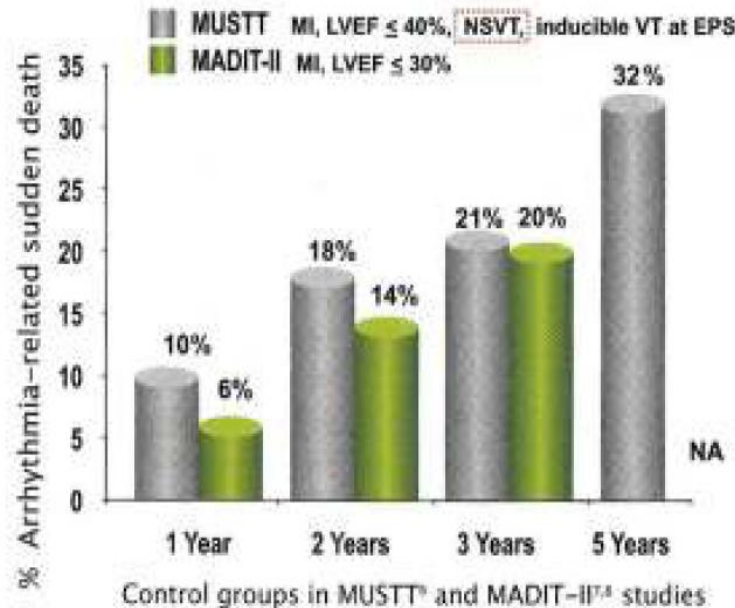
1.5

Primary Prevention with Symptoms

- NSVT
- Frequent PVCs, especially with different morphologies
- EF < 25%
- Pre-syncope or syncope

SCA risk in NSVT and frequent PVCs

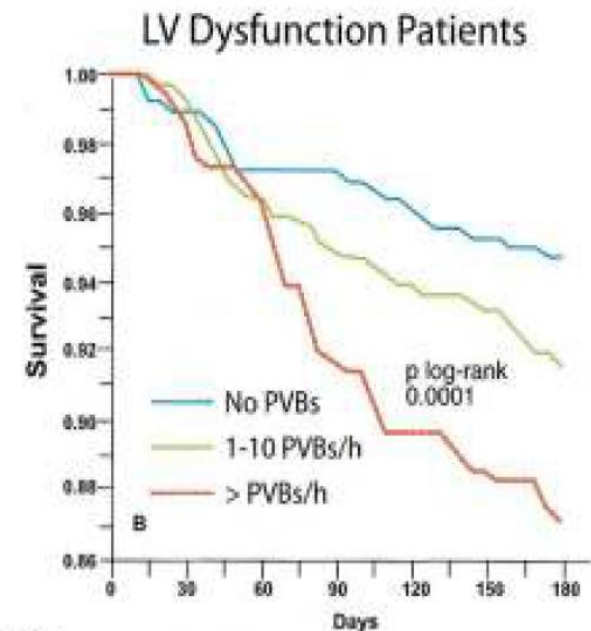
3 Post MI, Depressed EF Patients with Non-Sustained Ventricular Tachycardia (NSVT) and/or PVCs have Higher Risk of SCA



6 Buxton AE. *N Engl J Med.* 1999;341:1882-1890.
7 Moss AJ. *N Engl J Med.* 2002;346:877-883.

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

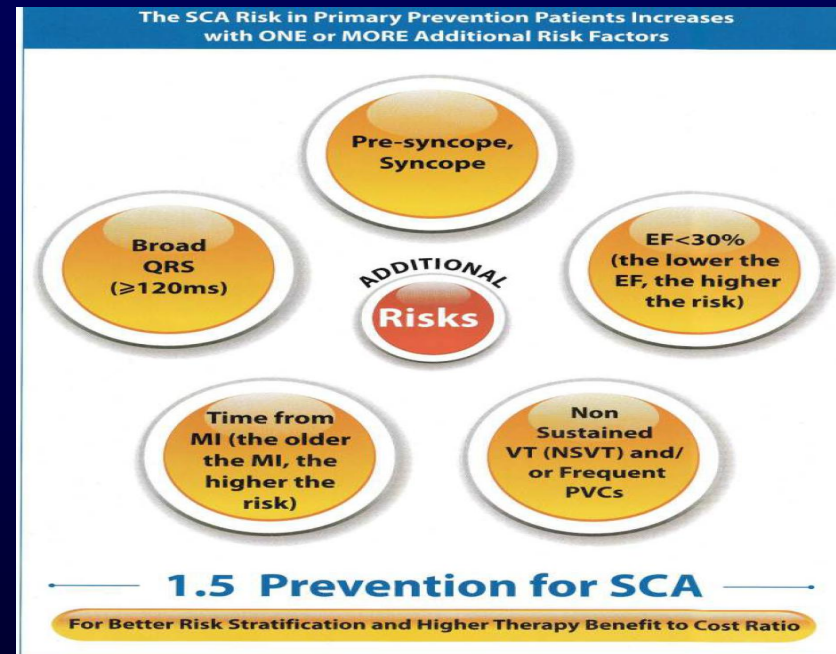
Survival significantly decreased with >10PVCs/hour



Maggiore AP. GISSI-2 Trial. *Circulation.* 1993;87:310-322.

Conclusions

1. Important and impact of ICD in primary prevention
2. Risk stratification for ICD therapy
3. Appropriate use of ICD primary prevention therapy
4. Rarely appropriate co morbid for ICD primary prevention therapy
5. 1.5 ICD indication



Questions and Comments

- Thank you for your attention.

