How Are we doing with Primary Prophylaxis ICD Implant…a call to arms…

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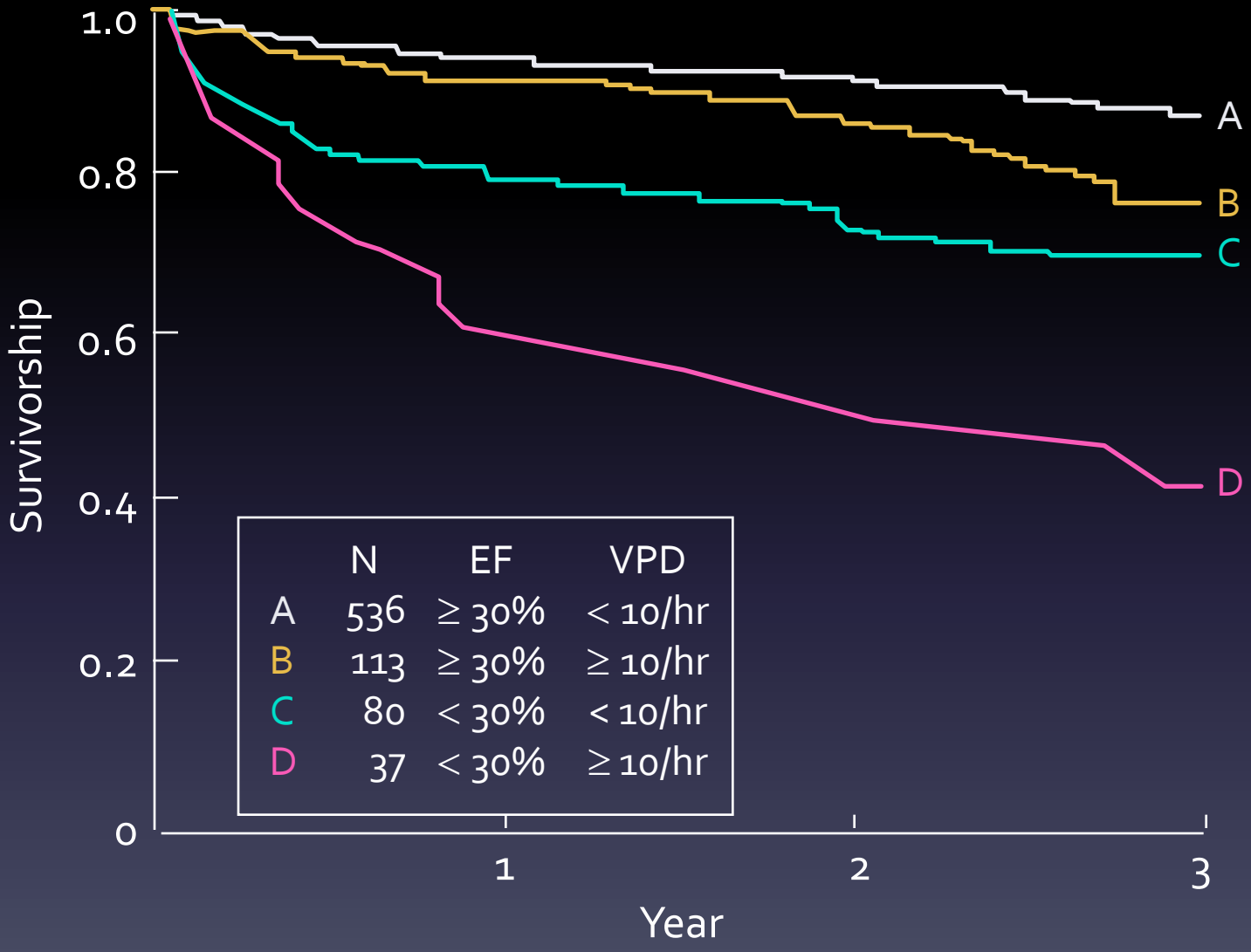
Learning Objectives

- Post MI Risk Stratification / Management
- "Other" Myopathy / Risk Groups
- ICD indications / Controversies
- Emerging Risk Stratifications Tools
- Awareness "Campaign" (Provider…Patient)
- How are we doing with Device Utilization ?

Survival After Acute MI

The Multicenter Post-Infarction Group



Bigger JT. Am J Cardiology. 1986;57:12B

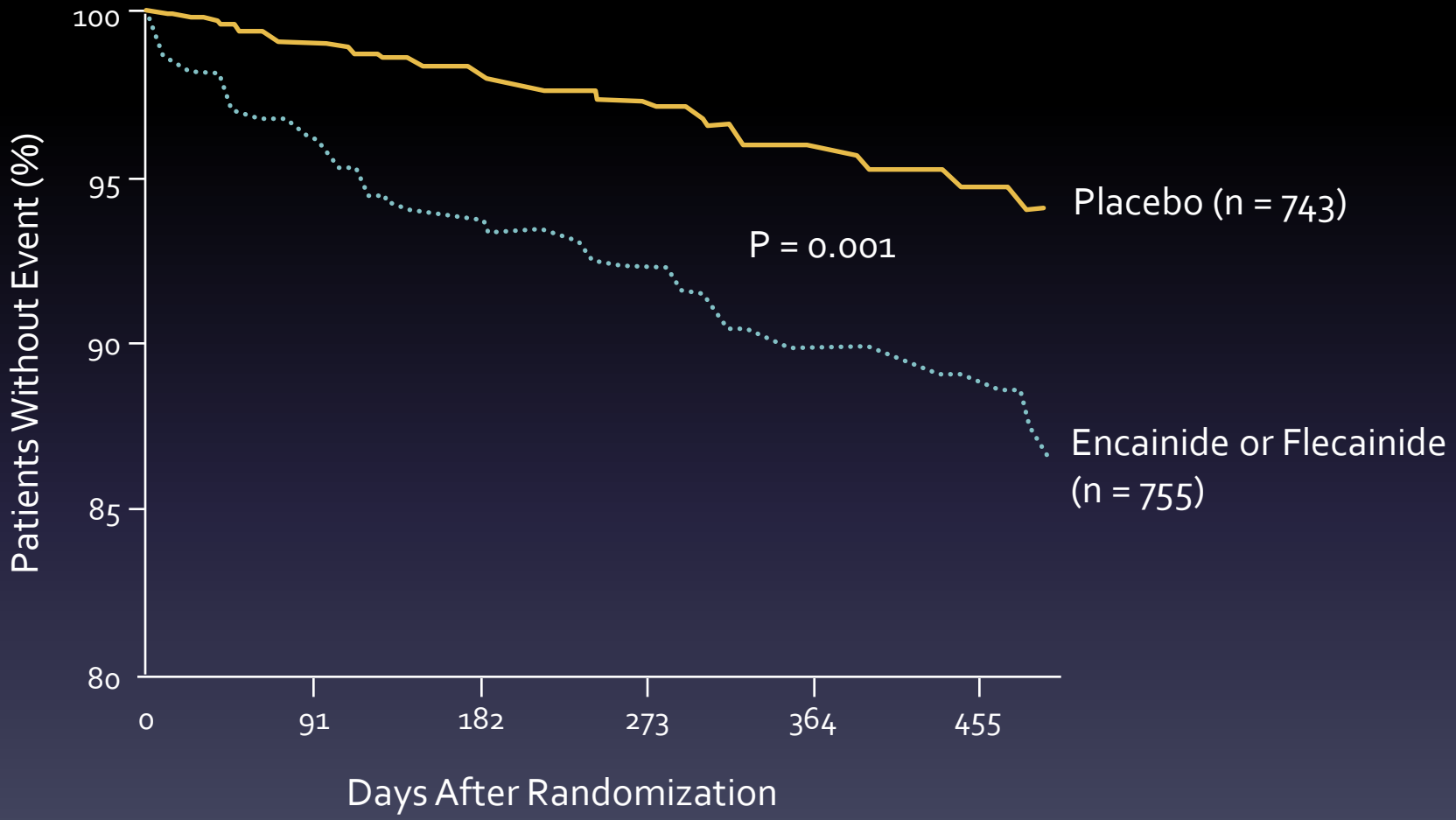
Post MI SCD Risk Modification

The Early Years…

- LV Dysfunction (HFrEF)
  - Beta Blockers
  - Afterload Reduction (ACE I / ARB)
- PVC Suppression Hypothesis
  - CAPS / CAST
    - Type Ic AA (Flecainide / Encainide / Propafenone*)
    - Increased Mortality on Therapy
  - ESVEM (Electrophysiology Study vs EKG Monitoring) 1993
    - Mexitil / Pirmenol / Procan / Propafenone / Quinidine / Sotalol
    - NO Benefit of EPS Risk Stratification / Minimal Survival Benefit

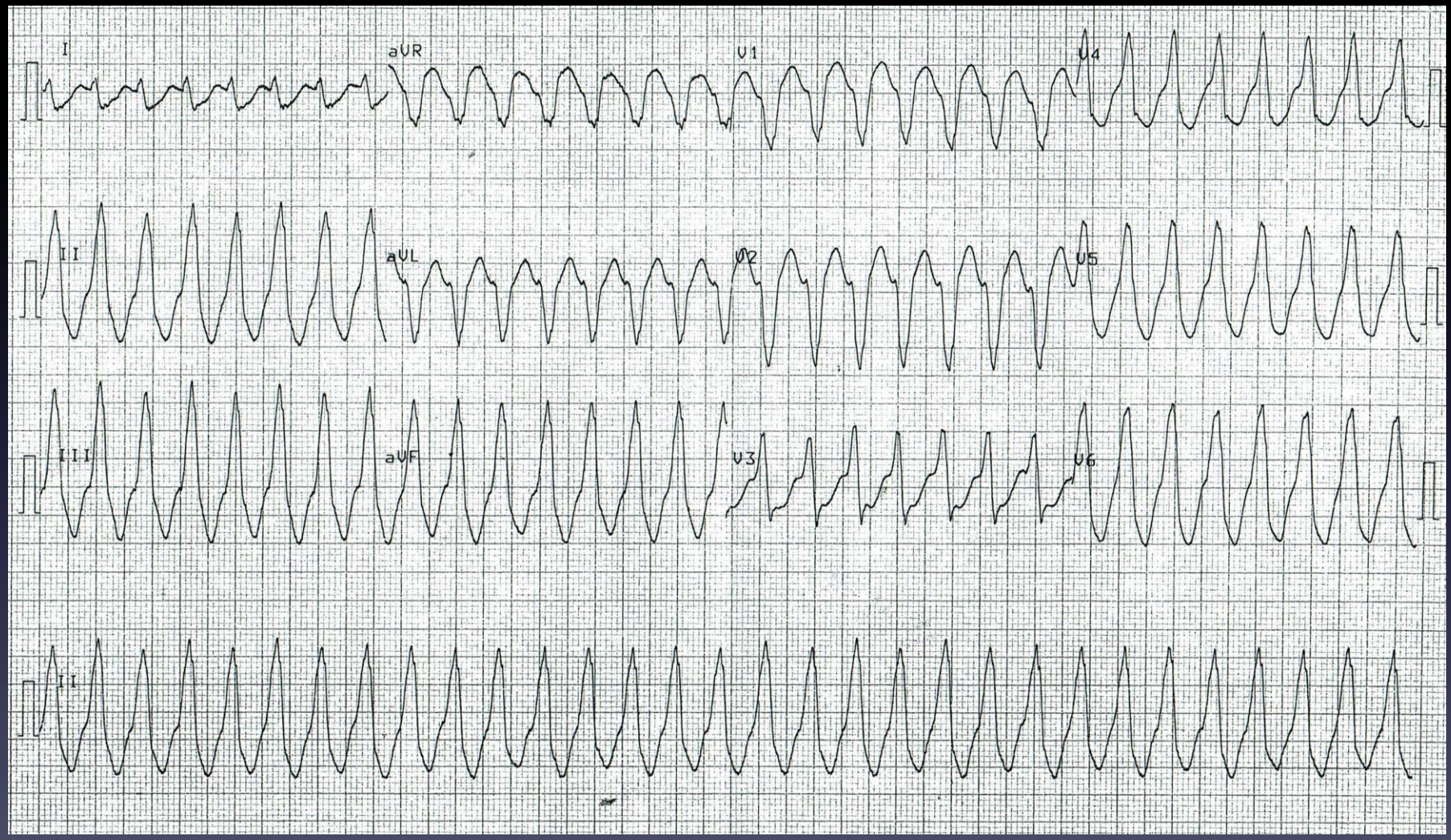
CAST-I

Patients Without Mortality / Cardiac Event



Echt DS. N. Engl J Med. 1991;324:781-788

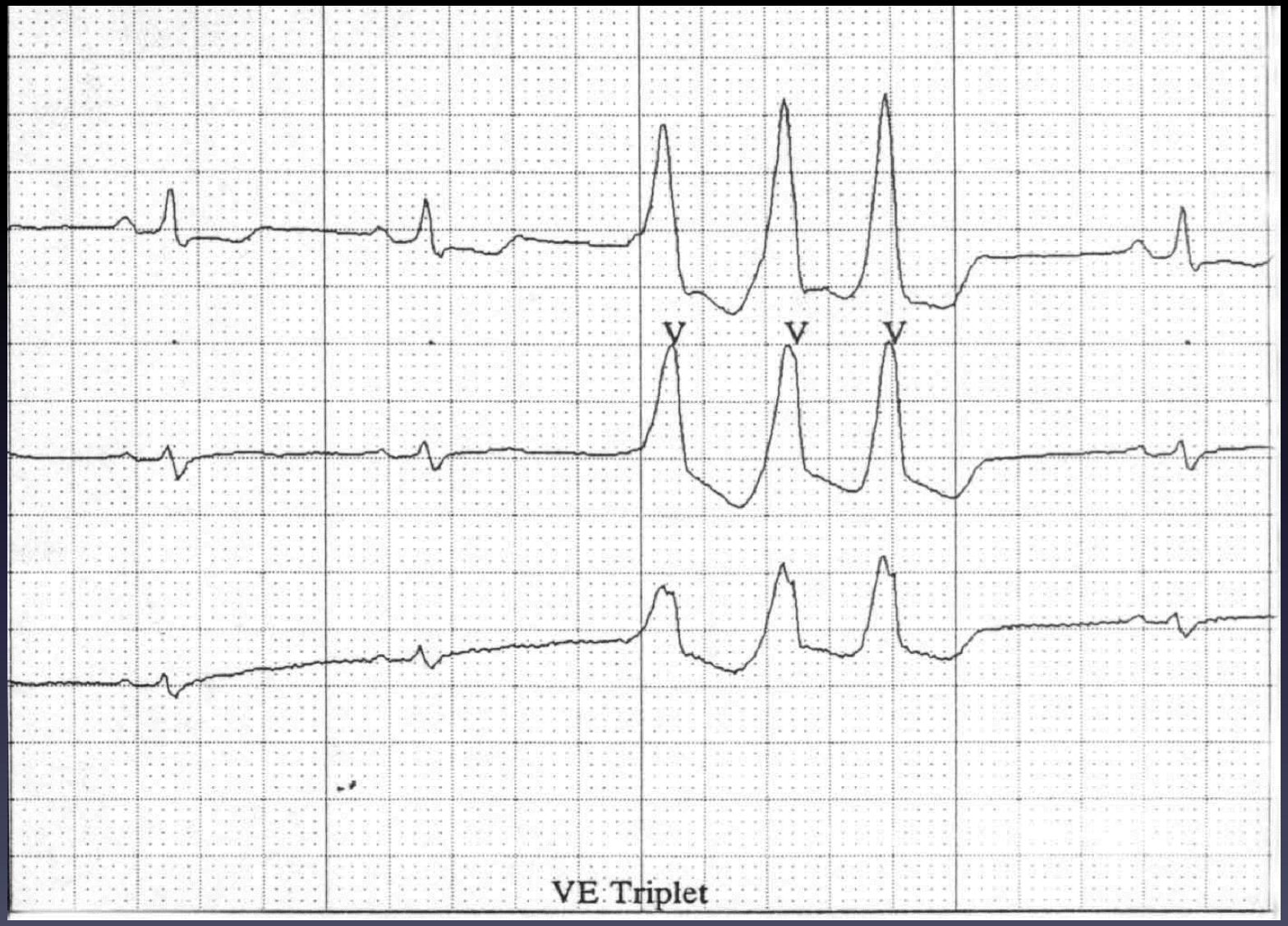
80 y/old w/ CAD on Flecainide for PAF

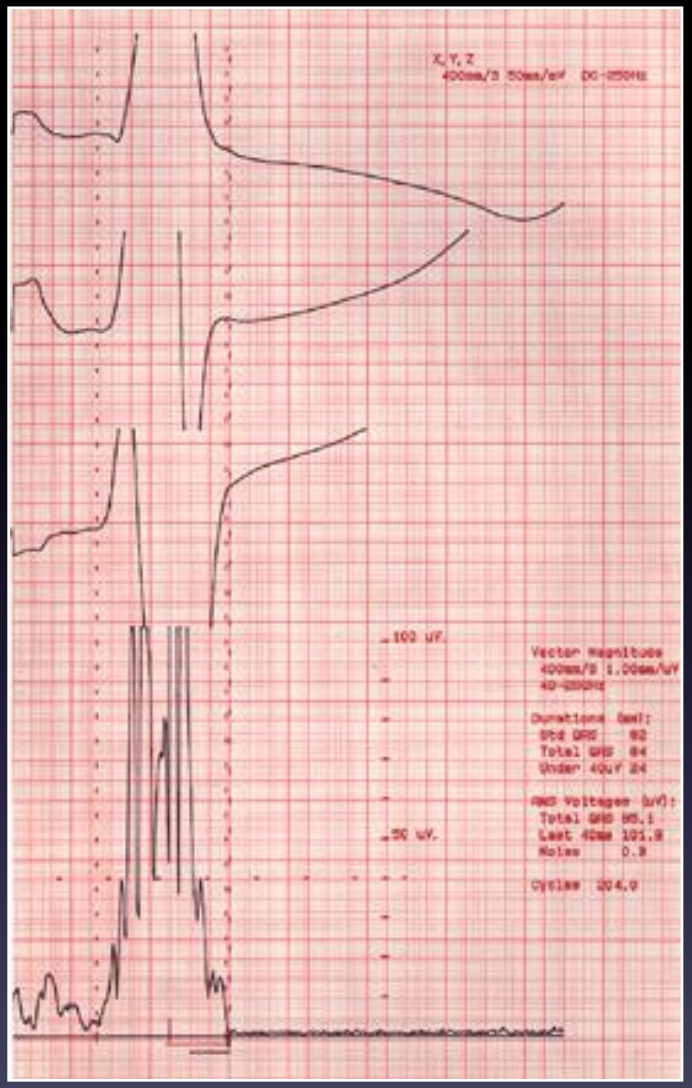


Non-invasive Risk Stratification

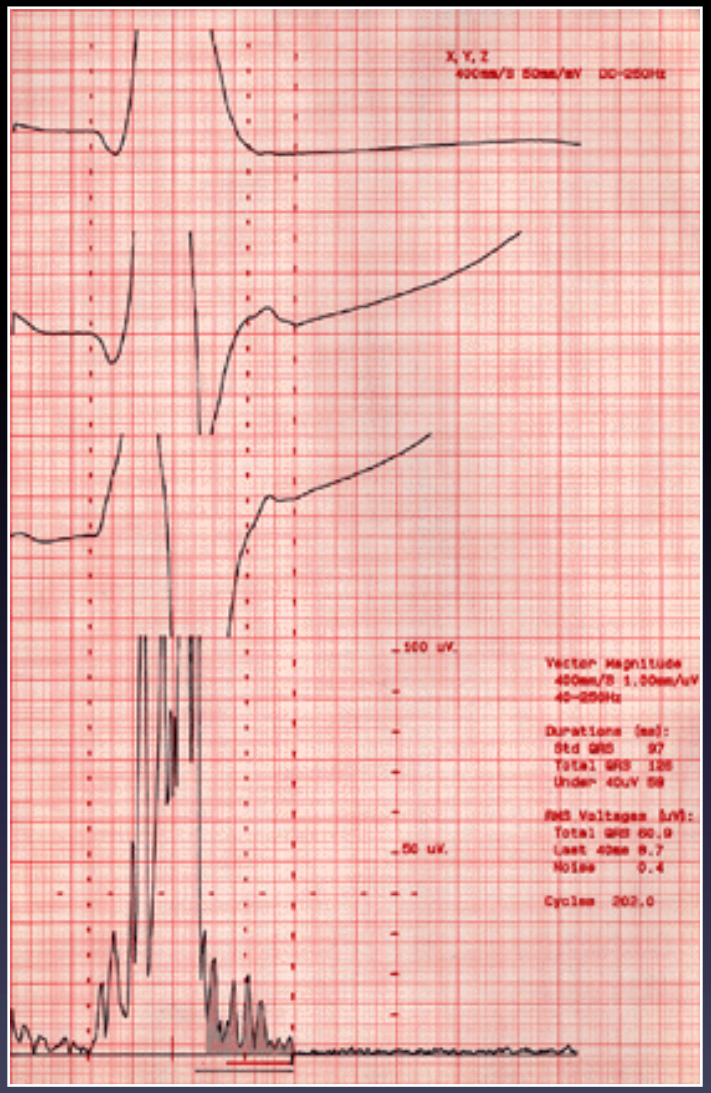
- LVEF
- 12 Lead EKG (Intervals / Morphology / Voltage)
- Holter Monitor
  - Non-sustained VT / Frequency / "Complexity"
- Signal Averaged EKG
- Heart Rate Variability
- Baroreflex Testing
- Microvolt T Wave Alternans
- Resting Heart Rate
- MRI Scar Burden Imaging

Non-Sustained Ventricular Tachycardia…





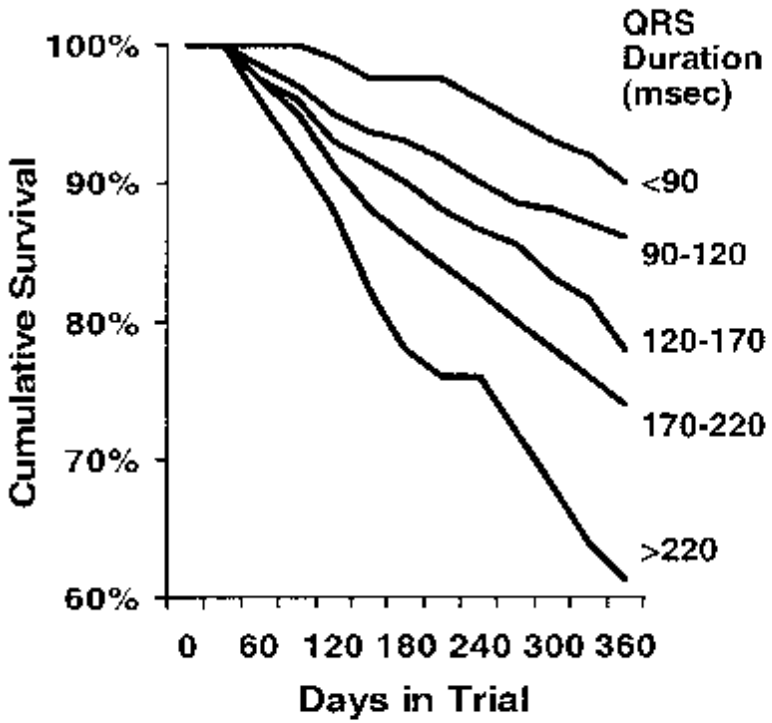
Normal Signal-Averaged ECG



SAECG with Late Potentials

Wide QRS – Proportional Mortality Increase

- **Vesnarinone Study[1] (VEST study analysis)**
- NYHA Class II-IV patients
- 3,654 ECGs digitally scanned
- Age, creatinine, LVEF, heart rate, and QRS duration found to be independent predictors of mortality
- Relative risk of widest QRS group 5x greater than narrowest

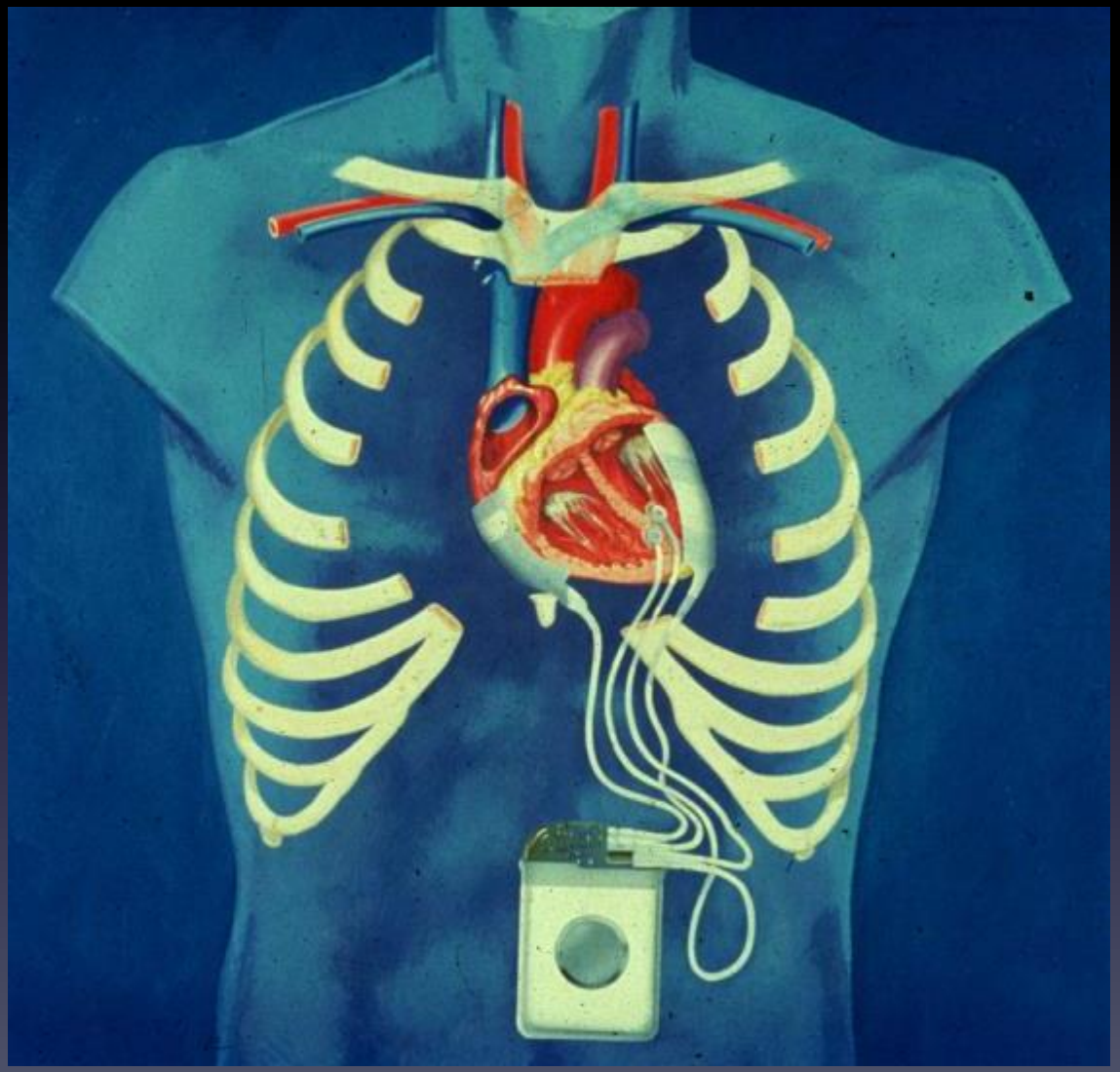


Adapted from Gottipaty et al.

[1] Gottipaty V, Krelis S, et al. ACC 1999 [Abstr];847-4.

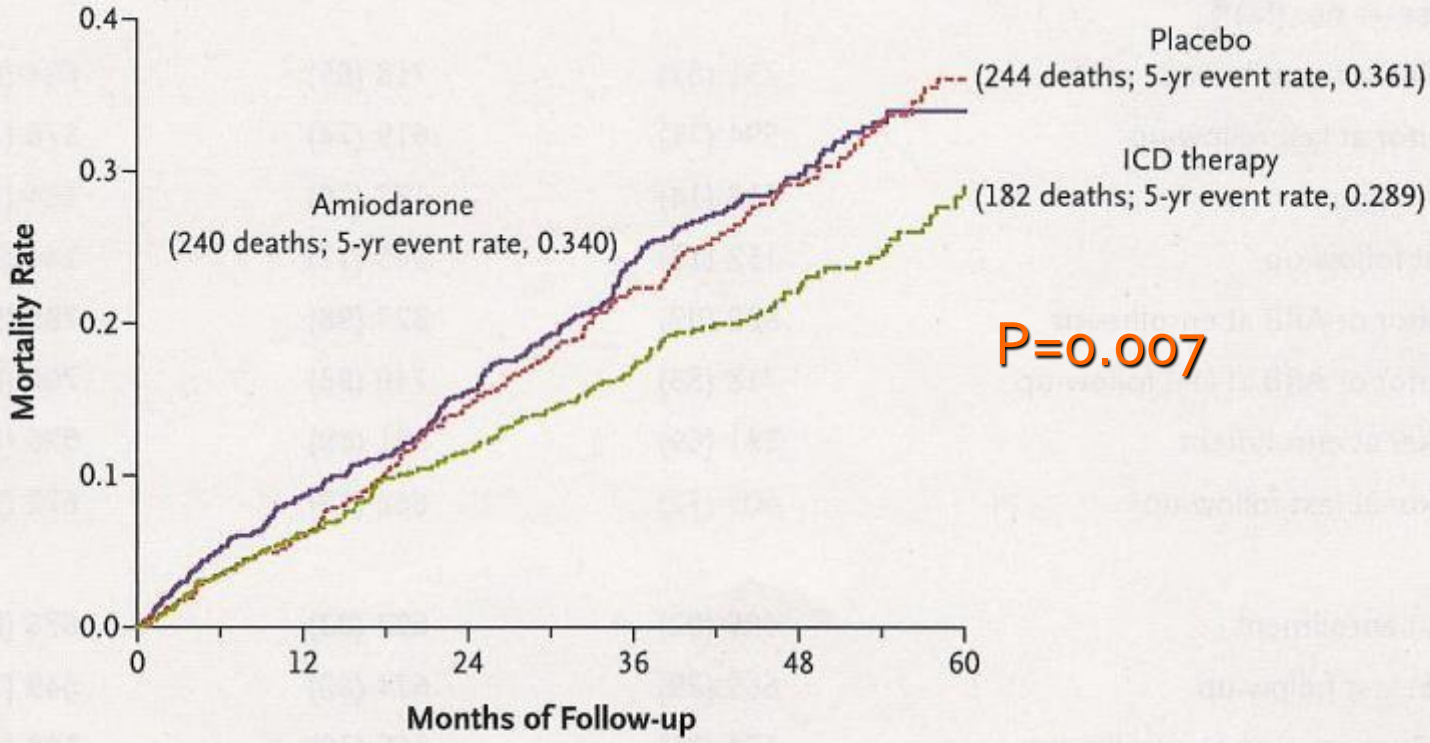
Epicardial ICD: 1980

Secondary Prevention / ≥ 2 Prior SCA Events



SCD-HeFT: *Mortality (n=2,521/ EF≤ 35)*

	Hazard Ratio (97.5% CI)	P Value
Amiodarone vs. placebo	1.06 (0.86–1.30)	0.53
ICD therapy vs. placebo	0.77 (0.62–0.96)	0.007

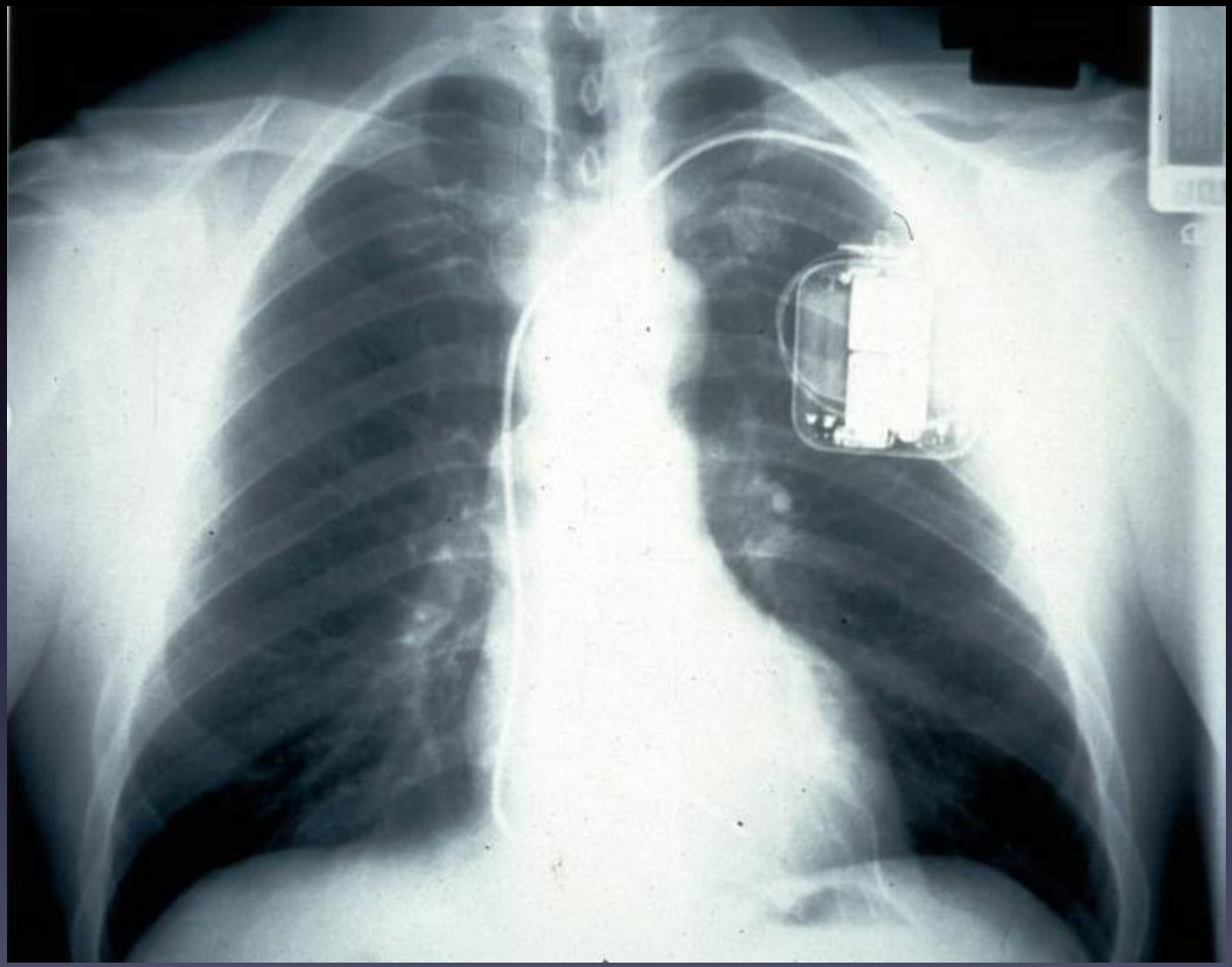


P=0.007

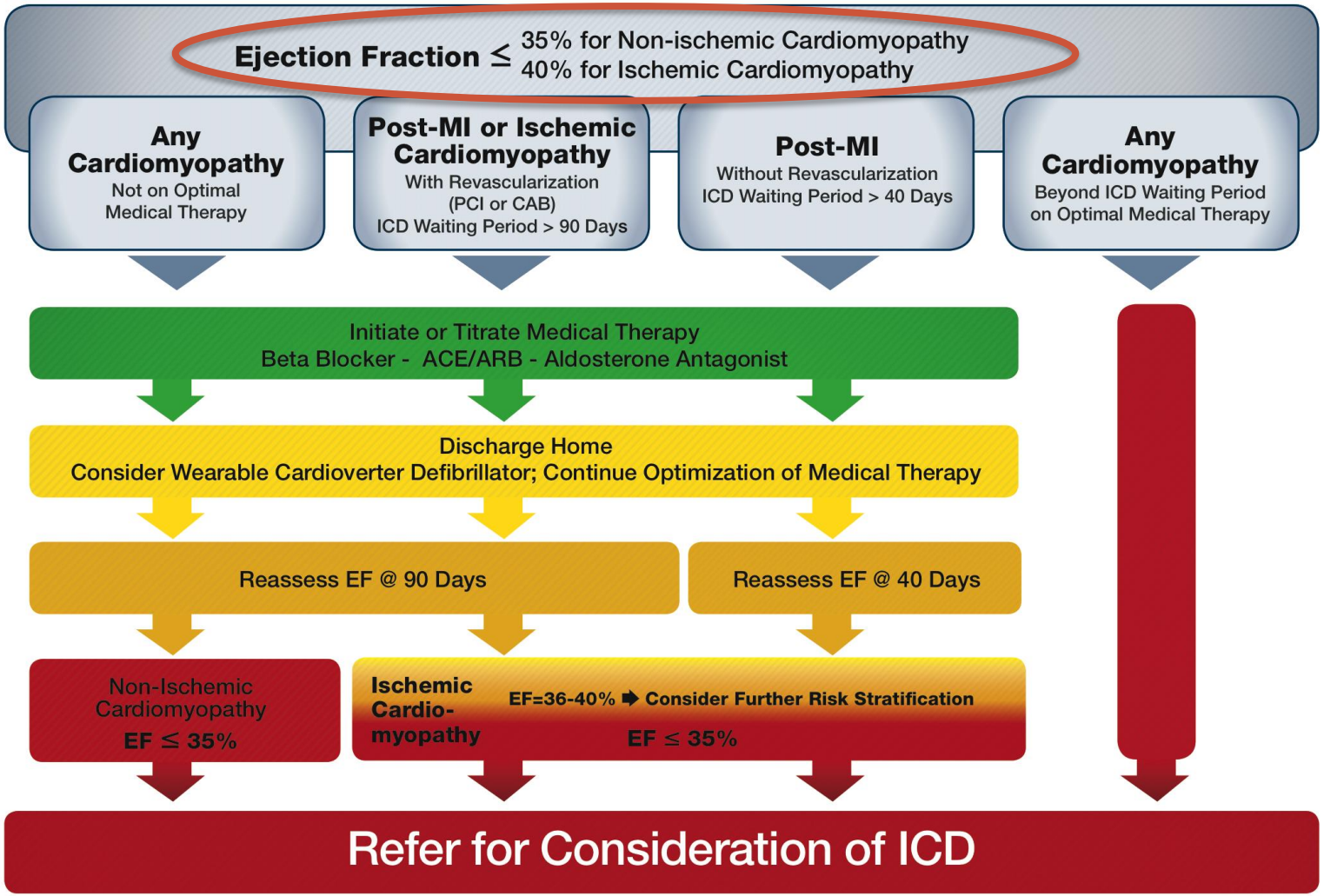
No. at Risk						
Amiodarone	845	772	715	484	280	97
Placebo	847	797	724	505	304	89
ICD therapy	829	778	733	501	304	103

NEJM 2005

Pectoral ICD: 1996-Current

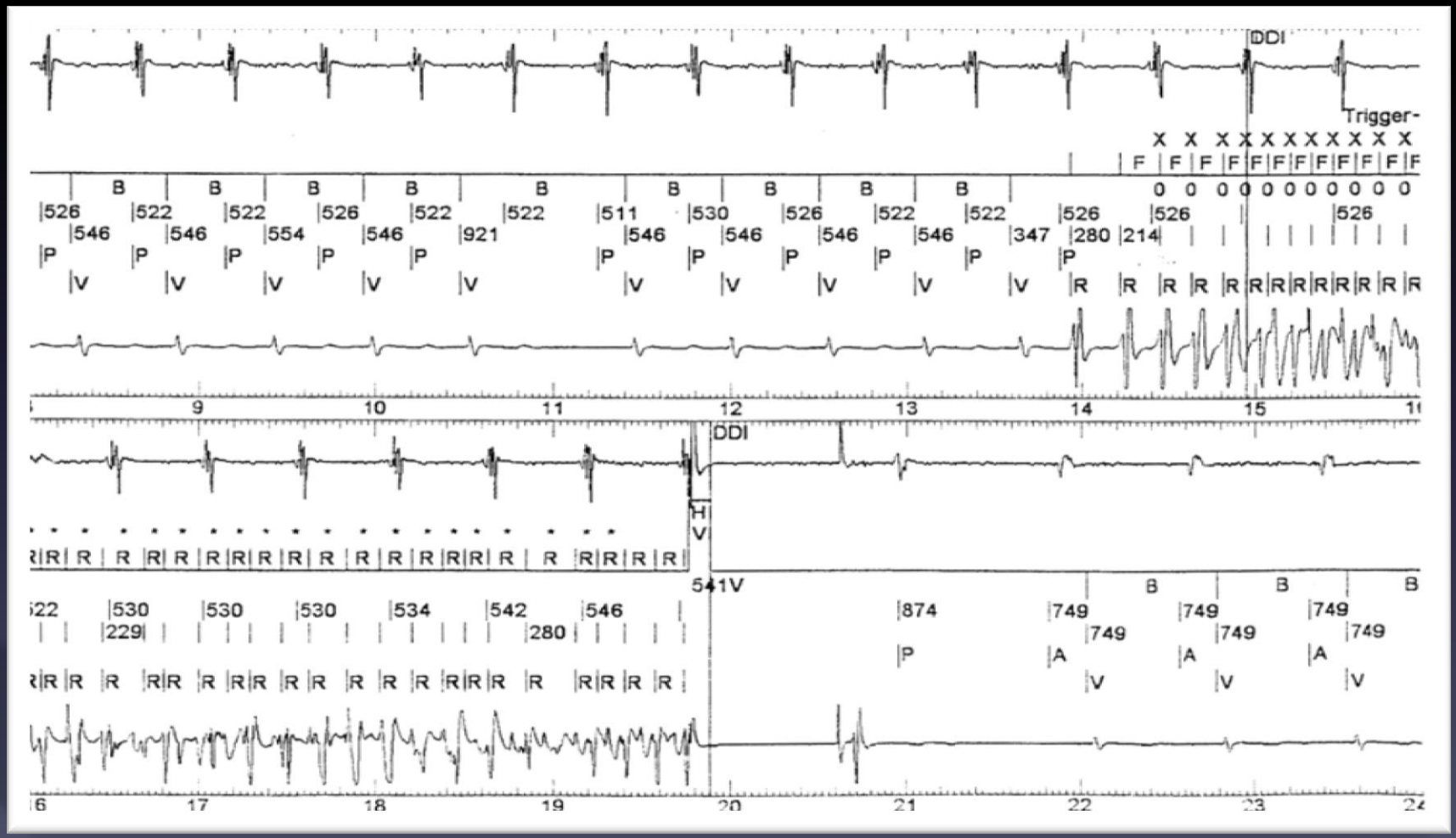


Sudden Cardiac Death Primary Prevention Protocols

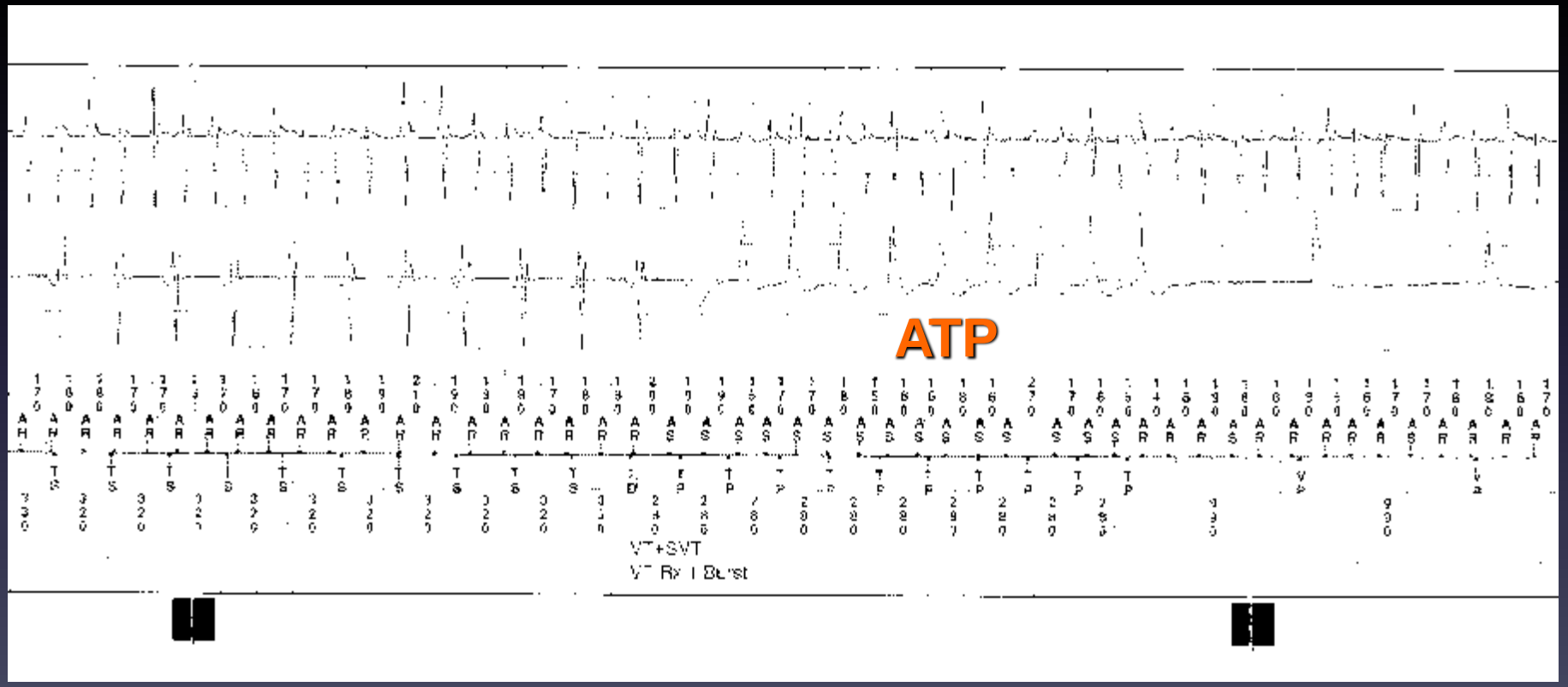


Heart Rhythm Society℠

EGM Tracing of Spontaneous VF Treated with ICD Shock



EGM Tracing of Afib and VT Treated with Anti-Tachycardia Pacing (ATP)



Post MI SCD Risk / Time Course

- The risk of sudden cardiac death post-MI is the highest in the first 30 days[1,2] (2008 / 2005)
  - Post-MI patients with heart failure are at 4-6 times greater risk of sudden cardiac death in the first 30 days after MI
- ICD Implant in first 40 d s/p MI in ” High Risk” Patients
  - DINAMIT (n=674;6-40 days / EF ≤35): HR 1.08 / p=0.66
  - IRIS (n=898;5-31 days / EF ≤40 or NSVT): HR 1.04 / p=0.78
- Patient condition can improve from the benefits of optimized medical therapy[3]
  - Significant improvements in EF are observed over the initial 8-10 weeks post-MI
  - REFINE Study average relative improvement in EF was 18% at 8-10 weeks

[1] Adabag AS, et al. Sudden Death After Myocardial Infarction. JAMA 2008; 300: 2022-2029.
[2] Solomon SD, et al. S D in Patients with Myocardial Infarction and Left Ventricular Dysfunction, Heart Failure, or Both. NEJM 2005; 352: 2581-2588.
[3] Exner DV. Non-invasive Risk Stratification Early s/p MI–The Risk Estimation post Infarction Non-invasive Evaluation (REFINE). JACC. 2007; 50: 2275-2284.
DINAMIT (NEJM 2005) / IRIS (NEJM 2009)

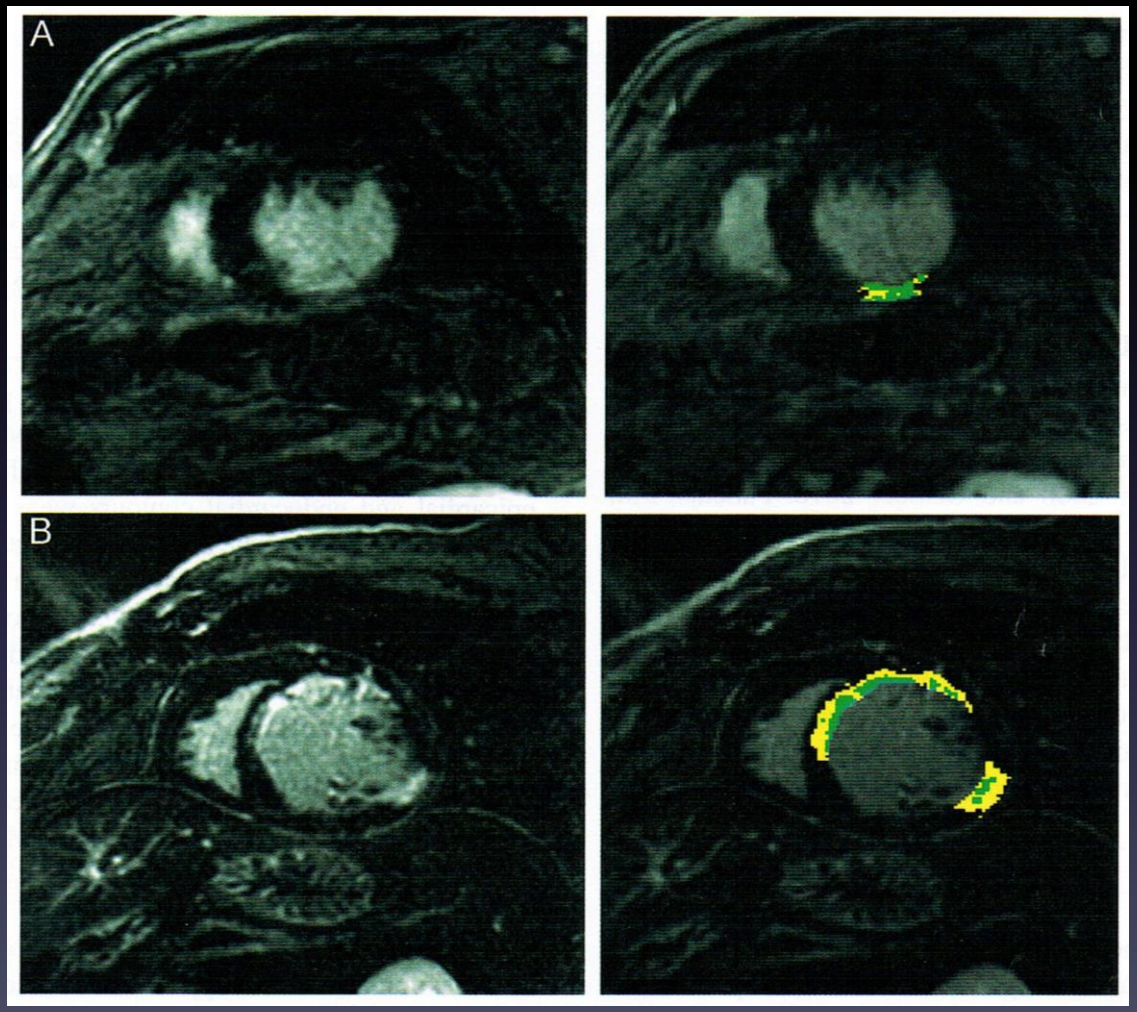
LifeVest "Wearable Defib" (WCD)

Zoll

LifeVest Indications: "Vulnerable" Periods

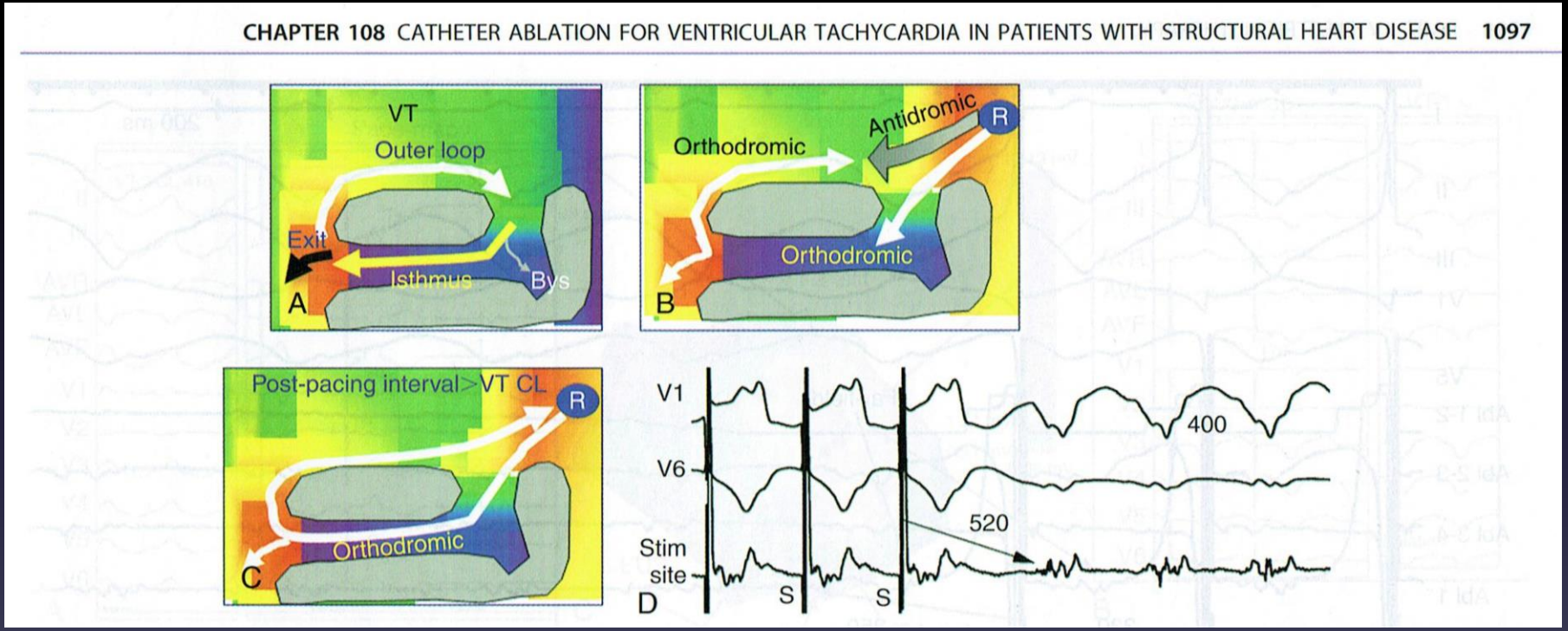
- Recent Intervention / SCA Risk (3 months)
  - PCI / CABG
- Recent MI / SCA Risk (40 days)
- Delay or Interruption of ICD Tx
  - Infection / Vascular / VT/VF Arrest with "Issues"
- Bridge to Transplant
- Inheritable Conditions During Risk Stratification
- Syncope with "High" Risk SCA Profile
- Newly Dx NIDCM with EF <35% (6-9 months)

Contrast Enhanced Delayed Gadolinium Magnetic Resonance Imaging for Scar



Zeiden-Shwirl et al. Heart Rhythm, Vol 12, No. 4, April 2015

Scar Reentry VT



WG Stevenson, U Tedrow in Zipes, Jalife Cardiac Electrophysiology 5th Edition 2009: 1097

Distribution of Ventricular Fibrosis Assocaited with Life-Threatening VTA in Pts with NIDCM

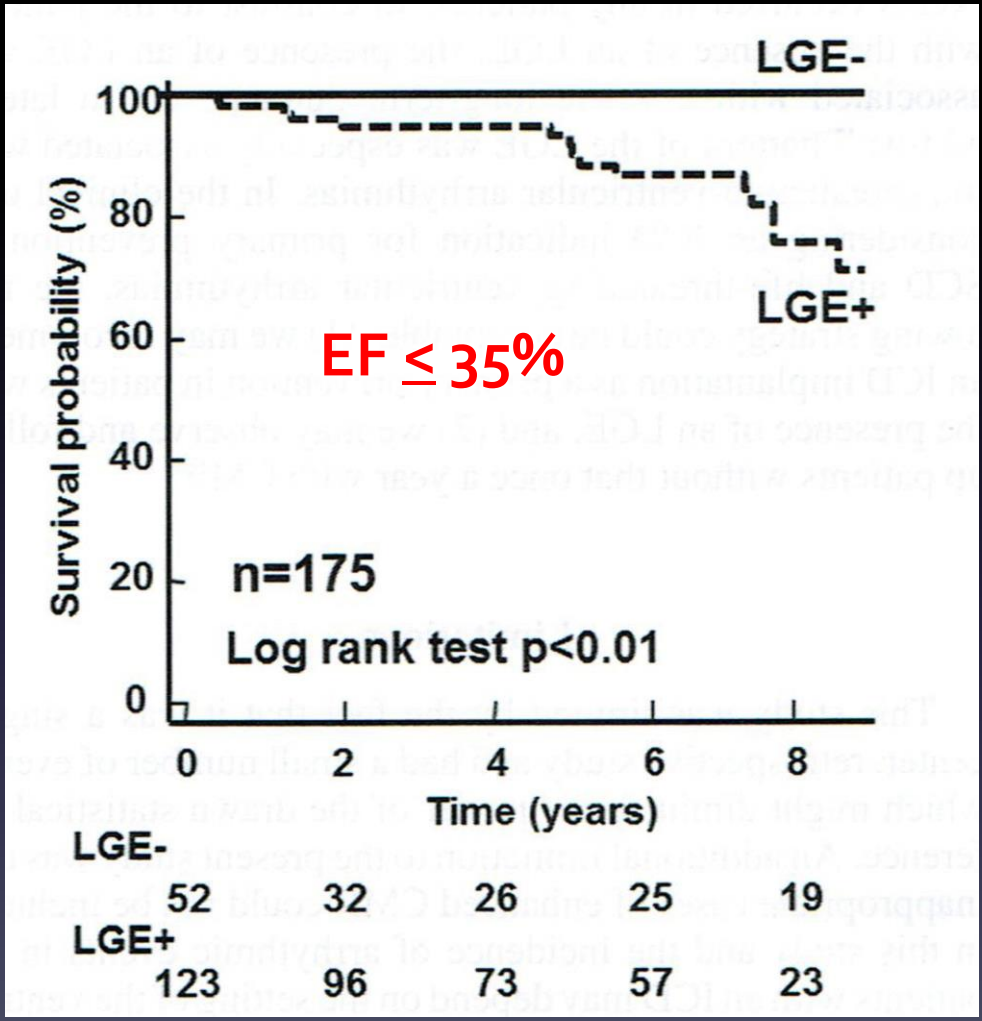
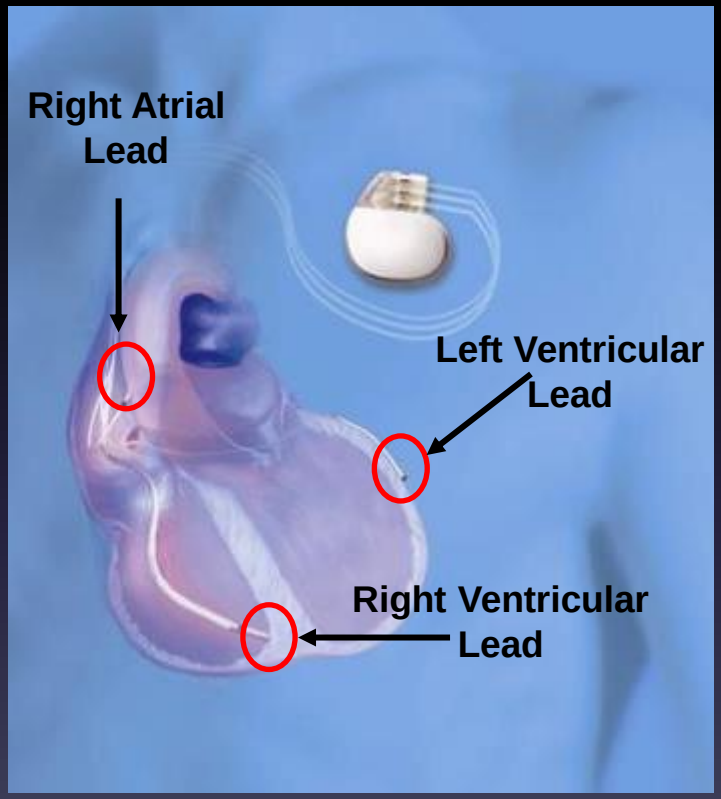
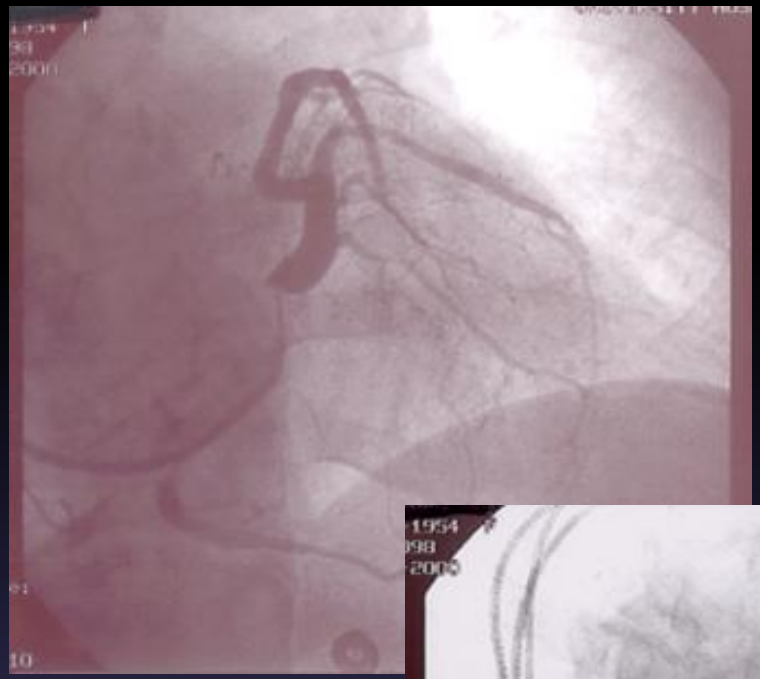


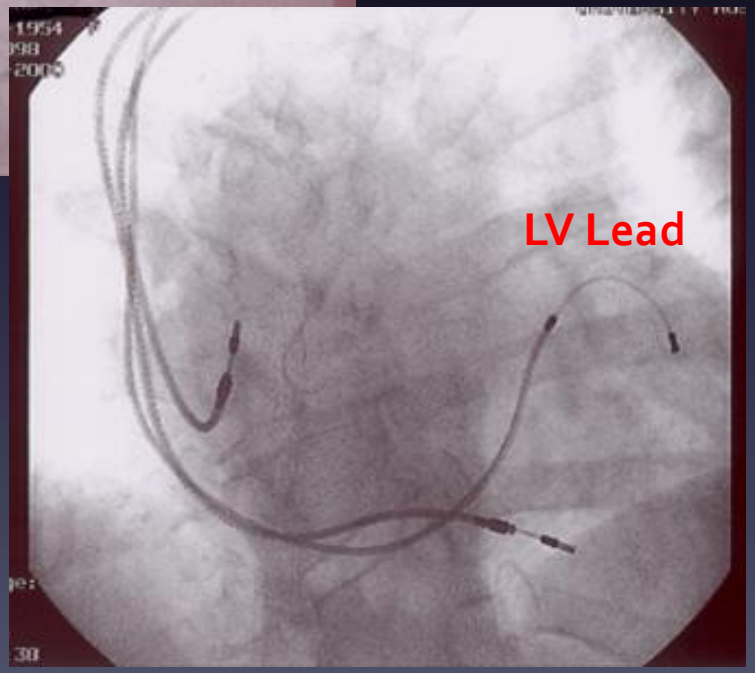
Fig. 1 SCD / VT or VF Requiring Therapy

Chimura et al.
JCEP 2015,
26:1239-1246

Cardiac Resynchronization Therapy (CRT)

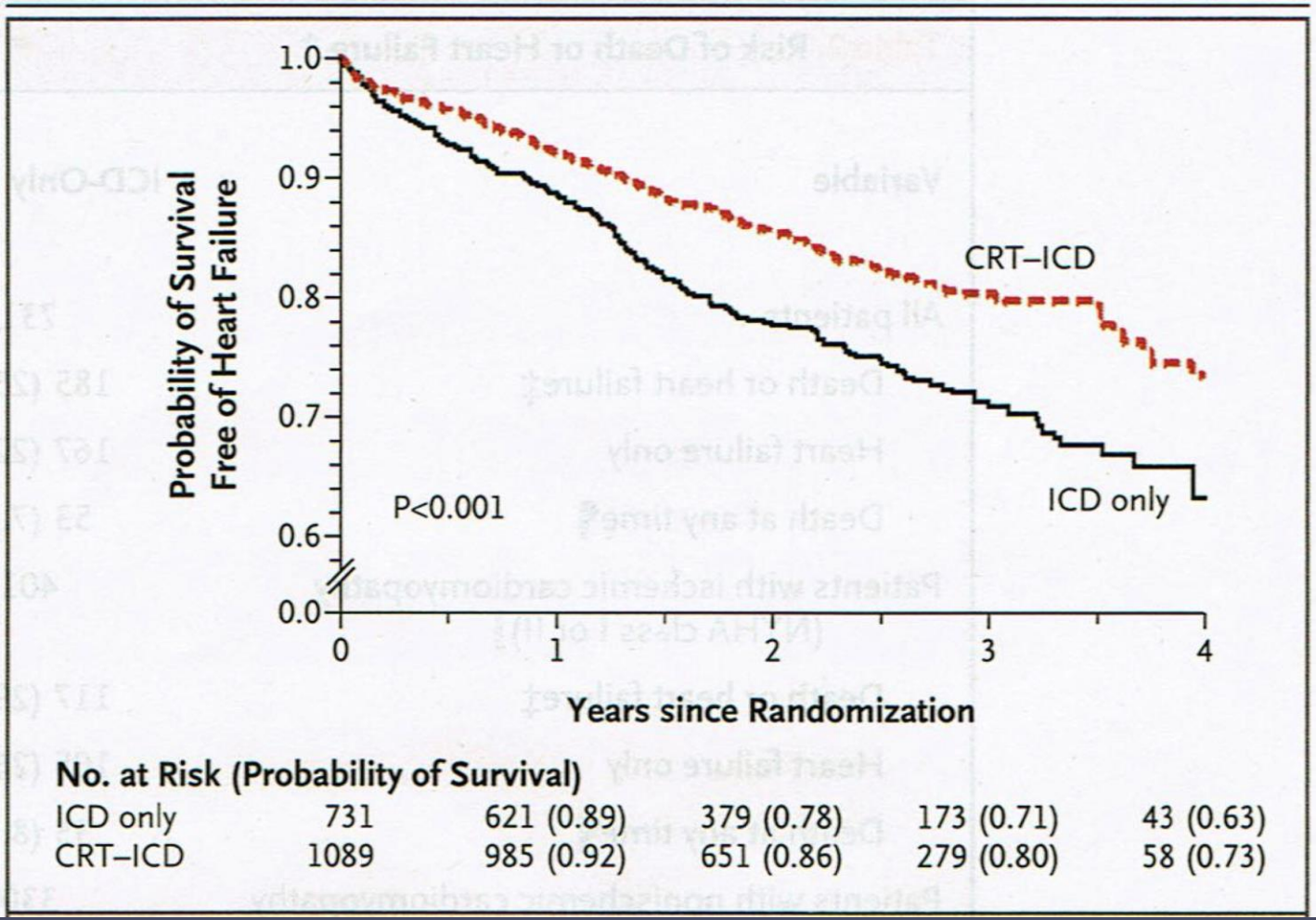






MADIT-CRT

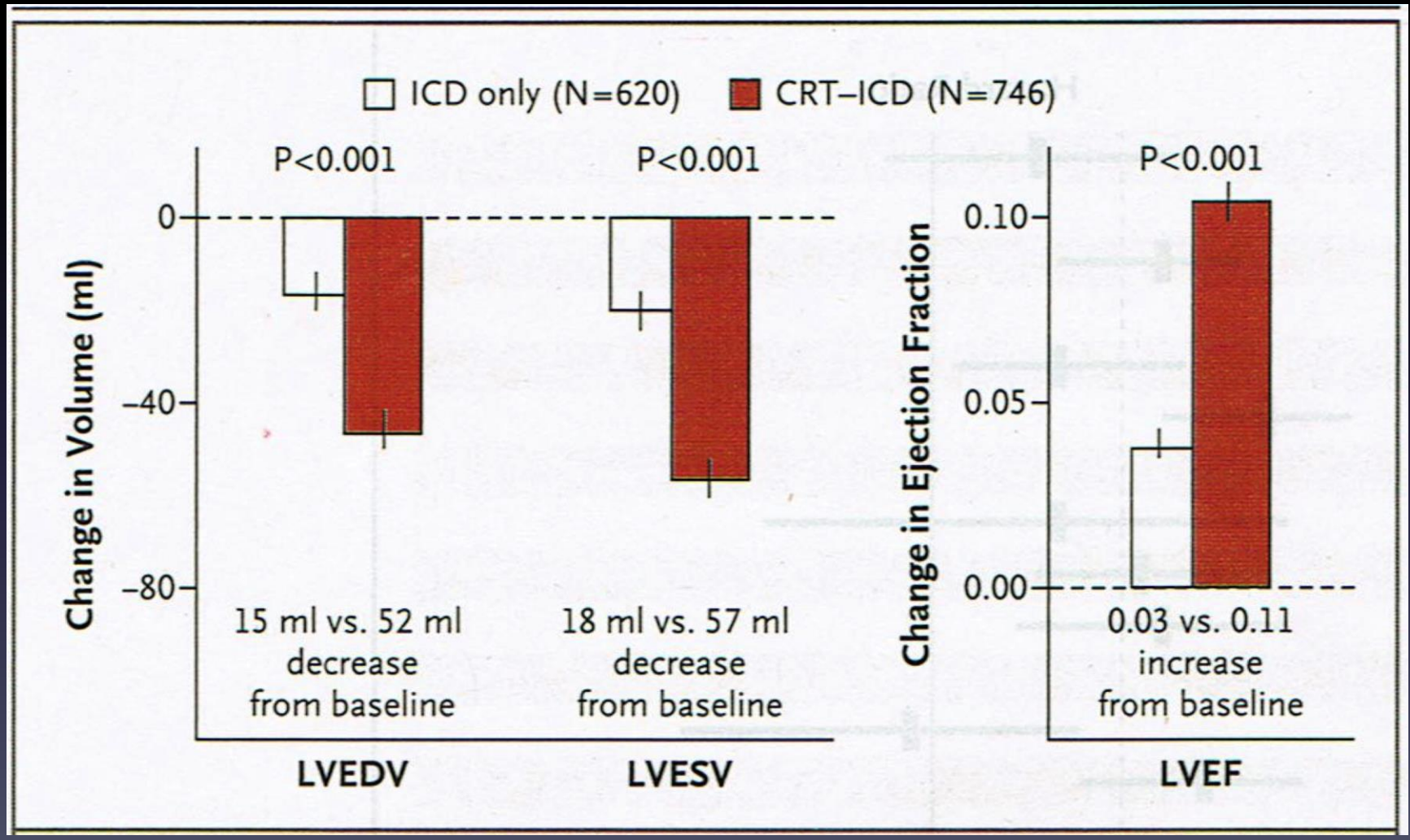
ICM / NIDCM w/ EF ≤ 30% & QRS ≥ 130 msec



Moss et al. NEJM 2009;361:1329-38

MADIT-CRT

LV Volumes / EF @ 1 yr

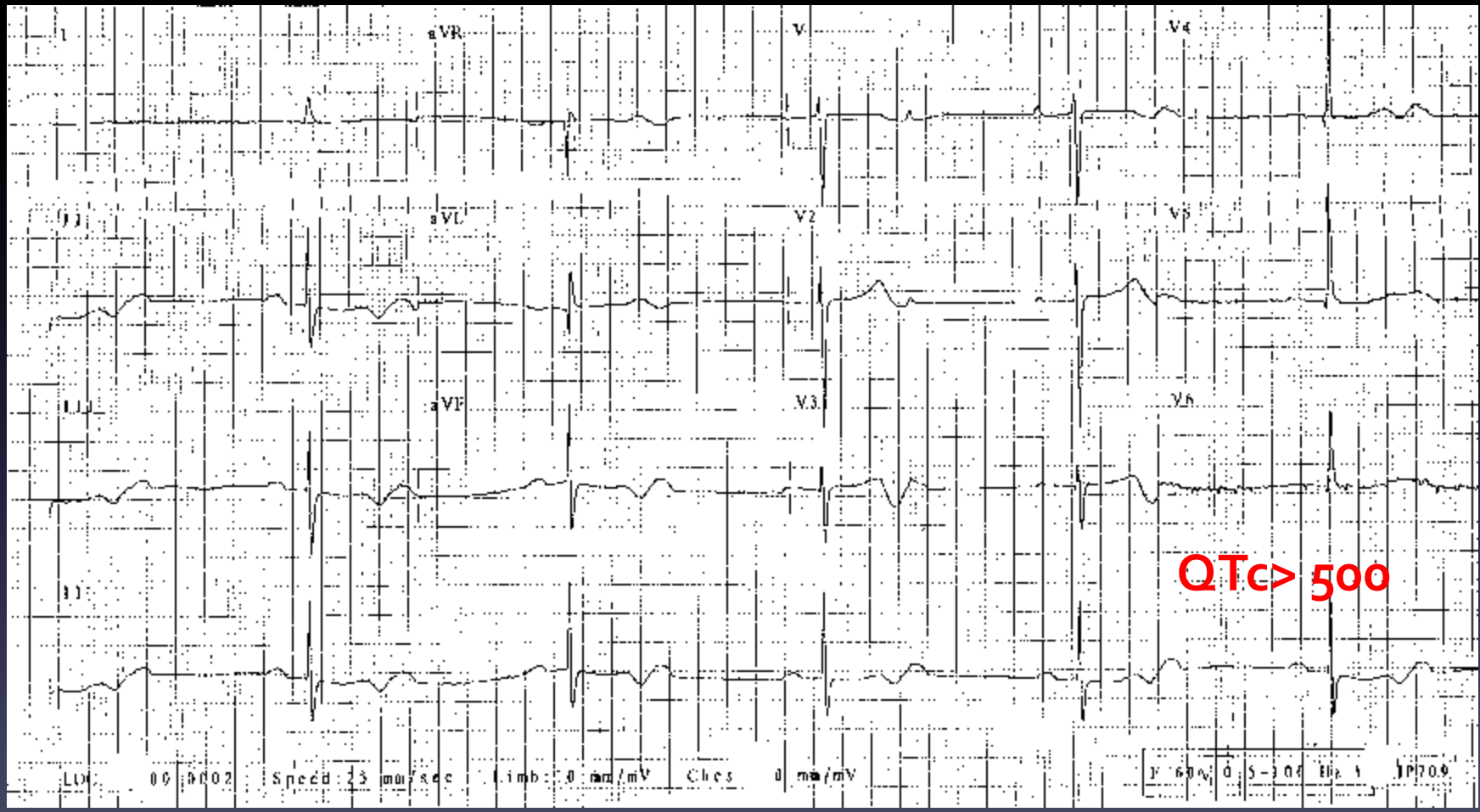


"Other" Potentially High Risk Patients

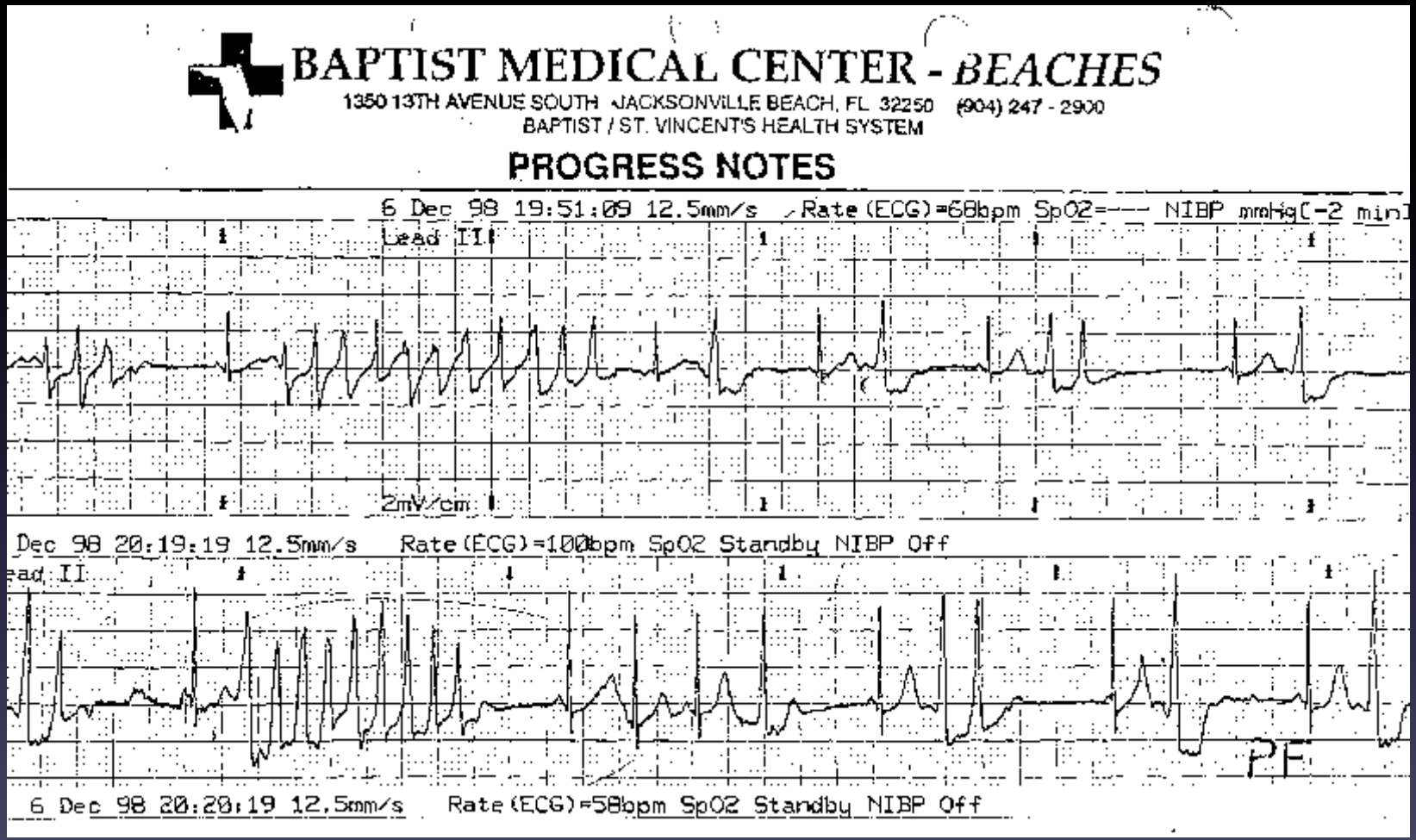
Genetic Screening may Help

- Primary Electrical / Ion Channel Disorder
  - Long QT / Short QT
  - Brugada Syndrome
  - CPVT (Catecholaminergic Polymorphic VT)
  - Early Repolarization (J waves Inferior / Lateral Leads)
- Arrhythmogenic RV Dysplasia (ARVD/C)
- Hypertrophic Cardiomyopathy

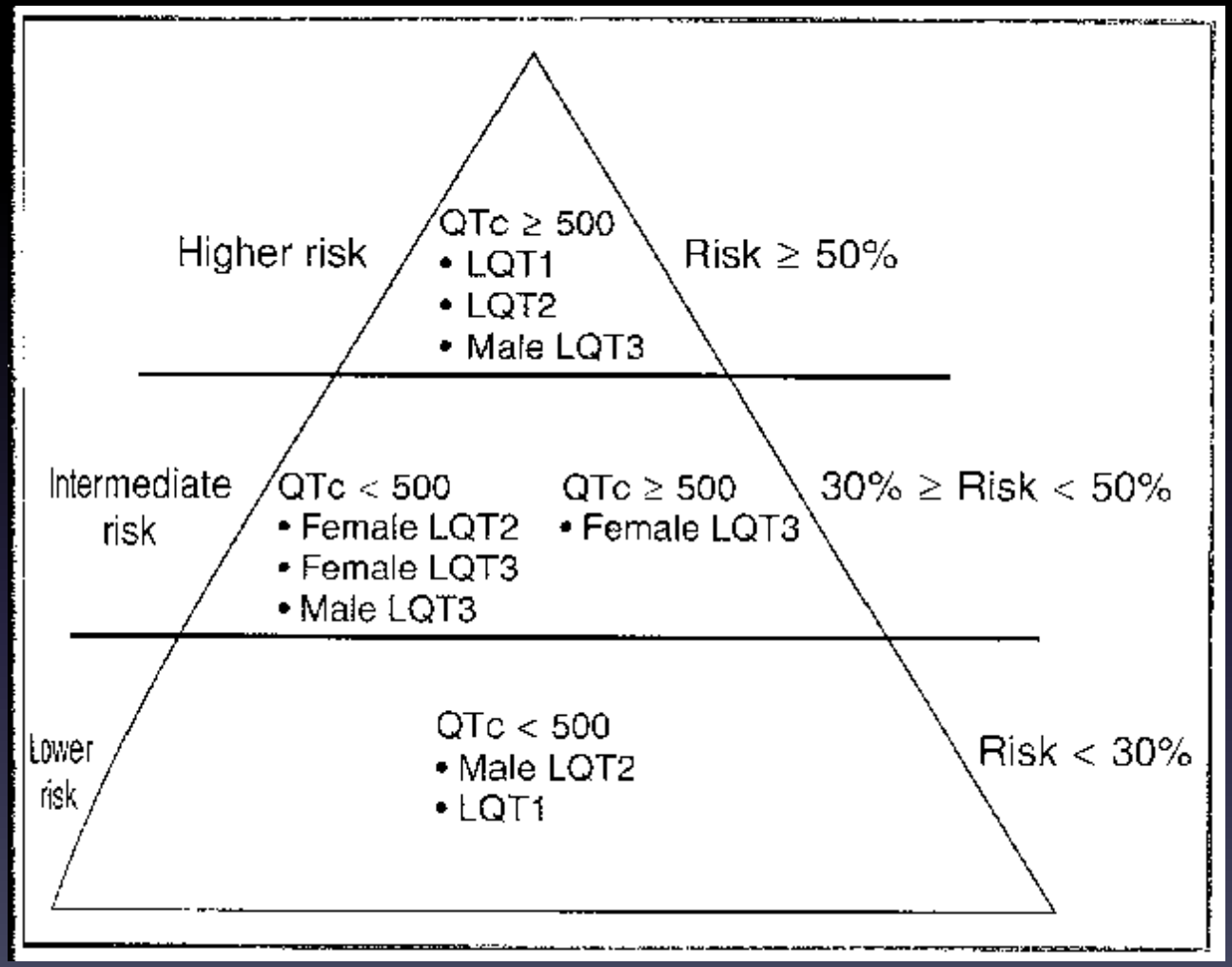
38 y/old Female w/ Palp & Syncope



38 y/old Female w/ Palp & Syncope (2)



Long QT Risk Stratification



Priori et al. NEJM 2003 348:1866-1874

22 y/old Female w/ Recurrent Syncope


BRUGADA
204

Brugada Epidemiologic Stratification

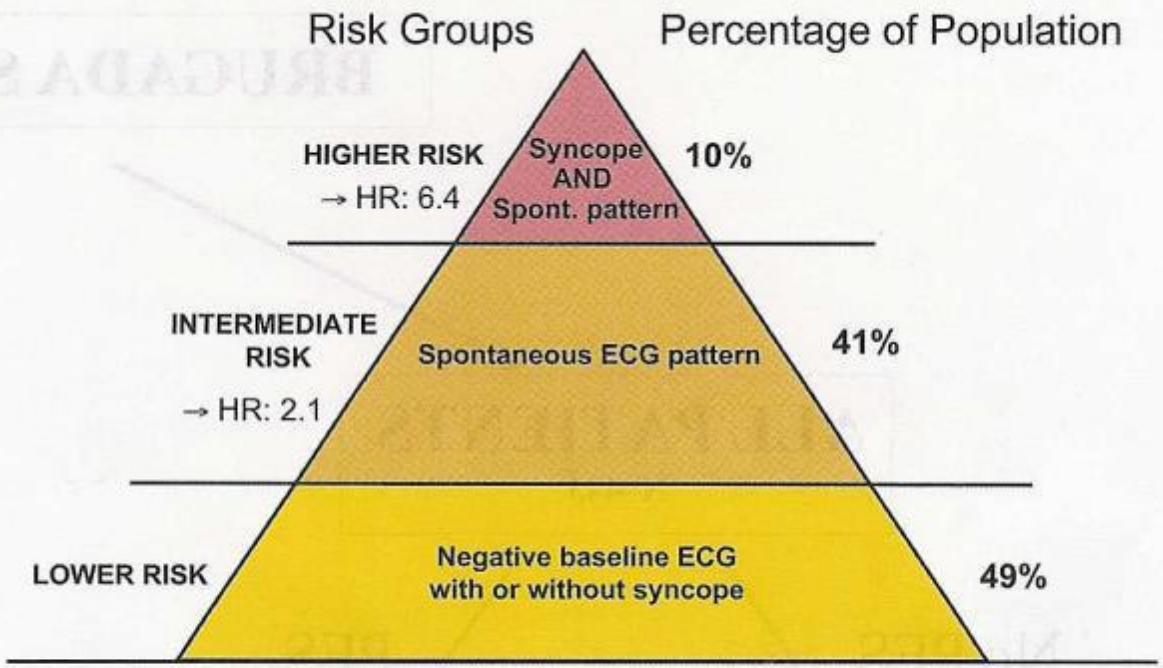
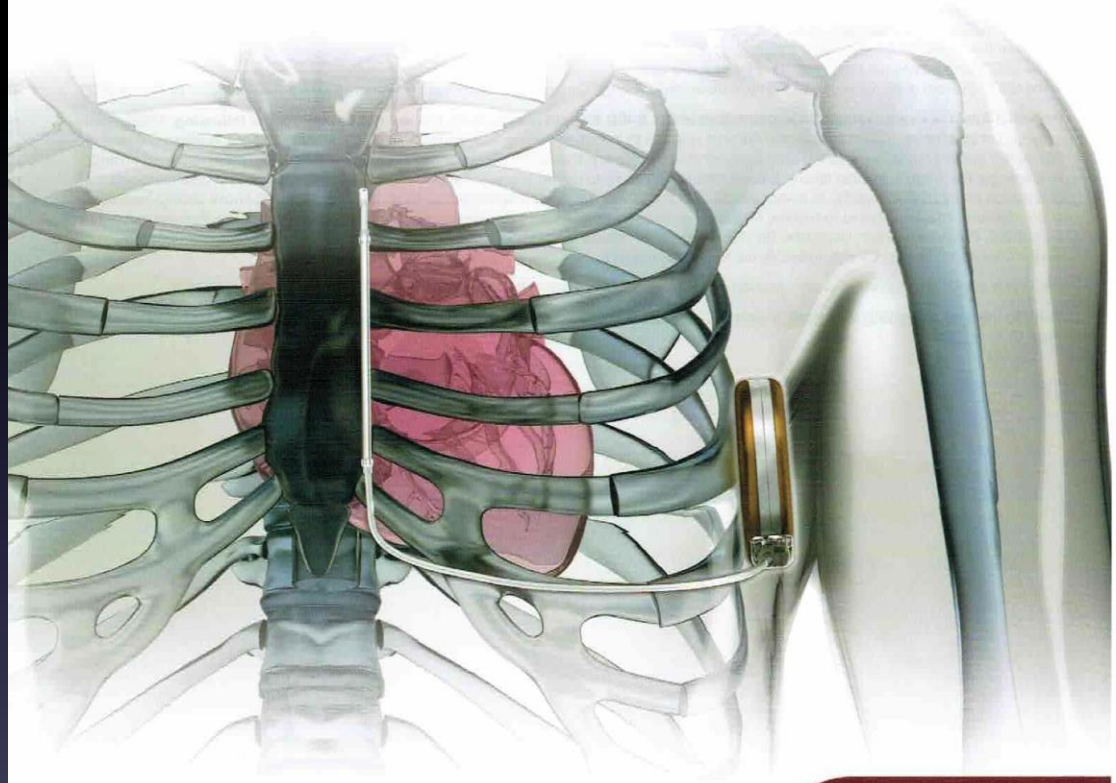


Figure 4. Risk stratification scheme in patients with Brugada syndrome according to clinical presentation. Reprinted with permission from *Circulation*.[35] Copyright 2002, American Heart Association.

Boston Scientific
Advancing science for life™

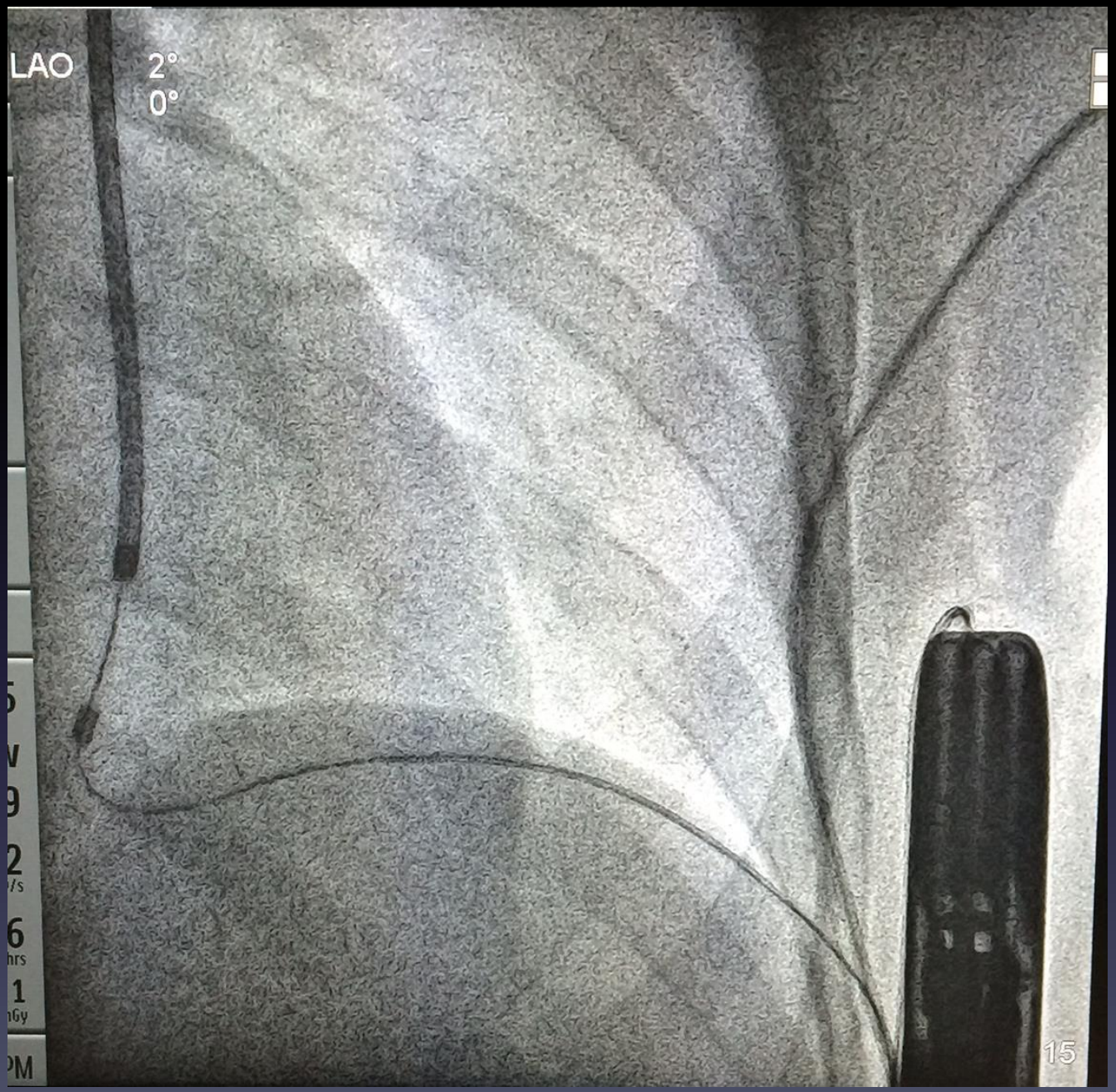
The S-ICD™ System

Protection Without Touching the Heart



The World's First and Only Subcutaneous ICD

The S-ICD System represents an exciting therapeutic solution for patients at risk of sudden cardiac arrest (SCA) that leaves the heart and vasculature untouched.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2°
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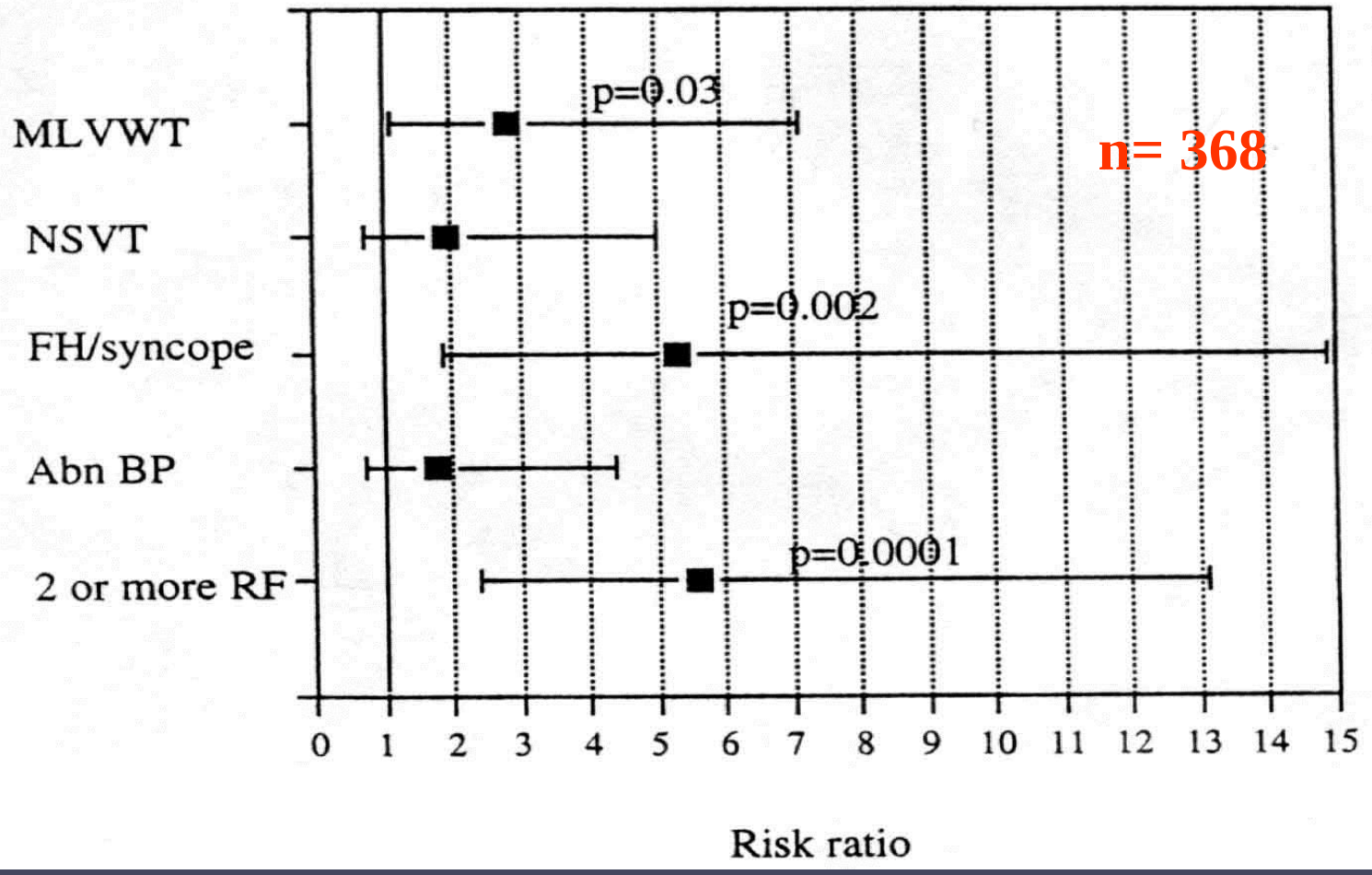
15

Hypertrophic Cardiomyopathy

Maron B.. NEJM 1987;316:780

Risk of Sudden Death in Hypertrophic Cardiomyopathy



JACC VOL. 36:7 / 2000

Appropriate ICD Use in High Risk HCM Patients

JACC VOL. 64, NO. 1, 2014
JULY 8, 2014:83–99

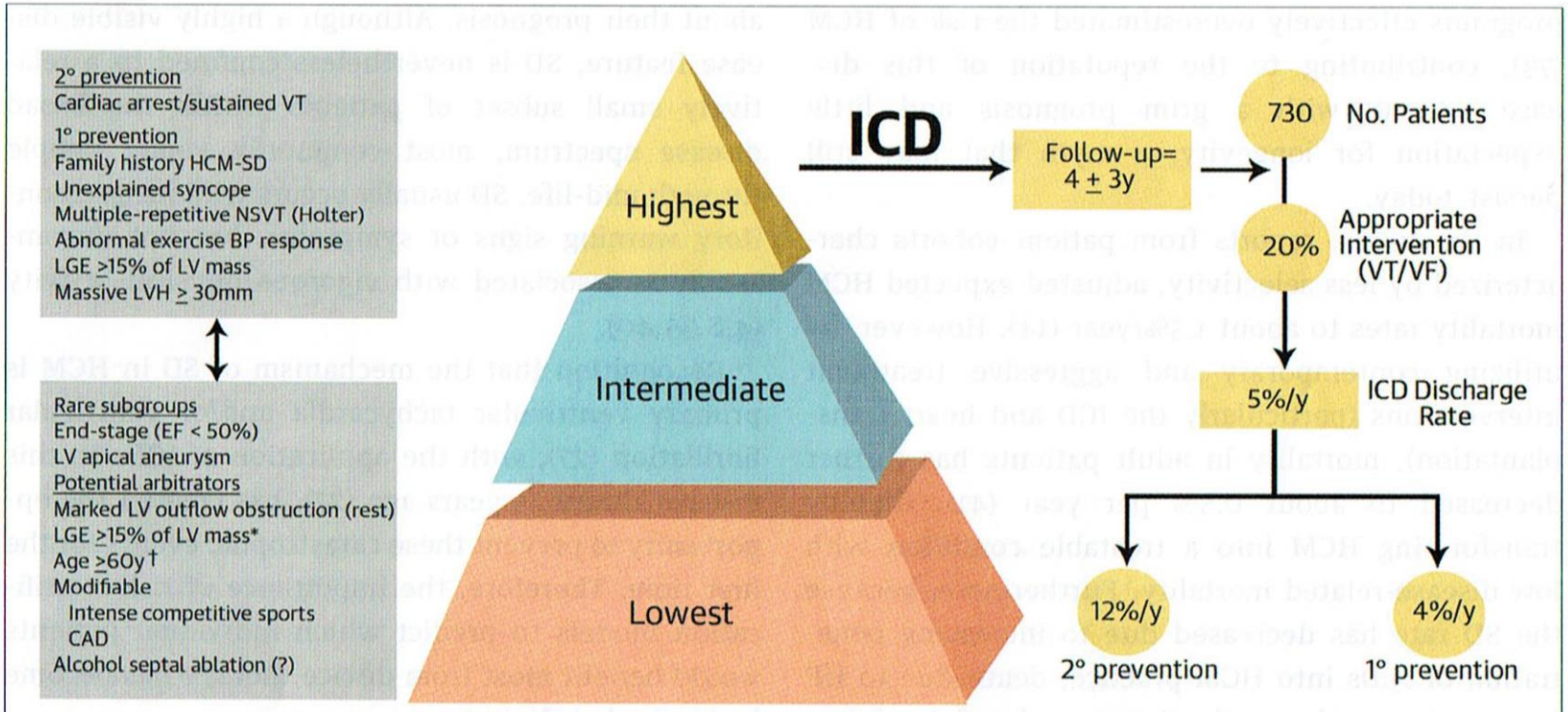
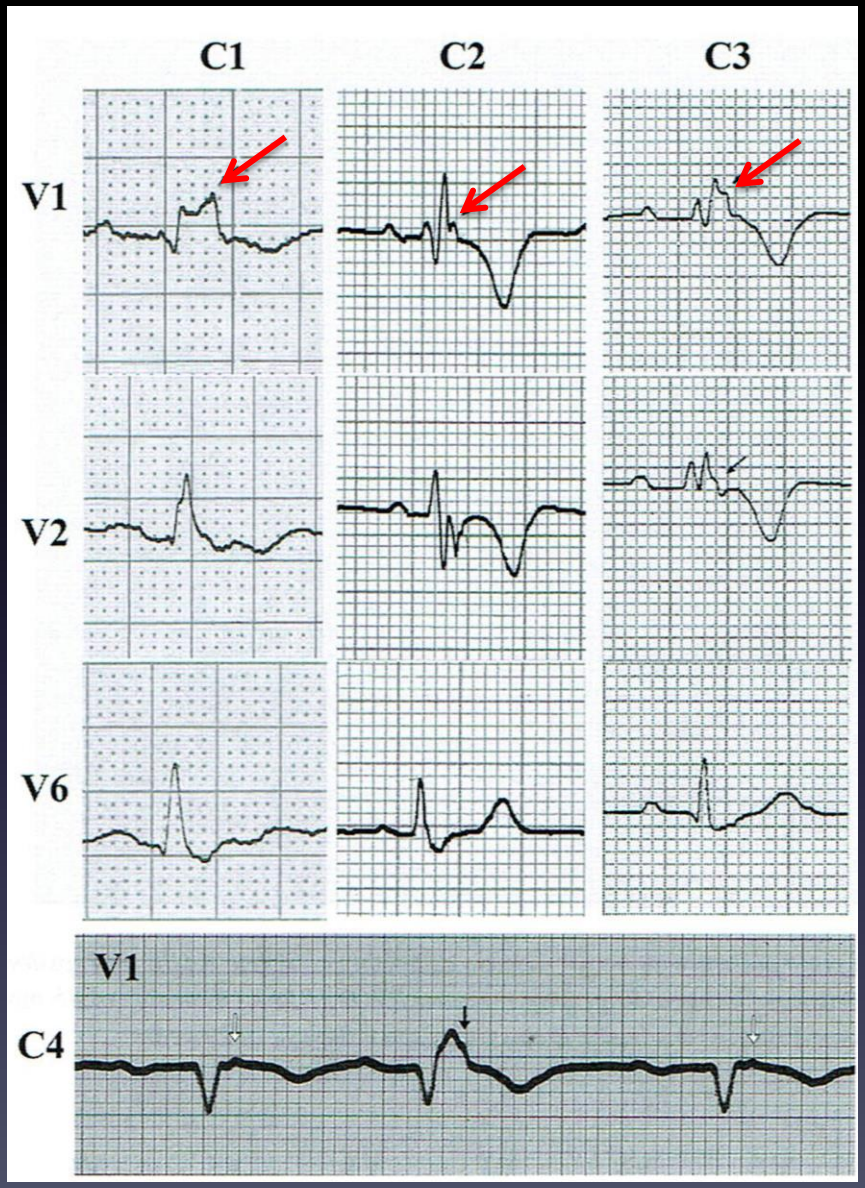


FIGURE 3 **Pyramid Profile of Risk Stratification Model Currently Used to Identify Patients at the Highest SD Risk Who May Be Candidates for ICDs and SD Prevention**

ARVD/C: RBBB / Epsilon Waves / ST-T Changes



Prontonotarios et al. JCEP 2015, 26:1204-1210

ARVD/C: Major / Minor Criteria

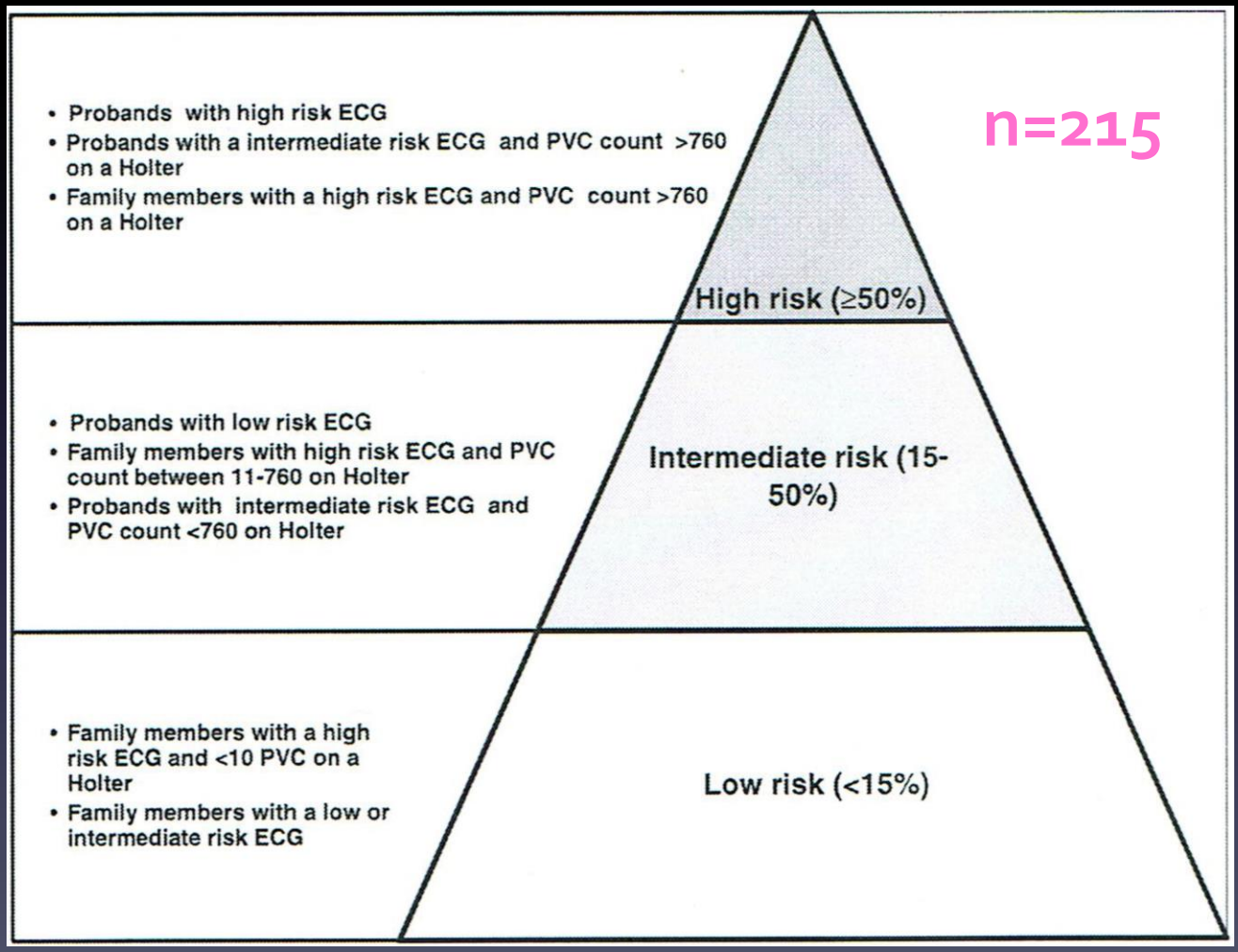
(2 Major / 1 Major plus 2 Minor / 4 Minor)

	Major Criteria	Minor Criteria
Structural or functional abnormalities	1. Severe dilation and reduction of RVEF with mild or no LV involvement 2. Localized right ventricular aneurysm (akinetic or dyskinetic areas with diastolic bulging) 3. Severe segmental dilatation of the RV	1. Mild global right ventricular dilation and/or EF reduction with normal LV 2. Mild segmental dilation of the RV 3. Regional right ventricular hypokinesis
Tissue characterization	Infiltration of RV by fat with presence of surviving strands of cardiomyocytes	
ECG depolarization/ conduction abnormalities	1. Localized QRS complex duration >110 ms in V_1, V_2, or V_3 2. Epsilon wave in V_1, V_2, or V_3	Late potentials in SAECG
ECG repolarization abnormalities		Inverted T waves in right precordial leads (V_2-V_3 aged >12 y in the absence of RBBB)
Arrhythmias		1. LBBB VT (sustained or nonsustained) on ECG, Holter, or ETT 2. Frequent PVCs (>1000/24 h on Holter)
Family history	Family history of ARVD/C confirmed by biopsy or autopsy	1. Family history of premature sudden death (<35 y) due to suspected ARVD 2. Family history of clinical diagnosis based on present criteria

The criteria state that an individual must have 2 major, or 1 major plus 2 minor, or 4 minor criteria from different categories to meet the diagnosis of ARVD/C. *Abbreviations*: EF, ejection fraction; ETT, exercise treadmill test; LV, left ventricle; PVC, premature ventricular contraction; RBBB, right bundle branch block; RVEF, right ventricular ejection fraction.

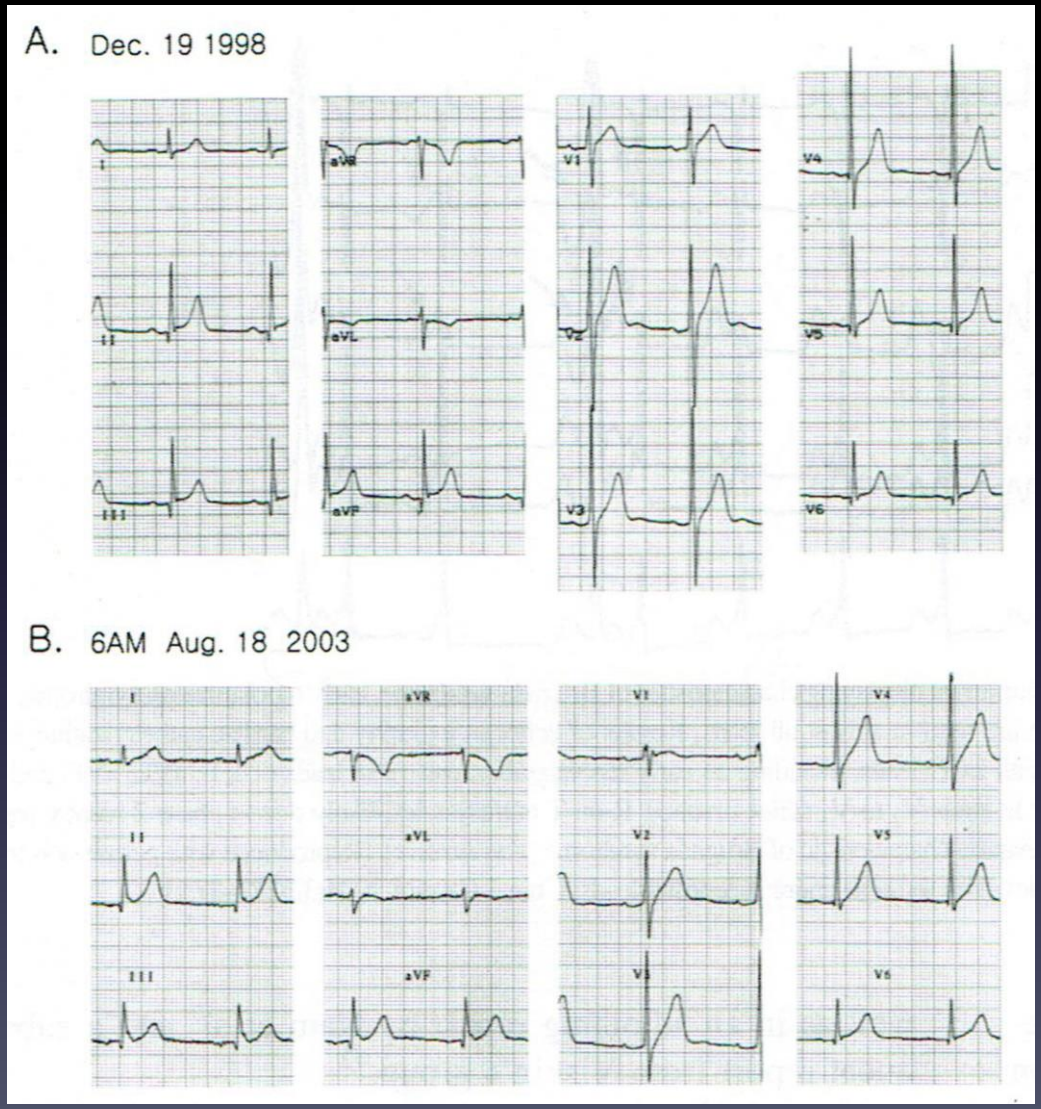
Risk Stratification in ARVD/C-Associated Desmosomal Mutation Carrier

Proband Status / EKG Abnml / PVC Burden



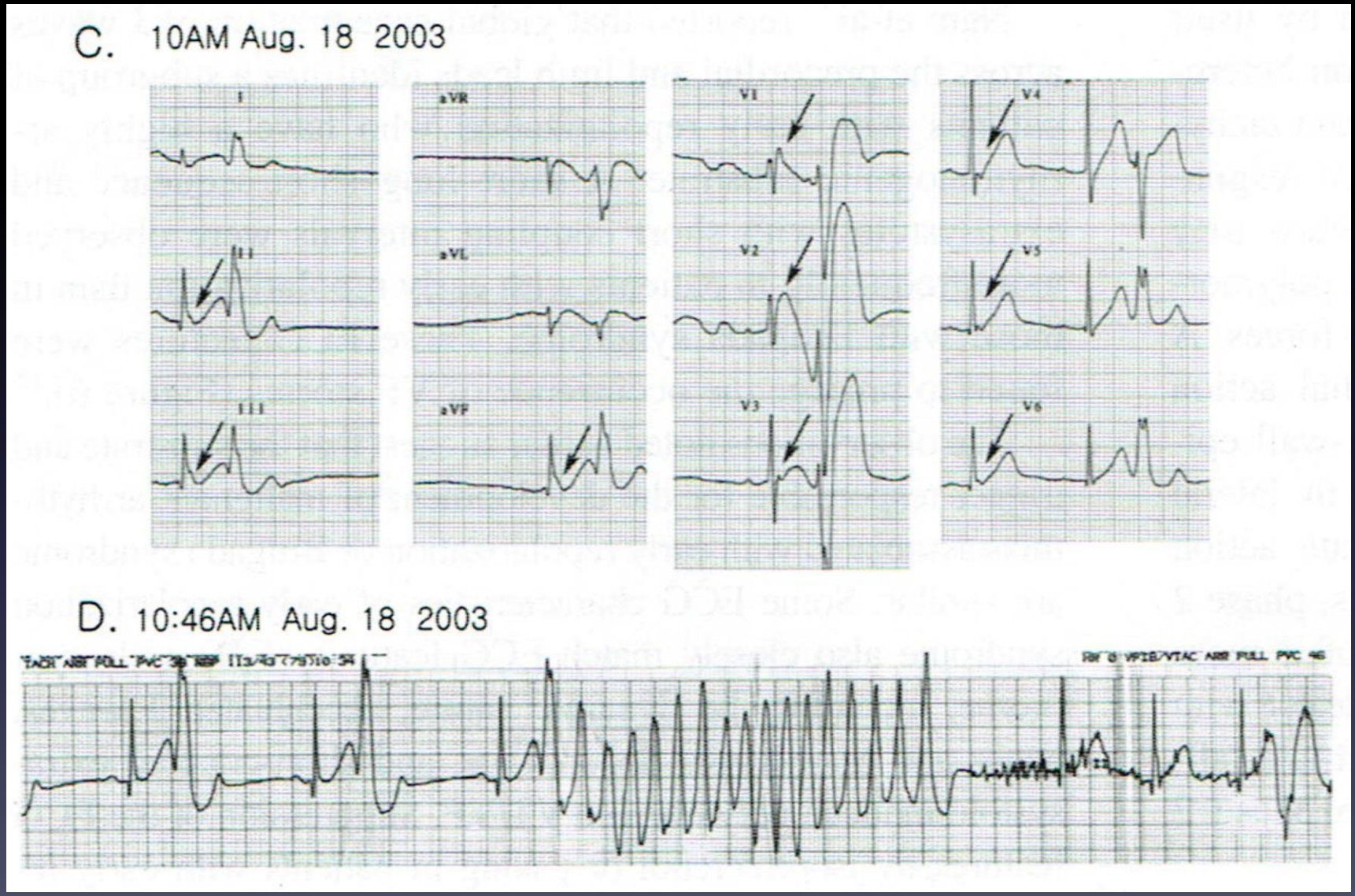
Bohnsale et al. Circ Arrhythmia Electrophysiol 2013;6:569-578

Pt w/ Dx of "Idiopathic VF"…Labile EKG (Early Repol / Brugada / J Wave Syndrome…)



Antzelevitch, Yan
Heart Rhythm
2010;7:549-558

Not all Early Repolarization is Benign…



Risk Class at Time of SCD

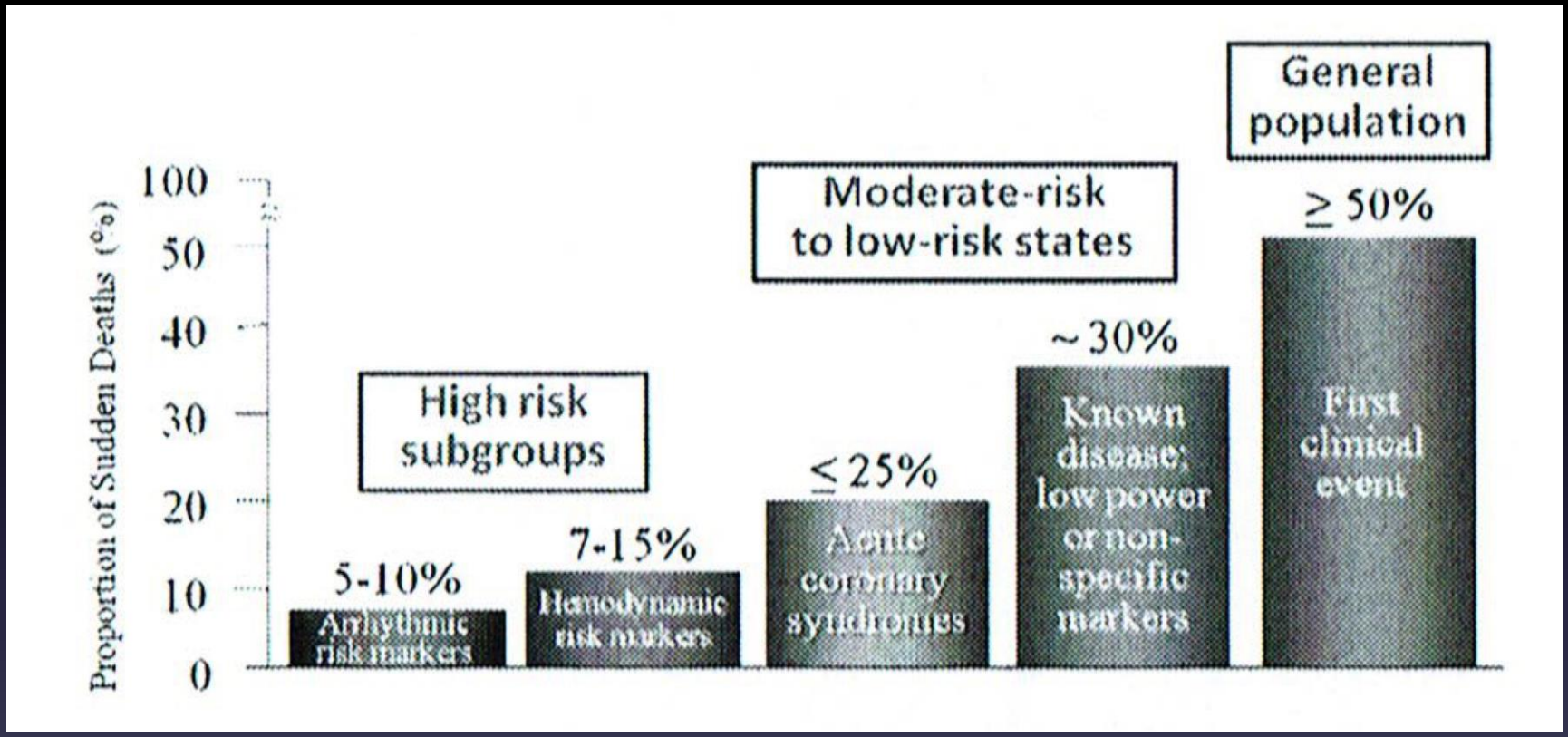


Fig 1 Distribution of Clinical Status of Victims at Time of SCD

Mitrani, Myerburg, Science Direct, Trends in CV Medicine 2015

1° Prophylaxis SCD Risk Stratification 2016

- Ejection Fraction
- 12 Lead EKG
  - Intervals / Morphology (WPW / Brugada etc.)
- Symptoms (Syncope / Palp / Sx CHF)
- Physical Exam (Murmur / Gallop / Rales / E)
- Family History (Syncope / SCD etc.)
- *Genetic Screening / MRI Scar Burden…??*

"Know Your Number" Campaigns…

- Cholesterol
- Blood Pressure
- Blood Sugar
- ***$$ Amount to Retire…***
- **Ejection Fraction…**
  - **Medtronic**

Are You At Risk for Sudden Cardiac Arrest?

Why heart patients need to know their EF number.

What is an EF number?

Ejection fraction (EF) is the percentage of blood that is pumped from your heart during each beat.

Why is it important?

EF is a key indicator of heart health and helps determine your treatment plan.

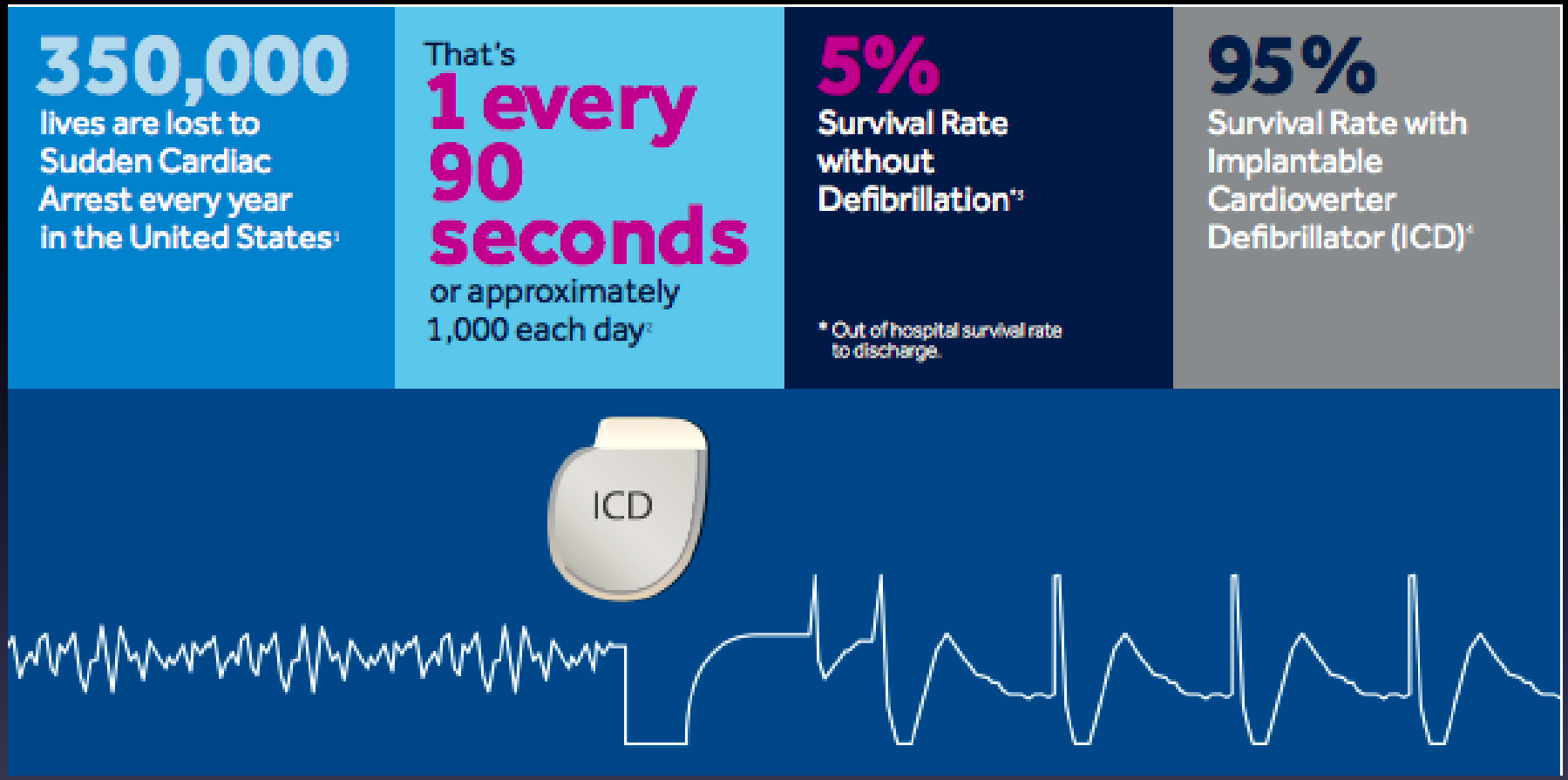
50-75%	36-49%	35% & Below
Heart's pumping ability is **NORMAL**	*Heart's pumping ability is* **BELOW NORMAL**	*Heart's pumping ability is* **LOW**

- EF should be measured and tracked regularly for people with heart failure or who have survived a heart attack.
- Heart patients with a low EF are at a greater risk for sudden cardiac arrest (SCA), a life-threatening condition.
- Talk to your heart doctor about your EF and find out your EF number.

For general information about EF, visit www.EFnumber.com

Medtronic

Courtesy of Medtronic



Courtesy of Medtronic

SUDDEN CARDIAC DEATH

post-PCI and post-MI

Assess It.
Discuss It.
Prevent It.

Find tools to help assess your patients' risk @ **SCDFacts.org**

1 in 5 post-PCI patients are at **high risk of dying.**[1]

#1 RISK FACTOR **Ejection Fraction** is the most powerful predictor of long-term mortality.[1]

The majority of mortality in post-PCI patients with low EF occurs in the **first 3 months.**[1]

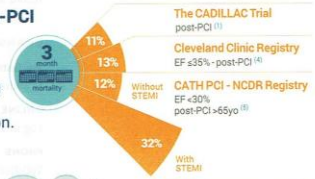
The risk of SCD post-MI is highest during the **first 30 days.**[2,3]

Rate of Sudden Death or Cardiac Arrest with Resuscitation (%/mo)

Post-MI patients with HF are at **4-6 times** greater risk of SCD in the **first 30 days** after MI.[2,3]

of 1 year mortality occurs in the **first 3 months** post-PCI.[1]

High-risk post-PCI patients experience significant mortality during recovery from revascularization.



BOTTOM LINE

1 in 10 high-risk post-PCI patients die, with about **60%** of this mortality due to **SUDDEN CARDIAC DEATH.**[1,5]

SOURCES: 1. Halkin A et al. Prediction of Mortality After Primary Percutaneous Coronary Intervention for Acute Myocardial Infarction: CADILLAC Risk Score. JACC 2005;45:1397–1405. 2. Adabag AS et al. Sudden Death After Myocardial Infarction. JAMA 2008;300:2022–2029. 3. Solomon SD et al. Sudden Death in Patients with Myocardial Infarction and Left Ventricular Dysfunction, Heart Failure, or Both. NEJM 2005;352:2581–2588. 4. Zishiri ET et al. Early Risk of Mortality after Coronary Artery Revascularization in Patients with Left Ventricular Dysfunction and Potential Role of the Wearable Cardioverter Defibrillator. Circulation: Arrhythmia and Electrophysiology. 2013;6:117–128. 5. Weintraub WS et al. Prediction of Long-Term Mortality After Percutaneous Coronary Intervention in Older Adults: Results From the National Cardiovascular Data Registry. Circulation. 2012;125:1501–1510. 6. Stone G et al. Prevention of Sudden Cardiac Arrest Post PTCA in High-Risk Patients. http://www.theheart.org/article/1202823.do (April 2011).

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20C0385 Rev A

Utilization rates of ICDs for 1°Prevention of SCD: A 2012 Calculation for a midwestern referral region

- Health Info Exchange Database
- N=1863 / 491 charts reviewed / EF ≤ 35 %
- Utilization Ratio for PPSCD ICD: 38 %
- URs: 48 % Males / 21 % Females (p=0.0002)
- Most patients with PPSCD Indication NOT receiving ICD did NOT have mention of ICD in chart @ discharge or during outpatient follow-up.

Hoang et al. Heart Rhythm 2014;11:849-855

Under-Utilization of ICDs in Pts w/ HF
The Current State of SCD Prophylaxis

- Prospective Registry (n=707) / EF ≤ 35 %
- ICDs Implanted in 200 (28%)
- Mortality: 37% w/o ICD / 25% w/ ICD (p=0.004)
- Top Reason for NOT Getting ICD…
  - Option Not Discussed: n=74 (23.2%)
  - Patients Refused: n=72 (22.6%)
  - EF Improved: n=52 (16.3%)

Pillarisetti et al. IPEJ 2015, 15(1):20-29

Final Thoughts / Summary

- EF(≤ 35%) "Best" SCD Risk Predictor…
- Keep other Risk Factors in Mind…
  - Family Hx / Syncope / Abnormal EKG / Cardiac Hx & Sx
  - Genetic Screening / MRI Scar Imaging …stay tuned
- CHF Tx Reduces Mortality / NOT Antiarrhythmics
- ICD's are Effective
- CRT Adds Another Level of Protection
- Patient & Physician Awareness "Campaigns"