

# Sudden Cardiac Death: High Risk Patients: Management of SCD Risk in Newly Dx Heart Failure Patients: Role of Wearable Defibrillator



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# Learning Objectives

## ➤ Sudden Cardiac Death

- Etiologies and Management strategies

Sudden Cardiac Death: The High Risk Groups:

Understanding the Heart Failure Problem

Ischemic Cardiomyopathy: Revascularization: Transitional Care

## ➤ Identifying the opportunity for reducing the risk of SCD in Newly-Diagnosed HF patients

- Importance of Optimal Medical Therapy titration for HF patients

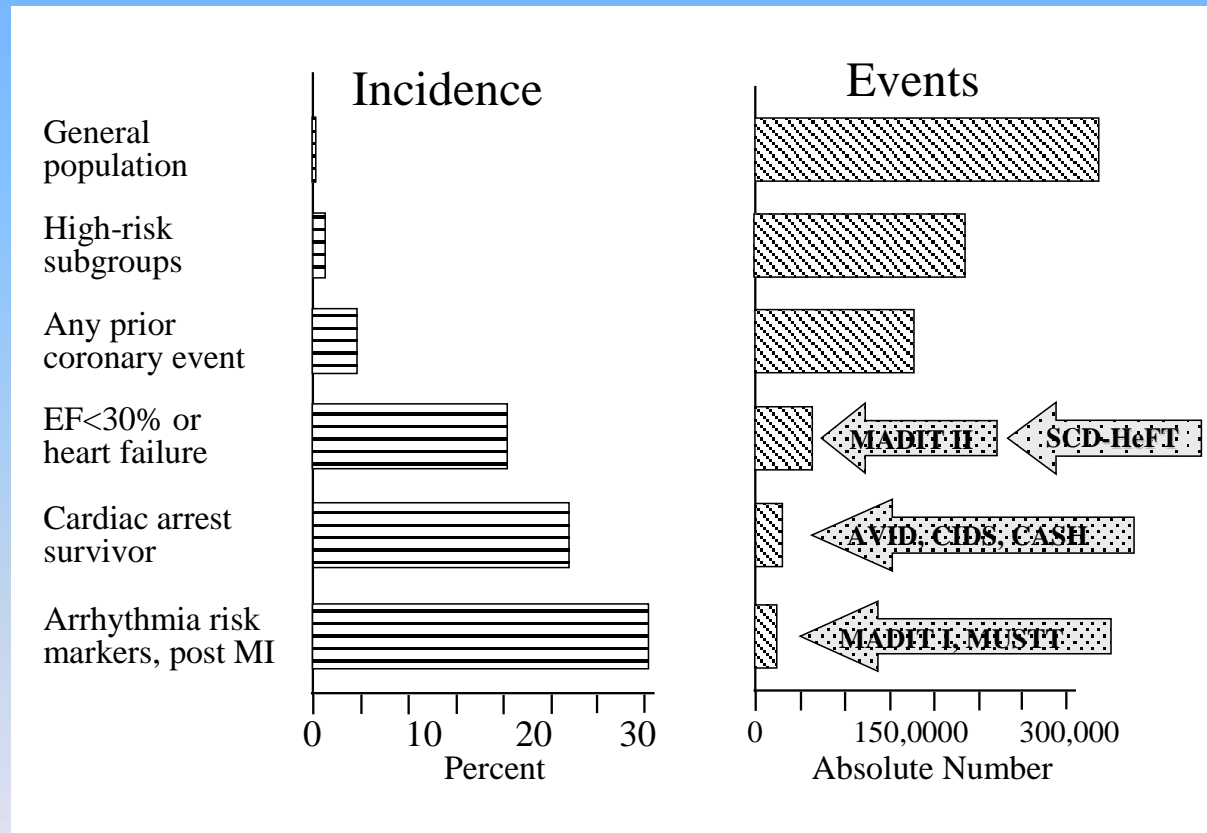
## ➤ LifeVest: Opportunity for SCD Risk Protection

- LifeVest Overview
- Patient Improvement

## ➤ SCD Screening

# Epidemiology of SCD

## Incidence of Sudden Cardiac Death



# Epidemiology of VA & SCD

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## Classification of Ventricular Arrhythmia by Disease Entity

- Chronic coronary heart disease
- Heart failure
- Congenital heart disease
- Neurological disorders
- Structurally normal hearts
- Sudden infant death syndrome
- Cardiomyopathies
  - ♥ Dilated cardiomyopathy
  - ♥ Hypertrophic cardiomyopathy
  - ♥ Arrhythmogenic right ventricular (RV) cardiomyopathy

# Mechanisms and Substrates

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## Mechanisms of Sudden Cardiac Death in 157 Ambulatory Patients

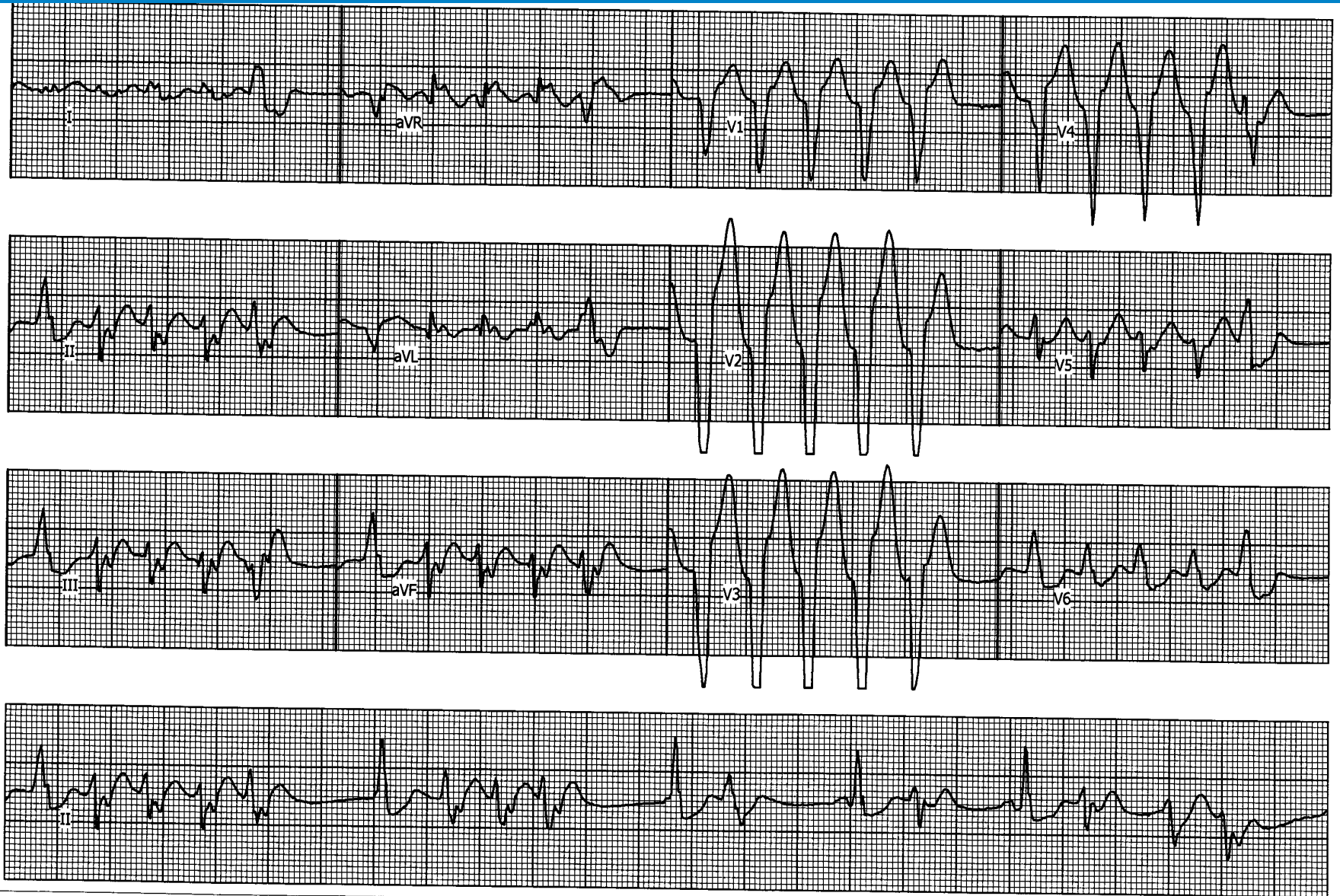
- Ventricular fibrillation - 62.4%
- Bradyarrhythmias (including advanced AV block and asystole) - 16.5%
- Torsades de pointes - 12.7%
- Primary VT - 8.3%

# Clinical Presentations of Patients with VA & SCD

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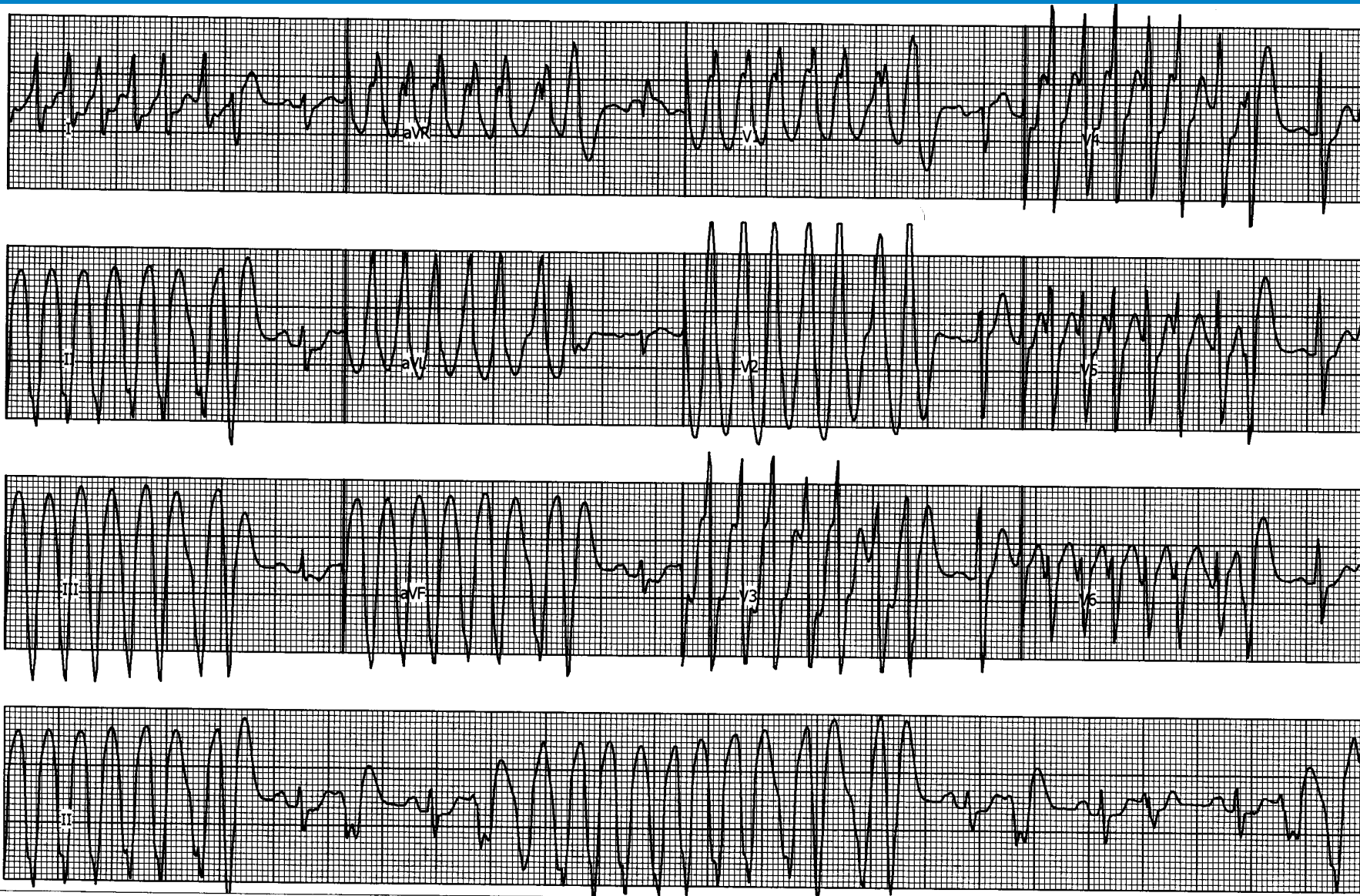
- Asymptomatic individuals with or without electrocardiographic abnormalities
- Persons with symptoms potentially attributable to ventricular arrhythmias
  - ♥ Palpitations
  - ♥ Dyspnea
  - ♥ Chest pain
  - ♥ Syncope and presyncope
- VT that is hemodynamically stable
- VT that is not hemodynamically stable
- Cardiac arrest
  - ♥ Asystolic (sinus arrest, atrioventricular block)
  - ♥ VT
  - ♥ Ventricular fibrillation (VF)
  - ♥ Pulseless electrical activity

# Nonsustained Monomorphic VT





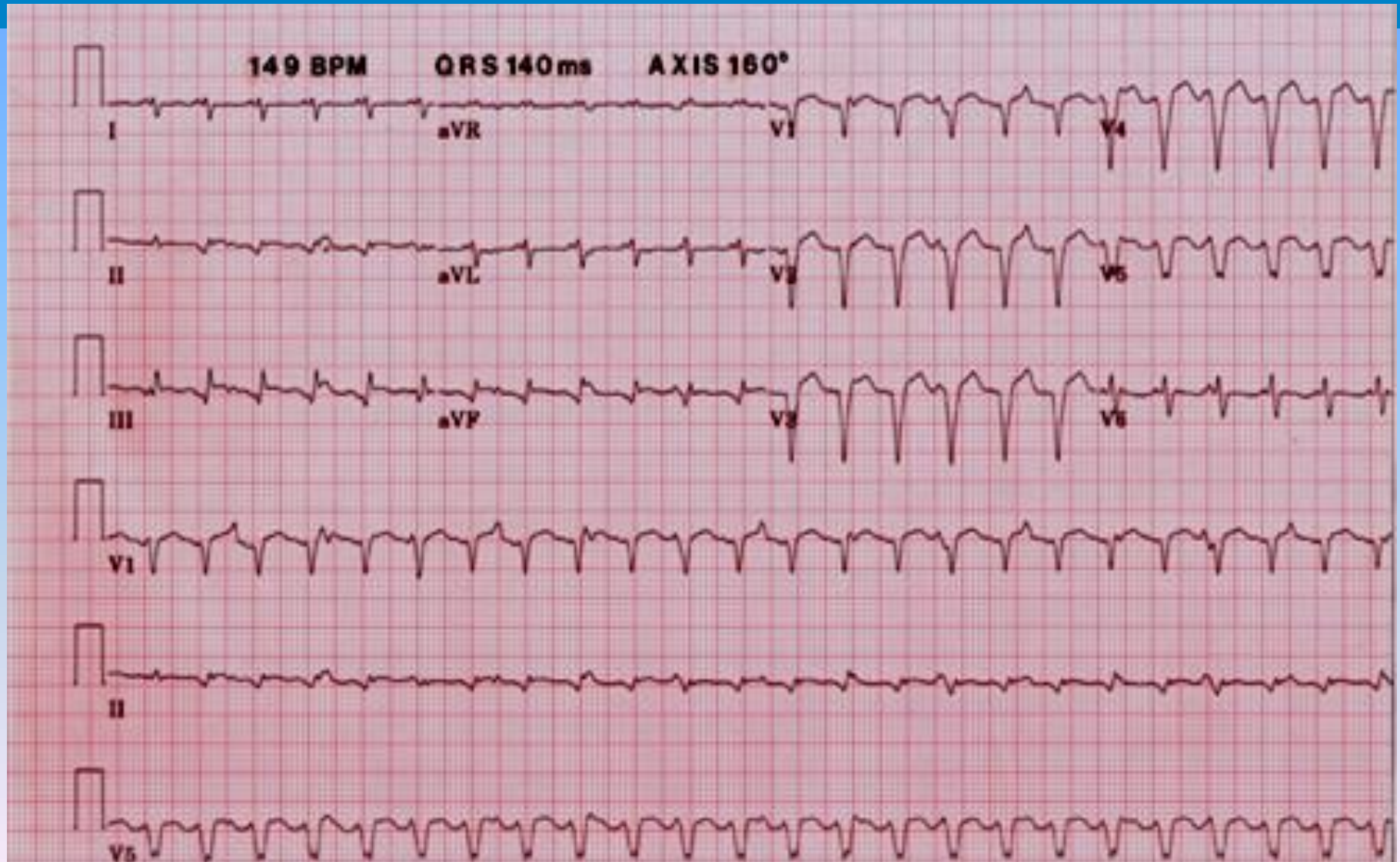
# Nonsustained LV VT



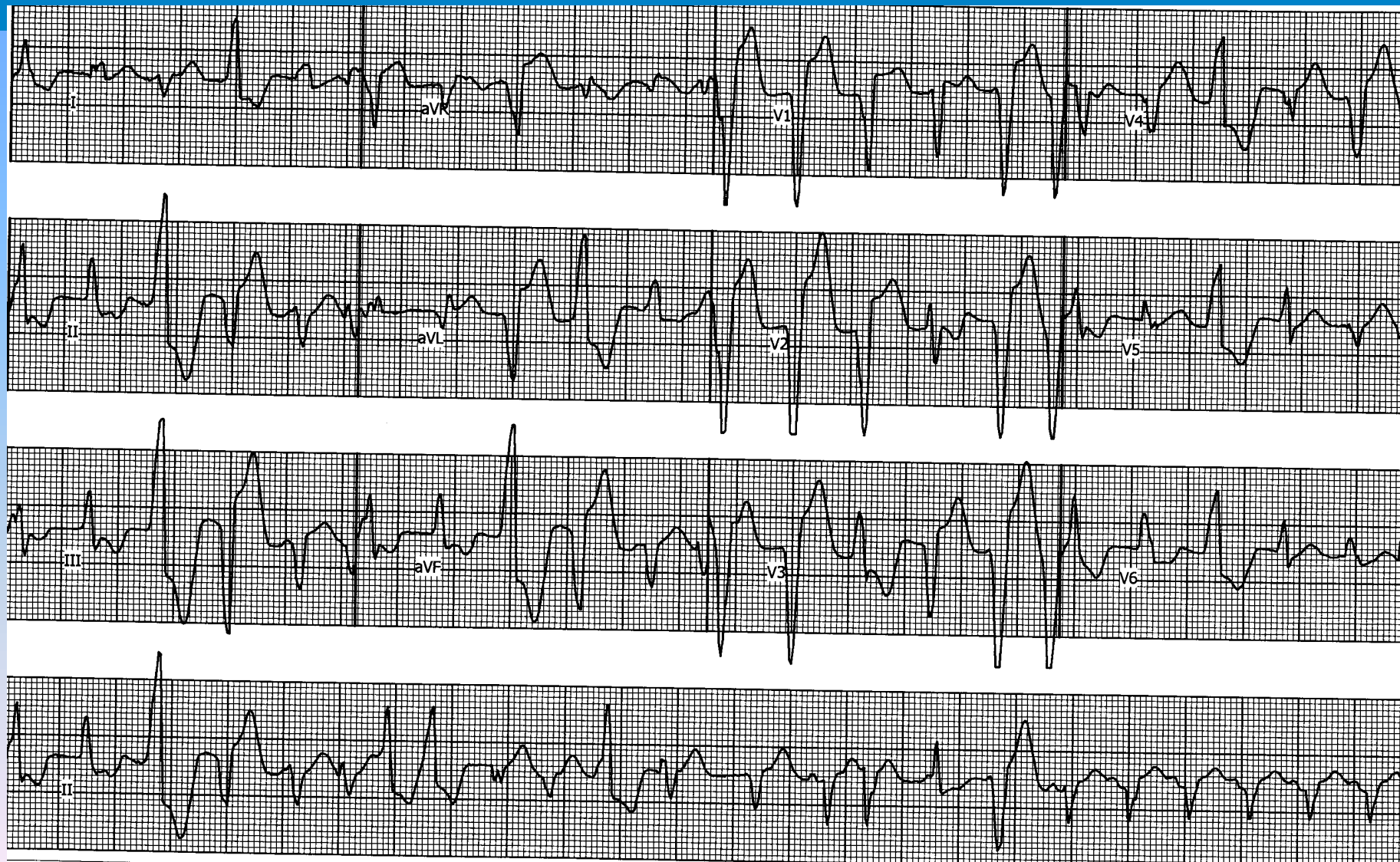


# Sustained Monomorphic VT

## 72-year-old woman with CHD



# Nonsustained Polymorphic VT



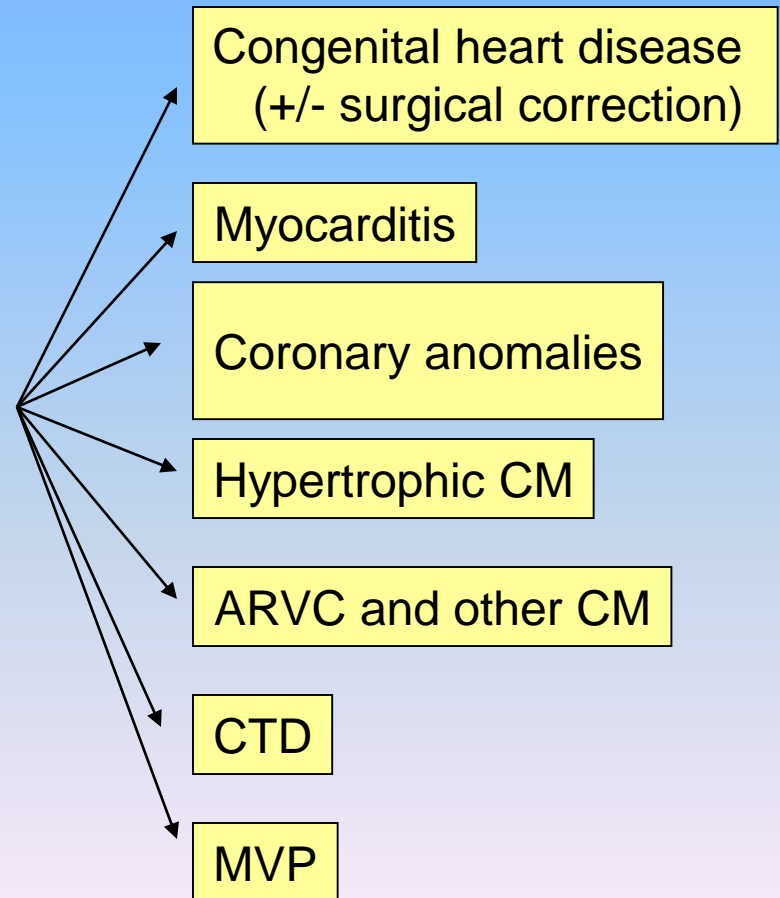
# Sudden Cardiac Death

➤ **Affects 350,000 – 400,000 each year in U.S. alone**

➤ **Only 5% survive**

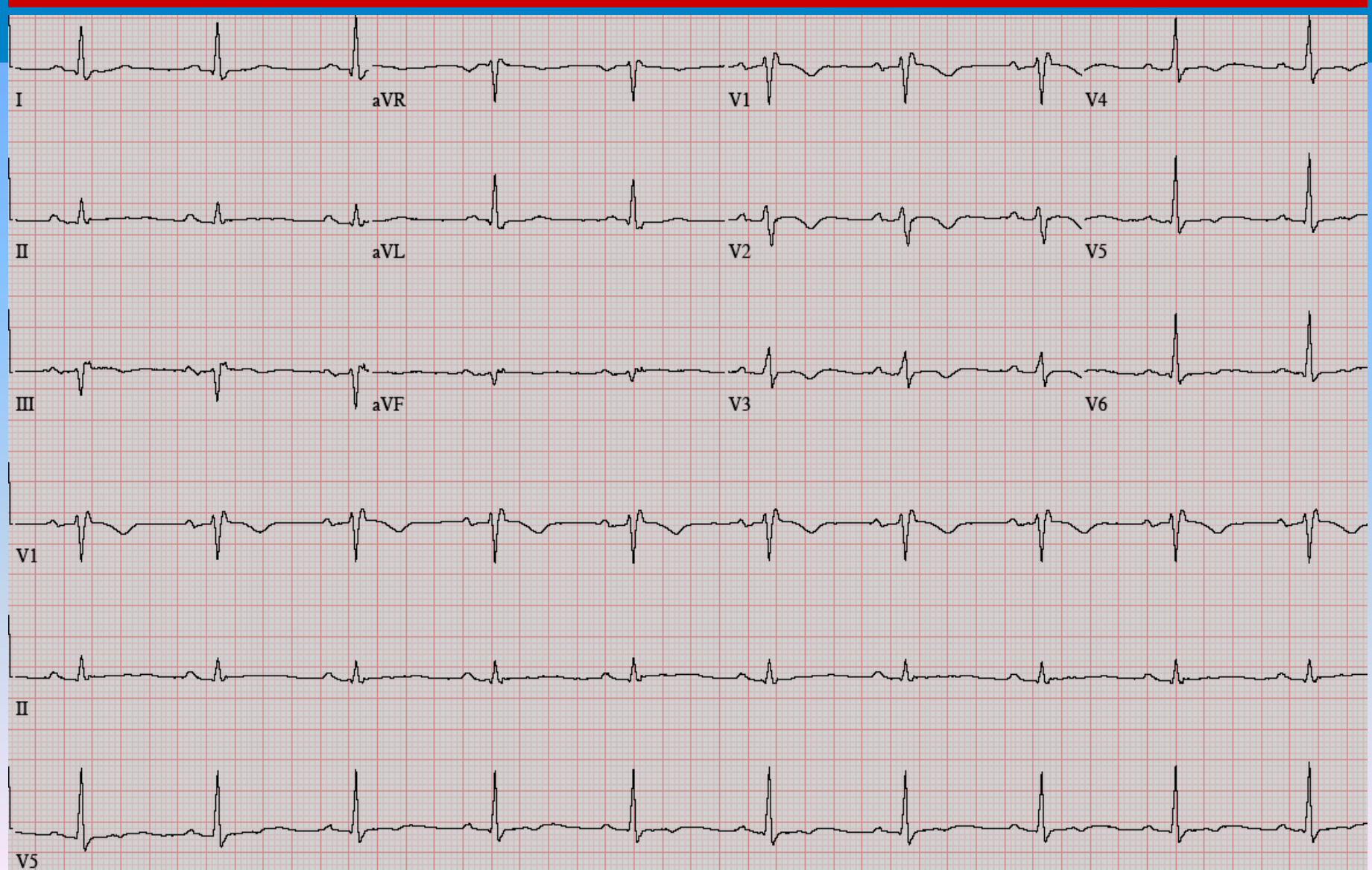
➤ **Causes**

- Structural heart disease
- *Genetic channelopathies*



# Arrhythmogenic RV Cardiomyopathy

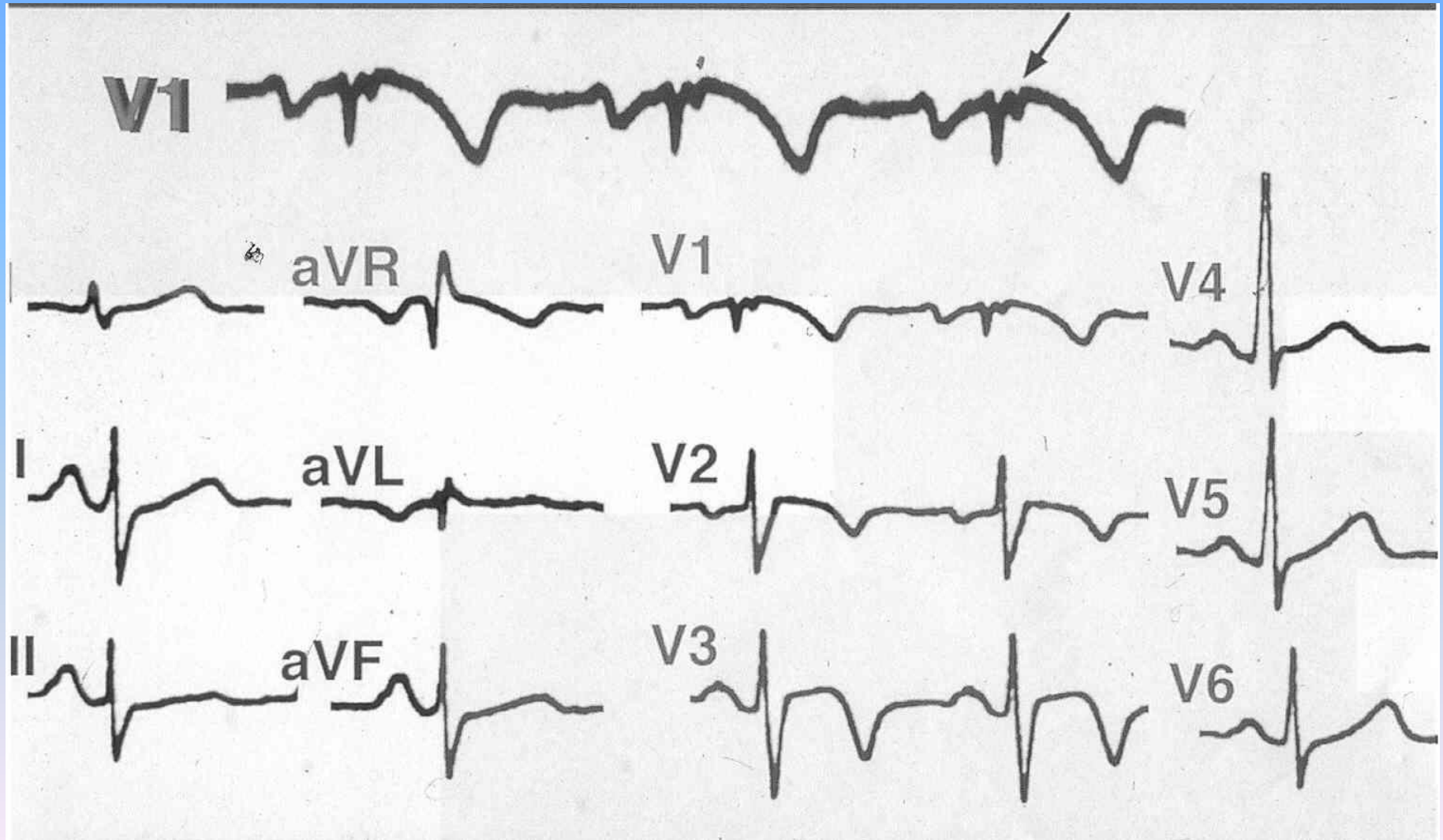
(RV conduction delay, inverted T-waves V1-V5)





# Arrhythmogenic RV Cardiomyopathy

## 12-lead ECG showing Epsilon wave



# Sustained Monomorphic VT

## 49-year-old man with ARVC



25mm/s 10mm/mV 150Hz 005E 12SL 237 CID: 1

EID:2020 EDT: 15:00 05-OCT-2006 ORDE

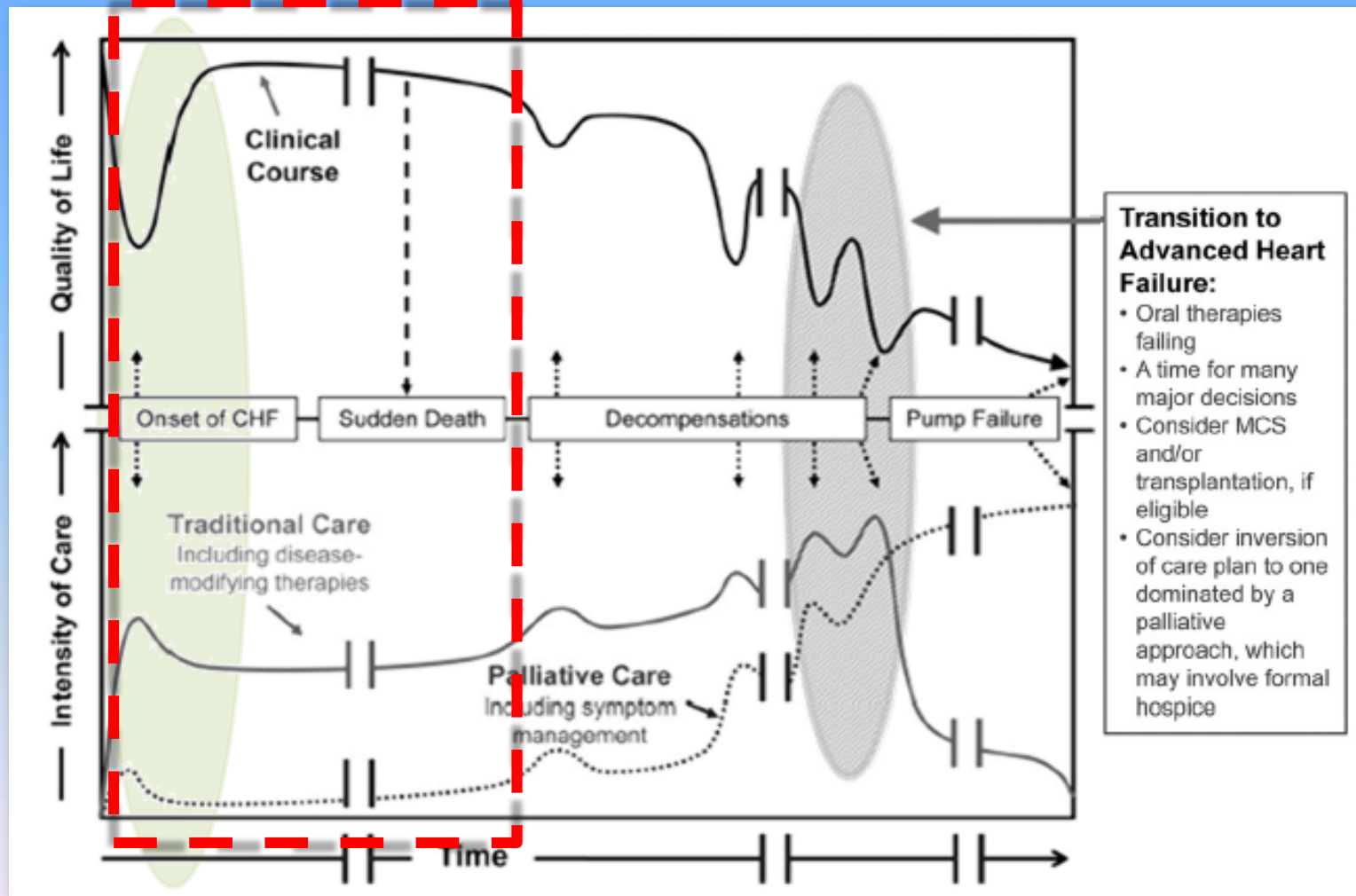
# Heart Failure – The Problem

- **More than 5 million Americans have heart failure**
- **~670,000 new HF cases per year**
- **5 year mortality = 50%**
  - In people diagnosed with HF, sudden cardiac arrest occurs at 6-9 times the rate of the general population
- **More than 1 million HF hospitalizations per year**
- **Leading cause of hospitalization in pts >65 years old**



# Identifying the Opportunity

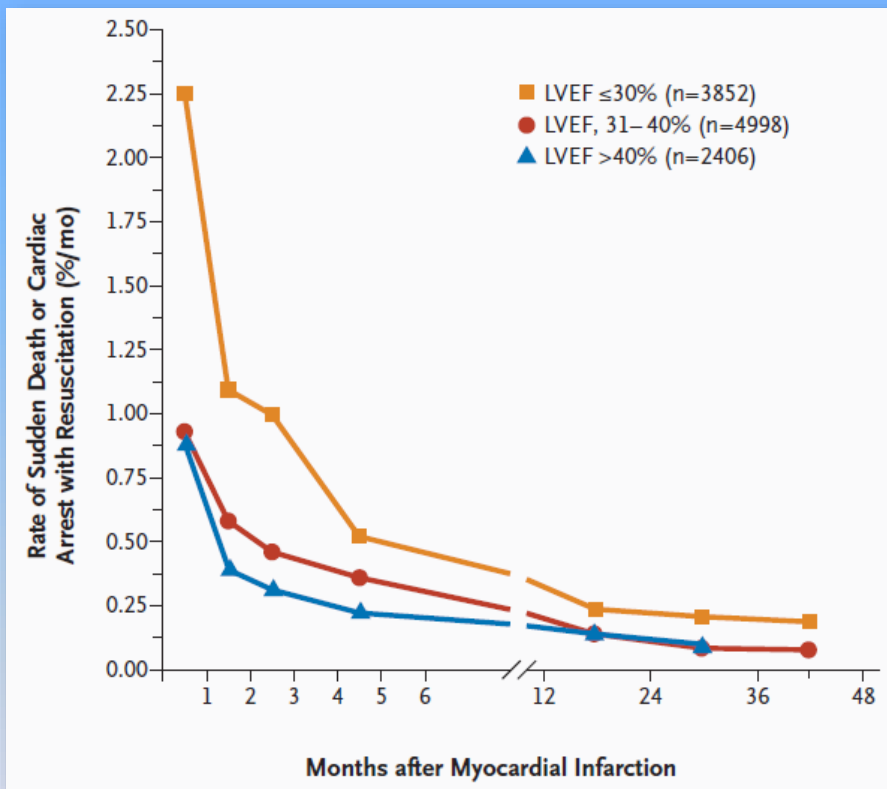
## Schematic Depiction of Comprehensive HF Care



# Understanding the Risk

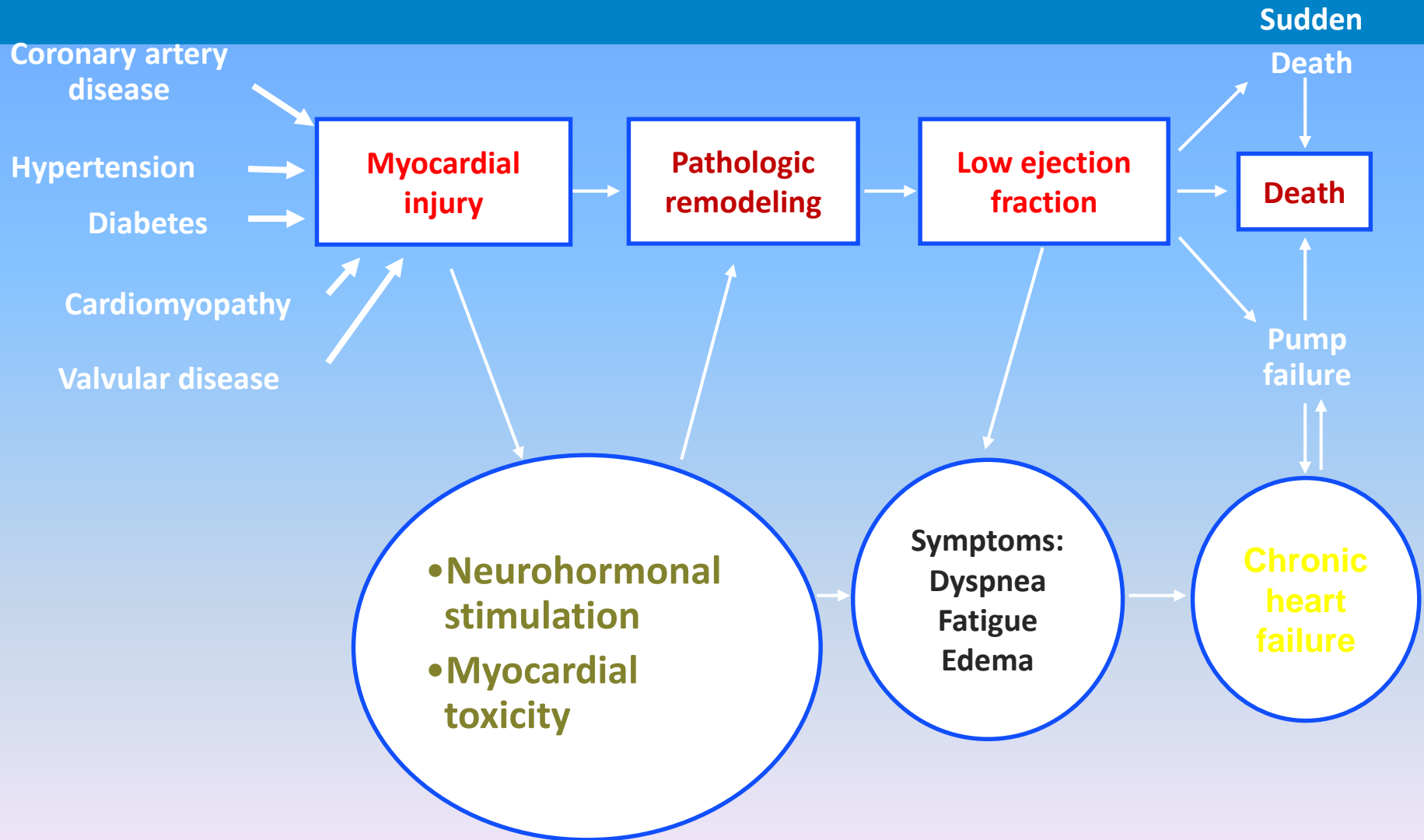
## ➤ The risk of SCD post-MI is the highest in the first 30 days<sup>1</sup>

- Post-MI patients with heart failure are at 4-6 times greater risk of SCD in the first 30 days after MI
- 83% of SCA occurred after hospital discharge.
- 74% of those resuscitated in the first 30 days were alive at 1 year



<sup>1</sup> Solomon SD, et al. Sudden Death in Patients with Myocardial Infarction and Left Ventricular Dysfunction, Heart Failure, or Both. NEJM 2005; 352: 2581-2588.

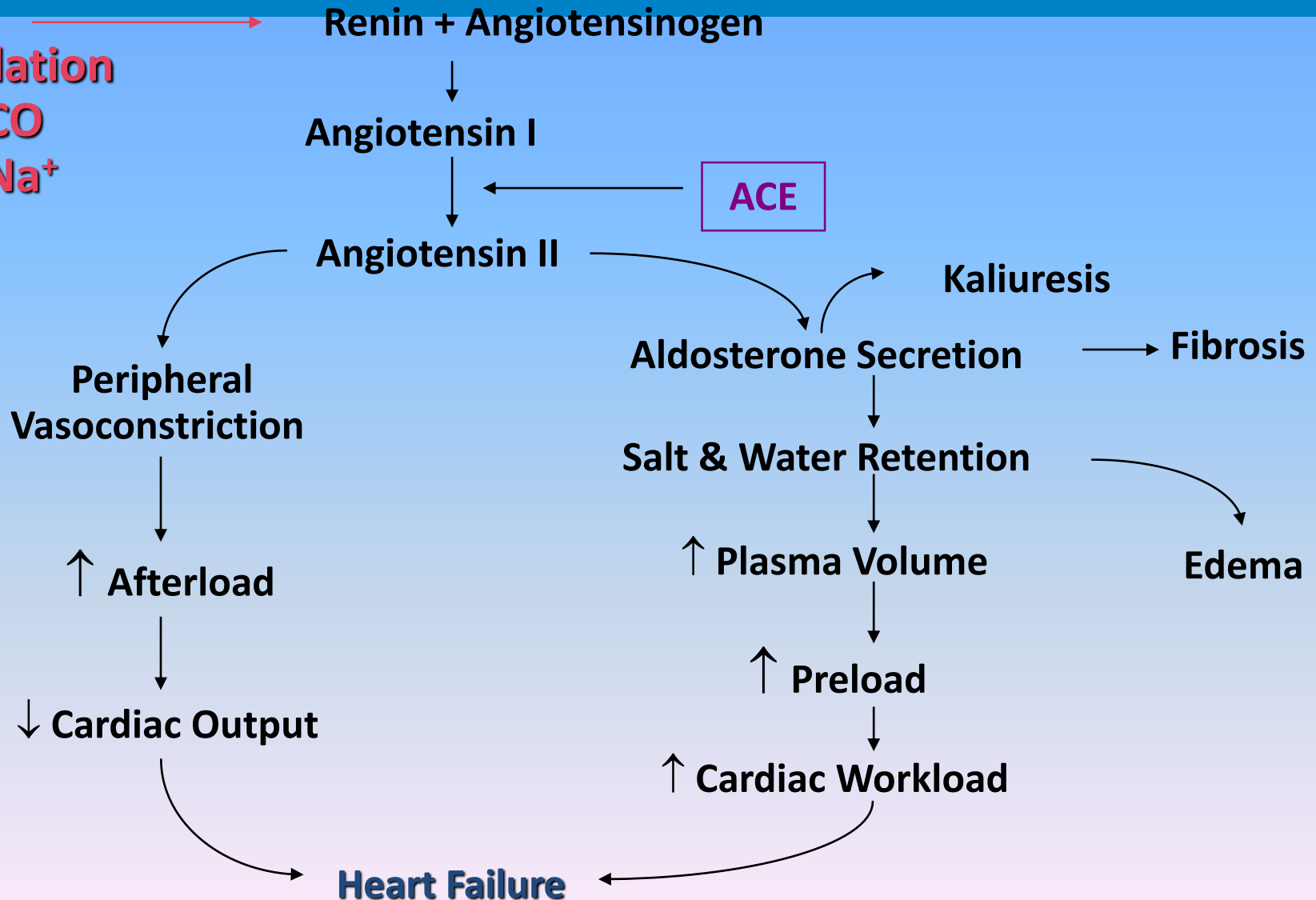
# Pathologic Progression of CV Disease

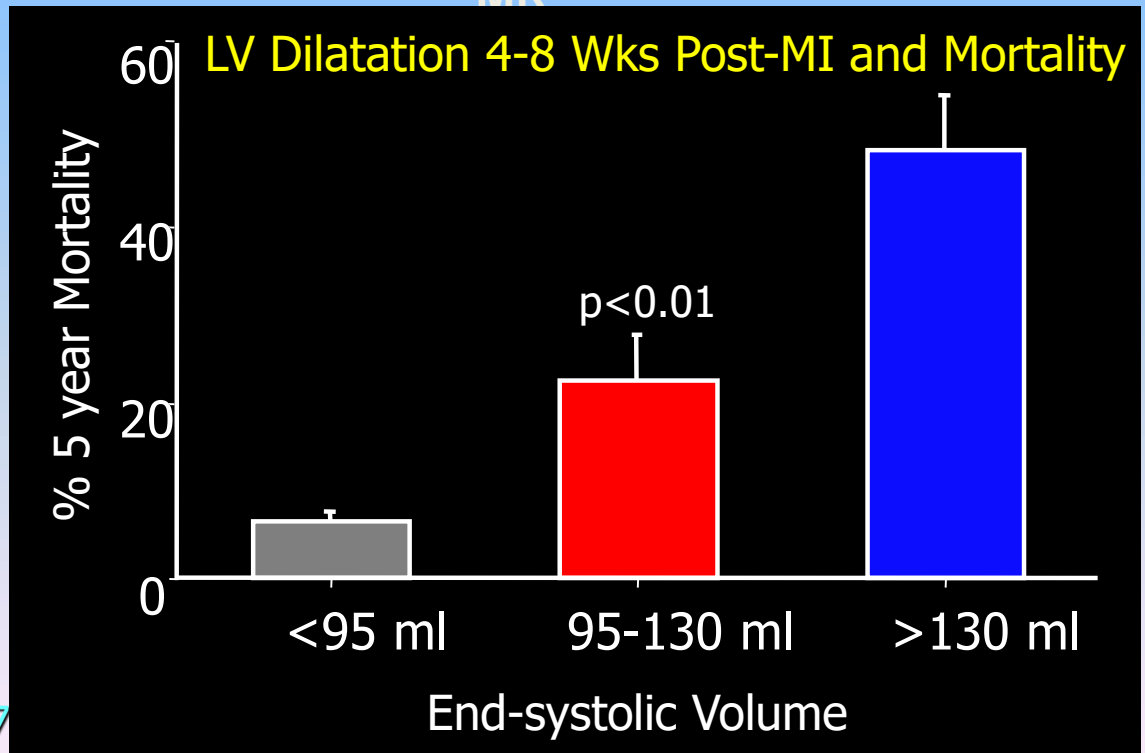
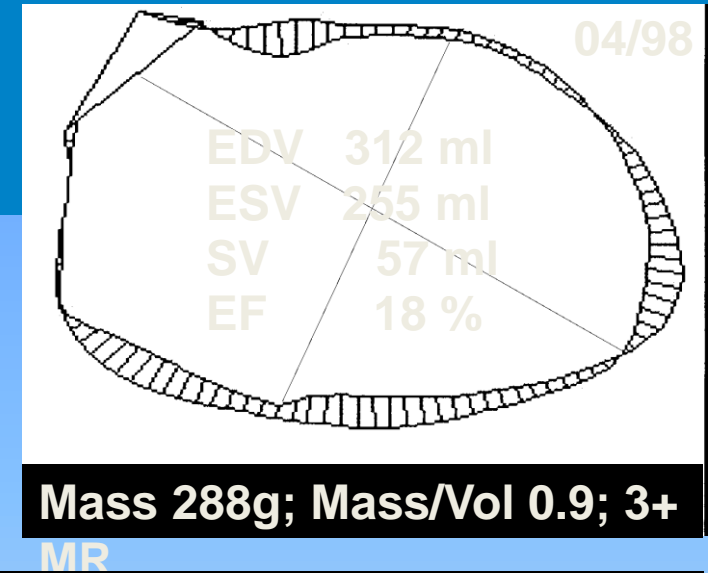
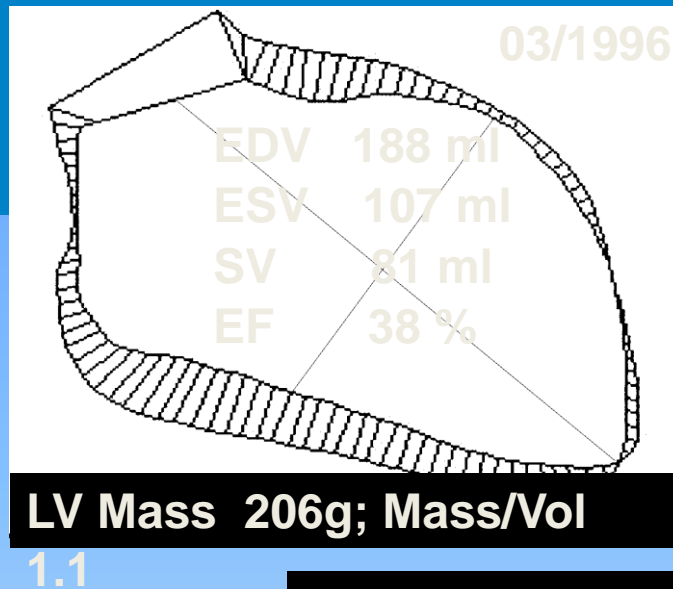


# Compensatory Mechanisms: Renin-Angiotensin-Aldosterone System

**Beta  
Stimulation**

- CO
- Na<sup>+</sup>





## LV Remodeling

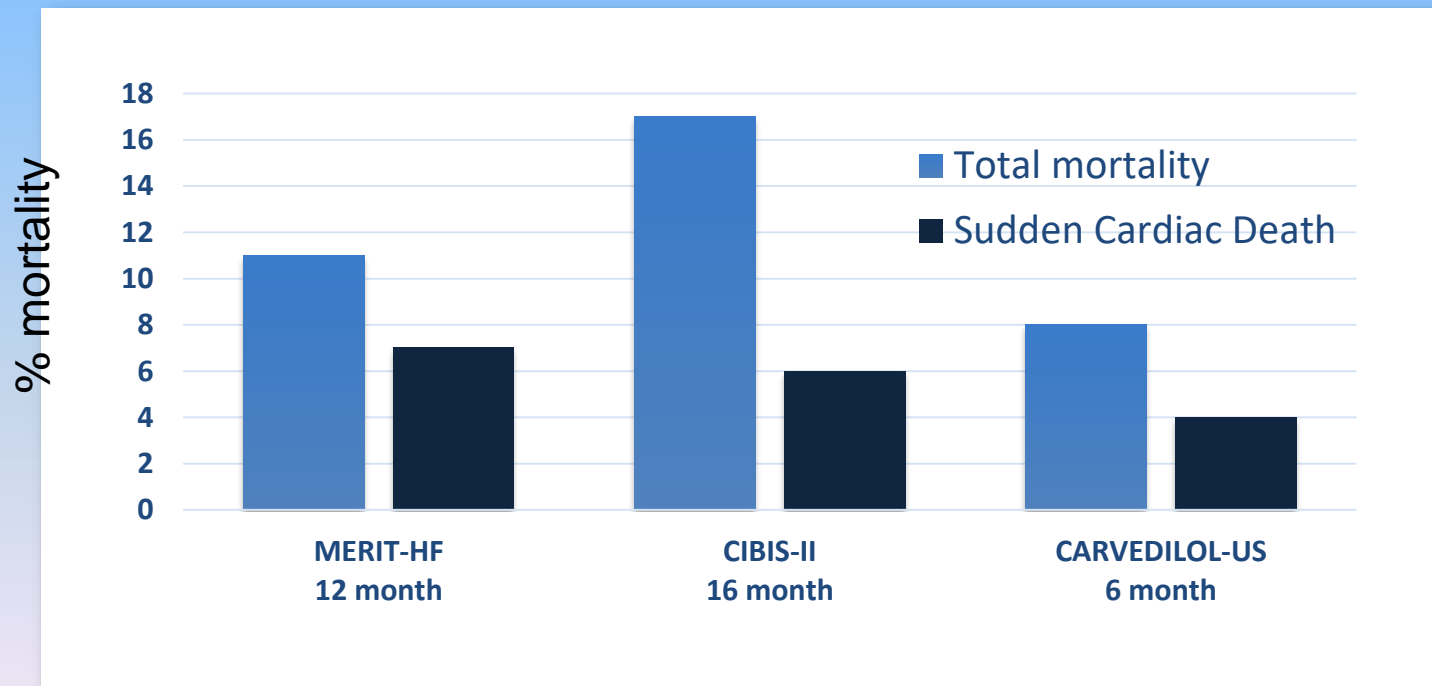
White Circulation 1987;76:44-57

# Understanding the Risk

## LV Systolic Dysfunction and SCD Risk

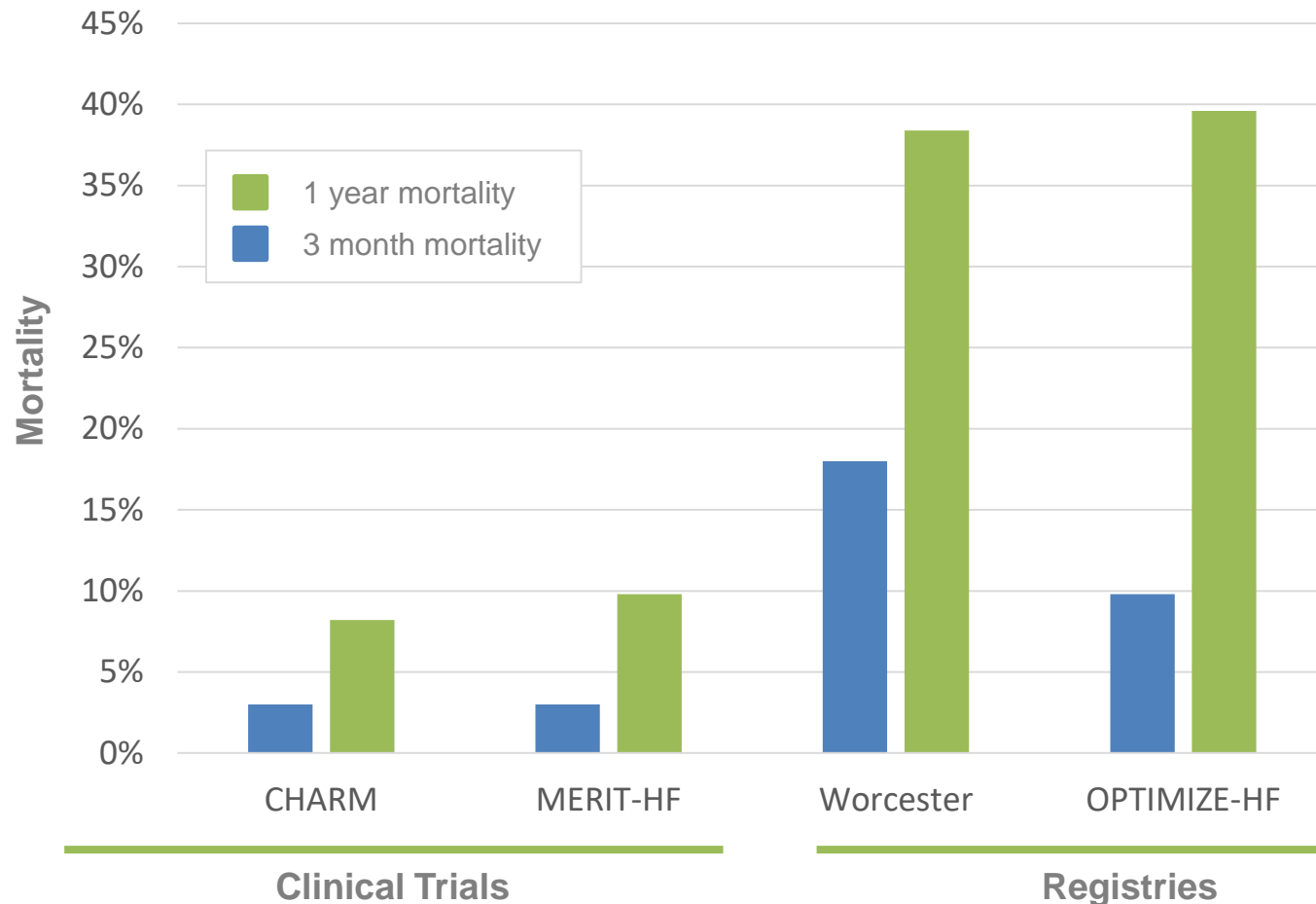
### ➤ SCD accounted for ~50% (35-64%) of total mortality

- EF was the single most important risk factor for SCD



# Mortality Rate in HF

## Clinical Trial vs. Registries

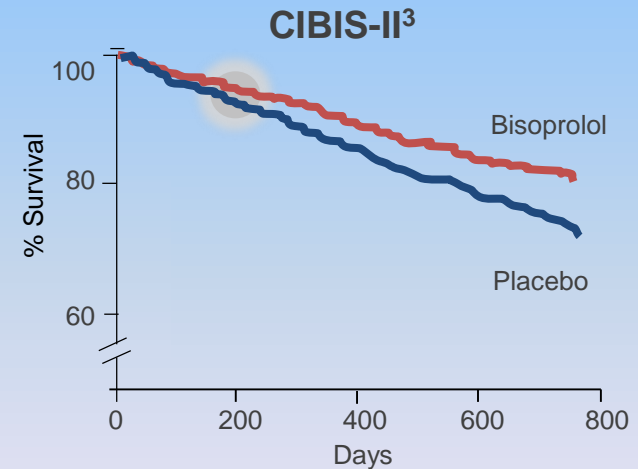
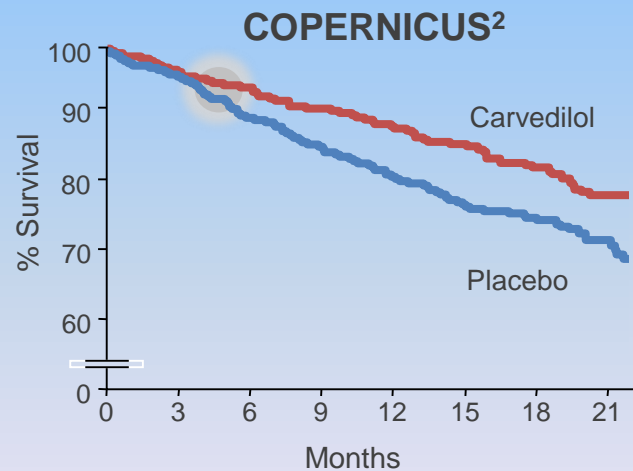
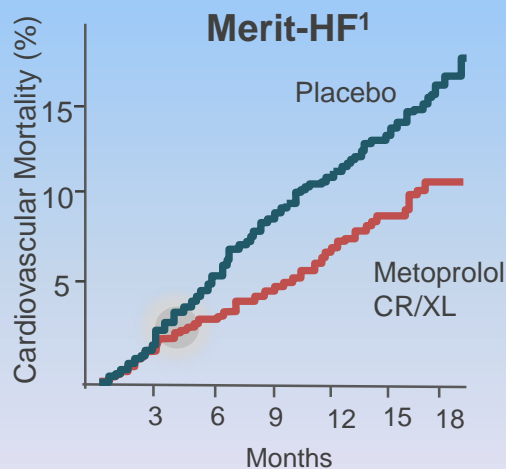




# Medical Therapy Optimization Required Prior To Managing Long-Term Arrhythmic Risk

## ➤ Medical optimization and stabilization can take 3 months or more.

- Beta blocker doses effective in HF are generally achieved in 8 to 12 weeks and do not impart any mortality benefit until at least 3 months



<sup>1</sup> Merit-HF Study Group. Effect of metoprolol CR/XL in chronic heart failure: Metoprolol CR/XL Randomized Intervention Trial in Congestive Heart Failure (MERIT-HF). *Lancet* 1999;353:2001-7.

<sup>2</sup> Packer M, et al. Effect of Carvedilol on survival in severe chronic heart failure. *NEJM* 2001;344:1651-8.

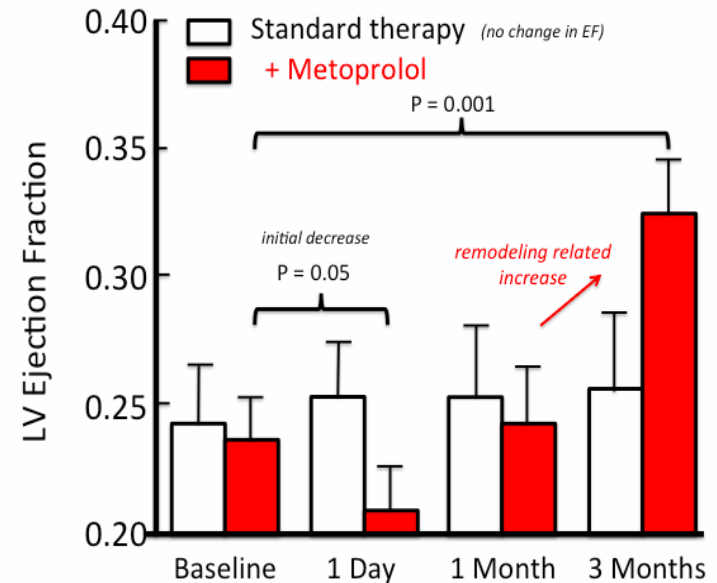
<sup>3</sup> CIBIS-II Investigators. The Cardiac Insufficiency Bisoprolol Study II (CIBIS-II). *Lancet* 1999;353:9-13.

# Medical Therapy Optimization Required HF Patient Improvement

## ➤ A HF patient's cardiac function can improve from the benefits of optimized medical therapy

- IMAC-2 study showed a mean LVEF increase of 17% in newly diagnosed cardiomyopathy patients<sup>1</sup>
- REFINE Study average relative improvement in EF was 18% at 8-10 weeks<sup>2</sup>

Time course of LVEF improvement with  $\beta$ -blocker use<sup>3</sup>



<sup>1</sup> McNamara D et al.. Clinical and Demographic Predictors of Outcomes in Recent Onset Dilated Cardiomyopathy. JACC 2011;58:1112-8.

<sup>2</sup> Exner D et al. Noninvasive Risk Assessment Early After a Myocardial Infarction. JACC 2007;50:2275-84.

<sup>3</sup> Hall S, et al. Time Course of Improvement in Left Ventricular Function, Mass and Geometry in Patients with

Congestive Heart Failure Treated With Beta-Adrenergic Blockade. JACC 1995;25:1154-61

# FDA Indications for Use

- The LifeVest System is indicated for adult patients who are at risk for sudden cardiac arrest and are not candidates for or who refuse an implantable defibrillator.



# LifeVest Offers Protection From SCD

## Time To Recovery and Assess Long-Term Risk

### ➤ LifeVest is part of the continuum of care for patients at high risk of SCA

- Protection from SCA during medical therapy optimization.
- Allows physician to assess long-term arrhythmic risk at the end of the Medicare ICD waiting period (40 days post-MI and 90 days post-PTCA/post-CABG).
- Patients return to the prescribing or referring physician at the term of their LifeVest prescription for follow-up to determine if:
  - 1) LifeVest usage should be extended,
  - 2) Long-term arrhythmic risk requires ICD implantation, or
  - 3) Cardiac recovery has mitigated arrhythmic risk, and ongoing follow-up with optimized medical therapy is appropriate.

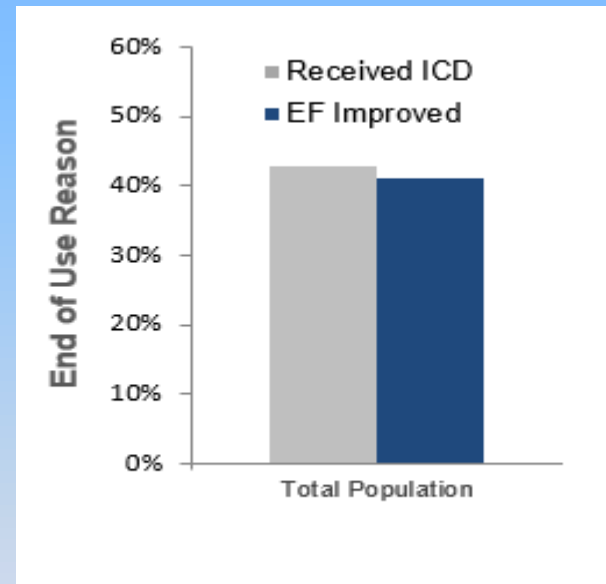
# LifeVest by the Numbers

- **98% first shock success rate**
- **92% shocked event survival (conscious ER arrival or stayed at home)**
- **Most (73%) treated within 60 seconds (remaining delayed from response button use or VT programming)**

# Outcomes Following LifeVest Use

## WEARIT-II Registry

- Prospective registry of WCD patients
- Results in patients representative of the HF population
  - 41%: LVEF improved and patients did not need an ICD
  - 42%: LVEF did not improve >35% and patients received an ICD



# Guidelines: LifeVest

- **ACC/AHA/ESC 2006 Guidelines for Management of Patients with Ventricular Arrhythmias and Prevention of Sudden Cardiac Death**
  - LifeVest is a therapeutic option, listed next to ICDs
- **2006 International Society for Heart and Lung Transplantation Guidelines for the Care of Cardiac Transplant Candidates**
  - LifeVest is a Class I recommendation
- **2009 Transvenous Lead Extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management (*endorsed by AHA*)**
  - LifeVest is an alternative to early re-implantation when there is concern for ongoing infection
- **2014 HRS/ACC/AHA Expert Consensus Statement on the Use of Implantable Cardioverter-Defibrillator Therapy in Patients Who Are Not Included or Not Well Represented in Clinical Trials**
  - LifeVest may play a role in patients at risk of sudden cardiac death in the early period after revascularization or awaiting cardiac transplantation
- **2014 AHA/ACC Guidelines for the Management of Patients with Non-ST-Elevation Acute Coronary Syndromes**
  - LifeVest may be considered for patients with ACS and reduced LVEF, when an ICD is not indicated
- **2014 EHRA/HRS/APHRS Expert Consensus on Ventricular Arrhythmias**
  - LifeVest recommended for high risk patients with ACS during medical therapy optimization.



# LifeVest Patient Example



# WCD allows time to develop long-term risk management strategies

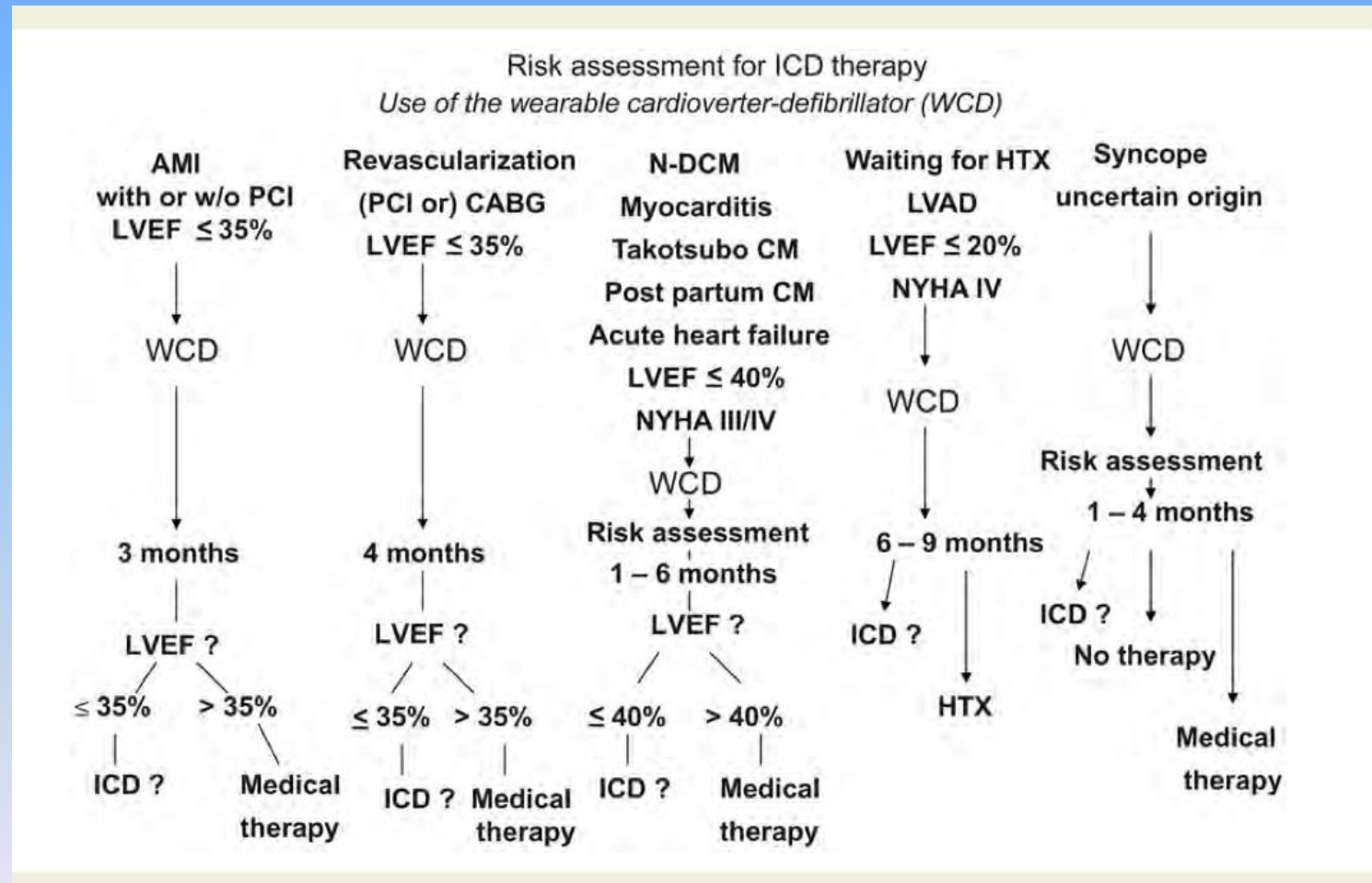


Figure 1. Risk stratification for ICD therapy: The role of the WCD (Klein et al. Eur Heart J 2013;34:2230-2242)

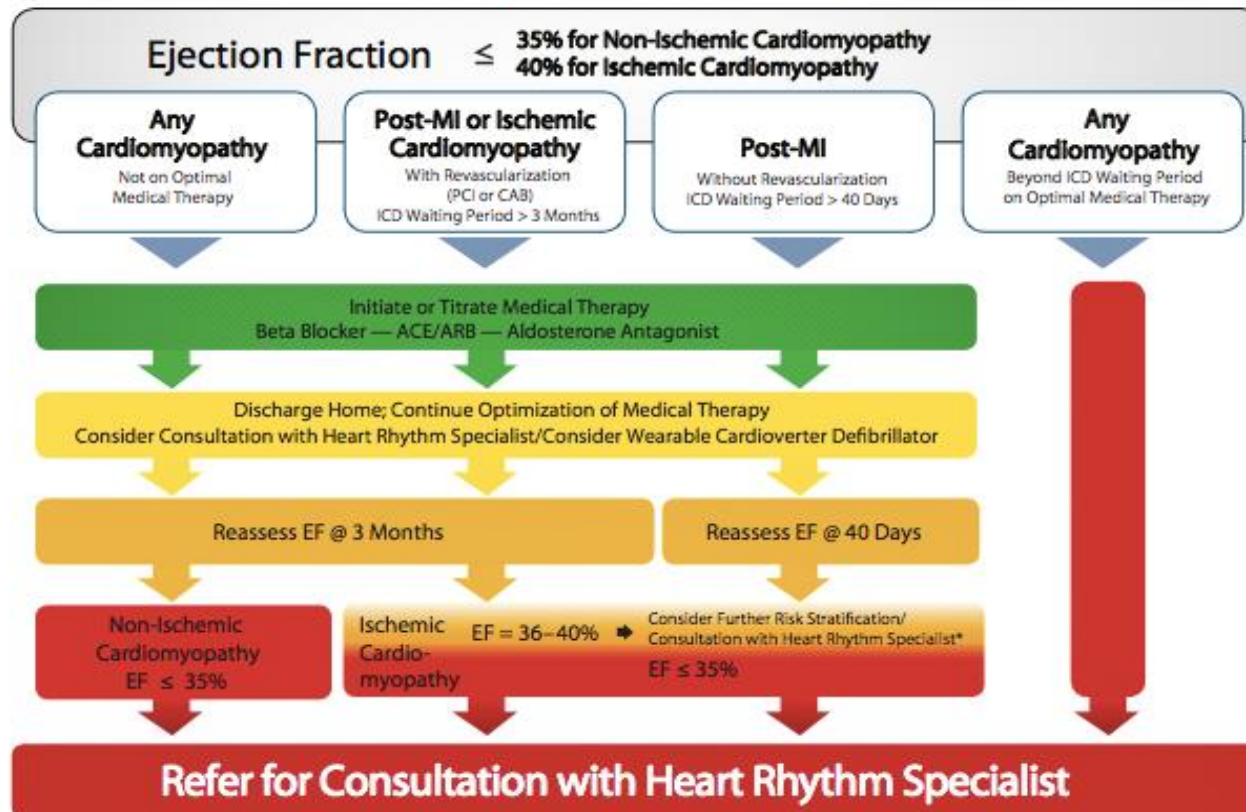
# Heart Rhythm Society

## Sudden Cardiac Death Primary Prevention Protocols



### Sudden Cardiac Death Primary Prevention Protocols

Learn more at  
[www.HRsonline.org](http://www.HRsonline.org)



\* Buxton AE, Lee KL, Fisher JD, Josephson ME, Prystowsky EN, Hafley G. A randomized study of the prevention of sudden death in patients with coronary artery disease. Multicenter Unsustained Tachycardia Trial Investigators. N Engl J Med. December 16, 1999;341(25):1882-1890.

Recommended by SCA Prevention Protocols Working Group (Version 2; Revised: 9/10/2012; Review date: 9/10/2013). All Rights Reserved. Copyright © 2012 Heart Rhythm Society

# Insurance Coverage

The LifeVest is covered by most health plans in the United States, including commercial, state, and federal plans. This list summarizes the types of patient conditions and situations that are covered. The patient's specific health plan coverage policy should be reviewed to determine coverage for prescribing a LifeVest.

- **Primary prevention (EF≤35% and MI, NICM, or other DCM) including:**
  - After recent MI (Coverage during the 40 day ICD waiting period).
  - Before and after CABG or PTCA (Coverage during the 90 day ICD waiting period).
  - Listed for cardiac transplant.
  - Recently diagnosed nonischemic cardiomyopathy (Coverage during the 3 to 9 month ICD waiting period).
  - NYHA class IV heart failure.
  - Terminal disease with life expectancy of less than 1 year.
- **ICD indications when patient condition delays or prohibits ICD implantation**
- **ICD explantation**

## Most Comprehensive and Up to Date HF Quality Measure Set

### Achievement Measures

- ACEI/ARB/ARNI at Discharge (Updated)
- Evidence-Based Specific Beta Blockers
- Measure LV Function
- Post-Discharge Appointment for Heart Failure Patients

### Quality Measures

- ARNI at Discharge (New)
- Aldosterone Antagonist at Discharge
- Anticoagulation for Atrial Fibrillation and Atrial Flutter
- Hydralazine Nitrate at Discharge
- DVT Prophylaxis
- CRT-D or CRT-P Placed or Prescribed at Discharge
- ICD Counseling Provided or Prescribed or Placed at Discharge
- Influenza Vaccination During Flu Season
- Pneumococcal Vaccination
- Follow-Up Visit Scheduled Within 7 Days or Less

### Reporting Measures

- Ivabradine at Discharge (New)
- Blood Pressure Control at Discharge
- Beta Blocker at Discharge
- Beta Blocker Medication at Discharge
- Lipid-Lowering Medications at Discharge
- Omega-3 Fatty Acid Supplement Use at Discharge
- Diabetes Treatment
- Diabetes Teaching
- Smoking Cessation
- Discharge Instructions
- QRS Duration Documented
- HF Disease Management Program Referral
- Follow-Up Visit or Contact Within 48 Hours of Discharge Scheduled
- ICD Placed or Prescribed at Discharge
- Advanced Care Plan

# Conclusions

- **Risks for SCD to be identified**
- **SCD screening tools can help to identify those patients at the highest risk**
- **Reduction in mortality by targeting high risks patients: Possible**
- **Post-MI patients with heart failure are at 4-6 times greater risk of SCD in the first 30 days after MI**
- **OMT optimization takes time and is different for every patient**
- **The LifeVest is an effective tool to protect HF patients with low EF during medication titration while long-term risk is being determined**





