

# Towards Better Device Management for Heart Failure

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**Heart Rhythm Congress 2009**

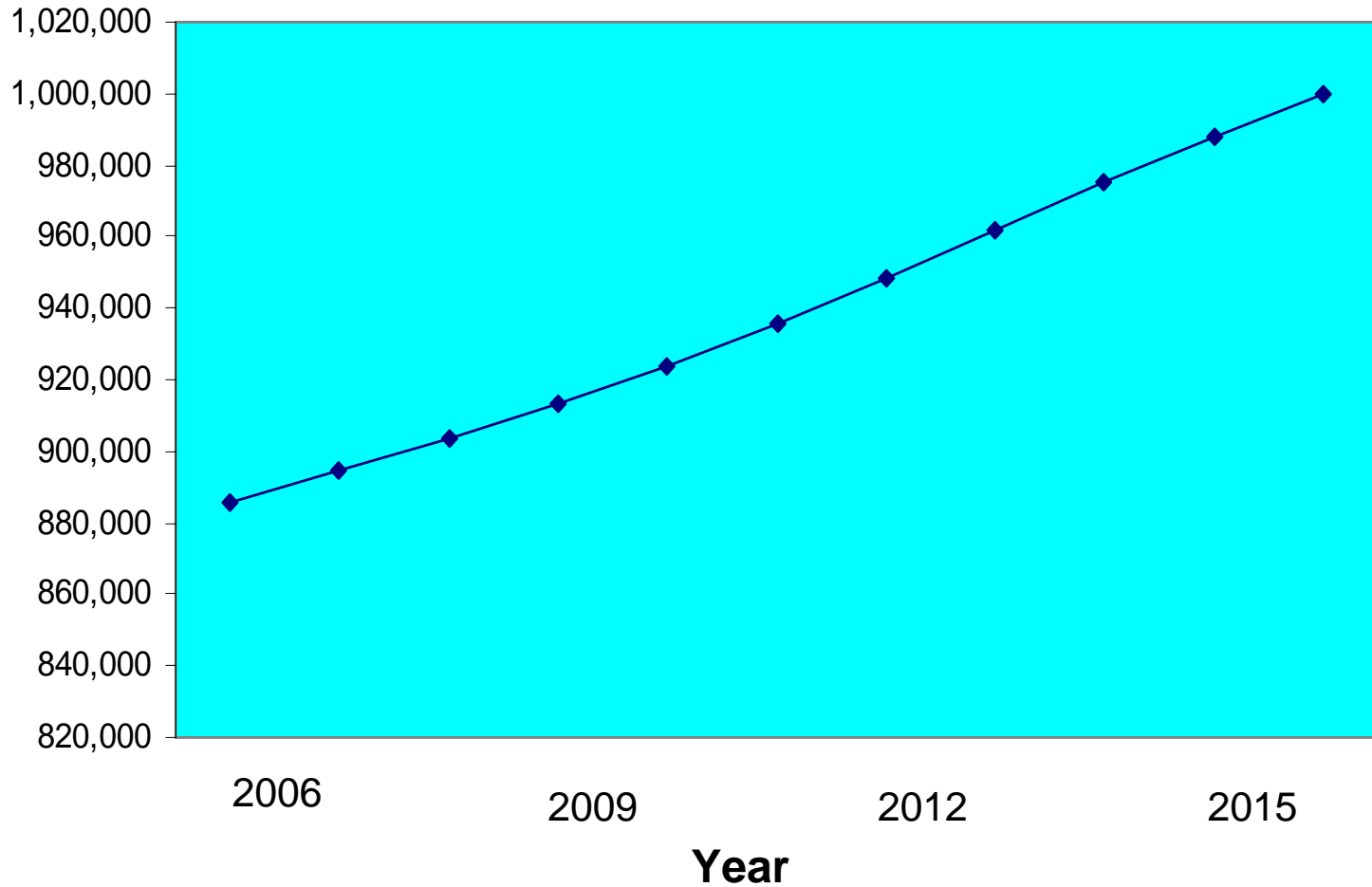


# Epidemiology of heart failure

- Approximately 5 million people in US have heart failure
- Europe
  - Prevalence 3.9% <sup>1</sup>
  - Annual incidence 1.3 cases per 1000 population age >25y
  - Rising to 11.6% cases in over 85 years

<sup>1</sup> Cowie et al *Eur Heart J* 1999

# Prevalence of heart failure in UK



# Economic burden of heart failure

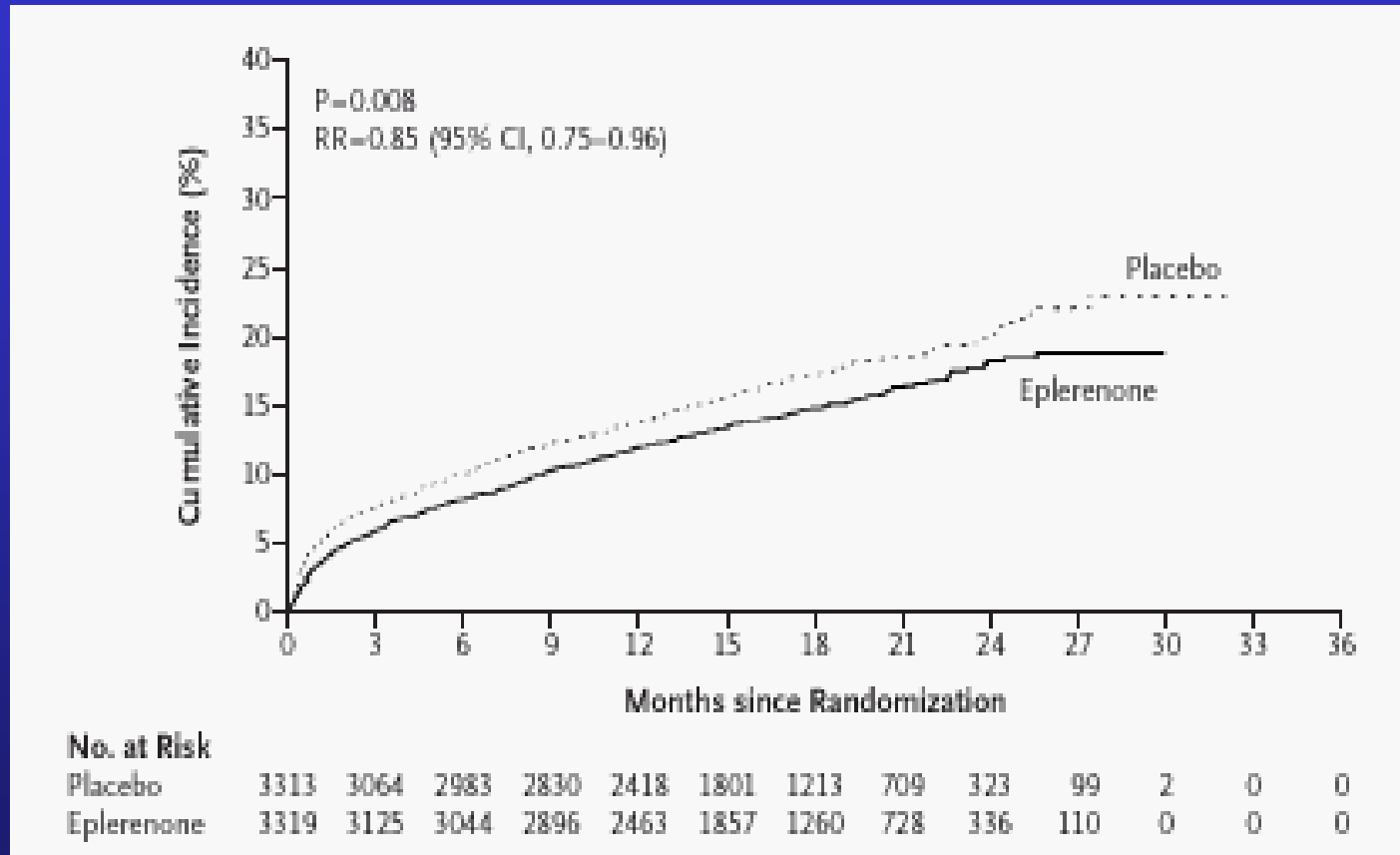
- Commonest cause of hospitalisation US and UK <sup>1</sup>
  - 78% of HF patients have at least 2 hospital admissions/year <sup>2</sup>
- Non-compliance & failure to seek care cause 67% of readmissions
- Annual cost of HF in the U.S. is estimated to be between \$15-38 billion <sup>3</sup>
- Accounts for 1.2 - 2% all health care costs
  - 60-70% related to hospital admissions

<sup>1</sup>Havranek EP, Abraham WT, *The Healthcare Economics of Heart Failure* 1998; 14:10-18

<sup>2</sup>English M and Mastream M. *Crit Care Nurse* 1995;18:1-6

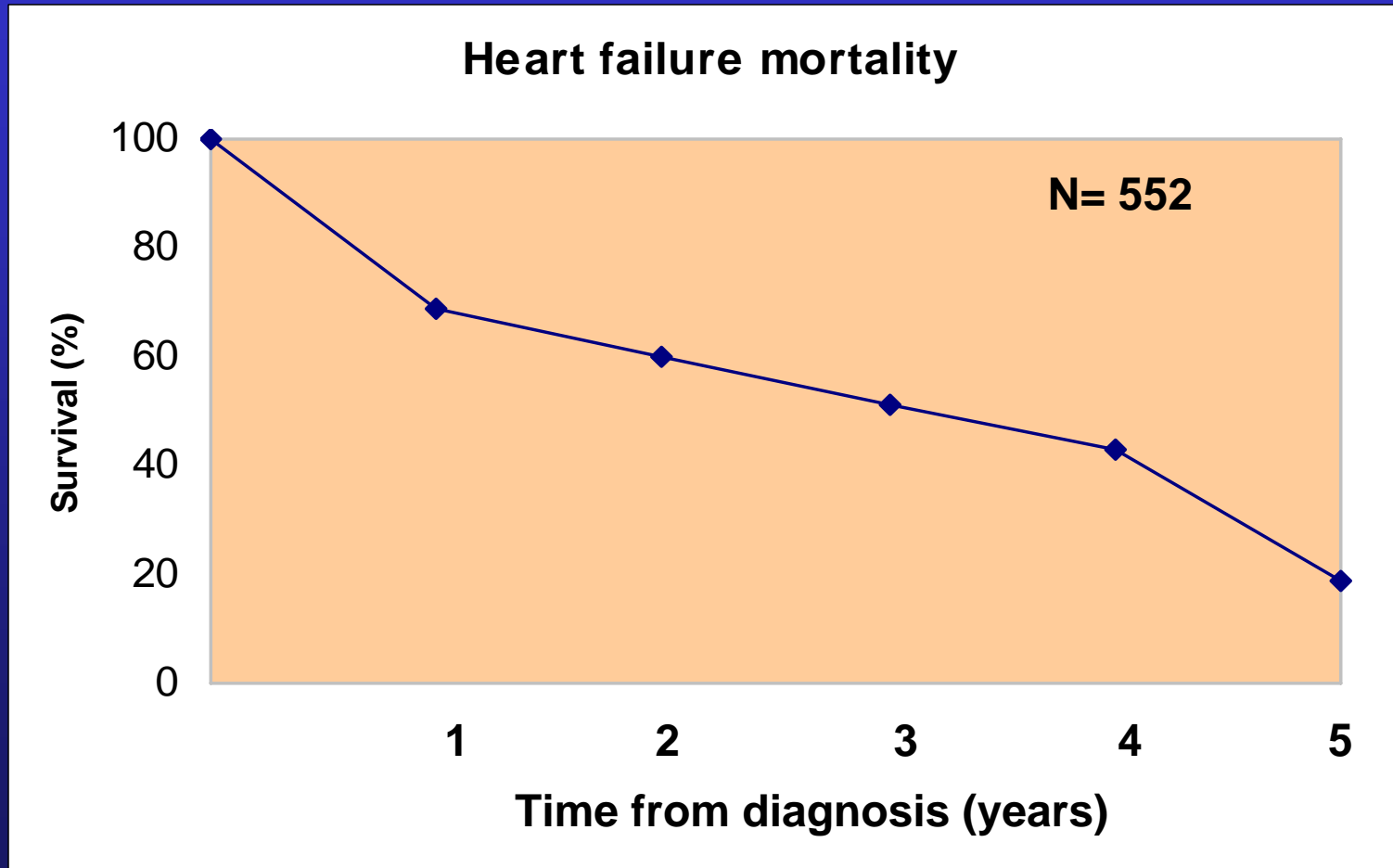
<sup>3</sup>2008 update: AHA Stats Committee and Stroke Stats Subcommittee *Circ* 2008; 117:e25-146

# HF: Rate of death from any cause

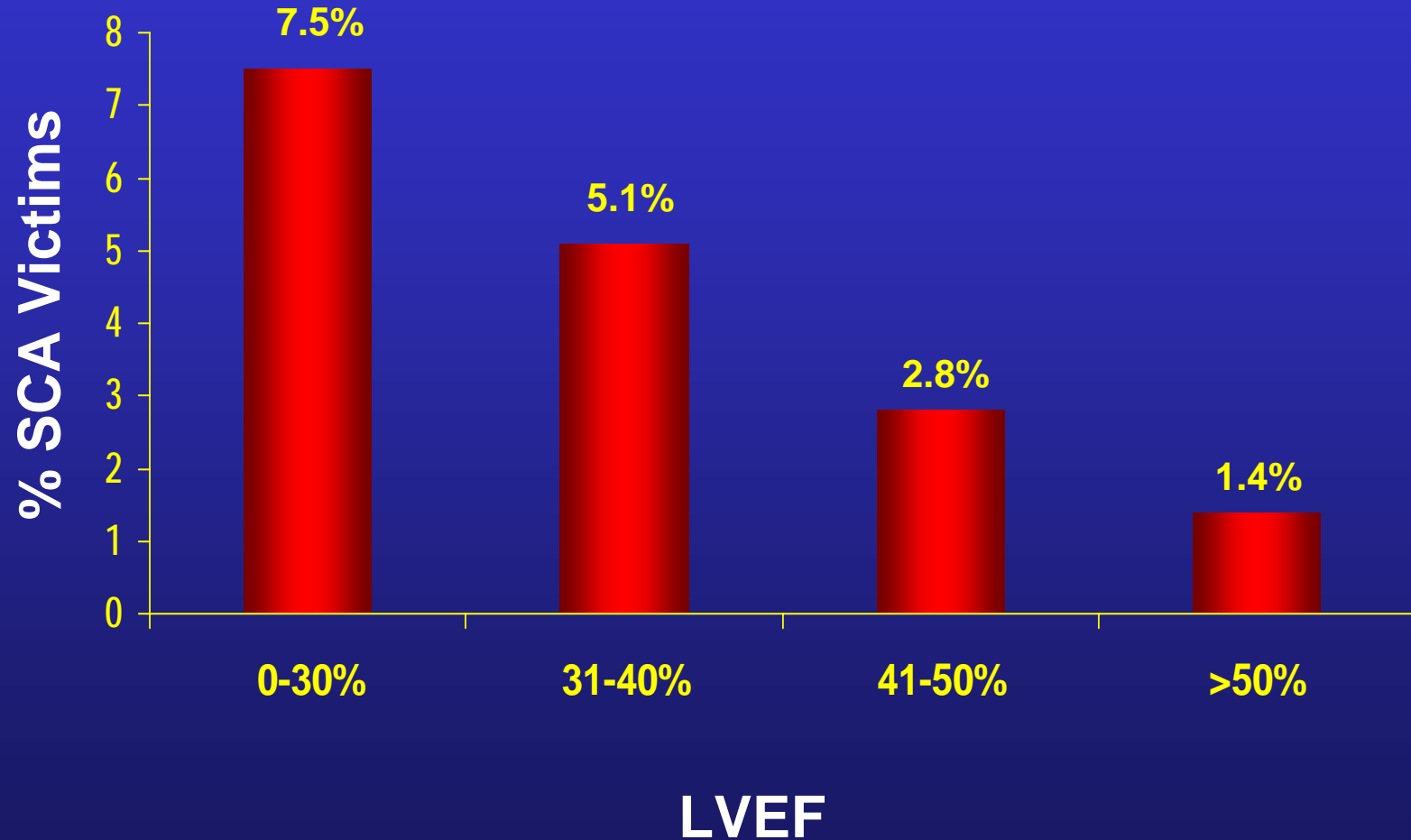


1 year mortality: 11.8% (eplerenone), 13.6% (placebo)

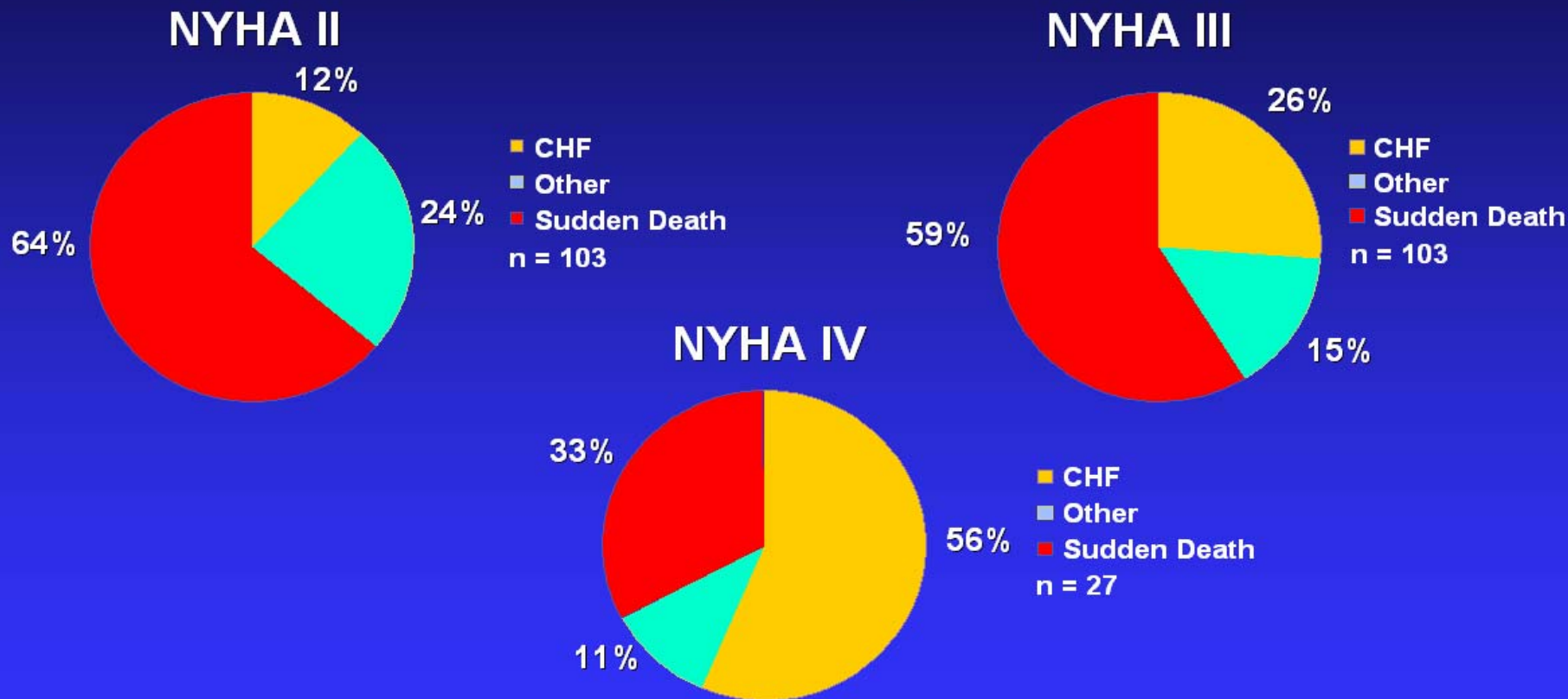
# Heart Failure Mortality



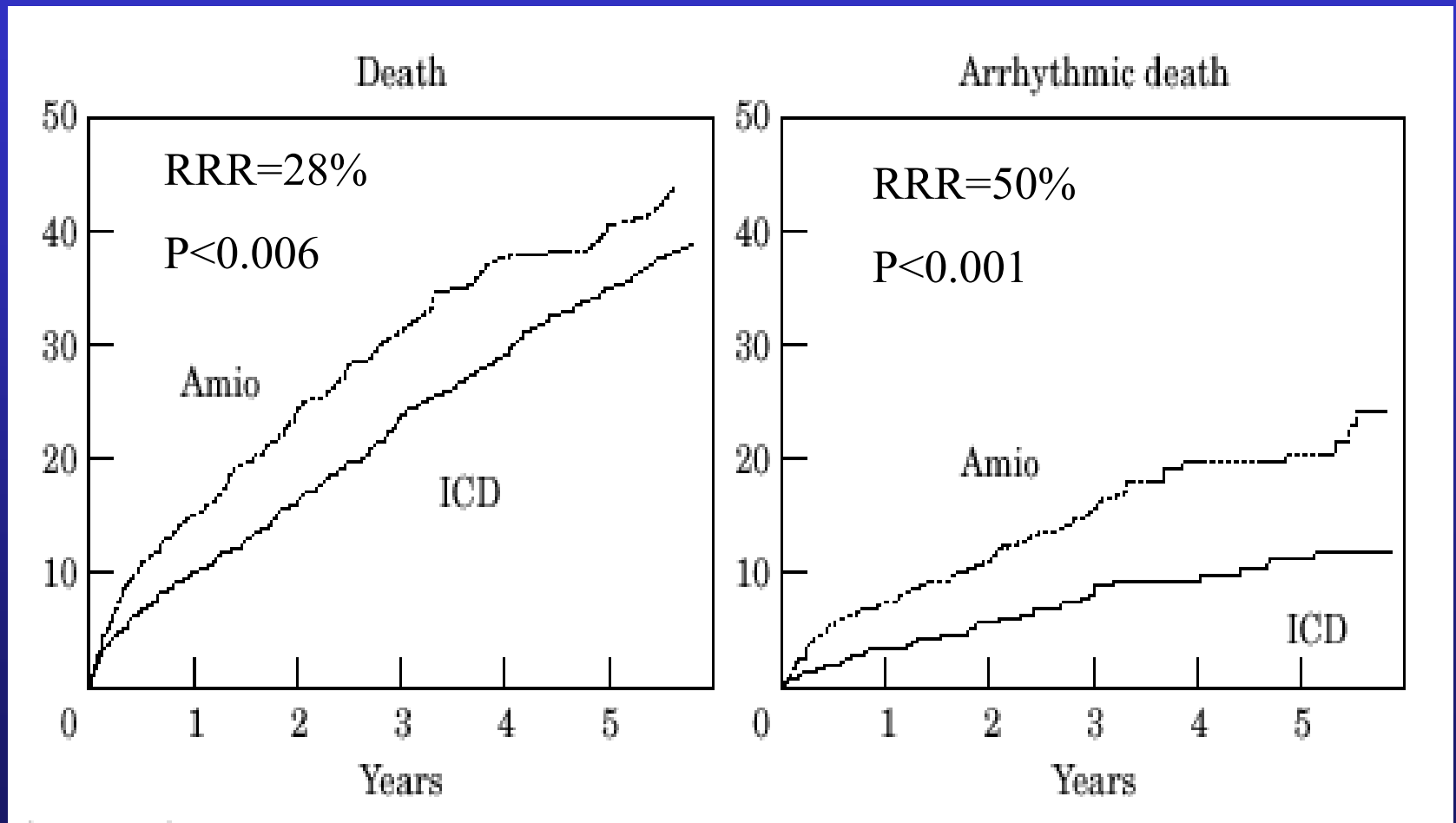
# LVEF and SCD Incidence



# Sudden Death accounts for ~ 50% of mortality in advanced heart failure



# Meta analysis of Secondary prevention Trials (AVID,CASH, CIDS)

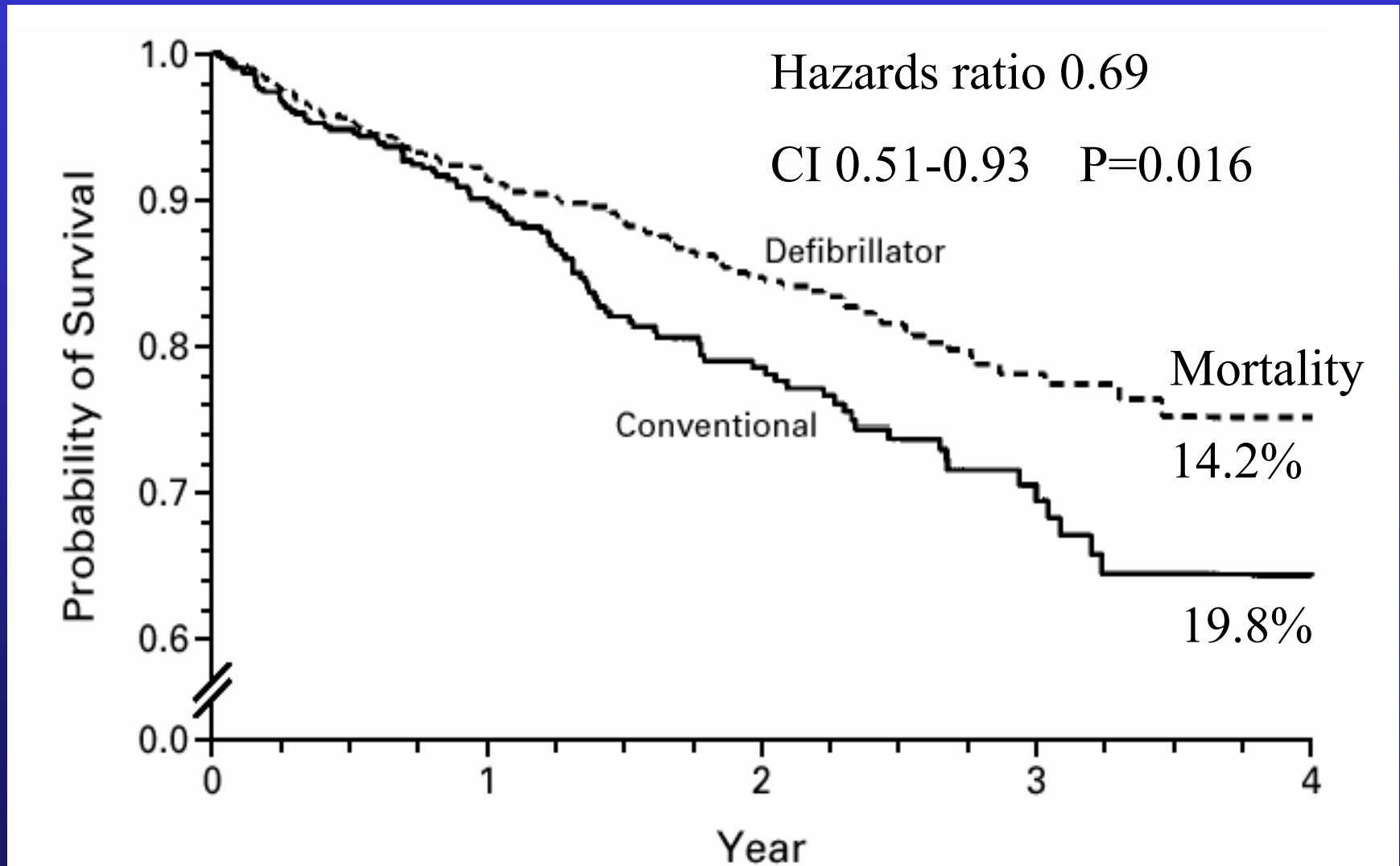


# NICE guidelines Jan 2006: review appraisal 11

- Secondary Prevention
  - SCD survivors in absence of reversible/treatable cause of VT/VF
  - Sustained MMVT with syncope/compromised
  - Sustained VT with  $EF < 35\%$ , NYHA I-III

*Based on AVID, CASH and CIDS trials*

# MADIT II Survival by Treatment Group



# MADIT II :8 year follow up

	HR	95% CI	p value
Total 8y F/U	0.63	0.35-0.75	<0.001
0-4 years	0.59	0.47-0.73	<0.001
4-8 years	0.71	0.52-0.96	0.02

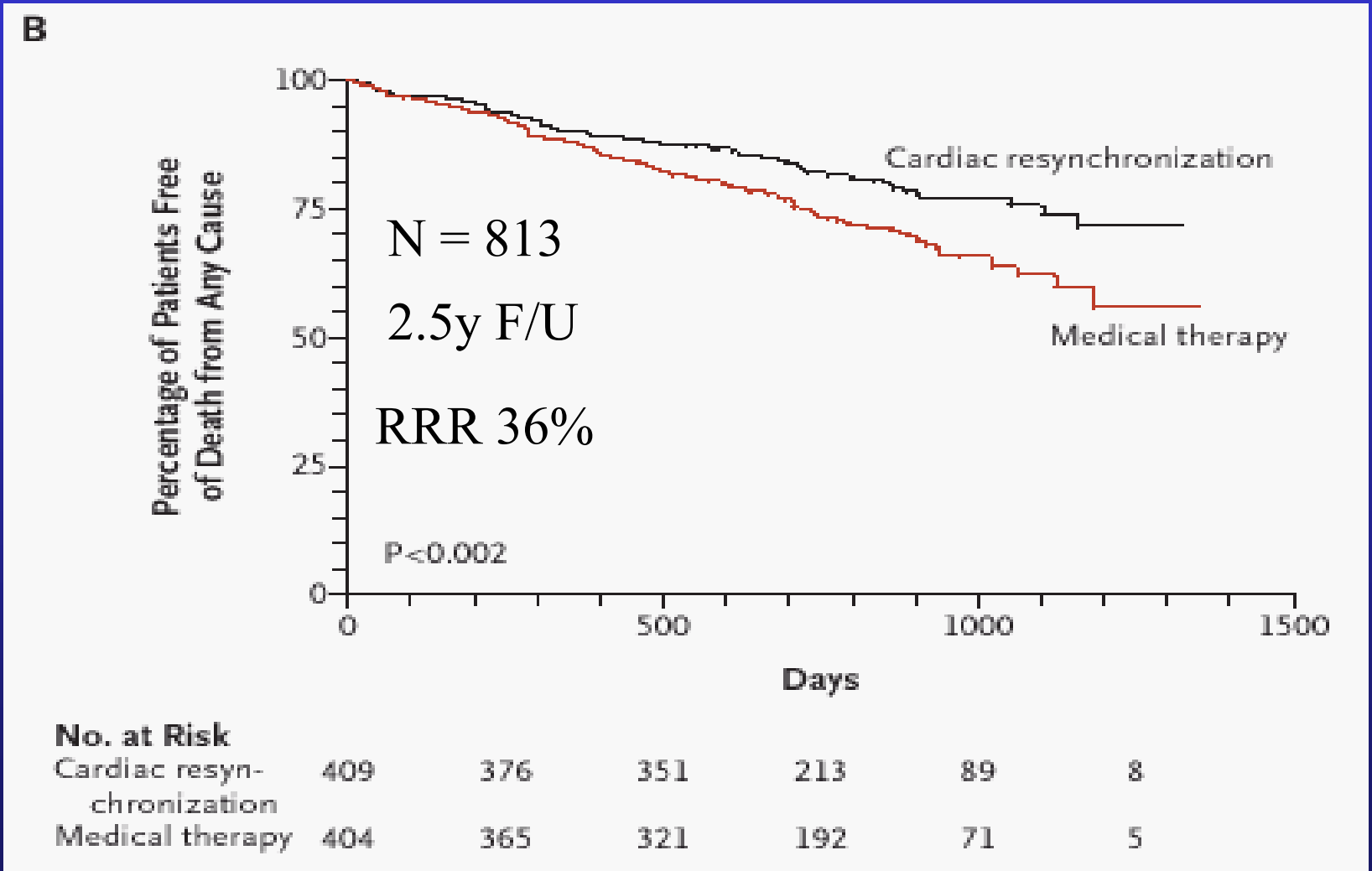
## ICD vs non ICD patients

2 years (0.2 Life Years Saved) 17 ICD implants to save 1 life  
8 years (1.2 Life Years Saved) 6 ICD implants to save 1 life

# MADIT II Post trial analysis: Benefit by device pacing type

Device type	HR	P value
Single chamber ICD vs no ICD (Back-up pacing)	0.70	0.009
DDD ICD vs no ICD Active RV pacing	0.88	0.35
Post trial DDD back-up pacing	0.53	0.006

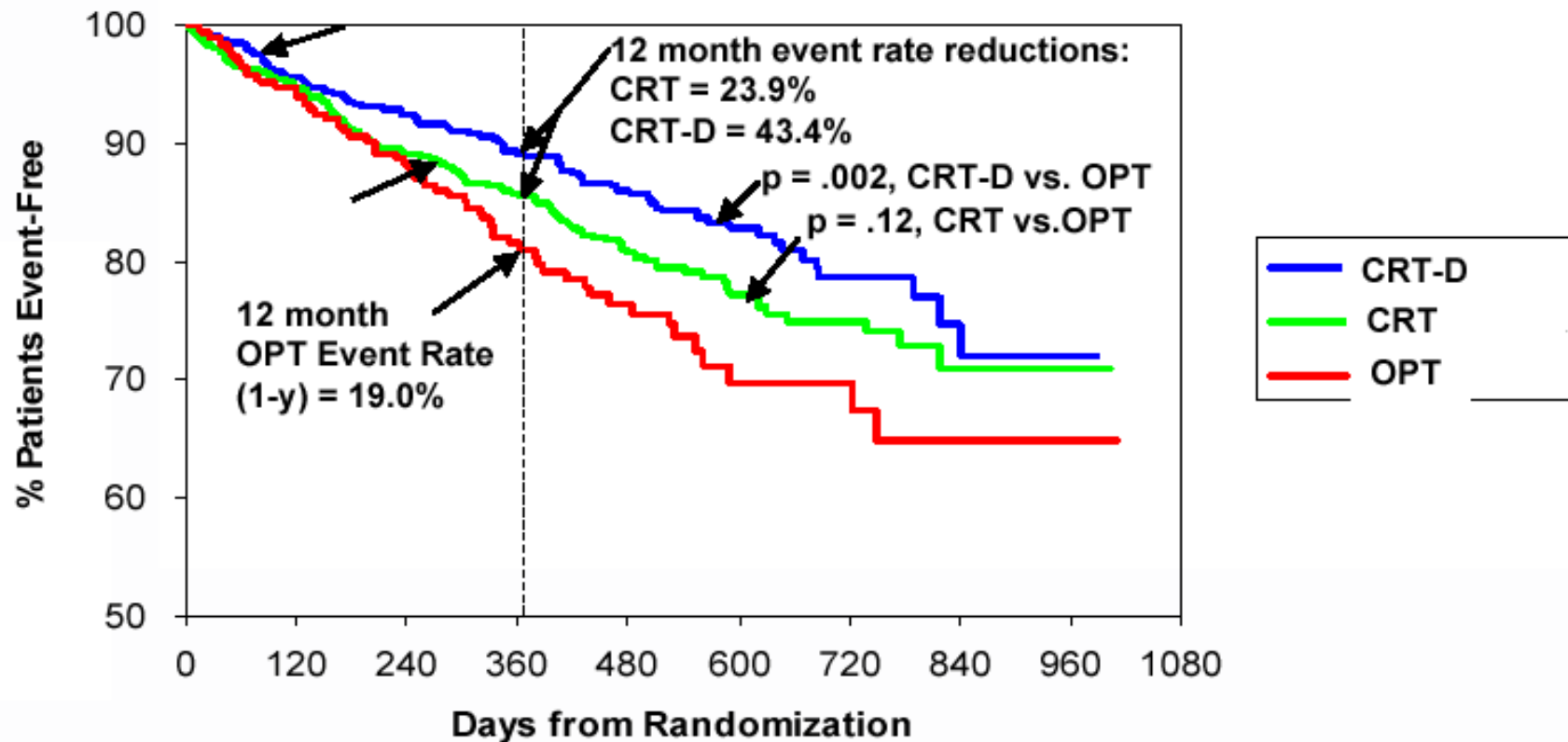
# CARE-HF all cause Mortality



# COMPANION: Secondary Endpoint- All cause mortality

RCT of patients with poor LV, QRS>120ms, NYHA III/IV to medical therapy / CRT / CRT-D

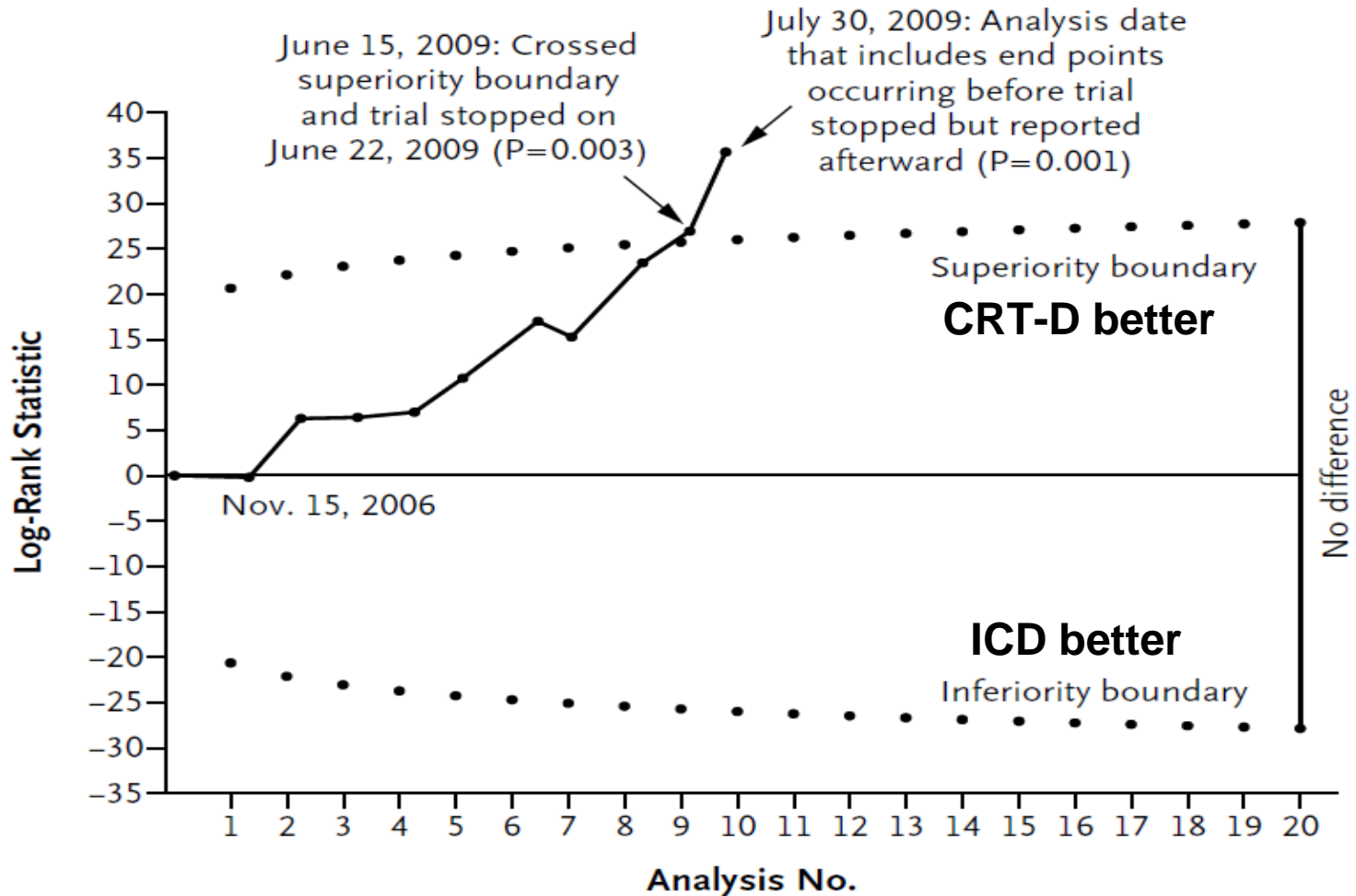
## Any Death



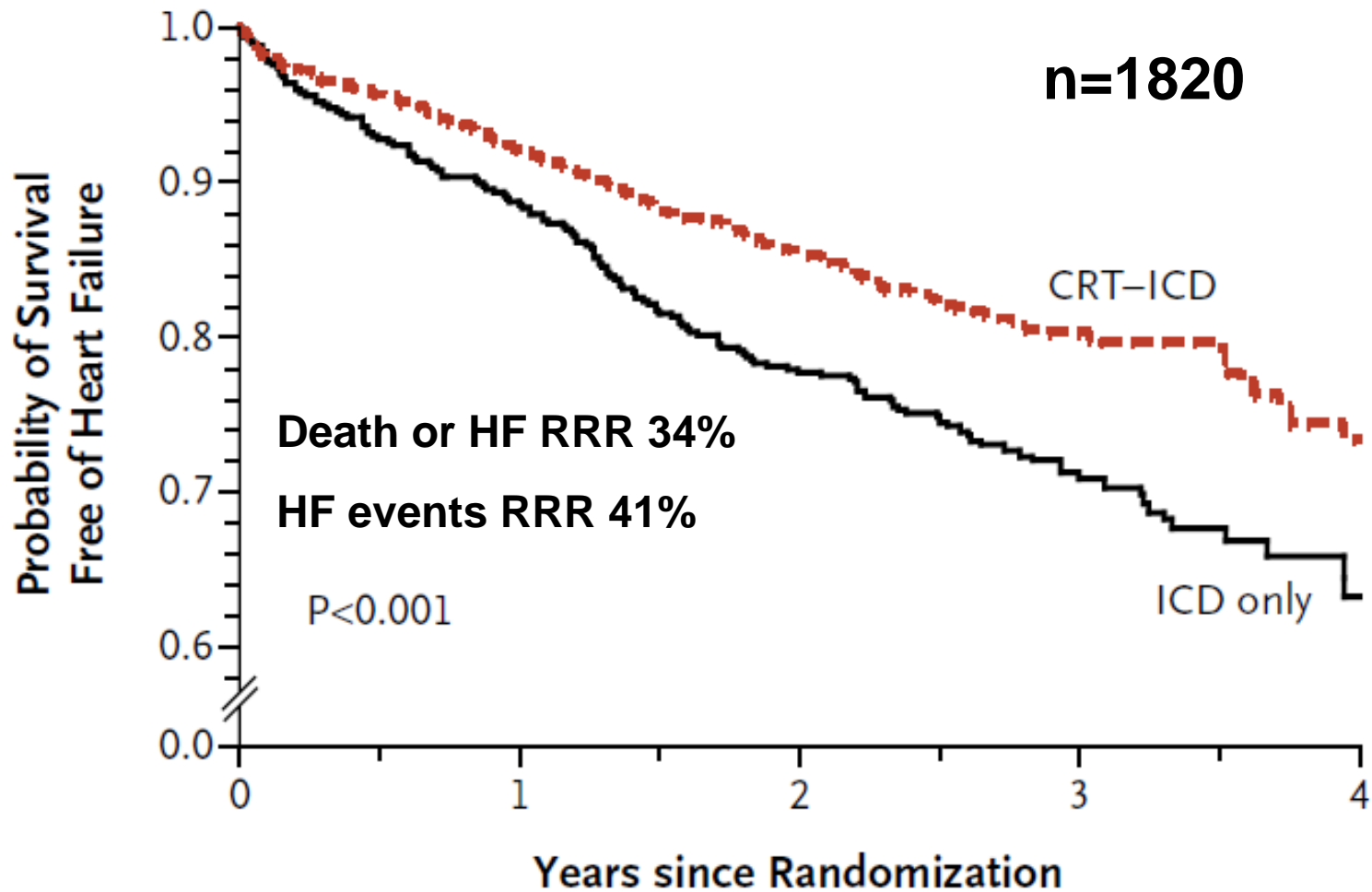
# MADIT - CRT

- Multi-centre randomised trial
- Mild heart failure patients (NYHA I-II)
- QRS > 130ms
- EF  $\leq$  30%
- Randomised to ICD vs CRT-D (2:3)
- 1° end point: deaths or heart failure events
- 4.5 year follow up

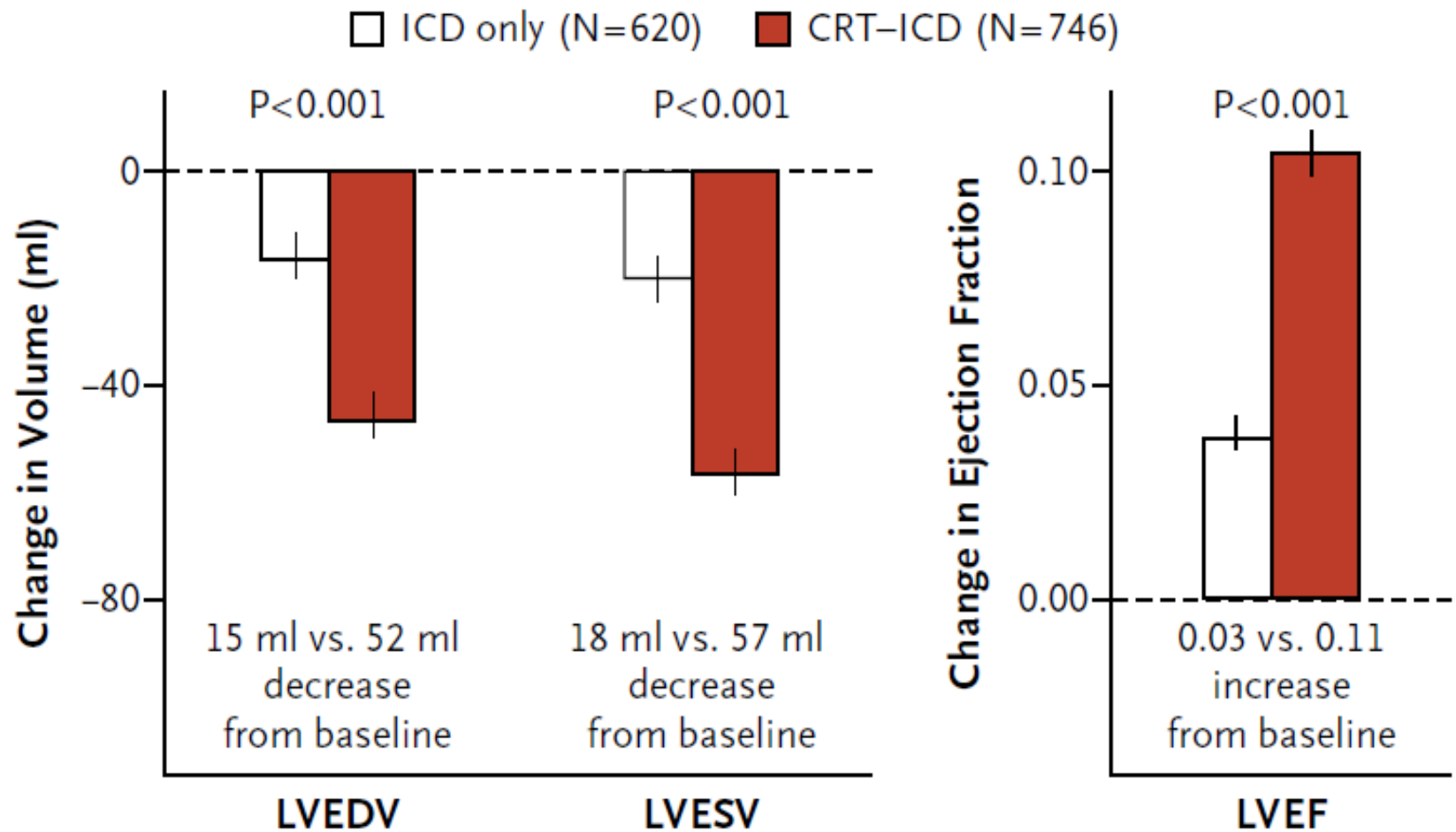
# MADIT -CRT



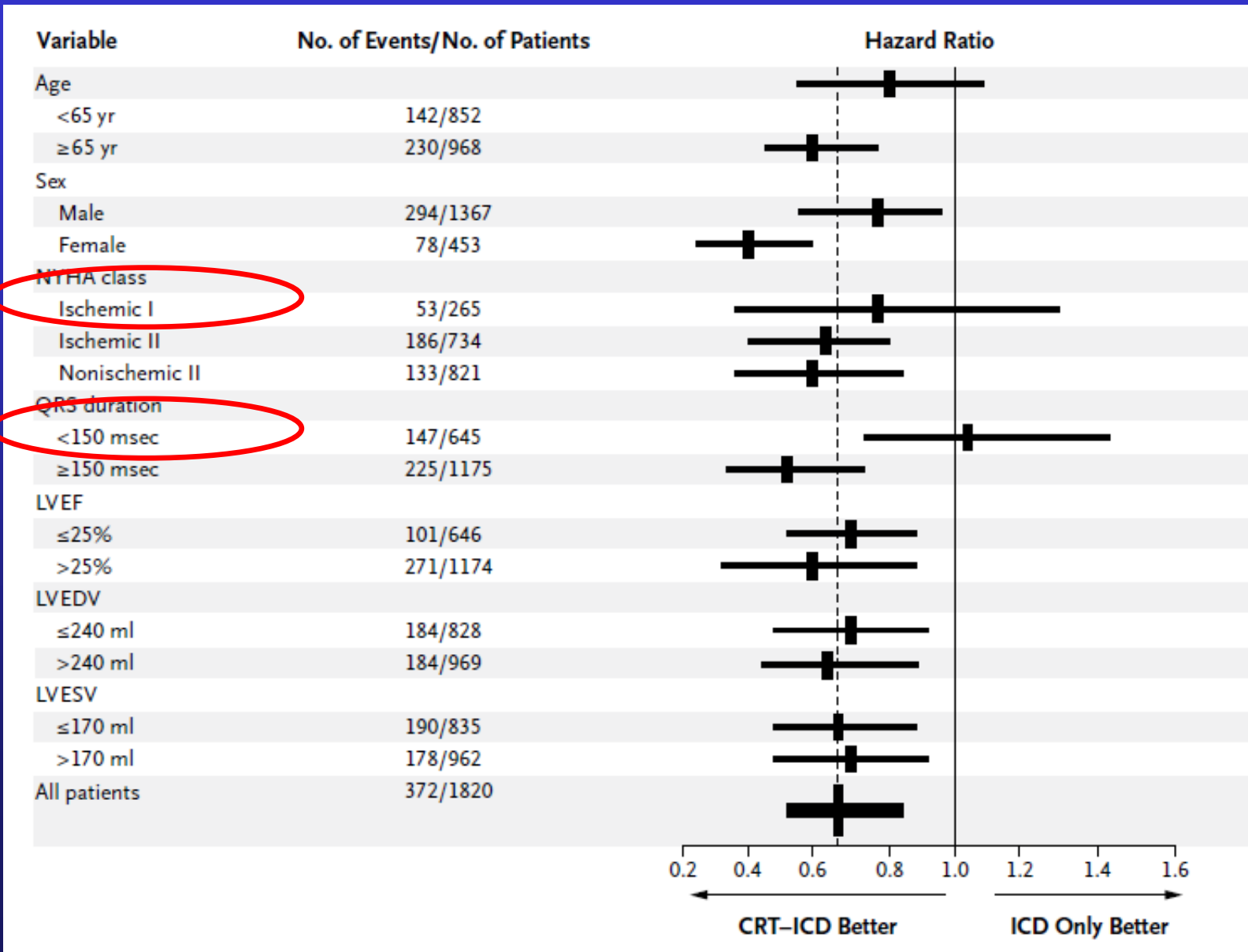
# MADIT- CRT



# MADIT - CRT



# MADIT- CRT



Study	n	NYHA	Rhythm	QRS	EF	% IHD	ICD	Results
MIRACLE	453	III / IV	Sinus	≥130	<35%	54%	No	+
MUSTIC SR	58	III	Sinus	>150	<35%	37%	No	+
MUSTIC AF	43	III	AF	>200 (paced)	<35%	30%	No	+
PATH CHF	41	III / IV	Sinus	≥120	<35%	29%	No	+
MIRACLE ICD	349	III / IV	Sinus	≥130	<35%	69%	Yes	+
CONTAK CD	490	II-IV	Sinus	≥120	<35%	69%	Yes	+
COMPANION	1520	III / IV	Sinus	≥120	<35%	55%	Yes	2° +
PATH CHF II	89	III / IV	Sinus	≥120			Both	+
MIRACLE ICD II	186	II	Sinus	≥130			Yes	2° +
CARE-HF	814	III / IV	Sinus	≥120	<35%	38%	No	+
MADIT CRT	1820	I / II	Sinus	≥130	<30%		Yes	+

# The Euro Heart Survey Program

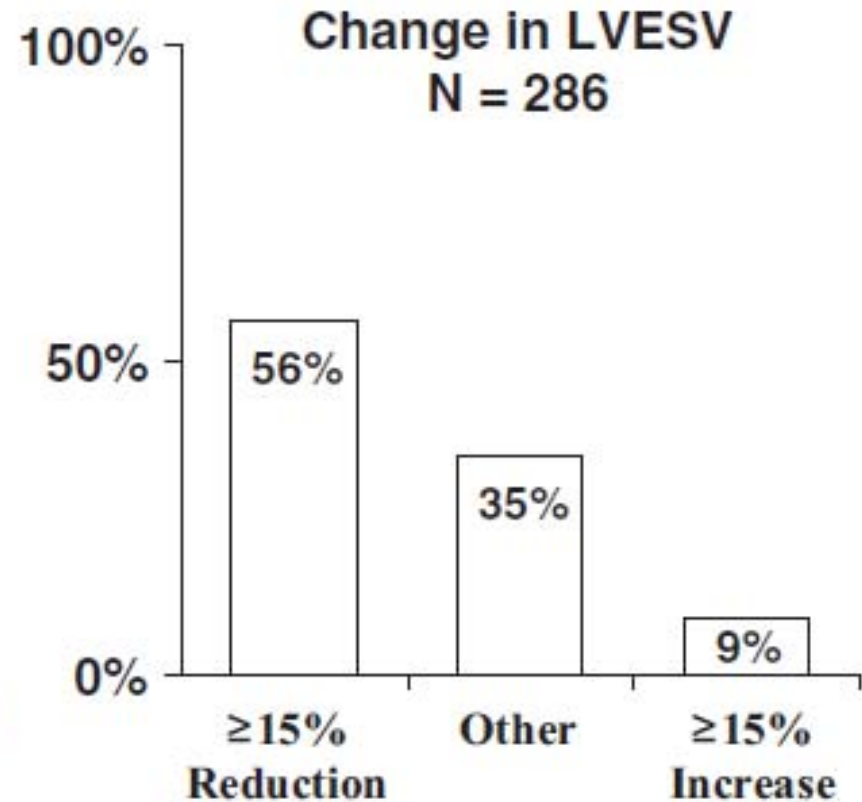
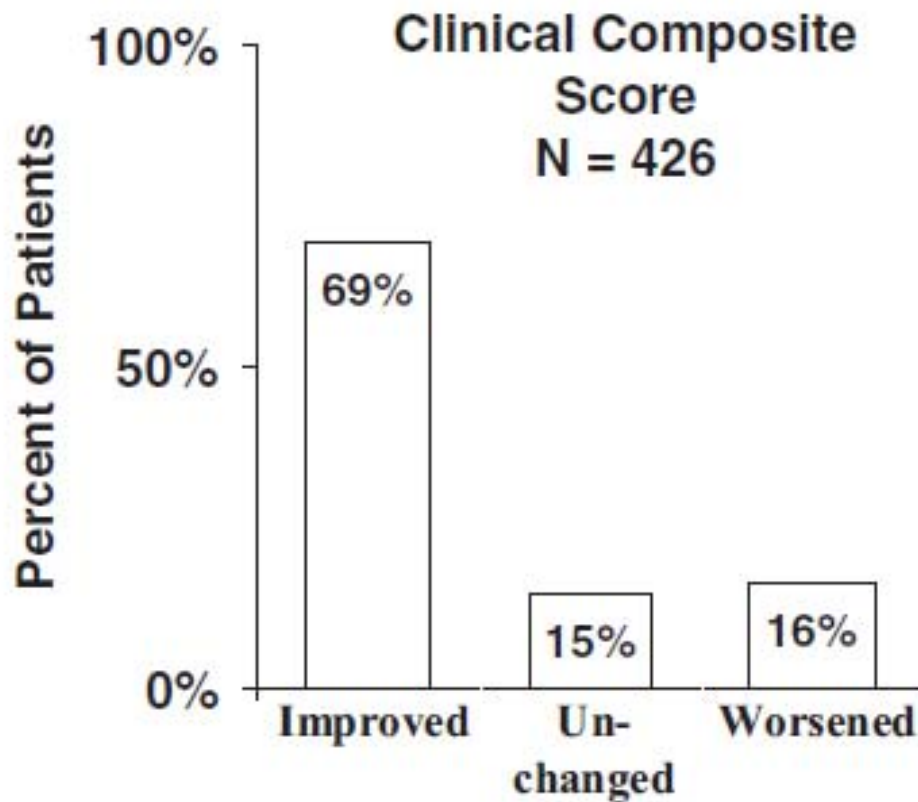
## Rate of prescription in overall population

ACE inhibitors	61.8%
ARB blockers	4.5%
Beta-Blockers	36.9%
Spironolactone	20.5%

# Predictor of response to CRT (PROSPECT) Trial

- 53 world wide device/echo centres
- Enrolling 498 patients with CRT indications
- 12 echo parameters assessing dyssynchrony
- All received site training for data acquisition
- Evaluation and core lab analysis

# Prospect Study



# Echo measures for dyssynchrony

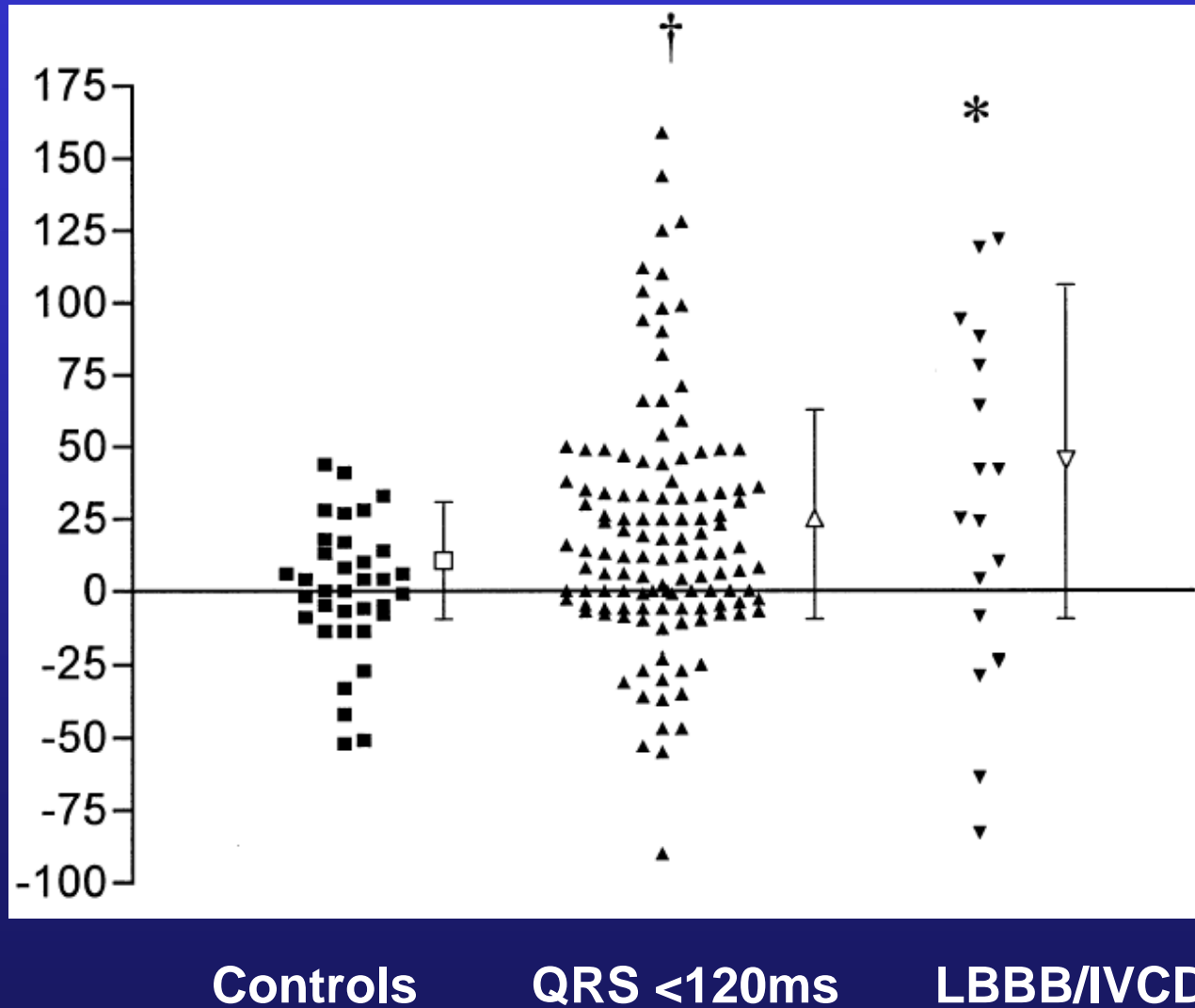
- There is poor agreement between standard echo and TDI for diagnosing dyssynchrony<sup>1</sup>
- Accuracy of assessment of intra LV dyssynchrony using TDI limited by poor test-retest reliability<sup>2</sup>

**Burri et al. Eur J Echo 2008;9:235**

**Vesley et al. Am J Cardiol 2008;101:645**

# Dyssynchrony with narrow QRS

Time delay basal septum to lateral wall (ms)



# Real World of CRT

- LV mechanics are complex
- No perfect tool for selection
- Lack precise answers for simple questions

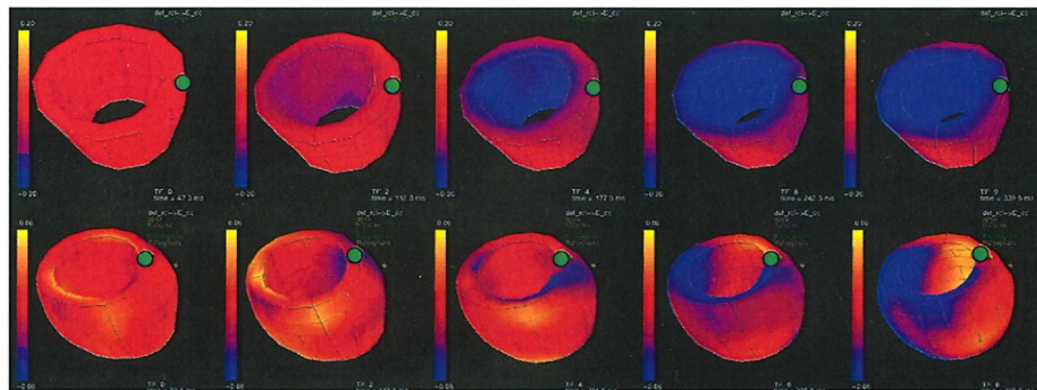
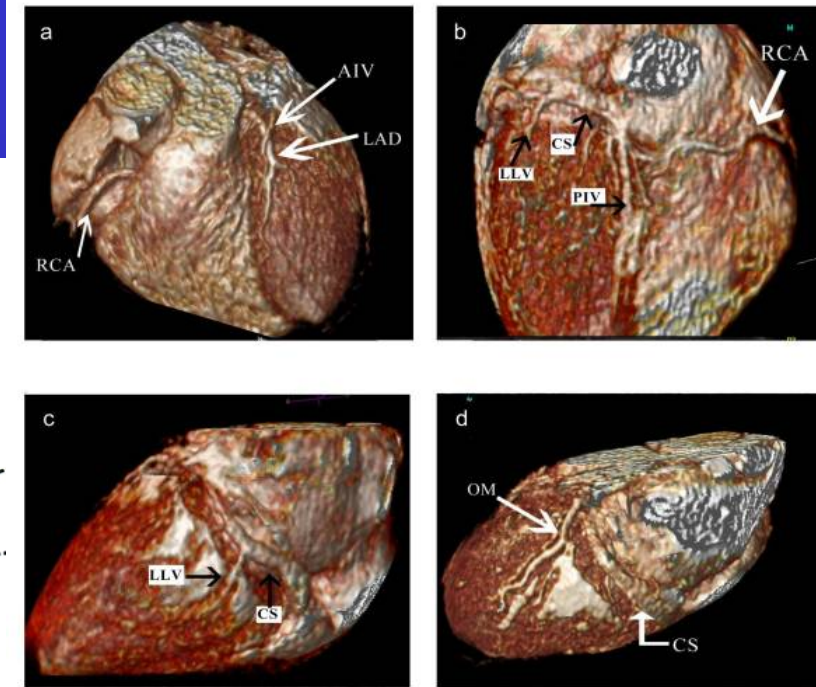
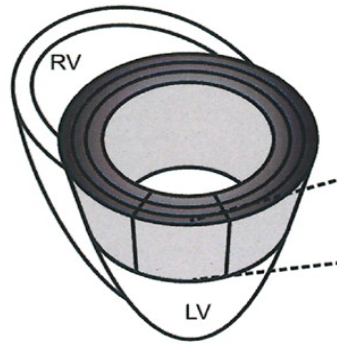
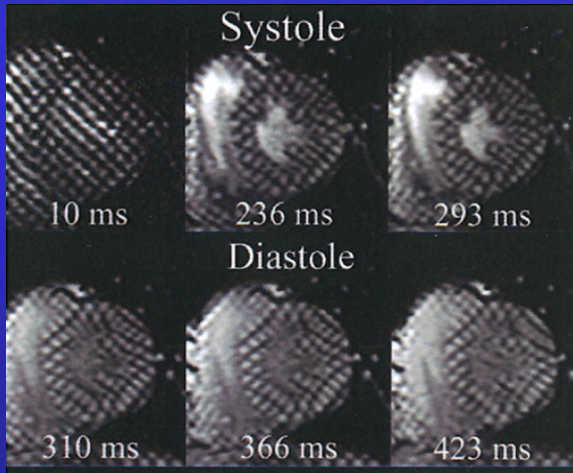
**CRT in symptomatic patients with low EF and QRS <120ms?**

**Optimal imaging modality for patient selection? Role of echo for dyssynchrony assessment?**

**CRT-P or D for symptomatic HF patients with wide QRS?**

**ICD threshold for LVEF 30-40 or greater?**

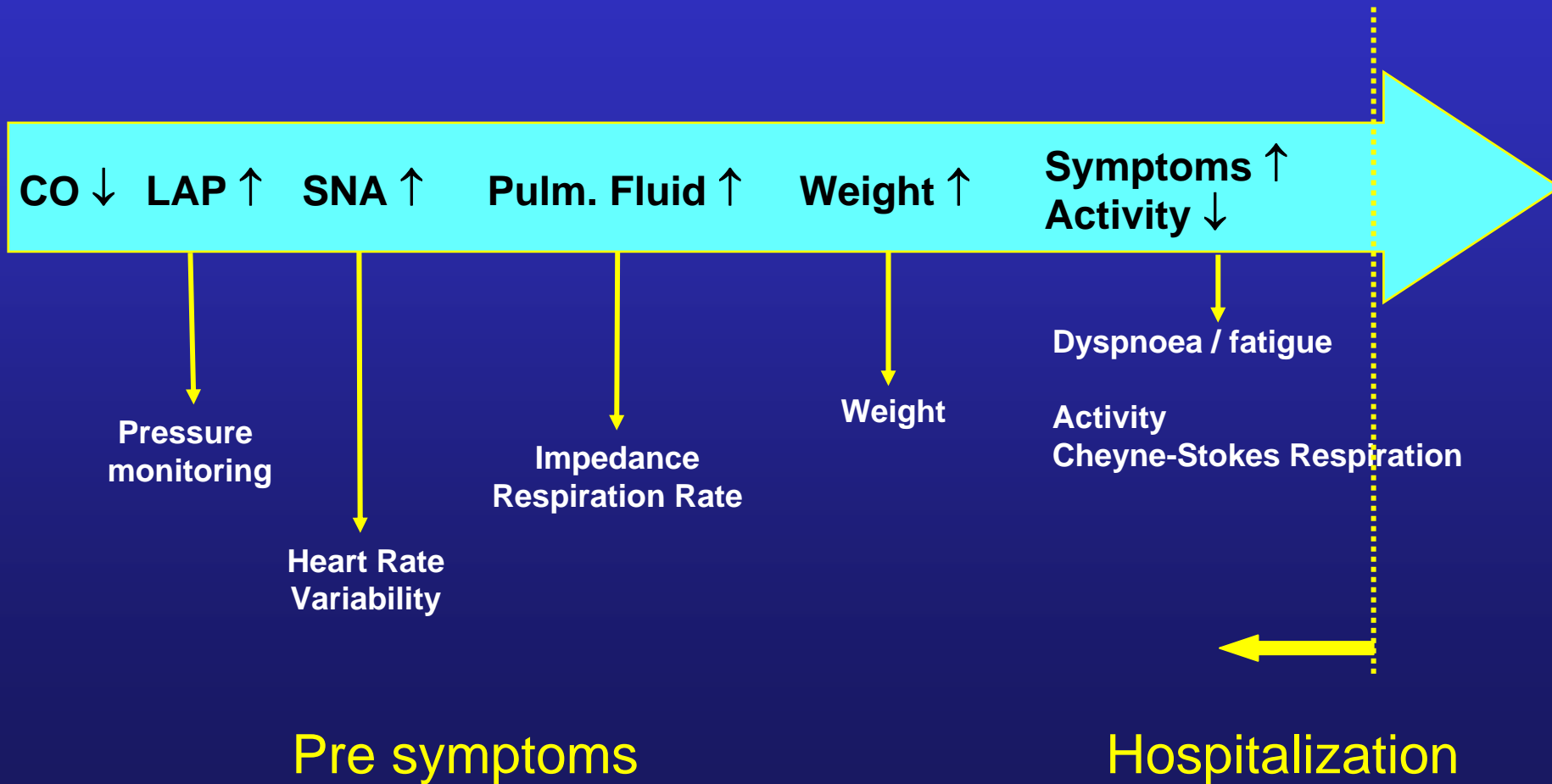
# Cardiac MR and CT

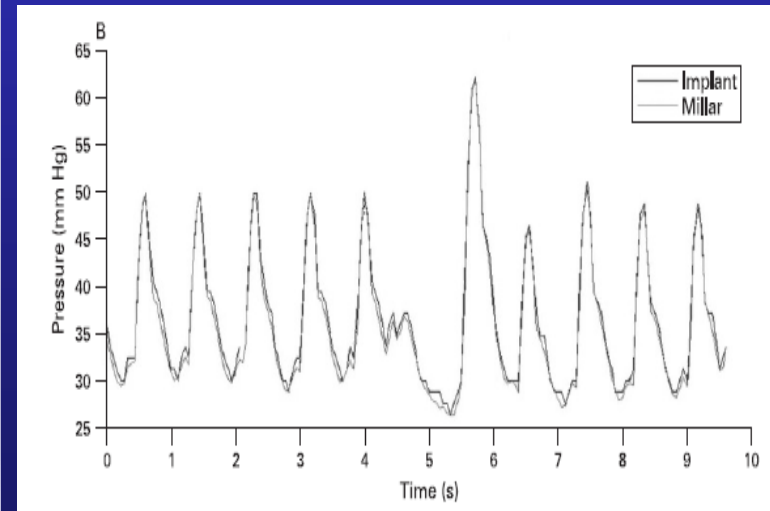
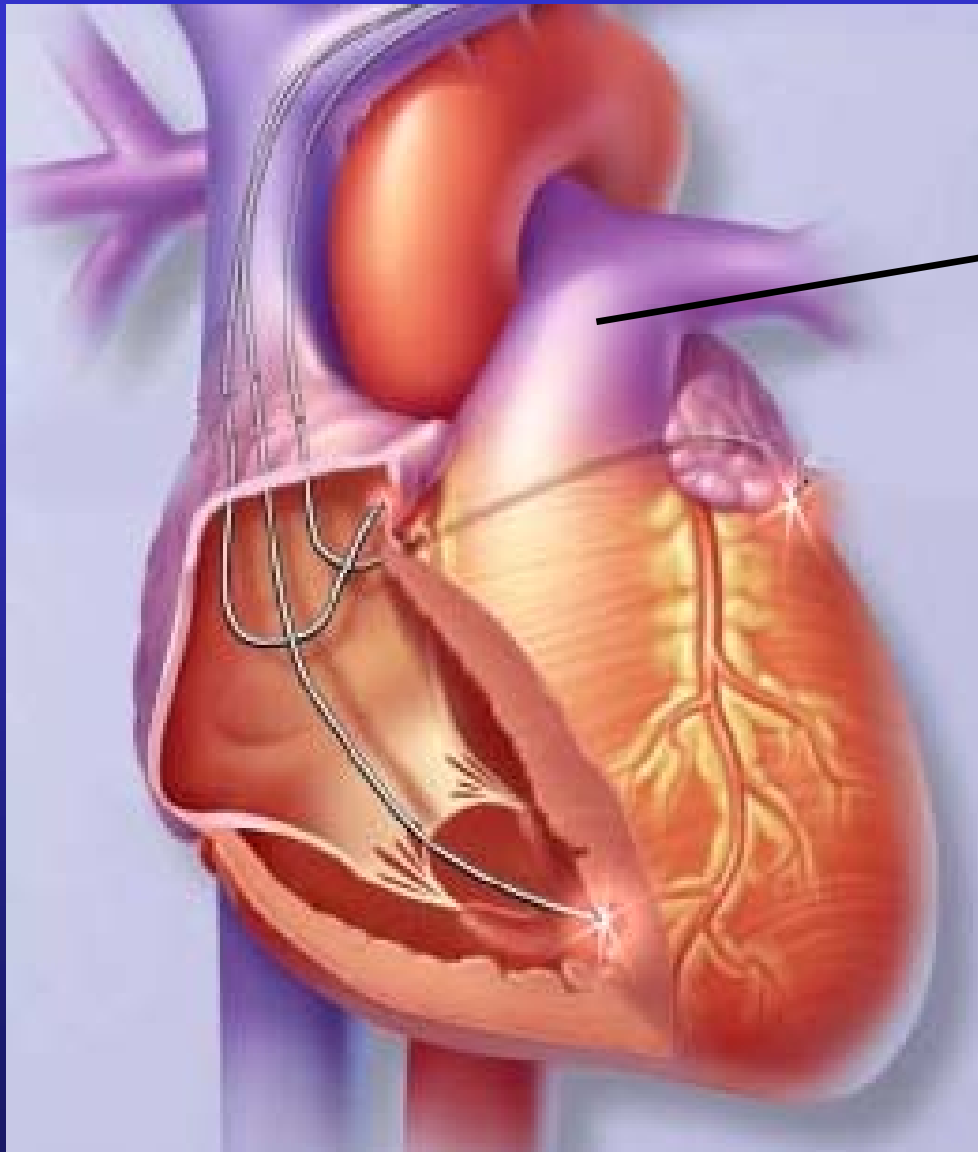


MRI myocardial tagging during systole to track myocardial strain

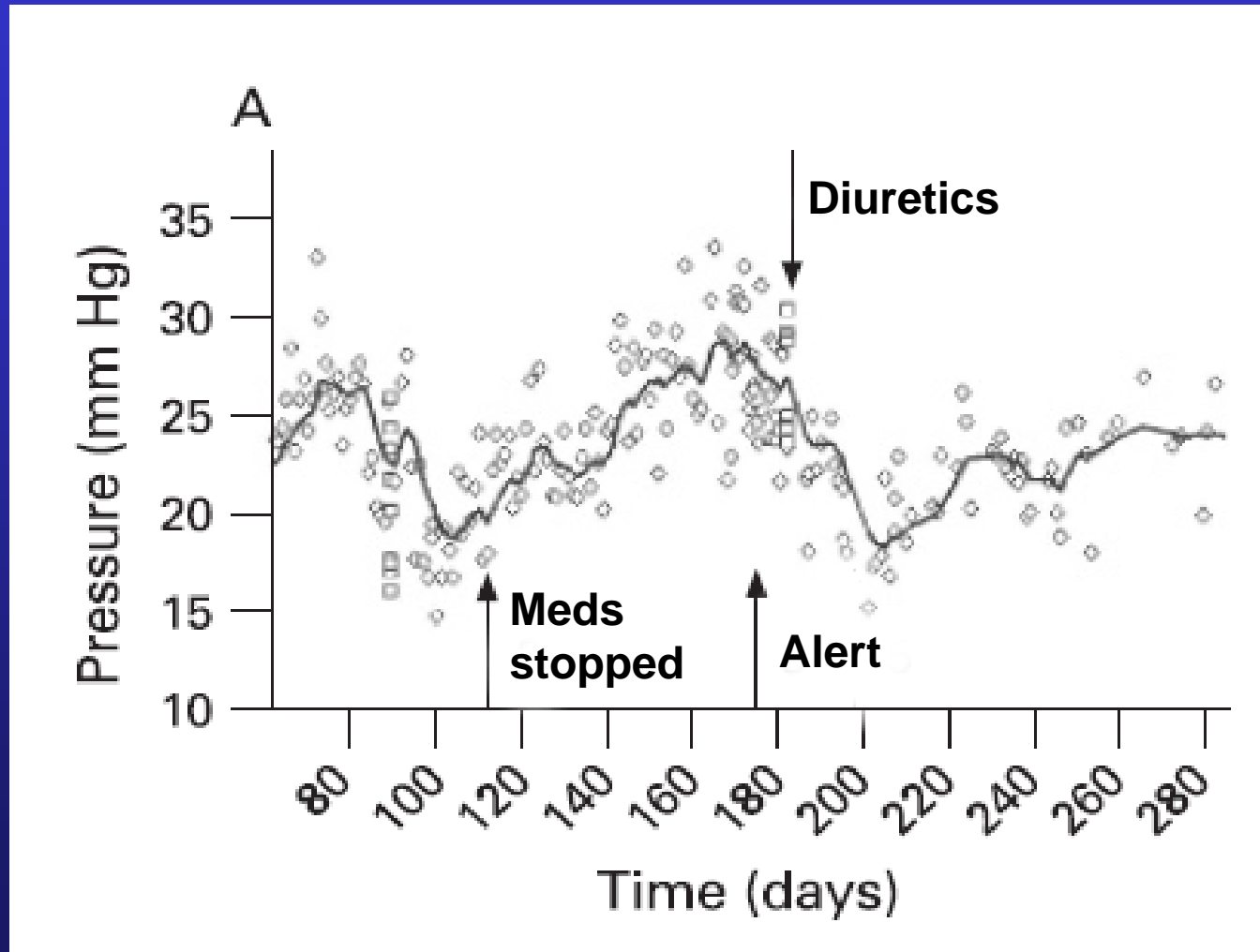
# Pathophysiology of Worsening HF

Typical Time Course of Decompensation





# PA monitor for early detection of HF



# LATITUDE: Patient management system

wireless transmitter



Daily automatic transmission to home communicator



call center



Data is reviewed and archived

*Implanting Physicians are alerted to device abnormalities, according to customizable rules*



external sensors  
(e.g. weight scale, BP)



*HF physicians are alerted to significant variations in weight or blood pressure*

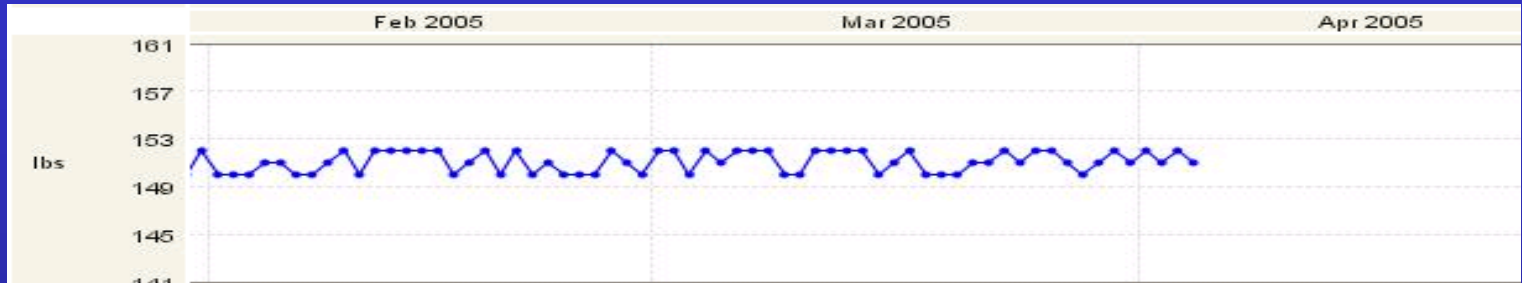
# Major advantages of Latitude

## Diagnostic information to assist with clinical management of CHF patients

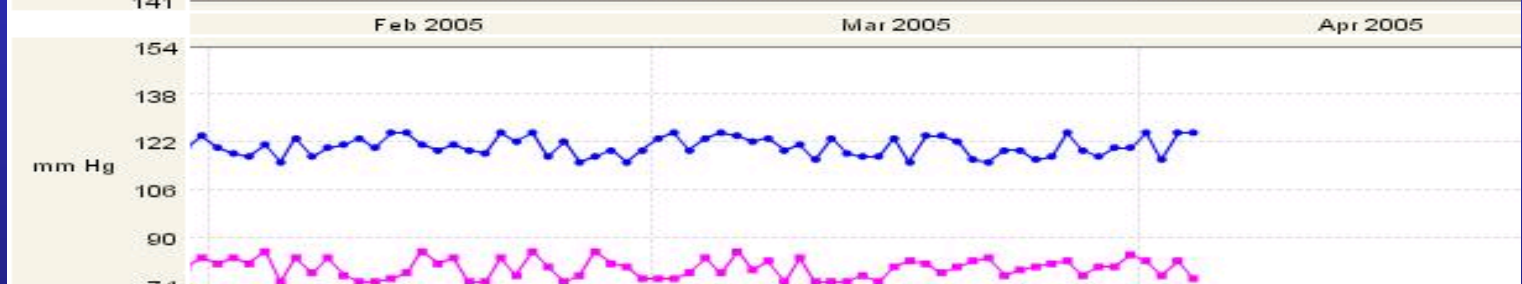
- Reduce routine hospital device visits
- Regular surveillance of device function and clinical events
- Early warning system to avert hospitalisations for heart failure
- Freedom of mobility for patients

# LATITUDE *automatic daily scheduled interrogations*

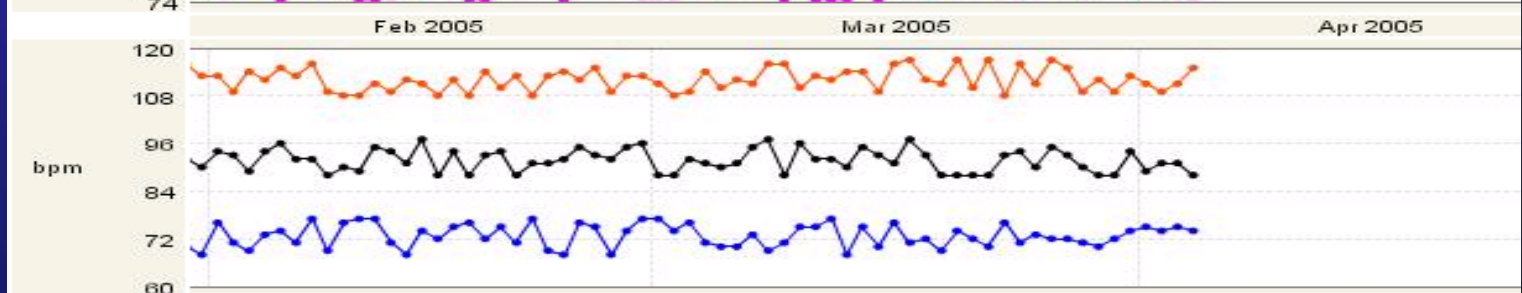
Weight



BP



HR



Activity



# Latitude home monitoring system

- **Red** Urgent notifications
  - Device battery EOL
  - High/low shock and pacing lead impedance
  - Active device therapies
  - High voltage detection on shock lead during charge
  - Tachy mode not set to monitor and therapy
  - Possible device malfunction or parameter error
  - Impending heart failure events

# Latitude home monitoring system

- *Yellow* Advisory notifications
  - Device reaching ERI
  - Significant pacing lead changes in amplitude, impedance and thresholds
  - Shock or ATP therapies
  - Ns arrhythmia episodes
  - Significant weight or PAP changes

# IS4 integrated ICD lead: 4SITE study



# Multipolar LV pacing



- Tailor made configuration options
- Superior programmability
- Overcome phrenic N stimulation and high thresholds
- ? Better CRT

# Potential Lead Optimization of the Future

## Automated Phrenic Nerve Detection

Device “listens” and adjusts for diaphragmatic stimulation

## Auto Vector Selection

- LV Capture Detection

- Threshold Measurement

- Search algorithm for optimal vector

# Future Heart Failure Sensors/Diagnostics

- Haemodynamic Measures
  - Volume overload, intracardiac pressures (PA, LA)
  - LV contractility sensors
- Standard Diagnostics
  - HRV – SDANN, Footprint
  - Heart Rate
  - Activity Log
  - Atrial Arrhythmia Burden
  - Respiration, RR, O<sub>2</sub> sats, tidal volume, apneic episodes
- Physiological response to activity
  - Heart rate, respiration rate, tidal volume *versus* activity
- Intra Thoracic Total Impedance - lung fluid
  - 4 vectors including RA, RV, LV, and orthogonal

# Summary

- Expanding indications for HF devices
- Need to develop robust tools for patient selection
- More effective monitoring and prevention of HF events
- Individualised therapy