Intracardiac Hemodynamic Monitoring – CardioMEMS

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Disclosures

- None

Objectives

- Understand the pathophysiology of congestion
- Learn how to use IHM – CardioMEMs
- Understand clinic benefits of IHM - CardioMEMs

Heart Failure – A Growing Global Concern

Prevalence and Incidence

- Overall **2.4%** prevalence: **5.1 million** patients >20 years of age with heart failure in 2010
- 825,000 people ≥ 45 years of age are newly diagnosed each year with HF
- HF prevalence in the US is projected to increase 25% from 2013 to 2030, resulting in **> 8M** people ≥ 18 years of age with HF.

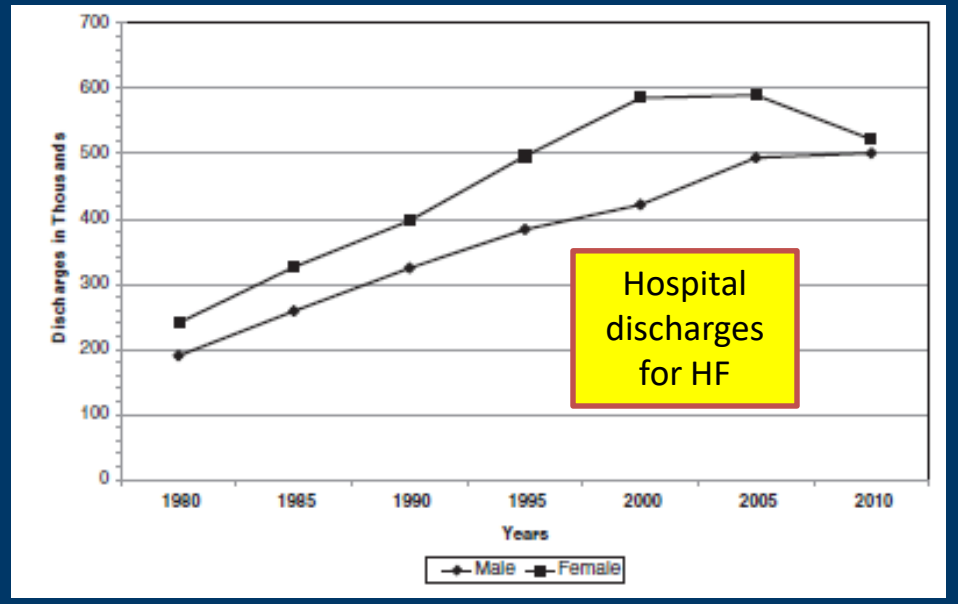
Mortality

- For AHA/ACC stage C/D patients diagnosed with HF:
  - 30% will die in the first year.
  - 60% will die within 5 years
- In 2009, **56000** death were attributable to HF

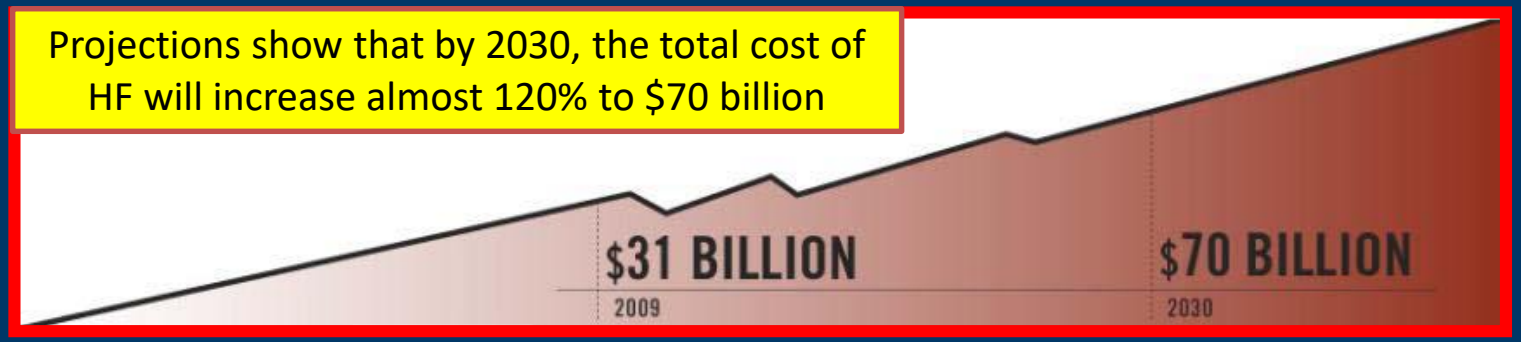
Circulation 2012; 125: e2–e220

Health care burden of Heart failure

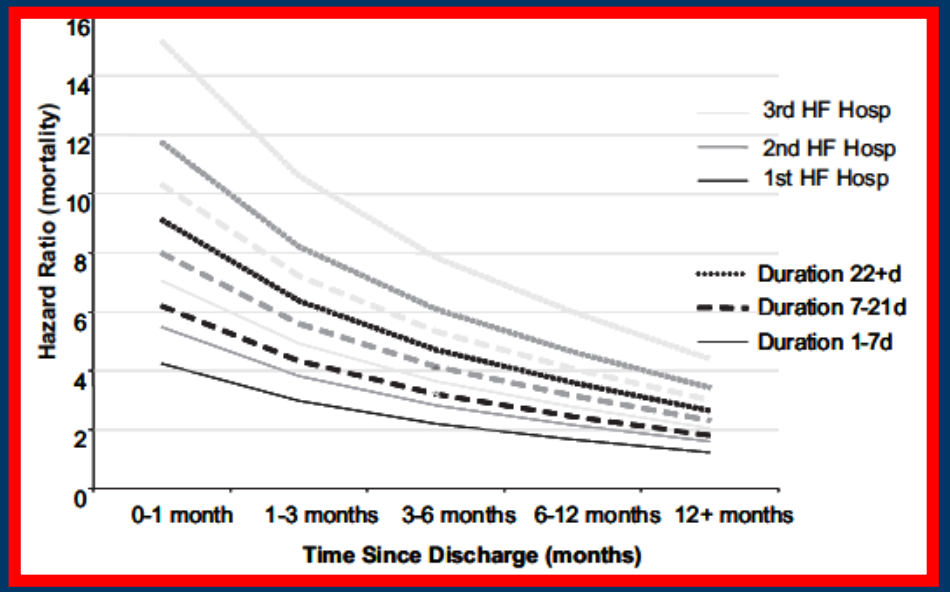
- In 2010, there were 1 million HF hospitalizations in the US
- The mean length of stay is ~6 days
- In-hospital mortality is ~2 to 4%
- In 2010, there were 1.80 million HF office visits

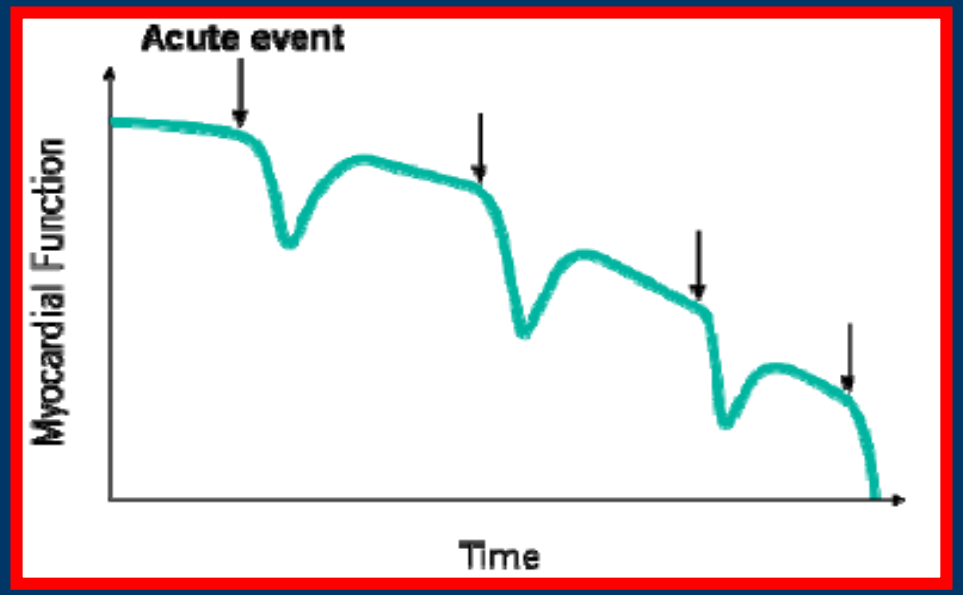


Projections show that by 2030, the total cost of HF will increase almost 120% to $70 billion



Prognostic implications of hospitalization





- HF is associated with high readmission rates: ~25% all-cause readmission within 30 days and ~50% within 6 months
- The mortality rate is increased after HF hospitalizations.

- With each subsequent HF-related admission, the patient leaves the hospital with a further decrease in cardiac function.

J Am Coll Cardiol 2009;54:386–96.

What is the cause of HF hospitalization?

Acute decompensated Heart failure (ADHF)

New onset or gradual or rapidly worsening HF signs and symptoms requiring urgent therapy for pulmonary and systemic congestion due to elevated ventricular filling pressures

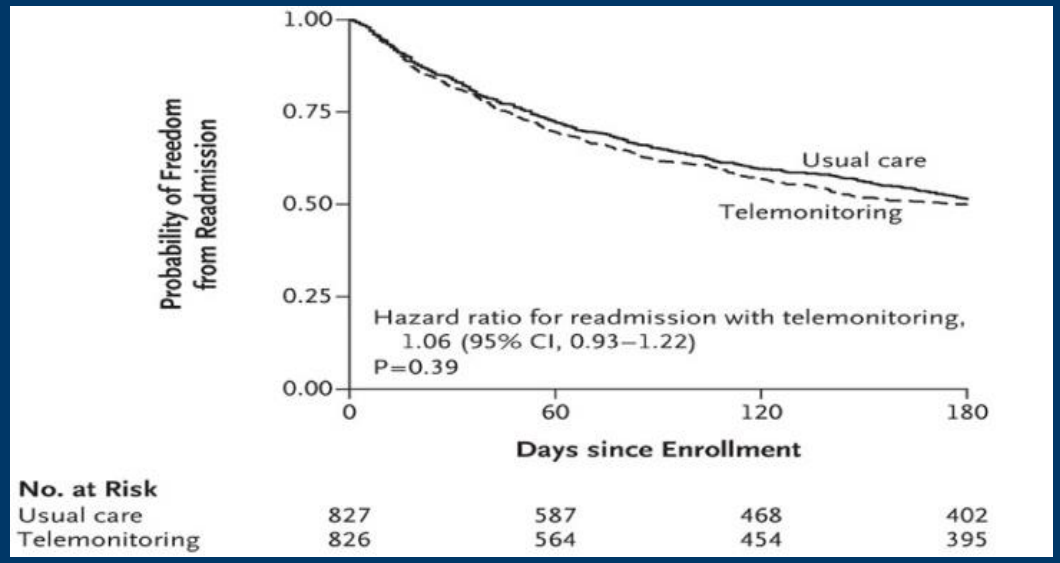
What do we know about these patients?

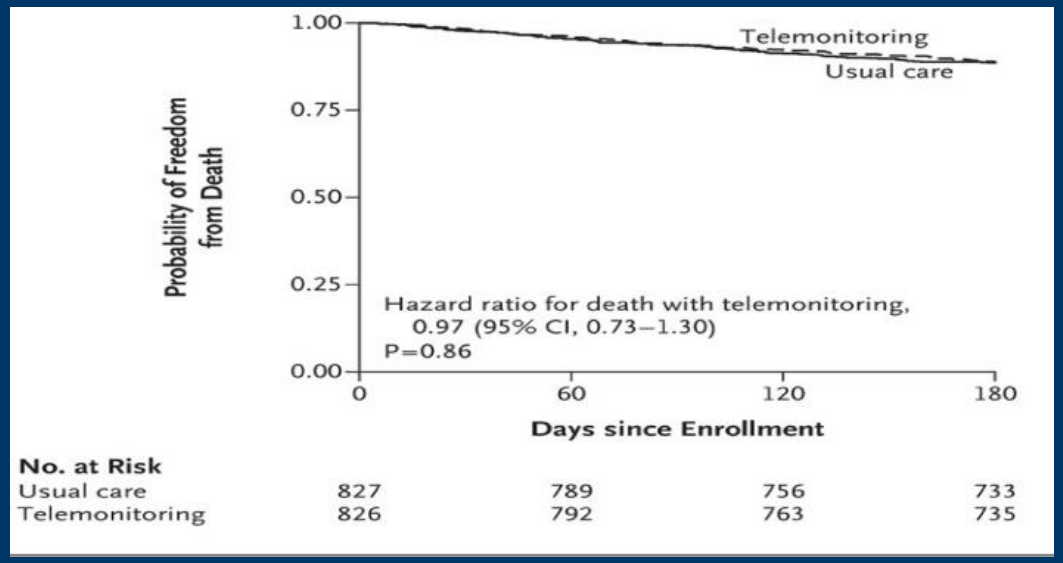
	ADHERE	OPTIMIZE HF
Prior HF (%)	75	87
New onset HF (%)	25	13
Cardiogenic shock (%)	2	<1
LVEF <40% (%)	59	52

The majority of patients admitted with ADHF are known to the medical system and to medical providers

Are there an **upstream strategies** that may be capable of **detecting early HF** destabilization and **implementing therapies** to restabilize the patient and **avert hospitalization?**

Benefit of Intensive weight and symptom monitoring



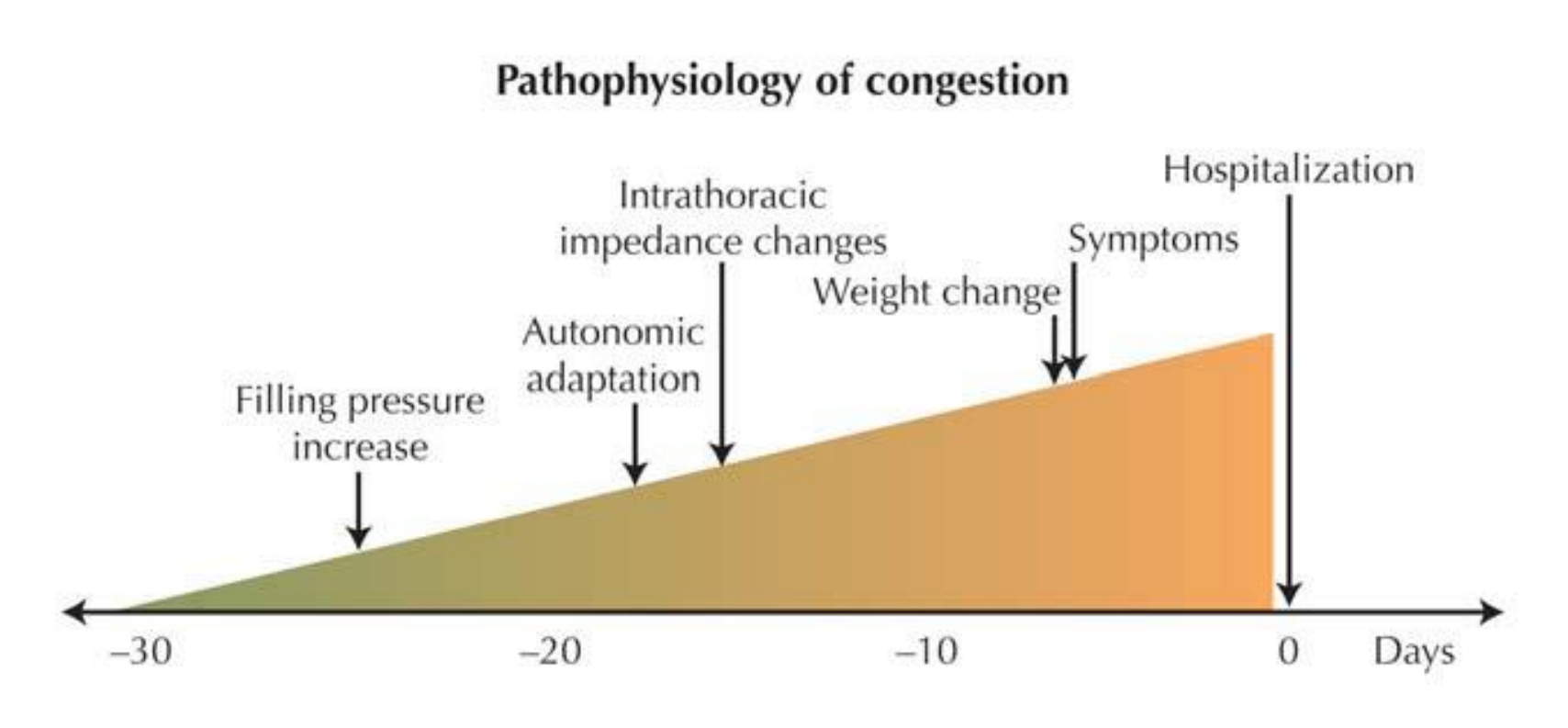


Daily measurement of body weight, for example, has a sensitivity of only 9% but a 97% specificity for the development of a HF exacerbation

Monitoring of weight and symptoms do not reduce readmission or death

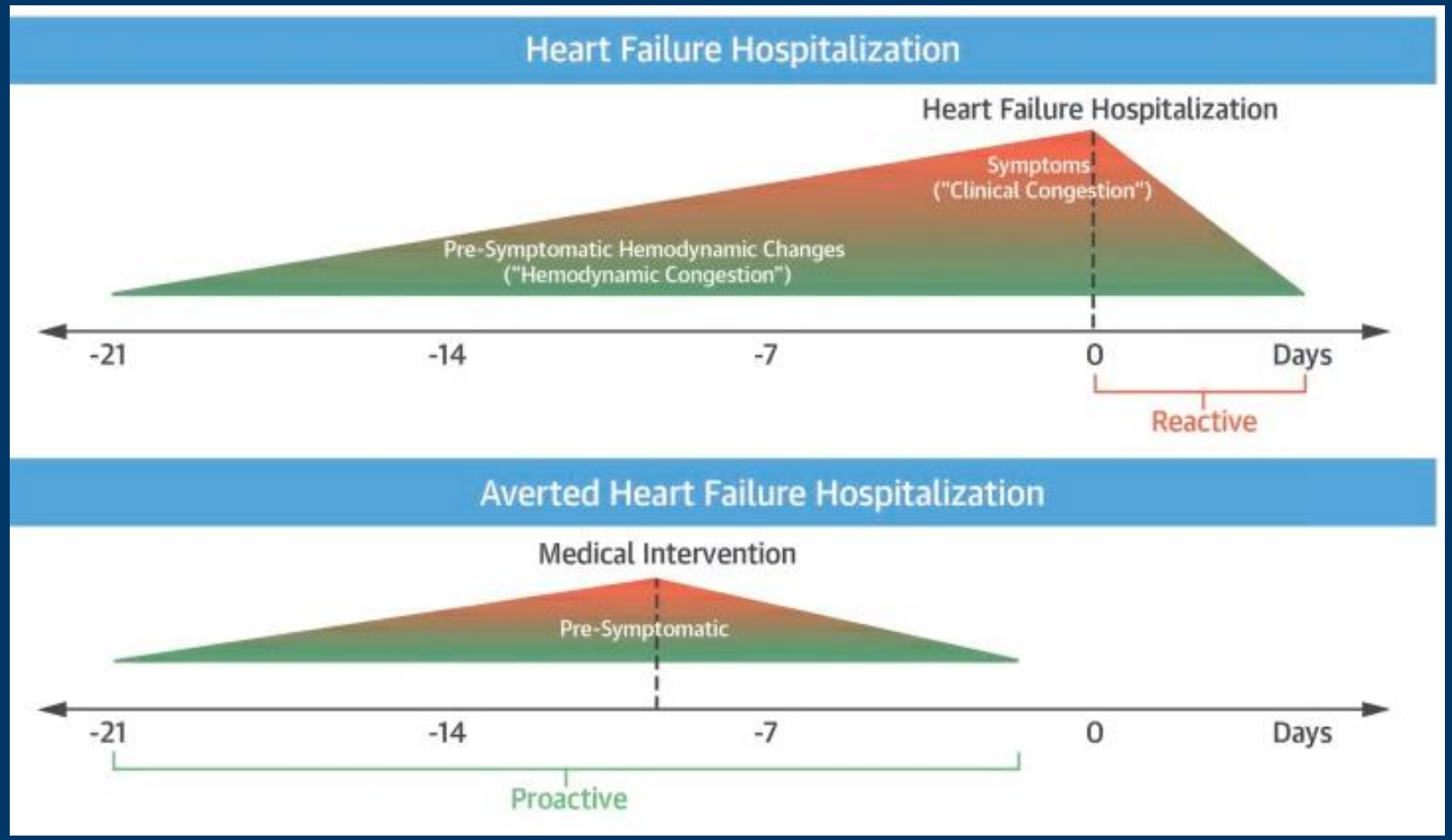
Chaudhry SI et al. N Engl J Med 2010;363:2301-2309
J Heart Fail 2005, **7:**953–957.

Time course of Decompensation

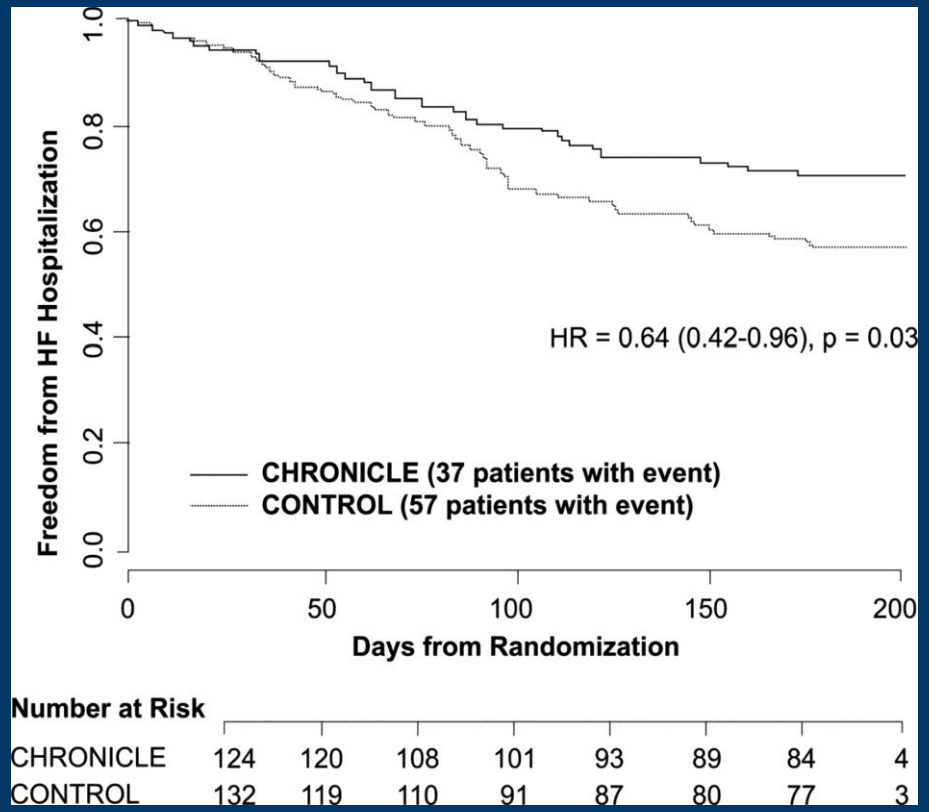


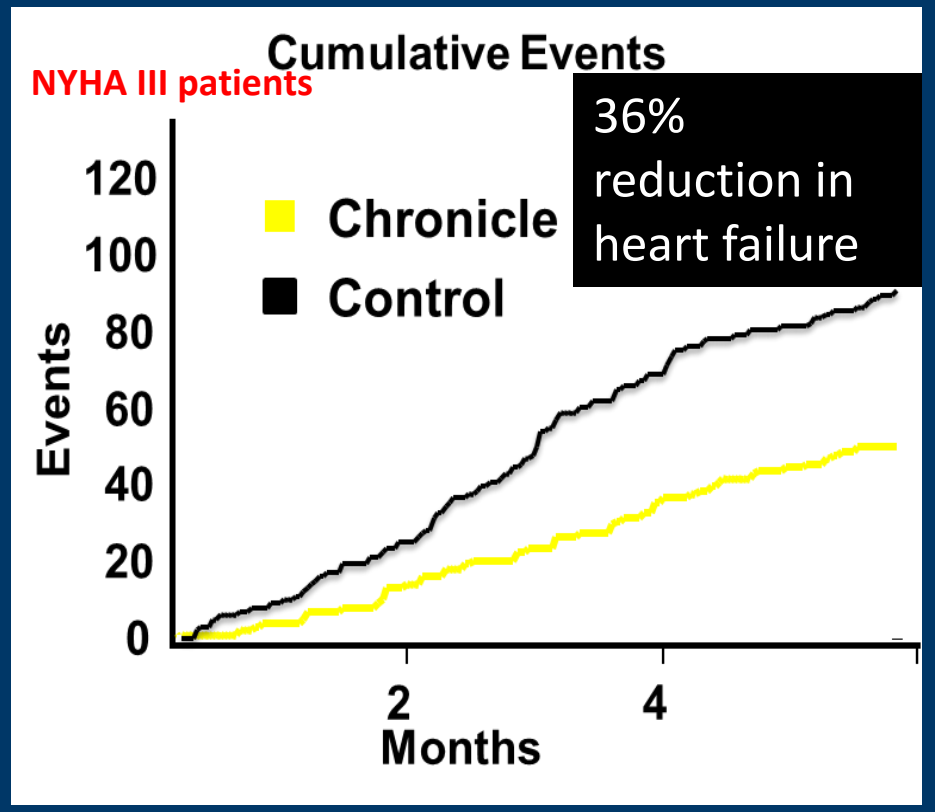
Adamson PB, et al. Curr Heart Fail Reports, 2009

The Concept of Pressure-Guided Heart Failure Therapy



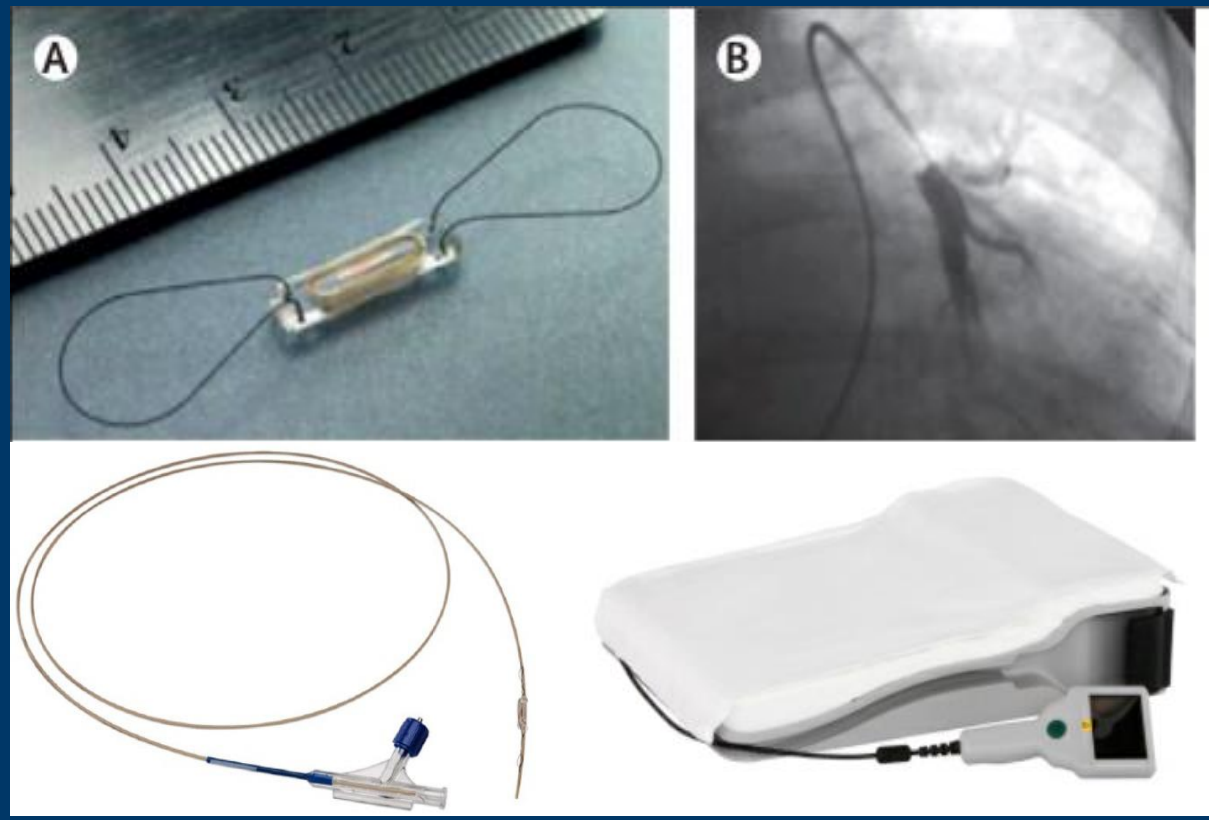
COMPASS-HF

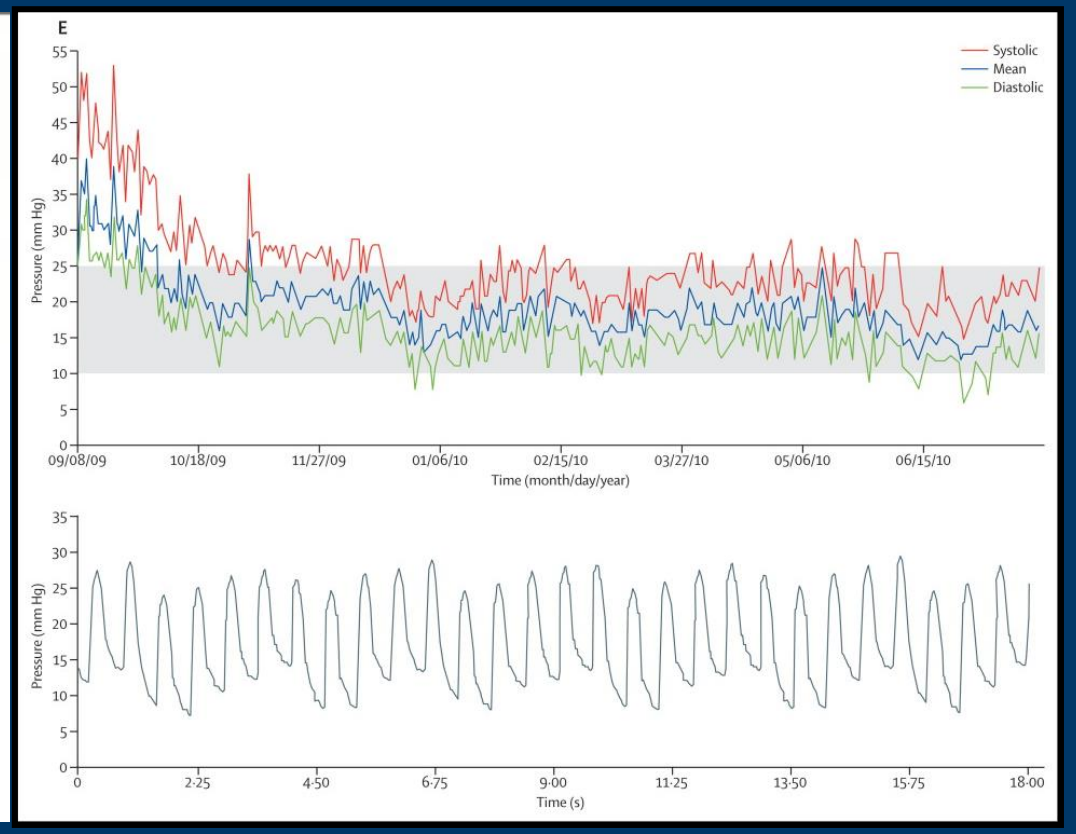




J Am Coll Cardiol. 2008;51(11):1073-1079

CARDIOMEMS


A
B


E
Systolic
Mean
Diastolic
Pressure (mm Hg)
Time (month/day/year)
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10/18/09
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06/15/10
Pressure (mm Hg)
Time (s)
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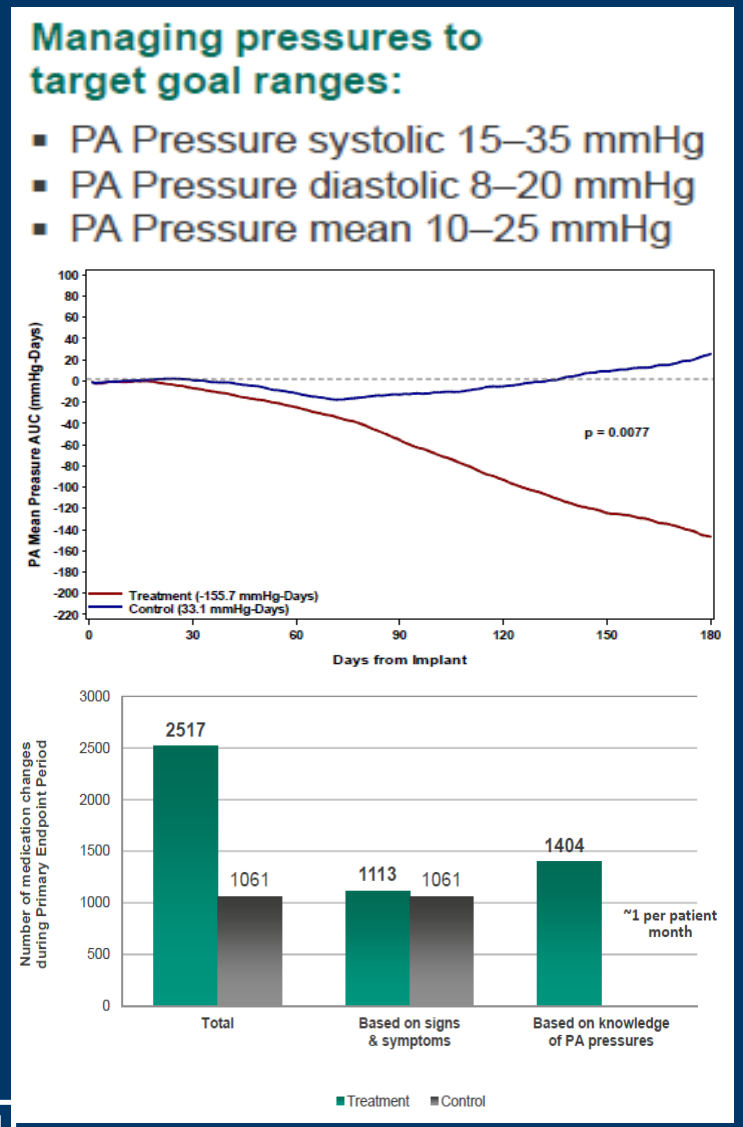
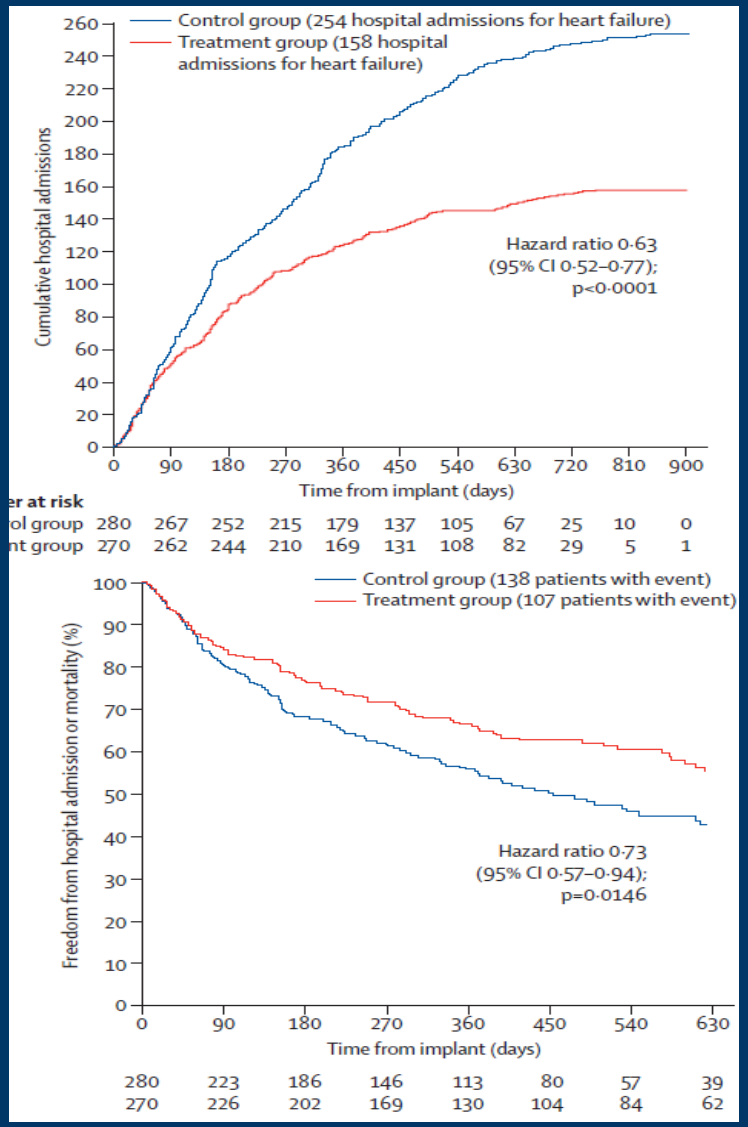
9·00
11·25
13·50
15·75
18·00

CHAMPION Clinical Trial





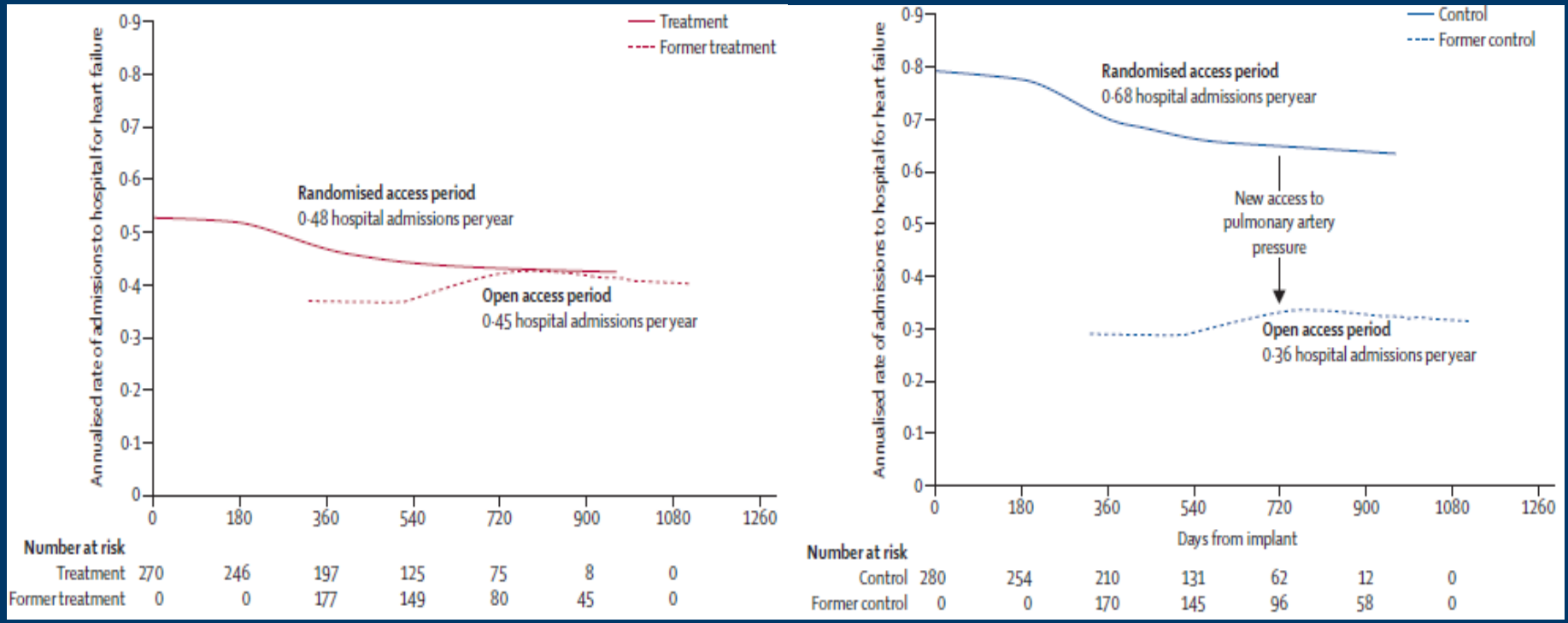
≤ 6 Months	> 6 Months	Study Duration
28% RRR	45% RRR	37% RRR
p < 0.0002	p < 0.0001	p < 0.0001

A Pressure-guided Therapy Reduces HF Hospitalizations

- Freedom from device- or system-related complications was 98.6%
- Overall freedom from pressure-sensor failures was 100%

Abraham et al Lancet 2011; 377: 658–66

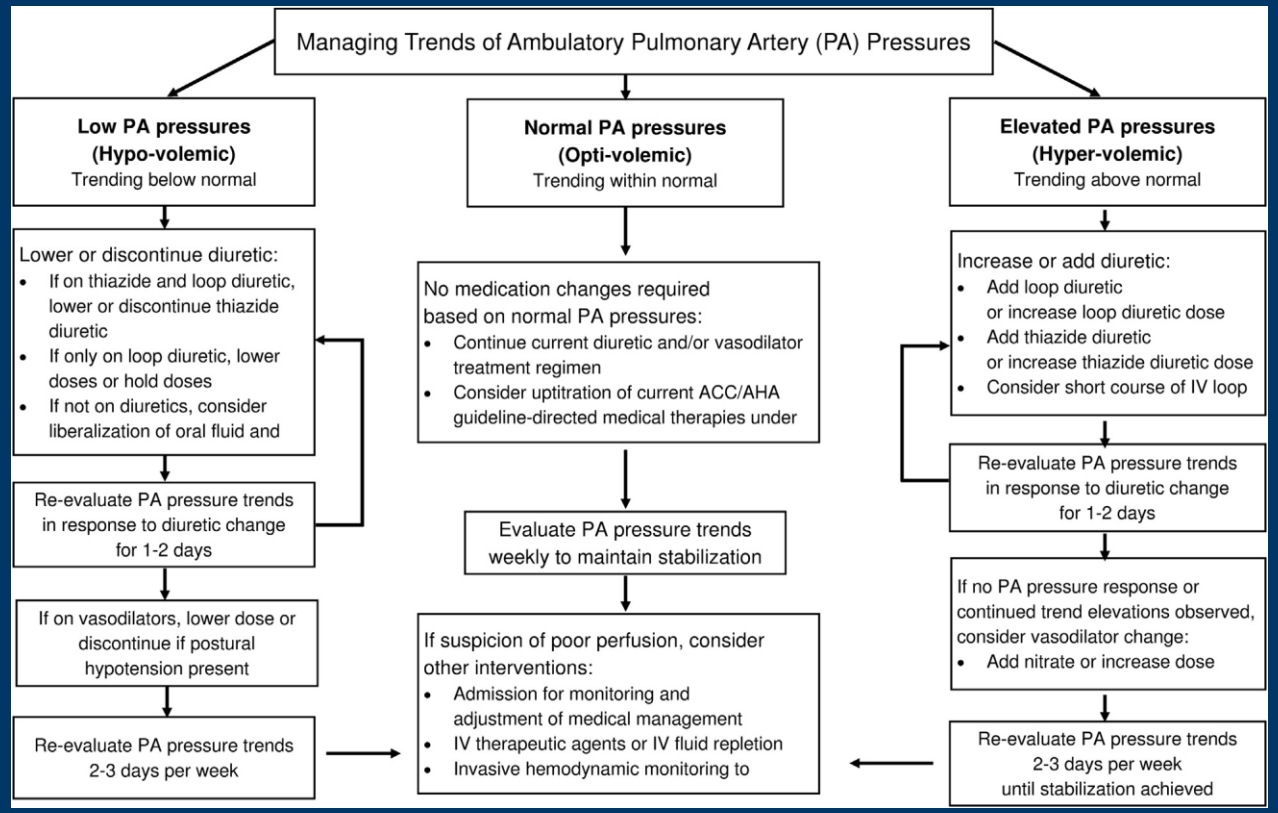
Complete follow-up results from the CHAMPION randomised trial

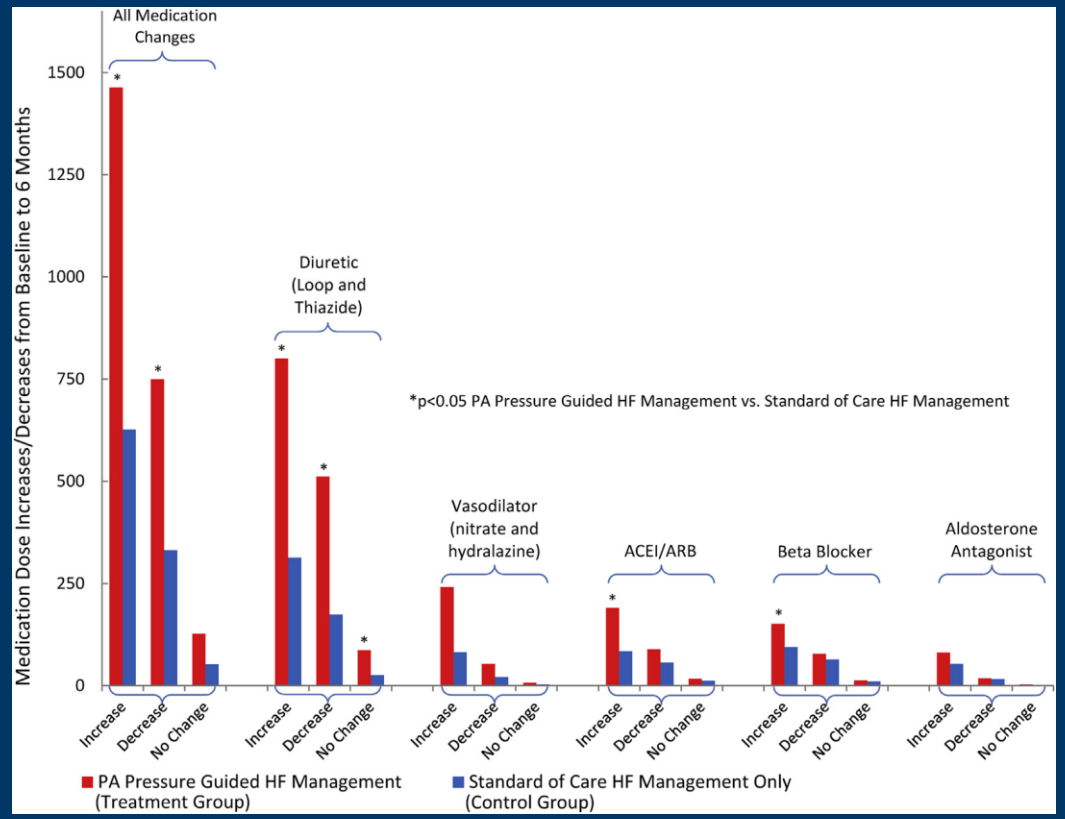


New access to pulmonary artery pressure during open access resulted in 48% reduction in admissions to hospital for heart failure

Abraham WT Lancet. 2015;387:453–461.

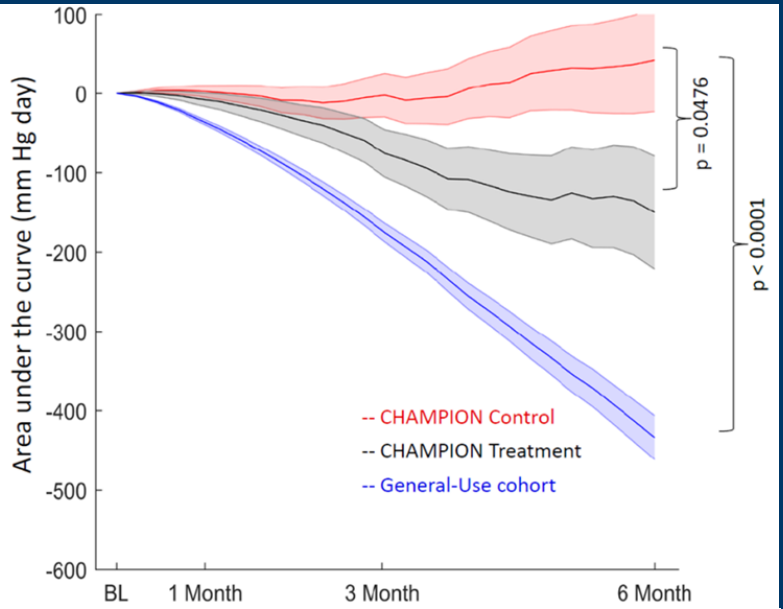
Interventions during the study



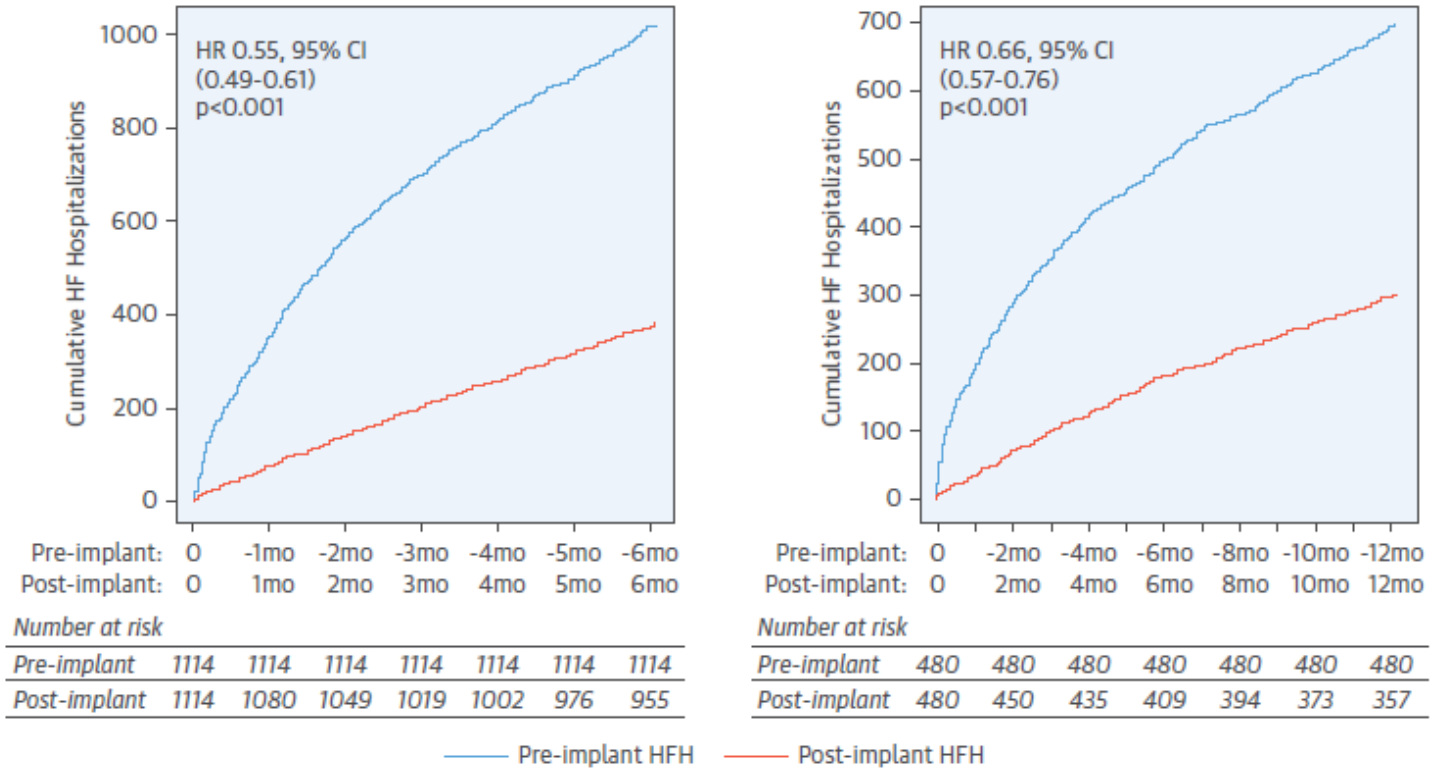


J Am Coll Cardiol HF 2016;4:333–44

Real world experience



Days between transmissions ranged from 1.07 days in the first 30 days after implantation to 1.27 days after 6 months. Use of the system was observed at a median of 98.6%



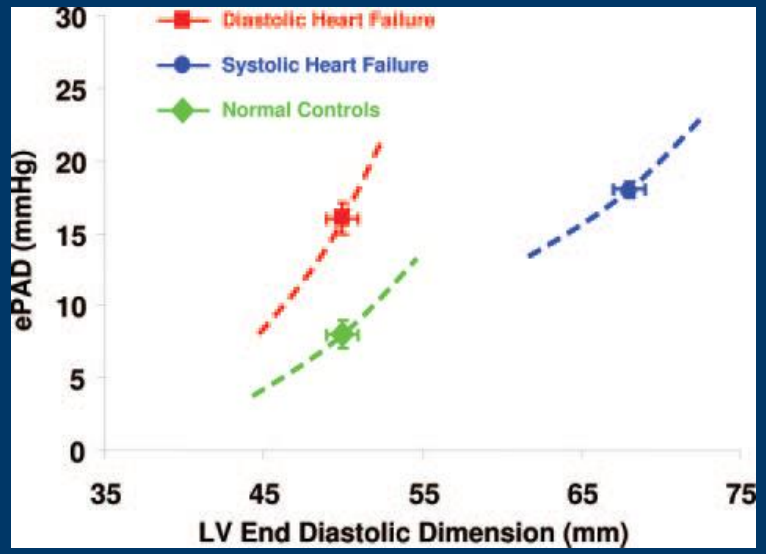
Average time from the most recent HFH to device implantation was 63.2 ± 47.5 days

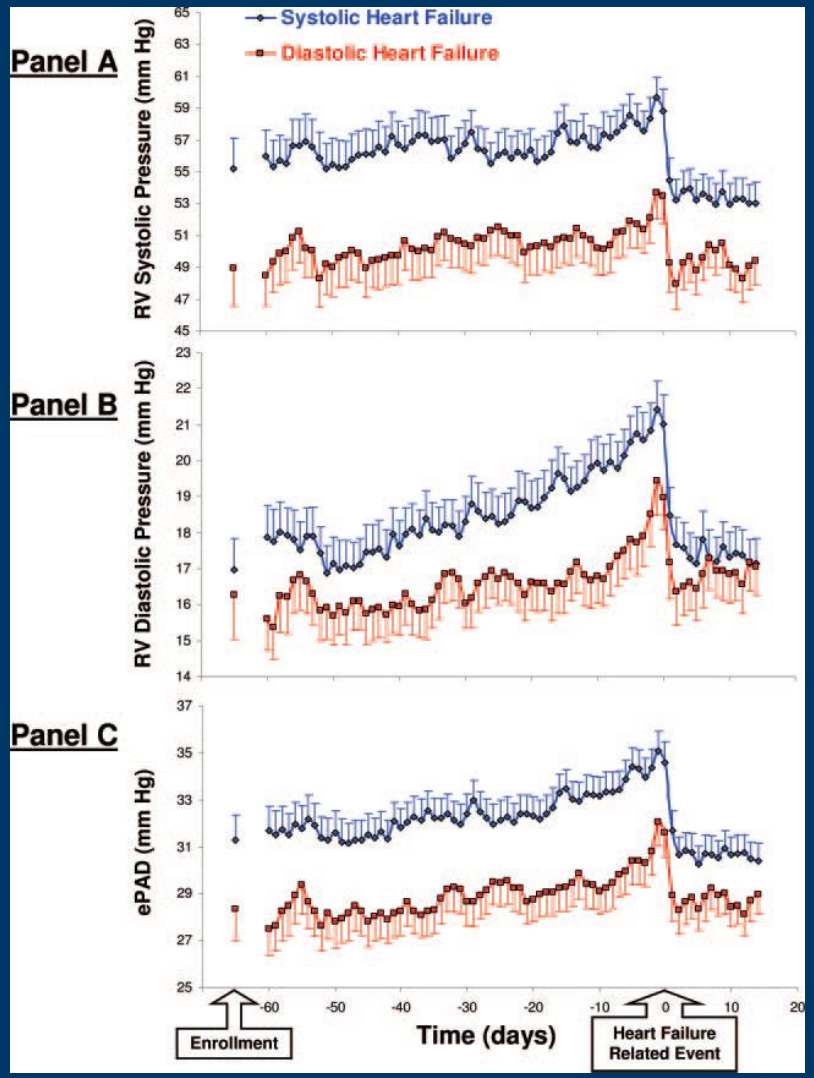
The median number of HFHs per patient was 0.92 at 6 months before and 0.37 at 6 months after device implantation

J Am Coll Cardiol 2017;69:2357–65

Circulation. 2017;135:1509–1517.

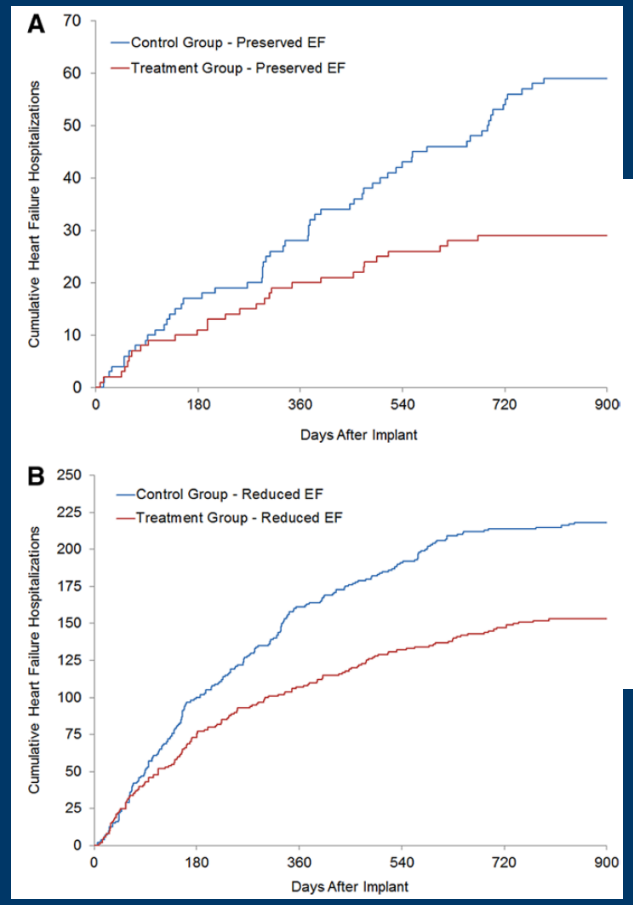
HFrEF vs. HFpEF

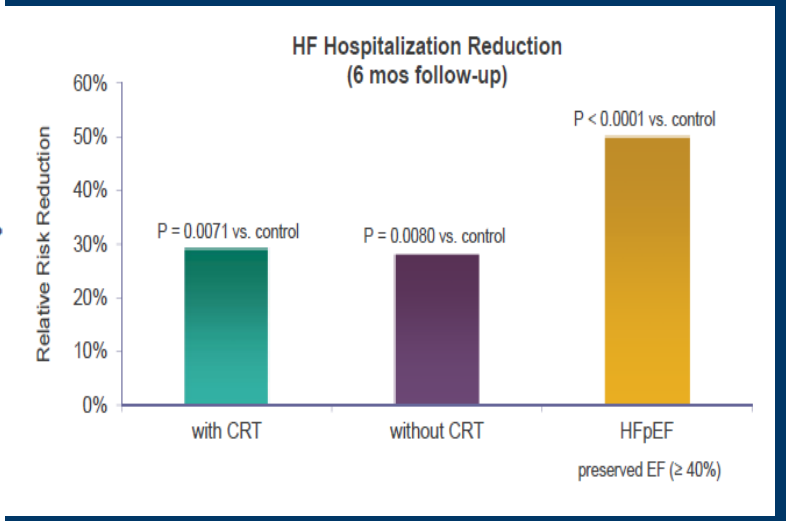


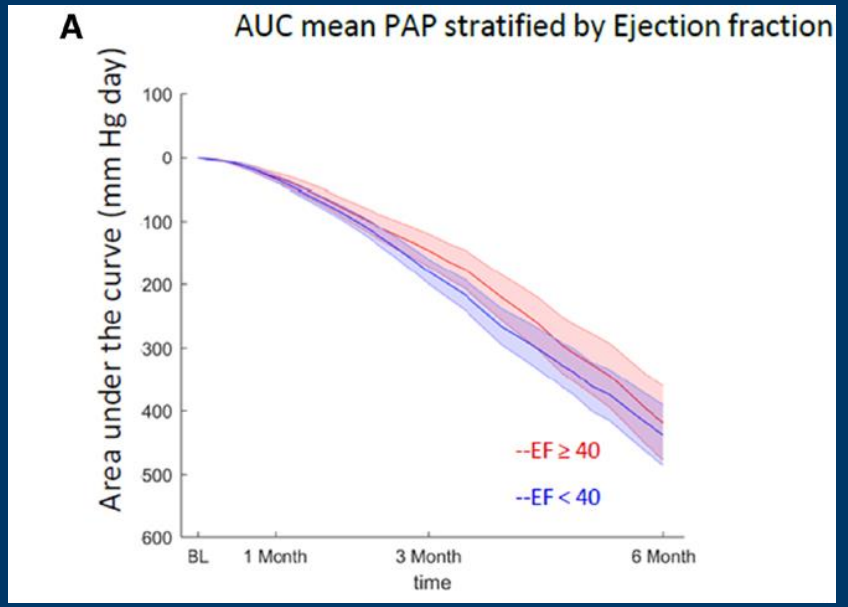


Circulation. 2008;118:1433-1441

HFrEF vs. HFpEF







Circ Heart Fail 2014; 7: pp. 935-944
Circulation. 2017;135:1509–1517.

Cost effectiveness

Parameter	Cost (USD)[1]
CardioMEMs device (per device)	$17,750
Implantation procedure	$1,280
Complications, each	$5,770
Hospitalizations	
HF hospitalization	$21,007
Non-HF hospitalization	$24,367
Monthly monitoring	$47
Outpatient costs, routine care (per year)	$19,576

	CardioMEMS	Standard of Care
Five-year costs and outcomes		
Total costs	$188,880	$162,772
Implant: device, procedure, complications	$19,111	$0
Inpatient costs	$108,124	$113,199
Outpatient costs (including monitoring)	$61,645	$49,573
Total accumulated QALYs	2.509	1.926
Incremental cost-effectiveness ratio (cost per QALY gained)	$44,832	

Clinical Cardiology. 2017;40:430–436

Contraindications

- Patients with an active infection
- History of recurrent deep vein thrombosis or pulmonary embolism
- Unable to tolerate a right heart catheterization
- Patients with an estimated glomerular filtration rate <25 ml/min who are unresponsive to diuretic therapy or on chronic renal dialysis
- Congenital heart disease or mechanical right heart valve
- Known coagulation disorders
- Hypersensitivity to aspirin or clopidogrel
- Patients who have undergone implantation of CRT-D within the past 3 months
- Body mass index (BMI) > 35 kg/m^2 and chest circumference >165 cm

Benefits of PA guided management

- Behavioral remodeling
- Return of volume homeostasis
- Reduction in ventricular and atrial size
- Improved activity and confidence to plan
- Patient empowerment

In Summary

- HF and HF hospitalizations are highly prevalent, associated with high morbidity and mortality rates, and has a high financial clinical burden
- Weight monitoring, telemedicine and other implantable electrical devices are not effective in reducing HF hospitalization.
- When used appropriately, implantable hemodynamic monitoring with CardioMEMS can be very effective reducing the risk of rehospitalization
- IHM is effective in patient with HFrEF and HFpEF
- Use of IMH is cost effective


Thank You