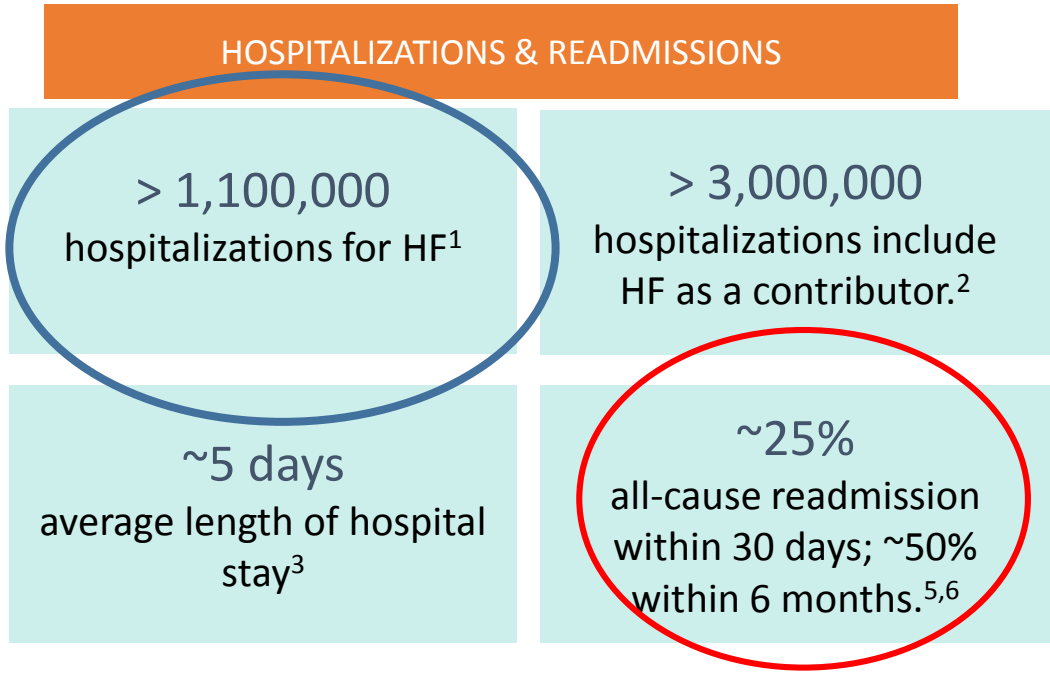
The role of remote monitoring in preventing readmissions after acute heart failure

October 20, 2017

Randall C Starling MD MPH FACC FAHA FESA FHFSA
Professor of Medicine
Kaufman Center for Heart Failure
Heart and Vascular Institute
Cleveland Clinic
Cleveland Ohio USA

ACC Middle East Conference 2017

USA Burden of Heart Failure



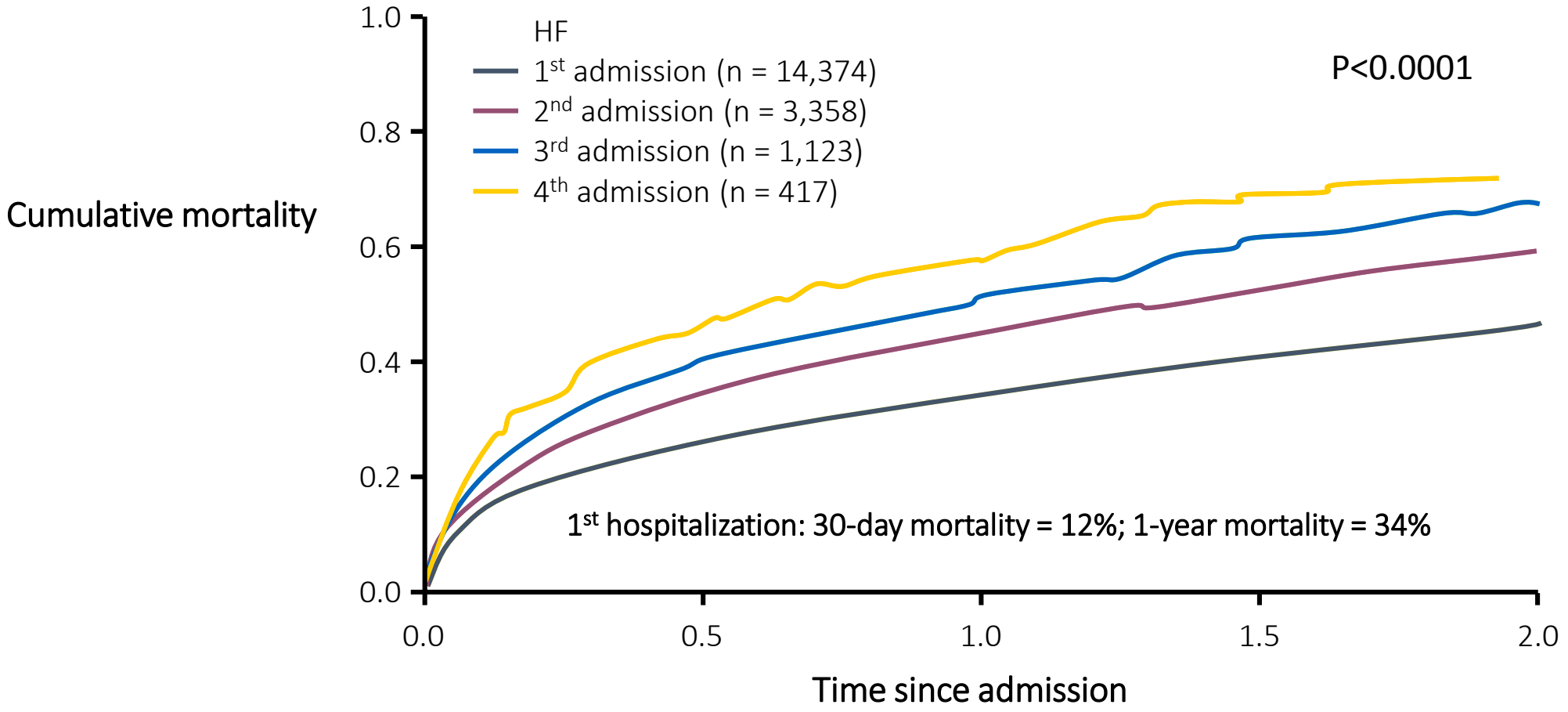
Despite advances in medical therapies to treat heart failure, the hospitalization rate has not changed significantly from 2000. As a result, heart failure continues to be a **MAJOR DRIVER OF OVERALL HEALTH CARE COSTS.**

*Study projections assumes HF prevalence remains constant and continuation of current hospitalization practices

1. CDC NCHS National Hospital Discharge Survey, 2000-10.
2. Blekcer et al. JACC, 2013.
3. Yancy et al. JACC, 2006.
4. Yancy CW, et al. Circulation, 2013.
5. Krumholz HM, et al. Circ Cardiovas Qual Outcomes 2009.
6. Wexler DJ, et al. Am Heart J, 2001.

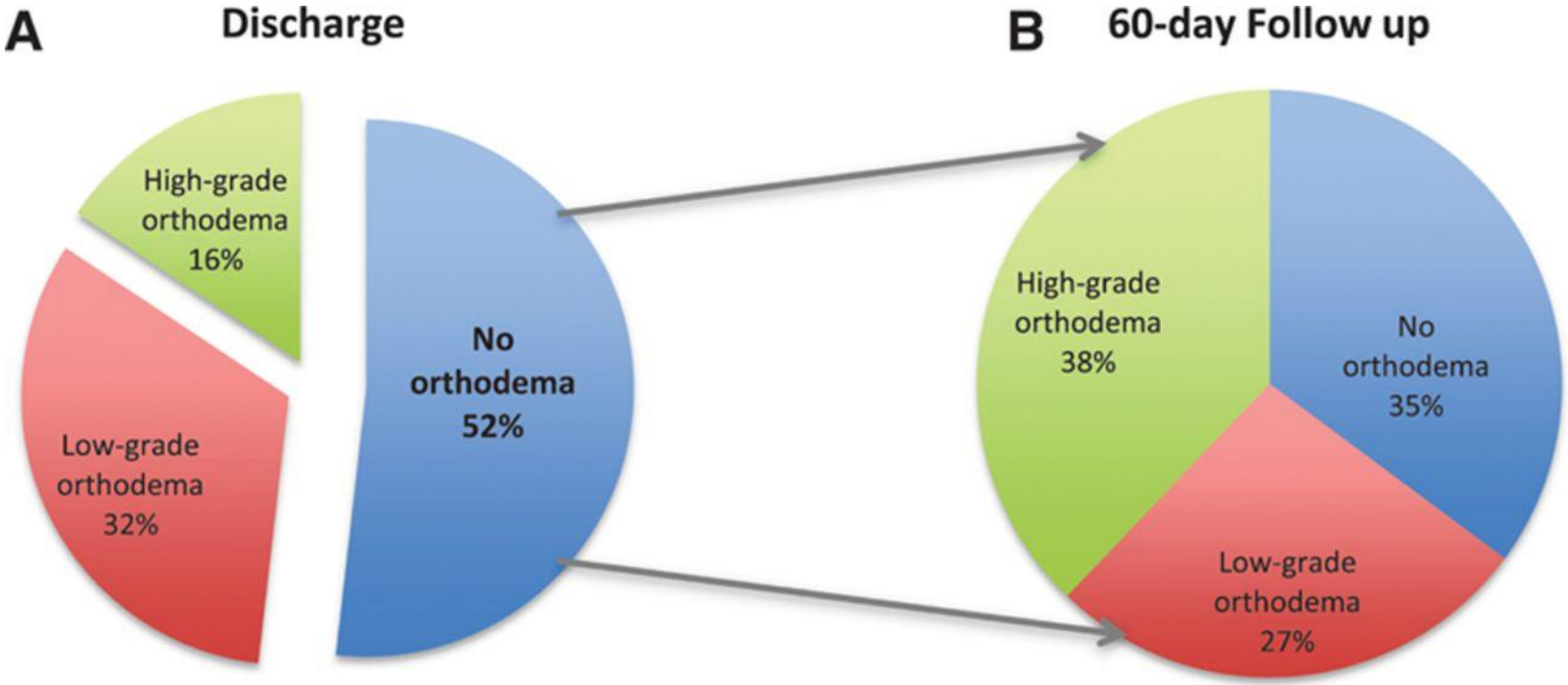
HF-Hospitalization is a Significant Event

Progressive decrease in survival with each subsequent HF admission



Setoguchi S, et al. *Am Heart J.* 2007;154:260-266.

Congestion status at discharge



52% No Congestion

35% No Congestion

Table 2. Orthodema Scores

Mild edema, no orthopnea	0	No congestion
Moderate edema, no orthopnea	1	Low-grade orthodema/congestion
Severe edema OR orthopnea	2	
Moderate edema and orthopnea	3	High-grade orthodema/congestion
Severe edema and orthopnea	4	

Anuradha Lala et al. Circ Heart Fail. 2015;8:741-748

60 day Event Rates Based on congestion status at discharge

"Weight loss did not consistently correlate congestion status as measured by orthodema"

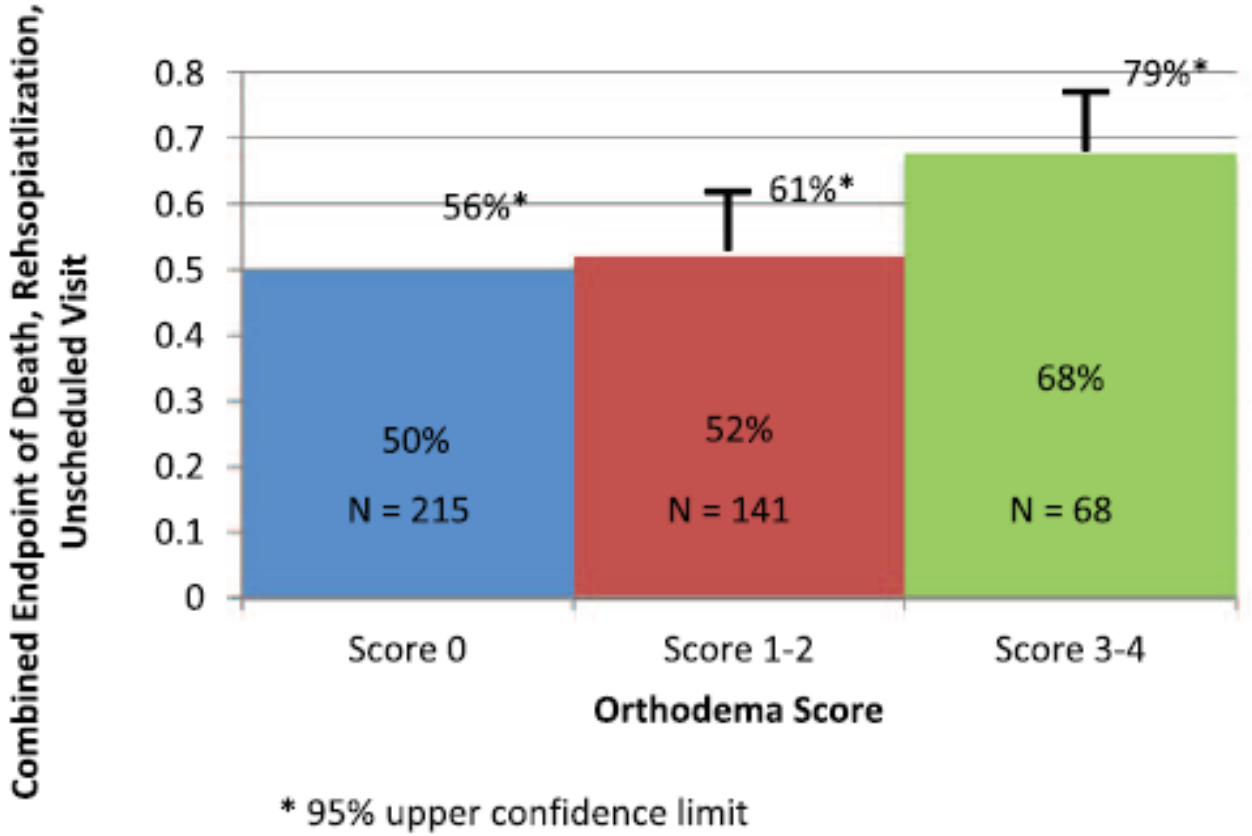
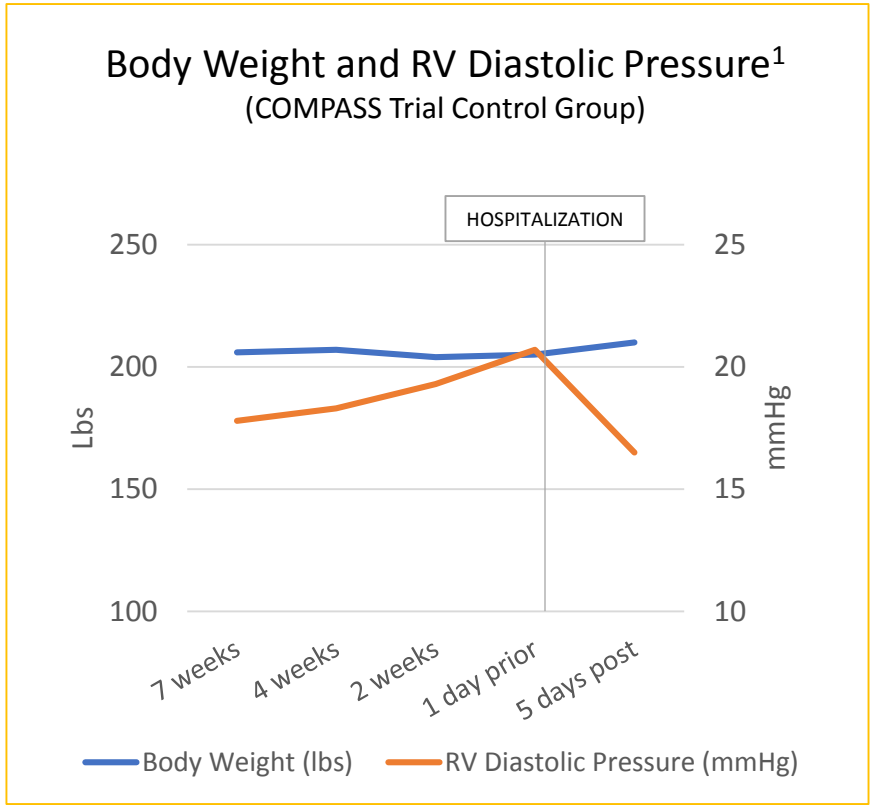


Figure 3. Sixty-day event rates based on discharge orthodema score to represent congestion (*P*=0.038).

Anuradha Lala et al. Circ Heart Fail. 2015;8:741-748

Weight Gain



Weight Gain	Sensitivity	Specificity
2 kg weight gain over 48-72 hrs[2]	9%	97%
2% weight gain over 48-72 hrs[2]	17%	94%
3 lbs in 1 day or 5 lbs in 3 days[3]	22.5%	-

NO CORRELATION
Daily weights do not correlate with filling pressures.

1. Data based on Zile MR, et al. Circulation, 2008.
2. Lewin J. et al. Eur J HF 2005.
3. Abraham WT. et al. Cong Heart Failure. 2011.

Clinical Examination

N = 366 Advanced Chronic HF patients, mean LVEF 25%±7

Variable	Estimate of	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
JVP	RAP	48	78	60	69
Edema		10	94	55	60
Pulse Press	Cardiac Index	27	69	52	44
S3	PCWP	36	81	69	54
Dyspnea		50	73	67	57
Rales		13	90	60	48

RESULTS

Data from clinical evaluations has poor sensitivity and predictive value in determining hemodynamic profile.

Clinical examination has
LIMITED RELIABILITY
in assessing filling pressures.

Capomolla S, et al. Eur J Heart Failure, 2005 Jun;7(4):624-30.

Clinical Surrogates of Rising Filling Pressures

Parameter	Surrogate for:
Symptoms (PND, orthopnea, etc.)	*LVEDP, RAP*
JVP	*RAP*
HJR	*RAP*
S3	*LVEDP*
Rales	*LVEDP*
Daily weight	*Body volume (LVEDP, RAP)*
BNP	*PCWP*
Intrathoracic impedance	*PCWP*
Heart rate variability	*Cardiac autonomic control*

THE GOAL:
Predict gradual decompensation leading to acute decompensation.

Impact of Clinical Surrogates on Hospitalizations

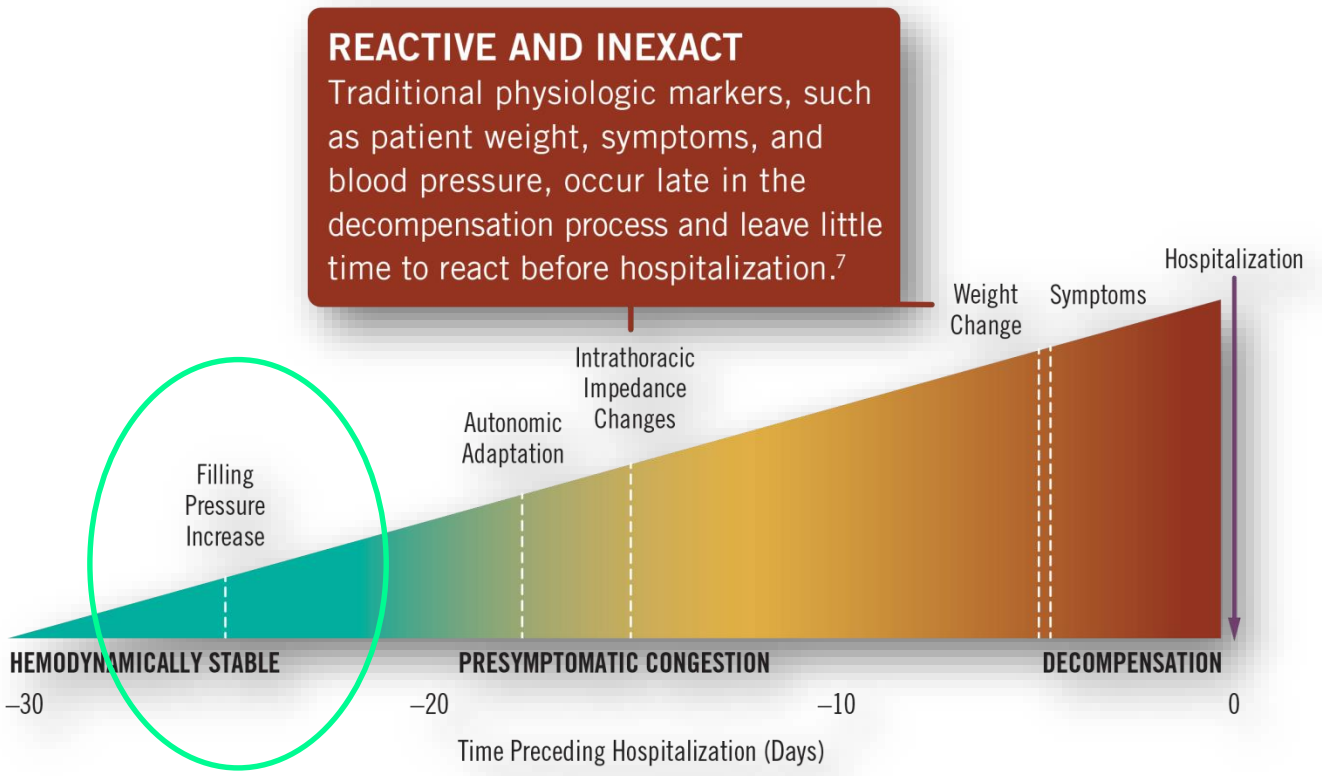
Trial	N	Parameter Monitored/ Clinician Interaction	Impact on HF Hospitalization	Citation
TELE-HF[1]	1,653	Signs/symptoms, daily weights	None	2010
TIM-HF[2]	710	Signs/symptoms, daily weights	None	2011
TEN-HMS[3]	426	Signs/symptoms, daily weights, BP, nurse telephone support	None	2005
BEAT-HF[4]	1,437	Signs/symptoms, daily weights, nurse communications	None	2015 Abstract
INH[5]	715	Signs/symptoms, telemonitoring, nurse coordinated DM	None	2012
DOT-HF[6]	335	Intrathoracic impedance with patient alert	Increased	2011
Optilink[7]	1,002	Intrathoracic impedance	None	2011
REM-HF[8]	1,650	Remote monitoring via ICD, CRT-D, or CRT-P	None	2016 Abstract
MORE CARE[9]	865	Remote monitoring of advanced diagnostics via CRT-D	None	2016
Total	**8,793**			

1. Chaudhry SI, N Engl J Med, 2010.
2. Koehler F, Circulation, 2011.
3. Cleland JG, JACC, 2005.
4. Ong MK, AHA 2015 LBCT.
5. Angermann DE, Circ Heart Fail,2012.
6. van Veldhuisen DJ, Circ 2011.
7. Bohm, M. Eur J. Heart Fail, 2011.
8. Cowie, MR. ESC 2016.
9. Boriani G, Eur J Heart Fail. 2016.

Multiple trials studying > 8,500 patients have demonstrated that current markers have

NO IMPACT ON HF HOSPITALIZATION.

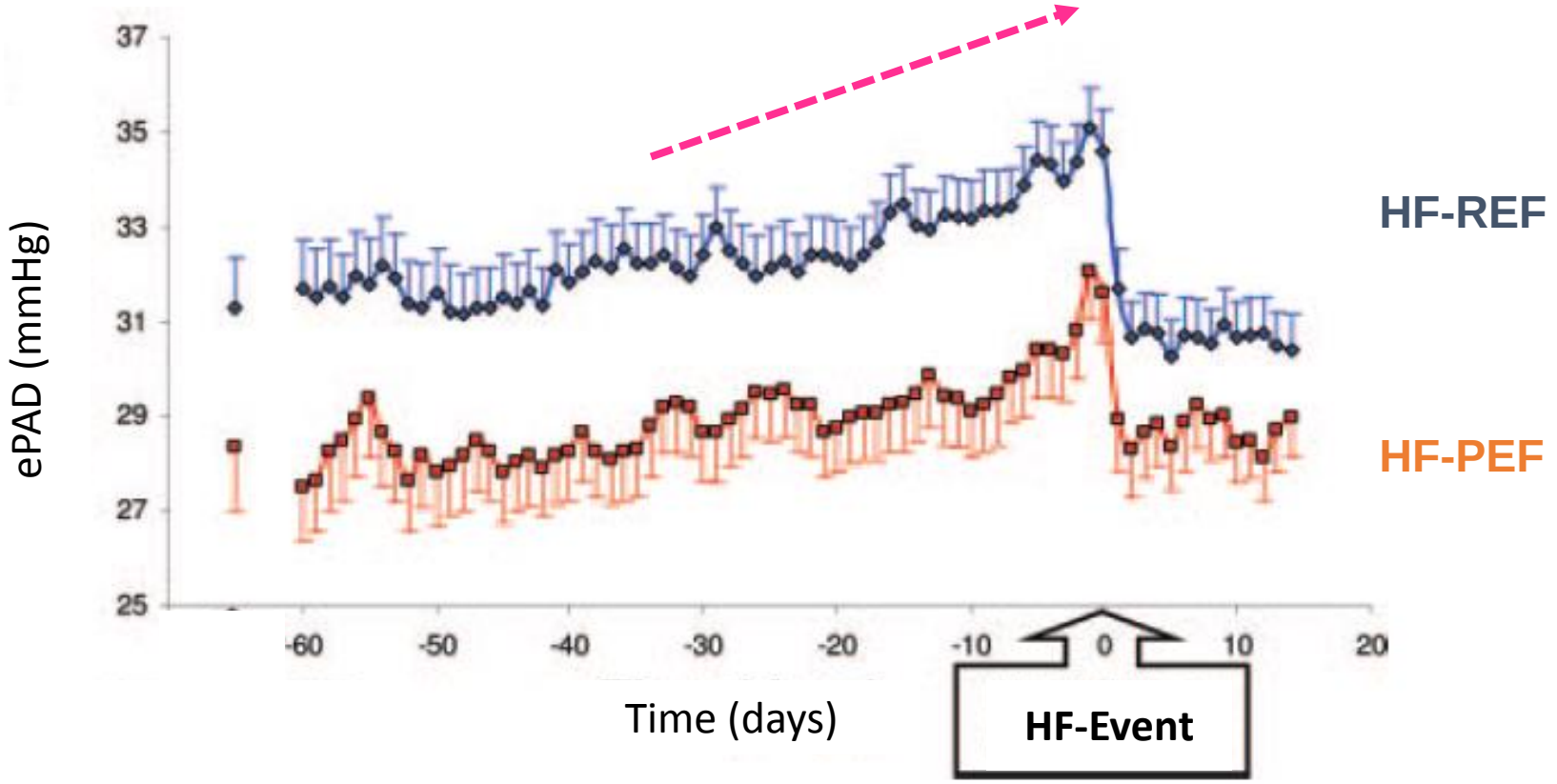
Why Are These Parameters Ineffective?



Graph adapted from Adamson PB, et al. Curr Heart Fail Reports, 2009.

Progressive Rise in Filling Pressures Leads to Hospitalization

Transition from Chronic Compensated to Acute Decompensated HF



Zile M, et al. Circulation. 2008;118:1433-1441.

Hemodynamic-Guided HF Management

Table 1 Characteristics of the five studies identified using implantable haemodynamic monitoring technology to guide heart failure management

Study details	Chronicle Feasibility ($n=32$)[27]	HOMEOSTASIS ($n=40$)[28]	CHAMPION ($n=550$)[21–24]	COMPASS-HF ($n=274$)[25]	REDUCEhf ($n=400$)[30]
Years of study	Published 2003	2005–2008	2007–2009	2003–2004	Published 2011
Study type	Prospective, observational	Prospective, observational, open	Prospective, single-blinded,	Prospective, single-blinded,	Prospective, single-blinded,
Device	monitor			monitor	
NYHA class	II–III	III–IV	III	III–IV	II–III
Previous hospitalization requirement	None	None	At least 1 HFH in the previous 12 months	At least 1 HFH in the previous 6 months	At least 1 HFH in the previous 12 months
Treatment recommendations	None	Target pressures with medication change suggestions	Target pressures with medication change suggestions	'Optivolaemic' ranges without medication change recommendation	'Optivolaemic' ranges without medication change recommendation
Average follow-up	17 months	25 months	18 months	6 months	12 months
Endpoint	HFH	Death or HFH[a]	HFH	HFH[b]	HFE

5 Trials, 1296 Chronic HF patients, permanently implanted sensors

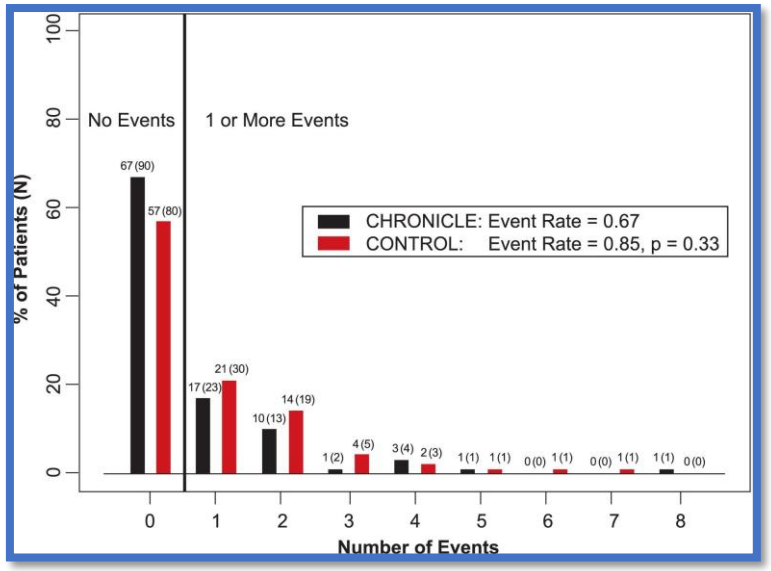
SIGNIFICANT IMPACT ON HF HOSPITALIZATIONS

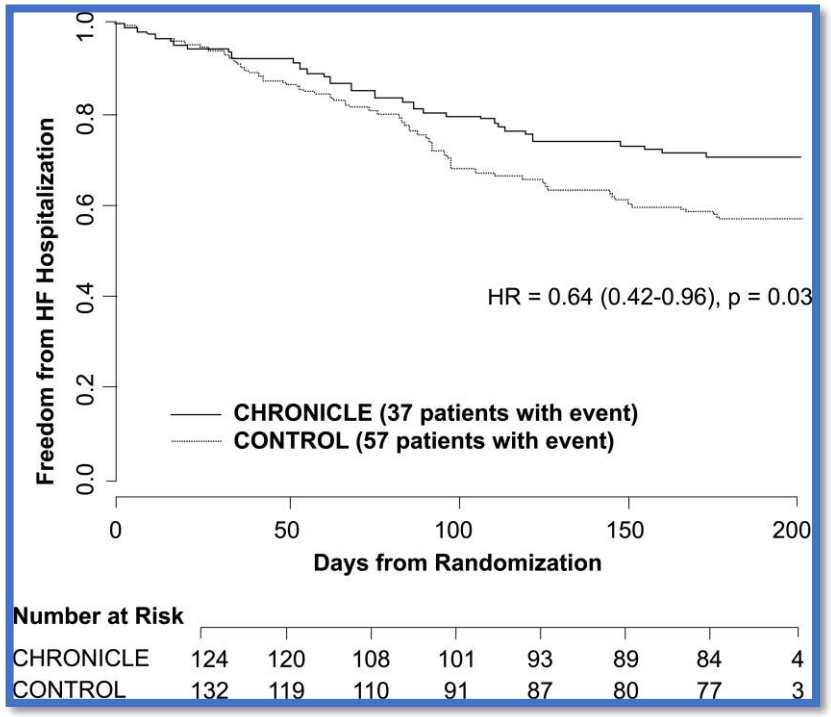
38% [HR 0.62] reduction in HF events

Adamson et al. Eur J Heart Fail (2017) 19, 426-433

Hemodynamic-Guided HF Management

COMPASS-HF (n=274 [n=134 device, n=140 control])





Did not significantly reduce total HF-related events but was associated with a 36% RRR in HF-hospitalization

Bourge et al. J Am Coll Cardiol 2008;51:1073-1079

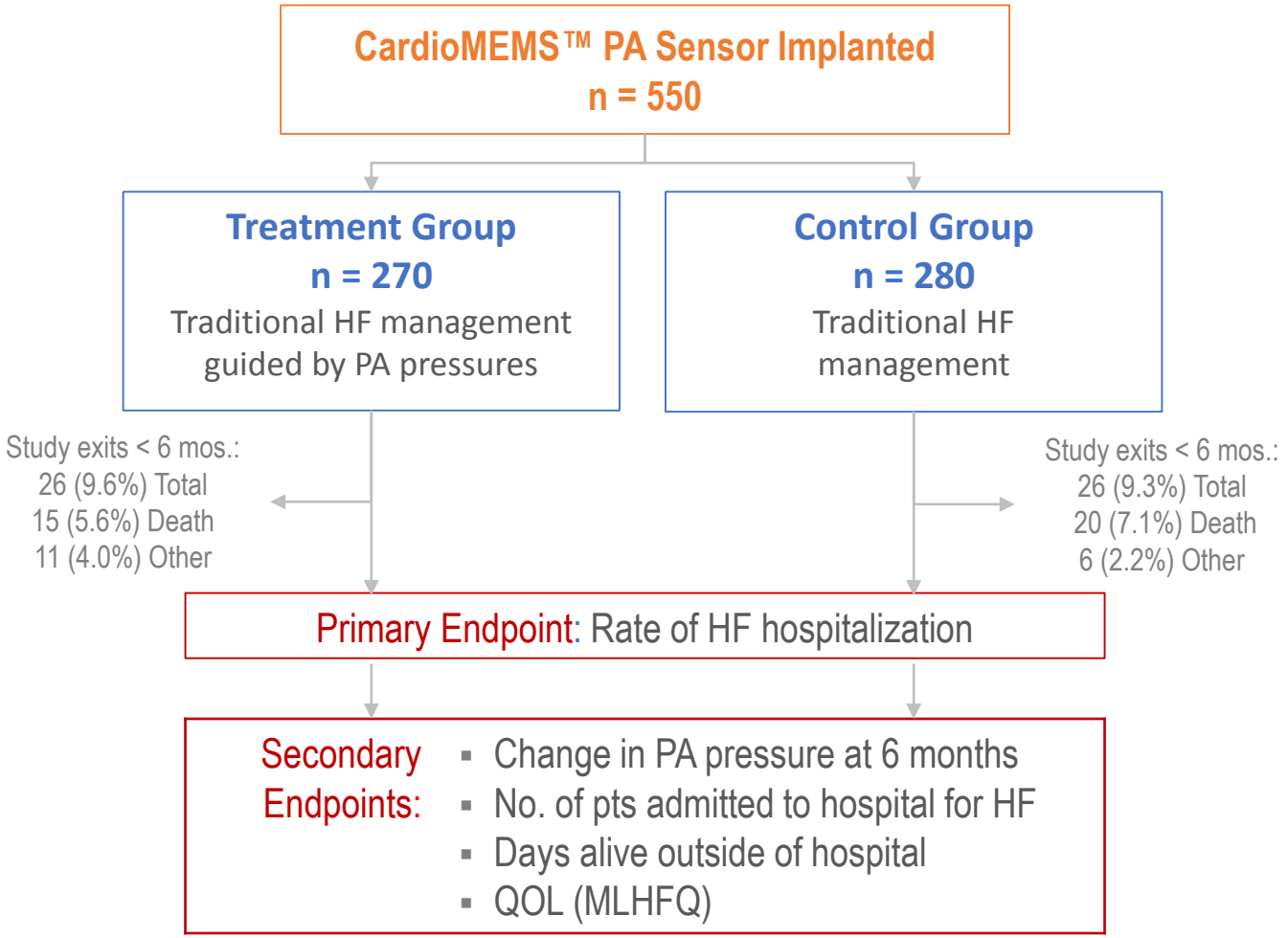
Hemodynamic-Guided HF Management

CHAMPION (n=550)

PURPOSE
Evaluate the safety and efficacy of the CardioMEMS™ HF System in reducing HF related hospitalizations in NYHA class III heart failure patients.

Treatment group managed to target PA pressures:

Systolic 15 – 35 mmHg
Diastolic 8 – 20 mmHg
Mean 10 – 25 mmHg

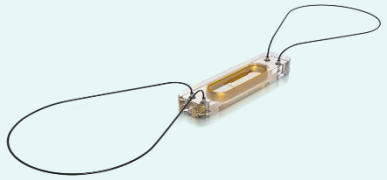


Abraham W, et al. Lancet, 2011;377(9766):658-66.

Hemodynamic-Guided HF Management

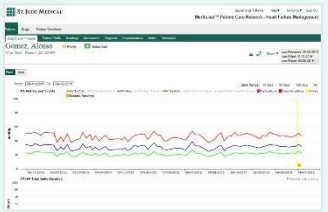
Cardiomems™ HF System

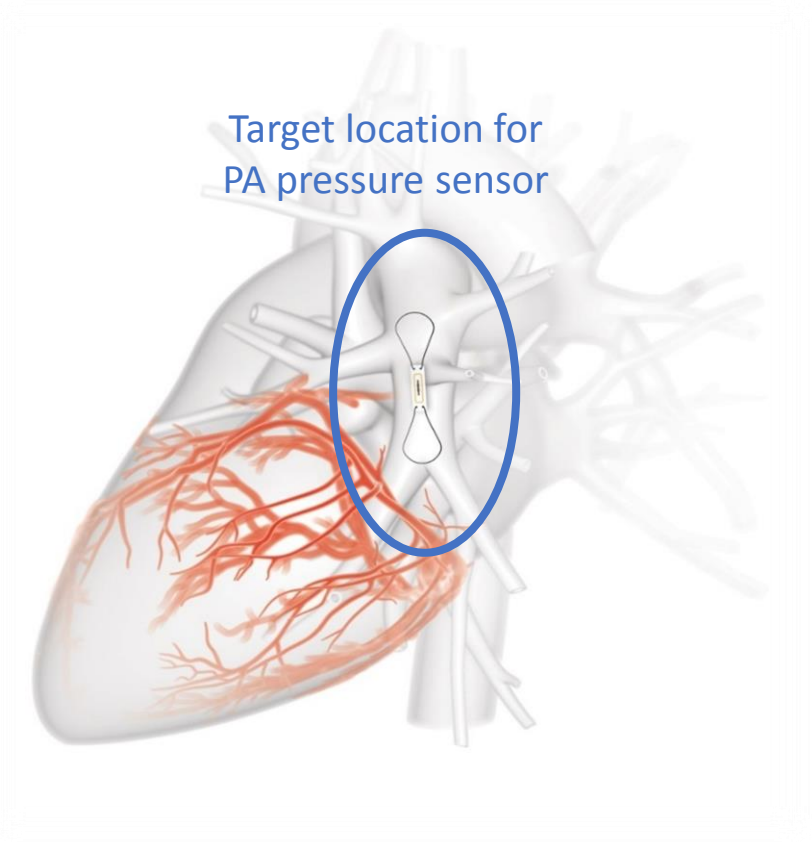
Pulmonary Artery Pressure Sensor



Patient Electronics System

Merlin.net™ PCN

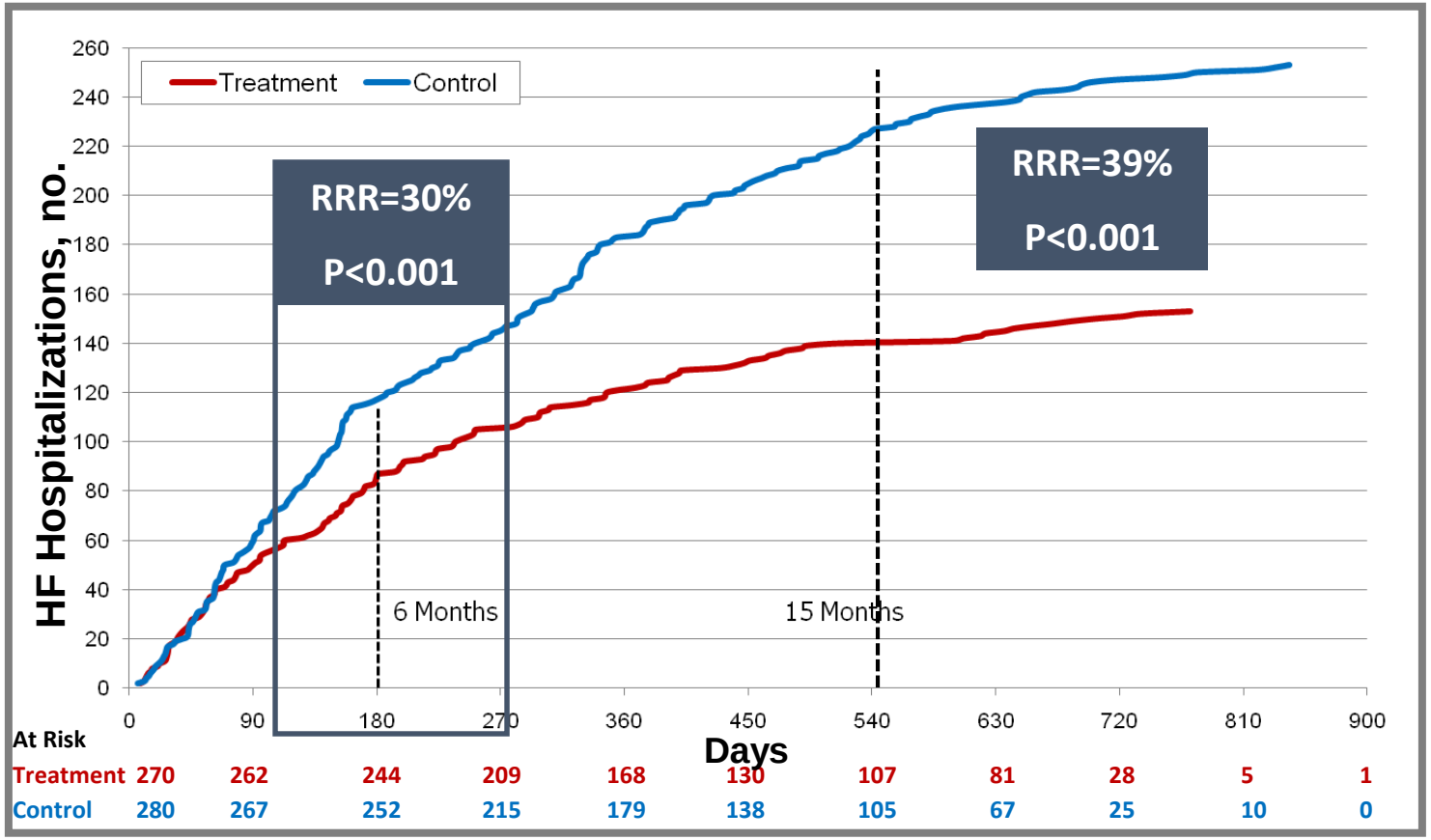




Abraham W, et al. Lancet, 2011;377(9766):658-66.

Hemodynamic-Guided HF Management

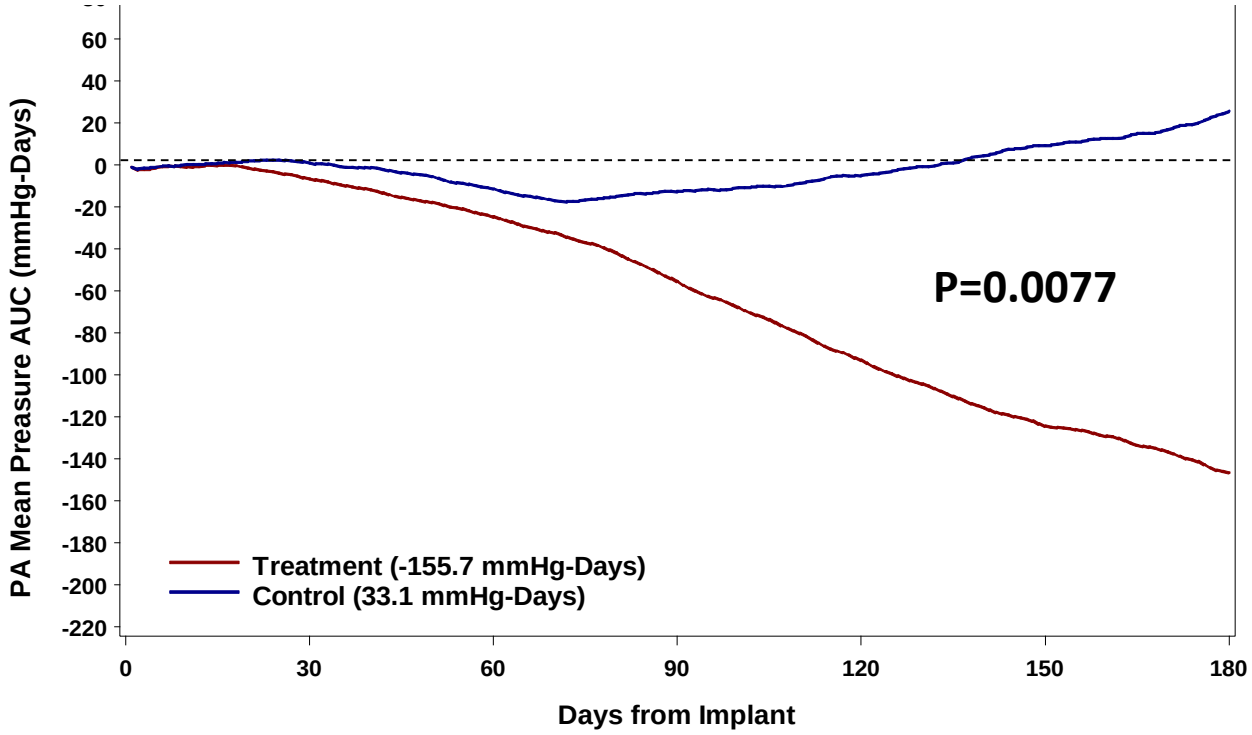
CHAMPION (n=550)



Abraham W, et al. Lancet, 2011;377(9766):658-66.

Hemodynamic-Guided HF Management

CHAMPION (n=550)



Systolic 15 – 35 mmHg
Diastolic 8 – 20 mmHg
Mean 10 – 25 mmHg

By targeting PA pressure ranges and titrating medications, **mean PA pressure was significantly reduced over time**.

Abraham W, et al. Lancet, 2011;377(9766):658-66.

Hemodynamic-Guided HF Management

CHAMPION (n=550)

		Treatment (n = 270)	Control (n = 280)	P-value
Primary Safety Endpoints	**Device-related or system-related complications**	3 (1%)	3 (1%)	
		Total 8 (1%)*		< 0.0001
	Pressure-sensor failures	0	0	< 0.0001
Secondary Endpoints	**Change from baseline in PA mean pressure (mean AUC [mm Hg x days])**	-156	33	0.008
	Number and proportion of patients hospitalized for HF (%)	55 (20%)	80 (29%)	0.03
	Days alive and out of hospital for HF (mean ± SD)	174.4 ± 31.1	172.1 ± 37.8	0.02
	Quality of life (Minnesota Living with Heart Failure Questionnaire, mean ± SD)	45 ± 26	51±25	0.02

ALL ENDPOINTS MET.

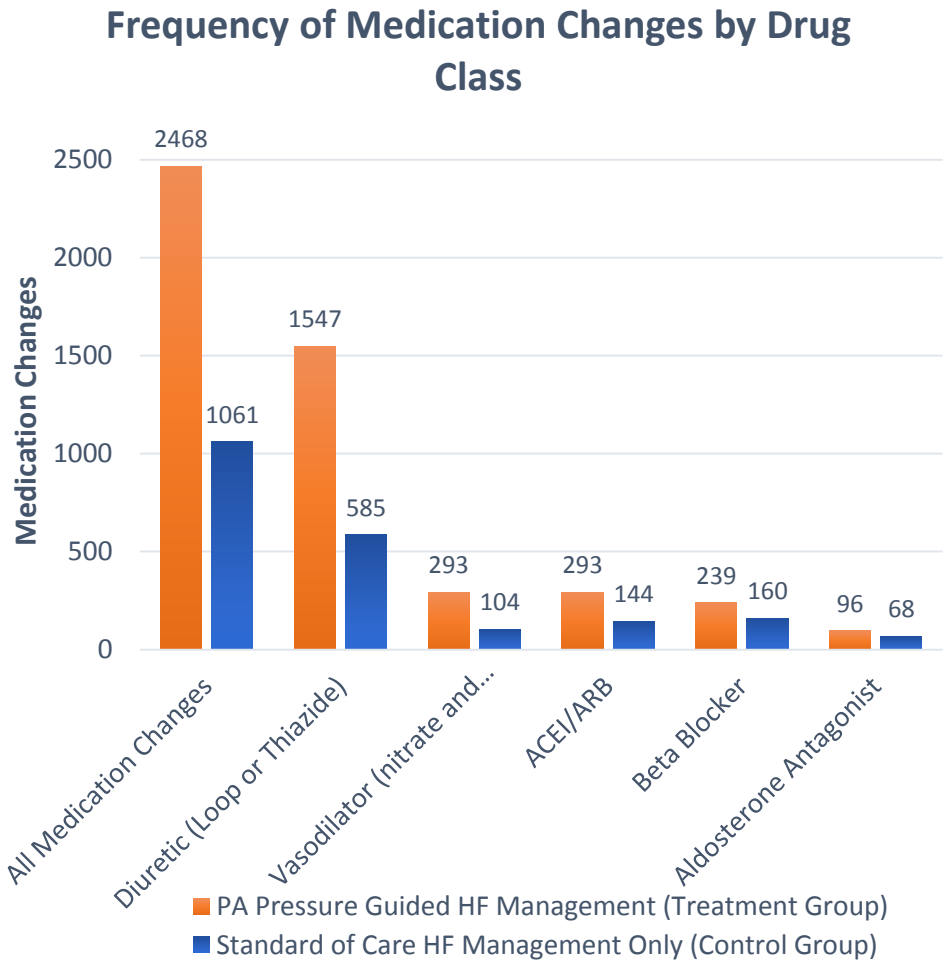
Both primary safety endpoints and all secondary endpoints were met at 6 months

Abraham W, et al. Lancet, 2011;377(9766):658-66.

PA Pressure-Driven Treatment Changes

PURPOSE

Analyze medical therapy data from the CHAMPION trial to determine which interventions were linked to decreases in HF hospitalizations during PA pressure guided management.



RESULTS

- Significantly more changes in medication doses in the Treatment Group than in the Control Group.
- Diuretics were the most frequently adjusted medication and the changes were significantly higher in the Treatment Group.

Medication changes based on PA pressure information were more effective in reducing HF hospitalizations than using signs & symptoms alone.

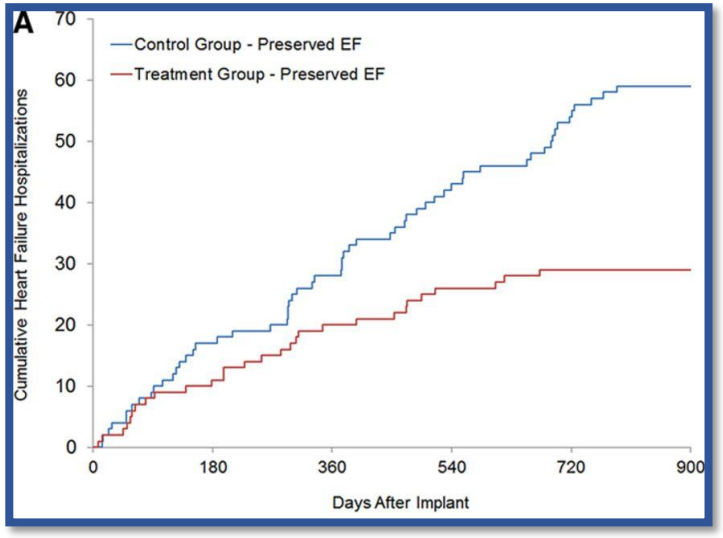
Costanzo et al., J Am Coll Cardiol HF 2016;4:333-44

HFpEF pts made up 22% of the trial cohort

PURPOSE

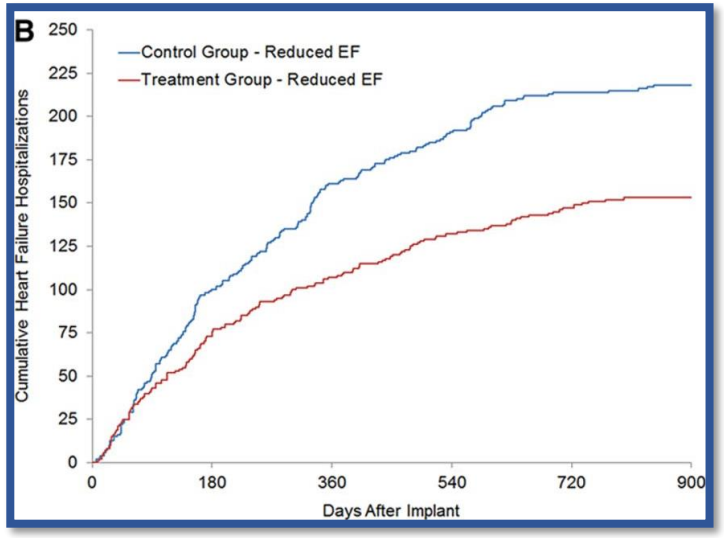
Evaluate the effect of PA pressure-guided therapy with the CardioMEMS™ HF System in patients with preserved ejection fraction (EF ≥ 40%), a group with no clinically proven therapies.

HFpEF



RRR 46% (HR 0.54, CI 0.38-0.70)

HFrEF



RRR 24% (HR 0.76, CI 0.61-0.91)

HF Hospitalization Reduction (18 mo follow-up)

n=115, p=0.0004

Adamson PB, et al. Circ Heart Fail, 2014;7:935-944

Journal of the American College of Cardiology
Vol. 61, No. 13, 2013
ISSN 0735-1097/$36.00
http://dx.doi.org/10.1016/j.jacc.2012.12.022

Published by Elsevier Inc.

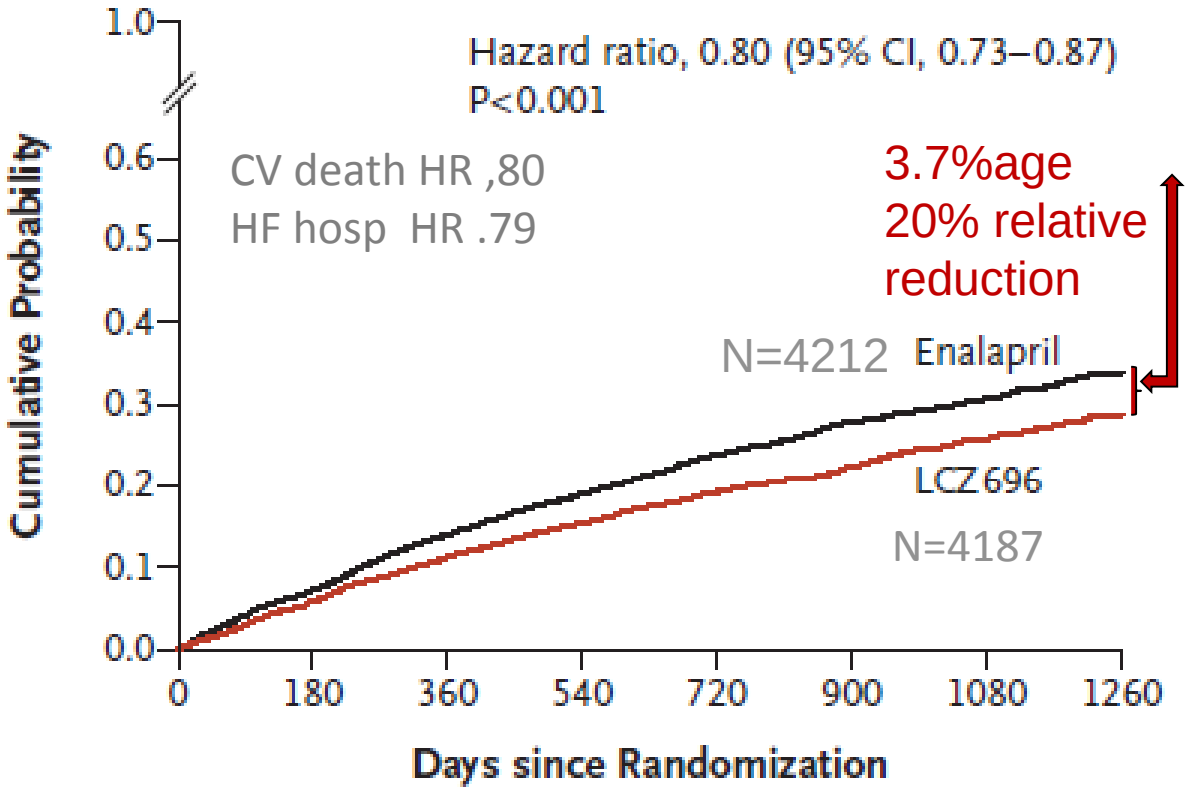
Incremental Cost-Effectiveness of Guideline-Directed Medical Therapies for Heart Failure

Gaurav Banka, MD,* Paul A. Heidenreich, MD,† Gregg C. Fonarow, MD*

Los Angeles and Palo Alto, California

Our analysis demonstrates that medical treatment of HFrEF is highly cost-effective and may even result in cost-savings. Greater efforts to ensure optimal adherence to guideline-directed medical therapy for HFrEF are warranted. (J Am Coll Cardiol 2013;61:1440–6) © 2013 by the American College of Cardiology Foundation

PARADIGM-HF: Cardiovascular Death or Heart Failure Hospitalization (Primary Endpoint)

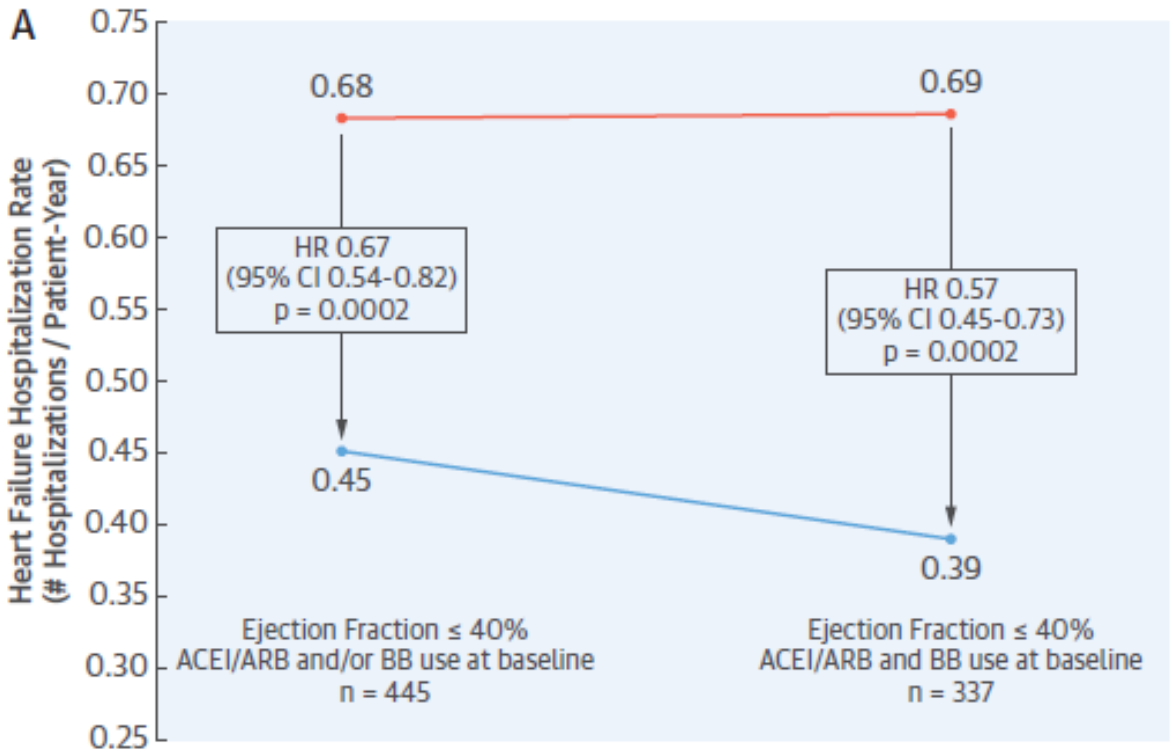


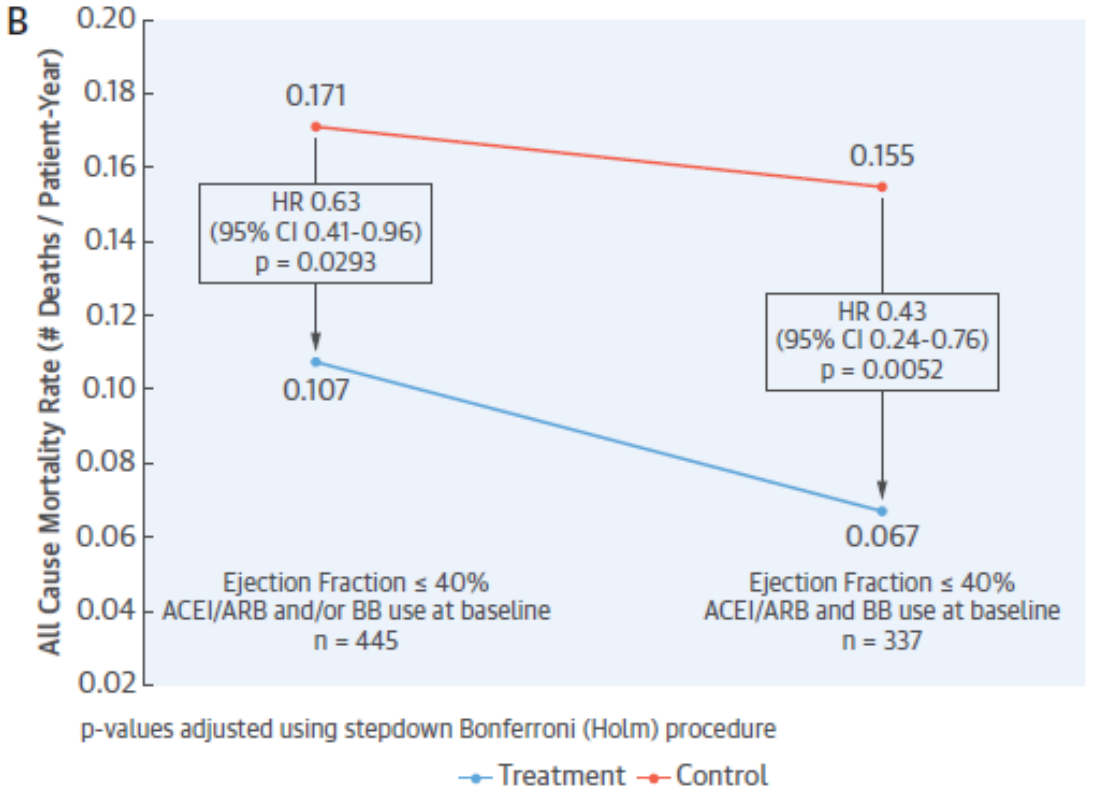
No. at Risk								
LCZ696	4187	3922	3663	3018	2257	1544	896	249
Enalapril	4212	3883	3579	2922	2123	1488	853	236

N Engl J Med 2014;371:993.

Pulmonary Artery Pressure Guided Management of HF rEF
Incremental Benefit with GDMT

Need to Validate Strategy of Optimal Neurohormonal Antagonists COMBINED with PA Pressure Guided Treatment





Givertz *et al.*
PA Pressure-Guided HF Management on Top of GDMT

JACC VOL. 70, NO. 15, 2017
OCTOBER 10, 2017:1875-86

Summary

- Congestion is a key predictor of HF events
- Typical clinical parameters do not accurately assess congestion
- Hemodynamic Guided treatment is the only remote monitoring technique shown to reduce HF admissions
- GDMT and PA pressure guided therapy appear to have a synergistic impact on HF outcomes
- Validation studies demonstrating the clinical impact of PA pressure guided therapy and BEST GDMT are necessary
- The VALUE added impact of PA guided treatment will be essential to demonstrate