

Contemporary Heart Failure Management: Implantable Devices for the Full Spectrum of Disease

September 21, 2019

Michael Zacharias, DO FACC
Assistant Professor of Medicine
Section of Heart Failure and Heart Transplantation
Medical Director, Mechanical Circulatory Support (MCS)
Assistant Program Director Advanced Heart
Failure/Transplant Fellowship Program

Contemporary Heart Failure Management: Implantable Devices for the Full Spectrum of Disease

Michael Zacharias DO, Cardiologist, UH Harrington Heart & Vascular Institute,
Assistant Professor of Medicine, Case Western Reserve University School of Medicine

Disclosures:

Conflict of Interest: None

Objectives

- Discuss signs/symptoms of advancing heart failure
- Discuss current invasive methods of monitoring heart failure
- Discuss current mechanical circulatory support therapies available for advanced heart failure

Overview

- Case
- Overview on Heart Failure
- Identifying Advanced Heart Failure
- Treatment options along the spectrum of disease
- Questions

Overview

- Case
- Overview on Heart Failure
- Identifying Advanced Heart Failure
- Treatment options along the spectrum of disease
- Questions

Case

- 67 y/o M with NICM (LVEF 30%) s/p ICD who was referred to the UH Advanced Heart Failure clinic for ongoing HF symptoms
- Recently hospitalized and diuretics were increased
- Medications
 - Metoprolol succinate 100 mg daily
 - Lisinopril 10 mg daily
 - Furosemide 80 mg twice a day
 - ASA 81 mg daily

Case

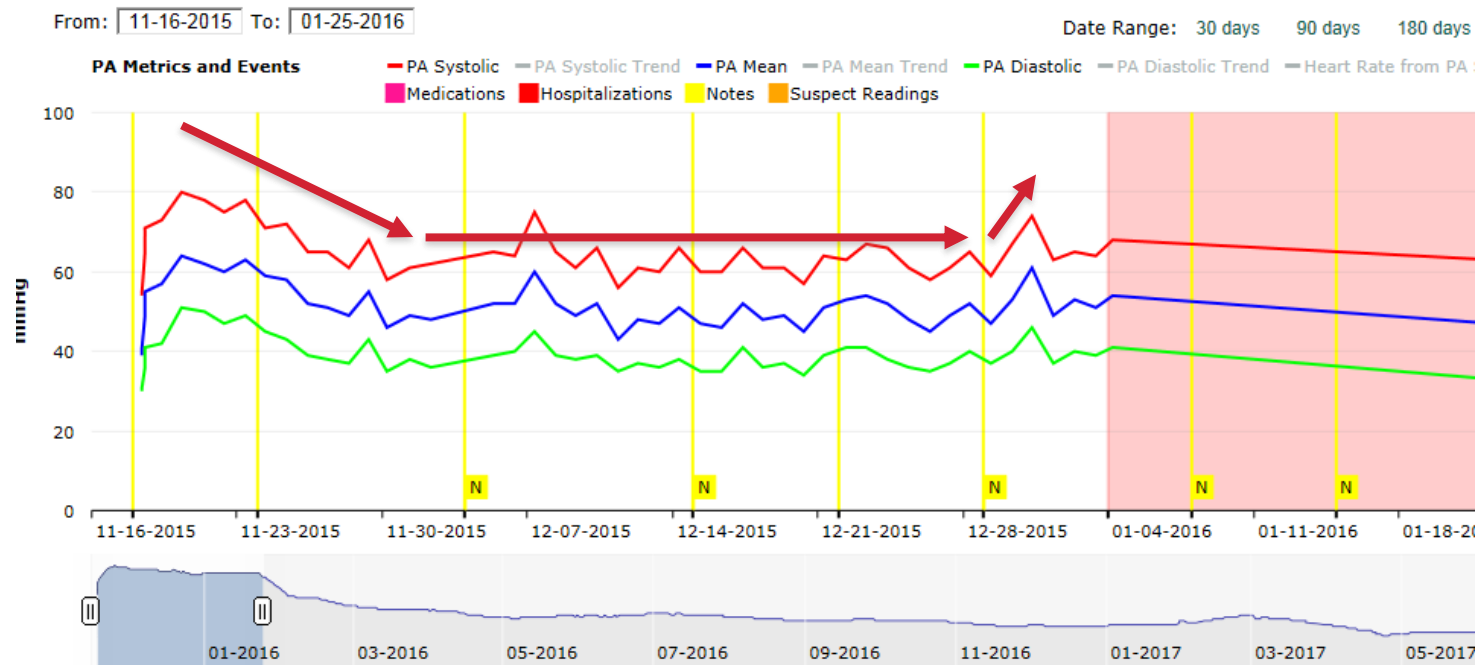
- He is seen in the Advanced Heart Failure clinic and felt to have NYHA class IIIb symptoms
- His medications are adjusted:
 - ACEi → ARNi
 - started on Spironolactone
- To further evaluate he undergoes an echo, right heart catheterization, and cardiopulmonary exercise test (CPET)

Case

- Echo
 - LVIDD: 6.4 cm
 - LVEF: 20-25%
 - Moderate MR
 - Normal RV size/function
- RHC
 - RA: 13
 - PA: 62/34/(43)
 - PCW: 30
 - CO/CI: 4.5/2.2
 - SVR: 1250 dynes
 - PVR: 2.8 WU
- CPET
 - VO₂: 14.7
 - VE/VCO₂: 44
 - RER: 1.01

Case

- 1 month later he undergoes implantation of CardioMEMS™ HF System

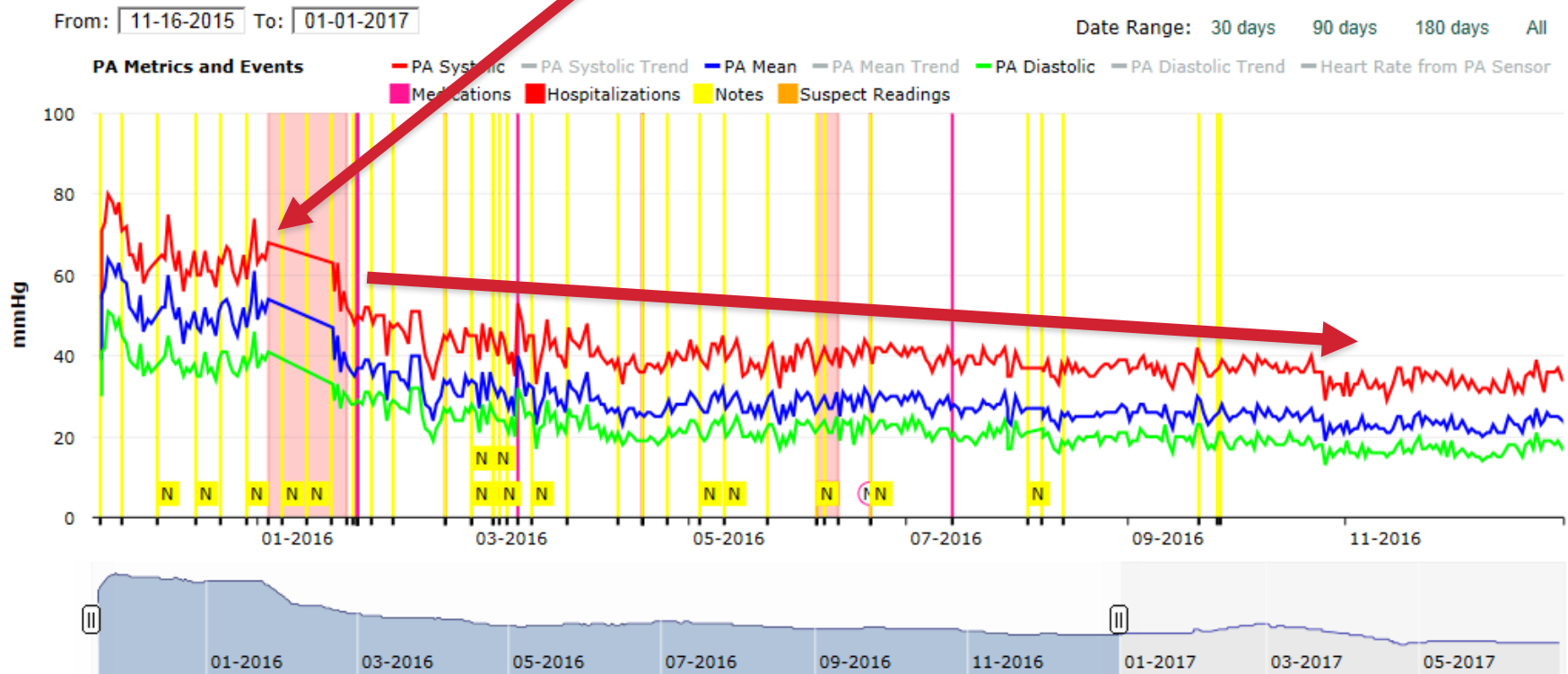


Case

- Despite diuresis (guided by CardioMEMS™ HF System) he is admitted two months later with ADHF
- Due to concern for low output he undergoes repeat RHC
 - PA sat: 51%
 - CO/CI: 3.1/1.5
 - Placed on inotropic support
- Case presented at Advanced HF Therapy Committee
- Given ABO (O) and pulmonary venous HTN decision is made to pursue durable MCS as a BTT
 - HeartMate II™ LVAD

Case

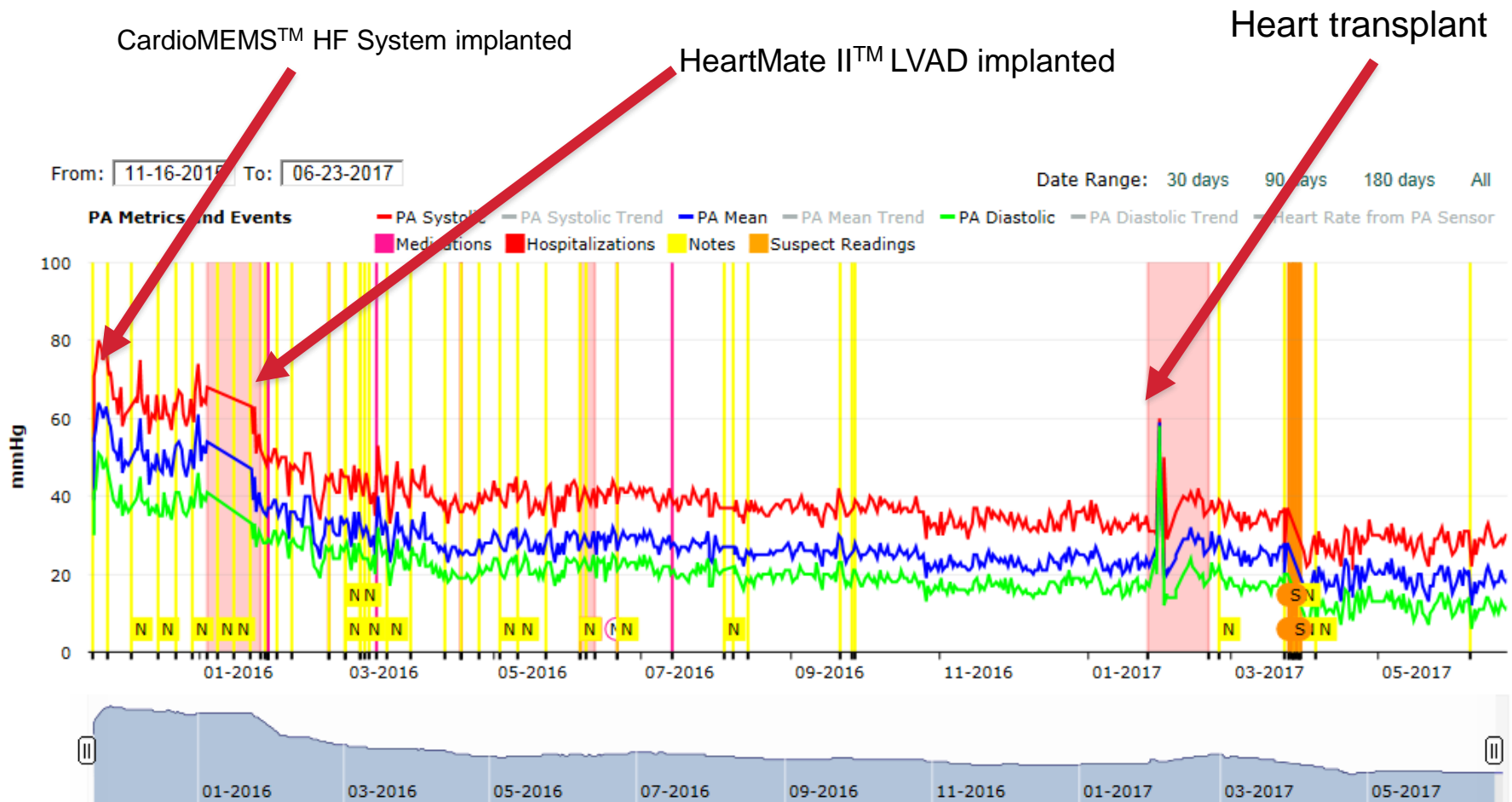
HeartMate II™ LVAD Implanted



Case

- Remained on LVAD support for ~1 year
- Underwent cardiac transplant
- Post-transplant course without complications
- Currently >2 years out living life to its fullest

Device therapy across the spectrum of disease



Overview

- Case
- Overview on Heart Failure
- Identifying Advanced Heart Failure
- Treatment options along the spectrum of disease
- Questions

How common is it?

- **5.7 million** Americans
- Estimated to grow to >30 million by 2030
- **Only** form of heart disease increasing in prevalence
- **1 in 5** Americans will develop heart failure
- Most common cause of hospitalizations
 - Primary diagnosis in >1 million discharges per year
 - Affects 10% of men, 8% women over age 60
 - **30-Day readmission rate 20-25%**

HF-associated mortality

- Post-hospitalization mortality
 - 30-day: 10%
 - 1-year: 20-30%
 - 5-year: 48%
- Higher mortality than many cancers at 5 years
 - Breast, lymphoma/leukemia, colon

Overview

- Case
- Overview on Heart Failure
- Identifying Advanced Heart Failure
- Treatment options along the spectrum of disease
- Questions

Advanced Heart Failure

- 4 R's
 - Recognition
 - Referral
 - Re-evaluation
 - Realistic

There is no “too early” communication!

What is “Advanced” Heart Failure?

- When conventional heart failure therapies and symptom management no longer work
- It does **NOT** mean, you have run out of options
 - Although, in some cases it may mean we shift the focus away from *quantity* of life to *quality* of life
- Referred to as ACC/AHA “**Stage D**” disease
- Primary options for stage D disease
 - Cardiac transplantation
 - Left ventricular assist device (LVAD)
 - Inotropic support
 - Hospice

Paths of HF

Stage C

-Stable

-Progressive

“Advanced”

Stage D

-Transplant

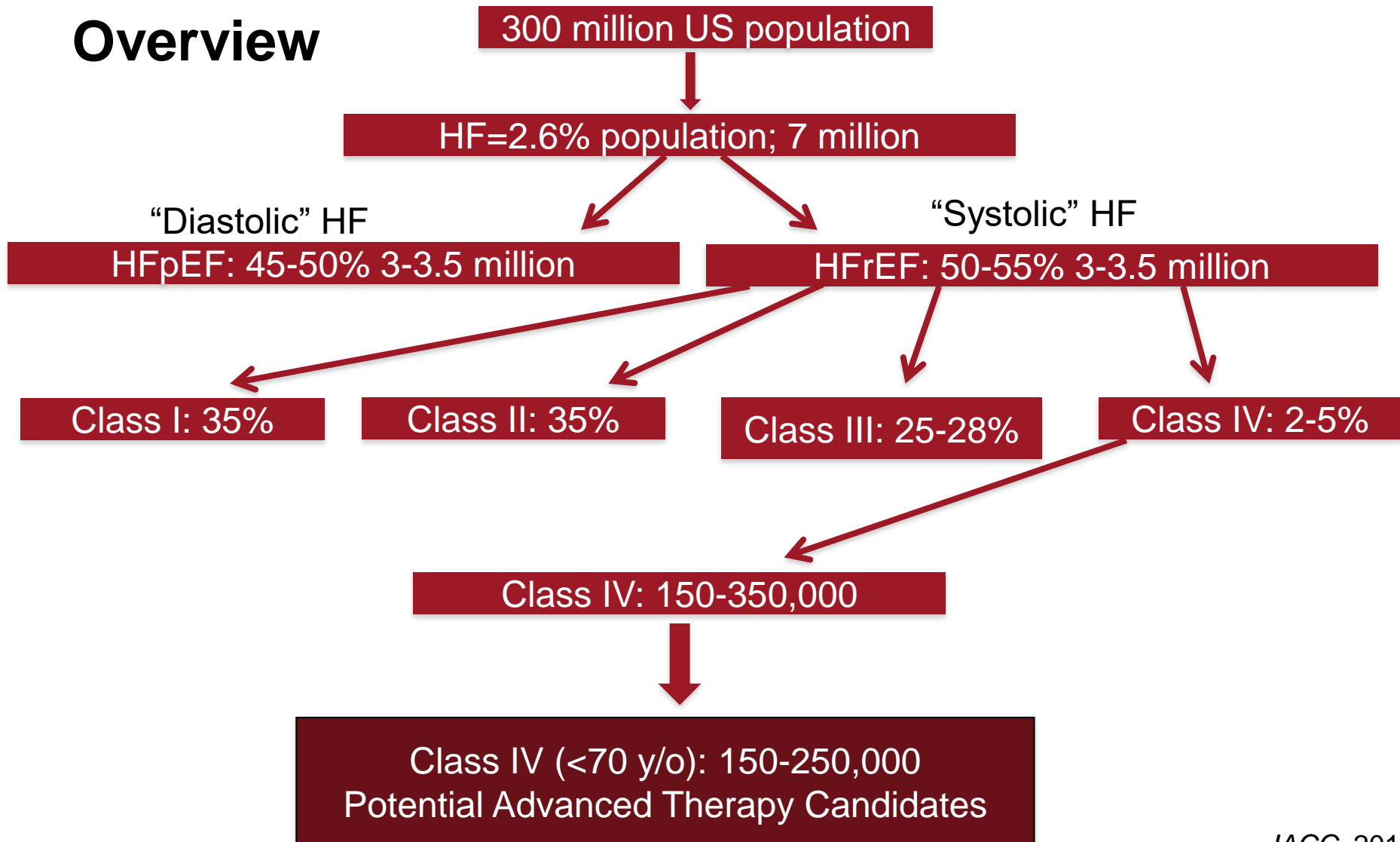
-LVAD

-Inotropes

-Hospice

Your patient

Overview



JACC. 2013.

A Tale of Two Presentations...

“Stable” advancing disease

“Crash and burn” shock

Clues to Advancing Heart Failure

Overview

- Case
- Overview on Heart Failure
- Identifying Advanced Heart Failure
- Treatment options along the spectrum of disease
- Questions

AHF management secrets

- Maximize afterload reduction (ie. ↓ BP)
- Reduce myocardial oxygen consumption (ie. ↓ HR)
- Relieve congestion
- Reassess
 - If improved → maintain
 - If declining → optimize GDMT
 - If still declining → consider advanced therapies

*

*If wt >85 kg; consider up to 50 mg bid

Device therapies for HF

- ICD/CRT
- PA pressure monitoring
- LVAD

ICD/CRT

- ICD
 - Management of ventricular arrhythmias
 - Primary vs secondary prevention
 - LVEF <35%
 - Single chamber vs dual chamber
- CRT
 - Improve mechanical dyssynchrony
 - “Biventricular” pacing
 - +/- ICD
 - LV wire via coronary sinus
 - LBBB (QRS >120 ms)

Volume monitoring

- Most pts admitted for ADHF have symptoms of congestion, resulting from increases in intra-cardiac and pulmonary artery pressures
- Increases in pressure can be seen days to weeks before the onset of symptoms
- COMPASS-HF trial showed that intra-cardiac pressures arose independently of weight changes
- Prior attempts of implanted hemodynamic monitoring has not proven to be beneficial

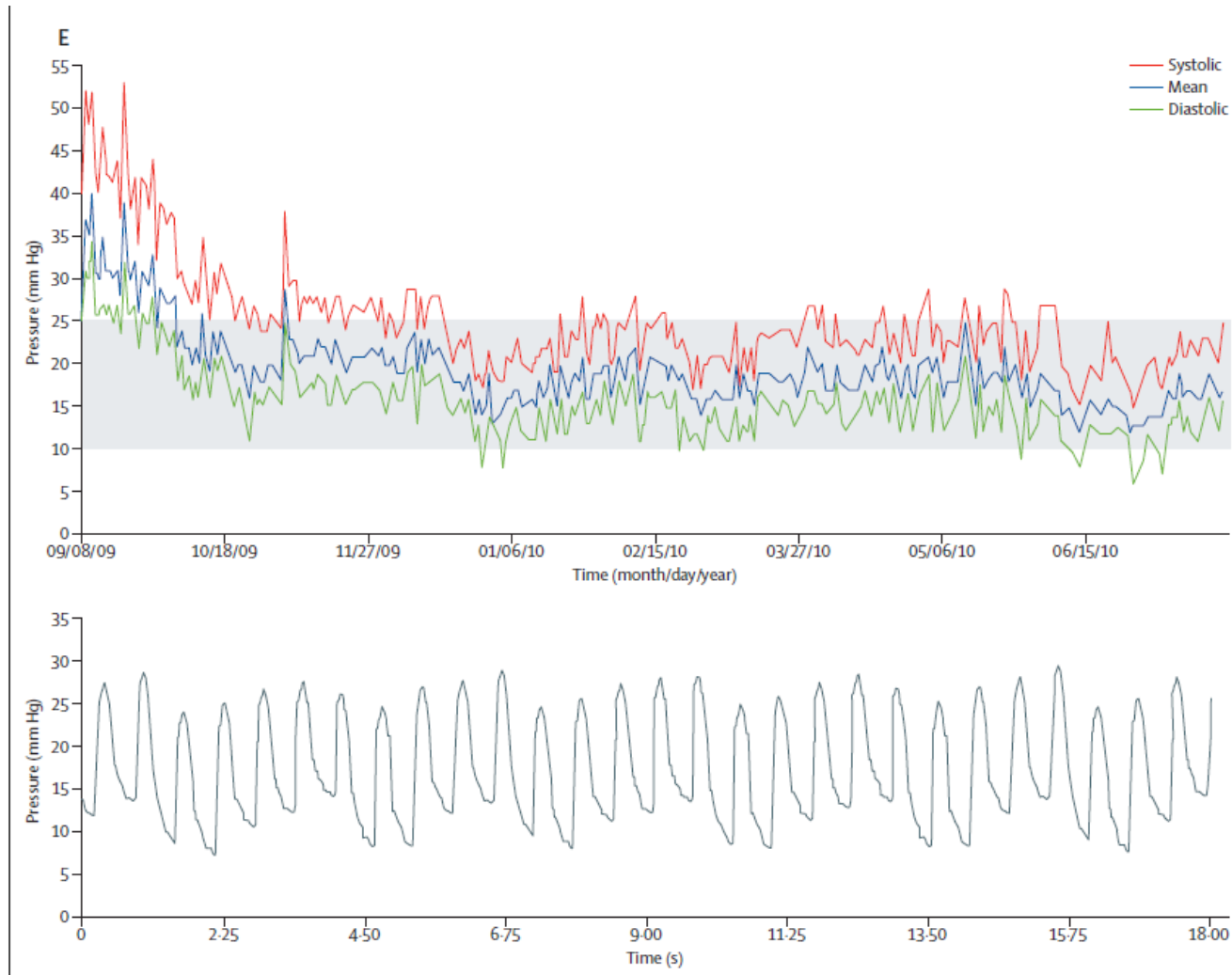
JACC 2008

Symptoms are late in the game

CardioMEMs®

- Continuous monitoring
- RHC
- Implanted into left PA
- No battery/replacement
- Remote monitoring

CardioMEMs



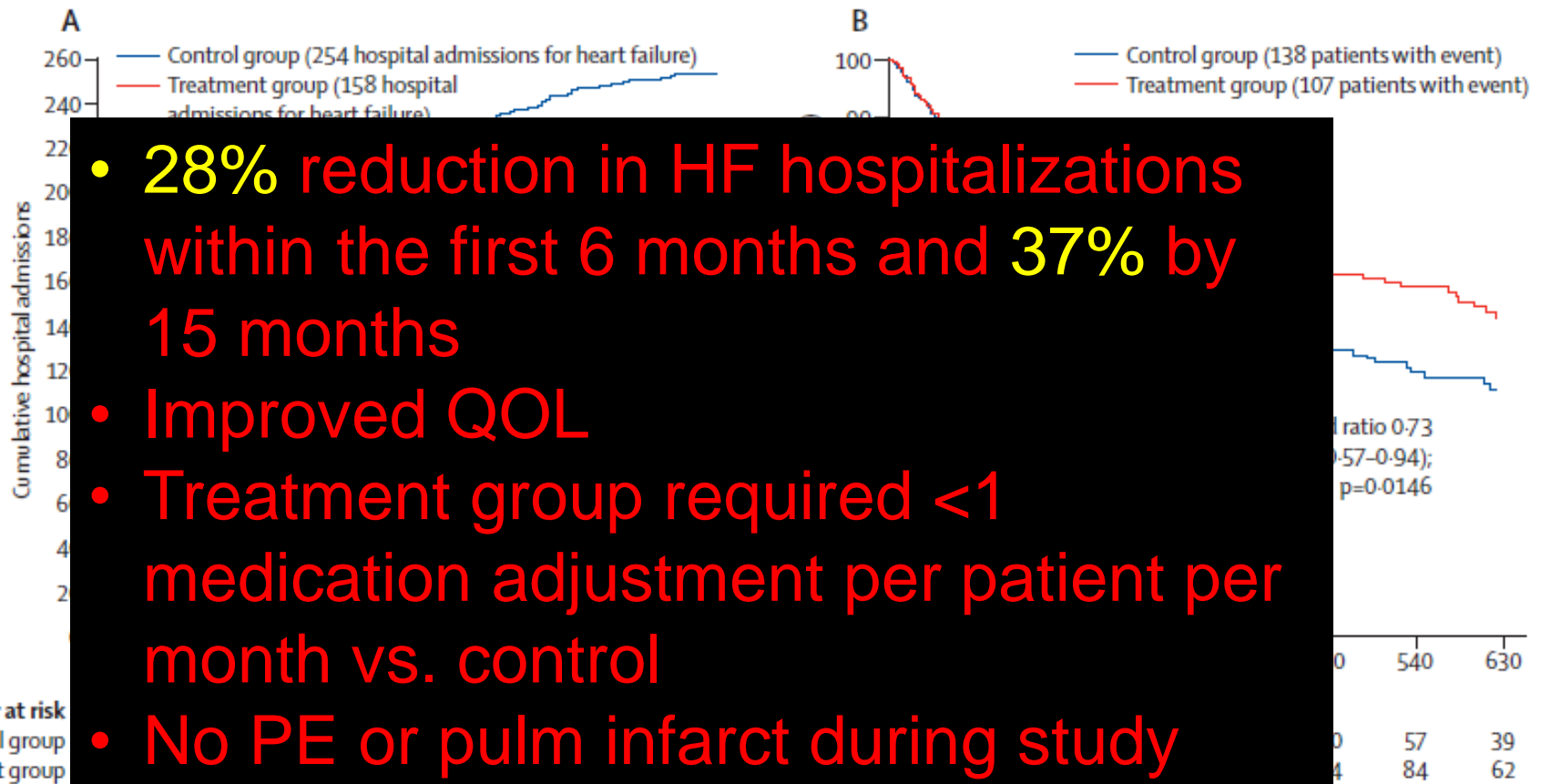


Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial

*William T Abraham, Philip B Adamson, Robert C Bourge, Mark F Aaron, Maria Rosa Costanzo, Lynne W Stevenson, Warren Strickland, Suresh Neelaganu, Nirav Raval, Steven Krueger, Stanislav Weiner, David Shavelle, Bradley Jeffries, Jay S Yadav, for the CHAMPION Trial Study Group**

- NYHA class III for at least 3 months, no LVEF cutoff, and hospitalized within the last year for HF
- 550 pts implanted
 - 270 randomized to treatment
 - 280 pts randomized to control group
 - Post-procedure medication
 - prior anticoagulants resumed
 - otherwise ASA 81 + Clopidogrel 75 x30 days, then ASA 81 alone
- Mean duration of follow up: 15 months

Lancet 2011



- 28% reduction in HF hospitalizations within the first 6 months and 37% by 15 months
- Improved QOL
- Treatment group required <1 medication adjustment per patient per month vs. control
- No PE or pulm infarct during study time

Lancet 2011

UH/VA experience

- 50-60% reduction in 1 year readmission rates for HF

Advanced Heart Failure treatment options

- Cardiac transplantation
- **Left ventricular assist device (LVAD)**
- Palliative inotropes
- Hospice

Left Ventricular Assist Device (LVAD)

- Intra-corporeal pump
- 1st generation: pulsatile
- 2nd/3rd generation: continuous
- Axial or Centrifugal flow pump
- Constant power source
- Antiplatelet/anticoagulant

The New England Journal of Medicine

Copyright © 2001 by the Massachusetts Medical Society

VOLUME 345

NOVEMBER 15, 2001

NUMBER 20



LONG-TERM USE OF A LEFT VENTRICULAR ASSIST DEVICE FOR END-STAGE HEART FAILURE

ERIC A. ROSE, M.D., ANNETINE C. GELIJNS, PH.D., ALAN J. MOSKOWITZ, M.D., DANIEL F. HEITJAN, PH.D.,
LYNNE W. STEVENSON, M.D., WALTER DEMBITSKY, M.D., JAMES W. LONG, M.D., PH.D., DEBORAH D. ASCHEIM, M.D.,
ANITA R. TIERNEY, M.P.H., RONALD G. LEVITAN, M.Sc., JOHN T. WATSON, PH.D., AND PAUL MEIER, PH.D.,
FOR THE RANDOMIZED EVALUATION OF MECHANICAL ASSISTANCE FOR THE TREATMENT OF CONGESTIVE HEART FAILURE
(REMATCH) STUDY GROUP*

- 129 patients with NYHA IV, stage D HF who were ineligible for cardiac transplantation
- Primary endpoint: death from any cause

NEJM 2001

Rise of the Machines — Left Ventricular Assist Devices as Permanent Therapy for Advanced Heart Failure

James C. Fang, M.D.

NEJM. 2009.

LVAD Complications

RV failure

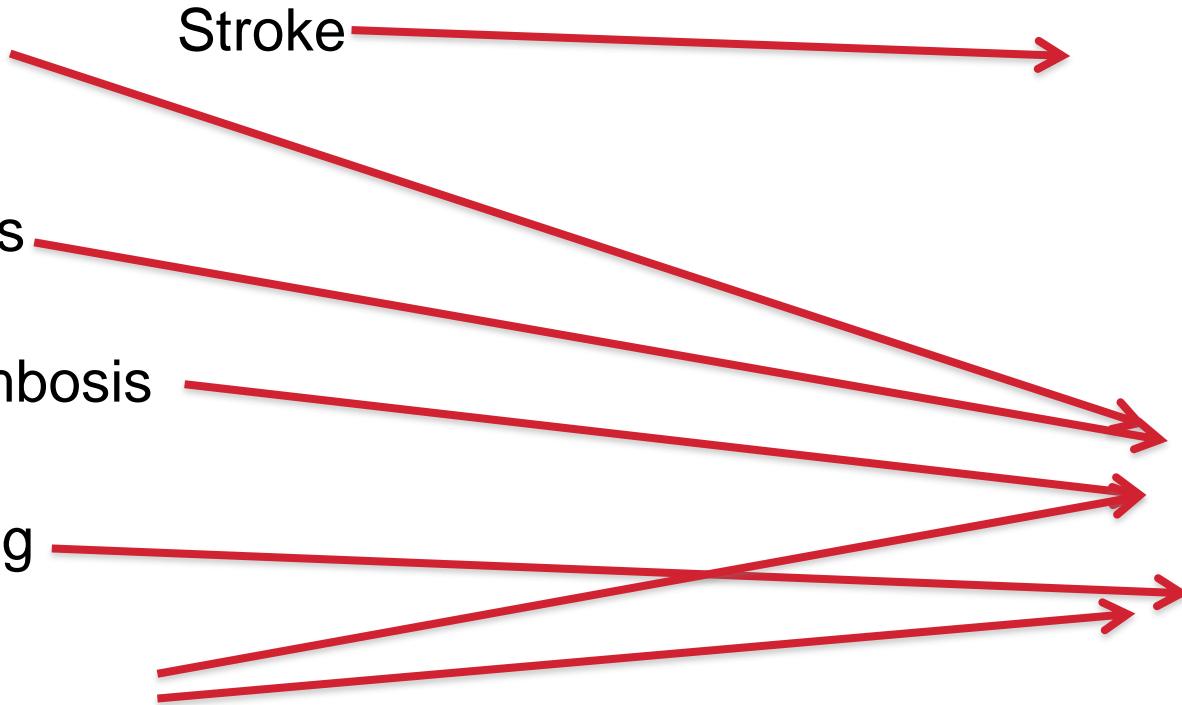
Stroke

Arrhythmias

Pump thrombosis

GI bleeding

Infection



LVAD Thrombosis

ORIGINAL ARTICLE

A Fully Magnetically Levitated Circulatory Pump for Advanced Heart Failure

Mandeep R. Mehra, M.D., Yoshifumi Naka, M.D., Nir Uriel, M.D., Daniel J. Goldstein, M.D., Joseph C. Cleveland, Jr., M.D., Paolo C. Colombo, M.D., Mary N. Walsh, M.D., Carmelo A. Milano, M.D., Chetan B. Patel, M.D., Ulrich P. Jorde, M.D., Francis D. Pagani, M.D., Keith D. Aaronson, M.D., David A. Dean, M.D., Kelly McCants, M.D., Akinobu Itoh, M.D., Gregory A. Ewald, M.D., Douglas Horstmanshof, M.D., James W. Long, M.D., and Christopher Salerno, M.D., for the MOMENTUM 3 Investigators*

- Investigate the effectiveness of a new magnetically levitated centrifugal continuous-flow pump that was engineered to avert thrombosis.
- 294 patients, 152 were assigned to the centrifugal-flow pump group and 142 to the axial-flow pump group

NEJM. 2017.

HeartMate 3™ LVAD

- Fully magnetically levitated
- Larger gaps in pump housing
- Built-in pulsatility

Significantly lower rate of pump replacement at 2 years

Current FDA Approved Durable MCS

HeartMate II™ LVAD

HeartMate 3™ LVAD

Heartware HVAD™

Total Artificial
Heart (TAH)

- BTT
- DT

- BTT
- DT

- BTT
- DT

- BTT

Future of LVAD

- Improved patient selection
- Smaller devices (w/o compromising support)
- Elimination of the driveline

Smaller devices

LVAD Driveline

- Sepsis was the most common cause of death (41%) in pts receiving LVADs in the REMATCH trial
- Goal: **eliminate** the driveline

Wireless Technology

- Transcutaneous energy transfer (TET)
- Magnetically coupled resonators that transfer power wirelessly
- Ex: wireless cellphone charging pads

Transcutaneous Energy Transfer (TET)

- Matching resonance and frequency to allow acoustic energy to be converted into kinetic energy

TET

U of Washington

Free Range Electrical Energy Delivery

U of Washington

What you really need to know

Patients with any of the following should be referred for evaluation for advanced heart failure therapies¹

I NEED HELP

I	IV inotropes
N	NYHA IIIB/IV or persistently elevated natriuretic peptides
E	End-organ dysfunction (Cr > 1.8 mg/dL or BUN > 43 mg/dL)
E	Ejection fraction ≤ 35%
D	Defibrillator shocks
H	Hospitalizations > 1
E	Edema (or elevated PA pressure) despite escalating diuretics
L	Low blood pressure, high heart rate
P	Prognostic medication — progressive intolerance or down-titration GDMT

Additional patient considerations for referral:

- **CRT non-responder**
- **Physical activity limited or impaired quality of life**

Reference: 1. 2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction: A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways. Yancy CW, Januzzi JL Jr, Allen LA, Butler J, Davis LL, Fonarow GC, et al. *J Am Coll Cardiol*. 2018 Jan 16;71(2):201-230.

“SHARK”

When to refer

- **S**odium (hyponatremia $\text{Na} < 136$)
- **H**ospitalizations
 - readmit in 30 days or ≥ 2 hospital stays in 6 months
- **A**rrhythmias (atrial/ventricular)
- **R**efractory to meds (ACE/ARB/BB)
- **K**idney failure ($\text{Cr} \geq 1.2$, or > 0.3 from b/l)

In summary

- Heart failure is a growing epidemic despite contemporary medical therapy
- New invasive technology allows earlier identification and management of volume status to prevent acute decompensation
- LVAD technology has continued to evolve/improve and now provides viable options (bridge or permanent therapy)
- Future advances of LVAD therapy look to identify patients earlier and limit complications

Thank You

Questions

Michael.Zacharias@uhhospitals.org