Updates in Heart Failure: Devices

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- Disclosures: none. I’m a fellow. ☺

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Let’s start with a case…

- 61 year old Caucasian male with **end stage ischemic cardiomyopathy with LVEF 20-25%** with persistent NYHA Class III-IV symptoms and CKDIII who presented to the heart failure clinic for consideration for advanced therapies.
  - BP 90/60. HR 102. BMI 39.
  - Na 134. Creatinine 1.7.
  - TTE: LVEDD 7 cm. LVEF 20%. Mild RV dilation and dysfunction. Moderate functional mitral regurgitation. Moderate functional tricuspid regurgitation.

Right Heart Catheterization	
Chamber	**Value**
Right Atrium	17 mmHg
Right Ventricle	72/10 (20) mmHg
Pulmonary Artery	67/37 (50) mmHg
Pulmonary Capillary Wedge Pressure	37 mmHg
Pulmonary Artery Saturation	42%
Cardiac Output/Index (Fick)	4.73/1.88
Pulmonary Vascular Resistance (Woods)	2.75 Woods Units

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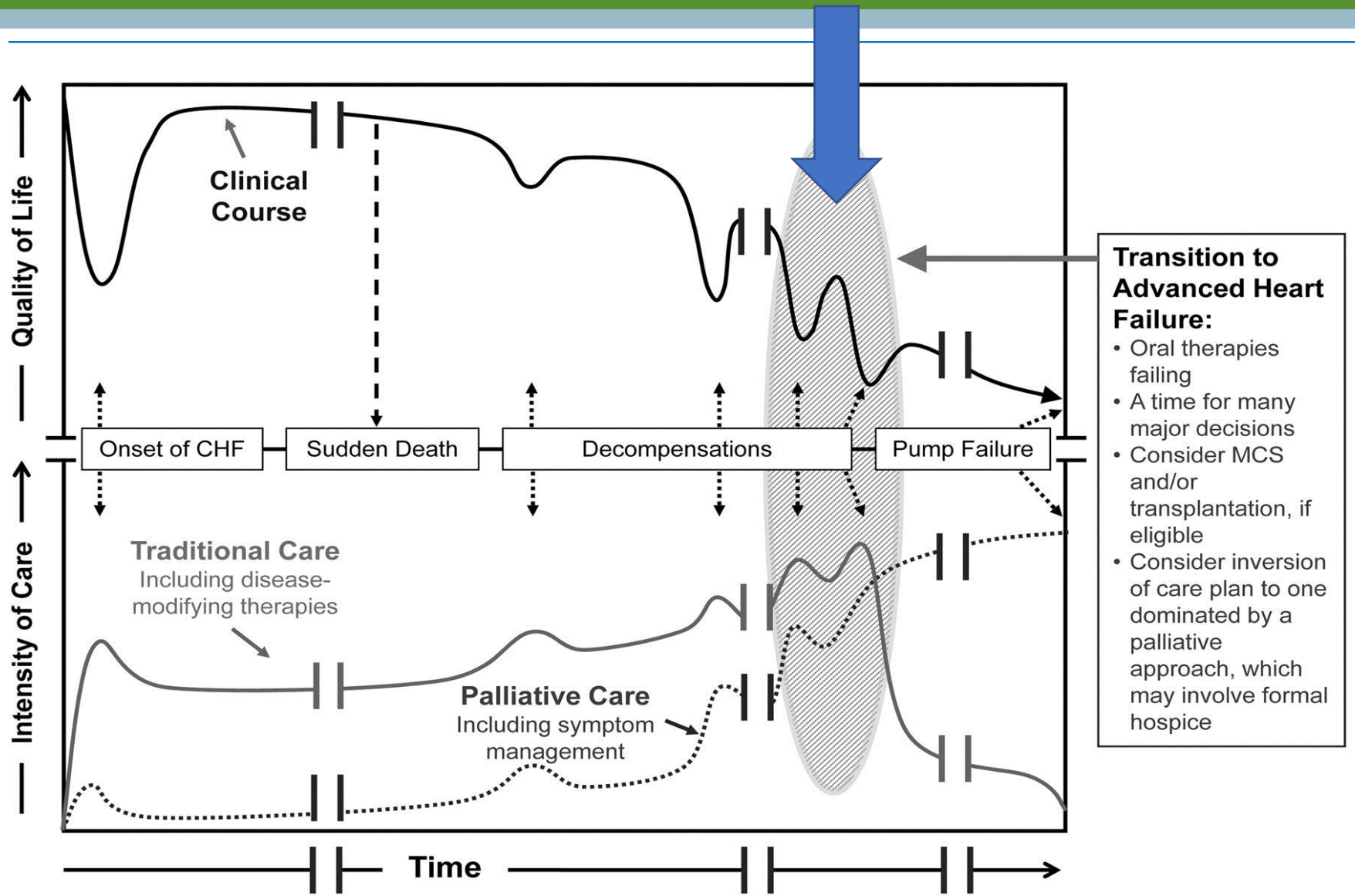
Natural Course of Heart Failure



Larry A. Allen et al. Circulation. 2012

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What would be your next step in management?

A. Continue with current medical therapy.
B. Palliative care referral.
C. Start working up for potential ventricular assist device.
D. Immediate listing for dual organ transplant for heart-kidney.
E. None of the above.

Live Content Slide

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Poll: What would be your next step in management?

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What would be your next step?

A. Continue with current medical therapy.
B. Palliative care referral.
C. Start working up for potential ventricular assist device.
D. Listing for dual organ transplant for heart-kidney.
E. None of the above.

Momentum 3 Trial- Heartmate 3 LVAD

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*

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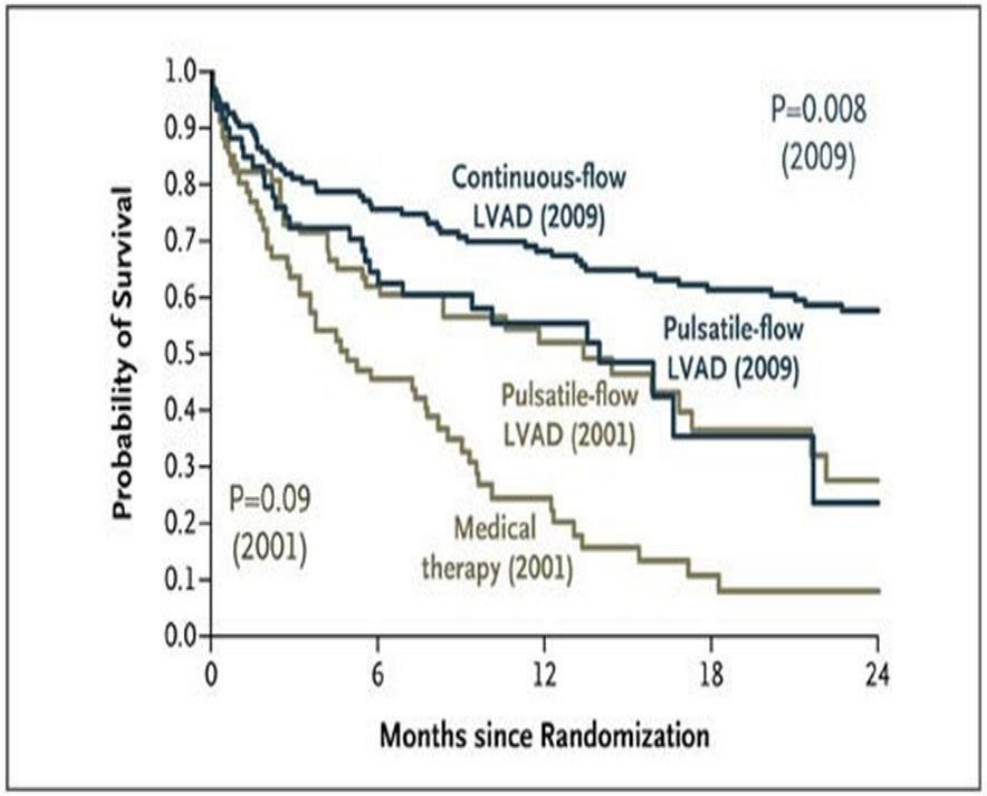
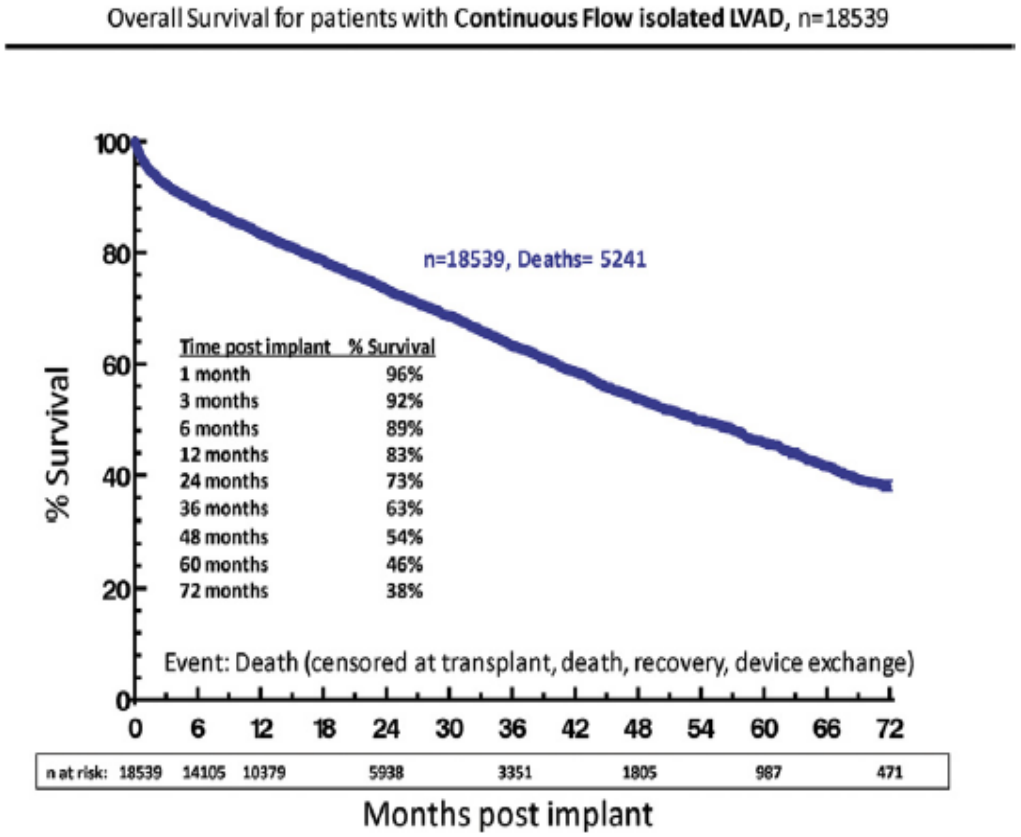
Background: LVAD

- **Left Ventricular Assist Systems (LVAS) improve survival and quality of life in patients with advanced heart failure refractory to medical therapy.**





Kormos et al. *STS Intermacs Annual Database*. JHLT 2019.

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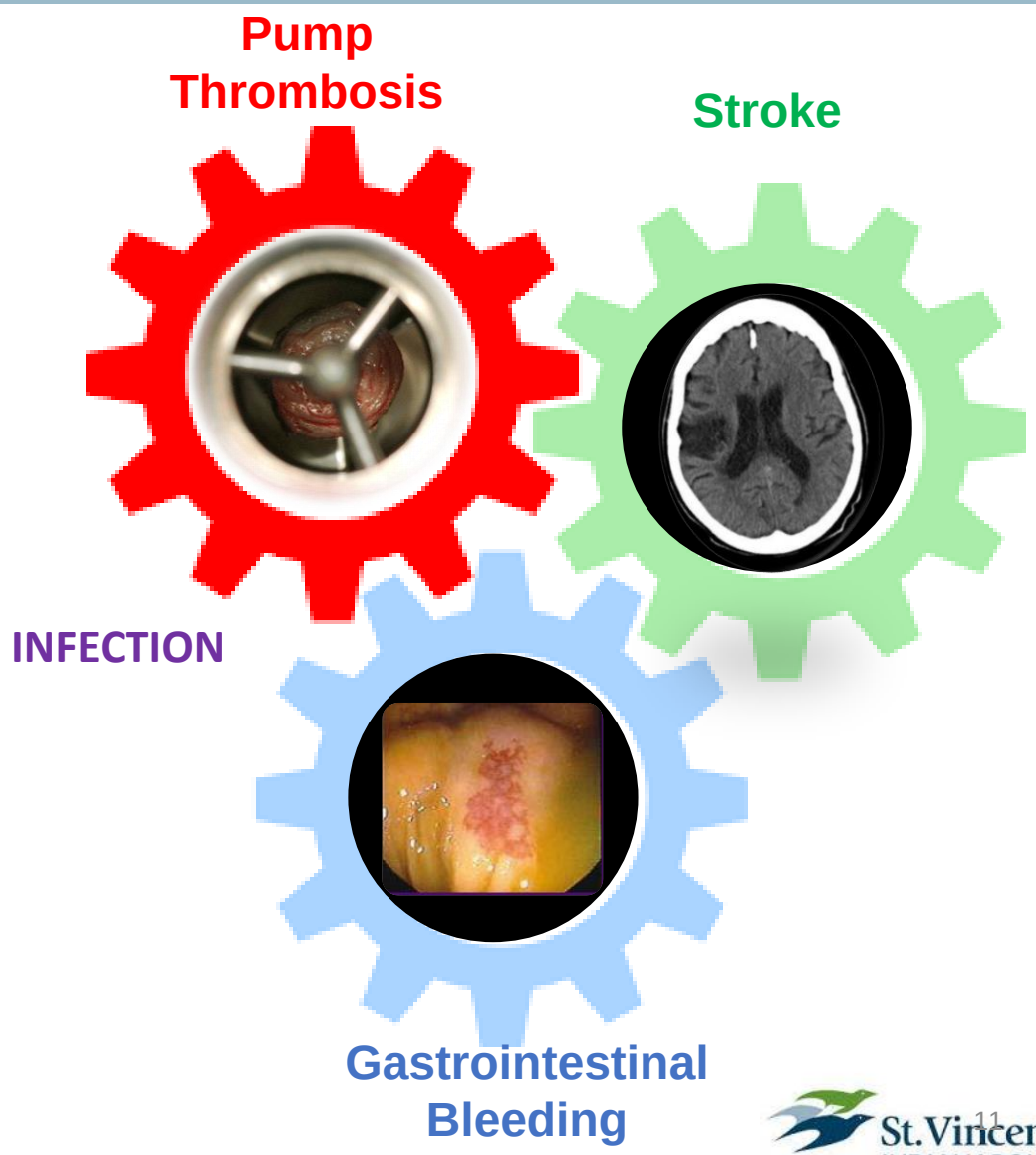
Complications of LVAD

- Despite improving survival and quality of life, patients with continuous-flow LVADs are burdened with complications.

1. Consequences of adverse interactions between the *pump and circulating blood elements* lead to hemocompability complications.
   - **Pump thrombosis**
   - **Stroke**
   - **Gastrointestinal bleeding**

2. Infection risk



Mehra MR. Eur Heart J 2019;40(8):673-7

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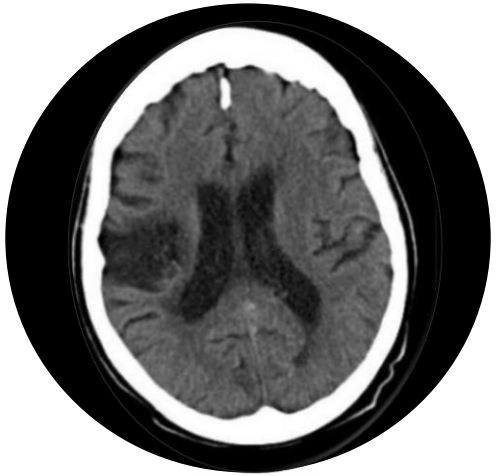
Complications of LVADs



What complication might occur?

1 year after surgery, about: [1,2,3]

- 5 to 6 patients out of 10 are readmitted to the hospital

55%

- 1 in 10 have a stroke

10%

- 2 in 10 develop a device-related infection

20%

- 2 in 10 have a serious bleed that requires medical attention

20%

- Nearly 2 in 10 have ongoing heart failure

17%

https://patientdecisionaid.org/wp-content/uploads/2016/06/LVAD-Decision-Aid-08.28.2019.pdf

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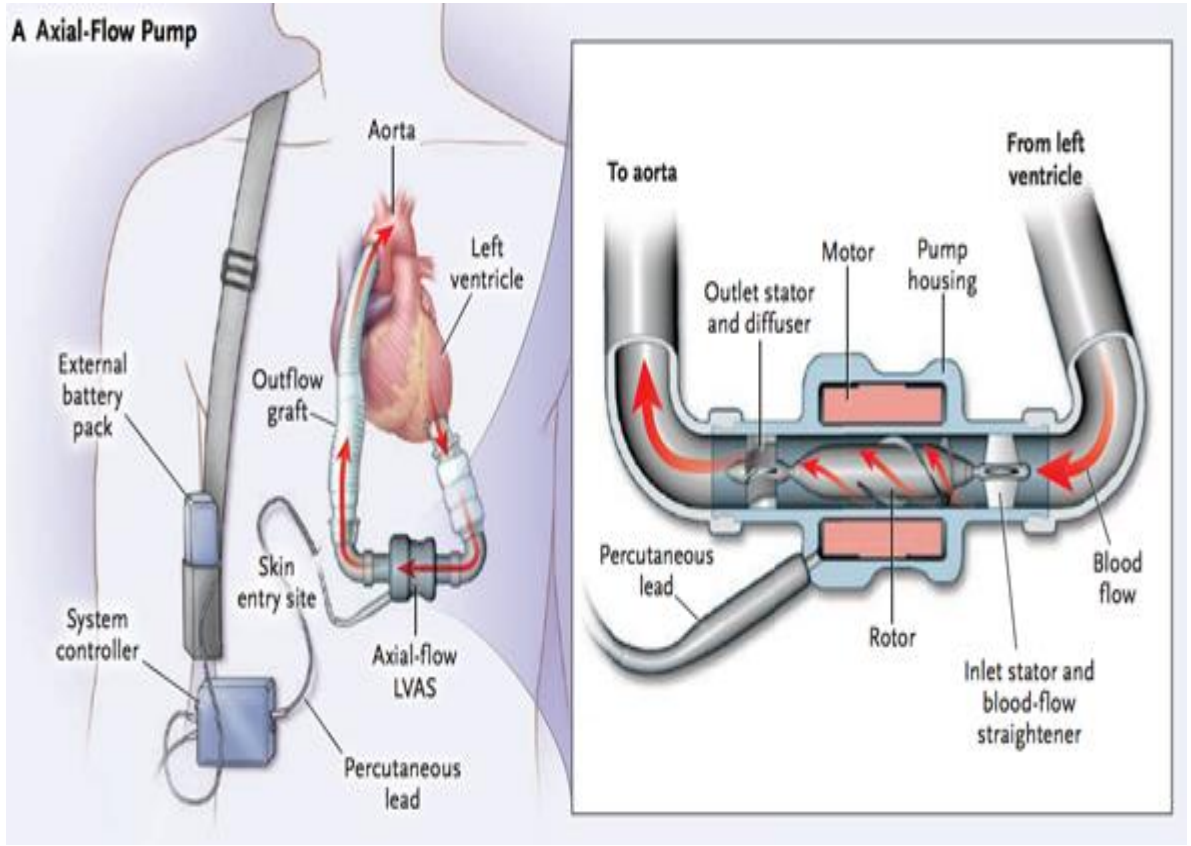
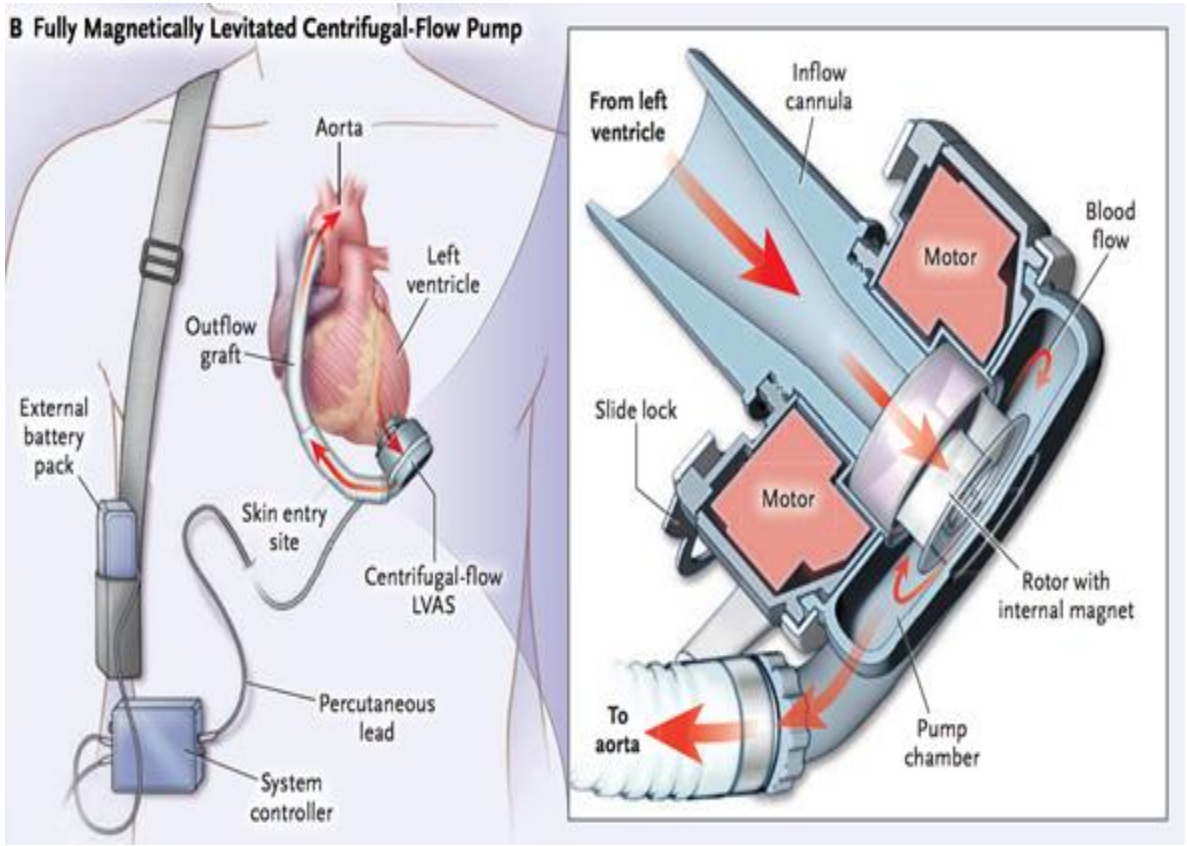
Momentum 3 Trial

HeartMate II (Axial Flow)



HeartMate III (Centrifugal Flow)



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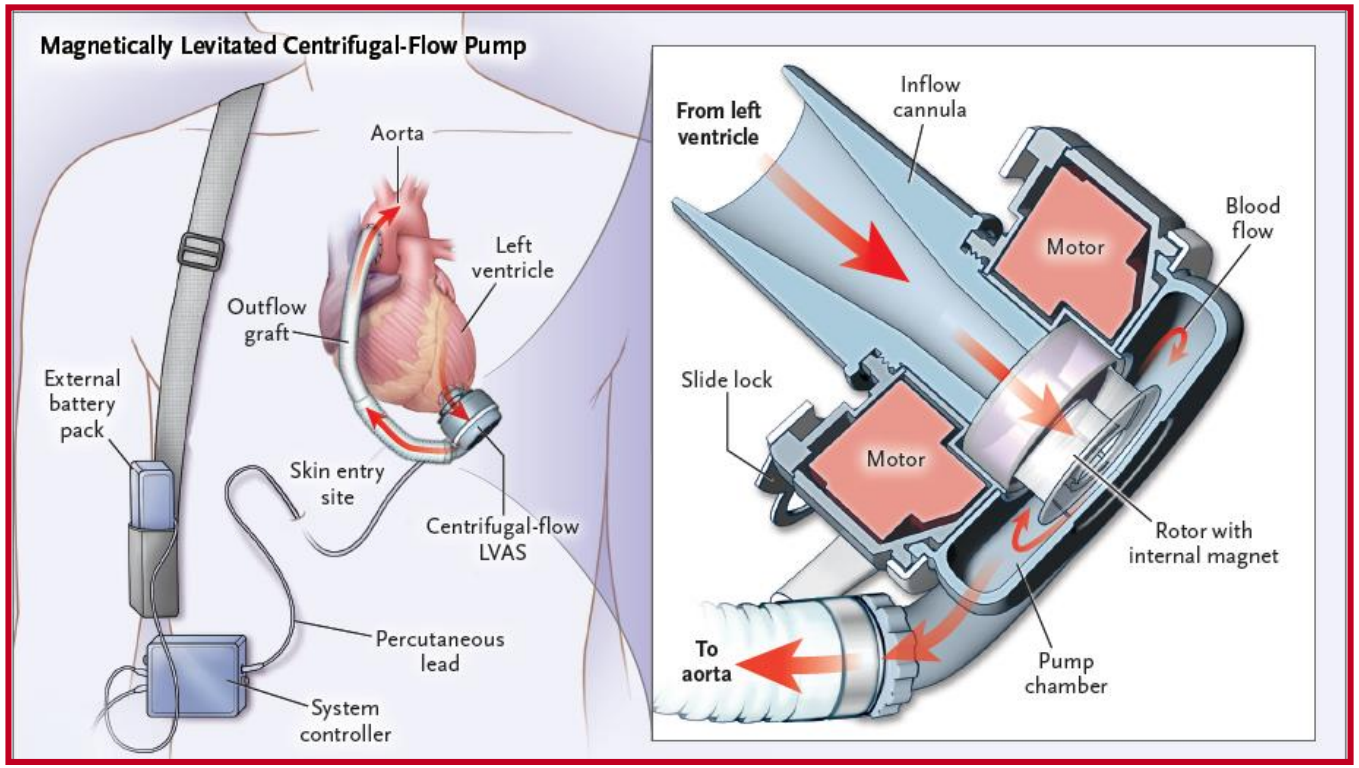
HeartMate 3 LVAD

The HeartMate 3 LVAS is a centrifugal-flow, fully magnetically levitated blood pump engineered to minimize destruction of red blood cells and thrombosis.



- **Wide** blood-flow passages to reduce shear stress
- **Frictionless** with absence of mechanical bearings
- **Intrinsic Pulse** designed to reduce stasis and avert thrombosis

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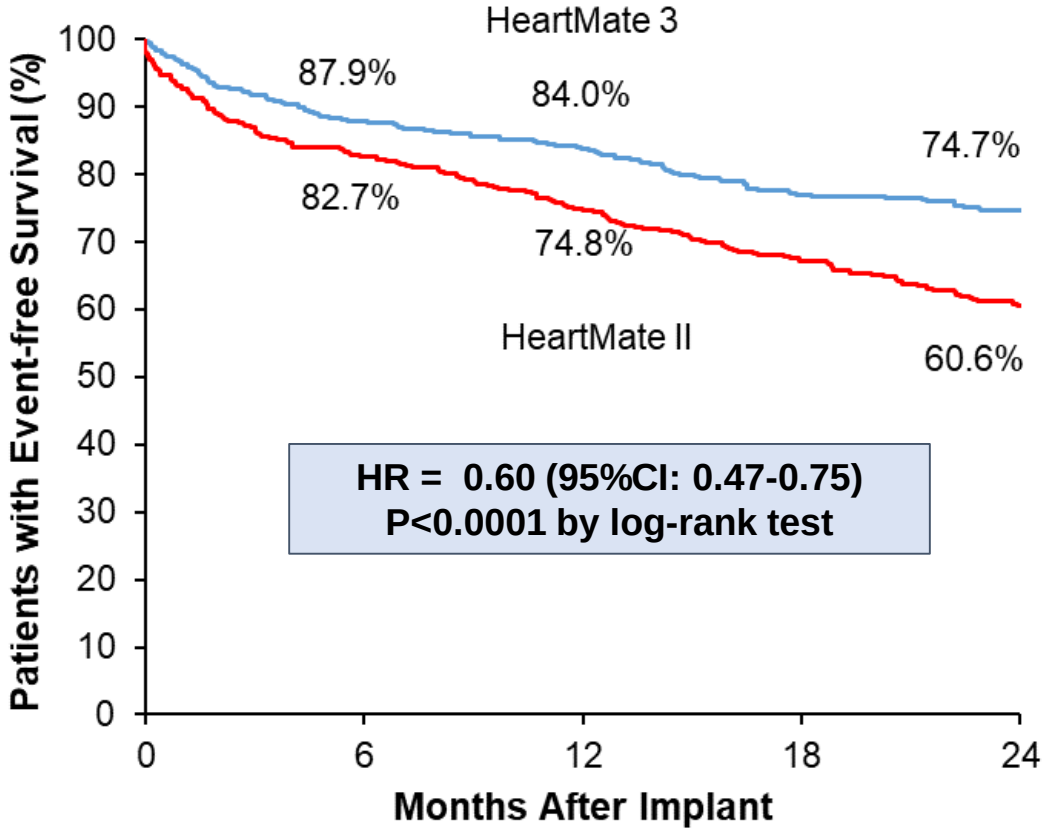
Momentum 3: Primary End Point (ITT)

Survival at 2 years free of disabling stroke (>3 mRS) or reoperation to replace or remove a malfunctioning device



No. at Risk:					
HeartMate 3	516	438	373	313	280
HeartMate II	512	401	321	264	223

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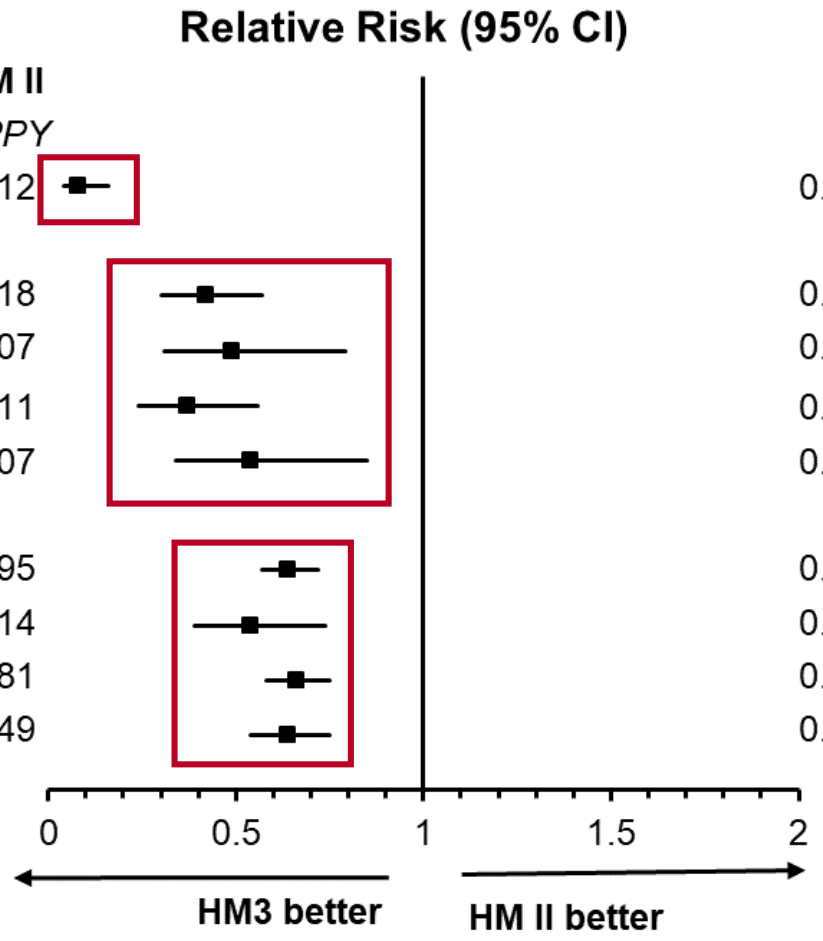
Principal Hemocompatibility-Related Adverse Events

Adverse Event	HM3 *n (%)*	HM II *n (%)*	HM3 *EPPY*	HM II *EPPY*	Relative Risk (95% CI)	*P-Value**
Suspected pump thrombosis	7 (1.4)	70 (13.9)	0.01	0.12	0.08 (0.04 - 0.16)	<0.0001
Any stroke	51 (9.9)	98 (19.4)	0.08	0.18	0.42 (0.30 - 0.57)	<0.0001
Hemorrhagic stroke	25 (4.9)	43 (8.5)	0.03	0.07	0.49 (0.31 - 0.79)	0.004
Ischemic stroke	29 (5.6)	65 (12.9)	0.04	0.11	0.37 (0.24 - 0.56)	<0.0001
Disabling stroke	26 (5.0)	38 (7.5)	0.04	0.07	0.54 (0.34 - 0.85)	0.008
Any bleeding	225 (43.7)	278 (55.0)	0.61	0.95	0.64 (0.57 - 0.72)	<0.0001
Requiring surgery	50 (9.7)	89 (17.6)	0.08	0.14	0.54 (0.39 - 0.74)	<0.001
Not requiring surgery	197 (38.3)	251 (49.7)	0.53	0.81	0.66 (0.58 - 0.75)	<0.0001
Gastrointestinal bleeding	126 (24.5)	156 (30.9)	0.31	0.49	0.64 (0.54 - 0.75)	<0.0001



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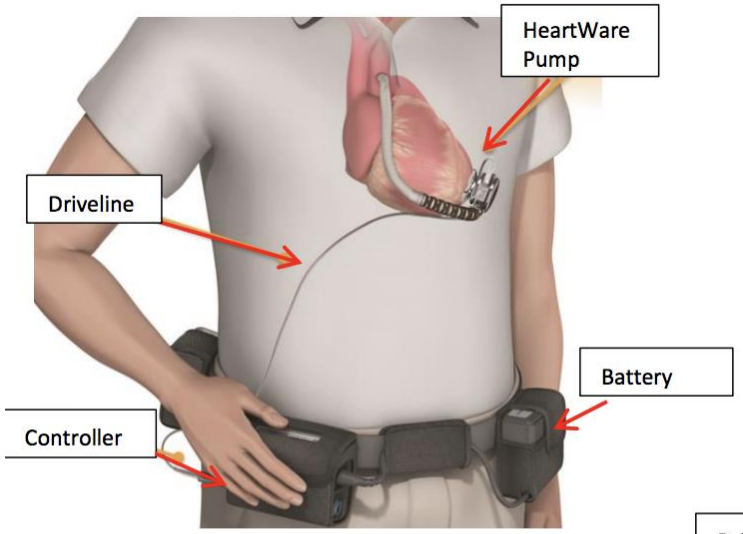
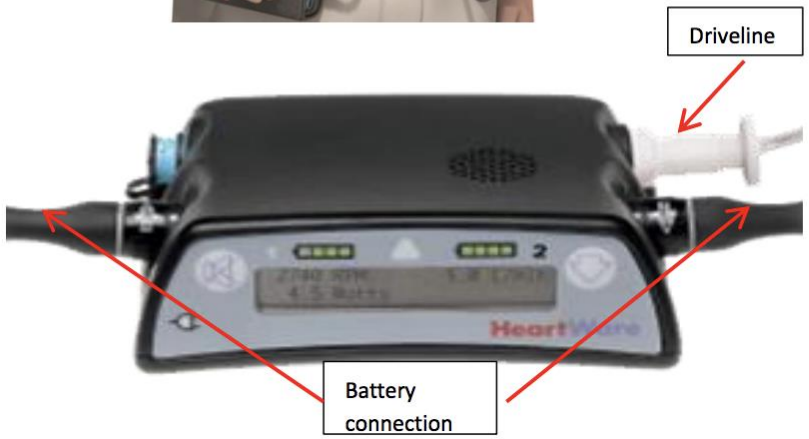
Summary: Heartmate 3

- In the largest LVAD study performed, the centrifugal-flow HeartMate 3 LVAS has demonstrated superior performance compared to the axial-flow HeartMate II pump with respect to:
  - Reduction in Pump Thrombosis
  - Reduction in Strokes of ***any type*** and of ***any severity***
  - Reduction in any Bleeding, particularly **gastrointestinal** bleeds
  - Reduction in Cardiac Arrhythmias, particularly ventricular arrhythmias
  - Reduction in readmissions and days spent in the hospital

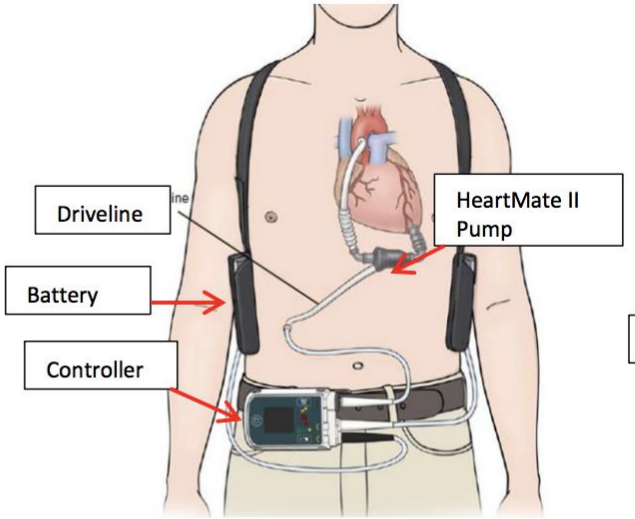
Current LVAD Options

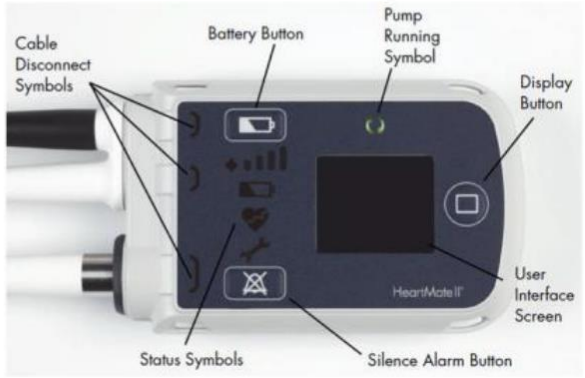
HeartWare HVAD



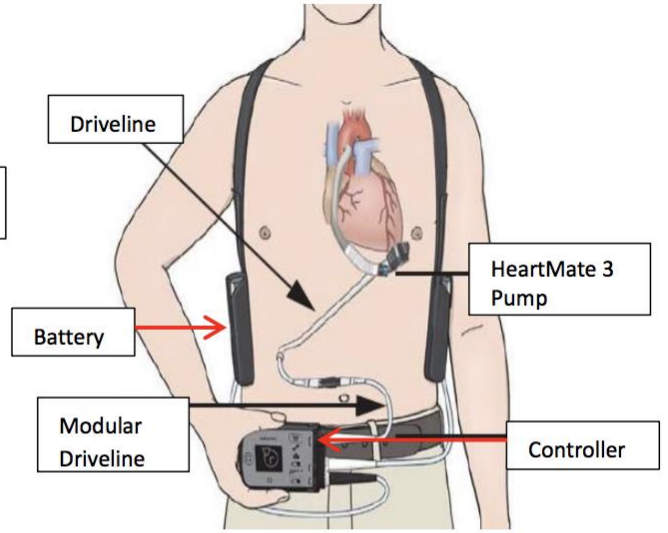


HeartMate II





HeartMate 3



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Back to our case…

- Patient C. had an uneventful immediate post-operative course after placement of Heartmate 3 LVAD device.

- Unfortunately, he continued to struggle with decompensated right ventricular heart failure with intermittent acute renal failure despite proper LV unloading by RHC and TTE along with close diuretic up-titration and adjustment.

What are potential next steps in management?

A. Heart transplant.

B. Insertion of Cardiomems.

C. Palliative care.

D. Add right ventricular support device (RVAD).

Live Content Slide

When playing as a slideshow, this slide will display live content

Poll: What are potential next steps in management?

What are potential next steps in management?

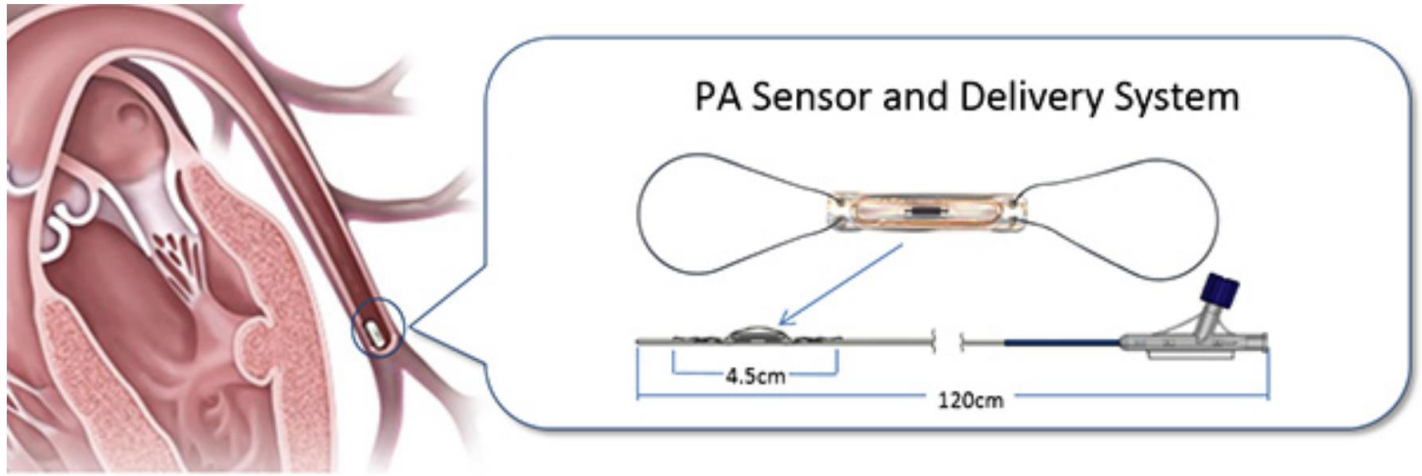
A. Listing for heart-kidney transplant.

B. Insertion of CardioMems?

C. Palliative care.

D. Add right ventricular support device (RVAD).

CardioMEMS



Patient Home Electronics Unit

Adamson ACC, 2015

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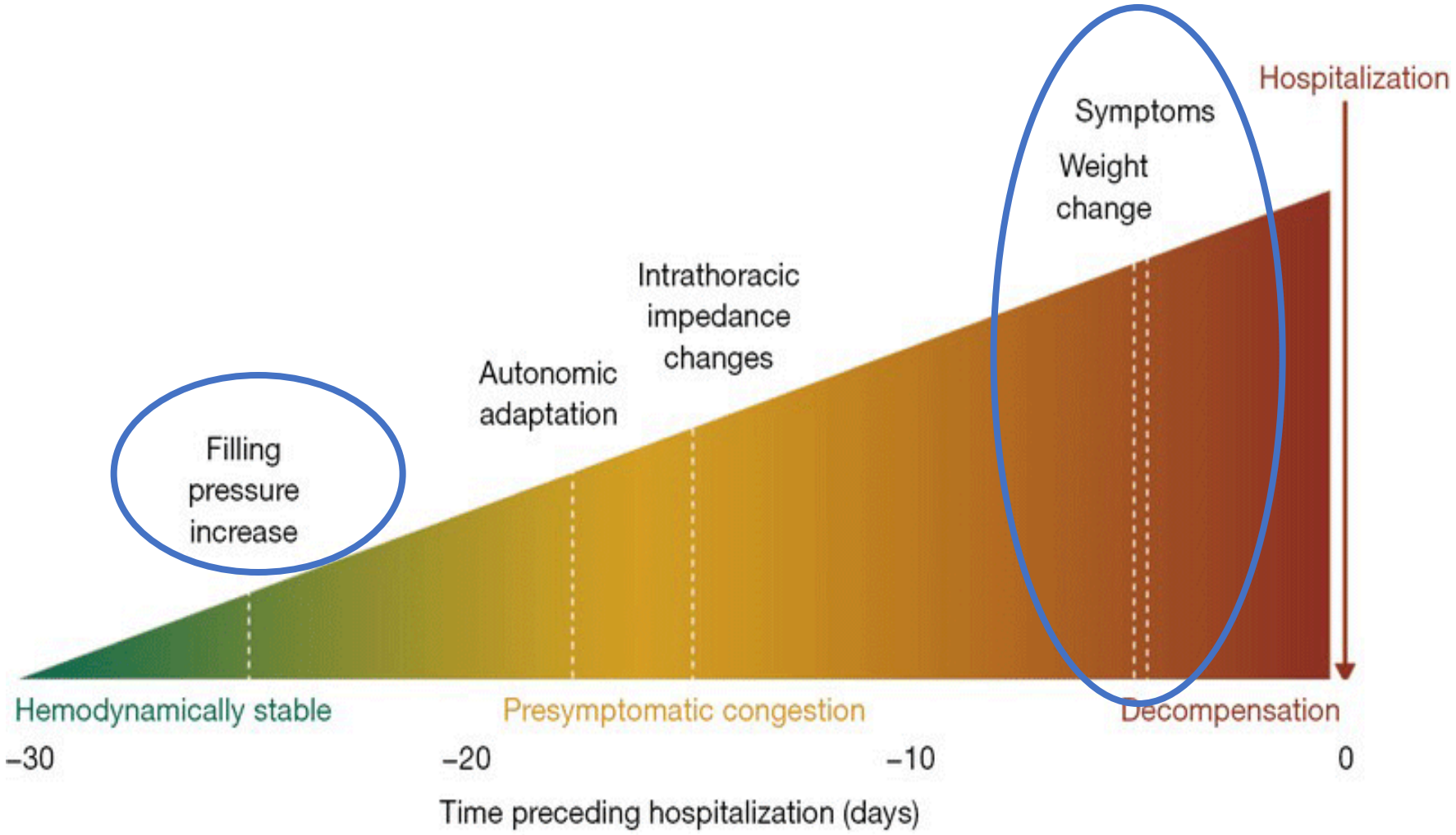
Cardiomems: Why does it work?



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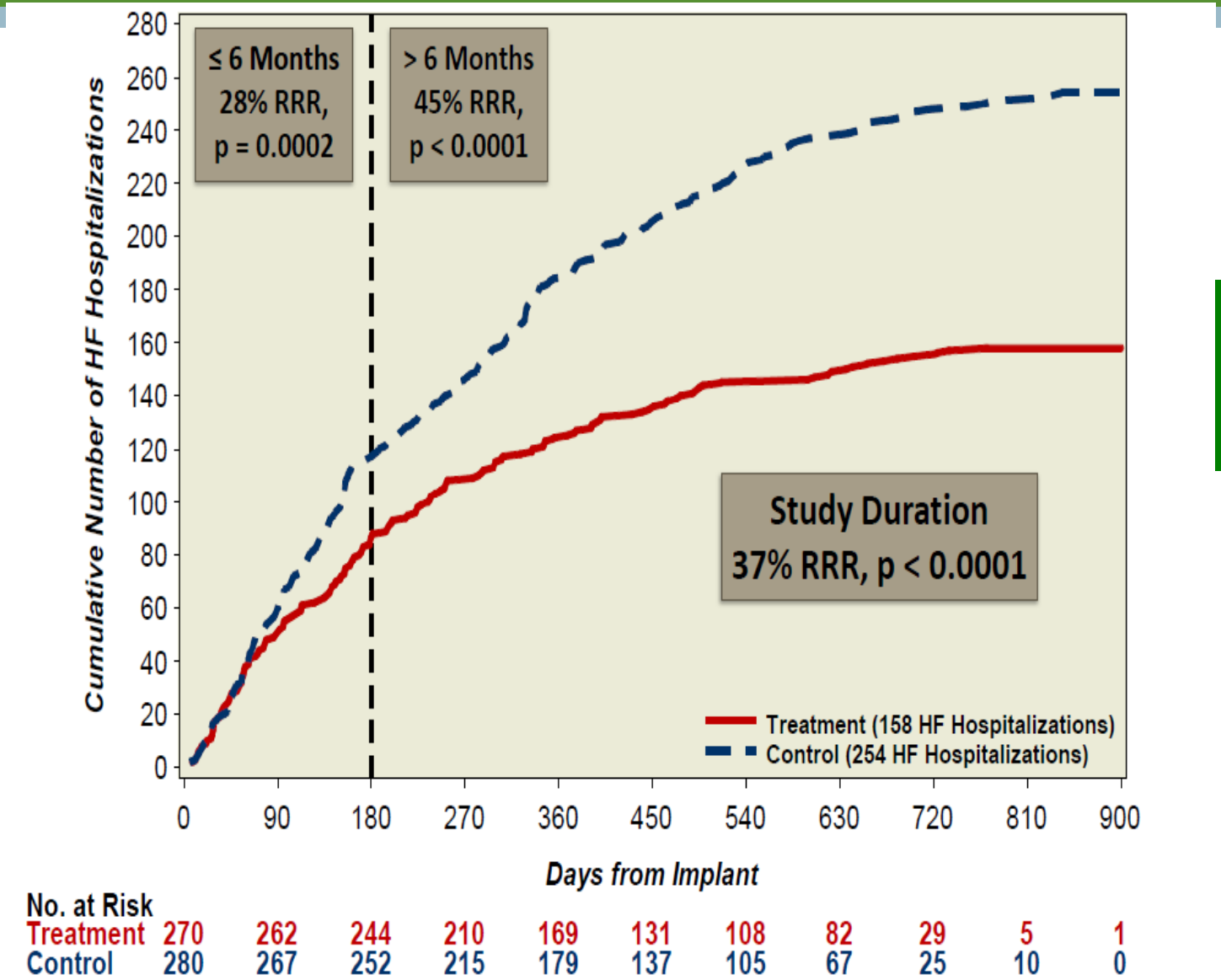
Cardiomems- CHAMPION: Reduction in HF Hospitalization



8 device or system-related complications

No sensor failures

Abraham WT, et al. Lancet, 2011.

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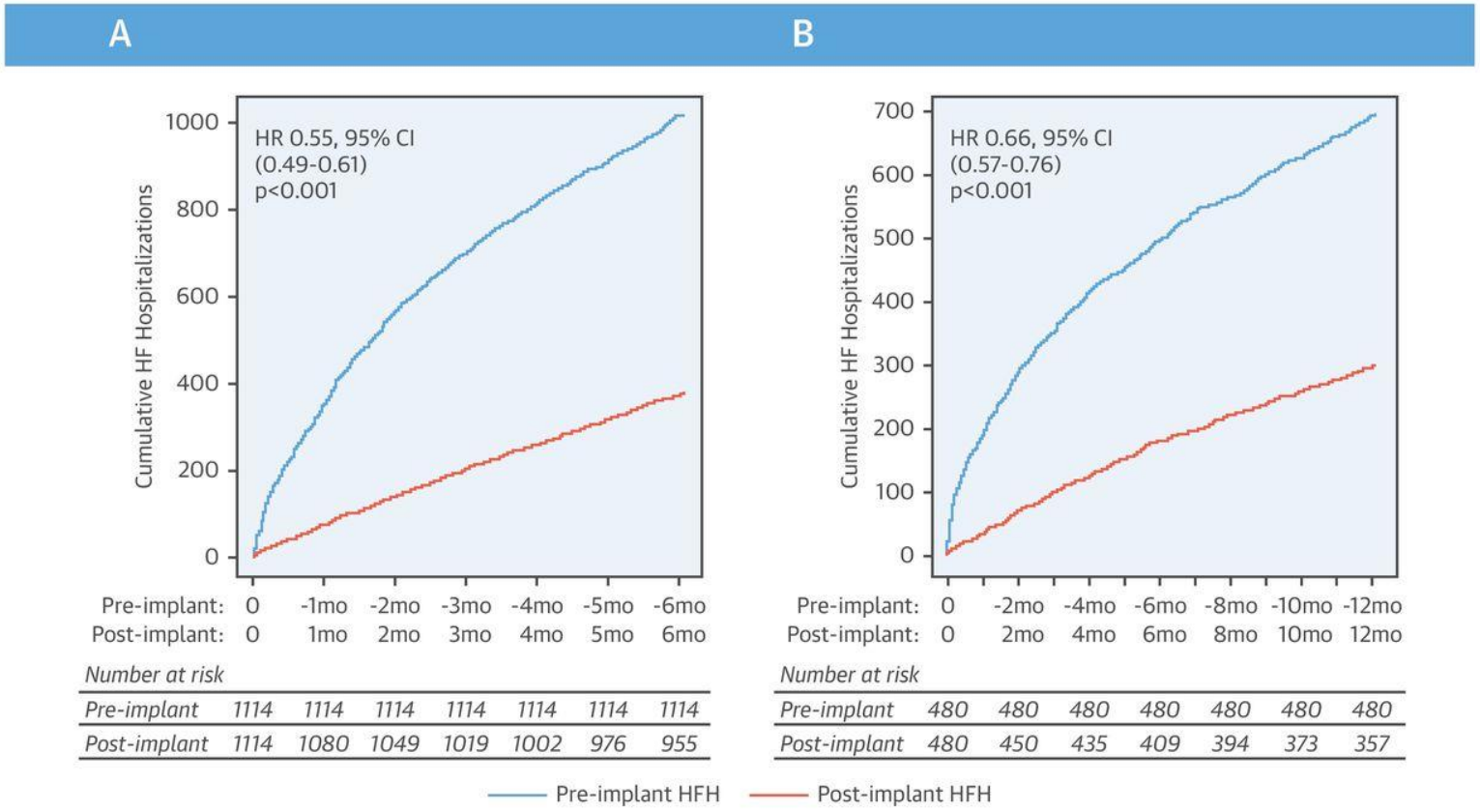
Cardiomems: Real Life Experience

CENTRAL ILLUSTRATION: Cumulative HFHs During the Period Before and After Pulmonary Artery Pressure Sensor Implantation



Desai, A.S. et al. J Am Coll Cardiol. 2017;69(19):2357-65.

JACC

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Cardiomems: Current Guidelines

- FDA Approval in May 2014
  - NYHA Class III
  - HF hospitalization in the last 12 months

- Not currently in the US guidelines
  - Is a class II indication in the European Guidelines

- Ongoing Trial: **Guide-HF** (NYHA Class II-IV) and Intellect (LVAD)

- FULL DISCLOSURE: Not currently studied specifically in LVAD patients.

Back to case…

- Patient C improved with CardioMems devices with direct PA monitoring with diuretic up-titration and no recurrent HF hospitalizations for 6 months.

- Unfortunately, he developed severe aortic regurgitation and underwent expedited dual transplant evaluation.

- Thus, he was listed for a heart-kidney transplant (BMI < 38 at the time) and was agreeable to accept HCV hearts.

A Word on Heart HCV Transplantation

- “Donor needs” do not match “donor availability” and wait list mortality remains high.
- However, with the advent of curative HCV direct antivirals, many transplant centers have had favorable outcomes with HCV donors.
  - First reported in liver and kidney transplantation.
  - HCV + donor cardiac transplantation began in 2017 with Vanderbilt as one of the leading centers initially with non-viremic donors.
- St. Vincent adopted HCV cardiac transplantation in 2/2018 that included viremic donors.

Our Experience at St. Vincent

- To date, 36 of our cardiac transplants since 2/2018 were HCV positive with 34/36 being viremic. All of these patients were treated with direct anti-viral therapy within 4 months.
- Compared to our non-HCV transplantations during the same time frame, we noted no increase in hospitalizations, rejection, infection, malignancy of death.

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Back to our patient

- He subsequently received a dual heart-kidney transplantation on 7/25/2019 and has been doing well post transplant.

- PS: He did agree to this picture.

Thank you!

A huge thank you to the excellent heart failure team at St. Vincent for assistance on preparing this talk.

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QUESTIONS!?

Kathleen Morris
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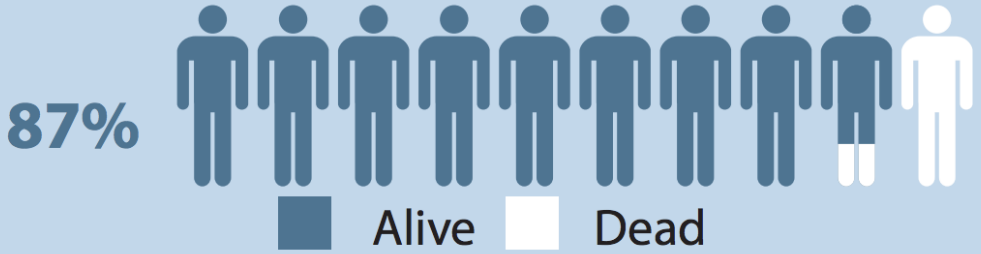
Life *with* an LVAD

How long might I live?

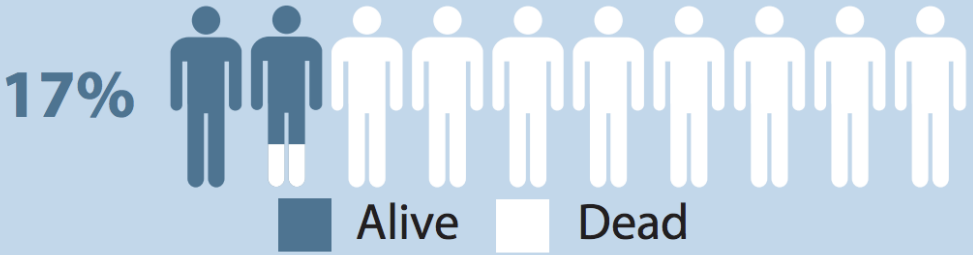
Patients usually live longer with an LVAD. Slightly less than 9 out of 10 patients who got an LVAD are still alive after 1 year. [1,2,3]



Life *without* an LVAD or transplant

How long might I live?

Patients usually do not live as long without an LVAD or transplant. Among the sickest patients, nearly 2 out of 10 who did not get an LVAD are still alive after 1 year.[1]



For patients able to live at home, survival may be higher.

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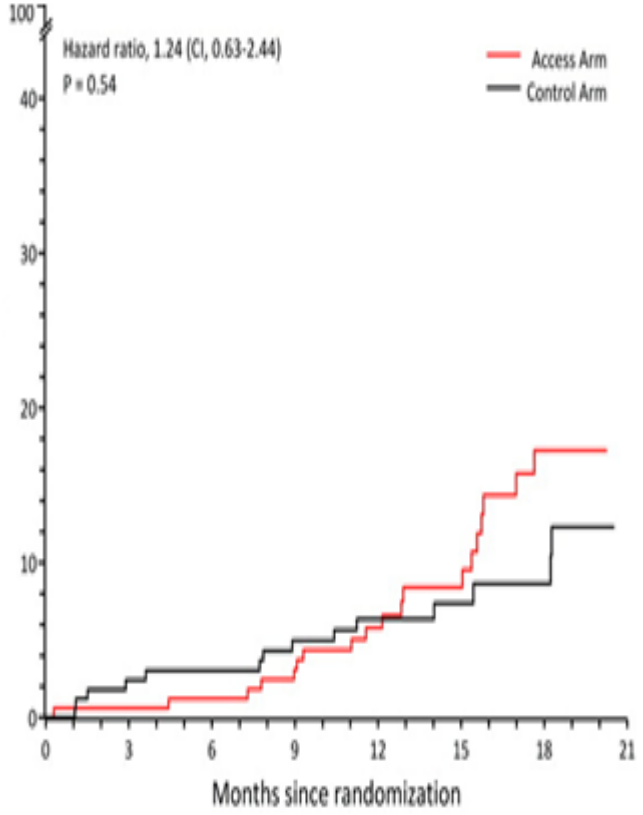
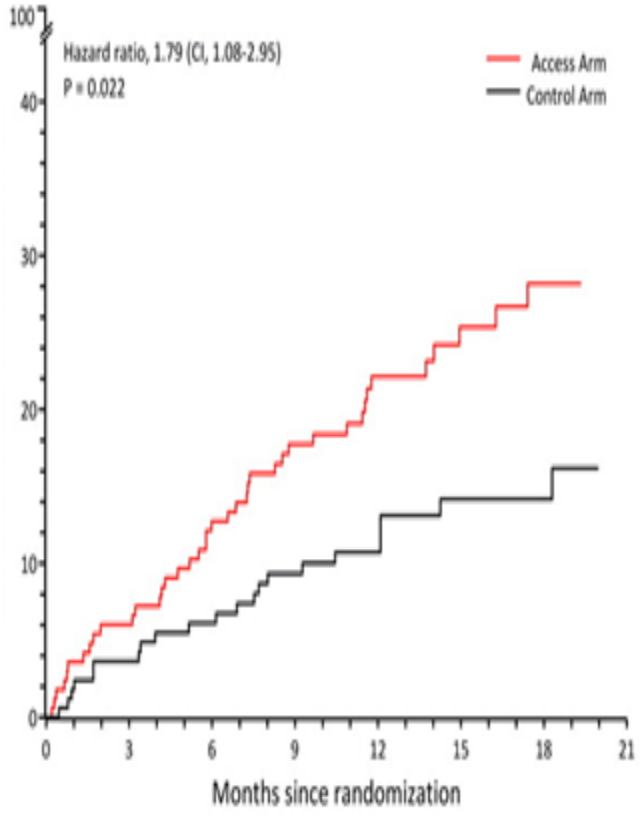
Tele-monitoring

Mortality



Hospitalization



Concordant findings from Tele-HF, TIM-HF, BEAT-HF

Anker et al, AHA Scientific Sessions 2010

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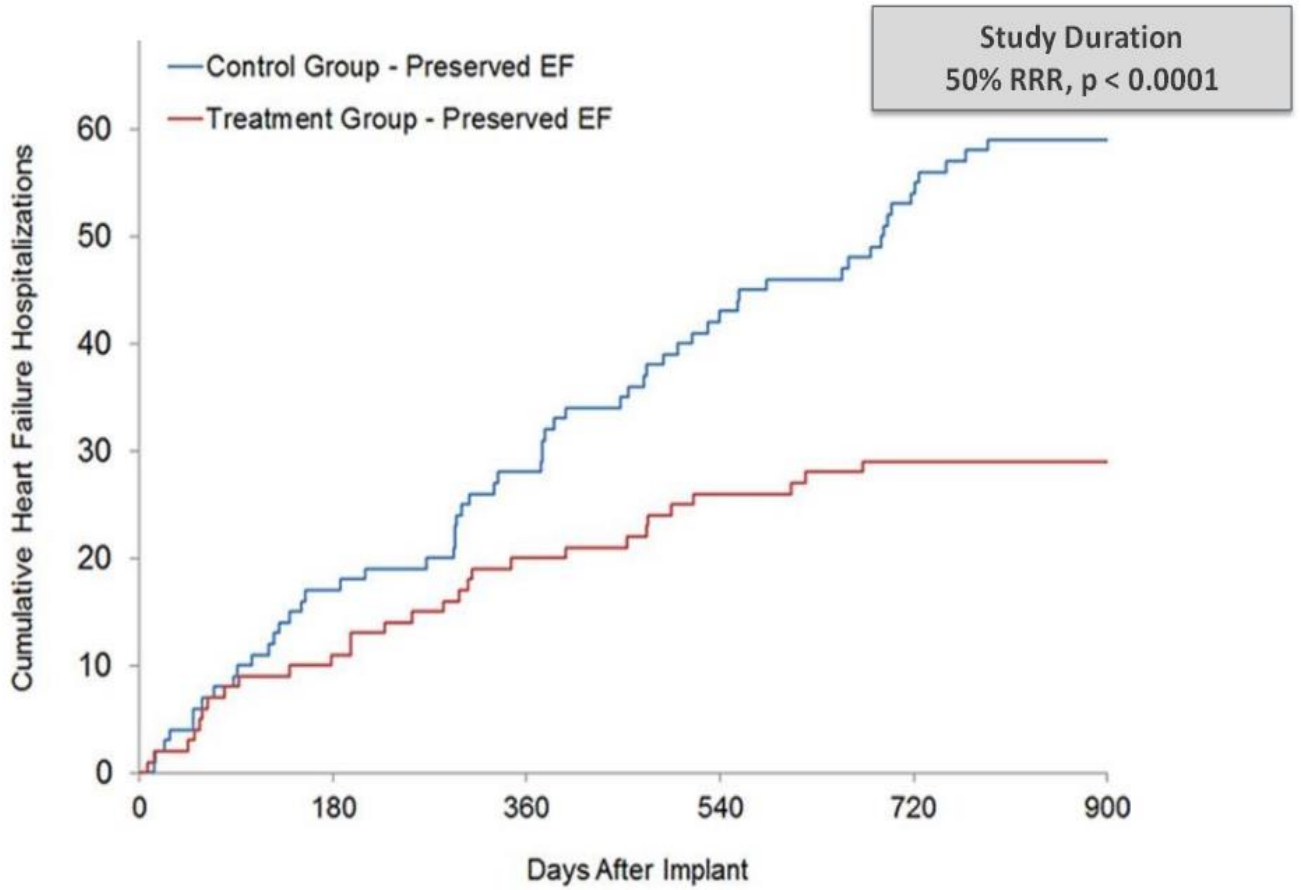
HFpEF



Adamson PB, et al. Circ HF 2014

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Heart Failure with Reduced EF (HFrEF, EF ≤ 40%)

Post - Implant Day 0

*Goal Range is +/- 5mmHg from the target PAD

Post - Implant Day 0 - 7

Post - Implant Day > Day 7

Set PAD Target based on RHC at implant,
Aspirin & Clopidogrel x 1 month, then Aspirin alone (or Coumadin)
Monitor 3x/week
Monitor 2x/week, After 30 Days decrease to weekly

PAD < 5mmHg Below Target

a) If loop diuretic ≥ 20mg/daily, then decrease by half
b) If loop diuretic ≤ 20mg daily, then discontinue
c) Check BMP and repeat PAD in 7 days

PAD < Goal

a) Reassess goal range if renal function stable

PAD At Goal

a) Resume half dose of diuretic
b) Repeat BMP in 7 days

PAD ≥5 and ≤ 10 mmHg Above Target

a) 1 - Double Standing diuretic ***OR*** 2 - Double ACE/ARB dosing, if on maximum dose and EF ≤ 35%, convert to valsartan/sacubitril
b) BMP and repeat PAD in 5 days

PAD At Goal

a) Continue Current Care
b) Repeat PAD in 5 days

PAD > Goal

a) Perform the remaining option above
b) Repeat BMP and PAD in 3 days. If remains > goal, consider repeating above or dose of metolazone

PAD > 10 mmHg Above Target

a) Double up diuretic (if on ≥ 240mg daily, metolazone 2.5mh QOD x 3 doses)
b) Repeat BMP and PAD in 5 days

PAD At Goal

a) Resume home diuretic
b) BMP in 7 days

≥5 and ≤ 10

a) Treat per protocol

≥ 10 above goal

a) If had not tried metolazone, then 2.5 mg QOD x 3 doses
b) If failed 2.5mg, 5mg QOD x doses
c) Consider admission

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