X Reunión. Estado del Arte en
INSUFICIENCIA CARDIACA
PRÁCTICA CLÍNICA Y MODELOS ORGANIZATIVOS
Sede: Hotel Meliá María Pita, A Coruña
A CORUÑA 27-28 SEPTIEMBRE 2024

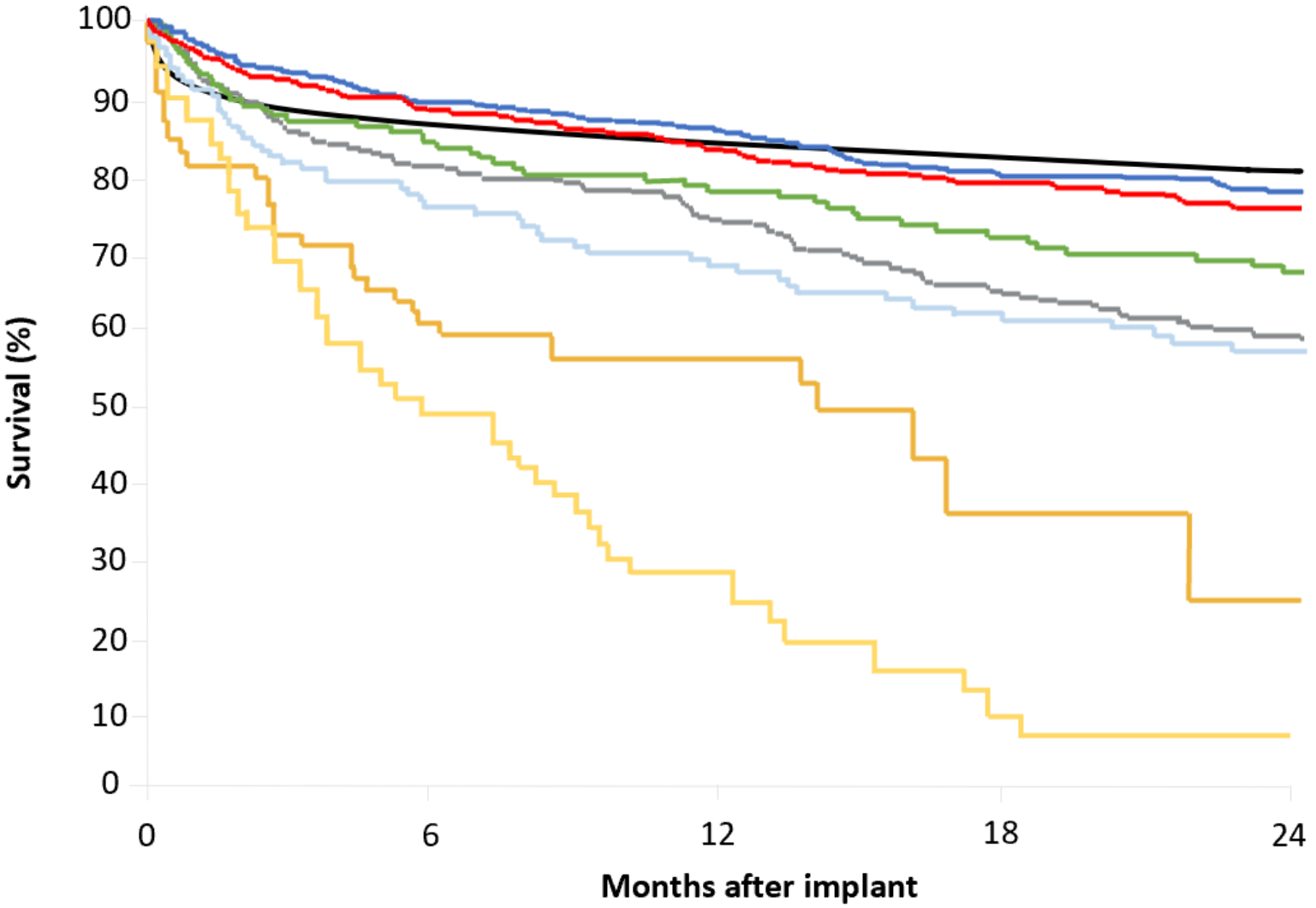
X Meeting. State of the Art in
HEART FAILURE
CLINICAL PRACTICE AND ORGANIZATIONAL MODELS
Venue: Hotel Meliá María Pita, A Coruña
#ACoruñaHF2024
A CORUÑA 27-28 SEPTEMBER 2024

LVADs
How to improve clinical outcomes?

Dr Fernando Riesgo Gil
Director of Cardiac Transplant
Consultant Cardiologist in Heart Failure, Transplantation & MCS
Harefield Hospital
Guy's and St Thomas' NHS Foundation Trust
Royal Brompton & Harefield NHS Foundation Trust

Young Nando proudly wearing a Depor shirt

Does LVAD therapy Work?



82% - Heart Transplant (2017)*[1]

79% - HeartMate 3 LVAD (2019)[2]

76% - HeartMate II™ LVAD (2019)[2]

68% - HeartMate II LVAD (2017)[3]

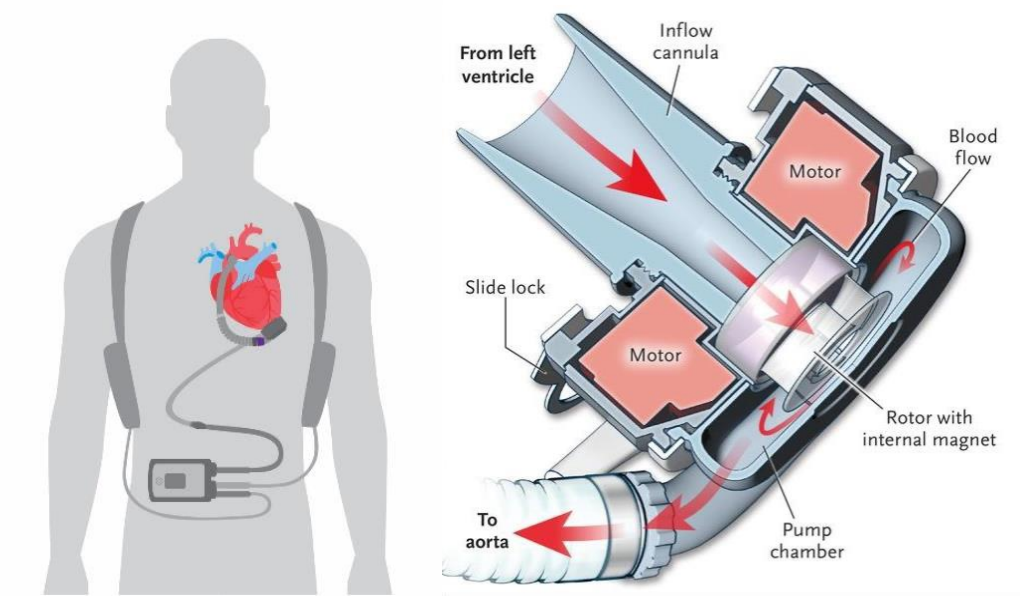
60% - HVAD† LVAD (2017)[3]

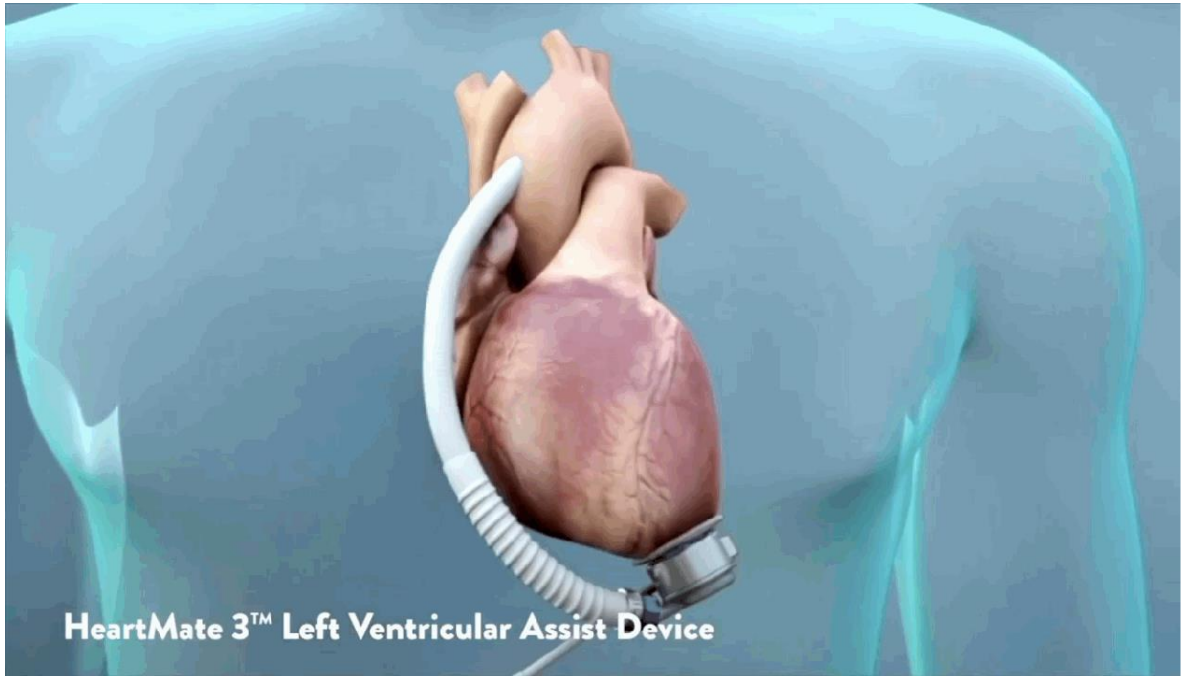
58% - HMII DT (2009)[4]

24% - HeartMate XVE (2009)[4]

8% - OMM – REMATCH (2001)[5]

HeartMate 3 Left Ventricular Assist Device





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

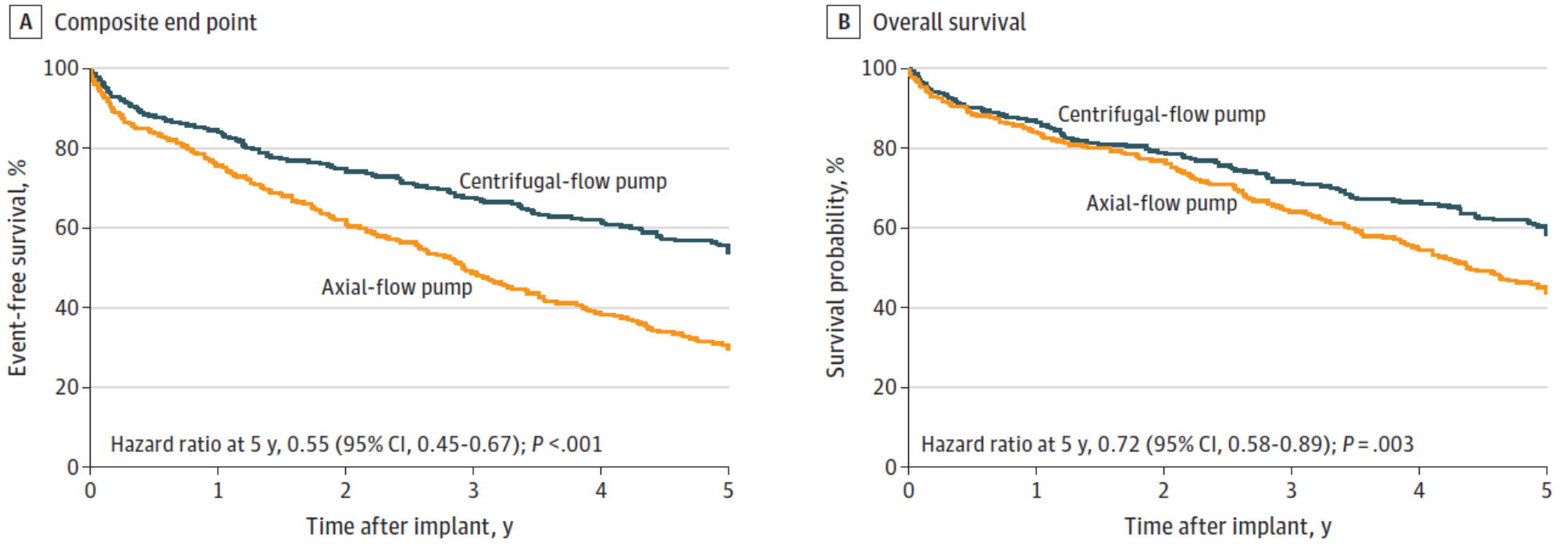
- **Wide** blood-flow passages to reduce shear stress
- **Frictionless** with absence of mechanical bearings
- **Intrinsic Pulse** designed to reduce stasis and avert thrombosis

Bourque, Cotter, Dague, et al, *ASAIO J* 2016;62:375-83
Mehra, Naka, Uriel, et al, *N Engl J Med.* 2017; 376:440-450

Mehra, Goldstein, Uriel, et al. *N Engl J Med.* 2018;378:1386-1395

Outcomes Heartmate 3 – MOMENTUM 3

Figure 2. Composite End Point and Overall Survival in a Study of 5-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices (LVADs)



No. of patients

Centrifugal-flow pump	515	373	280	208	177	138
Axial-flow pump	505	321	223	147	106	71

515	383	289	213	184	141
505	339	247	165	124	85

Mehra MR, et al. JAMA. 2022 Sep 27;328(12):1233-1242

Improve Short Term Outcomes

- Patient selection
- Patient optimization
- Surgical implant
- Anaesthetic Management
- Post OP / ITU Management

Patient Selection

- Severe LV systolic dysfunction and dilatation
- Refractory HF despite adequate guideline-based medical management
- **Optimal RV function**
- Preserved end-organ function
- *Exit strategy (Potentially suitable for HTx – UK as no DT option)*
- Motivated / Able to understand pros and cons
- Good social support / Excellent compliance
- No comorbidities with significant impact on survival, functional capacity and quality of life

Contraindications

ABSOLUTE

- Recent or evolving stroke
- Neurological deficits impairing the ability to manage device
- Severe biventricular failure
- Active systemic infections or major chronic risk for infection
- Severe pulmonary dysfunction (FEV1 <1 l)
- Impending renal or hepatic failure
- Multi organ failure
- Inability to tolerate anticoagulation - bleeding diathesis
- Significant underlying psychiatric illness

RELATIVE

- Chronic kidney disease with serum creatinine level > 3mg/dl
- Severe malnutrition (BMI < 21kg/m^2 in males and < 19kg/m^2 in women
- Morbid obesity (BMI >40 kg/m^2)
- Severe mitral stenosis or moderate aortic insufficiency
- Age > 70 years, unless minimal or no clinical risk factors

Important Factors To Consider

- Is Pulmonary Hypertension a problem?

- Structural Heart Disease – what is important?
  - AR
  - MS
  - Intracardiac shunt

- The RV Dysfunction Mystery
  - Female gender
  - Small Size
  - DCM
  - Ventilatory support
  - Poor renal Function
  - Abnormal Liver Function
  - Echocardiogram: reduced TAPSE, dilated RV, severe TR, impaired RV/RA strain
  - RHC: CVP >14 / CVP/PCWP >0.6 / RVSWi <5 / PAPi <1.8
  - RVFS / Michigan Score

Outcomes Heartmate 3 – Risk Prediction

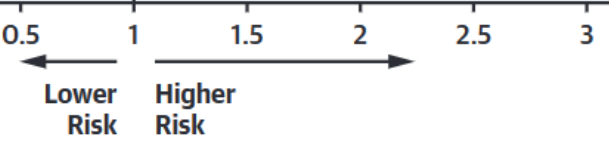
CENTRAL ILLUSTRATION Prediction of Survival After Implantation of a Fully Magnetically Levitated Left Ventricular Assist Device: The HeartMate 3 Survival Risk Score

The HM3RS provides individual survival prediction at 1 and 2 years post-implant

The HM3RS contains 6 predictors

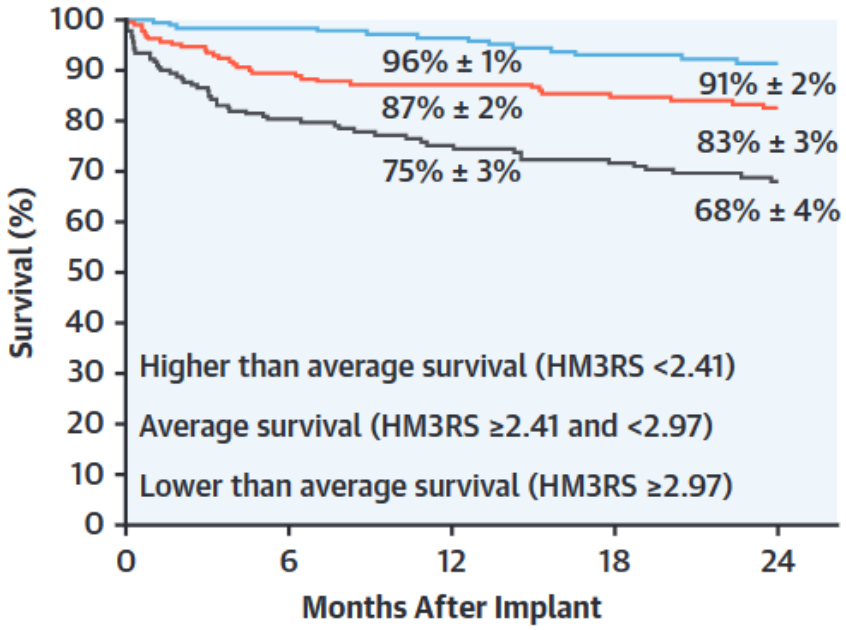
- 2 demographic variables
- 2 chemistry labs
- 1 echocardiogram parameter
- 1 invasive hemodynamic parameter

Baseline Characteristic	Parameter Estimate	Hazard Ratio (95% CI)	*P* Value
Age in years	0.03496		<0.001
Prior valve procedure or CABG	0.53029		<0.001
Na in mmol/L	−0.04112		0.005
BUN in mg/dL	0.01093		0.003
LVEDD <5.5 cm	0.62149		0.004
RAP/PCWP >0.6	0.44785		0.002



Validation AUC 0.76 at 1 year and 0.71 at 2 years

HM3RS =
0.03496 × (age in years) + 0.53029 (if prior CABG or valve procedure) − 0.04112 × (Na in mmol/L − 136) + 0.01093 × (BUN in mg/dL) + 0.62149 (if LVEDD <5.5 cm) + 0.44785 (if RAP/PCWP >0.6)



- Facilitate shared decision making
- Refine bridge-to-transplantation strategies
- Enhance implementation of LVAD therapy in advanced HF

Mehra MR, et al. JACC Heart Fail. 2022 Dec;10(12):948-959.

Hemodynamic Optimization Pre Implant

Medical Optimization

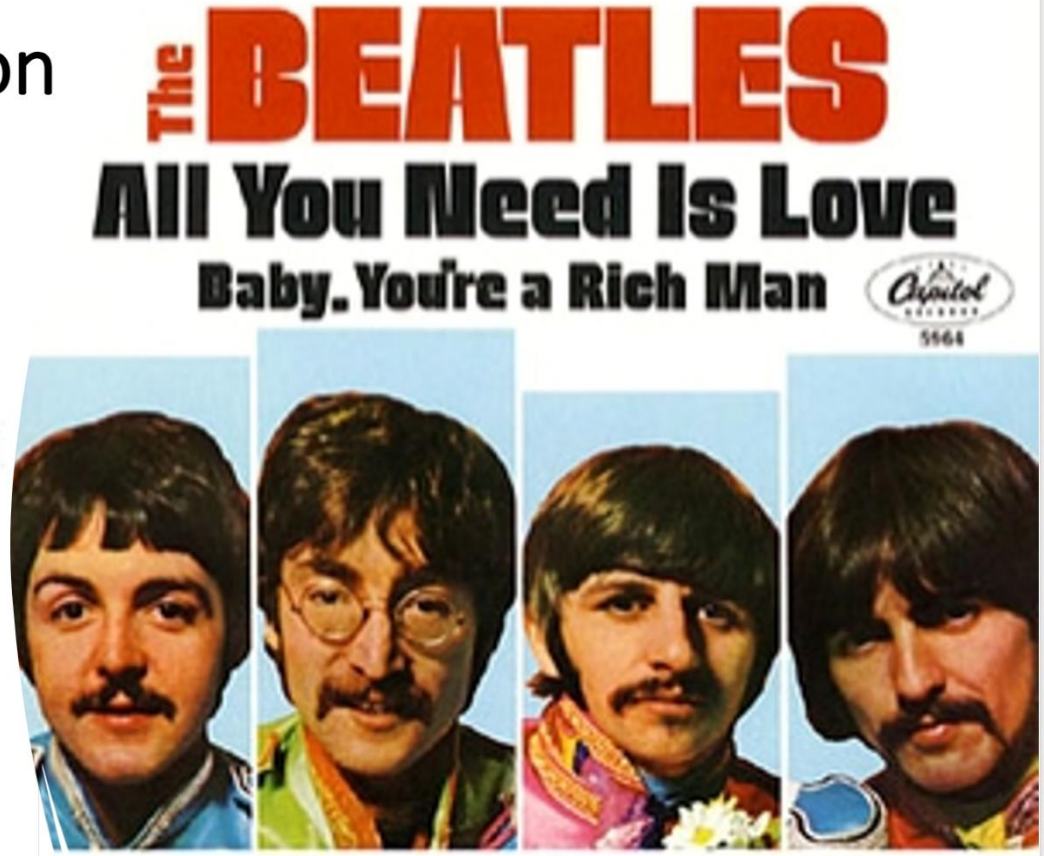
All You Need Is:

Lower vascular resistance

Optimize rhythm

correct **V**olume status

Enhance contractility



Targets:

- PCWP <15 - Diuretics

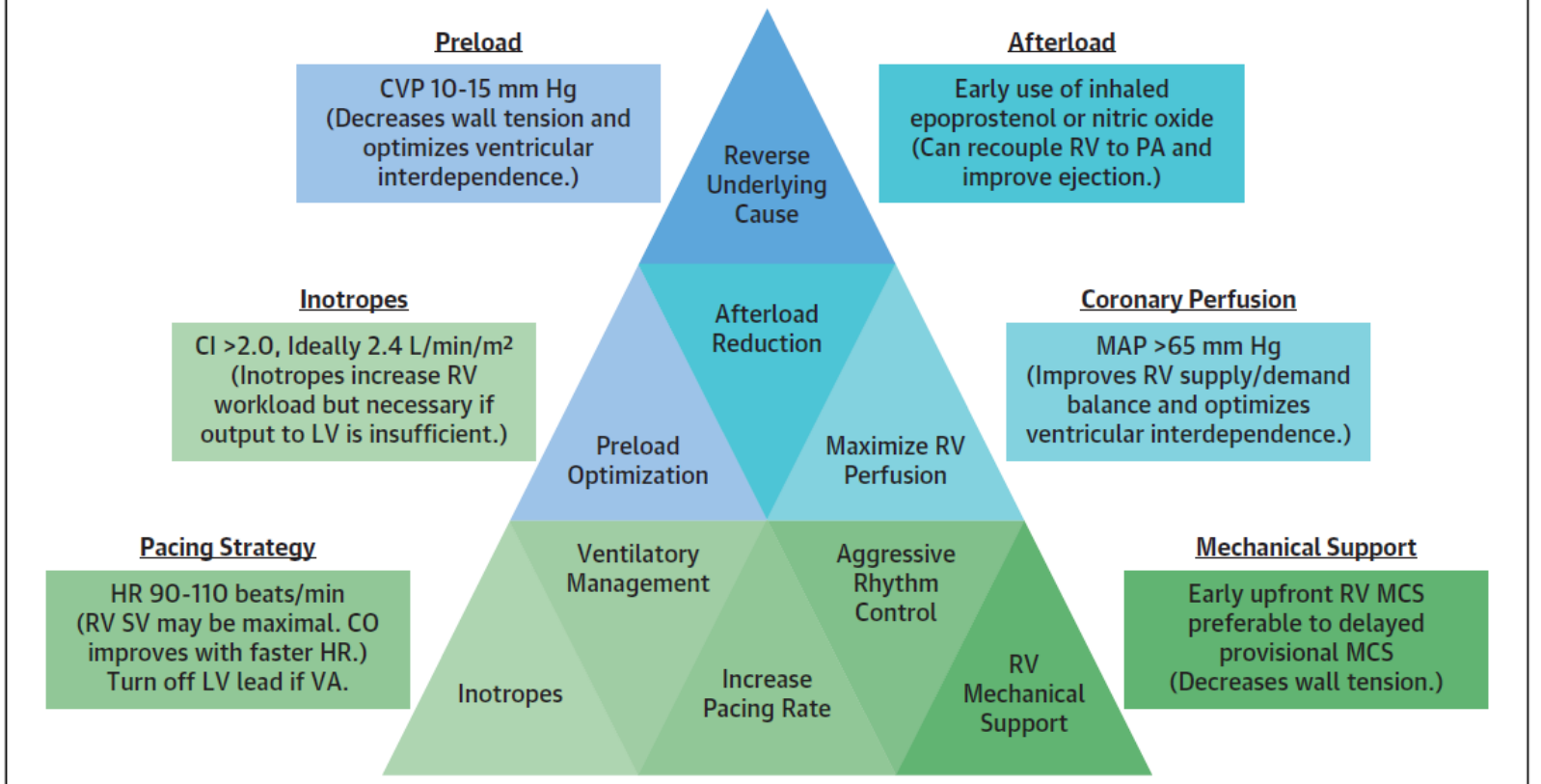
RAP <10 - Diuretics

SVR 800-1200 - Systemic Vasodilators

CI >2.2 - Inotropes

Acute RV Failure Management

FIGURE 1 Postoperative Management of Right-Sided Heart Failure After Left Ventricular Assist Device Placement

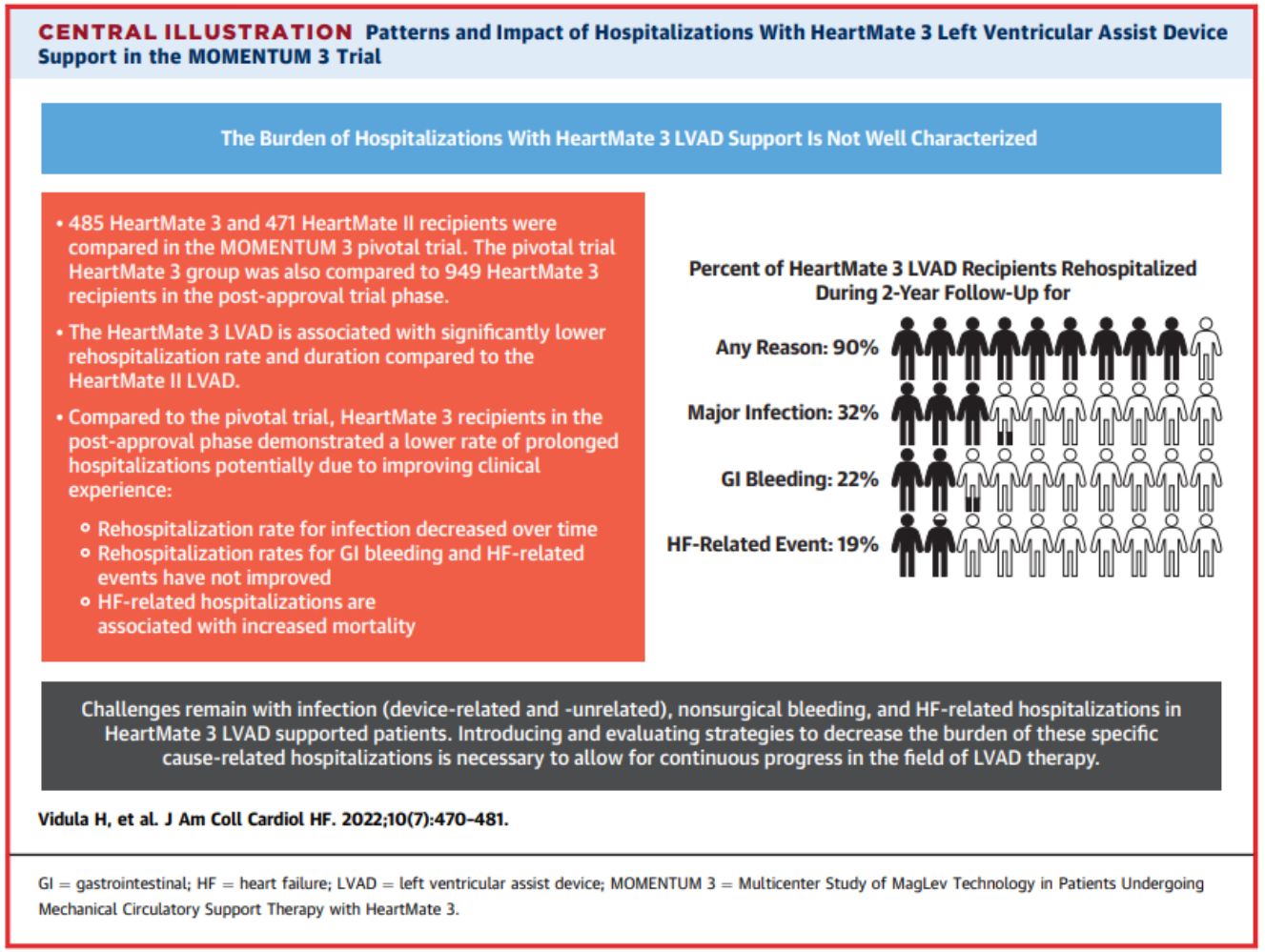


Postoperative management strategies and therapeutic targets to address right-sided heart failure. CI = cardiac index; CO = cardiac output; CVP = central venous pressure; HR = heart rate; LV = left ventricle or left ventricular; MAP = mean arterial pressure; MCS = mechanical circulatory support; PA = pulmonary artery; RV = right ventricle or right ventricular; SV = stroke volume; VA = ventricular arrhythmia.

Grinstein J et al. JACC Volume82,Issue1, 4 July 2023, Pages 70-81

Improve Long Term Outcomes

- HCRAE
  - Pump Thrombosis
  - Bleeding
- Heart Failure
- HDRAE
  - RV Failure
  - Aortic Regurgitation
- Device Related Infection
- Mechanical Problems



CENTRAL ILLUSTRATION Patterns and Impact of Hospitalizations With HeartMate 3 Left Ventricular Assist Device Support in the MOMENTUM 3 Trial

The Burden of Hospitalizations With HeartMate 3 LVAD Support Is Not Well Characterized

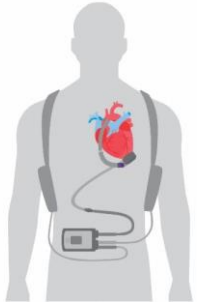
- 485 HeartMate 3 and 471 HeartMate II recipients were compared in the MOMENTUM 3 pivotal trial. The pivotal trial HeartMate 3 group was also compared to 949 HeartMate 3 recipients in the post-approval trial phase.
- The HeartMate 3 LVAD is associated with significantly lower rehospitalization rate and duration compared to the HeartMate II LVAD.
- Compared to the pivotal trial, HeartMate 3 recipients in the post-approval phase demonstrated a lower rate of prolonged hospitalizations potentially due to improving clinical experience:
  - Rehospitalization rate for infection decreased over time
  - Rehospitalization rates for GI bleeding and HF-related events have not improved
  - HF-related hospitalizations are associated with increased mortality

Percent of HeartMate 3 LVAD Recipients Rehospitalized During 2-Year Follow-Up for

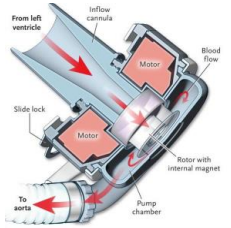
Challenges remain with infection (device-related and -unrelated), nonsurgical bleeding, and HF-related hospitalizations in HeartMate 3 LVAD supported patients. Introducing and evaluating strategies to decrease the burden of these specific cause-related hospitalizations is necessary to allow for continuous progress in the field of LVAD therapy.

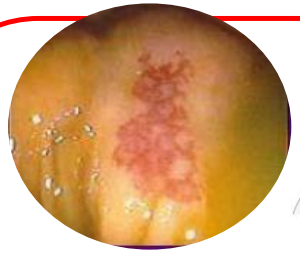
Vidula H, et al. J Am Coll Cardiol HF. 2022;10(7):470-481.

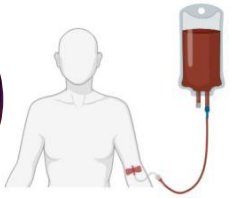
GI = gastrointestinal; HF = heart failure; LVAD = left ventricular assist device; MOMENTUM 3 = Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate 3.

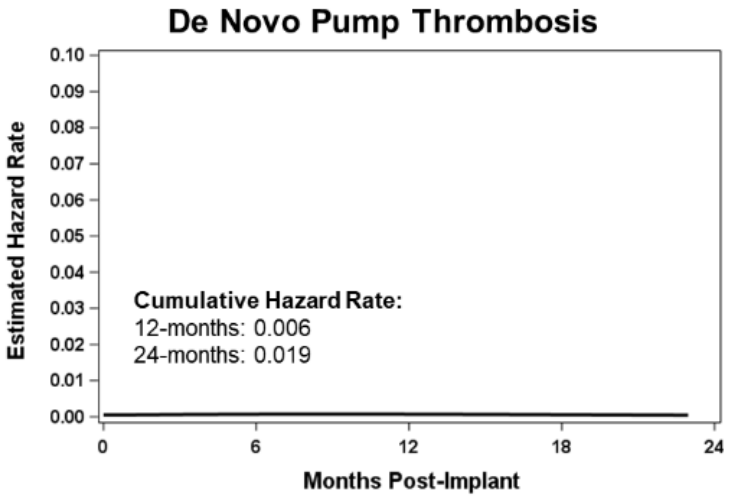


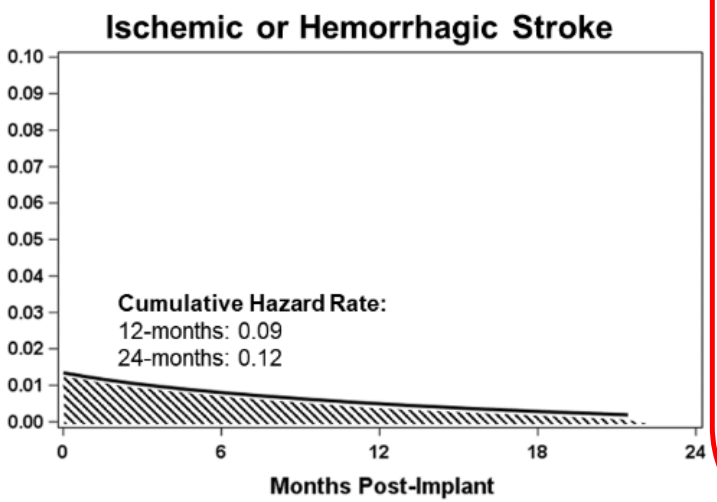
HEMOCOMPATIBILITY RELATED OUTCOMES

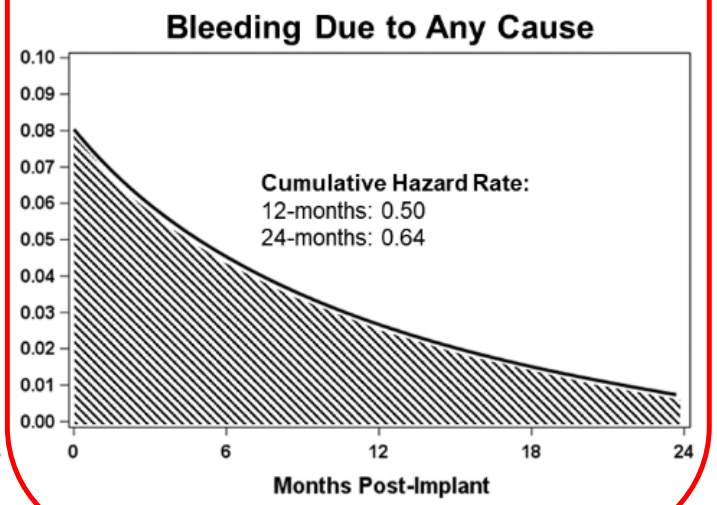










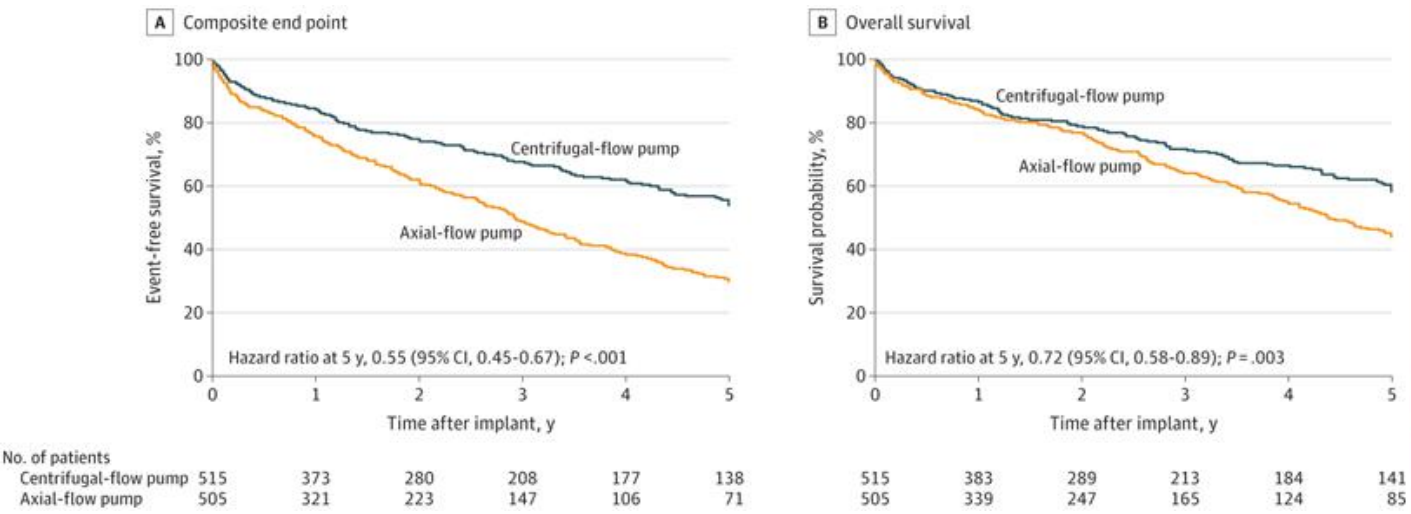


Opportunity to Reduce Residual Risk

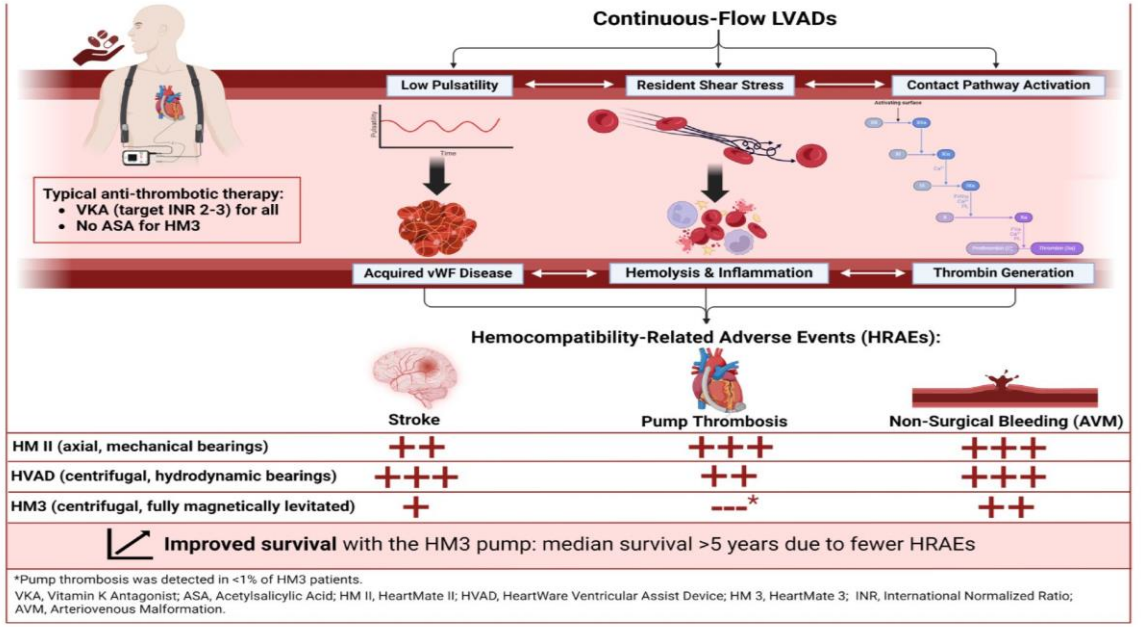
Mehra MR, Crandall DL, Gustafsson F, et al., *Eur J Heart Fail*. 2021;23(7):1226-1237

HCRAE: Thromboembolism

ARIES Trial



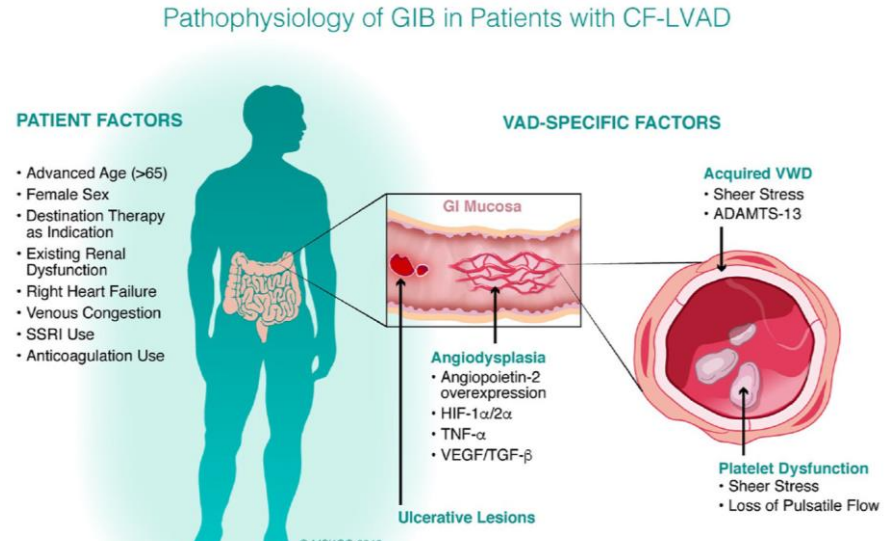
Mehra M et al. JAMA. 2023;330(22):2171-2181. doi:10.1001/jama.2023.23204

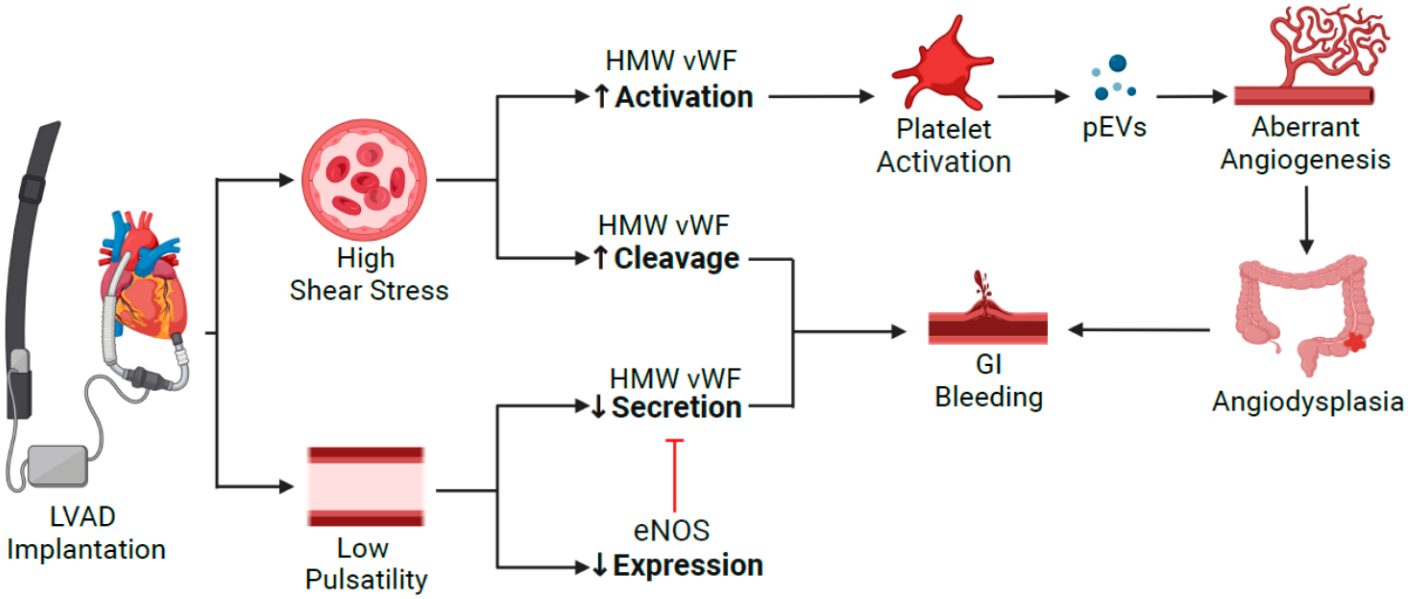


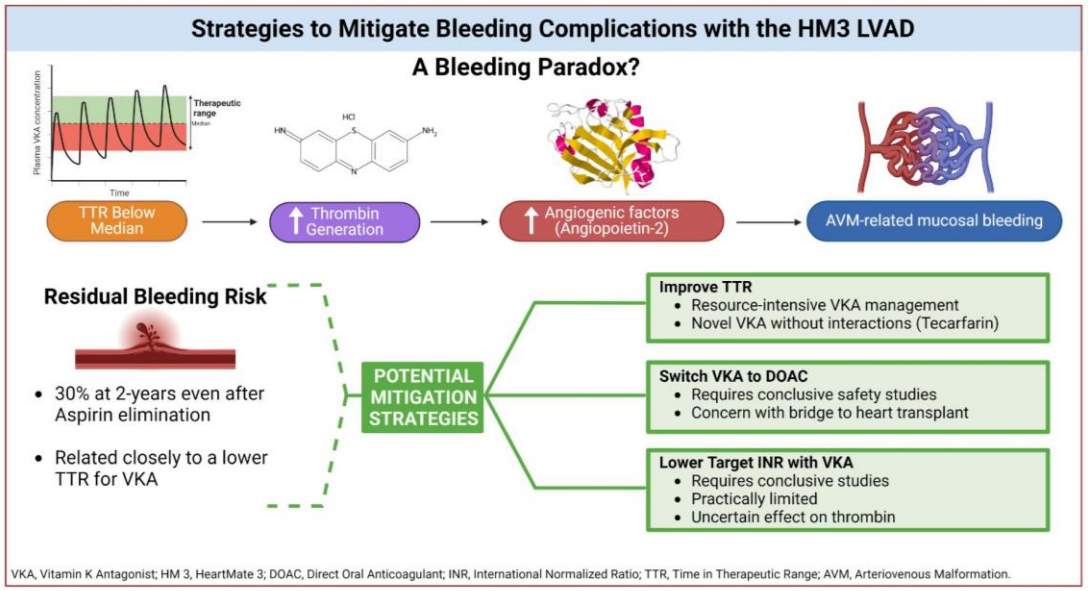
Cikes M, Yuzefpolskaya M, Gustafsson F, Mehra MR. *J Card Fail.* 2024; S1071-9164(24)00318-X.

- Most centers have adopted a VKA only regime without antiplatelet therapy unless there are additional indications
- Important to review indications to not overuse Aspirin

HCRAE: Bleeding



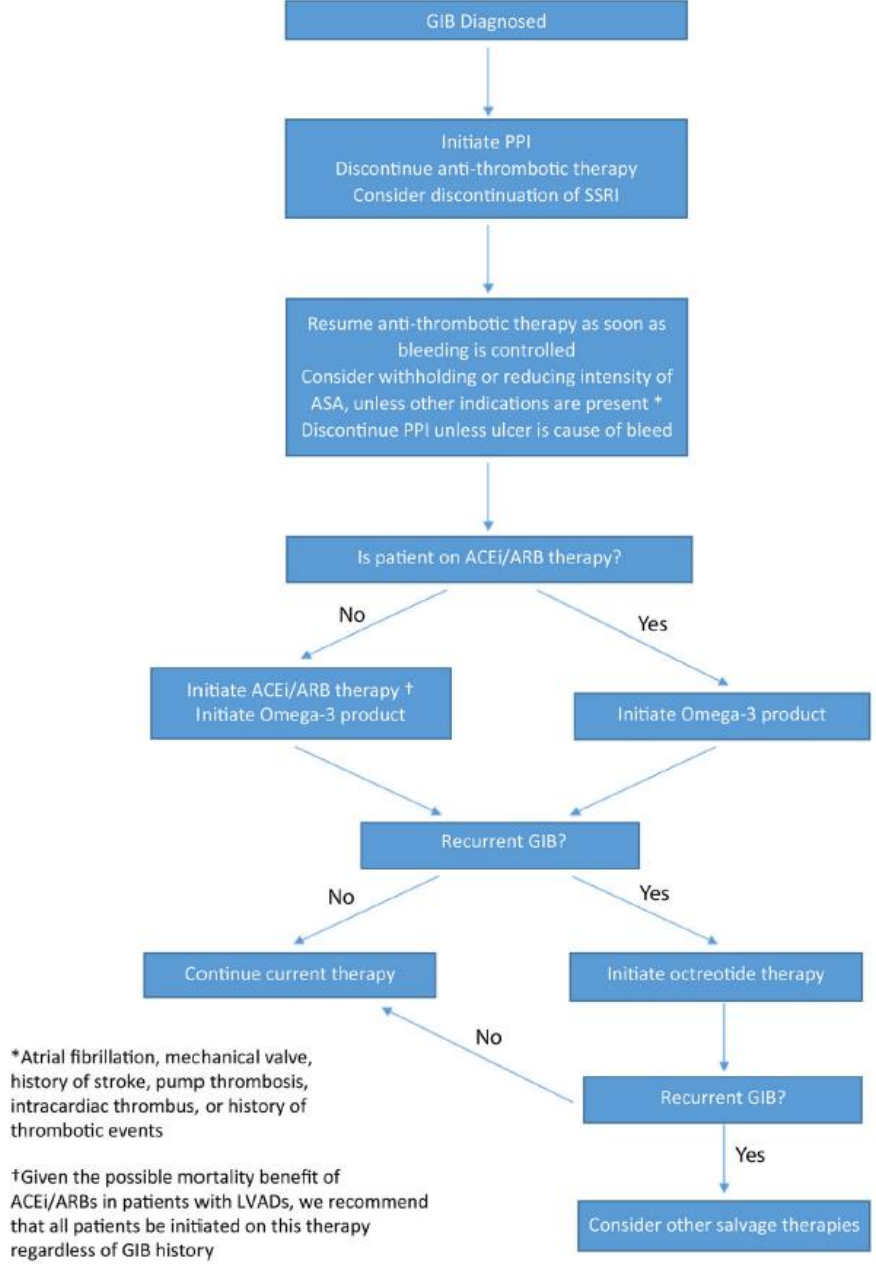




Cikes M, Yuzefpolskaya M, Gustafsson F, Mehra MR. *J Card Fail*. 2024; S1071-9164(24)00318-X.

HCRAE: Bleeding

- **Endoscopic Therapy**
- **Pharmacological Options:**
  - ACEI/ARB
  - Omega 3
  - *Digoxin*
  - *Doxycycline*
  - Somatostatin analogues:
    - Octreotide
    - Lanreotide
  - Thalidomide
  - Bevacizumab - anti–VEGF



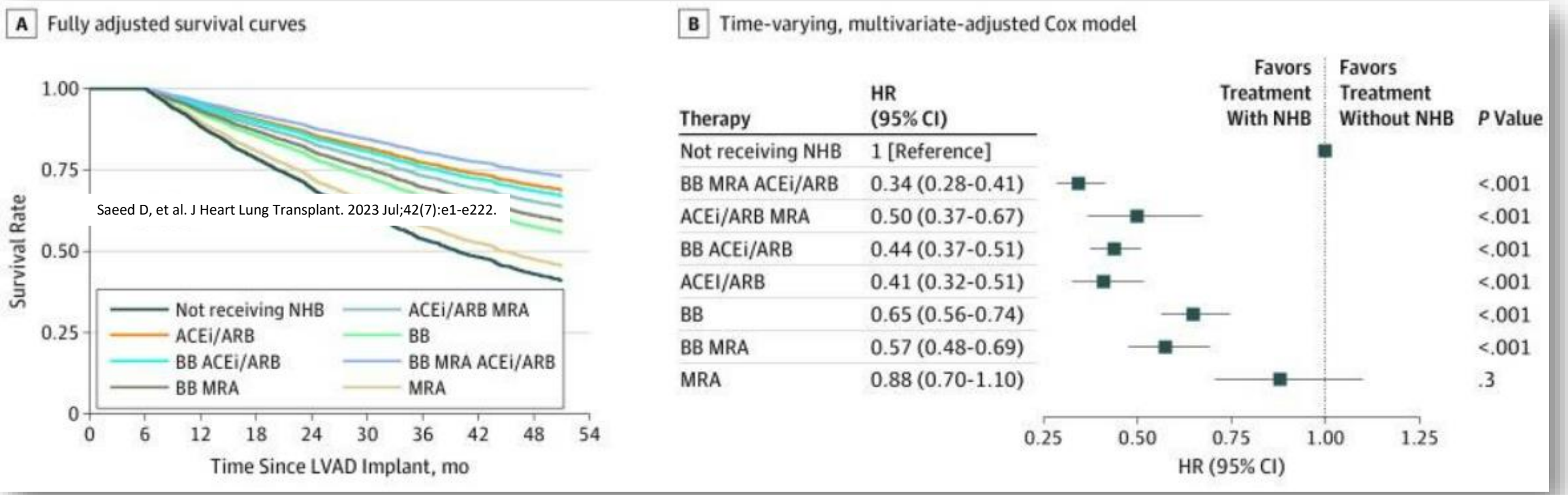
Gurvits GE et al. World J Gastroenterol 2017 June 14; 23(22): 3945-3953

Heart Failure Therapy

ISHLT Guidelines 2023

2. An ACE-inhibitor or ARB or ARNI should be used as tolerated and are warranted as disease/natural history-modifying agents.
Level of Evidence B. *(Modified)*
3. Beta-blockers should be used as tolerated and are warranted as disease/natural history-modifying agent and/or for rate control in patients with tachyarrhythmias.
Level of Evidence C *(Modified)*
4. *Continuing approval without change*

McCullough M, et al. JAMA Cardiol. 2020 Feb 1;5(2):175-182.



Saeed D, et al. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

Therapy	HR (95% CI)	P Value
Not receiving NHB	1 [Reference]	
BB MRA ACEi/ARB	0.34 (0.28-0.41)	<.001
ACEi/ARB MRA	0.50 (0.37-0.67)	<.001
BB ACEi/ARB	0.44 (0.37-0.51)	<.001
ACEI/ARB	0.41 (0.32-0.51)	<.001
BB	0.65 (0.56-0.74)	<.001
BB MRA	0.57 (0.48-0.69)	<.001
MRA	0.88 (0.70-1.10)	.3

Journal of the American Heart Association

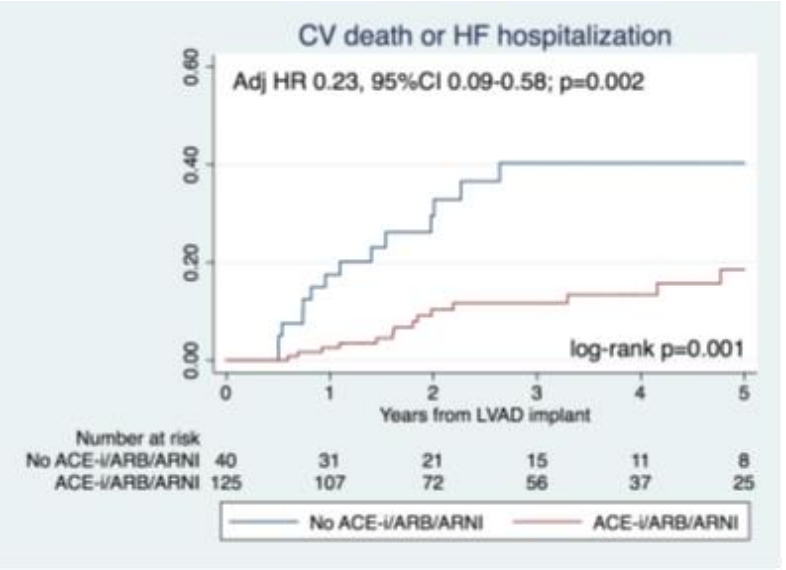
Volume 13, Issue 9, 7 May 2024

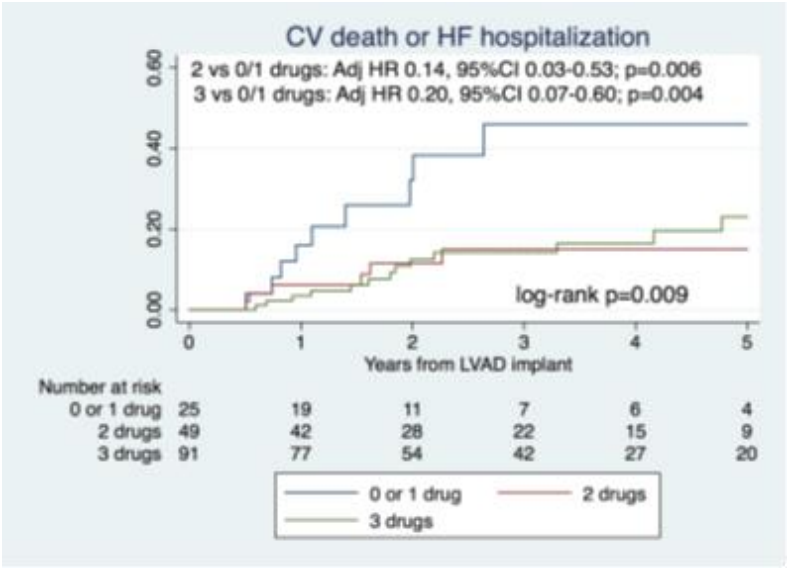
https://doi.org/10.1161/JAHA.123.032617

ORIGINAL RESEARCH

Association of Renin-Angiotensin-Aldosterone System Inhibitors With Clinical Outcomes, Hemodynamics, and Myocardial Remodeling Among Patients With Advanced Heart Failure on Left Ventricular Assist Device Support

Guglielmo Gallone, MD ; Javier Ibero, MD ; Andrew Morley-Smith, MD; Maria Monteagudo Vela, MD ; Francesca Fiorelli, MD; Mailen Konicoff, MD ; Gemma Edwards, RN; Binu Raj, RN ; Mayooran Shanmuganathan, MD ; Stefano Pidello, MD ; Simone Frea, MD ; Gaetano Maria De Ferrari, MD; Vasileios Panoulas, MD ; Ulrich Stock, MD ; Christopher Bowles, MD ; John Dunning, MD ; Fernando Riesgo Gil, MD





A detailed explantation assessment protocol for patients with left ventricular assist devices with myocardial recovery

María Monteagudo Vela [a,*], Verónica Rial Bastón[b], Vasileios Panoulas [b,c], Fernando Riesgo Gil[b] and Andre Simon[a]

[a] Department of Cardiothoracic Transplantation and Mechanical Circulatory Support, Harefield Hospital, Royal Brompton and Harefield NHS Foundation Trust, London, UK
[b] Department of Cardiology, Harefield Hospital, Royal Brompton and Harefield NHS Foundation Trust, London, UK
[c] Cardiovascular Sciences, National Heart and Lung Institute, Imperial College London, London, UK

* Corresponding author. Cardiothoracic and Transplant Surgeon, Royal Brompton and Harefield NHS Foundation Trust, Hill End Road, Harefield, Middlesex UB9 6JH, UK. Tel: +44-1895828892; e-mail: m.monteagudo-vela@rbht.nhs.uk (M. Monteagudo Vela).

Received 8 May 2020; received in revised form 8 September 2020; accepted 4 October 2020

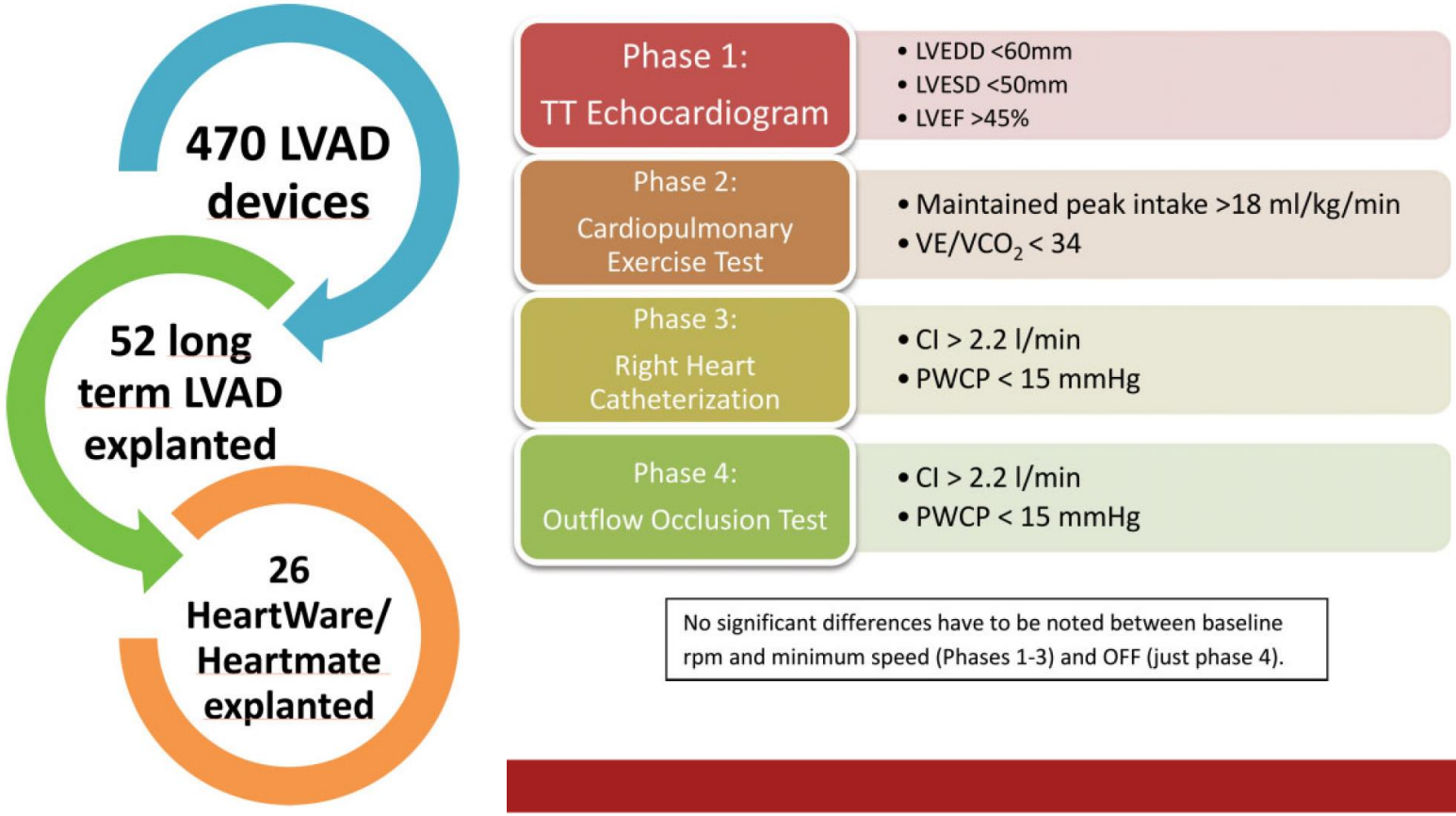
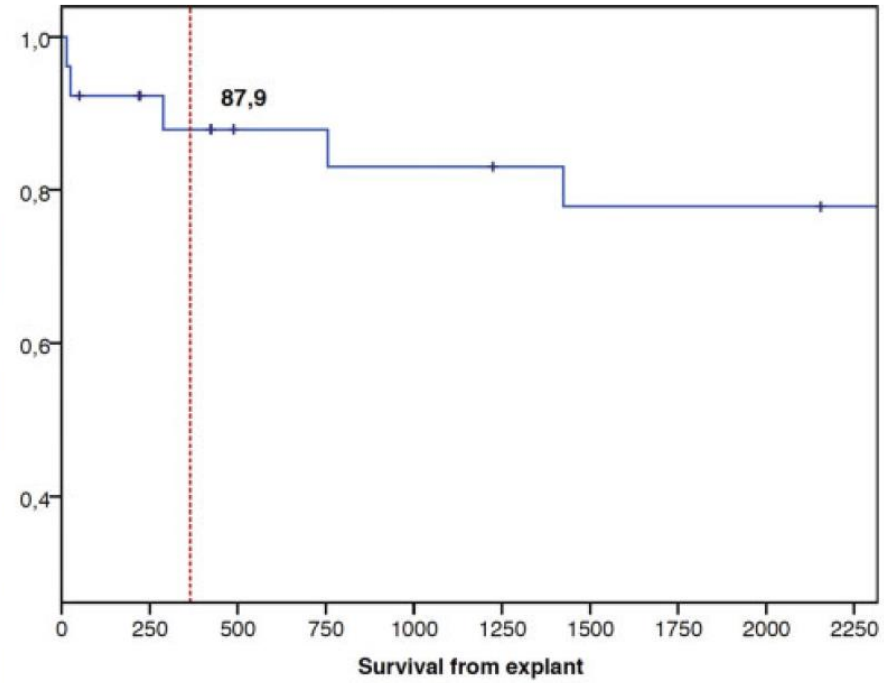


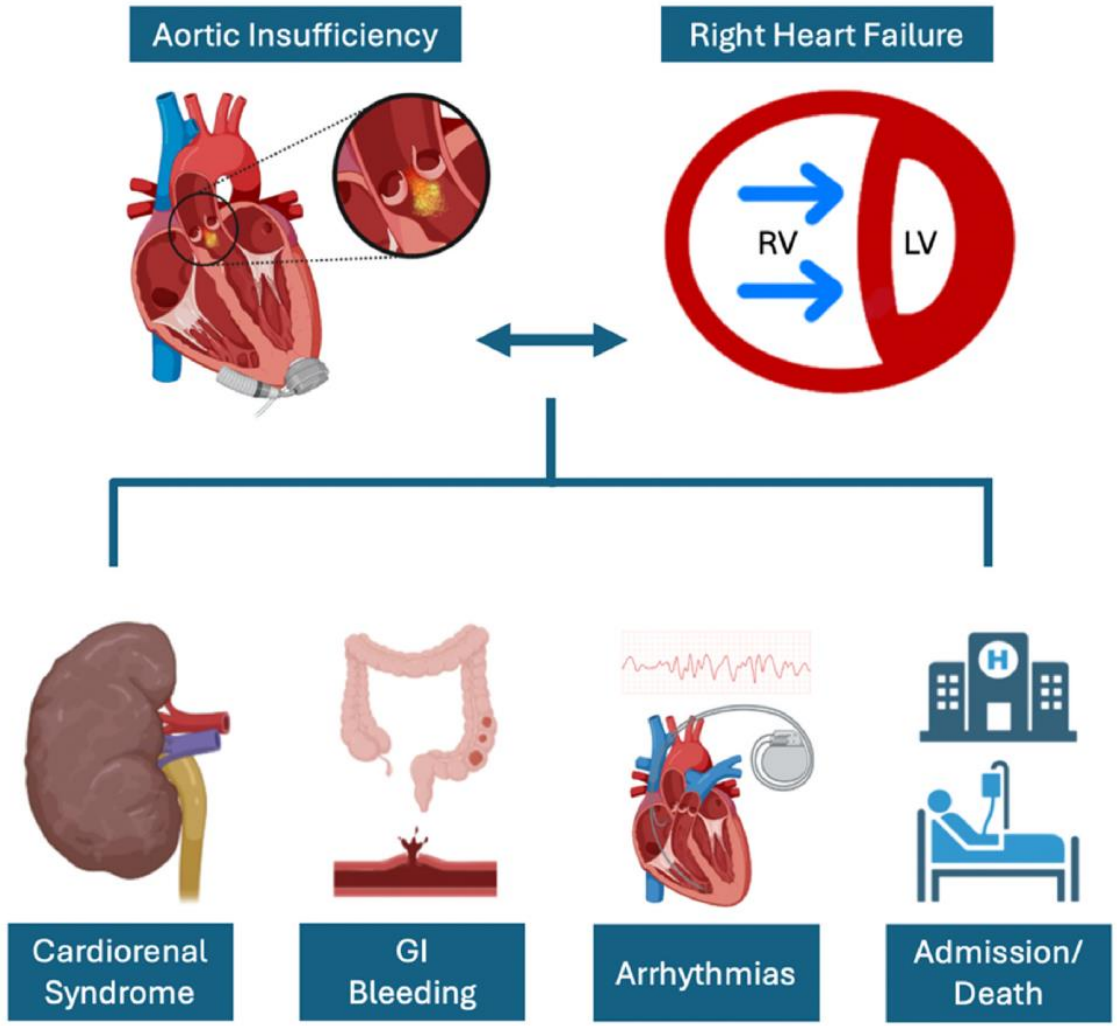
Figure 1: Inclusion criteria. LVAD: left ventricular assist device.

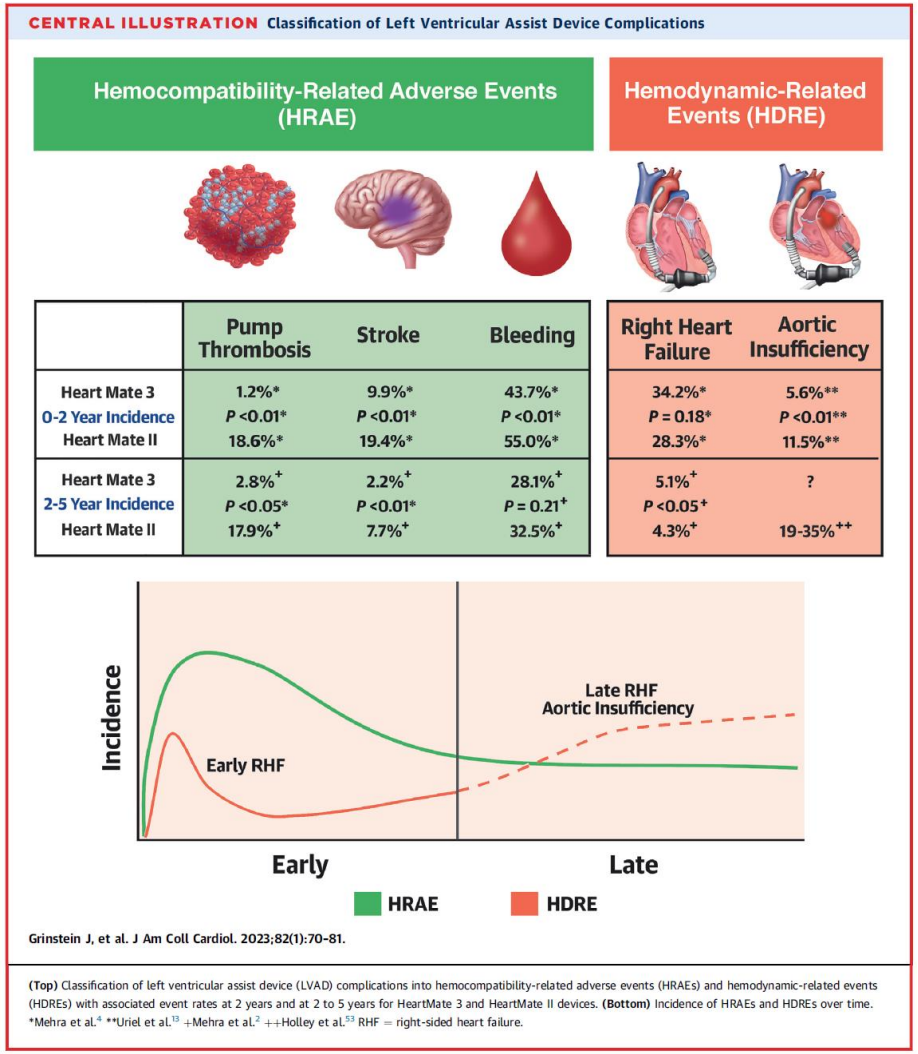


Time (days)	0	365	1825
N at risk	26	20	15

igure 5: Survival from explant shown in days.

Hemodynamic Related Adverse Events





CENTRAL ILLUSTRATION Classification of Left Ventricular Assist Device Complications

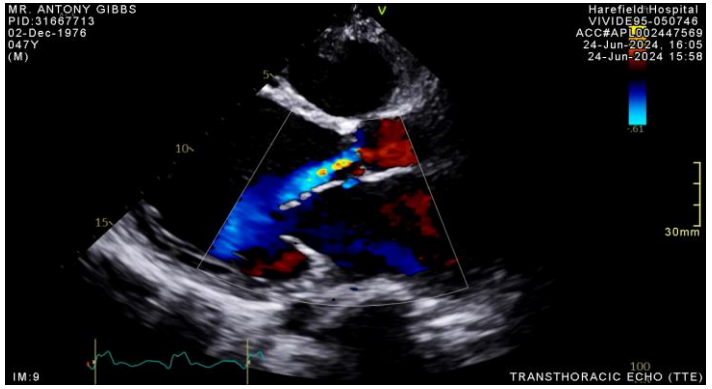
	Hemocompatibility-Related Adverse Events (HRAE)			Hemodynamic-Related Events (HDRE)	
	Pump Thrombosis	Stroke	Bleeding	Right Heart Failure	Aortic Insufficiency
Heart Mate 3 0-2 Year Incidence Heart Mate II	1.2%* *P* <0.01* 18.6%*	9.9%* *P* <0.01* 19.4%*	43.7%* *P* <0.01* 55.0%*	34.2%* *P* = 0.18* 28.3%*	5.6%** *P* <0.01** 11.5%**
Heart Mate 3 2-5 Year Incidence Heart Mate II	2.8%+ *P* <0.05* 17.9%+	2.2%+ *P* <0.01* 7.7%+	28.1%+ *P* = 0.21+ 32.5%+	5.1%+ *P* <0.05+ 4.3%+	? 19-35%++

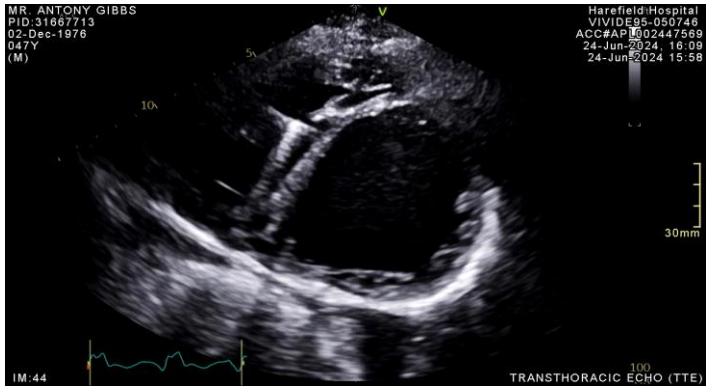
Grinstein J, et al. J Am Coll Cardiol. 2023;82(1):70-81.

(Top) Classification of left ventricular assist device (LVAD) complications into hemocompatibility-related adverse events (HRAEs) and hemodynamic-related events (HDREs) with associated event rates at 2 years and at 2 to 5 years for HeartMate 3 and HeartMate II devices. **(Bottom)** Incidence of HRAEs and HDREs over time. *Mehra et al.[4] **Uriel et al.[13] +Mehra et al.[2] ++Holley et al.[53] RHF = right-sided heart failure.

Saeed, Diyar et al.10.1016/j.healun.2024.06.018

Hemodynamic Related Adverse Events





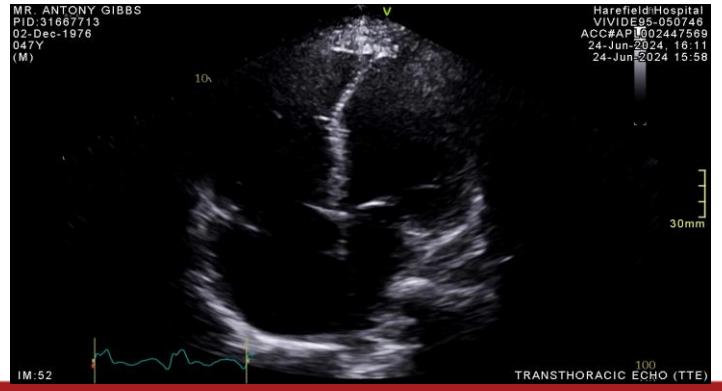
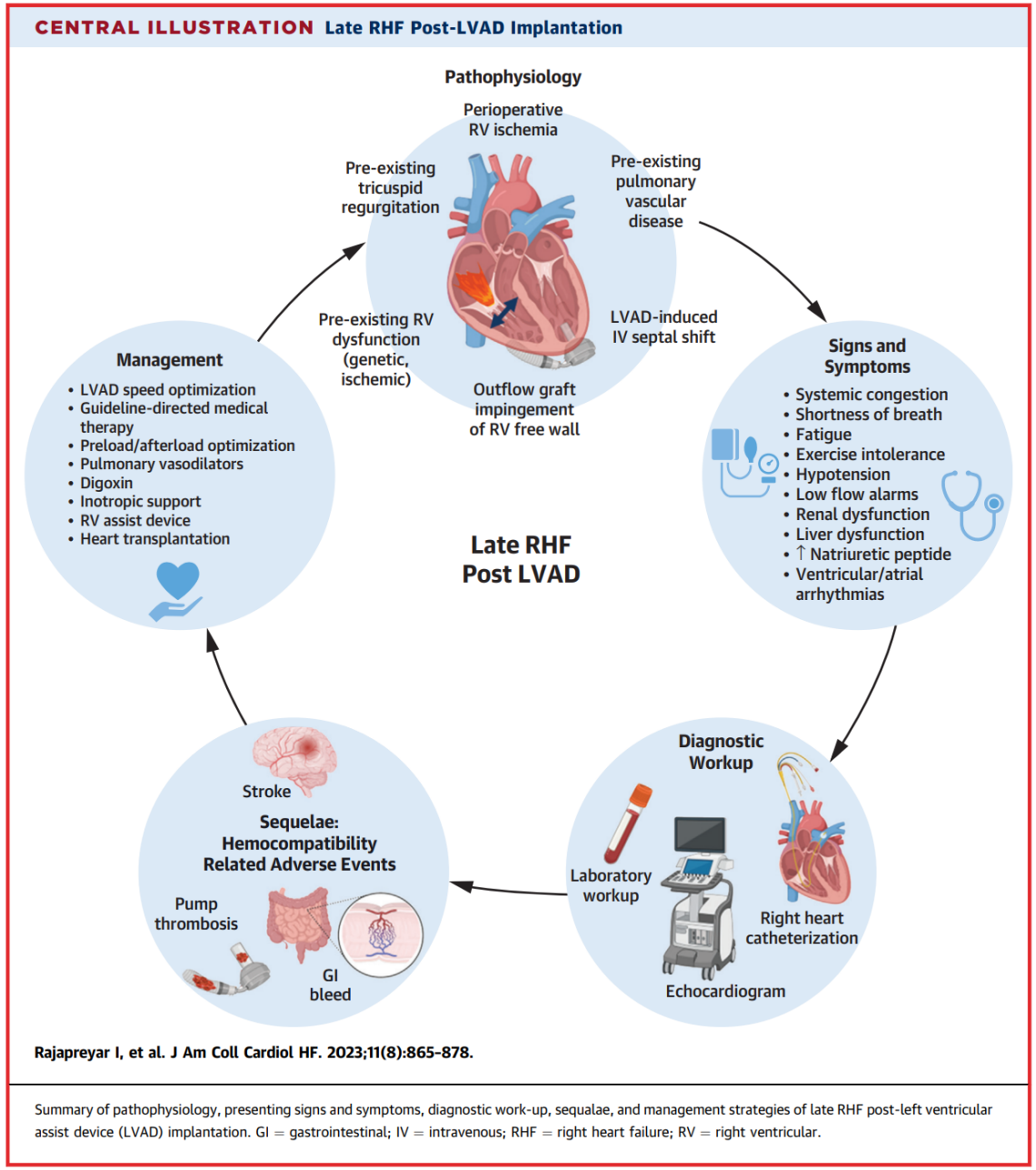


Table. **The Hemodynamic Classification System**

	Clinical phenotypes		
Intensity	Isolated AI	Isolated RHF	Combined AI and RHF
Tier I (mild)	Mild/moderate or greater AI on TTE with MAP <80 mm Hg	Moderate or greater RV dysfunction on TTE	Mild/moderate or greater AI on TTE with MAP <80 mm Hg and moderate or greater RV dysfunction on TTE
Hemodynamic criteria*	RAP <12 mm Hg PCWP 16–20 mm Hg LVAD flow within 1 L/min of measured output	RAP 13–16 mm Hg PCWP ≤15 mm Hg PAPI <2	RAP 13–16 mm Hg PCWP 16–20 mm Hg PAPI <2 LVAD flow within 1 L/min of measured output
Tier II (moderate)	Moderate or greater AI on TTE with MAP <80 mm Hg	Moderate or greater RV dysfunction on TTE and Clinical and laboratory evidence of RHF†	Moderate or greater AI on TTE with MAP <80 mm Hg and moderate or greater RV dysfunction on TTE
Hemodynamic criteria*	RAP <12 mm Hg PCWP >20 mm Hg LVAD flow ≥1 L/min of measured output	RAP >16 mm Hg PCWP ≤15 mm Hg PAPI <2 or Need for oral pulmonary vasodilators due to RHF and persistently elevated PVR	RAP 13–16 mm Hg PCWP 16–20 mm Hg PAPI <2 LVAD flow ≥1 L/min of measured output
Tier IIIA (moderate to severe)	Moderate or greater AI on TTE with MAP <80 mm Hg	Moderate or greater RV dysfunction on TTE and Clinical and laboratory evidence of RHF†	Moderate or greater AI on TTE with MAP <80 mm Hg and moderate or greater RV dysfunction on TTE
Hemodynamic criteria* and additional clinical criteria	Hemodynamics same as Tier II or Need for inotropes or valvular intervention to maintain adequate LVAD flow	Hemodynamics same as Tier II or Need for inotropes, systemic or inhaled pulmonary vasodilators or RV mechanical support to maintain adequate LVAD flow	RAP >16 mm Hg PCWP >20 mm Hg PAPI <2 LVAD flow ≥1 L/min of measured output or Need for inotropes, systemic or inhaled pulmonary vasodilators or RV mechanical support or valvular intervention to maintain adequate LVAD flow
Tier IIIB (severe)	Moderate or greater AI on TTE with MAP <80 mm Hg	Moderate or greater RV dysfunction on TTE and clinical and laboratory evidence of RHF†	Moderate or greater AI on TTE with MAP <80 mm Hg and moderate or greater RV dysfunction on TTE
Hemodynamic criteria* and additional clinical criteria	Hemodynamics same as Tier II/IIIA or progressive end-organ dysfunction or death attributable to AI	Hemodynamics same as Tier II/IIIA or progressive end-organ dysfunction or death attributable to RVF	Hemodynamics same as Tier IIIA or progressive end-organ dysfunction or death attributable to AI and RVF

Late RV Failure

- **Management:**
  - Preload Optimization
  - Contractility Augmentation
  - Afterload Reduction
  - Rhythm Control
  - Management of valvular disease
  - Device speed optimization
  - Pulmonary vasodilators
  - *Temporary RVAD*
  - *Transplant*



Rajapreyar I et al. JACC: HEART FAILURE VOL. 11, NO. 8, 2023 Late Right Heart Failure After LVAD AUGUST 2023: 865–878

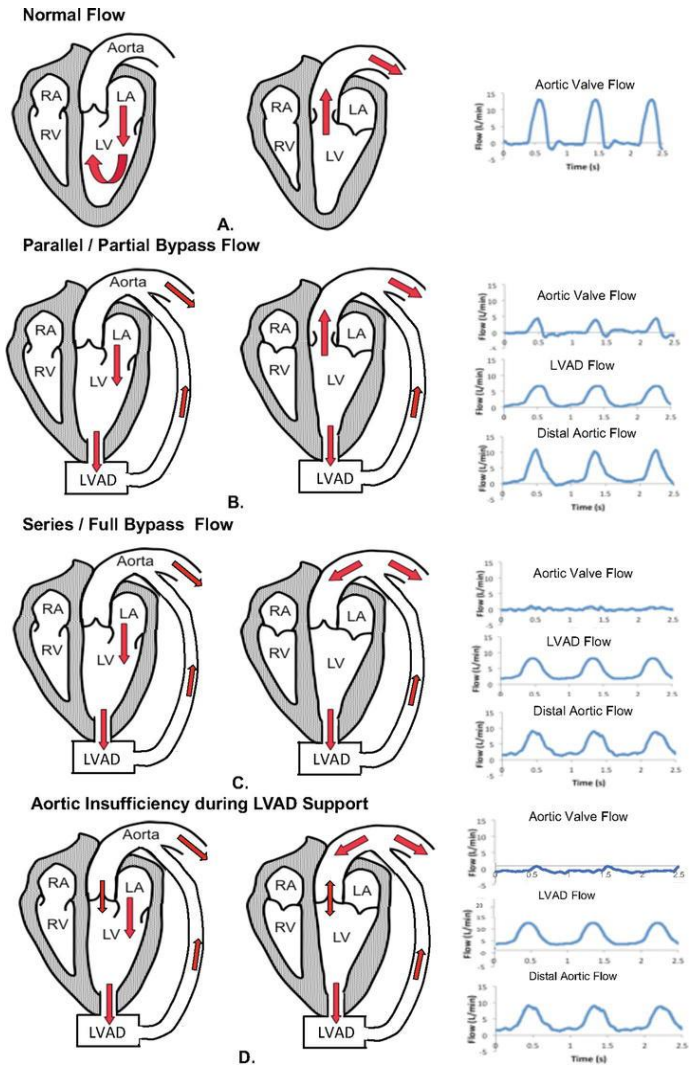
Refractory RV Failure in DT patients

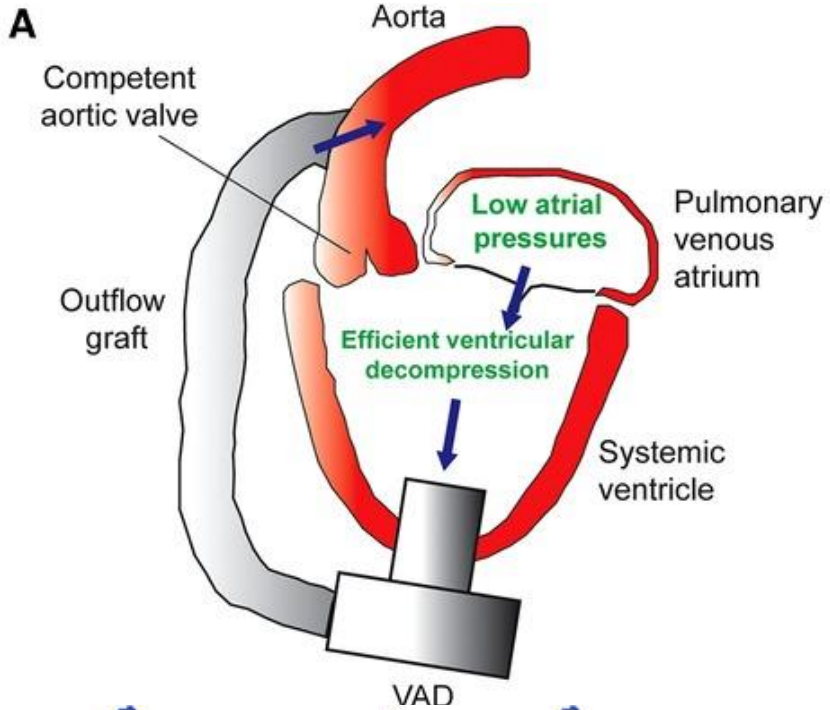
Oral milrinone for management of refractory right ventricular failure in patients with left ventricular assist devices

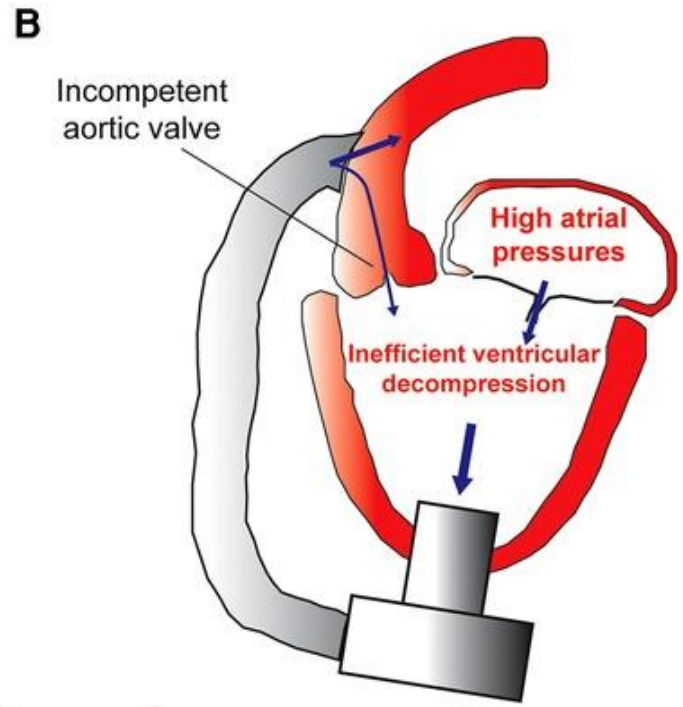
Waqas Akhtar[1], Charles Butcher[1], Andrew Morley-Smith[1], Fernando Riesgo Gil[1], Owais Dar[1], Veronica Baston[1], John Dunning[1] and Haifa Lyster[1,2]*

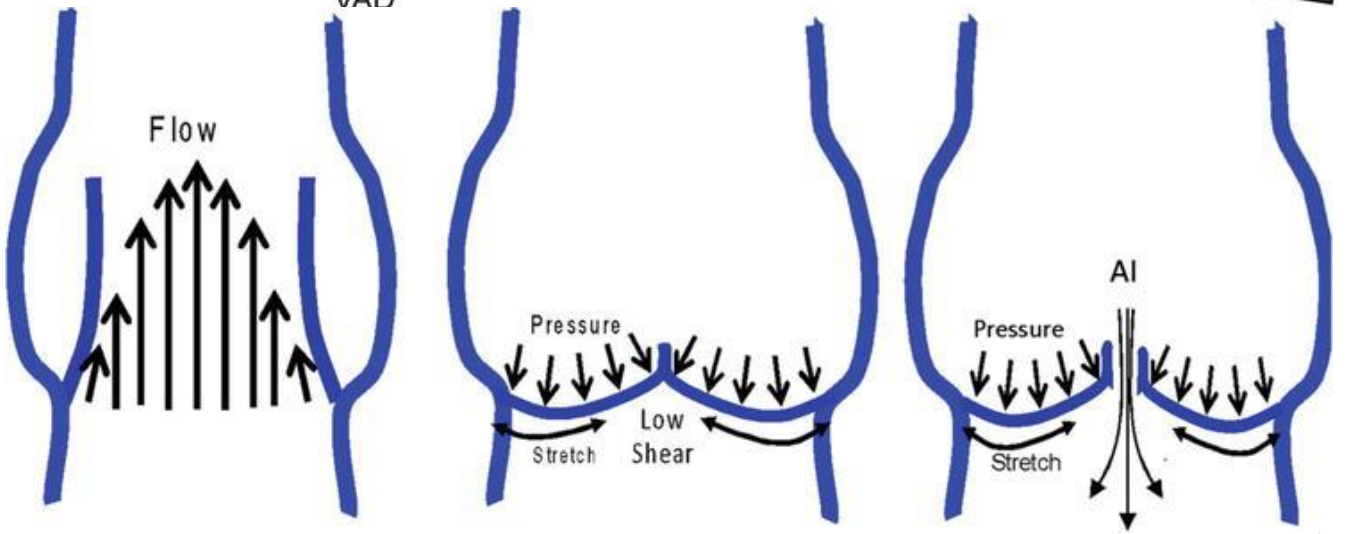
[1]*Department of Advanced Heart Failure, Transplant and Mechanical Support, Harefield Hospital, Hill End Road, Harefield, UB9 6JH, UK; and* [2]*King's College London, London, UK*

HDRAE: AR

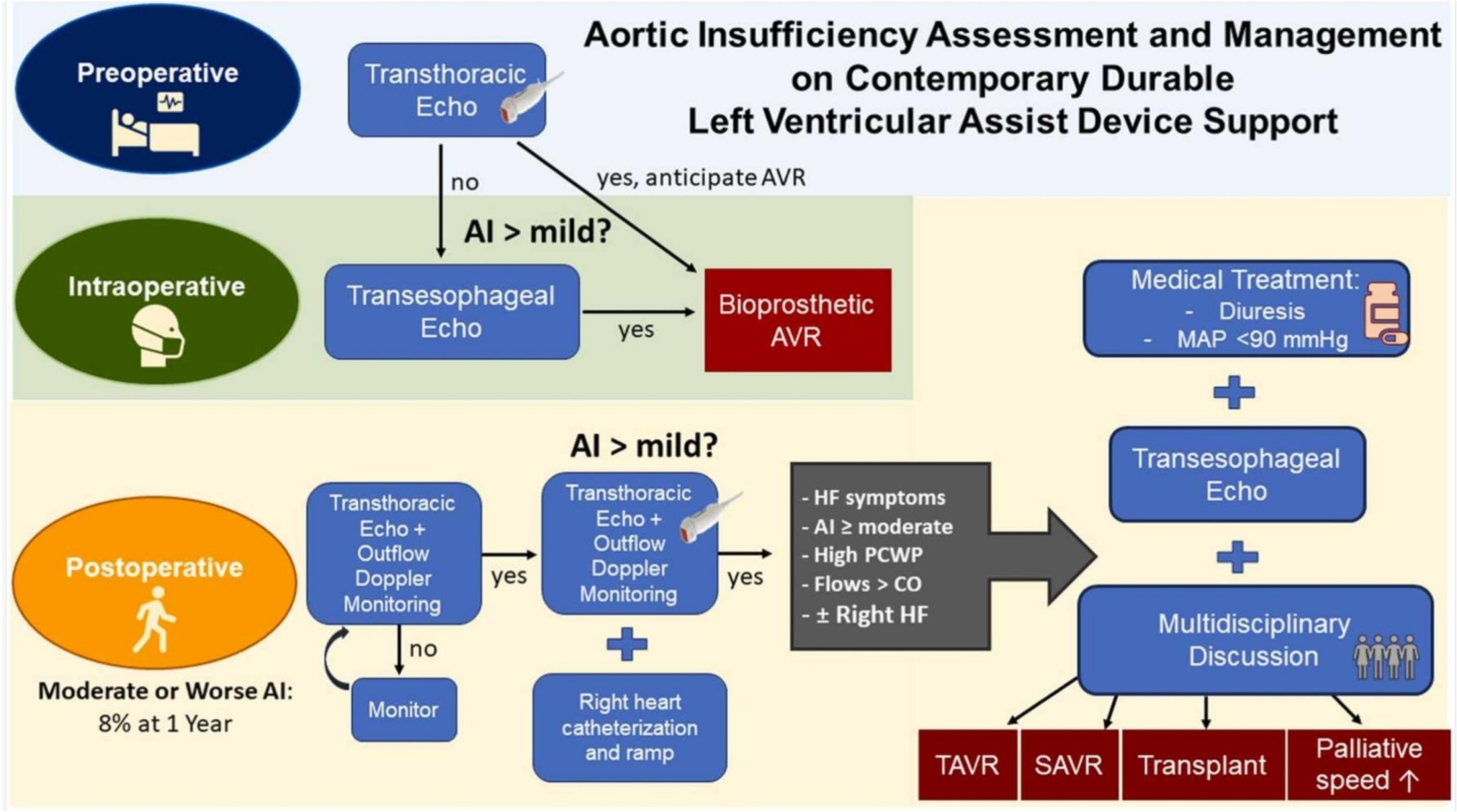

Normal Flow
Aorta
RA
LA
RV
LV
A.
Aortic Valve Flow
Parallel / Partial Bypass Flow
LVAD
B.
LVAD Flow
Distal Aortic Flow
Series / Full Bypass Flow
C.
Aortic Insufficiency during LVAD Support
D.
Time (s)


A
Aorta
Competent aortic valve
Low atrial pressures
Pulmonary venous atrium
Outflow graft
Efficient ventricular decompression
Systemic ventricle
VAD


B
Incompetent aortic valve
High atrial pressures
Inefficient ventricular decompression


Flow
Pressure
Stretch
Low Shear
AI
Pressure
Stretch

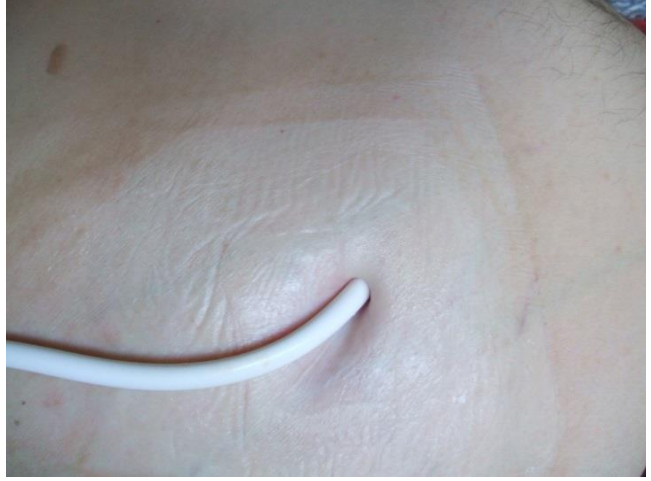
HDRAE: AR

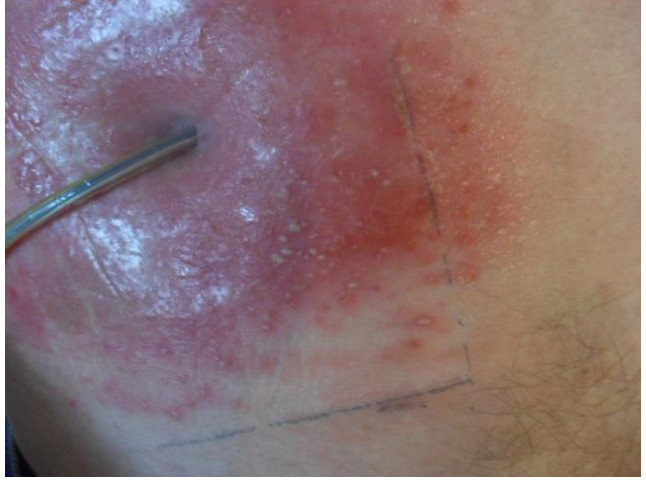


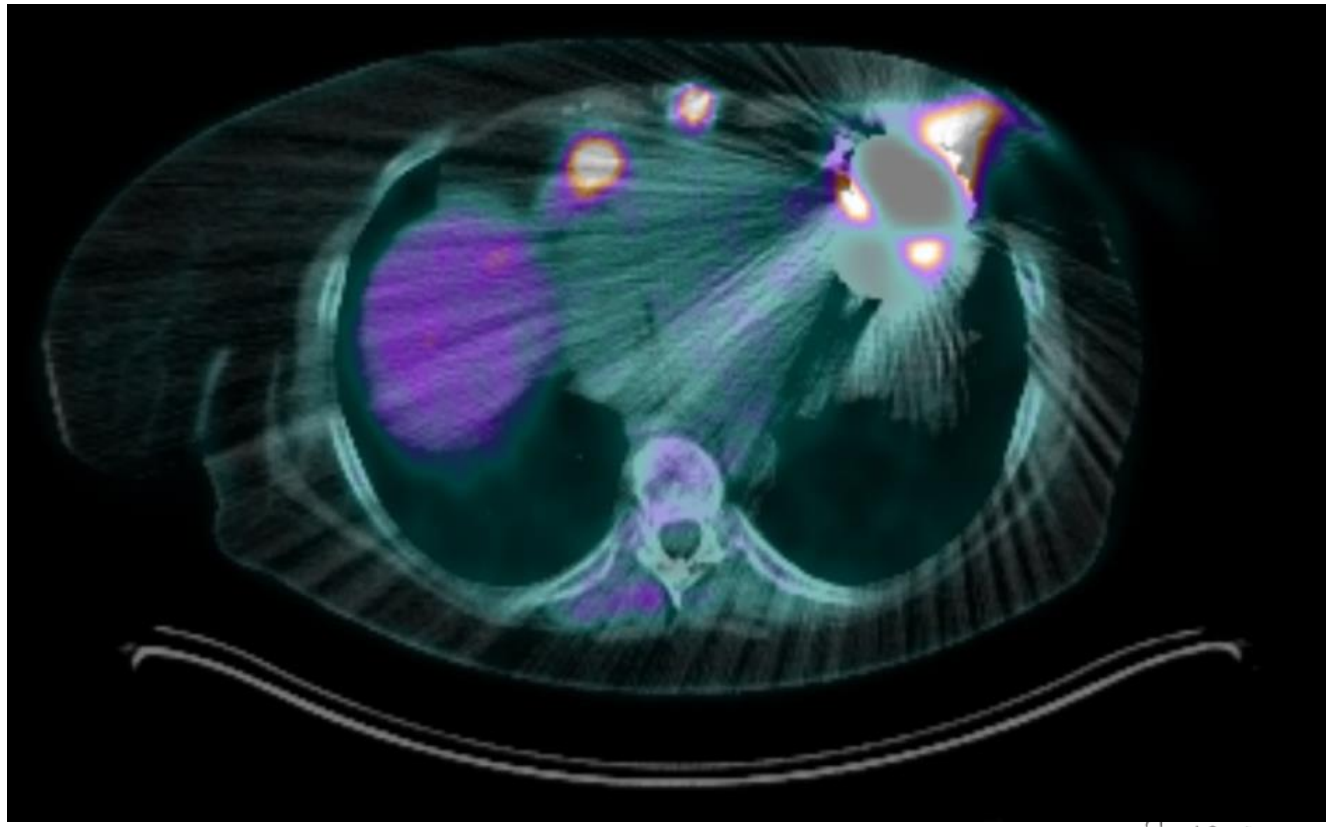
Saeed, Diyar et al.10.1016/j.healun.2024.06.018

Device-related infection

- **Types:**
  - **VAD-Specific**
    - Driveline
    - Tunnel
    - Pump pocket
    - VAD
  - **VAD associated**
    - Blood stream infections
    - Endocarditis
    - Mediastinitis
- **Prevention:**
  - Meticulous carer training
  - Rigorous sustained care
  - Small diameter flexible cable
  - External fixation
- **Treatment:**
  - Prolonged Iv antibiotics
  - Debridement/re-roofing
  - Transplant

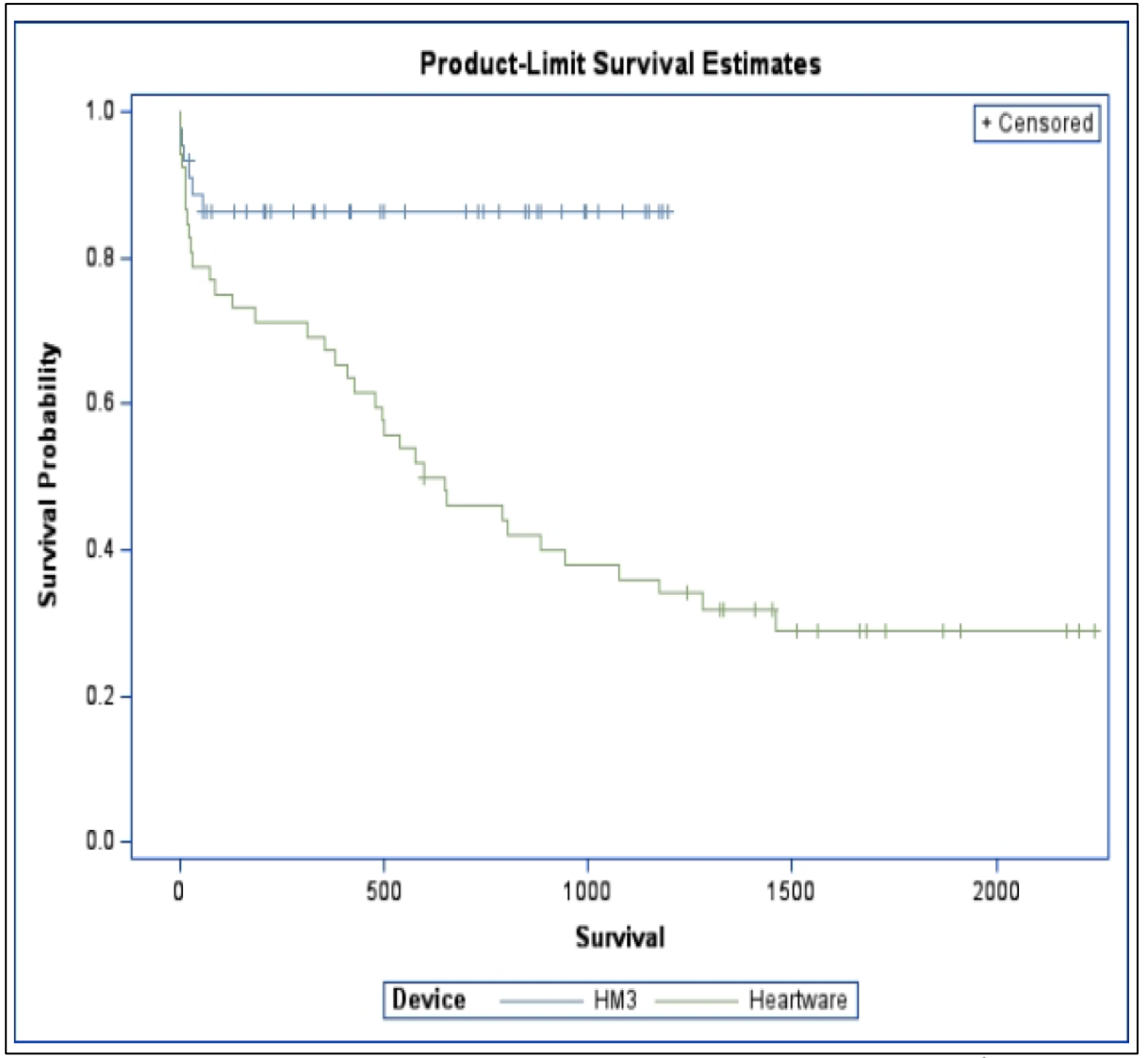






Results of "HM3 Era" in Harefield- From 2020

- Heartmate 3 only
- Strict selection criteria – largely BTC
- Robust preoperative optimization
- Improved postOp management
- Stop Aspirin
- HF medication optimization
- Close monitoring of HDRAE
- Dedicated LVAD-ID pathway
- Improved selection of BTT



Conclusions

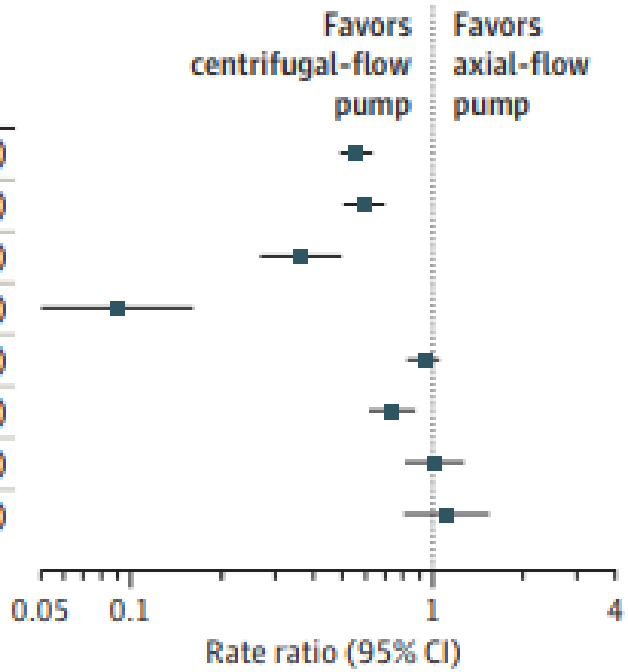
- LVAD is an excellent option for patients with Advanced HF after meticulous and patient selection
- Outcomes have significantly improved over the last few decades, but significant morbidity and mortality problems persist
- Anticipation and prevention are key to avoid long-term complications
- Once developed, some of this complications can be very difficult to treat but options do exist
- Further development in technology and management algorithms is needed to improve outcomes even more


Thanks

Outcomes Heartmate 3 – MOMENTUM 3

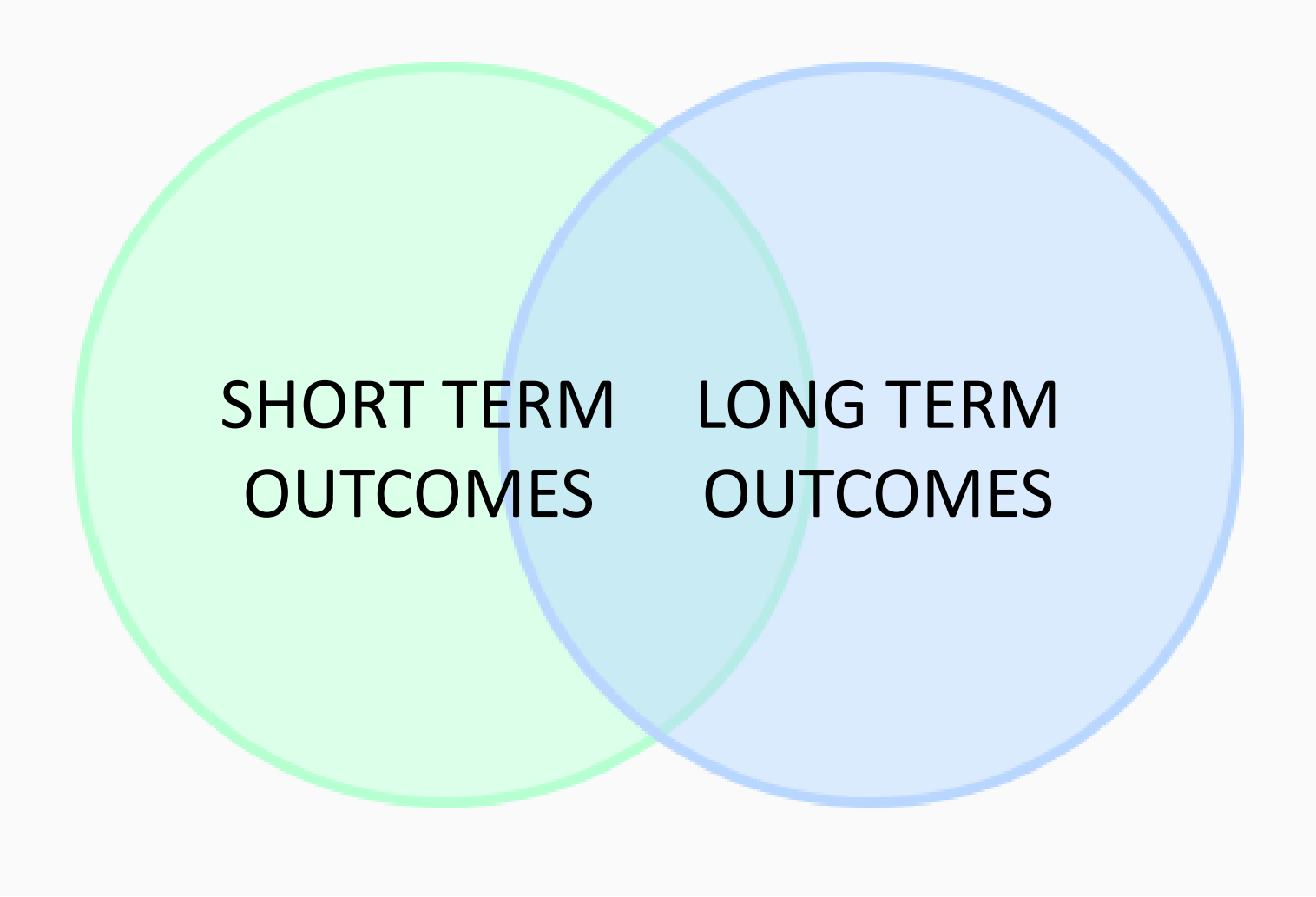
Figure 3. Serious Adverse Events in a Study of 5-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices

Serious adverse event	Events/patient-years: Centrifugal-flow pump (515 patients; 1234 patient-years)	Events/patient-years: Axial-flow pump (505 patients; 997 patient-years)	Rate ratio (95% CI)	*P* value[a]
Any bleeding	0.430	0.765	0.56 (0.50-0.63)	<.001
Gastrointestinal bleeding	0.252	0.423	0.60 (0.51-0.69)	<.001
Any stroke	0.050	0.136	0.37 (0.27-0.50)	<.001
Suspected or confirmed pump thrombosis	0.010	0.108	0.09 (0.05-0.16)	<.001
Any major infection	0.515	0.551	0.94 (0.83-1.05)	.25
Cardiac arrhythmia	0.207	0.283	0.73 (0.62-0.87)	<.001
Right heart failure	0.149	0.146	1.02 (0.82-1.27)	.87
Other neurologic event[b]	0.073	0.065	1.12 (0.81-1.54)	.49

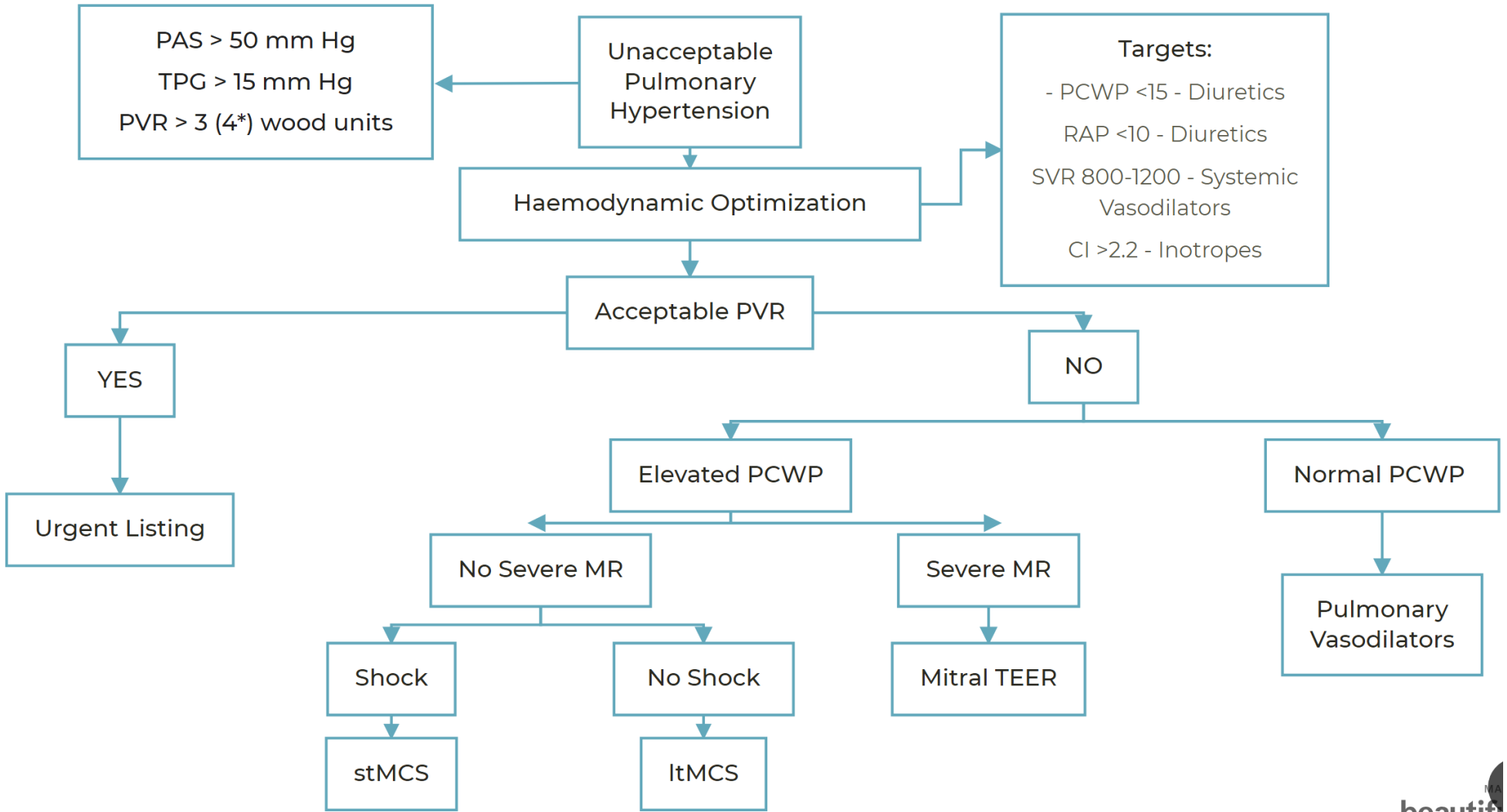


Mehra MR, et al. JAMA. 2022 Sep 27;328(12):1233-1242.

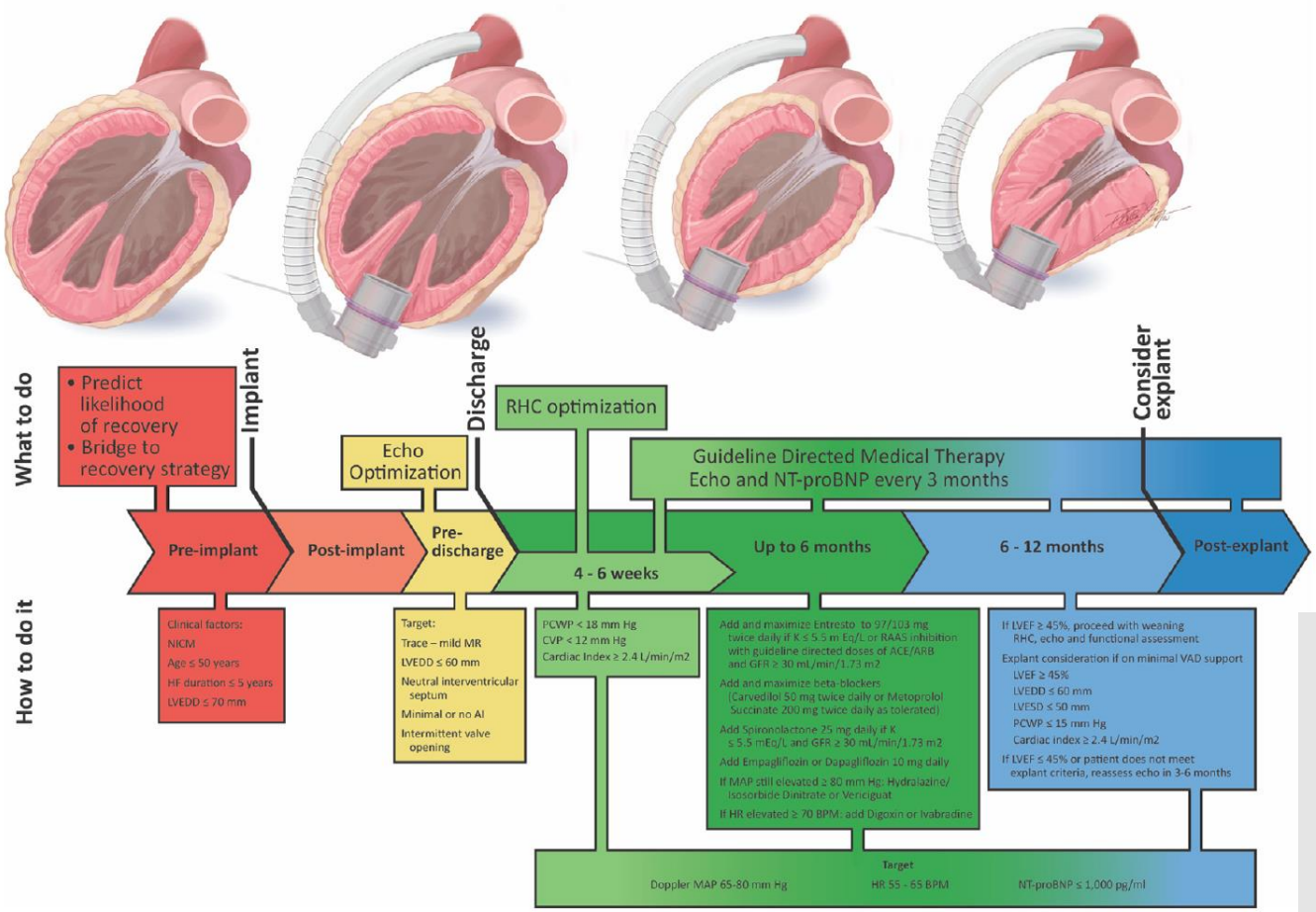
How to Improve LVAD Outcomes



Management of PHT pre HTx at Harefield



The Bridge to Recovery Journey



Pre-implant

Phenotype patients with high likelihood of recovery

Post-explant

Continue GDMT and long-term monitoring with echocardiography and biomarkers

Post-implant optimization

Guideline directed medical therapy (GDMT) for HF and pump optimization

Explant-testing

Consider explant vs. ongoing support vs. nsplant in Responders based on turn-down and exercise-based testing and patient preference. In Partial Responders, continue GDMT and re-assess

Post-implant follow-up

Echocardiography, NYHA class, right heart catheterization, biomarkers

Responder: LVEF ≥ 40% and LVEDD < 60 mm (approximately 10% of LVAD patients)

Partial Responder: Absolute improvement of LVEF > 5% compared to pre-implant LVEF but not to >40%, (approximately 30% of LVAD patients)

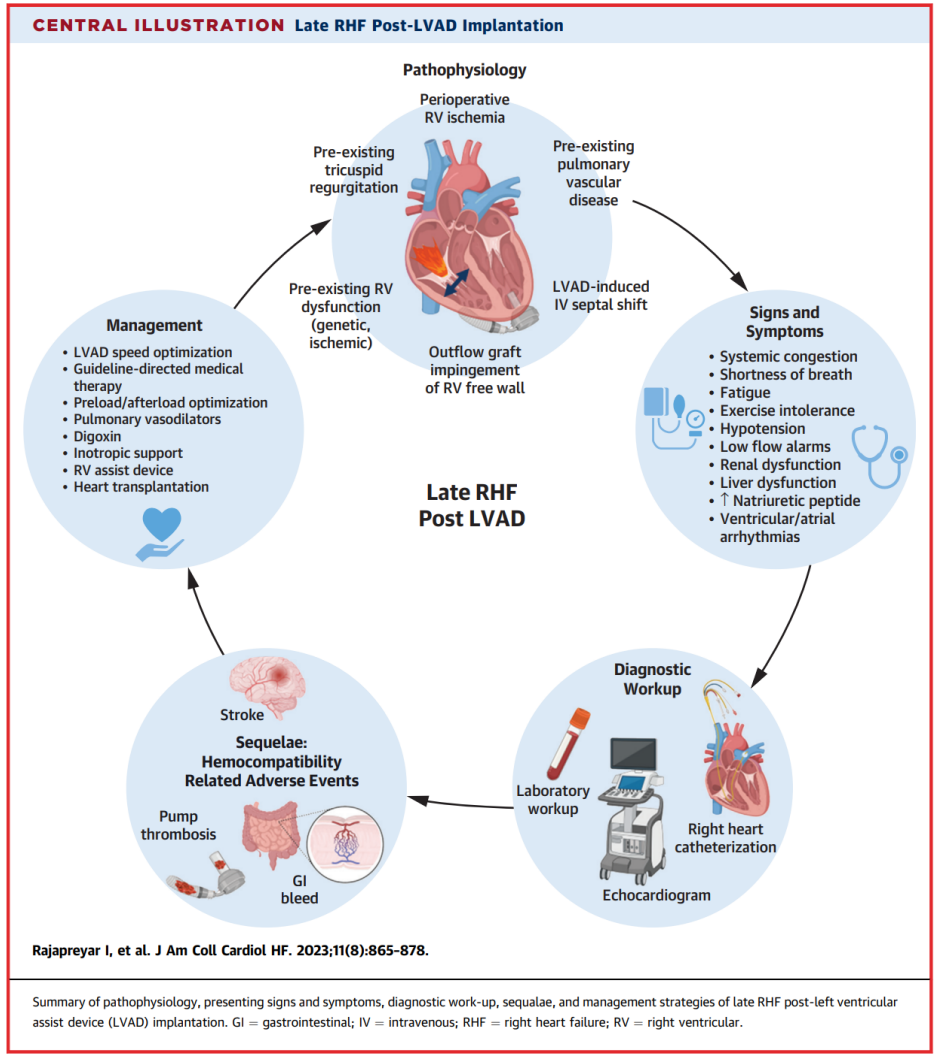
Class IIa:

1. Patients with dilated cardiomyopathy, particularly of recent onset and non-ischemic etiology refractory to maximal medical therapy, should be considered for DMCS as bridge-to-recovery. Pharmacological treatment should be with maximally tolerated neurohormonal modulation, and surveillance for recovery of left ventricular function should be undertaken.

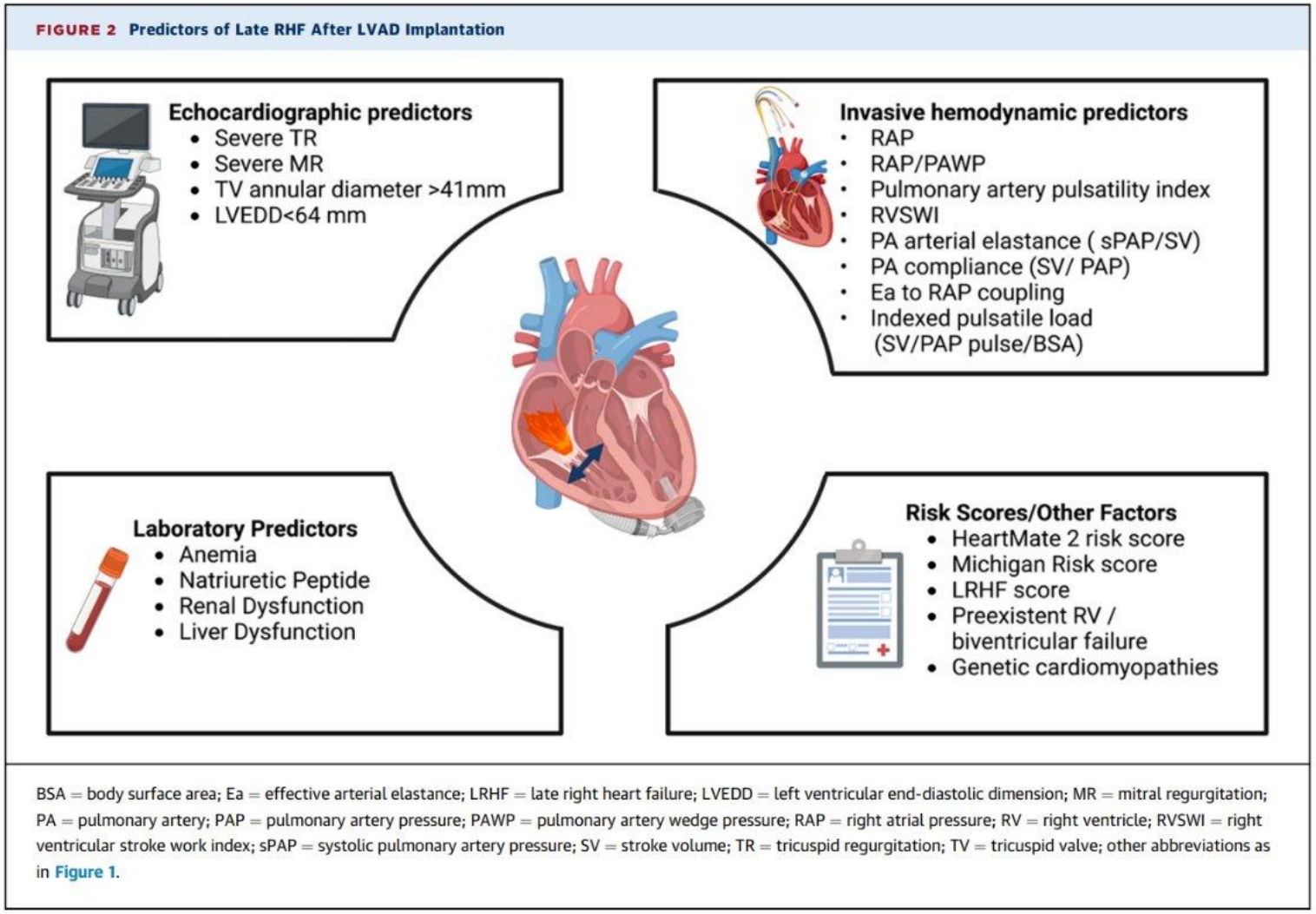
Level of Evidence: B. (New)

Kanwar M. J Heart Lung Transplant 2022;41:1324–1334

Late Right Ventricular Failure



Summary of pathophysiology, presenting signs and symptoms, diagnostic work-up, sequalae, and management strategies of late RHF post-left ventricular assist device (LVAD) implantation. GI = gastrointestinal; IV = intravenous; RHF = right heart failure; RV = right ventricular.



BSA = body surface area; Ea = effective arterial elastance; LRHF = late right heart failure; LVEDD = left ventricular end-diastolic dimension; MR = mitral regurgitation; PA = pulmonary artery; PAP = pulmonary artery pressure; PAWP = pulmonary artery wedge pressure; RAP = right atrial pressure; RV = right ventricle; RVSWI = right ventricular stroke work index; sPAP = systolic pulmonary artery pressure; SV = stroke volume; TR = tricuspid regurgitation; TV = tricuspid valve; other abbreviations as in Figure 1.

Rajapreyar I et al. J A C C : H E A R T F A I L U R E V O L . 1 1 , N O . 8 , 2 0 2 3 Late Right Heart Failure After LVAD A U G U S T 2 0 2 3 : 8 6 5 – 8 7 8

Late Right Ventricular Failure

- **Management:**

Medical Optimization

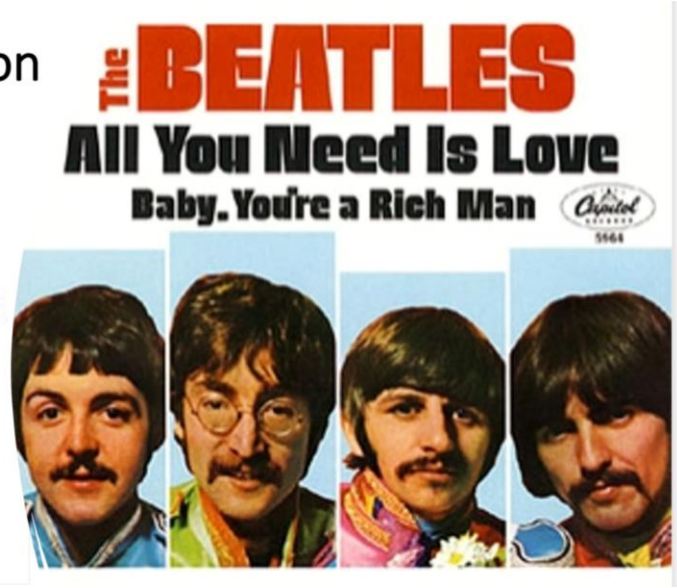
All You Need Is:

Lower vascular resistance

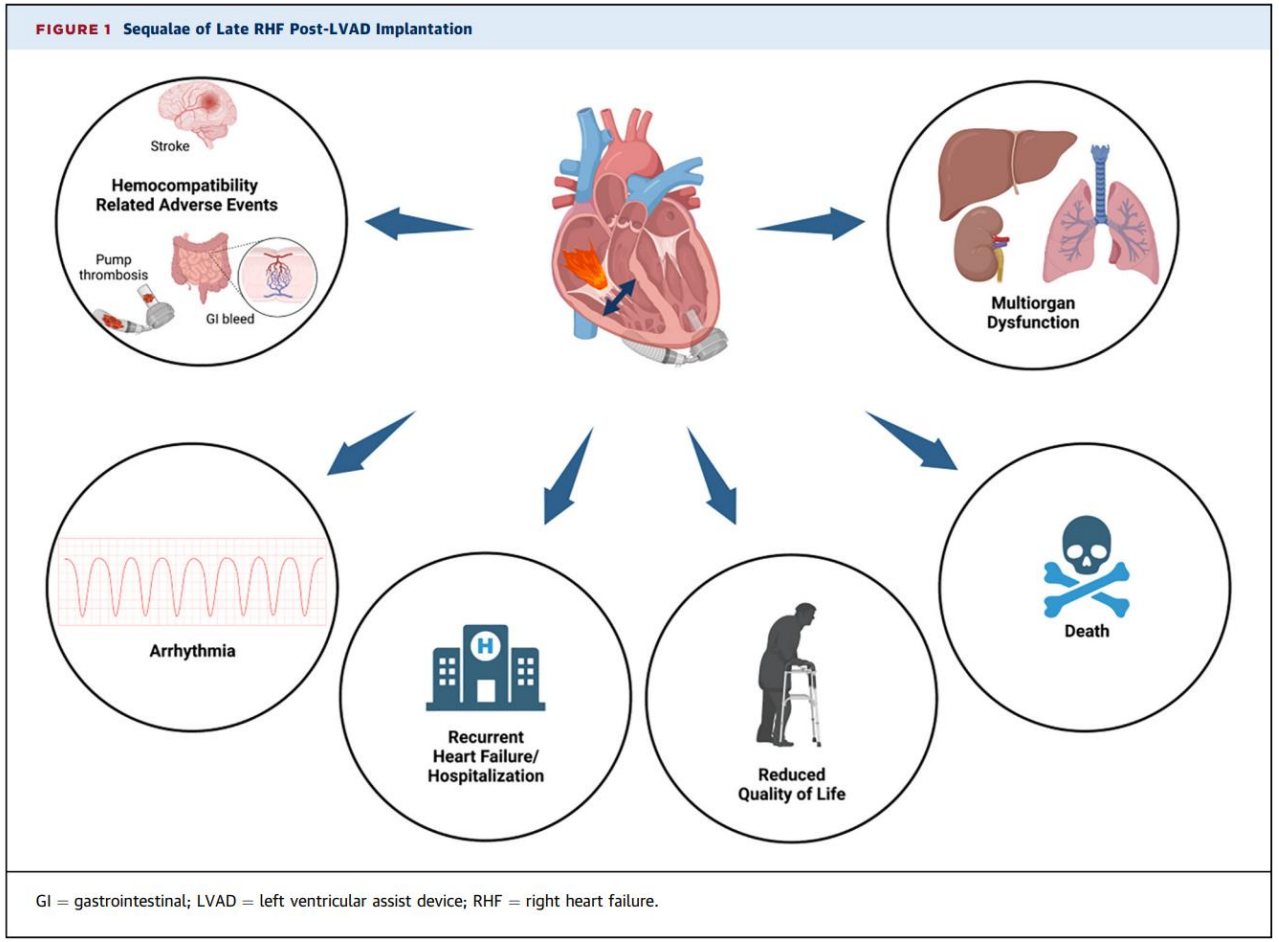
Optimize rhythm

correct **V**olume status

Enhance contractility



- *Temporary RVAD*
- *Transplant*



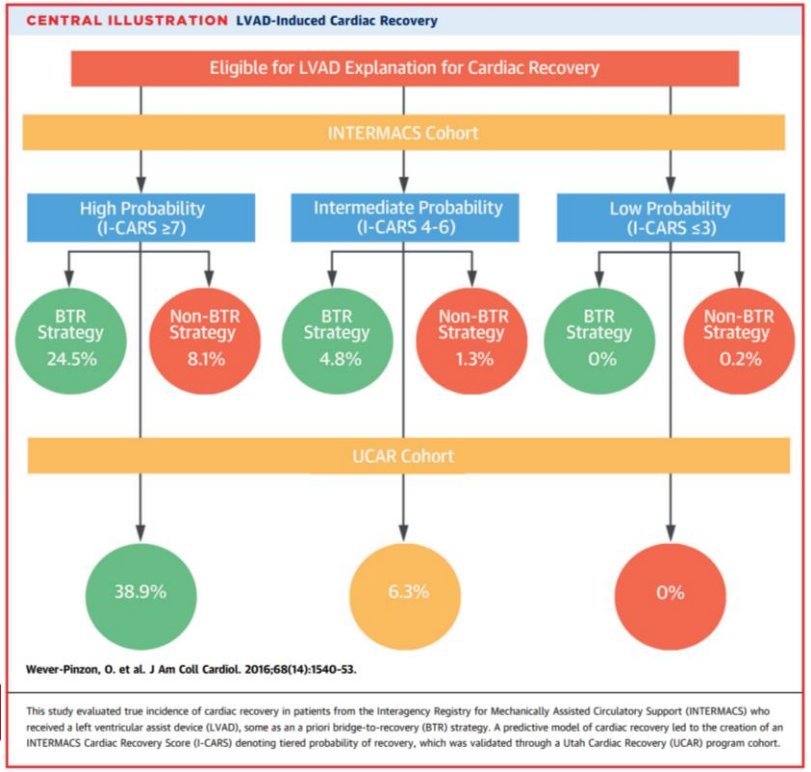
Rajapreyar I et al. J A C C : H E A R T F A I L U R E V O L . 1 1 , N O . 8 , 2 0 2 3 Late Right Heart Failure After LVAD A U G U S T 2 0 2 3 : 8 6 5 – 8 7 8

Pre-LVAD implantation prediction of cardiac recovery

- Factors associated with myocardial recovery:
  - Short HF duration (<5 years)
  - Non-ischemic cardiomyopathy (NICM)
  - Younger age <50
  - Normal or mildly impaired renal function (<1.2 mg/dl)
  - Not-large left ventricular end diastolic diameter (LVEDD) (<6.5 cm)
- HF aetiology – greatest rates
  - Myocarditis (7.7%)
  - Postpartum cardiomyopathy (4.4%)
  - Adriamycin-induced dilated cardiomyopathy (4.1%)
- Role of Genetic Testing: some genotypes are more likely to improve on medical therapy (TTN)
- Role of Bridge-to-Recovery LVAD Indication: Clinical intent at time of LVAD implantation is an important predictor of myocardial recovery as it creates a deliberate framework for clinical management

Table 2 Intermacs Cardiac Recovery Score (I-CARS)

Clinical Characteristic	Incidence Rate of Recovery v pts without characteristic (events/100-pts-yrs)	OR (95% CI)	Score
Nonischemic Cardiomyopathy	1.6 vs 0.3	4.7 (3.1-7.1)	3
Implanted ICD	2.9 vs 0.5	3.7 (2.6-5.2)	2
Age <50 years	2.2 vs 0.5	1.9 (1.4-2.7)	1
Time from Diagnosis <2 years	2.7 vs 0.5	2.2 (1.5-3.1)	1
Creatinine ≤1.2 mg/dl	1.4 vs 0.5	2.0 (1.4-2.7)	1
LVEDD <6.5 cm	1.6 vs 0.7	1.8 (1.3-2.5)	1
Total Score Range			0-9

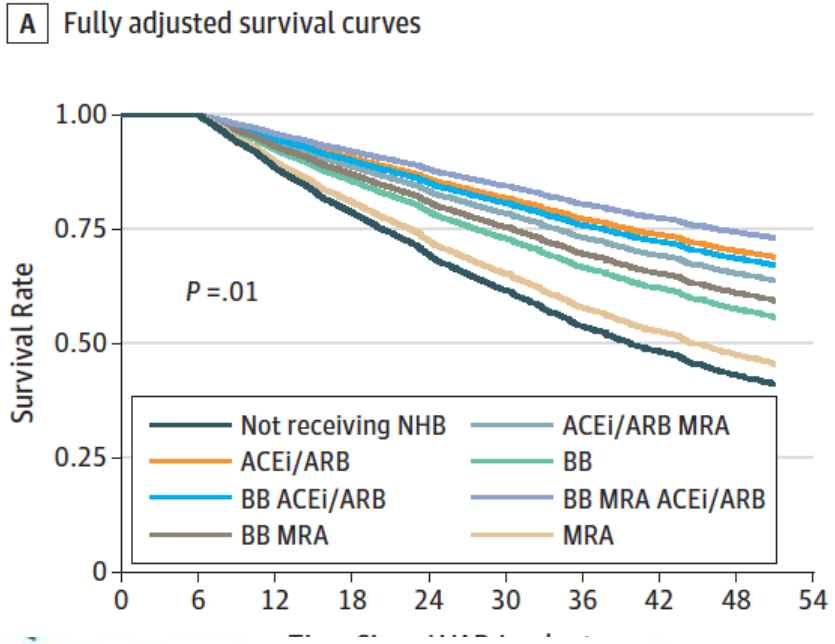


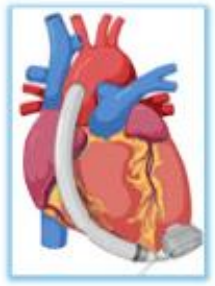
Kanwar M. J Heart Lung Transplant 2022;41:1324–1334

Promoting myocardial recovery with a LVAD

- Optimal LV unloading:
  - Echocardiogram goals:
    - LVEDD to <60 mm
    - Mitral regurgitation < moderate
    - Neutral interventricular septum
    - Minimal or no AR
    - Intermittent aortic valve opening
  - Haemodynamic goals:
    - PCWP <18 mm Hg
    - CVP <12 mm Hg
    - Cardiac index >2.2 L/min per m2

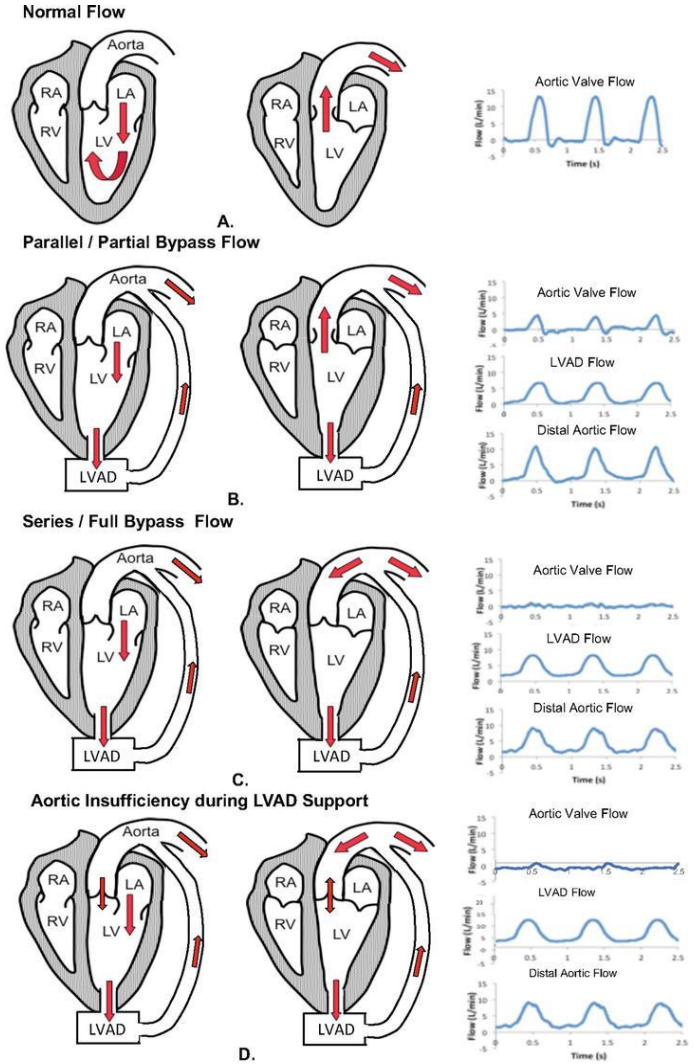
- Guideline Directed Medical therapy (GDMT):

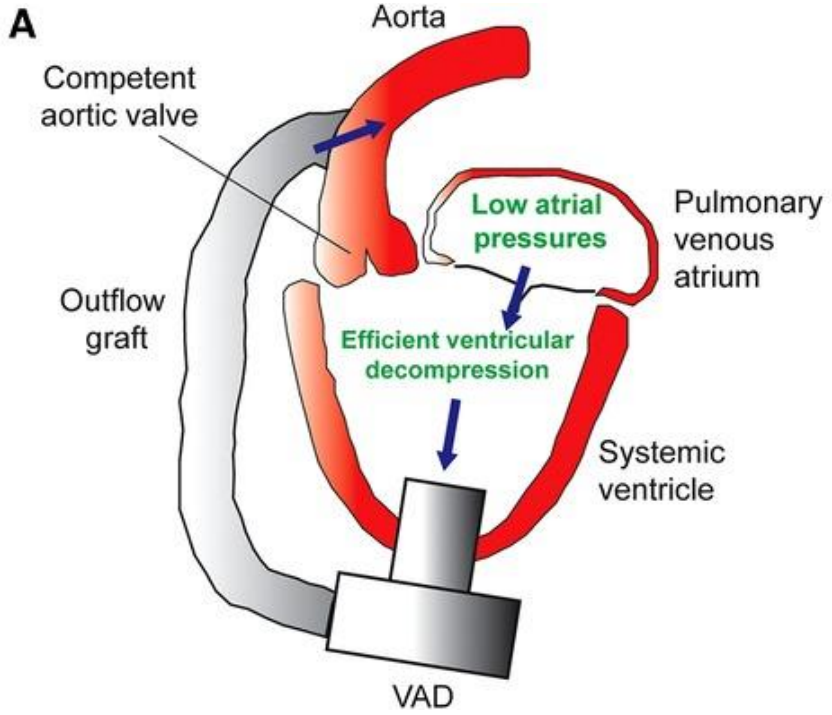




- β-blocker
- ARNI/ACE-i/ARB
- MRA
- SGLT2-inhibitor
- Diuretic
- CRT/ other GDMT interventions

HDRAE: AR





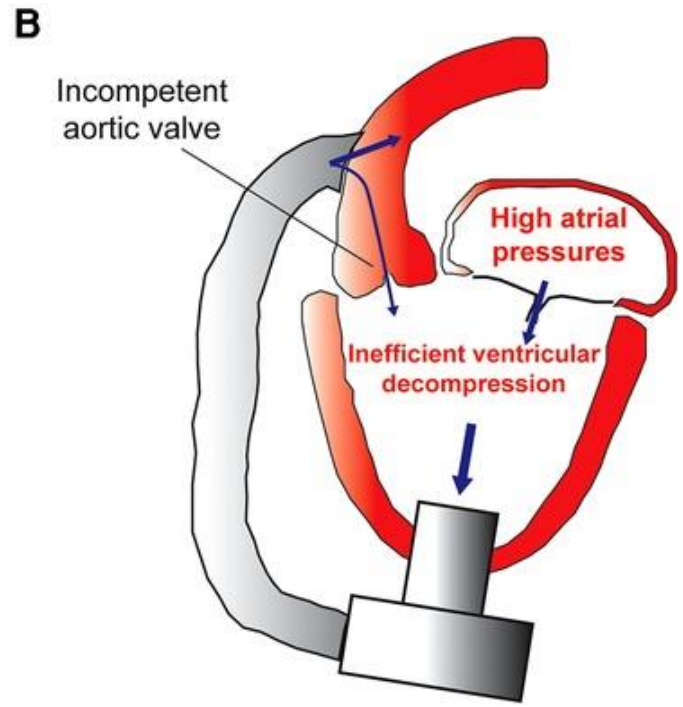


Table 2 Categorization of Patient Phenotypes in the Setting of Aortic Insufficiency (AI) With or Without Right Heart Failure (RHF) in Patients on HeartMate 3 Support
Source: Adapted from Grinstein et al.[17]

Hemodynamic phenotype	AI severity	Intervention	RAP	PCWP	LVAD flow	PI	Regurgitant flow
Isolated AI	Mild	Baseline	< 12 mm Hg	16-20 mm Hg	↑	↓	↑
		Speed augmentation	↔	↓	↑↑↑	↓↓	↑↑
		Blood pressure control	↔	↓	↑↑	↑	↔/↓
	Moderate-severe	Baseline	< 12 mm Hg	> 20 mm Hg	↑	↓↓	↑↑
		Speed augmentation	↔	↔/↓	↑↑↑	↓↓↓	↑↑↑
		Blood pressure control	↔	↓	↑↑	↔/↑	↔/↓
Combined AI and RHF	All	Baseline	> 12 mm Hg	> 16 mm Hg	↔/↑	↔/↓	↑↑
		Speed augmentation	↑	↔/↓	↑↑	↓↓	↑↑↑
		Blood pressure control	↔/↑	↔/↓	↑	↔/↑	↔

Abbreviations: AI, aortic insufficiency; LVAD, left ventricular assist device; PCWP, pulmonary capillary wedge pressure.

Patients can be phenotyped as having isolated AI or AI with RHF. In those with isolated AI, LVAD speed augmentation can increase device flow and reduce filling pressure, at the expense of increased AI regurgitant flow compared with baseline. In those with combined AI and RHF, device speed augmentation may yield less of an increase in net flow versus those with isolated AI due to right heart uncoupling, manifested as a further rise in right atrial pressure from increased right heart preload. In this setting, regurgitant flow may further increase. Blood pressure control to a target MAP will similarly increase net LVAD flow by 2 mechanisms: (1) augmenting flow through the LVAD via a reduction in the pressure head and (2) a reduction in the reverse transvalvular pressure gradient leading to less regurgitant flow through the aortic valve.

Assessing for myocardial recovery during LVAD support

	RESPONDER	PARTIAL RESPONDER	NON-RESPONDER
LVEF	≥40%	>5% from baseline But NOT >40%	No IMPROVEMENT
LVEDD	≤6.0 cm	INDEPENDENT	INDEPENDENT

RESTAGE-HF Minimum Explant Criteria	
LVEDD	<60 mm
LVESD	<50 mm
LVEF	>45%
LVEDP or PCWP	≤15 mmHg
Resting CI	>2.4 l/min/m^2
Peak VO2	>16 ml/kg/min

HAREFIELD Minimum Explant Criteria

Phase 1: TT Echocardiogram	• LVEDD <60mm • LVESD <50mm • LVEF >45%
Phase 2: Cardiopulmonary Exercise Test	• Maintained peak intake >18 ml/kg/min • VE/VCO_2 < 34
Phase 3: Right Heart Catheterization	• CI > 2.2 l/min • PWCP < 15 mmHg
Phase 4: Outflow Occlusion Test	• CI > 2.2 l/min • PWCP < 15 mmHg

No significant differences have to be noted between baseline rpm and minimum speed (Phases 1-3) and OFF (just phase 4).

Kanwar M. J Heart Lung Transplant 2022;41:1324–1334

A detailed explantation assessment protocol for patients with left ventricular assist devices with myocardial recovery

María Monteagudo Vela [a,*], Verónica Rial Bastón[b], Vasileios Panoulas [b,c], Fernando Riesgo Gil[b] and Andre Simon[a]

[a] Department of Cardiothoracic Transplantation and Mechanical Circulatory Support, Harefield Hospital, Royal Brompton and Harefield NHS Foundation Trust, London, UK
[b] Department of Cardiology, Harefield Hospital, Royal Brompton and Harefield NHS Foundation Trust, London, UK
[c] Cardiovascular Sciences, National Heart and Lung Institute, Imperial College London, London, UK

* Corresponding author. Cardiothoracic and Transplant Surgeon, Royal Brompton and Harefield NHS Foundation Trust, Hill End Road, Harefield, Middlesex UB9 6JH, UK. Tel: +44-1895828892; e-mail: m.monteagudo-vela@rbht.nhs.uk (M. Monteagudo Vela).

Received 8 May 2020; received in revised form 8 September 2020; accepted 4 October 2020

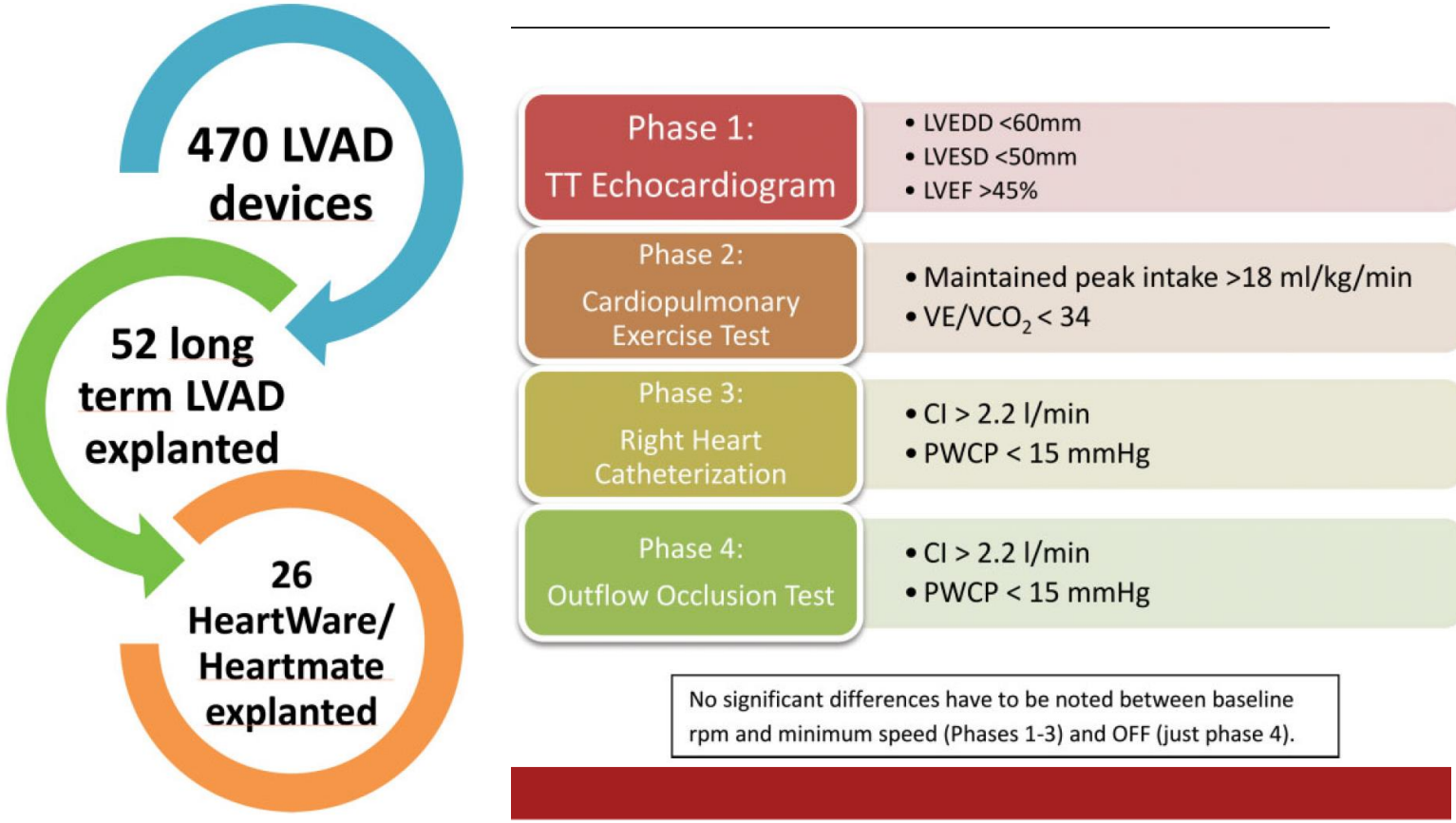
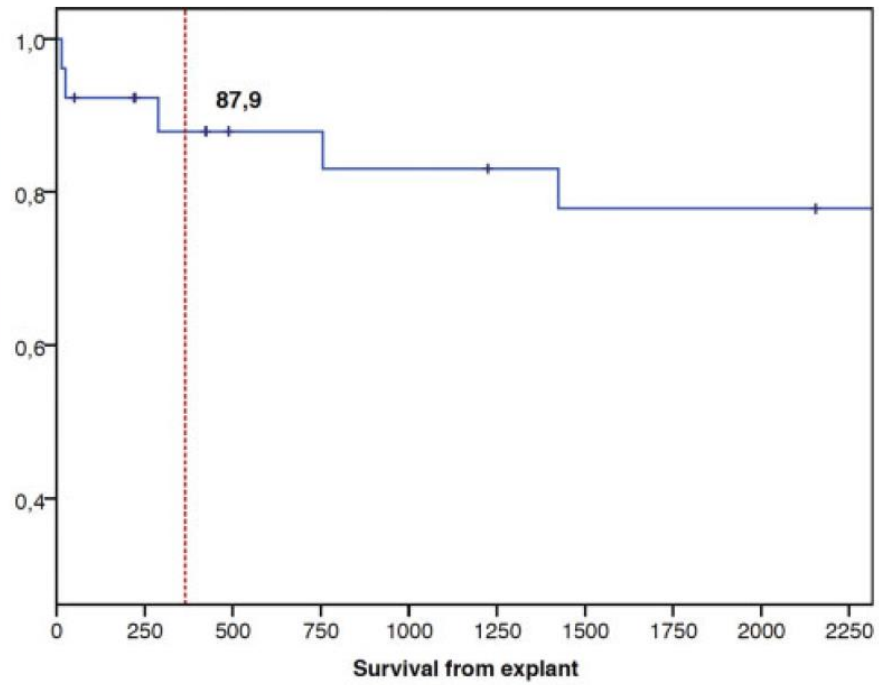


Figure 1: Inclusion criteria. LVAD: left ventricular assist device.



Time (days)	0	365	1825
N at risk	26	20	15

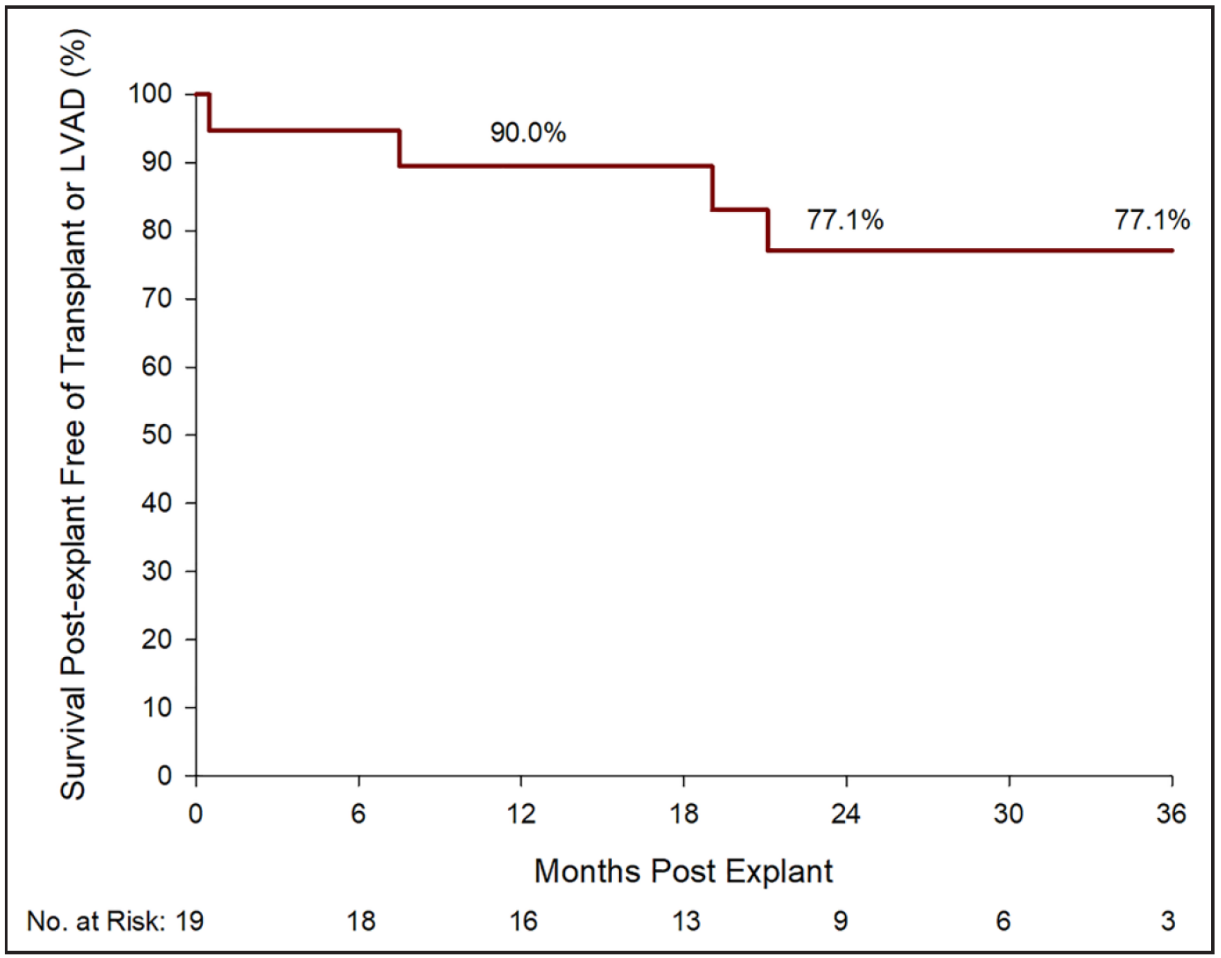
Figure 5: Survival from explant shown in days.

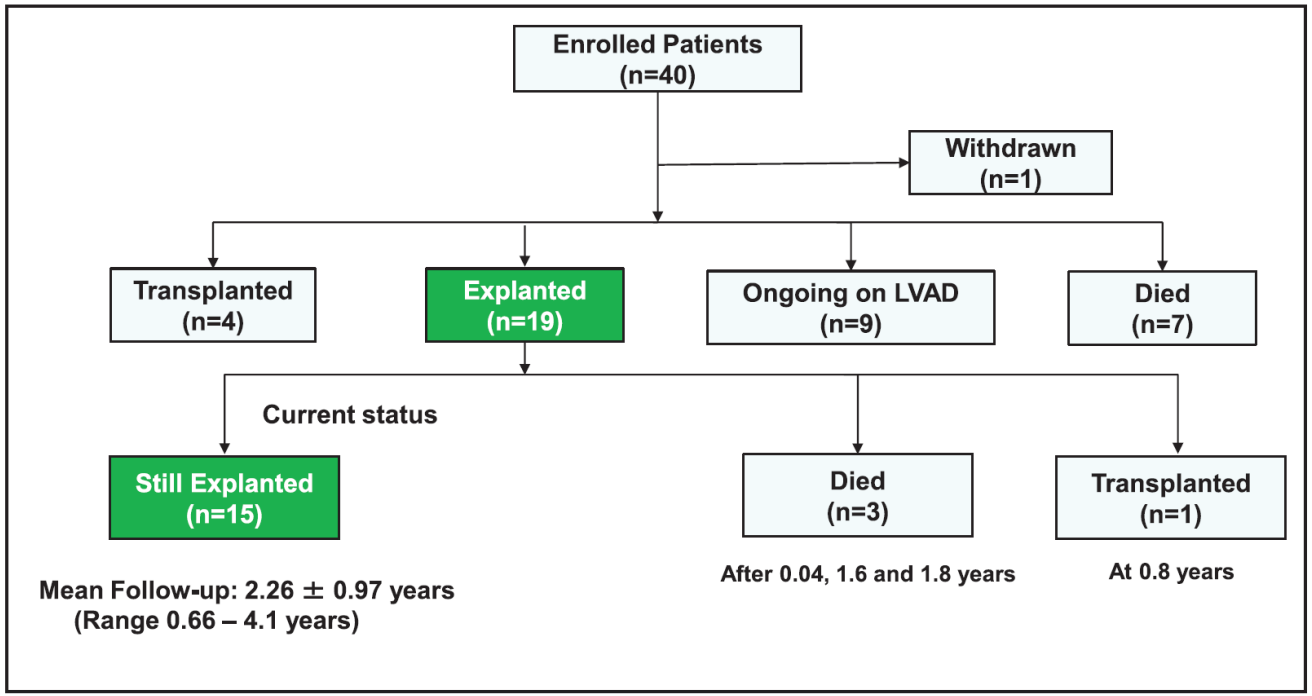
Circulation

ORIGINAL RESEARCH ARTICLE

Prospective Multicenter Study of Myocardial Recovery Using Left Ventricular Assist Devices (RESTAGE-HF [Remission from Stage D Heart Failure])

Medium-Term and Primary End Point Results

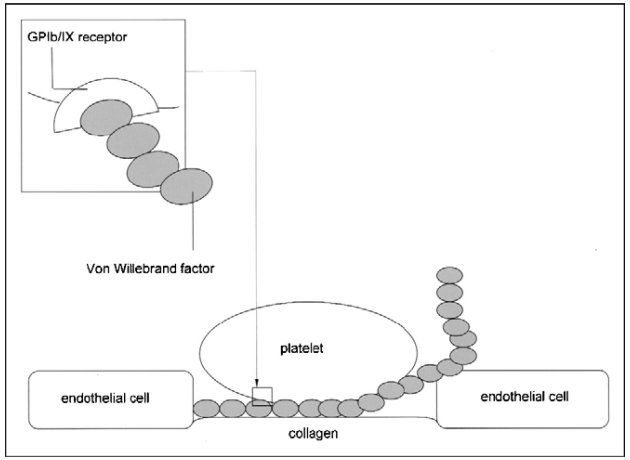


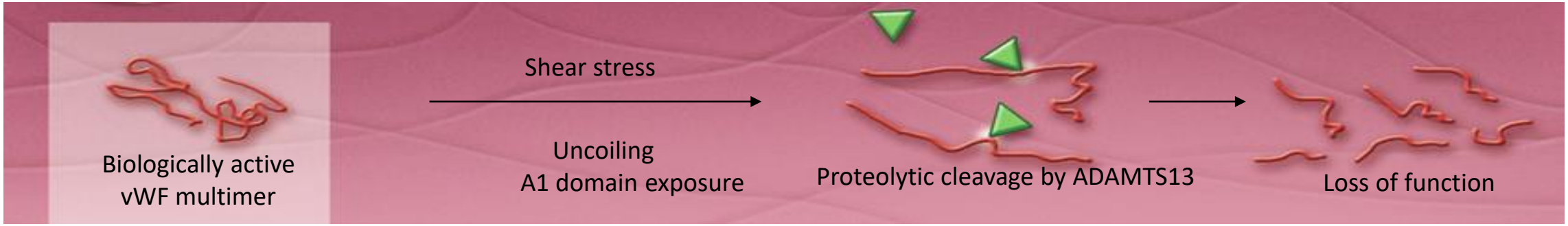


Birks et al, Circulation. 2020;142:2016–2028

Blood trauma

- Normally sub clinical
- Aortic stenosis associated with propensity to GI bleeding
  (Heyde's syndrome)
- High aortic shear stress and GI AVMs
- Conformational change in vWF multimer
- Susceptibility to proteolytic cleavage by ADAMTS13
- Acquired type 2A vWF syndrome[1]
- Also evidence of AvWS in MCS[2]





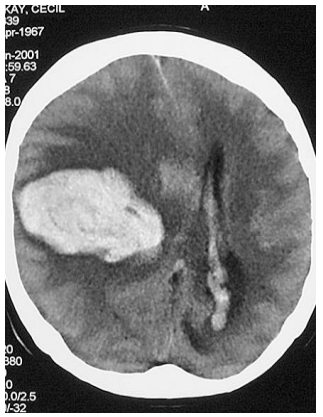
1. Vincentelli et al *NEJM* 2003;349:343-9
2. Eur J Cardiothorac Surg 2008;33:679-84

Problems with the VAD –AvWD hypothesis

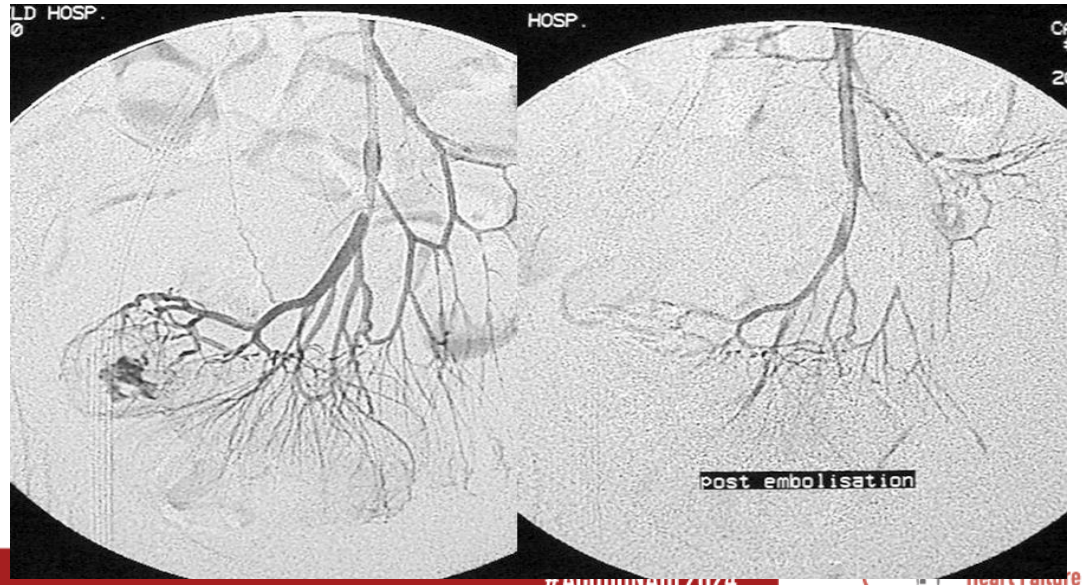
- Loss of VWF multimers occurs in nearly all patients, yet only a small proportion have significant bleeding
- No direct evidence vWF multimers are excessively cleaved by ADAMTS13
- Alternative cleavage proteases have not been investigated, e.g. granzyme, plasmin, *S aureus* V-8 protease. (Granzyme in inflammation increases VWF adhesive activity and disrupts VWF-FVIII interaction)
- Plasmin cleaves VWF fibrils resistant to ADAMTS13
- VWF antigen significantly increased in all patients, a condition not common in type 2 VWD
- Shrear stress induced conformational change in VWF multimers binds and activates platelets (gain-of function)
- VWF multimer loss may be caused by oxidative stress induced VWF binding to platelets
- Sufficient indirect evidence to implicate AvWD in the development of a pro-haehorragic state in MCS recipients

Nascimbene et al Blood 2016;127(25):3133-41

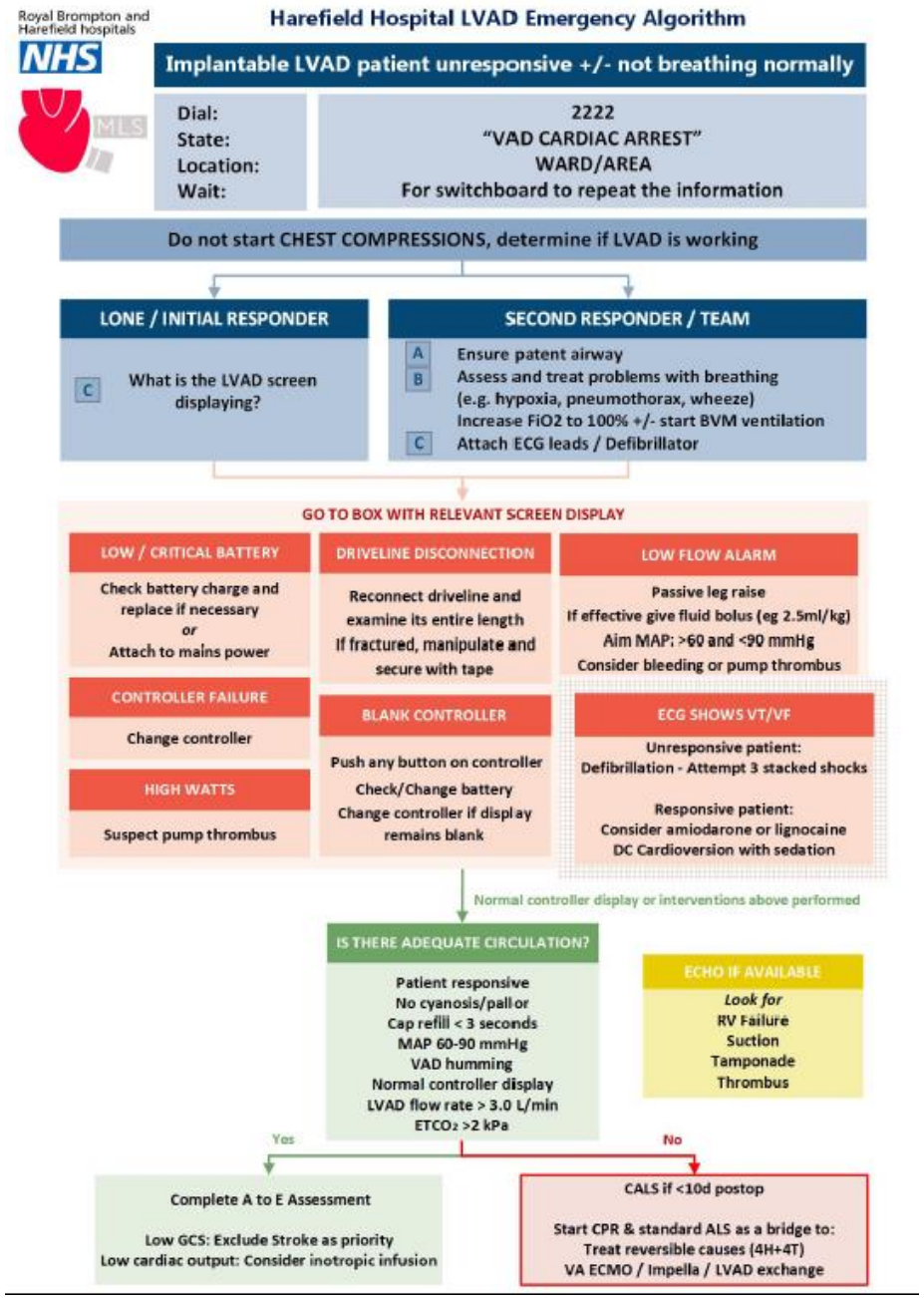
Bleeding in VAD recipients



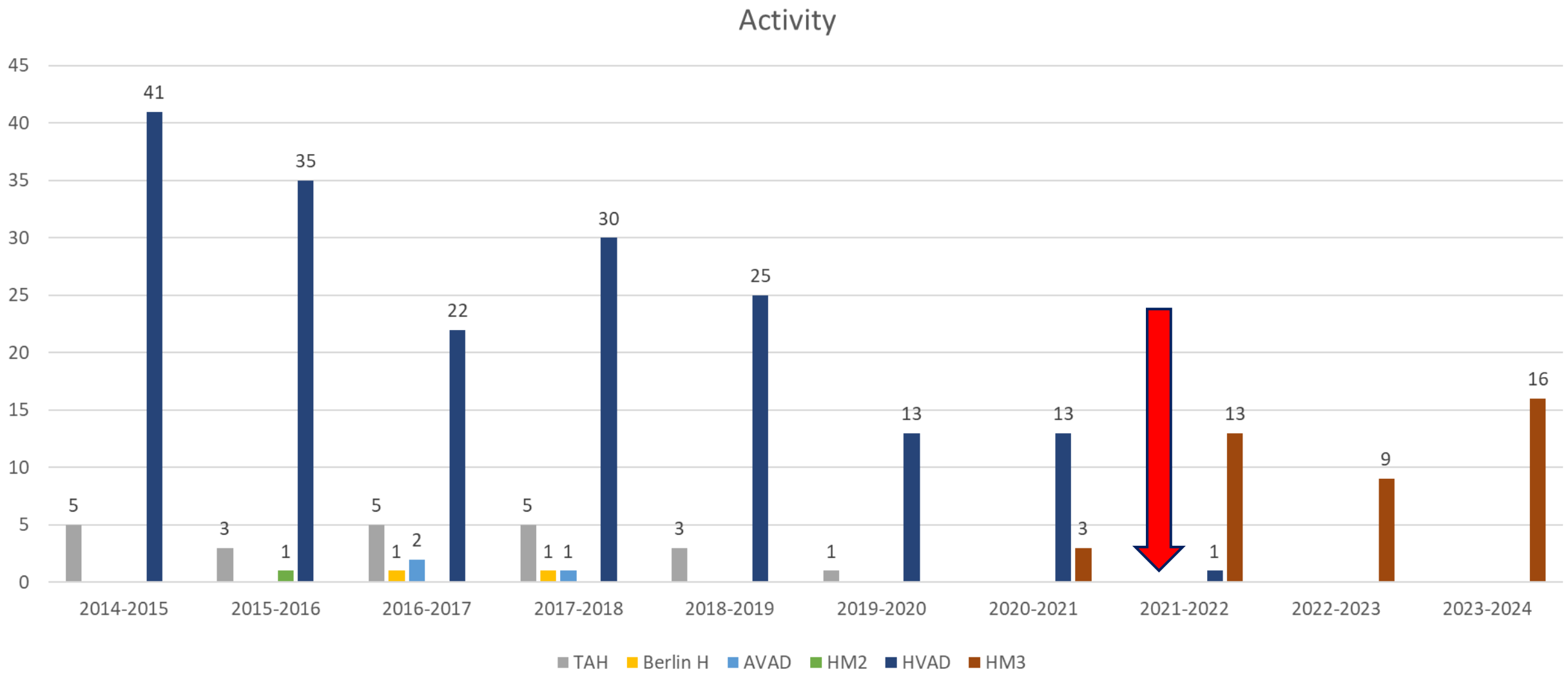
- All VAD recipients in pro-haemorrhagic state
- Higher incidence of bleeding in VAD recipients than those anticoagulated to a similar degree for other indications.
- Symptoms range in severity:
  - Mild chronic anaemia
  - Intermittent GI bleeding
  - Propensity for epistaxis
  - Catastrophic intracranial bleeding
- Attributable to low level blood trauma from elevated shear stresses
- Tight INR control
  - Self testing with Coaguechek
  - Warfarin dosing by VAD team
  - Avoid warfarin interactions wherever possible



Pre- and post embolisation of distal ileal and caecal branches of SMA


Royal Brompton and Harefield hospitals
NHS
MLS
Harefield Hospital LVAD Emergency Algorithm
Implantable LVAD patient unresponsive +/- not breathing normally
Dial: 2222
State: "VAD CARDIAC ARREST"
Location: WARD/AREA
Wait: For switchboard to repeat the information
Do not start CHEST COMPRESSIONS, determine if LVAD is working
LONE / INITIAL RESPONDER
C What is the LVAD screen displaying?
SECOND RESPONDER / TEAM
A Ensure patent airway
B Assess and treat problems with breathing (e.g. hypoxia, pneumothorax, wheeze)
Increase FiO2 to 100% +/- start BVM ventilation
C Attach ECG leads / Defibrillator
GO TO BOX WITH RELEVANT SCREEN DISPLAY
LOW / CRITICAL BATTERY
Check battery charge and replace if necessary
or
Attach to mains power
DRIVELINE DISCONNECTION
Reconnect driveline and examine its entire length
If fractured, manipulate and secure with tape
LOW FLOW ALARM
Passive leg raise
If effective give fluid bolus (eg 2.5ml/kg)
Aim MAP: >60 and <90 mmHg
Consider bleeding or pump thrombus
CONTROLLER FAILURE
Change controller
BLANK CONTROLLER
Push any button on controller
Check/Change battery
Change controller if display remains blank
ECG SHOWS VT/VF
Unresponsive patient:
Defibrillation - Attempt 3 stacked shocks
Responsive patient:
Consider amiodarone or lignocaine
DC Cardioversion with sedation
HIGH WATTS
Suspect pump thrombus
Normal controller display or interventions above performed
IS THERE ADEQUATE CIRCULATION?
Patient responsive
No cyanosis/pallor
Cap refill < 3 seconds
MAP 60-90 mmHg
VAD humming
Normal controller display
LVAD flow rate > 3.0 L/min
ETCO2 >2 kPa
ECHO IF AVAILABLE
Look for
RV Failure
Suction
Tamponade
Thrombus
Yes
No
Complete A to E Assessment
Low GCS: Exclude Stroke as priority
Low cardiac output: Consider inotropic infusion
CALS if <10d postop
Start CPR & standard ALS as a bridge to:
Treat reversible causes (4H+4T)
VA ECMO / Impella / LVAD exchange

Long-Term MCS by Device



A Coruña Heart Failure Academy

Aortic Regurgitation

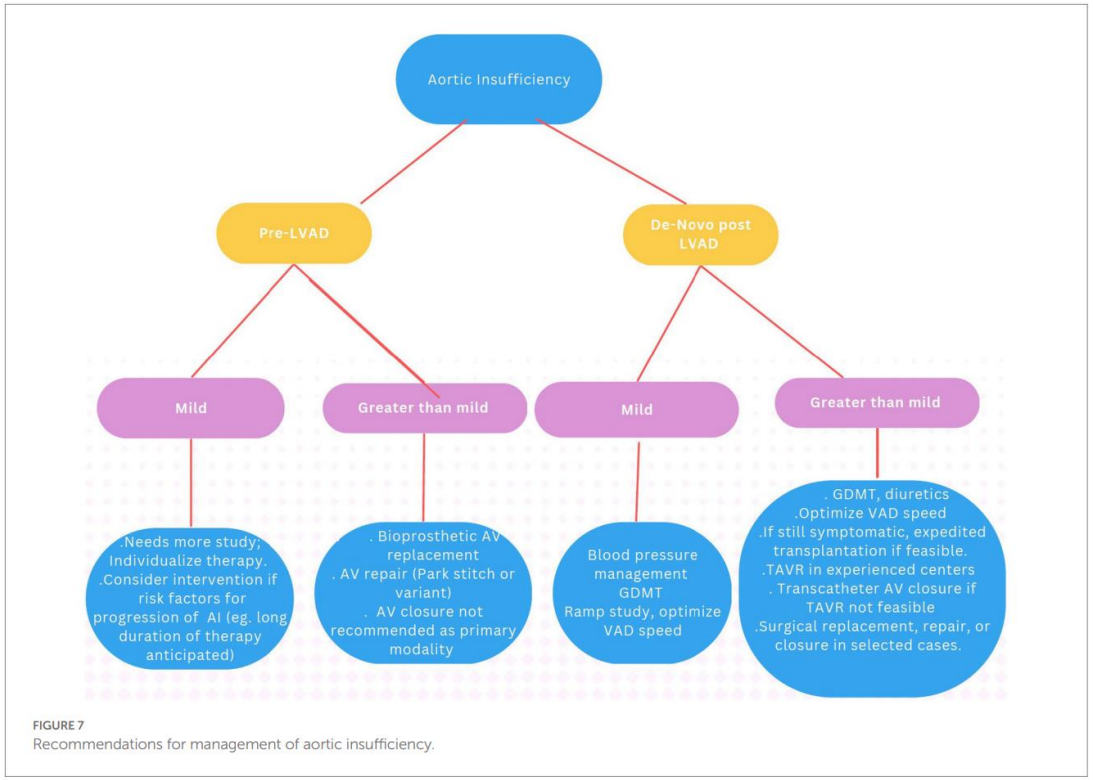


FIGURE 7
Recommendations for management of aortic insufficiency.

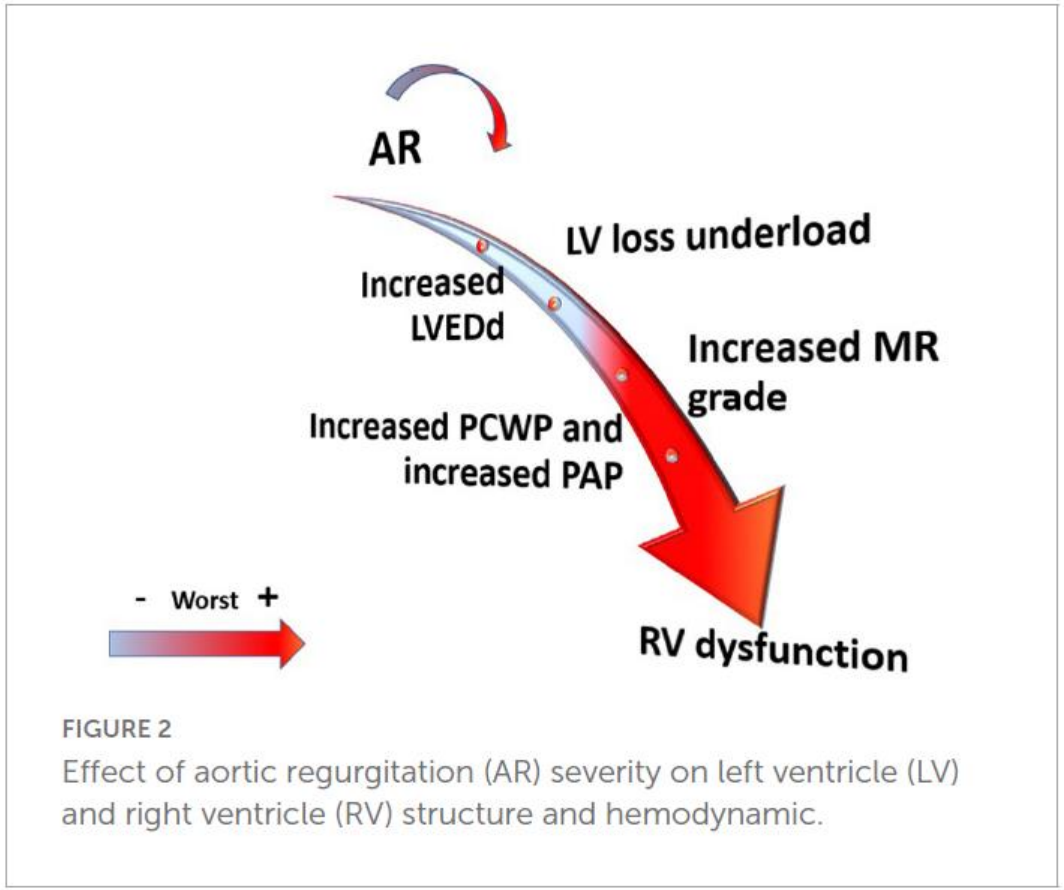
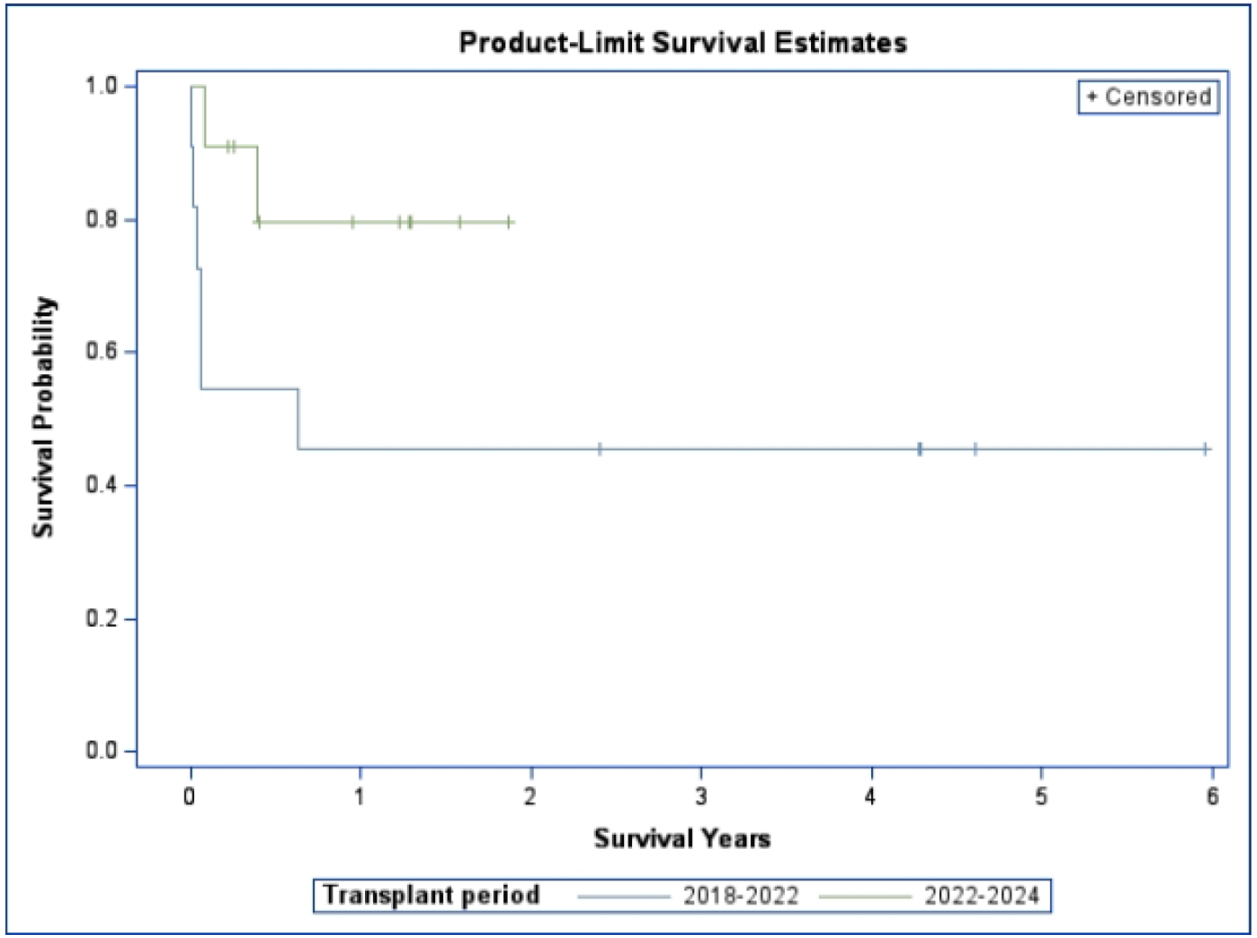


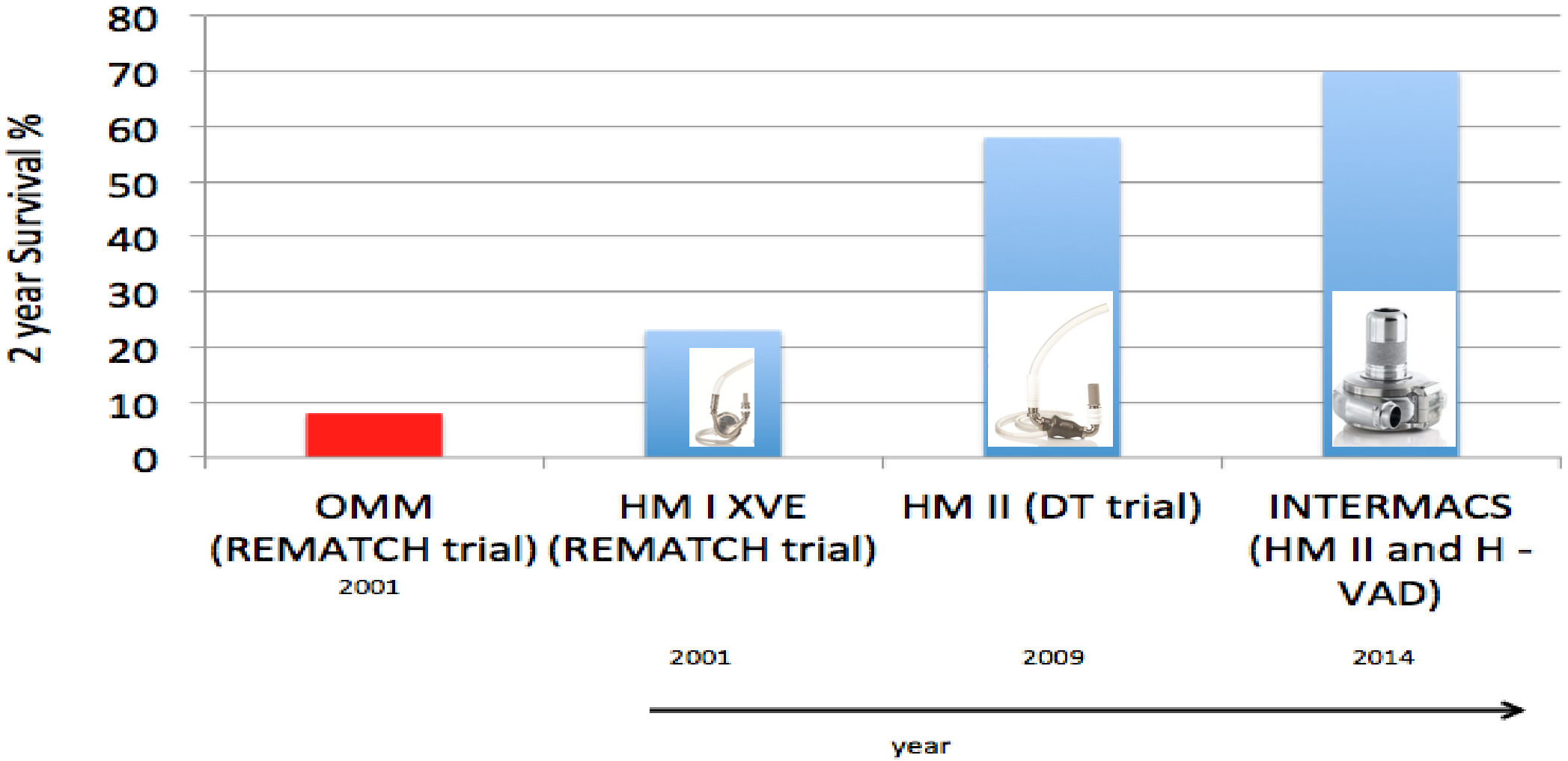
FIGURE 2
Effect of aortic regurgitation (AR) severity on left ventricle (LV) and right ventricle (RV) structure and hemodynamic.

LVAD to Transplant Results

- High 1-year mortality rate of VAD>Tx identified during Trigger Review – 45%
- 2018-2022:
  - 11x LVAD to Tx patients (11x HVAD)
    - 5x Alive – 45%
    - 6x RIP – 55%
- 2022-Now
  - 11x LVAD to Tx patients (7x HVAD and 3x HM3)
    - 9x Alive – 82%
    - 2x RIP – 18%



Two year survival of advanced heart failure patients treated with various LVADs compared to optimal medical therapy
(data from trials and INTERMACS registry)



MOMENTUM 3

2 Year Outcomes - 2019

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Fully Magnetically Levitated Left Ventricular Assist Device — Final Report

M.R. Mehra, N. Uriel, Y. Naka, J.C. Cleveland, Jr., M. Yuzefpolskaya, C.T. Salerno, M.N. Walsh, C.A. Milano, C.B. Patel, S.W. Hutchins, J. Ransom, G.A. Ewald, A. Itoh, N.Y. Raval, S.C. Silvestry, R. Cogswell, R. John, A. Bhimaraj, B.A. Bruckner, B.D. Lowes, J.Y. Um, V. Jeevanandam, G. Sayer, A.A. Mangi, E.J. Molina, F. Sheikh, K. Aaronson, F.D. Pagani, W.G. Cotts, A.J. Tatooles, A. Babu, D. Chomsky, J.N. Katz, P.B. Tessmann, D. Dean, A. Krishnamoorthy, J. Chuang, I. Topuria, P. Sood, and D.J. Goldstein, for the MOMENTUM 3 Investigators*

ABSTRACT

N Engl J Med 2019; 380:1618-1627

5 Year Outcomes - 2022

Research

JAMA | Original Investigation

Five-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices in the MOMENTUM 3 Randomized Trial

Mandeep R. Mehra, MD, MSc; Daniel J. Goldstein, MD; Joseph C. Cleveland, MD; Jennifer A. Cowger, MD, MS; Shelley Hall, MD; Christopher T. Salerno, MD; Yoshifumi Naka, MD, PhD; Douglas Horstmanshof, MD; Joyce Chuang, PhD; AiJia Wang, MPH; Nir Uriel, MD, MSc

Mehra MR, et al. JAMA. 2022 Sep 27;328(12):1233-1242.

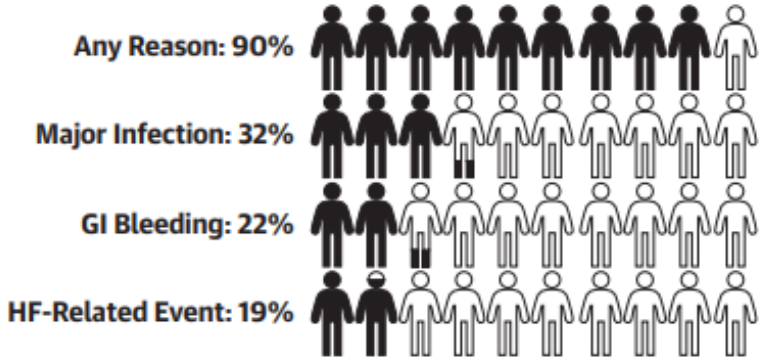
Outcomes Heartmate 3 – Hospital Admissions

CENTRAL ILLUSTRATION Patterns and Impact of Hospitalizations With HeartMate 3 Left Ventricular Assist Device Support in the MOMENTUM 3 Trial

The Burden of Hospitalizations With HeartMate 3 LVAD Support Is Not Well Characterized

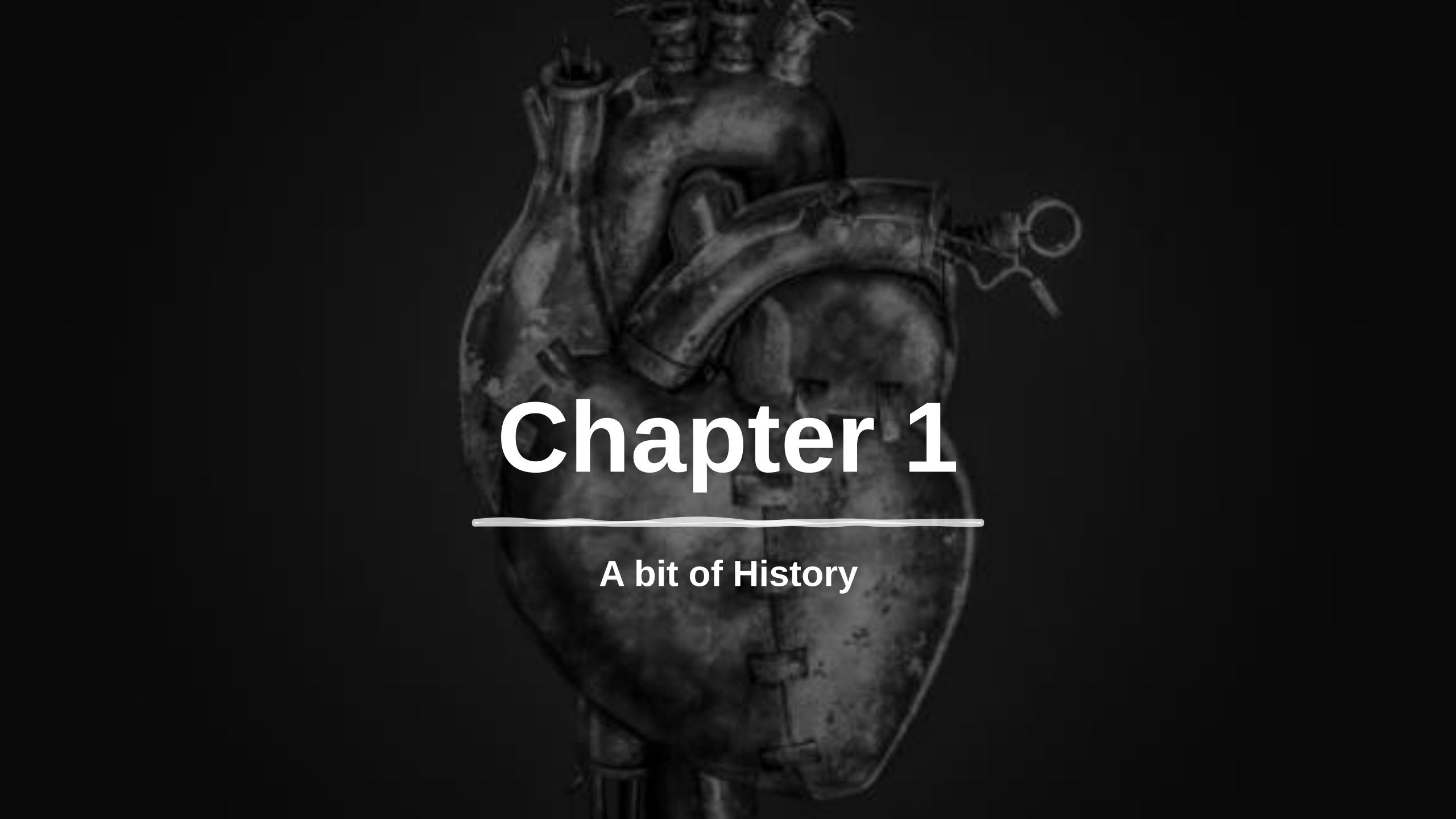
- 485 HeartMate 3 and 471 HeartMate II recipients were compared in the MOMENTUM 3 pivotal trial. The pivotal trial HeartMate 3 group was also compared to 949 HeartMate 3 recipients in the post-approval trial phase.
- The HeartMate 3 LVAD is associated with significantly lower rehospitalization rate and duration compared to the HeartMate II LVAD.
- Compared to the pivotal trial, HeartMate 3 recipients in the post-approval phase demonstrated a lower rate of prolonged hospitalizations potentially due to improving clinical experience:
  - Rehospitalization rate for infection decreased over time
  - Rehospitalization rates for GI bleeding and HF-related events have not improved
  - HF-related hospitalizations are associated with increased mortality

Percent of HeartMate 3 LVAD Recipients Rehospitalized During 2-Year Follow-Up for



Challenges remain with infection (device-related and -unrelated), nonsurgical bleeding, and HF-related hospitalizations in HeartMate 3 LVAD supported patients. Introducing and evaluating strategies to decrease the burden of these specific cause-related hospitalizations is necessary to allow for continuous progress in the field of LVAD therapy.

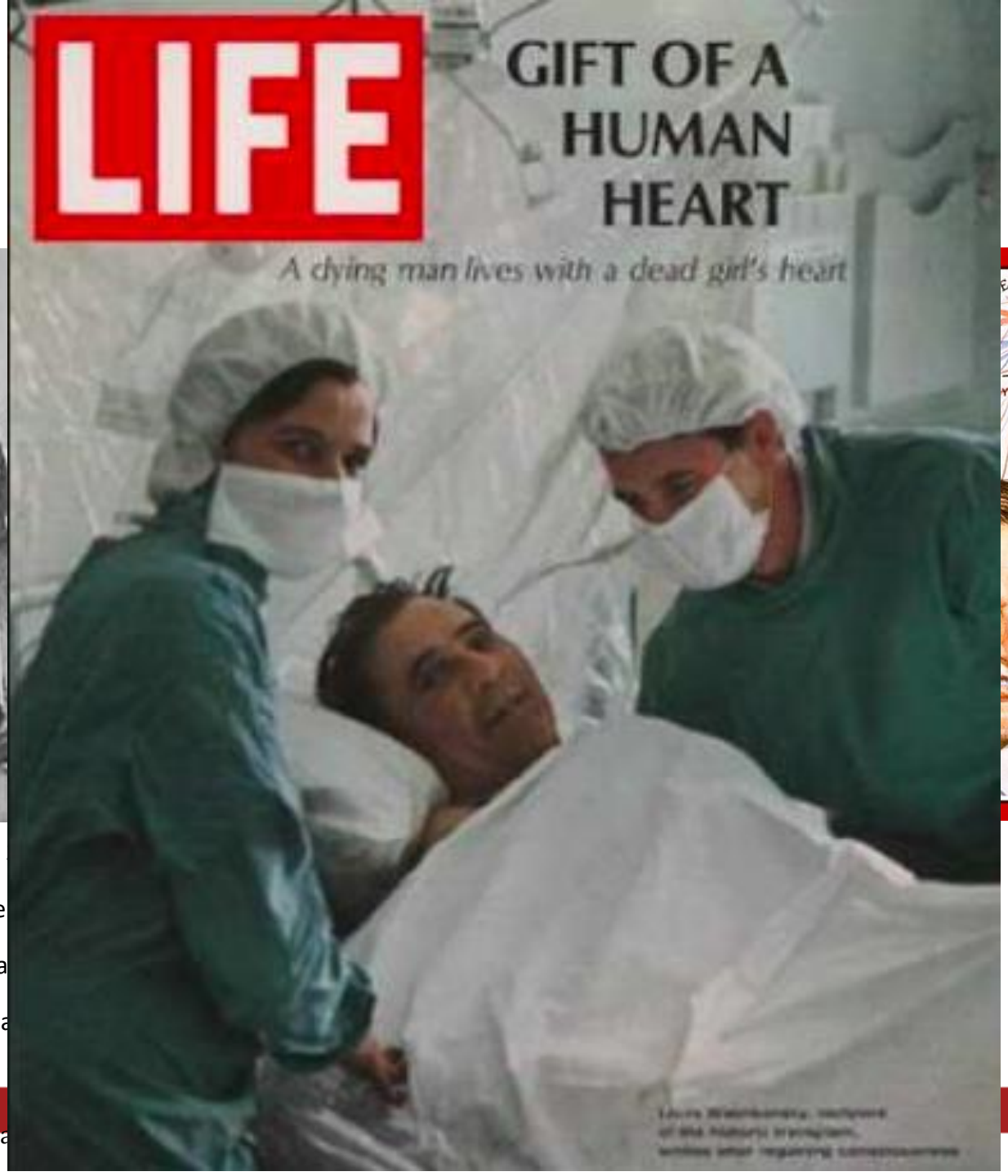
Vidula H, et al. J Am Coll Cardiol HF. 2022;10(7):470–481

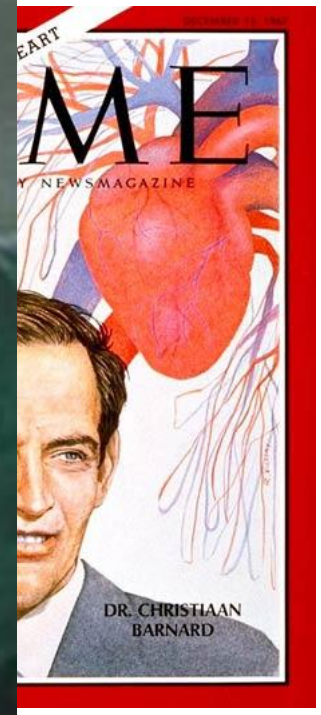


Chapter 1

A bit of History

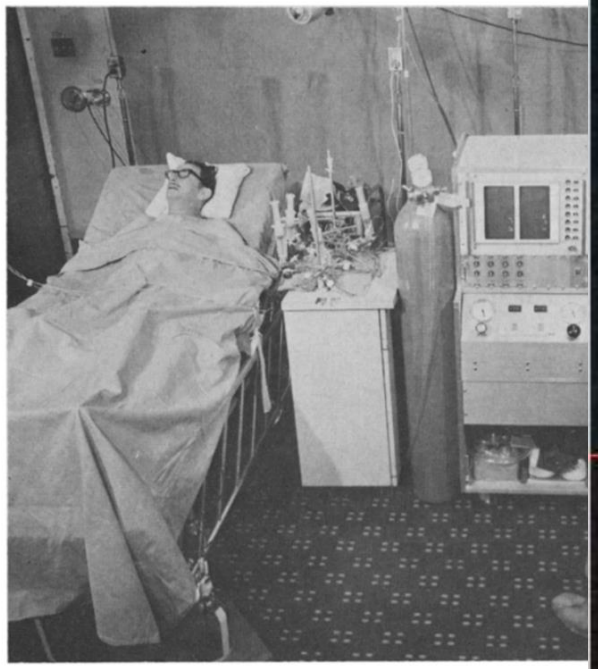
First

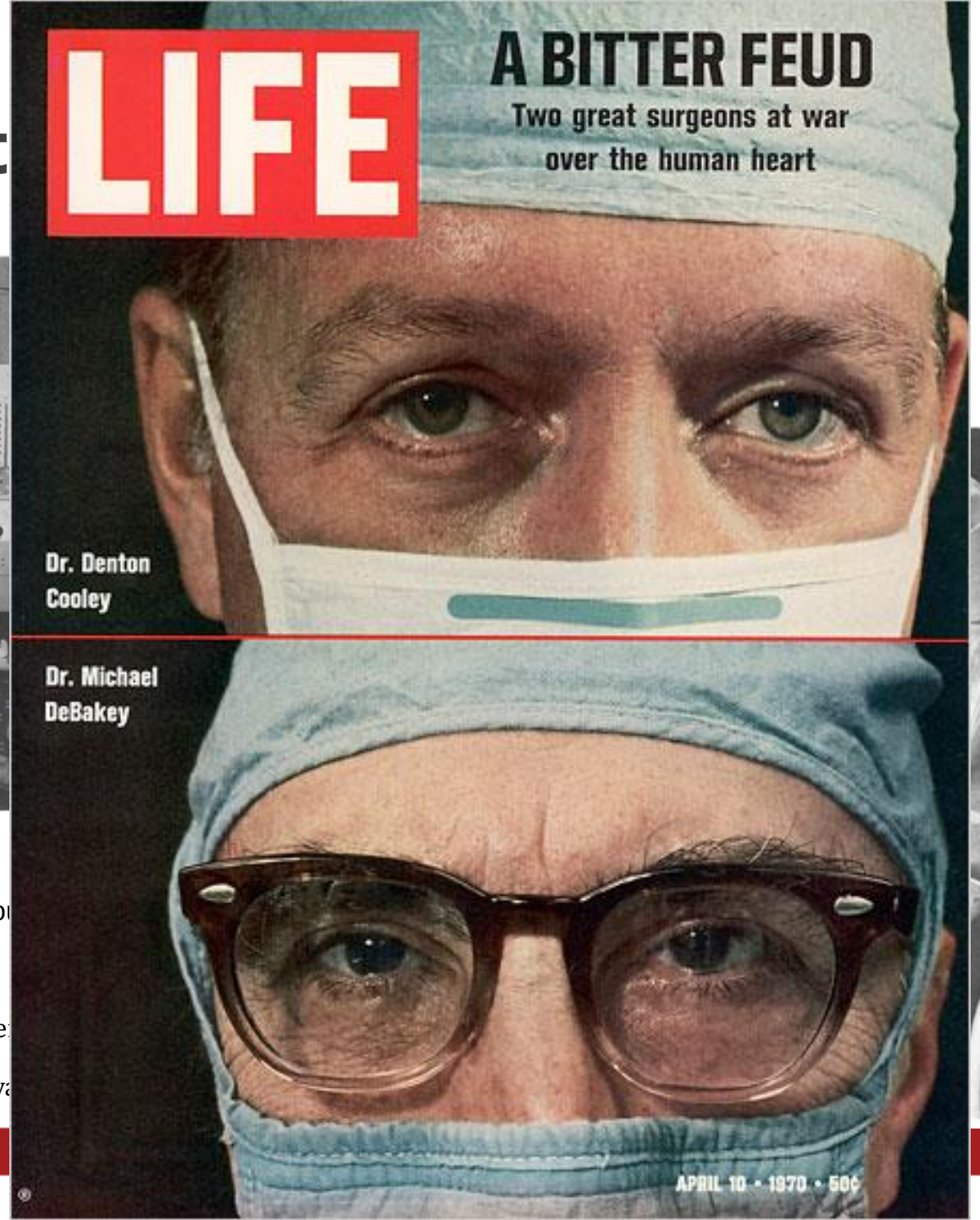


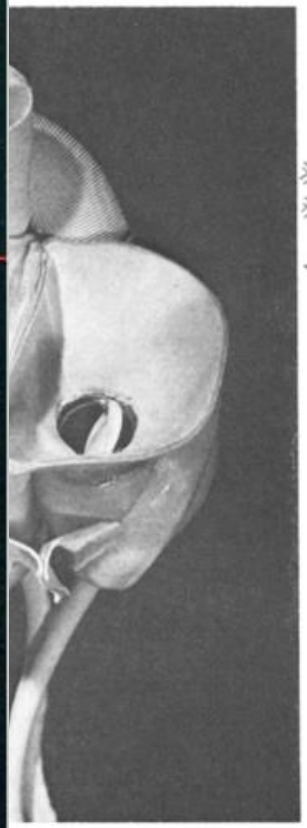


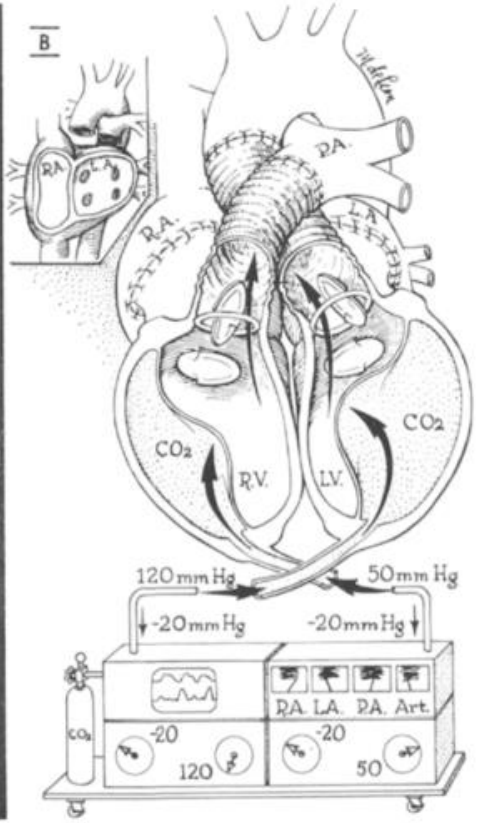
- **Date:** December
- **Location:** Groote
- **Surgeon:** Christia
- **Donor:** Denise Da
- **Recipient:** Louis
- **Outcome:** died a

First









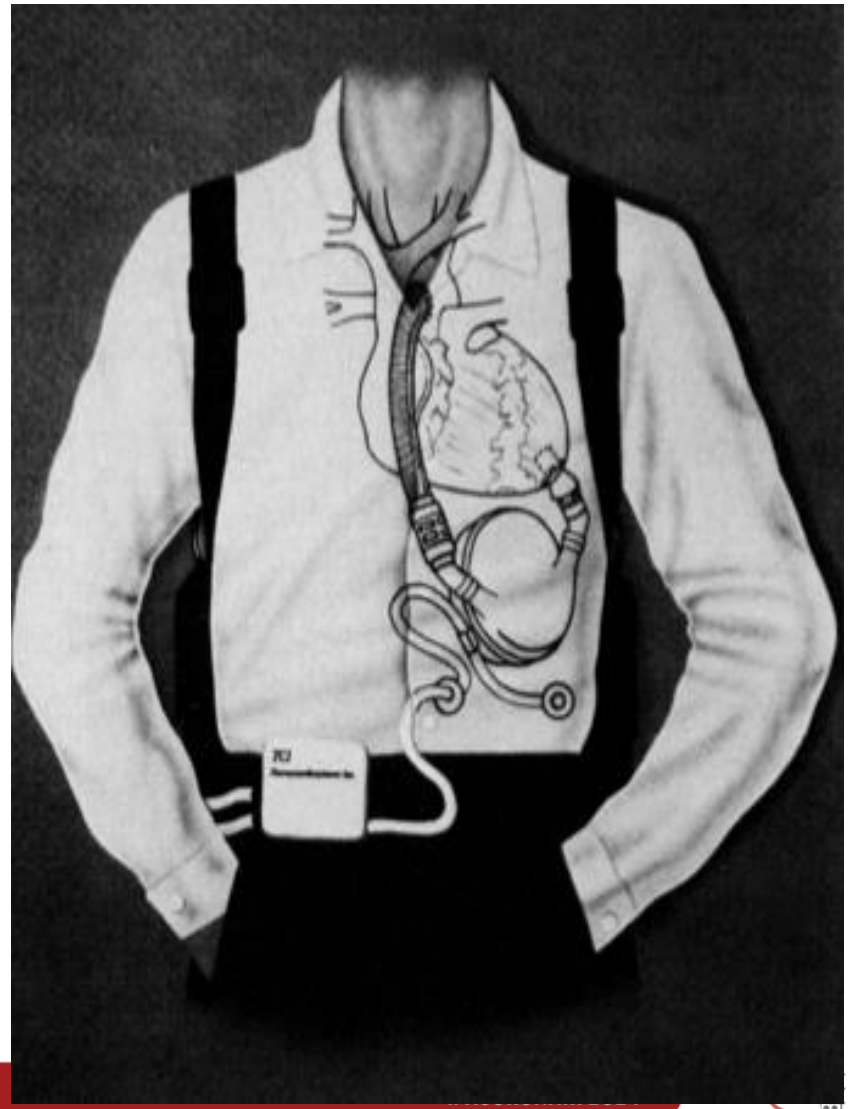
- **Date:** April 4, 1969
- **Location:** Texas Heart Institute. Ho
- **Surgeon:** Denton A Cooley
- **Patient:** 47 year old man with ischae
- **Outcome:** survived 3 days, then he wa

First Use of an Untethered, Vented Electric Left Ventricular Assist Device for Long-term Support

O.H. Frazier, MD

Abstract This report describes the first long-term (505-day) application of the vented electric (VE) HeartMate left ventricular assist device (LVAD) (Thermo Cardiosystems, Inc). The device consists of an abdominally placed, battery-powered titanium blood pump that, in contrast to earlier pneumatically powered systems, allows patients untethered freedom of movement. The batteries last 5 to 8 hours and can be changed on a rotating basis indefinitely. The patient, a 33-year-old man (90 kg, blood type O) with idiopathic cardiomyopathy, experienced end-organ heart failure (New York Heart Association [NYHA] class IV) while he was awaiting heart transplantation. When his hemodynamic criteria met those outlined in the protocol, we implanted the VE-LVAD as a bridge to transplantation. The patient was supported by the device for more than 16 months. His cardiac status returned to NYHA class I, and he was eventually allowed to take day trips outside the hospital as he awaited transplantation. The VE-LVAD enabled the patient to participate in activities such as eating in restaurants, going to movies, and practicing basketball shots. Unfortunately, the patient died suddenly due to a neurological thromboembolic event that occurred on day 503 of VE-LVAD support. The VE-LVAD improved native left ventricular function by chronic unloading, and ventricular remodeling resulted in a more normal configuration anatomically, physiologically, and ultimately, histologically and pathologically. (*Circulation*. 1994;89:2908-2914.)

Key Words • heart-assist device • transplantation • cardiomyopathy



Circulation.1994;89:2908-2914

1st published case report of durable ambulatory LVAD use 1994

- 33-year-old man with DCM
  - Weight 90kg, blood group O
  - Estimated waiting time for heart was 400 days
- Successfully resuscitated following a VF cardiac arrest
  - IABP and inotropic support dependent
  - Ongoing ventricular arrhythmias
- Crt 4.1 mg/dl, cardiac index 1.77 L/min/m2

- On September 3rd 1991 the VE-LVAD was successfully implanted.
- In August 1992, patient received approval to take day trips (restaurants, movies, and practiced his basketball shots)
- The success of these trips led to approval for overnight stays outside the hospital
- On January 17, 1993, the patient suffered a fatal stroke

Circulation.1994;89:2908-2914.

LVAD Devices

Heartmate 1

Heartmate 2

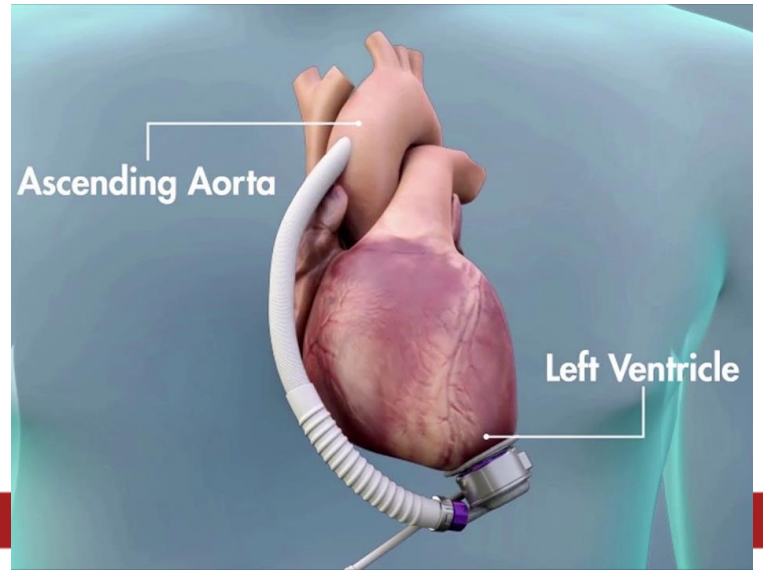
Heartware

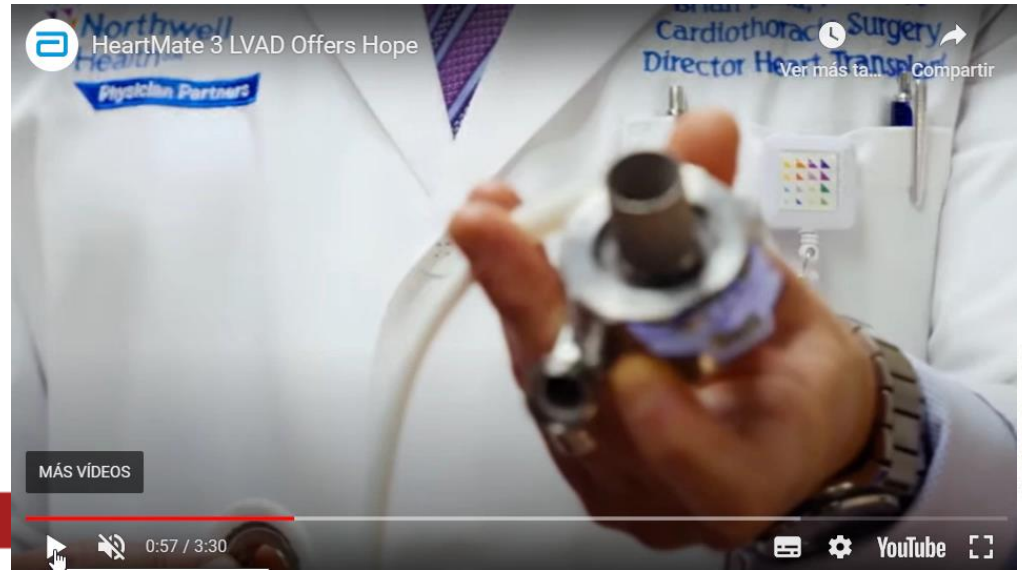
Heartware (HVAD)

On June 3, 2021, **Medtronic stopped the sale and distribution of the HeartWare Ventricular Assist Device (HVAD)** system given the increased risk of mortality and neurological adverse events in patients using the device, and a malfunction where the device may fail to restart.

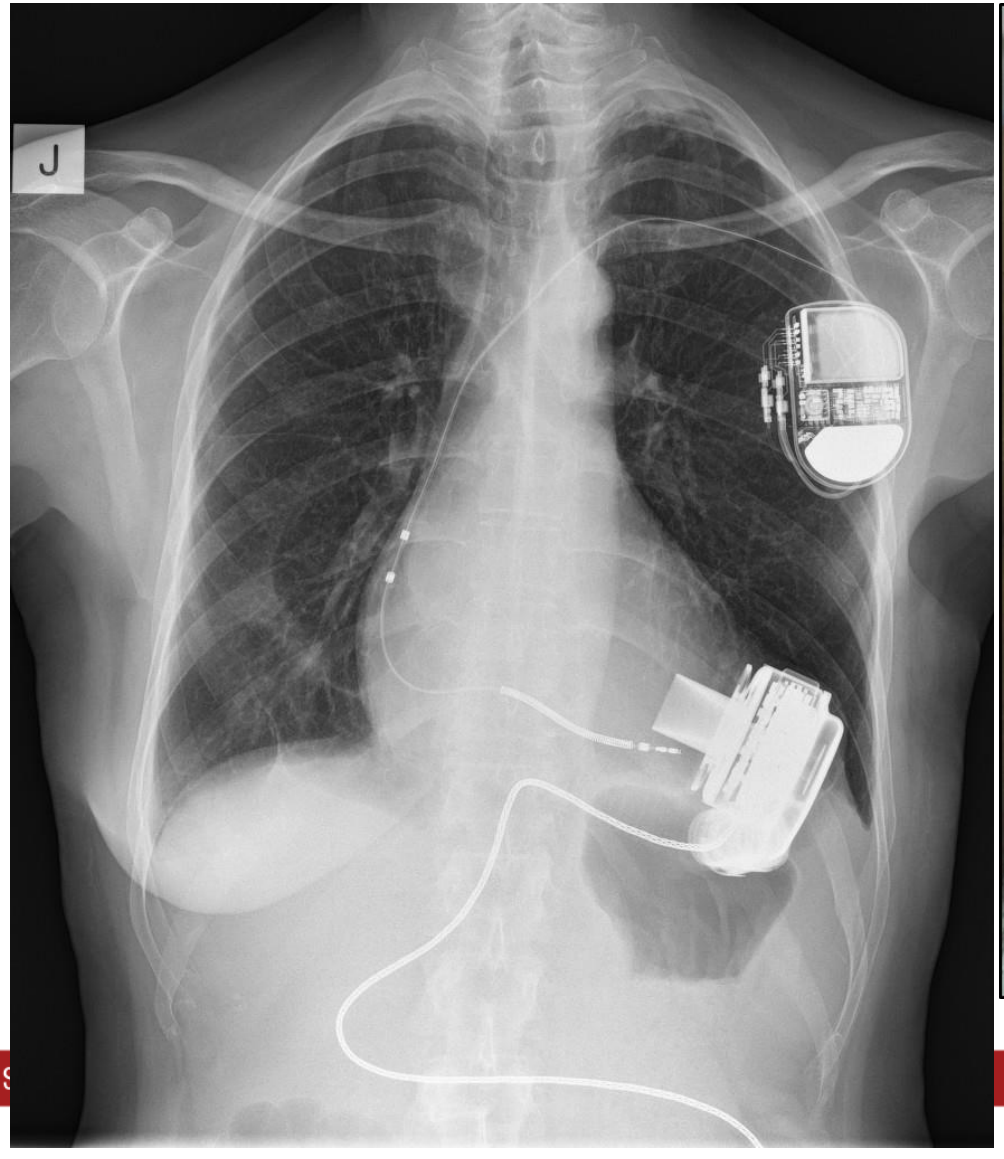
Heartmate 3

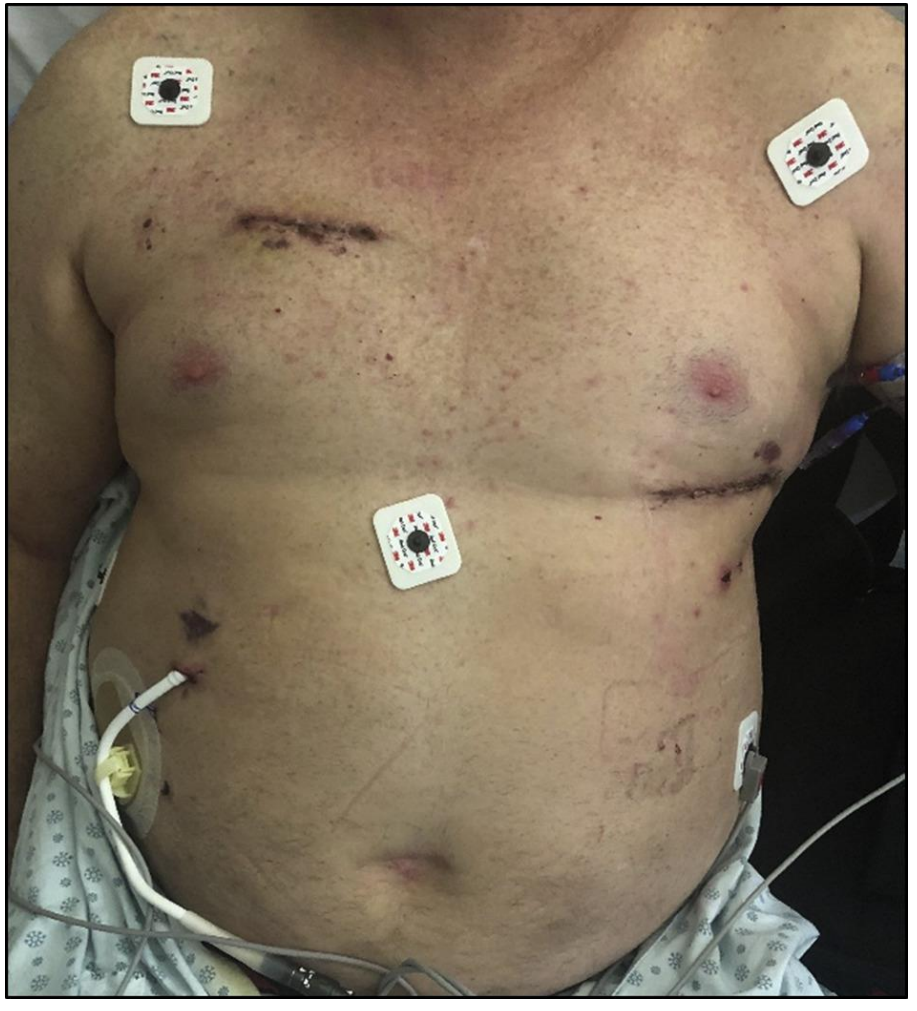
- Centrifugal-flow mechanism
- Fully levitated, self-centering rotor that does not require hydrodynamic or mechanical bearings
- Large, consistent blood flow pathways to reduce shear str
- Intrinsic pulsatility to reduce stasis and minimize thrombu





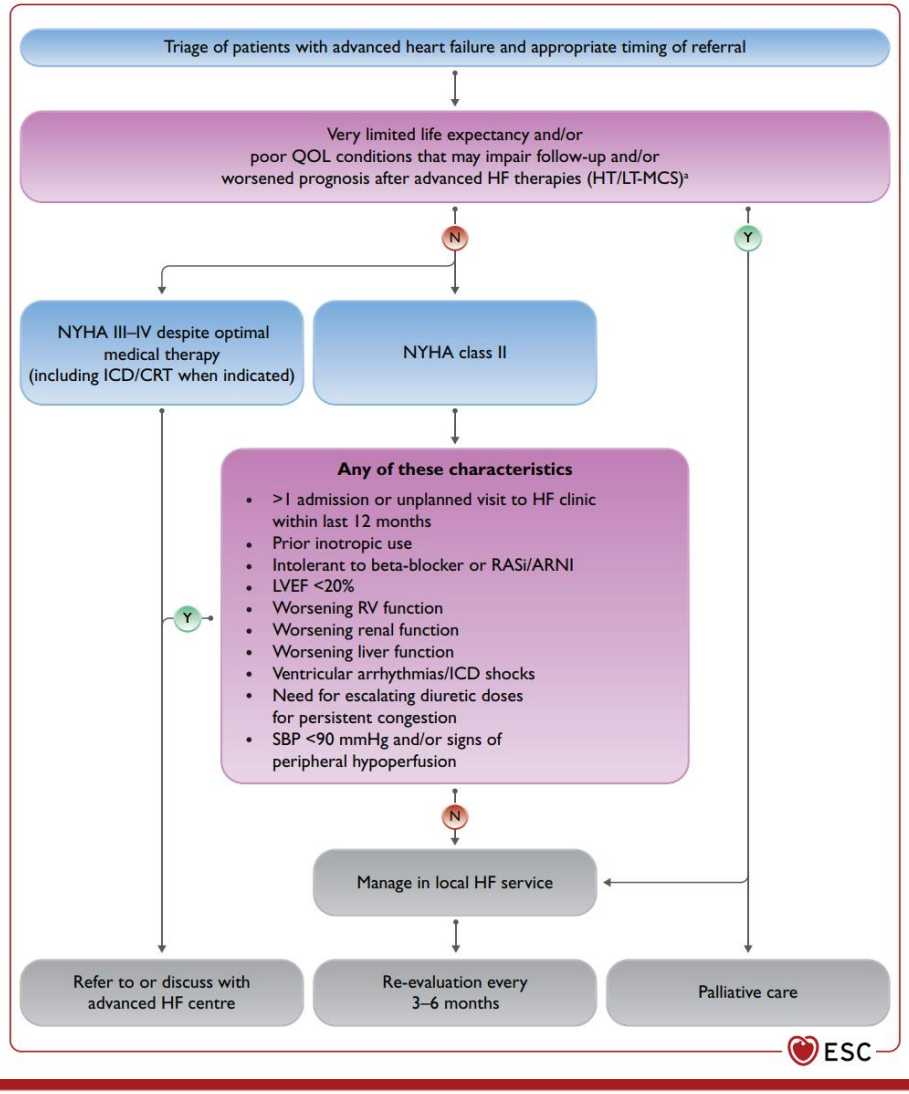
Heartmate 3

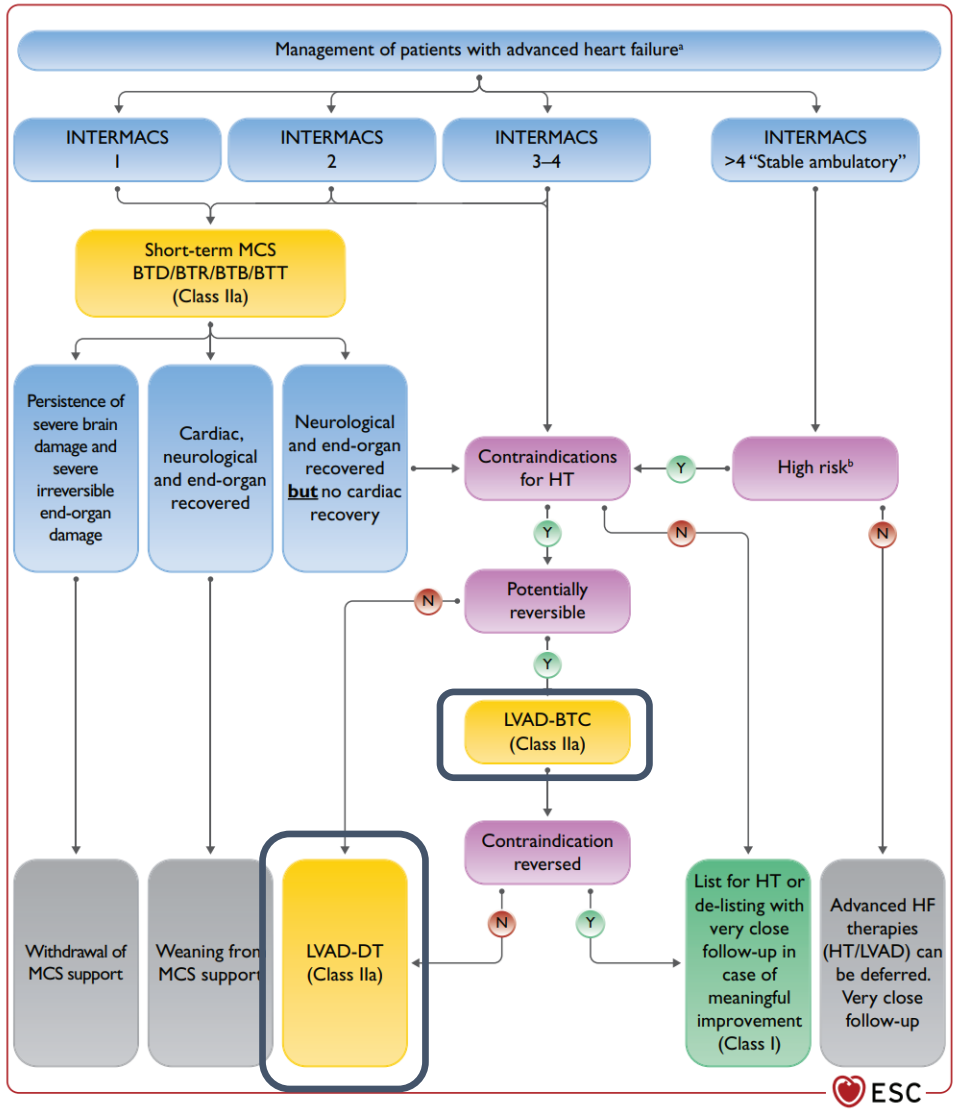




Chapter 2

Why do we care about machine hearts when we have Heart Transplant?

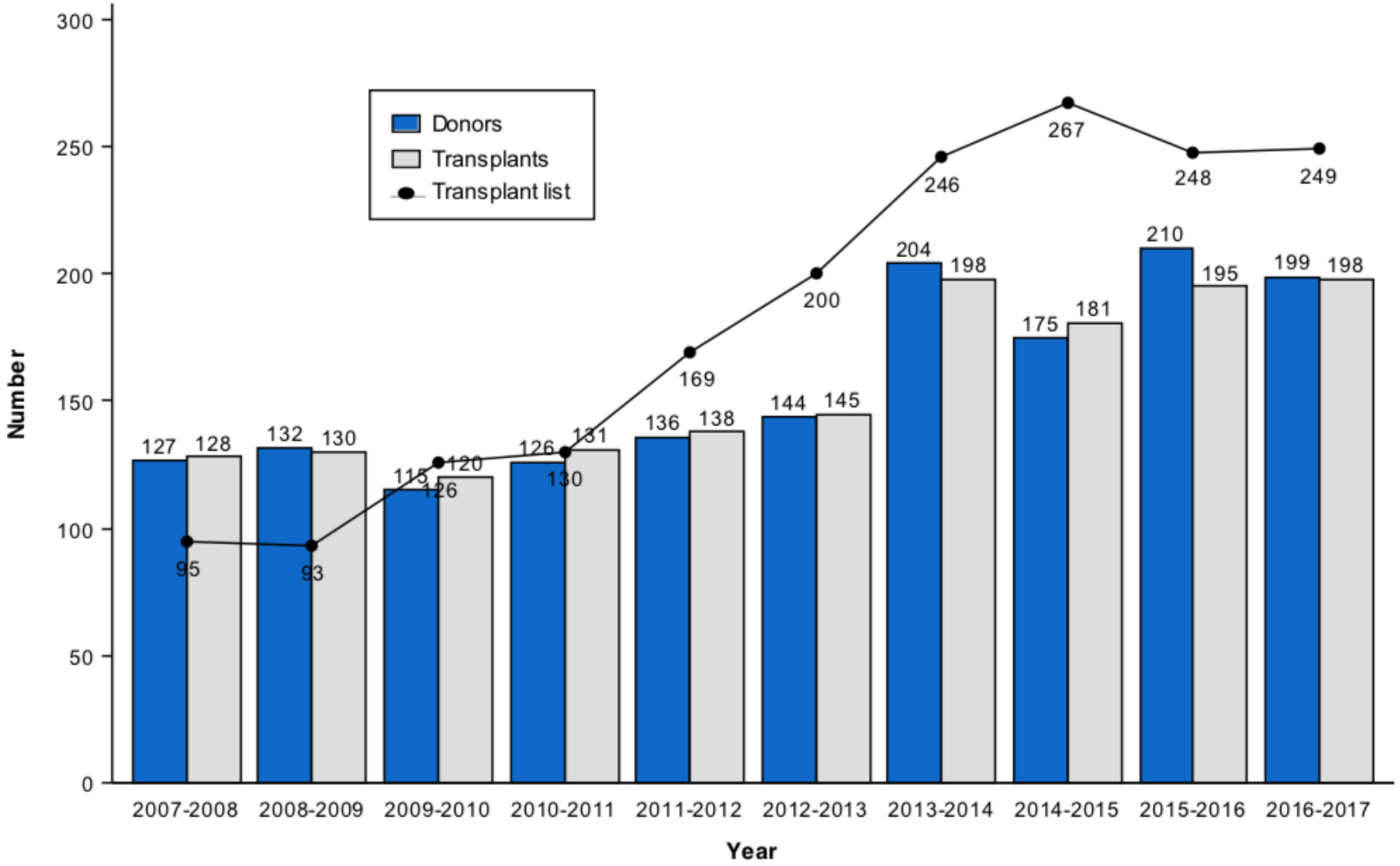




European Heart Journal (2021) 42, 35993726

Supply – Demand Problem

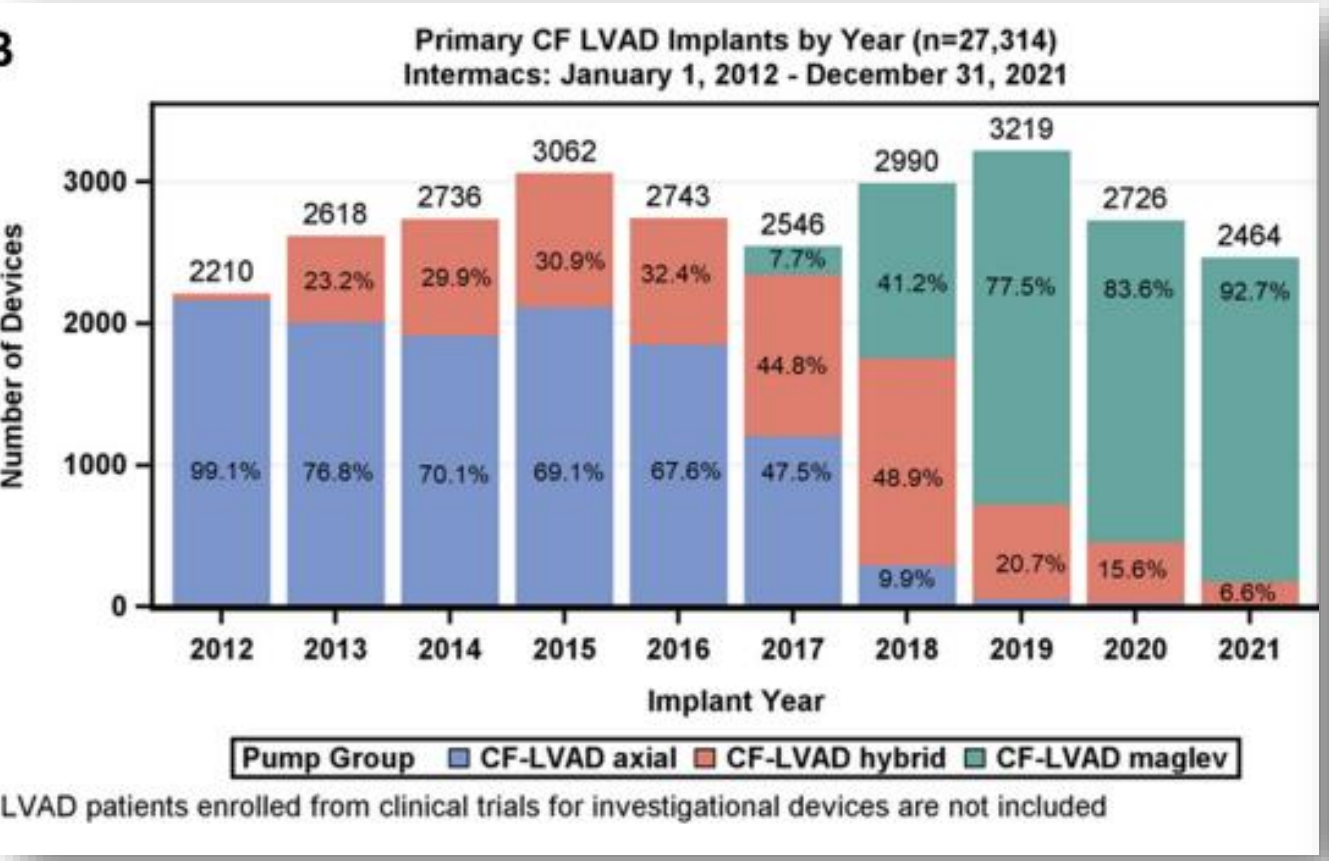
Figure 7.1 **Deceased donor heart programme in the UK, 1 April 2007 - 31 March 2017, Number of donors, transplants and patients on the active transplant list at 31 March**

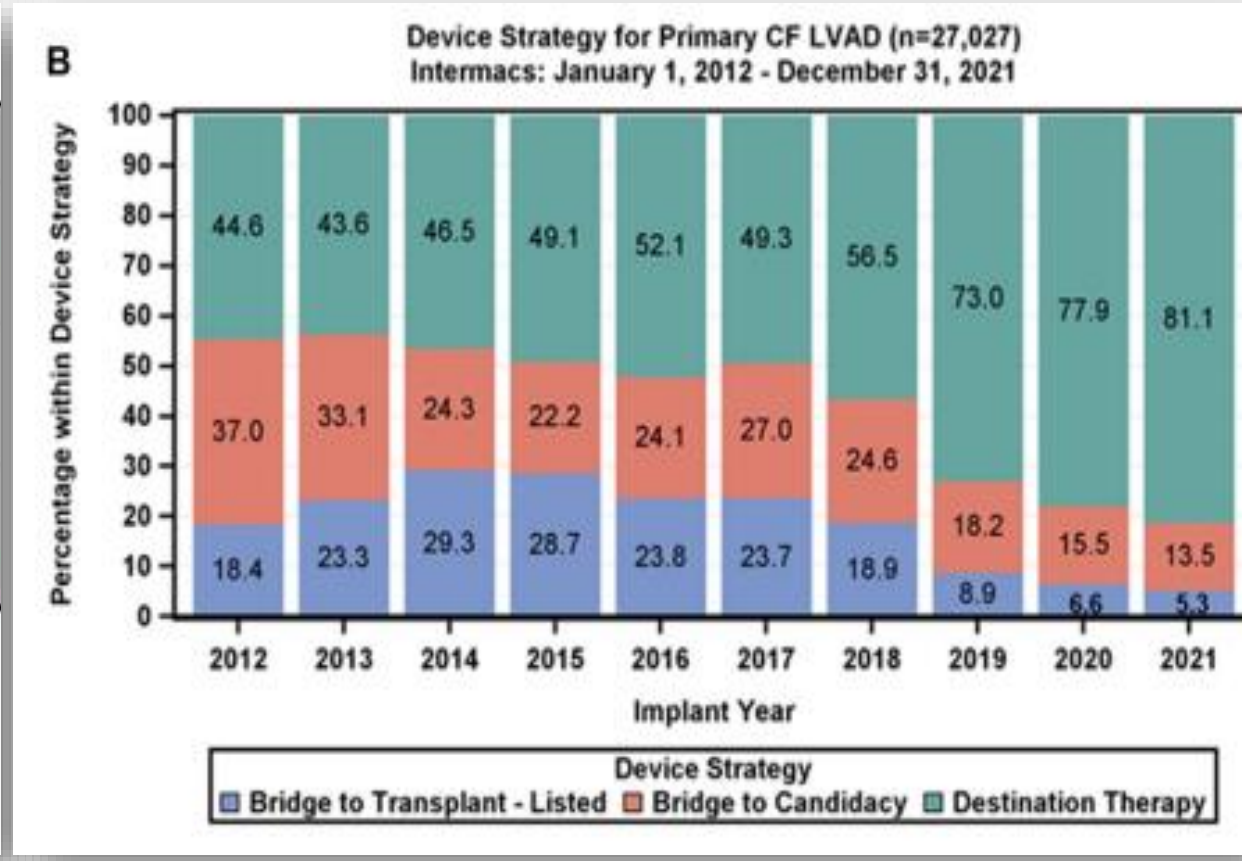


Bridge to decision (BTD)/ Bridge to bridge (BTB)	Use of short-term MCS (ECMO or Impella) in patients with cardiogenic shock until haemodynamics and end-organ perfusion are stabilized, contraindications for long-term MCS are excluded (brain damage after resuscitation) and additional therapeutic options including long-term VAD therapy or heart transplant can be evaluated.
Bridge to candidacy (BTC)	Use of MCS (usually LVAD) to improve end-organ function and/or to make an ineligible patient eligible for heart transplantation.
Bridge to transplantation (BTT)	Use of MCS (LVAD, BiVAD or TAH) to keep a patient alive who is otherwise at high risk of death before transplantation until a donor organ becomes available.
Bridge to recovery (BTR)	Use of MCS (short-term or long-term) to keep a patient alive until cardiac function recovers sufficiently to remove MCS.
Destination therapy (DT)	Long-term use of MCS (LVAD) as an alternative to transplantation in patients with end-stage HF ineligible for transplantation.

BiVAD = biventricular assist device; ECMO = extracorporeal membrane oxygenation; HF = heart failure; LVAD = left ventricular assist device; MCS = mechanical circulatory support; TAH = total artificial heart; VAD = ventricular assist device.

Current situation





Yuzefpolskaya M, et al. Ann Thorac Surg. 2023 Feb;115(2):311-327.

Chapter 3

Who is the ideal Man-Machine?

Target Population for LVAD Therapy

- Severe LV systolic dysfunction and dilatation
- Refractory HF despite adequate guideline-based medical management
- Optimal RV function
- Preserved end-organ function
- Exit strategy (Potentially suitable for HTx - UK)
- Motivated / Able to understand pros and cons
- Good social support / Excellent compliance
- No comorbidities with significant impact on survival, functional capacity and quality of life

Contraindications

ABSOLUTE

- Recent or evolving stroke
- Neurological deficits impairing the ability to manage device
- Severe biventricular failure
- Active systemic infections or major chronic risk for infection
- Severe pulmonary dysfunction (FEV1 <1 l)
- Impending renal or hepatic failure
- Multi organ failure
- Inability to tolerate anticoagulation - bleeding diathesis
- Significant underlying psychiatric illness

RELATIVE

- Chronic kidney disease with serum creatinine level > 3mg/dl
- Severe malnutrition (BMI < 21kg/m^2 in males and < 19kg/m^2 in women
- Morbid obesity (BMI >40 kg/m^2)
- Severe mitral stenosis or moderate aortic insufficiency
- Age > 70 years, unless minimal or no clinical risk factors

Pre-Implant Risk Factors

Table 8 Continuous-flow LVAD/BiVAD, IMACS, January 1, 2013 to December 31, 2016 (n = 13,618)

	Early hazard		Constant hazard	
Pre-implant risk factors for death	Hazard ratio	p-value	Hazard ratio	p-value
Demographics				
Older age (unit: 10 years)	1.44	<0.0001	1.23	<0.0001
Female	1.28	0.003	1.18	0.008
Higher BMI (unit: 5 kg/m^2)	1.12	<0.0001	1.04	0.021
Destination therapy strategy at time of implant			1.14	0.014
Not blood type O			0.89	0.013
Surgical complexities				
History of CABG	1.31	0.002	1.20	0.004
Concomitant surgery	1.34	<0.0001		
BiVAD	3.42	<0.0001		
Clinical status				
Patient Profile 1	1.77	<0.0001		
Patient Profile 2	1.51	<0.0001		
Not patient Profile 4 to 7			0.85	0.014
Primary diagnosis—congenital	5.23	0.002		
Peripheral vascular disease			1.41	<0.01
Intervention 48 hours pre-implant—ventilator	1.32	0.003		
BUN (unit: 10 mg/dl) higher	1.06	<0.0001	1.04	<0.0001
Creatinine (unit: 1 mg/dl) higher			1.08	0.004
Intervention with 48 hours pre-implant—dialysis	1.92	<0.0001		
Albumin (unit: 1 g/dl) lower	0.85	0.001	0.86	<0.0001
Sodium (unit: 10 mEq/liter) lower			0.86	0.004
AST (unit: 10 U/liter) higher	1.13	<0.0001		
ALT (unit: 10 U/liter) lower	0.94	<0.01		
Total bilirubin (unit: 5 mg/dl) higher	1.18	<0.0001		
Tricuspid regurgitation: moderate/severe	1.37	<0.0001		
Implantable cardioverter-defibrillator			1.21	0.004

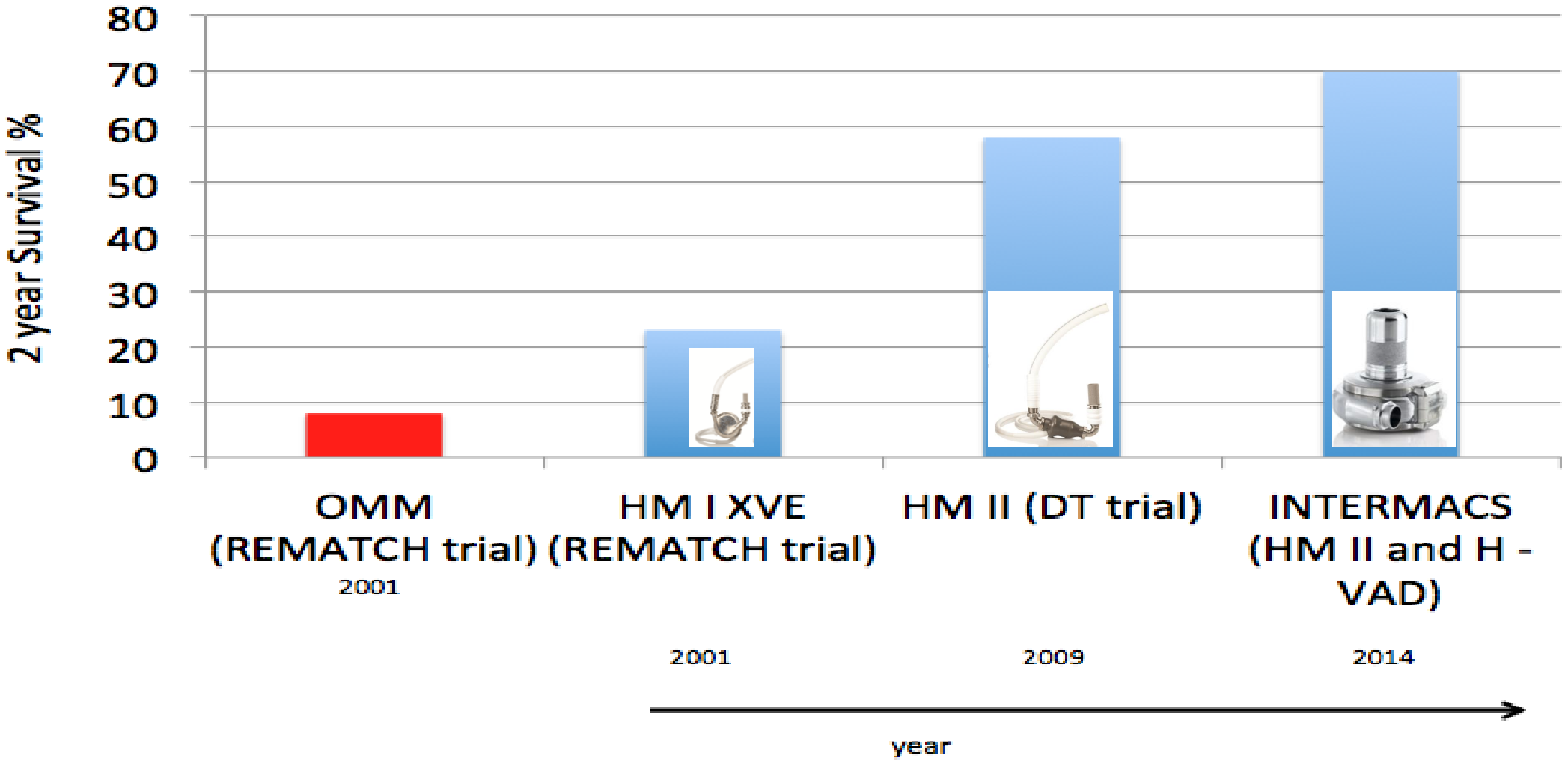
Important Factors To Consider

- Is Pulmonary Hypertension a problem?
- Structural Heart Disease – what is important?
  - AR
  - MS
  - Intracardiac shunt
- The RV Dysfunction Mystery – RVFS / Michigan Score
  - Female gender
  - Small Size
  - DCM
  - Ventilatory support
  - Poor renal Function
  - Abnormal Liver Function
  - Echocardiogram: reduced TAPSE, dilated RV, severe TR, impaired RV/RA strain
  - RHC: CVP >14 / CVP/PCWP >0.6 / RVSWi <5 / PAPi <1.8

Chapter 4

This is cool but, DOES IT WORK?

Two year survival of advanced heart failure patients treated with various LVADs compared to optimal medical therapy
(data from trials and INTERMACS registry)



MOMENTUM 3

2 Year Outcomes - 2019

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Fully Magnetically Levitated Left Ventricular Assist Device — Final Report

M.R. Mehra, N. Uriel, Y. Naka, J.C. Cleveland, Jr., M. Yuzefpolskaya, C.T. Salerno, M.N. Walsh, C.A. Milano, C.B. Patel, S.W. Hutchins, J. Ransom, G.A. Ewald, A. Itoh, N.Y. Raval, S.C. Silvestry, R. Cogswell, R. John, A. Bhimaraj, B.A. Bruckner, B.D. Lowes, J.Y. Um, V. Jeevanandam, G. Sayer, A.A. Mangi, E.J. Molina, F. Sheikh, K. Aaronson, F.D. Pagani, W.G. Cotts, A.J. Tatooles, A. Babu, D. Chomsky, J.N. Katz, P.B. Tessmann, D. Dean, A. Krishnamoorthy, J. Chuang, I. Topuria, P. Sood, and D.J. Goldstein, for the MOMENTUM 3 Investigators*

ABSTRACT

N Engl J Med 2019; 380:1618-1627

5 Year Outcomes - 2022

Research

JAMA | Original Investigation

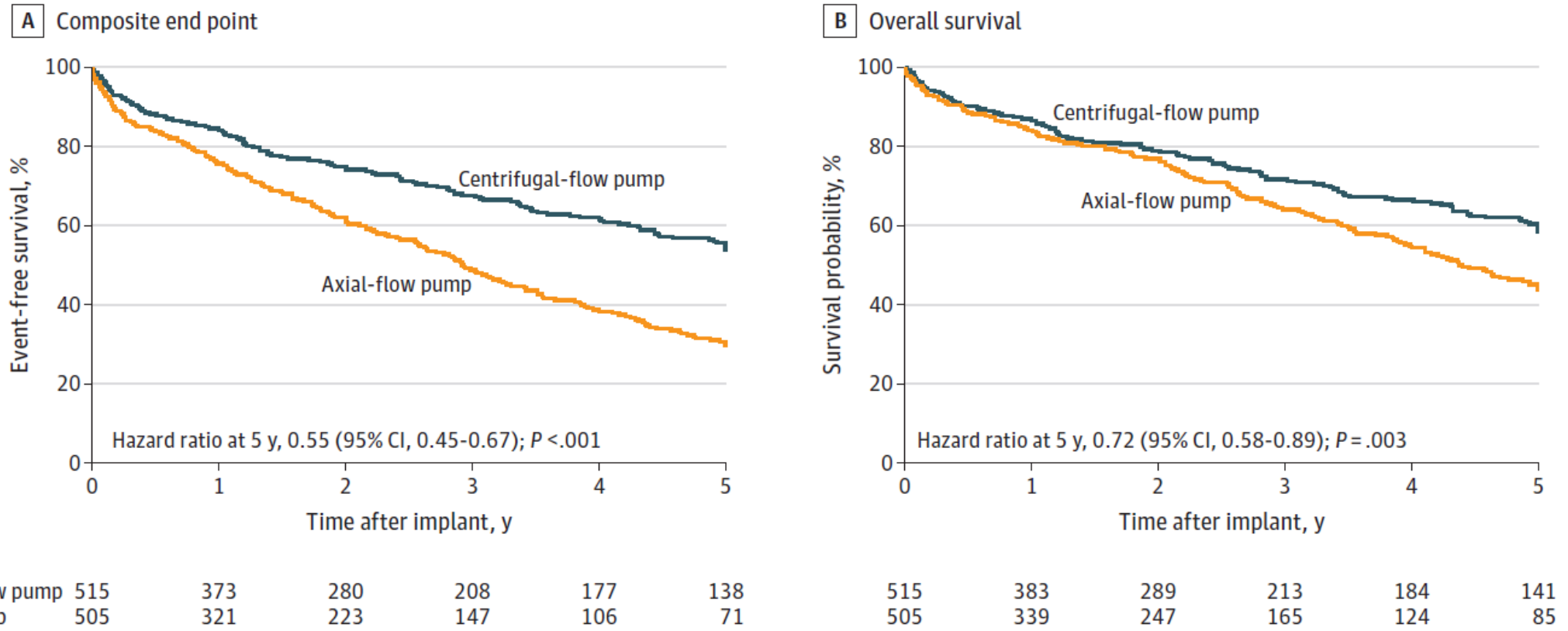
Five-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices in the MOMENTUM 3 Randomized Trial

Mandeep R. Mehra, MD, MSc; Daniel J. Goldstein, MD; Joseph C. Cleveland, MD; Jennifer A. Cowger, MD, MS; Shelley Hall, MD; Christopher T. Salerno, MD; Yoshifumi Naka, MD, PhD; Douglas Horstmanshof, MD; Joyce Chuang, PhD; AiJia Wang, MPH; Nir Uriel, MD, MSc

Mehra MR, et al. JAMA. 2022 Sep 27;328(12):1233-1242.

Outcomes Heartmate 3 – MOMENTUM 3

Figure 2. Composite End Point and Overall Survival in a Study of 5-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices (LVADs)



No. of patients

Centrifugal-flow pump	515	373	280	208	177	138
Axial-flow pump	505	321	223	147	106	71

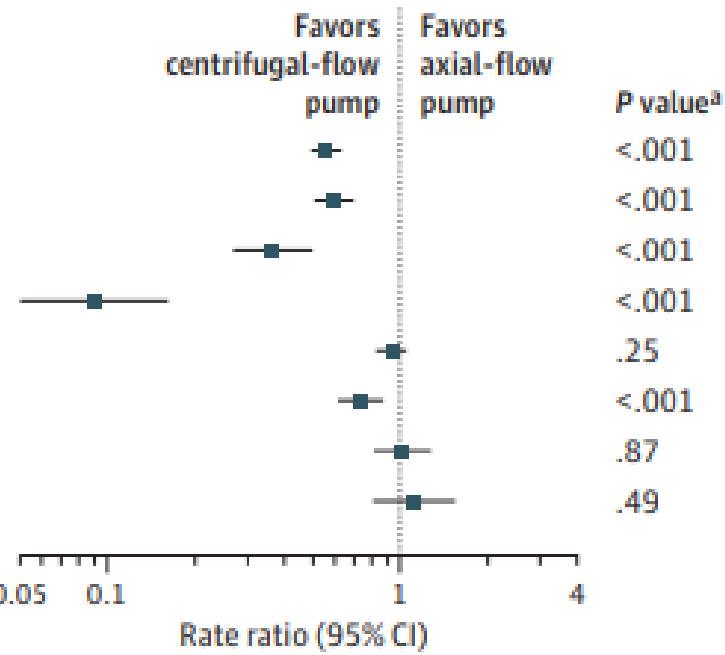
515	383	289	213	184	141
505	339	247	165	124	85

Mehra MR, et al. JAMA. 2022 Sep 27;328(12):1233-1242.

Outcomes Heartmate 3 – MOMENTUM 3

Figure 3. Serious Adverse Events in a Study of 5-Year Outcomes in Patients With Fully Magnetically Levitated vs Axial-Flow Left Ventricular Assist Devices

Serious adverse event	Events/patient-years: Centrifugal-flow pump (515 patients; 1234 patient-years)	Events/patient-years: Axial-flow pump (505 patients; 997 patient-years)	Rate ratio (95% CI)	*P* value[a]
Any bleeding	0.430	0.765	0.56 (0.50-0.63)	<.001
Gastrointestinal bleeding	0.252	0.423	0.60 (0.51-0.69)	<.001
Any stroke	0.050	0.136	0.37 (0.27-0.50)	<.001
Suspected or confirmed pump thrombosis	0.010	0.108	0.09 (0.05-0.16)	<.001
Any major infection	0.515	0.551	0.94 (0.83-1.05)	.25
Cardiac arrhythmia	0.207	0.283	0.73 (0.62-0.87)	<.001
Right heart failure	0.149	0.146	1.02 (0.82-1.27)	.87
Other neurologic event[b]	0.073	0.065	1.12 (0.81-1.54)	.49



Mehra MR, et al. JAMA. 2022 Sep 27;328(12):1233-1242.

Outcomes Heartmate 3 – Risk Prediction

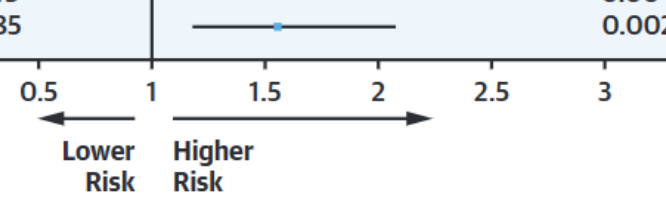
CENTRAL ILLUSTRATION **Prediction of Survival After Implantation of a Fully Magnetically Levitated Left Ventricular Assist Device: The HeartMate 3 Survival Risk Score**

The HM3RS provides individual survival prediction at 1 and 2 years post-implant

The HM3RS contains 6 predictors

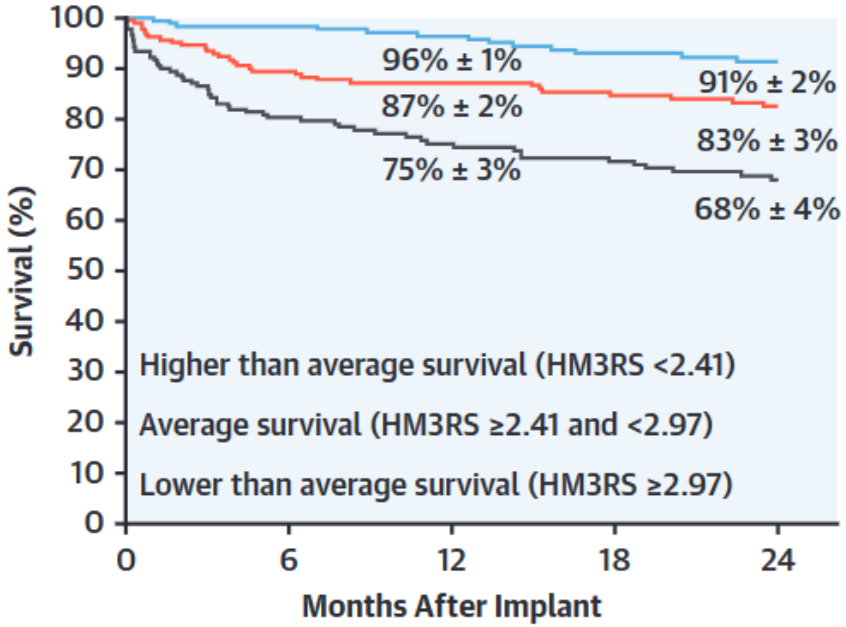
- 2 demographic variables
- 2 chemistry labs
- 1 echocardiogram parameter
- 1 invasive hemodynamic parameter

Baseline Characteristic	Parameter Estimate	Hazard Ratio (95% CI)	*P* Value
Age in years	0.03496		<0.001
Prior valve procedure or CABG	0.53029		<0.001
Na in mmol/L	−0.04112		0.005
BUN in mg/dL	0.01093		0.003
LVEDD <5.5 cm	0.62149		0.004
RAP/PCWP >0.6	0.44785		0.002



Validation AUC 0.76 at 1 year and 0.71 at 2 years

HM3RS =
0.03496 × (age in years) + 0.53029 (if prior CABG or valve procedure) − 0.04112 × (Na in mmol/L − 136) + 0.01093 × (BUN in mg/dL) + 0.62149 (if LVEDD <5.5 cm) + 0.44785 (if RAP/PCWP >0.6)



- Facilitate shared decision making
- Refine bridge-to-transplantation strategies
- Enhance implementation of LVAD therapy in advanced HF

Mehra MR, et al. JACC Heart Fail. 2022 Dec;10(12):948-959.

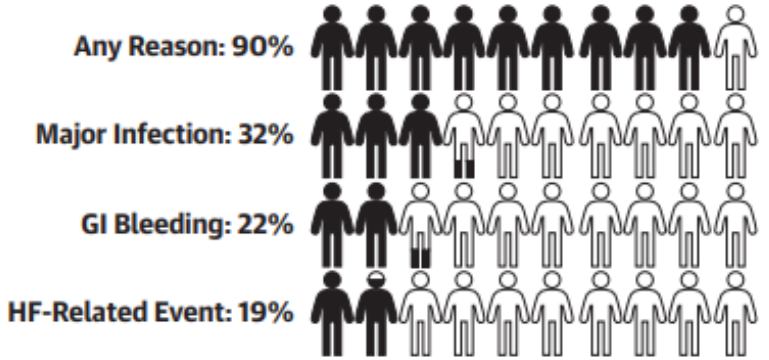
Outcomes Heartmate 3 – Hospital Admissions

CENTRAL ILLUSTRATION Patterns and Impact of Hospitalizations With HeartMate 3 Left Ventricular Assist Device Support in the MOMENTUM 3 Trial

The Burden of Hospitalizations With HeartMate 3 LVAD Support Is Not Well Characterized

- 485 HeartMate 3 and 471 HeartMate II recipients were compared in the MOMENTUM 3 pivotal trial. The pivotal trial HeartMate 3 group was also compared to 949 HeartMate 3 recipients in the post-approval trial phase.
- The HeartMate 3 LVAD is associated with significantly lower rehospitalization rate and duration compared to the HeartMate II LVAD.
- Compared to the pivotal trial, HeartMate 3 recipients in the post-approval phase demonstrated a lower rate of prolonged hospitalizations potentially due to improving clinical experience:
  - Rehospitalization rate for infection decreased over time
  - Rehospitalization rates for GI bleeding and HF-related events have not improved
  - HF-related hospitalizations are associated with increased mortality

Percent of HeartMate 3 LVAD Recipients Rehospitalized During 2-Year Follow-Up for



Challenges remain with infection (device-related and -unrelated), nonsurgical bleeding, and HF-related hospitalizations in HeartMate 3 LVAD supported patients. Introducing and evaluating strategies to decrease the burden of these specific cause-related hospitalizations is necessary to allow for continuous progress in the field of LVAD therapy.

Vidula H, et al. J Am Coll Cardiol HF. 2022;10(7):470–481

Chapter 5

When should we press the button?

Profile	Description	Time to MCS
1	„Crashing and burning“ – critical cardiogenic shock	Within hours
2	„Progressive decline“ – inotropes dependence with continuing detoriation	Within few days
3	“Stable but inotrope de… describes clinical stability on mild… moderate	Within few…
4	“Recurrent advanced h… “refractory” decompen…	
5	“Exertion intolerant” - … rest but are exercise int…	
6	„Exertion limited“ – a … but fatigue results a few…	
7	„Advanced“ describes … reasonable level of com… decompensation that is…	

Table 5 Device Strategy by Patient Profile, IMACS, January 1, 2013 to December 31, 2016 (n = 14,062)

	Device strategy at time of implant							
	Listed for transplant		Candidacy to transplant		Destination therapy		Other	
Patient profile at time of implant	*n*	%	*n*	%	*n*	%	*n*	%
1. Critical cardiogenic shock	526	13.2%	865	21.2%	885	15.4%	129	45.7%
2. Progressive decline	1,478	37.0%	1,315	32.2%	1,828	31.9%	93	32.9%
3. Stable but inotrope dependent	1,313	32.9%	1,212	29.7%	2,005	35.0%	28	9.9%
4. Resting symptoms	468	11.7%	534	13.1%	799	13.9%	16	5.6%
5. Exertion intolerant	107	2.6%	71	1.7%	115	2.0%	5	1.7%
6. Exertion limited	32	0.8%	23	0.5%	28	0.4%	4	1.4%
7. Advanced NYHA Class III	22	0.5%	20	0.4%	23	0.4%	1	0.3%
Unknown	38	0.9%	32	0.7%	41	0.7%	6	2.1%
Total	3,984	100.0%	4,072	100.0%	5,724	100.0%	282	100.0%

IMACS, International Society for Heart and Lung Transplantation Mechanically Assisted Circulatory Support; NYHA, New York Heart Association.

ROADMAP Study

JACC: HEART FAILURE VOL. 5, NO. 7, 2017
ISSN 2213-1779
http://dx.doi.org/10.1016/j.jchf.2017.02.016

CLINICAL RESEARCH

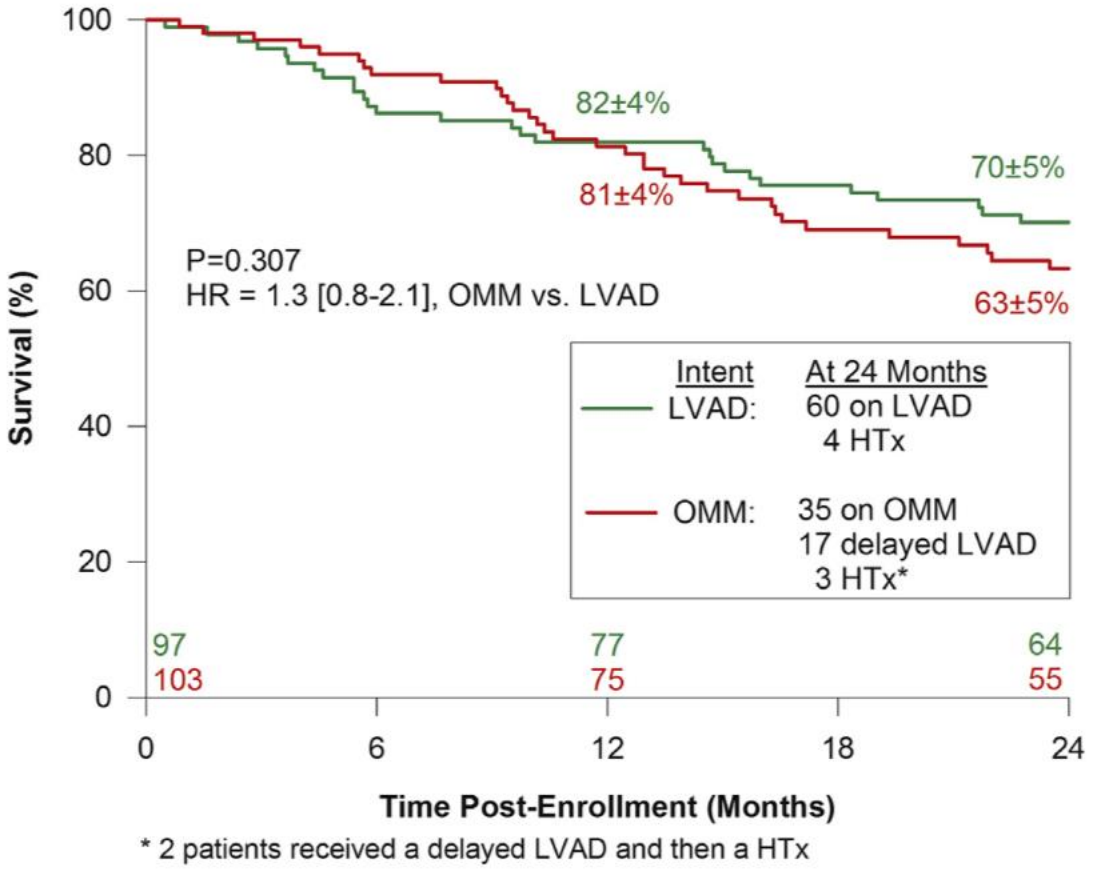
Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients

The ROADMAP Study 2-Year Results

Randall C. Starling, MD, MPH,[a] Jerry D. Estep, MD,[b] Douglas A. Horstmanshof, MD,[c] Carmelo A. Milano, MD,[d] Josef Stehlik, MD, MPH,[e] Keyur B. Shah, MD,[f] Brian A. Bruckner, MD,[b] Sangjin Lee, MS, MD,[g] James W. Long, MD, PhD,[c] Craig H. Selzman, MD,[e] Vigneshwar Kasirajan, MD,[f] Donald C. Haas, MD,[h] Andrew J. Boyle, MD,[i] Joyce Chuang, PhD,[j] David J. Farrar, PhD,[j] Joseph G. Rogers, MD,[d] for the ROADMAP Study Investigators

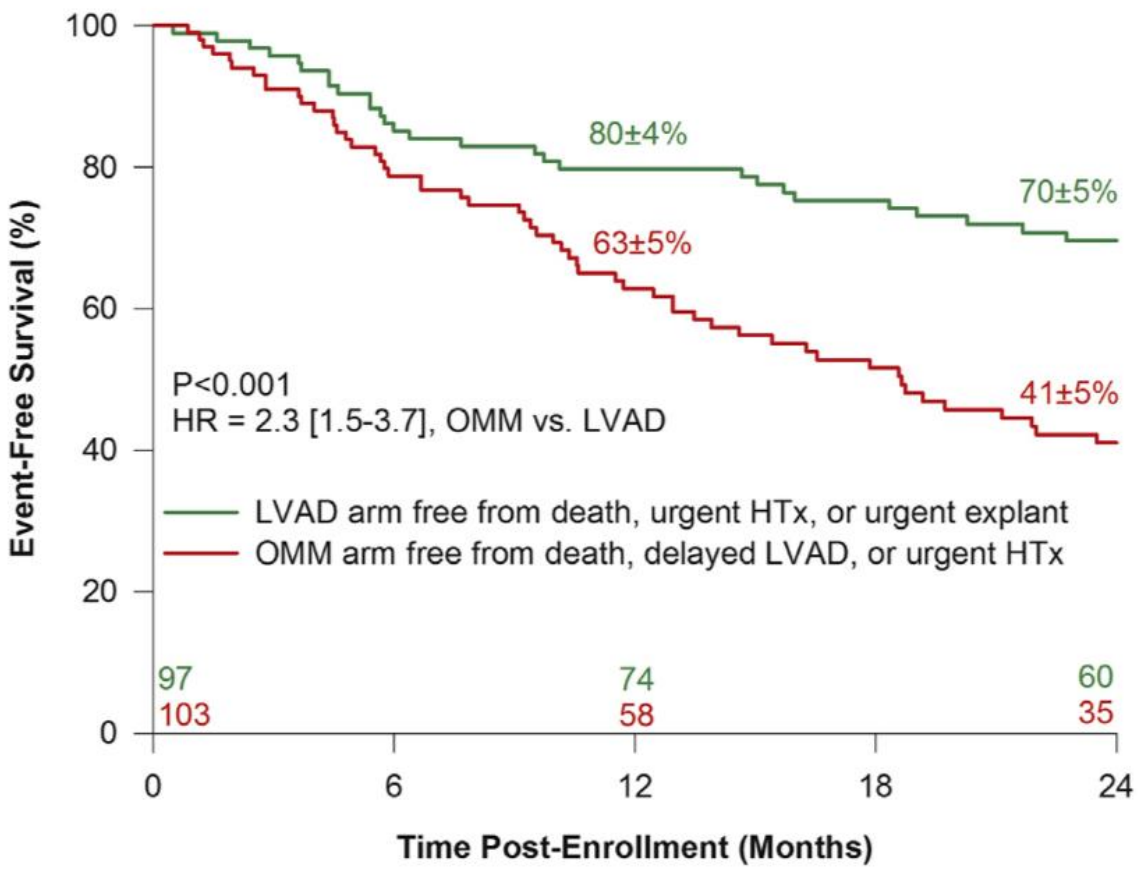
Survival in Ambulatory HF Patients – IM4-7

FIGURE 3 Intention-to-Treat Survival



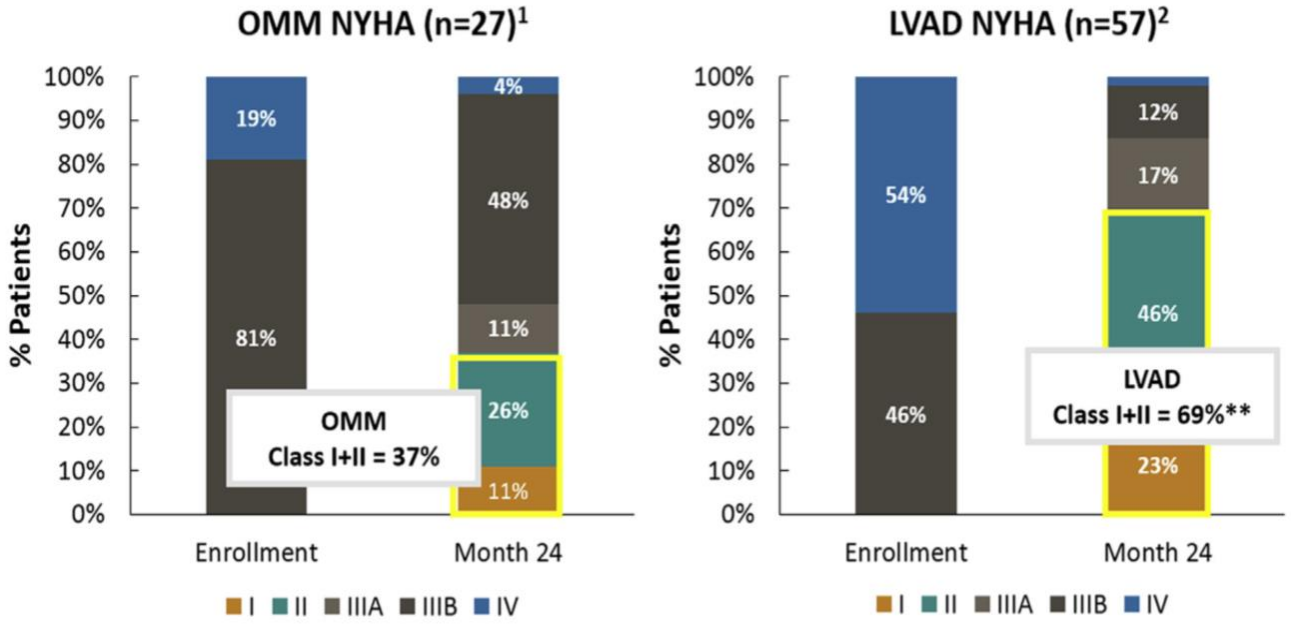
* 2 patients received a delayed LVAD and then a HTx

FIGURE 2 Survival as Treated



Benefit vs Risk

FIGURE 4 Changes in NYHA Classification in Patients Who Are Alive on Original Therapy at 2 Years



[1]Excluded OMM patients: 8 missing NYHA classification
[2]Excluded LVAD patients: 3 missing NYHA classification
**P<0.01 LVAD vs. OMM

TABLE 4 Cumulative AEs Within 2 Yrs of Enrollment

	OMM (n = 103) Patients (%) (eppy)	LVAD (n = 94) Patients (%) (eppy)	DT Trial as Reference (eppy)*
Bleeding	3 (3) (0.02)	51 (54) (1.09)†	1.13
GI bleeding	2 (2) (0.02)	31 (33) (0.68‡)†	NA
Driveline infection	NA	16 (17) (0.15)†	0.22
Pump thrombus	NA	11 (12) (0.08)‡‡	0.07§
Within 90 days		1 (1.1)	
Pump replacement††		7 (7.4)	
Stroke	4 (3.9) (0.03)	11 (11.7) (0.09)	0.08
Ischemic	3 (2.9) (0.02)	8 (8.5) (0.06)	0.05
Hemorrhagic	1 (1.0) (0.01)	4 (4.3) (0.03)	0.03
Arrhythmias VT/VF	13 (13) (0.12)	21 (22) (0.21)	0.46
Worsening heart failure‖	51 (50) (0.80)	13 (14) (0.13)†	NA
Right heart failure¶	3 (3) (0.02)	10 (11) (0.07)	0.13
Rehospitalizations	78 (76) (1.51)	81 (86) (2.55)†	2.64#
"Composite" event rate**	55 (53) (0.98)	72 (77) (1.74)†	2.09
Relative risk [95% CI]	OMM/LVAD: 0.56 [0.41-0.77]†		

Conclusions

1. Higher survival with improved functional status, improved QoL, and reduced depression in the LVAD group
2. No increased mortality with delaying LVAD implant while being monitored closely
3. More hospitalizations in the LVAD than the OMM group throughout the study
4. Greater rate of major AEs in LVAD than OMM subjects in year 1 but with a reduction in LVAD AEs in year 2
5. SHOULD WE PUT LVADs IN ALL OUR AHF PATIENTS?

INTERMACS 4 vs 5-7

The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

Left ventricular assist devices versus medical management in ambulatory heart failure patients: An analysis of INTERMACS Profiles 4 and 5 to 7 from the ROADMAP study

Keyur B. Shah, MD,[a] Randall C. Starling, MD, MPH,[b] Joseph G. Rogers, MD,[c] Douglas A. Horstmanshof, MD,[d] James W. Long, MD, PhD,[d] Vigneshwar Kasirajan, MD,[a] Josef Stehlik, MD, MPH,[e] Joyce Chuang, PhD,[f] David J. Farrar, PhD,[f] and Jerry D. Estep, MD[g] for the ROADMAP Investigators

From the [a]Department of Surgery, Virginia Commonwealth University, Richmond, Virginia, USA; [b]Division of Cardiology, Cleveland Clinic, Cleveland, Ohio, USA; [c]Division of Cardiology, Duke University, Durham, North Carolina, USA; [d]Division of Cardiology, INTEGRIS Baptist Medical Center, Oklahoma City, Oklahoma, USA; [e]Division of Cardiology, University of Utah School of Medicine, Salt Lake City, Utah, USA; [f]Abbott, Pleasanton, California, USA; and the [g]Division of Cardiology, Houston Methodist Hospital, Houston, Texas, USA.

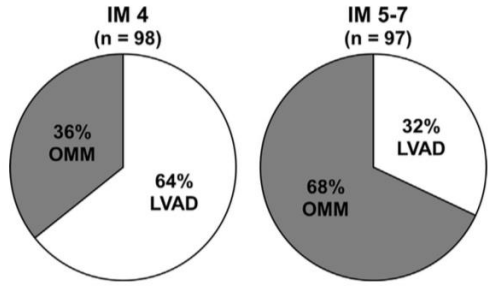


Figure 1 Distribution of LVAD and OMM patients in INTERMACS Profile 4 (IM 4) and Profile 5 to 7 (IM 5-7) groups.

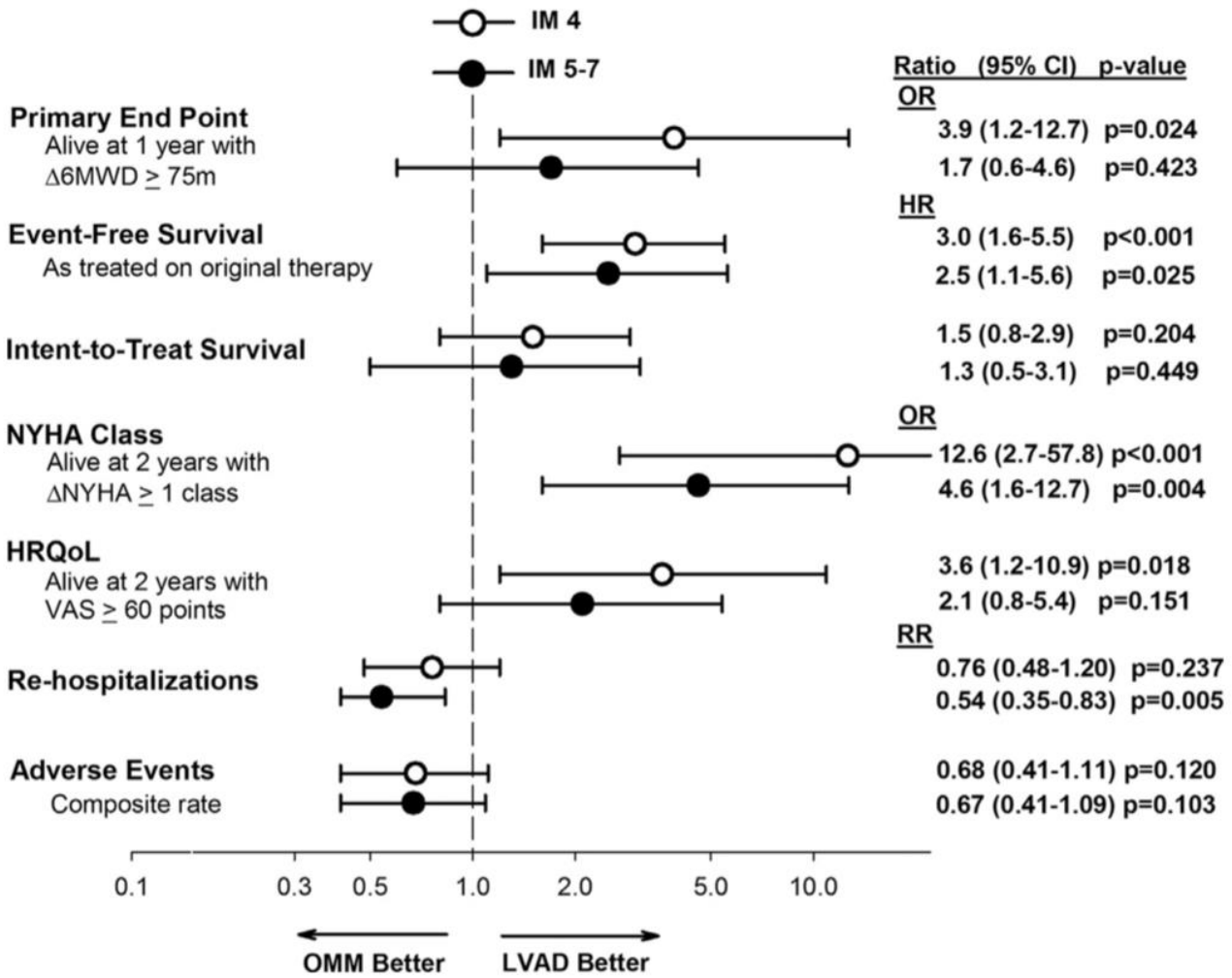
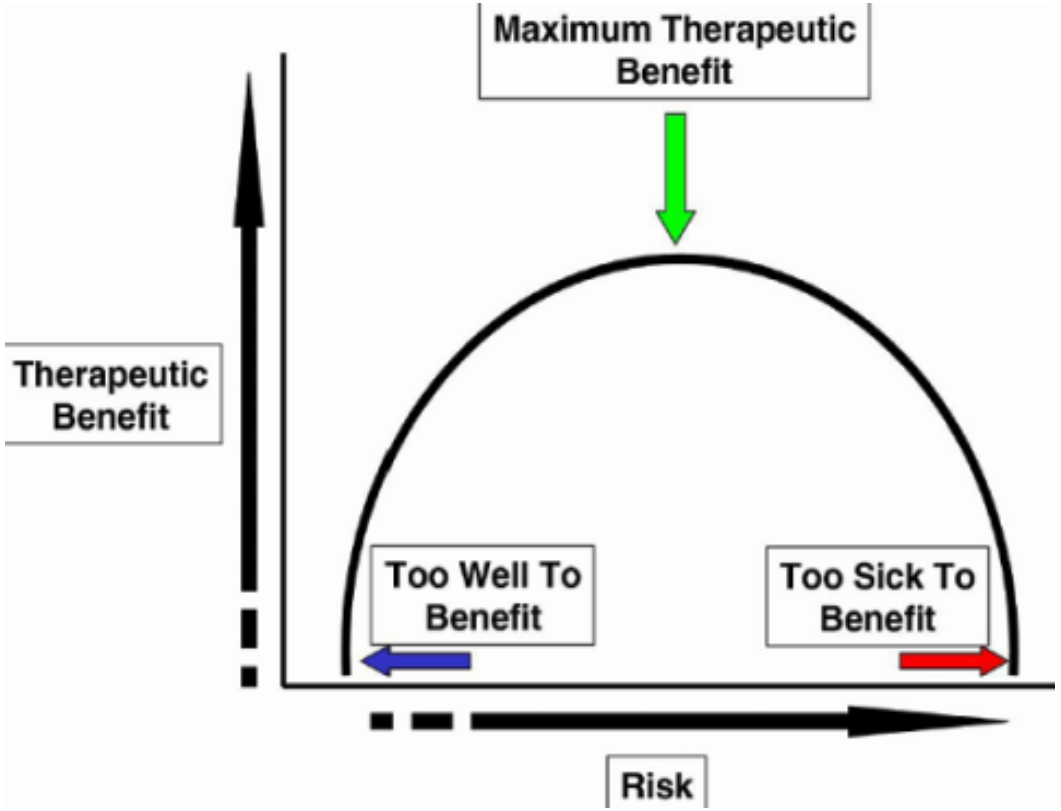


Figure 5 Risk–benefit analysis.

Conclusions

- The Patients who are IM4 have potential for significant symptomatic benefit with LVAD compared with continuing on OMM therapy, whereas those less symptomatic (IM5-7) derive less significant improvement and have more rehospitalizations.
- **LVAD therapy may be reasonable in select IM4 patients**
- **LVAD therapy should be deferred for most IM5-7 patients**



Despite maximal tolerated neurohormonal and device therapy:

- INTERMACS 3-4
- Cardio-renal syndrome
- Recurrent hospitalizations for congestion
- Peristent volume overload
- Required IV inotropes
- Inability to take activities of daily life (showering, dressing, etc)
- Cardiac catabolic state

Chapter 6

Don’t cry victory, yet

Outpatient management

Medical management

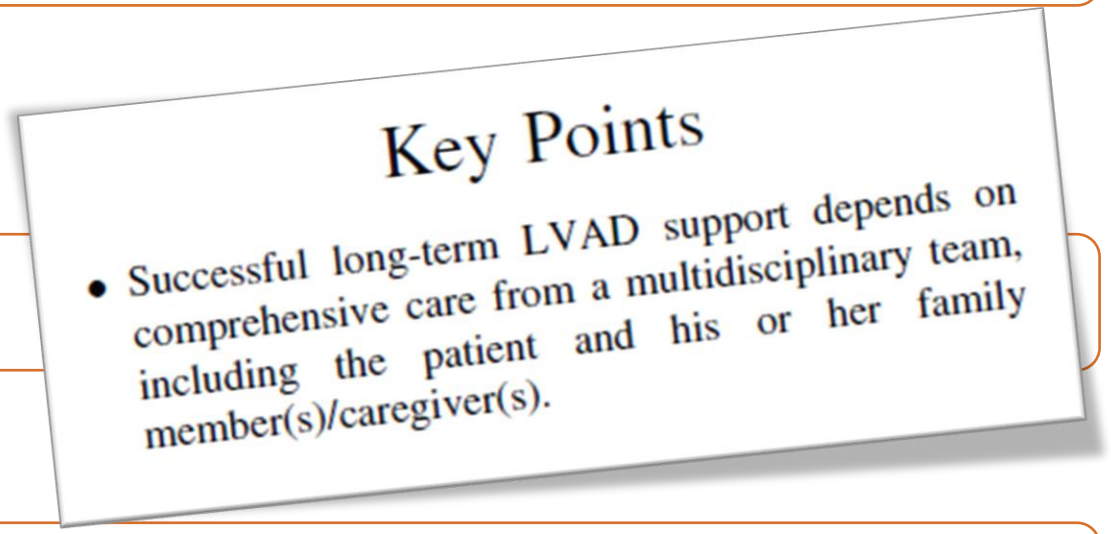
- Anticoagulation
- Heart failure treatment
- Hypertension

Device management

- Driveline care and exit wound management
- Settings of the LVAD

Tests during follow-up

- Echo
- Right heart catheterization
- CPET



Medical Management: Anticoagulation

Topic 4: Medical management of the DMCS patient

Recommendations for anticoagulation (1)

Class I

1. *Patients with DMCS should receive anticoagulation with warfarin to maintain an INR within a range as specified by each device manufacturer (Table 9). Level of evidence: B.*

Recommendations for antiplatelet therapy: (1)

Class I

1. *Chronic antiplatelet therapy with aspirin (81–325 mg daily) may be used in addition to warfarin in patients with DMCS. Level of evidence: C.*
2. *Antiplatelet therapy beyond aspirin may be added to warfarin according to the recommendations of specific device manufacturers. Level of evidence: C.*

Class IIb

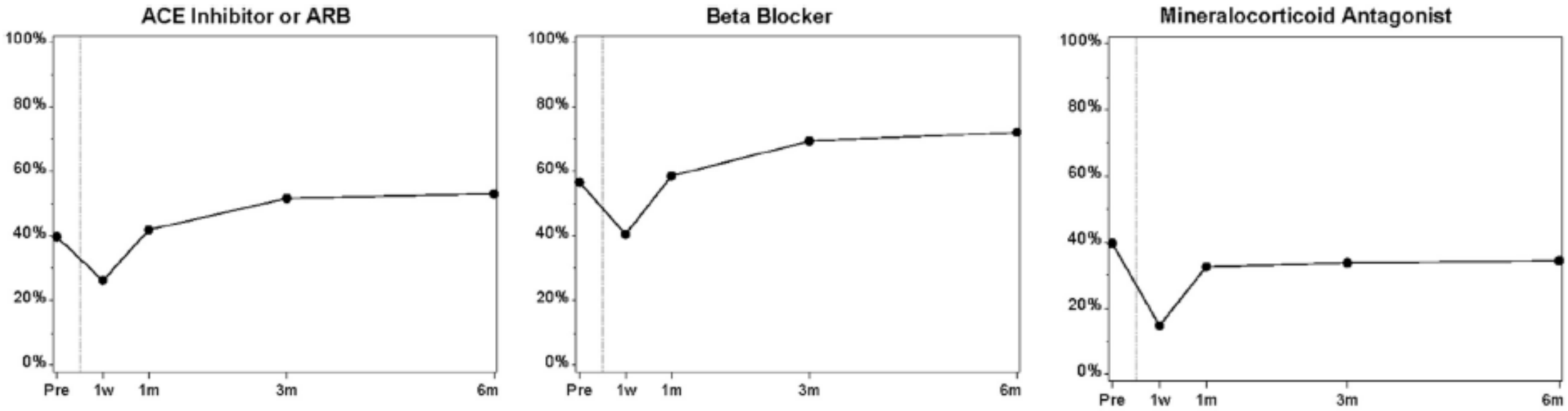
1. *Assessment of platelet function may be used to direct the dosing and number of antiplatelet drugs. Level of evidence: C.*

Device	Aspirin dose	INR TARGET
Heartmate 2	Aspirin 150 mg *(Reduced dose if platelets suppressed on 75 mg od)	INR 2-3
Heartware	Aspirin 150 mg *(Reduced dose if platelets suppressed on 75 mg od)	INR 2-3
TAH	Aspirin 150 mg *(Reduced dose if platelets suppressed on 75 mg od)	INR 2.5-3.5
Heartmate 3	Aspirin 75 mg od	INR 2-3

- If the patient exhibits a bleeding risk profile, a lower INR target could be considered: 1.8-2.5.
- Subcutaneous enoxaparin (Clexane) is only indicated if INR≤1.5

Saeed D, et al. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

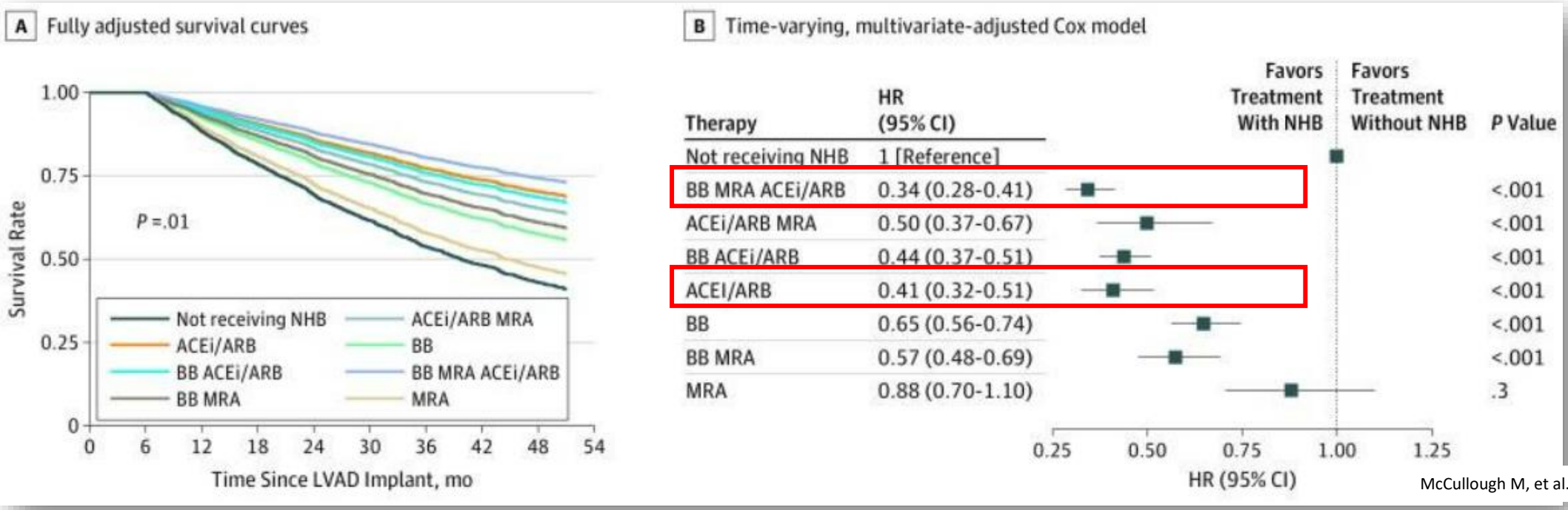
Medical Management: HF Medications



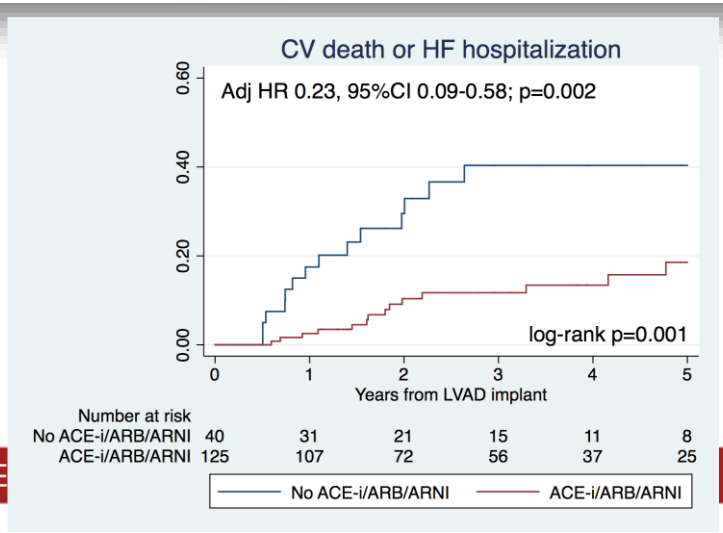
- Objetives
  - Reverse LV remodelling
  - Support RV function
  - Enhace biventricular recovery

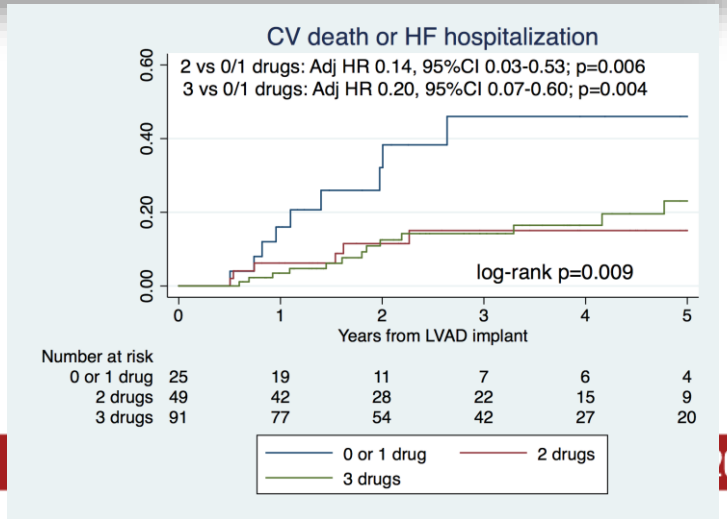
Khazanie P, et al. J Card Fail. 2016;22(9):672-9.

Medical Management: HF Medications



McCullough M, et al. JAMA Cardiol. 2020 Feb 1;5(2):175-182.





A Coruña Heart Failure Academy

Medical Management: HF Medications

4.3. Recommendations for heart failure therapy:	**4.3. Recommendations for heart failure therapy:**
Class I:	Class I:
1. Diuretics are useful for the management of volume overload during DMCS.	1. *Continuing approval without change*
Level of Evidence C.	
2. An ACE-inhibitor or ARB may be used for hypertension, or for risk reduction in patients with vascular disease and diabetes.	2. An ACE-inhibitor or ARB or ARNI should be used as tolerated and are warranted as disease/natural history-modifying agents.
Level of Evidence C.	Level of Evidence B. *(Modified)*
3. ACE-inhibitors and ARB have been shown to reduce the incidence of gastrointestinal bleeding and mortality in patients with LVADs.	3. Beta-blockers should be used as tolerated and are warranted as disease/natural history-modifying agent and/or for rate control in patients with tachyarrhythmias.
Level of Evidence B.	Level of Evidence C *(Modified)*
4. Beta-blockers may be used for hypertension or for rate control in patients with tachyarrhythmias.	4. *Continuing approval without change*
Level of Evidence C.	
5. Mineralocorticoid receptor antagonists (MRAs, or aldosterone antagonists) may be used to limit the need for potassium repletion in patients with adequate renal function.	5. *Continuing approval without change*
Level of Evidence C.	
Class II:	Class IIb:
1. Digoxin may be useful in the setting of atrial fibrillation with rapid ventricular response.	1. *Continuing approval without change*
Level of Evidence C	2. ARNI can be used instead of ACEI/ARB post LVAD implant, as recommended for patients with heart failure with reduced ejection fraction without LVAD.
	Level of Evidence C *(New)*
	3. Use of hydralazine and isosorbide mononitrate or dinitrate may be considered as second line therapy for hypertension control.
	Level of Evidence C. *(New)*

Saeed D, et al. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

Medical Management: HF Medications - ?Recovery

- Pharmacological therapy combined with optimal LVAD unloading could lead to myocardial reverse remodeling/recovery
- Target cohort:
  - DCM
  - Young
  - Short duration of symptoms
  - ?Specific Genotypes (i.e. TTN)
- Benefits:
  - Keep own heart!
  - Avoid IS
  - Delay / Avoid Transplant

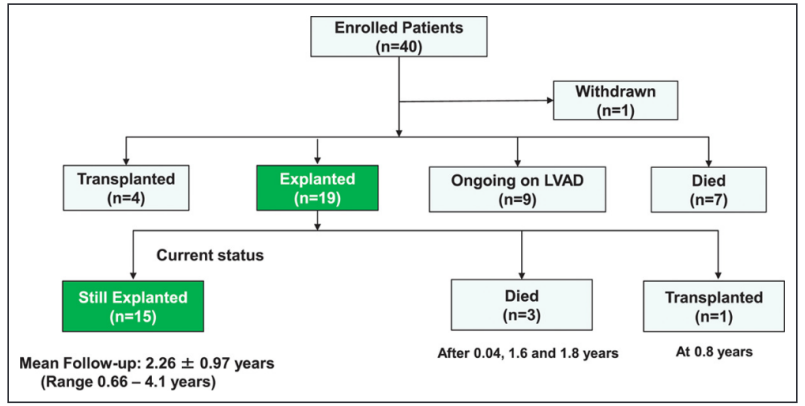


Figure 5. Flow chart showing the current status of all 40 enrolled patients. LVAD indicates left ventricular assist device.

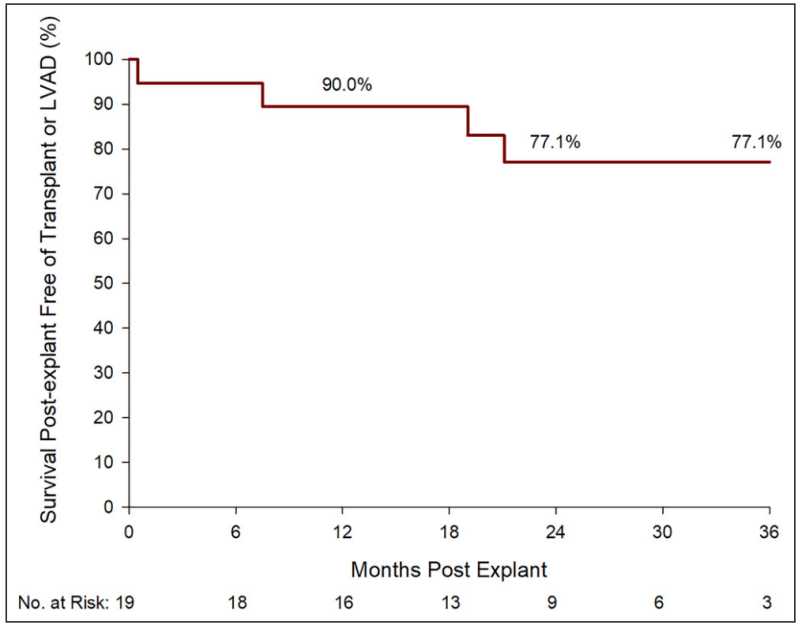


Figure 6. Postexplant survival free of transplantation or left ventricular assist device (LVAD)

Circulation 2020 Nov 24;142(21):2016-2028

Medical Management: Hypertension

4.5. Recommendations for hypertension management:

Replaced by the new and modified recommendations below

Class I:

1. Pharmacotherapy with neurohormonal blocking agents (angiotensin-converting enzyme inhibitor, angiogtensin receptor blocker, angiotensin receptor blocker-neprilysin inhibitors, beta-blocker, mineralocorticoid receptor antagonist) is preferred for blood pressure management in durable LVAD patients.

Level of Evidence B. *(New)*

Class IIa:

1. Patients with continuous flow LVADs should have a mean arterial pressure goal of 75-90 mm Hg.

Level of Evidence B. *(Modified)*

Class IIb:

1. Use of hydralazine and isosorbide mononitrate or dinitrate may be considered as second line therapy for hypertension control.

Level of Evidence C. *(New)*

2. Dihydropyridine calcium channel blockers, centrally acting alpha-2 receptors agonists (clonidine), and peripheral alpha-1 antagonists are third line agents in the management of hypertension in patients on DMCS support. These agents should be used when first and second line agents are contraindicated or as supplemental therapy in individuals with resistant hypertension.

Level of Evidence C. *(New)*

- Target
  - MAP 75– 90 mmHg

- **Accurate measurements can be challenging**
- **BP cuffs successfull 50% of the time**
- **Use of doppler and sphygmomanometer**
  - Doppler measurements fall between SBP and MAP
  - Closer to SBP

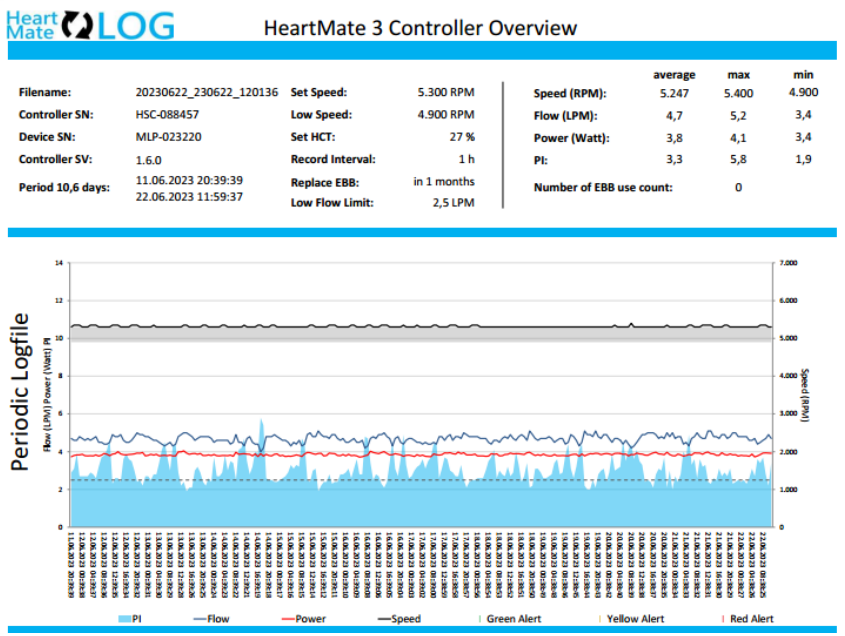
Saeed D, et al. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

Medical Management: Device Management

- Pump power
  - Normal range: 3-6W
- RPM
  - Normal range between 4700-6500
- Flows
  - Estimation based on:
    - Power
    - RPM
    - Hematocrit
  - Update hematocrit if change>5%
- Pulsatility index (PI)
  - Normal range: 1-10 (3-7)

Medical Management: Device Management

Condition	Flow Estimate	Power	PI	PI Event
Typical range	3–6 lpm	3–6 w	2–6	None
When to call	Drop of ≥1 L from baseline	±2 from baseline	±2 from baseline OR < 2	
Severe hypovolemia	↓	↓	↑	Yes
Hypertension	↓	↓	↑	Yes
Tamponade	↓	↓	↑	Yes
Severe RV failure	↓	↓	Variable	Yes
Arrhythmias	↓	↓	Variable	Yes
Inflow obstruction	↓	↓	↓	Yes
Outflow obstruction	↓	↓	↓	Yes
Aortic insufficiency	↑	↑	↓	Less frequent
Cardiac recovery	Variable	Variable	↑	Variable
IABP	↓	↓	↑	More frequent
Rotor thrombus	↑	↑	↓	Less frequent



Belkin MN, et al. J Card Fail. 2022 May;28(5):845-862.

Medical Management: Device Management

Review if speed is optimal

Objectives

- Maximise cardiac output
- Avoid:
  - RV failure
  - Suction events
  - Aortic regurgitation from fusion of leaflets

How?
1) Echo
2) RHC ☆

?Reason for change

- Ventricular reverse remodelling
- RV failure
- Development of aortic regurgitation

Cowger J, et al. Curr Opin Cardiol 2011;26:149-54.

Medical Management: Follow-up Tests

Echo

- Degree of LV decompression
  - LVEDD
  - Degree of MR
- Assess LV function→ To screen for myocardial recovery
- RV function→ RV dilatation, severity of TR
- Aortic valve
  - Opening→ Partial, intermitent, complete closure
  - Degree of AR

- Septum shift
- Pulmonary pressures
- Cannuli
  - Inflow and outflow
  - Consistently phasic, slightly pulsatile, low-velocity inflow and outflow patterns
  - Peak velocities <2.0 m/s and typically <1.5 m/s
- Other: Thrombus, pericardial effusion

Medical Management: Follow-up Tests

Echo

2.3. Recommendations for use of echocardiography in patients with DMCS:

Class I:

1. Echocardiography should be performed as part of the pre-operative assessment and routinely at regular intervals post-operatively to evaluate for signs of myocardial recovery and optimal DMCS function. Echocardiography can be used for setting optimal pump parameters.

Level of Evidence B.

2. In addition to routine studies, echocardiography should be performed as part of the evaluation of suboptimal DMCS function or in the presence of clinical signs of circulatory dysfunction, including congestive or low output symptoms.

Level of Evidence B.

2.3. Recommendations for use of echocardiography with DMCS:

1. *Continuing approval without change*

2. *Continuing approval without change*

Class IIa:

1. The frequency of routine echocardiography can be determined by individual programs but should be performed no less than annually.

Level of Evidence C. *(New)*

Saeed D, et al. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

Medical Management: Follow-up Tests

Right heart catheterization

- When to do it?
  - Persistent or recurrent HF symptoms after implant
  - Regularly in patients listed for heart transplant
  - To corroborate myocardial recovery
  - *At the discretion of the clinician to optimize LVAD speed and medical therapy to balance adequate left ventricular unloading, pulmonary artery hemodynamics, cardiac output, and right ventricular function in all LVAD patients in order to reduce heart failure hospitalization and hemocompatibility related adverse events.*

Saeed D, et al. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

Medical Management: Follow-up Tests

CPET

- After LVAD implant→ For exercise prescription
- Regularly as a functional capacity objective assessment
  - Every 6 months for the first two years and then yearly thereafter.

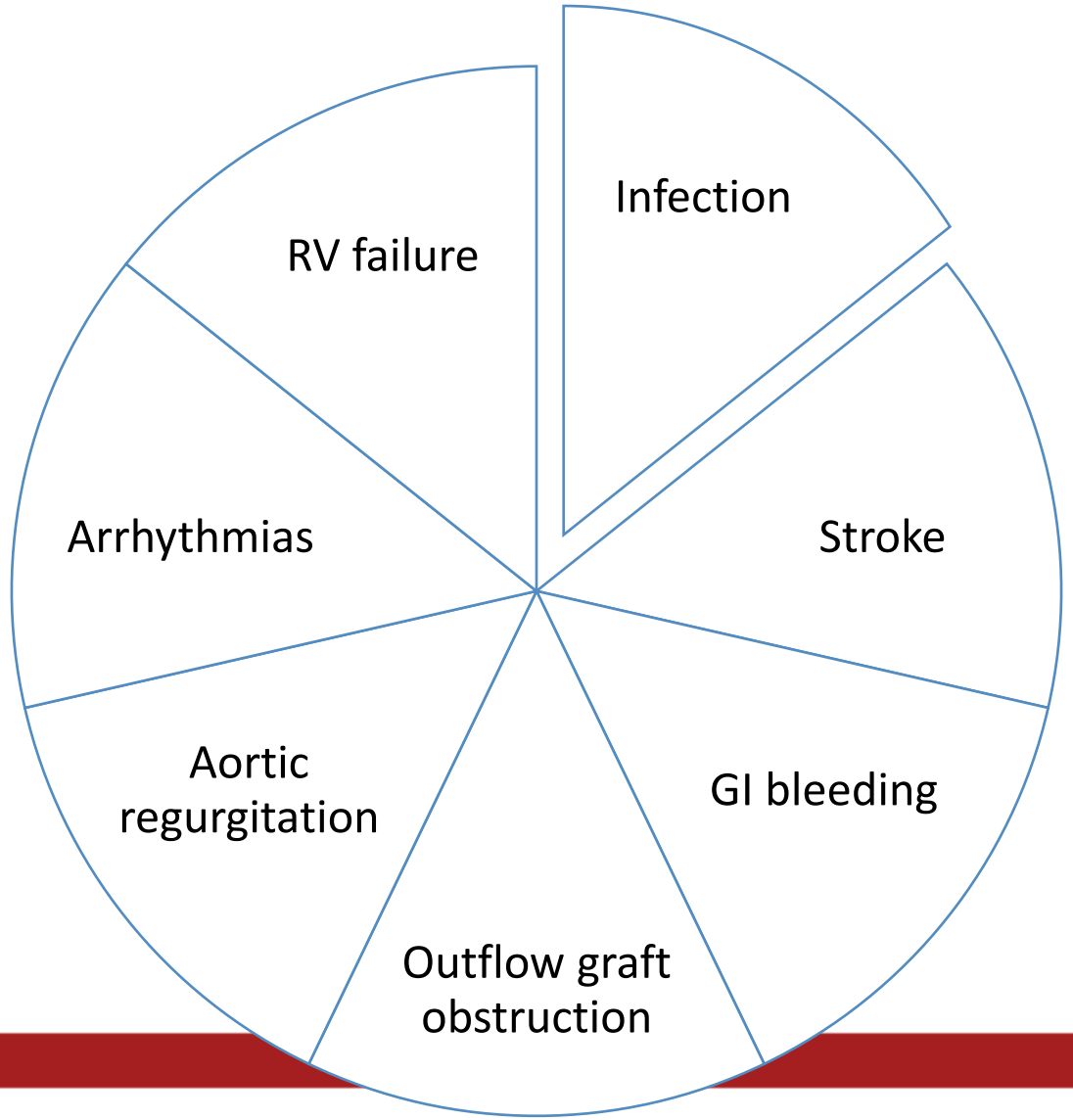
Saeed D, et al. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

Medical Management: Follow-up Tests

- Reactivation of ICD following implant
- Conservative ICD programming: maximise anti-tachycardia pacing and minimize shocks
- Routine generator change only if ICD in place for secondary prevention
- In patients with LVAD and no prior history of ventricular arrhythmias → reasonable to defer ICD placement if for primary prevention.
- If ICD needed post-LVAD → Avoid S-ICD
- CRT
  - No clear benefit of biventricular pacing
  - Reasonable to turn the LV lead off to preserve battery

Saeed D, et al. J Heart Lung Transplant. 2023 Jul;42(7):e1-e222.

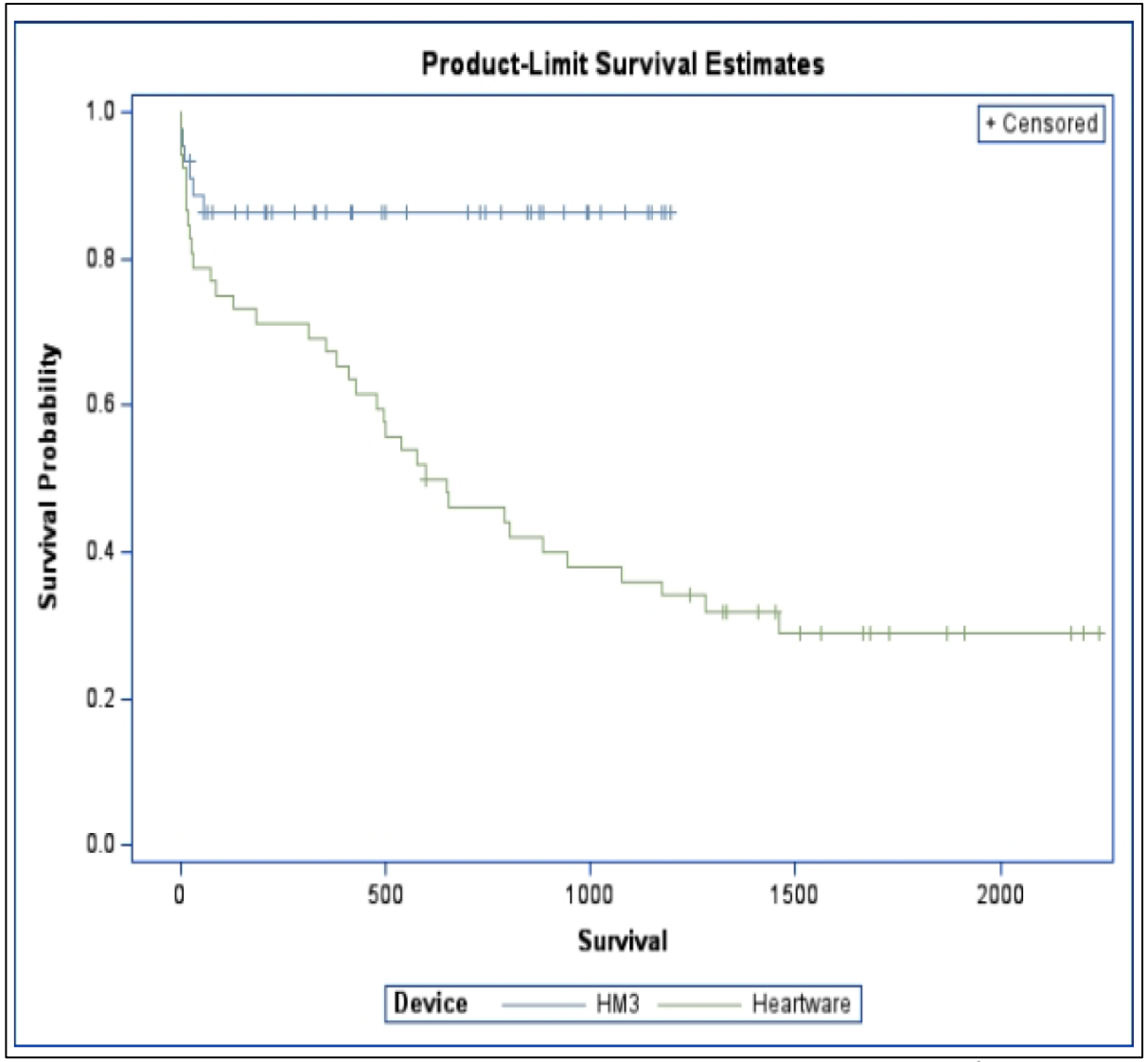
Medical Management: Complications

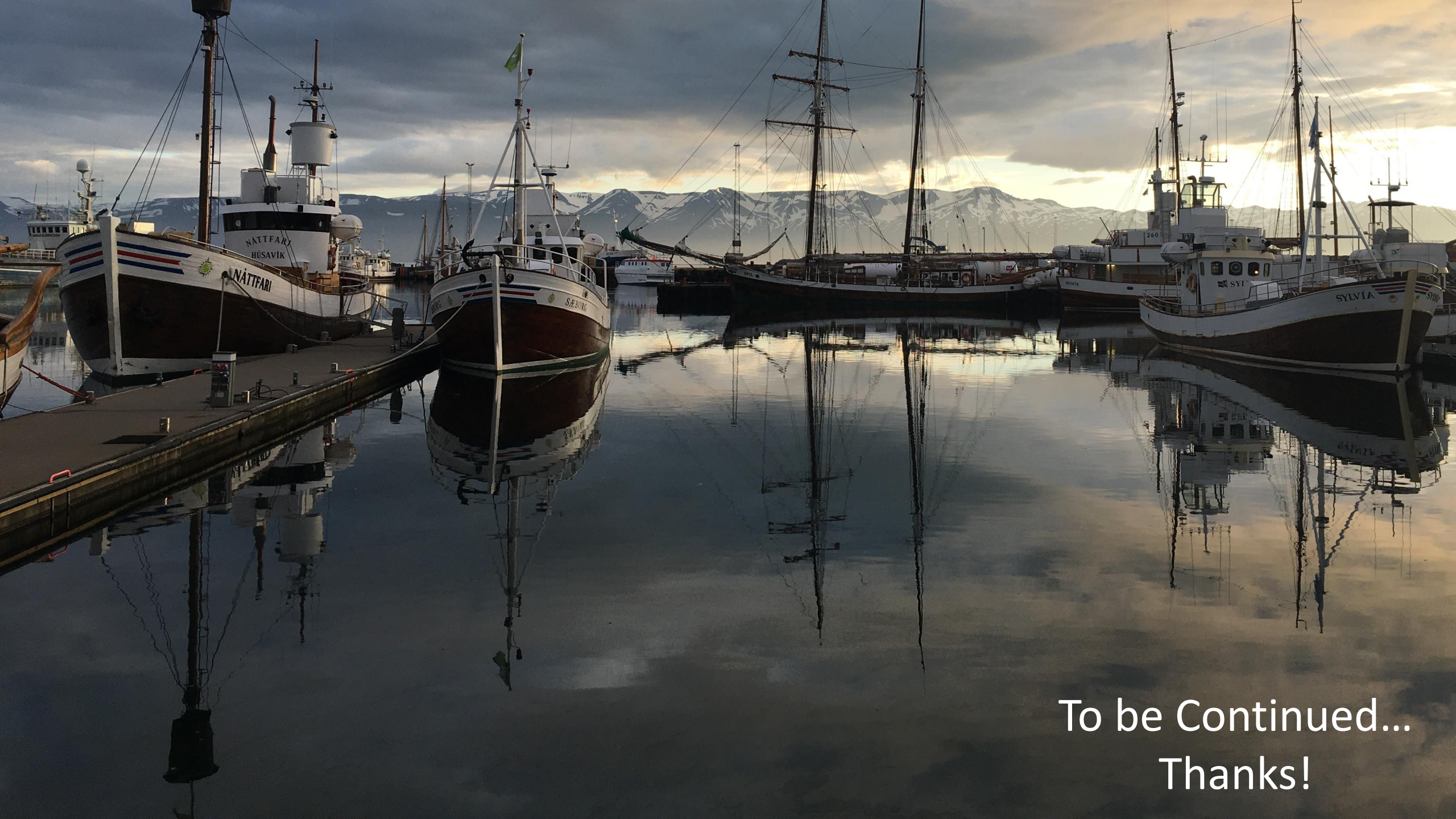


Results of "HM3 Era" in Harefield

- **From 2020**
- Heratmate 3 only
- Strict selection criteria – largely BTC
- Robust preoperative optimization

- Stop Aspirin use
- HF medication optimization
- Improved ID monitoring/management
- Improved selection of BTT





To be Continued…
Thanks!