

Implantable Durable MCS: Did we miss the boat?

KY-ACC 2026 Annual Conference

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Heart Failure Statistics in USA

7.7M

US adults living with heart failure, about 3% of adults

1 in 4

Americans will develop heart failure in their lifetime

452,573

deaths with HF as a contributing cause in 2023, 14.6% of all US deaths

+37%

rise in age-adjusted HF mortality, 2010 to 2023

1.27M

hospitalizations for heart failure in 2023

11.4M

adults projected to have heart failure by 2050

Source: HF Stats 2026, Heart Failure Society of America (Gorodeski et al., J Card Fail 2026)

Survival after HF hospitalization

5-year mortality after discharge, unadjusted (% died)

HFrEF



HFmrEF



HFpEF



~4 in 5

men and women died within 5 years of discharge, across all EF types

HR 0.89

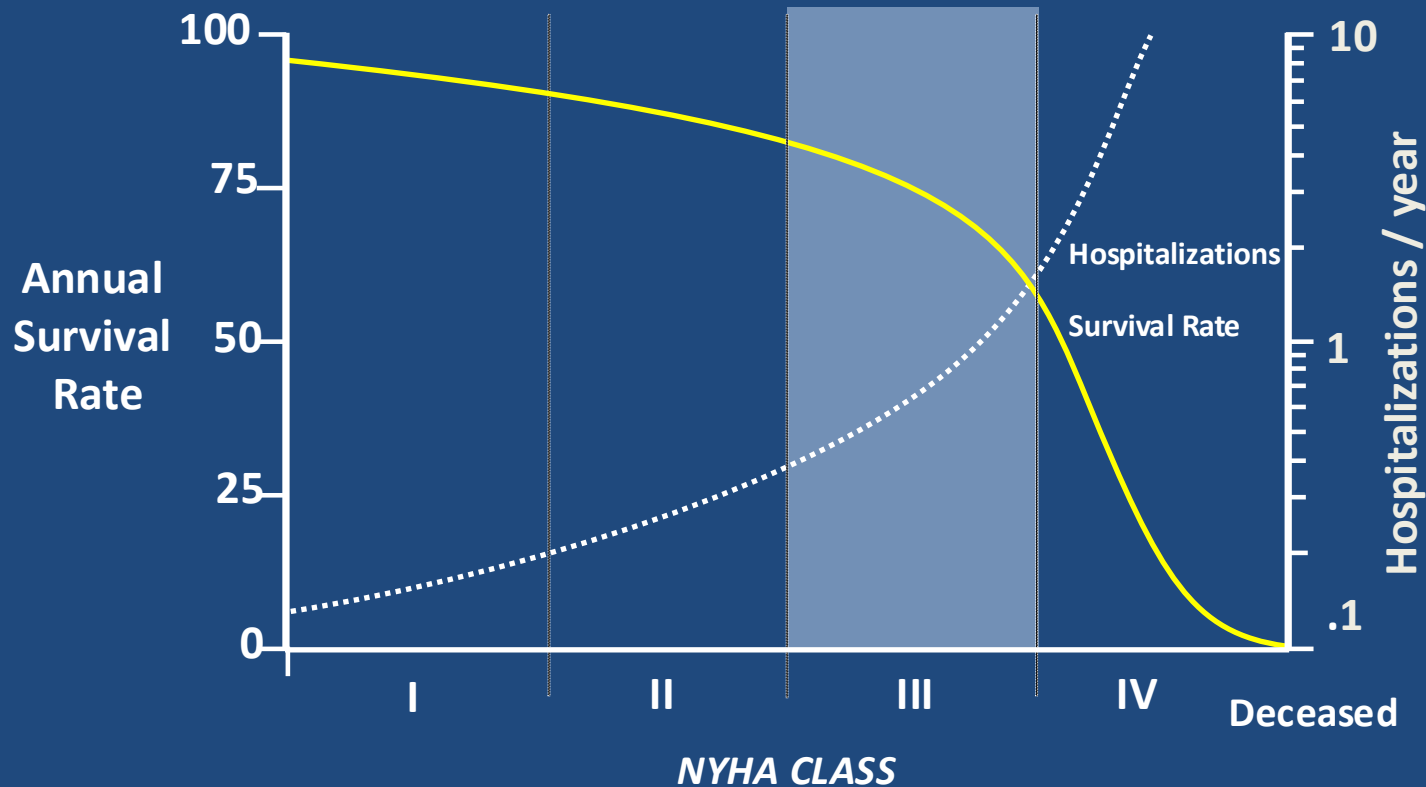
adjusted 5-year mortality, women vs men (95% CI 0.87–0.90)

17.0 vs 14.6

years of life lost vs the general population, women vs men (age 65–69, HFpEF)

Source: GWTG-HF registry linked to Medicare; 155,670 patients aged 65+, admitted 2006–2014, followed through 2019 (Keshvani et al., Eur J Heart Fail 2023)

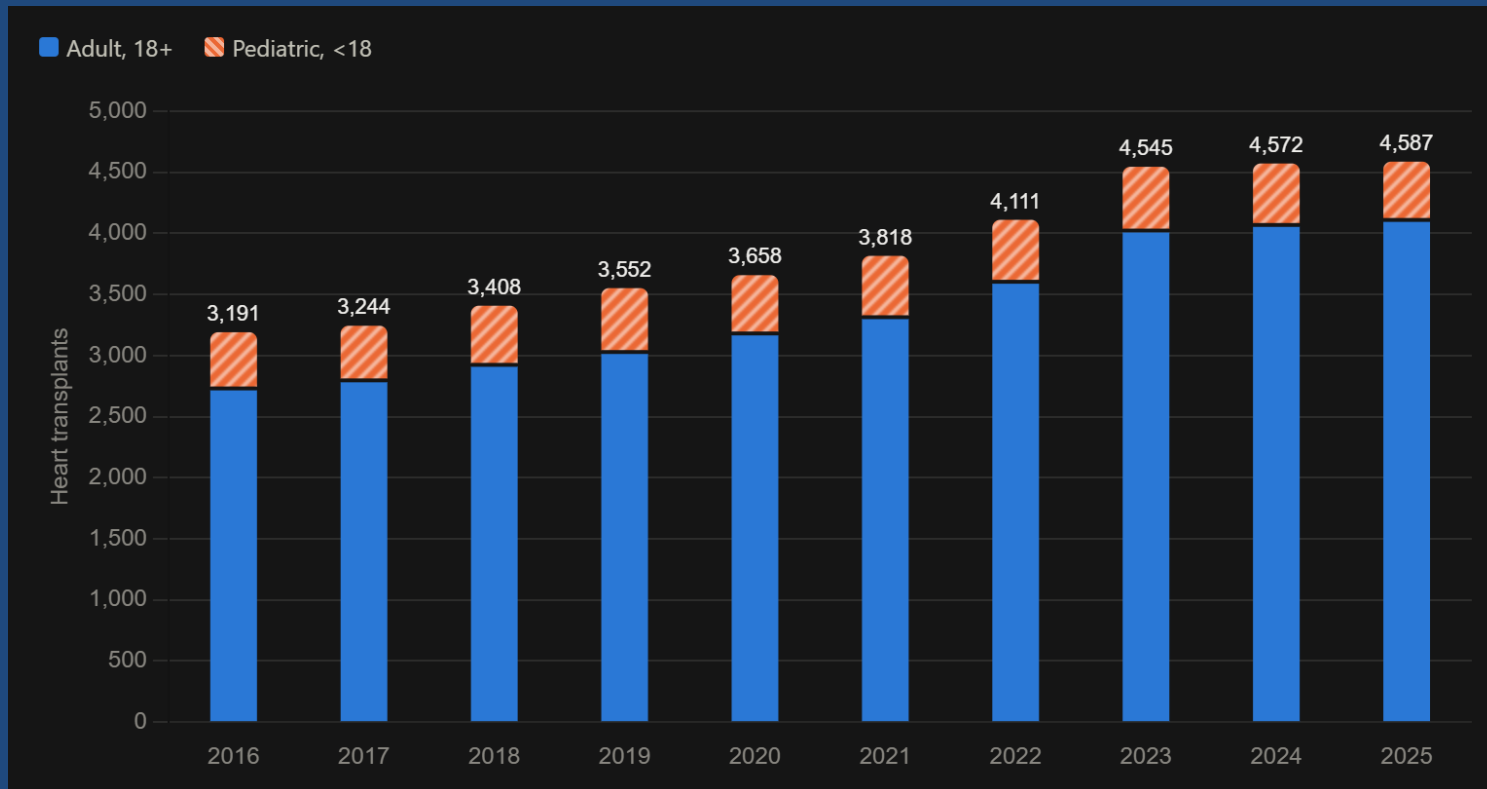
Natural History of Heart Failure



Class III

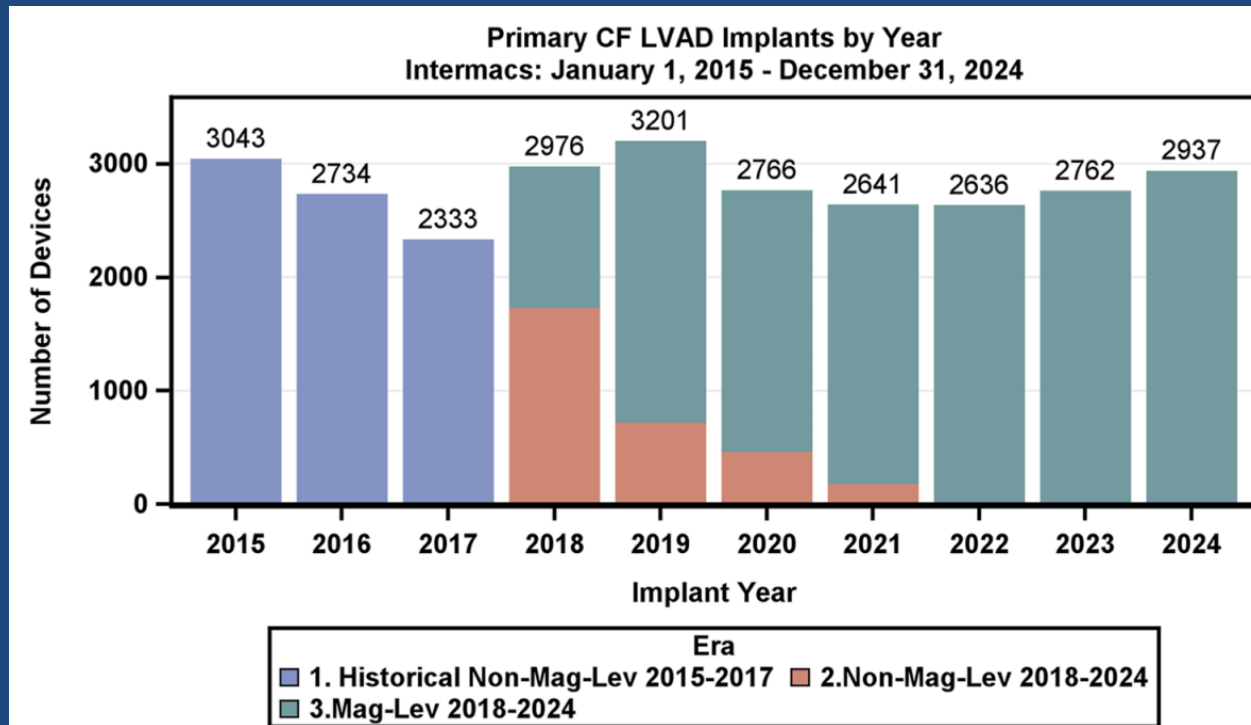
- 25% of HF Patients
- Frequent hospitalizations
- Worsening symptoms despite drug therapy
- Significant opportunity for new therapies

Total Heart Transplant US 2016-2025



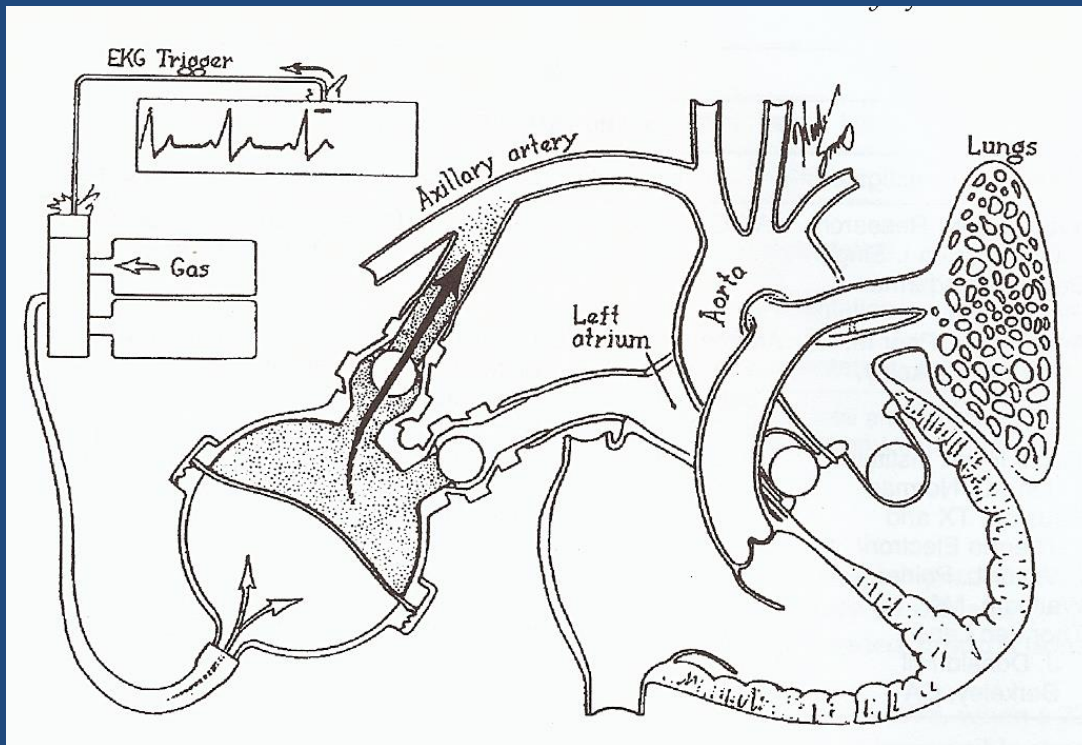
Original Figure based on OPTN data from,
<https://hrsa.unos.org/data/view-data-reports/national-data/#>

Total CF LVADS US 2016-2025



Nayak A et. al. Annals of Thoracic Surgery, 2025 INTERMACS Report

LVAD Bridge to Recovery - 1966



1974 – Workshop on Left Ventricular Assist

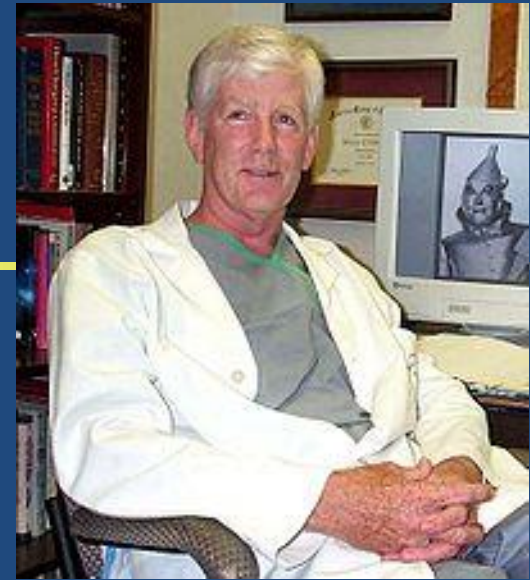
Transplantation has established that replacing the patient's own worn-out pump with a healthy one corrects the attendant circulatory ills. Hence, it can be expected that upon receipt of a well-functioning mechanical circulatory device, the patient will be restored to a healthy, productive life.

A handwritten signature in black ink, reading "Theodore Cooper". The signature is fluid and cursive, with a long horizontal stroke at the end.

Theodore Cooper, M.D.
Director, NHLI, and
Chairman of the Workshop on
Left Ventricular Assist Pump

William DeVries

- Born in 1943
- Trained at the University of Utah and Duke University
- Worked with Kolff to implant artificial heart in animals
- 1982: Implanted first artificial heart into Seattle dentist Barney Clark
- 1985: Implanted 2nd Jarvik into Bill Schroeder in Louisville KY



HeartMate II LVAD (n=200)

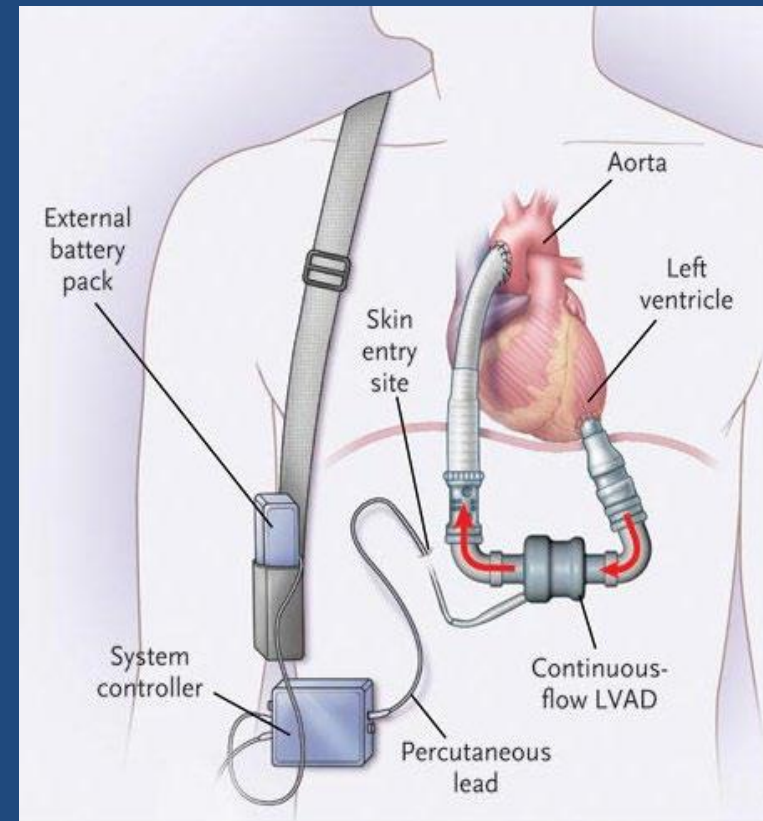
Non transplant eligible; most inotrope dependent

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device

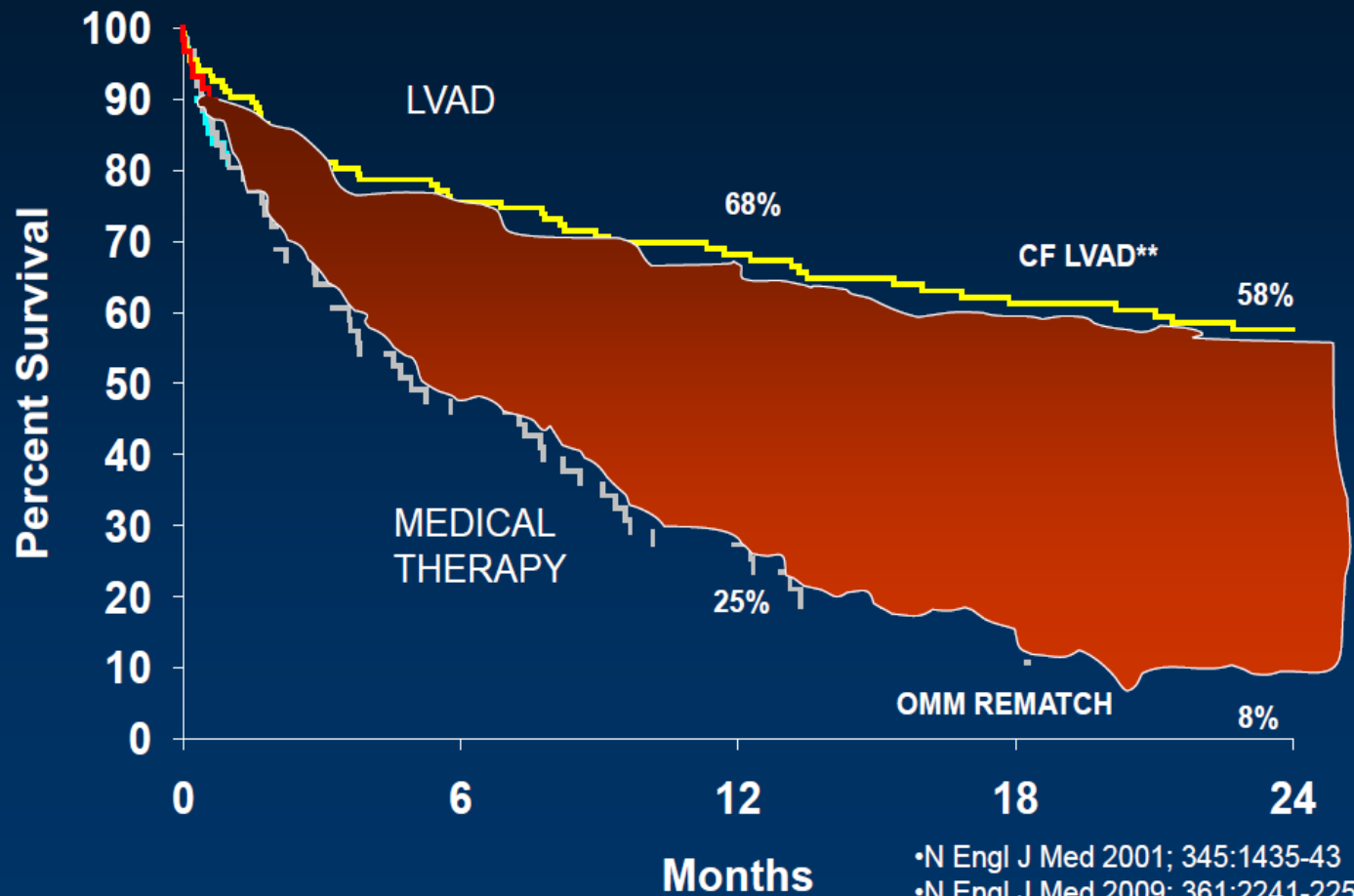
Mark S. Slaughter, M.D., Joseph G. Rogers, M.D., Carmelo A. Milano, M.D., Stuart D. Russell, M.D., John V. Conte, M.D., David Feldman, M.D., Ph.D., Benjamin Sun, M.D., Antone J. Tatroles, M.D., Reynolds M. Delgado, III, M.D., James W. Long, M.D., Ph.D., Thomas C. Wozniak, M.D., Waqas Ghumman, M.D., David J. Farrar, Ph.D., and O. Howard Frazier, M.D., for the HeartMate II Investigators*



NEJM 2009;361(23):2241-51.

Actuarial Survival vs REMATCH*

HeartMate II Destination Therapy Trial



The Future of LVAD Therapy: Why LVADs Will Replace Heart Transplant

Mark S. Slaughter, MD

CATCH-UP 2012

Heart Failure, Devices and Interventions

May 17, 2012

Overcoming the Limitations of Long-Term MCS Devices: Will Devices Replace Transplantation?

Mark S. Slaughter, MD
Professor and Chair
Department of Cardiovascular and Thoracic Surgery
University of Louisville

AATS 2018

The Changing Landscape for MCS and Heart Transplantation: Continued Improvement or Rearranging the Deck Chairs

Baylor Scott White 2020

Mark S. Slaughter, MD

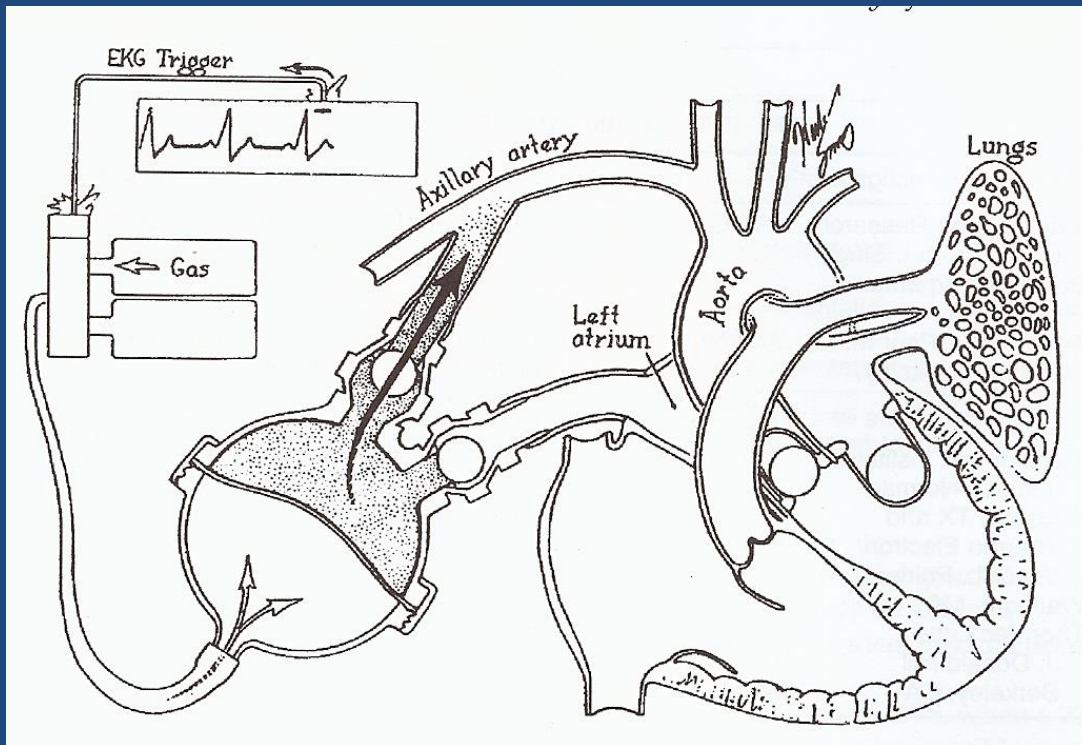
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LVAD Bridge to Recovery - 1966



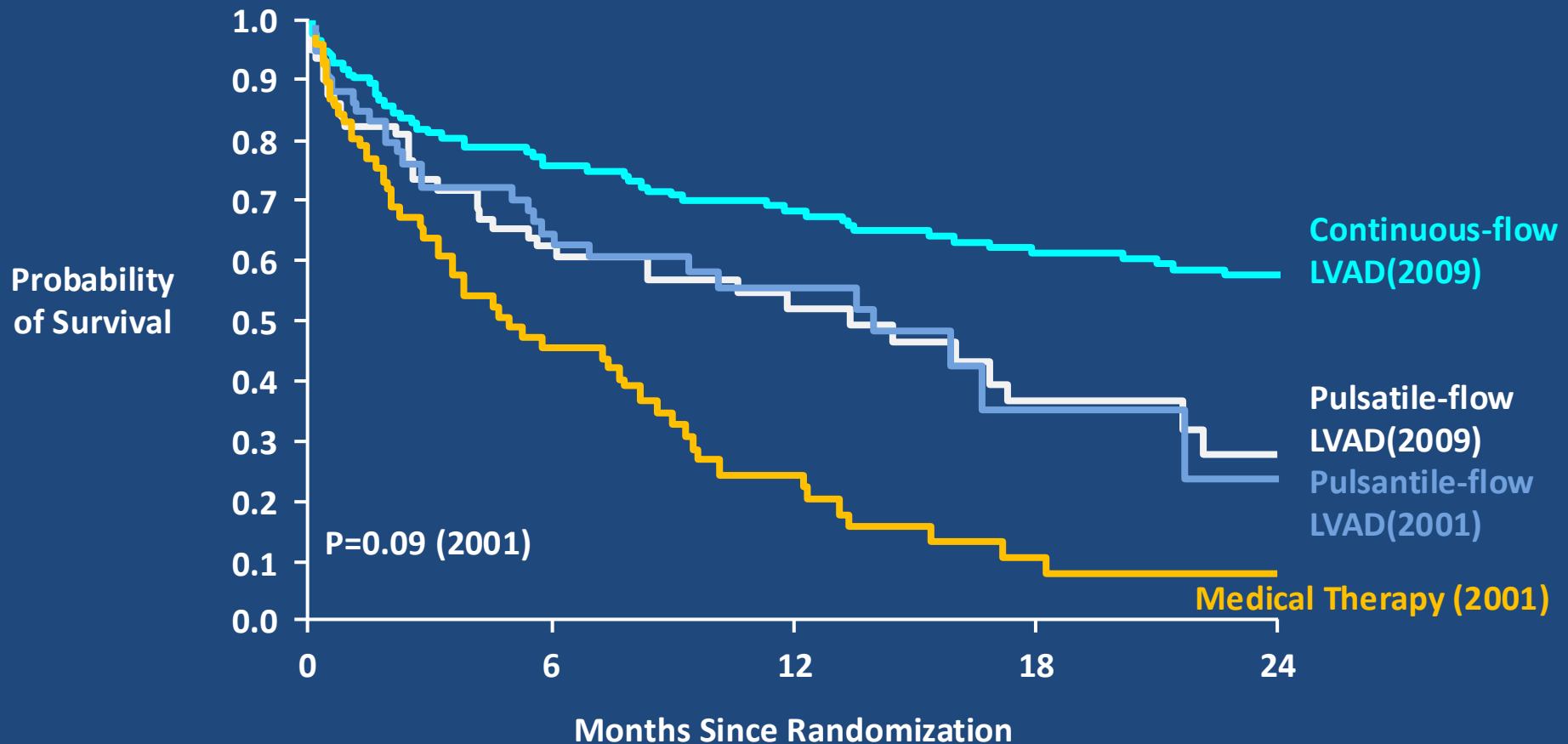




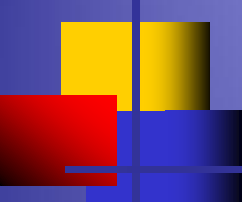


Destination Therapy Trials

Survival Rates in Two Trials of Left Ventricular Assist Devices (LVADs) as Destination Therapy



What is Clinically Meaningful Benefit?



Study (therapy)	1 year Mortality (%) Control vs Tx	1 yr Relative Benefit (%)	Absolute Benefit
SOLVD (ACE Inhibitor)	14 vs 11	21	3
CONSENSUS (ACE Inhibitor)	62 vs 45	27	17
ATLAS (ACEI dosing)	14 vs 13.3	5	0.7
COPERNICUS (Beta Blocker)	18.5 vs 11	41	7.5
RALES (Spironolactone)	25 vs 17	32	8
REMATCH (LVAD)	72* vs 49*	33*	24*

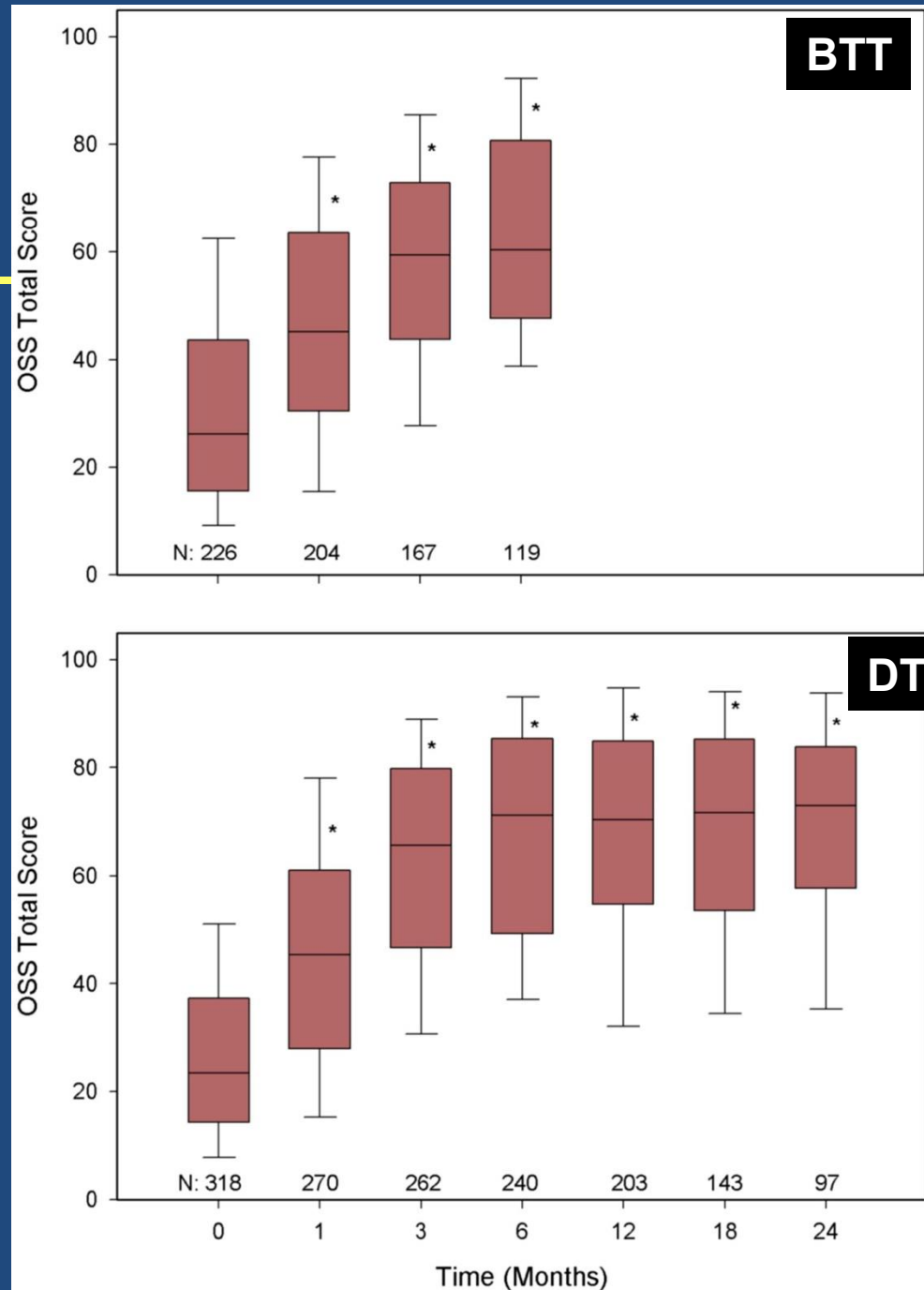
Source: Lynne Warner Stevenson, MD (3/4/02)

* 1 year mortality (4/02)

Both BTT and DT patients demonstrate an improvement in quality of life as indicated by the increasing KCCQ Overall Summary Score

At 2 years following LVAD implantation:
89% satisfaction in the outcome
87% would decide to have a LVAD again after knowing what they knew now

Kathleen Grady et al. *Journal of the American Heart Association* 2021



**Permanent Mechanical Circulatory
Support vs. Transplantation:
Is the Difference Real or Artificial?**

Treatment: Therapy

Heart Transplant

Cardiac replacement (foreign body)

Requires ongoing
immunosuppression/monitoring

Rx introduces potential problems

Psychosocial side effects/adjustments

No additional Rx

LVAD

Left ventricular assist /
replacement device (foreign body)

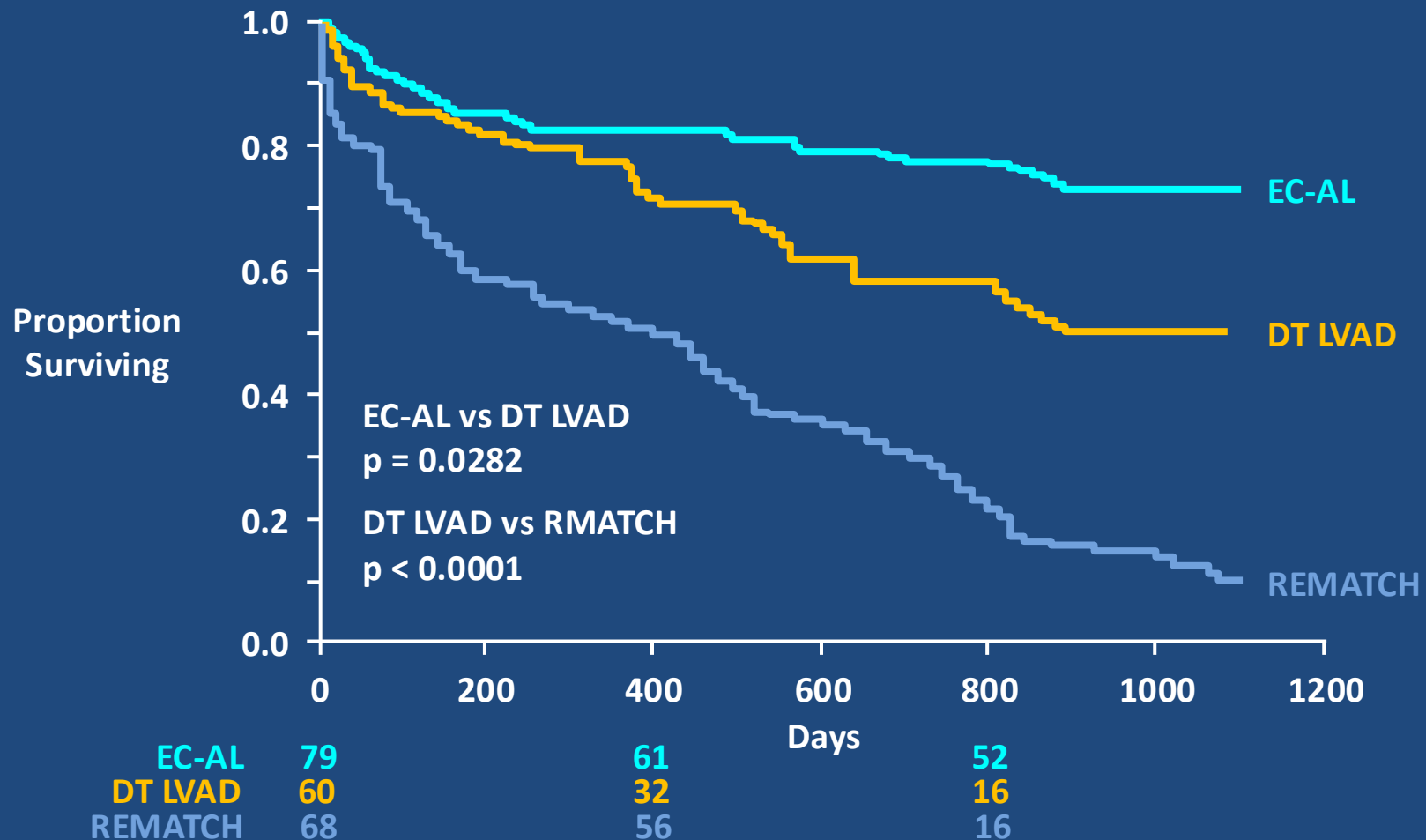
Anticoagulation/monitoring

Rx introduces potential problems

Psychosocial side
effects/adjustments

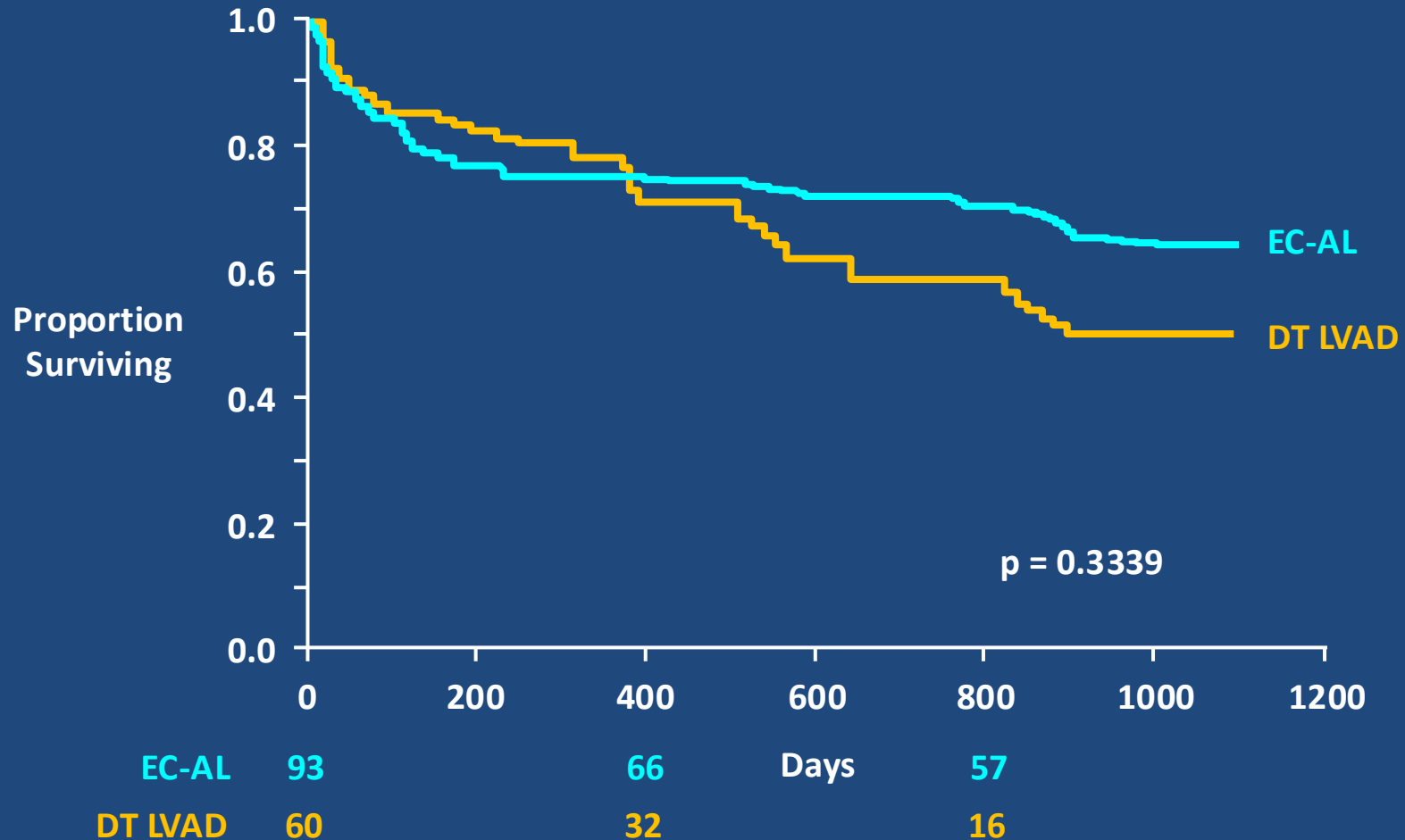
Replace if device fails

Left Ventricular Assist Device Destination Therapy Versus Extended Criteria Cardiac Transplant

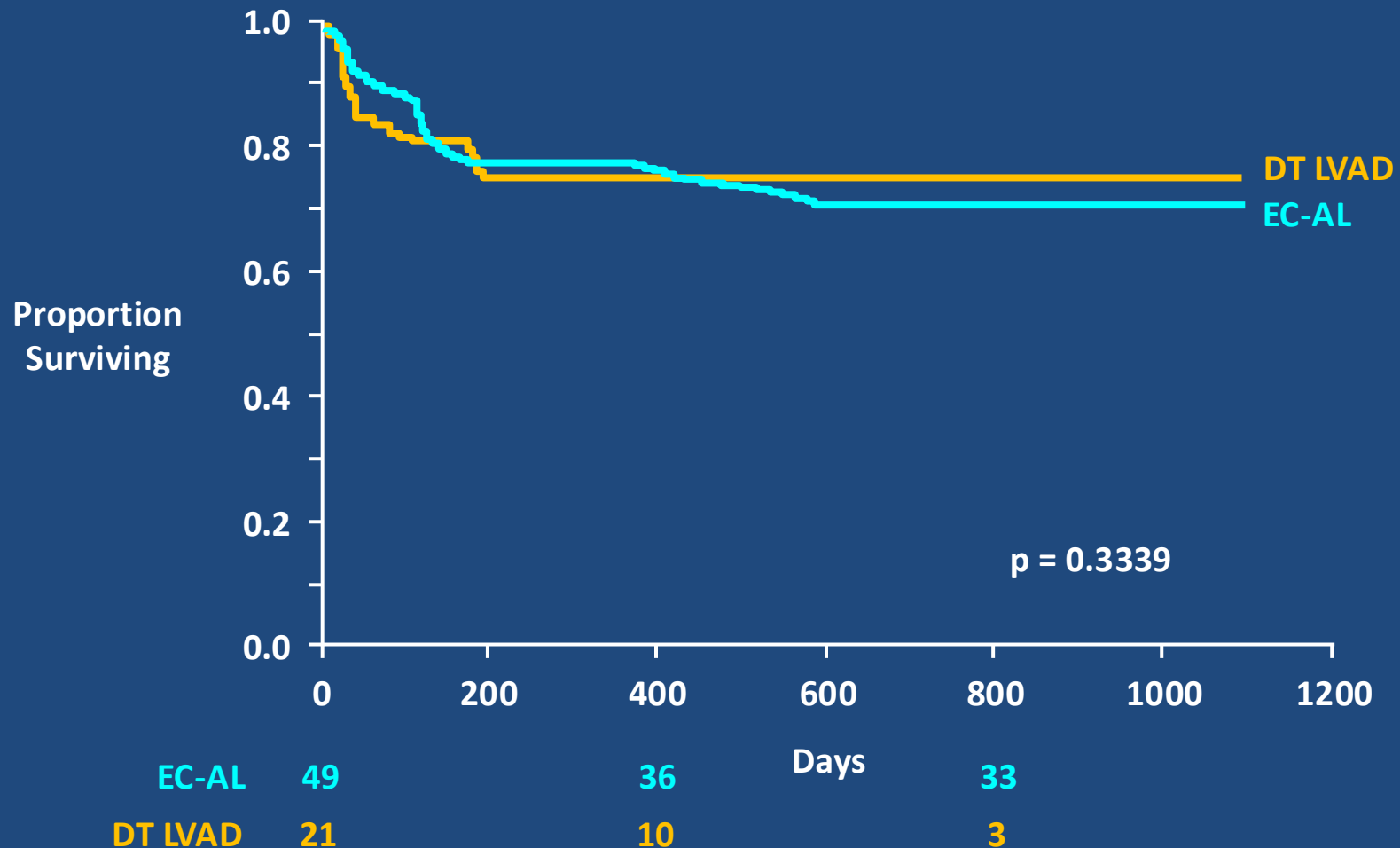


Survival DT-LVAD vs EC-AL

EC-AL patients are accounted for at time of listing for transplantation



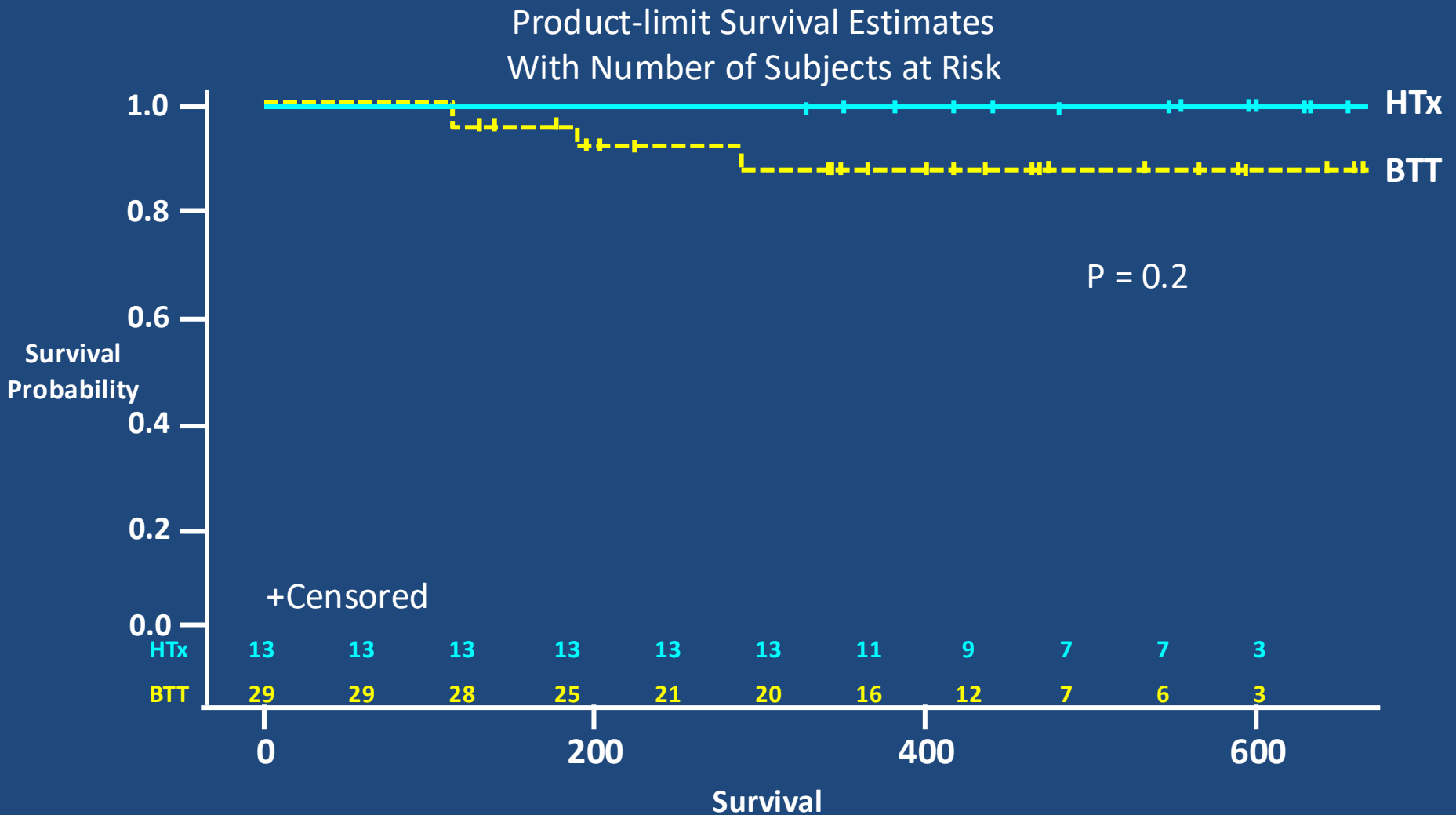
Survival DT-LVAD vs EC-AL After removal of HM XVE



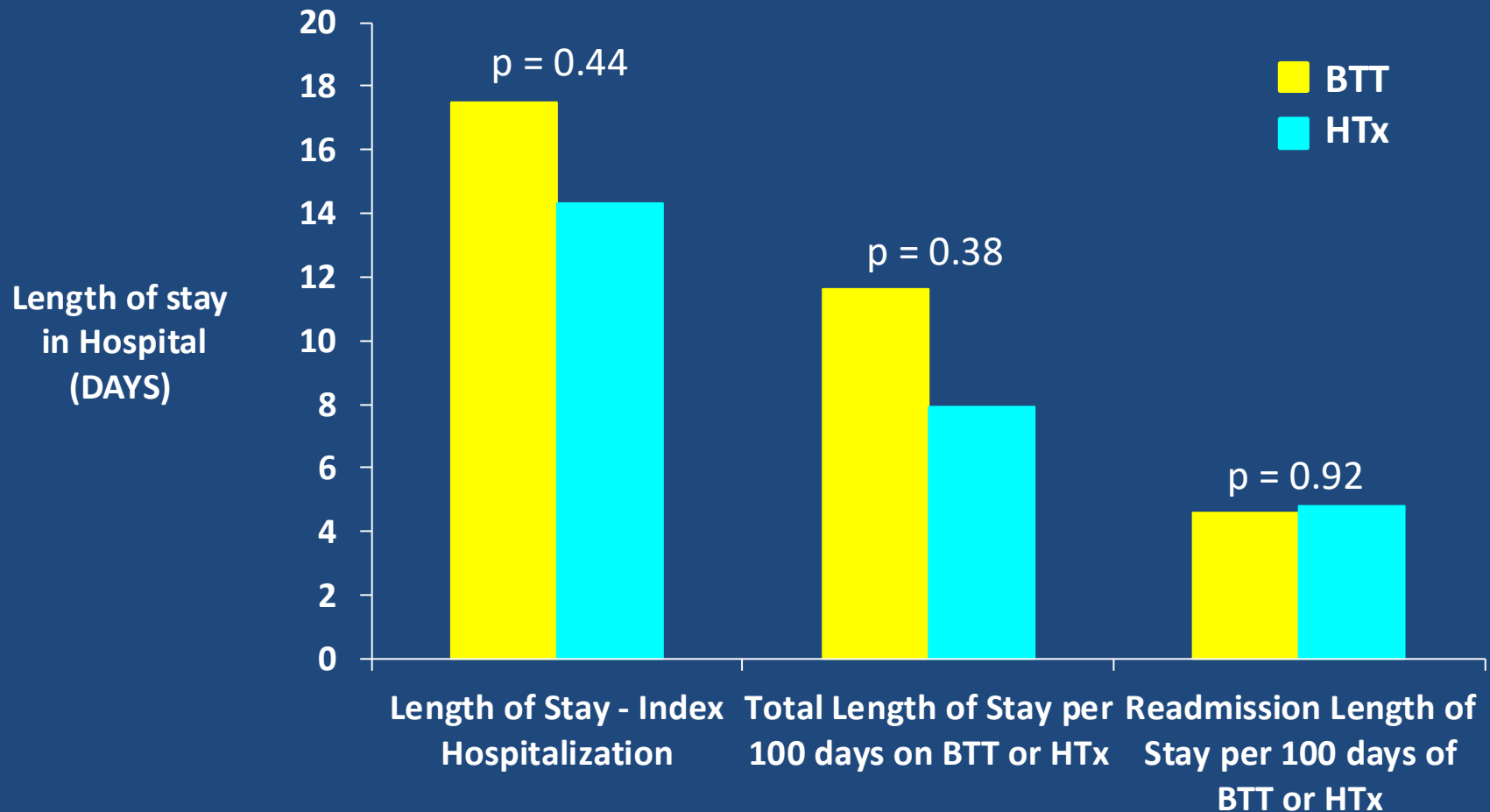
Heart Transplant vs. LVAD in Heart Transplant Eligible Patients

Slaughter et al, Ann Thoracic Surgery 2011

Actuarial Survival



Bridge to Transplantation Therapy (BTT) Vs. Heart Transplant (HTx) Length of Hospital Stay



Hospital Cost

Index Hospitalization Cost* (\$)	Mean	SD	N	p value
BTT	196,707	37,858	29	
HTx	127,978	44,117	13	0.0001
Pre Surgery Hospital Days	Mean	SD	N	p value
BTT	10.6	10.06	29	
HTx	3.9	13.25	13	0.07
Post Index Hospitalization Cost^ (\$)	Mean	SD	N	p value
BTT	33,302	70,098	29	
HTx**	38,437	48,268	13	0.81

*Index Hospitalization Cost Adjusted using Cost to Charge Ratio (CCR) for fiscal year 2009 = 0.325*Charges

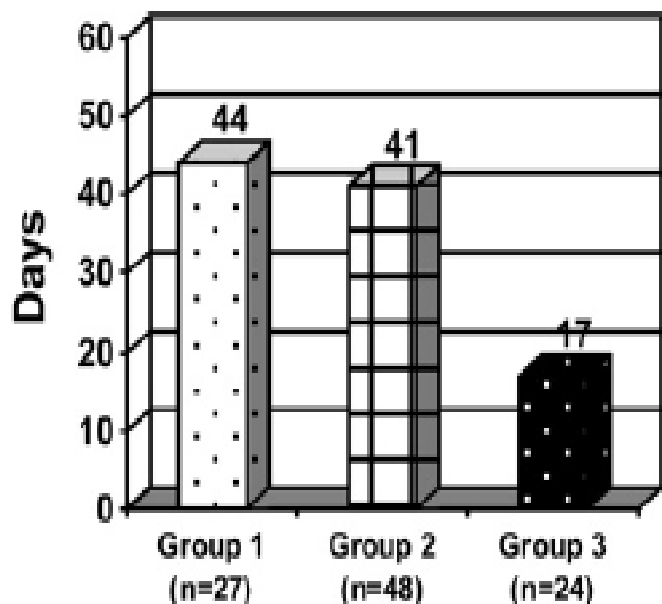
^ Post Index Hospitalization cost within 10 months of Implant/Transplant (adjusted by CCR)

**HTx Post Index Hospitalization Cost DO NOT include Right Heart Catheterization and Immunosuppressive Therapy Costs

Note: 1 patient in BTT had device replacement due to malfunction but was not removed from analyses

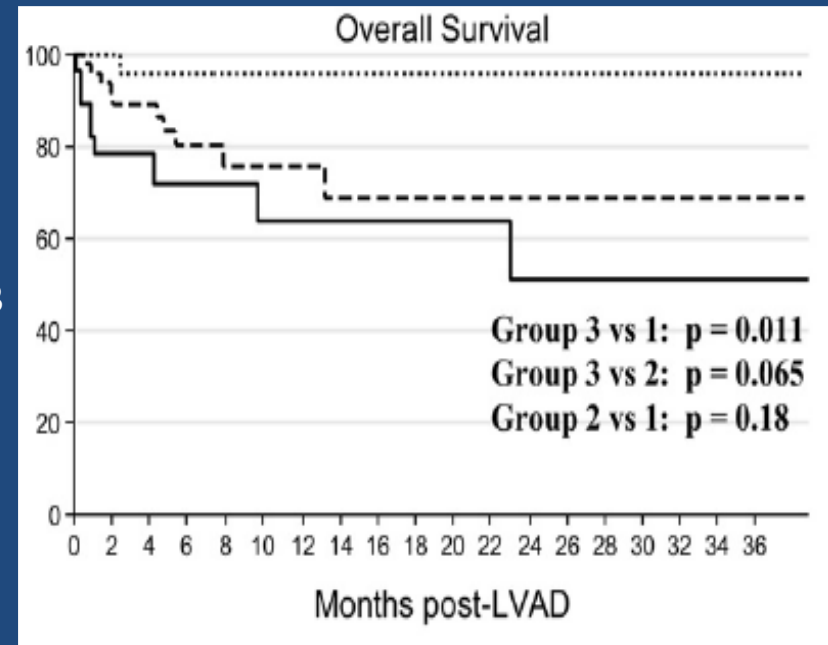
Clinical Outcomes Based on INTERMACS Profile

Length of Stay Post-VAD



Group 1: 1
Group 2: 2 or 3
Group 3: 4-7

Actuarial Survival Post-VAD



Less acutely ill, ambulatory patients in INTERMACS profiles 4-7 had better survival and reduced length of stay compared to patients who were more acutely ill in profiles 1-3.

ROADMAP Patient Population

NYHA Class III	Class IIIB		Class IV (Ambulatory)		Class IV (On Inotropes)		
INTERMACS Profiles	7	6	5	4	3	2	1
Percent of current implants in INTERMACS ¹	1.0%	1.4%	3.0%	14.6%	29.9%	36.4%	14.3%
FDA Approval: Class IIIB/IV							
CURRENTLY NOT APPROVED	LIMITED ADOPTION			GROWING ACCEPTANCE			
REVIVE-IT	ROADMAP Non-inotrope dependent						

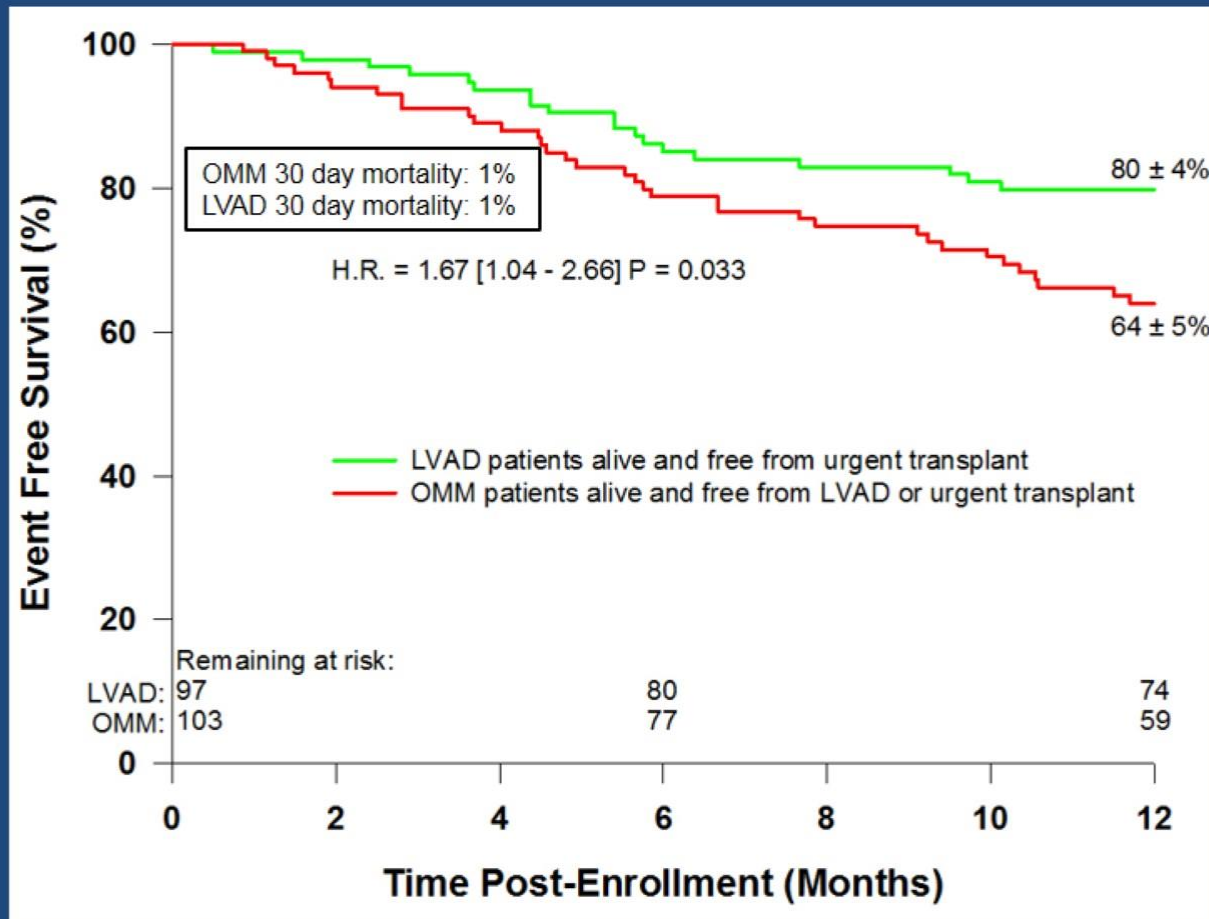
¹Kirklin et al J Heart Lung Transplant 2014; 33:555-64

Rogers JG et al: ROADMAP Trial Design: Am Heart J. 2015 Feb;169(2):205-210

GL-HM2-04150215

Jerry D. Estep, MD – Presented at ISHLT on April 17, 2015

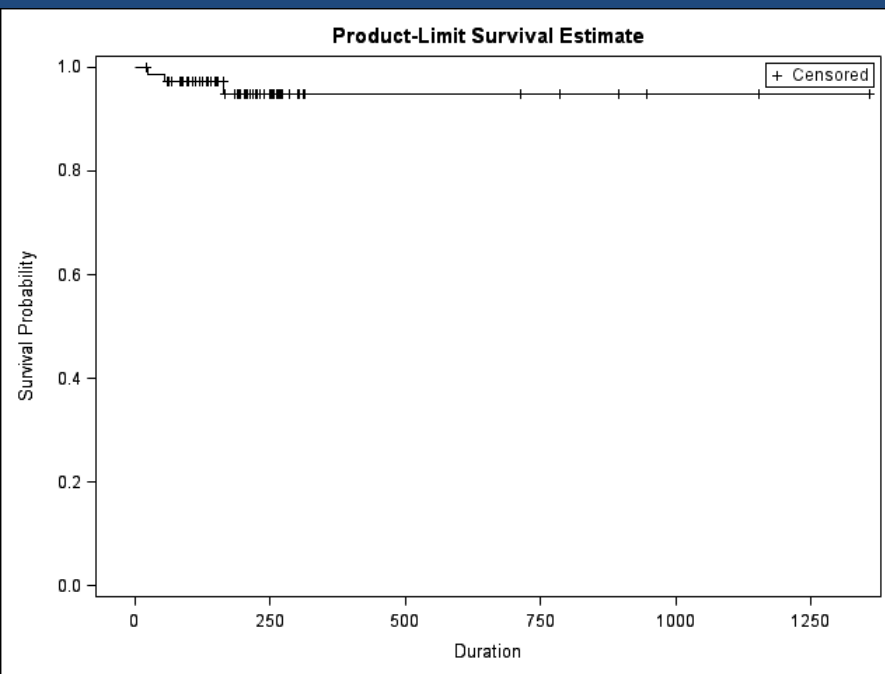
Survival As-Treated on Original Therapy



Survival of HM II patients in Japan

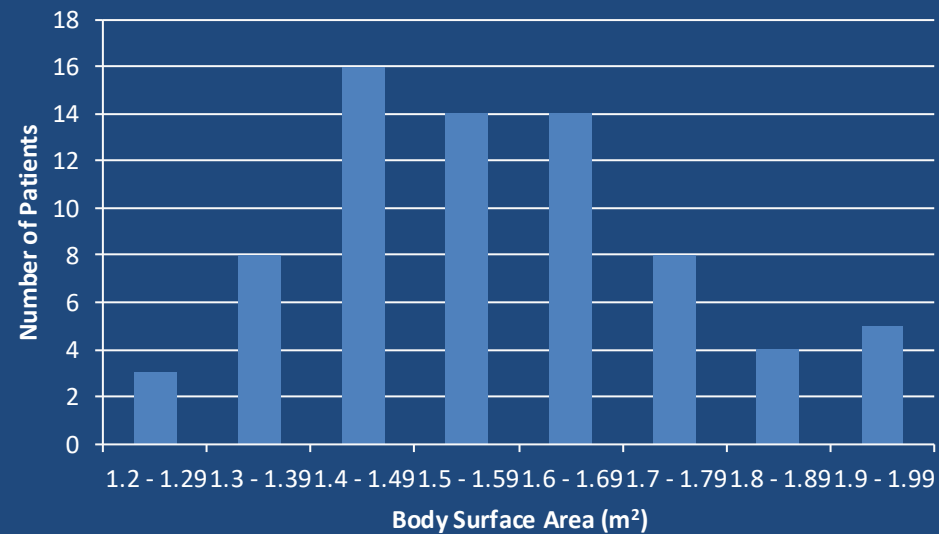
Vertical lines indicate patient censored for transplant, explant, or ongoing.

1 year survival = $95.0\% \pm 2.9\%$



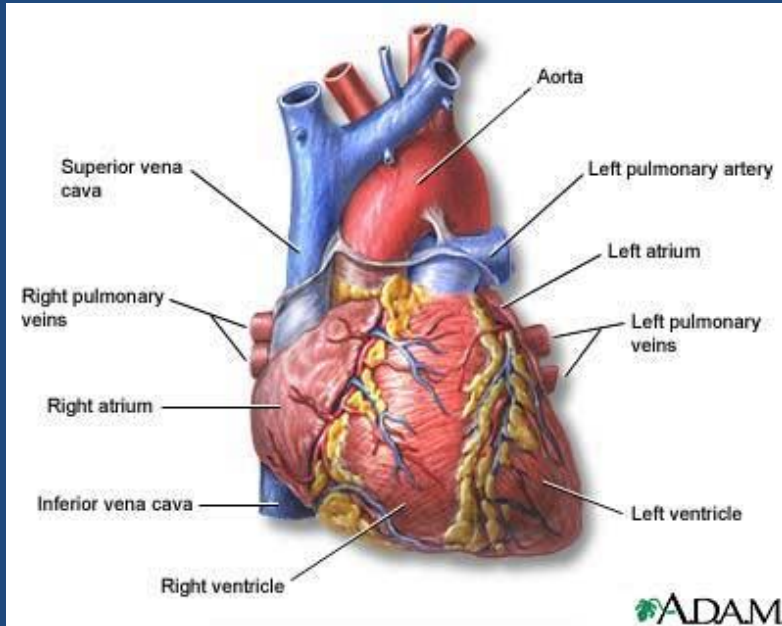
Thoratec Device Tracking data as of February, 2014

BSA Distribution of BTT Patients



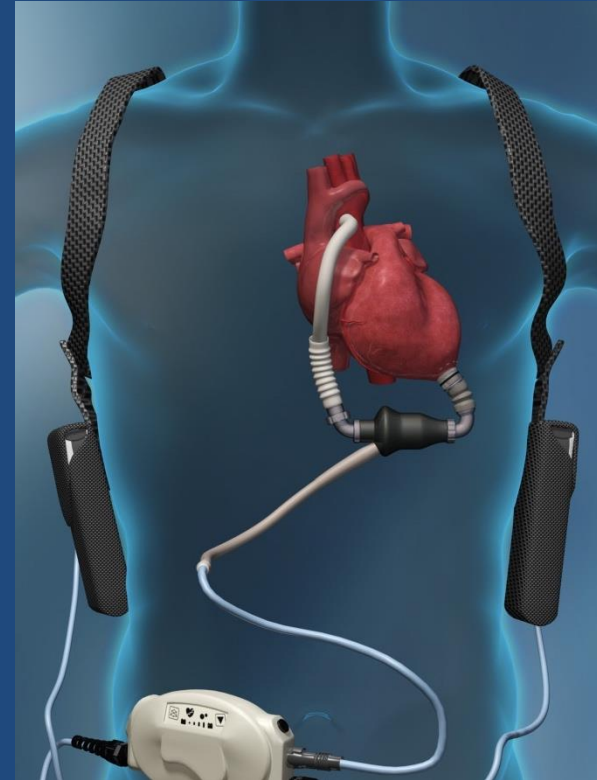
Which is the better pump?

Millions of yrs in development



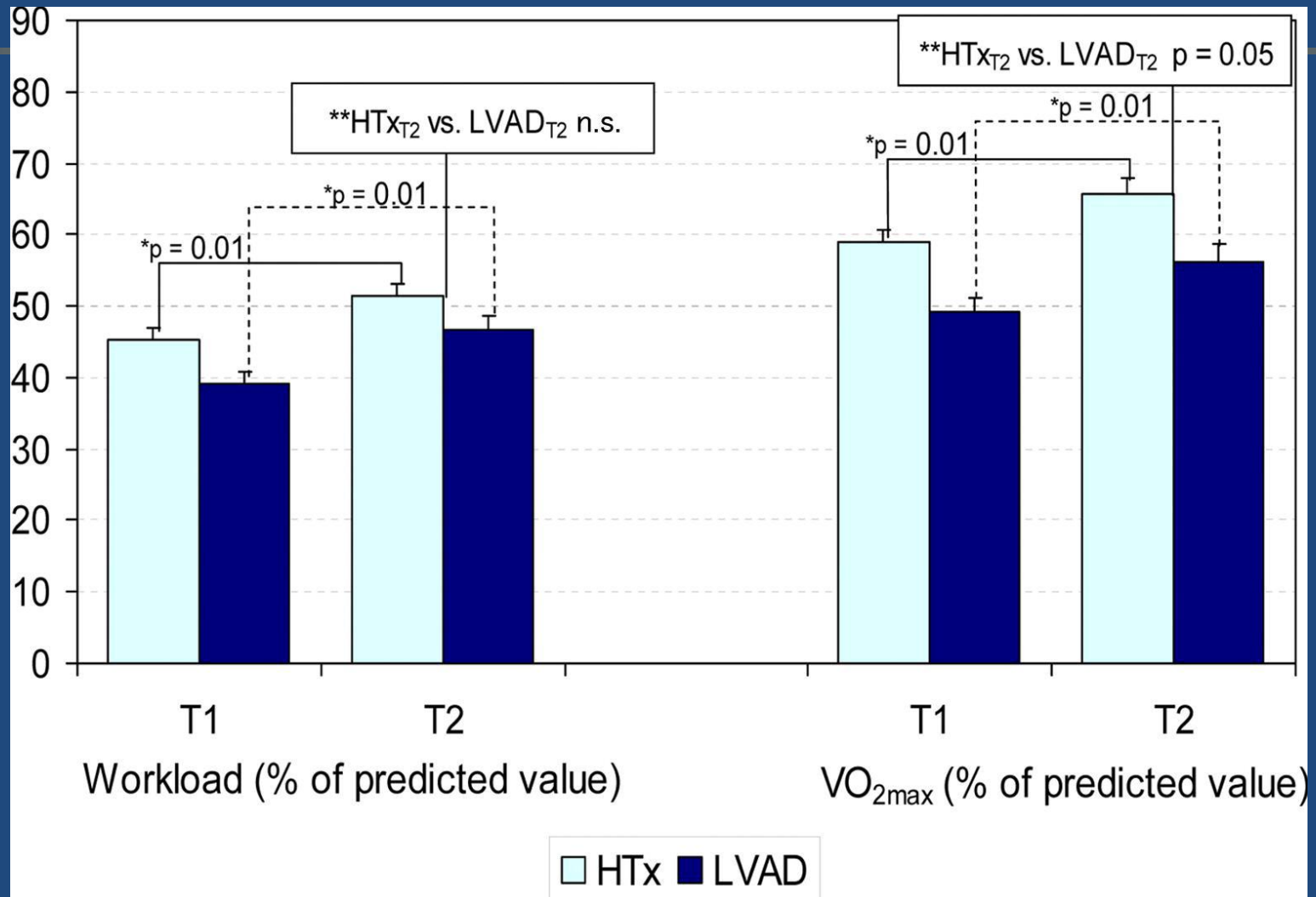
Biventricular support
Pulsatile flow; No external lines
Max Output 25-30 l/min
Lasts a lifetime
Responds to Preload and Afterload
No anticoagulation required

Decades in development



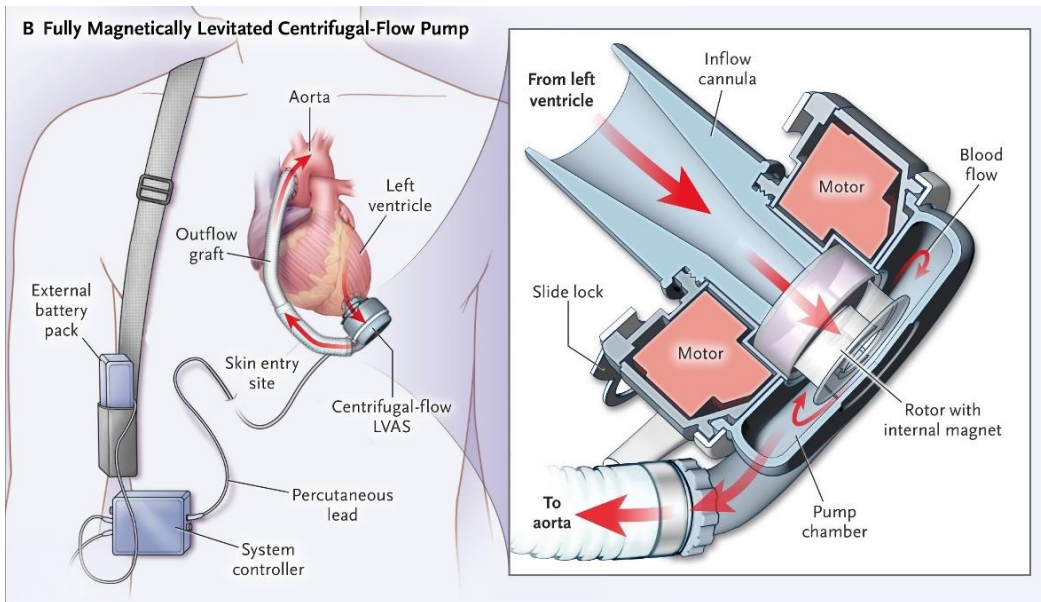
Univentricular support
Continuous flow; external power
Max CO 10-12 L/min
Preload responsive

Peak VO₂ in HTX (n=54) and LVAD HMII (n=36) 6wks (T1) and 8 mo (T2) post surgery



HeartMate 3 LVAD

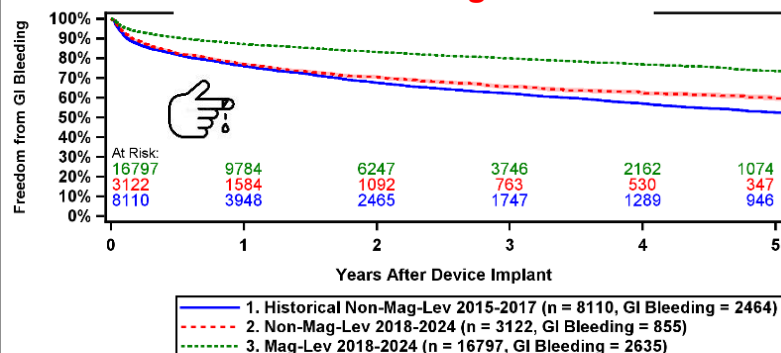
- The MagLev design of the HeartMate 3 LVAD reduced hemocompatibility related adverse events



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

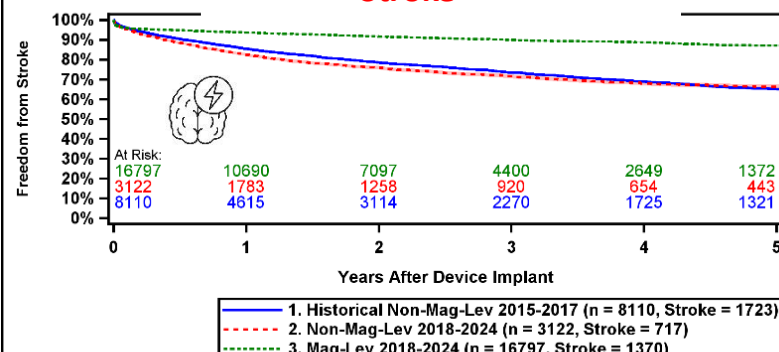
2025 InterMacS Annual Report. *Ann Thorac Surg.* 2025

GI Bleeding



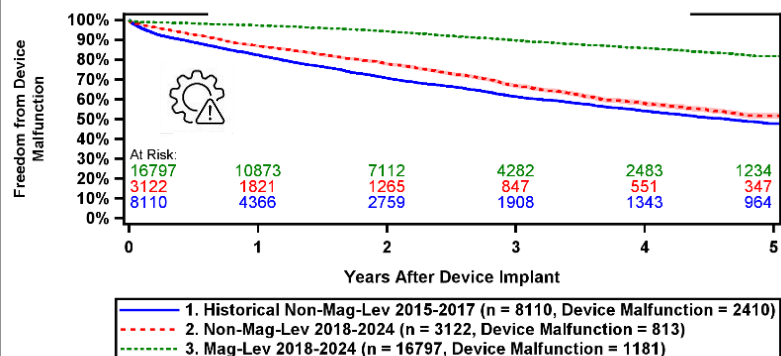
Shaded areas indicate 70% confidence limits
 p (log-rank) = <.0001
 Event: GI Bleeding (censored at death, tx, cess. of supp)

Stroke



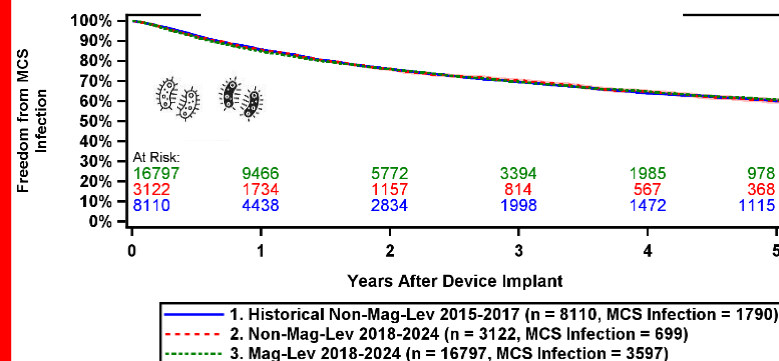
Shaded areas indicate 70% confidence limits
 p (log-rank) = <.0001
 Event: Stroke (censored at death, tx, cess. of supp)

Device Malfunction



Shaded areas indicate 70% confidence limits
 p (log-rank) = <.0001
 Event: Device Malfunction (censored at death, tx, cess. of supp)

Infection

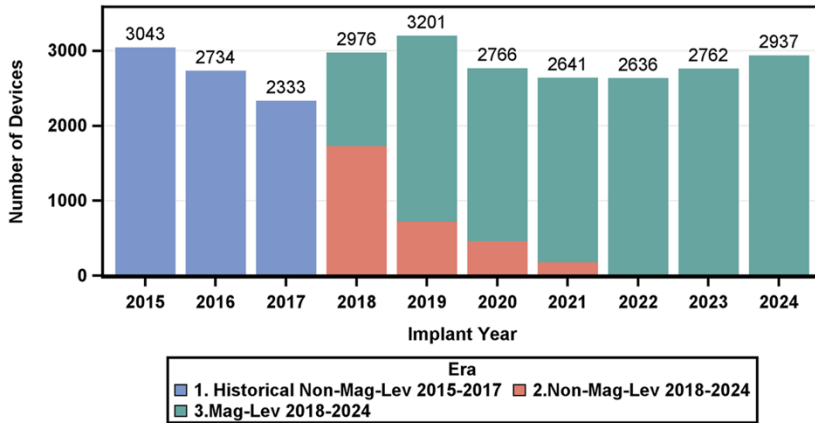


Shaded areas indicate 70% confidence limits
 p (log-rank) = 0.9248
 Event: MCS Infection (censored at death, tx, cess. of supp)

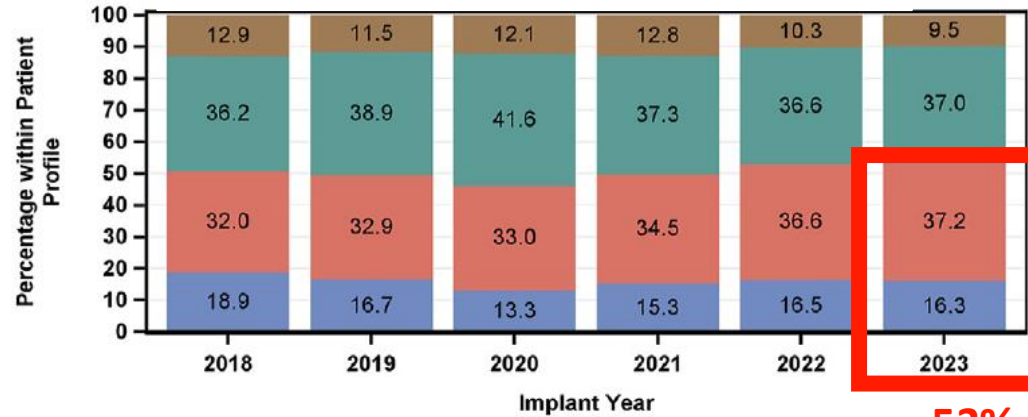
STS Intermacs: Durable LVAD Practice Patterns

Device Volume

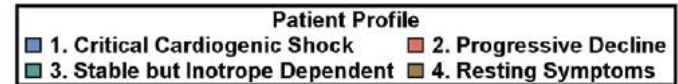
Primary CF LVAD Implants by Year
Intermacs: January 1, 2015 - December 31, 2024



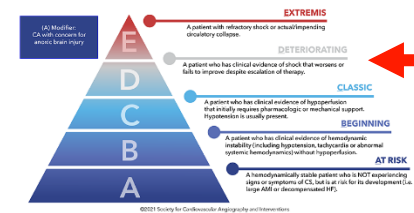
Patient Profile



53%

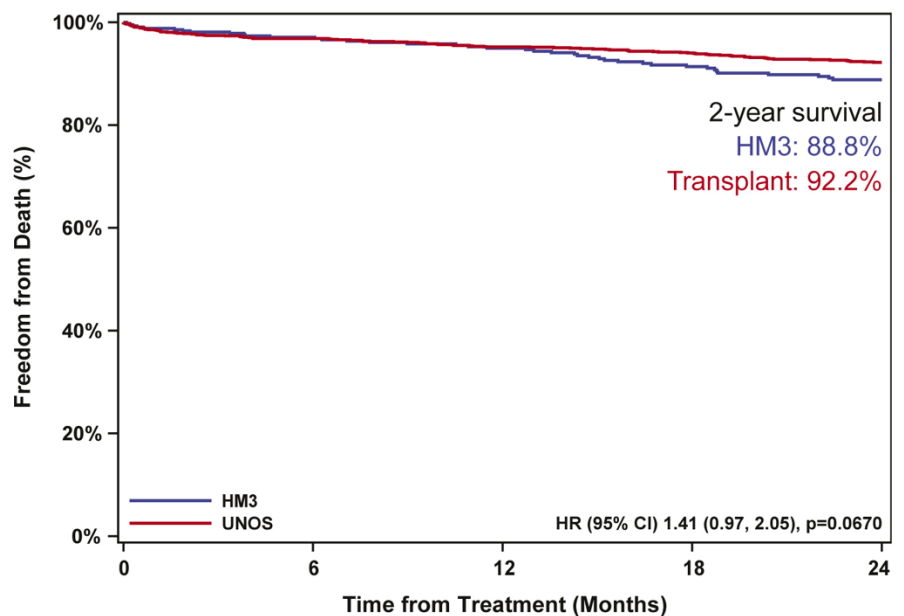


Profiles 5-7 comprise <3% of implants and not depicted in this figure

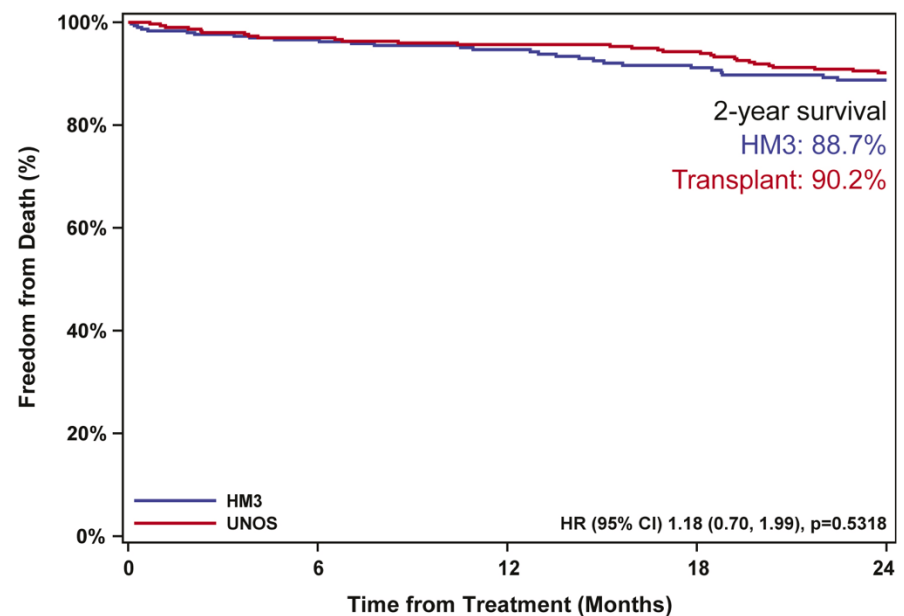


Heart Replacement Therapy in Young Patients (< 50 yrs)

A Survival From Time of Treatment: Overall Population

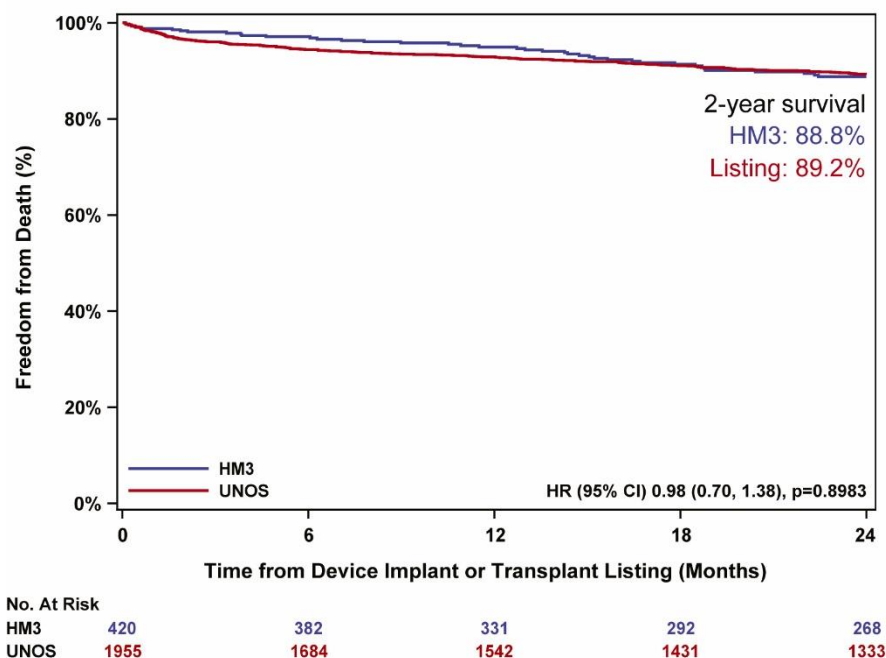


B Survival From Time of Treatment: Matched Population

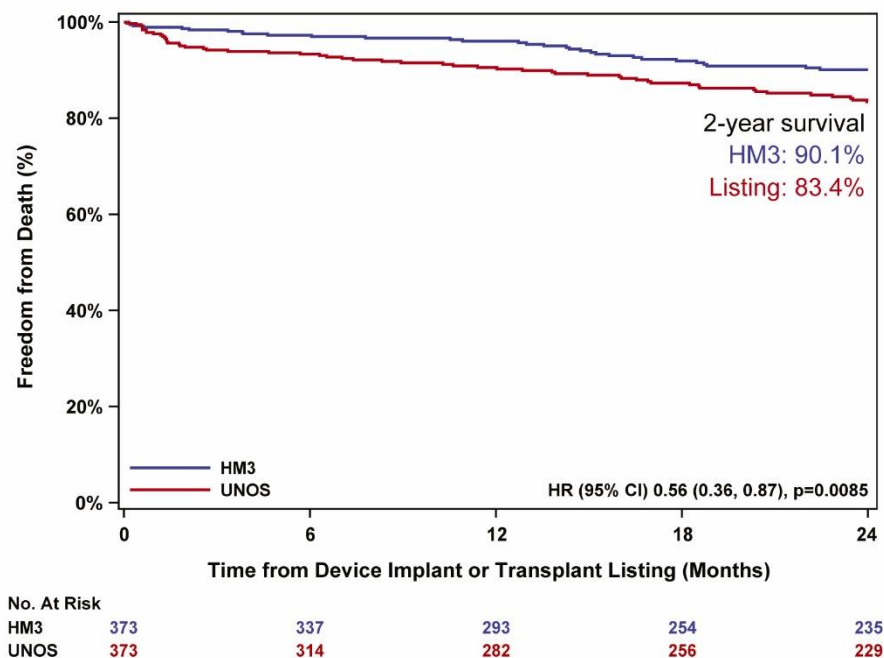


Heart Replacement Therapy in Young Patients (< 50 yrs)

A HM3 Survival and UNOS Survival From Listing:
Overall Population

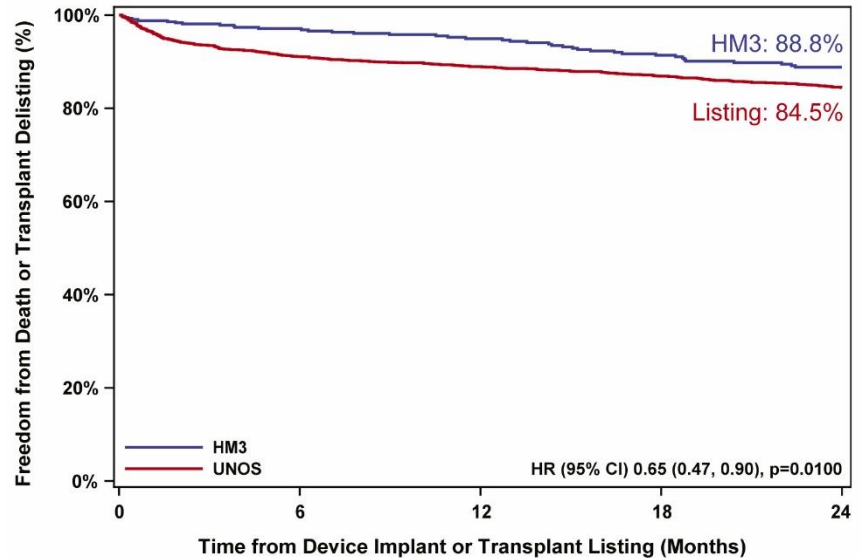


B HM3 Survival and UNOS Survival From Listing:
Matched Population



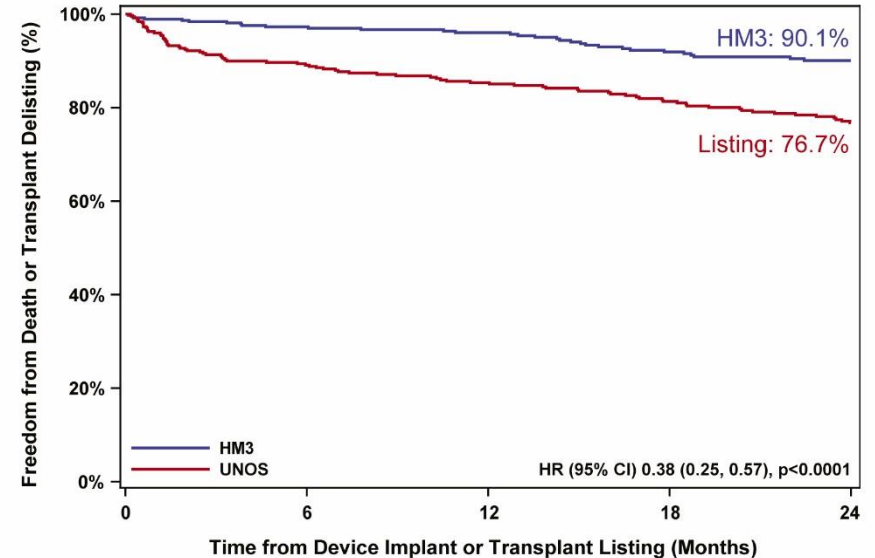
Heart Replacement Therapy in Young Patients (< 50 yrs)

A HM3 Survival and UNOS Survival and Freedom from Delisting Due to Deterioration: Overall Population



No. At Risk					
HM3	420	382	331	292	268
UNOS	1955	1684	1542	1431	1333

B HM3 Survival and UNOS Survival and Freedom from Delisting Due to Deterioration: Matched Population



No. At Risk					
HM3	373	337	293	254	235
UNOS	373	314	282	256	229

Durable LVADs

Did we miss the boat?

- Hemolysis, pump thrombosis essentially gone
- Stroke is similar for age adjusted population
- Survival for “transplant like” patients is similar to transplant
- Survival for DT patients excellent out to 5-7 years
- Young patients might have overall survival advantage if LVAD first
- Older patients that have potential for waitlist death should be considered for LVAD
- Definitely need TETS to reduce/eliminate driveline infection and continue to improve quality of life
- Need competition in the field for long term MCS continue to improve
- Who is deciding if a patient should be offered a LVAD?
- ***Nope, the boat is still at the dock!***

Thank You!

“I have gathered what I observed to be useful, and brought it together as a single body”

Vitruvius

Ten Books on Architecture (c. 25 B.C.)