DONALD AND BARBARA ZUCKER SCHOOL of MEDICINE AT HOFSTRA/NORTHWELL

Surgical Therapies for Advanced Heart Failure

Brian Lima, MD FACS
Director of Heart Transplantation Surgery
Associate Professor of Surgery

North Shore University Hospital
Northwell Health℠

CME ACCREDITED UPDATES IN MEDICINE ELEARNING SERIES

COURSE NAME:

Medicine RSS eLearning Modules

CME eLEARNING ACTIVITY NAME:

Surgical Therapies for Advanced Heart Failure

PROGRAM DESCRIPTION, EDUCATIONAL GOAL AND RATIONALE:

Evidence based guidelines are constantly changing and being updated for several core areas of Internal Medicine throughout the year. It is important for physicians to practice the most up-to-date standard of care in all specialties to promote patient health and well-being. Our series of lectures at the medicine regularly scheduled series promotes continuing education for the practicing internist and highlights important updates in medical practice in these core areas. Physicians in general practice often and do not have the time to keep themselves up-to-date with medical advances as they are busy seeing patients in the clinical setting. The Medicine Regularly Scheduled Series gives these physicians the opportunity to learn these advances in an academic setting.

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TARGET AUDIENCE:

Physician Partners and Premium Network
community-based providers

LEARNING OBJECTIVES:

Upon successful completion of this activity, participants should:

Identify stages of heart failure

Summarize the signs that a heart specialist is needed for the patient

Recognize the gap between heart transplants performed and patients with advanced HF

Identify the profiles for transplant patient selection

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FACULTY PRESENTER/AUTHOR:

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Director of Heart Transplantation Surgery,

North Shore University Hospital

Thomas McGinn, MD

Thomas McGinn MD MPH

Professor and Chair of Medicine

Donald and Barbara Zucker Hofstra /Northwell School of Medicine

SVP and Deputy Physician in Chief, Northwell Health

Course Director:

George Boutis, MD

Attending Physician

Department of Medicine

Northwell Health

Planners:

John Raimo, MD

Division of Hospital Medicine

Site Director, Internal Medicine Residency Program

Sean LaVine, MD

Site Director, Division of Hospital Medicine

Long Island Jewish Medical Center

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ACCREDITATION:

Northwell Health is accredited by the Accreditation Council for Continuing Medical Education to provide Continuing Medical Education for physicians.

CREDIT DESIGNATION:

Northwell Health designates this Continuing Medical Education activity for a maximum of ***1 AMA PRA Category I credits*** ™. Physicians should only claim credit commensurate with the extent of their participation in the activity

METHOD OF PHYSICIAN PARTICIPATION:

To receive credit the participants must:

Read/view the entire educational activity.

Input name and credentials to gain CME credit.

Answer at least 80% of the Post-Test questions correctly.

Complete and return Post-Test.

Complete and return Program Evaluation.

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COURSE HOST:

Department of Medicine

Northwell Health

ESTIMATED TIME TO COMPLETE ACTIVITY:

90 minutes

ACKNOWLEDGEMENT OF COMMERCIAL SUPPORT:

An announcement of program support will be made to all attendees at the beginning of each educational activity.

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DISCLOSURE POLICY:

Northwell Health adheres to the ACCME's Standards for Commercial Support. Any individuals in a position to control the content of a CME activity, including faculty, planners, reviewers or others are required to disclose all relevant financial relationships with commercial interests. All relevant conflicts of interest will be resolved prior to the commencement of the activity.

FACULTY DISCLOSURES:

Drs. Thomas McGinn, George Boutis, John Raimo and Sean LaVine have nothing to disclose. Dr. Lima received transportation and lodging from Abbot for a sponsored training course.

RELEASE DATE:	TBD
REVIEW DATE:	TBD
PROGRAM EXPIRATION:	7/30/19

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Objectives

Upon successful completion of this activity, participants should:

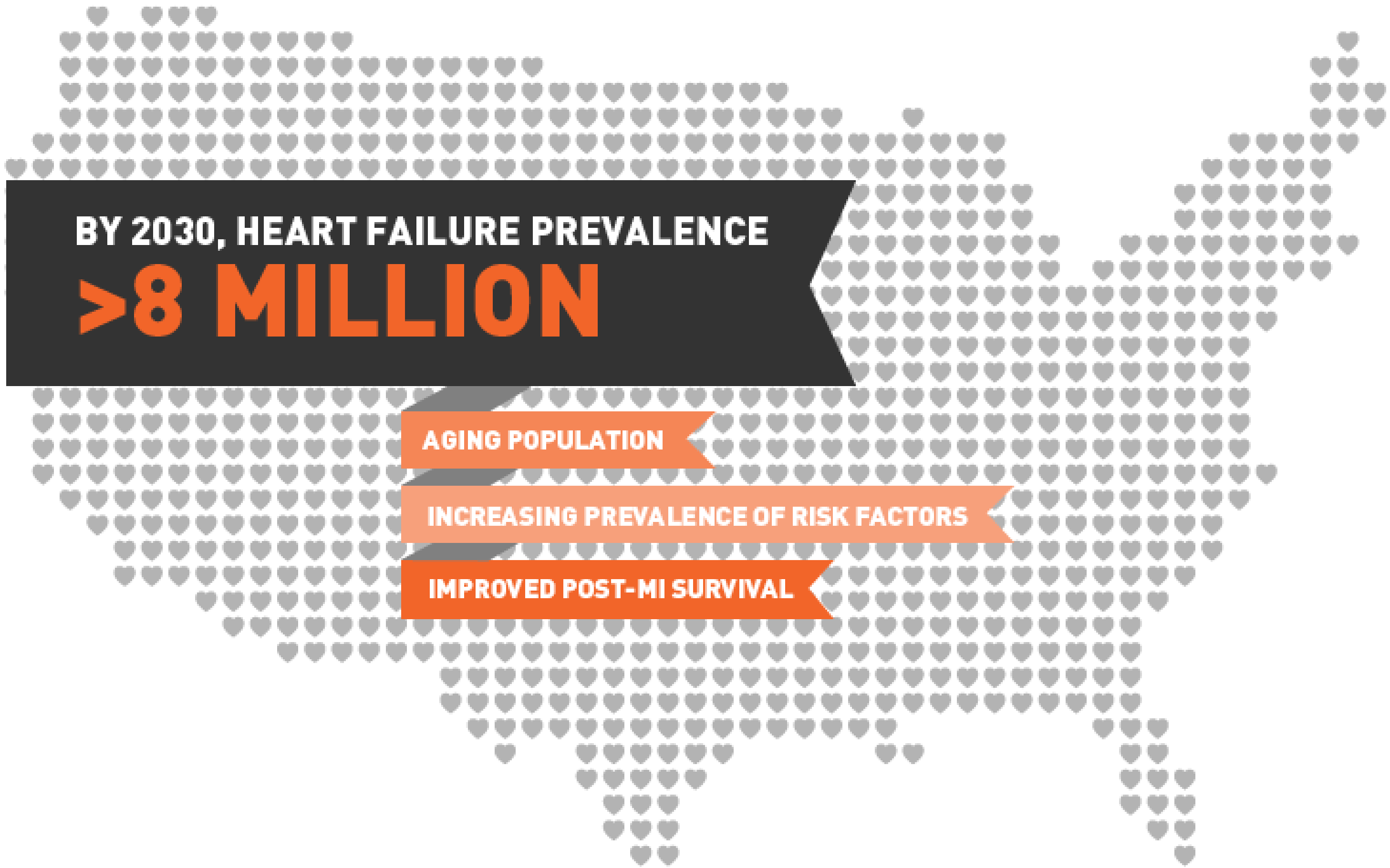
1. Identify stages of heart failure
2. Summarize the signs that a heart specialist is needed for the patient
3. Recognize the gap between heart transplants performed and patients with advanced HF
4. Identify the profiles for transplant patient selection

Agenda

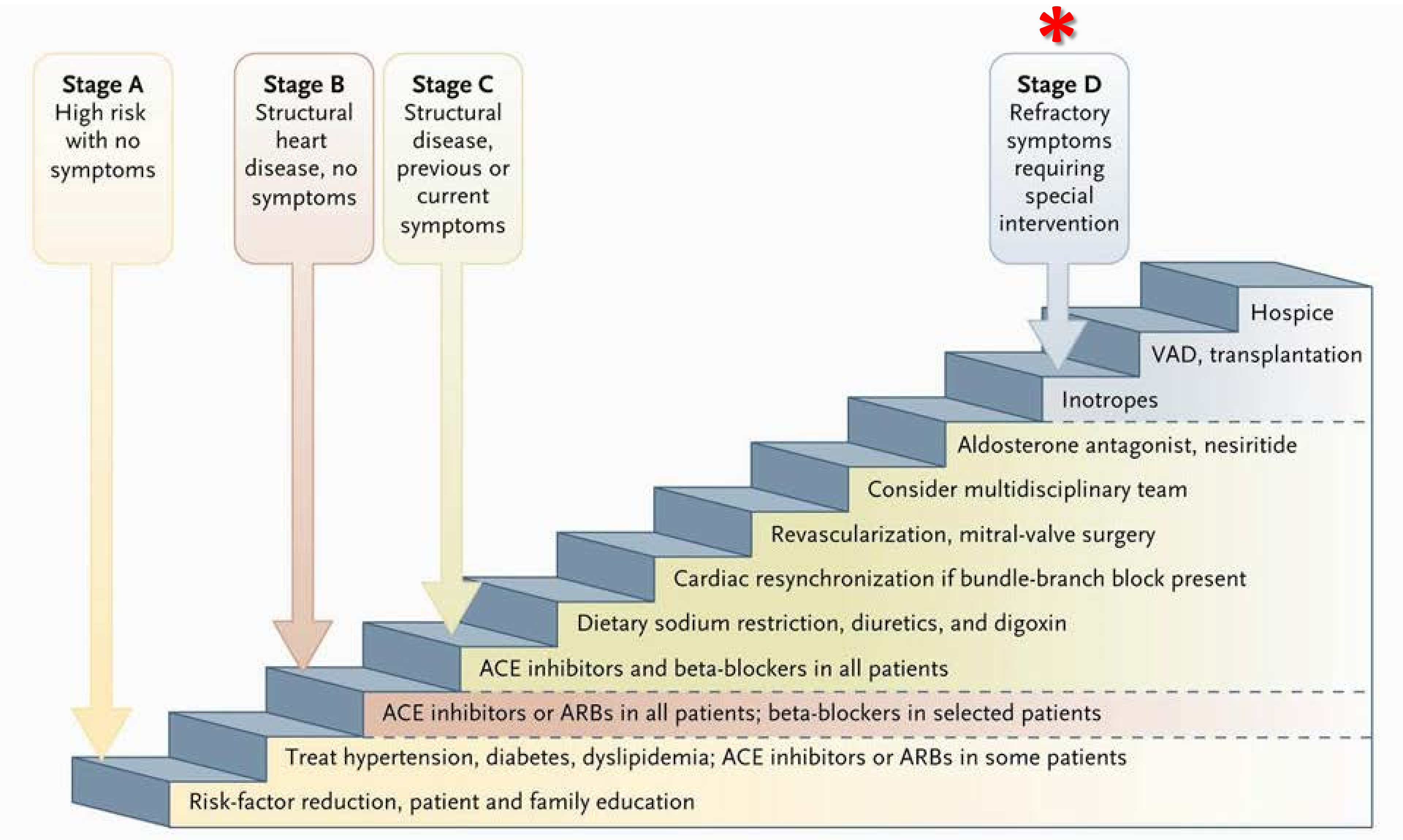
1. The Heart Failure Epidemic
2. The Heart Transplant Program
3. Patient Selection & Outcomes

The Heart Failure Epidemic

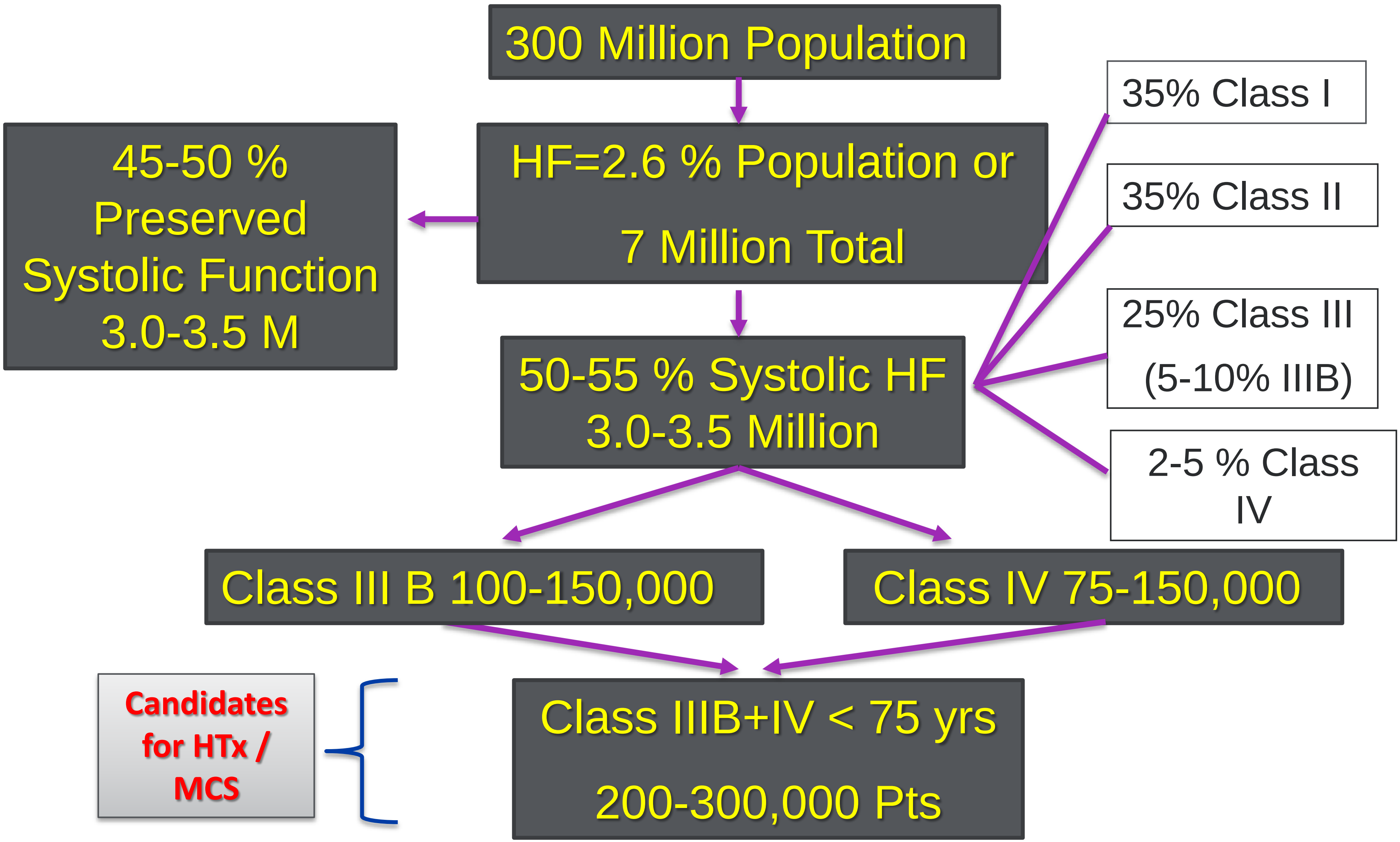
PREVALENCE OF HEART FAILURE IN THE US IS ESTIMATED AT 5.7 MILLION AND GROWING[1,2,7*]



Progression to "Advanced Heart Failure"

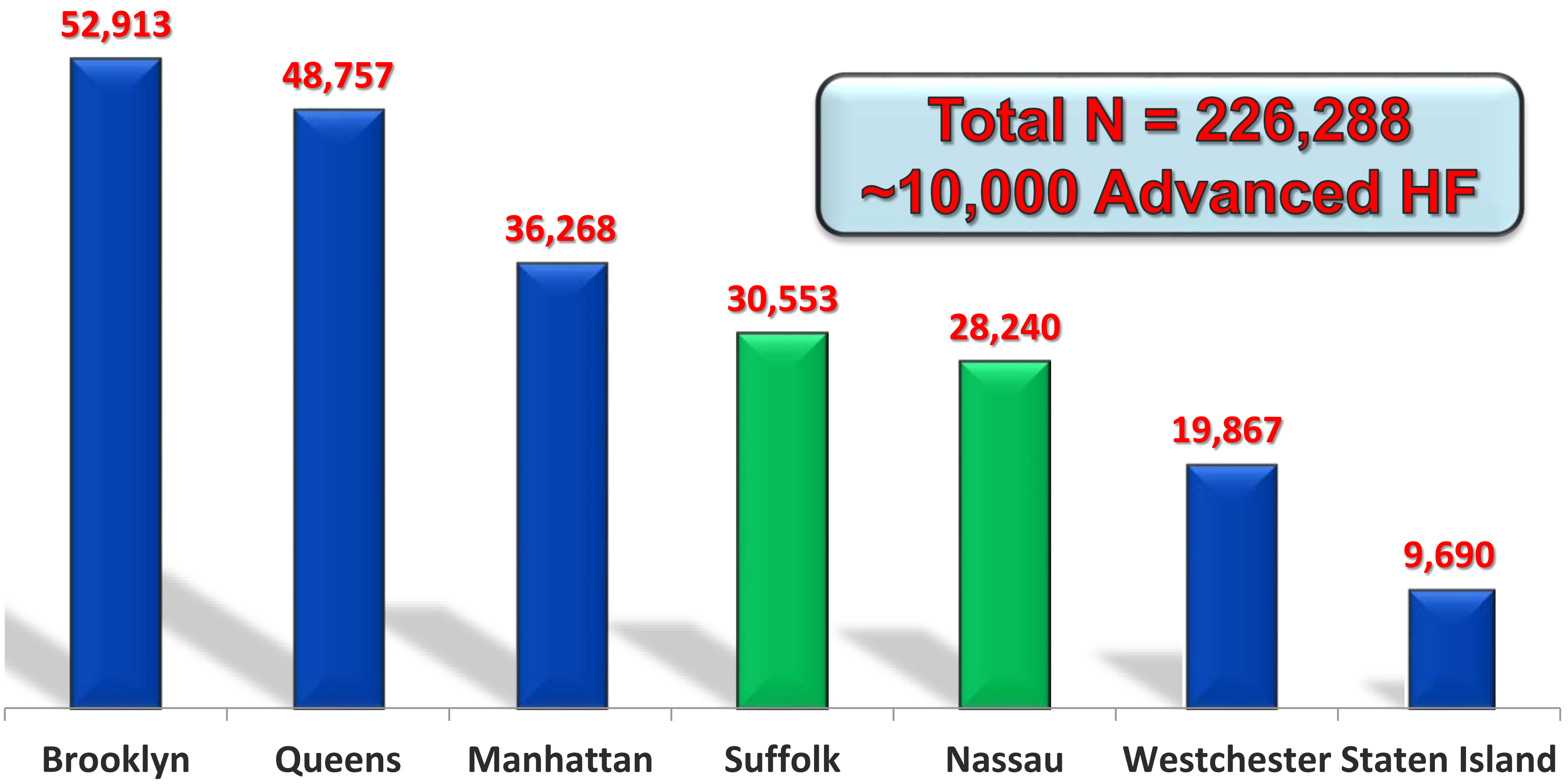


Current Estimate of Advanced HF



Who's At Risk for Heart Failure?

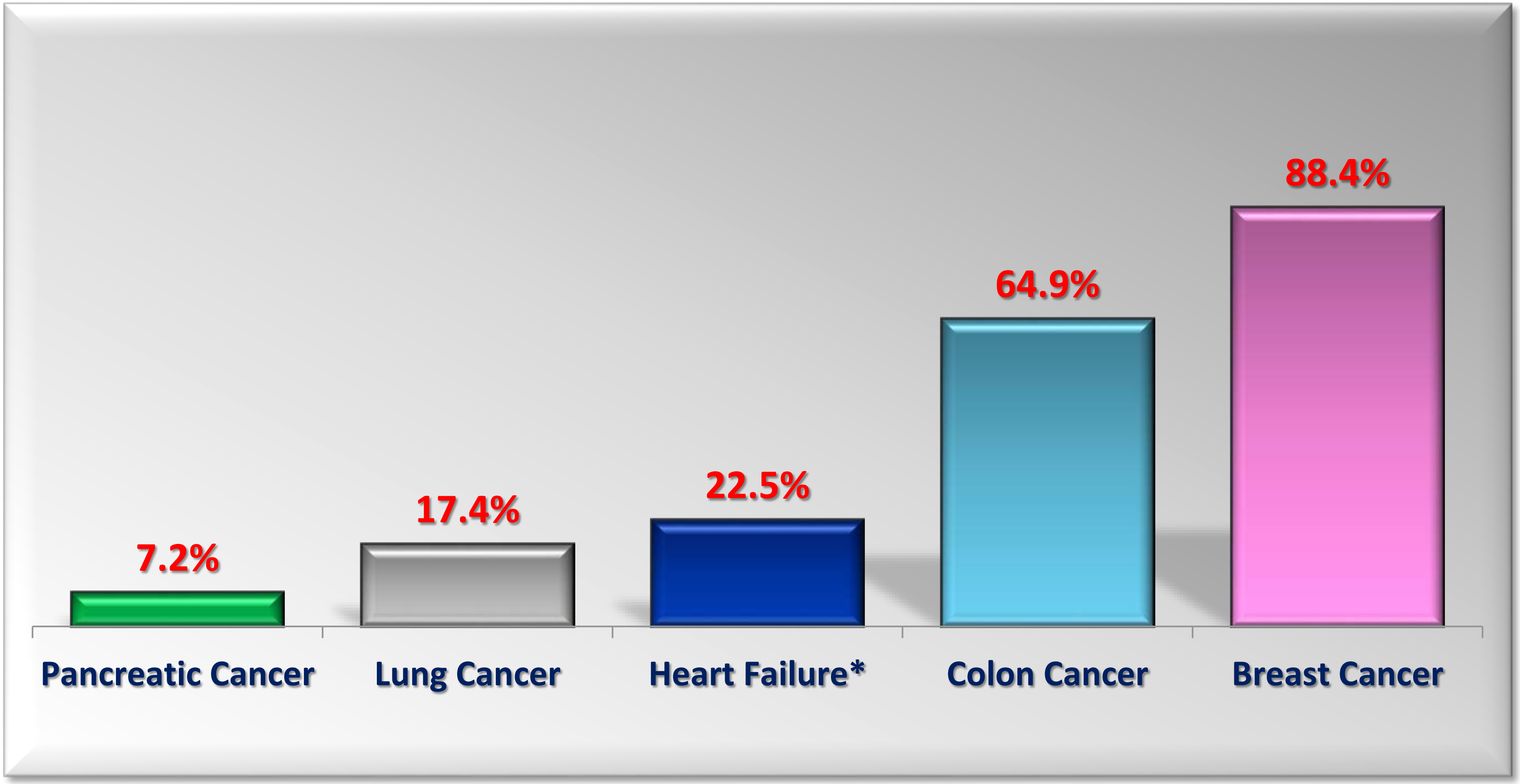
2.6% of the adult population is at risk



http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3033496/

5 Year Survival Following Hospitalization/Diagnosis

Heart failure has a 5 year survival rate that rivals deadly cancers



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Cancer Colon Alliance 2016v2 501C3
Arch Intern Med. 2007;167(5):490-496. doi:10.1001/archinte.167.5.490
NCI Division of Cancer Control and Population Sciences, 2012
http://www.cancer.org/cancer/breastcancer/detailedguide/breast-cancer-survival-by-stage

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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PUBLISHED BY ELSEVIER

VOL. 71, NO. 2, 2018
ISSN 0735-1097/$36.00
https://doi.org/10.1016/j.jacc.2017.11.025

EXPERT CONSENSUS DECISION PATHWAY

2017 ACC Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment: Answers to 10 Pivotal Issues About Heart Failure With Reduced Ejection Fraction

A Report of the American College of Cardiology Task Force on Expert Consensus Decision Pathways

For referral to a heart failure specialist, use the acronym I NEED HELP.

- **I:** Intravenous inotropes
- **N:** New York Heart Association (NYHA) class IIIB/IV or persistently elevated natriuretic peptides
- **E:** End-organ dysfunction
- **E:** EF $\leq$ 35%
- **D:** Defibrillator Shocks
- **H:** Hospitalizations > 1
- **E:** Edema despite escalating diuretics
- **L:** Low systolic BP $\leq$ 90, high heart rate
- **P:** Prognostic medication; progressive intolerance or down-titration of guideline-directed medical therapy (GDMT)

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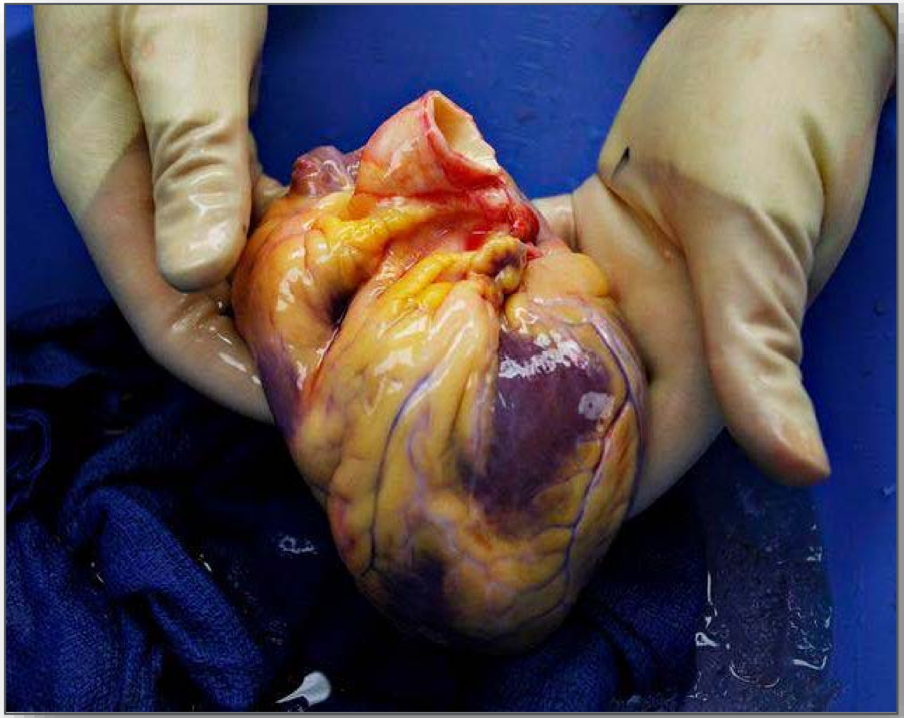
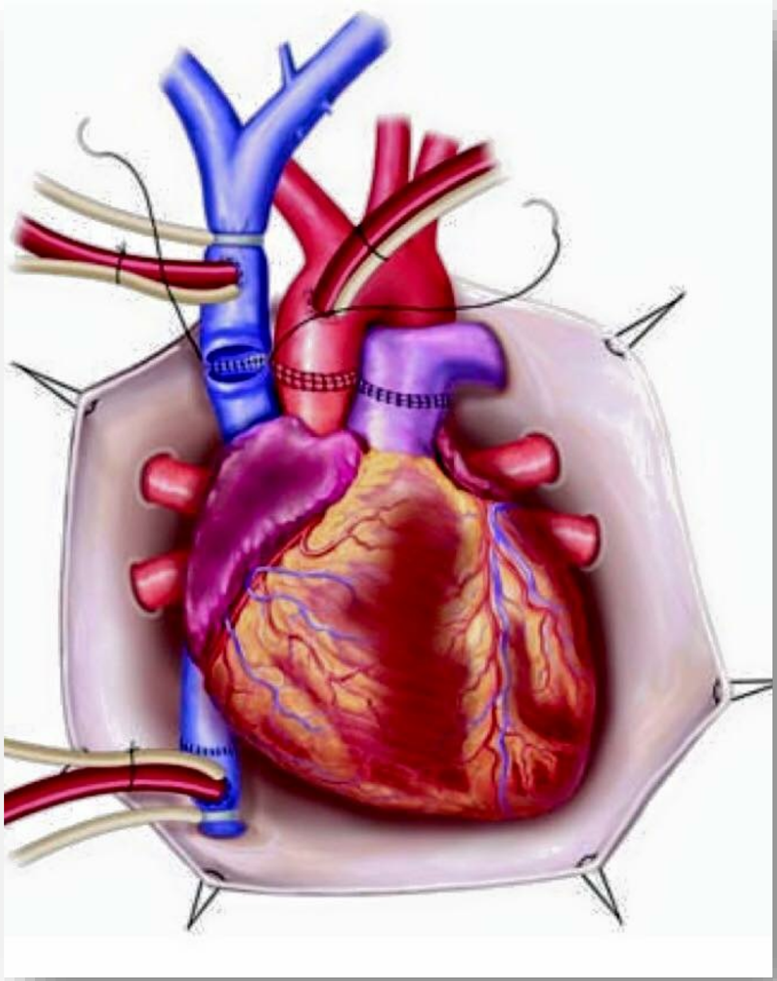
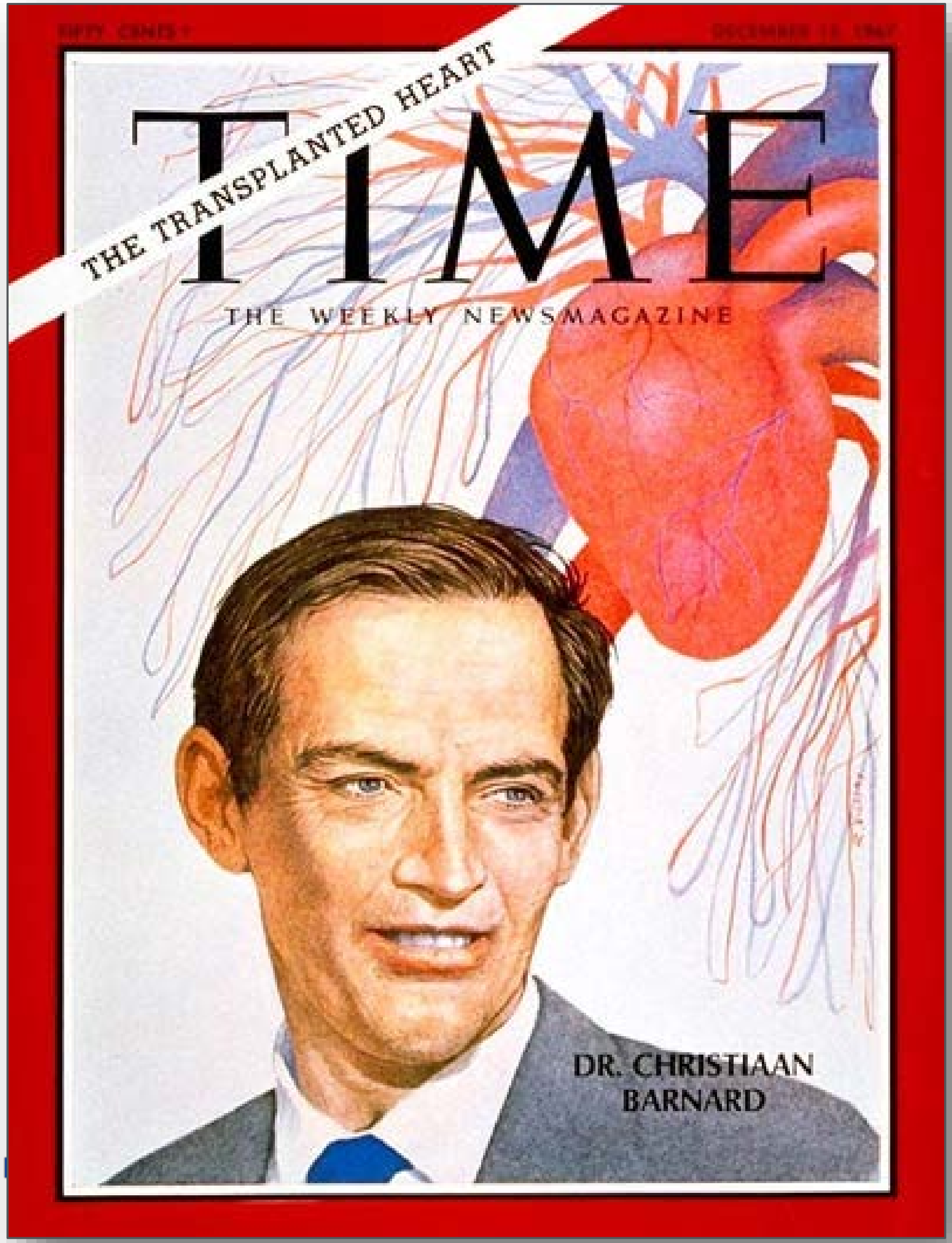
Heart Transplantation





1st Heart Transplant: December 3, 1967



Heart Transplant Program

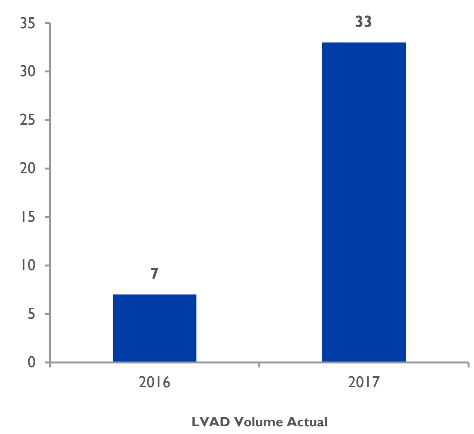
at the Sandra Atlas Bass Heart Hospital

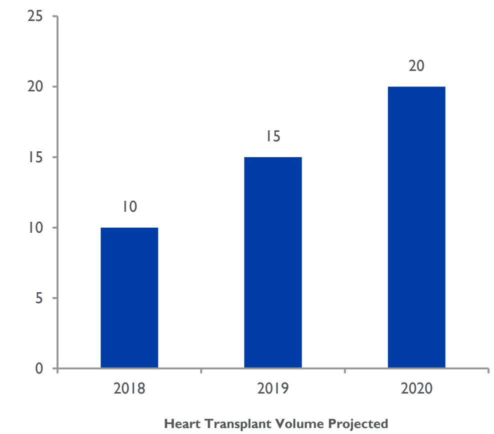
Heart Failure, LVAD & Transplant Program Highlights

- The Sandra Atlas Bass Heart Hospital is the only full service heart transplant program in Nassau, Suffolk, Queens, Brooklyn and Staten Island.
- Our physicians have performed a combined total of 500+ heart transplants at their previous institutions.
- Northwell Health and its affiliate hospitals collectively treat more heart failure patients than any health system in New York state.
- The Heart Hospital has the largest mechanical circulatory support program on Long Island with mortality and readmission outcomes better than its peers.

LVAD Success A Model

For Heart Transplant





Syed Hussain, MD, Lead Procurement Surgeon departs and then returns from SkyHealth Helicopter with **Scott Shukri, PA** and **Flight RN Jennifer Meyer** bringing a new heart to the first heart transplant recipient at the Sandra Atlas Bass Heart Hospital.

Sandra Atlas Bass Heart Hospital
Northwell Health

SkyHealth

Heart Transplant Program

at the Sandra Atlas Bass Heart Hospital (Integrated Programs of LIJ & NSUH)

Phase I: Build Heart Hospital

Phase II: Change Cardiac Care On Long Island in 11 Months

2015-2016
National recruitment brings all-star talent to North Shore University Hospital

James Taylor, MD
Co-Director, Heart Hospital

Harold Fernandez, MD
System Director, Surgical Heart Failure

Gerin Stevens, MD, PhD
System Director, Cardiomyopathy Services, Medical Director Heart Transplant Program

David Majure, MD, MPH
Medical Director, Mechanical Circulatory Support (LVAD)

Simon Maybaum, MD
VP, Cardiovascular Research
Heart Failure & Transplant Cardiologist

1997
North Shore University Hospital & **Long Island Jewish Medical Center** merge to form North Shore-LIJ Health System

2006
Combined Department of Cardiovascular and Thoracic Surgery

2011
Formation of System Wide Integrated Service Line

October 2014
Launch of SkyHealth

April 2015
Integrate Cardiac Services from Long Island Jewish Medical Center and bring them to North Shore University Hospital

April 2016
First LVAD performed

January 2017
Launch of the Sandra Atlas Bass Heart Hospital

March 2017
Applied to DOH For Heart Transplant

May 2017
Conditionally Approved for Heart Transplant by DOH

August 2017
Submitted Application for UNOS Membership & Approval
Submitted Application for NYCTC Approval

September/October 2017
Brian Lima, MD, Surgical Director of Heart Transplant Starts

Syed Hussain, MD, Lead Procurement Surgeon Starts

November 2017
Received Approval for UNOS & NYCTC Membership

Requested final DOH approval and DOH Survey

February 1st, 2018
Launch of Heart Transplant Program
DOH Survey and Final DOH Approval
First Listed Patient

February 18/19th, 2018
First Heart Transplant Performed On Long Island at NSUH

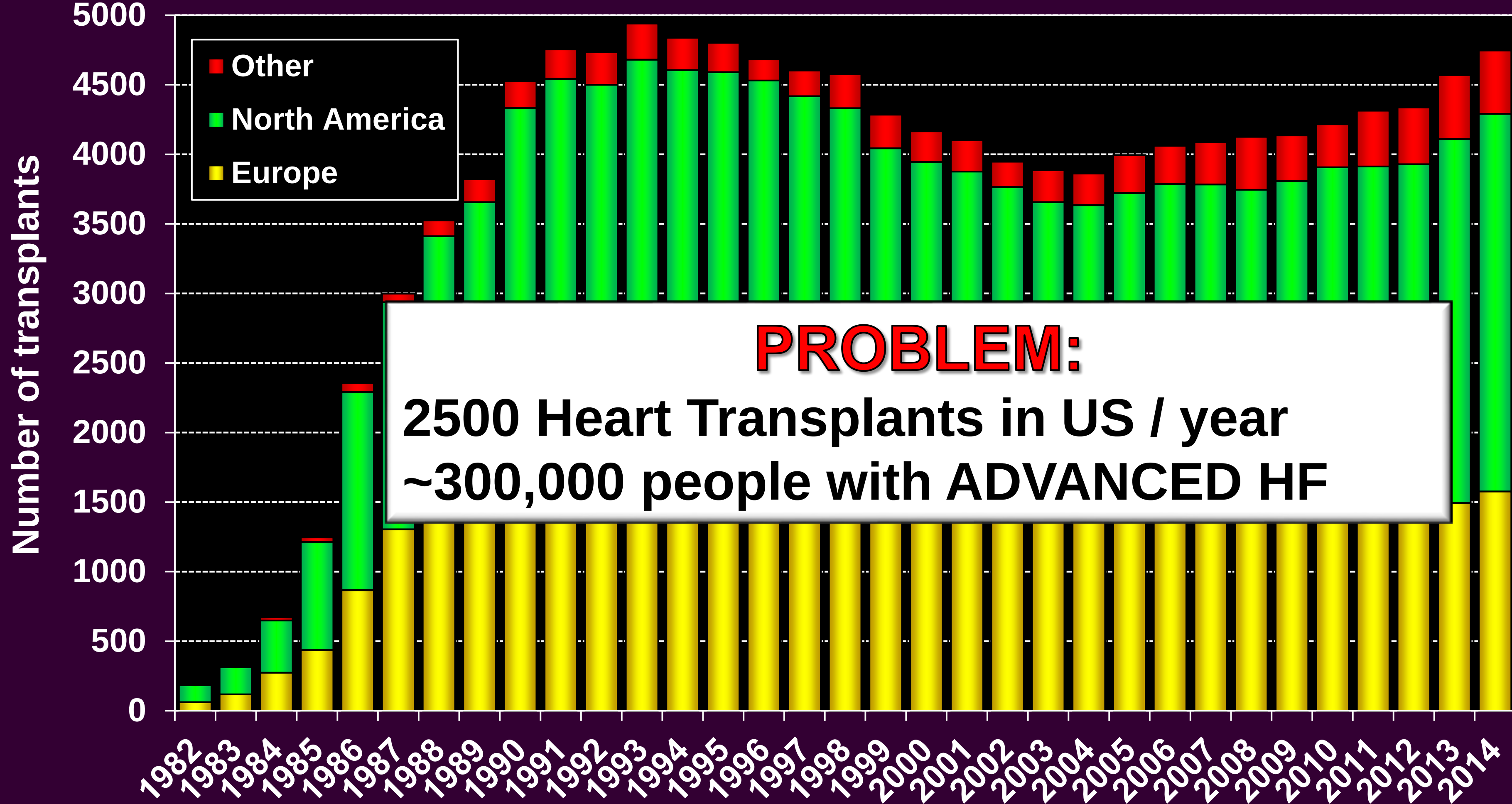
February 22/23nd, 2018
Second Transplant Performed

March 12th, 2018
Third Transplant Performed

March 18th, 2018
Fourth Transplant Performed

***5th Heart Transplant on April 1st, 2018**
***6th Heart Transplant on May 9th, 2018**
***7th Heart Transplant on June 29th, 2018**
***8th Heart Transplant on July 10th, 2018**

Adult and Pediatric Heart Transplants
Number of Transplants by Year and Location



PROBLEM:

2500 Heart Transplants in US / year

~300,000 people with ADVANCED HF

Comparison of Clinical Characteristics, Complications, and Outcomes in Recipients Having Heart Transplants <65 Years of Age Versus ≥65 Years of Age

Aayla Jamil, MBBS, MPH[a], Huanying Qin, MS[a], Joost Felius, PhD[a], Giovanna Saracino, MS[a], Aldo E. Rafael, MD[a,b], Juan C. MacHannaford, MD[a,b], Gonzalo V. Gonzalez-Stawinski, MD[a,b], and Brian Lima, MD[a,b,*]

(Am J Cardiol 2017;120:2207–2212)

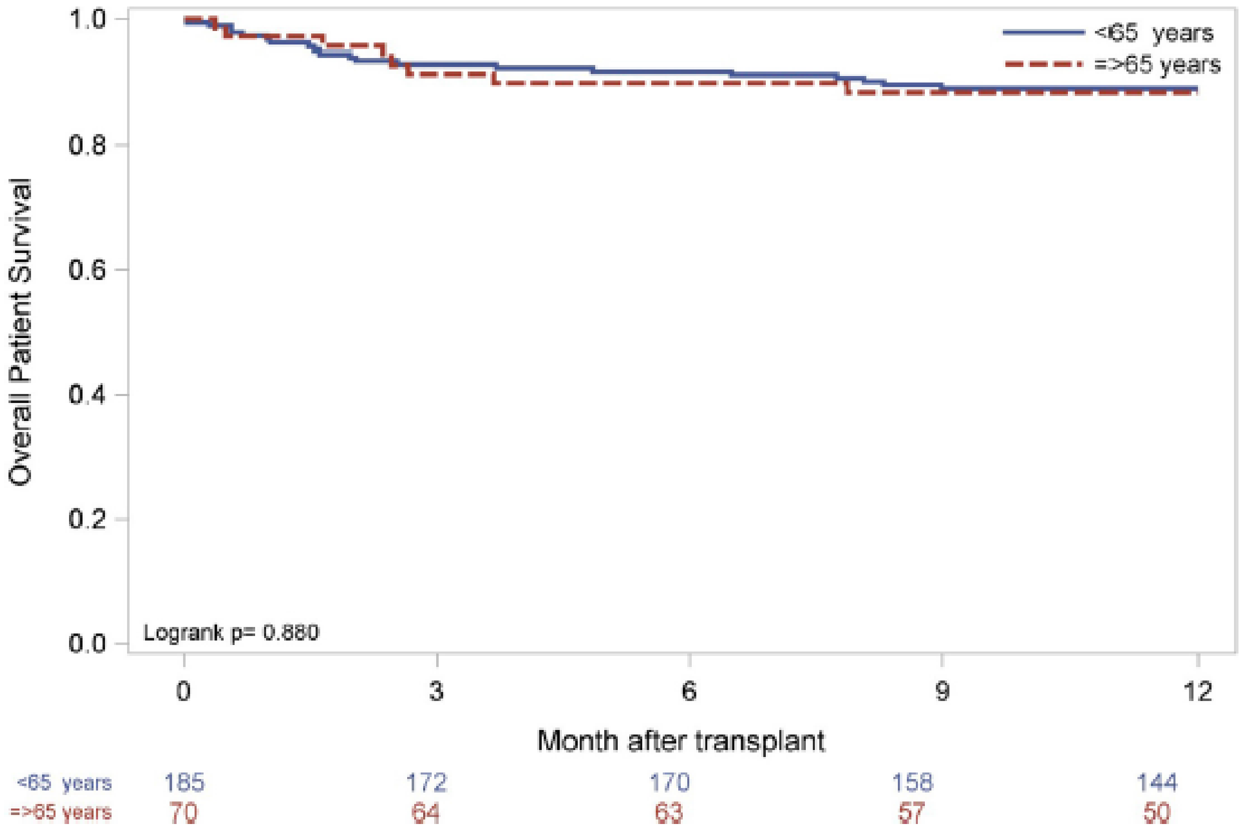
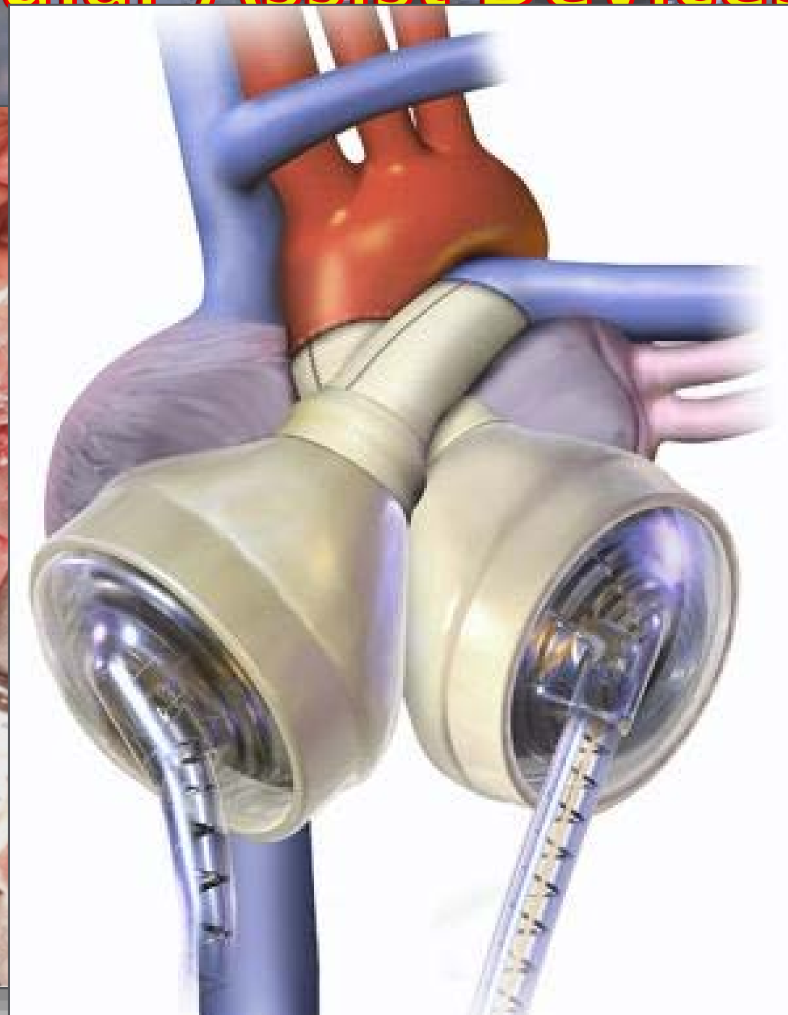
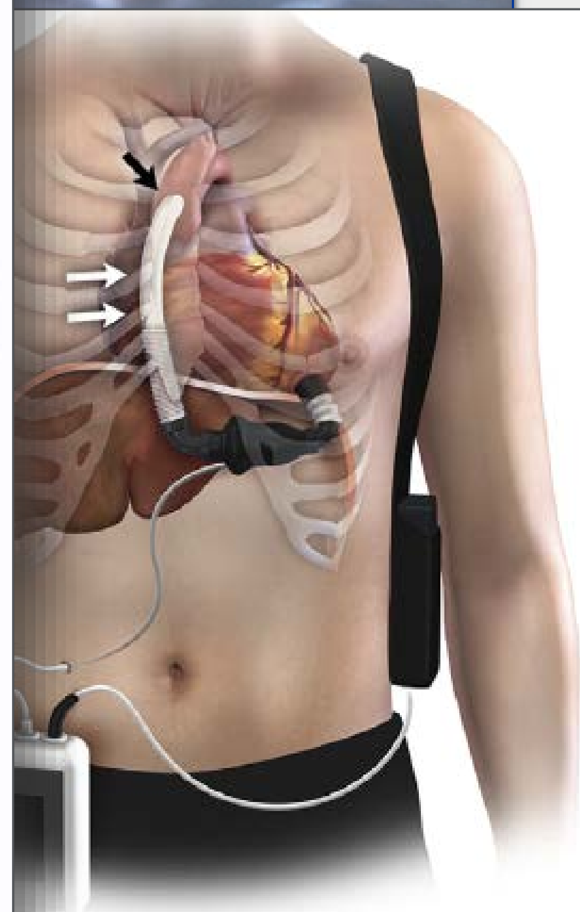


Figure 1. One-year survival by recipient age group using Kaplan-Meier analysis. Patient survival was not different between the 2 groups (p = 0.88).

Rise of the Machines: Left Ventricular Assist Devices (LVADs)





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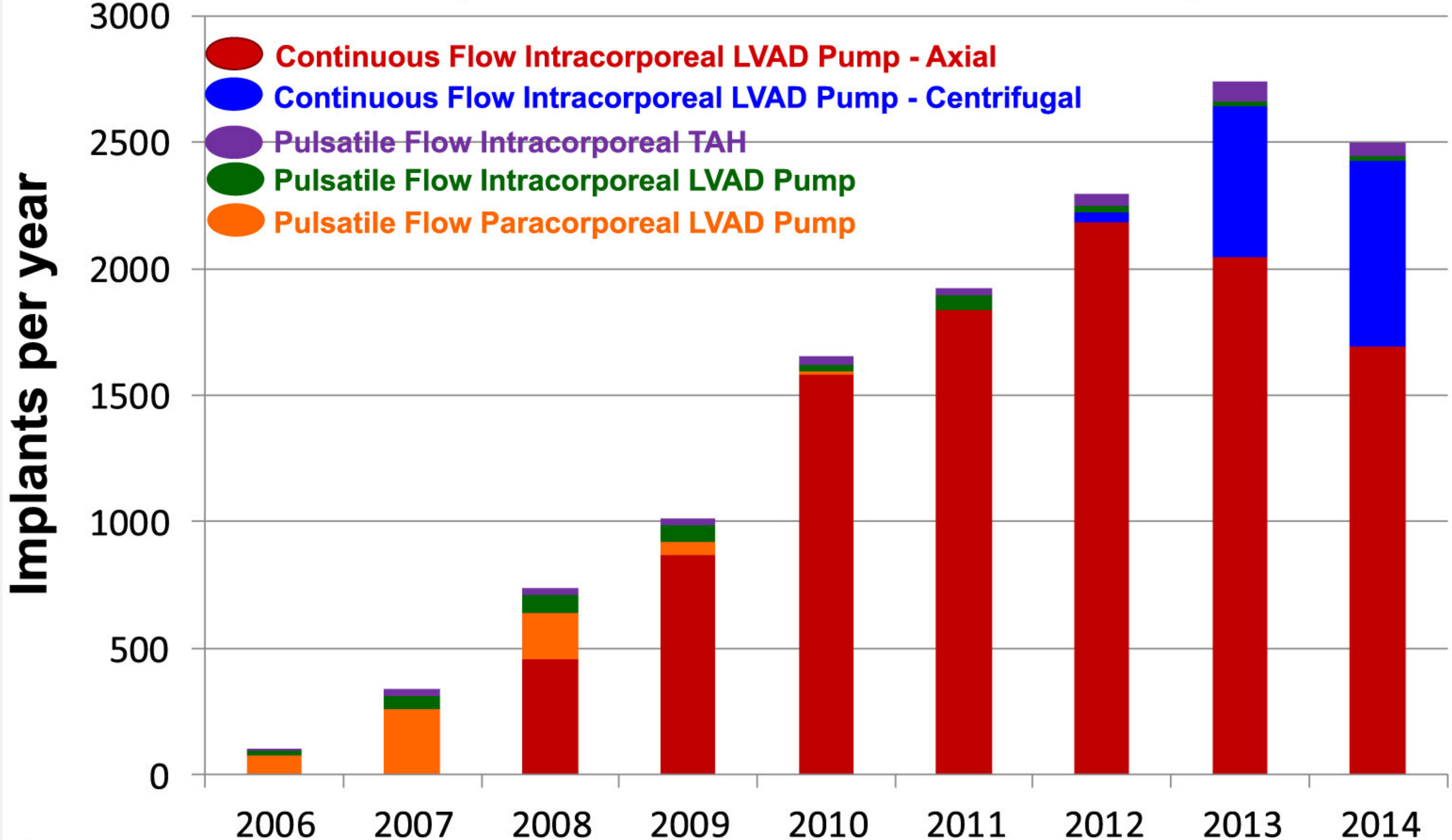
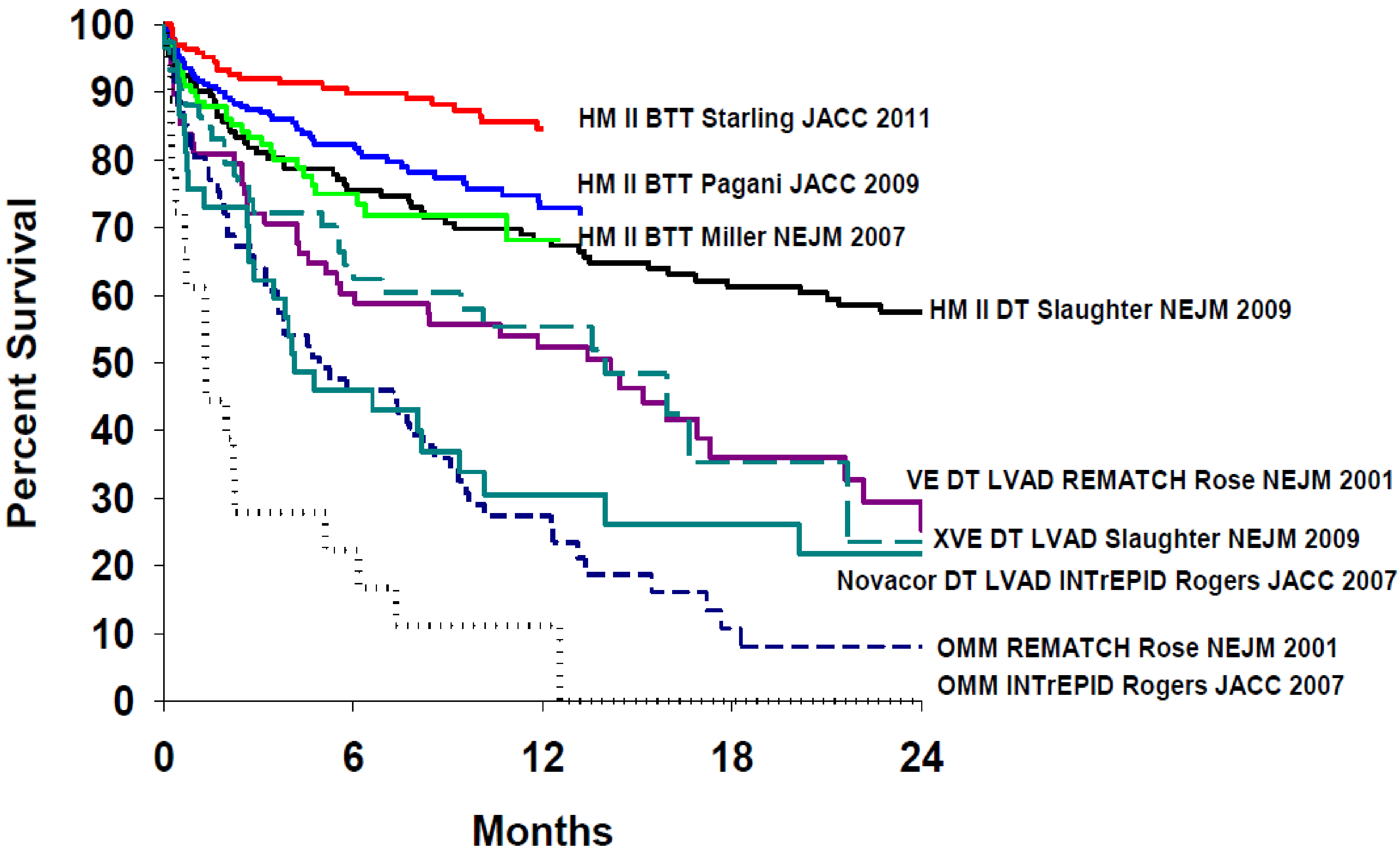
Intermacs

Implants: June 2006 – December 2014, n=13286

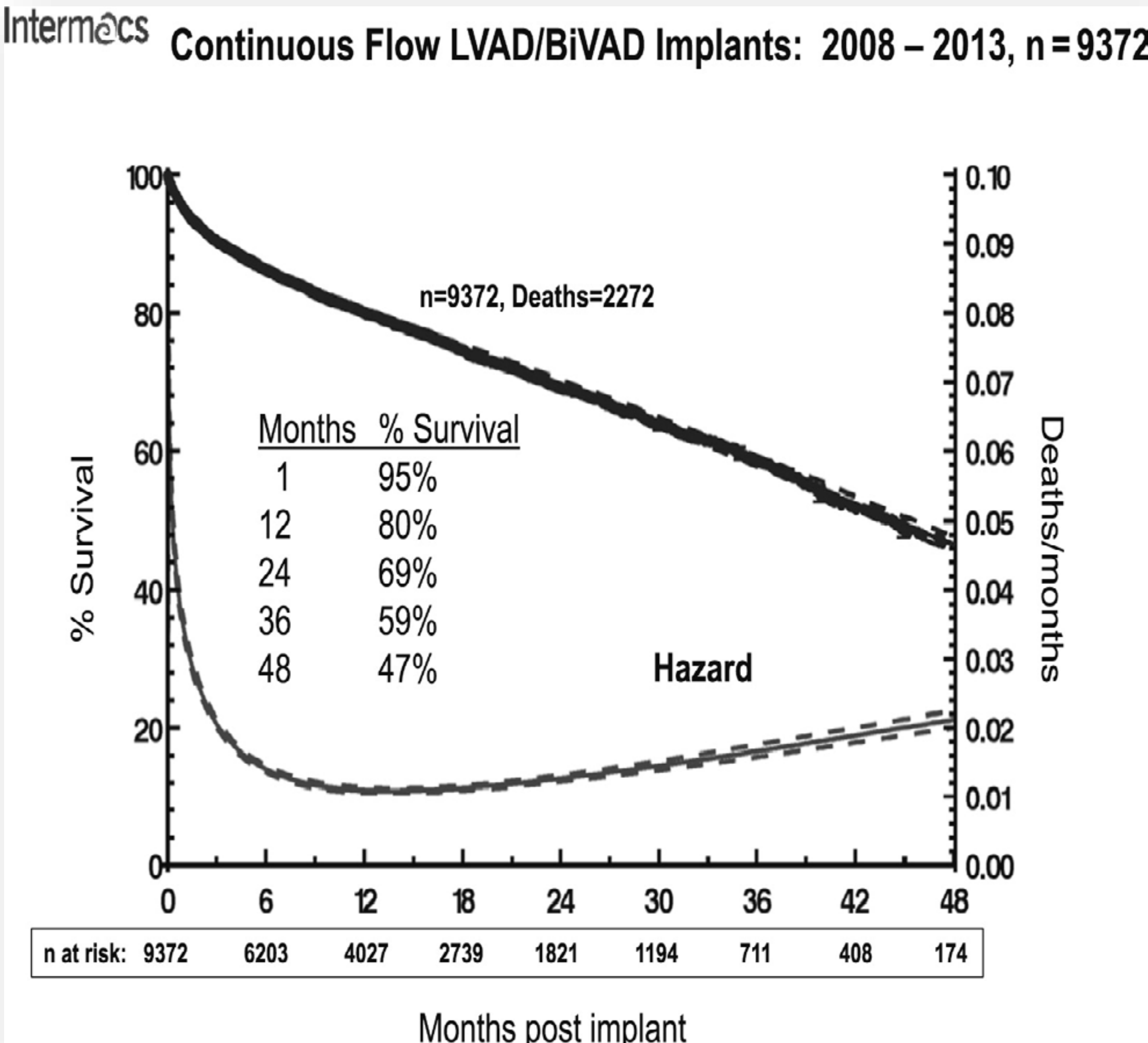


	2006	2007	2008	2009	2010	2011	2012	2013	2014
CF Intra Pump/Axial	0	0	459	867	1580	1838	2183	2044	1695
CF Intra Pump/Centrif	0	0	0	0	0	0	38	598	728
PF Intra TAH	1	22	30	24	29	26	41	74	54
PF Intra Pump	76	260	180	54	13	2	0	1	0
PF Para Pump	18	55	72	65	29	54	31	21	24

Improving Survival for CF LVAD Patients



Growing Experience, Improving Survival with Implantable VAD Therapy



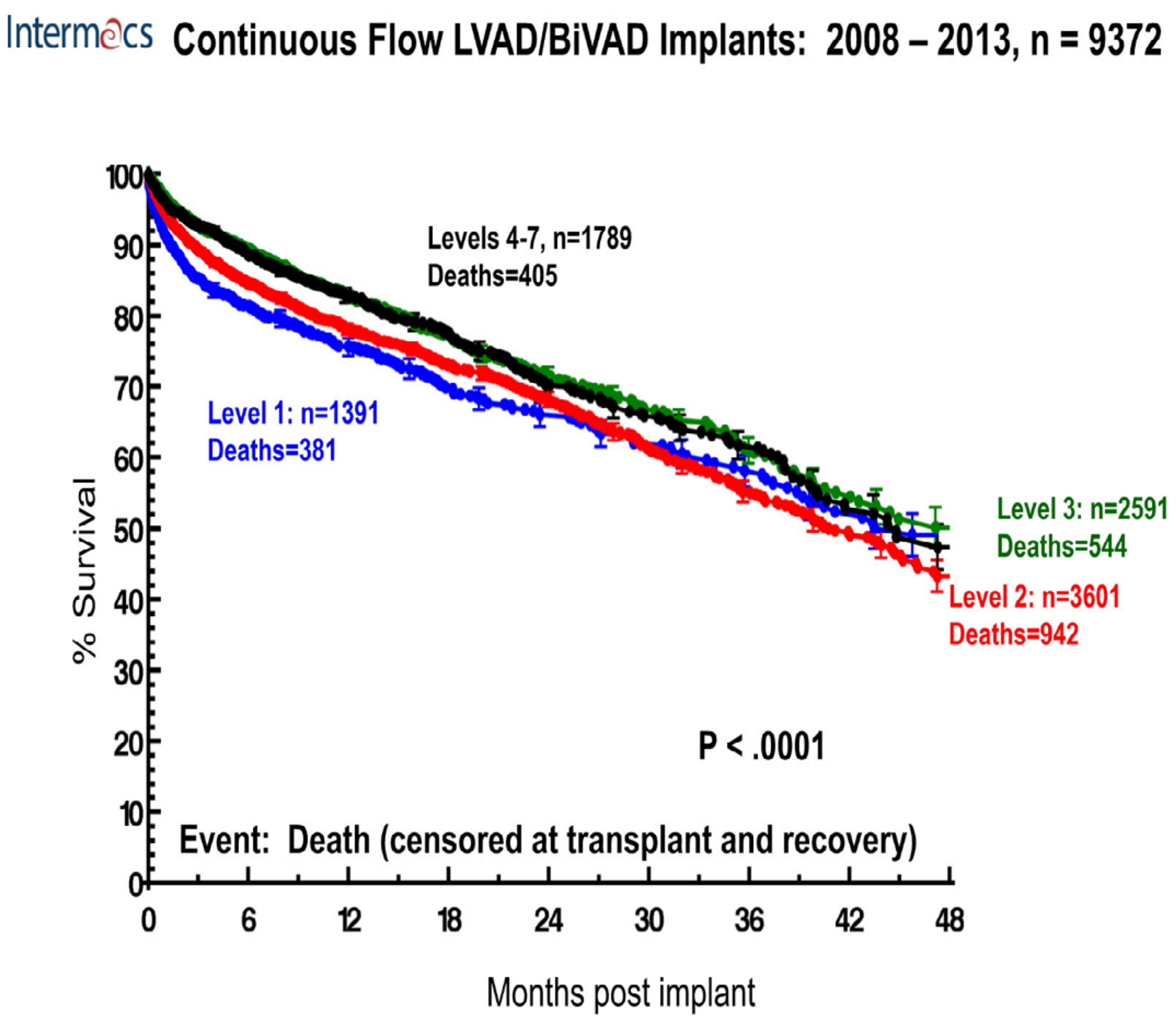
Also Improved:
- QOL
- Functional capacity

Patient Selection is Key

PROFILE-LEVEL	PRIMARY LVADs 12-09	*Official shorthand (after Lynne Stevenson)*	NYHA CLASS	*Modifier option*
INTERMACS LEVEL 1	633	"Crash and burn"	IV	
INTERMACS LEVEL 2	841	"Sliding fast" on ino	IV	
INTERMACS LEVEL 3	284	Stable but ino-dependent can be hosp or home	IV ish	*CURRENT VAD INDICATIONS*
INTERMACS LEVEL 4	185	Resting symptoms on oral therapy at home	ambul IV	+FF frequent flyer A for arrhythmia
INTERMACS LEVEL 5		"Housebound", comfortable at rest, symptoms with minimum activity ADL	ambul IV	+FF A
INTERMACS LEVEL 6		"Walking wounded"-ADL possible but meaningful activity limited	IIIB	+FF A
INTERMACS LEVEL 7	(5, 6, 7 = 119)	Advanced Class III	III	A only

INTERMACS, Interagency Registry for Mechanical Circulatory Support

Survival Inversely Related to INTERMACS Score



Novel Cardiac Coordinate Modeling System for Three-Dimensional Quantification of Inflow Cannula Malposition of HeartMate II LVADs

Brian Lima,*† Onur Dur,‡ Joyce Chuang,‡ Themistokles Chamogeorgakis,*† David J. Farrar,‡ Kartik S. Sundareswaran,‡ Joost Felius,† Susan M. Joseph,†§ Shelley A. Hall,†§ and Gonzalo V. Gonzalez-Stawinski*†

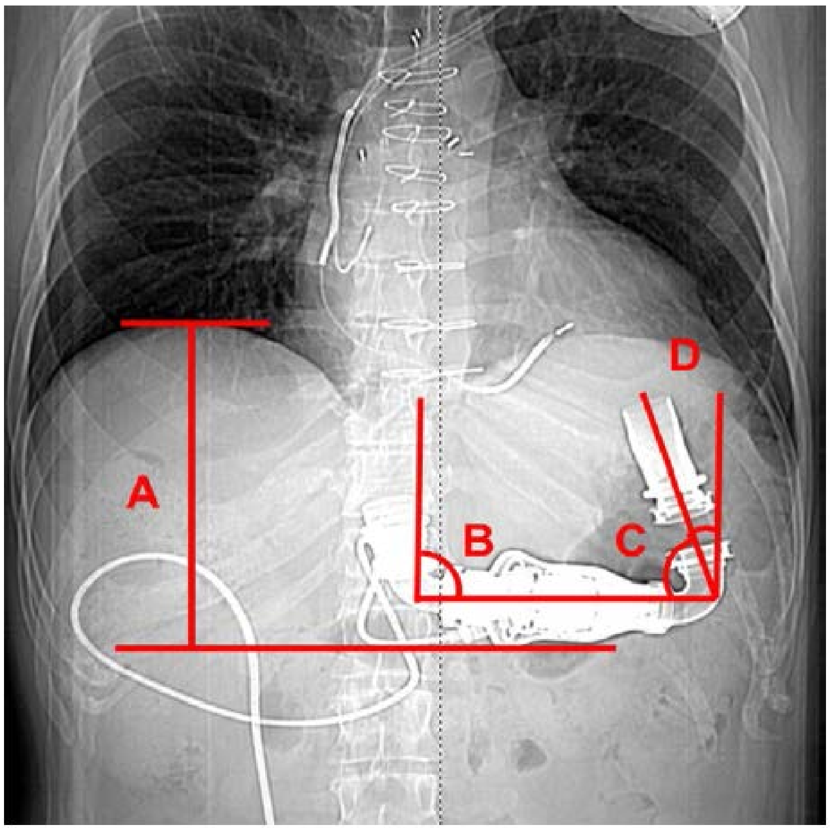
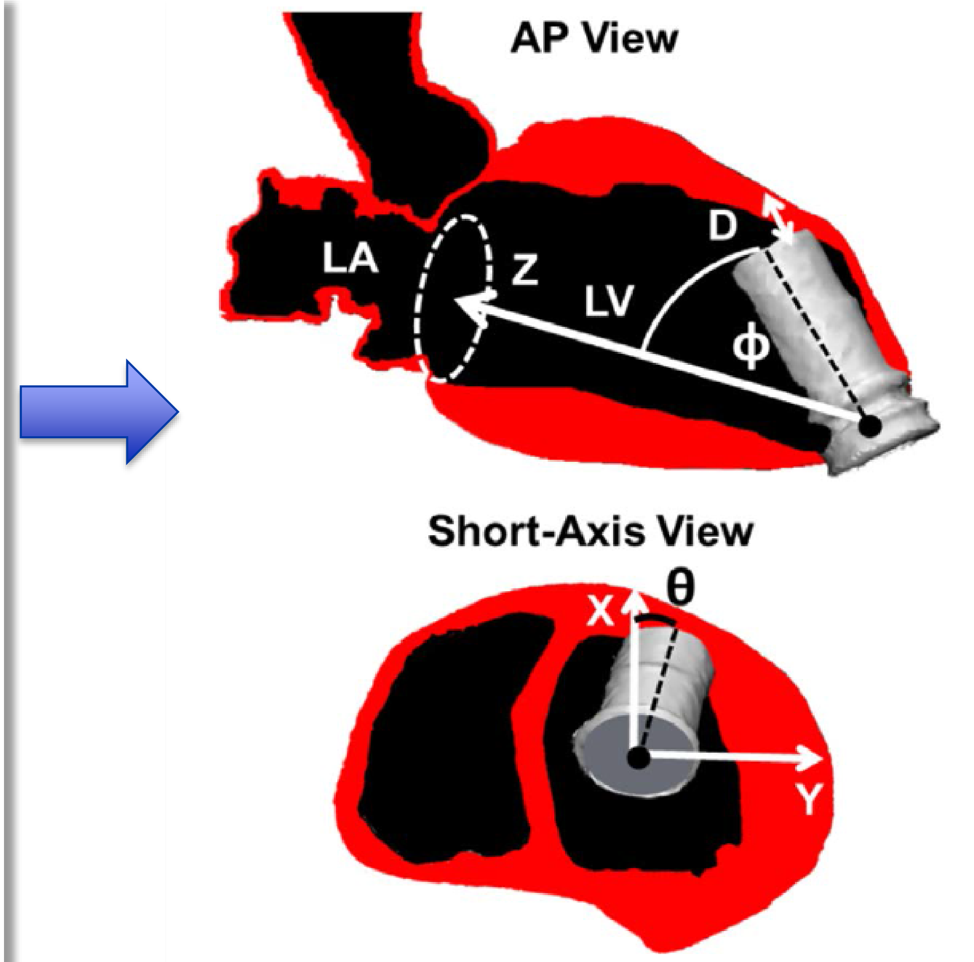


Figure 1. Coronal scout image showing 2D parameters: pump pocket depth (**A**), angle between pump and spine (**B**), angle between inflow cannula (IC) and pump body (**C**), and angle between IC and vertical (**D**). 2D, two dimensional.



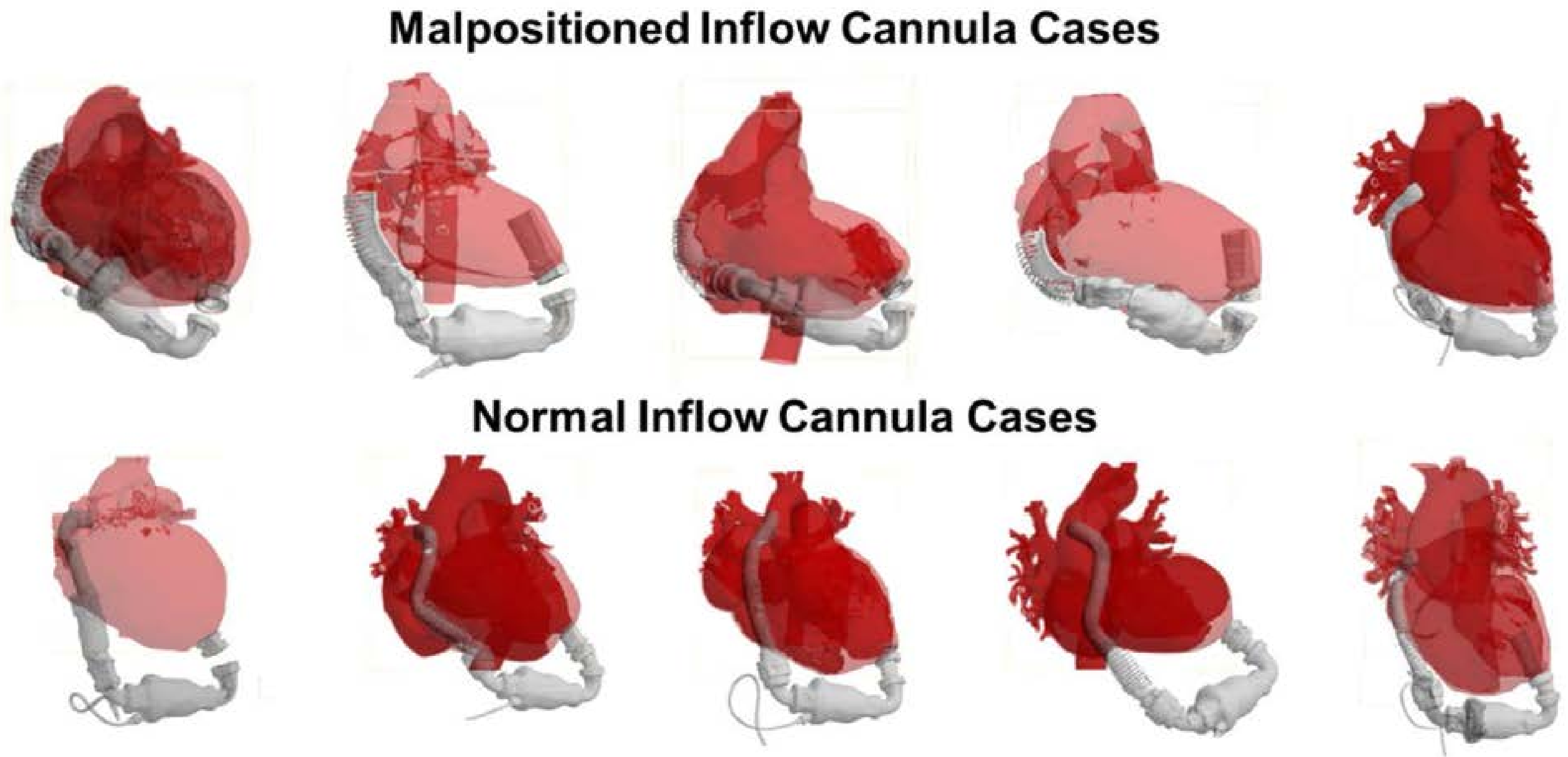


Figure 4. Results of 3D model creation of the five malpositioned (top row) and five normal (bottom row) inflow cannula cases. 3D, three dimensional.

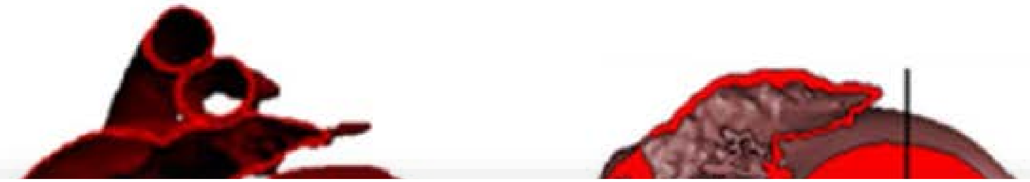


Table 3. Comparison of 3D Parameters of LVAD Inflow Cannula Alignment Between Normal and Malpositioned Cases

Parameter	Normal N = 5	Malpositioned N = 5	*p* Value
φ (°)	38 ± 8	47 ± 13	0.421
Θ (°)	−26 ± 32	−9 ± 17	0.327
D (mm)	48 ± 9	18 ± 21	0.017
Φ ≥ 40° and D ≤ 40 mm	4 (80%)	0	0.023
LV volume (ml)	324 ± 45	290 ± 155	0.690
LV length (mm)	107 ± 5	95 ± 8	0.031

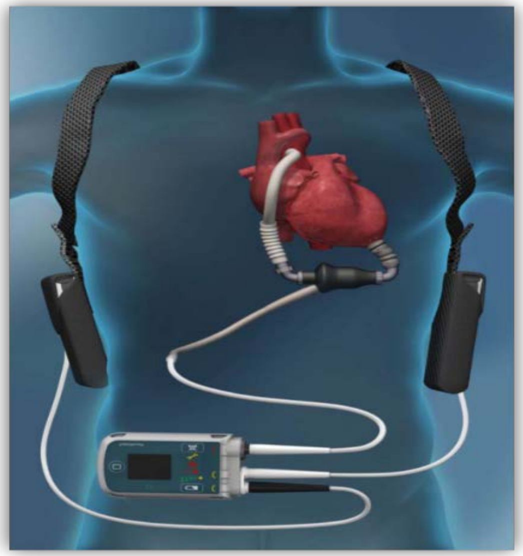
3D, three dimensional; LV, left ventricular; LVAD, left ventricular assist devices.

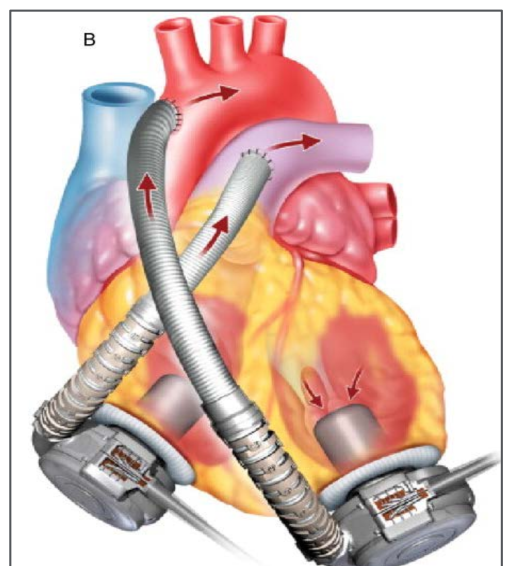
Figure 5. Example of 3D model from a normal case (**A**) and a malpositioned case (**B**). 3D, three dimensional.

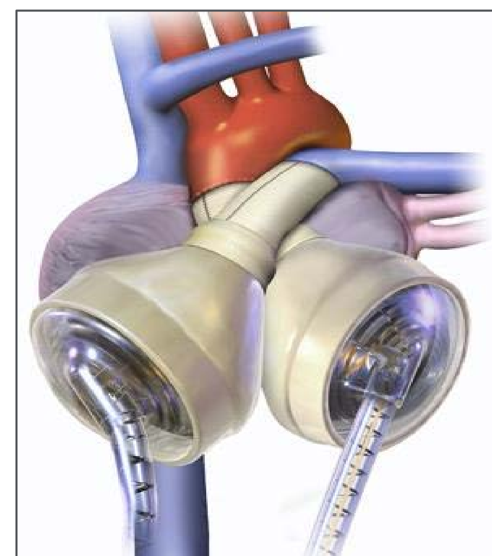
A Growing Arsenal of Chronic MCS Options

Implantable VAD:

- Ideal in optimized patient (≥INTERMACS 2)
- BTT / DT
- Improving adverse event profile
  - *Pump thrombosis
- ?TAH vs BiVADs for biventricular failure
  - TAH only as BTT
  - 80% to HTx







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HeartMate III*

Designed to be Hematologically-Compatible

Leverages Fully Magnetically Levitated Technology

Features

- Fully Magnetically Levitated
    - Large pump gaps designed to reduce blood trauma
    - Artificial pulse
- Textured blood contacting surfaces
- Wide range of operation
    - Full support (2 – 10 L/min)
- Advanced Design for Surgical Ease
    - Engineered apical attachment
    - Modular Driveline
- Designed for an Active Lifestyle
    - Pocket Controller

Program Status

- CE Mark clinical trials has completed enrollment

 *In development. Not approved for clinical use.

THORATEC CORPORATION for Life

B169-0313

Manhasset News

Northwell becomes first on L.I. to implant device for end-stage heart failure

By **Amelia Camurati** - December 12, 2017 370 0

Share on Facebook Tweet on Twitter

Dr. Harold Fernandez of the Sandra Atlas Bass Heart Hospital shows the advanced heart pump with cardiac team members, from left, nurse Kathleen Davidson, Dr. David Majure and Dr. Brian Lima. (Photo courtesy of Northwell Health)

The NEW ENGLAND JOURNAL of MEDICINE

2017

ORIGINAL ARTICLE

A Fully Magnetically Levitated Circulatory Pump for Advanced Heart Failure

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

The NEW ENGLAND JOURNAL of MEDICINE

2018

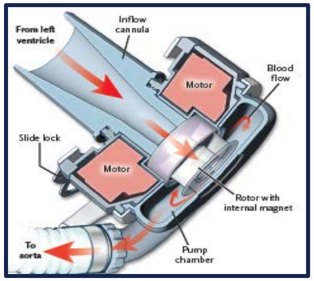
ORIGINAL ARTICLE

Two-Year Outcomes with a Magnetically Levitated Cardiac Pump in Heart Failure

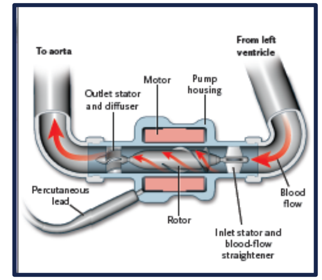
M.R. Mehra, D.J. Goldstein, N. Uriel, J.C. Cleveland, Jr., M. Yuzefpolskaya, C. Salerno, M.N. Walsh, C.A. Milano, C.B. Patel, G.A. Ewald, A. Itoh, D. Dean, A. Krishnamoorthy, W.G. Cotts, A.J. Tatooles, U.P. Jorde, B.A. Bruckner, J.D. Estep, V. Jeevanandam, G. Sayer, D. Horstmanshof, J.W. Long, S. Gulati, E.R. Skipper, J.B. O'Connell, G. Heatley, P. Sood, and Y. Naka, for the MOMENTUM 3 Investigators*

Study Design

HeartMate 3



Patient meets MOMENTUM 3 eligibility criteria?



HeartMate II

Randomization 1:1

Short Term (ST) Cohort
N=294
6-month follow-up

Long Term (LT) Cohort
N=366
24-month follow-up

Full Study Cohort
N=1028
24-month follow-up for powered secondary endpoint

Intent-to-Treat (ITT) Population
N=294

HeartMate 3
N=152

HeartMate II
N=142

Treatment failures
(not treated with study device)
N=1

Death: 1

Treatment failures
(not treated with study device)
N=4

No LVAD implant: 1
Withdrawal of consent: 1
Transplant: 1
Implanted with non-study LVAD: 1

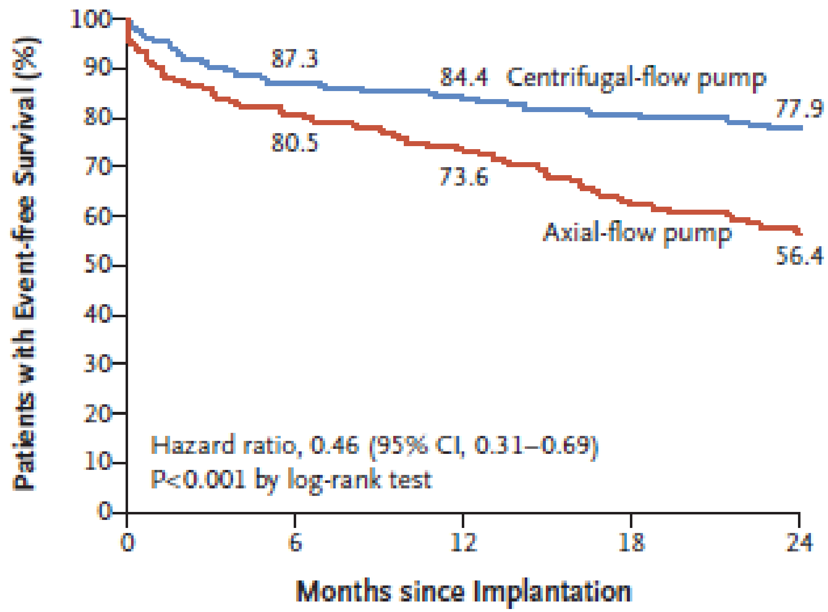
As Treated Population
N=289

Implanted with HeartMate 3
N=151

Implanted with HeartMate II
N=138

Caution – HeartMate 3 LVAS is an investigational device. Limited by Federal (United States) law to investigational use

PEP: Survival Free of Disabling Stroke or Reoperation to Replace/Remove Pump



No. at Risk					
Centrifugal-flow pump	190	161	141	122	111
Axial-flow pump	176	134	114	90	75

Figure 1. Kaplan–Meier Estimates of the Primary End Point in the Intention-to-Treat Population.

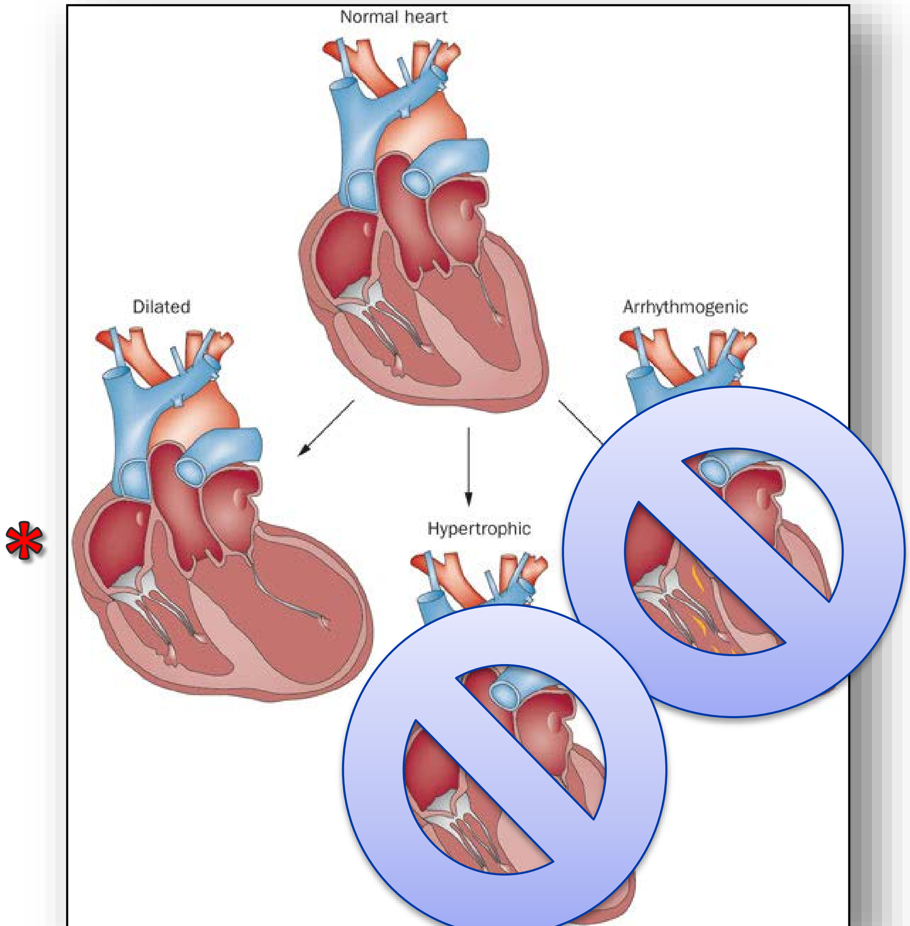
The intention-to-treat population included all the patients who underwent randomization. The primary end point was a composite of survival free of disabling stroke (with disabling stroke indicated by a modified Rankin score of >3; scores range from 0 to 6, with higher scores indicating more severe disability) or survival free of reoperation to replace or remove a malfunctioning device at 24 months after implantation. Rates of the primary end point at 6, 12, and 24 months are shown.

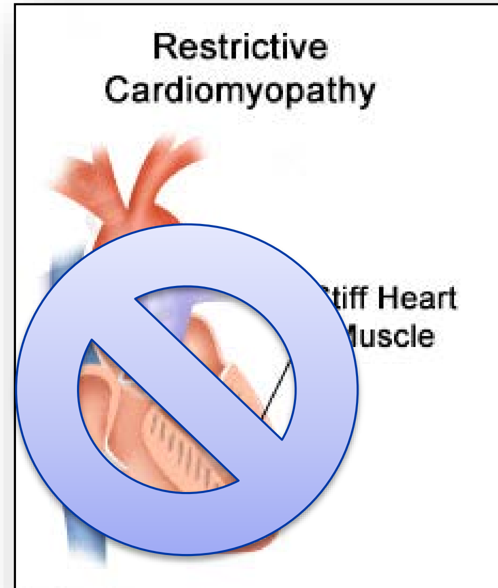
Table 3. Major Adverse Events in the Per-Protocol Population.*

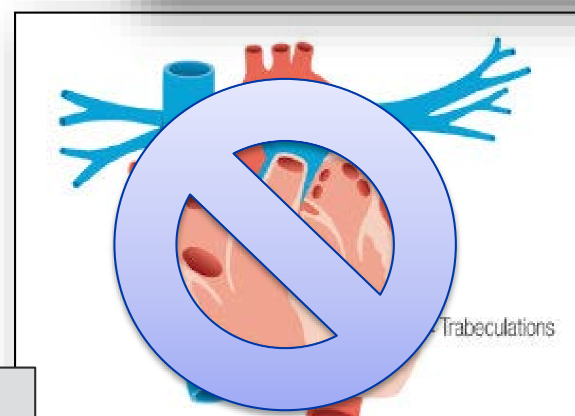
Event	Centrifugal-Flow Pump Group (N = 189)		Axial-Flow Pump Group (N = 172)		Hazard Ratio (95% CI)	P Value†
	no. of patients with event (%)	*no. of events*	*no. of patients with event (%)*	*no. of events*		
Suspected or confirmed pump thrombosis	2 (1.1)	2	27 (15.7)	33	0.06 (0.01–0.26)	<0.001
Pump thrombosis resulting in reoperation or removal of device	0	0	21 (12.2)	25	NA	<0.001
Stroke						
Any stroke	19 (10.1)	22	33 (19.2)	43	0.47 (0.27–0.84)	0.02
Hemorrhagic stroke	8 (4.2)	8	16 (9.3)	17	0.42 (0.18–0.98)	0.06
Ischemic stroke	12 (6.3)	14	23 (13.4)	26	0.44 (0.22–0.88)	0.03
Disabling stroke	13 (6.9)	15	9 (5.2)	11	1.25 (0.54–2.93)	0.66
Other neurologic event‡	22 (11.6)	25	15 (8.7)	16	1.27 (0.66–2.45)	0.39
Bleeding						
Any bleeding	81 (42.9)	187	90 (52.3)	206	0.71 (0.53–0.96)	0.07
Bleeding that led to surgery	23 (12.2)	29	30 (17.4)	34	0.66 (0.38–1.13)	0.18
Gastrointestinal bleeding	51 (27.0)	107	47 (27.3)	100	0.92 (0.62–1.37)	1.00
Sepsis	26 (13.8)	37	24 (14.0)	28	0.95 (0.55–1.66)	1.00
LVAS drive-line infection	45 (23.8)	68	34 (19.8)	59	1.15 (0.73–1.79)	0.37
Local infection not associated with LVAS	70 (37.0)	108	60 (34.9)	114	1.00 (0.71–1.42)	0.74
Right heart failure						
Any right heart failure	60 (31.7)	73	48 (27.9)	53	1.12 (0.77–1.64)	0.49
Right heart failure managed with RVAS	6 (3.2)	6	8 (4.7)	8	0.67 (0.23–1.94)	0.59
Cardiac arrhythmia						
Any cardiac arrhythmia	71 (37.6)	108	70 (40.7)	105	0.88 (0.63–1.23)	0.59
Ventricular arrhythmia	45 (23.8)	67	39 (22.7)	64	1.04 (0.67–1.59)	0.80
Supraventricular arrhythmia	33 (17.5)	40	36 (20.9)	37	0.79 (0.49–1.26)	0.42
Respiratory failure	45 (23.8)	61	39 (22.7)	46	1.04 (0.68–1.59)	0.80
Renal dysfunction	25 (13.2)	29	18 (10.5)	18	1.23 (0.67–2.25)	0.52
Hepatic dysfunction	8 (4.2)	8	7 (4.1)	7	0.98 (0.36–2.71)	1.00


If I only had an LVAD…

LVAD: One Size DOES NOT Fit All







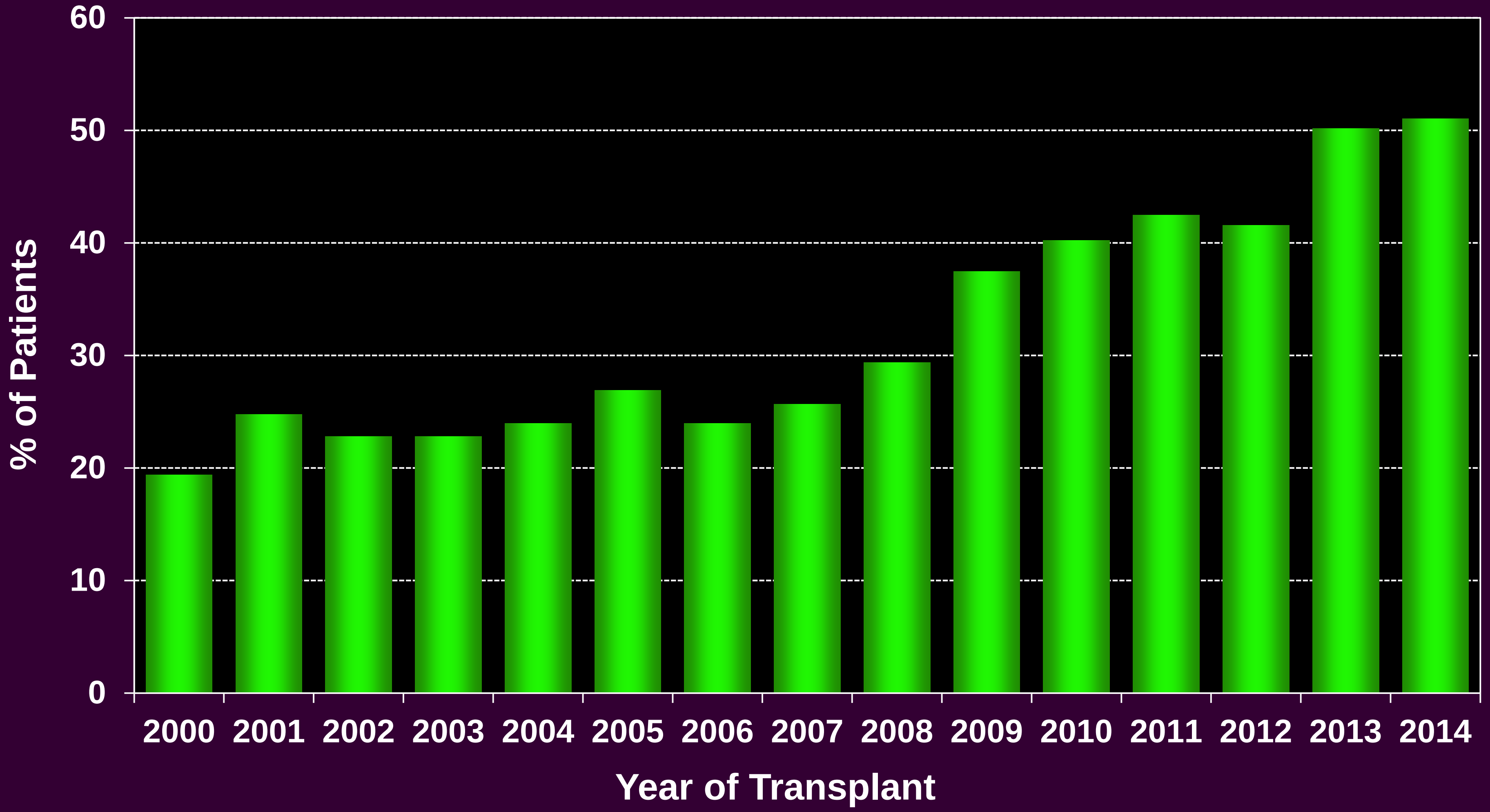
Requisites for LVAD candidacy:

- Univentricular (Left) failure
- Sizeable LV chamber (LVEDD ≥ 5cm)

Adult Heart Transplants

% of Patients Bridged with Mechanical Circulatory Support*

(Transplants: January 2000 – December 2014)

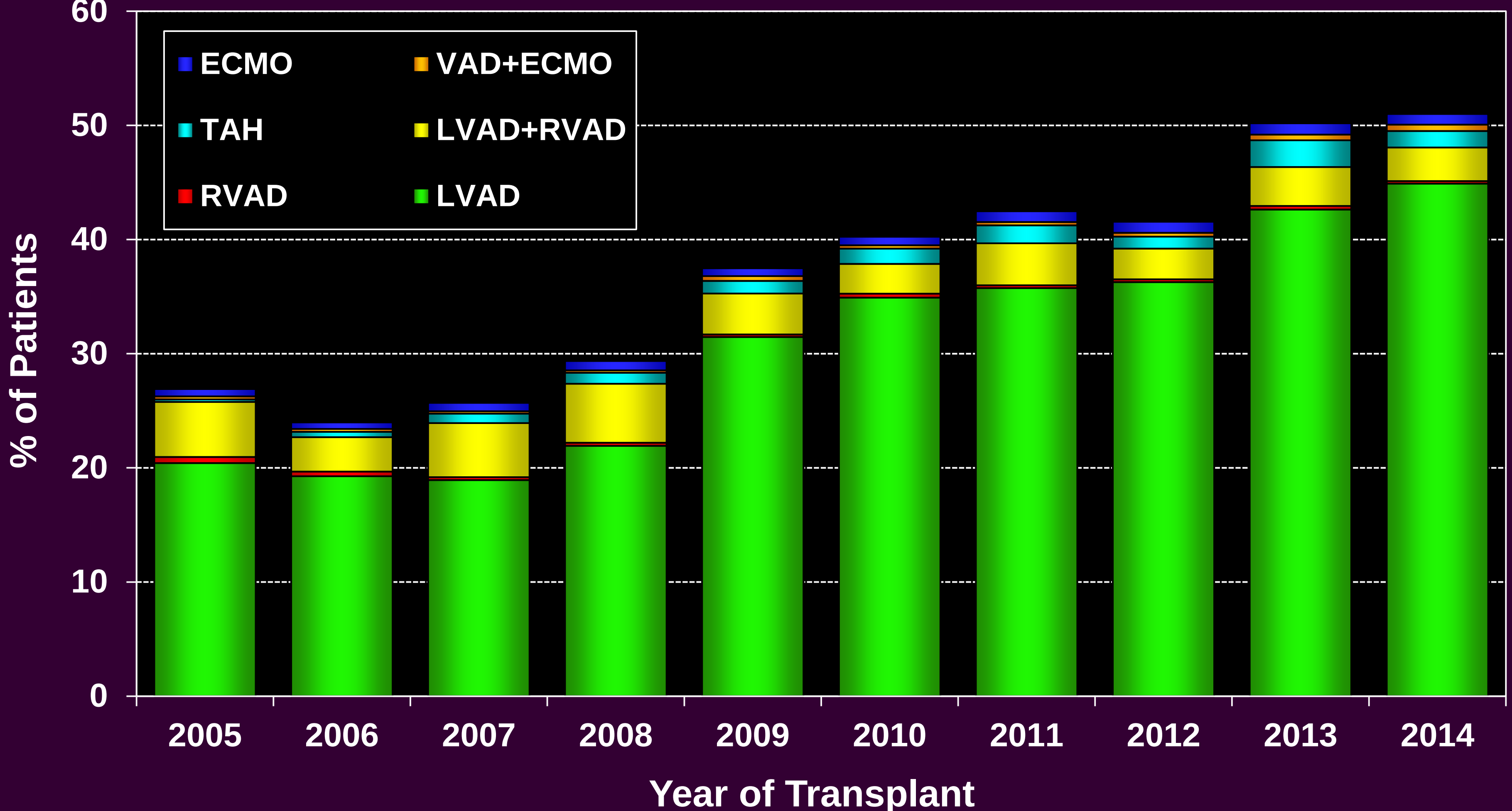


* LVAD, RVAD, TAH, ECMO

ISHLT • INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION
2016
JHLT. 2016 Oct; 35(10): 1149-1205

Adult Heart Transplants

% of Patients Bridged with Mechanical Circulatory Support* by Year and Device Type

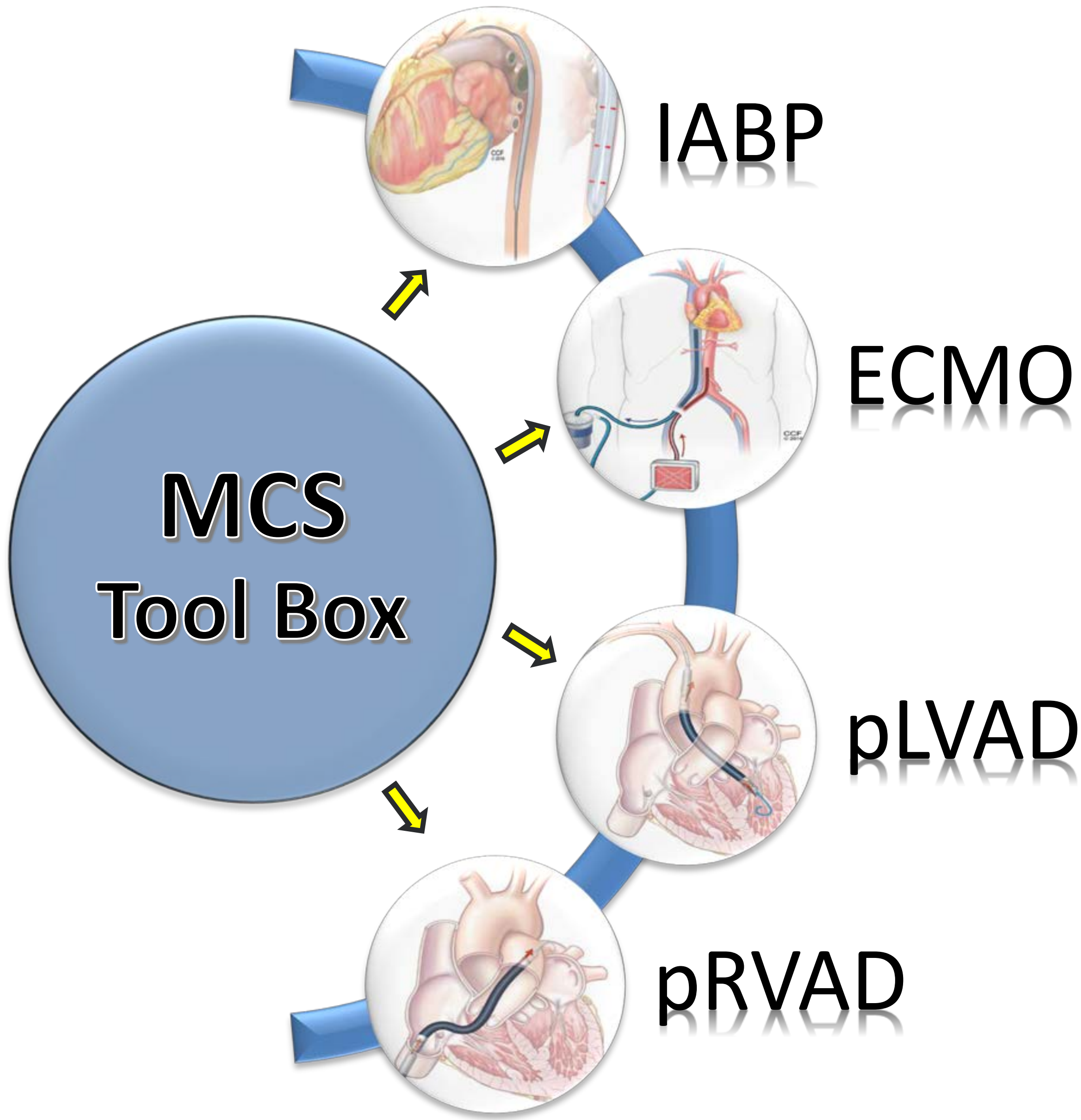


* LVAD, RVAD, TAH, ECMO

ISHLT • INTERNATIONAL SOCIETY FOR HEART AND LUNG TRANSPLANTATION
2016
JHLT. 2016 Oct; 35(10): 1149-1205

Increasing Role of Temporary MCS Modalities

- Stabilize patients in hemodynamic extremis
- Recovery of end-organ dysfunction
- Decipher candidacy for HTx vs LVAD
  - **New allocation policy for donor hearts will facilitate HTx for these pts**
- Recovery of Primary Graft Dysfunction (PGD) following HTx



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A Practical Approach to Mechanical Circulatory Support in Patients Undergoing Percutaneous Coronary Intervention

An Interventional Perspective

JACC: Cardiovascular Interventions 2016

Tamara M. Atkinson, MD,[a] E. Magnus Ohman, MD,[b] William W. O'Neill, MD,[c] Tanveer Rab, MD,[d]
Joaquin E. Cigarroa, MD,[a] on behalf of the Interventional Scientific Council of the American College of Cardiology

TABLE 1 Hemodynamic Criteria for Cardiogenic Shock

Clinical	
SBP <90 mm Hg for 30 min	
Supportive measures needed to maintain SBP >90 mm Hg	
End-organ hypoperfusion	
Cool extremities	
UOP <30 ml/h	
HR >60 beats/min	
Hemodynamic	
Cardiac index <2.2 ml/min/m^2	
PCWP >15 mm Hg	

The SHOCK trial defined cardiogenic shock according the clinical and hemodynamic criteria listed (11).

HR = heart rate; PCWP = pulmonary capillary wedge pressure; SBP = systolic blood pressure; UOP = urine output.

"Severe" Shock:

- Hemodynamics
  - CI <1.5
  - PCWP >30
  - LVEDP>30
- Vasoactive Medications
  - 2 or more

National Trends in the Utilization of Short-Term Mechanical Circulatory Support

Incidence, Outcomes, and Cost Analysis

Robert Stretch, MD,* Christopher M. Sauer, MD, MBA,* David D. Yuh, MD,† Pramod Bonde, MD†‡

JACC 2014

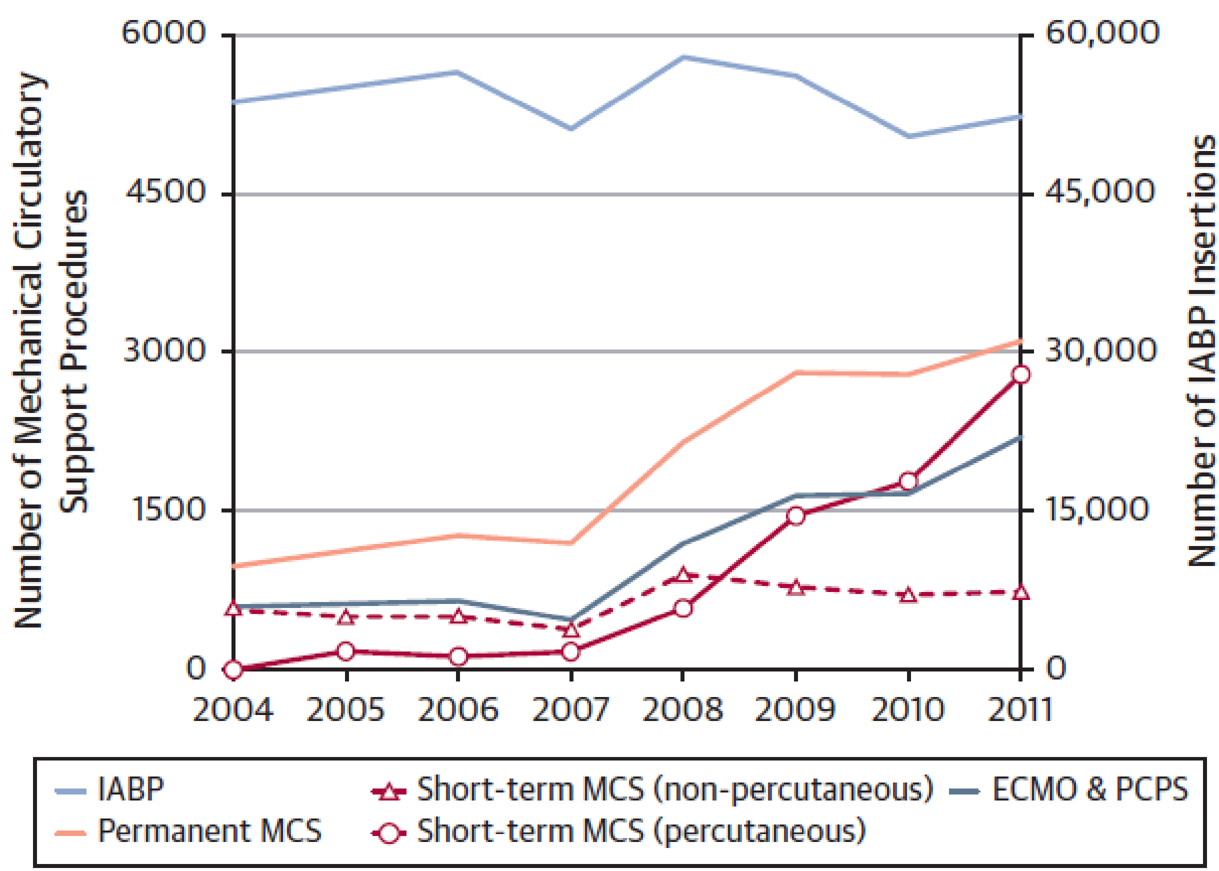

FIGURE 1 **Use of MCS Devices Between 2004 and 2011**

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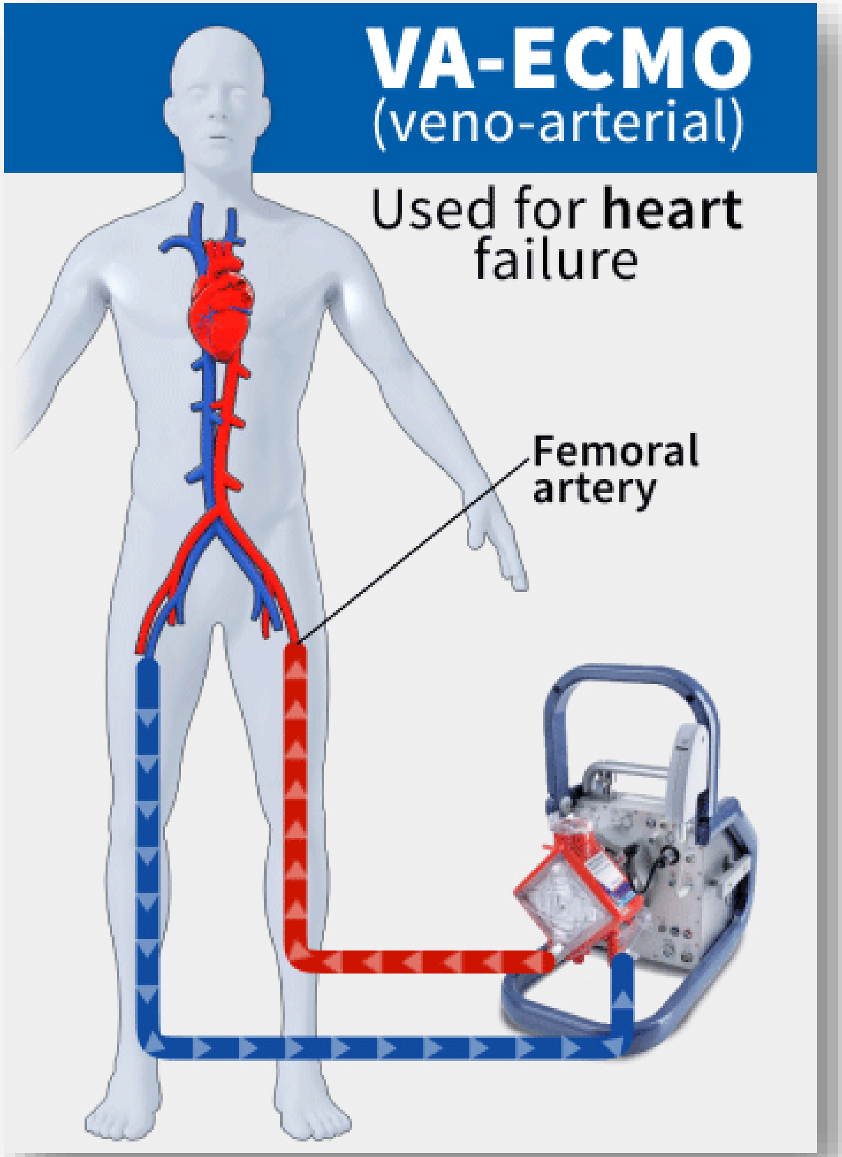
Extracorporeal Membrane Oxygenation (ECMO)



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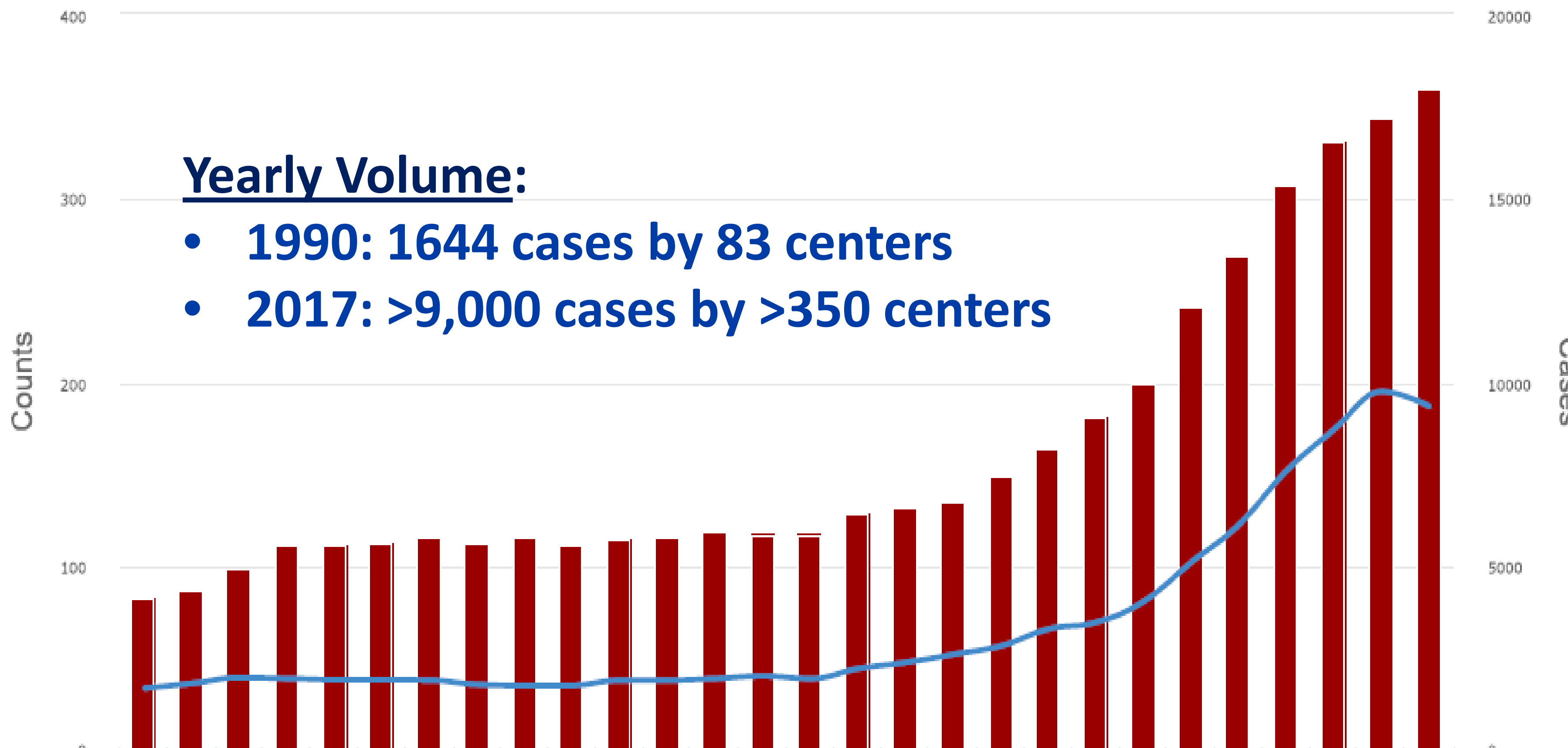
ECMO on the Rise

Centers by year

Yearly Volume:

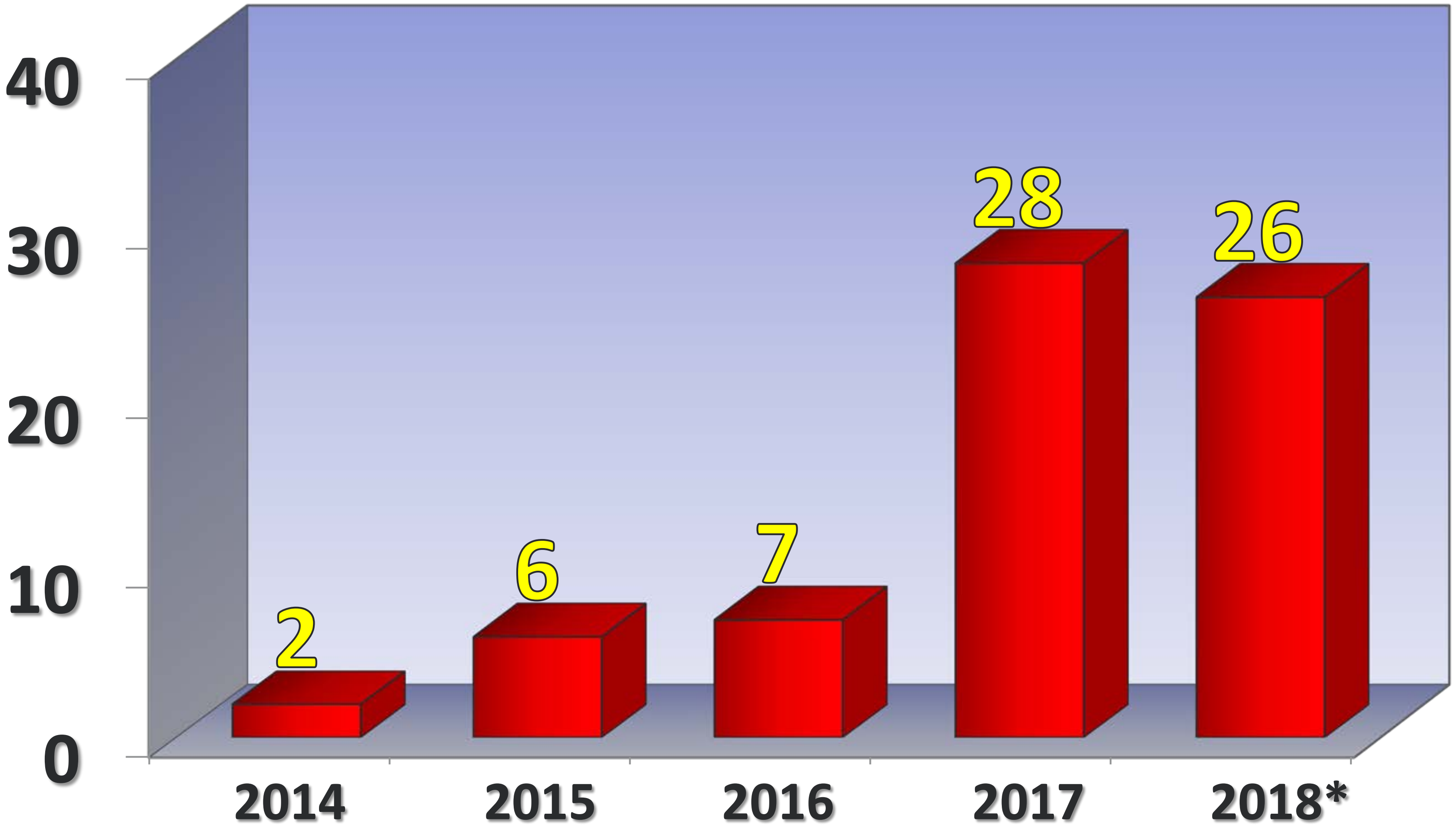
- **1990: 1644 cases by 83 centers**
- **2017: >9,000 cases by >350 centers**



	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
Counts	83	86	98	111	111	112	115	112	115	111	114	115	119	117
Cases	1644	1775	1933	1910	1879	1876	1868	1743	1720	1722	1859	1855	1908	1974

	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Counts	117	129	131	134	149	163	181	200	241	269	308	330	343	359
Cases	1907	2183	2346	2564	2802	3261	3443	4012	5083	6113	7583	8707	9736	9330

ECMO: North Shore University Hospital



ECLS Registry Report

International Summary

January, 2018

Extracorporeal Life Support Organization
2800 Plymouth Road
Building 300, Room 303
Ann Arbor, MI 48109

Overall Outcomes

	Total Runs	Survived ECLS		Survived to DC or Transfer	
Adult					
Pulmonary	15,686	10,463	66%	9,264	59%
Cardiac	15,201	8,489	55%	6,379	41%
ECPR	4,745	1,830	38%	1,381	29%

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1-833-NYC-ECMO

INDICATIONS

- **Refractory Cardiogenic Shock**
  - Cardiac arrest w/ ongoing CPR ***or***
  - Low cardiac output (C.I. ≤2), Hypotension (SBP <100), end organ malperfusion (rising lactate, Cr, LFTs, oliguria) ***and***
  - Failed conventional measures: inotropes/pressors/IABP

ETIOLOGIES

- AMI, ACS
- Post-cardiac surgery
- Drug overdose
- Myocarditis
- Pulmonary embolus
- Peripartum cardiomyopathy
- Anaphylaxis
- Acute-on-chronic advanced heart failure

CONTRAINDICATIONS

- Age > 75*
- Unwitnessed cardiac arrest or >30min of CPR prior to ECMO initiation
- Prolonged ventilation (≥7days)*
- Recent CVA/CNS hemorrhage
- Aortic dissection / severe AI
- Intolerance or other contraindication to anticoagulation
- Cirrhosis or ESRD
- Major immunosuppression / neutropenia
- Nonrecoverable comorbidity (<6months life expectancy

*****_Relative Contraindications_

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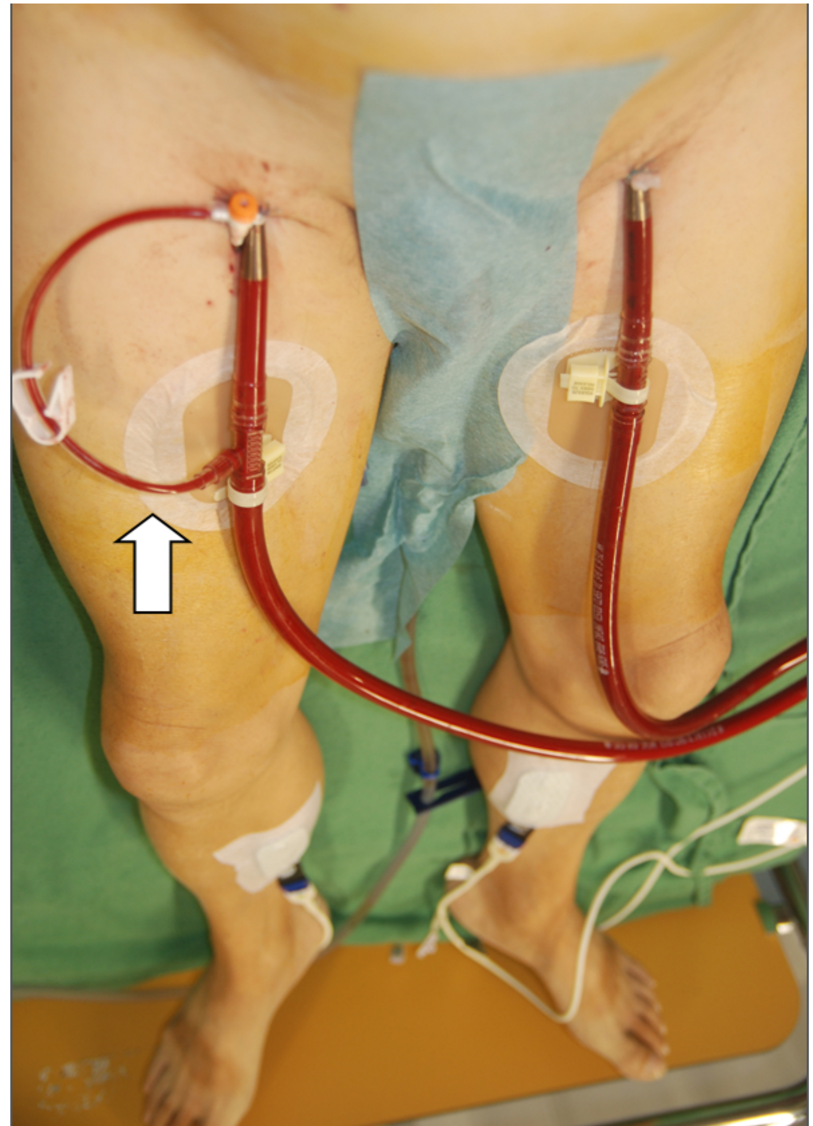
Contemporary extracorporeal membrane oxygenation therapy in adults: Fundamental principles and systematic review of the evidence

(J Thorac Cardiovasc Surg 2016;152:20-32)

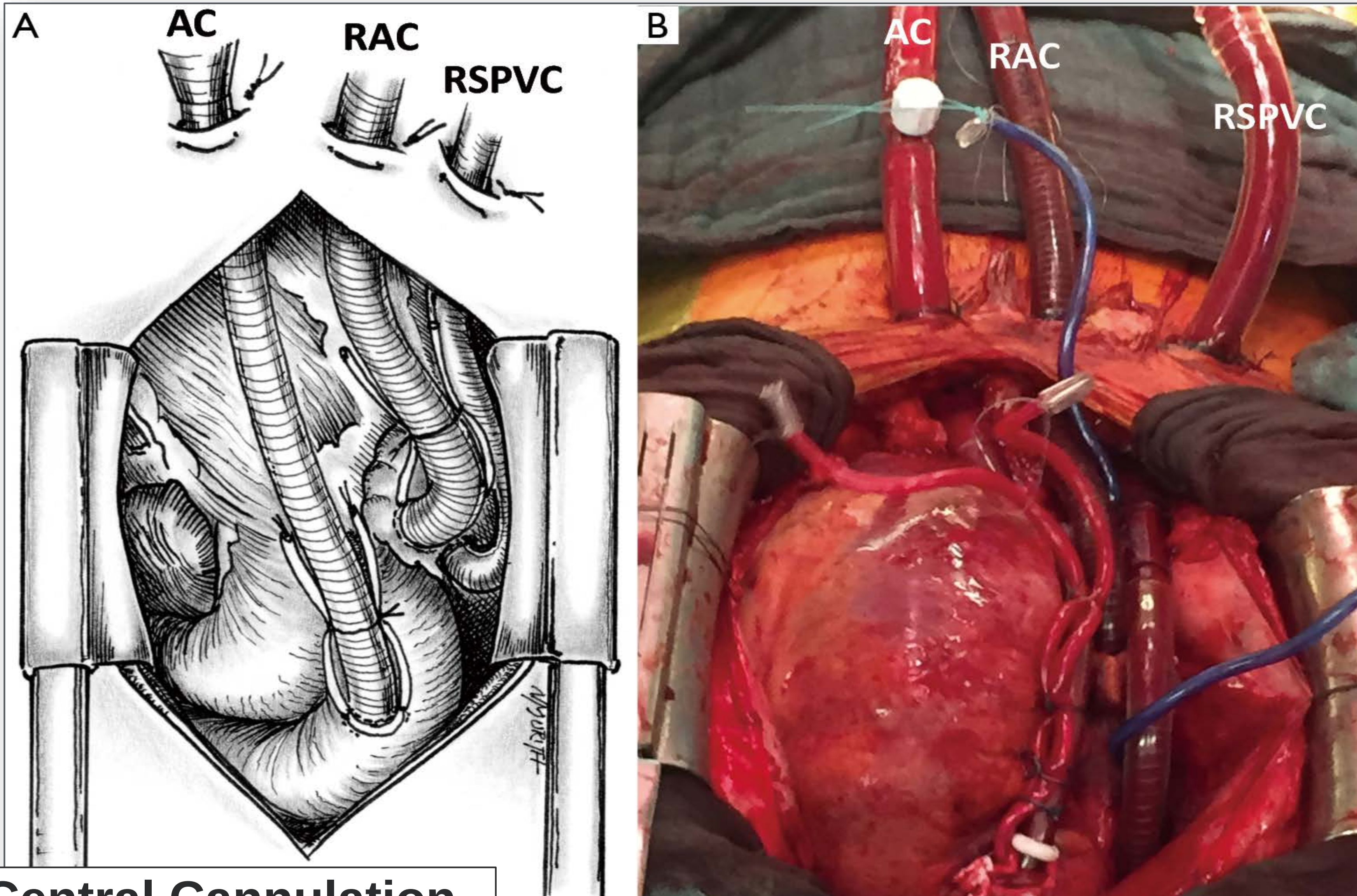
John J. Squiers, BSE,[a] Brian Lima, MD,[b] and J. Michael DiMaio, MD[a,b]

VA ECMO

- Pros
  - Full Biventricular Support
  - Ease of insertion
  - Various cannulation configurations (axillary, femoral, central)
- Cons
  - ?Unload LV
  - Limb complications (ischemia, hyperperfusion)
  - Bleeding



Implantation: Cannulation Options

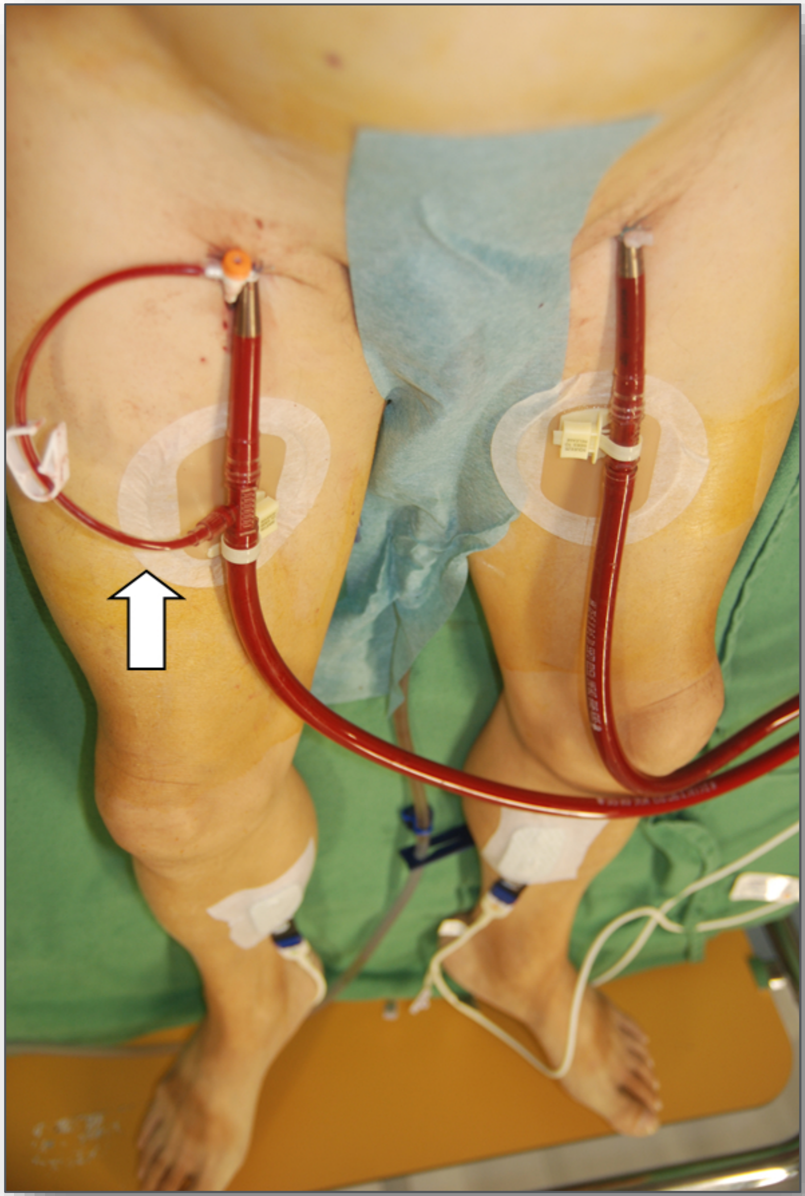


Central Cannulation

Implantation: Femoral VA ECMO

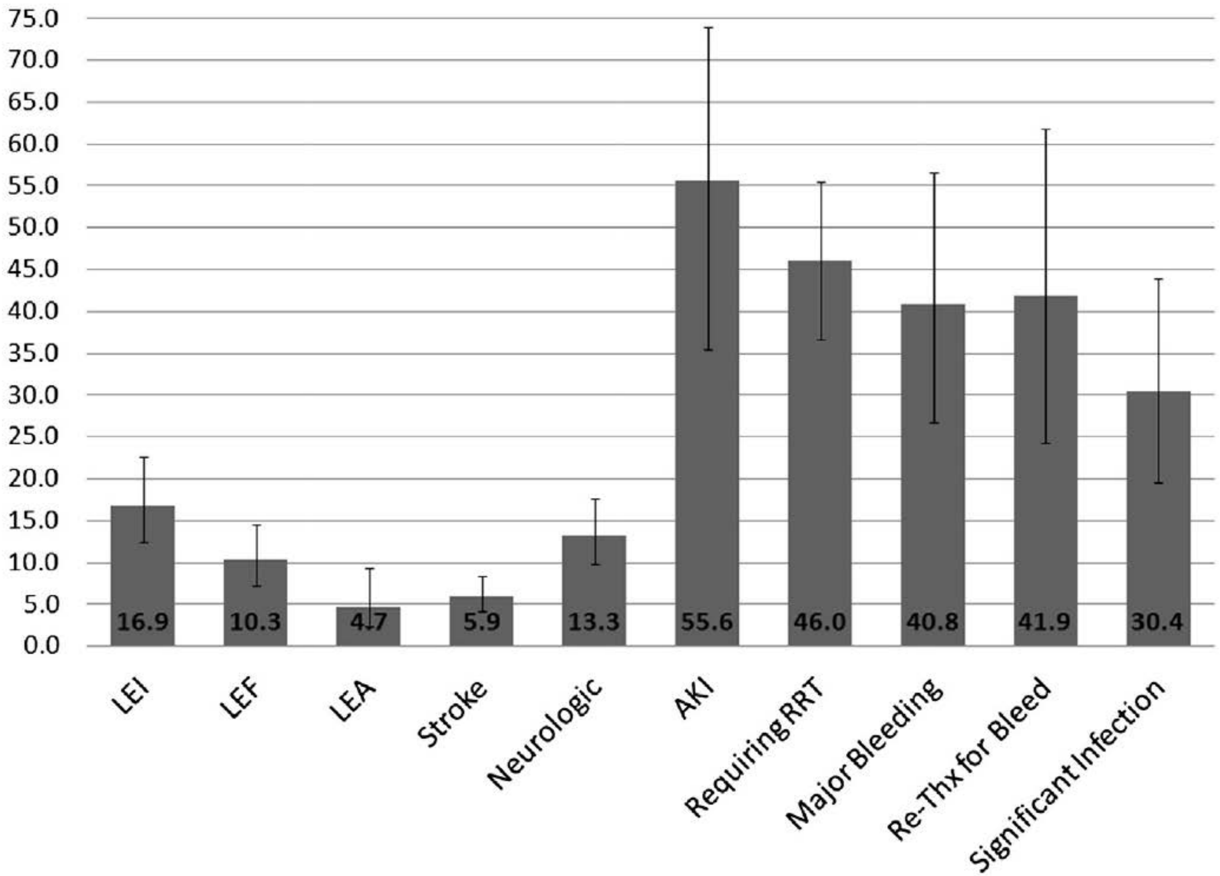
Peripheral Cannulation

- Percutaneous
  - Femoral Artery
    - Need separate SFA reperfusion cannula
  - Femoral Vein
- Groin Cutdown
  - Especially if no reperfusion cannula



VA ECMO in Cardiac Patients

Meta-analysis: Survival to Discharge = 534/1528 (**35%**)



LEI: lower-extremity infection
LEF: lower-extremity fasciotomy
LEA: lower-extremity amputation
AKI: acute kidney injury
Re-Thx: re-thoracotomy

From: Cheng et al. Complications of extracorporeal membrane oxygenation for treatment of cardiogenic shock and cardiac arrest: a meta-analysis of 1,866 adult patients. Ann Thorac Surg 2014;97:610-6.

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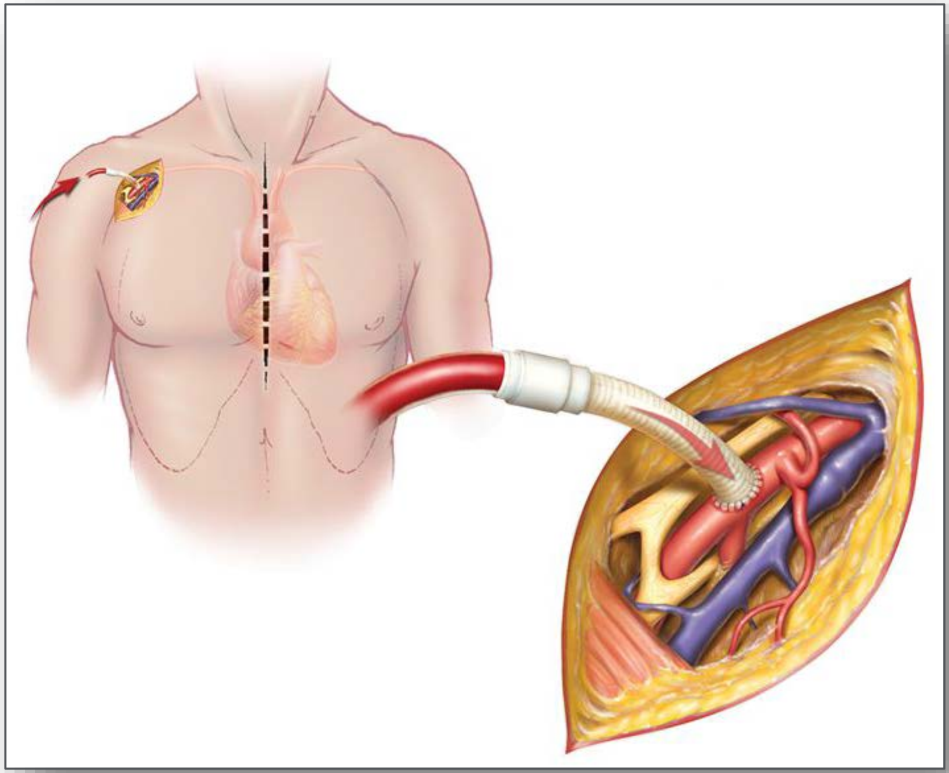
Outcomes of axillary artery side graft cannulation for extracorporeal membrane oxygenation

Themistokles Chamogeorgakis, MD,[a,b,c] Brian Lima, MD,[a] Alexis E. Shafii, MD,[a,c]
Dave Nagpal, MD,[a] Julie A. Pokersnik, CCP,[a] Jose L. Navia, MD,[a] David Mason, MD,[a] and
Gonzalo V. Gonzalez-Stawinski, MD[a,c]

Journal of Thoracic & Cardiovascular Surgery, 2013

2001-2011, **N=308**
VA ECMO pts:

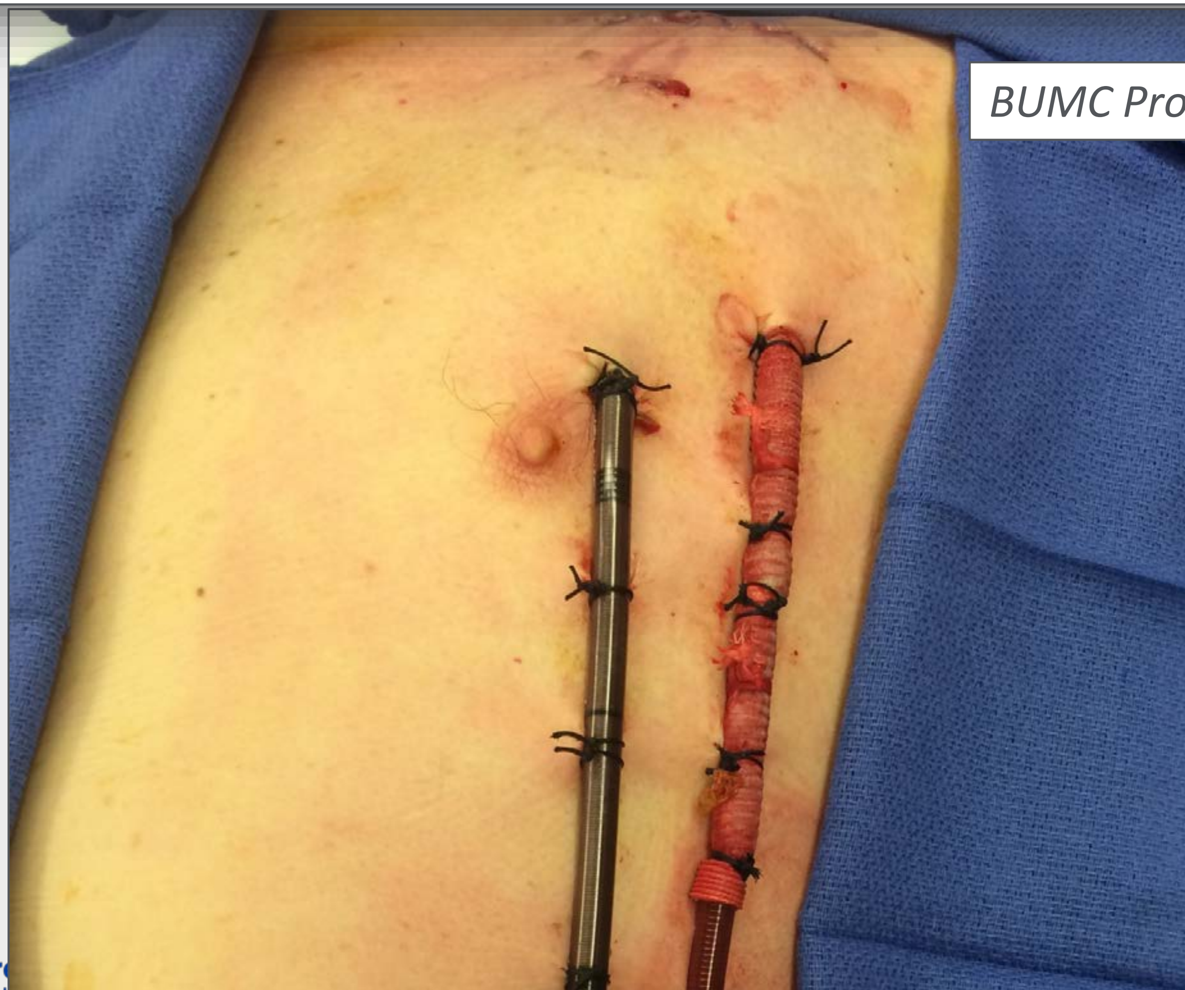
- **N= 81** (26%) axillary cannulation
  - N=20 (25%) *hyperperfusion syndrome upper extremity*
  - N=14 (17%) bleeding site complications

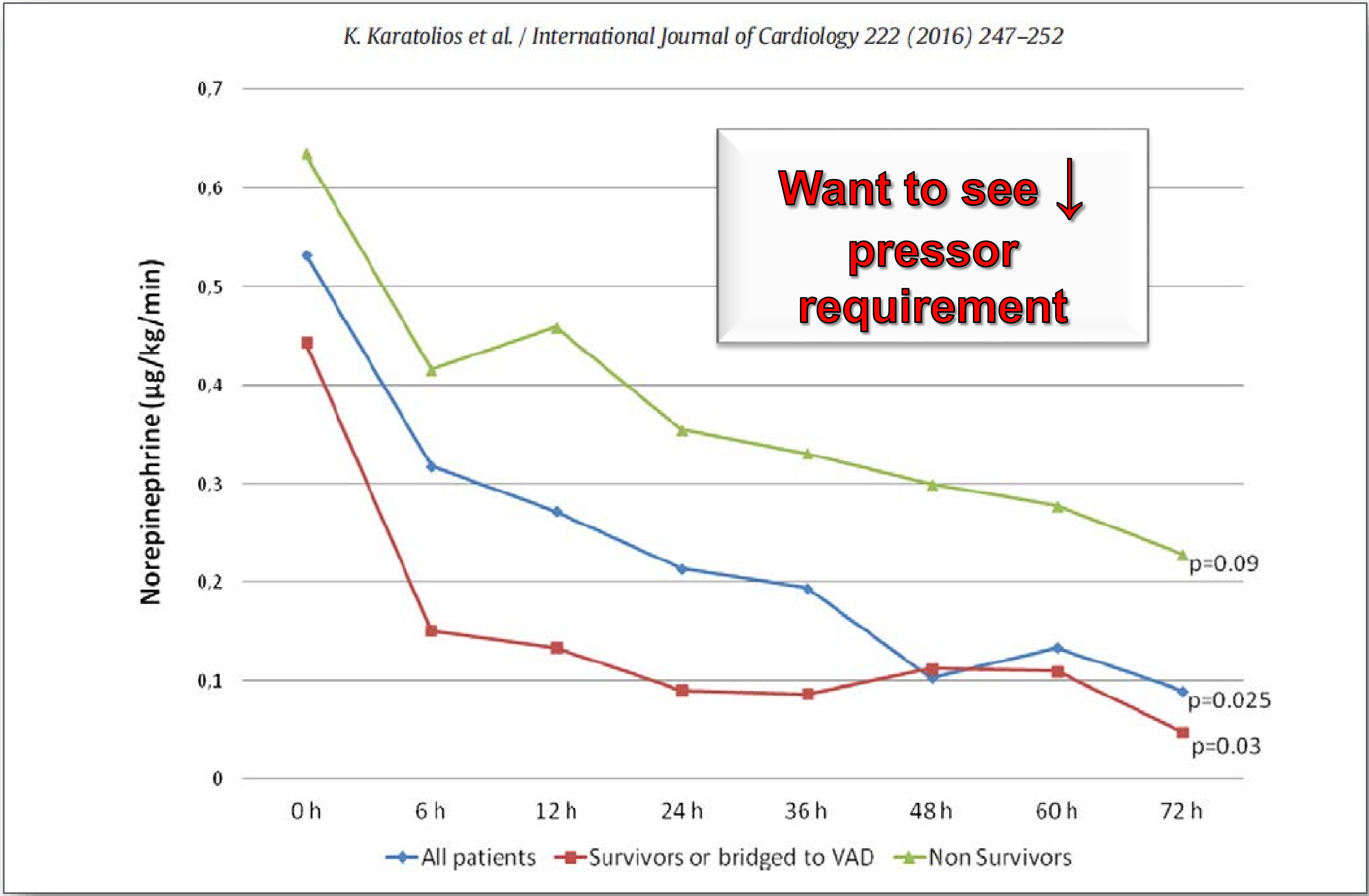


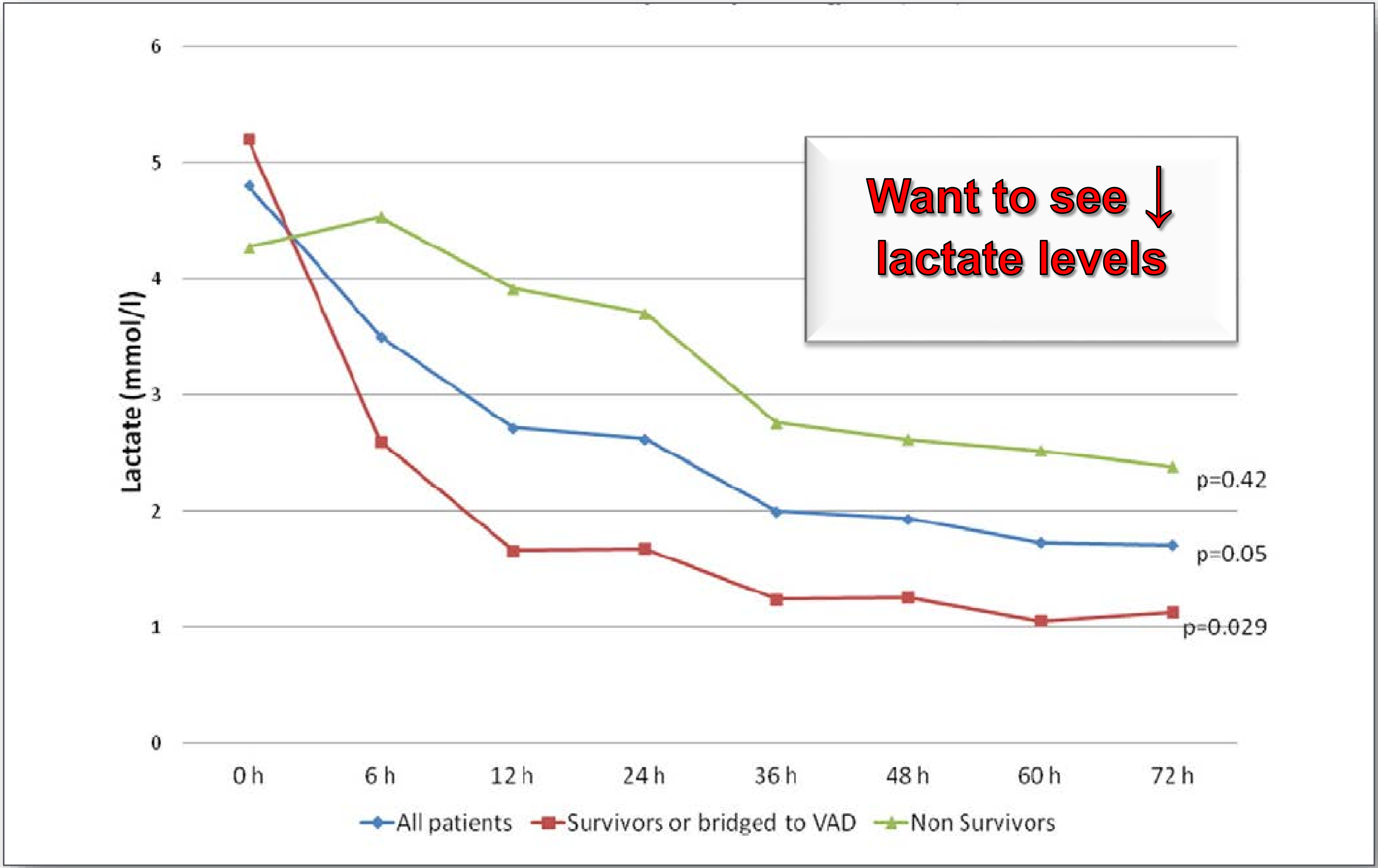
Ambulatory extracorporeal membrane oxygenation with subclavian venoarterial cannulation to increase mobility and recovery in a patient awaiting cardiac transplantation

Samuel Jacob, MD, Juan C. MacHannaford, MD, Themistokles Chamogeorgakis, MD, Gonzalo V. Gonzalez-Stawinski, MD, Joost Felius, PhD, Aldo E. Rafael, MD, Rajasekhar S. Malyala, MD, and Brian Lima, MD

BUMC Proceedings 2017




K. Karatolios et al. / International Journal of Cardiology 222 (2016) 247–252
Want to see ↓ pressor requirement
Norepinephrine (µg/kg/min)
0,7
0,6
0,5
0,4
0,3
0,2
0,1
0
0 h
6 h
12 h
24 h
36 h
48 h
60 h
72 h
p=0.09
p=0.025
p=0.03
All patients
Survivors or bridged to VAD
Non Survivors


6
5
4
3
2
1
0
Lactate (mmol/l)
0 h
6 h
12 h
24 h
36 h
48 h
60 h
72 h
p=0.42
p=0.05
p=0.029
All patients
Survivors or bridged to VAD
Non Survivors
Want to see ↓ lactate levels

VA ECMO→ Increased Afterload → LV Distention

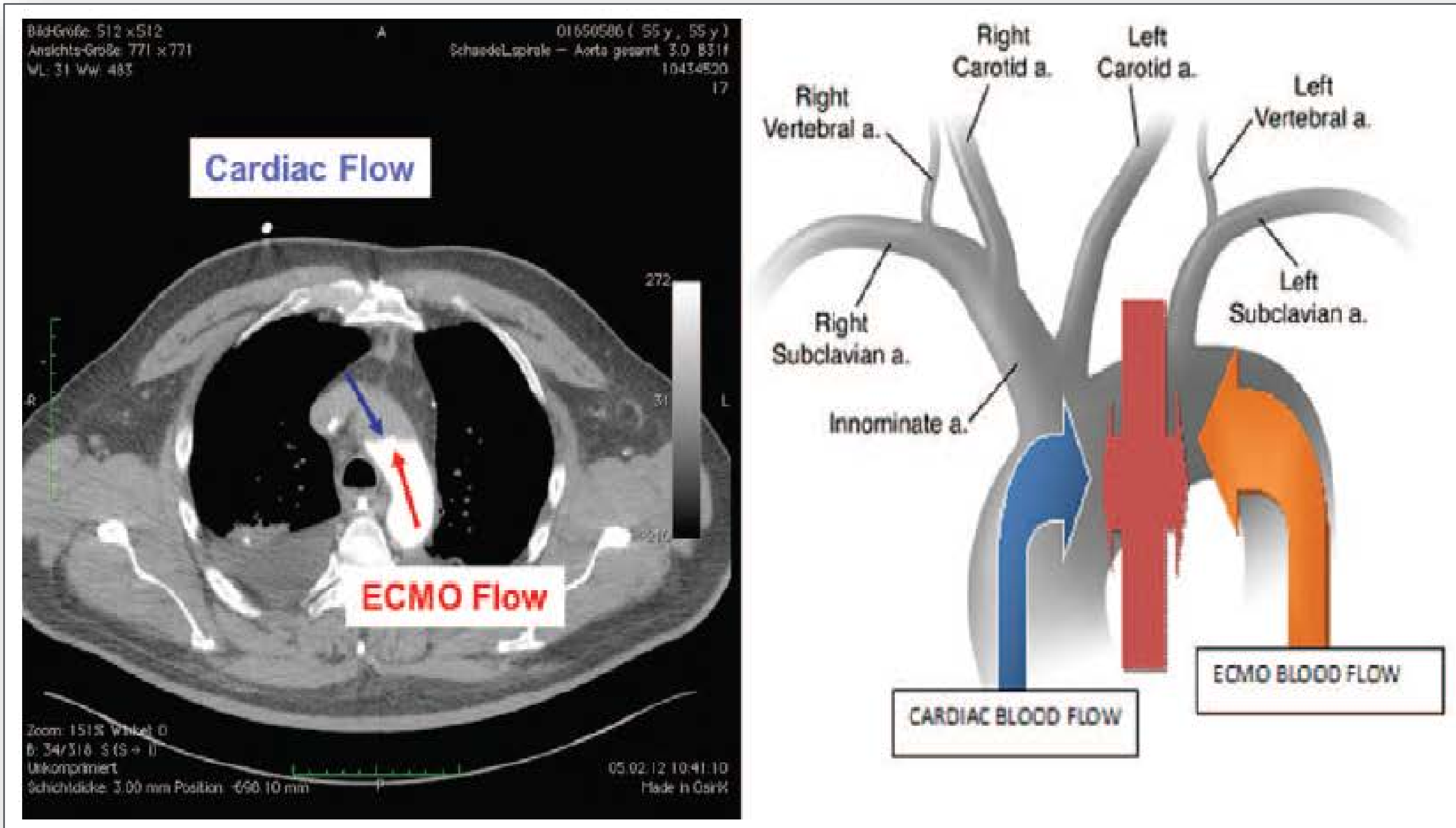
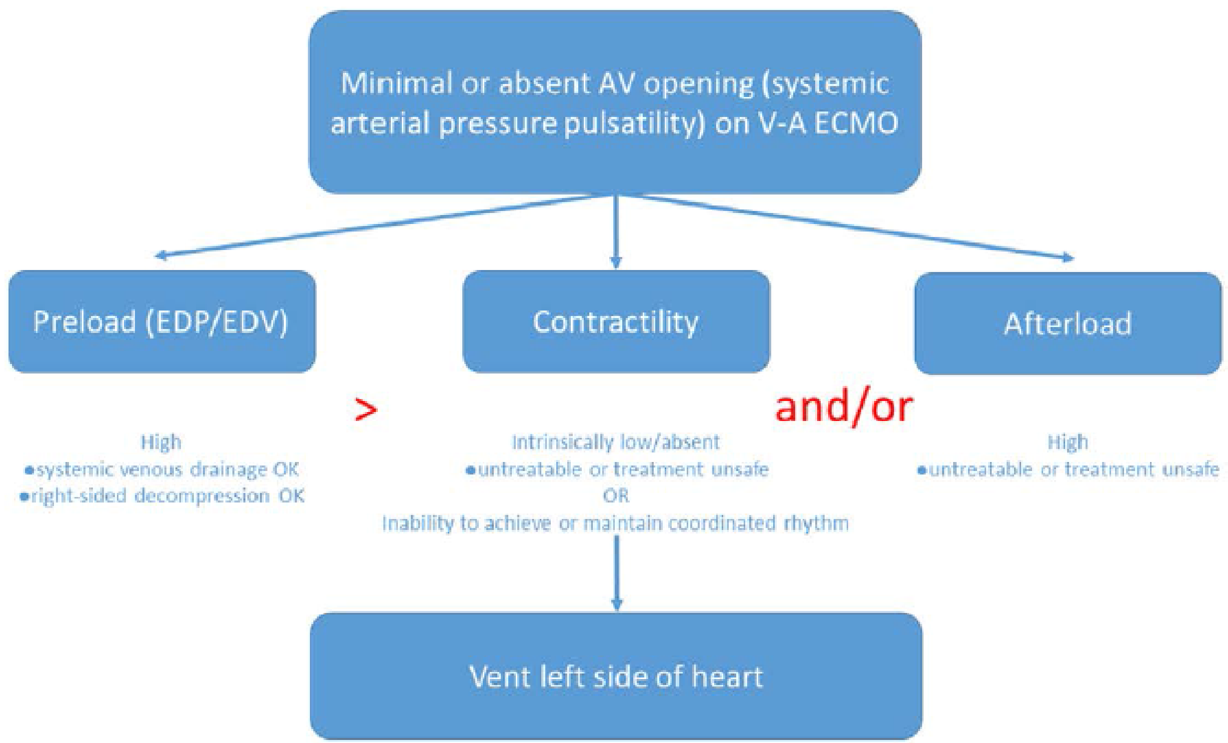


Figure 1. A CT scan of a patient on peripheral extracorporeal membrane oxygenation (ECMO) by cannulation of the femoral vessels. The contrast medium was injected into the arterial ECMO line. A watershed of the cardiac and ECMO flow is depicted in the aortic arch. This theoretically indicates an increased afterload by peripheral ECMO and retrograde aortic flow.

ASAIO Journal 2018 Review Article

Left Ventricular Distension in Veno-arterial Extracorporeal Membrane Oxygenation: From Mechanics to Therapies

Keshava Rajagopal



Our Philosophy: Preemptive LV venting vs Reactive / Delayed LV Venting

A Growing Arsenal of Acute MCS Options

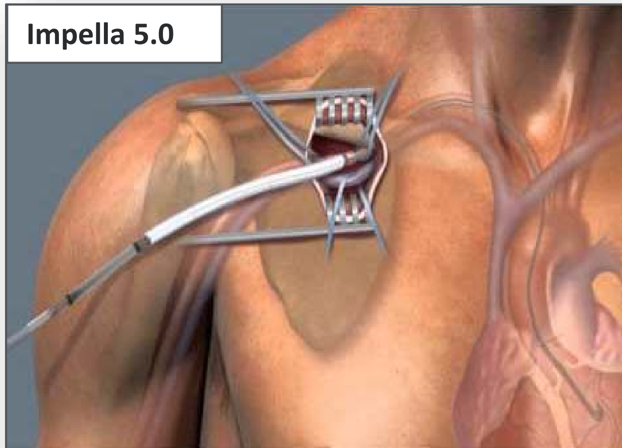
Percutaneous VAD:

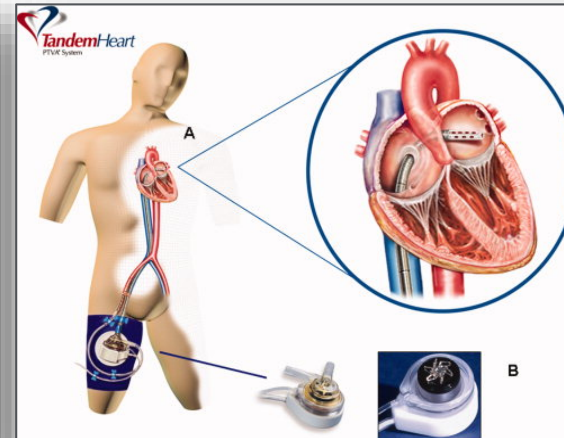
Pros

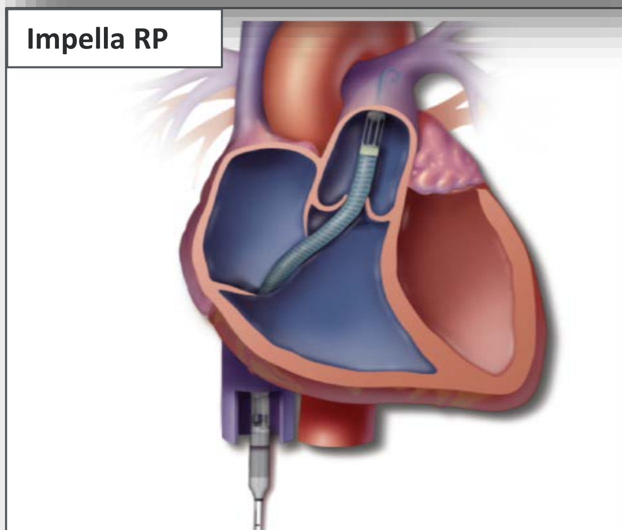
- Full Support
  - LVAD, RVAD
- Peripheral Insertion

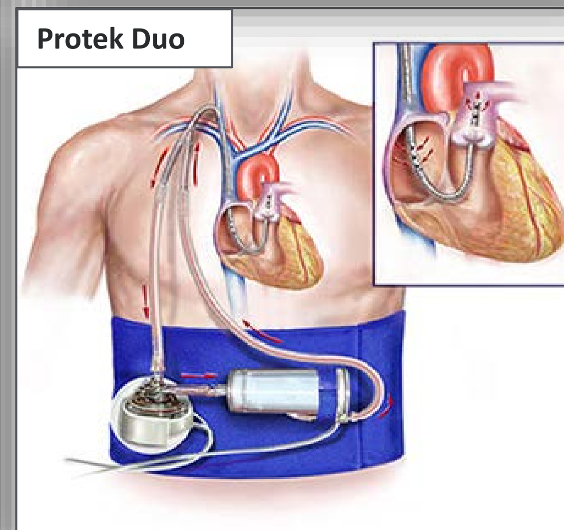
Cons

- Difficulty of Insertion
  - Logistics of transport, fluoro,etc
- Bleeding
- Hemolysis





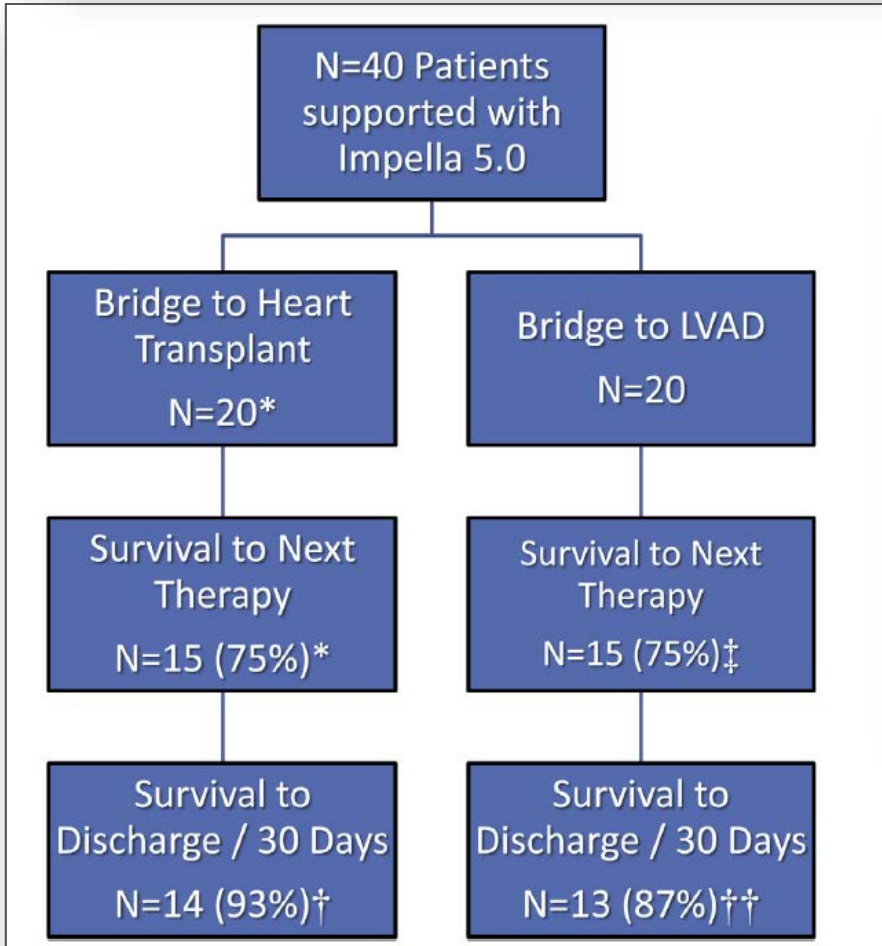


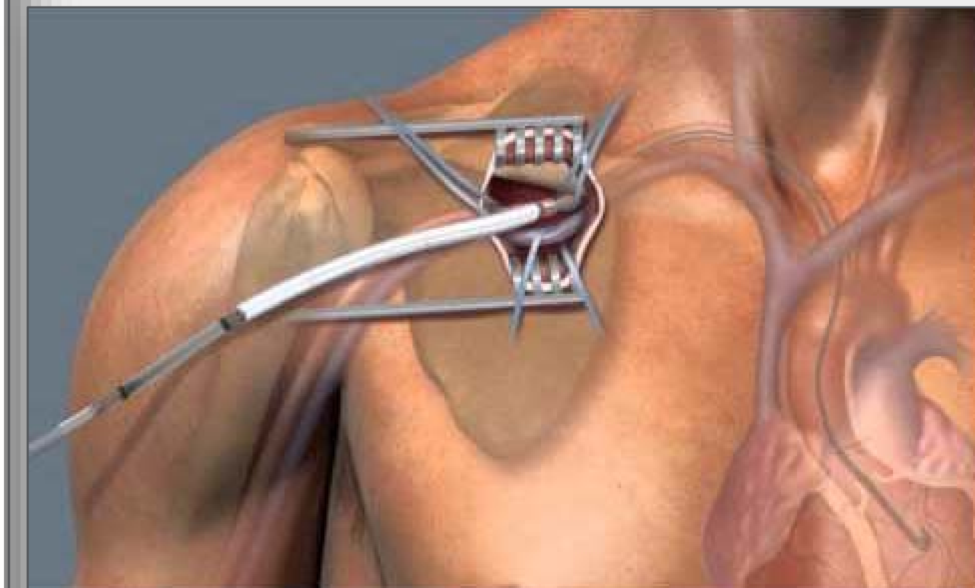


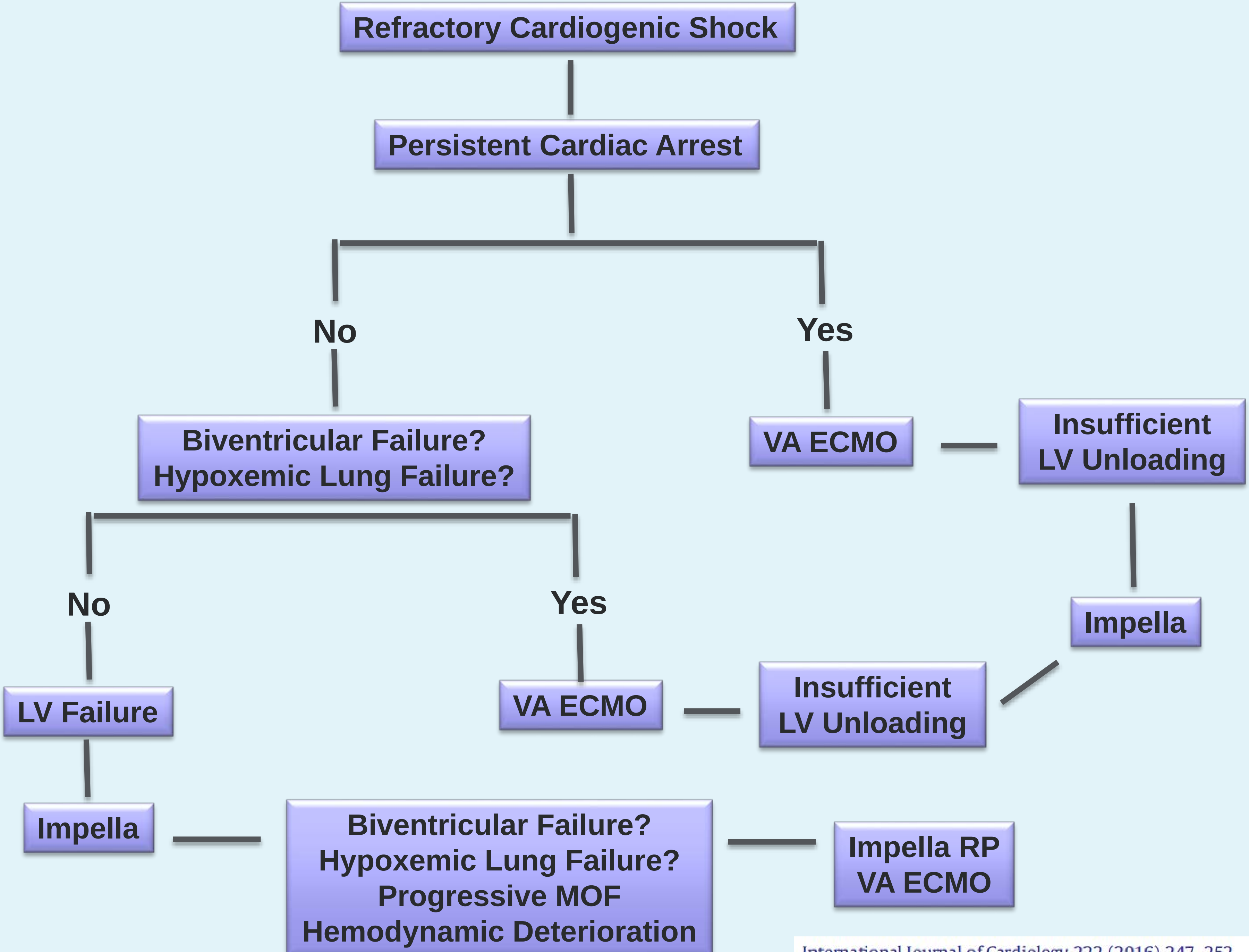
Effectiveness and Safety of the Impella 5.0 as a Bridge to Cardiac Transplantation or Durable Left Ventricular Assist Device

Brian Lima, MD[a,*], Parag Kale, MD[b], Gonzalo V. Gonzalez-Stawinski, MD[a], Johannes J. Kuiper, MD[b], Sandra Carey, PhD[b], and Shelley A. Hall, MD[b]

American Journal of Cardiology 2016

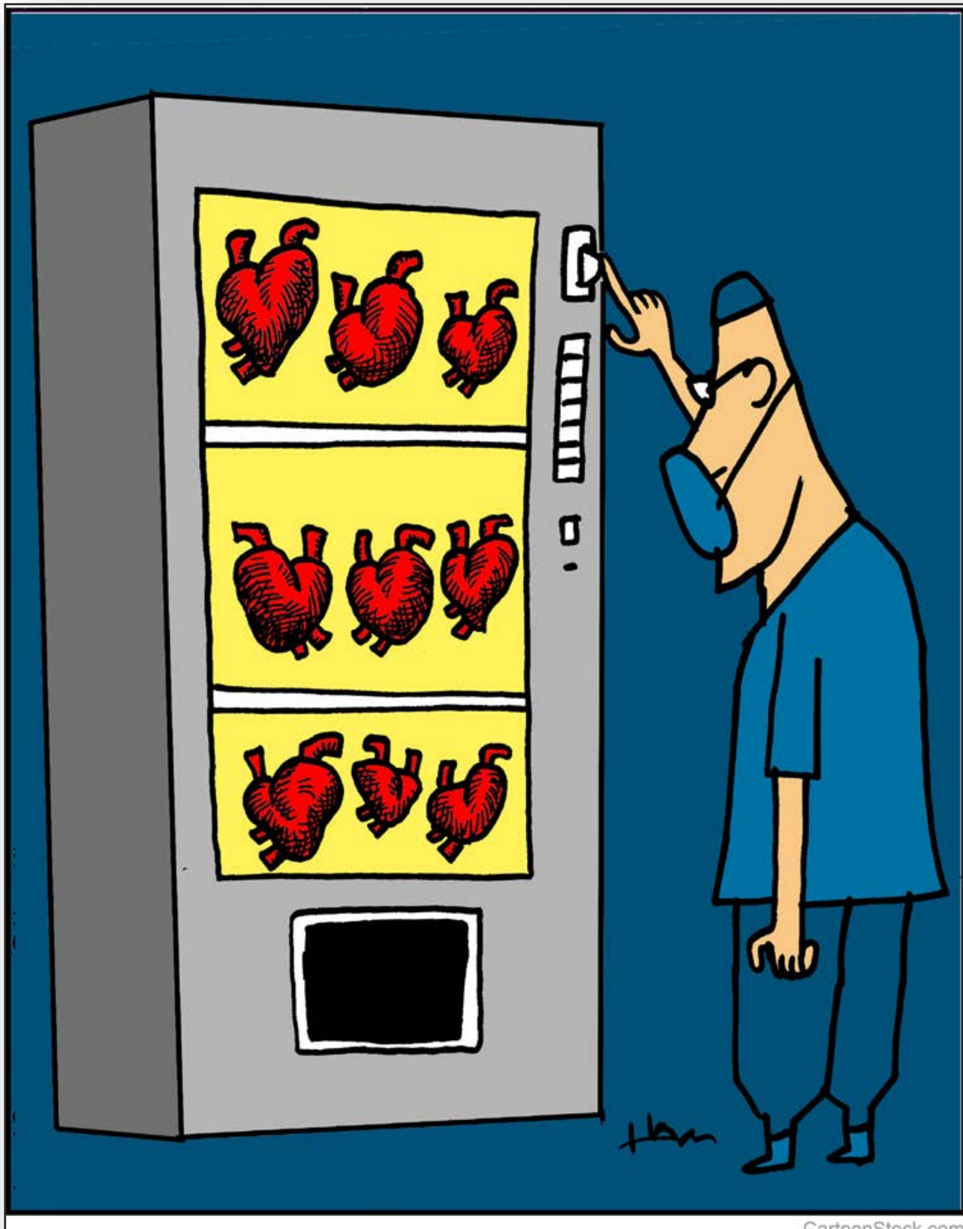






International Journal of Cardiology 222 (2016) 247–252

The Art of Donor Selection

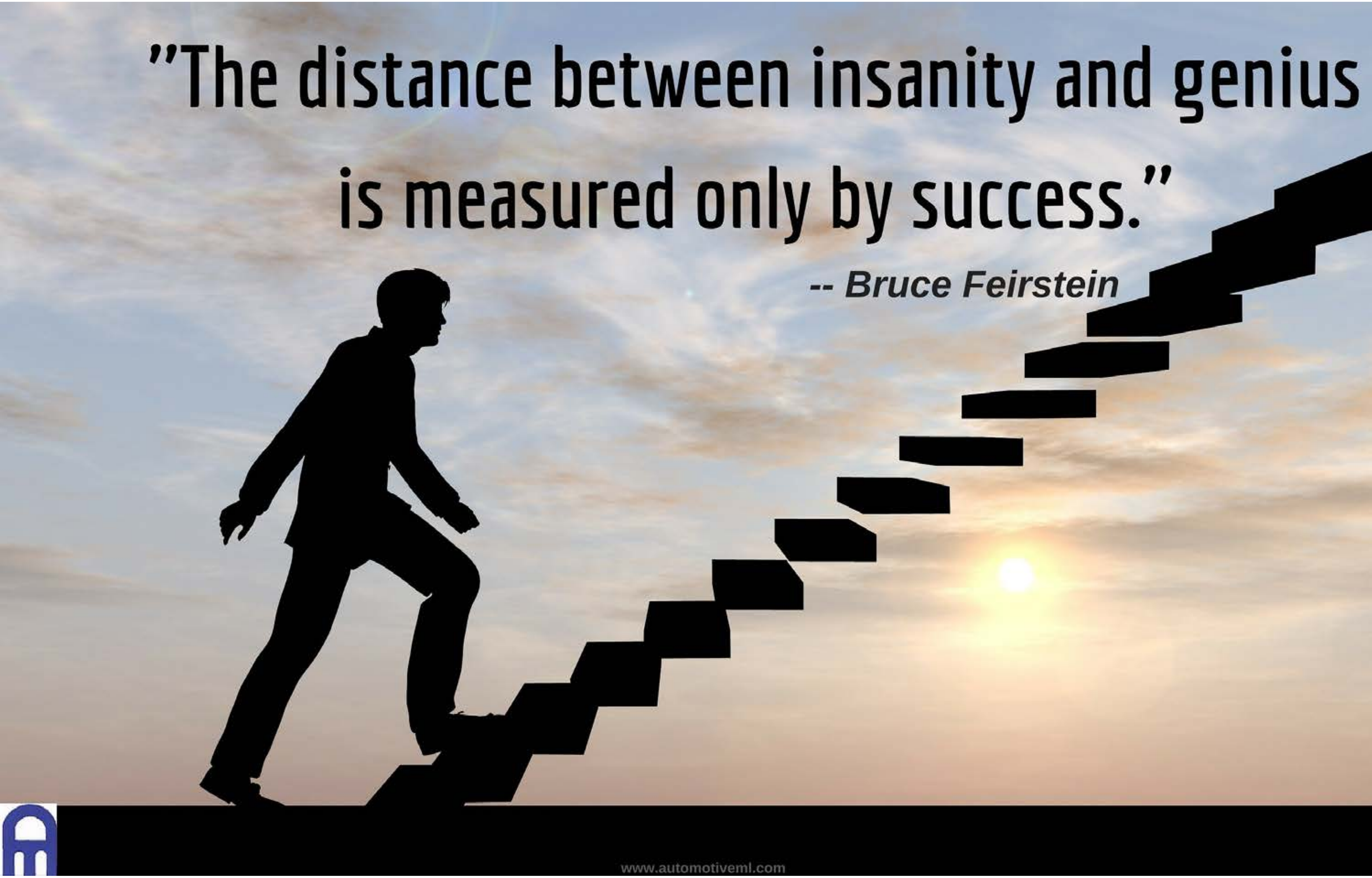


No such thing as a **"perfect heart"**

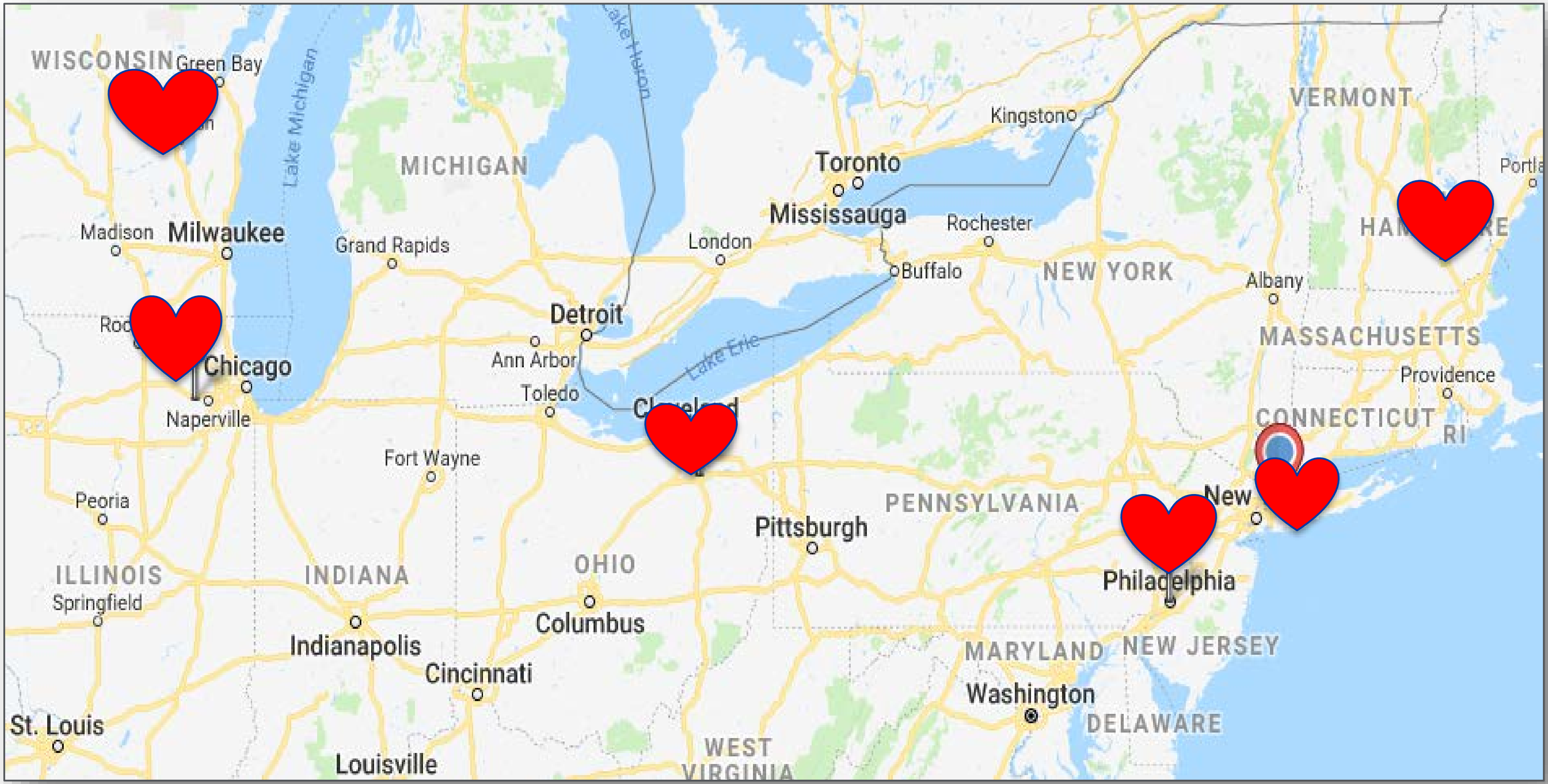
- *Right* heart for the *Right* patient at the *Right* time

"Shortage" of donor hearts may be self-imposed

- Overly stringent selection
- Risk factors ≠ contraindications


"The distance between insanity and genius
is measured only by success."
-- Bruce Feirstein
www.automotiveml.com

NSUH Heart Transplant Program: "We Go Where Our (*Donor*) Hearts Take Us"



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Northwell Health℠

Impact of donor age on cardiac transplantation outcomes and on cardiac function

Themistokles Chamogeorgakis[a,*], Susie Joseph[b], Shelley Hall[b], Gonzalo V. Gonzalez-Stawinski[a], Giovanna Saracino[c], Aldo Rafael[a], Juan MacHannaford[a], Ioannis Toumpoulis[d], Jose Mendez[b] and Brian Lima[a]

Interactive CardioVascular and Thoracic Surgery 23 (2016) 580–583

Table 2: Postoperative outcomes

Characteristics	<50 years (*N* = 164)	≥50 years (*N* = 27)	*P*-value
ICU LOS (days), median (range)	3.0 (2.0–5.0)	3.0 (2.0–5.0)	0.677
Total LOS (days), median (range)	8.0 (6.0–14.0)	9.0 (7.0–13.0)	0.457
LVEF (%), median (range)	60 (50–75)	65 (50–80)	0.121
In-hospital/30-day mortality, *n* (%)	5.0 (3.0)	1.0 (3.7)	>0.999
Severe rejection (3R) within 3 months, *n* (%)	3.0 (1.8)	1.0 (3.7)	0.459
Severe rejection (3R) within 1 year	3.0 (1.8)	1.0 (3.7)	0.459
Inotrope score, median (range)	17.6 (12.0–26.3)	14.8 (12.5–19.0)	0.075
Primary graft dysfunction, *n* (%)			
Mild	21 (17.2)	5 (26.3)	0.218
Moderate	5.0 (4.1)	0.0 (0.0)	
Severe	8.0 (6.6)	0.0 (0.0)	
Bacterial infection, *n* (%)	14.0 (8.5)	6.0 (22.2)	0.043

ICU: intensive care unit; LOS: length of stay; LVEF: left ventricular ejection fraction.

Conclusion: Appropriately selected hearts from donors >50y can be safely used for HTx w/o increased for PGD.

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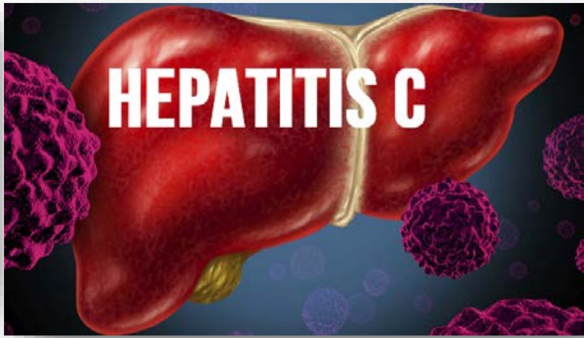
Brief Report

Accepting Hearts From Hepatitis C–Positive Donor: Can We Expand the Donor Pool?



- **Introduction of all-oral direct acting antiviral (DAA) therapies have revolutionized the care of HCV**
  - Fewer side effects / adverse events
  - **>90%** sustained virologic response (SVR) rates at 12 wks
    - **Harvoni®** (ledipasvir/sofosbuvir) FDA approved 2014 (genotype 1)
    - **Epclusa®** (velpatasivr/sofosbuvir) FDA approved 2015 (pangenotypic)
- **Prevalence of HCV**
  - General population: 1800 per 100,000
  - Deceased liver donors: 3100 per 100,000
  - Current heart donors: 550 per 100,000
- **Acceptance of HCV+ donors could expand the HCV+ patient contribution to the donor pool by 3X (1800/550) to 6X (3100/550)**

Northwell Health

Journal of Cardiac Failure 2017

Rational Heart Transplant From a Hepatitis C Donor: New Antiviral Weapons Conquer the Trojan Horse

ROBERT L. GOTTLIEB, MD, PhD,[1,2,3,4] TEENA SAM, PharmD,[1,2,3] SUZANNE Y. WADA, MD,[1,2,5] JAMES F. TROTTER, MD,[1,2,6] SUMEET K. ASRANI, MD,[1,2,6] BRIAN LIMA, MD,[1,2,3,7] SUSAN M. JOSEPH, MD,[1,2,3,4] GONZALO V. GONZALEZ-STAWINSKI, MD,[1,2,3,7] AND SHELLEY A. HALL, MD[1,2,3,4]

Dallas, Texas

Journal of Cardiac Failure 2017

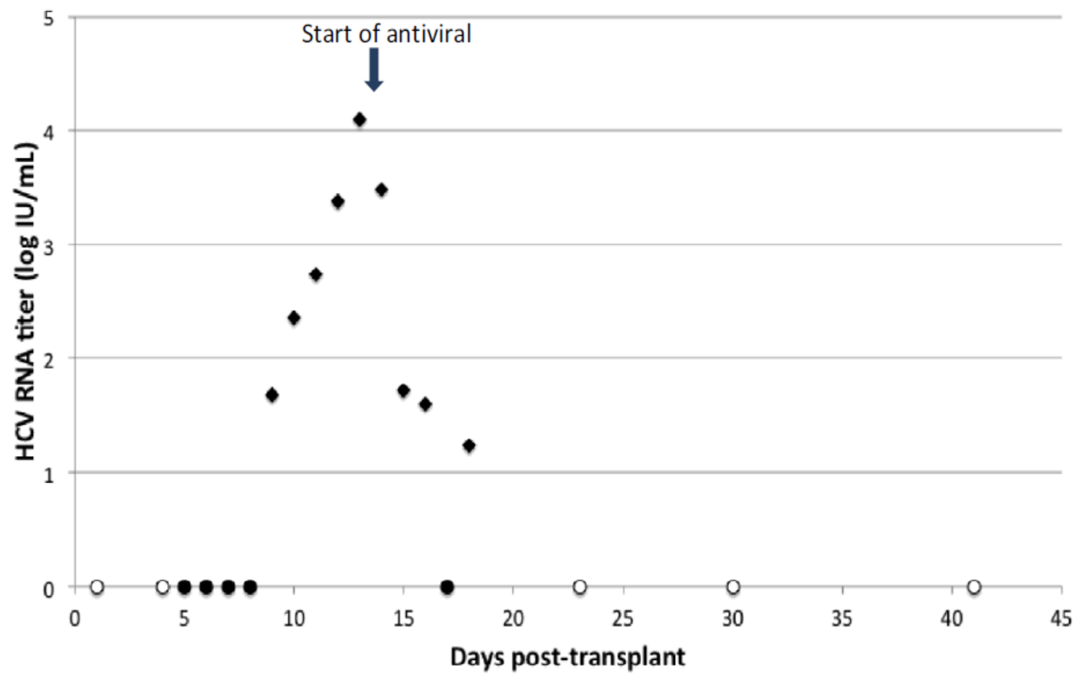
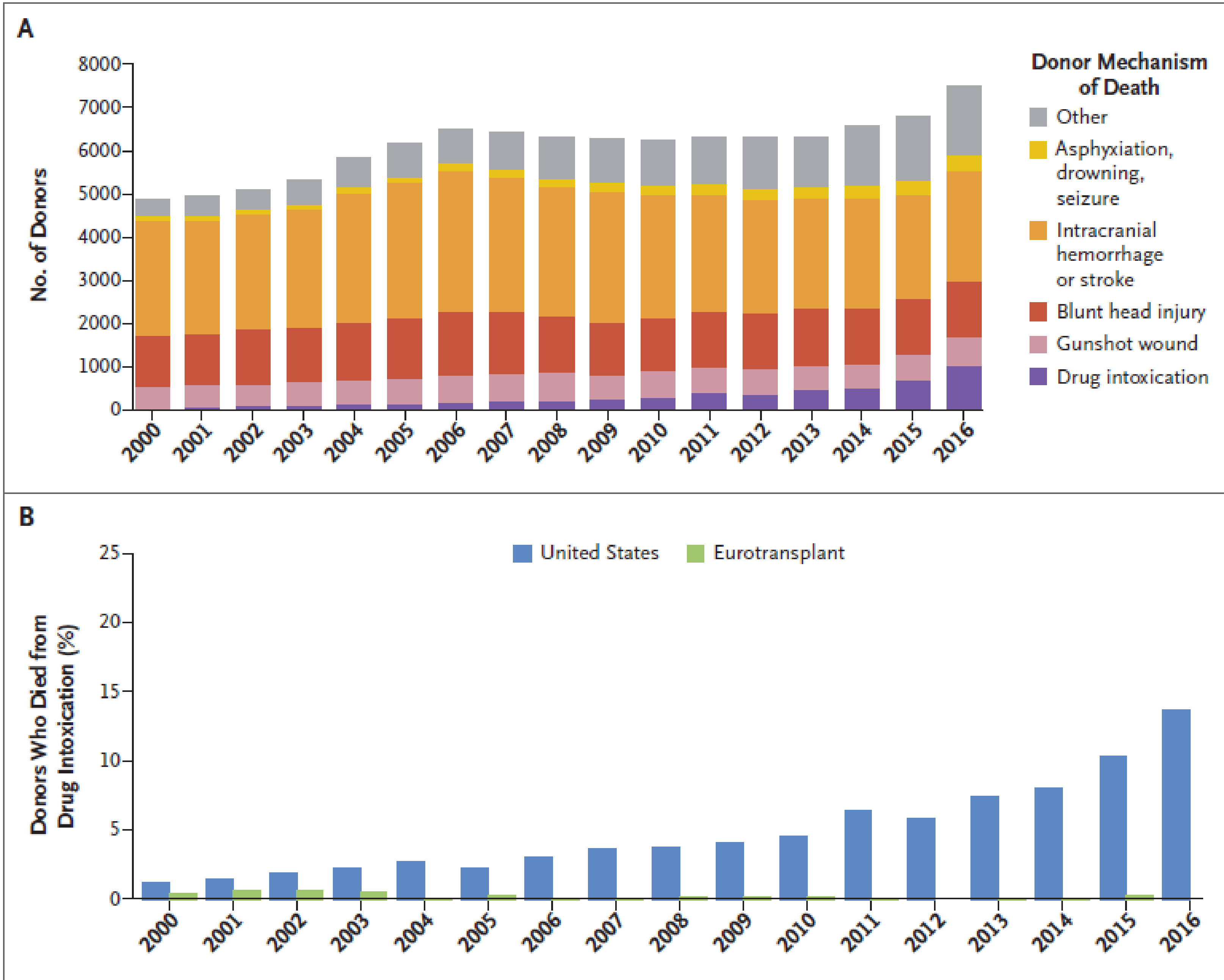
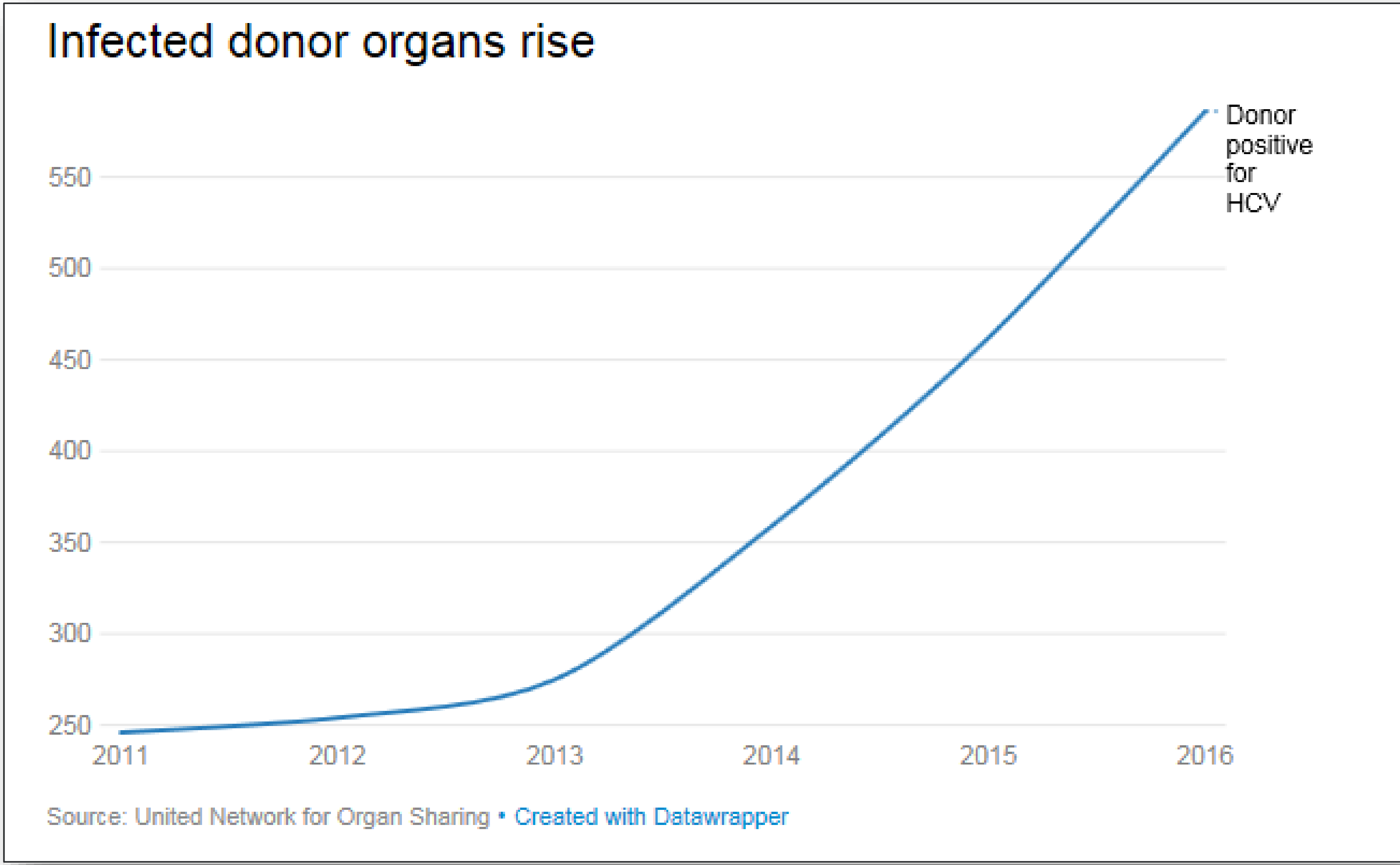


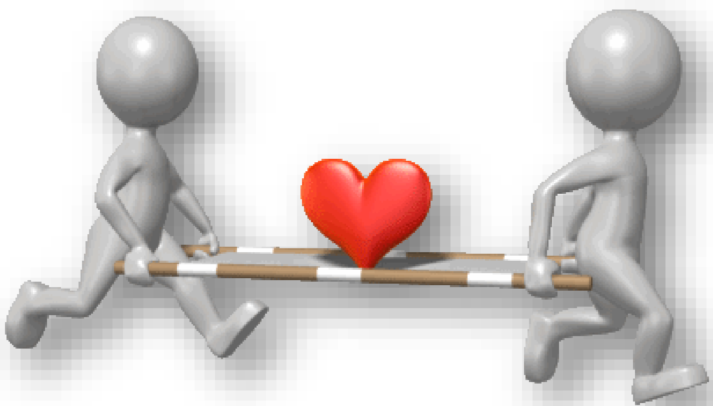
Fig. 1. Early post-transplantation viral kinetics and response to pangenotypic sofosbuvir-velpatasvir direct-acting anti–hepatitis C virus (HCV) therapy following cardiac donor–derived acute HCV genotype 3a transmission. Therapy was initiated on post-transplantation day 13.5 and continued through day 96. Day 0 = day of transplantation. Arrow indicates start of sofosbuvir (400 mg)–velpatasvir (100 mg) oral direct-acting antiviral therapy). Open circle = undetectable HCV titer (log 0 is undefined, placed at 0 on *y*-axis for clarity); solid circle = detectable viral titer but <15 IU/mL limit of quantification; diamond = quantifiable HCV titer. (Additional data not shown on graph are undetectable titers on post-transplantation days 52, 60, 67, 73, 81, 88, 104, 111, 117, 131, 139, 145, 153, 165, 173, 180, 188, 265, 299, 328, and 354).

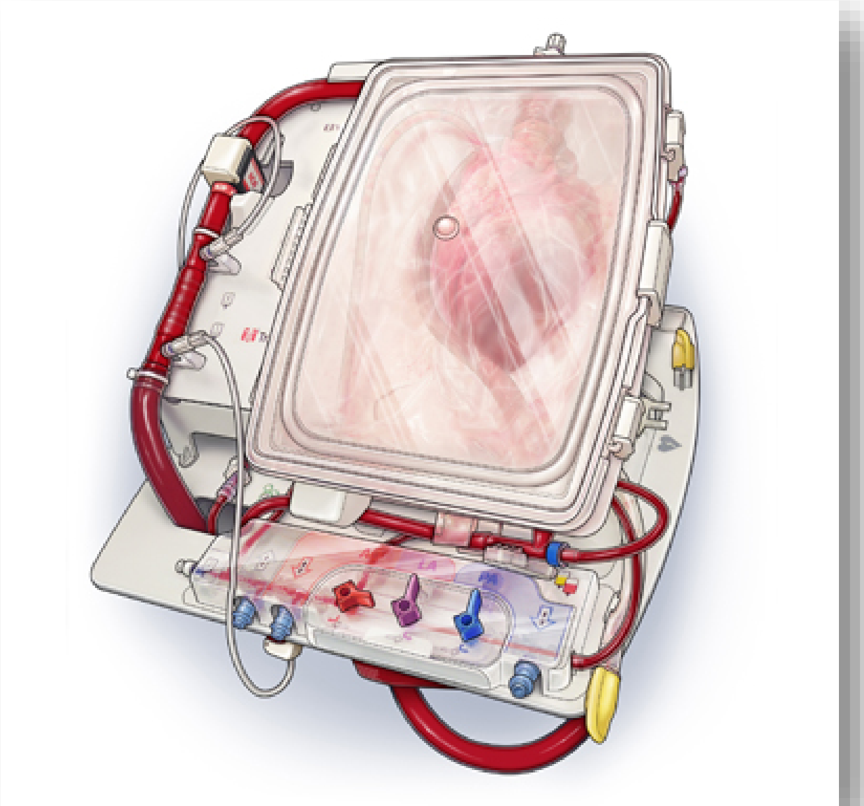

A
No. of Donors
8000
7000
6000
5000
4000
3000
2000
1000
0
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016
Donor Mechanism of Death
Other
Asphyxiation, drowning, seizure
Intracranial hemorrhage or stroke
Blunt head injury
Gunshot wound
Drug intoxication
B
United States
Eurotransplant
Donors Who Died from Drug Intoxication (%)
25
20
15
10
5
0
2000
2001
2002
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
2013
2014
2015
2016



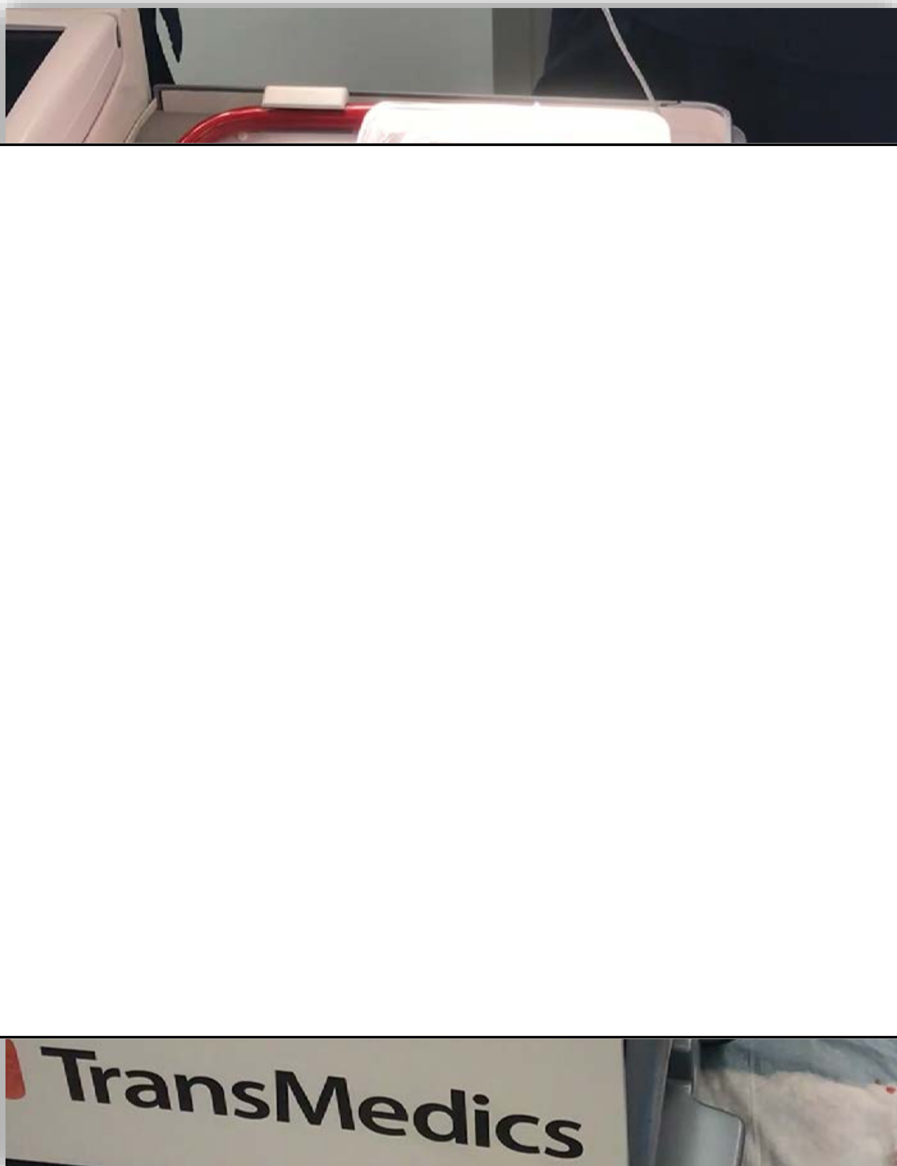
North Shore University Hospital
Northwell Health™

Donor Heart Preservation: Is There a Better Way?





Ex Vivo Heart Perfusion (Heart-in-a-Box)



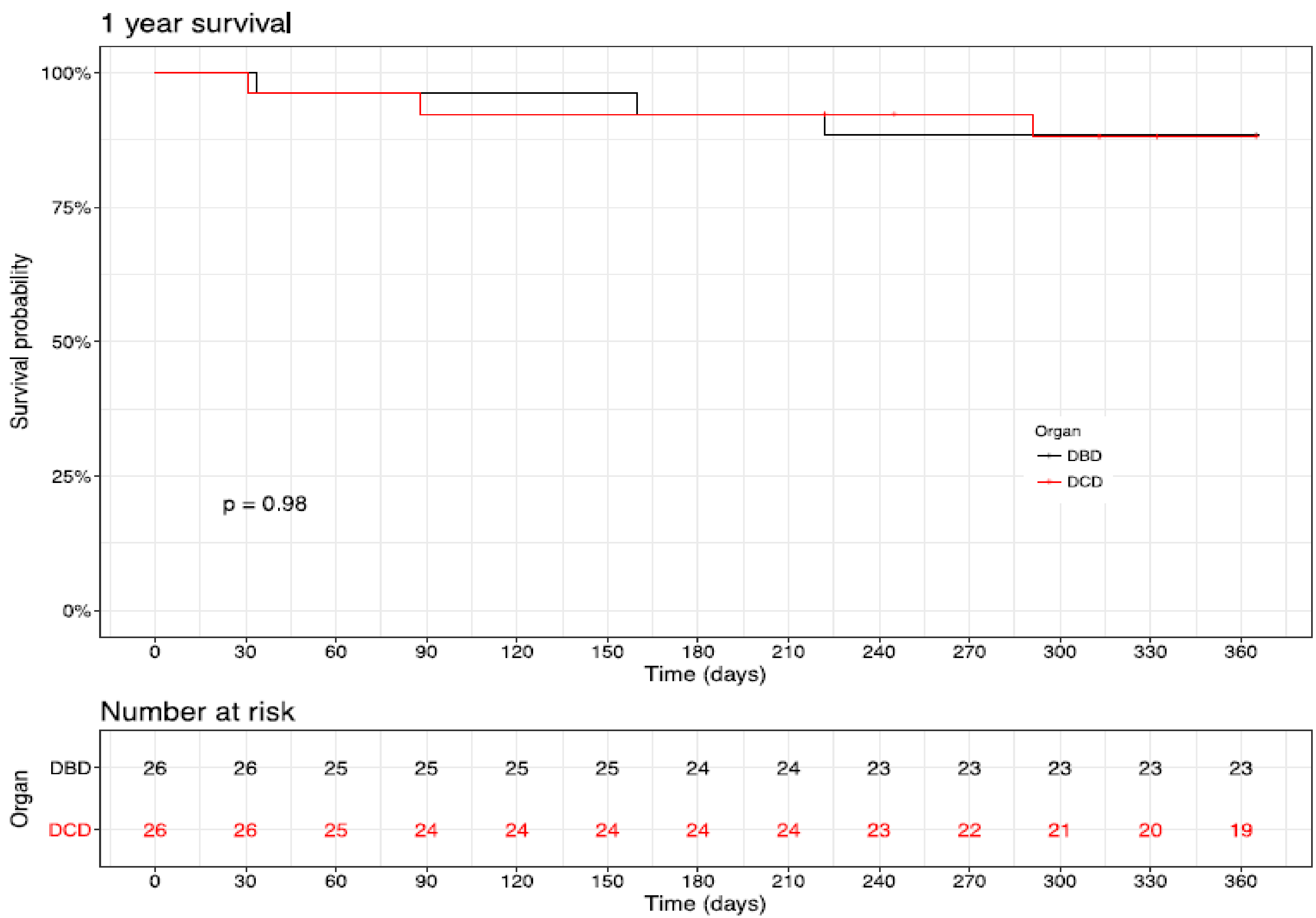
Theoretical advantages over cold ischemic storage:

- Allow extended "out of body" time
- Minimize myocardial injury
- Enable ex vivo donor heart assessment
  - "Extended Criteria" Donor Hearts
- Enable donation after cardac death (**DCD**)heart utilization
- **evice used in 7 countries, centers, with N > 200 nsplants**

SPECIAL FEATURE

Outcome after heart transplantation from donation after circulatory-determined death donors

The Journal of Heart and Lung Transplantation
2017



Conclusions

- Heart failure is a global epidemic
- HTx remains the gold standard of therapy
  - Limited by shortage of donor hearts
- New donor heart allocation policy may increase donation rates overall and eliminate geographic disparities
- Emergence of *ex vivo* heart perfusion may also broaden utilization of donor hearts, further enabling DCD HTx
- With new generative HCV therapies, HCV+ hearts may also be widely used

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