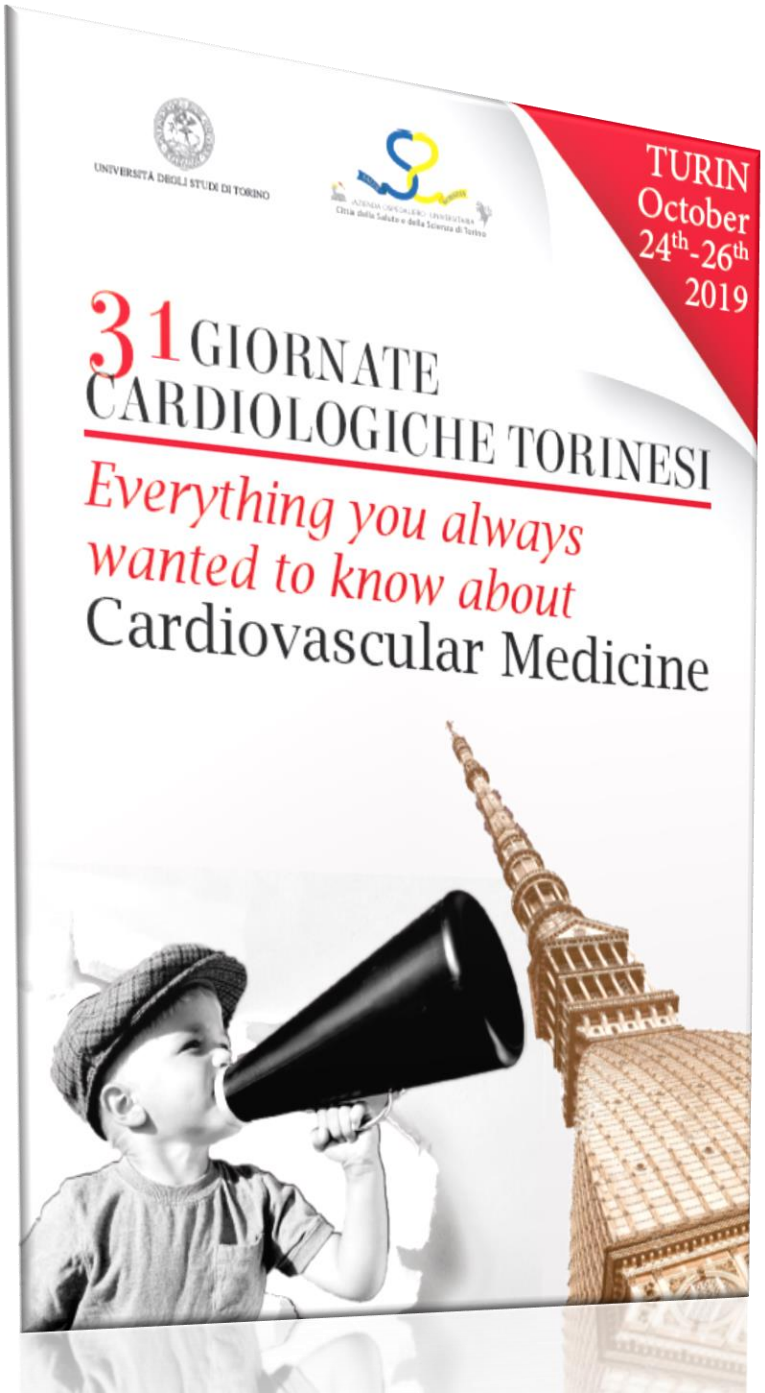


SISTEMA SANITARIO REGIONALE
AZIENDA OSPEDALIERA
SAN CAMILLO FORLANINI

Beating …. Artificial Heart Implantation

Current status of Artificial Heart

Francesco Musumeci MD, FECTS

Director Department of Cardivascular Medicine

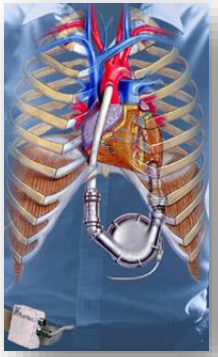
Director Cardiac Surgery and Transplantation

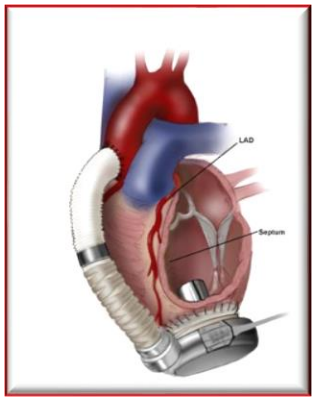
*San Camillo Hospital – **Rome, Italy***

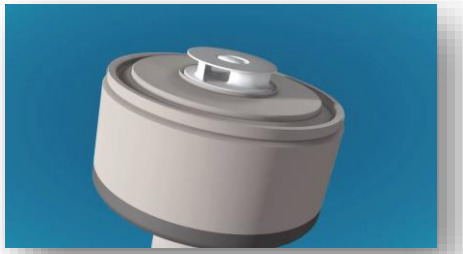
1966

DEBAKEY E LIOTTA

LVAD evolution



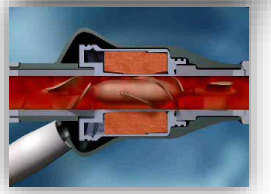




1° generation "volume displacement pump"

2° generation "continous flow rotary pump"

3° generation "FullMagnetic levitation"



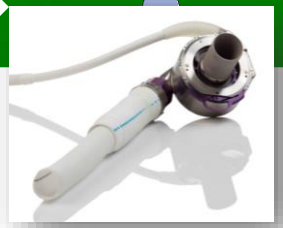
Ospedale S. Camillo Forlanini - Roma

HeartMate I

HeartMate II

HVAD HeartWare

HeartMate III



2002

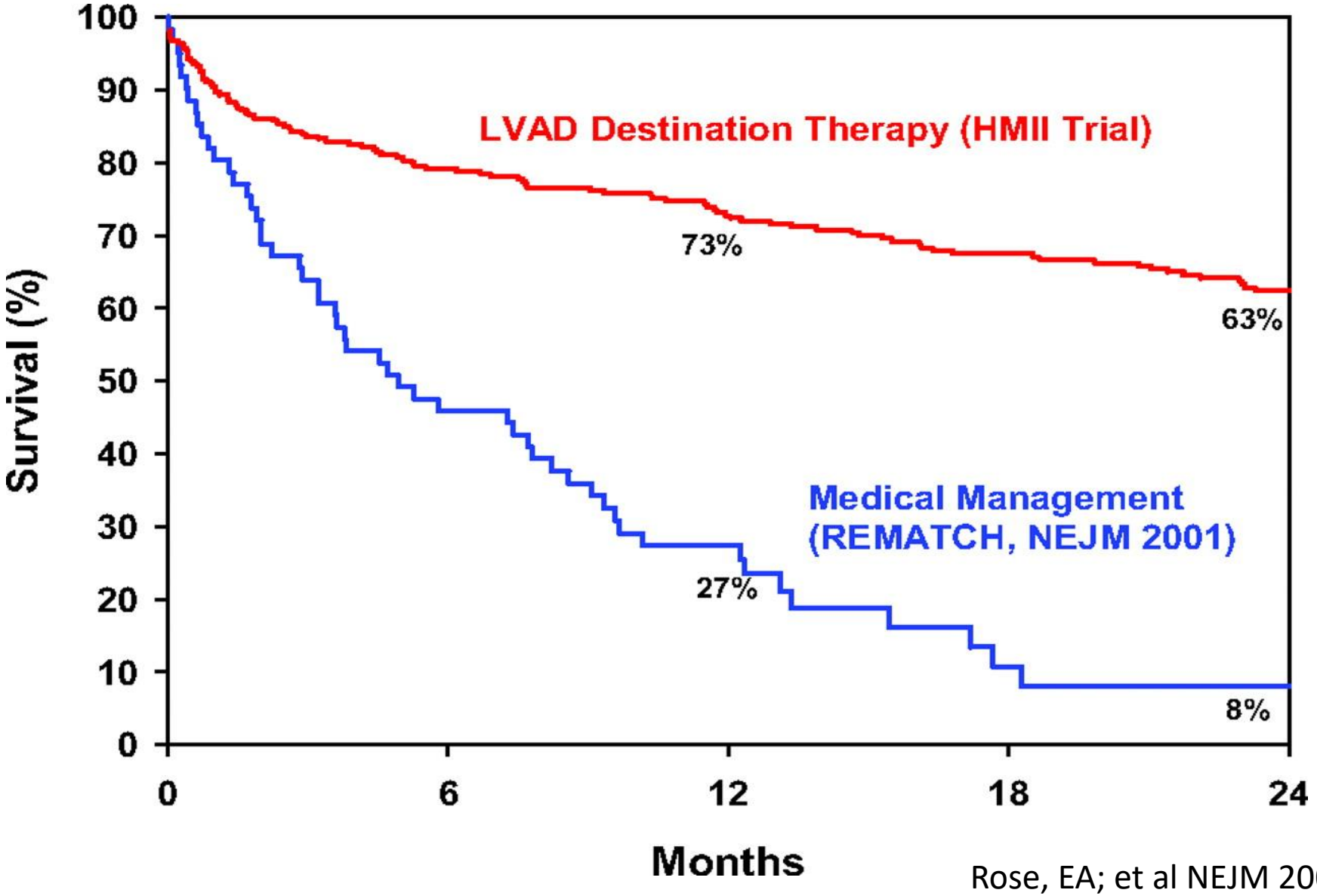
2005

2009

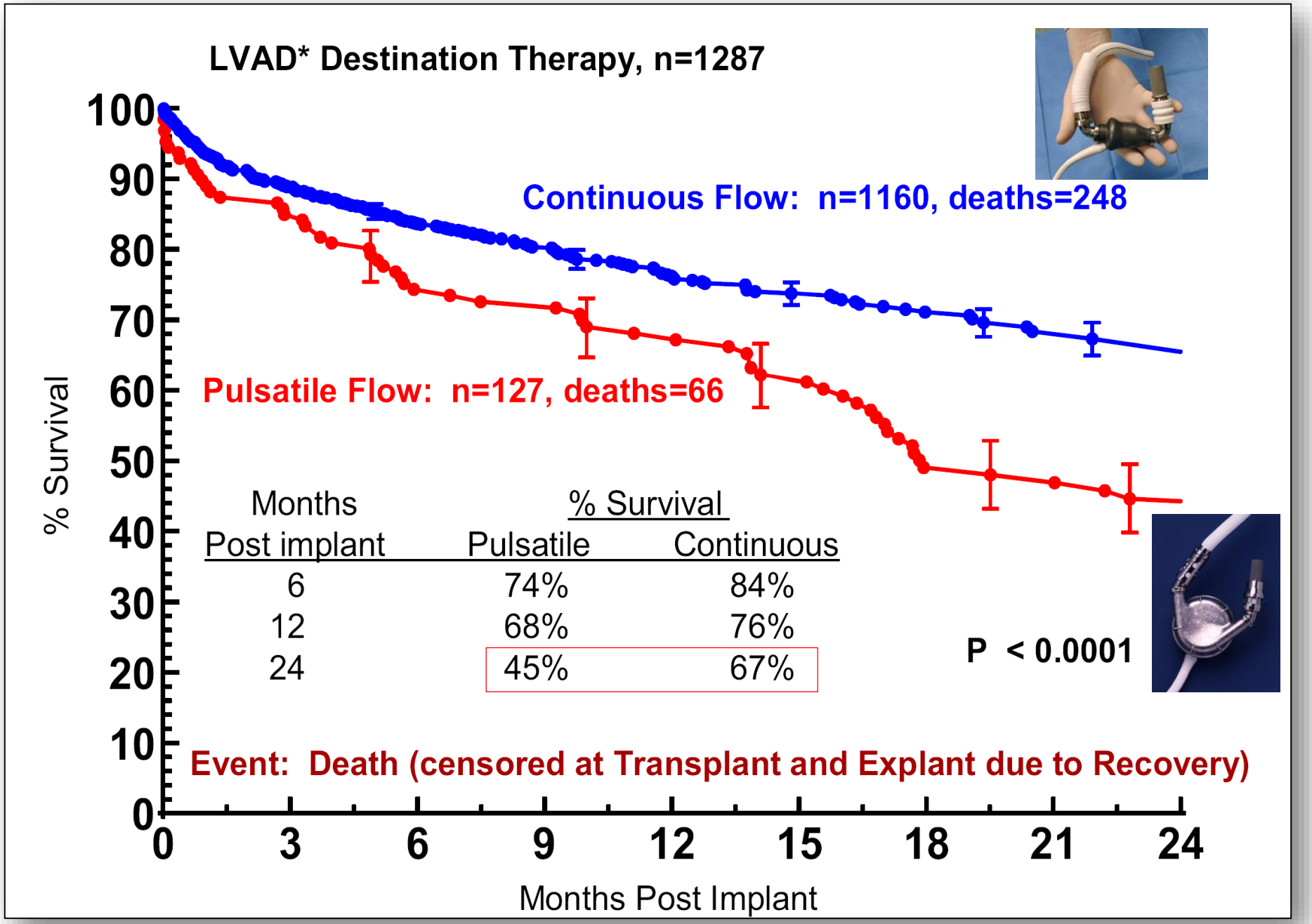
2013

2016

Medical Management vs. LVAD



Rose, EA; et al NEJM 2001

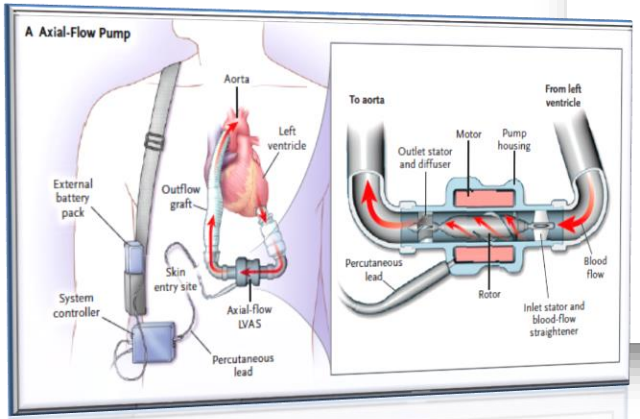


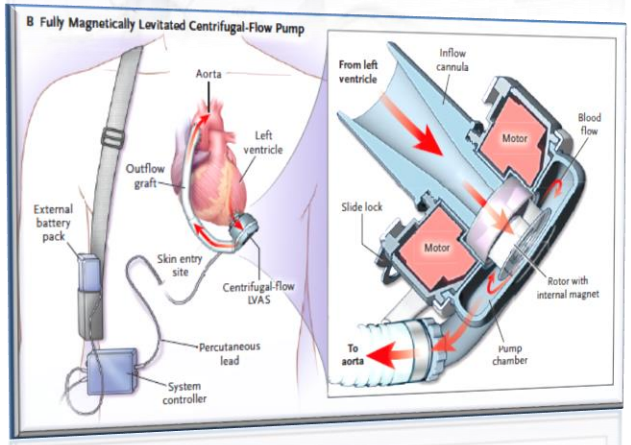
Kirklin JK. J Thorac Cardiovasc Surg 2012

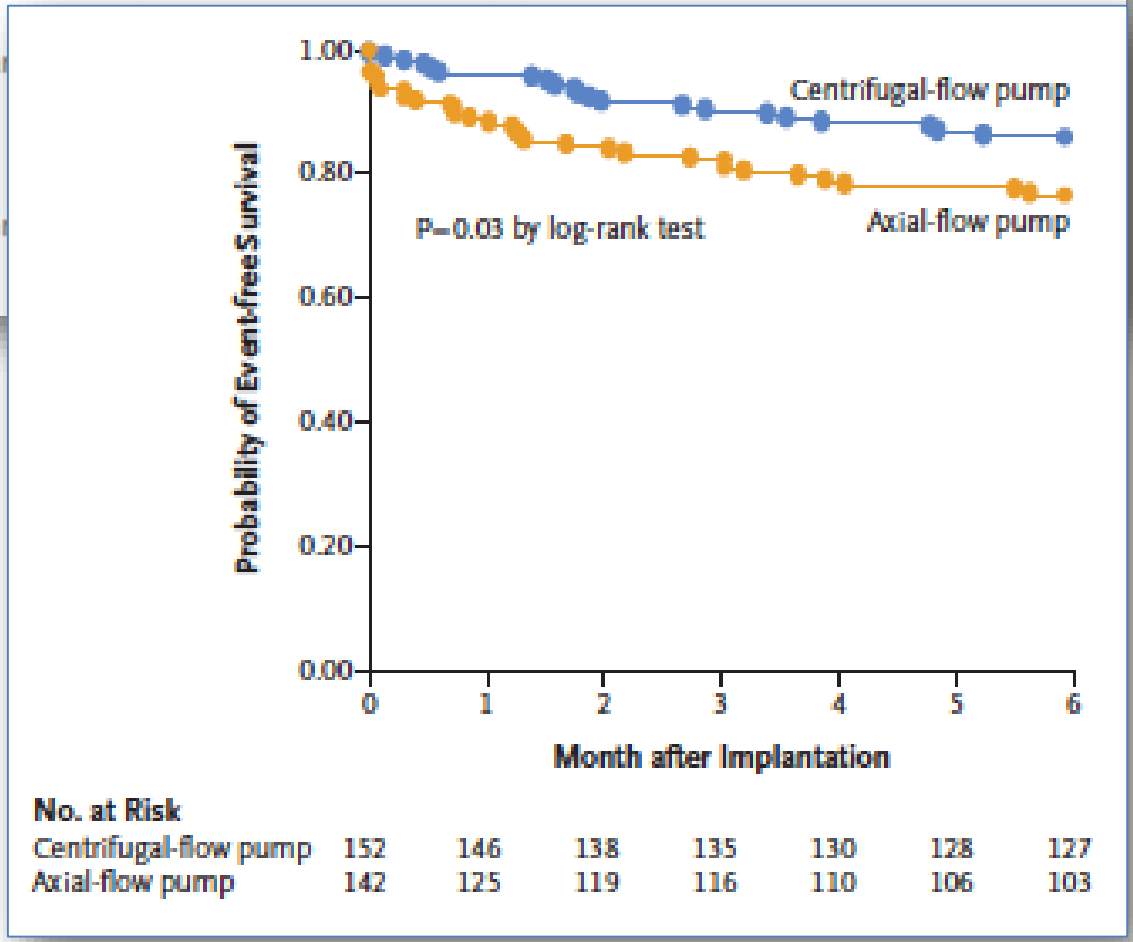
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Fully Magnetically Levitated Circulatory Pump for Advanced Heart Failure

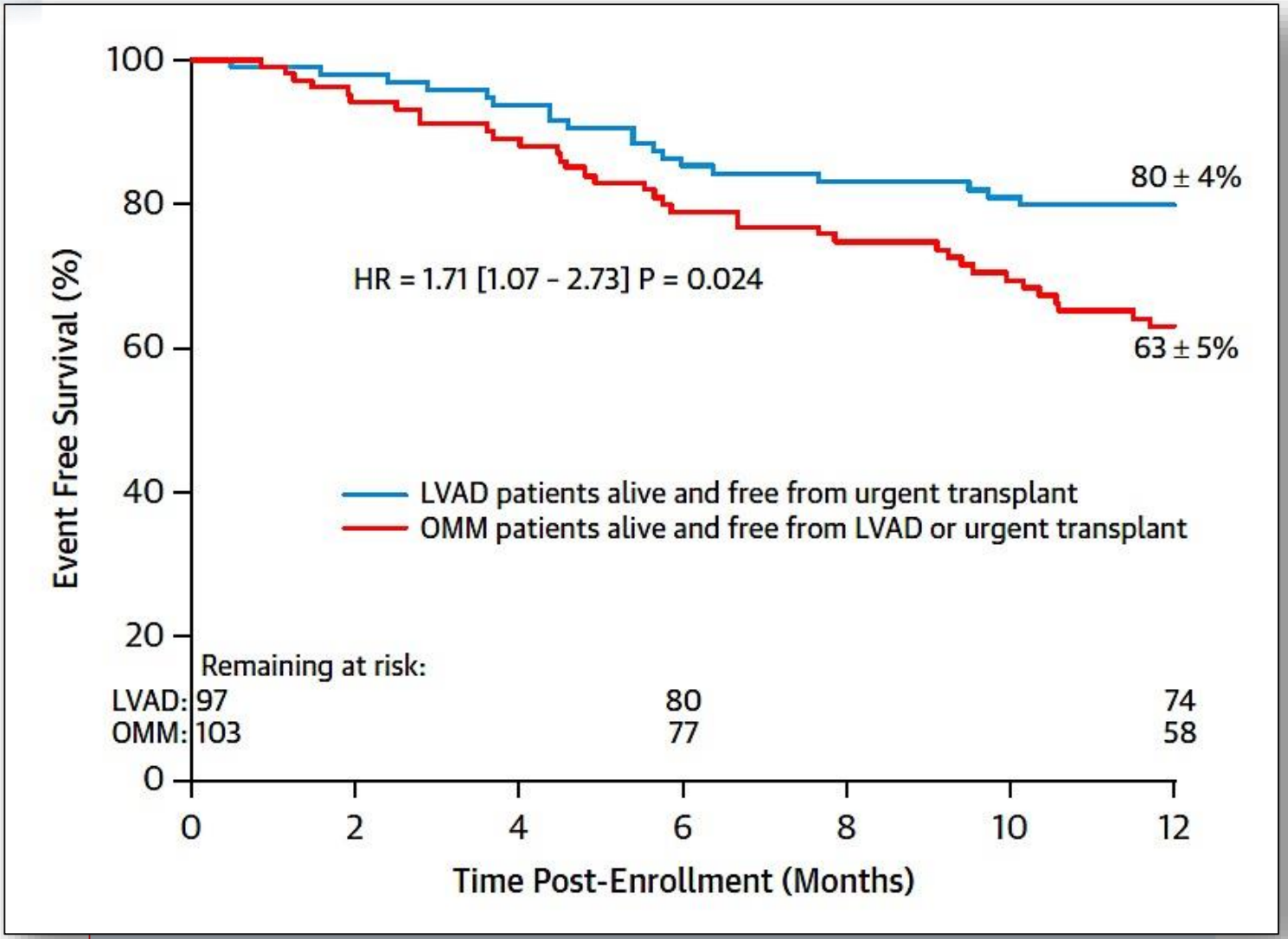






Risk Assessment and Comparative Effectiveness of Left Ventricular Assist Device and Medical Management in Ambulatory Heart Failure Patients

Results From the ROADMAP Study



LVAD Survival

ELSEVIER

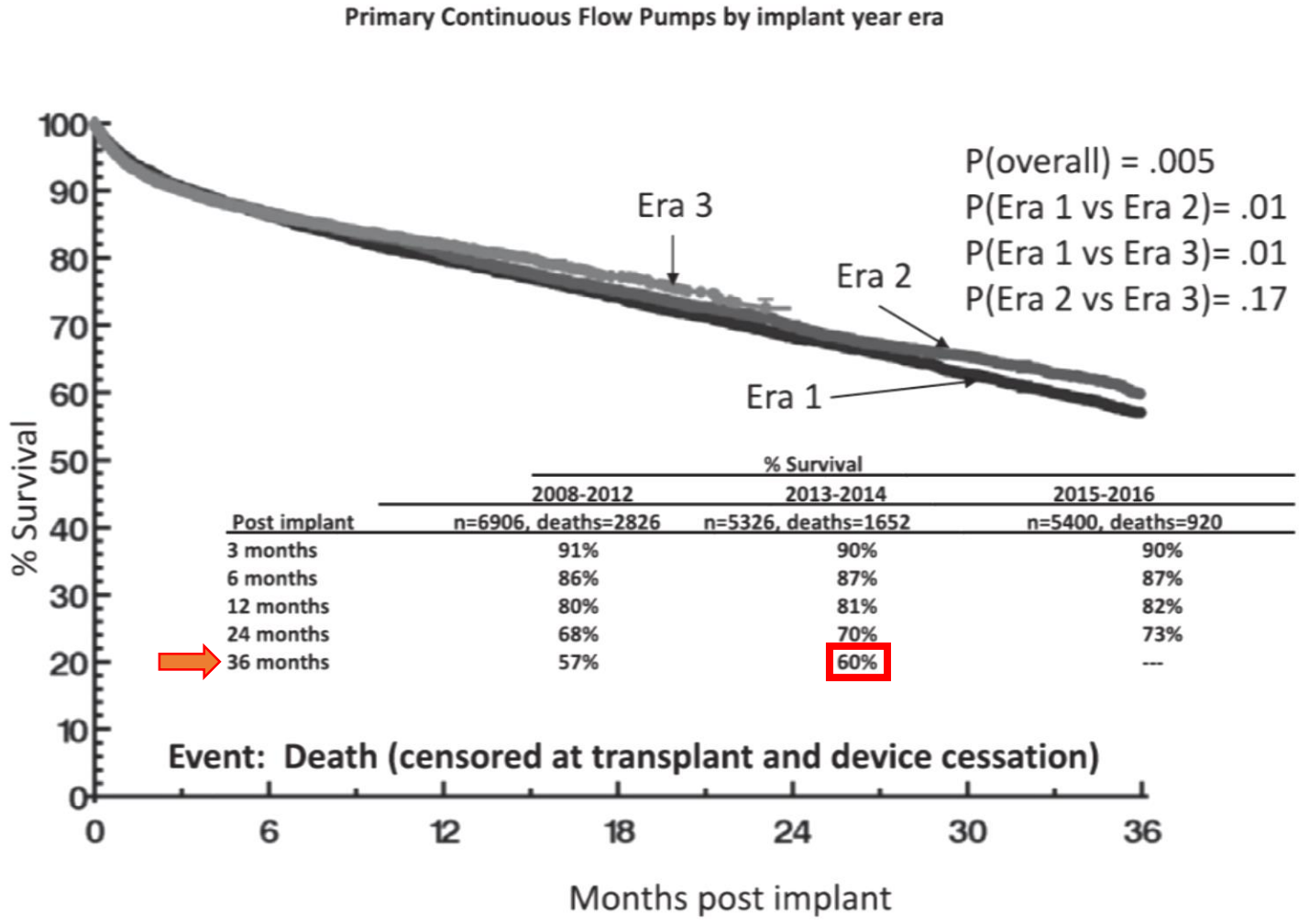
The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

2017 INTERMACS REPORT

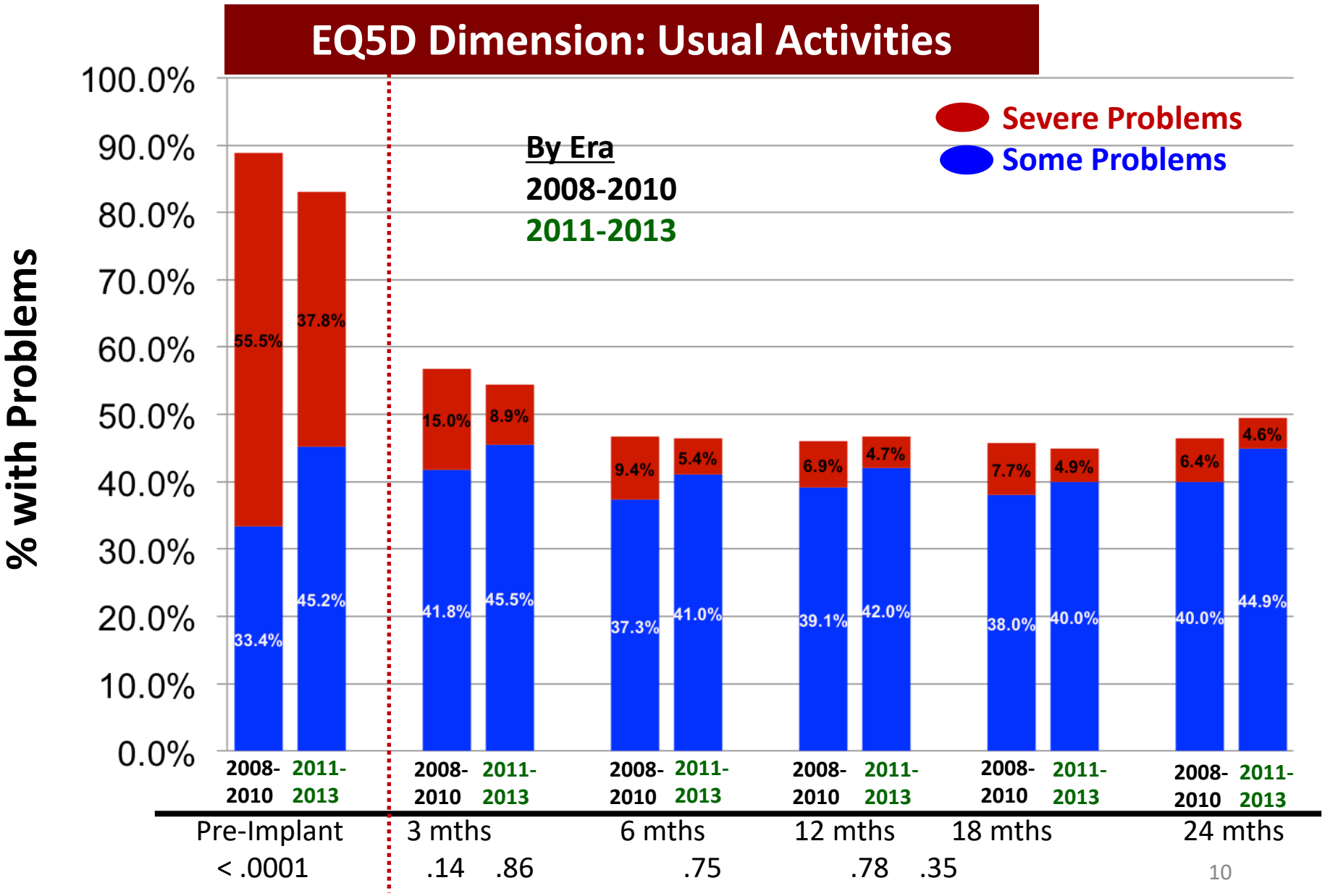
Eighth annual INTERMACS report: Special focus on framing the impact of adverse events

James K. K
Lynne W. S
Marissa A. I
David C. Na

*From the "Depa
Cardiac Surgery
Pittsburgh Medi
& Women's Hos
Massachusetts;
Lung, and Blood
College of Medi*

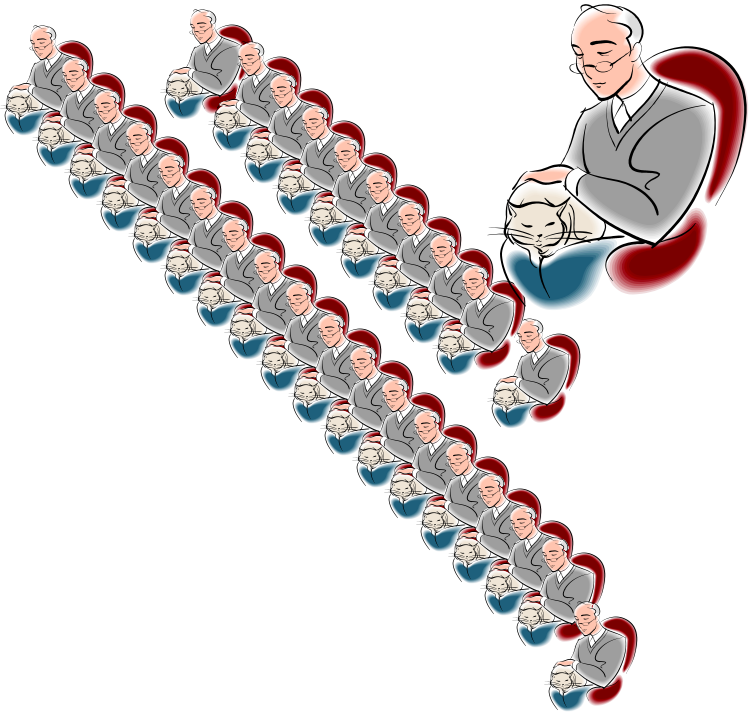


	% Survival		
	2008-2012	2013-2014	2015-2016
Post implant	n=6906, deaths=2826	n=5326, deaths=1652	n=5400, deaths=920
3 months	91%	90%	90%
6 months	86%	87%	87%
12 months	80%	81%	82%
24 months	68%	70%	73%
36 months	57%	60%	---

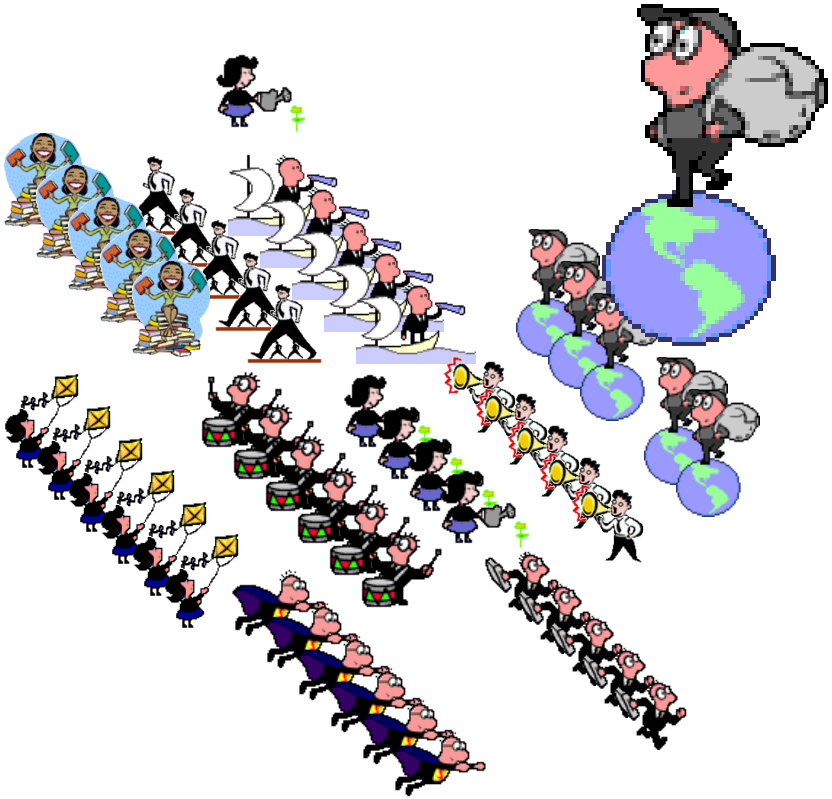

EQ5D Dimension: Usual Activities
Severe Problems
Some Problems
By Era
2008-2010
2011-2013
% with Problems
100.0%
90.0%
80.0%
70.0%
60.0%
50.0%
40.0%
30.0%
20.0%
10.0%
0.0%
55.5%
33.4%
37.8%
45.2%
15.0%
41.8%
8.9%
45.5%
9.4%
37.3%
5.4%
41.0%
6.9%
39.1%
4.7%
42.0%
7.7%
38.0%
4.9%
40.0%
6.4%
40.0%
4.6%
44.9%
2008-2010
2011-2013
Pre-Implant
3 mths
6 mths
12 mths
18 mths
24 mths
< .0001
.14
.86
.75
.78
.35

Long Term MCS

Maximize functional capacity and quality of life



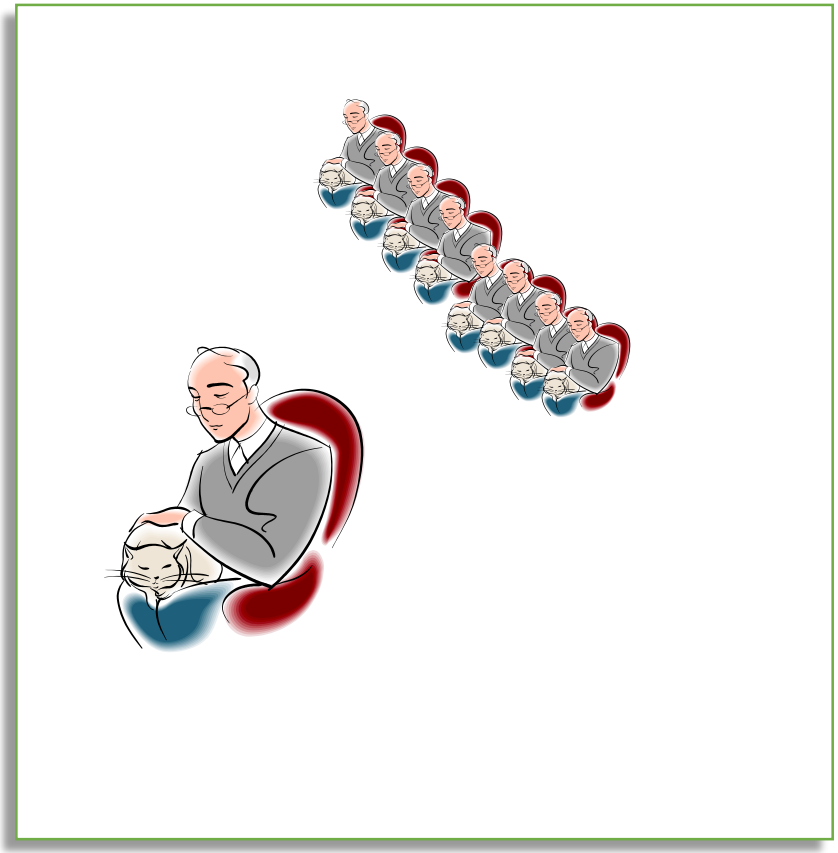
- OMT Therapy Group

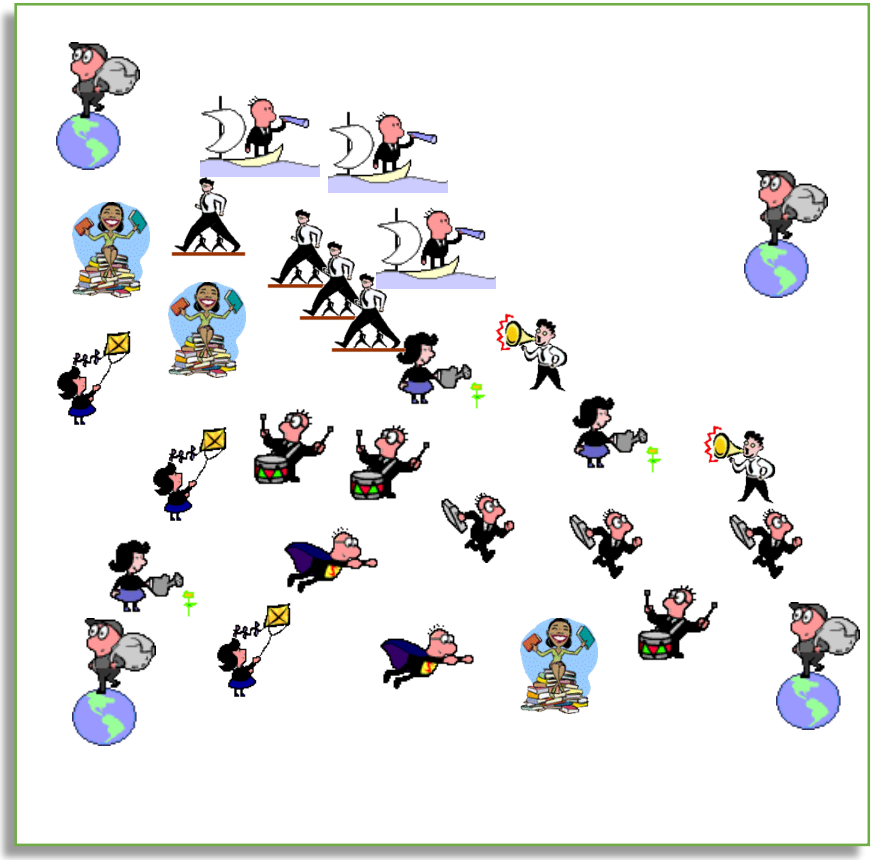


- VAD Therapy Group

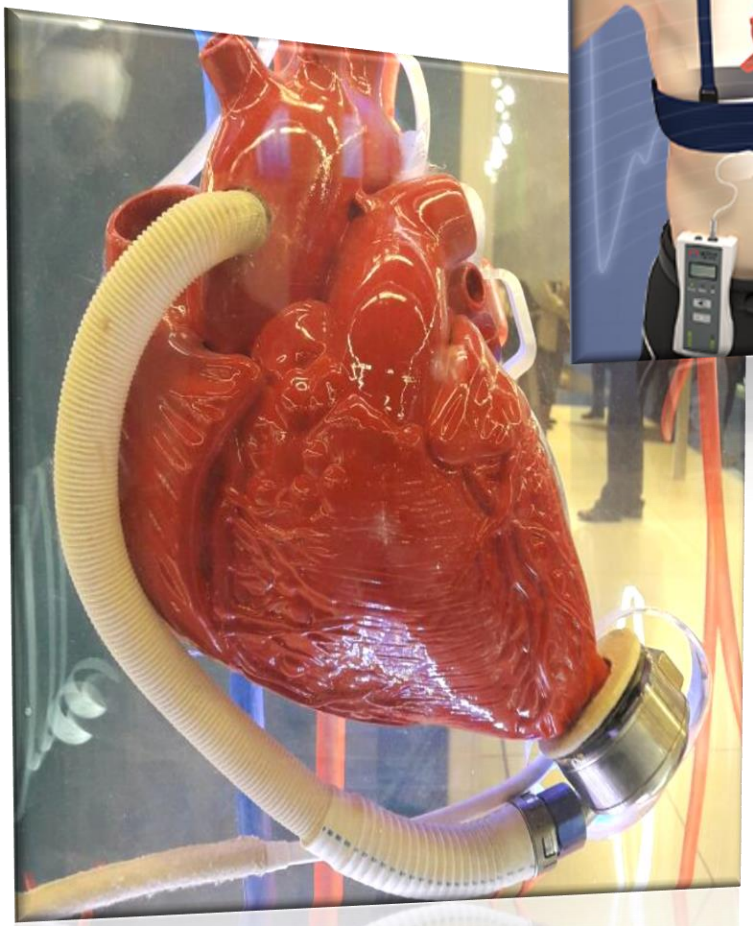
Long Term MCS

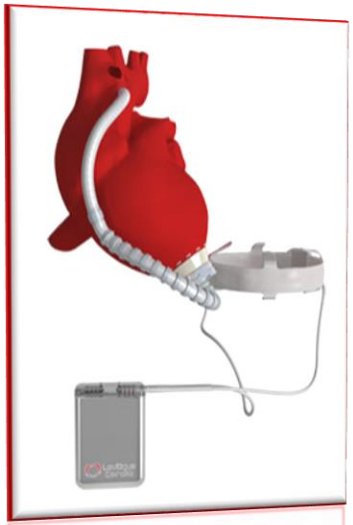
Decrease mortality associated with advanced heart failure

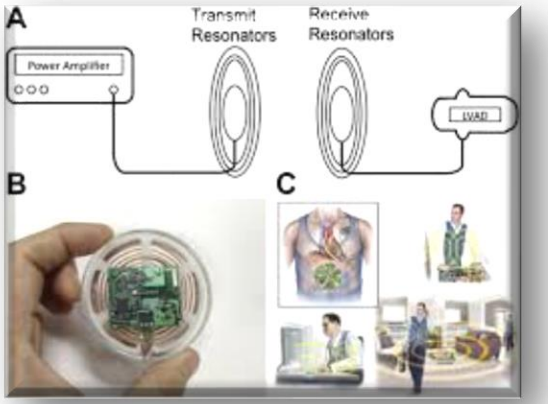


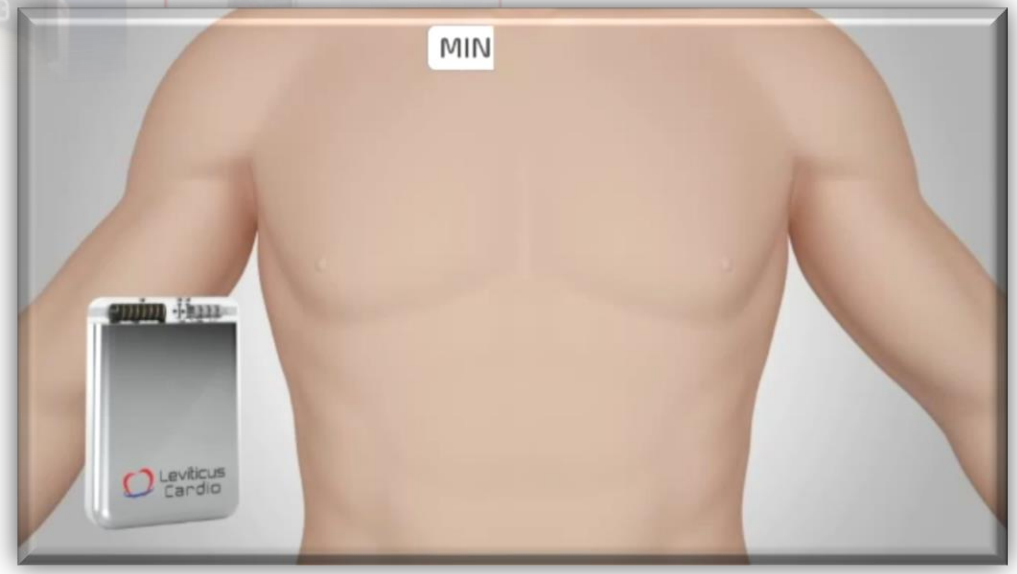


Transcutaneous LVAD energy

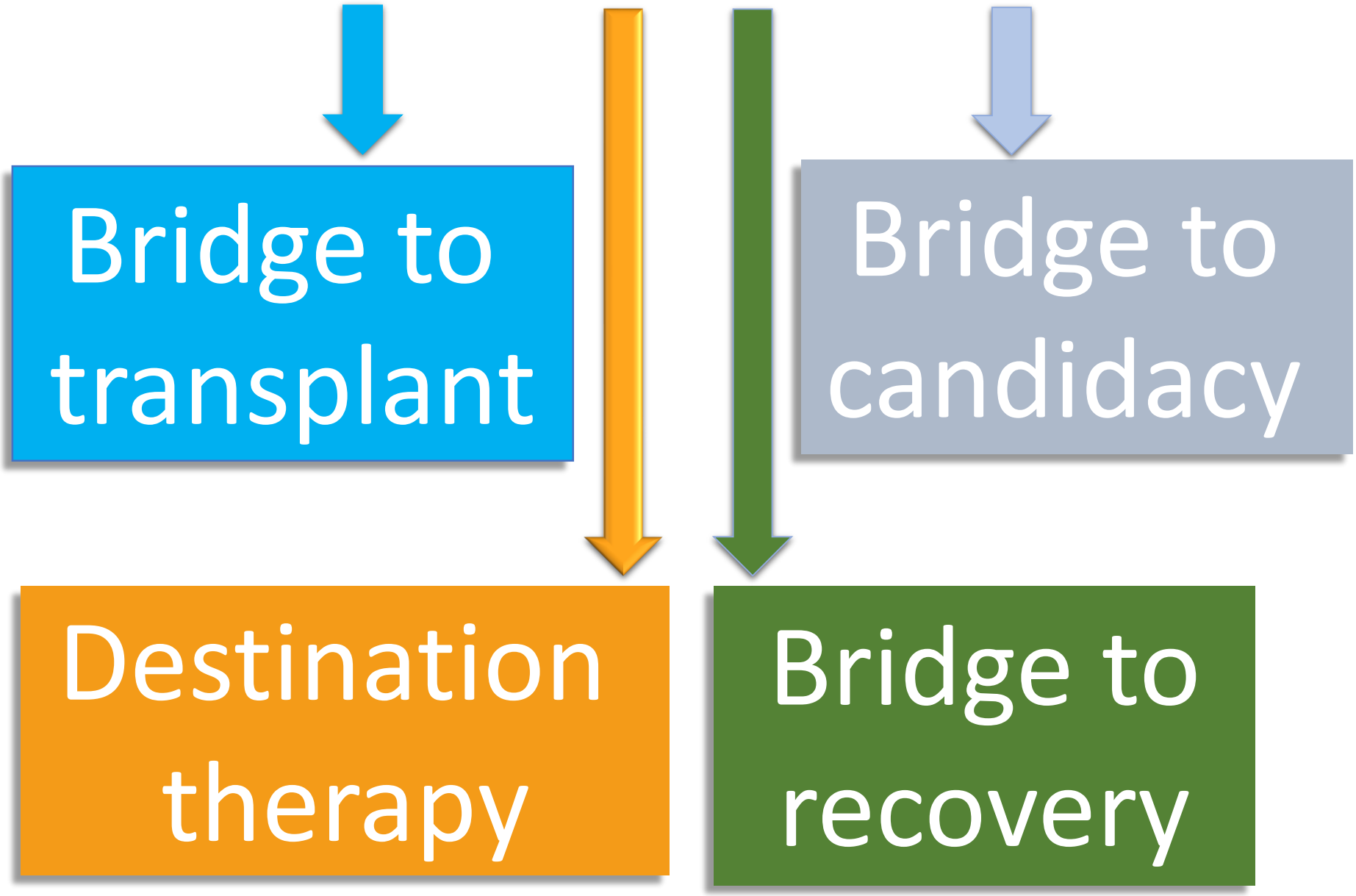








Long Term MCS



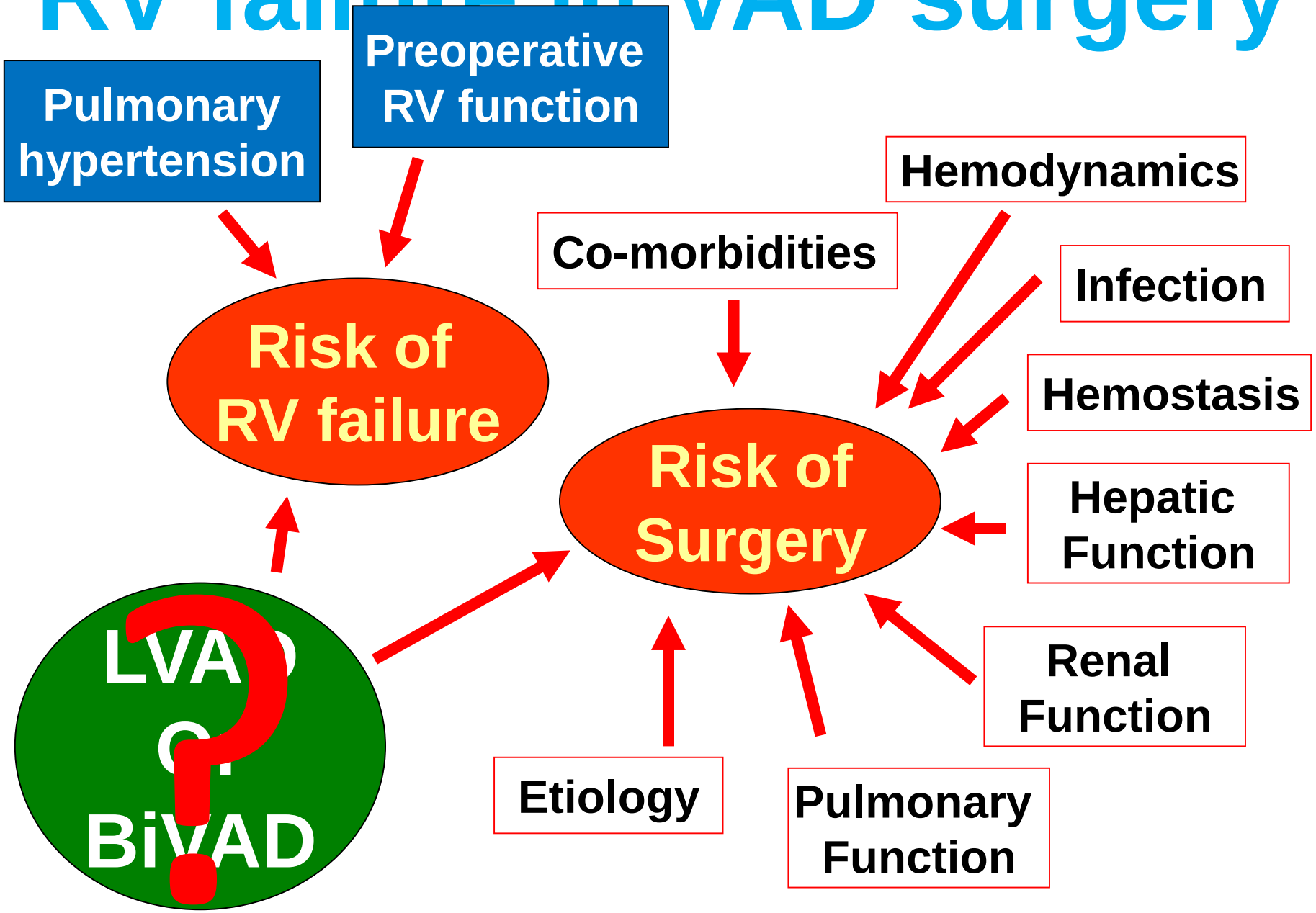
Total Artificial Heart

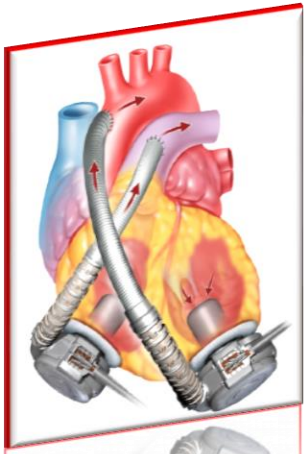
- When is indicated?
- What is available today for clinical use?

When LVAD?
When BiVAD/THA?

Key decision when assessing patients for VAD indication. Right ventricular failure during LVAD support is correlated with increased morbidity and mortality.

RV failure in VAD surgery





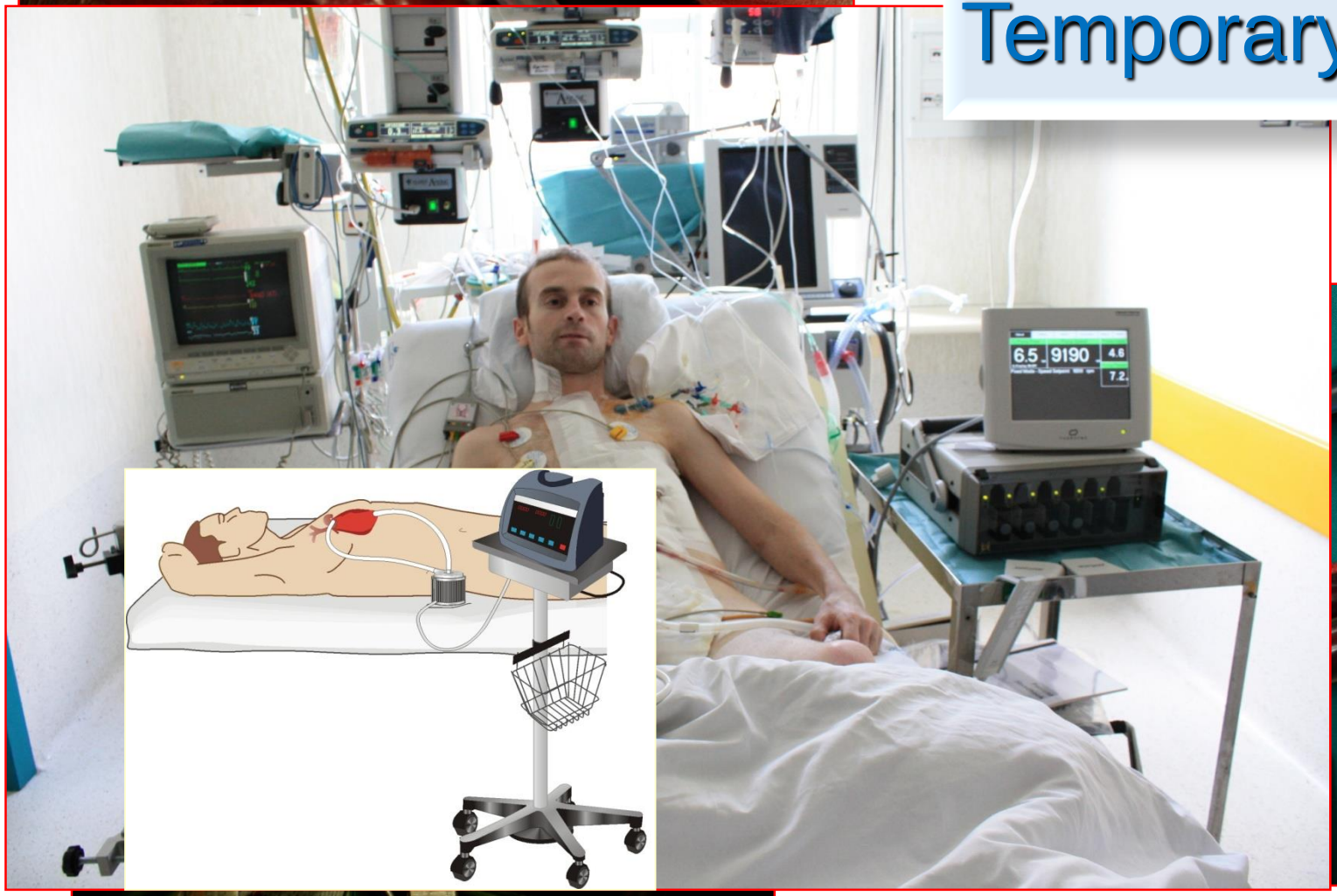
LV + RV disfunction

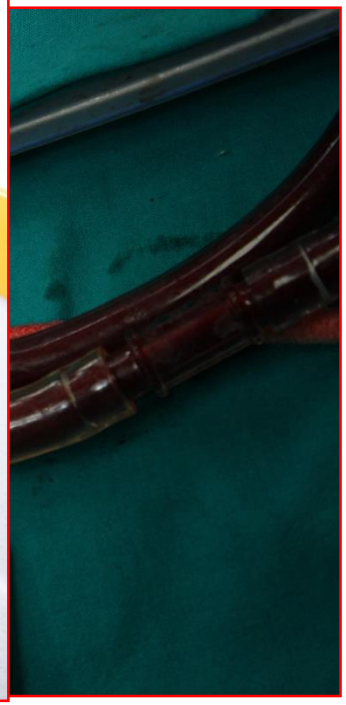
S. Camillo protocol

- LVAD + temporary right ventricular support
- Total Artificial Heart
- Bi-Ventricular support

LVAD + temporary RVAD

LVAD and
Temporary RVAD

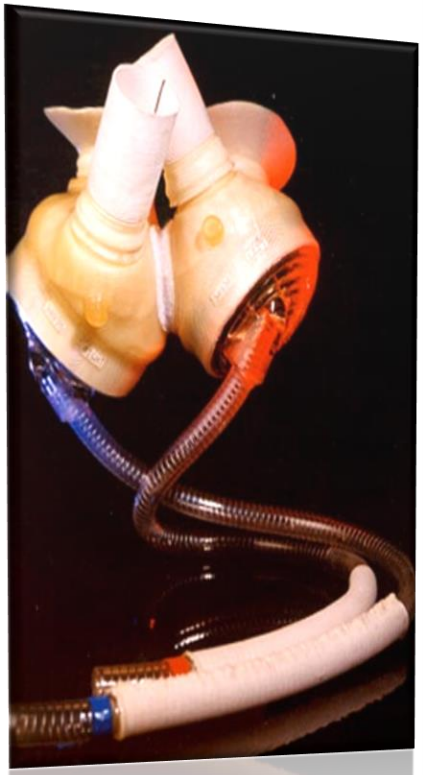




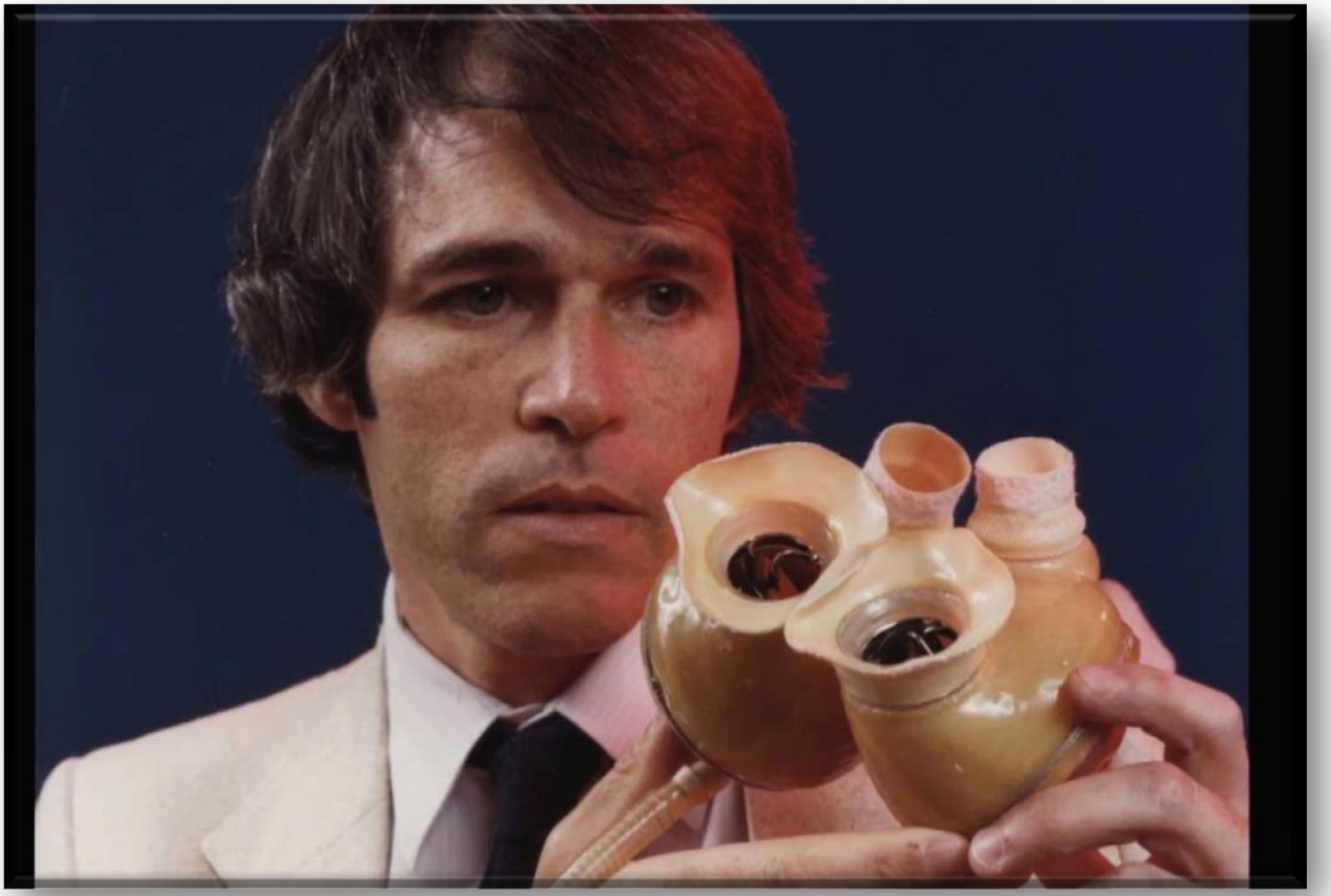
Clinical Criteria for BiVAD/TAH

- **Biventricular failure with pronounced RV failure**
  - *high CVP, low PAP, peripheral edema, seveve TR*
- **Profound cardiogenic shock with MOF**
  - ***renal failure*** *(oliguria and/or increase of creatinine)*
  - ***hepatic failure*** *(increase of bilirubin and GPT /GOT)*
  - ***lung failure*** *(edema, need for mechanical ventilation)*
  - *acidosis*
  - *high doses of inotropes*
  - *MAP < 60 mmHg*
- **Severe ventricular arrhythmia**

Total Artificial Heart
Jarvik 7

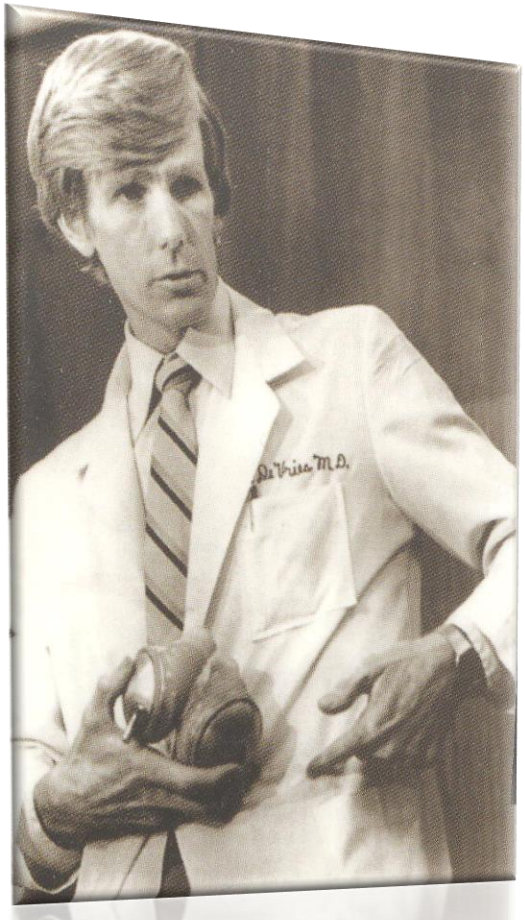


1981

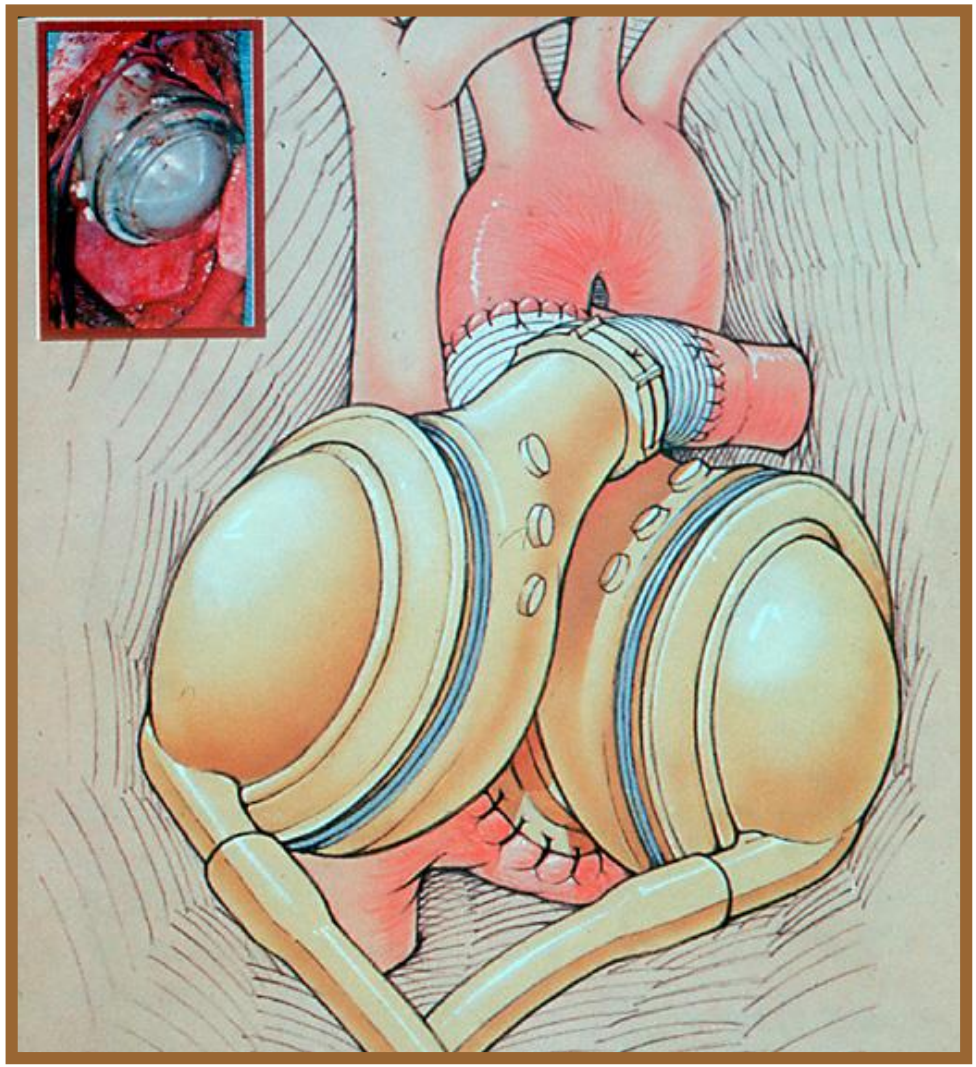


Total Artificial Heart Jarvik 7

First Implant 1982

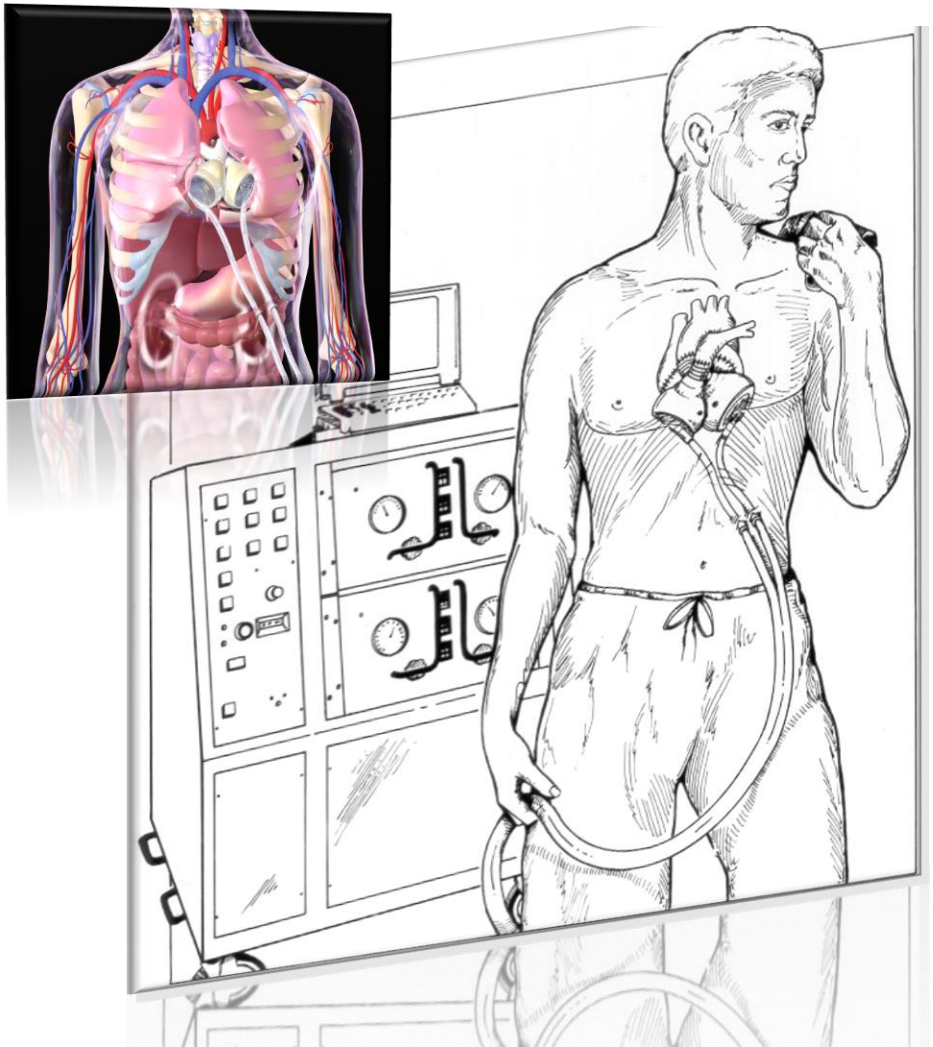


W. Devries

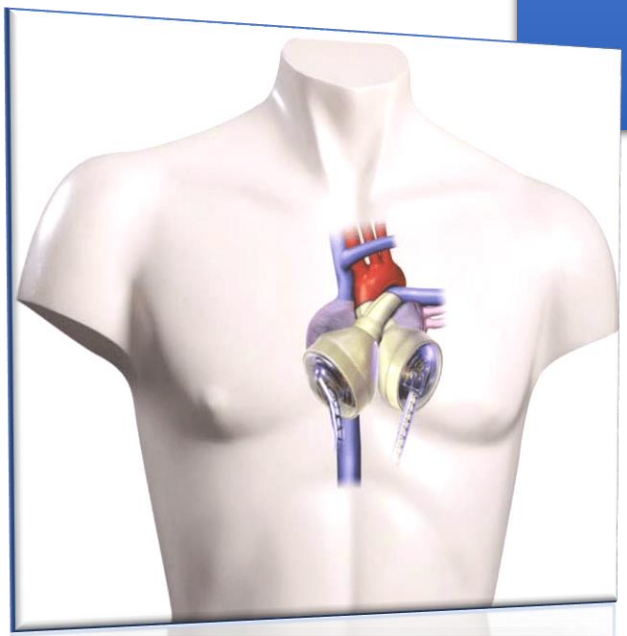


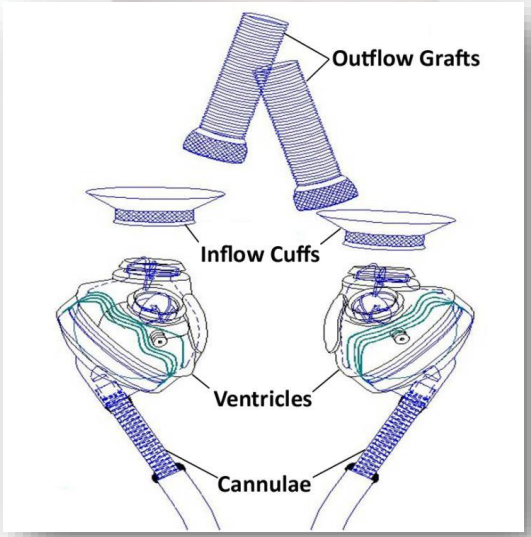
CardioWest

Total Artificial Heart



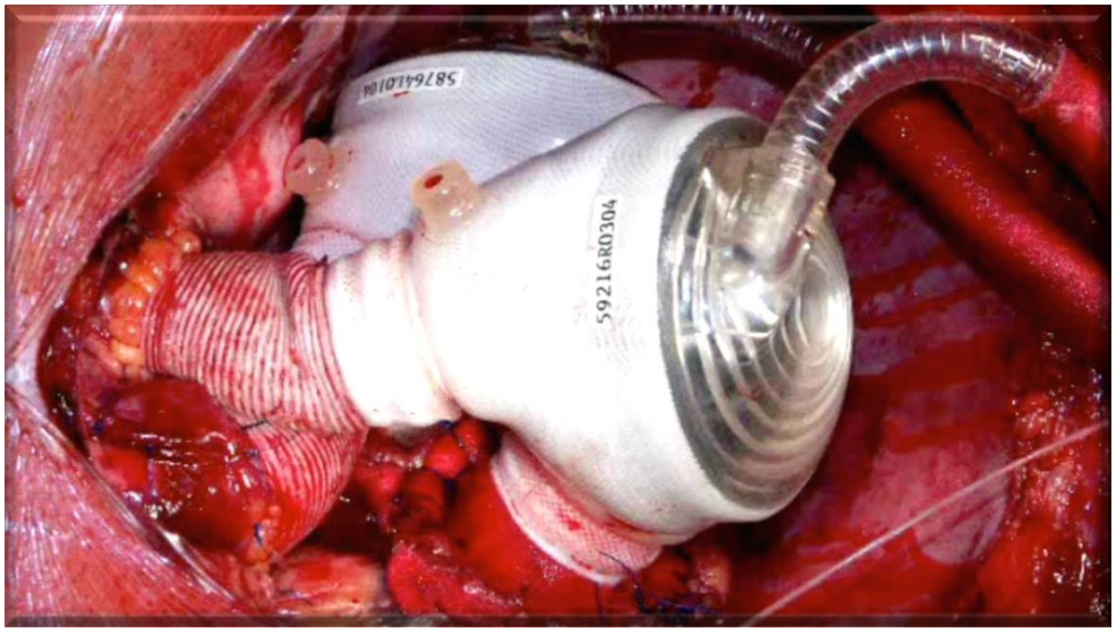
CardioWest
Total Artificial Heart



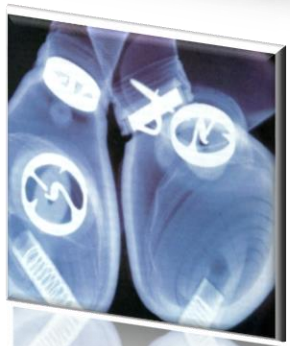


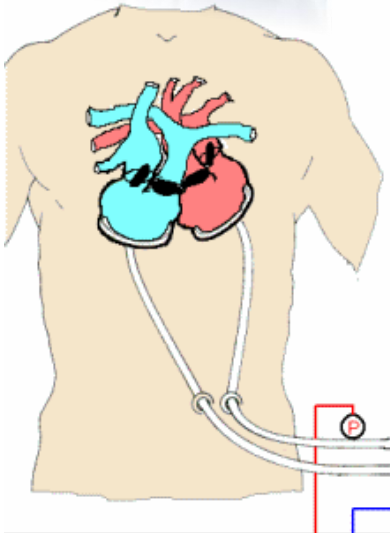
- Occupies space of diseased heart
  - Displaces 400 ml
  - Weighs 160 grams
- Blood flow path same as normal heart
- Adjustable ventricle orientation
- No surgical pocket required

CardioWest Total Artificial Heart



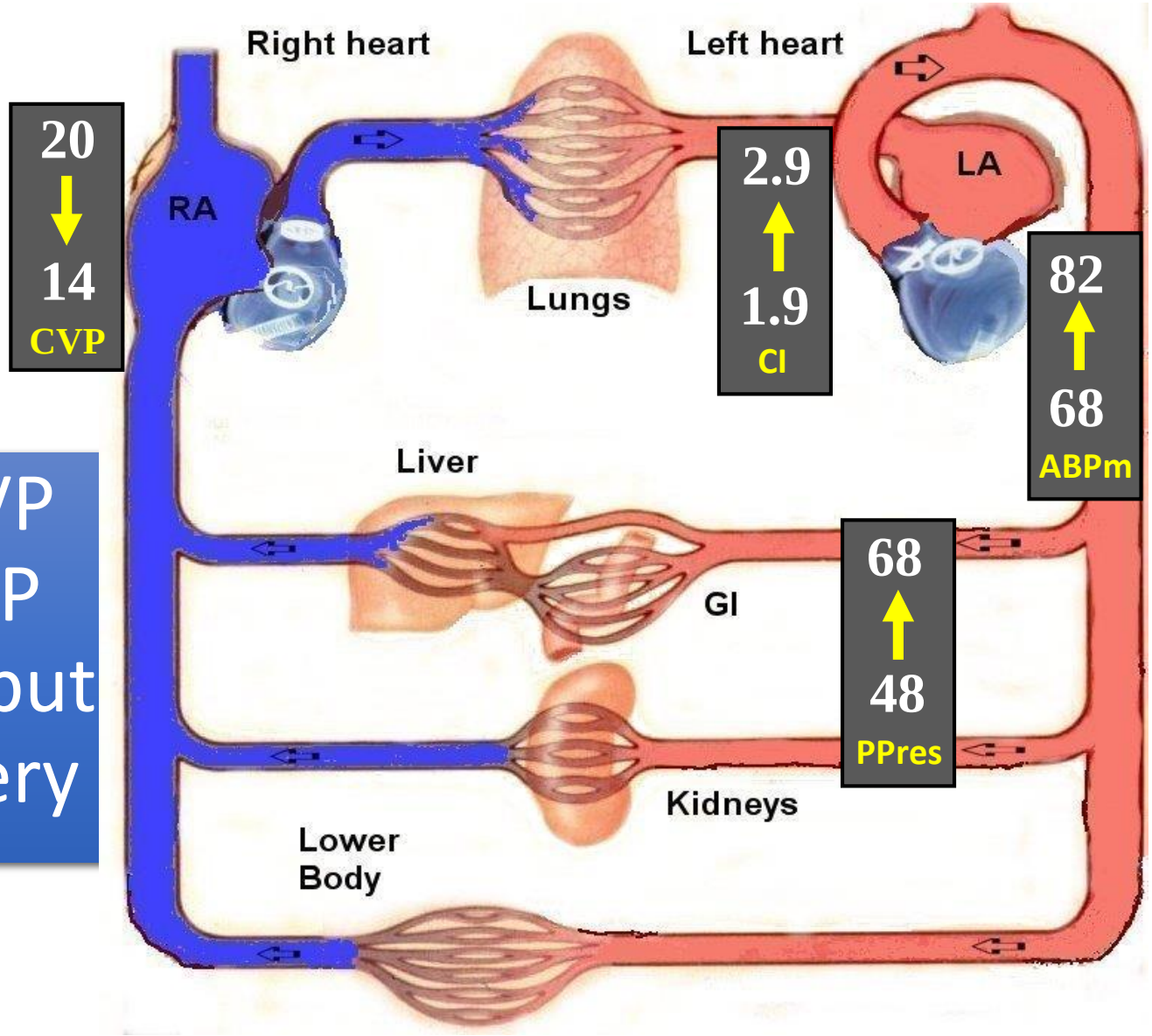
CardioWest
Total Artificial Heart





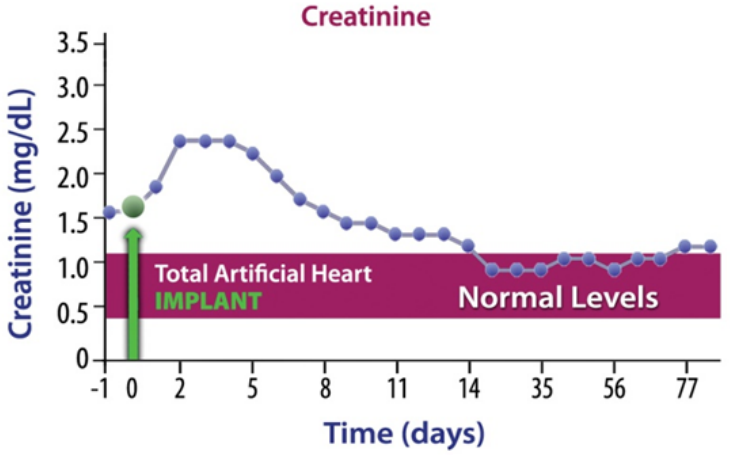
TAH Advantages

- Decreased CVP
- Overcome PAP
- ↑Cardiac Output
- Organ Recovery

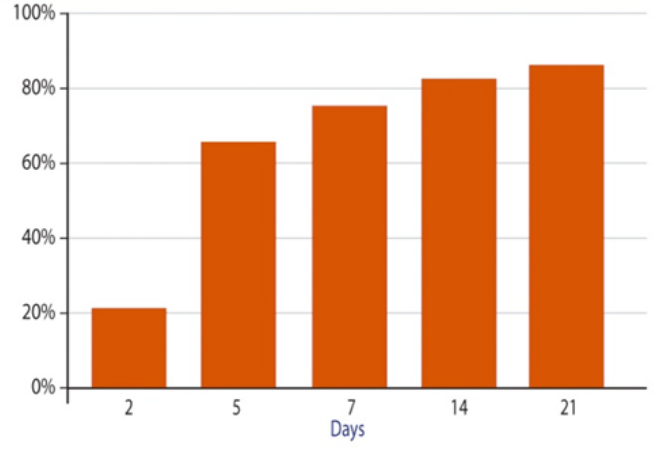


TAH Advantages: Recovery

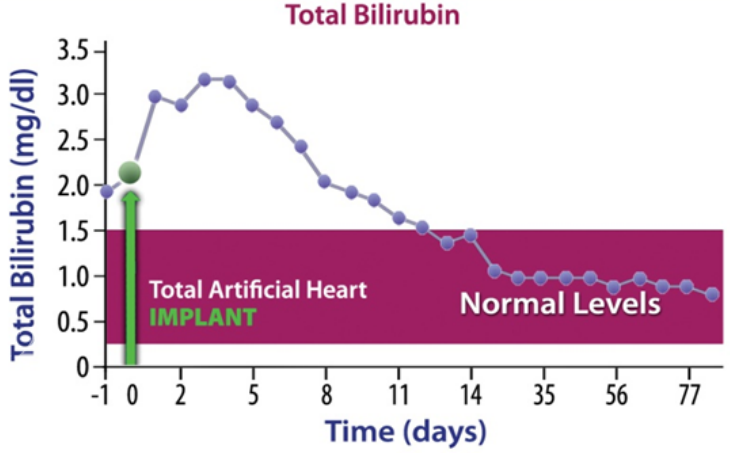
KIDNEY FUNCTION



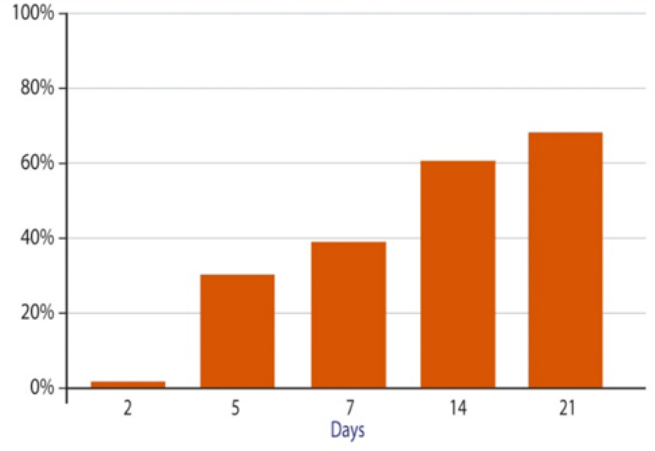
ABLE TO GET OUT OF BED



LIVER FUNCTION



ABLE TO WALK > 100 FT



CardioWest

Total Artificial Heart

MOST COMMON PRE-IMPLANT ETIOLOGIES*

as of December 2017

Idiopathic Dilated Cardiomyopathy	Ischemic Cardiomyopathy	Congenital and Genetic Conditions	Post-Heart Transplant Graft Failure
560+ Cases	470+ Cases	125+ Cases	110 Cases

CardioWest
Total Artificial Heart

BRIDGE TO TRANSPLANT (BTT) OR DESTINATION THERAPY (DT)?

BTT (APPROVED INDICATION)

- ✔ At risk of imminent death from biventricular heart failure
- ✔ Transplant-eligible

DT (APPROVED INDICATION)

- ✔ Life-threatening, irreversible biventricular heart failure (INTERMACS Profile 1-4)
- ✔ Ineligible for transplant and unlikely to become eligible in the future (e.g., contraindication to immunosuppression, cancer, elevated PRAs)

NEWS | JANUARY 30, 2015

FDA Approves Study of SynCardia Total Artificial Heart for Destination Therapy

19 patients not eligible for donor heart transplant will participate in the clinical study to evaluate the SynCardia Total Artificial Heart for permanent use

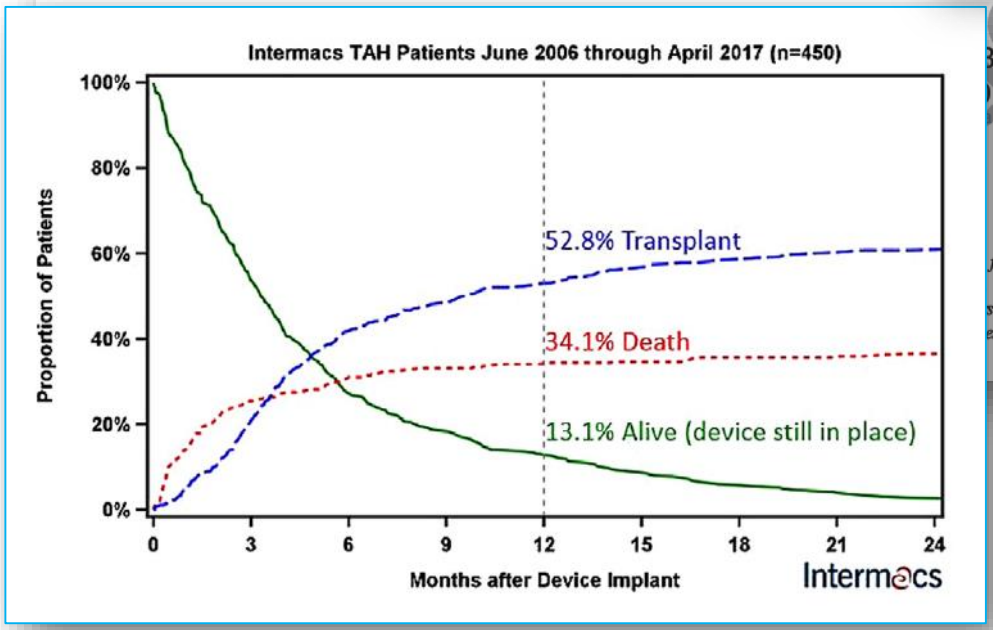
Risk factor for Death

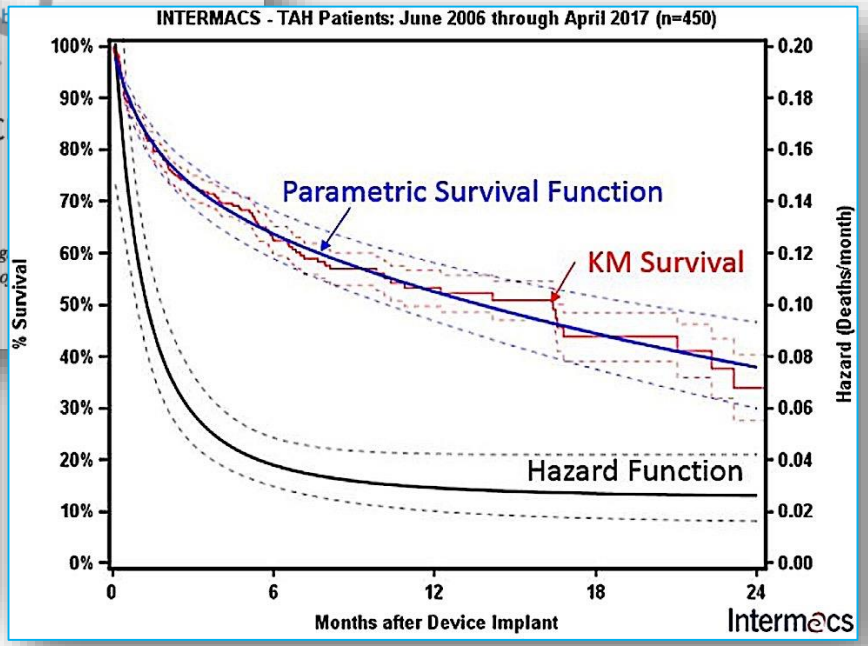
ELSEVIER

FEATURED PAPERS

Interagency registry for mechanically assist circulatory support report on the total artificial heart

Pre-Implant Risk Factor for Death	Early hazard HR	Early hazard *p*-value	Constant hazard HR	Constant hazard *p*-value
Age, year (older)[a]	1.6	0.001		
Pre-implant dialysis	2.5	0.006		
Creatinine (higher)			1.3	0.008
Albumin, g/dl (lower)[b]			1.9	<0.001
Total center TAH volume ≤10			3.0	<0.001



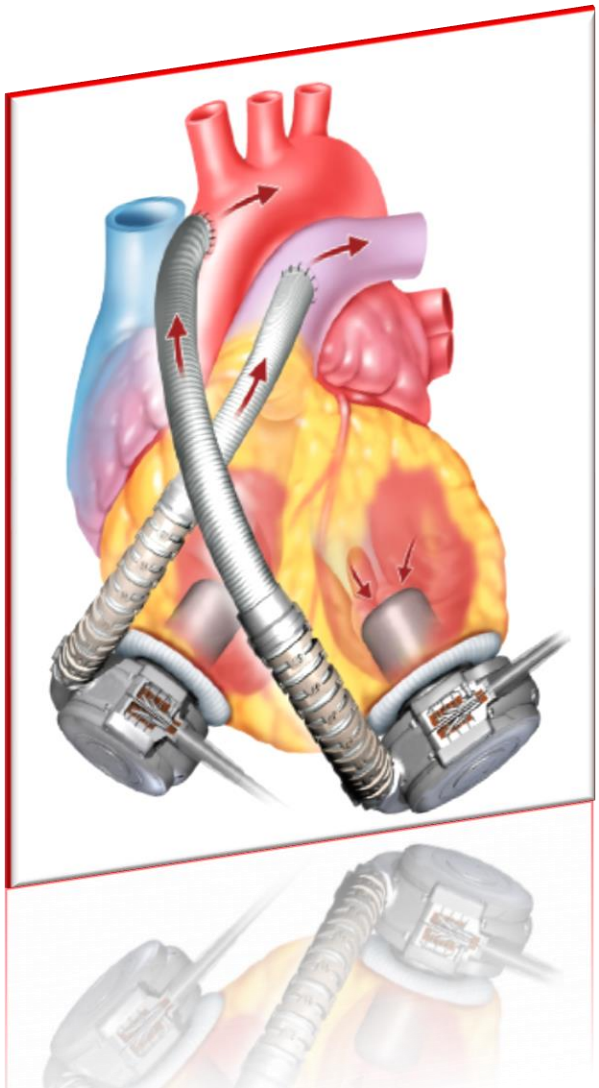


Transplantation 53%, mortality 34%, 13% alive on a device by 12 months

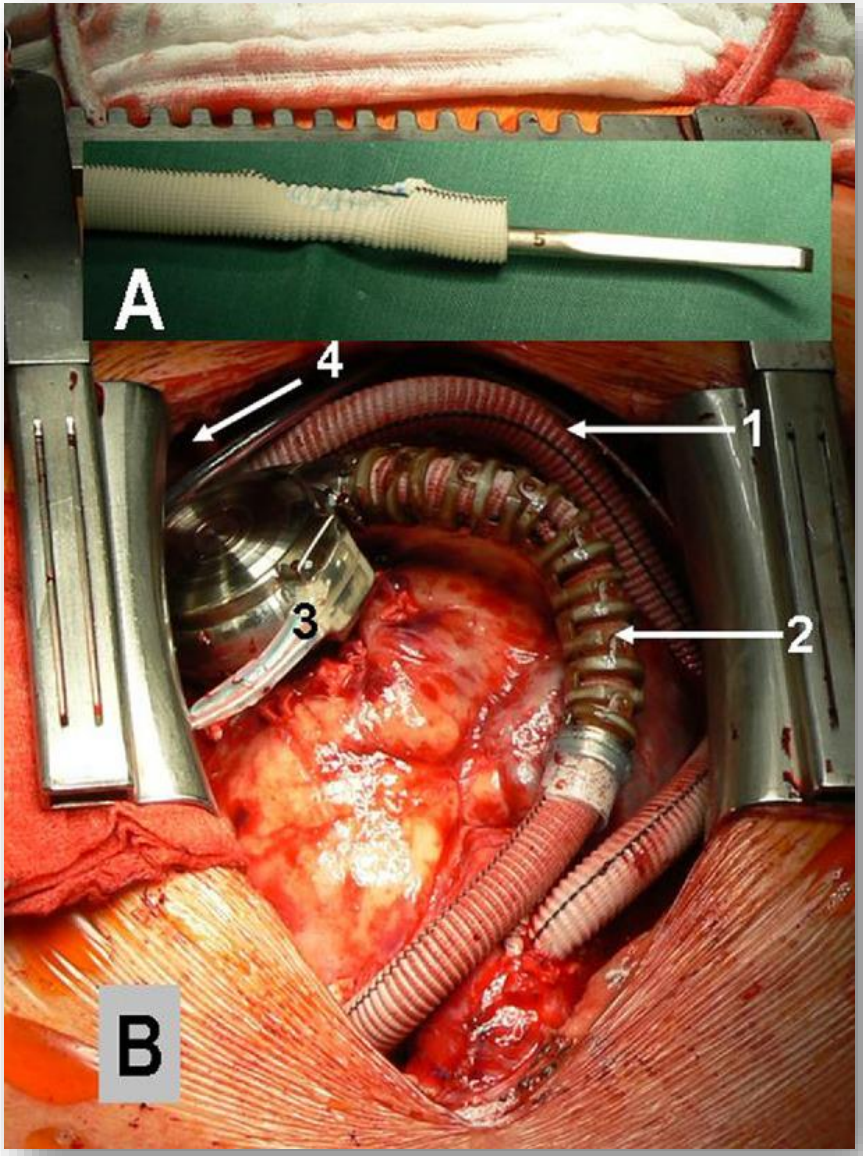
Survival: 53.2% at 1 year and 33.9% at 2 years

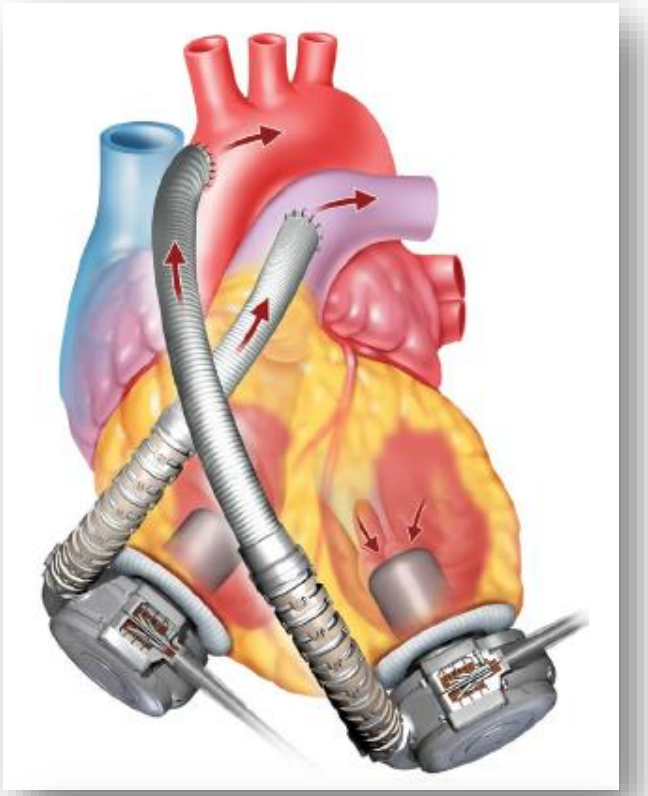
J Heart Lung Transplant 2018;37:1304–1312

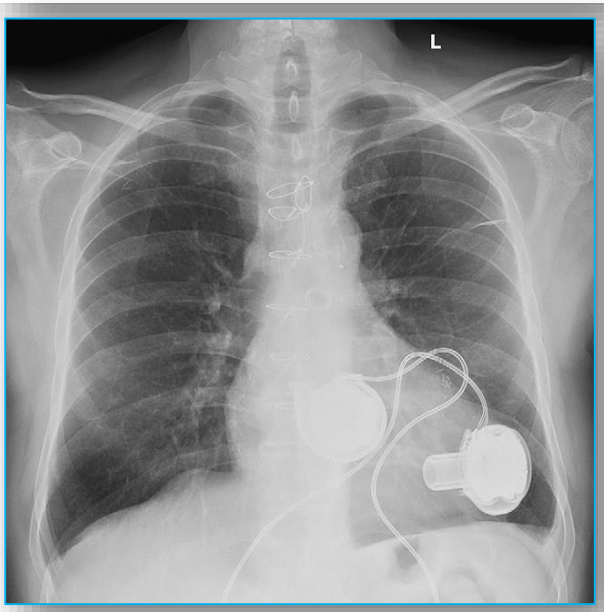
Bi-Ventricular disfunction



HeartWare Bi-VAD

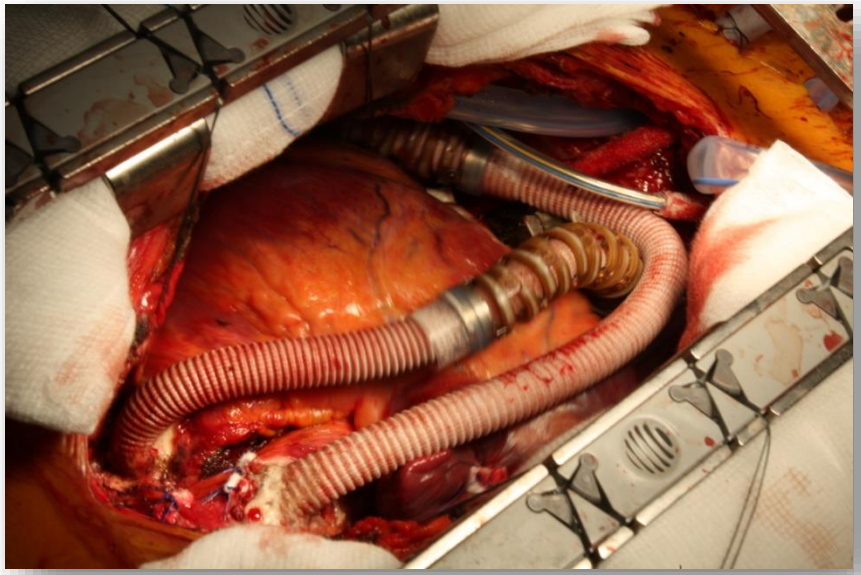






Free RV wall *(Berlin)*

Diaphragmatic RV wall *(Rome)*



Biventricular support with the HeartWare implantable continuous flow pump: An additional contribution

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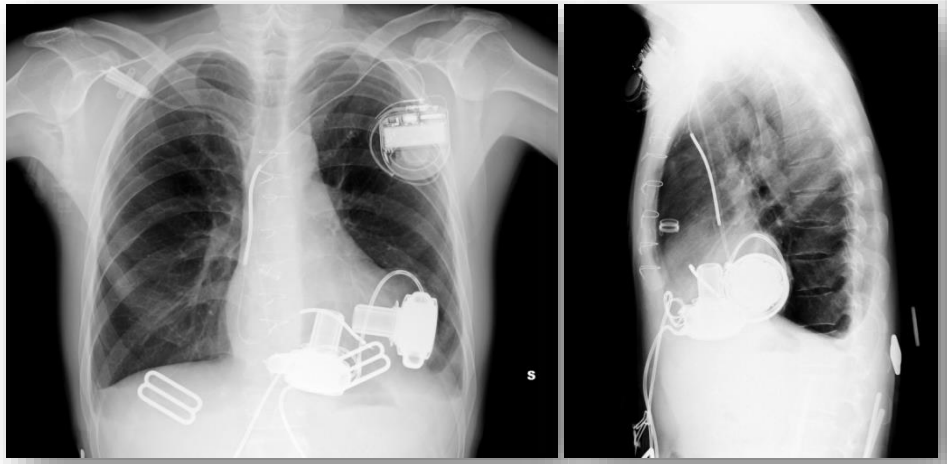
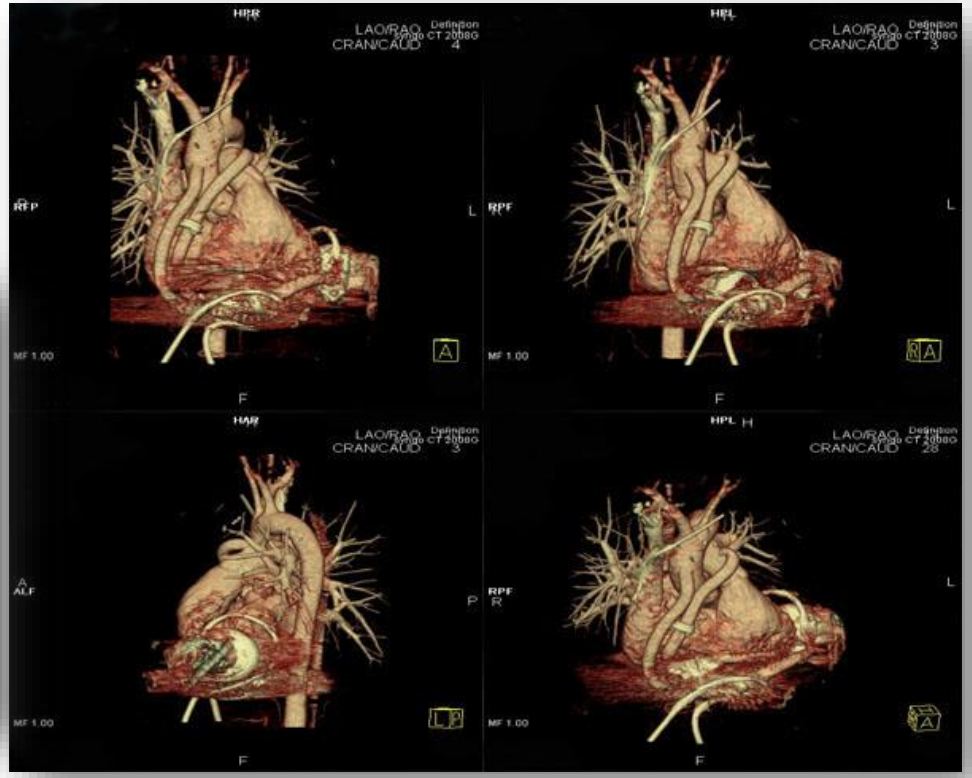
The Journal of Heart and Lung Transplantation

http://www.jhltonline.org

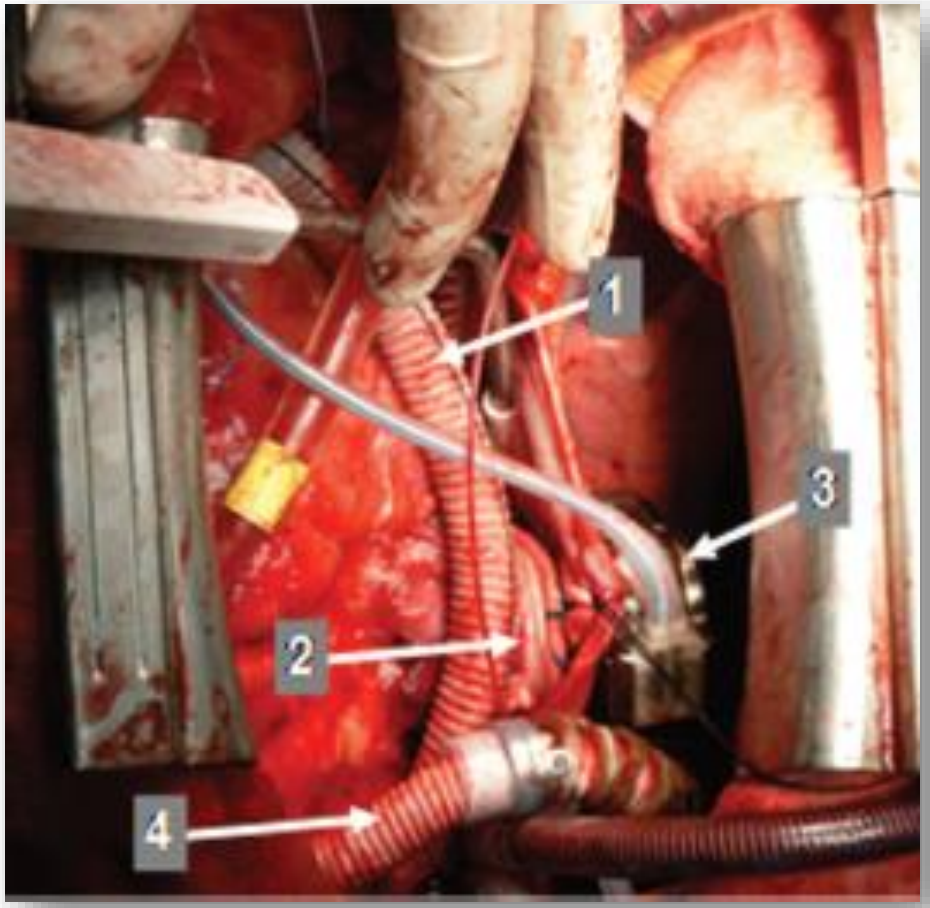


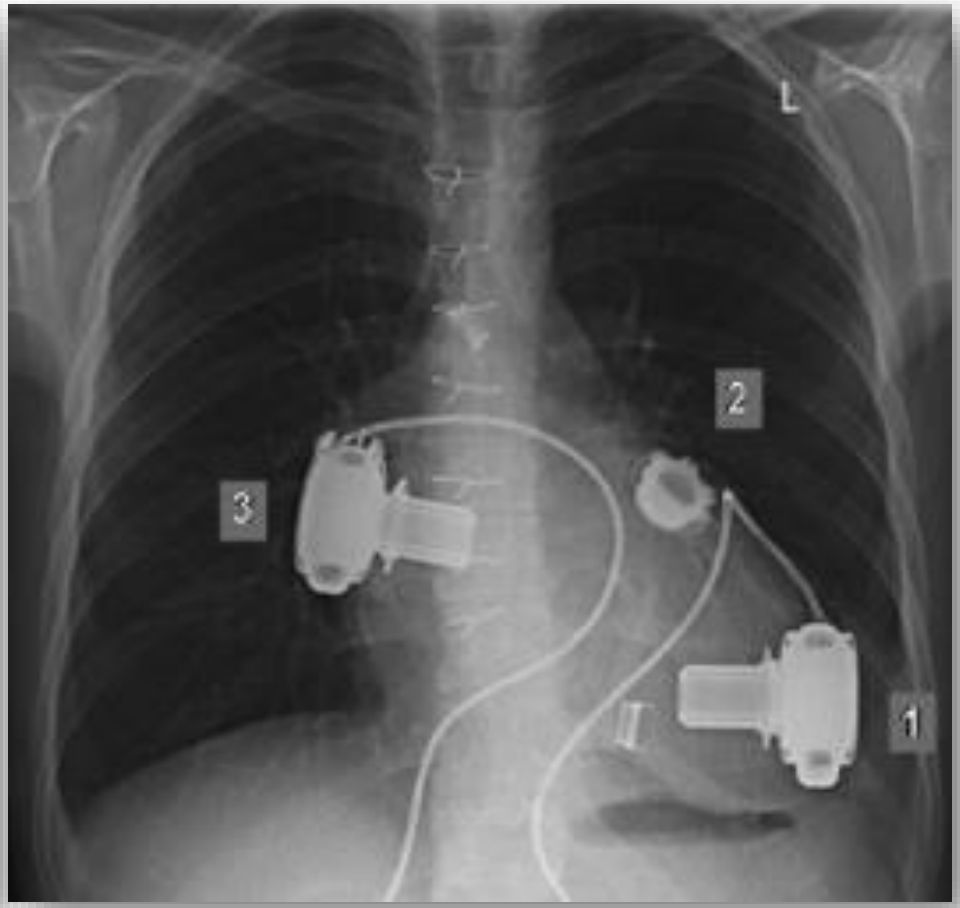


Alternative Technique for Implantation of Biventricular Support with HeartWare Implantable Continuous Flow Pump

ASAIO Journal 2011

Thomas Krabatsch, Alexander Stepanenko, Martin Schweiger, Marian Kukucka, Peter Ewert, Roland Hetzer, and Evgenij Potapov



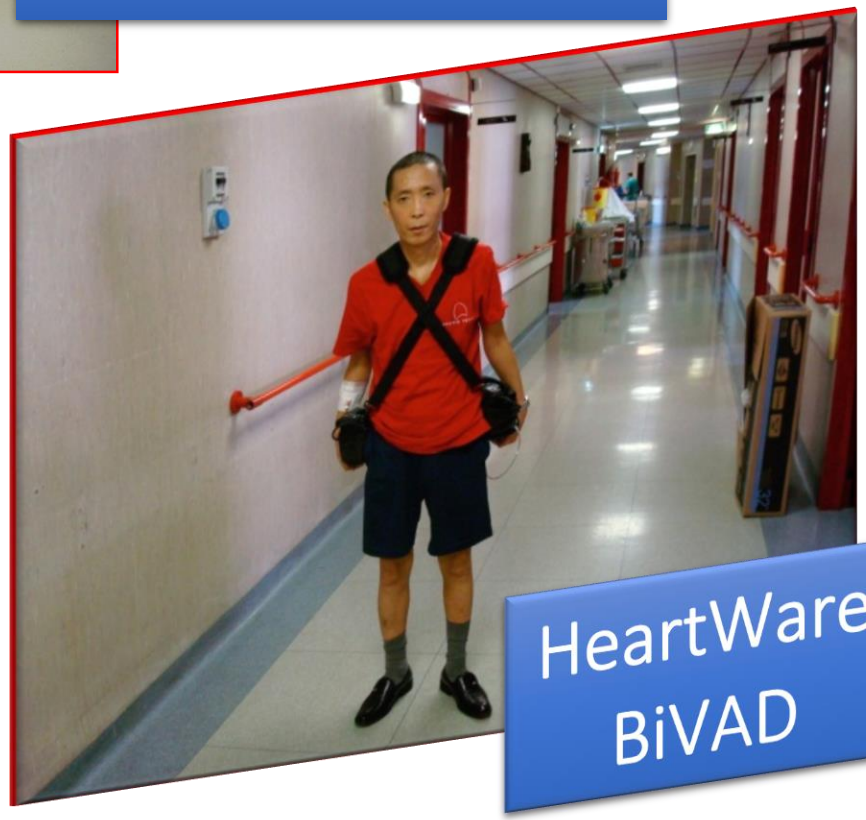


Right atrial wall *(Berlin)*

Biventricular Support Systems

CARDIOWEST
Total Artificial Heart

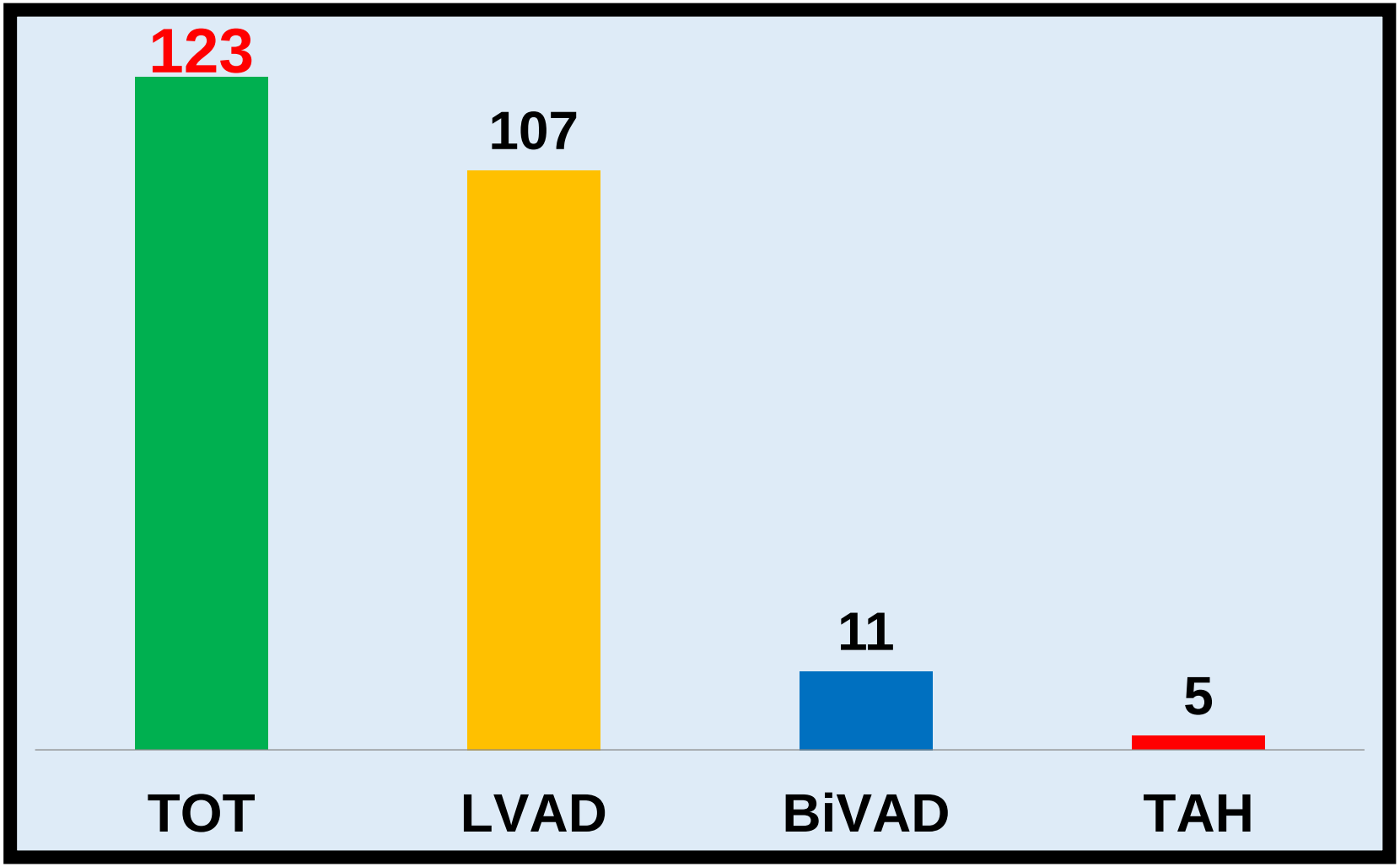
Thoratec BiVAD



HeartWare
BiVAD

Ospedale S. Camillo - Roma

MCS 2002 - 2019



Conclusions

Total Artificial Heart, when indicated, allowes a significant clinical improvement.

Conclusions

Factors influencing the choice of LVAD vs Total Artificial Heart vs Bi-VAD
▪ Heart pathology
▪ General condition of the patient
▪ The treatment endpoint
▪ Institutional experience
▪ Device availability
▪ Cost

Conclusions

- TAHs and BiVADs have differe
  of survival and are asso
  different adverse
- Survival r gher in patients with
  TAH with patients with
  able or paracorporeal BiVADs
- A randomized trial between TAHs and BiVADs may be of interest

Thank you for your attention!