Ventricular Assist Device

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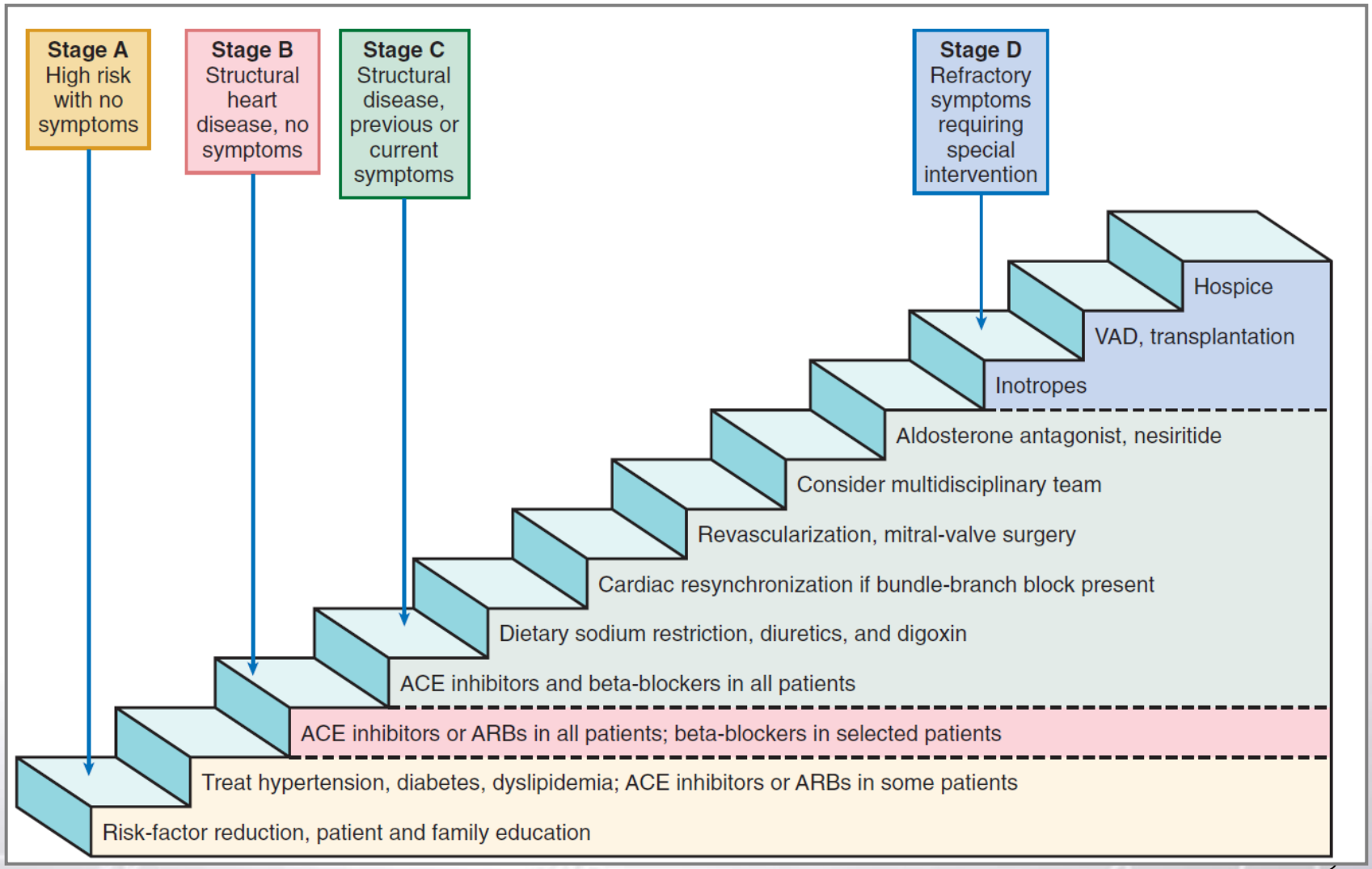
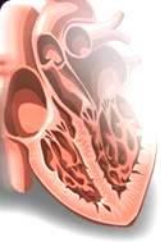
Introduction





General Criteria for candidacy for MCS

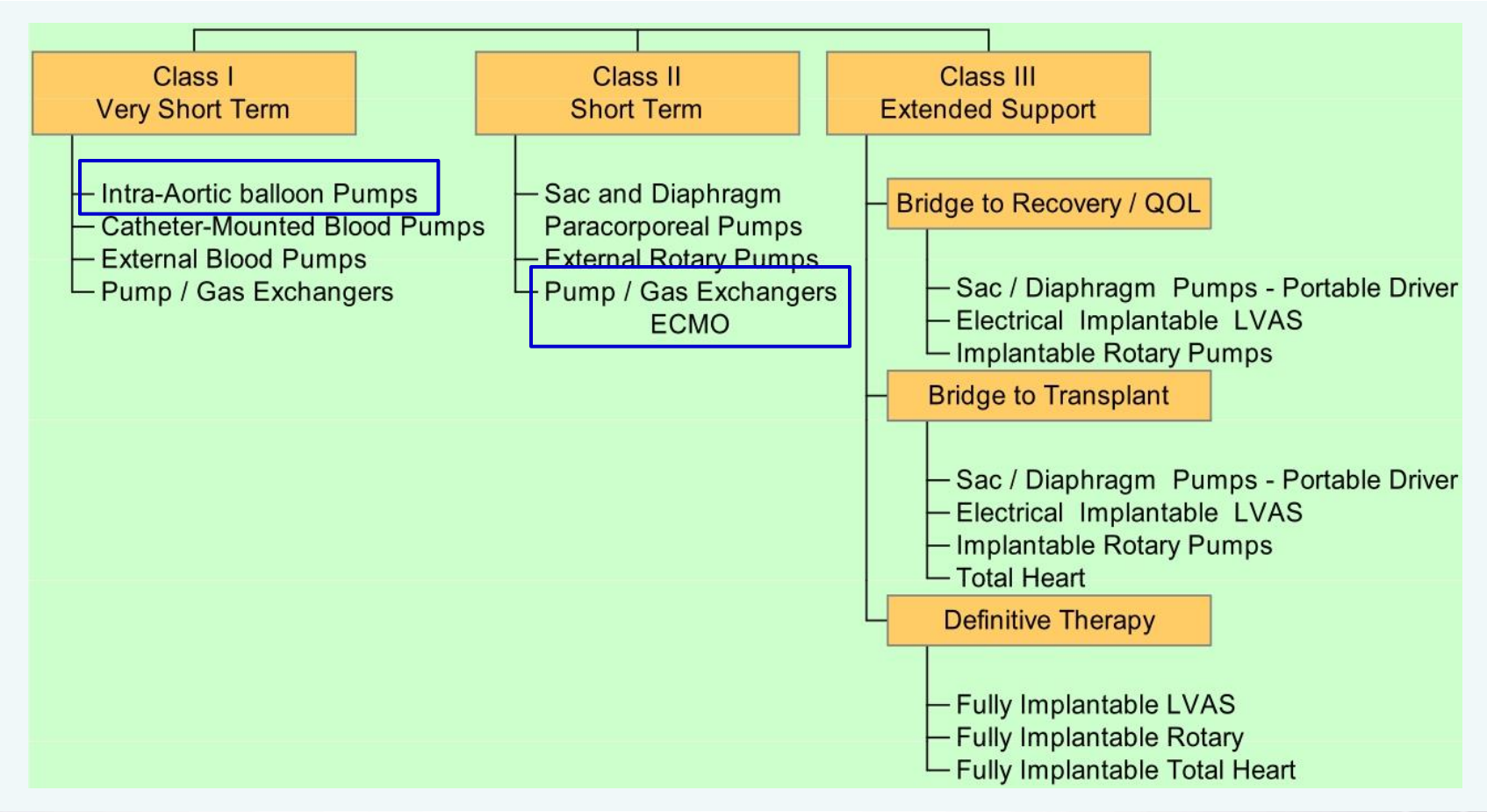
Refractory End stage HF (NYHA class IV or stage D HF)

- **Hemodynamics**
  - Cardiac index < 2.0L/min, Stroke volume
  - RA pressure>10mmHg, PCWP >15mmHg

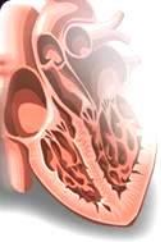
- **Clinical examination**
  - Cool and constricted extremities reflective of poor perfusion
  - Low BP, tachycardia, rales or distended neck veins

- **Laboratory data – impaired systemic perfusion**
  - Prerenal azotemia
  - Hepatic dysfunction
  - Prolong coagulation levels
  - Reduced urine output in response to diuretics

Length of support



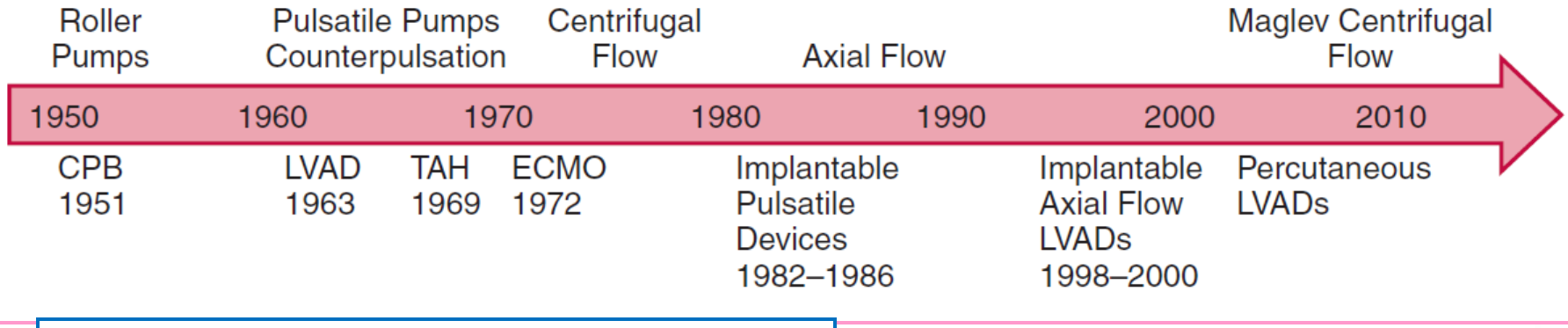
VAD

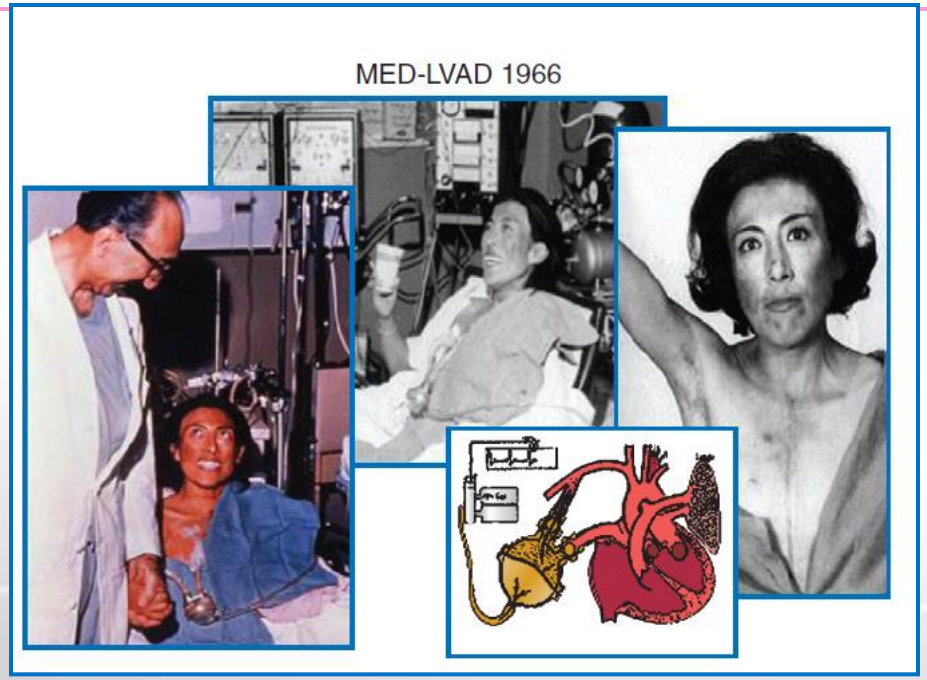


History of MCS

- ✓ 1800's LeGallois 'Concept of mechanical support'
- ✓ 1953 **Gibbon** **'Development of CPB'**
- ✓ 1957 Clevland Clinc. '1st Animal Implant (lives 90 min)'
- ✓ 1966 **DeBakey** **'First use of a pneumatic device as a B to R'**
- ✓ 1967 Barnard 'Heart Transplantation (pts lives 18 days)'
- ✓ 1969 **Cooley** **'Total Artificial Heart (TAH)'**
- ✓ 1970's Development of a variety of VAD
- ✓ 1982 **Dr. DeVries** **'First implantation of TAH as a permanent device -pts' name is Clark (112days alive) with Javik 7-**
- ✓ 1985 Multicenter evaluation of LVAD as a B to T
- ✓ 1991 Moratorium on the use of the TAH
- ✓ 1994 **FDA approval of a LVAD as a B to T (Heartmate)**
- ✓ 1996~ Randomized trial comparing
- ✓ 2003 **FDA approval as a DT**
- ✓ Present Wearable LVAD with medical therapy

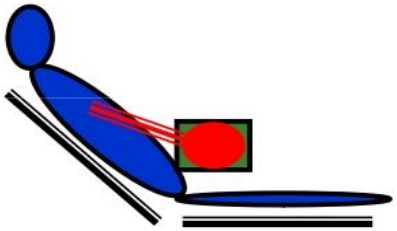
the evolution of the various types of blood pumps used for mechanical circulatory support (MCS)





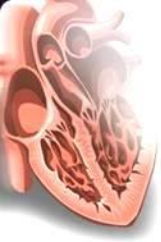
Position

Extra-corporeal:
Centrifugal pumps;
BVS5000; ECMO



Para-corporeal:
Thoratec;
MEDOS; Berlin Heart

Implantable:
Heartmate; Novacor;
CardioWest TAH; LionHeart
Micromed; HeartMate II;
AB-180; Jarvik 2000
**** VENTRASSSIT***

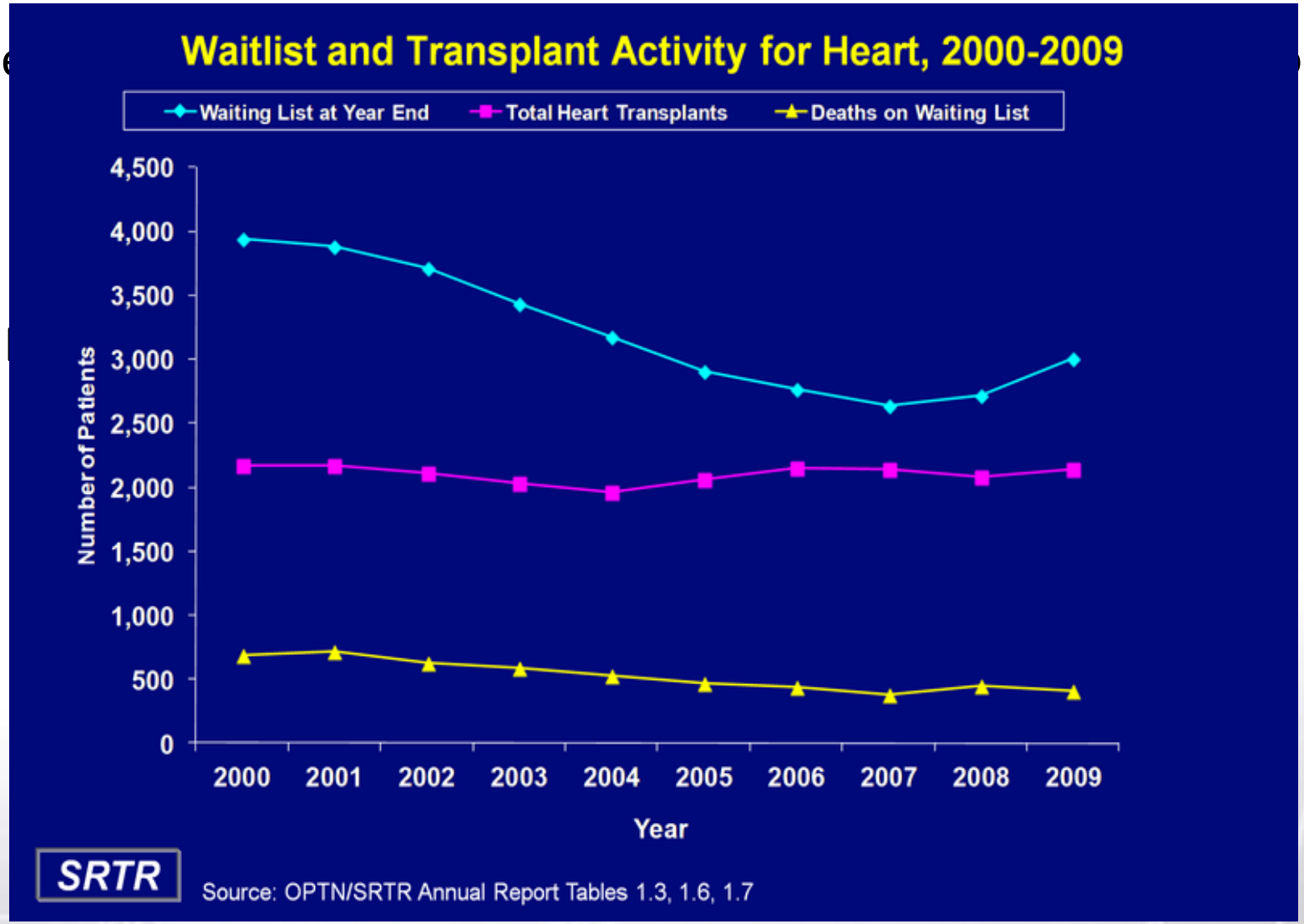


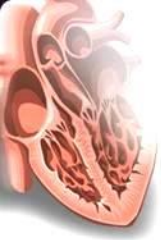
Ventricular Assist Device (VAD)

- A **mechanical pump** that is surgically attached to one of the **heart's ventricles** to augment or replace native ventricular function
- Can be used for the **left (L VAD), right (R VAD), or both ventricles (Bi VAD)**
- Are powered by external power sources that connect to the implanted pump via a percutaneous lead (driveline) that exits the body on the right abdomen
- Pump output flow can be pulsatile or nonpulsatile

Why Do We Need VADs?

He rld

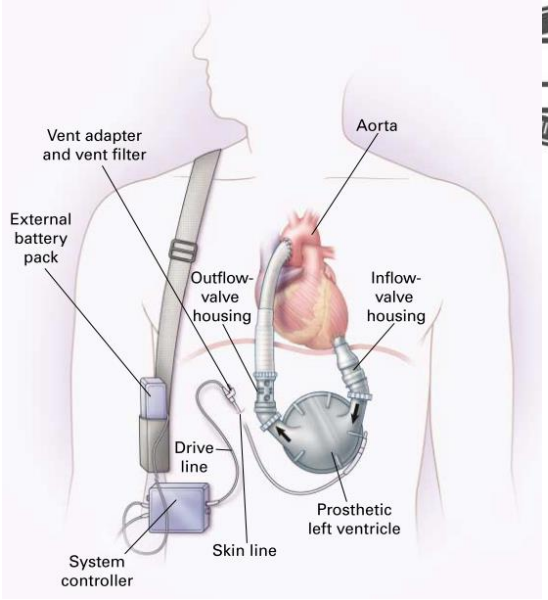


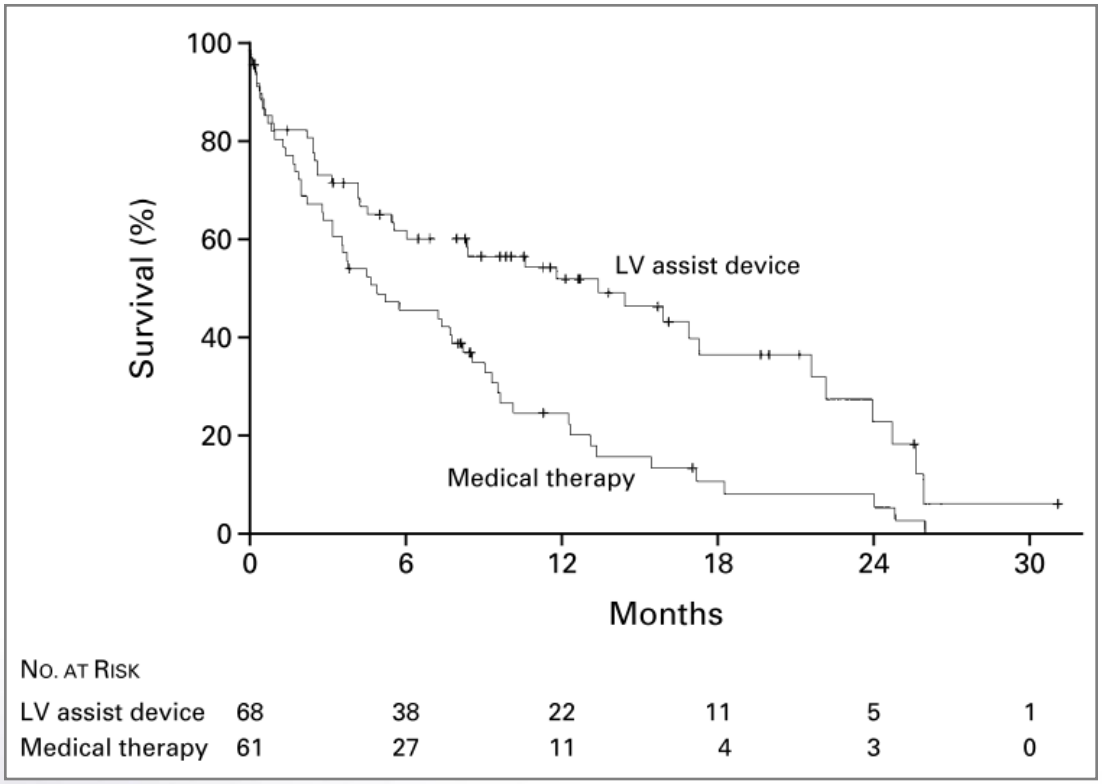


Purpose for VAD

- **Bridge to transplant (BTT)**
  - most common
  - allow rehab from severe CHF while awaiting donor
- **Bridge to recovery (BTR)**
  - unload heart, allow "reverse remodeling"
  - can be short- or long-term
- **"Destination" therapy (DT)**
  - permanent device, instead of transplant
  - currently only in transplant-ineligible patients
- **Bridge to candidacy (BTC)/ Bridge to decision (BTD)**
  - when eligibility unclear at implant
  - not true "indication" but true for many pts

REMATCH study





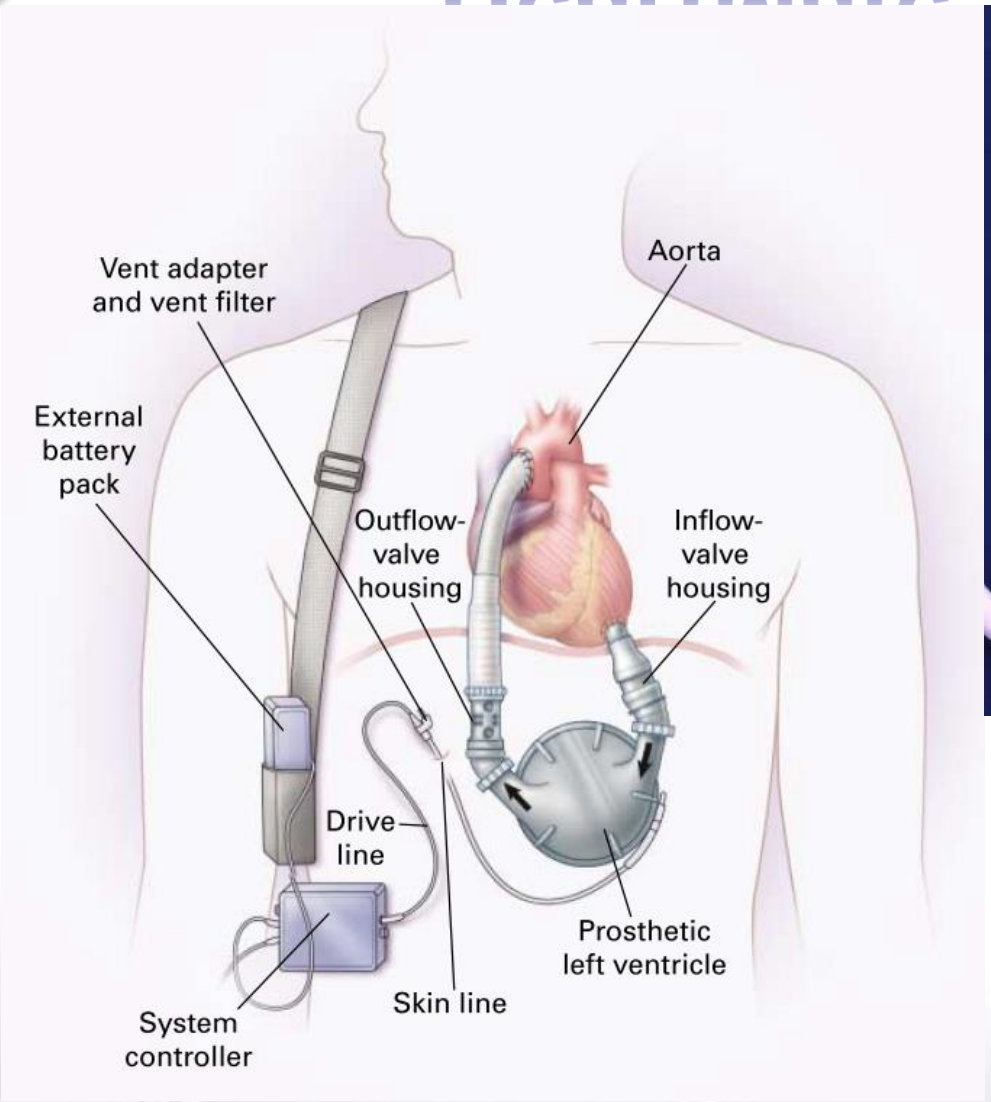
Entry criteria (129)

- ✓NYHA class IV or stage D HF
- ✓Low EF (<25%)
- ✓Low peak VO2 (<12ml/kg/min)
- ✓Significant functional limitation despite use of maximal medical Tx. for at least 60 of 90 days

Reduction of 48 % in the risk of death

Rose EA et al., N Engl J Med, Vol. 345, No. 20;November 15, 2001

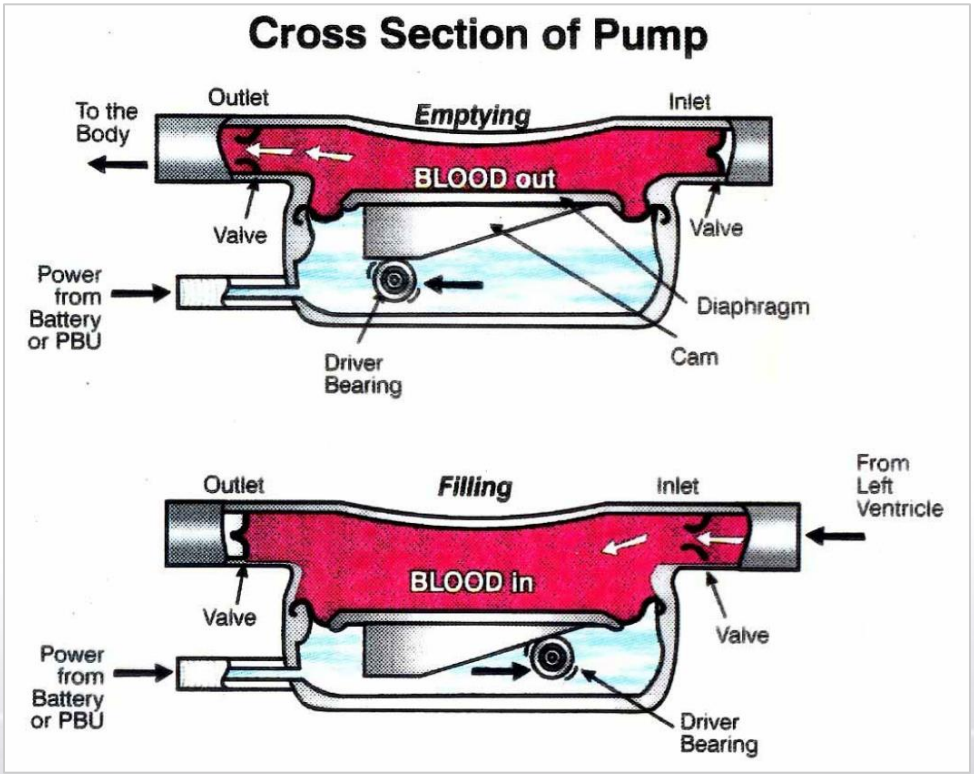
HeartMate XVE



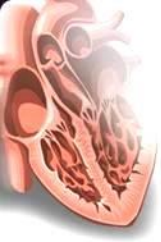
- ✓ 1150 g weight
- ✓ Stroke volume, max 83 mL
- ✓ Beating, max 120/min
- ✓ Flow rate up to 10 L/min

Pulsatile : HeartMate XVE

- ✓ 25 mm tissue valve (porcine) within Dacron graft
- ✓ Blood chamber/Polyurethane diaphragm/motor chamber
- ✓ Implanted in abdominal pocket
- ✓ Wearable battery pack + percutaneous line

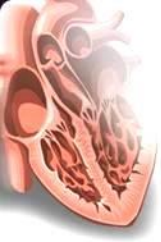


5m



Optimal candidates for VAD

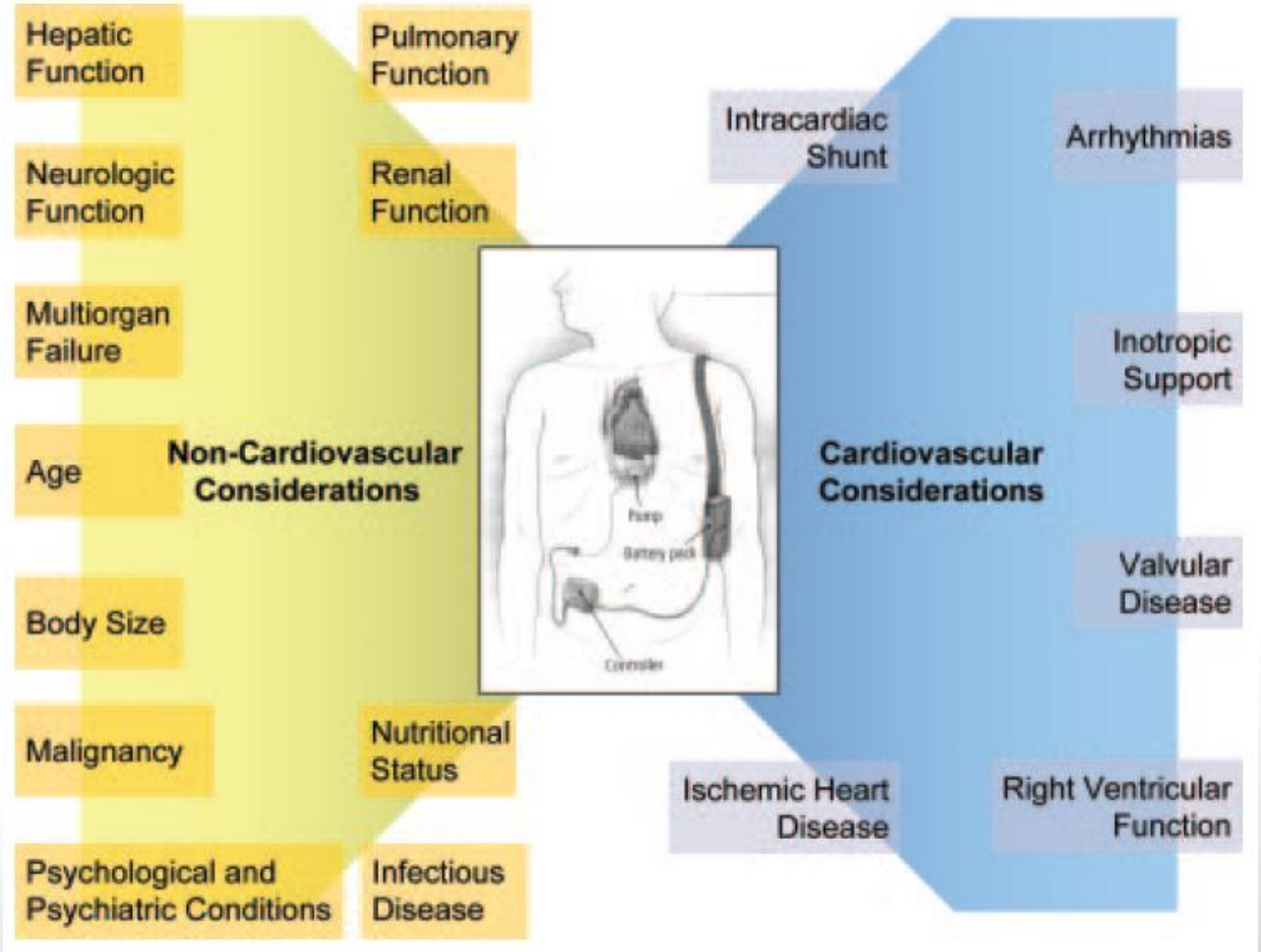
- NYHA functional class IV symptoms
- Life expectancy < 2 years
- **Not a candidate for heart transplantation***
- **Failure to respond to optimal medical management for at least 60 of the last 90 days***
- **Left ventricular ejection fraction ≤ 25%***
- Refractory cardiogenic shock or cardiac failure†
- **Peak oxygen consumption ≤12 mL /kg/min** with cardiac limitation
- Continued need for intravenous inotropic therapy limited by symptomatic hypotension, decreasing renal function, or worsening pulmonary congestion*
- Recurrent symptomatic sustained ventricular tachycardia or ventricular fibrillation in the presence of an untreatable arrhythmogenic substrate
- Body surface area > 1.5 m2*‡



Poor candidates for a VAD

- Include those with
  : irreversible renal failure
  : severe disease of the vascular system of the brain
  : cancer that has spread (metastasized)
  : severe liver disease
  : blood clotting disorders
  : severe lung disease
  : infections that do not respond to antibiotics
  : extreme youth or age

Factors involved in determining appropriateness of VAD implantation



Continuous-Flow Ventricular Assist Device

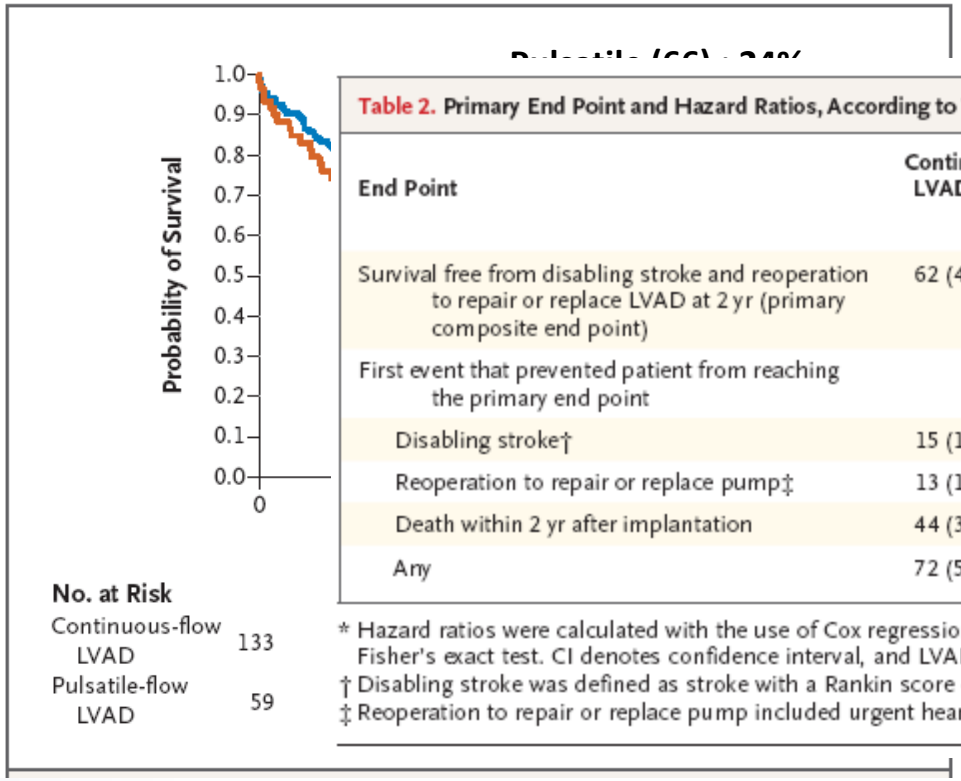
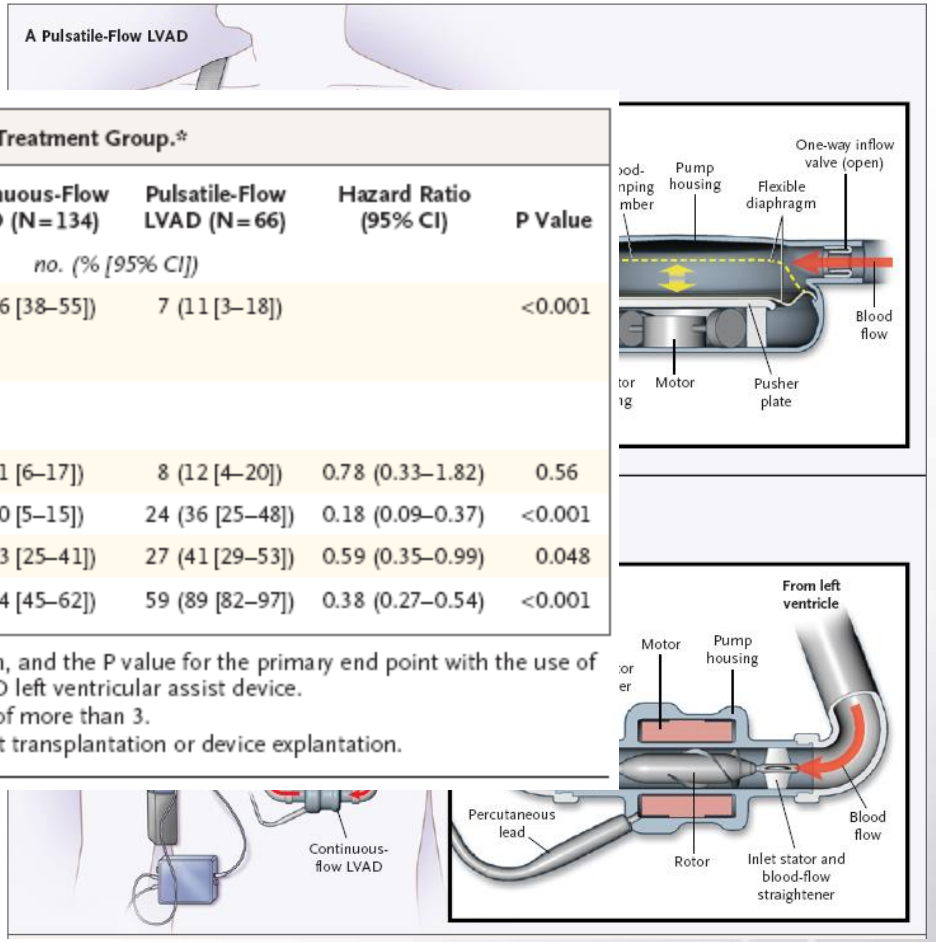


Table 2. Primary End Point and Hazard Ratios, According to Treatment Group.*

End Point	Continuous-Flow LVAD (N=134)	Pulsatile-Flow LVAD (N=66)	Hazard Ratio (95% CI)	P Value
	no. (% [95% CI])			
Survival free from disabling stroke and reoperation to repair or replace LVAD at 2 yr (primary composite end point)	62 (46 [38–55])	7 (11 [3–18])		<0.001
First event that prevented patient from reaching the primary end point				
Disabling stroke†	15 (11 [6–17])	8 (12 [4–20])	0.78 (0.33–1.82)	0.56
Reoperation to repair or replace pump‡	13 (10 [5–15])	24 (36 [25–48])	0.18 (0.09–0.37)	<0.001
Death within 2 yr after implantation	44 (33 [25–41])	27 (41 [29–53])	0.59 (0.35–0.99)	0.048
Any	72 (54 [45–62])	59 (89 [82–97])	0.38 (0.27–0.54)	<0.001

* Hazard ratios were calculated with the use of Cox regression, and the P value for the primary end point with the use of Fisher's exact test. CI denotes confidence interval, and LVAD left ventricular assist device.
† Disabling stroke was defined as stroke with a Rankin score of more than 3.
‡ Reoperation to repair or replace pump included urgent heart transplantation or device explantation.



N Engl J Med 2009;361:2241-51.

VAD : Flow nature

Position		Flow Nature: Pulsatile	Flow Nature: Continuous — Axial Pump	Flow Nature: Continuous — Centrifugal Pump
Position	Implatable	HeartMate I Novacor LionHeart AbioCor HeartSaver	HeartMate II Jarvic 2000 DeBakey VAD Streamliner InCor I, II	Levitronics VAD VentrAssist HeartQuest CorAid Kriton
Position	Paracorporeal	Thoratec VAD Berlin Heart BVS-5000 Medos VAD BCM FIBAP	Impella elect/recover A-Syst/ParaFlow	
Position	Percutaneous	System 98 XT ACAT/AutoCAT	TandemHeart Impella acute Raitan pump Orqis	

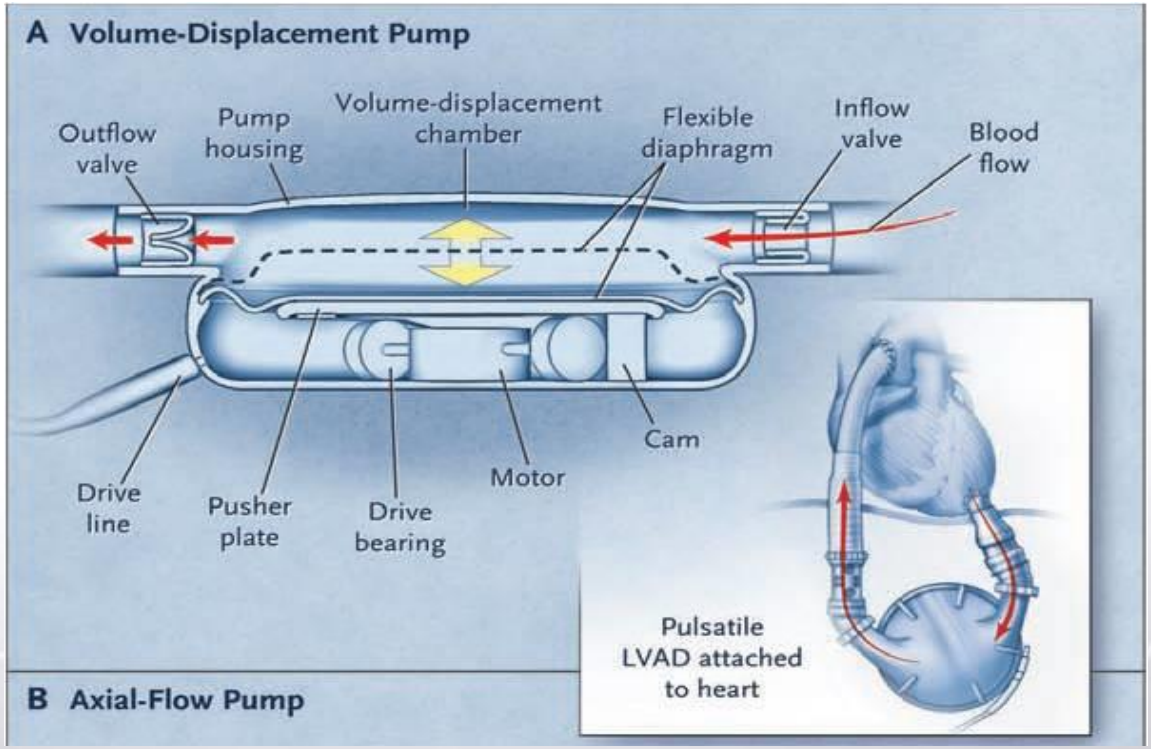
Pulsatile Flow Pumps

- ✓ **Heartmate I** –Thoratec Corporation, Pleasanton, CA, USA

  HeartMate 1000 Implantable Pneumatic (IP)

  HeartMate X Vented Electric (VE)

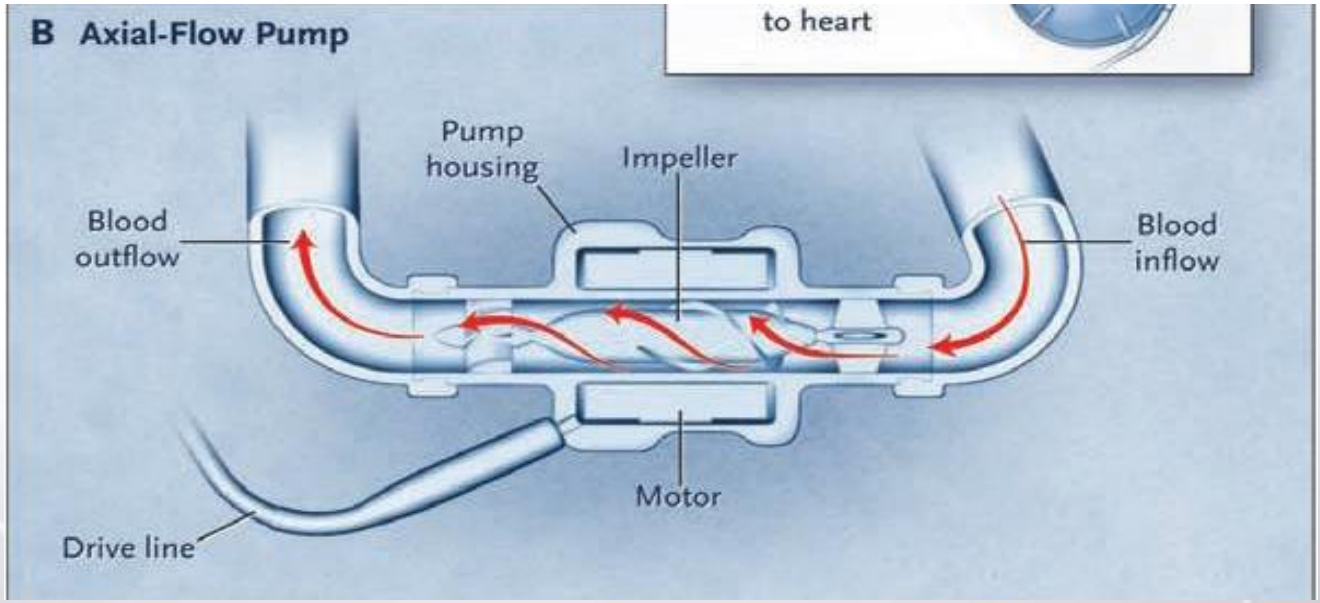
- ✓ **Novacor** – World Heart Corporation, Ottawa, Ontario, Canada



Continuous Flow Pumps

Axial Pump

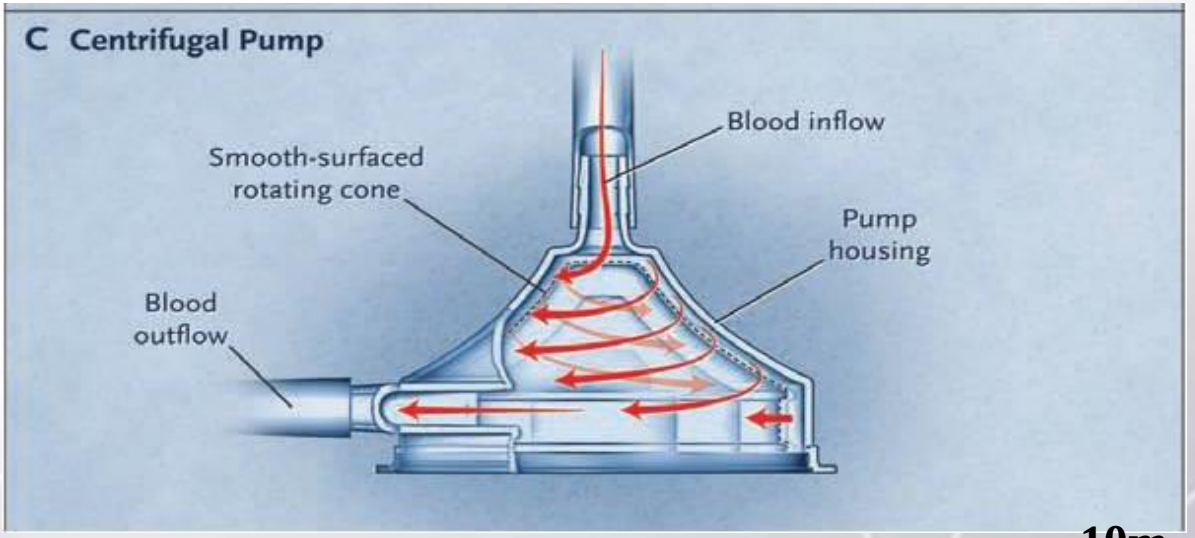
- ✓ **Heartmate II** –Thoratec Corporation, Pleasanton, CA, USA
- ✓ **Micromed-Debakey** – Micromed Cardiovascular, Inc., Houston, TX, USA
- ✓ **Jarvik 2000** – Jarvik Heart, Inc., New York, NY, USA



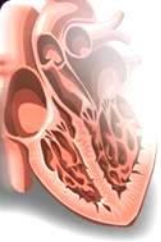
Continuous Flow Pumps

Centrifugal Pump

- ✓ **VentrAssist** – Ventracor, Inc., Foster City, CA, USA
- ✓ **Levitronics CentriMag**
- ✓ **Incor** – Berlin Heart, Germany, EU
- ✓ **DuraHeart** – Terumo Heart, MI
- ✓ **HVAD** – HeartWare, Sydney, Australia
- ✓ Eva Heart
- ✓ HeartQuest
- ✓ CorAide LVAS
- ✓ HeartMate III



10m



- Large Console
  → Mobility limitation
- Powered from external source
  → Infection

- **Implantable**
- Wearable battery pack
- **Less VAD failure**

Pulsatile Flow

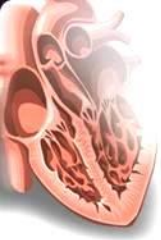
Volume displacement + Tissue valve

Continuous Flow

Electromagnetically levitated impeller

Axial pump

Centrifugal pump
bearingless



INTERMACS

Interagency Registry for Mechanically Assisted Circulatory Support

- Facilitate the refinement of **patient selection** to maximize outcomes with current and new device options
- Identify predictors of **good outcomes** and **risk factors** for adverse events after device implantation
- Develop consensus **“best practice” guidelines** to improve clinical management by reducing short-term and long-term complications of MCS device therapy
- Guide clinical application and evolution of next-generation devices
- Use INTERMACS information to **guide improvements** in technology, particularly as next-generation devices evolve

Kirklin JK et al., J Heart Lung Transplant 2008;27:1065–72.

INTERMACS patient profiles.

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

Previous studies

3rd INTERMACS

- **Early-phase risk factors**
  - Critical cardiogenic shock
  - High BUN level
  - Concomitant surgery at the time of MCSD implantation
  - Requirement for biventricular assistance
- **Constant(late)- phase risks**
  - Older age
  - Diabetes mellitus
  - Pulmonary hypertension
  - Lower serum sodium at the time of implantation
  - Use of pulsatile-flow LVAD

4th INTERMACS

- **1st infection** adverse event before 1momth
- INTERMACS level 1 before surgery
- BVAD
- High BUN
- Gender – no difference but increased risk of neurologic events

Circulation. 2012;126:1401-1406.

5th INTERMACS annual report

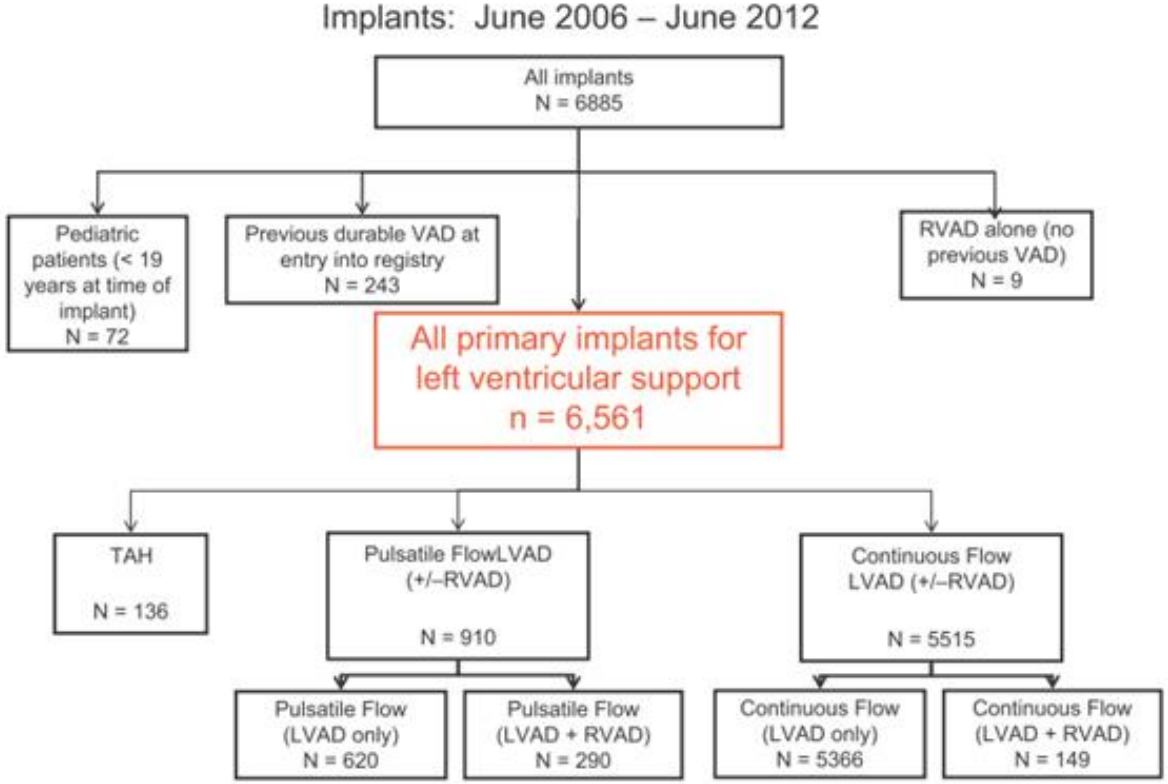
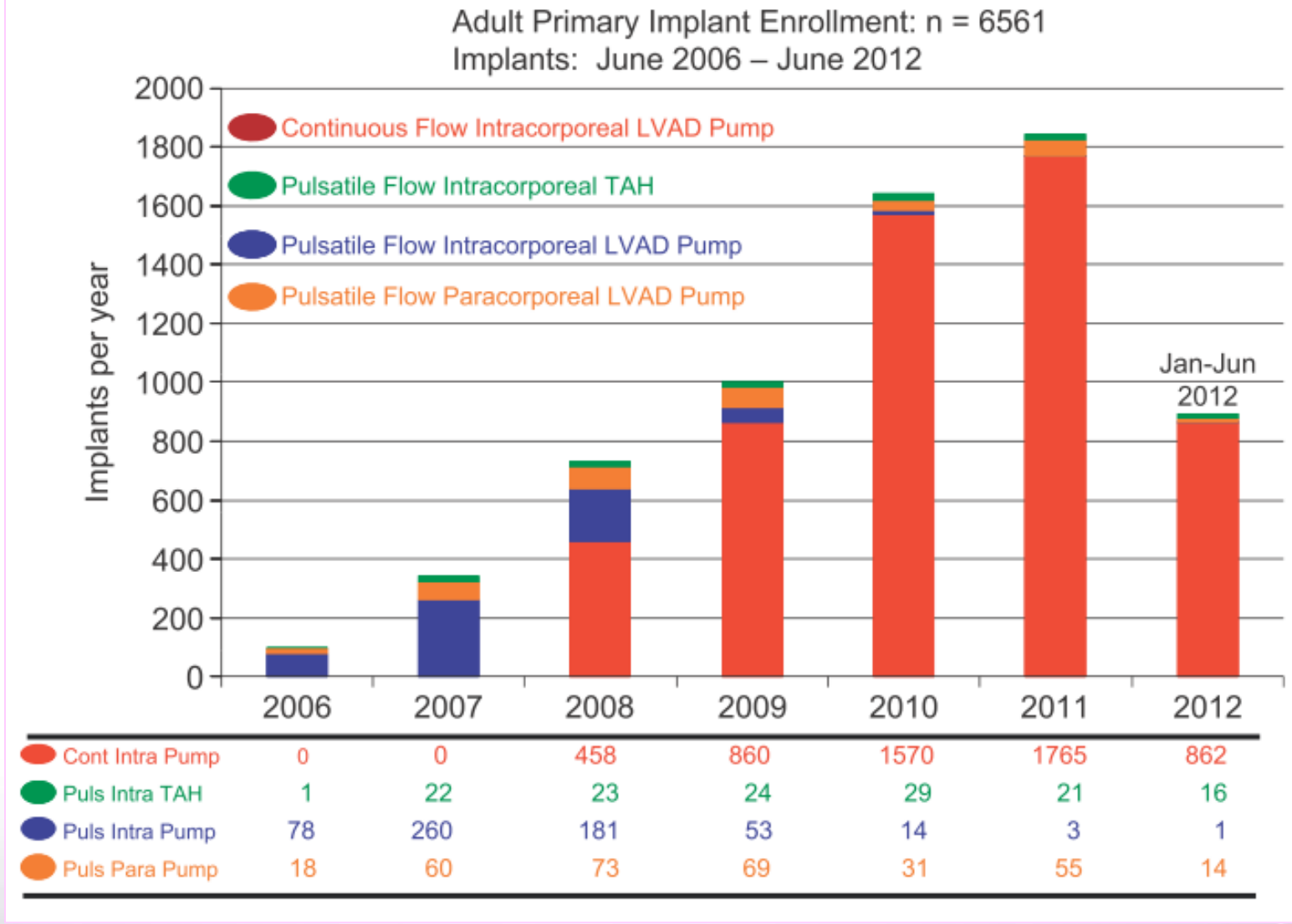


Figure Categories of patients who received durable mechanical circulatory support devices in the Interagency Registry for Mechanically Assisted Circulatory Support (INTERMACS) database between June 2006, and June 2012 are shown. LVAD, left ventricular assist device; RVAD, right ventricular assist device; TAH, total artificial heart.

Kirklin JK et al., J Heart Lung Transplant 2013;32:141–156



	2006	2007	2008	2009	2010	2011	2012
Cont Intra Pump	0	0	458	860	1570	1765	862
Puls Intra TAH	1	22	23	24	29	21	16
Puls Intra Pump	78	260	181	53	14	3	1
Puls Para Pump	18	60	73	69	31	55	14

Kirklin JK et al., J Heart Lung Transplant 2013;32:141–156

Table 2 Implants: June 2006–June 2012

	Implant Date Period					
	Pre 2001		2001		2012 (Jan-Jun)	Total
Device Strategy at Time of Implant	n	%	n	%	n	%
BTT Listed	1245					
BTT Likely	994					
BTT Moderate	392					
BTT Unlikely	127					
Destination Theraphy	714					
BTR	57					
Rescue Therapy	33					
Other	14					
Total	3876					

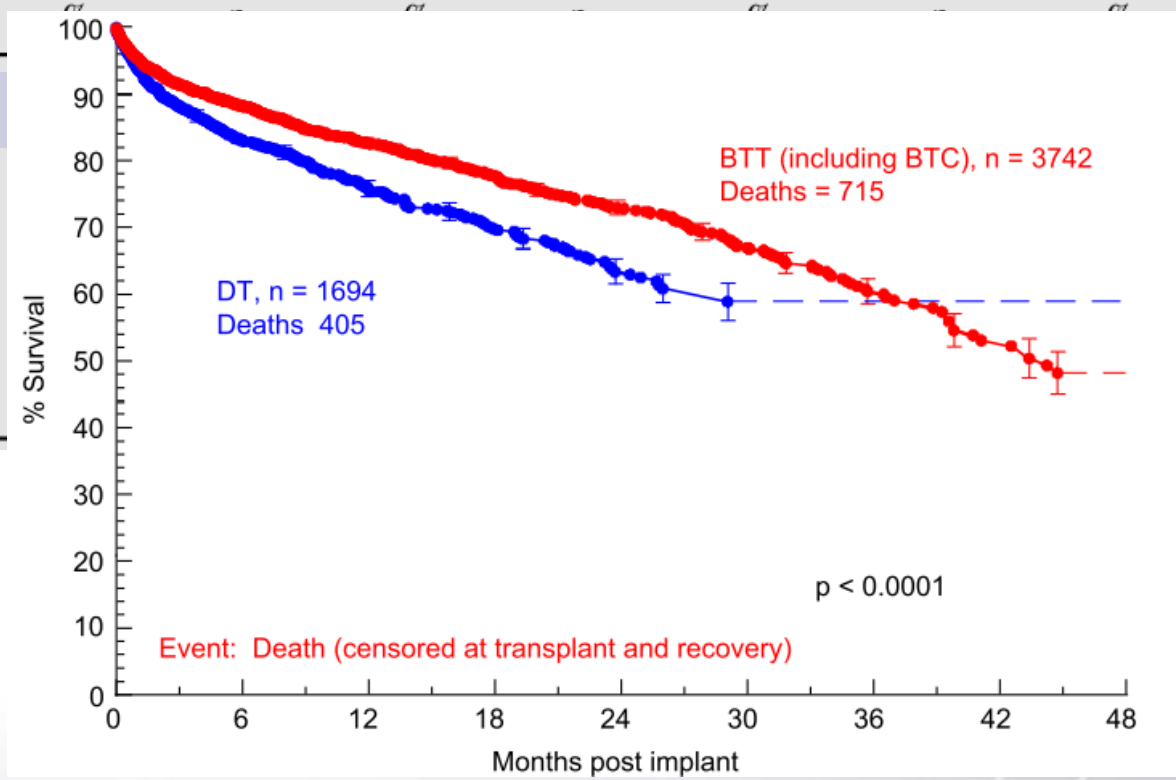
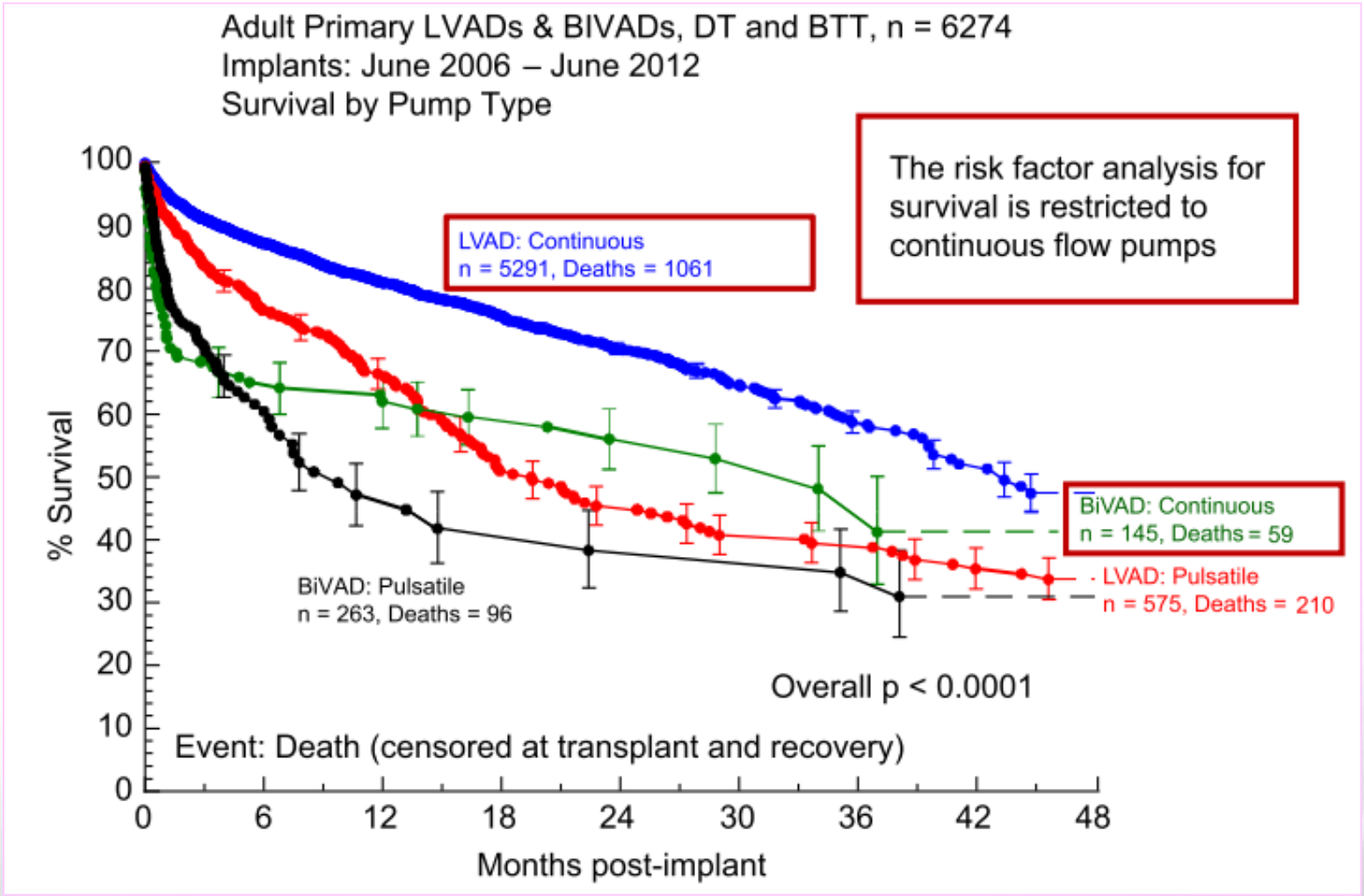


Table 4 Implants: June 2006–June 2012

	Implant Date Period							
	Pre 2001		2001		2012 (Jan-Jun)		Total	
Patient Profile at Time of Implant	n	%	n	%	n	%	n	%
Unspecified	1	0.0%	.	.	6	0.6%	7	0.1%
1 Critical Cardiogenic Shock	860	22.1%	298	16.0%	148	16.6%	1307	19.7%
2 Progressive Decline	1627	41.9%	708	38.0%	329	36.7%	2664	40.1%
3 Stable but Inotrope dependent	750	19.3%	519	27.8%	246	27.4%	1515	22.8%
4 Resting Symptoms	441	11.3%	233	12.5%	117	13.0%	791	11.9%%
5 Exertion intolerant	91	2.3%	66	3.5%	27	3.0%	184	2.7%
6 Exertion limited	59	1.5%	31	1.6%	14	1.5%	104	1.5%
7 Advanced NYHA Class 3	47	1.2%	6	0.3%	8	0.8%	61	0.9%
Total	3876	100.0%	1861	100.0%	896	100.0%	6633	100.0%

Type of Devices



Devices

Table Food and Drug Administration-Approved Devices

Type	Device
Durable devices	
Continuous flow	Thoratec HeartMate II
	Heartware HVAD
	MicroMed DeBakey Child VAD
Pulsatile extracorporeal	Thoratec PVAD
	Heart Excor
Pulsatile intracorporeal	HeartMate IP
	Heart Mate VE
	HeartMate XVE
	Thoratec IVAD
	NovaCor PC
	NovaCor PCq
Total artificial heart	SynCardia CardioWest
	AbioCor TAH
Temporary devices	
Short-term devices	Abiomed AB5000
	Abiomed BVS 5000
	Levitronix Centrimag
	Biomedicus
	Tandem Heart

VAD : Generation

LVAD Types

1st generation:
Pulsatile, with valves,
volume-displacement

Thoratec VAD,
Novacor VAD,
HeartMate I VAD

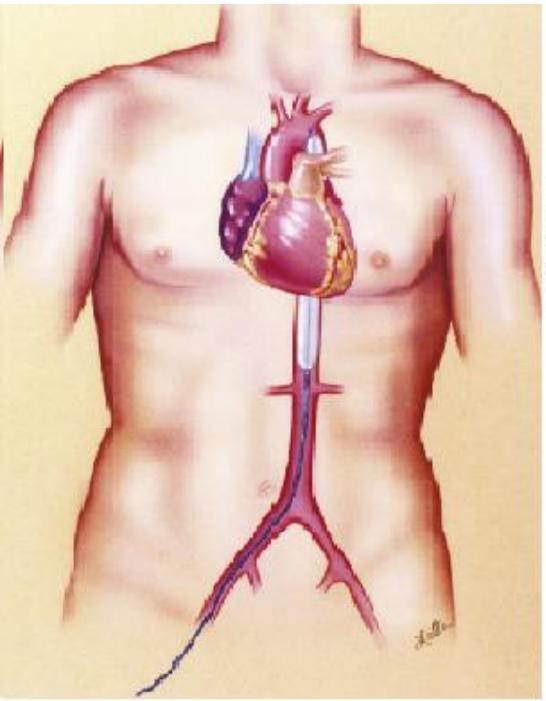
2nd generation:
Axial flow pumps
Single contact bearing

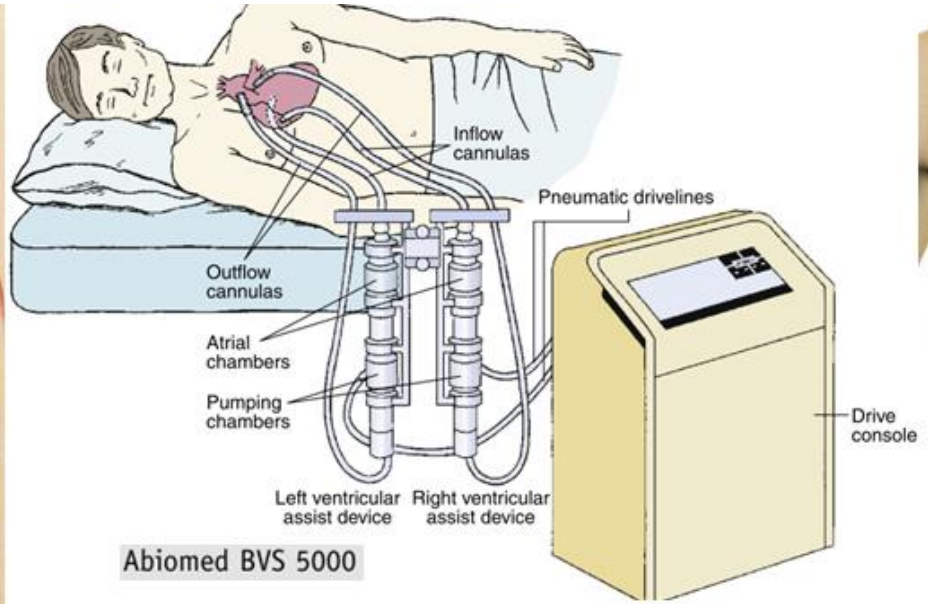
HeartMate II VAD,
Micromed-DeBakey VAD,
Jarvik 2000 VAD

3rd generation:
Centrifugal pumps,
Non-contact bearings

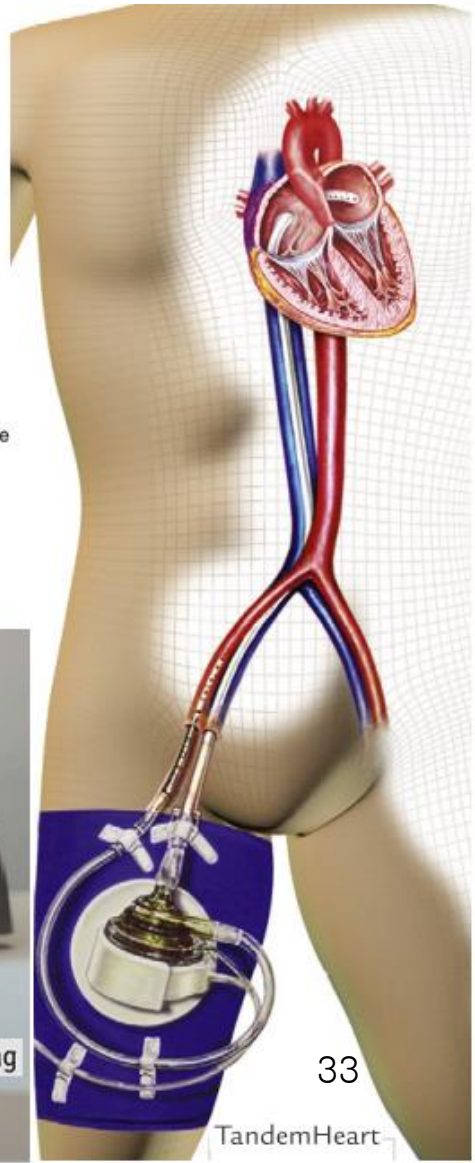
HVAD
Levacor VAD
VentrAssist VAD

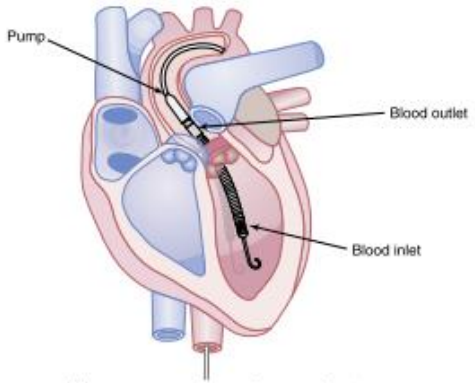
Temporary devices





Abiomed BVS 5000





Impella 2.5, 5.0, and LD devices.


Biomedicus

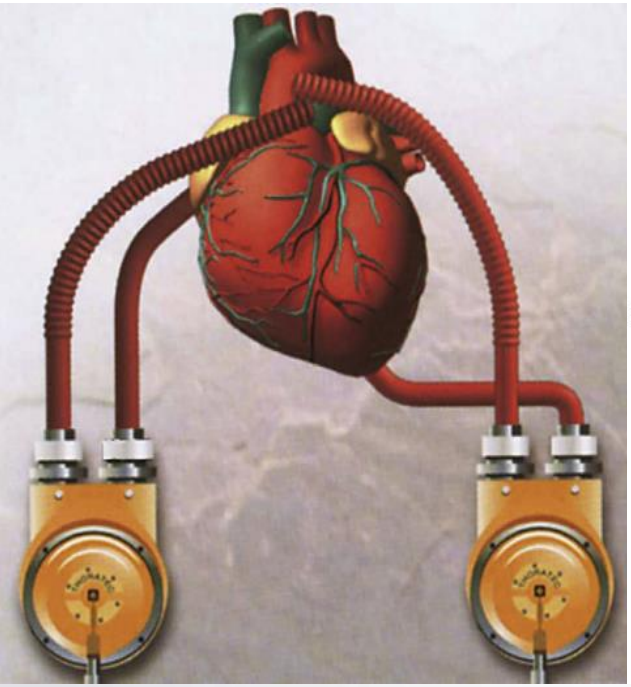

Levitronix Centrimag

Durable devices

✓ **Pulsatile flow**

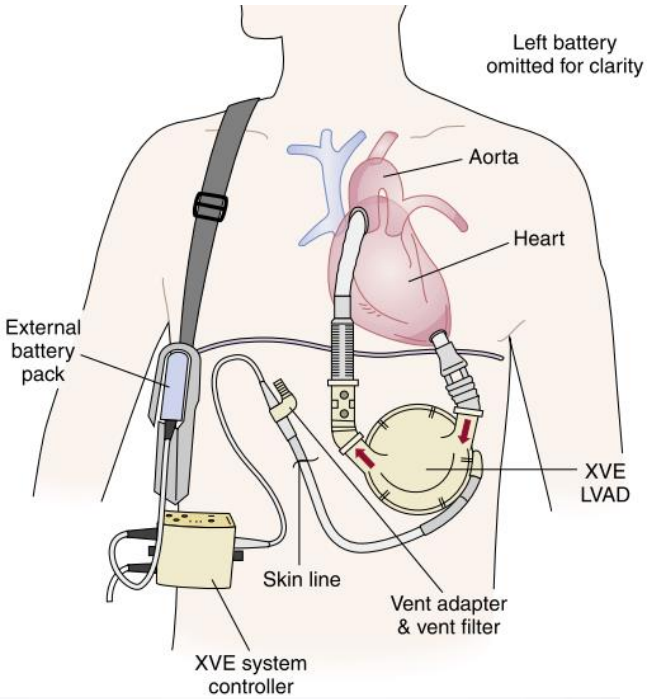
Extracorporeal

Thoratec PVAD

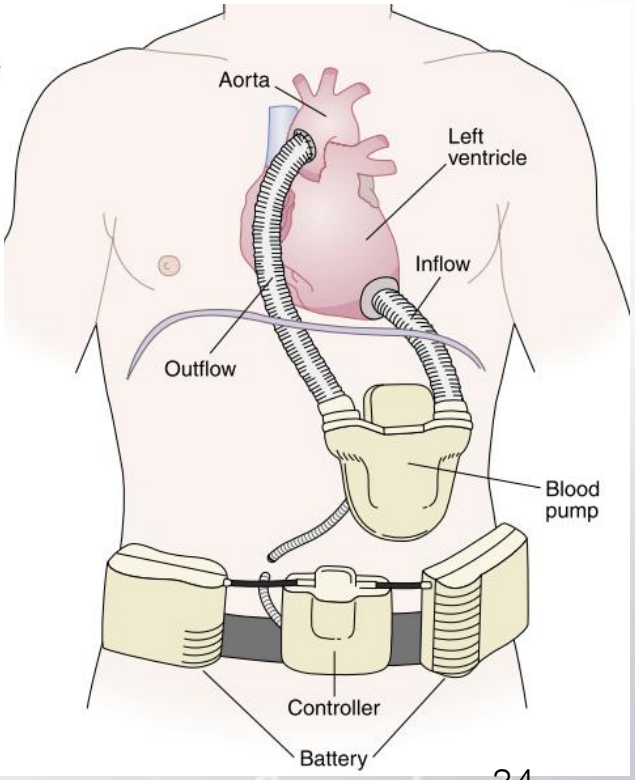


Intracorporeal

HeartMate XVE



Novacor PC



Durable devices

✓Pulsatile flow

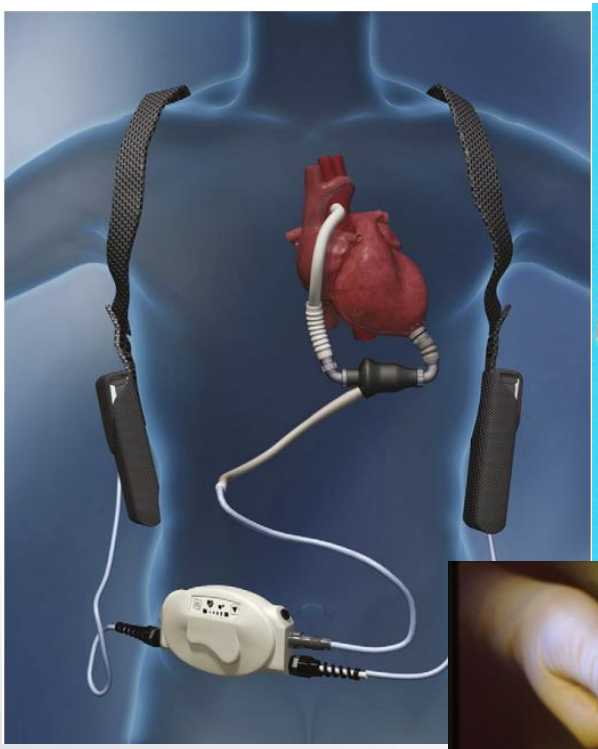
TABLE 8-3	Pulsatile Mechanical Circulatory Support Systems for Long-Term Support			
Device Name	**Manufacturer**	**Type of Pump**	**Type of Support**	**Pump Position**
HeartMate XVE LAVD	Thoratec Corp, Pleasanton, CA	Electric pulsatile pusher-plate	LVAD	Preperitoneal or intraperitoneal pocket
Thoratec PVAD	Thoratec Corp, Pleasanton, CA	Pneumatic pulsatile sac-type	Biventricular or univentricular	Paracorporeal
Thoratec IVAD	Thoratec Corp, Pleasanton, CA	Pneumatic pulsatile sac-type	Biventricular or univentricular	Preperitoneal pocket
CardioWest TAH	SynCardia Systems, Inc, Tucson, AZ	Pneumatic pulsatile sac-type	Biventricular	Intrapericardial

IVAD, intracorporeal ventricular assist device; LVAD, left ventricular assist device; PVAD, paracorporeal ventricular assist device; TAH, total artificial heart.

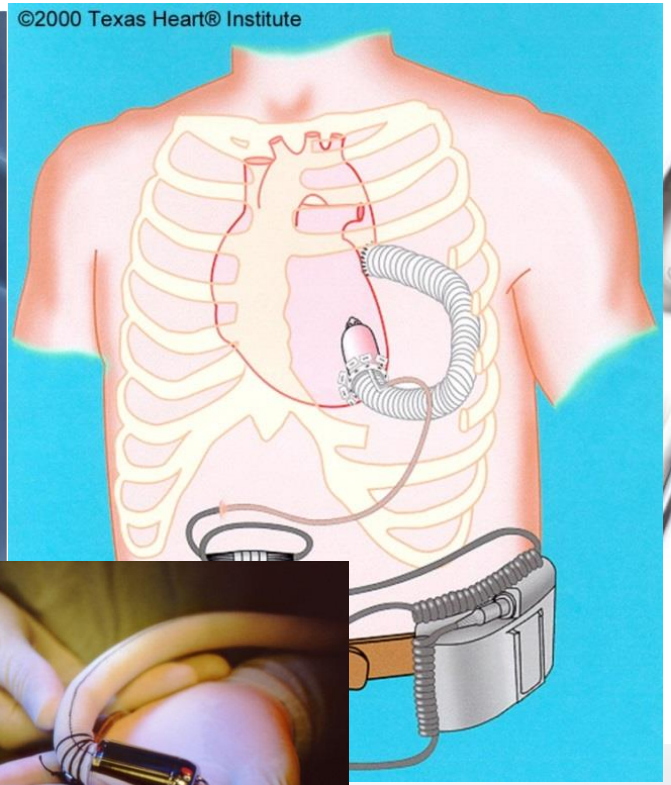
Durable devices

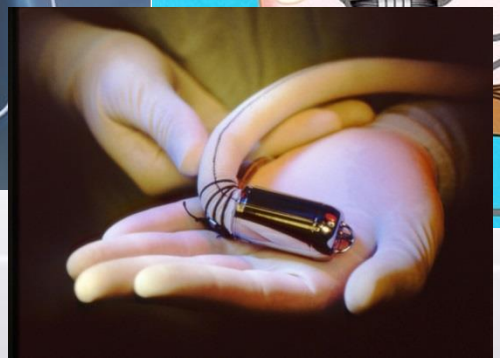
- ✓ **Continuous flow**

HeartMate II LVAD



Javik 2000



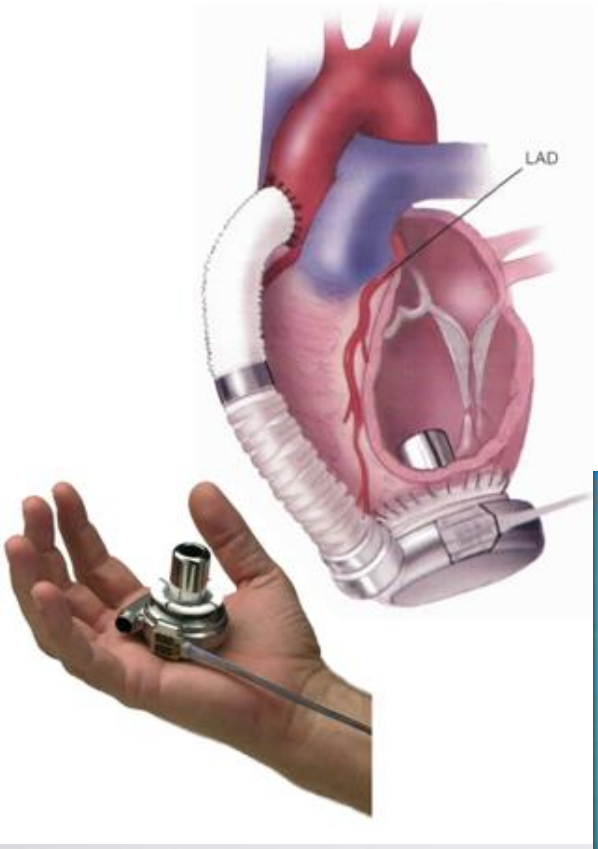


MicroMed Debakey Child VAD

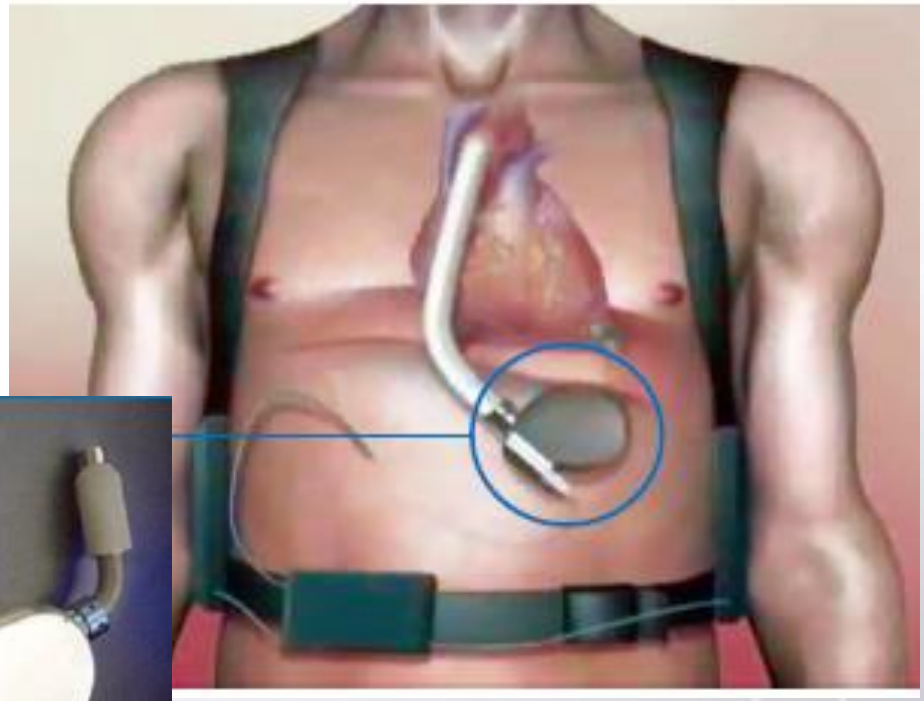
Durable devices

✓ **Continuous flow**

HVAD



Levacor



Durable devices

✓Continuous flow

TABLE 8-4	Continuous Flow Mechanical Circulatory Support Systems for Long-Term Support			
Device Name	**Manufacturer**	**Type of Pump**	**Type of Support**	**Pump Position**
HeartMate II	Thoratec Corp, Pleasanton, CA	Axial flow with blood-immersed bearings	LVAD	Preperitoneal pocket
Jarvik 2000	Jarvik Heart, Inc, New York, NY	Axial flow with blood-immersed bearings	LVAD	LV
Synergy	CircuLite, Inc, Saddle Brook, NJ	Axial flow with blood-immersed bearings	LVAD	Chest wall pocket
INCOR	Berline Heart, Berlin, Germany	Axial flow with blood-immersed bearings	LVAD	Preperitoneal pocket
DuraHeart	Terumo Cardiovascular, Ann Arbor, MI	Centrifugal flow; magnetic and	LVAD	Preperitoneal pocket
HVAD	HeartWare, Inc, Framingham, MA	Centrifugal flow; magnetic and hydrodynamic bearings	LVAD	Intrapericardial
Levacor	WorldHeart, Inc, Salt Lake City, UT	Centrifugal flow; magnetic bearings	LVAD	Preperitoneal pocket

LV, left ventricle; LVAD, left ventricular assist device.

HeartWare HVAD

Use of an Intrapericardial, Continuous-Flow, Centrifugal Pump in Patients Awaiting Heart Transplantation

Keith D. Aaronson, MD, MS*; Mark S. Slaughter, MD*; Leslie W. Miller, MD; Edwin C. McGee, MD; William G. Cotts, MD; Michael A. Acker, MD; Mariell L. Jessup, MD; Igor D. Gregoric, MD; Pranav Loyalka, MD; O.H. Frazier, MD; Valluvan Jeevanandam, MD; Allen S. Anderson, MD; Robert L. Kormos, MD; Jeffrey J. Teuteberg, MD; Wayne C. Levy, MD; David C. Naftel, PhD; Richard M. Bittman, PhD; Francis D. Pagani, MD, PhD; David R. Hathaway, MD; Steven W. Boyce, MD; for the HeartWare Ventricular Assist Device (HVAD) Bridge to Transplant ADVANCE Trial Investigators†

Background—Contemporary ventricular assist device therapy results in a high rate of successful heart transplantation but is associated with bleeding, infections, and other complications. Further reductions in pump size, centrifugal design, and intrapericardial positioning may reduce complications and improve outcomes.

Methods and Results—We studied a small, intrapericardially positioned, continuous-flow centrifugal pump in patients requiring an implanted ventricular assist device as a bridge to heart transplantation. The course of investigational pump recipients was compared with that of patients implanted contemporaneously with commercially available devices. The primary outcome, success, was defined as survival on the originally implanted device, transplantation, or explantation for ventricular recovery at 180 days and was evaluated for both noninferiority and superiority. Secondary outcomes included a comparison of survival between groups and functional and quality-of-life outcomes and adverse events in the investigational device group. A total of 140 patients received the investigational pump, and 499 patients received a commercially available pump implanted contemporaneously. Success occurred in 90.7% of investigational pump patients and 90.1% of controls, establishing the noninferiority of the investigational pump ($P<0.001$; 15% noninferiority margin). At 6 months, median 6-minute walk distance improved by 128.5 m, and both disease-specific and global quality-of-life scores improved significantly.

Conclusions—A small, intrapericardially positioned, continuous-flow, centrifugal pump was noninferior to contemporaneously implanted, commercially available ventricular assist devices. Functional capacity and quality of life improved markedly, and the adverse event profile was favorable.

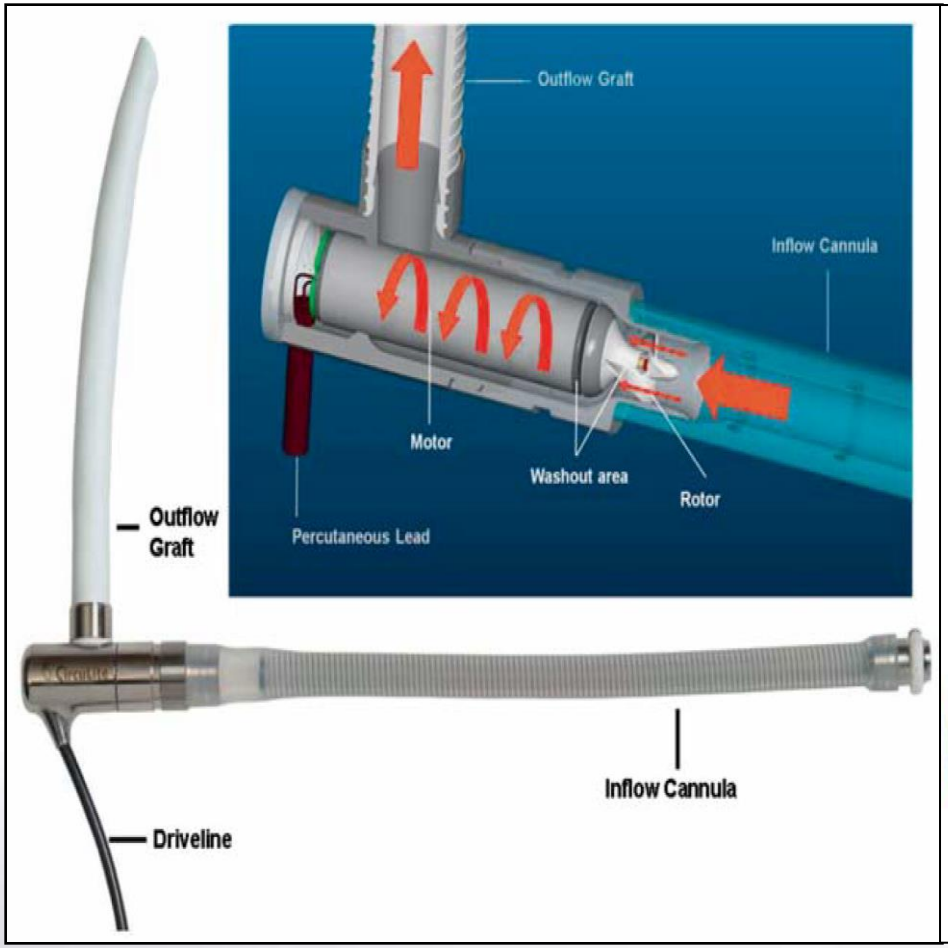
Circulation 2012;125:3191-3200.

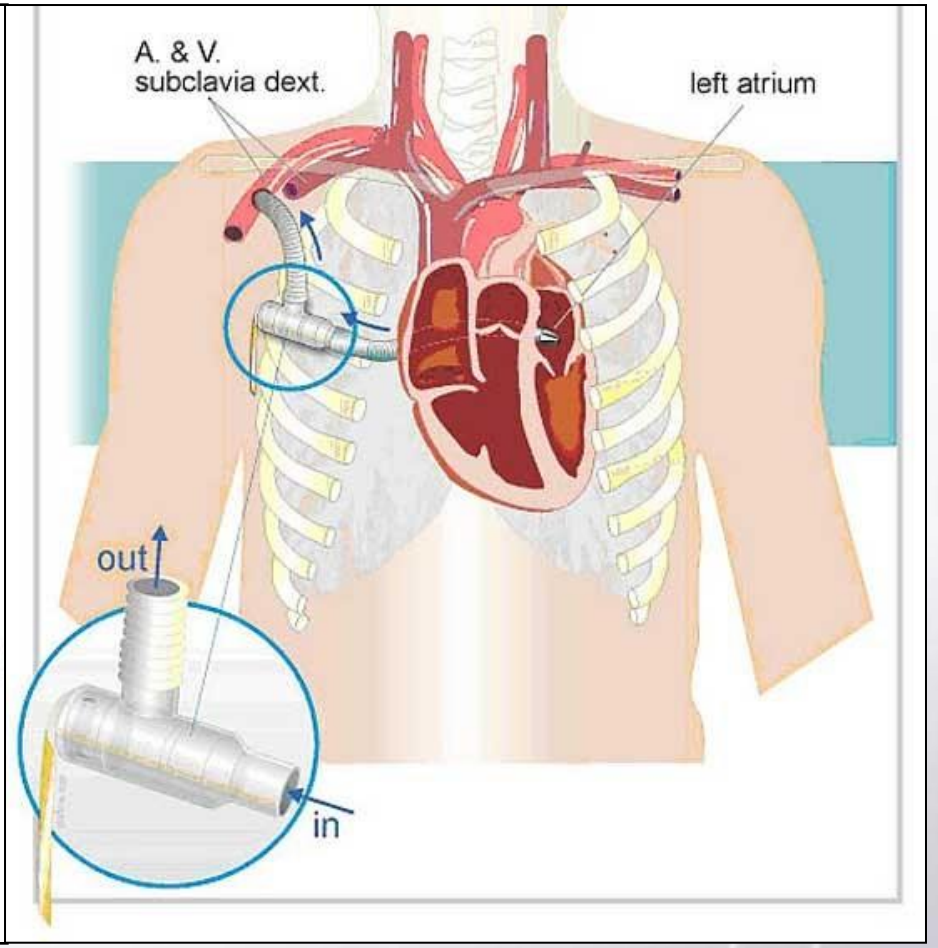
HeartWare HVAD

- Short intergrated inflow cannula
- Small size of the pump (50mL, 140g)
  - Pericardial positioning
  - Avoidance of a pump pocket
  - Available for smaller body sized patients
  - Potential benefit of reduction in bleeding and infection
- 10L/min of flow, speed : 1800 to 4000 rpm

- New, No sufficient cilnical data

CircuLite® Synergy® Device





Klotz S et al., Thorac Cardiov Surg 2010; 58, Suppl. 2: S173-S178

Durable devices

- ✓ **Total artificial heart (TAH)**

SynCardia CardioWest

AbioCor TAH

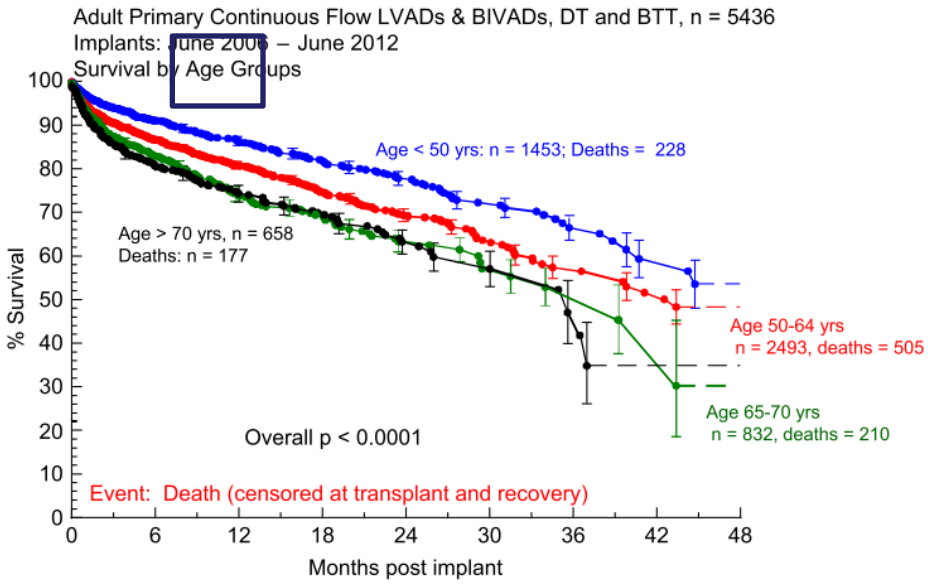
20m

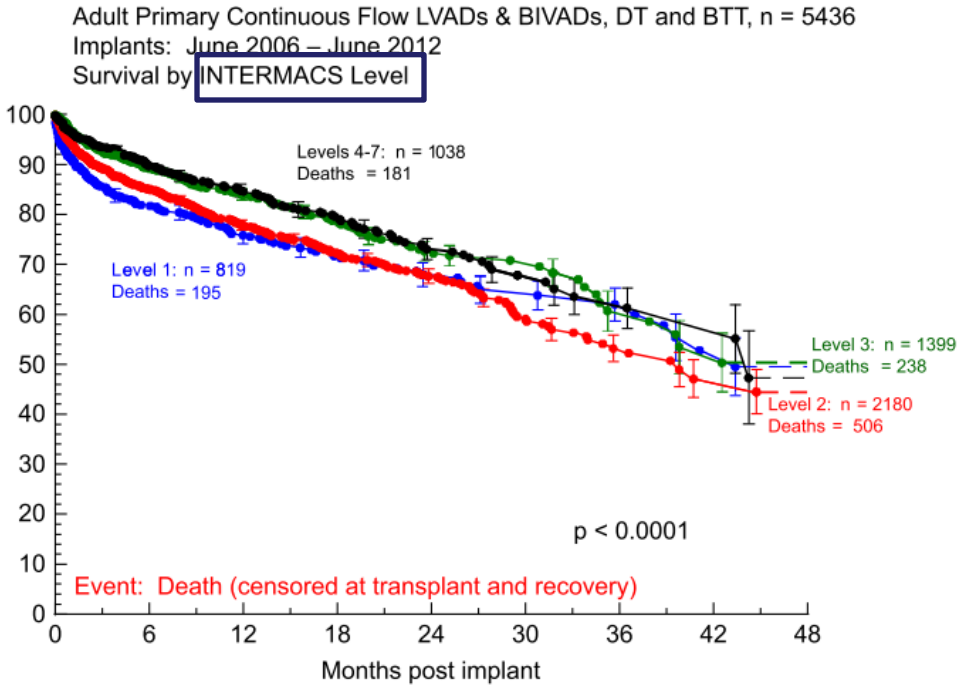
Risk factors for Death after MCS

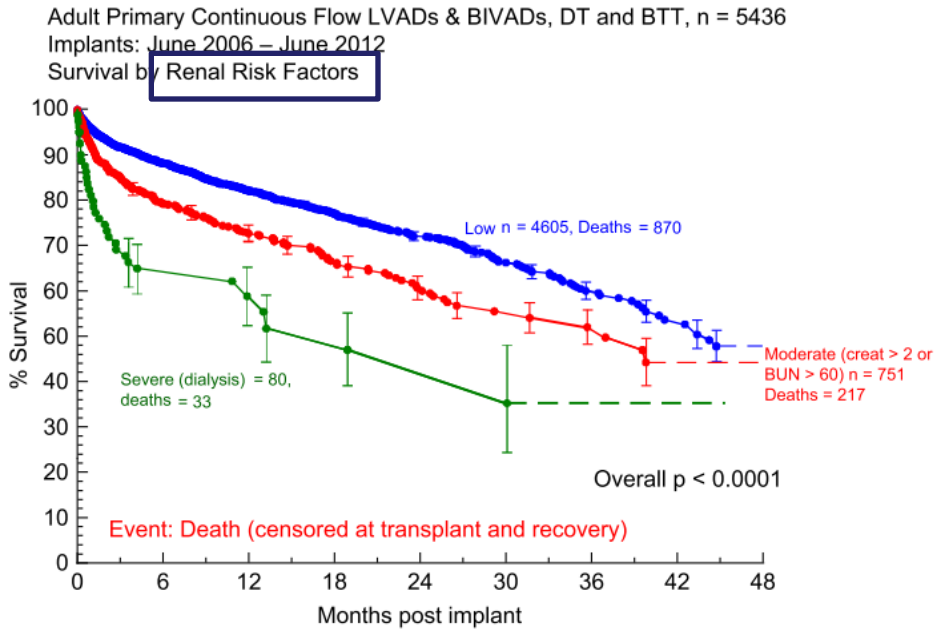
Table 3 Implants: June 2006–June 2012, Adult Primary Continuous-Flow LVADs and BiVADS, DT and BTT (n = 5,436)

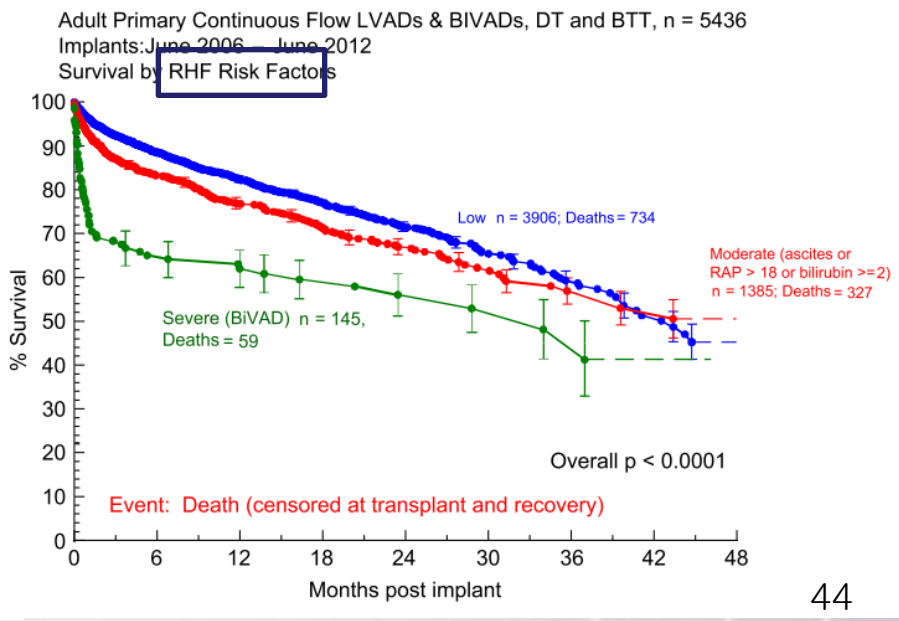
	Early hazard		Constant hazard	
Risk factors for death	Hazard ratio	p-value	Hazard ratio	p-value
Demographics				
Age (older)	1.69	<0.0001		
Body mass index (higher)	1.47	<0.0001		
Clinical status				
Ventilator	1.65	0.009		
History of stroke	1.69	0.009		
INTERMACS Level 1	2.45	<0.0001		
INTERMACS Level 2	1.89	0.0004	1.30	0.003
Destination therapy			1.25	0.01
Non-cardiac systems				
Diabetes			1.22	0.02
Creatinine (higher)			1.10	0.008
Dialysis	2.22	0.002		
Blood urea nitrogen (higher)	1.10	<0.0001		
Right heart dysfunction				
RVAD in same operation	3.73	<0.0001		
Right atrial pressure (higher)	1.36	0.002		
Bilirubin (higher)	1.08	<0.0001		
Ascites			1.32	0.05
Surgical complexities				
History of cardiac surgery			1.50	<0.0001
Concomitant cardiac surgery	1.34	0.02		

BiVAD, biventricular assist device; BTT, bridge to transplant; DT, destination therapy; INTERMACS, Interagency Registry for Mechanically Assisted Circulatory Support LVAD, left ventricular assist device; RVAD, right ventricular assist device.

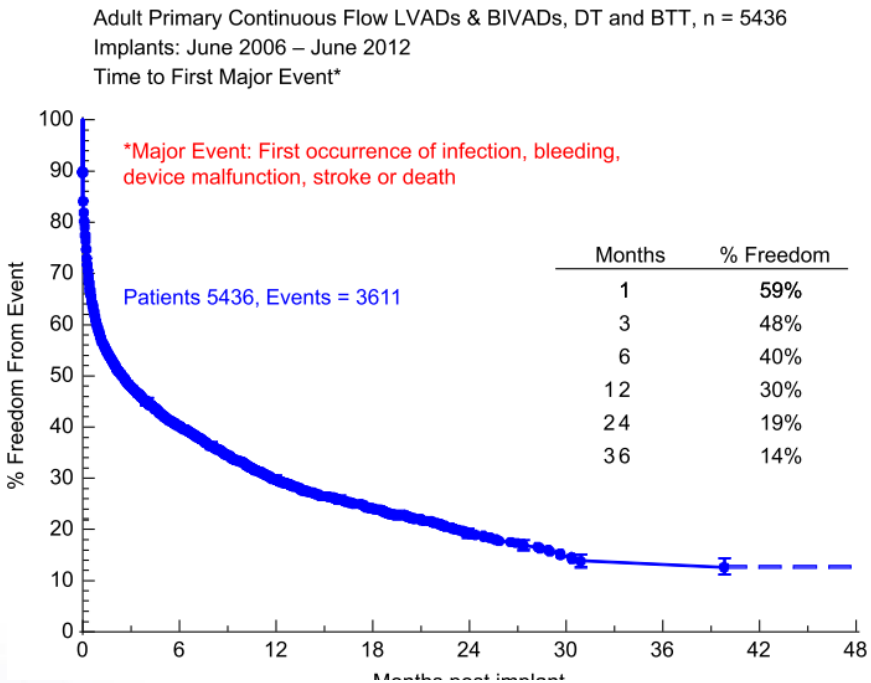

Adult Primary Continuous Flow LVADs & BIVADs, DT and BTT, n = 5436
Implants: June 2006 – June 2012
Survival by Age Groups
Age < 50 yrs: n = 1453; Deaths = 228
Age > 70 yrs, n = 658
Deaths: n = 177
Age 50-64 yrs
n = 2493, deaths = 505
Age 65-70 yrs
n = 832, deaths = 210
Overall p < 0.0001
Event: Death (censored at transplant and recovery)
% Survival
Months post implant


Adult Primary Continuous Flow LVADs & BIVADs, DT and BTT, n = 5436
Implants: June 2006 – June 2012
Survival by INTERMACS Level
Levels 4-7: n = 1038
Deaths = 181
Level 1: n = 819
Deaths = 195
Level 3: n = 1399
Deaths = 238
Level 2: n = 2180
Deaths = 506
p < 0.0001
Event: Death (censored at transplant and recovery)
Months post implant


Adult Primary Continuous Flow LVADs & BIVADs, DT and BTT, n = 5436
Implants: June 2006 – June 2012
Survival by Renal Risk Factors
Low n = 4605, Deaths = 870
Moderate (creat > 2 or
BUN > 60) n = 751
Deaths = 217
Severe (dialysis) = 80,
deaths = 33
Overall p < 0.0001
Event: Death (censored at transplant and recovery)
% Survival
Months post implant


Adult Primary Continuous Flow LVADs & BIVADs, DT and BTT, n = 5436
Implants: June 2006 – June 2012
Survival by RHF Risk Factors
Low n = 3906; Deaths = 734
Moderate (ascites or
RAP > 18 or bilirubin >=2)
n = 1385; Deaths = 327
Severe (BiVAD) n = 145,
Deaths = 59
Overall p < 0.0001
Event: Death (censored at transplant and recovery)
% Survival
Months post implant

Adverse events



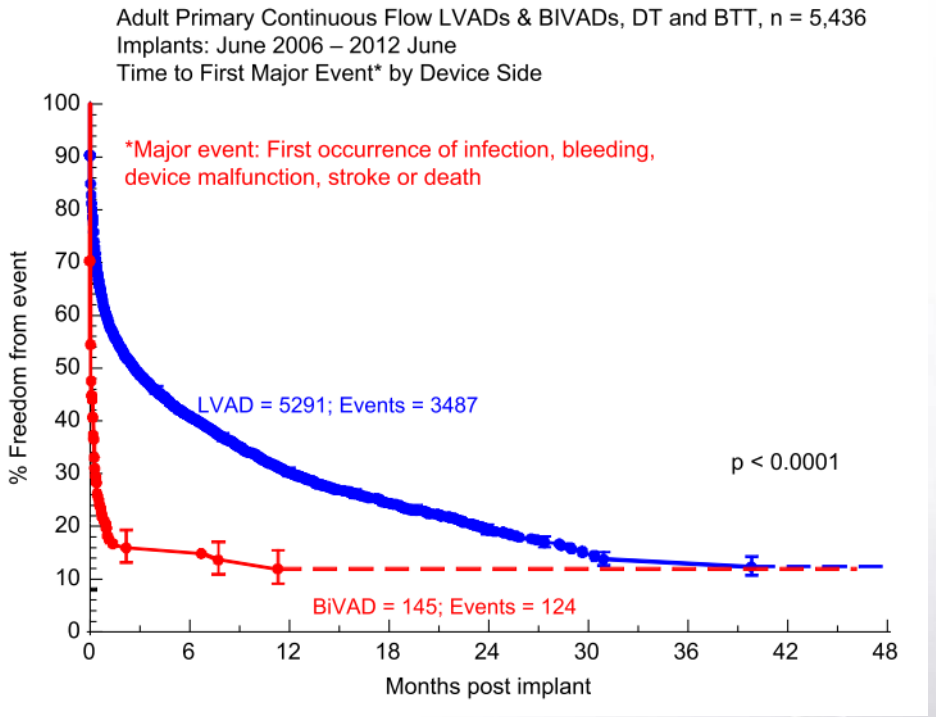
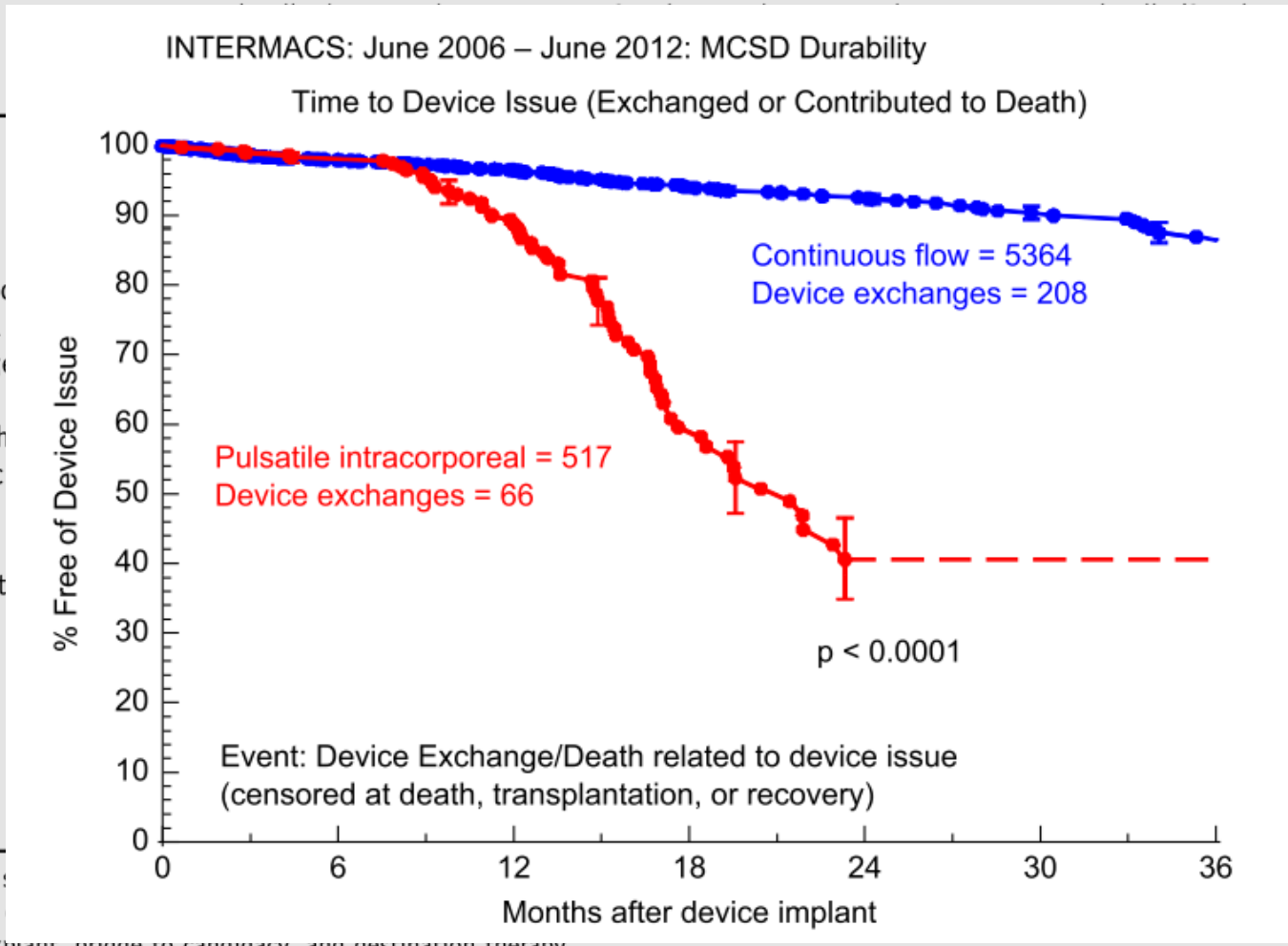


Table 5 Implants: June 2006–June 2012[a]

Adverse event	ous
	alue
Device malfunction	.0001
Bleeding	.0001
Cardiac/vascular	
Right heart failure	.001
Myocardial infarcti	.47
Cardiac arrhythmia	.0001
Pericardial drainag	.0001
Hypertension[b]	.0001
Arterial non-CNS th	.001
Venous thrombotic	.0001
Hemolysis	.69
Infection	.0001
Neurological dysfunct	.0001
Renal dysfunction	.0001
Hepatic dysfunction	.0001
Respiratory failure	.0001
Wound dehiscence	.0001
Psychiatric episode	.0001
Total burden	.0001



CNS, central nervous

[a]Adverse event rates

nt device strategy bridge to transplant, bridge to candidacy, and destination therapy.

[b]With current reporting, identification of hypertension with continuous-flow pumps is unreliable.

Complications

Event	Frequency
Bleeding	48%
Infection	18–59%
Neurological event	10–27%
RV failure	7–11%
Thromboembolism	12%
Device failure	12.8%

- **Early**
  - Bleeding
  - **Right sided heart failure**

: *Cardiac output is dependent on the ability of RV*

: Continuous collapse LV

→ interventricular septum diplaced LV side → RV dilatation effect → RV failure

  - Progressive multiorgan system failure
- **Late**
  - Infection
    - Nosocomial or Device related
  - Thromboembolism
  - Failure of device

Risk Scores for Mortality after VAD implantation

Variable*	OR/Risk Score
Platelet count ≤148×10^3/μL	7.7/7
Serum albumin ≤3.3 g/dL	5.7/5
INR >1.1	5.4/4
Vasodilator therapy	5.2/4
Mean PAP ≤25 mm Hg	4.1/3
AST >45 U/mL	2.6/2
Hematocrit ≤34%	3.0/2
BUN >51 U/dL	2.9/2
No intravenous inotropes	2.9/2
Destination therapy risk score:	
Low risk: 0 to 8	
Medium to high risk: 9 to 19	
Very high risk: >19	

Variable†‡	Relative Risk/Risk Score
Urine output <30 mL/h	3.9/3
CVP >16 mm Hg	3.1/2
Mechanical ventilation	3.0/2
PT >16 seconds	2.4/2
Reoperation	1.8/1
WBC >15 000/mm^3	1.1/0
Temperature >101.5°F	0/0
Bridge to transplantation risk score:	
Low risk: <5	
High risk: ≥5	

Variable§	OR/Risk Score
Respiratory failure and sepsis‖	11.2/1
Preexisting right heart failure	3.2/1
Age at implant >65 years	3.0/1
Acute postcardiotomy	1.8/1
Acute infarction	1.7/1
Bridge to transplantation risk score:	
Low risk: 0	
High risk: ≥1	

CVP indicates central venous pressure; INR, international normalized ratio; PT, prothrombin time; PAP, pulmonary artery pressure; AST, aspartate aminotransferase; WBC, white blood cell count; and BUN, blood urea nitrogen.

*Adapted from Lietz et al.[11]

†Adapted from Oz et al.[10]

‡All patients met hemodynamic criteria consisting of cardiac index <2.0 L · min^{-1} · m^{-2} with left atrial or pulmonary capillary wedge pressure >20 mm Hg.

§Adapted from Deng et al.[12]

‖Includes patients with preimplantation septicemia (fever >38.5°C) and positive blood cultures who required mechanical ventilation.

Circulation. 2009;119:2225-2232

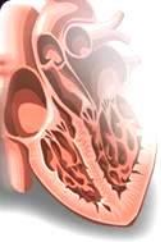
OPD F/U

- Patients and their family

  : Intensive education (battery, driveline care, warning sign)
- Monitoring

  : BP, volume control, Driveline care, anticoagulation adjustment (INR : 1.5-2.5)
- MCS program

  : team approach



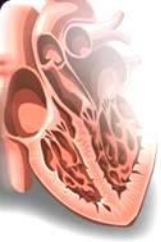
Summaries (1)

- Increased **prevalence and incidence** rate of HF
- Only effective treatment for end stage CHF is **heart transplant.**
- Much progress has been made over the last 2 decades in the field of **mechanical circulatory support (MCS).**

  (Extracorporeal & Implantable)

  ➔ Tx. Options for patients with advanced HF.
- **VADs** are now seen as a credible lifesaving option to support **the failing heart for short- and long-term therapy**.

  (B to R, B to Decision, B to T and DT)



Summaries (2)

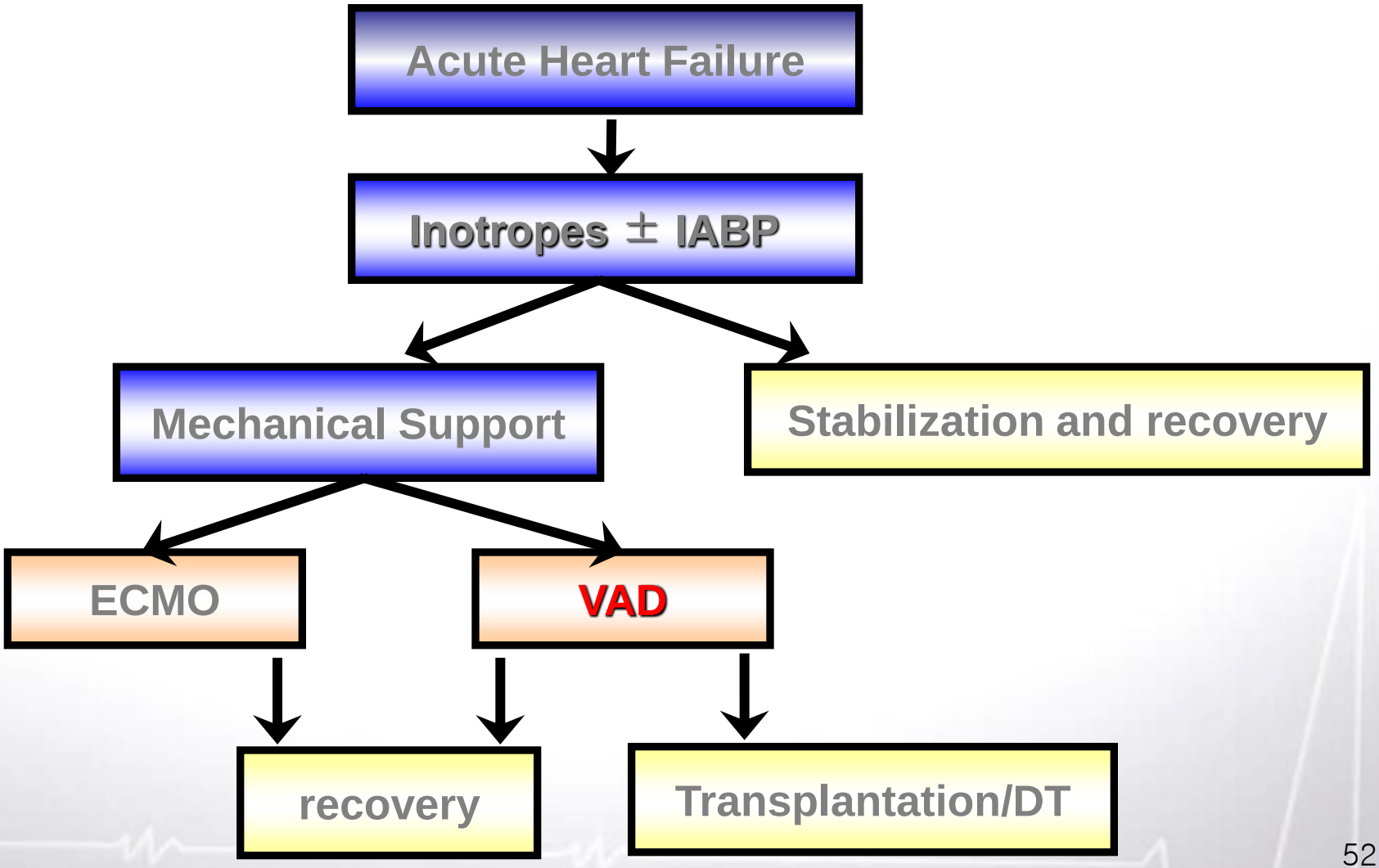
- Improved **understanding of cardiac and noncardiac risk factors** through prospective and retrospective analyses has **optimized care for patients with end stage heart failure**.

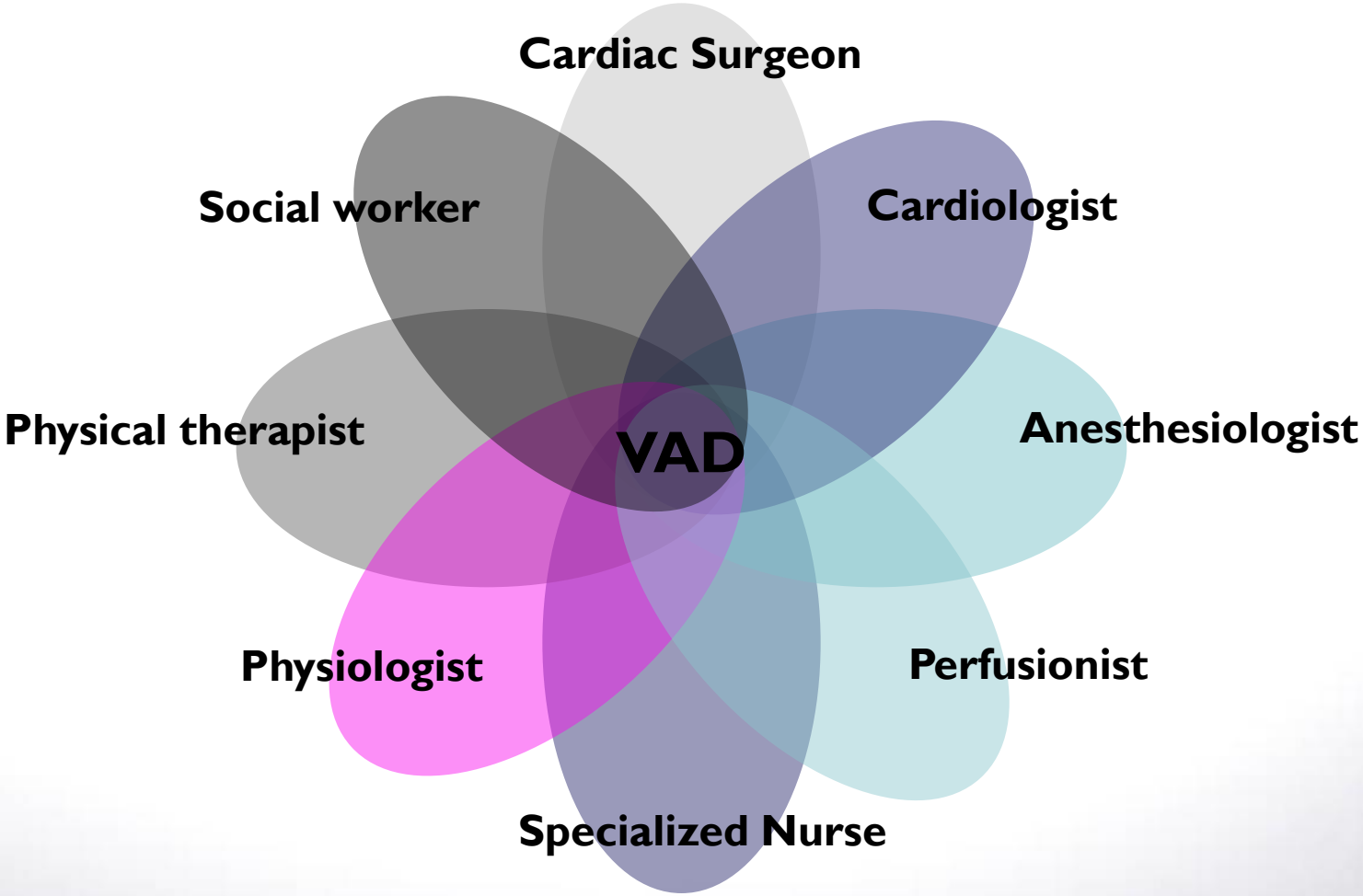
  ➔ extended survival and QOL ↑

- The ground work has been set for a **promising future for VADs** through the establishment of the INTERMACS registry, and there is continued widespread interest in improving the characterization and **selection of VAD patients**, as well **as the timing of surgery.**

  ➔ improving clinical outcome

Mechanical circulating support decision tree




Cardiac Surgeon
Cardiologist
Anesthesiologist
Perfusionist
Specialized Nurse
Physiologist
Physical therapist
Social worker
VAD

Thank you very much for your attention