Ventricular Assist Devices: Present & Future

Brian Lima, M.D.
Director of Clinical Research in Heart Transplantation & Mechanical Circulatory Support
Baylor University Medical Center

BaylorScott&White HEALTH

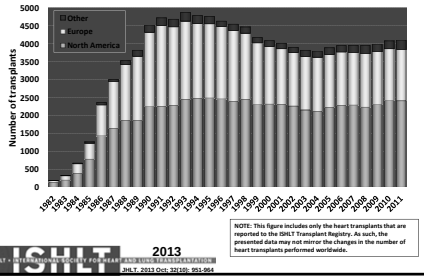
Cardiac and Thoracic Surgery at Baylor University Medical Center

Heart Failure: A Growing Global Epidemic

- By 2030 → 10 million Americans
- Limited donor organ availability
- Myriad device options for mechanical circulatory support (MCS):
  - Short-Term
  - Long-Term (implantable)

*Lima B, Mack M, and Gonzalez-Stawinski GV. Ventricular Assist Devices: The Future is Now. *Trends in Cardiovascular Medicine* 2014 (In Press)

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



NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, the presented data may not mirror the changes in the number of heart transplants performed worldwide.

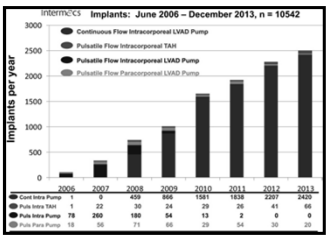
ISHLT 2013

JHLT. 2013 Oct; 32(10): 951-964

Strategies for VAD Therapy

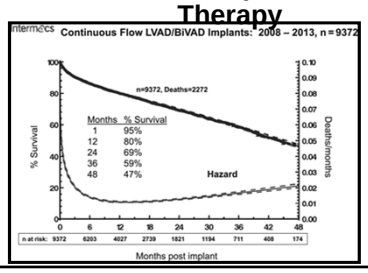
- Bridge to Transplant (BTT)
- Destination Therapy (DT)
- Bridge to Decision (BTD)

Exponential Rise in VAD Implantation



2006: N=100
2013: N=2500
*2500% INCREASE

Growing Experience, Improving Survival with Implantable VAD Therapy



Also Improved:
- QOL
- Functional capacity

≥7 years of support

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

ROADMAP

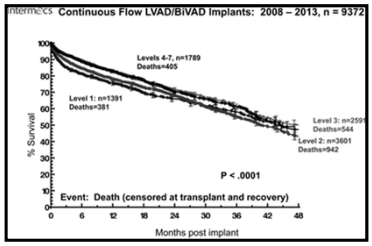
REVISIT

Fig. 24-4. INTERMACS patient profiles. ADL, activities of daily living; LVADs, left ventricular assist devices; NYHA, New York Heart Association.

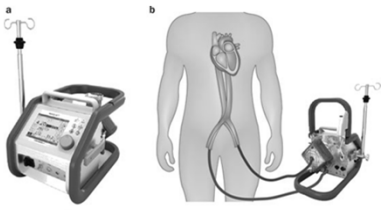
Copyright © 2010 by Saunders, an imprint of Elsevier Inc.

INTERMACS, Interagency Registry for Mechanical Circulatory Support

Survival Inversely Related to INTERMACS Score



Short-Term MCS: VA ECMO

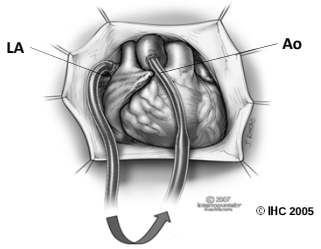


Short Term MCS: CentriMag System Components

Pump Motor Console / Monitor

CentriMag

Left Heart Cannulation

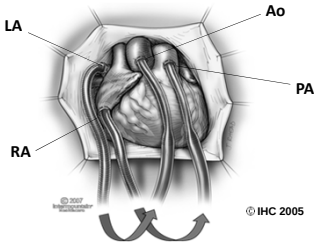


© IHC 2005

To CentriMag Pump & Console

CentriMag

Bilateral Support



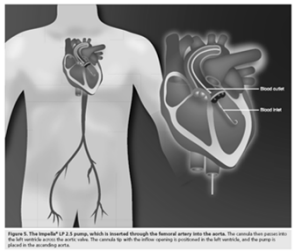
© IHC 2005

To CentriMag Pumps & Consoles

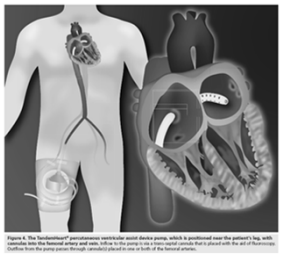
CentriMag

≥7 years of support

Short-Term MCS: Impella



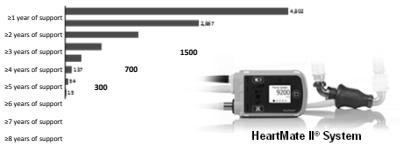
Short-Term MCS: Tandem Heart



Worldwide HeartMate II® Clinical Experience

*More than **18,000** patients worldwide have now been implanted with the HeartMate II LVAS.*

Over 7,000 patients on ongoing support



There is now a patient from the Pivotal Trial who has been on support with **HeartMate II for over a decade**.

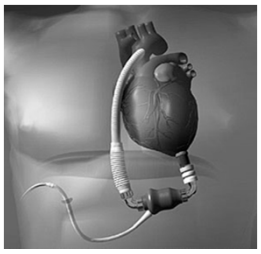
15

As of July 2014
*Based on clinical trial and device tracking data

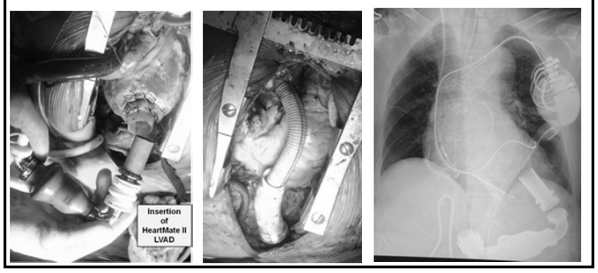
THORATEC for Life.

HeartMate II LVAD

- 2nd generation, continuous flow rotary pump
- Can deliver 10L/min of flow
- Battery life up to 12 hours
- FDA approved
  - BTT 2008
  - DT 2010

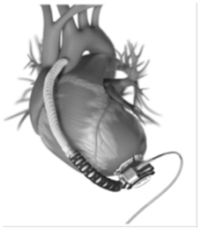


HeartMate II LVAD Insertion

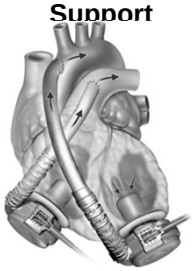


HeartWare HVAD

- 3rd generation, centrifugal continuous flow pump
- Hydromagnetically levitated rotor without bearings
- Can deliver 10L/min flow
- Only 140g, can be implanted within the pericardium
- Following ADVANCE trial, FDA approved for BTT in 2012
- ENDURANCE results pending



Bilateral HVADs for Biventricular Support



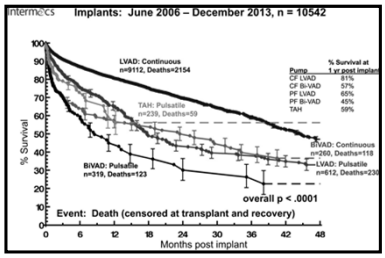
Limited Options for Durable Bi-V Support

- Most extensive experience with SynCardia Total Artificial Heart (TAH)
- FDA approved for BTT in 2007
- Pneumatically driven, pulsatile pump
- Orthotopically replaces native ventricles and all 4 valves
  - Bilateral ventriculectomy, atrial cuffs
  - Each chamber houses 2 Metronic mechanical valves
- 2 tunneled drivelines
- Total output of 8 L/min

Total Artificial Heart: SynCardia CardioWest

- 2004 Study by Copeland et al
  - N=130 patients (1993-2002)
  - 79% bridged to transplant vs. 46% in control group
- Recently FDA approved for DT (Humanitarian Use Designation)
- Only ~30 TAHs implanted yearly

Outcomes: Survival by Device Type



Outcomes: Quality of LIfe

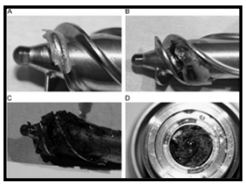
- "Severe Problems" with self-care
  - 50% pre-implant
  - < 5% at 3 months post-implant
- "Severe Problems with usual activities of daily living
  - >80% pre-implant
  - 5% post-implant
- 20-40% pts report some problems with these indices

Outcomes: Hemorrhage

- Therapeutic anticoagulation: INR 2-2.5
- Acquired von Willebrand factor deficiency
- Gastrointestinal AVMs
- 0.7 bleeding events / patient year
  - 45% GI bleeding (HM II)
  - More common in HVAD
- 30% rate of GI bleeding overall
- Hospital readmissions

Outcomes: Thromboembolic Complications

- Pump Thrombosis
  - 8% for HMII & HVAD
  - Power spikes on system controller
  - Elevated serum levels
    - LDH
    - Plasma free hemoglobin
  - Echocardiographic ramp study for diagnosis
  - Pump exchange for treatment



Outcomes: Infection

- 3 categories
  - Device-specific (pump, cannulae, pocket, driveline)
  - Device-related (endocarditis, bacteremia, mediastintitis)
  - Non-device-related
- Continuous Flow VAD-specific infections
  - 0.48 events / patient-year
  - Down from 0.90 events / patient-year with 1st generation pulsatile pumps
- Meticulous wound care at driveline site is essential

The Future

HeartMate III

HeartWare MVAD

Wireless LVAD