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)


Strategies for VAD Therapy

- Bridge to Transplant (BTT)
- Destination Therapy (DT)
- Bridge to Decision (BTD)
Patient Selection is Key

Survival Inversely Related to INTERMACS Score

Short-Term MCS: VA ECMO

Short Term MCS: CentriMag System Components

Left Heart Cannulation

Bilateral Support
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:

≥7 years of support

≥8 years of support

≥6 years of support

≥5 years of support

≥4 years of support

≥3 years of support

≥2 years of support

≥1 year of support

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

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 ventriculotomy, 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

≥7 years of support
≥7 years of support

Outcomes: Thromboembolic Complications

- Pump Thrombosis
- 8% for HMIII & 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, mediastinitis)
  - Non-device related
- Continuous Flow VAD-specific infections
  - 0.48 events / patient-year
    - Down from 0.90 events / patient-year with 1st generation pulsatile pump
  - Meticulous wound care at driveline site is essential

The Future

HeartMate III
HeartWare MVAD
Wireless LVAD