End Stage Heart Failure - Time to Bring the Hammer Down

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Cardiac Transplantation

• Gold Standard for end-stage heart failure refractory to medical therapy
• Growing waiting lists
• Limited donor availability
• Stringent eligibility criteria
• Need for alternative therapeutic measures (ie: mechanical circulatory support – MCS)
MCS Sub-Groups

- BTT – bridge to transplant
- BTC – bridge to candidacy
- DT – destination therapy
- BTR – bridge to recovery
INTERMACS
Interagency Registry for Mechanically Assisted Circulatory Support

- Established – June 2006
- > 6000 patients in database
- Annual growth rate ~ 1500/year
- Provides data re: current state of placement and outcomes
<table>
<thead>
<tr>
<th>Profile</th>
<th>Pt Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Critical cardiogenic shock inspite of support</td>
</tr>
<tr>
<td>2</td>
<td>Progressive decline with inotrope dependence</td>
</tr>
<tr>
<td>3</td>
<td>Clinically stable with inotrope support</td>
</tr>
<tr>
<td>4</td>
<td>Recurrent advanced HF that can be stabilized medically</td>
</tr>
<tr>
<td>5</td>
<td>Exertion intolerant; Can perform ADL’s</td>
</tr>
<tr>
<td>6</td>
<td>Exertion limited; can perform mild activity but fatigues</td>
</tr>
<tr>
<td>7</td>
<td>Non-lifestyle limiting HF</td>
</tr>
<tr>
<td>Strategy</td>
<td>Definition</td>
</tr>
<tr>
<td>----------</td>
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</tr>
<tr>
<td>BTT</td>
<td>Actively listed for transplant</td>
</tr>
<tr>
<td>BTC</td>
<td>Not actively listed; no absolute contraindications; recovery ?</td>
</tr>
<tr>
<td>DT</td>
<td>Ineligible for transplant</td>
</tr>
<tr>
<td>BTR</td>
<td>Needs extended support; recovery expected</td>
</tr>
</tbody>
</table>
First Generation LVAD’s

• Pulsatile – volume displacement
  ➢ Pusher plates
  ➢ Sacs
  ➢ Prosthetic valves
• Introduced textured blood contacting surface (HM I)
• Some required only antiplatelet therapy

• HeartMate I – Thoratec
  ➢ Implantable Pneumatic
  ➢ Vented Electric
• PVAD – Thoratec
• Novacor N100 – World Heart
First Generation LVAD’s

• Set the stage for successful MCS
• REMATCH – 2001 landmark study - NEJM
  - HeartMate vs Optimal Medical Management (OMM)
  - 46% reduction in death from any cause
  - 1 year survival – 52% LVAD vs 25% OMM
Second Generation LVAD’s

• Goals
  ➢ Smaller
  ➢ Reduction in complications
  ➢ Improved efficiency and durability

• Continuous axial flow pumps

• HeartMate II – Thoratec
• Jarvik 2000 – Jarvik Heart
• Micromed DeBakey – MicroMed Cardiovascular
Second Generation LVAD’s

• Initial concerns
  ➢ Nonpulsatile / Nonphysiologic

• Ultimate answer
  ➢ In capillary beds, normal physiologic “pulsatile” flow is \( \sim \frac{1}{1000}\)th of that seen in the aorta
    » Prothero et al, Biophys J. 1961; 1
Second Generation LVAD’s

- Continuous axial flow ➔
  - Internal rotor suspended via blood immersed bearings
  - Reduced prothrombotic sites
  - Fewer moving parts
  - No reservoir chamber required
  - No inflow or outflow valves
  - Textured titanium lining

- Impeller blade
  - Powered by electromagnetic motor
  - Rotary speeds 8000 – 15000 rpm
Second Generation LVAD’s

- Predicted to be 5 year devices
  - compared to 2 year First Generation devices
  - Explanted pump assessments → 10+ year predictions

- Coumadin Rx required

- HeartMate II BTT Trial – 2007 landmark Study – NEJM
  - Survival rates at 6 and 12 months – 75% and 68%
  - Significantly improved quality of life
  - Significantly improved functional capacity

- HeartMate II DT Trial – 2009 – NEJM
  - Significantly improved survival 2 years post-implant compared to HeartMate I
Pulsatile vs Continuous Flow LVADs
Long Term LV Support

Pulsatile / Volume Displacement  Continuous / Rotary

Varying the speed of the rotor can increase flow/output and change ventricular dimension and volume
Third Generation LVAD’s

- Continuous flow
- Distinguishing factor – noncontact bearings
  - Magnetic levitation (MAGLEV)
  - Rotation without friction / wear
- Goal is to further reduce prothrombotic sites

- HeartWare HVAD – HeartWare International
- DuraHeart – Terumo Heart
- Incor – Berlin Heart
- Levacor – World Heart
- HeartMate III – Thoratec

- All are centrifugal except Incor which is axial
The HeartWare® System with HVAD® Pump

- HVAD Pump
  - Continuous flow, centrifugal pump
  - 50cc / 160g, 50mm outside diameter
  - Provides full circulatory support
    - Wide-blade impeller is the only moving part
    - Hybrid magnetic / hydrodynamic suspension
      - Contactless design
      - Dual motors designed to provide power efficiency and redundancy
- Thin (4.2 mm), flexible driveline with fatigue-resistant cables
- User-friendly patient peripherals

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to the “Instructions For Use” for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events and Instructions prior to using this device.
Elegant Fluid Dynamics

**Primary flow path**
Washes flow channels and immediately enters outflow graft

**Secondary flow path**
Washes underside and center-post regions

**Tertiary flow path**
Provides fluid “cushion” & washes thrust bearings

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Contactless Design

*Pathology pictures after 427 days*

**Pump housing**  
**Impeller**

Images taken at Texas A&M University by Dr. Fred Clubb, D.V.M., Ph.D., DACLAM, Clinical Professor
Pericardial Placement – No Pump Pocket

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State of the Art
Assessing the Arsenal

• Assessing the Intel – INTERMACS 5TH Annual Report
  ➢ Significant increase in LVAD implants following publication of the 2007 HeartMate II BTT Trial
  ➢ By 2010, 99% of all implanted LVAD’s were continuous flow devices
  ➢ Shifting toward more DT implants
  ➢ Shifting toward implants in less compromised patients → higher INTERMACS bracket rankings
State of the Art
Assessing the Arsenal

• Risks factors for post-LVAD mortality
  ➢ Cardiogenic shock
  ➢ Right heart failure requiring BiV support
  ➢ Age
  ➢ BUN
  ➢ Pulmonary hypertension
  ➢ Pulsatile LVAD (historical significance only)

• Survival
  ➢ 1 year – 81%
  ➢ 2 years – 70%
Total Artificial Heart Syncardia

- FDA approved as BTT
- Certainly a “bigger gun”
- Proven efficacy in certain patient populations
  - Biventricular failure
    - Amyloid
    - Giant Cell myocarditis
  - Adult congenital population
- Previous limitations have centered around mobility and ability to discharge to outpatient status
  - Currently ~75% are able to be discharged to home
Syncardia Total Artificial Heart
Syncardia Total Artificial Heart
Syncardia Total Artificial Heart
Atrial Connectors
Syncardia Total Artificial Heart
Mechanical Med-Hall Valves
Now Replaced with Medtronic ATS BiLeaflet Valves
State of the Art
Looking Toward the Future

• Optimal MCS
  ➢ Durable
  ➢ Biocompatible
  ➢ Totally implantable – no driveline

• Transcutaneous energy transfer (TET)
  ➢ Patented 1994
  ➢ Induction-heating system → electromagnetic (EM) charge
  ➢ Outside EM interference has been a problem and limited use
  ➢ AbioCor – Abiomed // LionHeart – Arrow Int’l
    » TET reliability at 1 and 2 years – J CTS 2010
State of the Art
Ongoing Trials

Studies to assess MCS before the onset of higher risk HF

- **REVIVE-IT**
  - Randomized
  - DT
  - NYHA IIIb/IV who have not required needed inotrope therapy
  - HeartWare vs OMM

- **ROADMAP**
  - Nonrandomized
  - Multicenter, observational
  - INTERMACS 4-7 profiles
  - HM II vs OMM
State of the Art

Why go for the Big Hammer?

- Multiple studies over the past 11 years have consistently demonstrated superior outcomes re: clinical status when compared to OMM.
- Industry’s commitment to durable and efficient technology has BTC (HM II, HeartWare, and Syncardia TAH) and DT (HM II) as viable alternatives to OMM.
- Commitment continues → multiple devices seeking FDA approval
Hammers are available

Choose wisely
Thank you