Management of Advanced Congestive Heart Failure

Mechanical Circulatory Support

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Orlando, Florida – October 7-9, 2011
Mechanical Circulatory Support Program

Mission

Patient Care

Research

Education

To enhance and extend the quality of life in patients with end stage heart disease requiring advanced cardiopulmonary mechanical support through a commitment to research, education, and above all clinical excellence.
Congestive Heart Failure

Epidemiology

- 5 million Americans, 10 million worldwide
- 500,000 to 1 million new cases diagnosed yearly
- 70% of men, 79% of women with CHF have history of hypertension
- Huge economic impact in diagnosis, treatment, including AICD, Bi Ventricular pacing, transplant/LVADs
ACC/AHA stages of systolic HF and treatment options

Stage A
High risk with no symptoms

Stage B
Structural heart disease, no symptoms

Stage C
Structural disease, previous or current symptoms

Stage D
Refractory symptoms requiring special intervention

- Hospice
- VAD, transplantation
- Inotropes
- Aldosterone antagonist, nesiritide
- Consider multidisciplinary team
- Revascularization, mitral-valve surgery
- Cardiac resynchronization if bundle-branch block present
- Dietary sodium restriction, diuretics, and digoxin
- ACE inhibitors and β-blockers in all patients
- ACE inhibitors or ARBs in all patients; β-blockers*
- Treat hypertension, diabetes, dyslipidemia; ACE inhibitors or ARBs*
- Risk-factor reduction, patient and family education

*In appropriate patients

Some Things Pills Cannot Fix
Which device for what indication?
Mechanical Circulatory Support

*Types of support*

**Acute cardiogenic shock, heart failure**
- Cardiac arrest
- AMI
- post-cardiotomy shock
- cath lab cardiac arrest

**Chronic heart failure**
Criteria for Mechanical Support

- Cardiac Index < 2.0 L/min/m²
- PCWP > 20 mmHg
- SVR > 2,100 dynes/s/cm³
- Urine output < 20 ml/hr
- SBP < 80 mmHg

- Failure to wean inotropes
- End-organ damage
  - Nausea
  - Decreased mental status
  - Progressive renal or hepatic failure
  - Worsening arrhythmias
Contraindications for VAD Support

- Major irreversible neurologic deficits
- Hepatic fibrosis or cirrhosis
- Nonreversible end-organ dysfunction
- Non-correctable intra-cardiac shunts
- Active infection?
- Mechanical ventilation & $\text{FIO}_2 > 70\%$
- Morbid Obesity (BMI >40)
- Pregnancy
- Previous Heart Transplant
- Psychosocial dysfunction
Types of Mechanical Circulatory Support
ACUTE CIRCULATORY FAILURE IN CHRONIC CHF

- IABP
- ECMO
- ABIOMED BVS/AB Ventricle
- THORATEC CentriMag
- Impella
Hemodynamic Issues

- Pre-load dependent
- Independent of cardiac cycle
- Left ventricular assist device requires adequate RV function
Myocardial Recovery and Weaning

- Allow time for ATP stores to return!
- Average minimum of 3 days of ventricular decompression and end organ perfusion before weaning.
- TEE recommended Q24 hours and to assess wall motion while weaning.
- Average recovery occurs in 3-6 days.
Helicopter Transport
Durable Mechanical Circulatory Support
Durable mechanical circulatory support
Left Ventricular Assist Device

- Left ventricular assist device (LVAD) is a electric or battery-operated, mechanical pump-type device that's surgically implanted. It helps maintain the pumping ability of a heart that can't effectively work on its own.

- Right ventricular assist device (RVAD) can also support right side of heart (usually short-term, temporary)
Difficult decisions of end stage heart failure: *Mechanical Circulatory Support*

A balance:

The risks of multi-system organ failure from progressive heart failure (> 50% death in 1 year) versus The risks of surgical intervention for MCSD and ongoing MCSD support
INTERMACS: Patient Selection

Device Strategy

- *Bridge to Recovery*
- *Bridge to Transplant*
- *Destination Therapy*
Bridge to transplant (BTT) Recipient selection criteria for ventricular assist device

**Accepted as candidate for cardiac transplantation**
Absence of coagulopathy or gastrointestinal hemorrhage
Ventricular failure (CI < 1.8 L/min/m², left atrial pressure > 25 mmHg, systolic blood pressure < 90 mmHg), despite:
- Corrected metabolism (temperature, acid-base, electrolytes)
- Adequate preload, appropriate afterload reduction
- Maximal inotropic support
- Intra-aortic balloon pump assistance
## Preoperative risk scale for left ventricular assist device placement

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine output &lt;30 cc/h</td>
<td>3</td>
</tr>
<tr>
<td>Intubated</td>
<td>2</td>
</tr>
<tr>
<td>Prothrombin time &gt;16 sec</td>
<td>2</td>
</tr>
<tr>
<td>Central venous pressure &gt;16 mm Hg</td>
<td>2</td>
</tr>
<tr>
<td>Reoperation</td>
<td>1</td>
</tr>
</tbody>
</table>

* A combined score of >5 is associated with a 70% mortality risk.
Stratum C Case – Preoperative MRI
LVAD Types

1\textsuperscript{st} generation: Pulsatile, with valves, volume-displacement
e.g. Thoratec\textsuperscript{®}, Novacor\textsuperscript{®}, HeartMate I\textsuperscript{®}

2\textsuperscript{nd} generation: Small axial flow pumps
e.g. HeartMate\textsuperscript{®} II, DeBakey VAD\textsuperscript{®}, and Jarvik 2000\textsuperscript{®}

3\textsuperscript{rd} generation: Rotary pumps with non-contact bearings e.g. VentrAssist\textsuperscript{™}
VADs that Deliver a Pulse

- Abiomed BVS 5000 (short-term)
- Abiomed Ventricles (short-term)
- Heartmate XVE (long-term)
- Thoratec IVAD (long-term)
VADs that deliver Continuous Flow (No-Pulse)

- Heartmate II (long-term)
- Heartware (long-term) *investigational
- Ventrassist (long-term) *investigational
- Centrimag (short-term)
Heartmate XVE
HeartMate® VE
REMATCH

Randomized Evaluation of Mechanical Assistance for the Treatment of Congestive Heart Failure

- Prospective Randomized evaluation of LVAD’s vs. medical therapy in patients with CHF who are not transplant candidates
- 129 patients enrolled
  - 68 received (avg. age 68 yrs) VE LVAD (Heartmate)
  - 61 patients (avg. age 66 yrs) received optimal medical Rx
- End points included survival, quality of life, complications, device malfunctions
REMATCH

Survival (%)

Months

0 6 12 18 24 30

LV Assist Device

Medical Therapy

Rose E NEJM 2001
“In the Future We Need a LV Assist Device that Lasts Longer than Two Years”

Dr Bruce Lytle
Cleveland Clinic 2006
Next Generation LVADs

- Smaller, easier implant
- Bridge to recovery possibility, destination application
- Still requires aggressive anticoagulation
- Pump (Blood) flow estimation based upon pump speed/power
- Pre-load dependent, after-load sensitive
- Variable adaptability to changes in patients physical demands
Mechanical Circulatory Support

“The Future is Now”

- 2nd Generation-Axial flow LVAD’s
- 3rd Generation- Rotary flow pumps
- Total Artificial Heart
Thoratec Heartmate II

- Continuous, axial flow LVAD approved as BTT 2005 (CE Mark)
- FDA approval as BTT/DT 2008
- Clinical experience >700 implants worldwide
- 79% patients survive to transplant, recovery or ongoing support as DT mean support 169 days
- Requires aggressive anticoagulation
Third Generation VADs
Heartware

- Miniature Implantable LVAD
- Blood lubricated
- In US feasibility trials
Hemodynamic Targets

- Adequate systemic perfusion
- Estimated LVAD flow 4.5–6 L/min
- Doppler MAP 70–95 mmHg
- CVP 10–15 mmHg
What Happens? (Outcomes after Implant)
OSU Durable LVAD case Volume
January 2008 – December 2010

- 125 Total devices implanted into 112 unique patients
- 2008
  - 38 Implants
- 2009
  - 40 Implants
- 2010
  - 47 Implants

Source: PATS Axis Software VAD Database
Mechanical Circulatory Support

**Major Perioperative Challenges**

- Post-operative bleeding
- Right ventricular dysfunction
- Infections
- Anti-thrombotic therapy/bleeding complications
TOP SIX LVAD ISSUES THAT YOU MAY ENCOUNTER with VAD Patients after discharge

6. Arrhythmia
5. Hemolysis
4. Renal Failure
3. Infection
2. Volume overload: CHF, Right Heart Failure
1. GI Bleeding
HeartMate XVE Driveline Exit site
Dressing Change Policy

- Every other day
- Sterile technique
- Chloraprep/Alcohol cleaning solution
- NO BETADINE
- Patients should wear binder to protect and secure the driveline
INTERMACS Database

Data Submission Requirement of VAD Programs
<table>
<thead>
<tr>
<th>PROFILE-LEVEL</th>
<th># Pts Yr 1</th>
<th>Official Shorthand</th>
<th>General time frame for support</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERMACS</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LEVEL 1</td>
<td>82</td>
<td>“Crash and burn”</td>
<td>Hours</td>
</tr>
<tr>
<td>LEVEL 2</td>
<td>81</td>
<td>“Sliding fast”</td>
<td>Days to week</td>
</tr>
<tr>
<td>LEVEL 3</td>
<td>18</td>
<td>Stable but Dependent</td>
<td>Weeks</td>
</tr>
<tr>
<td>LEVEL 4</td>
<td>9</td>
<td>“Frequent flyer”</td>
<td>Weeks to few months, if baseline restored</td>
</tr>
<tr>
<td>LEVEL 5</td>
<td>4</td>
<td>“Housebound”</td>
<td>Weeks to months</td>
</tr>
<tr>
<td>LEVEL 6</td>
<td>3</td>
<td>“Walking wounded”</td>
<td>Months, if nutrition and activity maintained</td>
</tr>
<tr>
<td>LEVEL 7</td>
<td>4</td>
<td>Advanced Class III</td>
<td></td>
</tr>
</tbody>
</table>
Device Support by *Patient Profile*

P(comparing distribution) = 0.004

- Level 1: 30.00%
- Level 2: 20.00%
- Level 3: 10.00%
- Level 4: 5.00%
- Level 5, 6, 7: 5.00%

Competing Outcomes – Level 1: Critical Cardiogenic Shock (n=186)

- Transplanted: 40%
- Dead: 29%
- Alive: 26%
- Recovery: 5%

SPECIAL REPORT

The Next Frontiers

HEALTH & TECHNOLOGY: WHAT THE FUTURE MEANS FOR YOU

How Technology Will Heal Your HEART

Patient Power on The Web

Made-to-Order Medicine

Robotic Surgery

The AbioCor implantable replacement heart
Cardiowest Total Artificial Heart

- First and only Artificial Heart to receive FDA, Health Canada and CE Approval
- Highest bridge-to-transplant rate* 79% of all approved BTT devices
- Highest cardiac output of all mechanical circulatory support devices (up to 9.5L/min)
- Indicated for use as a bridge-to-transplant – complete circulatory support system for patients with irreversible biventricular heart failure
TAH-t Advantages

1) Decreased CVP
2) Overcome PAP
3) Cardiac output
4) Organ Recovery
Freedom Portable Driver: Stable Patients Transition from Implant/ICU Driver

- Portable – 12.5 lbs
- Backpack or Shoulder Bag
- Simple User Interface
  - Charge batteries
  - Change driver
  - CO, Rate, Left Fill Volume
- Charge from Many Sources
- Optional Extended Battery
- Service by Replacement
- Available at centers participating in IDE study
New VAD Technology Summary

- Key to success is matching recipient physiology/needs with VAD capabilities
- Newer generation VADS have many advantages—smaller size, efficient power utilization, effective end-organ perfusion
- Preload-dependent and afterload-sensitive
- Limitations include RV function, anticoagulation, durability
- Biventricular failure requires full hemodynamic support using TAH
Thank You