Mechanical Cardiac Support in Acute Heart Failure

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Disclosures

- Research Support and/or Consulting
  - NHLBI
  - Amgen
  - Cytokinetics
  - Roche Diagnostics
  - Otsuka
  - BG Medicine
The Evolution of Left Ventricular Assist Devices

JARVIK 2000
25 cc  90 g.

HEARTMATE II
114 cc, 340 g

HEARTMATE III
~120 cc, 350 g

HEARTMATE XVE
600 cc, 1200 g.

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Improving Survival with LVAD Therapy

REMATCH (HMVE)

INTrEPI (Novacor)

DT Registry (HMXVE)

INTERMACS Registry (Multiple Devices)

Desperation Therapy

Destination Therapy

2000 2005 2010
## Indications for VAD Therapy

<table>
<thead>
<tr>
<th>Indications</th>
<th>Description</th>
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<tbody>
<tr>
<td>Bridge to Recovery/Explantation</td>
<td>Device intended for short term support for a condition that is anticipated to reversible</td>
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<tr>
<td>Bridge to Bridge</td>
<td>Device intended for short term support (typically inserted in an emergent situation) until a more permanent device can be implanted</td>
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<tr>
<td>Bridge to Transplant*</td>
<td>Device typically intended for short- to intermediate-term support in patients actively listed for transplantation</td>
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<tr>
<td>Bridge to Decision</td>
<td>Device inserted to support a patient in whom the ultimate therapy is not able to be determined at the time of implantation. Device may be used for short or long-term support.</td>
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<tr>
<td>Destination Therapy*</td>
<td>Device inserted with the intention of long-term support in patients who are not candidates for transplantation</td>
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</tbody>
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Outline

- Which Patients?
- Which Device?
- What Next?
Clinical Profiles in AHF: Data from Euro Heart Failure Survey II

- Decomp. HF: 53%
- Pulm. Edema: 30%
- HTN HF: 9%
- Cardiogenic shock: 6%
- RHF: 2%

N=3580

Nieminen, M et al Eur Heart J 2006
Mortality in AHF by Clinical Classification

In hospital mortality

- Right HF
- HTN HF
- Shock
- Pulm edema
- Decomp HF
- De Novo AHF
- ADCHF
- All

Nieinen MS et al. Euro Heart J 2006
SBP in AHF: Higher is Better?

N=51,500

In-hospital mortality (%) vs. SBP on admission (mmHg)

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Gheorghiade M et al JAMA 2007
ADHERE CART: Predictors of Mortality

BUN 43
N=33,324

SYS BP 115
n=24,933

Less than

2.68%
n=25,122

5.49%
n=4,099

8.98%
n=7,202

21.94%
n=620

Greater than

2.14%
n=20,834

15.28%
N=2,048

6.41%
n=5,102

Highest to Lowest Risk Cohort
OR 12.9 (95% CI 10.4-15.9)

Fonarow et al., JAMA 2005
Outline

- Which Patients?
- Which Device?
- What Next?
Choices of Device

- Choices continue to evolve with changing technology
- Percutaneous
  - Intra-aortic balloon pump
  - Impella
  - Tandem-heart
  - Cancion (no longer in development)
  - ECMO
- Surgically implanted
  - Centrimag
  - Abiomed AB5000
  - Thoratec pVAD
  - Long term VADS (e.g., HeartMate II)
## The Physiology of Counterpulsation

<table>
<thead>
<tr>
<th>Enhanced coronary blood flow</th>
<th>Biophysical changes that occur include:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>- Diastolic balloon inflation increases intra-aortic pressure and coronary perfusion</td>
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<tr>
<td></td>
<td>- MAP increases from greater increase in diastolic pressure than reduction of systolic pressure</td>
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<tr>
<td></td>
<td>- Absolute change in coronary perfusion dependent upon vasoregulation</td>
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<tr>
<td>Left ventricular unloading</td>
<td>Biophysical changes that occur include:</td>
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<tr>
<td></td>
<td>- Displacement of blood into the periphery</td>
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<td>- Reduction of SBP</td>
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<td>- Reduction of LVEDP</td>
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<td>- Reduced LV wall stress</td>
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<td></td>
<td>- Reduced LV O2 consumption</td>
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<tr>
<td>Improved cardiac output</td>
<td>Biophysical changes that occur include:</td>
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<td>- Preserved or increased stroke volume</td>
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<tr>
<td></td>
<td>- Increased cardiac output as a result of afterload reduction</td>
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</tbody>
</table>

Rogers, J. Mechanical Devices in Cardiogenic Shock, AHA 2009
IABP as an Adjunct to Thrombolytic Therapy

Bar chart showing the mortality rates for IABP + lytic versus Lytic alone in randomized and observational studies:

- **TACTICS**
  - Randomized: 34% (IABP + lytic) vs 43% (Lytic alone); 6 months
  - Observational: 33% (IABP + lytic) vs 51% (Lytic alone)

- **Kovack**
  - Randomized: 43% (IABP + lytic) vs 21% (Lytic alone); 1 year
  - Observational: 57% (IABP + lytic) vs 15% (Lytic alone)

- **GUSTO-I**
  - Randomized: 68% (IABP + lytic) vs 67% (Lytic alone); 1 year
  - Observational: 67% (IABP + lytic) vs 67% (Lytic alone)

- **NRMI**
  - Randomized: 49% (IABP + lytic) vs 27% (Lytic alone); in-hospital

References:
- TACTICS: (n=57; P=0.23)
- Kovack: (n=46; P=0.02)
- GUSTO-I: (n=310; P=0.04)
- NRMI: (n=23,180; P<0.05)
Clinical Pearls about IABP in AHF

- Use “too early” rather than “too late”
- Often effective even in non-ischemic patients
- May be less effective in very young patients due to greater aortic distensibility
Percutaneous MCS Devices

Potential Clinical Utility of Percutaneous VADS

- Acute cardiogenic shock
- Chronic decompensated heart failure
- Post-cardiotomy
- Hemodynamically assisted high risk coronary interventions
- Supported percutaneous valve repair/replacement
- Supported ventricular arrhythmia ablation
Percutaneous Mechanical Support

TandemHeart pVAD

- Percutaneous insertion
  - 21F venous cannula passes to left atrium via a transseptal puncture
  - 15-17 F arterial cannula
  - Centrifugal flow pump that can provide 3.5-4 l/min at 7500 RPM
- Systemic anticoagulation required
- Approved for short-term support
TandemHeart

- Randomized trial of 42 patients with cardiogenic shock
  - 70% ACS
  - 30% Decompensated HF
  - 71% with shock despite IABP
- Centers implanting first patient were allowed to implant the TandemHeart in the “Roll In” phase (non-randomized).
- Mean support duration=2.5 days

Burkoff et al. Am Heart J 2006;152:469
TandemHeart Results

42 patients with cardiogenic shock randomized to IABP or TandemHeart

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(A) CI (% Baseline) vs Duration of Support (hours)
(B) MAP (% Baseline) vs Duration of Support (hours)
(C) PCWP (% Baseline) vs Duration of Support (hours)
TandemHeart

- No difference in 30 day survival rates (IABP 64% vs. TandemHeart 53%)
- No difference in frequency of adverse events
Impella Recover

- Miniaturized rotary blood pump (axial flow)
- Provides up to 2.5 (percutaneous) or 5.0 (surgical) L/min at maximum speed of 50,000 rpm
- Inserted retrograde across the AoV to unload the LV
- No extracorporeal blood
- Requires heparin
Impella Trials

- **PROTECT II**: Prospective, randomized trial of Impella vs IABP in patients undergoing non-emergent high-risk PCI

- **RECOVER II**: Prospective, randomized trial of Impella vs. IABP in patients with post-MI hemodynamic instability
Cancion: Continuous Aortic Flow Augmentation

- Outflow from iliac artery and inflow to proximal descending aorta
- External pump drives the system. 2000-5400 rpm provides flows of 1.1-1.5 L/min
- Decreased afterload by reducing the inertia of a standing column of blood in the aorta at the onset of systole
MOMENTUM Trial

- 169 patients (109 device; 59 control)
- Composite primary endpoint: PCWP and days alive and out of hospital at 35 days
- Stopped for futility and excess bleeding in the treatment arm
Extracorporeal Membrane Oxygenator

- Circuit Pressure Monitors
- Artificial Lung
- Pump
- Anticoagulation Level Test Device
- Heat exchanger
- $S_{v}O_2$ Monitor
- Heater Water Bath
- Bladder box controller
- Backup Battery
Surgically Implantable Temporary MCSD

- Centrimag
- Abiomed
- Thoratec pVad
Future of Percutaneously Placed MCS

Circulite Synergy

- Surgical or percutaneous implant
- Partial cardiac assist
- Flow 2-3 l/min
- Modeling suggests reduction of LVEDP 7-10 mm Hg
- 8-12 hours of untethered support

- 14 x 49 mm
- 25 gm
So, Which Device for my patient?

- Amount of Support Needed?
  - TandemHeart > Impella > IABP

- Duration of Support?

- Other issues (e.g., PVD, active bleeding)

- Local expertise?
Where to Next?

The eventual destination may not be immediately clear
Potential Outcomes of Device Implantation

Intention at Implant

- Bridge to Recovery
- Bridge to Transplant
- Bridge to Decision
- Destination Therapy

Ultimate Indication

- Recovery/Explantation
- Transplant
- Ongoing Support
Summary and Conclusions

- Percutaneous mechanical circulatory support devices are growing in capability and complexity
- Patient selection remains the most critical component of success with these devices
- Randomized data is sparse and complicated by the critical acute illness of many of these patients
- It is likely that centers invested in percutaneous circulatory support will require >1 device to satisfy the needs of the entire population
- Conceptually we are moving from total cardiac output replacement to partial hemodynamic support