Lundy J. Campbell, M.D.  
Assistant Professor  
University of California, San Francisco  

Mechanical Support of Heart Failure
Briefly discuss magnitude and principles of heart failure
Types of mechanical support
Data for mechanical support
What does this mean to you and why you should care
Magnitude of Heart Failure

- Nearly 5 million Americans affected
- Over 500K new cases diagnosed annually
- Greater than 200K in US with end-stage disease not amenable to medical therapy
- Fewer than 3000 donor hearts available worldwide per year
- Low 5 year survival with advanced HF stages
Survival curves according to HF stage

Log-rank $p<0.0001$

# at risk
Stage    0   640    640   639   637   635   464   218   34
A        454  453   451   449   446   322   133   22
B        691  687   685   677   673   475   239   29
C       195  193   187   178   166   114   54    5
C        44   42   38    36    33    18    8     1
D        5    5    5     4     2     1     0     0

Survival (years)
Goals of Advanced HF Treatment

- Stop progression of disease (vicious cycle)
- Reverse maladaptive remodeling
- Optimize patient for possible transplant
  - Improve functional status
  - Improve exercise capacity
  - Decrease co-morbidities
The Course of Stage D Heart Failure

Vicious cycle of Ventricular Remodeling

Ventricular Remodeling and Treatment Goals

A

- Left Ventricular Pressure vs Left Ventricular Volume
- ESPVR
- EDPVR
- ACUTE
- Chronic NH Activation Remodeling

B

- Goal of Treatment: Reverse Remodeling
- Left Ventricular Pressure vs Left Ventricular Volume
- ESPVR
- EDPVR
- CHF

A. Transesophageal echocardiogram of patient with HeartMate vented electric LVAD showing volume unloading of left atrium and left ventricle (LV), whereas right-sided chambers remain volume loaded.

Classes of Mechanical HF Therapy

- IABP
- VAD
  - LVAD
  - RVAD
  - BiVAD
- ECLS (ECMO)
  - VAD + Oxygenator
- Novel Technology
Is This Important to You?

- If you have a cath lab
  - IABP
- If you have CT surgery
  - IABP, ECLS
- If you have neither (or any of the above)
  - VAD
• Good for short-term use
  – Post-MI, post-bypass cardiogenic shock
• Improves diastolic perfusion during balloon inflation
• Improves cardiac index during balloon deflation
ECLS

- Essentially a VAD plus membrane oxygenator
- Used for post-bypass cardiac failure
- Used for respiratory failure
- Can function as a lung, a VAD or both
- Acceptable results in specific pediatric disease states, no good data in adults
- Probably good for adults as a bridge to a VAD or transplantation (rescue circuit)
ECLS

EXTRACORPOREAL LIFE SUPPORT

FiO₂ 0.4
Rate 5-10
P 30/15

TV V/P

Bronchoscopy Lung Therapy BP

Dry Weight

Patient VO₂ VCO₂

Circuit

Blood Flow Hct>40 DO₂

VV Access

SAT

Nutrition Heparin ACT

DP

O₂ Carbogen VECO₂

Pump
VAD Classifications

- Support type classification
  - LVAD, RVAD, BiVAD
- Pump type classification
  - Volume displacement (pulsatile flow)
  - Centrifugal (non-pulsatile flow)
  - Axial-flow (non-pulsatile flow)
- VAD indications
  - Temporary support (bridge to recovery)
  - Bridge to transplant
  - Destination therapy
VAD Pump Types

A Volume-Displacement Pump

B Axial-Flow Pump

C Centrifugal Pump

Volume-Displacement VADS

- Pulsatile flow
- Thoratec Heartmate LVAS
- Thoratec VAD
- Novacor LVAS
- Abiomed AB 5000
- Total artificial hearts
  - Syncardia CardioWest device
  - Abiomed Abiocor
Abiomed AB 5000
Heartmate
Centrifugal VADS

- Heartmate III
- ECLS (ECMO) circuit
- Tandem Heart
Tandem Heart
Axial Flow VADS

- Heartmate II
- Jarvik 2000
- Micromed DeBakey VAD
- Impella system
HEARTMATE II  Continuous-Flow Left Ventricular Assist Device

Jarvik 2000 LVAD

Impella System
Complications of VADs

- Bleeding
- Infection
  - Local (pocket)
  - Sepsis
- Stroke/Embolism
- Device thrombosis
- Device Failure/Malfunction
- Right heart failure
Data Regarding Mechanical Support

- VAD as a bridge to transplant
- VAD as a bridge to recovery
- VAD as destination therapy (REMATCH trial)
- Other studies: A note of caution
129 Class IV heart failure patients (ineligible for heart transplant) randomized to LVAD vs medical therapy

Primary end-point: Death from any cause

Rose et al. NEJM 2001; 345: 1435-1443
VAD as Destination Therapy

- 1 year survival: 52% VAD vs 25% medical
- 2 year survival: 23% VAD vs 8% medical
- 28% VAD infection within 3 months
- 42% bleeding within 6 months
- 35% device failure at 24 months

Rose et al. NEJM 2001; 345: 1435-1443
Uncontrolled multicenter study of 133 patients with end-stage HF awaiting transplant

Outcome: Proportion of patients at 180 days who had:
- Undergone transplantation
- Had cardiac recovery
- Had ongoing mechanical support

VAD as Bridge to Transplant

- Principle outcome in 75% of patients
- Survival rate
  - 75% at 6 months
  - 68% at 12 months
- At 3 months most pts had improvement by 2 NYHA classes
- Adverse events: Stroke, bleeding, RH failure, lead infections

VAD as Bridge to Recovery

- 15 patients with severe HF d/t non-ischemic cardiomyopathy
- All with severely reduced EF on inotropes
- All patients received Heartmate I or II LVAD
- 11 patients had sufficient recovery to undergo explantation at a mean 320 days post implantation

VAD as Bridge to Recovery

Ejection Fraction (Panel A), Left Ventricular End-Diastolic Diameter (Panel B), and Left Ventricular End-Systolic Diameter (Panel C) before Implantation and after Explantation, and Maximal Oxygen Consumption (VO2 Max) (Panel D) with Exercise before and after Explantation.
VAD as Bridge to Recovery

- Cumulative rate of freedom from recurrent HF among survivors
  - 100% at 1 year
  - 88.9% at 4 years
- Quality of life among survivors assessed as nearly normal at 3 years

A Word of Caution: Be Careful With The Data

CAUTION

THIS SIGN HAS SHARP EDGES
DO NOT TOUCH THE EDGES OF THIS SIGN

ALSO, THE BRIDGE IS OUT AHEAD
Reversal of Cardiogenic Shock by Tandem Heart pVAD

- 18 pts with cardiogenic shock after MI
- Mean cardiac index before support was 1.7±0.3 L/min per m²
- Mean cardiac index improved to 2.4±0.6 L/min per m²
- Overall 30 day mortality was 30%
- Improved SBP, PAP, PCWP, CVP
Hemodynamic parameters before and after VAD implantation

41 pts w/ cardiogenic shock randomized to IABP or VAD

Primary outcome “Cardiac Power Index” and other hemodynamic variables

Tandem Heart Results

MOMENTUM Trial: HF Unresponsive to Medical Therapy

- 168 patients randomized to flow augmentation with ORQIS Cancion system
  - <1.5L/min up to 96 hours vs medical therapy
- Endpoints:
  - Technical: Device could be placed effectively
  - Hemodynamic: Decreased PCWP >5mmHg
  - Clinical: At 35 days:
    - 10 days out of hospital
    - No alternative mechanical support
    - Alive
    - No readmission for heart failure

CANCION SYSTEM

Heart
Descending Aorta
Right Femoral Artery
Outflow Catheter

Kidneys
Left Femoral Artery
Inflow Catheter

Flow Sensor
Pump Motor
Controller

Momentum Trial

CAFA Effect on Hemodynamics

Cardiac index (L/min/m2)

PCWP (mmHg)

Momentum Trial

Primary Efficacy Endpoint
(device n=109, control n=59)

<table>
<thead>
<tr>
<th></th>
<th>Device</th>
<th>Control</th>
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<tbody>
<tr>
<td>PCWP success</td>
<td>n=43</td>
<td>n=20</td>
</tr>
<tr>
<td>Clinical success</td>
<td>n=44</td>
<td>n=21</td>
</tr>
<tr>
<td>Overall success</td>
<td>n=19</td>
<td>n=8</td>
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</tbody>
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Momentum Trial

Kaplan-Meier curves for all-cause mortality (top) and all-cause mortality or recurrent HF hospitalization (bottom)

What You May See in Your Hospital

VAD patients sent home typically present to community hospital first
Patient Presenting Problems

- Bleeding
- Stroke
- Embolism
- Infection
- Hypotension
  - Device failure
  - Right heart failure
  - Decreased preload
  - Decreased afterload
VAD/Heart Failure Treatment

- Echocardiogram
  - Right heart failure
  - Preload / Afterload
- Fluid therapy
- Pressors
- Inotropes
  - If Right heart function is poor
- Call for advice, and arrange for Transfer to “VAD center”

- Note: May have normal, little or no arterial waveform on arterial line monitoring