Cardiac Assist Devices: Who Gets What?

Dimensions in Cardiac Care
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Tiffany Buda, RN
Maria M Mountis, DO, FACC
Section of Heart Failure and Cardiac Transplant Medicine
Department of Cardiovascular Medicine, Heart and Vascular Institute
Disclosures

• No financial disclosures
• No conflicts of interest
Objectives

• Describe potential candidates for temporary/short term devices
• Describe temporary/short term devices
• Describe potential candidates for long term devices
• Describe long term devices
• Identify selection process for choosing which device for which patient.
Sick patient

Chronic support

Temporary support

Unclear situation

Durable VADs

1. Support circulation
2. Oxygenate patient

Choice dictated by clinical status:
ECMO
Impella
Tandem Heart
Goals of Emergency Support

• Restore and stabilize systemic hemodynamics
• Minimize ongoing myocardial loss
• Allow safe bridge to recovery, decision, transplant, or permanent device
Who would benefit from temporary support?

- Acute cardiogenic shock
- Acute myocardial infarction
- Acute myocarditis
- Complications post MI
  - Papillary muscle rupture
  - Ventricular septal defect
- Post cardiotomy failure
- Acute on chronic (end-stage) heart failure
- Electrical “storm” or post-VT ablation

Advantages of Percutaneous Device

• Placed quickly
• Avoid need for “open surgery”
• Placed at many centers even those without VAD or transplant program
• More easily removed in setting of recovery
• Placed by interventional cardiologists and surgeons
• Allow for recovery or transport to another center
Disadvantages of Percutaneous Devices

- Bleeding
- Ischemic limb
- Unable to mobilize or rehab
- Sepsis
- Short duration of use
Temporary Circulatory Support Options

ECMO

Tandem Heart

Impella

Cleveland Clinic
ECMO
Extracorporeal Membrane Oxygenation

• Device capable of supporting:
  – failing heart
  – failing lungs
  – both failing heart and lungs

• Device provides:
  – blood flow
  – capable of providing oxygen
Indications

• Cardiogenic shock
  – Acute MI
  – Endstage heart failure

• Post-Cardiotomy
  – unable to wean from bypass
  – post-op shock
  – acute rejection

• Hypoxia
  – ARDS
  – Pulmonary infection
  – rejection
ECMO

- Anticoagulation required
- Short term support
- Hemolysis, thrombocytopenia
- Non-pulsatile flow
- No patient mobility
- Central or peripheral access
- Veno-veno or veno-arterial cannulation
Peripheral ECMO
ECMO

CARDIOHELP SYSTEM

http://www.cardiohelp-us.com/cardiohelp-system/introduction/
ECMO
Cleveland Clinic Experience

- Blood pump
  - Rotaflow centrifugal pump
  - Low cost, small size
  - 0-5 L/min
- Oxygenator
  - Quadrox D
  - Minimal plasma leak
  - Long-lasting
ECMO for Cardiogenic Shock

<table>
<thead>
<tr>
<th>Pro’s</th>
<th>Con’s</th>
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<tbody>
<tr>
<td>• Rapid response/initiation</td>
<td>• Non-pulsatile flow</td>
</tr>
<tr>
<td>• Bedside application</td>
<td>• Limb ischemia/hyperperfusion</td>
</tr>
<tr>
<td>• Minimally invasive</td>
<td>• LV distension</td>
</tr>
<tr>
<td>• Biventricular support</td>
<td>• Limits recovery</td>
</tr>
<tr>
<td>• Pulmonary support</td>
<td>• Pulmonary hemorrhage</td>
</tr>
<tr>
<td></td>
<td>• No support of coronary perfusion</td>
</tr>
<tr>
<td></td>
<td>• LV/Aortic thrombus</td>
</tr>
<tr>
<td></td>
<td>• Cerebral hypoxia</td>
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</table>
CentriMag Pump Components

2nd Generation CentriMag Primary Console/Monitor

Thoratec CentriMag® VAS/ECMO

• Temporary mechanical circulatory support (up to 30 days)
• Post Cardiotomy shock
• LVAS/RVAS/BIVAS/ECMO support
• Up to 9.9 LPM flow/5500 rpms
• Enhances ventricular unloading
Tandem Heart® PTVA
CardiacAssist Inc.
Tandem Heart® PTVA Cardiac Assist Inc.

- Postcardiotomy shock
- Cardiogenic shock
- Bridge to definitive therapy
- Short term support
- Continuous Flow-Centrifugal
- 0-5 L/min.
- Administer anticoagulant through an Infusion system
- Electrically driven through a controller
- Anticoagulation
### Tandem Heart

<table>
<thead>
<tr>
<th><strong>Pro’s</strong></th>
<th><strong>Con’s</strong></th>
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</thead>
<tbody>
<tr>
<td>• Percutaneous</td>
<td>• Bleeding</td>
</tr>
<tr>
<td>• Partial LV unloading</td>
<td>• Hemolysis</td>
</tr>
<tr>
<td>• Bi-ventricular support with 2 devices</td>
<td>• Limb ischemia</td>
</tr>
<tr>
<td>• Duration of support: 3 weeks</td>
<td>• Infection with longer support times</td>
</tr>
<tr>
<td>• Versatile (easily convert to ECMO)</td>
<td>• Trans-septal puncture</td>
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</table>

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**Tandem Heart**

- Inflow: left atrium via trans-septal puncture
- Outflow: femoral artery
- ↓ LAP and PCWP
- ↓ Myocardial oxygen demand
- ↑ MAP and CO
2–21 French Transseptal Catheters

Internal Jugular RVAD
IJ: 17 Fr Medtronic Catheter

Fem: 21 Fr TS Catheter

www.cardiacassist
Impella 2.5, CP, 5.0, LD Circulatory Support System

• Indications
  – Partial Support for up to 6 hours
  – Partial Support during a procedure
  – Cardiogenic shock
  – Post MI

• Contraindications
  – Mechanical Aortic Valve
  – Aortic valve stenosis/calcification (> 2+, orifice area 1.5 cm²)
  – Moderate to severe AI (≥2+)
  – Severe PAD
**Impella 5.0**

- 21F micro-axial flow pump
- 9F peripheral insertion
- Flow: 0 - 5L/min
- Duration of support: 7 days
- Fully unloads left ventricle
Impella

**Pro’s**
- Simple insertion
- Percutaneous
- Duration of support: days
- LV unloading

**Con’s**
- Bleeding
- Limb ischemia
- Infection with longer support times
- Only LV support
- Fluoroscopy or echo placement
- Thrombus on device
So…who gets which device?

• Some days it feels like it’s a coin toss.
• BUT, the choice is always made for a patient with advanced heart failure to live a longer life and hopefully a better quality of life! A life with less hospital admissions, ease of breathing, ability to walk a little further, perform activities of daily living, play with their kids or grandkids, take a walk, travel, enjoy their family and friends, and perhaps go back to work!
• So, in the end, we have to match the right patient with the right device while keeping in mind their comorbidities and potential complications of each device!
Advanced Heart Failure

• Patients with significant cardiac dysfunction (low Ejection Fraction, low cardiac output and low peak VO2 on metabolic stress test).

• Symptoms of heart failure:
  – dyspnea, fatigue, early satiety, lower extremity edema, abdominal bloating, confusion
  – end-organ hypoperfusion at rest: renal failure, liver failure, anemia, irritability

• Refractory symptoms requiring specialized interventions to manage symptoms or prolong life
Ominous prognostic factors

- Intolerance of beta-blockers (symptomatic low blood pressure)
- Intolerance of ACE-I/ARBs (symptomatic low blood pressure)
- Recurrent hospitalizations (more than 2 in one year)
- Need for inotropes (even for 24 hours)
- Hyponatremia
- Progressive renal insufficiency (cardiorenal syndrome) – rising BUN even if creatinine looks ok (these patient have little muscle mass)
- Rising bilirubin
- *****Note: No mention of EF or BNP levels*****
ADHERE® CART: Predictors of Mortality

33,324 patients!

BUN 43
N=33,324

SYS BP 115
n=24,933

2.66%
n=26,152

5.49%
n=4,099

2.14%
n=20,834

2.68%
n=25,122

8.96%
n=7,202

SYS BP 115
n=7,150

Cr 2.75
2,045

15.28%
N=2,048

12.42%
n=1,425

21.94%
n=620

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

### Baseline Characteristics

<table>
<thead>
<tr>
<th>Clinical</th>
<th>Medications</th>
<th>Diuretics</th>
<th>Lab Data</th>
<th>Devices</th>
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<tbody>
<tr>
<td>Age</td>
<td>63</td>
<td>ACE-I</td>
<td>Furosemide</td>
<td>Hgb</td>
</tr>
<tr>
<td>Gender</td>
<td>Male</td>
<td>Beta-blocker</td>
<td>Bumetanide</td>
<td>Lymphocytes</td>
</tr>
<tr>
<td>NYHA Class</td>
<td>3</td>
<td>ARB</td>
<td>Torsemide</td>
<td>Uric Acid</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>80</td>
<td>Statin</td>
<td>Metolazone</td>
<td>Total Chol</td>
</tr>
<tr>
<td>EF</td>
<td>20</td>
<td>Allspurinol</td>
<td>HCTZ</td>
<td>Sodium</td>
</tr>
<tr>
<td>Syst BP</td>
<td>120</td>
<td>Aldosterone blocker</td>
<td>QRS &gt; 120 msec</td>
<td>None</td>
</tr>
</tbody>
</table>

### Interventions

- **ACE-I**
- **Beta-blocker**
- **Statin**
- **Aldosterone Blocker**

Note: Some devices may be disabled if CMS clinical criteria are not met. See below.

http://SeattleHeartFailureModel.org
Stage A
High risk with no symptoms

Stage B
Structural heart disease, no symptoms

Stage C
Structural disease, prior or current symptoms

Stage D
Refractory symptoms requiring special intervention

Stages & steps: treatment of systolic HF

- Hospice
- VAD, TX
- Inotrope, nesiritide
- Brief inotrope or nesiritide
- Digoxin
- Aldosterone antagonists
- CRT, ICD if applicable
- Sodium restriction, diuretics
- ACEI, BB in all. Is patient candidate for surgery?
- ACEI, ARB’s if intolerant of ACEI, BB if MI or low LVEF
- Treat HTN, DM, CAD, dyslipidemia. ACEI or ARB
- Risk factor reduction, patient and family education

ACEI, BB in all. Is patient candidate for surgery?
1. **Critical Cardiogenic Shock**: low BP unresponsive to support, compromised organ perfusion.

2. **Progressive Decline**: not in imminent danger but worsening despite inotropic support, with declining renal function, nutrition, ambulation, other.

3. **Stable but Inotrope dependent**: unable to be weaned from inotropic support.

4. **Recurrent advanced heart failure**: recurrent congestion despite good maintenance, needing repeated interventions beyond escalation of oral diuretics.

5. **Exertion intolerant**: comfortable at rest without obvious fluid overload but limited activities of daily living (ADL).

6. **Exertion limited**: comfortable at rest and with ADL but meaningful activity limited.

7. **Advanced NYHA Class 3**: patients clinically stable with a reasonable level of comfortable activity, despite previous decompensations.
Adult and Pediatric Heart Transplants
Number of Transplants by Year and Location

NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, the presented data may not mirror the changes in the number of heart transplants performed worldwide.
UNOS Waiting List for all Organs

Organ Procurement and Transplantation Network

Matching donors and recipients
The OPTN ensures fair distribution of organs in the U.S. Many factors determine a match, including blood type, waiting time, illness severity and other medical criteria. Learn more.

At a Glance
- **124,005** people need a lifesaving organ transplant (total waiting list candidates).
- Of those, **79,422** people are active waiting list candidates. To join as a donor, visit:

1. **19,426** transplants performed this year (Total Transplants January - August 2014 as of 11/1/2014)
2. **9,512** donors (Total Donors January - August 2014 as of 11/1/2014)
114 Individuals waiting for hearts at CCF

<table>
<thead>
<tr>
<th>Overall by Organ</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Current U.S. Waiting List</td>
<td></td>
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<tr>
<td>For TAC = UNOS, Donor, and Recipient</td>
<td></td>
</tr>
<tr>
<td>Based on OPTN as of November 1, 2014</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Change Report</th>
<th>Overall</th>
<th>Heart</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Count</td>
<td>114</td>
<td>114</td>
<td></td>
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</table>

Data subject to change based on future data submission or correction. Totals may be less than the sums due to patients included in multiple categories.
Terminology and Classification of MCS Devices

<table>
<thead>
<tr>
<th>Ventricle Supported</th>
<th>Anatomical Position</th>
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<tbody>
<tr>
<td>Left ventricular assist device</td>
<td>Extracorporeal pump</td>
</tr>
<tr>
<td>Right ventricular assist device</td>
<td>Intracorporeal pump</td>
</tr>
<tr>
<td>Biventricular assist device</td>
<td>Paracorporeal pump</td>
</tr>
<tr>
<td>Total artificial heart</td>
<td>Orthotopic TAH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Pump Mechanism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration of support</td>
<td>Pulsatile, volume displacement</td>
</tr>
<tr>
<td>Short-term MCS</td>
<td>• Pneumatic or electrical actuation</td>
</tr>
<tr>
<td>Patient remains within hospital</td>
<td>- Continuous-flow rotary pump</td>
</tr>
<tr>
<td>Long-term, “Durable” MCS</td>
<td>• Axial design</td>
</tr>
<tr>
<td>Patient discharged to home - “hands free” untethered mobility</td>
<td>- Bearing-supported rotor</td>
</tr>
<tr>
<td>Indication</td>
<td>- Magnetic suspension</td>
</tr>
<tr>
<td>Bridge to recovery</td>
<td>- Centrifugal design</td>
</tr>
<tr>
<td>Bridge to transplant</td>
<td>• Passive or active magnetic levitation</td>
</tr>
<tr>
<td>Destination therapy</td>
<td>• Hydrodynamic (fluid forces)</td>
</tr>
</tbody>
</table>

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Slide Courtesy of Dr. Francis Pagani
### Destination Therapy: Option for Patients Who Do Not Qualify for Cardiac Transplantation

#### Contraindications for Cardiac Transplantation

<table>
<thead>
<tr>
<th>General</th>
<th>Specific</th>
<th>Relative</th>
</tr>
</thead>
</table>
| • Any condition limiting a successful transplant outcome | • Elevated pulmonary vascular resistance  
• Active infection  
• Advanced Kidney disease that may end up on dialysis  
• Advanced COPD/emphysema  
• Diabetes with end-organ damage  
• Cross-match incompatibility  
• Active psychiatric disease  
• Substance or tobacco abuse | • Age (70 here at CCF)  
• Peripheral vascular disease  
• Malignancy  
• Size/Obesity  
• Number of sternotomies |
**Terminology**

**Bridge to Transplant** = patient has nothing else wrong with them other than their heart

**Destination Therapy** = everyone else

**Bridge to Recovery** = we may not know until they start showing recovery of their EF and then we can contemplate removing the device

BTT ↔ DT
Device Selection Flow Chart

Advanced Heart Failure
- Listed for OHTx
- Acute Cardiogenic Shock
  - Unknown OHTx Status
  - Eligible for OHTx

Short Term Mechanical Circulatory Support
- Recovery
- BTT
- DT

Long Term Mechanical Circulatory Support
- OHTx – Possible Destination
- Recovery
- Destination – Possible OHTx


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Device Strategy

The following tables summarize pre-implant device strategy at your site and INTERMACS over time.

### CMNC-8111

<table>
<thead>
<tr>
<th>Pre-implant Device Strategy</th>
<th>2010</th>
<th>2011</th>
<th>2012-2014 (Jan-Jun)</th>
<th>Total</th>
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<tbody>
<tr>
<td>BTT - Listed</td>
<td>30</td>
<td>24</td>
<td>52</td>
<td>106</td>
</tr>
<tr>
<td>BTT - Likely</td>
<td>35</td>
<td>6</td>
<td>10</td>
<td>57</td>
</tr>
<tr>
<td>BTT - Moderate</td>
<td>14</td>
<td>2</td>
<td>4</td>
<td>23</td>
</tr>
<tr>
<td>BTT - Unlikely</td>
<td>3</td>
<td>3</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Destination Therapy</td>
<td>2</td>
<td>3</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>Bridge to Recovery</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Rescue Therapy</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Other</td>
<td>1</td>
<td>1</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>85</td>
<td>56</td>
<td>124</td>
<td>365</td>
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### INTERMACS

<table>
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<tr>
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<th>2011</th>
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<td>1041</td>
<td>905</td>
<td>1414</td>
<td>3361</td>
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<td>BTT - Likely</td>
<td>588</td>
<td>615</td>
<td>1221</td>
<td>2424</td>
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<tr>
<td>BTT - Moderate</td>
<td>210</td>
<td>362</td>
<td>588</td>
<td>1160</td>
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<tr>
<td>BTT - Unlikely</td>
<td>58</td>
<td>48</td>
<td>102</td>
<td>208</td>
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<tr>
<td>Destination Therapy</td>
<td>170</td>
<td>132</td>
<td>253</td>
<td>555</td>
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<tr>
<td>Bridge to Recovery</td>
<td>44</td>
<td>27</td>
<td>25</td>
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<td>Rescue Therapy</td>
<td>25</td>
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<tr>
<td>Other</td>
<td>9</td>
<td>2</td>
<td>18</td>
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<td><strong>TOTAL</strong></td>
<td>2164</td>
<td>1050</td>
<td>6044</td>
<td>1860</td>
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Patient Profiles

The following tables summarize pre-implant INTERMACS patient profile levels at your site and INTERMACS over time.

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<tr>
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<td>31</td>
<td>20</td>
<td>10</td>
<td>14</td>
<td>65</td>
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<tr>
<td>Progressive Decline</td>
<td>20</td>
<td>14</td>
<td>23</td>
<td>30</td>
<td>76</td>
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<tr>
<td>Stable but Inotropic Dependent</td>
<td>10</td>
<td>18</td>
<td>27</td>
<td>28</td>
<td>54</td>
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<tr>
<td>Resting Symptoms</td>
<td>10</td>
<td>18</td>
<td>22</td>
<td>24</td>
<td>56</td>
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<tr>
<td>Exertional Intolerant</td>
<td>2</td>
<td>3</td>
<td>12</td>
<td>17</td>
<td>32</td>
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<tr>
<td>Exertional Limited</td>
<td>1</td>
<td>1</td>
<td>3</td>
<td>7</td>
<td>11</td>
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<tr>
<td>Advanced NYHA Class 3</td>
<td>2</td>
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<td>4</td>
<td>5</td>
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<tr>
<td><strong>Total</strong></td>
<td>85</td>
<td>58</td>
<td>100</td>
<td>124</td>
<td>263</td>
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<th>2012 - 2014 (Jan-Jun)</th>
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<td>644</td>
<td>532</td>
<td>977</td>
<td>1520</td>
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<tr>
<td>Progressive Decline</td>
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<td>Stable but Inotropic Dependent</td>
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<td>952</td>
<td>1624</td>
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<tr>
<td>Resting Symptoms</td>
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<td>477</td>
<td>684</td>
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<tr>
<td>Exertional Intolerant</td>
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<td>156</td>
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<tr>
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<td>142</td>
<td>311</td>
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<tr>
<td>Advanced NYHA Class 3</td>
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<tr>
<td><strong>Total</strong></td>
<td>2184</td>
<td>3570</td>
<td>6049</td>
<td>11600</td>
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What Does Medicare Cover?

VADs as Bridge-to-Transplant
The VADs used for bridge-to-transplant are covered only if they have received approval from the FDA for that purpose, and the VADs are used according to the FDA-approved labeling instructions. All of the following criteria must be fulfilled in order for Medicare coverage to be provided for a VAD used as a bridge-to-transplant:

- The patient is approved and listed as a candidate for heart transplantation by a Medicare-approved heart transplant center and is active on the Organ Procurement and Transplantation Network (OPTN) heart transplant waitlist.
- The implanting site, if different than the Medicare-approved transplant center, must receive written permission from the Medicare-approved heart transplant center under which the patient is listed prior to implantation of the VAD.
What Does Medicare Cover?

VADs as Destination Therapy
Destination therapy is for patients that require mechanical cardiac support. The VADs used for destination therapy are covered only if they have received approval from the FDA for that purpose.

Patient Selection
The VADs are covered for patients who have chronic end-stage heart failure (New York Heart Association Class IV end-stage left ventricular failure) who are not candidates for heart transplantation at the time of VAD implant and meet all of the following conditions:

- Have failed to respond to optimal medical management (including beta-blockers and ACE inhibitors if tolerated) for at least 45 of the last 60 days, or have been balloon pump-dependent for 7 days, or IV inotrope-dependent for 14 days; and,
- Have a left ventricular ejection fraction (LVEF) < 25%, and,
- Have demonstrated functional limitation with a peak oxygen consumption of ≤ 14 ml/kg/min unless balloon pump- or inotrope-dependent or physically unable to perform the test.
Has anyone ever done a metabolic stress test??
HeartMate II Left Ventricular Assist System

- FDA Approved for BTT and DT
- A surgically implanted, continuous-flow device sits in parallel with the native left ventricle
  - Left ventricle to ascending aorta
- Percutaneous driveline
- Electrically powered
- Set with fixed speed
- ASA and coumadin necessary
- Evidence Based Heart Failure Medications Ongoing
Heartware HVAD Device

FDA Approved for BTT
Clinical Trial for DT

Considerations:
Surgical approach (thoracotomy)
Comorbid Conditions – ie prior CVA or GI bleeding
ASA and Coumadin Necessary
Evidence Based Heart Failure Medications Necessary

Choice of device based on medical team and patient conversations

Cleveland Clinic
Issues in the implantation of durable VADs

• **Proper selection of patients**
  – Recognizing the patient who is “too sick”, with end-organ damage
  – Recognizing the patient who is too debilitated or malnourished
  – Recognizing the patient who needs bi-ventricular support

• **Timing of surgery**
  – Especially important in the elderly “destination” patient
**Total Artificial Heart**

- FDA approved as BTT
- Used in patients with biventricular heart failure or any indication where left ventricular support alone will not suffice, i.e., VT, VSD
- Body habitus has to be appropriate
- Freedom Driver available
Patient Experience – Bridge to Transplant/Recovery
Patient Experience – Destination Therapy
Thank You!
Some medical humor.....

THE ARGYLE SWEATER
BY SCOTT HILBURN

SAME HERE. ME TOO.

I NEED A HEART.

TOOK WORDS RIGHT OUT MOUTH.

Poker Night at Dick Cheney's.