OBJECTIVES

- Discuss the success of heart transplantation & LVAD technology for patients with systolic heart failure
- Determine the optimal time HF patients should be referred for consideration of advanced therapies

ADVANCED HEART FAILURE

HEART TRANSPLANT OUTCOMES

Stehlik J et al. ISHLT 2011 Registry

NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, this should not be construed as evidence that the number of hearts transplanted worldwide has declined in recent years.

HEART TRANSPLANTATION IS A LIMITED RESOURCE

Stehlik J et al. ISHLT 2011 Registry

NOTE: This figure includes only the heart transplants that are reported to the ISHLT Transplant Registry. As such, this should not be construed as evidence that the number of hearts transplanted worldwide has declined in recent years.
EVOLUTION OF LVAD TECHNOLOGY

TERMINOLOGY

- **Destination therapy (DT)**
  - VAD therapy in patients whom eventual transplantation is NOT being considered
  - Typically due to age

- **Bridge to transplant (BTT)**
  - VAD therapy in patients who are transplant candidates / listed for transplant
REMATCH (2001) DT LVAD

- 129 patients w/ NYHA IV HF ineligible for transplant were randomized to OMT versus HeartMate I L-VAD
- At 1 year, significant survival benefit with L-VAD therapy (52% vs. 25%; p = 0.002)
- No significant survival benefit at 2 years
- Frequency of adverse events was 2.4 times higher in VAD group versus OMT

Rose EA et al. NEJM 2001;345:1435-43

HEARTMATE II FOR DT

- HeartMate II outcomes from 2007-09 compared to 2005-07
- Trend towards improved survival in later cohort (63% versus 58% at 24 months)

Park SJ et al. Circ Heart Failure 2012;5:241-8
HEARTMATE II FOR DT SYMPTOM IMPROVEMENT

In both cohorts, over 75% of survivors had NYHA class I or II symptoms at 24 months.

Trend towards improved functional status in later cohort.

DESTINATION THERAPY: WHERE WE HAVE COME

Park SJ et al. Circ Heart Failure 2012;5:241-8
HEARTMATE II for BTT

Almost 80% underwent transplant, LVAD removal for recovery, or had ongoing LVAD support at 18 months.

Of those transplanted, survival was 96% at 1 month; 86% at 1 year.

Pagani FD et al. JACC 2009;54:312-21
INCREASING USE OF MCS

Kirklin JK et al. J Heart Lung Transplant 2012;31:117-26

MORE TRANSPLANT PATIENTS ARE BRIDGED WITH DEVICES

Stehlik J et al. ISHLT 2011 Registry
WHEN TO REFER

- Acute cardiogenic shock
- End-stage ischemic heart disease
- Chronic systolic heart failure, failing conventional medical therapy
- Intractable ventricular arrhythmias

CARDIOGENIC SHOCK

- In its most severe form:

  “Patients with life-threatening hypotension despite rapidly escalating inotropic support, critical organ hypoperfusion, often with rising lactate levels”

- Are these patients candidates for LVAD support?
INTERMACS CLASSIFICATION

<table>
<thead>
<tr>
<th>Profile 1</th>
<th>Critical cardiogenic shock</th>
<th>Patient with life-threatening hypotension despite rapidly escalating isotropic support and critical organ hypoperfusion, often confirmed by worsening acidosis and/or lactate levels.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profile 2</td>
<td>Progressive decline</td>
<td>Patient with declining function despite intravenous isotropic support, which may be manifest by worsening renal function, nutritional depletion and inability to restore volume balance.</td>
</tr>
<tr>
<td>Profile 3</td>
<td>Stable but inotrope-dependent</td>
<td>Patient with stable blood pressure, organ function, nutrition and symptoms on continuous intravenous isotropic support (or a temporary circulatory support device or both), but demonstrating repeated failure to wean from support due to recurrent symptomatic hypotension or renal dysfunction.</td>
</tr>
<tr>
<td>Profile 4</td>
<td>Resting symptoms</td>
<td>Patient can be stabilized close to normal volume status but experiences daily symptoms of congestion at rest or during activities of daily living (ADL). Dosages of diuretics generally fluctuate at very high levels. More intensive management and surveillance strategies should be considered, which may in some cases reveal poor compliance that would compromise outcomes with any therapy. Some patients may shuttle between Profiles 4 and 5.</td>
</tr>
<tr>
<td>Profile 5</td>
<td>Exertion intolerant</td>
<td>Comfortable at rest and with ADL but unable to engage in any other activity, living predominantly within the house. Patients are comfortable at rest without refractory symptoms, but may have underlying refractory elevated volume status, often with renal dysfunction. If underlying nutritional status and organ function are marginal, patients may be more at risk than INTERMACS Profile 4, and require definitive intervention.</td>
</tr>
<tr>
<td>Profile 6</td>
<td>Exertion limited</td>
<td>Patient without evidence of fluid overload is comfortable at rest, and with ADL and minor activities outside the home but fatigues after the first few minutes of any meaningful activity. Attribution to cardiac limitation requires careful measurement of peak oxygen consumption, in some cases with hemodynamic monitoring to confirm severity of cardiac impairment.</td>
</tr>
<tr>
<td>Profile 7</td>
<td>Advanced NYHA III</td>
<td>A placeholder for more precise specification in the future, this level includes patients who are without current or recent episodes of unstable fluid balance, living comfortably with meaningful activity limited to mild physical exertion.</td>
</tr>
</tbody>
</table>

INTERMACS CLASSIFICATION & SURVIVAL

- Survival to discharge significantly worse in group 1 patients in a series of BTT/DT patients

- Longer length of stay in group 1 & 2

INTERMACS CLASSIFICATION & SURVIVAL


CARDIOGENIC SHOCK
OTHER MECHANICAL OPTIONS?

- Short-term device that can rapidly provide circulatory support and restoration of end-organ function

- Utilized as a “bridge to decision”
  - Myocardial recovery
  - LVAD or heart transplantation
  - Palliative care
BRIDGE TO DECISION

Acute Refractory Cardiogenic Shock
(Multiple Vasopressors, Inotropes, IABP, mechanical ventilation)

Peripheral ECMO

Neurologically Intact
Cardiac Recovery

Neurologically Intact
No Cardiac Recovery

No Neurological Recovery
+/- Multisystem Organ Failure

ECMO Weaned Off
Recovery

Bridge to Procedure

Withdraw ECMO Support


Veno-arterial extracorporeal membrane oxygenation using Levitronix centrifugal pump as bridge to decision for refractory cardiogenic shock

Claudio F. Russo, MD, Aldo Cannata, MD, Marco Lanfranconi, MD, Giuseppe Bruschi, MD, Filippo Milazzo, MD, Roberto Paimo, MD, and Luigi Martinelli, MD

<table>
<thead>
<tr>
<th>Patient</th>
<th>Gender</th>
<th>Age</th>
<th>Etiology</th>
<th>Serum creatinine</th>
<th>Total bilirubin</th>
<th>IABP</th>
<th>MV</th>
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<td>34</td>
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<td>0.6</td>
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<td>Y</td>
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<td>Idiopathic dilated cardiomyopathy</td>
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<td>1.4</td>
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<td>8</td>
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<tr>
<td>11</td>
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<td>Y</td>
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<td>14</td>
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<tr>
<td>15</td>
<td>M</td>
<td>32</td>
<td>Acute myocardial infarction</td>
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<td>0.4</td>
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</tbody>
</table>

- 80% of patients weaned successfully from support or bridged to LVAD/transplant
- 20% died on support due to MSOF


<table>
<thead>
<tr>
<th>Patient</th>
<th>Implant site</th>
<th>Pump speed (rpm)</th>
<th>Pump flow (L/min)</th>
<th>ECMO duration (days)</th>
<th>Weaned from ECMO</th>
<th>Bridge to HTx</th>
<th>Bridge to LVAD</th>
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<td>24</td>
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<tr>
<td>9</td>
<td>P</td>
<td>3900</td>
<td>3.9</td>
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<tr>
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<td>4200</td>
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<td>15</td>
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<td></td>
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</tr>
</tbody>
</table>

Series of temporary VAD support at Columbia reported 74% survival to discharge

Worku B et al. J Heart Lung Transplant 2012;31:611-7
MCS OPTIONS IN CARDIOGENIC SHOCK

- LVAD support is option, but high risk
- “Bridge to decision” strategies employing extracorporeal devices are successful
  - Fast to deploy
  - Allow time for organs to recover and final decision to be made
  - Easy to explant if recovery is present
- Referral before end-organ damage is irreversible

ACUTE RENAL FAILURE IN HF

- Indication to consider advanced therapies?
- Worsening renal function is common in patients admitted with acute decompensation of HF
- Adverse prognostic indicator in short-term
ACUTE RENAL FAILURE IN HF

- 467 patients with acute CHF were divided into 3 groups:
  - No WRF
  - Transient WRF
  - Persistent WRF
- WRF was increase in Cr > 0.5 mg/dL
- Primary outcome 6 month mortality

Aronson D and Burger AJ. J Cardiac Fail 2010;16:541-7
**RENAL FAILURE IN HF**

- 1200 patients with CHF
- Measured baseline Cr and WRF (Cr rise by > 0.3 mg/dL) during 6 months
- Both baseline renal dysfunction AND WRF independently predicted higher mortality

Aronson D and Burger AJ. J Cardiac Fail 2010;16:541-7

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**RENAL FUNCTION AFTER LVAD**

Hasin T et al. JACC 2012;59:26-36
RENAL FUNCTION AFTER LVAD

Hasin T et al. JACC 2012;59:26-36

ACUTE RENAL FAILURE AFTER LVAD PORTENDS WORSE PROGNOSIS

Significant decrease in survival in LVAD patients who require CVVHD post-op

CVVHD patients were older, higher incidence of IABP pre-op, and had lower albumin levels and higher LFTs than rest of study cohort

Topkara VK et al. J Heart Lung Transplant 2006;25:404-8
**RENAL FAILURE**

- The beginning of renal insufficiency (even if mild) is an adverse prognostic sign and can indicate need to consider referral for VAD/transplant.

- Severe irreversible renal failure is a contraindication to heart transplantation alone and relative contraindication for LVAD placement.

**REFERRAL FOR ISCHEMIC HEART DISEASE**

- Failure of revascularization to improve LVEF / symptoms.

- Revascularization not attempted due to lack of myocardial viability.

- Assessment of viability.
Without revascularization, patients with ischemic CM have a poor prognosis.

Heart failure refractory to medical therapy
- Inability to tolerate medical therapy
- Non-responder to cardiac resynchronization therapy

Suboptimal quality of life and/or frequent exacerbations necessitating hospitalizations

Eminent death is not necessary!
### HOW GOOD IS CLINICAL ASSESSMENT IN PREDICTING PCWP > 22 mm Hg?

<table>
<thead>
<tr>
<th>H&amp;P Finding</th>
<th>Frequency</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Positive</th>
<th>Negative</th>
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</thead>
<tbody>
<tr>
<td>PPP &lt;= 25%</td>
<td>16/188</td>
<td>10</td>
<td>96</td>
<td>87.5</td>
<td>28</td>
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<tr>
<td>SBP &lt;= 100</td>
<td>75/188</td>
<td>42</td>
<td>66</td>
<td>77</td>
<td>29</td>
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<tr>
<td>SBP &lt;= 90</td>
<td>25/188</td>
<td>12</td>
<td>84</td>
<td>68</td>
<td>26</td>
</tr>
<tr>
<td>Fatigue (at rest/any activity)</td>
<td>177/189</td>
<td>94</td>
<td>8</td>
<td>74</td>
<td>33</td>
</tr>
<tr>
<td>Cool extremities</td>
<td>34/189</td>
<td>20</td>
<td>88</td>
<td>82</td>
<td>28</td>
</tr>
<tr>
<td>&quot;Cold&quot; profile</td>
<td>52/188</td>
<td>33</td>
<td>86</td>
<td>86.5</td>
<td>32</td>
</tr>
</tbody>
</table>

Values expressed as percentages unless otherwise indicated. LR indicates likelihood ratio; OR, odds ratio.

Drazner MH et al. Circ Heart Fail 2009;1:170-77

### HOW GOOD IS CLINICAL ASSESSMENT IN PREDICTING LOW CARDIAC INDEX (< 2.3 L/min/m2)?

<table>
<thead>
<tr>
<th>H&amp;P Finding</th>
<th>Frequency</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Predictive Value</th>
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<tbody>
<tr>
<td>PPP &lt;= 25%</td>
<td>16/188</td>
<td>10</td>
<td>96</td>
<td>87.5 28</td>
</tr>
<tr>
<td>SBP &lt;= 100</td>
<td>75/188</td>
<td>42</td>
<td>66</td>
<td>77 29</td>
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<tr>
<td>SBP &lt;= 90</td>
<td>25/188</td>
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<td>84</td>
<td>68 26</td>
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<tr>
<td>Fatigue (at rest/any activity)</td>
<td>177/189</td>
<td>94</td>
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<td>74 33</td>
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<td>Cool extremities</td>
<td>34/189</td>
<td>20</td>
<td>88</td>
<td>82 28</td>
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<td>&quot;Cold&quot; profile</td>
<td>52/188</td>
<td>33</td>
<td>86</td>
<td>86.5 32</td>
</tr>
</tbody>
</table>

Drazner MH et al. Circ Heart Fail 2009;1:170-77
RIGHT HEART CATHETERIZATION (SWAN GANZ CATHETERIZATION)

- Objective measure of heart failure severity
- Assess severity of volume overload
- Assess cardiac output
  - Is the patient low-output?

In series of 450 patients admitted to HF service with diagnosis of HF

Nohria A et al. JACC 2003;41:1797-1804
RIGHT HEART CATHETERIZATION

- Identification of low-output state is a poor prognostic sign and may signal need for transplant/VAD consideration

- However, optimization of medical therapy (with help of RHC monitoring) can allow patients to achieve euvolemia and normal cardiac output

CHRONIC SYSTOLIC HF

- Is frequent hospitalization/decompensation required for patients to be considered for transplant/VAD?

- Majority of patients transplanted in US:
  - Mechanical device in place (typically LVAD)
  - Requiring inotropic support, either at home or in hospital (milrinone/dobutamine)
  - Other unusual conditions: persistent VT, severe ischemia, congenital heart disease
### PATIENT SCENARIOS

#### Patient A
- 62 year old w/ nonischemic CM X 15 years
- No other health problems
- Slowly progressive sx, now Class IIIB
- On OMT including CRT
- No CHF hospitalizations X 12 months

#### Patient B
- 64 year old w/ nonischemic CM X 10 years
- DM and BMI 37
- Class IIIB symptoms
- OMT (narrow QRS so no CRT)
- No HF hospitalizations X 3 years

#### PATIENT SCENARIOS

#### Patient A
- LVEF 10%; normal RV
- RHC as outpatient:
  - CVP 8
  - PA 56/22 (38)
  - PCWP 21
  - CO 3.5 L/min
  - CI 1.8 L/min/m2
- Impression: Low-output HF

#### Patient B
- LVEF 15% (LVEDD 9.1); normal RV
- RHC as outpatient:
  - CVP 14
  - PA 60/24 (40)
  - PCWP 26
  - CO 3.9 L/min
  - CI 1.9 L/min/m2
- Impression: Low-output HF

**TRANSPLANT**

**LVAD**
INCREASING USE OF LVAD IN AMBULATORY HF
“WALKING WOUNDED”

<table>
<thead>
<tr>
<th>Parameter</th>
<th>HW II (n = 659)</th>
<th>Control (n = 659)</th>
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<td>Demographic data</td>
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</tr>
<tr>
<td>Male sex ratio</td>
<td>511 (78%)</td>
<td>414 (63%)</td>
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</tr>
<tr>
<td>Age (yrs)</td>
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</tr>
<tr>
<td>0–18</td>
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<td>19–29</td>
<td>20 (3%)</td>
<td>22 (3%)</td>
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<tr>
<td>40–49</td>
<td>64 (48%)</td>
<td>87 (51%)</td>
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</tr>
<tr>
<td>60–79</td>
<td>93 (35%)</td>
<td>54 (32%)</td>
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<tr>
<td>Race</td>
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<tr>
<td>Caucasian</td>
<td>126 (74%)</td>
<td>113 (87%)</td>
<td>0.289</td>
</tr>
<tr>
<td>African American</td>
<td>29 (17%)</td>
<td>17 (12%)</td>
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</tr>
<tr>
<td>Asian</td>
<td>15 (9%)</td>
<td>17 (11%)</td>
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</tr>
<tr>
<td>Body surface area (m²)</td>
<td>2.03 ± 0.20</td>
<td>2.06 ± 0.26</td>
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<td>41 (24%)</td>
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<td>2</td>
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<td>21 (12%)</td>
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<td>6, 6, 7</td>
<td>11 (7%)</td>
<td>9 (5%)</td>
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</tbody>
</table>

Starling et al. JACC 2011;57:1890-8

LVAD IN THE “LESS SICK” HF PATIENTS

NHLBI’s Program for VAD Therapy for Moderately Advanced Heart Failure: The REVIVE-IT Pilot Trial

J. TIMOTHY BALDWIN, PH.D.1 AND DOUGLAS L. MANN, MD2
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Letter to the Editor
Ventricular assist devices: Bridge to continued employment
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WHAT ABOUT RIGHT VENTRICULAR FUNCTION?

- L-VAD support requires functioning right ventricle
- RV function difficult to quantify
- If biventricular support is required, cardiac transplantation or artificial heart would be necessary
- Assessing RV function in VAD candidates is an area of active research

WAITING TOO LONG FOR VAD

- Liver dysfunction
- Renal failure
- Inability to consider transplantation (not enough time to list)
- Deconditioning
- Nutritional compromise
PREDICTORS OF DEATH AFTER VAD

- 420 patients from 75 institutions with VAD placement were prospectively entered into registry
- Included BTT and DT patients

<table>
<thead>
<tr>
<th>Risk factors for death</th>
<th>Relative risk</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>INTERMACS Level 1</td>
<td>1.59</td>
<td>0.02</td>
</tr>
<tr>
<td>Age (older)</td>
<td>1.41</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Ascites</td>
<td>2.04</td>
<td>0.003</td>
</tr>
<tr>
<td>Bilirubin (higher)</td>
<td>1.49</td>
<td>0.05</td>
</tr>
<tr>
<td>BiVAD implant</td>
<td>2.12</td>
<td>0.002</td>
</tr>
<tr>
<td>Total artificial heart</td>
<td>2.41</td>
<td>0.03</td>
</tr>
</tbody>
</table>

* Determined using multivariate analysis.
* Compares increased risk from age 50 to 60 years.
* Compares increased risk from bilirubin = 1 to 6 mg/dl

IF RV FAILURE IS A PROBLEM..... TOTAL ARTIFICIAL HEART
### ANYBODY NOT TO REFER?

<table>
<thead>
<tr>
<th>Not a transplant candidate due to…</th>
<th>VAD candidate?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of compliance</td>
<td>NO</td>
</tr>
<tr>
<td>DM with end-organ damage</td>
<td>MAYBE</td>
</tr>
<tr>
<td>Extensive vascular disease</td>
<td>Likely NO</td>
</tr>
<tr>
<td>Recent cancer</td>
<td>YES (need for chemo may be issue)</td>
</tr>
<tr>
<td>Irreversible pulmonary hypertension</td>
<td>YES (PA pressures will come down)</td>
</tr>
<tr>
<td>Chronic renal failure (Cr &gt; 2.5)</td>
<td>NO (HD centers don’t take VAD pts)</td>
</tr>
<tr>
<td>Active smoking</td>
<td>YES</td>
</tr>
<tr>
<td>Obesity</td>
<td>YES (but weight loss is unlikely)</td>
</tr>
</tbody>
</table>

### IS AGE A CONTRAINDICATION?

**HEART TRANSPLANTATION**

![Survival Curve](image)

Goldstein DJ et al. *J Heart Lung Transplant* 2012; in press
IS AGE A CONTRAINDICATION? LVAD

Adamson RM et al. JACC 2011;57:487-95

CONCLUSIONS

- Early referral is better than late referral
- VAD outcomes continue to improve and may reach success seen with heart transplantation
- Systolic HF patients with limiting symptoms, evidence of low-output HF, evidence of end-organ injury or frequent hospitalizations should be considered for advanced therapies.
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