Durable Left Ventricular Assist Devices
Current Therapies and New Advancements
I have no disclosures
Definition of Mechanical Circulatory Support

• Mechanical devices assisting or replacing the left, right, or both ventricles of the heart to pump blood in cases of refractory heart failure.

• Durable Devices
  • Medtronic HVAD
  • Abbott Heartmate III
  • Abbott Heartmate II
  • Syncardia Total Artificial Heart
Definition of “Refractory Heart Failure”

• No real consensus criteria/definition
  • Peak oxygen consumption (VO2 max) <14 ml/kg/min via Cardiopulmonary exercise testing (CPET)

• Prognostic Scoring Systems pool clinical & lab values
  • Heart Failure Survival Score
    • CAD, IVCD, HR, LVEF, Na+, MAP, pVO2
      • 1 year survival: High risk=35%, Med risk = 60%, Low risk=88%
  • Seattle Heart Failure Model
    • Age, Gender, EF, SPB, diuretics, Lab Values, Devices

• INTERMACS
INTERMACS

• Interagency Registry for Mechanically Assisted Circulatory Support
  • National Registry for VAD patients
  • NHLBI, CMS, FDA→STS National Database

<table>
<thead>
<tr>
<th>Class</th>
<th>Profile Description</th>
<th>Urgency of treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Critical cardiogenic shock</td>
<td>Definitive intervention needed within hours</td>
</tr>
<tr>
<td>2</td>
<td>Progressive decline on inotropic support</td>
<td>Definitive intervention need within a few days</td>
</tr>
<tr>
<td>3</td>
<td>Stable but inotrope dependent</td>
<td>Definitive intervention elective over a period of weeks to months</td>
</tr>
<tr>
<td>4</td>
<td>Resting symptoms home on oral therapy</td>
<td>Definitive intervention elective over a period of weeks to months</td>
</tr>
<tr>
<td>5</td>
<td>Exertion intolerant</td>
<td>Variable urgency, depends upon nutrition, organ function, and activity</td>
</tr>
<tr>
<td>6</td>
<td>Exertion limited</td>
<td>Variable urgency, depends upon nutrition, organ function, and activity</td>
</tr>
<tr>
<td>7</td>
<td>Advanced NYHA Class III symptoms</td>
<td>Intervention may not be currently be indicated</td>
</tr>
</tbody>
</table>
# New CMS NCD for LVAD

<table>
<thead>
<tr>
<th>ITEM</th>
<th>PREVIOUS NCD 20.9.1</th>
<th>FINAL NCD EFFECTIVE ON DECEMBER 1ST, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covered devices and treatment</td>
<td>FDA indicated for BTT and/or DT</td>
<td>FDA approved for short-term (e.g., bridge-to-recovery and bridge-to-transplant) or long-term (e.g., destination therapy) mechanical circulatory support</td>
</tr>
<tr>
<td>Coverage criteria</td>
<td>1. Post-cardiotomy</td>
<td>Patients who meet the following criteria:</td>
</tr>
<tr>
<td></td>
<td>2. Bridge-to-Transplant (BTT)</td>
<td>• Have New York Heart Association (NYHA) Class IV heart failure; and</td>
</tr>
<tr>
<td></td>
<td>3. Destination Therapy (DT)</td>
<td>• Have a left ventricular ejection fraction (LVEF) ≤ 25%; and</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Are Inotrope dependent;</td>
</tr>
<tr>
<td></td>
<td></td>
<td><strong>QR</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Have a Cardiac Index (CI) &lt; 2.2 L/min/m², while not on inotropes, and also meet one of the following:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Are on optimal medical management (OMM), based on current heart failure practice guidelines</td>
</tr>
<tr>
<td></td>
<td></td>
<td>for at least 45 out of the last 60 days and are failing to respond; or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Have advanced heart failure for at least 14 days and are dependent on an intra-aortic balloon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>pump (IABP) or similar temporary mechanical circulatory support for at least 7 days</td>
</tr>
</tbody>
</table>
Factors Determining MCS Candidacy

- Hepatic Function
- Pulmonary Function
- Neurologic Function
- Renal Function
- Multiorgan Failure
- Social Support Network
- Body Size/Blood Type

Non-Cardiovascular Considerations

- Age
- Body Size
- Malignancy
- Psychological and Psychiatric Conditions
- Nutritional Status
- Infectious Disease

Cardiovascular Considerations

- Intracardiac Shunt
- Arrhythmias
- Inotropic Support
- Valvular Disease
- Ischemic Heart Disease
- Right Ventricular Function
Evolution of the LVAD
Evolution of Devices: Controllers
Durable Devices: Differences in Design

- **Axial Flow**
  - Use rotating impeller to create vacuum to move fluid
  - Motion drives fluid through housing and out outlet

[Image of a heart and a pump]

https://www.globalpumps.com.au
Differences in Design

• Centrifugal
  • Use rotating impeller to create vacuum to move fluid
  • Motion drives fluid through housing and out outlet

https://www.globalpumps.com.au
Durable LVAD Choice Up Until This Year

Heartmate III  HVAD

Surgical Implantation
Trends in Durable LVADs
Revised Heart Allocation Policy

OLD

• Status 1A
  • Acute hemodynamic instability requiring MCS
    TAH
    IABP
    ECMO
    LVAD and/or RVAD for 30 days

• Status 1B
  • LVAD and/or RVAD outside of 30 days listing

• Status 2
  • At home waiting on PO meds

NEW

• Status 1A
  • Acute hemodynamic instability requiring MCS
    TAH
    IABP
    ECMO
    LVAD and/or RVAD for 30 days

• Status 1B
  • LVAD and/or RVAD outside of 30 days listing

• Status 2
  • At home waiting on PO meds
HM 3 vs HVAD

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Retrospective 1-year outcome follow-up in 200 patients supported with HeartMate 3 and HeartWare left ventricular assist devices in a single centre

Marcus Mueller (a) (a), Christoph Hoermandinger (a), Gregor Richter (b), Johanna Mulzer (a), Dmytro Tsyganenko (a), Thomas Krabatsch (a,c), Christoph Starck (a), Julia Stein (a), Felix Schoenrath (a,c), Volkmar Falk (a,c,d,e) and Evgenij Potapov (a,c)

(a) Department of Cardiothoracic and Vascular Surgery, German Heart Center Berlin, Berlin, Germany
(b) Department of Vascular Surgery, St. Gertraudens Hospital, Berlin, Germany
(c) DZHK (German Centre for Cardiovascular Research), Partner Site, Berlin, Germany
(d) Department of Cardiothoracic Surgery, Charité-Universitätsmedizin Berlin, Berlin, Germany
(e) ETH Zurich, Zurich, Switzerland

* Corresponding author. Department of Cardiothoracic and Vascular Surgery, German Heart Center Berlin, Augustenburger Platz 1, 13353 Berlin, Germany. Tel: +49-30-45932160; e-mail: manuel.keller@dhz-b.de (M. Mueller).

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How do Patients do on LVAD Therapy?
Survival

Kaplan-Meier Survival for Primary Continuous Flow LVAD Stratified by Era (n=25,551)
Intermacs: January 1, 2010 - December 31, 2019

<table>
<thead>
<tr>
<th>Months after Implant</th>
<th>2010-2014</th>
<th>2015-2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>80.5%</td>
<td>82.3%</td>
</tr>
<tr>
<td>24</td>
<td>69.1%</td>
<td>73.1%</td>
</tr>
<tr>
<td>36</td>
<td>58.5%</td>
<td>63.5%</td>
</tr>
<tr>
<td>48</td>
<td>48.9%</td>
<td>55.0%</td>
</tr>
<tr>
<td>60</td>
<td>40.9%</td>
<td>46.8%</td>
</tr>
</tbody>
</table>

At risk:
10,944
14,607

3,981
3,219

1,965
311

Months After Device Implant

2010-2014 (n = 10944, Deaths = 4415)
2015-2019 (n = 14607, Deaths = 3982)
Infections and GI Bleeding

A

Time to First Infection (n=14,607)
Intermacs: January 1, 2015 - December 31, 2019

<table>
<thead>
<tr>
<th>Months after Implant</th>
<th>% Free from Infection</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>58.9%</td>
</tr>
<tr>
<td>24</td>
<td>46.4%</td>
</tr>
<tr>
<td>36</td>
<td>38.2%</td>
</tr>
<tr>
<td>48</td>
<td>31.5%</td>
</tr>
<tr>
<td>60</td>
<td>26.9%</td>
</tr>
</tbody>
</table>

Months After Device Implant

Primary CF LVAD (n = 14607, Infection = 6728)

B

Time to First GI Bleeding (n=14,607)
Intermacs: January 1, 2015 - December 31, 2019

<table>
<thead>
<tr>
<th>Months after Implant</th>
<th>% Free from GI Bleed</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>79.1%</td>
</tr>
<tr>
<td>24</td>
<td>71.7%</td>
</tr>
<tr>
<td>36</td>
<td>66.6%</td>
</tr>
<tr>
<td>48</td>
<td>61.8%</td>
</tr>
<tr>
<td>60</td>
<td>58.8%</td>
</tr>
</tbody>
</table>

Months After Device Implant

Primary CF LVAD (n = 14607, GI Bleeding = 3405)
Stroke and Re-Admissions

C

Time to First Stroke (n=14,607)
INTERMACS: January 1, 2015 - December 31, 2019

<table>
<thead>
<tr>
<th>Months after Implant</th>
<th>% Free from Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>87.3%</td>
</tr>
<tr>
<td>24</td>
<td>81.3%</td>
</tr>
<tr>
<td>36</td>
<td>76.3%</td>
</tr>
<tr>
<td>48</td>
<td>71.6%</td>
</tr>
<tr>
<td>60</td>
<td>68.0%</td>
</tr>
</tbody>
</table>

D

Time to First Rehospitalization (n=14,607)
INTERMACS: January 1, 2015 - December 31, 2019

<table>
<thead>
<tr>
<th>Months after Implant</th>
<th>% Free from Rehospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>27.8%</td>
</tr>
<tr>
<td>24</td>
<td>14.6%</td>
</tr>
<tr>
<td>36</td>
<td>8.2%</td>
</tr>
<tr>
<td>48</td>
<td>5.1%</td>
</tr>
<tr>
<td>60</td>
<td>3.6%</td>
</tr>
</tbody>
</table>

At risk: 14,607
Surgical Complications of LVADs

- Anti-coagulation
- RV Failure
- Infection
Surgical Complications of LVADs

- Balance of Anti-coagulation

Pump Thrombosis
Embolic Stroke

Acute hemorrhage
Hemorrhagic Stroke
GI Bleeding
RV Failure

Incidence of RV Failure 9-44%

~10-15% LVAD cases require mechanical RV support

JHLT 2019 Vol 38:114-126
Management of RV Failure

- Optimize preload
  - Maintain CVP < 15 mm Hg
    - Diuresis/CVVHD
- Control CPB time, avoid or reduce cross clamp time, reduce transfusions
- Optimize afterload
  - Pulmonary vasodilators
    - Milrinone, dobutamine, Inhaled NO, Sildenafil (Phosphodiesterase inhibitor)
    - Avoid Hypoxia, hypercarbia, acidosis
- Inotropes (Chemical RVAD)
- Timely use of mechanical support
Pre-Op Hemodynamic Measurements: PAPi

\[ PAP_i = \frac{(P_{systolic} - P_{diastolic})}{RA} \]

where RA is the mean right atrial pressure.

- 1.7 vs 3.6, p<.0005
- <2.0 in 74% of patients requiring RVAD
- No patients >3.1 required RVAD
Left Thoracotomy LVAD Implantation

- Keeps pericardium intact
- Post op severe RVF reduced in thoracotomy vs sternotomy group:
  - 16 vs 39%, p=.03
- Temp RVAD reduced:
  - 3 vs 26%, p=.005

Temporary RVAD
Directions for the Future

• The concept of the next generation design will be small, fully implantable*, low in cost to manufacture, and provide physiologic pulsatile flow. In addition, this system will be fail-safe, easy to control, and provide long-term durable# support.

Ann Thor Surg 2001 Vol 7(3) Suppl 1

•* Wireless battery charging
•# Hemocompatible
When should you refer a patient for LVAD?

- VO2max, EF, HF scores?
- Consider the CV and non-CV considerations for candidacy
- Better to err on the side of too early rather than too late
Thank you!
BIVADs

PVADs no longer available
Off label usage of HVAD
  Smaller size
UCLA Experience:
  5 BIVAD HVADs
    1 death from peri-operative stroke
    3 successfully bridged to OHT
    1 Currently DT

HVAD BIVAD Single Institution Study
  11 patients from Jun 2014-May 2016
  4314 total support days
  7 transplanted
  3 awaiting OHT/reconsideration for listing
  1 death from hemorrhagic stroke

ASAIO, 2017 Aug 23
Decline in Durable LVAD as BTT in new UNOS Listing Era

**Outcomes Of Heart Transplant Recipients Bridged With Percutaneous Versus Durable LVADs**

**Author Block:** Y. Xia¹, J. Kim², A. Nsair³, A. Ardehali¹, R. Shemin¹, M. Kwon¹, Surgery, Division of Cardiac Surgery, UCLA, Los Angeles, CA, David Geffen School of Medicine at UCLA, Los Angeles, CA, Medicine, Cardiology, UCLA, Los Angeles, CA,

**Abstract:**

**Purpose** The new UNOS heart allocation policy prioritizes patients with percutaneous ventricular support devices over durable LVADs. We examined one-year survival of heart transplant recipients successfully bridged with Impella versus durable LVADs in the most recent era.

**Methods** We retrospectively reviewed all primary adult orthotopic heart transplant recipients in the UNOS registry between Jan 1, 2016 to June 12, 2020. Recipients were identified as having an isolated durable LVAD or Impella device at the time of transplant. Those bridged with ECMO, RVAD, BIVAD, or TAH were excluded. One-year survival was examined with the Kaplan Meier method and multivariable Cox proportional hazards regression.

**Results** Of 10,492 heart transplant recipients in the study period, 4610(44%) were bridged with a durable LVAD and 158(2%) with Impella. Impella use increased following the UNOS allocation policy change (3% vs 1% of transplants, p<0.01) and a higher proportion were status 1 or 2 compared to those bridged with durable LVADs (96% vs 26%, p<0.01). Median days between listing and transplant were 40, 218, and 13 days for no MCS, durable LVAD, and Impella, respectively (p<0.01). Impella-bridged recipients were less likely to be obese (25% vs 41%, p<0.01), have diabetes (24% vs 31%, p<0.01), ischemic cardiomyopathy (28% vs 35%, p<0.01), prior cardiac surgery (27% vs 73%, p<0.01), and were more likely to be on inotropes at the time of transplant (65% vs 6%, p<0.01). On multivariate analysis, neither bridge with durable LVAD (aHR 1.25, 95% CI 0.97-1.62, p = 0.08) nor Impella (aHR 1.07, 95% CI 0.55-2.08, p=0.84) was associated with a difference in one-year survival following heart transplantation.

**Conclusion** Impella utilization as bridge to transplant has tripled in the current era of heart transplantation with no significant difference in one-year survival compared to those bridged with durable LVADs. Percutaneous LVAD platforms can be cautiously considered in the sickest patients requiring LVAD bridge to transplantation.

**ISHLT 2021 41st Annual Meeting and Scientific Sessions**
Concurrent vs Staged RVAD