Ventricular Assist Devices for Permanent Therapy: Current Status and Future Prospects

Francis D. Pagani MD PhD
Professor of Cardiac Surgery
University of Michigan
April 28th, 2012
Disclosures

• NHLBI and HeartWare: Contract research REVIVE-IT Study, National Co-PI
• HeartWare: Contract research ENDURANCE Study, National Co-PI
Important Perspectives of VAD Therapy

• INTERMACS (Inter-agency Registry for Mechanically Assisted Circulatory Support)
INTERMACS
Interagency Registry of Mechanically Assisted Circulatory Support

- National Institutes of Health (NIH) – sponsored collaborative database
- Food and Drug Administration (FDA) – approved durable mechanical circulatory support devices
- Mandatory reporting - Centers for Medicare and Medicaid Services regulate reimbursement
- Data entry – June 2006
Important Perspectives of VAD Therapy

• INTERMACS (Inter-agency Registry for Mechanically Assisted Circulatory Support)

• Definition of durable, long-term mechanical circulatory support devices
Criteria for Durable “Long-term” Mechanical Circulatory Support (MCS) Designation

- Durable (reliable performance for > 3-5 years)
- Intracorporeal
  - requires operative placement or minimally-invasive techniques
  - Device design intended for both:
    - Bridge to transplantation
    - Destination therapy
- “Hands free” untethered mobility > 12 hours / day
  - distinguishes paracorporeal systems from intracorporeal systems
  - minimize requirement for frequent battery changes
  - quiet operation
- Discharge to home capabilities
Important Perspectives of VAD Therapy

• INTERMACS (Inter-agency Registry for Mechanically Assisted Circulatory Support)
• Definition of durable, long-term mechanical circulatory support devices

• Indications for VAD therapy for long-term use
Current US FDA-Approved Indications for Long-term MCS Therapy

- **Bridge to Transplantation**
  - listed for heart transplantation
  - Advanced heart failure at risk of imminent death
  - Failing optimal medical management

- **Destination Therapy (Permanent use of devices as an alternative to heart transplantation)**
  - persistent NYHA class IV symptoms for 45 of the previous 60 days with optimal medical management
  - left ventricular ejection fraction \( \leq 25\% \)
  - peak oxygen consumption \( <14 \text{ mL} \cdot \text{kg}^{-1} \cdot \text{min}^{-1} \) or dependent on inotropes for at least 14 days or IABP for at least 7 days if unable to exercise
  - not a candidate for heart transplantation
Indications for Long-term VAD Therapy
Indications for Long-term VAD Therapy

• Evaluation for transplantation is a dynamic process
• Patients change transplant status frequently following VAD therapy
• Resolution of relative contraindications
  – Pulmonary hypertension
  – Renal insufficiency
  – Debilitation / Frailty
• Occurrence of new contraindications or patient preference
  – Elevated panel reactive antibodies
  – Stroke
Primary Device Strategy by Year of Implant: June 23, 2006, to Dec 31, 2011

**a** Patient currently listed for transplant

**b** Patient definitely not eligible for transplant

<table>
<thead>
<tr>
<th>Device strategy</th>
<th>2006 No. (%)</th>
<th>2007 No. (%)</th>
<th>2008 No. (%)</th>
<th>2009 No. (%)</th>
<th>2010 No. (%)</th>
<th>2011 No. (%)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bridge to recovery</strong></td>
<td>4(3.9)</td>
<td>14(4.0)</td>
<td>15(2.0)</td>
<td>12(1.2)</td>
<td>12(0.8)</td>
<td>15(0.9)</td>
<td>72</td>
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<tr>
<td><strong>Bridge to transplant</strong></td>
<td>45(43.7)</td>
<td>148(42.6)</td>
<td>367(49.4)</td>
<td>491(49.4)</td>
<td>463(28.9)</td>
<td>370(22.8)</td>
<td>1884</td>
</tr>
<tr>
<td><strong>Bridge to transplant</strong></td>
<td>36(35.0)</td>
<td>132(38.0)</td>
<td>302(40.6)</td>
<td>433(43.6)</td>
<td>598(37.4)</td>
<td>600(37.0)</td>
<td>2101</td>
</tr>
<tr>
<td><strong>Destination therapy</strong></td>
<td>16(15.6)</td>
<td>47(13.5)</td>
<td>47(6.3)</td>
<td>47(4.7)</td>
<td>511(31.9)</td>
<td>620(38.3)</td>
<td>1288</td>
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<tr>
<td><strong>Rescue therapy</strong></td>
<td>2(1.9)</td>
<td>6(1.7)</td>
<td>12(1.6)</td>
<td>5(0.5)</td>
<td>8(0.5)</td>
<td>5(0.3)</td>
<td>38</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>0(0.0)</td>
<td>0(0.0)</td>
<td>0(0.0)</td>
<td>5(0.5)</td>
<td>9(0.6)</td>
<td>10(0.6)</td>
<td>24</td>
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<tr>
<td><strong>Total</strong></td>
<td>103</td>
<td>347</td>
<td>743</td>
<td>993</td>
<td>1614</td>
<td>1620</td>
<td>5407</td>
</tr>
</tbody>
</table>
INTERMACS

**Primary Continuous Flow LVADs (+/- RVADs): n = 3405***

- Bridge to Transplant Listed, n=1221, deaths=153
- Destination Therapy, n=740, deaths=132
- Bridge to Candidacy, n=1391, deaths=247

By initial Device Strategy

Event: Death (censored at transplant or explant recovery)

$p < .0001$

Months after Device Implant

J Heart Lung Transplant 2012;31:117–26
INTERMACS

Bridge to Transplant
Transplant - 42% at 1 year

Bridge to Candidacy
Transplant - 26% at 1 year

Destination Therapy
Transplant - 3% at 1 year
Important Perspectives of VAD Therapy

• INTERMACS (Inter-agency Registry for Mechanically Assisted Circulatory Support)
• Definition of durable, long-term mechanical circulatory support devices
• Indications for VAD therapy for long-term use
  • **Selection of patients with less acuity of illness**
INTERMACS Patient Profiles

AHA/ACC classification

NYHA classifications

INTERMACS Profiles

Stage C

Class III

Class IIIb/IV

Class IV

Stage D

Approved Range of DT Approval and CMS Coverage

Less Sick

Sick

INTERMACS 4: Resting symptoms on oral therapy at home

INTERMACS 5: Exertion intolerant

INTERMACS 6: Walking Wounded

Less Sick

Generally Accepted

Not Broadly Accepted

Ambulatory Class IIIIB and IV
## Patient Selection

### Table 2  Pre-implant Adult Patient Profiles by Year of Implant: June 23, 2006, to June 30, 2011

<table>
<thead>
<tr>
<th>Patient pre-implant profile</th>
<th>Implant year</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Total</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>2006 No. (%)</td>
<td>2007 No. (%)</td>
<td>2008 No. (%)</td>
<td>2009 No. (%)</td>
<td>2010 No. (%)</td>
<td>2011 (Jun) No. (%)</td>
<td></td>
</tr>
<tr>
<td>1. “Critical cardiogenic shock” (patient has life threatening hypotension and profound low cardiac output with rapidly escalating inotropic pressor support)</td>
<td>42 (40.8)</td>
<td>155 (45.2)</td>
<td>213 (29.3)</td>
<td>204 (21.5)</td>
<td>186 (12.3)</td>
<td>102 (14.0)</td>
<td>902</td>
</tr>
<tr>
<td>2. “Progressive decline” (patient has been demonstrated “dependent” on inotropic support but nonetheless shows signs of continuing deterioration)</td>
<td>40 (38.8)</td>
<td>122 (35.6)</td>
<td>310 (42.7)</td>
<td>443 (46.7)</td>
<td>637 (42.0)</td>
<td>302 (41.4)</td>
<td>1,854</td>
</tr>
<tr>
<td>3. “Stable but inotrope-dependent” (patient is clinically stable on mild-moderate doses of intravenous inotropes, or has a temporary circulatory support device, after repeated documentation of failure to wean without symptoms)</td>
<td>8 (7.8)</td>
<td>33 (9.6)</td>
<td>110 (15.2)</td>
<td>162 (17.1)</td>
<td>384 (25.3)</td>
<td>202 (27.7)</td>
<td>899</td>
</tr>
</tbody>
</table>
Important Perspectives of VAD Therapy

• INTERMACS (Inter-agency Registry for Mechanically Assisted Circulatory Support)
• Definition of durable, long-term mechanical circulatory support devices.
• Indications for VAD therapy for long-term use.
• Selection of patients with less acuity of illness.
• Superiority of Continuous Flow over Pulsatile Flow technology.
First Generation Pulsatile Volume Displacement Pumps

Thoratec pVAD

HeartMate VE

Novacor
Long-Term MCS Devices

- Pulsatile devices 1994 to 2005
- Implantable devices approved for BTT 1998
- REMATCH Trial 2001 – Destination Therapy indication in 2002
History of Destination Therapy

REMATCH Trial

The New England Journal of Medicine

LONG-TERM USE OF A LEFT VENTRICULAR ASSIST DEVICE FOR END-STAGE HEART FAILURE


History of DT – REMATCH Trial

- Randomized clinical trial
  - optimal medical therapy vs. pulsatile flow LVAD
- Non-transplant candidates (n=129)
  - EF ≤ 25%,
  - peak VO2 < 12 ml/kg/min,
  - or continuous infusion inotropes
- FDA approval for HM I (XVE) as destination therapy

Continuous Flow Rotary Pump

Advantages
- No heart valves
- No flexible diaphragm
- No large housing to accommodate pump “stroke volume”
- Fewer moving parts
- Potential for biventricular application

Disadvantages
- Minimal pulse
- Significant AI if pump malfunction occurs
- Operated in fixed mode speed may limit cardiac output
- Afterload dependent

Miller, Pagani, Russell, et al. NEJM August 2007
Volume Displacement vs. Continuous Flow Rotary Pumps

- Volume displacement pumps
  - Pulsed (“physiologic”) flow based on device function of positive displacement
  - VAD flow = beat rate x stroke volume

- CF pumps
  - Pump flow follows native cardiac pulse
  - Flow increases and decreases in response to LV pressure
  - Sensitive to pressure differential across the pump ($P_{Aortic} - P_{LV}$)
  - Pump flow determined by pump speed and power

Both have average flow between 4-5 L/min
Continuous Flow Rotary Pumps

- Flow:
  - Directly proportional to rotor speed
  - Inversely proportional to pressure $\Delta$ across inlet and outlet orifices

![Graph showing flow variability](image-url)

- Red dot represents ventricular diastole
- Yellow dot represents ventricular systole
Advanced Heart Failure Treated with Continuous-Flow Left Ventricular Assist Device

Mark S. Slaughter, M.D., Joseph G. Rogers, M.D., Carmelo A. Milano, M.D., Stuart D. Russell, M.D., John V. Conte, M.D., David Feldman, M.D., Ph.D., Benjamin Sun, M.D., Antone J. Tatooles, M.D., Reynolds M. Delgado, III, M.D., James W. Long, M.D., Ph.D., Thomas C. Wozniak, M.D., Waqas Ghumman, M.D., David J. Farrar, Ph.D., and O. Howard Frazier, M.D., for the HeartMate II Investigators*

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Pulsatile versus Continuous Flow Pumps

Superiority of CF Pumps

![Graph showing survival probability over months since randomization for continuous-flow (LVAD) and pulsatile-flow (LVAD) pumps. The graph indicates a significant difference in survival between the two groups, with a p-value of 0.008 by the log-rank test. The table below the graph lists the number of patients at risk at various time points: for continuous-flow LVAD: 133, 95, 82, 69, 62; for pulsatile-flow LVAD: 59, 32, 19, 5, 2.]


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Primary Endpoint

Survival at 24 months, free from disabling stroke or re-operation for device replacement (intention-to-treat)

Primary Composite Endpoint (% of Patients)

- 62/134 (46%) for CF LVAD
- 7/66 (11%) for PF LVAD

P < 0.001

NEJM 2009;361(23):2241-51.
### Adverse Event Profile: Continuous Flow versus Pulsatile Pump

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Continuous-Flow LVAD (N=133) (211 patient-yr)</th>
<th>Pulsatile-Flow LVAD (N=59) (41 patient-yr)</th>
<th>Relative Risk (95% CI)</th>
<th>P Value for Interaction</th>
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<tr>
<td></td>
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<td>no. of Events/Patient-Yr</td>
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</tr>
<tr>
<td>Pump replacement</td>
<td>12 (9)</td>
<td>0.06</td>
<td>20 (34)</td>
<td>0.51</td>
</tr>
<tr>
<td>Stroke</td>
<td>24 (18)</td>
<td>0.13</td>
<td>8 (14)</td>
<td>0.22</td>
</tr>
<tr>
<td>Ischemic</td>
<td>11 (8)</td>
<td>0.06</td>
<td>4 (7)</td>
<td>0.10</td>
</tr>
<tr>
<td>Hemorrhagic</td>
<td>15 (11)</td>
<td>0.07</td>
<td>5 (8)</td>
<td>0.12</td>
</tr>
<tr>
<td>LVAD-related infection</td>
<td>47 (35)</td>
<td>0.48</td>
<td>21 (36)</td>
<td>0.90</td>
</tr>
<tr>
<td>Local non-LVAD infection</td>
<td>65 (49)</td>
<td>0.76</td>
<td>27 (46)</td>
<td>1.33</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding requiring PRBC</td>
<td>108 (81)</td>
<td>1.66</td>
<td>45 (76)</td>
<td>2.45</td>
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<td>Bleeding requiring surgery</td>
<td>40 (30)</td>
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<tr>
<td>Managed with RVAD</td>
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<td>0.02</td>
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<td>Cardiac arrhythmia</td>
<td>75 (56)</td>
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INTERMACS
Survival for Pulsatile vs Continuous Flow

Primary LVADs (+/- RVAD): n= 4267

By Pump Type

Continuous Flow Pump, n=3405, deaths=541
Pulsatille Flow Pump, n=862, deaths=308

% Survival

<table>
<thead>
<tr>
<th>Month</th>
<th>CFP</th>
<th>PFP</th>
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<tbody>
<tr>
<td>3 mo</td>
<td>91%</td>
<td>79%</td>
</tr>
<tr>
<td>6 mo</td>
<td>88%</td>
<td>70%</td>
</tr>
<tr>
<td>12 mo</td>
<td>82%</td>
<td>61%</td>
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<tr>
<td>24 mo</td>
<td>74%</td>
<td>43%</td>
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Event: Death (censored at transplant or explant recovery)

p < .0001

Months after Device Implant

J Heart Lung Transplant 2012;31:117–26
INTERMACS

- Continuous Flow Intracorporeal LVAD Pump (+/- RVAD)
- Pulsatile Flow Intracorporeal TAH
- Pulsatile Flow Intracorporeal LVAD Pump (+/- RVAD)
- Pulsatile Flow Paracorporeal LVAD Pump (+/- RVAD)

<table>
<thead>
<tr>
<th>Year</th>
<th>Cont Intra Pump</th>
<th>Puls Intra TAH</th>
<th>Puls Intra Pump</th>
<th>Puls Para Pump</th>
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<td>2006</td>
<td>1</td>
<td>2</td>
<td>82</td>
<td>18</td>
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<tr>
<td>2007</td>
<td>1</td>
<td>22</td>
<td>263</td>
<td>61</td>
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<td>2008</td>
<td>464</td>
<td>22</td>
<td>183</td>
<td>74</td>
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<tr>
<td>2009</td>
<td>843</td>
<td>24</td>
<td>55</td>
<td>71</td>
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<tr>
<td>2010</td>
<td>1526</td>
<td>27</td>
<td>12</td>
<td>36</td>
</tr>
<tr>
<td>2011</td>
<td>1548</td>
<td>15</td>
<td>2</td>
<td>55</td>
</tr>
</tbody>
</table>
Adoption of CF Pump Technology
Paradigm Shift

- Obvious and clear benefits of CF over PF technology
- Improvement in survival
- Significant technical advantages at implant due to size
- Reduction in major adverse events:
  - Pump replacement / mechanical malfunction
  - Infection
  - Lower incidence of right heart failure
Ventricular Assist Device Innovation

1st Generation
- Pulsatile Technology
- FDA Approved BTT 1998
- DT 2002
- Bearings

2nd Generation
- Continuous Flow Technology
- Axial Design
- FDA Approved BTT 2008
- DT 2010
- Bearings with stator

3rd Generation
- Continuous Flow Technology
- Centrifugal Design
- Investigational PMA pending
- Bearingless with magnetic and hydrodynamic levitation
- Minaturization
- Durability
Continuous Flow LVAD with Centrifugal Design

• HVAD miniaturized implantable blood pump
  • About the size of a “D” battery
  • Provides up to 10 L/min of flow
  • Centrifugal design, continuous flow
  • Hybrid magnetic / hydrodynamic impeller suspension
  • Optimizes flow, pump surface washing, and hemocompatibility

• Thin (4.2 mm), flexible driveline with fatigue resistant cables

• Lightweight patient peripherals
Axial versus Centrifugal Technology Improvement in Patient Survival
Continuous Flow Rotary Pumps with Centrifugal Design

- Impeller levitation
  - Magnetic coupling
    - Active (electrical current)
    - Passive (rare earth magnet)
  - Hydrodynamic
    - Fluid forces
  - Hybrid
    - Combination of passive or active magnetic coupling with or without hydrodynamic assistance
Centrifugal Technology

• Hydrodynamic performance
  – Flat pressure-flow response curve
  – Greater safety margin from “suction events”
• Non-contact bearing design
  – Larger gaps between impellor and device housing
  – Shear stress (importance of transit time – exposure to device)
• Blood – Device interface
• Improved flow estimation
• Increased sensitivity to afterload
Ventricular Assist Device Innovation

- Continued miniaturization
- Feasibility of BiVAD or TAH applications due to small size
- Miniaturization of external components with telemetry / remote monitoring capabilities
- Totally-implantable systems
- Minimally-invasive implantation capabilities
- Remote energy transfer systems
- Partial support devices
Ventricular Assist Device Innovation
New Devices in Clinical Trials 2012-2015

- **Thoratec HeartMate III**
  - *Centrifugal* flow pump design with magnetic levitation of impellor

- **HeartWare MVAD**
  - *Axial* flow pump design with hydromagnetic levitation of impellor

- **Terumo DuraHeart II**
  - *Centrifugal* flow pump design with magnetic levitation of impellor

- **HeartMate X**
  - *Axial* flow pump design with advanced bearing support of impellor
Summary

• Rapid adoption of continuous flow technology in the US.
• Superior survival with continuous flow technology compared to pulsatile technology.
• Destination therapy is becoming the largest indication for device use.
• Inferior survival with use of MCS in Profile 1 – Critical cardiogenic shock and Profile 2 – Rapid decline.
Conclusions

• Improvements in device technology have led to superior patient outcomes and greater adoption of MCS therapy.

• Further expansion of MCS therapy into a less ill population of patients with advanced heart will require ongoing technology improvements.
• END