State of the Art: Updates in VADs and Transplant for Advanced Heart Failure

Jonathan D. Rich, MD
Medical Director, MCS Program
Northwestern University
Disclosures

• Medtronic, Abbott: Consultant
Heart Failure: Scope of the Problem

- US prevalence*: 5.8 million
- US annual incidence: 670,000
- Annual mortality: 282,754
  - 5-10% depending on severity
- Cost: $39.2 billion
  - 53% of cost due to hospitalization

The Clinical Course of Heart Failure

Cost of final 2 yrs of life: $156K
75% for hospitalizations during last 6 months

Current Estimates of Advanced HF Pts

300 Million Population

- 45-50% Preserved Systolic Function 3.0-3.5 M

- HF=2.6% Population* or 7 Million Total

- 50-55% Systolic HF 3.0-3.5 Million

- Class III B 100-150,000
- Class IV 75-150,000

Theoretical Candidates for MCS/Transplant

- Class III B+IV < 75 yrs 200-300,000 Pts

- 35% Class I
- 35% Class II
- 25% Class III (5-10% III B)
- 2-5% Class IV

Miller L
Adult and Pediatric Heart Transplants
Kaplan-Meier Survival
(Transplants: January 1982 – June 2015)

Median survival = 10.7 years;
Median survival conditional on surviving 1 year = 13.3 years

N = 118,788
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.
CRT-D in NYHA IV

![Graph showing event-free survival over time for different treatments with Kaplan-Meier curves.](image)

- CRT vs OPT: HR=0.67, (95% CI 0.41, 1.10), p=0.11
- CRT-D vs OPT: HR=0.63, (95% CI 0.39, 1.03), p=0.06
- CRT-D vs CRT: HR=0.99, (95% CI 0.63, 1.58), p=0.98

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Events (%)</th>
<th>Censored (%)</th>
<th>Median FU Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>CRT-D (n=83)</td>
<td>37 (45%)</td>
<td>46 (55%)</td>
<td>14.1 months</td>
</tr>
<tr>
<td>CRT (n=79)</td>
<td>35 (44%)</td>
<td>44 (56%)</td>
<td>15.5 months</td>
</tr>
<tr>
<td>OPT (n=55)</td>
<td>30 (55%)</td>
<td>25 (45%)</td>
<td>10.1 months</td>
</tr>
</tbody>
</table>

How about Continuous Inotropes?

Fig. 1. The probability of survival is plotted over time; 3-, 6-, and 12-month survivals were 51%, 26%, and 6%, respectively. One subject who underwent aortic valve replacement after 2.4 months of COSI has not been included in this analysis.
Mechanical Circulatory Support (REMATCH) Trial

HeartMate II vs. HeartMate XVE LVAD

**Continuous-flow VAD (HM II)**
- 1/7 size; 1/4 weight
- Quiet
- 40% smaller percutaneous lead
- One moving part
- Long term durability

**Pulsatile-flow VAD (XVE)**
- Large size
- Noisy
- Large percutaneous lead
- Limited durability
HeartMate II Trial

Slaughter M et al. NEJM 2009;361:2241-51
The Rise of the Machines

Figure 1
Survival Rates in LVAD Clinical Trials

The Rise of the Machines
Current Management of Advanced Stage HF
The Right Time for LVAD or Transplant: The “Perfect Window”
RECENT DT HM II EXPERIENCE

Transplantation

HM II DT

OMM (n=61)

Slaughter, et al NEJM 2009
PRESENT BTT and DT HMII EXPERIENCE

Pr [alive] vs Time (months)

Transplantation

DT HM II LVAD

OMM (n=61)

Select centers reported 2012
INTERMACS - Kaplan-Meier Survival for Continuous Flow LVADs (with or without RVAD implant at time of LVAD operation) by Pre-Implant Device Strategy
Primary Prospective Implants: June 23, 2006 to March 31, 2014

Pre-Implant Device Strategy
- Bridge to Transplant (n = 2644, Deaths = 464)
- Bridge to Candidacy (n = 3544, Deaths = 863)
- Destination Therapy (n = 3668, Deaths = 1161)

Shaded areas indicate 70% confidence limits
p (log-rank) = <.0001
Event: Death (censored at transplant or recovery)
The Major Challenge Facing LVADs in 2017 is not Survival: It is Complications

*Major Event: First occurrence of infection, bleeding, device malfunction, stroke or death

Patients 5436, Events = 3611

<table>
<thead>
<tr>
<th>Months</th>
<th>% Freedom</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>59%</td>
</tr>
<tr>
<td>3</td>
<td>48%</td>
</tr>
<tr>
<td>6</td>
<td>40%</td>
</tr>
<tr>
<td>12</td>
<td>30%</td>
</tr>
<tr>
<td>24</td>
<td>19%</td>
</tr>
<tr>
<td>36</td>
<td>14%</td>
</tr>
</tbody>
</table>
Quality of Life in LVADs

6 Minute Walk Distance

NYHA Functional Class

Minnesota Living with Heart Failure

Kansas City Cardiomyopathy Score

* p<0.05 vs. baseline

J Am Coll Cardiol 2010; 55: 1826-34
The Heartmate II LVAD
The Heartware HVAD
The Heartmate 3 LVAD
Heartware HVAD Implant
Patient with HVAD BIVADs
The Future (is here!)

Heartmate III™

MVAD™

Circulite™
Advanced Heart Failure: Therapeutic Options
“And in the end, it’s not the years in your life that counts, it’s the life in your years.”

Abraham Lincoln
THANK YOU!