BVAD vs TAH for severe biventricular failure

PRO: BVAD

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Introduction

• It is GREAT to have the luxury of this debate
• Tremendous options now for BV failure
Biventricular Failure

• Severe RV failure can occur in about 25% of patients after LVAD
• Patients receiving RVAD several days later have worse outcomes than those receiving LVAD and RVAD simultaneously
• Importantly, identification of patients who need permanent biventricular support
Predicting RV Failure After VAD

- CVP/PCWP ratio ≥0.63, preop ventilator, BUN>39 mg/dL
- Michigan RV failure risk score (vasopressor, AST≥80, bilirubin ≥2, creatinine ≥2.3)
- Preoperative IABP, elevated PVR, DT indication
- Age, ascites, bilirubin, INTERMACS 1
- Tricuspid annular motion <7.5 mm
- Right-to-left ventricular end-diastolic diameter >0.72
- Procalcitonin, neopterin, NTproBNP, big endothelin-1
- Low RVSWI

Kormos RL et al, JTCVS 2010
Matthews JC et al, JACC 2008
Drakos SG et al, Am J Cardiol 2010
Holman WL et al, JHLT 2009

Puwanant S et al, JHLT 2008
Kukucka M et al, JHLT 2011
Hennig F et al, Gen TCVS 2011
Fitzpatrick JR 3rd et al, JHLT 2008
Need for Biventricular Support – Diagnostic Clues

- **Hemodynamics** – CVP > PA pressures, high CVP and low PA pressures
- **Laboratory** – significant hepatic and renal dysfunction
- **ECHO** – mostly unreliable, unless large dilated RV (RV bigger than LV), severe TR
- **Clinical** – refractory VT/VF, significant vasopressor requirement
BVAD vs. TAH

Let me at em...
I'll rock em and sock em!
TAH

TAH RESULTS

## TAH Complications

### Table 3. Adverse Events, Including Those That Affected Outcomes, from the Time of Study Entry to 30 Days after Transplantation.

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>All Patients Who Received an Implant (N=95)</th>
<th>Patients Who Received an Implant per Protocol (N=81)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>All Events (no. of events)</td>
<td>Event Affecting Outcome (number of patients (percent))</td>
</tr>
<tr>
<td>Bleeding</td>
<td>102 (59 (62))</td>
<td>15 (16)</td>
</tr>
<tr>
<td>Device malfunction</td>
<td>19 (16 (17))</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Fitting complication</td>
<td>5 (5 (5))</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Reduced cardiac index</td>
<td>13 (9 (9))</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Reduced blood pressure</td>
<td>27 (18 (19))</td>
<td>8 (8)</td>
</tr>
<tr>
<td>Hemolysis</td>
<td>5 (4 (4))</td>
<td>0</td>
</tr>
<tr>
<td>Hepatic dysfunction</td>
<td>37 (33 (37))</td>
<td>13 (14)</td>
</tr>
<tr>
<td>Infection</td>
<td>172 (73 (77))</td>
<td>18 (19)</td>
</tr>
<tr>
<td>Neurologic event</td>
<td>35 (26 (27))</td>
<td>6 (6)</td>
</tr>
<tr>
<td>Operation</td>
<td>31 (23 (24))</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Peripheral thromboembolism</td>
<td>18 (13 (14))</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Renal dysfunction</td>
<td>34 (29 (31))</td>
<td>16 (17)</td>
</tr>
<tr>
<td>Respiratory dysfunction</td>
<td>61 (34 (36))</td>
<td>15 (16)</td>
</tr>
<tr>
<td>Technical or procedural problem</td>
<td>11 (3 (3))</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Other problem</td>
<td>10 (9 (9))</td>
<td>6 (6)</td>
</tr>
</tbody>
</table>
Transplant vs. VAD

Severe biventricular failure

Palliative care/Inotropes

BTT VAD
IABP

BVAD

TAH

GOOD LUCK
45 M.P.H.
Between November 2012 and June 2015, 38 patients were identified from INTERMACS received durable, intracorporeal continuous flow centrifugal pumps for biventricular support.

- Mean age was 47 years, and 74% of patients were male.
- Nineteen participating centers implanted devices in 38 patients
- 11 patients died with device in place, 9 patients received a heart transplant, and 18 were alive on support with the right ventricular assist device in place.
- Survival outcomes were 68% at 6 months and 62% at 12 months.

Arabia, et al Ann Thor Surg 2018
Contemporary BVAD experience

• The left ventricular assist device was placed in the left ventricle apex in 91% of cases, and in 9%, the location was not specified.

• The right ventricular assist device was placed in the right ventricle in 50%, right atrium in 37%, and not specified in 13%.

• The adverse events included infection 50%, bleeding 44%, respiratory failure 31.6%, and malfunction 26.3%; neurologic dysfunction 26.3%; renal dysfunction 18.4%; and arrhythmia 18.4%.

Arabia, et al Ann Thor Surg 2018
The 1-, 6-, and 12-month survival for the CCF BiVAD population was 89%, 68% and 62%, respectively.
Comparison of total artificial heart and biventricular assist device support as bridge-to-transplantation

Contemporary BVAD experience

- Between Jan 2005 and Dec 2015, patients with either TAH (n=212) or BVAD (n=366) at time of transplantation were evaluated.
- UNOS data base

What happens as BTT: BVAD vs TAH

<table>
<thead>
<tr>
<th>Variable</th>
<th>TAH group (n = 212)</th>
<th>BiVAD group (n = 366)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>49.8 ± 12.9</td>
<td>47.2 ± 13.9</td>
<td>0.04</td>
</tr>
<tr>
<td>Gender: male (%)</td>
<td>87</td>
<td>74</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Idiopathic cardiomyopathy (%)</td>
<td>38</td>
<td>36</td>
<td>0.6</td>
</tr>
<tr>
<td>Ischemic cardiomyopathy (%)</td>
<td>23</td>
<td>30</td>
<td>0.07</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>27.3 ± 5.2</td>
<td>25.6 ± 4.7</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>22</td>
<td>18</td>
<td>0.2</td>
</tr>
<tr>
<td>UNOS Status 1A (%)</td>
<td>94</td>
<td>86</td>
<td>0.002</td>
</tr>
<tr>
<td>Days on wait-list (days)</td>
<td>169.5 ± 255.2</td>
<td>142.3 ± 245.6</td>
<td>0.009</td>
</tr>
<tr>
<td>PAP mean (mmHg)</td>
<td>33.4 ± 12.3</td>
<td>30.5 ± 10.7</td>
<td>0.02</td>
</tr>
<tr>
<td>Creatinine (mg/dL)</td>
<td>1.7 ± 1.2</td>
<td>1.3 ± 0.8</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Bilirubin (mg/dL)</td>
<td>1.5 ± 4.7</td>
<td>1.4 ± 1.3</td>
<td>0.15</td>
</tr>
<tr>
<td>Ischemic time (hours)</td>
<td>3.3 ± 0.9</td>
<td>3.5 ± 1.1</td>
<td>0.08</td>
</tr>
</tbody>
</table>

TAH patients were older, more likely to be male gender, higher BMI, longer UNOS waiting time and longer ischemic time

**TABLE 2A**  Complication rates for patients on the wait-list with TAH or BiVAD

<table>
<thead>
<tr>
<th>Complications on wait-list</th>
<th>TAH</th>
<th>BiVAD</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal failure/dialysis (%)</td>
<td>52 (24)</td>
<td>35 (10)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Infection (%)</td>
<td>46 (22)</td>
<td>104 (28)</td>
<td>0.005</td>
</tr>
</tbody>
</table>

TAH, total artificial heart; BiVAD, biventricular assist device.

**TABLE 2B**  Complication rates after transplantation

<table>
<thead>
<tr>
<th>Complications after transplant</th>
<th>TAH</th>
<th>BiVAD</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stroke (%)</td>
<td>14 (6.6)</td>
<td>16 (4.5)</td>
<td>0.3</td>
</tr>
<tr>
<td>Renal failure/dialysis (%)</td>
<td>56 (26)</td>
<td>49 (14)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Need for pacemaker (%)</td>
<td>9 (4.3)</td>
<td>11 (3.0)</td>
<td>0.07</td>
</tr>
<tr>
<td>Graft failure (%)</td>
<td>23 (11)</td>
<td>32 (9)</td>
<td>0.4</td>
</tr>
</tbody>
</table>

TAH, total artificial heart; BiVAD, biventricular assist device.

What happens as BTT : BVAD vs TAH

Survival Estimates

p=0.8

Survival Probability

TOTAL DAYS ON WAITING LIST/INCLUDING INACTIVE TIME

436
154
44
34
9
10

<table>
<thead>
<tr>
<th>Cause of death supported while on wait-list</th>
<th>TAH</th>
<th>BiVAD</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of death</td>
<td>22</td>
<td>45</td>
<td>0.7</td>
</tr>
<tr>
<td>Infection: septicemia (%)</td>
<td>1 (5)</td>
<td>4 (9)</td>
<td>0.2</td>
</tr>
<tr>
<td>Multiple organ failure (%)</td>
<td>8 (36)</td>
<td>14 (31)</td>
<td>0.3</td>
</tr>
<tr>
<td>Stroke or hemorrhage (%)</td>
<td>5 (23)</td>
<td>8 (18)</td>
<td>0.7</td>
</tr>
<tr>
<td>Variable</td>
<td>p-Value</td>
<td>Hazard ratio</td>
<td></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------</td>
<td>--------------</td>
<td></td>
</tr>
<tr>
<td>Gender: male</td>
<td>0.7</td>
<td>1.056</td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>0.15</td>
<td>1.297</td>
<td></td>
</tr>
<tr>
<td>UNOS Status 1A</td>
<td>0.001</td>
<td>0.5</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>0.2</td>
<td>1.007</td>
<td></td>
</tr>
<tr>
<td>Creatinine</td>
<td>0.004</td>
<td>1.188</td>
<td></td>
</tr>
<tr>
<td>BMI</td>
<td>0.1583</td>
<td>1.026</td>
<td></td>
</tr>
<tr>
<td>Bilirubin</td>
<td>0.2</td>
<td>1.018</td>
<td></td>
</tr>
<tr>
<td>Total artificial heart</td>
<td>0.1</td>
<td>1.290</td>
<td></td>
</tr>
</tbody>
</table>
Results With Syncardia Total Artificial Heart Beyond 1 Year

Torregrossa, Gianluca; Morshuis, Michiel‡; Varghese, Robin†; Hosseinian, Leila†; Vida, Vladimiro*; Tarzia, Vincenzo*; Loforte, Antonio§; Duveau, Daniel¶; Arabia, Francisco‖; Leprince, Pascal#; Kasirajan, Vigneshwa***; Beyersdorf, Friedhelm††; Musumeci, Francesco§; Hetzer, Roland‡‡; Krabatsch, Thoamas‡‡; Gummert, Jan‡; Copeland, Jack‡‡§§; Gerosa, Gino*

ASAIO Journal: November/December 2014 -
TAH beyond 1 year

• 1075 patients implanted with TAH between 1989 and 2011
• Only 53 had device > 1 year
• Despite renal replacement therapy in 30 patients, 73% of these recovered

Torregrossa et al ASAIO 2014
Eighth annual INTERMACS report: Special focus on framing the impact of adverse events

James K. Kirklin, MD, Francis D. Pagani, MD, PhD, Robert L. Kormos, MD, Lynne W. Stevenson, MD, Elizabeth D. Blume, MD, Susan L. Myers, BBA, QMIS, Marissa A. Miller, DVM, MPH, J. Timothy Baldwin, PhD, James B. Young, MD, and David C. Naftel, PhD
Implants: June 2006 – December 2016

All implants
n= 22866

Hx of previous durable VAD
N=3845

RVAD alone (no previous VAD)
N=34

All Primary implants for Left Sided Support
n= 18987

TAH (Pulsatile Flow)
N=396

Pulsatile Flow LVAD (+/- RVAD)
N=957

Continuous Flow LVAD (+/- RVAD)
N=17634

Pulsatile Flow (LVAD only)
N=608

Pulsatile Flow (LVAD + RVAD):
N=349

Continuous Flow (LVAD only)
N=17016

Continuous Flow (LVAD + RVAD):
N=618
BVAD vs TAH

Implants: June 2006 – December 2016

CFBiVADs vs. TAH, n=991

<table>
<thead>
<tr>
<th>Pump</th>
<th>n</th>
<th>deaths</th>
<th>1 yr</th>
<th>2 yrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>CFBiVAD (2006-2012)</td>
<td>231</td>
<td>133</td>
<td>56%</td>
<td>49%</td>
</tr>
<tr>
<td>CFBiVAD (2013-2016)</td>
<td>387</td>
<td>171</td>
<td>55%</td>
<td>47%</td>
</tr>
<tr>
<td>TAH (2006-2012)</td>
<td>147</td>
<td>37</td>
<td>59%</td>
<td>44%</td>
</tr>
<tr>
<td>TAH (2013-2016)</td>
<td>226</td>
<td>93</td>
<td>52%</td>
<td>37%</td>
</tr>
</tbody>
</table>

P(overall) = .03
P(CFBiVad vs. TAH) 2013-2016 = .77
P(CFBiVAD vs.TAH) 2008-2012 = .04
Biventricular Failure – BVAD

• Easier first operation
• Easier to manage because of extensive experience with continuous flow technology
BUT....

There are clearly some populations where BVAD is insufficient and TAH makes more sense

– Restrictive cardiomyopathy
– Rejection with severe graft failure
– Cardiac tumors
– Severe Ischemic VSD
– Thrombosed ventricles

• ...assuming the patient is big enough
What to choose

• Clinical Situation
  – Each has its pros and cons
  – One may be best suited for certain scenarios
• What you have?
  – Availability and expertise
• What you are good at?
  – Life saving interventions don’t have to be perfect
  – They just can’t be too late
  – If you are thinking about it, it probably needs to be done
OUTCOMES AND ADVERSE EVENTS

• Direct comparisons are difficult
  – Patient selection has evolved
  – There is a learning curve
• Overall AE burden from a patient perspective is different
  – “Pick your poison”
Limitations of TAH

• Steep learning curve

• Lack of familiarity

• Bleeding

• Readmissions

• BSA < 1.8 m (2)

• More likely to remain in hospital

• Freedom driver limitations
  • Heavy, noisy, limited duration of battery

“Consider the BVAD you will...young Jedi”
Advantages of BVAD

- Easier first operation
- Familiarity with CF technology
- More applicable to smaller size and female
- Potential for myocardial recovery and explant
- Ability to go home

“Consider the BVAD you will...young Jedi”
“It’s tough to make predictions…especially about the future.”
Yogi Berra