LV assist devices for Pediatric Heart Failure

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Relevant Financial Relationship Disclosure Statement

I have no financial relationships with a commercial entity producing healthcare-related products and/or services.
Objectives

• Understand why we use VADs in children
• Discuss device selection as it pertains to advanced heart failure management in children
  – Size
  – Etiology of HF
  – Anticipation duration of support
  – Goals of support
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Why do we use VADs?
Pediatric Heart Transplants
Recipient Age Distribution by Year of Transplant

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 increased and/or decreased in recent years.
Bridge to Transplantation (BTT)

• ~500 children are transplanted worldwide every year, but the number of children added to wait list each year continues to grow

• VADs can provide
  • Long term support for months to years
  • Allow nutritional and physical rehabilitation
  • Improvement in transplant candidacy
Why do we need VADs?

We run out of time......
Bridge to Decision (BTD)

- Traditional ECMO associated with higher mortality and morbidity beyond weeks of support
- Cannot wake patients and adequately evaluate neurological function
- VADs can provide:
  - Ability for intermediate term support (wks to mths) to determine further course of management
    - Recovery?
    - Transplantation?
    - Palliative care/redirection of care?
Why do we need VADs?

AG: 10 yo pre VAD 17 kg
AG: 10 yo post VAD 24 kg

In CICU  In School
Bridge to Candidacy (BTC)

- Patients not considered suitable transplant candidates due to possibly modifiable factors:
  - Elevated pulmonary vascular resistance from high left atrial pressures
  - Morbid Obesity
  - End organ dysfunction (renal and hepatic)
  - Cancer awaiting period of remission
  - Psychosocial issues
  - Poor compliance with previous medical regimes
Use of centrifugal left ventricular assist device as a bridge to candidacy in severe heart failure with secondary pulmonary hypertension

Ramesh S. Kutty, Jayan Parameshwar, Clive Lewis, Pedro A. Catarino, Catherine D. Sudarshan, David P. Jenkins, John J. Dunning and Steven S. Tsui

- 28 patients (HeartWare 8, VentrAssist 21)
- 17/28 ineligible for HTX due to high PVR and TPG
- 4/28 also received RVADs
- 30 d mortality 7.7%, 1 yo post-tx survival 91%

<table>
<thead>
<tr>
<th></th>
<th>Systolic PAP</th>
<th>Mean PAP</th>
<th>TPG</th>
<th>PVR (iWU)</th>
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<tbody>
<tr>
<td>Pre-op</td>
<td>57 ± 9.5</td>
<td>42 ± 4.4</td>
<td>14 ± 3.9</td>
<td>5 ± 1.5</td>
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<tr>
<td>Post-op</td>
<td>32 ± 7.5</td>
<td>18 ± 5.5</td>
<td>9 ± 3.3</td>
<td>2.1 ± 0.5</td>
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</table>
**Boston Experience: VAD for PVR rehab**

- 3/17 HeartWare placed in setting of ↑ PVRi

<table>
<thead>
<tr>
<th></th>
<th>CI  (L/min/m2)</th>
<th>RAP (mmHg)</th>
<th>Mean PAP (mmHg)</th>
<th>PCWP (mmHg)</th>
<th>PVR (iWU)</th>
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<tbody>
<tr>
<td>Pre-op</td>
<td>1.7 (1.5-2.5)</td>
<td>10 (10-14)</td>
<td>50</td>
<td>30 (28-38)</td>
<td>10 (5.6-11)</td>
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<tr>
<td>2 wks</td>
<td>3.2 (3.1-3.2)</td>
<td>14 (7-14)</td>
<td>23 (18-23)</td>
<td>14 (12-15)</td>
<td>2.8 (1.9-3.2)</td>
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<tr>
<td>1 yr</td>
<td>3.9</td>
<td>13</td>
<td>26</td>
<td>18</td>
<td>2.1</td>
</tr>
</tbody>
</table>

* Values median (range)
Recovery?

• Now over 2 years since explantation, with normal ejection fraction, and free of HF sx
Bridge to Recovery

• **Goal**: unload ventricle and facilitate remodeling

• Limited experience to date with use of VAD in children for recovery
  – 11% of children supported with Berlin Heart EXCOR
  – 6% of children supported with HeartWare device
  – More experience with ECMO and temporary devices used in setting of myocarditis

• Challenges to BTR is defining recovery and predicting who will recover and when to do it
Why do we need VADs?
Destination Therapy

- Mounting group of patients who are not candidates for HTX but who could benefit from improved *Quality of Life (QOL)* with VAD
  - Duchenne Muscular Dystrophy
  - Highly sensitized patients (e.g. Failing Fontan)
  - Certain cancers with low likelihood of remission
  - Post-transplant graft dysfunction due to rejection or graft vasculopathy (2nd and 3rd grafts)

Redefining DT VAD for Children

- Not really “destination”, as this implies we know where we are going
- Reality, is that this strategy has the most uncertainty
  - Neither know the duration, or how it will unfold
- “Palliative” = Uncertainty of prognosis
- **Palliative VAD goal:**
  - *Add life to years rather than years to life*
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  – Goals of support
Device Selection

1. Size (patient and ventricle)
2. Etiology of failure
   • Systolic vs diastolic
   • CM vs CHD
   • Acute vs chronic
3. Anticipated duration of support
4. Goals of support: transplant, decision, candidacy, recovery, destination
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# Size and Device Options

<table>
<thead>
<tr>
<th>3kg-15 kg</th>
<th>15-35kg</th>
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<tbody>
<tr>
<td>ECMO</td>
<td>ECMO</td>
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<tr>
<td>Rotaflow</td>
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<td>Rotaflow</td>
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<tr>
<td>Pedimag</td>
<td>Centrimag</td>
<td>Centrimag</td>
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<td>Berlin Heart</td>
<td>TandemHeart</td>
<td>TandemHeart</td>
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<td></td>
<td>Impella</td>
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<td></td>
<td>Berlin Heart</td>
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<td></td>
<td>HeartWare</td>
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<td>Select HM II</td>
<td>Select HM II</td>
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<td></td>
<td></td>
<td>Syncardia TAH</td>
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</tbody>
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Pump Inside or Outside the Body

**Paracorporeal**
- Berlin Heart EXCOR®
- Rotaflow®
- Pedimag/Centrimag®

**Intracorporeal**
- HeartWare HVAD®
- HeartMate II®
- Syncardia TAH®
- Jarvick® (PumpKIN Trial)*

* Jarvick device not yet commercially available, study enrollment 2017
Device Selection

1. Size (patient and ventricle)
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   - Systolic vs diastolic
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Etiology of HF

• Diastolic HF in children is better treated with continuous flow devices than pulsatile
  – Berlin Heart replicates diastolic dysfunction with preserved systolic function

• Innovative implantation strategies and pre-implant imaging necessary in CHD

• If deterioration in function is acute, then recovery may be possible, and could consider temporary support
Device Selection

1. Size (patient and ventricle)
2. Etiology of failure
   - Systolic vs diastolic
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Short Term MCS Options

• V-A ECMO
• Percutaneous VADs
  – Impella 2.5
  – Tandem Heart
  – NOTE: size of patient and vessel an important consideration
Impella® Percutaneous VAD
Long Term MCS Options

• Berlin Heart EXCOR
  – children <15 kg with systolic HF
  – Cardiomyopathy
• Rotaflow/Centrimag with EXCOR cannula
  – children <15 kg with systolic ± diastolic HF
  – CHD (especially single ventricle)
• HeartWare
  – children > 15 kg with systolic/diastolic HF
• Syncardia TAH
  – Children >40kg with biventricular failure
Berlin Heart EXCOR
What you see at the bedside...
What you see at the bedside...
Berlin Heart EXCOR®

• Uni or BiV pulsatile support >3 kg
  – *Only long term VAD for children 3-15 kg*
• ~18-30 % risk of stroke or neuro event
• Controller is the IKUS (large ~ 100 lbs)
• Cannot be discharged home
• Indications:
  1. Bridge to transplantation
  2. Bridge to recovery
Paracorporeal continuous flow VADs with EXCOR cannula

Rotaflow
Centrimag
Pedimag
Paracorporeal CF devices

• Collection of continuous flow pumps that can be connected in various configurations with durable cannula +/- oxygenator

• Example: Maquet® Rotaflow, Abbott® Centrimag/Pedimag, TandemHeart
HeartWare
HeartWare HVAD

- Intracorporeal continuous flow VAD
- 160 gram pump and cannula
- Placed within pericardial sac with outflow graft to As AO
- Can achieve up to 10L/min cardiac output
- Indications
  - Bridge to transplant
  - Bridge to candidacy
  - Bridge to recovery
  - Destination therapy
Parts of the device
Special considerations in children

• Need ~ >25 mm from apex to MV to accommodate inflow cannula

• Difficult to position in setting of CHD (single vent, hypertrophy, significantly dilated ventricle that then decompresses)

• Peripheral component weight 3.3 lbs, need to assess fit for smaller and younger patients
Syncardia Total Artificial Heart
Syncardia® TAH

- Remove the WHOLE heart: all valves, all myocardium
- Anastomose to atrial cuff and PA/Ao
- Pulsatile biventricular support
- 2 pump sizes
  1. 70cc pump: 10 L/min flow (BSA > 1.7 m²)
  2. 50cc pump: ~6L/min flow (BSA ~ 1m²)*
     - * not currently available, still investigational
Syncardia® TAH
Conclusion

• Field of VAD support in children has expanded dramatically over the last 20 yrs
• Improved survival as bridge to transplant with contemporary VADs
  – 35% with ECMO
  – 76% with Berlin Heart
  – 85% with HeartWare
• Limitations to expanding VAD in children related to risk of adverse events, cost, and necessary expertise and infrastructure
Thank you
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