VAD Strategies and Outcomes in Congenital Heart Disease

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No Disclosures
Major situations for MCS in the care of patients with congenital heart disease:

- Temporary support after cardiac surgery with the intent of recovery
- Bridge-to-transplant therapy in the setting of progressive heart failure, usually after previous cardiac surgery.
Major situations for MCS in the care of patients with congenital heart disease:

- Temporary support after cardiac surgery with the intent of recovery
- Bridge-to-transplant therapy in the setting of progressive heart failure, usually after previous cardiac surgery.
- Rarely, long term “Destination” therapy
Decisions prior to reoperative sternotomy: Lessons from Dr. Dearani

- Two biggest risk factors for early mortality in reoperative surgery for congenital heart disease:
  - Serious cardiac injury (OR 2.6)
  - NYHA III/IV (OR 3.3)
Preparation for possible destabilizing cardiac bleeding during reoperative sternotomy

- Control of bleeding with partially opened sternotomy
- Options for rapid cannulation
Decisions prior to reoperative sternotomy

• For example, exposure of innominate in supra-sternal notch; cannulation through 4 mm Gortex graft sewn on innominate artery
Emergent Femoral Cannulation for ECMO or REDO CPB Cannulae Selection

<table>
<thead>
<tr>
<th>Arterial Cannula ($\Delta p60$)</th>
<th>Flow (L/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size (fr)</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>$\leq 0.520$</td>
</tr>
<tr>
<td>10</td>
<td>$\leq 1.0$</td>
</tr>
<tr>
<td>12</td>
<td>$\leq 1.6$</td>
</tr>
<tr>
<td>14</td>
<td>$\leq 2.3$</td>
</tr>
<tr>
<td>15</td>
<td>$\leq 2.0$</td>
</tr>
<tr>
<td>17</td>
<td>$\leq 3.0$</td>
</tr>
<tr>
<td>19</td>
<td>$\leq 4.0$</td>
</tr>
</tbody>
</table>

**EOPA Arterial Cannula**

<table>
<thead>
<tr>
<th>Size (Fr)</th>
<th>Flow (L/min)</th>
</tr>
</thead>
<tbody>
<tr>
<td>18 Fr EOPA cannula (fits in 6mm graft)</td>
<td>3.7</td>
</tr>
</tbody>
</table>

**End to side Anastomosis with Goretex Grafts for Femoral Cannulation for ECMO or Redo Sternotomy**

1/4 x 3/8 connector fits in 8mm graft
3/16 x 1/8 connector fits in a 3.5mm graft

*We have used a 5mm Dialysis catheter and were able to achieve 100mls per min with a male perfusion adaptor attached to 3/16 or ½ pump tubing connected to the dialysis catheter in a 3-5 kg patient*

*Physical limitations of the vessel will ultimately determine cannula size*
Durable VADs available in the U.S. applicable to pediatric patients

- Berlin Heart Excor
- HeartWare HVAD
- HeartMate II
- DeBakey Child
- Thoratec PVAD
Berlin Heart EXCOR

- Paracorporeal pump with an electro-pneumatic drive system
- Pediatric blood pumps available in sizes 10, 25, and 30 ml (also 50, 60, and 80 ml pumps for larger patients)
• Chambers and polyurethane ports are transparent, allowing direct visualization to detect thrombus and monitoring of chamber filling and emptying
HeartWare
HeartWare’s left ventricular assist pump and anatomic configuration.

At only 45cc, the HVAD is the smallest full output pump in development

The HVAD is implanted directly in the pericardial space
SynCardia Total Artificial Heart
The Challenges of MCS in patients with congenital heart disease
Patients with congenital heart disease accounted for 0.7% (54) of 7290 devices implanted. The vast majority are in the setting of prior cardiac operations.
The application of MCS for Single Ventricle Physiology is especially challenging
MCS in Single Ventricle Physiology

- Single ventricle with prior palliative surgery but without separation of systemic and pulmonary circulations
- Post-Fontan (after separation of pulmonary and systemic circulations)
Pre-Fontan Situation

- Inflow from single ventricle (or rarely the common atrium)

- Outflow to ascending aorta

- Pulmonary blood flow maintained/adjusted via systemic-to-pulmonary artery shunt with or without a prior bidirectional Glenn shunt or pulmonary artery band
Failing Fontan Circuit

- Primary ventricular dysfunction (systolic or diastolic)
- Failing Fontan physiology (preserved ventricular function but moderate or worse elevation of pulmonary vascular resistance)
- Most cases are mixed
PHTS: 1993-2001: Fontan Study

Fontan at Listing (n=97)

Percent Survival

Years After Listing

Ventilator at Listing

P<.0001

Ventilator (n=17, 7 deaths)

No Ventilator (n=80, 8 deaths)
PHTS: 1993-2001: Fontan Study

Fontan at Listing (n=97)

Status II (n=44, 3 deaths)

Status I (n=50, 11 deaths) - continuous inotropes

Survival vs Years after Listing

Percent Survival

Year

Listing

Status at Listing

P=.002
Fontan with Primary Ventricular Dysfunction

- Ventricle-to-aorta circuit usually effective
- Best post-Fontan situation for MCS Rx
Failing Fontan Physiology

• May need isolated drainage of IVC, SVC into pulmonary artery

• Often requires an compliance chamber to allow effective VAD filling

• Combined levels of dysfunction may require biventricular support
Implantation of Berlin Heart on the Right Circulation

MCS Outcomes in CHD
Patients with a VAD at time of Transplant (n=3746)

Year of Transplant

Percent of Patients with a VAD

- 2001: 0.00%
- 2002: 5.00%
- 2003: 10.00%
- 2004: 15.00%
- 2005: 20.00%
- 2006: 25.00%
- 2007: 30.00%
- 2008: 35.00%
- 2009: 40.00%
- 2010: 45.00%
- 2011: 50.00%

Pediatric Heart Transplant Study
PHTS: Jan 1993 – Dec 2009, ECMO Study

Survival after Listing (n=4,365)

- On ECMO at listing (n=408, events=134)
- On VAD at listing (n=171, events=19)
- All others at listing (n=3,786, events=482)

Event: Death after listing censored at transplant

p<.0001
Berlin Heart EXCOR

Neurologic Dysfunction

- Occurs in 30% of patients supported
- Leading cause of mortality
- Thromboembolic strokes twice as common as hemorrhagic strokes
Risk Factors for Death

- Lower weight
- BIVAD support
- Elevated bilirubin
- Renal dysfunction

Almond et al, Circulation 2013
<table>
<thead>
<tr>
<th>Category</th>
<th>Mortality</th>
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<tbody>
<tr>
<td>Cardiomyopathy (n=143)</td>
<td>16%</td>
</tr>
<tr>
<td>CHD:</td>
<td></td>
</tr>
<tr>
<td>2 ventricle (n=40)</td>
<td>50%</td>
</tr>
<tr>
<td>1 ventricle (n=19)</td>
<td>42%</td>
</tr>
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Almond et al, Circulation, 2013
Poor outcome with Berlin Heart
- 93% mortality (13/14) in infants < 5kg with congenital heart disease (not specified whether previous cardiac surgery, but those infants after Stage 1 palliation for single ventricle/HLHS would be the highest risk)

Almond et al, Circulation, 2013
Emerging Pediatric Devices
NHLBI’ s Program for the Development of Pediatric Circulatory Support Devices

J. Timothy Baldwin, Ph.D.
Program Officer, NHLBI
Pediatric Circulatory Support Systems

PediaFlow Ventricular Assist Device
*University of Pittsburgh*
Harvey Borovetz, Ph.D.

PediPump
*Cleveland Clinic*
Lerner College of Medicine-CWRU
Brian Duncan, M.D.

Pediatric Cardiopulmonary Assist System
*Enson, Inc.*
Mark Gartner, M.S.

Child-size and Infant-size Jarvik 2000 LVADs
*Jarvik Heart, Inc.*
Robert Jarvik, M.D.

Pulsatile Pediatric Ventricular Assist Devices
*Penn State University*
Bill Weiss, Ph.D.
HeartWare MVAD Transapical

- Ascending aorta graft attachment
- Descending aorta graft attachment
CircuLite Micro-pump Technology Platform

- German engineered
- Flow range: 0.3 - 6.0 L/minute
- Provides partial or full support
- Minimally invasive (pacemaker-like placement)
- Maintains heart physiologic function
- Long implantable life
- Synergy device weighs only 25 grams

Minimally Invasive Circulatory Support

- Minimally Invasive Surgical System
  - Inflow cannula surgically placed into left atrium
  - Outflow graft to subclavian artery using surgical anastomosis
  - Pump is under the skin in a pacemaker-like pocket
  - Mini-thoracotomy procedure
  - >75 patients implanted

- Next-generation Endovascular System
  - Inflow cannula into left atrium via subclavian vein using transseptal system
  - Outflow to subclavian artery using an anastomotic connector
  - Pump is under the skin in a pacemaker-like pocket
  - Interventional procedure
  - FIM 2013

**Impella RP: Description**

- The Impella RP is a 3D catheter-based system, implanted via the femoral vein.
- Used as a temporary circulatory support device for treatment of RV failure (per IDE support can be provided up to 14 days).
- Size 22 Fr pump on a 11 Fr catheter.
- Flows > 4 L/min.
- The device inlet resides in the inferior vena cava (IVC).
- The device outlet resides in the pulmonary artery (PA).
SynCardia Total Artificial Heart

70cc SynCardia temporary Total Artificial Heart

50cc SynCardia Total Artificial Heart
Conclusions

• Except in very small infants, durable MCS devices provide superior BTT support compared to traditional ECMO
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• In the setting of CHD with profound circulatory failure, MCS support is nearly always implemented in the setting of 1 or more prior cardiac operations
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• In the setting of CHD with profound circulatory failure, MCS support is nearly always implemented in the setting of 1 or more prior cardiac operations

• Single ventricle (SV) conditions pose the greatest challenge to successful MCS BTT therapy with currently limited outcomes data
Conclusions

- In SV, MCS therapy is least likely to provide effective BTT support when used before the bidirectional Glenn stage.
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• Emerging devices focus on various features of rotary design, non-sternotomy implant, small size, and/or biventricular support.
The End