Pediatric Perfusion Population – Newborns to People My Age!

Heart Failure in Children

- 14,000 Children hospitalized annually for heart failure in the United States
- Annual United States pediatric heart transplants remain stable at 500-600/year
- 20% of children waiting for a heart transplant will be bridged by a VAD
Challenges in using VAD or ECMO for Pediatric Heart Failure

- **VAD**
- Limited available VAD pumps to accommodate lower pump flows and pressures
- Troubling outcomes—Increased mortality and stroke rates especially with smaller patients
- Multiple VAD sizes to stock for a wide patient population
- Cost—$$$

- **ECMO**
- Poor long term survival as a bridge to transplant
- Over a 15-year period in the United States, only half of all babies supported with ECMO as a bridge to heart transplantation survived to hospital discharge
- Extracorporeal Membrane Oxygenation for Bridge to Heart Transplantation: Among Children in the United States: Analysis of Data From the Organ Procurement and Transplant Network and Extracorporeal Life Support Organization Registry
  - Christopher S. Almond, MD, MPH; Tamerle P. Rangwala, MD, MPH
  - Circulation 2011;123:2975-84

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**CONGENITAL HEART DISEASE**

Perioperative mechanical circulatory support in children: An Analysis of the Society of Thoracic Surgeons Congenital Heart Surgery Database

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Objectives: Analyses of mechanical circulatory support (MCS) in pediatric heart surgery have primarily focused on single-center outcomes or narrow applications. We describe the patterns of use, patient characteristics, and MCS-associated outcomes across a large multicenter cohort.

Methods: Patients (aged <18 years) in the Society of Thoracic Surgeons (STS) Congenital Heart Surgery Database (2000-2010) were included. The characteristics and outcomes of those receiving postoperative MCS were described, and Bayesian hierarchical models were used to examine variations in the adjusted MCS rates across institutions.

Results: Of 96,596 operations (80 centers), MCS was used in 2.4%. The MCS patients were younger (13 vs 195 days, P < .0001) and more often had STS-defined preoperative risk factors (57.2% vs 32.7%, P < .0001). The operations with the greatest MCS rates included the Norwood procedure (17%) and complex biventricular repairs (arterial switch, ventricular septal defect, and arch repair [14%]). More than half of the MCS patients did not survive to hospital discharge (52.2% in 29% of non-MCS patients, P < .0001). MCS-associated mortality was greatest for truncus arteriosus and Ross-Konno operations (both >70%). The hospital-level MCS rates adjusted for patient characteristics and case mix varied by 15-fold across institutions, with both high- and low-volume hospitals having substantial variation in MCS rates.

Conclusions: Perioperative MCS use varied widely across centers. The MCS rates were greatest overall for the Norwood procedure and complex biventricular repairs. Although MCS can be a life-saving therapy, more than half of MCS patients will not survive to hospital discharge, with mortality >70% for some operations. Future studies aimed at better understanding the appropriate indications, optimal timing, and management of MCS could help to reduce the variation in MCS rates across hospitals and improve outcomes.

(O Theme Categories: Aug 2014;17:058.802)

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**How Do We Currently Manage Heart Failure in a Diverse Pediatric Patient Population?**
Lurie Children’s of Chicago
Armada of VAD Supplies

- Thoratec PVAD
- Medtronic Biomedicus
- Berlin Heart (consignment)
- Heartware
- TandemHeart - Adult congenital cases/cath lab surprises
- 500K worth of VAD supplies!

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Case Report

Successful Bridge to Transplant Using the TandemHeart® Left Ventricular Assist Device in a Pediatric Patient

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Neale Zingle, CCP, and Carl L. Backer, MD

Abstract

A nine-year-old girl (23 kg) was successfully bridged to heart transplantation with the TandemHeart® centrifugal pump for 10 days. Although this cardiac assist device has been used in adults for short-term mechanical support, its use in the pediatric population has not been widely reported. The TandemHeart® was easy to implant, achieved appropriate flows in this pediatric patient, and allowed for extubation and ambulation while awaiting a donor heart.

World Journal Pediatric Congenital Heart Surgery 2012;3:249-250

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TandemHeart VAD

Centrifugal Pump

- Used for short-term mechanical support in many adult centers
- Head floated by continuous saline infusion-10 ml/hr
- Speed: 3500 – 7500 RPM
- Flow: 1.5 – 8 L/min
- Low prime: 10ml
Shunt Concept: Modified Shunt in Circuit to Accommodate Lower Flow Rates

Testing of the Modified TandemHeart with Shunt

- Bench top trials: Tested flow rates, pressures using saline
- To the lab: Hemolysis and plasma free hemoglobin studies using Bovine blood
- Surgically implanted in 7 piglets (6 to 14 kg)
- Supported piglets for 4 hours: levels of hemolysis did not increase and full hemodynamic support was achieved

Modified TandemHeart

- Modified TandemHeart LVAD with recirculation shunt allows a lower range of flow: Less than 1.5 L/min
  - Shunt flow is controlled by a partial occlusion clamp
  - Arterial flow to patient is calibrated using a Transonics flow probe. Adjust flow with SVR of patient
  - Standard right angled venous cannula used in dome of left atrium
  - Aortic Dacron graft attaches to modified circuit
TandemHeart with Modified Shunt
Patients with Flow Rate Equal or Less Than 1.5 L/min

- Gate clamp
- Recirculation shunt
- Flow probe
- VAD inflow line

De-airing TandemHeart LVAD

- VAD submerged in saline-filled basin

Standard CPB (RA, Ao)

- CPB venous cannula
- Dome of left atrium
- CPB arterial cannula
Arterial Perfusion Graft

Tunneling of VAD Inflow Cannula

Connecting Outflow Tubing
Benefits of the Modified TandemHeart with Recirculation Shunt

- Recirculation shunt allows a lower range of flow to the patient—less than 1.5 L/min
- Pump head close to patient—low prime 10-30 ml with modified circuit
- Adjustable flow without raising RPMs to meet patients changing SVR
- Flow dynamics—no stasis
- Venturi effect—augmented inflow because of shunt flow in modified circuit, also avoids cannula “suck down”
- No special cannulas or tubing—regular stock items
- No commitment to transplantation
- One VAD to stock for all patients

Modified TandemHeart Ventricular Assist Device for Infant and Pediatric Circulatory Support

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Purpose. The development of pediatric ventricular assist device (VAD) circuits with lower flow ranges for infants and small children is ongoing. We present our results with modifying a readily available adult VAD to support the pediatric population.

Description. The TandemHeart VAD (CardiacAssist, Pittsburgh, PA) circuit was modified to include a variable restrictive recirculation shunt to permit lower flow ranges in small pediatric patients.

Evaluation. Initial benchtop flow rates and pressures were studied. Hemolysis trials were performed using whole bovine blood to compare plasma-free hemoglobin levels between modified and unmodified VAD circuits. The modified VAD was surgically implanted in 7 piglets (6 to 14 kg) and which supported them for 4 hours. Levels of hemolysis did not increase and full hemodynamic support was achieved. The modified TandemHeart VAD with a recirculation shunt was subsequently implanted in pediatric patients who were bridged to transplant successfully.

Conclusions. Because of its simplicity, availability, low prime volume, greater patient flow range, and lower cost, the modified TandemHeart VAD with a recirculation shunt should be considered as an alternative to extracorporeal membrane oxygenation and other pulsatile VADs in children.

TandemHeart Patient Population

13 Consecutive Patients:

- Age: 0.9 – 16.3 years (median = 7.0 years)
- Four patients were placed on ECMO before VAD
- BSA: 0.40 – 2.08 m² (median = 0.8 m²) 10 pts BSA<1.0 m²
- Anticoagulation:
  - Heparin started 12-24 hrs post-op (ptHt 60-80 and anti-Factor Xa 0.35-0.7 U/ml)
  - Aspirin 3.5-5mg/kg/day (48hrs post-op)
- 2 patients were Heparin resistant-1 Bivalrudin, 1 Argatroban
- Diagnosis:
  - 8 Dilated cardiomyopathy
  - 3 Restrictive cardiomyopathy
  - 1 Myocarditis
  - 3 Single ventricle/(Failed) Glenn physiology
13 TandemHeart LVAD

- 5 patients received modified recirculation shunts. 3 of these patients had Maquet Quadrox D placed in modified shunt (BSA=0.41 - 0.74m²; median .59 m²)
- 8 patients had non-modified shunt circuits. 1 patient had Maquet Quadrox D oxygenators placed in arterial outflow.

Results

- Median time on VAD was 20 days (range 2-140 days)
- 12 patients were successfully transplanted. One patient was weaned and explanted
- Post-transplantation all patients survived and were discharged at a median of 26 days (range 17-83 days)
- One explanted patient- 10 months out and no sign of heart failure

Complications

- Two non-modified shunt patients had cerebral vascular accidents (CVA) while on VAD
- One patient- On ECMO switched to Tandem VAD with oxygenator (CVA resolved). One patient 140 days on VAD some residual neurological impairment (patient was Heparin resistant)
- Infection: None
- Re-operation:
  - 2 bleeding
Lurie Children’s of Chicago
VAD Results

- VAD mortality 2008-2011 pre-TandemHeart use was 33% (3/9 patients)
- VAD mortality 2012-2015 using TandemHeart and Modified TandemHeart circuit was 0% (0/13 patients)
- Transplant wait list mortality has also dropped from 10% (5/52 patients) to 4% (4/91 patients)

Conclusions

- TandemHeart® VAD can be used successfully in a broad range of pediatric and adult congenital patients awaiting heart transplantation
- Recirculation shunt allows patient flows below 1.5 L/min and design facilitates placement of in-line oxygenator
- Very low prime, 10-30ml with Modified Shunt
- Recent studies- centrifugal flow characteristics may be advantageous compared to pulsatile VADs
- Components (cannulas and pump) readily available
- Explantable-No commitment to transplantation
- Cost-VAD stock budget- Over 500K to currently 40K

Thank You