Pediatric Mechanical Circulatory Support - What to Use

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Disclosure

I have no relevant financial relationships to disclose.
**Brief History**

1964 – NHLI establishes US Artificial Heart Program
1966 – DeBakey implants VAD after failure to wean from CPB after AVR, MVR; 10 days of support; home in 1 month
1969 – Cooley implants TAH, supported for 64 hrs, died after Tx
1975 – NHLI sponsored ECMO trial
1975 – NIH sponsored multicenter trial for temporary LVAD support with Pierce-Donachy pump (Thermo Electron Corp…Thoractec)
1977 – NHLI Heart and Vascular Division issues RFP for totally implantable VAD
1982 – DeVries implants Jarvik 7 (TAH) in Barney Clark, survives 112 days
**Brief History**

1984 – Portner’s Novacor (implantable) provides first successful bridge to Tx
1994 – FDA approves HeartMate LVAD for BTT
1996 – REMATCH trial – HeartMate VE
1998 – Debakey micromed implanted (axial-flow pump)
1999 – LionHeart
2002 – HeartMate XVE approved for destination therapy
2008 – HeartMate II approved for BTT
2010 – HeartMate II approved for destination
2011 – Berlin Excor pediatric VAD approved for BTT
2012 – HeartWare approved as BTT


Classifications

- Paracorporeal vs Intracorporeal
- Pulsatile vs Continuous Flow
- Axial vs Centrifugal vs Impeller
- Short-term vs Long-term

Development in general has gone from large, extracorporeal, pulsatile, shorter term to small, intracorporeal, continuous, longer-term
Variety of Devices

Thoratec products – HeartMate (IP, IVAD, PVAD, XVE, II)

HeartWare

Micromed DeBakey

Novacor

Abiocor

Abiomed

Syncardia

Levitronix

TandemHeart

Rotaflow

Impella

Jarvik

Berlin Excor

Medos

...and others
Mechanical support - Options
Practical Considerations

Realistically, how many devices can you stock?

Number of VADs per year and experience with device?

What is really needed to cover your patient population?
Our Current CHW Strategy

Berlin EXCOR

HVAD

Rotaflow (paracorporeal for AV loop)

Syncardia (70cc sunset for 50cc trial site)

Infant Jarvik (trial site, ???)
Our Current CHW Strategy - EXCOR

5 pump sizes from 10ml to 60ml
Paracorporeal
Original trial
  bleeding complications high
  CVA (thromboembo 2x hemorr)
Our Current CHW Strategy - EXCOR
HeartWare-HVAD

Titanium, suspended impeller, passive magnetic and hydrodynamic
No bearings
Device weight 160 gm
Intrapericardial placement (modifications)
10 L/min?
Preload and afterload sensitive
BSA 1.5?
Neo-pump pocket creation?

Good performance documented in > 2500 implants
Centrifugal Head AV Loop

Paracorporeal, centrifugal
All size patients
Cannulation options for both RVAD and LVAD arrangement
Support time (days to few weeks)
SynCardia Total Artificial Heart

Pneumatic displacement with polyurethane bladder
Flow is measured by air flow
70 cc displacement (50 entering IDE)
BSA 1.7’ish (1.5?)
Flow up to 9 L/min

>1250 implants and > 70% BTT

Size, sensitization?
Infant Jarvik 2000 (as part of PumpKIN)

Rotor supported by 2 ceramic bearings
Titanium impeller
< 0.8 BSA
4-15 kg
3L/min at reasonable power

Adult Jarvik implanted in 200 patients worldwide
CE mark in 2005

Infant Jarvik (PumpKIN) ???
Patient Category

< 17-20kg range
  Short-term to intermediate – AV loop or EXCOR
  Longer - term – EXCOR

>20kg
  Short-term to intermediate – AV loop
  Long-term – HVAD if size fit
Patient Category – Specific Circumstances

BiVAD scenarios

RVAD AV loop to explant or conversion to durable
Total artificial heart

Post-transplant rejection

Challenge
Total artificial heart if size fit
Patient Category – Specific Circumstances (continued)

Single ventricle
   Infant/toddler Glenn – EXCOR
   Adolescent/teen or older – HVAD (modifications per specific mode of failure and anatomical considerations)
   TAH, modifications
   Creativity (TAH 0.5, fenestration, shunt,)

Very sick patients – bridge to bridge strategy
On the Horizon

CircuLite Synergy
HeartMate III then X?
MVAD
Both Thoratec and HeartMate are working on wireless energy transfer

Increasing trend toward INTERMACS 2-5

ROADMAP trial will eval HM II in ambulatory IIIb/IV patients not dependent on inotropes – completion date scheduled for Dec 2015

REVIVE-IT – NHLBI sponsored trial eval HM II in class III patients, primary completion date Jan 2015
Thank you
Syncardia 0.5 and/or Fenestration
On the Horizon

CircuLite Synergy
Implantable miniaturized axial flow
Designed for partial support (adult)
1.5-4 L/min
CE mark in 2012
US IDE trial planned
You adjust RPM
On the Horizon

HeartMate III
Centrifugal flow
Magnetically levitated rotor
Theorized to provide capability for pulsatile
Finishing animal trials
First clinical implant was scheduled for 2013
On the Horizon

HeartMate X
Axial flow
Design still being finalized
On the Horizon

HeartWare MVAD
Continuous axial flow with wide blade impeller
Same suspension technology as HVAD
1-5 L/min
On the Horizon

Wireless power

Thoratec partnering with WiTricity
High-efficiency energy transfer using resonant coils

HeartWare also working on transcutaneous energy transfer
HeartAssist Monitoring
On the Horizon

Patient selection

Increasing trend toward INTERMACS 2-5

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Pediatric Issues and Areas of Focus

PHTS database, 2006 report
- 99 children, mean age 13 yr, mean weight 56 kg
- 6 mo survival: > 14 y/o > 90%
  < 10 y/o < 38%

2013 report from Berlin EXCOR database
- 47 centers, 204 patients, median age 1.6 yrs, median weight 10kg
- Median support time 40 days (1,435)
- 12 mo survival 75%
- Lower weight, bivad, increased bili risk factors for early mortality
- Reduced GFR strongest risk factor for late mortality
Pediatric Issues and Areas of Focus

EXCOR (cont)

Early mortality
- 65% if < 5 kg
- 14% if > 10 kg

Major bleeding 45%

Major infection 44%

Neuro morbidity 29%  Thromboembolic 2X > Hemorrhagic

80% had GFR < 30% predicted
Basic Connections