Innovation in LV assist as a bridge to transplant in children

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Disclosure Statement

I have no financial relationships with a commercial entity producing any related products

I will discuss off-label and/or investigational use of some ventricular assist devices

Nobody actually knows what is the “right way” of supporting children to transplant

All that we know is because of the patients and families who have trusted us with their lives in the pursuit of something better
Objectives

• Review the history of pediatric VAD
• Understand key areas of advancement and innovation
  1. Device design and options for children
  2. Long term care: Inpatient and Outpatient
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Timeline of Pediatric VAD in North America

- **1991**: Development of BH EXCOR in Germany
- **1996**: CE mark approval EXCOR in Europe
- **2000**: First child in North America
- **2004**: The New York Times - Story about 5 mos implanted at Stanford generates buzz
- **2005**: FDA requests IDE trial from BH
- **2007**: IDE trial enrollment begins for EXCOR
- **2011**: FDA approval of BH EXCOR
- **2012**: Discharging pediatric VAD patients on HVAD and HM II begins
- **2017**: VAD accepted treatment. Discharge is common
Ultimate Goal

• Primary indication for VADs in children remains bridge to transplant
• But ultimate goal is full replacement of biological heart with comparable quantity and quality of life
  – Improvements in device technology (more miniaturization of implantable and peripheral equipment including batteries)
  – Increased understanding and experience with device management in the outpatient setting
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Innovations in Pediatric Devices?

• Currently only 1 device labelled for use in children as a bridge to transplant in the US
  – Berlin Heart EXCOR®
    • No change in device design since its inception in 1991, apart from the addition of a 15 cc pump in 2014
    • Limitations of the device are related to its paracorporeal design that results in high thrombogenicity (29% incidence of stroke) and large mobile driving unit (IKUS) that prevents outpatient management
Outpatient Berlin Heart?

- First and only BH EXCOR patient discharged home in North America was in Canada 2009
- Currently testing mobile driving unit for pump sizes <50 cc with ~ 4 hours of battery time,
- Plan for use beginning in Europe 2018
Expanding VAD Options for Children

• **How?**

1. Application of devices intended for alternative support strategies (paracorporeal continuous flow temporary support VADs)

2. Application of devices designed for use in adults (intracorporeal CF VADs)
Expanding VAD Options for Children

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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
Paracorporeal CF devices

**Pros**

- Continuous flow may be optimal for certain circulations/physiology
  - Restrictive physiology
  - Diastolic dysfunction in single ventricle circulation
  - Severe AVVR
- Direct flow measurement
- Lower price point $$$
  - Berlin heart 35K
  - Centrimag 12 K
  - Rotaflow 800$

**Cons**

- Thrombogenicity?
  - Is it pump related or connectors
- Hemolysis
- ICU bound?
- Still limited mobilization
Expanding VAD Options for Children

• **How?**

1. Application of devices intended for alternative support strategies (paracorporeal cf temporary support VADs)

2. Application of devices designed for use in adults (intracorporeal CF VADs – HeartWare® HVAD)
HeartWare HVAD

- Centrifugal continuous flow intracorporeal VAD
- 160 grams in weight, 25 mm inflow with 10 mm flexible outflow graft
- Wide bladed impeller that uses hydrodynamic force to passively levitate a magnetic impeller
HeartWare and Patient Size?

- ~15 kg with adequate LVESD (~>45 mm)
- Concern about increased risk of stroke and pump thrombosis in lower operating speed range
- Only 33% of children <20kg discharged home with HVAD device vs 48% of children >20Kg and 80% of adults
Life with a HeartWare
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Advances in Care Management

Inpatient
Outpatient
Improving Inpatient Care

• We can keep them alive, but are we letting them live?

• Obstacles to inpatient QOL:
  – Lack of privacy
  – Lack of freedom (dependency on nursing, physicians, allied health for all activities)
  – Lack of predictability
  – Lack of control
Solutions for vexing inpatient problems

• Empower, Educate and Enable
  – Weekly interdisciplinary meetings ran by parents addressing their concerns
  – Train parents in VAD competencies same as nursing staff to allow them to leave the floor
  – Buy an extension cord
  – Make a 110,000$ stroller with 25$ straps from Home Depot
Outpatient VAD Care

• Expected in the field of adult VADs and becoming increasingly common in children
• In Boston 88% of children were discharged home, and 100% of those returned to school
• Obstacles to discharge:
  – Infrastructure of dedicated VAD program: nurse and physician available 24/7
  – Short wait list times to transplant at some centers, no incentive to discharge home
Outpatient VAD Care

- Find **solutions** rather than **restrictions**
- Improve patient and family preparedness for home with simulation based education
  - Simulation curriculum to teach VAD competencies and scenarios on mannequins
- Plan for discharge regardless of wait list times
- Comprehensive consistent communication
  - Tailor communication strategies based on patient’s preference (Text, email, call, VADapp)
Boston KIDS VAD app
Future Directions

• We need to gain more “wisdom” by sharing clinical knowledge and experiences across centers, cities and countries
  – ACTION learning network; learning forum across North America and expanding to Europe to share our guides, protocols, education and experience
  – For more info or to join info.action@cchmc.org or email Christina.vanderpluym@childrens.Harvard.com

• Think outside the box when caring for these patients, from device implantation to outpatient management
“It is always impossible until it is done”
-Nelson Mandela
Thank you
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