Introduction to Ventricular Assist Device (VAD)
Overview Objectives

1. Defining Pediatric Heart Failure
2. Patient Selection for a VAD
3. Device Types: Pulsatile vs. Continuous Flow
4. Patient Management Highlights
Defining Pediatric Heart Failure
Definition:
A clinical syndrome that results from any structural or functional impairment of ventricular filling or ejection. Cardinal symptoms include breathing difficulty, feeding intolerance, and decreased activity.

– ACTION Heart Failure Committee
Different Etiologies of Pediatric Heart Failure

1. Congenital Heart Disease (CHD)

2. Cardiomyopathy
   - Dilated
   - Restrictive
   - Hypertrophic

3. Myocarditis & Cardiotoxicity
Overview:

• When heart chambers and connections are not formed properly during fetal development, surgeries to correct the anatomical defects may cause stress and damage to the heart.

• Majority of patients with heart failure associated with CHD have single ventricle physiology.
Many pediatric heart failure patients that need advanced therapies have congenital heart disease.

- The indication for >40% of all North American pediatric transplants is congenital heart disease and many of these children need a VAD to support them while they are awaiting a suitable donor.

- For more information, visit: https://ishltregistries.org.registries/slides.asp?yearToDisplay=2019
Cardiomyopathy

Overview:

- An abnormality of the heart muscle that may be present from birth or can be caused by other diseases

Types include:
- Dilated Cardiomyopathy
- Restrictive Cardiomyopathy
- Hypertrophic Cardiomyopathy
Overview:

- **Cardiotoxicity**: Heart muscle injury often caused by certain medications and treatments, such as chemotherapy or radiation
- **Myocarditis**: A heart muscle injury often caused by certain infections
2. Patient Selection for a VAD
VAD Therapy in Pediatric Advanced Heart Failure

What is a VAD?
• A device used to support patients (who do not respond to medical management) with advanced heart failure.

How does a VAD work?
• A VAD is implanted to bypass or augment the function of one or both ventricles of the heart. It circulates blood to vital organs.
What are the challenges of pediatric VAD therapy?

- The varied age and size range of the pediatric population.
- The various etiologies of pediatric heart failure.
- The complex anatomical structures of congenital heart disease patients.
- Difficult to predict when a child needs a VAD. Often decompensates quickly.
VAD therapy is becoming increasingly more common.

- The percent of patients that need a VAD as a bridge to transplant varies with the age of the child.
- 1/3 of patients are supported to transplant with a VAD.
- For more information, visit: https://ishltregistries.org/registries/slides.asp?yearToDisplay=2019
VAD Implantation Indications

- Decompensated heart failure unresponsive to medical management
- Escalating inotropic support
- End-organ dysfunction
  - Liver Failure
  - Renal Failure
  - Respiratory Failure
  - Poor nutritional status
  - Decreased activity
VAD Implantation
Contraindications

- Bleeding or clotting disorders
- Severe neurological deficits
- Irreversible end organ dysfunction
- Social support or nonadherence concerns (rarely)
Patient Selection: When does a child need a VAD?

**INTERMACS Profiles**

<table>
<thead>
<tr>
<th>Profile</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Critical cardiogenic shock (33% of pediatric patients)*</td>
</tr>
<tr>
<td>2.</td>
<td>Progressive decline on inotropic support (55% of pediatric patients)</td>
</tr>
<tr>
<td>3.</td>
<td>Stable but inotrope dependent</td>
</tr>
<tr>
<td>4.</td>
<td>Resting symptoms home on oral therapy</td>
</tr>
<tr>
<td>5.</td>
<td>Exertion intolerant</td>
</tr>
<tr>
<td>6.</td>
<td>Exertion limited</td>
</tr>
<tr>
<td>7.</td>
<td>Advanced NYHA Class III symptoms</td>
</tr>
</tbody>
</table>

**NOTE:**

Outcomes are better if implanted before the patient becomes a profile 1. Timing is difficult to predict in children.

*3rd annual Pedimacs Report  
NYHA, New York Heart Association*
The sicker the patient is at implant, the less likely they are to survive.

- INTERMACS 1 patients have a 50% survival at 6 months
- INTERMACS 2 and 3 patients have an 80–90% survival

**Patient Selection: Pediatric VAD Support Options by Age**

<table>
<thead>
<tr>
<th>Pediatric Subpopulation</th>
<th>Approximate Age Range</th>
<th>VAD Support Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborn / Infant</td>
<td>Birth to 1 month of age. 1 months to 2 years of age</td>
<td>Berlin Heart EXCOR®, CentriMag™/PediMag™/RotaFlow™</td>
</tr>
<tr>
<td>Child</td>
<td>2 to 12 years of age</td>
<td>Berlin EXCOR®, HVAD™ System, HeartMate 3™ LVAD, CentriMag™/PediMag™/RotaFlow™</td>
</tr>
<tr>
<td>Adolescent</td>
<td>13 to 21 years of age</td>
<td>HVAD™ System, HeartMate 3™ LVAD, SynCardia Total Artificial Heart (TAH-t), CentriMag™/PediMag™/RotaFlow™</td>
</tr>
<tr>
<td>Young Adult</td>
<td>22 + years of age</td>
<td>HVAD™ System, HeartMate 3™ LVAD, SynCardia Total Artificial Heart (TAH-t), CentriMag™/PediMag™/RotaFlow™</td>
</tr>
</tbody>
</table>

*The FDA, for the purposes of medical devices, classifies anyone through the age of 21 as pediatric due to biological factors (under 22 years old).*
Therapeutic Goals (Bridges) for VAD Implantation

Bridge to Transplant (49%)*
• Support the heart until the patient can receive a new heart

Bridge to Recovery (7.6%)
• Temporarily support the heart while the function stabilizes
• Explant the device

Bridge to Eligibility/Decision (38%)
• Unsure of long term: recovery vs transplant/destination

Destination Therapy (1.3%)
• Not a transplant candidate but desire to improve quality and quantity of life
• Patient will have VAD indefinitely

*3rd annual Pedimacs Report
Support Duration

**Short Term**
- Use for weeks/months
- Potential of recovery or unsure of long-term plan for patient
- Patient must stay in the hospital

**Long Term**
- Use for months/years
- Usually for bridge to transplant or destination therapy
- Patient may be able to be discharged
Flow Delivery

Pulsatile Flow VADs

- Operate by using a pneumatic air compressor that delivers air to a two-sided pump.
- Device is set by systolic/diastolic pressures, rate, and percent systole. It mimics the movement of the heart with ejection and fill phases.
- The patient is pulsatile due to the device ejecting the blood to the body.

Device examples:
- Berlin Heart EXCOR®
- SynCardia Total Artificial Heart (TAH-t)*

Continuous Flow VADs (CF VADs)

- Operate by using an impeller or rotor, a round disc with blades, that spins and propels blood forward.
- Device is set by revolutions per minute (RPM).
- The patient may not have palpable pulse.

Device examples:
- HeartMate 3™ LVAD*
- HVAD™ System
- CentriMag™/PediMag™
- Rotaflow™

*approved pediatric use
3

Device Types: Pulsatile vs. Continuous Flow
Pulsatile devices have a two-sided chamber (air on one side and blood on the other) separated by a strong flexible membrane:

- The blood chamber is connected directly to the heart, which fills with blood during every beat.
- The air chamber is connected to the pneumatic driver that pushes and pulls air against the membrane. As the membrane moves, the blood fills and ejects through the blood side.
- The care team will alter the air pressure and the beats per minute to give the patient the right amount of blood flow for them.
Continuous flow devices have an impeller or rotor that spins and sends blood out to the body:

- Revolutions per minute (RPM) is the number of times the impeller/rotor spins per minute and is the only thing the care team can change.
- Power is measured in Watts and is the energy it takes to move the impeller/rotor.
- Flow is the cardiac output that the device generates. It is calculated based on an algorithm of blood viscosity (HCT) and power.
Patient Management Highlights
Optimizing the Pump

Optimize Preload
• Keep patient euvoletic - each patient has their own target
• Prevent dehydration

Control Afterload
• Avoid hypertension – each patient has their own target

Control Bleeding & Prevent Thrombosis
• Titrate anticoagulation carefully
• Watch closely for signs of bleeding and thrombosis
Device Optimization

Before VAD

After VAD
Major VAD Complications

Bleeding
• Patient requires anticoagulation to prevent thrombus

Stroke
• Risk of developing a thrombus in pump that can go to brain

Infection
• Bacteria can track along driveline and lead to severe infection

Right Heart Failure
• If only the left side receives a VAD the right side may fail

Device Malfunction
• Rare complication – if pump stops it will need to be replaced
In 2020:

We served 127 new patients...

with these conditions...

for these goals.
We’re making an impact.

We’re improving safety and efficiency of VADs in children and end-stage heart failure.

145 New Devices Implanted

Device Type
- Berlin Heart EXCOR®: 65
- PediMag™, CentriMag™, & Rotaflow: 43
- HVAD™ System: 17
- HeartMate 3™ LVAD: 16
- Impella: 3
- Other: 1

Outcomes
- 87% of patients had positive outcomes.
- 11% of patients had a stroke.
- 24% of patients had a bleeding event.
- 26% of patients had an infection event.

3 Unique device implants across ACTION centers.
The care team gathers info to make informed decisions regarding device type, strategy, duration, and plan for implant procedure. Patients/caregivers meets care team and gets VAD education.

Typical implantation takes 6–12 hours depending on the device type. The surgeon will implant the device via sternotomy approach while the patient is on cardiopulmonary bypass.

During the immediate post operative period, it is critical to monitor for bleeding, stroke and RV failure (if LVAD only).
VAD Patient Journey

VAD De-escalation & Rehabilitation
Focus on de-escalation, pain management, and rehabilitation.

VAD Education & Discharge (if applicable)
If discharge eligible, patients/caregivers are required to complete VAD education prior to being discharged.

Living with a VAD
Pediatric VAD patients who live at home or require prolonged hospitalization deserve to have fun and have a great quality of life.
Appendix: VAD Terminology

<table>
<thead>
<tr>
<th>Support type</th>
<th>LVAD</th>
<th>SVAD</th>
<th>RVAD</th>
<th>BIVAD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paracorporeal Pulsatile</td>
<td>Paracorporeal Continuous</td>
<td>Intracorporeal Continuous</td>
<td>Corporeal Pulsatile</td>
<td></td>
</tr>
</tbody>
</table>
## Appendix: Short Term VAD Reference

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacture</th>
<th>Pediatric FDA indication</th>
<th>Type</th>
<th>Output</th>
<th>Patient Size Industry Recommendation</th>
<th>Support Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>RotaFlow™</td>
<td>Getinge</td>
<td></td>
<td>Paracorporeal/Continuous Flow</td>
<td>Up to 10 LPM</td>
<td>All</td>
<td>6 hrs (US)/ Up to 30 d</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(Europe)²</td>
</tr>
<tr>
<td>PediMag™</td>
<td>Abbott</td>
<td>X</td>
<td>Paracorporeal/Continuous Flow</td>
<td>Up to 1.5 LPM</td>
<td>&lt;20 kg</td>
<td>LVAD: 6 hrs (US), 30 d</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(Europe)/RVAD: 30 d</td>
</tr>
<tr>
<td>CentriMag™</td>
<td>Abbott</td>
<td></td>
<td>Paracorporeal/Continuous Flow</td>
<td>Up to 10 LPM</td>
<td>Not studied in patients &lt;18 yrs</td>
<td>LVAD: 30 days (US), 30 d</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>(Europe)/RVAD: 30 d</td>
</tr>
<tr>
<td>TandemHeart™</td>
<td>LivaNova</td>
<td></td>
<td>Paracorporeal / Continuous Flow</td>
<td>Up to 5 LPM</td>
<td>&gt;1.3 m²</td>
<td>6 hrs</td>
</tr>
<tr>
<td>Tandem Life Protek Duo™</td>
<td>LivaNova</td>
<td></td>
<td>Paracorporeal/Continuous Flow</td>
<td>Up to 4.5 LPM</td>
<td>Requires 29F Sheath</td>
<td>6 hrs</td>
</tr>
<tr>
<td>Impella 2.5™, CP™, 5.0™, 5.5™</td>
<td>Abiomed</td>
<td></td>
<td>Intracorporeal/Continuous Flow / Intravascular</td>
<td>2.5: up to 2.5 LPM/CP: up to 4.3 LPM</td>
<td>2.5, CP: advisory board &gt;1.0m²</td>
<td>4 days Impella 2.5, CP) to 14 d (Impella 5.0 and 5.5)</td>
</tr>
<tr>
<td>Impella RP™</td>
<td>Abiomed</td>
<td></td>
<td>Intracorporeal/Continuous Flow/Intravascular</td>
<td>Up to 4.0 LPM</td>
<td>&gt;1.5 m²</td>
<td>14 d</td>
</tr>
</tbody>
</table>
## Appendix: Long Term VAD Reference

<table>
<thead>
<tr>
<th>Device</th>
<th>Manufacturer</th>
<th>Pediatric FDA indication</th>
<th>Type</th>
<th>Output</th>
<th>Patient Size Industry Recommendation</th>
<th>Support Time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berlin Heart EXCOR®</td>
<td>Berlin Heart</td>
<td>X</td>
<td>Intracorporeal/Continuous Flow</td>
<td>0.6 – 8 lpm</td>
<td>&gt;2.2 kg (smallest patient)</td>
<td>BTT (US), BTT, DT (Europe)</td>
</tr>
<tr>
<td>HVAD™ System</td>
<td>Medtronic</td>
<td></td>
<td>Intracorporeal/Continuous Flow</td>
<td>2 - 10 lpm</td>
<td>≥1.2 m²</td>
<td>BTT, DT</td>
</tr>
<tr>
<td>HeartMate 3™ LVAD</td>
<td>Abbott</td>
<td>X</td>
<td>Intracorporeal/Continuous Flow</td>
<td>Up to 10 lpm</td>
<td>≥1.0 m²</td>
<td>BTT, DT or short and long term</td>
</tr>
<tr>
<td>Jarvik 2015™ LVAD</td>
<td>Jarvik</td>
<td></td>
<td>Intracorporeal/Continuous Flow</td>
<td>0.5 – 3 lpm</td>
<td>Study Cohort 8–30kg</td>
<td>No approval, trial ongoing</td>
</tr>
<tr>
<td>SynCardia Total Artificial Heart (TAH-t) 50cc™</td>
<td>SynCardia</td>
<td>X</td>
<td>Corporeal/Paracorporeal Continuous</td>
<td>Up to 7.5 lpm</td>
<td>&gt;1.2 –1.85 m² Needs room in the chest</td>
<td>BTT</td>
</tr>
<tr>
<td>SynCardia Total Artificial Heart (TAH-t) 70cc™</td>
<td>SynCardia</td>
<td></td>
<td>Intracorporeal/Paracorporeal Continuous</td>
<td>Up to 9.5 lpm</td>
<td>≥1.7 m² Needs room in the chest²</td>
<td>BTT/DT</td>
</tr>
</tbody>
</table>
All set!

Let’s move on to the next step in your training.