Ventricular Assist Device Therapy Update - TCH experience

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Disclosures

• I will be discussing the off-label use of medical devices

• Authorization granted by parents/patients for photo images utilized during this presentation
Objectives

• Explain indications for VAD therapy

• Describe different forms of VAD therapy

• Explain potential complications of VAD therapy

• Describe VAD therapy trends unique to TCH
Indications for MCS intervention

• All states of cardiac failure that are either reversible (variable period of time) or that require transplantation

• Patient population
  - CMO/Myocarditis
  - Malignant arrhythmia
  - Failure to wean off CPB and post op arrest
  - Failing Fontan? /Single Ventricle?
  - TCAD- re-transplant?
Current MCS Protocol at TCH

- Child in need of mechanical support
  - VV ECMO
  - VA ECMO

- Cardiopulmonary support
  - Lung Recovery

- Cardiac only
  - VAD
    - Expected Recovery (<2 weeks)
      - Acute process:
        - Myocarditis
        - Acute graft rejection
        - Unknown process
      - NO: only LV support needed
      - YES: short-term VAD
        - Short-term VAD
          - Rotaflow® (any size)
          - Impella® 2.5/CP (BSA>0.7)
          - Impella®5.0: LV>7cm, Ao >1.5
        - Recovery (BTR)
      - Chronic process:
        - DCM
        - End stage CHD
        - Bridge to decision
  - NO: biventricular support needed

- Respiratory only
  - Lung Transplant
  - Recovery (BTR)

- BiVAD
  - HeartWare®
  - Syncardia® TAH 50cc: BSA >1.2 and <1.8
  - Syncardia® TAH 70cc: BSA >1.7

- Long-term VAD
  - EXCOR Berlin®: >5kg and BSA <0.7
  - Jarvik 2015®: >8kg and <30kg
  - HeartWare®: BSA ≥0.7
  - (Heartmate III: BSA ≥ 1.2)

- Heart Transplant (BTT)
- Bridge to Candidacy (BTC) Destination (DT)
Individualized VAD Strategy

✓ Careful evaluation of the patient’s disease process

✓ Consideration of prior surgeries (Sternotomy, how many more?)

✓ Selection of the optimal assist device (size, flow needed, BSA)

✓ Appropriate cannulas (Inflow/outflow position, size of cannula, bridging Berlin w/ Rotaflow?)

✓ Personalized flow calculations
  Weight x 150 (constant) = 100% flow  (Ex: 9kg x 150 = 1350mls for 100% Flow)
  (10cc Berlin Pump X 130 BPM = 1300cc/min approx. 100% Flow)
Contraindications

• Catastrophic neurologic injury/ intracranial hemorrhage

• MSOF, uncontrolled sepsis/active infection – *Fungal

• Multiple anomalies/metabolic disease

• Active bleeding/Anticoagulation intolerance

• Hypercoagulable

• Too small or too big

• Number of Sternotomy procedures- How many is too many? Congenital staging procedures?
Assist Devices utilized at TCH

Berlin Heart®  HeartWare®  Heartmate II®  Heartmate III®

Jarvik 2015®  SynCardia®  Impella®  Rotaflow®
Device Variations

- HeartWare ® (Long term), Heartmate 3 ® (Long term), and Rotaflow ® (Short term)
  - Centrifugal Flow (Mag- Lev)- 3rd Generation

- Jarvik ®, Heartmate II ® (Long term) and Impella ® (Short term)
  - Axial Flow- 2nd Generation

- Berlin Heart ® and SynCardia ® (Long term)
  - Pneumatic-Pulsatile Pump- 1st Generation

Intracorporeal / Paracorporeal / Extracorporeal........
Short Term VAD Support

Indications

- Need for post operative support
  - Failure to wean from bypass
  - Bridging between forms of MCS
  - Temporary RV Support (w/ LVAD)
- Low cardiac output state
  - Not related to surgery
    - Myocarditis
    - Cardiomyopathy
    - Acute transplant rejection
Impella (Axial flow)

- Motor size is 12 fr.
- Can flow up to 2.5- 5.0LPM (RP for right sided support)
- Has been used in tandem with ECMO
- Placement is key
- Insertion in Cath lab/OR
- Use: 2015- present
- (N: 31)
Maquet Rotaflow (Centrifugal flow)

Constrained Vortex
- Negative Pressure at Inlet of pump
- Positive Pressure at Outlet of pump

Complications:
- Hemolysis/Thrombosis
- Bleeding
- Temperature maintenance
- Air entrapment

Use: 2009 - present  N: 48
A **magnetically levitated** pump rotates and causes fluid to accelerate before being released at the outflow port.

- Pump inlet is under negative pressure which draws in fluid.

- Pump outlet (CO or flow) is PRELOAD dependent and AFTERLOAD sensitive.
HeartWare®

- Magnetically suspended Impeller- Hydrodynamic-no bearings, made of Titanium- Continuous Flow
- Operating speeds of 1800 to 4000 RPM
- Can Flow up to 10 LPM
- Recommended BSA ≥0.7
- Power sources: Battery/Wall/Car adaptors
- 6 hrs to charge fully depleted batteries
- No Pump Pocket
- Smallest patient @ TCH: 13.2kg

- Percutaneous drive line connects to external controller.
- A portion of the drive line contains a woven polyester fabric which encourages tissue in-growth at the skin exit site.
- Use: 2011- present (N: 55)
Clinical screen

HeartWare® Monitor

Used to adjust device parameters
Displays real time and historical pump information (flow/power, alarms)
(Password Protected)

Controller

Regulates pump function and monitors the system
Indicates alarms and battery life
Displays alarms/intervention
Controller has 30 day data storage

Lithium Ion Batteries

Each battery allows up to 6 -12hrs of operation
Recharges up to 500 cycles
**HeartWare® Pump Waveform Characteristics**

**Flow Waveform**

Maximum value of the HVAD flow waveform (PEAK) 
> 2 liters above trough)

- Minimum value of the HVAD flow waveform (TROUGH)
- Trough value should be 
  >2 L/min and there should be 
  >2 L/min of pulsatility

**Flow Pulsatility**

- Difference between waveform maximum (peak) and minimum (trough)
- Dependent on heart contractility and HVAD operating points
  - Systole → max HVAD flow
  - Diastole → min HVAD flow

**NOTE:** Flow waveforms provide additional information about the patient condition, preload/afterload/potential conditions
(RV failure, Tamponade, dysrhythmia)
Long Term VAD Support: Axial Flow Pumps

Works off of the same principle as the Archimedes screw.

Advantageous over pulsatile pumps because of their valve free structure with continuous flow.

Axial pumps operate at higher RPMs (>8000) compared to centrifugal pumps at lower RPMs (>2000) which can potentially lead to clinical implications such as hemolysis.
Heartmate II®

- Most widely used ventricular assist device in the world, made of Titanium
- Limiting factor is the pump size because a pump “pocket” must be created for implantation
- Recommended for patients w/ BSA >1.3
- Delivers up to 12 liters flow
- Power sources: Battery/wall
- Battery support: 10-12hrs (pair)
- 4 hr recharge time (fully depleted batteries)
- Controller supplies 15 minutes emergency power (accidental power d/c)
- Controller displays speed/flow/power, records alarms/data-event recording
- Use: 2008-2014 (N: 17)
Clinical Screen

• Access to:
  - Setting adjustments
  - (Speed/alarm limits)
  - Alarm log file
  - Save/transfer data

• Displays:
  - Primary operating parameters
  - Information updated every second
  - Alarms color coded
    (red-high priority, yellow-low priority)
LONG TERM VAD Support: Pneumatic (Pulsatile) Pumps - Berlin Heart®

- First generation of ventricular assist devices
- Pneumatic driver (compressor) / Hand pump
- Diaphragm separates the blood/air chamber
- Tri-leaflet polyurethane valves (unidirectional flow)
- Multi cannula: Atria/ Apex/ Arterial (diameter 5mm -12mm)
- Multi size: 10, 15, 25, 30, 50, 60mls
- Use: 9/2005- present
- (N: 55)
Driver (IKUS®)-Pump Console

- A sturdy mobile driving unit called the IKUS controls the Berlin pump
- Houses compressors (3) and pressure/suction regulators
- Displays information about the pump parameters
- Access for pump setting adjustments (Password protected)
- Computer logs alarms
- 30 minute battery supply (hours of service)
- Alert every 10 minutes (when on battery)
- Power display/hours of service
- Hand pump (loss of power)
- Weight: 219 pounds
Long Term VAD Support: Pneumatic (Pulsatile) Pumps: SynCardia® Total Artificial Heart (TAH)  
Size limitation: (10cm AP measured at T10; Pump size: 50mls / 70-mls)  

No Rhythm (Complete Caridectomy)  

Pneumatic driver (C2 or Freedom driver-pulsatile)  

Powered by Wall adaptor/ battery/ hand-pump  

Made of Polyurethane, 4 Mechanical valves (25mm)  

Use: 5/2011 - present  

(N: 2)
SynCardia® TAH System

Implantable TAH

Drivelines

External Driver

<table>
<thead>
<tr>
<th>70cc TAH</th>
<th>50cc TAH</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 ml</td>
<td>270 ml</td>
</tr>
</tbody>
</table>
What we have learned...

VAD Operating Characteristics

- **Preload**
  - Conditions that may lead to a decrease in preload:
    - Compromised right ventricular volume (e.g. RVF, Tamponade)
    - Low intravascular volume
    - Increase in pump speed (a volume/speed mismatch)
    - Increased ventilator settings (Peep, PS)
  - A reduction in preload may lead to:
    - Reduced VAD Flow (Cardiac Output)
    - Suction condition (Chamber Collapse)

- **Afterload**
  - Conditions that may lead to an increase (or high) afterload:
    - Increased system vascular resistance, kink outflow graph
    - Increased pump speed
  - A high afterload may lead to:
    - Retrograde flow/flow stagnation (increased risk of pump thrombosis)
    - Reduced VAD flow (Cardiac Output)
<table>
<thead>
<tr>
<th>Protocol Tests</th>
<th>Result/Range/Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>PT-INR (Coumadin)</td>
<td>HeartWare/Jarvik: 2-3 (often 2.5-3) Berlin/TAH : 2.5-3.5</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>PTT</td>
<td>60-80 (VAD- Heparin- varies with patient)</td>
</tr>
<tr>
<td>PTT Hepzyme</td>
<td>70-80 (VAD- BiVAL- varies with patient)</td>
</tr>
<tr>
<td>ACT</td>
<td>180-200 (ECMO)</td>
</tr>
<tr>
<td>DIC panel</td>
<td>Daily (if on BiVAL) → Monday/Thursday</td>
</tr>
<tr>
<td>ECMO panel</td>
<td>Daily (if on Heparin) → Monday/Thursday</td>
</tr>
<tr>
<td>Fibrinogen**</td>
<td>Increases w/ inflammation</td>
</tr>
<tr>
<td>D- Dimer **</td>
<td>Increase as fibrin formation</td>
</tr>
<tr>
<td>Anti-Thrombin**</td>
<td>Treat when &lt;100</td>
</tr>
<tr>
<td>Heparin</td>
<td>0.3-0.5 units/mL (Berlin, TAH)</td>
</tr>
<tr>
<td></td>
<td>0.2-0.4 (HeartWare)</td>
</tr>
<tr>
<td>LDH, Plasma Hgb, U/A for blood</td>
<td>Daily daily when assessing for hemolysis</td>
</tr>
<tr>
<td>LDH Isoenzymes **(Misc Labs in EPIC- send out)</td>
<td>When LDH &gt;1000</td>
</tr>
<tr>
<td>ECHO</td>
<td>Monthly (VAD optimization, inflow cannula, AI, AV opening)</td>
</tr>
<tr>
<td>CXR</td>
<td>Daily→monthly (Effusion, pneumothorax, pump placement)</td>
</tr>
<tr>
<td>VS</td>
<td>Per unit policy: DOPPLER BP STANDARD OF CARE on continuous flow VAD’s (70-80mmHg)</td>
</tr>
</tbody>
</table>
TCH VAD program approach ~ Benefits of Extended VAD Support

- Nutritional Optimization (BSA growth)
- Stability of home, care system-support system
- Medication/care/clinic compliance
- Better Transplant Candidacy

Pre VAD

1 Year Post VAD support
Potential Complications associated w/ VAD therapy…

• Driveline infections

• Device Malfunction, driveline integrity

• Gastrointestinal bleeding (AVM’s) rare in younger pts

• Epistaxis

• Thromboembolic events (Improvement w/ BiVAL)

• Renal failure

• Psychosocial issues and risk taking behaviors

• What’s new to help reduce associated complications…
Mechanical updates~ New Devices
Jarvik 2015® Pump (Axial flow)

Pumpkin Clinical Trial

Flow: 1 - 3.5 liters per minute (LPM)

Running Speed: 10,000 to 18,000 rpm

Power consumption: < 7 watts

Afterload sensitive

- Goal Doppler: 40-50mmHg (8-10kg)
- Goal Doppler: 50-60mmHg (10-20kg)

No Inflow
Jarvik 2015® Pump (Axial flow)

Used for >8kg and <30kg (Fits 6 kg)

Controller displays power /alarms

(no flow, speed adjusted with dial)

Power: 1 or 2 batteries (19.5hrs each)

Battery charge time 6 hrs

Use: 2018 – present (N: 4)

Jarvik supported-
see controller and batteries
System Components Overview

- Jarvik 2015 VAD
- Li-ion Battery Charger
- FlowMaker Controller
- Lithium-ion Battery
- Y Cable
- Li-ion Battery Cable
- Extension Cable

See IU475 §6 for further detail
Jarvik 2015 Performance (HQ curve)

Typical MAP (via arterial pressure line or doppler) = 60 mmHg
Typical CVP (via venous pressure line or estimated) = 10 mmHg
Pressure drop across VAD (outlet P – inlet P) = 60 – 10 = 50 mmHg
Pump speed = 16,000 rpm

See IU0475 §1 for further detail
Mechanical updates ~ New Devices

Heartmate III® (Centrifugal flow)

• Made of Titanium—Fully Magnetically Levitated
• Large pump gap-space designed to reduce blood trauma across rotor
• Artificial pulse (automatic speed ramp every 2 seconds by 2000rpm)
• Textured blood contacting surfaces (creates pseudo-neo-intima)
• Full support (2 – 10 L/min)
• Modular Driveline (replacement of portion if damaged)
• Pocket Controller displays 6 recent alarms, flow/speed/power/PI
• Battery supply 10-12 hrs/mobile power unit
• Requires BSA $\geq$ 1.2
System Components

14 V Li-Ion Batteries (Hmate II)

Universal Battery Charger (Hmate II)

Pocket Controller (NEW)

System Monitor (Hmate II)

Power Module (Hmate II)

Go Gear Wearable's (Hmate II)

Mobile Power Unit (NEW)

Modular Driveline (NEW)
TCH VAD program approach…

- VAD evaluation protocol checklist
- VAD training pre -> post implant
- Close the Pre-implant education loop with patient/families meeting (VAD Ambassadors)
- VAD Rounding list
- VAD D/C protocol
- Protocols: bleeding/stroke
- Community outreach post-implant
- 24hr VAD Call phone “HOT LINE”
- 3D CT pre-op “Virtual Fit”
HeartWare® Placement Techniques

• The standard Intra-pericardial placement often results in unfavorable inflow arrangement

• Infra-diaphragmatic placement decreases angle of inlet to septum

“Rectus Sparing Approach”

- Driveline is the Achilles’ Heel of implantable VAD’s
- Less developed abdominal wall muscles in sick children
- Reduce trauma to tunneling track
- Reduces postoperative pain/inflammation
- Assists in prevention of driveline infections
- Better “seeding” “ingrowth” of the driveline (anchored!)
TCH VAD approach~
Complicated Anatomy

Fontan ~ Single Ventricle
TCH VAD approach ~
Can a heart remodel / recover?

HeartWare® Recovery on Device to Explant!
TCH VAD program approach...individualized care

Some dressings/vad packs too big, some too small → find the size that works
TCH VAD program ~ Dedicated VAD Clinic

- Regimented Outpatient protocol
  - Labs
  - Doppler BP management
- Screening speed adjustment ECHO
  - RHC
- Cardiac CT
Community Integration - Outreach back to local area
Home discharge locations of current TCH VAD supported patients as of 4/2019
Patients return to home, school, celebrating family and life...
Camp Pump it Up….
(Letting kids be kids)
1st Annual TCH VAD Celebration Day 6/30/2018

Coming to 8/9/2019- 2nd Annual TCH SUPER-HERO VAD CELEBRATION DAY...save the date...details to come...
Key Points

- Pediatric patients can be implanted with CF adult devices
- Pediatric VAD patients have good outcomes and can be discharged home safely
- Children can return to school and travel with CF devices
- Pediatric VAD patients learn a “NEW NORMAL way of life”
- Pediatric MCS is entering a new era w/ a PARADYGM SHIFT
- Device related complications may increase w/ prolonged support
- Multi-Disciplinary approach is necessary for successful outcomes!
Challenges

Program development-financial support-education
Availability of technology
Sizing of device to fit child - inflow cannula placement
Timing of device implant, transitioning to adult program
Anatomic/Congenital challenges/Prior Surgery
Future Directions.....

✓ Smaller device “Miniaturized”

✓ “Water Proof”

✓ Longer battery supply

✓ Durable components

✓ Internal charging pad

✓ “Cordless” driveline

✓ “Pediatric friendly”
Future Developments

- Synergy (CicuLite)®
- Pedia Flow®
- Heart Assist 5®
- HeartWare® MVAD
Thank you!!

If I only had a “Heart” - VAD