Cincinnati Children's
Heart Institute



Pediatric Mechanical Circulatory Support (MCS)

Ivan Wilmot, MD

Heart Failure, Transplant, MCS

Assistant Professor

The Heart Institute

Cincinnati Children's Hospital Medical Center

The University of Cincinnati College of Medicine

Disclosures

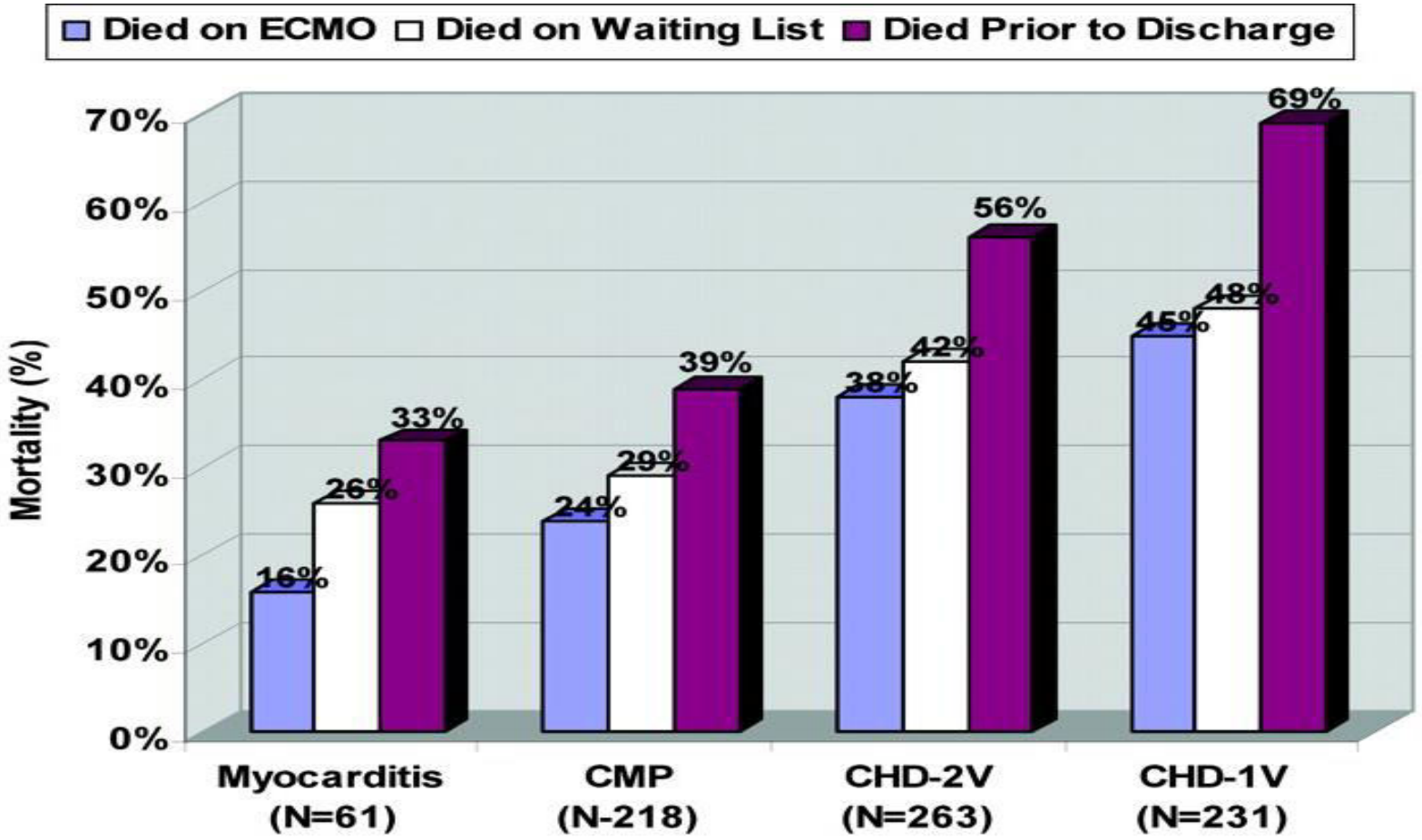
- None

- Off-label use of FDA approved adult devices will be discussed

Pediatric Heart Failure

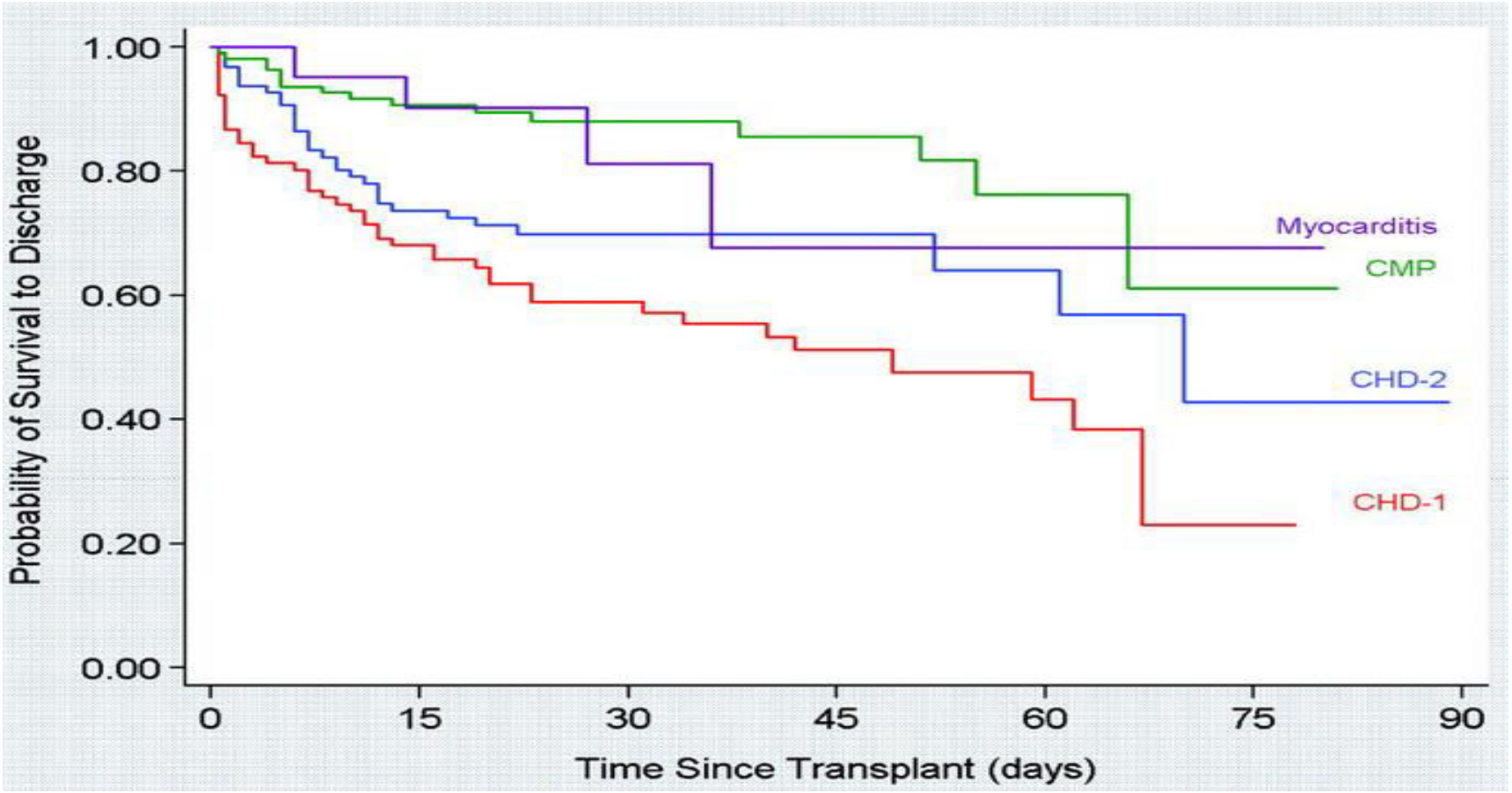
- Children with heart failure refractory to medical therapy have very limited therapeutic options
- Traditionally, such children were listed for heart transplantation with hopes to support them adequately to heart transplant
- Extracorporeal membranous oxygenation (ECMO), although used in the past as bridge to transplant (BTT), has been associated with poor outcomes

Survival on ECMO as bridge to transplant and to discharge (1994-2009)



Almond C S et al. Circulation 2011

Post transplant survival of patients bridged to transplant on ECMO



Almond C S et al. Circulation 2011

Pediatric Heart Failure

- In contrast to adults with HF, children with HF vary in size, anatomy (congenital heart disease), and total number.
- As the pediatric population living with HF expands, increasing demands on alternatives to ECMO have arisen.
- These factors pose significant technological and financial concerns on the development of alternative forms of Mechanical Circulatory Support (MCS) for children with HF.

MCS

- Mechanical Circulatory Support (MCS) is the use of a mechanical pump/s to support a weakened heart muscle.
  - Ventricular Assist Device (VAD) to assist a weakened ventricle
  - Total Artifical Heart (TAH) to replace biventricular failing heart

MCS

- Mechanical Circulatory Support (MCS) can be used in the following roles:
  - Bridge to Transplant (BTT)
  - Bridge to Recovery (BTR)
  - Bridge to Decision/Candidacy (BTD)
  - Chronic Therapy

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The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

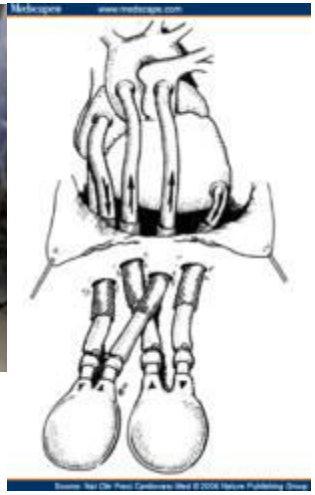
Prospective Trial of a Pediatric Ventricular Assist Device

Charles D. Fraser, Jr., M.D., Robert D.B. Jaquiss, M.D., David N. Rosenthal, M.D., Tilman Humpl, M.D., Ph.D., Charles E. Canter, M.D., Eugene H. Blackstone, M.D., David C. Naftel, Ph.D., Rebecca N. Ichord, M.D., Lisa Bomgaars, M.D., James S. Tweddell, M.D., M. Patricia Massicotte, M.D., Mark W. Turrentine, M.D., Gordon A. Cohen, M.D., Ph.D., Eric J. Devaney, M.D., F. Bennett Pearce, M.D., Kathleen E. Carberry, R.N., M.P.H., Robert Kroslowitz, B.S., and Christopher S. Almond, M.D., M.P.H., for the Berlin Heart Study Investigators

MCS

- The EXCOR Berlin Heart IDE FDA study from July, 2011 compared outcomes in both infants & toddlers (BSA < 0.7, cohort 1), and children (BSA 0.7-1.5, cohort 2) managed on
  - ECMO vs. VAD

EXCOR Berlin Heart



- Uni - or Bi- Ventricular Support
- Longest application > 1000 days
- Wide selection of blood pumps and cannulas
- Specially designed small pumps and cannulas for infants and children
- Easy visual inspection of the blood pumps (pump performance and/or deposit formation)
- Paracorporeal design allows for ease of exchange due to upsize or thrombus

EXCOR Berlin Heart

EXCOR® Device Description

Paracorporeal ventricular assist device (VAD)

10 ml 25 ml 30 ml 50 ml 60 ml

Atrial Apical Arterial

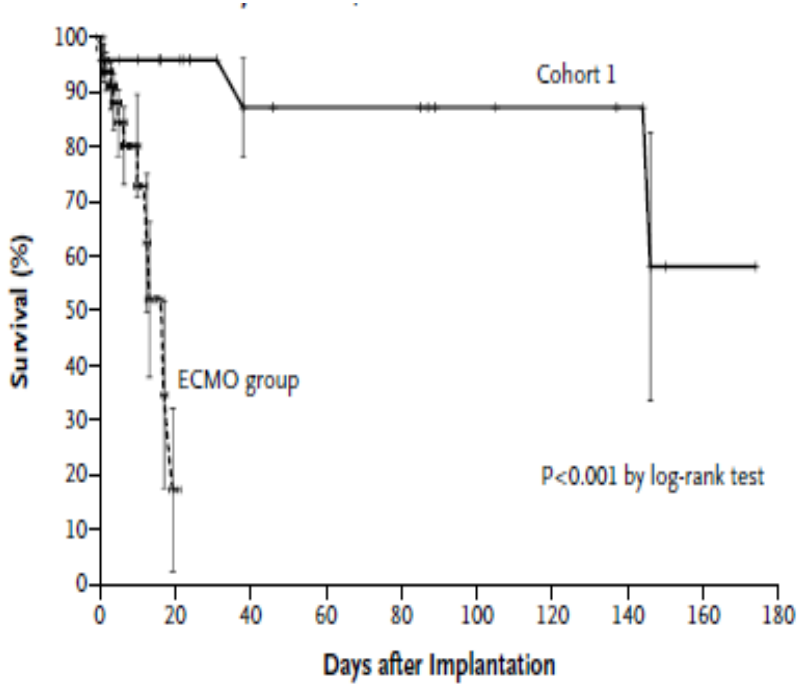
IKUS® driving unit

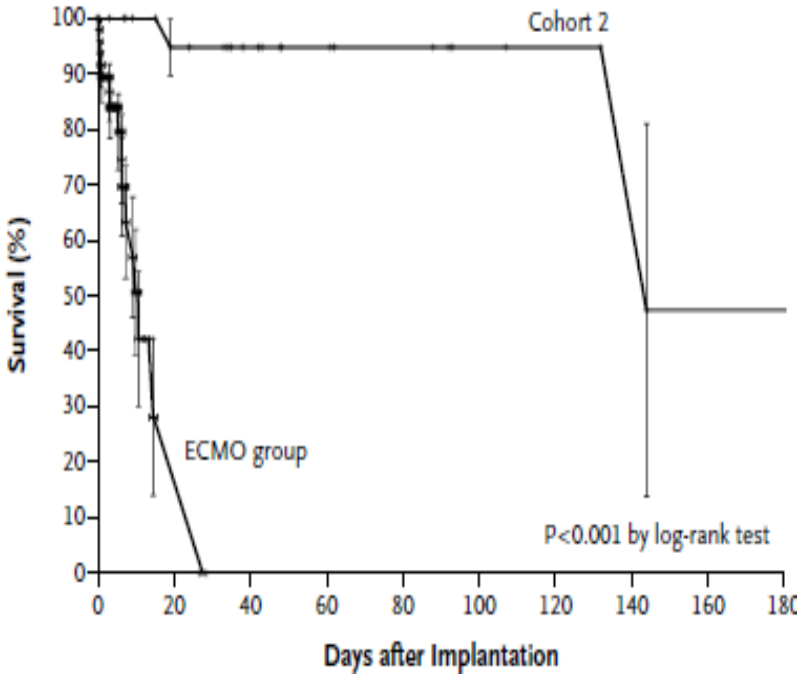
EXCOR Berlin Heart


IKUS® driving unit

- EXCOR® Ikus Driving Unit
  - Electro pneumatic driving unit
  - Suitable for all EXCOR® blood pumps
  - Uni- and biventricular operation
  - Battery back-up
  - Hand pump provided for emergency use
  - Various operating modes for BVAD support

EXCOR Berlin Heart IDE Outcomes





Fraser et al NEJM 2012

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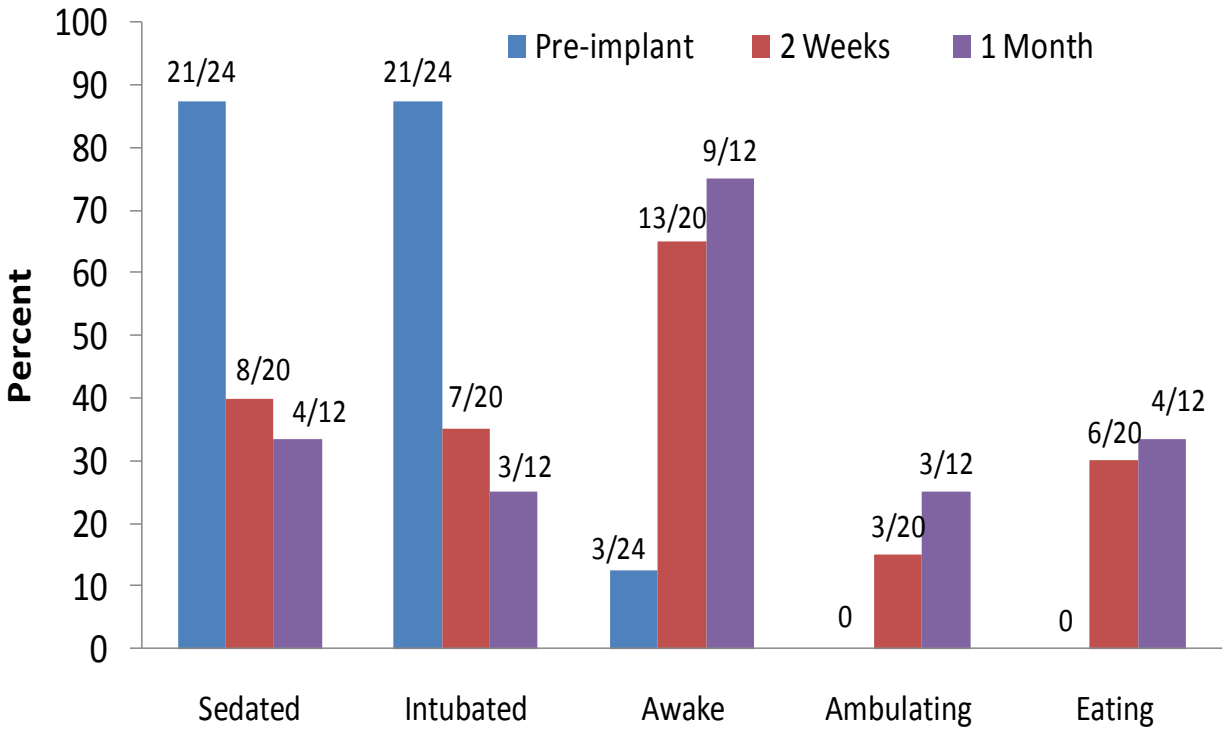
EXCOR Berlin Heart IDE Outcomes

Trial Results: Cohort 1 Patient Status

Berlin Heart®



Note: median age of this cohort is 12 months

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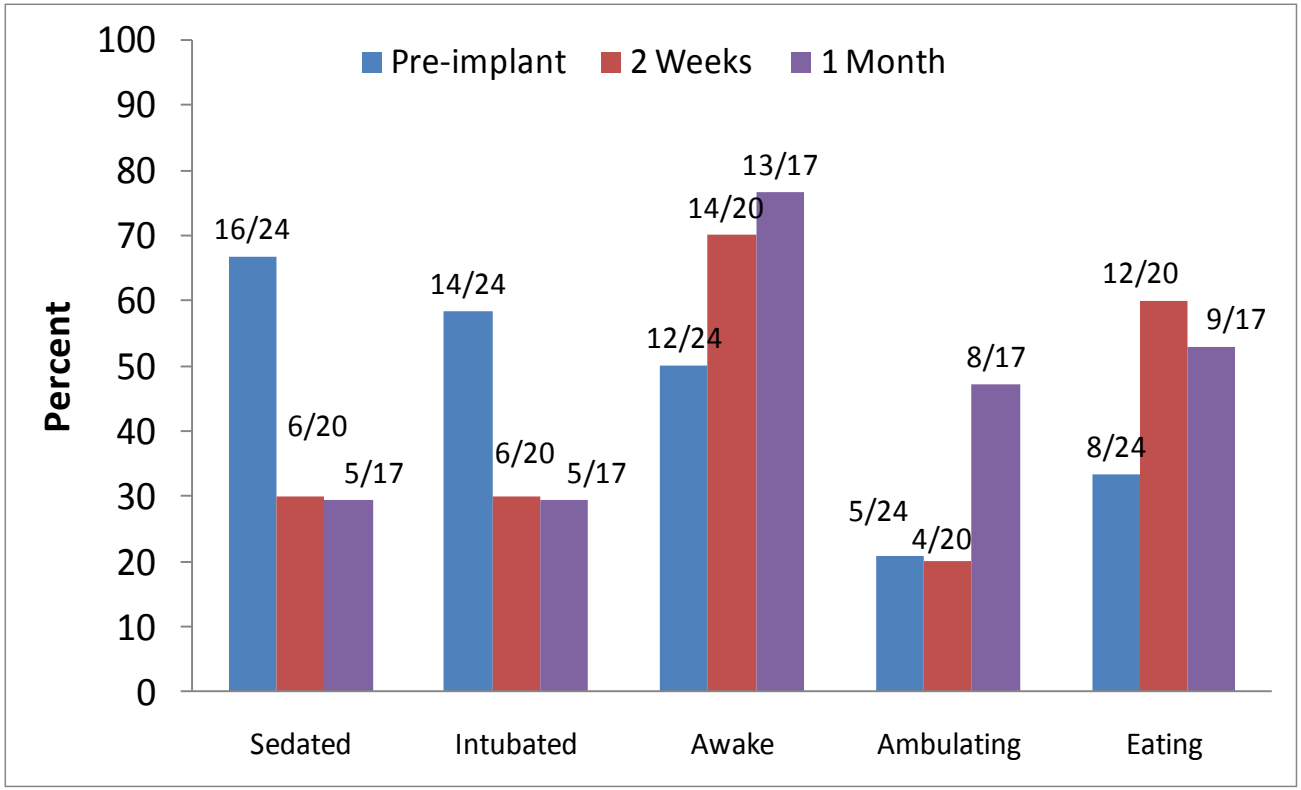
EXCOR Berlin Heart IDE Outcomes

Trial Results: Cohort 2 Patient Status

Berlin Heart®



MCS

- EXCOR Berlin Heart IDE study led to FDA approval of the device in U.S.A. on December 16, 2011
- Although this study showed a significant mortality benefit, significant morbidity remained
  - Bleeding 44%
  - Stroke 29%

MCS

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Journal of Cardiac Failure Vol. 17 No. 6 2011

Effectiveness of Mechanical Circulatory Support in Children With Acute Fulminant and Persistent Myocarditis

IVAN WILMOT, MD,[1] DAVID L. S. MORALES, MD,[2] JACK F. PRICE, MD,[1] JOSEPH W. ROSSANO, MD,[1] JEFFREY J. KIM, MD,[1] JAMIE A. DECKER, MD,[1] MARY CLAIRE MCGARRY, CCP, RRT, BS, LP,[2] SUSAN W. DENFIELD, MD, FACC,[1] WILLIAM J. DREYER, MD, FACC,[1] JEFFREY A. TOWBIN, MD,[1,3] AND JOHN L. JEFFERIES, MD, MPH, FACC[1,3]

Houston, Texas

ABSTRACT

Background: Acute fulminant myocarditis is a life-threatening disease in children. A limited number of reports suggest that mechanical circulatory support (MCS) may be used to successfully bridge children with acute fulminant myocarditis to recovery or transplantation. We evaluated the effectiveness of MCS in children with myocarditis and identified risk factors associated with adverse outcomes.

Methods and Results: Between 2001 and 2009, 16 children were treated for myocarditis at our institution; each child received MCS provided by extracorporeal membrane oxygenation, ventricular assist device(s), or both. Of these patients, 75% (12/16) survived: 7 recovered ventricular function, and 5 underwent successful orthotopic heart transplantation. In patients who were bridged to recovery, mean left ventricular ejection fraction significantly improved from initiation to termination of MCS (20 ± 9.3% to 62 ± 5%; $P = .0004$). Viral pathogens were detected in 11 patients by polymerase chain reaction, and viral presence was associated with death or need for transplantation ($P = .011$). Upon histologic analysis, absence of viral infection and lack of myocardial inflammation were associated with recovery (P values .011 and .044, respectively).

Conclusions: In children with acute fulminant and persistent myocarditis, MCS is a life-saving treatment strategy, particularly in the absence of viral infection. (*J Cardiac Fail 2011;17:487–494*)

Key Words: Carditis, children, heart assist devices, extracorporeal membrane oxygenation.

MCS

- This retrospective study evaluated MCS in the management of patients with acute fulminant myocarditis and persistent myocarditis from 1995 to 2009 at Texas Children's Hospital, Houston, TX
- MCS included ECMO and/or VAD
- Primary outcome measures: Bridge to recovery (BTR), Bridge to transplant (BTT), or death

Wilmot et al. J Car Fail. 2011

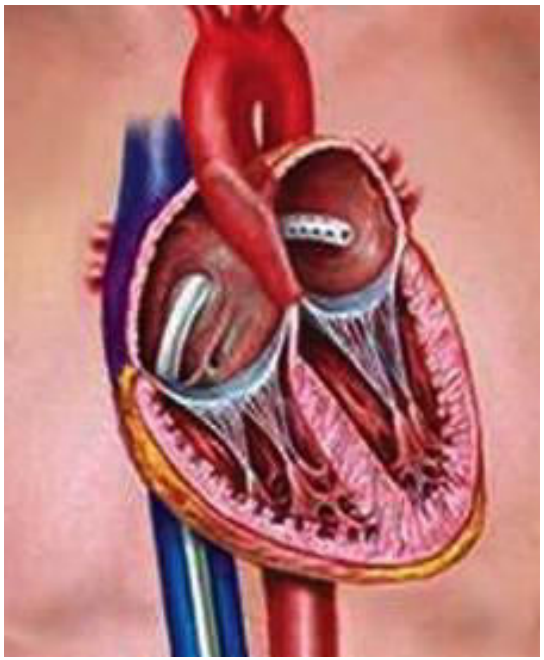
MCS

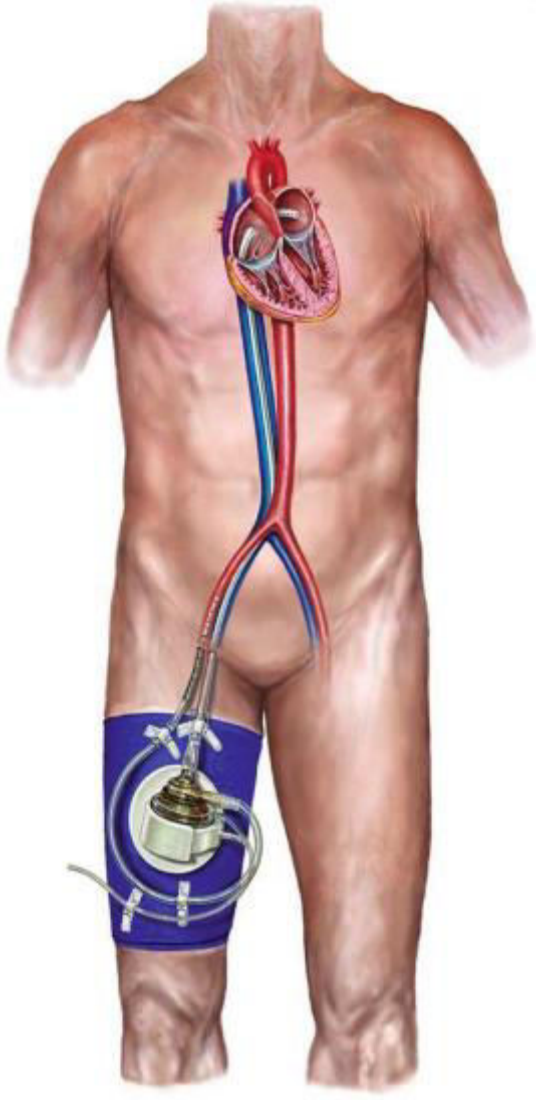
- Details of MCS
  - Temporary mechanical circulatory support was provided using: ECMO or short-term VAD
  - Short-term VADs: BioMedicus Biopump®, Rotoflow®, Tandem Heart®
  - Long-term VADs: MicroMed DeBakey VAD Child, Thoratec VAD, HeartMate II LVAD

Wilmot et al. J Car Fail. 2011

TandemHeart®

Percutaneous placed
short-term LVAD





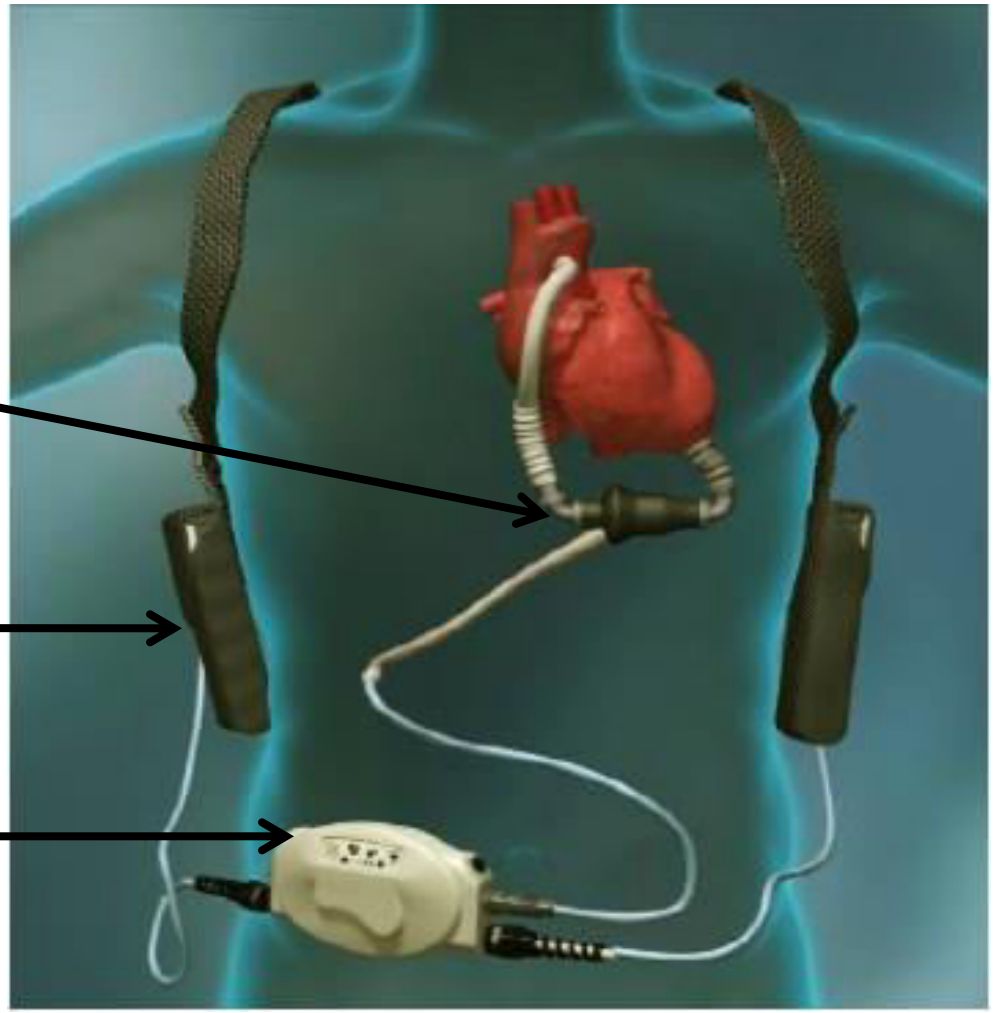
Courtesy of Cardiac Assist Inc, Pittsburg, PA

HeartMate II LVAD

Surgically placed long-term LVAD

Battery pack

External console



Courtesy of Thoratec Corp., Pleasanton, CA

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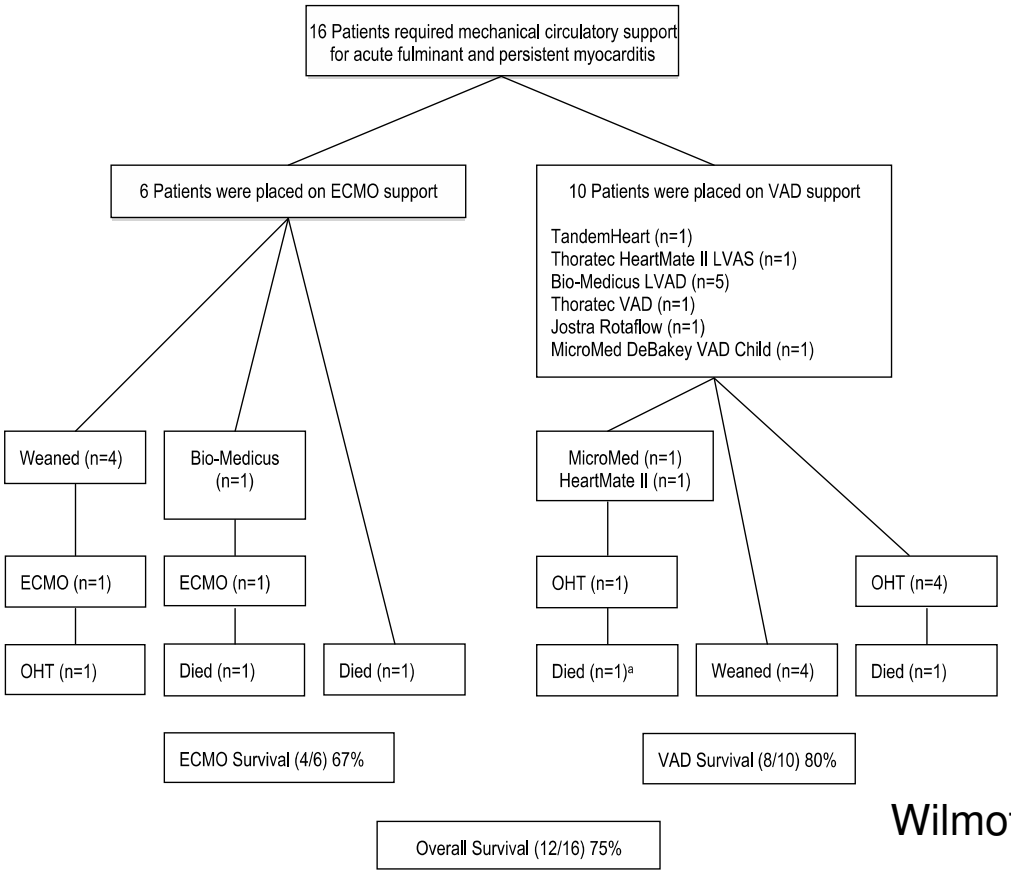
MCS in Children with Myocarditis Outcomes



Wilmot et al. J Car Fail. 2011

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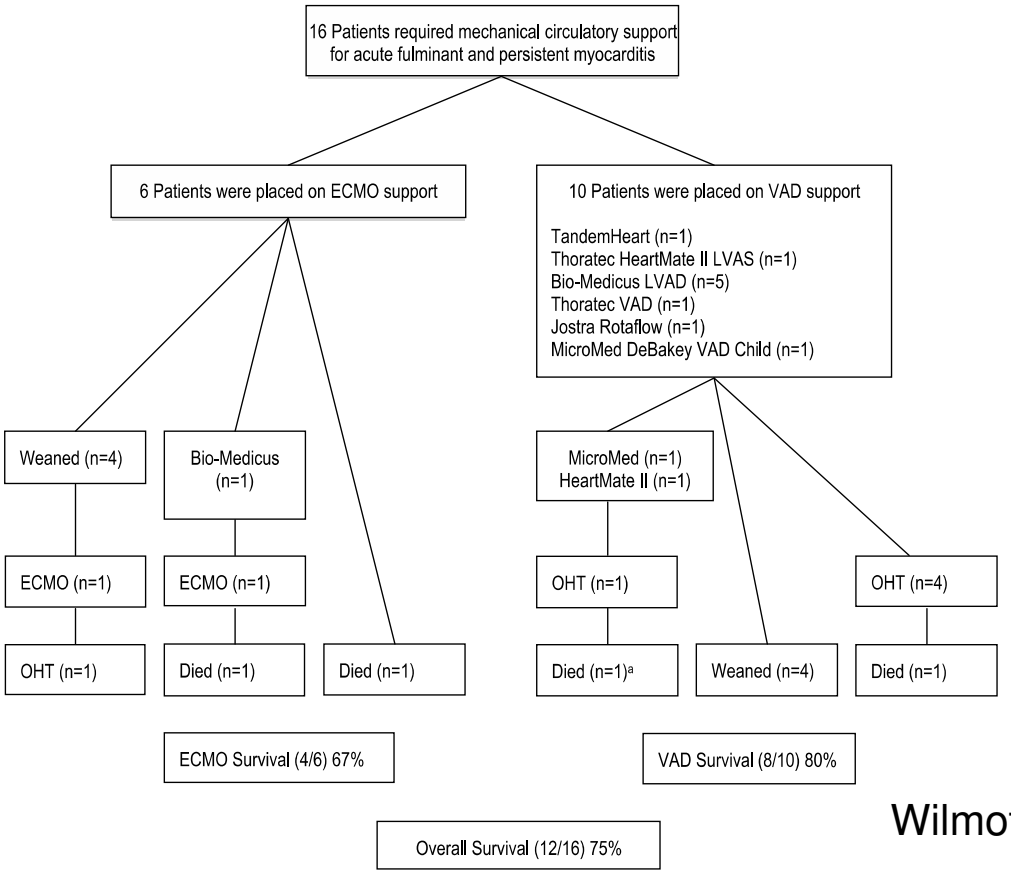
MCS in Children with Myocarditis Outcomes



44% BTR

67% ECMO Survival

80% VAD Survival

Wilmot et al. J Car Fail. 2011

MCS

- Increasing literature reports show promising VAD results in the pediatric HF population.
- In the setting of limited heart transplant donors, and increasing numbers of children with HF, many centers are utilizing VAD's as a bridge to transplant (BTT).

Chen et al. Eur J Cardiothorac Surg 2005
Lorts et al. Curr Opin Organ Transplant 2015

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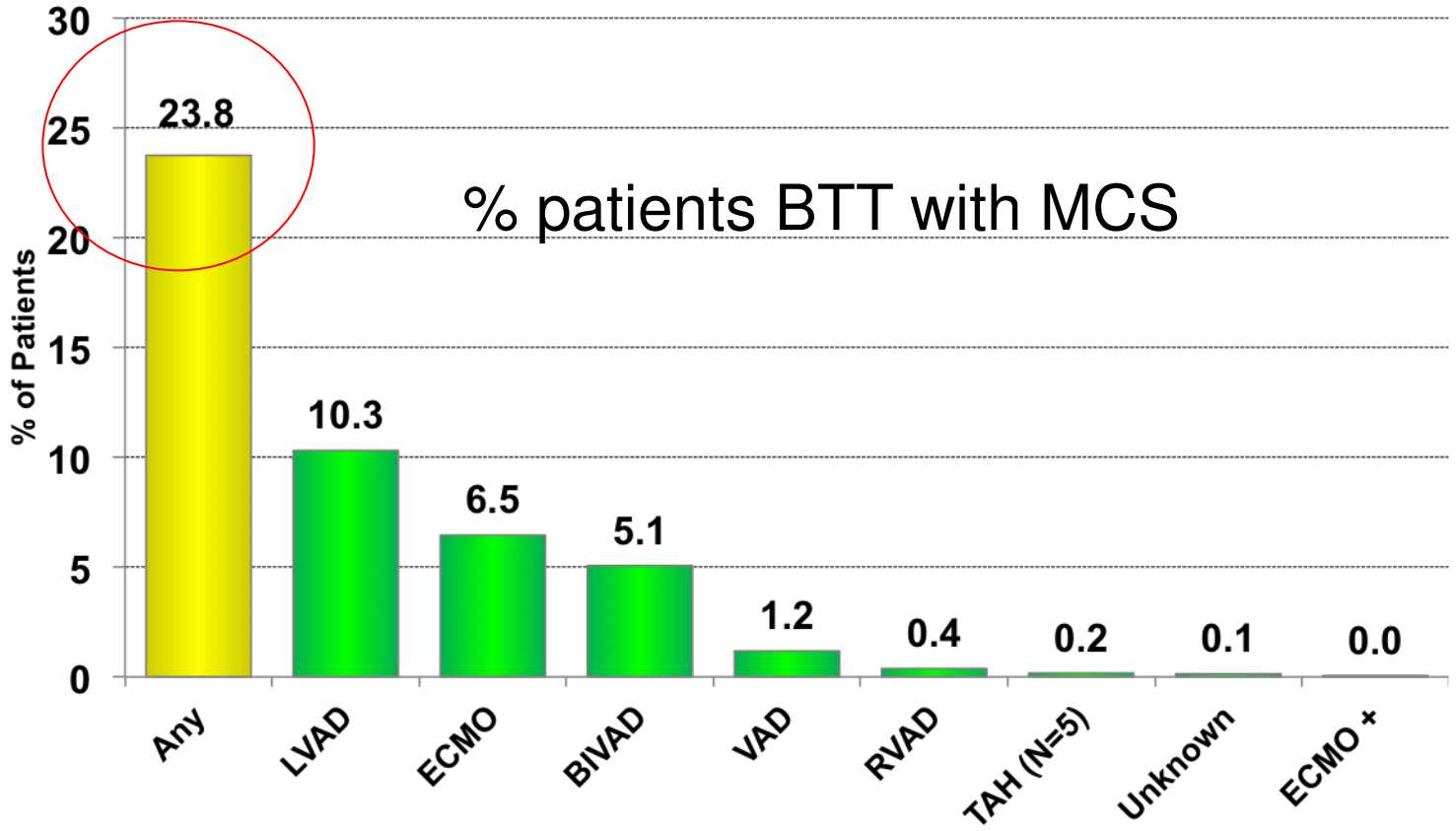
Increased Number of Participating Centers in PediMACS

Blume et al-AHA 2014

ISHLT BTT with MCS (2004-2013)



ISHLT. 2013

MCS

- With the increased utilization of MCS in the pediatric HF population, the ISHLT recently released updated Guidelines for the Management of Pediatric HF in 2014.
- These guidelines include MCS use in the pediatric HF population including indications for MCS, patient selection, timing of implant, device selection, and recommendations.

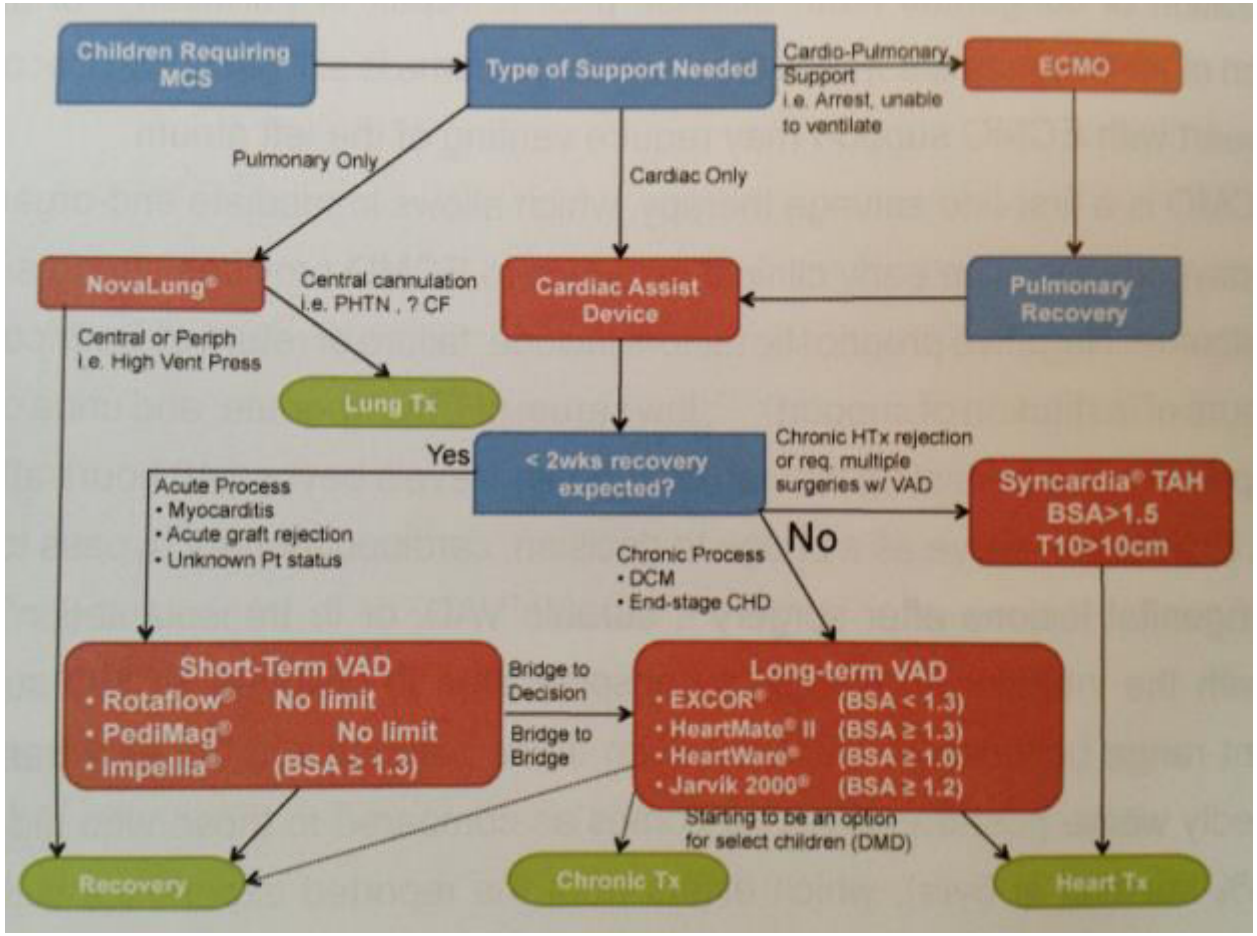
ISHLT Guidelines for the Management of Pediatric Heart Failure, 2014

MCS

- MCS is reserved for children with acute life-threatening cardiovascular events or severe HF symptoms despite maximal medical therapy.
- MCS should be considered if a child requires inotropic infusions to maintain cardiovascular stability and other organ systems begin to be compromised.

ISHLT Guidelines for Management of Pediatric Heart Failure, 2014

ISHLT Guidelines Pediatric MCS Protocol



ISHLT Guidelines for the Management of Pediatric Heart Failure, 2014

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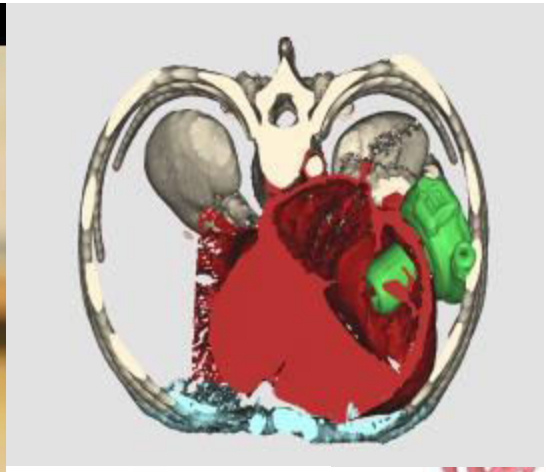
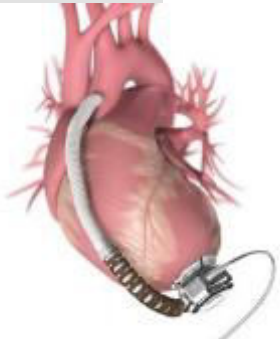
Special Pediatric MCS Considerations

- An increased interest in *chronic therapy* for pediatric patients
  - Muscular dystrophy
  - Cancer patients post chemotherapy
  - Patients with contraindications to transplant (elevated pulmonary vascular resistance)

MCS

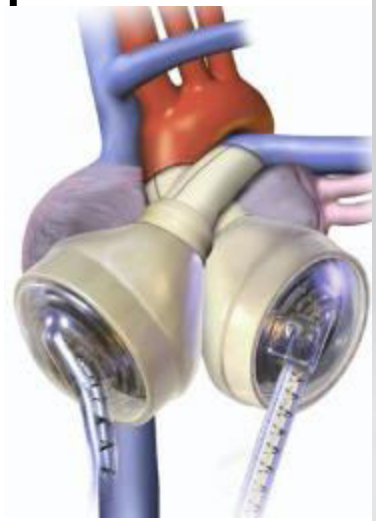
- DMD patient implanted with HeartWare LVAD

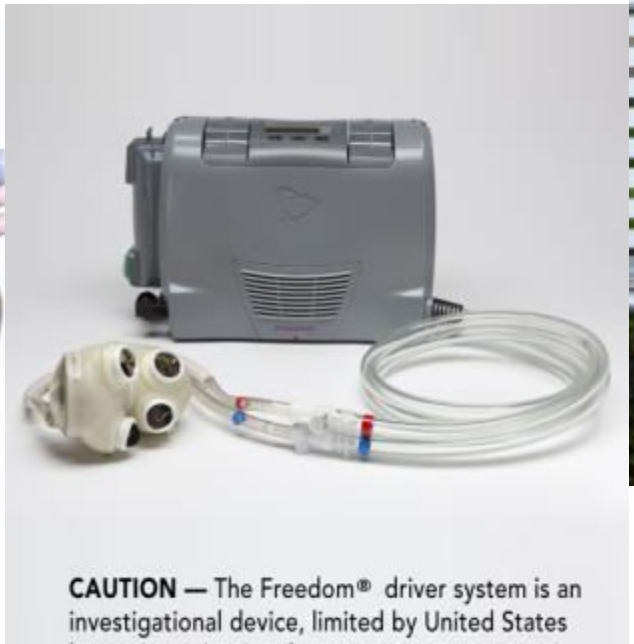




MCS

-Transplant patient with chronic rejection and subsequent Syncardia TAH placement as BTT





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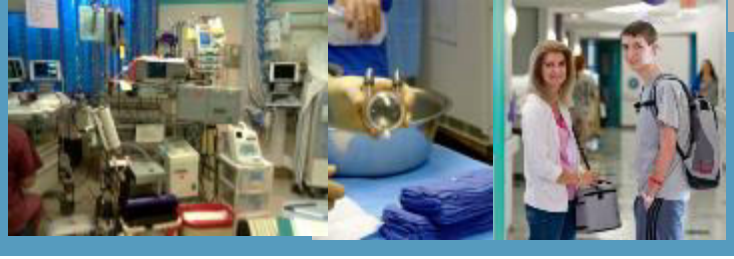

Conclusions

- Although children with HF refractory to medical therapy have limited options, recent advances in MCS can provide superior outcomes when used as a bridge to transplant (BTT).
- The Berlin Heart EXCOR VAD provide a MCS option for both infants and children, however morbidity concerns remain.
- MCS can be used successfully as a bridge to transplant (BTT), bridge to recovery (BTR), and bridge to decision (BTD).

Conclusions

- 2014 ISHLT Guidelines for the Management of Pediatric HF include indications for MCS, patient selection, timing of implant, device selection, and recommendations.
- There is an increasing interest in MCS as a chronic therapy in pediatrics.
- The future of MCS in children appears promising with increasing options available in this vulnerable population

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Cincinnati Children's
Heart Institute

Thank You