

The Clinical Context for Utilization of MCS in Children

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Overview

- Spectrum of Support Goals
- Types of Devices
- Diverse Clinical Scenarios
 - Pre-device
 - On device
 - Post-device (generally also post-transplant)
- Implications for Assessment techniques and timing



MCS is New for Children

- ECMO used for first time in children in 1974
- Berlin Heart EXCOR currently in IDE trial
- DeBakey Child VAD approved by FDA in 2004
- Thoratec pVAD used sporadically
- Overall utilization data still skimpy
- Use of MCS for bridge-to-transplant has been uncommon until recently
 - From 1993-2003 in US: 2000 pediatric OHT with 99 episodes of MCS (i.e. 10 per year, 5% of transplants)
 - More recently, 20%+ of transplants, with 60+ episodes per year



Support Goals

- Bridge to decision
 - Includes bridge to rehabilitation of end-organs and bridge to better understanding
- Bridge to (anticipated) recovery
 - Myocarditis
 - Post-cardiotomy
- Bridge to transplantation

Not always 100% clear at time of implant

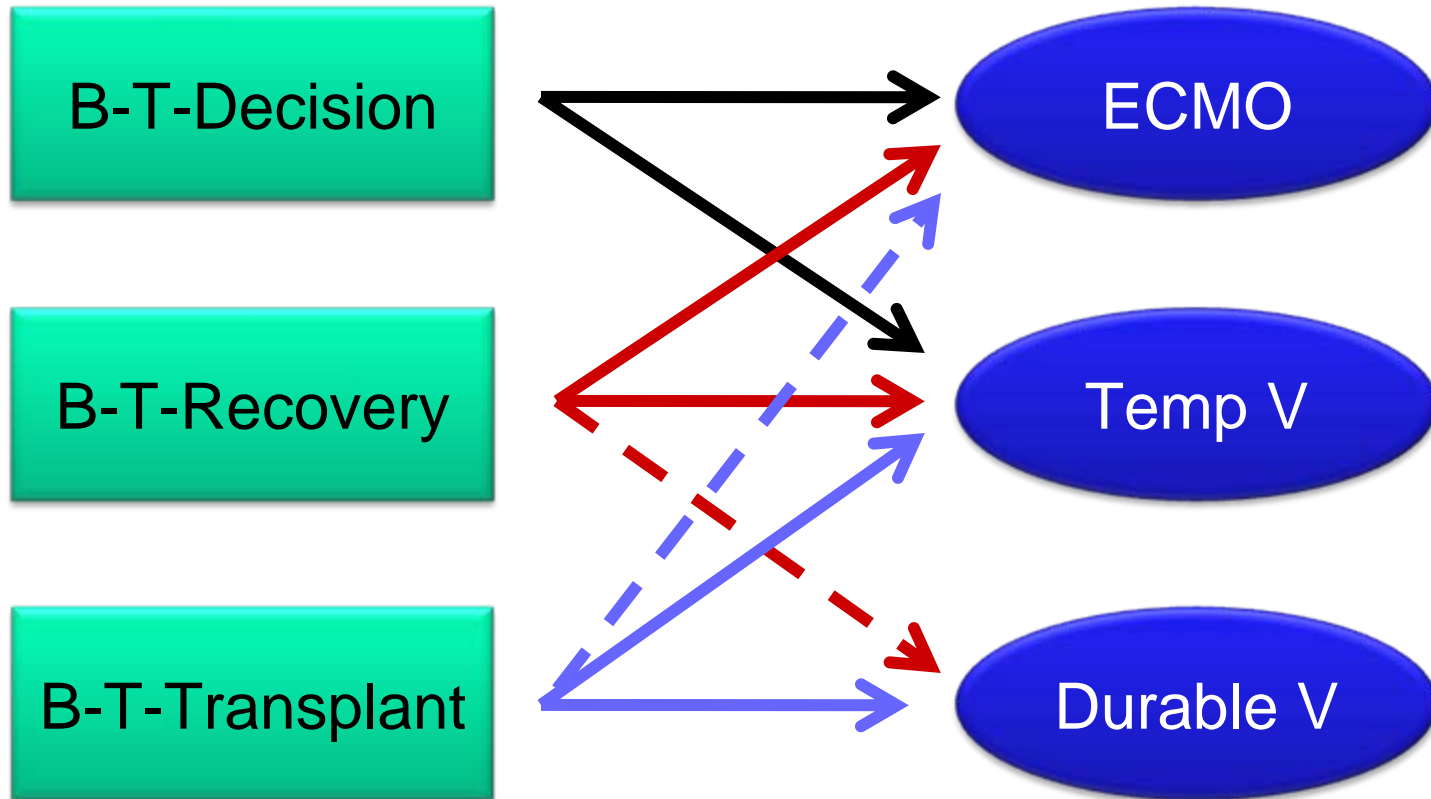


General Forms of MCS Support

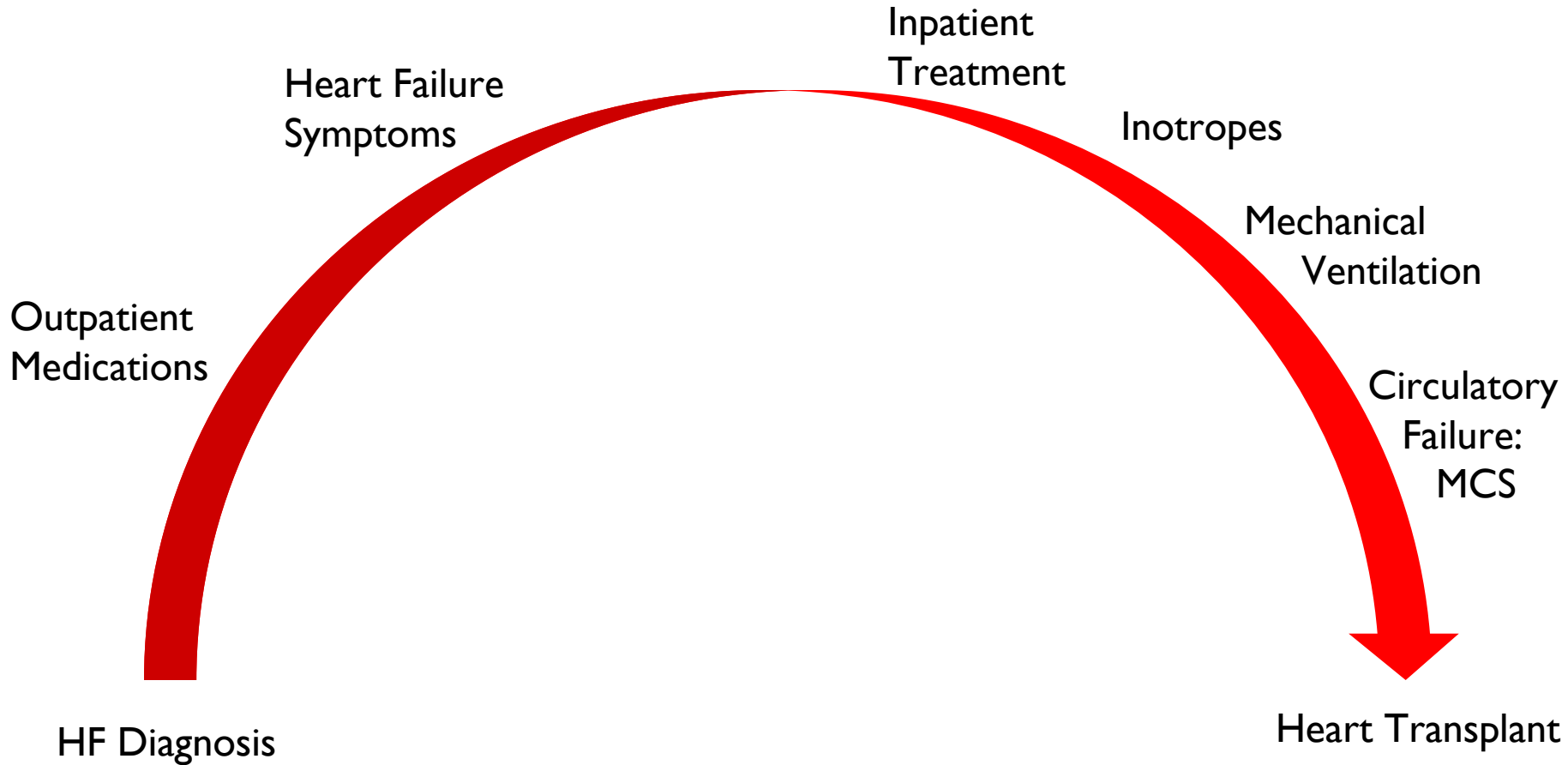
- ECMO
- Temporary MCS
 - Biomedicus
 - Levitronix
 - Rotaflow
- Durable MCS
 - Berlin EXCOR
 - Thoratec PVAD
 - Heartmate II
 - Abiomed



Relationship Between Device and Scenario



The Arc of Heart Failure



This is a series of events, not a timeline.



It's not really an arc....

Patient listed IA for OHT, on milrinone infusion, develops intractable VT and requires support urgently and “unexpectedly”

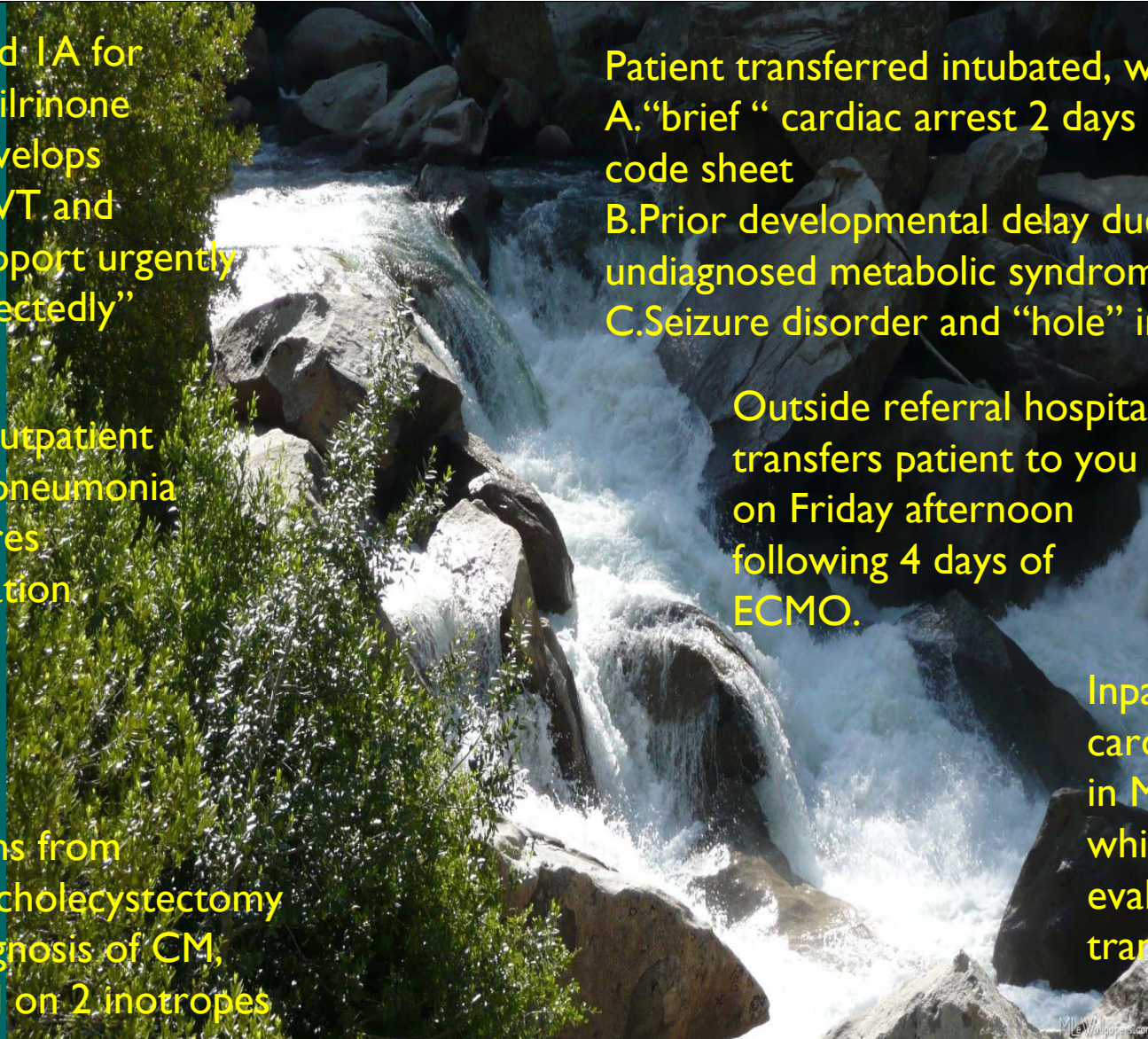
“Stable” outpatient develops pneumonia and requires hospitalization

Patient returns from laparoscopic cholecystectomy with new diagnosis of CM, intubated and on 2 inotropes

Patient transferred intubated, with history of
A. “brief “ cardiac arrest 2 days prior with no code sheet
B. Prior developmental delay due to undiagnosed metabolic syndrome
C. Seizure disorder and “hole” in brain

Outside referral hospital transfers patient to you on Friday afternoon following 4 days of ECMO.

Inpatient has cardiac arrest in MRI scanner while being evaluated for transplant



Clinical Events After Initiation of MCS

- Still messy sometimes
 - Possible hemodynamic instability in peri-operative period
 - Patient may have prolonged intubation, or may remain intubated until time of transplantation
 - Particularly likely for smaller patients
 - While intubated, events occur which suggest possible CNS injury
 - Hypertension
 - Seizures
 - Device debris and embolization
 - Periods of intense anticoagulation with non-CNS bleeding observed
- Other times, patients are awake, ambulatory and more easily assessed



Transplantation!

- End of on-device assessment
- Hopefully not end of patient assessment
- Additional confounders in evaluating device-associated adverse events
 - Perioperative events of transplantation
 - Anesthesia-related events
 - Cardiopulmonary bypass
 - Hemodynamic instability
 - CNS toxicity of
 - Steroids
 - Calcineurin inhibitors
 - Hypertension
 - All of which complicate later assessment



Timing of Baseline Assessment

- Neither too soon (i.e. before last adverse event)
- Nor too late (after patient is too unstable to be properly assessed)
- But disease progression and AE's are unpredictable....
- And we don't want to frequently repeat investigations such as CT...



Considerations for Baseline Assessment

- Process should be flexible
- Should gather information most relevant to sum of preceding events
- May need to be conducted 24/7
- May not be fully executed in everyone so each part should contribute independent information
- Will depend upon support goal and device selection



Assessment on Device

- Process should be flexible
- Should gather information most relevant to sum of preceding events
- May need to be conducted 24/7
 - Will have both predictable and unpredictable elements which vary with clinical situation
- May not be fully executed in everyone so each part should contribute independent information
- Will depend upon support goal and device selection



Assessment After Device Removal

- Needs immediate and delayed aspects
 - Confounders of acute illness vs. those of chronic disease
 - Additional or unrecognized injury vs. neurologic plasticity and recovery
- Must resist confounding effects of time
 - Shaddy Carvedilol trial
 - Everyone who survived improved on global scales
 - Likely due to effects of age-related developmental progress
 - Neuro-developmental and QOL tools need well-validated normative values across full age spectrum including transition pre/post 18 years of age
 - Should be selected with long-term follow-up in mind



Summary

- Components of Assessment
 - Developmental
 - Neurologic
 - Functional and Anatomic
 - Quality of Life
- Timing
 - Baseline (pre)
 - On Device
 - Post-device Removal
 - Long-term
 - Robust tools for varying ages
 - Plasticity of younger brain
 - Delayed recognition of static injury in developing child

