Translating Device and Mechanical Support Guidelines to ACHD Research

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Disclosures

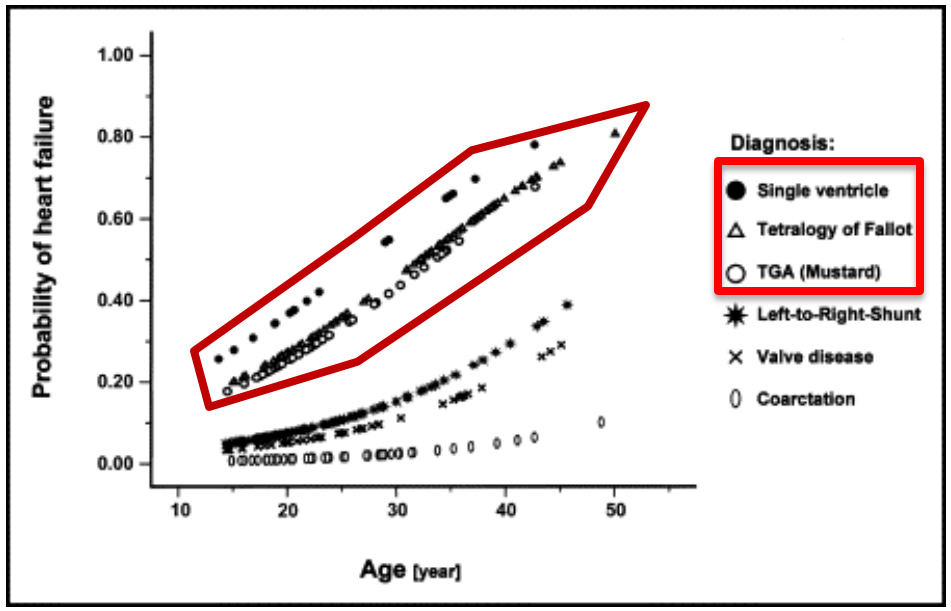
- No financial disclosures
- May discuss off-label or investigational devices

Objectives

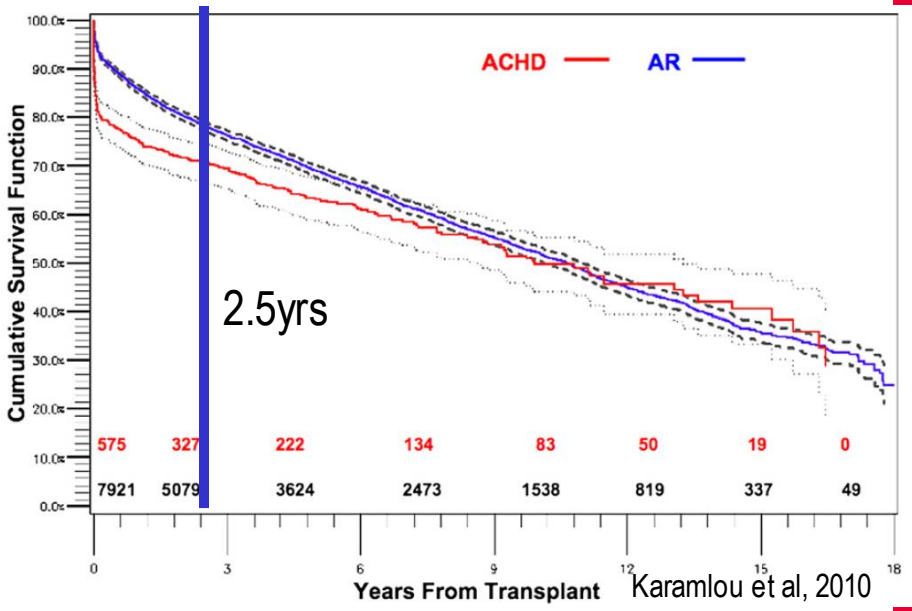
- Identify the ACHD populations that may benefit from mechanical device support
- Describe current MCS guidelines and application to ACHD patients
- Describe new mechanical circulatory support on the horizon

ACHD Patients May be Underserved by Devices

- ACHD comprises 3% of the HF population Burchill, 2016
  - 20% of ACHD may have HF requiring Tx Karamlou et al., 2010.
- 6.8% of heart Tx performed for ACHD Karamlou et al., 2010
  - 41% increase since 1998
  - Long-term tx outcomes are similar to non-ACHD
- ACHD patients wait longer for Tx and have higher wait-list mortality Ross et al., 2016
  - 152 days vs 119 days Davies et al, 2011
  - PRAs, Status 2, etc.
- Few ACHD patients on devices compared to others Everitt et al., 2011
  - 44% ICD vs 75%
  - 9% MCS vs 19%
- **Indicates potentially underserved device population**



Norozi et al., 2006



Karamlou et al, 2010

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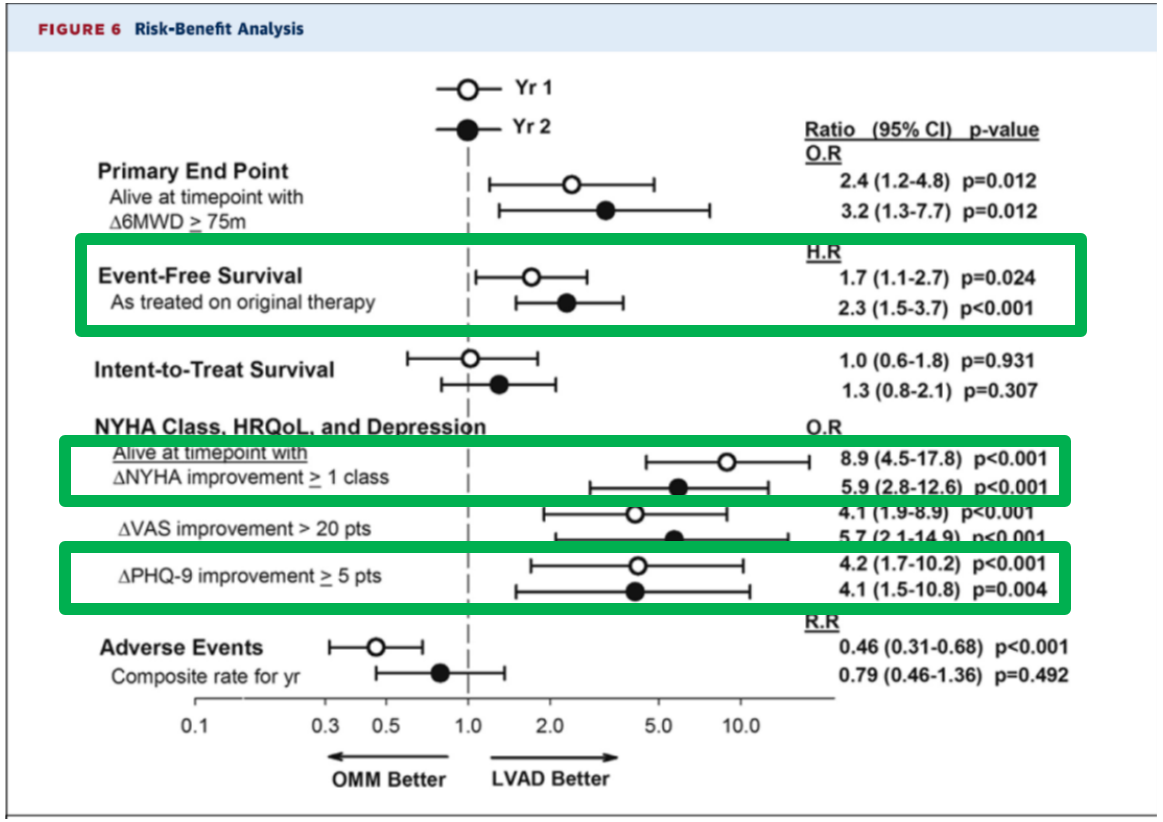
What can we learn from non-ACHD MCS?

- LVADs are beginning to overtake Optimal Medical Management
  - Better Event-free survival
  - Better improvement in QOL
  - Better improvement in NYHC



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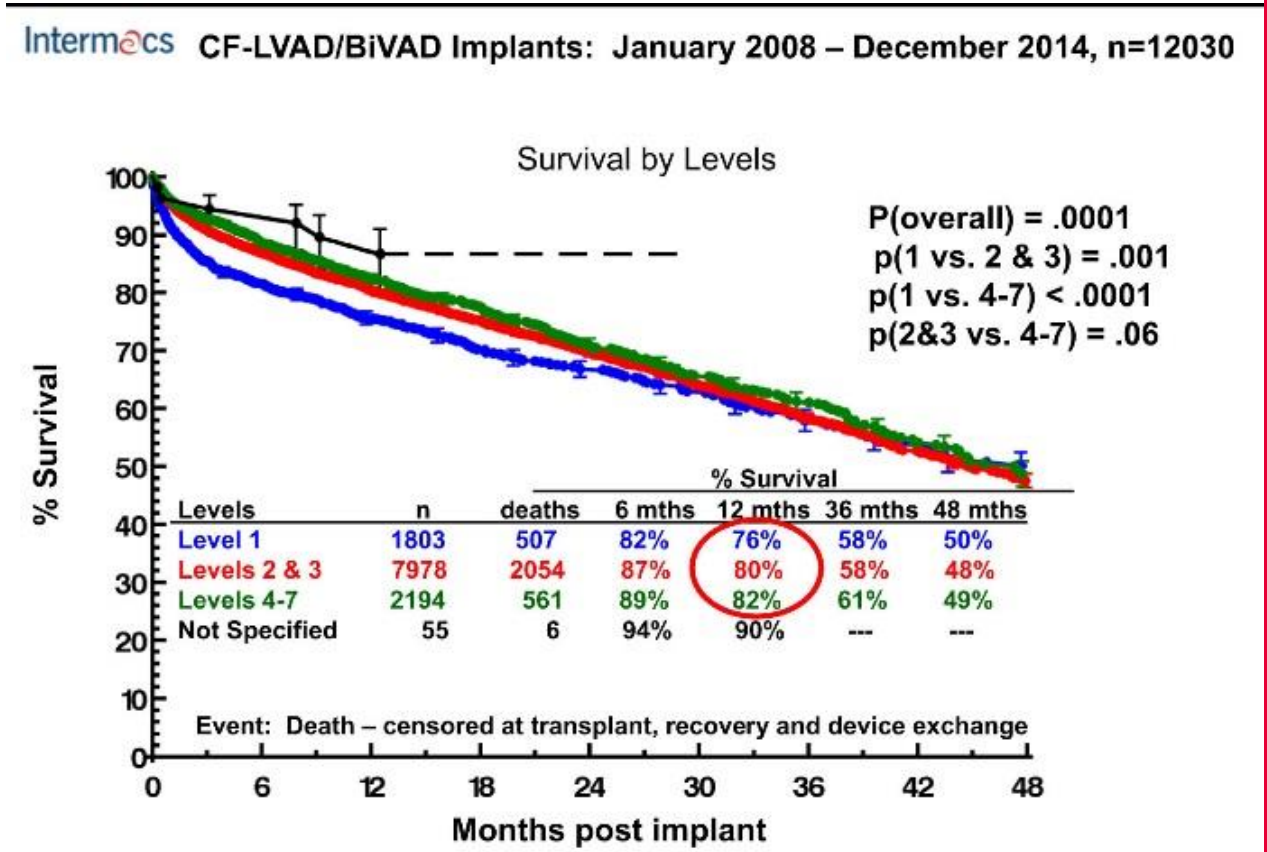
Starling et al., JACC: HF, 2017

What can we learn from non-ACHD MCS?

- Early LVADs tend to do better than late LVADs
  - 1—Critical cardiogenic shock
  - 2—Progressive decline
  - 3—Stable but inotrope-dependent
  - 4—Resting symptoms
  - 5—Exertion-intolerant
  - 6—Exertion-limited
  - 7—Advanced NYHA Class III



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Kirklin et al., JHLT, 2015

How to ACHD MCS Patients Differ from non-ACHD MCS Patients?

- Similar INTERMACS profiles
- Tend to be younger: 42 vs 57 years of age
- Very different MCS strategies
  - BTT instead of DT intention
  - TAH and biVAD usage was more than double in ACHD patients
- Higher rates of certain adverse events (~1.5-4xs)
  - Early and late renal dysfunction
  - Early and late hepatic dysfunction
  - Early and late respiratory failure
  - Late infection
  - **Very likely related to the incoming state of the patient**

Device Strategy (Pre-implant)	Primary Diagnosis	
	Congenital Heart Disease	Not Congenital Heart Disease
	N (%)	N (%)
BTT Listed	39 (51%)	3786 (29%)
BTT Likely	17 (22)	2819 (21%)
BTT Moderate	6 (8%)	1271 (10%)
BTT Unlikely	3 (4%)	411 (3%)
Destination Therapy	10 (13%)	4737 (36%)
BTR	1 (1%)	100 (1%)
Rescue Therapy	0 (0%)	76 (1%)
Other	0 (0%)	12 (0.1%)
Totals	76 (100%)	13,212 (100%)

Device Type	Primary Diagnosis	
	Congenital Heart Disease	Not Congenital Heart Disease
	N (%)	N (%)
LVAD	59 (78%)	12231 (93%)
BiVAD	9 (12%)	688 (5%)
TAH	8 (10%)	293 (2%)
Totals	76 (100%)	13212 (100%)

VanderPluym et al., JHLT, 2017

How have ACHD MCS Tx patients fared?

Table 2: Outcomes in the MCS and non-MCS groups

	Non-MCS, *n* = 1130	MCS, *n* = 83	OR	95% CI	*P*-value
Graft ischaemic time (min)	205.4 ± 70.5	221.3 ± 75.9			0.06
Cardiac reoperation	161 (14.3)	14 (16.9)	1.22	(0.67, 2.22)	0.51
Non-cardiac operation[a]	178 (15.8)	19 (22.9)	1.58	(0.93, 2.72)	0.09
Transfused	149 (16.2)	50 (60.2)	9.98	(6.22, 15.99)	<0.001
Chest tube > 2 weeks	54 (4.78)	7 (8.4)	1.83	(0.81, 4.17)	0.14
Post-transplant dialysis	174 (15.4)	17 (20.5)	1.41	(0.81, 2.47)	0.22
Pacemaker	23 (2.0)	4 (4.8)	2.43	(0.82, 7.22)	0.10
Stroke	26 (2.3)	1 (1.2)	0.52	(0.07, 3.86)	0.51
Post-transplant LOS	22.6 ± 30.6	30.6 ± 44.6			0.031
Mortality within 30 days	152 (13.5)	9 (10.8)	0.78	(0.38, 1.60)	0.62

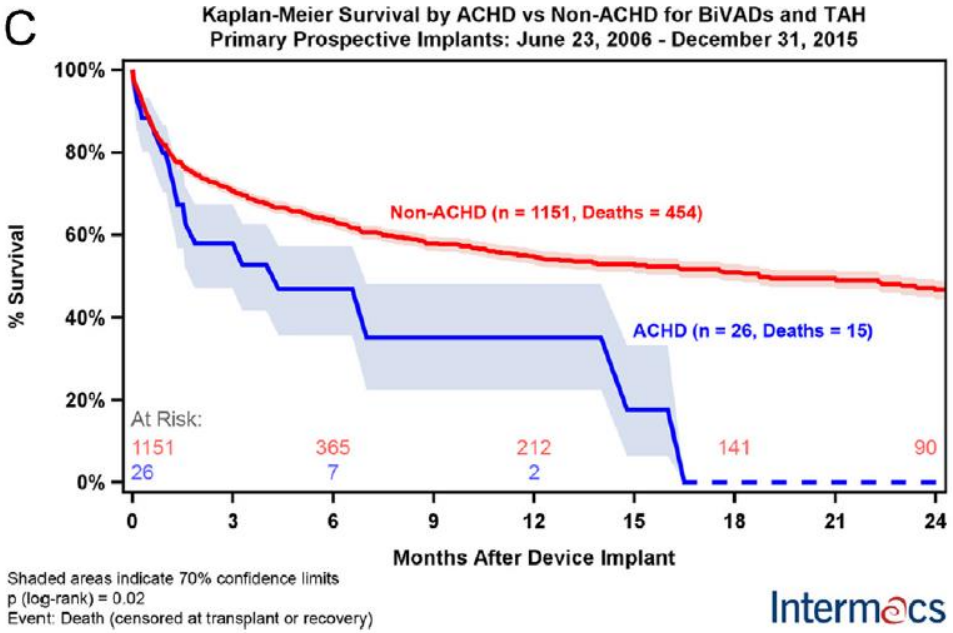
Values are listed as number (percentage) or mean ± SD, as appropriate. LOS = length of stay.
[a]Non-cardiac operation in the same transplant admission.

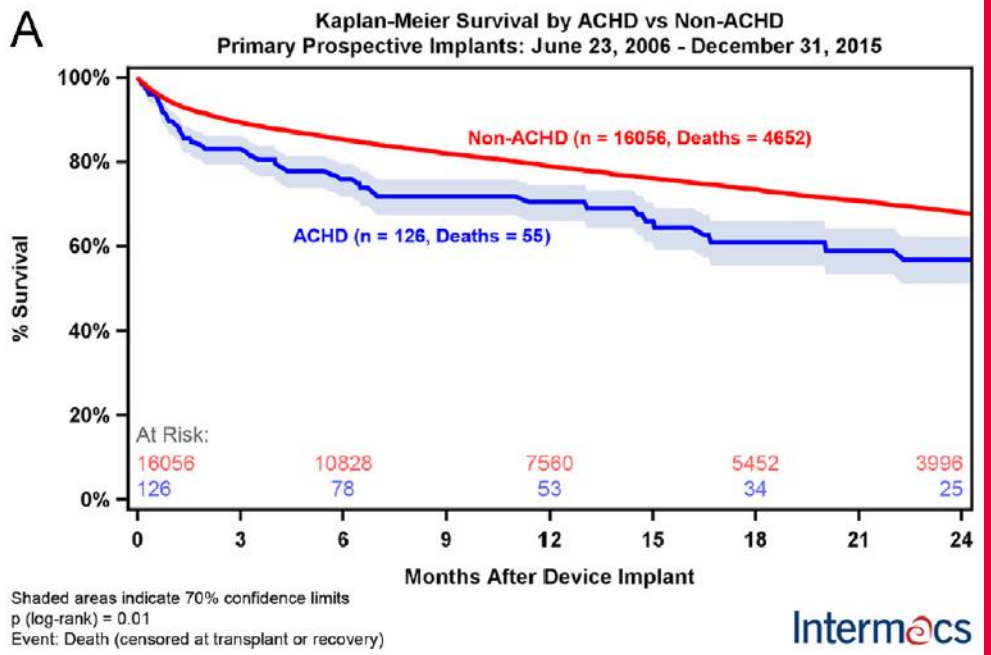
Maxwell et al., Eur J Cardiothorac Surg 2014

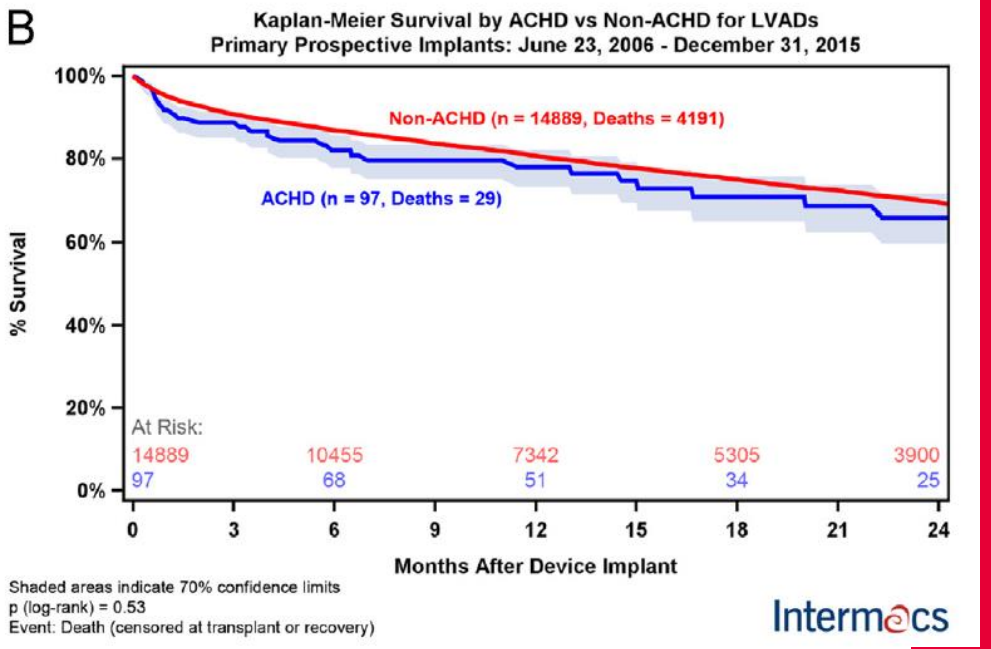
- 10x risk for bleeding
- Longer length of stay (~1 week)
- No difference in 30-day mortality

How have ACHD Patients Fared on MCS?

- Survival compared to non-ACHD patients has traditionally been lower overall
  - LVAD results are equal
  - BiVAD/TAH are the primary source of differences
    - Higher INTERMACS levels at implant
    - More renal and pulmonary dysfunction at implant
    - “Last Resort”?



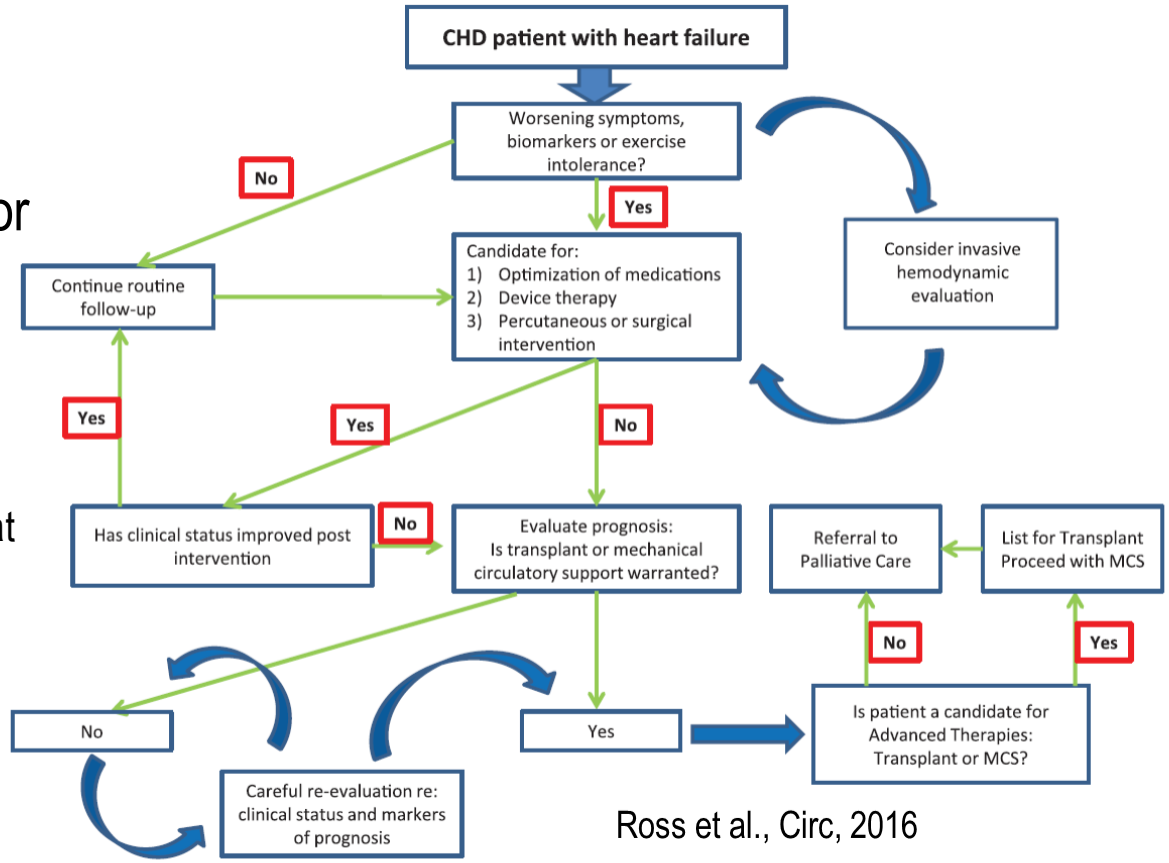




VanderPluym et al., JHLT, 2017

Current MCS Guidelines for Heart Failure* ISHLT, 2013

- All ACHD patients should have thorough imaging and documentation of vascular anatomy to guide decision-making
  - Class I
- Patients with complex heart disease, atypical situs, or residual intraventricular shunts who are not candidates for LV support should be considered for TAH
  - Class IIa
- Other issues more likely found in ACHD patients
  - Aortic Valve
    - > Mild regurgitation should be fixed or replaced with bioprosthetic at implant (Class I)
  - Intracardiac shunts
    - ASD should be closed at time of implant (Class I)
    - LVAD w/ unrepairable VSD or free wall rupture is not recommended (Class III)
  - Fontan patients
    - Should have an US assessment of liver and aggressive therapy aimed at restoring function (Class I)
    - Confirmed cirrhosis or increased MELD scores are poor candidates (Class III, level B)



Ross et al., Circ, 2016

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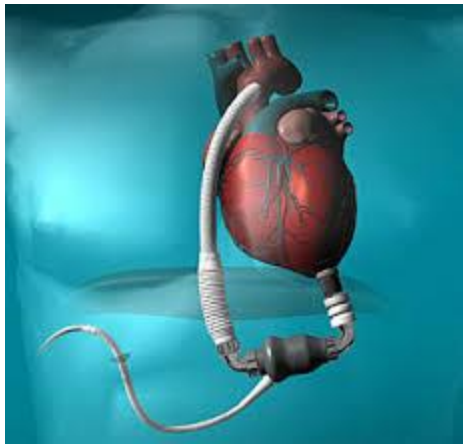
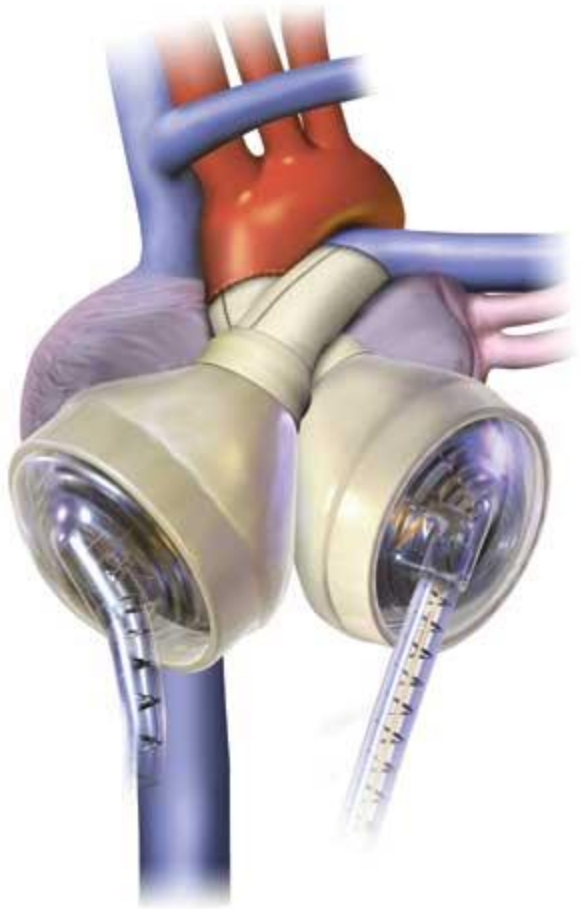
* All Level of Evidence C unless otherwise noted

Current Devices

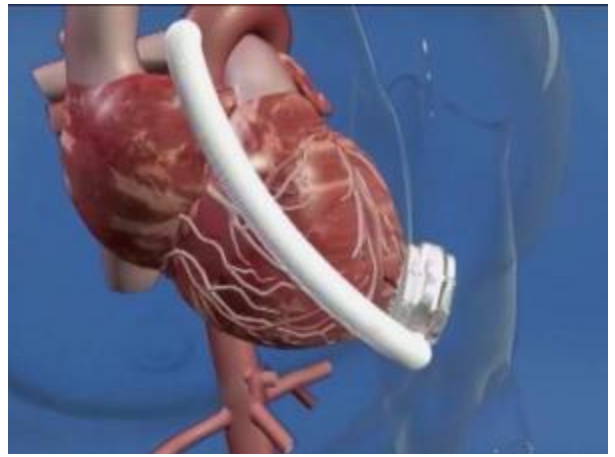


HeartMate II

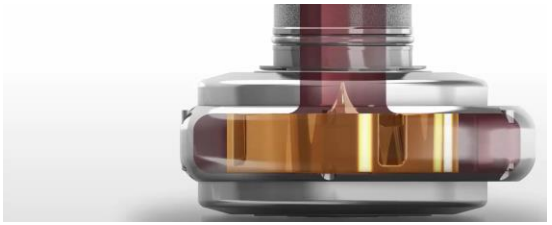
HeartMate III



Syncardia TAH



Heartware H-VAD



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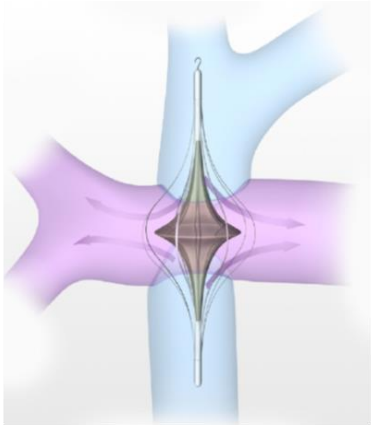
On the Horizon



Rodefeld, et al., Ped Card Surg Annual, 2011

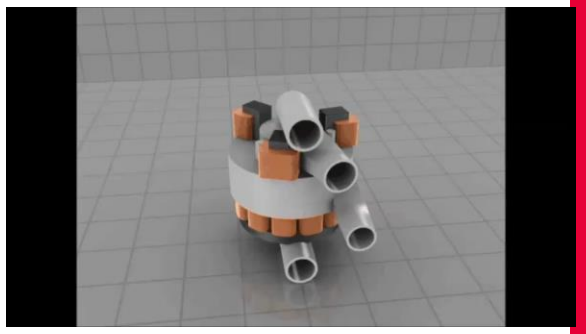
Jarvik Pediatric

Heartware M-VAD

Bivacore

VADovations REVOLUTION

Carmat TAH



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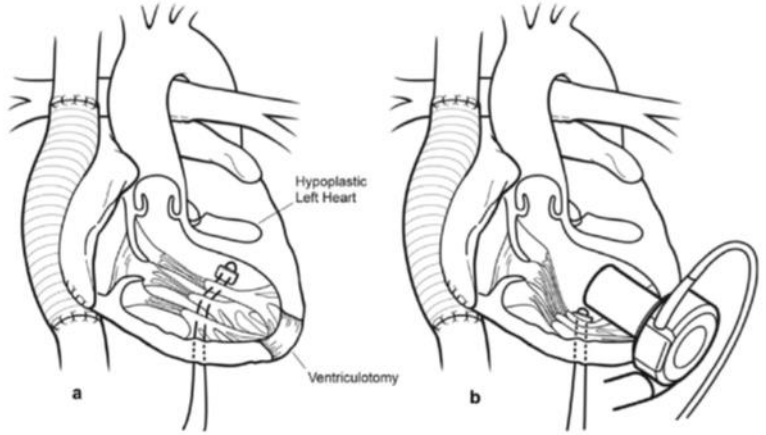
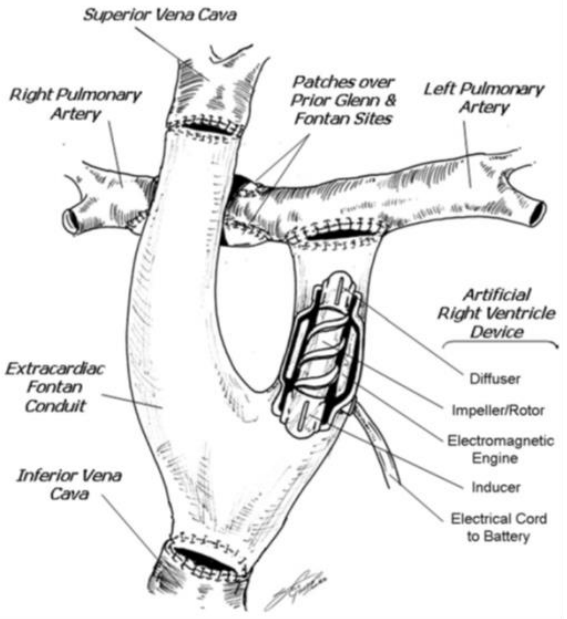
Summary of Challenges and Prospects for ACHD MCS

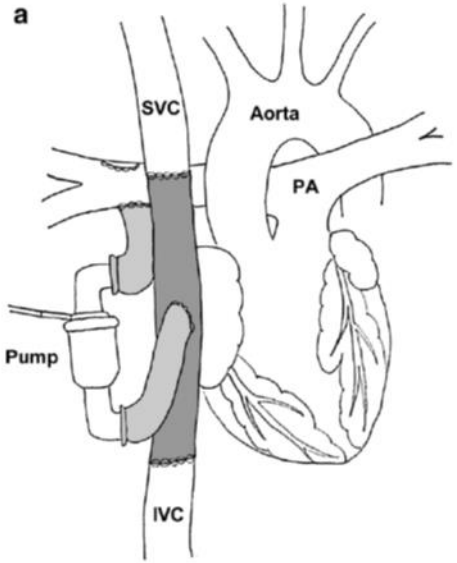
- ACHD Patients, particularly Fontan patients may be underserved by MCS and benefit from some level of support in the early stages of HF
- Challenges
  - Physiologic burden leading to organ compromise
    - Liver cirrhosis and coagulopathy
    - Ascites, compromised nutrition and cachexia with consequent poor wound healing
  - Technical challenges of cannula positioning, reconfiguring anatomy
    - RV Trabeculations, TPCP geometry, creation of compliant atria
    - Partner with pediatric congenital surgeons
  - Postoperative bleeding is a significant but manageable risk
- Lessons from non-ACHD
  - VAD early
    - Better outcomes
    - Potentially reverse organ dysfunction?
    - Gain 30 days of status 1A
  - Utilize DT or BTD as an option
  - Continuous flow pumps fare better than those with valves



Woods et al., Ped Card Surg, 2017



Lacour-Gayet et al., ATS, 2009



Shimizu et al., J Physiol Sci, 2016

What can MCS Do for You?