

Berlin Heart Active: Optimizing Use for Challenging Anatomy

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Disclosures

- Off label use

Objectives

- Active Driver Experience
- Anatomic Challenges
- Future State

Active Driver



IKUS Drive Unit



Active Driver

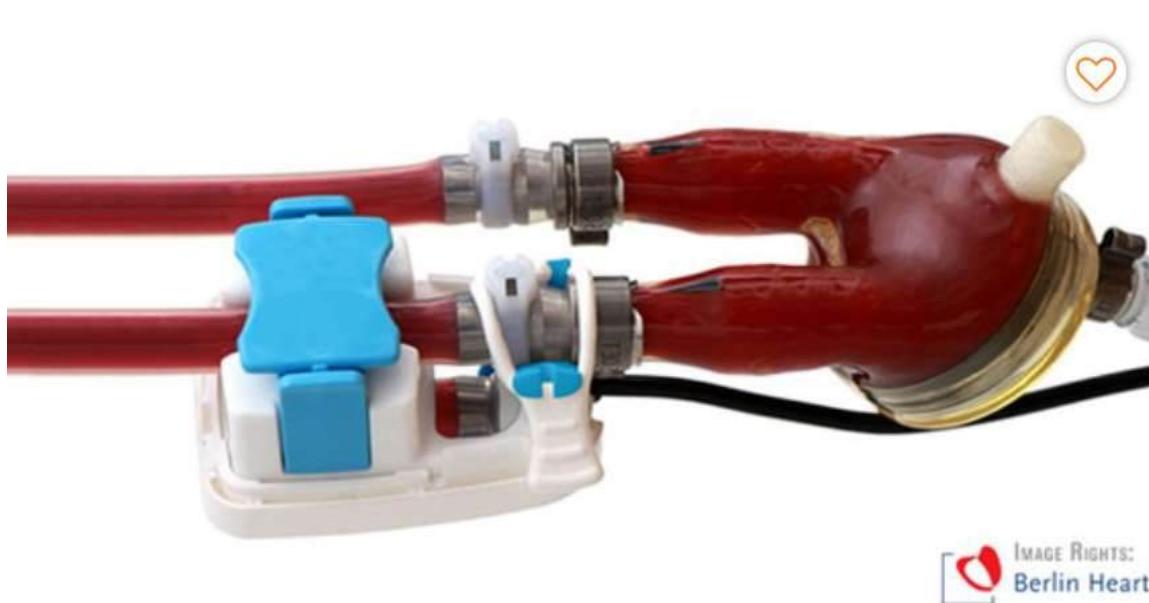


IKUS Drive Unit

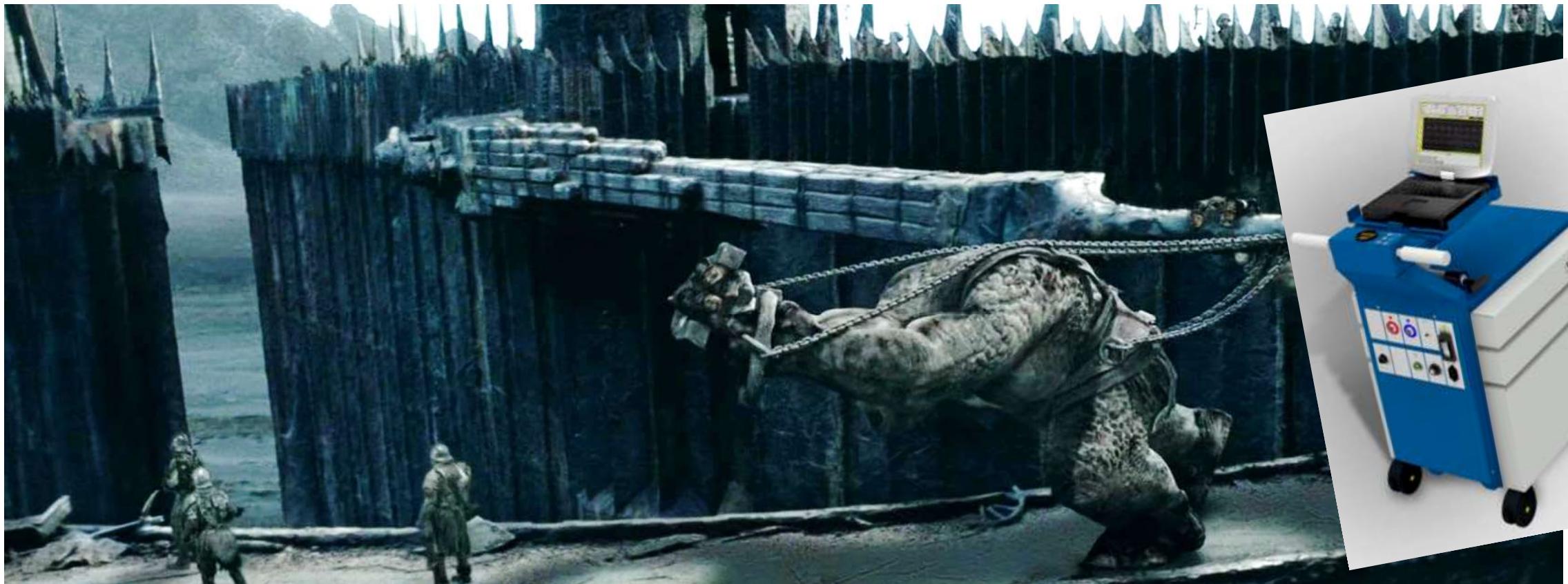


Active Driver

IKUS Drive Unit







First North American experience with the Berlin Heart EXCOR Active driver

Jennifer Conway, MD,^{a,b} Tara Pidborochynski, MSc,^b Diana Ly, BN,^c Leah Mowat, BN,^c Darren H. Freed, MD, PhD,^{d,e} Izak De Villiers Jonker, MD,^e Mohammed Al-Akabi, MD,^e Paula Holinski, MD,^f Vijay Anand, MD,^f and Holger Buchholz, MD^d

- Flow probe temp alarms
- Low flow alarms
 - Only once had to change
- Caregivers trained
- More mobility

Table 1 Demographic and Clinical Characteristics of the Cohort

Characteristic	Total cohort (n = 7) N (%) or median (IQR)
<i>Demographic and clinical</i>	
Age at implant (years)	2.5 (0.8, 4.3)
Sex	
Male	2 (28.6)
Female	5 (71.4)
Diagnosis	
Non-CHD	5 (71.4)
CHD	2 (28.6)
Weight (kg)	12.1 (8.9, 19.2)
Height (cm)	84.7 (70.9, 103.3)
<i>Cannulation strategy</i>	
LVAD	4 (57.1)
BiVAD	3 (42.9)
<i>Outcome of support</i>	
Transplant	6 (85.7)
Death on device	1 (14.3)
Total time on VAD support (days)	75.0 (49.0, 135.5)
<i>EXCOR Active driver</i>	
Time to transition (days)	12 (9.5, 18.5)
Time on EXCOR Active driver (days)	65.0 (32.0, 81.0)
Parents/caregivers trained on EXCOR Active (yes)	7 (100)

Abbreviations: BiVAD, Biventricular assist device; CHD, congenital heart disease; cm, centimeter; IQR, interquartile range; kg, kilogram; LVAD, left ventricular assist device; VAD, ventricular assist device.

Besides mobility, what biggest advantage?

- Mobility is still the biggest advantage
 - More pieces to think about when going on road trips
 - And every perfusionist does it a little differently
- Less obtrusive
 - Quieter
 - Smaller
- Technology is modern/easier

Other advantages?

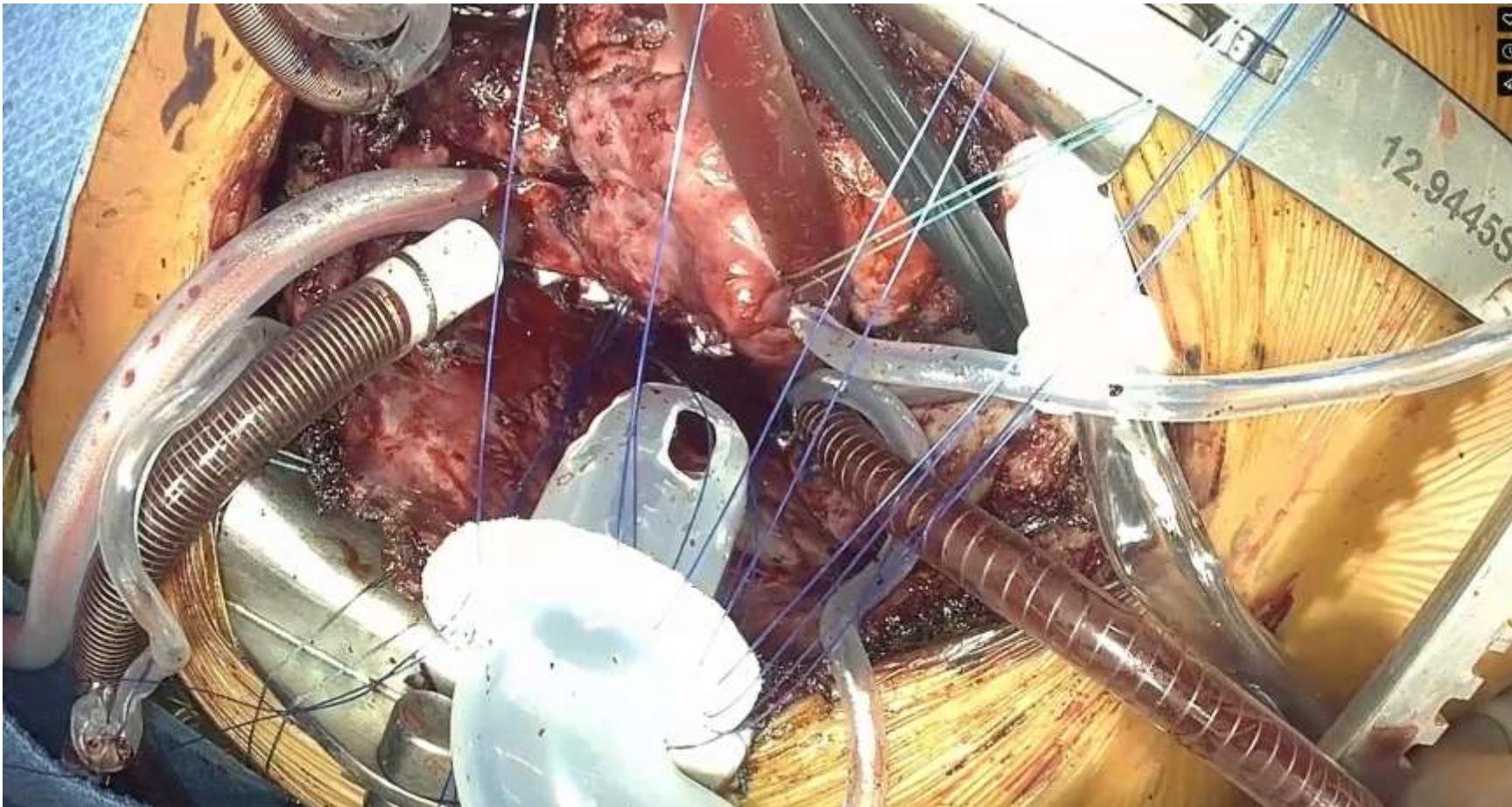
- Flow probe
 - Not perfect
 - Not sure it's always accurate
 - Something for bedside nurse to hyperfocus on
- Trends in systolic/diastolic pressure
 - e.g. increasing diastolic pressure can be indication that atrial septum getting more restrictive in stage 1 hybrid

Challenges and your response?

- We tinker more
 - IKUS was set and forget
 - Have to titrate settings far more often
 - Specifically inadequate response to high SVR
 - May have to switch to manual mode
- More low flow alarms (painful)
- Software glitches – change out driver at unplanned times
- More other alarms (have to call more) – might get better

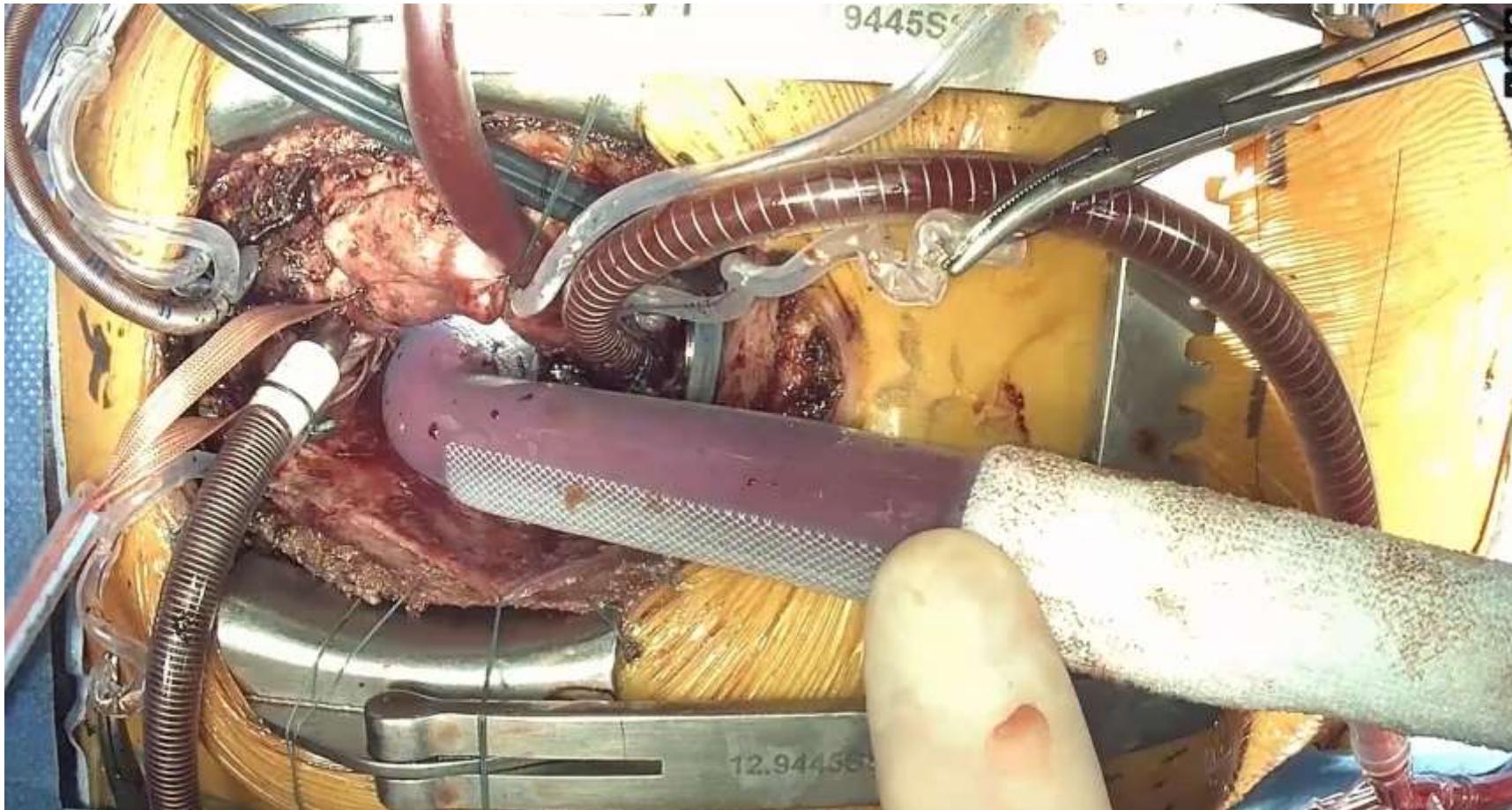
Challenging Heart Disease

Challenge: Restrictive & Hypertrophic CM



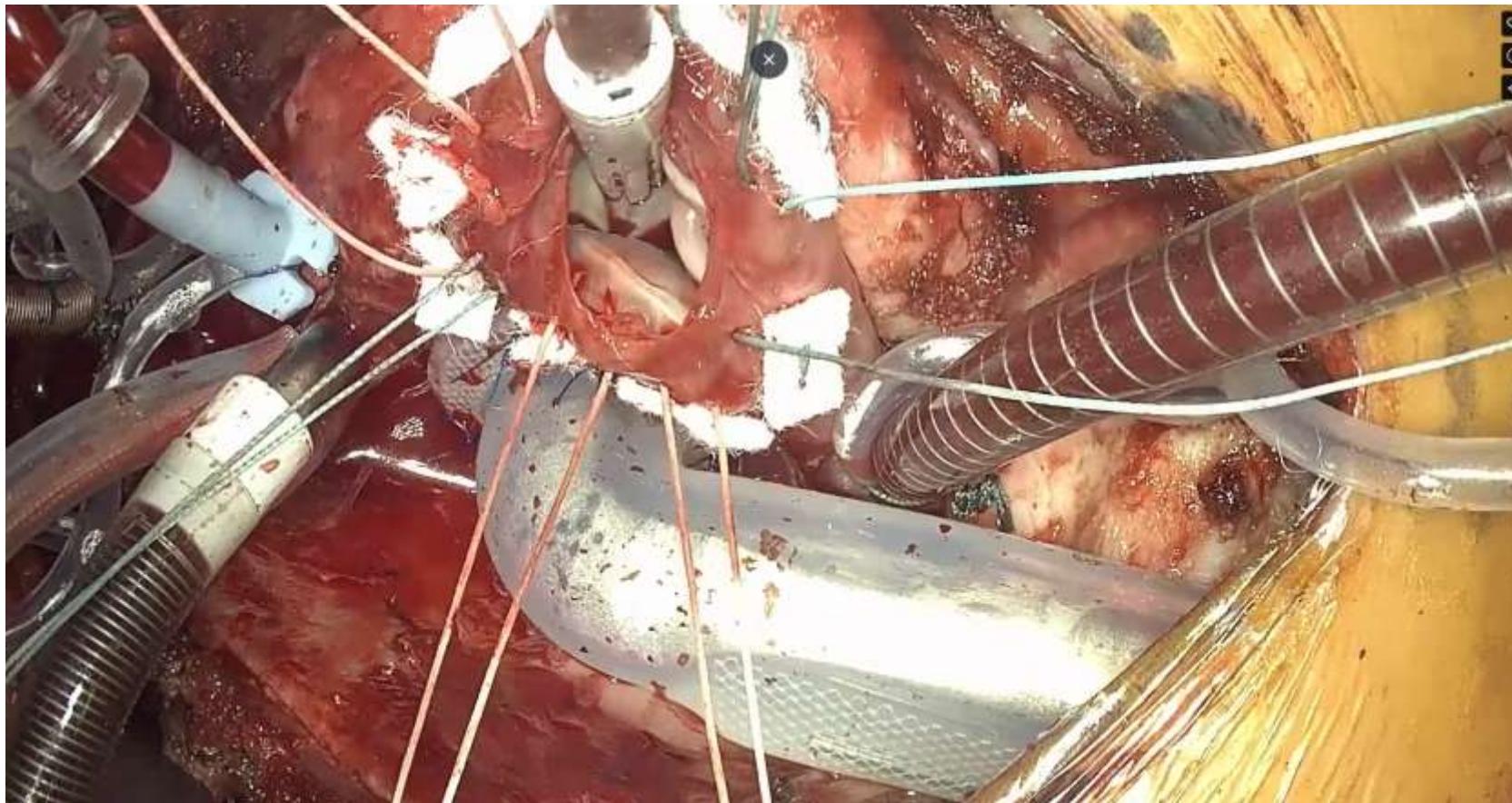
Kari, 2024

Challenge: Restrictive & Hypertrophic CM



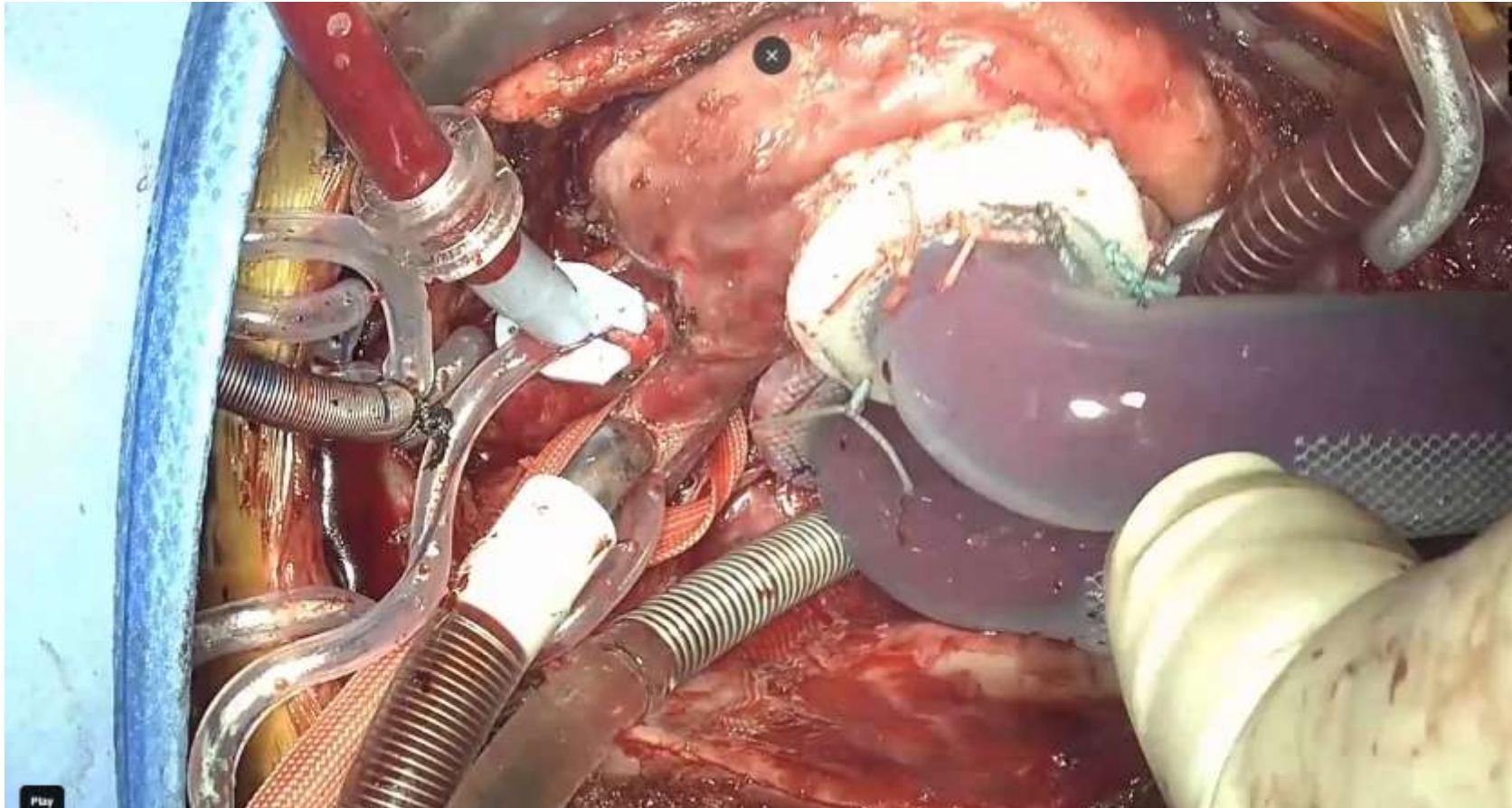
Kari, 2024

Challenge: Restrictive & Hypertrophic CM

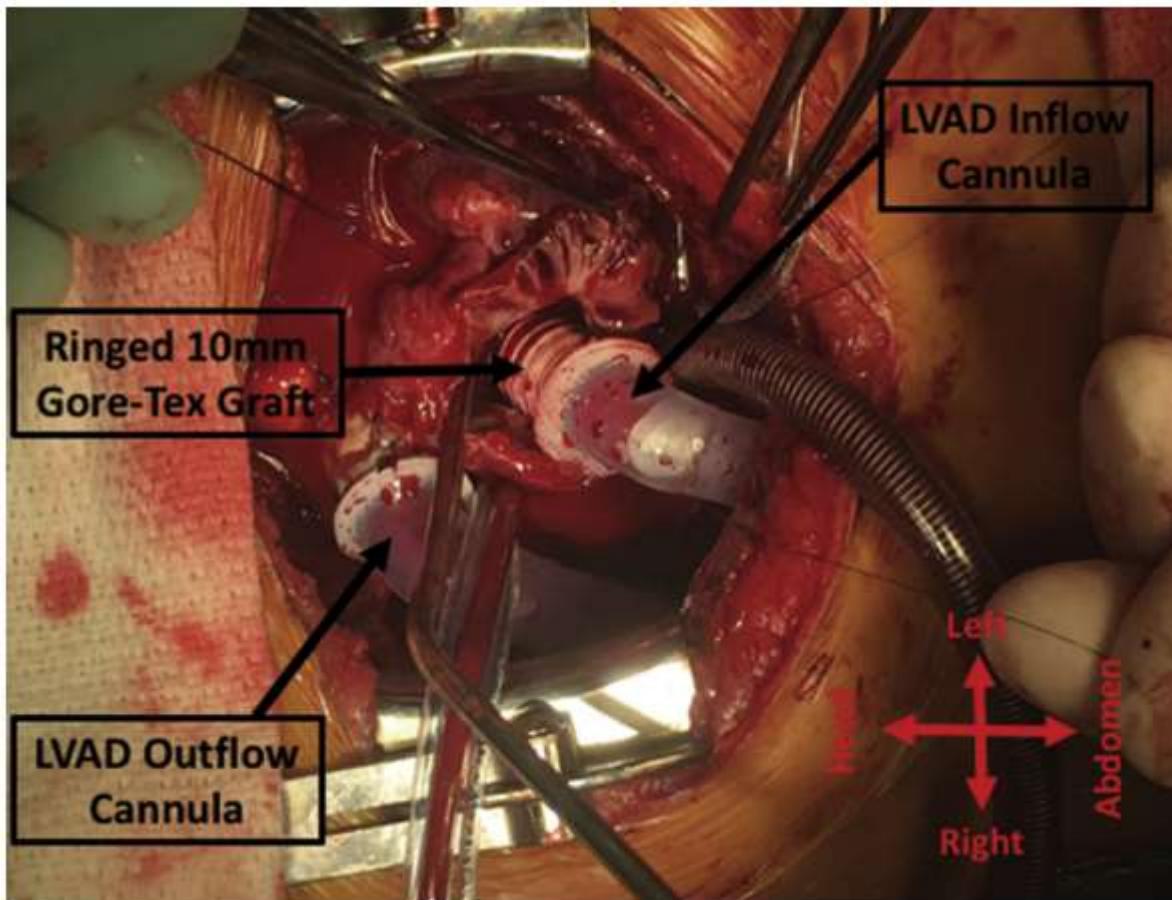


Kari, 2024

Challenge: Restrictive & Hypertrophic CM



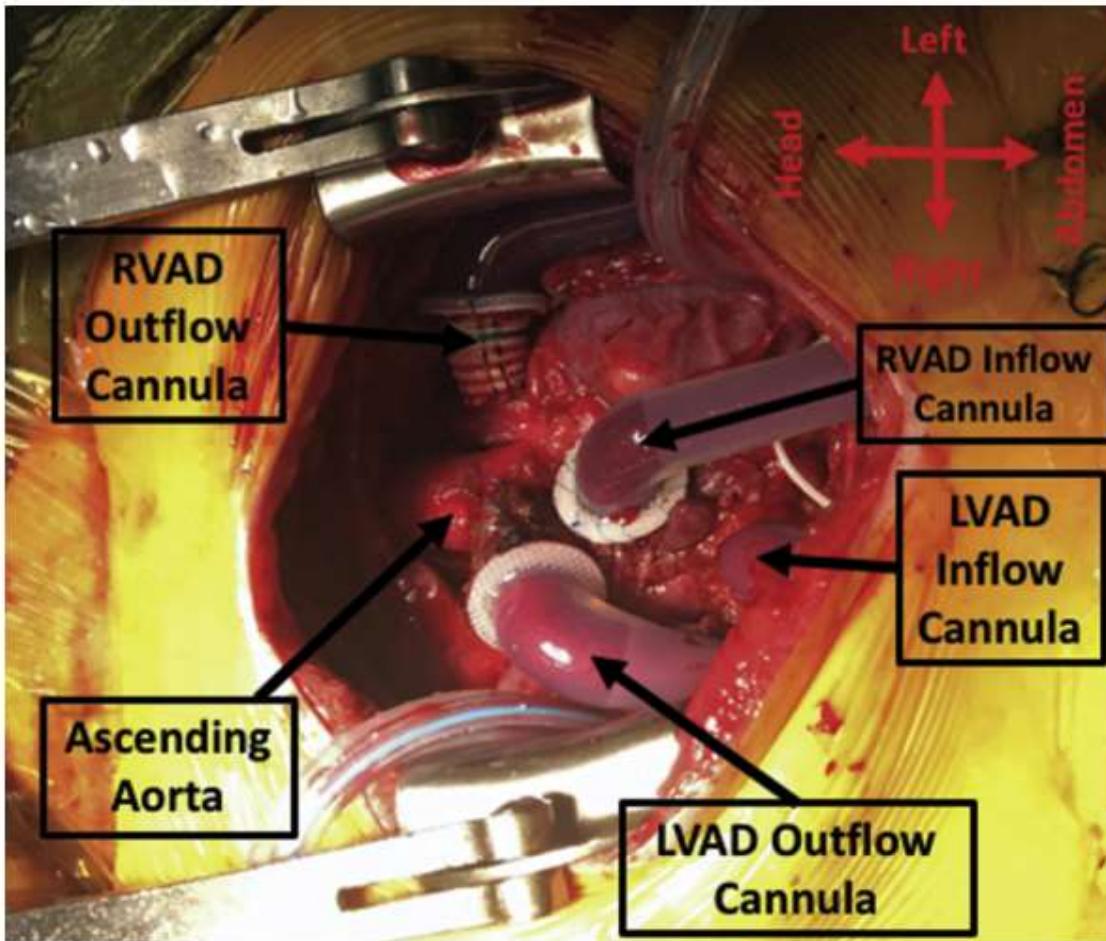
Challenge: Restrictive & Hypertrophic CM



- 3mo with HCM supported on ECMO for 17d
- Went for LVAD
- Used 10mm ringed Gortex graph that traversed RA and anastomosed to ASD
- 6mm EXCOR inflow cannula

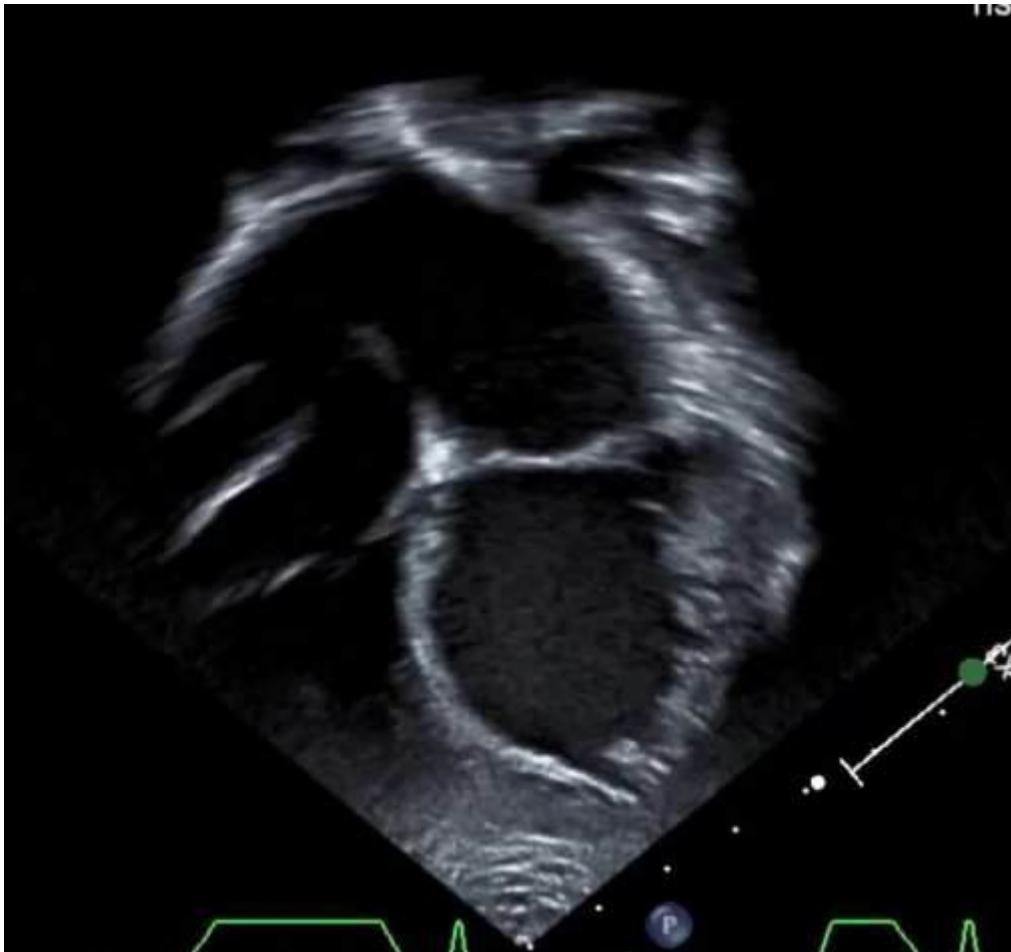
Dykes, 2017

Challenge: Restrictive & Hypertrophic CM



- Several hours had signs of RV failure (high CVP, poor LVAD filling, RV dysfunction)
- Cannulated RA appendage

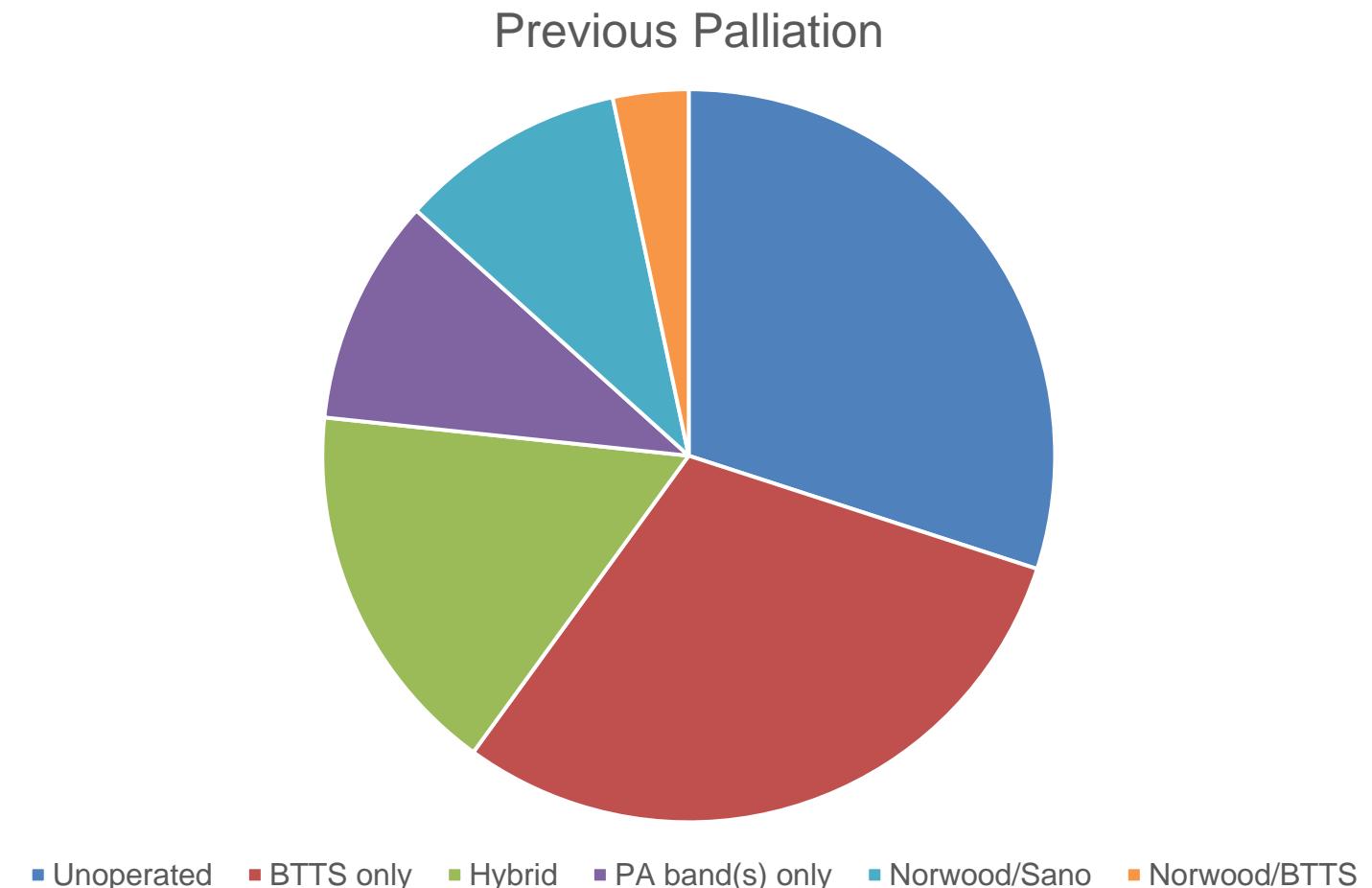
Challenge: Restrictive & Hypertrophic CM



- 2yo with restrictive CM, diminished fx
- Failed medical management
- LVAD
 - Inflow 6mm EXCOR cannula attached to 10mm ringed Gortex
- Supported for 8m

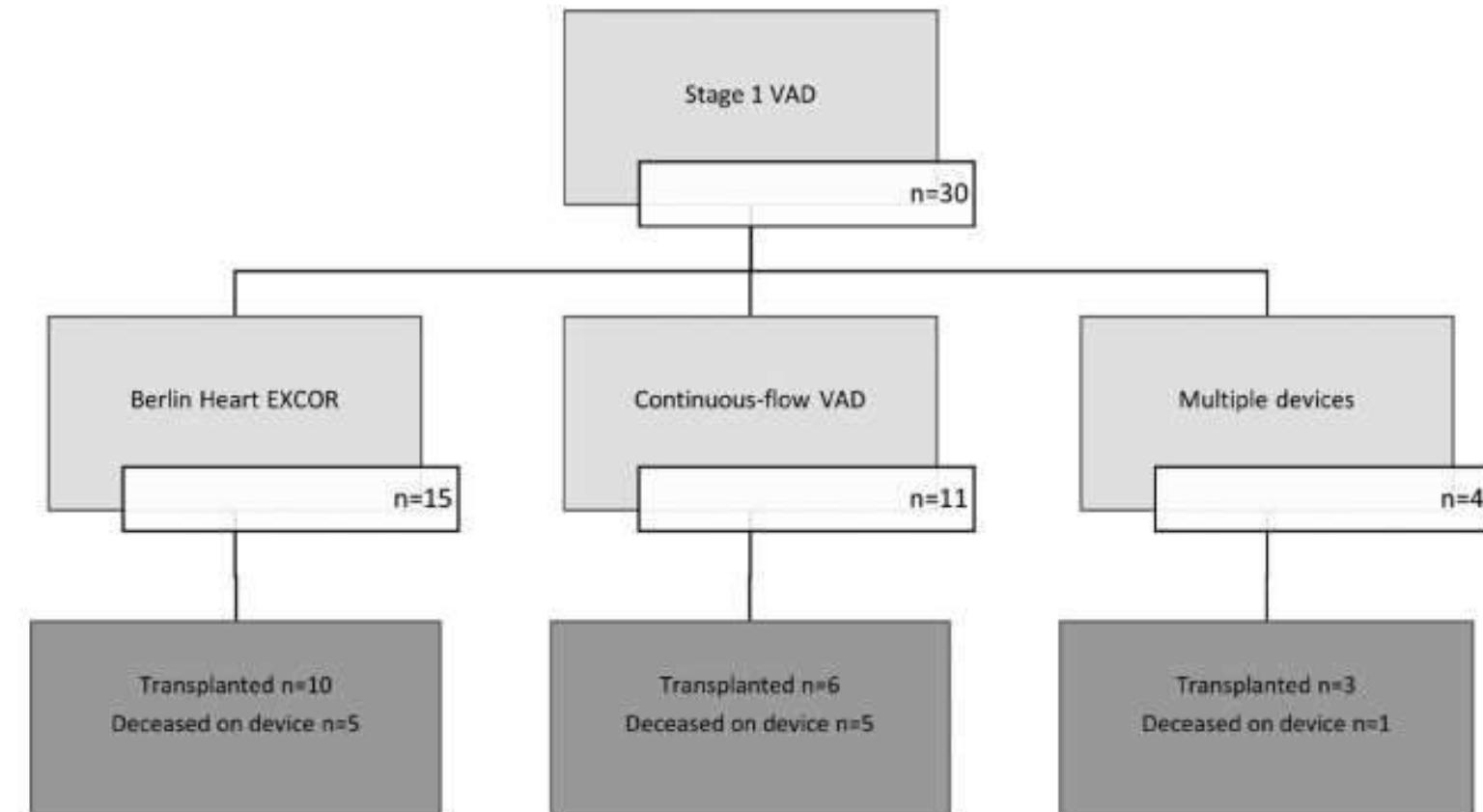
Challenge: “Stage 1” for Single Ventricle

- ACTION Network
 - 30 patients
 - 3/2018 to 10/2020
- Demographics
 - 73% RV
 - Med age 0.9m
 - Med wt 3.7kg
- Sick group
 - 30% ECMO
 - 90% ventilated
 - 13% - no inotropes



Joong, 2022

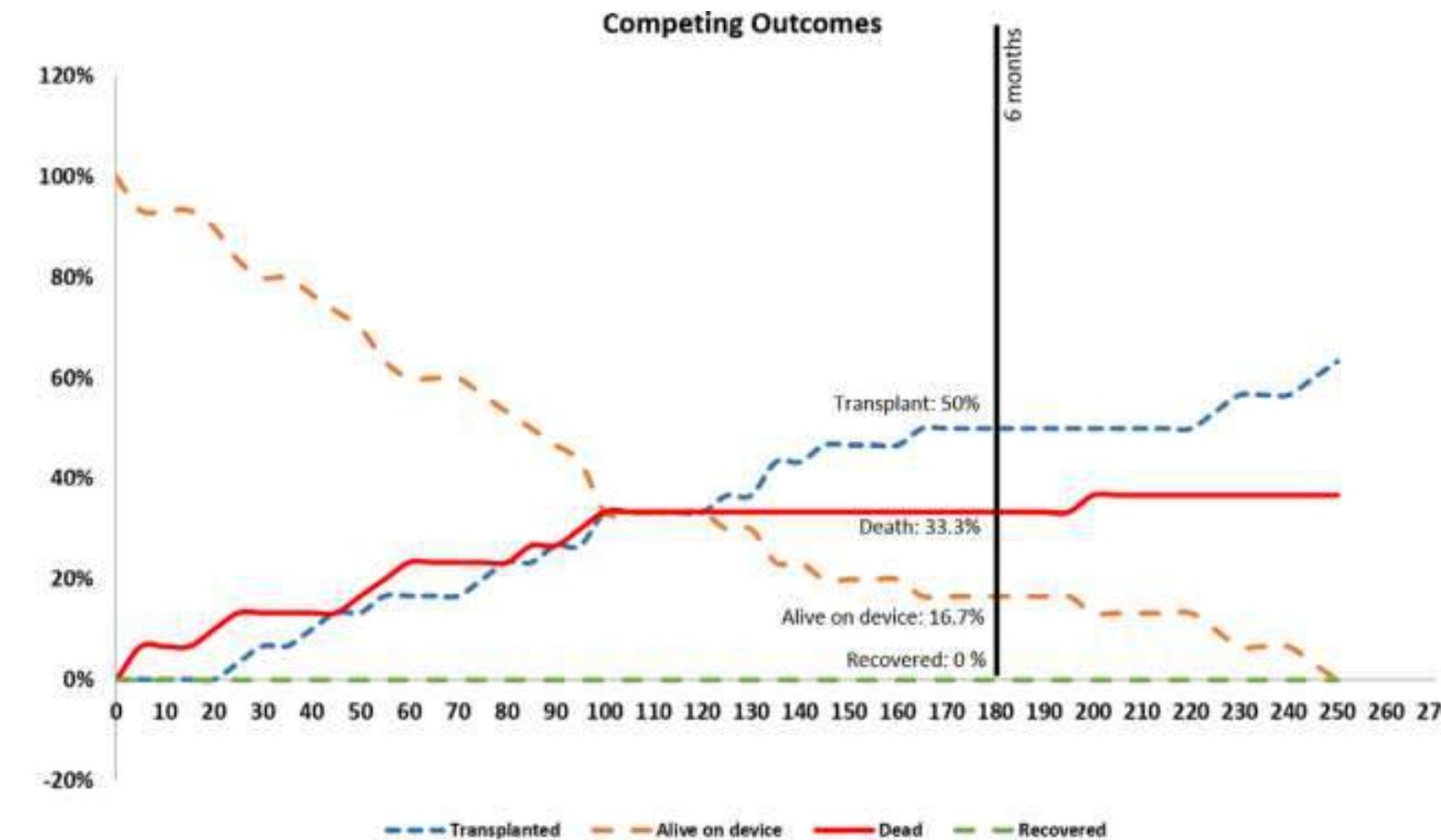
Challenge: “Stage 1” for Single Ventricle



- 90% inflow in atrium
- 33% had + procedure
 - 3 Sano → shunt
 - 3 AVV repair
 - 3 atrial septectomy
 - 1 BDG
 - 1 PA bands
 - 1 arch

Figure 1. Flow diagram demonstrating patient outcome stratified by VAD type. VAD, ventricular assist device.

Challenge: “Stage 1” for Single Ventricle

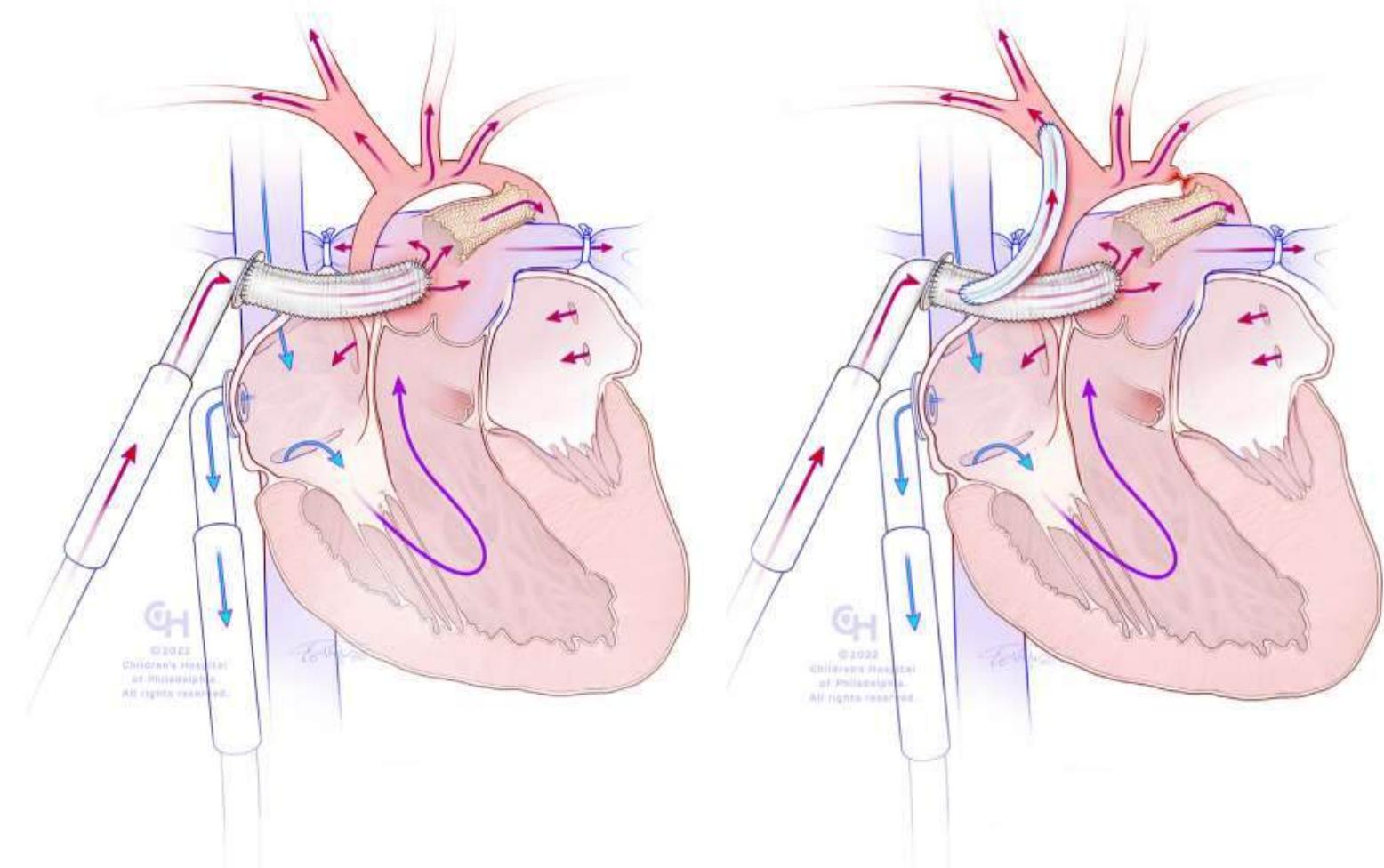


Complications by patient (80%):

- 5 ischemic strokes
- 1 hemorrhagic stroke
- 5 major bleed
- 13 major infection

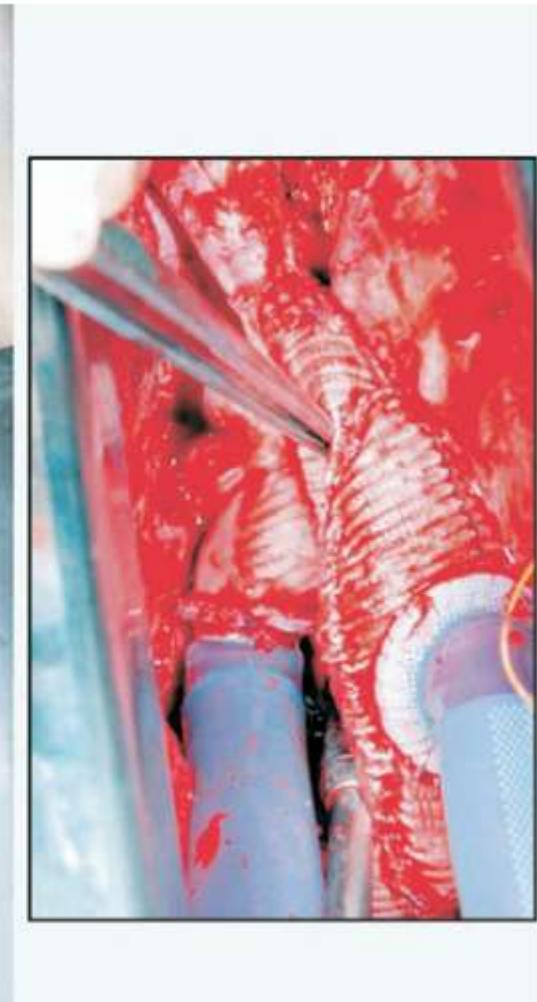
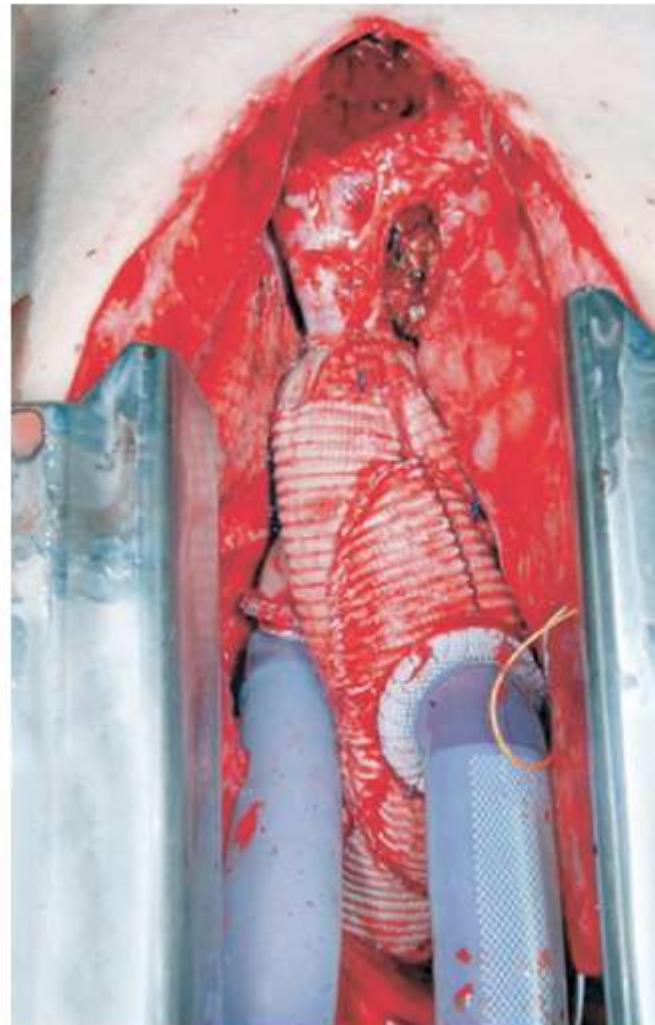
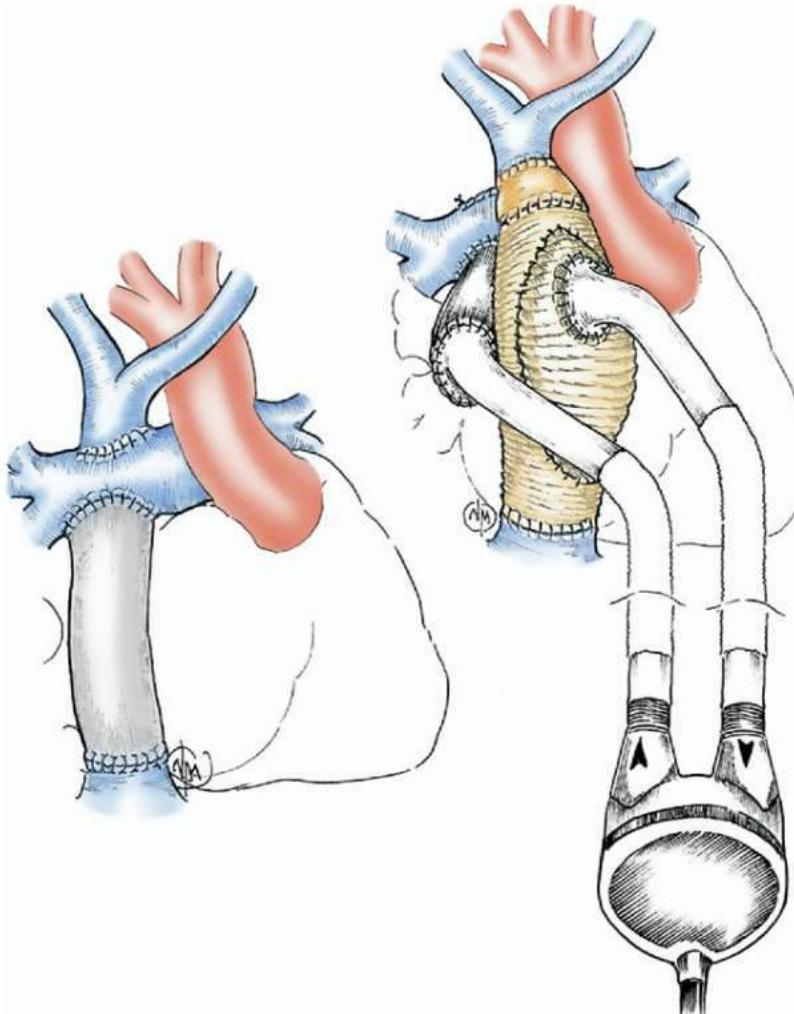
VAD from the Start?

- Report on 3 patients off bypass
 - 1 & 2 died at tx
 - 3 survived through
- 2 more patients
 - 4th: stroke with atrial septal stent
 - 5th: on bypass atrial septectomy



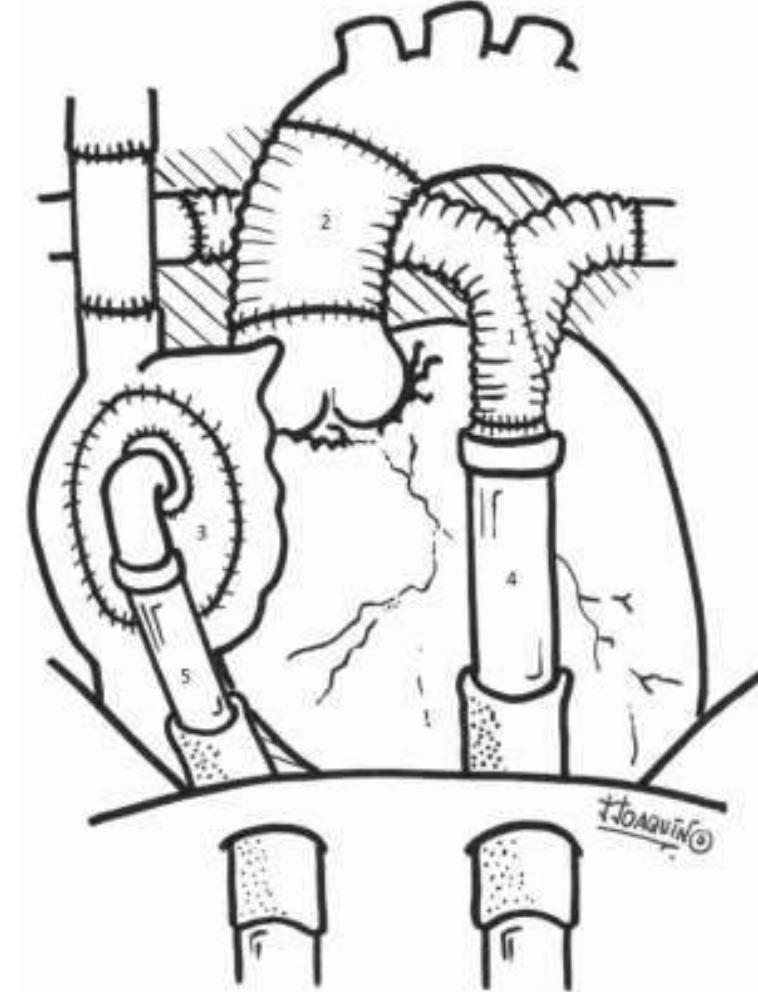
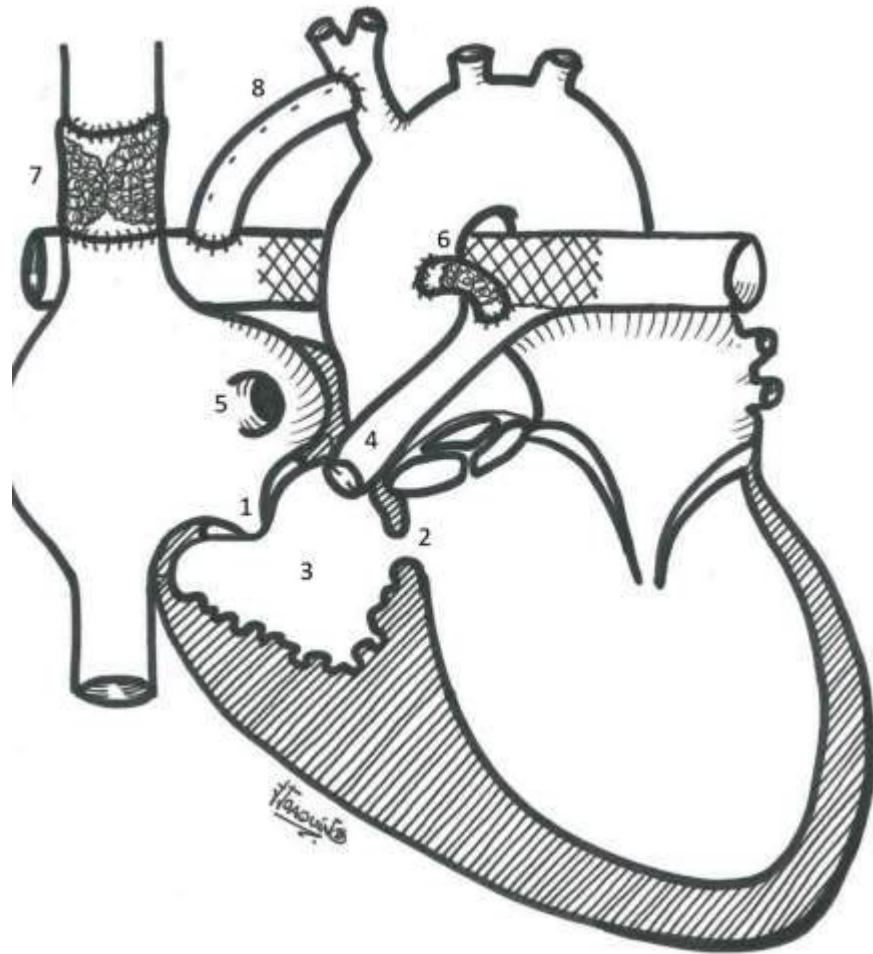
Mavroudis, 2022

Challenge: TCPC & Sub P VADs

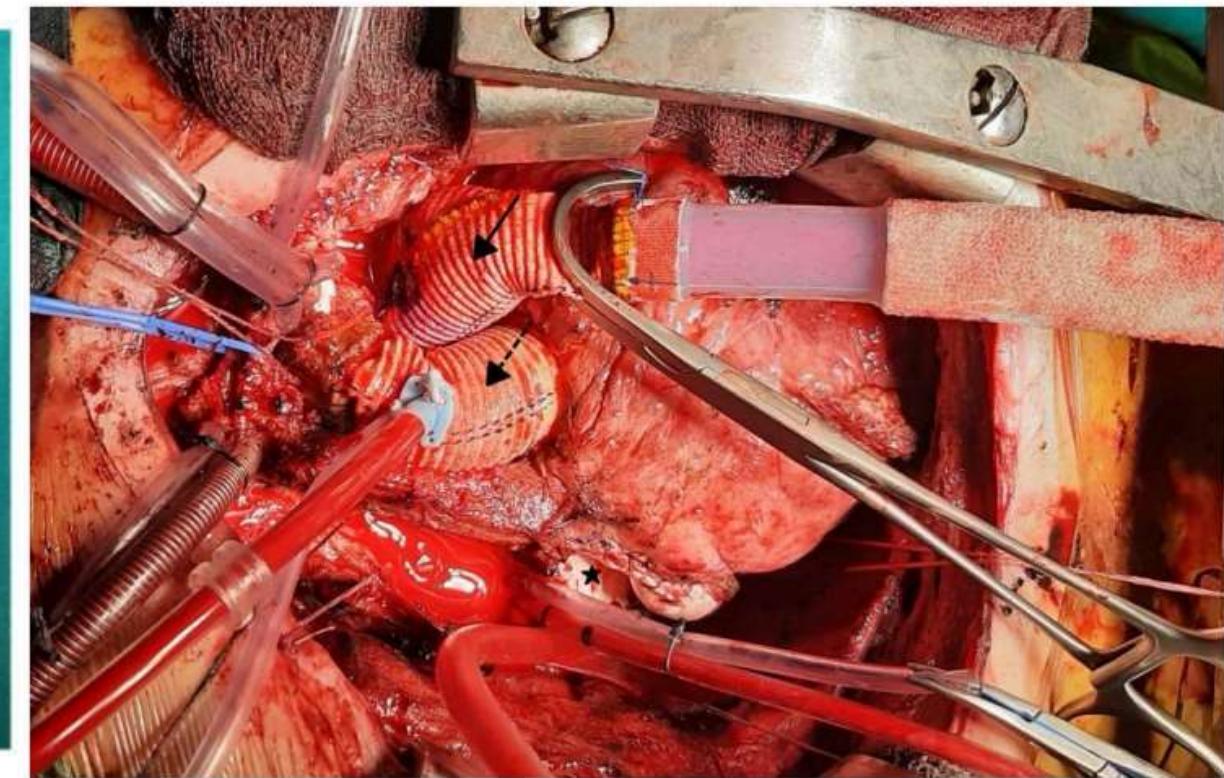
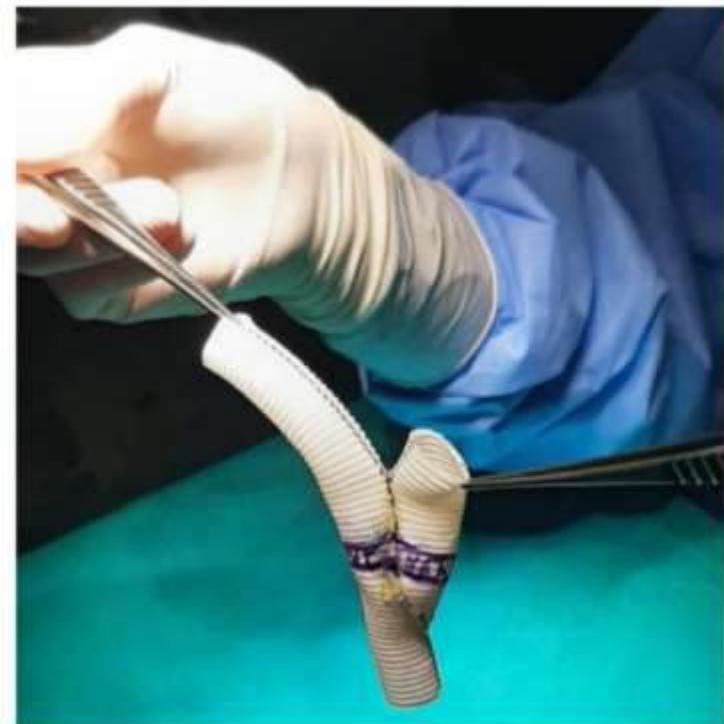


Petre, 2008

Challenge: TCPC & Sub P VADs



Challenge: TCPC & Sub P VADs

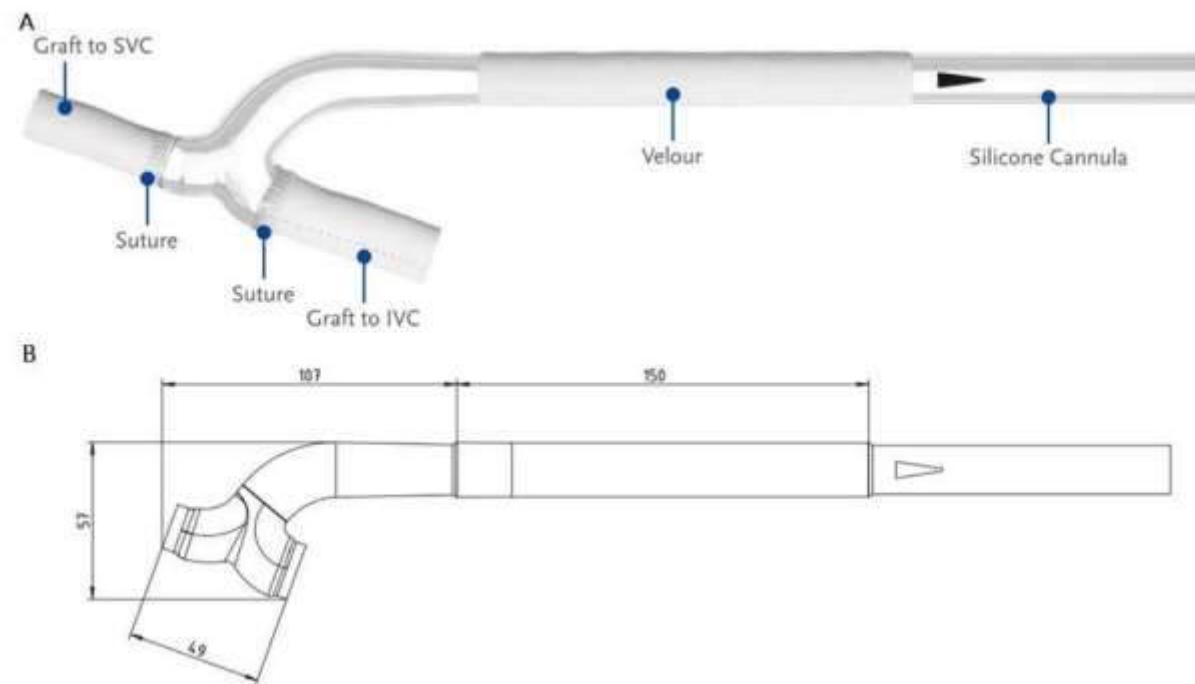


Challenge: TCPC & Sub P VADs

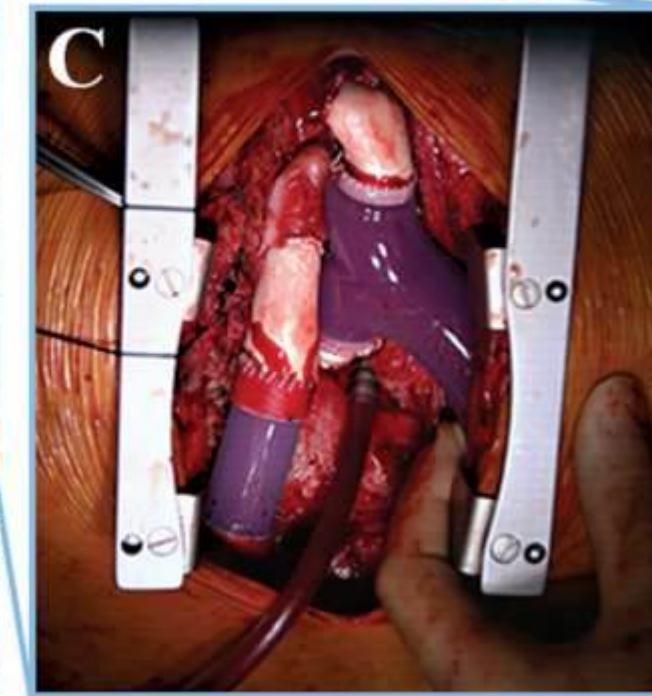
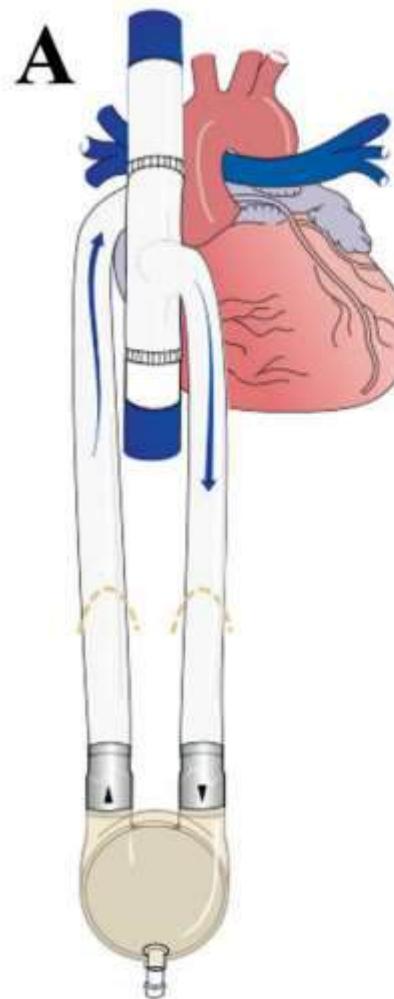
- RegiVe Study
- Regimented f/u for 6m
- Regimented labs
- Cannula sizes

Article number	Pump connector inner diameter [mm]	Inner diameter SVC [mm]	Inner diameter IVC [mm]	Distance SVC-IVC [mm]
C1418F-002m	12 (50-, 60-, and 80-mL blood pumps)	14	18	49
C1620F-002m		16	20	
C1822F-002m		18	22	

Challenge: TCPC & Sub P VADs

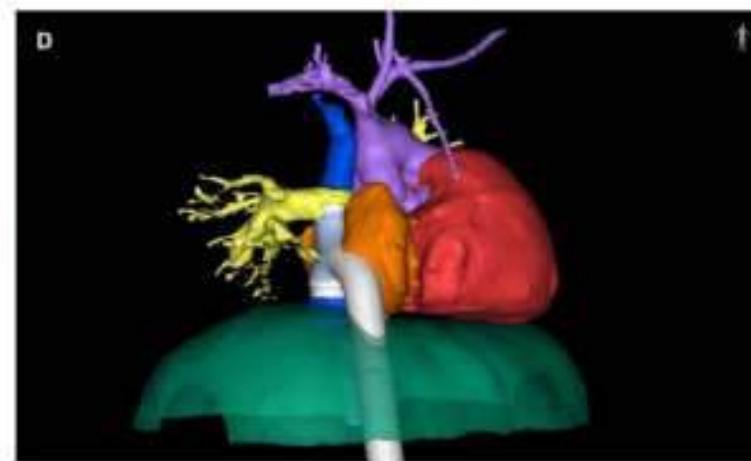
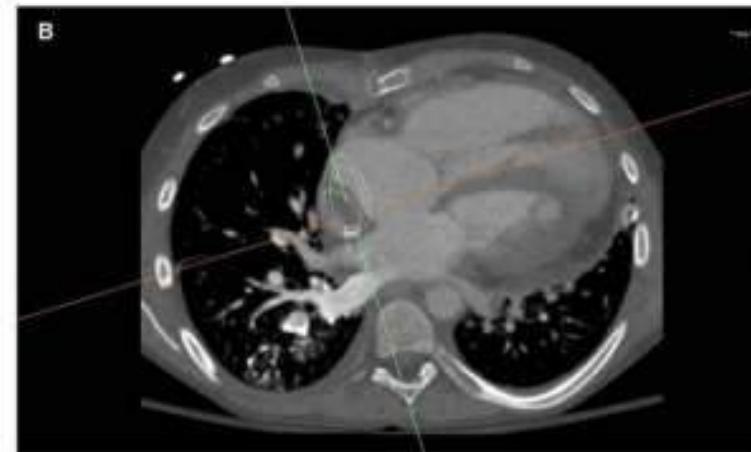
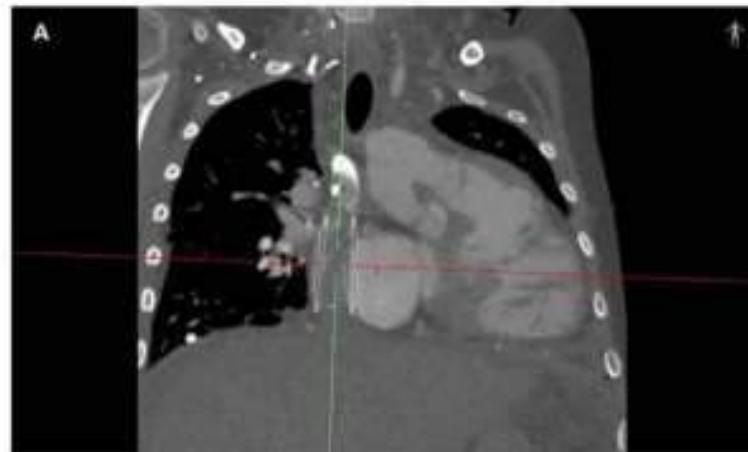


Challenge: TCPC & Sub P VADs

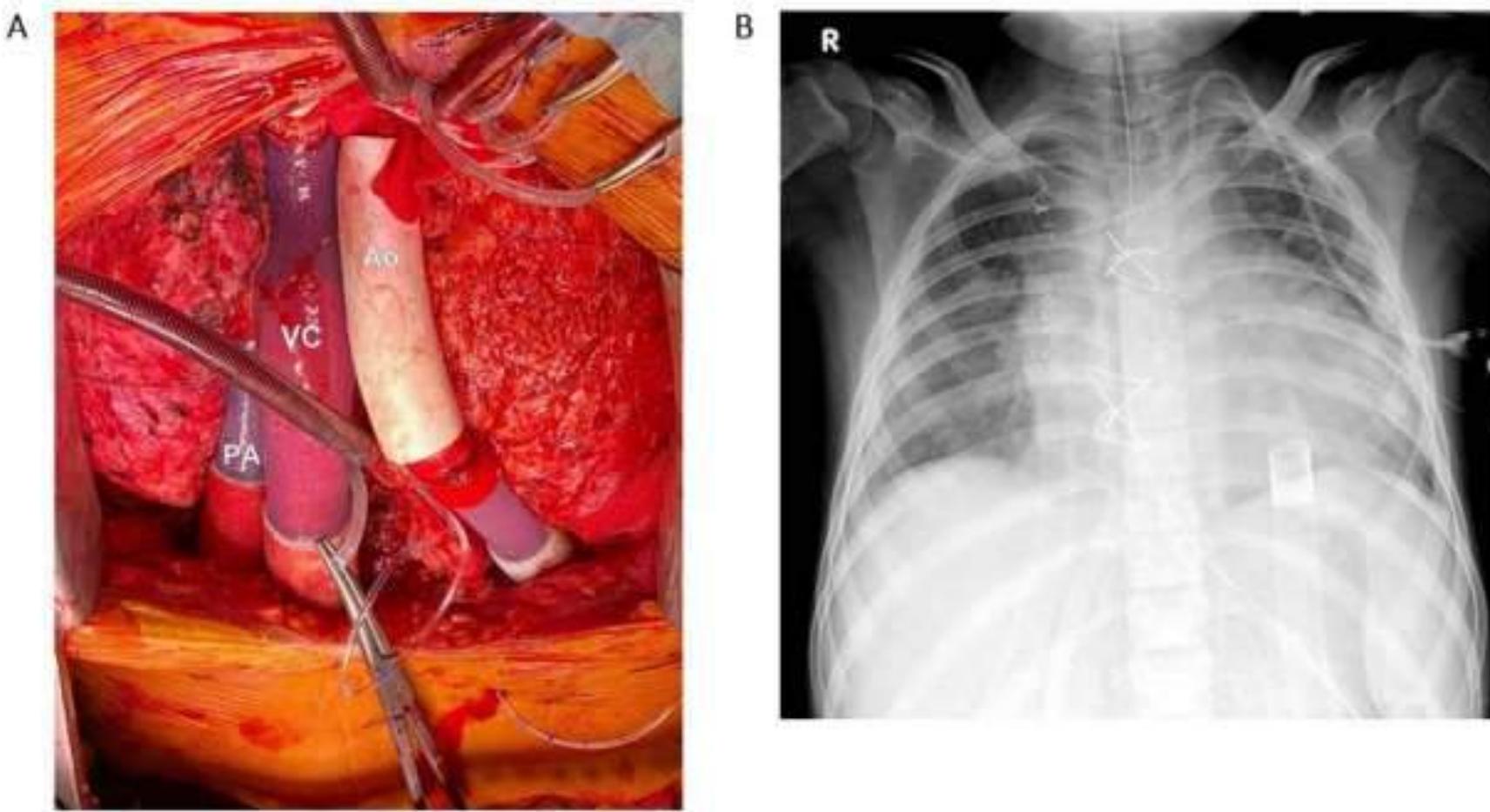


Dal Sasso, 2022

Challenge: TCPC & Sub P VADs



Challenge: TCPC & Sub P VADs



The Future

- How should I know, I work in the ICU



The Future

- How should I know, I work in the ICU
- At home
 - Training
 - Medications & lab monitoring
 - In person visits, televisits, in home visits
 - What interdisciplinary team members
- Fontans
- Babies

References

- Conway J, Pidborochynski T, Ly D, Mowat L, Freed DH, De Villiers Jonker I, Al-Akabi M, Holinski P, Anand V, Buchholz H. First North American experience with the Berlin Heart EXCOR Active driver. *J Heart Lung Transplant*. 2024 Nov;43(11):1861-1863. Epub 2024 Aug 10. PMID: 39134164.
- Dal Sasso E, Schöndorf T, Schlüter KJ, Miera O, De Rita F, Menon AK; European EXCOR® Pediatric Investigator Group (EEPIG). A Novel Strategy for the Mechanical Subpulmonary Support in Failing Fontan Patients. *Thorac Cardiovasc Surg*. 2022 Dec;70(S 03):e34-e41. Epub 2022 Nov 11. PMID: 36368697; PMCID: PMC9665118.
- Domínguez Del Castillo JJ, Merino Cejas CM, Gómez Guzmán E, Frías Pérez MA. Bridge to transplant in single-ventricle anatomy: subpulmonary support with EXCOR ventricular assist device associated with pulmonary artery reconstruction. *Eur J Cardiothorac Surg*. 2024 May 3;65(5):ezae174. PMID: 38656949.
- Dykes JC, Reinhartz O, Almond CS, Yarlagadda V, Murray J, Rosenthal DN, Maeda K. Alternative Strategy for Biventricular Assist Device in an Infant With Hypertrophic Cardiomyopathy. *Ann Thorac Surg*. 2017 Aug;104(2):e185-e186. PMID: 28734448.
- Joong A, Maeda K, Peng DM; ACTION Learning Network Investigators. Ventricular Assist Device Outcomes in Infants and Children With Stage 1 Single Ventricle Palliation. *ASAIO J*. 2022 Nov 1;68(11):e188-e195. Epub 2022 Nov 3. PMID: 36326704.
- Kari FA, Hörer J, Michel S. Biventricular assist device implant using biatrial cannulation for restrictive cardiomyopathy. *Multimed Man Cardiothorac Surg*. 2024 May 10;2024. PMID: 38727533.
- Mavroudis CD, O'Connor MJ, Wittlieb-Weber C, Edelson JB, Edwards JJ, Berger JH, Lin KY, Rossano J, Maeda K. Hybrid stage 1 palliation with simultaneous off-pump ventricular assist device placement in neonates with high-risk single ventricle anatomy: Initial experience. *JTCVS Tech*. 2023 Nov 2;24:164-168. PMID: 38835568; PMCID: PMC11145030.
- Prêtre R, Häussler A, Bettex D, Genoni M. Right-sided univentricular cardiac assistance in a failing Fontan circulation. *Ann Thorac Surg*. 2008 Sep;86(3):1018-20. PMID: 18721610.