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Cardiac Center



DISCLOSURES

- No relevant financial disclosures
- Discuss off label use of ventricular assist devices (VADs) in children



OUTLINE

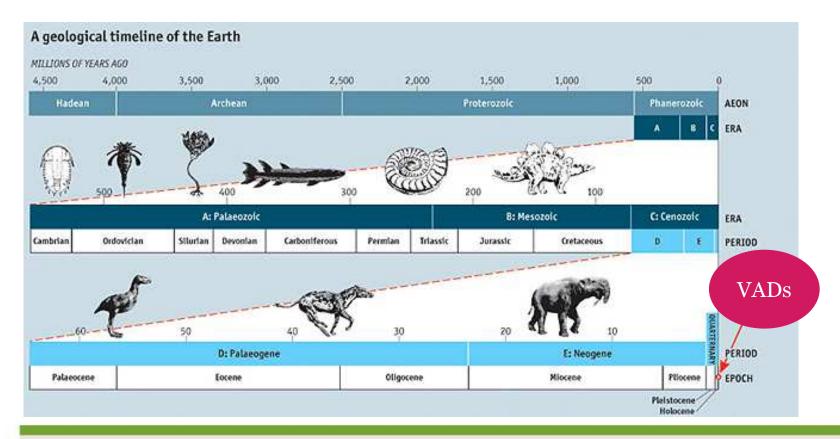
- Historical perspective
- Outcomes of children supported with continuous flow VADs
- Present challenges / future opportunities



A BRIEF HISTORY OF TIME.... OF VADS



A BRIEF HISTORY OF TIME.... OF VADS



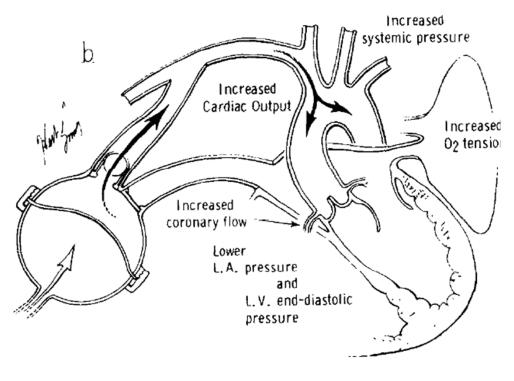


A BRIEF HISTORY OF TIME.... OF VADS

- Gibbons developed first 'heart lung machine' ushering in the era of open-heart surgery
 - 1953
- NHLBI funded the 'Artificial Heart Program'
 - 1964
- DeBakey and Cooley implanted the first LVAD and total artificial heart (TAH)
 - 1966 & 1969



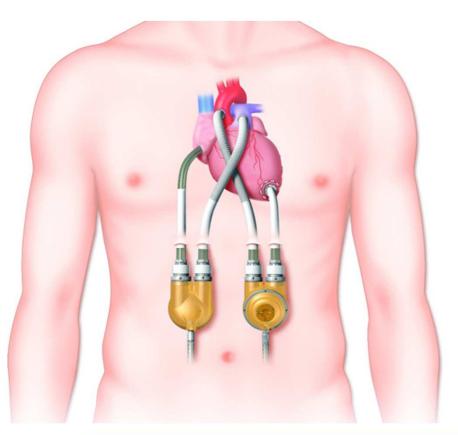
EARLY EXPERIENCE





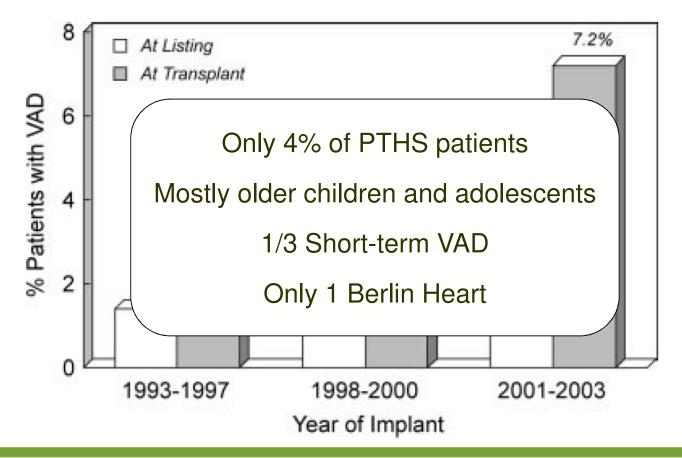


PNEUMATIC PULSATILE PUMPS



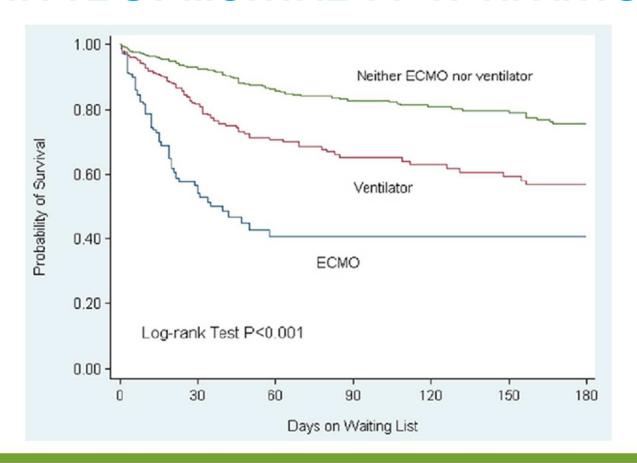


HISTORICAL PERSPECTIVE





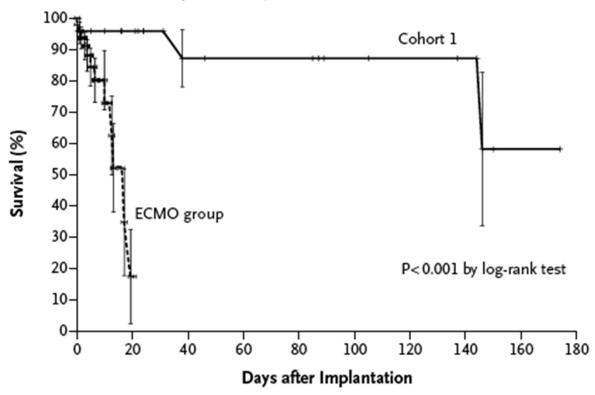
WAITLIST MORTALITY IN INFANTS





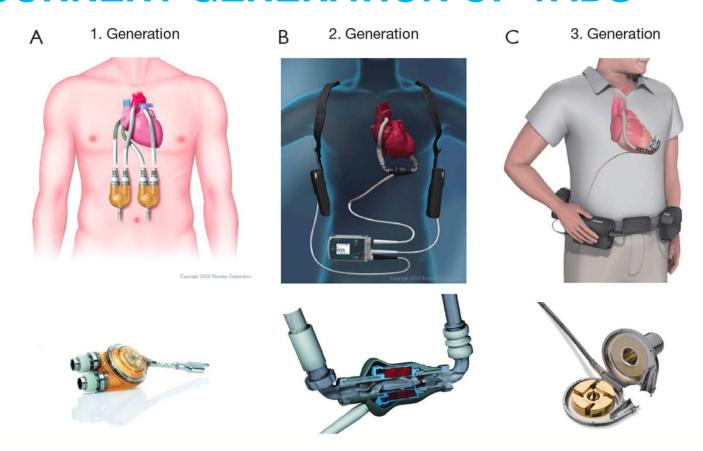
BERLIN HEART TRIAL

A Freedom from Primary End Point, Cohort 1

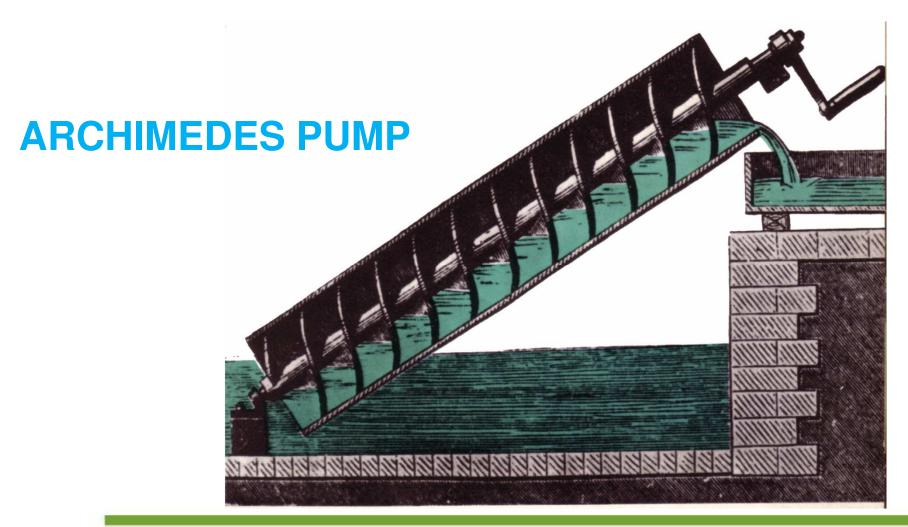




CURRENT GENERATION OF VADS









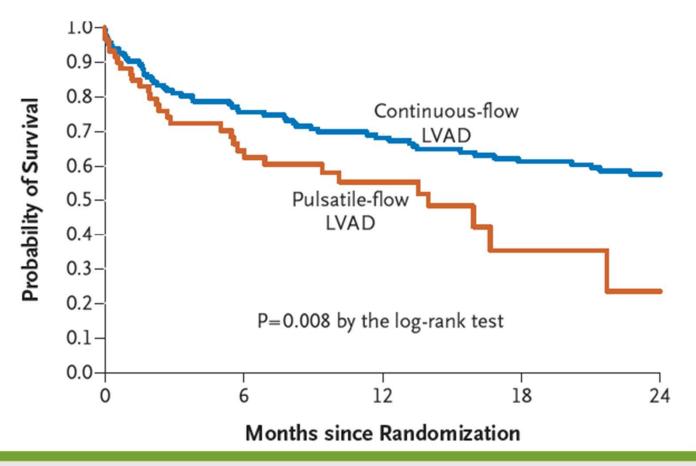
HEARTWARE





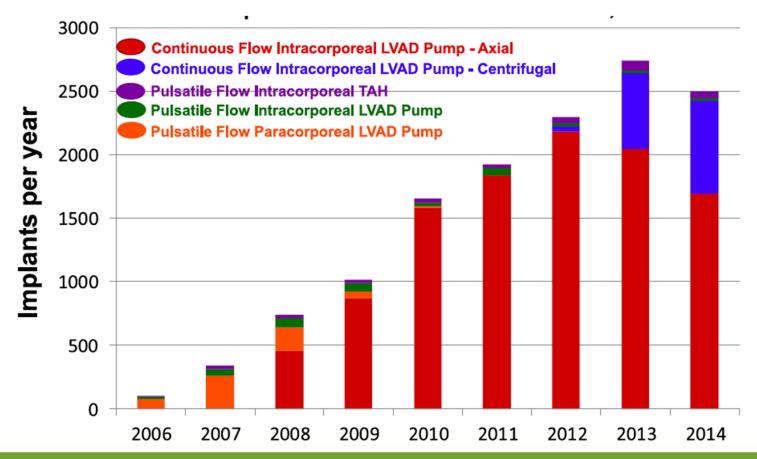


RISE OF CONTINUOUS FLOW VADS





'EXPLOSION' OF ADULT VADS





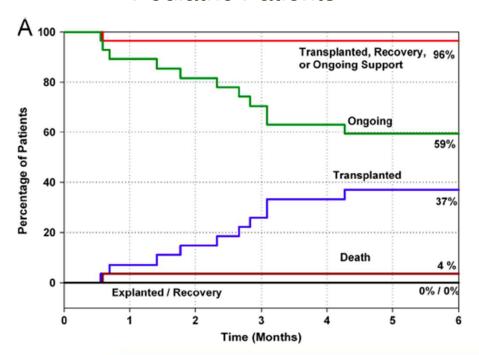
HEARTMATE II IN CHILDREN

Variable ^a	Pediatric	Young adult	n value
	(n = 28)	(n = 359)	<i>p</i> -value
Demographics			
Patients from	7 (25)	0 (0)	< 0.001
Children's Hospital			
Females	9 (32)	113 (31)	0.942
Body surface	1.91 (1.47-	2.08 (1.12-	0.022
area, m ²	2.65)	3.10)	
Weight, kg	76.1 (50-	87.7 (29.0-	0.025
	132.8)	177.5)	
Race and ethnicity			
White	12 (43)	198 (56)	0.441
Black	14 (43)	122 (34)	
Hispanic	5 (18)	32 (9)	
Asian	0 (0)	8 (2)	
Other	3 (11)	21 (6)	
Not reported	1 (4)	10 (3)	
Primary diagnosis			
Congenital heart	2 (7)	8 (2)	0.158
disease			
Cardiomyopathy	25 (89)	347 (97)	< 0.022
Other	1 (4)	3 (<1)	0.260

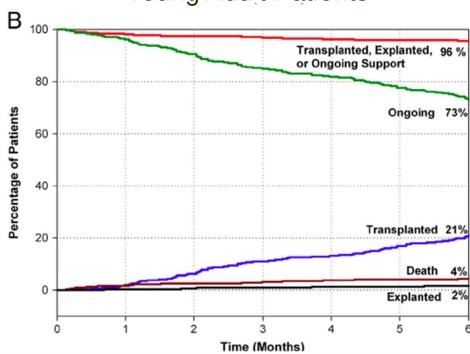


HEARTMATE II IN CHILDREN

Pediatric Patients



Young Adult Patients





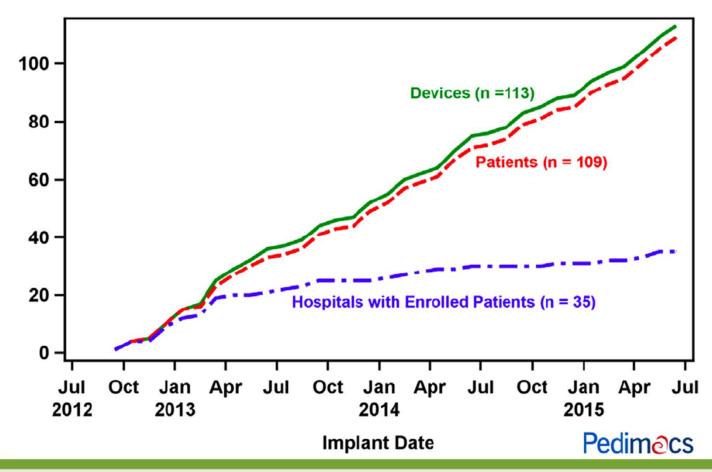
HEARTWARE







CONTINUOUS FLOW VADS



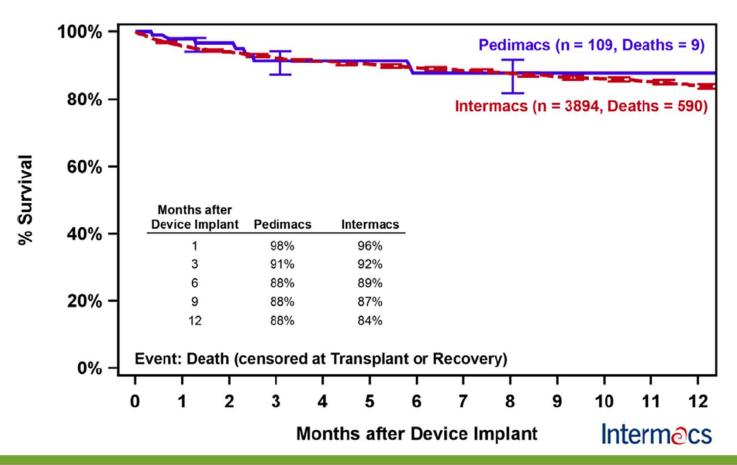


CONTINUOUS FLOW VADS IN CHILDREN

Characteristics	PediMACS $(n = 109)$	INTERMACS $(n = 3,894)$
Age. median [vears (range)]	15 (0.6–18.9)	56 (19.0-84.1)
<6 years [<i>n</i> (%)]	4 (4)	NA
6–10 years [<i>n</i> (%)]	17 (16)	NA
11–18 years [<i>n</i> (%)]	88 (81)	NA
19–30 years [<i>n</i> (%)]	NA	225 (6)
31–50 years [<i>n</i> (%)]	NA	1,088 (28)
51–70 years [<i>n</i> (%)]	NA	2,521 (65)
> 70 years [<i>n</i> (%)]	NA	60 (2)
Weight, median [kg (range)]	62 (16–141)	86 (9–258)
<20 kg [<i>n</i> (%)]	4 (4)	2 (1)
20–40 kg [<i>n</i> (%)]	21 (19)	39 (1)
41–70 kg [<i>n</i> (%)]	47 (43)	826 (21)
70–100 kg [<i>n</i> (%)]	28 (26)	2,059 (53)
> 100 kg [<i>n</i> (%)]	9 (8)	963 (25)



SURVIVAL ON CONTINUOUS FLOW VADS

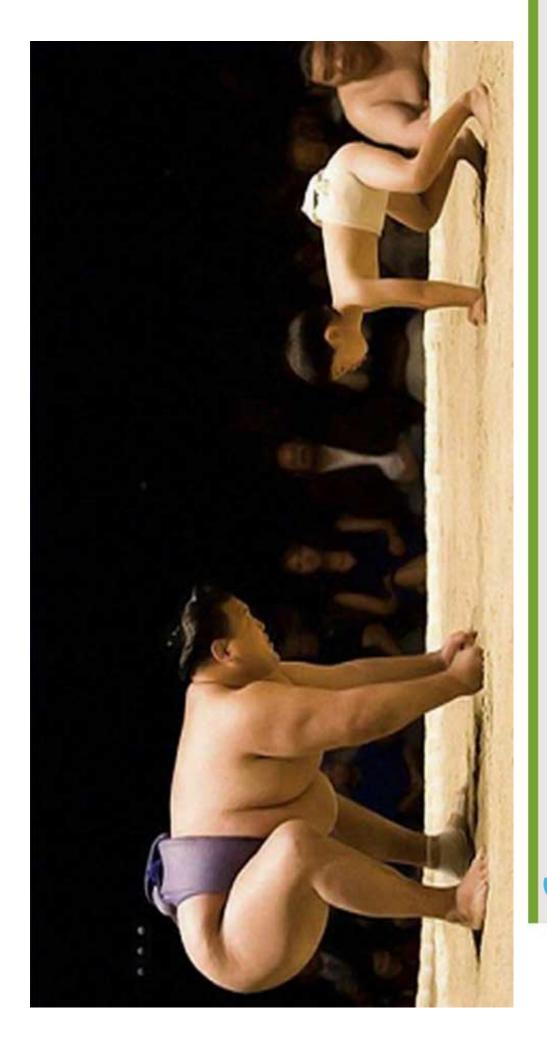




ADVERSE EVENTS

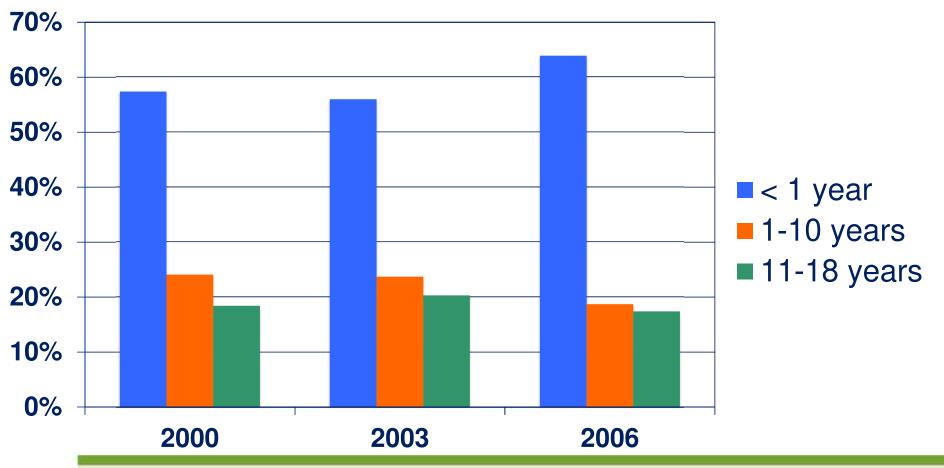
	PediMACS (n = 109)				INTERMACS (n = 3,894)			
Adverse event type	Early events	Early event rate	Late events	Late event rate	Early events	Early event rate	Late events	Late event
Arterial non-CNS thromboembolism	2	0.9	0	0.0	45	0.4	9	0.03
Bleeding	31	14.2	6	2.2	1,342	12.8	884	2.7
Cardiac arrhythmia	15	6.9	2	0.8	1,031	9.8	370	1.1
Device malfunction	6	2.8	10 ^a	3.7 ^a	261	2.5	390ª	1.1 ^a
Hepatic dysfunction	4	1.8	0	0.0	110	1.0	49	0.2
Infection	28	12.9	12	4.5	1,319	12.5	1,267	3.9
Myocardial infarction	0	0.0	0	0.0	4	0.04	9	0.03
Neurologic dysfunction	9	4.1	2	0.8	433	4.1	425	1.3
Other serious adverse event	15ª	6.9 ^a	3	1.1	1,322	12.6ª	612	1.9
Pericardial drainage	9ª	4.1 ^a	0	0.0	148ª	1.4ª	7	0.02
Psychiatric episode	9ª	4.1 ^a	0	0.0	192ª	1.8ª	81	0.2
Rehospitalization	30	13.8	44	16.5	2,077	19.7	5,281	16.2
Renal dysfunction	6	2.8	1	0.4	353	3.4	115	0.3
Respiratory failure	14	6.4	0	0.0	633	6.0	173	0.5
Venous thromboembolism	1	0.5	0	0.0	114	1.1	12	0.04
Wound dehiscence	0	0.0	1	0.4	38	0.4	13	0.04







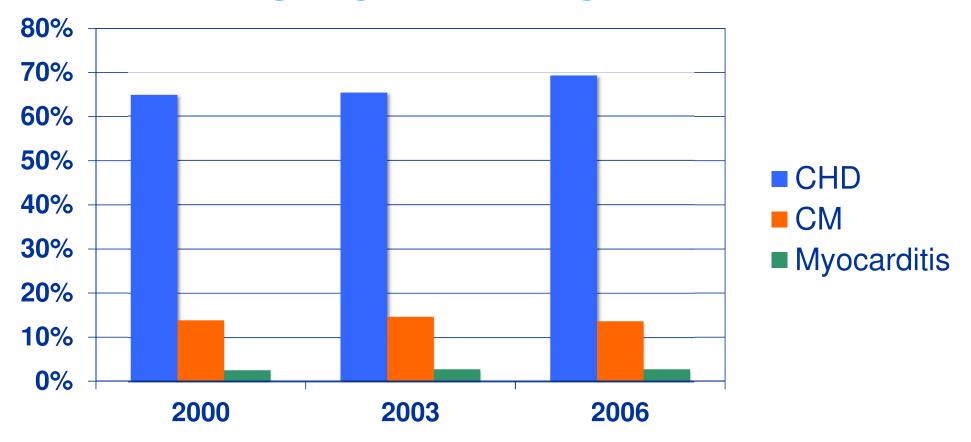
AGE AT ADMISSION





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DISEASE MATTERS





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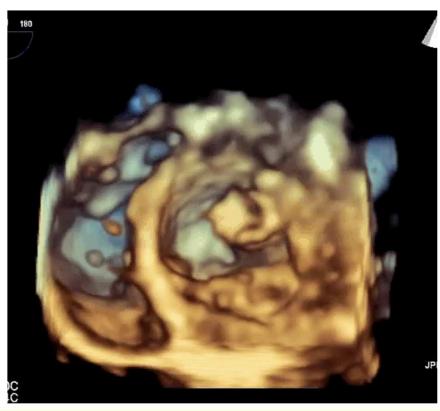
FIT STUDIES





INTRAOPERATIVE ECHOCARDIOGRAM







INNOVATIVE SURGERY

Systemic Atrioventricular Valve Excision and Ventricular Assist Devices in Pediatric Patients

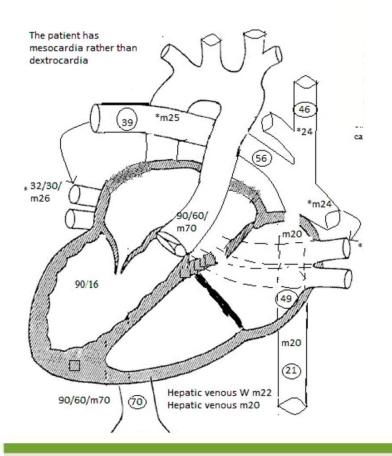


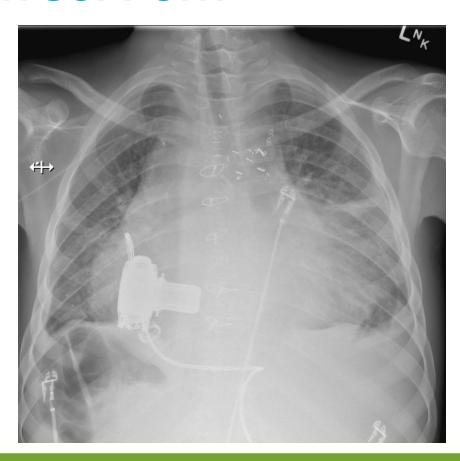
Deipanjan Nandi, MD, Kelley D. Miller, CPNP, Carley M. Bober, CRNP, Tami M. Rosenthal, MBA, Lisa M. Montenegro, MD, Joseph W. Rossano, MD, J. William Gaynor, MD, and Christopher E. Mascio, MD

Division of Cardiology, Department of Perfusion Services, Department of Anesthesia & Critical Care Medicine, and Division of Cardiothoracic Surgery, Cardiac Center, The Children's Hospital of Philadelphia, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania



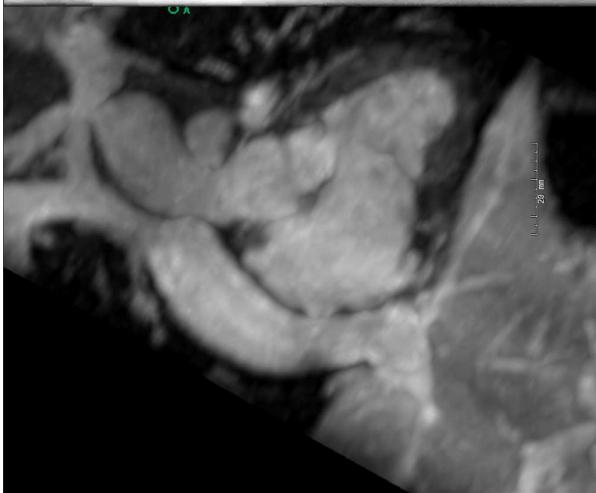
FONTAN SUPPORT











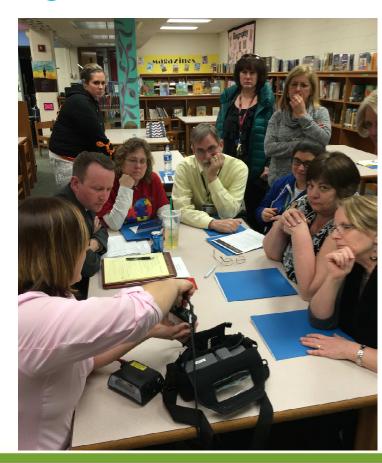
FONTAN PATIENT ON HEARTWARE





SCHOOL TRAINING



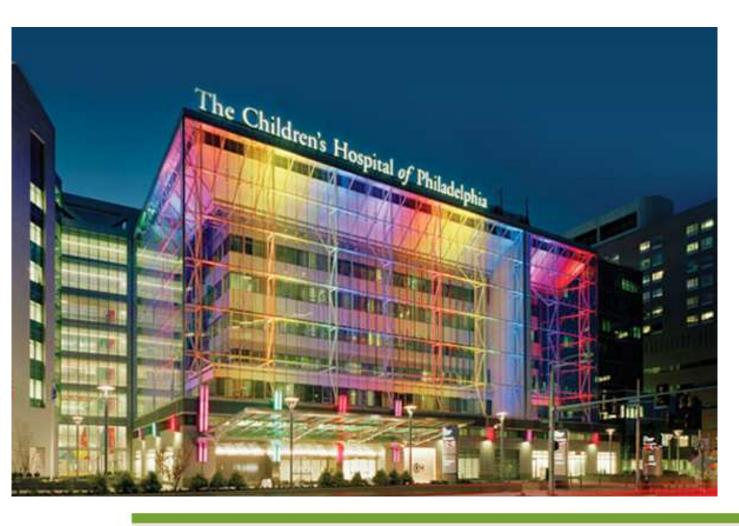




CONCLUSION

- Tremendous advancements in mechanical circulatory support for children over the last decade
- Off-label use of continuous flow devise is common in the management of advanced heart failure in children Excellent outcomes
- Better support options are needed for small children and those with complex congenital heart disease

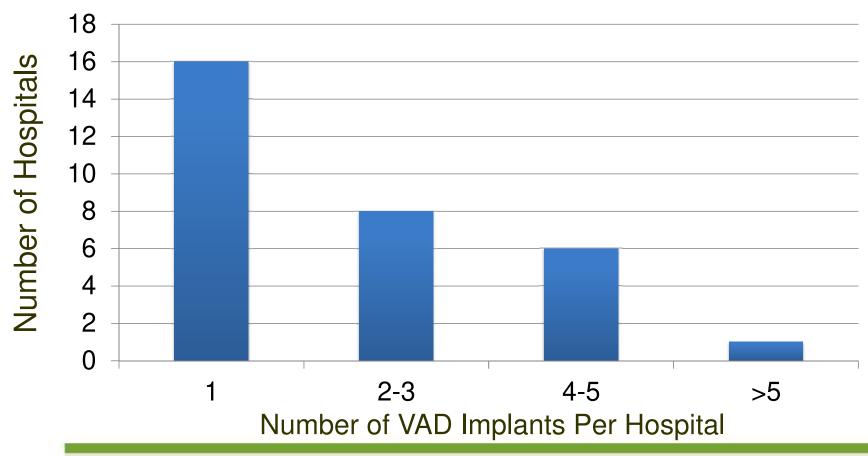




Thank You



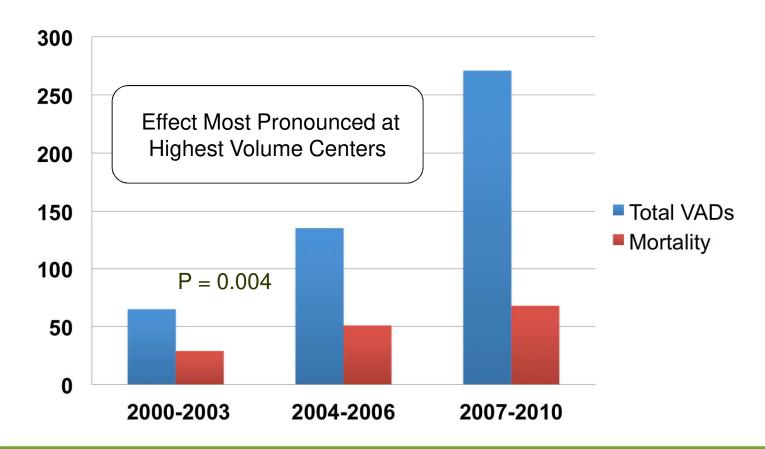
CONTINUOUS FLOW VADS AND HOSPITAL VOLUME





Rossano JW, et al. JHLT 2016

VAD UTILIZATION & OUTCOMES





WORLDWIDE PHENOMENON

