CONGENITAL CARDIOLOGY TODAY
Timely News & Information for Congenital/Structural Cardiologists & Cardiothoracic Surgeons Worldwide
International Edition
Vol. 20 - Issue 12
December 2022

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Comparison of Patent Ductus Arteriosus Stent and Blalock-Taussig Shunt as Palliation for Neonates with Sole Source Ductal-Dependent Pulmonary Blood Flow: Results from the Congenital Catheterization Research Collaborative

Bauser-Heaton H, Qureshi AM, Goldstein BH, Glatz AC, Ligon RA, Gartenberg A, Aggarwal V, Shashidharan S, McCracken CE, Kelleman MS, Petit CJ.
Pediatr Cardiol. 2022 Jan;43(1):121-131. doi: 10.1007/s00246-021-02699-7. PMID: 34524483

Commentary from Dr. Manoj Gupta

Take Home Points

1. Patent ductus arteriosus (PDA) stenting is an accepted method for securing pulmonary blood flow in cyanotic neonates. In neonates with pulmonary atresia and single source ductal-dependent pulmonary blood flow (SSPBF), PDA stenting remains controversial.
2. Thirty-five patients with PDA stents and 156 patients with BTS were included. Interstage reintervention rates were higher in the PDA stent cohort (48.6% vs. 15.4%, p<0.001).
3. This study supports the use of PDA stenting as a form of palliation in neonates with single source ductal-dependent pulmonary blood flow (SSPBF).

Introduction

In the most recent *American Heart Association* Scientific Statement, PDA stenting in the setting of SSPBF received a Class IIb recommendation of "might be reasonable." The authors hypothesized that, SSPBF as a barrier to PDA stenting may be overcome as centers and operators gain experience with the technical approach to stenting and supporting labile neonates with a single, prostaglandin-sensitive source of pulmonary blood flow. Children's Hospital of Atlanta, Cincinnati Children's Hospital Medical Center, Texas Children's Hospital, and Children's Hospital of Philadelphia cohorts were analyzed during this study from January 2008 to December 2015.

Methods

Patients included in the cohort had a congenital cardiac diagnosis consistent with ductal dependent SSPBF and underwent Blalock-Taussig Shunt (BTS) or PDA stent palliation in the neonatal period (≤30 days of age). Procedural outcomes, including complications,

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length of stay (LOS), need for post-procedural inotropic support, mechanical ventilation, and diuretic use post-palliation, were collected. Branch pulmonary artery diameter (measured at the hilum) was reviewed at the time of initial palliation, as well as immediately prior to definitive surgical repair or next palliative stage (e.g., bidirectional Glenn anastomosis) using available imaging. "Reintervention" was defined as those exclusively on the PDA stent or the BTS if the reintervention occurred prior to surgical repair or planned palliation and was focused solely on the shunt or stent itself and did not involve the branch pulmonary arteries or other areas.

Results

During the study period, 191 neonates with SSPBF underwent either PDA stent (n=35) or BTS (n=156). The baseline characteristics of the two cohorts were equivalent with a few notable exceptions. The PDA stent cohort was composed of more neonates with pulmonary atresia and intact ventricular septum (PA-IVS) compared with the BTS cohort (49% vs 28%, p=0.022). Single ventricle heart disease, presence of genetic syndrome, and pre-intervention clinical status were similar between the cohorts. Following initial palliation, ICU LOS was not different between the two cohorts (median ICU LOS 10 days for PDA and 7 days for BTS, p = 0.341). Hospital LOS was also similar between groups (p=0.178). The PDA stent cohort was less likely to receive inotropic support (p<0.01) or to be discharged on diuretics (OR 0.45, 95% CI [0.21–0.97], p = 0.042).

Complications and Reinterventions

Procedural complications occurred in both groups at similar rates. However, major procedural complications occurred in nine infants undergoing BTS and in no patients undergoing PDA stenting (p= 0.146). Adjusted analysis indicated no difference in overall rates of complications between PDA stent and BTS cohorts.

Reintervention was more common in the PDA stent cohort when comparing any reintervention or reintervention on the shunt or stent itself. Reintervention on the PDA stent itself was more common than on the BTS (adjusted p < 0.001). Similarly, the rate of any reintervention following initial palliation was higher in the PDA stent cohort (adjusted p < 0.001). When considering timing of reintervention, it appears that the greatest period of risk for reintervention was >1 month from initial palliation.

Table 2 *Outcomes based on treatment strategy*

Outcome	*n*	PDA stent *n* = 35 (18.3%)	BT shunt *n* = 156 (81.7%)	*p*
Any reintervention	191	19 (54.3%)	34 (21.8%)	**< 0.001**
Reintervention on ductal stent or surgical shunt	191	17 (48.6%)	24 (15.4%)	**< 0.001**
Procedural complications	191	5 (14.3%)	28 (17.9%)	0.60
Major procedural complications	191	0 (0.0%)	9 (5.8%)	0.15
Death	191	5 (14.3%)	20 (12.8%)	0.79
Age at death, days		20 (15–105) Min, max 10;189	60 (18–80) Min, max 8, 198	0.91
Diuretic use at discharge	187	18 (52.9%)	109 (71.2%)	**0.04**
Total duration of ventilation, days	190	2 (1–13)	2 (1–5)	0.59
Duration of inotrope use, days	188	0 (0–0)	2 (0–4)	**< 0.001**
ECMO use post-procedure	190	2 (5.7%)	8 (5.2%)	1.00
Antiplatelet/anticoagulation use at hospital discharge	191	32 (91.4%)	144 (92.3%)	0.74
Age at definitive surgery, days	153	180 (150–214)	162 (125–200)	0.43
Time from first intervention to definitive surgery, days	158	172 (144–185)	148 (117–191)	0.41
Definitive surgical repair				
Stage 2 palliation	186	13 (39.4%)	83 (54.2%)	0.13
Complete anatomic repair		9 (27.3%)	41 (26.8%)	
Other		4 (12.1%)	6 (3.9%)	
None needed		2 (6.1%)	3 (2.0%)	
Planned but has not yet occurred		5 (15.2%)	20 (13.1%)	
PA plasty performed at definitive surgical repair	152	15 (60.0%)	54 (42.5%)	0.11
PA intervention following definitive surgical repair/staged palliation	153	3 (12.0%)	29 (22.7%)	0.23

Bold values indicate statistical significance ($p < 0.05$)

Table 6 *Unadjusted and adjusted effects of treatment strategy on PA growth outcomes*

Continuous outcome	*n*	Unadjusted			Adjusted
		PDA stent	BT shunt	*p* value	*p* value
Model[a]					
PA symmetry index, initial	179	0.81 (0.72–0.92)	0.87 (0.79–0.95)	0.081	**0.02**
PA symmetry index, at stage II or definitive repair	166	0.88 (0.77–0.97)	0.82 (0.71–0.92)	0.059	0.86
Change in PA symmetry	160	0.07 (− 0.10 to 0.17)	− 0.06 (− 0.19 to 0.07)	**0.007**	0.45
Nakata index (mm^2/m^2), initial	166	109 (70–149)	128 (96–157)	0.125	0.07
Nakata index (mm^2/m^2), at stage II or definitive repair	143	158 (117–226)	148 (98–248)	0.661	0.17
Change in Nakata index	133	50 (− 29 to 131)	24 (− 28 to 113)	0.716	0.16

Bold values indicate statistical significance ($p < 0.05$)

Pulmonary Artery Growth & Interventions

The pulmonary arteries were somewhat smaller pre-intervention in the PDA stent cohort (unadjusted median Nakata index 109 mm2 /m2, 25th–75th 70–149) compared with the BTS cohort (unadjusted Nakata index 128 mm2 /m2 , 25th–75th 96–157, adjusted p=0.071).

The increase in Nakata index from palliation to definitive repair or bidirectional Glenn was not statistically significant between cohorts. Interestingly, the branch pulmonary arteries were more asymmetric at the time of initial palliation in the PDA stent cohort (PA symmetry index 0.81, 25th–75th 0.72–0.92) compared with the BTS cohort (PA symmetry index 0.87, 25th–75th 0.79–0.95, adjusted p=0.016). At time of surgical repair or palliation, pulmonary artery symmetry was similar, with a symmetry index of 0.88 (25th–75th 0.77–0.97) in the PDA stent cohort compared with 0.82 (25th–75th 0.71–0.92), p= 0.857). At time of definitive surgical repair or staged surgical palliation, surgical pulmonary artery plasty was common in both cohorts, with 60.0% of the PDA stent cohort and 42.5% of the BTS cohort undergoing pulmonary artery plasty.

Discussion

Although overall complication rates were equivalent, complications were more severe in the BTS group. The group palliated with PDA stenting underwent a higher rate of reinterventions compared with the surgical BTS group. Importantly, the two palliative cohorts had similar measures of PA growth, symmetry, and size at time of definitive repair/palliation, suggesting that candidacy for surgical repair or single ventricle palliation was preserved regardless of palliative modality. The current study does not include an equal balance of BTS and PDA stent patients and does not include data on any unsuccessful PDA stent "attempts." The late reinterventions noted in the PDA stent cohort likely relate to the known issues of neointimal proliferation which commonly occurs in infants following PDA stenting and appears to be more common in infants with highly tortuous Type III PDAs.

Conclusion

While PDA anatomy and the SSPBF physiology pose challenges, PDA stenting appears to offer equivalent clinical outcomes and durability as an initial palliative strategy compared with surgical BTS.

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This article was originally published by the CHiP Network, Comparison of Patent Ductus Arteriosus Stent and Blalock-Taussig Shunt as Palliation for Neonates with Sole Source Ductal-Dependent Pulmonary Blood Flow: Results from the Congenital Catheterization Research Collaborative.

MANOJ GUPTA, MD

Chief Section Editor of Pediatric & Fetal Cardiology Journal Watch
CHiP Network
New York City, NY, USA

Nationwide Registry-Based Analysis of Infective Endocarditis After Pulmonary Valve Replacement

Stammnitz C, Huscher D, Bauer UMM, Urban A, Nordmeyer J, Schubert S, Photiadis J, Berger F, Klaassen S; German Competence Network for Congenital Heart Defects Investigators.J Am Heart Assoc. 2022 Mar;11(5):e022231. doi: 10.1161/JAHA.121.022231. Epub 2022 Feb 18.PMID: 35179045

Commentary from Dr. Shailendra Upadhyay

Take Home Points

- Bovine jugular vein valves (Contegra/Melody) have the highest risk of infective endocarditis, irrespective of the mode of deployment (surgical or percutaneous)
- Male sex and higher number of previous pulmonary valve replacements increase risk of infective endocarditis

This study is the largest retrospective analysis of the German NR-CHD (National Register for Congenital Heart Defects) comparing the risk of infectious endocarditis (IE) after percutaneous pulmonary valve implantation or surgical pulmonary valve replacement in Congenital Heart Disease.

TABLE 3 *Impact Factors on the Occurence of IE in Multivariable Cox-Regression*

	HR (95% CI)	*P* value
All types of PVR		
Type of PVR		
Homograft	1	
Heterograft excl. Contegra	2.60 (0.91–7.43)	0.075
Contegra	6.72 (2.80–16.16)	<0.001
Melody	5.49 (2.12–14.19)	<0.001
Sex		
Female	1	
Male	1.81 (1.02–3.20)	0.044
No. of previous PVR	1.45 (1.04–2.00)	0.026
Age at study inclusion, y	1.02 (0.99–1.04)	0.141
Subgroup with Contegra or Melody		
Type of PVR		
Contegra	1	
Melody	1.01 (0.44–2.32)	0.978
Sex		
Female	1	
Male	1.34 (0.71–2.52)	0.365
No. of previous PVR	1.36 (0.92–2.02)	0.127
Age at study inclusion, y	1.02 (0.99–1.05)	0.200

HR indicates hazard ratio; IE, infective endocarditis; and PVR, pulmonary valve replacement.

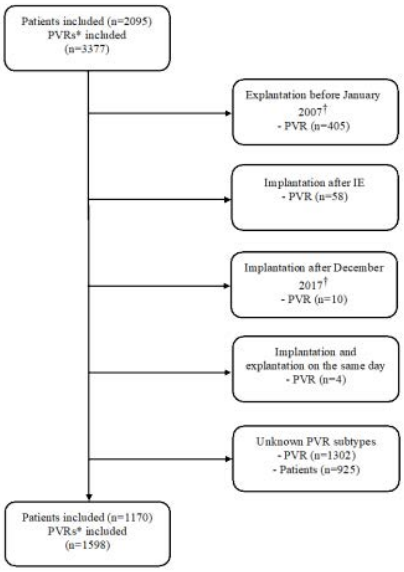
All patients with CHD with at least one surgical pulmonary valve replacement (SPVR) or percutaneous pulmonary valve replacement (PPVI) before January 1, 2018 (January 2007-Dec 2017) were included and followed up for the combined end point (grafts infected or explanted, or the patient was deceased).

The study included 1170 patients (median age 12, 5-20 years, 56% males, 68% < 18 years) that included 1598 surgical pulmonary valve replacement (SPVR) including – aortic/pulmonary homograft, heterograft including Contegra, bio-prosthetic valved conduits using Bovine/Porcine materials, mechanical valves and percutaneous pulmonary valve implantation (PPVR) including Melody and Edward Sapien valves.

Diagnoses included: Tetralogy of Fallot (TOF) – most common, Truncus Arteriosus, Aortic stenosis and s/p Ross operation. Total follow-up was 9397 years (per patient median 10 years). Clinical characteristics of patients is noted in **Table 2**.

IE occurred in 4.8% during a 10-year median follow-up (6-10 years), **Tables 1** and **2.**

FIGURE S1 *Study flow chart*



Study design for the recruitment of patients with PVR in the National Register for Congenital Heart Defects, Berlin, Germany. *Number of PVR in the patients. †Cases of pulmonary-valve-related IE were recorded during the period of January 1st, 2007 until December 31st, 2017.
PVR, pulmonary valve replacement; IE, infective endocarditis; CHD, congenital heart defect.

TABLE 1 *Study population*

		PPVI			SPVR					
	Patients	Total	Melody	Edwards Sapien	Total	Heterograft excluding Contegra	Contegra	Homograft	Mechanical valve	*P* value*
No. of PVR, n (%)	1598 (100)	293 (18.3)	241 (15.1)	52 (3.3)	1305 (81.7)	278 (17.4)	445 (27.8)	558 (34.9)	24 (1.5)	
No. of patients, n (%)†	1170 (100)	279 (23.9)	230 (19.7)	52 (4.4)	1096 (93.7)	251 (21.5)	403 (34.4)	523 (44.7)	24 (2.1)	
Male sex, n (% of patients)	659 (56.3)	169 (60.6)	138 (60.0)	33 (63.5)	622 (56.8)	140 (55.8)	242 (60.0)	297 (56.8)	8 (33.3)	0.088
Age at implantation of PVR, y‡	11 (4–17)	17 (13–26)	16 (13–24)	19 (13–29)	9 (3–16)	12 (5–19)	4 (0–9)	12 (5–18)	17 (9–22)	<0.001
PVR size, mm‡§	20 (17–23)	22 (20–22)	21.5 (20–22)	23 (23–26)	20 (16–23)	22 (18–25)	16 (14–20)	22 (20–24)	23 (21–25)	<0.001
IE, n (%)	56 (4.8‖)	18 (6.1)¶	18 (7.5)¶	0	38 (2.9)¶	7 (2.5)¶	24 (5.4)¶	7 (1.3)¶	0	<0.001
Previous PVR‡	0 (0–1)	1 (1–2)	1 (1–2)	1 (1–2)	0 (0–1)	0 (0–1)	0 (0–1)	0 (0–1)	0 (0–1)	<0.001
Age at first PVR, y‡	5 (0–14)	4 (0–12)	4 (0–11)	10 (0–18)	5 (0–14)	6 (0–17)	1 (0–6)	6 (1–15)	11.5 (4–19)	<0.001
Age at study inclusion, y‡	12 (5–20)	13 (8–20)	13 (8–20)	13.5 (8.5–24)	12 (5–20)	12 (5–19)	5 (1–10)	16 (9–22)	22.5 (17–32)	<0.001
<18 y at study inclusion, n (%)	792 (67.7)	191 (68.5)	160 (69.6)	32 (61.5)	749 (68.3)	174 (69.3)	372 (92.3)	294 (56.2)	7 (29.2)	
≥18 y at study inclusion, n (%)	378 (32.3)	88 (31.5)	70 (30.4)	20 (38.5)	347 (31.7)	77 (30.7)	31 (7.7)	229 (43.8)	17 (70.8)	
Follow-up, y‡	10 (6–10)‖	4 (2–6)¶	4 (2–6)¶	3.5 (2–5)¶	6 (3–10)¶	5 (2–8)¶	5 (2–8)¶	7 (4–10)¶	10 (8–10)¶	<0.001
Patient-years of follow-up	9397‖	1180¶	1001¶	179¶	7553¶	1423¶	2311¶	3613¶	206¶	

IE indicates infective endocarditis; PPVI, percutaneous pulmonary valve implantation; PVR, pulmonary valve replacement; and SPVR, surgical pulmonary valve replacement.
*Melody, Edwards Sapien, heterografts excluding Contegra, Contegra, homografts, and mechanical valves were compared.
†Some patients had different pulmonary valve replacement over the observation period.
‡Median (interquartile range).
§The pulmonary valve replacement size was known in 1247 (78.0%) of 1598 pulmonary valve replacement.
‖Calculated based on the number of patients.
¶Calculated based on the number of pulmonary valve replacement.

FIGURE 1 *Survival free from infective endocarditis (IE)*

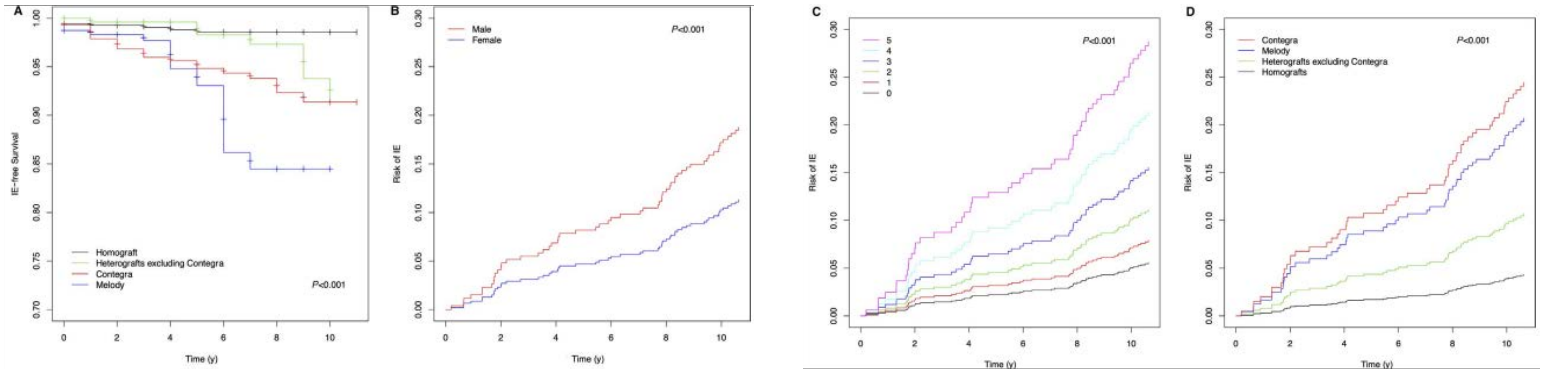


TABLE S4 *Impact factors on the occurrence of IE in univariable Cox-regression*

	All patients		Female sex		Male sex		Patients <18 years at study inclusion		Patients ≥18 years at study inclusion	
Subgroup	HR (95% CI)	P-value	HR (95% CI)	P-value	HR (95% CI)	P-value	HR (95% CI)	P-value	HR (95% CI)	P-value
Type of PVR										
Homograft	1		1		1		1		1	
Heterograft Excl. Contegra	2.60 (0.91-7.43)	0.074	2.44 (0.15-39.06)	0.528	2.76 (0.89-8.58)	0.079	3.14 (0.89-11.15)	0.076	1.19 (0.12-11.41)	0.883
Contegra	5.62 (2.42-13.07)	<0.001	13.55 (1.69-108.48)	0.014	4.25 (1.65-10.91)	0.003	5.12 (1.75-14.97)	0.003	8.06 (1.63-39.98)	0.011
Melody	7.81 (3.20-19.05)	<0.001	22.90 (2.78-188.30)	0.004	5.01 (1.79-14.01)	0.002	6.05 (1.89-19.40)	0.002	12.05 (3.00-48.32)	<0.001
PVR size (mm) *	0.97 (0.89-1.04)	0.371	0.95 (0.82-1.11)	0.545	0.96 (0.88-1.06)	0.417	1.02 (0.93-1.12)	0.610	0.85 (0.65-1.11)	0.233
Sex										
Female	1		-		-		1		1	
Male	1.95 (1.10-3.44)	0.022	-		-		2.03 (1.02-4.04)	0.044	1.57 (0.54-4.51)	0.407
Number of previous PVR	1.63 (1.23-2.17)	<0.001	1.41 (0.82-2.40)	0.214	1.71 (1.22-2.39)	0.002	1.71 (1.21-2.42)	0.002	1.39 (0.79-2.45)	0.255
Age at study inclusion, yrs	0.99 (0.97-1.02)	0.569	1.01 (0.97-1.05)	0.586	0.99 (0.96-1.02)	0.450	-		-	-
<18	1		1		1		-		-	-
≥18	0.63 (0.86-2.89)	0.139	0.81 (0.46-3.35)	0.674	0.62 (0.75-3.53)	0.222	-		-	-

IE, infective endocarditis; PVR, pulmonary valve replacement; n.a., not applicable; HR, hazard ratio; CI, confidence interval.*PVR size was known in 1247/1598 PVR

FIGURE 2 *Characteristics of patients with IE after PVR*

	Patients	Melody	SPVR				*P* value*
			Total	Heterograft excluding Contegra	Contegra	Homograft	
Patients with IE/patients with PVR, n (%)	56/1170 (4.8)	18/230 (7.8)	38/1096 (3.5)	7/251 (2.8)	24/403 (6.0)	7/523 (1.3)	
PVR with IE/ number of PVR, n (%)	56/1598 (3.5)	18/241 (7.5)	38/1305 (2.9)	7/278 (2.5)	24/445 (5.4)	7/558 (1.3)	
Male sex, n (% of patients)	39 (69.6)	11 (61.1)	28 (73.7)	6 (85.7)	16 (66.7)	6 (85.7)	0.579
PVR size, mm†,‡	20 (18–22)	19 (18–22)	20 (17–22)	25 (20–26)	20 (16–20)	21.5 (16.5–23)	0.071
Age at implantation of PVR, y†	13.5 (9–20)	16 (14–24)	11 (5–18)	18 (9–22)	9 (4–12)	18 (12–21)	0.002
Age at IE, y†	16.5 (13–24)	21.5 (16–29)	15 (11–21)	23 (13–27)	13 (9–18)	19 (12–32)	0.004
Time between PVR and IE, y†	4 (1–6)	5 (2–6)	3 (1–7)	5 (2–11)	3 (1–6)	0 (0–5.5)	0.231
Time between IE and next PVR, mo†	2 (0–8)	0 (0–2)	3 (0–12)	2 (0–25)	3 (0–12)	6 (1–26)	0.193
Previous PVR†	1 (0–2)	1 (1–2)	0 (0–1)	1 (0–2)	0 (0–1)	0 (0–2)	0.006
Age at first PVR, y†	3.5 (0–12)	2.5 (0–9.5)	6 (0–12)	9 (1–16)	4 (0–10)	12 (0–21)	0.437
Time between first PVR and IE, y†	11 (3–16)	18 (13.5–21)	7.5 (2–13)	13 (7–15)	4 (2–11)	5.5 (0–15)	<0.001
Age at study inclusion, y†	12 (7–18)	14.5 (10–21.5)	10.5 (4.5–16)	16 (9–17)	9 (3–13)	12 (7–30)	0.039
<18 y at study inclusion, n (%)	42 (75.0)	11 (61.1)	31 (81.6)	6 (85.7)	21 (87.5)	4 (57.1)	
≥18 y at study inclusion, n (%)	14 (25.0)	7 (38.9)	7 (18.4)	1 (14.3)	3 (12.5)	3 (42.9)	
Pathogen§							0.014‖
Staphylococci, n (%)	18 (32.1)	11 (61.1)	7 (18.4)	1 (14.3)	4 (16.7)	2 (28.6)	
Streptococci, n (%)	15 (26.8)	5 (27.8)	10 (26.3)	3 (42.9)	7 (29.2)	0	
Other pathogens, n (%)	8 (14.3)	1 (5.6)	7 (18.4)	2 (28.6)	4 (16.7)	1 (14.3)	

IE indicates infective endocarditis; PVR, pulmonary valve replacement; and SPVR, surgical pulmonary valve replacement.
*Melody valves, heterografts excluding Contegra, Contegra valves, and homografts, were compared.
†Median (interquartile range).
‡The pulmonary valve replacement size was known in 35 (62.5%) of 56 pulmonary valve replacements.
§Negative blood culture in one case (heterograft), and not available in 14 (25.0%) cases (4 homografts, 1 heterograft excluding Contegra, 8 Contegra valves, 1 Melody valve).
‖Staphylococci were compared with other pathogens.

IE After homograft 1.3%; IE After heterograft 4.3% [Heterograft non Contegra 2.5% and Contegra 5.4%]; IE After Melody 7.5%. IE showed no significance influence on the overall survival of the patients ([HR], 3.57; P=0.20).

Bovine jugular vein valves (Contegra and Melody) had the highest risk of IE, **Table S4**, irrespective of the mode of deployment, either surgical or percutaneous. In the multivariable analysis, the risk of IE was increased in the male sex, in patients with a higher number of previous pulmonary valve replacement and for bovine jugular vein valves (with a similar risk for Melody versus Contegra valves), **Table 3.**

Conclusion

- Homograft or non Contegra heterograft replacement has the least risk of IE.
- Bovine jugular valves (Contegra/Melody) have the highest risk of IE whether deployed surgically or percutaneously.
- Male sex and higher number of previous PVR add significant IE risk.
- Other significant risk factors for IE are male sex and higher numbers of previous PVR.
- The Edwards-Sapien valve may be useful for PPVI in high-risk subgroups for IE, however data are limited.

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This article was originally published by the CHiP Network,
Nationwide Registry-Based Analysis of Infective Endocarditis Risk After Pulmonary Valve Replacement.

SHAILENDRA UPADHYAY, MD

Section editor of ACHD Journal Watch
CHiP Network
Connecticut, USA

PICS Society Symposium 2022 Chicago: Highlights

Kamel Shibbani, MD

This month we would like to celebrate the success of our recent 25th Anniversary PICS Symposium in the windy city of Chicago. We would like to revisit some of the highlights of that milestone event this past September at this eagerly anticipated "back together again" and VERY well-attended meeting!

Preceding the meeting, Drs. Vivian Dimas and Darren Berman led the second annual PICS Fellows and Early Career (FEC) course, an intensive two-day session that provided tomorrow's future leaders opportunities to complement the training received at their home institutions, hone their skills on a variety of simulators, network with their peers and much more. This unique course has quickly become a 'must attend' event for all CHD interventionalists in-training or early in their careers.

Dr. Hijazi then began the Symposium's 25th Anniversary with a welcome speech that highlighted developments with the meeting and with the PICS Society overall. He noted the importance of attendees joining the PICS Society and taking advantage of important membership benefits:

1. Free subscription to the Society's official journal, *Pediatric Cardiology* (thank you Editor-In-Chief Dr. Karim Diab)
2. Free membership in the highly successful PICS/CCISC DocMatter Community (thank you B. Braun Interventional Systems Inc. and NuMED)
3. Opportunities for committee service
4. Free subscription to our official News & Information partner, *Congenital Cardiology Today*

SAVE THE DATES
TWO Exciting PICS Meetings in 2023

PICS Istanbul
March 15th – 18th, 2023
in partnership with the Turkish Society/ Association of Pediatric Cardiology and Cardiac Surgery, and with the Interventional Pediatric Cardiology (IPC) meeting led by Dr. Mario Carminati.
www.picsistanbul.com

PICS 26th Annual Symposium
August 27th – September 1st, 2023
in Washington DC, embedded within the 8th World Congress of Pediatric Cardiology and Cardiac Surgery.
www.wcpccs2023.org

New this year to PICS was a dedicated Lymphatics Session chaired by Dr. Yoav Dori. This exciting new field has the potential to dramatically increase options for treating our patients. A half-day just scratched the surface BUT was an important beginning. Watch for much more to come.

The meeting continued the tradition of live cases with excellent educational cases from Chicago, Ohio, Minnesota, Canada, Qatar, and for the first time (and very proudly so) from Egypt (thank you Dr. Maiy H. El Sayed). The conference included six main sessions and ten breakout sessions, with topics spanning the spectrum from fetal interventions and neonates to Adult Congenital Heart Disease.

Day one, cases filled the morning schedule while the main afternoon session focused on imaging with updates on 3DRA, CT Image Guidance for Transthoracic Pulmonary Vein Recanalization, and Integrating CT into Cath Interventions. The afternoon also included a well-attended breakout session on "Things we Have Always Wanted in Our Toolbox That May Actually Almost be Here," as well as important talks from the FDA covering regulatory considerations past, present and potentially in the future. Oral abstracts concluded the first day, followed by a PICS Society Welcome Reception for networking and renewing old friendships after so many months of Zooming!

The second day at the PICS Society Symposium 2022 continued with a busy and informative program. Live case transmissions continued in the morning from nearby institutions in Chicago. Our industry partners put forth lunch symposiums that focused on special devices and techniques, before the afternoon sessions of the second day began. The much-awaited lymphatic session took the lion's share of the second afternoon. Breakout sessions also included topics on: complication prevention in the cath lab, nuances of newly approved devices, a PICES session, and the breakout for our always popular Spanish/Latin session. The PICS Lifetime Achievement Awards concluded the second day, with Drs. Mazeni Alwi, Bharat Dalvi and Carlos Pedra all recognized for their outstanding achievements in the field.

Day three started with a presentation from the Executive Director of the PICS Society, Norm Linsky. He updated attendees as to how, during its short existence, the Society has become the "must join" organization for our global community, in partnership with the many outstanding national and regional societies throughout the world. We then shifted gears to live cases from Ohio and Minnesota, followed by our third-day afternoon sessions. These afternoon sessions covered topics from new transcatheter interventions in Fontan patients to non-cardiac interventions, structural interventions for congenital patients, as well as coarctation from the neonate to the adult. Breakout sessions also included a Nursing and Associated Professionals dedicated session.

The day ended on a very collegial note at the PICS Society social event. We paid special tribute to the winners of the "Young Investigator Award," Drs. Borik and Salavitabar, as well as a special award to our Senior Patient Advocate, Mrs. Natalie Poli. Congratulations to you all!

The final day started with a major focus on our fastest growing patient population: patients with Adult Congenital Heart Disease. The discussion ranged from risk and risk mitigation to performing the reverse Potts shunt, simulation in ACHD interventions, integration of advanced imaging platforms in ACHD interventions, difficult decision making in ACHD interventions and learning curves with new valve technologies in the RVOT. A breakout session covered decisions made in the cath lab involving transcatheter pulmonary valves, COA intervention, PDA stenting, RVOT stenting and pulmonary vein interventions. A session about pmVSD followed, as well as several taped cases. Saving the best for last, the PICS Society's favorite "My Nightmare Case in the Cath Lab" concluded the academic activities for the 2022 PICS Society Symposium.

As in years past, highlights of several key sessions will be available online at CHDinterventions.org. Watch your email for an update.

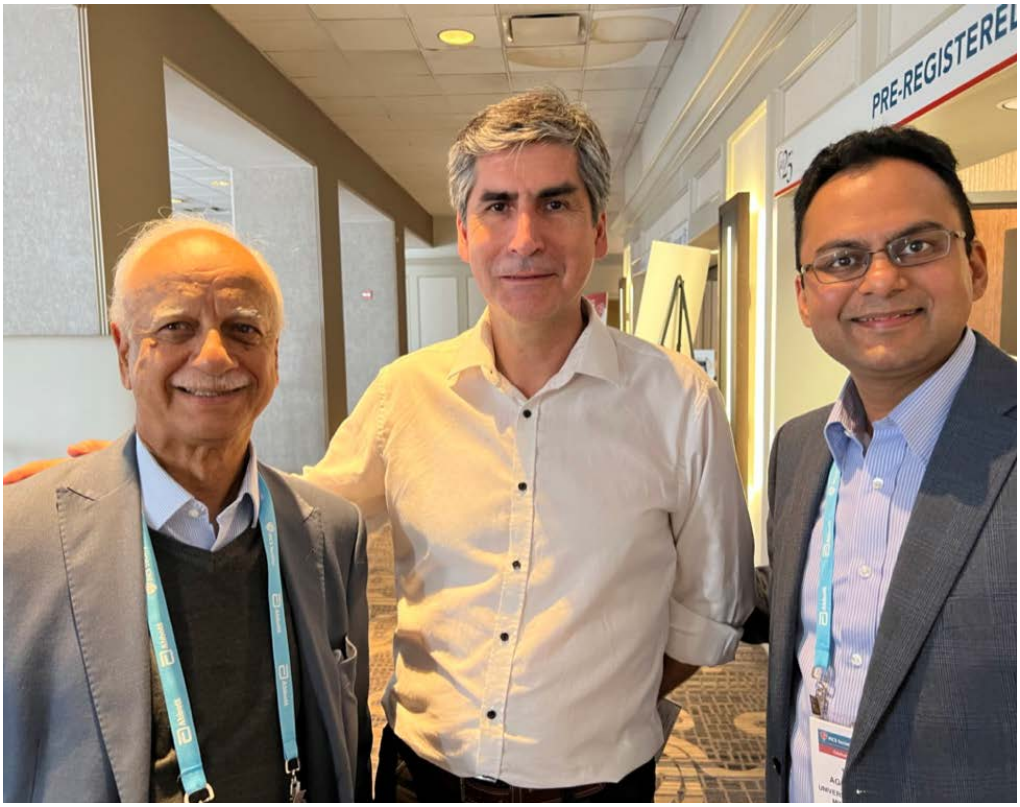
In addition to the formal program, the PICS Symposium is increasingly becoming THE place for your profession to conduct important business. As such, several of the Society's many committees and working groups met and planned future activities. This year the PICS Humanitarian Working Group, the Education Committee, the Working Group on Regulatory Reform and others held highly productive meetings onsite – watch for updates in future columns in CCT.

This meeting would not have been possible without the visionary support of our industry partners, which will be acknowledged separately. Thank you!

We look forward to seeing you in August 2023 at the 26th Annual PICS Symposium as we begin our next quarter century! Also be sure to keep in mind PICS Istanbul in March 2023. As always, PICS is committed to excellence in professional education and "news you can use," along with ample opportunities to learn, network, and most importantly, advance our ability to treat the patients we are honored to serve.

Course Co-Director Dr. Dan Levi leading one of the many hands-on sessions at the Fellows/Early Career Course.

Course Co-Director Dr. Gregor Krings and Ms. Inês Silva, DocMatter Clinical Engagement Specialist. Inês was awarded the PICS Certificate of Special Recognition – congratulations and thank you, Inês!



Sir Dr. Shakeel Qureshi (on left), Dr. Varun Aggarwal (on right) celebrating the induction of Dr. Francisco Garay (center) as a NEW Fellow of the PICS Society (FPICS). Congratulations to Dr. Garay and the many others welcomed into the Society in Chicago.

Heart Rhythm Society Announces Semi-Finalists in First-Ever HRX Pitch Competition

Five Early-Stage Companies Shared Emerging Research and Innovations in Cardiovascular Digital Health

The Heart Rhythm Society (HRS) announced they will showcase innovation and science from five early-stage innovators as part of the HRX 2022 meeting. The Breakthrough Innovations in Cardiovascular Digital Health pitch competition were made possible by an in-kind donation and in collaboration with The Massachusetts Medical Device Development Center.

The semi-finalist teams advanced to the live pitch competition following a selection process review by a panel of five cardiovascular digital health experts. The top three teams will each earn monetary awards: 1st place: $30,000, 2nd place: $15,000, and 3rd place: $10,000.

"With the design of HRX, the Heart Rhythm Society aims to aid and champion organizations making a difference via innovations in digital health," said pitch competition moderator, G. Stuart Mendenhall, MD, FHRS, a cardiac electrophysiologist at Scripps Memorial Hospital in La Jolla, CA. "This arena is a rapidly growing and increasingly important aspect of cardiovascular care, and we aim to help this technology become implemented to improve patient health, improve outcomes, and reduce the costs of heart disease to society."

The five pitch teams will present timely digital health innovations focused on cardiovascular care, with an emphasis on artificial intelligence (AI) and consumer wearables:

- **Anumana:** AI-based electrocardiogram to serve as a deep predictive tool and biomarker of disease
- **General Prognostics (GPx):** The world's first bloodless blood test aiming to eradicate preventable heart failure readmission
- **Relay Response:** Medical software deployed on consumer smartphones and smartwatches for rescuers performing CPR
- **ReadMyRhythm (RMR):** A cloud-based, digital healthcare platform that will identify and diagnose cardiac arrhythmias in consumers with wearable devices
- **TeleHealth Care Solutions LLC (TCS):** VPExam Virtual Care tool to reduce morbidity and mortality in complex cardiac patients

"The Breakthrough Innovations pitch competition embodies the spirt of HRX – we're convening in San Diego to accelerate innovation and transform cardiovascular patient care," said Dr. Ki Chon, Krenicki Chair Professor and Head of Biomedical Engineering at University of Connecticut, who will be serving as one of five pitch competition judges. "Of course, this ambitious goal requires inventive thinking, collaboration, inspiration, and in many instances, funding."

Congratulations to the 2022 HR Pitch Competition Awardees:

- ***First Place:*** **Relay Response**
- ***Second Place:*** **VPExam**
- ***Third Place:*** **Anumana**

About the Heart Rhythm Society

The Heart Rhythm Society (HRS) is the international leader in science, education, and advocacy for cardiac arrhythmia professionals and patients and is the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. Its mission is to eliminate death and suffering due to heart rhythm disorders. Incorporated in 1979 and based in Washington, D.C., it has a membership of more than 7,500 heart rhythm professionals in more than 90 countries around the world. For more information, visit www.HRSonline.org.

Atrium Health Sanger Heart & Vascular Institute Using New Technology to Preserve Donor Hearts for Lifesaving Transplants

New System Keeps a Donated Heart Beating as it's Transported

Atrium Health Sanger Heart & Vascular Institute's heart transplant team is using new technology to keep hearts viable while being transported to a waiting heart transplant recipient. The portable technology, called the TransMedics Organ Care System (OCS), expands the amount of time a donated heart can be suitable for transplant, helping make more donated hearts available for those who need them.

"Once a heart is removed from a deceased donor due to cardiac death, the portable system revives the heart and keeps it beating, infusing it with blood from the donor that is supplemented with nutrients and oxygen," said Dr. Eric Skipper, a cardiothoracic heart transplant surgeon at Atrium Health Sanger Heart & Vascular Institute. "The system also allows us to carefully assess the heart's functional quality and viability for transplant before we reach the operating room to perform the transplant."

According to Skipper, OCS eliminates the time restraints that can require turning down a donated heart. Previously, the Sanger Heart & Vascular Institute transplant team could only accept donor hearts from within a 500-mile radius. That's because there is a 4-hour cold storage limitation for the organ and the travel time between the deceased donor and a patient waiting for a transplant in Charlotte would exceed that. Now, with the use of the new technology, the donor pool has expanded because the heart can be kept viable for up to eight hours and be received from up to 1,000 miles away. It also allows for the acceptance of higher-risk hearts, including those from older donors and donors who are initially put on life support before withdrawing care, referred to as donation after cardiac death donors.

The first patient to receive a donated heart preserved via the new technology at Atrium Health had their transplant completed recently and is currently recovering in the hospital.

"This was a patient who was potentially looking at a long wait for an organ transplant," said Skipper. "But because of the ability to utilize this technology, they were able to receive a heart very quickly."

Sanger Heart & Vascular Institute is the only transplant center in the greater Charlotte region currently using this technology and was identified as an ideal location because it is a high-quality and high-volume transplant center. The transplant team utilized Atrium Health's MedCenter Air to transport the team to and from the donor location.

The U.S. Food and Drug Administration approved the use of this device in April 2022 to preserve hearts for donation after cardiac death. The approval followed results from a multi-center clinical trial comparing the use of the technology to the traditional cold storage method of preserving donated hearts during transport. The study found that using the OCS resulted in 90 patients (of the 180 randomized and transplanted patients) receiving organs that were previously unable to be used prior to this technology. Those recipients had a one-year survival rate of 93.3% compared to an 87.3% one-year survival rate among a control group where OCS was not used.

"We were always limited to accepting organs from donors who suffered immediate brain death," said Dr, Joseph Mishkin, an advanced heart failure transplant cardiologist at Sanger Heart & Vascular Institute. "We now can accept organs from donors who have suffered an irreversible brain injury but do not meet formal brain death criteria. In these instances, the family has decided to withdraw care. The donor's organs can now be a life-saving gift for others."

Across the U.S., more than 3,300 people are on the waiting list for a heart transplant and 95 of those are waiting in North Carolina, according to the U.S. Department of Health & Human Services Organ Procurement and Transplantation Network.

"We face a nationwide shortage of donated organs. I expect this technology to transform the transplant industry, increasing the national donor supply and helping us transplant more patients in need," said Mishkin.

About Atrium Health

Atrium Health is a nationally recognized leader in shaping health outcomes through innovative research, education and compassionate patient care. Based in Charlotte, North Carolina, Atrium Health is an integrated, nonprofit health system with more than 70,000 teammates serving patients at 40 hospitals and more than 1,400 care locations. It provides care under the Atrium Health Wake Forest Baptist name in the Winston-Salem, North Carolina, region, as well as Atrium Health Navicent and Atrium Health Floyd in Georgia and Alabama. Atrium Health is renowned for its top-ranked pediatric, cancer and heart care, as well as organ transplants, burn treatments and specialized musculoskeletal programs. A recognized leader in experiential medical education and groundbreaking research, Wake Forest University School of Medicine is the academic core of the enterprise, including Wake Forest Innovations, which is advancing new medical technologies and biomedical discoveries. Atrium Health is also a leading-edge innovator in virtual care and mobile medicine, providing care close to home and in the home. Ranked nationally among U.S. News & World Report's Best Hospitals in eight pediatric specialties and for rehabilitation, Atrium Health has also received the American Hospital Association's Quest for Quality Prize and its 2021 Carolyn Boone Lewis Equity of Care Award, as well as the 2020 Centers for Medicare & Medicaid Services Health Equity Award for its efforts to reduce racial and ethnic disparities in care. With a commitment to every community it serves, Atrium Health seeks to improve health, elevate hope and advance healing – for all, providing $2.46 billion last year in free and uncompensated care and other community benefits.

A New CARE Collaborative Project

The Coronary Anomalies Research and Education (CARE) Collaborative has been busy. We have some exciting news to share with you about the anomalous aortic origin of a coronary artery (AAOCA) project funded by PCORI!

As a reminder, the **CARE Collaborative** is a group of clinicians, research investigators, and patients/families from University of Texas at Austin, Boston Children's Hospital, Children's Hospital of Philadelphia, and Texas Children's Hospital studying AAOCA. As you know, patients with AAOCA are at an increased risk of **sudden cardiac death**, especially during exercise. The mechanism of sudden cardiac death, the risk for individual patients, and the effectiveness of different therapies are unknown. These uncertainties result in anxiety for patients and families. To date, there has been no patient, family, nor provider engagement to define research priorities and the most relevant outcomes to be measured in this vulnerable population.

Since the inception of this collaborative, our main goal has been **to identify and prioritize patient-centered questions and gaps in care considered to be the most critical by patients and families.** Over the course of this funding period, we have been working towards that goal by disseminating surveys to identify questions and gaps that matter most to our patients and providers.

As we get closer to the final few stages of having the most pertinent questions identified, we would like you – our stakeholders and partners – to join us on this journey!
Here's how we hope you and your organization will continue to be involved:

1. **Attend our stakeholder engagement virtual meeting (Date TBD – early January expected)** to learn more about the research process so far and upcoming next steps. This is aimed to be informal and more as an opportunity for a conversation on what we have been up to, how we hope to disseminate our findings and, perhaps more importantly, hear from you how we can apply what we have learned in a broader way in other conditions that may lead to sudden death in the young (among others).
2. **Attend our final dissemination webinar** to be informed on the findings from the analysis and the final list of unanswered questions about AAOCA in early 2023.

We hope you will join us on our journey to identify unanswered questions by creating a focused and intentional research agenda for these patients and families while also addressing gaps in the AAOCA community!

Please, do not hesitate to reach out if you have any questions. Looking forward to connecting soon!

The CARE Collaborative

Contact: Silvana Molossi at smolossi@bcm.edu

FEBRUARY

15-18

PICS Istanbul 2023
Istanbul, Turkey
https://www.picsistanbul.com/

16-18

The 7th Annual Advances in Congenital Heart Disease Summit: Transposition of the Great Arteries: The Master Class
Orlando, FL, USA
https://www.clevelandclinicmeded.com/live/courses/CongenitalHeart23/

25-28

CRT23 – Cardiovascular Research Technologies
Washington, DC, USA
https://www.crtmeeting.org/Default.aspx

MAY

18-20

SCAI 2023 Scientific Sessions
Phoenix, AZ, USA
https://scai.org/scai-2023-scientific-sessions

JUNE

23-26

ASE 2023 – Foundations and the Future of Cardiovascular Ultrasound
National Harbor, MD, USA
https://www.asescientificsessions.org/

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PICS Society
Pediatric *and Congenital* Interventional Cardiovascular Society

ISSN 1554-7787 print. ISSN 1554-0499 electronic.
Published monthly.