Oregon Health & Science University
School of Medicine

Scholarly Projects Final Report

Title
Two decades of follow up after surgical pulmonary valve replacement in the era with transcatheter pulmonary valve replacement

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This project was conducted in the Scholarly Projects Curriculum

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Scholarly Project Final Report

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Project/Research Question
How has transcatheter pulmonary valve replacement in congenital heart defect patients affected the rate of redo sternotomy and surgical intervention?

Type of Project
This single institution retrospective study

Key words
pulmonary valve replacement, Congenital heart defects, transcatheter, redo sternotomy, pulmonary valve

Submission to Archive
No restrictions

Next Steps

This helps set the background for the increased use of ePTFE valves for pulmonary valve replacements in congenital cardiac patients. There is much debate about what is the ideal valve material due to the physiologic dysfunction that happens with normal growth. Future students could dive into the outcomes of each individual valve and possibly to a non-inferior study for ePTFE valves.

Scholarly Project Final Report

Report*:*

Introduction *(≥250 words)*

Pulmonary valve replacement (PVR) is one of the most frequent surgeries in congenital heart surgery.[1] Since there is no ideal pulmonary valve with long-term durability, PVR has been complicated by the need for reintervention primarily from valve dysfunction.[1,2] Those with congenital heart defects (CHD) often require multiple surgeries and have a high burden of redo sternotomy. Redo sternotomy comes with is increased risk of morbidity and mortality, and its increased operation time since during the index operation the pericardium has been divided the increase in scar tissue makes the redo sternotomy much more difficult. Therefore, research has leaned on trying to minimize the amount of redo sternotomy needed in these particular patients.[3] In the current era, percutaneous options have allowed a non-invasive approach for patients needing reintervention and increasingly, multiple institutions have begun to use a combined approach of transcatheter PVR (tPVR) and surgical PVR (sPVR) to reduce the rates of surgical intervention. This allows surgeons to pick an valve at the index operation that could possibly later accommodate another transcatheter valve inside the original valve from the index operation.[4] While the current landscape evolves to a combined approach, the need for long-term institutional data grows as well. The work has shifted to trying to find the ideal valve that will allow growth of the heart as the patient grows, but may also allow for possible future transcatheter intervention to reduce the rates of surgical intervention.[5] The purpose of this study was to investigate the long-term outcomes of patients with CHD undergoing PVR in the current era of the sPVR and tPVR comprehensive approach in a single institute.

Methods *(≥250 words)*

This was an IRB24166 approved research study. All patients who underwent sPVR at our institution from 2004-2023 were queried from our institutional database. This yielded a total of 435 patients who collectively underwent 512 PVR procedures. Patients with Norwood procedure, who had a right ventricle to pulmonary artery conduit with an interior valve, were excluded from the study. Basic demographic data were collected. Pulmonary valve placed at original surgical intervention was noted to assess long-term durability. Reintervention was assessed by either redo sPVR or tPVR from the original listed sPVR. The most recent echocardiogram was used to assess clinical status. Pressure gradient through the pulmonary valve and status of regurgitation was used to assess clinical function of the pulmonary valve. Timing of reintervention by sPVR or tPVR was used to assess long-term durability of the valve.

The 5 main valves associated with initial surgical valve placement were: Allograft, bovine valve (Carpenter-Edwards Perimount Valve) (Edwards Life Sciences, Irvine, CA), stentless porcine valve (Hancock porcine-valved Dacron conduit) (Medtronic, Minneapolis, MN), stented porcine valve (Epic bioprosthetic valve) (Abbott, Chicago, IL), and the handmade expanded Polytetrafluoroethylene valved conduit (ePTFE). The 2 transcatheter valves were the Melody Valve (Medtronic, Minneapolis, MN) and the Edwards Sapien 3 valve (Edwards Life Sciences, Irvine, CA). Valve choice was primarily the surgeons' decision and institutional preference. Implantation of ePTFE valves was initiated in 2022 due to historical benefits over other types of valves, yet allograft remains a large portion for the neonate population.

Kaplan Meier Survival curves were used to assess long term durability of various endpoints. Curves with standard error and hazard ratios (HR) were calculated and drawn with the use of GraphPad Prism software (GraphPad Software, Boston, MA). P-values were calculated between comparison groups using the student's t-test and significance was seen at p-values less than 0.01. Log-rank analysis was implemented for comparison of survival curves.

Results *(≥500 words)*

Of the total patients included 236 out of 435 were male. The average age of patients at the time of surgery was 20 years. At the original listed surgery, the patient diagnoses was predominated by Tetralogy of Fallot (TOF) 231 (53%) followed by truncus arteriosus 38 (9%), transposition of great arteries 32 (8%), isolated pulmonary stenosis 27 (6%), pulmonary atresia with intact ventricular septum 16 (4%), aortic valve disease 14 (3%), ventricular septal defect 10 (2%), interrupted aortic arch 6 (1%), atrioventricular septal defect 4 (1%), and other related abnormalities 57 (13%) (**Table 1**). The average time until most recent follow up was 7.7 years (0-20.2). Long-term echo findings demonstrated that 87% of patients had a pulmonary insufficiency of mild or less at their most recent follow up (**Table 1**). There were 50 total tPVR with 46 Melody valves and 4 being Sapien valves. There were only 3 sPVR placed after placement of a tPVR, which were due to endocarditis (**Table 1**). The log-rank HR when comparing freedom from all PVRs to sPVR was 1.88 with (95% CI 1.4 - 2.5) and the reported p-value was <.0001(**Figure 1**). The average time until pulmonary intervention by tPVR or sPVR was 6 years (0-18) (**Table 1**). The survival or transplant free rate was found to be 403 (93%) (**Figure 2**).

Of the individual valves placed (462) it was predominated by the allograft 34% (158), bovine valve 28% (128), stented porcine valve 19% (87), stentless porcine 14% (65), expanded Polytetrafluoroethylene (ePTFE) 4% (19) or other valves 1% (5) (**Table 1**). The average age for patients undergoing sPVR was 12.0 years in allograft, 26.7 years in the bovine valve, 25.7 years in the stented porcine valve, 17.3 years in the stentless porcine valve, and 7.1 years in the ePTFE. At 19 years, 85% patients (393) were sPVR free, and 75% patients (345) did not undergo tPVR or sPVR (**Figure 2**). At 18 years, 56% (89/158) of allograft and 73% (94/128) of bovine valve patients were free from any PVR (**Figure 3**). At 18 years, 67% (106/158) of allograft and 94% (121/128) of bovine valve patients were free from sPVR (**Figure 4**). Although follow up duration is shorter at 15 years, 97% (84/87) of stented porcine valve patients and 92% (60/65 patients) of stentless porcine valved conduit patients were free from any PVR (**Figure 3**). At 15 years, 97% (84/87) of patients who underwent placement of stented porcine valve and 92% (60/65) of those who underwent stentless porcine valved conduit were free from sPVR (**Figure 4**). The ePTFE while demonstrating 100% freedom from any PVR was limited to 2 years maximum follow up (**Table 2**).

Each valve provided a unique long-term prevention from either sPVR or tPVR. Statistical analysis was done to measure the differences in each curve. The ePTFE valve was difficult to define as its follow up time was short (2 years). There was not a significant difference in freedom from tPVR or sPVR when comparing the stented porcine valve, stentless porcine valve, and bovine valve with each other. Freedom from isolated sPVR did yield a difference significant at the 95% CI between the bovine valve vs. stentless porcine valve. Compared to the allograft valves, the bioprosthetic valves yielded significant differences looking at freedom from any PVR or isolated sPVR. The bovine valve, stented porcine valve, and stentless porcine valve provided a reduced risk of reintervention from tPVR or sPVR (**Table 3**).

Discussion *(≥500 words)*

Patients with CHD are known to have a high burden of reintervention frequently caused by the deterioration of valvular function, growth physiology, or other related complications.[1,2,6,8,23] PVR in the adult populations is still complicated by increased morbidity and mortality, which causes a disproportionate shift for surgeons to prefer PVR in younger paitents.[15,22] First outlined in 2002 by Bonhoeffer, the tPVR option has allowed for a reduction in need for surgical reintervention.[14, 19,20] Schmidt et al which included over 4,000 tPVR, the largest study yet, showed an increase of about 35% in use of the SAPIEN valve over their short study period.[27] This trend continues to gain importance as outcomes are improving in patients following tPVR, demonstrated by Hribernik et al in which tPVR has similar 5 year mortality outcomes. Of the patients who died in the tPVR group, their mortality was complicated by pre-procedure comorbidities when compared to the surgical valve group which had no pre-existing comorbidities.[7] Even with this growing expansion, few studies have tried to assess the long-term durability of individual valves in an isolated approach.[1,22] The source of complexity is thereby determined in the granular details and variable criteria for reintervention. McElhinney et al showed in their analysis of over 2,000 patients, that surgical reintervention was reduced about 10% following tPVR. The analysis demonstrated that numerous factors such as, but not limited to, age, valve choice, weight, and presence of previous valve all had impact on reintervention.[21] Therefore, investigation into the outcome of individual valves remains a significant area of study.[7,11,13, 26]

Porcine valves have been known to provide excellent long-term durability, Kwon et al demonstrated in their analysis that bioprosthetic valves have demonstrated a 52-83% freedom from reintervention. They noted the high degree of variability within these studies due to differences in patient age population, valve choice, and indication for surgery, which most likely account for the wide range in freedom.[25] Another benefit to the bioprosthetic valves is there ability for valve in valve procedures, Shahanavaz et al found in their small study the possibility of placing tPVR in previous bioprosthetic pulmonary valves. They demonstrated that even when size is limiting, intentional fracture of the bioprosthetic valve with tPVR can lower valve gradient and they had no adverse events following procedure.[16] With tPVR as a viable option, valve in valve procedures may continue to emerge, as they offer a unique ability to avoid surgical intervention when possible.[16,17,18] The use of bioprosthetic valves still remains a challenge in younger patients often due to size and the inability to accommodate a large valve in smaller anatomy.[1]

Allografts remain a first choice in neonatal patients, but its limitations remain the often dysfunction that follows as the individuals physiology changes with normal growth.[12] Similarly follow up of the ePTFE valve demonstrates high reintervention rates with Kim et al demonstrating a freedom from valve dysfunction of 63% at 10 years.[9] Chang et al demonstrated excellent mid-term outcomes at 90% freedom from reintervention as 5 years.[10] The use of ePTFE still has variable use but might demonstrate a beneficial alternative to allograft. Ootaki and associates demonstrated that with their unique technique excellent midterm outcomes can be achieved with 90% freedom from tPVR at 10 years and none of their valves requiring surgical reintervention.[24]

Given the wide variability, the urgent question becomes which valve is best for surgeons. Xenograft valves remain first choice for older patients given their established long-term outcomes, yet for infant patients valve choice is not as clear as physiologic growth remains a large obstacle.[3,5] The use of tPVR while relatively new has helped alleviate the burden of redo surgical intervention, yet an ideal valve remains the point of investigation.[25] Valve conduits such as the ePTFE have seen a rise in interest with their versatile nature, and in established centers can offer greater than 90% freedom of any intervention.[24,25] The continued investigation of valve choice and valve development is needed to elucidate the ideal valve for the pulmonary position, especially in infant patients who are most at risk for multiple surgical interventions.

We acknowledge the limitations of our study. While being comprehensive this single institution observational provides limitation to the generalizability of the findings. In our analysis we are inherently predicting outcomes survival curves based upon historic behavior. While being a long-term study, not every patient had long term follow up data limiting the predictability of the findings. These concerns warrant the need for further studies investigating the rates for reinterventions of individual valves in institutions who engage in a comprehensive approach of sPVR and tPVR.

Conclusions *(2-3 summary sentences)*

In patients with CHD requiring sPVR, a comprehensive approach using tPVR and sPVR can significantly reduce the rate of future surgical intervention on a long-term scale. While neonatal patients remain the highest risk for reintervention, ePTFE offers a possible solution with excellent mid-term outcomes.

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Tables and Figures:

Male (Female)	236 (199)
Age at time of procedure[1](years)	20 [7,31]
BSA[1]	1.3 [1,2]
Diagnoses at Initial PVR	
Tetralogy of Fallot	231 (53%)
Other[2]	57 (13%)
Truncus arteriosus	38 (9%)
Transposition of great arteries	32 (7%)
Pulmonary valve stenosis	27 (6%)
Pulmonary atresia	16 (4%)
Aortic valve disease	14 (3%)
Ventricular septal defect	10 (2%)
Interrupted aortic arch	6 (1%)
Atrioventricular septal defect	4 (1%)
Pulmonary Valves N= 462	
Allograft	158 (34%)
Bovine valve	128 (28%)
Stented porcine valve	87 (19%)
Stentless porcine valve	65 (14%)
Expanded Polytetrafluoroethylene	19 (4%)
Other[3]	5 (1%)
Postoperative	
Time to most recent follow up[1] (years)	7.7 [3,13]
Time until first pulmonary valve intervention[1]	6 (0-18)
Transcatheter Valves	
Melody	46 (10%)
Sapien	4 (1%)
Echo at Most Recent Follow Up	
Gradient[1] (mmHg)	24.6 [16,31]
Degree of Pulmonary Insufficiency	
None	151 (44%)
Trace	73 (21%)
Mild	74 (22%)
Moderate	33 (10%)
Severe	13 (4%)

Table 1: Patient demographics Perioperatively and Postoperatively

[1]Mean [IQR1, IQR3], [2]Individual negligible numbers, [3]St.Jude Medical, Contegra, Shelhigh

Table 2: Perioperative and Postoperative characteristics with long-term follow up by valve

N=462	**Stented Porcine**	**Stentless Porcine**	**Allograft**	**ePTFE**	**Bovine**
Age at initial surgery[1, *]	25.7 [11,38]	17.3 [4.5,27]	12 [0.6,16]	7.08 [2.1,11]	26.7 [14,37]
Bodyweight (Kg)[2, *]	57.2 [36,73]	48.4 [19,72]	38.7 [6.8,69]	30.3 [11,34]	64.0 [47,84]
Height (M)[3, *]	1.53 [1.6,1.4]	1.38 [1.0,1.7]	1.18 [0.7,1.7]	1.10 [0.8,1.3]	1.57 [1.5,1.7]
Time Until Most Recent Follow up[4,*]	5.42 [4.0,7.0]	4.27 [2.2,5.7]	10.0 [3,16]	0.52 [0.2,0.9]	10.3 [8,14]
Gradient at most recent follow up[5, *]	29.1 [21,35]	21.2 [12,27]	26.7 [16,36]	12.3 [10,13]	22.8 [15,27]
Pulmonary insufficiency at most recent follow up					
None	33 (40%)	40 (63%)	38 (45%)	9 (56%)	30 (31%)
Trace	21 (36%)	12 (19%)	19 (22%)	4 (25%)	17 (18%)
Mild	20 (25%)	5 (8%)	14 (16%)	2 (13%)	33 (34%)
Moderate	4 (5%)	4 (6%)	19 (22%)	0 (0%)	15 (16%)
Severe	3 (4%)	3 (5%)	5 (6%)	1 (6%)	1 (1%)

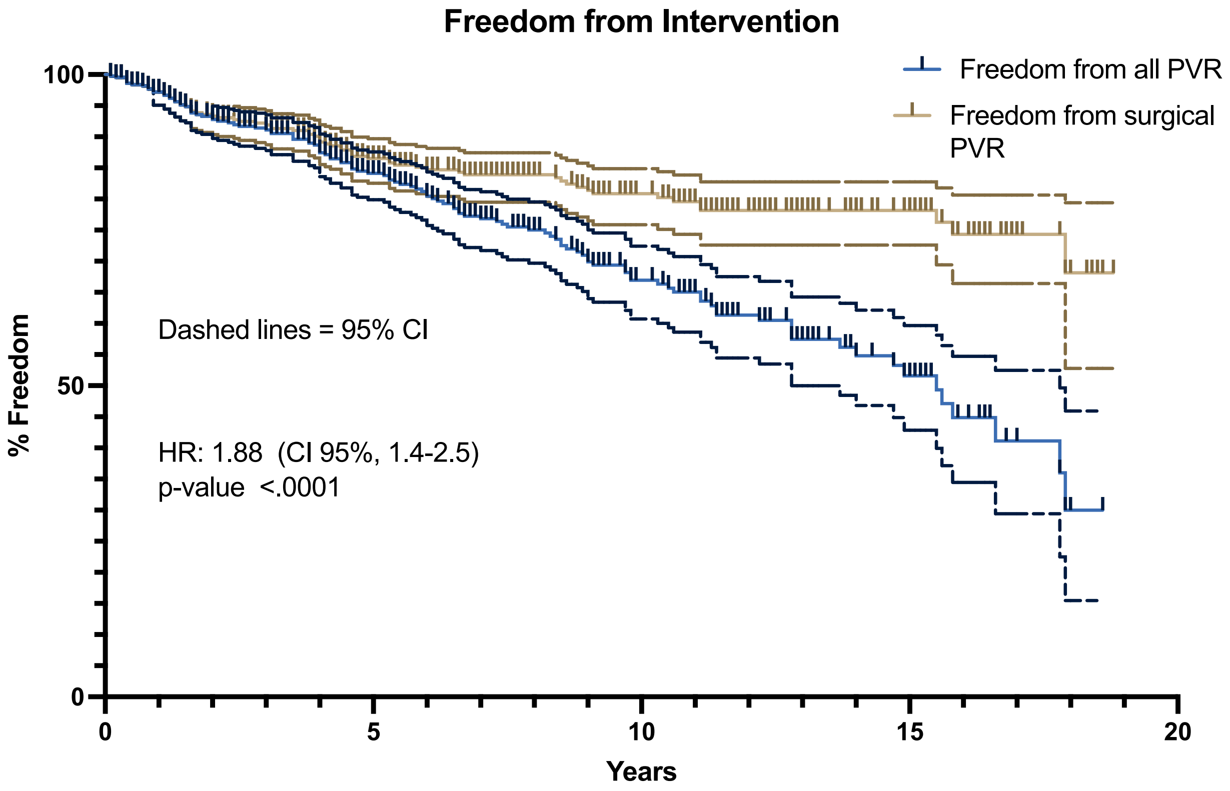
[*] Mean [IQR1, IQR3]

[1] Significance was seen comparing every valve against each other (p-value <0.01), except bovine valve vs. stented porcine valve and allograft vs. ePTFE. [2] Significance was seen comparing: Stented porcine valve vs. allograft, stented porcine valve vs ePTFE, Stentless porcine vs. bovine valve, allograft vs. bovine valve, ePTFE vs. bovine valve (p-value <0.01). [3] Significance was seen comparing every valve with each other (p-value <0.01) except stented porcine valve vs bovine valve and allograft vs ePTFE. [4] Significance was seen comparing every valve with each other (p-value <0.01) except stented porcine valve vs. bovine valve and allograft vs. ePTFE. [5] Significance was seen comparing every valve against each other (p-value <0.01), except allograft vs. bovine valve, stentless porcine vs. stented porcine valve, and stentless porcine vs. bovine valve.

Table 3: Statistical Analysis of Kaplan Meier survival curves by valve type

Comparison Survival Curves	Log Rank p-value	Log-Rank Hazard Ratio (95% CI)
Freedom from Any PVR		
stented porcine vs. bovine	0.51	0.77 (0.34-1.70)
stented porcine vs. stentless porcine	0.49	0.66 (0.19-2.28)
stented porcine vs. allograft	<.0001	0.21 (0.13-0.34
Stented porcine vs. ePTFE	0.91	Undefined
bovine vs. stentless porcine	0.85	0.92 (0.37-2.27)
bovine vs. allograft	.0002	0.47 (0.32-0.69)
bovine vs. ePTFE	0.82	Undefined
stentless porcine vs. allograft	.0008	0.25 (0.15-0.43)
stentless porcine vs. ePTFE	0.83	Undefined
allograft vs. ePTFE	0.38	Undefined
Freedom from Surgical PVR		
stented porcine vs. bovine	0.82	0.84 (0.18-3.93)
stented porcine vs. stentless porcine	0.0692	0.25 (0.05-1.13)
stented porcine vs. allograft	<.0001	0.07 (0.04-0.12)
stented porcine vs. ePTFE	0.91	Undefined
bovine vs stentless porcine	0.04	0.32 (0.08-1.38)
bovine vs. allograft	<.0001	0.10 (0.06-0.17)
bovine vs. ePTFE	Undefined	Undefined
stentless porcine vs. allograft	0.0024	0.28 (0.15-0.50)
stentless porcine vs. ePTFE	0.83	Undefined
allograft vs. ePTFE	0.38	Undefined

Figure 1:



All PVR	242	108	30	0
Surgical PVR	250	133	48	1

Number at risk

Figure 2:

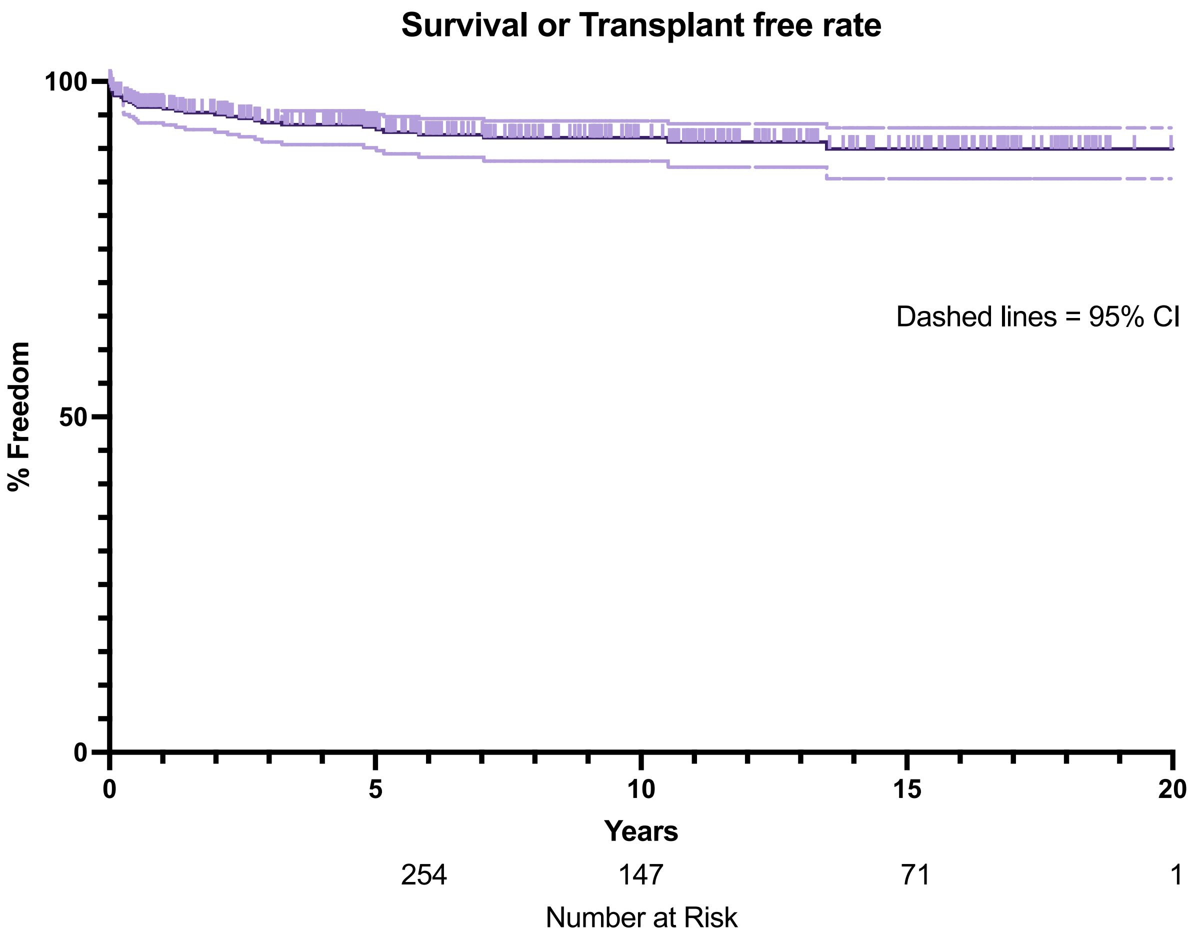
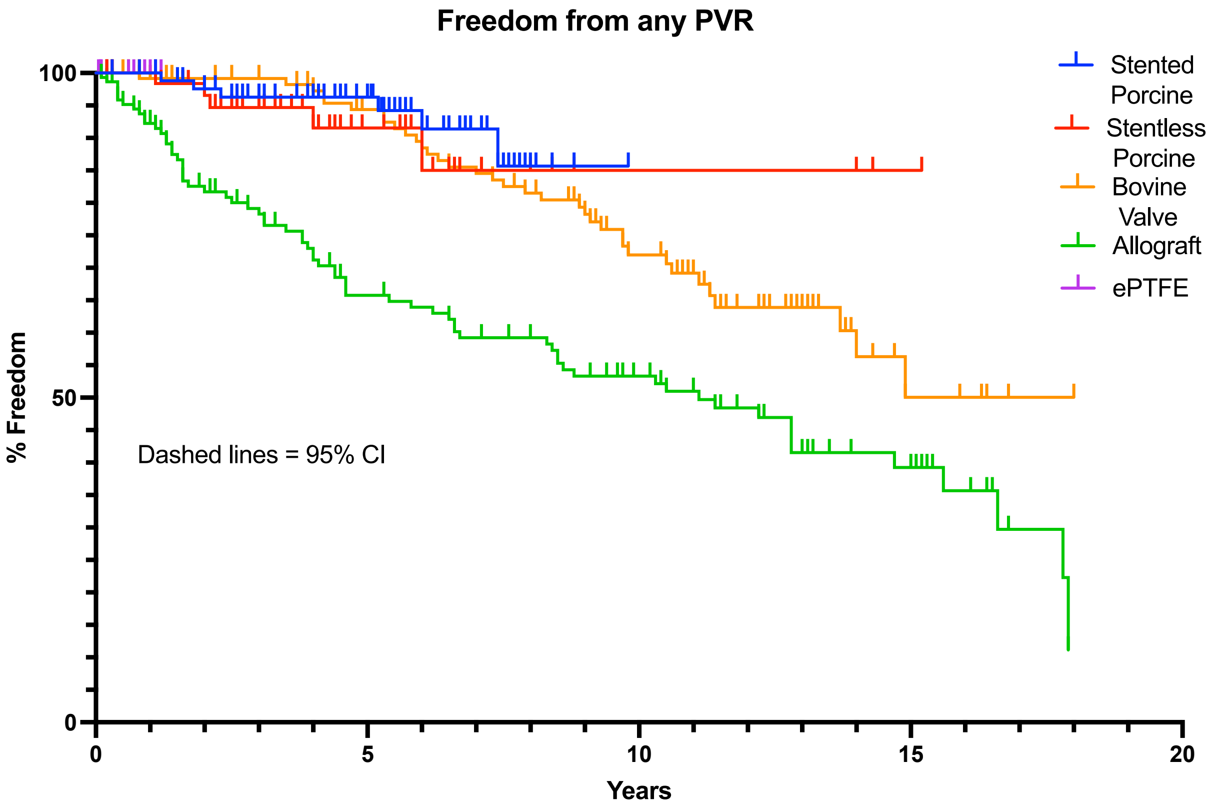

Survival or Transplant free rate
% Freedom
100
50
0
Dashed lines = 95% CI
0
5
10
15
20
Years
254
147
71
1
Number at Risk

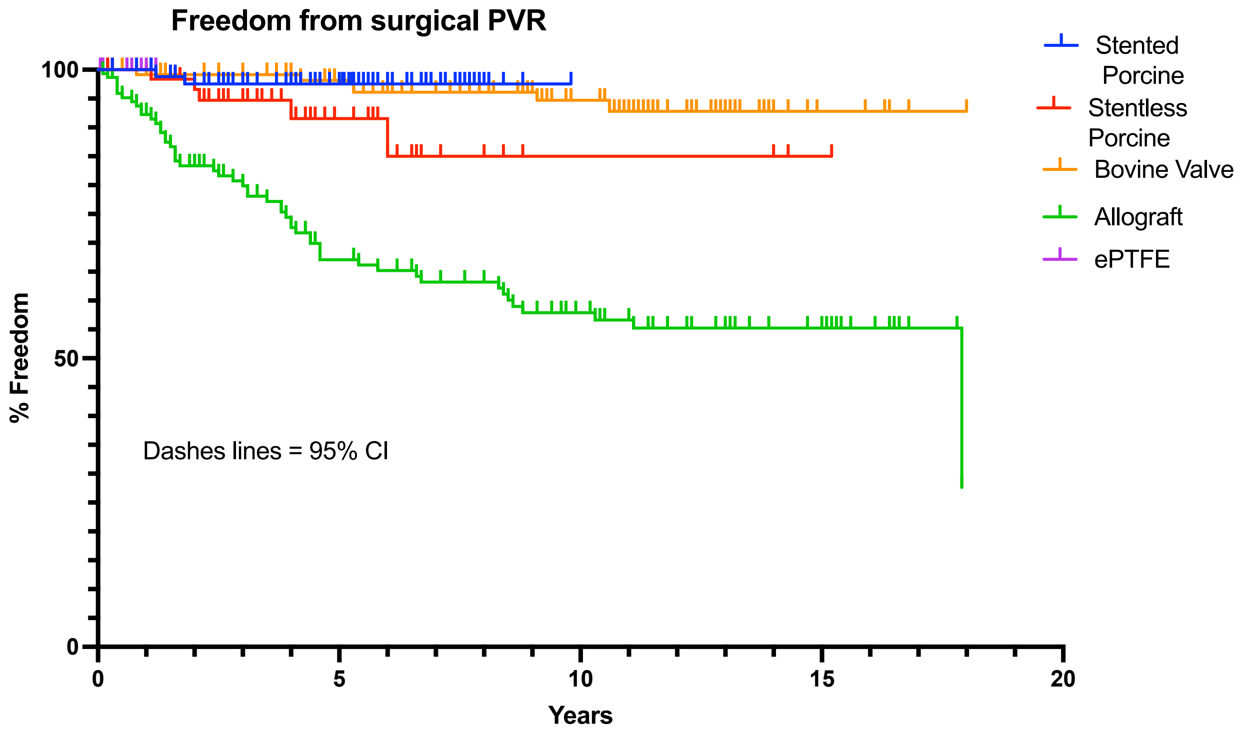
Figure 3:



Epic	50	0	0	
Hancock	20	0	0	
Homograft	75	47	17	0
ePTFE	0			
CE	97	55	9	2

Number at Risk

Figure 4:



Epic	50	0	0	
Hancock	20	4	1	
Homograft	75	47	17	2
ePTFE	0			
CE	97	53	7	2

Number at Risk