Evaluation and comparison of patch materials used for pulmonary arterioplasty in pediatric congenital heart surgery

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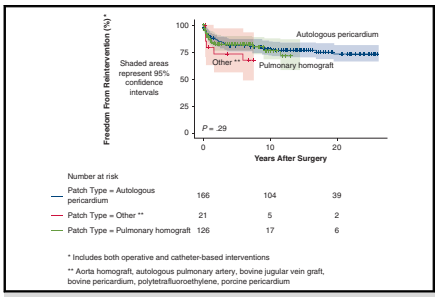
ABSTRACT

Objective: To evaluate the long-term performance of the patch materials we have used to augment the pulmonary arterial tree across a wide spectrum of diagnoses and anatomical locations.

Methods: Retrospective, single-center review of 217 consecutive pediatric patients at a tertiary referral center from 1993 to 2020 who underwent patch arterioplasty of the pulmonary arterial tree from the pulmonary bifurcation to the distal pulmonary arterial branches. Reintervention data were collected and analyzed. Lesion-specific anatomy and other variables were analyzed as risk factors for reintervention.

Results: There were 280 total operations performed (217 initial operations and 63 reoperations) and 313 patches used. The patches used were autologous pericardium (166, 53.0%), pulmonary homograft (126, 40.3%), and a heterogeneous group of other materials (21, 6.7%). Overall patient survival was 86.2%, freedom from reoperation was 81.0% and freedom from reintervention (FFR) was 70.6%, with a median follow-up of 13.8 years (interquartile range, 6.3-17.9 years). For all patches, 10-, 20-, and 27-year FFR was 76.6%, 70.6%, and 70.6%, respectively. FFR was similar among all 3 patch type groups ($P = .29$). Multivariable Cox regression analysis showed that diagnoses of pulmonary atresia with ventricular septal defect and major aortopulmonary collateral arteries and hypoplastic left heart syndrome, patches placed at initial cardiac operation, and increasing number of cardiac operations were risk factors for reintervention.

Conclusions: Autologous pericardium and pulmonary homograft patches performed similarly. Although patch type conferred no difference in need for reintervention, other risk factors did exist. Namely, diagnoses of pulmonary atresia with ventricular septal defect and major aortopulmonary collateral arteries and hypoplastic left heart syndrome, patch placement at a patient's first cardiac operation, and increasing number of cardiac operations were risk factors for reintervention. (JTCVS Open 2023;15:424-32)



Freedom from reintervention (FFR) for patches used in the pulmonary circulation.

CENTRAL MESSAGE

Autologous pericardium and pulmonary homograft had similar rates of freedom from reintervention when used as patches in the pulmonary circulation in common congenital heart disease diagnoses.

PERSPECTIVE

Until recently, few data have been available regarding the performance of patch material in the pulmonary circulation for common congenital heart disease diagnoses. Our goal was to help expand the pool of knowledge by comparing pulmonary homograft with autologous pericardium. We also evaluated risk factors for the need for reintervention.

Augmentation of the pulmonary arteries (PAs) with patch material is commonly performed for several pediatric congenital heart defects. This need can arise at either initial cardiac operation or subsequent reoperations. An important choice to be made at the time of operation is the material used for patch pulmonary arterioplasty. Until recently, few data were available comparing commonly used patch materials.[1-3] The goals of our study were to evaluate the materials we have used in patch arterioplasty of the PAs in children with congenital heart disease and describe

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Abbreviations and Acronyms

BDG = bidirectional Glenn
FFR = freedom from reintervention
FRO = freedom from reoperation
HLHS = hypoplastic left heart syndrome
MAPCA = major aortopulmonary collateral arteries
PA = pulmonary artery
PA/VSD = pulmonary atresia with ventricular septal defect
RV = right ventricle
TCPC = total cavopulmonary connection
VSD = ventricular septal defect

long-term outcomes. Specifically, we wanted to see whether patch material type—or any other factors—were associated with need for earlier reintervention after initial patch angioplasty.

METHODS

Patients

All patients younger than 18 years of age who received a surgical patch augmentation of the pulmonary arterial tree were retrospectively reviewed for the period January 1, 1993, through December 31, 2020. All patients were operated on at the Pediatric Heart Center of the Skåne University Hospital in Lund, 1 of 2 centers in Sweden that perform surgery for children with congenital heart disease. Pediatric heart surgery in Sweden was centralized to 2 centers in 1993, with each center serving one half (approximately 5 million people) of the Swedish population. Patients with patching at or distally to the pulmonary bifurcation were included. Both single- and 2-ventricle patients were included. Patients with pulmonary atresia with ventricular septal defect (PA/VSD) and major aortopulmonary collateral arteries (MAPCAs) and subsequent unifocalization also were included. Right ventricle (RV)-PA conduit placement or exchange was not an indication for inclusion unless clinically significant branch PA stenoses were also treated. Patients with only patching of the main PA were excluded. Patients were excluded from the study if it was not possible to accurately ascertain any of the study end points, listed to follow.

Study Design

The Regional Ethical Review Board in Lund, Sweden, granted approval for this study (Dnr 2017/133, April 11, 2017). Given the retrospective nature of the study and the large number of patients involved, need for individual patient consent was waived. Patients included were collected through registries maintained by the Division of Pediatric Cardiac Surgery and Tissue Bank in Lund. Perioperative clinical and imaging data were obtained from both the electronic and archived medical records. Study end points were overall survival, freedom from reoperation (FRO), and freedom from reintervention (FFR), measured from the time of operation through December 31, 2020. Reoperation was defined as a surgical intervention that included the area of previous patch arterioplasty. Reintervention was defined as either reoperation or catheter-based intervention in an area of prior patch placement, whichever occurred first.

Stenoses were described by several factors. Congenital lesions were those that were established to be present at birth. Those that developed either with time alone or because of previous intervention were listed as acquired. Proximal stenoses were those that began from either the pulmonary bifurcation or proximal branch PAs and did not extend either for a length more than 2 cm or onto the lobar branch arteries. Otherwise, they were listed as distal stenoses. A stenosis was listed as unilateral if only the left or right side of the pulmonary arterial tree was involved at a given operation. A stenosis was listed as bilateral if either the pulmonary bifurcation was involved or if there were separate lesions on both sides of the pulmonary arterial tree. Short lesions were those less than a length of 2 cm.

Patch Material

The patches we used were fresh autologous pericardium, cryopreserved branch pulmonary artery homograft, and a smaller group of materials consisting of aorta homograft, autologous pulmonary artery, bovine pericardium, bovine jugular vein graft, porcine pericardium, and polytetrafluoroethylene. Autologous pericardium was not fixed with glutaraldehyde. Cryopreserved pulmonary homograft patches were procured from the Tissue Bank in Lund and were thawed and prepared according to routine before use. Generally, autologous pericardium was preferred early in the study period, with pulmonary homograft predominating later in the study period. Patch choice was determined by the surgical team.

Intervention: Indications and Techniques

Although specific thresholds may have changed throughout the duration of the study, decisions regarding primary operation, reoperation, or reintervention were made on an individual basis in a multidisciplinary conference. Early in the study period, surgical intervention predominated. More transcatheter interventions were used as techniques evolved, which subsequently led to more liberal indications for intervention. Currently, indications include increased RV pressure (>2/3 systemic pressure), pressure gradients >20 mm Hg across stenotic lesions, abnormal differential flow on MRI (<30%) for branch PA stenosis, or significant lumen reduction.

Transcatheter interventions included balloon or stent angioplasty. Conventional balloon angioplasty was preferred earlier in the study period, in patients weighing less than 10 kg, or in patients with multiple stenoses in smaller pulmonary branches. Cutting balloons were mainly used in patients with branch stenoses refractory to conventional ballooning or before stenting in PA/VSD/MAPCA patients after unifocalization. "Adult-sized" balloon-expandable stents were mainly used in PA branch stenoses in older patients. Coronary stents were used occasionally in neonates and infants to treat severe postsurgical stenoses.

Pulmonary arterioplasty was performed on cardiopulmonary bypass with a warm to mildly hypothermic beating heart. When combined with other cardiac procedures, the pulmonary arterioplasty was usually performed after removing the aortic crossclamp while the patient was being rewarmed. All efforts were made to ameliorate stenoses as distal as clinically warranted and feasible, similarly to the methods described by Mainwaring and colleagues[4] and Monge and colleagues.[5] Unifocalization procedures with concurrent pulmonary arterioplasty were often performed before any other additional cardiac surgical repair. Early in the study period, patients with hypoplastic left heart syndrome (HLHS) uniformly received patch augmentation of the pulmonary bifurcation during the Norwood procedure. Only patients who developed an indication for further pulmonary patch arterioplasty at second or third stages of univentricular palliation were included in the study. The number of cardiac operations was noted for each patient, including nonpatch-related procedures (ie, systemic-to-pulmonary shunt operations).

Follow-up

Patient survival status was verified with the national population registry. Reoperations were noted through a registry maintained by the Division of Pediatric Cardiac Surgery. Reinterventions in the form of cardiac catheterizations were ascertained through both the Swedish national health care registry (Swedcon) and a registry maintained by the Division of Pediatric Cardiology.

Data Analysis

Data were reported as counts, percentages, means, standard deviations, medians, and interquartile ranges. Between-group differences were assessed by χ^2 or Fisher exact test for qualitative variables and analysis of variance for continuous variables. Survival analyses were produced using the Kaplan–Meier method; between-group differences were assessed using the log rank sums test. Univariable Cox regression analysis was performed to investigate risk factors for reintervention. Those that were neither strongly correlated with other variables nor had a P value >.20 were included in the multivariable Cox proportional hazards model. The few missing data were imputed using mean values. Statistical analyses were performed using SPSS, version 25, software (IBM Corp) and R, version 4.2.2 (R Foundation for Statistical Computing).

RESULTS

Throughout the 28-year study period, 227 patients underwent patch augmentation of the pulmonary arterial circulation. Ten patients (4.4%) were residing in another country at the time of analysis and were excluded from the study. The remaining 217 patients were included in this study, encompassing a range of ages and operative strategies (Table 1). There were 280 operations (217 initial operations and 63 reoperations) performed with 313 patches (166 autologous pericardium, 53.0%; 126 pulmonary homograft, 40.3%; and 21 other, 6.7% [Table 2]). The index operation was performed in neonates (N = 37, 17.1%), infants (N = 74, 34.1%), and children (N = 106, 48.8%). There were 64 patients (29.5%) who received single-ventricle palliation, of which HLHS (26, 40.6%) and PA with intact ventricular septum (8, 12.5%) were the most common diagnoses. The most common diagnoses to receive an operation were tetralogy of Fallot (47, 16.8%) and HLHS (54, 19.3%). The diagnoses receiving the most patches were HLHS (57, 18.2%), PA/VSD with MAPCAs (55, 17.6%) and without MAPCAs (32, 10.2%), and tetralogy of Fallot (53, 16.9%). Neither age ($P = .36$), weight ($P = .29$), nor sex ($P = .71$) differed with respect to patch type, although there were significant differences with respect to diagnosis ($P < .01$). There were 326 additional procedures performed in concert with pulmonary arterioplasty; the most common were initial RV-PA valved conduit placement (72, 22.1%), bidirectional Glenn (BDG) anastomosis (58, 17.8%), and VSD closure (51, 15.6%). Patients with syndromes included 2 with Alagille syndrome, 2 with DiGeorge syndrome, 1 with Williams syndrome, and 1 with heterotaxy.

TABLE 1. Baseline patient characteristics of patients undergoing pulmonary patch arterioplasty

Variable	Value (N = 217)*
Male sex	121 (55.8)
Weight, kg	8.1 (6.0-13.0)
Age at index operation, mo	11.2 (4.8-45.1)
Neonate (<30 d)	0.1 (0.1-0.2)
Infant (30 d-1 y)	6.2 (5.0-8.6)
Child (1-18 y)	46.5 (17.8-108.8)
Single ventricle	64 (29.5)

*Data are presented as number (%) for categoric variables and median (interquartile range) for continuous variables.

At index operation, single patches were implanted in 145 patients, whereas 72 patients received more than one patch. On univariable Cox regression analysis, patients receiving single patches had a lower risk for reintervention (hazard ratio, 0.25; 95% confidence interval, 0.09-0.72, P value = .01). Among our HLHS cohort, 57 total patches were implanted; 21 were placed before BDG, 35 were placed after BDG but before total cavopulmonary connection (TCPC), and one was placed after TCPC. Seven patches were implanted solely on the right side of the pulmonary arterial tree; 3 solely on the left; and 47 that encompassed the pulmonary bifurcation. One of the solely right-sided patches required reintervention; 2 of the solely left-sided patches required reintervention; and 23 of those encompassing the pulmonary bifurcation required reintervention.

Description of the initial stenoses requiring surgical patch arterioplasty is given in Table 3. The stenoses treated were predominantly proximal, short, and acquired. There were roughly the same number of unilateral and bilateral stenoses. The patched lesions that ultimately required reintervention are further listed; in a nontime-dependent fashion, bilateral lesions ($P < .01$) had a greater reintervention rate whereas diffuse/combined lesions had a lower rate ($P < .05$) compared with discrete (either short or long) lesions. Of the 49 initial interventions performed after initial pulmonary patch arterioplasty, 38 (77.6%) were surgical and 11 (22.4%) were catheter-based.

Follow-up was 100% with respect to overall survival, FRO, and FFR, with a median follow-up of 13.8 years (interquartile range, 6.3-17.9 years). Overall survival was 86.2% and FRO was 81.0% at 27 years after operation. For all patches, 10-, 20-, and 27-year FFR was 76.6%, 70.6%, and 70.6%, respectively (Figure E1). For autologous pericardium, 10-, 20-, and 27-year FFR was 77.9%, 73.1%, and 73.1%, respectively. For pulmonary homograft, 10-, 20-, and 26-year FFR was 76.9%, 60.9%, and 60.9%, respectively. For all other patch material, 10-, 20-, and 27-year FFR was 58.8%, 58.8%, and 58.8%, respectively (Figure 1). FFR was similar among the 3 listed patch type groups ($P = .29$).

Risk factors were assessed for reintervention after patch arterioplasty by univariable Cox regression analysis, both by the anatomy of the native lesion (Table 4) and by other patient and operative characteristics (Table 5). Similar to Table 3, bilateral lesions were a risk factor for reintervention, whereas diffuse/combined lesions had a lower risk compared with discrete (either short or long) stenoses. Neither stenosis location nor etiology was associated with reintervention. With respect to nonanatomic factors, male sex ($P = .03$), younger age ($P < .01$), low operative weight

TABLE 2. Pulmonary arterioplasty patches used at operation for undergoing pulmonary patch arterioplasty; listed by patch type, diagnosis, and baseline variables

Patient characteristics	Patches, N (column %)	Patch type: Autologous pericardium Patches, N (column %, row %)	Patch type: Pulmonary homograft Patches, N (column %, row %)	Patch type: Other* Patches, N (column %, row %)	*P* value
Total	313 (100)	166 (100.0, 53.0)	126 (40.3, 100.0)	21 (6.7, 100.0)	
Diagnosis					<.01
TOF	53 (16.9)	39 (23.5, 73.6)	14 (11.1, 26.4)	0 (0.0, 0.0)	
PA/VSD/MAPCA	55 (17.6)	17 (10.2, 30.9)	34 (27.0, 61.8)	4 (19.0, 7.3)	
HLHS	57 (18.2)	24 (14.5, 42.1)	29 (23.0, 50.9)	4 (19.0, 7.0)	
PA/VSD	32 (10.2)	16 (9.6, 50.0)	14 (11.1, 43.8)	2 (9.5, 6.3)	
PA/IVS	20 (6.4)	10 (6.0, 50.0)	6 (4.8, 30.0)	4 (19.0, 20.0)	
TA	10 (3.2)	8 (4.8, 80.0)	2 (1.6, 20.0)	0 (0.0, 0.0)	
Others†	86 (27.5)	52 (31.3, 60.5)	27 (21.4, 31.4)	7 (33.3, 8.1)	
Male	183 (58.5)	95 (57.2, 51.9)	74 (58.7, 40.4)	14 (66.7, 7.7)	.71
Weight, kg, mean ± SD	12.1 ± 11.1	12.2 ± 11.6	11.3 ± 10.1	15.5 ± 12.9	.29
Age, y, mean ± SD	2.9 ± 4.0	2.8 ± 3.8	2.8 ± 4.1	4.1 ± 4.8	.36

TOF, Tetralogy of Fallot; *PA/VSD/MAPCA*, pulmonary artery/ventricular septal defect/ major aortopulmonary collateral arteries; *HLHS*, hypoplastic left heart syndrome; *IVS*, intact ventricular septum; *TA*, truncus arteriosus; *SD*, standard deviation. *Aorta homograft, autologous pulmonary artery, bovine jugular vein graft, bovine pericardium, polytetrafluoroethylene, porcine pericardium. †Anomalous aortic origin of pulmonary artery, atrioventricular septal defect (complete or partial), congenitally corrected transposition of the great arteries, complex single ventricle not otherwise specified, double-inlet left ventricle, double-inlet right ventricle, double-outlet right ventricle, double-outlet left ventricle, interrupted aortic arch, pulmonary stenosis (valvar, subvalvar, or supravalvar; PS), transposition of the great arteries with or without VSD with or without PS, tricuspid valve atresia or stenosis, VSD (single or multiple).

($P < .01$), a diagnosis of PA/VSD/MAPCAs ($P = .02$) or HLHS ($P < .01$), patch placed at a patient's first cardiac operation ($P < .01$), and increasing number of cardiac operations ($P < .01$) were associated with reintervention. Weight was strongly correlated with age, so it was not included in the final multivariable model (Table 6). Factors remaining associated with reintervention in the multivariable model included a diagnosis of PA/VSD/MAPCAs ($P = .02$) or HLHS ($P = .01$), patch placed at a patient's first cardiac operation ($P < .01$), and increasing number of cardiac operations ($P = .02$).

TABLE 3. Native pulmonary artery stenosis characteristics of patients undergoing pulmonary patch arterioplasty

Factor	Patches* N (column %)	Reintervention† N (row %)	*P* value
Location	312 (100.0)	70 (22.4)	
Proximal	223 (71.5)	47 (21.1)	.59
Distal	10 (3.2)	2 (20.0)	
Both	79 (25.3)	21 (26.6)	
Etiology	312 (100.0)	70 (22.4)	
Congenital	68 (21.8)	19 (27.9)	.35
Acquired	191 (61.2)	42 (22.0)	
Combined	53 (17.0)	9 (17.0)	
Laterality	312 (100.0)	70 (22.4)	
Unilateral	153 (49.0)	24 (15.7)	<.01
Bilateral	159 (51.0)	46 (28.9)	
Size	312 (100.0)	70 (22.4)	
Short	186 (59.6)	44 (23.0)	.04
Long	92 (29.5)	24 (26.1)	
Diffuse/combined	34 (10.9)	2 (5.9)	

*One patch of 313 lacked significant anatomic description to be included. †Reinterventions include both surgical and catheter-based interventions.

COMMENT

In this study, we sought to evaluate how different patch materials performed when used to augment the pulmonary arterial tree (Figure 2). Only a small number of reports thus far exist in the literature,[1-3] and we hoped to add to that pool of knowledge. We had a comparatively long experience of 28 years and included only children in our study. The diagnostic groups we assessed were similar to those reported elsewhere while also including single-ventricle patients and those with unifocalization procedures. We used autologous pericardium, pulmonary homograft, and a smaller heterogeneous group of materials to perform patch arterioplasty. We further assessed risk factors for reintervention by analyzing initial lesion, patient, and operative characteristics.

Our primary finding showing similar performance among patch types is consistent with findings reported by others.[1-3] This included the smaller third group, which consisted of a collection of a smaller number of different patches. Given the smaller number of individual patches in this group, drawing meaningful conclusions for each constituent patch type would be challenging, at best. However, the 2 patch materials we have used and continue to use the most for such purposes—autologous pericardium and

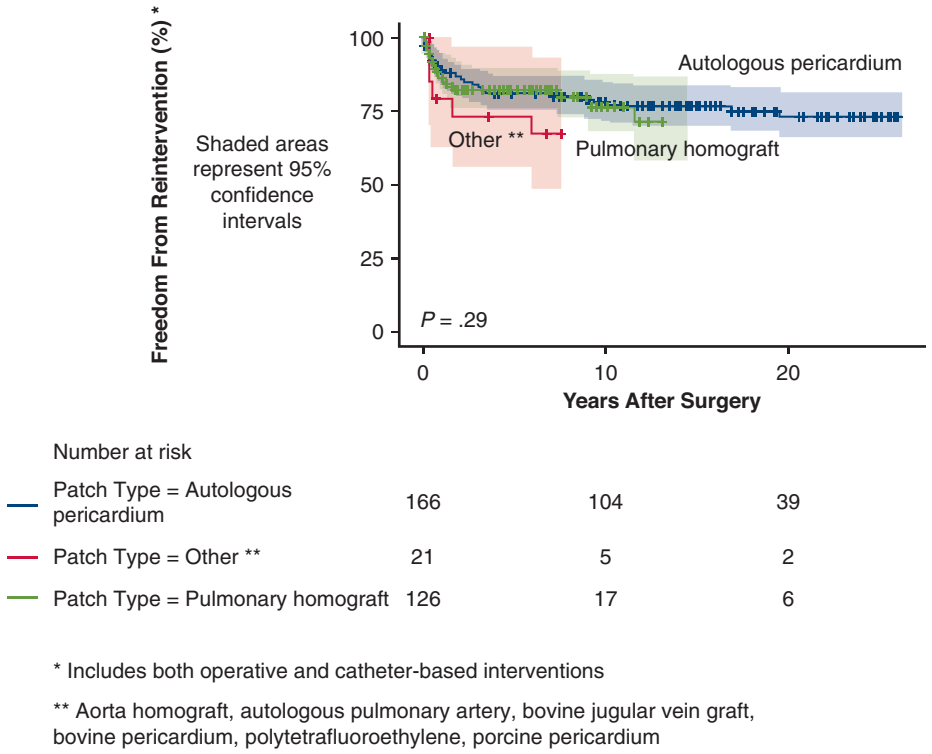

FIGURE 1. Freedom from reintervention (FFR) for patients undergoing pulmonary patch arterioplasty; listed by patch type.

pulmonary homograft—performed similarly. Furthermore, this similarity persisted when controlling for different diagnoses and operative strategies in the regression analyses.

TABLE 4. Univariable Cox proportional hazards analysis for reintervention of patients undergoing pulmonary patch arterioplasty; listed by native pulmonary artery stenosis characteristics

Factor	Univariable HR (95% CI)	*P* value
Location		
Proximal	Reference	
Distal	0.86 (0.21-3.56)	.84
Both	1.23 (0.74-2.06)	.43
Etiology		
Congenital	Reference	
Acquired	0.70 (0.41-1.21)	.20
Combined	0.55 (0.25-1.21)	.14
Laterality		
Unilateral	Reference	
Bilateral	2.18 (1.33-3.58)	< .01
Size		
Short	Reference	
Long	1.05 (0.64-1.73)	.84
Diffuse/combined	0.18 (0.04-0.75)	.02

HR, Hazard ratio; *CI*, confidence interval.

Reported rates of FFR on similar patient groups range from 46% to 80% at 10 years after operation.[1-3] Our 10-year FFR compares favorably at 76.6%. At 27 years of follow-up, our FFR for all patches is 70.6%; similar long-term follow-up was sparce in the literature, making comparisons difficult. Of the 49 initial interventions performed after initial pulmonary patch arterioplasty, 38 (77.6%) were surgical and 11 (22.4%) were catheter-based. It was again difficult to find similar comparisons in the literature. We preferred surgical reintervention earlier in the study period, particularly as catheter-based experience and technology was still maturing. Surgical intervention predominates still, for example, in PA intervention in patients with HLHS even after TCPC. Catheter-based interventions on patients with HLHS are more common after TCPC than are interstage PA lesions, which are predominantly surgically treated.

We described initial lesion characteristics and analyzed them, hoping to gain insight into risk factors for need for early reintervention. On univariable analysis, we found that bilateral lesions had a greater rate of reintervention than unilateral lesions, similar to the findings of Cresalia and colleagues.[2] Although their findings persisted through the multivariable analysis, our multivariable analysis failed to show a significant difference. As all variables were not identical between our models, this difference is perhaps attributable to the different factors included in our analysis.

Diagnoses of PA/VSD/MAPCAs and HLHS were associated with reintervention. Patients with PA/VSD/MAPCA

TABLE 5. Univariable Cox proportional hazards analysis for reintervention of patients undergoing pulmonary patch arterioplasty; listed by factors other than native pulmonary artery stenosis characteristics

Factor	Univariable	
	HR (95% CI)	*P* value
Male sex	1.78 (1.07-2.96)	.03
Age at operation	0.87 (0.79-0.95)	<.01
Weight at operation	0.94 (0.90-0.98)	<.01
Diagnosis		
TOF	Reference	
PA/VSD/MAPCA	2.70 (1.20-6.08)	.02
HLHS	5.05 (2.31-11.05)	<.01
PA/VSD	0.57 (0.15-2.11)	.40
PA/IVS	0.94 (0.25-3.47)	.92
TA	0.68 (0.09-5.38)	.72
Others*	0.71 (0.29-1.76)	.46
Patch placed at first cardiac operation	5.06 (3.15-8.15)	<.01
Number of previous cardiac operations	0.69 (0.53-0.91)	<.01
Operative strategy		
Single-ventricle correction	Reference	
2V correction without unifocalization	0.65 (0.39-1.10)	.11
2V correction with unifocalization	1.30 (0.65-2.74)	.49
Previous operation type		
No PA patch angioplasty	Reference	
PA patch angioplasty	0.88 (0.46-1.68)	.71
Patch type		
Autologous pericardium	Reference	
Pulmonary homograft	1.08 (0.64-1.81)	.77
Others†	1.90 (0.84-4.25)	.12

HR, Hazard ratio; *CI*, confidence interval; *TOF*, tetralogy of Fallot; *PA/VSD/MAPCA*, pulmonary artery/ventricular septal defect/major aortopulmonary collateral arteries; *HLHS*, hypoplastic left heart syndrome; *IVS*, intact ventricular septum; *TA*, truncus arteriosus; *2V*, 2-ventricle. *Anomolous aortic origin of pulmonary artery, atrioventricular septal defect (complete or partial), congenitally corrected transposition of the great arteries, complex single ventricle not otherwise specified, double-inlet left ventricle, double-inlet right ventricle, double-outlet right ventricle, double-outlet left ventricle, interrupted aortic arch, pulmonary stenosis (valvar, subvalvar, or supravalvar; PS), transposition of the great arteries with or without VSD with or without PS, tricuspid valve atresia or stenosis, VSD (single or multiple). †Aorta homograft, autologous pulmonary artery, bovine jugular vein graft, bovine pericardium, polytetrafluoroethylene, porcine pericardium.

TABLE 6. Multivariable Cox proportional hazards analysis for reintervention of patients undergoing pulmonary patch arterioplasty

Factor	Multivariable	
	HR (95% CI)	*P* value
Etiology		
Congenital	Reference	
Acquired	0.56 (0.27-1.17)	.12
Combined	0.70 (0.28-1.76)	.44
Laterality		
Unilateral	Reference	
Bilateral	0.94 (0.47-1.89)	.86
Size		
Short	Reference	
Long	1.08 (0.57-2.03)	.82
Diffuse/combined	0.22 (0.05-1.08)	.06
Male sex	1.38 (0.78-2.43)	.27
Age at operation	0.91 (0.82-1.02)	.09
Weight at operation	*	
Diagnosis		
TOF	Reference	
PA/VSD/MAPCA	3.53 (1.23-10.15)	.02
HLHS	4.61 (1.53-13.88)	.01
PA/VSD	0.96 (0.25-3.76)	.96
PA/IVS	1.56 (0.38-6.05)	.56
TA	1.72 (0.17-12.51)	.72
Others†	0.73 (0.32-2.21)	.73
Patch placed at first cardiac operation	6.64 (2.95-14.97)	< .01
Number of previous cardiac operations	1.45 (1.05-2.00)	.02
Operative strategy		
Single-ventricle correction	Reference	
2V correction without unifocalization	0.87 (0.40-1.88)	.72
2V correction with unifocalization	0.52 (0.14-1.88)	.32
Patch type		
Autologous pericardium	Reference	
Pulmonary homograft	0.82 (0.47-1.43)	.48
Others‡	2.29 (0.95-5.51)	.06

HR, Hazard ratio; *CI*, confidence interval; *TOF*, tetralogy of Fallot; *PA/VSD/MAPCA*, pulmonary artery/ventricular septal defect/major aortopulmonary collateral arteries; *HLHS*, hypoplastic left heart syndrome; *IVS*, intact ventricular septum; *TA*, truncus arteriosus; *2V*, 2-ventricle. *Variable eliminated from final multivariable model. †Anomolous aortic origin of pulmonary artery, atrioventricular septal defect (complete or partial), congenitally corrected transposition of the great arteries, complex single ventricle not otherwise specified, double-inlet left ventricle, double-inlet right ventricle, double-outlet right ventricle, double-outlet left ventricle, interrupted aortic arch, pulmonary stenosis (valvar, subvalvar, or supravalvar; PS), transposition of the great arteries with or without VSD with or without PS, tricuspid valve atresia or stenosis, VSD (single or multiple). ‡Aorta homograft, autologous pulmonary artery, bovine jugular vein graft, bovine pericardium, polytetrafluoroethylene, porcine pericardium.

often have complex reconstructions of the pulmonary arterial tree including unifocalization procedures. The natural course of MAPCAs is one prone to recurrent, multilevel stenosis formation. However clinically disappointing this may be, this finding was not unexpected. As described in a previous report, we routinely augment the systemic arterial outflow of our patients with HLHS.[6] While done predominantly to prevent recoarctation of the thoracic aorta, this also offers the advantage of relieving compression on mediastinal structures that can be caused by performing a primary anastomosis. In addition, as RV-PA shunts were favored over modified Blalock-Taussig shunts with time,

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Are There Performance Differences in Materials Used for Pulmonary Arterioplasty?

January 1993 – December 2020

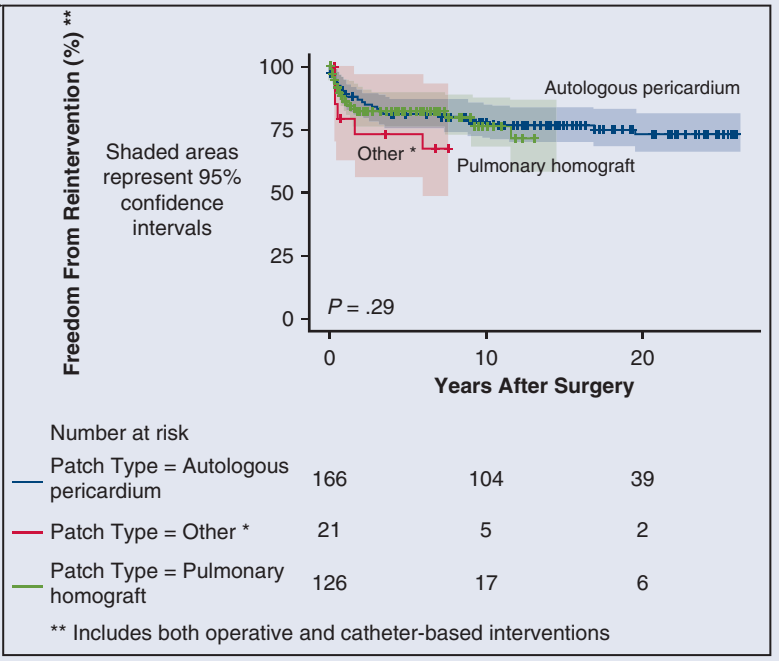
313 patches used in pediatric patients undergoing pulmonary arterioplasty

- 166 autologous pericardium
- 126 pulmonary homograft
- 21 other *

Using Multivariable Cox regression analysis...

Patch Type	Hazard Ratio	95% Confidence Interval	*P*-value
Autologous pericardium	Reference		
Pulmonary homograft	0.84	0.48 – 1.47	.54
Other *	2.41	1.00 – 5.82	> .05

... and Kaplan-Meier survival estimates



Autologous pericardium and pulmonary homograft perform similarly when used as **pulmonary arterioplasty patches** in the surgical repair of common pediatric congenital heart disease diagnoses.

* Aorta homograft, autologous pulmonary artery, bovine jugular vein graft, bovine pericardium, polytetrafluoroethylene, porcine pericardium

FIGURE 2. Brief description of study methods, results, and implications.

near-uniform patching of the PA confluence was performed to combat the potential deleterious effects of a relatively stiff shunt on fragile PA anatomy. Clearly, further refinements in the management of patients with HLHS are required to combat persistent morbiditity, of which the need for reintervention in the pulmonary arterial tree is but one.

A patch arterioplasty performed at a patient's initial cardiac operation was associated with reintervention. Since other variables were controlled for, attributing this to simply young, small children outgrowing their patches seems to be an incomplete explanation. Although materials implanted in young, small children have been shown in similar contexts to be a risk factor for reintervention,[2] neither low weight nor young age was a risk factor for reintervention in our study. In contrast to RV-PA conduits,[7] for example, the patches used in pulmonary arterioplasty are noncircumferential, allowing for native tissue growth. Many studies involving homograft implants attribute similar results to a robust inflammatory or immunologic response mounted against patch material presented to the body at an initial operation.[6] This explanation would be germane to our patient population, as well.

Increasing number of cardiac operations was a risk factor for reintervention. Although intuitively sensical, the mechanism of this interaction is not necessarily clear. Whether this is a function of the cumulative deleterious effects of reoperative surgery or a demonstration of the clinical course of vulnerable initial anatomy is not clear and would require further study.

Availability and cost are important considerations in surgical repair, as well. We generally tried to use autologous

pericardium. In reoperations in which either pericardium had already been previously harvested or was no longer suitable for use, we most often chose pulmonary homograft. Ebert and colleagues[1] compared both the performance and costs of different patches, finding equivalent performance with disparate costs. Operative materials continue to be developed and refined. For example, decellularized homograft patches have shown promising early results.[8] Cost considerations and performance comparisons will continue to be paramount to offer effective planning, counseling, and treatment.

The limitations of this study include its retrospective nature subject to selection bias. We tended to use more autologous pericardium earlier in the study period, with more pulmonary homograft later. There were significant differences among patch groups with respect to diagnoses treated, demonstrating a treatment bias. We did not use analyses that accounted for the measurement of interventions in the same individual patients, ie, a mixed model analysis. Although more complicated, such a model could have lent some further clarity to risk factor analysis, particularly with respect to repeated cardiac interventions.

The need for intervention and subsequent reintervention in the pulmonary arterial tree is a common one in congenital heart surgery, particularly among certain diagnoses. We found that the patches we used most—autologous pericardium and pulmonary homograft—performed similarly. Patients with a diagnosis of PA/VSD/MAPCAs or HLHS were at risk for reintervention. Increasing number of cardiac operations was a risk factor for reintervention, and patches placed during a patient's first cardiac operation were at risk for reintervention. Continued further appreciation of which diagnoses, lesions, and other factors predisposing to need for reintervention can help guide both expectations and treatment paradigms.

Conflict of Interest Statement

The authors reported no conflicts of interest.

The *Journal* policy requires editors and reviewers to disclose conflicts of interest and to decline handling or reviewing manuscripts for which they may have a conflict of interest. The editors and reviewers of this article have no conflicts of interest.

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Key Words: pulmonary, patch, arterioplasty homograft, autologous pericardium

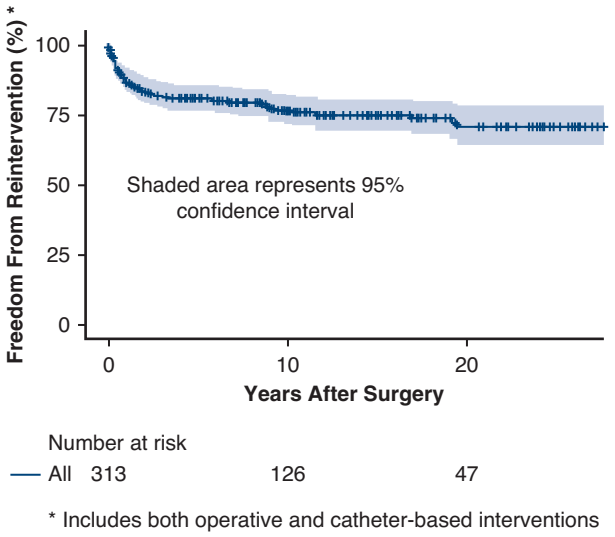

FIGURE E1. Freedom from reintervention (FFR) for patients undergoing pulmonary patch arterioplasty; all patch types.