Original Article

Mid-term results following pulmonary artery patch augmentation in congenital heart disease

Maria von Stumm[1,2]^, Tim Hildebrandt[1], Thibault Schaeffer[1,2], Paul Philipp Heinisch[1,2], Stanimir Georgiev[3], Cordula Wolf[3,4], Peter Ewert[3], Jürgen Hörer[1,2], Julie Cleuziou[1,2]

[1]Department of Congenital and Pediatric Heart Surgery, German Heart Center Munich, School of Medicine, Technical University of Munich, Munich, Germany; [2]Division of Congenital and Paediatric Heart Surgery, University Hospital of Munich-Ludwig-Maximilian University of Munich, Munich, Germany; [3]Department of Congenital Heart Defects and Pediatric Cardiology, German Heart Center Munich, School of Medicine & Health, Technical University of Munich, Munich, Germany; [4]DZHK (German Centre for Cardiovascular Research), Partner Site Munich Heart Alliance, Munich, Germany

Contributions: (I) Conception and design: M von Stumm, J Cleuziou; (II) Administrative support: P Ewert, J Hörer; (III) Provision of study materials or patients: P Ewert, J Hörer; (IV) Collection and assembly of data: M von Stumm, T Hildebrandt; (V) Data analysis and interpretation: M von Stumm, T Hildebrandt, J Cleuziou; (VI) Manuscript writing: All authors; (VII) Final approval of manuscript: All authors.

Correspondence to: Maria von Stumm, MD. Department of Congenital and Pediatric Heart Surgery, German Heart Center Munich, School of Medicine, Technical University of Munich, Lazarettstr 36, 80636 Munich, Germany; Division of Congenital and Paediatric Heart Surgery, University Hospital of Munich-Ludwig-Maximilian University of Munich, Munich, Germany. Email: stumm@dhm.mhn.de.

Background: Treatment of pulmonary artery (PA) stenosis in congenital heart disease is associated with adverse outcomes. The aim of this retrospective cohort study was to compare outcomes after surgical patch augmentation of PA stenosis in patients with biventricular congenital heart disease using different patch materials.

Methods: We identified all patients from our institutional congenital heart disease database who underwent patch augmentation for PA stenosis on the main pulmonary artery (MPA) or PA branches between 2012 and 2018. Patch materials used were glutaraldehyde fixated autologous pericardium (AP), expanded polytetrafluoroethylene (ePTFE), equine pericardium (EP), and bovine pericardium (BP). The primary study endpoint was the composite of catheter-based re-intervention or re-operation to relieve recurrent stenosis at the site of prior implanted patch material.

Results: A total of 156 patients (median age, 5 months, range, 0–85 months; median weight, 6.2 kg, range, 2.8–15.0 kg) underwent patch augmentation using 163 patches (ePTFE =99, 61%; EP =34, 21%; AP =25, 15%; BP =5, 3%). Overall, 131 (84%) patients underwent patch augmentation at the MPA, and 25 (16%) patients underwent patch augmentation at one or both PA branches. Over a mean follow-up period of 4±2 years, 30 patients (19%) reached the study endpoint. Freedom from primary endpoint was 92%±3% for the MPA and 25%±9% for PA branches at 5 years, respectively (P<0.001). Comparison of patch materials revealed similar re-intervention rates between ePTFE, AP, and EP. In contrast, outcomes were significantly decreased following the usage of BP when compared to other materials (ePTFE *vs.* BP, P=0.01; EP *vs.* BP, P=0.005). In the multivariable analysis, lower weight at index operation, patch augmentation of PA branches, and usage of BP were independently associated with re-intervention.

Conclusions: Patch augmentation of the MPA was associated with acceptable outcomes, while patch augmentation of PA branch stenosis remained independently associated with re-intervention. None of the used patch materials demonstrated superiority; however, BP had a higher rate of re-interventions.

Keywords: Congenital pulmonary artery stenosis (congenital PAS); pulmonary artery (PA); patch augmentation; patch plasty

^ ORCID: 0000-0001-9578-0430.

Submitted Jul 15, 2023. Accepted for publication Nov 02, 2023. Published online Nov 24, 2023.
doi: 10.21037/tp-23-382
View this article at: https://dx.doi.org/10.21037/tp-23-382

Introduction

Pulmonary artery stenosis (PAS) in congenital heart disease occurs isolated or as an additional feature of complex congenital heart defects, with a significant impact on mortality and morbidity (1,2). PAS can affect one, multiple, or all segments of the pulmonary vasculature, including the main pulmonary artery (MPA), right pulmonary artery (RPA), left pulmonary artery (LPA), and peripheral pulmonary branches distal to the hilum. From a morphological aspect, the stenotic arterial segment can vary from diffuse hypoplasia to circumscriptive stenosis.

Most patients with PAS are treated with surgical patch augmentation, often in combination with surgical repair of concomitant cardiac defects (1). However, the risk for recurrence or persistence of PAS after surgical patch augmentation is high, and 54% of patients require a re-intervention over a period of 10 years (1). Recurrent stenosis might be associated with biomechanical deficiencies of the implanted patch material and unfavorable postoperative pulmonary hemodynamics resulting in impaired vascular growth of native pulmonary artery (PA) tissue (3). Decision on which material to use is mainly driven by the surgeon's experience or the availability of patch material. Over the last decade, several different patch materials, including native, artificial, decellularized allogeneic, and xenogeneic materials, were used for surgical patch augmentation of PAS (4-6). However, all currently available patch materials are far from perfect, and outcomes following patch implantation are limited. In line with this, the ideal patch material remains a matter of debate. Therefore, we sought to report our experience with surgical PA patch augmentation using four different patch materials and outline risk factors for persistent or recurrent PAS. We present this article in accordance with the STROBE reporting checklist (available at https://tp.amegroups.com/article/view/10.21037/tp-23-382/rc).

Highlight box

Key findings

- Patch augmentation of the main pulmonary artery (MPA) was associated with acceptable outcomes, while patch augmentation of pulmonary artery (PA) branches remained independently associated with re-intervention. Neonates and young infants aged below 4 months and weighing under 5.2 kg at index procedure showed an increased risk for re-intervention.

What is known and what is new?

- Recurrence or persistence of pulmonary artery stenosis following surgical patch augmentation is a known complication.
- This retrospective single-center study aims to analyse the impact of patch site (MPA, PA branches) and patch material (expanded polytetrafluoroethylene, autologous pericardium, equine pericardium, bovine pericardium) on outcomes following surgical patch augmentation.

What is the implication, and what should change now?

- All four investigated patch materials were associated with re-interventions, and the ideal patch material has yet to be clarified. Therefore, frequent monitoring and a high suspicion for recurrent stenosis are indicated, especially in neonates and young infants.

Methods

Study design and patient population

For this study, we used a retrospective cohort study design. We reviewed all consecutive patients from our institutional electronic congenital heart disease database who underwent surgical patch augmentation for PAS at the German Heart Center Munich between January 2012 and December 2018. Surgical patch augmentation was defined as "reconstruction" or "arterioplasty" of PAS with implantation of patch material to the MPA, including transannular patches (TAPs), or to the PA branches up to the hilum. Patients who underwent patch augmentation in non-stenotic PAs during procedures such as arterial switch or repair of anomalous left coronary artery arising from the PA were excluded. Furthermore, patients without native pulmonary arteries (i.e., patients with pulmonary atresia with ventricular septal defect with major aortopulmonary collaterals, type c) were excluded.

The study population included patients with biventricular anatomy who underwent surgical patch augmentation as an isolated procedure or as a concomitant procedure during palliative surgeries (i.e., shunt surgery) or during the repair of other cardiac lesions. We excluded single-ventricle patients and patients above 18 years to ensure a more homogeneous study population.

Patients who underwent a previous catheter-based intervention, such as stent implantation at MPA or PA branches, were excluded from the study. Previous palliative procedures, such as shunt surgery, balloon angioplasty of the pulmonary valve, or stent insertion to the arterial duct, were not exclusion criteria. We assumed that these procedures did not alter the native pulmonary vasculature. In cases of missing follow-up data, patients were excluded from further analysis.

Surgical technique

The operation was routinely performed through a median sternotomy, and cardiopulmonary bypass was established through aortic and bicaval cannulation. Depending on the type of baseline surgery, mild hypothermia (32 °C) and cardioplegic arrest were used. Patches were sutured in a similar technique of running monofilament suture (Prolene 6-0 or 7-0, ETHICON®, New Jersey, USA). Transannular patch repair was routinely performed without additional pulmonary valve reconstruction (i.e., monocusp patch repair).

During the study period, we used four patch materials: glutaraldehyde fixated autologous pericardium (AP), expanded polytetrafluoroethylene (ePTFE) (GORE-TEX® Cardiovascular Patch, Arizona, USA; thickness 0.4 mm), equine pericardium (EP) (Matrix Patch™, Auto Tissue, Berlin, Germany) and bovine pericardium (BP) (CardioCel®, Admedus, Perth, Western Australia, Australia). The decision on which patch was used was made at the discretion of the attending surgeon.

AP was routinely fixated at the operating table in a glutaraldehyde 0.2% solution for 10 minutes. EP and BP were rinsed in saline as instructed by the manufacturer.

Follow-up protocol

After discharge, all patients underwent regularly scheduled follow-up visits, including a transthoracic echocardiography examination in an outpatient setting. Echocardiographic parameters included peak gradient (mmHg) and peak velocity (m/s) at the level of the priorly augmented PA segment. When the mean gradient was above 40 mmHg or the peak velocity was above 4 m/s, diagnostic right ventricular angiography was scheduled. Simultaneously, the need for re-intervention and the type of treatment strategy was discussed in a multidisciplinary conference with congenital cardiologists and congenital cardiac surgeons. During angiography, right ventricular systolic pressure (mmHg), pressure gradients at all PA segments (mmHg), and minimal and maximal lumen reduction (mm) were assessed.

The primary treatment of choice for recurrent PAS was a catheter intervention, including balloon angioplasty or stenting the PA. If the PAs were not accessible for re-intervention, a re-operation was planned.

Clinical endpoints

The primary study endpoint was the composite of catheter-based re-intervention and re-operation at the site of patch implantation. The secondary endpoint was mortality.

Post-hoc subgroup analyses by patch site and by patch material

Specific subgroups were formed to assess differences regarding patch sites and patch material. For patch site subgroup analysis, we summarized patients who received a TAP and patches on the MPA as the MPA group. The comparison group consisted of patients after patch implantation of the PA branches (i.e., LPA or RPA, or both).

For patch material subgroup analysis, subgroups were formed by each patch material that was used during the study period.

Statistical analysis

Categoric variables are described using frequencies (percent), and normally distributed continuous variables are presented as median with range. Comparison of normally distributed continuous variables was performed by unpaired *t*-test, while the comparison of not normally distributed continuous variables was performed by Wilcoxon rank test. Fisher's exact test was used for univariable comparisons of categorical variables. Freedom of re-intervention in study groups was compared using univariable log-rank test (Kaplan-Meier method). Predictors of the primary endpoint variable were subsequently assessed by univariable and multivariable Cox regression analysis. To analyze continuous variables, which were not normally distributed, they were transformed into binary variables using the 25th percentile as the cut-off point. This was for age >4 *vs.* ≤4 months; and for weight ≤5.2 *vs.* >5.2 kg. All P values <0.05 were considered statistically significant. All statistical

Table 1 Patient characteristics (n=156)

Patient characteristics	Values
Sex, n [%]	
Male	84 [54]
Female	72 [46]
Age group, n [%]	
<30 days	6 [4]
<1 year	128 [82]
≥1–<5 years	21 [13]
≥5–<10 years	1 [1]
Age (months), median (range)	5 (0–85)
Weight (kg), median (range)	6.2 (2.8–15.0)
Cardiac defect, n [%]	
TOF with PS	104 [67]
TOF with PA	14 [9]
DORV TOF	9 [6]
Primary PS	22 [14]
Others*	7 [4]
Staged repair, n [%]	57 [37]

*, other cardiac diagnoses include primary peripheral pulmonary artery stenosis, pulmonary atresia with intact ventricle septum, unilateral absence of a pulmonary artery, hemitruncus. TOF, tetralogy of Fallot; PS, pulmonary stenosis; PA, pulmonary atresia; DORV TOF, double outlet right ventricle Fallot type.

Table 2 Operative details

Operative details	Values
Type of surgery, n [%]	
Corrective surgery	146 [94]
Palliative surgery	10 [6]
Procedure time (min), median (range)	237 (125–466)
Patch sites, n [%]	
Transannular patch	98 [58]
Main PA	43 [25]
LPA	17 [10]
RPA	12 [7]
Patch material, n [%]	
ePTFE	99 [61]
EP	34 [21]
AP	25 [15]
BP	5 [3]

PA, pulmonary atresia; LPA, left pulmonary artery; RPA, right pulmonary artery; ePTFE, expanded polytetrafluoroethylene; EP, equine pericardium; AP, autologous pericardium; BP, bovine pericardium.

analyses were performed using the SPSS V.26.0 statistical package (IBM Corp.).

Ethics statement

The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional ethics committee of School of Medicine, Technical University of Munich, Germany (2023-3-S-KH) and individual consent for this retrospective analysis was waived.

Results

Patient characteristics

During the study period of 7 years, 254 patients underwent PA reconstruction. Among these patients, 98 were not eligible for study inclusion. The study population comprised 156 patients, including 135 infants aged below one year (see *Table 1*). Mean follow-up time was 4±2 years. The underlying congenital heart defect was tetralogy of Fallot (TOF) or a morphological variant of TOF in most patients (82%). A staged repair was performed in 57 (37%) patients. Palliative procedures included shunt operations (n=28; 49%), angioplasty at the level of the pulmonary valve or pulmonary arteries (n=21; 37%) and ductal stenting (n=8; 14%).

Operative details

A total of 163 patches were implanted at 170 patch sites in our study cohort, comprising 156 patients (see *Table 2*). One patient received three patches at three sites (TAP, LPA, RPA), six patients received two patches at two sites (i.e., TAP + LPA; TAP + RPA), and six patients received one extended patch covering two sites (i.e., LPA + RPA; MPA + RPA; TAP + LPA). The remaining patients received one patch at one site. Overall, 131 (84%) patients underwent patch augmentation at the main PA, and 25 (16%) patients

underwent patch augmentation at one or both PA branches. Distribution of implanted patch material differed by patch site. ePTFE was significantly more often implanted at the MPA than at the PA branches (MPA: 71% *vs.* PA: 16%, P<0.001). On the contrary, EP was significantly more often used at the PA branches than at the MPA (MPA: 13% *vs.* PA: 52%, P<0.001). Distribution of patch material AP and BP showed no differences between patch sites.

Survival

Survival to hospital discharge or 30 days postoperatively was 100%. Four late deaths (2.6%) were observed. The first death occurred in a male child one month after surgical repair of an isolated PS with TAP (ePFTE) at home due to unknown reasons. The second death occurred in a female child with pulmonary atresia with ventricular septal defect (VSD) and major aorto-pulmonary collateral arteries (MAPCAs), who died from massive hemoptysis caused by an LPA-bronchial fistula 6 months after corrective surgery with TAP (ePTFE) and patch augmentation of RPA (EP) and LPA (EP). The third death occurred in a male child who suffered from VACTERL (vertebral defects, anal atresia, cardiac defects, tracheo-esophageal fistula, renal anomalies and limb anomalies) association and died one year after TOF repair using TAP (ePTFE) of progressive bronchomalacia. The last death was a male child who suffered from Opitz-G syndrome and pulmonary atresia with VSD. The child underwent enlargement of RPA (ePTFE) and LPA (ePTFE) during shunt surgery and received two stents after 3 months to the RPA and LPA. Due to the progression of the underlying syndromic disease, the treatment concept was altered to palliative care, and the patient died 15 months after patch implantation at home. Overall, survival was 97%±1% at 5 years following PA patch augmentation.

Freedom of any re-intervention

Over the study period, 30 (19%) patients reached the primary endpoint, including 19 catheter-based and 11 surgical re-interventions. Freedom from the primary endpoint was 80%±3% at 5 years for the whole cohort (see *Figure 1A*).

Impact of patch site

Subgroup analysis by patch site revealed that patients after MPA patch augmentation required fewer re-interventions than patients after patch augmentation of the PA branches (MPA: 8% *vs.* PA: 72%, P<0.001) (see *Table 3*). Freedom from the primary endpoint was significantly higher in patients after MPA patch augmentation *vs.* patients after PA branch patch augmentation (at 5 years: 92%±3% *vs.* 25%±9%; P<0.001) (see *Figure 1B*).

Impact of patch material

Subgroup analysis of patch material corrected for patch site revealed that for patients undergoing patch implantation at the MPA, BP was associated with a significantly higher rate of re-interventions compared to ePTFE or EP at 5 years (EP *vs.* BP: 100% *vs.* 75%±2%, P=0.005; ePTFE *vs.* BP: 89%±4% *vs.* 75%±2%, P=0.01) (*Figure 1C*). For patients with patch augmentation of the PA branches, no differences between patch materials regarding freedom of re-intervention were found (*Figure 1D*). The exact numbers of all patch materials implanted, and the numbers of re-intervened patches are depicted in *Table 3*. Of note, all five ePTFE patches implanted at the PA branches needed a reintervention.

PA re-intervention

Overall, there were 11 early and 19 late re-interventions (*Table 4*). The median time to re-intervention was 3 months (range, 0–71 months). Surgical enlargement of pulmonary branch arteries and relief of recurrent obstruction of the right ventricular outflow tract was necessary in 54% and 46% of patients, respectively. Catheter-based re-interventions consisted of stent insertion (53%) and balloon angioplasty (36%) for recurrent PAS.

Echocardiographic measurements in patients with recurrent PAS before reintervention revealed a median peak gradient of 81 mmHg and a peak velocity of 4.4 m/s. Measurements during pulmonary angiography revealed severely elevated pressure of the right ventricle (RV) (median, 70 mmHg) with stenosis gradients of 52 mmHg.

Risk factors for re-intervention

The rate of re-intervention was related to the age and weight of patients (*Table 5*). Children younger than 4 months and with a weight below 5.2 kg had a significantly increased risk for re-intervention compared to those who underwent patch augmentation at an older age or with a

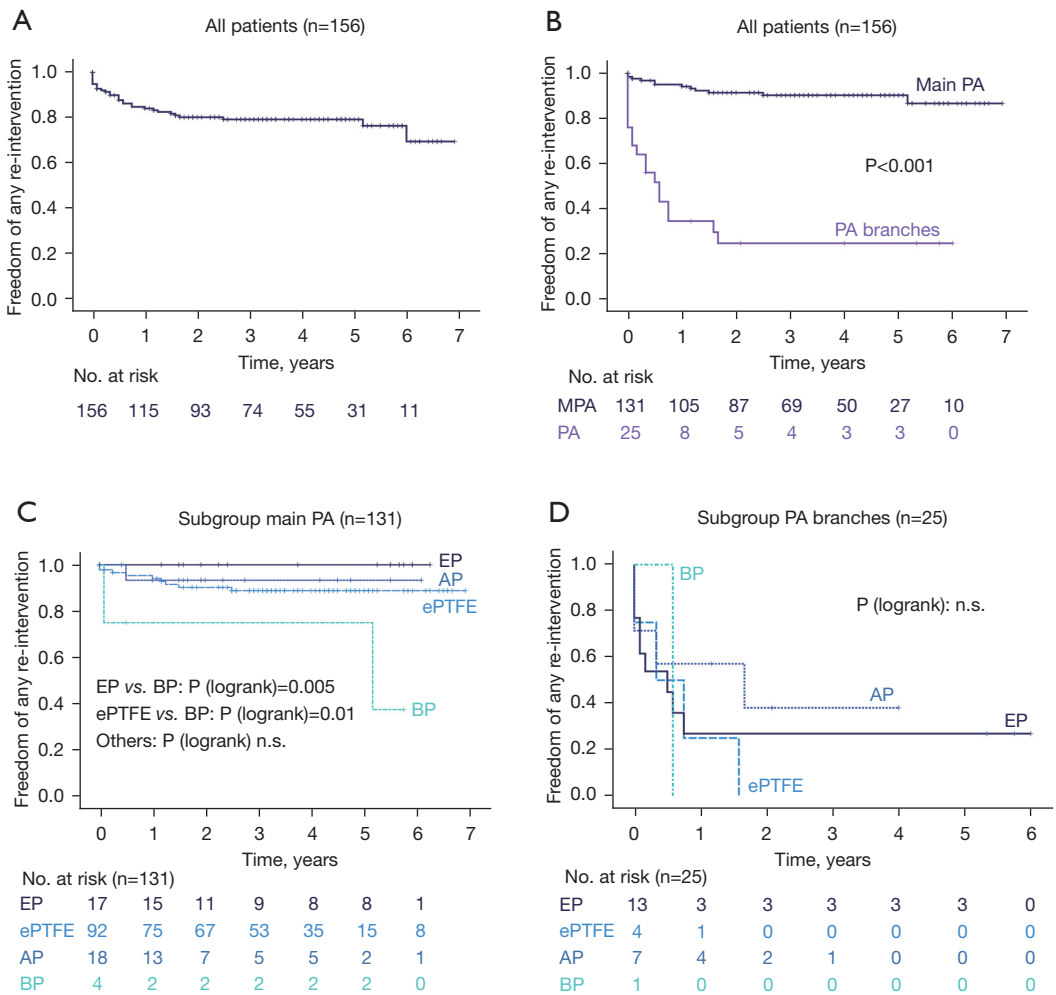

Figure 1 Freedom of re-intervention. The graphic shows the freedom of any re-intervention of all patients (A) and after division into two groups by patch site including main PA and PA branches (B). The graphics show the freedom of any re-intervention in the subgroup main PA (C) and PA branches (D). Both subgroups were further divided by patch material that was used. PA, pulmonary artery; EP, equine pericardium; AP, autologous pericardium; ePTFE, expanded polytetrafluoroethylene; BP, bovine pericardium; n.s., not significant.

higher weight. Given the significant correlation between weight and patient age (Pearson r=0.66, P<0.001), patient age was excluded from the multivariable analysis to avoid collinearity. Multivariable analysis showed that lower weight at index operation, patch augmentation of PA branches, and usage of BP remained independently associated with re-intervention (*Table 6*).

Discussion

We present a large retrospective single-center cohort study of mid-term outcomes after surgical pulmonary patch augmentation and provide insights regarding risk factors for re-intervention. Freedom of re-intervention was 80%±3% at 2 years in our cohort, which was comparable to previously published results ranging from 77% to 85% (1,4,6). However, division of our cohort by patch site revealed that freedom of re-intervention was inferior in patients with patches at PA branches compared to patients with patches at MPA (at 5 years: MPA 92%±3% *vs.* PA 25%±9%; P<0.001). In line with this, patch implantation at PA branches was identified as an independent risk factor for re-intervention in the multivariate analyses. Similar results were found by Ebert *et al.*, who reported a lower risk for re-intervention in patients undergoing patch augmentation at the MPA compared to PA branches [hazard ratio (HR)

Table 3 Distribution of implanted and re-intervened patches

Patch material	Implanted patches, n	Re-intervened patches, n	Re-intervention rate (%)
Transannular patch			
ePTFE	70	6	9
AP	9	1	11
EP	15	0	0
BP	4	2	50
MPA			
ePTFE	24	3	13
AP	9	0	0
EP	7	0	0
BP	0	0	0
LPA			
ePTFE	3	3	100
AP	5	3	60
EP	8	7	88
BP	1	1	100
RPA			
ePTFE	2	2	100
AP	3	2	67
EP	7	3	43
BP	0	0	0

ePTFE, expanded polytetrafluoroethylene; AP, autologous pericardium; EP, equine pericardium; BP, bovine pericardium; MPA, main pulmonary artery; LPA, left pulmonary artery; RPA, right pulmonary artery.

Table 4 Pulmonary artery re-intervention (n=30)

Re-intervention and re-operation	Values
Type of re-intervention, n [%]	
Re-intervention	19 [63]
Re-operation	11 [37]
Location recurrent PAS, n [%]	
RVOT	5 [17]
PV	3 [10]
MPA	2 [7]
LPA	16 [53]
RPA	8 [27]
Imaging measurements before re-intervention, median (range)	
Echocardiography	
Peak gradient (mmHg)	81 (30–120)
Peak velocity (m/s)	4.4 (2.8–5.5)
Angiography	
Systolic RV pressure (mmHg)	70 (36–91)
Gradient stenosis (mmHg)	53 (23–73)
Minimal diameter (mm)	3 (0–11)
Lumen reduction (%)	57 (20–100)

PAS, pulmonary artery stenosis; RVOT, right ventricular outflow tract; PV, pulmonary valve; MPA, main pulmonary artery; LPA, left pulmonary artery; RPA, right pulmonary artery; RV, right ventricle.

=0.4; 95% confidence interval (CI): 0.2–11] (4). In addition, age and weight were identified as independent risk factors for re-intervention, which are similar findings compared to the previously published literature (1,4,6).

Another confounder of freedom of re-intervention might be patch material. In our analysis, none of the used patch materials (ePTFE, EP, AP, BP) showed superiority over the other materials regarding re-intervention. In the BP subgroup, three out of five patients needed a re-intervention, and usage of BP was independently associated with re-intervention in the multivariate analysis. Although, the size of the BP subgroup was small (n=5), which might have affected the statistical power of our analysis. Of note, in the current literature, two histological studies examined graft failure of BP patches in congenital aortic valve disease. They found signs of early calcification and fragmentation of the collagen matrix in explanted BP patches (7,8). The authors concluded that BP should not be used as the first choice for congenital aortic valve repair (7). Based on our findings, we draw similar conclusions and do not recommend BP as the first choice for PA patch augmentation.

Though, due to the limited sample size of our subgroups, our findings should only be generalized with further evidence from larger samples.

Patch design and biomechanical properties of patch material are important aspects for successful PA patch augmentation in the long term. Recently, Lashkarinia *et al.* evaluated computer-aided surgical patch designs for augmentation of the MPA, which were further validated in an *in-vitro* model using rapid-prototype replicas (3). The

Table 5 Univariate risk factor analysis for pulmonary artery stenosis re-intervention

Factor	HR	95% CI	P value
All patients (n=156)			
Age at index operation	0.88	0.79–0.97	0.03
≤4 months†	2.20	1.09–4.47	0.03
>4 months	Ref		
Weight at index operation	0.64	0.51–0.81	<0.001
≤5.2 kg†	3.95	1.93–8.08	<0.001
>5.2 kg	Ref		
Female sex	0.90	0.44–1.85	0.78
Staged repair	2.41	1.2–4.8	0.02
Patch augmentation of PA branch	13.2	6.3–27.5	<0.001
Patch augmentation of MPA/TAP	Ref		
Subgroup main PA (n=131)			
ePTFE	1.30	0.35–4.86	0.69
EP	0.04	0–39.13	0.35
AP	0.65	0.08–5.02	0.67
BP	6.74	1.44–31.50	0.02

†, 25th percentile of the study cohort. HR, hazard ratio; CI, confidence interval; Ref, reference; PA, pulmonary atresia; MPA, main pulmonary artery; TAP, transannular patch; ePTFE, expanded polytetrafluoroethylene; EP, equine pericardium; AP, autologous pericardium; BP, bovine pericardium.

Table 6 Multivariate analysis for risk factors for pulmonary artery stenosis re-intervention

Factor	HR	95% CI	P value
Weight at index operation	0.77	0.63–0.94	0.009
Staged repair	1.07	0.48–2.37	0.88
Patch augmentation of PA branch	11.44	4.60–26.41	<0.001
BP	4.45	1.29–15.41	0.02

HR, hazard ratio; CI, confidence interval; PA, pulmonary atresia; BP, bovine pericardium.

researchers demonstrated that patches that were too short in relation to the length of the stenosis had an increased stress level. On the contrary, when the patch length was designed to be longer than 20% of the length of the stenosis, the maximum stress appeared upon the native arterial wall and not at the patch. This might be more favorable since native arterial tissue can remodel and adapt as a response to stress in contrast to patch materials.

Furthermore, they compared the biomechanical properties of four different patch materials, including PTFE, Dacron, porcine xenopericardium, and human pericardium. Interestingly, 0.7 mm thick PTFE was associated with the lowest stress difference at the transition between the patch and artery. In addition, PTFE patches showed no deformation at patch corners with a smooth transition to arterial tissue, while Dacron and porcine xenopericardium patches created "bumpy corners". The authors concluded that PTFE has better biomechanical properties than biological patches.

In our study, all five patients who underwent patch augmentation at the PA branches with ePTFE needed re-interventions. Although, we used a thinner patch (0.4 mm) than Lashkarinia *et al.*, which could have an impact on the biomechanical properties. Overall, the ideal geometry and structure of patches have yet to be clarified. In the future, tissue-engineered patches may potentially emerge as a superior alternative (9).

Limitations

Our study possesses all the limitations of a retrospective study that was conducted at a single congenital heart disease center. The patch type was chosen by the surgeon at the time of surgery and was not assigned in a randomized fashion. Five surgeons operated at our center during the study period, and their respective techniques could not be standardized. The follow-up period of our study was relatively short; thus, long-term complications related to the use of patch material remain unknown.

In addition, analysis of the durability and effectiveness of patch material after PA patch augmentation implies methodical difficulties. While echocardiographic examination and angiography imaging of recurrent PAS reveal quantitative data (i.e., pressure, velocity, diameter), other criteria, such as the quality of the native tissue, are hard to verify. Based on this missing information, the differentiation between patch failure *vs.* impaired growth of native PA tissue is challenging to distinguish. Furthermore, it remains impossible to demonstrate that the patch material is the only cause of re-intervention at the PAs. Other features, such as flow dynamics and their impact on growth, are unknown and could not be elucidated through this study.

Conclusions

Patch augmentation of the MPA was associated with acceptable outcomes, while patch augmentation of PA branch stenosis remained independently associated with re-intervention. Neonates and young infants aged below 4 months and weighing under 5.2 kg showed an increased risk for re-intervention. Frequent monitoring and a high suspicion for recurrent stenosis are indicated, especially during the first few postoperative years. None of the used patch materials demonstrated superiority; however, usage of BP should be cautiously reconsidered.

Acknowledgments

Funding: None.

Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at https://tp.amegroups.com/article/view/10.21037/tp-23-382/rc

Data Sharing Statement: Available at https://tp.amegroups.com/article/view/10.21037/tp-23-382/dss

Peer Review File: Available at https://tp.amegroups.com/article/view/10.21037/tp-23-382/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://tp.amegroups.com/article/view/10.21037/tp-23-382/coif). J.C. serves as an unpaid editorial board member of *Translational Pediatrics* from January 2023 to December 2024. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by institutional ethics committee of School of Medicine, Technical University of Munich, Germany (2023-3-S-KH) and individual consent for this retrospective analysis was waived.

References

1. Cresalia NM, Armstrong AK, Romano JC, et al. Long-Term Outcomes After Surgical Pulmonary Arterioplasty and Risk Factors for Reintervention. Ann Thorac Surg 2018;105:622-8.
2. European Congenital Heart Surgeons Association. 2023.
3. Lashkarinia SS, Piskin S, Bozkaya TA, et al. Computational Pre-surgical Planning of Arterial Patch Reconstruction: Parametric Limits and In Vitro Validation. Ann Biomed Eng 2018;46:1292-308.
4. Ebert N, McGinnis M, Johnson W, et al. Comparison of Patch Materials for Pulmonary Artery Reconstruction. Semin Thorac Cardiovasc Surg 2021;33:459-65.
5. Y Fraint H, E Richmond M, A Bacha E, et al. Comparison of Extracellular Matrix Patch and Standard Patch Material in the Pulmonary Arteries. Pediatr Cardiol 2016;37:1162-8.
6. Murin P, Weixler VHM, Kuschnerus K, et al. Pulmonary artery augmentation using decellularized equine pericardium (Matrix Patch™): initial single-centre experience. Eur J Cardiothorac Surg 2021;60:1094-101.
7. Nordmeyer S, Kretzschmar J, Murin P, et al. ADAPT-treated pericardium for aortic valve reconstruction in congenital heart disease: histological analysis of a series of human explants. Eur J Cardiothorac Surg 2019;56:1170-7.
8. Deutsch O, Bruehl F, Cleuziou J, et al. Histological examination of explanted tissue-engineered bovine pericardium following heart valve repair. Interact Cardiovasc Thorac Surg 2020;30:64-73.
9. Richert E, Nienhaus A, Ekroll Jahren S, et al. Biogenic polymer-based patches for congenital cardiac surgery: a feasibility study. Front Cardiovasc Med 2023;10:1164285.

Cite this article as: von Stumm M, Hildebrandt T, Schaeffer T, Heinisch PP, Georgiev S, Wolf C, Ewert P, Hörer J, Cleuziou J. Mid-term results following pulmonary artery patch augmentation in congenital heart disease. Transl Pediatr 2023;12(11):1992-2000. doi: 10.21037/tp-23-382