Původní sdělení | Original research article

18-Year Outcomes of Aortic Leaflet Extension Valvuloplasty Using Autologous Pericardium and Polytetrafluoroethylene: Single-Centre, Propensity-Matched Analysis

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Kľúčové slová:
Aortálna valvuloplastika pomocou extenzie cípov
Párovanie na základe propenzitných skórov
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Vrodená chyba aortálnej chlopne

SÚHRN

Úvod: Valvuloplastika aortálnej chlopne s extenziou cípov sa rutinne používa v liečbe chýb aortálnej chlopne u detí a dospievajúcich. Materiál použitý na valvuloplastiku môže ovplyvniť funkciu aortálnej chlopne a jej trvácnosť.
Ciele: Zhodnotiť dlhodobé výsledky valvuloplastiky aortálnej chlopne technikou extenzie cípov pomocou autológneho perikardu alebo polytetraflóretylénu (PTFE) a odhaliť rizikové faktory vedúce k reoperácii aortálnej chlopne na našom pracovisku.
Metódy: Retrospektívna analýza 89 pacientov, ktorí sa podrobili valvuloplastike aortálnej chlopne technikou extenzie cípov pomocou autológneho perikardu alebo PTFE na našom pracovisku v období 2005 – 2023.
Výsledky: 89 pacientov (75 % mužského pohlavia) sa podrobilo valvuloplastike aortálnej chlopne technikou extenzie cípov pomocou autológneho perikardu (n = 42) alebo PTFE (n = 47). Medián veku pacientov bol 14 rokov (IQR: 7 mesiacov – 26 rokov). Počas strednej dĺžky sledovania 13,3 roka (IQR: 1 mesiac – 18 rokov) sme zaznamenali 4 úmrtia a u 41 (46 %) pacientov bola potrebná reoperácia priemerne 7,8 ± 4,2 roka od primárnej operácie. V skupine s autológnym perikardom to nastalo u 24 (57 %) pacientov a v skupine s PTFE u 17 (36 %) pacientov. Celkové prežívanie pacientov v čase 18 rokov od operácie bolo 95 %. Reoperovanosť v celom súbore v 5 rokoch od operácie bola 12,4 %, v 10 rokoch 43 % a v 15 rokoch 64,6 %. Pri multivariabilnej Coxovej analýze boli identifikované nasledujúce rizikové faktory pre reoperáciu na aortálnej chlopni: aortálna insuficiencia ako primárna diagnóza, diameter aortálnej chlopne, infekčná endokarditída, dĺžka klemu na aorte a mimotelového obehu a predchádzajúca valvuloplastika v minulosti.
Záver: Dlhodobé výsledky aortálnej valvuloplastiky technikou extenzie cípov pomocou autológneho perikardu alebo PTFE u pacientov s vrodenou chybou aortálnej chlopne odrážajú vynikajúce prežívanie bez významného rozdielu z hľadiska výskytu reoperácií kvôli dysfunkcii aortálnej chlopne medzi obomi skupinami pacientov.

Keywords:
Aortic leaflet extension valvuloplasty
Congenital aortic valve disease
Polytetrafluoroethylene
Propensity score matching
Tricuspidalization

ABSTRACT

Background: Aortic valve repair with leaflet extension is routinely utilized in the management of aortic valve disease in children and adolescents. The material chosen may have an effect on the valve function and durability.
Aims: To evaluate long-term outcomes of aortic valve repair using autologous pericardium and polytetrafluoroethylene (PTFE) leaflet extensions and to investigate risk factors for aortic valve reoperation at single centre.
Methods: A retrospective single-centre review of 89 patients undergoing aortic valvuloplasty by leaflet extensions with either autologous pericardium or PTFE from 2005 to 2023.
Results: Eighty-nine patients (75% male) underwent aortic leaflet extension valvuloplasty, using either autologous pericardium (n = 42) or PTFE (n = 47). Median age was 14 years (IQR: 7 months–26 years). During median follow-up duration of 13.3 years (IQR: 1 month–18 years), there were 4 deaths and 41 (46%) patients required reoperation at a mean of 7.8 ± 4.2 years, 24 (57%) within autologous pericardium group, and 17 (36%) within PTFE group. Overall survival at 18 years was 95%. Overall reoperation-free survival at 5, 10 and

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15 years was 87.6%, 57%, and 35.4%, respectively. Multivariable Cox analysis identified primary diagnosis of aortic regurgitation, aortic annulus diameter, infective endocarditis, aortic cross-clamp and cardiopulmonary bypass time, and preoperative aortic surgical valvuloplasty as risk factors for aortic valve reoperation.
Conclusions: Long-term results of aortic leaflet extension valvuloplasty, utilizing either autologous pericardium or PTFE, in patients with congenital aortic valve disease suggest excellent survival with no significant difference in the reoperation rate for aortic valve dysfunction between the groups.

Introduction

Aortic valve plasty with leaflet extensions is a surgical technique used in both children and adolescents to manage aortic valve disease.[1] It has gained popularity among surgeons due to its efficiency in treating both aortic valve stenosis and regurgitation.[2] It also offers advantages of avoiding anticoagulation therapy, having a low risk of thrombosis, allows for potential growth of aortic annulus and has favorable hemodynamics.[3] Autologous pericardium, fresh or glutaraldehyde-treated was traditionally used for aortic leaflet extension valvuloplasty, although it has some disadvantages, including calcification and eventual attrition. In order to develop more durable materials for aortic valvuloplasty, alternative biological materials were introduced, such as decellularized bovine pericardium (CardioCel, Admedus, Queensland, Australia), CorMatrix (CorMatrix Cardiovascular, Inc, Atlanta, GA, USA) and equine pericardium (Matrix patch, Auto Tissue GmbH, Berlin, Germany).[2,4–6] Moreover, in 2008 we were the first to use 0.1-mm expanded polytetrafluroethylene (PTFE) membrane (W.L. Gore & Assoc., Flagstaff, AZ, USA) for aortic leaflet extension, and initial outcomes on 13 patients were published in 2012.[7] However, optimal material is yet unknown and needs to be explored further.

Only few studies reported the long-term results of aortic leaflet extension valvuloplasty in children and young adults.[1,3,8] Moreover, only one study in literature published mid-term results of using PTFE for aortic valvuloplasty,[9] and long-term outcomes are still to be investigated. Hence, we sought to assess long-term clinical outcomes of aortic valvuloplasty using autologous pericardium and PTFE with respect to patient survival, reoperation-free and aortic valve replacement (AVR) survival in pediatric patients, and adolescents with congenital aortic valve disease at our institution.

To our knowledge, this is the first retrospective comparison of autologous pericardium and PTFE patch material utilized for aortic leaflet extension valvuloplasty.

Aortic valvuloplasty by tricuspidalization with leaflet extension technique

Our surgical technique had been published previously,[7] and did not change throughout study period. In addition, surgical technique video is available online on a CTSnet website.[10] Autologous pericardium was treated with glutaraldehyde 0.625% solution for 8 minutes, and then rinsed in isotonic saline prior to use. Initially, we used autologous pericardium; however, since 2008, we have transitioned to utilizing a 0.1 mm PTFE membrane as a leaflet extension material. Briefly, all patients were operated through a full median sternotomy in mild hypothermia using cold blood Del Nido cardioplegia solution. The cardiopulmonary bypass was initiated via single or double caval and aortic cannulation.

The aortic valve was exposed through a transverse aortotomy. The raphe was divided to aortic wall, and a commissurotomy and shaving were performed in some cases if there was commissural fusion and thickening of the leaflets. After native leaflets were excised, the length of each leaflet was measured separately using a silk tie.

The height of leaflets was determined by mesuring the height of the native left coronary leaflet. Then rectangular patches of autologous pericardium or 0.1 mm PTFE (W.L. Gore & Assoc., Flagstaff, AZ, USA) were created and sewed to the free edges of leaflets with 6-0 polypropylene or polybutester (Vascufil) sutures. A central stitch was used to join the three patches to adjust and assess geometry and coaptation of the valve. The constructed leaflets were suspended at the level of newly created commissures using sutures' free ends and secured outside the aorta with pericardial pledgets. All procedures were done by the same surgeon at our centre.

Patients and methods

Patients

Study included patients who had undergone aortic valvuloplasty with leaflet extensions at Department of Pediatric Cardiac Surgery, Children's Heart Centre, Bratislava, Slovakia, between 31 August 2005 and 31 August 2023. Medical records of the patients were reviewed retrospectively.

The patients with congenital aortic valve disease, who were referred for aortic valvuloplasty by leaflet extension using autologous pericardium or PTFE were included. Patients without retrievable medical or operation records, and those undergoing aortic leaflet extension valvuloplasty using equine pericardium (Matrix patch, AutoTissue GmbH, Berlin, Germany) were excluded from the study.

Demographic data, primary diagnosis, gender, aortic valve morphology, previous procedures: surgical or balloon aortic valvuloplasty, aortic annulus and ascending aorta size, age at operation, extension height and material, pre- and post-operative echocardiographic findings, follow-up clinical data and reoperation data were collected. We also analyzed treatment outcomes, patient survival, and duration of freedom from reoperation.

All patients were evaluated by transthoracic echocardiography preoperatively, perioperatively by transesophageal echocardiography, and postoperatively at regular intervals (3–12 months). The aortic valve annulus and root dimensions were measured in parasternal long-axis views.

Patients were assigned to two groups (based on the extension material): autologous pericardium and PTFE. Propensity score-matching analysis method was done, and 38 patients (19 matched pairs) were chosen for comparison.

Study endpoints were survival, freedom from reoperation, and freedom from AVR. Freedom from reoperation was defined as the time period between aortic valvuloplasty and aortic valve reoperation. Freedom from AVR was defined as the time period between aortic valvuloplasty and aortic valve replacement with either mechanical or biological prosthesis. Patients in both groups received aspirin for 6 months postoperatively.

Decisions regarding the primary operation or reoperation were made individually in a multidisciplinary conference. Indication criteria for aortic valvuloplasty or reoperation were severe aortic stenosis (AS) with mean gradient ≥50 mmHg and/or severe aortic regurgitation (AR) with dilated left ventricle (Z-Score ≥3) and IE.

Statistical analysis

All continuous variables are expressed as mean and standard deviation (SD) or median with interquartile range (IQR) as appropriate. Categorical variables are presented as numbers with percentages. Comparisons for categorical variables were calculated with chi-squared (χ^2) or Fisher's exact test. Shapiro–Wilk test was employed to determine the normality of distribution. Student's t-test was used to compare continuous variables in the unmatched cohort, unless the data were not distributed normally; in these instances, Mann–Whitney U-test was used. Comparisons within the matched cohort were constructed using a paired-sample t-test, or Wilcoxon signed rank test, where appropriate.

Kaplan–Meier survival analysis was used to evaluate freedom from reoperation and AVR, and to estimate a rate of survival. Comparisons between groups were tested by log-rank test. A univariable and multivariable Cox regression models were contructed to assess factors associated with reoperation. Variables with a *p*-value <0.1 in the univariable analysis were used for the multivariable stepwise Cox regression model.

Propensity score matching (PSM) method was used to match two groups on a set of 4 explanatory variables (age, weight, gender, and primary diagnosis). Propensity score was estimated using a logistic regression model with 1 : 1 nearest neighbor matching without replacement based on a caliper width of 0.2 times the standard deviation (SD) of the logit of propensity score.[11] Standardized difference in means between two groups pre- and post-matching was used to evaluate the matching quality.

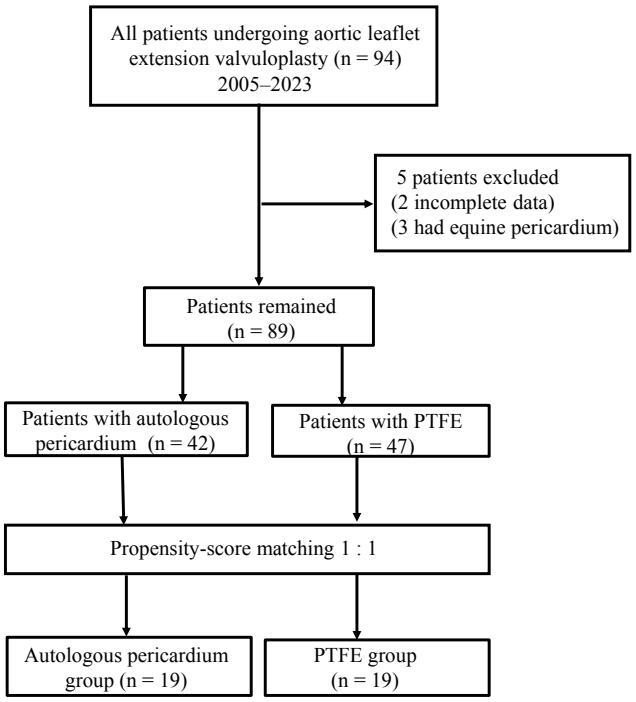

Fig. 1 – Flowchart of the study. PTFE – polytetrafluoroethylene.

For all tests, a $p \leq 0.05$ was considered statistically significant. Statistical analyses were performed using R statistical software (version 4.3.1, R Foundation for Statistical Computing, Vienna, Austria).

Results

A total of 89 patients were included. Of these, 42 (47%) underwent aortic valvuloplasty using autologous pericardium and 47 (53%) using PTFE. Median follow-up for the entire cohort was 13.3 years (IQR: 1 month–18 years). Median follow-up was 15.2 years (IQR: 1 month–18 years) for autologous pericardium group and 8 years (IQR: 2 weeks–14.8 years) for PTFE group ($p = 0.01$). The majority of the patients 71 (80%) had a bicuspid aortic valve (BAV). The study flow chart is shown in **Figure 1.**

Overall previous balloon valvuloplasty was performed in 34 (38%) patients. Additional previous procedures included surgical aortic valvuloplasty (n = 11), ventricular septal defect closure (n = 2), coarctation repair (n = 2), and correction of interrupted aortic arch with ventricular septal defect (n = 1). Baseline characteristics, operative, and postoperative data in each group are presented in **Tables 1** and **2**.

Survival

Survival rate at 1, 5, 10 and 18 years was 97.7% (95% CI 94–100%), 96.4% (95% CI 92–100%), 95% (95% CI 90–99.8%) and 95% (95% CI 90–99.8%), respectively (**Fig. 2**). Overall, 4 (4.5%) patients died during follow-up (including 30-day mortality), 1 (2%) patients in the autologous

Table 1 – Demographic characteristics of patients undergoing aortic leaflet extension valvuloplasty

	Before matching				After matching		
Variable	**Total (n = 89)**	**Autologous pericardium (n = 42)**	**PTFE (n = 47)**	**SMD**	**Autologous pericardium (n = 19)**	**PTFE (n = 19)**	**SMD**
Age (years)	13.5 (5.6)	13.9 (6.2)	13.1 (5.0)	0.14	12.2 (6.9)	12.6 (5.1)	0.06
BSA (m^2)	1.40 (0.46)	1.40 (0.48)	1.40 (0.45)	0.02	1.30 (0.55)	1.37 (0.44)	0.14
Weight (kg)	49 (22)	48 (22)	49 (22)	0.02	45 (25)	45 (20)	0.03
Follow-up (years)	11.4 (5.6)	15.4 (3.0)	7.9 (5.0)	1.8	14.3 (4.3)	8.2 (5.4)	1.2
Age group, n (%)				0.26			0.51
<5 years	9 (10%)	5 (12%)	4 (8.5%)		5 (26%)	2 (11%)	
5–10 years	10 (11%)	5 (12%)	5 (11%)		1 (5.3%)	3 (16%)	
10–15 years	29 (33%)	11 (26%)	18 (38%)		4 (21%)	5 (26%)	
>15 years	41 (46%)	21 (50%)	20 (43%)		9 (47%)	9 (47%)	
Gender, n (%)				0.06			0.001
Male	22 (25%)	11 (26%)	11 (23%)		4 (21%)	4 (21%)	
Female	67 (75%)	31 (74%)	36 (77%)		15 (79%)	15 (79%)	
Diagnosis, n (%)				1.1			<0.001
Aortic stenosis	43 (48%)	10 (24%)	33 (70%)		10 (53%)	10 (53%)	
Aortic regurgitation	10 (11%)	5 (12%)	5 (11%)		2 (11%)	2 (11%)	
Mixed aortic valve disease	36 (40%)	27 (64%)	9 (19%)		7 (37%)	7 (37%)	
History of balloon aortic valvuloplasty, n (%)	34 (38%)	17 (40%)	17 (36%)	0.08	7 (37%)	5 (26%)	0.22
History of surgical aortic valvuloplasty, n (%)	11 (12%)	5 (12%)	6 (13%)	0.02	1 (5.3%)	5 (26%)	0.6
Preoperative transaortic valve peak gradient (mmHg)	82 (24)	78 (13)	83 (27)	0.5	76 (12)	78 (29)	0.02
Preoperative aortic regurgitation grade, n (%)				0.75			0.4
None or trivial	14 (16%)	3 (7.1%)	11 (23%)		3 (16%)	4 (21%)	
Mild	14 (16%)	3 (7.1%)	11 (23%)		3 (16%)	5 (26%)	
Moderate	36 (40%)	22 (52%)	14 (30%)		7 (37%)	4 (21%)	
Severe	25 (28%)	14 (33%)	11 (23%)		6 (32%)	6 (32%)	
Aortic valve anatomy, n (%)				0.64			0.9
Unicuspid	5 (5.6%)	2 (4.8%)	3 (6.4%)		1 (5.3%)	2 (11%)	
Bicuspid	71 (80%)	29 (69%)	42 (89%)		12 (63%)	17 (89%)	
Tricuspid	13 (15%)	11 (26%)	2 (4.3%)		6 (32%)	0 (0%)	

Continuous and categorical variables are expressed as mean ± SD and n (%), respectively.
BSA – body surface area; PTFE – polytetrafluoroethylene; SD – standard deviation; SMD – standardized mean difference.

pericardium group and 3 (6.3%) patients in the PTFE group ($p = 0.28$).

There was one (1.2%) early death within post-operative period of 30 days. The patient was a 2-year-old male who could not have been weaned off cardiopulmonary bypass due to ventricular arrhythmia, and a left ventricular assist device was instituted. Later on, it was switched to extracorporeal membrane oxygenation. Eventually, he died of a *thromboembolic event* and cerebral edema 2 days postoperatively. There were three (3.4%) late deaths due to non-cardiac causes, and no deaths were related to the structural failure of aortic valve after valvuloplasty.

In a matched cohort, survival rate was 97.7% (95% CI 92–100%) at 1 year and 94.3% (95% CI 86.7–100%) at 5, 10, and 18 years. Overall 1 (2.6%) patient died during follow-up in autologous pericardium group, and no death occurred in PTFE group ($p = 0.93$). **Figures S1 A and B in the Supplementary material show overall survival and survival by groups after matching.**

Freedom from reoperation

During the study period, 41 patients (46%) underwent reoperation, with an incidence of 24 (57%) and 17 (36%) in autologous pericardium and PTFE group, respectively. Overall median time to reoperation was 8.4 years (IQR, 4 months to 14.7 years), and mean time was 7.8±4.2 years. Median interval to reoperation was 7.8 years (IQR: 4 months to 14.7 years) and 7.5 years (IQR: 2.4 to 13.6 years) for

Table 2 – Operative and postoperative data

	Before matching				After matching		
Variable	Total (n = 89)	Autologous pericardium (n = 42)	PTFE (n = 47)	SMD	Autologous pericardium (n = 19)	PTFE (n = 19)	SMD
Aortic annulus size (mm)	21.2 (5.0)	21.9 (5.1)	20.6 (4.9)	0.35	19.9 (5.7)	20.2 (4.9)	0.05
Ascending aorta size (mm)	29 (7)	30 (7)	28 (7)	0.22	27 (8)	27 (8)	0.019
Extension height (mm)	16 (3)	16 (2)	17 (3)	0.19	16 (3)	16 (2)	0.07
Cardiopulmonary bypass (min.)	144 (48)	165 (51)	125 (36)	0.89	166 (68)	125 (39)	0.73
Cross-clamp (min.)	105 (25)	114 (22)	96 (25)	0.76	113 (25)	92 (25)	0.83
Hospital LOS (days)	8 (5)	6 (3)	9 (6)	0.53	7 (2)	9 (5)	0.65
Reduction ascending aortoplasty, n (%)	12 (13.5%)	8 (19%)	4 (8.5%)	0.28	4 (21%)	2 (10.5%)	0.72
Postoperative aortic regurgitation grade, n (%)				0.35			0.38
None or trivial	60 (67.5%)	29 (69%)	31 (66%)		12 (63%)	11 (58%)	
Mild	29 (32.5%)	13 (31%)	16 (34%)		6 (32%)	8 (42%)	
Postoperative transaortic valve peak gradient (mmHg)	13 (11)	10 (10)	15 (12)	0.39	13 (12)	15 (13)	0.13

Continuous and categorical variables are expressed as mean±SD and n (%), respectively.
LOS – length of stay; PTFE – polytetrafluoroethylene; SD – standard deviation; SMD – standardized mean difference.

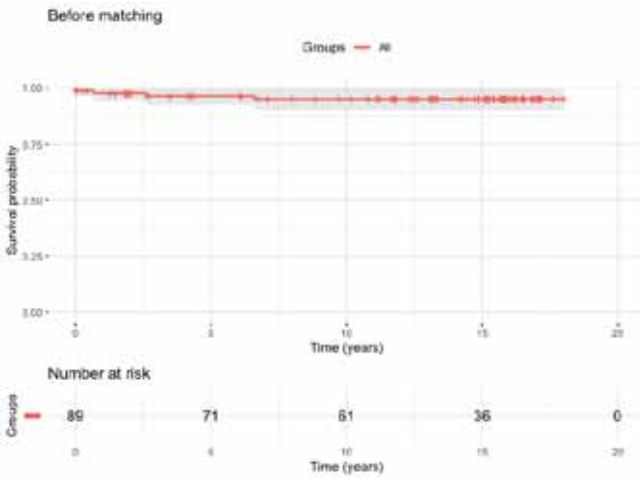

Fig. 2 – Kaplan–Meier curve showing overall survival.

autologous pericardium and PTFE group, respectively, (p = 0.25).

The indications for reoperation were severe AS (n = 18; 44%), severe AR (n = 16; 39%), and IE (n=7; 17%). Overall freedom from reoperation at 1, 5, 10 and 15 years was 98.8% (95% CI, 96.6–100%), 87.6% (95% CI 80–94.8%), 57% (95% CI 45.4–69%) and 35.4% (95% CI 22.7–48%), respectively (**Supplementary material, Fig. S2A**).

Among the 41 patients requiring reoperation, 33 underwent AVR, 5 had Bentall procedure, one had a re-aortic valvuloplasty with PTFE leaflet extensions, 1 had aortic root replacement with aortic homograft, and one underwent a Ross–Konno operation.

Freedom from reoperation at 1, 5 and 10 years was 97.6% (95% CI 92.8–100%), 88% (95% CI 77–97.8%) and 67.9% (95% CI 53.5–82%) in autologous pericardium group, and 100% (95% CI 100–100%), 86.2% (95% CI 75–97%) and 39.4% (95% CI 20–58%) in PTFE group, respectively. No statistically significant difference regarding the reoperation rate was observed between two groups (p = 0.14). Freedom from reoperation according to the type of patch material is shown in **Supplementary material, Fig. S2B**.

There were 18 (42.8%) reoperations in the matched cohort. Overall median time to reoperation was 8.2 years (IQR 4.5months to 14.7 years). Overall 15-years freedom from reoperation was 37.4% (95% CI 18.8–56%) (**Fig. 3A**). In autologous pericardium group, freedom from reoperation at 1, 5 and 10 years was 100% (95% CI 100–100%), 89% (95% CI 74–100%), and 54.2% (95% CI 30–77%), respectively. In PTFE group, the freedom from reoperation at 1, 5 and 10 years was 100% (95% CI 100–100%), 93% (95% CI 79–100%), and 34% (95% CI 7–60%), respectively. There was no statistically significant difference between the groups (p = 0.39). **Fig. 3B** shows freedom from reoperation in the matched cohort by groups.

Freedom from AVR

Overall, freedom from AVR at 1, 5, 10 and 15 years was 100% (95% CI 100–100%), 90% (95% CI 82–96%), 59% (95% CI 47–70%) and 37% (95% CI 24–50%), respectively (**Supplementary material, Figs S3A** and **S3B**).

In the matched cohort, the overall 15-year freedom from AVR was 41.7% (95% CI 22.2–61%) (**Fig. 4A)**. In autologous pericardium group, the freedom from AVR at 1, 5 and 10 years was 100% (95% CI 100–100%), 94% (95% CI 83–100%) and 57.4% (95% CI 33–81%), respectively. In PTFE group, freedom from AVR at 1, 5 and 10 years was 100% (95% CI 100–100%), 86% (95% CI 75–97.5%) and 39.4% (95% CI 20–58%), respectively (**Fig. 4B)**. No statistically significant difference between the groups was found (p = 0.18).

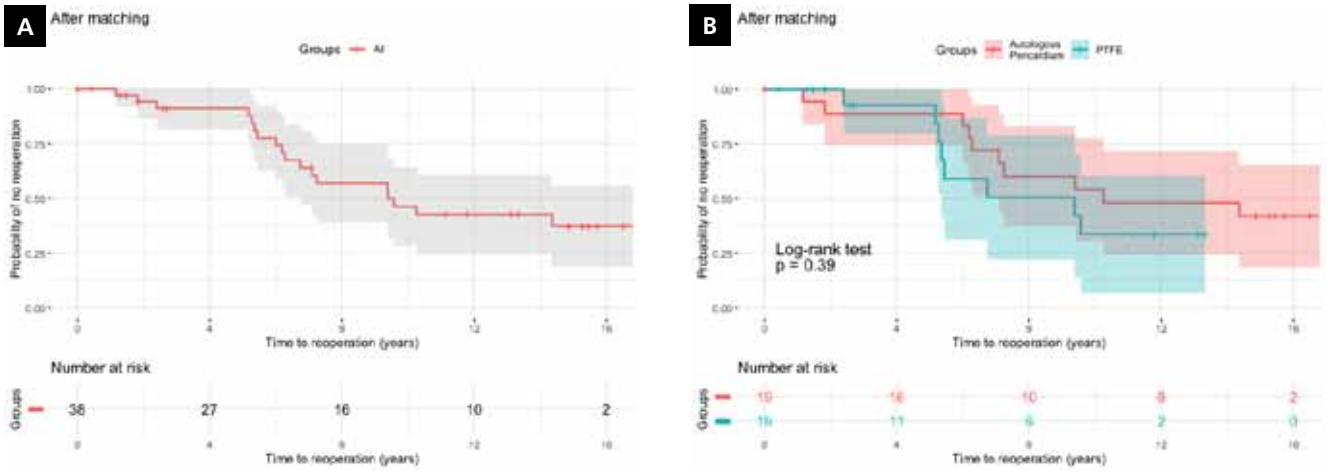

Fig. 3 – Kaplan–Meier curves showing freedom from reoperation in matched cohort, (A) all patients (B) by groups. PTFE – polytetrafluoroethylene.

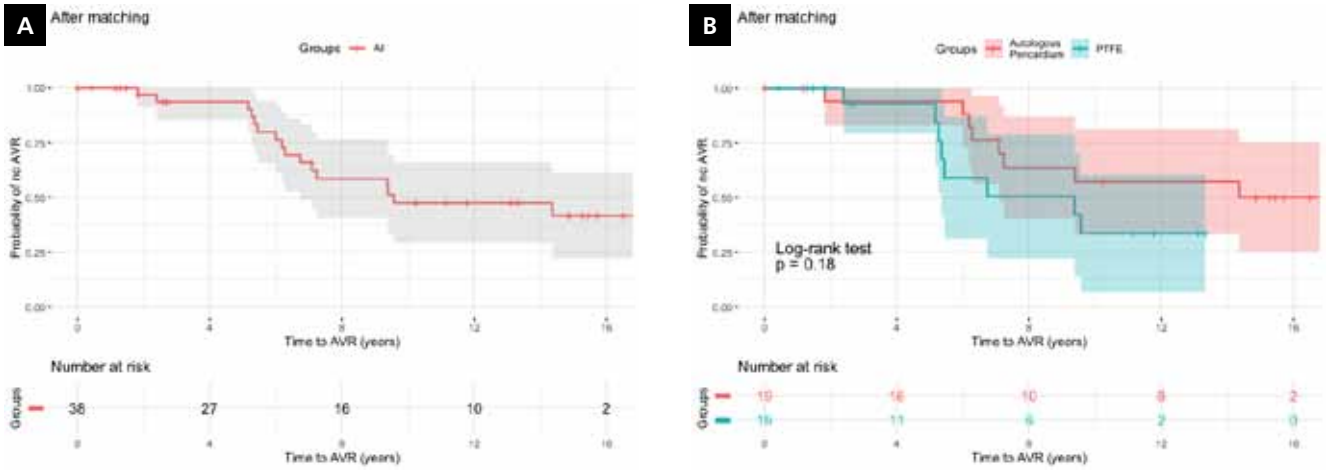

Fig. 4 – Kaplan–Meier curves showing freedom from AVR in matched cohort, (A) all patients, (B) by groups. PTFE – polytetrafluoroethylene.

Risk factors

The univariable and multivariable Cox regression analyses identified a primary diagnosis of AR (HR 2.5, 95% CI 1.2–5.2, p = 0.017), aortic annulus diameter (HR 1.1, 95% CI 1–1.2, p = 0.038), IE (HR 4.3, 95% CI 1.53–12.5, p = 0.006), aortic cross-clamp time (HR 0.96, 95% CI: 0.94–0.99, p = 0.014), cardiopulmonary bypass time (HR 1.02, 95% CI 1–1.2, p = 0.017) and previous surgical aortic valvuloplasty (HR 2.7, 95% CI 1.1–6.7, p = 0.027) as risk factors for aortic valve reoperation. The results of the Cox regression analysis of risk factors for reoperation are presented in **Table 3.**

Infective endocarditis

Overall 7 patients underwent reoperation due to IE: 5 of 42 (11.9%) in the autologous pericardium group, and 2 of 47 (4.2%) in the PTFE group. However, there was no statistically significant difference between the two groups (p = 0.24). During the follow-up, there was no recurrence of IE in these patients. Patients had reoperation after a mean of 29 days (20–42 days) of antibiotic therapy, with the exception of one patient who required urgent surgery due to large vegations on the valve. The most commonly used preoperative antibiotic was vancomycin (70%), followed by gentamicin (55%), ceftriaxone (50%), and piperacillin/tazobactam (35%).

Discussion

Aortic valvuloplasty by leaflet extension with tricuspidalization is a useful surgical procedure which effectively repairs aortic valve stenosis and regurgitation. In addition, it improves left ventricular dimensions in children and young adults.[1,3,4] Several patch materials have been used to extend and augment the aortic leaflets, including fresh or glutaraldehyde-treated autologous pericardium, bovine and equine pericardium. Furthermore, our group introduced and used the 0.1mm PTFE membrane, which showed a satisfactory result in the pulmonary position.[7,12,13]

PTFE has unique physical properties such as increased flexibility and exceptional tensile strength. Furthermore, it has high biocompatibility, and its microporous structure is believed to prevent cellular penetration and subsequent calcification, which is a typical cause of valve dysfunction.[7]

Overall survival rate in our cohort at 18 years was 95% (95% CI 90–99%). This is comparable to similar reports from Vergnat et al.[15] and Kwak et al.[16] Overall freedom from reoperation for the entire cohort at 5, 10 and 15 years was 87.6% (95% CI 80–94.8%), 57% (95% CI 45.4–69%) and 35.4% (95% CI 22.7–48%), respectively. Freedom from reoperation for the matched cohort at 5, 10 and 15 years was 91% (95% CI 81–100%), 46% (95% CI 28–64%), and 37.4% (95% CI 18.8–56%), respectively. This is in agreement with the data about similar patients published by Al Halees et al.[16] and Polimenakos et al.[1]

During the follow-up in the matched cohort, there were no significant differences between two groups regarding survival, reoperation-free, and AVR-free survival rates, with survival rate of 94.7% at 10 years in autologous pericardium versus 92.9% at 10 years in the PTFE group, (p = 0.93). Freedom from reoperation was 54% at 10 years in the autologous pericardium group versus 34% at 10 years in the PTFE group (p = 0.14). Furthermore, the freedom from AVR in autologous pericardium and PTFE group at 10 years was 57.4% and 39.4%, respectively (p = 0.18).

Multivariable Cox regression analysis identified the patients with a primary diagnosis of AR to be more at risk for reoperation. Other authors observed similar results and found that pre- amd postoperative AR was associated with the need for aortic valve reoperation.[1,17] This might be due to the difficulty of the left ventricular myocardium in adjusting volume overload compared to pressure overload.[18] In addition, the aortic annulus diameter, aortic cross-clamp, cardiopulmonary bypass time, and IE were associated with a higher risk for reoperation. Polimenakos et al.[1] and Vergnat et al.[15] published similar findings. The extension material type was not associated with either reoperation or AVR risk in our Cox regression analysis (**Table 3**).

Unlike Vergnat et al.[15] we found that prior surgical aortic valvuloplasty was a significant risk factor for reoperation (in multivariable Cox regression analysis). However, these patients included those with previously failed balloon aortic valvuloplasty. From our perspective, these patients had more dysplastic aortic valves, which could have affected the performance of the aortic valve following subsequent aortic leaflet extension valvuloplasty.

Our results differ from those published by Karliova et al.[9] who had used a PTFE patch material for aortic valvuloplasty and converting unicuspid into bicuspid aortic valves. In contrast, our aortic valvuloplasty technique restores tricuspid configuration while three neocomissures provide better support for the leaflet extensions. At the same time, we believe that tricuspidalization provides a larger central opening while minimizing blood turbulence.[1]

Aortic leaflet extension valvuloplasty also has the advantage of allowing aortic annular growth until a more permanent replacement alternative becomes available, such as the currently preferred Ross procedure with inclusion technique or prosthetic valve replacement.[5,19,20]

Infective endocarditis remains a concern for patients undergoing aortic valve surgery. The incidence varied across the literature, which could be related in part to the patch material utilized for leaflet reconstruction and the patient's dental hygiene habits. Overall the incidence of IE requiring reoperation in our study was 7.8% for all

Table 3 – Risk factors for reoperation and AVR by univariable and multivariable Cox regression analyses, all patients

Variables	Univariable analysis		Multivariable analysis	
	HR (95% CI)	p-value	HR (95% CI)	p-value
Gender	0.86 (0.42–1.76)	0.68		
Weight at surgery (kg)	0.99 (0.98–1.01)	0.57		
Age at surgery (years)	0.98 (0.93–1.04)	0.66	0.92 (0.85–1.01)	0.082
History of balloon aortic valvuloplasty	1.31 (0.69–2.48)	0.41		
Primary diagnosis				
AS	3.5 (1.48–8.6)	0.01	1.01 (0.51–1.97)	0.97
AR	3.2 (1.6–7.3)	0.037	2.5 (1.17–5.2)	0.017
Patch material	1.65 (0.83–3.2)	0.15		
AoV diameter (mm)	1.04 (0.97–1.12)	0.22	1.1 (1.01–1.21)	0.038
Infective endocarditis	2.21 (0.91–5.3)	0.078	4.3 (1.53–12.5)	0.006
History of surgical valvuloplasty	1.68 (0.74–3.8)	0.21	2.7 (1.12–6.7)	0.027
Extension height (mm)	1.04 (0.91–1.18)	0.54		
Extension height ≤ 12 mm	1.51 (0.46–4.96)	0.49		
Extension height ≤ 15 mm	0.92 (0.49–1.7)	0.79		
Reduction ascending aortoplasty	0.45 (0.12–0.6)	0.22		
Cross-clamp (min.)	0.99 (0.98–1.01)	0.60	0.96 (0.94-0.99)	0.014
Cardiopulmonary bypass (min.)	1 (0.99-1.01)	0.92	1.02 (1-1.04)	0.017

AR – aortic regurgitation; AS – aortic stenosis.

patients, with a lower incidence for PTFE (2/47) compared to autologous pericardium (5/42). Nevertheless, there was no statistically significant difference ($p = 0.24$). Moreover, Wiggins et al.[4] reported a 5% IE rate after aortic valve leaflet repair in children. Furthermore, Karliova et al.[9] showed that IE occurred in two (18%) of the eleven patients in their study.

Limitations

The limitations of our study include a single-centre character, retrospective analysis and the shorter median follow-up time for the PTFE group compared to the autologous pericardium group.

Conclusions

The long-term results of aortic leaflet extension valvuloplasty, utilizing either autologous pericardium or PTFE, in patients with congenital aortic valve disease suggest excellent survival with no significant difference in the rate of reoperation for aortic valve dysfunction between the groups.

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Conflict of interest
The authors have declared that no competing interests exist.

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Ethical statement
The Study was approved by Institutional Review Board of National Institute of Cardiovascular Diseases, Bratislava, Slovakia (Approval Number: 62/2023), and the need for informed consent was waived because of the retrospective nature of the study.

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Appendix A – Supplementary data
Supplementary data associated with this article can be found in the online version.