Open Access

Original Article

Comparative Analysis of Early Outcomes In Polytetrafluoroethylene (Ptfe) Patch Versus Bovine Pericardial Patch for Monocusp For Right Ventricular Outflow Tract Reconstruction of Tetralogy of Fallot (Tof) Repair

Muhammad Majid, Dawood Kamal Mehsood, Intisar ul Haq, Nasir Ali Khan*, Muhammad Abdullah, Muhammad Adnan Akram****

Department of Paediatric Cardiac Surgery, Armed Forces Institute of Cardiology/National Institute of Heart Diseases/National University of Medical Sciences (NUMS) Pakistan,*Department of Cardiac Surgery, Armed Forces Institute of Cardiology/National Institute of Heart Diseases/National University of Medical Sciences (NUMS) Pakistan,**Department of Paediatric Cardiac Anesthesia, Armed Forces Institute of Cardiology/National Institute of Heart Diseases/National University of Medical Sciences (NUMS) Pakistan

ABSTRACT

Objective: To compare early outcomes of polytetrafluoroethylene patch (PTFE) versus bovine pericardial patch for monocusp in right ventricular outflow tract reconstruction of Tetralogy of Fallot (TOF) repair.

Study design: Quasi-experimental study.

Place and Duration of Study: Department of Paediatric and Congenital Cardiac Surgery, Armed Forces Institute of Cardiology and National Institute of Heart Diseases (AFIC-NIHD), Rawalpindi, Pakistan, from Jun 2024 to May 2025.

Methodology: A total of 32 children aged ≤15 years, with transannular TOF were recruited through non-probability consecutive sampling and non-randomly allocated into groups based on the TOF repair technique: Group PTFE or Group bovine pericardial patch. All operative procedures were performed with median sternotomy under cardiopulmonary bypass (CPB) with moderate hypothermia. Early outcomes were compared between groups including peri-operative pulmonary regurgitation and residual right ventricular outflow tract pressure gradient (RVOT-PG), CPB time, aortic cross-clamp (ACC) time, ventilation time, Intensive Care Unit (ICU) stay and mortality.

Results: Out of 32 patients, 19(58.80%) were male and 13(41.20%) were female while median age was 2.25 (6.50-1.58) years. Moderate pulmonary regurgitation (PR) was observed in 11.80% of the cases in PTFE group as compared to 29.40% of cases in Bovine group, however, this difference was not statistically significant (p>0.05) where RVOT-PG was significantly higher in the PTFE group (32.94±8.47 vs. 24.12±11.72 mmHg, p=0.01) on peri-operative echocardiogram.

Conclusion: Similar early results were seen with RVOT reconstruction using PTFE and bovine pericardial monocusps, although it was statistically not significant, PTFE provided better protection against moderate pulmonary regurgitation.

Keywords: Pericardium, Polytetrafluoroethylene, Pulmonary Regurgitation, Tetralogy of Fallot, Treatment Outcome

How to Cite This Article: *Majid M, Mehsood DK, Haq IU, Khan NA, Abdullah M, Akram MA. Comparative Analysis of Early Outcomes In Polytetrafluoroethylene (Ptfe) Patch Versus Bovine Pericardial Patch for Monocusp For Right Ventricular Outflow Tract Reconstruction of Tetralogy of Fallot (Tof) Repair. Pak Armed Forces Med J 2026; 76(Suppl-3): S602-S606. DOI: https://doi.org/10.51253/pafmj.v76i2.13578*

INTRODUCTION

Congenital Heart Defects (CHDs) affect 1–2% of live births[1] with Tetralogy of Fallot (TOF) being a common cyanotic CHD, occurring in 0.62 per 1000 live births,[2] making it the most frequent CHD in Pakistan, accounting for 24.40% of the total burden.[3] It is characterized by four structural abnormalities: right ventricular outflow tract obstruction (RVOTO), ventricular septal defect (VSD), right ventricular hypertrophy (RVH), and overriding of the aorta.[4] Surgical intervention aims to alleviate RVOTO and close the VSD while preserving the patient's native pulmonary valve.[2] However, in instances where the valve is hypoplastic, a transannular incision may be necessary to divide the pulmonary annulus,[4] which may result in free pulmonary regurgitation (PR) associated with progressive right ventricular dilatation and dysfunction.[5] To mitigate free PR, the reconstruction of RVOTO with a monocusp is currently practiced[6] as it has demonstrated effectiveness in reduction of PR in the early and midterm periods compared to RVOTO reconstruction with a simple transannular patch (TAP) without a monocusp. Materials employed in constructing a monocusp include a 0.1 mm polytetrafluoroethylene (PTFE) membrane, bovine pericardium, and glutaraldehyde-fixed autologous pericardium.[4] The right atrial appendage has also been utilized for monocusp construction in the RVOT7,[8] It appears advantageous in preventing severe pulmonary insufficiency (PI) and facilitates the preservation of RV function.[9,10] The majority of the existing literature compares PTFE and autologous pericardium or monocusp against non-monocusp repairs. Comparing

Correspondence: Dr Muhammad Majid, Department of Paediatric Cardiac Surgery, AFIC/NIHD Pakistan

Received: 20 Jun 2025; revision received: 07 Nov 2025; accepted: 13 Nov 2025

PTFE with bovine pericardial monocusps directly and statistically is lacking, especially when it comes to assessing early postoperative outcomes. To address this, the study aims to compare the early postoperative results of bovine pericardial monocusp valves and PTFE utilized in RVOT reconstruction during TOF surgery. This will provide evidence to advise the best material selection in settings with limited resources like Pakistan.

METHODOLOGY

This was a quasi-experimental study conducted at the Paediatric and Congenital Cardiac Surgery Department of the Armed Forces Institute of Cardiology and National Institute of Heart Disease, (AFIC-NIHD), Rawalpindi, Pakistan. The research was carried out with approval from the Institutional Ethics Review Board (IERB) (ltr#9/2/R&D/2024/302; dated 30th May 2024). Patients were enrolled through non-probability purposive sampling. Sample size was calculated using the World Health Organisation (WHO) sample size calculator for comparing two independent samples, taking a 95% confidence interval and 5% margin of error. The anticipated population proportion of postoperative complications for the PTFE group was 73%, while for the bovine pericardial patch group it was 6%, after which the estimated sample size came out to be 26 patients with 13 in each group, [9] however, data was collected from 34 patients, 17 in each group. Sample size was limited due to infrequent use of these techniques at our institute.

Inclusion Criteria: Patients, belonging to either gender, up to 15 years in age or having transannular repair with monocusp were included

Exclusion Criteria: Patients undergoing TOF repair with pulmonary valve sparing, TOF repair with pulmonary atresia with RV to PA conduit, TOF with absent pulmonary valve or TOF with atrioventricular septal defect were excluded from the study.

Patients were enrolled after taking informed consent and non-randomly allocated into one of two groups based on the monocusp material used for RVOT reconstruction: Group PTFE or Group bovine. All operative procedures were performed with median sternotomy and cardiopulmonary bypass (CPB) with moderate hypothermia. Aortic and bicaval cannulation were done while previous Blalock Taussig shunts were ligated if present. The heart was arrested with anterograde cold cardioplegia, and VSD was closed with Dacron patch in interrupted and continuous fashion with prolene 5/0 pledgeted sutures. Right ventricular outflow obstructing bands were resected via trans right atrial approach or transpulmonary approach to relieve the RVOTO. In all our patients, the aim was to save the native pulmonary valve. The size of the valve was assessed with Hegar dilator, if the size of the pulmonary valve was less than z – 2 and valve was very hypoplastic or dysplastic, a transannular incision was given then a PTFE monocusp or a bovine pericardial monocusp was incorporated in reconstruction of RVOT as per the surgeon's preference and availability of the PTFE and bovine pericardium.

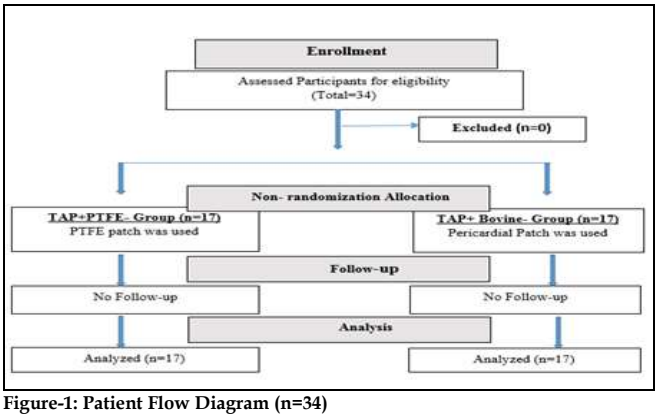

Figure-1: Patient Flow Diagram (n=34)

In PTFE group, a PTFE patch was taken, the length of which was equal to the length of the incision from the apex of infundibulotomy incision to pulmonary annulus while the width of the free edge of the PTFE monocusp was almost equal to the diameter of the native annulus. The upper margin of the PTFE monocusp was placed at the level of the pulmonary commissures and was stitched to both sides of the transannular incision and the inferior margin was attached to the apex of the RVOT incision at three points. Another autologous pericardial patch was placed over the PTFE patch, and both were sutured together with the RVOT epicardium to close the transannular incision. The autologous pericardium was extended towards the main pulmonary artery (MPA) to fashion MPA-plasty, while in bovine group, a commercially made monocuspid bovine pericardial patch was used according to the z-score of the pulmonary valve of the patient, as shown in Figure-2.

After coming off CPB on completion of the repair, epicardial echocardiography was performed in each case for pulmonary regurgitation, residual RVOT gradient and other parameters of the repair like left ventricular function and stability of the VSD patch.

After the surgery, the patients were shifted to Paediatric Cardiac ICU and an independent team of paediatric cardiologists performed transthoracic echocardiography to look for PR, residual RVOT gradient and other parameters of the TOF repair. An independent team of ICU care staff noted the post-operative ICU parameters of the patient such as, ventilation time, ICU time and inotropic duration. All perioperative data was entered on a data collection tool. VIS max was calculated as maximum inotropic score at single point in time during the whole post-operative ICU course according to the equation:

[Dopamine dose (μgkg−1 min−1) + Dobutamine (μgkg−1min−1)] + [100 × epinephrine dose (μgkg−1 min−1)] + [50 × levosimendan dose (μg kg−1min−1)] + [10 × milrinone dose (μg kg−1 min−1)] + [10000 × vasopressin (units kg−1min−1)] + [100 × norepinephrine dose (μg kg−1min−1)]7.

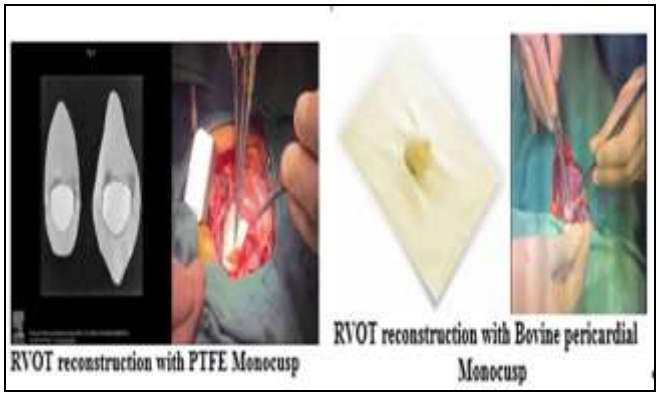

Figure-2: RVOT Reconstruction in TOF Patients using Different Materials(n=34)

Mortality was defined as death during the same hospital admission after the surgery or within 30 days after the surgery, whichever came later. Statistical Package for the Social Sciences (SPSS) version 23.00 was used to analyse the data. Depending on the normality of data, continuous variables such age, oxygen saturation, RVOT pressure gradient (RVOT-PG), cross-clamp time, CPB time, VIS max, inotropic duration, ICU stay, and ventilation time were reported as median (IQR) except BMI. Frequencies and percentages were used to represent categorical data, such as gender, mortality and the severity of PR. Independent t-test was employed for data that was normally distributed, and the Mann-Whitney U test was utilized to compare the medians of continuous variables across the two groups: TAP + Bovine vs. TAP + PTFE. To find association between categorical data, the Chi-square test was applied where a p-value ≤0.05 were regarded as statistically significant.

RESULTS

This study enrolled 34 patients. Individuals in the TAP + bovine pericardial patch group had a median age of 3.00 (11.00–2.00) years, compared to 2.00 (8.00–2.00) years in the TAP + PTFE group (p=0.18) while gender distribution showed 35.30% males and 64.70% females in the bovine group. (p=0.36)

Table-I: Demographic Characteristics of Study Participants (n=34)

Variables		TAP+ Bovine pericardial patch (n=17)	TAP + PTFE (customized) (n=17)	*p*-value
Age (years)		Median (IQR)		0.18
		3.00(11.00-2.00)	2.00(8.00-2.00)	
BSA (m2)		Mean± SD		0.20
		0.50±0.11	0.46±0.07	
Gender n (%)	Male	6(35.30%)	8(47.10%)	0.36
	Female	11(64.70%)	9(52.90%)	

BSA=body Surface Area; TAP=Transannular annular Patch; PTFE=Polytetraflouroethylene

Prolonged cross-clamp time (95 vs. 86 min, p=0.04) and CPB time (82 vs. 71 min, p=0.04) were observed in the PTFE group. ICU stay, ventilation time, and inotropic support, showed no significant differences (p>0.05), however, RVOT PG was significantly higher in the PTFE group (33.33±9.98 vs. 23.60±11.58 mmHg, p=0.01) at epicardial echo and discharge echo. The main variable of concern between the two groups was the severity of PR as moderate PR was observed in 11.80% of the cases in PTFE group as compared to 29.40% of the cases in bovine group, however, this difference was not statistically significant (p>0.05), as shown in Table-II.

Mortality in PTFE group was 5.90% as compared to 11.80% in bovine group but the difference was statistically not significant (p>0.05), as shown in Figure-3.

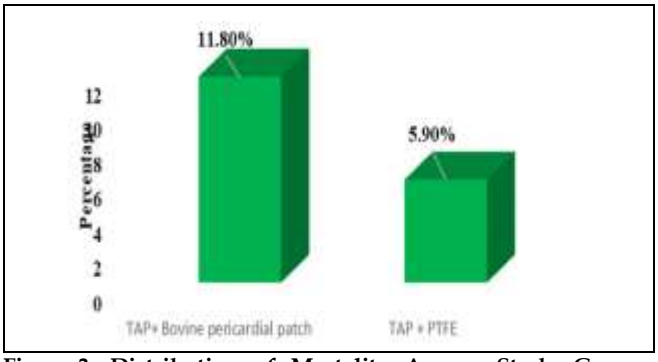

Figure-3: Distribution of Mortality Among Study Groups (n=34)

DISCUSSION

In TOF repair, the surgical objective is to preserve the native pulmonary valve while sufficiently widening the RVOT to facilitate the passage of right-sided cardiac output.[11] as moderate to severe free PR has also been associated with increased perioperative mortality in transannular TOF repair.[12] To mitigate these complications, surgeons have incorporated monocusp valves into the RVOT. While no severe PR was found in our research, which is in line with the results of another study.[13] which found that moderate PR was present in most patients (n= 31, 73.10%). Likewise, 27 patients (79.40%) in our study had mild PR. Historically, a non-valve TAP was used to enlarge the annulus, pulmonary artery, and RV infundibulum in order to relieve RVOT blockage in CHD where, even though TAP was successful in removing the obstruction, it frequently resulted in RV failure and increasing PI and RV dilatation.14 Monocusps have been sourced from homografts in countries with active heart transplant programs, where donor hearts and their components can be biologically preserved and stored, while also being fabricated from biological materials such as autologous pericardium and bovine pericardium, and PTFE monocusps have also been utilized, however, there is limited research on the superiority of one monocusp material over another. One author.[15] mentioned an overall mortality rate of 7.40%, whereas our study reported a slightly higher mortality rate of 8.82%, which might be due to different surgical techniques, postoperative care, institutional practices, or patient characteristics, such as a higher percentage of high-risk cases, and given the variability in TOF anatomy, this condition presents a broad spectrum of severity with differences in RVOTO.[16] Consequently, the degree of PR observed in two distinct groups cannot be solely attributed to the type of monocusp used in surgical intervention. Other contributing factors include the length of the transannular incision and the final circumference of the RVOT achieved, both of which significantly influence the degree of free PR and the extent of RV obstructing bands resection by the same surgeon varies among patients due to differences in the morphology, thickness, and strength of RV bands.[17] The higher mortality rate observed in the bovine group cannot be entirely ascribed to the bovine monocusp, as mortality in this cohort was primarily due to RV failure secondary to RV band resection, transannular incision leading to free PR, and lung reperfusion injury, as noted in previous literature.[18]

LIMITATIONS OF STUDY

One of the study's limitations is that it only assesses early postoperative results, which limits comprehension of the two materials' medium and long-term efficacy and durability. Furthermore, there are many structural variations in CHDs, even among patients with the same diagnosis, which makes it difficult to perform a true randomized controlled trial in congenital cardiac surgery. This variation makes randomized comparisons challenging and restricts the viability of standardizing surgical techniques and patient selection.

Table-II: Comparison of Perioperative Outcomes between Study Groups (n=34)

Variables		TAP+ Bovine pericardial patch (n=17)	TAP + PTFE (customized) (n=17)	*p*-value
Preoperative parameters		**Mean± SD**		
Oxygen saturation (SpO2)		77.94±9.99	71.05±15.42	0.77
RVOT-PG		**Median (IQR)**		
		70.00(78.00-70.00)	70.00(90.00-70.00)	0.46
Degree of PR	Mild	12(70.60%)	15(88.20%)	0.39
	moderate	5(29.40%)	2(11.80%)	
Intra-operative Parameters		**Median (IQR)**		
Cross Clamp Time(minutes)		86.00(94.00-79.00)	95.00(120.00-87.00)	0.04
CPB Time (minutes)		71.00(99.00-64.00)	82.00(115.00-72.00)	0.04
Epicardial Echo RVOT PG		**Mean± SD**		0.03
		23.60±11.58	32.14±9.12	
Post-operative Parameters		**Median (IQR)**		
VIS max		8.80(13.90-5.30)	9.10(15.00-6.60)	0.74
Inotropic duration		73.00(92.00-43.00)	53.00(84.00-35.00)	0.75
ICU time (hours)		55.00(137.00-48.50)	70.00(117.00-50.00)	0.66
Ventilation Time (hours)		18.00(22.00-17.00)	20.00(24.00-17.00)	0.74
Echocardiographic Parameters				
RVOT PG (mmHg)		Mean± SD		0.01
		23.69±11.19	32.14±9.02	
PR	Mild	Frequency (%)		0.39
		12(70.60%)	15(88.20%)	
	Moderate	5(29.40%)	2(11.80%)	
Echocardiography (At discharge)		Mean± SD		
RVOT PG (mmHg)		23.60±11.58	33.33±9.98	0.01
PR		n (%)		0.39
	Mild	12(70.60%)	15(88.20%)	
	Moderate	5(29.40%)	2(11.80%)	
Complication		n (%)		
Peritoneal Drainage		9(52.90%)	7(41.20%)	0.73
		8(47.10%)	10(58.80%)	

TAP=Transannular annular Patch; PTFE=Polytetraflouroethylene; BMI=Body Mass Index; RVOT PG= Right Ventricular Outflow Tract Pressure Gradient; PR= Pulmonary Regurgitation; ICU= Intensive care unit; CPB= Cardiopulmonary Bypass Time; VIS= Vasoactive inotropic support

CONCLUSION

In transannular TOF repair, RVOT reconstruction using a PTFE monocusp and TAP yields results comparable to those achieved with bovine pericardium in the early postoperative period. Both materials demonstrate similar efficacy in reducing postoperative complications and maintaining satisfactory right ventricular function.

ACKNOWLEDGEMENT

We are sincerely grateful to our supervisor for his valuable guidance and support, which played a crucial role in the conduct of this research. We also extend our heartfelt thanks to the Research and Development Department, AFIC/NIHD, for their continuous support and contribution towards the successful completion of this research paper.

Conflict of Interest: None.

Funding Source: None.

Authors' Contribution

Following authors have made substantial contributions to the manuscript as under:

MM & DKM: Data acquisition, data analysis, critical review, approval of the final version to be published.

IUH & NAK: Study design, data interpretation, drafting the manuscript, critical review, approval of the final version to be published.

MA & MAA: Conception, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be 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.

REFERENCES

1. Rago M, Winlaw DS, Farajikhah S, Dehghani F, Naficy S. Pediatric pulmonary valve replacements: clinical challenges and emerging technologies. Bioeng Transl Med 2023; 8: e10501. https://doi.org/10.1002/btm2.10501
2. Romeo JLR, Etnel JRG, Takkenberg JJM, Roos-Hesselink JW, Helbing WA, van de Woestijne P, et al. Outcome after surgical repair of tetralogy of Fallot: a systematic review and meta-analysis. J Thorac Cardiovasc Surg 2020; 159: 220–236.e8. https://doi.org/10.1016/j.jtcvs.2019.08.127
3. Mehsood DK, Ahmad K, Ul-Haq I, Umair Younus R, Imran M, Majid M. Comparative analysis in early outcomes of different surgical repair techniques in adult patients with unrepaired tetralogy of Fallot – 10 years experience. Pak Armed Forces Med J 2024; 74(Suppl-1): S68–S73. https://doi.org/10.51253/pafmj.v74iSUPPL-1.11763
4. Zhang L, Liu B, Li H, Wang C, Yang S, Li Z. Epidemiology of congenital heart disease in Jinan, China from 2005 to 2020: a time trend analysis. Front Cardiovasc Med 2022; 9: 815137. https://doi.org/10.3389/fcvm.2022.815137
5. Bhushan R, Chugh V, Loona M, Bandey J, Jhajhria NS, Grover V, et al. Intracardiac repair in late adolescent and adult tetralogy of Fallot – early and midterm results from a tertiary care centre. Braz J Cardiovasc Surg 2022; 37: 511–516. https://doi.org/10.21470/1678-9741-2020-0528
6. Siddiqi U, Adewale A, Pena E, Schulz K, Ilbawi M, El-Zein C, et al. Preserving the pulmonary valve in tetralogy of Fallot repair: reconsidering the indication for valve-sparing. J Card Surg 2022; 37: 5144–5152. https://doi.org/10.1111/jocs.17156
7. Waqar T, Ansari MZA, Khan K. Clinical outcome of right ventricle outflow tract management for repair of tetralogy of Fallot with three contemporary surgical strategies. Pak J Med Sci 2021; 37: 1313–1318. https://doi.org/10.12669/pjms.37.5.3961
8. Wei X, Li T, Ling Y, Chai Z, Cao Z, Chen K, et al. Transannular patch repair of tetralogy of Fallot with or without monocusp valve reconstruction: a meta-analysis. BMC Surg 2022; 22: 18. https://doi.org/10.1186/s12893-022-01474-6
9. Temur B, Aydin S, Suzan D, Kirat B, Demir IH, Erek E. Comparison of different pulmonary valve reconstruction techniques during transannular repair of tetralogy of Fallot. J Card Surg 2021; 36: 56–61. https://doi.org/10.1111/jocs.15133
10. Amirghofran A, Edraki F, Edraki M, Ajami G, Amoozgar H, Mohammadi H, et al. Surgical repair of tetralogy of Fallot using autologous right atrial appendages: short- to mid-term results. Eur J Cardiothorac Surg 2021; 59: 697–704. https://doi.org/10.1093/ejcts/ezaa374
11. Shi WE, Song FX, Li X, Jun LS, Hao Z. Surgical outcome after complete repair of tetralogy of Fallot with absent pulmonary valve: comparison between bovine jugular vein valved conduit and monocusp valve patch. World J Pediatr 2018; 14: 510–519. https://doi.org/10.1007/s12519-018-0169-z
12. Patukale A, Daley M, Betts K, Justo R, Dhannapuneni R, Venugopal P, et al. Outcomes of pulmonary valve leaflet augmentation for transannular repair of tetralogy of Fallot. J Thorac Cardiovasc Surg 2021; 162: 1313–1320. https://doi.org/10.1016/j.jtcvs.2020.12.145
13. Rokonujjaman M, Islam SS, Ghafoor N, Siraj N, Ahmad ST, Rahman MA, et al. Surgical repair of TOF: outcome of right ventricular outflow tract reconstruction using modified monocusp at pulmonary valve level – a single cardiac hospital experience in Bangladesh. Anwer Khan Mod Med Coll J 2021; 12: 82–90. https://doi.org/10.3329/akmmcj.v12i2.64698
14. Kumar M, Turrentine MW, Rodefeld MD, Bell T, Brown JW. Right ventricular outflow tract reconstruction with a polytetrafluoroethylene monocusp valve: a 20-year experience. Semin Thorac Cardiovasc Surg 2016; 28: 463–470. https://doi.org/10.1053/j.semtcvs.2016.05.003
15. Rasool F, Khan A, Shah S, Rahim SS, Kibria G, Kazmi T. RVOT reconstruction strategies in TOF: single center experience. J Popul Ther Clin Pharmacol 2024; 31: 64–70. https://doi.org/10.53555/vqtmwr03
16. Choi SJ, Kwon JE, Roh DE, Hyun MC, Jung H, Lee YO, et al. Importance of pulmonary valve morphology for pulmonary valve preservation in tetralogy of Fallot surgery: comparison of echocardiographic parameters. Clin Exp Pediatr 2020; 63: 189–194. https://doi.org/10.3345/kjp.2019.01060
17. Benedict R, Nalluri R, Vemala V. Novel technique of monocuspid reconstruction of pulmonary valve in children requiring transannular patch for right ventricular outflow tract relief during tetralogy of Fallot surgery. Indian J Thorac Cardiovasc Surg 2025; 41: 83–88. https://doi.org/10.1007/s12055-023-01575-5
18. Daniel S, Gupta P, Bansal K, Nigam A, Agarwal S, Geelani MA. Monocusp pulmonary valve reconstruction in Tetralogy of Fallot: early results and evaluation using 2D echocardiography and 3-T cardiac MRI. Indian J Thorac Cardiovasc Surg 2025. https://doi.org/10.1007/s12055-024-01652-4