

Comparative Analysis in Early Outcomes of Different Surgical Repair Techniques in Adult Patients with Unrepaired Tetralogy of Fallot –10 Years Experience

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ABSTRACT

Objective: To compare early outcomes of different surgical repair techniques used in adult patients with unrepaired Tetralogy of Fallot.

Study Design: Analytical Cross-sectional study.

Place and Duration of Study: Armed Forces Institute of Cardiology/National Institute of Heart Diseases, Rawalpindi Pakistan, from Jan 2014 to Dec 2023.

Methodology: Seventy seven adults with unrepaired Tetralogy of Fallot were recruited through universal sampling and divided into 3 groups of Tetralogy of Fallot repair techniques, Group A: Pulmonary Valve Sparing, Group B: Transannular patch +MonoCusp, Group C: TAP+Pulmonary Valve Replacement. Chi-square and one-way ANOVA were applied to compare early outcomes like Cardiopulmonary Bypass time, Aortic cross clamp time, reopening for bleeding, mortality, in-hospital stay etc. with repair techniques. $p < 0.05$ was considered as statistically significant.

Results: Out of seventy seven patients, 50(64.9%) were males and 27(35.1%) were females. Median age of participants was 19(IQR=18-22) years. Group A had 35(45.5%) patients, while Group B and Group C included 20(25.9%) and 22(28.6%) patients respectively. Group A had shorter CBP time, ACC time, Intensive Care Unit stay and inotropic support etc. ($p < 0.05$). Single case of mortality in group A 1(2.9%) out of 35 and in Group C 1(4.5%) out of 22 patients was observed, while high mortality of 4(20.0%) cases was observed in Group B.

Conclusion: Efforts should be made to preserve the patient's native pulmonary valve and annulus since PVS TOF repair provides better early results. When dividing, a hypoplastic pulmonary valve annulus cannot be avoided. TAP + PVR produces better results than TAP + MonoCusp.

Keywords: Outcomes, Pulmonary Valve Replacement, Pulmonary Valve Sparing, Tetralogy of Fallot, Transannular Patch.

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INTRODUCTION

Tetralogy of Fallot (TOF) is the most prevalent congenital heart disease (CHD), accounting for 3-5% of all such conditions, and has an incidence of 0.28-0.34 per 1000 live births.¹ Early complete repair in the first year of life is the standard treatment in developed countries.² The pediatric population in Pakistan has a higher incidence of CHD compared to non-Asian cohorts,³ and TOF accounts for 24.4% of the CHD burden in Pakistan, making it the most common CHD in the country.⁴

Pakistan is a low-middle income country with inadequate access to specialized pediatric cardiac services due to the scarcity of such services and the high cost of heart surgery. According to one estimate, there are only 0.08 pediatric cardiac surgeons per million people in Pakistan, which is one of the lowest

rates in the world.⁵ This situation leads to a growing number of CHD children reaching adulthood without treatment and a significant number of patients presenting for primary complete repair of TOF in adulthood. Late repairs are associated with poorer outcomes due to right ventricle (RV) fibrosis, poor pulmonary artery growth, and other complications associated with prolonged cyanosis and right-to-left shunt lesions.⁶

Although this late presentation is not common in the medical literature from developed countries, it provides a unique surgical experience to surgeons of low-middle-income countries. The purpose of this study was to share our experience with the early outcomes of different primary complete TOF repair techniques used in adults with unrepaired TOF.

METHODOLOGY

This Analytical Cross-sectional study was carried out at the Paediatric and Congenital Heart Surgery

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Department of the Armed Forces Institute of Cardiology/National Institute of Heart Diseases, Rawalpindi. The study analyzed data from surgical records spanning 10 years, from January 2014 to December 2023. The research was conducted with approval from the Institutional Ethical Review Board (IERB) (Ltr#9/2/R&D/2024/302).

Inclusion Criteria: All unrepaired TOF patients, ≥ 18 years of age regardless of gender at the time of primary complete repair, were included.

Exclusion Criteria: Adult TOF-repaired patients who underwent a redo surgery for a residual lesion were excluded from the study.

During study period, $n=1259$ patients underwent primary complete repair of TOF at our institute. Only $n=77$ patients met the inclusion criteria, thus primary complete repair in adults with unrepaired TOF made up 6.1% of our total cohort. Primary Complete Repair of TOF involved three techniques, which included ventricular septal defect (VSD) repair and relief of Right Ventricular Outflow Tract (RVOT) obstruction:

Group-A: TOF Repair-Pulmonary (Pulm) Valve Sparing: After VSD repair, the RV bands were resected, and a pulm valve commissurotomy, if necessary, was performed. The pulm valve and annulus were preserved.

Group-B: TOF Repair-Trans-Annular Patch (TAP)+MonoCusp: After VSD repair, the RV bands were resected, hypoplastic pulmonary annulus was divided, and a MonoCusp was created using glutaraldehyde-fixed autologous pericardium, bovine pericardium, or polytetrafluoroethylene (PTFE) 0.1mm membrane. The TAP was constructed with bovine pericardium.

Group-C: TOF Repair-TAP+Pulmonary Valve Replacement (PVR): After VSD repair, the RV bands were resected, and the pulm valve annulus was divided. A bioprosthetic (Bioprost) or mechanical (Mech) valve was implanted at the pulm annulus. The TAP was constructed with bovine pericardium. The decision between a bioprost and mech valve was made before surgery after appropriate counseling of the patient.

Data of every patient who met the inclusion criteria was entered on a proforma: patients' demographics, type of TOF repair, additional surgical procedures, cardiopulmonary bypass (CPB) time, Aortic Cross-Clamp (ACC) time, maximum Vasoactive-Inotropic Score (VISmax), Inotropic duration,

Mechanical Ventilation duration, Intensive Care Unit (ICU) stay duration, RVOT gradient, degree of Pulmonary Regurgitation (PR), re-exploration for bleeding, total pleural/pericardial fluid loss and mortality. Mortality was defined as death during the same admission after the surgery or within 30 days after the surgery; whichever came later. VISmax was calculated as maximum inotropic score at single point in time during the whole post-operative (op) ICU course according to the equation: $[\text{Dopamine dose } (\mu\text{gkg}^{-1} \text{ min}^{-1}) + \text{Dobutamine } (\mu\text{gkg}^{-1} \text{ min}^{-1}) + [100 \times \text{epinephrine dose } (\mu\text{gkg}^{-1} \text{ min}^{-1})] + [50 \times \text{levosimendan dose } (\mu\text{g kg}^{-1} \text{ min}^{-1})] + [10 \times \text{milrinone dose } (\mu\text{g kg}^{-1} \text{ min}^{-1})] + [10,000 \times \text{vasopressin (units kg}^{-1} \text{ min}^{-1})] + [100 \times \text{norepinephrine dose } (\mu\text{g kg}^{-1} \text{ min}^{-1})]$.⁷

Data was analyzed using Statistical Package for the Social Sciences (SPSS) version-23.00. Continuous variables were expressed as Mean \pm SD. Categorical variables were expressed as frequency (%). Chi-square test was applied to find the association between the categorical variables like gender, complications with type of repair techniques and one-way ANOVA was applied to compare continuous variables in study groups. $p < 0.05$ was considered as statistically significant.

RESULTS

Among 77 patients, males were 50(64.9%) and females were 27(35.1%). The median age of participants was 19(IQR=18-22) years. Pulmonary Valve Sparing repair technique (Group A) was used in 35(45.5%) patients, while TAP with MonoCusp (Group B) and TAP with PVR (Group C) technique was used in 20(25.9%) and 22(28.6%) patients respectively as shown in Figure-1.

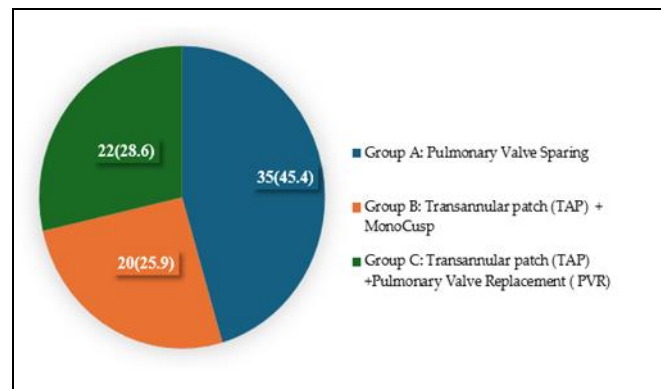


Figure-1: Different TOF Repair Techniques Employed (n=77)

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12(15.6%) patients had additional procedures: Left Pulmonary Artery Plasty 2(2.6%), Major Aorto-Pulmonary Collateral Arteries coiling 6(7.8%), Blalock-Taussig Shunt Take Down 3(3.9%), and Aortic Valve Replacement 1(1.3%). The mean CPB time was 131.01±44.69 minutes. Median VIS max score was calculated as 13(IQR=7.00-25.00). The overall 30-day mortality was 6(7.8%). Descriptive statistics of all variables are mentioned in Table-I.

minutes) than Group B (160.60±38.94 minutes) and Group C (158.41±36.56 minutes). Median ACC time was {58(IQR=45-114) minutes} for Group A and for Group B and C, it was calculated as {123(IQR=99-204) minutes} and {117(IQR=105-160) minutes} respectively. Higher mean ICU stay was observed in group B (113.10±80.16 hours) than Group A (60.29±50.25 hours) and Group C (62.68±50.25 hours). Median Inotropic Duration in Group A was noted as {39.2(IQR=5-134)

Table-I: Baseline, Intra-Operative, Post-Operative Characteristics and Outcomes of Study Participants (n=77)

Variables	Frequency (%) / (Mean± SD)		
Demographics			
Gender	Male	50(64.9)	
	Female	27(35.1)	
Age (years){Median(IQR)}	19(18-22)		
Height(cm)	149.78±29.67		
Weight(kg)	52.56±10.43		
Intra-Operative Variables			
TOF Repair Technique	Pulmonary Valve Sparing		
	TAP + MonoCusp		
	TAP+PVR	Bioprosth	7(9.1)
		Mech	15(19.5)
Additional Procedure	Left Pulmonary Artery Plasty (LPA)		
	Major Aortopulmonary Collateral Arteries (MAPCA) Coiling		
	Blalock-Taussig Shunt Takedown		
	Aortic Valve Replacement (AVR)		
	None		
CPB Time (min)	131.01±44.69		
ACC Time (min) {(Median (IQR)}	100(61-123)		
Post-Operative Variables			
ICU stay (hours) {Median (IQR)}	56(37-95)		
Inotropic duration (hours) {Median (IQR)}	41(16-71)		
Ventilation time (hours) {Median (IQR)}	18(7-32.5)		
VIS max score {Median (IQR)}	13(7-25)		
RVOT gradient (mmHg)	30.02±9.33		
Degree of Pulmonary Regurgitation	Mild	42(54.5)	
	Moderate	7(9.1)	
	None	28(36.4)	
Complications			
Pleural/pericardial drainage in ml {Median (IQR)}	360(30-640)		
Re-opening for bleeding	No	65(84.4)	
	Yes	12(15.6)	
Outcome			
Outcome	Alive	71(92.2)	
	Dead	6(7.8)	

TAP=Trans-annular Patch; PVR= Pulmonary Valve Replacement; RVOT= Right Ventricular Outflow Tract; TOF= Tetralogy of Fallot; CPB=Cardiopulmonary Bypass; ACC= Aortic Cross-Clamp; ICU= Intensive Care Unit; VIS= Vasoactive Inotropic Score

Table-II showed the association of outcomes with different TOF repair techniques. In this study, the mean difference of all the intra-op and post-op variables was found to be statistically significant ($p<0.05$) except age ($p=0.47$) and mortality ($p=0.06$). Group-A had lesser mean CPB time (96.89±24.34

hours) than Group B {72(IQR=45.5-268.5) hours} and Group C {39.5(IQR=31-84) hours}. Ventilation time was lesser for Group A {9(IQR=5-90) hours} as compared to Group B {29(IQR=20-213) hours} and Group C {18(IQR=16-58) hours} and only in 1 (2.9%) patient, re-opening for bleeding was done in Group A ($p=0.04$).

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Table-II: Association of Intra-Operative/Post-Operative variables with TOF Repair Techniques (n=77)

Variables	TOF Repair			p-value	
	Group -A Pulmonary Valve Sparing (Total=35)	Group -B TAP+ Monocusp (Total=20)	Group -C TAP + PVR (Total=22)		
			BioProsth (Total=7)		Mech (Total=15)
Age(years) {Median (IQR)}	19(18-34)	19(18-30)	19(19-31)	0.47	
Intra-Op Variables					
CPB Time (minutes)	96.89±24.34	160.60±38.94	158.41±36.56	0.001	
Aortic Cross Clamp Time (minutes) {Median (IQR)}	58(45-114)	123(99-204)	117(105-160)	0.001	
Post-Op Variables					
ICU Stay(hours)	60.29±50.25	113.10±80.16	62.68±50.25	0.003	
Inotropic Duration (hours) {Median (IQR)}	39.2(5-134)	72(45.5-268.5)	39.5(31-84)	0.001	
Ventilation time (hours) {Median (IQR)}	9(5-90)	29(20-213)	18(16-58)	0.001	
VIS max Score {Median (IQR)}	9(5-57)	35(16-64)	12(7-48)	0.001	
RVOT Gradient (mmHg)	33.54±9.41	28.50±8.98	25.81±7.56	0.05	
Degree of Pulmonary Regurgitation	Mild Moderate None	23(65.7) 0 12(34.3)	13(65.0) 7(35.0) 0 16(72.7)	6(27.3) 0 16(72.7)	0.001
Complications					
Re-Opening for Bleeding	Yes No	1(2.9) 34(97.1)	5(25.0) 15(75.0)	6(27.3) 16(72.7)	0.04
Pleural/Pericardial Drainage (ml) {Median (IQR)}	250(190-2260)	540(320-3020)	360(270-650)	0.03	
Outcome					
Outcome	Alive Dead	34(97.1) 1(2.9)	16(80.0) 4(20.0)	21(95.5) 1(4.5)	0.06

TAP=Trans-annular Patch; PVR= Pulmonary Valve Replacement ;RVOT= Right Ventricular Outflow Tract; ICU= Intensive Care Unit; VIS= Vasoactive Inotropic Score; CPB= Cardiopulmonary Bypass

Group A and C each had low mortality {1(2.9%) and 1(4.5%)} respectively, while high mortality {4(20%)} was observed in Group B but difference between groups in terms of mortality was insignificant ($p=0.06$)

DISCUSSION

The management of TOF in pediatric patients has been well documented in the literature from developed countries. However, the surgical management of adults with unrepaired TOF, who are more commonly treated in low-middle income countries, is less well described.⁸ These patients often have additional features, such as an extremely restrictive RV physiology caused by fibrosis, polycythemia, and coagulation abnormalities, as a result of prolonged hypoxemia.^{6,9} These features present significant challenges in post-operative management in the ICU, leading to higher morbidity and mortality rates compared to pediatric patients.⁸ Therefore, the development of effective surgical repair techniques for adults with unrepaired TOF is crucial to improve early outcomes.

We presented a comprehensive analysis of 10-years surgical data, during which three surgical techniques were predominantly employed. As in standard pediatric TOF repair, our primary objective was to preserve the patient's native pulmonary valve annulus/valve, as this has been shown to offer both short and long-term benefits, such as preserving the right ventricular function.¹⁰⁻¹² This finding was consistent with our adult patients' outcomes as well. A significant proportion of our patients, 35(45.5%), underwent pulmonary valve-sparing TOF repair, which resulted in shorter times for CPB, ACC, ventilation, inotropic support, and ICU stay, all of which were statistically significant ($p<0.05$). Unfortunately, there was one mortality case (2.9%), which resulted from lung reperfusion injury and ultimately led to sepsis and MODS. Since around half of our cohort (Group A) had a pulmonary valve annulus that could be salvaged, we can infer that the reason these persons were able to reach adulthood was because they had less severe RVOT obstruction at birth.

When the pulmonary valve annulus is hypoplastic, division of the pulm annulus with TAP becomes inevitable. TAP with MonoCusp creation is a common practice in pediatric TOF to prevent free PR, which can provide respite to the pressure-restrictive ventricle in the early post-op period.¹² Different materials have been used to create a MonoCusp: Autologous Pericardium, Bovine Pericardium, PTFE Patch, and Homograft; all have provided promising competence in early post-op periods but deteriorating PR in mid-term and long-term follow-up.¹³⁻¹⁵ 20(25.9%) of our cohort had TAP with MonoCusp. This group had longer CPB and ACC time; longer ventilation time, inotropic duration, and ICU stay; and higher VISmax; all being statistically significant ($p < 0.05$). The mortality was highest 4(20%) in this group. The reason for death in all these patients was right ventricle failure. 13(65.0%) patients had mild Pulmonary Regurgitation (PR) post-operatively and they all were among the survivors. 7(35.0%) patients had moderate PR, and 4(20.0%) of them died. We believe that the degree of PR had a strong association with poorer outcomes in this group ($p = 0.001$).

Apropos, it is widely recognized that having a competent valve in RVOT leads to positive early post-op outcomes. While the role of PVR for free PR in adults with repaired Tetralogy of Fallot (TOF) is well-established,^{16,17} its application in primary complete repair of adults with unrepaired TOF has been less extensively studied. Researchers from China, Liu H. *et al.* shared their experience with three surgical techniques (TAP+PVR, TAP Only, Pulm Valve Sparing) in 56 adults with unrepaired TOF, and concluded that TAP+PVR may be a promising approach to protect against right heart failure and mortality when annulus preservation is not feasible.¹⁸ A similar study by Jain A. *et al.* from India involved 37 adolescents and adults with unrepaired TOF and found that constructing the RVOT with TAP+PVR (Bioprosth) provided excellent early and mid-term outcomes.¹⁹ The CPB and ACC times in Group C 22(28.6%) were similar to those in Group B, however, there were statistically significant differences in the ventilation time, inotropic duration, and ICU stay, as well as a lower VISmax. These findings were in line with previous research. In this group, there was just one death (4.5%).

When it comes to repaired adult TOFs with free PR, the decision between a mechanical and a bioprosthetic valve at the pulmonary location is now favoring the mechanical prosthesis because of its

longevity and decreased risk of valve thrombosis when patients are properly selected and managed.^{20,21} 7(9.1%) of the participants in Group C selected a bioprosthetic valve, while 15(19.5%) went with a mechanical valve. A patient's preference for a bioprosthetic valve over a mechanical valve was influenced by their gender, bleeding disorders, and future pregnancy prospects. There was only one death in the mechanical group, which was caused by lung reperfusion injury from a missed MAPCA rather than any mortality in the bioprosthetic group.

LIMITATIONS OF STUDY

The current is a retrospective study, with a focus on comparing early outcomes. Mid-term results are not included as many patients were unable to comply with regular follow-up due to socio-economic factors. The study relies on data from various surgeons with different preferences for specific surgical techniques and different time periods. The selection of the reconstruction technique for the RVOT was also influenced by the patients' economic constraints, with MonoCusp being more affordable than PVR.

CONCLUSION

In the present era, adults with unrepaired TOF have encouraging early results with primary complete repair. Efforts should be made to preserve the patient's native pulmonary valve and annulus since pulmonary valve sparing TOF surgery provides better early results. When dividing a hypoplastic pulm valve annulus can not be avoided, TAP with PVR produces better early results than TAP with MonoCusp.

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Conflict of Interest: None

Authors' Contribution

Following authors have made substantial contributions to the manuscript:

DKM & KA: Concept, study design, drafting the manuscript, approval of the final version to be published

IUH & RUY: Data acquisition, critical review, approval of the final version to be published

MI & MM: Data acquisition data analysis, data interpretation, 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.

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