Latest follow-up after primary surgical correction of tetralogy of Fallot in adulthood

Original Article

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ABSTRACT

Background: Tetralogy of Fallot (TOF) is a prevalent congenital heart disease that requires early surgical intervention in infancy to enhance survival rates. However, some overlooked cases of TOF can persist into adulthood. Yet, they are vulnerable to serious complications from the long-standing cyanosis, which emphasizes the need for surgical correction. Nevertheless, primary surgical repair poses greater risks compared to pediatric cases due to coagulation defects, myocardial dysfunction, and previous palliative procedures. Additionally, severely dysplastic pulmonary valves often cannot be preserved, and a transannular patch can result in severe pulmonary regurgitation (PR), leading to complications such as right ventricle dysfunction and arrhythmia. Hence, in adult patients, pulmonary valve replacement (PVR) is a strong bailout option when valve preservation techniques fail to achieve satisfactory outcomes.

Aim: The objective of this study is to examine information gathered from 56 adult patients with TOF who received primary repair with PVR. The study will investigate the patients' preoperative characteristics, operative details, early postoperative progress, and recent follow-up results. The study findings will enhance the current understanding of PVR outcomes and the challenges adult TOF patients face.

Patients and Methods: We studied 56 patients, 16 years of age or older, who underwent primary surgical correction of TOF in adulthood using PVR from March 2013 till March 2023. We examined their preoperative characteristics, operative technical details, postoperative outcomes, and findings from their last follow-up visit.

Results: The mean age is 22.16±7.06 years. Twenty-one (37.5%) patients had palliative procedures. The majority were in NYHA grade 3. The mean oxygen saturation was 76.7%, while the mean hemoglobin level was 19.18. Cyanotic spells occurred in 10.71% of patients, and palpitations in 3.57%. The mean right ventricular outflow tract (RVOT) pressure gradient (PG) was 94.55 mmHg. Twenty-eight patients had a PVR with a freestyle valve, while the other half received tissue valves or homografts. The postoperative mean RVOT PG was 14.93 mmHg. There was no significant gradient difference between the different valve types. The mean ICU stay was 3.73 days, while the mean hospital stay was 8.64 days. Pleural effusion was the most common complication occurring in seven patients. While high intercostal tube drainage requiring evacuation occurred in four patients. Only one patient required revision of his ventricular septal defect patch due to significant residual. Cerebrovascular stroke occurred in two patients and resolved completely before discharge. The cohort was followed yearly. The mean follow-up years was 3.52 years. Fifty-four patients remained in NYHA 0. The mean RVOT PG was 21.3 mmHg, without significant difference between valves. Eleven patients had grade 1 PR and one had grade 2 PR.

Conclusion: TOF repair in adulthood using PVR is a safe, effective, and reproducible strategy. A longer follow-up period is mandatory to determine the degeneration rates of the biological valves used.

Key Words: Adult tetralogy of Fallot, pulmonary valve replacement, tetralogy of Fallot.

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INTRODUCTION

Tetralogy of Fallot (TOF) is a common cyanotic congenital heart disease that necessitates early surgical correction in infancy to improve survival rates[1]. However, some neglected cases of TOF can persist into adulthood, often associated with additional sources of pulmonary blood flow or milder forms of the disease.

Despite these alternative pathways, individuals with TOF are susceptible to developing serious complications, emphasizing the importance of surgical correction[2]. Primary surgical repair in adult TOF patients poses a higher risk compared to pediatric cases due to coagulation defects, myocardial dysfunction, and previous palliative procedures[3,4].

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Furthermore, severe cases of TOF often exhibit significant dysplasia in the pulmonary valve annulus and/or the right ventricular outflow tract (RVOT), necessitating a transannular patch (TAP) repair. However, TAP repair can lead to severe pulmonary regurgitation (PR), causing complications such as right ventricle dilatation and dysfunction, reduced functional status, arrhythmia, and even sudden death[5]. TAP repair may be unavoidable in infants, but close follow-up is necessary until pulmonary valve replacement (PVR) becomes feasible[6,7]. In adult patients, PVR becomes crucial to prevent additional complications when preserving the pulmonary valve is impossible.

However, limited literature exists regarding the outcomes of primary repair in adult TOF patients using PVR. Therefore, this study aims to analyze data from 56 adult TOF patients who underwent primary repair with PVR, focusing on preoperative characteristics, operative details, early postoperative course, and recent follow-up findings. The findings of this study will contribute to the existing knowledge on PVR outcomes and challenges in adult TOF patients.

PATIENTS AND METHODS:

Study design and setting

This research was performed at Department of Cardiac Surgery, Aswan Heart Centre, Magdi Yacoub Foundation, Aswan, Ain Shams University, Cairo, and National Heart Institute, Egypt.

Sample size and inclusion/exclusion criteria

The study included a total of 56 patients aged between 16 and 47 years, who were diagnosed with TOF and underwent a primary total surgical correction in adulthood with PVR. Patients with specific conditions such as TOF with complete atrioventricular canal defect, TOF with pulmonary atresia and multiple aortopulmonary collateral arteries, TOF with absent pulmonary valve, repair using valve-sparing technique, or younger than 16 years were excluded from the study.

Data collection

Data were collected from March 2013 to March 2023 and included various preoperative, intraoperative, postoperative, and follow-up variables. Preoperative variables encompassed demographics, presenting symptoms, oxygen saturation, hemoglobin level, previous palliative procedures, and echocardiogram results. Intraoperative variables included the type of prosthesis, use of RVOT augmentation patch, main pulmonary artery (MPA) augmentation patch, and pulmonary arteries reconstruction. Postoperative variables consisted of total ICU length of stay, presence of pleural effusion or chylothorax, postoperative bleeding, postoperative heart block, early mortality (<30 days), and echocardiogram results. Follow-up variables assessed symptoms, oxygen saturation, and echocardiogram results.

Operative details

All patients underwent primary total repair of TOF with PVR using a median sternotomy and full cardiopulmonary bypass. The surgical procedure involved excision of the dysplastic valve, closure of the ventricular septal defect (VSD) with a Gortex patch, and resection of hypertrophied septo-parietal muscle bands.

The choice of a pulmonary valve prosthesis depended on the size of the MPA. MPAs with sufficient size were fitted with a stented bovine aortic tissue valve, while severely dysplastic MPAs were more likely to be replaced using a stentless aortic valve (freestyle) or a pulmonary homograft. Although the pulmonary homograft was the preferred option, a freestyle valve was more frequently available for most patients.

Additional reconstruction of the pulmonary outflow tract was performed using RVOT augmentation patch, MPA augmentation patch, or pulmonary branch reconstruction when needed.

Statistical analysis

The collected data were revised, coded, tabulated, and analyzed using the Statistical analysis was done using IBM SPSS statistics for windows, Version 26.0. Armonk, NY: IBM Corp. Descriptive statistics presented the data, including mean, SD, range, median, interquartile range, frequency, and percentage. Analytical statistics involved paired t tests, analysis of variance, Kruskal–Wallis test, post-hoc tests, Fisher's exact test, McNemar test, marginal homogeneity test, and Friedman test. The level of significance (*P value*) was used to determine statistical significance.

Ethical considerations

The study followed ethical considerations and obtained approval from the Cardiothoracic Surgery Department at Ain Shams University Hospital and Aswan Heart Center. The protocol and corresponding documents were submitted for ethical and research approval.

RESULTS:

A total of 56 patients diagnosed with TOF were included in this study. The mean age of the study group was 22.16±7.06 years, ranging from 16 to 47 years, with a majority of males (53.6%). The mean weight was 52.34±12.26 kg, ranging from 21 to 79 kg, and the mean height was 163.05±11.96 cm, ranging from 131 to 184 cm.

The mean body surface area was 1.54±0.21, ranging from 0.91 to 1.99.

Among the study group, 16 (28.6%) patients had additional diagnoses besides TOF. The most common additional diagnoses were LAD crossing RVOT in six (37.5%) patients and major aortopulmonary collateral arteries (MAPCAs) in five (31.25%) patients, while left SVC was the least frequent, occurring in one (6.25%) patient.

Regarding previous palliation, 21 (37.5%) patients had undergone some form of palliation before the study. The most common palliation procedures were LMBT shunt in 10 (47.62%) patients and RMBT shunt in eight (38.1%) patients. RVOT stent and central BT shunt were the least common, occurring in one (4.76%) patient.

Preoperative symptoms were assessed for the study group. The majority of individuals (85.71%) had moderate to severe symptoms of heart failure (NYHA grade 3), while a small percentage (1.79%) had no or mild symptoms (NYHA grade 0 and 1). The mean oxygen saturation was 76.7±8.31%, with a range of 45–89%. The mean hemoglobin level was 19.18±2.22 g/dl, ranging from 13.7 to 23 g/dl. Cyanotic spells were experienced by 10.71% of patients, and palpitations were reported by 3.57% of patients. No cases of cerebrovascular stroke (CVS) or infective endocarditis (IE) were reported.

Preoperative echocardiography findings showed that the mean tricuspid annular plane systolic excursion (TAPSE) was 2.18±0.5, the mean left ventricular ejection fraction was 62.24±9.32% and the mean RVOT pressure gradient (PG) was 94.55±19.55. The majority of patients had no tricuspid regurgitation (TR) (grade 0), followed by mild TR (grade 1), and only one patient had moderate TR (grade 3). Most patients had no PR, with only one having moderate PR (grade 3).

Additional repair surgeries were performed on 37.5% of the patients (Table 1). The most common additional procedures were RMBT shunt takedown and LMBT shunt takedown, each performed in 23.81% of patients. Other procedures, such as TV repair, BDG takedown, and aortoplasty, were performed in less than 5% of patients. Half of the patients required PVR with a freestyle valve, while the other half received tissue valves or homografts.

RVOT patch reconstruction was required in most patients (85.71%), with Dacron being the most commonly used patch material (79.17%). MPA reconstruction was performed in 60.71% of patients, with autologous pericardium being the most frequently used patch material (58.82%).

The reconstruction of pulmonary artery branches was not required in most patients (82.14%). Only a small number of patients (16.1%) underwent augmentation, downsizing, or relocation of their pulmonary arteries. Preoperative MAPCAs closure was performed in five (8.93%) patients on the day before surgery.

Table 1: Operative details

Operation additional repair	21 (37.5)
Right MBT shunt takedown	5 (23.81)
TV repair	1 (4.76)
BDG takedown	1 (4.76)
Aortoplasty	1 (4.76)
Takedown of LMBT RMBT shunt	2 (9.52)
LPA reconstruction	4 (19.05)
Left MBT shunt takedown	5 (23.81)
Supra coronary aortic replacement	2 (9.52)
PVR with	
Tissue valve	20 (35.71)
Homograft	8 (14.29)
Freestyle	28 (50)
RVOT patch	
No	8 (14.29)
Yes	48 (85.71)
RVOT patch type	
Dacron	38 (79.17)
Bovine pericardium	6 (12.5)
Gortex	3 (6.25)
Aortic wall	1 (2.08)
MPA patch	
No	22 (39.29)
Yes	34 (60.71)
Type	
Dacron	12 (35.29)
Bovine pericardium	2 (5.88)
Autologous pericardium	20 (58.82)
Pulmonary arteries reconstruction	
No	46 (82.14)
Yes	10 (17.86)
Augmentation/downsizing/relocation	
No	47 (83.93)
Bifurcation augmentation	3 (5.36)
RPA reconstruction	2 (3.57)
LPA reconstruction	4 (7.14)
MAPCAs closed pre-op	
No	51 (91.07)
Yes	5 (8.93)

Data are presented as n (%).
MPA, main pulmonary artery; PVR, pulmonary valve replacement; RVOT, right ventricular outflow tract.

Postoperative echocardiography showed that the mean RVOT was 14.93±7.55, with a range of 2–30. The majority of individuals (60.71%) had no TR (grade 0), while a smaller percentage (37.5%) had mild TR (grade 1), and only one patient had moderate TR (grade 2). Most patients had no PR, but one had mild PR (grade 1). Among the patients, four (7.14%) had residual VSD, with three of them being restrictive and requiring no additional intervention. One patient had a significant VSD, resulting in postoperative pulmonary overflow, requiring revision of the VSD patch intraoperatively.

In terms of valve types used, significant differences observed in the number of patients requiring an RVOT patch. The freestyle valve group had the highest percentage, followed by the tissue valve group, and the homograft group had the lowest percentage. Regarding the need for a MPA patch, there was a significant increase in the number of patients in the tissue valve and freestyle valve groups compared to the homograft group (Table 2).

Table 2: Postoperative comparison between different valves

	PVR with				
	Tissue valve	Homograft	Freestyle	Test of significance	
	n (%)/median (IQR)	*n* (%)/median (IQR)	*n* (%)/median (IQR)	*P* value	Significance
RVOT patch					
No	3 (15)[a]	5 (62.5)[b]	0[c]	<0.001[(F)]	S
Yes	17 (85)[a]	3 (37.5)[b]	28 (100)[c]		
MPA patch					
No	4 (20)[a]	8 (100)[b]	10 (35.71)[a]	<0.001[(F)]	S
Yes	16 (80)[a]	0[b]	18 (64.29)[a]		
RVOT PG	12 (9–21.5)	8 (3.5–16.5)	15 (10.5–22.5)	0.085[(K)]	NS
TR grade					
0	15 (75)	5 (62.5)	14 (50)	0.09[(F)]	NS
1	5 (25)	2 (25)	14 (50)		
2	0	1 (12.5)	0		
Pulmonary regurge					
0	20 (100)	8 (100)	27 (96.43)	1.00[(F)]	NS
1	0	0	1 (3.57)		

MPA, main pulmonary artery; PG, pressure gradient; PVR, pulmonary valve replacement; RVOT, right ventricular outflow tract; TR, tricuspid regurgitation; S, Significant; NS, Significant.

There were no statistically significant differences in RVOT peak gradient, TR grades, or PR grades between the three valve groups.

The mean number of days spent in the ICU was 3.73±1.6, ranging from 2 to 8 days. The mean length of hospital stay was 8.64±3.15 days, ranging from 4 to 20 days. The most common complication noted was pleural effusion, occurring in 12.5% of patients. CVS and acute kidney injury were observed in 3.57 and 1.79% of patients, respectively. However, chylothorax, complete heart block, and IE did not occur in any of the patients. High intercostal tube drainage requiring re-exploration occurred in 7.14% of cases. The majority of patients (91.07%) did not require reoperation, and among those who did, the most common cause was pericardial effusion evacuation (Table 3).

Table 3: Prevalence of complications and ICU, hospital duration of stay

	Mean±SD/*n* (%)	Median (IQR)	Range
ICU days	3.73±1.6	3 (3–4.5)	(2–8)
Hospital days	8.64±3.15	9 (7–10)	(4–20)
Pleural effusion	7 (12.5)		
Chylothorax	0		
CHB	0		
IE	0		

CVS	2 (3.57)
High ICT drainage requiring re-exploration	4 (7.14)
AKI	1 (1.79)
Need for reoperation	
No	51 (91.07)
Yes	5 (8.93)
Cause	
Pericardial effusion evacuation	4 (80)
VSD patch dehiscence	1 (20)

AKI, acute kidney injury; CHB, complete heart block; CVS, cerebrovascular stroke; ICT, intercostal tube; IE, infective endocarditis; VSD, ventricular septal defect.

During the last follow-up, the mean duration of follow-up was 3.52±2.15 years, ranging from 0.95 to 8.12 years. Most patients (91.07%) had no dyspnea. The mean TAPSE was 1.79±0.34, the mean LVEF was 57.84±9.47%, and the mean RVOT was 21.32±12.29. In terms of TR, 28 (50%) patients had no TR (grade 0), 21 (37.5%) had mild TR (grade 1), and seven (12.5%) had moderate TR (grade 2). Regarding PR, 44 (78.57%) patients had no PR, 11 (19.64%) had mild PR (grade 1), and only one patient had moderate PR (grade 2) (Table 4).

The last follow-up details were also analyzed among the three types of valves used (Table 5).

Table 4: Last follow-up visit findings

	Mean±SD/*n* (%)	Median (IQR)	Range
Years of follow-up	3.52±2.15	3 (1.4–5.41)	0.95–8.12
Dyspnea			
No	51 (91.07)		
Yes	5 (8.93)		
NYHA			
0	51 (91.07)		
1	4 (7.14)		
2	1 (1.79)		
SaO_2	99.00	99.00	99.00
TAPSE	1.79±0.34	1.8 (1.58–2.04)	0.91–2.6
LVEF echo	57.84±9.47	59.65 (51.9–63.4)	31–74.3
RVOT PG	21.32±12.29	18 (15–25)	4–85
TR			
0	28 (50)		
1	21 (37.5)		
2	7 (12.5)		
Pulmonary regurge			
0	44 (78.57)		
1	11 (19.64)		
2	1 (1.79)		

LVEF, left ventricular ejection fraction; PG, pressure gradient; RVOT, right ventricular outflow tract; SaO2, oxygen saturation; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation.

Table 5: Comparison between the last follow-up findings of different valves

	PVR with		
	Tissue valve	Homograft	Freestyle
	Mean±SD/median (IQR)/*n* (%)	Mean±SD/median (IQR)/*n* (%)	Mean±SD/median (IQR)/*n* (%)
TAPSE	1.71±0.35	1.7±0.4	1.88±0.31
LVEF echo	62.53±5.57	58.93±7.2	54.19±10.82
RVOT PG	18 (13.5–24)	19 (14.5–35.5)	18 (15–25)
TR			
0	6 (30)	6 (75)	16 (57.14)
1	7 (35)	2 (25)	12 (42.86)
2	7 (35)	0	0
Pulmonary regurge			
0	14 (70)	7 (87.5)	23 (82.14)
1	5 (25)	1 (12.5)	5 (17.86)
2	1 (5)	0	0

LVEF, left ventricular ejection fraction; PG, pressure gradient; PVR, pulmonary valve replacement; RVOT, right ventricular outflow tract; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation.

The follow-up of NYHA functional class, oxygen saturation, and echocardiography findings across different time points showed a significant increase in the number of patients with NYHA class 0 at the last follow-up compared to baseline. TAPSE, LVEF%, and RVOT measurements showed a slight decrease at the last follow-up compared to the baseline. There was a significant decrease in patients with grade 0 PR at the last follow-up compared to baseline and immediate postoperative follow-up, but no significant difference in TR was observed (Tables 6, 7).

Table 6: Comparison between preoperative, postoperative, and last follow-up findings

	Baseline	Immediate postoperative	Last follow-up	Test of significance	
Whole group	*n* (%)/mean±SD/ median (IQR)	*n* (%)/mean±SD/median (IQR)	*n* (%)/mean±SD/ median (IQR)	*P* value	Significance
NYHA					
0	1 (1.79)		51 (91.07)	<0.001(MH)	S
1	1 (1.79)		4 (7.14)		
2	6 (10.71)		1 (1.79)		
3	48 (85.71)		0		
SaO_2	76.7±8.31		99	<0.001(T)	S
TAPSE	2.18±0.5		1.79±0.34	<0.001(T)	S
LVEF echo	62.24±9.32		57.84±9.47	<0.001(T)	S

RVOT PG	95 (80–110)	13.5 (10–20)	18 (15–25)	<0.001(F)	S
TR					
0	31 (55.36)	34 (60.71)	28 (50)	0.134(F)	NS
1	15 (26.79)	21 (37.5)	21 (37.5)		
2	9 (16.07)	1 (1.79)	7 (12.5)		
3	1 (1.79)	0	0		
PR					
0	55 (98.21)	55 (98.21)	44 (78.57)	<0.001(F)	S
1	0	1 (1.79)	11 (19.64)		
2	0	0	1 (1.79)		
3	1 (1.79)	0	0		

LVEF, left ventricular ejection fraction; PG, pressure gradient; RVOT, right ventricular outflow tract; SaO2, oxygen saturation; TAPSE, tricuspid annular plane systolic excursion; TR, tricuspid regurgitation; S, Significant; NS, Significant.

Table 7: Comparison between valve types across different time periods

	PVR with		
RVOT PG	Tissue valve [median (IQR)]	Homograft [median (IQR)]	Freestyle [median (IQR)]
Baseline	108 (82–120)	80 (65–96.5)	95 (82.5–100)
Immediate postoperative	12 (9–21.5)	8 (3.5–16.5)	15 (10.5–22.5)
Last follow-up	18 (13.5–24)	19 (14.5–35.5)	18 (15–25)

PG, pressure gradient; PVR, pulmonary valve replacement; RVOT, right ventricular outflow tract.

DISCUSSION

In this study, we investigated the outcomes of primary repair of TOF accompanied by PVR in adult patients. A total of 56 patients underwent surgery between 2013 and 2023, based on clear indications derived from their poor preoperative clinical condition. Interestingly, 33 individuals reached adulthood without undergoing any prior palliative procedures but exhibited similar adverse clinical presentations as the other patients.

Performing primary repair in adult TOF patients poses several challenges, including increased bleeding susceptibility, the presence of MAPCAs, mediastinal adhesions from prior palliative procedures, and dysplastic pulmonary valve and artery branches. However, the patients' diminished quality of life necessitates definitive surgical treatment[3]. Our surgical approach involved resecting the hypertrophied septo-parietal bands and closing the VSD. We made efforts to preserve the native valve[8] but opted for PVR if it would result in significant PR or right ventricular (RV) pressure of more than two-thirds of the systemic pressure. We avoided TAP due to its adverse effects on restrictive RV physiology[5].

The presence of MAPCAs was assessed preoperatively using multislice computed tomography imaging, and closure was performed during surgery or percutaneously before the operation. Eliminating systemic-to-pulmonary shunting helped minimize postoperative pulmonary overflow and lung injury[9], as well as improve myocardial protection and intraoperative visualization[3].

We used different types of valves for PVR, including the stentless porcine aortic root (freestyle), stented bovine pericardial tissue valve, and pulmonary homograft. The choice depended on the size of the MPA, with a preference for a pulmonary homograft when available. Patients with a homograft did not require additional patches for the MPA, while those with a stentless aortic root typically needed an MPA patch. Proper angulation, curvature, and conduit diameter were maintained through RVOT patches.

Early postoperative outcomes were satisfactory. Only two patients suffered from CVS, which did not leave any neurological deficits. One case of acute kidney injury and pleural effusion. Postoperative bleeding was controlled, and specific valve types did not significantly affect complications. Complete heart block and arrhythmias were rare in our cohort. Talwar *et al*.[3], presented a similar cohort where they treated 46 adult TOF patients. While mean ICU stay, hospital stay, and postoperative bleeding were similar to our results. Two early deaths occurred due to severe hematemesis and sudden ventricular fibrillation.

Postsurgery, peak PGs in the RVOT decreased significantly, and TR improved in some patients. PR was minimal, demonstrating the effectiveness of PVR in reducing it and decreasing arrhythmia incidence. Follow-up examinations showed no mortality or need for reoperation. Degeneration signs in biological valves were monitored, but no significant issues were observed.

While valve-sparing techniques provide physiological outcomes[8], they may not always be feasible. And their results might not be optimum regarding postoperative PR and residual stenosis. Bacha, in personal series, demonstrate that almost 80% developed atleast moderate PR at their latest follow-up, which was not the case in our series, where only one (1.79%) patient had moderate PR. Surgeons should prioritize patient-specific decisions and avoid personal biases. PVR with appropriate prostheses yielded favorable short and midterm results. Mechanical prostheses are not recommended due to high doses of anticoagulation, and biological prostheses may require future replacements due to degeneration. Homografts and stentless bioprostheses offer good hemodynamics, but their availability and surgical requirements should be considered. Stented bioprostheses were more readily available but required adequate MPA size.

In conclusion, standardized protocols and high surgical quality measures are vital for successful outcomes in adult TOF patients undergoing primary repair with PVR. Careful consideration of valve options and patient-specific factors is necessary for optimal results.

CONCLUSION

The primary repair of TOF in adult patients has demonstrated safety and effectiveness, resulting in enhanced patient well-being. Even in cases where PVR is required, the outcomes have been consistently positive and satisfying. It is imperative to conduct long-term follow-up to monitor valve degeneration and identify any signs of clinical decline.

CONFLICT OF INTEREST

No conflict of interest disclosure.

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