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Reintervention after repair of tetralogy of Fallot: a one-decade single-center experience

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Abstract

Background Reinterventions after tetralogy of Fallot repair (TOF) remains a common clinical problem. The objective of this study was to evaluate types of reintervention after TOF repair and identify the risk factors for reinterventions.

Methods This retrospective study was conducted from 2010 to 2022 and included 171 patients with complete TOF repair. Patients were grouped according to the occurrence of reintervention into two groups: patients who did not have reintervention ($n = 138$) and those who required reintervention ($n = 33$).

Results Median follow-up was 36 (13–67) months. The first reintervention was required in 33 patients. Freedom from the first reintervention at 1, 3, 5, and 7 years was 91%, 85%, 81%, and 76%, respectively. Surgical reintervention was required in 12 patients and transcatheter *intervention* in 21 patients. Second reinterventions were required in 11 patients; 4 had surgery, and 7 had a transcatheter *intervention*. Third reinterventions were performed on two patients; one had surgery, and one had a transcatheter *intervention*. The most common interventions were performed at the level of pulmonary arteries ($n = 17$), followed by the pulmonary valve and the right ventricular outflow tract ($n = 15$). The risk of reintervention was associated with the low weight (*HR*: 0.65 (95% *CI*: 0.48–0.88); $P = 0.005$) and small LPA diameter (*HR*: 0.36 (95% *CI*: 0.21–0.60); $P < 0.001$) at the time of the primary intervention and the nonuse of the transannular patch (*HR*: 0.27 (95% *CI*: 0.08–0.85); $P = 0.026$).

Conclusions The risk of reintervention is high after tetralogy of Fallot repair. In our experience, the smaller the left pulmonary artery and weight at the repair time increased the risk of reintervention. Using a transannular patch in our series was associated with a lower risk of reintervention.

Keywords Tetralogy of Fallot repair, Residual defects, Pulmonary incompetence, Pulmonary artery, Transannular patch, Right ventricular outflow tract

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Background

Surgical repair of tetralogy of Fallot (TOF) undergoes continuous refinement; however, reinterventions after TOF repair remain a common clinical problem [1]. The risk of reinterventions ranges from 3 to 16% [2, 3]. Reinterventions could be performed for several reasons, including residual defects, conduit change, right ventricular outflow tract (RVOT) obstruction, pulmonary artery stenosis, and pulmonary and tricuspid valve regurgitation [4–6].

Reinterventions after TOF repair are associated with increased morbidity and mortality [7]. Several strategies have been proposed to decrease the risk of reinterventions after TOF repair, including concomitant tricuspid repair, avoiding the use of the transannular patch, and early total repair [6, 8]. The objectives of this study were to evaluate types of reintervention after TOF repair and identify the risk factors for reinterventions.

Methods

Patients

This retrospective study was conducted from 2010 to 2022 and included all patients who had complete TOF repair. We included patients who had primary or staged repairs. Patients were grouped according to the occurrence of reintervention into two groups: patients who did not have reintervention ($n = 138$) and patients who required reintervention ($n = 33$). The institutional review board approved the study.

Data and outcomes

Data required for this study was collected from our congenital cardiac surgery registry. Preoperative data included gender, age, and weight at surgery, pulmonary valve annulus, diameters of the left and right pulmonary arteries, and previous palliation. Operative data included using a transannular patch (TAP), pulmonary valve sparing, pulmonary valve reconstruction, pulmonary artery plasty, and conduits. Study outcomes were hospital complications, including the length of ICU and hospital stay, residual defects, and hospital mortality. The freedom from reinterventions, types, and numbers was recorded.

Techniques

The TOF repair was performed through median sternotomy in all patients. Aorto-bi-caval cannulation was performed, and antegrade cardioplegia was used. Ventricular septal defect was closed through right atriotomy approach, and relief of right ventricular outflow tract (RVOT) obstruction was performed through both right atriotomy and right ventriculotomy in case of transannular patch or RV-PA conduit. Transannular patch was performed in 105 (71.92%) patients, pulmonary valve sparing was achieved in 59 (34.50%) patients, and eight patients (4.7%) had pulmonary valve reconstruction. Patients with postoperative hemodynamic instability or low saturation had an echocardiographic evaluation. Follow-up was performed in the outpatient clinic after discharge, and echocardiographic studies were performed according to the discretion of the pediatric cardiologists. The vital status was confirmed by phone calls.

Statistical analysis

Data were presented as median (25th–75th percentiles) for continuous data and numbers and percentages for nominal data. For the comparison of continuous variables, the *t*-test or Mann-Whitney was used when appropriate, and the chi-squared or Fisher exact test was used for nominal data when appropriate. Time to event was plotted using the Kaplan and Meier curve, and factors associated with reinterventions were evaluated using Cox regression analysis. Model selection was performed using the stepwise method with forward selection. A P-value of less than 0.05 was considered significant, and all analyses were performed using Stata 17 (StataCorp-College Station, TX, USA).

Results

Preoperative data

There was no difference in age, weight, gender, and pulmonary artery diameters between patients who had reintervention and who did not. Ten patients had previous palliation with a Blalock-Taussig shunt, and 5 had palliation with a stent (PDA or RVOT stent). There was no difference in palliation between both groups (Table 1).

Operative and postoperative data

There was no difference between both groups in transannular patch use, conduit use, pulmonary valve reconstruction, and pulmonary artery plasty. Patients who had reintervention had a significantly higher prevalence of residual ventricular septal defects (VSD) and significantly prolonged ICU and hospital stay. No difference was reported in the prevalence of residual pulmonary stenosis or regurgitation. Hospital mortality occurred in 3 patients (2.19%) in the no-reintervention group vs. 2 (6.45%) in the reintervention group ($P = 0.230$) (Table 2).

Follow-up and reinterventions

The median follow-up was 36 (13–67) months. The first reintervention was required in 33 patients (19.3%), 12 of them surgical intervention (7%), and 21 required catheter intervention (12%). The interval between primary repair and first intervention is ranging from 3 days postoperatively up to 8 years after TOF repair. The median weight at the first reintervention was 10 [6–13] kg. Freedom from the first reintervention at 1, 3, 5, and 7 years was 91%, 85%, 81%, and 76%, respectively. Surgical reintervention was required in 12 patients. Surgical reoperations were RVOT patch ($n = 1$), left pulmonary artery (LPA) plasty ($n = 1$), insertion of permanent pacemaker ($n = 2$), right ventricle to pulmonary artery conduit ($n = 2$), tricuspid valve repair ($n = 2$), mitral valve replacement (MVR) ($n = 1$), transannular patch ($n = 1$), right ventricular to pulmonary artery conduit plus mitral valve repair ($n = 1$), and double chamber right ventricle repair ($n = 1$).

Table 1 Comparison of the baseline data between patients who had reintervention after tetralogy of Fallot repair vs. those who did not

	Total ($n = 171$)	No reintervention ($n = 138$)	Reintervention ($n = 33$)	p-value
Age at surgery (months)	8 (5–13)	9 (6–15)	7 (5–11)	0.205
Weight at surgery (kg)	7 (6–8.6)	7 (6–8.8)	6 (5–8)	0.030
Male	100 (59.17%)	81 (58.70%)	19 (61.29%)	0.791
Pulmonary annulus diameter (mm)	5 (4.1–7)	5.5 (4.5–5.5)	5 (4–6)	0.082
Absent pulmonary valve	11 (6.43%)	9 (6.52%)	2 (6.06%)	0.923
RPA (mm)	5 (4–6.5)	5 (4–7)	5 (4–6)	0.738
LPA (mm)	5 (4–6)	5 (4–6)	4 (3–5)	0.095
Previous palliation				
BT shunt	10 (5.84%)	7 (5.07%)	3 (9.09%)	0.408
Shunt diameter (mm)	6 (6–9)	6 (2–12)	6 (6–6)	0.800
Stent	5 (2.92%)	2 (1.44%)	3 (9.09%)	0.05
Stent diameter (mm)	2.5 (2–3)	2.5–7	2 (2–3)	0.400

BT Blalock-Taussig, *RPA* Right pulmonary artery, *LPA* Left pulmonary artery. Data are presented as median (Q1-Q3) or numbers and percentages

Transcatheter interventions were required in 21 patients. Transcatheter interventions were LPA stent ($n = 2$), pulmonary valve ballooning ($n = 4$), RVOT stent ($n = 1$), LPA balloon ($n = 1$), right pulmonary artery (RPA) balloon ($n = 2$), RPA and LPA stent ($n = 2$), atrial septal defect (ASD) closure ($n = 3$), RPA and LPA ballooning ($n = 1$), main pulmonary artery and LPA stent ($n = 1$), VSD device closure ($n = 2$), RVOT ballooning ($n = 1$), and RPA stent plus LPA ballooning ($n = 1$).

The number of patients who needed second reintervention is 11 patients (6%), four required surgical intervention (2%), and 7 required catheter intervention (4%). The time interval between first and second intervention ranges from 1 month up to 67 months.

Table 2 Comparison of the operative and postoperative data between patients who had reintervention after tetralogy of Fallot repair vs. those who did not

	Total ($n = 171$)	No reintervention ($n = 138$)	Reintervention ($n = 33$)	p-value
Transannular patch	105 (71.92%)	85 (72.65%)	20 (68.97%)	0.693
Conduit	7 (4.09%)	6 (4.35%)	1 (3.03%)	> 0.99
Pulmonary valve sparing	59 (34.50%)	47 (34.06%)	12 (36.36%)	0.802
Pulmonary valve reconstruction	8 (4.68%)	7 (5.26%)	1 (3.03%)	> 0.99
	3 (tricuspid)	3	0	
	1 (bicuspid)	1	0	
	4 (monocuspid)	3	1	
Pulmonary artery plasty	7 (4.09%)	4 (2.90%)	3 (9.09%)	0.132
ICU stay (days)	6 (4–9)	6 (4–8)	8 (5–15.5)	0.007
Hospital stay (days)	10 (7–15)	10 (7–14)	16.5 (10.5–28.5)	< 0.001
Echocardiography				
Residual VSD	58 (33.92%)	40 (28.99%)	18 (54.55%)	0.005
Residual pulmonary stenosis	121	99	22	0.524
	20 (17–35) mmHg	20 (18–32) mmHg	21 (16–35) mmHg	0.825
Residual pulmonary incompetence				0.894
Trivial	23 (13.53%)	20 (14.49%)	3 (9.38%)	
Mild	52 (30.59%)	42 (30.43%)	10 (31.25%)	
Moderate	24 (14.12%)	19 (13.77%)	5 (15.63%)	
Severe	71 (41.76%)	57 (41.30%)	14 (43.75%)	
Hospital mortality	5 (2.98%)	3 (2.19%)	2 (6.45%)	0.230

ICU Intensive care unit, *VSD* Ventricular septal defect. Data are presented as median (Q1-Q3) or numbers and percentages

The median weight at the second reintervention was 17 [14–21] kg. Surgical reoperations were performed in 4 patients: mitral valve repair ($n = 1$), redo MVR ($n = 1$), Contegra change (Medtronic Inc., Minneapolis, MN, USA) ($n = 1$), and pacemaker battery change ($n = 1$). Transcatheter reinterventions were performed in 7 patients: VSD device closure ($n = 2$), ballooning of RPA and LPA stenting ($n = 2$), RPA and LPA stenting ($n = 1$), LPA stenting ($n = 1$), and melody valve implantation (Medtronic Inc., Minneapolis, MN, USA) ($n = 1$).

Two patients needed third reinterventions (1%): one of them surgical and another catheter intervention. The time interval between second and third intervention ranges from 7 months up to 140 months. The median weight at the third reintervention was 41.5 kg (16–67 kg). Surgery with Contegra change was done in one patient, and LPA stenting and RPA stent balloon dilatation were done in the second patient.

The risk of reintervention was associated with the low weight and small LPA diameter at the time of the primary intervention and the nonuse of the transannular patch (Table 3).

Assessment of patients during their last follow-up showed residual VSD in 18 patients (10.53%) had residual VSD (14 in the no-reintervention group (10.14%) and 4 (12.12%) in the reintervention group; $P = 0.740$). Residual pulmonary valve incompetence did not differ significantly between groups. Trivial PI was reported in 11 patients (6.47%) [7 (5.07%) vs. 4 (12.5%)], mild in 37 patients (21.76%) [31 (22.46%) vs. 6 (18.75%)], moderate in 13 patients (7.65%) [9 (6.52%) vs. 4 (12.50%)], and severe in 109 patients (64.12%) [91 (65.94%) vs. 18 (56.25%)] ($P = 0.264$). The median pulmonary valve pressure gradient was 20 (15–30) mmHg [20 (15–30) vs. 18 (14–25), $P = 0.378$] in the no reintervention vs. reintervention group, respectively Fig. 1.

Table 3 Risk factors for reintervention

	HR (95% *CI*)	*p*
Left pulmonary artery diameter	0.36 (0.21–0.60)	< 0.001
Transannular patch	0.27 (0.08–0.85)	0.026
Weight	0.65 (0.48–0.88)	0.005

Discussion

Tetralogy of Fallot is a common cyanotic heart disease [9]. Reinterventions after TOF repair still present a clinical problem, which increases morbidity and mortality [6]. Several techniques have been developed to alleviate the drawbacks of TOF repair and reduce the risk of reinterventions. Despite that, the risk of reintervention remains high. In this study, we reported the outcomes of 171 patients who underwent TOF repair in the last decade. Reinterventions were required in 33 patients (19.3%). In a study by Bakhiatry et al., reintervention was needed in 16 out of 120 patients (13%) [8]. In systematic review by Romeo et al., the incidence of reintervention was 2.26% per year which is similar to our study [10]. We did not report differences in the baseline characteristics between patients who required reintervention and those who did not.

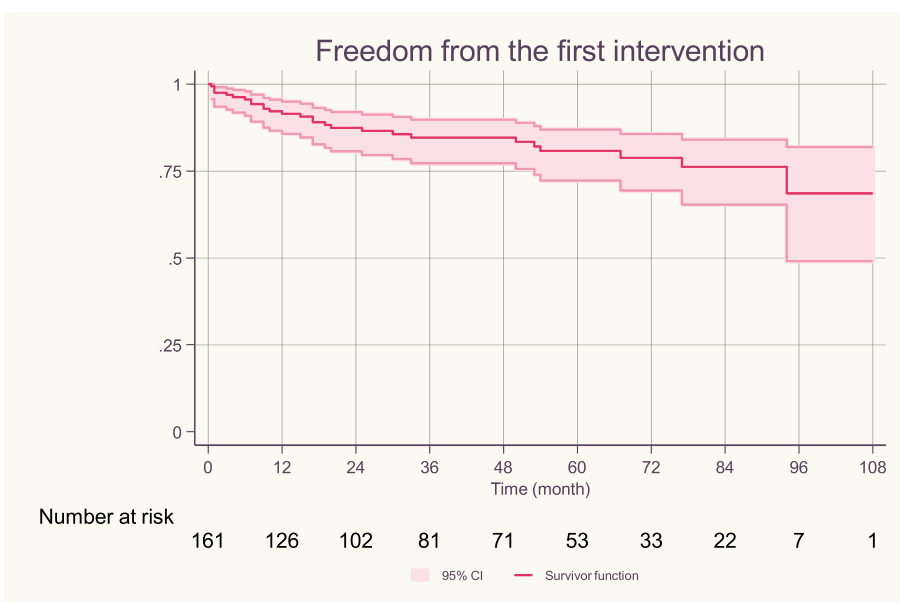

Fig. 1 Freedom from reinterventions after tetralogy of Fallot repair

Several factors could contribute to the need for reinterventions after TOF repair. Progressive pulmonary valve regurgitation and right ventricular overload are major causes of reinterventions [11]. The repair strategy was shifted from those targeting the relief of pulmonary stenosis to preserving the pulmonary valve [12]. Pulmonary valve preservation could be performed in patients with a small pulmonary valve when the use of a transannular patch could be avoided, and it was found that the pulmonary valve Z-score is not a risk factor for recurrent RVOT obstruction [13]. Hashemi and associates reported that the most common cause of reinterventions after TOF repair was pulmonary regurgitation (51%), followed by RVOT dilatation [14]. Another study [15] reported that pulmonary valve stenosis was the most common cause of reinterventions. In our series, we found that the non-use of the transannular patch was associated with the risk of reintervention. In patients with severe pulmonary regurgitation, pulmonary valve replacement could be beneficial to avoid the progression of right ventricular dilatation and dysfunction. Lim and associates found that early pulmonary valve replacement before the development of symptoms was beneficial in their series [16]. However, the optimal timing and procedures for pulmonary valve regurgitation after TOF repair remain controversial [17, 18].

Other series addressed the effect of pulmonary artery anatomy on the risk of reoperations. Luo and associates reported that a larger pulmonary artery bifurcation angle was a risk factor for reoperation [19]. In our series, most interventions were performed through a transcatheter approach on the right or left pulmonary artery branches. We found small preoperative left pulmonary artery diameter as a risk factor for reintervention. Bakhtiary and associates reported that repair at a young age with well-developed pulmonary arteries was associated with a lower risk of reintervention [8]. On the other hand, we found that lower weight was a predictor of reinterventions.

Residual VSD is still a challenging clinical problem after TOF repair [20, 21]. The rate of residual VSD varies in the literature because of the variability in the criteria for diagnosing and reporting VSD and the possibility of spontaneous closure. In our series, we performed transcatheter closure of residual VSD; however, it remained a substantial burden at the last follow-up in our patients. Another cause of reintervention after TOF repair is tricuspid regurgitation [22]. Two patients had reoperation for tricuspid regurgitation in our series. Prophylactic tricuspid valve repair at the time of TOF repair could be performed to decrease the risk of reoperation; however, this needs confirmation in further studies [6].

This series showed that the risk of reoperation is still high, despite the advancement of surgical techniques. However, most reinterventions can be performed via the transcatheter approach. Most of the reinterventions reported in our series occurred at the level of the pulmonary arteries, and the small diameter of the left pulmonary artery was a predictor for reintervention. The second most common cause of reintervention was the interventions on the RVOT and pulmonary valve levels. The results of this study indicated that more work is required to improve the outcomes of TOF repair. Operating on patients with well-developed pulmonary arteries and adequate body weight could decrease reintervention risk.

Study limitations

The study is a retrospective with its inherent selection bias. Several surgical techniques were performed at the discretion of the treating surgeons and according to their experience. Despite the high rate of reintervention, the number is not high for a thorough evaluation of all factors that could affect reinterventions.

Conclusions

The risk of reintervention is high after tetralogy of Fallot repair. In our experience, the smaller the left pulmonary artery and weight at the time of repair increased the risk of reintervention. Using a transannular patch in our series was associated with a lower risk of reintervention. Future strategies are required to decrease reintervention rates after TOF repair.

Abbreviations

TOF	Tetralogy of Fallot repair
RVOT	Right ventricular outflow tract
VSD	Ventricular septal defects
LPA	Left pulmonary artery
MVR	Mitral valve replacement
ICU	Intensive care unit
PDA	Patent ductus arteriosus

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None

Authors' contributions

MHM, conceived and planned the study, drafted the manuscript, and the "corresponding author"; AAA, conceived the presented idea and conducted the literature search analysis and interpretation of data; AFM, drafted the manuscript and conducted the statistical analysis and interpretation of data; WBA, drafted the manuscript and conducted the statistical analysis and interpretation of data; MGR, conducted the literature search and data collection; MAR and MSS, data collection, analysis, and procession; AAA, supervised the study and contributed to the interpretation of the results; and THE, contributed to the design and implementation of the research, statistical analysis, and interpretation. The authors read and approved the final manuscript.

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Availability of data and materials
Data are available upon request with the corresponding author.

Declarations

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IRB from KFSH and RC-J IRB Committee

Consent for publication
Not applicable

Competing interests
The authors declare that they have no competing interests.

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