

# The impacts of right ventricular outflow tract reconstruction on ventricular function in patients with tetralogy of Fallot

## Fallot tetralojisinde sağ ventrikül çıkış yolu tamir yöntemlerinin ventrikül fonksiyonu üzerine etkileri

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### ABSTRACT

**Objectives:** This study aimed to compare the impacts of right ventricular outflow tract reconstruction modalities on ventricular function in patients with tetralogy of Fallot.

**Patients and methods:** The files and echocardiographic examinations of 70 patients (34 males, 36 females; mean age: 5.8±8.4 years; range, 0.6 month to 31 years) who underwent total reconstruction for tetralogy of Fallot between January 2010 and December 2014 were retrospectively analyzed.

**Results:** Transannular patch was performed in 53 (75.7%) patients (Group A), valve-sparing surgery in four (5.7%) patients (Group B), pulmonary valve replacement with xenograft in five (7.1%) patients (Group C), and pulmonary valve replacement with homograft in eight (11.4%) patients (Group D). Twenty-eight (53%) patients in Group A needed adrenaline, while adrenaline was not needed in other groups (p=0.017). Patients in Groups C and D needed less inotropes. Pulmonary failure was observed in 52 (98.11%) patients in Group A after 28.53±16.77 months of follow-up with transthoracic echocardiography (p<0.001). While heart failure was observed in one (25%) patient in Group B, it was not encountered in Groups C and D (p<0.001). A decrease in ejection fraction and fractional shortening values over time was noted in patients in Group A (p<0.001). The slight increase in ejection fraction and fractional shortening values in patients in Group B was not considered significant (p=0.216). The increase in ejection fraction rates in Groups C and D was significant (p=0.046 and p=0.047, respectively). The minimal increase in the fractional shortening values in Group B was significant (p=0.045).

**Conclusion:** Pulmonary valve-sparing surgical technique should be preferred in suitable patients. Close follow-up with echocardiography and cardiac magnetic resonance imaging is important for the monitoring of ventricular functions in patients with transannular patch application. However, pulmonary valve replacement is considered the primary treatment method.

**Keywords:** Homograft, pulmonary insufficiency, tetralogy of Fallot, transannular patch, xenograft.

### ÖZ

**Amaç:** Bu çalışmada, Fallot tetralojisi hastalarında sağ ventrikül çıkış yolu tamir yöntemlerinin ventrikül fonksiyonu üzerine etkileri karşılaştırıldı.

**Hastalar ve Yöntemler:** Ocak 2010 - Aralık 2014 tarihleri arasında Fallot tetralojisi nedeni ile total rekonstrüksiyon uygulanan 70 hastanın (34 erkek, 36 kadın; ort. yaş: 5.8±8.4 yıl; dağılım, 0.6 ay - 31 yıl) dosyaları ve ekokardiyografik incelemeleri retrospektif olarak incelendi.

**Bulgular:** Hastaların 53'üne (%75.7) transanüler yama (Grup A), dördüne (%5.7) kapak koruyucu cerrahi (Grup B), beşine (%7.1) ksenogreftle pulmoner kapak replasmanı (Grup C), sekizine (%11.4) homogreftle pulmoner kapak replasmanı (Grup D) uygulandı. Grup A'daki 28 (%53) hastada adrenaline ihtiyacı olurken diğer gruplarda adrenaline ihtiyaç olmadı (p=0.017). Grup C ve D'deki hastalarda daha az inotrop ihtiyacı oldu. Transtoraksik ekokardiyografi ile 28.53±16.77 ay takip sonrası Grup A'daki 52 (%98.11) hastada pulmoner yetmezlik görüldü (p<0.001). Grup B'deki bir (%25) hastada kalp yetmezliği görülürken Grup C ve D'deki hastalarda kalp yetmezliği görülmedi (p<0.001). Grup A'daki hastalarda ejeksiyon fraksiyonu ve fraksiyonel kısalma değerlerinde zaman geçtikçe azalma görüldü (p<0.001). Grup B'deki hastalarda ejeksiyon fraksiyonu ve fraksiyonel kısalma değerlerindeki hafif artma anlamlı olarak değerlendirilmedi (p=0.216). Grup C ve D'de ejeksiyon fraksiyonu oranlarındaki artış anlamlı olarak değerlendirildi (sırasıyla, p=0.046 ve p=0.047). Grup B'de fraksiyonel kısalma değerlerindeki minimal artış anlamlı olarak değerlendirildi (p=0.045).

**Sonuç:** Uygun hastalarda pulmoner kapak koruyucu cerrahi teknik tercih edilmelidir. Transanüler yama uygulanan hastalarda ekokardiyografi ve kardiyak manyetik rezonans görüntüleme ile ventrikül fonksiyonlarının yakın takibi önemlidir. Ancak pulmoner kapak replasmanı primer tedavi yöntemi olarak değerlendirilmektedir.

**Anahtar sözcükler:** Homogreft, pulmoner yetmezlik Fallot tetralojisi, transanüler yama, ksenogreft.

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The incidence of congenital heart disease in newborns has been reported to be 4 to 50 in 1,000 live births.<sup>[1]</sup> Tetralogy of Fallot (TOF) accounts for 4% of all congenital heart diseases. Currently, the early results of total correction in patients with TOF have improved, but there are still a few late problems, such as arrhythmia, unexpected sudden death, reduced functional capacity, and right ventricular outflow tract (RVOT) reoperation.<sup>[2]</sup> Following surgical repair of TOF, pulmonary regurgitation (PR) often presents as the dominant residual lesion causing progressive right ventricular (RV) enlargement, functional impairment, and, potentially, sudden cardiac death.<sup>[3]</sup> Although numerous efforts have been made over the decades to overcome these issues, significant debate remains regarding the preferred management strategy for patients with TOF, such as the optimal timing of total repair, the RVOT reconstruction method, and the ventricular septal defect (VSD) closure approach. However, there is little information on comparison and late follow-up results between various RVOT reconstruction techniques in TOF repair.<sup>[2]</sup> Tetralogy of Fallot includes a broad clinical and anatomical spectrum, and surgical management also differs according to these spectrums.

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## PATIENTS AND METHODS

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In this study, the files of 70 patients (34 males, 36 females; mean age: 5.8±8.4 years; range, 0.6 month to 31 years) who underwent surgery for RVOT obstruction (RVOTO) with the diagnosis of TOF in the Ankara University Faculty of Medicine, Department of Cardiovascular Surgery, between January 2010 and December 2014 were retrospectively reviewed. Patients with TOF + pulmonary atresia or TOF + absence of the pulmonary valve were not included in the study. For the elimination of RVOTO, the patients were divided into four groups to compare the early- and the mid-term results: expansion with transannular patch (Group A), pulmonary valve-sparing surgery (Group B), pulmonary valve replacement (PVR) with xenograft (Group C), and PVR with homograft (Group D). A written informed consent was obtained from each patient. The study was conducted in accordance with the principles of the Declaration of Helsinki.

## Surgical technique

In all patients, cardiopulmonary bypass was performed following aortobicaval cannulation, and the heart was stopped with antegrade crystalloid cardioplegia at intervals of 20 to 25 min by placing a cross-clamp on the aorta under mild to moderate hypothermia (30 to 32°C). The RVOT and VSD were examined through the tricuspid valve from the right atriotomy. Resection of the hypertrophic muscles causing RVOTO and closure of the VSD were performed from the right atriotomy whenever possible. If adequate exposure could not be achieved by the atrial route, a vertical incision was made in the pulmonary artery, and the pulmonary valve and RVOT were examined. If the pulmonary annulus was adequate, the pulmonary valve was not dysplastic, and there was fusion only in the commissures, only commissurotomy was performed by preserving the valve and annulus. In cases where the pulmonary annulus was narrow compared to the body surface area (BSA), the pulmonary arteriotomy was extended towards the annulus and, if necessary, towards the ventricle, and sometimes the VSD was closed from here. Ventriculotomy was kept as small as possible. The RVOT was expanded with a transannular patch. In deciding the patch size, the RVOT and pulmonary annulus were measured with Hegar plugs following muscle resection. The remaining pulmonary valves were protected by suturing to the transannular patch, taking care to match the transannular incision to the commissure as much as possible. In addition, if there was stenosis in the branches of the pulmonary artery, the transannular patch was extended towards that region, and the stenosis area was widened. Left ventricular and RV pressures were compared after weaning from cardiopulmonary bypass. Repair was considered adequate if the RV/left ventricular pressure ratio was <0.70. Conventional and modified ultrafiltration were used in all patients.

## Statistical analysis

Statistical analysis was performed using the IBM SPSS version 20.0 software (IBM Corp., Armonk, NY, USA). Normally distributed variables were expressed as mean ± standard deviation (SD), while nonnormally distributed variables were presented as median (min-max). Frequency and percentage were used for nominal variables. When the number of groups was two, the significance of the difference between the groups in terms of means was investigated

**Table 1**  
Demographic characteristics of patients and surgical procedures

	Operation type															p					
	Group A (n=53)					Group B (n=4)					Group C (n=5)						Group D (n=8)				
	n	%	Mean±SD	Median	Min-Max	n	%	Mean±SD	Median	Min-Max	n	%	Mean±SD	Median	Min-Max		n	%	Mean±SD	Median	Min-Max
Age (year)	16	30.2	0-1/16	2.0	0.6-8.0	0	0		3.2	2.0-7.0	0	0		3.0	2.0-15.0	0	0		12.0	7.0-31.0	<0.001
1.04.1937	30	56.6				3	75				4	80				0	0				
4.10.2012	7	13.2				1	25				0	0				4	50				
>10/5	0	0				0	0				1	20				4	50				
Sex	30	56.6				0	0				3	60				3	37.5				
Female	23	43.4				4	100				2	40				5	62.5				0.158
Male																					
BSA (cm <sup>2</sup> )			0.55±0.26	0.45	0.30-1.57			0.59±0.11	0.57	0.47-0.75			0.69±0.44	0.56	0.43-1.48			1.44±0.33	1.59	0.92-1.71	<0.001
CPB time (min)			145.90±47.29	50-281				116.00±23.11	95-149				185.4±65.48	80-247				131.63±23.00	97-175	97-175	0.115
X-Clamp time (min)			98.57±38.49	83	70-94			82.50±11.79	98	26-225			142.60±65.62	160	40-217			97.50±22.98	91.5	64-136	0.158
Hospital stay time (day)			10.87±3.78	10	5-24			7.20±0.70	7	6-8			8.40±2.10	8	5-11			9.75±2.82	10	5-14	0.065
ICU stay time (day)			3.19±2.02	3	1-8			1.75±0.96	1.5	1-3			3.00±3.94	1	1-10			1.50±0.76	1	1-3	0.851
AV complete block	49	92.45				3	75				5	100				8	100				0.385
No	4	7.5				1	25				0	0				0	0				
Yes																					
Arrhythmia	50	94.34				3	75				5	100				8	100				0.158
No	3	5.66				1	25				0	0				0	0				
Yes																					
Pacemaker	52	96.7				4	100				5	100				8	100				1
No	1	3.3				0	0				0	0				0	0				
Yes																					

SD: Standard deviation; BSA: Body surface area; CPB: Cardiopulmonary bypass; ICU: Intensive care unit; AV: Atrioventricular; X: Cross.

with a t-test, and the significance of the difference in terms of median values was investigated with the Mann-Whitney U test. When the number of groups was more than two, the significance of the difference between the groups in terms of means was investigated with the analysis of variance, and the significance of the difference in terms of median values was investigated with the Kruskal-Wallis test. Nominal variables were evaluated with the Pearson chi-square test or Fisher exact test. While investigating the relationship between continuous variables, the distribution was evaluated with the Spearman correlation test in nonnormally distributed variables, and the Pearson correlation was used in normally distributed variables. A p-value <0.05 was considered statistically significant.

## RESULTS

The type of repair performed and the demographic characteristics of the patients are shown in Table 1. Transannular patch was performed in 53 (75.7%)

patients (Group A), valve-sparing surgery in four (5.7%) patients (Group B), pulmonary valve replacement with xenograft in five (7.1%) patients (Group C), and pulmonary valve replacement with homograft in eight (11.4%) patients (Group D). Approximately half of the patients (n=37) were between the ages of 1 to 4 years (p<0.001). In addition, operations in Group D were performed at an older age than the other groups, was with a statistically significant difference (p<0.001; Table 1). Group D had a smallest BSA, and Group A had a smaller BSA (p<0.001; Table 1).

When the operative findings were examined, it was found that there was no correlation between the type of surgery and the duration of cardiopulmonary bypass and cross-clamp (p=0.115 and p=0.158, respectively; Table 1). When the patients were compared according to the length of stay in the hospital and the intensive care unit, there was no significant difference between the

**Table 2**  
Comparison of inotrope use by groups

	Operation type								p
	Group A		Group B		Group C		Group D		
	n	%	n	%	n	%	n	%	
Inotrop									
No	8	15.1	1	25	4	80	6	75	0.001
Yes	45	84.9	3	75	1	20	2	25	
Dopamin									
No	13	24.52	2	50	4	80	6	75	0.045
Yes	40	75.47	2	50	1	20	2	25	
Adrenalin									
No	25	47.17	4	100	5	100	8	100	0.017
Yes	28	52.83	0	0	0	0	0	0	
Noradrenalin									
No	49	92.45	4	100	5	100	8	100	1.000
Yes	4	5.71	0	0	0	0	0	0	
Milrinon									
No	16	30.19	1	25	5	100	8	100	0.025
Yes	37	69.81	3	75	0	0	0	0	
Dobutamin									
No	50	94.34	4	100	4	80	8	100	0.554
Yes	3	5.66	0	0	1	20	0	0	

groups in terms of hospital and intensive care unit stays ( $p=0.065$  and  $p=0.851$ , respectively; Table 1). When the relationship between arrhythmia, complete atrioventricular block, pacemaker need, and operation type was compared, there was no significant difference between the groups ( $p=0.158$ ,  $p=0.385$ , and  $p=1.000$ , respectively; Table 1).

When the patients were evaluated according to the postoperative inotropic needs, it was observed that an inotrope was used in six of eight patients in Group D, and it was not needed in two of them. It was observed that one patient in Group C needed inotropes. Groups C and D needed significantly less inotropes compared to other groups ( $p=0.001$ ). In addition, Groups C and D did not need milrinone ( $p=0.025$ ; Table 2). In patients in Groups B, A, and C, a significant decrease was observed in postoperative RVOT gradients compared to before the operation ( $p=0.041$ ,  $p<0.001$ , and  $p=0.021$ , respectively; Table 3).

Pulmonary regurgitation was observed in 51 (96.23%) patients in Group A in transthoracic echocardiography performed in the first postoperative year ( $p<0.001$ ). Grade 2 PR was seen in 15 patients, Grade 2-3 PR in 24 patients, Grade 3 PR in 14 patients, and Grade 3-4 PR in two patients. Pulmonary regurgitation was not observed in Groups C and D ( $p<0.001$ ; Table 4).

## DISCUSSION

Early results of total repair of TOF have improved since the procedure was first introduced in the 1950s. The operative mortality rate has steadily decreased and is now close to 0% even for newborns and toddlers. This study shows that total correction of TOF can be achieved with a very low operative mortality (0.3%), as other studies have shown.<sup>[4-6]</sup> However, there are still long-term issues that require RVOT procedures, such as development of PR or pulmonary stenosis, progressive RV dysfunction or dilatation, decreased functional capacity, arrhythmias, and sudden cardiac death.<sup>[7-10]</sup>

Bacha et al.<sup>[7]</sup> evaluated the long-term results of 57 patients who underwent early surgery for TOF. Applying a transannular patch did not reduce long-term survival; on the contrary, it was associated with a lower incidence of RVOTO.

We also performed total reconstruction with transannular patch in 53 of 70 patients in our study.

**Table 3**  
Pulmonary insufficiency follow-up up to the first year

Operation type	Preoperative			1 <sup>st</sup> month			6 <sup>th</sup> month			1 <sup>st</sup> year			Last control			$\rho$
	Mean±SD	Median	Min-Max	Mean±SD	Median	Min-Max	Mean±SD	Median	Min-Max	Mean±SD	Median	Min-Max	Mean±SD	Median	Min-Max	
Group A	78.57±19.23	80	38-130	0.00±0.00	0	0-0	0.00±0.00	0	0-0	0.00±0.00	0	0-0	0.00±0.00	0	0-0	<0.001
Group B	31.00±5.22	32	25-35	10.50±3.0	10	8-14	11.00±1.1	11	10-12	11.50±1.9	11	10-14	11.75±2.8	12	8-15	0.041
Group C	33.00±9.36	45	40-65	4.80±1.09	4	4-6	4.80±1.09	4	4-6	4.80±1.09	4	4-6	5.20±0.90	6	4-6	0.021
Group D	8.50±13.55	4	0-40	4.88±0.83	5	4-6	6.25±1.39	6	4-8	6.50±1.07	6	5-8	10.75±8.2	6	5-24	0.139

SD: Standard deviation.

**Table 4**  
One-year pulmonary insufficiency rates according to surgery groups

	Operation type								<i>p</i>
	Group A		Group B		Group C		Group D		
	n	%	n	%	n	%	n	%	
Postoperative 1 <sup>st</sup> year PR									
Normal	0	0.00	3	75.0	5	100.0	8	100.0	
Grade 1	0	0.00	1	25.0	0	0.00	0	0.00	
Grade 1-2	2	3.77	0	0.00	0	0.00	0	0.00	
Grade 2	15	28.30	0	0.00	0	0.00	0	0.00	<0.001
Grade 2-3	24	45.28	0	0.00	0	0.00	0	0.00	
Grade 3	10	18.87	0	0.00	0	0.00	0	0.00	
Grade 3-4	2	3.77	0	0.00	0	0.00	0	0.00	
Postoperative 1 <sup>st</sup> year PR									
No	2	3.77	4	100.0	5	100.0	8	100.0	<0.001
Yes	51	96.23	0	0.00	0	0.00	0	0.00	

PR: Pulmonary valve regurgitation.

Atrial fibrillation was observed in two patients who were repaired with a transannular patch, ventricular tachycardia was observed in one patient, and a pacemaker was required in one (1.43%) of the five patients with complete atrioventricular block. While the need for permanent pacemaker was 1.1% in the study of Luijten et al.<sup>[11]</sup> with 453 patients, Üstünsoy et al.<sup>[12]</sup> reported 2.8% in 104 patients, and Therien et al.<sup>[13]</sup> reported 1%. Gatzolius et al.<sup>[14]</sup> examined 16 of 793 patients with sudden cardiac death, and they mentioned that ventricular tachycardia associated with pulmonary failure may be the main hemodynamic cause. Therefore, preservation of the pulmonary valve structure may reduce the risk of sudden death. In our study, in terms of complete atrioventricular block, arrhythmia, and permanent pacemaker need, there was no difference between the operation groups due to the low number of patients. However, similar to the literature, these complications were more common in patients who underwent repair with a transannular patch.

We followed our patients for 22.5±16.7 months. Grade 1-2 PR was observed in one patient in Group B, while PR was not observed in patients in Groups C and D. However, PR increased over time in Group A. In the first month, Grade 1-2 PR was observed in five (9.43%) patients, Grade 2 PR was observed in

19 (35.85%) patients, Grade 2-3 PR was observed in 22 (41.51%) patients, and Grade 3 PR was observed in seven (13.21%) patients. In the final controls, Grade 1-2 PR was observed in one (1.89%) patient, Grade 2 PR in 16 (30.19%) patients, Grade 2-3 PR in 20 (37.76%) patients, Grade 3 PR in 12 (22.64%) patients, and Grade 3-4 PR in four (7.55%) patients. Luijten et al.<sup>[11]</sup> conducted a long-term follow-up of 453 patients, 65% of whom underwent total reconstruction with a transannular patch. While 3.6% of the patients did not have PR, they detected Grade 1-2 PR in 26.8%, Grade 2-3 PR in 43.5%, and Grade 3-4 PR in 26.1%. Gatzolius et al.<sup>[14]</sup> had similar results. Pulmonary regurgitation results were similar in the 26 patients who were followed up for a mean of seven years by Özkan et al.<sup>[15]</sup> who applied transannular patch. In our study, the results of PR in Group A were similar to those in the literature.

In our study, there was a significant decrease in the RVOT gradient in all groups. Boni et al.<sup>[16]</sup> reported 12.5% residual stenosis in a series of 24 patients who underwent valve-sparing surgery. Özkan et al.<sup>[15]</sup> also did not report residual stenosis in their study, in which they accepted a gradient above 20 mmHg. In our study, similar results were obtained with the literature.



For the surgical repair of patients with TOF with pulmonary stenosis, the results are considered a useful criterion for evaluating the surgical method to be followed. With preoperative evaluation and postoperative management, TOF surgery falls in the middle of the difficulty spectrum of all congenital heart procedures. Tetralogy of Fallot itself includes a wide spectrum in terms of difficulty. Patients with TOF with pulmonary stenosis can almost always undergo an operation. With appropriate timing and indication, valve-sparing surgery, transannular patch, xenograft, and homograft PVR were successfully applied in our clinic with acceptable risk rates in patients with TOF.

The most important limitation of this study is that the patients could not be followed up after one year.

In conclusion, pulmonary valve-sparing surgery should be preferred in suitable patients. Follow-up with echocardiography and cardiac magnetic resonance imaging is important for ventricular functions in patients with transannular patches. However, PVR is considered the primary treatment method.

**Data Sharing Statement:** The data that support the findings of this study are available from the corresponding author upon reasonable request.

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