ORIGINAL ARTICLE

Tetralogy of Fallot Repair in Patients 40 Years or Older

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OBJECTIVE: **To report the outcomes of patients with tetralogy of Fallot (TOF) undergoing surgical repair at age 40 years or older.**

PATIENTS AND METHODS: **We reviewed records of patients (age, ≥40 years) who underwent TOF repair from January 1, 1970, through December 31, 2007. Symptoms, palliative procedures, surgical reports, and long-term outcomes were analyzed.**

RESULTS: **Fifty-two patients (30 men [58%]) had surgery at a mean ± SD age of 50±8 years; 27 (52%) had prior palliative surgery at a mean ± SD age of 17±11 years. Procedures for TOF repair included pulmonary valve replacement (n=10), transannular patch (n=10), and native pulmonary valve preservation (n=32). The 30-day mortality rate was 6% (stroke, n=2; ventricular fibrillation, n=1). A mean ± SD follow-up of 14.9±9.3 years was feasible in 48 of 49 survivors; improvement in functional class was observed in 42 patients. Reoperation was performed in 7 patients (4 for pulmonary regurgitation). Twenty-nine patients died (mean ± SD age, 65±12 years); causes of death were cardiac (n=7), noncardiac (n=4), and unknown (n=18). Mean ± SD age at death was younger in patients with previous palliation (59±11 years vs 70±12 years; *P*=.03). The 10-year survival rate was lower than expected compared with an age- and sex-matched population (73% vs 91%; *P*<.001).**

CONCLUSION: **Complete repair of TOF in patients 40 years or older is feasible but carries increased operative risk. Surgical survivors have improvement in functional class; however, survival remains lower than expected. Reduced survival and need for reoperation emphasize the importance of pulmonary valve replacement at the time of initial repair and long-term follow-up.**

***Mayo Clin Proc.* 2010;85(12):1090-1094**

CI = confidence interval; HR = hazard ratio; NYHA = New York Heart Association; TOF = tetralogy of Fallot

Tetralogy of Fallot (TOF), which was first described in 1888 by Etienne-Louis Fallot,[1] is the most common cyanotic, congenital heart disease; it consists of a ventricular septal defect, right ventricular outflow tract obstruction, aortic override, and right ventricular hypertrophy. Surgical repair of TOF has been performed since 1955.[2] Early primary repair has been recommended since the 1970s and is now routinely performed with excellent results.[3] However, we still occasionally encounter patients who have not undergone repair or have had only a palliative procedure; these patients thus are considered for surgical correction later in life.[4,5] Few studies describe the outcome of such patients. However, the chronic hypoxia that is characteristic of patients with unrepaired or palliated TOF may cause cerebral complications because of the right-to-left shunt, myocardial dysfunction, and an increased incidence of ventricular and atrial arrhythmias.[6-8]

This study was designed to analyze symptoms, operative technique, and outcome in patients who were 40 years or older when complete TOF repair was undertaken. We further aimed to compare outcomes of patients who did and did not receive prior palliation.

PATIENTS AND METHODS

The Mayo Clinic Institutional Review Board approved this study, and all patients or their families gave written informed consent. Using our surgical database, we identified all patients 40 years or older with the diagnosis of TOF. Patients underwent complete repair from January 1, 1970, through December 31, 2007. Preoperative data were collected, including symptoms, New York Heart Association (NYHA) functional class, hemoglobin level, cardiac catheterization data such as oxygen saturation and cardiac index, and data from previous palliative procedures. Follow-up data were obtained through clinical visits, questionnaires, refill requests, and evidence of death (through death certificates or the Social Security Death Index).

Surgical Procedure

All patients underwent standard surgical procedures, including sternotomy and cardiopulmonary bypass. Aortic cross-clamping was used in all patients. All surgery was performed with extracorporeal circulation using hypothermia. Data from the operative procedures and techniques were collected, including cardiopulmonary bypass time and aortic cross-clamp time.

Statistical Analyses

Continuous data values were expressed as mean ± SD. Contingency tables were analyzed for association using the χ^2 or Fisher exact test (when appropriate). Continuous variables were compared with the appropriate 2-sample test: a 2-sample *t* test when the variable distributions were symmetric and a Wilcoxon rank sum test otherwise. Sur-

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vival was evaluated by using Kaplan-Meier analysis with 95% confidence intervals (CIs). A log-rank test was used to compare 10-year survival rates of the patients with and without previous palliative surgery and an age-matched control population. Cox proportional hazards regression was used to test for associations with long-term survival. The threshold for statistical significance was established at $P \leq .05$.

RESULTS

Of the 63 patients identified from our surgical database, 9 patients with a double-outlet right ventricle and 2 with complex TOF (TOF with pulmonary atresia) were excluded. Clinical characteristics of the 52 remaining patients are shown in Table 1; patients were stratified by whether they had previously undergone palliative procedures.

Of the 27 patients who underwent palliative procedures, 12 (44%) had a left Blalock-Taussig shunt, with 1 patient requiring a subsequent Brock procedure. Four patients (15%) had a right Blalock-Taussig shunt, with 1 patient having a subsequent sternotomy without intervention. Four patients (15%) had a Potts anastomosis performed, and 5 patients (19%) had a Brock procedure. Two patients (7%) underwent pulmonary valvotomy. One patient had mediastinal exploration without any intervention (not considered a palliative procedure). Only 3 patients (11%) had aortopulmonary collaterals described, with 1 requiring ligation.

Previous palliation did not affect age at complete repair or NYHA functional class. However, patients with previous palliation had greater incidence of cyanosis and arrhythmias. Arrhythmias included atrial fibrillation (n=7), ventricular tachycardia (n=4), and supraventricular tachycardia (n=1).

Left ventricular ejection fraction was normal in 8 (30%) of 27 patients with previous palliation and 24 (96%) of 25 patients without it (P=.02). A decrease in left ventricular ejection fraction could not be predicted by preoperative cyanosis.

Preoperative Cardiac Catheterization Findings and Operative Procedures

Findings of cardiac catheterization are summarized in Table 2. The cardiac index was slightly lower in patients with previous palliation; otherwise, differences between groups were not significant. Operative procedure data are shown in Table 3. In patients with scars from previous palliative procedures, cardiopulmonary bypass times and aortic cross-clamp times were considerably longer than in patients without previous palliation. Some patients underwent additional operative procedures at the time of repair (some had >1 additional procedure), including tricuspid annuloplasty (n=8), atrial septal defect closure (n=13), patent foramen ovale closure (n=10), coronary artery bypass graft (n=2), mitral valve annuloplasty (n=2), aortic valve replacement (n=1), aortoplasty (n=1), and ligation of the left atrial appendage (n=1).

TABLE 1. **Clinical Characteristics**[a,b]

Characteristic	All patients (N=52)	Previous palliation		
		Yes (n=27)	No (n=25)	*P* value
Male	30 (58)	17 (63)	13 (52)	.58
Age at diagnosis (y)	29±19	15±10	43±14	<.001
Age at palliation (y)	NA	17±11	NA	NA
Age at TOF surgery (y)	50±8 (range, 40-68)	49±8	50±7	.56
NYHA functional class				.43
I	2 (4)	0 (0)	2 (8)	
II	10 (19)	6 (22)	4 (16)	
III	33 (64)	18 (67)	15 (60)	
IV	7 (13)	3 (11)	4 (16)	
Syncope	8 (15)	3 (11)	5 (20)	.46
Dyspnea	49 (94)	27 (100)	22 (88)	.10
Angina	3 (6)	2 (7)	1 (4)	>.99
Endocarditis	3 (6)	2 (7)	1 (4)	>.99
Cyanosis	35 (67)	22 (81)	13 (52)	.04
Stroke	5 (10)	2 (7)	3 (12)	.66
Clubbing	28 (54)	17 (63)	11 (44)	.38
Arrhythmias	12 (23)	11 (41)	1 (4)	.002
Any heart failure	8 (15)	5 (19)	3 (12)	.72

[a] NYHA = New York Heart Association; TOF = tetralogy of Fallot; NA = not applicable.
[b] Categorical data are provided as number (percentage) of patients and continuous data as mean ± SD, unless otherwise indicated.

Early Deaths

Three patients died perioperatively. One patient was a previously palliated 45-year-old woman who had undergone a surgical repair in 1990 (suture closure of an atrial septal defect, mitral valve annuloplasty, closure of her left Blalock-Taussig shunt, resection of subpulmonary stenosis,

TABLE 2. **Findings During Cardiac Catheterization**[a,b]

Finding	All patients (N=52)	Previous palliation		
		Yes (n=27)	No (n=25)	*P* value
Oxygen saturation (%)	86±8 (n=49)	85±7 (n=26)	87±10 (n=23)	.29
Preoperative hemoglobin (g/dL)	16.6±2.5	16.6±2.6	16.7±2.3	.99
Cardiac index (L/min/m^2)	2.4±0.8	2.1±0.6	2.7±0.9	.03
Infundibular pulmonary stenosis	51 (98)	26 (96)	25 (100)	>.99
Valvular pulmonary stenosis	31 (60)	19 (70)	12 (48)	.16
Supravalvular pulmonary stenosis	2 (4)	1 (4)	1 (4)	>.99
Right-sided aortic arch	17 (33)	10 (37)	7 (28)	.56
Anomalous coronary arteries	3 (6)	2 (7)	1 (4)	>.99
Coronary artery disease	6 (12)	2 (7)	4 (16)	.41

[a] Categorical data are provided as number (percentage) of patients and continuous data as mean ± SD.
[b] SI conversion factor: To convert hemoglobin values to g/L, multiply by 10.

TABLE 3. **Operative Procedures and Duration of Surgery**[a,b]

Variable	All patients (N=52)	Previous palliation		*P* value
		Yes (n=27)	No (n=25)	
Cardiopulmonary bypass time (min)	135±59 (range, 62-323)	151±60	117±55	.02
Aortic cross-clamp time (min)	73±41	83±40	62±40	.03
Shunt take down	NA	18 (67)	NA	NA
Ventricular septal defect closure				.60
Patch	49 (94)	26 (96)	23 (92)	
Suture	3 (6)	1 (4)	2 (8)	
Pulmonary valve				.30
Preservation	32 (62)	14 (52)	18 (72)	
Transannular patch	10 (19)	6 (22)	4 (16)	
Replacement	10 (19)	7 (26)	3 (12)	
Closure of atrial septal defect or patent foramen ovale	23 (44)	12 (44)	11 (44)	>.99
Ratio right ventricle:systemic pressure, postoperative	0.46±0.13	0.46±0.13	0.46±0.13	.91
Perioperative death (within 30 d)	3 (6)	2 (7)	1 (4)	>.99

[a] NA = not applicable.
[b] Categorical data are provided as number (percentage) of patients and continuous data as mean ± SD, unless otherwise indicated.

and transatrial patch closure of a ventricular septal defect). She died of a postoperative stroke.

The second patient was a 44-year-old unpalliated man who had an operation in 1966 (closure of a ventricular septal defect with a polytetrafluoroethylene patch, pulmonary valvotomy, and excision of infundibular stenosis). At operation, a markedly hypertrophied right ventricle was noted. The patient died on postoperative day 1 of ventricular fibrillation.

The third perioperative death occurred in a 64-year-old woman with a previous left Blalock-Taussig shunt who underwent repair in 2007 (ventricular septal defect patch closure, pulmonary valve replacement with a 27-mm St Jude porcine bioprosthesis [St Jude Medical, St Paul, MN], tricuspid valve repair with a Carbomedic 23-mm flexible annuloplasty ring [Sorin Group USA, Arvada, CO], and closure of her Blalock-Taussig shunt). She died of an early postoperative stroke that likely was caused by chronic atrial fibrillation.

Follow-up

Follow-up was possible in 48 of the 49 survivors for 15±9 years (range, 0.7-38.0 years). Follow-up data were obtained through clinical visits (n=27), questionnaires or refill requests (n=10), and evidence of death (n=29); data are summarized in Table 4. Postoperative improvement in NYHA functional class was noted in 42 patients (88%); only 5 patients remained in functional class III or IV. Functional class tended to be better in patients without previous palliation.

Age-adjusted hazard ratios (HRs) for death were calculated for the following baseline parameters: functional class; history of stroke, syncope, cyanosis, arrhythmia, chronic heart failure, cardiac index, or coronary artery disease; techniques of pulmonary valve replacement vs preservation; pulmonary valve stenosis; and prior palliation. Only valvular pulmonary stenosis (HR, 2.1; 95% CI, 0.98-4.7; *P*=.06) and prior palliation (HR, 2.1; 95% CI, 0.93-4.7; *P*=.08) were associated with increased risk of death, but the differences were not statistically significant.

TABLE 4. **Follow-up Data**[a,b]

Variable	All patients (N=48)	Previous palliation		*P* value
		Yes (n=25)	No (n=23)	
Duration of follow-up (y)	14.9±9.3	12.4±6.7	17.5±10.9	.05
Postoperative improvement	42 (88)	22 (88)	20 (87)	>.99
NYHA functional class				.06
I	22 (46)	8 (32)	14 (61)	
II	21 (44)	15 (60)	6 (26)	
III	4 (8)	1 (4)	3 (13)	
IV	1 (2)	1 (4)	0 (0)	
Reoperation	7 (15)	5 (20)	2 (9)	.42
Interval between surgery and death (y)	16±11	12±8	20±12	.06
Age at death (y)	65±12	59±11	70±12	.03

[a] NYHA = New York Heart Association.
[b] Categorical data are provided as number (percentage) of patients and continuous data as mean ± SD.

Twenty-nine patients died; mean ± SD age at death was 65±12 years. The 10-year survival rate was significantly lower than that of an age- and sex-matched population (73% vs 91%; *P*<.001). Patients with previous palliation had worse survival, but the difference was not statistically significant (*P*=.08). The cause of death was unknown for 18 patients. For the remaining 11 patients, the most frequent cause of death was cardiac in nature (n=7; 64%).

Reoperation was necessary in 7 patients; these data are summarized in Table 5. The most common cause for reoperation was severe pulmonary regurgitation (n=4).

DISCUSSION

Our data emphasize that complete repair of TOF is feasible in older patients but is associated with a 6% early mortality rate. Surgical survivors have frequent and marked improvement in NYHA functional class; however, survival rates remain lower than expected. Reduced long-term survival is often due to cardiac death, and the need for reoperation emphasizes the importance of long-term, informed follow-up.

Operative Risk

Currently, operative mortality in intracardiac repair for TOF is less than 1%.[3] However, operative mortality is age dependent; in experienced centers, it is nearly 0% for patients 12 months or younger and 4.4% for patients older than 12 months.[3] In a series of 39 patients who underwent

TABLE 5. **Reoperation Data**[a,b]

Patient	Reason for reoperation	Palliation	First repair	Symptoms	Reoperation
1	Severe PR	Age 4: left BT Age 10: attempt at surgery	Age 40: patch closure VSD, resection infundibular hypertrophy, resection PV, closure left BT, patch for PA, RVOT, MPA	Fatigue, right-sided heart failure	Age 55: PVR 29-mm SJM bioprosthesis, RV to PArt roof augmentation
2	Heart failure	Age 11: left BT	Age 44: 25-mm Hancock outflow conduit, ASD closure, AVR 14 A SE, de Vega annuloplasty	Heart failure	Age 57: heart transplant
3	Severe PR	None	Age 57: resection PV, transannular RVOT reconstruction with patch, patch VSD closure, tricuspid annuloplasty, PFO closure	Heart failure	Age 57: PVR 25-mm Ionescu-Shiley, small residual VSD suture closure
4	Recurrent VSD	None	Age 55: resection muscular diaphragm RV, patch closure VSD, CABG × 2	Dyspnea	Age 57: patch closure recurrent VSD, MVR, tricuspid annuloplasty
5	Severe PR	Age 7: left BT, then Brock procedure	Age 42: transatrial repair with suture closure PFO, patch closure VSD, TA patch	Heart failure	Age 46: PVR 25-mm SJM, suture closure residual VSD, patch left PA
6	Severe TR	Age 6: left BT	Age 45: closure RCA to RA fistula, resection PV, patch closure VSD, patch enlargement MPA, PA, and RVOT, 28-mm CE bioprosthesis	Edema, dyspnea, recurrent VT	Age 59: TVR with 35-mm CE porcine heterograft, AICD
7	Severe PR	Age 42: right BT	Age 60: ligation BT shunt, suture closure PFO, patch closure VSD, resection subvalve PS, TA patch	Fatigue, dyspnea	Age 64: 27-mm Ionescu-Shiley heterograft

[a] AICD = automated implanted cardioverter-defibrillator; ASD = atrial septal defect; AVR = aortic valve replacement; BT = Blalock-Taussig; CABG = coronary artery bypass graft; CE = Carpentier-Edwards; MPA = main pulmonary artery; MVR = mitral valve replacement; PA = pulmonary atresia; PArt = pulmonary artery; PFO = patent foramen ovale; PR = pulmonary regurgitation; PS = pulmonary stenosis; PV= pulmonary valve; PVR = pulmonary valve replacement; RA = right atrium; RCA = right coronary artery; RV = right ventricle; RVOT = right ventricular outflow tract; SE = Starr Edwards; SJM = St. Jude Medical; TA = transannular patch; TR = tricuspid regurgitation; TVR = tricuspid valve replacement; VSD = ventricular septal defect; VT = ventricular tachycardia.

[b] All ages are presented as years.

TOF repair at the age of 26.6 years,[9] the early mortality rate was 5.1%, which is very similar to that of our patients, who were older at the time of repair. More of our patients (52% vs 10%) had a previous palliative procedure that resulted in potential operative complications, including adhesions, vascular distortion, and pulmonary vascular disease. Outcomes can be excellent if early palliation is performed with a nonneonatal transatrial-transpulmonary repair.[10]

Functional Improvement and Arrhythmias

Despite the late repair, functional improvement in our patients was impressive and similar to that in other series. These findings emphasize that long-term hypoxia and polycythemia do not prevent postoperative symptomatic improvement. Still, NYHA functional class was worse at follow-up in our patients than in other series; for example, of 151 patients who underwent repair at a mean ± SD age of 14.3±6.4 years, 94% were in NYHA class I at follow-up,[11] whereas 46% in our series were in class I.

The risk of late cardiac death may be higher than expected for patients in the late-repair group, likely because of arrhythmias. The preoperative incidence of arrhythmias, especially atrial fibrillation and ventricular tachycardia, was high. We lack follow-up data on arrhythmias in the postoperative setting, but we recommend routine Holter monitoring in these patients. Atrial fibrillation was more frequently documented than ventricular tachycardia in our patient population; this may reflect the impact of massive hypertrophy of the right ventricle, with its concomitant diastolic dysfunction and subsequent propensity to atrial arrhythmias. Life-threatening ventricular arrhythmias can occur after surgical repair, being more common after transventricular compared with transatrial reparative approaches.[12] Late pulmonary valve replacement in TOF does not appear to reduce the incidence of ventricular tachycardia or death.[13]

Reoperations

Reoperations were necessary in 7 (14%) of 49 survivors. The most frequent cause for reoperation was severe pulmonary regurgitation (n=4), similar to reoperations for patients who are younger at repair.[14,15] Our 4 patients had a transannular patch with no pulmonary valve replacement at the time of primary repair. These data suggest that adult patients referred for repair should have the pulmonary valve spared or replaced at the time of TOF repair. A transannular patch that results in severe pulmonary valve regurgitation is not well tolerated by adult patients with TOF who have advanced hypertrophy of the right ventricle.

Our data on reoperation frequency are similar to other published long-term results. Bacha et al[16] studied a cohort of adult patients undergoing TOF repair and observed that reoperations were necessary in 3 patients for ventricular

septal defect closure and pulmonary valve replacement. Follow-up in that study was relatively short (45 months), and many of those patients may have undergone late corrective surgery after they were lost to follow-up. It is essential that all patients with TOF repair be properly informed of their cardiac disease, the potential for residua, and the importance of routine follow-up.

Long-Term Survival

The 10-year survival rate for our patients was 73%, which was better than would be expected for those with unrepaired TOF (only 24% survive to age 10 years).[17,18] Nevertheless, it was significantly less than the expected survival rate of 91%. Our observed survival rate was also lower than that of patients undergoing surgery at a younger age (20-year survival, 86%).[16] These data are insufficient to confirm whether postoperative survival is determined by the type of surgical repair. In another study, univariate analysis showed that predictors of long-term survival in young patients (operation at age 20.6 years) were reoperation and associated cardiac anomalies.[19] In our study, only prior palliation and associated valvular (rather than infundibular) pulmonary stenosis appeared to increase the risk of later death.

Study Limitations

With the long study period (dating back to 1970), 35 patients (67%) underwent repair before 1990. Therefore, the operative technique used varied with time. We note that the transatrial-transpulmonary approach was used in only 2 patients. Comprehensive echocardiography-Doppler examinations were not performed in many patients. These data could not be integrated into the analysis. This was a retrospective study with follow-up that did not routinely include Holter monitoring, exercise tests, or regularly scheduled visits at our clinic.

CONCLUSION

Complete repair of TOF is feasible in patients 40 years or older but is associated with an increased operative risk. Surgical survivors have marked improvement in functional class; however, survival rates remain lower than expected. Reduced long-term survival and need for reoperation emphasize the importance of long-term, informed follow-up.

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