

Symptomatic Neonatal Tetralogy of Fallot: Repair or Shunt?

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Background. The management of neonates with symptomatic tetralogy of Fallot (TOF) requiring surgical intervention in the first month of life remains controversial. We reviewed our experience with neonates 30 days or greater with TOF from 2002 to 2008 requiring surgical intervention.

Methods. Thirty-seven consecutive symptomatic nonrandomized neonates with TOF or its variants (including TOF with complete atrioventricular septal defect or absent pulmonary valve but excluding pulmonary atresia) had either a shunt ($n = 17$) or primary repair ($n = 20$). The shunted patients more commonly required emergency operation (24% vs 0%; $p = 0.036$); otherwise, the two groups were similar.

Results. One infant with preoperative bowel ischemia died one day postoperatively after emergency shunting. There were two late deaths 11 and 12 months postoperatively, both in primary repair patients. The 16 surviving shunted patients had TOF repair 216 ± 99 days after the

original shunt. The shunted patients had shorter intensive care unit and hospital stays for the first operation, which became equivalent when the second hospitalization (repair) values were added. The primary repair patients more frequently had a transannular patch and a tendency to more frequent delayed sternal closure. Four primary repair (20%) and two shunted (12.5%) patients required subsequent cardiac operations after complete repair ($p =$ not significant).

Conclusions. Shunting or primary repair of neonates with symptomatic TOF provides equivalent mortality and results. Shunted patients had fewer transannular patch repairs despite having more emergent initial operations. Compared with the primary repair group, shunted patients had decreased intensive care unit and hospital stays for the first hospitalization, which were neutralized when the second operation (repair) values were added.

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Neonates born with tetralogy of Fallot (TOF) and its variants (excluding pulmonary atresia with ventricular septal defect) uncommonly develop symptoms necessitating early surgical intervention within 30 days of birth. Although some centers have demonstrated good results with elective early primary repair of TOF in asymptomatic infants, the management of the symptomatic neonate is more controversial. Surgical options for these children include palliation with a systemic-to-pulmonary artery shunt or a complete primary repair. To evaluate the outcome of these strategies, we reviewed our single institutional experience from 2002 to 2008 with 37 consecutive nonrandomized symptomatic neonates with TOF.

Patients and Methods

Approval for this retrospective study was obtained from the Emory University School of Medicine Human Invest-

igation Committee. The need for patient consent was waived.

Patient Population

From 2002 to 2008, 37 consecutive nonrandomized symptomatic neonates less than 30 days of age with a diagnosis of TOF had either a modified Blalock-Taussig shunt ($n = 17$) or primary repair ($n = 20$). Variants of TOF, including associated complete atrioventricular septal defect and absent pulmonary valve syndrome, were included but neonates with pulmonary atresia were excluded. The choice of operation was based on the individual patient and the preference of the attending surgeon. In general, neonates who were smaller and required emergency operation were shunted; those with favorable anatomy and good-sized branch pulmonary arteries had primary repair. Table 1 depicts the patient characteristics. All patients were symptomatic defined as prostaglandin dependent or having unacceptable systemic arterial saturations or hypercyanotic spells. The shunted patients were of similar age compared with the primary repair patients but tended to be smaller by weight (2.8 ± 0.7 kg vs 3.1 ± 0.5 kg; $p = 0.09$). Six of the eight patients less than 2.5 kg were shunted, including both patients less than 2.0 kg (1.5 and 1.6 kg). All four emergency operations were in the shunted group. Six patients had DiGeorge syndrome

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Table 1. Patient Characteristics by Group

Variable	Shunted (n = 17)	Primary Repair (n = 20)	p Value
Age (days, mean ± SD)	10.9 ± 7.5	9.7 ± 7.9	0.64
Weight (kg, mean ± SD)	2.8 ± 0.7	3.1 ± 0.5	0.09
Emergency operation (n, %)	4 (24%)	0 (0%)	0.036
Prostaglandin dependent (n, %)	10 (59%)	16 (80%)	0.28
Syndrome (eg, Down, DiGeorge) (n, %)	6 (35%)	7 (35%)	>0.99

(four in the shunted group, two in the primary repair group), two in each group had Down syndrome, and, in the primary repair group, one patient each had Turner syndrome, Alagille syndrome, and a complex chromosomal translocation. Three patients in the primary repair group had absent pulmonary valve syndrome and two patients in the shunted group had an associated complete atrioventricular septal defect. During the same seven-year period at our institution, 17 additional patients with TOF older than 30 days (age range, 32 to 171 days) underwent a modified Blalock-Taussig shunt and 269 children older than 30 days (mean age 264 days, median age 161 days) had complete repair of TOF or its variants excluding pulmonary atresia.

Operative Technique

All shunted patients had creation of a modified Blalock-Taussig shunt with a 3.0 mm or 3.5 mm shunt from the innominate artery or the right subclavian artery to the right pulmonary artery through a sternotomy approach without cardiopulmonary bypass. The ductus arteriosus was ligated. At the shunt operation, 6 of the 17 shunted patients (35%) had a pulmonary arterioplasty with autologous pericardium, typically to the proximal left pulmonary artery at the ductal insertion site.

Techniques for complete repair in both the shunted and in the primary repair groups were similar. Cardiopulmonary bypass was established with bicaval cannulation using moderate hypothermia and cold cardioplegic arrest. The ventricular septal defect typically was closed through the right atrium and a small atrial communication was left open. If the pulmonary annulus had a z score greater than -2, a nontransannular right ventricular outflow patch was fashioned. Otherwise, a transannular right ventricular outflow tract patch was employed or if the postrepair right ventricular to left ventricular systolic pressure ratio was greater than 0.80. Only one patient (in the primary repair group) had the use of a monocusp patch. Two patients in the shunted group had a right ventricular to pulmonary artery conduit at the time of complete repair due to a small pulmonary annulus and anomalous origin of the left anterior descending coronary artery from the right coronary artery crossing the right ventricular outflow tract. All patients in the shunted group had division of the shunt at the time of complete repair and correction of any shunt-related pulmonary artery distortion or stenosis.

Statistics

Continuous variables were compared by analysis of variance and are presented as mean ± standard deviation. Nominal variables were compared by χ^2 analysis with the Fisher exact test. Life-table analysis was done by the Kaplan-Meier survival method with significance determined by log-rank analysis. All statistical tests were considered significant if the p value was less than 0.05.

Results

There was one early death in the shunted group in a 23-day, 2.4 kg infant with preoperative necrotizing enterocolitis who was emergently taken to the operating room with unacceptably low arterial saturations. Despite an adequate shunt, he died one day postoperatively of relentless bowel ischemia and ongoing acidosis. There were no other operative or hospital deaths in either group. All 16 surviving shunt patients had complete repair of TOF 216 ± 99 days after the shunt operation (median 179 days; range, 95 to 447 days). Only one shunted patient was more than one year old at the time of complete repair (15 months).

The shunted patients had shorter intensive care unit (ICU) and hospital stays for the first operation compared with the neonates undergoing primary repair (Table 2). Combining the values for the two admissions for the shunted group (shunt admission and subsequent complete repair admission) these values approach those of the primary repair group (Table 2). Even though all of the shunted patients required repeat sternotomy at the time of complete repair, the times for aortic cross-clamping, cardiopulmonary bypass, and operating room duration

Table 2. Postoperative Results by Group

Variable	Shunted (n = 17) ^a	Primary Repair (n = 20)	p Value
Postoperative ventilation, 1st op (days)	2.3 ± 1.4	9.3 ± 16.2	0.0882
Postoperative ICU stay, 1st op (days)	4.1 ± 2.7	11.8 ± 12.1	0.0173
Postoperative hospital stay, 1st op (days)	11.1 ± 11.2	21.1 ± 18.0	0.055
Total postoperative ventilation (days) ^b	5.7 ± 2.8	9.3 ± 16.2	0.3932
Total postoperative ICU time (days) ^b	10.5 ± 5.3	11.8 ± 12.1	0.67
Total postoperative hospital stay (days) ^b	22.0 ± 14.2	21.1 ± 18.0	0.88
Nontransannular patch (n, %) ^a	4 (25%)	0 (0%)	0.0309
Delayed sternal closure at repair (n, %) ^a	2 (12%)	8 (40%)	0.13

^a n = 16 when analyzing values for the repair operation in the shunted group due to one early shunt death; ^b Includes combined values for shunt and repair hospitalizations in shunted group.

ICU = intensive care unit; op = operation.

Table 3. Operating Room Results by Group

Variable	Shunted (n = 17) ^a	Primary Repair (n = 20)	p Value
Operating room time, 1st op (minutes)	196.4 ± 49.7	346.6 ± 75.1	<0.0001
Operating room time for repair (minutes) ^a	338.2 ± 37.6	346.6 ± 75.1	0.69
Total operating room time (minutes) ^b	539.6 ± 66.5	346.6 ± 75.1	<0.0001
Aortic cross-clamp time for repair (minutes) ^a	52.8 ± 25.5	55.5 ± 21.5	0.73
Perfusion time for repair (minutes) ^a	119.2 ± 23.6	120.9 ± 37.7	0.87

^a n = 16 when analyzing values for the repair operation in the shunted group due to one early shunt death; ^b Includes combined values for shunt and repair hospitalizations in shunted group.

op = operation.

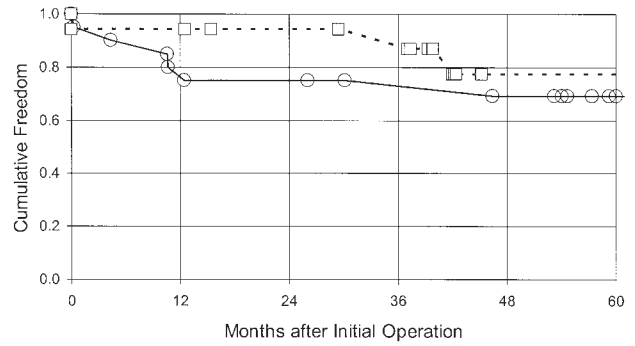
for the two groups were quite similar (Table 3). The combined operating room time for the shunt operation and eventual complete repair for the shunted group was compared with the primary repair group. The shunted group had significantly longer combined operating room times than the primary repair group (539.6 ± 66.5 vs 346.6 ± 75.1 minutes; *p* < 0.0001).

At the time of complete repair, 2 of the 16 surviving shunted patients (12%) required delayed sternal closure compared with 8 of the 20 (40%) primary repair patients (*p* = 0.13; Table 2). At complete repair, 3 of the 16 shunted patients (19%) required patch augmentation of the right pulmonary artery at the shunt site. Nineteen of the 20 primary repair patients had a transannular patch; the twentieth patient had placement of a monocusp valve. Ten of the shunted patients had a transannular patch at the time of complete repair; four had a nontransannular patch and two had a right ventricular-to-pulmonary artery conduit due to anomalous origin of the left anterior descending coronary artery. The use of a non-transannular patch was significantly higher in the

Table 4. Postoperative Mortality and Cardiac Reoperations

Patient Group	Complication	Mortality or Reoperation	Days After Initial Operation	Days After Complete Repair
Primary	Heart failure	Mortality	323	323
Primary	Respiratory failure	Mortality	377	377
Shunted	Necrotizing enterocolitis	Mortality	1	—
Primary	Complete heart block	Permanent epicardial pacemaker	9	9
Primary	Recurrent LPA atresia	Branch pulmonary arterioplasty	133	133
Primary	Recurrent RVOT obstruction	Revise transannular RVOT patch	321	321
Primary	Right ventricular enlargement/failure	Pulmonary valve replacement	1,411	1,411
Shunted	Right ventricular enlargement/failure	Pulmonary valve replacement	1,127	988
Shunted	Conduit stenosis	Conduit replacement	1,278	1,000

LPA = left pulmonary artery; RVOT = right ventricular outflow tract.



Month	Patients at Risk					
	0	12	24	36	48	60
Primary Repair	20	17	16	14	13	7
Shunted	17	16	14	13	5	5

Fig 1. Kaplan-Meier actuarial freedom from death or cardiac reoperation by group. Shunted patients (n = 17) are shown as shaded boxes; patients with primary repair (n = 20) are shown as open circles (*p* = 0.50).

shunted patients (4 of 16; 25%) compared with the primary repair group (0 of 20, 0%) (*p* = 0.0309; Table 2).

On mean follow-up of 47.0 ± 24.5 months from the original operation, there have been two late deaths at 11 and 12 months, both in the early complete repair group. The cause of death was relentless heart failure in one patient and respiratory failure in the other (a patient with absent pulmonary valve syndrome). Six patients had cardiac reoperations ranging from 9 days to 3.5 years after the complete repair, four in the primary repair group and two in the shunted group. Other than one early reoperation for pacemaker implantation for surgical heart block, all reoperations dealt with the right ventricular outflow tract. The details are shown in Table 4. Figure 1 shows freedom from death or cardiac reoperation by Kaplan-Meier analysis.

Comment

Early Outcomes

It is uncommon for neonates age 30 days or less with TOF (excluding pulmonary atresia) to develop symptoms ne-

cessitating early surgical intervention. These infrequent patients present with unacceptable hypoxemia or ductal-dependent circulation. Although initial reports suggested that primary repair of TOF at less than three months of age was associated with a high mortality [1], over the past several years multiple reports have demonstrated increasing success with primary repair of TOF in younger infants [2–6]. Despite these promising papers, there is little information about symptomatic neonates with TOF. An early report from Children's Hospital in Boston [7] reviewed 14 symptomatic infants less than 30 days of age with TOF and pulmonary stenosis. Four of these 14 patients died in the hospital, resulting in a 28.6% mortality.

A more favorable report from the University of Michigan [8] reported 30 neonates 28 days or less of age with tetralogy or pulmonary atresia in whom 16 had TOF with pulmonary stenosis. There were no hospital deaths in this series, but 25% of the 16 children with TOF and pulmonary stenosis required reoperation within a mean of 15 months after the initial operation. During the same period, the authors note that seven patients had palliation with a shunt rather than a complete repair with no early or late deaths. An update of that Michigan series published in 2000 [9] showed ongoing superb surgical results in 31 children with TOF without pulmonary atresia, but there persisted to be an only 61% freedom from reoperation at five years in this group.

More recently, Tamesberger and colleagues [10] reported no mortality in 25 consecutive symptomatic neonates 28 or less days undergoing complete primary repair of TOF. On median follow-up of 56 months, there were three repeat operations (12%) and seven catheter-based reinterventions (28%).

In our series with 37 consecutive nonrandomized neonates, 20 underwent a complete primary repair whereas 17 had a systemic-to-pulmonary artery shunt. The mortality in both groups was equivalent with only one death in a shunted patient who was moribund due to necrotizing enterocolitis. Our results with primary repair are consistent with other reports showing low mortality rates with primary repair of TOF in children under the age of one [2–6, 11, 12].

Transannular Patch Use

Although there are some long-term follow-up studies that suggest that the use of a transannular patch for repair of the right ventricular outflow tract in TOF does not adversely affect long-term outcomes with regard to further reintervention or mortality [13, 14], it is commonly accepted that the avoidance of a transannular patch is desirable [11, 15]. In this study, none of the 20 primary repair patients had a nontransannular right ventricular outflow tract patch, whereas 25% of the initially shunted patients were repaired with a nontransannular patch ($p = 0.0309$). The incidence of transannular patch use at the time of complete repair in younger patients ranges from 90 to 100% [2–4, 7, 16]. A report from Paris [17] reviewing 56 patients with TOF less than six

months of age showed a significantly lower incidence of transannular patching in the patients who were initially palliated with a shunt (9% transannular patches) compared with 41 patients who underwent initial complete repair (56% transannular patches).

It is likely that, in the symptomatic neonate with unacceptable hypoxemia or ductal dependence, the anatomic substrate would trend toward a small right ventricular outflow tract; thus, it seems logical that there would be an increased need for the use of a transannular patch with primary complete repair. In our series, a quarter of the patients who had an initial shunt exhibited enough outflow tract growth so that a transannular patch was avoided at the time of eventual repair. The mechanism for this growth is unclear. Perhaps the early increase in pulmonary blood flow in symptomatic neonates allows for outflow tract growth. A report from Belgium [18] described 19 infants with TOF who were palliated with initial balloon dilatation of the pulmonary valve. Eleven of these infants avoided the use of a transannular patch at the time of complete repair. Others have corroborated a decreased incidence of transannular patching in patients who have staged repairs or who undergo repair at a later age [10, 11, 16, 17].

Hospital Resource Utilization

In the current economic climate of cost containment and efficient care, it is important to look at resource utilization in these sick neonates. A previous report from Duke [19] suggested that hospital costs were higher for infants undergoing shunting followed by eventual repair than for infants undergoing primary repair. However, there were only four patients in their initially shunted group. The length of stay for the initial hospitalization was similar between their two groups, which contrasts with our experience (Table 2). In the Duke paper, the average hospital stay for complete repair for the initially shunted patients was 28.8 days, whereas in our series this value was only 11.1 days. Initial resource utilization in our series as measured by operating room time, ICU stay, and hospital stay was shorter in the shunted patients compared with the primary repair patients (Tables 2; 3). Combining the values for both the shunt operation and the eventual complete repair, the total ICU and hospital stay were quite similar (Table 2) although the combined operating room times were longer for the patients in the shunted group (Table 3).

Others have demonstrated increased utilization of hospital resources in infants undergoing primary repair of tetralogy. Van Arsdell and colleagues [20] showed that primary repair of TOF at less than three months of age was associated with a statistically prolonged time of ventilation and hospital stay compared with older children undergoing repair. Ooi and colleagues [21] from Southampton also showed significantly increased ICU stays and time on the ventilator for infants younger than three months of age undergoing tetralogy repair compared with older patients.

Late Outcomes and Reinterventions

With a mean follow-up of almost four years, late mortality in this series was zero in the shunted group and 10% in the primary repair group ($p =$ not significant), although one of the two deaths was noncardiac related (respiratory failure). Long-term survival after tetralogy repair in infancy in published series varies from 86 to 97% at 20 years [6, 12, 14]. Freedom from reintervention in the catheterization laboratory or the operating room in these patients ranges from 81% at 5 years [4] to 79 to 96% at 20 years [6, 12, 14].

Focusing on patients with TOF who had operation as a neonate (age \leq 30 days) as was done in this study, an early series from Boston [7] reported a 5-year actuarial survival of 74% and a freedom from reoperation at 5 years of 76%. Kolcz and Pizarro [22] reported 46 neonates in which 8 of the 44 hospital survivors (18.2%) required surgical or catheter-based reintervention a median of 9.8 months postoperatively. The Michigan group also reported a significant need for reoperation of 25 to 32% with an actuarial freedom from reoperation of 61% at five years for primarily repaired neonates with tetralogy and pulmonary stenosis [8, 9]. This compares with the actuarial freedom from death or reoperation at five years in the current series of 69% for the primary repair group and 77% for the shunted group ($p = 0.4972$; Fig 1). Clearly, neonates with symptomatic TOF requiring early operation have a finite incidence of the need for later intervention.

Staged Versus Primary Repair

Some argue that the use of a Blalock-Taussig shunt in these symptomatic neonates can be riskier than a primary repair. A review of neonates from Southampton, England [23] showed a 6% early mortality and a 33% late mortality with modified Blalock-Taussig shunts; however, there were only eight children in this series of 51 neonates who carried a diagnosis of TOF with no early deaths. A report from Melbourne, Australia [11] indicated that mortality with shunting for TOF in over 100 patients approached zero with only one death in ten years. This compares with a paper from Toronto [24] reporting 65 children with TOF who received a modified Blalock-Taussig shunt. There was one early mortality from shunt thrombosis and four noncardiac-related deaths.

In the current report, the shunted patients tended to be smaller than the primarily repaired patients and had a significantly higher incidence of emergency operation (Table 1). Despite this, excluding the one preoperatively moribund patient, the early survival rates were the same (no mortality). The shunted patients had no interstage mortality. Complete repair was performed with no mortality and a 25% use of nontransannular patches (all of the primarily repaired patients had a transannular patch). Only three of the shunted patients required reconstruction of the pulmonary artery at the shunt insertion site at the time of complete repair.

Despite the trend toward complete repair of TOF at younger ages, some centers advocate an individualized approach to the management of TOF in infants and neonates rather than complete primary repair in all [16, 25, 26]. A multiinstitutional report from the Pediatric Cardiac Care Consortium [27] showed that for patients three months or less of age, the mortality for a shunt versus a repair was similar (6.2% vs 8.0%). Even strong proponents for early complete repair regardless of age or size [28] have reported a mortality rate of 14.3% in symptomatic neonates undergoing complete primary tetralogy repair [22].

Comment

Our series was limited to symptomatic neonates with tetralogy. We found no statistically significant differences in early mortality comparing shunted patients with primarily repaired patients. On follow-up out to seven years, the freedom from death or reoperation was not different between the two groups although it is important to realize that the only patients whose repair incorporated a nontransannular patch were in the shunted group. Because the choice of operation was at the discretion of the surgeon, there exists the possibility that there was some inherent selection bias between the two groups and we might have seen different results if the patients had been randomized. Nonetheless, our results suggest that the initial surgical approach for the symptomatic neonate with TOF can be equally efficacious with a shunt or a complete repair. Our data dispel the current prevailing thought that palliation with a shunt in TOF, even in neonates, always should be avoided in favor of early complete repair. Shunted patients can do as well as primarily repaired patients and have a greater likelihood of avoiding a transannular patch at the time of repair. Thus, the choice of operation should be individualized according to patient, surgeon, and institutional factors.

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