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Article

Modified Transannular Patching Palliation versus Modified Blalock-Taussig-Thomas Shunt in Infants with Severe Tetralogy of Fallot with Diminutive Pulmonary Arteries

Yuehu Han[1,†], Yanjie Guo[2,†], Le Duan[1,†], Tianjiang Li[1], Hailong Zhu[1], Guocheng Sun[1], Chunhu Gu[1,*]

[1]Department of Cardiovascular Surgery, Xijing Hospital, Fourth Military Medical University, 710032 Xi'an, Shaanxi, China
[2]Department of Cardiology, Xi'an International Medical Center Hospital, 710100 Xi'an, Shaanxi, China
*Correspondence: felix1918@163.com (Chunhu Gu)
[†]These authors contributed equally.

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Abstract

Objective: The purpose of this study was to compare pulmonary arterial (PA) growth and morbidity, mortality, reintervention and complete repair rates after modified transannular patching palliation (mTAP) versus modified Blalock-Taussig-Thomas shunt (mBTS) for palliation in infants with severe tetralogy of Fallot (TOF) with diminutive pulmonary arteries. **Methods**: This was a retrospective case review study of 107 patients (64 males) with severe TOF who underwent staged repair with either mTAP (n = 55) or mBTS (n = 52) over an 8-year period. Procedure-related PA growth and morbidity, mortality, reintervention and complete repair rates were compared. **Results**: Two deaths occurred in the mBTS group due to sudden cardiac arrest, and five patients needed reintervention after the mBTS procedure because of shunt thrombosis or stenosis. Postoperative complications of mBTS included sudden cardiac arrest, shunt thrombosis/stenosis, vocal cord palsy and diaphragmatic palsy. Unlike in the mBTS group, no death, severe complications or reintervention occurred in the mTAP group. Oxygen saturations post mTAP and mBTS were significantly higher, which improved from 67.73 $\pm$ 4.36% to 94.33 $\pm$ 2.19% in the mTAP group and from 68.24 $\pm$ 3.87% to 86.87 $\pm$ 3.38% in the mBTS group. The increase in oxygen saturation and pulmonary artery growth (from pre- to post palliation) was significantly better with mTAP than with mBTS palliation ($p < 0.01$). All 55 patients showed complete repair after mTAP, and the time from palliation to complete repair was significantly shorter in the mTAP group. **Conclusions**: In a severe form of TOF with the hypoplastic PA tree, mTAP seems to be a better strategy that is safe and better facilitates satisfactory pulmonary arterial growth until complete repair than the mBTS procedure.

Keywords

congenital heart disease; tetralogy of Fallot; pulmonary arterial; Blalock-Taussig-Thomas shunt; infant; surgical procedure

Introduction

Primary repair is routinely performed in older children with "stable" tetralogy of Fallot (TOF), while early interventions are required in neonates and young infants with "cyanotic" TOF, especially those with severe hypoplasia of the pulmonary artery tree [1–3]. In most centers, a modified Blalock-Taussig-Thomas shunt (mBTS) procedure continues to be an important option in staged management to augment pulmonary blood flow in infants with diminutive pulmonary arteries. However, the outcome of the shunt procedure is not always satisfactory [4–6]. If the pulmonary artery (PA) tree in patients with TOF is too hypoplastic, a shunt procedure may be difficult and even contraindicate because the shunting, kinking, stenosis or other effects often lead to reinterventions. Moreover, it fails to stimulate growth of the pulmonary artery. There are a few reports about the use of a transannular patch without repair of the ventricular septal defect in small infants with diminutive pulmonary arteries [7], but the safety and efficacy were not clarified. On the basis of previous research and our clinical experiences, modified transannular patching palliation (mTAP) has become an alternative to mBTS for initial palliation in infants suffering from TOF with severe hypoplasia of the pulmonary vessels in our center. Compared with the earlier palliative transannular patching procedure, restricted enlargement of the right ventricular outflow tract (RVOT) plays a key role in mTAP, as this can preserve right ventricle (RV) function to maintain a proper pressure gradient between the RV and PA and effectively stimulate the growth of the pulmonary artery. All of our patients who have undergone the mTAP procedure have showed com-

plete repair, and none have dead. Few studies have evaluated the outcomes of mTAP and mBTS or their ability to augment pulmonary blood flow. Therefore, the purpose of this study was to compare the specific prepalliation characteristics and the morbidity, mortality, reintervention, and complete repair rates of TOF patients with diminutive pulmonary arteries after mTAP versus mBTS.

Material and Methods

Patient Population

This study protocol was performed after being approved by the Air Force Medical University Institutional Review Board. This retrospective cohort study enrolled 107 symptomatic patients (64 males) with TOF who underwent initial palliation (mTAP or mBTS) between January 2012 and December 2019. TOF patients with a McGoon index $<$1.2, a Nakata index $<$120 mm^2/m^2, an O_2 saturation $<$70% and a z score of both pulmonary arteries less than –2.00 were enrolled. We excluded patients who also had atrioventricular septal defects, major aortopulmonary collaterals, total anomalous pulmonary venous return, or another complex cardiac anomaly. Patients' specific prepalliation characteristics (e.g., prematurity, medical management), morbidity, length of pediatric intensive care unit (PICU) stay and related complications (e.g., shunt thrombosis), mortality, length of hospital stay and reintervention rates were compared. Doppler and two-dimensional (2D) echocardiography and clinical evaluation were performed routinely before and after surgery. For patients with diminutive pulmonary arteries, we routinely perform computed tomography (CT) examination because CT more accurately assesses the diameter of the pulmonary artery. The follow-up time was the same in the two groups. The patient underwent cardiac ultrasound 3, 6 and 12 months within the first year after surgery and then every six months thereafter. Once pulmonary artery growth met the criteria for complete repair surgery, complete repair surgery was scheduled. We retrospectively reviewed medical records and echocardiographic and surgical data to compare variables between groups. We measured PA diameter by echocardiographic and CT imaging and calculated the z score from the body surface area (BSA)-adjusted z score.

All cases were discussed before the surgery by the multidisciplinary team. Risk factors affecting the performance of the mBTS (e.g., low weight, small pulmonary arteries and significant complications) influenced our decision making. Initially, the reason to choose the mTAP procedure was severe associated complications, which were thought to be negatively affected by the mBTS procedure (e.g., prepalliative gut and brain pathologies, prematurity). Second, low-weight infants were more likely to undergo mTAP. As our experience grew, patients with more complex anatomy and hypoplastic pulmonary arteries (z score $<$–2.5) were successfully palliated with mTAP.

Surgical Technique

Modified Transannular Patching Palliation

All operations were performed via a median sternotomy with cardiopulmonary bypass. A transatrial approach was employed, and the obstructing hypertrophied infundibular muscle bands were partially dissected. Then, the diameter of the pulmonary valve annulus was assessed by inserting calibrated dilators across the RVOT into the pulmonary artery trunk. A short incision (3–5 mm) was made from the main pulmonary artery across the pulmonary valve annulus via the anterior commissure to preserve valvar function as much as possible and to minimize the severity of pulmonary regurgitation that results from transannular patching. The incision from the main pulmonary artery extended through the orifice of the left pulmonary artery in patients with proximal left pulmonary artery stenosis. A piece of glutaraldehyde-fixed pericardium was used to augment the right ventricular outflow. In our experience, the incision or excision of the parietal and septal bands could not be too thorough and the pressure gradient should be kept between 30 and 40 mmHg. We tried to make the diameter of the enlarged pulmonary annulus and artery approximately 80% of the normal size. This helps preserve right ventricular function and provide sufficient pulmonary artery blood flow. In addition, an appropriate patching size avoids excessive pulmonary blood and increases RV burden. After the palliative procedure, complete repair surgery on most patients is performed to simply close the ventricular septal defect, and a small number of patients require dissection of residual RVOT hypertrophic bundles.

Modified Blalock-Taussig-Thomas Shunt

In the mBTS group, after induction of general anesthesia, expanded polytetrafluoroethylene grafts were placed from the proximal brachial artery to the ipsilateral right or left PA through the standard thoracotomy approach. The diameter of the shunts was determined by the infant's weight and body length. The median shunt diameter in the mBTS group was 3.5 mm (3.5 to 4.0 mm).

Statistical Analysis

All statistical analyses were done with SPSS ver. 22.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean $\pm$ standard deviation (SD). Comparisons between the patient groups were made with Student's t test or Fisher's exact test. $p < 0.05$ was statistically significant.

Table 1. Patient characteristics of the palliation procedure (mean ± SD).

Variable	Fallot + mTAP	Fallot + mBTS	*p* value
	N = 55	N = 52	
Male, n	36	28	0.221
Prematurity, n	13	9	0.418
Weight at palliation, kg	6.93 ± 1.59	7.73 ± 1.50	0.009
Weight at palliation <2.5 kg, n	13	9	0.418
Age at palliation, days	104.42 ± 50.31	121.33 ± 50.08	0.085
Prostaglandin infusion prepalliation, n	12	11	0.993
Spelling prepalliation, n	23	17	0.329
Beta blocker prepalliation, n	31	28	0.794
Before complete repair			
Tract/shunt diameter, mm	7.42 ± 1.17	3.70 ± 0.25	<0.01
O_2 saturation postoperative, %	94.33 ± 2.19	86.87 ± 3.38	<0.01
McGoon ratio	1.74 ± 0.21	1.48 ± 0.18	<0.01

mTAP, modified transannular patch; mBTS, modified Blalock-Taussig-Thomas shunt.

Results

Over the study period, 55 infants underwent the mTAP procedure (age, 104.42 ± 50.31 days; weight, 6.93 ± 1.59 kg), and 52 infants underwent mBTS placement (age, 7.73 ± 1.50 days; weight, 7.73 ± 1.50 kg). All baseline characteristics were similar between the 2 groups (Table 1). The 2 groups did not differ significantly in terms of underlying anatomy or other important patient characteristics. Prepalliative management was comparable for the patients in both groups.

Medical Data of the Palliation Procedure

Two deaths occurred in the mBTS group due to sudden cardiac arrest, and five patients needed reintervention after the mBTS procedure because of shunt thrombosis or stenosis. Postoperative complications of mBTS placement included sudden cardiac arrest, shunt thrombosis/stenosis, vocal cord palsy and diaphragmatic palsy (Table 2). Unlike in the mBTS group, no death, severe complications or reintervention occurred in the mTAP group. Oxygen saturations after mTAP and mBTS were significantly higher, which improved from 67.73 ± 4.36% to 94.33 ± 2.19% in the mTAP group and from 68.24 ± 3.87% to 86.87 ± 3.38% in the mBTS group (Table 3). The increase in oxygen saturation (pre-post palliation) was significantly better with mTAP than with mBTS (Table 1).

Medical Data of Complete Repair

Within the study period, all 55 patients showed complete repair after mTAP. In the mBTS group, 49 of 52 patients showed complete repair (Table 4). The time from palliation to complete repair and the aortic cross-clamp times were significantly shorter in the mTAP group (Table 4). The median weight and age at the time of surgical repair, cardiopulmonary bypass time, and length of intensive care unit (ICU) and hospital stay are listed in Table 4.

Pulmonary Artery Growth

Before complete surgical repair, the z score, McGoon ratio and Nakata index of the pulmonary artery were significantly higher after both the mTAP and mBTS procedures (Table 3). The McGoon ratio and the tract/shunt diameter were significantly better in the mTAP group (Table 1). The average time from palliation to complete repair was shorter in the mTAP group than in the mBTS group. All of the above results indicated better pulmonary artery growth capacity following the mTAP procedure (Fig. 1).

Discussion

Most asymptomatic patients with TOF undergo primary surgical repair at age 4–9 months or at a body weight of approximately 5–9 kg [8]. Various types of anatomical features are associated with TOF, which lead to different clinical and hemodynamic outcomes. Children presenting small pulmonary arteries and/or a hypoplastic pulmonary anatomy can be treated with staged correction [9]. An ideal palliation procedure should not only increase O_2 saturation and resolve hypoxic spells but also prepare patients for subsequent complete physiological and anatomical correction. The traditional palliative procedure used in patients with TOF and severe pulmonary stenosis is the mBTS procedure or central shunt placement [10]. However, mBTS for palliation is associated with certain problems, particularly shunt thrombosis or stenosis, that decrease pulmonary blood flow, limit PA growth and increase the chances of sudden death and morbidity [11–13]. The young age, low weight, small PA diameter and complex cardiac anatomy

Table 2. Relevant complications post palliative procedure and reinterventions.

Variable	Fallot + mTAP	Fallot + mBTS	*p* value
	N = 55	N = 52	
Sudden cardiac arrest, n	0	2	0.234
Death, n	0	2	0.234
Shunt/stent thrombosis, n	0	5	0.058
Vocal cord palsy, n	0	2	0.234
Diaphragmatic palsy, n	0	1	0.486
Patients needing reintervention, n	0	5	0.058
Redo BT-shunt/additional shunt, n	0	5	0.058

BT-shunt, Blalock-Taussig-Thomas shunt.

Table 3. Comparison of pulmonary artery variables before palliation and before complete repair (mean ± SD).

Variable	Before Palliation	Before complete repair	*p* value
Fallot + mTAP			
RPA z score	–3.12 ± 0.31	1.26 ± 0.24	<0.01
LPA z score	–3.04 ± 0.41	1.14 ± 0.27	<0.01
McGoon ratio	0.89 ± 0.13	1.74 ± 0.21	<0.01
Nakata index	115.36 ± 2.78	192.89 ± 23.92	<0.01
O_2 saturation, %	67.73 ± 4.36	94.33 ± 2.19	<0.01
Fallot + mBTS			
RPA z score	–3.01 ± 0.27	1.12 ± 0.27	<0.01
LPA z score	–2.97 ± 0.41	1.07 ± 0.28	<0.01
McGoon ratio	0.96 ± 0.15	1.48 ± 0.18	<0.01
Nakata index	114.23 ± 2.72	184.33 ± 20.72	<0.01
O_2 saturation, %	68.24 ± 3.87	86.87 ± 3.38	<0.01

RPA, right pulmonary artery; LPA, left pulmonary artery.

of infants are major risk factors for shunt failure [14–16]. Thus, mBTS seems to be not the best therapeutic strategy for all patients with TOF with diminutive pulmonary arteries.

Initial palliation has been reported to include enlargement of the right ventricular outflow tract without ventricular septal defect closure. Early attempts often resulted in congestive heart failure requiring prolonged treatment in the ICU and a high hospital mortality rate, which may have been the result of inappropriate excision of RV muscle bands, the size of the enlarged RVOT and the outcome of postoperative excessive or insufficient pulmonary blood flow. Hence, in the process of our clinical practice, we have developed a novel initial palliation management procedure, mTAP. We have grown experienced with and set standards for this procedure, and it has proven to be an effective and safe technique for infants with severe TOF and diminutive pulmonary arteries.

We compared the results of two different palliation techniques (mTAP *vs.* mBTS) for the initial management of severe TOF with diminutive pulmonary arteries. Unlike the mBTS group, the mTAP group had no deaths, severe complications or reinterventions. Our study demonstrated that oxygen saturation was more greatly increased and that pulmonary arterial growth was better after mTAP than after mBTS placement. The patients who underwent initial mTAP had better and more uniform growth of the branch PAs than the patients who received mBTS, and the time from palliation to complete repair was markedly shorter in the mTAP group.

We believe that it is key for TOF patients to resume antegrade blood flow as soon as possible. In the mTAP group, we relieved RV myogenic obstruction and broadened the size of the RVOT, and systemic venous blood was redirected to the pulmonary circulation via the physiological pathway of normal pulmonary blood flow, resulting in more effective oxygen uptake and pulmonary artery growth. Compared with the mBTS procedure, mTAP achieves this without decreasing diastolic aortic perfusion pressure and without the resultant coronary perfusion, which leads to more stable hemodynamics. Although the mBTS improves oxygen saturation and resolves hypoxia, it has no effect on the obstruction of the RVOT, and the obstruction will worsen with time. This leads to greater excision of the hypertrophic muscle band and a longer RV incision during complete surgical repair, thereby seriously hindering the postoperative recovery of RV function. In addition, the number and diameter of collateral branches may continue to increase after the mBTS procedure. The above problems do not exist after the mTAP procedure.

Table 4. Characteristics of patients who showed complete repair (mean ± SD).

Variable	Fallot + mTAP	Fallot + mBTS	*p* value
	N = 55	N = 52	
Time from palliation to complete repair, days	166.36 ± 47.80	241.83 ± 85.89	<0.01
Patients who underwent surgical repair, n	55	49	0.222
Weight at the time of repair, kg	10.42 ± 1.67	12.19 ± 2.30	<0.01
Age at repair, days	287.69 ± 80.84	346.25 ± 86.46	<0.01
CPB time at repair, min	95.95 ± 13.33	111.1 ± 11.08	<0.01
X-clamp time at repair, min	45.89 ± 10.51	64.27 ± 6.07	<0.01
Length of ICU stay post repair, days	1.87 ± 0.54	1.92 ± 0.67	0.671
Length of hospital stay post repair, days	7.23 ± 1.35	11.35 ± 2.36	<0.01

CPB, cardiopulmonary bypass; ICU, intensive care unit; X-clamp-time, aortic cross-clamp time.

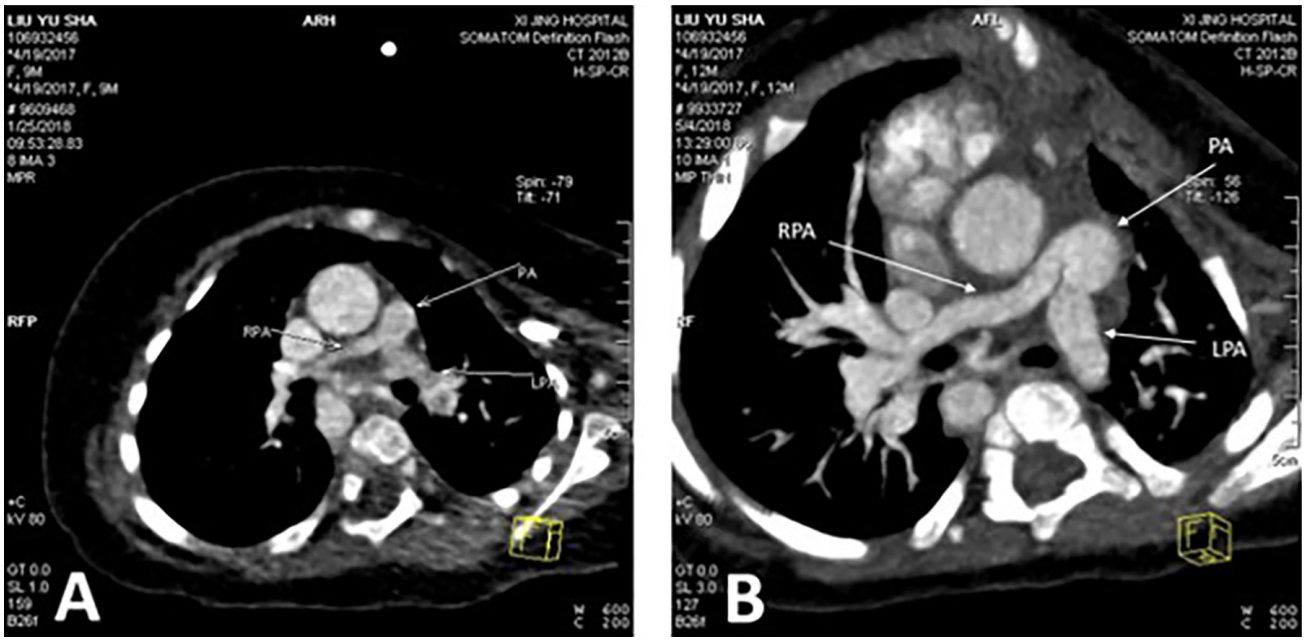

Fig. 1. CT image of a 9-month-old female TOF patient. (A) CT image before the mTAP procedure (McGoon ratio: 1.08). (B) CT image before complete surgical repair (3 months after the mTAP procedure, McGoon ratio: 1.87). CT, computed tomography; TOF, tetralogy of Fallot.

The key point and difficulty of the mTAP procedure is the extent of RV hypertrophy muscle band relief and RVOT widening. Insufficient widening of the RVOT makes it difficult to stimulate the development of the pulmonary artery effectively, and overwidening can cause more fatal results, which leads to overburdening of both the right and left ventricles and excessive pulmonary blood flow and further causes extensive postoperative pulmonary mucosal edema, tracheal extubation difficulty and even heart failure. To limit early pulmonary overcirculation, we restricted the enlargement of the right ventricular outflow tract and maintained a proper pressure gradient between the RV and PA. In the past, it was widely believed that the treatment of tetralogy of Fallot required the complete relief of obstruction in the right ventricular outflow tract. However, with long-term follow-up, pulmonary valve regurgitation and right ventricle dysfunction have become well recognized. Lately, there has been a push to preserve the pulmonary valve and annulus, and a higher residual RVOT gradient after surgery can be accepted. One report showed that a higher postoperative RVOT pressure gradient was associated with less pulmonary regurgitation and smaller right ventricular dimensions [17]. In our experience, we must ensure that the incision or excision of the parietal and septal bands is not too thorough, and the pressure gradient should stay at 30–40 mmHg, and we believe that the diameter of the enlarged pulmonary annulus and artery should be approximately 80% of the normal size. The average RVOT gradient 3 months after mTAP was 31.8 ± 15.2 mmHg. By about one year after complete repair, the gradient began to fall and stabilized over time. Thinking of the right ventricle as an inflated balloon, we cannot loosen the tie fully because the balloon will deflate. Residual RV gradients are supposed to have beneficial effects on postopera-

tive RV function, avoid RV dilation, and provide sufficient pulmonary artery blood flow [18,19]. In addition, an appropriate patching size avoids excessive pulmonary blood and increases the RV burden.

mTAP allows for better postoperative PA growth than other methods because balanced distribution of pulsatile blood flow from the RV to the PA has a more positive effect on PA growth. We speculated that it was also related to the unique pressure waveform and appropriate oxygen saturation of the right ventricle blood. Some cohort studies reported that RVOT patching showed a considerably higher complete repair rate than systemic-pulmonary shunt placement, including BT shunt placement. We think that the increased flow through the natural channel should encourage significant growth of the pulmonary artery and root, which promote the development of the left and right ventricles. This would mean that fewer patients would achieve complete correction with serious outflow obstruction, which increases the likelihood of right ventricular failure when the septal defect is closed or necessitates division of the pulmonary annulus, with consequent severe pulmonary regurgitation. The evidence from this series indicates that the pulmonary artery indeed grows enough after this procedure. Additional advantages of the RVOT patch procedure are that it permits direct visual assessment of the anatomy of the heart and that it can easily be chosen as an alternative if there are features that might prejudice total correction and there is no shunt to be closed at the time of total correction.

Conclusions

In conclusion, we have demonstrated the versatility of mTAP in staged treatment of TOF. In a severe form of TOF with a hypoplastic PA tree, compared to the mBTS procedure, mTAP seems to be a better and safer strategy that can facilitate satisfactory pulmonary arterial growth until complete repair is achieved.

Availability of Data and Materials

The authors confirm that the data supporting the findings of this study are available within the article.

Author Contributions

CG contributed to the conception of the study. YH contributed significantly to the study design and manuscript preparation. YG, LD and TL contributed data collection and analyses. HZ and GS contributed to the conception and clinical treatment of the work. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript. All authors have participated sufficiently in the work to take public responsibility for appropriate portions of the content and agreed to be accountable for all aspects of the work in ensuring that questions related to its accuracy or integrity.

Ethics Approval and Consent to Participate

This study was approved by the Medical Ethics Committee of the First Affiliated Hospital of the Fourth Military Medical University (KY20212037-F-2), and the need for informed consent was waived.

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Conflict of Interest

The authors declare no conflict of interest.

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