

Right Ventricular Outflow Tract Reconstruction in Infant Truncus Arteriosus:**A 37-Year Experience**

Running Head: Reconstruction in truncus arteriosus

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ABSTRACT

Background. Multiple conduits for right ventricular outflow tract reconstruction exist, though the ideal conduit that maximizes outcomes remains controversial. We evaluated long-term outcomes and compared conduits for right ventricular outflow tract reconstruction in children with truncus arteriosus.

Methods. Records of patients who underwent truncus arteriosus repair at our institution between 1981 and 2018 were retrospectively reviewed. Primary outcomes included survival and freedom from catheter reintervention or reoperation. Secondary analyses evaluated the effect of comorbidity, operation era, conduit type, and conduit size.

Results. One-hundred patients met inclusion criteria. Median follow-up time was 15.6 years (interquartile range, 5.3-22.2 years) Actuarial survival at 30 days, 5 years, 10 years, and 15 years was 85%, 72%, 72%, and 68%, respectively. Early mortality was associated with concomitant interrupted aortic arch (HR 5.4; 95% CI, 1.7-17.4; $p=0.005$).

Median time to surgical reoperation was 4.6 years ($n=58$; interquartile range, 2.9-6.8 years). Right ventricle to pulmonary artery continuity was established with an aortic homograft ($n=14$), pulmonary homograft ($n=41$), or bovine jugular vein conduit ($n=36$) in most cases. Multivariate analysis revealed longer freedom from reoperation with the bovine jugular vein conduit compared to the aortic homograft (HR 3.1; 95% CI, 1.3-7.7; $p=0.02$) with no difference compared to the pulmonary homograft. Larger conduit size was associated with longer freedom from reoperation (HR 0.7; 95% CI, 0.6-0.9; $p<0.001$).

Conclusions. The bovine jugular vein conduit is a favorable conduit for right ventricular outflow tract reconstruction in patients with truncus arteriosus. Concomitant interrupted aortic arch is a risk factor for early mortality.

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Glossary of Abbreviations

BJVC	Bovine jugular vein conduit
ECMO	Extracorporeal membrane oxygenation
IAA	Interrupted aortic arch
IQR	Interquartile range
RV-PA	Right ventricle - pulmonary artery
RVOT	Right ventricular outflow tract
TA	Truncus arteriosus
TA-IAA	Truncus arteriosus with interrupted aortic arch

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Truncus arteriosus (TA) is a rare congenital cardiac malformation characterized by a single arterial trunk that arises from the base of the heart, overrides the interventricular septum, and supplies the systemic, pulmonary, and coronary circulations. TA comprises an estimated 0.21-0.34% of all cases of congenital heart disease and presents with a right-sided aortic arch or an interrupted aortic arch (IAA) in 18-36% and 11-14% of cases, respectively.¹ Other associated conditions include DiGeorge syndrome, atrioventricular septal defect (ASD), aortic coarctation, and coronary artery anomalies.

The ideal conduit for right ventricular outflow tract (RVOT) reconstruction during TA repair remains controversial. The aortic homograft was used in the first successful repair of TA and is still utilized in some institutions, though use of the aortic homograft has largely fallen out of favor due to a propensity for obstruction, early stenosis, and adherence to surrounding structures which increases difficulty of reoperation.²⁻⁴ Improved outcomes with longer freedom from conduit dysfunction and decreased graft calcification are reported with the pulmonary homograft.^{5,6} However, significant regurgitation and stenosis leading to early reoperation have been documented.^{7,8}

Due to concerns of limited durability, availability, and cost of homografts, attention has turned to alternative approaches. Some studies report beneficial outcomes using direct right ventricle to pulmonary artery (RV-PA) anastomosis for TA repair.⁹ RVOT reconstruction using porcine xenografts has been accomplished, though successful operations are often documented in older patients with recommended use beyond the neonatal period.¹⁰ The valved bovine jugular vein conduit (BJVC; Contegra, Medtronic, Minneapolis, MN) demonstrates hemodynamic and tissue handling properties similar to homografts, with additional benefits of natural continuity between the valve and conduit, less obstruction and regurgitation, and favorable long-term results when compared to other conduit types.^{8,11-19} However, concerns of stenosis, thrombus formation, and endocarditis have been reported.¹⁹⁻²³

Given the controversy regarding the optimal conduit for TA repair, we aimed to compare survival and reintervention outcomes by conduit type for RVOT reconstruction in children undergoing TA repair at our institution.

PATIENTS AND METHODS

Patients

All patients who underwent TA repair between November 1981 and April 2018 at Riley Hospital for Children at Indiana University Health in Indianapolis, Indiana were included. Electronic medical records were retrospectively reviewed. This study was approved by the local institutional review board and due to the retrospective nature of this study, the need for informed consent was waived.

Patients were grouped according to TA anatomy as defined by Collett and Edwards classification.²⁴ Conduit function was assessed using transthoracic echocardiography with color and spectral Doppler patterns per the American Society of Echocardiography. Conduit failure was defined by moderate or greater valve incompetence and/or peak RV-PA gradient greater than or equal to 40 mmHg. In agreement with the Society of Thoracic Surgeons (STS) definition, early mortality was defined as death within the first 30 postoperative days or during the same hospitalization in which initial repair was performed. Primary outcomes included overall survival, freedom from catheter reintervention, and freedom from reoperation. Secondary analyses were performed to evaluate the effect of comorbidity, operation era, conduit type, and conduit size.

Surgical technique

Our technique of repair for truncus arteriosus has been previously described.² Homograft size was determined by upsizing the conduit 1-2 sizes from the pulmonary valve Z-score for the patient. Each

conduit was cut as short as possible posteriorly and the left pleural space was opened widely to avoid sternal compression of the valve and prevent conduit valve regurgitation.

Statistical analysis

Data were analyzed using SPSS for Windows version 25 (SPSS, Inc., Chicago, IL) and R version 3.5.0 (R Foundation for Statistical Computing, Vienna, Austria). Categorical data are listed as n (%) and continuous data are listed as median [interquartile range (IQR)]. The Kaplan-Meier product limit method and Cox proportional hazards regression methods were used for analysis of survival, freedom from catheter reintervention, and freedom from reoperation. Multiple regression analysis was performed as conditional backward stepwise proportional hazards regression. Mortality and operative reintervention were identified as competing risks, necessitating the development of a cause-specific Cox proportional hazard model for each outcome.

RESULTS

Patient demographics

During the study period, 103 patients with TA were evaluated at our institution. Of these, 3 patients were excluded due to initial TA repair performed at an outside hospital (n=2) or definitive treatment with heart transplantation (n=1). The remaining 100 patients with primary repair in infancy were included in the analysis. Patient demographics are summarized in Table 1.

Operative details

In 84% of patients, TA repair was performed in the first 100 days of life, with a median age of 33 days (IQR 20-71 days). The median weight at operation was 3.2 kg (IQR 2.8-4.0 kg). Total cardiopulmonary bypass duration ranged from 85 to 480 minutes (mean, 183 ± 73 min). Aortic cross-clamp duration ranged from 23 to 247 minutes (mean, 89 ± 40 min). RV-PA continuity was established with a cryopreserved aortic homograft (n=14), cryopreserved pulmonary homograft (CryoLife, Inc., Kennesaw, GA) (n=41), bovine jugular vein conduit (Contegra, Medtronic Inc., Minneapolis, MN)

(n=36), valved heterograft conduit [woven Dacron graft containing a glutaraldehyde-preserved porcine valve (Medtronic, Inc., Minneapolis, MN)] (n=4), non-valved polytetrafluoroethylene (PTFE) tube (W.L. Gore & Associates, Inc., Naperville, IL) (n=3), or Gore-Tex monocusp (W.L. Gore & Associates, Inc., Naperville, IL) (n=1). In one case, direct anastomosis to the right ventricle was performed according to the technique described by Barbero-Marcial and associates.⁹ Median conduit diameter size was 12 mm (IQR 11-12 mm).

Five patients underwent truncal valve repair at the time of initial TA repair. Aortic root replacement was performed in 1 patient using a 12 mm aortic homograft. A second patient underwent an aortic root replacement with concomitant Nicks aortic annular enlargement.²⁵ Aortic valvuloplasty was performed in 2 patients. One child underwent aortic valvuloplasty with conversion to aortic root replacement.

Trends over time

Subgroup analysis by operation era revealed significant trends over time at our institution (Table 2). Earlier eras were associated with increased age and weight at initial repair and decreased 30-day survival compared to operations performed in later eras. Our preference of conduit material for RVOT reconstruction technique has also changed over time. The aortic homograft, Dacron valved porcine conduit, non-valved PTFE tube, and direct anastomosis techniques were used in the 1980s and early 1990s. The pulmonary homograft was the conduit of choice in the 1990s and the second most common conduit used in the 2000s. Since 2000, the BJVC has been our conduit of choice for RVOT reconstruction for TA repair (Figure 1).

Delayed sternal closure was performed for 43 patients. A significant association between delayed sternal closure and operation era was found, with delayed sternal closure occurring more often with later

operation eras ($p<0.001$). No instances of mediastinal infection following delayed sternal closure were reported.

Follow-up

Excluding 26 patients who died in the first 2 post-operative years, patients were followed for a median of 15.6 years (IQR 5.3-22.2 years). No patient was lost to follow-up. Actuarial survival at 30 days, 5 years, 10 years, and 15 years was 85%, 72%, 72%, and 68%, respectively.

Mortality

A total of 30 mortalities (30%) occurred after truncus arteriosus repair (Table 3). There were 16 early mortalities (16%) that occurred at a median interval of 7 days (IQR 0-18 days) after TA repair. Cardiovascular complications were the most common cause of early mortality, occurring in 12 patients (75% of early deaths). Univariate analysis revealed a significant relationship between early mortality and cardiopulmonary bypass duration ($p<0.001$), aortic cross-clamp duration ($p=0.001$), concomitant neo-aortic valve repair ($p<0.01$), operations performed in the 1980s ($p=0.006$), and TA-IAA ($p=0.001$). Statistical significance of the hazard association of TA-IAA was maintained on multivariate analysis (HR 5.4; 95% confidence limit, 1.7-17.4; $p=0.005$) (Table 4).

Late mortality occurred in 14 patients (14%). Of these, 10 patients (71%) died within the first 2 postoperative years, with an additional 4 deaths occurring at postoperative years 3, 12, 14, and 17. Mortality due to cardiovascular complications occurred in 1 patient who experienced cardiac arrest on postoperative day 61 following an apneic event at home, though surgical repairs were intact. Additional causes of late mortality included acute respiratory distress syndrome (21%) and sepsis (29%), none of which appeared to be related to the type of implanted cardiac material.

Morbidity

Early reoperations, defined as cardiac reoperations for events other than delayed sternal closure during the post-TA repair hospitalization, occurred in 11 patients. Indications for early re-operation included re-exploration for mediastinal bleeding and cardiac tamponade in 8 patients; low cardiac output syndrome status-post delayed sternal closure in 1 patient; and open cardiac massage for low cardiac output in 2 patients, 1 of whom succumbed to cardiac arrest. Postoperative ECMO support was required for 14 patients, 1 of whom died while on ECMO support.

Reintervention

Median time to surgical or catheter reintervention was 3.8 years (n=61; IQR 0.7-6.4 years) and actuarial freedom from surgical or catheter reintervention was 88%, 77%, and 44% at 6 months, 1 year, and 5 years, respectively. Between TA repair and the first reoperation for RVOT reconstruction, catheter reintervention was performed in 23 patients. Median freedom from catheter reintervention in these 23 patients was 0.6 years (IQR 0.2-2.3 years). Indications for catheter reintervention included conduit failure (n=5), branch pulmonary artery stenosis (n=10), and both conduit failure and branch pulmonary artery stenosis (n=8). Several variables were analyzed as potential risk factors for catheter reintervention, but no significance was identified on univariate and multivariate analyses (Table 5).

Reoperation

RVOT reoperation occurred in 58 patients. Median time to surgical reoperation was 4.6 years (IQR 2.9-6.8 years). Actuarial freedom from reoperation was 88%, 43%, and 5% at 1, 5, and 10 years, respectively. In most cases, the primary indication for reoperation was conduit failure (n=55). Two patients underwent RVOT reconstruction at the time of aortic valve repair but did not meet full criteria for conduit failure. One patient underwent reoperation due to endocarditis on a 20-month-old 12 mm BJVC. No patient died during reoperation. Currently, 13 patients are alive and have not yet required re-operation, with median freedom from reoperation of 3.2 years (IQR 2.1-6.7 years).

Kaplan-Meier analysis demonstrated a significant relationship between conduit material and freedom from reoperation (Figure 2). Following initial TA repair, patients who received a BJVC experienced longer freedom from reoperation overall compared to patients who received either an aortic or pulmonary homograft ($p=0.05$).

Univariate and multivariate analyses revealed a significant relationship between conduit material and freedom from reoperation. Compared to the BJVC, patients who received the aortic homograft exhibited shorter freedom from reoperation (HR 3.1; 95% confidence limit, 1.3-7.7; $p=0.02$), but no significant difference was observed with the pulmonary homograft (HR 1.8; 95% confidence limit, 0.9-3.6; $p=0.10$). A competing risks model of mortality and freedom from reoperation in relation to conduit material revealed a similar relationship regarding freedom from reoperation. Compared to the BJVC, the aortic homograft underperformed (HR 3.8; 95% confidence limit, 1.1-14.0; $p=0.04$) while no significant difference was observed with the pulmonary homograft (HR 2.1; 95% confidence limit, 0.8-5.8, $p=0.15$). Larger conduit size was associated with decreased risk of reoperation compared to smaller conduit size (HR 0.7; 95% confidence limit, 0.6-0.9; $p<0.001$) (Table 6).

COMMENT

This study serves as an extension upon our previous report of TA repair at Riley Hospital for Children at Indiana University Health.² To our knowledge, this is the largest single-center investigation of the effect of conduit material on freedom from reintervention in children with TA. Previous published reports on RVOT reconstruction with the BJVC demonstrate favorable results.¹¹⁻¹⁹ In the present study, RVOT reconstruction with BJVC exhibited longer freedom from reoperation compared to the aortic homograft, with no difference compared to the pulmonary homograft. Given the increased cost, decreased supply, and limited size availability of aortic and pulmonary homografts, the BJVC offers a favorable alternative for RVOT reconstruction.

Among 36 patients who received the BJVC at initial TA repair, 1 case (2.8%) of endocarditis was reported. At our institution, the rate of endocarditis in the BJVC is lower in the truncus arteriosus

population, possibly due to younger patient age at initial repair and time to reoperation. We recently published a retrospective institutional review of 315 BJVCs placed during RVOT reconstruction.¹⁸ A total of 21 cases (6.6%) of endocarditis were reported, half of which were managed with antibiotic therapy alone. Mery et al. evaluated risk factors for endocarditis and reintervention among 792 valved conduits placed during RVOT reconstruction.¹⁹ Although the BJVC was identified as a risk factor for endocarditis, it was associated with a lower risk for reintervention and replacement compared to other conduit types. We have observed long-term favorable outcomes with the BJVC at our institution, though our observed rate of endocarditis with the BJVC is consistent with other reports.¹⁹⁻²¹

In our prior report published in 2001, several potential risk factors for early mortality were identified, yet only operation era and IAA were significant on multivariate analysis. Indeed, 17 years later, both variables remain significant risk factors for early mortality. As operation technique and surgical experience evolved, operative mortality has decreased in later decades. Associated IAA is a risk factor for early mortality following initial TA repair in this and other previous reports.²⁶⁻²⁹ Conversely, others do not identify IAA as a risk factor, and favorable long-term results with one-stage repair of TA-IAA have been reported.³⁰⁻³³ While uncommonly performed, concomitant neo-aortic valve repair was associated with early mortality similar to other reports.^{34,35} In contrast, a recent multicenter study of 216 patients reported no significant association with late mortality or major adverse cardiac event in 37 patients who underwent concomitant truncal valve repair.^{19,36}

Previous studies have indicated that conduit size may influence conduit longevity and overall freedom from reoperation. RVOT reconstruction using a conduit size with a Z-score between +1 and +3 leads to increased durability and hemodynamic function.⁴ Smaller sizes have been associated with conduit

failure and shorter time to reintervention.^{19,37-40} In the present study, conduit size was not associated with early mortality or freedom from catheter reintervention but was associated with freedom from reoperation. Compared to smaller conduits, larger conduits were associated with decreased risk of reoperation. However, caution is advised against using excessively large conduits which may lead to obstruction (distal conduit buckling), turbulent flow, or regurgitation.

There are several important limitations of this study. Due to the rarity of truncus arteriosus, this study is limited by sample size. As a retrospective study, information availability is limited to archived records and follow-up echocardiographic information was unavailable for several patients. Also, records were recovered at a single institution where surgical technique and expertise may impact long-term results.

In conclusion, our experience provides encouraging long-term results for RVOT reconstruction in children with truncus arteriosus. Early mortality following initial repair has significantly declined in later operation eras, though risk may remain elevated in patients with TA-IAA. Due to favorable cost, supply, and long-term results, the BJVC is an ideal conduit of choice for RVOT reconstruction in patients with TA. Additional multicenter studies are needed to validate these findings on a larger scale.

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Table 1: Patient demographics

	n
Sex	
Male	48
Female	52
Truncus arteriosus anatomy	
Type I	44
Type II	43
Type III	8
Type IV	0
Undefined	5
Truncal valve anatomy	
Bicuspid aortic valve	7
Tricuspid aortic valve	77
Quadricuspid aortic valve	16
Comorbidity	
DiGeorge syndrome	23
Interrupted aortic arch, type A	4
Interrupted aortic arch, type B	6
Right-sided aortic arch	22
Patent ductus arteriosus	18
Coronary artery anomaly	9
Hypoplastic aortic arch	4
Coarctation of the aorta	3

Table 2: Patient demographics and operative outcomes by era

	Era of initial operation			
	1981-1989 (N=10)	1990-1999 (N=44)	2000-2009 (N=23)	2010-2018 (N=23)
Age (days)	102.5 (72-613)	29 (3-732)	26 (7-56)	40 (3-245)
Weight (kg)	5.9 (3.4-12.6)	3.3 (1.8-9.6)	3.0 (2.0-4.1)	3.4 (2.3-5.4)
Delayed sternal closure	0 (0%)	8 (18%)	17 (74%)	18 (78%)
Conduit Type	AH: 4 (40%) PH: 1 (10%) PX: 3 (30%) NI: 1 (10%) DA: 1 (10%)	AH: 9 (20%) PH: 30 (68%) BJVC: 1 (2%) PX: 1 (2%) MC: 1 (2%) NVG: 2 (5%)	PH: 10 (43%) BJVC: 13 (57%)	AH: 1 (4%) BJVC: 22 (96%)
Conduit size	12.0 (8.0-19.0)	12.0 (9.0-19.0)	12.0 (10.0-12.0)	12.0 (9.0-14.0)
30-day survival	6 (60%)	29 (66%)	15 (65%)	20 (87%)

Numerical data are listed as median (range), categorical data listed as n (%)

AH: aortic homograft; BJVC: bovine jugular venous conduit; DA: direct anastomosis; MC: monocusp;

NVG: non-valved graft; PH: pulmonary homograft; PX: porcine xenograft

Table 3: Mortality after TA repair

Cause of death	Early mortality	Late mortality
	N=16	N=14
Unable to wean from bypass	2	0
Unable to wean from mechanical ventilation	1	0
Pulmonary hypertensive crisis	1	0
Cardiac arrest	4	1
Cardiogenic shock	5	0
Acute respiratory distress syndrome	0	3
Sepsis	2	4
Cerebral herniation	0	1
Unknown	1	5

Table 4: Risk factors for early mortality

Variable	Univariate	Multivariate		
	<i>p</i> value	HR	95% CI	<i>p</i> value
Age at operation	0.56			
Weight at operation	0.16			
TA-IAA	0.001	5.4	1.7-17.4	0.005
Coronary artery anomaly	0.18			
Conduit material				
Aortic homograft	0.06	2.2*	0.6-8.0	0.25
Pulmonary homograft	0.61	0.6*	0.2-2.2	0.40
Conduit size	0.46			
Decade [†]				
1980s	0.006			
1990s	0.46			
2000s	0.65			

*Compared to bovine jugular vein conduit (BJVC)

[†]Compared to 2010s

TA-IAA: Truncus arteriosus with interrupted aortic arch

Table 5: Risk factors for catheter reintervention

Variable	Univariate	Multivariate		
	<i>p</i> value	HR	95% CI	<i>p</i> value
Age at operation (days)	0.39			
Weight at operation (kg)	0.84			
TA-IAA	0.99			
Coronary artery anomaly	0.87			
Conduit material				
Aortic homograft	0.29	0.4*	0.1-2.0	0.29
Pulmonary homograft	0.18	0.6*	0.2-1.3	0.18
Conduit size	0.99			
Decade [†]				
1980s	0.99			
1990s	0.08			
2000s	0.18			

* Compared to bovine jugular vein conduit (BJVC)

[†]Compared to 2010s

TA-IAA: Truncus arteriosus with interrupted aortic arch

Table 6: Risk factors for reoperation

Variable	Univariate	Multivariate		
	<i>p</i> value	HR	95% CI	<i>p</i> value
Age at operation (days)	0.26			
Weight at operation (kg)	0.30			
TA-IAA	0.29			
Coronary artery anomaly	0.25			
Conduit material				
Aortic homograft	0.038	3.1	1.3-7.7	0.015
Pulmonary homograft	0.33	1.8	0.9-3.6	0.099
Conduit size	0.001	0.7	0.6-0.9	<0.001
Decade [†]				
1980s	0.40			
1990s	0.62			
2000s	0.15			

* Compared to bovine jugular vein conduit (BJVC)

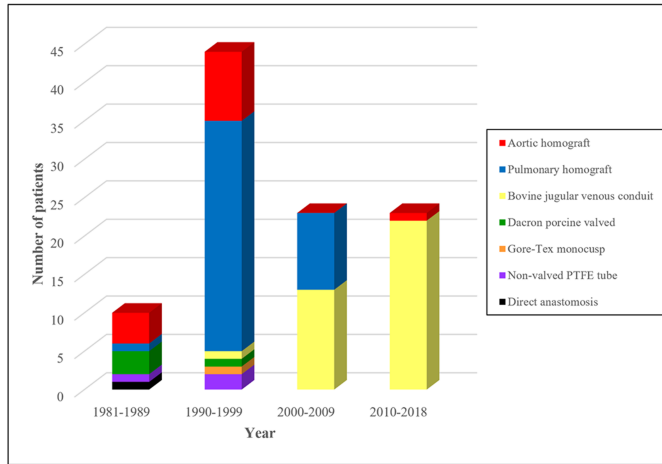
[†]Compared to 2010s

TA-IAA: Truncus arteriosus with interrupted aortic arch

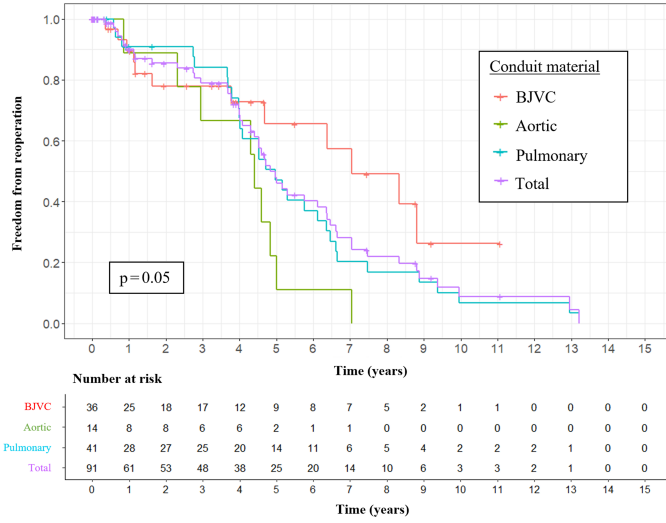
FIGURE LEGENDS

Figure 1: Era analysis of conduit material used for RVOT reconstruction

Figure 2: Kaplan-Meier analysis of freedom from reoperation (Aortic: aortic homograft; BJVC: bovine jugular venous conduit; Pulmonary: pulmonary homograft)



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