# Alternatives to Obtain Right Ventricular to Pulmonary Artery Continuity

## Original Article

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#### **ABSTRACT**

**Background:** The practice of using valved right ventricular to pulmonary artery (RV-PA) conduit for right ventricular outflow tract (RVOT) reconstruction was innovated by Ross and Somerville in 1966. The current application of pulmonary homograft for RVOT reconstruction is the most widely used. Both techniques have limitations for use, especially regarding availability and occurrence of degenerations. The evolution of Contegra valved conduit had achieved excellent results, but unfortunately, several studies reported negative feedbacks, which had expressed the limitation of its use.

**Aim:** Evaluation of the mid-term outcome of RVOT reconstruction using different strategies in a variety of congenital heart diseases in our institute.

Patients and Methods: A retrospective cohort single center study involving 57 pediatric patients who underwent RVOT reconstruction surgery between 2010 and 2017 for correction of the following lesions: Ventricular septal defect and Pulmonary atresia, transposition of great arteries with ventricular septal defect and pulmonary stenosis, truncus arteriosus and tetralogy of Fallot with absent pulmonary valve. Two groups of comparison were created, group 1 includes 27 patients who had a handmade non-conduit repair, their mean age was 26.87± 14.03 months, and their mean body weight was  $10.48\pm3.49$  kg. The other 30 patients had bovine jugular vein conduit repair (group 2) and their mean age was  $23.17\pm10.77$  months, where the *P value* was 0.266. Their mean body weight was  $10.35\pm2.27$ ; where the *P value* was 0.868.

**Results:** Number of cases who needed re-intervention in group 1 was three (11%) and in group 2 was 10 (33%), and the *P value* was 0.046. The late mortality in group 1 was four (14.8%) and in group 2 was five (16.7%), and the *P value* was 0.848.

**Conclusion:** Ideal RVOT reconstruction technique identification is still a matter of case circumstances, available resources, and surgeon/center experience. This promotes the innovations of new techniques for RVOT reconstruction.

Key Words: Artery continuity, contegra, right ventricular outflow tract reconstruction.

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### **INTRODUCTION**

The presence of some congenital heart diseases (CHDs) with deficient right ventricle (RV) to pulmonary artery (PA) continuity triggered the creation of different modes for right ventricular outflow tract (RVOT) reconstruction.

These congenital cardiac diseases could be classified according the type of RVOT defect as [1]:

- A. Absent RVOT: e.g. Pulmonary atresia (PA), truncus arteriosus (TA).
- B. Unsuitable RVOT: e.g. D- transposition of great arteries (D-TGA)+Ventricular septal defect (VSD) +pulmonary stenosis (PS), L-TGA+PS, complicated double outlet right ventricle.

C. Induced: e.g. Ross procedure.

Rastelli and colleagues performed the first operation for RVOT reconstruction in 1964; they used a nonvalved pericardial tube for RVOT reconstruction in a case of pulmonary atresia [2].

Ross and Somerville used a valved aortic allograft for RVOT reconstruction in 1966, which served the surgical repair of many complex cardiac defects with RVOT discontinuity [3].

Through 1980s, the use of synthetic RVOT conduit was launched using porcine-valved Dacron conduit because of unavailable allografts and limitations in storage and preservation techniques [4].

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Non-conduit RVOT repair to obtain RV to PA continuity was evolved to avoid problems of conduit repair, e.g. allow growth with age [1]. In 1982, the Lecompte maneuver (the main pulmonary artery is divided and turned in front of the aorta then sewed again to RVOT) was evolved to correct D-TGA with VSD and PS. After that, Nikaidoh procedure (translocation of the aortic root from its anterior position to be connected to the VSD receiving LV cardiac output, while the PA is resected and connected to RV) appeared in 1984 [5,6].

In 1999, VenPro Corp. produced Contegra bovine jugular vein (BJV) conduit for RVOT reconstruction surgery, then Medtronic incorporation acquired it in 2001. Contegra was then used worldwide because it could be available in variable sizes, with economic cost and with less complication [7–9].

It contains a native bovine tri-leaflet valve preserved in glutaraldehyde, which can be used in low-pressure circulation. The conduit is available from size 12 to 22 (internal diameter in millimeters) [10].

Also, different strategies were applied for surgical RVOT reconstruction, but an optimal strategy is still a matter of debate [11].

#### PATIENTS AND METHODS

A retrospective cohort study involving 57 pediatric patients who underwent RVOT reconstruction surgery at National Heart Institute, between 2010 and 2017 for correction of the following lesions:

- A. VSD and PA (VSD+PA)
- B. Transposition of great arteries, VSD, and PS (D-TGD+ VSD +PS)
- C. TA
- D. Tetralogy of Fallot with absent pulmonary valve (TOF+ Absent PV)

The follow-up period is 3 years for each patient.

Two groups of comparison were created; group 1 included 27 patients who had a handmade nonconduit repair. The concept of handmade conduit started in our institute from the early 2000s when case reports provided by our colleagues as they used autologous pericardium. Then we continued developing the concept by using bovine pericardium, a Polytetrafluoroethylene sheet, and Dacron tubes according to the size of the patient using a nomogram established for this.

Bovine pericardium or Dacron tube were used to construct tube graft and for leaflet reconstruction, treated autologous pericardium or polytetrafluoroethylene sheets were used.

Their mean age was 26.87±14.03 months, and their mean body weight (BW) was 10.48±3.49 kg. The other 30 patients had conduit repair using Contegra; valved bovine internal jugular vein conduit (Medtronic Inc., MN, USA) (group 2), their mean age was 23.17±10.77 months. Their mean BW was 10.35±2.27.

Approval of the local and the national ethics committee was obtained for the study under the certificate number [IHc 00086]. We obtained data from our medical records and direct communication with patients. Loss of follow-up is less than 10%; there is no competitive risk in the groups of patients.

#### Surgical technique

- A. Midline sternotomy and standard cardiopulmonary bypass techniques were applied in most cases with moderate hypothermia (28–32°C).
- B. Determination of conduit size and its comparison with normal pulmonary valve size for body surface area (BSA) (z score) at the time of operation.
- C. Oversizing was defined as a z score of 2.0 or greater.
- D. The RVOT conduit was inserted between the pulmonary bifurcation and the RV at the level of the crista supra-ventricular is as shown in Figs. 1, 2 and 3.
- E. In-group 1, Dacron tube, bovine or glutaraldehydetreated pericardium was used to provide continuity between the PA, and in some cases autologous pericardium was fashioned.
- F. Vertical infundibulotomy was made to provide proximal anastomosis.
- G. A patch of Dacron, bovine, or autologous pericardium was used to cover the enlarged infundibulotomy.

#### Follow-up

Transthoracic echocardiography was performed by pediatric cardiologists for all patients immediately after the operation, and serial echocardiographic examinations were conducted 3 days, 3 months, 6 months, and annually thereafter.

Continuous-wave Doppler was used to assess PS.

Pulsed wave and color-Doppler were used to evaluate pulmonary regurgitation.

Chest radiography was done every 6 months.

The primary outcomes: Mortality, and the need for reintervention (surgery, or trans-catheter intervention).

The secondary outcomes:

- A. Significant pulmonary regurgitation by echocardiography.
- B. Significant RVOT obstruction (Peak pressure gradient > 60 mmHg by echocardiography).
- C. Symptomatic patients with NYHA (New York Heart Association) class greater than II.

Anticoagulation was used routinely for 6 months after surgery in the form of warfarin for 3 months with a target international normalized ratio of about 1.5–2, and aspirin for life.

#### Statistical analysis

Statistical data analysis was performed using IBM Statistics SPSS (Statistical Package for the Social Sciences) for Windows, version 25 (IBM Corp., Armonk, New York, USA).

All obtained data were presented as mean and standard deviation for normally distributed variables, while as median and interquartile range for non-normally distributed variables.

Shapiro-Wilk test was used to assess normality.

Student t-test was used for normally distributed variables and Mann-Whitney U test for non-normally distributed variables.

 $X^2$  test was used to test categorical variables.

Kaplan–Meier analysis was used for event-free survival evaluation and comparison between groups.

All tests were two-sided, P less than 0.05 was considered statistically significant, and P greater than or equal to 0.05 was considered nonstatistically significant.

#### RESULTS

The study groups included 57 pediatric patients who had RVOT reconstruction for different cardiac lesions, two groups of comparison were created, group 1 includes 27 patients who had handmade non–conduit repair, their mean age was 26.87±14.03 months, and their mean BW was 10.48±3.49 kg. The other 30 patients had BJV conduit (Contegra) repair (group 2) and their mean age was 23.17±10.77 months. Their mean BW was 10.35±2.27.

There was no statistically significant difference between the two groups of study regarding the baseline characteristics (age, sex, BW, height, BSA, and BMI), which indicates matching between the two groups regarding demographic criteria (Table 1).

In-group 1, there were 10 (37%) cases having VSD+PA, seven (25.9%) cases having D-TGD+ VSD +PS, four (14.8%) cases having TA, six (22.2%) cases having TOF with absent PV. In-group 2, there were 11 (36.7%) cases having VSD+PA, 10 (33.3%) cases having D-TGD+ VSD +PS, five (16.7%) cases having TA, four (3.3%) cases having TOF with absent PV. Here, the P value between the two groups was 0.817 which indicates matching between the two groups regarding congenital cardiac lesions (Table 2).

The late mortality in group 1 was four (14.8%) cases and in group 2 was five (16.7%) cases and the P value was 0.848 (Table 3).

The re-intervention in group 1 is 11.1% (three cases), and the re-intervention in group 2 is 33.3% (10 cases), and the *P value* was 0.046, which is statistically significant (Table 3) which is attributed mainly to re-stenosis and degeneration of the Contegra conduit.

Significant valve regurgitation was found in nine (33.3%) cases in group 1, and in 12 (40%) cases in group 2, with the P value equal to 0.602 (Table 3).

At Kaplan–Meier analysis (Figure 4), freedom from severe pulmonary regurgitation at 18, 24, 30, and 36 months resulted in 100, 81, 45, and 18%, respectively, in group 1 (non–conduit repair) [mean survival 26.7 months, confidence interval (CI) 95%, 23.1–30.4; median survival 24 months, CI 95%, 18.5–29.5, and in group 2 (conduit repair) at 30, 36, 40, 42, and 48 months, it was 100, 82, 40, 32, and 15%, respectively, (mean survival 38.3 months, CI 95%, 35–41.7, median survival 36, CI 95% 32–40, Logrank P<0.001).

Freedom from right ventricular dysfunction (Figure 5) at 40, 42, 48, 54, 66, and 72 months resulted in 100, 85, 70, 42, 28, and 14%, respectively, in group 1 (non–conduit repair) [mean survival 52.9 months, CI 95%, 43.9–61.8; median survival 48 months, CI 95%, 40.3-55.7], and in group 2 (conduit repair) at 36 and 66 months, it was 100%, and 12%, respectively, (mean survival 46 months, CI 95%, 26.4–65.6, median survival 36, CI un-identified, Log-rank P=0.428).

Freedom from significant RVOT pressure gradient (Figure 6) at 34, 40, 42, 44, 52, 54, and 60 months resulted in 100, 88, 77, 66, 54, 45, and 21%, respectively, in group 1 (non–conduit repair) [mean survival 49.9 months, CI 95%, 42.9–54.9; median survival 52 months, CI 95%, 28.6–75.4], and in group 2 (conduit repair) at 22, 24, 28, 30, 32, 36, and 40 months, it was 100, 82, 66, 58, 41, 24, and 8%, respectively, (mean survival 29.7 months, CI 95%, 26.3–33, median survival 30, CI 26.7–33.3, Log-rank P<0.001).

**Table 1:** Baseline demographic and clinical characteristics for group 1 and group 2 patients.

Variable	Group 1 (N=27)	Group 2 (N=30)	Test	P value
Age (year)				
Mean±SD	$26.87 \pm 14.03$	23.17±10.77	t- test	0.266
Median	27.00	22.50	1.124	NS
Range	(4–50)	(4–42)		
Sex, n (%)				
Males	13 (48.1)	18 (60.0)	$X^2$	0.370
Females	14 (51.9)	12 (40.0)	0.805	NS
Body weight (kg)				
Mean±SD	10.48±3.49	10.35±2.27	t- test	0.868
Median	10.5	10.5	0.171	NS
Range	(5–16)	(5.5–14)		
Height (cm)				
Mean±SD	74.18±13.88	69.18±9.53	MW	0.200
Median	68.50	66.50	325	NS
Range	(60–101)	(60–91)		
Body surface area (m2)				
Mean±SD	$0.42 \pm 0.013$	$0.393\pm0.091$	MW	0.987
Median	0.37	0.370	404	NS
Range	(0.29-0.67)	(0.31-0.60)		
Body mass index (kg/m2)				
Mean±SD	15.14±1.96	15.98±1.25	t- test	0.055
Median	15	16.17	-1.959	NS
Range	(11.31–19.11)	(13.02–18.59)		

Table 2: Congenital cardiac lesions in patients groups.

	VSD, PA, n (%)	D-TGA, VSD, PS, n (%)	TA, n (%)	TOF, Absent PV, n (%)	$X^2$	P
Group 1	10 (37)	7 (25.9)	4 (14.8)	6 (22.2)	0.933	0.817
Group 2	11 (36.7)	10 (33.3)	5 (16.7)	4 (13.3)		

Table 3: Reintervention, significant regurgitation, and late mortality in patient groups.

Outcome	Yes, n (%)	No, n (%)	$X^2$	P value
Reintervention				,
Group 1	3 (11)	24 (89)	3.986	0.046*
Group 2	10 (33)	20 (67)		
Significant regurgitation				
Group 1	9 (33.3)	18 (66.7)	0.271	0.602
Group 2	12 (40)	18 (60)		
Late mortality				
Group 1	4 (14.8)	23 (85.2)	0.037	0.848
Group 2	5 (16.7)	25 (83.3)		



Fig. 1: Intraoperative photo of handmade conduit.

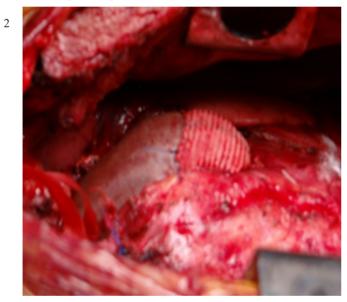


Fig. 2: Intraoperative photo of handmade conduit.

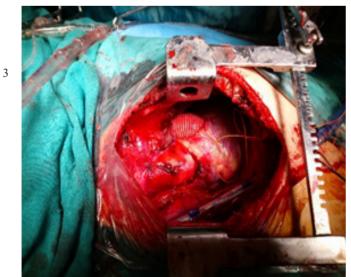
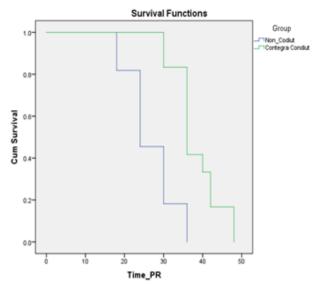
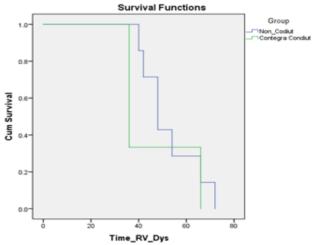


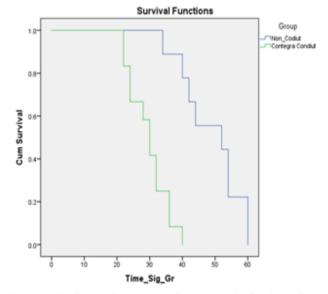
Fig. 3: Intraoperative photo of handmade conduit.



**Fig. 4:** Kaplan–Meier curves for survival, freedom from severe pulmonary regurgitation in patients groups.



**Fig. 5:** Kaplan–Meier curves for survival, freedom from right ventricular dysfunction in patients groups.



**Fig. 6:** Kaplan–Meier curves for survival, freedom from significant RVOT pressure gradient in patients groups.

#### **DISCUSSION**

RVOT reconstruction has been the standard surgical treatment of variety of complex CHD. Our study aimed at evaluation of the mid-term outcome of RVOT reconstruction using different strategies in a variety of CHDs. The use of Contegra BJV conduits (Medtronic, Minneapolis, MN, USA) has the advantage of easy handling and time saving.

It has been recommended by some centers as the favorite method for RVOT reconstruction [8].

Our study involved 57 pediatric patients who underwent RVOT reconstruction, they were divided into two groups, we assigned the cases who had hand-made non-conduit repair in group 1, while group 2 involved patients who had bovine valved conduit repair. There was no statistically significant difference between the two groups regarding demographic criteria (age, sex, BW, length, BSA, and BMI) and the congenital cardiac lesions, which indicates matching between the two groups regarding demographic criteria and cardiac defects requiring RVOT reconstruction, to avoid confounding.

Patients' mortality and the need for re-intervention are considered the primary outcome in our patients. Regarding mortality, we had a nonstatistically significant difference between the two groups.

Similar to our result, Padalino and colleagues reported a nonsignificant difference in mortality between their two groups of patients who had nonconduit and Contegra conduit repair in cases of RVOT reconstruction for TA, with P value equal to  $0.70^{[12]}$ .

In addition, Poinot and colleagues who reported 87 operations of RV to PA conduit in children (60 contegra and 27 homograft) found nonsignificant difference in mortality between their two groups [13].

In contrast to our results in Lacour–Gayet and colleagues' study, the non–conduit repair was associated with a significant increase in operative mortality, which may be attributed to postoperative pulmonary hypertension<sup>[14]</sup>.

Contegra showed good results, easy application, and different sizes availability, many centers used it as the standard method for RVOT reconstruction [15], also some studies reported that cases who had Contegra RVOT reconstruction showed less rate of explantation in comparison to cases who had pulmonary homograft [16].

In our patients, survival from severe pulmonary regurgitation was significantly higher in the Contegra group in comparison to non-conduit group, which explains relative favorability of Contegra conduit in short-term results.

Our patients showed significant survival from significant RVOT pressure gradient in nonconduit group in comparison to the contegra group with *P value* less than 0.001. In addition, there was a statistically significant increase in the number of late re-interventions after 3 years in group 2 patients (who had Contegra conduit) in comparison to group 1 patients (who had hand-made nonconduit repair). In group 1, degeneration was the main cause for re-intervention, which was frequently done by transcatheter balloon dilation. In group 2, the main cause of re-intervention was restenosis, which was managed by surgical explantation of the conduit and re-implantation of a new one.

Similar to our study, Padalino *et al.* who reported a study on 29 patients after TA repair, found that conduit repair of TA is associated with more re-interventions and earlier development of complications in comparison to non–conduit repair [12].

Poinot *et al.* observed more calcifications in cases who had homograft for RVOT reconstruction, but earlier dissection and explantation in the contegra group [13].

In contrast to our results, Christenson et al. performed RVOT reconstruction in 205 children, they reported that Contegra grafts have a very low early reoperation rate and could therefore be used in neonates and children younger than 3 years of age, if a blood group—compatible homograft cannot be found [17].

Despite the great favorability of contegra conduit, some centers reported noticeable problems associated with cases having contegra conduit, e.g. aneurysm formation<sup>[18]</sup>, infective endocarditis <sup>[19]</sup>, and thrombus formation <sup>[20,21]</sup>.

All our patients received anticoagulation routinely for 6 months after surgery in the form of warfarin for 3 months, and aspirin for life, so that a minor number of patients (two patients) had thrombus formation.

Helal and colleagues in their study had compared long-term adverse events between BJV conduit, aortic homograft, and porcine-valved conduits. They reported low mortality, unrelated to the type of conduit. There was a high rate of re-interventions due to graftrelated adverse events. BJV conduit was durable but at the expense of needing more frequent cardiac catheterization interventions, and more risk of infective endocarditis. The male sex and younger age were more associated with adverse events [22].

In our study, we did not recruit cases of porcine-valved conduit, as well as aortic homografts, due to limited resources and budgets.

#### **CONCLUSION**

RVOT reconstruction techniques showed a matter of debate among different center. Although contegra conduit repair is much easier and was suggested by many centers, our experience recommends the use of nonconduit repair for RVOT reconstruction despite its relatively more effort and professionalism requirement, but the need for re-intervention is significantly lower than that of conduit repair.

#### LIMITATIONS

Being a single center and a retrospective cohort study should be considered, the results cannot be generalized.

The nonconduit repair is relatively more recent than conduit repair; longer periods of follow-up may be needed.

#### **CONFLICTS OF INTEREST**

There are no conflicts of interest.

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