# Outcome of right ventricular outflow reconstruction using valved conduit in the treatment of tetralogy of Fallot with absent pulmonary valve

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Abstract: Tetralogy of Fallot (TOF) with the absent of pulmonary valve is unusual; with about 3% of patients with tetralogy of Fallot possess this valve syndrome. Also, it is described by tetralogy of Fallot with either primitive ridges or the whole absence of pulmonic valve tissue and generally with a hypoplastic valve annulus. The absence of mature pulmonary valve tissue leads to severe regurgitation, which is often connected with large dilatation of the proximal branch of pulmonary arteries. The dilated pulmonary compress the tracheobronchial tree resulting in respiratory distress. Management of TOF/APV shows two points of controversy regarding the surgical technique of RVOT reconstruction and reduction of dilated pulmonary arteries. Patients and methods: The study includes 20 patients of TOF/APV who underwent surgical repair using bovine jugular vein valve conduit (contegra) in the Abu El Reesh specialized pediatric hospital (Japanese Hospital), Cairo University in the period from January 2015 to July 2018. Results: in our study there were 8 males about 40% and 12 females about 60% the average age was  $16.55m \pm$ 13.83 months and the mean weight was  $10.2 \pm 3.578$  Kilograms, the main presentation was shortness of breath in 12 patients, the remaining 8 patients discovered accidentally, the Cardiopulmonary bypass time was ranged from 85 to 130 with mean 111.9±22.46 min and cross-clamp time was ranged from 45 to 110 with mean 91± 8.49 min, all patients need inotropic support and operative mortality represent 5%. Conclusion: there are two points of discussion in the surgical therapy of children with TOF/APV concerning the surgical technique of RVOT reconstruction and reduction of the size of the enlarged pulmonary arteries.

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# 1. Introduction

Tetralogy of Fallot (TOF) had contained a malalignment ventricular septal defect (VSD), infundibular relating to the lungs stenosis, overriding aorta, and right ventricular hypertrophy (RVH) (1). In the occurring neonatal time, inadequate oxygenation of the blood may be present (cyanosis), these are finding of greater pulmonary vascular resistance (PVR) may be reasons a right-to-left shunt at the level of the VSD or the incapacity to effectively ventilate the patient. After the fall in pulmonary vascular resistance, respiratory hardness is the greatest important symptom in severe cases (2,3).

Congestive heart failure (CHF) can happen as an outcome of a great left-to-right ventricular shunt. This participates to an enlarged left atrium, which, over with dilated lungs arteries, outcomes in airway pressure. The presence of considerable is tricuspid regurgitation and also greater the danger of heart failure (4,5,6).

Surgical reform mechanisms change in conformity with the special anatomy in a given patient, especially the gravity of lungs artery dilation. The reform is control on carrying out the integrity of lungs circulation, which one determination proposes best carried out by utilizing the right ventricle–to– pulmonary artery conduit or great a lungs valve (7). Meanwhile, two surgical reviews as long as an addition optimistic picture when surgical strategies are individualized and jointed with attacker postoperative ventilator administration and more interventions pointing to alleviate airway obstruction (8,9).

The definition of Contegra is a pulmonary valved conduit consisting of a heterologous (bovine) jugular vein with a tri-leaflet venous valve and a natural sinus slightly larger in diameter than its lumen (10). Moreover, Maddali et al. (11) and Sandica et al. (12) observed that the Contegra pulmonary valved conduit may be utilized for different indications. Valve competency has become better at decrease pressure loads; therefore, physicians may choose to consider alternative procedures or treatments for patients exhibiting, or at danger for, high pulmonary pressures. These agents proposed that the choice of surgical technique must be left to the discretion of the individual surgeon.

The aim of this study was to record our experience in the treatment of tetralogy of Fallot (TOF) with absent pulmonary valve using valve conduit.

# 2. Patients and Methods:

This study is an observational retrospective study. The study was conducted at the Pediatric cardiothoracic surgery unit at Abu El Reesh specialized pediatric Hospital Cairo University, Cairo, Egypt between January 2015 to July 2018. The study was approved and conducted in accordance with the guidelines of the local Ethics. Eligible patients' legal guardian had the procedures explained, and if they agreed to have the infant operated upon, an assent was signed up a detailed preoperative, intraoperative and postoperative evaluation. Infants (8 males and 12 females) were eligible to participate in this study if they have TOF/APV undergoing surgical repair using bovine jugular vein valve conduit (contegra) execluding redo fallot and TOF with multiple patients' MAPCAS. Preoperatively basic demographics and medical history were obtained. Then infants were examined clinically and undergone an echocardiography assessment to demonstrate turbulence through the RV outflow tract. Pulmonary regurgitation is readily identified.

# Surgical technique:

Routine Aorta bicaval cannulation with appropriate cannulae is according to body weight. Closure of VSD with a Dacron patch usually transatrial by retracting the tricusped valve leaflets, then reduction of the aneurysmally dilated pulmonary artery and or dilated pulmonary artery branch then distal anastomosis between the valve conduit and pulmonary artery done first followed by proximal anastomosis with RV. Desiring the left side of the heart after VSD closure was done then RVOT reconstruction using valve conduit is done on a beating heart.

The Intraoperative parameters were:

Cross clamp time, Total bypass time.

Total operative time, In tropic support.

Post-operative:

All patients were transferred to the ICU on mechanical ventilation with continuous monitoring of haemodynamics.

# **Postoperative parameters:**

Mechanical ventilation time. Inotropic support. ICU stay. Ward stay. Postoperative chest infection. Chest tube drainage. Blood transfusion. Re-exploration. Mortality. Statistical analysis

Results were expressed as mean, standard deviation, minimum, maximum and number (percent). Statistical analysis was performed using SPSS computer program (version 21 windows) (IBM Inc., Chicago, Illinois, USA).

### 3. Results:

#### **Preoperative results:**

In our study group there were 8 males about 40 % and 12 females about 60%. The average age was  $16.5 \pm 13.83$  months. The mean weight was  $10.2\pm 3.578$  Kilograms ranged from 7 to 20 Kilograms. These results are tabulated in Table (1).

Age (Months)	
Range	7-61
Mean $\pm$ SD	$16.5 \pm 13.83$
Gender	
Male	8 (40%)
Female	12 (60%)
Weight	
Range	7-18
Mean $\pm$ SD	$9.55 \pm 2.89$

Table (1): Physical characteristics of two study groups.

Data are expressed as mean  $\pm$  SD or number (%)

The finding from the Table (2) observed that the main presentation was shortness of breath and mild respiratory distress in 12 patients while the remaining 8 patients were asymptomatic and accidentally discovered during routine follow up in 6 patients or examination for other cause (gastroenteritis) in 2 patients where ejection systolic and early diastolic murmer was heard at the left sternal border so echocardiography was recommended and when done

reveal tetralogy of Fallot with absent pulmonary valve.

The mean preoperative oxygen saturation was  $89.2\% \pm 1.7045$  ranged from 85% to 92%.

The mean preoperative RVOT pressure gradiant was 69 mmHg±15.526 ranged from 50 mmHg to 90 mmHg.

The preoperative pulmonary regurge was moderate in 9 patients and severe in 11 patients.

The mean size of VSD was 12.65mm $\pm 3.12$  with range from 8mm to 18 mm.

In our study the associated cardiac anomalies were ASD in 6 patients, PFO in 4 patients, persistent left SVC in one patient and right sided aortic arch in one patient.

# **Operative results:**

The operative results are tabulated in Table (3) and the results are summarized as follows.

All patients undergo surgical reconstruction of the RVOT using bovine jugular vein valved conduit (contegra) with a size ranged from 12 to 16 where contegra size 12 was used in 2 patients, contegra size 14 was used in 7patients and contegra size 16 was used in 11 patients while the surgical treatment of dilated pulmonary differ according to the age of patient,degree of pulmonary dilatation and compression of tracheobronchial tree where 8 patients need no surgical intervention to their pulmonary while 8 patients underwent pulmonary artery plication and the remaining 4 patients underwent reduction of the aneurysmally dilated pulmonary by excising elliptical strips of anterior arterial wall.

Cardiopulmonary bypass time ranged from 85 to 130 with mean 111.9±22.46 min.

Cross clamp time ranged from 45to 110 with mean  $91\pm8.49$  min.

Table (2): Summary of preoperative results					
Main presentation:					
Mild respiratory distress&shortness of breath.	12				
Asymptomatic and accidentally discovered.	8				
Preoperative oxygen saturation:					
Mean (± SD)	89.2% (±1.7045)				
Range	85% to 92%				
Preoperative RVOT pressure gradient					
Mean (± SD)	$69 \pm 15.526$				
Range	50 mmHg to 90 mmHg				
Size of VSD:					
Mean (± SD)	12.65mm±3.12				
Range	8mm to 18 mm.				
Preoperative pulmonary regurgesevere pulmonary regurge moderate	11				
pulmonary regurge	9				
Associated cardiac anomalies					
ASD	6				
PFO	4				
Rt. Side aortic arch	1				
Persistent left SVC	1				

# Table (3): Showing the summary of operative results

RVOT reconstruction by Bovine jugular vein valve conduit (contegra)		
Size12	2	
Size14	7	
Size16	11	
Pulmonary artery arterioplasty		
No intervention.	8	
Showing that 90% of patients extubated in the first 14 hours.	8	
Reduction by excision of anterior wall.	4	
Cardiopulmonary bypass time		
Mean (±SD)	111.9±22.46 min	
Range	95 – 200 min	
Aortic cross clamp time		
Mean (±SD)	91 ± 8.49 min	
Range	30-110	

#### **Postoperative results:**

The duration of postoperativeventilation is reported in Table (4) and the results illustrated that

the median duration of postoperative ventilation was 8 hours with IQR (6.25 - 8.75).

Duration of ventilation	Number of patients	Percentage of patients
4 hours	2	10%
5 hours	1	5%
6 hours	2	10%
7 hours	2	10%
8 hours	8	40%
9 hours	1	5%
12 hours	1	5%
14 hours	1	5%
15 hours	1	5%
344 hours	1	5%

Table 4: Showing the duration of postoperativeventilation

Postoperative oxygen saturation, RVOT pressure and complication.

All cases needed inotropic support representing 100%. Whereas 9 cases transferred to the ICU on 0.5 mic/kg/minmilirinone that was withdrawn smoothly over a mean duration of 31.556 hours ( $\pm 8.53$  hours) while 6 patients were transferred to ICU on 0.7 mic/kg/min milirinone and 50 nano/kg/minadrenaline that was withdrawn over a mean duration of 32 hours (±4.56 hours)one patient was transferred to the ICU on dobutrex 10 mic/kg/min and adrenaline 50 nano/kg/min that was withdrawn smoothly over 36 hoursalso one patient was transferred to ICU on 0.5 mic/kg/min milirinone and 100 nano/kg/min noradrenaline that was withdrawn smoothly over 30 hours another patient was transferred to ICU on 10 mic/kg/min dobutrex and 50 nano/kg/min noradrenaline was withdrawn smoothky over 24 hour, the last two patient one wastransferred to the ICU on mic/kg/minandnoradrenaline dobutrex 10 100 nano/kg/ min that was hardly withdrawn over 3 days due to RV stunning and the other was transferred to ICU on 1 mic/kg/min milirinone and100 nano/kg/min noradrenaline after 4 hours in ICU blood pressure falls down and the inotropic support increased to 200 nano/kg/min noradrenalinethen the condition

improved gradually and the inotropic support gradually withdrawn over 5 days. These results are reported in Table (5).

The mean postoperative oxygen saturation was  $97.7\% (\pm 1.75\%)$  with range from 94% to 100%.

The mean postoperative RVOT pressure gradiant was 9.3mmHg±2.45 ranged from7mmHg to 14 mmHg.

Regarding postoperative pulmonasryregurge, no regurge in 5 patients, trivial regurge in 9 patients and mild regurge in 6 patients.

Regarding postoperative complications tiny residual VSD occurred in one patient that need no intervention for follow up and wound infectionalso occurredin one patient.

Regarding operative mortality (operative mortality means death within one month of surgery or before discharge from the hospital)only one case died22 days after surgical intervention but before discharge from the hospital so considered operative mortality representing 5%.this case died due to unsatisfactory relief of respiratory distress due to persistent bronchomalacia caused by long term compression of the tracheobronchial tree resulted in prolonged ventilation and ventilator associated pneumonia ended by death from sepsis.

Post-operative oxygen saturation	
Mean (±SD)	97.7% (±1.75%)
range	94% to 100%.
Post-operative RVOT pressure grandient	
Mean (±SD)	9.3mmHg±2.45
Range	from7mmHg to 14 mmHg
Post-operative complication:	
Tiny residual VSD	1
Wound infection	1
Mortality percentage:	5%

Table 5:	Summary	of	posto	perative	results:
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#### 4. Discussion:

To the better of our information, this is the second African study on TOF/APV as the first study

was done in South Africa in 2018 that involve 15 patients with TOF/APV but surgical intervention

occurs only in 4 patients however in our study surgical repair occur in all 20 patients (13).

Our data is in agreement with the published literature which shows that TOF/APV is a rare congenital cardiac lesion, compromising 3% of all TOF patients, and characterized by aneurismal dilatation of the relative to the lungs arteries and aplasia or rudimentary advancement of the relating to the lungs valve with generally a mild hypoplastic annuli (13).

In this study, there were 12 females about 60% and 8 males about 40% the average age was 16.5 months (range 7–61 months) and the mean weight was 10.2 kg (range 7–20kg). Comparing these results with other studies we found that gender prevalence was variable, as female was representing 68% in a study byAlsoufi et al. (8) but male was representing 77% in a study by Hu et al. (14) andTalwar et al. (2017) and the gender prevalence was 1:1.

In our institute policy for early intervention for the cases of TOF/APV with a mean age 16.5 months. Our early intervention follows previous experience of other studies as Hu et al. (14) on 42 patients with median age 9.5 months and median weight 8 Kg. However, in some centers they operate on older ages with mean age 8.5 years as reported by Shahidet al. (7) and on 6.4 years as reported by Talwar et al. (5)

The demographic features of the study group show that there is no gender prevalence in tetralogy of Fallot with absent pulmonary valve. However, the timing of surgical intervention is variable according to each institute's policy. In our study, the mean preoperative oxygen saturation was  $89.5\% \pm 1.75$ (ranged from 85% to 92%) which improved after surgery as the mean postoperative oxygen saturation was 97.7%±1.75 which (ranged from 94% to 100%). These result was similar to other studies asTalwar et al. (5) in which the mean preoperative oxygen saturation was  $80.13\% \pm 14.1$  (range from 62%) to 99%) which improved after surgery as the mean post operative oxygen saturation was 99% (range from97% to 100%)and Shahidet al. (7) in which mean preoperative oxygen saturation was 93% (range from 825 to 100%) which improved after surgery as post operative oxygen saturation the was 98.5% (ranged from 955 to 100%).

The mean bypass time was  $111.9 \pm 22$  min (range 85–130min) and the mean cross-clamp time was  $91 \pm 8.5$  min (range 45–110 min). Comparing these results with other studies we found that the mean bypass time was almost equal as it was 106, 137 in studies by Alsoufi et al. (8) and Hu et al. (14) respectively.

In our study some surgeons prefer to complete RVOT reconstruction on beating heart after removal of cross clamp and this was done in 5 cases while other surgeon prefer to complete RVOT reconstruction on cross clamp and this was done in the remaining 15 cases this explain the wide range of cross clamp time (from 45 minute to 110 minute). Comparing two surgical techniques, there was no considerable various in the ICU stay, morbidity and mortality.

Regarding the surgical techniques used in RVOT reconstruction and pulmonary arterioplasty we found that surgical reconstruction of RVOT done using bovine jugular vein valve conduit (contegra) with good postoperative results regarding the pulmonary regurge and RVOT pressure gradiant as there is no post operative pulmonary regurge in5 patients, trivial pulmonary regurge in9 patients and mild pulmonary regurge in6 patients however the mean preoperative RVOT pressure gradiant was 69mmHg 15.526(ranged from 50 to 90) decreased after surgical reconstruction of RVOT with bovine jugular vein valved conduit (contegra) to 9.3 mmHg± 2.45 (ranged from7 to 14).

Regarding pulmonary arterioplasty, pulmonary plication done in 8 patients, pulmonary reduction by excising the anterior wall done only in 4 patients, the remaining 8 patients need no intervention in the pulmonary artery.

The study done by Hu et al. (14) which involve 42 patients with absent pulmonary valve RVOT reconstruction done by 3 different surgical techniques transannular patch in 17 patient, monocusp valve in 18 patients and valve conduit in 6 patients (bovine jugular vein valve conduit in 4 patients and homograft valve conduit in 2 patients) the last patient by Gore-tex conduit however the surgical treatment of dilated pulmonary artery. 7 patients did not receive any intervention to their pulmonary arteries, reduction pulmonary arterioplasty done in the remaining 35 patients (7 patients by plication and 28 patients by anterior wall resection). All the surviving patients in this study show post operativemoderate pulmonary regurge but without any symptoms or signs indicating reoperation for pulmonary insufficiencyand six patients show postoperative pulmonary stenosis 2 of them need surgical reoperation for enlargingthe narrow pulmonary artery 1 and 6 months after surgical treatment respectively.

In the previous study they found no significant difference in survival among the 3 different types of RVOT reconstruction and prefer monocusp valve for RVOT reconstruction. However in the study done by Alsoufi et al. (8) whichinvolve 62 patients with tetralogy of Fallot /absent pulmonary valve, RVOT reconstruction done by trans annular patch in 4 patients and mono-cusp valve in 8 patients, bioprosthetic valve in18 patients and the remaining 31 patients by valved conduit and regarding the surgical treatment of the dilated pulmonary, 29 patients need no intervention in their pulmonary artery,pulmonary artery plication done in 15 patients and reduction of pulmonary artery by excising elliptical strips of pulmonary arterial wall (6 anterior,6 posteriors, 6 combined anterior and posterior).

This study was needed in seven patients and involved relating to the lungs artery suspension in 4 patients and in nominates artery suspension in 2 patients and right upper and lower lobectomy in two patients, all seven infants were less than 3 months old. Therefore absent pulmonary valve has evolved with time during this study to their current strategy that involved full intracardiac reform with VSD closure, infundibular resection, lowering of the dilated relating to the lungs arteries reconstruction of the RVOT with valved conduit, and suspension of the left relating to the lungs artery to the chest wall upon closure of the chest.

Talwar et al. (5) which involve 73 patients with TOF/APV, RVOT reconstruction done by bovine jugular vein valved conduit (contegra) in 22, patients, monocusp homograft in21 patients,transanular patch in15 patients nuns bicuspid homemade valve in 6 patients,transannular patch with monocusp in 6 patients and PTFE tubegraft with monocusp in 3 patients. While regarding surgical management of the dilated pulmonary arteries, 63 patients need no intervention, pulmonary artery plication in 8 patients and pulmonary artery reduction in 2 patients.

No pulmonary regurge in 14 patients, mild pulmonary regurge in21 patients, moderate pulmonary regurge in 8 patients and severe pulmonary regurge in 19 patients only 5 of them are symptomatic and need reoperation while the remaining 14 were asymptomatic and were treated conservatively and advised for frequent follow up. While 3 patients were reoperated for RV-PA conduit change due to significant RVOT gradiant, in this study they found that no various in reoperation ratios was found among valved conduit, mono-cusp, or valve less mechanisms and their current strategy for surgical treatment of TOF/APV is RVOT reconstruction with either homograft or monocusp valve with plication or decreasing of the dilated relating to the lungs artery if needed.

Wang et al.(15) which involve 22 patients with TOF/APV, where surgical reconstruction of RVOT was done by bovine jugular vein valved conduit in 10 patients, by homograft valve conduit in 2 patient and monocusp valve patch in 10 patients and regarding pulmonary arterioplasty 15 patients need no intervention while 4 patients underwent pulmonary plication and 3 underwent pulmonary reduction by excision of anterior wall.

In this study, they compare the use of valve conduit with the use of the mono-cusp patch in RVOT reconstruction and found that there is no significant difference in the systolic pressure gradient RV-PA between this two groups before the operation and7days after an operation. The results showed that the gradient lowering greatly from 88.47±18.47 mmHg before the operation to 20.71±8.11 mmHg 7- day post operation and then it higher to 45.03±26.09 mmHg in the last follow up. However, in the mono-cusp group, there was a lessening direction in the pressure gradient during these 3-time points ( preoperative,7-day postoperative and last follow up)and they did not find any difference between the two groups regarding PULMONARY REGURGE so they prefer monocusp valve patch as surgical technique for RVOT reconstruction (7).

In a study done by Yong et al. (4) which involve 52 patients with absent pulmonary valve syndrome where surgical reconstruction of RVOT done by valved conduit in 16 patients and by mono-cusp valve repair in 16 patients and valve less repair in 20 patients while surgical reduction of the pulmonary artery was done in 39 patients by plication or resection.the lecompte maneuver was performed in 2 patients, they found that there is no difference in reoperation rate between valved conduit, mono-cusp, or valve less techniques but there was tendency to use valved conduit ( they prefer valved conduit in RVOT reconstructionas competent pulmonary valve improve he early postoperative hemodynamic and is important in reducing long term risk of arrhythmia and late RV dysfunction).

The above date from different studies can be explained as following that there are two points of discussion in the surgical therapy of children with TOF/APV connected to the administration of dilated relating to the lungs and to the surgical technique of RVOT reconstruction. Some groups of the surgeon have recommended various palliative maneuvers to completely remove the compression effect of the dilated pulmonary on the airway (8).

There is no doubt that reduction pulmonary arterioplasty should be applied for all patients but the procedure is individualized for each patient during surgery based on the degree of aneurysmal dilatation and the degree of airway compression. Another area of controversy is the management of the pulmonary valve and the surgical technique for RVOT reconstruction (8).

All cases were weaned from cardiopulmonary bypass on a low dose of inotropic support in the form of Milrinone and adrenaline which was smoothly withdrawn in ICU with a mean duration of ICU stay was  $4.6 \pm 4.3$  days (ranged from 3 to 22 days) which was similar to other studies by Alsoufi et al. (8), Hu et al. (14) and Shahid et al. (7) with mean duration of ICU stay were 4, 4 and 3 days respectively.

The mortality was one case representing 5 % due to unsatisfactory relief of respiratory distress due to persistent bronchomalacia caused by long term compression of the tracheobronchial tree resulted in prolonged ventilation and ventilator associated pneumonia ended by death from sepsis. Mortality in other studies ranged from 5% by Talwar et al. (5) to 10 % by Alsoufi et al. (8) to ventilator associated pneumonia and myocardial dysfunction.

#### **Conclusion and Recommendations**

Bovine jugular vein valve conduit (contegra) is the maneuver of choice in the reconstruction of RVOT in patients with TOF/APV. Valve repair is better than valve less repair in RVOT reconstruction in patients with TOF/APV as the elimination of postoperative pulmonary regurge. Further studies with a larger sample size to obtain statistically significantresults.

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### Ethical clearance:

Cleared by the ethical committee of cardiothoracic surgery department faculty of medicine Cairo University.

#### No Conflict of Interest

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