

# Surgical Repair of TOF: Outcome of Bicuspid Pulmonary Valve Reconstruction with Trans Annular Patch - A Single Cardiac Hospital Experience in Bangladesh

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## Authors' contributions

This work was carried out in collaboration among all authors. Author MR designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors SMSI, STA, MAR, MIK, AAS and NG managed the analyses of the study. Author NS managed the literature searches. All authors read and approved the final manuscript.

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## ABSTRACT

**Background and Objectives:** Basic components for Intra-cardiac repair of TOF are the same in every cardiac center except the timing which varies according to the capability of the team. Free PR is inevitable in case of a trans-annular patch which ultimately leads to RV dilatation, dysfunction, arrhythmia and failure with time. There is an ongoing endeavor to reconstruct the RVOT with the aim to avoid free PR in physiological repair. If RVOT reconstruction is done, RV dysfunction is absent or delayed which can avoid further re intervention. Monocuspid reconstruction of PV is commonly practiced in many centers but its long term outcome is poor though it helps to achieve a less stormy ICU course. Modified monocusp or bicuspid PV

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reconstruction is adopted in many centers using 0.1 mm PTFE membrane. We represented the results of bicuspid PV reconstruction using a 0.1mm PTFE patch in repair of TOF with a trans-annular patch.

**Methodology:** A total, 42 patients diagnosed as TOF were treated from January 2016 to October 2020. Age ranged from 18 months to 35 years, weighing 10 kg to 70 kg. 38 patients had TOF, 4 had DORV with PS. The trans-annular patch was followed by implantation of a 0.1-mm PTFE modified monocusp valve using posterior fixation.

**Results:** Among total 28 male and 14 females. Mean age  $9.58 \pm 5.6$  yrs and BSA  $0.90 \pm 0.34$  kg/m<sup>2</sup>. Bypass time was  $187 \pm 31$  min, cross-clamp time  $123.63 \pm 25.42$  min. Out of 42 patients, 9(21.43%) had a PV gradient 0-10 mm/Hg, 24(57.14%) had 10-20 mm/Hg, and 9(21.43%) had >20 mm/Hg in the post-operative echocardiogram. PR gradient was trivial in 7(16.67%), mild in 31(73.1%), moderate in 4(9.52%) patients. First, a follow-up echocardiogram revealed PR gradient remained trivial in 4(10%) patients, augmented from trivial to mild in 3(7.5%) and mild to moderate in 05(12.5%) patients. It remained moderate in 03(7.5%). There was no severe PR. ICU stay was  $89 \pm 32.6$  hours and mean hospital stay  $11.48 \pm 2.1$  days.

**Conclusions:** Initial results using a trans-annular patch with a modified monocusp valve to repair the RV outflow tract in cases of tetralogy of Fallot were promising. There were only a slight pressure gradient and mild regurgitation in most of the cases. A medium or long-term follow-up study is required to confirm these findings and compare them with results obtained using other techniques.

*Keywords: Tetralogy of fallot; trans-annular patch; pulmonary valve gradient; regurgitation.*

## 1. INTRODUCTION

It has been more than five decades since the first total surgical correction of Tetralogy of Fallot (TOF) was done. Outflow tract enlargement is a basic concept in surgical correction of heart diseases with Right ventricular outflow tract obstruction (RVOTO) like TOF [1,2]. In patients with borderline Pulmonic Valve (PV) annulus, trans-annular patch enlargement of RVOT is mandatory which ends up with inevitable free pulmonary regurgitation and chronic Right ventricular (RV) volume overload. Ventriculotomy, pulmonary insufficiency with chronic RV volume overload, leads to progressive RV dilatation, dysfunction and arrhythmias associated with impaired functional capacity in the long term [3]. So most surgeon has an attempt to reconstruct the of RVOT to avoid the long term complication & decreasing the probability of early & late interventions. This reconstruction is achieved with prosthetic valves, homografts or xenografts in pulmonary position [4-11]. Due to tissue degeneration, subsequent stenosis & regurgitation can be expected over time among these artificial valves. Monocusp reconstruction of the pulmonary valve is practiced for a long time but it became less popular due to the early development of pulmonary regurgitation though it provides good support in the early postoperative period [5,9]. To overcome this issue, implantation of an expanded poly tetra fluoro ethylene (PTFE)

bicuspid valve is an option that facilitates early recovery after surgery & also gives medium to long term benefits [4,7-10,12,13]. In our centre, we are also practicing the bicuspid pulmonary valve reconstruction using 0.1 mm PTFE patch in pulmonary position and we are following the system proposed by Nunn et al. [12].

## 2. METHODS AND MATERIALS

In total, 42 consecutive patients who needed enlargement of the right outflow tract with a trans annular patch (TAP) were treated between Jan 2016 and October 2020. Of these, 38 had TOF and 4 double outlets right ventricle (DORV) with PS. Four patients had previously undergone palliative treatment with a modified Blalock-Taussig shunt. The ages of patients ranged from 18 months to 35 years and weight from 10 kg to 70 kg. Pre-operative workup was common for all cases. Transthoracic echocardiogram and CT aortopulmonary angiogram were routine for all cases. CT scan was used for proper evaluation of main pulmonary arteries and branch PAs. Cardiac catheterization was done only for cases with MAPCA's for evaluation and coiling. Three patients required MAPCA coiling preoperatively. Pre-operative Mc Goon ratio and Nakata index were a very good guide for probable trans annular patch augmentation of RVOT. Moreover, this technique also implemented if post-operative RV: LV pressure ratio more than 0.5 and significant RVOT gradient (25 mmHg) at the level

of the pulmonary valve in cases where the pulmonary valve was preserved initially. After surgical correction, epicardial echocardiography was performed to determine infundibular morphology and the degree of pulmonary regurgitation and stenosis, classified as mild, moderate, or severe. The pressures were determined by direct puncture of the right ventricular infundibulum, right ventricle proper, and main pulmonary artery. All the patients under went echocardiography before discharge to determine the pulmonary gradient and the degree of pulmonary neovalvular regurgitation. TEE was not used initially as it was not available before 2020 in our centre.

Pulmonary atresia and major coronaries crossing RVOT cases were excluded from this study. Patients below 10 kg were not included as the long term efficacy of valve function is not clear among the patients with small pulmonary artery diameter.

## 2.1 Surgical Technique

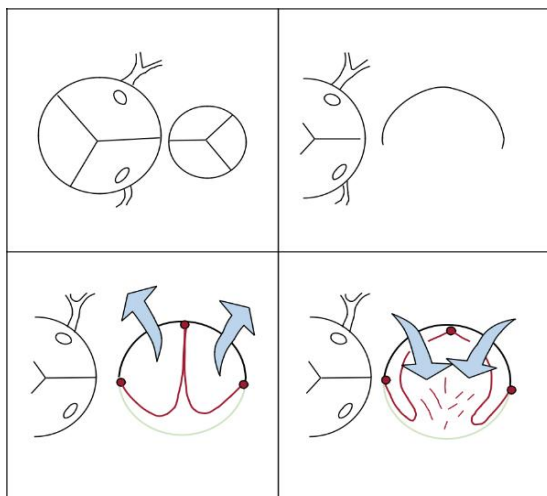
The surgical technique includes standard cardiopulmonary bypass. Mild hypothermia with bicaval cannulation and aortic cross clamping. Deaeration was facilitated by CO2 insufflation into the operative field. Following transatrial closure of the ventricular septal defect (VSD), the outflow tract was enlarged with a TAP (Fig. 1). The pulmonary neo valve was a 90°-120° semicircle of 0.1-mm PTFE membrane whose radius equaled the distance between the

commissure of the native pulmonary valve and the lower vertex of the ventriculotomy incision. Its fanlike shape is most characteristic and offers a very generous free edge compared to classic monocusp valves.

The central point of the curved free edge (circular) is sutured to the posterior side of the native pulmonary artery in the commissural plane. The vertex of the patch is tied to the vertex of the ventriculotomy incision and the two ends of the suture are used to join the straight sides of the patch to both edges of the ventriculotomy incision. Finally, the TAP (glutaraldehyde treated autologous pericardium or commercially available bovine pericardium) is fixed to the edges using an independent suture, thereby covering the pulmonary neo valve (Fig. 1). Both the pleurae left open with large bore drains. Two RV pacing wires were fixed with prolene sutures. Delnido cardioplegia solution used in all cases and repeated after 70 minutes. Milrinone used in every patient in the theatre and ICU. Overnight ventilation maintained in all cases.

## 3. RESULTS

Among the 42 patients, 28(66.67%) were male and 14(33.33%) were female. The mean age of the patients was 9.58±5.6 yrs and the mean BSA was 0.90±0.34 kg/m<sup>2</sup>. In respect of the blood group, 12 were O+ve, 1 was A-ve, 8 were A+ve, 1 was A-ve, 11 were B+ve, 3 were B-ve and AB+ve were 4. The mean total cardiopulmonary



A: Relative sizes of aortic and pulmonary valves in tetralogy of Fallot.

B: Pulmonary artery, open and flat.

C: Expanded polytetrafluoroethylene (PTFE, red) fixed at the central point and edges (in the shape of a 3) with a transannular patch (green) in systole (arrows, blue).

D: PTFE valve (red) in diastole (arrows, blue), moving toward the perimeter of the pulmonary neo artery (native artery shown in black and patch of pericardium shown in green).

**Fig. 1. Diagrammatic description of neo pulmonary valve design**

bypass time was 187±31 minutes and the mean aortic occlusion time was 123.63±25.42 minutes. The mean total operation time was 6.06±0.65 hours. Out of 42 patients, 9(21.43%) had a PV gradient 0-10 mm/Hg, 24(57.14%) had 10-20 mm/Hg, and 9(21.43%) had >20 mm/Hg in the post-operative echocardiogram. PR gradient was trivial in 7(16.67%), mild in 31(73.1%), moderate in 4(9.52%) patients. A follow-up echocardiogram revealed PR gradient remained trivial in 4 (10%) patients, augmented from trivial to mild in 3(7.5%), stationary to mild in 25(62.5%), and mild to moderate in 5(12.5%) patients. It remained moderate in 3(7.5%) patients.

**Table 1. Gradient across the reconstructed PV**

Gradient (mmHg)	Number
0-10	9(21.43%)
10-20	24(57.14%)
>20	9(21.43%)

*This Table 1 represents the gradient across the pulmonary valve after surgery*

2(4.76%) patients required peritoneal dialysis in the ICU. Between them, one expired on the 3rd POD and another rescued. The rescued patient required total of 10 cycles of peritoneal dialysis.

Re-exploration and reintubation were required in 2(4.76%) patients. Total 2(4.76%) patients developed low output syndrome which managed medically.

Neurological symptoms in the form of hemiplegia developed in 3(7.14%) patients which were improved later. The mean total ICU stay time was 89±32.6 hours and the mean total hospital stay was 11.48±2.1 days. Total two patients died in the whole series.

#### 4. DISCUSSION

TOF is a common CHD and most of the cardiac centers are practicing the repair of this lesion according to the capability of the team. The

outcome of TOF repair was not excellent in the early era of cardiac surgery. Staged surgery was a common practice in smaller children. Now a days, the results of repair are considered excellent irrespective of timing & surgical technique [3,4,14]. Currently, as a part of surgical procedure, trans-annular patch augmentation is randomly used in TOF repair. The use of trans-annular patches dramatically reduced the death but simultaneously it causes pulmonary insufficiency. After the repair of TOF, the physiology of RV changes. Before surgery, there was pressure overload in RV. After the relief of RVOTO, RV turns into a volume overloaded chamber. This change along with ventriculotomy usually leads to acute response early after surgery [3] This acute response and physiological changes after surgery is well tolerated in most of the patients but some patients develop right ventricular failure. Subsequent pathophysiological changes cause progressive RV dysfunction, long-term re-intervention & even sudden death.

To overcome this problem, the use of pulmonary neovalve in TOF correction has two benefits. Firstly, excellent ICU course and secondly, it reduces the rate of pulmonary insufficiency in the medium & long term. There are several techniques used for implantation of the PTFE valve in the pulmonary position. In our study we are presenting our experience by using the technique proposed by Nunn et al. In this technique, there is the flexibility of the size and shape of neovalve according to the need of the patient.

In the field of congenital heart surgery, a 0.1 mm PTFE membrane is widely used as a valve substitute in pulmonary valve position. It has good biocompatibility and its microporus structure is expected to impede cellular penetration & subsequent calcification. So, in our study, we have used a 0.1 mm PTFE patch. Freehand insertion of valves in the RV outlet does allow the valve to be readily tailored.

**Table 2. PR gradient**

Gradient	After surgery/During discharge	After 3 months
Trivial	7(16.67%)	4(10%)
Mild	31(73.1%)	Trivial to mild 3 (7.5%) Mild to mild 25 (62.5%)
Moderate	4 (9.52%)	Mild to moderate 5(12.5%) Moderate to moderate 3(7.5%)

*Table 2 demonstrates the quantification of pulmonary regurgitation after surgery and follow-up after 3 months*

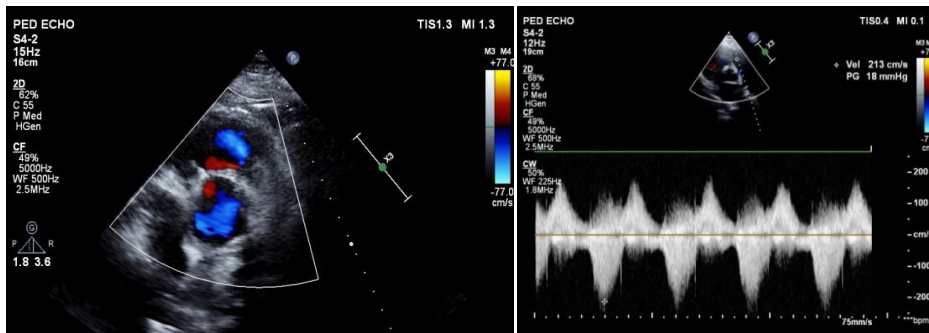


Fig. 3 depicts echocardiogram finding of reconstructed PV with minimum gradients across the neo valve

Fig. 2. Echocardiogram after PV reconstruction

Optimization of the closure mechanism is mandatory to achieve the optimum outcome from this neovalve. Here we fix the central point of the curved edge to the commissural plane to get optimum closure during diastole. Thus, the minimum radius of the neovalve should be equal to the distance between this plane, which is immediately below the pulmonary bifurcation and the vertex of the ventriculotomy incision. The calculation of the chord and consequent angle of the circular sector remains a matter of debate. Simple trigonometric formulas can be applied to obtain the final diameter after placement of the TAP. A circular sector with an angle close to 120° showed good outcomes in our series and others. As the free edge is kept generous, it aroused a question, whether it will create an obstruction to outflow. But, this did not occur due to the elasticity of the extremely thin material used (0.1 mm). Moreover, the material is so thin that oral platelet aggregation inhibitors were not required [12,13].

#### 4.1 How the Valve Works

The distal fixation of the neovalve takes the shape of a three or double-arched vault. Its operation resembling that of a bileaflet prosthesis with anteroposterior orientation. It is specifically the bileaflet configuration that halves the time it takes for the free edge to move over the perimeter of the pulmonary artery compared to the classic monocusp valves. This mechanism optimizes the opening and closing of the neovalve in systole and diastole, respectively (Fig. 1) [12].

Prevention of valve incompetence is the major challenge in hand sewn pulmonary valves, so the shape and placement of the free edge of the PV leaflet carries an important role. If we place the free edge as distal as possible in the main pulmonary artery, it will increase the competence

of the valve without prolapse. Leaflet area is also important and the addition of a fixation suture at the free edge of the leaflet posteriorly increases the leaflet area. If we look at other advantages, it will reduce the wall stress in the leaflet, forces the free edge to coapt without prolapse, and decreases the time it takes the two halves of the free edge to move from fully closed to fully open positions. It also allows a greater degree of over correction in size in the RV outlet because the valve can be crafted to fill any outlet. The hinge point in the leaflets changes as the two leaflets move from fully open to fully closed position. It may prevent a buildup of fibrinous material at a hinge point [4] It was thought that, oversizing of the valve could reduce the volume delivered to the pulmonary arteries by each RV systole. That volume is added to the pulmonary flow for that systole and returns from there to the pulmonary arterial side of the valve when it closes. This is how the RV systolic volume is delivered to the pulmonary arterial tree.

During echocardiographic there is some regurgitation is observed at the origin of the pulmonary branches instead of the infundibulum. Echocardiography may overestimate the degree of regurgitation in these patients but this is beyond the aims of this study.

It is always possible to implant an oversized pulmonary neovalve according to the need of the patients. Larger sized valves were associated with a longer duration of valvular competence. In cases of post-procedural pulmonary regurgitation in young adults, prosthetic pulmonary valve should be considered [12,13,14]. Study by Nunn et al demonstrated excellent late results in 93% and only trivial or mild pulmonary regurgitation compared to 50% in the Indianapolis group [10]. In our series, regurgitation was also mild in most of the cases (more than 90%). It is observed in



Post-operative picture showing Computed Tomographic image of PV reconstruction. Well dilated RVOT and line of Neo pulmonary valve.

**Fig. 3. Post-operative CT aortopulmonary angiogram**

many studies that, the bicuspid PTFE valves in the pulmonary position is durable in the medium term, could maintain its competency in the follow-up period, and not resulted in significant obstruction in the RV outlet [12].

## 5. CONCLUSIONS

Bicuspid pulmonary valve reconstructed with 0.1 mm PTFE patch is free of calcification and there is structural deterioration. Monocusp valves were incompetent in almost all the cases during the follow-up period. On the contrary bicuspid valve with a 0.1mm, PTFE membrane retained its competency in 93% of cases. It is also simple and replicable. The initial results are promising. Only mild regurgitation and a slight pressure gradient were observed during the follow-up period. A medium or long-term follow-up study is required to acknowledge these findings. A comparative study with other techniques of RVOT reconstruction is required to ensure its efficacy in the long term.

## CONSENT AND ETHICAL APPROVAL

As per international standard or university standard guideline patients consent and ethical approval has been collected and preserved by the authors.

## COMPETING INTERESTS

Authors have declared that no competing interests exist.

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