

ORIGINAL ARTICLE

Surgical Outcome of Right Ventricular Outflow Tract Reconstruction Using Bicuspid Pulmonary Valve in Tetralogy of Fallot Repair: A Single Centre Experience

Mohammad Rokonujjaman¹, SM Shaheedul Islam², Nawshin Siraj³, Nusrat Ghafoor⁴, Syed Tanvir Ahmad⁵, Md. Atiqur Rahman⁶, Md. Ibrahim Khalilullah⁷, Abdullah-Al- Shoyeb⁸, Mahfuza Begum⁹, Md. Golam Saklayen¹⁰

Abstract

Background: Tetralogy of Fallot (TOF) is one of the most common congenital cardiac defect. In patients with small PV annulus, it has to be augmented to certain diameter by cutting annulus. In these cases, transannular patch is used free PR is inevitable. Free PR with transannular patch ultimately leads to RV dilatation, dysfunction, arrhythmia and failure with time. 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 reconstruction is a good choice where 0.1mm PTFE patch is used.

Objectives: We are presenting the results of bicuspid PV reconstruction using a 0.1mm PTFE patch as a method of RVOT reconstruction in repair of TOF with transannular patch.

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

Results: Among total patients 28 were male and 14 were female. Mean age 9.58 ± 5.6 yrs. Bypass time was 187 ± 31 min, cross-clamp time 123.63 ± 25.42 min. Out of 42 patients, 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 no significant deterioration of PR gradient. ICU stay was 89 ± 32.6 hours and mean hospital stay 11.48 ± 2.1 days.

Conclusion: Initial results using a transannular patch with a modified monocusp valve to repair the outflow tract in cases of Tetralogy of Fallot were excellent. There were only a slight pressure gradient and mild regurgitation in most of the cases.

Keywords: Tetralogy of Fallot, transannular patch, pulmonary valve gradient, regurgitation.

1. Associate Professor & Consultant, Cardiac Surgery, Ibrahim Cardiac Hospital & Research Institute, Dhaka.
2. Associate Professor & Consultant, Cardiac Surgery, Ibrahim Cardiac Hospital & Research Institute, Dhaka.
3. Associate Professor & Sr. Consultant, Radiology & Imaging, Ibrahim Cardiac Hospital & Research Institute, Dhaka.
4. Associate Professor & Consultant, Radiology & Imaging, Ibrahim Cardiac Hospital & Research Institute, Dhaka.
5. Assistant Professor & Associate Consultant, Cardiac surgery, Ibrahim Cardiac Hospital & Research Institute, Dhaka.
6. Registrar & Specialist, Cardiac Surgery, Ibrahim Cardiac Hospital & Research Institute, Dhaka.
7. Assistant Professor & Associate Consultant, Cardiac Anesthesiology, Ibrahim Cardiac Hospital & Research Institute, Dhaka.
8. Registrar & Specialist, Cardiac Surgery, Ibrahim Cardiac Hospital & Research Institute, Dhaka.
9. Registrar & Specialist, Cardiac Surgery, Ibrahim Cardiac Hospital & Research Institute, Dhaka.
10. Assistant Registrar, Cardiac Surgery, Ibrahim Cardiac Hospital & Research Institute, Dhaka.

Correspondence to: Dr. Mohammad Rokonujjaman, Associate Professor & Consultant, Department of Cardiac Surgery, Ibrahim Cardiac Hospital & Research Institute, Dhaka, Bangladesh. Cell: 01711311200, Email: drselim74@gmail.com

Received: 1 December 2020; **Accepted:** 23 December 2020

Introduction

It has been more than five decades since the first total surgical correction of Tetralogy of Fallot (TOF) done. Treatment of this defect varies from MBT shunt to total repair. Universally the choice and outcome of repair depends on the age, body weight and complexity of the lesion. But the maturity of the team largely matters to get optimum outcome with same characteristic of the patient. Outflow tract enlargement is a basic concept in surgical correction of heart diseases with Right ventricular outflow tract obstruction (RVOTO) like TOF. In patients with borderline PV annulus, transannular patch enlargement of RVOT ends up with inevitable free pulmonary regurgitation and chronic RV volume overload. Ventriculotomy, pulmonary insufficiency with chronic RV volume overload, leads to progressive RV dilatation and dysfunction and arrhythmias associated with impaired functional capacity in the long term.¹ So every surgeon has an attempt to reconstruct the of RVOT to avoid the long term complication and decreasing the probability of early and late interventions. This reconstruction can be done in many ways like using prosthetic valves, homografts or xenografts in pulmonary position.²⁻⁹ One of the important problem with biological and artificial valves are tissue degeneration, subsequent stenosis and regurgitation with time. Use of artificial valves has many limitations including anticoagulation, redo surgery and cost involvement. With this view, oncuspid 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.^{3,7} Moreover, for a country like Bangladesh, cost and management of artificial valve is a big deal. To overcome this issue, implantation of an expanded poly tetra fluoro ethylene (PTFE) bicuspid valve is a good option for the reconstruction of RVOT fater TOF surgery for the patients who require trans annular patch augmentation of PV annulus. This kind of reconstruction facilitates early recovery after surgery and also gives medium to long term benefits.^{2,5-8,10,11} 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 al¹⁰.

Materials and Methods

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 used 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 (as TEE was not available before 2019) to determine infundibulum 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.

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.

The surgical technique includes standard cardiopulmonary bypass. Mild hypothermia with bicavalcanulation 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 whose radius equaled the distance between the commissure of the native pulmonary valve and the lower vertex of the ventriculotomy incision. Its fanlike shape its most characteristic feature offers a very generous free edge compared to classic monocusp valves.

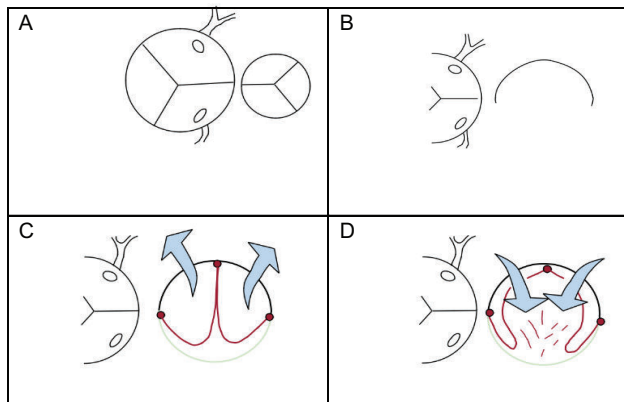


Fig 1 A: Relative sizes of aortic and pulmonary valves in tetralogy of Fallot. B: Pulmonary artery, open and flat. C: Expanded polytetrafluoroethylene (PTFE, red) fixed at the central point and edges (in the shape of a 3) with a transannular patch (green) in systole (arrows, blue). D: PTFE valve (red) 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).

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 which is shown diagrammatically in 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.

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/m². 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 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 (Table I). 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%), 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 II).

Table I	
Gradient across the reconstructed pulmonary valve	
Gradient (mmHg)	Number (%)
0-10	9(21.43)
10-20	24(57.14)
>20	9(21.43)

2(4.76%) patients required peritoneal dialysis in the ICU. Among 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 was managed medically.

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

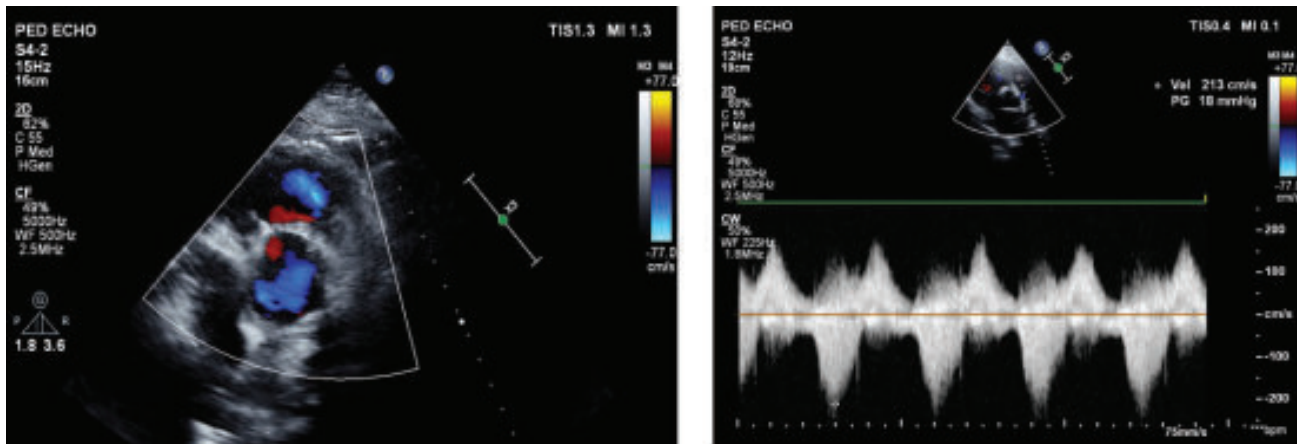


Fig 2 Echocardiogram finding of reconstructed PV with minimum gradients across the neo valve

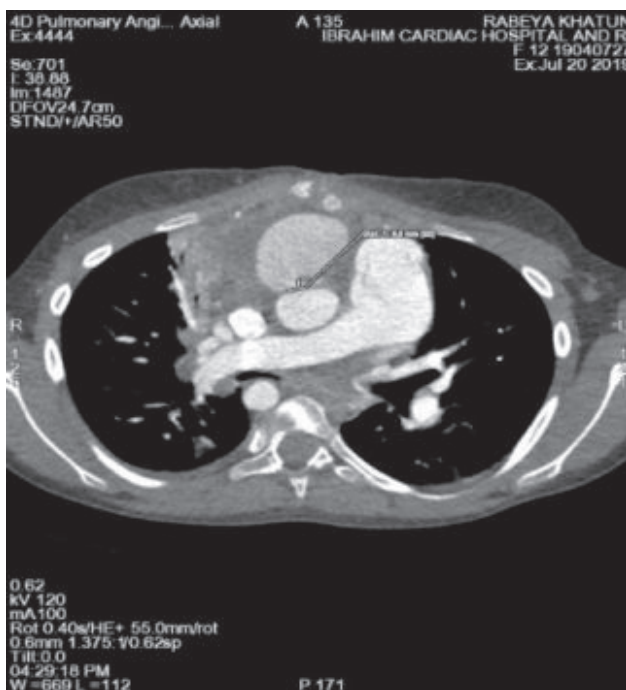


Fig 3: Post-operative computed tomographic image of PV reconstruction showing well dilated RVOT and line of neo pulmonary valve

Neurological symptoms in the form of hemiplegia developed in 3(7.14%) patient 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.

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. In the initial days, outcome of TOF repair was not excellent in maximum centres. Staged surgery was a common practice in smaller children and with narrow PV annulus. Now a days, the results of repair are considered excellent irrespective of timing and surgical technique.^{1,2,10} Transannular patch augmentation is randomly used in TOF repair where the PV annulus is small and post operative RV:LV pressure ratio is more than 0.5. The use of transannular patches dramatically reduced the death but of course at the cost of severe pulmonary insufficiency. After the repair of TOF, the physiology of RV changes. After the relief of RVOTO, RV turns into a volume overloaded chamber. This changes

along with ventriculotomy usually leads to acute response early after surgery.¹ This response is well tolerated in most patients but some patients develop right ventricular failure. This free PR causes progressive RV dysfunction, long term re intervention and even sudden death.

RVOT reconstruction in TOF correction has two benefits. Firstly, excellent ICU course and secondly, it reduces the rate of pulmonary insufficiency in the medium and long term. PTFE valve can be implanted in many ways in the pulmonary position. In our study we are presenting our experience by using the technique proposed by we can choose the size and shape of neovalve according to the need of the patient in this technique.

In the field of congenital heart surgery, a 0.1mm 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 and subsequent calcification. So, in our study, we used a 0.1mm PTFE patch. The material is thin enough to give a shadow similar to natural pulmonary valve which is found in post operative CT scan (Fig 3).

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.¹⁰ The total length of the patch, and subtraction amount of tissue taken up by the suture line. A circular sector with an angle close to 120° showed good outcomes in our series and others.¹⁰ As the free edge is kept generous, it aroused a question of 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.^{10,11}

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).¹⁰

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.² Blood in each RV systole, not only is ejected through the valve but also empties the volume of blood on the pulmonary arterial side of the leaflets. 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 echocardiogram, we could see some regurgitation 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. Post operative echocardiogram is depicted in Fig 2 which shows RVOT gradient and pulmonary regurgitation.

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.^{10,11} 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 many studies that, the bicuspid PTFE valves in the pulmonary position as a RVOT reconstruction technique 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.¹⁰

Conclusion

RVOT reconstruction in case TOF repair with TAP is essential to achieve optimum post operative outcome. Bicuspid valve or modified monocusp reconstruction of RVOT with a 0.1mm, PTFE membrane could retain its competency in 93% of cases which is simple and replicable. The initial results are appreciating. 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. It can be applied safely in TOF repair where transannular patch is used.

References

1. Anagnostopoulos P, Azakie A, Natarajan S, Alphonso N, Brook M, Karl T. Pulmonary valve cusp augmentation with autologous pericardium may improve early outcome for tetralogy of Fallot. *J Thorac Cardiovasc Surg* 2007;**133**:640-47.
2. Turrentine MW, McCarthy RP, Vijay P, McConnell KW, Brown JW. PTFE monocusp valve reconstruction of the right ventricular outflow tract. *Ann Thorac Surg* 2002;**73**:871-80.
3. Gundry SR, Razzouk AJ, Boskind JF, Bansal R, Bailey LL. Fate of the pericardial monocusp pulmonary valve for right ventricular outflow tract reconstruction. Early function, late failure without obstruction. *J Thorac Cardiovasc Surg* 1994;**107**:908-12.
4. Roughneen PT, DeLeon SY, Parvathaneni S, Cett F, Eidem B, Vitullo DA. The pericardial membrane pulmonary monocusp: surgical technique and early results. *J Card Surg* 1999;**14**:370-74.
5. Yamagishi M, Kurosawa H. Outflow reconstruction of tetralogy of fallot using a Gore-Tex valve. *Ann Thorac Surg* 1993;**56**:1414-16.
6. Iemura J, Oku H, Otaki M, Kitayama H. Expanded polytetrafluoroethylene monocuspid valve for right ventricular outflow tract reconstruction. *J Thorac Cardiovasc Surg* 2007;**133**:640-47.
7. Bigras JL, Boutin C, McCrindle BW, Rebevka IM. Short term effect of monocuspid valves on pulmonary insufficiency and clinical outcome after surgical repair of tetralogy of Fallot. *J Thorac Cardiovasc Surg* 1996;**112**:33-37.
8. Bechtel JF, Lange PE, Sievers HH. Optimal size of a monocusp patch for reconstruction of a hypoplastic pulmonary root: an experimental study in pigs. *Eur J Cardiothorac Surg* 2005;**27**:807-14.
9. Koh M, Yagihara T, Uemura H, Kagisaki K, Hagino I, Ishizaka T, et al. Long term outcome of right ventricular outflow tract reconstruction using a handmade tri-leaflet conduit. *Eur J Cardiothorac Surg* 2005;**27**:807-14.
10. Nunn GR, Bennetts J, Onikul E. Durability of hand-sewn valves in the right ventricular outlet. *J Thorac Cardiovasc Surg* 2008;**136**:290-96.
11. Quintessenza JA, Jacobs JP, Morell VO, Giroud JM, Boucek RJ. Initial experience with a bicuspid polytetrafluoroethylene pulmonary valve in children and adults: a new option for right ventricular outflow tract reconstruction. *Ann Thorac Surg* 2005;**79**:924-31.