

Surgical Repair of TOF: Outcome of Right Ventricular Outflow Tract Reconstruction Using Modified Monocusp at Pulmonary Valve Level- A Single Cardiac Hospital Experience in Bangladesh.

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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 reconstruction is adopted in many centers using 0.1mm PTFE membrane. We represented the results of Modified Monocusp 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 and 4 had DORV with PS. The trans-annular patch was followed by implantation of a 0.1-mm PTFE valve using posterior fixation.

Results: Among the total 42 patients, 28 were male and 14 were females. Mean age was 10.51 ± 7.49 yrs and BSA was 0.90 ± 0.34 kg/m². Mean total bypass time was 187 ± 31 min, cross-clamp time was 123.63 ± 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. 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 ± 32.6 hours and mean hospital stay 11.48 ± 2.1 days.

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Conclusions: Initial results using a transannular patch with a modified monocuspl 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: Pulmonary valve gradient, regurgitation, Tetralogy of Fallot, transannular patch.

Introduction:

Tetralogy of Fallot (TOF) is the commonest cyanotic congenital heart disease (CHD).¹ It has been more than five decades since the first total surgical correction of Tetralogy of Fallot done.² 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 pulmonary valve (PV) annulus, trans annular patch enlargement of right ventricular outflow tract (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 As there will be tissue degeneration, subsequent stenosis & regurgitation can be expected over time among these artificial valves. Monocuspid 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) modified monocuspl 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 modified monocuspl pulmonary valve reconstruction using 0.1 mm PTFE patch in pulmonary position according to the technique proposed by Nunn and his colleagues.¹²

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 pulmonary stenosis (PS). Four patients had previously undergone palliative treatment with a modified Blalock-Taussig (MBT) 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 pulmonary arteries (PA). Cardiac catheterization was performed for evaluation and coiling of major aorto pulmonary collateral arteries (MAPCA). Three patients required MAPCA coiling pre-operatively. Pre-operative Mc Goon ratio and Nakata index were a very good guide for probable trans annular patch augmentation of RVOT. Moreover, this technique was also implemented if post operative RV: LV pressure ratio was more than 0.5 and RVOT gradient at the level of the pulmonary valve was significant (>25 mmHg). 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. All the patients underwent 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 at 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.

Fig.1: Schematic presentation of neo valve design.

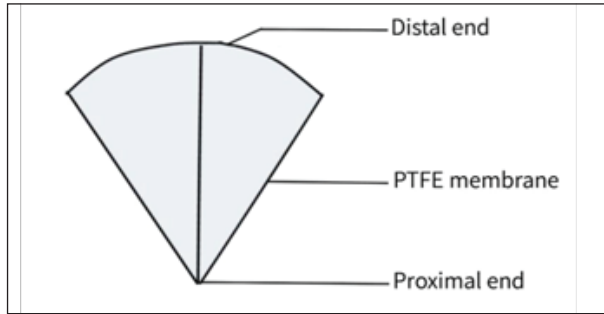


Fig.1A: Tailored PTFE membrane.

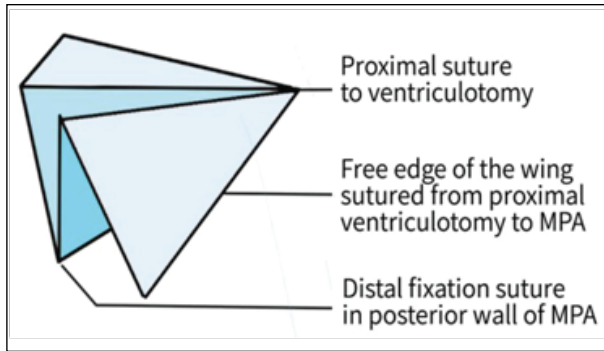


Fig.1B: Design of the PTFE membrane valve.
MPA=main pulmonary artery

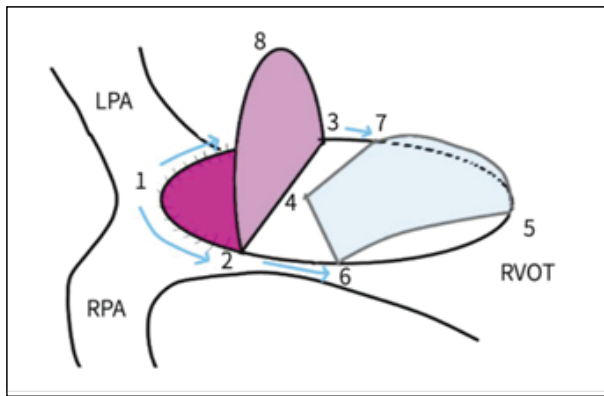


Fig.1C: Pericardial patch augmentation started at the distal end of the incision (point 1) and continued proximally on both sides. Distal fixation suture in the middle of the posterior wall of main pulmonary artery (point 4) 5 mm proximal to the right pulmonary artery origin. Proximal suture from the vertex of ventriculotomy to the proximal end of PTFE membrane (point 5). The free-edge angles of the wing fixed to the RVOT-MPA junction at pulmonary annulus (points 6 and 7). LPA=left pulmonary artery; MPA=main pulmonary artery; PTFE=polytetrafluoroethylene; RPA=right pulmonary artery; RVOT=right ventricular outflow tract

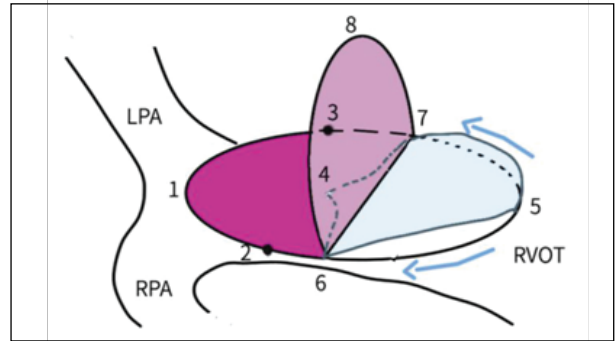


Fig.1D: Pericardial patch suturing continued proximally on both sides of the main pulmonary artery till pulmonary annulus (points 6 and 7). Pericardial patch (point 8), PTFE membrane (point 5) and infundibulotomy margin (starting from point 5) were sutured in a single layer in a continuous fashion from proximal to distal extent, starting from point 5 to point 6 and then from point 5 to point 7. LPA=left pulmonary artery; PTFE=polytetrafluoroethylene; RPA=right pulmonary artery; RVOT=right ventricular outflow tract

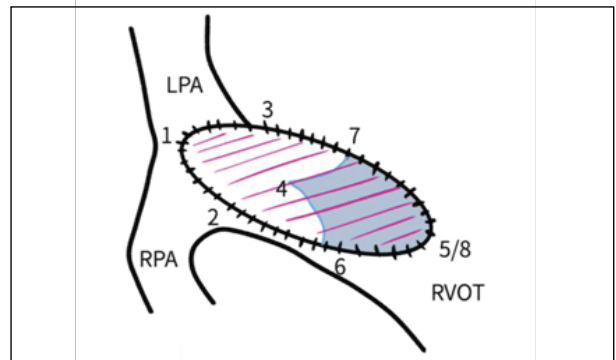


Fig.1E: At the level of the pulmonary annulus (points 6 and 7), the sutures were tied to the distal sutures used to fix the pericardial patch to MPA to complete the repair. LPA=left pulmonary artery; MPA=main pulmonary artery; RPA=right pulmonary artery; RVOT=right ventricular outflow tract

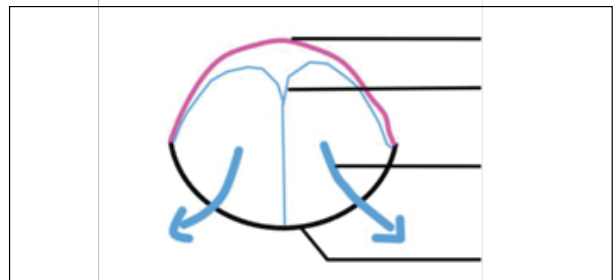


Fig.1F: Cross-sectional view of PTFE membrane valve showing blood flow during systole. MPA=main pulmonary artery; PTFE=polytetrafluoroethylene

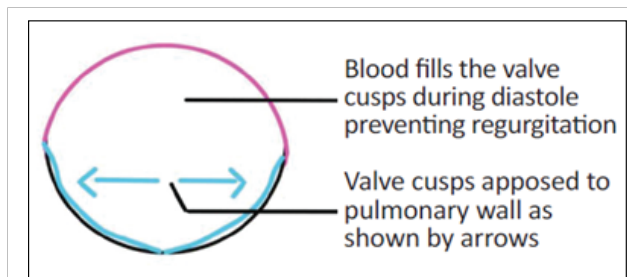


Fig.1G: Cross-sectional view of PTFE membrane valve during diastole. PTFE=polytetrafluoroethylene

Surgical Technique: 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) and reconstruction of PV with 0.1 mm PTFE patch, the outflow tract was enlarged with a trans annular patch(TAP) (Figure 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 is fixed to the edges using an independent suture, thereby covering the pulmonary neo valve (Figure 1). Per-operative view of modified monocusp pulmonary valve reconstruction is depicted in figure-2.

We had used glutaraldehyde treated autologous pericardium or commercially available bovine pericardium to cover the RVOT. 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 intensive care unit (ICU). Overnight ventilation maintained in all cases.

Fig.2: Per operative picture of neo pulmonary valve reconstruction.

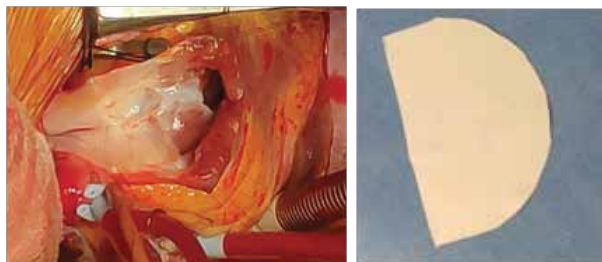


Fig.2A: Infundibulum opened up to distal MPA

Fig.2B: Tailored PTFE patch



Fig.2C: Anchoring of PTFE patch to the RVOT

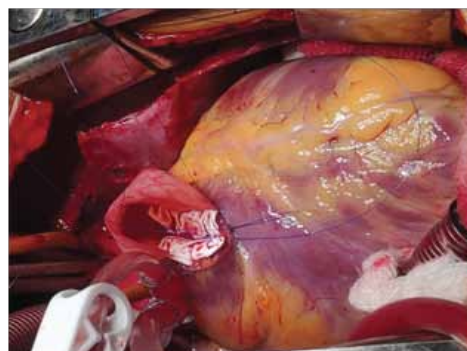


Fig.2D: Fixation of Trans-annular patch in RVOT covering the neo valve

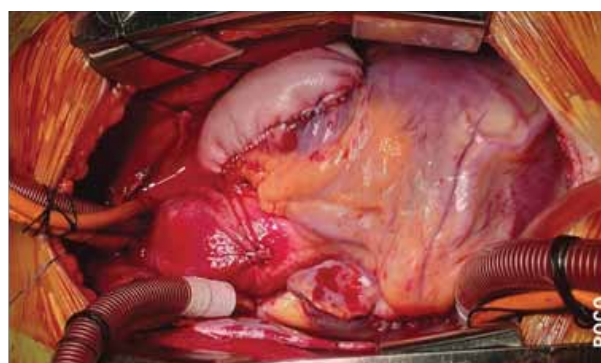


Fig.2E: Trans-annular patch is completed and heart is contracting.

How the valve works: The distal fixation of the neo valve 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 neo valve in systole and diastole, respectively (Figure-1 and 2).

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.

RESULT:

Among the 42 patients, 28(66.67%) were male and 14(33.33%) were female. The mean age of the patients was 10.51±7.49 yrs and the mean body surface area(BSA) was 0.90±0.34 kg/m². 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. Pulmonary regurgitation (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 post-operative day 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.

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*

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.

DISCUSSION:

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.^{3,4,12} Kim H and his colleagues reported that their mortality rate was only 0.3% after TOF repair.¹⁴ Currently, as a part of surgical procedure, transannular patch augmentation is randomly used in TOF repair where PV annulus is small. The use of transannular patches dramatically reduced the death but simultaneously it causes pulmonary insufficiency. After the repair of TOF converts pressure overloaded RV to volume loaded 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.¹⁵

Fig-3: Echocardiogram after PV reconstruction

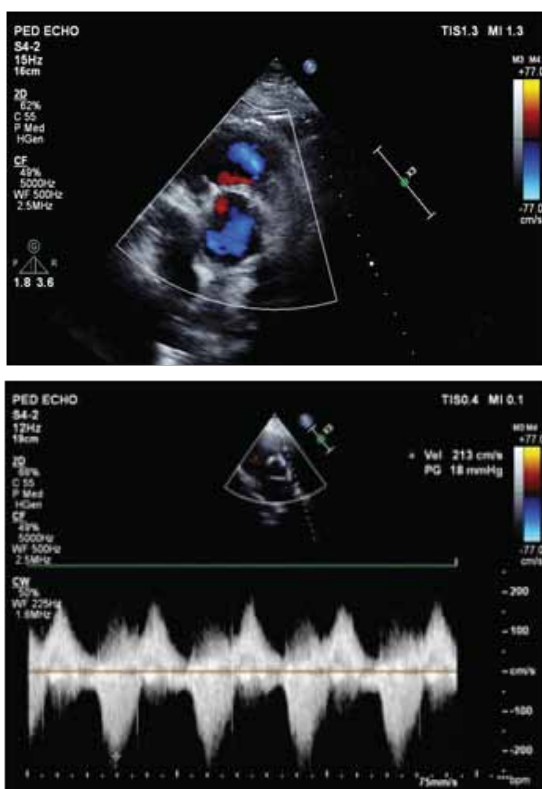


Fig 3 depicts echocardiogram finding of reconstructed PV with minimum gradients across the neo valve.

To encounter the pulmonary regurgitation (PR) after repair of tetralogy of Fallot along with trans annular patch (TAP), RVOT reconstruction is done in the form of bioprosthetic valves, homografts, and mechanical valves.¹⁹⁻²¹ Among these, bioprosthetic valves are probably the most widely used because they are readily available and do not require permanent anticoagulation therapy. However, durability of bioprosthetic valves in the pulmonary position is suboptimal as a result of structural valve deterioration (SVD), mainly in the form of leaflet calcification.¹⁶⁻²⁰ 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 described by Nunn and colleagues¹², Quintessenza and colleagues¹³, Cheul Lee and colleagues²¹ etc. In our study we are presenting our experience by using the technique proposed by Nunn.¹² In this technique, there is the flexibility of the size and shape of neovalve according to the need of the patient.

The 0.1-mm PTFE membrane has good biocompatibility, and its microporous structure is expected to impede cellular penetration and subsequent calcification, which is a common cause of valvular dysfunction.²² However, Turrentine and colleagues²³ noted that an explanted PTFE monocusp valve was found to be covered by thin fibrocollagenous tissue predominately made up of fibroblasts. This fibrous capsule contained extensive neovascularization without evidence of calcification. Conversely, Ando and Takahashi²⁴ reported that an explanted PTFE valve showed neither cellular infiltration nor calcification. Keeping all these controversies in mind, we have used a 0.1mm PTFE patch for PV reconstruction in our study. Post operative CT image of PTFE valve is seen as negative shadow at the PV level which is thin like a native PV (Fig:4)

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.¹² 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.¹² 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}

Pulmonary regurgitation was the key variable in the study. In the study of Quintessenza and colleagues¹³, 42 out of 126 patients who received the 0.1 mm PTFE bicuspid valve and were followed up for three years, reported 28 patients (66%) with grade 3 (moderate) PR. Nunn and colleagues¹², in their follow-up of 25 patients over 2.7 years, showed 93% of the cases having mild pulmonary incompetence.

Gil-Jaurena and colleagues²⁵, in their follow-up of 21 patients with bicuspid PTFE valves, reported 19 (90%) patients with mild and 2 (10%) patients with moderate pulmonary incompetence at discharge. Sasson et al.²⁶, in their follow-up of 30 patients with monocusp implantation over seven months to five years reported mild PR in 62.9%, moderate PR in 22.3% and severe PR in 14.8% cases. Brown et al.²⁷ showed midterm results obtained one year after PTFE monocusp valve insertion; the trace-to-mild degree of PI was detected in 60% of all patients, with moderate-to severe PR in only 13%. Rawat S and colleagues²⁸ showed, PR was absent in six (40%), trivial in one (7%) and mild in eight (53%) patients at six months of follow-up. None of the patients had moderate or severe pulmonary incompetence over the six-month follow-up. In our study there was no transformation to severe PR and most of the patients were in mild PR stage.

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 In our series, regurgitation was also mild in most of the cases (more than 90%). Echocardiographic view of post-operative RVOT gradient after PV reconstruction is depicted in figure-3.

It is observed in many studies that, the modified monocusp 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

Figure-4: Post-operative CT aortopulmonary angiogram



Post-operative picture showing Computed Tomographic image of PA reconstruction.

Well dilated RVOT and line of Neo pulmonary valve

CONCLUSIONS

We found that, bicuspid pulmonary valve using 0.1 mm PTFE membrane is inexpensive, feasible, easy to construct with simple learning curve. These valves show excellent pulmonary competence and does not escalate the RVOT gradient over the short-term follow-up. There is immediate relief from PR. The effect of bicuspid PTFE membrane valves on RV function needs a long-term follow-up. However, this was a single-center study, which limits its generalizability, and also consist of a relatively small number of patients with short-term follow-up. A long-term follow-up study is required to confirm these findings and to compare them with the results obtained using other techniques.

Conflict of interest: We have no conflict of interest.

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