ORIGINAL ARTICLE

IMMEDIATE AND EARLY OUTCOME OF PULMONARY VALVE CUSP AUGMENTATION FOR REPAIR OF TETRALOGY OF FALLOT (TOF)

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ABSTRACT

Background: Different techniques have been used to reconstruct an unobstructed right ventricle to pulmonary artery tract with minimal pulmonary regurgitation.

Objectives: To determine the immediate and early outcome of pulmonary valve cusp augmentation for repair of tetralogy of Fallot (TOF)

Methods: A descriptive study of 36 cases of TOF repair done from July 2020 to December 2022 at Faisalabad Institute of cardiology (FIC). Autologous pericardium used to augment the pulmonary valve cusp to increase the size of pulmonary valve orifice. Patients were followed in immediate and early post operative period by doing echocardiography to observe the outcome including pulmonary valve regurgitation (PR) and right ventricular outflow tract obstruction (RVOTO)

Results: Median age was 12 years (4–21). Immediate Post repair echocardiography showed no PR in 77.8 % of patients (n=28) while 8 patients had mild PR (22.2%). Majority of patients (61.1%) had mild RVOT obstruction, 13 patients (36.1%) had moderate RVOT obstruction while one patient had severe RVOT obstruction. Mean gradient across RVOT was 36.72 (+/- 11.08). The data on most recent follow up showed no PR in 83.3% (n=30) patients, while 6 patients (16.7%) had mild pulmonary regurgitation. Mild RVOTO was seen in 47.2 % of patients (n=17), 50% (n=18) patients had moderate RVOTO while one patient had severe RVOTO. Mean RVOT gradient was 40.8 +/- 15.20. There was no statistically significant difference between immediate and at last follow up RVOT gradient (p-value = 0.119)

Conclusion: Augmentation of the pulmonary valve cusp in selective cases of TOF is a useful technique to avoid the need of transannular patch in significant number of cases

Keywords: Tetralogy of Fallot, right ventricular outflow tract, cusp augmentation, transannular.

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INTRODUCTION

Primary repair of tetralogy of Fallot (TOF) frequently requires division of the annulus to relieve the severe pulmonary stenosis and reconstruction of the right ventricular outflow tract with transannular patch[1]. This results in free pulmonary regurgitation (PR) leading to the significant immediate and long-term complications. The results of repair of TOF with a competent pulmonary valve comparing with transannular patch are better[2]. The ventricular function and survival are better with a competent pulmonary valve[3].

Transannular patch is unavoidable in those cases where the pulmonary stenosis is due to the severe hypoplastic

valve annulus[4]. Severe Pulmonary valve stenosis is frequently due to cusp tethering rather than commissural fusion, or it may be combination of both. The free edge of the cusp is considerably shorter than the diameter of the pulmonary trunk, which is already smaller than the required. So, the valve cannot open adequately, and the pulmonary trunk is pulled inward at the point of commissural attachment at the level of sinotubular junction. This results in localized narrowing and corseting of the trunk at distal valve level. Tethering is common in bicuspid valve but rare in tricuspid valve. Thickening of cusps further add in the obstruction. With significantly small free edge of the valve cusps, it is not possible to relief the obstruction without scarifying the pulmonary valve.

Different techniques have been used to reconstruct an unobstructed right ventricle to pulmonary artery tract with minimal pulmonary regurgitation[5]. Homograft[6], valve conduit[7,8], tissue or mechanical valve[9], pericardial or PTFE monocusp[10], PTFE bicuspid valve and recently tricuspid Ozaki pericardial valve[11,12,13] are the techniques in practice currently.

In those cases where the severe pulmonary stenosis is due to tethering of the pulmonary valve, having short free edge of the cusps, stenosis is relieved by augmentation of free edge of the one or two cusps by insertion of the pericardial patch in the center of the cusp from free edge of the cups to the annulus. The stenosis is relieved without crossing the annulus and competency of the pulmonary valve is also maintained.

The technique of pulmonary valve cusp augmentation for repair of TOF to relieve the stenosis and avoid PR has not been described widely in our part of the world and in this regard the data is scanty in Pakistan. In this study we described the technique of pulmonary valve cusp reconstruction and its immediate and early outcome with special consideration of pulmonary regurgitation and residual stenosis.

METHODS

This study was conducted at Faisalabad institute of cardiology from July 2020 to Dec 2022.The study included all patients who underwent primary repair of TOF requiring reconstruction of pulmonary valve cusp by a pericardial patch augmentation during the study period. All the study subjects were operated by the principal investigating surgeon. Patient who had pulmonary valve repair due to iatrogenic injury, or underwent transannular patch were excluded from the study. Patients who were operated for endocarditis or those patients where pulmonary valve reconstruction was performed with replacement of complete cusp with pericardial neo cusp were also excluded from study.

All patients had aorto- bicaval cannulation, cardiopulmonary bypass (CPB) with moderate hypothermia, ante-grade blood cardioplegia, transatrial, transpulmonary repair of tetralogy of fallot. The pulmonary valve was examined after pulmonary arteriotomy. If the free edge of the cusps were found to be significantly shorter, and it was realized that even after commissurotomy the valve orifice will not allow the required sizer or even 1-2 size smaller than the required, the pulmonary cusp (usually anterior) was incised in the middle upto the annular attachment. Then the annulus was measured with the sizer. If the size of the annulus was found to be acceptable (-2 to -3 z-score), the cusp was augmented with the pericardial patch. Before the augmentation of the cusp the RVOT resection was completed transatrially and transpulmonary. Ventricular septal defect (VSD) was closed transatrially in all cases with the Dacron patch by interrupted stitches. If there was infundibular hypoplasia the infundibulum was also patched with pericardium without crossing the annulus.

The pulmonary cusp was augmented with autologous pericardium in all cases on aortic cross clamp. The size of the patch was tailored by measuring the height of the pulmonary valve cusp. The width of the patch was calculated by measuring the total length of the free edge of valve cusps, and desired orifice of the valve (The length of the free edges of the pulmonary cusps should be equal to the circumference of the normal pulmonary artery size). The circumference of the desired pulmonary valve size calculated. The length of the free edges of both native cusps measured and this number is subtracted from the calculated circumference of the desired pulmonary valve size. This will be the width of the patch. Then the patch was trimmed in such a way that the height of the patch will be 1 cm higher than the measured height of the cusp to be augmented and the width is according to previous calculation. The stitching is started in the middle at annular level and continued on each side and tied at the top of the cusp avoiding stitches to continue on the free edge. Finally, ≥ 5mm of the pericardial patch should be hanging beyond the cusp level which helps in coaptation with another cusp. If the size of the patch is too wide to achieve the target which will result in prolapse of the cusp, then the posterior cusp was also augmented in the middle (dividing the calculated width of the patch in two equal halves). Pulmonary artery was also augmented with autologous pericardial patch as required.

The medical record including demographic data like age and gender (male/female) and clinical data as well as operative record of each patient was retrieved from dedicated hospital database and reviewed. For each patient we gathered data on the operative repair

including cardiopulmonary bypass time, aortic clamp time, description of the RVOT management, and additional surgical procedures performed. The postoperative course was then reviewed. Ventilation times, inotropic support, intensive care unit (ICU) stay, chest tube drainage, hospital stay and mortality was recorded from hospital database. Immediate and echocardiography on discharge, done by dedicated paediatric cardiologist of the hospital was reviewed to record the RVOT gradient and pulmonary regurgitation in each case. The patient echo data was also recorded for the same values on follow-up after surgery especially most recent echo on the conclusion of the study. Late complications, follow-up interventions, and reoperations were noted if any. Pulmonary insufficiency (PI) severity was graded in a similar fashion. Follow-up echo data was reviewed for RVOT gradient and the pulmonary regurgitation.

All data were analyzed with SPSS V-16. Quantitative variables with a normal distribution were expressed as the mean standard deviation. Variables without a normal distribution were expressed as median and range. Qualitative variables were expressed as frequency or percentage. Repeated measures ANOVA was applied to see the difference between immediate and at last follow up RVOT gradient. P-value ≤ 0.05 was taken as significant.

RESULTS

One hundred and thirty-four patients of tetralogy of Fallot were operated during the study period. Seven patients (5.2%) had transannular patch augmentation. A total of 36 patients had pulmonary valve cusp augmentation during repair and were analyzed. As regard gender of the study subjects, 66.6 % were male (n=24) while 33.3% female (n=12) with male to female ratio of 2:1. The base line demographic characteristics and operative data are summarized in Table 1.

Table1: Summary of demographic and procedural data of patients

Characteristics	Mean	Range
Age(Years)	12	4-21
Weight(Kilograms)	30	11-57
Height(centimeter)	134	112-156
Cardio-pulmonary-bypass-time	131	96-211
Cross-clamp time (minutes)	108	73-173

All patients who had cusp augmentation were having bicuspid pulmonary valve. Two patients had patch augmentation of both anterior and posterior cusp while rest of 34 patients had augmentation of anterior cusp of the pulmonary valve. Three patients underwent repair/plasty of branch pulmonary artery due to hypoplasia of the vessel. Table 2 shows the immediate Post operative ICU parameters which were monitored till discharge of the patients from hospital.

Table 2: Post operative ICU monitoring parameters of patients

ICU Parameters	Mean	Range
Ventilation duration (Hours)	4	2-9
Inotropes duration (Hours)	18	7-29
Chest drainage (ml)	636	270-1060
ICU stay (Hours)	48	24-98
Hospital stay (Days)	4.6	3.2-6

Not a single patient needed re-intubation after extubation from ventilator support. Chest re-opening was done in 3 patients (8.3%) due to excessive chest drainage. No operative mortality was observed during or immediate post operative period or in follow up.

Post repair echocardiography done on first post operative day to look for residual pulmonary valve stenosis, RVOT gradient, pulmonary regurgitation, residual VSD and tricuspid valve regurgitation. Similarly, Patients had echocardiography on follow-up serially. The Mean follow-up period was 12 +/- 4 months. The data on most recent follow up was recorded and analyzed for RVOT gradient and pulmonary regurgitation. Table 3 shows the Echocardiographic parameters in immediate post operative period and the most recent follow up Echocardiographic characteristics.

Table 3: Immediate Post operative and most recent follow up echocardiography parameters

Echocardiography parameters	Immediate Post operative Frequency (%)	Most recent Follow up Frequency (%)
Pulmonary regurgitation (PR)		
No PR	28 (77.8)	30 (83.3)
Mild PR	8 (22.2)	6 (16.7)
Moderate PR	0(0.0)	0 (0.0)
Severe PR	0 (0.0)	0(0.0)
RVOT Obstruction (RVOTO)*		
Mild	22 (61.1)	17 (47.2)
Moderate	13 (36.1)	18 (50)
Severe	1 (2.8)	1 (2.8)
RVOT Gradient	36.72 ±11.08	40.80 ± 15.20
Tricuspid Regurgitation (TR)		
Mild	18 (50)	5 (13.9)
Moderate	0 (0.0)	0 (0.0)

*Mild RVOT Obstruction <36 mm of Hg. Moderate RVOT obstruction. 36-64 mm Hg. Severe RVOT obstruction. >64 mm of Hg..

Progression of RVOT gradient from mild to moderate was observed in 9 patients (25%) on follow up Echocardiography while regression of RVOT gradient from moderate to mild was noted in 2 patients (5.5%) on follow up Echocardiography. One patient having severe RVOT obstruction in immediate post operative period regressed to moderate, and one patient having moderate RVOT obstruction progressed to severe RVOT obstruction. There was no statistically significant difference between immediate and at last follow up RVOT gradient (p-value = 0.119).

DISCUSSION

There are different techniques commonly practiced to maintain a competent right ventricular outflow tract, which reduces the immediate and late post operative complications and need for re-intervention[14]. Once the annulus of the pulmonary valve is divided, the PTFE/ pericardial mono-cusp, or bicuspid valve only provide initial benefit, but most of them will require re-intervention at later stage for pulmonary valve regurgitation[15,16]. Most of the present data describes >25% patients require division of the annulus with or without mono-cusp reconstruction[17]. While in our data out of 134 patients only 7 (5.2%) of the patient had division of the pulmonary valve annulus. Thus, augmentation of the cusp gives the possibility of RVOT reconstruction without requiring a transannular patch. Augmentation of the pulmonary valve cusp in selective cases avoids need for transannular patch. Our results are consistent with the studies, regarding ICU stay, ventilation time, inotropic support hospital stay and the mortality[18, 19], which is significantly low in our study as well. The objective of the repair was to preserve the annulus, with accepting even a little higher gradient. With the augmentation of the cusp the pulmonary regurgitation was mild only in 8 cases while 28 (77.8%) had no PR. With a follow-up of about more than a year there is no progress of pulmonary regurgitation, rather a few patients improved in follow-up.

The RVOT gradient was a major concern while trying to avoid transannular incision. It was obvious that we might have to accept somewhat higher gradients[20]. The immediate post-operative gradient was 36.7 +/- 11, which was still less than 0.5 of RV/LV in 34(94%) patients. On follow-up the RVOT gradient was increased on follow-up in 7 patients where it increased from mild to moderate RVOT obstruction. Although none of the patients required re-intervention but this needs to be followed for long term results regarding the RVOT gradient as well as regurgitation whether the patients may need intervention at later stages.

CONCLUSION

Tethering of pulmonary valve where the annulus of the pulmonary valve is normal but the effective orifice of the pulmonary valve at commissure level is significantly smaller than desired is managed by division the pulmonary valve and transannular patch. Augmentation of the pulmonary valve cusp in selective cases can be a useful technique to manage these cases. This will avoid the need of transannular patch in significant number of cases where we can have a competent pulmonary valve resulting in good postoperative outcome, and hopefully may reduce need for re-intervention in later life.

ETHICAL APPROVAL

The study was approved by the Ethical Review Committee of Faisalabad Institute of Cardiology, Faisalabad, vide Reference No. 15-2023/DME/FIC/FSD Dated 20.01.2023.

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AUTHOR'S CONTRIBUTIONS

ZRK: Principal author, designed the study, methodology and did data analysis and described, wrote introduction and discussion

ARM: Data collection, discussion writing, critical analysis

HG: Abstract writing, References and data collection