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**PROJECT REPORT**

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DM Cardiology*

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## DECLARATION

*I, Dr. Deepa S Kumar, hereby declare that the project in this book was undertaken by me under the supervision of the faculty, Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology.*

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# **TITLE**

EARLY AND ONE-YEAR OUTCOME AND PREDICTORS OF  
ADVERSE OUTCOME FOLLOWING MONOCUSP  
PULMONARY VALVE RECONSTRUCTION FOR PATIENTS  
WITH TETRALOGY OF FALLOT-A PROSPECTIVE  
OBSERVATIONAL STUDY

## *Introduction*

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## **INTRODUCTION**

Immediate and late post-operative outcome after intracardiac repair for tetralogy of Fallot (TOF) with no significant residual right ventricular outflow tract (RVOT) obstruction or ventricular septal defect (VSD) is governed by pulmonary regurgitation (PR) and right ventricular (RV) function. Surgical repair of TOF with small pulmonic valve annulus requires the placement of trans-annular patch, which inevitably results in pulmonary regurgitation. This results in sudden hemodynamic conversion of an obstructed, pressure loaded right ventricle to a volume-loaded RV. Pulmonary regurgitation leads to acute and late deterioration of RV systolic and diastolic function. One option is the use of valved conduits but their disadvantages are lack of durability, lack of growth, and valvular dysfunction. An effective alternative is the creation of a monocusp RVOT patch. Reconstruction of RVOT with monocusp pulmonary valve prevents pulmonary valve insufficiency in the immediate post-operative period and for a variable duration later on<sup>1</sup>. Despite longer cardiopulmonary bypass and ischemic times, it has been shown to reduce intensive care unit stay and decreases operative morbidity and mortality<sup>2</sup>.

Residual pulmonary insufficiency of milder grades following monocusp valve reconstruction progresses over a course of time. The pace of progression varies and is unpredictable<sup>3</sup>. The factors contributing to progression of pulmonary regurgitation are not clear. These presumed factors include fibrocollagenous incorporation of the monocusp valve, lack of proper frame for the valve, residual stenotic lesions in pulmonary vasculature, size of branch pulmonary arteries and mobility of the monocusp.

In this context we undertook this prospective observational study to assess the severity of pulmonary regurgitation and trans pulmonary valve gradient in the immediate post - operative period and one year after insertion of monocusp valve. We also attempted to find out predictors of progression of PR one year after surgery and to determine whether the progression is inexorable related to inherent properties and weakness of polytetrafluoroethylene (PTFE) monocusp valve or whether there are potentially correctable parameters which contribute to progression of PR after this surgery.

## *Aims of the Study*

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## **AIMS OF THE STUDY**

1. To assess the severity of pulmonary regurgitation and trans pulmonary valve gradient in the immediate post-operative period and one year after insertion of monocusp valve.
2. To find out anatomical substrates responsible for progression of PR.

## *Review of Literature*

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## **REVIEW OF LITERATURE**

Surgical repair of tetralogy of Fallot (TOF) with small pulmonic valve (PV) annulus requires the placement of trans-annular patch. The resultant pulmonary regurgitation (PR) lead to acute and late deterioration of right ventricular systolic and diastolic function<sup>4</sup>. It is established that pulmonary insufficiency is the most important factor that produces chronic RV dilation because of volume overload and results in reduction in RV ejection fraction late after surgical correction<sup>5,6</sup>. The surgical management of patients with tetralogy of Fallot (TOF) and significant right ventricular outflow tract (RVOT) obstruction at the valve level, who are not candidates for a valve-sparing repair, has historically been conducted in one of two ways: (1) transannular patch or (2) valved conduit insertion. The advantages of a transannular patch are that it relieves right ventricular (RV) hypertension immediately and the RVOT usually grows proportionally with the child. Reoperation for RVOT stenosis is generally uncommon. The disadvantage of the transannular patch is the sudden hemodynamic conversion of an obstructed, pressure loaded RV to a volume-loaded RV, which causes temporary and/or delayed RV dysfunction. The chronic volume overload

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of the RV and resultant ventricular dysfunction may necessitate late pulmonary valve insertion. One option is the use of valved conduit which yields initially a nearly competent pulmonary valve. Conduit insertion is particularly useful in patients who have peripheral unrepaired pulmonary stenosis or elevated pulmonary vascular resistance. The obvious disadvantages of currently available valved conduits are their lack of durability owing to shrinkage, lack of growth, and/or early valvular dysfunction.

An attractive alternative strategy for many years has been the creation of a monocusp RVOT patch, which has the potential advantage of abolishing pulmonary regurgitation and lacks the disadvantages of both a trans-annular patch and a homograft valve conduit in certain patient populations. . In 1967, Marchand introduced monocuspid homografts with excellent results<sup>7</sup>.

The monocusp has been shown, particularly in the immediate postoperative period, to prevent pulmonary valve insufficiency<sup>1</sup>. This may be associated with faster recovery of RV function, a lower central venous pressure, and less chest tube drainage. The construction of the monocusp is simple, very inexpensive, and reproducible. The potential

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disadvantage in comparison to insertion of a pulmonary valve or valved conduit is that, at least in some patients, there appears to be a faster progression to recurrent pulmonary valve insufficiency, although late stenosis is rarely, if ever, seen using this technique. The monocusp RVOT patch can be created with autologous or bovine pericardium<sup>8</sup>, allograft pulmonary valve cusp<sup>9</sup>, or the (off label) use of a polytetrafluoroethylene (PTFE) membrane<sup>2,10,11</sup>.

The reconstruction of the pulmonary valve depends on several factors: (1) the anatomic conditions of the pulmonary valve, which might be atretic, stenotic, or there are cases where the pulmonary valve is absent; and (2) the type of valved prosthesis used, such as monocuspid or bicuspid. Despite definite early patient improvement, all biological valve reports have within them a significant incidence of recurrent valvar insufficiency and/or obstruction<sup>12</sup>. A study of 36 patients utilizing homografts<sup>14</sup> and heterografts<sup>15</sup> for pulmonary valve replacement noted 9 of 34 patients developed moderate to severe PI and 17 of 34 patients developed significant obstruction within 80 month follow-up. In a similar study, the reported incidence of homograft insufficiency was 50% mild and 28% moderate to severe within a 4.9 years follow-up<sup>12</sup>. Recent

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evidence <sup>16</sup> suggests an immunologic basis for this early graft failure pattern.

In light of the above, interest shifted to a nonimmunologic, nondegenerating, and relatively durable material such as PTFE for pulmonary valve replacement <sup>2</sup>.

PTFE membrane is used to make vascular grafts, patches, membranes and stitches in pediatric cardiac surgery. Vascular grafts are used for construction of arterial shunts in neonates with complex cyanotic heart defects, for palliative reconstruction of interrupted aortic arch, for construction of extraanatomic aortic by-pass and total cavopulmonary connection. The PTFE patches are suitable for closure of septal defects, plastic reconstruction of the right and the left ventricular outflow tracts, correction of coarctation of the aorta and plastic repair of stenoses on the main pulmonary artery and its branches. PTFE stitches can be used for plastic reconstruction of atrioventricular valves. Membranes represent very good pericardial substitutes after complex surgeries with valve replacement or the use of a valved conduit, where reoperation must be suspected. In neonates and small children with signs of heart failure after surgery, it is possible to use PTFE membranes for transient wound cover when the chest is left opened.

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In 1993, Yamagishi and Kurosawa<sup>10</sup>. and Oku and colleagues<sup>11</sup> independently introduced 0.1-mm PTFE pericardial membrane as a readily available material with good characteristics for monocusp valve construction and compared it with other monocusp leaflet materials. Animal studies suggested that 0.1-mm PTFE functioned as well as, or better than, fresh or glutaraldehyde-treated pericardium for monocuspid valve construction<sup>17</sup>. 0.1-mm PTFE has demonstrated improved leaflet mobility and pliability and lower transvalvar gradients and does not allow cellular in-growth and thickening. Experience with 19 patients followed from 3 to 16.1 years utilizing a PTFE monocusp for RVOT reconstruction suggests reasonable long-term durability and freedom from degeneration<sup>18</sup>. A larger experience<sup>2</sup>, consisting of 115 patients using a PTFE monocusp for RVOT reconstruction, with follow-up from 6 months to 8 years, mean 2.6 years, demonstrated no stenosis, calcification, or embolization. There was, however, significant development of PI graded as moderate to severe after 35 months in this monocusp study. Thus, the PTFE monocusp valve has functioned very well in most patients for the first 2 to 3 years and up to 10 years in some patients, and the monocusp has not produced recurrent RVOT obstruction. Function of the monocusp persists out to 12 years, but some

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regurgitation develops as the RVOT grows<sup>2</sup>. It is inexpensive and easy to construct. Despite longer cardiopulmonary bypass and ischemic times, it reduces ICU stay and, in both TOF and VSD/PA patients, decreases operative morbidity and mortality.

Subsequently, an experimental study demonstrated superior function of a bicuspid over a monocuspid patch for reconstruction of a hypoplastic pulmonary root in pigs, with less pulmonary insufficiency in bicuspid versus monocuspid patches<sup>19</sup>. In Sao Paulo, Brazil, RVOT reconstruction in patients with tetralogy of Fallot was accomplished using a bicuspid porcine pulmonary prosthesis. This bicuspid porcine pulmonary prosthesis was found to be a simple, reliable procedure with good results in postoperative medium term follow-up<sup>20</sup>. In Japan, Yamagishi and Kurosawa<sup>10</sup> have created and implanted more than 200 bicuspid PTFE valves. With follow-up of up to 14 years, echocardiography demonstrates that 80% of the valves are still moving. In other centres also, most of the patients benefited with either trace or mild residual PI and nonsignificant outflow tract gradients. The NYHA symptomatic class improved in the vast majority of patients and RVEDD decreased significantly<sup>21</sup>.

## *Materials & Methods*

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## **MATERIALS AND METHODS**

Approval for the study was obtained from the institutional ethical committee. Consecutive patients who underwent intracardiac repair with trans-annular patch and monocuspid valve reconstruction of RVOT for tetralogy of Fallot for a six month period from May 1, 2011 were included in the study after obtaining informed consent. Anonymity of the patients was maintained during the recruitment and analysis. Trans-thoracic echocardiography was performed before the surgery and the anatomy was assessed in detail. The levels of obstruction in the RVOT and pulmonary valve and pulmonary artery and branches were determined. The dimensions of pulmonary annulus, main pulmonary artery and right and left pulmonary arteries just before the first branch were determined and McGoon index was calculated. Pulmonary annulus z scores were not analysed. Significant pulmonary artery stenosis was defined as an abrupt narrowing  $> 40\%$ <sup>22</sup> or as an acceleration of the peak flow velocity of at least 50% in one or both pulmonary artery branches compared with the main pulmonary artery (MPA)<sup>23</sup>. Presence and severity of pulmonary and tricuspid regurgitation were assessed. Right ventricular area in systole and diastole in apical four chamber view was

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obtained and right ventricular fractional area change (FAC) was determined. Wherever needed supplementary information was obtained with cardiac catheterization or magnetic resonance imaging (MRI).

### **Surgical Procedure**

The patients underwent intracardiac repair under cardiopulmonary bypass. Trans right atrial closure of VSD with 0.6mm PTFE patch was performed. MPA was opened longitudinally upto the annulus and pulmonary valvotomy done. Annulus was assessed by passing the required Hegar dilator and incision was extended across the annulus and resections of obstructive bands were done. All attempts were made to preserve the native valve leaflets.

The measurements for the monocusp were taken, the length of the monocusp was the distance from the apex of the RVOT incision to the pulmonary annulus level, the width at the free edge was equal to the circumference of the native annulus. A monocusp was fashioned from 0.1mm PTFE membrane taking care to avoid tapering the edge that is to be sutured to the RVOT. The patch was fixed to the apex of the RVOT incision and the edges were sutured to the muscle using 6-0 polypropylene in a continuous fashion, the free edge finally apposed to

the annulus. Appropriate Hegar dilator was passed to assess the adequacy of the opening. Two surgical hemostat clips were placed at the free edge so as to increase the weight at the region, we believe that this increases the mobility of the monocusp. A liberal transannular patch was placed so as to accommodate the monocusp. Post bypass, right ventricle systolic pressure to left ventricle systolic pressure ratio of  $< 0.7$  was accepted. Pulmonary regurgitation was assessed with intra-operative echo (trans-esophageal or epicardial echo).

Trans-thoracic echocardiography was performed within 5 days of the surgical procedure. Presence and severity of PR were assessed and quantified based on ratio of width of PR jet to width of RVOT. Severity was arbitrarily graded as mild (PR jet width  $< 25\%$  of RVOT width), moderate (PR jet width  $25\text{-}50\%$  of RVOT width) and severe (PR jet width  $> 50\%$  of RVOT width) <sup>24,25</sup>. Trans pulmonary gradient was assessed using continuous wave Doppler and quantified as mild ( $< 36$  mm Hg) and significant ( $> 36$  mm Hg) <sup>25</sup>. The presence and severity of residual branch pulmonary stenosis were quantified using pulse Doppler. The following dimensions were obtained vis, pulmonary annulus, main and branch pulmonary arteries, RV End Diastolic Area and RV End Systolic Area. Presence and severity of TR was assessed using area of

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the TR jet compared with RA area<sup>25</sup>. The mobility of the monocusp prosthesis was assessed visually and notes were made regarding preserved mobile native leaflets.

These patients were re-evaluated with trans-thoracic echocardiography one year after the surgery. Severity of PR and progression of PR were assessed. Mobility and calcification of the monocusp valve were looked for. Pulmonary artery and branches and RVOT were also assessed and RV function was assessed using FAC. Changes in electrocardiography in rhythm, PR interval, QRS duration, presence of arrhythmias were noted.

**Statistical methods:**

Analysis was performed using the Statistical Package for the Social Sciences (SPSS) software. Continuous variables are presented as mean +/- SD and significance of association analysed with paired t test. Categorical variables are presented as percentages and significance of association analysed with Fisher's exact test. p value of 0.05 or lower was considered statistically significant.

## *Results*



## **RESULTS**

30 patients underwent intracardiac repair of tetralogy of Fallot with transannular patch and monocusp valve reconstruction of RVOT during the study period. 24 patients underwent intracardiac repair without placement of a trans-annular patch during the same period.

### **Baseline characteristics**

Median age of the group who underwent monocusp valve reconstruction was 36.5 months (range 3 to 444 months). 17 patients were males. Mean McGoon index was 1.75 (SD 0.31). All of them had narrow pulmonary valve annulus and RVOT stenosis related to mal-alignment and hypertrophied muscle bundle. Additional narrowing of supra-valvar main pulmonary artery segment was noted in eight patients and 11 patients had stenosis of the branch pulmonary arteries. Mean QRS duration before surgery was 86.7 msec (SD 9.59). None had any previous shunt surgery prior to the intracardiac repair. One patient had severe aortic regurgitation due to bicuspid aortic valve (aortic valve repair was done concomitantly) and one had mitral valve prolapse with moderate

mitral regurgitation. One patient had a major aorto-pulmonary collateral which was treated with coil closure prior to surgery (Table 1).

**Table 1: Baseline characteristics and clinical data**

Age in months (median; range)	36.5 (3-444 months)
Males/Females (n)	17/13
QRS duration before surgery (mean; SD)	86.67 (9.59)
MC Goon Index (mean; SD)	1.76 (0.31)
Branch stenosis before surgery(n)	11
Supravalvar stenosis before surgery(n)	8
RV FAC before surgery(mean; SD)	0.51
Right arch	6

### **Immediate outcome**

There was no operative mortality. The mean cardiopulmonary bypass (CPB) time was 176 minutes (SD 93.5) and mean aortic cross-clamp (ACC) time was 114 minutes (SD 28.6). Mean CPB time for

intracardiac repair without monocusp reconstruction during this period was 148 minutes and mean ACC time was 95 minutes. Mean number of inotropes used per patient was 1.48 (SD 0.67) for a mean duration of 2.58 days (SD 0.97). The choice of inotrope was dobutamine +/- adrenaline.

The median duration of hospital stay was 8 days (range 5-44 days). None of the patients had residual ventricular septal defect. Two patients had right ventricular dysfunction in the immediate post-operative period. Both the patients had only mild pulmonary regurgitation. One patient was a three year old with significant malnutrition (weight of 8 kg) and severe cyanosis and recurrent spells prior to surgery, and the other patient had severe left pulmonary artery origin stenosis preoperatively which persisted after intracardiac repair. The right ventricular dysfunction of both patients resolved within a few days.

Mean RVOT gradient after surgery was 19.1 mm Hg (SD 8.45) with three patients having RVOT gradient more than 36 mm Hg. 18 patients had mild PR and 10 had moderate PR and two had severe PR (Table 2). Most of the patients had single jet of PR, with three patients

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having two jets of PR. Of the 12 patients with more than mild PR, one patient had pulmonary artery branch stenosis and one had supra-valvar main pulmonary artery stenosis. These patients were not noted to have smaller MPA diameter or any other unfavorable anatomy before surgery. The mean percentage of PR, defined as ratio of PR jet width to RVOT width, in the immediate post-operative period was 22.54% (SD 1.47). The monocusp valves in all the patients were noted to be freely mobile in the immediate post-operative echocardiograms. Mean QRS duration after surgery was 121.3 (SD 15.9).

**Table 2: Progression of PR after 1 year**

	<25 %	25-50 %	>50%
Immediate post-op (n)	18	10	2
1 year later (n)	2	18	10

**One year outcome:**

There was no mortality during the study period. None of the patients required reoperation during this period. Mean RVOT gradient one year after surgery was 16.8 (SD 8.06). At one year, pulmonary

regurgitation had progressed (Figures 1,2), with 10 patients having severe PR .Of the 18 patients who had mild pulmonary regurgitation in the post-operative period, 15 progressed to moderate and one progressed to severe regurgitation at one year. Of the 4 patients who had no regurgitation in the post-operative period, 3 developed mild and one developed moderate regurgitation The progression to severe regurgitation was more in the 10 patients who had moderate regurgitation in the post-operative period with 7 of them developing severe PR at one year. The two patients who had severe regurgitation in the post-operative period remained asymptomatic at one year, with no evidence of RV dysfunction at one year

Branch pulmonary artery stenosis was noted in eight patients and one had supraavalvar MPA stenosis. Only one patient had RVOT gradient more than 36 mm Hg. This patient had significant gradient (48 mm Hg) at the level of monocusp valve which was calcific and immobile. Mean QRS duration remained the same at one year. None had significant arrhythmia or conduction defect other than right bundle branch block (Table 3). During the follow up, one patient had culture negative infective endocarditis with large vegetation attached to the monocusp valve and was successfully treated with antibiotics (Figure 3).

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**Table 3: Variables at one year**

PS gradient (mean; SD)	16.83(8.06)
RV FAC (mean; SD)	0.51(0.08)
Branch stenosis (n)	8
Supravalvar MPA stenosis (n)	1
Presence of mobile, functioning monocusp valve (n)	18
Preserved and functioning native valve (n)	22
QRS duration (mean; SD)	121.00(19.18)

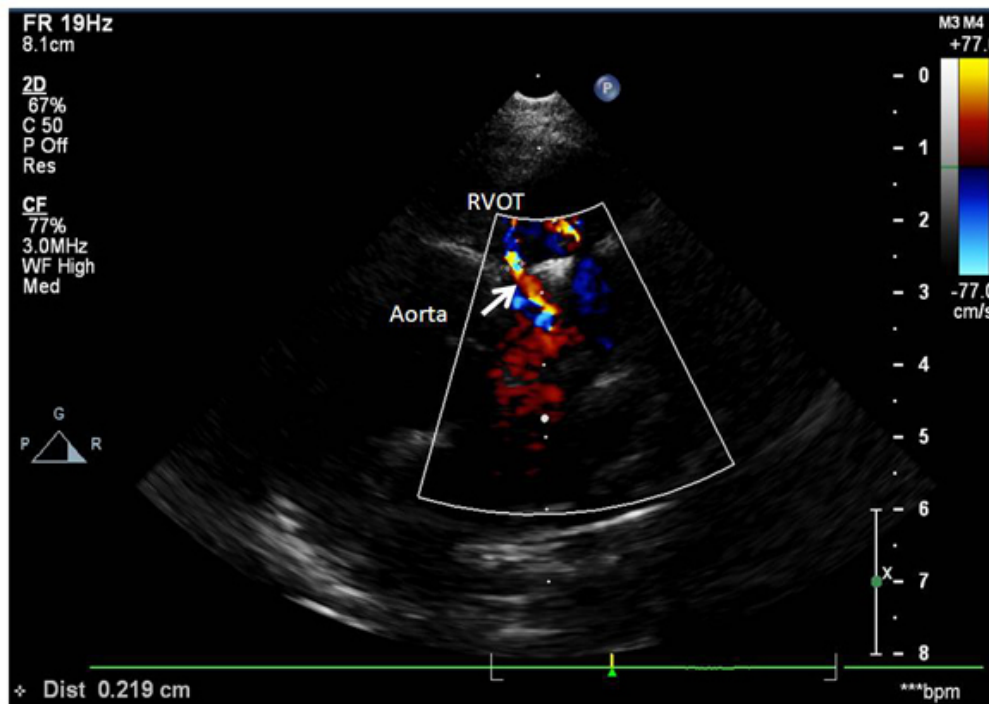


Figure 1: Parasternal short axis view demonstrating pulmonary regurgitation (arrow) at one year follow-up

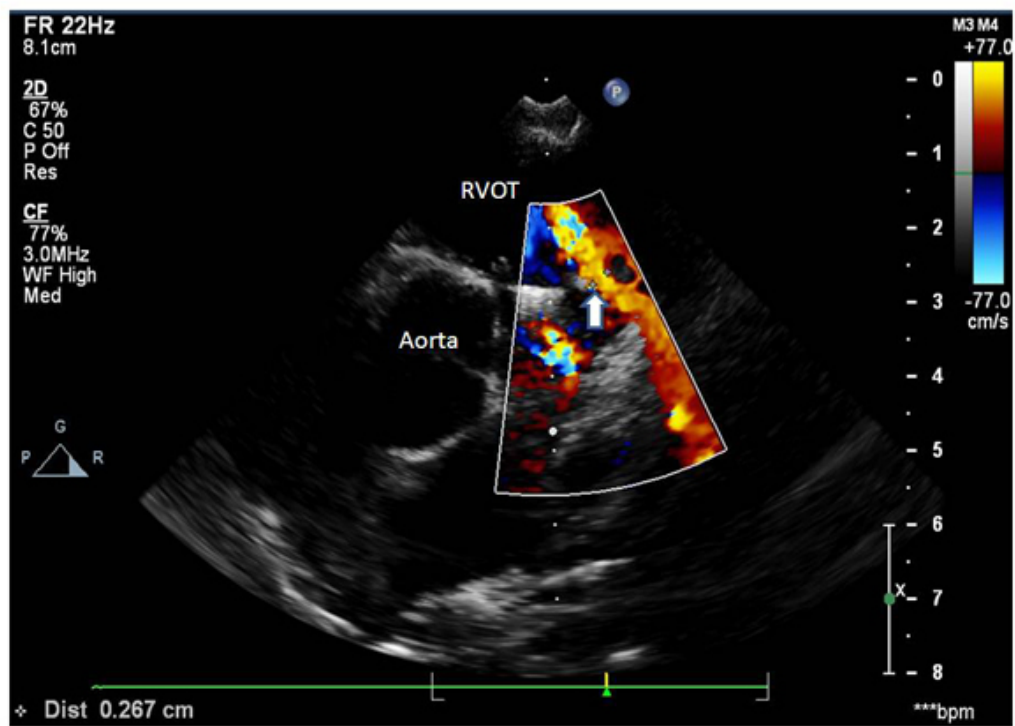


Figure 2 : Image from the same patient in figure 1 demonstrating a second jet of pulmonary regurgitation (arrow)

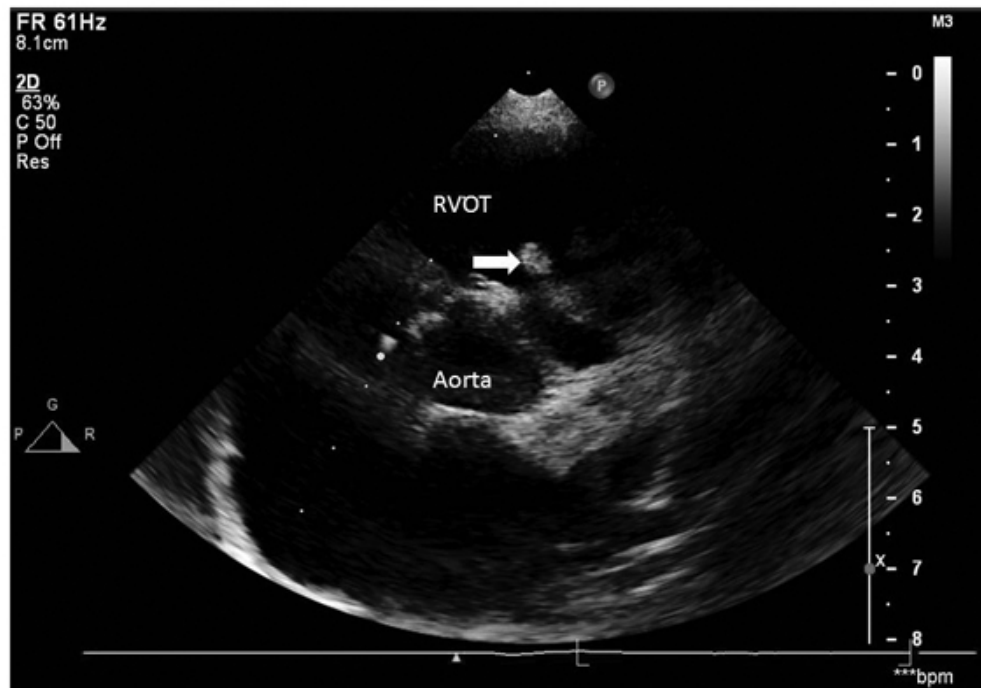


Figure 3 : Image demonstrating a vegetation (arrow) attached to the monocusp pulmonary valve

None of the variables like age, McGoon index, presence of pulmonary branch stenosis or supraaortic pulmonary stenosis, MPA diameter, mobility of monocusp valve and / or native valve were found to have any significant association with progression of PR. Patients with McGoon index  $< 1.5$  showed a trend toward more regurgitation in the immediate post-operative period, which was not statistically significant. It was also noted that patients with more residual RVOT gradient had lesser degree of PR though the values did not have statistical significance. The RV end-diastolic and end-systolic dimensions at one year did not show significant increase over the immediate post-operative values, indicating that significant volume overload has not occurred during the study period (Tables 4, 5).

<b>Table 4: Comparison of Percentage of PR immediately after surgery based on selected variables</b>				
		Percentage of PR immediately after surgery		p#
		<25 %	>= 25%	
		Number (%)	Number (%)	
Age	< 24months	5 (27.8)	3(25)	0.604
	>= 24	13(72.2)	9(75)	
	Mean $\pm$ SD	73.59 $\pm$ 104.5	98.92 $\pm$ 101.57	
McGoon Index	< 1.5	1(5.6)	4(33.3)	0.068
	>= 1.5	17(94.4)	8(66.7)	
	Mean $\pm$ SD	1.8 $\pm$ 0.27	1.69 $\pm$ 0.37	
Branch stenosis before surgery	Absence	11(61.1)	8(66.7)	0.534
	Presence	7(38.9)	4(33.3)	
Supraaortic stenosis before surgery	Absence	11(61.1)	11(91.7)	0.073
	Presence	7(38.9)	1(8.3)	

**Table 5: Comparison of percentage of PR at one year after surgery based on selected variables**

Variables		Percentage of PR one year after surgery		p#
		<50	>=50	
		Number (%)	Number (%)	
Age	< 24	6 (30)	2 (20)	0.45
	>= 24	14 (70)	8 (80)	
	Mean ± SD	89 ± 115.5	73.7 ± 73.4	
McGoon Index	< 1.5	3 (15)	2 (20)	0.55
	>= 1.5	17 (85)	8 (80)	
	Mean± SD	1.8 ± 0.3	1.7 ± 0.4	
Branch stenosis one year after surgery	Absence	15 (75)	7 (70)	0.55
	Presence	5 (25)	3 (30)	
Supravalvar stenosis one year after surgery	Absence	19 (95)	10 (100)	0.67
	Presence	1 (5)	0	
Mobile, functioning monocusp valve	Absence	7 (35)	5 (50)	0.34
	Presence	13 (65)	5 (50)	
Functioning native valve	Absence	6 (30)	2 (20)	0.45
	Presence	14 (70)	8 (80)	

## *Discussion*

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## **DISCUSSION**

We studied the effect of monocusp valve reconstruction following intracardiac repair with trans-annular patch in 30 patients with TOF. The patients were from a wide age range of 3 to 444 months, with a median age of 36.5 months. Placement of monocusp valve resulted in abolishing severe PR after surgery in vast majority of patients. Even though the mean CPB time has increased in these patients due to the additional procedure of reconstructing the RVOT with monocusp valve, it has resulted in favorable hemodynamics due to the reduction of PR. Only two patients had RV failure in the post-operative period, but both were unrelated to the degree of pulmonary regurgitation. We could not find any anatomical factor consistently associated with significant PR in the immediate post-operative period. At the end of one year, however, we found that regurgitation had progressed in most of the patients, with the progression to severe regurgitation being more in the patients who had moderate (7/10) regurgitation than those who had mild (1/18) regurgitation in the post-operative period. The patients who had severe PR were kept under close follow-up to decide on need for and optimal timing of pulmonary valve replacement.

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Fibrocollagenous incorporation of the monocusp leaflet is likely one cause of the observed progressive PR<sup>2,3</sup>. Differences in function and durability have also been proposed to be the result of technical challenges imposed by the outflow tract into which it is constructed<sup>2</sup>. Studies have reported that the efficacy of valve function depends on an optimal size of the patch: too large a patch will cause regurgitation, and too small a patch will result in stenosis<sup>26</sup>. It is also important to note that the monocusp valve is implanted without a supporting framework as in prosthetic heart valves and the lack of the frame contributes to early failure. However the role of other contributing factors like residual stenotic lesions in pulmonary vasculature, which add pressure overload onto the monocusp valve, size of branch pulmonary arteries (small pulmonary arteries results in higher central pulmonary artery pressure after surgery) and mobility of the monocusp in accelerated failure of monocusp valve is not clear.

A previous study on 19 patients followed from 3 to 16.1 years utilizing a PTFE monocusp for RVOT reconstruction had suggested reasonable long-term durability and freedom from degeneration<sup>18</sup>. A larger experience, consisting of 115 patients using a PTFE monocusp for RVOT reconstruction, with follow-up from six months to eight years,

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mean 2.6 years, demonstrated no stenosis, calcification, or embolization. There was, however, significant development of regurgitation graded as moderate to severe after 35 months<sup>10</sup>.

In our study, the monocusp valve was found to be calcific and relatively immobile in 12 of 30 patients. In an in vitro experiment where PTFE valves were implanted in the tricuspid valve position in 12 sheep, macroscopic calcification was detected in seven specimens and always involved the commissural areas. In most cases the PTFE cusps showed a grossly visible pannus that was thinner and less extensive than usually seen in bioprostheses. There was a complete lack of infiltrating cells within the cuspal material, but their results suggest that the valves have a moderate overall calcification rate<sup>27</sup>. In contradistinction to this study, Turrentine et al<sup>2</sup> found no calcification in the membrane but rather a well-vascularized layer of nonobstructive fibrocollagenous tissue incorporated within the PTFE with focal areas of endothelialization. This fibrous capsule was found to be continuous with the patch and valve and contained extensive neovascularisation without evidence of calcification. Function of the monocusp has been reported to persist out to 12 years, though our experience showed that calcification and loss of mobility was seen in a significant number even at one year. Even in the presence of

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functioning, mobile monocusp valve (18/30), five patients had significant regurgitation, indicating that monocusp valve did not effectively prevent progression of pulmonary regurgitation with advancement of time.

However it should be noted that RV dilation and RV dysfunction were not observed in any of our patients (except in 2 patients in the immediate post-operative period, which completely resolved prior to discharge) suggesting that abolishment of severe PR by the monocusp valve resulted in favorable outcome. The RV end-diastolic and end-systolic dimensions did not change significantly over one year, indicating that the monocusp valve offers good protection against early development of RV volume overload. RV Fractional area change (RV FAC) also remained fairly constant throughout the study period and none had evidence of RV dysfunction (defined as RV FAC <0.35) at one year.

Mean QRS duration, which is strongly associated with RV function and prognosis in TOF, also remained fairly constant during the study period, which maybe related to the relatively unchanged RV dimensions<sup>28,29</sup>.

We attempted to find predictors of progression of PR by analyzing probable variables affecting outcome like age, McGoon index, MPA diameter, presence of branch / supra-valvar stenosis, QRS duration and residual RVOT gradient. None of the variables were found to have any statistical significance in predicting outcome though increasing RVOT gradient showed trend towards protection against rapid progression of PR. This is in concordance with studies<sup>30</sup> that have shown favourable effects of persisting RVOT gradients on late post-operative outcome in TOF. Kilner et al. showed that mild or moderate fixed pulmonary valvular stenosis can decrease regurgitant fraction to 17 or 10 %, respectively, even in the absence of a functional valve<sup>31</sup>. Other investigators also have been able to demonstrate a protective effect of a residual RVOTO but could not detect differences in pulmonary regurgitation<sup>32,33</sup>.

As we could not show an association between any anatomic or physiological variable and progression of PR, we assume that progression of PR is an inexorable process, mainly related to the RVOT dynamics, such as increase in RVOT diameter with time and also due to lack of supporting frame work for the monocusp valve.

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## *Limitations of the Study*

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## **LIMITATIONS OF THE STUDY**

The sample size was limited and conclusions regarding predictors of adverse outcome cannot be reliably drawn from this small study group. We had no control group to compare the progression of pulmonary regurgitation with and without monocusp valve reconstruction. Longer follow up is also required to further evaluate the loss of function of monocusp valve and its contribution, if any, to worsening RVOT gradient and/or pulmonary regurgitation.

*Conclusions*



## CONCLUSIONS

ICR with monocusp pulmonary valve reconstruction reduce immediate post-operative pulmonary regurgitation. PTFE monocusp valve was found to undergo calcification and loss of function in a significant number of patients at one year follow up. Pulmonary regurgitation also progressed at 1 year follow up. RV dilation was not observed in any patient at one year of follow-up. This study could not identify any predictors of progression of pulmonary regurgitation though patients with McGoon index  $<1.5$  showed a trend toward more regurgitation, while patients with more residual outflow gradient had lesser regurgitation.

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