Short-term clinical and echocardiographic outcomes after use of polytetrafluoroethylene bicuspid pulmonary valve during the repair of tetralogy of Fallot

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ABSTRACT

Background : **Application of transannular patch (TAP) during the repair of tetralogy of Fallot (TOF) leads to the development of pulmonary regurgitation (PR). This PR is known to cause right ventricular (RV) volume overload and dysfunction which in turn leads to increase in both morbidity and mortality both in immediate and long-term periods. Here, we sought to analyze the effects of polytetrafluoroethylene (PTFE) pulmonary bicuspid valve on the early outcome of patients with TOF repair where TAP is needed.**

Subjects and Methods : **This is a retroprospective, observational study where PTFE bicuspid pulmonary valve was incorporated in all consecutive patients undergoing repair of TOF involving the application of TAP. Postoperative inhospital course was assessed, and patients were followed till 6 months for the status of PR and peak RV outflow tract (RVOT) gradient.**

Results : **38 patients were enrolled in the study. The mean age of participants was 53.66 ± 78.67 months. Extubation in operating room was done in 31 (81.58%) patients. Duration of ventilator support was 10.48 ± 24.22 h, and duration of hospital stay was 7.95 ± 3.08 days. These data were compared with three recent studies where only TAP was applied. Extubation in operating room, mechanical ventilation time, and hospital stay were significantly improved in the present study. Out of 37 live patients, four (10.81%) patients had no PR, 28 (75%) had mild, 1 (2.7) had moderate, and 4 (10.81%) had severe PR. Average RVOT peak gradient was 18.8 ± 8.1 mmHg.**

Conclusion : **Incorporation of PTFE bicuspid pulmonary valve during the repair of TOF appears to facilitate early extubation and thus reduces ventilator-associated comorbidities. Study needs further long-term follow-up to look for behavior of PTFE bicuspid valve.**

Keywords : Congenital heart disease, pulmonary regurgitation, tetralogy of Fallot

INTRODUCTION

Tetralogy of Fallot (TOF) patients needing transannular patch (TAP) during surgery end up with free pulmonary regurgitation (PR) and postoperative hospital course in these patients can be complicated by low cardiac output state related to early right ventricular (RV) dysfunction. Various additional factors, such as age and weight at the time of repair, use of TAP, cardiopulmonary bypass (CPB)

Access this article online

Quick Response Code:

Website: www.annalspc.com

DOI: 10.4103/apc.APC_51_18

How to cite this article: Wankhade PR, Aggarwal N, Joshi RK, Agarwal M, Joshi R, Mehta A, *et al.* Short-term clinical and echocardiographic outcomes after use of polytetrafluoroethylene bicuspid pulmonary valve during the repair of tetralogy of Fallot. Ann Pediatr Card 2019;12:25-31.

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time, and surgical era, have its effects on early morbidity and mortality.[1-4]

Despite better advances and techniques, the long-term mortality still remains high in these patients undergoing TAP repair and subsequent free PR.[5] The two most common causes of mortality are sudden cardiac death and cardiac failure. The basic pathophysiology is structural deterioration of the right ventricle due to chronic PR resulting in arrhythmias and sudden cardiac death.[6-9]

Several strategies have been tried to minimize the PR[10-12] with the intraoperative use of valved conduits, pericardial valves, polytetrafluoroethylene (PTFE) monocuspid valve, and PTFE bicuspid pulmonary valve. The use of valved conduits has disadvantage of lack of durability, lack of growth, and valvular dysfunction. The use of pericardial valve has failed to prevent the development of PR. Use of PTFE monocuspid valve has shown mixed results, most of which are unfavorable.[11] PTFE bicuspid pulmonary valve has shown some promising results.[12] Few observational series have shown significant decrease in PR over short-to-medium term when PTFE bicuspid pulmonary valve was incorporated during repair of TOF resulting in better outcome.[12]

We aimed to study the short-term effects of PTFE bicuspid pulmonary valve when used during the repair of TOF with emphasis on early postoperative course and development of PR over short-term period.

SUBJECTS AND METHODS

Methodology

Approval for the study was obtained from the institutional ethical committee. Consecutive patients who underwent intracardiac repair with TAP and RV outflow tract (RVOT) reconstruction using PTFE bicuspid valve in TOF were included in the study after obtaining informed consent. Patients with absent pulmonary valve, branch pulmonary artery stenosis, residual ventricular septal defect, sepsis, and additional metabolic diseases were excluded from the study. Patients were included prospectively from December 2015 to December 2016, as well as retrospectively who have been operated at the center, meeting all the requirements for study within last 3 years. For retrospectively enrolled patients, data were collected from hospital records. The anonymity of the patients was maintained during the recruitment and analysis. Clinical and echocardiographic evaluation of the patients was done before surgical repair. Postoperative inhospital assessment included postoperative course, inotrope requirement, ventilatory support requirement, complications, mortality, and duration of hospital stay. Postoperatively, clinical and echocardiographic follow-up was done at 1 week, 3 months, and 6 months intervals. In all follow-up visits, clinical status and echocardiographic evaluation were done. Postoperative echocardiographic parameters primarily stressed on the status of prosthetic pulmonary valve, RVOT gradient, and degree of PR.

Echocardiographic parameters for PR were based on recommendations given by the European Association of Echocardiography and included PR jet width compared to pulmonary annulus, color flow PR jet width, jet density and deceleration rate-continuous wave, pulmonary systolic flow compared to systemic flow-pulse wave, jet width/RV outflow diameter, diastolic flow reversal, regurgitation fraction, PR index, pulmonary valve, and RV size.

Surgical procedure

Standard steps of CPB for intracardiac repair are performed. Once decision for performing transannular incision is confirmed, the following steps are undertaken to insert a PTFE bicuspid pulmonary valve [Figures 1 and 2].

1. The inadequate pulmonary annulus and the distal infundibulum (RVOT) were then split in continuity with the pulmonary arteriotomy until a Hegar appropriate opening was achieved. Whenever required additional infundibular resection was performed through the ventriculotomy [Figure 1A and B]
2. If the native pulmonary valve is severely dysplastic, it is excised in toto, else the pliable leaflets are retained (especially the posterior)
3. Sizing of the 0.1-mm nonporous PTFE membrane (square size) for the construction of bicuspid valve done as described in Figure 1C
4. One corner of this patch is sutured to the middle of posterior wall of main pulmonary artery (MPA), 5-mm proximal to the origin of the right pulmonary artery (RPA) using 6-0 polypropylene buttressed with a soft PTFE pledget [Figure 1D]
5. The opposite corner is sutured to the proximal extent of the ventriculotomy, preferably onto its endocardial aspect, using double-armed 6-0 polypropylene in continuous manner. This suture line is continued up to the points joining the remaining two corners of the patch with the cut ends of the annulus at RVOT-MPA junction. This will create two cusps akin to a pair of nostrils [Figure 1E]
6. This is overlaid with a liberal untreated autologous pericardial TAP which is sized in such a way that it will comprise two-third of the reconstituted circumference of the pulmonary annulus and MPA using 6-0 polypropylene continuously [Figure 1F and G].

Statistical methods

Analysis was performed using the IBM SPSS (version 20.0, Armonk, New York, USA) software. Continuous

variables are presented as mean ± standard deviation, and significance of association analyzed with paired *t*-test. Categorical variables are presented as percentages and significance of association analyzed with Fisher's exact test. $P = 0.05$ or lower was considered statistically significant.

RESULTS

During the study period, 47 patients underwent intracardiac repair of TOF with TAP and PTFE bicuspid valve reconstruction of RVOT. After exclusion, a total of 38 patients were enrolled in the study. Six patients were excluded due to absent pulmonary valve, and one patient each due to associated tracheal stenosis, post-TOF repair Blalock– Taussig shunt due to persistent cyanosis and lost to follow-up.

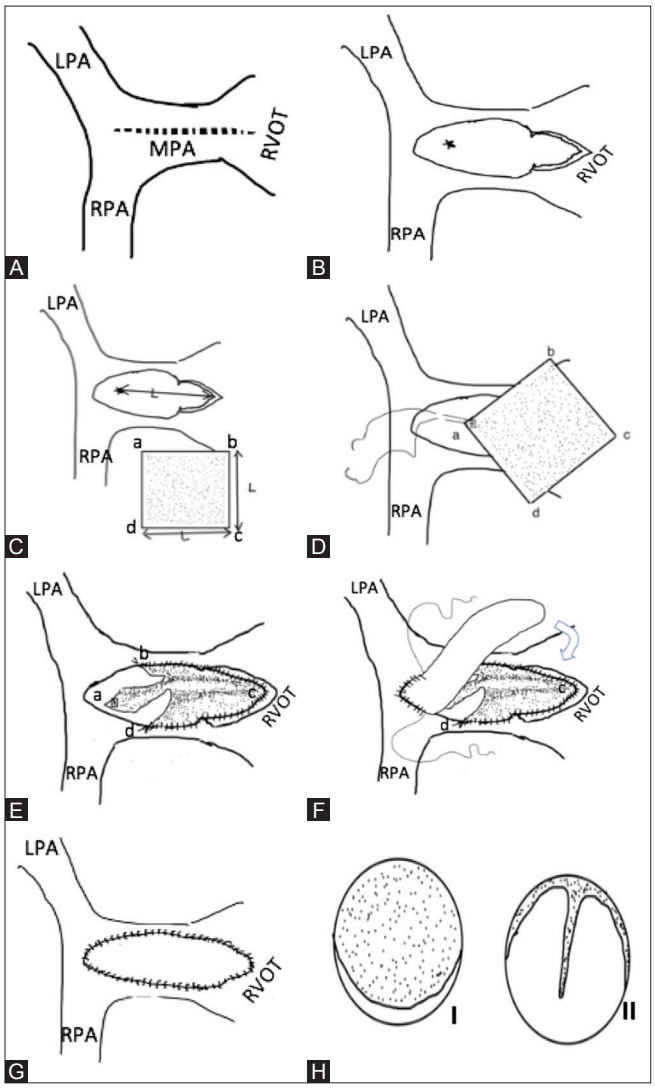

Figure 1: Schematic operative steps. (A) Dashed line indicates extent of incision, (B) star mark (*) demarcates distal point on middle of posterior wall of main pulmonary artery 5 mm proximal to right pulmonary artery origin, (C) square-shaped polytetrafluoroethylene patch with side measuring "L" is fashioned, (D) Corner "a" of patch sewn to distal point, (E) corner "c" of patch sutured to endocardium of right ventricular outflow tract and continued in both directions to stitch point "b" and "d," (F) TAP overlaid including myocardial aspect of right ventricular outflow tract, (G) completed view, (H) cross-sectional view; I: Closed position, II: Open position. TAP: Transannular patch

Baseline characteristics

Male preponderance was noted in the present study population. Ten patients had previously undergone shunt surgery before the intracardiac repair and six patients had undergone preoperative major aortopulmonary collaterals coil embolization [Table 1].

Intraoperative variables

Out of 38 patients, 31 (81.58%) patients were extubated in operating room itself [Table 2].

Postoperative inhospital course in the present study

Inhospital course of these patients was studied for the duration of ventilatory support, inotropic support, hospital stay, and complications [Tables 3 and 4].

Table 1: Baseline characteristics of patients in the present study

Baseline characteristics	Values
Age (months), median; range	16.5 (13.5-51)
Males/females (*n*)	30/8
Weight (mean) (kg)	13.83±11.66
Height (mean) (cm)	92.31±31.5
Prior palliative shunt (*n*)	10 (26.32%)
Preoperative MAPCA coiling (*n*)	6 (15.79)

MAPCA: Major aortopulmonary collateral arteries

Table 2: Intraoperative variables in the present study

Intraoperative variables	Values
ACC time (min) (mean)	66.55±14.04
CPB time (min) (mean)	187.11±32.97
Extubation in OR, *n* (%)	31 (81.58)

ACC: Aortic cross-clamp, CPB: Cardiopulmonary bypass, OR: Operating room

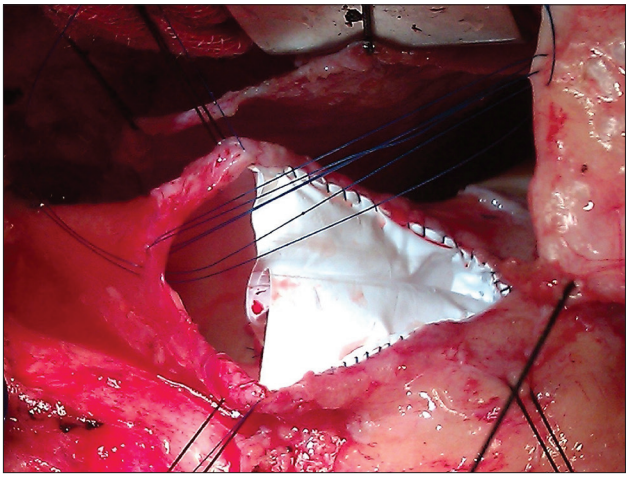

Figure 2: Intraoperative view showing hand sewn polytetrafluoroethylene bicuspid pulmonary valve *in situ* with transannular pericardial patch being sutured

Follow-up at 6 months in the present study

There was one mortality in first postoperative month due to complete heart block (CHB) for which permanent pacemaker implantation was strongly advised. Out of 37 live patients at 6 months, most of them had mild or no PR; 4 had no PR, 28 had mild PR, 1 had moderate, and 4 had severe PR [Figure 3].

We compared the results of this study with other recent studies which used only TAP application.

Ismail et al. versus present study
Our data were compared to study done by Ismail *et al.*[13] where no valve was used.

As there was significant difference in age between two groups, variables between two groups were compared with age-matched controls [Tables 5 and 6]. Average CPB time was significantly higher in the present study (mean: 104 ± 32 min vs. 185.60 ± 34.65 min; $P \leq 0.001$).

Egbe et al. (tetralogy of Fallot repair without valve) versus present study
Compared to Egbe *et al.*[2] who studied outcomes in 97 infants undergone TOF repair. TAP was applied in 60% of patients. Patients were divided in two groups according to the era of study, i.e., early (2001–2006) and late (2007–2012). The present study was compared with both the groups [Table 7].

Bigras et al. (Group-A – tap without valve; Group-B – tap with monocusp patch valve) versus present study
The present study data were compared with Bigras *et al.*[14] where no valve was used [Table 8].

DISCUSSION

Very few studies have been published about use of PTFE bicuspid pulmonary valve during TOF repair. To assess early outcome after the use of PTFE bicuspid pulmonary valve, we reviewed single-center experience and compared the results with the previously published studies in which only TAP was used without any valve.

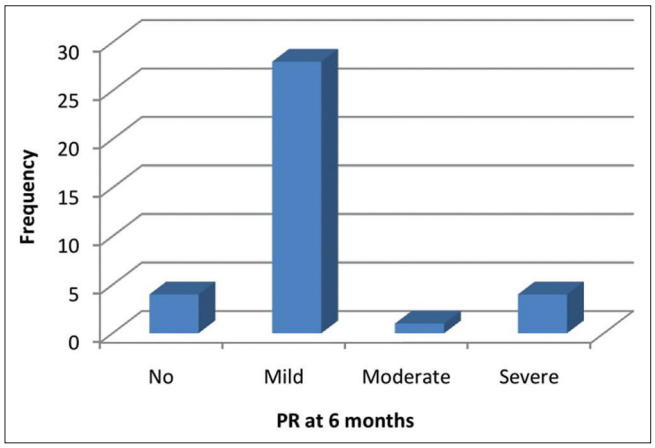

Figure 3: Pulmonary regurgitation at 6 months

Intraoperative variables

In the present study, mean aortic cross-clamp time was 66.55 ± 14.04 min and CPB time was 187.11 ± 32.97 min. CPB time was significantly higher in the present study compared to other studies.

Extubation in operating room

In the present study, 81.58% of patients were extubated in operating room itself. Compared to Egbe *et al.* number of patients extubated in operating room was significantly higher (early Group – $n = 9$ [17%] vs. $n = 31$ [81.58%], $P \leq 0.001$; late Group – $n = 17$ [38%] vs. $n = 31$ [81.58%]; $P \leq 0.001$). Invasive ventilatory support itself is the important factor for inhospital comorbidities. Although mortality was not different between two studies, duration of intensive care unit (ICU) stay and hospital stay was significantly

Table 3: Postoperative inhospital course

Postoperative variables	Values
Invasive ventilation time (mean) (h)	10.48±24.22
Inotrope duration (mean) (h)	54.26±32.9
Maximum number of inotropes (*n*)	1.31±1.01
ICU stay (mean) (days)	5±2.56
In-hospital stay (mean) (days)	7.95±3.08

ICU: Intensive care unit

Table 4: Complications of surgical repair of tetralogy of Fallot in the present study

Complication	*n* (%)
Arrhythmias	3 (7.89)
Complete heart block	1 (2.63)
Junctional rhythm	1 (2.63)
Supraventricular tachycardia	1 (2.63)
ALCOS	3 (7.89)
Pleural effusion	3 (7.89)
Febrile episodes	5 (13.15)
Pulmonary complications	4 (10.52)
Thrombocytopenia	5 (13.15)
Recurrent locked jaw	1 (2.63)
Pneumothorax	1 (2.63)
Chylothorax	1 (2.63)

ALCOS: Acute low cardiac output state

Table 5: Preoperative and operative data: Comparison between age-matched groups: Ismail *et al.* versus present study

Variable	Ismail *et al.* (*n*=64)	Current study (age matched) (*n*=33)	*P*
Male/female	44/20	27/6	
Average age (months)	18.8±24.4 (SD)	27.24±32.10 (SD)	0.15
Average weight (kg)	8.6±4.4 (SD)	9.89±3.97 (SD)	0.16
Average of bypass time (min)	104±32 (SD)	185.60±34.65 (SD)	<0.001

SD: Standard deviation

lower in the present study indicating toward less postoperative comorbidities (discussed below). The reason for this difference might be much younger age group enrolled in Egbe *et al.* study.

Duration of mechanical ventilatory support

Duration of mechanical ventilatory support is one important factor related to in hospital comorbidities. In the present study, mean duration of invasive ventilatory support was 10.48 ± 24.22 h. Duration of mechanical ventilatory support was significantly lesser in the present study when compared with three other studies. As mentioned above, mortality was not statistically different, but ICU and hospital stay was significantly lower in the present study.

Table 6: Comparison of hospital outcome between age-matched groups: Ismail *et al.* versus present study

Variable	Current study (age matched) (*n*=33)	Ismail *et al.* (Group-1) (*n*=48)	*P*
Average inotropes duration (h)	55.89±33.23 (SD)	64.6±58.7 (SD)	0.44
Maximum number of inotropes	1.33±1.02 (SD)	2±0.7 (SD)	<0.001
Average ventilation time (h)	11.69±25.75 (SD)	50.3±67 (SD)	0.0023
Pleural effusion, *n* (%)	3 (9.09)	8 (16.6)	0.263
Arrhythmias, *n* (%)	3 (9.09)	10 (20)	0.133
Pericardial effusion, *n* (%)	0 (0)	6 (12.5)	0.038
ARF (with temporary dialysis), *n* (%)	0 (0)	1 (2)	0.615
New onset of seizure, *n* (%)	0 (0)	4 (8.3)	0.136
Chylothorax, *n* (%)	1 (3.03)	3 (6.25)	0.460
Average ICU length of stay (days)	5.18±2.68 (SD)	4.8±3.6 (SD)	0.60
Average hospital length of stay (days)	8.27±3.15 (SD)	10.9±7.4 (SD)	0.058
Average of postoperative $RVOT_{max}$ PG (mmHg)	19.28±8.30 (SD)	17±9 (SD)	0.25

RVOT: Right ventricular outflow tract, ICU: Intensive care unit, PG: Peak gradient, ARF: Acute renal failure, SD: Standard deviation

Inotropic support

Assessment of inotropic support was done with two variables, i.e., maximum number of inotropes used and duration of inotropic support. In the present study, mean number of inotropes used was1.31 ± 1.01 and mean duration of inotropic support was 54.26 ± 32.9 h. Mean number of inotropes used was significantly lower in the present study compared to Ismail *et al.*, but duration of inotropic support was not significantly different. Egbe *et al.* also reported the duration of inotropic support which was not different from the present study.

Intensive care and inhospital stay

ICU stay and inhospital stay are the indicators of morbidity. Hospital stay more than 8 days was considered prolonged. In the present study, mean duration of ICU stay was 5 ± 2.56 days and duration of inhospital stay was 7.95 ± 3.08 days. Four patients (10.52%) had prolonged hospital stay. Reasons for prolonged stay were bradycardia secondary to AV dissociation in one patient, low cardiac output state in two patients, and persistent sinus tachycardia in one patient.

Compared to Ismail *et al.*, total hospital stay was less in the present study. Compared to Egbe *et al.* and Bigras *et al.*, both ICU stay and total hospital stay were significantly less in the present study ($P \leq 0.05$). In Ismail *et al.* and Egbe *et al.*, patients were much younger compared to the present study whereas compared to Bigras *et al.*, there was no significant age difference than the present study.

Complications

Reported incidence of CHB in post-TOF repair patient is 2.5%–5.5%. Egbe *et al.* in a study of 97 patients reported 1% incidence of CHB. Incidence of junctional rhythm was reported to be 7.9% in a study of 101 patients done by Hashemzadeh *et al.* 13 patients (7.8%) in the present study reported arrhythmias. One patient had CHB, one patient developed junctional tachycardia, and one developed supraventricular tachycardia.

Table 7: Comparison between Egbe *et al.* versus present study

Variable	Current study (*n*=38), *n* (%)	Egbe *et al.* (Early 2001-2006) (*n*=52), *n* (%)	*P*	Egbe *et al.* (Late 2007-2012) (*n*=45)	*P*
Age (months) (median)	16.5 (13.5-51)	5.1 (1-9)	<0.001	4.8 (1-8)	<0.001
Weight (kg) (median)	9.16 (7.73-13.15)	5.4 (3.1-9.4)	<0.001	5.1 (3.2-9.8)	<0.001
CPB time (min) (median)	180.5 (164.5-209.25)	121 (61-205)	0.003	113 (65-196)	0.001
ACC time (min) (median)	62.5 (56.25-76.5)	58 (35-104)	0.731	63 (30-101)	0.905
ICU stay (days)	4 (3.25-6)	7 (4-20)	0.001	6 (2-21)	0.006
Hospital stay (days) (median)	7 (6-9.75)	7 (4-28)	0.007	8 (2-38)	0.007
Patients extubated in OR	31 (81.58)	9 (17)	<0.001	17 (38)	<0.001
Mechanical ventilatory support (h) (median)	0 (0-5.61)	36 (0-112)	0.002	13 (0-136)	0.001
Inotropic support (h) (median)	48.28 (38-68.79)	32 (16-91)	0.940	36 (18-104)	0.553
ECMO support	0 (0)	2 (4)	0.111	2 (4)	0.094
JET	1 (2.6)	2 (4)	0.376	0 (0)	0.137

ACC: Aortic cross-clamp, CPB: Cardiopulmonary bypass, OR: Operating room, ECMO: Extracorporeal membrane oxygenation, JET: Junctional ectopic tachycardia, ICU: Intensive care unit

Table 8: Comparison between Bigras *et al.* versus present study

Variable	Current study (*n*=38)	Bigras *et al.* (Group-A) (*n*=20)	*P*
Age (months)	16.5 (13.5-51)	18 (7-52)	0.196
Weight (kg) (median)	9.16 (7.73-13.15)	10 (6-17)	0.092
CPB time (min) (mean)	187.11±32.97	129±55	<0.001
ACC time (min) (mean)	66.55±14.04	55±21	0.015
ICU stay (days) (median)	4 (3.25-6)	3 (0-19)	0.059
Hospital stay (days) (median)	7 (6-9.75)	13 (7-30)	<0.001
Mortality (%)	1 (2.63)	2 (10)	0.114

CPB: Cardiopulmonary bypass, ACC: Aortic cross-clamp, ICU: Intensive care unit

Five patients developed febrile episodes, four patients had pulmonary complications, and three patients developed acute low cardiac output state. Five patients developed thrombocytopenia out of which only one patient needed platelet transfusion. Three patients developed pleural effusion that required prolonged pleural drainage (more than 5 days). One patient had unusual complication of recurrent locked jaw, one had pneumothorax, and one had chylothorax. All complications were managed conservatively.

Follow-up at 6 months

All 37 live patients at 6-month follow-up were asymptomatic. Mean RVOT gradient was not hemodynamically significant (18.8 ± 8.1 mmHg). Other studies using monocuspid valves such as Ismail *et al.* and Sasikumar *et al.*[11] reported RVOT gradient in the same range.

In the present study, PR was seen in 33 patients. Twenty-eight (75%) had mild, one (2.7%) had moderate, and 4 (10.8%) patients had severe PR. The major positive outcome of this study compared to previous studies is significant decrease in morbidity parameters in the form of decreased ventilatory support, decreased ICU stay, and decreased overall hospital stay. Decrease ventilatory support is probably the reflection of significant increase in extubation in operating room itself. Extubation in operating room may be the result of improved anesthesia care, intensive care measures, and surgical technique. Use of PTFE bicuspid pulmonary valve decreased the torrential PR that develops after TAP preventing sudden hemodynamic conversion of an obstructed, pressure loaded right ventricle to a volume-loaded right ventricle. This subsequently decreased the risk of right heart failure and subsequent risk of comorbidities including reduced hospital stay.

Mortality

The present study reported zero intrahospital surgical mortality. Although one patient expired within first postoperative month due to CHB, this patient had been advised to undergo permanent pacemaker implantation. Knott-Craig *et al.* reported a decrease in surgical mortality after primary repair of TOF in all ages from 11% before 1990 to 2.1% after 1990.[15] Two additional series by Reddy *et al.* and Touati *et al.* reported similar low mortality rate of 1%–3% after primary repair with tendency for slightly higher mortality rates in neonates.[16,17] Number of patients in present study is too small to reach any reasonable inference. The present study excluded patients with absent pulmonary valve which were included in studies by Reddy *et al.* and Touati *et al.* The anatomic complexity of their patient population must have contributed significantly to the slightly higher mortality in their study group compared to ours. Egbe *et al.* also reported zero operative mortality which also excluded patient population with absent pulmonary valve and pulmonary atresia. Like present study, Egbe *et al.* reported one patient undergoing pacemaker implantation in early postoperative period.

Limitations

This study carries the inherent limitations of an observational study regarding its susceptibility to bias and confounding, restricting their ability to define causality. Comparison of the present study has been done with other studies from other centers. Different centers have different overall conditions including experience and infrastructure, so comparative results of this study might not draw very precise conclusions.

CONCLUSION

Adding a PTFE bicuspid valve technique did show additional benefit over the classical TAP technique. The short-term outcome of patients with TOF repair with PTFE bicuspid pulmonary valve is excellent, and it leads to marked decrease in morbidity. In the present study, more number of patients could be extubated in operating room; average ventilatory time was reduced subsequently reducing the hospital stay and overall treatment cost. Long-term follow-up is needed to assess the outcome of PTFE bicuspid pulmonary valve in intracardiac repair of TOF with respect to the development of pulmonary stenosis and PR.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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