Received: 13 June 2018 | Revised: 5 August 2018 | Accepted: 7 August 2018

DOI: 10.1111/chd.12670

ORIGINAL ARTICLE

WILEY Congenital Heart Disease

Monocusp valve placement in children with tetralogy of Fallot undergoing repair with transannular patch: A functioning pulmonary valve does not improve immediate postsurgical outcomes

Nikki M. Singh MD[1] | Rohit S. Loomba MD[2] | Todd M. Gudausky MD[1] | Michael E. Mitchell MD[3]

[1]Division of Pediatric Cardiology, Medical College of Wisconsin, Herma Heart Institute at Children's Hospital of Wisconsin, Milwaukee, Wisconsin

[2]Advocate Children's Heart Institute, Advocate Children's Hospital, Oak Lawn, Illinois

[3]Division of Pediatric Cardiothoracic Surgery, Medical College of Wisconsin, Herma Heart Institute at Children's Hospital of Wisconsin, Milwaukee, Wisconsin

Correspondence:
Nikki M. Singh, MD Herma Heart Institute and Children's Hospital of Wisconsin, 9000 W. Wisconsin Ave, MS 713, Milwaukee, WI 53226.
Email: Nikki.Singh@cchmc.org

Abstract

Introduction: In patients with tetralogy of Fallot (TOF), use of transannular patch (TAP) may be required in order to relieve significant right ventricular outflow tract obstruction, subsequently resulting in pulmonary insufficiency (PI). The monocusp valve has been used to temporarily reduce insufficiency in hopes to improve short and midterm outcomes. The purpose of this study was to assess for potential benefits of the monocusp valve in this subset of patients.

Design: Between 2005 and 2016, 119 patients with TOF with pulmonary stenosis who underwent repair with TAP were analyzed, 43 (36.1%) had a monocusp valve placed. Immediate outcomes were assessed by postoperative echocardiograms, ICU data including time to extubation, chest tube duration, reintervention, length of stay, and mortality.

Results: Median age of repair was similar for monocusp group at 143.5 days and nonmonocusp at 137.0 days ($P = .93$). Peak preoperative right ventricular outflow tract obstruction was higher in the monocusp group (80 mm Hg vs. 70 mm Hg, $P \leq .01$). Patients who had monocusp placed had longer bypass time. There was less PI for monocusp group immediately after repair and at discharge ($P \leq .01$). There was no difference in days of intubation, chest tube duration, length of hospitalization, reintervention rates, or mortality.

Conclusion: Decreasing the degree of PI with a monocusp valve in patients undergoing repair for TOF repair with TAP does not improve clinical outcomes in the immediate postoperative period.

KEYWORDS

monocusp valve, outcomes, pulmonary valve insufficiency, tetralogy of Fallot, transannular patch

1 | INTRODUCTION

Tetralogy of Fallot (TOF) is the most common form of cyanotic congenital heart disease and one of the earliest defined forms of congenital heart disease. Transannular incision through the pulmonary valve and patching is sometimes necessary to relieve severe outflow tract obstruction.[1] Over time the severity of pulmonary insufficiency (PI) has been found to lead to volume loading of the right ventricle, leading to complications such as arrhythmias, congestive heart failure, exercise intolerance, and sudden cardiac death.[2-4] As a result, the best timing of pulmonary valve replacement continues to be evaluated.[5-7] Surgical techniques have changed to preserve the pulmonary valve at time of initial repair.[8-10]

In the case of transannular patch (TAP) repair, once the valve is opened and a TAP is placed, the physiology of the heart changes dramatically. Instead of being pressure loaded due to outflow tract obstruction, the right ventricle becomes volume loaded due to free PI. As early as the 1970s, the monocusp valve has been used to decrease PI in hopes of diminishing chest tube output and hospital length of stay in the immediate postoperative period.[9,11-14] There are different materials which can be used to create a monocusp, including homograft, pericardium, and Gore-Tex (W. L. Gore and Associates, Flagstaff, Arizona). The durability of the valve is limited and progressive insufficiency is inevitable. Data regarding the immediate postoperative and longer-term function of the monocusp valve are limited. (Figure 1).

We hypothesized that those patients with TOF who underwent a complete repair with a TAP and monocusp valve would have improved perioperative or postoperative characteristics compared to those patients who underwent complete repair with a TAP without placement of monocusp valve.

2 | METHODS

The following protocol was reviewed and approved by the Institutional Review Board at the Children's Hospital of Wisconsin.

Children who underwent complete repair of TOF from January 2005 through January 2016 at the Children's Hospital of Wisconsin were identified. To be included in this study, patients must have had TOF with pulmonary stenosis and could not have one of the TOF variants such as pulmonary atresia with major aortopulmonary collaterals. Furthermore, patients were included in the study only if their complete repair included a transannular incision and patch. Those who had a TOF variant or underwent a repair other than one consisting of TAP incision and patch were also excluded.

Clinical information including demographics, diagnosis, preoperative hospital course, and postoperative hospital course was collected via chart review. Echocardiographic data were collected from echocardiographic reports for the echocardiogram done prior to complete repair, the immediate postoperative transesophageal echocardiogram, and discharge echocardiogram. Echocardiograms were not reviewed by the authors of this paper to gather study data. Operative data, including whether or not a monocusp valve was placed, was collected from the operative report.

Demographic, clinical, operative, and echocardiographic data were compared between those with and without a monocusp valve placed at the time of complete repair. Descriptive characteristics were compared using a Fisher exact test while continuous variables were compared using a Mann-Whitney U test due to the nonnormal distribution of the data. These analyses were first done on the entire cohort and then on those who underwent repair in the neonatal period (<30 days of age).

Continuous variables are reported as median and range while descriptive variables are reported as absolute frequency and percent. All statistical analyses were done using SPSS Version 23.0 (IBM, Chicago, Illinois). A P value of .05 was considered statistically significant.

3 | RESULTS

3.1 | Entire cohort

A total of 119 patients were included in the final analyses. Of these, 43 (36.1%) had a monocusp placed at the time of complete repair.

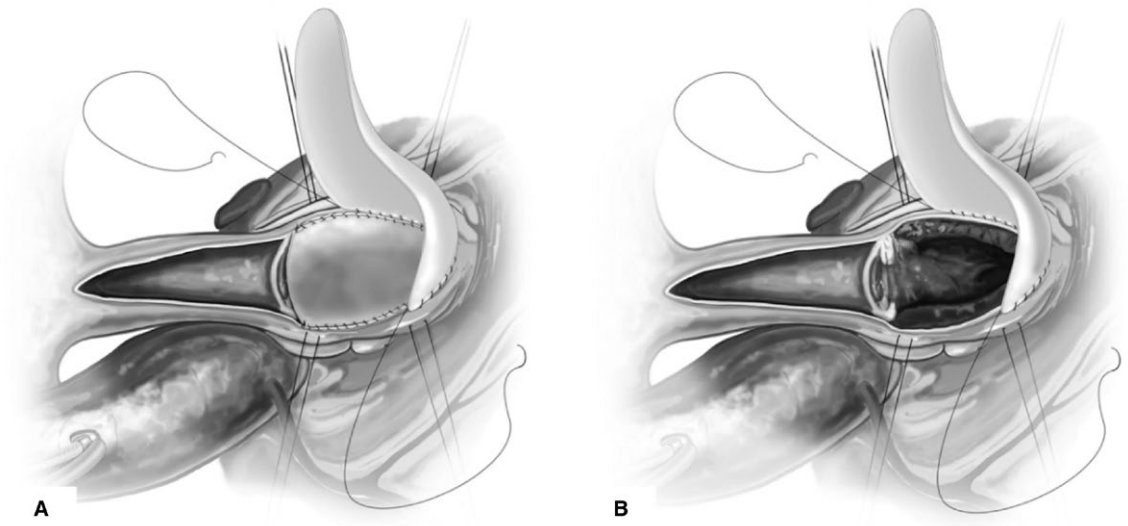

FIGURE 1 (A) Transannular patch with a monocusp valve; (B) Transannular patch without a monocusp valve

There was no difference in gender or presence of identified syndrome between the two groups. The proportion of patients in the groups that were ductal-dependent (requiring prostaglandins) or symptomatic, defined as being ductal-dependent or having cyanotic spells was also similar. A total of 41 (53.9%) patients in the nonmonocusp group were symptomatic while 16 (37.2%) patients in the monocusp group were symptomatic. A statistically similar proportion of patients required beta-blockade or intubation preoperatively in both groups. No patient in either group required extracorporeal membrane oxygenation (ECMO), preoperatively. Blalock-Tausig shunt placement or right ventricular stent placement was performed in 4 (5.3%) of those in the nonmonocusp group and 2 (4.7%) of those in the monocusp group ($P = .26$). Preoperative peak right ventricular outflow tract gradient was greater in those in the monocusp group with the median peak gradient by echocardiography being 80.0 mm Hg in this group versus 70.0 mm Hg in the nonmonocusp group ($P < .01$). Those in the monocusp group were also more likely to have moderate or severe PI preoperatively (4.7% vs. 0%, 1.3% $P = .03$) (Table 1).

The median age at surgery was similar between both groups at 143.5 days in those in the nonmonocusp group and 137.0 days in the monocusp group ($P = .93$). Weight at surgery also did not differ between the two groups. For those in the monocusp group, in which material used to construct the valve was documented, a majority (64.0%) had a pericardial monocusp placed although CorMatrix (CorMatrix Cardiovascular, Inc, Roswell, Georgia) (20.0%) and

TABLE 1 Preoperative patient characteristics and operative data

	Non-monocusp ($n = 76$)	Monocusp ($n = 43$)	*P* value
Gender (male)	39 (51.3)	27 (62.8)	.22
Syndromic	6 (7.9)	8 (18.6)	.08
Ductal dependent	5 (6.6)	3 (7.0)	.93
Symptomatic (ductal dependent or having cyanotic spells)	41 (53.9)	16 (37.2)	.07
Preoperative beta-blocker	25 (32.9)	8 (18.6)	.09
Preoperative intubation	8 (10.5)	2 (4.7)	.26
Preoperative extracorporeal membrane oxygenation	0 (0)	0 (0)	–
Intervention prior to complete repair	4 (5.3)	2 (4.7)	.88
Right ventricular outflow tract stent	3	2	
Preoperative peak right ventricular outflow tract gradient(mm Hg)	70.0 (34.0-100.0)	80.0 (42.0-125.0)	<.01
Preoperative pulmonary insufficiency			.03
None	57 (75.0)	22 (51.2)	
Trivial	17 (22.4)	18 (41.9)	
Mild	1 (1.3)	1 (2.3)	
Moderate	1 (1.3)	0 (0.0)	
Severe	0 (0.0)	2 (4.7)	
Preoperative tricuspid valve regurgitation			.05
None	8 (10.5)	0 (0.0)	
Trivial	61 (80.3)	40 (93.0)	
Mild	6 (7.9)	1 (2.3)	
Moderate	1 (1.3)	2 (4.7)	
Severe	0 (0.0)	0 (0.0)	
Age at surgery (d)	143.5 (5.0-2,063.0)	137.0 (10.0-1,471.01)	.93
Weight at surgery (kg)	5.8 (2.9-9.6)	5.1 (2.6-9.3)	.74
Bypass time (min)	143.0 (88.0-270.0)	162.0 (120.0 391.0)	.04
Cross-clamp time (min)	104.0 (55.0-180.0)	114.0 (57.0-235.0)	.04
Extubated in the operating room	48 (63.2)	25 (59.5)	.69
Chest closed in the operating room	74 (97.4)	38 (88.4)	.04

Denominator for some fields differ from column total due to missing data

Gore-tex (16.0%) were also used. Median bypass time was greater in the monocusp group (162.0 minutes vs. 143.0 minutes, $P = .04$) and median cross-clamp time was also greater in the monocusp group (114.0 minutes vs. 104.0 minutes, $P = .04$). A smaller proportion of patients in the monocusp group had their chest closed in the operation room (88.4% vs. 97.4%, $P = .04$) (Table 2). Postoperative transesophageal echocardiography demonstrated moderate or severe PI in 7 (23.4%) in the monocusp group compared to 51 (86.4%) in the nonmonocusp group ($P < .01$). Right ventricular function was normal at the time of postoperative transesophageal echocardiography in fewer patients in the monocusp group compared to the nonmonocusp group (71.0% vs. 94.9%, $P < .01$). There was no significant difference peak right ventricular outflow tract gradient (Table 2).

Postoperatively, a majority of both groups were extubated in the operating room (OR), 48 of the 76 monocusp patients (63.2%) and 25 of the 43 nonmonocusp patients (59.5%) ($P = .69$). Comparing the

TABLE 2 Postoperative outcomes and echocardiograms

	Non-monocusp ($n = 76$)	Monocusp ($n = 43$)	P value
Postoperative arrhythmia	15 (19.7)	14 (32.6)	.11
Postoperative extracorporeal membrane oxygenation	0 (0.0)	2 (4.7)	.06
Duration of mechanical ventilation (d)	0.0 (0.0-10.0)	0.5 (0.0-25.0)	.01
Duration of chest tubes (d)	3.0 (1.0-30.0)	4.0 (1.0-28.0)	.07
Chylous chest tube output	1 (1.4)	3 (7.0)	.10
Total postoperative hospital length of stay (d)	8.0 (3.0-180.0)	11.0 (4.0-70.0)	.43
Peak right ventricular outflow tract gradient at postoperative transesophageal echocardiogram	6.0 (2.0-35.0)	6.5 (4.0-32.0)	.96
Pulmonary insufficiency at postoperative transesophageal echocardiogram			<.01
None	0 (0.0)	7 (23.3)	
Trivial	2 (3.4)	7 (23.3.)	
Mild	6 (10.2)	9 (30.0)	
Moderate	11 (18.6)	4 (13.3)	
Severe	40 (67.8)	3 (10.1)	
Tricuspid insufficiency at postoperative transesophageal echocardiogram			.19
None	5 (9.4)	3 (10.0)	
Trivial	40 (75.5)	17 (56.7)	
Mild	6 (11.3)	9 (30.0)	
Moderate	2 (3.8)	1 (3.3)	
Severe	0 (0)	0 (0.0)	
Right ventricular function at postoperative transesophageal echocardiogram			<.01
Normal	56 (94.9)	22 (71.0)	
Mildly diminished	3 (4.1)	7 (22.6)	
Moderately diminished	0 (0.0)	2 (6.4)	
Peak right ventricular outflow tract gradient at discharge	13.0 (4.0-77.0)	12.0 (4.0-46.0)	.38
Pulmonary insufficiency at discharge			<.01
None	0 (0.0)	1 (3.1)	
Trivial	0 (0.0)	6 (18.8)	
Mild	3 (5.0)	11 (34.4)	
Moderate	7 (11.7)	5 (15.6)	
Severe	50 (83.3)	12 (28.1)	
Inpatient mortality	1 (1.3)	0 (0)	0.55

Denominator for some fields differ from column total due to missing data

total number mechanical ventilation days for both cohorts, those in the monocusp group had greater duration of mechanical ventilation at 0.5 days (0.0-25.0) compared to 0.0 days (0.0-10.0 days) in the nonmonocusp group (P = .01). Chest tube duration did not differ between the two groups, monocusp at 4 days and nonmonocusp at 3 days (P = .07). Only 3 (7.0%) patients in the monocusp group and 1 (1.4%) patients in the nonmonocusp group had chylous chest tube output (P = .10).

Postoperative extracorporeal membrane oxygenation (ECMO) was required in 2 (4.7%) of those in the monocusp group and 0 of those in the nonmonocusp group (P = .06). Both patients who required ECMO had low cardiac output syndrome develop shortly after surgical repair which was resistant to medical management and therefore required mechanical circulatory support. The first patient had complete repair at 187 days of age and remained on ECMO for 7 days prior to decannulation. The second required neonatal repair at 10 days of age due to hypercyanotic spell. He was decannulated after 10 days on VA ECMO. This patient also required a pacemaker prior to discharge for complete heart block. Neither required additional intracadiac surgical interventions prior to discharge.

Development of arrhythmias prior to discharge was not significantly different between the groups (P = .11). Only one patient from the monocusp group required a pacemaker prior to discharge (as mentioned above). Median postoperative length of stay was 11.0 days in the monocusp group and 8.0 days in the nonmonocusp group (P = .43) (Table 2). Moderate or severe PI was present in 57 (95%) of those in the nonmonocusp group compared to 12 (28.1%) of those in the monocusp group by echocardiography at the time of discharge (P < .01).

There was no significant difference in reintervention, either surgical or cardiac catheterizations interventions, between groups (P = .33). Three patients required reintervention (2 surgical and 1 cardiac catheterization) prior to discharge, all from the nonmonocusp valve cohort. There were no patients from the monocusp group who required reintervention. One patient had persistent chest tube output following initial repair and subsequently found to have residual right ventricular outflow tract obstruction and a residual ventricular septal defect (VSD) and was taken back to the OR for VSD closure, infundibular muscle resection, and ligation of thoracic duct. The second surgical patient required reintervention for residual VSD and is further discussed below. The interventional cardiac catheterization was in a patient who initially underwent right ventricular outflow stent placement at 4 days of life, subsequently underwent VSD closure, TAP repair without a monocusp valve at 3 months later and required LPA balloon dilation several days after repair due to desaturation.

There was no significant difference in mortality between the two groups. There were no deaths in the monocusp group and only one (1.3%) death in the nonmonocusp group (P = .55) (Table 2). The only mortality was in a patient who underwent initial repair surgical repair at 49 days of age with TAP without monocusp placement, resection of infundibular muscle and VSD patch closure after a hypercyanotic spell while on propranolol. After repair there was noted to be a residual VSD with concerns for pulmonary hypertension with right to left shunting across the defect. Underwent RV-PA conduit revision with residual VSD closure at 79 days of age. For unclear reasons had persistent capillary leak, low cardiac output and required dialysis for renal failure. Due to progressive multisystem organ failure care was ultimately withdrawn.

3.2 | Neonatal complete repair

A total of 17 patients underwent complete repair in the neonatal period (age at time of repair ≤30 days). Of these, seven (5.8%) had a monocusp placed. There was no significant difference in the proportion of neonatal patients who were ductal dependent or symptomatic. There was also no difference in the proportion of neonatal patients who required preoperative beta-blockade, intubation, or ECMO. No neonatal patient underwent Blalock-Tausig shunt or right ventricular outflow tract stenting prior to complete repair. Median preoperative peak right ventricular outflow tract gradient by echocardiography was higher in the neonatal monocusp group compared to the neonatal nonmonocusp group (84.0 mm Hg vs. 55.0, P < .01). There was no difference in other echocardiographic parameters preoperatively (Table 3).

Median age and weight at time of complete repair in those undergoing complete repair in the neonatal period did not differ between the two groups. Bypass and cross-clamp times did not differ between the neonatal groups either. The proportion of neonatal patients who were extubated in the OR or had their chest closed in the OR also did not differ (Table 3).

Postoperative transesophageal echocardiography demonstrated no statistically significant difference in the proportion of patients with moderate or severe PI (25% in the neonatal monocusp group vs. 87.5% in the neonatal nonmonocusp group, P = .20). The peak right ventricular outflow tract gradients in neonates with monocusp was 6.0 (4.0-46.0) was and nonmonocusp 4.0 (3.0-34.0) (P = .29) (Table 4).

Postoperatively, there were no differences in the duration of mechanical ventilation or chest tubes between the two neonatal groups. No patient in either group had chylous chest tube drainage. There was no significant difference between postoperative arrhythmias or need for ECMO either. Total postoperative hospital stay was also not statistically different. (Table 4).

Echocardiography at the time of discharge demonstrated that all patients, irrespective of group, had moderate or severe PI and without difference in right ventricular function or tricuspid insufficiency (Table 4).

4 | DISCUSSION

Our single-center study of 119 patients reviewed immediate outcomes of patients who who underwent complete repair of TOF with a TAP. Patients who had a monocusp did not have an advantage

TABLE 3 Neonatal preoperative characteristics and operative data

	Non-monocusp (n = 10)	Monocusp (n = 7)	P value
Gender (male)	5 (50.0)	6 (85.7)	.12
Syndromic	2 (20.0)	1 (14.3)	.76
Ductal dependent	4 (40.0)	1 (14.3)	.25
Symptomatic (ductal dependent or having cyanotic spells)	9 (90.0)	5 (71.4)	.32
Preoperative beta-blocker	3 (30.0)	0 (0.0)	.11
Preoperative intubation	3 (30.0)	1 (14.3)	.45
Preoperative extracorporeal membrane oxygenation	0 (0.0)	0 (0.0)	–
Intervention prior to complete repair	0 (0.0)	0 (0.0)	–
Preoperative peak right ventricular outflow tract gradient(mm Hg)	55.0 (36.0-66.0)	84.0 (52.0-105.0)	<.01
Preoperative pulmonary insufficiency			.32
None	9 (90.0)	5 (71.4)	
Trivial	1 (10.0)	2 (28.6)	
Mild	0 (0.0)	0 (0.0)	
Moderate	0 (0.0)	0 (0.0)	
Severe	0 (0.0)	0 (0.0)	
Preoperative tricuspid valve regurgitation			.27
None	2 (20.0)	0 (0.0)	
Trivial	7 (70.0)	7 (100.0)	
Mild	0 (0.0)	0 (0.0)	
Moderate	1 (10.0)	0 (0.0)	
Severe	0 (0.0)	0 (0.0)	
Age at surgery (d)	15.5 (5.0-27.0)	14.0 (10.0-26.0)	.78
Weight at surgery (kg)	3.3 (2.9-3.6)	3.1 (2.6-4.1)	.85
Bypass time (min)	143.0 (88.0-202.0)	182.0 (121.0-234.0)	.10
Cross-clamp time (min)	96.5 (57.0-131.0)	133.0 (57.0-156.0)	.10
Extubated in the operating room	2 (20.0)	2 (28.6)	.68
Chest closed in the operating room	9 (90.0)	6 (85.7)	.78

Denominator for some fields differ from column total due to missing data

in immediate postoperative outcomes, despite having significantly less PI.

Preoperatively, clinical characteristics between these two groups were very similar in regards to age, weight at time of surgery, and positive genetic testing. Also similar was reported cyanotic spells or ductal dependence, need for preoperative beta-blockers, intubation or need for surgical or catheter-based intervention prior to repair. Hence, determination of why certain patients received monocusp vs. those who did not could not be made outside of surgeon preference at time of repair as all other preoperative characteristics were similar.

Surgically, patients who had a monocusp valve placed required longer bypass and cross-clamp time, likely related to time needed to construct the monocusp valve and surgically place the valve. In fact, patients who had a monocusp were less likely to have their chest closed in the OR but similar rates of extubation prior to transfer out of the OR. This could imply that although the preoperative characteristics were similar between the groups, the patients who had a monocusp may have had a more challenging operative course and labile hemodynamics.

The immediate difference in right ventricular function as noted by the postoperative transesophageal echocardiogram is interesting. While most of those in the monocusp group only had mild dysfunction, this was still present in a larger proportion of the monocusp group when compared to the nonmonocusp group. It cannot be said with certainty why this occurred but it could be related to the increased cardiopulmonary bypass and cross-clamp times in this group. It is possible that it for these same reasons that there was a difference in postoperative mechanical ventilation time.

The longevity of a monocusp valve's function is variable but in this study patients with monocusp continued to have less PI even at time of discharge, indicating that any benefit of decrease PI showed

TABLE 4 Neonatal postoperative outcomes and echocardiograms

	Non-monocusp (n = 10)	Monocusp (n = 7)	P value
Postoperative arrhythmia	2 (20.0)	3 (42.9)	.30
Postoperative extracorporeal membrane oxygenation	0 (0.0)	1 (14.3)	.21
Duration of mechanical ventilation (d)	3.0 (2.0-10.0)	6.0 (4.0-25.0)	.11
Duration of chest tubes (d)	3.5 (1.0-7.0)	6.0 (2.0-28.0)	.06
Chylous chest tube output	0 (0.0)	0 (0.0)	–
Total postoperative hospital length of stay (d)	12.5 (6.0-37.0)	27.0 (15.0-70.0)	.06
Peak right ventricular outflow tract gradient at postoperative transesophageal echocardiogram	4.5 (4.0-20.0)	5.0 (4.0-25.0)	.56
Pulmonary insufficiency at postoperative transesophageal echocardiogram			.20
None	0 (0.0)	1 (25.0)	
Trivial	1 (12.5)	1 (25.0)	
Mild	0 (0.0)	1 (25.0)	
Moderate	1 (12.5)	0 (0.0)	
Severe	6 (75.0)	1 (25.0)	
Tricuspid insufficiency at postoperative transesophageal echocardiogram			.36
None	0 (0.0)	0 (0.0)	
Trivial	7 (87.5)	3 (60.0)	
Mild	1 (12.5)	1 (20.0)	
Moderate	0 (0.0)	1 (20.0)	
Severe	0 (0.0)	0 (0.0)	
Right ventricular function at postoperative transesophageal echocardiogram			.18
Normal	8 (100.0)	4 (80.0)	
Mildly diminished	0 (0.0)	1 (20.0)	
Moderately diminished	0 (0.0)	0 (0.0)	
Peak right ventricular outflow tract gradient at discharge	4.0 (3.0-34)	6.0 (4.0-46.0)	.29
Pulmonary insufficiency at discharge			.20
None	0 (0.0)	0 (0.0)	
Trivial	0 (0.0)	0 (0.0)	
Mild	0 (0.0)	0 (0.0)	
Moderate	1 (11.1)	2 (40.0)	
Severe	8 (88.9)	3 (60.0)	
Inpatient mortality	1 (10)	0 (0.0)	.21

Denominator for some fields differ from column total due to missing data

have been demonstrated during the hospitalization period. However, regardless of the degree of PI, the qualitative right ventricular function was similar between both groups immediately postoperative and at time of discharge. The nonmonocusp groups also had similar length of hospitalization, postoperative arrhythmias, need for ECMO, chest tube duration, duration of ventilation, and overall total hospital length of stay. There was also no difference in mortality or need for reintervention prior to discharge.

We also analyzed the neonatal population separately to assess whether the use of the monocusp in this higher risk population would impact outcomes. The total number of patients in this subset was fairly small but, of the neonates had a monocusp valve, the postoperative comes were similar without different in duration of mechanical ventilation, hospital length of stay or discharge echocardiograms. Interestingly, even the degree of PI was similar, which could be related to the limited numbers in the groups.

Sasson et al in 2013 published their institutional outcomes with monocusp valve placement. They had a total of 163 patients with the diagnosis of TOF with pulmonary stenosis, divided into three cohorts: pulmonary valve sparing procedure, TAP without monocusp, and TAP with monocusp. Their study noted decreased duration of mechanical ventilation, intensive care unit stay, and chest tube duration.[13] Although Sasson and colleagues noted improved postoperative outcomes, it is important to note they had a significantly older mean age at time of repair in all their cohorts (27 months in the nonmonocusp and 20.5 months in the monocusp group) compared to our population (4.8 months in the nonmonocusp and 4.6 months in the monocusp group). It could be postulated that the monocusp valve may be useful in older populations but in younger children, such as our population, there is no clear benefit and therefore prolonging bypass and cross-clamp time is unnecessary.

More recently Kumar et al reviewed their 20-year outcomes and found improved outcomes with use of monocusp valve. They included patients with pulmonary atresia with VSD in their analysis, a group we chose to exclude given their inherently more complex pulmonary arterial tree, and those with double outlet right ventricle.[12] In these more complex cases, the monocusp valve may potentially help improve outcomes, but based on our experience we can conclude the use of monocusp valve did not improve immediate outcomes in those with TOF with pulmonary stenosis alone.

While we cannot say with certainty what happens to the monocusp valve itself that leads to the progression of PI, it has been noted previously in surgical studies that sizing and type of material used of the monocusp can affect its function.[11,14,15] Some proponents of a valve in the right ventricular outflow tract have had noted that the monocusp valve has not been particularly effective and started using a bicuspid valve that can be constructed of Gore-tex or polytetrafluoroethylene membrane. Descriptive studies have demonstrated data that may indicate that such valves may outperform monocusp valves.[16,17] However, no direct comparison of the two has been performed. Also, development of fibrosis of the constructed valve is thought to contribute to loss of valve function. In our study, it seems unlikely that fibrosis plays a major part in loss of function as by echocardiography the monocusp valves usually don't appear thickened in a fashion consistent with fibrosis. Additionally, fibrosis of the monocusp would likely make the monocusp more rigid in nature and results in some degree of RVOT obstruction which is not seen to be an issue in a large proportion of these patients.

5 | LIMITATIONS

The study is limited by its single center, nonrandomized and retrospective nature. Rationale for placing monocusp valve could not be determined. This decision was dependent on surgeon preference, inherently creating a selection bias of who received monocusp valves. However, based on preoperative clinical data these two groups were very similar. Additionally, we were unable to consistently capture the material used for the monocusp and the preparation for this material and therefore unable to effectively analyze the impact of monocusp material on outcomes. Another limitation of our study is that our assessment of the right ventricle was based on qualitative function analysis. Using methods such as right ventricular strain analysis could be helpful to provide another means of assessing function. Long-term data could not uniformly be collected given many patients were referrals to our center and follow-up data is not available for those patients. Despite the limitations, we feel that our study presents a large series of data comparing those with and without a monocusp and provides data upon which to base larger prospective studies.

6 | CONCLUSION

Although the degree of PI is significantly less in patients with monocusp valves immediately following surgical repair, the use of monocusp valve in repair of TOF with TAP does not improve outcomes in the immediate postoperative period. Therefore placement of a monocusp valve, which prolongs bypass and cross-clamp time, is not required in patients undergoing TOF repair with TAP.

CONFLICT OF INTEREST STATEMENT

All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

AUTHOR CONTRIBUTIONS

Nikki M. Singh, MD: Concept/Design; Data collection, Data analysis/interpretation, Drafting article, Critical revision of article, Approval of article.

Rohit S. Loomba, MD: Concept/Design, Data collection, Statistics, Data analysis/interpretation, Critical revision of article, Approval of article.

Todd M. Gudausky MD: Concept, Data interpretation, Critical revision of article, Approval of article.

Michael E. Mitchell MD: Concept, Data interpretation, Critical revision of article, Approval of article

ORCID

Nikki M. Singh http://orcid.org/0000-0002-4125-9794
Rohit S. Loomba http://orcid.org/0000-0002-9116-2835

REFERENCES

1. Choi KH, Sung SC, Kim H, et al. A novel predictive value for the transannular patch enlargement in repair of tetralogy of Fallot. *Ann Thorac Surg*. 2016;101:703-707.
2. Bove EL, Byrum CJ, Thomas FD, et al. The influence of pulmonary insufficiency on ventricular function following repair of tetralogy of Fallot. Evaluation using radionuclide ventriculography. *J Thorac Cardiovasc Surg*. 1983;85:691-696.
3. Gatzoulis MA, Balaji S, Webber SA, et al. Risk factors for arrhythmia and sudden cardiac death late after repair of tetralogy of Fallot: a multicentre study. *Lancet*. 2000;356:975-981.
4. Mercer-Rosa L, Ingall E, Zhang X, et al. The impact of pulmonary insufficiency on the right ventricle: a comparison of isolated valvar pulmonary stenosis and tetralogy of fallot. *Pediatr Cardiol*. 2015;36:796-801.
5. Ammash NM, Dearani JA, Burkhart HM, Connolly HM. Pulmonary regurgitation after tetralogy of Fallot repair: clinical features, sequelae, and timing of pulmonary valve replacement. *Congenit Heart Dis*. 2007;2:386-403.
6. Geva T. Repaired tetralogy of Fallot: the roles of cardiovascular magnetic resonance in evaluating pathophysiology and for pulmonary valve replacement decision support. *J Cardiovasc Magn Reson*. 2011;13:9.
7. Villafane J, Feinstein JA, Jenkins KJ, et al. Hot topics in tetralogy of Fallot. *J Am Coll Cardiol*. 2013;62:2155-2166.
8. Sen DG, Najjar M, Yimaz B, et al. Aiming to preserve pulmonary valve function in tetralogy of Fallot repair: comparing a new approach to traditional management. *Pediatr Cardiol*. 2016;37:818-825.
9. Simon BV, Swartz MF, Egan M, Cholette JM, Gensini F, Alfieris GM. Use of a dacron annular sparing versus limited transannular patch with nominal pulmonary annular expansion in infants with tetralogy of Fallot. *Ann Thorac Surg*. 2017;103:186-192.
10. Chai PJ, Jacobs JP, Quintessenza JA. Modern surgical management of patients with tetralogy of Fallot. *Cardiol Young*. 2013;23:905-909.
11. Brown JW, Ruzmetov M, Vijay P, Rodefeld MD, Turrentine MW. Right ventricular outflow tract reconstruction with a polytetrafluoroethylene monocusp valve: a twelve-year experience. *J Thorac Cardiovasc Surg*. 2007;133:1336-1343.
12. Kumar M, Turrentine MW, Rodefeld MD, Bell T, Brown JW. Right ventricular outflow tract reconstruction with a polytetrafluoroethylene monocusp valve: a 20-year experience. *Semin Thorac Cardiovasc Surg*. 2016;28:463-470.
13. Sasson L, Houri S, Raucher Sternfeld A, et al. Right ventricular outflow tract strategies for repair of tetralogy of Fallot: effect of monocusp valve reconstruction. *Eur J Cardiothorac Surg*. 2013;43:743-751.
14. Gundry SR, Razzouk AJ, Boskind JF, Bansal R, Bailey LL. Fate of the pericardial monocusp pulmonary valve for right ventricular outflow tract reconstruction. Early function, late failure without obstruction. *J Thorac Cardiovasc Surg*. 1994;107:908-912; discussion 912-903.
15. Turrentine MW, McCarthy RP, Vijay P, Fiore AC, Brown JW. Polytetrafluoroethylene monocusp valve technique for right ventricular outflow tract reconstruction. *Ann Thorac Surg*. 2002;74:2202-2205.
16. Lee C, Lee CH, Kwak JG. Polytetrafluoroethylene bicuspid pulmonary valve replacement: a 5-year experience in 119 patients with congenital heart disease. *Ann Thorac Surg*. 2016;102:163-169.
17. Lee C, Lee CH, Kwak JG et al. Bicuspid pulmonary valve implantation using polytetrafluoroethylene membrane: early results and assessment of the valve function by magnetic resonance imaging. *Eur J Cardiothorac Surg*. 2013;43:468-472.

How to cite this article: Singh NM, Loomba RS, Gudausky TM, Mitchell ME. Monocusp valve placement in children with tetralogy of Fallot undergoing repair with transannular patch: A functioning pulmonary valve does not improve immediate postsurgical outcomes. *Congenital Heart Disease*. 2018;13:935–943. https://doi.org/10.1111/chd.12670