Implantation of monocusp valve prolongs the duration of chest tube drainage in children with tetralogy of fallot after corrective surgery

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Abstract

Background: Right ventricular outflow tract obstruction relief is one of the major procedures during the total correction of tetralogy of Fallot (TOF). Pulmonary insufficiency (PI) is usually inevitable after a transannular incision with a patch repair is performed. Therefore, some surgeons advocate to place a monocusp valve within the transannular patch (TAP) in order to decrease the severity of the PI. However, the monocusp valve seemed not be very effective in some patients who underwent the complete TOF repair.

Methods: Patients who had the classic form of TOF between January 2009 and January 2017 and underwent the corrective surgery with a TAP by the same cardiovascular surgeon were identified for further analysis. Clinical information including demographics at operation, perioperative data, and postoperative outcome were collected retrospectively and compared between the group with and without a monocusp valve.

Results: A total of 24 TOF cases were included in the final analysis, and 16 (66.7%) patients received a monocusp valve placement. The patients' characteristics before and during the surgery were similar between the two groups. The median duration of chest tube drainage after the total correction in the monocusp group was longer than those without the valve ($p = 0.04$). There was no difference in the immediate postoperative data, including the inflammation/infection status, the duration of mechanical ventilation, and the length of ICU and hospital stay.

Conclusion: Implantation of a monocusp valve during the total TOF correction using a TAP did not bring benefit to improve the immediate postoperative outcomes, especially the duration of the pleural drainage. Further study with a prospective design and a larger number of cases is needed.

Keywords: Chest tube; Monocusp valve; Pleural effusion; Pulmonary insufficiency; Tetralogy of Fallot; Transannular patch

1. INTRODUCTION

Tetralogy of Fallot (TOF) is the most common cyanotic congenital heart disease (CHD), classically characterized by right ventricular outflow tract (RVOT) obstruction, ventricular septal defect (VSD), right ventricular hypertrophy, and overriding of the aorta,[1,2] which is predominant in males.[2] The first complete intracardiac repair by C. Walton Lillehei was reported in 1954.[3] Early surgical techniques included repair of the VSD via a large right ventriculotomy and extensive resection of the RVOT musculature and pulmonary valve leaflets. Extending the ventriculotomy across the pulmonary valve into the main pulmonary artery (PA) and repairing by a pericardial patch to augment the outflow tract was advocated since 1956,[4] which was the origin of the "transannular patch implantation." Subsequently, the transatrial-transpulmonary approach has been advantageous in terms of early and middle-term outcomes by avoiding ventriculotomy and its associated scarring and dysfunction.[5] In the 1980s, some surgeons preferred to operate the patients with preservation of the pulmonary valve, even at the expense of a modest residual stenosis.[6] With the advancement in surgical techniques, most patients with TOF could ensure long-term survival after the surgical correction.[1,7]

If there was a significant RVOT obstruction at the pulmonary annulus level or hypoplasia of the valve, a transannular incision

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with a patch repair was one of the methods to completely relieve the outflow tract obstruction. However, immediately the competency of pulmonary valve leaflet was destroyed by placement of the TAP, pulmonary insufficiency (PI) was created inevitably,[8] which would cause late right ventricular dilatation and dysfunction.[9] Regarding this complication, some cardiovascular surgeons advocated for the placement of a monocusp valve in the TAP in order to alleviate the PI.[8] There are different materials that can be used to create a monocusp valve, including homograft,[10] autologous pericardium,[11] or polytetrafluoroethylene (PTFE).[8,12,13] To date the efficacy of this valve is still controversial. Several articles demonstrated a good postoperative outcome with the placement of a monocusp valve.[8,14] However, the monocusp valve was found to develop calcification and dysfunction within one year.[15] In addition, some evidence showed that it might not be very effective in the postoperative stage,[16] during which it even had no benefit in the prevention of PI.[16,17]

Pleural effusion is one of the most common complications after the total correction of TOF.[18] The mechanism involves increased pressure gradient between the pleurae after relief of the RVOT obstruction.[19] In addition, prolonged pleural effusion is an important morbidity factor after TOF repair, which would prolong the hospital stay.[20] Several risk factors, including cardiopulmonary bypass (CPB) time, low oxygen saturation preoperatively, wound infection, and longer duration of mechanical ventilation, would cause prolonged pleural effusion after TOF repair.[19] Sasson et al.[14] found a longer CPB time in the group with monocusp valve reconstruction, but shorter duration of pleural drainage in this group. Singh et al.[21] also found a longer CPB time in the monocusp group, but no difference in the duration of postoperative pleural drainage between these two groups. Actually, no related literature has focused on the postoperative pleural effusion associated with the prior implantation of the monocusp valve.

Therefore, in order to evaluate the influence of the monocusp valve on the postoperative stage, we conducted a retrospective study to review patients with TOF who underwent total correction with a TAP performed by a single surgeon at our institution. The aim of this study was to compare the postoperative clinical outcome, especially the duration of pleural drainage between the patients who received a monocusp valve placement or not.

2. METHODS

2.1. Patients

Children who underwent total correction of TOF with TAP from January 2009 to January 2017 at Taipei Veterans General Hospital were identified. Patients older than 18 years and those who could not be evaluated during the duration of the chest tube drainage postoperatively were excluded. Patients with complicated congenital cardiac defects apart from the TOF pathology with pulmonary stenosis (i.e., atrioventricular septal defect, double outlet right ventricle, or pulmonary atresia) were also excluded. Preoperative information including prior procedures, demographics at operation (sex, age, and body weight), laboratory data, oxygen saturation, and RVOT gradient determined by continuous-wave Doppler echocardiography were reviewed from the medical records retrospectively. All of the enrolled patients underwent cardiac catheterization with angiography or cardiac computed tomography prior to the surgery, from which McGoon ratio and Nakata index were calculated.

All the patients were operated by the same cardiovascular surgeon. Under cardiopulmonary bypass, the VSD was closed by a patch repair through the right atrium. Subsequently, the surgeon performed a transannular incision and reconstructed with a patch for the RVOT obstruction. The decision to either implant a monocusp valve or not was mainly taken by the surgeon. A monocusp was fashioned from 0.1-mm PTFE membrane. After the surgery, all the children were sent to the ICU for postoperative care followed by the routine procedures. The patient was extubated when the consciousness and blood gas levels met the requirement for extubation and the hemodynamic status was stable. Perioperative and postoperative data including aortic clamping time, CPB time, postoperative C-reactive protein (CRP) value, duration of mechanical ventilation, duration of chest tube drainage, and the length of ICU and hospital stay were also reviewed retrospectively.

In our institution, if the pleural drainage amount was less than 2 ml/kg/day for more than 48 hours postoperatively, the chest tube would be removed thereafter. Patients underwent further imaging after removal of the chest tube, including X-ray or sonography of the chest. If clinically significant pleural effusion was noted, re-intubation for pleural drainage was applied and the cumulative duration was computed finally.

Regarding postoperative follow-up, the patients underwent echocardiography before discharge at the ward, from which the severity of the pulmonary insufficiency (PI) and pressure gradient across the RVOT were recorded by color and continuous-wave Doppler.

2.2. Statistics

The demographics at the time of surgery and postoperative outcomes were compared between those with and without monocusp valve placement during the total correction. The descriptive variables were reported as absolute frequency and percentage while the continuous variables were reported as median and range, and the range of data all indicated from minimal to maximal value. The SPSS software (Statistical Package for the Social Science; SPSS Inc., Chicago, IL), release 23th versions for Windows was used. The descriptive variables were compared using a Fisher exact test while the continuous variables were compared using a non-parametric Mann–Whitney U-test due to the non-normal distribution of the data. The results were considered to be statistically significant if the p value was <0.05.

2.3. Ethics

The study was approved by the Institutional Ethical Review Board of Taipei Veterans General Hospital (2019-10-001AC), and informed consent was waived because the present study employed a retrospective design.

3. RESULTS

A total of 45 patients with TOF underwent the corrective surgery, and 24 patients who fulfilled the inclusion criteria were enrolled in the final analysis. Of these, 16 (66.7%) had a monocusp valve placement at the time of total correction of TOF. The patients' characteristics in each group before and during the surgery are presented in Table 1. There was no difference in sex (p = 0.68) and body weight at surgery (p = 0.18) between the two groups. The median age at surgery was smaller in the group without a monocusp (14.18 months vs 9.8 months, p = 0.05). Blalock-Thomas- Taussig (B-T-T) shunt was created before corrective surgery in 3 (18.75%) of the patients in the monocusp group and none in the other group (p = 0.53). On the other hand, one patient (12.5%) underwent prior transcatheter balloon dilatation for the valvar pulmonary stenosis before surgery in the group without a monocusp valve, but none in the monocusp valve group (p = 0.33). Basic laboratory data before the total correction was similar between these two groups. The median preoperative oxygen saturation between the two groups did not show a significant difference (80.45% vs 81.25%, p = 0.61),

Table 1

Patients' characteristics before and during the total correction of TOF

	With a monocusp valve (n = 16)	Without a monocusp valve (n = 8)	*p*
Male sex, n (%)	8 (50%)	5 (62.5%)	0.68
Age (m/o)	14.18 (6.53–65.53)	9.80 (5.57–19.53)	0.05
Body weight (kg)	9.29 (7.11–8.75)	7.71 (5.6–11.1)	0.18
Prior intervention			
B-T-T shunt placement	3 (18.75%)	0	0.53
Balloon dilatation	0	1 (12.5%)	0.33
Laboratory data			
WBC (/cumm)	8.50 (1.02–15.5)	10.15 (4.9–13.6)	0.33
Hb (g/dl)	15.00 (11.3–19.2)	14.25 (11.5–19.2)	0.39
PLT (/cumm)	279.00 (84–390)	253.50 (171–404)	0.58
BUN (mg/dl)	13.00 (5–18)	14.00 (6–16)	0.89
Cr (mg/dl)	0.40 (0.32–0.6)	0.35 (0.2–0.55)	0.20
O_2 saturation (%)	80.45 (70.3–93.9)	81.25 (70.9–97.3)	0.61
Peak RVOT gradient (mmHg) by echocardiography	71.57 (45.97–97.22)	79.57 (70.22–96.04)	0.10
McGoon ratio	2.07 (1.54–2.50)	2.15 (1.50–2.79)	0.84
Nakata index (mm^2/m^2)	264.12 (84–499)	370.43 (145–741)	0.31
Aortic-clamp time (min)	128.50 (94–172)	103.00 (78–179)	0.13
CPB time (min)	178.50 (132–300)	179.00 (121–341)	0.74

There was no significant difference in the variables of the characteristics before and during the corrective surgery. The range of data in brackets indicated from minimal to maximal value.
CPB, cardiopulmonary bypass; RVOT, right ventricular outflow tract; TOF, tetralogy of Fallot.

as well as the peak RVOT pressure gradient (71.57 mmHg vs 79.57 mmHg, $p = 0.10$). The median aortic-clamp time and CPB time showed no significant difference between the two groups.

Patients' outcomes after the total correction in each group are presented in Table 2. The CRP level was measured by laboratory test postoperatively, and no significant difference between the two groups was found ($p = 0.87$). The median duration of chest tube drainage was longer in the monocusp valve group than in those without the valve (23.0 days vs 14.50 days, $p = 0.04$). The duration of the mechanical ventilation was similar between these two groups (2 days vs 3.5 days, $p = 0.83$). The median length of postoperative ICU stay was 18.0 days (3.0–85.0) in the monocusp valve group and 9.0 days (3.0–33.0) in the other group ($p = 0.36$). The median length of postoperative hospital stay was 29.50 days (28.0–91.0) in the group with a monocusp valve and 19.50 days (13.0–42.0) in the other group ($p = 0.19$). Peak RVOT gradient recorded by echocardiography before discharge had no difference between these two groups (22.28 mmHg vs 20.25 mmHg, $p = 0.89$). No patients required reintervention in both groups. One patient (6.25%) in the monocusp valve group was supported on extracorporeal membrane oxygenation (ECMO) postoperatively, because he developed a low cardiac output syndrome one day after the corrective surgery and was resistant to the initial medical management, and the ECMO was decannulated six days later,

Table 2

Patients' outcomes after the total correction of TOF

	With a monocusp valve (n = 16)	Without a monocusp valve (n = 8)	*p*
CRP value (mg/dl)	3.50 (1.29–13.86)	3.57 (0.11–8.22)	0.87
Duration of chest tube placement (d)	23.00 (7–82)	14.50 (4–27)	0.04*
Duration of mechanical ventilation (d)	2.00 (0–24)	3.50 (1–12)	0.83
Length of ICU stay (d)	18.00 (3–85)	9.00 (3–33)	0.36
Length of hospital stay (d)	29.50 (28–91)	19.50 (13–42)	0.19
Peak RVOT gradient (mmHg) by echocardiography	22.28 (4.24–44.09)	20.25 (11.16–90.63)	0.89
Other complications:			
ECMO support	1 (6.25%)	0	1.00
Chylothorax	4 (25%)	2 (25%)	1.00
Pneumothorax	2 (12.5%)	0	0.54
Diaphragmatic palsy	2 (12.5%)	0	0.54
Sepsis	1 (6.25%)	0	1.00
Acute kidney injury	1 (6.25%)	1 (12.5%)	1.00
Postoperative PI			0.77
None	2 (12.5%)	1 (12.5%)	
Minimal	2 (12.5%)	0	
Mild	6 (37.5%)	4 (50%)	
Moderate	5 (31.25%)	3 (37.5%)	
Severe	0	0	

Postoperative data revealed significantly longer duration of the chest tube drainage in the monocusp valve group ($p = 0.04$). The range of data in brackets indicated from minimal to maximal value.
CRP, C-reactive protein; d, days; ICU, intensive care unit; ECMO, extracorporeal membrane oxygenation; TOF, tetralogy of Fallot.

when the hemodynamic status improved. During the period of ECMO support, acute kidney injury was also noted. The renal function finally became normal after transient hemodialysis and peritoneal dialysis. There were four patients (25.0%) in the monocusp valve group and two (25.0%) in the other group who had a chylous chest tube output (p = 1.00). There was no postoperative death in these two groups.

Regarding postoperative PI, 11 patients (68.75%) in the monocusp valve group and 7 (87.5%) in the group without the monocusp valve had at least mild PI. No severe PI was documented between these two groups in the immediate follow-up.

4. DISCUSSION

The present study demonstrated that, in pediatric patients who underwent a total TOF correction with TAP, implantation of a monocusp valve did not help to reduce the duration of the chest tube drainage. Due to the fact that prolonged pleural drainage has been recognized as one of the major morbidity factors that leads to a longer hospital stay following the surgical repair of a CHD,[22] this finding could provide a unique and practical insight into caring for children with TOF.

The normal pleural fluid exchange is regulated by several mechanism, including the Starling pressure gradient across the mesothelia, the conductance of filtering and absorbing portions of the mesothelia, and the capacity and power of the lymphatic pump.[23] On the other hand, the vascular anatomy is often abnormal in TOF patients, with thin-walled pulmonary arteries, but dilated lumens of the pulmonary arteries, capillaries, and veins.[24] Surgical correction in TOF eliminated the RVOT obstruction, which caused an acute and a significant increase in pulmonary blood flow, considerably increasing the gradient across the pleura. These mechanism resulted in intrapleural fluid accumulation.[20] Several risk factors correlated with prolonged pleural drainage after surgical repair of TOF, including male gender, age at repair, body weight, bypass time, low oxygen saturation before surgery, wound infection after surgery, duration of endotracheal intubation, length of hospital stay, and Nakata index.[19] Preoperative low oxygen saturation and postoperative wound infection were the major factors.[19] In the present study, those factors did not significantly differ between the two groups.

Some evidence showed that insertion of the monocusp valve did help in improving the immediate PI after surgery,[8,13–15,25] as well as the clinical conditions,[12,14] after the transannular incision was performed during the total correction of TOF. Among those studies, Sasson et al. found that TAP with a monocusp valve decreased the duration of chest tube drainage.[14] In comparison with the present study, the median age at the time of surgical repair in their cohorts were relatively older (20.5 months in the monocusp group and 27 months in the TAP group) than our participants (14.18 months in the monocusp group and 9.8 months in the TAP group). Therefore, it could be hypothesized that a monocusp valve might be helpful in the older patients, especially when the total correction was carried out beyond infancy. It is difficult to propose a definite etiology why the duration of chest tube placement, as well as the persistence of the pleural effusion, was longer in the group with a monocusp valve placement. However, as mentioned above, our participants were relatively younger at the age of total correction. Therefore, the effect of a monocusp valve might be vague. On the other hand, the present study also demonstrated a lesser degree of the postoperative PI in the monocusp group with respect to patients without a monocuspid valve. We presumed that more antegrade pulmonary flow after the surgery would cause an increase in intravascular hydrostatic pressure, resulting in prolonged pleural effusion. In addition, the design of the monocusp valve, including both the size and material, would also affect the function of this valve.[16,19,26] Therefore, we could suppose that the insertion of a monocusp valve might not be indicated in all children with TOF in whom a TAP is considered as the surgical technique. The experience of the cardiovascular surgeon and the criteria of patient selection may also play important roles in achieving better postoperative outcomes.

In our study, the clinical characteristics before surgical correction of TOF between the two groups were similar in terms of sex, body weight, laboratory data, O_2 saturation, and peak RVOT pressure gradient. The McGoon ratio and Nakata index in the monocusp valve group were smaller than in the other group, implying that there is an greater trend of small PA size among patients in whom the valve was implanted. Overall, the decision of monocusp valve placement depended mainly on the preference of the cardiovascular surgeon at the time of surgical intervention. Some surgeons chose to implant a monocusp valve with a pulmonary annulus Z-value ≤ –2 or a completely dysplastic and nonfunctioning pulmonary valve.[11] In addition, the aortic-clamp time and CPB time during the operation did not show a significant difference between the two groups. Those results were also consistent with the study by Pande[11] and Samadi.[27] However, other studies have indicated that the CBP time and aortic-clamp time would be longer in the group with a monocusp valve placement.[12–14] At our institution, before the total correction of TOF, patients would undergo cardiac catheterization with angiogram or computed tomography with angiography to illustrate the cardiac anatomy. This may imply that, the construction and placement of a monocuspid valve may not be challenging in patients with labile hemodynamics if the surgeon had prior schemed for reconstruction of the RVOT. After the corrective surgery, the index regarding inflammation or infection, duration of mechanical ventilation, and length of ICU stay and hospitalization were similar between the two groups. Therefore, these findings may further strengthen the association between the monocusp valve and prolonged pleural effusion among the pediatric patients who underwent the surgical correction of TOF with a TAP.

One of the 24 patients underwent transcatheter balloon dilation for pulmonary valve prior to the corrective surgery because of the severe pulmonary stenosis and cyanosis; the patient had the lowest McGoon ratio (1.50) and Nakata index (145 mm^2/m^2), and corrective surgery was done at the age of seven months without a monocusp valve. Meanwhile, most of the cases underwent a one-stage corrective surgery, except three patients who were performed a modified B-T-T shunt, but experienced cyanotic spells in the infant stage, who then underwent the total correction with implantation of a monocusp valve beyond the infancy. The same findings in the study by Sasson et al. also demonstrated that more patients with a monocusp valve had prior surgery of palliative shunt than patients in other groups.[14]

During the early follow-up, we found that the severity of the immediate PI does not progress with associated symptoms. This finding is consistent with the conclusion by Singh et al., who found that the clinical outcomes were not well correlated with PI in the immediate postoperative period.[21] Since the aim of the present study was to evaluate the immediate postoperative outcome of TOF, the mid-term and long-term outcome of these patients might be focused in the future study.

Several limitations of the present study should be considered. First, the number of cases was relatively smaller. In order to minimize the technical and selection bias from different cardiovascular surgeons, we enrolled patients who underwent the surgery by the same surgical team with the method of TAP. As a result, the number of participants was also limited. Second, the present study was a retrospective design. To the best of our knowledge, a prospective study involving patients who underwent the total correction of TOF with TAP is still lacking. Therefore, it is recommended to conduct a study with a prospective design and a larger number of cases to strengthen the evidence.

In conclusion, the present study shared the experience of children with TOF who underwent the total correction with TAP at our institution and compared the postoperative outcomes between the groups with and without a monocusp valve placement. The duration of chest tube drainage was longer in the group with a monocusp valve postoperatively. As a result, placing a monocusp valve may not improve the immediate postoperative outcomes of TOF.

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