

# Surgical Results of Monocusp Implantation with Transannular Patch Angioplasty in Tetralogy of Fallot Repair

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**Background:** Monocusp reconstruction with a transannular patch (TAP) results in early improvement because it relieves residual volume hypertension during the immediate postoperative period. However, few reports have assessed the long-term surgical outcomes of this procedure. The purpose of the present study was to evaluate the mid-term surgical outcomes of tetralogy of Fallot (TOF) repair using monocusp reconstruction with a TAP. **Methods:** Between March 2000 and March 2009, 36 patients with a TOF received a TAP. A TAP with monocusp reconstruction (group I) was used in 25 patients and a TAP without monocusp reconstruction (group II) was used in 11 patients. We evaluated hemodynamic parameters using echocardiography during the follow-up period in both groups. **Results:** At the most recent follow-up echocardiography (mean follow-up, 8.2 years), the mean pulmonary valve velocities of the patients in group I and group II were  $2.1 \pm 1.0$  m/sec and  $0.9 \pm 0.9$  m/sec, respectively ( $p=0.001$ ). Although the incidence of grade 3-4 pulmonary regurgitation (PR) was not significantly different between the two groups (group I: 16 patients, 64.0%; group II: 7 patients, 70.0%;  $p=0.735$ ) during the follow-up period, the interval between the treatment and the incidence of PR aggravation was longer in group I than in group II (group I:  $6.5 \pm 3.4$  years; group II:  $3.8 \pm 2.2$  years;  $p=0.037$ ). **Conclusion:** Monocusp reconstruction with a TAP prolonged the interval between the initial treatment and grade 3-4 PR aggravation. Patients who received a TAP with monocusp reconstruction to repair TOF were not to progress to pulmonary stenosis during the follow-up period as those who received a TAP without monocusp reconstruction.

**Key words:** 1. Tetralogy of Fallot  
2. Transannular patch  
3. Monocusp reconstruction

## Introduction

Transannular patch (TAP) angioplasty is a surgical option for the repair of tetralogy of Fallot (TOF) presenting with substantial stenosis at the level of the pulmonary valve (PV) annulus. However, because a TAP angioplasty induces substantial regurgitant flow, this can impair the proper functioning of the right ventricle

(RV) [1]. In particular, the sudden hemodynamic change resulting from an obstructed and pressure-loaded RV chamber being converted to a volume-loaded RV chamber may aggravate the function of the RV during the acute phase and lead to chronic volume overload, which results in late RV dysfunction [2,3].

In order to eliminate acute and chronic volume overload, some experts have advocated monocusp

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valve insertion with a TAP [4-6]. Sasson et al. [7] reported that, compared with a TAP alone, monocusp reconstruction with a TAP shortened the length of stay in the intensive care unit, the duration of pleural drainage, and the ventilation time. However, despite early hemodynamic advantages, the effects of monocusp reconstruction are limited in duration due to progressive degeneration [8]. Almost all previous studies have examined a small number of patients with mixed characteristics. Additionally, no mid-term or long-term surgical data assessing only TOF patients have been published [4,8]. The purpose of this study was to evaluate the mid-term surgical outcomes of monocusp reconstruction with a TAP used during TOF repair.

## Methods

We retrospectively reviewed the surgical outcomes of 36 patients (64.3%) who received a TAP among 56 patients who underwent TOF repair between March 2000 and March 2009. We divided the patients into two groups: group I (TAP with monocusp reconstruction; n=25, 69.4%) and group II (TAP without monocusp reconstruction; n=11, 30.6%).

### 1) Surgical indications and procedures

Monocusp reconstruction was performed on patients with a PV annulus Z-value of  $< -2$  and/or long right ventricular outflow tract (RVOT) stenosis. The choice of procedure was also based on the surgeon's preference. The transannular incision extended from the bifurcation of the main pulmonary artery, through the annulus, and onto the RV free wall, covering the shortest possible distance and spanning the entire length of the infundibular septum. The vertical length of the monocusp equaled the distance from the lowest part of the RVOT incision to the level of the pulmonary annulus, and the width at the free edge was equal to the circumference of the native annulus. A monocusp was fashioned from a 0.1-mm polytetrafluoroethylene membrane (W. L. Gore & Associates Inc., Flagstaff, AZ, USA) in all patients. A monocusp was fixed to the muscle using a 7-0 polypropylene continuous sutures running along the free edge that was apposed to the annulus.

### 2) Patient follow-up

All patients received regular follow-up by a pediatric cardiologist. The mean duration of follow-up was  $9.5 \pm 3.7$  years (group I,  $8.8 \pm 3.2$  years; group II,  $6.8 \pm 4.4$  years;  $p=0.107$ ), and the mean duration between the initial repair and the date of the late echocardiographic follow-up was  $8.2 \pm 3.7$  years (group I,  $10.3 \pm 3.1$  years; group II,  $7.6 \pm 4.4$  years;  $p=0.107$ ). The mean interval of echocardiographic follow-up was  $2.2 \pm 1.9$  years (group I,  $2.3 \pm 2.1$  years; group II,  $2.0 \pm 1.5$  years;  $p=0.077$ ). Pulmonary regurgitation (PR) was recorded by mapping the dimensions of the regurgitation jet with pulsed and color flow Doppler echocardiography. This regurgitation was graded from 0 to 4 (0, none; 1, trivial; 2, mild; 3, moderate; and 4, severe). The maximum velocities across the PV were obtained using continuous Doppler echocardiography.

### 3) Statistical analysis

Categorical variables were expressed as frequencies and percentages. Continuous variables were expressed as the mean  $\pm$  standard deviation. Comparisons between the two groups were analyzed using the Mann-Whitney U-test and the chi-square test. The postoperative absence of grade 3-4 PR among participants was analyzed using the Kaplan-Meier method and compared with the results obtained using the log-rank test.

## Results

### 1) Patient characteristics

The study population consisted of 18 male (50.0%) and 18 female (50.0%) patients. The basic patient characteristics are presented in Table 1 according to treatment method. No significant difference was found in body weight ( $p=0.123$ ) or body surface area ( $p=0.258$ ) between the two groups. Furthermore, no significant difference was found in the preoperative pulmonary annulus Z-value ( $p=0.263$ ) or the pulmonary artery index ( $p=0.189$ ) between the two groups. Additionally, no significant difference was found in the cardiopulmonary bypass time ( $p=0.871$ ) or the aorta cross-clamp time ( $p=0.729$ ) between the two groups. In 5 patients (13.9%), 9 procedures had been previously performed before the TOF total repair (Table 2).

Characteristic	Group I (n=25)	Group II (n=11)	p-value
Sex (male/female)	14/11	4/7	0.278
Age at operation (mo)	13.7±6.5	9.7±5.5	0.100
Body weight (kg)	9.2±1.7	7.7±2.1	0.123
Body surface area (m <sup>2</sup> )	0.42±0.04	0.37±0.09	0.258
PV diameter (mm)	6.7±2.2	7.3±2.2	0.594
Z-value of PV diameter	-3.6±2.0	-2.7±1.9	0.263
PA index	245.9±139.1	290.1±120.7	0.189
Main PA size (mm)	6.6±2.2	7.0±2.0	0.885
Cardiopulmonary bypass time (min)	150.3±47.4	146.0±37.3	0.871
Aortic cross clamp time (min)	101.7±25.3	96.7±29.4	0.729
Mean duration of follow-up (yr)	8.8±3.2	6.8±4.4	0.107
Mean duration of echocardiographic follow-up (yr)	10.3±3.1	7.6±4.4	0.107

Values are presented as mean±standard deviation. PV, pulmonary valve; PA, pulmonary artery.

Procedure	Group I	Group II
Blalock-Taussing shunt	5	1
Left pulmonary artery patch angioplasty	1	0
Pulmonary valve valvotomy	1	0
Diaphragm plication	1	0

**2) Additional procedures**

Additional procedures were performed in 7 patients (19.4%). Left pulmonary artery angioplasty was the most common additional procedure; it was performed in 5 patients in group I (20.0%) and 1 patient in group II (10.0%). Right pulmonary artery angioplasty was performed in 1 patient in group I (4.0%).

**3) Echocardiographic data**

**(1) Immediate postoperative results:** No operation-related deaths occurred. The immediate postoperative PV velocity of group I and group II was 2.0±0.5 m/sec and 1.5±1.0 m/sec, respectively; this difference was not statistically significant (p=0.249). Likewise, no significant difference was found in the immediate postoperative PR grades (p=0.108) (Fig. 1).

**(2) Patient follow-up:** Among patients with grade 3 or higher PR, 4 patients (25.0%) in group I and 3 patients (27.3%) in group II developed mild to moderate peripheral pulmonary stenosis (PS); no significant difference in the necessity of reoperation was found between the two groups (p=0.822) (Fig. 2).

Three patients (12.0%) in group I developed a PV

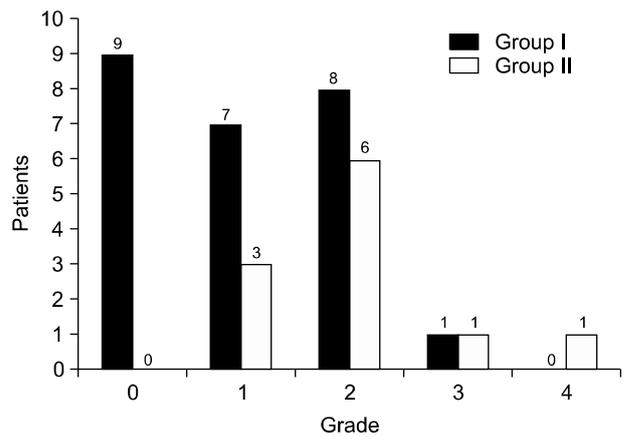
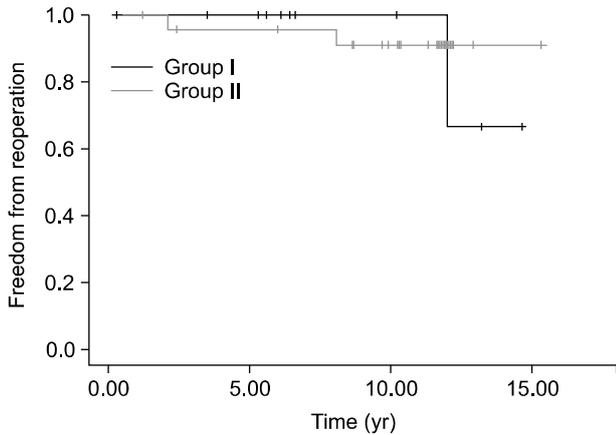
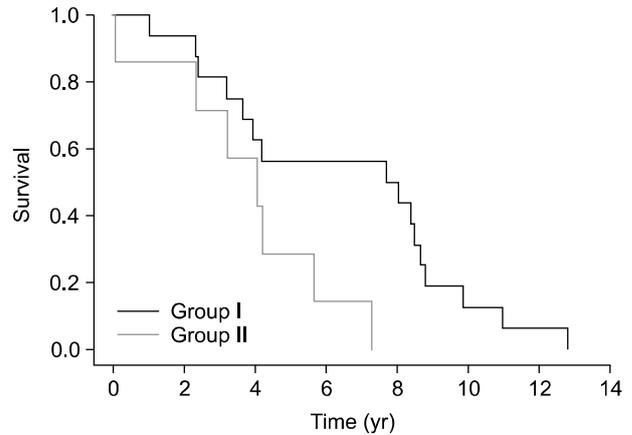


Fig. 1. Pulmonary regurgitation grade during the immediate post-operative period. No significant difference was found between group I and group II in immediate follow-up echocardiography (p=0.108).

velocity of more than 3.5 m/sec during the follow-up period (Table 3). Two patients also experienced severe PR and underwent reoperation at 8.1 years and 2.1 years, respectively. Mild valvular PS and moderate peripheral PS were observed in the echocardiography of one patient. In this patient, the main pathologies of the PS were peripheral PS and tissue around the RVOT, not the monocuspid valve. During the operation performed on another patient (case 2), severe PS was observed to have developed due to a thickened remnant valve that had been left in place during monocusp implantation; the monocusp valve was not the cause of stenosis.



**Fig. 2.** Comparison of the extent to which patients in each group were free from reoperation. No significant difference was found between the two groups. Group I: 5 years, 95.8%±4.1%; 10 years, 91.3%±5.9%; group II: 5 years, 100.0%; 10 years, 66.7%±27.2%;  $p=0.822$ .



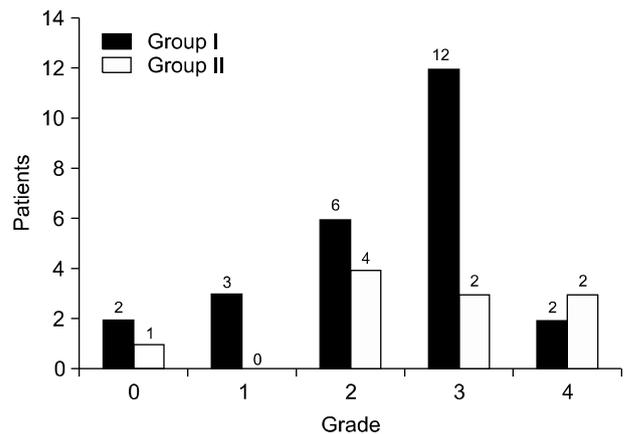
**Fig. 3.** Comparison of the extent to which patients in each group were free from the aggravation of PR. More patients in group I were free from grade 3–4 PR than in group II. PR, pulmonary regurgitation. Group I: 3 years, 81.3%±9.8%; 5 years, 56.3%±12.4%; 10 years, 43.8%±12.4%; group II: 3 years, 71.4%±17.1%; 5 years, 42.9%±18.7%;  $p=0.025$ .

**Table 3.** Three patients with PV velocities  $\geq 3.5$  m/sec in group I

Case	PV velocity (m/sec)	Duration of last follow-up (yr)
1	3.5	8.1
2	4.0	2.1
3	3.7	8.8

PV, pulmonary valve.

The incidence of grade 3 or higher PR was similar between two groups (group I: 16 patients, 64.0%; group II: 7 patients, 70.0%;  $p=0.735$ ). However, when we analyzed the mean interval between the initial treatment and the aggravation of grade 3 or higher PR after excluding patients with an immediate postoperative PR of grade 3–4 in both groups, the mean interval between initial treatment and aggravation was longer in group I ( $6.5 \pm 3.4$  years) than in group II ( $3.8 \pm 2.2$  years) ( $p=0.037$ ). Among the patients who showed more than a moderate degree of PR in the immediate postoperative period, 3 patients with moderate PR in both groups and 1 patient with severe PR in group II showed the same degree of PR during 4.4 years of follow-up. Additionally, more patients were free from grade 3–4 PR in group I than in group II ( $p=0.025$ ) (Fig. 3). No significant difference was found in the PR grade between the two groups in their most recent follow-up echocardiography ( $p=0.333$ ) (Fig. 4). Furthermore, the PV velocity was greater in group I ( $2.1 \pm 1.0$  m/sec) than in group II ( $0.9 \pm 0.9$  m/sec) as assessed during their last echocardiographic follow-up (mean,  $8.2 \pm 3.7$  years) ( $p=0.001$ ).



**Fig. 4.** Pulmonary regurgitation grade assessed in the most recent follow-up echocardiography. No significant difference was found between the groups ( $p=0.333$ ).

## Discussion

Surgical management of patients with substantial stenosis at the level of the valve during TOF repair, who are not candidates for valve-sparing repair, has been performed using either a TAP or a valved conduit implantation. The advantages of the TAP are that it relieves RV hypertension during the immediate postoperative period and that the RVOT usually grows proportionally with growth. However, the dis-

advantage of the TAP is that the acute hemodynamic conversion of an obstructed and pressure-loaded RV to a volume-loaded RV causes temporary and/or delayed RV dysfunction. Thus, one surgical option to prevent acute hemodynamic conversion is the creation of a monocusp patch at the RVOT. Additionally, some reports have suggested that monocusp reconstruction can prevent immediate PR and improve short-term clinical outcomes [7,9,10]. Furthermore, the monocusp is simple, inexpensive, and reproducible [11]. However, Sasikumar et al. [12] reported that calcification and loss of mobility were observed in a significant number of patients 1 year after the operation. Additionally, some studies have reported a significant incidence of inherent valvular insufficiency and/or obstruction [7,12,13]. In our study, although the incidence of grade 3 or higher PR was similar between the two groups, the interval between the initial repair and grade 3-4 PR aggravation was longer in group I. Additionally, more patients were free from grade 3-4 PR in group I at 3 and 5 years than in group II.

Thus, monocusp reconstruction may prevent the progression of PR. The monocusp valves displayed various morphologies during follow-up echocardiography. Some monocusp valves were attached to the pulmonary artery wall and were nonfunctional. However, other monocusp valves were fixed to the middle of the RVOT. We hypothesize that the immobile monocusp valves that were fixed to the middle of the RVOT may have acted as an anti-regurgitation device, prolong the interval between initial TOF repair and PR aggravation. However, this mechanism has yet to be elucidated.

Our study found that the PV velocity in group I during late echocardiographic follow-up was greater than that observed in group II. Additionally, 3 patients had a PV velocity of more than 3.5 m/sec during the follow-up period. However, it was difficult to assess the progression of the PV obstruction because the absolute mean PV velocity of group I was  $2.1 \pm 1.0$  m/sec.

Among the 3 patients in group I who developed a PV velocity of more than 3.5 m/sec during the follow-up period, the main pathology of PS in 2 patients (discussed above) was not the monocusp itself. In addition, the PS in the third patient developed at 8.8 years; for this patient, we suspect that the mono-

cuspid valve was not the cause of PS because, after 8.8 years, the monocusp was small compared to the pulmonary annulus. Thus, we suspect that monocusp reconstruction did not aggravate PS during the follow-up period.

Although the results of this study do not explain how the monocusp reconstructions were influenced by RV function during the follow-up period, we hypothesize that the monocusp reconstruction with a TAP used during TOF repair can delay PV replacement and prevent the aggravation of RV dysfunction.

In conclusion, monocusp reconstruction with a TAP prolonged the time between the initial repair and PR aggravation compared to a TAP without monocusp reconstruction. Furthermore, monocusp reconstruction did not aggravate PS at the mid-term follow-up period. This study is limited by several factors. First, the cohorts were not prospectively randomized. Second, the patient sample size was small and significant differences were not present between the groups. Third, the indications for operation were undefined. Finally, we could not measure the motion of the monocusp valve with ideal method.

### Conflict of interest

No potential conflict of interest relevant to this article was reported.

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