
SHORT-TERM EFFECT OF MONOCUSPID VALVES ON PULMONARY INSUFFICIENCY AND CLINICAL OUTCOME AFTER SURGICAL REPAIR OF TETRALOGY OF FALLOT

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In the surgical repair of tetralogy of Fallot, monocuspid valves are sometimes inserted within a transannular patch to prevent pulmonary insufficiency. To determine whether this monocuspid valve prevents short-term postoperative pulmonary insufficiency and improves clinical outcome, we reviewed clinical data and preoperative and postoperative echocardiographic variables from 61 patients who underwent one of three different procedures for repair of tetralogy of Fallot between August 1992 and March 1994. We compared features from 24 patients who had undergone transannular patch repair with a monocuspid valve (patch-valve) with those from 17 patients who had undergone patch repair without a monocuspid valve (patch) and 20 patients who had undergone repair without a transannular patch (no patch). We used the ratio of pulmonary valve insufficiency jet width to pulmonary artery diameter, as measured by color-flow Doppler flowmetry, as an index of severity of pulmonary insufficiency. Moderate to severe pulmonary insufficiency was arbitrarily defined as a ratio of at least 0.50. We found no significant differences in ratios among the patch-valve group (0.73 ± 0.25 , mean \pm standard deviation), the patch group (0.79 ± 0.20), and the no patch group (0.59 ± 0.23). The percentages of patients with moderate to severe pulmonary insufficiency did not differ among the three groups (patch-valve 80%, patch 90%, no patch 64%). Clinical data (including mortality, number of reoperations, intensive care unit and hospital lengths of stay, and postoperative hemodynamics) were similar in the three groups. We conclude that insertion of a monocuspid valve in repair of tetralogy of Fallot does not prevent short-term postoperative pulmonary insufficiency and does not improve immediate postoperative outcome for these patients. (*J Thorac Cardiovasc Surg* 1996;112:33-7)

After the surgical repair of tetralogy of Fallot with a transannular patch, infants have pulmonary insufficiency.¹ This pulmonary insufficiency may be detrimental in either the short term or the long term.²⁻⁶ The short-term postoperative period is characterized by a sudden hemodynamic change from a pressure-loaded right ventricle to a volume-loaded ventricle; the addition of pulmonary insufficiency further increases the volume load on the right

ventricle. The long-term postoperative period is characterized by chronic volume overload of the right ventricle. As a result, the ventricle may dilate and may be unable to maintain normal pulmonary circulation.⁷ The insertion of a monocuspid valve within the transannular patch to prevent pulmonary insufficiency has been supported by various investigators.⁸⁻¹² Such a procedure has been shown, however, to fail to prevent pulmonary insufficiency in the long term.¹²⁻¹⁶ Whether the insertion of a monocuspid valve improves short-term postoperative pulmonary insufficiency^{12, 17} or outcome is as yet unclear. The purposes of this retrospective study were to determine by echocardiography whether the insertion of a monocuspid valve within a transannular patch improves short-term pulmonary insufficiency after repair of tetralogy of Fallot and to determine from clinical data whether patients undergoing transannular patch repair who receive a monocuspid

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valve have a better early postoperative clinical outcome than those who do not.

Materials and methods

We reviewed the echocardiographic data and charts of all patients who had complete repair of tetralogy of Fallot at The Hospital for Sick Children, Toronto, Canada, between August 1992 and March 1994. We excluded patients who underwent insertion of a conduit or a bioprosthetic valve. Sixty-one patients were included in the study.

In our institution, a transannular patch is inserted when the pulmonary valve orifice or right ventricular outflow tract is more than 2 SD smaller than normal after intraoperative pulmonary valvotomy. There is no institutional policy other than surgeon preference concerning the insertion of a monocuspid valve. We divided the population study into three groups according to type of repair: patients who underwent transannular patch repair with insertion of a monocuspid valve (patch-valve, $n = 24$), patients who underwent transannular patch without insertion of a valve (patch, $n = 17$), and patients who underwent pulmonary valvotomy without a transannular patch (no patch, $n = 20$).

Patients in the no patch group served as a reference group. In the patch-valve group, three types of monocuspid valve were used. Seven patients had a monocuspid valve constructed from a portion of autologous pericardium, 11 patients had a commercial monocuspid valved patch (Polystan, Copenhagen, Denmark), and six patients had a patch excised from a homograft aortic valve conduit containing one aortic valve cusp in continuity with the anterior mitral leaflet. The widths of the Polystan and homograft monocuspid valve patches were selected to achieve a normal pulmonary anulus diameter for body surface area. The autologous pericardial monocuspid valve was constructed by securing a portion of pericardium 30% larger than the width of the outflow tract patch.

We reviewed patients' preoperative echocardiograms and their charts at the time of the operation. From the preoperative echocardiograms, we collected variables reflective of the severity of the tetralogy of Fallot, including dimensions of the left, right, and main pulmonary artery and the right ventricular outflow tract gradient as measured by continuous-wave Doppler flowmetry. To evaluate for patient selection bias regarding repair type, we compared patients' ages, weights, and hemoglobin levels, and noted whether previous systemic-pulmonary (modified Blalock-Taussig) shunt had been required. We also compared the frequency of insertion of a monocuspid valve among the four surgeons.

Postoperative echocardiography was used to determine whether the monocuspid valve prevented short-term postoperative pulmonary insufficiency. Specifically, we evaluated the valve's competency and relief of the pulmonary outflow tract obstruction by assessing three variables: pulmonary valve insufficiency jet width, as measured by color Doppler flowmetry; pulmonary valve diameter in early diastole; and right ventricular outflow tract gradient, as measured by continuous-wave Doppler flowmetry. From these variables, we calculated the ratio of pulmo-

nary insufficiency to pulmonary artery diameter, which is an index of the severity of pulmonary insufficiency. We arbitrarily decided that a ratio of at least 0.50 would represent moderate to severe pulmonary insufficiency.

To determine whether patients with a transannular patch and a monocuspid valve had a better clinical outcome after operation than did patients without a monocuspid valve, we collected data from the operation and from the hospitalization. The data related to the operation included cardiopulmonary bypass time, aortic crossclamp time, postoperative right ventricle-aorta pressure ratio, and the type of monocuspid valve inserted. The data related to the postoperative course included length of stay in the intensive care unit, length of hospitalization, death during hospitalization, and need for reoperation. We considered all patients who required reopening or closure of the chest once in the intensive care unit to have undergone reoperation. In addition, we assessed hemodynamic variables recorded in the intensive care unit at 6, 12, 24, and 48 hours after operation. These included need for oxygen (inspired fraction of oxygen), acid-base status (pH and base excess), partial pressures of oxygen and carbon dioxide, mean blood pressure, central venous pressure, urine output, and need for inotropic support.

The statistical analyses of continuously distributed data were performed with one-way analysis of variance followed by a Bonferroni adjustment test to determine significant differences between groups. Nonparametric data were analyzed by χ^2 and Kruskal-Wallis analysis of variance. Analysis of variance with repeated measurements was performed for data sampled at different time intervals. A p value less than 0.05 was considered significant. Data are expressed as means (\pm standard deviation) and medians (with ranges).

Results

The preoperative echocardiograms and the patients' characteristics were similar at operation (Table I). Postoperative pulmonary insufficiency, as indicated by the ratio of pulmonary valve insufficiency jet width over pulmonary artery diameter, was similar in the two groups that underwent transannular patch repair without or with a monocuspid valve (Table II). This ratio was also similar among the different types of monocuspid valves (0.68 ± 0.31 for autologous pericardium [$n = 7$], 0.77 ± 0.28 for Polystan valves [$n = 11$], and 0.70 ± 0.10 for homograft valves [$n = 6$]).

Clinical outcomes were similar between the two groups that underwent transannular patch repair with or without a monocuspid valve (Table III). One patient in the patch-valve group had a prolonged postoperative course and remained in the intensive care unit for 67 days. The patch-valve group had a longer cardiopulmonary bypass time than did the no patch group (Table III). Clinical outcomes were similar for the no patch group, except that fewer

Table I. Preoperative characteristics

	Patch-valve (n = 24)	Patch (n = 20)	No patch (n = 17)
Preoperative echocardiography			
Age (mo)	23 (0-5)	17 (5-50)	16 (8-62)
RVOT gradient (mm Hg)	67 (44-90)	73 (41-119)	69 (39-91)
PA diameter (cm)	0.8 ± 0.2	1.0 ± 0.3	0.9 ± 0.1
LPA proximal diameter (cm)	0.7 ± 0.2	0.7 ± 0.2	0.8 ± 0.2
RPA proximal diameter (cm)	0.7 ± 0.2	0.7 ± 0.1	0.7 ± 0.1
RPA distal diameter (cm)	0.8 ± 0.2	0.8 ± 0.2	0.8 ± 0.2
Patient characteristics			
Previous shunts (no. patients)	12	4	8
Age at operation (mo)	26 (10-98)	18 (7-52)	17 (11-63)
Weight at operation (kg)	10 (7-20)	10 (6-17)	10 (4-20)
Hemoglobin at operation (gm/L)	152 ± 15	147 ± 20	154 ± 26

Data are means ± standard deviation, except for age, RVOT, age at operation, and weight at operation, which are expressed as median with range in parentheses. *RVOT*, Right ventricular outflow tract; *PA*, pulmonary artery; *LPA*, left pulmonary artery; *RPA*, right pulmonary artery.

Table II. Postoperative echocardiographic variables

	Patch-valve (n = 24)	Patch (n = 20)	No patch (n = 17)
Age (mo)	23 (10-98)	18 (7-52)	17 (11-64)
Time after operation (days)	7 (0-61)	3 (0-41)	4 (0-43)
RVOT gradient (mm Hg)	8 (1-51)*	7 (1-17)*	27 (6-51)
PA diameter (cm)	1.5 ± 0.2*	1.4 ± 0.3	1.2 ± 0.3
PI jet width (cm)	1.0 ± 0.4*	1.0 ± 0.2*	0.6 ± 0.2
PI/PA ratio	0.73 ± 0.25	0.79 ± 0.20	0.59 ± 0.23
PI/PA ratio ≥0.50 (% of patients)	80	90	64

Data are means ± standard deviation except for age, time after operation, and RVOT, which are expressed as median with range in parentheses. *RVOT*, Right ventricular outflow tract; *PA*, pulmonary artery; *PI*, pulmonary insufficiency.

**p* < 0.05 vs no patch group.

patients were receiving inotropic drugs at 48 hours after operation than in the two other groups (Table III).

Among the four surgeons, surgeon 3 inserted a monocuspid valve less frequently than did the other three (surgeon 1, 75% of patients; surgeon 2, 78%; surgeon 3, 21%; surgeon 4, 80%; *p* < 0.01).

Discussion

This study shows that the insertion of these different types of monocuspid valves does not prevent short-term pulmonary insufficiency after repair of tetralogy of Fallot. The reason for persistence of pulmonary insufficiency even when a monocuspid valve is inserted is unclear. The persistent pulmonary insufficiency we observed could be explained by such factors as the long distance to be covered by the monocuspid leaflet during rapid closure or irregular movements of the valve during closure as a result of leaflet buckling.¹⁸ Another cause could be that some monocuspid valves were tailored too wide.¹⁷ In addition, in contrast to other reports,^{11, 19} we found

that the different types of valve used did not affect pulmonary insufficiency, although this conclusion is limited by the small number of patients (7 autologous pericardium valves, 11 Polystan valves, and 6 homograft valves).

We found that 80% of patients who underwent transannular repair with insertion of a monocuspid valve had moderate to severe pulmonary insufficiency, which contrasts with the prevalence of 16% reported by Gundry and coworkers.¹² This discrepancy could be explained by the different methods used to detect pulmonary insufficiency. Our classification of pulmonary insufficiency was based strictly on echocardiography, whereas their classification relied on either clinical examination, catheterization, or echocardiography, according to availability, which may have been less sensitive. Differences in surgical technique could also explain the discrepancy.

Our study also shows that patients who undergo transannular patch repair with the insertion of a monocuspid valve do not have a better clinical

Table III. *Surgical and postoperative variables*

	<i>Patch-valve</i> (<i>n</i> = 24)	<i>Patch</i> (<i>n</i> = 20)	<i>No patch</i> (<i>n</i> = 17)
Bypass time (min)	149 ± 34*	129 ± 55	107 ± 22
Aortic crossclamp time (min)	47 ± 15	55 ± 21	47 ± 11
RV/AO pressure ratio after operation (%)	47 ± 11	50 ± 13	51 ± 15
Stay in intensive care (days)	6 (3-67)	3 (0-19)	4 (2-17)
Stay in hospital (days)	15 (8-65)	13 (7-30)	11 (6-26)
Number of deaths	1	2	2
Reoperations (no. of patients)	7	6	5
Postoperative variables at 48 hours			
FIO ₂	0.47 ± 0.17	0.40 ± 0.10	0.48 ± 0.13
pH	7.46 ± 0.06	7.46 ± 0.03	7.41 ± 0.04
Base excess (mmol/L)	0.2 ± 2.9	-0.1 ± 2.2	-1.1 ± 2.3
PO ₂ (mm Hg)	112 ± 37	122 ± 42	122 ± 35
PCO ₂ (mm Hg)	34 ± 6	34 ± 4	37 ± 6
Mean blood pressure (mm Hg)	74 ± 7	70 ± 10	72 ± 8
Central venous pressure (mm Hg)	12 ± 4	14 ± 5	14 ± 4
Urine output (ml · kg ⁻¹ · hr ⁻¹)	2.5 ± 1.5	2.2 ± 1.4	2.1 ± 1.4
Inotropic drug use (no. of patients)	20*	12*	6

Data are means ± standard deviation, except for stay in intensive care unit and in hospital, which are expressed as median with range in parentheses. *RV*, Right ventricle; *AO*, aorta; *FIO₂*, inspired fraction of oxygen; *PO₂*, oxygen tension; *PCO₂*, carbon dioxide tension.

**p* < 0.05 vs no patch group.

outcome after operation than do patients without a monocuspid valve. Neither did they have a worse outcome, except for the minor finding that cardiopulmonary bypass time was longer than in the reference group (no patch). The high reoperation rate was the result of inclusion of patients with delayed sternal closure within several days of the initial operation.

The clinical outcomes may have been affected by the lack of objective criteria or by selection bias. The criteria reported in the literature for insertion of a monocuspid valve are vague. Some authors recommend insertion of a monocuspid valve in cases of elevated pulmonary vascular resistance or in the presence of multiple pulmonary artery stenoses.¹⁹ In our study, the preoperative echocardiographic results and patient characteristics at operation were similar among the three groups. Selection bias seems most related to the surgeon, as demonstrated by the different frequencies of monocuspid insertion among the surgeons. A randomized clinical trial may be warranted. The wide range of intervals for postoperative echocardiography also may have affected the degree of pulmonary insufficiency, although 91% of the patients had echocardiography performed within 14 days after operation.

In conclusion, insertion of these three types of monocuspid valve within a transannular patch for the surgical repair of tetralogy of Fallot does not

prevent short-term postoperative pulmonary insufficiency. Furthermore, the immediate clinical outcome in patients that underwent transannular patch repair with the insertion of a monocuspid valve is not improved with respect to patients without a monocuspid valve. Although monocuspid valve insertion to prevent short-term postoperative pulmonary insufficiency may potentially improve early hemodynamic function, better surgical techniques for constructing and inserting a pulmonary monocuspid valve and better selection criteria are needed.^{18,20} We are currently evaluating an alternative method of pulmonary monocuspid valve construction and insertion.

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