Right Ventricular Outflow Tract Prosthesis in Total Correction of Tetralogy of Fallot

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SUMMARY Right ventricular outflow tract obstruction was relieved by placing outflow patches across the pulmonary annulus in 39 of 195 patients who underwent total correction of tetralogy of Fallot. The mortality rate in these 39 patients was 12.8%, which did not differ significantly from the overall mortality of 11.3% (p = 1.00). The ratio of the pulse pressure to pulmonary artery systolic pressure as an index of pulmonary insufficiency was dependent on the cross-sectional area index (CSAI) of the pulmonary annulus after enlargement, as shown in the regression equation Y = 1 - 0.63/(X - 0.07) (r = 0.79, p < 0.05). When the CSAI was 2.5 cm²/m² or less and a single cusp was mounted on the outflow patch, the pulmonary insufficiency was negligible and the right ventricular end-diastolic pressure was 10 mm Hg or less. In patients without outflow patches, the right ventricular-to-pulmonary arterial systolic pressure gradient and the right ventricular-to-aortic systolic pressure ratio 1 month after surgery was dependent on the CSAI, as shown in the regression equation Y = 54.0/X² + 5.6 (r = 0.76, p < 0.01) and Y = 0.42/X² + 0.36 (r = 0.72, p < 0.01), respectively. These two equations may also be applied in the case of patients with outflow patches with a single cusp. Thus, when the outflow patch is used, the CSAI must be larger than 1.75 cm²/m² and less than 2.5 cm²/m², and a single cusp should be mounted on the outflow patch.

TOTAL CORRECTION of tetralogy of Fallot consists of repair of the right ventricular outflow tract obstruction, complete closure of the ventricular septal defect and avoidance of injury to the conduction tract. Although there is better understanding of the pathologic anatomy and physiology of this entity, and techniques of repair have been highly satisfactory, some problems remain. Numerous reports have dealt with the relief of the right ventricular outflow tract obstruction and surgical results have improved, but there are no simple, reliable criteria for assessing residual stenosis and postoperative pulmonary insufficiency. We introduced the concept of the cross-sectional area index (CSAI) of the pulmonary annulus after enlargement, and carried out a retrospective investigation of the relation between this index and surgical results (residual pulmonary stenosis, residual shunt, pulmonary insufficiency and complete atrioventricular block). We previously described criteria for enlargement of the right ventricular outflow tract. The present study concerns surgical and postoperative hemodynamic results, particularly postoperative pulmonary insufficiency, in patients in whom outflow patches across the pulmonary valve ring were placed.

Materials and Methods

From September 1968 to September 1978, 195 patients underwent total correction of tetralogy of Fallot in the Department of Cardiovascular Surgery of Kinki University and Heart Institute of Amagasaki Hospital. These patients were classified according to the type of relief of the right ventricular outflow tract obstruction (table 1).

The subjects included 39 patients in whom outflow tract patches traversing the pulmonary valve ring were placed. The outflow patches were of autopericardium covered with Dacron cloth. A pericardial single cusp was mounted in 32 patients, and no cusp was used in the remaining seven. Ninety patients without outflow patches across the pulmonary annulus served as controls in the estimation of the residual pulmonary stenosis and residual right ventricular hypertension.

Cardiac catheterization and angiography were performed preoperatively on all patients, and 1 month postoperatively on 23 out of the 34 survivors with and on 90 patients without outflow patches. The right ventricular and aortic pressures were measured simultaneously, and the pressure gradient between the right ventricle and the main pulmonary artery was obtained from the pullback pressure curve from the pulmonary artery to the right ventricle. The CSAI of the pulmonary annulus after enlargement was calculated as: CSAI = π(d/2)²/BSA, where d is the diameter (in cm) of the pulmonary valve ring after enlargement measured at operation and BSA is body surface area (in m²). The degree of regurgitation of contrast medium refluxing into the right ventricle in the pulmonary arteriogram was classified into grades 1, 2, 3 and 4 from the least to greatest regurgitation, with the right ventricle separated longitudinally into four equal parts in a lateral projection (fig. 1). At this time, no consideration was given to artificial regurgitation due to the catheter inserted into the pulmonary artery.

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TABLE 1. Relief of Right Ventricular Outflow Obstruction

<table>
<thead>
<tr>
<th>Infundibulectomy</th>
<th>No. of cases</th>
<th>No. of deaths</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patch across pulmonary valve ring</td>
<td>39</td>
<td>5</td>
<td>12.8</td>
</tr>
<tr>
<td>With or without valvulotomy</td>
<td>131</td>
<td>13</td>
<td>9.9</td>
</tr>
<tr>
<td>Patch on RV only</td>
<td>3</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Patch on supravalvular area</td>
<td>14</td>
<td>2</td>
<td>14.3</td>
</tr>
<tr>
<td>Patch on both RV and supravalvular area</td>
<td>3</td>
<td>1</td>
<td>33.3</td>
</tr>
<tr>
<td>Pulmonary valve implantation</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Rastelli's procedure</td>
<td>4</td>
<td>1</td>
<td>25</td>
</tr>
<tr>
<td>Total</td>
<td>195</td>
<td>22</td>
<td>11.3</td>
</tr>
</tbody>
</table>

Abbreviation: RV = right ventricle.

Results

Operative Results

Five of the 39 patients with an outflow patch died, for a mortality rate of 12.8%, which was not significantly higher than the overall mortality rate of 11.3% (table 1, p = 1.00). The causes of death were pulmonary edema with pulmonary hypertension in two patients, acute renal failure due to hemolysis and low cardiac output in two, and cerebral bleeding in one patient. In the two patients with the pulmonary edema, the right ventricular outflow tract was enlarged (CSAI > 1.75 cm²/m²), and pulmonary edema with pulmonary hypertension developed immediately after the operation. Subsequent investigation revealed that the average diameter indexes of the arterial pathway to the right upper lobe were less than 4 mm/m², maximum left atrial volume was less than 20 cm³/m² and left ventricular end-diastolic volume less than 40 cm³/m². These values indicate that the pulmonary vascular bed and the left heart were too small to tolerate primary total correction. In the two patients with acute renal failure, who had previous surgery before our criteria for enlargement of the right ventricular outflow tract were established, the ventricular septal defect was subpulmonary, and the right ventricular outflow tract was enlarged only by infundibulectomy and valvulotomy. In these two patients, severe residual pulmonary stenosis resulted from closing the defect, and weaning from the extracorporeal circulation was impossible. The outflow tract had to be enlarged by inserting an outflow patch across the pulmonary valve ring. Though the postoperative hemodynamics were relatively stable, severe hemolysis occurred due to the lengthy perfusion, and the patients died. The remaining fatality was secondary to cerebral hemorrhage. The operative results have improved since April 1973, when our criteria for enlargement of the right ventricular outflow tract were established, and eight of the 108 patients have died, for a mortality rate of 7.4%.

Hemodynamic Results

Postoperative Pulmonary Insufficiency

To evaluate postoperative pulmonary insufficiency, the ratio of the pulse pressure to systolic pressure of the pulmonary artery, the right ventricular end-diastolic pressure and the degree of regurgitation of contrast medium refluxing into the right ventricle in the pulmonary arteriogram were compared with the CSAI. Figure 2 shows the relation between the ratio of the pulse pressure to systolic pressure of the pulmonary artery and the CSAI of the pulmonary annulus. This relation was expressed by the regression equation: 1 - 0.63/(CSAI - 0.07) (r = 0.79, p < 0.05). The ratio of the pulse pressure to systolic pressure of the pulmonary artery is dependent on the CSAI of the pulmonary annulus.

Among the 16 patients who underwent pulmonary arteriography, five patients with a CSAI of 2.6 cm²/m² or more (i.e., pulse pressure-to-systolic pressure ratio of 0.75 or more) had grade 3 or 4 regurgitation. In contrast, regurgitation of grade 2 or less was seen in nine of the 11 patients with a CSAI of 2.5 cm²/m² or less. The two patients with grade 3 regurgitation had outflow patches without a single

FIGURE 1. Grade of pulmonary insufficiency. The right ventricle was vertically separated into four equal parts in a lateral projection, and pulmonary insufficiency was classified into grades 1, 2, 3 and 4; grade 1 indicates the least regurgitation.
cusp. In all patients except one with grade 4 regurgitation, contrast medium refluxing into the right ventricle was cleared into the pulmonary artery in one systolic contraction.

Right Ventricular End-diastolic Pressure

The average value of the right ventricular end-diastolic pressure in 23 patients was 9.3 mm Hg (range 5–17 mm Hg), which is higher than normal. Figure 3 shows the relation between CSAI and the right ventricular end-diastolic pressure. In 15 of the 17 patients with a CSAI of 2.5 cm²/m² or less, the right ventricular end-diastolic pressure was 10 mm Hg or less and the regurgitation was of grade 2 or less. The remaining two patients had a right ventricular end-diastolic pressure of 15 mm Hg and a regurgitation of grade 3, and had an outflow patch without a cusp. Five of the six patients with a CSAI of 2.6 cm²/m² or more had a right ventricular end-diastolic pressure of 11 mm Hg or more, and five patients who underwent pulmonary arteriography had regurgitation of grade 3 or more. Thus, when the right ventricular outflow tract is enlarged by an outflow tract patch, it is imperative that a pericardial cusp be mounted on the outflow patch and that the CSAI be 2.5 cm²/m² or less.

Residual Pulmonary Stenosis and Residual Right Ventricular Hypertension

The systolic pressure gradient between the right ventricle and the pulmonary artery was used as an index of residual pulmonary stenosis, and the ratio of right ventricular pressure to aortic systolic pressure was used as an index of residual right ventricular hypertension. Figures 4 and 5 show the relation between the CSAI and the right ventricular-to-pulmonary arterial systolic pressure gradient and the right ventricular-to-aortic systolic pressure ratio, respectively, in the control patients. The following equations were obtained: right ventricular-to-pulmonary arterial systolic pressure gradient = 54.0/(CSAI)² + 5.6 (r = 0.76, p < 0.01), and right ventricular-to-aortic systolic pressure ratio = 0.42/(CSAI)² + 0.36 (r = 0.72, p < 0.01).

Most of the patients with outflow patches (indicated by open circles) were distributed within the range of the two curves C and tended to be the same as those without outflow patches. Thus, it appeared that the right ventricular-to-pulmonary arterial systolic pressure gradient and the right ventricular-to-aortic systolic pressure ratio become smaller as the CSAI increased, in accordance with these formulas, in the patients with as well as those without outflow patches. However, in patients with outflow patches without a cusp and with higher grades of regurgitation, the right ventricular-to-pulmonary arterial systolic pressure gradient and the right ventricular-to-aortic systolic pressure ratio were not distributed within the range in the two curves C, and the right ventricular pressure was high.

![Figure 2. Relationship between the ratio of pulmonary artery (PA) pulse pressure to PA systolic pressure and the cross-sectional area index of the pulmonary annulus. Open circles indicate patients with an outflow patch with a single cusp and open squares indicate patients with an outflow patch without a cusp. The numbers refer to the grade of pulmonary regurgitation (fig. 1). Black circles indicate patients who did not undergo pulmonary arteriography.](http://circ.ahajournals.org/doi/abs/10.1161/01.CIR.62.3.606)
Discussion

In total correction of tetralogy of Fallot, the main factors affecting the operative results are anatomic deformities, including the size of the pulmonary vascular bed, as well as residual pulmonary stenosis, residual shunt, pulmonary insufficiency and complete atrioventricular block.

In two of our five fatalities, the average diameter index of the arterial pathway to the right upper lobe was less than 4 mm/m², and it appears that the pulmonary vascular bed was too small to tolerate primary total correction. Setsue et al. postulated that left-heart development is poor and primary total correction is not indicated for patients with a maximum left atrial volume of 20 cm³/m² or less and a left ventricular end-diastolic volume of 40 cm³/m² or less. In both of these patients, these conditions were fulfilled. Both patients who died of acute renal failure underwent surgery before our criteria for enlargement of right ventricular outflow tract had been established. The acute renal failure occurred mainly because of severe hemolysis due to a prolonged extracorporeal circulation. The pulmonary arteries were large, but the ventricular septal defects were subpulmonary. The right ventricular outflow tract had to be re-enlarged by means of an outflow patch, because right ventricular outflow tract obstruction occurred when the ventricular septal defect was closed after infundibulotomy with valvulotomy, and weaning from extracorporeal circulation was impossible. Although the postoperative hemodynamics were relatively stable, the patients died of acute renal failure after severe hemolysis. The tetralogy with a subpulmonary ventricular septal defect is referred to as tetralogy of Fallot with absent conus septum or with agenesis of the crista supraventricularis, and the ventricular septal defect is known as a supracristal ventricular septal defect or as an intracristal ventricular septal defect. In two patients, the upper edge of the defect was in contact with the pulmonary valve; therefore, these patients had tetralogy of Fallot with absent conus septum. The tetralogy of Fallot with this type of defect has anatomic characteristics that are likely to produce right ventricular outflow tract obstruction as a result of closure of the ventricular septal defect. This is difficult to predict from preoperative evaluation. Therefore, when a supracristal ventricular septal defect is evident in an angiocardiogram, it should be
anticipated that an outflow patch will be necessary to relieve the outflow tract obstruction.

Pulmonary insufficiency after total correction of tetralogy of Fallot cannot be avoided, and occurs in almost all patients with outflow patches across the pulmonary annulus.6, 7 The amount of regurgitation due to this pulmonary insufficiency depends on the size of the regurgitant orifice, the right ventricular-pulmonary arterial diastolic pressure gradient, diastolic filling period, cardiac output, right ventricular contractility, and residual stenosis.8, 9 Because there is no convenient method to measure regurgitation accurately, the ratio of the pulse pressure to systolic pressure and the contrast medium refluxing into the right ventricle in the pulmonary arteriogram were investigated, and a comparison was made with the CSAI. Albertal et al.10 stated that pulmonary insufficiency exists when the ratio of the pulse pressure to systolic pressure of the pulmonary artery is greater than 0.55; however, because various factors affect regurgitation, the ratio of the pulse pressure to systolic pressure does not always accurately indicate the amount of regurgitation, which is clearly dependent on CSAI. However, the ratio of pulse pressure to systolic pressure does express the amount of regurgitation, to some extent, under certain conditions. When this value is 0.75 or more, or even when it is less than 0.75 in the patients with outflow patches without a cusp, regurgitation is grade 3 or more. In the patients with outflow patches with a cusp and a ratio of pulse pressure-to-systolic pressure of the pulmonary artery of less than 0.75, regurgitation is grade 2 or less. Right-heart failure, producing elevation of the right ventricular end-diastolic pressure and right atrial pressure, and depression of the right ventricular output are considered to be the result of pulmonary insufficiency.7, 11-13 In the present study, patients with a large CSAI, a ratio of the pulse pressure-to-systolic pressure greater than 0.75 and a high grade of regurgitation showed a high right ventricular end-diastolic pressure. Opinions about the long-term prognosis of pulmonary insufficiency vary. Kaplan et al.7 reported that pulmonary insufficiency appears to be well tolerated in the first few years but may result in a dilated right ventricle and elevation of the right ventricular end-diastolic pressure. Others have stated that pulmonary insufficiency presents no problem either clinically or hemodynamically;6, 14-16 and that prognosis is better if a pulmonary insufficiency is combined with a mild degree of pulmonary stenosis.17, 18 Because there is no method to prevent pulmonary insufficiency completely unless a substitute valve or an outflow tract conduit is used, the degree of both pulmonary insufficiency and pulmonary stenosis presents problems. Our present investigation was done 1 month postoperatively and long-term results are unclear. However, 1 month after surgery, pulmonary insufficiency was negligible when the CSAI was 2.5 cm²/m² or less and a single cusp was mounted on the outflow patch. Therefore, when the right ventricular outflow tract is enlarged by an outflow patch, the CSAI should be in the range of 1.75-2.5 cm²/m² from the standpoint of both residual pulmonary stenosis and postoperative pulmonary insufficiency. Moreover, it is essential that a single pericardial cusp be mounted on the outflow patch.

Malm et al.,19 Hawe et al.18 and Ruzylo et al.6 reported standards for the evaluation of residual stenosis and residual right ventricular hypertension. We prepared our own standards from the two regression equations, divided into three grades, defined by a right ventricular-to-aortic systolic pressure ratio of 0.5 and a right ventricular-to-pulmonary arterial systolic pressure gradient of 23 mm Hg, which corresponds to a CSAI of 1.75 cm²/m² and by a right ventricular-to-aortic systolic pressure of 0.70 and a right ventricular-to-pulmonary arterial systolic pressure of 50 mm Hg, which corresponds to a CSAI of 1.1. Further, on the basis of the equations we can predict the values of the right ventricular-to-aortic systolic pressure ratio and the right ventricular-to-pulmonary arterial systolic pressure gradient 1 month after surgery. Even though these equations were obtained in patients without an outflow patch, they can also be applied to the patients with outflow patches, as long as a cusp is attached.

In conclusion, the concept of CSAI is most useful in evaluating postoperative pulmonary insufficiency in patients with an outflow patch across the pulmonary annulus; pulmonary insufficiency is negligible as long as the CSAI is 2.5 cm²/m² or less and a cusp is mounted on the outflow patch. Thus, when the right ventricular outflow tract is enlarged by an outflow patch across the pulmonary annulus, the CSAI should be 1.75-2.5 cm²/m².

Acknowledgment
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References
Systolic Time Intervals in Isolated Ventricular Septal Defect in the Adult

Ola Alfred Nesje, M.D.

SUMMARY  Little information is available on the length of the systolic time intervals in adult patients with isolated ventricular septal defects (VSD). In the present study the external carotid pulse and the phonoe- and electrocardiogram were recorded in 17 patients, mean age 29 years, with angiographically proved VSD. They had unidirectional left-to-right shunts with ratios of pulmonary-to-systemic blood flow (Qp/Qs) of 1–5.22. Their right ventricular pressures were normal or only moderately elevated.

Left ventricular ejection time was consistently abbreviated, the degree of abbreviation relating significantly with Qp/Qs (r = −0.70, \( p < 0.01 \)). The prejection period was prolonged but the relationship between its degree of prolongation and Qp/Qs did not reach statistical significance (r = 0.41, \( p > 0.05 \)). The relationship between the prejection period/left ventricular ejection time ratio (PEP/LVET) and Qp/Qs was statistically significant (r = 0.51, \( p < 0.05 \)).

We conclude that in adult VSD patients with normal right ventricular pressures, a hemodynamically important shunting, i.e., Qp/Qs above 1.4 or left-to-right shunt exceeding 30% of pulmonary blood flow, may be excluded in the presence of a normal left ventricular ejection time or a normal PEP/LVET ratio.

SEVERAL REPORTS have been published on the phonocardiographic findings in children and adolescents with isolated ventricular septal defect (VSD).1–4 Little information is available, however, about the length of the systolic time intervals (STIs) and the contour of the externally recorded carotid pulse in these young patients;5–6 and no reports, to our knowledge, have been published on such noninvasive investigations in adult patients with VSD.

The present study was therefore undertaken to determine the length of the STI in adult patients who have an isolated VSD with unidirectional left-to-right shunting and to determine any relationship between deviations of the STI and the magnitude of the shunt.

Materials and Methods

The patients were six women and 11 men with an age range of 15–64 years (mean 29.2 years) (table I). All patients were in sinus rhythm. Right- and left-heart catheterizations were performed in all patients. The oxygen saturation of mixed venous blood was estimated according to the formula 3SVC + IVC/4, where SVC is the superior and IVC the inferior vena cava.7 Hydrogen inhalation tests were performed in patients in whom there was no difference or only a minimal difference in the oxygen saturation of mixed venous and pulmonary arterial blood. The tests were positive in the pulmonary artery and the right ventricle and negative in the right atrium in all patients. Cardiac output was measured by the Fick method.
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