SURGERY FOR CONGENITAL HEART DISEASE

EXTENDED AORTIC ROOT REPLACEMENT WITH AORTIC ALLOGRAFTS OR PULMONARY AUTOGRAFTS IN CHILDREN

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Objectives: To evaluate the early results and effectiveness of left ventricular outflow tract enlargement with aortic allograft or pulmonary autograft in children with complex left ventricular outflow tract obstruction. **Method:** The records of 30 children who underwent aortic root enlargement and replacement with either an aortic allograft (22 patients) or pulmonary autograft (8 patients) between January 1987 and June 1997 were reviewed. The predominant diagnosis was complex left ventricular outflow tract obstruction ($n = 19$), associated with aortic incompetence in 11 children. Before root enlargement, 27 children underwent surgical valvotomy (14 patients), balloon dilatation (10 patients), or both interventions (3 patients). Mean age at root enlargement was 5.4 ± 3.5 years (range, 2 days–16 years). Most of the children (27 patients) underwent a Konno aortoventriculoplasty. Concomitant septal myectomy was performed in 4 children, mitral valve procedure in 5 children, and endocardial fibroelastosis resection in 1 child. **Results:** Five children (17%) died in hospital. Four of these were infants less than 2 months old. All had acute aortic incompetence as the result of recent intervention necessitating urgent operation. The fifth child, aged 10 years, died of myocardial failure 2 weeks after the operation. During the follow-up period (mean length, 4.1 ± 2.8 years), sudden death occurred in 1 child 3 months after the operation. Follow-up echocardiograms (obtained for 23 of the surviving 24 children within 3 ± 2.3 years) showed a left ventricular outflow tract gradient reduced from a mean of 65 to 11 mm Hg ($P = .001$); Z value increased from a mean of -0.5 to 4.1 ($P < .001$), and aortic incompetence was trivial or mild except in 2 children. **Conclusion:** Urgent aortic root enlargement in decompensating neonates carries higher mortality rates. In older children, the early results of root enlargement and implantation of allograft or autograft are good. (J Thorac Cardiovasc Surg 1999;118:503-9)

Complex left ventricular outflow tract (LVOT) obstruction in children poses a challenge to the cardiac surgeon. LVOT obstruction is frequently characterized by a combination of subvalvular and valvular stenosis. Both elements of obstruction may require sur-

gical therapy, which may include enlargement of the aortic root in addition to replacement of the aortic valve. The therapeutic option of enlargement of the LVOT with insertion of a mechanical or bioprosthetic valve remains limited in children. The need for life-long

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Fig 1. Age distribution of 30 patients who underwent operation for complex LVOT obstruction.

Table I. Preoperative characteristics of 30 children studied

Characteristic	Value
Mean age (y)	5.7 ± 5
Male	23
Female	7
Mean body surface area (m ²)	0.68 ± 0.47
Mean weight (kg)	22 ± 21
Previous interventions (n)	
Surgical interventions	14
Balloon angioplasties	10
Combined	13
Mean No. per patient	1.4
Associated diagnoses* (n)	
Bicuspid aortic valve	10
Supravalvular aortic stenosis	4
Coarctation	4
Endocardial fibroelastosis	2
Double-outlet right ventricle	1

*Seventeen children.

anticoagulation and the risks of thromboembolism, hemorrhage, and prosthetic endocarditis are important drawbacks of mechanical prostheses.^{1,2} Although anticoagulation is not required when a bioprosthetic valve is inserted, these valves degenerate rapidly in children.^{3,4} Furthermore, substantial pressure gradients across small prostheses make these alternatives unattractive for young growing children.

The term *extended aortic root replacement* was coined by McKowen and associates⁶ to describe the

insertion of an aortic allograft as a tubular conduit to enlarged aortic roots. The insertion of a pulmonary autograft in combination with the Konno technique^{7,8} has also emerged as an alternative technique for aortic root enlargement. Patients with these conduits do not require anticoagulation, and the incidences of thromboembolism and endocarditis is low.^{9,10}

The purpose of our study was to evaluate the early results and effectiveness of LVOT enlargement with either aortic allograft or pulmonary autograft in children with complex LVOT obstruction.

Subjects and method

Patients. Between January 1987 and June 1997, at The Hospital for Sick Children in Toronto, Canada, 69 children underwent aortic valve replacement, among which 30 children underwent aortic root enlargement with either aortic allograft or pulmonary autograft for complex LVOT obstruction. Details of hospital records were analyzed, including examination, operative reports, preoperative and postoperative investigations, and echocardiographic follow-up. Follow-up data were obtained by office examination, telephone calls, or by direct contact with the referring physicians.

All children had LVOT obstruction. Indications for operation included isolated LVOT obstruction in 19 children and LVOT obstruction with aortic incompetence in 11 children. Three of the children had subacute bacterial endocarditis superimposed on the hemodynamic lesion (stenosis, 1 child; incompetence, 1 child; mixed, 1 child). Mixed lesions (aortic incompetence/stenosis) occurred among children with previous interventions. Age at extended aortic root replacement

(Fig 1) was 5.4 ± 3.5 years (range, 2 days–16 years); other characteristics of the children are summarized in Table I.

Previous procedures. Twenty-seven children (90%) had 37 interventions before aortic root enlargement (8 children had 2 interventions, and 1 child had 3 interventions). One or more surgical valvotomies were performed in 14 children; 1 or more balloon valvotomies were performed in 10 children, and a combination of both was performed in 3 children. The interval from last surgical valvotomy to the enlargement procedure was a median of 34.6 months (lower and upper quartiles, 7–63 months), compared with a median of 1 day (lower and upper quartiles, 0–11 months) for balloon valvotomy ($P = .01$).

Preoperative assessment. All children underwent preoperative echocardiography to measure aortic anulus size, to assess the pulmonary valve in cases where a pulmonary autograft was planned, and to assess gradients across the LVOT. Mean anulus diameter was 12 ± 6.3 mm (range, 4–24 mm); cumulative peak pressure gradient across the LVOT obstruction was 65 ± 25 mm Hg (40–111 mm Hg); and Z value was -0.5 ± 1.8 . Linear dimensions were indexed to the body surface area to allow comparison of measurements between patients of various sizes. Corresponding Z values were as follows:

$Z = (\text{measured value} - \text{mean value of normal control}) / \text{SD of normal control}$

Echocardiographic data for normal children were derived from data published by Habbal and Somerville.¹¹ Mitral valve disease was present in 5 children, and endocardial fibroelastosis was present in 2 children.

Preparation of aortic allografts. Allografts used in this series were prepared locally at the Hospital for Sick Children. The donor is screened for infectious diseases. The aortic allograft conduits are harvested under sterile techniques from a beating donor heart or within few hours of death. Then the aortic valve is dissected such that the junction with the innominate, left common carotid artery, and left subclavian artery remain with the valve. The dissected allograft is placed in a solution of RPMI 1640 cell culture solution media with 240 $\mu\text{g/mL}$ cefoxitin, 120 $\mu\text{g/mL}$ lincomycin, 150 mg of colistimethate (Coly-mycin M), and 50 $\mu\text{g/mL}$ vancomycin at 2°C to 6°C for 24 ± 2 hours to sterilize it. Culture samples are taken after sterilization. Then the allograft is rinsed in Ringer's lactate solution and placed in a solution of cell culture media with 8% to 12% dimethyl sulfoxide ($\text{C}_2\text{H}_6\text{OS}$). The allograft is then packaged in a double bag. Freezing and storage is carried out in a controlled-rate freezer (Planer KRYO10; Planer Products Ltd, Sudbury-on-Thames, Middlesex, United Kingdom) at a rate of approximately -1°C per minute. The allografts are stored at -100°C or lower.

A nonsterile team member does the thawing by placing the frozen allograft in 2 L of warm sterile saline solution for a maximum of 15 minutes. Rinsing is done in the sterile field by adding 1 L of 5% dextrose in lactated Ringer's solution to the basin. The allograft is allowed to soak for at least 5 minutes before implantation.

Operative technique. Standard technique for cardiopul-

monary bypass with moderate hypothermia and multidose or continuous antegrade blood cardioplegia was used. The aorta was transected well above the valve commissures. The diseased aortic valve was removed, and large coronary buttons were mobilized. To relieve the subvalvular obstruction in 27 patients, an incision was made in the right ventricular infundibulum, followed by an incision across the aortic anulus and extended into the conal septum, as described by Konno and coworkers.¹² Posterior root enlargement was performed in 3 patients, as described by Manouagian and Seybold-Epting.¹³

All aortic allografts ($n = 22$) implanted had been cryopreserved. The attached anterior leaflet of the donor mitral valve was used to patch the septal defect that was created in enlargement of the subvalvular lesion.

In children with pulmonary autografts ($n = 8$), the conduit was harvested by division of the main pulmonary artery at the bifurcation; dissection was then carried posteriorly to expose the right ventricular muscle bar. An incision in the right ventricular outflow tract was made at a reasonable distance from the pulmonary valve, to allow the defect in the conal septum to be patched.⁸ Special care was taken to avoid injury to the first septal perforator.

Both the allografts and autografts were implanted as "mini-roots" with continuous or interrupted proximal (surgeon's preference) and continuous distal suture lines. Excision of the native sinus wall with and implantation of the coronary buttons completed the LVOT reconstruction. The right ventricular outflow tract was reconstructed with a pulmonary allograft.

Mean total cardiopulmonary bypass time was 187 ± 58 minutes for allografts, compared with 232 ± 43 minutes for autografts ($P = .02$). Myocardial ischemic time was 124 ± 43 minutes for allografts versus 137 ± 42 minutes for autografts ($P = .24$).

Additional procedures were performed in 10 children: septal myectomy (4 patients), mitral valve repair (4 patients), mitral valve replacement (1 patient), and endocardial fibroelastosis resection (1 patient).

Postoperative evaluation. Follow-up in surviving children is complete in all cases. Mean follow-up was 4.1 ± 2.8 years (range, 1 month–10 years). Results were assessed by echocardiography, degree of aortic incompetence, presence of residual ventricular septal defect, degree of residual LVOT obstruction, transvalvular gradient, mitral regurgitation, and annular size. Follow-up echocardiograms were obtained within 3 ± 2.3 years for 23 of 24 children.

Statistical analysis. Data are expressed as means ± 1 SD. A 2-tailed, paired Student t test was used to compare continuous variables and Mann-Whitney U statistics for highly skewed data. Discrete variables were compared with the χ^2 test. Risk factors were identified by logistic regression. Variables tested were age, weight, body surface area, previous intervention, type of enlargement, annular size, Z value, conduit used, and myocardial ischemic time. Pearson's correlation and linear regression was used to determine the relation between preoperative and postoperative Z values. Kaplan-Meier curves were used to estimate survival.

Fig 2. Survival of children after aortic root enlargement (by Kaplan-Meier analysis).

Table II. Comparison of mean variables before and after operation

Variables	Before	After	P value
Gradient* (mm Hg)	65 ± 25	11 ± 10	.001
Annular size (mm)	12 ± 6.3	17 ± 10.6	.02
Z value	-0.5 ± 1.8	4.1 ± 2.2	<.001

*Pressure gradient across left ventricular outflow tract.

Results

Mortality and morbidity. Five children (17%) died early after operation, 4 within 24 hours. Four children were younger than 2 months, were urgently referred for operation, and had severe aortic incompetence after failed intervention (balloon angioplasty, 3 children; surgical valvotomy, 1 child). Two of these children had implantation of aortic allografts; and two children had insertion of a pulmonary autograft. The fifth child (10 years old) had low cardiac output syndrome and multi-organ dysfunction after aortic allograft implantation and died 2 weeks later. There was no statistical difference ($P = .81$) between the proportion of children with allografts or autografts who died.

During follow-up there was 1 late death; a 5-year-old child who died 3 months after Konno enlargement of the aortic root and implantation of an aortic allograft. An arrhythmia was likely responsible for the out-of-hospital sudden death.

One reoperation for pulmonary artery stenosis was

needed in a child who had had a pulmonary autograft.

Five-year survival is 78% (95% confidence interval, 0.71-0.85; Fig 2). The longest follow-up was 10 years in a child who underwent a Konno procedure with a 20-mm aortic allograft implanted at age 6 years. He remains asymptomatic, with a gradient of 13 mm Hg across the LVOT and no aortic incompetence. Univariate risk factor analysis revealed lower operative age (estimate, -0.24; SE, 0.12; $P = .02$) and weight (estimate, -0.28; SE, 0.11; $P = .01$), smaller body surface area (estimate, -0.20; SE, 0.07; $P = .01$) and annulus size (estimate, -0.30; SE, 0.13; $P = .01$), and urgency of operation (estimate, 1.005; SE, 0.31; $P < .01$) to be predictors of death. Multivariate analysis revealed urgent operation (estimate, 0.735; SE, 0.319; $P = .01$) and young age at operation (estimate, -0.58; SE, 0.24; $P = .02$) to predict death.

Echocardiographic studies. Echocardiographic follow-up revealed no ventricular septal defect or mitral regurgitation. Aortic incompetence was graded as absent in 14 patients, mild in 7 patients, and moderate in 2 patients. Preoperative to postoperative changes in mean pressure gradient, annular size, and Z value of the aortic annulus were all statistically significant (Table II).

Five of the 7 children with mild aortic incompetence in follow-up had aortic allograft implantation. Echocardiography immediately after operation showed no aortic regurgitation in 3 children and mild in 2 children. The other 2 children with mild aortic incompe-

Table III. Comparison of patients with allograft and autograft

Variable	Allograft	Autograft	P value
Patients (n)	22	8	—
Age at operation (y)	5.5 ± 4.6	4.9 ± 6.1	.32
Weight (kg)	21 ± 18	25 ± 22	.5
Anulus (mm)			
Before operation	12 ± 4.6	15 ± 10	.60
After operation	19 ± 3.9	18 ± 11.3	.10
Z values			
Before operation	-0.5 ± 2.0	-0.6 ± 1.0	.60
After operation	4.4 ± 2.3	2.3 ± 0.5	.10
Cardiopulmonary bypass time (min)	187 ± 58	232 ± 43	.02
Ischemic time (min)	124 ± 43	137 ± 42	.24

Data are means.

tence had pulmonary autograft implantation; both had no aortic incompetence early after operation.

The 2 children with moderate aortic incompetence had undergone a Konno enlargement procedure and implantation of an aortic allograft in combination with septal myectomy, at the ages of 3 months and 2.8 years, respectively. Echocardiography immediately after the operation showed mild aortic incompetence, which worsened later. The most recent echocardiographic follow-up was 1.5 years and 5.5 years, respectively; latest clinical follow-up was 3 and 7 years. Both are clinically well.

In this cohort, children undergoing allograft or autograft implantation were of similar age and size of anulus before and after operation, although the autograft group had a lower Z value after operation (Table III). In addition, there was a higher correlation between preoperative and postoperative Z values in the autograft group ($r = 0.88$) than in the allograft group ($r = 0.45$; Fig 3).

Discussion

Management of complex LVOT obstruction in children remains difficult. The complex is essentially 2 lesions: a “tunnel-like” subvalvular component and valvular stenosis (with associated hypoplasia of the aortic anulus). Their severity determines the choice and outcome of any surgical repair. Localized myectomy with or without patch enlargement of the interventricular septum,^{14,15} with preservation of the aortic valve is possible in those cases where the aortic valve and aortic anulus are morphologically normal. The presence of valvular and subvalvular obstructions requires simultaneous repair of both lesions. Enlargement of the aortic and subaortic regions with an incision in the conal septum is the only acceptable technique in small children

Fig 3. Scattergram and linear regression for the relationship between preoperative and postoperative Z values in both groups.

with tunnel-like obstruction of the left ventricle. In older children, posterior enlargement through an incision in the subaortic curtain (with or without incising the mitral valve) is an acceptable alternative.

The incidence of aortic root enlargement in children is relatively higher compared with adults. This is mainly due to the fact that the indication of aortic valve replacement in children is mainly congenital and commonly is associated with some form of hypoplasia of the anulus or the LVOT. The question remains as to the best choice of valve replacement in children. Some of the issues considered in children are durability, size availability, anticoagulation requirements, and growth potential. The durability of bioprosthetic valves is limited in children because of rapid calcification leading to clinically significant stenosis.⁴ Mechanical prostheses require lifelong anticoagulation and carry a risk of thromboembolism and hemorrhage.² Moreover, neither of these prostheses is of a size suitable for implantation in a neonate.

Aortic allografts are available in a variety of sizes and do not require anticoagulation. However, degeneration remains a concern, as does the lack of growth potential. Previous reports by Clarke and colleagues^{16,17} have indicated accelerated degeneration of allografts in 11 surviving children under the age of 3 years, which has led them and others¹⁸ to administer cyclosporine (INN: ciclosporin) to some children to prolong allograft life, on the presumption that the degeneration is immunogenically mediated. Eight of the children who underwent operation in our series

were under 3 years of age. Our mean follow-up was 3 years, slightly longer than Clarke's follow-up of 2.3 years. None of the children in our series has required explantation of the allograft. Gerosa and colleagues¹⁹ also reported good results of allografts implanted in children; compared with those children having pulmonary autografts, the children in their report fared well in terms of death and freedom from reoperation, endocarditis, and complications. There was slightly faster valve degeneration in the allograft group, although the follow-up period in the allograft group was almost 3 times as long making the comparison inconclusive.

Pulmonary autografts are usually of appropriate size, do not require anticoagulation, and are resistant to immunologically mediated degeneration and to endocarditis. The great advantage of pulmonary autografts over allografts is their growth potential in small children.^{20,21} Insertion of a pulmonary autograft is technically demanding, requiring expertise in harvesting and implantation of the conduit; it also converts a single-valve disease into potentially a double-valve disease. In our series, there was no significant difference in myocardial ischemic time between allografts and autografts; however, total cardiopulmonary bypass time was longer in the autograft group because of the time required to reconstruct the right ventricular outflow tract. This has not translated into a difference in early mortality rates; nevertheless, one child required reoperation for right ventricular outflow tract obstruction in the autograft group. Others²² have also reported low mortality and morbidity rates in reoperations after pulmonary autograft implantation. Two of the children with pulmonary autograft implantation progressed from no to mild aortic incompetence in the follow-up period. The ramification of this change is still to be seen with longer follow-up. Dilatation in the pulmonary autograft could be a concern in the long run.

The indication for operation is usually the presence of significant gradient, which in this complex is at more than one level and for this reason an evaluation of the entire LVOT should be done before the operation. Although preoperative Z values were similar between the autograft and allograft groups, the mean postoperative Z value was greater for the allograft group, likely because the surgeon selected a larger conduit to accommodate growth of the child, whereas autograft size at the time of implantation remains entirely dependent on the child's anatomy. The ability to insert a larger conduit is advantageous in neonates; nevertheless, the growth potential of pulmonary autografts certainly makes them appealing to the surgeon. When compared

with allografts, the growth potential of pulmonary autografts may avoid the necessity for further operations in the LVOT at a later date when allograft becomes restrictive. There is some evidence that suggests rapid degeneration of allografts in the pulmonary position for children less than 2 years old.²³ Although this may be an indication for operation in children with pulmonary autograft implantation, it is a reasonable trade off to accept reoperating on the right ventricular outflow tract, which is relatively straightforward rather than reoperating multiple times on the LVOT.

The analysis revealed that young age and urgent operation contributed to a worse outcome. These 2 factors are highly correlated among our children because of the fact that 4 young children had catheter interventions followed by urgent operation. The effect of each factor on outcome is difficult to separate. However, the indication for operation was urgent and may have contributed to a worse outcome more than the presence of young age, *per se*. These results identify these high-risk decompensating children, and careful consideration of these children should be done before intervention.

In our series, one child underwent resection of endocardial fibroelastosis. Children with this pathologic condition may have small left ventricles. Biventricular repair is possible in almost all children, regardless of the size of the LVOT, as long as there remains a near-"normal" preservation of the left atrioventricular valve and left ventricle.²⁴

Echocardiographic follow-up revealed good results overall. Only 2 children progressed to moderate aortic incompetence, and both children have remained minimally symptomatic. These echocardiographic follow-up results are short to midterm, and longer follow-up is required to draw solid conclusions on the fate of each of the conduits in the setting of aortic root enlargement.

In conclusion, our series confirms the effectiveness of relieving LVOT obstruction with the use of extended aortic root replacement with either aortic allografts or pulmonary autografts, showing continued relief of the obstruction during the intermediate follow-up period. Urgent operation in neonates after a failed valvotomy was associated with a high mortality rate. Results for balloon dilatation of critical stenosis have improved in recent years; it remains our initial treatment of choice in neonates with critical aortic stenosis. Continued follow-up of children undergoing allograft implantation at a young age is critical so that late performance of these conduits can be documented.

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