

Use of Right Ventricular Remodeling Surgery with a Porcine Pulmonary Prosthesis for Congenital Heart Disease

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ABSTRACT

Background: The reconstruction of the right ventricular outflow tract (RVOT) in congenital heart disease has attracted the interest of cardiac surgeons determined to alleviate the anatomic obstruction and restore RV function.

Methods: From June 1991 to September 2008, 203 consecutive patients (mean, 3.0 years; range, 2 months to 35 years) underwent operations. These patients were classified into 5 groups: group 1, tetralogy of Fallot with pulmonary hypoplasia (144 cases, 70.9%); group 2, pulmonary atresia (PA) with ventricular septal defect (VSD) (32 cases, 15.7%); group 3, truncus arteriosus (12 cases, 5.9%); group 4, transposition of the great arteries with left ventricular outflow tract obstructions (8 cases, 3.9%); and group 5, PA with intact ventricular septum (7 cases, 3.4%). Remodeling surgery of the RV consisted of patch closure of the VSD (n = 176), tricuspid valvoplasty repair (n = 25), infundibulum muscle resection, and reconstruction of the RVOT (all patients). The Lecompte procedure was performed in 8 patients in group 4, and the one and a half ventricle technique was performed in 7 patients in group 5.

Results: There were 21 hospital deaths (10.3%); 180 patients (88.6%) survived. Patients were followed up from 4 to 206 months (mean, 98.0 months). Sixteen patients (8.8%) underwent reoperation for prosthesis dysfunction, with 2 in-hospital deaths (12.5%). The rest of the patients (164, 80.7%) remain free of reoperation.

Conclusion: Earlier reconstruction of the pulmonary valve and the RVOT may preserve ventricular performance for a long period. Nevertheless, the porcine pulmonary prosthesis has shown satisfactory results when it has been used for the reconstruction of different types of RV obstructions.

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INTRODUCTION

The results of biventricular surgical repair of congenital heart disease with obstruction of the pulmonary ventricle have been satisfactory. A surgical technique introduced more than 5 decades ago [Cohen 1956] is closely associated with adequate pulmonary valve (PV) repair and right ventricular outflow tract (RVOT) reconstruction [Graham 1976].

The use of prostheses with no valves induced the development of pulmonary valve insufficiency (PVI), which for many years was considered a benign residual lesion that patients tolerated reasonably well; however, this particular technique and other causes of ventricular dysfunction have now been questioned [Carvalho 1992; Marie 1992; Bricker 1995; Harrison 1997; Owen 2000]. With increasing durations of follow-up, however, significant late morbidity and mortality have been observed in a fraction of patients [Murphy 1993; Therrien 2002].

More recently, the clinical relevance of PVI after enlargement of the hypoplastic pulmonary ring and trunk was confirmed once medium- and long-term results of the surgery became better known. Studies on the issue have established the need to repair the PV with a valved prosthesis and thereby minimize or prevent PVI, which is considered the cause of late RV dysfunction [Oku 1986; Nollest 1997]. Therefore, RV diastolic function should be carefully monitored during the long-term follow-up of patients who have undergone surgical correction for tetralogy of Fallot (TOF) with transannular enlargement, truncus arteriosus (TA), pulmonary atresia with ventricular septal defect (PA/VSD), PA with intact ventricular septum (PA/IVS), and transposition of the great arteries (TGA) with VSD and left ventricular outflow tract obstruction (LVOTO).

Doppler echocardiography has shown that the diastolic flow in the pulmonary artery is synchronized with atrial systole and the respiratory cycle. The RV diastolic volume in postoperative recovery determines the decrease in diastolic compliance, which may be detected as a continuous laminar flow in the pulmonary artery [Davlouros 2002].

PVI is one of the most important factors causing RV dilation due to a volume increase and an ejection fraction decrease after surgical correction. A spectrum of PVI has been quantified with more refined methods of evaluation, such as magnetic resonance imaging (MRI), as well as exercise testing in the follow-up of patients who have undergone operations to

alleviate pulmonary obstruction associated with RV dilation and hypertrophy.

The development of akinetic regions and aneurysmic dilation of the RVOT, which are related only in part to transannular patching, are common. They contribute to the increase in RV diastolic volume and the decrease in RV ejection fraction and are related to the degree of PVI.

LV systolic dysfunction, aortic regurgitation, and RV dilation and dysfunction occur in adults with TOF, TA, PA/VSD, TGA with VSD and LVOTO, PA/IVS, and so forth and are related to the length of palliation with arterial shunts.

Measures to maintain or restore PV function and to avoid PVI, RVOT aneurysm, or akinesia are mandatory for the preservation of RV and LV function late after pulmonary ventricle repair.

This report reviews our experience with 203 consecutive patients treated with RVOT remodeling with a preserved porcine pulmonary prosthesis (bicuspid and trileaflet).

PATIENTS AND METHODS

Study Group

We report the surgical technique and late follow-up of pulmonary ventricle performance and preserved porcine pulmonary prostheses used for PV repair and RVOT reconstruction in patients with pulmonary ventricle obstruction. This clinical study was performed in the Cardiovascular Division at the São Paulo Federal University between June 1991 and December 2008.

This prosthesis was initially tested in an experimental model in March 1990 [Maluf 1991], and after demonstration of good performance, it was approved for clinical use [Maluf 2000] by the Medical Ethical Committee of this institution in June 1991. In 2006, the Medical Ethical Committee of the São Paulo Federal University approved the MRI and computed tomography (CT) study of patients with follow-up times of >10 years.

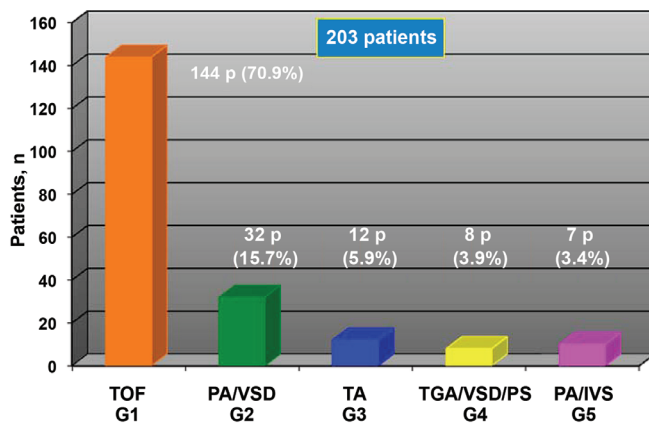


Figure 1. Patient characteristics. p indicates patients; TOF, tetralogy of Fallot; PA/VSD, pulmonary atresia/ventricular septal defect; TA, truncus arteriosus; TGA/VSD/PS, transposition of the great arteries with VSD and pulmonary stenosis; PA/IVS, pulmonary atresia/intact ventricular septum.

Two hundred three consecutive patients (mean age, 3.0 years; range, 4 months to 35 years) underwent operations. The patients were classified into the following 5 groups according to the diagnosis of the cardiac malformation: group 1, TOF with pulmonary hypoplasia (144 cases, 70.9%); group 2, PA/VSD (32 cases, 15.7%); group 3, TA (12 cases, 5.9%); group 4, TGA with VSD and LVOTO (8 cases, 3.9%); and group 5, PA/IVS, (7 cases, 3.4%) (see Figure 1).

Preoperative pulmonary hypertension, defined as a pulmonary artery pressure >50% of the systemic pressure, was noted in 12 (5.9%) of the patients with TA. Cardiac catheterization was performed in 80% of the patients. More recently, MRI and CT have been used to define pulmonary branch anatomy, especially in patients with PA/VSD.

Prosthesis Construction

The biological material underwent several phases in the manufacture of the prostheses. The valve and pulmonary trunk were isolated from the swine’s heart; the prosthesis was then subjected to cleaning, tanning, and tissue conservation. We then manufactured 4 prosthesis models for the different anatomic types of RV reconstruction that were planned. These prostheses were prepared in series according to Braile Biomédica specifications (Braile Biomédica, São José do Rio Preto, São Paulo, Brazil; <http://www.braile.com.br>) with strict medical quality control. These prostheses are available commercially from Braile Biomédica and have been used for RVOT reconstruction by pediatric cardiovascular surgery groups in Brazil (Figure 2).

Pulmonary Bicuspid Prosthesis. The pulmonary bicuspid prosthesis (PBP) was manufactured with 2 segments of the pulmonary artery. One segment included the trunk, ring, and PV; the other included only the pulmonary trunk (supravalar area). The diameter of the pulmonary ring was measured with a Hegar dilator, and the grafts were classified according to

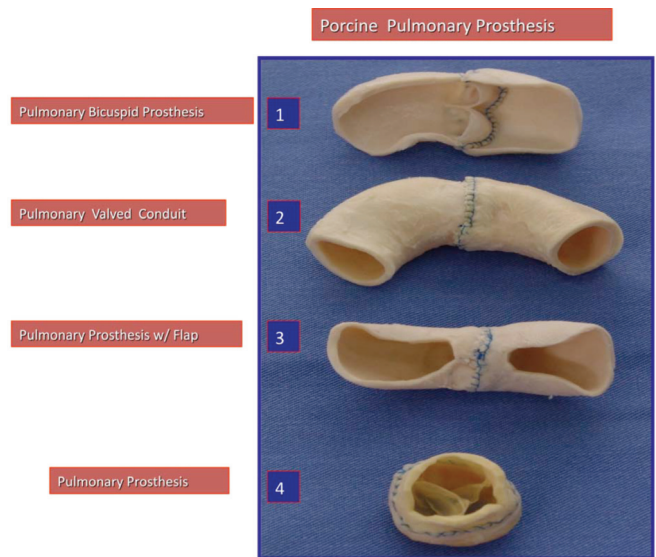


Figure 2. Four types of porcine pulmonary prostheses.

Table 1. Tetralogy of Fallot: Patient Preoperative Data

| Characteristic | |
|---------------------------|----------------------|
| Patients, n | 144 |
| Mean age (range) | 3.2 y (5 mo to 35 y) |
| Blalock-Taussig shunt, n | 30 (20.8%) |
| Absent pulmonary valve, n | 4 (2.7%) |
| Pulmonary atresia, n | 15 (10.4%) |

the size in millimeters. One longitudinal incision was made in the concave part to remove a slice of the wall with one of the PV cusps. A proportional wall segment was removed from the nonvalved portion. Finally, continuous anchored polypropylene 5-0 suture was used to ligate the 2 structures at their proximal tips via superposition with an extension of 3 to 5 mm. The suture was started at the graft's concave face and followed the insertion of the fibromuscular ring cusp. A similar suture was made on the convex side [Pacifico 1977].

Pulmonary Valved Conduit. The pulmonary valved conduit (PVC) was manufactured with 2 entire segments of the pulmonary trunk (one with the trileaflet PV); the tips of these segments were ligated with a running suture.

Pulmonary Prosthesis with Flap. The pulmonary prosthesis with flap (PPF) was manufactured similarly to the PVC, with 2 large flaps created at the pulmonary and ventricular tips.

Pulmonary Prosthesis. The pulmonary prosthesis (PP) was manufactured by using a short segment of the pulmonary artery that included the PV.

Surgical Procedure

Our current strategy for RVOT remodeling used these 4 types of preserved porcine pulmonary prostheses. The PBP was used to repair the PV and for RVOT reconstruction in patients <1 year old (patients with a narrow pulmonary ring and an estimated pulmonary ring size of <15 mm). The trileaflet PVC prosthesis was used in patients >1 year old with PA. The PPF was used in patients >1 year old with a hypoplastic pulmonary ring and pulmonary trunk. The PP was used in patients with a regular pulmonary ring or an absent PV (estimated pulmonary ring size >15 mm).

Other associated procedures used for remodeling the RV included VSD repair, an LV-to-aorta tunnel, tricuspid repair, and pulmonary artery branch plasty procedure.

Group 1 (TOF). This group consisted of 144 patients (70.9%) between 5 months and 35 years of age (mean, 3.2 years). Thirty (20.8%) of these patients had received a systemic pulmonary shunt as a palliative procedure before the operation. The PV was absent in 4 cases (2.7%), and 15 patients (10.4%) had PA (Table 1).

The surgery was carried out with cardiopulmonary bypass (CPB), which was established with bicaval cannulation and mild hypothermia. Aortic cross-clamping with intermittent potassium cold blood cardioplegia was used for the intracardiac repair. Vacuum-assisted venous drainage was used routinely.

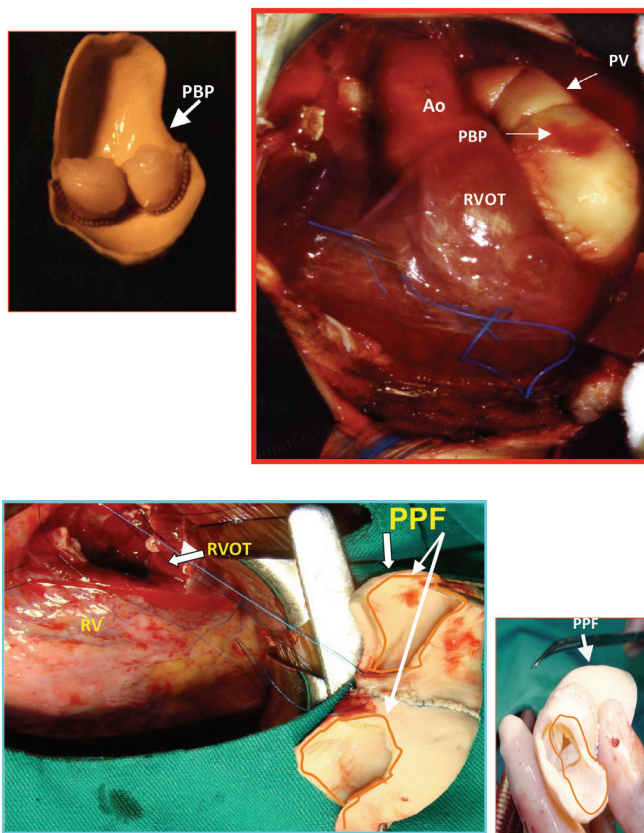


Figure 3. A, Surgical photography of a patient (11 months, 7.0 kg) with tetralogy of Fallot (TOF). Pulmonary valve (PV) reconstruction of the right ventricular outflow tract (RVOT) with pulmonary bicuspid prosthesis (PBP). Ao indicates aorta. B, Surgical photography of 5-year-old patient (17.0 kg) with TOF. Pulmonary trunk and RVOT reconstruction with pulmonary prosthesis with flap (PPF).

The VSD was accessed via a right atriotomy or right ventriculotomy approach and closed with a treated bovine pericardium patch and running suture. Relief of the RVOT obstruction was obtained via wide resection of all septum-parietal and parietal-parietal muscle bundles of the pulmonary infundibulum. The pulmonary annulus itself appeared narrowed in all cases. The incision was extended through the pulmonary annulus up to the main pulmonary artery, and the entire area was used to implant the PBP (Figure 3A). All prosthesis implantations, primary or reoperation, were performed on the beating heart.

For pulmonary ventricle reconstruction in patients younger than 1 year, a PBP was implanted and adjusted to the rudimentary PV of the patient. In patients older than 1 year, a PPF (trileaflet PV) was implanted in the native pulmonary annulus with running suture. The pulmonary trunk and the RVOT were reconstructed with the 2 flaps (pulmonary and ventricular flaps) of this prosthesis (Figure 3B).

The diameter of the RV-pulmonary trunk junction at the level of the preoperative pulmonary annulus was previously measured in the lateral angiogram. In this study, the term

pulmonary annulus diameter was also used in referring to the postoperative status. The diameter of the pulmonary annulus was measured during the operation by a classic nomogram method [Pacífico 1977]. The size of the graft was chosen according to the patient's weight. The size was 8 to 10 mm for patients weighing <10 kg; a graft of 12 to 20 mm was used for patients >10 kg.

In patients who had PA or no PV and were younger than 1 year, a new valvar cusp was constructed with tissue from the posterior wall of the pulmonary artery. This modification provided support for the PBP.

Group 2 (PA with VSD). In this group, all 32 patients (15.7%) were older than 14 months. Three of the patients had aortic-pulmonary collateral arteries and had undergone previous unifocalization surgery and a Blalock-Taussig shunt. The surgical approach was a right ventriculotomy. After resection of the infundibulum muscle and closure of the VSD, the pulmonary arteries or the rudimentary pulmonary trunk was sectioned and sutured at the upper angle of the right ventriculotomy. Finally, a trileaflet PPF was implanted with running suture at the neopulmonary annulus, and the pulmonary and ventricular flap of this graft was used to reconstruct the pulmonary ventricle.

Group 3 (TA). In this group, 12 patients (5.9%) younger than 6 months underwent operations for type I or type II TA. During the surgical approach, the pulmonary artery was disconnected from the ascending aorta, and the left aortic sinus was reconstructed with a bovine pericardium patch. The VSD was closed via an RV approach, and the LV was connected to the aortic root.

In 10 of the patients, the posterior wall of the RVOT was constructed with a pulmonary flap of the left pulmonary artery [Barbero-Marcial 1989], but in accordance with these authors' technical specifications, we did not use a monocuspid patch. For the reconstruction of the pulmonary ventricle, we adapted a PBP to the neopulmonary annulus. In the remaining 2 patients, we used a PVC to reconstruct the RVOT.

Group 4 (TGA with Pulmonary Stenosis). There were 8 patients (3.9%) in this group. The patients had a mean age of 3 years (range, 2-8 years) and had TGA with VSD and LVOTO (Figure 4A). The Lecompte technique [Lecompte 1991] (also known as the REV (*réparation à l'étage ventriculaire*) procedure, which was introduced for the correction of TGA with VSD and LVOTO, was performed in all of these cases. The REV procedure consisted of an approach via an upper-right ventriculotomy, extensive resection of the conal septum, and enlargement of the VSD. Then, a pericardium or polytetrafluoroethylene (PTFE) patch and running suture were used to construct a tunnel connecting the LV to the aortic root. Later, the aorta and the pulmonary artery were sectioned, the PV was closed, the Lecompte maneuver was performed, and, finally, the aortic and pulmonary outflow tracts were reconstructed (Figure 4B).

In 6 cases, a PPF was used for RVOT reconstruction (Figure 4C), and a PVC was used in the 2 remaining cases. One of the patients, who had undergone a Rastelli procedure [Rastelli 1969] 3 years before, presented with an RV-pulmonary artery prosthesis obstruction and severe RV

failure. This patient underwent an emergency operation that was converted to a Lecompte operation. After aortic section, the Lecompte maneuver was performed, and the pulmonary artery was positioned in front of the aorta. A PBP was used for RVOT reconstruction.

Group 5 (PA with IVS). There were 7 patients (3.4%) in the PA/IVS group (mean age, 4.0 years; range, 1-12 years). Three of the patients had undergone the first stage of the operation (Blalock-Taussig shunt plus pulmonary valvotomy) in the neonatal period and the second stage (Glenn operation) at 1 year (Figure 5A).

In these patients, a "normal" tricuspid valve (*z* score >-4.0) and a hypoplastic but potentially usable RV were observed. The repair consisted of patch closure of the atrial septal defect, tricuspid valvoplasty repair, and reconstruction of the RVOT with a PPF (one and a half ventricle repair with pulsatate bidirectional Glenn) (Figure 5B).

The remaining 4 patients underwent a pulmonary valvotomy in the neonatal period. The tricuspid valve and the RV had nearly normal morphology, size, and function. In these patients, the RVOT was reconstructed with a PPF.

Surgical Recuperation

Conventional ultrafiltration was used in all patients during CPB. In the last 12 years, modified ultrafiltration was used after CPB. It was possible to discontinue CPB in all cases, and no patient had delayed sternal closure. Sinus rhythm was maintained in all patients before their discharge from the hospital. Temporary cardiac arrhythmias were detected in 10% of the patients during their hospital stay. No pacemaker was indicated or implanted in any of the patients in this group. Dobutamine and milrinone were used more frequently for cardiopulmonary support.

RESULTS

Early and Late Mortality

There were 21 hospital deaths (10.3%). The mortality rates by group were as follows: group 1 (TOF), 15 patients (10.4%); group 2 (PA/VSD), 3 patients (9.3%); group 3 (TA), 2 patients (16.6%); group 4 (TGA with VSD and LVOTO), 1 patient (12.5%); group 5 (PA/IVS), 0 patients (0.0%).

There were 4 late deaths (2.1%). Death in 2 patients with TOF was caused by cardiac arrhythmia and bacterial endocarditis. The cause of death in the other 2 patients, one with TA and the other with PA/VSD, was ventricular dysfunction.

Morbidity

Forty nonfatal complications (21.9%) occurred in the 182 early-surviving patients. Residual pulmonary branch stenosis was detected in 3 patients. There were 159 patients (78.3%) free of reoperation.

Reintervention

Seventeen patients (9.6%) underwent reintervention for residual defects or prosthesis dysfunction at 24 to 120 months after their operations. Two patients developed aneurysmic

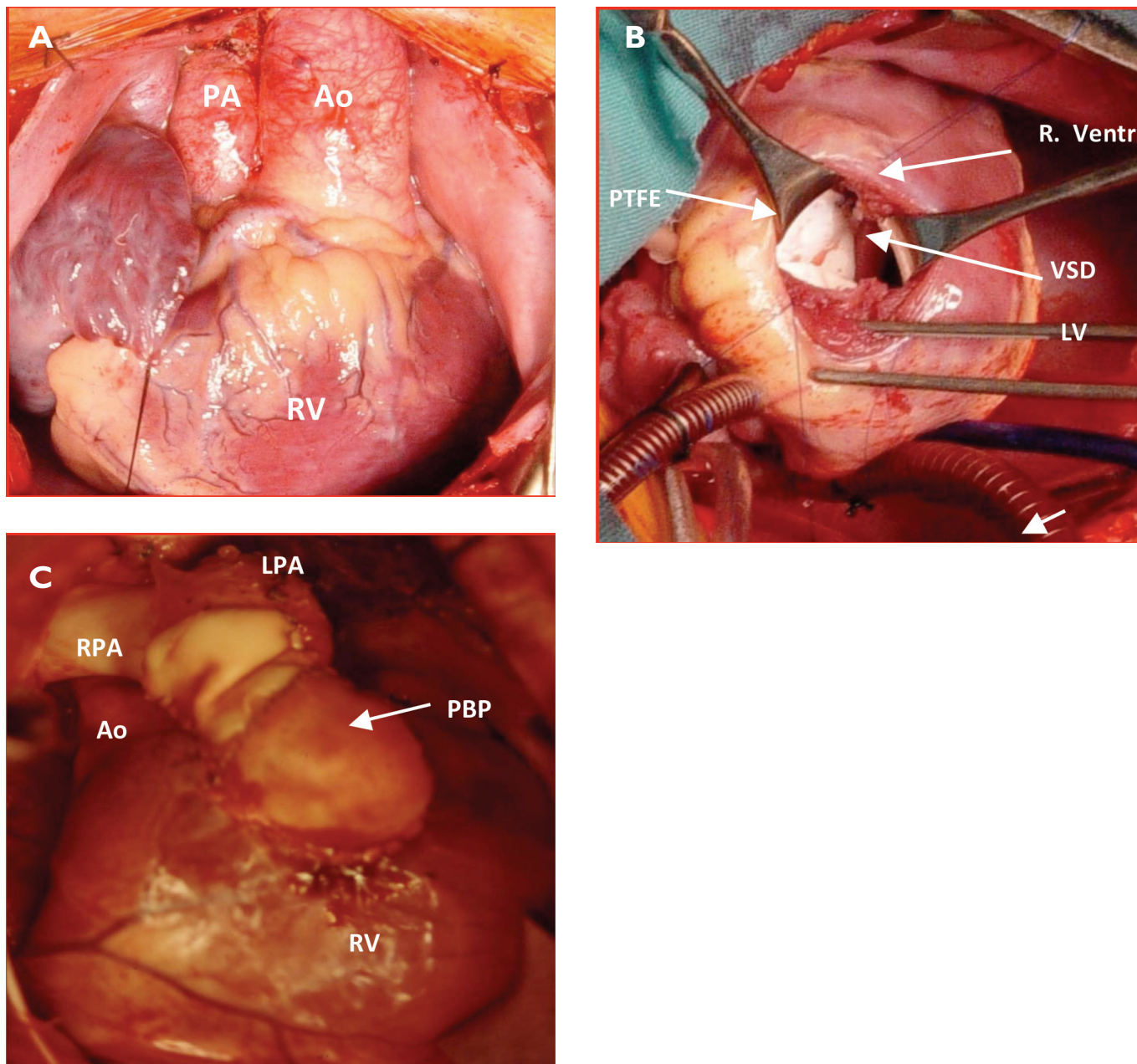


Figure 4. A, Surgical photography of patient (2 years, 12.0 kg) with transposition of the great arteries with ventricular septal defect and pulmonary stenosis. PA indicates pulmonary artery; Ao, aorta; RV, right ventricle. B, Surgical photography of Lecompte operation. R. Ventr. indicates RV; PTFE, polytetrafluoroethylene patch; VSD, ventricular septal defect; LV, left ventricle. C, Surgical photography of Lecompte operation. Right ventricular outflow tract reconstruction with pulmonary bicuspid prosthesis (PBP). LPA indicates left pulmonary artery; RPA, right pulmonary artery; Ao, aorta; RV, right ventricle.

dilatation of the pulmonary prosthesis, 1 patient after TOF correction and the other after a one and a half ventricle correction. Both patients died after reoperation because of ventricle dysfunction and surgical bleeding.

A pathologic study of the removed prosthesis showed a calcification island that compromised the external wall but preserved the integrity of the leaflet. Nevertheless, the 2 cases with aneurysmic dilatation showed a sling wall and no presence of calcification (imperfect tissue fixation?).

Two patients presented with residual pulmonary stenosis localized at the origins of the right and left branches. Both cases required implantation of a pulmonary stent.

Follow-up

Reconstruction of the PV and remodeling of the RV were an essential component in the treatment of many of the patients with congenital heart disease. Fourteen patients (7.9%) were lost during follow-up. Of the surviving patients,

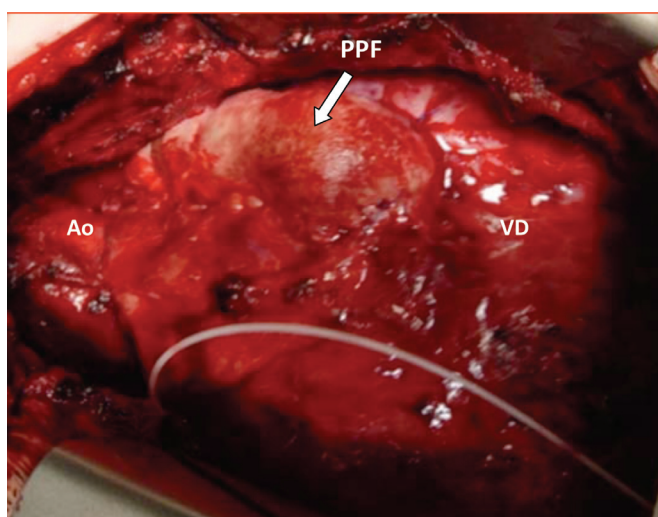
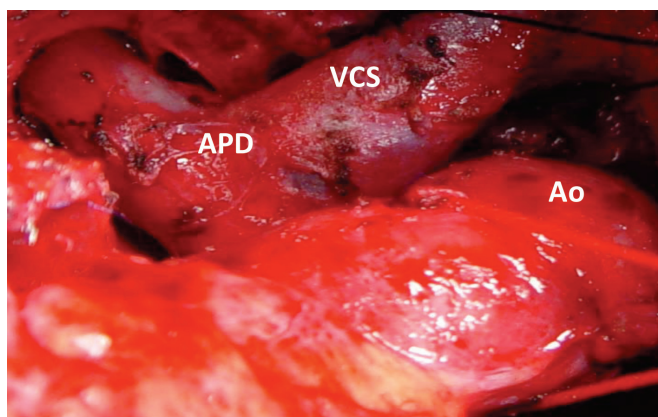


Figure 5. A, Surgical photograph of patient (12 years, 45.0 kg) with pulmonary atresia with intact ventricular septum. Glenn operation. VCS indicates superior vena cava; APD, right pulmonary artery; Ao, aorta. B, Surgical photograph of one and a half ventricle operation. Right ventricular outflow tract reconstruction with pulmonary prosthesis with flap (PPF); VD, right ventricle; Ao, aorta.

162 (79.8%) were followed up for a period ranging from 4 to 204 months (mean, 108 months). The estimated actuarial survival rate at 204 months was 86.6% (Figure 6). Follow-up of these patients included a clinical examination, an exercise stress test, a metabolic stress test, a Doppler echocardiography study, a hemodynamic study, and MRI and CT evaluations. We do not have a complete data set for all of the variables for the entire cohort of patients described in this report.

Doppler Echocardiography Study

Doppler echocardiography was the most frequent auxiliary study used to analyze the results of cardiac surgery and prosthesis performance. This study was performed twice a year during follow-up. The echocardiogram allowed evaluation of many of the parameters of RV function, including RV performance and RV dimensions. In addition, if tricuspid regurgitation was present, the Doppler index allowed an

Table 2. Tetralogy of Fallot: Postoperative Hemodynamic Study of 15 Patients*

| Characteristic | |
|-----------------------------------|-------------------|
| Age, y | 8.2 (5-16) |
| Female sex, n | 6 (40%) |
| Weight, kg | 23.6 (16-49) |
| Height, cm | 125.6 (107-167) |
| Body surface area, m ² | 0.986 (0.75-1.55) |
| Postoperative follow-up, mo | 84 (72-108) |
| Absent pulmonary valve, n | 3 (20%) |
| Pulmonary atresia, n | 2 (13.3%) |

*Data are presented as the mean (range) where indicated.

estimate of RV pressures, RV–pulmonary artery gradients, and pulmonary and tricuspid valve function.

Of the surviving patients, 143 were discharged from the hospital with an RV–pulmonary artery gradient of <30.0 mm Hg and trivial to moderate PVI. During the follow-up, the Doppler echocardiogram was decisive for reoperation in 10 patients and was indicative for a hemodynamic procedure in 2 other patients.

Among the 162 patients (79.8%) with regular late follow-up, a slightly increased PVI was detected in 20 patients (12.3%), but only 1 patient had important pulmonary valve regurgitation.

Hemodynamic Evaluation

Hemodynamic studies were carried out in the first 15 (9.2%) of the 162 surviving patients with regular follow-up. All 15 patients had TOF; the mean follow-up was 65.1 months (range, 48-87 months). Patient age ranged from 5 to 16 years (mean, 8.2 years) (Table 2). In all cases, right ventriculography was carried out in the right anterior oblique and left anterior oblique positions, and pulmonary arteriography was performed in the anterior posterior projection. The dimensions of the RV were established during the cardiac cycle.

Measurements were obtained by visualizing the heart images (including the prosthesis for the insertion of valves) and comparing them with the catheter's diameter in a superposed graded film with the identical magnification.

In some cases it was difficult to establish the position of the pulmonary ring because of the presence of the RVOT prosthesis. The degree of PVI was evaluated quantitatively after the injection of contrast solution into the pulmonary artery. PVI was classified as mild when regurgitation was <50% (group A) and as moderate when it was >50% (group B) [Maluf 2000] (Figure 7).

Hemodynamic Data

Of the 15 patients who underwent hemodynamic and angiographic evaluation, no residual blood flow from the left to right ventricle or significant gradient between the RV and the pulmonary artery was observed [Maluf 2000].

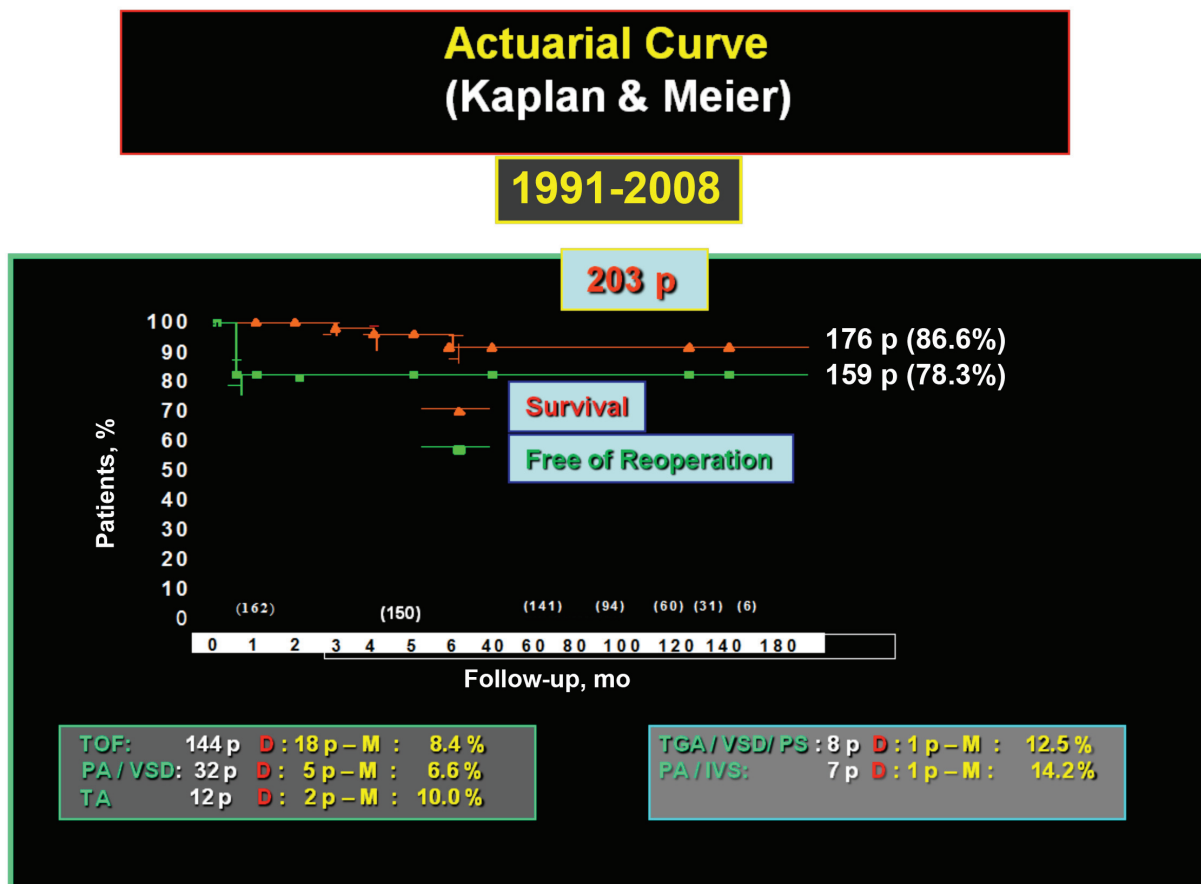


Figure 6. Actuarial survival curve for patients who underwent right ventricular remodeling. p indicates patients; TOF, tetralogy of Fallot; D, dead; M, mortality; TGA, transposition of the great arteries; VSD, ventricular septal defect; PS, pulmonary stenosis; PA, pulmonary atresia; IVS, intact ventricular septum; TA, truncus arteriosus.

MRI and CT Study of the Heart

Cardiac MRI and CT study has become an available method for diagnostic and postoperative follow-up [Vliegen 2002] (Figure 8). To assess the responses of PV reconstruction and remodeling of the RV with a PBP or PPF, we used CT imaging, PVI evaluation, and MRI analysis of biventricular function in patients who underwent repair of TOF, PA/VSD, TA, TGA with VSD and LVOTO, and PA/IVS.

In 2006, 10 patients with 10 years of follow-up underwent MRI and CT evaluations. The parameter of cardiac function was evaluated with the patient at rest. The RV ejection fraction was normal (ie, >45%) in 8 patients (80%), and the MRI analysis was well suited for assessing cardiac response. Findings revealed a discrete PVI in the PBP and a trivial PVI in the PPF.

Statistical Analysis

Statistical analyses of continuous variables were performed with a paired *t* test, and the categorical variables were analyzed with the Student *t* test. The Kaplan-Meier method was used to prepare the patients' survival curve. The log-rank test was used to compare 2 or more functions. For all tests, a *P* value <.05 was considered statistically significant.

COMMENTS

Patients undergoing TOF repair surgery have an excellent prognosis and good late survival in approximately 90% of the cases by 10 years after the surgery. In 95% of the cases, it is possible for the patient to achieve successful social reintegration and regain good physical ability during exercise; 79.3% practice sports [Ilbawi 1987].

Reconstruction of the PV and remodeling of the RV with valved prostheses are an essential component of the treatment of patients with TOF and others with congenital heart diseases involving pulmonary ventricle obstruction.

It is difficult to establish the number of patients who underwent surgical correction of TOF and required reoperation. In general, the number depends on the anatomical lesion of each patient and the kind of surgical approach used, as well as on the kind of surgical reconstruction used.

Multiple surgical options for PV reconstruction are available for these patients. They include the use of mechanical valves, mechanical conduits, monocuspid homografts or patches, pulmonary and aortic homografts, stented and stentless heterografts, heterograft conduits, bovine jugular vein conduits, and autologous pericardial valves. The use of a

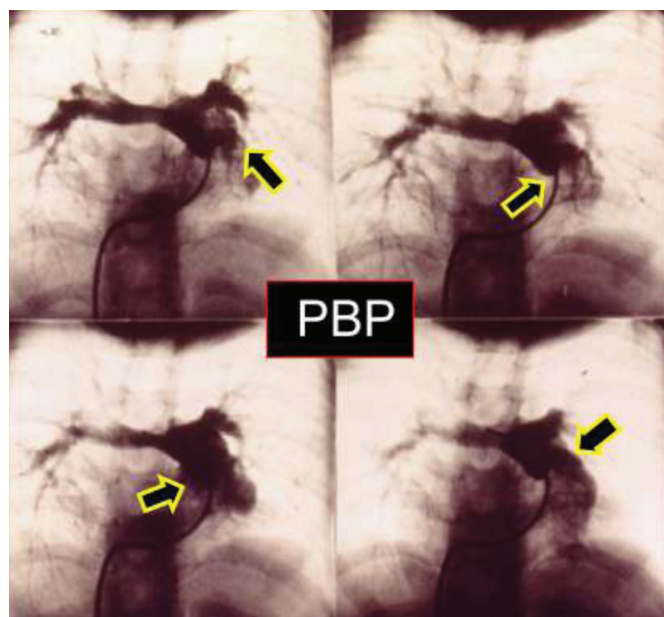


Figure 7. Postoperative pulmonary arteriography images of implanted pulmonary bicuspid prosthesis (PBP).

mechanical valve in the pulmonary position has been reported for a few patients, but their use had fallen out of favor because of the frequent occurrence of thromboembolic phenomena and valve failure [Ibbawi 1987; Miyamura 1987; Kiyota 1992; Vouglatas 1996; Rosti 1998].

In 1967, Marchand [1967] introduced a monocuspid homograft, with excellent results. This type of RVOT repair was very well accepted and routinely adopted in several services. The presence of diastolic murmurs and early postoperative evaluations indicating different degrees of PVI were interpreted in early postoperative follow-ups as an inadequate alignment of the leaflet graft with the PV native leaflets.

In 1968, Eguchi and Asano [1968] published their clinical experience with the use of a bicuspid pulmonary homograft and a bicuspid pulmonary heterograft. An autologous pericardial segment sutured to the pulmonary ring was used to reconstruct the RVOT. A subsequent publication by these investigators [Eguchi 1972] described aneurysmal dilatation of the autologous pericardial segment at late follow-up. Therefore, when enlargement of the pulmonary ring is strictly necessary, the use of an open tile-shaped prosthesis in patients younger than 1 year allows the ring to grow at the expense of the posterior wall. On the other hand, once this valved prosthesis is adjusted for the correct closure at the time of the operation, the growth of the pulmonary ring might make the prosthesis less contingent. On the other hand, the growth of the native valve might also be expected, although it can hardly be clinically proved [Maluf 2000]. A larger experience [Turrentine 2002] with a PTFE monocuspid valve for RVOT reconstruction in 115 patients with a mean follow-up of 2.6 years (range, 6 months to 8 years) demonstrated the significant development of VPI graded as moderate to severe after 35 months.

Homograft valves have become widely used for reconstructing the RVOT in congenital heart disease [Bull 1987; Hawkins 1992; Albert 1993; Bando 1995; Hazekamp 2001]. Midterm and long-term follow-up studies, however, have clearly demonstrated conduit obstruction and early valve insufficiency [Stark 1998] and more-frequent degeneration and progressive calcification in aortic homografts [Niwaya 1999].

Some investigators [Wells 2002; Brown 2005] have suggested that the durability of cryopreserved pulmonary homografts is similar to that of pulmonary homografts used for the Ross procedure. When the trileaflet prosthesis is implanted in the orthotopic position, as in the patient undergoing Ross aortic valve replacement, it can be easily accommodated, thereby maintaining valvar competence [Yamagishi 1993; Oury 1998].

The limited durability of homograft conduits, especially in small sizes, has prompted the search for alternative conduits, such as the PBP [Maluf 2000], the bicuspid homograft [Bové 2002], and the PTFE bicuspid valve [Quintessenza 2005], that allow the growth of the posterior face of the pulmonary ring and the posterior wall of the pulmonary trunk [Maluf 2009]. The superiority of the bicuspid prostheses for reconstructing a hypoplastic pulmonary root has been demonstrated in experimental studies [Sievens 1993]; these results were confirmed in clinical experience [Maluf 2000].

PVI may have a negative impact on RV function, leading to the need for reoperation for the insertion of a competent valve at the RVOT. There are no ideal options for correcting VPI. Studies that included adult TOF patients following PV replacement with various prostheses generally obtained good long-term results with both porcine xenografts and homografts.

VSD or pulmonary stenosis could impair long-term results and significantly change the patient's prognosis. Beginning in 1991, we began using a preserved PBP in infants and a PPF in children to reconstruct the PV and the RVOT in TOF patients, with the aim of decreasing the residual VPI [Maluf 1991, 2000]. This series of patients had an excellent prognosis and a good late-survival rate of approximately 80% by 17 years after the surgery. Seventy-eight percent of the surviving patients with late follow-up results are free of reoperation and show good physical ability during exercise and in the practice of sports. The hemodynamic evaluation of these patients showed that the mean individual RV/LV length ratios did not increase over time.

Although preliminary studies of the use of valved bovine jugular vein conduits [Brown 2006] found short- to intermediate-term durability, Boudjemline et al [2003] and Zavarella et al [2004] reported findings of extensive fibrosis due to intimal proliferation at the conduit's pulmonary anastomosis. In the patients who underwent PPF implantation, a technical modification was introduced to reduce the development of pulmonary stenosis via intimal proliferation at the conduit. The modification involved constructing an enlarged pulmonary anastomosis after constructing a flap at the distal graft's tip. This procedure also was used in reconstructing the pulmonary ventricular outflow tract in patients with PA/VSD, TA, PA/IVS, and TGA with VSD

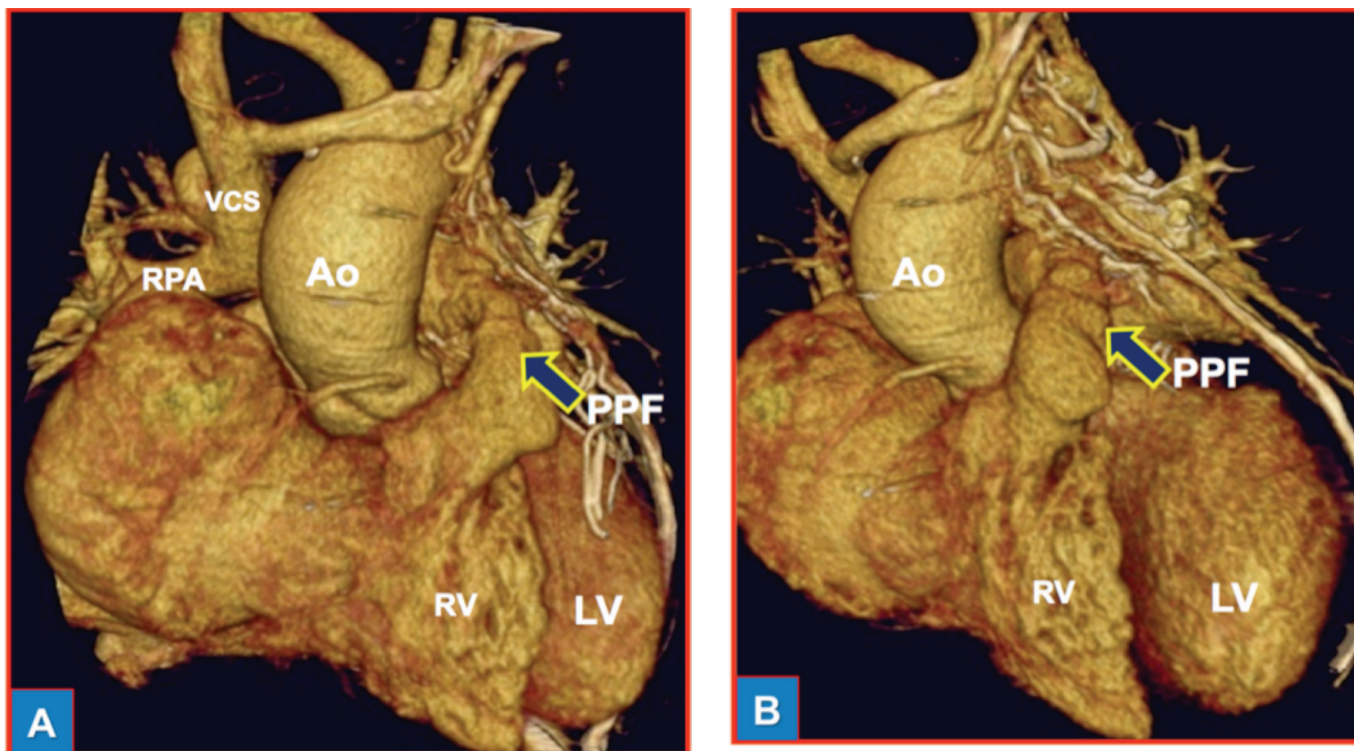


Figure 8. A, Computed tomography scan (frontal view) of one and a half ventricle operation. Glenn anastomosis plus reconstruction of the right ventricle (RV) outflow tract with a pulmonary prosthesis with flap (PPF). SVC indicates superior vena cava; RPA, right pulmonary artery; Ao, aorta; LV, left ventricle. B, Computed tomography scan (left lateral view) of one and a half ventricle operation. Reconstruction of the pulmonary valve and RV outflow tract with a PPF.

and LVOTO. In the PA/VSD group, all of the patients were >14 months of age, and only 18 patients had undergone palliative procedures (Blalock-Taussig shunt and unifocalization procedure). All patients underwent pulmonary arteriography to assess the diameter of the pulmonary artery (trunk and right and left branches) for determining the McGoon index [McGoon 1975]. Although other quantitative methods have been used to study the degree of pulmonary development, we determined the Nakata index [Nakata 1984] or the pulmonary artery index to measure the pulmonary area. All of the patients in our series had pulmonary artery index values >150 mm/m².

We were able to close the VSD during the operation in all patients. After CPB, the RV/LV pressure ratio was measured; this relationship was below 0.58% in all cases.

In the TA group, we used 2 types of prosthesis to reconstruct the PV and remodel the RVOT. PBP implantation was a surgical alternative to correcting TA type I and type II at an early age (<6 months) with the technique without a conduit [Lecompte 1991]. In 8 patients of our series, RVOT reconstruction with a bicuspid prosthesis was possible. The posterior wall of the RVOT was constructed with a flap of the left pulmonary artery; this prosthesis was adjusted with a PBP and running suture. There were 2 hospital deaths caused by pulmonary hypertension crises. The VPI in the immediate post-operative period was trivial in all 7 surviving patients. At this time, no patient has yet undergone reintervention; however,

3 patients actually are in New York Heart Association functional class II and present with moderate VPI.

The second type of prosthesis, PP, was implanted in patients older than 6 months. Two patients underwent operation with this technique. One of these patients, who had had RV dysfunction with significant VPI, had undergone an operation with a valveless woven Dacron conduit 5 years earlier in another center.

The pulmonary ventricle may be compromised by morphologic problems, functional problems, or both. The morphologic defect may be defined by the tricuspid valve z value. In general, this value also reflects the corresponding ventricle volume [Kirklin 2003].

The RVOT is corrected via a variety of techniques, including muscle resection, valvotomy with division of the pulmonary annulus along with the commissure, and reconstruction of the RVOT with a transannular pericardial patch or biological valved prosthesis.

In our series, 7 patients with PA/IVS successfully underwent correction with the one and half ventricle technique. All of these patients, who had previously undergone a Glenn procedure, underwent the same procedure: atrial septal defect closure and reconstruction of the RVOT with a PPF. One patient underwent a transcatheter closure of the residual Blalock-Taussig shunt. The RV performance and RV-pulmonary artery junction were evaluated with MRI, and the RVOT reconstruction was evaluated with a CT study

(Figure 8). The PV–pulmonary artery gradient was <30 mm Hg in all 3 patients.

The Lecompte procedure, which was introduced for the treatment of TGA with VSD and LVOTO, consisted of the construction of an LV-to-aorta tunnel via the ventricle approach after resection of the conal septum [Vouhé 1992]. The RVOT reconstruction is performed after the pulmonary artery is moved to be in front of the aorta (Lecompte maneuver). A valved prosthesis is used for the PV reconstruction.

The pulmonary outflow tract is reconstructed with 2 techniques. When the aorta and the pulmonary artery are in an anteroposterior position, the reconstruction of the RVOT is possible after transversal aorta and pulmonary artery section and PV reconstruction in front of the aorta. When the aorta and the pulmonary artery are in a side-by-side position, the Lecompte maneuver is dispensed with, and a valved conduit is necessary to reconstruct the pulmonary outflow tract. In our series, when the great arteries had an anteroposterior relationship, it was not difficult to pull the pulmonary artery down to the right ventriculotomy site without tension in order to reconstruct the pulmonary outflow with a PBP. When the pulmonary artery and the aorta were in a side-by-side position, however, the Lecompte maneuver was also used, and the pulmonary outflow tract was reconstructed with a PP.

CONCLUSION

The clinical follow-up of 176 patients (86.6%) for a mean of 108 months (range, 4–204 months) allowed the following conclusions: (1) RV remodeling constitutes a safe and standardized technique, (2) early reconstruction of the PV and the RVOT can preserve ventricular performance for a long period, (3) prosthesis function can be analyzed during follow-up, and (4) the porcine pulmonary prosthesis has demonstrated satisfactory long-term results.

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