

Repeat Right Ventricular Outflow Tract Reconstruction Using the Medtronic Freestyle Porcine Aortic Root

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Background and aim of the study: A variety of valve substitutes are used for right ventricular outflow tract (RVOT) reconstruction in children and young adults after previous RVOT surgery that has led to significant pulmonary insufficiency and/or stenosis. Herein, the authors' experience with pulmonary valve replacement (PVR) using a porcine valved conduit late after previous RVOT surgery was reviewed. **Methods:** Between August 2002 and April 2005, 31 patients (mean age 14.5 ± 9.5 years; range: 1.2-33.1 years) underwent PVR using the Medtronic Freestyle porcine aortic root. These patients averaged two prior operations (range: 1-5) for the following diagnoses: tetralogy of Fallot \pm pulmonary atresia (n = 21); persistent truncus arteriosus (n = 5); aortic stenosis (Ross-Konno procedure) (n = 2); pulmonary atresia with intact ventricular septum; (n = 1); congenital pulmonary stenosis (n = 1); and transposition of the great arteries (n = 1). Of these patients, 29 (93.5%) underwent additional procedures at the time of pulmonary valve insertion including: branch pulmonary artery reconstruction (n = 21), atrial septal defect closure (n = 5), ascending aorta replacement (n = 4), pacemaker or defibrillator placement (n = 3), tricus-

pid valve repair (n = 2), ventricular septal defect closure (n = 2), and other procedures (n = 2).

Results: There were no early or late deaths. The mean hospital stay was 8.3 ± 5.9 days (range: 4-25 days). One patient had a subarachnoid hemorrhage with transient left hemiparesis, and two patients had acute tubular necrosis with temporary dialysis treatment. All patients were well at a mean follow up of 13 ± 9.3 months (range: 0.5-31 months). Echocardiography showed trivial or no pulmonary insufficiency in 30 patients (96.7%). The calculated mean peak systolic RVOT gradient by echocardiography was 23.4 ± 7.6 mmHg.

Conclusion: The Medtronic Freestyle bioprostheses demonstrated excellent short-term results for repeat RVOT reconstruction. This valve's hemodynamic characteristics are comparable to those of homografts, and it is an attractive alternative given the limited availability of homograft valves. A lack of availability in sizes smaller than 19 mm limits use of this valve in pediatric patients, and long-term results remain to be determined.

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Pulmonary regurgitation following transannular patch repair of the RVOT is generally well tolerated for many years. Chronic right ventricular (RV) volume overload will eventually lead to RV dilatation with or without tricuspid regurgitation. At some point in time, RV failure will result, manifested by exercise intolerance, dysrhythmias and increased risk of sudden death (1). Most of these patients will require repeat intervention for pulmonary valve placement, while others with previously placed pulmonary valves may develop pulmonary stenosis with significant RV hypertrophy leading to repeat pulmonary valve placement.

A variety of valve substitutes has been used for this purpose, including mechanical valves, homograft and xenograft valves (2,3). None of these valves is ideal, as

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Table I: Primary diagnoses.

Diagnosis	Patients (n)	Previous interventions/diagnosis (n)
Tetralogy of Fallot	17	35
Persistent truncus arteriosus (DiGeorge syndrome-3)	5	8
Pulmonary atresia and ventricular septal defect	4	16
Aortic stenosis	2	4
Congenital pulmonary stenosis	1	1
Transposition of the great arteries	1	3
Pulmonary atresia with intact ventricular septum	1	3

some may have unfavorable hemodynamic performance at smaller sizes and others in the long term may develop structural degeneration with stenosis and/or insufficiency.

The Medtronic Freestyle valve (Medtronic, Minneapolis, MN, USA) is a stentless porcine aortic root bioprosthesis that was introduced for aortic valve replacement. Recently, some surgical centers have used the Medtronic Freestyle valve for reconstruction of the RVOT, albeit with varying results (4,5). Herein is presented a retrospective review of the authors' experience with repeat RVOT reconstruction using the Medtronic Freestyle porcine aortic root.

Clinical material and methods

Patients

Between August 2002 and April 2005, 31 patients (mean age 14.5 ± 9.5 years; range: 1.2 to 33.1 years) underwent repeat RVOT reconstruction using the Medtronic Freestyle porcine aortic root.

The primary diagnoses in the majority of patients were associated with a right heart lesion (Table I). Patients with pulmonary atresia and ventricular septal defect (VSD) had the highest number of previous inter-

ventions. The mean number prior operations was 2.26 (range: 1 to 5). Patients who underwent biventricular repair using transannular patch reconstruction of the RVOT had a comparable number of previous interventions as those who received a conduit as part of their previous repair, with no statistically significant age difference. Details of previous surgical interventions are listed in Table II.

Indications for surgery

The indications for surgery were generally based on the development of symptomatic RV failure or, preferably, earlier echocardiographic signs of RV dilatation with new findings of tricuspid insufficiency and/or arrhythmia development. In some patients, RVOT reconstruction was performed as the secondary procedure. Twenty-nine patients (93.5%) underwent additional procedures at the time of pulmonary valve insertion, consisting mainly of branch pulmonary artery repair (Table III).

Surgical technique

The surgical technique for repeat RVOT reconstruction consisted of repeat sternotomy and standard cardiopulmonary bypass (CPB) using two caval cannulae

Table II: Previous surgical interventions.

Intervention (n)	Patients
Biventricular repair with transannular patch	20
Biventricular repair with a conduit	18
Systemic to pulmonary shunt	11
Pulmonary artery stent placement	4
Open aortic valvotomy	2
Ross procedure	2
Unifocalization procedure	2
Pulmonary artery banding	1
Arterial switch operation	1
Pacemaker implantation	1

Table III: Additional procedures at pulmonary valve implantation.

Procedure (n)	Patients
Pulmonary artery reconstruction	21
Atrial septal defect closure	5
Ascending aorta replacement	4
Right ventricular muscle division/resection	4
Residual ventricular septal defect closure	2
Maze procedure	2
Tricuspid valve annuloplasty	2
Pacemaker implantation	2
Pulmonary stent removal	2
Implantable cardiac defibrillator	1
Aortic valve repair	1

and a single aortic arterial inflow cannula. If the operation was limited to the right side of the heart with no known septal defects, a transesophageal echocardiographic bubble study was performed to exclude a septal defect. If the study showed no intracardiac shunting, the aorta was not cross-clamped and the procedure performed using normothermic CPB with the heart beating. After initiation of CPB, with or without aortic cross-clamping, the operation was started by resecting the previously placed conduit or right ventricle to pulmonary artery connection. The branch pulmonary arteries were then evaluated, and in 21 patients patch enlargement of the branch pulmonary arteries was performed using bovine pericardium. Typically, the pulmonary artery confluence was made larger than the distal end of the porcine conduit. Meticulous attention was paid to avoid narrowing this anastomosis, as it was easy to purse-string the pliable branch pulmonary arteries. Previously placed stents were removed in two patients. Any branch pulmonary artery stenosis was eliminated if at all possible.

The porcine aortic root itself is firmer than a homograft or bovine jugular vein (Contegra; Medtronic, Minneapolis, MN, USA) and tends to resist minor distortions. Clearly, as it is somewhat more rigid, it is also less malleable than a homograft or bovine jugular vein. These characteristics led to the authors modifying the technique for RVOT reconstruction. Frequently, there was sufficient space for a relatively large-diameter conduit, but not sufficient to fit the entire length of the conduit. The Freestyle conduit was almost always cut shorter. The distal part of the conduit was usually trimmed obliquely so that the posterior part was shorter. The end-to-end anastomosis between the distal conduit and the branch pulmonary arteries was performed using continuous polypropylene suture. The right ventricular outflow itself was then examined

to ensure there was no residual muscular outflow obstruction. In some patients a dilated outflow patch had to be resected to eliminate any aneurysmal dilatation of the RVOT. The proximal part of the conduit was then anastomosed to the right ventricle, again using a continuous polypropylene suture, generally at the level of the native pulmonary valve annulus. In some patients it was necessary to place a gusset of bovine pericardium between the anterior part of the RVOT and the proximal conduit in order to avoid distortion of the conduit. The coronary buttons were not resected; neither was the structure of the porcine aortic root modified, as has been suggested by other surgeons (4).

The distribution of valve size versus patient body weight is shown graphically in Figure 1. The most common valve size implanted was the 29 mm in patients of body weight between 35 and 100 kg.

Follow up

All patients underwent periodic routine follow up examinations by the referring cardiologist. A retrospective review of the clinical data from these patients forms the basis of this report.

Results

There were no operative or late deaths. The mean hospital stay was 8.3 ± 5.9 days (range: 4 to 25 days). One patient had a subarachnoid hemorrhage with seizures and transient left hemiparesis. Two patients had acute tubular necrosis and were treated briefly with ultrafiltration hemodialysis. Two patients developed postpericardiotomy syndrome with significant pericardial effusion which responded to steroid treatment.

All patients were well at a mean follow up of 13 ± 9.3 months (range: 1.5 to 32 months). No reoperations or valve revisions were necessary, and all patients were clinically asymptomatic.

Echocardiography showed trivial or no pulmonary insufficiency in 30 patients (96.7%). The calculated mean peak systolic RVOT gradient by echocardiography was 23.4 ± 7.6 mmHg (Table IV).

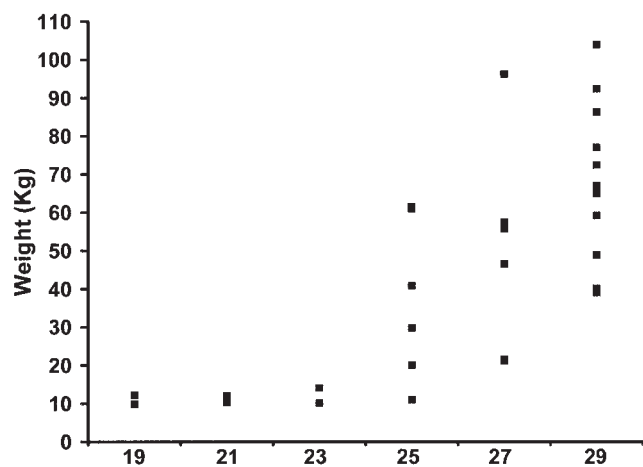


Figure 1: Distribution of porcine aortic valve size versus patient body weight.

Table IV: Pressure gradient across the right ventricular outflow tract (RVOT).

Pressure gradient (mmHg)	Peak systolic pressure gradient at RVOT	Mean gradient at RVOT
None	18	18
10-20	5	13
20-30	5	-
30-40	3	-
> 40	-	-

Discussion

Residual pulmonary insufficiency and branch pulmonary artery stenosis are unfortunately often seen particularly late following the repair of many right heart defects. Chronic pulmonary insufficiency, the most commonly seen residual defect, will result in increased RV dimensions with increasing tricuspid valve regurgitation (6), ventricular dysrhythmias (7), and decreased RV function (6). The development of these chronic changes is variable, and will ultimately result in RV failure. These changes may become significant at an earlier stage, given the tendency in recent years for early primary repair of tetralogy of Fallot and related heart defects (8).

Although pulmonary valve implantation has been reported to improve RV dimensions and function (9,10), the optimal timing of reintervention remains the subject of debate. There is clear evidence that at some point late after primary repair with chronic pulmonary insufficiency, pulmonary valve implantation will not achieve improvement in RV dimension and function (11). These findings have led to new strategies of long-term follow up and indications for reintervention, in patients with residual RVOT lesions, mainly chronic pulmonary insufficiency (12). The present authors' approach is to reoperate on these patients at an early stage, when signs of newly developed tricuspid regurgitation, dysrhythmia, RV dilatation or clinical symptoms of exercise intolerance develop. Volume calculations from magnetic resonance imaging have been helpful in quantifying some of these chronic changes in the right ventricle. In the present group, most patients had complex RVOT lesions consisting of a dilated right ventricle and outflow tract combined with branch pulmonary artery stenosis. In order to achieve good long-term results, branch pulmonary artery stenosis and any aneurysmal dilatation of the RVOT must be eliminated along with implantation of a competent, unobstructed valve.

Three major groups of valve substitutes - mechanical, xenografts and homografts - have been used to reconstruct the RVOT in children and young adults. Results using these valve substitutes have been extensively reported for the past 25 years, and the limitations of each type of valve are well known (3,13). Homograft valves have generally become the standard by which other valves are judged. Homograft valves have shown the best long-term results when used in conjunction with pulmonary autograft replacement of the aortic valve (3,13). This extended longevity is commonly attributed to the valve's orthotopic implantation. However, nearly all of these patients have a normal right ventricle with normal branch pulmonary arteries, in the absence of any annular dilatation or

peripheral pulmonary arterial stenosis, creating an ideal physiologic environment for the implanted homograft valve. In all other patient subgroups, however, homograft valves generally failed at an early stage, mainly due to recurrent significant pulmonary insufficiency (12,14). Some authors have argued that this 'mild' early insufficiency is not clinically significant. However, when the indication for repeat surgery is chronic pulmonary regurgitation and RV failure, it is difficult to ignore recurrent pulmonary valve insufficiency, however mild. Early recurrent pulmonary insufficiency may be attributed to residual branch pulmonary artery stenosis or elevated pulmonary vascular resistance, for example, as sometimes seen in patients with pulmonary atresia and VSD after unifocalization of the aorto-pulmonary collaterals. In other instances, in the absence of any anatomic distortion and flow disturbance, this early regurgitation may simply be a manifestation of the same process that ultimately destroys these implanted valves. A common scenario would be an infant following repair for persistent truncus arteriosus, in whom progressive flow disturbance may be detected by echocardiography soon after surgery. Most of the present patients had tetralogy of Fallot repair, and the majority had some degree of residual branch pulmonary artery stenosis. A few of the patients also had less than optimal pulmonary vascular beds with elevated pulmonary vascular resistance. This early failure of the homograft valve led to a search for a better valve substitute for these subgroups of patients (12,14).

In recent years, new versions of xenograft valves - the stentless conduits - have emerged as an attractive alternative for RVOT reconstruction. The Medtronic Freestyle valve is a stentless porcine aortic root bioprosthesis, available in sizes from 19 to 29 mm. The valve is manufactured using a technique that fixes the leaflets at zero pressure, while the aortic root is pressurized to 40 mmHg. In addition, the valve is treated with an anticalcification agent (alpha amino-oleic acid). Although originally designed for aortic valve replacement, this conduit has shown excellent short- to mid-term results in the pulmonary position (4,5). The Freestyle valve is thicker and firmer when compared to homografts of bovine jugular vein - a characteristic which probably renders the valved conduit more durable in the face of higher distal pulmonary pressures and possibly resists the damaging effects of annular or RV outflow dilatation. Given the comparative rigidity of this conduit, valve leaflet distortion due to slight anatomic malpositioning may be averted. Clearly, the manufacturer claims that their new 'anticalcification' treatment will also confer improved longevity to these valves. This claim is obviously not yet substantiated, particularly in the pulmonary position.

A recent report has focused attention on early stenosis of the Freestyle conduit, resulting in early repeat surgery (15). The cause of this early stenosis is unclear. One group observed exuberant fibrosis which seemed to entrap and externally compress the valve conduit, resulting in significant stenosis (4). These authors, however, modified the conduit by resecting the native porcine coronary artery stumps. These defects were then repaired with polytetrafluoroethylene (PTFE) patches (4). It is surmised that the use of PTFE material causes the development of extensive fibrosis, resulting in significant early graft stenosis in smaller patients. However, no other group has yet reported this problem.

One major drawback of the Freestyle valve conduit is that it was intended for use only in adult-sized patients. Currently, the smallest valve size available is 19 mm, and this limits its use to infants and smaller children (Fig. 1). Given these size limitations, the present authors continue to use homografts in neonates and small children for RVOT reconstruction.

The present study was of short-term nature, and clearly a longer follow up is needed to determine the rate of structural valve deterioration and function. The use of anticalcification agents and fixation at low pressure may show better long-term performance over previously available xenograft valves (3,13).

These early results with the Freestyle valve are encouraging, and the early regurgitation experienced with homografts has not been identified. Serial echocardiography has demonstrated minimal or no pulmonary insufficiency in 96% of patients, with minimal pulmonary stenosis at a mean follow up of nine months. The Freestyle porcine valve appears to function very well at short-term follow up in those patients with complex RVOT obstruction and, despite the risk of repeat surgery, operative and late mortality have been gratifyingly minimal. In future, the use of transvenously implanted pulmonary valves may allow patients with these reconstructed RVOT and valve conduits to avoid additional surgery.

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