We implanted hybrid valves in 14 patients noncoronary cusp, and the anterior wall was reconstructed using a patch made of bovine pericardium or ePTFE with bicuspid ePTFE valves.

Although the Ross procedure is a well-established approach to aortic valve disease in pediatric patients and young adults, there still is no ideal method of right ventricular outflow tract (RVOT) reconstruction, especially in children. To achieve improved RVOT reconstruction with long-term valve function and growth potential, we have developed a hybrid valve which combines the autologous aortic valve and expanded polytetrafluoroethylene (ePTFE) valves. The posterior wall of RVOT was reconstructed using the autologous aortic wall with a noncoronary cusp, and the anterior wall was reconstructed using a patch made of bovine pericardium or ePTFE with bicuspid ePTFE valves. We implanted hybrid valves in 14 patients (age 5–18 years). During the follow-up period (2.4–8.8 years), there were no mortalities or morbidities, and no patients required reoperation. Echocardiography showed no significant stenosis and regurgitation, and preserved valve motion in all patients. The z-value of the diameters of the pulmonary annulus in early and late follow-up was −1.4 and −1.8, respectively, the difference not being significant. Creation of a hybrid valve was associated with excellent mid- to long-term results. Given its theoretical growth potential, we speculate that this valve could be a good choice for RVOT reconstruction in the Ross procedure, especially for young children.

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Keywords: Congenital heart disease; Ross procedure; Right ventricular outflow tract reconstruction; Expanded polytetrafluoroethylene valve; Autologous aortic valve

1. Introduction

The Ross procedure is an established surgical treatment of aortic valve disease, but there is no consensus on the optimal material for right ventricular outflow tract (RVOT) reconstruction especially in children. Competent valves are required to avoid pulmonary regurgitation and consequent right ventricular volume overload. Although various valved conduits or patches have been used [1], their availability and long-term durability are either unknown or unsatisfactory. Moreover, in the case of pediatric patients, growth potential is an important issue [2].

Since 1985, we have developed a fan-shaped valve, made from a 0.1-mm-thick expanded polytetrafluoroethylene (ePTFE) membrane (Preclude Pericardial Membrane, W.L. Gore & Associates, Inc, Flagstaff, AZ) [3], and verified that although the valves retain sufficient mid-term function, some eventually become fixed in the open position [4].

From 2001, we have developed an improved version which we expect to function reliably for a longer period. The improvement introduced was the creation of a bulging sinus on an ePTFE. The sinus generates vortex flow similar to that created by the sinus of Valsalva which helps native semilunar valves close. The vortex flow should help reduce wear and stress, thus increasing the longevity of the valves. Bulging sinuses were formed on the ePTFE using specially designed instruments in our institute. Between February 2001 and December 2005, these valves were implanted in 157 patients undergoing RVOT reconstruction, showing excellent early to mid-term results (no mortality or morbidity) and preservation of right ventricular function. But for the pediatric patients who needed a valved conduit, we needed to address the issue of growth potential. For this purpose we developed a hybrid valve by combining the autologous aortic noncoronary cusp and a bicuspid ePTFE valve in 1997 [5].

We describe the method we used to implant these hybrid valves in 14 pediatric patients undergoing a Ross procedure between 1997 and 2006, and present our findings on follow-up examinations performed up to 2–8 years after an operation.
2. Materials and methods

2.1. Patients

Between November 1997 and July 2006, 14 patients underwent RVOT reconstruction as part of a Ross procedure using an expanded polytetrafluoroethylene-autologous aortic hybrid valve. At the time of operation, their median age was 10.5 years (range 5–18 years), and their median body weight was 29.5 kg (range 14–52 kg). Indications for the Ross procedure were aortic regurgitation in seven patients, aortic stenosis in three and combined aortic stenosis and regurgitation in four. A bicuspid aortic valve was present in seven patients. Two patients had previously undergone balloon valvoplasty, one patient open commissurotomy, and one patient both balloon valvoplasty and open commissurotomy.

2.2. Operative techniques

In all patients, the aortic valve was replaced using the root replacement technique with a coronary artery reimplantation. The ascending aorta was transected approximately 5 mm above the sinotubular junction. After detachment of the coronary cuffs from the aortic wall, the noncoronary cusp was harvested along with the adjacent aortic wall (Fig. 1a). The length of the aortic wall with noncoronary cusp was approximately 3 cm and suitably long. The right side of the aortic fibrous ring of the noncoronary cusp was preserved to avoid injury to the atrioventricular conducting tissue beneath the anulus. The valve leaflet was sewn directly to the aortic wall.

This technique was also adopted for patients with bicuspid valve and a thin noncoronary cusp and aortic wall. In patients with aortic stenosis or status post-valvuloplasty and with slightly thicker leaflets, the latter were excised and a decision made for utilization.

After reconstruction of the aortic root, the autologous aortic wall with the noncoronary cusp was anastomosed to the RVOT posterior wall (Fig. 1b). We anastomosed a patch bearing the bicuspid fan-shaped ePTFE valve to the RVOT anterior wall facing the autologous noncoronary cusp (Fig. 1c). The patches were made of bovine pericardium in six patients, ePTFE without bulging sinuses in one, and ePTFE with bulging sinuses (Fig. 2) in the remaining seven patients. The valves were placed proximally at the same level as the original pulmonary annulus (i.e. the two ePTFE valve leaflets were adjusted to the same height of the transplanted aortic noncoronary cusp leaflet, to avoid regurgitation). The size of the ePTFE valve was adjusted to the size that expanded the diameter of the neoplumony annulus to 120% of the normal value.

Cardiopulmonary bypass times were 257.4±47.4 min and aortic cross-clamp times were 139.9±19.2 min.

From 2001, only ePTFE patches with bulging sinuses have been utilized; various sized patches (the diameter of the sinus was either 13.5, 15, 17.5 or 20 mm) have been pre-assembled and sterilized before the operation.

2.3. Follow-up and data collection

Follow up for the patient cohort was 2.4–8.8 years (mean±S.D., 64.5±24.5 months). Pulmonary regurgitation, mean blood pressure gradient across the valves, and the diameter of the pulmonary annulus were periodically assessed in all patients by transthoracic two-dimensional color-flow Doppler echocardiography in the M-mode. The degree of pulmonary regurgitation was classified as none, trivial, mild, moderate, or severe, according to features of the jet flow measured by pulsed Doppler echocardiography; of particular interest was the width of the jet at its source and its depth of extension into the ventricle.

Nine patients underwent postoperative cardiac catheterization and six patients underwent magnetic resonance angiography. No patients required routine anticoagulation or anti-aggregant therapy. Preoperative and postoperative data were collected retrospectively from the patients’ medical records. All data are expressed as means±S.D.

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**Fig. 1.** (a) The pulmonary autograft is first excised, and then the ascending aorta is transected. After detaching the coronary cuffs from the aortic wall, the noncoronary cusp is harvested along with the adjacent aortic wall. LCA, Left coronary artery; RCA, Right coronary artery; PA, pulmonary artery; LVOT, left ventricular outflow tract; RVOT, right ventricular outflow tract. (b) The operative technique of right ventricular outflow tract reconstruction. After reconstruction of the aortic root, the autologous aortic wall with the noncoronary cusp is anastomosed to the RVOT posterior wall. (c) A patch bearing the bicuspid fan-shaped ePTFE valve is anastomosed to the RVOT anterior wall. PA, pulmonary artery; RVOT, right ventricular outflow tract; Ao, Aorta.

**Fig. 2.** Fan-shaped valves are anastomosed to the edge of the bulging sinuses. (a) Bicuspid fan-shaped ePTFE valves. (b) An ePTFE patch with bulging sinuses. (c) View from lateral.
There were no mortalities or morbidities, and no patients required reoperation or reintervention. From the most recent echocardiograms, pulmonary regurgitation was absent in five patients, trivial in two, and mild in seven. There was no moderate or severe regurgitation in any case. Postoperatively, the mean ± S.D. peak pressure gradient between the right ventricle and the pulmonary artery was 20.8 ± 14.6 mmHg after one year, 25.0 ± 16.1 mmHg after two years, 32.8 ± 11.0 mmHg after three years and 28.7 ± 17.9 mmHg after four years (Fig. 3). The postoperative diameter of the pulmonary annulus, which was measured at the level of the commissure between the noncoronary cusp and the ePTFE valves, was −1.4 ± 1.7 of the z-value after one year, −3.4 ± 0.6 after two years, −2.6 ± 1.5 after three years and −1.6 ± 2.1 after four years (Fig. 4). For seven patients followed-up more than five years, the diameter of the pulmonary annulus was −1.8 ± 2.4 of the z-value.

In nine patients who underwent postoperative cardiac catheterization, the central venous pressure was 6.4 ± 3.0 mmHg, the diastolic pulmonary artery pressure was 7.0 ± 1.9 mmHg, the systolic right ventricular pressure was 45.1 ± 9.7 mmHg, the right ventricular end diastolic volume was 112.6 ± 18.4% of normal and the right ventricular ejection fraction was 53.2 ± 6.0%. Most recent echocardiography, cardiac catheterization or magnetic resonance angiography demonstrated that the anterior ePTFE leaflets and the posterior autologous noncoronary cusps were functioning well in all patients. No leaflets were fixed in the open position, and none showed signs of calcification or peel formation. All patients were in good clinical condition and none were scheduled for reoperation.

4. Comments

There is currently no satisfactory conduit material for RVOT reconstruction in the Ross procedure, especially in children. Even homografts, the most commonly used material for RVOT reconstruction, are plagued with long-term calcification and failure [1, 6–8]. A range of materials including autologous pericardiums, porcine pulmonary valves [2, 8, 9], and bovine jugular veins [8–11] have been used, but their long-term durability are either unsatisfactory [2, 9–11] or unknown. It is inevitable that many of these children will require reoperation because of valve failure (stenosis or insufficiency) due to calcification or fibrosis, lack of growth potential, or other reasons. A good prosthetic valve that is readily available and will be reliable for a long time is, therefore, needed. To date, ePTFE valves have demonstrated good results [5, 12–14].

The ePTFE membranes used to create artificial heart valves have good biocompatibility, and their microporous structure impedes cellular penetration, thereby making it resistant to calcification that would hinder its mobility. To date, no stenotic lesions have been observed at the site of an ePTFE valve [4, 13, 14]. In our experience, the patches were initially made of bovine pericardium, then ePTFE without bulging sinuses, and ePTFE with bulging sinuses in the last five years. We have observed no difference in the result among these three configurations, although we believe that the latter mode of reconstruction (ePTFE patch with bulging sinuses) might be the most advantageous.

This technique is relatively simple, with cardiopulmonary bypass time and aortic cross-clamp times not significantly different when compared to another 13 patients undergoing homograft or tricuspid ePTFE valved conduits (the cardiopulmonary bypass times were 264.5 ± 71.5 min or aortic cross-clamp times were 153.2 ± 44.4 min). This technique can furthermore be suitable for most patients with aortic insufficiency and/or aortic stenosis who have a mobile noncoronary cusp even in bicuspid valves. We believe that patients with aortic regurgitation have good substrate for RVOT reconstruction with a hybrid valve as the aortic leaflets are usually pliable. Even patients with mild sclerosis and aortic stenosis might be good candidates.

In our series, the youngest patient was five years old, but we nevertheless think that this technique is suitable even for infants or neonates.

In our series, the pressure gradient between right ventricle and pulmonary artery increased during the first three years after operation, and began to decrease thereafter. The diameter of the pulmonary annulus also decreased during the first two years after operation, and began decreasing three years following operation. This suggests that the autologous aortic wall remains viable and grows in the pulmonary position, leading to a decrease in pressure.
gradients between right ventricle and pulmonary artery. The pressure gradient between right ventricle and pulmonary artery was relatively high in our series. This might be due to mild pulmonary stenosis, with the diameter of the pulmonary annulus after the operation being approximately −2 of the z-value. This might be echocardiographically over-estimated since those patients who demonstrated pressure gradients between right ventricle and pulmonary artery over 30 mmHg by echocardiography, were consistently below 30 mmHg on cardiac catheterization. However, the pressure gradient was not progressive through the follow-up period. The degree of pulmonary regurgitation is also important [15] and, in our series, all patients had mild or less regurgitation, there were no moderate or severe cases. Right ventricular function was preserved in all nine patients who underwent postoperative cardiac catheterization.

A hybrid valve, consisting of a combination of a portion of the autologous aortic valve and a bicuspid fan-shaped ePTFE valved patch, showed excellent mid- to long-term results. The growth potential of RVOT should be retained, as the autologous aortic valve consisting of the posterior wall of the RVOT might be viable.

Although further laboratory and clinical studies are necessary to make a firm conclusion, these preliminary data suggest that this hybrid valve could be a good choice and a useful alternative to homografts and other forms of valved conduits for RVOT reconstruction especially in pediatric patients undergoing the Ross procedure.

References


Conference discussion

Dr A. Abu (Amman, Jordan): This technique is not new. In the 70s, Dr Cooley adopted a policy to do every repair in the right ventricular outflow obstruction, and after follow Tетralogy. And this repair was on the right side, to do, in the transannular patch, to do a pocket from a redundant pericardium which before fixed with a glutaraldehyde.

Dr Sairanen: Yes, you are right. Many of these numerous new modifications are based on old techniques presented before. But I think this is a very special one of them.

Dr D. Metras (Marseille, France): First of all, what is the thickness of the Gore-Tex membrane you utilize to construct your monocusp. It looks to me to be a 0.6 mm, which is rather thick, whereas, as John Brown has described in Indianapolis, we use very often monocusp patch with a membrane of PTFE. My second question is that it's an experience of 14 patients over a period of nine years. Does that mean that you selected these patients particularly or is that a consecutive series?

Dr Miyazaki: To answer the first question, we commonly use the monocusp patch. With our new technique we use an autologous noncoronary cusp and a bicuspid Gore-Tex valve.

Dr Metras: Yes. But what thickness of the Gore-Tex, do you know?

Dr Miyazaki: The valve leaflet is made of a 0.1 mm thick ePTFE membrane. As for the second question, we did select those 14 patients. We think this technique is suitable for patients having aortic regurgitation, because the aortic noncoronary cusp remains flexible. And we think this technique is likely suitable for patients under 20 kg who have growth potential. Because we can make tricuspid ePTFE valves with bulging sinuses that demonstrated excellent results, so for patients over 20 kg, we will use tricuspid ePTFE valves?