Early report

Percutaneous replacement of pulmonary valve in a right-ventricle to pulmonary-artery prosthetic conduit with valve dysfunction

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Summary

Background Valved conduits from the right ventricle to the pulmonary artery are frequently used in paediatric cardiac surgery. However, stenosis and insufficiency of the conduit usually occur in the follow-up and lead to reoperations. Conduit stenting can delay surgical replacement, but it aggravates pulmonary insufficiency. We developed an innovative system for percutaneous stent implantation combined with valve replacement.

Methods A 12-year-old boy with stenosis and insufficiency of a prosthetic conduit from the right ventricle to the pulmonary artery underwent percutaneous implantation of a bovine jugular valve in the conduit.

Findings Angiography, haemodynamic assessment, and echocardiography after the procedure showed no insufficiency of the implanted valve, and partial relief of the conduit stenosis. There were no complications after 1 month of follow-up, and the patient is presently in good physical condition.

Interpretation We have shown that percutaneous valve replacement in the pulmonary position is possible. With further technical improvements, this new technique might also be used for valve replacement in other cardiac and non-cardiac positions.

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Introduction

The treatment of congenital heart disease has become increasingly interventional as the armamentarium of tools grows. The most important advancements in interventional cardiology are the development of devices for closure of septal defects, and stents with or without covering.[1]

The development of extracardiac conduits for the establishment of right-ventricular to pulmonary-artery continuity has been one of the major advances in paediatric cardiac surgery. Conduits have permitted repair of previously uncorrectable congenital heart defects, and facilitated the treatment of other complex diseases. The prosthetic conduits are either valveless,[2] or use xenograft,[3–8] pericardial,[9] or homograft valves.[10–12] However, conduit failure inevitably occurs after a period that largely depends on the type of valve mounted in the conduit. Progressive obstruction of the conduit secondary to calciferous stenosis of the heterograft valve or accumulation of fibrous peel within the conduit necessitates its surgical replacement. In addition, somatic growth, infection, and conduit incompetence can also indicate a surgical substitution.[5] Conduits with porcine valves require replacement about 7·4 years (range 1·1–17·7) after implantation.[8] However, long-term results seem to be more encouraging with autologous pericardial valves.[10,13] Conduits made with bovine jugular valves have recently become popular in surgery, but their long-term performance in the clinical setting still remains to be established.

Conduit stenting during percutaneous catheterisation has emerged as an efficient technique to reopen the conduit narrowing, thereby delaying the need for surgery.[14–18] However, this technique is not entirely satisfactory because the valve in the conduit has to be sacrificed, which then leads to pulmonary insufficiency. Pulmonary regurgitation chronically overloads the right ventricle, compromising its long-term function.[19] Despite the rare but possible complications of stent placement,[14–18] a non-surgical technique to correct the conduit obstruction without compromising the competence of the valve is therefore attractive. By preserving adequate long-term right-ventricular function, this option potentially diminishes the number of surgical interventions in patients who need numerous open-heart operations during their life.

In an animal study, we reported having done a percutaneous pulmonary valve replacement using a valve from a bovine jugular vein mounted inside an expandable stent.[20] The experiment showed that valve function was good after mounting of the device. We succeeded in implanting a valved stent in seven of 11 animals; the valve remained functional after 2 months in

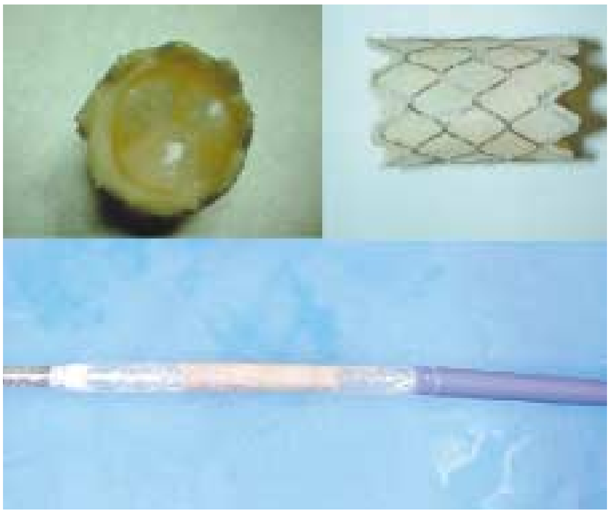

Figure 1: **Valved stent**
Upper left: closed valve mounted in the stent. Upper right: profile of the valved stent before compression. Below: valved stent in the delivery system.

five of the animals. In one, early calcification of the valve occurred, which was probably related to suboptimal preparation of the biological valve.

Here we report the first human application of this new device.

Methods

Patient

Our patient was a 12-year-old boy with pulmonary atresia and a ventricular septal defect who had had a central aortopulmonary shunt at the age of 11 days and a right modified Blalock-Taussig shunt at 10 months of age. At 4 years, he had had total repair with closure of the ventricular septal defect, and placement of an 18 mm Carpentier-Edwards conduit from the right ventricle to the pulmonary artery. Before the procedure, the patient was mildly symptomatic (New York Heart Association class II). Echocardiography and doppler imaging showed significant stenosis and insufficiency of the conduit leading to moderate dilatation of the right ventricle.

Approval for percutaneous pulmonary valve replacement was obtained by a certified ethics committee (CCPPRB, Paris, France). The boy's parents gave written informed consent before the procedure.

Methods

An 18-mm bovine internal jugular vein with a native valve was dissected, then reduced in profile and finally mounted in an expanded vascular platinum stent. The valved stent (figure 1) was then sterilised and cross-linked with glutaraldehyde.

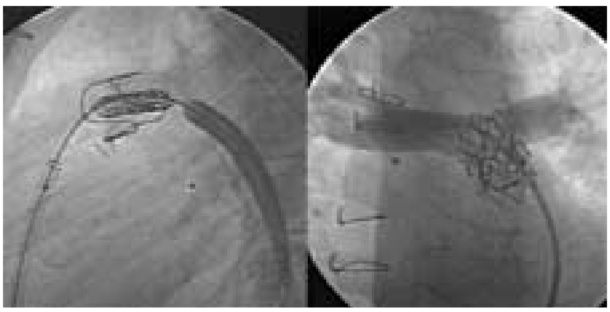

Figure 2: **Angiographies**
Left: valved stent in the Carpentier-Edwards conduit before deployment. Right: angiography after expansion of the valved stent showing valvar competence.

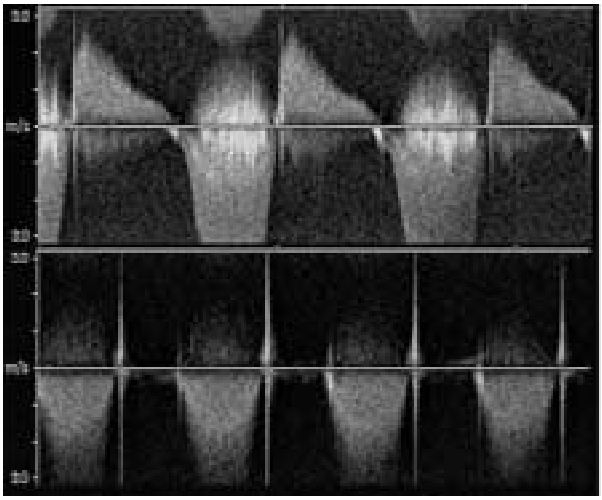

Figure 3: **Doppler imaging**
Upper panel: pulmonary regurgitation before implantation of the valve. Lower panel: perfect competence of the implanted valve.

Under general anaesthesia, catheterisation was done through the right femoral vein, and the patient was heparinised. Angiographic studies and haemodynamic assessment of the right-ventricular outflow tract were obtained to identify the position and extent of the obstruction and regurgitation. After positioning of a stiff guidewire in the pulmonary artery, the valved stent was mounted on the delivery system as shown in figure 1. The delivery system was composed of an 18-mm balloon catheter, front-loaded in a specially made 18-F long sheath (NuMed, NY, USA; Arrow, PA, USA). The system was then connected to the guidewire and advanced into the pulmonary artery through the obstructed conduit. Thereafter, the stent was uncovered and deployed by balloon inflation in the precise position of the obstruction. The delivery system was then removed. The procedure ended with angiographic studies and haemodynamic assessment. Echocardiography was done the next day and before discharge from hospital.

Results

Angiography before implantation of the valve showed a calciferous narrowing of the Carpentier-Edwards conduit. Pressure measurements under general anaesthesia revealed a systolic right-ventricular pressure of 80 mm Hg, and a systolic systemic pressure of 95 mm Hg. Pulmonary arterial pressures distal to the stenosis were 30/8, with mean of 16 mm Hg.

The bovine jugular venous valve mounted into the platinum stent was successfully delivered into the degenerated valve of the conduit (figure 2).

The haemodynamic study after implantation showed a limited reduction of the systolic pressure ratio between the right ventricle and the aorta from 85% to 66%. However, after 1 month, the pressure ratio had decreased further to almost 50%. Good valve function was confirmed by angiography (figure 2) and by an increase in the diastolic pulmonary-arterial pressures (30/16, mean 20 mm Hg).

There was no significant clinical event after implantation. Echocardiography confirmed the residual obstruction in the conduit, and a perfectly competent pulmonary valve was shown by doppler imaging (figure 3). Five days after the procedure, the size and systolic function of the right ventricle were normal, and the patient was discharged in excellent physical condition.

Discussion

We previously reported an experimental trial of percutaneous pulmonary valve implantation in lambs.[20] We fixed a valved segment of a bovine jugular vein into a stent, and delivered the assembly according to standard stent-placing techniques. The ability to reduce the venous external wall allowed compression of the vein to a very low profile without damaging the valve at re-expansion. By use of the jugular approach, implantation within the animal was technically difficult due to the narrow angle of the delivery system in the right ventricle. However, we succeeded in seven of 11 animals. A straighter catheter approach through the femoral vein, as used routinely in human beings, was impossible because of the small dimensions of this vein in the lamb. Optimum results after 2 months were obtained in five animals. Problems in the experimental series were related to technical failure, to the anatomy of the lamb, or to suboptimum preparation of the biological valve. Bovine venous valves exist in sizes of about 8–24 mm; this range covers all our needs in cardiac surgery.

Here, we report the first successful implantation of a biological cardiac valve by the percutaneous technique in a human being. After implantation, there was no residual insufficiency, as shown by normal diastolic pulmonary pressures, angiography, and, in particular, by doppler imaging (figure 3). After 1 month of follow-up, the boy was New York Heart Association class I, and doppler images revealed a continued lack of insufficiency. Disappointingly, there was only partial relief of the conduit obstruction because of the hard calcifications in the conduit which were resistant to dilatation. However, prediction of the relief of stenosis before stent implantation is impossible. We opted to reassess the patient during follow-up, and to consider redilatation with a stronger balloon if necessary. Systemic pressures at the end of the procedure were relatively low owing to general anaesthesia, and the gradient after the implantation was only 25 mm Hg, with pulmonary-arterial systolic pressures at 30 mm Hg. As shown in our previous experimental work, redilatation in the follow-up assessment is likely to improve the relief of the stenosis without interfering with the valve function.

Biological valves used in surgery are frequently mounted in a metal structure. The technique applied here uses a vascular stent as the supporting structure. This modification presents an opportunity to carry out non-surgical implants of cardiac valves by a percutaneous approach. Further studies and technical improvements in the system are obviously necessary. Other indications such as valve replacement in the aortic position or in the venous system for chronic venous insufficiency should be explored. The proximity of the coronary orifices to the native aortic valve obviously presents difficulties in percutaneous aortic-valve replacement by this technique.

Contributors

Philipp Bonhoeffer had the idea for pulmonary-valve implantation, did the research, and performed the surgery. Younes Boudjemline assisted in the research and development of the valved stent. He prepared the manuscript with Damien Bonnet. Zakhia Saliba and Yacine Aggoun assisted during the implantation. Philippe Acar did the imaging. Daniel Sidi and Jérôme Le Bidois were responsible for the patient's care. Jacques Merckx was responsibole for anaesthesia. Jean Kachaner assisted in the preparation of the document for ethical approval.

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References

1 Oesterle SN, Whitbourn R, Fitzgerald PJ, et al. The stent decade: 1987 to 1997. Stanford Stent Summit faculty. *Am Heart J* 1998; **136:** 578–99.
2 Downing P, Danielson G, Schaff H, Puga FJ, Edwards WD, Driscoll DJ. Replacement of obstructed right ventricular-pulmonary arterial valved conduits with nonvalved conduits in children. *Circulation* 1985; **72** (suppl II): II84–II87.
3 Jonas RA, Freed MD, Mayer JE, Castaneda AR. Long-term follow-up of patients with synthetic right heart conduits. *Circulation* 1985; **72**(suppl II): II77–II83.
4 McGoon DC, Danielson GK, Puga FJ, Ritter DG, Mair DD, Ilstrup DM. Late results after extracardiac conduit repair for congenital cardiac defects. *Am J Cardiol* 1982; **49:** 1741–49.
5 Razzouk AJ, Williams WG, Cleveland DC, Coles JG, Rebeyka IM, Trusler GA, Freedom RM. Surgical connections from ventricle to pulmonary artery: comparison of four types of valved implants. *Circulation* 1992; **86**(suppl II): II154–II158.
6 Kirklin JW, Blackstone EH, Maehara T, et al. Intermediate-term fate of cryopreserved allograft and xenograft valved conduits. *Ann Thorac Surg* 1987; **44:** 598–606.
7 Bull C, McCartney FJ, Horvath P, et al. Evaluation of long-term results of homograft and heterograft valves in extracardiac conduits. *J Thorac Cardiovasc Surg* 1987; **94:** 12–19.
8 Champsaur G, Robin J, Curtil A, et al. Long-term clinical and hemodynamic evaluation of porcine valved conduits implanted from the right ventricle to the pulmonary artery. *J Thorac Cardiovasc Surg* 1998; **116:** 793–804.
9 Schlichter AJ, Kreutzer C, Mayorquim RC, et al. Long-term follow-up of autologous pericardial valved conduits. *Ann Thorac Surg* 1996; **62:** 155–60.
10 Cleveland DC, Williams WG, Razzouk AJ, et al. Failure of cryopreserved homograft valved conduits in pulmonary circulation. *Circulation* 1992; **86** (suppl II): 150–53
11 Bando K, Danielson GK, Schaff HV, Mair DD, Julsrud PR, Puga FJ. Outcome of pulmonary and aortic homografts for right-ventricular outflow tract reconstruction. *J Thorac Cardiovasc Surg* 1995; **109:** 509–18.
12 Stark J, Bull C, Stajevic M, Jothi M, Elliot M, de Leval M. Fate of subpulmonary homograft conduits: determinants of late homograft failure. *J Thorac Cardiovasc Surg* 1998; **115:** 506–14.
13 Schlichter AJ, Kreutzer C, Mayorquim RC, et al. Five to fifteen-year follow-up of fresh autologous pericardial valved conduits. *J Thorac Cardiovasc Surg* 2000; **119:** 869–79.
14 Saliba Z, Bonhoeffer P, Aggoun Y, et al. Traitement des obstructions des prothèses tubulaires par implantation percutanée de stents. *Arch Mal Cœur Vaiss* 1999; **92:** 591–96.
15 Ovaert C, Caldarone CA, McCrindle BW, et al. Endovascular stent implantation for the management of postoperative right ventricular outflow tract obstruction: clinical efficacy. *J Thorac Cardiovasc Surg* 1999; **118:** 886–93.
16 O'Laughlin MP, Slack MC, Grifka RG, Perry SB, Lock JE, Mullins CE. Implantation and intermediate-term follow-up of stents in congenital heart disease. *Circulation* 1993; **88:** 605–14.
17 Hosking MC, Benson LN, Nakanishi T, Burrows PE, Williams WG, Freedom RM. Intravascular stent prosthesis for right ventricular outflow obstruction. *J Am Coll Cardiol* 1992; **20:** 373–80.
18 Powell AJ, Lock JE, Keane JF, Perry SB. Prolongation of right ventricular to pulmonary artery conduit life span by percutaneous stent implantation intermediate-term results. *Circulation* 1995; **92:** 3282–88.
19 Bove EL, Byrum CJ, Thomas FD, et al. The influence of pulmonary insufficiency on ventricular function following repair of tetralogy of Fallot: evaluation using radionuclide ventriculography. *J Thorac Cardiovasc Surg* 1983; **85:** 691–96.
20 Bonhoeffer P, Boudjemline Y, Saliba Z, et al. Transcatheter implantation of a bovine valve in pulmonary position. *Circulation* 2000; **102:** 813–16.