Balloon dilatation of porcine bioprosthetic valves in the pulmonary position

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ABSTRACT Balloon dilatation (BD) of bioprosthetic valves was investigated in vivo and in vitro. Four children with stenotic bioprosthetic porcine valves in the pulmonary position underwent BD of the valve 10 to 24 months after its insertion. Average valve gradient was reduced from 47.5 to 27 mm Hg. Obstruction at the conduit-branch pulmonary artery connection became apparent after dilatation of the valve. These distal stenoses were also dilated. BD technique was tested in vitro with the use of nonstenotic valves in fresh conduits. No damage to the valve or to the conduit was found when oversized balloons were used in a standard fashion or intentionally inflated until rupture. It is concluded that conduit replacement may be deferred by balloon dilatation of obstructed biological valves and/or a stenotic conduit–pulmonary artery anastomosis.


PERCUTANEOUS balloon dilatation (BD) has been used successfully to relieve stenoses in native pulmonary,1–3 aortic,4 and mitral5 valves in both children and adults. In the present study, the BD technique was used to dilate four stenotic porcine bioprosthetic valves in right ventricular–to–pulmonary arterial conduits in children. The favorable experience suggests that balloon dilatation in this setting may be a useful nonoperative modality that may serve to postpone surgical replacement of a valve conduit.

Materials and methods

Patient population. In the past 7 years, 41 children have been seen at our institution with porcine (aortic valve) bioprostheses used as pulmonary valves, 39 inserted at our center and two implanted elsewhere. Thirty valves were within conduits and 11 were placed as orthotopic xenografts. Seven patients died in the immediate or early postoperative period and follow-up was available, ranging from 2 months to 6 years 2 months (mean = 2 years 5 months), for 34 patients. Valve failure necessitating intervention occurred in nine children at a mean postoperative time of 2 years and 10 months. Five patients underwent conduit replacement and four recent patients underwent BD. The patients in the BD group are discussed below.

Patient 1, with truncus arteriosus type A-1,6 underwent reparative surgery at the age of 5 months with insertion of a 12 mm porcine valved conduit between the right ventricle and the pulmonary arteries concurrent with closure of the ventricular septal defect (table 1). At catheterization 10 months after surgery, stenosis of the bioprosthetic valve was found. BD was performed. At repeat catheterization four months after BD, there was only a trivial (6 mm Hg) gradient across the dilated valve, but severe stenosis of the branch right pulmonary artery was found. Replacement of the conduit was performed.

Patient 2 had had repair of truncus arteriosus performed elsewhere at 5 months of age. She underwent diagnostic cardiac catheterization at 2½ years of age at our center, where a stenotic porcine valve was detected. BD of the valve was performed (figure 1), and an attempt was made to dilate a severely stenotic right pulmonary artery (RPA). This was not successful because the “standard” extrusion catheter was too stiff to be placed in the RPA ostium. Asymmetric pulmonary blood flow was confirmed, with 24% distribution to the right lung. Four months later, a soft extrusion 8 mm balloon catheter was first used to dilate the 2 mm RPA, followed by BD with a standard extrusion 10 mm catheter. Significant improvement in the RPA pulse wave contour was noted (figure 2) and 2 weeks after the BD of the RPA, right lung perfusion was 40%.

Patient 3 underwent repair of coarctation and pulmonary artery banding at 5 weeks of age for transposition of the great arteries, ventricular septal defect, and coarctation of the aorta. Additional palliation was provided by a systemic-to-pulmonary artery anastomosis when the patient was 8 months of age. At 2½ years of age, a Damus-Rastelli7–10 procedure was performed with use of a 16 mm conduit; plastic repair was performed on both branch pulmonary arteries (table 1).

Cardiac catheterization was performed 1 year after surgery. An 80 mm Hg gradient was recorded between the right ventricle and the branch pulmonary arteries. BD of the valve, the left pulmonary artery (LPA), and the RPA was performed. Follow-up echocardiographic examination indicated persistent reduction of the gradient; repeat diagnostic cardiac catheterization has not been performed.

Patient 4 received a diagnosis of transposition of the great arteries with ventricular septal defect and straddling left-sided atroventricular valve when she was 3 days of age. Two days later, a pulmonary artery band was placed. When the patient...
wound was 16 months of age, a Damus-Rastelli7-9 procedure was performed with use of a 14 mm conduit. Postoperative extracorporeal membrane oxygenation was necessary. At cardiac catheterization 10 months after surgery, a 55 mm Hg gradient was found from the right ventricle to the branch pulmonary arteries and the child was referred for therapeutic cardiac catheterization. BD of the valve and both branch pulmonary arteries was performed.

**Technique of balloon dilatation.** Written informed consent was obtained before each procedure. After completion of hemodynamic and angiographic studies, a No. 7F Goodall-Lubin catheter was advanced across the stenotic valve from a femoral venous approach. A 260 cm long, 0.035 inch thick exchange wire was positioned in a branch pulmonary artery (usually the left) as distally as possible, preferably at the level of the diaphragm, to provide as much "anchor" as possible for the balloon catheter, which was usually stiff and often had to traverse acute angulations within the right heart. Leaving the wire in place, both catheter and sheath were removed. A Mansfield balloon dilatation catheter (usually standard extrusion) was advanced along the wire into the conduit.

The balloon catheter/inflator system was loaded with Renografin 60 diluted to 25% usual strength with flush solution; trapped air was removed from the system. The balloon was not test-inflated because the expanded balloon would not return to a smooth, flat position on the shaft; this made insertion into the patient more difficult and more traumatic on the vein. After advancement through the right heart, the midpoint of the balloon was positioned at the stent of the bioprosthetic valve and location was confirmed fluoroscopically with low-pressure (<1 atmosphere) inflation.

High oxygen was administered by face mask throughout the BD procedure. (Although the inflations were maintained only for a short time, it is believed that hypoxia should be avoided in ventricles that are stressed before repair and continue to be pressure-overloaded by the stenotic bioprosthetic valve.) Usually at this point in the procedure, additional sedation and supplemental heparin were necessary. BD was performed at least twice for 20 sec each to an inflation pressure halfway between the recommended pressure and an empirically determined bursting pressure; usually this was 1.0 to 1.5 atmospheres greater than the recommended pressure limit on the package.

Repeat hemodynamic studies — including measurement of cardiac output — and angiography were then performed. The same precautions were taken as during BD of native pulmonary valve stenosis; i.e., contrast was delivered well away from the site of BD. In each case, distal obstruction was found and the same balloon and technique was used to dilate these stenoses. Measurement grids were also filmed to measure precisely the balloon size during inflation.

**Study of BD of valved conduits in vitro.** Conduits contain-
ing porcine valves were tested by BD with the use of oversized balloons. An 18 mm balloon was first inflated in a 12 mm valve to 3 atmospheres for 20 sec twice; the balloon was then withdrawn and reinflated at 3 atmospheres for 20 sec at the proximal end of the conduit with the balloon half in and half out of the conduit. In a second 12 mm conduit, the 18 mm balloon was positioned across the valve and inflated until rupture. The balloons were inflated with Renografin 60 diluted to half strength with tap water. This experiment was repeated with the use of a pair of 14 mm conduits and a 20 mm balloon and then with a pair of 16 mm conduits with a 23 mm balloon.

Results
Balloon dilatation reduced the average transvalvular gradient from 47.5 to 25 mm Hg and reduced the right ventricular pressure to a level below that of left ventricular pressure (table 2). In patient 1, right ventricular systolic pressure changed from suprasystolic to 60% of left ventricular systolic pressure (figure 3). In every case, pulmonary artery pressure rose, usually from a relatively nonpulsatile waveform to a normal tracing (figure 1). Measurements of the inflated balloon corresponded closely (within 0.2 mm) with the size indicated on the package.

Porcine valve competence was assessed by two-dimensional echocardiography interfaced with Doppler flow instrumentation. Patient 1 had a trace degree of pulmonary regurgitation before BD; this increased to moderate after the procedure. The other three children had no regurgitation before BD; after BD, there was trace regurgitation in two of the three.

The conduit removed from patient 1 four months after BD was grossly intact (figure 4). A proliferative intimal lesion was found approximately 1 cm proximal to the valve cusps. The cusps were intact without tears but were retracted to a partially open position. Histo-

### Table 2

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**TABLE 2**

Hemodynamic effects of BD

RV = right ventricular systolic pressure in mm Hg; MPA = main pulmonary artery systolic pressure in mm Hg; RV/LV = ratio of systolic pressures in the right ventricle and left ventricle; CI = cardiac index in liters/min/m².
logic examination revealed that the stenotic intimal prolifera-
tion was composed of moderately cellular fibrous tissue of indeterminate duration, without hemorrhage or dissection. The valve was mildly calcified at its periphery. The calcific deposits were focal, at the cuspal bases, and in the (porcine) aortic wall incorporated into the bioprosthesis. Obstruction at the level of the proximal fibrous tissue proliferation was greater than that at the level of the valve.

The experiments in vitro yielded two forms of results: technical — related to the inflation procedure, and pathologic — from examination of the balloon-inflated conduits. Rupture of the balloons in the conduits was extremely difficult. The balloons distored, extended proximally and distally along the shaft, and accepted a large increase over the usual volume before rupture, which occurred at 8 atmospheres in the 12 mm conduit and at over 11 atmospheres in the 14 and 16 mm conduits.

The conduits and valves were examined grossly and microscopically by one of us (F. J. S.) with no knowledge of which had standard inflation and which had balloon rupture. All conduits and valves dilated in vitro were intact without cuspal tears or commissural dehiscence. One of the six had several longitudinal tears in the porcine atrial muscle shelf that was incorporated into the valve during manufacture. This did not appear to compromise either patency or competence of this valve.

Discussion

Insertion of valve-containing conduits is needed in certain types of congenital heart surgery: repair of truncus arteriosus, Rastelli operation for transposition of the great arteries, and left ventricular apex–descending aorta anastomosis. Biological valves are generally used so that anticoagulation can be avoided. However, the durability of bioprosthetic valves is limited. While degeneration of these valves occurs in patients of all ages, valve failure is accelerated in children, usually due to the deposition of calcium in the valve cusps producing stenosis or the development of an obstructive pseudointima in the proximal conduit. When obstruction develops, pressure overload of the ventricle occurs, often necessitating replacement of the conduit.

BD in our four patients appeared to reduce the valve gradient and thereby decrease the right ventricular pressure to a level where surgery was not considered necessary. Furthermore, a certain degree of valve function appears to have been preserved since three of the four patients had only mild regurgitation of the valve after BD.

The mechanism by which BD opens the stenotic valve is unclear. Whether commissural fusion of the leaflets was severed and/or immobile basilar hinge points were loosened was not determined in our study. In our limited surgical experience with stenotic bioprosthetic valves under direct vision, deterioration of

FIGURE 4. Valved conduit after balloon dilatation (conduit removed from patient 1; see text). A, Inflow view demonstrating obstructive pseudointimal proliferative lesion proximal to valve, with stenosis as indicated by arrows. B, Cross section of proliferative lesion, close to the valve. C, Distal view demonstrating stiffened valve cusps fixed in "mid" position presenting an orifice (indicated by the arrows) larger than that at the level of the proximal pannus. D, Valve radiograph that shows multifocal calcification primarily at the basal cuspal attachments and the aortic wall segments incorporated in the porcine bioprosthesis.
the leaflets did not appear to be homogeneous, i.e., one leaflet was relatively intact while there was fusion of the other two leaflets. Since valve function seemed somewhat preserved after BD, it is possible that the surgical observation may be common and that BD separates the fused commissure.

The one porcine valve available for direct inspection after BD showed leaflets in the mid position with a proximal pannus that appeared to be more obstructive than the valve itself. It seems probable that this proximal narrowing developed after the BD since there was no evidence of this obstruction either by pressure measurement or angiography. If the pannus formed as a reaction to the BD, then the technique may be of limited usefulness. We suspect that this is not the case because in the other three patients there has been no evidence of return to high right ventricular pressure during follow-up, which has admittedly been short (9 to 12 months).

The unmasking of more distal obstruction by BD of the bioprosthesis valve is clinically important. Before BD, with severe valvular obstruction, the pulmonary artery pressure was very low, making the finding of a large distal pressure gradient quite unlikely. Furthermore, since the obstructive valve prevents delivery of a large, rapid bolus of contrast into the pulmonary arteries during angiography, visualization of stenosis at the distal anastomoses may be suboptimal. Echocardiography has been of limited assistance in these patients because imaging of the distal conduit is often very difficult and good angles with which to measure gradients by Doppler flow analysis have been unattainable. However, after BD of the valve, pulmonary artery pressure rises (figure 2), making distal gradients more determinable, and angiography can be used to better visualize the conduit–pulmonary artery connections. It is imperative to seek out these stenoses and dilate them concurrent with the valve dilatation since the residual distal obstructions may cause persistence of the right ventricular hypertension, which was the initial indication for intervention.

Despite the apparent safety of oversized balloons, we believe that balloon size should be similar to that of the valve anulus. Larger balloons will tolerate lower inflation pressures and therefore lesser hoop stress. Oversize balloons are unlikely to provide any advantage over a balloon similar in size to the valve. Second, our data shows that an adequate reduction in gradient can be achieved with valve-sized balloons. Thus, balloons similar in size to the valve anulus should be chosen. However, there is some leeway, i.e., when the valve is 14 mm, a 15 mm balloon would seem superior to a 12 mm balloon, and a 20 mm balloon would probably be appropriate for a 16 mm conduit.

When stenosis of a bioprosthesis valve is found, it should be dilated first because it is quite safe and after BD, distal stenoses may be more apparent. After BD of the valve, angulated angiography of the pulmonary arteries should be performed. The lateral plane in approximately 20 degrees of cranial obliquity seems to separate the ostia of the two branches well (figure 2).

Indications for BD of stenotic bioprosthetic pulmonary valves cannot be derived from our study. We continue to use the level of systemic (or near systemic) right ventricular pressure as an indication for intervention, but it is possible that the indications should be liberalized because BD is extremely safe, does not require thoracotomy, and may even be repeated. If echocardiography does not provide data of a reassuring nature with respect to the right ventricular pressure, we recommend early diagnostic cardiac catheterization, with the physician prepared to perform BD if stenosis of the valve is encountered.

It may be appropriate to perform BD of a stenotic bioprosthetic valve even when replacement will be necessary in the immediate future. If the patient has suprasystemic right ventricular pressure, even a mild reduction in right ventricular pressure overload may decrease the risk of anesthetizing the patient for the surgery.

The finding of the obstructive pannus in the conduit in patient 1 is of concern. It is unlikely that this was present at the time of BD and therefore it developed in the 5 months between BD and conduit replacement. If this was stimulated by BD, then the procedure may not be valuable. Only larger series with longer follow-up will answer this question.

Clinical implications and speculations. BD of stenotic bioprosthetic pulmonary valves appears to be a safe, useful procedure. Valve function appears to be relatively preserved by BD, i.e., BD does not convert a stenotic conduit into a "valveless" conduit. BD may allow deferral of conduit replacement, thereby promoting subsequent insertion of a larger conduit. Distal stenoses of the branch pulmonary arteries are often unmasked by BD of the stenotic valve and these obstructions may also be dilated.

BD of bioprosthetic valves in positions other than the pulmonary position may also be useful. Feit et al.\textsuperscript{12} recently used BD to open a stenotic porcine valve in the tricuspid position. This technique may also be helpful for stenotic bioprosthetic mitral or aortic valves.

Because of the problems of early valve failure in
children, homograft valves are being used with increasing frequency. When these fail, they generally become insufficient rather than stenotic. However, if stenosis of a homograft valve occurs, BD may be a reasonable procedure to consider.

We express our gratitude to Johnson & Johnson Cardiovascular for their contribution of conduits and to Medi-Tech Corp. for their donation of balloon catheters.

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Balloon dilatation of porcine bioprosthetic valves in the pulmonary position.
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Circulation. 1987;76:109-114
doi: 10.1161/01.CIR.76.1.109
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
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Print ISSN: 0009-7322. Online ISSN: 1524-4539

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