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Sustained high pressure double balloon angioplasty of calcified conduits

N Sreeram, P Hutter, E Silove

Abstract

***Objective*—To assess the efficacy of prolonged high pressure angioplasty for dilatation of calcified and stenotic cardiac conduits in children.**

***Design*—A prospective study of consecutive patients presenting with calcified and stenotic conduits.**

***Setting*—Two tertiary paediatric cardiology departments.**

***Methods*—Sustained (up to five minutes), high pressure (up to 18 atmospheres), double balloon angioplasty was performed in six calcified and stenotic cardiac conduits (five consecutive patients, three male, two female, age 4 to 17 years). Four patients had right ventricle to pulmonary artery (RV-PA) conduits, and one had two venous conduits in a Fontan circulation.**

***Results*—Marked reductions in right ventricle to pulmonary artery gradients, from a median (range) of 48 (40 to 62) mm Hg to 11 (5 to 16) mm Hg, and in right ventricle to femoral artery pressure ratios, from a median of 0.8 (0.72 to 0.86) to 0.4 (0.33 to 0.44), were achieved for all RV-PA conduits. All five patients had sustained clinical improvement at follow up (median follow up 12 months) and none has required reintervention or surgery.**

***Conclusions*—Prolonged high pressure double balloon angioplasty may have a role in prolonging the interval between conduit replacements in a subset of patients with complex heart defects.**

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Keywords: angioplasty; conduit; calcification; congenital heart disease; interventional cardiology

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The extracardiac conduit operation has allowed definitive palliation of many congenital heart defects. However, regardless of the type of conduit used, conduit failure over time is inevitable.[1] Standard balloon angioplasty[2–4] and stent implantation[5–7] have had limited success. We describe a technique of transcatheter dilatation of calcified conduits using two balloons simultaneously, with prolonged high pressure inflation.

Methods

PATIENTS

We studied five consecutive patients (three male, two female) ranging in age from 4 to 17 years. All had undergone multiple surgical procedures culminating in placement of a valved conduit as part of a definitive repair. In four cases, conduits were placed between the right ventricle and the pulmonary arteries (RV-PA conduit). The fifth patient had two valved homograft conduits placed between the inferior vena cava and right atrium, and between the right atrium and pulmonary artery, respectively, during a Fontan repair. The specific diagnoses, previous surgical procedures, and details of the conduits placed are given in table 1. At follow up, all patients showed chest *x* ray changes of calcification of the conduit associated with Doppler echocardiographic evidence of significant stenoses within the conduit. Additional indications for conduit dilatation included the presence of symptoms such as fatigue or decreasing exercise tolerance. Informed consent and institutional review board approval were obtained as appropriate before all procedures.

TECHNIQUE

Under general anaesthesia, and after recording pressure gradients across the conduit, one balloon was introduced from each femoral vein. The combined effective balloon diameter was chosen to be up to 125% of the nominal diameter of the conduit.[8] Balloons ranging in diameter between 8 and 15 mm were chosen. The following balloons were used in various combinations: 8 mm (3 cm length), 10 mm (4 cm), and 12 mm (4 cm) Blue Max balloons (Meditech; Boston Scientific, Boston, Massachusetts, USA); 10 mm (4 cm), 12 mm (4 cm), and 15 mm (3 cm) NuMed Mullins high pressure balloons (NuMed, Canada Inc, Cornwall, Ontario, Canada); and 8 mm (2 cm), 10 mm (3 cm), and 12 mm (3 cm) Z-Med balloons (NuMed, Canada Inc). Each balloon was appropriately positioned across the conduit and inflated by independent operators to achieve inflation pressures of between 10 and 18 atmospheres or until rupture. In some cases, when the waist was not abolished at the maximum recommended inflation pressure of the balloons, higher inflation pressures were used. In this manner, it was ensured that both balloons were fully expanded and any waist formation of one or both balloons was abolished as completely as possible (fig 1).

Where a stenosis also affected the origin of one branch of the pulmonary artery (one patient), both guiding wires were positioned within that pulmonary artery so that the distal ends of both balloons were also within the same artery. The femoral arterial pressure was monitored continuously during balloon inflation. Balloon dilatation was continued for up to five minutes, regardless of whether the waist was abolished sooner, in the belief that "remodelling" of calcified conduits could be achieved in this way. During inflation the balloons were

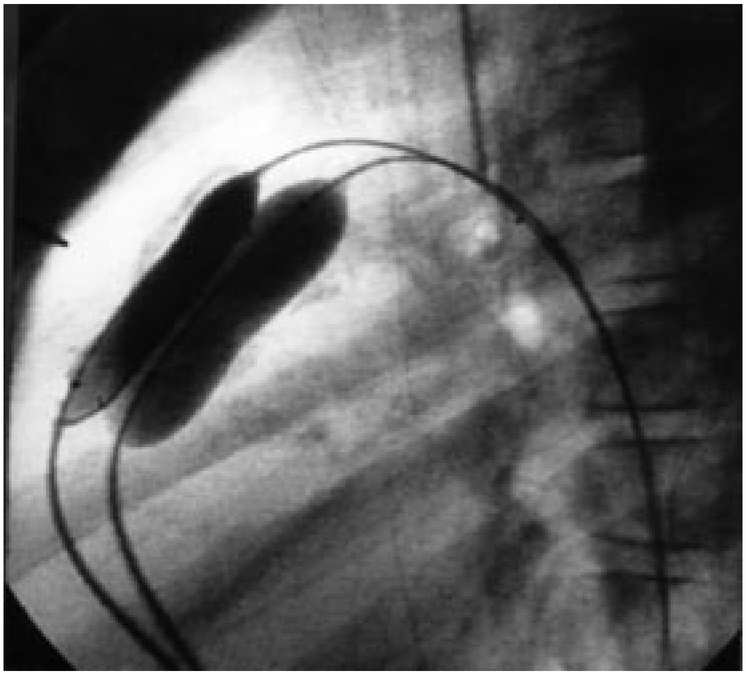

Figure 1 Two high pressure balloons inflated simultaneously within the calcified conduit (patient 1), with full expansion of both balloons.

advanced or retracted simultaneously or relative to each other to ensure complete dilatation of the entire length of the conduit. If the systemic arterial pressure fell to an unacceptable level (arbitrarily defined as a reduction of ⩾ 30% from the baseline value before balloon inflation), one or both balloons were temporarily deflated until the systemic output had recovered to near baseline values. Finally, withdrawal gradients were remeasured along the entire length of the conduit. Repeat angiography was routinely performed at the end of the dilatation procedure in all four patients with RV-PA conduits.

Results

Before dilatation, the median gradient measured at catheterisation across the four RV-PA conduits was 48 mm Hg (range 40 to 62 mm Hg). The largest gradient was recorded at the junction of the proximal end of the conduit with the right ventricular myocardium. Additional stenoses were seen as follows: valvar (one patient), junction of the conduit and left pulmonary artery (one patient), and multiple stenoses (one patient). All RV-PA conduits showed evidence of mild to moderate regurgitation. Both venous conduits in the fifth patient had multiple stenoses. The smallest diameter of the stenosis for the RV-PA conduits ranged from 8.5 to 18 mm, but could not be measured for the two venous conduits despite multiple angiographic projections. During dilatation, all patients had a decrease in systemic arterial blood pressure (of between 15% and 40% of the baseline value), and this necessitated temporary deflation of both balloons in two of the four patients, and of one balloon in the other two patients. After dilatation, the median gradient across the RV-PA conduits decreased to 11 mm Hg (range 5 to 16; fig 2). The right ventricle to femoral artery systolic pressure ratio decreased from 0.8 (range 0.72 to 0.86) to 0.4 (range 0.33 to 0.44). The pulmonary artery diastolic pressure after dilatation was between 0 and 5 mm Hg. The gradient reduction across the two venous conduits was from 7 to 2 and 3 to 0 mm Hg respectively. The minimum diameter of stenoses in the RV-PA conduits ranged from 8.5 to 19 mm, and appeared unchanged in two of the four conduits.

COMPLICATIONS

Balloon rupture was a frequent occurrence, and between three and eight balloons were used for each procedure. All ruptured balloons

Table 1 Demographic and haemodynamic data

Patient	Age (years)	Diagnosis	Previous operations	Level of obstruction	Interval (months)†	Balloons‡	Gradient (mm Hg) Pre	Gradient (mm Hg) Post	RV:FA Pre	RV:FA Post	Doppler Pre	Doppler Post	Doppler FU
1	15	AoV stenosis	Valvotomy; re-valvotomy; Ross procedure (pulmonary autograft + **21 mm valved homograft RV-PA conduit**; replacement AoV	Proximal conduit	24	15 mm + 12 mm	45	7	0.75	0.43	100	36	41
2	8	Dextrocardia, cTGA, VSD, PA	R A-P shunt; **16 mm Hancock conduit** + VSD closure	Proximal conduit and valve	72	12 mm + 10 mm	50	15	0.86	0.44	88	31	44
3	10	PA/VSD	R A-P shunt; **18 mm homograft conduit** + VSD closure	Proximal conduit and LPA origin	40	15 mm + 10 mm	40	5	0.72	0.33	74	34	46
4	4	Common arterial trunk	PA banding; **12 mm homograft conduit** + VSD closure	Multiple	24	8 mm + 8 mm	62	16	0.85	0.37	100	38	44
5*	17	TA	R and L A-P shunts; Fontan procedure; insertion of **two 22 mm valved homograft conduits** from IVC to RA and from RA to PT	Multiple/ multiple*	127	15 mm + 15 mm	3/7*	0/2*	–	–	–	–	–

*Refers separately to the two shunts. Gradients are between IVC and RA and RA and PT, respectively.
†Time from conduit placement to balloon angioplasty.
‡Balloon diameters correspond to the largest combination of balloons used in dilating each conduit.
AoV, aortic valve; A-P, aorto-pulmonary shunt; cTGA, congenitally corrected transposition; FU, Doppler gradient at last follow up examination; IVC, inferior vena cava; L, left; LPA, left pulmonary artery; PA, pulmonary atresia; PT, pulmonary trunk; R, right; RA, right atrium; RV:FA, right ventricle to femoral artery systolic pressure ratio; TA, tricuspid atresia; VSD, ventricular septal defect.

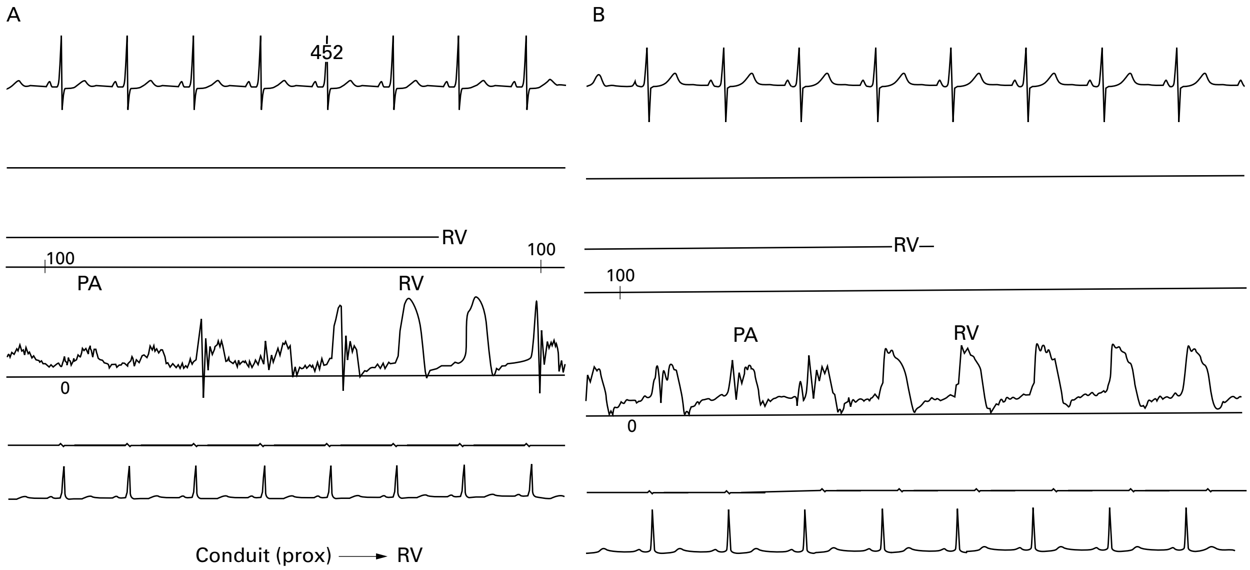

Figure 2 (A) Pressure recording during catheter withdrawal through the conduit before balloon angioplasty, showing a gradient of 45 mm Hg. Scale: 0–100 mm Hg. (B) Pressure recording post-dilatation, showing a gradient of < 10 mm Hg. The pulmonary arterial pressure in early diastole is 0, suggesting significant pulmonary valve incompetence. Scale: 0–100 mm Hg. PA, pulmonary artery; RV, right ventricle.

could be removed through the femoral vein without detachment of any fragments or undue blood loss. Apart from mild transient sensory loss along the distribution of the superficial femoral nerve in one patient there were no procedure related complications, and all patients were discharged from hospital on the following day.

FOLLOW UP

Continuous wave Doppler echocardiographic estimation of residual peak instantaneous gradients after dilatation was a median of 35 mm Hg (range 31 to 38), compared with median predilatation gradient of 94 mm Hg (74 to 100). All conduits showed a qualitative improvement on colour Doppler ultrasound studies. At a median follow up of 12 (3 to 17) months, none of the four patients with RV-PA conduits has had any measurable increase in the Doppler gradient, and all are symptomatically improved. The patient with the Fontan circulation is clinically improved, but has not been recatheterised.

Discussion

BACKGROUND

Bioprosthetic conduit failure limits the usefulness of this type of surgery in young patients.[1] In previous studies of balloon dilatation of calcified conduits[2–4] the only consistent successes have been reported in patients in whom the stenosis was mainly at valvar level. Attendant problems of stent implantation within conduits have included incomplete relief of stenosis, stent fracture or distortion (presumably from contact with beating myocardium or by compression from the sternum), stent displacement, and stent embolisation.[5 6]

POTENTIAL ADVANTAGES

Although none of the patients in this series has had the conduit explanted, we speculate that prolonged double balloon dilatation has several potential advantages that make it particularly suitable for conduit dilatation. Smaller balloons allow higher dilatation pressures to be achieved, a factor which may be of importance in "remodelling" heavy deposits of calcium during balloon inflation. The less severe decrease in systemic blood pressure with two balloons[9] and the prolonged inflation times that can therefore be achieved may also be important in this respect. Further evidence for remodelling of the conduit or its junction with right ventricular myocardium as a mechanism of effective dilatation is provided by the fact that significant reductions of gradients were often achieved without an obvious increase in the minimum diameter of the measured stenosis.

LIMITATIONS

Clearly, the number of patients reported is small, and follow up is relatively short. It is not possible to distinguish between the beneficial effects of high pressure dilatation versus the duration of balloon inflation. Additional studies on a larger series of patients are required to confirm the benefit of prolonged double balloon inflation, and to determine which aspect of the procedure (inflation pressure versus duration of inflation) is more important in achieving sustained relief of stenosis. It is unclear whether the technique will be equally effective in patients in whom intimal "peel" formation is the mechanism of conduit obstruction. Dilating the conduit along its entire length despite the presence of a discrete stenosis on gradient measurement is important, as additional stenoses are often unmasked after effective dilatation of the first lesion.

POTENTIAL COMPLICATIONS

Major drawbacks of this technique are the increase in the degree of conduit regurgitation (as evidenced by the very low diastolic pressures within the pulmonary trunk after dilatation) and the frequency of balloon rupture. Thus far, all balloons have ruptured longitudinally, and have been removed without difficulty through the femoral vein. The use of two balloons may be advantageous, as the stress is not distributed along the entire balloon circumference, thereby lessening the risk of transverse rupture.[3] Conduit rupture is also a potential complication which was not encountered. Previous studies have shown that Dacron conduits are generally resistant to rupture at high pressures of up to 10 atmospheres. No such studies have been reported for homograft conduits. To minimise the risk, we advocate effective balloon diameters to be between 100% and 125% of the nominal conduit diameter.

CONCLUSIONS

Sustained double balloon angioplasty appears to provide satisfactory immediate relief of gradients across calcified conduits, without undue complications. The beneficial effect persists at short term follow up. Although there is an increase in the degree of pulmonary regurgitation, in the absence of associated stenosis within the conduit regurgitation alone appears to be well tolerated. The technique may be useful in prolonging the life of biological conduits, allowing definitive replacements using oversized conduits to be performed after somatic growth is completed.

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