

Stent implantation for aortic coarctation and recoarctation

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Abstract

Objective—To determine the early results of balloon expandable stent implantation for aortic coarctation or recoarctation.

Design—Prospective observational study. **Setting**—Two paediatric cardiology tertiary referral centres.

Patients—17 patients, median age 17 years (range 4.4 to 45) and median weight 61 kg (17 to 92). Six had native aortic coarctation and 11 had aortic recoarctation; 14 had upper limb systolic hypertension. Of those with recoarctation, eight had had at least one previous balloon dilatation attempt and two of these patients also had further surgical interventions.

Intervention—Balloon expandable Palmaz iliac stent implantation.

Main outcome measures—Systolic pressures gradients, minimum aortic diameter, upper limb blood pressures, and incidence of aneurysm formation.

Results—18 stents were implanted during 18 procedures in the 17 patients. Mean peak systolic pressure gradient fell from 26 mm Hg (95% confidence interval (CI), 21 to 31 mm Hg) before to 5 mm Hg (2 to 8 mm Hg) after stent implantation ($p < 0.001$), and mean minimum aortic diameter increased from 7 mm (95% CI, 6 to 8 mm) before to 11.3 mm (10 to 12.6 mm) after implantation ($p < 0.001$). Complications occurred in five patients (bleeding in two, stent migration in two, and aneurysm formation in one). Two patients remained borderline hypertensive and eight were receiving antihypertensive treatment at most recent assessment.

Conclusions—Stent implantation for aortic coarctation and native coarctation gives good immediate results. Careful follow up is necessary to evaluate complications and the long term effect on blood pressure.

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Keywords: coarctation; aortic recoarctation; stents

Balloon dilatation has largely been accepted as the treatment of choice for recoarctation of the aorta but is less well established in the treatment of native aortic coarctation despite similar results.¹ Within the first year of life, and particularly within the first month, the high restenosis rate and the rate of femoral arterial complications after balloon dilatation of aortic coarctation supports surgical repair as the preferred option.^{2–5} In older patients, however,

balloon dilatation of both native and aortic recoarctation has a higher success rate with a lower incidence of restenosis than in infancy^{1–8} but there are concerns about acute aortic dissection^{7,9} and the late development of aneurysms.^{10,11} It is of note that aneurysm formation is a recognised complication after various types of surgical repair,^{12,13} particularly when the results are evaluated by routine magnetic resonance imaging.¹⁴

Balloon expandable endovascular stents have a long history in the treatment of peripheral¹⁵ and subsequently atherosclerotic¹⁶ coronary artery disease. Since 1989, stent implantation has been applied in congenital heart disease principally in pulmonary arteries and systemic veins.¹⁷ After balloon dilatation, vessel recoil may lead to restenosis. Stents prevent this and thus maintain the effectiveness of dilatation within these structures. In addition, the integrity of the vessel is maintained by preventing the extension of any vessel tears or dissection between vessel layers that may have occurred after balloon angioplasty. Some studies have already described the application of endovascular stents in the treatment of aortic coarctation or recoarctation.^{18,19} While the use of stents in younger children is limited by their ultimate maximum expanded diameter, their application in older children, adolescents, and adults appears promising.

We report our experience of stent implantation in both native and postoperative coarctation of the aorta in older children and adults. In older patients with native coarctation or those postoperative patients who had no previous balloon angioplasty, we elected to proceed directly to stent implantation in order to reduce aneurysm risk. We wish to emphasise the role of staged dilatation in an attempt to further reduce the incidence of aneurysms that may occur after stent implantation,¹⁹ and the use of spiral computed tomography (CT) in the non-invasive follow up evaluation.

Methods

PATIENT POPULATION

Between November 1993 and June 1998, 17 patients (three female, 14 male) underwent stent implantation for aortic coarctation or recoarctation. The median age at the time of stent implantation was 17 years (range 4.4 to 45 years) and the median weight was 61 kg (range 17 to 92 kg).

Six patients had native coarctation and 11 had aortic recoarctation (table 1). Of those with aortic recoarctation, the initial type of surgical repair was subclavian flap aortoplasty

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Table 1 Patient details

Patient	Age (years)	Weight (kg)	Diagnosis	Previous surgery	Previous catheter intervention	Upper limb BP	Drug treatment
1	14	60	COA	SCFlap, Dacron patch, conduit	BD × 1	160/50	Capropril/nifedipine/ atenolol
2	29	67	COA, AS	SCFlap, E/E, AVR	BD × 1	160/90	Nifedipine/Aldactide
3	35	92	COA	E/E	None	160/100	None
4	6	20	COA, AS	None	None	138/88	None
5	8	22	COA	SCFlap	BD × 2	115/66	Atenolol
6	16	75	COA	Dacron patch	None	146/69	None
7	24	57	COA	Dacron patch	BD × 1	145/80	None
8	10	17	COA, Supra AS	None	None	158/80	None
9	43	58	COA, AS	None	None	140/70	None
10	45	74	COA, AS	None	None	155/85	None
11	45	83	COA	None	None	180/110	None
12	26	64	COA	None	None	156/74	None
13	8	28	COA	E/E	BD × 1	120/70	Propranolol
14	18	62	COA, TOF	Conduit	None	160/80	Enalapril/nifedipine/ acebutolol
15	16	67	COA	SCFlap	BD × 1	155/100	Enalapril/nifedipine
16	4	19	COA	E/E	BD × 1	150/90	Nifedipine
17	13	45	COA	SCFlap	BD × 1	190/105	Amlodipine/perindopril

AS, aortic stenosis, AVR, aortic valve replacement; BD, balloon dilatation; BP, blood pressure; COA, coarctation of the aorta; E/E, resection and end to end anastomosis; SCFlap, subclavian flap aortoplasty; Supra AS, supraaortic stenosis; TOF, tetralogy of Fallot.

in five, onlay Dacron patch repair in two, resection of coarctation with end to end anastomosis in three, and insertion of a 12 mm conduit bypass graft in one. Of those initially repaired by subclavian flap aortoplasty, one had also undergone balloon dilatation of recoarctation followed by Dacron patch repair and subsequently implantation of a conduit from the left common carotid artery to the descending aorta. This patient has been described in an earlier case report.²⁰ One patient had two previous balloon dilatations; two had one previous balloon dilatation, and one had resection of recoarctation with end to end anastomosis followed by balloon dilatation. Two of the three patients who initially had repair by resection of coarctation with end to end anastomosis and one of the two patients who previously had repair by Dacron patch also underwent unsuccessful balloon dilatation. Therefore 23 previous procedures in all had been performed in these 11 patients to treat coarctation.

Four patients also had additional aortic valve stenosis, one of whom had previous mechanical aortic valve replacement and two had undergone aortic valve replacement using pulmonary autografts after having had the coarctation treated with stent implantation. One patient had moderate aortic stenosis, which had not required treatment at the time of writing. One patient had Williams syndrome and mild supraaortic stenosis. One patient had previous repair of tetralogy of Fallot and a double aortic arch. This patient was later noted to have a long segment coarctation which had been treated by the insertion of a 12 mm conduit bypass graft.

INDICATIONS FOR INTERVENTION

All patients had reduced femoral pulses and Doppler echocardiographic evidence of coarctation of the aorta. Fourteen patients had evidence of resting upper limb systolic hypertension (systolic blood pressure > 95th centile for age) and six of these also had significantly raised diastolic pressures (> 95th centile for age). The remaining three were normotensive, but one had evidence of significant aortic stenosis requiring treatment and the remaining

two were on antihypertensive drugs. The blood pressures had been measured supine during outpatient clinic visits using standard mercury sphygmomanometers. Eight patients were receiving antihypertensive treatment with either a single drug (3) or a combination of drugs (5) before intervention.

STENT IMPLANTATION TECHNIQUE

Written informed consent was obtained from the patients—or in the case of children, from their parents—for the procedures, all of which were performed under general anaesthesia. Percutaneous entry was made into the femoral artery for angiography, and for the measurements of the ascending and descending aortic pressures and pullback gradients across the coarctation site. For stent delivery, percutaneous puncture was made into the contralateral femoral artery in 13 of the patients and a cut-down was performed onto the right common carotid artery in the remaining four. In these four youngest patients, a carotid artery approach was chosen in view of the diameter of the long introducing sheath required for the stent deployment. Following the measurement of a pullback pressure gradient, an arch aortogram was performed (fig 1A) and the diameters of the transverse arch, minimum diameter of the coarctation site, and the diameter of the descending aorta at the level of the diaphragm, together with the length of the narrowed segment, were measured using electronic calipers. The measured catheter diameter or the 1 cm divisions on a “marker” catheter (USCI Inc, Billerica, Massachusetts, USA) were used to correct for magnification. The angiographic catheter was left across the coarctation site for check angiography to aid positioning of the stent and was withdrawn just before deployment of the stent.

Palmaz “iliac stents” (7 × 308, 9 × 4014, 2 × 5014; Johnson and Johnson, Warren, New Jersey, USA) were manually crimped onto a variety of balloons (12 Olbert: Boston Scientific, Watertown, Massachusetts, USA; four Cristal: E Merck Inc, Montmorency, France; one Blue-max: Boston Scientific; and one Powerflex: Cordis Europa, Roden, Netherlands).

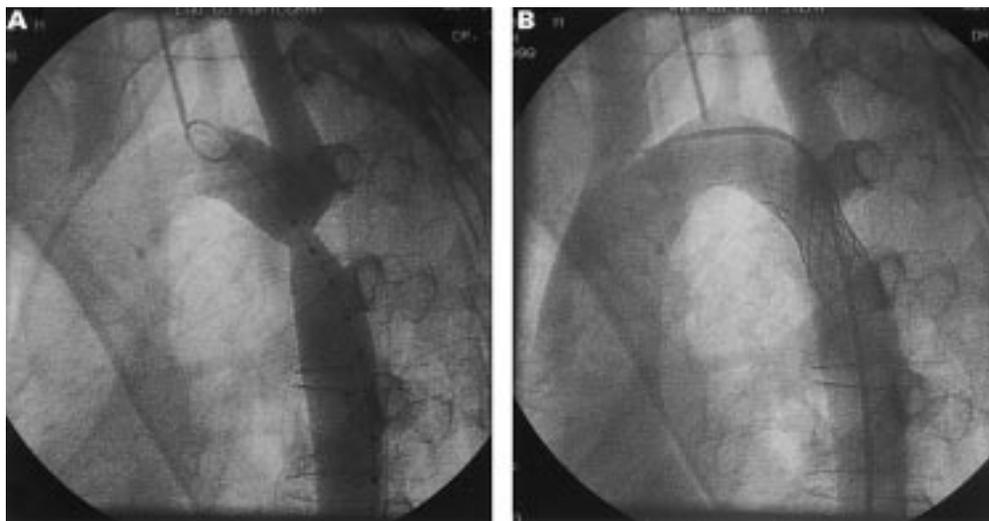


Figure 1 (A) Long axis aortogram using a “marker” pigtail catheter showing discrete native coarctation in a patient who also had severe aortic valve stenosis. (B) Repeat aortogram following expansion of a Palmaz 4014 stent using an 18 mm “Cristal” balloon. The stent is partially covering the origin of the left subclavian artery.

After dilating the site of arterial access, an 11 F Mullins long transeptal sheath (Cook Europe, Bjaeverskov, Denmark) was advanced over an Amplatz SuperStiff guidewire (Meditech, Watertown, Massachusetts, USA) through the femoral or common carotid artery across the coarctation site. Depending on the diameter of the balloon on which the stent was to be mounted, it was occasionally possible to use a smaller sheath, for example 9 F. The stent/balloon assembly was then advanced through the sheath to the desired site. After a final check angiogram, both the angiographic catheter and the sheath were withdrawn to uncover the stent, and the balloon was inflated using an Indeflator. In the first three patients stents were fully expanded to the diameter of the normal vessel on either side of the coarctation, but in subsequent patients care was taken not to fully expand the balloon, or else an undersized balloon was chosen intentionally in order to reduce the likelihood of aortic wall damage. After the stent was deployed, simultaneous pressure measurements were made using the angiographic catheter and the delivery sheath, and a further aortogram was performed

(fig 1B). At the conclusion of the procedure, the carotid artery cutdown sites were repaired and haemostasis obtained.

Antibiotics were given one hour before stent implantation and continued for 48 hours afterwards. A heparin bolus of 50–100 units/kg was injected intravenously following establishment of arterial access and continued as an infusion of 15–30 units/kg/hour for 48 hours after the end of the procedure, to maintain an activated clotting time of 200 seconds. All the patients received an antiplatelet dose of aspirin (3–5 mg/kg/day) beginning on the day after the procedure and continuing for six months. In addition, four patients were fully anticoagulated with warfarin, including the patient with a mechanical aortic valve, and three patients at the start of the series.

FOLLOW UP INVESTIGATIONS

All except one patient underwent evaluation with spiral computed tomography between two days and 46 months after stent implantation (median interval 7.5 months). The early scans were performed in the two patients proceeding to aortic valve replacement. Helical

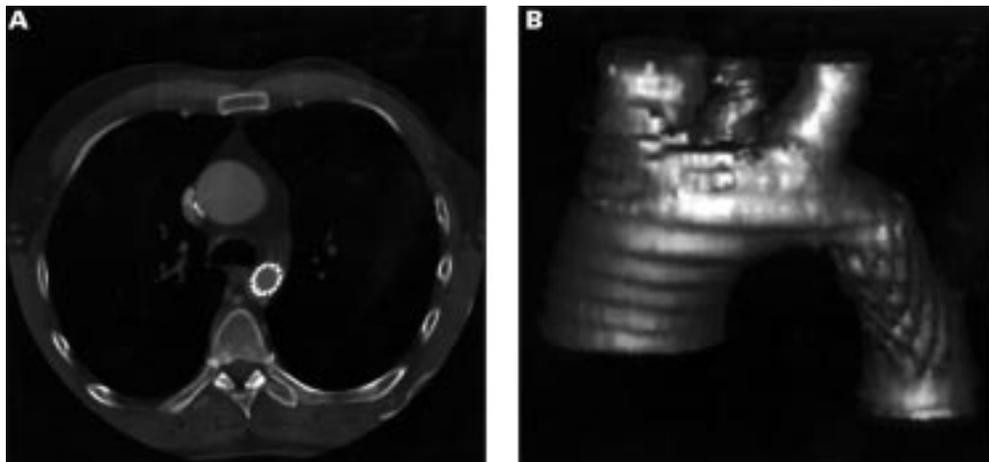


Figure 2 (A) Follow up spiral computed tomography (CT) with contrast showing stented aorta in cross section. (B) Axial three dimensional reconstruction of CT images in the same patient showing no evidence of aneurysm formation.

Table 2 Aortic measurements and results of stent implantation

Patient	Minimum diameter (mm)	Arch diameter (mm)	Aorta at diaphragm (mm)	Stent minimum diameter (mm)	Ratio stent to arch diameter	Ratio stent to aorta diameter at diaphragm	Systolic gradient pre-stent (mm Hg)	Systolic gradient post-stent (mm Hg)	Stent redilate
1	6.4	11.3	12.0	11.9	1.05	0.99	40	0	Yes
2	10.1	20.0	22.0	12.8	0.64	0.58	12	0	
3	9.1	19.1	21.5	14.0	0.73	0.65	17	10	
4	7.4	16.0	14.4	13.6	0.85	0.94	13	0	
5	5.1	11.3	10.4	7.4	0.65	0.71	34	20	Yes
6	8.8	18.5	13.9	11.0	0.61	0.78	20	10	Yes
7	8.3	11.0	13.0	10.5	0.95	0.81	13	5	
8	5.3	11.4	8.8	7.0	0.60	0.80	20	0	Yes
9	7.0	18.4	16.2	13.2	0.72	0.81	20	0	
10	10.3	30.0	22.0	16.0	0.53	0.73	25	2	
11	7.9	22.4	16.2	13.3	0.59	0.82	31	0	
12	4.5	16.5	14.2	12.0	0.73	0.85	23	0	
13	4.3	10.0	10.0	7.4	0.74	0.74	30	2	Yes
14	2.0	16.0	12.0	10.0	0.63	0.83	55	10	Yes*
15	9.0	14.0	25.0	13.0	0.93	0.52	25	10	
16	5.0	11.0	12.0	7.0	0.64	0.58	30	8	
17	7.0	11.0	17.0	12.0	1.09	0.71	31	15	

*Second stant implanted.

CT acquisition was performed during single breath holding with a 3 mm slice thickness and a pitch of 1.66 (fig 2A). Axial images were reconstructed at 2 mm increments and used to generate high quality multiplanar reformatted three dimensional images (fig 2B). During acquisition, 150 ml of intravenous non-ionic contrast medium (Ultravist 240 mg/ml) was administered at a rate of 3 ml/s.

Seven patients underwent repeat cardiac catheterisation. The indications for second catheterisation were clinical evidence of recoarctation in one patient, continued hypertension in four, and the presence of an aneurysm on computed tomography in one. The remaining patient, a 10 year old boy, underwent a second elective catheterisation a year after the initial stent procedure to dilate the stent further.

STATISTICS

Results are given as medians with ranges or as means with 95% confidence intervals (CI). Comparisons were made using the paired Student *t* test. A *p* value of < 0.05 was considered significant.

Results

IMMEDIATE RESULTS

Eighteen stents were implanted during 18 procedures in 17 patients (table 2). The mean peak systolic pressure gradient fell from 26 mm Hg (95% CI, 21 to 31 mm Hg, range 12 to 55 mm Hg) before to 5 mm Hg (95% CI, 2 to 8 mm Hg, range 0 to 20 mm Hg) after stent implantation (*p* < 0.001), and the mean minimum aortic diameter increased from 7 mm (95% CI, 6 to 8 mm, range 2 to 10 mm) before to 11.3 mm (95% CI, 10 to 12.6 mm, range 7 to 16 mm) after stent implantation (*p* < 0.001). The mean ratio of the expanded stent diameter to the transverse aortic arch diameter was 0.75 (95% CI, 0.67 to 0.83) and the mean ratio of the expanded stent diameter to the descending aorta diameter was 0.76 (95% CI, 0.7 to 0.82). The peak systolic gradients were > 20 mm Hg under general anaesthesia in 13 patients (76%) before stent implantation, and between 10 and 20 mm Hg

in the remainder. The median fluoroscopy time for the procedure was 17.5 minutes (range 12.4 to 39 minutes).

COMPLICATIONS

Procedure related complications occurred in five patients. The early complications included a groin haematoma in one, haemorrhage from the carotid arteriotomy site requiring further surgical repair in one, and stent migration during deployment in two. There were no other vascular complications at the site of arterial access. Late complication of a small aneurysm related to the stent occurred in one patient.

Stent migration during implantation occurred in two patients with recoarctation of the aorta after previous subclavian flap repair. In both, the narrowest segment of the aorta was just distal to the origin of the left common carotid artery beyond which the aorta widened at the site of subclavian flap repair site to 18 mm diameter in the first patient and to 35 mm diameter in the second. Palmaz P308 stents were used in both patients. In the first patient the stent slipped during expansion using a 12 mm balloon and embolised to the abdominal aorta where it was expanded further to 16 mm diameter. A further P308 stent was then placed across the coarctation site, expanded using a 14 mm balloon and the proximal and distal ends further expanded using a 16 mm balloon. In the second patient, the stent slipped back over the balloon just after expansion. The balloon was reinflated to 14 mm inside the stent, the assembly was readvanced across the coarctation site, and the balloon expanded further to 16 mm (equivalent to the diameter of the transverse arch), after which the stent remained in position.

Formation of a small aneurysm was detected at angiography six months later in one patient (No 14). This patient had a long segment coarctation of 2 mm diameter previously treated by a conduit bypass graft and had a systolic pressure gradient of 55 mm Hg. A P4014 Palmaz stent was expanded to 12 mm with a good immediate angiographic result. Late angiography performed because of a residual systolic pressure gradient of 30 mm



Figure 3 Three dimensional reconstruction of spiral computed tomographic images with contrast taken nine months after stent implantation in the patient shown in fig 1. The stent has been outlined in a different shade of grey from the aorta. Note continued patency of the left subclavian artery.

Hg, showed an aneurysm at the midpoint of the stent. At that time a further P5014 stent was implanted overlapping the initial stent in an attempt to prevent extension of the aneurysm. Serial computed tomography over the next two years has shown no increase in the size of the aneurysm.

FOLLOW UP RESULTS

Spiral computed tomography

Computed tomography was performed at least once during follow up in 16 patients after the initial procedure and apart from the one patient mentioned above, none had aneurysm formation. All the scans showed continued patency of the stent and of any head and neck vessels with origins partly covered by the stent (fig 3).

Recatheterisation and stent redilatation

Recatheterisation was performed in seven patients after a median interval of 11.3 months (range 6 to 35 months) from the initial procedure. In five patients, further balloon dilatation was performed with reduction of residual peak systolic pressure gradients from a mean of 15 mm Hg to a mean of 2 mm Hg, and three of these patients have since undergone spiral computed tomography with no evidence of aneurysm formation. In one patient a gradient of only 6 mm Hg was found at recatheterisation and reintervention was not performed. The remaining patient, who had the aneurysm, has had two recatheterisations, at 9 months and 17 months after the second stent implantation. On each occasion, the peak systolic gradient across the stented area was 35 mm Hg; however, as the aneurysm was still present, albeit small, no further intervention was performed.

Blood pressure

No patients had acute hypertensive crises immediately after stent implantation. At the most recent follow up, eight patients were normotensive and were not receiving any treatment (including two patients who had previ-

ously been treated with antihypertensive drugs). One untreated patient had borderline systolic hypertension (152/62 mm Hg). Eight patients were still on antihypertensive treatment, which consisted of one drug in five patients and a combination of drugs in three. One of these patients still had borderline systolic and diastolic hypertension (150/95 mm Hg).

Discussion

The choice of treatment of aortic coarctation and recoarctation is between balloon dilatation or surgery using several different techniques. Each type of treatment is associated with a variety of complications. While balloon dilatation may produce good results in around 60–75% of the patients,^{1–8} it is associated with a low but important incidence of aneurysm formation. On theoretical grounds, therefore, it was felt that stent implantation would avoid aneurysm formation. In our series, stent implantation has been shown to be effective in acutely reducing the pressure gradient, but it was still associated with aneurysm formation, albeit with a low incidence. In hypertensive patients, the upper limb blood pressures are brought under control more easily, although continued antihypertensive treatment is often required. Follow up computed tomography showed continued patency of the stents, and no new aneurysm formation was noted even after redilatation of the stents. In the rare clinical situation of aortic coarctation combined with aortic stenosis, treatment of the coarctation with stents may have an important role. In this, stent implantation avoids the operative hazards of treating both conditions surgically²¹ and makes subsequent aortic valve surgery more straightforward. We encountered a low incidence of complications at the level of vascular access. Patients who underwent a surgical approach from the carotid artery should have ultrasound angiography follow up of the cutdown site at a later date.

We did not attempt to compare the results obtained with stent implantation with either surgery or balloon angioplasty techniques, in particular in the patients with aortic recoarctation. However, many of these patients had already undergone unsuccessful previous surgical or balloon angioplasty procedures. Surgery in this situation may be technically more difficult, may often involve the use of patches or conduits, and runs a potential risk of causing compromise to the spinal blood supply. Surgical repair using synthetic patches is fraught with serious complications such as a high incidence of aneurysm formation and late death from aneurysm rupture.²² While balloon dilatation may be considered to be better than surgery, there is high proportion of cases (25%) with a suboptimal outcome as defined by a residual gradient or major complications.¹ In that large series of 907 patients, these complications included death (0.7%), transmural aortic tear (0.7%), and stroke (0.6%).

The mechanism of successful balloon dilatation of coarctation involves tearing of the aortic intima and media. In vitro histological

studies^{23 24} and in vivo studies by intravascular ultrasound^{25 26} have confirmed this mechanism. However, it is impossible to control the extent of tearing, which may extend transmurally. In addition, no safe upper limit has been defined for the required balloon diameter in relation to any aortic diameter measurement. Thus there will inevitably be a risk of aneurysm formation with balloon dilatation. In contrast, during stent implantation it is not necessary to overdilate the coarcted segment to produce a good and predictable result. In addition the stent can buttress the aortic wall, thus preserving its integrity and preventing the extension of any tears that may be produced. However, in spite of this, aneurysm formation was encountered in one patient who had an unusual long segment coarctation. It is possible that in this patient it resulted from overdilatation of the narrow segment from 2 mm to 12 mm. In another study of stent implantations for aortic coarctation/recoarctation,¹⁹ the incidence of aneurysms was 13%. Following this complication in our series, we have modified our policy to adopt an approach of performing a staged dilatation. Thus the balloon is either not fully inflated to the diameter of adjacent measured normal vessel at the time of the stent implantation, or a smaller sized balloon is chosen. If necessary a further dilatation is performed after six to 12 months in order to achieve complete expansion of the stent. In five of 17 patients in our study, redilatation of the stents was successfully achieved without any complications. If and when a significant aneurysm develops, a covered stent could be implanted. We are aware of covered stents having been used in adult patients with abdominal aortic aneurysms²⁷ and thoracic aortic transection.

Redilatation of stents in animal models of coarctation has produced conflicting results. Morrow *et al* re-expanded stents in five animals and noted compression of the media beneath the struts but no evidence of dissection of the intima or media.²⁸ However, Mendelsohn *et al* encountered aortic rupture and death in two of seven animals at redilatation.²⁹ To our knowledge, aortic rupture has not occurred during redilatation of the aortic stents in humans. Improvements in stent design including rounding of sharp edges or even the use of absorbable materials might further lower the risk of such transmural damage during both dilatation and redilatation. The avoidance of predilatation with a balloon just before stent implantation may also reduce the risk of aortic damage.

Successful balloon dilatation of both native³⁰ and recurrent coarctation³¹ of the aorta can bring upper limb hypertension under control in the medium term, even in adult patients. In our series, the patients were often hypertensive before stent implantation in spite of combinations of antihypertensive drugs. In the medium term, blood pressure has either normalised or has been easier to control with a more simplified drug regime. There is a theoretical concern that aortic stents may cause increased aortic wall impedance³² and therefore systolic hypertension during exercise, but such a mechanism may

occur in the post surgical aorta owing to scar formation or patch aortoplasty.

One further theoretical concern might be the compromise of blood flow to small side branches arising from the aorta, particularly those supplying the spinal cord. Continued patency of side branches in the coronary circulation has been demonstrated after stent implantation³³ and there have been no reports of spinal cord damage after aortic stent implantation thus far.

CONCLUSIONS

Stent implantation for aortic recoarctation and native coarctation is successful in older children and adult patients and the acute results are encouraging. Upper limb blood pressure can be brought under improved control although some patients continue to require antihypertensive treatment. Short term follow up shows continued relief of stenosis with a low incidence of complications but longer follow up is necessary.

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