INTERVENTIONAL CARDIOLOGY AND SURGERY

The adult patient with native coarctation of the aorta: balloon angioplasty or primary stenting?

C Zabal, F Attie, M Rosas, A Buendía-Hernández, J A García-Montes

Heart 2003;**89**:77–83

See end of article for authors' affiliations

Correspondence to: Dr Zabal, Departments of Adult Congenital Heart Disease and Paediatric Cardiology, Instituto Nacional de Cardiología "Ignacio Chávez", Juan Badiano No 1, Secc XVI, 14080 Mexico DF, Mexico; zabal@cardiologia.org.mx

Accepted 14 August 2002

Objective: To compare results of dilatation of native coarctation of the aorta with and without stent implantation.
Design: Open, observational, non-randomised study.
Patients: 54 consecutive adult patients: 32 with balloon angioplasty alone (group 1) and 22 with stent placement (group 2).
Interventions: Balloon dilatation from 1995 to 1997; dilatation with Palmaz stent placement from 1997 to 1999.
Main outcome measures: The primary end point was a composite index of failure including heart related death, a residual gradient of > 20 mm Hg, the need of reintervention, and aneurysm formation.
Results: Peak systolic gradient (mean (SD)) was reduced both in group 1 (from 63.3 (22.8) to 10.7 (10.8) mm Hg, $p < 0.001$) and group 2 (from 63.9 (20.8) to 2.7 (4.3) mm Hg, $p < 0.001$), but Δ change was significantly greater in group 2. A residual gradient of > 10 mm Hg was shown to be the best cut off point to separate risk groups, representing a hazard ratio (HR) of 9.59 compared with a residual gradient of ⩽ 10 mm Hg (95% confidence interval (CI) 1.92 to 47.8). From multivariate Cox regression analysis, the only risk marker was the residual gradient (HR 8.9, 95% CI 1.2 to 63.0). The type of the coarctation and the use of stent were the factors associated with a residual gradient of ⩽ 10 mm Hg.
Conclusions: Mid term outcome in adult patients with native aortic coarctation receiving percutaneous treatment is strongly related to the immediate residual gradient. When treating these cases, efforts should be made to obtain gradients under 10 mm Hg, either by angioplasty alone or by placing a stent. Patients with discrete aortic coarctation have similar mid term results when the immediate residual gradient is ⩽ 10 mm Hg despite the implantation of a stent. To achieve these gradients, patients with hypoplastic isthmus or tubular coarctation should be treated with primary stenting. Further studies including exercise tests and non-invasive imaging are still needed before definitive conclusions can be drawn.

Primary balloon angioplasty with or without stent implantation is now a widely accepted therapeutic procedure for recurrent aortic coarctation,[1–3] and is proposed by some for native coarctations.[4 5] However, it has recently been suggested that stenting provides better treatment because it may reduce the complication rate and improve the mid term and long term outcome.[6–13] Balloon angioplasty as a primary treatment in adults has not been generally accepted because of the perception that the risk of complications is greater than in childhood. The role of primary stenting also remains controversial, and more information and clinical experience is required.[14–24]

In this open, observational, non-randomised study, we evaluated 54 consecutive adult patients who underwent balloon angioplasty for coarctation, comparing the results between balloon angioplasty alone and primary stent placement. Clinical, anatomical, and haemodynamic data were further analysed for their relevance to early and mid term outcome.

METHODS

Patients

From 1995 to 1999, consecutive adult patients presenting with isolated native coarctation of the aorta were offered balloon angioplasty alone (group 1, 1995 to 1997) or primary stenting (group 2, 1997 to 1999) as an alternative to surgery. For the purposes of this study the inclusion criteria were: clinical evidence of coarctation of the aorta with a systolic pressure gradient of at least 20 mm Hg between the upper and lower limbs, and age at diagnosis ⩾ 18 years. Diagnosis was supported by transthoracic echocardiography or magnetic resonance imaging, and finally confirmed during the interventional procedure. Patients with severe comorbid disease, complex associated cardiac malformations, critical rheumatic valve disease, evidence of coronary artery disease at entry, or a contraindication to femoral intervention were excluded.

Catheterisation technique

We used techniques similar to those described previously by others.[3 6 10 20] Heparin 3000 IU was given intravenously as soon as the arterial introducer was in place.

When we began doing this procedure we incorporated several recommendations for reducing the risk of early complications. Thus the initial balloon size was selected on the basis of the smallest diameter between the transverse aortic arch and the aorta at the level of the diaphragm. Inflation was continued until the indentation caused by the coarctation was eliminated or until a pressure of 5 atm had been reached. Although a second dilatation with increasing balloon pressure has been recommended to eliminate the balloon waist, the procedure we followed if the residual peak systolic pressure gradient still

Abbreviations: B/CoA, balloon/coarctation diameter ratio; B/Sub, balloon/subclavian diameter ratio; Car/Sub, carotid/subclavian diameter ratio; HR, hazard ratio.

Table 1 Demographic and preprocedural data

Variable	Whole group (n=54)	Stent		p Value
		No (n=32)	Yes (n=22)	
Age (years)	24.2 (9.1)	23.3 (9.9	25.9 (7.9)	0.264
Male/female (% male)	34/20 (63)	20/12 (62.5)	14/8 (63.6)	0.932
Systolic BP (mm Hg)	154.7 (18.7)	153.2 (18.3)	158 (19)	0.292
Diastolic BP (mm Hg)	87.5 (14.0)	85.9 (14.9)	89.2 (12.9)	0.458
Antihypertensive drugs (%)				0.166
0 (%)	17 (31.5)	13 (40.6)	4 (18.2)	
1 (%)	20 (37)	12 (37.5)	8 (36.4)	
2 (%)	13 (24.1)	6 (18.7)	7 (31.8)	
3 (%)	4 (7.4)	1 (3.1)	3 (13.6)	
Juxtaductal/postductal (% postductal)	23/31 (57.4)	16/16 (50)	7/15 (68.2)	0.181
Coarctation anatomy				0.528
Diaphragmatic (%)	41 (75.9)	25 (78.1)	16 (72.7)	
Isthmic hypoplasia (%)	9 (16.7)	4 (12.5)	5 (22.7)	
Tubular (%)	4 (7.4)	3 (9.4)	1 (4.5)	

Values are mean (SD) or n (%).
BP, blood pressure.

exceeded 20 mm Hg was to insert the next larger balloon size—without exceeding the diameter of the aorta at the level of the diaphragm—and to repeat the procedure. If the residual gradient nonetheless remained ⩾ 20 mm Hg, another inflation was not performed and, before 1997, the procedure was terminated. After 1997 stent placement was considered.

Special precautions were taken to avoid manipulating the tip of the catheter or guidewire over the recently dilated area. A complete haemodynamic profile was acquired, including gradients and angiographic measurements of the coarctation site and of the proximal and descending aorta.

For cases undergoing primary stenting, the maximum balloon diameter was 20 mm. A Palmaz stent (P308 or P4014, Johnson and Johnson Interventional Systems Co, Warren, New Jersey, USA) was mounted on a 14, 15, 16, 18, or 20 mm diameter, 3 cm long, balloon catheter (Z-Med or Z-Med II, NuMED Canada Inc, Ontario, Canada; Maxi LD, Cordis Co, Miami, Florida, USA). To prevent displacement during inflation, an Amplatz superstiff guide wire (Meditech, Watertown, Massachusetts, USA) was anchored in the subclavian artery (either the left or the right according to the angle of the aorta) and the balloon was inflated as quickly as possible. Most patients required only one or two balloon inflations for stent deployment. After the procedure was finished, patients stayed overnight and were discharged the next day on aspirin 100 mg daily for three months, and given antihypertensive drug treatment when necessary.

Data collection

Data were collected by two different research workers and compared. Another research worker undertook a third review if any discrepancies were detected. Before the intervention a complete haemodynamic profile was recorded, including the diameters of the transverse aortic arch, the isthmus, the coarctation, and the descending aorta on the lateral view.

Anatomical types

Because previous studies have suggested a different outcome according to the anatomical characteristics of the coarctation, we analysed independently three anatomical types of coarctation: discrete, isthmic hypoplasia (defined as a diameter ⩽ 75% of the transverse aorta), and tubular or diffuse stenosis (defined as a coarctation length of > 10 mm).

Success and primary end point

Early success was defined as a residual gradient of ⩽ 20 mm Hg, precluding the need for early reintervention (that is, after less than one year). The primary end point of this study was a composite index of failure of the procedure, including heart related death, recoarctation, aneurysm formation, an echocardiographic gradient of > 20 mm Hg, the need of reintervention, and clinical hypertension despite medical treatment.

Follow up

Patients were followed as clinically indicated. The gradient between the systolic pressure in upper and lower limbs was always measured at each follow up visit. Chest *x* ray and echocardiography were done at three, six, and 12 months in the first year after the procedure and then annually. If recoarctation (clinical or Doppler gradient of > 20 mm Hg) or aneurysm formation (discrete bulging of the aorta at the dilatation site to > 150% of the diameter of the descending aorta at the level of the diaphragm) was suspected, magnetic resonance imaging or a new angiographic study was undertaken. This approach has previously been classified as "reasonable", with 100% sensitivity for detecting both recoarctation and aneurysm, and 93% sensitivity for detecting aneurysm alone.[25] Antihypertensive drug treatment was discontinued when possible. Exercise testing was not done routinely in this group of patients, so exercise data were not included in the analysis.

Statistical analysis

Quantitative data are expressed as mean (SD). A paired *t* test or Wilcoxon test was used as indicated to compare two mean values. Factors associated with acute procedural outcomes were sought with *t* tests and Kruskal–Wallis analysis of variance. Outcomes during follow up were described and estimates of event-free probability were plotted as Kaplan–Meier curves. The association of patient characteristics, early and late results, use of stent, and anatomical types of coarctation were each tested in a univariate Cox proportional hazard regression model. A probability value of $p < 0.05$ was set as the level of significance.

RESULTS

Immediate results

Fifty four patients with native isolated aortic coarctation were included in the study; 41 were discrete, four were tubular, and nine were of isthmic hypoplasia type.

A stent was implanted in 22 patients (40.7%)—five with isthmic hypoplasia, one with tubular coarctation, and remainder with a discrete coarctation of the aorta—either as a primary approach or because the residual gradient after balloon angioplasty was greater than 20 mm Hg.

Table 2 Procedural and follow up data

Variable	Whole group (n=54)	Stent		p Value
		No (n=32)	Yes (n=22)	
Car/Sub ratio	0.904 (0.134)	0.934 (0.120)	0.897 (0.120)	0.263
B/Sub ratio	1.17 (0.26)	1.11 (0.19)	1.20 (0.17)	0.52
B/CoA ratio	4.53 (1.54)	4.50 (1.70)	4.40 (1.20)	0.671
Number of dilatations	2.1 (0.8)	2.1 (0.8)	2.0 (0.9)	0.412
Predilatation gradient (mm Hg)	63.1 (21.8)	63.3 (22.8)	63.9 (20.8)	0.839
Postdilatation gradient (mm Hg)	7.9 (10.1)	10.7 (10.8)	2.7 (4.3)	**0.001**
Gradient reduction (%)	87.3 (15.8)	83.2 (13.5)	96.1 (6.4)	**<0.001**
Diameter increment of coarctation (%)	359.8 (111.4)	329.1 (98.8)	410.9 (112.5)	**0.004**
Success (%)	51 (94.4)	29 (90.6)	22 (100)	0.071
Days in hospital	1.96 (2.32)	2.26 (2.50)	1.18 (0.85)	**0.039**
Follow up (months)	43.1 (27.5)	59.6 (24.2)	21.6 (10.4)	**<0.001**
Systolic BP (mm Hg)	124.8 (15.3)	127.7 (17.0)	120.7 (11.6)	0.1
Diastolic BP (mm Hg)	76.0 (12.1)	76.2 (14.1)	75.2 (7.6)	0.764
Echo gradient (mm Hg)	10.1 (10.1)	14.1 (10.9)	4.4 (5.0)	**<0.001**
Antihypertensive drugs				0.475
0 (%)	22 (40.7)	15 (46.9)	7 (31.8)	
1 (%)	29 (53.7)	15 (46.9)	14 (63.6)	
2 (%)	3 (5.6)	2 (6.2)	1 (4.5)	
Patients with event (%)	8 (14.8)	7 (21.9)	1 (4.5)	0.063
Unsuccessful dilatation (%)	3 (5.6)	3 (9.4)	0	
Recoarctation (%)	3 (5.6)	3 (9.4)	0	
Aneurysm (%)	2 (3.7)	2 (6.2)	0	
Echo gradient >20 mm Hg (%)	5 (9.3)	5 (15.6)	0	
Hypertension (%)	3 (5.6)	3 (9.4)	1 (4.5)	

Values are mean (SD) or n (%). B/CoA, ratio between diameters of the balloon and the aorta at the level of the coarctation; BP, blood pressure; B/Sub, ratio between diameters of the balloon and the aorta at the level of the left subclavian artery; Car/Sub, ratio between diameters of the balloon and the aorta at the level of the left carotid and left subclavian arteries.

Table 1 gives demographic data and comparisons between the study groups. Age and sex distribution and the anatomy of the coarctations were similar in the two groups. Antihypertensive treatment was given in 69% of the study population, and 42% took at least two drugs.

The mean time of follow up was longer in patients receiving angioplasty alone than in those with stent implantation (table 2). Although the carotid/subclavian (Car/Sub) diameter ratio, balloon/subclavian (B/Sub) ratio, and balloon/coarctation (B/CoA) ratio were not significantly different between group 1 and group 2, patients who underwent stent implantation had a smaller residual gradient (2.7 (4.3) mm Hg, $p < 0.001$). A smaller residual gradient was also associated with an increase in the aortic diameter at the coarctation level. The mean peak systolic gradient was reduced from 63.3 (21.8) to 7.3 (10.1) mm Hg in the whole population ($p < 0.001$). Despite significant reductions found in both group 1 (from 63.3 (22.8) to 10.7 (10.8) mm Hg, $p < 0.001$) and group 2 (from 63.9 (20.8) to 2.7 (4.3) mm Hg, $p < 0.001$), the Δ change was significantly greater in group 2 (table 2).

Neither paradoxical hypertension nor post-coarctectomy syndrome was observed after angioplasty. One patient had a local haemorrhage at the puncture site which required blood transfusion. Two patients developed a small aneurysm at the coarctation site after balloon angioplasty: one patient with a tubular coarctation had a residual gradient of 34 mm Hg after balloon angioplasty and was sent for surgery; the other had a discrete coarctation of the aorta with a 14 mm Hg residual gradient and the aneurysm has not increased in size after 61 months of follow up.

Dilatation was unsuccessful in three cases in group 1: two with a tubular coarctation (including the case mentioned above), and also a 61 year old woman with a borderline discrete coarctation (Car/Sub ratio = 76%) and a 55 mm Hg residual gradient that had declined to 37 mm Hg after 36 months of follow up. All cases with stent implantation were considered successful.

Mid term results

Of the 54 patients, eight had an event at 48 months of follow up. All except one of these events developed before 12 months, and they are shown in table 2, broken down by group. The estimated overall event-free survival in the total group was 95% at 12 months, 92% at 24 months, 86% at 36 months, and 75% at 48 months of follow up. Although there appeared to be trend to develop an event in patients over 25 years of age, this was not significant (hazard ratio (HR) 2.27, 95% confidence interval (CI) 0.54 to 9.54, $p = 0.2637$). The anatomical type of coarctation, Car/Sub ratio, B/Sub ratio, and residual gradient after angioplasty were associated with an increased risk of developing the primary end point; the univariate hazard ratios for this are shown in table 3. The tubular type of coarctation was strongly associated with the risk of developing an event, with a hazard ratio of 10.7 (95% confidence interval (CI) 2.38 to 48.7, $p < 0.002$) when compared with the discrete type. The residual gradient was the most important risk marker for developing an event during follow up. A residual gradient of > 10 mm Hg was shown to be the best cut off point for separating risk groups, with a hazard ratio of 9.59 when compared with a residual gradient of $\leqslant 10$ mm Hg (95% CI 1.92 to 47.8). The outcome in patients with discrete coarctation submitted to balloon angioplasty in whom we achieved a residual gradient of $\leqslant 10$ mm Hg ($n = 23$) was not significantly different from cases with discrete anatomy submitted to stent implantation ($n = 16$).

Multivariate analysis

From a multivariate Cox regression model—which included age, stent use, coarctation anatomy, Car/Sub, B/Sub, B/CoA, and residual gradient—the only risk marker to emerge was residual gradient (HR 8.9, 95% CI 1.2 to 63.0) (table 4). Analysis of the variables involved in the residual gradient showed that the anatomical type of coarctation and stent use were the principal factors associated with a residual gradient of $\leqslant 10$ mm Hg after the procedure (table 5).

Table 3 Categorical predictors of outcome from univariate analysis

Variable	Number of patients	Number of events	Cumulative probability of event after time zero (time in months) 6	12	24	36	48	HR*	95% CI	p Value†
Total	54	8	0.06	0.06	0.08	0.14	0.26			
Age (years)										
⩽25	34	4	0.05	0.05	0.05	0.24	0.19	1	(reference)	
>25	20	4	0.06	0.06	0.06	0.06	0.43	2.27	0.54to9.54	0.2637
Stent										
No	32	7	0.06	0.06	0.09	0.16	0.27	2.15	0.24to19.6	0.4970
Yes	22	1	0.05	0.05	0.05	0.05		1	(reference)	
Anatomy										
Discrete	41	4	0.05	0.05	0.08	0.08	0.13	1	(reference)	
Hypoplasia	9	1	0	0	0	0.22	0.22	1.24	0.14to11.11	0.8477
Tubular	4	3	0.25	0.25	0.25	0.63	1	10.77	2.38to48.70	**0.002**
Car/Sub										
⩽0.90	22	5	0.14	0.14	0.14	0.24	0.46	3.57	0.84to15.17	0.0576
>0.90	32	3	0	0	0.03	0.07	0.13	1	(reference)	
B/Sub										
⩽1.3	46	5	0.04	0.04	0.07	0.1	0.14	1	(reference)	
>1.3	8	3	0.11	0.11	0.11	0.45	1	5.38	1.23to23.47	**0.0125**
B/CoA										
⩽4	28	3	0.07	0.07	0.11	0.11	0.11	1	(reference)	
>4	26	5	0.04	0.04	0.04	0.16	0.39	1.89	0.45to7.90	0.3743
Predilatation gradient (mm Hg)										
⩽50	19	3	0.048	0.048	0.11	0.11	0.21	1	(reference)	
>50	35	5	0.06	0.06	0.06	0.15	0.26	0.95	0.22to3.96	0.9399
Postdilatation gradient (mm Hg)										
⩽10	44	2	0.05	0.05	0.05	0.05	0.05	1	(reference)	
>10	10	6	0.08	0.08	0.17	0.35	0.60	9.59	1.92to47.80	**0.0058**

*The Cox hazard ratio with the most favourable category as the reference value.
†Significance for comparison with the most favourable category of subgroup (log-rank statistic).
B/CoA, ratio between diameters of the balloon and the aorta at the level of the coarctation; B/Sub, ratio between diameters of the balloon and the aorta at the level of the left subclavian artery; Car/Sub, ratio between diameters of the balloon and the aorta at the level of the left carotid and left subclavian arteries; CI, confidence interval.

Table 4 Forward Cox logistic regression analysis of selected variables: multivariate analysis for proportional hazard (dependent variable: event)

Variable	β	Wald	df	*R*	HR (95% CI)	p Value
Postdilatation gradient	2.1867	7.1269	1	0.2989	8.9 (1.79 to 44.3)	**0.0076**

Model significance: overall score (1 df) = 10.37, –2 LLR = 48.75, p = 0.0013.
β, regression coefficient; df, degrees of freedom; CI, confidence interval; HR, exponential function of β coefficients using natural log 2.74, numerically equivalent to hazard ratio; –2 LLR, –2 log likelihood ratio of the model; Wald, Wald χ^2 test.

Table 5 Forward Cox logistic regression analysis of selected variables: multivariate analysis for proportional hazard (dependent variable: residual gradient)

Variable	β	Wald	df	*R*	HR (95% CI)	p Value
Anatomy	1.5413	5.2918	1	0.2359	4.67 (1.26 to 17.36)	**0.0214**
Stent	–2.8898	5.6694	1	–0.2491	0.056 (0.005 to 0.599)	**0.0173**

Model significance: overall score (2 df) = 15.61, –2 LLR = 43.53, p = 0.0004.
β, regression coefficient; df, degrees of freedom; CI, confidence interval; HR, exponential function of β coefficients using natural log 2.74, numerically equivalent to hazard ratio; –2 LLR,–2 log likelihood ratio of the model; Wald, Wald χ^2 test.

DISCUSSION

Most untreated patients with coarctation of the aorta will die before 50 years of age.[26] Unfortunately, the diagnosis of coarctation may be missed and the patient may present in later childhood with hypertension. Although the first balloon angioplasty of aortic coarctation was described in 1982,[27] its use was not popularised until the 1990s. The early limitations were related to the technique used and the devices available. The basic mechanism of balloon angioplasty is expansion of the constricted lumen, which produces tears and cracks in the intima and various degrees of splits in the media.[28] After balloon deflation, however, there is a well recognised recoil phenomenon, and intravascular buttressing with metallic stents began to be used to provide support for the vessel wall following the balloon inflation.[29]

Balloon angioplasty for aortic coarctation is an alternative procedure in children, but primary stenting has a major limitation—its failure to adapt to the somatic growth of the vessel, though further re-expansion at a later date has been achieved in some series.[6 7 12]

Aortic coarctation in adult patients represents a medical challenge, and its approach needs to be reviewed. The use of balloon angioplasty with or without stenting in this subgroup of patients remains controversial and there is no consensus

view. Previous studies of balloon angioplasty in adults consistently showed an improvement in the coarctation gradient.[14–23] However, the magnitude of the residual gradient was quite variable. Our results support the few previously published reports suggesting an improvement in the coarctation gradient, and we also compared balloon angioplasty with primary stenting for native aortic coarctation. Because of the theoretical advantages of stenting over simple balloon dilatation—that is, a potentially reduced incidence of recoarctation, a lower probability of developing aneurysms, better results in non-discrete coarctations, and the encouraging cumulative results—we decided in 1997 to offer primary stenting as treatment of first choice in adults with native aortic coarctation.

Early results and residual gradient

Previous studies reported a residual mean gradient ranging from 8 (10) mm Hg to 18 (15) mm Hg, and residual gradients of > 20 mm Hg were found in 7–28% of patients undergoing balloon angioplasty alone.[17 18] Although our results were similar, we observed a significant difference between angioplasty alone and primary stenting (residual gradient 10.7 (10.8) mm Hg *v* 2.7 (4.3) mm Hg, respectively; p = 0.001). These data need to be interpreted with caution, as there was a secular time difference, and the anatomical type of coarctation was a crucial determinant of the residual gradient. Thus in the non-discrete cases who underwent balloon angioplasty alone, a residual gradient of > 20 mm Hg was observed in 57%, but a residual gradient of this degree did not occur in any of the cases submitted to primary stenting. This finding confirms that in patients with unfavourable anatomy, primary stenting provides an immediate result that is superior to that obtained by balloon angioplasty alone.[14 22] Early aneurysm formation was observed in two cases submitted to balloon angioplasty alone. One of these cases was sent for surgery because stent technology was unavailable to us at that time.

Conversely, the results observed in cases with the discrete type of coarctation show that the use of balloon angioplasty alone should not be discounted. In these cases, recoarctation was observed in only three instances of balloon angioplasty (9.3%) versus no case in the primary stenting group. All of these three cases had an immediate residual gradient of > 10 mm Hg.

Hypertension

At follow up, clinical hypertension or the continued use of antihypertensive drugs has been reported in 27–68% of patients.[17 21 24 30 31] In our study, 59% of patients were still taking antihypertensive drugs after the procedure, but the number of drugs was reduced significantly. Twenty two cases (40.7%) had a normal blood pressure without drug treatment. Control of blood pressure was also substantially better; thus, of 17 patients (31.5%) who were taking two or more antihypertensive drugs before angioplasty, only three (5.6%) were still requiring two drugs or more after the procedure. We found that those patients with a systolic arterial pressure of ⩾ 165 mm Hg before dilatation had a higher risk of persisting hypertension after the procedure (HR 2.7, 95% CI 1.2 to 6.7). This has been reported by others.[32]

Aneurysm

Although incidence figures for aneurysm formation at the angioplasty site have been reported in both immediate and long term studies, they have been extremely variable (from 0–55%).[15–23] The true incidence and the factors related to the development of aneurysms have not been established. Damage to the vessel wall caused by angioplasty, overstretching of the aorta by large balloons, technical difficulties (either during the procedure or in defining an aneurysm), and associated aortic cystic medial necrosis have been suggested as significant contributing factors.[15–21 28] Even the natural history of these aneurysms is unknown, but most investigators agree that if they are small they will not increase in size with time. Nevertheless, case series have reported encouraging results with primary stenting compared with angioplasty alone.[6–13 22 24] It needs to be clarified whether primary stenting can indeed reduce the incidence of aneurysm formation. Our incidence of immediate aneurysm formation was low (3.7%), with no intermediate or late aneurysms, and aneurysms only presented in cases treated with angioplasty alone (our definition of an aneurysm has been reported previously[4]). We believe this low incidence could have been the result of various technical factors such as limiting balloon size to ensure the aorta was not overstretched, good fixation and rapid inflation of the balloon to decrease its mobility, and avoiding, as far as possible, repeated inflations.

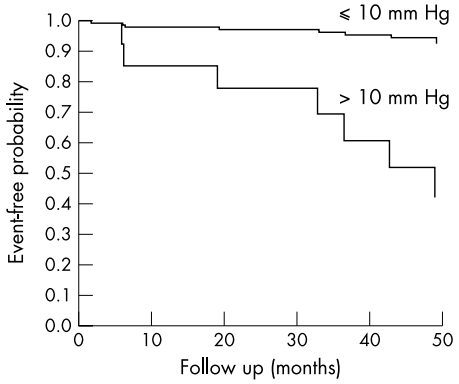


Figure 1 Event-free survival function according to the residual gradient.

A new technical advance is the development of the balloon-in-balloon (BIB) system (Numed Inc), which allows better stabilisation of the balloon, the possibility of repositioning the stent when the first balloon has been inflated, and the almost complete avoidance of stent flaring.[33] Further studies are required to address these approaches.

The anatomical proximity of the coarctation to the left subclavian artery makes stent placement near or up to the ostium unavoidable. In our stented cases with isthmic (n = 5) or tubular hypoplasia (n = 1), we did not need to obstruct any main arterial branch to achieve a residual gradient of < 10 mm Hg. The clinical impact of this is unknown and remains to be determined.

Follow up

Because the use of primary stenting was recommended years after balloon angioplasty alone had been employed, a secular time bias is unavoidable, and the follow up time was greater in the balloon angioplasty group. However, our data suggest (as shown in fig 1) that minimising the residual gradient below 10 mm Hg, irrespective of the anatomical type of coarctation or the use of a stent, can ensure survival without events in more than 95% of patients after up to four years of follow up. When the residual gradient was > 10 mm Hg, there was almost a ninefold increased in risk of developing an event during the follow up period. As shown in fig 2, patients with the tubular type of coarctation had the worst prognosis, as a gradient of under 10 mm Hg was achieved only in one case submitted to stent implantation.

Predictors of the primary end point

The risk of developing the primary end point (a composite index of treatment failure) in our study was, as expected, correlated with the immediate residual gradient (> 10 mm Hg). The factors associated with a smaller residual gradient were the anatomical type (discrete coarctation) and the use of a stent. It is noteworthy that the risk of having an event in

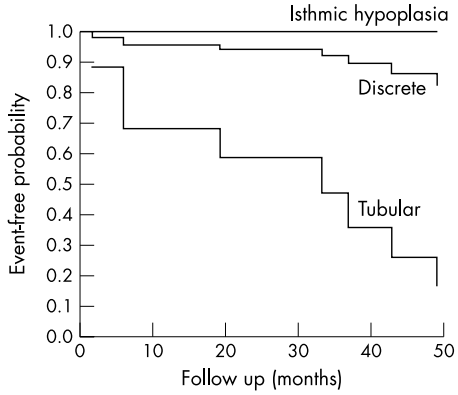


Figure 2 Event-free survival function according to coarctation anatomy.

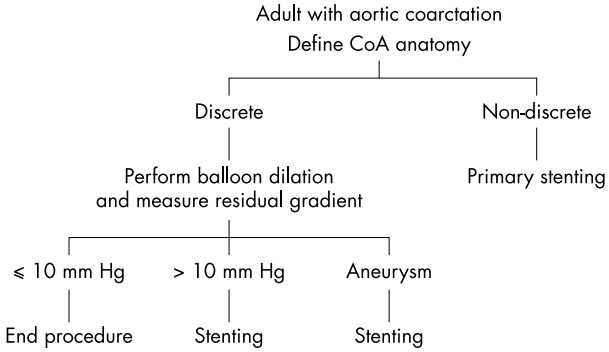


Figure 3 Proposed decision making flow chart.

patients with the discrete form of coarctation was present only if there was a residual gradient of > 10 mm Hg.

Possible implications for decision making

We believe that this study may provide support for decision making in adults with native aortic coarctation. Patients with unfavourable anatomy (tubular coarctation or isthmic hypoplasia) should be treated by primary stenting. Patients with a discrete coarctation and a residual gradient after primary balloon dilatation of > 10 mm Hg should also be stented. Patients with discrete coarctation and a residual gradient after a primary balloon dilatation of ⩽ 10 mm Hg may be left without stenting if there is no evidence of aneurysm formation. Our proposal for a decision making flow chart is shown in fig 3. Patients in whom there is proximity between the coarctation and the left subclavian artery must be viewed with caution and a surgical procedure may be required.

Limitations

Although this is the largest reported group of adult patients managed by stent implantation for coarctation of the aorta, the relatively small number of patients still makes accurate evaluation of risk difficult and infrequent complications less likely to be observed. The follow up time was short in relation to patients' expected life span, thus preventing observation of late complications which may have important future consequences.

There were other two major limitations to the study design. First, we did not compare the study population with a surgical cohort. A randomised comparison with surgical patients would be the optimal assessment but would require multicentre involvement for it to be accomplished within a reasonable time. Second, we did not perform an exercise test evaluation during follow up. Exercise induced hypertension is often observed and has uncertain clinical significance. It would be of interest in the future to compare the effectiveness of stenting with surgical techniques in preventing exercise induced hypertension.

Conclusions

The mid term outcome in adult patients with native aortic coarctation given percutaneous treatment is strongly related to the immediate post-treatment residual gradient. When treating these cases, we should try to obtain gradients of less than 10 mm Hg, either by angioplasty alone or by placing a stent. Patients with discrete aortic coarctation have similar mid term results when the immediate residual gradient is ⩽ 10 mm Hg after balloon dilatation whether or not they also have stent implantation. To achieve these gradients, patients with a hypoplastic isthmus or tubular coarctation should have primary stenting. Further studies, including exercise tests and non-invasive imaging, are still needed before definitive conclusions can be drawn.

Authors' affiliations

C Zabal, F Attie, M Rosas, A Buendía-Hernández, J A García-Montes, Departments of Adult Congenital Heart Disease and Paediatric Cardiology, Instituto Nacional de Cardiología "Ignacio Chávez", Mexico DF, Mexico

REFERENCES

1 **Hijazi ZM**, Geggel RL. Balloon angioplasty for postoperative recurrent coarctation of the aorta. *J Intervent Cardiol* 1995;**8**:509–16.
2 **Yetman AT**, Nykanen D, McCrindle BW, *et al*. Balloon angioplasty of recurrent coarctation: a 12-year review. *J Am Coll Cardiol* 1997;**30**:811–16.
3 **Moore P**, Lock JE. Catheter intervention: balloon angioplasty: experimental studies, technology and methodology. In: Lock JE, Keane JF, Perry SB, eds. *Diagnostic and interventional catheterization in congenital heart disease*, 2nd ed. Boston: Kluwer Academic Publishers, 2000:119–49.
4 **Zabal C**, Attie F, Martinez–Rios MA, *et al*. Balloon angioplasty for native aortic coarctation: short- and intermediate-term results evaluated with angiography and magnetic resonance imaging. *J Cardiovasc Diagn Proc* 1996;**13**:223–32.
5 **Rao PS**. Long-term follow-up results after balloon dilatation of pulmonic stenosis, aortic stenosis, and coarctation of the aorta: a review. *Prog Cardiovasc Dis* 1999;**42**:59–74.
6 **Bulbul ZR**, Bruckheimer E, Love JC, *et al*. Implantation of balloon-expandable stents for coarctation of the aorta: implantation data and short-term results. *Cathet Cardiovasc Diagn* 1996;**39**:36–42.
7 **Ebeid MR**, Prieto LR, Latson LA. Use of balloon-expandable stents for coarctation of the aorta: initial results and intermediate-term follow-up. *J Am Coll Cardiol* 1997;**30**:1847–52.
8 **Ledesma M**, Diaz y Diaz E, Alva Espinosa C, *et al*. Stents in aortic coarctation. Immediate results. *Arch Inst Cardiol Mex* 1997;**67**:399–404.
9 **Magee AG**, Brzezinska-Rajszys G, Qureshi SA, *et al*. Stent implantation for aortic coarctation and recoarctation. *Heart* 1999;**82**:600–6.
10 **Thanopoulos BD**, Hadjinikolaou L, Konstadopoulou GN, *et al*. Stent treatment for coarctation of the aorta: intermediate term follow up and technical considerations. *Heart* 2000;**84**:65–70.
11 **Alcibar J**, Pena N, Onate A, *et al*. Primary stent implantation in aortic coarctation. Mid-term follow-up. *Rev Esp Cardiol* 2000;**52**:797–804.
12 **Marshall AC**, Perry SB, Keane JF, *et al*. Early results and medium-term follow-up of stent implantation for mild residual or recurrent aortic coarctation. *Am Heart J* 2000;**139**:1054–60.
13 **Saliba Z**, Aggoun Y, Iserin L, *et al*. Balloon angioplasty with stent implantation in recoarctation of the aorta: an attractive alternative. *Arch Mal Coeur Vaiss* 2001;**94**:427–32.
14 **Sievert H**, Bussmann WD, Pfrommer W, *et al*. Transluminal angioplasty of aortic isthmus stenosis in juveniles and adults. *Dtsch Med Wochenschr* 1987;**112**:1371–3.
15 **Attia IM**, Lababidi ZA. Early results of balloon angioplasty of native aortic coarctation in young adults. *Am J Cardiol* 1988;**61**:930–1.
16 **Rico J**, Sobrino N, Calvo L, *et al*. Percutaneous transluminal angioplasty in aortic coarctation in young adults. *Rev Esp Cardiol* 1989;**42**:415–17.
17 **Tyagi S**, Arora R, Kaul UA, *et al*. Balloon angioplasty of native coarctation of the aorta in adolescents and young adults. *Am Heart J* 1992;**123**:674–80.
18 **Fawzy ME**, Dunn B, Galal O, *et al*. Balloon coarctation angioplasty in adolescents and adults: early and intermediate results. *Am Heart J* 1992;**124**:167–71.
19 **Phadke K**, Dyet JF, Aber CP, *et al*. Balloon angioplasty of adult aortic coarctation. *Br Heart J* 1993;**69**:36–40.
20 **Diethrich EB**, Heuser RR, Cardenas JR, *et al*. Endovascular techniques in adult aortic coarctation: the use of stents for native and recurrent coarctation repair. *J Endovasc Surg* 1995;**2**:183–8.

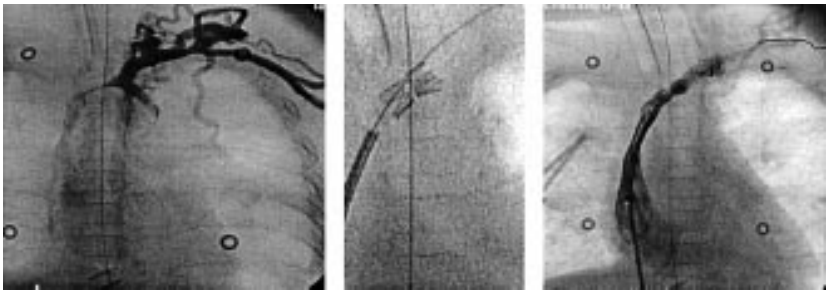
21 **Fawzy ME**, Sivanandam V, Galal O, *et al*. One- to ten-year follow-up results of balloon angioplasty of native coarctation of the aorta in adolescents and adults. *J Am Coll Cardiol* 1997;**30**:1542–6.
22 **Burkhard-Meier C**, Deutsch HJ, Hartmann I, *et al*. The treatment of aortic isthmus stenosis in adults using balloon dilatation and stent implantation. *Dtsch Med Wochenschr* 1998;**123**:361–5.
23 **Koerselman J**, de Vries H, Jaarsma W, *et al*. Balloon angioplasty of coarctation of the aorta: a safe alternative for surgery in adults: immediate and mid-term results. *Cathet Cardiovasc Intervent* 2000;**50**:28–33.
24 **Harrison DA**, McLaughlin PR, Lazzam C, *et al*. Endovascular stents in the management of coarctation of the aorta in the adolescent and adult: one year follow up. *Heart* 2001;**85**:561–6.
25 **Therrien J**, Thorne SA, Wright A, *et al*. Repaired coarctation: A "cost-effective" approach to identify complications in adults. *J Am Coll Cardiol* 2000;**35**:997–1002.
26 **Campbell M**. Natural history of coarctation of aorta. *Br Heart J* 1970;**32**:633–40.
27 **Singer MI**, Rowen M, Dorsey TJ. Transluminal aortic balloon angioplasty for coarctation of the aorta in the newborn. *Am Heart J* 1982;**103**:131–2.
28 **Lock JE**, Castaneda-Zuniga WR, Bass JL, *et al*. Balloon dilatation of excised aortic coarctations. *Radiology* 1982;**143**:689–91.
29 **O'Laughlin MP**, Perry SB, Lock JE, *et al*. Use of endovascular stents in congenital heart disease. *Circulation* 1991;**83**:1923–39.
30 **Schrader R**, Bussmann WD, Jacobi V, *et al*. Long-term effects of balloon coarctation angioplasty on arterial blood pressure in adolescent and adult patients. *Cathet Cardiovasc Diagn* 1995;**36**:220–5.
31 **Fawzy ME**, Sivanandam V, Pieters F, *et al*. Long-term effects of balloon angioplasty on systemic hypertension in adolescent and adult patients with coarctation of the aorta. *Eur Heart J* 1999;**20**:827–32.
32 **Daniels SR**, James FW, Loggie JMH, *et al*. Correlates of resting and maximal exercise systolic blood pressure after repair of coarctation of the aorta: a multi-variable analysis. *Am Heart J* 1987;**113**:349–53.
33 **Cheatam J**, Tower A, Villnave D. A new technique to improve safety and efficacy in deploying balloon expandable intravascular stents in congenital heart disease: the Numed balloon-in-balloon (BIB) delivery catheter [abstract]. *Cardiol Young* 2000;**10**(suppl 2):3.

IMAGES IN CARDIOLOGY

First human use of a new PFM "Babystent"

A new stent, the PFM "Babystent", has been developed in cooperation with the Humboldt University Berlin, Charité, and the PFM company. The purpose of this new stent technology is the development of a small stent which can be implanted in neonates without the need for surgical removal throughout the individual's life. The minimal sheath diameter needed for implantation of this premounted stent is 4 French gauge. The stent diameter can be redilated from 4 to 23 mm in the patient.

After a 14 month experimental study period in an animal model the first human implantation was performed in a 5 month old preterm baby, weighing 2.6 kg. The Babystent was inserted into a subtotally occluded innominate vein. The stenoses caused severe venous congestion and occurred after complete occlusion of the superior caval vein due to a longstanding central line. The decision to implant the new Babystent was made after several unsuccessful attempts at treatment by surgical thrombectomy, two attempts of interventional ballooning, and surgical venoplasty.



The implantation of a stent 4 mm in diameter and 8 mm in length was uneventful. Further redilations of the stent to its maximum diameter will be necessary. The implantation of the PFM-Babystent is an alternative to balloon dilation for the treatment of arterial or venous stenoses in neonates. Further investigations on the long term follow up are needed to assess the stent function after several redilations over a lifelong period.

M B E Schneider
G Fischer
P E Lange
martin.schneider@charite.de

ELECTRONIC PAGES

eHEART: *www.heartjnl.com*

The following electronic only articles are published in conjunction with this issue of *Heart*.

Unruptured congenital aneurysm of the left sinus of Valsalva in an adult with complex left heart malformations

A Hakami, B Stiller, R Hetzer

A 26 year old man who presented with the first signs of right heart failure was found to have a large congenital aneurysm of the aortic sinus of Valsalva and of the left coronary sinus. These were combined with left heart anomalies in the form of a bicuspid aortic valve, a rare variant of a persistent left superior vena cava with blood flow from the left atrium through the brachiocephalic vein into the superior vena cava and a kink in the aortic arch. An aortic coarctation had been corrected with a patch 12 years earlier. Although the aneurysm was not perforated and there were no clinical signs of infarction, the aneurysm was resected prophylactically and the left coronary artery was reinserted through a bypass with a Gore-Tex conduit. The case is noteworthy because this diagnosis is very rare and its early treatment may prevent several complications. The clinical features, treatment, and outcome are discussed.

(*Heart* 2003;**89**:e3) www.heartjnl.com/cgi/content/full/89/1/e3

Coronary artery aneurysm with a fistulous connection to the right atrium mimicking a sinus of Valsalva aneurysm

V Shrivastava, E Akowuah, G J Cooper

Coronary artery aneurysms are uncommon and may be complicated by rupture, thromboembolic phenomenon, and more rarely fistulation into one of the cardiac chambers. This case report highlights the difficulty in making a preoperative diagnosis of a coronary artery aneurysm that has fistulated into the right atrium and lists possible differential diagnoses.

(*Heart* 2003;**89**:e4) www.heartjnl.com/cgi/content/full/89/1/e4