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Causes of Recoarctation After Balloon Angioplasty of Unoperated Aortic Coarctation

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During the 35 month period ending December 1987, 30 children, aged 14 days to 13 years, underwent balloon angioplasty of unoperated aortic coarctation with resultant reduction in coarctation gradient from 43.6 ± 20.4 to 9.5 ± 7.6 mm Hg (p < 0.001). None of the patients required immediate surgical intervention. On the basis of results of 6 to 30 month follow-up catheterization data in 20 children, the patients were classified as follows: Group A, 13 patients with good results (gradient ≤ 20 mm Hg and no recoarctation on angiograms) and Group B, 7 patients with fair or poor results (gradient ≥ 21 mm Hg with or without recoarctation on angiography). No patient developed aortic aneurysm at the site of angioplasty.

Thirty variables were examined by multivariate logistic regression analysis and four factors were identified as risk factors for development of recoarctation: 1) age <12 months, 2) aortic isthmus < 2/3 the size of the ascending

Several short-term and a few intermediate-term results of balloon angioplasty of previously unoperated aortic coarctation have been reported (1-19). Recurrence of coarctation or aneurysmal formation at the site of coarctation dilation have been reported (2,6,14-20). The reasons for these complications at intermediate-term follow-up have been studied only to a limited degree (17). Although we have not encountered aneurysm (14,19), we have found recurrence of coarctation. The purpose of this study is to investigate the causes of recurrence of coarctation after balloon angioplasty of unoperated coarctation. aorta immediately proximal to the right innominate artery, 3) coarcted aortic segment <3.5 mm before dilation, and 4) coarcted aortic segment <6 mm after angioplasty. The identification of risk factors may help in selection of patients for balloon angioplasty. Avoiding or minimizing the number of risk factors may help reduce the chance of recoarctation after angioplasty.

The intermediate-term follow-up results with regard to recoarctation are comparable with those after surgical repair of coarctation. Recoarctation after angioplasty was dealt with by repeat balloon angioplasty or surgical resection for those requiring treatment and clinical follow-up for the remaining children. These results suggest that balloon angioplasty for native coarctation is an effective alternative to a surgical approach.

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Methods

Study patients. During the 35 month period ending December 1987, 30 infants and children, aged 14 days to 13 years, underwent balloon dilation of unoperated aortic coarctation. These represented all infants and children with coarctation of the aorta seen by us during this 35 month period with the exception of 1) three infants who required ductal ligation and pulmonary artery banding in addition to coarctation repair, and 2) two children with long segment tubular coarctation without a definite shelf who were thought not to be suitable for balloon angioplasty and underwent surgical repair. Twenty-five infants and children previously reported by us (11,13,14,19) are included in this study. Informed consent was obtained from the parents of each patient. The indications for balloon angioplasty were congestive heart failure or hypertension, or both, not controlled by conventional medical management.

The technique of coarctation balloon angioplasty has been described in detail in our previous publications (13,14,19) and is not described here except to point out some

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Table 1. Study Group (20 patients)

Group	No. of Patients	Regrouping
Group 1: good result	13	Group A
Gradient ≤20 mm Hg*		(n = 13)
No recoarctation on angiography		
No aneurysm		
Group II: fair result	4	Group B
Gradient 21 to 30 mm Hg* with or without recoarctation on angiography		(n = 7)
No aneurysm		
Group III: poor result	3	
Gradient >30 mm Hg*		
Recoarctation on angiography		
No aneurysm		

*Systolic pressure gradient across the dilated aortic coarctation at follow-up.

important technical aspects of the procedure, namely: 1) 100 U/kg of heparin (maximum 2,000 U) was administered immediately after introduction of the arterial catheter; the heparin effect was neither reversed nor continued after balloon angioplasty. 2) The size of the balloon chosen for angioplasty was two times (or more) the size of the coarcted segment but no larger than the size of the descending aorta at the level of the diaphragm as measured form a frozen frame of the video recording. 3) At no time was a catheter or guide wire manipulated over the area of freshly dilated coarctation of the aorta.

Follow-up. Follow-up cardiac catheterization and angiography was performed 6 to 30 months (mean 11.6 \pm 5.7) after balloon angioplasty. Twenty infants and children have follow-up data and were classified into four groups: Group I, good results; Group II, fair results; and Group III and Group IV, poor results based on the pressure gradient across the area of previously dilated coarctation and angiographic appearance (Table 1). The data listed in Tables 2 to 5 were obtained in a conventional manner; aortic measurements are averages of measurements made in anterioposterior and lateral views in the majority of cases and left anterior oblique and right anterior oblique views in a few cases, after correcting for magnification. The ascending aorta was measured immediately proximal to the origin of the right innominate artery and the aortic isthmus was measured midway between the origin of the left subclavian artery and the coarcted aortic segment.

Statistical methods. Student's two-tailed t test was used for comparison of data obtained before and after angioplasty as well as for comparison of the groups. Frequency distributions were compared using Fisher's exact test. Multivariate logistic regression analysis was performed to identify significant factors responsible for recoarctation. The level of statistical significant was set at p < 0.05.

	Group A	Group B	рV	alue	
	(mean \pm SD or number)	(mean \pm SD or number)	t	Logistic	
No. of patients	13	7			
Type of coarctation			0.35*		
Discrete	13	6			
Diffuse	0	1			
Associated PDA	2	1	1.0*		
Severity of isthmic hypoplasia ⁺			0.007‡		
Severe	1	4			
Moderate	6	3			
Mild	7	0			
Size of isthmus/size of aorta proximal to right innominate artery	0.66 ± 0.13	0.47 ± 0.1	0.004	0.002	
Size of isthmus (mm)	12.1 ± 4.1	6.9 ± 2.9	0.008	0.005	
Size of coarcted segment (mm)	4.0 ± 1.9	2.51 ± 0.72	0.02	0.03	
Size of isthmus/size of coarcted segment	3.5 ± 1.9	2.73 ± 0.7	0.21	0.24	
Size of DAo immediately distal to coarcted segment/size of coarcted segment	4.77 ± 2.67	4.44 ± 1.56	0.73	0.72	
Size of DAo at diaphragm/size of coarcted segment	3.84 ± 2.1	3.73 ± 0.97	0.87	0.89	
Size of DAo immediately distal to coarcted segment/size of isthmus	1.34 ± 0.33	1.6 ± 0.26	0.09	0.06	

*Fisher's exact test; †isthmic hypoplasia: size of isthmus/size of the ascending aorta; $\leq 0.5 =$ severe; 0.5 to 0.66 = moderate; >0.66 = mild; ‡Kruskal-Wallis. DAo = descending aorta; PDA = patent ductus arteriosus.

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	Group A (mean \pm SD)	Group B (mean ± SD)	p Value		
	(n = 13)	(n = 7)	t	Logistic	
Size of coarctation (mm)	10.0 ± 3.1	6.2 ± 2.5	0.01	0.008	
Size of coarctation after angioplasty/size of coarctation before angioplasty	2.89 ± 1.53	2.47 ± 0.65	0.40	0.44	
Size of isthmus/size of coarctation after angioplasty	1.21 ± 0.2	1.13 ± 0.22	0.42	0.39	
Size of DAo immediately distal to coarctation/size of coarctation after angioplasty	1.66 ± 0.35	1.85 ± 0.55	0.36	0.33	
Size of DAo of diaphragm/size of coarctation after angioplasty	1.32 ± 0.33	1.53 ± 0.21	0.15	0.13	

Table 3. Local Anatomic Factors (after angioplas	ty) ir	1 20 I	Patients
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Abbreviations as in Table 2.

Results

Clinical features. Thirty children (23 boys and 7 girls) with a weight range of 2.1 to 50 kg (mean 14.7) underwent cardiac catheterization and balloon angioplasty of aortic coarctation. Sixteen, including 4 neonates, were <24 months old; the remaining 14 were children aged 2 to 13 years. Other cardiac defects were present in 23 of these children and included aortic stenosis in 9, patent ductus arteriosus in 8, ventricular septal defect in 7, atrial septal defect in 2, membraneous subaortic stenosis in 1 each. Bicuspid aortic valve was present in 11 children including the 9 with aortic stenosis. Twelve of the 16 infants had moderate to severe heart failure, and all but 3 patients were hypertensive.

Immediate results. After balloon angioplasty, the systolic pressure proximal to the coarctation of the aorta decreased (126.9 \pm 26.2 [mean \pm SD] versus 112.0 \pm 19.2 mm Hg, p < 0.02) as did the systolic pressure gradient across the aortic coarctation (from 46.3 \pm 20.4 to 9.5 \pm 7.6 mm Hg, p < 0.001). As a result of angioplasty, the coarcted segment

increased in diameter from 3.5 ± 2.0 to 8.3 ± 3.6 mm (p < 0.001). The condition of the infants with heart failure improved after angioplasty. Systemic hypertension also decreased (p < 0.02). All patients were discharged home within 24 to 48 h after the procedure. None of the patients required immediate surgical intervention.

Follow-up results. Twenty children had repeat cardiac catheterization and angiography 6 to 30 months (mean 11.6) after balloon angioplasty. For the group of children in whom follow-up catheterization data were available, the systolic pressure gradient across the coarctation $(51.1 \pm 21.6 \text{ versus} 10.3 \pm 7.5 \text{ mm Hg}, p < 0.001)$ and systolic pressure proximal to the coarctation $(133.1 \pm 25.7 \text{ versus} 116.0 \pm 19.5 \text{ mm Hg}, p < 0.05)$ decreased immediately after angioplasty. The size of the coarcted aortic segment increased from 3.5 ± 1.7 to $8.7 \pm 3.4 \text{ mm}$ (p < 0.001) after balloon angioplasty. On follow-up approximately 1 year later, systolic pressure gradient across the coarctation $(15.3 \pm 12.7 \text{ mm Hg}, p < 0.001)$, systolic pressure proximal to the coarctation $(105.2 \pm 16.1 \text{ mm Hg}, p < 0.001)$ and size of the coarcted segment (9.4 ±

Table 4. Physiologic Variables (before and after angioplasty) in 20 Patients

	Group A (mean ± SD)	Group B (mean ± SD)	p Value		
	(n = 13)	$(mean \pm 3D)$ (n = 7)	t	Logistic	
Systolic pressure proximal to coarctation, before angioplasty (mm Hg)	132.0 ± 27.9	134.3 ± 23.0	0.92	0.92	
Systolic pressure gradient across coarctation, before angioplasty (mm Hg)	$45.8~\pm~16.9$	60.7 ± 27.3	0.15	0.13	
Systolic pressure proximal to coarctation, after angioplasty (mm Hg)	118.5 ± 21.3	111.3 ± 16.0	0.44	0.41	
Systolic pressure gradient across coarctation, after angioplasty (mm Hg)	9.3 ± 7.3	11.9 ± 7.8	0.48	0.45	
Systolic pressure proximal to coarctation, after angioplasty/before angioplasty	$0.9~\pm~0.09$	0.84 ± 0.13	0.21	0.18	
Systolic pressure gradient across coarctation. before angioplasty/after angioplasty	11.2 ± 8.4	7.55 ± 5.81	0.52	0.57	

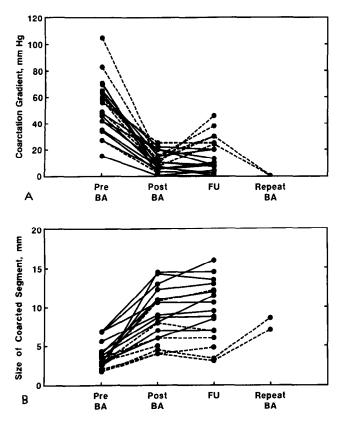
	Group A	Group B	p Value		
	(mean \pm SD)	$(\text{mean} \pm \text{SD})$	t	Logistic	
Balloon size/size of coarcted segment	3.29 ± 1.19	2.85 ± 0.84	0.40	0.36	
Balloon size/size of the isthmus	1.01 ± 0.22	1.09 ± 0.41	0.66	0.56	
Balloon size/size of DAo immediately distal to the coarctation	0.74 ± 0.18	0.73 ± 0.42	0.92	0.90	
Balloon size/size of DAo at the diaphragm	0.95 ± 0.27	0.78 ± 0.24	0.18	0.14	
Maximal pressure achieved in the balloon (atm)	5.6 ± 1.7	6.6 ± 1.4	0.22	0.20	
Number of balloon inflations	3.92 ± 0.76	5.0 ± 1.8	0.18	0.07	
Total duration of balloon inflation (s)	33.0 ± 8.6	40.0 ± 21.0	0.43	0.28	

Table 5. Technical Factors During Balloon Angioplasty	Table 5.	Technical	Factors	During	Balloon	Angiop	lasty
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Abbreviations as in Table 2.

3.9 mm, p < 0.001) were improved when compared with preangioplasty values. Despite improvement as a group, several children developed recoarctation. Pressure gradient

Figure 1. Panels A and B, Longitudinal follow-up data after balloon angioplasty (BA) of coarctation of the aorta. In 13 children (solid lines), the gradient across the coarctation and the size of the coarcted segment either improved or remained unchanged. In seven children (dashed lines), the pressure gradient worsened with or without change in the size of the coarcted segment. Two of these children underwent repeat balloon angioplasty with improvement and one infant is awaiting angioplasty. Two infants underwent surgical resection. Two children have diffuse narrowing of the aorta without significant systemic hypertension and are being followed up (FU) clinically.



across the coarctation and the size of the coarcted segment for each patient before, immediately after and at follow-up are shown in Figure 1.

On the basis of individual results at recatheterization, these 20 children were classified into four groups (Table 1). There were 13 children with good results (Group I), 4 with fair results (Group II) and 3 with poor results (Group III); no patient developed aneurysm. For the purpose of description and further analysis, Group I is renamed Group A (13 patients) and Groups II and III were combined to form Group B (7 patients).

In Group A (children with good results), the gradient across the coarctation decreased (45.8 \pm 16.9 versus 9.3 \pm 7.3 mm Hg, p < 0.001) and the coarcted aortic segment increased (4.0 \pm 1.9 versus 10.0 \pm 3.1 mm) immediately after balloon angioplasty; these respective values improved further to 8.2 \pm 6.4 mm Hg and 10.9 \pm 3.1 mm, at follow-up catheterization. In Group B (children with fair and poor results), the coarctation gradient decreased from 60.7 ± 27.3 to 11.9 ± 7.8 mm Hg, p < 0.01. However, on follow-up, the gradient (30.8 ± 7.9 mm Hg) returned toward preangioplasty values. Similarly, the coarcted aortic segment increased (2.5 \pm 0.7 versus 6.2 \pm 2.5 mm, p < 0.01) immediately after angioplasty, which remained unchanged (6.1 \pm 3.3 mm, p > 0.1) on follow-up. At follow-up, Group A children had a lower systolic pressure proximal to coarctation (100.4 \pm 13.7 versus 115.5 \pm 17.1 mm Hg, p < 0.05), a lower gradient across the coarctation (8.2 \pm 6.4 versus 30.8 \pm 7.9 mm Hg, p < 0.001) and a larger segment of dilated aortic coarctation (10.9 \pm 3.1 versus 6.1 \pm 3.3 mm, p < 0.01) than Group B children. None of the Group A children required surgical repair or repeat balloon angioplasty. Four of the seven infants from Group B on restudy at 8 to 11 months after initial balloon angioplasty required repeat balloon angioplasty or surgical resection at follow-up. The remaining three children did not require further intervention because of a low gradient and near normal systemic pressure (Table 6).

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	Age at	Duration of		Systolic Pressure Proximal to Coarctation (mm Hg)		Gradient Across the Aortic Coarctation (mm Hg)		the Aortic Coarctation (mm			ircted (mm)	
Patient No.	Angioplasty	Follow-Up	Pre	Post	FU	Pre	Post	FU	Pre	Post	FU	Outcome/Comment
Fair results 1	7 yr	10 mo	155	105	100	83	15	30	3.0	10.8	12.2	Diffuse narrowing of isthmus; followed up clinically
2	4 mo	8 mo	120	115	121	58	7	24	1.67	4.0	3.1	Repeat balloon angioplasty with reduction of gradient to 0; coarctation segment increased to 7.1 mm
3	8 yr	7 mo	175	139	127	105	15	30	2.7	8.0	6.9	No discrete recoarctation seen: followed up clinically
4 Poor results	12 mo	14 mo	120	125	95	56	25	25	3.5	6.0	6.0	No repeat angioplasty done because of nonavailability of appropriate sized balloon catheter
5	19 days	15 mo	125	95	140	43	9	46	2.0	4.0	4.8	Because of nonavailability of appropriate sized balloon catheter, surgical resection o recoarctation was performed without incident
6	1 m o	10 mo	110	100	-	20	0		3.0	6.0	_	Reoperated elsewhere. 4 mo after initial balloon angioplasty
7	3 mo	11 mo	135	100	110	60	12	31	1.7	4.5	3.4	Repeat balloon angioplasty with reduction of gradient to 0; coarctation segment increased to 8.0 mm.

Table 6.	Details	of the	Seven	Patients	With	Fair and	Poor	Results	(Group	5 B)
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FU = follow up; Post = immediately after balloon angioplasty; Pre = before balloon angioplasty.

Causes of Recoarctation

Thirty variables were examined by multivariate logistic regression analysis to identify factors for recurrence of coarctation in Group B patients (Tables 2 through 5).

General factors. The age at angioplasty was lower in Group B (children with poor results) $(2.5 \pm 3.5 \text{ years})$ than in Group A $(5.9 \pm 4.5 \text{ years})$, but this difference did not attain statistical significance (p > 0.05). However, 5 of 7 infants <1 year old developed recoarctation whereas only 2 of 13 children >1 year old developed recoarctation (p = 0.02). The duration of follow-up (11.2 \pm 6.5 versus 10.7 \pm 2.9 months) was not significantly different (p > 0.1) for these two groups.

Local anatomic factors (Tables 2, 3 and 7). The type of coarctation, discrete or diffuse, did not appear to be different in the groups. Similarly, the presence of associated patent ductus arteriosus did not influence recoarctation. The size of the isthmus, both absolute and relative to the size of the ascending aorta, appeared to have a significant effect (p < 0.005). The more severe the isthmic hypoplasia, the higher was the chance for recurrence of coarctation after balloon angioplasty (Table 7). The size of the coarcted aortic segment was smaller (p < 0.01) both before and after angio-

plasty in the group with recoarctation (Group B). Because the greater number of small infants in Group B could explain this finding, we attempted to remove the effect of age by normalizing the size of the coarcted segment to the size of various aortic segments; after this procedure there was no statistical difference (p > 0.1) between the groups in size of the coarcted segment. However, when absolute size of the coarcted segment was examined, all seven recurrences of coarctation were in the group with a preangioplasty coarcted segment diameter <3.5 mm and five were in the group with a postangioplasty coarcted segment diameter <6 mm.

Physiologic variables (Table 4). No physiologic variables appeared to be significantly different between the groups. Neither the level of preangioplasty gradient across the coarctation nor systolic pressure gradient after angioplasty appears to influence the recurrence of coarctation.

Technical factors (Table 5). Several technical factors (balloon size and pressure and number of inflations) were examined and were very similar in both groups.

Multiple risk factors (Tables 2 to 5 and 8). Multivariate logistic regression analysis identified three major risk factors: 1) size of the isthmus (both absolute and relative to the

	Number of Patients in This Specific Group	Number of Patients With Aortic Recoarctation	p Value*	
Size of the isthmus/size of the ascending aorta ≤0.5	5	4	0.02	
Size of the isthmus/size of the ascending aorta >5	15	3	0.03	
Size of isthmus/size of the ascending aorta ≤0.66	14	7	0.05	
Size of isthmus/size of the ascending aorta >0.66	6	0	0.05	

 Table 7. Relation of Size of Isthmus (normalized to the ascending aorta) With Recurrence of Coarctation in 20 Patients

*Fisher's exact test.

size of the ascending aorta proximal to the right innominate artery, 2) size of the coarcted segment before balloon angioplasty, and 3) size of the coarcted segment immediately after angioplasty (Tables 2 to 5). Further analysis by classification into either group on the basis of multivariate logistic regression and by contingency tables (not shown) revealed only age <1 year to be influencial in recoarctation. A gradient across the coarctation >50 mm Hg before angioplasty and balloon/descending aorta (at the level of the diaphragm) ratio did not seem to be associated with recurrence of coarctation. The effects of multiple risk factors for coarctation are examined in Table 8; the presence of two or more risk factors appears to be associated with a high rate of recoarctation; the larger the number of risk factors the higher is the chance for recoarctation.

 Table 8. Influence of Multiple Risk Factors on the Recurrence of Coarctation After Balloon Angioplasty*

No. of Risk Factors	No. of Patients in Specified Group	No. of Patients With Recurrence	p Value†
4	6	5	0.007
<4	14	2	0.007
≥3	7	5	0.02
<3	13	2	0.02
≥2	13	7	0.04
<2	7	0	0.04

*Risk factors: 1) age <1 year; 2) size of the aortic isthmus <2/3 the size of the ascending aorta immediately proximal to the right innominate artery; 3) diameter of the coarcted aortic segment before angioplasty <3.5 mm; 4) diameter of the dilated coarcted segment (after angioplasty) <6 mm. \pm Fisher's exact text.

Discussion

Risk factors for development of recoarctation. The present study involves one of the largest series of patients in whom cardiac catheterization and angiographic follow-up data after balloon angioplasty of unoperated coarctations are documented. Aneurysm formation reported in some of the previous studies (15,17,18,20) was not found in any patient in this study; however, recoarctation was observed in a significant number of patients. Although recurrence of coarctation and aneurysm formation have previously been reported (2,6,16-20), only one group of workers (17) has previously attempted systematic examination of factors responsible for these poor results. In the current study, several demographic, anatomic, physiologic and technical factors were extensively examined and several "risk factors" were identified that might predispose to recurrence of coarctation. These include 1) age; infants <1 year of age appear to have a high likelihood of recoarctation. 2) Size of the aortic isthmus; the smaller the aortic isthmus, the greater the chance for recurrence. 3) Absolute size of coarcted aortic segment before balloon angioplasty; there appears to be a significant risk of recurrence if the coarcted segment is <3.5mm before angioplasty. 4) Size of the dilated coarcted segment; there appears to be a high likelihood of recurrence when the dilated segment of coarctation is <6.0 mm. The presence of two or more of these risk factors is associated with a high rate of recurrence. A systolic pressure gradient across the aortic coarctation >50 mm Hg before angioplasty has been implicated in the recurrence of coarctation after successful angioplasty (17). The data from our study do not support this contention.

The identification of risk factors may help in the selection of patients for angioplasty of unoperated coarctation. Avoiding or minimizing the number of risk factors may help reduce the chance for recoarctation after balloon angioplasty.

Intermediate-term follow-up results. The rate of recoarctation on intermediate-term follow-up in our group of 35% (7 of 20 patients if both poor and fair results are included) or of 15% (3 of 20 patients if only poor results are included) is similar to that reported by other investigators (2,6,16-20). These investigators restudied 7 to 14 patients 1 to 31 months after balloon coarctation angioplasty and observed recoarctation in 14 to 31% and aneurysm formation in 8 to 55%. A high incidence of recurrence after balloon angioplasty in young infants is comparable with that seen with surgical resection of coarctation (21–26). Despite these findings we continue to recommend balloon angioplasty of native aortic coarctation in infants and young children as the initial treatment of choice because balloon dilation offers a safer alternative to surgical repair in infants. Of the seven patients with recoarctation in the current series, four infants required repeat balloon angioplasty or surgical resection. The remaining three patients did not need further intervention. Therefore, with balloon angioplasty, surgery may be avoided or postponed until the child is larger and the risk of death and recoarctation (21-26) associated with surgery is less. Recoarctation can be treated with either repeat balloon angioplasty or surgical resection as shown in this study. Thus we continue to consider balloon angioplasty for native coarctations as an effective alternative to surgical repair (13,14,19).

Conclusions. Several risk factors that might predict recurrence of coarctation after balloon angioplasty have been identified. These include very young age, small size of the aortic isthmus and narrow coarcted aortic segment before and immediately after angioplasty. Avoiding or minimizing risk factors may help reduce the likelihood of recoarctation after balloon angioplasty. The recurrence rate of coarctation is similar to that seen with surgical therapy, especially in young children, and the recoarctation could be treated effectively at follow-up by repeat angioplasty or surgery. These data suggest that balloon angioplasty is an effective alternative to surgical therapy of native aortic coarctation.

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