Balloon Angioplasty of Postsurgical Recoarctation in Infants
The Risk of Restenosis and Long-Term Follow-Up

Sunita Maheshwari, MD, Elchanan Bruckheimer, MBBS, John T. Fahey, MD, FACC, William E. Hellenbrand, MD, FACC
New Haven, Connecticut

OBJECTIVES
This study was undertaken to evaluate the long-term results of balloon angioplasty (BA) for postsurgical recoarctation in infants.

BACKGROUND
Balloon angioplasty is a well-accepted modality for the treatment of recoarctation. However, infants remain a group of concern because of their size, risk for complications and the potential for restenosis with growth. Age <12 months has been determined to be a risk factor for the development of recoarctation after angioplasty for native coarctation. Although studies on postsurgical coarctation have found no relationship between age at angioplasty and the development of recoarctation, few studies specifically addressing infants have been performed.

METHODS
Clinical, echocardiographic, hemodynamic and angiographic data on 22 consecutive children <1 year of age who underwent BA between 1986 and 1996 were reviewed.

RESULTS
A successful result, defined as a postprocedure gradient of ≤20 mm Hg, was achieved in 20 of 22 (91%) infants with a reduction in the systolic peak pressure gradient from 48 ± 27 to 9 ± 10 mm Hg (p < 0.001) and an increase in coarctation diameter from 2.7 ± 1.1 to 5.2 ± 1.5 mm (p < 0.001). At long-term follow-up of a median of 56 months (0.6 to 12 years), the restenosis rate after an initial optimal result was 16% (3 of 19). Five (24%) infants required reintervention (2 initially unsuccessful; 3 recoarctation), with a success rate of 95% after two procedures. Suboptimal long-term outcome correlated with a lower infant weight.

CONCLUSIONS
Balloon angioplasty can be safely performed in infants, with good long-term results. The risk of restenosis is low and can be successfully managed with repeat angioplasty. (J Am Coll Cardiol 2000;35:209–13) © 1999 by the American College of Cardiology

The immediate results with balloon angioplasty (BA) for coarctation (CoA) of the aorta are gratifying. However, concerns remain about its use in children, especially in infants, who are at a higher risk for complications because of their size, smaller vessels and the potential for restenosis with growth.

The acute results of BA for native and postoperative recurrent CoA in infants appear to be similar (1). However, the long-term recoarctation rate in native CoA in infants remains high (2). The mechanism of recoarctation, although undetermined, is presumably different in native and postsurgical CoA, as the substrate is different. Potentially, growth in childhood with a growth lag of the coarcted segment could play a role in restenosis. This hypothesis would make age a factor in determining the long-term results of BA in both native and postsurgical CoA of the aorta in infants. Age less than 12 months has been determined to be a risk factor for the development of recoarctation after angioplasty for native coarctation (2,3).

However, studies on postsurgical CoA have found no relation between age at angioplasty and the development of recoarctation (4), although a specific study focusing on infants to determine their outcome has not been performed, to our knowledge. As a sizable number of infants have undergone BA for postsurgical CoA at our institution and follow-up for up to 12 years is now available, we performed this retrospective study to analyze the long-term impact of BA in this subgroup of children and to determine the incidence of recoarctation in infants with growth.
Abbreviations and Acronyms

- AAo = ascending aorta
- BA = balloon angioplasty
- CoA = coarctation
- DAO = descending aorta

METHODS

Twenty-two consecutive infants underwent BA at our institution for recurrent CoA of the aorta after surgical repair between May 1986 and July 1996. Eighteen of these infants had been operated on at our hospital. During that period, the total number of infants undergoing CoA repair at our institution was 80 (recoarctation: 22%). In the catheterization laboratory, a peak-to-peak gradient $\geq 20$ mm Hg in the presence of angiographic evidence of CoA was used as the criteria to attempt BA.

Angioplasty. All cases were done under conscious sedation using local anesthesia. The technique for BA of a CoA has been well described (5,6). In brief, after administering heparin (100 IU/kg), a diagnostic right and left heart hemodynamic catheterization is performed. The CoA site is crossed in a retrograde fashion, and peak and mean pressure gradients are recorded on pullback or by simultaneous ascending and descending aortic pressure measurements. Biplane angiography is performed, and the diameters of the aorta at the level of the isthmus, CoA segment and descending aorta (DAO) distal to the CoA and at the level of the diaphragm are measured. A balloon of a size equal to or slightly less than the diameter of the DAO at the level of the diaphragm is selected. The balloon catheter is passed over an exchange guide wire and inflated until the “waist” disappears using a low-pressure balloon initially, and a higher-pressure balloon if necessary. An angiographic catheter is then advanced to the ascending aorta (AAo) over the guidewire, and hemodynamic and angiographic studies are repeated. Angioplasty is repeated with a larger balloon (not larger than the diameter of the aorta at the level of the diaphragm) if the residual gradient is $> 20$ mm Hg and there is angiographic evidence of persistent narrowing without any evidence of significant intimal tears.

Follow-up. The details of the clinical history and cardiac catheterization were retrospectively reviewed. Follow-up data were obtained by review of the cardiology charts, the most recent echocardiogram and/or MRI (magnetic resonance imaging) and, when available, results of repeat cardiac catheterization. Restenosis was clinically determined either by measurement of arm-to-leg gradients by sphygmomanometry using the leg through which vascular access was not obtained and/or by echocardiographic evaluation in cases where arm-to-leg gradients were not reliable (one patient, anomalous origin of the right subclavian artery below the level of the CoA and subclavian flap procedure). Standard echocardiographic findings were used for the diagnosis of CoA including two-dimensional imaging of an anatomic narrowing and/or Doppler evidence of a high-velocity jet with antegrade flow extending into diastole.

Statistical analysis. Results are expressed as a mean $\pm$ SD or as a median with a range. Comparison between values before and after BA was made by two-tailed paired $t$ tests. A $p$ value $\leq 0.05$ was considered significant. Factors associated with a need for, and time to, reintervention were initially sought using a univariable Cox proportional hazards model. The variables significant in the univariable analysis were then tested in a multivariable analysis. This analysis was performed using SAS statistical software.

RESULTS

Patient demographics. Twenty-two infants (13 male, 9 female) $< 1$ year of age underwent BA for recurrent CoA at a median age of 5.8 months (range: 1.5 to 11.7 months) and median weight of 6.1 kg (range: 2.4 to 8.4 kg). The median age at surgery was 6.5 days (range: 1 to 38 days), and the mean time from surgical repair to angioplasty was $5.9 \pm 3.4$ months. The surgical procedures included end-to-end anastomosis ($n = 6$), extended end-to-end ($n = 7$), subclavian flap ($n = 7$) and a Norwood repair ($n = 2$). Although eight (36%) infants had an isolated CoA, others had associated defects, including a bicuspid aortic valve ($n = 1$), ventricular septal defect ($n = 5$), both a bicuspid aortic valve and a ventricular septal defect ($n = 3$), Shone’s complex ($n = 3$), double inlet left ventricle ($n = 1$), Scimitar syndrome ($n = 1$) and hypoplastic left heart syndrome after stage 1 Norwood repair ($n = 2$).

The reason for referral for possible angioplasty was the presence of recoarctation as determined clinically by the referring cardiologist based on an arm-leg gradient $\geq 20$ mm Hg determined by sphygmomanometry or on echocardiographic findings as detailed in the preceding section. Nineteen of the 22 patients were felt to have recurrent obstruction, while three of the infants had documented residual gradients $\geq 20$ mm Hg in the immediate surgical postoperative period.

Immediate results. The hemodynamic and angiographic results before and after angioplasty are summarized in Table 1.

We considered a residual peak systolic gradient of $\leq 20$ mm Hg at the end of the procedure a successful result. Of the 22 patients who underwent angioplasty, the procedure was successful in 20. Although two patients were considered to have an unsuccessful result based on the criteria used to define success of a gradient $\leq 20$ mm Hg, the gradient had decreased from 93 to 30 mm Hg in one infant and from 120 to 35 in the other infant. Balloon angioplasty was not repeated with a larger balloon in these two patients, because the initial balloon size was equal to the diameter of
the DAo at the level of the diaphragm and because of the presence, angiographically, of intimal tears.

**Follow-up.** Criteria for a successful result on follow-up were a blood pressure gradient ≥20 mm Hg; absence of echocardiographic evidence of recoarctation, and/or a peak-to-peak systolic pressure gradient ≥20 mm Hg on repeat cardiac catheterization.

The median length of follow-up was 56 months, with a mean of 55 months (range: 0.6 to 12 years). Four patients were followed at other institutions, and clinical follow-up was obtained by contacting the primary cardiologist. Of these four patients, one was lost to follow-up; therefore, follow-up data were obtained on 21 patients.

**Reintervention.** We defined reintervention as a procedure performed for either recurrent CoA after an optimal initial angioplasty, or for a persistent residual gradient after the first procedure. As in the first angioplasty, we considered a residual peak systolic gradient of ≥20 mm Hg at the end of the procedure a successful result. Five patients required reintervention, including the two infants with the initial unsuccessful result who on subsequent angioplasty had the obstruction successfully relieved. The other three infants developed recoarctation after initially satisfactory procedures and underwent repeat angioplasty 6, 9 and 20 months after the initial procedure. Two of these were successful, but one was unsuccessful with a persistent gradient of 25 mm Hg. This patient subsequently underwent an unsuccessful attempt at surgical relief of the CoA, followed by a third unsuccessful angioplasty, and died two years later of sepsis.

Interestingly, all the reinterventions were performed in the first two years after the initial BA. This is demonstrated in the Kaplan-Meier curve (Fig. 1).

The following variables possibly associated with the need for reintervention were initially analyzed using a univariable analysis: type of coarctation repair (p = 0.6); age of the infants (p = 0.1); weight of the infants (p = 0.05); pre-peak systolic gradient (p = 0.05); CoA diameter pre- (p = 0.5) and post-BA (p = 0.2); AAo (p = 0.7), transverse arch (p = 0.4) and isthmus (p = 0.1) dimensions (as is and after calculating a ratio based on body weight); mean CoA:DAo ratio (p = 0.3); balloon:CoA ratio (p = 0.2); balloon diameter (p = 0.08); balloon:DAo ratio (p = 0.9); and balloon:isthmus ratio (p = 0.3). By univariable analysis, a lower weight and a higher pre-peak systolic gradient were associated with an increased likelihood of reintervention. However, in the multivariable model, only weight remained significantly associated with an increased risk of reintervention (risk ratio: 0.5, CI: 0.3 to 1).

**Mortality.** During the period of follow-up, two patients died of unrelated causes 9 and 48 months after the procedure. One had Shone’s complex and died in the operating room during an attempt at a mitral valve replacement; the other was asplenic and succumbed to overwhelming sepsis. There was no mortality related to the procedure, and the two late deaths in the group were unrelated procedurally or otherwise to the CoA.

**Follow-up after reintervention.** On follow-up of the surviving 19 patients, there was no evidence of recoarctation (gradient ≥20 mm Hg) by blood pressure measurements or echocardiography. Nine patients underwent repeat cardiac catheterization for unrelated causes (mitral stenosis, 1; subaortic membrane, 2; pulmonary hemorrhage, 1, Kawasaki disease, 1; pre-Fontan, 2; pre-Glenn, 1; SVC obstruction, 1) and had no evidence of recoarctation (residual

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**Table 1. Hemodynamic and Angiographic Parameters Before and After BA**

<table>
<thead>
<tr>
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<th>Pre-BA</th>
<th>Post-BA</th>
<th>% Change</th>
<th>p Value</th>
</tr>
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<tbody>
<tr>
<td>Systolic peak pressure gradient (mm Hg)</td>
<td>48 ± 27</td>
<td>9 ± 10</td>
<td>↓ 80 ± 21</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>AAo peak systolic pressure (mm Hg)</td>
<td>127 ± 25</td>
<td>107 ± 17</td>
<td>↓ 16 ± 28</td>
<td>&lt; 0.005</td>
</tr>
<tr>
<td>DAo peak systolic pressure (mm Hg)</td>
<td>79 ± 16</td>
<td>98 ± 19</td>
<td>↑ 24 ± 19</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean CoA diameter (mm)</td>
<td>2.7 ± 1.1</td>
<td>5.2 ± 1.5</td>
<td>↑ 93 ± 86</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean CoA: DAo ratio</td>
<td>0.4 ± 0.1</td>
<td>0.7 ± 0.2</td>
<td>↑ 75 ± 72</td>
<td>&lt; 0.001</td>
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![Figure 1. Kaplan-Meier curve demonstrating proportion free from reintervention after initial balloon angioplasty (BA) (n at initial BA = 22). Note that all the reinterventions were performed in the first two years after the initial BA.](image-url)

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gradient ≤20 mm Hg), although two patients with no gradient at rest had a 25 to 30 mm Hg gradient after administration of isoproterenol. A controversial decision to place a stent for mild angiographic narrowing was made in one patient to improve his post-Fontan hemodynamics. This was not considered “reintervention” for recoarctation as the gradient in the catheterization laboratory was ≤20 mm Hg.

Persistent systemic hypertension requiring treatment with antihypertensive medications was not detected in any of the 19 patients on follow-up. Aneurysms were not detected in any of the 15 patients who were evaluated by MRI and/or follow-up angiography. Femoral artery occlusion was noted in one patient, secondary to a cutdown procedure at the time of the initial catheterization, which was performed in the earlier part of this series.

**DISCUSSION**

The merits, especially in the short term, of angioplasty are clear. Long-term results can now be critically analyzed, as more than 15 years have passed since the initial series of BA for recurrent CoA (7). Our study sought to ascertain whether the initial success in the cardiac catheterization laboratory was sustained and to determine the incidence of restenosis in infants as compared with older children and with infants with native CoA.

**Initial success.** In our series, the initial success rate was 91% (20 of 22 patients), which compares favorably with the 72% to 90% (4,6,8–10) reported in other series of recurrent CoA and which included children from all age groups, and also with the high success rate in native CoA. Data from Valvuloplasty and Angioplasty of Congenital Anomalies (VACA) registry (11) suggest that better results seem to occur when angioplasty is performed at an earlier rather than a later age after residual obstruction is found. Thus, infants may have a better result from BA than older children with surgical recoarctation, possibly because of less scar tissue and fibrosis. This may explain our high initial success rate of 91%.

**Reintervention.** In our series of infants with recoarctation, 76% (16 of 21 infants) required only one BA. After two procedures the success rate was 95% (20 of 21 patients). The reported incidence of restenosis in follow-up studies of BA performed on children of all ages varies from 0% to 28% (4,8–10). A recent 12-year review of BA for recoarctation in children by Yetman et al. (4), published in this *Journal*, which is the longest follow-up study to date, reports a reintervention rate of 28% and a restenosis rate of 25% (19 of 74 patients). In our study, which also has a follow-up of up to 12 years, and which included only infants, the reintervention rate was 24% (5 of 21 patients), whereas the restenosis rate was 16% (3 of the 19 patients with an initial optimal result).

Another long-term study (10), which included 16 infants, had no evidence of restenosis at a median follow-up of five years. The lower incidence of restenosis in infants may suggest that infant aortas are capable of remodeling at the site of the CoA and growing with time, despite relatively small pre- and postnatal dimensions.

Our data suggested that infants with lower weights had a higher incidence of reintervention. Additionally, although the difference between the ages of the group that required one versus two interventions did not attain statistical significance, in part due to our small numbers, the trend suggested that younger infants had a higher incidence of residual gradients and restenosis with growth.

**Complications.** In addition to the encouraging finding of a low risk of restenosis in our study, the incidence of significant long-term complications was also low. No acute aneurysms were noted, and later development of aneurysms was not found in the 15 patients who were evaluated by either repeat angiography or MRI. No patients had hypertension requiring therapy, although 24-h blood pressure monitoring was not employed in the evaluation. In addition, no unusual long-term complications have been noted.

The surgical literature reports a restenosis rate varying from 7% to 30% in children after surgical correction of recoarctation (12,13). Although the incidence of recurrent recoarctation is similar with BA, the advantages of angioplasty vis-à-vis surgery in infants are well-known and include the avoidance of general anesthesia, a second thoracotomy and a shorter hospital stay.

Both the morbidity and the mortality associated with the angioplasty procedure itself have been reduced considerably since earlier reports. The VACA registry reported a 2.5% mortality in 1990 (11). Mortality rates after surgery for recoarctation have also decreased from a reported incidence of 33% in 1965 (14) to 5% to 7% in recent series (12,15). Although mortality after surgery has decreased, the risk is still significant. Additionally, the operative morbidity remains relatively high (12). Acute complications and morbidity after BA are low (4), especially with the advent of low-profile balloons that require smaller sheaths and with refinements in the angioplasty technique. In our series, there were no mortalities related to the procedure, thus making angioplasty, a safe alternative to surgery for infants.

**Native recoarctation.** By contrast to our findings in recurrent CoA in infants, the reported results in native CoA remain less satisfying. Rao et al. (2), in a five- to nine-year follow-up series, reported a 50% incidence of restenosis in infants (5 of 6 neonates and 7 of 18 infants 1 to 12 months of age). This would suggest that factors other than age are responsible for the disparity in results between native and recurrent CoA angioplasty; the presence of ductal tissue in native CoA could potentially be a factor contributing to restenosis in those infants.

**Conclusions.** This study confirms the finding of other studies that BA is safe and effective in the treatment of
recurrent CoA. In children <1 year of age, it has good long-term results. The risk of restenosis with growth in childhood is low and can be successfully managed with repeat angioplasty. Smaller size of the infants correlated with a suboptimal long-term outcome.

Reprint requests and correspondence: Dr. William E. Hellenbrand, Section of Pediatric Cardiology, 333 Cedar Street, Yale–New Haven Hospital, New Haven, Connecticut 06520. E-mail: william.hellenbrand@yale.edu.

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