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Five- to Nine-Year Follow-Up Results of Balloon Angioplasty of Native Aortic Coarctation in Infants and Children

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Objectives. **To evaluate the usefulness of balloon angioplasty for relief of native aortic coarctation, we reviewed our experience with this procedure, with special emphasis on follow-up results.**

Background. **Controversy exists with regard to the role of balloon angioplasty in the treatment of native aortic coarctation.**

Methods. **During an 8.7-year period ending September 1993, 67 neonates, infants and children underwent balloon angioplasty for native aortic coarctation. A retrospective review of this experience with emphasis on long-term follow-up forms the basis of this study.**

Results. **Balloon angioplasty produced a reduction in the peak-to-peak coarctation gradient from 46 ± 17 (mean ± SD) to 11 ± 9 mm Hg ($p < 0.001$). No patient required immediate surgical intervention. At intermediate-term follow-up (14 ± 11 months), catheterization (58 patients) and blood pressure (2 patients) data revealed a residual gradient of 16 ± 15 mm Hg ($p > 0.1$). When individual results were scrutinized, 15 (25%) of 60 had recoarctation, defined as peak gradient >20 mm Hg. Recoarctation was higher ($p < 0.01$) in neonates (5 [83%] of 6) and infants (7 [39%] of 18) than in children (3 [8%] of 36), respectively. Two infants in our early experience had surgical resection with excellent results. Three patients had no discrete narrowing but had normal arm blood pressure and had no intervention. The remaining 10 patients had repeat balloon angioplasty with reduction in peak gradient from 52 ± 13 to 9 ± 8 mm Hg ($p < 0.001$). Reexamination 31 ± 18 months after repeat angioplasty revealed a residual gradient of 3 to 19 mm Hg (mean 11 ± 6). Three (5%) of 58 patients who underwent follow-up angiography developed an aneurysm. Detailed evaluation of the femoral artery performed in 51 (88%) of 58 patients at follow-up catheterization revealed patency of the femoral artery in 44 (86%) of 51 patients. Femoral artery occlusion, complete in three (6%) and partial in four (8%), was observed, but all had excellent collateral flow. Blood pressure, echocardiography–Doppler ultrasound and repeat angiographic or magnetic resonance imaging data 5 to 9 years after angioplasty revealed no new aneurysms and minimal (2%) late recoarctation.**

Conclusions. **On the basis of these data, it is concluded that balloon angioplasty is safe and effective in the treatment of native aortic coarctation; significant incidence of recoarctation is seen in neonates and infants; repeat balloon angioplasty for recoarctation is feasible and effective; and the time has come to consider balloon angioplasty as a therapeutic procedure of choice for the treatment of native aortic coarctation.**

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Since the initial description of transluminal balloon angioplasty of native aortic coarctation in the early 1980s, several groups of workers have used this technique in the treatment of aortic coarctation. However, there is a considerable controversy among cardiologists and surgeons with regard to whether the native aortic coarctations should be balloon dilated or surgically treated. Some workers (1–8) advocate balloon angioplasty, but others (9–11) recommend against it. The recommendations in favor of using balloon angioplasty have been further clouded by reports of development of aneurysms at the site of coarctation dilation (12,13). The majority of the published reports are based on immediate and short-term results. Absence of long-term (greater than 5 years) follow-up, inadequate evaluation of femoral arterial patency at follow-up and lack of actuarial analysis of the data have plagued many of the published reports. The purpose of this study is to report on a large series of patients undergoing balloon coarctation angioplasty with emphasis on examination of issues just mentioned in an attempt to evaluate objectively the usefulness of balloon angioplasty in the treatment of native aortic coarctations.

Subjects and Methods

Study subjects. During an 8.7-year period ending September 1993, 67 infants and children underwent balloon angioplasty; 30 of these procedures were performed at King Faisal Specialist Hospital and Research Center, Riyadh, Saudi Arabia between February 1985 and December 1987, and 37 had

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balloon dilation at the University of Wisconsin Children's Hospital, Madison, Wisconsin, between September 1987 and September 1993. Ten additional patients with aortic coarctation seen during this period did not undergo balloon angioplasty because they required ductal ligation and banding of the pulmonary artery along with relief of aortic obstruction (five infants), the coarcted aortic segment was atretic (three infants) or long (one infant), or femoral arterial artery access was not accomplished (one infant). Immediate and short-term results of 52 of the 67 patients have been included in our previous publications (1–4). Informed consent was obtained from the parents of each child. The indications for balloon angioplasty were congestive heart failure or hypertension or both, not controlled by conventional medical management.

Balloon angioplasty technique. The technique of balloon angioplasty of aortic coarctation and data acquisition before and following angioplasty have been described in detail in our previous publications (1–3,14,15) and are not described here except to point out some important technical aspects of the procedure. 1) A dose of 100 U/kg body weight of heparin (maximum 2,500 U) was administered before introduction of the balloon angioplasty catheter; the heparin was neither continued nor its effect reversed after balloon angioplasty. 2) The size of the balloon chosen for angioplasty was two or more times the size of the coarcted aortic segment but no larger than the descending aorta at the level of diaphragm. We selected a balloon size that is midway between the size of the aortic isthmus (or transverse aortic arch) and the size of the descending aorta at the level of diaphragm. If there was not adequate relief of obstruction (pressure gradient reduction to <20 mm Hg and angiographic improvement), a balloon as large as the diameter of the descending aorta at the level of diaphragm was chosen for additional dilation. 3) Pressure of balloon inflation was monitored, and attempt was made not to exceed that stated by the manufacturer. 4) At no time were the tips of a catheter or guide wire manipulated over the area of freshly dilated coarctation of the aorta.

The balloon angioplasty procedure was performed percutaneously through the right or left femoral artery in all but two neonates; the latter two underwent the procedure through their umbilical arteries (16).

Follow-up. Follow-up included clinical evaluation (including arm and leg cuff pressures) and echocardiographic–Doppler ultrasound studies at 1 day and 3, 6 and 12 months after balloon angioplasty and yearly thereafter. Cardiac catheterization and aortography were performed 4 to 12 months after angioplasty; in some cases it was performed at a longer interval if it had not been performed by 12 months after angioplasty. During cardiac catheterization, assessment of the status of the femoral artery on the side of balloon angioplasty was attempted in addition to evaluation for residual or recurrent coarctation and aneurysms at the site of balloon angioplasty. Magnetic resonance imaging or repeat aortographic studies were also performed 24 to 90 months after angioplasty.

Statistical methods. Results are expressed as mean value ± SD for continuous, normally distributed variables. Median values and ranges are given for data with skewed distribution. Comparison between values before and after balloon angioplasty was made by two-tailed *t* tests, and comparison between groups was performed by analysis of variance. Categoric variables were compared using chi-square or Fisher exact tests. Analysis of event-free survival rates was carried out by the Kaplan-Meier method. The level of statistical significance was set at $p < 0.05$. When multiple comparisons were made, the Bonferroni correction was applied.

Table 1. Associated Congenital Heart Defects*

Defect	No. of Patients
Patent ductus arteriosus	2
Ventricular septal defect	11
Bicuspid aortic valve	11
Aortic stenosis	9
Aortic insufficiency	5
Subvalvar membranous aortic stenosis	4
Atrial septal defect	3
Systemic venous anomalies†	2
"Hypertensive cardiomyopathy"	2
Double-inlet left ventricle	1
Hypoplastic left heart syndrome	1
Atrioventricular canal with severe right-sided dominance	1
Sequestration of right lower lobe	1
No associated defects	17

*Turner's syndrome was present in two children. †Persistent left superior vena cava and infrahepatic interruption of the inferior vena cava with azygous continuation.

Results

Study subjects. Sixty-seven children (47 boys, 20 girls; mean [±SD] weight 15.7 ± 14.1 kg, median 11, range 2.1 to 60) underwent cardiac catheterization and balloon angioplasty for aortic coarctation during an 8.7-year period preceding September 1993. They ranged in age from 2 days to 15 years (mean age 3.9 ± 4.3). Ten were neonates (≤30 days old), 20 were infants between 1 and 12 months old and the remaining 37 were children between 1 and 15 years old. Other cardiac defects were present in 50 (75%) of 67 patients (Table 1). No infant had undergone a previous operation for aortic coarctation or previous balloon angioplasty. Twenty-one of the 30 infants <1 year old had moderate to severe heart failure, and all but 9 were hypertensive, defined as arm blood pressure greater than 95th percentile for the age.

Immediate results. The peak-to-peak systolic pressure gradient decreased ($p < 0.001$) from 46 ± 17 (mean ± SD) to 11 ± 9 mm Hg after angioplasty for the entire group (Fig. 1). Significant ($p < 0.001$) pressure gradient reduction was observed in each group (neonatal: 34 ± 11 vs. 4 ± 5 mm Hg; infants: 47 ± 15 vs. 14 ± 8 mm Hg; children: 48 ± 21 vs. 11 ± 9 mm Hg). The diameter of the coarcted aortic segment increased ($p < 0.001$) from 3.5 ± 1.8 to 7.6 ± 3.1 mm for the

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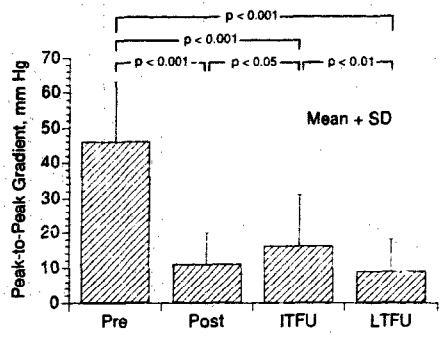

Figure 1. Immediate and follow-up results after balloon angioplasty for aortic coarctation. Peak-to-peak systolic pressure gradients across the coarctation (mean + SD) are shown. Note significant ($p < 0.001$) drop in the gradient after angioplasty (Post). The gradient increases ($p < 0.05$, not significant when Bonferroni correction was applied) slightly at a mean follow-up of 14 months (range 4 to 56). However, these values are lower ($p < 0.001$) than those before angioplasty (Pre). At late follow-up (LTFU), 6 months to 9 years (median 5 years) after balloon angioplasty, blood pressure–measured arm–leg peak pressure difference is lower than catheterization-measured peak gradients before ($p < 0.001$) balloon angioplasty and those obtained at intermediate-term follow-up (ITFU) ($p < 0.01$).

entire group. Significant improvement ($p < 0.001$) was seen in each age subgroup. No patient required immediate surgical intervention. Further details on immediate results can be found in our previous reports (1–4,14).

Initial mortality. There was no initial mortality, defined as death within 30 days of the procedure in the infant and children groups. One neonate with double-inlet left ventricle, L-transposition of the great arteries, no pulmonary stenosis and severe obstruction at the bulboventricular foramen (this was not recognized at the time of catheterization and balloon angioplasty) died 2 days after balloon angioplasty while awaiting surgical palliation. No autopsy was available, but it was thought that the cause of death was most likely related to a rapid fall in pulmonary vascular resistance in the setting of bulboventricular foramen obstruction, causing low systemic output. Thus, the initial mortality rate was 1.5% (1 of 67) for the entire group and 10% (1 of 10) for the neonatal group.

Complications. Significant blood loss occurred in 13 children (during catheter/guide wire exchanges), requiring blood transfusion. Four of these children had low hemoglobin (9.6 to 10.2 g%) before the procedure, which was partly responsible for the need for transfusion. The children requiring transfusion were 2.1 ± 4.1 years old, and those who did not need transfusion were 3.9 ± 4.3 years old ($p > 0.1$). The need for transfusion has decreased in more recent cases, related to better designed catheter/guide wire exchange systems. Decreased femoral pulses with a cool extremity on the side used for angioplasty occurred in 13 patients. The age of the children with a diminished pulse was 34 ± 48 months, not significantly different ($p > 0.1$) from that (53 ± 54 months) of the children with a normal pulse after balloon angioplasty. Warming of the contralateral extremity alone (in six children) and additional administration of low-molecular weight dextran or heparin (in six children) were undertaken with improvement in circulation within several hours of the procedure. The remaining 8-year old child, because of persistence of decreased perfusion, underwent thrombectomy, followed by improvement. Four children complained of tightness in the chest during balloon inflation. There was no recurrence of this complaint. Elevated blood pressure, forme fruste postcoarctectomy syndrome, requiring no more than a single dose of antihypertensive medication occurred in three children.

Late mortality. There were three late deaths >30 days after balloon angioplasty. The first neonate with a large ventricular septal defect died at home 2 months after angioplasty, before the scheduled appointment for surgical correction. Sepsis was thought to be the cause of death by the local physician. The other two neonates died after surgical palliation of forme fruste hypoplastic left heart syndrome, 5 and 6 weeks after balloon angioplasty, respectively. There were no late deaths in the infant and children groups. Thus, the late mortality rate was 4.5% (3 of 66) for the entire group and 33% (3 of 9) for the neonatal group.

Intermediate-term follow-up results. Follow-up catheterization and angiography were performed in 58 patients 4 to 56 months (mean 14 ± 11 months) after balloon angioplasty. There were four deaths (see initial and late mortality sections), three patients were lost to follow-up, and it was too soon after angioplasty to warrant catheterization in the remaining two patients. Residual gradients across the previously dilated aortic coarctation was calculated by combining the catheterization-derived peak-to-peak systolic pressure gradients in 53 children with arm and leg cuff peak systolic pressure difference in the remaining 2 children who did not undergo recatheterization (total n = 60). The residual gradients were 16 ± 15 mm Hg; these continue to be lower ($p < 0.001$) than those before balloon angioplasty and slightly higher ($p < 0.05$; not significant when Bonferroni correction was applied) than the gradients immediately following angioplasty (Fig. 1). Angiographically measured coarcted segments in 58 children (mean 8.1 ± 3.8 mm) remained improved ($p < 0.001$) compared to preangioplasty measurements but unchanged ($p = 0.44$) compared to immediate postangioplasty diameters.

Recoarctation. Residual and recurrent obstructions cannot be easily distinguished from each other, and the term "recoarctation" is used to describe both of these entities and is defined as a peak-to-peak systolic pressure gradient in excess of 20 mm Hg with or without angiographically demonstrated narrowing (17). Although there is only a modest increase (11 ± 9 vs. 16 ± 15 mm Hg; $p < 0.05$) in peak gradients and no change in balloon-dilated coarcted aortic segments (7.6 ± 3.2 vs. 8.1 ± 3.8 mm, $p = 0.07$) when follow-up values are compared with immediate postangioplasty data as a group, scrutiny of individual values revealed a significant incidence of recoarctation in 15 (25%) of the 60 patients (Fig. 2). The incidence of recoarctation is higher in the neonates (5 [83%] of

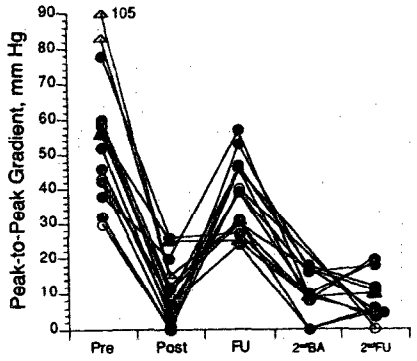

Figure 2. Peak-to-peak systolic pressure gradients across the aortic coarctation in 15 patients who had restenosis after balloon angioplasty. Although the initial (Pre) gradient decreased immediately after balloon angioplasty (Post), it returned toward preangioplasty values at follow-up catheterization (FU) a mean of 10 months later (range 4 to 26, median 9). Repeat balloon angioplasty (2nd BA) again showed reduction in the gradient. Blood pressure–measured gradients at further follow-up (2nd FU) 31 ± 18 months later (range 10 to 64) showed sustained improvement. **Solid circles** = patients who underwent repeat balloon angioplasty at intermediate-term follow-up; **solid triangles** = balloon angioplasty during late follow-up; **open circles** = operation at intermediate-term follow-up; **open triangles** = operation at late follow-up.

6, $p < 0.001$) and infants (7 [39%] of 18, $p = 0.011$) than in children (3 [8%] of 36).

Causes of recoarctation. On the basis of individual results at recatheterization, 58 patients were divided into two groups: group I, with good results, defined as peak-to-peak systolic pressure gradient ≤20 mm Hg and no angiographically demonstrated narrowing; and group II, with poor results secondary to recoarctation defined in the section on "recoarctation" (17). Thirty variables (listed in our previous report on this subject [17]) were examined by multivariate logistic regression analysis to identify factors responsible for recoarctation in a manner similar to that described elsewhere (17): The identified risk factors (Table 2) are essentially similar to those observed in our initial study (17). The younger the age and smaller the diameter of the aortic isthmus, the preangioplasty coarctation segment and the postangioplasty coarctation segment, the greater is the chance for recoarctation.

Management of recoarctation. Early in our experience, two patients underwent surgical resection with good result. Three children did not have discrete narrowing (had isthmus narrowing), and no systemic hypertension was present. No treatment was recommended. They are followed by periodic clinical evaluation (see Late follow-up). The remaining 10 patients underwent repeat balloon angioplasty (Fig. 2). In these 10 children, the initial peak-to-peak gradients were 52 ± 13 mm Hg (range 32 to 78) and were reduced ($p < 0.001$) to 9 ± 8 mm Hg by initial balloon angioplasty. At follow-up catheterization performed 9.5 ± 6.2 months (range 4 to 26) later, the gradients increased significantly ($p < 0.001$) to 39 ± 11 mm Hg (range 24 to 57). Repeat balloon angioplasty (4 to 26 months after initial angioplasty) reduced ($p < 0.001$) the gradients to 10 ± 6 mm Hg (range 0 to 18). Peak gradients 31 ± 18 months (range 10 to 64) after repeat angioplasty remained low (11 ± 6 mm Hg, $p = 0.5$).

Aneurysms. The follow-up angiograms were scrutinized for aneurysm formation at the site of balloon angioplasty in a manner described by Bromberg et al. (18) and Pinzon et al. (19). A total of 3 aneurysms were observed, giving an incidence of 5% (3 of 58).

In two children the aneurysms were small, and during a 1- and 4-year follow-up, respectively, no further increase in the size of the aneurysm was noted. The third child had a moderate-sized aneurysm (Fig. 3) and underwent successful surgical resection.

Femoral artery complications. The data at follow-up catheterization were scrutinized for femoral artery complications. Following retrograde left heart catheterization was undertaken in 20 patients via the same femoral artery through which the initial balloon angioplasty had been performed. This ipsilateral femoral artery catheterization at follow-up was considered evidence for patency of the femoral artery. Contralateral femoral artery was used at the time of follow-up study in 36 patients. In 29 of these patients, descending aortography with angiographic visualization of the femoral artery initially used for balloon angioplasty (Fig. 4A) was performed. In two patients in whom umbilical artery was initially used for balloon angioplasty, right femoral artery was

Table 2. Results of Logistic Regression Analysis Utilizing 30 Variables*

	Group I (n = 43)	Group II (n = 15)	p Value: *t* Test	p Value: Logistic Regression
Age at angioplasty (mo)	60 ± 50	17 ± 31	0.004	0.014
Size of isthmus (mm)	10.0 ± 3.9	6.3 ± 2.4	0.001	0.006
Size of coarcted segment (mm)				
Before angioplasty	4.2 ± 1.9	2.5 ± 0.7	0.001	0.01
After angioplasty	8.6 ± 3.1	5.7 ± 1.9	0.001	0.006

*Only variables found to be significantly different are presented. Data presented are mean value ± SD, unless otherwise indicated.

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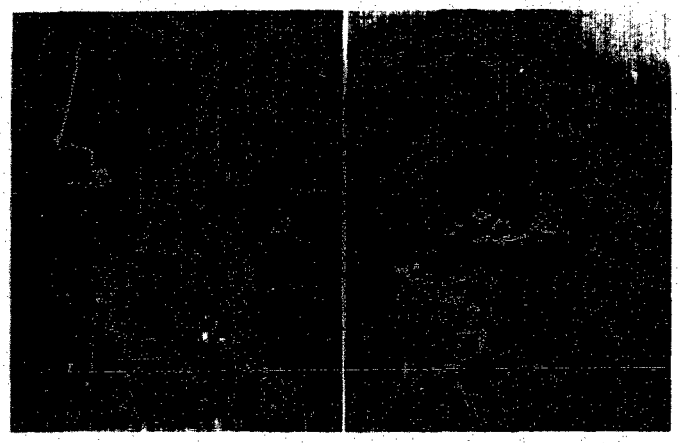
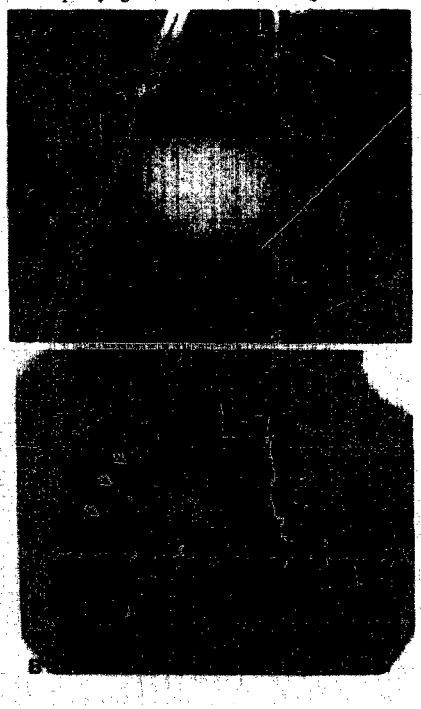


Figure 3. Selected cineangiographic frames in posteroanterior (**a**) and left anterior oblique (**b**) views demonstrating an aneurysm (**arrow**) on angiographic study performed 24 months after balloon angioplasty. This patient underwent surgical resection.

used for restudy. Thus, 51 (88%) of 58 had their femoral arteries evaluated for patency. Forty-four (86%) of 51 femoral arteries were patent at follow-up. Partial blockage was observed in 8% (4 of 51), and complete blockage (Fig. 4B) in 6% (3 of 51) of patients. Good collateral circulation was visualized (Fig. 4b), and the children did not complain of claudication. Data on limb growth abnormalities are not available at this time.

Figure 4. Selected frames from descending aortograms while filming femoral arteries. Balloon angioplasty had been performed through the right femoral artery 1 year before this study in both children. The catheters (c) were introduced through the left femoral artery, and the tip of the catheter was positioned in the lower part of the abdominal descending aorta (not shown). Note good opacification of the right iliac and femoral arteries (**A**) in a patient without blockage of the femoral artery. In another child (**B**), note complete blockage of the femoral artery (**open arrows**). Also note good collateral circulation (**arrowheads**) opacifying the distal femoral artery.



The femoral artery complications appear to occur more frequently in the neonatal and infant group (4 [21%] of 19) than in the children (3 [9%] of 32), but this was not statistically different ($p = 0.24$). The femoral artery occlusions seen at follow-up do not seem to have consistent relation with decreased perfusion seen immediately after balloon angioplasty; four femoral artery occlusions occurred in patients in whom there was no evidence for decrease in perfusion immediately after angioplasty, and in the remaining three patients the leg perfusion abnormalities were seen immediately after angioplasty. In seven patients in whom there was perfusion deficiency immediately after angioplasty, the femoral arteries were patent at follow-up.

Late follow-up. *Late interventions.* Three children with evidence for recoarctation at the time of intermediate-term follow-up in whom no intervention was recommended developed hypertension, and their coarctation gradients increased further. Two of these children underwent surgical repair 60 and 87 months following initial balloon angioplasty, respectively. The third child underwent repeat balloon angioplasty 72 months after balloon angioplasty. One additional child who did not have evidence for recoarctation at the intermediate-term follow-up developed recoarctation (peak-to-peak gradient 34 mm Hg) 60 months after angioplasty. This child underwent repeat balloon angioplasty successfully. Thus, an additional 2% (1 of 60) developed late recoarctation. Another patient had patent ductus arteriosus with left to right shunt. This ductus was present before and immediately after balloon angioplasty and was occluded with a Rashkind occluder (USCI) 7 years after balloon angioplasty.

Blood pressures and gradients. Data on measured blood pressure gradient at the last follow-up clinical examination (6 months to 9 years, median 5 years) were available in 60

patients, and the residual gradient was 9 ± 9 mm Hg (Fig. 1). Right arm systolic blood pressure measured at last follow-up clinical examination was plotted on age- and gender-specific percentile graphs developed by the Second Task Force on Blood Pressure Control in Children (20). Fourteen (23%) of 60 children plotted above 95th percentile, and 58 (87%) of 67 were hypertensive before balloon angioplasty ($p < 0.001$). The age at initial balloon angioplasty (6.2 ± 4.7 years) for these 14 hypertensive children was slightly greater than the age of the remaining patients (3.9 ± 4.2 years), but this did not attain statistical significance ($p = 0.086$).

Doppler studies. Doppler peak flow velocity in the descending aorta at follow-up (6 months to 9 years) was 2.5 ± 0.7 m/s, which does not represent a significant ($p = 0.361$) change from the immediate postangioplasty value (2.6 ± 0.5 m/s) but remains improved ($p < 0.001$) compared with the preangioplasty value of 3.6 ± 0.7 m/s. Similarly, Doppler calculated instantaneous peak gradients across the coarctation site were 21 ± 13 mm Hg, not significantly different ($p = 0.164$) from those seen immediately after balloon angioplasty (24 ± 11 mm Hg) but lower ($p < 0.001$) than preangioplasty gradients (50 ± 19 mm Hg).

Aortograms and magnetic resonance imaging. Magnetic resonance imaging of the arch of the aorta or aortography, or both (≥2 years after balloon angioplasty) was performed in 34 patients at a mean of 4 years (range 24 to 90 months) after the initial balloon angioplasty. Two or more such studies in the same patients were available for review in 28 patients at a mean interval between studies of 41 months. No additional patients developed aneurysms at the site of previous balloon angioplasty.

Event-free survival rates. Interventions related to treatment of recoarctation, aneurysm formation or patent ductus arteriosus are treated as events, and event-free survival curves are calculated for each of the neonatal, infant and children subgroups and are depicted in Figure 5. As can be seen, the event-free survival rates are better ($p < 0.001$) for the children than for infants and certainly for neonates.

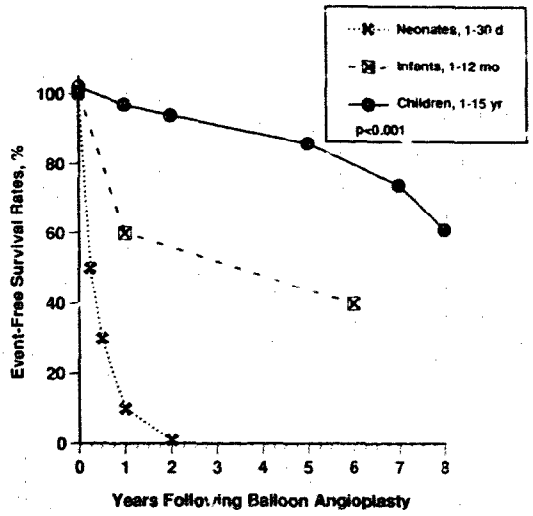


Figure 5. Actuarial event-free survival curves of neonates (<30 days old), infants (1 to 12 months old) and children (1 to 15 years old) undergoing balloon angioplasty for treatment of aortic coarctation. Note that event-free survival rates are better for children than for the neonatal and infant groups.

Discussion

Sos et al. (21) demonstrated that the coarcted aortic segments could be balloon-dilated in a neonate postmortem. Lock et al. (22,23) extended these observations and showed that surgically excised coarcted aortic segments and experimentally created coarctations in lambs could be opened up by balloon angioplasty. Clinical application in human subjects followed. On the basis of initial poor results (24) and development of aneurysms after balloon angioplasty (12,13), some workers (9–11) questioned the utility of this procedure in native aortic coarctation. Despite an initial report of poor results (24), subsequent experience with balloon angioplasty of native coarctations (1–8,10,25–28) appears encouraging. Because of these differing experiences and recommendations, we felt that a review of our, reasonably large-sized experience with emphasis on late follow-up results and complications is in order in an attempt to determine the role of balloon angioplasty in the treatment of native coarctations.

Immediate results. Reduction of pressure gradient across the aortic coarctation and improvement in symptomatology in this group of patients are similar to that observed by other workers (5–8,10,11,25–28). Particularly noted beneficial effects in neonates and infants were rapid control of congestive heart failure and our ability to wean the infants from ventilatory support.

Initial and late mortality. Both the initial and late mortality seen in this group of patients appear to be secondary to associated cardiac defects and are unlikely to be related to the balloon angioplasty (29).

Intermediate-term follow-up results. *Gradient reduction.* Peak systolic pressure gradients fell at short-term follow-up for the group as a whole, and reduction in gradient is similar to that reported by others (5–8,26–28).

Recoarctation. When individual results are scrutinized, recoarctation, defined as peak-to-peak gradients >20 mm Hg, occurred in 25% of patients. The recoarctation rate was higher in neonates and infants than in children.

Repeat balloon angioplasty for recoarctation was successful in 10 children in whom we opted for repeat procedure. This response is similar to that observed in eight children by Lababidi (28). Further follow-up at a mean of 31 months revealed continued relief of obstruction.

The causes of recoarctation were investigated in a manner similar to that performed in our previous investigation (17) utilizing a subset of these study subjects. Four risk factors were identified and include 1) age, 2) size of aortic isthmus, 3) size

of coarcted aortic segment before dilation, and 4) size of coarcted aortic segment after angioplasty. The younger the child and smaller the size of the aortic isthmus and coarcted segment (both before and after angioplasty), the greater is the chance for recoarctation.

Aneurysms. The incidence of aneurysms at the site of angioplasty is 5% in our study subjects and is similar to that observed by some workers (6–8,25–28,30) but is lower than that seen by other investigators (12,13). The reasons for these differences in incidence are not clear. We may postulate that development of aneurysms may reflect the use of large balloon, inadvertent manipulations of catheters or guide wires in the region of freshly dilated aortic coarctation, and misinterpretation or overinterpretation as possible causes. The observation of Isner et al. (31) of severe depletion and disarray of elastic tissue (cystic medial necrosis) in two-thirds of resected aortic coarctation segments may give a pathologic basis for development of aneurysms. However, such findings may be seen in the normal aorta (32). In addition, these findings have not been supported as a cause of aneurysmal formation by the studies of other workers (33).

Should aneurysms develop, they may potentially increase the risk of aortic dissection in women during pregnancy.

Although development of aneurysms after balloon angioplasty is of concern, they are also known to occur after coarctation surgery of all types. Development of late aneurysms is best documented after repair with synthetic onlay patch grafts (18,34–38); the prevalence seems to vary between 11% and 24%. Occurrence of aneurysms following resection and end-to-end anastomosis and subclavian flap angioplasty is also documented (19,39). In an excellent study, Pinzon et al. (19) reviewed 215 aortograms performed 4.2 ± 4.1 years after surgical repair of coarctation of the aorta and found a 30% (64 of 215) incidence of aneurysms, defined as the ratio >1.5 of the repair site to the descending aorta at the level of diaphragm. The aneurysms consisted of diffuse enlargement in 20 patients, focal anterior bulges in 24 patients and focal posterior bulges in 20. The incidence of aneurysms was similar in all three types of commonly used repair methods: 27% (26 of 97) with resection and end-to-end anastomosis, 32% (29 of 92) with subclavian flap repair and 35% (9 of 21) with synthetic onlay patch repair. These data clearly show that aneurysms do occur after all types of coarctation repair and that their prevalence is significant. However, the exact incidence is not known because only 27% of the patients undergoing coarctation repair during the study period were studied by aortography (19).

Based on these data, it can be stated that aneurysms after therapy for aortic coarctation are not unique for the balloon procedure but can and do occur after operation. Causes and natural history of these aneurysms should be scrutinized in future studies, but formation of aneurysm should not be a deterrent for use of balloon angioplasty in the treatment of native aortic coarctations.

Femoral artery occlusion. In the present study we evaluated the femoral artery status at follow-up catheterization and found blockage in 14% (complete in 8% and partial in 6%) of the femoral arteries used for balloon angioplasty. However, there was good collateral flow. Use of smaller sized and low-profile balloon catheters may reduce the femoral artery complication rate. When feasible, use of the umbilical artery approach (16) should be considered in the neonate, and this will certainly spare the femoral arteries. Longer term follow-up than is currently available along with measurements (length and circumference relative to the contralateral extremity) of lower extremity used for angioplasty may be necessary to further evaluate long-term adverse effects of balloon angioplasty.

Comparison with operation. There are scanty data comparing balloon angioplasty procedure with surgical intervention. The available data are reviewed. In an attempt to compare safety and efficacy of balloon angioplasty with surgical correction of aortic coarctation, we scrutinized 49 studies (published during 1980 to 1991) reporting on results of operation in infants <1 year old and 9 studies reporting on the results of balloon angioplasty and compared them (4,14). Shaddy et al. (40) prospectively randomized 36 patients 3 to 10 years old to either balloon angioplasty (20 patients) or operation (16 patients) to compare their relative efficacies. We (29) compared efficacy and safety of balloon angioplasty with surgical correction in infants ≤3 months old.

On the basis of these reviews (4,14,29,40), it appears that effectiveness of balloon angioplasty is comparable to that of operation; mortality rates are similar (and are probably related to the associated cardiac defects and not to the type of intervention performed), and morbidity and complication rates are lower with balloon than with surgical therapy. Thus, it may be suggested that balloon angioplasty is an effective alternative to operation for relief of aortic coarctation.

Some of the complications, namely, recoarctation, aneurysm formation and femoral artery compromise, were discussed earlier. Other complications such as paraplegia (41,42) and paradoxic hypertension (41,43–45) are seen with significant frequency after surgical repair, but such complications are either rare or, if present, very mild and inconsequential after balloon angioplasty.

Late follow-up. Despite the problems of recoarctation and aneurysms, some requiring repeat intervention at intermediate-term follow-up, the late follow-up results (5 to > years) appear encouraging in that there was minimal (2%) incidence of late recoarctation and no late aneurysm formation. In the majority of children, the arm blood pressure remained normal. Although these are encouraging results, longer term, 15- to 20-year follow-up is necessary to reaffirm the usefulness of balloon angioplasty in the treatment of aortic coarctation.

Comments and conclusions. The data from the present study and those reviewed in published reports show that balloon angioplasty is an effective procedure in relieving obstruction caused by native aortic coarctation and the attendant symptoms. The mortality and complication rates after balloon angioplasty are not high, and therefore, the procedure may be considered safe. There is a significant incidence of recoarctation in the neonate and young infant, but the impor-

tant feature of balloon angioplasty in the neonate and young infant is that it produces abatement of symptoms of heart failure and hypertension and helps to avoid immediate operation. Should recurrences occur, it can be treated by repeat balloon angioplasty or even surgery, if one prefers, when the infant is stable and less acutely ill. Development of aneurysms at the site of balloon angioplasty is of concern, and a patient who develops an aneurysm should be followed up with periodic evaluation of its size, or surgical resection should be performed. Aneurysms, though of concern, have also been seen after all varieties of surgical correction. Comparison with operation, though limited, has suggested similar mortality and recurrence rates but with less morbidity in the balloon group than in the surgical group. With fewer days in-hospital, the cost of management with balloon angioplasty is likely to be lower.

In conclusion, the data presented and those reviewed from the published reports show that balloon angioplasty is effective in relieving aortic obstruction with an acceptable complication rate and in many respects compares favorably with surgical repair. On the basis of these data, we conclude that balloon angioplasty is an effective and safe alternative to surgical therapy of native aortic coarctation.

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