Comparison of Angioplasty and Surgery for Unoperated Coarctation of the Aorta

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Background. The use of balloon coarctation angioplasty instead of surgery as treatment for unoperated coarctation of the aorta is controversial. The efficacy and complications of the two procedures have not been studied before in a prospective fashion.

Methods and Results. Thirty-six patients were prospectively randomized to either angioplasty (20 patients) or surgery (16 patients). Immediate results and patient follow-up, including physical examination, angiograms, and magnetic resonance imaging, were compared between groups. Reduction in peak systolic pressure gradient across the coarctation was similar (86%) immediately after both balloon coarctation angioplasty and surgery. On follow-up, aneurysms were seen only in the angioplasty group (20%) and not in the surgery group (0%). No aneurysms have shown progression or required surgery. The incidence of other complications was similar in both groups, although two patients experienced neurological complications after surgery. Although not statistically different, the incidence of restenosis (peak systolic pressure gradient ≥20 mm Hg) tended to be greater in the angioplasty group (25%) than in the surgery group (6%). Restenosis after angioplasty occurred more frequently in patients with an aortic isthmus/descending aorta diameter ratio <0.65 and was associated with an immediate catheterization residual peak systolic pressure gradient across the coarctation ≥12 mm Hg.

Conclusions. Immediate gradient reduction is similar after balloon coarctation angioplasty and surgical treatment of unoperated coarctation of the aorta. The risks of aneurysm formation and possibly restenosis after angioplasty are higher than after surgery, although the risks of other complications are similar. Balloon coarctation angioplasty may provide an effective initial alternative to surgical repair of unoperated coarctation of the aorta in children beyond infancy, particularly in patients with a well-developed isthmus. Further follow-up is necessary to determine the long-term risks of postangioplasty aneurysms. (Circulation 1993;87:793–799)

Key Words • coarctation • balloon angioplasty • aneurysm • congenital heart surgery

Balloon dilation of unoperated congenital left-sided obstructive cardiac lesions has replaced surgery in many instances. Balloon valvuloplasty for congenital aortic stenosis is considered by many to be the treatment of choice to relieve obstruction.1–3 Similarly, balloon valvuloplasty for congenital mitral stenosis may have distinct advantages over surgery.4 In contrast, the utility of balloon coarctation angioplasty for treatment of unoperated coarctation of the aorta remains controversial. Some authors have advocated angioplasty for unoperated coarctation as the treatment of choice in neonates as well as older children,5–8 whereas others have refrained from using angioplasty in this clinical setting because of concerns about restenosis and aneurysm formation.9 These and other studies have reported results after angioplasty for both unoperated and postoperative coarctation of the aorta.10–12 Although long-term results are unknown, intermediate-term follow-up has generally been very good.13–15 Concerns regarding aneurysm formation in 0–43% of patients after angioplasty in unoperated coarctation have tempered initial enthusiasm for this technique.6,13–15 However, postoperative aneurysms have also been reported in patients undergoing surgical repair of unoperated coarctation of the aorta.16–18 Thus, to compare the efficacy and safety of these two modes of treatment, we devised a prospective, randomized study comparing balloon coarctation angioplasty and surgical treatment of unoperated coarctation of the aorta.

Methods

Between August 1985 and November 1990, all patients between the ages of 3 and 10 years who were seen at Primary Children’s Medical Center with the clinical diagnosis of hemodynamically significant unoperated coarctation of the thoracic aorta were offered enrollment in a study comparing angioplasty and surgical treatment of coarctation of the aorta. All patients who presented with a diagnosis of coarctation of the aorta after the age of 3 years were offered enrollment in the study at that time. Those patients who presented before the age of 3 years who were asymptomatic were offered enrollment in the study after 3 years of age. This study

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Received May 12, 1992; revision accepted November 19, 1992.
was approved by the Institutional Review Board of Primary Children's Medical Center, and informed consent was obtained from parent or guardian before enrollment in the study. Associated cardiac lesions could be present so long as the coarctation was considered to be the most significant problem at the time. Exclusion criteria included connective tissue disorder, Turner's or Noonan's syndrome, suspected bacterial endocarditis, previous surgery involving the aorta, and a coarcted segment of aorta >1 cm in length. During this time, 36 patients were enrolled in the study. The parents of 10 additional patients refused enrollment, and the patients underwent surgical repair of the coarctation. Because these 10 patients were not enrolled in the study, they are excluded from further analysis. Each patient was assigned to a treatment group through a random drawing with equal probability of receiving either treatment.

After enrollment in the study, percutaneous femoral artery and vein puncture and catheterization were performed by standard techniques. Heparin (100 units/kg) was administered after arterial cannulation. The pressure gradient across the coarctation was determined, and an aortogram was performed in biplane long-axis views. The anatomy was assessed and measured with in situ calibration. The patient was then randomly assigned to either angioplasty or surgery. If the patient was randomized to surgery, the catheterization was completed, and the patient was electively scheduled for surgery. If the patient was randomized to angioplasty, the smallest diameter of the uninvolved thoracic aorta proximal to the coarctation was measured, and this measurement was used to determine the size of the balloon angioplasty catheter to be used. In all patients, the smallest diameter of the uninvolved thoracic aorta was the aortic diameter near the origin of the left subclavian artery. The balloon catheter diameter closest to the size of this measurement was initially chosen. The patient was then administered propranolol (0.025 mg/kg i.v.) or, more recently, labetalol (0.5–0.75 mg/kg i.v.) in two or three divided doses.

Angioplasty was performed by techniques similar to those previously described. The angioplasty balloon was positioned across the coarctation and inflated with dilute contrast through a pressure manometer and under fluoroscopic visualization. The inflation was continued until the indentation caused by the coarctation was eliminated or until a maximal inflation pressure of 5–7 atm was reached. If the residual peak systolic pressure gradient exceeded 8 mm Hg, a balloon of the next larger size was inserted, and the angioplasty was repeated. If pedal pulses were not palpable or easily audible by Doppler examination within 4 hours after angioplasty, the patient was administered heparin (50–100 units/kg i.v.) and started on a continuous intravenous infusion of heparin (20–60 units/kg/hr) to maintain the venous partial thromboplastin time at 1.5–2 times control. After discharge from the hospital, patients received oral propranolol (1 mg/kg every 6–8 hours) for 6 weeks. In the surgical group, 13 patients had resection of the coarcted segment with end-to-end anastomosis, two had placement of an interposition graft, and one patient had Gore-Tex patch repair of coarctation. All surgical patients received treatment for postoperative hypertension with intravenous antihypertensive medications.

Follow-up outpatient evaluation was performed initially 2–6 weeks after angioplasty or surgery and then routinely as needed. One year after the procedure, the parents or guardians were asked to allow the investigators to perform a repeat aortic catheterization and aortogram to assess the residual pressure gradient and angiographic appearance of the repaired coarctation site. In those who refused angiography, a magnetic resonance imaging (MRI) scan was performed. All aortograms and MRI studies were examined for evidence of aneurysms and were interpreted by two separate investigators who were unaware of which treatment each patient had received. Aneurysms were defined according to the definition of Beekman et al6 as either a fusiform dilatation at the coarctation site with a diameter ≥150% of the aortic diameter at the diaphragm or a discrete saccular dilatation at the site that was not present at the preangioplasty aortogram. If an aneurysm was detected on follow-up aortogram or MRI, the angioplasty or preoperative aortogram was carefully reviewed to ascertain that this irregularity of the aorta was not present before treatment. Patients found to have an aneurysm underwent serial annual MRI scans to follow the progress of the aneurysm.

To determine whether aortic anatomy before angioplasty predisposes patients to the development of aneurysms or restenosis, retrospective examination of all pretreatment aortograms was performed. The average diameter of each aorta was measured by biplane angiography in the following areas as previously described by Rao and Carey19: ascending aorta beyond any poststenotic dilatation, uninvolved aortic isthmus, and descending aorta at the diaphragm. To standardize these measurements between patients, each measurement was expressed as the ratio of that measurement to the diameter of the descending aorta at the diaphragm. Pretreatment aortic measurements were compared between patients with and without aneurysms after treatment and between patients with and without restenosis after treatment.

To compare costs of each mode of treatment, the entire cost of the balloon angioplasty or surgical procedure, including all hospital and physician fees incurred by each patient during the entire hospital stay for balloon angioplasty or surgery, was tabulated for each patient.

Statistical Analysis

Comparisons between groups with regard to demographic, angiographic, ultrasonographic, hemodynamic, and financial data were made by a two-tailed Student's t test. Comparisons of categorical data between groups were made by a Fisher's exact test. Nonparametric data (follow-up residual gradients) were compared by the Mann-Whitney U test. Differences were considered statistically significant for p <0.05. All data are expressed as mean±SD unless otherwise stated.

Results

There were no significant differences between patient groups with regard to age, sex, weight, or pretreatment peak systolic pressure gradient across the coarctation (Table 1). Associated lesions were bicuspid aortic valve
in 28 patients, mild subaortic stenosis in one patient, and a tiny patent ductus arteriosus in one patient who underwent surgery. All patients had a discrete coarctation of the aorta <1 cm in length. In the angioplasty group, the measured diameter of the uninjured thoracic aorta at time of angiography was 11.9±2.2 mm (range, 9–16.5 mm). In this group, the final balloon size used was 1.1±0.1 (range, 0.9–1.3) times greater than the diameter of the uninjured thoracic aorta. Seven patients had peak systolic pressure gradients >8 mm Hg after initial angioplasty and thus underwent angioplasty with the next larger balloon.

**Gradient Reduction and Follow-up**

The immediate reduction in peak systolic pressure gradient across the coarctation was 86% after both angioplasty (43.8±15.1 to 6.2±5.9 mm Hg) and surgery (47.9±12 to 6.7±7.3 mm Hg) (Figure 1). Eighteen of 20 angioplasty patients were discharged from the hospital the day after the procedure. Two patients required 2 days of hospitalization: one patient with severe hypertension requiring intravenous antihypertensive medica-

**Restenosis**

Restenosis at the coarctation site was defined as a peak systolic pressure gradient ≥20 mm Hg at follow-up.8,15 Restenosis occurred in five patients (25%) after angioplasty (Table 2). Cardiac catheterization of these patients 19.0±10.7 months after angioplasty demonstrated a peak systolic pressure gradient across the coarctation of 26.6±8.5 mm Hg. Restenosis probably reflects a poor result from treatment, since in the angioplasty group a residual pressure gradient ≥12 mm Hg across the coarctation immediately after angioplasty was associated with restenosis on follow-up in two thirds of patients. Restenosis also occurred in one surgical patient (6%), whose catheterization systolic gradient 4 months after end-to-end anastomosis repair of coarctation was 35 mm Hg. In the angioplasty group, there were no significant differences in the pretreatment angiographic aortic measurements between patients who did develop and those who did not develop restenosis or aneurysms (Table 3). However, a small aortic isthmus was a risk factor for restenosis. Only two angioplasty patients had standardized aortic isthmus ratios <0.65, and both of these patients developed restenosis. Similarly, two surgery patients had pretreatment standardized aortic isthmus ratios <0.65, and one of these developed restenosis. In contrast to other investigators,8 we found no correlation between the incidence of restenosis and the preangioplasty gradient across the coarctation, since restenosis developed in 29% of patients with preangioplasty gradients ≥50 mm Hg and in 23% of patients with gradients <50 mm Hg.

**Table 1. Characteristics of Patients Undergoing Angioplasty or Surgery**

<table>
<thead>
<tr>
<th></th>
<th>Angioplasty (n=20)</th>
<th>Surgery (n=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>6.3±2.0</td>
<td>5.7±2.1</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>16</td>
<td>8</td>
</tr>
<tr>
<td>Female</td>
<td>4</td>
<td>8</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>21.6±8.1</td>
<td>19.5±4.8</td>
</tr>
<tr>
<td>Pretreatment gradient (mm Hg)</td>
<td>43.8±15.1</td>
<td>47.9±12.0</td>
</tr>
</tbody>
</table>

**Figure 1.** Graphs showing peak systolic pressure gradient across the coarctation measured before (pre-BCA) and after (post-BCA) angioplasty (top panel) and before (pre-surgical) and after (post-surgical) surgery (bottom panel).
Complications

The incidence of aneurysms was 20% after angioplasty, whereas no aneurysms were seen after surgery (Table 2). The aneurysms seen in the angioplasty patients were varied and ranged from fusiform in two patients (Figure 3) to saccular in two patients (Figure 4). There has been no progression of the size or extent of the aneurysms on subsequent annual MRI scans performed on all patients who demonstrated aneurysms on initial follow-up angiography. No patient has undergone surgical resection of the aneurysm.

Similar numbers of complications (excluding aneurysms) were seen in both groups of patients (Table 2). No deaths occurred in either group. In the angioplasty group, one patient developed severe hypertension and near syncope, which required intravenous hydralazine and nitroprusside. One patient had significant postangioplasty bleeding from the femoral artery, which was not treated with blood transfusion because of religious objections. Two patients had acutely diminished pulse in the leg through which the angioplasty was performed, which was successfully treated with intravenous heparin for 24 hours. In the surgery group, one patient (who had a tiny patent ductus arteriosus ligated at the time of coarctation surgery) developed transient vocal cord paralysis, which resolved with no treatment. One patient developed a paraparesis, which is improving. In this patient, the preoperative aortogram showed moderate collateral vessels, and no hypotension was noted during surgery. Two patients had postoperative bleeding, one of whom required a blood transfusion and one of whom required reexploration.

The cost of balloon angioplasty ($5,292±898) was 58% less than the cost of surgical repair ($12,478±2,455) of coarctation of the aorta ($p<0.001$).

Discussion

This prospective, randomized study compares angioplasty and surgical treatment of unoperated coarctation.

Table 2. Incidence of Restenosis, Complications, and Aneurysms After Balloon Angioplasty or Surgical Repair of Coarctation

<table>
<thead>
<tr>
<th></th>
<th>Restenosis</th>
<th>Aneurysms</th>
<th>Complications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>Angioplasty</td>
<td>5 (25%)</td>
<td>4 (20%)</td>
<td>4 (20%)</td>
</tr>
<tr>
<td>(n=20)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgery</td>
<td>1 (6%)</td>
<td>0 (0%)</td>
<td>4 (25%)</td>
</tr>
<tr>
<td>(n=16)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Two, diminished pulse</td>
<td>One, bleeding</td>
<td>One, hypertension</td>
</tr>
<tr>
<td></td>
<td>Two, bleeding</td>
<td>One, paraparesis</td>
<td>One, vocal cord paralysis</td>
</tr>
</tbody>
</table>

Table 3. Pretreatment Angiographic Standardized Aortic Measurements Comparing Angioplasty Patients With and Without Aneurysms and With and Without Restenosis

<table>
<thead>
<tr>
<th></th>
<th>No Aneurysms (n=4)</th>
<th>Aneurysms (n=16)</th>
<th>Restenosis (n=5)</th>
<th>No restenosis (n=15)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascending aorta</td>
<td>1.30±0.18</td>
<td>1.45±0.27</td>
<td>1.35±0.31</td>
<td>1.44±0.24</td>
</tr>
<tr>
<td>Aortic isthmus</td>
<td>0.84±0.09</td>
<td>0.86±0.18</td>
<td>0.80±0.23</td>
<td>0.87±0.14</td>
</tr>
<tr>
<td>Descending aorta</td>
<td>1.17±0.09</td>
<td>1.23±0.10</td>
<td>1.18±0.09</td>
<td>1.23±0.10</td>
</tr>
</tbody>
</table>
of the aorta in children 3–10 years of age. To the best of our knowledge, this study is the first to compare these two treatment modalities prospectively. The study was performed in this older age group to minimize both the risks of arterial compromise in angioplasty patients and the risks of recoarctation after end-to-end anastomotic...
repair. The optimal timing for angioplasty or surgical repair of coarctation is controversial. However, with exceptions,20 many authors continue to advocate elective surgical treatment of coarctation after 2 years of age.21,22 One major concern of angioplasty has been the incidence of aneurysm formation in patients undergoing this treatment modality. Because of the risk of aneurysm, particular attention was paid to obtaining good angiographic or MRI follow-up in both groups of patients.

In this study, aneurysms were seen only after angioplasty. The incidence and morphology of aneurysms are comparable to previous reports.8,13,14 The significance of aneurysms after balloon angioplasty is still unknown. Studies in lambs with surgically created coarctation have demonstrated intimal and medial tears early after successful balloon dilatation, with subsequent healing of the intima on late examination.23 Pathological examination of aortas from children undergoing resection of aneurysms after angioplasty has revealed a disruption or absence of muscle and elastic lamellae in the area of the aneurysms.13,24 In the present study, MRI indicated no progression in the size of the aneurysms. At this time, we have elected not to surgically resect the aneurysms but to continue to follow these patients serially for evidence of progression. However, if additional surgical intervention becomes warranted, a recent report has demonstrated the safety and efficacy of surgical repair of unsuccessful angioplasty of unoperated coarctation.25 It must be stressed that the follow-up period of this study is relatively short for determination of the natural history of aneurysms after angioplasty. Thus, long-term follow-up is essential to determine whether progressive enlargement of these aneurysms will occur. In both surgical patients with suspected aneurysms by MRI who were found not to have aneurysms by angiography, metallic clips at the coarctation repair site were felt to be responsible for the artificial aneurysms because of the ability of ferromagnetic material to create an artifact evident as a round zone of signal void.26 Care must therefore be exercised in interpreting the presence of aneurysms by MRI after surgery where metallic clips may be present.

Restenosis occurred in 25% of angioplasty patients in this study. Although there was a strong trend toward a greater incidence of restenosis in the angioplasty group (five of 20) than in the surgical group (one of 16), this difference was not statistically significant between the two groups (p = 0.15). This lack of statistical significance could certainly reflect the relatively small number of patients in this study, and thus, the incidence of restenosis could be higher in the angioplasty patients if a larger number of patients were studied. Restenosis after balloon coarctation angioplasty has been related to several factors, including a small aortic isthmus and coarcted segment, inadequate relief of coarctation demonstrated angiographically immediately after angioplasty, and young age.15 Our data suggest that if the diameter of the aortic isthmus is < 0.65 times the diameter of the aorta at the diaphragm, the risks of restenosis are significantly increased for either surgery or angioplasty. This is not unexpected, since successful angioplasty of the coarcted segment may have little effect on the aortic isthmus. Furthermore, the presence of an immediate residual pressure gradient ≥ 12 mm Hg across the coarctation was a predictor of restenosis on subsequent follow-up.

A similar number of complications occurred in our study after angioplasty and after surgery. Complications reported after balloon coarctation angioplasty have included aneurysm formation, diminished pulse requiring medication or femoral artery surgical thrombectomy, severe hypertension, cerebrovascular accident with hemiparesis, ventricular fibrillation, and death.20,22,28 The one incident of transient vocal cord paralysis in the present study was almost certainly related to surgical ligation of a tiny patent ductus arteriosus, a known complication. After angioplasty, a 10% incidence of weakened pulse at the site of angioplasty was found, which is comparable to previous reports. No patients in the surgical group had any evidence of diminished pulse at the site of catheterization. Severe hypertension is a reportedly rare complication after balloon angioplasty and was seen in only one patient. Since preangioplasty treatment with labetalol was instituted, no patients have had severe postangioplasty hypertension. All surgical patients received postoperative treatment of systemic hypertension with intravenous antihypertensive medication, and no episodes of severe refractory hypertension or postcoarctectomy syndrome occurred. In contrast to the angioplasty group, β-blocker medication was not used before surgery in the surgical group to decrease the incidence of postoperative hypertension, as has been suggested by other investigators.29 It is possible that pretreatment of the surgical group with β-blocker medication would have decreased the need for postoperative antihypertensive medication. In the one surgical patient who suffered paraparesis, it is presumed that this was secondary to a period of hypoperfusion of the spinal cord during surgery. This rare complication appears to be related to several factors, including the anatomy of the arterial supply to the cord, the presence of collateral vessels, and the occurrence of intraoperative hypotension.27 Since the patient in our study who developed paraparesis had angiographic evidence of good collaterals and no intraoperative hypotension, perhaps anatomic anomaly of the arterial blood supply to the spinal cord predisposed the patient to paraparesis. The patient now has an almost normal gait and is developing normally.

Finally, the cost of balloon coarctation angioplasty is significantly (38%) less than the cost of surgical repair of unoperated coarctation of the aorta. The majority of this cost differential is a result of the longer hospital stay, and this is clearly one advantage of balloon angioplasty over surgical repair of unoperated coarctation.

In summary, balloon coarctation angioplasty of unoperated coarctation of the aorta provides an effective and less expensive alternative to surgical repair in the majority of patients. The risk of aneurysm formation is higher after angioplasty, and the intermediate-term follow-up shows no significant progression of these aneurysms. The risk of restenosis may be greater in the angioplasty group, particularly in patients with a small aortic isthmus. However, significant neurological complications can occur after surgery. We conclude that
balloon coarctation angioplasty can be used as an initial alternative to surgical repair of unoperated coarctation of the aorta in children beyond infancy, particularly in patients with a well-developed aortic isthmus.

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Circulation. 1993;87:793-799
doi: 10.1161/01.CIR.87.3.793
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 1993 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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