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Stent Implantation for Coarctation of the Aorta in Children <30 kg

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Objectives Our aim was to determine key characteristics of stents commonly implanted in the aorta through bench testing and to describe our technique and acute results in patients weighing <30 kg.

Background Despite the increasing use of stents for interventional treatment for coarctation of the aorta (CoA) in larger patients, use of large stents is controversial in small children.

Methods Methods included bench testing of large stents, and retrospective review of all patients over 1 year of age who had stent implantation for treatment of CoA. Patients were divided into 2 groups based on weight. Paired comparisons were made before and after stent implantation, and group outcomes were compared.

Results Sixty patients comprised the entire sample, with 22 patients assigned to group I (<30 kg) and 38 patients assigned to group II (≥30 kg). The mean minimum diameters of the CoA (group I 5.0 to 10.7 mm; group II 8.0 to 15.0 mm) and the ratio of the coarctation diameter to the descending aorta diameter measured at the level of the diaphragm (CoA/DAo ratio) (group I 0.4 to 0.93; group II 0.46 to 0.94) increased significantly in both groups (all $p < 0.05$). The mean systolic gradient decreased significantly in both groups (group I 23.0 to 2.0 mm Hg; group II 24.0 to 2.8 mm Hg; both $p = 0.001$). No difference was found between the groups in the CoA/DAo ratio, residual systolic gradients, or the decrease in systolic gradient after stent implantation. There were no significant complications in patients under 30 kg.

Conclusions As in larger patients, use of large stents for treatment of CoA in small children is effective and safe in the short term. In these patients, stent redilations will be required, and follow-up is ongoing. (J Am Coll Cardiol Intv 2009;2:877–83) © 2009 by the American College of Cardiology Foundation

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Patients with coarctation of the aorta (CoA) may present at any age, but most present in infancy or early childhood. Surgery is usually performed in infants presenting under 1 year of age. After infancy, interventional techniques are chosen over surgery because they are less invasive and result in less procedure-related morbidity (1). Angioplasty is most often the treatment of choice in small children, whereas stent implantation is usually preferred in older patients. Although reports of stent implantation in older patients with CoA demonstrate immediate results superior to angioplasty with fewer complications, angioplasty without stent implantation continues to be preferred in small children (2–6).

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We hypothesized that stent implantation is safe and effective in all children over 1 year of age who undergo interventional treatment of CoA. The objectives of this study are to determine key characteristics of stents commonly implanted in the aorta through bench testing and to describe our technique and acute results in patients weighing <30 kg.

Abbreviations and Acronyms

CoA = coarctation of the aorta

CoA/DAo ratio = the ratio of the coarctation diameter to the descending aorta diameter measured at the level of the diaphragm

Methods

First, laboratory bench testing of stents commonly used in larger patients was performed. Then, a retrospective review of pediatric patients over 1 year of age who underwent treatment of CoA in the interventional catheterization laboratory was conducted. We compared our results in small children (<30 kg) to our contemporaneous results in older patients (≥30 kg).

Laboratory testing. Laboratory testing of 2 stents commonly used in patients >30 kg, Palmaz-Genesis (PG) 2910B and PG1910B (Cordis Corp., Miami Lakes, Florida) and ev3 IntraStent Mega LD (ev3 Inc., Plymouth, Minnesota), was performed to determine the smallest sheath that could be used to implant these stents. The maximum diameters and shortening characteristics of these stents were determined to evaluate their redilation potential. The stents were manually crimped onto balloon angioplasty catheters with a minimum dilation diameter of 7 mm (Opta-Pro, Cordis Corp.). Attempts were made to push them through sheaths (Cordis Corp.), beginning with the recommended sheath for the balloon catheter alone (5-F). The sheath size was increased sequentially by 1-F size until it accommodated the balloon angioplasty catheter with mounted stent. Subsequently, the stents were serially dilated using 10 to 22 mm diameter balloon angioplasty catheters and the stent diameters and lengths after each dilation were recorded.

Retrospective review. The clinical and catheterization databases were reviewed to identify patients over 1 year of age, who had interventional treatment of CoA performed at Mattel Children's Hospital at UCLA between June 2003 and June 2006 and at Rady Children's Hospital, San Diego between July 2006 and July 2008. Patients who had aortic CoA after surgical aortic arch reconstruction, such as post-Norwood patients and patients with post-transplant suture-line stenosis of the aorta were excluded. Stent patients were separated into 2 groups according to weight.

Clinical, catheterization, and angiographic data were studied to determine patient characteristics, procedural technique and characteristics, results of procedure, and procedural complications. Outcome measures recorded pre- and post-procedure included minimum diameter at the coarctation site, the ratio of the coarctation diameter to the descending aorta diameter measured at the level of the diaphragm (CoA/DAo ratio), and systolic gradient across the coarctation.

Statistical methods. Statistical analysis was performed using SPSS version 16 for windows 2007 (SPSS Inc., Chicago, Illinois). Demographic, clinical, procedural, and hemodynamic data were analyzed to describe the sample, and these data were examined for skewness and outliers. Descriptive and procedural data were compared between groups. Differences between groups' pre- and post-intervention hemodynamics and angiographic outcome measures were calculated using the paired t tests. Differences in outcome measures between the 2 groups were then made using independent samples t tests.

Procedural technique. Informed consent was obtained from the patient or legal guardian. Catheterizations were performed under general anesthesia. Patients were heparinized to maintain an activated clotting time >200 s. Arterial and venous accesses were obtained, and standard right and left heart catheterizations were performed. Hemodynamic evaluation included recording the gradient across the aortic arch and the CoA site. Angiography included aortograms in the posteroanterior and lateral projections. The measurements of the aorta were made from the angiograms including the narrowest diameter and length of the coarctation, the diameter of the transverse arch and the aorta at the diaphragm. Stents were selected, positioned, and deployed from the femoral artery as described in previous reports (2–6). The short arterial sheaths were exchanged for long sheaths after positioning a stiff guidewire in the right subclavian artery or the ascending aorta. In group I, we were guided by our bench testing and attempted to use the smallest possible sheaths that would accommodate large stents selected in part for redilation potential adequate to accommodate the patients' growth. All stents were manually crimped on high pressure balloons, inserted through the sheath, and positioned using angiography. After stent implantation, hemodynamics and angiography were repeated.

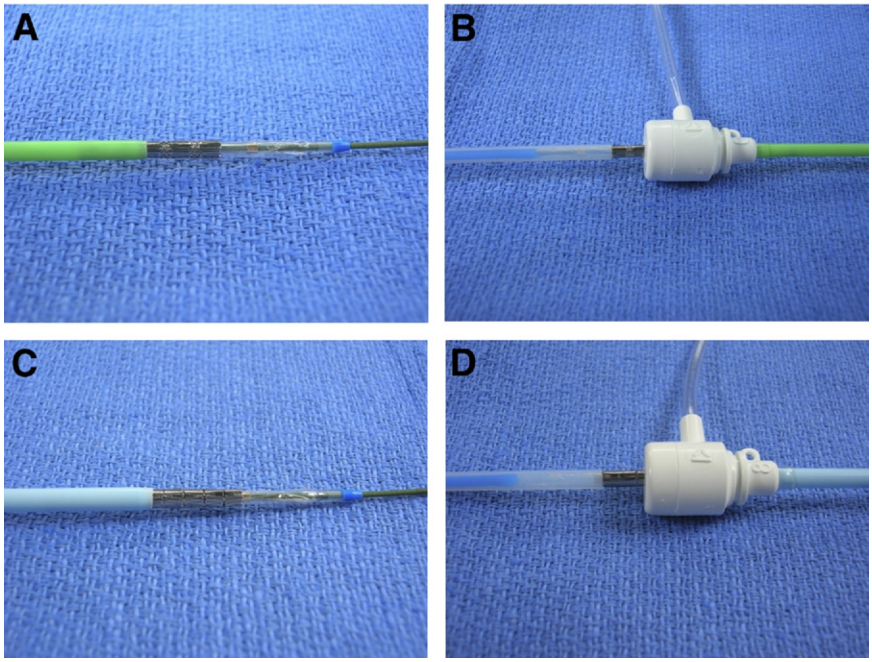

Figure 1. **Bench Testing of ev3 and PG2910B Stents**

(A) PG2910B stent crimped over balloon catheter; **(B)** stent balloon system being introduced through 6-F sheath; **(C)** ev3 stent crimped over balloon catheter; and **(D)** stent balloon system being introduced through the 8-F sheath.

Patients were recovered and observed overnight in the hospital. All patients were treated with low-dose aspirin.

Results

Bench testing. The smallest sheath that accommodated the PG2910B stent was 6-F when it was mounted on a 7-mm balloon angioplasty catheter (Figs. 1A and 1B). The 6-F sheath also accommodated an 8-mm diameter balloon, which allowed further dilation of the stent. Further dilations of the PG2910B stent over 9-, 10-, and 12-mm balloons were achieved by upgrading the sheath size to 7-F.

The smallest sheath that accommodated the ev3 Mega LD stent was 8-F, when mounted on a balloon with an inflation diameter of ≤12 mm (Figs. 1C and 1D). Further dilation of the stent using a 14-mm balloon was successfully performed through the 8-F sheath.

Results of serial dilations of the PG2910B and the ev3 Mega LD stents appear in Table 1. The maximum diameter

Table 1. **Laboratory Bench Testing Results**

Balloon Diameter, mm	Stent Diameter, mm		Stent Length, mm	
	PG2910B	ev3 Mega	PG2910B	ev3 Mega
Baseline			29	27
10	10	10	27	27–28
14	14	14	23	27
18	18	18	19	25–26
20	19	20	13	25
22	19	22	12.5	23

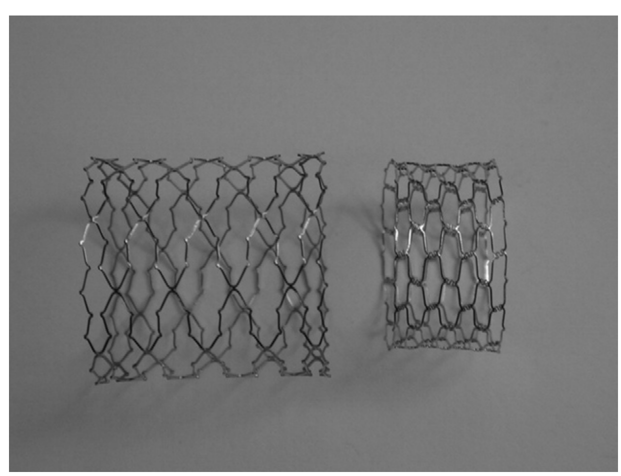

Figure 2. **ev3 and PG2910B Stents at Maximal Expansion**

The open cell structure of the ev3 stent helps maintain its length (23 mm) and allows it to achieve larger diameter (22 mm), as compared with the shortening (12.5 mm) of the PG2910B stent with lesser diameter (19 mm) seen on maximal expansion.

Table 2. Descriptive Data of Patients in Both Groups (n = 60)

	Group I	Group II
Mean age (yrs)	5.6 ± 4.0	17.1 ± 5.9
Mean weight (kg)	19.8 ± 5.3	56.9 ± 17.5
CoA diameter (mm)		
Pre	5 ± 1.9	8 ± 2.7
Post	10.7 ± 2.3	15 ± 2.16
CoA/DAo ratio		
Pre	0.4 ± 0.17	0.46 ± 0.16
Post	0.93 ± 0.16	0.94 ± 0.12
Mean gradient (mm Hg)		
Pre	23 ± 0.3	24 ± 18
Post	2 ± 3.1	2.8 ± 4.5

CoA/DAo ratio = the ratio of the coarctation diameter to the descending aorta diameter measured at the level of the diaphragm; CoA Pre = diameter at coarctation site before stent; CoA Post = diameter of CoA after stent; Mean gradient Pre = mean systolic gradient before stent; Mean gradient Post = mean systolic gradient after stent.

achieved for the PG stent was 19 mm, and for the ev3 stent was 22 mm, using a 22-mm balloon angioplasty catheter, shown in Figure 2. The initial lengths for the PG and ev3 stents were 29 mm and 27 mm, respectively. Final lengths were 13 mm for the PG (45% of the initial length) and 23 mm for the ev3 (85% of the initial length). However, when the PG stent was expanded to 18 mm, the length only shortened to 19 mm (66% of the initial length).

Table 3. Demographics, Sheath, Stent, and Balloon Sizes Used in Patients Under 30 kg

Patient #	Gender	Weight, kg	Age, yrs	Sheath, F	Stent	Max Balloon, mm
1	F	9.7	1	6	PG2910B	7
2	F	12.2	2.8	6	PG1910B	8
3	M	13.6	2.6	7	PG2910B	10
4	M	14.5	4.4	6	PG2910B	8
5	M	14.5	4.5	6	PG1910B	7
6	M	14.8	2.5	6	PG1910B	8
7	M	15	3.3	7	PG1910B	12
8	M	17	4.5	8	PG1910B	10
9	M	17.5	5.7	8	ev3	12
10	M	20	4	8	PG1910B	12
11	F	20.4	5.0	7	PG1910B	10
12	M	21	9.4	7	PG2910B	10
13	M	21.8	9.9	9	PG2910B	12
14	M	21.9	5	8	ev3	14
15	M	22.2	6.7	9	PG2910B	12
16	M	23.5	8	8	PG2910B	12
17	M	24.5	7	10	ev3	12
18	M	25	6.1	9	PG2910B	12
19	M	25.7	10	10	ev3	14
20	M	27	3.7	7	PG1910B	12
21	M	27	8.0	8	ev3	12
22	F	27	9.3	9	ev3	12

Sheath = size of sheath used; Stent = type of stent used; Max Balloon = maximum balloon inflation diameter for stent placement.

Table 4. Hemodynamic Results in Patients Under 30 kg (Group I, n = 22)

Patient #	DAo, mm	Gradient Pre, mm Hg	Gradient Post, mm Hg	Pre-CoA, mm	Pre-CoA/DAo	Post-CoA, mm	Post-CoA/DAo
1	7.1	16	8	3.3	0.5	7	1
2	8	22	8	3	0.4	7.3	0.9
3	10	21	0	4.5	0.5	10	1.1
4	8	22	2	4.2	0.6	8	1.1
5	9.2	40	0	1.3	0.1	7	0.8
6	14	10	1	5	0.35	8	0.6
7	14.4	17	0	5.5	0.4	12	0.8
8	12.7	25	8	5.7	0.45	10	0.8
9	12	24	0	4	0.3	12	1.0
10	10	15	2	6.2	0.62	9.5	0.95
11	10	10	0	7.5	0.8	10	1.1
12	12	27	9	4.9	0.4	12	1.0
13	15.5	49	1	2	0.1	11	0.7
14	16.4	20	4	8.3	0.5	14	0.85
15	11.2	23	1	5.3	0.5	10	0.9
16	16.5	38	0	5.2	0.54	10	0.97
17	13	37	0	3	0.23	12	0.92
18	13.5	21	0	4	0.3	12	0.9
19	21	15	2	6.8	0.32	14	0.7
20	12.5	12	0	6.1	0.5	12	1.0
21	12	26	0	8	0.7	12	1.1
22	12	11	0	6.7	0.6	12	1.3

DAo = diameter of aorta at the level of the diaphragm; Gradient Post = systolic gradient after stent placement; Gradient Pre = systolic gradient before stent placement; Post-CoA = minimal diameter at the coarctation site after stent placement; Post-CoA/DAo = ratio of the coarctation diameter to the descending aorta diameter measured at the level of the diaphragm after stent placement; Pre-CoA = minimal diameter at the coarctation site before stent placement; Pre-CoA/DAo = ratio of the coarctation diameter to the descending aorta diameter measured at the level of the diaphragm before stent.

Retrospective review of patient records. Sixty-three patients over 1 year of age underwent interventional treatment of simple CoA. Three parents selected angioplasty rather than stent implantation for their children, and thus were excluded. Therefore, 60 patients comprised the clinical portion of the study sample. Patients who weighed less than 30 kg were assigned to group I (n = 22) and those who weighed ≥30 kg comprised group II (n = 38). The sample characteristics are summarized in Table 2.

GROUP I. Mean patient age was 5.6 years and mean weight was 19.8 kg. Eleven patients had native COA and 11 had recurrent COA. Of the patients with recurrent CoA, 6 were post-surgery and 5 post-balloon angioplasty. Detailed descriptive and procedural data for group I patients (<30 kg) are displayed in Tables 3 and 4. Figure 3 shows the representative angiograms (Patient #9 reported in Tables 3 and 4) before and after stent implantation.

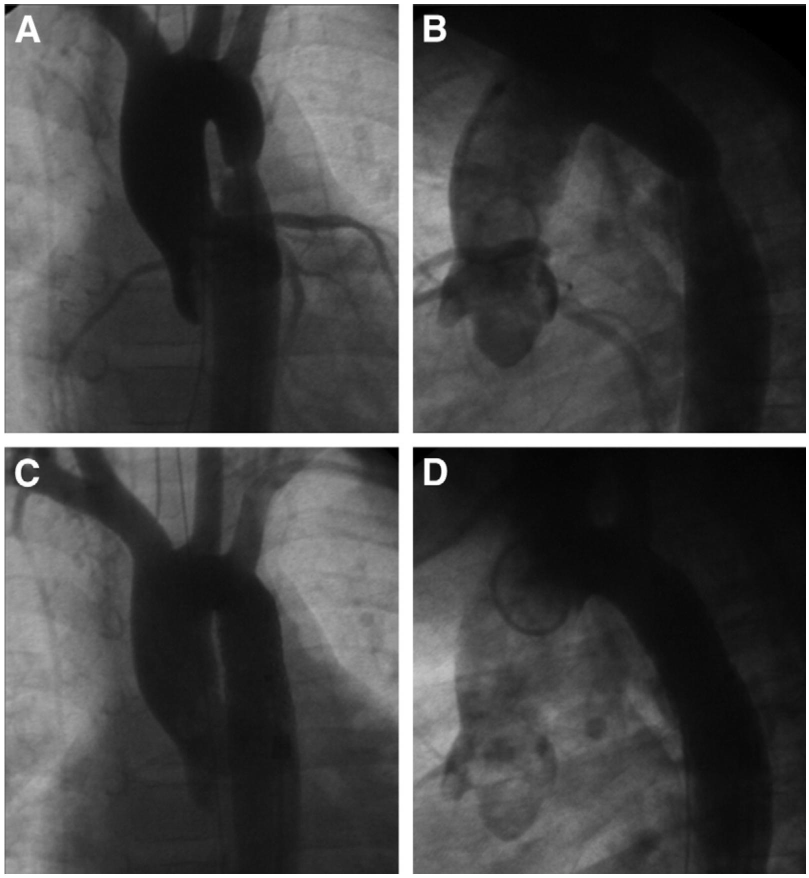

Figure 3. Angiograms Before and After Stent Placement in Patient #9

(A and B) Anteroposterior and lateral aortic angiography demonstrating native coarctation in a 5-year-old, 17.5-kg patient. **(C and D)** Post-intervention angiography after stent angioplasty with ev3 Mega LD stent, deployed with 12-mm Cordis Opta Pro balloon angioplasty catheter using 8-F femoral arterial access.

Types of stents used are reported in Figure 4. Final patient sheath sizes ranged from 6- to 10-F. Final balloon diameters ranged from 7 mm to 14 mm. Stents were either from the PG series or the ev3 Mega LD series. Sheaths of 6-F accommodated PG stents with final balloon diameters of 7 or 8 mm in 5 of the 6 smallest patients.

The mean minimum CoA diameter increased significantly from 5 ± 1.9 mm pre-procedure to 10.7 ± 2.3 mm post-stent angioplasty ($p = 0.001$). The CoA/DAo ratio also increased significantly from 0.4 ± 0.17 to 0.93 ± 0.16 ($p = 0.001$). Pre-stent systolic gradients ranged from 10 to 40 mm Hg, with a mean of 23 ± 10.3. Post-stent systolic gradients decreased significantly ranging from 0 to 9 mm Hg, with a mean of 2.0 ± 3.1 mm Hg ($p = 0.001$).

GROUP II. Patients ranged in age from 6.6 to 41.7 years, with a mean age of 17.1 ± 5.9 years. Weights ranged from 30.9 to 94.4 kg, with a mean of 57 ± 17.5 kg. Twenty-two had native CoA and 16 had recurrent CoA. Nine were post-surgery and 7 were post-balloon angioplasty. The mean minimum CoA diameter increased significantly from 8 ± 2.7 mm pre-procedure to 15 ± 2.16 mm post-stent angioplasty ($p = 0.001$). In group II, the CoA/DAo ratio also increased significantly from 0.46 ± 0.16 to 0.94 ± 0.12 ($p = 0.036$). Pre-stent systolic gradients ranged from 7 to 54 mm Hg, with a mean of 24 ± 18 mm Hg. Post-stent systolic gradients decreased significantly ranging from 0 to 19 mm Hg, with a mean of 2.8 ± 4.5 mm Hg ($p = 0.001$).

Group comparisons. Patients in both groups had significant paired increases in coarctation diameters and in the CoA/DAo ratio as well as decreases in gradients across the area of CoA post-stent implantation. When these results were compared between the 2 groups, group II patients (≥30 kg) had significantly greater diameter increase ($p = 0.006$) and CoA/DAo ratio increase ($p = 0.001$). No significant differences were found between patients under and over 30 kg in post-stent CoA/DAo ratio, residual mean systolic gradients, or decrease in mean systolic gradients post-procedure.

Complications. No complications were reported in group I patients. Complications were seen in 3 group II patients. Loss of femoral pulse was seen in 2 patients, which resolved

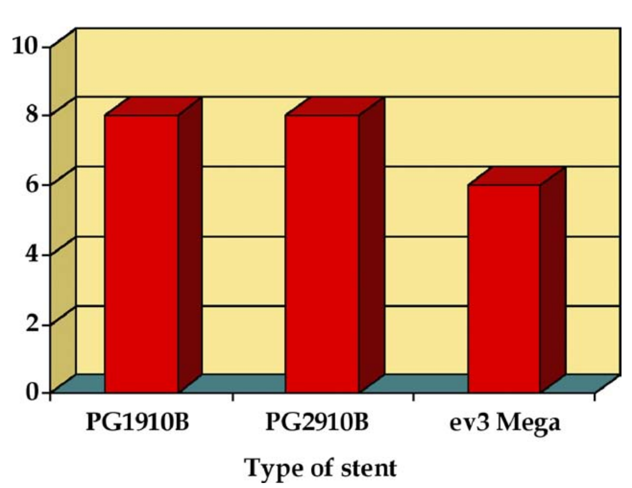

Figure 4. Type of Stents Used in Group I Patients

X axis denotes the stents used: ev3, PG1910B, and PG2910B stents. Y axis shows the total number of patients who had each type of stent placed.

within 24 h with intravenous heparin therapy. One patient had formed a small aortic aneurysm at the site of previous balloon angioplasty. He developed aortic dissection after stent implantation. Twelve Gianturco coils (Cook Inc., Bloomington, Indiana) were placed through the side of the stent to close the aneurysm and limit further aortic dissection. The alternative option was to place a covered stent across the dissection, which would have been the treatment of choice had one readily been available.

Discussion

The results of this study demonstrate the safety and efficacy of immediate results of stent implantation to correct CoA in small children. No difference was found between patients under and over 30 kg in post-stent CoA/DAo ratio, residual systolic gradient, or decrease in systolic gradient post-procedure. The stents we implanted in the patients under 30 kg have the potential for redilation to diameters that can accommodate somatic growth through adulthood. Moreover, our results of stent implantation in both groups are similar to those that have been previously reported in sample populations of larger patients (7–10).

Although balloon angioplasty without stent implantation continues to be advocated as the initial treatment of CoA in small children (2), the results of angioplasty have been suboptimal because of residual gradients and stenoses. Most institutions define procedural success as a residual gradient less than 20 mm Hg and report average residual gradients between 6.2 ± 5.9 mm Hg and 16 ± 15 mm Hg. (2,4,5,11–14). In perhaps the most extensive review of angioplasty procedures, McCrindle et al. (6) evaluated data from 970 angioplasties at 25 centers from 1982 to 1995. Median residual gradient after angioplasty was 9 mm, and a residual systolic gradient of >20 mm was observed in 19% of native and 25% of recurrent CoAs. Angioplasty reports to date have set the standard for success at a level that essentially justifies persistent residual CoA in a high percentage of patients. In our series, the median residual systolic gradients observed in both groups were 0.5 mm Hg.

Complications after angioplasty alone may be greater than after stent implantation. The risk of aneurysm formation after balloon angioplasty has been reported in up to 10% of cases (4,14,15). In contrast, stent implantation has had a lesser risk of aneurysm formation (8,16,17). In a study comparing stent placement versus balloon angioplasty in adolescents and adults with CoA, Pedra et al. (13) reported a lower risk of aortic wall abnormalities in stented patients. In their study, of the 15 patients who underwent balloon angioplasty, 8 had wall abnormalities, consisting of 2 dissections, 4 irregularities, and 2 aneurysms. In contrast, they found only 1 of 21 stent patients developed an aneurysm. In our series, no wall abnormalities were observed among 22 patients under 30 kg, and only 1 abnormality was observed in the larger patients.

To date, there is no longitudinal evidence supporting long-term benefit of stent implantation in young patients. However, there are surgical data suggesting that younger patients who experience relief of aortic obstruction have a lower incidence of residual hypertension and morbidities than do patients who achieve relief at older ages. Heger et al. (18) demonstrated vascular dysfunction to be more persistent in patients operated after 9 than among those operated before 9 years of age. In another study, Toro-Salazar et al. (19), in their analysis of 254 patients operated between 1948 and 1976, reported operative mortality in 7% of their study sample, persistent hypertension in 30% (after 10 years) to 46% (after 50 years), with best survival results in patients having had surgery under 5 years of age. Therefore, such long-term trends may be seen in patients who have their CoA treated early and effectively in the interventional catheterization laboratory.

The principle disadvantage of stent implantation in young children is the need for stent redilation to accommodate growth. As demonstrated by our bench studies, we believe that in most of our patients the stents we implanted have adequate redilation potential to achieve adult aortic dimensions. The feasibility of in vivo redilation has been confirmed by both animal studies (19), and clinical data in older children and adults (9,16,20–22). Morrow et al. (23) demonstrated the feasibility of re-expansion of the stents in the aorta of swine, without significant injury to the neointima, the media, or the adventitia.

There are limited previous reports of stent implantation for primary treatment of CoA in small children. Golden and Hellenbrand (2), in their review of the Congenital Cardiovascular Interventional Study Consortium data consisting of

588 stent placements for CoA in children and adults from 17 centers, report only 7% (40 of 588) of the patients were under 6 years of age. Schaeffler et al. (24) reported 9 patients with a median weight of 14 kg (range 5.5 to 19 kg) who underwent successful stent placement for CoA. In our study, we report 22 patients with a median weight of 20.7 kg (range 9.7 to 27 kg). Thirty-seven percent of the patients (22 of 60) were under 30 kg and had successful implantation of large stents.

This is the first report describing excellent acute outcomes and low risk among a group of small children with CoA who were consistently treated by stent implantation. Mid- and long-term outcomes of stent implantation in small children with CoA are needed. Stent redilations and data collection through follow-up evaluations are ongoing.

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Key Words: coarctation of aorta ■ stent ■ angioplasty ■ pediatric heart disease ■ congenital heart disease ■ pediatric interventional cardiology.