

Use of Balloon-Expandable Stents for Coarctation of the Aorta: Initial Results and Intermediate-Term Follow-Up

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Objectives. In this study we report our preliminary results and intermediate-term follow-up (up to 3.5 years) of stent implantation for coarctation of the aorta (COA).

Background. Balloon angioplasty has gained acceptance as a modality of treatment for COA. Some patients do not respond optimally to balloon angioplasty alone. Balloon-expandable stents have been used in pulmonary arteries and large systemic arteries such as the femoroiliac vessels, with a significant improvement in vessel patency and a reduction in the pressure gradient compared with balloon angioplasty alone.

Methods. Nine patients (>10 years old) with COA in whom balloon dilation alone was thought to be ineffective underwent stent implantation. Seven patients had a previous operation or balloon dilation, or both, to relieve their coarctation but had a significant residual/recurrent gradient.

Results. At the time of stent implantation, the systolic and mean gradients decreased from a mean (\pm SEM) of 37 ± 7 and 14 ± 3 mm Hg to 4 ± 1 and 2 ± 0.6 mm Hg, respectively ($p \leq$

0.002). The coarctation diameter increased from a mean of 9 ± 1 to 15 ± 1 mm ($p < 0.002$). The patients have been followed for up to 42 months (mean 18, median 13) with no complications; the stents remain in position with no fracture. One patient underwent further successful dilation 3 years after stent implantation because of an exercise-induced gradient. No other intervention has been required. The systolic gradient at latest follow-up is 7 ± 2 mm Hg. Only two (a 44-year old with diabetes and a 50-year old with long-standing hypertension) of five patients previously requiring antihypertensive treatment still remain on medications for blood pressure control.

Conclusions. The use of stents in COA is a feasible alternative to surgical repair or balloon angioplasty in selected patients with an effective gradient reduction. Intermediate-term follow-up shows excellent gradient relief, with no complications in this group of patients.

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Balloon dilation has gained acceptance in the treatment of coarctation of the aorta (COA). It has been advocated as the therapy of choice in postoperative coarctation (1-4) and as an acceptable alternative to surgical repair in native coarctation (5,6). However, a significant number of patients develop re-coarctation after balloon angioplasty (7-9). To improve the results of balloon angioplasty, patients >10 years of age with COA, evaluated at the Cleveland Clinic since 1993, were considered for stent implantation. We report our initial experience and short- to intermediate-term follow-up of these patients.

Methods

Patients. All patients undergoing stent implantation for COA at the Cleveland Clinic Foundation between January 1993 and November 1996 were included in the study. There were nine patients (two males and seven females) between 14

and 63 years old. Their weight ranged from 47 to 133 kg (median 61).

Catheterization technique. Informed consent was obtained from all the patients, or the parent, if the patient was a minor. The study was initiated after approval of the Institutional Review Board of the Cleveland Clinic Foundation. After 1 year, stent implantation was no longer considered investigational and only the patient's (or parent's) informed consent was required. All patients underwent routine cardiac catheterization under general anesthesia. Hemodynamic data, including systolic and mean gradients, and angiographic measurement of the coarctation site, the proximal aorta and the descending aorta at the level of the diaphragm were acquired. With the aid of a guide catheter, a long stiff guide wire was placed across the stenotic area. This was used to position a 10F, 11F or 12F sheath and dilator across the coarctation site. The dilator was then removed and a Palmaz stent (P308, 3 cm long and 3.4 mm unexpanded diameter; Johnson & Johnson Interventional Systems Co.), mounted on a balloon dilation catheter (12, 15, 18 or 20 mm Z-med or Tyshack, NuMed, Inc.), was advanced inside the sheath to the stenotic area. The balloon size chosen was the nearest size equal to the diameter of the transverse aortic arch not to exceed the diameter of the descending aorta at the level of the diaphragm (maximum 20 mm). The long sheath was withdrawn to expose the

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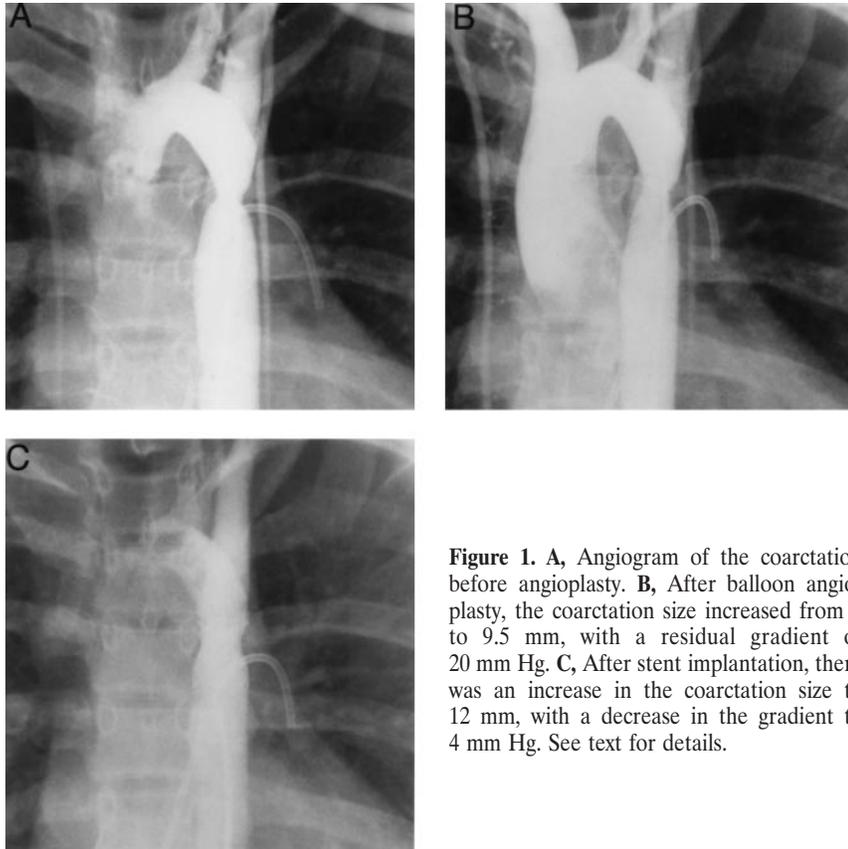


Figure 1. **A**, Angiogram of the coarctation before angioplasty. **B**, After balloon angioplasty, the coarctation size increased from 7 to 9.5 mm, with a residual gradient of 20 mm Hg. **C**, After stent implantation, there was an increase in the coarctation size to 12 mm, with a decrease in the gradient to 4 mm Hg. See text for details.

balloon-mounted stent, which was carefully positioned at the coarctation site. The balloon was then inflated using the recommended pressure (4 to 5 atm). In some instances, further inflation of the proximal and distal ends of the balloon was done to ensure flaring of the stent ends. Repeat hemodynamic and angiographic data were acquired (Fig. 1).

Anticoagulation. We have maintained our patients on aspirin for at least 1 year after the procedure to avoid platelet aggregation. Because this is a high pressure, high flow area, it was not thought necessary to use warfarin to anticoagulate the patients.

Follow-up. All patients had follow-up at 1 month and yearly thereafter. This included a complete history and physical examination, blood pressure measurements in all extremities and a chest roentgenogram. An echocardiogram and an exercise test were obtained at the discretion of the referring cardiologist. To assess any residual stenosis across the coarctation, the higher value of the arm and leg blood pressure measurement gradients or the Doppler-derived corrected gradients (10) was used.

Data analysis. The pre-stent and post-stent implantation data were compared using the paired Student *t* test. A *p* value ≤ 0.05 was considered statistically significant. The data are expressed as the mean value \pm SEM (except for the follow-up period, which is expressed as the median value because of the skewed distribution). Clinical success was considered to be a

gradient reduction across the coarctation segment to ≤ 20 mm Hg at rest.

Results

A total of 10 procedures involving stent implantation were performed in nine patients (Table 1); one patient required further balloon dilation of the stent 3 years after implantation. Seven patients had previous surgical repair of the coarctation; six had previous balloon dilation of the coarctation. Balloon angioplasty was performed immediately before stent implantation in four patients. When hemodynamic assessment demonstrated the persistence of an unacceptable gradient despite adequate dilation, a decision was made to implant a stent. Two patients with native coarctation had stent placement as an initial procedure; one patient with severe scoliosis and restrictive lung disease was considered high surgical risk and the other patient refused surgical intervention. The balloon dilation size was 15 mm in four patients, 18 mm in three, 20 mm in two and 12 mm in one. The last patient is a young adult of small build whose descending aorta measured 11 mm. The systolic and mean gradients (Table 2) decreased significantly from 37 ± 7 to 4 ± 1 mm Hg and 14 ± 3 to 2 ± 0.6 mm Hg, respectively, after stent implantation. The size of the coarctation site increased from 9 ± 1 to 15 ± 1 mm ($p < 0.002$). Two patients had a hypoplastic distal transverse arch where a stent

Table 1. Patient Data

Pt No.	Age (yr)/ Gender	Weight (kg)	Diagnosis	Surgical Repairs	Previous Balloon Dilation	Balloon Dilatation Immediately Before Stent Placement	Anti-HTN Medications
1	14/F	61	COA, HTN, hypoplastic transverse arch	Patch graft, then tube graft	+	+	BB
2	17/F	48	COA distal to left subclavian, mild HTN	End to end anastomosis	+	+	None
3	18/F	61	Severe AS, coarctation	End to end anastomosis, Ross procedure	+ of AS, COA	+	None
4	63/M	54	COA, HTN, scoliosis, restrictive lung disease	None	-	-	ACEI
5	45/F	133	COA, HTN, diabetes mellitus	End to end anastomosis	+	-	BB
6	28/F	71	COA, HTN	End to end anastomosis, PDA ligation	+	+	BB
7	19/F	62	AS, AI, COA, hypoplastic transverse arch	End to end anastomosis	+ of AS, COA	-	None
8	18/M	47	COA, VSD, CVA after surgical repair	VSD closure, two COA surgical repairs, including end to end anastomosis and subclavian turnout	-	-	None
9	50/F	70	COA, HTN	None	-	-	ACEI, CCB

ACEI = angiotensin-converting enzyme inhibitor; AI = aortic insufficiency; AS = aortic stenosis; BB = beta-blocker; CCB = calcium channel blocker; COA = coarctation of the aorta; CVA = cerebrovascular accident; F = female; HTN = hypertension; M = male; PDA = patent ductus arteriosus; Pt = patient; VSD = ventricular septal defect; + = balloon angioplasty or valvuloplasty, or both; - = no previous balloon angioplasty.

was placed with adequate gradient relief (Fig. 2). The end of the stent extended slightly into the orifice of the left subclavian artery or the left common carotid artery in these patients. Immediate post-stent angiography showed normal flow to both vessels.

Follow-up. No patient has been lost to follow-up. Detailed medical evaluations are available up to 42 months after the procedure (average 18, median 13). Chest roentgenograms have shown all stents to be in good position with no fracture or dislodgment. No patient has reported any symptoms of dizziness, numbness, unexplained weakness or claudications. There were no episodes suggestive of thromboembolic phenomena.

No clinically detectable femoral artery problems were encountered either immediately after the procedure or at follow-up.

Before stent implantation, five patients had hypertension requiring antihypertension treatment. Only two patients (a 45-year old diabetic patient and a 50-year old patient with long-standing hypertension) still require antihypertension treatment despite elimination of the gradient after the stent implantation. One patient who previously had exercise-induced hypertension had a normal blood pressure exercise response 1 year after stent implantation. Another patient, with a 15-mm Hg gradient at rest, who is a competitive athlete, developed an 82-mm Hg gradient at peak exercise testing at 3-

Table 2. Hemodynamic Findings Before and After Stent Implantation

Pt No.	Before Stent Implantation				After Stent Implantation				Follow-Up			
	Coa Size (mm)	Coa/Prox Ao	Coa/DAo	Cath Systolic Gradient (mm Hg)	Cath Mean Gradient (mm Hg)	Coa Size (mm)	Coa/Prox Ao	Coa/DAo	Cath Systolic Gradient (mm Hg)	Cath Mean Gradient (mm Hg)	Gradient (mm Hg)	Period (mo)
1	9	0.6	0.57	44	21	13	0.87	0.83	8	4	0†	40
2	7	0.41	0.41	30	25	12	0.71	0.71	4	5	18	42
3	9	0.45	0.5	36	10	14	0.7	0.78	8	0	9	34
4	4	0.28	0.34	86	12	16	1	1.2	0	0	0	21
5	12	0.52	0.57	35	12	17	0.74	0.81	12	2	16	8
6	8	0.47	0.62	36	32	14	0.82	1.1	2	0	0	13
7	10	0.47	0.5	18	4	17	0.89	0.89	2	2	9	1
8	9	0.84	0.84	17	4	11	1	1	0	1	12	1
9	15	0.56	0.58	28	14	19	0.7	0.73	2	2	0	1
Mean ± SEM	9 ± 1	0.5 ± 0.03	0.55 ± 0.05	37 ± 7	14 ± 3	15 ± 1*	0.82 ± 0.04*	0.89 ± 0.06*	4 ± 1*	2 ± 0.6*	7 ± 2*	18 (13)‡

*p < 0.002 versus pre-stent values. †Value given is postballoon redilatation 3 years after stent implantation. ‡Because of the skewed distribution of the follow-up period, average (and median) values are given. Follow-up gradients are the higher of the blood pressure measurements or the Doppler-estimated gradients. Cath = catheterization; Coa = coarctation; DAo = descending aorta at the level of the diaphragm; Prox Ao = proximal aorta.

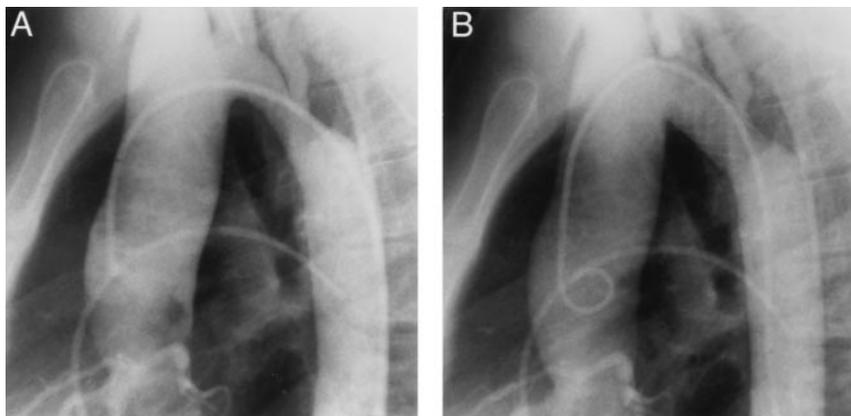


Figure 2. **A**, The angiogram before stent deployment demonstrates the presence of coarctation with a hypoplastic transverse arch. **B**, After stent deployment, the angiogram demonstrates the position of the stent extending to cover part of the transverse arch. There is no angiographic evidence of flow obstruction in the arch vessels.

years follow-up. At 38 months after stent implantation, she underwent a repeat cardiac catheterization and stent redilation using an 18-mm balloon with elimination of the rest gradient (15-mm balloon was used in the initial implantation). A follow-up stress test revealed a maximal gradient of 27 mm Hg at peak exercise. This patient's stent spanned across the left subclavian artery and part of the left common carotid artery at initial implantation because of a hypoplastic transverse arch. Repeat angiography 3 years later demonstrated normal flow to both the left subclavian and left common carotid arteries (Fig. 3). At latest follow-up, the mean (\pm SEM) rest gradient in all patients across the coarctation site, taking the higher value of the blood pressure measurements or Doppler-estimated corrected gradients, is 7 ± 2 mm Hg (median 9, <20 in all patients).

Discussion

Balloon-expandable stents have been used in the vascular system since the mid-1980s (11-14). Shortly after the initial successful experience with balloon-expandable stents in the iliac arteries, these stents were introduced in the management of stenotic lesions in congenital heart disease both postoperatively and as an alternative to surgical repair (15). Their usefulness has been demonstrated in a number of stenotic lesions. In 1993, O'Laughlin et al. (16) reported the early and intermediate-term follow-up of stents implanted in the pulmonary arteries and the venous system to relieve obstruction. Their results demonstrated that the stents retained their efficacy and continued to provide beneficial effects with no significant complications. The use of stents has been expanded

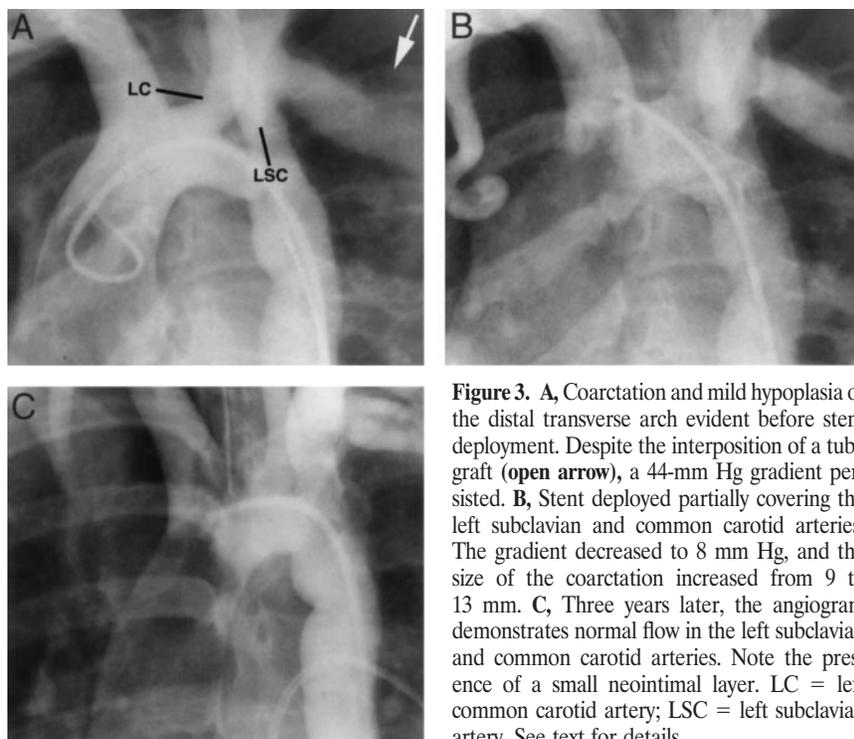


Figure 3. **A**, Coarctation and mild hypoplasia of the distal transverse arch evident before stent deployment. Despite the interposition of a tube graft (open arrow), a 44-mm Hg gradient persisted. **B**, Stent deployed partially covering the left subclavian and common carotid arteries. The gradient decreased to 8 mm Hg, and the size of the coarctation increased from 9 to 13 mm. **C**, Three years later, the angiogram demonstrates normal flow in the left subclavian and common carotid arteries. Note the presence of a small neointimal layer. LC = left common carotid artery; LSC = left subclavian artery. See text for details.

to involve other stenotic lesions, such as right ventricle to pulmonary artery homografts (17). Animal studies in 1994 demonstrated the feasibility of stents in treating experimental coarctation. Follow-up of animals with stents showed continued relief of the coarctation gradient with no evidence of intraluminal thrombosis (18). Encouraging initial and short-term results have been reported in a small number of patients who underwent stent implantation for COA (19-21). Our results show that the beneficial effects appear to persist up to 3.5 years after stent implantation.

Recoarctation after balloon angioplasty has been seen in 18% to 31% of patients with native coarctation (7,8) and in 9% to 80% (9,22) of those with postoperative coarctation. Recurrence was found to depend on the age of the patient, the nature of the lesion and size of the balloon used. Late follow-up of patients treated with balloon angioplasty showed that 32% of the patients with recurrent coarctation had not had adequate gradient relief (<20 mm Hg) at the initial angioplasty procedure, despite an adequate balloon/isthmus ratio (8). Two possible mechanisms of recurrence include elastic recoil of the tissue and the presence of long segment narrowing, especially the transverse aortic arch. Intravascular stents can maintain the patency of a stenotic lesion by eliminating the elastic recoil of the tissue and can extend over a relatively long segment of stenosis.

In this study, we report our initial experience and short- to mid-term follow-up of nine patients. In four of our patients, initial balloon angioplasty performed in the same cardiac catheterization failed to satisfactorily eliminate the gradient (Fig. 1). In these patients the stenosis was dilatable, but recoil of the dilated segment resulted in persistence of an unacceptable gradient. Stents provide support to prevent recoil of the coarctation segment; thus, long-term enlargement of the stenotic site is achieved. As more experience and confidence in this procedure are gained, it may be possible to select patients who should have a stent implanted without immediate balloon angioplasty beforehand. This will give the advantages of shortening the procedure and avoiding wire manipulation in a freshly dilated segment (21).

Extension of a stent into the orifices of the branches of the aortic arch is a concern, as the struts can cause obstruction to the flow in major vessels. In adult-size patients, however, the struts of a dilated stent are very small relative to the diameter of the subclavian and carotid arteries. In two of our patients with a hypoplastic distal transverse arch, a stent extended slightly over the orifice of the left common carotid artery or left subclavian artery, or both. Immediate post-stent angiography demonstrated no flow obstruction to any of these vessels (Fig. 2B and 3B). Repeat angiography 3 years after stent implantation in one of these patients demonstrated no flow obstruction in either vessel (Fig. 3C). No patient has complained of any symptoms suggestive of limb ischemia or decreased cerebral blood flow. Despite the encouraging results, longer follow-up of these patients is required before definite conclusions can be made.

Redilation of stents. The incidence of significant restenosis in previously placed stents in the branch pulmonary arteries has been reported to be low (3%) (23). Redilation of stents in the branch pulmonary arteries has been successful up to 3 years after implantation. However, there continues to be concern about the frequency of success or safety of redilation of previously implanted stents. The data on redilation of stents in animal models of coarctation remain conflicting. In one study (18), redilation of stented coarctation 6 months after initial implantation was successful with no untoward sequelae. However, in a canine puppy model for coarctation, Mendelsohn et al. (24) reported aortic dissection in two of seven animals during redilation of previously implanted stents. The success of redilation of stents in coarctation sites 3 years after implantation has not been previously demonstrated in humans. Because the results of redilation are not yet established, the selection of patients in our center is limited to those in whom the stent can be dilated at the initial implantation to a diameter large enough that the growth of the patient would not necessarily result in relative stent stenosis. In this study, one patient underwent successful redilation 3 years after implantation with no complications. The balloon used was 18 mm (initial implantation was done using a 15-mm balloon). This allowed further expansion of the stent and elimination of a residual waist.

Conclusions. In selected patients with COA, stent implantation may be a feasible alternative to relieve stenosis. Follow-up of these patients up to 3.5 years has demonstrated continued gradient relief.

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