Endovascular Stents for Coarctation of the Aorta: Initial Results and Intermediate-Term Follow-Up

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Balloon-expandable endovascular stents have been used successfully in the treatment of stenotic large vessels in various locations in humans (1–7) and in animal models of coarctation of the aorta (CoA) (8). We report our experience in using such stents for patients with native or recurrent CoA, including both discrete and long-segment obstruction, and offer this approach as an alternative to surgery or balloon angioplasty (BA).

METHODS

Protocol. This study was performed in compliance with the regulations of the Human Investigation Committee of our institution. As this was a retrospective study, data regarding patients' clinical status were collected by chart review. No tests were performed on any of the subjects as part of the study protocol. Patient confidentiality was maintained during data analysis and manuscript preparation.

Definition. Coarctation of the aorta was defined as systolic arm-to-leg blood pressure gradient ≥20 mm Hg or echocardiographic, magnetic resonance imaging (MRI) or angiographic evidence of CoA. Isthmus or transverse aortic arch (TAR) hypoplasia was defined as a ratio of the diameter of these structures to the descending aorta (DAo) at the level of the diaphragm <0.6 (9–11). Successful outcome was defined as a peak systolic residual gradient after stent implantation of <20 mm Hg.

Patients. Thirty-four consecutive patients with CoA underwent cardiac catheterization with the intention to treat by stent implantation at our institution between May 1993 and July 1999. Characteristics of the patients and of the CoA are summarized in Tables 1 and 2. The results of six patients who underwent surgery. Follow-up for 29 ± 17 months (range: 5 to 81 months) demonstrated no evidence of re-coarctation, aneurysm formation, stent displacement or fracture. Systolic blood pressure (SBP) decreased from 136 ± 21 mm Hg before stent placement to 122 ± 19 mm Hg at follow-up (p = 0.002). The SBP gradient decreased from 39 ± 18 mm Hg to 4 ± 6 mm Hg, and peak Doppler gradient decreased from 51 ± 26 mm Hg to 13 ± 11 mm Hg at follow-up (p < 0.001).

CONCLUSIONS

Intravascular stent placement for native and recurrent CoA has excellent results in the short and intermediate terms. Long-term outcome remains to be evaluated. (J Am Coll Cardiol 2001;38:1518–23) © 2001 by the American College of Cardiology.
was performed crossing the coarctation site in a retrograde manner before biplane angiography, and the appropriate measurements were obtained. A long trans-septal sheath was advanced over a guide wire across the coarctation site, positioning the tip of the wire either in the left or right subclavian artery. In 33 patients, we used either a Palmaz 308 or 188 stent (Johnson & Johnson Interventional Systems, Somerville, New Jersey). In one patient, a 28 CP stent (NuMED Inc., Nicholville, New York) was implanted. The stent was mounted and cramped onto a balloon catheter. The diameter of the first balloon was chosen to be at least twice the diameter of the coarctation site in order to stabilize the position of the stent before using larger balloons. The initial smaller balloon with the stent mounted on it required a smaller sheath than the larger balloons used subsequently. In 23 patients, at least two balloons were required to expand the stent to its final diameter. Larger balloons were also used to flare the ends of the stent to oppose the aortic wall in patients with post-stenotic aortic dilation to allow complete endothelization of the stent. The combination of high pressure (HP) and low pressure (LP) balloons used included: Z-Med and Tyskhab balloons (B. Braun Medical Inc., Bethlehem, Pennsylvania), Meditech balloons (XXL, Black Diamond, Blue Max; Boston Scientific Corp., Watertown, Massachusetts), as well as balloon-in-balloon (BIB, NuMED Inc.). Repeat angiography and pressure measurements were performed after stent implantation.

## Table 1. Characteristics of the Patients (n = 34)

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>No. (%)</th>
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<tbody>
<tr>
<td>Men/women</td>
<td>25/9</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>16 ± 8 (4–36)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>56 ± 23 (18–145)</td>
</tr>
<tr>
<td>Body surface area (m²)</td>
<td>1.5 ± 0.3 (0.8–2.4)</td>
</tr>
<tr>
<td>Symptoms</td>
<td>10 (29%)</td>
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<tr>
<td>Hypertension</td>
<td>22 (65%)</td>
</tr>
<tr>
<td>Isolated CoA</td>
<td>7 (21%)</td>
</tr>
<tr>
<td>Associated cardiac defects</td>
<td>27 (79%)</td>
</tr>
<tr>
<td>Bicuspid aortic valve</td>
<td>13</td>
</tr>
<tr>
<td>VSD with/without repair</td>
<td>6</td>
</tr>
<tr>
<td>Left heart obstruction</td>
<td>10*</td>
</tr>
<tr>
<td>Isthmus/arch hypoplasia</td>
<td>9</td>
</tr>
<tr>
<td>Others</td>
<td>5</td>
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</tbody>
</table>

*Five patients had aortic stenosis; two had hypoplastic left heart syndrome and underwent bidirectional Glenn shunt or Fontan procedure; one had Turner’s syndrome, and two had Shone’s complex.

Stents were placed in 33/34 patients attempted.

CoA = coarctation of the aorta; VSD = ventricular septal defect.

**Results**

### Initial results.

The stents were implanted in the stenotic area in 33 of 34 patients (97%) (Fig. 1). In one patient with recoarctation eight years after subclavian flap repair, a 16 mm HP balloon ruptured, and the partially inflated stent migrated and was expanded without complications in the right external iliac artery. No further therapy was attempted. This was the only patient who did not have stent placement for his coarctation. He had no complications upon follow-up with MRI. In the 33 remaining patients in whom the stents were placed across the site of obstruction, the peak systolic pressure gradient decreased from 32 ± 12 mm Hg to 4 ± 11 mm Hg (p < 0.001) immediately after

### Statistical analysis.

Data are presented as the mean ± SD. Comparison for individual parameters before and after stenting were performed using the two-tailed paired t test. Comparison between patients who had native CoA and those with recoarctation, as well as between those with tubular versus discrete coarctation, was made using the two-tailed unpaired t test for continuous-valued data. For categorical data, chi-square analysis was used. Linear and multiple regression analyses were performed to test the effect of growth and age of the patients adjusting for variable lengths of follow-up using SAS statistical software. A p value <0.05 was considered statistically significant.

### Follow-up.

Clinical details, blood pressure data and results of echocardiogram, chest X-ray, MRI and catheterization were determined by retrospective chart review.
stent implantation. The ratio of the final balloon diameter to coarctation diameter before stent placement was 2.7 ± 1.9 (range: 1.4 to 12), while final balloon diameter to DAo diameter ratio was 1.0 ± 0.2 (range: 0.7 to 1.5). Although 10 patients had final balloon diameter/DAo diameter ratio ≥1, their final stent diameter/DAo diameter ratio remained ≤1 because larger balloons were necessary to expand the stent adequately. The ratio of coarctation diameter to DAo diameter increased by 50% from 0.46 ± 0.16 to 0.92 ± 0.16 (p < 0.001). Balloons used had a mean diameter of 17 ± 2 mm (range: 12 to 20 mm), while the arterial sheaths used ranged from 8F to 14F.

Suboptimal outcome. A 34-year-old patient had a 5-cm long re-coarctation after surgical repair in childhood. Two telescoping stents were placed but could not be expanded adequately despite the use of single and double balloons inflated up to 25 atms. The patient had a residual gradient of 60 mm Hg and was referred for surgery.

Complications. Major complications (defined as those requiring surgical treatment) occurred in two patients (6%), and minor complications occurred in four patients (12%). Major complications included a retroperitoneal hematoma secondary to bleeding from the external iliac artery in a 16-year-old child because of high femoral artery puncture and a fragment of ruptured balloon embolized to the left axillary artery in another 19-year-old patient.

Minor complications included: additional stent placement in the DAo distal to the coarctation site in two

Figure 1. Initial implantation of Palmaz 308 stent in a 15-year-old patient with native coarctation of the aorta and 18-month angiography follow-up. (A and B) Initial postero-anterior and lateral angiography showed an 8-mm coarctation with a 35-mm Hg pressure difference. (C and D) The diameter increased to 18 mm immediately after stent implantation. (E and F) Repeat angiography 18 months later shows no recurrent obstruction and no aneurysm. There is some remodeling of the aorta with minimal neointimal proliferation.
patients after the partially inflated stent migrated and had to be fully expanded in the DAo. In one patient, the procedure was aborted after the stent migrated and had to be inflated in the right external iliac artery (as mentioned above). Another patient developed a small femoral arteriovenous fistula two weeks after the procedure with spontaneous resolution. Acute dissection or aneurysm formation did not occur in any of the patients. **Deaths.** There were no deaths related to the procedure. One 16-year-old patient with Shone’s complex who had a documented influenza A sepsis and Adult Respiratory Distress syndrome had stent placement for CoA and balloon valvuloplasty of mitral stenosis to try to improve her low output state before she was placed on extracorporeal membrane oxygenation (ECMO). She died two weeks later from complications related to ECMO. **Repeat catheterization and stent dilation.** Four patients underwent repeat cardiac catheterization 16 ± 5 months after their initial stent implantation (range 10 to 21 months). Two patients were catheterized for follow-up of their stenting procedure, and the other two for pre-surgical evaluation of additional cardiac defects. None of these patients was found to have aneurysm formation, stent displacement or fracture (Fig. 1). One patient had a recurrent peak gradient of 24 mm Hg across the stent secondary to somatic growth and increased cardiac index without intimal hyperplasia. He underwent successful stent dilation from 13 to 17 mm using an 18-mm HP balloon with reduction of the peak gradient to 8 mm Hg. Another patient had stent implantation at 12 years of age (and weight of 57 kg) for CoA using a 13-mm LP balloon. Re-catheterization 16 months later (at weight of 70 kg) showed a 10-mm Hg gradient across the stent, which was eliminated as the stent was dilated from 11 to 14 mm using an 18-mm HP balloon to accommodate somatic growth. The other two patients had no gradient across the stent. **Follow-up procedure.** The 31 patients who were successfully stented and alive were followed for 29 ± 17 months (median: 28 months, range: 5 to 81 months). Follow-up blood pressure data are available for 28/31 patients. Two patients had aberrant right subclavian arteries, and the repair involved the left subclavian artery, while the third had no recorded blood pressure after the procedure. Sphygmomanometric systolic blood pressure (SBP) gradient decreased from 39 ± 18 mm Hg before stent placement to 4 ± 6 mm Hg at follow-up (p < 0.001), while SBP decreased from 136 ± 21 mm Hg to 122 ± 19 mm Hg at the last follow-up (p = 0.002). Doppler echocardiographic data are available for 28/31 patients. Peak Doppler pressure gradient decreased from 51 ± 26 mm Hg before stent implantation to 13 ± 11 mm Hg at follow-up (p < 0.001). A total of 22/31 patients (71%) were hypertensive and 13 (42%) were on antihypertensive medications before stent implantation. At their last follow-up visit, only 8/31 (26%) remain hypertensive and on antihypertensive medications (p < 0.05), and all the patients are asymptomatic. There was no evidence of recurrent coarctation, aneurysm formation or stent displacement or fracture identified by follow-up echocardiography and chest X-ray (in 30 patients), MRI (in 1 patient) or repeat catheterization (in 4 patients). There were no significant differences in the initial or follow-up results between patients with native and those with recurrent CoA or between patients with tubular versus discrete coarctation. Linear and multiple regression analyses, adjusting for the variable duration of follow-up, showed no significant effect of age or body surface area on the change in SBP (p = 0.6 and 0.4, respectively), the change in peak Doppler echocardiography gradient (p = 0.3 and 0.9, respectively) or the change in SBP cuff gradient (p = 0.1 and 0.5, respectively). **Residual arch gradient.** In 7/31 (23%) patients, a mild gradient in the TAR of 5 to 20 mm Hg became unmasked after the stent was successfully placed in the original coarctation site, despite having no gradient in the TAR before stent implantation. At follow-up, 3/7 continue to have a mild gradient (≤20 mm Hg) and isthmus/arch hypoplasia. **DISCUSSION** Balloon-expandable endovascular stents have been used in various locations since the 1980’s (1–8,12–14). Stents support the integrity of the vessel wall after balloon dilation by opposing the recoil of the elastic vascular stenosis and reapplying the torn intima to the media. This minimizes the extension of wall tears and subsequent dissection or aneurysm formation that could occur after BA alone (3,7,12,14,15). Acute aortic dissection and aneurysms can develop in 1% to 4% and 4% to 11.5% of patients, respectively, after BA (11,12,16–19). Stents provide a homogenous framework for smooth endothelial growth along the aortic wall that reduces the risk of thrombosis, neointimal hyperplasia and subsequent restenosis (1). **Initial results.** Stent implantation was performed in 33/34 patients catheterized with the intention to treat, and excellent initial results occurred in 32 of 33 patients stented, regardless to the type of their coarctation, comparable to what has been previously reported (6,7,20–22). This is considerably better than BA alone where suboptimal initial results were reported in 19% to 25% of patients, especially in tight coarctation sites (≥3.5 mm) and long segments of narrowing (10–12,16,23,24). **Complications.** Stent migration is a recognizable complication of stent placement (6,20,22). The use of the balloon-in-balloon catheter (BIB, NuMED Inc.) may provide more control of the inflation by using the better anchoring mechanism of the inner smaller balloon that is inflated first. Balloon rupture occurred in five patients, resulting in stent migration in three, but the ruptured balloons were retrieved successfully through the sheaths in four patients. Balloon rupture can be minimized by using a balloon that has the same length or slightly shorter than the stent and keeping
the exchange wire as straight as possible during inflation, a factor that could be more difficult to achieve in the TAR than in the DAo or other locations.

Complications related to the arterial access were reported in up to 19% of patients with CoA after BA or stent placement (6,16,18–20). This is higher than the 6% (2/34) in our study. The vascular complications in our study were related to the femoral artery cannulation and could have been prevented.

Stent re-dilation. Despite one report in animals of acute aortic rupture and death upon attempted stent re-dilation (25), several studies in animal models and in humans with CoA have shown that stents can be further expanded to accommodate somatic growth, up to three years after implantation (3,7,8,13,22). Our experience is still limited though in regards to the safety and long-term effects of multiple stent expansions, especially in younger patients. It is also unknown to what diameter a stent can be safely expanded at initial implantation. The diameter of the stented coarctation segment should not generally exceed the diameter of the isthmus and/or DAo at the level of the diaphragm. In patients with hypoplastic isthmus or tight coarctation (<4 mm), the stent should be expanded to a reasonable diameter (12 to 14 mm) and then re-dilated in six months.

Follow-up. We had no cases of aneurysm formation detected by echocardiography, repeat catheterization or MRI. Echocardiography, however, may be less sensitive than angiography, spiral computed tomography or MRI in detecting aneurysms after stent placement. Magnetic resonance imaging has a limited role in CoA after stent placement since the metallic artifact (or noise) prevents detailed evaluation of the aortic segment within the stent, despite adequate visualization of the aorta proximal and distal to the stent. Magee et al. (20) reported one patient with a small aneurysm detected by angiography, which remained stable for two years upon follow-up with serial computed tomograms.

Residual arch obstruction. Stents can be very effective in relieving arch obstruction. Three patients had obstruction in the TAR and had no residual gradient either initially after stent implantation or at follow-up. On the other hand, the relief of distal obstruction in the DAo unmasked TAR stenosis in three patients who also have isthmus or TAR hypoplasia and continue to have a mild gradient at follow-up. Isthmus and arch hypoplasia were shown to be risk factors for early and late failure after BA in CoA (10,11,19,23,24,26).

Study limitations. The use of stents in CoA remains limited to older children and adults because of the large delivery systems required and the need of multiple stent expansions to accommodate growth. It is unclear whether the noncompliant aortic stents would alter the flow pattern in a way that contributes to the occurrence of late re-stenosis and aneurysm formation in the growing aorta. We still lack adequate long-term follow-up of these patients.

Conclusions. Coarctation of the aorta can be successfully and safely managed with endovascular stents. They provide an alternative form of therapy in patients with native or recurrent CoA in the short and intermediate terms. Questions remain to be answered on the impact of stents on blood flow dynamics and the best management in patients with arch hypoplasia. Long-term follow-up is, thus, needed.

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REFERENCES