کارگاه های آموزشی مرکز اطلاعات علمی جهاد دانشگاهی

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پروپوزال نویسی
Coarctoplasty with Self-Expandable Stent Implantation for Treatment of Coarctation of Aorta in Adults

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Background: Balloon angioplasty for treatment of coarctation of the aorta in adults, though promising, is sometimes limited by significant residual gradient (>20 mmHg). Few studies have been reported on use of balloon-expandable stents in such a situation. We evaluated the use of self-expandable stents in patients with coarctation of the aorta.

Methods: Eight hypertensive patients (age 15 to 27 years) with coarctation of the aorta (n = 6) or recoarctation (n = 2) and peak systolic gradient of >40 mmHg underwent stent implantation. Balloon predilatation was done and self-expandable nitinol aortic stents (Optimed) were implanted in all patients.

Results: The mean ± SD peak systolic gradient decreased from a baseline of 55 ± 15 (range: 40 – 75) to 5 ± 2 (range: 3 – 7) mm Hg after angioplasty. Nitinol stents were easier to deploy and conformed better to aortic anatomy as compared with balloon-expandable stents. The mean ± SD diameter of the coarcted segment increased from 3 ± 1 mm to 16 ± 2 mm. There were no complications in our series. On 6- to 9-month follow-up, all the implanted stents remained in their original positions and none showed evidence of fracture. Significant improvement in hypertension was seen in 7 out of 8 patients.

Conclusion: Stent implantation is safe and effective in treating coarctation of the aorta. Self-expandable stents were easy to implant, had good adaptation to the wall of the aorta, and in most patients had similar efficacy in reducing coarctation of the aorta as surgical repair.

Keywords: Angioplasty • coarctation of aorta • recoarctation • self-expandable stent

Introduction

Several studies have documented the efficacy and limitations of balloon dilation of native coarctation of the aorta (CoA) in adults.1 – 8 Although the results are encouraging, immediate results may be suboptimal because of elastic recoil occurring soon after balloon dilation. Also, patients with hypoplasia of the isthmus or the postcoarctation of the descending aorta, have higher frequency of suboptimal results, resulting in higher residual gradients.2, 9 Hemodynamic and echocardiographic abnormalities such as systemic hypertension, abnormal exercise response, hyperdynamic systolic function, increased ventricular mass, and impaired diastolic function have been observed in these patients on follow-up.10, 11 Similarly, at late follow-up, restenosis (coarctation gradient > 20 mmHg) has been reported in 7% to 36% of patients, particularly in children, after balloon aortoplasty.1, 2, 6 – 9 This has been attributed to an incomplete acute result, recurrent stenosis, and associated transverse arch hypoplasia.

Early experimental works12 followed by a few clinical reports have demonstrated the efficacy of stent implantation in overcoming some of the limitations of balloon aortoplasty. These series have used balloon-expandable stents for relieving coarctation.13 – 23 These stents do not completely appose to the aortic wall and sometimes become dislodged or misplaced. Self-expandable nitinol
Aortic stents adapt better to the wall of the aorta, avoiding dislodgment. They have recently been reported to be effective in improving results of aortic angioplasty in aorto-arteritis (Takayasu disease). However, little information is available on the efficacy of these self-expandable stent implantation for native CoA in adult patients.

**Materials and Methods**

**Patients**
Eight adult (≥15 years) patients underwent intervention of CoA (n = 6) and recoarctation (ReCoA) (n = 2) from October 2004 through September 2005. For all of them, balloon predilatation, self-expandable stent implantation, and postdilatation were done.

**Procedure**
Written informed consent was obtained from all patients. Initially, all of them underwent retrograde femoral artery catheterization under local anesthesia by Seldinger technique. All of our patients were treated with 325 mg Aspirin from two days before the procedure and were given 5000 units heparin during the procedure. The coarctation segment was crossed with a flexible-tip guide wire 0.035 inch in diameter; a pig-tail catheter was then passed over the wire into the arch of aorta. Descending thoracic aortography was performed under the 60-degree left anterior oblique view or lateral view to delineate the coarctation segment.

The technique used for the balloon aortoplasty has been well-described earlier. Hemodynamic data and angiographic measurements of the coarctation segment, aortic isthmus between the coarctation segment and the left subclavian artery, and the descending thoracic aorta at the level of the diaphragm were measured. The diameter of the balloon was chosen so that it equals that of the normal portion of transverse arch or proximal isthmus at the level of the origin of the left subclavian artery but not greater than that of the descending thoracic aorta at the level of the diaphragm. In patients with severe coarctation (≤4 mm), graded dilatation, i.e., initial dilation with a smaller balloon with progression to a larger balloon, was performed. The maximum balloon diameter did not exceed five times the diameter of the coarcted segment. The balloon was inflated across the coarctation until the waist disappeared or the maximum inflation pressure of the balloon was reached. Hemodynamic measurements were repeated to evaluate the results of balloon dilatation. All patients were subsequently taken up for stent implantation.

In all patients, self-expandable nitinol aortic stents (Sinus-Aorta/Optimed) were deployed. The stent length was chosen in such a way to allow reliable placement, adequate coverage of the coarctation site with the coarctation segment in the middle of the device, and to allow a good covering of the isthmus in patients with associated isthmic hypoplasia. Radiopaque scale was apposed to the back of the patient across the coarctation site to exactly localize the origin of the left subclavian artery and the coarctation segment.

The delivery system was flushed with sterile saline and introduced retrogradely through transfemoral 12F introducer sheath over the extra-stiff guide wire. After positioning the stent across the target site, the exact position was confirmed with the help of markers, as described above, using fluoroscopy. Keeping the delivery system straight, the stent was deployed as the outer sheath was withdrawn by manipulating the trigger on the delivery system. After deployment, intrastent balloon dilation was performed in all cases by a balloon two mm larger than the previously-used balloon. Angiography was repeated. When the heart rate reached near the preballoon angioplasty rate, pressure was recorded across the stented segment. No heparin or anticoagulation was given after completion of the procedure. Aspirin, 100 mg/day, was administered for six more months.

Patients were followed for six to nine months. Follow-up included complete history taking, physical examination, regular assessment of blood pressure in all extremities, determination of the antihypertensive medication needs, and chest roentgenography. Improvement in hypertension was evaluated on resting systolic blood pressure recording of the right arm. Computerized tomography (CT) was performed six months after the procedure in four patients. Angiographic restudy was not performed in any patients.

**Results**
There were eight patients (five males and three females) aged between 15 and 27 years. Baseline demographic data are shown in Table 1.

Five patients had discrete native coarctation;
one had associated isthmic hypoplasia and two had reCoA. All patients had systemic hypertension (systolic blood pressure >140 mmHg) on their first visit. Their mean ± SD systolic blood pressure was 168 ± 24 (range: 144 – 200) mm Hg. Five patients were receiving mono-therapy, and the remaining three were on more than one antihypertensive drug.

Immediate results

Hemodynamic and angiographic data before and after the procedure are summarized in Table 2. There was a significant decrease in peak systolic gradient (PSG) after balloon angioplasty. Stents were successfully implanted in all patients. After successful stenting, the mean ± SD PSG across the coarctation decreased from 55 ± 15 to 5 ± 2 mm Hg (P < 0.05). The mean ± SD diameter of the coarctation segment increased from 3 ± 1 to 16 ± 2 mm, and the percentage of stenosis, in comparison with the descending thoracic aorta at the level of diaphragm, was significantly decreased (P < 0.05). The balloon used had a mean ± SD diameter of 15.0 ± 2.3 (range: 12 – 20) mm. Optimed self-expandable stents used were 16 – 26 mm in diameter and 40 – 80 mm in length.

Stent implantation improved the results of balloon angioplasty in all patients (Table 2). In all patients with stent implantation, PSG was significantly decreased across the coarctation, and the diameter of the coarcted segment was increased after stent implantation (P < 0.05) (Figure 1).

After dilatation, the femoral pulse improved in all patients. There were no complications in our series. All patients were discharged 48 hours after the procedure.

Follow-up

On follow-up, all the implanted stents remained in their original position and none showed evidence of fracture on chest roentgenogram after six to nine months. CT scan six months after stent implantation in four patients showed that the self-expandable stent conformed to the aortic wall; already mentioned no aneurysm was formed in these patients. Recatheterization and angiography were not performed in any patients. No increase in gradient was observed in patients on echocardiography control. The distal end of the stent was not in contact with the aortic wall in two of the eight patients with implanted nitinol stents. No adverse consequences such as distal embolism or hemolysis was observed as a consequence of nonadherence of the stent. None of the patients had aneurysm formation. Measurements of the stent immediately after implantation were compared with similar measurements at follow-up with CT scan in two patients that showed improvement (beneficial later remodeling) in the minimum stent diameter.

Hypertension improved immediately after stent implantation in seven patients. On long-term follow-up, improvement in hypertension was observed in all patients. The mean ± SD systolic blood pressure was decreased from 168 ± 24 to 130 ± 10 mmHg (P < 0.05), confirming a sustained reduction in blood pressure. The mean ± SD number of antihypertensive medications was decreased from 2 ± 1 drugs per patient before procedure to 0.5 ± 0.5 on follow-up evaluation.

Discussion

Over the last two decades, percutaneous balloon angioplasty has been used for treatment of recurrent coarctation and native coarctation. Histologic and intravascular ultrasound studies in various groups have shown that balloon dilatation relieves the aortic obstruction by tearing of intima extending into the media. Aneurysm formation, incomplete relief, and restenosis are important limitations of the procedure. Endovascular stent implantation has been reported to improve results in a number of congenital stenotic vascular lesions and after angioplasty of

**Table 1. Characteristics of patients and devices.**

<table>
<thead>
<tr>
<th>Patients</th>
<th>Sex</th>
<th>Age</th>
<th>Disease</th>
<th>Size of stent</th>
<th>Peak systolic gradient (mmHg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F</td>
<td>23</td>
<td>ReCoA</td>
<td>24 × 60</td>
<td>40</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>27</td>
<td>CoA</td>
<td>20 × 80</td>
<td>45</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>27</td>
<td>ReCoA</td>
<td>16 × 60</td>
<td>45</td>
</tr>
<tr>
<td>4</td>
<td>M</td>
<td>17</td>
<td>CoA</td>
<td>26 × 60</td>
<td>60</td>
</tr>
<tr>
<td>5</td>
<td>M</td>
<td>16</td>
<td>CoA</td>
<td>22 × 70</td>
<td>75</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>20</td>
<td>CoA</td>
<td>20 × 60</td>
<td>50</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>18</td>
<td>CoA</td>
<td>20 × 40</td>
<td>55</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>20</td>
<td>CoA</td>
<td>18 × 40</td>
<td>50</td>
</tr>
</tbody>
</table>

ReCoA = recoarctation; CoA = reducing coarctation of the aorta.

**Table 2. Immediate hemodynamic results in coarctoplasty.**

<table>
<thead>
<tr>
<th>Peak systolic gradient (mmHg)</th>
<th>Pre</th>
<th>Postballoon</th>
<th>Poststent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nitinol stent (n = 8)</td>
<td>55 ± 15 (40 – 75)</td>
<td>25 ± 10 (15 – 35)</td>
<td>5 ± 2 (3 – 7)</td>
</tr>
</tbody>
</table>

n = number of patients.
the aorta in aorto-arteritis.24

In 1991, O’Laughlin et al13 reported the first use of an endovascular stent to treat CoA. Since then, the usefulness of stent implantation for treatment of CoA has been under evaluation. Stent implantation has the possible advantage over balloon angioplasty alone in that the stent once dilated, supports the wall of the aorta, preventing elastic recoil, hence, maintaining the increase in diameter. This makes over-dilatation of the coarcted segment unnecessary.28 Sustained relief of obstruction may decrease the incidence of restenosis. This is particularly important for patients with an unfavorable anatomy such as long tubular coarctation and isthmic hypoplasia. Furthermore, since the stent reapplies the intima to the media, it may also prevent dissection and aneurysm formation.28–31

Complications

One of the major problems encountered during placement of the balloon-expandable stent in many series was the stent migration/embolization.10, 17, 19, 21 This may happen during either implantation or follow-up. The thoracic aorta either proximal or distal to the coarctation site, is dilated in a number of cases resulting in improper apposition of these stents to the aortic wall despite attempts at flaring the proximal and distal ends. Incompletely apposed stents may migrate distally because of the force of forward blood flow and pulsation of the aortic wall. This problem was observed in some studies during initial experience and has been an important concern. We have used self-expandable nitinol aortic stents in all of our patients. This resulted in firm apposition of the stent with the arterial wall, negating the chances of stent migration. By this approach, patients were treated by balloon angioplasty and then stent implantation. Primary stent implantation may, however, strengthen the aortic wall and may reduce the chance of aneurysm formation. The major advantage of the Palmaz balloon-expandable stent is its higher radial strength, and so it is chosen for patients with isthmic hypoplasia.

Self-expandable nitinol aortic stents are radiopaque and can be followed by chest roentgenography/fluoroscopy. They do not have sharp edges like the Wallstent (Boston Scientific) and therefore are atraumatic. The radial strength of nitinol aortic stents also appears to be better than that of the Wallstent. The radial strength of nitinol aortic stents can be further improved, as has been done in the self-expandable nitinol framework of Talent Thoracic Stent Graft (Medtronic Inc). Subsequent dilatation to preprogrammed diameters is also possible. Nitinol aortic stents are easy to deploy, do not shorten on expansion, and can be accurately positioned. The Palmaz stent, on the other hand, is a rigid, sharp-edged endoprosthesis that may be difficult to deliver in a tortuous aorta. It can rupture the delivery balloon, causing vascular injury.10 Hamdan et al19 reported balloon rupture in five of 34 patients undergoing stent implantation. Flaring of the edges of the stent that are sharp may cause trauma to balloon33 and vessel wall. During expansion, the partially expanded balloon may act as a flotation catheter causing premature catheter and stent movement during deployment.

None of our patients developed acute or subacute thrombus formation or any evidence of distal embolization. The stented segment of the aorta has a wide diameter and high flow rate, making thrombus formation unlikely.
Follow-up

Significant restenosis is rare after stent implantation, except in infants. In our series, one patient with a self-expandable stent developed insignificant increase in gradient at the coarctation, detected with echocardiography six months later. This may be due to the lower radial strength of self-expandable stent. Hamdan et al performed repeated dilation in two patients on follow-up. Stent implantation in adolescents and adults as opposed to children, has the advantage in that further dilation of stent, due to somatic growth is not required in the future. Safety of stent redilatation in CoA is not well established.

Compared with balloon angioplasty, the incidence of aneurysm formation, though lower, is not completely eliminated by the use of stents as compared with balloon angioplasty. On follow-up, no case of aneurysm formation was detected in the present series. The gradual outward expansion of a self-expandable nitinol stent would be much less traumatic to the aortic vessel wall as compared with sudden expansion by a larger-diameter balloon or balloon-expandable stents. In case that aneurysm formation occurs after angioplasty, it is possible to coil embolize the aneurysm through the stent struts or implant covered stents to decrease the chance of aortic rupture. In cases with preexisting aneurysm or postangioplasty aneurysm, aortic stent grafting may be an alternative to surgery. Mild to moderate beneficial late remodeling after implantation of self-expandable stents observed in this series is an important finding. It supports the use of such stents after coarctation balloon angioplasty. Stent fracture caused by metal fatigue, though not observed in this series, is a possibility and requires long-term follow-up.

After successful stenting, improvement in hypertension occurs in most patients, though normalization may not always be possible. Long-standing hypertension in these adult patients may be an important factor in persistence of hypertension despite successful angioplasty. Long-term follow-up is required to assess the effect of normalization of blood pressure, with smaller dose of antihypertensive medications in preventing long-term complications, such as stroke, heart failure, and premature coronary artery disease, observed on late follow-up in the natural history of patients with CoA. A comparison of study population with a surgical cohort may be done at centers with expertise in both techniques. Further improvements in stent design, developing self-expandable stents of higher radial strength, will further improve the results.

Implantation of self-expandable stents is an effective and safe treatment in adults with native CoA or ReCoA. Self-expandable stents can be implanted accurately across the coarctation. These stents can further reduce the gradients, do not have problems with dislodgment/migration, and adapt better to the aortic wall; beneficial late remodeling on follow-up is an added benefit. Aneurysm formation, though not observed in our series, requires long-term follow-up.

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