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Clinical research

Results and mid–long-term follow-up of stent implantation for native and recurrent coarctation of the aorta

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Aims Since the late 1980s, endovascular stents have been used in the treatment of several vascular lesions. In the last decades, stent implantation has been proposed as a reliable option for the treatment of coarctation of the aorta. In this setting, it seems to have some advantages, rendering it superior to angioplasty alone.
Methods and results Between December 1997 and December 2004, 71 consecutive patients (44 males and 27 females) underwent cardiac catheterization for native or recurrent coarctation of the aorta. Seventy-four stents were implanted. All discharged patients were enrolled in a follow-up programme. Every patient underwent clinical evaluation, echo-colour Doppler studies, and exercise ECG at 1 and 6 months after the stent implantation. Peak systolic gradient dropped from 39.3 ± 15.3 to 3.6 ± 5.5 mmHg ($P = 0.0041$). The diameter of the coarcted segment increased from 8.3 ± 2.9 to 16.4 ± 3.8 mm ($P = 0.037$). In our series, one death occurred in a 22-year-old girl with a recurrent coarctation of the aorta, just after stent implantation. The rate of minor complications was <2%. Re-dilatation of a previously implanted stent was performed in three patients.
Conclusion In our experience (the largest reported to the best of our knowledge), stenting of a coarctation/re-coarctation of the aorta represents a safe alternative treatment without a significant mid–long-term complication.

Introduction

Since the late 1980s, endovascular stents have been used in the treatment of several vascular lesions. Initially, stent implantation was designed for the management of stenoses of iliac and pulmonary arteries, but in the last decades, stent implantation has been proposed as a reliable option for the treatment of coarctation of the aorta. In this setting, it seems to have some advantages, which render it superior to angioplasty alone. Unlike angioplasty, there is no need to over dilate the coarcted segment when a stent is implanted; the stent can be dilated to the desired diameter and a further dilation achieved with a larger balloon, if necessary. Stent implantation prevents acute re-modelling of aortic wall.[1–8]

In this study, we evaluated the medium to long-term results and complications of a large series of patients with native or recurrent coarctation of the aorta, treated with stent implantation in a single centre.

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Methods

Patients

Between December 1997 and December 2004, we retrospectively reviewed all 71 consecutive patients (44 males and 27 females) who underwent cardiac catheterization for native or recurrent coarctation of the aorta. There are various definitions of recurrent coarctation of the aorta, but we used the definition proposed in the ESC guidelines.[9]

The mean age of the patients was 21.8 ± 6.2 years (range 7.1–65.6 years; 29 patients <18 years; 20 with a native coarctation and nine with a recurrent coarctation) and their mean weight was 57.7 ± 7.2 kg (range 81.0–15.0 kg). Nineteen patients had a recurrent coarctation of the aorta after previous surgery (three patch aortoplasty, 10 end-to-end anastomoses, four subclavian artery flap aortoplasty, one end-to-end anastomosis and subsequent subclavian flap for re-coarctation, and one Gore-Tex conduit insert). Fifty-two patients had a native coarctation. All patients were studied together, because it has been previously demonstrated that there are no differences in terms of early results (pressure gradient and minimum stent diameter) between the two groups (native and recurrent).[10]

We define re-coarctation if a patient had a right arm systolic blood pressure >95th percentile for age, an arm-to-leg estimated gradient >20 mmHg, and a similar gradient at the catheterization. We define an aneurysm at a spiral computed tomography (CT) scan or magnetic resonance imaging (MRI) study as a focal dilatation at the coarctation repair site and confirmed during the catheterization. Informed consent was obtained from all patients or from their parents before the procedure.

Procedure

All patients referred to our centre were hospitalized after MRI studies of the aorta. All patients underwent general anaesthesia. Intravenous heparin (100 IU/kg, maximum of 5000 IU) was given after arterial cannulation. The peak systolic gradient was measured, and an aortic arch angiogram was performed in different projections (anteroposterior, laterolateral, and left-anterior oblique views). The diameter of the aorta was measured on-line at the distal transverse arch (just proximal to the origin of the left subclavian artery), at the site of obstruction, and in the descending aorta at the level of the diaphragm. The technique used for the stent implantation has been described previously.[8,11,12] With the aid of a guide catheter, a long, stiff wire was placed across the stenotic area. A long sheath introduced into the femoral artery was advanced across the lesion over the guide wire. The tip of the wire was positioned either in the ascending aorta or in the right subclavian artery. The dilator was then removed and a balloon-expandable stent was advanced inside the sheath to the coarctation site. The balloon size chosen was nearest in size to the diameter of the transverse aortic arch without exceeding the diameter of the descending aorta at the level of the diaphragm. Different stents were used depending on the availability in the market and following the indication of the literature about results and outcomes. When a covered stent became available, we used it in patients without contraindications as possibility of occlusion of side branches and in patients who are fully or nearly fully grown, as it may not be possible to re-dilate them without damaging the polytetrafluoroethylene covering material. The long sheath was withdrawn to expose the stent–balloon complex, which was carefully placed across the stenotic site. The balloon was manually inflated. Repeat haemodynamic and angiographic data were acquired. The femoral arterial access was surgically sutured if the sheath used was larger than 10F.

All discharged patients were enrolled in a follow-up programme. Every patient underwent clinical evaluation, echo-colour Doppler studies, and exercise ECG at 1 and 6 months after the stent implantation. The last 33 patients underwent spiral CT scan studies at 1 and 6 months after stent implantation. When necessary, angiography was performed. Our aim was to evaluate the rate of re-coarctation, hypertension during exercise ECG, and the need of re-dilatation of the stent.

Data analysis

Data are presented as a frequency or percentage for nominal variables, as the median for ordinal variables, and as the mean (SD) for continuous variables. Differences in parameters before and after the procedure were compared using a paired *t*-test or sign test as appropriate. All tests were two-sided. A *P*-value less than 0.05 was considered to be statistically significant.

Results

Seventy-four stents were implanted in 71 patients. The stents used are summarized in *Table 1*. In some patients, more than one balloon catheter was used (Z-Med, BALT, BiB balloons). The mean diameter of the balloon dilatation catheter was 17 $\pm$ 3 mm (range 10–25 mm). The peak systolic gradient dropped from 39.3 $\pm$ 15.3 to 3.6 $\pm$ 5.5 mmHg ($P = 0.0041$). The diameter of the coarcted segment increased from 8.3 $\pm$ 2.9 to 16.4 $\pm$ 3.8 mm ($P = 0.037$). In one patient, closure of a ventricular septal defect (VSD) with a 6-mm Amplatzer Muscular VSD device (AGA Medical Co., Golden Valley, MN, USA) was performed simultaneously.

Table 1 List of used stents

Number	Type of stent
24	Palmaz 4014
15	Palmaz 5014
12	Palmaz 308
10	Genesis 3910
3	Genesis 2910
3	Cheatham-Platinum 8/39
2	Cheatham-Platinum 8/34
1	Cheatham-Platinum 6/39
1	Cheatham-Platinum 8/45
2	Covered Cheatham-Platinum 8/39
1	Covered Cheatham-Platinum 8/45

Complications

According to previous reports, we considered the following adverse events related to the interventional procedure as major complications: (i) death, (ii) life-threatening event (i.e. cardiac arrest and severe hypotension), (iii) the requirement for surgical intervention, and (iv) permanent anatomic or functional lesions. Minor complications were considered to be any transient event resolved with specific treatment (i.e. transient arterial thrombosis or arrhythmic episode).[13] One death occurred in our series in a 22-year-old girl (without genetic disease), with a recurrent coarctation of the aorta following an end-to-end anastomosis. She had severe re-coarctation with a saccular aneurysm between the subclavian artery and the isthmus. The aortic diameters above and below the lesion were 14 and 16 mm, respectively. The coarctation segment measured 10.2 mm. A Palmaz stent 5014 (J&J Interventional Systems Co., Warren, NJ, USA) was mounted on a 16 mm/5 cm BiB balloon catheter. A Mullin's long sheath (COOK Inc., Bloomington, IL, USA) was positioned across the coarcted site. Two COOK detachable coils (5-PDA5 and 8-PDA5) were implanted to occlude the aneurysm, after the stent. There was no gradient on pullback through the stent. The vascular access was sutured by surgeons. The patient was returned to the recovery area and thereafter developed sudden, severe circulatory collapse. Intravenous fluids were rapidly infused. Ultrasonography revealed a large echo-dense area in the left chest, consistent with a haemothorax. The patient was returned to the catheter laboratory in circulatory collapse, where the patient underwent cardiac surgery, which showed an aortic rupture. The patient deteriorated and could not be resuscitated.

In one patient (with a gradient of 23 mmHg between the ascending and descending aorta), three Palmaz 4014 stents were used. The first stent was mounted on a Balt balloon 14 mm/40 mm and re-dilated with a 16 mm/40 mm balloon catheter. It dislodged under the lower level of the coarcted segment. A second stent with a telescopic shape was then implanted using a Balt 16 mm/40 mm balloon catheter.

Both stents dislodged into the abdominal aorta. The last stent was implanted to stabilize the previous two (with a 18 mm/40 mm balloon catheter) in the abdominal aorta. After discussion with the parents, the procedure was aborted because they refused consent to its continuation.

Two more cases of stent displacement were observed (P4014 stent with BALT 25 mm/45 mm and CP 8/34 stent with Z-Med II 18 mm/40 mm), without subsequent events. In one patient, a periaortic haematoma was observed after stent implantation (absent at follow-up). In two patients, a femoral pseudo-aneurysm required vascular surgical correction.

Follow-up

After discharge, all patients were followed-up in the outpatient clinic for a median period of 3.1 years (range 6 months to 7 years). The mean residual gradient assessed by Doppler was 13 $\pm$ 4 mmHg (range 0–32 mmHg).

Four patients underwent stent re-dilatation. In the first patient, re-dilatation was performed 21 months after stent implantation. This patient had two previous surgical operations (end-to-end anastomosis and, then, a subclavian artery flap). The patient underwent successful stent implantation (Palmaz 5014 stent with BALT 12 mm/50 mm balloon catheter), but after 21 months, a pressure gradient of 33 mmHg was recorded at catheterization and the stent was re-dilated with a 15 mm/50 mm balloon catheter, the gradient dropped to 7 mmHg. In the second patient, re-dilatation was performed after 13 months. This patient had a CP 28 mm eight zig stent implanted, which was dilated up to 12 mm with a 12 $\times$ 35 mm BiB balloon. The re-dilatation was performed with a 15/50 mm Balt balloon. The peak systolic gradient dropped from 32 to 9 mmHg.

The third patient (a 27-year-old woman) was re-catheterized following Doppler evidence of a residual significant gradient, 1 year after the implantation of a Palmaz-Genesis 3910 stent dilated up to 12 mm. Angiography confirmed re-coarctation (peak gradient of 24 mmHg) and detected an aneurysm that had formed at the proximal end of the stent. Re-dilation of the stent and implantation of a covered CP stent eight zig 39 mm were carried out successfully.

In the last patient (a 19-year-old man), an aneurysm was observed after stent implantation in a native coarctation. The stent was a Palmaz 5014 dilated up to 12 mm, and the peak-to-peak systolic gradient dropped from 57 to 23 mmHg. CT scanning and catheterization were performed 1 year later and showed a 4-mm segment of aneurysmatic aortic tissue; he underwent implantation of a CP covered stent 45 mm eight zig dilated up to 16 mm, with complete exclusion of the aneurysm. The gradient dropped from 32 to 9 mmHg.

Exercise ECG performed 6 months after the procedure revealed hypertension in 10 patients (mean 212 $\pm$ 16/89 $\pm$ 7 mmHg): six of them had a residual gradient. These 10 patients were started on therapy with beta-blockers, and at present, eight of them are still on therapy. Two patients interrupted the therapy without medical advice.

Of the whole series of 71 patients, 18 (25.3%) practice sport on a regular basis without problems.

Discussion

This report of our experience of stent implantation for the treatment of coarctation of the aorta (the largest so far reported, to the best of our knowledge) shows that this procedure significantly reduces the systolic gradient and increases the coarcted diameter. These data are consistent with those previously reported by other groups.[1,8,14–19]

To achieve these results, we used different series of stents: the Palmaz 8 series and the Cheatham-platinum (CP) six-zig stent (NuMed Inc., Hopkinton, NY, USA) that belongs to large stents category. The most commonly used stent in paediatric cardiology is probably the Palmaz 8 series because of its good radial strength, despite of its sharp edges and stiffness. All these stents are made of stainless steel, except the CP stent which is hand-made from heat-tempered 90% platinum and 10% iridium wire and are, consequently, more radio-opaque and safer during MRI.

We treated longer stenotic segments with stents included in the extra-large group: Palmaz XL series and CP eight-zig stent. The Palmaz XL stents offer some advantages because of their expansibility, radial strength, and lesser foreshortening than the Palmaz 8 series, despite requiring larger sheaths. The CP eight-zig stents have features similar to those of the Palmaz XL, with the advantages of being more radio-opaque and having rounded edges.

The Palmaz-Genesis XD stents (Cordis J&J Interventional Systems Co.) are designed for an expansion range of 10–18 mm, thus they can be considered as either large or extra-large stents.

The Palmaz-Genesis XD series was introduced to allow larger expansion diameters while retaining the favourable features of the first Genesis stents, such as possibility of insertion in transverse-curved vessels with a good radial strength.

We used CP covered stents in three patients. This type of stent is more radio-opaque than steel stents, thus avoiding MRI disturbances. It has rounded edges and can be implanted using any angioplasty balloon or the BIB balloon. The main disadvantages of covered stents are (i) the possibility of occlusion of side branches and (ii) they can only be used in patients who are fully or nearly fully grown, as it may not be possible to re-dilate them without damaging the polytetrafluoroethylene covering material.[20,21]

Various complications of stenting a coarctation of the aorta have been reported (*Table 2*);[1,8,12–18] the most serious complication is aortic acute dissection. We think that the use of covered stents may prevent this risk.

Another complication is stent migration; the use of a balloon-in-balloon catheter (BIB) (NuMed Inc.) may provide better control during the inflation and positioning of the stent. This system consists of a balloon inside a balloon: the inner balloon is half the diameter of the outer balloon and 1 cm shorter than the outer balloon. The major advantage of this system is that after inflation of the inner balloon, the position of the stent can be adjusted, before inflation of the outer one and stent implantation.

Vascular problems at the femoral access are related to size of the sheath and include loss of femoral pulses associated with ischaemic lesions. We prefer surgical suture of the

Table 2 Brief review of the literature

Patients	Complications	Re-dilation	Late aneurysm	Follow-up (mean)	Reference
32	One stent migration, one aortic dissection	Eight patients	None	1.5 years	Johnston *et al.*[1]
21	Two stent migration	Two patients; 4[a]	Three spiral CT scan		Cheatam *et al.*[14]
54	Two minor complications (arrhythmias, paradoxical hypertension), two stent migration, one major (vascular surgery)	Two patients	One		Ledesma *et al.*[15]
34	Two major (surgery); four minor	Four patients	None	28 months	Hamdam *et al.*[16]
27	One stent migraton, two major (balloon rupture and cerebral embolism)	None	Three	1.8 years	Harrison *et al.*[10]
17	None	None	None	33[b]	Thanopoulos *et al.*[17]
17	Two stent migration, two major (haematoma and carotid haemorrhage)	5 + 1[a]	One		Magee *et al.*[8]
48	One major (acute dissection; one stent migration), nine minor (loss of femoral pulse)	One	Two	2 years	de Lezo *et al.*[18]
33	One major (myocardial infarction), two minor (complete HB, loss of femoral pulse), one stent displacement	None	None	27[b]	Marshall *et al.*[19]

[a]Additional stents.
[b]Median value.

femoral arterial access if the sheath used was larger than 10F. All our patients were re-studied with Doppler ultrasound of the vessels used for access, and no stenoses were observed.

One of the most significant points in managing these patients is the possibility of re-dilating the stent. Over-dilatation seems to be the factor most strongly pre-disposing to re-stenosis, whereas the mechanism that reduces the stent lumen is neointimal proliferation. This phenomenon is more evident in pulmonary artery re-stenosis, in which the stent lumen achieves a uniform vessel diameter. When re-coarctation was observed in a stented segment, re-modelling of the coarcted aorta, neointimal proliferation at the site of the residual waist, and changes of blood flow were found. As reported by Duke *et al.*,[22] stent re-dilatation is an effective procedure that increases the diameter of a previously implanted stent and thus decreases the pressure gradient. The major indication for re-dilatation is deliberated or forced under expansion at first implantation and re-stenosis of coarctation of the aorta.[23] In our series, re-dilatation was performed without complications, confirming the feasibility and the clinical importance of this procedure.

The follow-up assessment of these patients is of great importance. Recent data report that CT scans and MRI are similarly useful for the non-invasive evaluation of the thoracic aorta in patients with coarctation of the aorta.[24] In 2002, we started our programme of follow-up using CT scanning to detect the anatomical characteristics of any aneurysm formation or intrastent peeling. We believe that this technique is better because of the absence of stent-related interferences, which can occur during MRI. All our patients underwent exercise testing during the follow-up. This test is of limited value in the assessment of the residual gradient[25] but is necessary for any patient wanting to undertake physical activity and/or sport. The problem is what to do for patients who manifest hypertension during exercise but do not have residual stenosis. Our policy is to start beta-blocker treatment, although it is unclear for how long these should be administered and what kind of limitations we should impose on these patients.

Conclusions

Study limitations

This investigation is a retrospective study. Follow-up assessment has changed over time. We have tailored follow-up according to our experience, information from non-invasive imaging techniques, and on the basis of new data and considerations from literature.[24,25]

We treated recurrent coarctation only if the residual gradient was significant, but it has been recently shown that mild residual descending aortic narrowing in post-coarctectomy patients is independently associated with a higher mean daytime blood pressure and carotid intima-media thickness, data suggesting that a lower threshold for treatment may be indicated for these patients.[26] Further research is needed for this special group.

Our policy

Our patients, with either native or recurrent coarctation of the aorta, currently undergo MRI before interventional percutaneous procedures to define the anatomy and the site of the stenotic segment as precisely as possible. We usually perform catheterization as described earlier and we currently prefer a primary stenting more than an angioplasty.[27] We use a BiB balloon catheter to dilate a Genesis stent or a Cheatham-platinum covered stent. The decision about the specific stent is related to the diameter of the coarctated segment, the exact position of the coarctation, and the possible need for a second dilatation of the stent after implantation.

We prefer not to flare the ends of the stent with a balloon of larger size as proposed by some authors, because there is no clear evidence of the usefulness of this strategy and because of the risk of acute stent migration and the suggested increase in the risk of aneurysm formation.[28]

We perform CT scans at 1 and 6 months after discharge to detect eventual early aneurysm formation and follow it over time. Exercise testing is planned for all patients, especially for those who would like to practise sport, in order to assess blood pressure increase and effort tolerance.

Stent implantation is a reliable technique for the management of both native and recurrent coarctation of the aorta. It is effective in relieving the pressure gradient and in increasing the diameter of the stenotic segment. Information gained by non-invasive imaging methods is essential to have a precise definition of the anatomical features of the aorta before interventional procedures and for detecting even small tears after final stent implantation.

Some questions about the long-term results of stent treatment of coarctation of the aorta, the incidence of aneurysm, and the effects of a stiff aortic segment on blood flow still remain to be unanswered. Further data on these aspects are required.

Conflict of interest: none declared.

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