Stents in the Management of Coarctation of the Aorta in Adolescent and Adult – Experience from a Developing Country

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In our setup, a significant number of older children, adolescents and adults are diagnosed as having coarctation of aorta (CoA) as diagnosis is often missed in early life. The traditional approach to such patients has been surgery and various techniques have been used to resect or patch it. Balloon dilation for CoA has been limited by concerns over the risk for acute dissection, late restenosis, or aneurysm. The objective of this study was to assess the early and mid-term results of stenting as primary treatment in older children, adolescents and adults with coarctation of the aorta. Punjab Institute of Cardiology-a tertiary referral center for paediatric & adult cardiology. All patients seen with coarctation of the aorta between October 1999 and September 2002 and considered suitable for stent implantation underwent attempted stent implantation. Follow up was obtained for all patients and a subgroup (n = 4) had spiral CT scan at mean (SD) of 1.3(0.5) years to assess residual gradient and stent-CoA morphology. We implanted Cheatham Platinum (CP) stents from NuMED with BIB balloon in 18 adolescents and adults with native coarctation of the aorta. All procedures were done under general anaesthesia. There were 10 males and 8 females, two of them real sisters. The median age was 24 years (range 12-40 yrs). The indication of intervention was systemic hypertension in all pts. Stents were placed in 17 patients, of whom one had a prior balloon dilation. Hypertension was present in all patients (mean pressure174 (26)/90(13) mm Hg), of whom 16 were on antihypertension drugs. CoA gradients were 50 (20) mmHg (range 38–106mm Hg) at baseline and 3 (5) mm Hg after the procedure. One patient had an unsuccessful procedure as the stent foreshortened significantly at full inflation and slipped from the site of coarctation. It was expanded lower down in aorta. One underwent a second procedure as stent was not fully inflated first time due to severe hypoplasia of coarctation segment. At 1.8 (1) years after the procedure the mean pressure was 136 (14)/74 (11) mm Hg with seven patients on antihypertension treatment. None of the 16 patients where complete relief was achieved at first attempt has shown recoarctation on echocardiography. No adverse systemic hypertension has been noticed. Stent implantation in coarctation of aorta in elder children, adolescents and adults is an attractive alternative to surgery. Use of CP stents with BIB balloon allows a better control over site of placement and better stability. It achieves complete relief of obstruction with minimal complications and good intermediate term results.

Keywords: angioplasty; coarctation of the aorta; congenital heart defects; stents

In developing countries like Pakistan, significant number of adolescents and adults are diagnosed as having coarctation of the aorta as diagnosis is often missed in early life. The traditional approach to such patients has been surgery and various techniques have been used to resect or patch it. Surgical correction of coarctation of the aorta (CoA) improves patient's natural history and assists in control of hypertension. Residual problems of recurrent CoA include need for reoperation, persistent hypertension, and the uncertain significance of exercise induced hypertension[1,2,3,4,5,6].

Over the past two decades non-surgical catheter directed management for CoA has been attempted by using balloon angioplasty (7-25). Although initial procedural success has been well documented, balloon management has been complicated by aortic dissection[13,20,21,23] cerebrovascular accidents[15,16,17,18] incomplete relief of the CoA gradient[8,11,12,13,14,15,23,24] and aneurysm formation[23,26]. Perhaps the most limiting feature of CoA angioplasty is significant residual gradient (> 20mm Hg) at late follow up in 7–36% of patients[8,9,10,13,14,15,16,17,27]. Residual gradient has been attributed to an incomplete immediate result, recurrent stenosis, and associated transverse arch hypoplasia.

Endovascular stents have been applied in the management of CoA as an alternative to balloon dilation alone[16,28,35]. Stent use has been limited by the maximal diameters that can be achieved without inducing strut fatigue; follow up of their use has been of limited duration. Recently, CP stents have become available (Chetham Platinum, Neu-Med, USA), which has Bib Balloon and can be expanded up to 25 mm in diameter, well within the arch diameter of an adult aorta. We report the immediate and early follow up of a group of consecutive adolescents and adults for whom stent angioplasty for CoA was the primary management strategy, including haemodynamic and angiographic assessment after implantation.

Patients and methods

Patient population

Consecutive adolescent and adult patients (n=18, weight 35-7950 kg) referred for management of Coarctation of the

aorta at Punjab Institute of Cardiology between October 1999 and September 2002 were offered catheter directed management of their lesion if considered suitable. Because efficacy, safety, and cost issues are important in our set up patient were excluded because of wall calcification, isthmal hypoplasia, CoA location (for example, near the left subclavian artery), or arch irregularity. Informed consent was obtained for all patients before the procedure.

Technique of implantation

Vascular access was achieved from the right femoral artery in all patients and 3000–5000 IU of heparin sulfate was administered. The CoA gradient was measured and an aortic arch angiogram was taken in either the left lateral or left anterior oblique view (Fig 1). This image was measured on line to determine the diameter of the aorta proximal and distal to the site of obstruction. The diameter of the outer balloon was chosen to equal that of the normal portion of the transverse arch or proximal isthmus at the level of the take off of the left subclavian artery. Generally, because of post-stenotic dilatation of the thoracic aorta, the balloon size selected for the procedure had an inflation diameter less than that of the distal aorta. The location of the CoA relative to landmarks within the chest was noted for reference during positioning.

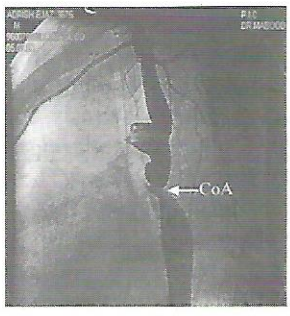

Fig. 1 A descending aortogram showing a tight juxtaductal coarctation of aorta distal to the origin of left subclavian artery.

A 0.035 extra stiff Amplatzer exchange wire was placed in the ascending aorta. Over this guide wire a 11-14F long Mullins transseptal sheath (depending upon size of the child and the stent selected), was passed across the coarctation. A CP (Cheatham Platinum) stent (NuMed Inc. Hopkinton NY, USA) mounted over a BiB Balloon (Inner Balloon and Outer Balloon) was used. The whole assembly was passed through the sheath and after correct positioning, inner balloon was inflated first. The position was rechecked by angiography and then the outer balloon inflated fully. Both balloons were deflated with inner being deflated first. Aortogram was repeated to look at the appropriate apposition of the stent to the aortic wall and to look for any evidence of dissection or aneurysm formation (Fig 2). In some cases the CoA site was immediately distal to the subclavian artery and the stent was then deployed across the artery ostium.

Al patients were discharged from the hospital the following day.

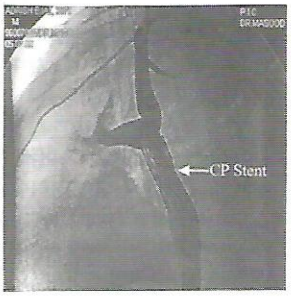

Fig. 2 An aortogram showing the stent in position covering the coarctation segment and completely opposing the vessel wall.

Follow up protocol

Patients were scheduled for clinical follow up at six weeks, 6 moths, one year, two years and three years after the procedure. If they were normotensive at the first follow up assessment, patients on antihypertension drugs were given a trial off treatment.

All Patients (n = 18) underwent echocardiography on all follow up visits and reassessment was done both clinically, radiologically and on echocardiography.

Results

Population

Eighteen patients (10 males) underwent stent implantation for CoA. Mean age at procedure was 24(13.1) years (range 12–40 years). One patient had previous balloon angioplasty. Hypertension was present in 18 patients, with a mean systemic blood pressure of 174 (26)/90(13) mm Hg, and 17 patients were on antihypertension drugs. Seven patients were taking more than one drug; of the nine patients on monotherapy, Five were on a beta-blocker, three were on an angiotensin converting enzyme inhibitor, and one was on a calcium channel blocker.

Procedure

Baseline blood pressure proximal to the CoA was 154 (30)/85 (15) mm Hg (mean 103 (18) mmHg), and distal to the CoA was 104 (19)/76 (12) mmHg (mean 84 (13) mm Hg) ($p = 0.001$ systolic mean pressure difference). The mean peak gradient was 50(20) mmHg. CoA minimum diameter was 6.6 (3.6) mm (range 2–16 mm). Of the four-stent lengths available, 4.5cm was placed in two patients; the 3.9 cm stent was placed in 10 patients and the 2.8cm stent in the remainder. The CoA was dilated with a 20x10 mm diameter balloon in 12 patients, a 16x8 mm balloon in 3 patients and a 12x6 mm balloon in 2 patients. In one patient the stent foreshortened significantly and shifted position during balloon inflation, resulting in stent deployment distal to the CoA site, and was redilated within the descending aorta to stabilise its position. An additional covered stents is planned to seal the dissection, which developed in this patient. One patient had minor distal

migration of the stent during placement, although its final position adequately covered the CoA.

Blood pressures immediately following implantation were 136 (33)/80 (19)mmHg (mean 98 (23)mmHg) proximal and 130(34)/80 (19)mmHg (mean 97 (24)mmHg) distal to the CoA (table 1). This was a slightly greater ascending systolic than descending systolic pressure ($p = 0.04$), with no difference in ascending or descending mean pressures. The mean peak gradient was 3(5)mmHg, significantly less than before the procedure ($p = 0.001$), and the minimum diameter within the stent increased to 16.9 (2.6) mm (range 9–20 mm, $p = 0.001$). The ratio of the CoA site to the transverse arch diameters rose from 0.35 (0.2) (range 0.18–1.00, $n = 25$) to 0.92 (0.15) (range 0.62–1.13, $n = 18$) ($p < 0.001$).

Table1: Immediate Haemodynamic & angigraphic data of all patients following stend implantation.

	Pre	Post	P. Value
Ascending Aortic Pressure (mean)	154(30)/85 (15)mmHg	136(33)/80 (19) mmHg	P=0.001
Descending Aortic Pressure (mean)	104(19)/76 (12)mmHg	130(34)/80 (19)mmHg	P=0.01
Mean Peak Gradient	50(20)mmHg	6(5)mmHg.	P <0.001
Coarctation diameter (mean)	6.6(3.6) mm	16.9(2.6) mm	P=0.04
Ratio of CoA to transverse arch	0.35(0.2)	0.92 (0.15)	P< 0.001

Procedure complications

One patient with severe coarctation and marked post stenotic dilatation in whom the stent foreshortened developed a large dissection of the aorta with neck at the site of coarctation. In one patient the dilation balloon ruptured during stent inflation but was withdrawn easily.

Clinical follow up

One patient had a covered stent for a persistent arterial duct at the time of stent implantation and has been reported separately. The remaining 17 patients had clinical follow up at a mean of 1.8 (1.0) years (range 0.1–3 years). Average blood pressure was 130 (14)/74 (11) mmHg, and clinical gradient was 4 (8) mmHg (range 0–32 mmHg). Seven patients were still receiving antihypertension treatment at their last assessment.

Echocardiographic assessment

Follow up echocardiographic haemodynamic assessment was obtained in all patients. None of the 16 patients where complete relief was achieved has shown recoarctation on echocardiography.

Discussion

In the present study CoA balloon dilation with endovascular stent implantation resulted in a significant reduction in the CoA site gradient. At clinical follow up only seven of 18 patients were taking antihypertension drugs. The average blood pressure in all patients was 136 (14)/74 (11)mmHg.

Our experience with these initial patients showed that the C-P stents could be successfully implanted in elder children, adolescent and adult patients with aortic coarctation without any important complications.

Despite the fact that we elected to under-inflate the stents in one of the patients, a tiny aneurysm was noted in one patient. This, however, disappeared on further dilation of the stent at a second procedure. It is possible that redilation resulted in the tucking of the flap by the stent against the aortic wall. Because of financial considerations, we subsequently implanted the stents to the maximum required diameter measured just beyond the left subclavian artery. Whilst the rationale for staged dilation of the stents is to prevent vessel rupture and aneurysm formation, such a policy may have financial implications for patients in countries such as Pakistan as this approach requires a further balloon procedure for full dilation later adding to the expenses for the patient. Further experience is needed to justify staged dilation of the stents and to identify the type of morphology in which staged dilation is advisable.

In aortic recoarctation, at present it seems reasonable to reserve stents for those patients in whom balloon dilation has failed to relieve the stenosis. The long-term implication of endoarteritis and late re-stenosis remain a concern. The complications of stent implantation such as aneurysm formation and restenosis have been reported with Palmaz stents and there is no reason to expect this to be any different with other stents. The C-P stent is made of platinum and its design is such that proximal and distal edges of the stent are rounded and the zig design allows the stents to be over-dilated without important shortening of the stent. The stents are implanted using a BiB balloon catheter, which allows the precise placement of the stent across the coarctation and allows the position of the stent to be adjusted even when the stent is inflated without there being any concerns that the stent will embolise elsewhere.

Previous studies of balloon angioplasty in adults consistently showed an improvement in the CoA gradient[13,14,17,19,22,25]. However, studies with more than 10 patients reported a residual mean gradient ranging from 8 (10)mmHg to 18(15)mmHg, and residual gradients of >20 mm Hg were found in 7%–26% of patients. At follow up, clinical hypertension or continued use of antihypertension drugs was reported in 27–68% of patients, and late haemodynamic restenosis (when reported) was found in 7–9%[13,14,17]. Other late complications were aneurysm formation in 7–15% and aortic dissection requiring urgent surgery in three patients[13 14 25].

To address these concerns, endovascular stents have been proposed as a potential technique to improve upon balloon angioplasty alone. As such, they have been applied in the setting of congenital heart disease for a number of

indications including pulmonary arterial stenosis, and conduit and systemic venous obstructions with good sustained results. Previous evaluations of stent management of CoA have included case reports (29 34) and small series (n<10) in which patients were often selected because their conditions were judged to be inappropriate for balloon angioplasty alone. These studies used smaller stents than were available for our study (often 3cm length and over stretched diameter 18mm). Nevertheless, case series have reported encouraging results compared with those reported for angioplasty alone. For many patients, there was no residual gradient and mean residual gradients were 1 (1.6) mmHg, 32 2 (3)mm Hg, 28 4(1)mmHg, 31 and 13.3 (23.2) mm Hg 30 in four studies. In three studies with clinical follow up and a combined population of 25 patients, five remained hypertensive at follow up[28,30,31].

Excellent immediate haemodynamic results were obtained in this study, with a reduction in CoA gradient to 3 (5) mm Hg and only one of 18 patients with a residual gradient of 20 mm Hg. Further, echocardiographic reassessment in 18 patients showed that the CoA site gradients remained low with persistent but dilatable stenosis documented in only one of these patients. Persistent hypertension at clinical follow up was present in seven of 18 patients, less than has been reported for angioplasty alone[13,14,17,19,22,25].

Aneurysms remain a potential issue of concern but were not found in any of our patients. The morphology of the lesion and potential for aneurysm development in this latter patient deserves further comment.

Anatomical proximity of the CoA to the left subclavian artery makes stent placement near or up to the ostium unavoidable. Angiographic and haemodynamic observations in instances where placement was close to or impinging upon the left subclavian ostium revealed no evidence of flow compromise. That this is not a surprise rests with the unobstructive character of flow through the stent struts.

There are potential problems in the long-term follow up of endovascular stents, which were not observed in this study. Specifically, there is the possibility of stent migration into the descending aorta, although because no migration was detected in the first year we think that this will be unlikely. Metal fatigue has not been observed because the implants were expanded well within their rated diameters. If metal fatigue were to occur, it may not result in an embolic complication because the majority of the stent is covered with endothelium. The possibility for device erosion is not known.

Limitation

Although this is the largest reported group of patients managed with stent implantation from Pakistan this study was limited by the relatively small number of patients, making accurate evaluation for risk difficult and infrequent complications less likely to be observed. Similarly, the follow up time was short in relation to the patients' expected lifespan, thus preventing observation of latecomplications, which may have important future consequences.

There were three major limitations to the study design. Firstly, waded not compare the study population with a surgical cohort. A randomised comparison with surgical patients would be theoptimal assessment but would require multicentre involvement to accomplish within a meaningful time. Such a study would be limited to centres that can offer expertise in both techniques. Secondly, we did not perform an exercise test evaluation during follow up. Exercise induced hypertension is frequently observed, with uncertain clinical significance. It would be of interest in the future to compare the effectiveness of stent techniques with surgical techniques in preventing exercise induced hypertension. Third limitation is the absence of angiographic data in follow up.

Conclusion

Our initial experience with C-P stent implantation using a BIB balloon catheter shows that these stents can be deployed safely and effectively. The placement of the stent is precise by the use of these balloons We have shown that stent implantation as primary management for CoA is an effective intervention for gradient reduction with acceptable procedural risk. Application of this technique has significantly improved upon the problem of restenosis observed following angioplasty alone. We believe that stent implantation can be recommended as an acceptable alternative to surgery for CoA.

Further experience is required to determine the long-term results and complications of these stents in patients with aortic coarctation.

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