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### Procedural Outcome and Short Term Follow Up of Patients Undergoing Endovascular Stenting for Coarctation of Aorta: A Single Centre Experience

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### Abstract

**Background:** Endovascular stenting is the preferred option in managing coarctation of aorta (COA) in older children and adults. Covered stents are used in selected or high risk category of patients. We present our experience with stenting of coarctation of aorta.

**Materials and Methods:** Patients with severe coarctation of aorta who underwent endovascular stenting during the period July 2013 to July 2016 were retrospectively analysed. CT aortogram was used for pre procedural imaging. Procedural outcome complications and short term follow up were noted.

**Results:** 22 patients (seven females) aged 1-52 years (median 29), weighing 7.8 -86.4 (median 55.1) kg, underwent stenting of COA. All except one had post subclavian coarctation. 68.2% of patients had hypertension and were on treatment. Mean gradient at catheterisation was  $71.7 \pm 28.6$  mm hg and mean gradient post procedure was  $3.6 \pm 4.4$  mmhg. A total of 22 stents were deployed, Covered CP (12), Cook Formula (1), Advanta V12 Atrium (2), Intrastent Mega(3), Palmaz (2), Andrastent.(1),Bare CP (1). Covered stents were used in 59.1%. The mean stent length was  $35 \pm 12.5$  mm. Pre dilatation was done in two patients including one with near interruption. Post dilatation was needed in 36.4% of patients. Procedural complications included retroperitoneal hemorrhage in one which resulted in mortality. Follow-up ranged from 1 month to 3.5 years. 36.4% required continuation of antihypertensive therapy even after stenting. One patient with presubclavian coarctation required redilatation 6 months after stenting.

**Conclusions:** Stent implantation is a safe and effective alternative to surgical repair in COA. It provides immediate and near complete relief of obstruction which is sustained on short term follow up. Long term follow up is required to look for restenosis, aneurysm formation and persistent systemic hypertension.

#### INTRODUCTION

Coarctation is the third most prevalent form of congenital heart disease, with an incidence of  $\sim 20$  to 60 patients per 100,000 live birth accounting for 5 to 8% of all congenital heart defects <sup>(1)</sup>. The

coarctation is mostly juxtaductal located at the insertion of the ductusarteriosus with the aorta, just distal to the origin of the left subclavian artery. There is a morphological spectrum of abnormalities, ranging from a discrete stenosis

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distal to the left subclavian artery to a hypoplastic aortic arch and isthmus that typically presents in infancy. Majority of coarctations are newly diagnosed in childhood and only less than 25% are recognized beyond 10 years of age<sup>(3)</sup>. The clinical presentation of patients with coarctation is variable. They may become symptomatic early in the neonatal period with congestive heart failure (CHF) or may present late with hypertension. Indication for intervention in coarctation include a pressure gradient across the coarctation segment of more than 20mmhg at rest or more than 50% decrease in lumen diameter at the narrowed site. Significant coarctation if left untreated will have varying degrees of morbidity like hypertension, stroke, ventricular hypertrophy, heart failure and may not survive beyond fourth decade of life<sup>(2)</sup>. The mean age at death is 33 to 35 years, and 90% of patients with untreated coarctation are dead by the 6th decade. Neonates and infants who are symptomatic should have urgent intervention as soon as the infant is stabilized. If hypertension and heart failure are not present, elective surgical or balloon therapy in children between the ages of 1 and 5 years is suggested. Medical management without intervention to relieve the aortic obstruction is not advisable because even effective treatment after 5 years of age is likely to result in residual hypertension. The past 5 decades have seen many improvements in therapeutic options for treatment of native coarctation of aorta in children and adults. Surgical correction was first performed in mid 1940s and continues to be the standard method of therapy for coarctation <sup>(4,5)</sup>. The treatment of coarctation has evolved since the first surgical repair by Crafoord in 1944. Surgical techniques have provided the mainstay of intervention since that time, with gradual improvement in morbidity and mortality rates and with modern techniques, the results are generally significant morbidity and excellent. However postoperative discomfort remains. Endovascular techniques provide minimally invasive а alternative to conventional open surgery and allow a shorter hospital stay. This form of therapy has

quickly gained acceptance in many centers. Early and intermediate results suggest angioplasty and stenting have an important role in the management of aortic coarctation, particularly in adults and older children. The transcatheter approach was first performed using balloon angioplasty in 1980s and intravascular stent treatment gaining wider acceptance in the 1990s .At many centres transcatheter approach has become the treatment of choice for children and adults with native coarctation of aorta. However, the optimal form of management is controversial. Hence the relevance of our study to assess procedural outcome and short term follow up of patients undergoing endovascular stenting for coarctation of aorta.

#### **OBJECTIVES OF THE STUDY**

To analyse clinical profile, procedural outcome and short term follow up of patients undergoing endovascular stenting for coarctation.

#### MATERIALS AND METHODS

This is a single centre observational study conducted in a tertiary care pediatric cardiology centre. All patients who underwent stenting for coarctation between 7/2013 to 7/2016 were retrospectively analysed. Consecutive sampling was done. Excluded patients with middle aortic syndrome and patients with coarctation in whom balloon dilatation or surgery was done. Baseline, immediate and short term outcomes after coarctation stenting were analysed. All details were collected about clinical profile of patients, site of lesion, presence of hypertension, LV dysfunction and other associated abnormalities .Procedural details like stent length, acute reduction in gradient, need for post dilatation were also analysed. All details were collected from database and patients were called and follow up was done. All the details were entered in a proforma. Ethical committee and institutional research committee clearance was obtained. Informed consent was obtained from all the patients.

#### RESULTS

Total of 22 patients underwent coarctation stenting during the study period. Mean age was  $27.14\pm 12.9$  years with a range of 1-52 years. 68% were males. On analyzing the symptoms, it included

Dyspnoea on exertion	31.8%
Claudication	22.7%
Epistaxis	4.5%
Chest pain	4.5%
Hemiparesis	4.5%
Asymptomatic	36.4%

68.2% of patients had hypertension and were on treatment.

On analysing the anatomy

Amato 1	68.2%
Amato 11	22.7%
Amato 111	9.1%

95.5 % were post subclavian coarctation and 4.5% was presubclavian coarctatation.Mean gradient preprocedure was  $71.7\pm28.6$  mmhg which was reduced to  $36\pm4.4$  mmhg post procedure. Covered stent was used in 59.1% of cases. A total of 22 stents wereused which included.

Covered CP	12 (54.5%)
Atrium covered	2 (9.1%)
Intra stent Mega	3(13.6%)
Palmaz	2(9.1%)
Formula stent	1(4.5%)
Bare CP	1(4.5%)
Andra stent	1(4.5%)

Average stent length was  $35\pm 12.25$  with a range of 11- 50 mm. Predilatation was done in two patients of which one was a case of near interruption. Post dilatation was needed in 36.4% of cases. Procedural complications included retroperitoneal hemorrhage in one which resulted in mortality. Follow-up ranged from 1 month to 3.5 years. On follow up 36.4% required continuation of antihypertensive therapy even after stenting. One patient with presubclavian coarctation required redilatation 6 months after stenting.

### DISCUSSION

Treatment options available for coarctation Balloon Surgery, include angioplasty and Stenting. Balloon angioplasty was introduced in 1980s as an alternative approach to treat recurrent coarctation following surgery. Both surgery and balloon angioplasty had major drawbacks like recoarctation, residual hypertension and aortic wall injury causing dissection and aneurysm formation. To overcome some of these limitations stent therapy was introduced in 1990s. In older children and adults, endovascular therapy with either balloon angioplasty or stent placement is commonly preferred over surgery. Although balloon angioplasty typically results infavourable acute results, it is associated with a higher rate of both recurrent obstruction and aortic wall injury than stent therapy. Balloon angioplasty has limitations in that elasticrecoil of vessel wall and intimal dissection may not result in effective relief of the blood vessel narrowing.

Stent implantation is superior to balloon angioplasty in terms of lower residual gradients, reduced rates of restenosis and is more effective in mild coarctation. Stents by exerting radial forces prevent vessel wall elastic recoil. Stents compress dissection flaps against vessel wall and provide effective relief of obstruction. They reinforce the weakened areas within the aortic wall. Intimal and medial damage are less following stenting compared with balloon dilation. Where intimal tears occur stent provides a surface for formation of neo intima over the tear allowing healing to occur without intimal dissection. As a result, stent placement is usually preferred when patient size and coarctation anatomy are suitable. In 1964, Dotter and Judkins while exploring balloon angioplasty introduced the concept of stents (19). O' Laughlin and associates were the first to utilize a stent for management of corctation <sup>(20)</sup>. Redington and his colleagues implanted an 8 mm self-expanding stent

in 10-week-old girl who had poor result following balloon angioplasty <sup>(21)</sup>. Suarez de Lezo and his

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colleagues were the first to report a series 10 patients with AC in whom stents were implanted <sup>(22)</sup>. The first balloon expandable stent was patented in 1988. By 1996 the use of stents for treatment of coarctation was reported and by the end of 20<sup>th</sup> century stent therapy for older children and adults became widely accepted despite the absence of clinical trials or stents approved by FDA for this indication.

An ideal stent should have the following characteristics:(1) low profile so that it can be delivered via small diameter delivery sheaths, (2) can easily be crimped or available premounted, (3) has atraumatic rounded edges, (4) high level of flexibility so that it can be implanted around curved blood vessels, (5) minimal stent shortening on expansion, (6) high degree of radial force so as to keep tight and scarred lesions open, (7) feasibility for re-expansion to adult size, (8) open cell design, (9) MRI compatible, (10) minimal neointimal proliferation, and (11) biodegradable material to minimize tissue reaction and maximize tissue remodeling. The indications for using stents are: (1) long segment coarctation, (2) hypoplasia of the isthmus or aortic arch, (3)coarctations which are tortuous and have malalignment of proximal with distal aorta, (4) recurrent aortic coarctation or an aneurysm following previous surgery or balloon angioplasty, and (5) to address complications of balloon angioplasty such as aortic tears or large intimal flaps (23,24). The objective of stent deployment is to reduce coarctation gradient to less than 10 mm Hg and/or produce greater than 90% improvement of aortic constriction by angiography.

First series of aortic stent implantations in 10 patients was by Suarez de Lezo et al<sup>(22)</sup>. Reduction of peak systolic pressure gradient across AC from  $43 \pm 12$  to  $2 \pm 3$  mm Hg and improvement ratio of isthmus/descending aortic diameter from 0.65  $\pm$  0.14 to  $1 \pm 0.08$  occurred. Similar results have been reported in subsequent studies. Decreased peak systolic pressure gradient across the coarctation and increased diameter of the coarctation segment and were seen following stent

outcomes implantation. The treatment of Coarctation were good in our study cohort. Mean gradient at catheterisation was  $71.7 \pm 28.6$  mm hg and mean gradient post procedure was  $3.6 \pm 4.4$ literature mmhg. In our search. similar encouraging results have been reported in other countries - Harrison et al found that the mean peak pressure gradient of 46 ± 20 mmHg at baseline was reduced to a mean gradient of  $4 \pm 6$ (range 0–26) mmHg at follow-up 1–3 years later <sup>(6)</sup>. In Hamdan et al's study the peak systolic pressure gradient measured at catheterisation decreased from  $32 \pm 12$  mmHg to  $4 \pm 11$  mmHg, while the echocardiographic Doppler gradient decreased from  $51 \pm 26$  mmHg to  $13 \pm 11$  mmHg at follow-up<sup>,(7)</sup>. Other similar reports showed significant improvement in the pressure gradients and CoA diameters before and after stent (11, 12, 13, 15, 18)In a recent multi implantation institutional and colleagues study, Forbes presented results of 217 patients who had stent implantation to treat AC. The upper to lower extremity pressure gradient decreased from 40  $\pm$ 24 to  $4.9 \pm 13.2$  mm Hg (p < 0.01) immediately following the stent implantation. At the time of discharge 81% of the patients had gradient < 15mm Hg <sup>(25)</sup>.

In our study group one patient with severe presubclavian coarctation required re-dilatation 6 months after stenting. Re-dilation has also been reported in other series. <sup>(8,9,10,13)</sup>. A higher initial pressure gradient is indicative of a more severe CoA, which may be predictive of a future requirement for re-dilation. It is also safer to be more conservative with the initial balloon inflation, and return later for re-dilation with a larger balloon, which can usually be done successfully. Pre-dilation before stenting may also be helpful in cases of very severe CoA. In our study group predilatation was done in two patients including one with near interruption. Post dilatation was needed in 36.4% of cases.

In the series from the Congenital Cardiovascular Interventional Study Consortium (CCICS) database,<sup>(14)</sup> successful stenting of coarctation was

reported in 98.6% (580 out of 588) patients. Complication occurred in 11.7% cases. Significant complications are aneurysms (2.2%), aortic dissection (1.5%), stroke (1%), femoral vessel injury (2.6%) and death in 0.3%

Serious complications have also been reported with stent implantation. <sup>(14)</sup>. The complications associated with CoA stenting include damage to the femoral artery and thrombus formation due to the large sheaths and balloon catheters required. Balloon catheter rupture is another potential complication. At the time of stent implantation, there is also the risk of inappropriate placement and/or stent migration following balloon dilation. As stents are frequently placed near carotid vessels, there is also a risk of cerebrovascular events. <sup>(17)</sup> Other possible complications include acute aortic rupture, aortic dissection and aneurysm formation. In our study group procedural complications included retroperitoneal hemorrhage in one which resulted in mortality. Another patient in our study developed right common femoral artery thrombosis .Another wellrecognised complication is the persistence of hypertension in patients with Coarctation even after successful correction (12,15,16). On follow up 36.4% of our patients required continuation of antihypertensive therapy even after stenting.

### CONCLUSIONS

Stent implanation is a safe and effective alternative to surgical repair in COA. It provides immediate and near complete relief of obstruction which is sustained on short term follow up. Long term follow up is required to look for restenosis, aneurysm formation and persistent systemic hypertension.

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