

# Contemporary Outcomes Following Endovascular Therapy of Coarctation of Aorta- Experience from a Tertiary Care Centre in India

SAHIL MAHAJAN<sup>1</sup>, ARPUDH MICHAEL ANANDARAJ<sup>2</sup>, LIJO VARGHESE<sup>3</sup>, OOMMEN KATTUNILAM GEORGE<sup>4</sup>

## ABSTRACT

**Introduction:** Since 1980s, endovascular therapy has evolved as an important therapeutic strategy for Coarctation of the Aorta (CoA).

**Aim:** This study sought to present a comprehensive contemporary data on the efficacy and safety of endovascular therapy in all age groups with both native and recurrent CoA in patients presenting to a tertiary care centre in Southern India.

**Materials and Methods:** This single centre retrospective study included 91 consecutive patients who underwent Balloon Angioplasty (BA) or stenting for CoA between November 2002 and October 2017. Clinical, angiographic and procedural data was collected and outcomes including procedural success, complications, incidence of re-stenosis and hypertension at follow-up were evaluated. The effect of pre-specified variables on the procedural result was also evaluated using chi-square or two sample t-test, as appropriate.

**Results:** Of the 91 patients, 63 were males; median age was 20 years {interquartile range (IQR):11-29}. The median follow-up duration was 17 months (IQR -7.5 to 36 months). Eighty four (92%) cases were with native coarctation. Fifty five (60%) had discrete coarctation and 36 (40%) had associated tubular hypoplasia of isthmus. Seventy two (79%) patients underwent stent implantation and 19 (21%) underwent BA. Immediate procedural success was achieved in 68 (94%) patients in the stent implantation group and 13 (68%) patients in BA group. Sixty percent of the failures were from BA group. Twelve (18%) patients had re-obstruction on follow-up. Seven (11%) patients underwent re-intervention.

**Conclusion:** Endovascular therapy is a relatively safe and effective treatment modality in CoA when done carefully at experienced centres and in appropriately selected patients.

**Keywords:** Angiography, Balloon angioplasty, Stenosis, Stent

## INTRODUCTION

CoA accounts for approximately 6% to 8% of patients with congenital heart disease. Endovascular treatment-percutaneous BA and stenting has gained wide acceptance as effective therapy since the initial report of BA for CoA was reported in 1982 [1].

The advantage of stent implantation over plain BA is that it supports the wall of the aorta, preventing elastic recoil, thus maintaining the luminal area and decreasing the chances of re-stenosis. This makes over-dilatation of the coarctation segment unnecessary [2]. However, stenting is always not possible especially in children where BA or surgical coarctoplasty remain the treatment of choice [3]. In adults, surgical repair or catheter based stenting is the recommended therapy for aortic coarctation.

This study sought to provide comprehensive contemporary outcome data from patients of all age groups presenting to a large referral center in southern India. It is also the largest single centre experience of endovascular therapy of CoA from India and reports immediate and intermediate term outcomes.

## MATERIALS AND METHODS

### Study Population and Design

This was a retrospective, single institutional experience in endovascular management of patients with native as well as recurrent CoA done between November 2002 and October 2017, 91 consecutive patients (both children and adults) who underwent BA or stenting for CoA were included. All patients who underwent endovascular treatment for coarctation of aorta during the above-mentioned period were included. Adolescence was defined by age group 10-19 years and adults as those who were 20 years

or older. Those patients who underwent surgical treatment alone were excluded. Institutional review board approved the study (letter number 10997 dated 22.11.2017).

The available medical records of the patients and angiograms were studied retrospectively. For analysis, patients were divided into two groups. One group comprised of children less than 10 year old and the other group included those greater than 10 years (adolescents and adults) since treatment strategies vary between these age cut-offs [4,5]. CoA was defined as systolic arm-to-leg blood pressure gradient  $\geq 20$  mmHg with echocardiographic, 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 to be  $< 0.6$  [6]. Successful outcome was defined as peak systolic residual gradient after stent implantation or BA of  $< 20$  mmHg.

### Data Collection

Collected data included demographic variables and associated anomalies. Coarctation morphology was further specified by the location and as native or recurrent. Clinical data was collected at baseline, before discharge and at follow-up. Follow-up data collected included upper and lower extremity systolic/diastolic blood pressure, echocardiographic gradient across the coarctation segment and the use for anti-hypertensive medication.

Hypertension in children and adolescents was defined as Systolic BP (SBP) and/or Diastolic BP (DBP) at or above the 95<sup>th</sup> percentile [7]. Similarly, for adults, a systolic blood pressure in excess of 130 mmHg or a diastolic blood pressure in excess of 80 mmHg was defined as hypertension [8].

Angiographic data was obtained before stent implantation using two or three separate projections (Antero-posterior or Left anterior oblique or lateral) to measure the diameter of the coarctation (minimum), as well as the aorta at the level of diaphragm. Angiography was repeated after stent implantation to evaluate for the presence of residual stenosis, stent expansion and other aortic complications.

The procedural data gathered include sheath size, pre-dilating balloon size (if used), balloon size (on which the stent was crimped) and type of stent used, systolic pressure gradient before and after coarctoplasty, procedure related aortic complications, access site complications, balloon rupture, stent-related complications - stent migration or coverage of left sub-clavian artery and procedural success. The acute procedural complications assessed included acute embolic events, cerebrovascular accidents, acute procedural aortic dissection, access site complications and mortality.

### Procedure

A written informed consent was obtained from all the patients before the procedure. All patients underwent retrograde common femoral artery catheterization under local anaesthesia (for adults) and general anaesthesia (children) by the Seldinger technique, and intravenous heparin (100 IU/kg) was administered after arterial cannulation. The technique used to cross the coarctation segment in different situations is described below:

1. In the majority of cases, the coarctation segment was crossed successfully retrogradely. In most cases, with a 0.035-inch-diameter flexible-tip glide wire (Terumo, Europe NV), and a pig-tail catheter was passed over the wire into the arch of aorta. Descending thoracic aortography was performed in 45-60 degree left anterior oblique view or lateral views to delineate the coarctation segment and the aorta at the level of diaphragm.
2. In patients with very tight coarctation, in which the wire could not be passed retrogradely, a radial or brachial artery access was used. An 0.035-inch-diameter, straight-tip glide wire was passed across the tight stenosis. The glide wire was then snared out through the valved sheath in the right femoral artery. The rest of the procedure was then performed through the femoral approach.
3. In the occluded cases, recanalisation was done using coronary chronic total occlusion wire and balloons from left radial or brachial access.

In all adolescent and adults, long sheaths (8 to 12 French) with dilator was advanced through the femoral artery and placed across the coarctation. The dilator was removed, leaving the guide wire and the sheath across the stenotic lesion. The diameter of the balloon was equal to or 1 mm greater than the diameter of the proximal aortic isthmus, but not greater than the diameter of the descending aorta at the level of the diaphragm [9]. The choice of the stent (pre-crimped bare stent, manually crimped bare or covered stent) depended on various factors such as occlusion at coarctation segment, severe calcification and proximity of left sub-clavian artery to coarctation segment. The balloon was inflated to pressures ranging from 3-12 atmospheres (atm), as recommended by the manufacturer.

After the procedure, repeat aortography and pressure measurements distal and proximal to the stented segment were obtained. In most patients, haemostasis was achieved by manual compression. All patients received aspirin 3-5 mg/kg daily for six months along with anti-hypertensive medications (where indicated).

### Outcomes

If the systolic pressure gradient was <20 mmHg post-procedure, the procedure was considered as successful. Reduction of gradient, increase in aortic diameter, changes in blood pressure,

complications, requirement for anti-hypertensive medications, re-interventions and long-term complications were recorded.

### Follow-up

The follow-up included arm and leg blood pressure measurements and echocardiographic assessment. Repeat catheterization study was done only if clinically warranted.

First clinical follow-up was usually at 3-6 months after the procedure. Further follow-ups were available at a range of 1-5 years.

### STATISTICAL ANALYSIS

Data were described as absolute and relative frequencies for categorical variables, while means, SD, medians, and range were used for continuous variables. Categorical data were compared by chi-square test or by Fisher's-exact test in case of expected frequencies <5. Comparisons of quantitative variables between the two groups were performed by Student's t-test and test for paired data, as appropriate. Statistical analysis was performed using STATA 11.0 (StataCorp, USA).

### RESULTS

Basic demographic and clinical data is summarised in [Table/Fig-1]. Between November 2002 and October 2017, a total of 91 consecutive patients (63 males and 28 females) with a median age of 20 years {interquartile range (IQR):11-29} and a diagnosis of native as well as recurrent CoA, underwent cardiac catheterization and aortography. Seventy one (78%) patients had systemic hypertension when seen first, with systolic blood pressure of 121.7±21 mmHg in children and 152±22.53 mmHg in adults. Fifteen (16.4%) patients were on a single anti-hypertensive while 38 (41.7%) were taking more than one anti-hypertensive before the procedure. Ten (10.9%) were not on any drug and data was unavailable for the remaining 5 (5.4%) patients.

	Children (0.04-10 years)	Adolescents and adults (11-60 years)
	Median (range) or n (%)	Median (range) or n (%)
Age (years)	4 (0.04-10)	25 (11-60)
<b>Gender</b>		
Male	13 (62)	50 (71)
Female	8 (38)	20 (29)
<b>Presentation</b>		
Systemic hypertension	6 (29)	48 (69)
On single drug	3 (14)	12 (17)
On multiple drugs	0	38 (54)
On no drugs	2 (10)	8 (11)
Data not available	1 (5)	4 (6)
Incidental	6 (29)	16 (23)
Claudication	2 (10)	11 (16)
Congestive heart failure	6 (29)	0
Others	1 (5)	2(3)

[Table/Fig-1]: Demographic and clinical data.

[Table/Fig-2] summarises the coarctation characteristics. Eighty four (92%) cases were native coarctation. Fifty five (60%) had discrete coarctation and 36 (40%) had associated isthemic tubular hypoplasia. Out of 7 patients with recurrent coarctation, 3 had previous surgical repair, whereas the remainder had transcatheter BA (n=4). Six (6.5%) patients had complete occlusions.

### Immediate Angiographic and Haemodynamic Result

Haemodynamic and angiographic data are summarised in the [Table/Fig-3]. Seventy two (79%) out of 91 patients underwent stent implantation and the remaining underwent BA. Immediate procedural success was achieved in 68 (94%) of 72 patients in the stent implantation group and 13 (68%) out of 19 patients in BA group.

Type	Children	Adolescents and adults
	n=21, (%)	n=70, (%)
Native	18 (86)	66 (94)
<b>Recoarctation</b>	3 (14)	4 (6)
After BA only	3	1
After surgery only	0	3
After both	0	0
<b>Location</b>		
Pre-ductal	2 (9)	7 (10)
Post ductal	17 (82)	52 (74)
Juxta ductal	2 (9)	11 (16)
<b>Anatomy</b>		
Discrete coarctation	16 (76)	39 (56)
Tubular hypoplasia isthmus	5 (24)	31 (44)
Isolated CoA	3 (14)	0
Associated cardiac anomalies	18 (86)	70 (100)
Bicuspid aortic valve	11 (54)	33 (47)
Aortic stenosis	2 (10)	10 (14)
Aortic regurgitation	1 (5)	9 (13)
Patent ductus arteriosus	8 (38)	2 (3)
Ventricular septal defect	3 (14)	1 (1)
Aberrant right subclavian artery origin	1(5)	0
Turner's syndrome	2(10)	2 (3)
Others	5 (24)	2 (3)
<b>LV systolic function</b>		
Normal	14 (67)	66 (94)
L V dysfunction	7 (13)	4 (6)

[Table/Fig-2]: Characteristics of the CoA.

Dimensions	Children (n=21)			Adolescents and adults (n=70)		
	Pre	Post	p-value	Pre	Post	p-value
Coarctation diameter (mm) (Mean±SD)	2.62±0.94	7.78±2.55	0.0036	2.97±1.51	13.56±2.51	<0.001
<b>Hemodynamics</b>						
Peak systolic gradient (mmHg)	37.85±18.41	15.04±16.91	0.0002	58.72±23.82	5.2±6.84	<0.0001
After balloon angioplasty (mmHg)	42.92±19.09	20.36±21.3	0.0049	37.75±5.85	18.5±4.79	0.0022
After stenting (mmHg)	42.00±16.08	7.5±8.52	0.0009	60.03±23.88	4.39±6.12	<0.0001
<b>Inflation pressure (atmospheres)</b>						
Balloon angioplasty	7.6			10		
Stenting	4.8			4.18		

[Table/Fig-3]: Haemodynamic and angiographic data.

Ten (11%) had failed procedures. Stents partly overlapped the left sub-clavian artery in 10 (11%) cases but was of no haemodynamic significance in any of these cases.

[Table/Fig-4] summarises the stents which were used. In the majority of patients, bare stents manually crimped on a pre-sized balloon were used, such as Palmaz stents (Johnson & Johnson). In few cases, ProStar Plus stent (Vascularconcepts, India) was used, which is a pre-crimped balloon expandable stent. In certain cases, covered stents were used, such as, Covered Cheatham-Platinum (covered CP) stent (NuMED, NY), Atrium ADVANTA V12 (Maquet Getinge) and Optimus XL stent (Andramed medical devices). In two patients self expandable stent, Wall Stent (Boston Scientific Corporation), was used and in one patient Zenith (Cook Inc) endovascular graft was used. Only two patients required an additional stent and in both of them it was due to stent migration. After endovascular treatment, the mean pre-procedural peak systolic pressure (±SD) gradient reduced significantly from 37.85±18.41 mmHg to 15.04±16.91 mmHg (p<0.0002). The mean coarctation segment diameter increased from 2.62±0.94 mm to 7.78±2.55 mm in children and from 2.97±1.51 mm to 13.56±2.51 mm in adults.

Type of stent	Children	Adolescents and adults
	Number (%)	Number (%)
Covered	0	4 (6)
Not covered	6 (100)	62 (94)
<b>Name of stent/stent graft</b>		
Palmaz stent	5 (83)	51 (77)
Atrium covered stent	0	3 (4)
Zenith stent graft	0	1 (2)
Cheatham-Platinum (CP)	0	2 (3)
Covered CP	0	1 (2)
Prostar plus	0	5 (7)
Wall stent	0	2 (3)
Andra stent	1 (17)	1 (2)

[Table/Fig-4]: List of used stents.

### Failed Procedures

Immediately after procedure 10 patients (11%) had gradient  $\geq 20$  mmHg. Out of these, 6 (60%) patients were children and 4 (40%) were in the >10 year age group. Similarly 6 (60%) had undergone BA alone (all children) and 4 (40%) had undergone stenting (adolescents). Most patients (n=9) had native coarctation and only one out of 10 failed procedures was a recurrent coarctation. The four cases in the stented group who had failures were further analysed-one had an undersized stent, one had significant residual waist on the stent despite high pressure dilatation, one was subsequently diagnosed to have Takayasu's arteritis and reason was not known in the fourth case.

### Follow-Up

The follow-up included clinical outpatient visits and echocardiography. Of the 91 patients, 23 patients did not return for follow-up, and for

additional three patients, follow-up data was unavailable. The median follow-up duration was 17 months. (IQR-7.5 to 36 months).

Echocardiography follow-up was available for 25 patients. The mean peak systolic gradient (mmHg) pre-procedure was 68.32±20.83 and at the last follow-up visit was 28.96±16.34 (p<0.001).

### Restenosis

Twelve patients had re-obstruction (those who had post-procedure gradient of less than 20 mmHg but either on clinical or echo follow-up showed gradient more than 20 mmHg) on follow-up. Out of these 7 patients were post-stenting and 5 had undergone BA. Eight were in adolescents or adults age group and 4 were in children's age group.

### Re-Interventions

Seven out of 91 patients underwent repeat interventions. Three were those who had undergone BA and 4 were those who had undergone stenting initially. One patient underwent surgical coarctoplasty, 1 patient underwent stenting and the remaining 5 patients underwent repeat BA. Repeat procedures were successful in all patients. No patient had more than one repeat intervention.

## Aortic Wall Complications and Other Adverse Events

Three patients had minor aortic dissection during the procedure, two were children and one was adult. All three patients had non flow limiting aortic dissections so they were managed conservatively. Four patients had stent migration acutely, in one patient, stent was deployed in abdominal aorta just above the origin of celiac artery and patient was managed with BA alone, in two patients second stent was used and in the fourth, although the stent migrated, the coarctation segment remained stented. Two patients had blood loss from the access site during the procedure requiring transfusion. One patient had right common femoral artery thrombosis post-procedure which was managed conservatively with heparin infusion and repeat Doppler of lower limb which showed partial recanalization. In 10 patients, left sub-clavian artery was covered by stent but none of them had flow limitation.

## Blood Pressure

Follow-up blood pressure data were available for 18/21 children and 47/70 adults. Right arm mean systolic blood pressure in children was  $121.70 \pm 42$  mmHg before procedure and on last follow-up visit was  $112.1 \pm 39$  mmHg ( $p$  0.2797). In adults right arm mean systolic blood pressure pre-procedure was  $152 \pm 22.53$  mmHg and on last follow visit was  $134.63 \pm 24.38$  ( $p$  0.0005), confirming a sustained reduction in blood pressure which was significant in adults but not in children.

## DISCUSSION

Treatment of CoA has evolved over the years. In 1991, O'Laughlin MP et al., reported the first use of an endovascular stent to treat CoA [10]. Our retrospective study spanning over 15 years provides the largest single centre experience on endovascular therapy for CoA from India.

In our series, the male: female ratio was 2.3:1. The most common presentation in our patients was systemic arterial hypertension, followed by incidental detection. Six patients presented with congestive cardiac failure, out of these 5 were  $\leq$ one-year-old.

The most common associated cardiac anomaly was bicuspid aortic valve, seen in 44 (48%) patients, similar to what has been reported in literature [11]. The most common location of coarctation was postductal ( $n=69$ ) which is usually the most common location [12]. Of the remaining, 13 had juxtaductal coarctation and 9 had pre-ductal coarctation. Most common clinical manifestation in infants and neonates was congestive cardiac failure. Young children, adolescents and adults presented mostly with systemic hypertension.

As in previous reports [13], both BA and stenting of CoA resulted in significant angiographic improvement and gradient reduction. Out of 91 patients, 81 patients underwent successful coarctoplasty. Mean peak systolic gradient post-procedure in patients who underwent BA was  $20.36 \pm 21.3$  mmHg in children and  $18.5 \pm 4.79$  mmHg in adolescents and adults group. In patients who underwent stenting, mean peak systolic gradient post-procedure was  $7.5 \pm 8.52$  mmHg in children and  $4.39 \pm 6.12$  in adults. Although peak systolic gradient reduced significantly in both groups but it was more in patients who underwent stenting than in those who underwent BA.

BA relieves the aortic obstruction by causing tears in the intima extending into the media [14,15]. Peak systolic gradient was lesser after stent implantation because, once dilated the stent supports the wall of the aorta and prevents elastic recoil. Six out of 10 patients who had failed procedures were children, out of which 5 had undergone BA alone and one underwent stenting. This further reinforces the fact that elastic recoil which is more in children and after BA as compared to stenting is one of the important factors contributing to sub-optimal initial result. Other advantages of stent over BA is that over dilation of the coarctation segment is not required and also since the

stent will plaster smaller tears which will prevent dissection and progressive pseudo-aneurysm formation [2]. In 67 patients (out of 72 who underwent stenting) bare metal stents were used, covered stents were used in 4 patients and stent graft in one. Stent graft, (with single fenestration fashioned by vascular surgeons for the left subclavian artery) was used because of the associated aneurysmal dilation of descending thoracic aorta distal to coarctation.

Covered stents were used whenever there was associated saccular aneurysm with coarctation and in cases of advanced age with increased calcification where the chance of aortic complication was high. Covered stents for coarctoplasty can be considered in long-segment native aortic coarctation, complex anatomy (e.g., near interruption), aortic re-coarctation after previous treatment, associated aneurysms, associated patent ductus arteriosus or beyond third-fourth decade [16,17].

There are many complications of BA as well as stenting of CoA. Technical complications can be stent migration during the procedure, stent fracture, balloon rupture, and overlap of the aortic arch vessels by the stent. Out of these, we encountered only stent migration in 4 (4.3%) patients and overlap of left sub-clavian artery in 10 (11%) patients. None of the patients with overlap of arch vessels had flow limitation. Three out of four patients with stent migration had balloon expandable stents and one had self expandable stent. Factors which can lead to stent migration include improper positioning, under-sizing of balloon and slow inflation. In this study only, 3 (3.2%) patients had aortic dissection, two out of three patients had localised minor non-flow dissections after balloon coarctoplasty and third patient had Stanford type B aortic dissection post-stenting. Since this was non flow limiting with true lumen filling all abdominal aorta branches and no gradient between arch and femoral artery, it was managed conservatively. Follow-up CT angiogram done after four years showed no change in size of dissection but with thrombosed false lumen, therefore patient was managed medically till last follow-up. Some studies have quoted risk factors for dissection as age greater than 20 years, pre-dilating a lesion before stenting and the use of CP stent. Emergency surgery can be life saving in severe aortic dissection but of late it can be treated successfully with endovascular grafts. Thus we should be prepared to manage this complication and large diameter covered stents or grafts should be at hand for use in emergency situations. Aneurysm formation is a rare complication, in our study only five patients had follow-up CT angiography, nine patients had repeat catheterization study and none of them had any aneurysm formation on follow-up. There were no procedure related deaths.

## LIMITATION

This was a retrospective, single centre study and follow-up data was not available for all patients. The incidence of adverse events, aortic wall complications, stent migration, number of failed procedures and re-interventions were fairly low, limiting the statistical power of the study to identify predictors of these outcomes.

## CONCLUSION

Endovascular treatment of CoA is a technically challenging, evolving therapy. We conclude that endovascular therapy is a relatively safe and effective treatment modality when done carefully at experienced centres and in appropriately selected patients.

It is clear that further research including universal follow-up imaging is necessary to determine incidence of and predictors for various complications.

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**PARTICULARS OF CONTRIBUTORS:**

1. Assistant Professor, Department of Cardiology, Christian Medical College and Hospital, Vellore, Tamil Nadu, India.
2. Assistant Physician, Department of Cardiology, Christian Medical College and Hospital, Vellore, Tamil Nadu, India.
3. Associate Professor, Department of Cardiology, Christian Medical College and Hospital, Vellore, Tamil Nadu, India.
4. Professor, Department of Cardiology, Christian Medical College and Hospital, Vellore, Tamil Nadu, India.

**NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:**

Dr. Arpudh Michael Anandaraj,  
Department of Cardiology, Christian Medical College and Hospital, Vellore-632004, Tamil Nadu, India.  
E-mail: arpudh@gmail.com

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