

# Stenting of Aortic Coarctation: Immediate and Intermediate Follow-up Results

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## ABSTRACT

**Background:** Coarctation of the aorta occurs in about 6% to 8% of patients with congenital heart disease. Surgery, balloon dilatation, and stent implantation have all proven effective in the treatment of moderate or severe obstruction.

**Objective:** Assess the initial and intermediate term results of stent implantation in all age groups with both native and recurrent coarctation of aorta. **Patients and design:** A total of 23 patients (14 [65.4%] males and 9 [34.6%] females) with congenital COA who had undergone aortic stenting angioplasty were recruited. Nineteen (82.6%) of these patients had native COA and four (17.38%) had recurrent COA (one after previous coarctation stenting with stent fracture and three after balloon dilatation). Clinical data was collected at baseline, before discharge, and at follow-up and included upper and lower extremity systolic/diastolic blood pressure, as well as the need for antihypertensive medication, and echocardiographic data like COA gradient, associated lesions and concentric LVH. During procedure pre and post cath gradient across coarctation segment taken, along with assessment for any complications. **Results:** Immediately after stent implantation the peak systolic cath gradient (mean (SD)) fell from 61.6 (13.3) to 8.1 (3.6) mm Hg ( $p=0.00$ ). The diameter of the stenotic lesion increased from 4.58 (0.5) mm to 14.8 (1.3) mm ( $p < 0.05$ ). There were no deaths or procedure related complications. Only one patient (4.34%) developed early complications. Acute procedural success was 91%. During the follow-up of one month 3 (13%) of the patients had re-stenosis. At a mean follow up of 14 months, 4 cases of re-coarctation were identified echocardiographically and 43.47% had chronic systemic hypertension, requiring drug therapy. **Conclusions:** Stent implantation for the treatment of coarctation of the aorta appears to have very low morbidity and mortality, and good intermediate term results. Endovascular stenting could be an effective and safe method, even in all age group of patients with native and recurrent COA.

**Key words:** Coarctation of aorta, Coarctationstenting, Recoarctation, Intermediate, Congenital heart disease.

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## INTRODUCTION

Although the optimal treatment of coarctation of the aorta (COA) remains arguable, the endovascular treatment of both native and recurrent coarctation has gained a widespread acceptance since the mid 1990s, especially in adolescents and adults.<sup>1</sup> As has been observed with other balloon dilatation techniques, there has been a recent shift from balloon angioplasty alone to stent implantation. Balloon dilatation can injure the intima and part of the media, so although the vessel diameter is increased, fibrous scar tissue can form over a period of months<sup>2,3</sup> that may result in recoil, restenosis and aneurysmal disease. Advantages of using a stent are the radial support to the vessel wall and the apposition of the torn vessel intima to the media with the possibility to perform redilatation with no need for oversizing to avoid major transmural tears.<sup>4,5,6</sup> The primary purpose of this report is to provide a detailed review of composite procedural success including recurrent obstruction/repeat interventions, aortic wall complications, with a particular focus on immediate and intermediate outcomes.

## MATERIALS AND METHODS

### Study Population

The study was designed as a prospective, observational registry. The study was approved by the hospital ethics committee, and written informed consent was obtained from the parents or guardians of all the patients. From August 2011 to January 2015, twenty three patients with coarctation of the aorta underwent stent implantation at the Sri Jayadeva Institute of Cardiovascular sciences Bangalore.

### Inclusion criteria

Presence of significant coarctation based on one or more of the following:

1. UL /LL gradient >20 mm Hg.
2. UL /LL gradient >10 mm Hg plus either decreased LV function or aortic insufficiency.
3. UL /LL gradient >10 mm Hg plus significant collateral flow.

### Exclusion criteria

1. Refusal to sign consent
2. Known or suspected arteriitis.

### Data Collection

Collected data included demographic variables (age, weight, and gender) as well as associated anomalies. The coarctation morphology was further specified by its baseline classification (native and recurrent) and the location. Clinical data was collected at baseline, before discharge, and at follow-up and included upper and lower extremity systolic/diastolic blood pressure, as well as the need for antihypertensive medication. A blood pressure exceeding the 9<sup>th</sup> centile obtained for children of similar age (using the 50<sup>th</sup> centile for height) was defined as hypertensive. Similarly, for adults, a systolic blood pressure in excess of 140 mm Hg or a diastolic blood pressure in excess of 90 mm Hg was defined as hypertensive. Hemodynamic data collected before and after stent placement included ascending and descending aortic pressures (systolic, diastolic, and mean). Angiographic data was obtained before stent implantation using two separate projections (AP or LAO, as well as lateral), and included the diameter of the coarctation. Angiography was repeated using

two projections after stent implantation to evaluate for the presence of residual or new arch pathology.

### PROCEDURE

Percutaneous cardiac catheterization was routinely performed from the femoral or inguinal region. Intravenous heparin (100 U/kg) was given immediately after arterial cannulation. A pigtail angiographic catheter was advanced into the ascending aorta and systolic pressure differences across the area of coarctation were recorded. Subsequently biplane aortograms were obtained and aortic diameter measurements carried out on the lateral view. A long transeptal sheath, 6 French to 12 French in size, and a dilator set were 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 stent mounted on balloon was used like Palmaz. 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. The balloon was inflated to pressures ranging from 3–12 atm, as recommended by the manufacturer. After the procedure, repeat aortography and pressure measurements distal and proximal to the stented segment were obtained. All patients received aspirin 3–5 mg/kg daily for six months. They were followed up clinically at one and three months after the procedure and then every six months. Follow up included arm

and leg blood pressure measurements and echocardiogram done for assessment of restenosis.

### Outcome Parameters

Outcome parameters included as well as the rate of acute and intermediate term procedural success the incidence of adverse events. Secondary outcome parameters included the immediate post-procedural systolic gradient obtained in the catheterization laboratory, concentric LVH, the need for anti-hypertensive medication were noted.

### STATISTICAL ANALYSIS

The data was analysed by using SAS-16.50 version, Univariate and multivariate analysis were employed to draw the significant inference (Logarithmic transformed data for applied for nominal scale).

### RESULTS

#### Basic demographic and clinical data (Table I)

A total of 23 patients (14 [65.4%] males and 9 [34.6%] females) with congenital COA were recruited. Native coarctation was seen in 19 patients (82.6%) and recurrent coarctation in four patients (17.38%). Out of 4 cases of re-CoA one has previous stenting with stent fracture (4.34%) and three underwent balloon coarctoplasty (13.04%). The youngest patient who underwent stent implantation was a 15 days old infant who

**Table 1: Demographic and clinical profile of the patient**

SL	Variable	No (Mean±SD)	Confidence interval- 95%		P-Value
			Lower	Upper	
I	Age				
01	Male	14(27.28±5.02)	17.44	31.71	0.00**
02	Female	09(27.66±6.35)	15.21	40.10	0.14ns
	Overall Mean	23(27.43±5.82)	16.02	30.83	
II (a)	Pre ULG	50.08±10.26	29.97	70.18	0.22 ns
	Pre Eco	56.26±15.63	25.64	86.89	0.36 ns
III	BAV				
	Yes	09(39.13%)	7.43	10.23	0.01**
	No	14(60.86%)	12.08	16.33	0.00**
III	Other lesion				
	a).No	12(52.17%)	10.18	17.48	0.00**
	b).Moderate AS	02(8.69%)	0.98	3.65	0.86 ns
	c).Severe AS	01(4.34%)	-	-	-
	d).Mild AR	03(13.04%)	1.16	4.50	0.99 ns
	e)Coarct Aneurysm	01(4.34%)	-	-	-
	f).Large VSD	01(4.34%)	-	-	-
	g).Left SCA Stenosis	02(8.69%)	0.76	3.50	0.82 ns
	h).S/P PDA ligation	01(4.34%)	-	-	-
IV	Native/ recurrent				
	Native	19(82.60%)	15.55	21.63	0.00**
	RC	03(13.04%)	1.56	4.86	0.44 ns
	RS	01(4.34%)	-	-	-
V	Concentric LVH				
	Yes	13(56.52%)	11.28	15.14	0.00**
	No	10(43.47%)	8.50	12.08	0.00**

VI	Hypertension				
	Yes	19(82.60%)	17.42	22.36	0.00**
	No	04(17.39%)	2.10	5.50	0.21 ns

ULG-upper-lower limb gradient, BAV- Bicuspid aortic valve, AS-aortic stenosis, VSD-ventricular septal defect, SCA-subclavian artery, PDA- patent ductus arteriosus, RC-recurrent coarctation after balloon coarctoplasty, RS- recurrent coarctation after coarctation stenting, LVH-left ventricular hypertrophy.

**Table 2: Univariate relation between Follow up details at one month-concentric LVH, ECHO GRADIENT, HTN**

SL	Variables	Mean±SD	CI-95%		P-Value
			Lower	Upper	
01	Echo gradient	12.73±6.68	10.16	13.18	0.06ns
02	Concentric LVH				
	Yes	13(56.52%)	11.28	15.14	0.00**
	No	10(43.47%)	8.50	12.08	0.00**
03	Hypertension				
	Yes	19(82.60%)	17.42	22.36	0.00**
	No	04(17.39%)	2.10	5.50	0.21 ns

LVH-left ventricular hypertrophy.

had severe coarctation of the aorta. COA was associated with Bicuspid aortic valve (BAV) in 9 patients (39.1%). Other associated lesions noted were moderate aortic stenosis in 2 (8.69%), severe aortic stenosis in 1 (4.34%), mild aortic regurgitation in 3 (13.04%), ventricular septal defect in 1 (4.34%) and left subclavian artery stenosis in 2 patients (8.69%). Mean upper to lower limb gradient was 50.08±/-10.26 mm Hg before the procedure. Pre-echocardiographic gradient was 56.26±/-15.63 mm Hg. Hypertension was seen in 19 patients (82.6%) and Concentric left ventricular hypertrophy in 17 patients (73.9%).

### Immediate Angiographic and Hemodynamic Results (Table 2)

Twenty three stents were implanted in 23 patients, CP stent in 7, Palmaz 4014 in in four, Palmaz 5014 in one, atrium in four, cordis stent in two, luminax in one, Falmax stent in one and coronary stent in one. The latter was used in the 15 days old infant. Immediately after stent implantation the peak systolic cath gradient (mean (SD) fell from 61.6 (13.3) to 8.1 (3.6) mm Hg (p=0.00). The diameter of the stenotic lesion increased from 4.58 (0.5) mm to 14.8 (1.3) mm (p <0.05) (Table 2). There were no deaths or procedure related complications. Only one patient (4.34%) developed early complication in the form of acute limb ischemia and underwent femoral embolectomy. Immediately after procedure only two patients (8.69%) had gradient above 20 mmHg.

**Table 3: Comparison of variables before and after the procedure.**

SL	Variables	Mean ± SD	CI-95%		P-Value
			Lower	Upper	
I	Baseline (Before procedure)				
01	Echo gradient	56.26±21.47	19.86	75.63	0.18 ns
01	Pre Cath gradient	61.65±13.26	35.66	87.63	0.18 ns
02	Post Cath gradient	8.17±3.65	-1.01	15.32	0.00**
	II Immediate post procedure				
03	Echo gradient	12.30±2.44	7.51	17.08	0.00**
04	Percentage of COA	84.25±7.55	69.46	99.06	0.00**
05	Complications	No-22 Yes-01			
	III At one Month Duration				
	Echo gradient	12.73 ± 6.68	5.66	19.63	0.00**
	Concentric LVH	No-06 (26.08%)			
		Yes -17 (73.9%)			
IV	Late follow up				
01	Echo gradient	14.51±7.63	7.21	22.63	0.00**
02	Mean duration of FU	14.08±2.77	3.12	15.08	0.00**
10	Concentric LVH				
	Yes	10(43.47%)	6.40	13.25	0.00**
	No	13(56.52%)	11.58	16.18	0.00**

COA-coarctation of aorta, LVH-left ventricular hypertrophy.

**Table 4: ECHO gradient after procedure-gradient less than 10,10-20,>20 mmHg at one month follow up.**

Gradient range	N	Mean gradient Mean ± SD	Duration of FU	COA Pre	COA-Post	P-value
10	11(47.82%)	7.36±1.91	11.63±8.61	4.67±0.63	14.92±1.30	0.00**
10-20	09(39.13%)	14.88±2.08	18.22±9.32	4.53±1.41	14.84±1.20	0.00**
>20	03(13.04%)	26±3.60	10.66±1.15	4.38±0.22	14.14±1.79	0.63ns
Pooled	23(100.0%)	12.73±6.68	14.08±8.74	4.58±0.05	14.79±1.31	

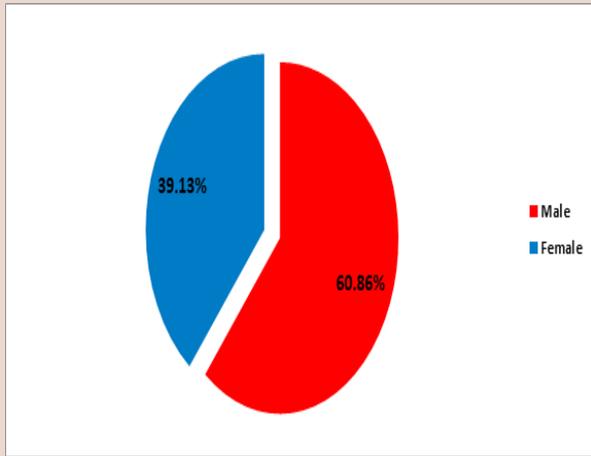


Figure 1: Distribution of gender.

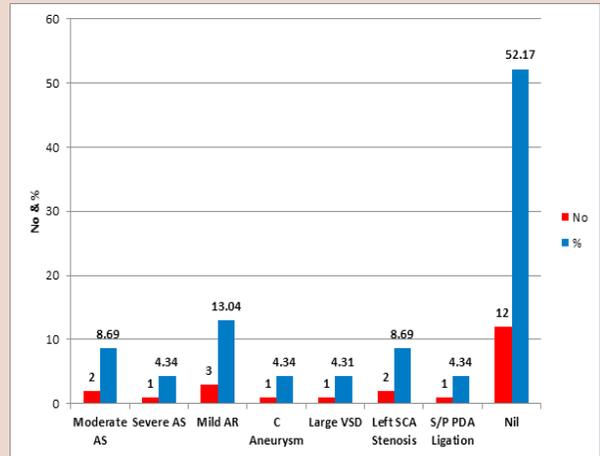


Figure 2: Distribution of other associated lesions.

AS-aortic stenosis, AR-aortic regurgitation, C-coarctsegment, VSD-ventricular regurgitation, SCA-subclavian artery, PDA-patent ductus arteriosus.

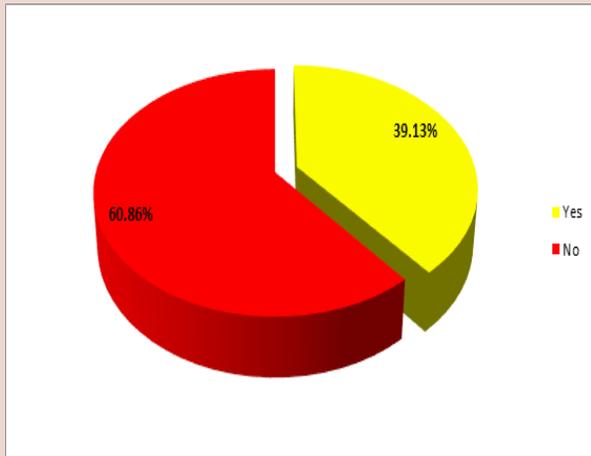


Figure 3: Association of BAV (Bicuspid aortic valve).

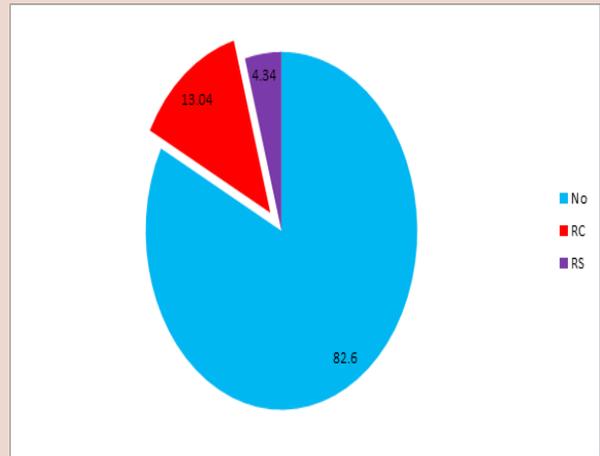


Figure 4: Native versus recurrent coarctation.

No-native, RC-recurrent after balloon coarctoplasty, RS-recurrent after coarctation stenting.

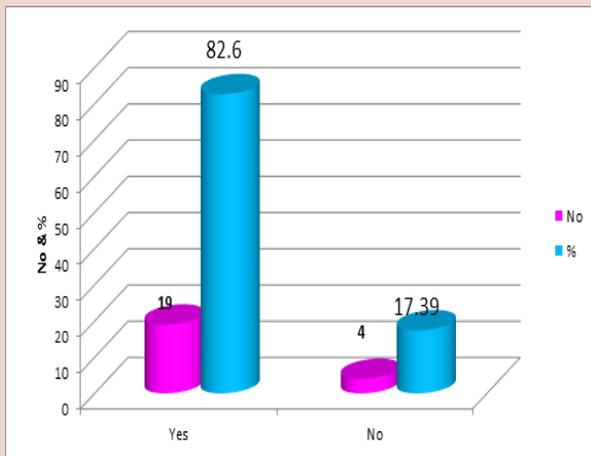


Figure 5: Status of hypertension at baseline.

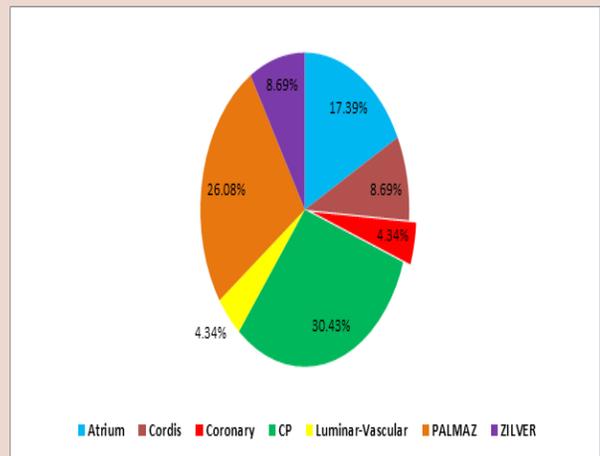
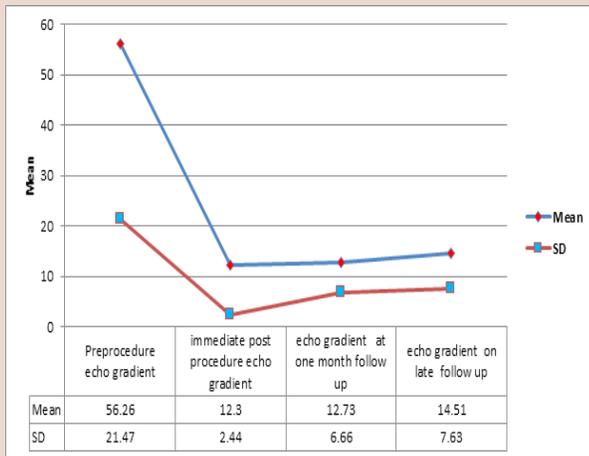
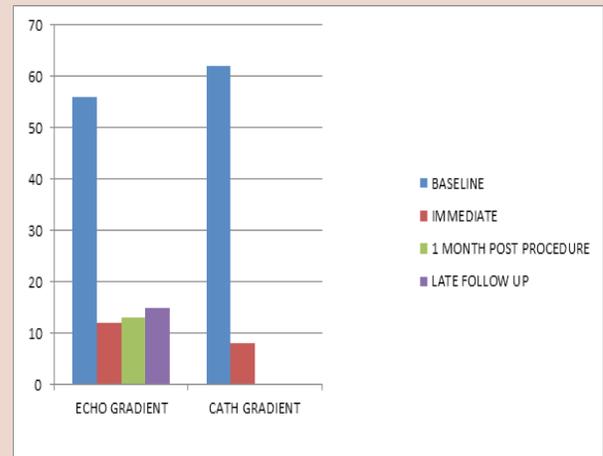


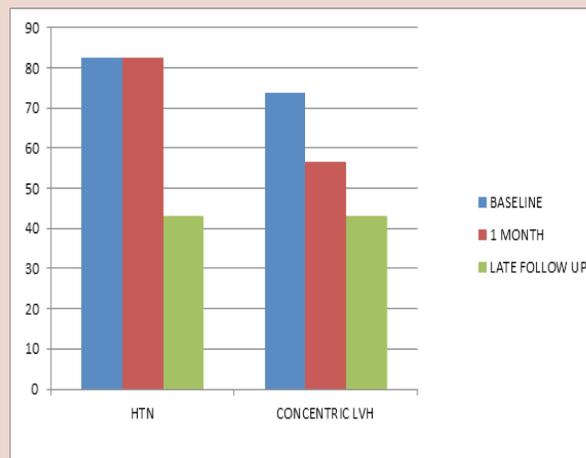
Figure 6: Stent types used in this study.



**Figure 7:** Mean echo gradient at baseline,immediate .one month and late follow up.



Echo & Cath Gradient before and after Coa Stenting.



Regression of Htn & Concentric Lvh after Coa Stenting.

### FOLLOW UP DATA.

During follow up, at 1 month and 14 months 3 (13%) and 4 (17.3%) patients had residual gradient more than 20 mm Hg respectively, but none underwent re-procedure. 13 of the 23 patients (56.5%) were normtensives compared to 19 patients (82.6%) prior to procedure (pvalue=0.00). Concentric LVH regression was seen in 41.1% (10 post procedure versus 17 prior to procedure) (p=0.00) and 43.47% had chronic systemic hypertension, requiring drug therapy. Persistent LVH was correlating directly with the post procedural gradient more than 10mm Hg and long duration of hypertension. There were no early or late deaths, or any evidence of early or late aneurysm formation, endocarditis, thromboembolism or any other complication related to stent implantation throughout the follow up period.

### DISCUSSION

COA, first described by Morgagni in 1760, encompasses a wide spectrum of presentations from cardiogenic shock in the neonate to murmur and upper-limb hypertension in adults. In 1982, balloon dilation was introduced as an alternative to surgery. Stents were first used in the early 1990s to treat COA in children.<sup>7,8</sup> Since then, balloon-expandable endo-

vascular stents have been drawn upon successfully to handle large vessel stenoses, including COA. Angioplasty with a stent creates a ‘controlled tear’ in the aortic wall supported by the framework of the stent upon dilation, minimizing the risk of dissection or aneurysm formation, which could occur after balloon dilation alone. Several clinical series have documented the effectiveness of coarctation stenting for native COA or re-COA.<sup>9,10</sup> Studies have shown excellent results in short and intermediate follow-up, with success rates approaching 97% in selected patients.

To date, clinical reports on stent implantation for isolated coarctation of the aorta have been sporadic. Overall, procedural success was acutely 91.3% with cumulative intermediate-term success being 87% at 1 month (Table 4) and 82.7% late 14 months mean follow up. Mortality following stent implantation for coarctation has been zero in all previous studies<sup>11,12</sup> as well as in the present study. Potential stent related complications include incomplete stent expansion, stent fracture, distal migration, and thromboembolic episodes. More unusual complications include aortic disruption and femoral artery damage. Late aneurysm formation requiring intervention has ranged from 0-7% in previous studies.<sup>13</sup> None of these complications was encountered in the present study. This study confirms the fairly low rate of acute procedure-related adverse events

seen in other recent studies.<sup>14</sup> The low morbidity in our series might reflect the high accuracy of stent placement achieved.

Our study documented a significant decline in resting hypertension over the follow-up period. This was more pronounced between discharge and intermediate follow-up when compared with intermediate and long term follow-up. 43.47% had chronic systemic hypertension, requiring drug therapy which is higher than the 11–33% reported in the literature following stent placement.<sup>14,15</sup> Surgical series have reported need for long-term antihypertensive medication at about 25%.<sup>16,17</sup>

## LIMITATIONS

The present study has some limitations, first and foremost amongst which are its small sample volume and insufficient follow-up duration. The inability to compare results between conventional surgical procedures, balloon dilatation, and balloon expandable stents results from the lack of a prospective randomized study. The study also did not assess the confounding factors for LVH like antihypertensive which also affect concentric LVH.

## CONCLUSION

Stent implantation for the treatment of coarctation of the aorta appears to have very low morbidity and mortality, and good intermediate term results. Endovascular stenting could be an effective and safe method, even in all age group of patients with native and recurrent COA. Persistence of concentric LVH was related to higher post procedural gradient (>10 mm Hg) and long duration of hypertension. Further studies with larger populations and longer follow-up periods are required to evaluate the long-term outcome in such patients.

## ACKNOWLEDGEMENT

None

## CONFLICT OF INTEREST

None

## ABBREVIATION USED

COA: Coarctation of aorta; LVH: Left Ventricular Hypertrophy.

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