

## Immediate and Short-term Follow-Up of Aortic Coarctation Balloon Angioplasty and Stenting

Hasan Mottaghi Moghadam<sup>1</sup>, Behzad Alizadeh<sup>2</sup>, , Nazanin Hazrati<sup>3</sup>

<sup>1</sup>Associate Professor, Pediatric Department, Mashhad University of Medical Sciences, Mashhad, Iran.

<sup>2</sup>Assistant Professor, Pediatric Department, Mashhad University of Medical Sciences, Mashhad, Iran.

<sup>3</sup>M.D, Mashhad University of Medical Sciences, Mashhad, Iran.

### Abstract

#### Background

Aortic Coarctation (CoA) is one of the congenital heart diseases with the rate of 5-8% of Coronary heart diseases (CHDs). Balloon angioplasty is now one of the effective way of treatment for CoA, native or Re-coarctation (Re-CoA). We aimed to assess the immediate and short term response to angioplasty and stenting, and also complications.

#### Materials and Methods

Balloon angioplasty with or without stenting was performed in 53 patients with native or Re-coarctation angioplasty (39 balloon angioplasty alone, and 14 balloon and stenting). Pressure gradient across the CoA segment was measured initially by Echo and pre, and Post procedure. Echocardiography was also used for follow up assessment during 24 hours, one and 6 months afterward.

**Results:** Among 53 patients, 52.8% were male. There were 98.2% native and 3.8% Re-CoA. The mean age of patients was  $8.65 \pm 8.37$  years, and the mean weight was  $25.82 \pm 20.73$  kg. The mean pressure gradient across the CoA site before angioplasty was  $24.88 \pm 12.32$ , and post procedure gradient was  $4.77 \pm 6.42$  ( $p < 0.001$ ). One of the patients experienced aneurysm formation at CoA segment site post balloon angioplasty.

#### Conclusion

On the basis of these data balloon angioplasty is safe, and effective in the treatment of native or Re-CoA. These results suggest that CoA angioplasty could be an effective alternative to a surgical approach, and gives good immediate results, although follow up studies are necessary to evaluate complications, and the long term effect on blood pressure in comparison to surgical approach.

**Key Words:** Aortic Coarctation, Balloon Angioplasty, Children, Congenital Heart Disease.

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#### \*Corresponding Author:

Behzad Alizadeh, Assistant professor, Pediatric Dep. Mashhad University of Medical Sciences, Mashhad, Iran.

Email: behalizadeh@yahoo.com

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## 1- INTRODUCTION

Aortic Coarctation (CoA) is one of the congenital heart diseases with the prevalence of 5% to 8% among Coronary heart diseases (CHDs) (1). The prevalence is higher in male (1.5-2 times to female) (2-5). This heart defect may present during early hours of life up to early adulthood with different symptoms and signs (2-5), although twenty five percent of all patients with CoA are diagnosed before 10 years of age (1). Severe heart failure in neonatal period and hypertension in children and adulthood are among the common cause of mortality and morbidity in these patients. Whether surgical repair or interventional approach (balloon dilation and stent enlargement), is always a debate. Usually surgical approach is used in infants and young children, but nonsurgical repair is recommended in older children and young adults (1).

Because of acceptable advantages of non-surgical repair being increasingly implemented; balloon angioplasty has provided good outcomes with reduction in morbidity and mortality (6). Surgical repair is along with some complications like re-intervention requirement, and hypertension remaining (7). The safety and effectiveness of stent therapy for CoA in blood pressure gradient reduction has been revealed (1, 8). In this study, balloon angioplasty with or without stenting was performed for 53 patients with native or Re-coarctation (Re-CoA) angioplasty.

## 2- MATERIALS AND METHODS

### 2-1. Method

This is a cohort prospective study, performed in at Imam Reza hospital, (affiliated to Mashhad University of Medical Sciences, Iran), during the years of 2011 to 2015. The study protocol was approved by the Ethics Committee of Mashhad University of Medical Sciences. In this study, fifty-three patients

with discrete Coarctation of Aorta diagnosed by echocardiography enrolled by census (51 patients with native CoA and 2 patients with Re-CoA after previous treatment), were studied. The inclusion criteria involved cytosolic Coarctation gradient  $\geq 20$  mmHg in echocardiography, definite anatomy for CoA, and body weight  $\geq 10$  kg, presence of significant native Coarctation based on the following:  $> U/L$  PPG=20 mm Hg,  $U/L$  PPG  $\geq 10$  mmHg with either decreased LV function (EF  $< 30\%$ ) or moderate to severe aortic insufficiency, and  $U/L$  PPG  $\geq 10$  mmHg plus significant collateral flow.

Exclusion criteria included the presence of tubular CoA; significant isthmus or transverse aortic arch hypoplasia defined as a ratio of the diameter of these structures to the descending aorta at the level of the diaphragm of  $< 0.6$  (25); blind CoA (or acquired aortic atresia); presence of aortic aneurysms before the intervention (adjacent ductal ampulla was not considered a contraindication); severe comorbid diseases; contraindications for a femoral intervention; and failure to comply with follow-up. According to these criteria, 53 consecutive patients agreed to be followed under a strict prospective protocol and underwent stent implantation.

Questionnaires for the initial intervention and re-intervention were filled out under supervision of the participating physician. The parameters has been assessed by one physician include sex, age, weight (all measured in the standard way), associated congenital heart defect, ascending and descending aorta pressures before and after angioplasty, left ventricular pressure measured during left heart catheterization invasively by Saadat Monitoring Device (Alborz, Saadat corporation by - Tehran, Iran). Before angioplasty all cases underwent clinical evaluation including: chest X-ray radiography, upper and lower extremities blood pressure measurement, 12-lead standard electrocardiogram (ECG),

echocardiograms with measurement of the Doppler gradient across the CoA segment by Vivid 3 Ultrasound Machine. The catheterization was considered standard of care by participating institutions. Patients were routinely followed-up for 6 months post-angioplasty according to the following protocol: 24 hours, 1 month and 6 months post-discharge. Echocardiography was performed on each visit.

## 2-2. Balloon Angioplasty and Stenting Technique

The balloon diameter was selected equivalent or lesser than 1-2 mm of the descending aorta at the level of the diaphragm. Conscious sedation (Midazolam 0.1 to 0.3 mg/kg) was used in all patients, they received 50mg/Kg IU intra-venous heparin and after that catheter balloon was introduced in to the arterial sheath. The balloon was inflated for 5-10 seconds until relief of the waist was determined. In the case of CoA stenting we used Cheatham-platinum (CP) stents mounted on Bioenteric Intra-gastric balloons from NeuMed Company, Canada. Hemodynamic measurement and angiographic imaging was performed before and after angioplasty in lateral and LAO views. The successful procedure was determined when pressure gradient reduced less than 20 mmHg across the CoA site.

## 2-3. Statistical analysis

All data from 53 patients were collected. For normality of quantitative variables, we have used Lilliefors and Shapiro-Wilk test. To comparison the pre and post angioplasty and stenting data, the paired sample t-test was used. For evaluating effect of sex, age and weight on the variables before and after intervention the regression analysis was used and a P-value <0.05 was considered significant. Statistical analysis was performed with SPSS® version 19.0.

## 3- RESULTS

In this study, balloon angioplasty with and without stenting was performed for 53 patients with native or Re-coarctation angioplasty. Among the participations 28(52.8%) were male and 25(47.2%) were female. The mean age of patients was  $8.65 \pm 8.37$  years and weight  $25.82 \pm 20.73$  kg. Angioplasty with/without stenting was performed on 53 patients for treatment of native CoA (n=51, 96.22%) or residual CoA (n=2, 3.77%). Balloon angioplasty and stenting was performed for 14(26.4%) patients and balloon angioplasty alone was performed in 39 (73.5%) patients.

All procedures were successful and there was aneurysm formation in one of the patients. Blood transfusions were not required after procedure. No hematoma was occurred in patients. Associated congenital heart defects are presented in **Table-1**. As shown in table 35.8% of patients had no congenital heart defect and the percentage of *bicuspid aortic valve (BAV)* patients was 17%. The patients with Valvular AS and VSD included 7.5 %, and 22.6% of our patents, respectively. Only 3.8% of patient had Atrioventricular Septal Defect (AVSD).

Catheterization data are shown in **Table.2**. There were no other anatomic, clinical, or demographic differences among patients. The mean pressure gradient across the CoA site before angioplasty was  $24.88 \pm 12.32$  and post Procedure gradient was  $4.77 \pm 6.42$ . There was a significant difference between them ( $p < 0.001$ ). The mean pressure gradient across the CoA site before angioplasty was  $24.88 \pm 12.32$  and post procedure gradient was  $4.77 \pm 6.42$ . There was a significant difference between them ( $p < 0.001$ ). The mean descending aorta systolic pressure, pre-intervention, was  $89.54 \pm 3.24$  and post-intervention gradient was  $115.37 \pm 2.91$ . There was statistical differences between them ( $p < 0.001$ ). The mean descending aorta diastolic pressures increased from  $62.09 \pm$

2.10 mmHg to  $72.83 \pm 2.07$  mm (p<0.001). Other catheterization data summarizes in **Table.2**. Follow-up by

ECO in the next 6 months has had favorable results.

**Table 1-** Associated congenital heart defect

Diagnosis	Frequency	Percent
None	19	35.8
BAV	9	17.0
Valvular AS	4	7.5
VSD	12	22.6
AVSD	2	3.8
AS+VSD	1	1.9
Valvular AS+BAV	3	5.7
BAV+VSD	1	1.9
BAV+ MS	1	1.9
BAV+VALVULAR AS+VSD+ MS	1	1.9
Total	53	100.0

BAV: Bicuspid aortic valve; Valvular AS: aortic valve stenosis; VSD: Ventricular septal defect; Cath = catheterization; AVSD: Atrioventricular Septal Defect; MS: Multiple sclerosis.

**Table 2-** Catheterization data in pre and post angioplasty

Variables	Pre angioplasty	Post angioplasty	P- value
AAo systolic pressure (mm Hg)	137.18±3.94	125.07 ± 2.62	0.004
DAo systolic pressure (mm Hg)	89.54 ± 3.24	115.37 ± 2.91	<0.001
AAo-DAo systolic gradient (mm Hg)	52.73 ± 2.45	10.45 ± 1.64	0.409
AAo diastolic pressure (mmHg)	76.03 ± 2.06	75.33 ± 2.03	0.001
DAo diastolic pressure (mmHg)	62.09 ± 2.10	72.83 ± 2.07	<0.001
AAo-DAo diastolic gradient (mm Hg)	14.60 ± 1.68	3.52 ± .96	.012
AAo mean pressure (mmHg)	98.35 ± 2.60	94.22 ± 2.35	<0.001
DAo mean pressure (Hg)	74.45 ± 2.35	90.20 ± 2.29	<0.001
AAo-DAo mean pressure (mmHg)	24.88 ± 1.69	4.77 ± .88	0.491

DAo = Descending aorta, AAo: Ascending aorta.

#### 4- DISCUSSION

Balloon angioplasty for Aortic Coarctation has been used as an effective alternative to the standard surgical therapy in most patients with discrete coarctation of the aorta according to previous studies (9-20). El Sayed Massoud et al. study showed reduction in CoA systolic gradient to  $\leq 20$  mmHg, achieved in 43 of the 46 patients (93%) post balloon angioplasty (21). Ringel et al. study using stent therapy

showed some complications like local groin hematoma, jailed left subclavian, and mild anterior chest pain, occurred in 26 patients (23%) (1). Our study presents the results of balloon angioplasty with or without stenting for native CoA in children and young adults. There wasn't any early complication among our patients using Stents. Re-stenosis by definition; more than 20 mmHg pressure gradient across the CoA segment, may accrue in long-term follow up but is not a frequent event in immediate results (22, 23). Two patients

(3.8%) in our study were referred due to restenosis after CoA surgery repair. Aneurysm formation is also another long-term complication with the incidence of 1.8- 6% in different studies (24, 25). Balloon over sizing during Angioplasty is the primary reasons for this complication (26-29). One of our patients developed aneurysm after balloon angioplasty in our study. She was a 49 day old girl with a long segment CoA and aortic isthmus narrowing, also massive pericardial effusion and Heart failure with poor general condition, not suitable for surgery. Balloon angioplasty performed using (4×20) and (6×20) Mini Tyshak balloons, respectively. Pericardial-synthesis was also performed for massive pericardial effusion simultaneously. Aneurysm was first detected 42 days after angioplasty in follow up study. MR-angiography is one of the diagnostic ways in long-term follow-up for this complication (30).

In another study Patel et al. assessed balloon angioplasty results of CoA in infants and neonates. Four among 17 (24%) patients failed balloon angioplasty and underwent surgical repair (6). There was not any failure in our study. Troy A. Johnston et al. used endovascular stents for treatment of native or Re-CoA in thirty-two patients with the mean age of 15.2 years. They concluded that in those patients with Long-segment Coarctation and poor results after balloon angioplasty, stent therapy may achieve better results.

They also noted that some adverse events like aneurysm formation and restenosis may be seen more in balloon dilation rather than stent therapy due to its resistance against inward recoil forces (31). Post CoA angioplasty syndrome is one of the serious complications which may accrue after angioplasty in some patients. This appears as hypertension, abdominal pain with tenderness, fever, ileus, vomiting, melaena and leukocytosis. Acute rising in blood pressure in the

arteries below the CoA segment may be the cause of this syndrome. It is more common post-surgical approach for CoA repair (32). There was not any case of Post CoA angioplasty syndrome in our study.

## 5- CONCLUSION

The results of current study indicate the efficacy and benefit of angioplasty, as a tool in the management of human native Coarctation and also Re-coarctation, with minimal early morbidity and low risk of serious adverse events. The immediate results are encouraging. Although, long-term assessment are need.

## 6- ABBREVIATION

BAV: bicuspid aortic valve,  
 Valvular AS: Aortic valve stenosis,  
 VSD: Ventricular septal defect,  
 Cath = Catheterization,  
 DAo = Descending aorta at the level of the diaphragm,  
 Prox Ao = Proximal aorta,  
 AS = Aortic stenosis,  
 COA = Coarctation of the aorta,  
 AVSD: Atrioventricular septal defect.

## 7- CONFLICT OF INTEREST: None.

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