

## Immediate and Intermediate Outcomes of Balloon Angioplasty in Neonatal Type Coarctation of Aorta in Sulaimani Cardiac Center

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### Abstract

**Background and objectives:** Coarctation of aorta is the fourth most prevalent heart disease in infants requiring catheterization and surgery during the first year of life. Unfortunately the initial clinical manifestations in infants are non-specific and mainly consist of tachypnea, poor feeding and failure to thrive which result in delays in the correct diagnosis and therapeutic interventions. The aim of the study was to assess the immediate and intermediate outcome of balloon angioplasty in neonatal type coarctation of aorta. **Methods:** It is a case series study of 13 young infants with neonatal coarctation of aorta their ages were between 10 days to 18 months and were admitted to intensive care unit of pediatric teaching hospital and Shar hospital neonatal care unit in Sulaimani. Balloon angioplasty was done for them in Sulaimani cardiac center between February 2014 to October 2017. **Results:** Balloon angioplasty was done for 13 young infants with good result in 10/13 cases without any complication. There was significant mean pressure gradient changes before and after the procedure ( $48 \pm 18.57$  mmHg and  $28.15 \pm 16.12$  mmHg, respectively). The complications of balloon angioplasty were divided into immediate complications which occurred within 24h post angioplastic procedure and included peripheral cyanosis 1 case (7.7%), small aneurysm formation 1 case (7.7%), and intermediate complications which occurred within 6 months of the angioplasty showed repeated dilatation of coarctation in 1 case (7.7%), while in 10 cases (76.9%) there were no any complications. **Conclusions:** Balloon angioplasty is a safe and effective treatment option in infants with coarctation of aorta; however, timely diagnosis and improvement in angioplasty techniques are necessary to improve the outcome.

**Keywords;** Coarctation of aorta; Balloon angioplasty; Infant.

### Introduction

Coarctation of aorta (COA) is seen in 6%-8% of patients suffering from congenital heart diseases. Coarctation of aorta has been reported to be the fourth most prevalent heart disease in infants requiring catheterization and surgery during the first year of life<sup>1</sup>. Similar to other obstructive conditions of the left side, coarctation of aorta is more prevalent in males compared to females, with a male-to-female ratio ranging from 1.23 to 1.741. In 1760, Prussian anatomist Johann Freidreich Meckel characterized coarctation of the aorta as an extraordinary dilatation of the heart which came from the fact that aortic conduit was too narrow<sup>2</sup>. Coarctation of aorta is typically located near the aortic attachment of the ligamentum arteriosum or patent ductus arteriosus but neonatal coarctation is characterized by relative hypoplasia of the transverse aorta in the presence of a relatively large pulmonary trunk, a combination that is believed to reflect

an in utero decrease in aortic arch flow together with an increase in flow through the main pulmonary artery and the ductus<sup>3</sup>. The coarctation ridge is located either immediately proximal to the aortic insertion of the ductus or opposite to the aortic insertion (juxtaductal) or immediately distal to the aortic insertion, types of coarctation; Firstly: Infantile type preductal; occur as a discrete juxtaductal obstruction or as tubular hypoplasia of the transverse aorta starting at one of the head or neck vessels and extending to the ductal area. Secondly: Adult type referred to isolated juxtaductal which, if mild usually not recognized until later childhood<sup>4</sup>. Open surgical treatment was the only choice until balloon angioplasty treatment introduced as an alternative therapy for COA in the 1980s, the mortality rate after surgery in these infants ranges from 2% to 10% and the mortality rate is higher in cases associated with intra-cardiac defects<sup>5-7</sup>. In addition to the late complications of restenosis and aneurysm formation<sup>8</sup>. Surgical repair

has some major immediate complications such as spinal cord injury, arrhythmia with cardiopulmonary arrest<sup>9</sup>. Transcatheter balloon dilation of stenotic lesions has been used in the pediatric patient over the last few years, though several studies have compared the outcomes of surgical and transcatheter approaches, their results have been inconsistent due to the small number of patients. Recently, the results of a meta-analysis of 9 studies comparing the outcomes of surgery versus balloon angioplasty (BA) approach for CoA showed that (BA) was comparable to surgery when considering the immediate results, but it did not provide better mid- and long-term outcomes and even increased the incidence of aneurysm formation<sup>10</sup>. In 1983, Lababidi performed the first balloon angioplasty (BA) for coarctation of aorta (CoA)<sup>11</sup>. Balloon angioplasty was indicated in infants younger than 6 months of age if the following conditions were met<sup>12-13</sup>; First, the presence of congestive heart failure or circulatory shock; Second, a lowered or absent femoral pulse with a systolic pressure gradient (PG) across the coarctation that exceeded 20 mmHg as measured by transthoracic echocardiogram, Third, a discrete COA with or without mild aortic arch hypoplasia. Patients with a significant hypoplastic aortic arch with a transverse arch or aortic isthmus diameter of <50% of the descending aorta were excluded<sup>14</sup>. The strongest association is with a bicuspid aortic valve that is either functionally normal, stenotic or incompetent, two shunt lesions accompany coarctation of aorta namely, patent ductus arteriosus and ventricular septal defect<sup>15</sup>. Coarctation of aorta is especially frequent in patients with Turner syndrome with incidence of 12%<sup>16</sup>. Although BA is a less invasive procedure and has been performed for more than 20 years, its use as a treatment for native COA during childhood especially in young infants, remains controversial. Many studies have reported a high incidence of restenosis and aneurysm formation when performing BA in neonates and young infants age < 3 months<sup>17</sup>. The aim of the study was to assess the immediate and intermediate outcome of balloon angioplasty in neonatal type Coarctation of aorta.

## Patients and Methods

A case series study of 13 young infants with neonatal

coarctation of aorta their ages between 10 days to 18 months, ten of them under 3 months of age admitted intensive care unit of pediatric teaching hospital and Shar hospital neonatal care unit in Sulaimani. All the procedure was done by the same pediatric cardiologist in that center between February 2014 to October 2017, eight of them were females and five of them were males. The inclusion criteria include children below 2 years of age with tachypnea and shortness of breath or shortness of breath with cyanosis or some of them had failure to thrive with neonatal type coarctation of aorta.

Exclusion criteria were cases of coarctation of aorta above 2 years of age.

Informed consent was obtained from the parents, after clinical assessment and after the usual laboratory studies (complete blood count, renal function test, virology screen, chest radiograph, electrocardiograph ECG, and Doppler echocardiographic studies) were done for them and suggested aortic coarctation cardiac catheterization was performed both to confirm the clinical diagnosis and for possible balloon angioplasty. Cardiac catheterization and balloon angioplasty were performed under general anesthesia using a retrograde femoral arterial approach in all patients. Radial arterial pressure was monitored during the procedure. Four French introducer sheaths was initially used and changed during the procedure according to balloon size and the pressures of ascending and descending aorta were measured.

Biplanar angiography was performed before and after the angioplasty in straight frontal and lateral projections. The balloon catheters (zotarolimus-eluting coronary stent system) or (everolimus eluting coronary stent system) were inserted and positioned in the narrowest site over a floppy-tip guide wire, positioning in ascending aorta and left subclavian artery. The patients were intravenously administered 100IU/kg of heparin after vascular access was achieved. The initial diameter of the balloon for the angioplasty was equal to or 1-2 mm greater than the diameter of the aortic arch at or proximal to the level of the left subclavian artery, and didn't exceed the diameter of the aorta at the diaphragm. The balloon size ranged from 4×20 mm to 6×20 mm. The balloon was inflated 2-3 times under fluoroscopic guidance for each patient under the

pressure stated by the manufacturer. The balloon dilation was considered successful if the peak systolic pressure gradient across the coarctation site was <20 mmHg or decreased by more than 50% and the coarcted segment increased in diameter by more than 50%. This study was approved by ethical committee of Kurdistan Board for Medical Specialties.

### Results

A total of 13 patients with coarctation of aorta, who had underwent balloon angioplasty were evaluated in Table 1: 8 patients (61.5 %) were female and 5 patients (31.5) were male.

**Table (1):** Sex distribution of patients participated in the study.

Gender	No.	%
Female	8	61.5
Male	5	38.5
<b>Total</b>	<b>13</b>	<b>100</b>

In Table 2 most of cases were below three months of age (10) 77%, the mean age at diagnosis in days (mean ± SD) was 90.92 ± 141.767.

**Table (2):** Age at diagnosis of patients participated in the study.

Ages at diagnosis	No.	%
Bellow 3 months	10	77
3-6 months	2	15.3
Above 6 months	1	7.7
<b>Total</b>	<b>13</b>	<b>100</b>

The most frequent chief complaint of the patients were tachypnea and shortness of breath 5(38.5%) cases, shortness of breath and cyanosis 4(30.8%) cases, and failure to thrive 4(30.8%) cases, Table 3.

**Table (3):** Clinical presentation at diagnosis of patients participated in the study.

Presentation	No.	%
SOB+Tachypnea	5	38.5
SOB+Cyanosis	4	30.75
Failure to thrive	4	30.75
<b>Total</b>	<b>13</b>	<b>100</b>

Most cases of COA were associated with other congenital heart disease in Table 4 show; bicuspid aortic valve and left ventricular dysfunction 3 (23.1%), ASD and pulmonary hypertension with left ventricular dysfunction 3(23.1%), restrictive subaortic VSD and pulmonary hypertension with left ventricular dysfunction 2(15.3%), non-restrictive VSD 1 (7.7%), mild mitral regurgitation 1(7.7%), and no associated anomaly in 3 (23.1%). Echo study before balloon angioplasty showed severe COA 8(61%), moderate COA 5(39%). The length of stenosis was (mean ±SD) 2.00 ± 0.73 .

**Table (4):** Associated anomalies in neonate with coarctation of aorta

Associated Anomaly	No.	%
Bicuspid aortic valve+Left ventricular dysfunction	3	23.1
ASD+PHT+Left ventricular dysfunction	3	23.1
Non- restrictiveVSD	1	7.7
Restrictive subaortic VSD+PHT+Left ventricular dysfunction	2	15.3
Mild mitral regurgitation	1	7.7
No associated anomaly	3	23.1
<b>Total</b>	<b>13</b>	<b>100</b>

The mean pressure gradient before and after procedure as in Table 5 and Table 6 will explain the difference and the changes that occur in pressure gradient before and after the angioplasty they were 48 ± 18.57 and 28.15 ±16.12,mmhg, respectively (p-value=0.001). The complications of balloon angioplasty were divided in to immediate complications within 24h post angioplastic procedure which included peripheral cyanosis 1case (7.7%), small aneurysm formation 1 case (7.7%), and intermediate complications within 6 month of the angioplasty which show repeated dilatation of coarctation in 1 case (7.7%), while in 10 cases (76.9%) there were no any complications. In this study all 13 cases had a negative family history of congenital heart disease, and consanguinity was negative in 11(84%) and positive consanguinity in 2(16%).

**Table (5):** No. of Patients in different ranges of pressure gradient before and after balloon angioplasty

Pressure gradient	No. of patients with Pressure Gradient before Balloon Angioplasty	No. of patients with Pressure Gradient after Balloon Angioplasty
1-10 mmHg	0	4
11-20 mmHg	0	1
21-30 mmHg	3	1
31-40 mmHg	2	3
41-50 mmHg	2	4
51-60mmHg	1	0
61-70 mmHg	5	0

**Table (6):** Pressure gradient changes with the angioplasty

No	Pressure gradient before balloon angioplasty	Pressure gradient after balloon angioplasty
1	55 mmHg	45 mmHg
2	70 mmHg	35 mmHg
3	65 mmHg	6 mmHg
4	50 mmHg	12 mmHg
5	65 mmHg	45 mmHg
6	50 mmHg	30 mmHg
7	65 mmHg	48 mmHg
8	22 mmHg	5 mmHg
9	35 mmHg	33 mmHg
10	25 mmHg	35 mmHg
11	22 mmHg	10 mmHg
12	35 mmHg	18 mmHg
13	70 mmHg	45 mmHg

**Discussion**

Current study enrolled 13 cases under age of 2 years who underwent percutaneous balloon angioplasty, in Sulaimani cardiac center; 8 cases (61.5%) were females and 5 cases (31.5%) were males, the mean pressure gradient before and after procedure was  $48 \pm 18.57$  and  $28.15 \pm 16.12$  mmhg ,respectively which was of significant difference; this is agreed with study done by Molaei<sup>18</sup>, in which the mean pressure gradient before and after procedure was  $34.48 \pm 15.39$  and  $5.84 \pm 3.79$  mmHg, respectively and with another study done by Amoozgar<sup>19</sup> where their pressure gradient reduced significantly from  $48.29 \pm 21.62$  mmHg before the procedure to  $13.21 \pm 9.96$  mmHg after the procedure, success of balloon angioplasty was achieved in 91/95 patients (95.7 %) and four patients underwent a second balloon angioplasty after 2-3 months, same result shown in another study done by Biomy<sup>20</sup> where the peak systolic gradient significantly decreased from  $51.97 \pm 15.24$  to  $9.075 \pm 8.71$  mmHg.

Other study done by Rao<sup>21</sup>, which included 20 infants aged 3 days to 12 months; their median age was 2.7 months and underwent balloon angioplasty with a resultant

significant reduction in peak systolic pressure gradient from  $40 \pm 12$  mmHg to  $11 \pm 8$  mmHg, same result was shown in a study done by Lan<sup>22</sup>, who included 37 young infants with COA and underwent BA, twenty-eight patients were males and nine were females, with ages ranged from 6 days to 6 months( mean  $66 \pm 45$  days) ,the peak systolic pressure gradient also decreased significantly from  $41.0 \pm 16.0$  mmHg to  $13.0 \pm 11.0$  mmHg.

In the majority of patients in our study the COA was accompanied by other cardiovascular anomalies<sup>15</sup>. In present study immediate successful relief of coarctation was obtained in 10 cases (76.9%) , peripheral cyanosis was present in 1 case (7.7%) and small aneurysm formation 1 case (7.7%), the intermediate complications which occurred within 6 months of the angioplasty with repeated dilatation of coarctation in 1 case (7.7%),while compering to Molaei<sup>18</sup> which showed injury to the femoral artery (6-17%) and 3 patients (12%) developed thrombosis of the femoral artery, other acute complications included hemorrhage from the femoral artery, cerebrovascular accidents and paradoxical hypertension, five cases (20%) required transfusion of blood and 2 cases (8%) received antihypertensive agent due to an increase in blood pressure after the procedure and continued receiving such medication throughout the follow up period. The prevalence of aneurysm after angioplasty has been reported to be 5%-15%<sup>18</sup>. While in study done by Biomy<sup>20</sup> showed the immediate successful relief of coarctation was obtained in 92.5% with recoarctation incidence reached 17.5% by the end of the 1st year follow-up and aneurysm formation at site of coarctation in 2 cases 5%. In study done by Lan<sup>22</sup>, intraoperative complications were formation of two small aneurysms and four patients had decreased femoral pulses which were resolved by heparin infusion.

## Conclusions

Balloon angioplasty is safe and effective treatment option in infants with COA, however timely diagnosis and improvement in angioplasty techniques are necessary to improve the outcome.

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