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Improvement of Left Ventricular Mass Following Balloon Angioplasty of Native Coarctation of the Aorta: Midterm follow-up in Cairo University, Children's Hospital

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Authors' contributions

This work was carried out in collaboration between all authors. Author AELS designed the study. Author MF wrote the protocol, and wrote the first draft of the manuscript. Author AF recruited the cases and performed the statistical analysis, and managed the analyses of the study, and authors SEIS, FAA and AEIA supervised case recruitment and managed the literature searches. All authors read and approved the final manuscript.

Research Article

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ABSTRACT

Objectives: We evaluated mid-term results of balloon angioplasty (BAP) of native coarctation of the aorta (CoA) in children. There is paucity of data on left ventricular hypertrophy (LVH) and left ventricular mass (LVM) post balloon dilatation of native CoA, hence we also assessed LVM regression.
Study Design: Thirteen children were included (11 boys, 2 girls) with median age at intervention of 16 months (4-96 months) and all underwent BAP for native CoA. Patients were followed-up by transthoracic echocardiography assessment of left ventricular function, LVM, recoarctation, and other complications. Follow-up period ranged from 9–36 months (mean±SD, 24.38±8.22 months).
Results: The mean peak systolic gradient decreased to ≤20 mmHg in 11 patients (84.6%), mean peak systolic gradient decreased from 61.15±12.44 mmHg before to 18.85±13.72 mmHg and 15.38±6.27 mmHg immediately after angioplasty and at last follow-up, respectively (P=0.00). There was recurrence of mean pressure gradient in two

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patients; the first patient was 4 months old and had a successful balloon angioplasty six months later and surgery was performed in the second patient. Ventricular function improved in all patients, mean left ventricular mass index (LVMI) during diastole significantly decreased from 142.27±131.22 before angioplasty to 69.55±54.38 g/cm^2 at last follow-up (P=0.038). None of the patients developed aneurysms or any other complications at last follow-up.

Conclusion: Considering its mid-term outcome, BAP is a successful and reliable procedure in the treatment of CoA. Follow-up by LVMI can be a noninvasive tool to assess mid and long term improvement.

Keywords: Angioplasty; balloon; aortic coarctation/therapy; heart defects.

1. INTRODUCTION

Coarctation of the aorta (CoA) accounts for 6%-8% of congenital cardiac diseases [1]. It is usually a discrete narrowing; however, it may present with tubular hypoplasia of the transverse aortic arch or can develop at various levels of the abdominal aorta. Clinical findings vary from cardiac failure and shock in neonates to asymptomatic hypertension, weak femoral pulses or murmur in infants and children [1,2]. Treatment includes surgical intervention, balloon angioplasty (BAP), or stenting in older age children [3,4]. There is no ambiguity in opinion for postoperative re-coarctation ballooning and is considered as the treatment of choice [5]; however, transcatheter BAP of native CoA in children remains a controversial topic due to the perceived risks to vessel integrity, long-term vessel stability and initial success of the procedure [6]. Studies with medium to long-term data indicate that BAP is effective and safe in management of native coarctation of the aorta in older children [7,8,9,10].

The aim of this study was to evaluate the results, complications and midterm outcomes obtained by BAP of native CoA in pediatric patients, and to assess the regression of left ventricular hypertrophy (LVH) post-dilatation by measurement of left ventricular mass index (LVMI) as an objective echocardiographic method for follow-up.

2. METHODS

This retrospective study included 13 patients with the diagnosis of native CoA who underwent BAP at the Pediatric Cardiology Unit, Cairo University, Children's Hospital during the period from January, 2008 to December, 2010. Inclusion criteria: All infants or children presenting with native discrete coarctation diagnosed by echocardiography and/or computed angiographic tomography. Exclusion criteria: Patients with complex coarctation (i.e. hypoplastic aortic arch and a long and tubular CoA), and those with associated cardiac anomalies requiring simultaneous surgical intervention.

Informed consents from the patients' caregivers were obtained. All patients' files were reviewed, with special concern to: body measurements, blood pressure (BP) values and BP gradient between upper and lower limbs; hypertension was defined as either systolic or diastolic blood pressure >95th percentile for age and sex, femoral pulsations (graded from 0, 1, 2, and 3 as absent, weak, mild, and normal), cardiac examination data, radiological and electrocardiographic findings.

Echocardiographic data before and immediately after angioplasty were reviewed and reported. Two-dimensional color Doppler and continuous-wave Doppler examinations were performed. Furthermore, LVMI was determined by the American Society of Echocardiography recommended formula [11]:

$$\text{LVMI } (g/m^2) = 1.04\ [(\text{IVST} + \text{LVID} + \text{PWT})^3 - \text{LVID}^3] - 13.6 / \text{Body surface area}$$

IVST: inter-ventricular septum thickness, LVID: left ventricular internal dimension, PWT: posterior wall thickness.

LVMI is considered an objective method to delineate LVH and facilitate follow-up.

Coarctation pressure gradient and coarctation site diameter before and immediately after angioplasty, aortic isthmus diameter and descending aorta diameter at level of diaphragm were measured. Presence or absence of diastolic flow was recorded; detection of pulmonary hypertension, tricuspid regurge or mitral regurge, and other associated congenital anomalies if present. Furthermore, coarctation site/descending aorta diameter at level of diaphragm (CoA/D) ratio were estimated.

Procedures were performed under general anesthesia. The aorta was catheterized in a retrograde fashion using 4 or 5 french introducing sheath (Cordis). All patients were anticoagulated using 50-100 u/kg heparin. Angiocardiographic examination was performed with a Biplane (Philips®, Germany)[1] machine. Diameters of the aortic isthmus, coarctation segment, and the descending aorta at the level of the diaphragm were measured. Standard methods for BAP in native coarctation were used [12]. Balloon diameter was chosen to be 2.5 to 3 times the diameter of narrowing, but not exceeding the diameter of the descending aorta at the level of the diaphragm. Different types of balloon were used according to the availability as (Cordis Power Flex® Extreme PTA Balloon Dilatation Catheter, USA)[2] and (Tyshak® Mini PTV Balloon Dilatation Catheter, USA)[3] were the most frequently used due to their low profile and the need for smaller femoral sheath sizes. Size, type, and inflation pressure of the balloon used were recorded. Ratio of the balloon to isthmus diameter, ratio of balloon to CoA site diameter, and ratio of balloon to the descending aorta at level of the diaphragm diameter were estimated.

After BAP, a subsequent angiogram was obtained to measure the diameter of narrowing. Pull back gradient across the site of coarctation was done. Intensive care unit length of stay post -procedure and any complications were recorded.

2.1 Follow-Up Evaluation

Assessment of body measurements, clinical assessment, and cardiac and transthoracic echocardiographic examination, after one month and every six months post-procedure were done. Data were compared with pre-angioplasty data to assess left ventricular function and LVMI and development of recoarctation and any other complication.

Recoarctation was defined as detection of a systolic gradient >20 mmHg between the

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descending aorta and ascending aorta or a narrowing at the site of previous coarctation less than 50% of the aortic diameter at diaphragmatic. Recoarctation was confirmed by demonstration of a systolic gradient of at least 20 mmHg in lower-upper extremity blood pressure measurements and a diastolic flow at the site of stenosis in echocardiographic assessment. Aneurysm was defined as any dilation or out-pouching of the aorta with a diameter ≥120% of that of the normal adjacent aorta. Success was defined as reduction in the sphygmanometric blood pressure gradient between the upper and lower limbs ≤20 mm Hg, and freedom from reintervention.

2.2 Statistical Analysis

Data were statistically described in terms of range, mean±SD, median, frequencies and percentages when appropriate. Comparison of numerical variables between the study groups was done using Mann Whitney *U* test for independent samples. Within group, comparison between pre and post values was done using Wilcoxon signed rank test for paired (matched) samples. For comparing categorical data, χ^2 test was performed. Exact test was used instead when the expected frequency is <5. *P*-values <0.05 was considered statistically significant. All statistical calculations were done using computer programs SPSS® (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft® Windows.

3. RESULTS

Out of thirteen patients, 11 were males (84.6%) and 2 were females (15.4%). The median age at intervention was 16 months (rang, 4-96 months); while the median age at follow-up was 48 months (range, 27-120 months). The mean weight at intervention was 11.42±4.72 kg (range, 4.5-19 kg), mean height 79.30±12.39 centimeters (range, 64-100 centimeters), and mean body mass index (BMI) 0.47±0.13 kg/m^2 (range, 0.28-0.71 kg/m^2).

CoA was isolated in 7 patients (53.84%), and was accompanied by other cardiovascular anomalies in 6 patients (46.16%) (Table 1).

Table 1. Associated cardiac lesions*

Lesion (n =13)	N	%
Associated intracardiac lesions	6	46.16
Atrial septal defect	5	
Ventricular septal defect	1	
Shone's complex	3	23.07
Bicuspid aortic valve	3	
Congenital aortic valve stenosis	2	
Mitral valve accessory tissue	2	
Subaortic discrete membrane	1	
Mitral stenosis	1	
Severely reduced left ventricular function	3	23.07
Aberrant right subclavian artery	1	7.96

**More than one lesion may be present in the same patient.*

The mean balloon diameter was 8.83±2.16 mm, the mean inflation pressure was 3.75±0.26 mmHg, the mean ratio of balloon to isthmus diameter was 1.10±0.27 mm, the mean ratio of balloon to aortic diameter at the level of the diaphragm was 0.81±0.18 mm and the mean ratio of balloon to CoA segment diameter was 2.76±0.73 mm.

3.1 Immediate Outcome

Systolic PG across the coarctation site significantly decreased from 61.15±12.44 mmHg (range, 45-80 mmHg) to 18.85±13.72 mmHg (range, 5-50 mmHg ($p<0.00$). The mean diameter of the stenotic segment (CoA site diameter) significantly increased from 3.42±1.10 mm to 7.00±1.47 mm ($p<0.00$). An immediate satisfactory result (gradient ≤20 mmHg and/or diameter increase to at least 50% of aorta) was obtained in 11/13 patients (84.62%). In the remaining 2 patients (15.38%), immediate residual PG of 45 and 50 mmHg were present and the diameters of the narrowed segment remained unchanged at 6 and 5 mm, respectively (Figs. 1 and 2).

Transient loss of femoral pulses was noted in 3 cases (23.07%) which improved after intravenous high molecular weight heparin. Procedure-related balloon rupture, severe vascular complication, arrhythmia or mortality was not encountered.

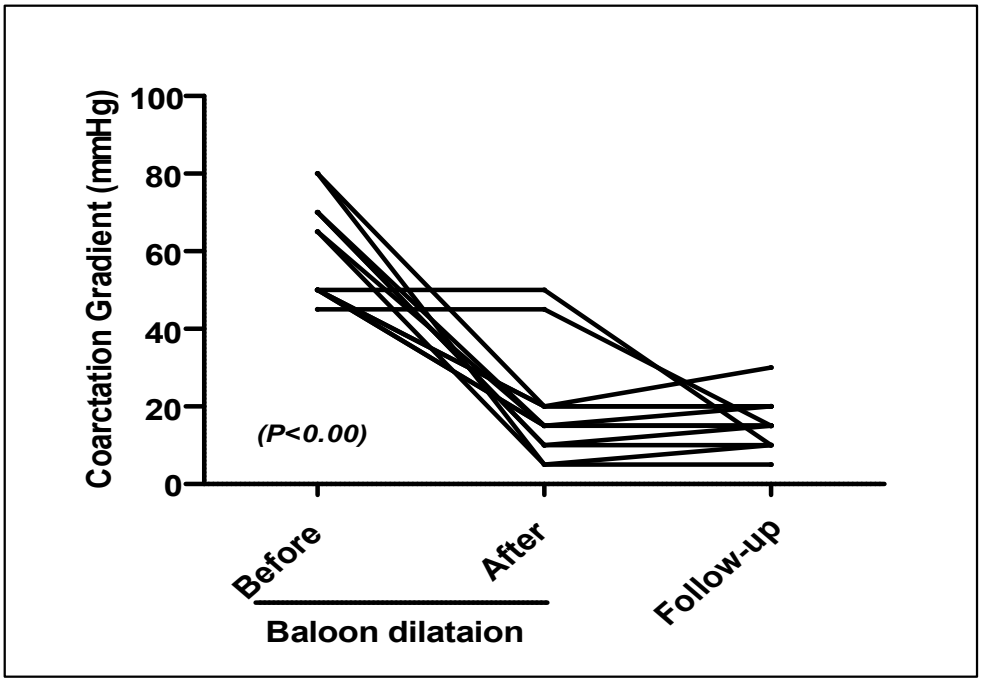

Fig. 1. Systolic pressure gradient across the coarctation before and after angioplasty, and at the follow-up period. Two pairs of patients had identical results

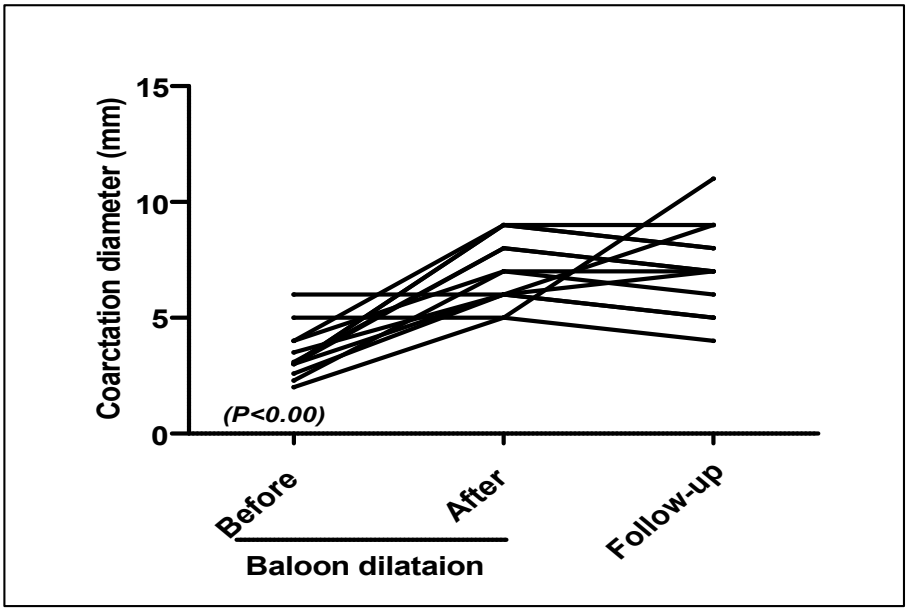

Fig. 2. Diameter of the aorta at the coarctation before and after angioplasty, and at the follow-up period

3.2 Follow-Up Data

Follow-up was obtained in all patients for a period ranging from 9 to 36 months with a mean of 24.38±8.22 months after intervention. The median age at follow-up was 48 months (range, 27-120 months).

Table 2 demonstrates significant improvement in femoral pulsations and systolic blood pressures before angioplasty and at the follow-up (*P*-value <0.05).

Table 2. Improvement of femoral pulsations and systemic blood pressures before angioplasty and at follow-up

Item	Before angioplasty (n=13)	Follow-up (n=13)	*P*-value
Femoral pulse	*n (%)*	*n (%)*	0.002*
• Abnormal	**13 (100%)**	**5 (38.46%)**	
– Absent	9 (69.23%)	0 (0%)	
– Weak	3 (23.07%)	2 (15.38%)	
– Mild	1 (7.69%)	3 (23.07%)	
• Normal	**0 (0%)**	**8 (61.54%)**	
Blood pressure	*mean±SD*	*mean±SD*	***P*-value**
• BP/UL Systolic (mmHg),	150.85±11.98	113.46±13.96	0.001*
• BP/UL Diastolic (mmHg),	90.54±18.13	76.92±9.98	0.028*
• BP/LL Systolic (mmHg),	88.23±14.14	97.69±10.93	0.034*
• BP/LL Diastolic (mmHg),	59.62±13.10	64.15±10.81	0.136

BP =blood pressure; UL = Upper limb; LL = Lower limb
**P-value <0.05 is significant.*

Table 3 shows a significant reduction in the mean systolic pressure gradient and the mean Doppler derived peak instantaneous gradient (PIG) across the coarctation site before and immediately after BAP, and at the follow-up (*P*-value=0.001). The means of peak systolic PG, measured before and after angioplasty and at the follow-up, were nearly similar to those of the Doppler derived PIG, measured at the same times, with no statistically significant differences between them (*P*-value>0.05). Although the mean peak systolic PG and the mean PIG had decreased immediately after dilatation with further reduction at the follow-up, that degree of reduction was not statistically significant (P>0.05).

Table 3. Comparison between the mean pressure gradient and mean peak instantaneous gradient before and after angioplasty, and at the follow-up

Item	Before angioplasty mean±SD	After angioplasty mean±SD	Follow-up mean±SD	*P*-value
Pressure gradient (mmHg)	61.15±12.44	18.85±13.72	15.38±6.27	0.001*
Peak instantaneous gradient (mmHg)	62.69±13.00	21.15±12.27	15.85±7.31	0.001*

**P-value <0.05 is significant.*

Systemic BP decreased in all patients in whom the peak systolic PG decreased to ≤20 mmHg immediately after BAP, with the exception of two patients where no improvements were detected, their ages at intervention were 4 and 8 years (Fig. 1); these patients underwent surgical resection (coarctectomy).

Antihypertensive treatment was started in 4 patients post-angioplasty and stopped in 3 on follow-up. Only one patient continued on B blockers to control his hypertension despite relieve of coarctation gradient.

Table 4 shows a significant improvement in the isthmus diameter with a significant increase of I/D ratio. There was a significant increase in the mean diameter of the stenotic segment (CoA site diameter) (Fig. 2). Four children were <1 year old and here, a small increase in diameter represented a substantial increase in size when related to the normal aorta. The dimensions of the CoA segment, as well as the ratio of CoA site diameter/descending aorta diaphragm (CoA/D) increased significantly, with mean percentage increases of 209±17% and 187±15% respectively (*P*-value=0.00).

Table 4. Hemodynamic and angiographic data before angioplasty and at follow-up

Item	Before angioplasty	Follow-up	*P*- value
	mean±SD	mean±SD	
Isthmus diameter (mm)	7.92±1.38	9.69±1.55	0.005*
CoA site diameter (mm)	3.42±1.10	7.15±1.91	0.000*
Aorta at diaphragm (mm)	10.53±1.76	11.84±1.67	0.064
I/D ratio	0.74±0.07	0.82±0.09	0.036*
CoA/D ratio	0.32±0.09	0.60±0.15	0.000*

CoA= Coarctation of aorta; I/D = Isthmus/ Descending aorta at diaphragm diameter; CoA/D = coarctation site/Descending aorta at diaphragm diameter

Table 5 shows a highly significant decrease in the IVS thickness and LVPW thickness, both during systole and diastole. Moreover, there was no increment of LVID regardless the increasing ages of the patients. The mean LVMI during diastole decreased from 142.27±131.22 before BAP to 69.55±54.38 g/m^2 at the follow-up (*P*-value=0.038).

Table 5. Echocardiographic morphometric measurements data before angioplasty and at the last follow-up

Item	Before angioplasty (n=13) mean±SD	Follow-up (n=13) mean±D	*P*- value
IVS d (cm)	0.68±0.15	0.56±0.08	0.002*
LVID d (cm)	3.04±0.87	3.01±0.73	0.161
LVPW d (cm)	0.85±0.24	0.74±0.25	0.002*
LVMI d (g/m^2)	142.27±131.22	69.55± 4.38	0.038*
IVS S (cm)	1.19±0.21	1.03±0.15	0.002*
LVID S (cm)	1.99±0.59	1.73±0.38	0.034*
LVPW S (cm)	1.27±0.13	1.07±0.24	0.002*
EF (%)	60.54±0.12	78.00±4.39	0.000*
FS (%)	38.8±3.23	43.23±3.27	0.003*
PA (cm)	1.29±0.48	1.24±0.36	0.500
Ao (cm)	1.28±0.17	1.23±0.16	0.187
RV (cm)	1.77±0.78	1.49±0.32	0.078
LA (cm)	1.74±0.35	1.55±0.46	0.421

IVS = Inter-ventricular septum thickness; LVID = Left ventricular internal dimension; LVPW = Left ventricular posterior wall thickness; LVMI = left ventricular mass index; d = diastole; S = Systole; EF = Ejection fraction; FS = Fractional shortening; PA = Pulmonary artery diameter; Ao = Aortic valve diameter; RV = Right ventricle dimension; LA = Left atrium dimension
**P-value <0.05 is significant.*

Only one patient (7.69%) developed restenosis with PG of 30 mmHg. He had successful repeated BAP six months later. Procedure related aneurysmal dilatation was ruled out by MRI in 6 patients at last follow-up and by echocardiography in the remaining patients.

Fig. 3 illustrates an example of a patient with severe CoA that was successfully managed by BAP.

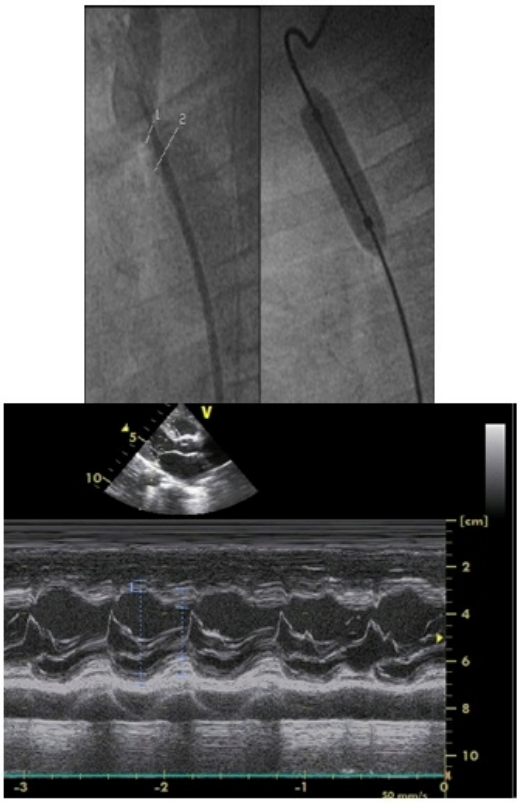

Fig. 3. A 14-month old patient with severe coarctation (peak pressure gradient 80 mmHg and hypertension (135/90) treated with angioplasty; postangioplasty pressure gradient was 5 mmHg. Left: preangioplasty aortography. Center: postangioplasty aortography. Right: echocardiography done 3 years after angioplasty; the patient presented normal blood pressure values (100/75) and the arm-leg pressure gradient was 5 mmHg

4. DISCUSSION

Coarctation is a challenging condition seen in pediatric cardiology patients with congenital heart defects [2]. BAP is a minimally invasive procedure that involves inserting a catheter into a large blood vessel, usually in the groin and passing it up to the area of narrowing, and then inflated within the narrow area [7].

CoA is commonly associated with other cardiac anomalies; additional lesions have an impact on outcome [13]. In our study, CoA was associated with other cardiovascular anomalies in 46.16% of patients. ASD was the most commonly associated lesion, while bicuspid aortic valve and small VSD were also reported to a lesser extent. The association between CoA and other cardiac anomalies was demonstrated previously, however; bicuspid aortic valve was the most commonly associated lesion [14,15].

In our study, we concentrated on careful choosing of balloon size and inflation pressure according to manufacturing company; the mean balloon diameter was 2.76 times the CoA

segment diameter. Small balloons do not produce adequate relief of obstruction and large balloons may produce aortic rupture or aneurysm formation. Initial balloon dilatation is performed with a balloon whose diameter is an average of aortic isthmus or transverse aortic arch and descending aorta at the level of the diaphragm [16]. Our choice of proper balloon size was supported by other investigators; the use of balloon that is midway between the size of the aortic isthmus (or transverse aortic arch) and the size of the descending aorta at the level of diaphragm was recommended [2,17].

Decrease in the peak systolic PG at the site of stenosis to 20 mmHg or below after BAP indicates a successful result [1,18]. In our study, immediate successful results were obtained in 11 patients (84.62%). However, in 2 patients (15.38%), the immediate success criteria were not achieved, for whom early surgical intervention was planned. The relatively small balloon size diameters used in these two cases “2 times” as coarctation diameters comparable to that is used for the other cases “2.9 times” as coarctation diameter might be related to this failure rate.

Our success rate was 87% similar to Okur et al. [5] and Ovaert et al. [9] reported an immediate success rate of 85% and 87% respectively. This rate is similar to reported surgical series with recoarctation rate range from 7-30% [18]. In our hospital there are long surgical waiting lists and limited number of cardiac intensive care beds; which favours the direction of patients towards catheter intervention as catheter patients can be discharged to the ward. Other studies reported success rates that vary from 73% to 90% [17,19]. However, patients of these two studies were older than our patients.

Hypertension after coarctation repair caused by anatomic aortic alterations, structural wall alteration of thoracic and peripheral vessels, poor compliance of the arterial tree, altered renin-angiotensin system, sodium and water retention, and neural reflex [20]. In our study, 4 patients (30.77%) were normotensive after receiving angiotensin converting enzyme inhibitor, and only one patient still having hypertension, his high BP was controlled after β-blocker treatment.

LVMI is increased in marked hypertension in CoA patients [21]. In our study, the hemodynamic effects upon the cardiovascular system developed by hypertension improved significantly; there was a highly significant decrease in IVS and LVPW thickness, and so the mean LVMI decreased significantly at the follow-up, and LVEF% was increased significantly. LVH was the most frequent hemodynamic effect detected before BAP and improved significantly at the follow-up. Similarly, Okur et al. [5] noted a decreased LVMI and an increased LVEF% in CoA patients at their follow-ups. There are not many reports in literature on LVMI following BAP for CoA, however there is enough evidence relating regression of LVMI following treatment of hypertension related to renal etiology. Kupferman et al. [22] demonstrated that the change in LVMI in hypertensive children had a significant correlation with the percentage change in systolic blood pressure Z scores.

Regarding the complications of BAP; loss of femoral pulses, aneurysm formation and the development of recoarctation (especially in infants), have been of particular concerns. Risk factors for recoarctation and aneurysm formation include young age (28 days) and a hypoplastic isthmus [23,24].

Femoral artery injuries and thrombosis are the most common complications of BAP. These were reported in 21% of newborns and infants, and in 9% of children [1]. In our study, transient loss of pulse after the procedure was detected in 3 patients (15.78%). Similarly Ovaert et al. [9] and Okur et al. [5] had detected a similar finding. The incidence of balloon

rupture varies from 0% to 9.5% [19,25]; we did not encounter this problem in our patients. No deaths occurred in our patients.

A peak systolic PG ≥ 20 mmHg at the site of stenosis indicates restenosis. Factors associated with the development of restenosis include age below 12 months, a segment diameter <3.5 mm and 6 mm before and after the procedure, respectively [23]. Factors associated with restenosis after BAP include: young patient age (neonate), associated arch hypoplasia and a small CoA diameter [26,27]. In our study one of patients developed restenosis whose age was 5 months at intervention, to whom a repeated BAP was planned.

In order to assess growth of the isthmus and stenotic segment; I/D ratio and the CoA/D ratio before BAP and at follow-up were compared, there was a significant improvement in the isthmic diameter, and in stenotic diameter. These results come in agreement other studies which used these ratios to detect restenosis on following up their patients also reported similar results [5,24,28]. Our result shows that 4 patients were <1 year of age. This demonstrates that the procedure is effective in infants as well, so long as patients are carefully selected and risk factors avoided [10,26].

In our study, surgical intervention by end-to-end anastomosis was performed in two cases with early failure. Of these two cases, no one developed restenosis during the 2 year-follow-up period. Restenosis after surgery is related to age, with a high likelihood to occur in newborns [26]. Restenosis rates after surgical management of CoA restenosis occurring following BAP vary from 7% to 30% [18]. BAP had been recommended as a treatment of choice for recurrent postoperative CoA; Yetman et al. [29] reported early optimal results after repeated BAP for recurrent coarctation of 72%, and their patients remained free from reintervention during a median follow-up of 39 months.

Aneurysm was defined as any dilation or out-pouching of the aorta with a diameter ≥120% of that of the normal adjacent aorta [24]. Several factors are implicated development of aneurysm such as ruptures occurring in the intima and media layers of the aorta during surgery, improper balloon size, and inappropriate manipulations of the catheter or guide wire in the dilated area [10]. None of our patients developed aneurysm. However, previous studies had reported an incidence of aneurysm formation ranged from 0 to 55%, with an average of about 5 to 10% [7,26]. Brown and Bruwer [24] and Hassan et al. [30] had reported a rate of 11% and 7% respectively. The discrepancy between studies can be explained by a number of factors including age at procedure, technique, and absence of a clear and consistent definition of an aneurysm in the initial older studies. The low incidence of complications in our study, comparable to other studies, could be attributed to the fact that we used only low profile balloon with careful choosing of the balloon size.

5. CONCLUSION

In conclusion our study supports the previous studies showing that BAP is an effective and safe method for the treatment of native CoA in both the immediate and midterm periods; therefore, BAP could be a good alternative to surgical intervention, in our local population. Better selection of patients, low-profile balloons, and optimization of general care can reduce the incidence of complications, and a close follow-up of patients is required for late complications such as restenosis and aortic aneurysm. A second angioplasty (simple or with stenting) in cases of recoarctation may be needed to improve the results of this technique in the medium and long-term.

6. STUDY LIMITATION

The main limitation of study was the relatively low number of patients; a greater number of patients are needed and their long-term results.

CONSENT

Written consents were taken from every parent/surrogate of the study candidates. If they had questions, a study physician would clarify the consent form from a standardized set of key points that covered each section. Parents who indicated that they understood and agreed to the terms of the study provided the consent. Those who could sign or draw their names did so; those who could not gave a thumb impression.

ETHICAL APPROVAL

The Scientific Research Committee of Pediatrics Department, Faculty of Medicine-Cairo University, approved the study design. Data confidentiality was preserved according to the Revised Helsinki Declaration of Bioethics.

CONFLICTS OF INTEREST

Authors have declared that no competing interests exist.

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