Yaseen et al. Scr Med. 2025 Jul-Aug;56(4):683-90. DOI:10.5937/scriptamed56-58422

ORIGINAL ARTICLE

Balloon Angioplasty in the Treatment of Children With Native Aortic Coarctation: Is Reintervention Predictable?

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Citation:
Yaseen MJ, Akram NN, Abdulridha YI. Balloon angioplasty in the treatment of children with native aortic coarctation: is reintervention predictable? Scr Med. 2025 Jul-Aug;56(4):683-90.

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Abstract

Background/Aim: Reintervention after balloon angioplasty is often considered inevitable in children with coarctation of the aorta (COA). The present study aimed to evaluate predictors of re-intervention after balloon angioplasty for COA, with the goal of identifying patient and procedural characteristics that may influence long-term outcomes.
Methods: A retrospective study involved children who underwent balloon angioplasty for COA at a specialised interventional cardiovascular centre over a period of four years. A two set of data were collected: first, the clinical-demographical data (age, sex, weight, associated congenital heart disease, syndromic features). Second, procedure-related data (type of anaesthesia, heparin use, type and number of balloons used, fluoroscopy duration, procedure outcome and complications). Early interventional success is considered if the peak systolic pressure gradient (PG) achieves less than 20 mm Hg. All patients were followed for 12 months during which the pressure gradient was measured periodically by echocardiography and any reintervention was documented.
Results: A total of 37 children underwent balloon angioplasty during the study period. Most children (62.2 %) underwent the procedure after the first year of life. The procedure was successful early in 35 (95 %) of cases. On follow-up for 12 months, 8 patients (22 %) needed re-intervention. Eight factors were identified as significantly associated with the likelihood of re-intervention, including younger age, lower ejection fraction, use of two balloons, procedural complications, longer duration, smaller COA size, higher residual pressure gradient and a lower reduction in the peak systolic PG.
Conclusion: This study emphasised the multifactorial nature of re-intervention risk following balloon angioplasty for COA. Careful consideration of patient age, ventricular function, anatomical characteristics, procedural complexity and immediate haemodynamic results is essential to decrease the need for reintervention.

Key words: Angioplasty, balloon, coronary; Aortic coarctation; Child; Infant; Coronary restenosis.

Received: 23 April 2025
Revision received: 12 July 2025
Accepted: 12 July 2025

Introduction

Coarctation of the aorta (COA) is a relatively common congenital heart disease, ranking fifth among congenital defects and constituting less than 10 % of all cardiac birth defects, with an estimated incidence of 1 in 2500 live births.[1] It's seen more frequently in male infants and presents

with variable clinical manifestations, ranging from completely asymptomatic cases identified accidentally during evaluation for hypertension or heart murmur to severe heart failure, which can eventually lead to the infant's death if not corrected early.[2]

Once diagnosed, children with COA are assigned to one of two therapeutic modalities: either surgical correction or balloon angioplasty. Although surgical correction remains the gold standard modality of treatment in paediatric COA, the balloon intervention is increasingly recognised as the preferred modality of treatment, particularly in children with native or recurrent coarctation after surgical intervention.[3–5] The use of balloon angioplasty for COA was a significant milestone in the field of interventional cardiology, first introduced by John M Morrow in the early 1980s.[6] Since its inception, the procedure has demonstrated a high success rate; however, it is not free of complications and reintervention is frequently required after the procedure.[2, 7, 8]

Recent studies reported high safety and efficacy of balloon angioplasty for native COA in infancy with outcomes comparable to those in older children and adults.[9, 10] The success rate of the procedure is varied in range 84-100 % in Iraq, affected by factors that are either related to patients' characteristics, procedural technique, or the expertise of the operator.[11] However, the immediate outcome doesn't correlate with mid- and long-term outcomes, including the need for reintervention.[12]

Reintervention after balloon angioplasty is often considered inevitable in many cases of COA; however, predictors of reintervention are inconsistently reported and data related to it remain inconclusive.[8] Identifying patients at higher risk for re-intervention is essential for optimising patient selection, improving procedural outcomes and tailoring long-term follow-up protocols. While previous studies have explored potential risk factors-including patient age, anatomy of the lesion and balloon-to-aorta ratio, as potential predictors, results remain variable and context-dependent. Given these considerations, the present study aims to investigate clinical and procedural predictors associated with the need for re-intervention after balloon angioplasty for COA. A better understanding of these factors may contribute to more precise risk stratification and inform long-term management protocols.

Methods

This retrospective study involved children who underwent balloon angioplasty for native COA over a four years period, from February 2020 to February 2024, at the Iraqi Centre of Cardiac Diseases, Medical city complex, Baghdad, Iraq. Patient involved in the study after matching the following inclusion criteria: age less than 18 years, COA managed by balloon angioplasty without stent placement and no history of previous intervention for COA were done. Patients were excluded from the study if they met any of the following criteria: age greater than 18 years, a previous re-intervention for COA, those with COA as part of a complex congenital heart disease and those with incomplete or missing data. The diagnosis of COA was confirmed in all patients by the presence of a peak pressure gradient (PG) of > 20 mm Hg across descending aorta by echocardiography.

In all patients two set of data were collected: first clinical and demographical data (age, sex, weight, presence of associated congenital heart disease and syndromic features). Second a procedure-related data (type of anaesthesia, heparin administration, type and number of balloons used, fluoroscopy duration, procedure outcomes and complications). The procedure was considered successful if achieve less than 20 mm Hg drop in systolic pressure gradient. All patients were followed for 12 months post-procedure. During follow-up, pressure gradients were measured periodically via echocardiography and any need for reintervention was documented.

All patients underwent the procedure under general anaesthesia with right femoral artery accessed by 5 or 6 French sheaths, selected according to patient age and body weight. Intravenous heparin was administrated in all patient aiming to maintain an activated clotting time above 200 s. Peak-to-peak PG across the coarctated segment recorded initially and then after balloon inflation. An aortogram was performed in biplane projections (standard lateral and 20-degree left anterior oblique) in catheterisation laboratory, measuring the diameter of aorta at isthmus which is equal to the size of the used balloon, Multiple balloon inflation two-four times each, inflation less than 10 seconds, till the waist of the narrow segment disappeared. But if the target PG was not achieved, a larger balloon was used but never exceed that of aorta at the level of diaphragm. All

patients monitored overnight inside the hospital and if the peripheral pulse in the leg ipsilateral to the femoral artery accessed is absent more than one hour post sheath removal, an additional intravenous dose of heparin (75 IU/kg) was administered.

Statistics

Data was analysed using the Statistical Package for Social Sciences (SPSS) version 26. Descriptive statistics were used to summarise numerical variables, which were presented as mean, standard deviation. Categorical variables were reported as frequencies and percentages (%). A p-value less than 0.05 was considered statistically significant.

Results

A total of 37 children with COA underwent balloon angioplasty during the study period. Most children (62.2 %) underwent the procedure after the first year of life and the median age at time of procedure was 26 months. Males had the predominance in the study sample account for (59.5 %) and the average weight of children at time of procedure was 12 kg. Most children 29 (76 %) has associated congenital heart diseases with patent ductus arteriosus being the most documented in (37.8 %). Only two cases had Turner syndrome, as seen in Table 1.

The balloon angioplasty in all cases were done under general anaesthesia and all children received heparin. Most cases 28 (75.7 %) managed with one balloon and from those Ospyka balloon being the mostly used one used in 17 (45.9 %) patients. Seven patients develop complications that include pulseless lower limbs which documented in 6 (16.2 %) cases, while in one case, the balloon had been damaged during the procedure. The mean duration of fluoroscopy was 6 ± 2.6 minutes, as seen in Table 2.

Regarding outcome, the procedure was successful early in 35 (95 %) of cases. On follow-up for 12 months, 8 patients (22 %) needed re-intervention (Figure 1 and 2).

Four clinical factors were significantly related to reintervention these include: patients age of less than 1 year p = 0.0001, having low ejection fraction p = 0.09, using two balloons during the

Table 1: Clinical and demographical characteristics of the studied sample (n = 37)

Variables	Values
Age	
Median (months)	26
Range (months)	1-72
Neonate and children <1 year (N)	14
1 year and above (N)	23
Gender, n (%)	
Male	22 (59.5)
Female	15 (40.5)
Weight, kg	
Median	12
Range	2-19
Associated congenital heart disease, n (%)	
PDA	14 (37.8)
Bicuspid AV	11 (29.7)
VSD	7 (18.9)
ASD secondary	5 (13.5)
SHONE complex	1 (2.7)
None	9 (24.3)
Turner syndrome, n (%)	
Present	2 (5.4)
Absent	35 (94.6)

ASD: atrial septal defect; AV: aortic valve; PDA: patent *ductus arteriosus;* VSD: ventricular septal defect;

Table 2: Procedure-related characteristics of the studied patients (n = 37)

Variables	Values N (%)
Heparin use	37 (100.0)
General anaesthesia	37 (100.0)
Number of balloons	
One	28 (75.7)
Two	9 (24.3)
Type of balloon used	
Ospyka balloon alone	17 (45.9)
Tyshake balloon alone	10 (27.0)
PCI balloon and Ospyka balloons	6 (16.2)
PCI and Tyshake balloons	2 (5.4)
PCI balloon alone	1 (2.7)
Ospyka and Tyshake balloons	1 (2.7)
Complications	
Pulseless lower limbs	6 (16.2)
Damaged balloon	1 (2.7)
Variables	**Mean ± SD**
Duration of fluoroscopy, (minutes)	6.00 ± 2.60
Size of COA pre-Cath, (mmHg)	2.28 ± 0.79
Size of COA post-Cath, (mmHg)	7.31 ±2.42
Pressure gradient before Cath, (mm)	47.24 ± 0.00
Pressure gradient post Cath, (mm)	13.50 ± 6.28
Mean pressure drop, (mm)	33.73 ± 7.97

COA: coarctation of the aorta; PCI: percutaneous coronary intervention;

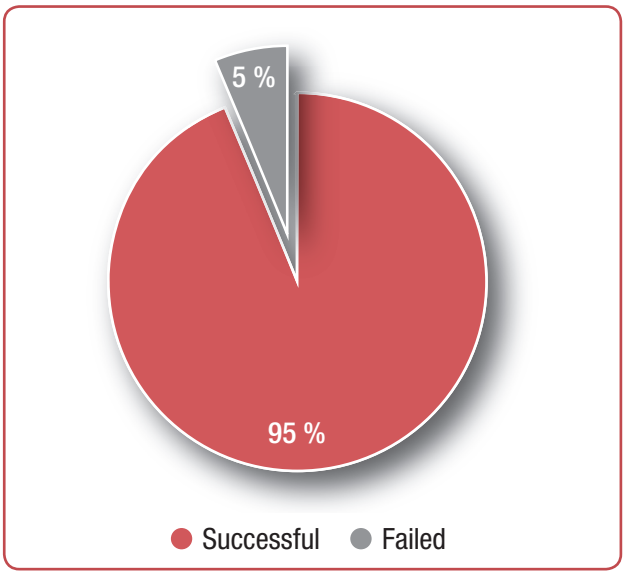

Figure 1: Early outcome of balloon angioplasty in children with native coarctation of the aorta (COA)

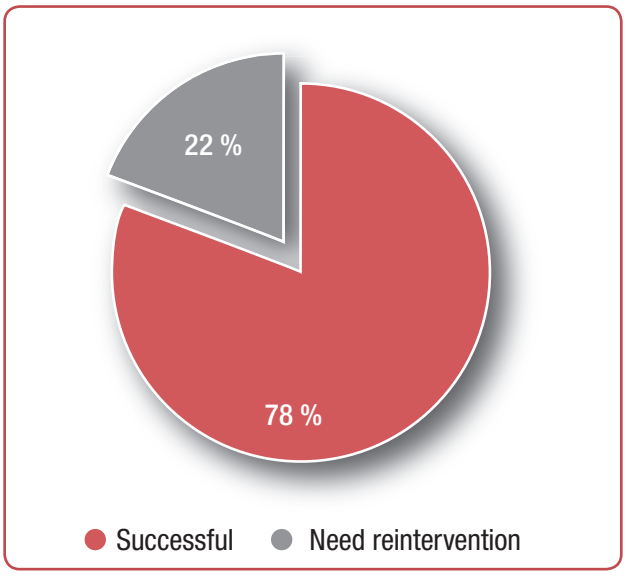

Figure 2: Midterm outcome of balloon angioplasty in children with native coarctation of the aorta (COA)

Table 3: Clinical factors associated with re-reintervention in children with coarctation of the aorta (COA)

Variables N (%)	Need re-intervention N = 8 (%)	Do not need re-intervention N = 29 (%)	p-value
Gender			
Male	6 (75.0)	16 (55.2)	0.4310
Female	2 (25.0)	13 (44.8)	
Age			
Less than one year	8 (100.0)	6 (20.7)	0.0001
More than one year	0 (0.0)	23 (79.3)	
Number of balloons used			
One	1 (12.5)	22 (75.9)	0.0020
Two	7 (87.5)	7 (24.1)	
Ejection friction			
Low	4 (50.0)	4 (13.8)	0.0290
Normal	4 (50.0)	25 (86.2)	
Associated congenital heart			
Absent	0 (0.0)	9 (31.0)	0.0700
Present	8 (100.0)	20 (69.0)	
Complications			
Absent	2 (25.0)	28 (96.6)	0.0001
Present	6 (75.0)	1 (3.4)	

procedure p = 0.002 and patients developed complications following the procedure p = 0.0001. While patients' gender and presence of other congenital heart disease did not significantly relate to the need for reintervention (Table 3).

Four procedural factors were associated with need for reintervention include: duration of the procedure (p = 0.01), size of COA pre- and post-Cath (p = 0.0001), pressure gradient post Cath (p = 0.011) and the mean pressure drop (p = 0.0001) (Table 4).

Table 4: Procedure related factors associated with need for reintervention

Variables N (%)	Need re-intervention N = 8 (%)	Do not need re-intervention N = 29 (%)	p-value
Duration of the procedure	9.13	6.50	0.0100
Size of COA pre-Cath	1.35	2.54	0.0001
Size of COA post-Cath	4.16	8.17	0.0001
Size of balloon	8.88	10.67	0.2650
Pressure gradient before Cath	42.75	48.48	0.1330
Pressure gradient post Cath	18.38	12.17	0.0110
Mean pressure drop	24.38	36.31	0.0001

Cath: catheterisation; COA: coarctation of the aorta;

Discussion

This study aimed to identify significant predictors of re-intervention in Iraqi paediatric patients undergoing balloon angioplasty for COA. Presented analysis revealed eight clinical and procedural factors that were significantly associated with increased risk of re-intervention. These findings carry important implications for patient selection, procedural planning and post-operative monitoring.

The most striking association with reintervention was patients age under 1 year of age (p = 0.0001), suggesting that younger age is a strong risk factor for restenosis or suboptimal long-term outcomes following balloon angioplasty. This is consistent with prior studies that have demonstrated higher rates of recurrent obstruction in neonates and infants, likely due to the relative elasticity of vascular tissues in early life and the ongoing somatic growth which can alter the dynamics of the previously treated segment.[13, 14] The study by Rao and Chopra[15] emphasised the significance of patient age at the time of the procedure in determining the likelihood of requiring reintervention. Specifically, they found that 31 % of neonates and infants under the age of one required reintervention, compared to only 8 % in children older than one year. These findings are consistent with the results of the current study, in which all patients requiring reintervention were managed under one year of age. This suggests that younger age at the time of the procedure may serve as a predictor for the future need for reintervention. These results could match the expert preference of surgical option for management of COA in children infancy.[16, 17]

The number of the balloons used during balloon angioplasty were significantly correlated to the need of reintervention as reintervention were significantly associated with use of two balloon (p = 0.002). The first reported use of the two-balloon technique for transluminal angioplasty of aortic coarctation appears done by Dr Vincent J D'Souza in 1984. His work introduced the concept of using two balloons simultaneously to achieve more uniform dilation and reduce complications associated with single-balloon angioplasty.[18] Later on 1987 John W Moore and colleagues were among the first to describe the use of two balloon method in treating re-coarctation after surgery.[19] Although safety and efficacy of double balloon technique were extensively studied on short term, none of the previously published study compare the need for reintervention by the number of the balloon used.[20] In this study the use of two balloons during the intervention emerged as another significant predictor for re-intervention, possibly reflecting either complex anatomical morphology or initial suboptimal response to single-balloon dilation. This factor likely denotes a technically more challenging lesion or the need for staged dilation, both of which may predispose to residual stenosis or vessel recoil.

In the current study, low ejection fraction was statistically correlated with increased re-intervention rates (p = 0.09). This aligns with the notion that compromised left ventricular function may reflect more severe haemodynamic burden pre-procedurally or inadequate myocardial recovery post-intervention, both of which could predispose patients to poorer outcomes and ne-

cessitate further corrective procedures.[21] As previous studies concur that low ejection fraction in most patients with COA improve as early as few days post intervention.[22, 23] So, delayed recovery may point to the presence of residual lesions or complications that may affect myocardial ability to regain normal function and dimensions and a possible need for re-intervention.

Procedure duration (p = 0.01) and post-procedural complications (p = 0.0001) were understandably associated with higher re-intervention rates which may reflect procedural complexity or technical difficulties during angioplasty. Prolonged interventions may indicate operator difficulty in achieving adequate dilation or addressing complications, both of which can influence long-term outcomes. The documented complications in the current studied sample consist only of pulseless lower limb and ruptured balloons. Complications documented in previous literatures such as vascular injury, aneurysm formation, or haemodynamic instability may compromise the efficacy of the initial procedure or contribute to the development of secondary lesions, thus necessitating further intervention.[24–26] The short period (one year) of follow up in the current study could explain absence of documentation of other common complications like aneurysm which reported in up to 9 % following balloon angioplasty.

Anatomically, smaller diameter of the coarctation both pre- and post-procedure was a consistent predictor of re-intervention (p = 0.001). This finding is in line with previous literature that has shown that smaller native and residual diameters are associated with higher rates of restenosis.[27, 28] It underscores the importance of achieving adequate luminal expansion during the index procedure and highlights the limitations of balloon angioplasty in severely narrowed or hypoplastic segments. Haemodynamic parameters also showed statistically significant association with the need for reintervention as higher residual pressure gradient post-catheterisation (p = 0.011) and a lower drop in mean pressure (p = 0.0001) were both significantly associated with the need for re-intervention. These parameters are direct indicators of the procedural success and residual haemodynamic burden. A high residual gradient implies incomplete relief of obstruction, while a minimal pressure drop may reflect inadequate therapeutic effect. These findings highlight the critical role of immediate post-procedural haemodynamic assessment in predicting long-term outcomes.

Taken together, these results emphasise the multifactorial nature of re-intervention risk following balloon angioplasty for COA. While the procedure remains a less invasive alternative to surgical repair, careful consideration of patient age, ventricular function, anatomical characteristics, procedural complexity and immediate haemodynamic results is essential. Identifying high-risk patients pre-procedurally could guide clinicians in selecting alternative treatment strategies or planning more aggressive surveillance and follow-up protocols.

Although generalisation of the results of the current study hindered by small sample size and being done in a single centre which represent a major limitation. To the best of our knowledge, this study is the first to establish a significant correlation between the balloon angioplasty used for COA and the need for re-intervention. The study finding provides new insights into the impact of procedural choice on long-term outcomes, contributing to the existing body of knowledge in this field. Further longitudinal studies with larger sample sizes are warranted to validate these findings and to develop comprehensive risk stratification models that can better inform clinical decision-making in this vulnerable patient population.

Conclusion

Balloon angioplasty remains an effective therapeutic approach for coarctation of the aorta in children. Several factors were identified as significantly associated with the likelihood of re-intervention, including younger age, lower ejection fraction, use of two balloons, procedural complications, longer duration, smaller COA size, higher residual pressure gradient and a lower reduction in mean pressure, so careful patient selection is fundamental when determining the most appropriate intervention for children with COA.

Ethics

The Ethics Committee of Mustansiriyah University issued the study approval with a decision No IRB 40, dated 29 September 2024.

Acknowledgement

None.

Conflicts of interest

The authors declare that there is no conflict of interest.

Funding

This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Data access

The data that support the findings of this study are available from the corresponding author upon reasonable individual request.

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