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Original Article

Post Procedural Left Pulmonary Artery Stenosis and Aortic Coarctation Following Transcatheter Closure of Ductus Arteriosus in Infants and Associated Outcomes

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ABSTRACT

Objective: To determine the frequency of Left Pulmonary Artery (LPA) stenosis and aortic coarctation following transcatheter closure of ductus arteriosus and to assess the post-procedural outcomes.

Study Design: Quasi- Experimental study.

Place and Duration of Study: Armed Forces Institute of Cardiology/ National Institute of Heart Diseases, Rawalpindi, Aug 2023 to Jan 2024.

Methodology: Forty Seven patients of both gender who underwent Patent Ductus Arteriosus (PDA) closure and weight having < 10kg were included.All patients were admitted one day prior to the procedure, base line laboratory tests including complete blood count, C-reactive protein, chest x-ray, echocardiography and ECG were performed.Patients were kept in post cath ward/HDU for observations and monitoring for any complications. Patients were called up on day 1, day 7, 1st month, 3rd month and 6th month for follow-up.

Results: Out of 47 patients, 18(38.3%) were males and 29(61.1%) were females with mean age 7.67±3.77 months. After PDA closure, 12(25.5%) patients developed coarctation across descending aorta, 3(6.3%) patients developed LPA stenosis which improved with time and none patient had significant coarctation or LPA stenosis at 6 month follow up. PDA type, size, device type and weight of participants were significantly associated with coarctation of aorta and LPA stenosis (p<0.05).

Conclusion: Transcatheter PDA device closure is an effective and safe treatment in small infants, although there is small risk of aortic coarctation, left pulmonary artery stenosis and Left ventricular dysfunction that resolved in majority of patient without any further intervention over time.

Keywords: Aortic coarctation, Complications, Left pulmonary artery stenosis, Patent ductus arteriosus, Transcatheter closure

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INTRODUCTION

Congenital heart diseases are the most common congenital defects present at birth with estimated prevalence of 3.4/1000 live birth in Pakistan.[1] Of all congenital abnormalities, PDA accounts for 6%–11% of cases and affects around 1 in 2,500–5,000 live births.[2] As many as 60% of preterm infants and 80% of newborns weighing less than 1200 g are likely to have a patent ductus arteriosus (PDA).[3] Epidemiological studies indicate a 2%–4% higher risk of PDA recurrence in siblings among term newborns.[4] Given the incidence of PDA, it is twice more likely to occur in girls than in boys.[5] Although the ductus arteriosus typically closes during the first 72 hours after birth, persistent patent ductus arteriosus (PDA) is estimated to occur in 57/100,000 live births for term babies and significantly more frequently in preterm babies.[6] Heart failure, chronic lung disease, necrotizing enterocolitis, intraventricular hemorrhage, and death have all been linked to hemodynamically significant PDAs.[7] Historically, when medical therapy was either contraindicated or ineffective, surgical ligation was the favored technique of closure. However, the surgical PDA ligation is linked to hemodynamic impairment, vocal cord paralysis, phrenic nerve palsy, pneumothorax, chylothorax, and musculoskeletal abnormalities in addition to bleeding and wound infection.[8]

For larger infants, children, and adults, transcatheter PDA is preferred. The transcatheter technique was discovered to be more affordable, faster to recover from, less likely to leave residual PDA, and less prone to problems than surgical ligation even in premature infants.[9]

Transcatheter closure of PDA in smaller newborns has been the subject of numerous series. Significant and unique problems in this population

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include left pulmonary artery (LPA) stenosis and aortic Stenosis/coarctation (Blood velocity >2 m/sec).[10] related to devices. There have been limited studies assessing these important variables in our country. Our study is expected to provide insight into these potential possibilities acting as a framework for future large scale local studies improving patient care. This study assesses short term following TC-PDA, including frequency of LPA stenosis and aortic coarctation, risk factors for their development, and whether there is persistence or improvement over time. It will also updates our understanding of the acute procedural outcomes. With transcatheter closure being a standard treatment, understanding the frequency of complications is important for optimizing patient outcomes. By monitoring infants under 10 kg, this study provides valuable insights into the occurrence and recovery of these complications, contributing to more informed clinical decision-making and improving long-term outcomes.

METHODOLOGY

This Quasi-experimental study was conducted from Aug 2023 to Jan 2024 in Paediatric Cardiology department of Armed Forces Institute of Cardiology/ National Institute of Heart Diseases, Rawalpindi, after the approval from Institutional Ethical Review Board (letter #9/2/R&D/2023/282-18th Aug 2023). Study was conducted by selecting patients using non-probability consecutive sampling

The sample size of n=7 patients was determined using WHO sample size calculation software, considering prevalence 0.4% of PDA patients11, a confidence level of 95%, and 5% margin of error. However total n=47 patients were enrolled in this study

Inclusion criteria: All babies with PDA who were less than 10 kg in weight and of either gender were included.

Exclusion criteria: PDA with associated anomalies(i.e. aortic arch abnormalities like Coarctation of Aorta, pulmonary stenosis, Tetralogy of Fallot, Transposition of great arteries, duct dependent pulmonary and systemic circulation).

Study was conducted in patients where procedure was indicated, parents were counselled about the procedure details, associated risks and possible outcomes. Written informed consent taken, anonymity of patients was maintained and patients' data was kept confidential.

All patients were admitted one day prior to the procedure, base line laboratory tests including complete blood count, C-reactive protein, chest x-ray, echocardiography and ECG were performed. PDA was categorized as small (<0.5), moderate (>0.5 to 1) or large size (>1) based on ratio of the smallest duct diameter to the ostium of LPA using the following equation: Ductal diameter (mm)/diameter of the ostium of LPA(mm). Anesthesia fitness was taken. All procedures done under general anesthesia through femoral approach. Vascular access was obtained in femoral artery and aortogram was done in true lateral projection to assess size, type and narrowest point of PDA. Krichenko Angiographically classified duct into five types: type A ''conical'' ductus, with ampulla at aorta and narrow point at the pulmonary end. Type B ''window'' ductus, with no ampulla and narrow end. Type C, ''tubular'' ductus, Type D ''complex'' ductus, with several narrowing, Type E ''elongated'' ductus, narrowing away from the anterior edge of the trachea. After careful assessment of PDA, PDA device selection was made considering size, type, length of PDA, post procedural patients were kept in post cath ward/HDU for observations and monitoring for any complications. Patients were called for follow up on day 1, day 7, 1 month,3 month and 6 month follow-up. Figure-1 illustrated the quasi experimental study design (patient selection, intervention done, follow up and analysis)

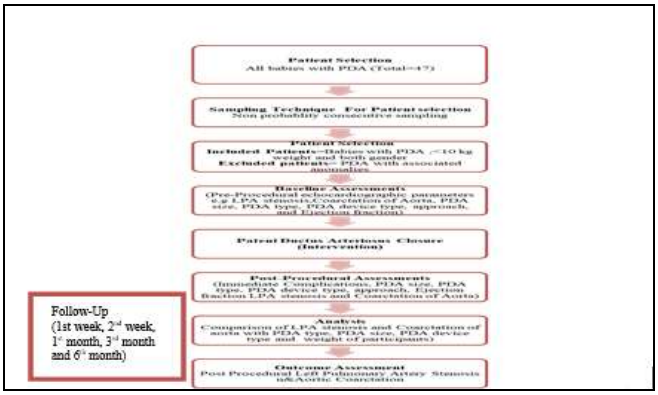

Figure-1: Flow chart depicting Quasi-experimental study design with single group approach

Data were entered and analyzed by using Statistical Package of Social Science SPSS version 27:00, mean and standard deviation were computed for quantitative variable like age. Normality of the continuous variable, age, was examined using the Shapiro-Wilk test, which confirmed that the data was normally distributed. Percentage and frequencies were

reported for qualitative variables like gender, weight, PDA size, PDA type, PDA device type, approach, LPA stenosis and Coarctation of Aorta. Chi-square test/Fischer Exact test was applied to find the association of PDA type, PDA size, PDA device type and weight of participants with coarctation of aorta and LPA stenosis. $p \leq 0.05$ was considered statistically significant.

RESULTS

A total of 47 patients underwent transcatheter closure of PDA during study period, out of which 18(38.3%) were males and 29(61.7%) were females with mean age 7.67±3.77 months. 17(36.2%) patients had less than 5 kg and 30(63.8%) patients had more than 5 kg weight (weight range:2.3kg-10kg). None of patient had pre-procedural LPA stenosis or coarctation of Aorta and all had good ventricular function. All cases were done under general anesthesia through femoral approach. Both femoral artery and venous approach were accessed in 46(97.8%) patients, and only femoral venous approach was accessed in 1(2.1%) patient. The post procedural LPA stenosis observed in 3(6.4%) out of 47 patients. Out of 13 patients with large PDAs,2(4.3%) patients developed Moderate LV dysfunction soon after device closure which was managed with inotropic support preload and afterload reducing agent 10(21.3%) patients developed mild LV dysfunction which was managed with diuretics and afterload reducing agent. Follow up at different intervals showed improvement in LV function in both groups. Table-I summarizes demographics, Pre procedural parameters, PDA device related characteristics and immediate complications of study participants.

PDA device selection was made considering the size and Morphology of Duct, Aorta and pulmonary artery. Type A PDA was the most common one (85.1%) in our study population. Majority patients with PDA type A had occlusion with ADO-I device and significant association was found between PDA type and device type (p=0.01)(Table-II).

All patients 3(100%) who developed LPA stenosis had <5kg weight with large Type C PDAs, out of which 2(66.7%) patients underwent closure of PDA with VSD device while in 1(33.3%) patient an ADO- II was used. Statistically significant association was observed between LPA stenosis and weight, PDA type, size and device type (p<0.05). Mild flow acceleration across descending aorta was observed in 6(50%) patients and Coarctation of Aorta observed in 6(50%) patients, out of total 12 patients, 9(75.0%) weighted less than 5 kg and 3(25.0%)weighted more than 5 kg. 8(66.7%) patients had large size PDA and 4(33.3%) had moderate sized PDA. Table V showed significant association of Coarctation of aorta with PDA type, PDA size , PDA Device type and weight of participants(p<0.05) as shown in Table III.

Figure-2 summarized the immediate post procedural complications. 2(4.3%) patients had device embolization in to descending aorta, device was retrieved percutaneously in 1(50.0%) patient, and 1(50.0%) device was retrieved surgically and PDA was ligated. One (2.1%) patient had excessive bleeding from prick site which was managed with pressure dressing and fresh frozen plasma transfusion. No death was reported in study period.

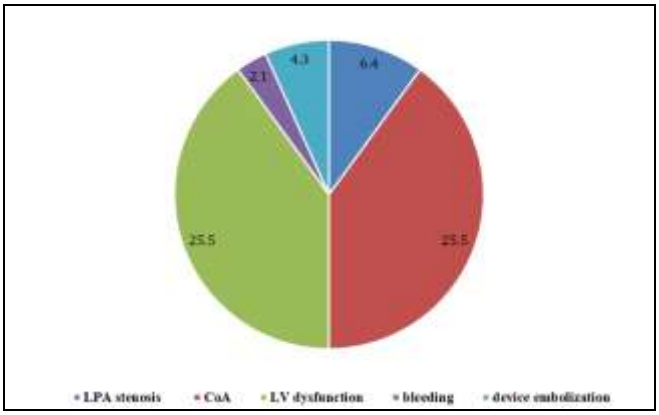

Figure-2 Frequency of Immediate Post procedural Complications (n=47)

DISCUSSION

This study, consistent with the previous studies demonstrated that Transcatheter closure of ductus arteriosus is a standard management with very low morbidity, however this procedure can be technically challenging in small infants particularly with large size PDA and associated with risk of Coarctation of aorta, LPA stenosis and LV dysfunction. LPA stenosis and aortic coarctation associated to devices are significant and special issues. Numerous series have discussed transcatheter closure of PDA in smaller infants.[11-14] In our study Type A PDA (krichenko classification) was the most common anatomical form 40(85.1%) which is consistent with local study in which Rafique *et al.*, reported 76.7% patients had Type A PDA. Current study, showed 12(25.5%) out of 47 patients developed Mild coarctation/flow acceleration in descending aorta following device closure, which improved with time and by 6 month follow up, none

Table-I Demographics, Pre Procedural Parameters and PDA Device Related Characteristics of Study Participants(n=47)

Variables		Mean±SD
Age(months)		7.67±3.77
		Frequency (%)
Weight(kg)	<5	17(36.2%)
	≥5	30(63.8%)
Gender	Male	18(38.3%)
	Female	29(61.7%)
Pre-procedural Parameters		
LPA stenosis	Normal	47(100%)
CoA	No	46(97.9%)
	Mild Flow acceleration	1(2.10%)
LVEF (%)	Good LV Function (EF>50%)	47(100%)
PDA types (krichenko classification)	A	40(85.1%)
	B	1(2.10%)
	C	6(12.8%)
PDA size	Small	13(27.7%)
	Moderate	21(44.7%)
	Large	13(27.7%)
PDA device type	ADO I	30(63.8%)
	Occlutech Reverse shank	7(14.9%)
	VSD device	8(17.0%)
	ADO II	2(4.30%)
Approach	RFA and RFV	41(87.2%)
	RFA and LFV	3(6.4%)
	RFV and LFA	2(4.3%)
	RFV only	1(2.1%)

Post-Operative Complications		**Follow up**				
		1st day	**1st week**	**1st month**	**3rd month**	**6th month**
		Frequency (%)				
LPA stenosis	Normal	44(93.6)	44(93.6)	44(93.6)	44(93.6)	47(100.0)
	Mild Flow acceleration	3(6.4)	3(6.4)	3(6.4)	3(6.4)	-
CoA	No	35(72.3)	35(74.5)	38(80.9)	39(83.0)	42(89.4)
	Mild Flow acceleration	6(12.8)	6(12.8)	6(12.8)	7(14.9)	5(10.6)
	Mild Coarctation	6(12.8)	6(12.8)	3(6.4)	1(2.1)	-
LVEF(%)	Good LV Function (EF>50%)	35(74.5)	42(89.4)	47(100.0)	47(100.0)	47(100.0)
	Mild LV Dysfunction (EF 40%-54%)	10(21.3)	5(10.6)	-	-	-
	Moderate LV dysfunction (EF 30%-39%)	2(4.3)	-	-	-	-

CoA= Coarctation; LPA=left pulmonary artery; LVEF= Left ventricular ejection fraction; PDA= Patent Ductus Arteriosus; ADO= Amplatzer Ductal Occluder; VSD= Ventricular Septal Defect

Table-II Association of PDA Type with PDA Device Type (n=47)

Variables		PDA Device Type [Frequency (%)]				
		ADO -I (n=30)	**Occlutech Reverse Shank (n=7)**	**VSD (n=8)**	**ADO II (n=2)**	***p*-value**
PDA Type	A	30(100)	6(85.7)	3(37.5)	1(50.0)	0.01
	B	0	1(14.3)	0	0	
	C	0	0	5(62.5)	1(50.0)	

PDA= Patent Ductus Arteriosus; ADO= Amplatzer Ductal Occluder; VSD= Ventricular Septal Defect

of patient had residual coarctation.[15] Sathanandam et al. have reported coarctation in 1% of patient using piccolo occluder device.[16] Backes *et al.,* reported successful Transcatheter closure of PDA in 46/52 infants having weight less than 4 kg. One patient (2.17%) had flow acceleration following device closure which resolved completely on follow up. Five individuals (10.8%) experienced minor LPA stenosis which resolved completely in three and two patients continued to have mild LPA stenosis.[17] Similarly in our study, 3(6.38%) out of 47 patients with large size window type PDA(krichenko type C) whose PDA was closed with devices other than ADO 1 developed LPA stenosis which was hemodynamically insignificant and resolved completely on 6 months follow up. Zahn *et al.,* showed successful device closure of PDA in 21 of 24 patients weighing less than 3 kg, one patient (14.28%) had LPA stenosis that was addressed with stenting however no coarctation observed.[18] However, our study reported 3(6.38%) patients had LPA stenosis

Table-III Comparison of LPA Stenosis and Coarctation of Aorta with PDA Type, PDA Size, PDA Device Type and Weight of Participants (n=47)

Variables		LPA stenosis		
		No (n=44)	Yes (n=03)	*p*-value
		Frequency (%)		
Weight(kg)	<5	14(31.8)	3(100.0)	0.04
	≥5	30(68.2)	0	
PDA Type	A	40(90.9)	0	0.02
	B	1(2.3)	0	
	C	3(6.8)	3(100.0)	
PDA Size	Small	13(29.5)	0	0.03
	Moderate	21(47.7)	0	
	Large	10(22.7)	3(100.0)	
PDA Device Type	ADO I	30(68.2)	0	0.01
	Occlutech Reverse Shank	7(15.9)	0	
	VSD	6(13.6)	2(66.7)	
	ADO II	1(2.3)	1(33.3)	
Variables		**Coarctation of Aorta**		
		No (n=35)	**Yes (n=12)**	***p*-value**
		Frequency (%)		
Weight(kg)	<5	8(22.9)	9(75.0)	0.04
	≥5	27(77.1)	3(25.0)	
PDA Type	A	33(94.3)	7(58.3)	0.01
	B	1(2.9)	0	
	C	1(2.9)	5(41.7)	
PDA Size	Small	13(37.1)	0	0.02
	Moderate	17(48.6)	4(33.3)	
	Large	5(14.3)	8(66.7)	
PDA Device Type	ADO I	27(77.1)	30(63.8)	0.03
	Occlutech Reverse Shank	4(11.4)	7(14.9)	
	VSD	3(8.6)	8(17.0)	
	ADO II	1(2.9)	2(4.3)	

out of 47 patients. In our study, 12(25.5%) out of 47 patients with large PDA developed LV dysfunction because of sudden decrease in preload to LV (frank starling mechanism), but was transient and improved with preload and after load reducing agents, only 2(16.6%) out of 12 patients who developed LV dysfunction needed inotropic support and that was too for just 24 hours. On 1 week follow up LV function normalized. Talat *et al.* reported LV systolic dysfunction in 21(24.4%) of 86 patients within 24 hours of occluder device closure, majority of which improved on 3 monthly follow up.[19] Bischoff *et al.* have demonstrated that there is a decrease in echocardiography markers of left ventricular systolic and diastolic function following percutaneous PDA closure in small infants.[20] In our study 2 (4.25%) devices were embolized, out of which one (50%) was retrieved percutaneously and one(50%) retrieved surgically which is comparable with study of Pepeta *et al.* showing successful closure of PDA in 58 out of 59 infants weighing less than 6 kg with Amplatzer Duct Occluder type two additional sizes (ADO II AS) with 3(5.17%) embolization of the device which were retrieved percutaneously.[21] Epcacan *et al.* demonstrates ballon assisted device release techniques in selected patients with high risk of device embolization or coarctaion and found it useful technique to minimize the risk of iatrogenic coarctation/device embolization.[22]

Our study is expected to provide insight into these potential possibilities acting as a framework for future large scale local studies improving patient care. Current findings will help pediatric patients receiving this intervention to achieve better outcomes and make better clinical decisions

This study depicted that transcatheter closure of PDA in small infants is a safe effective and low morbidity treatment strategy although associated with some complication, but this can be minimized in expert hands by proper patient selection, prior planning, appropriate device selection and close monitoring of complications, majority of which are transient and go away by themselves.

LIMITATIONS OF STUDY

This study was conducted at a single center, and we didn't include patients in whom PDA was associated with other Congenital Heart diseases, Furthermore different devices types and sizes availability was also an issue.

CONCLUSION

Transcatheter closure of the patent ductus arteriosus is a safe, effective, and relatively low-morbidity therapy, as demonstrated by this study. While aortic coarctation, LPA stenosis, and LV dysfunction are risks associated with large-size PDA in small infants, these complications eventually resolve on their own without requiring further therapy or interventions

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Authors' Contribution

Following authors have made substantial contributions to the manuscript:

AS & KA:, Study design & Concept, data interpretation, drafting the manuscript, approval of the final version to be published

MS & SR: Study design & Concept, data acquisition, critical review, approval of the final version to be published

SI: Data acquisition, data analysis, approval of the final version to be published

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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