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Anatomical Characteristics of Patent Ductus Arteriosus and Choice of Transcatheter Occluder Devices

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ABSTRACT

Objective: To determine the anatomical characteristics of Patent Ductus Arteriosus, choice of transcatheter occluder device and outcomes of Patent Ductus Arteriosus device closure.

Study Design: Analytical Cross-sectional study.

Place and Duration of Study: Paediatric Cardiology Department, Armed Forces Institute of Cardiology/National Institute of Heart Diseases, Rawalpindi Pakistan, from Jan-July 2023.

Methodology: A total of n=90 patients regardless of age and gender presenting with Patent Ductus Arteriosus, who underwent device closure were enrolled in this study by universal sampling. Data of the patients was collected on pre-designed proforma. Pearson's Chi-square test was applied to find association of morphological type of ductus and the weight of patient with the type of device used. *p*-value < 0.05 was considered as statistically significant.

Results: Among n=90 patients, 56(62.2%) were females and 34(37.8%) were males with median age of 1(IQR=0.6-4.25) years who underwent transcatheter device closure. The most common ductus types treated were Krichenko type-A 70(76.7%). Devices used were VSD device 15(16.7%), ADO-II 6(6.7%) and ADO-I device (conventional duct occluder) 69(76.7%). Median fluoroscopy time was 8.40(7.2-12.07) minutes. Statistically significant relationships were observed between Krichenko classification of Patent Ductus Arteriosus, weight of patient and type of device used to occlude the Patent Ductus Arteriosus (p<0.001). Success rate was 88(97.7%). Complications occurred in only 2(2.2%) patients in the form of device embolization. In 1(1.1%) patient, embolized device was retrieved while, the other patient was referred for surgical retrieval.

Conclusion: Transcatheter Patent Ductus Arteriosus device closure is a standard and safe procedure for closure of ductus with varied morphologies. However, a variety of devices were used to close the ductus with a high success and low morbidity and mortality rate.

Keywords: Device occlusion, Embolization, Krichenko classification, Patent ductus arteriosus, Transcatheter occluder device.

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INTRODUCTION

Patent Ductus Arteriosus (PDA) is a clinical condition in which the duct between proximal left pulmonary artery and the descending aorta fails to close after birth, that results in left-to-right shunt from the aorta to the pulmonary artery and increasing Left Ventricular (LV) preload.[1] It is one of the most common congenital heart defects.[2] with an incidence of 5%–10% of all congenital heart disease in infants which can be as high as 1 in 500 births in preterm babies.[3] Echocardiography is the diagnostic investigation of choice. It can present in many ways, however, the natural history depends upon its size.[4,5] Hemody-namically significant PDA leads to Left Ventricle (LV) volume overload and remodeling, finally resulting in severe complications, such as congestive heart failure, Eisenmenger syndrome, atrial arrhythmias and endarteritis.[1,5]

Untreated PDA can result in numerous cardiac and pulmonary problems. Transcatheter closure of PDA is the established method for closing the majority of PDAs.[6] Pulmonary vascular disease and increased pulmonary flow are both prevented by this treatment. Endarteritis and endocarditis are both reduced with the closure of defect. Closure time depends upon both the severity of symptoms and the size of the defect.[7] Asym-ptomatic newborns are managed conservatively and monitored for spontaneous closure.4 Patients with large PDA presenting with congestive heart failure require immediate attention for the closure of the defect.[5] When a percutaneous method is not feasible, such as in the case of congestive heart failure in new-borns or pulmonary hypertension, surgical closure remains the only treatment option.[2]

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PDA closure is now the preferred technique for PDA closure in infants and is one of the safest interventional cardiac procedures with a 95% success rate. Several devices have been authorized for PDA closure which are safe and successful.[8] Literature has reported success rate of 97% to 99% after PDA closure via ranscatheter route[6] with lower morbidity and mortality (0.2%) in patients undergoing ranscatheter PDA occlusion.[9] According to Khan *et al.*, in 51 consecutive cases over a year, PDA device closure was successful in 100% of cases.[6] The morphology of a PDA is crucial in determining the appropriate device for occ-lusion. Tubular PDAs present a significant difficulty for interventional cardiologists. The Amplatzer Duct Occluder-II (ADO-II) device was designed to address these issues.[10] Risks associated with PDA device closure (including device embolization, residual leak, iatrogenic coarctation, left pulmonary artery (LPA) stenosis, thromboembolism, cardiac perforations and vascular injuries) are minimal and depends upon the operator as well as the cardiac facility in which the procedure is done. Limited studies have been published in Pakistan regarding type of device used based upon anatomical classification. Our objective was to share our experience of a tertiary paediatric cardiac care center in Pakistan regarding the PDA closure, mor-phological types of ductus closed, choice of device depending upon morphology, procedural details and associated complications.

METHODOLOGY

This Analytical Cross-sectional study was conducted at Paediatric Department of AFIC/NIHD, Rawalpindi, Pakistan. Data was collected from January to July 2023 after the ethical approval from Institutional Ethical Review Board (Ltr. # 9/2/R&D/2024/295).

Sample size was calculated using the WHO sample size calculator, considering 6% prevalence of Patent Ductus Arteriosus (PDA) [11], 95% confidence level and 5% margin of error. The calculated sample size was found to be n=87. However, data was collected from total n=90 patients using universal sampling.

Inclusion criteria: Patients regardless of age and gender presenting with PDA, who underwent device closure were enrolled in this study.

Exclusion criteria: Patients who had other congenital heart diseases with duct dependent pulmonary circulation and severe pulmonary hypertension were excluded.

All patients underwent detailed pre-procedure assessment including history, detailed physical examination, ECG, Chest X-ray, complete blood count, quantitative CRP and detailed trans thoracic echo-cardiography (2-D, color and continuous wave Doppler) to assess size of the PDA, left ventricular dimensions, function and pulmonary artery pressures. Diameter of narrowest portion of ductus was recorded. Left ventricular ejection fraction was quantified. After getting an informed written consent, patient was taken to Cath lab. Procedure was performed under general or local anesthesia depending upon patient's age and ability to cooperate. Vascular access was obtained in right femoral artery and vein using anatomic landmarks. Aortogram was performed in true lateral projection to determine size (diameter at aortic end, pulmonary end and length of PDA) shape and narrowest diameter of PDA. Krichenko *et al*. 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, with narrowing away from the anterior edge of the trachea.[11] Ductus was classified morphologically as one of the Types A to E or F (having a tortuous morphology that does not fit in the Krichenko classi-fication). Duct was then crossed with Judkin's right heart catheter over 0.035 exchange length 260 cm wire antegradely from pulmonary side into descending aorta and exchanged with a delivery sheath. Device was selected appropriate to the size and morphology of ductus on angiogram (correlation of the echocardiographic size of the PDA with the angio-graphic measurement was done to avoid under-sizing the device when PDA spasm occurs during the catheterization) and was passed through delivery sheath into descending aorta and aortic end was deployed. Entire assembly consisting of device and sheath were pulled back as a single unit and remaining device was uncovered within the duct making sure that pulmonary end of the device was flared appropriately inside the pulmonary artery. Post deployment aorto-gram was performed to confirm device position, residual leak or any obstruction. Device was released after confirming acceptable deployment. After the procedure, monitoring of

patient was done including vital signs, prick site and peripheral pulses.

Data was analyzed using Statistical Package for the Social Sciences version-28.00. Continuous variables were expressed as Mean±SD. Categorical variables were expressed as frequency (%). Chi-square test and Fischer Exact test were applied to find association between categorical variables. $p<0.05$ was considered as statistically significant.

RESULTS

In this study, n=90 patients were included. Out of these, 34(37.8%) were males and 56(62.2%) were females. Age of the patients ranged from 01 month to 32 years with median age of 1(IQR=0.6-4.25) years. Median weight of the patients was 7.5(IQR=5.5-13.25) kg (Table-1).

Mean duration of hospital stay was 22.76±2.54 hours. Mean fluoroscopy time was 8.4(IQR=7.2-12.07) minutes The most common ductus types treated were Krichenko type-A 70(76.7%). VSD devices (MFO, Amplatzer muscular VSD Occluder) to occlude PDA was used in 15(16.7%) patients, Amplatzer duct Occluder – II was used in only 6(6.7%) patients and remaining 69(76.7%) patients' underwent device closure with conventional duct occluder (Amplatzer duct Occluder-I or similar design from different manufacturers Occlutech duct occluder, Lifetech duct occluder, SHSMA duct occluder). Descriptive statistics are summarized in Table-I.

The PDA's morphology plays a critical role in selecting the right device for occlusion. Figure-1 showed type of PDA devices used to obstruct the Ductal Arteriosus.

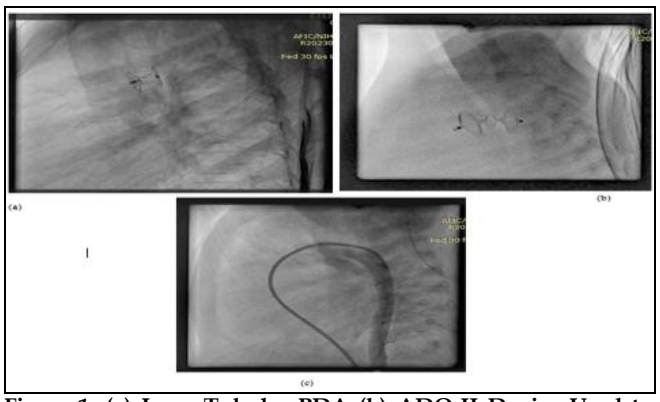

Figure-1: (a) Long Tubular PDA (b) ADO-II Device Used to Occlude PDA(c) VSD Device Used to Occlude PDA

Echocardiography done before discharge, confirmed that all devices were in place. The overall success rate was observed in 88(97.7%) patients. Complications occurred in 2(2.2%) patients in the form of device embolization. In 1(1.1%) patient, embolized device was retrieved in the Cath lab while, in other patient it could not be retrieved and was referred for surgical retrieval and ligation of the ductus. No substantial gradient or obstruction was found in the

Table-I: Demographic and Clinical Parameters of Study Participants (n=90)

Study Variables		Frequency (%)
Age (years) {median (IQR)}		1(0.6-4.25)
Hospital stay (hours) (mean ± SD)		22.76±2.54
Fluoroscopy time (minutes) {median (IQR)}		8.4(7.2-12.07)
Weight (kg) {median (IQR)}		7.5(5.5-13.25)
Gender	Male	34(37.8)
	Female	56(62.2)
Patient condition	Stable	89(98.9)
	Critical	1(1.1)
Mode of anesthesia	General	86(95.6)
	Local	4(4.4)
Access	Venous only	2(2.2)
	Arterial only	1(1.1)
	Both arterial and venous	87(96.7)
Site of arterial puncture	RFA	70(77.8)
	LFA	18(20.0)
	None	2(2.2)
Site of venous puncture	RFV	82(91.1)
	LFV	7(7.8)
	None	1(1.1)
Name of device Manufacturer	SHASMA	29(32.2)
	Occlutech	4(4.4)
	Amplatzer	8(8.9)
	Lifetech MFO	5(5.6)
	Lifetech PDA	44(48.9)
Krichenko Classification	A	70(76.7)
	B	4(4.4)
	C	9(10.)
	E	5(5.6)
	F	2(2.2)
Type of Device used	ADO I	69(76.7)
	VSD	15(16.7)
	ADO II	6(6.7)
Echo size	Tiny	1(1.1)
	Small	46(51.1)
	Moderate	37(41.1)
	Large	6(6.7)
Complications	Absence of pulse after 2 hour	12(13.3)
	Device embolization	2(2.2)
Success rate		88(97.7)

RFA: Right femoral artery; LFA: Left femoral artery; LFV: Left femoral vein; RFV: Right femoral Vein VSD: Ventricular Septal Defect; MFO: Multifunctional occluder device; SHSMA Shanghai Shape Memory Alloy; ADO: Amplatzer Ductal Occluder;PDA:Patent Ductus Arteriosus

Table–II: Comparison of Krichenko Classification with Type of Devices and Weight of Study Participants (n=90)

Variables		Krichenko Classification					*p*-value
		Type-A n=70 Frequency (%)	Type-B n=4 Frequency (%)	Type-C n=9 Frequency (%)	Type-E n=5 Frequency (%)	Type-F n=2 Frequency (%)	
Device used	ADO-I	66(94.3)	1(25.0)	2(22.2)	--	--	<0.001
	VSD	4(5.7)	3(75.0)	4(44.4)	4(80.0)	--	
	ADO-II	--	--	3(33.3)	1(20.0)	2(100)	
Weight (kg)	≤5	12 (17.1)	--	6(66.7)	--	2(100)	<0.001
	>5	58(82.9)	4(100)	3(33.3)	5(100)	--	

**VSD: Ventricular Septal Defect; ADO: Amplatzer Ductal Occluder*

descending aorta or left pulmonary artery during the final follow-up of all patients.

ADO-I device was used in 66(94.3%) patients with PDA type-A while Type- C was occluded by VSD device in 4(44.4%) patients. Moreover, 6(6.67%) patients underwent closure with ADO-II device, out of which 2(33.3%) were Type-F and 3(50.0%) were Type-C PDAs. Statistically significant relationship was observed between anatomical type (Krichenko classification) of PDA with type of device used and weight of study participants (p<0.001) (Table-II.).

Table-III showed the significant association of type of devices with weight of the patients (p=0.04). ADO-I device was used in 56(81.2%) patients with weight >5 kg while ADO-II device was implanted in 2(33.3%).

Table–III: Comparison of Type of Devices Used and Weight of Study Participants (n=90)

Weight(kg)	Device used			*p*- value
	ADO I n=69 Frequency (%)	VSD n=15 Frequency (%)	ADO II n=6 Frequency (%)	
≤5 Kg	13 (18.8)	3(20.0)	4(66.6)	0.04
>5 Kg	56(81.2)	12(80.0)	2 (33.3)	

**VSD: Ventricular Septal Defect; ADO: Amplatzer Ductal Occluder*

DISCUSSION

PDA is a common congenital heart disease with an incidence of 5%-10% of all congenital heart defects.[2] The success rate after PDA device closure depends on the PDA anatomy and appropriate device size selection.[6] Our study reported a success rate of 88(97.7%) with 2(2.2%) complication rate. Aortic angiogram revealed that the most common ductus type treated was Krichenko type-A 70(76.7%), mean duration of hospital stay was 22.76±2.54 hours. Conventional duct occluder device by various manufacturers was most commonly used 69(76.7%) among the study population, followed by VSD 15(16.7%) and ADO-II 6(6.7%) devices. Statistically significant relationship was observed between anatomical type (Krichenko classification) of PDA with type of device used (p<0.001) and weight of patients (p<0.001). In addition to that, significant results were observed between devices used and weight of the patients (p=0.04).

Most of the cases in our study were females 56(62.2%) which outnumbered males as reported in previous literature. Khan *et al*., reported the majority of females with PDA (64.7%) in their study.6 Likewise, Mehmmood et al., reported male to female ratio of 1:2 in a Pakistani population with PDA.12 The mean hospital stay after PDA device closure reported by our study was 22.76±2.54 hours comparable to a local study by Khan *et al*., that reported 22 hours of hospital stay.6 However Zulqarnain *et al*., reported a relatively prolonged hospital stay which was 37.9 hours.[13]

Our data revealed that 6(6.7%) patients underwent closure with ADO-II device, out of which 2(33.3%) were Type-F and 3(50.0%) were Type-C PDAs, with 97.7% success rate. Sultan *et al*., reported success rate of 98.2%.[9] A recent article by Maksymenko *et al*., reported an overall success rate of 97.2%.[16] Yıldız K *et al*, reported a success rate of 94.2% after transcatheter PDA closure, which is consistent with previous studies14,17, and a success rate of 94.6% was reported by a study from Tukey.[18] Yıldız *et al*., suggested that the ADO devices provide an effective and reliable method for transcatheter PDA closure having a success rate of 100%.[14] In a recent study from Turkey by Osman *et al*., ADO II achieved a success rate of 98.7%, which was higher than other devices.[15] Similarly, according to El-Saiedi *et al*., tubular PDAs with a diameter <3mm (n=5) were closed by ADO-II type, the VSD device was used for 5 patients with type C ducts. In patients with type C PDA, 76% were able to achieve complete closure, which rose to 96% after

one month. In contrast, patients with other types of PDA had a rate of 74.4%, which rose to 95.3% after one month.[10]

Device embolisation is a significant complication of the surgery. Embolisation commonly takes place in the pulmonary artery, although it can potentially become dislodged and enter the systemic circulation. The occurrence of this complication is uncommon and was observed during the initial use of PDA device closure, primarily due to inadequate sizing or abnormal shape of the duct. The rate of device embolisation varied in different studies, with a maximum rate of 16% reported in early experiences. However, as more experience was gained, a greater variety of devices became available, and a better understanding of the various duct morphologies was achieved, the rate of device embolisation decreased to zero.8 We observed device embolization in 2(2.2%) patients. In one of the patients, only venous access was being used resulting in poor imaging landmarks on deployment of device as aortogram could not be done while in second patient, actual duct size was underestimated likely due to ductal spasm. Retrieval of embolized device in the catheterization lab was done in 1(1.1%) patient while, the other patient was sent for surgical retrieval. Yıldız *et al*., reported that device embolisation occurred in 1.4% of the patients. One of these resulted from catheter manipulation following device implantation, whereas the other two cases happened inevitably.14 Backs *et al*., in a meta-analysis reported 2.6% rate of PDA device embolization.[19]

A recent study by Nour *et al*., reported 5% complication rate and major complications were observed in 2% of patients (6 individuals), while minor complications were observed in 3% of patients (9 individuals). Major complications included device embolisation in 4 patients and significant hemolysis requiring blood transfusion in 2 patients. Minor vascular complications, such as hematoma and arterial venous fistula, were observed in 3 patients. Benign arrhythmia was observed in 3 patients, and minimal device encroachment either on the left pulmonary artery (LPA) or descending aorta was observed in 3 patients.8 However, some studies have reported higher complications, El-Saiedi *et al*., reported 9% complications rate, major complications were reported in 2.2% (n=24) patients including device embolisation (n=11) or malposition (n=13). The remaining complications were minor, such as minor bleeding, anaesthesia or airway-related issues, arrhythmia, allergic reactions, and medication errors.10 Following percutaneous PDA closure, there is a potential for the devices to extend into the aorta or cause narrowing in the left pulmonary artery. Yildiz *et al*. documented the presence of a little narrowing in the left pulmonary artery in one patient. Upon conducting the final examination of all patients, no instances of blockage or substantial gradient were observed in the descending aorta or left pulmonary artery.[14] Similar to their findings, our study reported no stenosis of left pulmonary artery. Stenosis has been documented during transcatheter PDA closure, particularly in individuals weighing less than 4 kg and with a higher minimum diameter of the PDA. Although a slightly lower level of stenosis/flow disruption may be inevitable, a notable stenosis was uncommon and was observed in just six cases (0.8%), with four cases classified as moderate and two as severe stenosis.[20]

Some authors have reported residual shunt in their study. Yıldız *et al*., reported the decline in rate of residual shunt from 1.8% to 0.1% during the first-year follow-up.14 On contrary, no case of residual shunt was observed in our study.

Previous studies have reported higher incidence of complication in the coil group as compared to device (3% vs 2%;$p > 0.05$) and reported that higher event rates were more likely to occur with younger and low body weight patients (10% vs 2%;$p < 0.001$).[8,17] In our study, we used devices in all the patients which could be the reason of a lower complication rate. The rate of embolisation can be reduced by the persistent endeavours of researchers to enhance the effectiveness and safety of device deployment. A multivariate study revealed that low body weight, raised pulmonary artery pressure (hypertensive PDA), procedural time, fluoroscopy time, and device size are all independent risk factors associated with a greater likelihood of complications.[8]

LIMITATIONS OF STUDY

This study was limited to single-center with relatively small sample size. Scarce resources and insufficient access to diverse devices on shelf was another constraint. Further studies are required to validate our findings to establish the relationship of PDA anatomy and choice of device

CONCLUSION

PDA transcatheter closure for occlusion of ductus of varied morphologies with a variety of devices is safe and effective procedure, and has high success rate with lower morbidity and mortality.

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Conflict of Interest: None

Authors' Contribution

Following authors have made substantial contributions to the manuscript:

SR & SI: Concept, drafting the manuscript, critical review, approval of the final version to be published

KA & AM: Study design, critical review, approval of the final version to be published

AA & AW: Data acquisition, data analysis, data interpretation, approval of the final version to be published

AS & JK: Data acquisition, critical review, 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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