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Transcatheter Patent Ductus Arteriosus (PDA) Device Closure: Comparative Outcomes Between Conventional Versus Single Vessel Approach

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ABSTRACT

Objective: To determine post procedural outcomes, complications, and effectiveness of transcatheter PDA closure using single-vessel and Conventional Arteriovenous access in pediatric patients.

Study Design: Analytical Cross-Sectional.

Place and Duration of Study: Armed Forces Institute of Cardiology/National Institute of Heart Diseases (AFIC/NIHD), Rawalpindi, Pakistan; January 2024- December 2025.

Methodology: The study included 269 children with isolated PDA (<12 years, <30 kg) were enrolled. Data were collected retrospectively and prospectively from patients of transcatheter PDA closure. Children with other associated congenital cardiac anomalies, pulmonary hypertension, or PDA-dependent cardiac defects were excluded from the study. Participants were divided into two groups; A and B, where Group A had single vessels and Group B had the conventional arteriovenous approach. Device closures were performed and all metrics pertaining to the procedures, the complications, and the outcomes post procedure were documented.

Results: Transcatheter PDA closure was performed in 269 children using a single vessel approach (Simple Vessel Approach (n=145) and conventional arteriovenous approach (n=124). Baseline age, weight, and PDA size were similar across groups. Fluoroscopy time and contrast volume did not differ significantly. Compression time was longest with femoral arterial access and shortest with the arteriovenous approach, and anticoagulation strategies varied by access route (p<0.001). Most patients were discharged on the first post-procedure day. In-hospital mortality was low (1.5%), and the majority had no complications.

Conclusion: Single vessel approach appears safe and feasible alternatives to conventional arteriovenous access for pediatric PDA closure, with low in-hospital complication rates. Access route selection was significantly associated with device choice.

Keywords: Catheterization, Complications, Femoral Vein, Femoral Artery, Patent Ductus Arteriosus, Pediatric, Transcatheter Device Closure.

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INTRODUCTION

Over 4.18 million children under the age of five had CHD worldwide, a 3.4% rise from 1990. Between 1990 and 2021, DALYs fell by 55.7% and CHD-associated mortality by 56.2%.[1] It accounts for approximately 5–10% of all congenital heart diseases, particularly in premature infants.[2] A consistent gender difference has also been observed, with PDA occurring twice as often in girls as in boys.[2]

In South Asia, including Pakistan, the burden of CHD presenting during infancy is considerable. Asia as a whole has reported a higher CHD incidence (~9.3 per 1,000 live births) compared with global averages, with PDA among the commonly observed congenital lesions in pediatric cohorts.[3] In Pakistan, the burden of congenital heart disease is substantial; a large retrospective study from a tertiary care center in Karachi reported structural cardiac abnormalities in 43.5% of children undergoing echocardiography, with acyanotic lesions comprising nearly 80% of diagnosed defects, underscoring the significant clinical workload and public health impact of CHD in the local population.[4] Subsequent decades have seen continued refinement in transcatheter options, ranging from coil embolization to the development of biodegradable occlusion devices.[5]

Standard transcatheter PDA closures usually employ a femoral artery approach for anatomical delineation and device positioning, while deployment of the device is done through the venous route.[6] However, In infants and young children, concerns associated with hospital stays, as well as prolonged fluoroscopy exposure, increased contrast volume, and extended hospital stays, are particularly relevant.[6,7] To maintain procedural accuracy while minimizing complications, other strategies employing venous only

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or modified arterial techniques have been investigated.[6]

Despite these advancements, limited data exist on comparing procedural challenges, outcomes, and complication profiles between single vessel and conventional arteriovenous access in pediatric PDA device closure. This gap highlights the need for focused evaluation. Therefore, the present study aimed to assess the procedural difficulties, complications, and overall effectiveness of transcatheter PDA closure performed via Single vessel approach in comparison with the conventional arteriovenous approach in the pediatric population.

METHODOLOGY

This study was an analytical cross-sectional study of PDA device closure in pediatric population in AFIC/NIHD, Rawalpindi, Pakistan, from Jan 2024 to December 2025.The patients were selected according to non-probability consecutive sampling. Ethical approval was granted by the institutional ethical review board (AFIC/ IERB Letter No: 9/2/R&D/2025/350) on 30th April 2025.

Sample size was calculated using WHO sample size calculator, according to 0.4% prevalence of PDA[7] the minimum calculated sample size was 7 patients using a 95% confidence level and a 5 % margin of error. The data was collected from 269 patients.

Inclusion Criteria: Children of either gender presented with isolated patent ductus arteriosus (PDA), weighing less than 30 kg, and aged below 12 years were eligible for inclusion

Exclusion Criteria: Patients were excluded if they had PDA associated with other congenital cardiac lesions, evidence of pulmonary hypertension, or PDA-dependent cardiac defects.

Eligible patients were admitted a day before the procedure, and routine laboratory investigations, including complete blood count, renal and liver function tests, hepatitis B and C serology, and chest X-ray, were performed. Patients were divided into two groups: Group A underwent femoral vein access (FVA), and femoral artery access (FAA), and Group B had both femoral artery and vein cannulated for conventional arteriovenous access (CAA). Heparin (100 IU/kg) was administered at the time of the procedure. Baseline angiograms were obtained in LAO 90° and RAO 30° views to assess PDA morphology and size. Pulmonary artery pressures were measured in patients with pulmonary hypertension, and device closure was performed in patients with Qp/Qs >2:1. Aortic angiograms were used as landmarks for device selection in Groups B, while in Group A, the femoral vein alone was used for baseline aortogram and device deployment. Device placement, residual shunt (residual leakage), complete occlusion, femoral arterial occlusion, hematoma formation, and device dislodgment were monitored during and after the procedure. Procedure time and fluoroscopy time were recorded as operational outcome measures.

After the procedure, demographic and clinical data were documented along with echocardiographic assessment of PDA type and size, and baseline left ventricular function.

PDA closure, detect residual leak, device dislodgment, and left ventricular function Complications such as femoral artery occlusion, bleeding, hematoma, sepsis, pleural or pericardial effusion, pulmonary edema, device embolization, residual shunt, left ventricular dysfunction, and mortality were recorded. PDA devices were categorized by size as small (3.5/5 mm, 6/4 mm), medium (8/6 mm, 10/8 mm), and large (≥10/12 mm), based on the device's aortic and pulmonary diameters for each patient. Krichecko angiographically classified duct in 3 types, type A conical ductus with ampulla at aorta and a narrow point at pulmonary end. Type B window ductus with no ampulla and narrow end. Type C tubular ductus.[8]

For statistical analysis all continuous variables were assessed for normality using the Shapiro-Wilk test. Continuous variables were reported as median and interquartile range (IQR) as they were not normally distributed; age, height, PDA size, fluoroscopy time, contrast volume, venous sheath, arterial sheath, delivery sheath, compression time. Weight was normally distributed variable it was reported in Mean±SD. To evaluate the effectiveness of the access routes (Groups A, B, and C), the Kruskal-Wallis test was applied for comparisons between the access groups and continuous dependent variables. Categorical variables, including mortality, discharge status, and complications, were compared across access groups using the Chi-square test. A p-value ≤0.05 was considered statistically significant.

RESULTS

A total of 269 pediatric patients underwent PDA device closure. Of these, 27(10.0%) had femoral venous single-vessel access, 118(43.9%) had femoral arterial

single-vessel access, and 124(46.1%) underwent the conventional arteriovenous approach. Overall, females comprised 171(63.6%) of the cohort, while males accounted for 98(36.4%).

The mean body weight was approximately 14.5±5 kg across groups, and the median age ranged from 5.7 to 7.1 years. Median PDA size by angiography ranged from 4.0 to 4.5 mm. Baseline demographic and anatomical variables did not differ significantly among the three access routes (p>0.05).

Table-I: Baseline Characteristics of Participants by Access Route (n=269)

Characteristic		Single Vessel approach		Conventional Arteriovenous Approach (n=124)
		Femoral Venous Approach (n=27)	Femoral Arterial Approach (n=118)	
		Frequency (%)		
Gender	Male	9(33.3%)	34(28.8%)	55(44.4%)
	Female	18(63.7%)	84(71.2%)	69(55.6%)
		Mean±SD		
Weight (kg)		14.66±5.68	14.43±4.50	14.66 ± 5.39
		Median (IQR)		
Age (years)		5.70 (3.00 – 9.10)	7.00 (3.80 – 9.00)	7.10 (4.00 – 9.3)
Height (cm)		105.00 (98.00 – 108.00)	104.00 (87.00 – 109.00)	104.00 (94.00 – 109.00)
PDA size (Angio)		4.00 (3.00-5.00)	4.50 (3.50-7.00)	4.00 (3.00- 6.00)
PDA size (echo)		3.00 (2.00-6.00)	4.00 (3.00-6.00)	4.00 (3.00-6.00)

PDA; Patent Ductus Arteriosus

Compression time differed significantly across access techniques, being lowest with the conventional arteriovenous approach and highest with the femoral arterial approach (p<0.001). Heparin administration and streptokinase use showed highly significant differences between these groups (both p<0.001), with heparin being mostly used in the conventional approach and streptokinase used mainly in the simple venous and arterial approaches. The pulse status at the end of the procedure showed significant differences (p<0.001), with absent pulses being recorded almost exclusively in the femoral artery approach group. Krichenko duct morphology showed a significant association with the chosen access route (p<0.001), as did the distribution of device companies used (p<0.001) as shown in Table-II.

All other variables-including fluoroscopy time, contrast volume, sheath sizes, delivery sheath size, PDA catheter type, device size category, mode of anesthesia, and use of VSD devices-did not demonstrate statistically significant differences between the three approaches.

Discharge patterns were generally similar across all access routes. Most patients were discharged the day after the procedure, with only one discharge on the procedure day in the venous group and two second-day discharges in the arterial group. In-hospital mortality was low (overall 1.5%), occurring only in the venous (3.7%) and arterial (2.5%) groups, with no deaths in the both-access group. Discharge timing was largely similar across groups, with most patients discharged the next day (p=0.047). In-hospital mortality was low, occurring only in the venous and arterial groups (p=0.085). Procedural complications were uncommon, with majority of patients having no complications (p=0.016). Individual complications, including residual leaks, SVT, bradycardia, and minor procedural events, occurred at low frequencies across all groups, as shown in Table-III.

DISCUSSION

In this study of 269 pediatric patients, PDA device closure via single vessel; venous or femoral arterial or conventional arteriovenous access was highly successful with low complications and mortality (1.5%). While most procedural metrics were similar, differences in compression time, anticoagulation use, pulse status, and device selection were noted, potentially affecting post-procedure care and resource utilization.

The recent advances have mentioned the utility of the femoral vein only for PDA closure in small children as an alternate to standard approach, as reported by Uppal *et al.*, who compared venous-only versus standard arterial and venous approaches in 135 children and reported no major complications in the venous group, with vascular complications limited to 7.2% in the standard group.[6] Similarly, our study found the venous-only route to be safe, with minimal vascular complications, supporting the feasibility of a less invasive approach. The subsequent evaluation for vascular thrombosis, bleeding, and use of thrombolytics priduces morbidity in young children.[1,3] Zou *et al.*, reported in 2021 that CVA / SVA / FAA can be carried out in children safely with shorter procedure time in FAA and SVA as compared to CAA.[9] Similarly, the difference was noticed in terms of size estimation and PDA length which depended upon aortic angiogram. FAA was successful in cases of ADO II device which required smaller delivery sheath and

wire supports as well as tubular ducts were successfully occluded.

Present study revealed that the Krichenko classification of PDA morphology showed significant effect on outcome across the conventional vs non-conventional routes. The effect on femoral artery flow after procedure was higher in FAA group and subsequent use of thrombolytic agents. The selection

Table-II: Procedural Metrics of Participants Across Access Routes (n=269)

Variable		Single Vessel approach		Conventional Arteriovenous Approach (n=124)	*p*-value
		Femoral Venous Approach (n=27)	Femoral Arterial Approach (n=118)		
		Median (IQR)			
Fluoroscopy time (min)		8.05(6.00–14.10)	7.32 (5.30-11.55)	7.48 (5.25-11.48)	0.84
Contrast volume (mL)		35.00(20.00-50.00)	30.00 (20.00-50.00)	40.00 (29.50-50.00)	0.15
Venous sheath (F)		5.00(5.00-5.00)	5.00 (5.00-5.00)	5.00 (5.00-5.00)	0.50
Arterial sheath (F)		-	4.00 (4.00-5.00)	4.00 (4.00-4.00)	0.42
Delivery sheath (F)		6.00(5.00-7.00)	6.00 (6.00-7.00)	6.00 (6.00-7.00)	0.22
Compression time (min)		7(6-10)	10 (10-10)	6 (5-8)	<0.001
		Frequency (%)			
PDA catheter	Pigtail	0(0%)	10(8.4%)	-	1.00
	JR	4(14.8%)	77(65.2%)	-	
PDA device size *	Small	8(29.6%)	17(14.4%)	12(9.7%)	0.37
	Medium	15(55.6%)	77(65.2%)	75(60.5%)	
	Large	2(7.40%)	20(16.95%)	29(23.4%)	
Heparin administration	Given	15(55.6%)	18(16.9%)	109(87.9%)	<0.001
	Not Given	12(44.4%)	100(84.07%)	15(12.1%)	
Streptokinase administration	Given	7(25.9%)	95(80.5%)	0(0.0%)	
	Not Given	20(74.1%)	23(19.5%)	124(100.0%)	<0.001
Mode of anesthesia	General anaesthesia	25(92.5%)	108(91.5%)	111(89.51%)	0.73
	Local anaesthesia	1(3.7%)	10(8.5%)	12(9.7%)	
Pulse	Not applicable	5(18.5%)	11(9.3%)	0(0.0%)	<0.001
	Absent	2(7.4%)	85(72.0%)	0(0.0%)	
	Present	20(74.1%)	22(18.6%)	123(100.0%)	
VSD device for PDA	VSD device used for PDA	2(7.4%)	15(12.7%)	9(7.3%)	0.45
	PDA device used for PDA	24(88.9%)	102(86.4%)	110(88.7%)	
	PDA device used for VSD	0(0.0%)	1(0.8%)	0(0.0%)	
Krichenko classification	Type A	16(59.3%)	108(91.5%)	83(66.9%)	<0.001
	Type B	7(25.9%)	8(6.8%)	28(22.9%)	
	Type C	3(11.9%)	1(0.9%)	5(4.3%)	
PDA device company	Shashma	8(29.6%)	39(33.1%)	29(23.4%)	<0.001
	Cardiofix	2(7.4%)	2(1.7%)	14(11.3%)	
	Occlutech	6(22.2%)	7(5.9%)	10(8.1%)	
	AGA	6(22.2%)	29(24.6%)	20(16.3%)	
	Cocoon	0(0.0%)	0(0.0%)	9(7.3%)	
	MFO	4(14.8%)	14(11.9%)	12(9.7%)	
	LifeTech	1(3.7%)	27(22.9%)	29(23.6%)	

**Device sizes were grouped as Small (3.5/5, 6/4), Medium (8/6, 10/8), and Large (≥10/12),*
PDA; Patent Ductus Arteriosus, VSD; Ventricular Septal Defect

Table-III: Post-Procedural Outcomes of Participants by Access Route (n=269)

Outcome		Single Vessel approach		Conventional Arteriovenous Approach (n=124)	*p*-value
		Femoral Venous Approach (n=27)	Femoral Arterial Approach (n=118)		
		N (%)			
Discharge day	On procedure day	1(3.7%)	0(0.0%)	0(0.0%)	0.04
	1st post op day	26(96.3%)	115(98.3%)	124(100%)	
	2nd post op day	0(0.0%)	2(1.7%)	0(0.0%)	
Mortality (in hospital)		1(3.7%)	3(2.5%)	0(0.0%)	0.08
Complications	No complications	23(85.2%)	105(89.0%)	114(91.9%)	0.01
	VT during cath	0(0.0%)	0(0.0%)	2(1.6%)	
	Bradycardia during cath	0(0.0%)	1(0.8%)	2(1.6%)	
	Desaturation during cath	0(0.0%)	4(3.4%)	0(0.0%)	
	Very small PDA	2(7.4%)	2(1.7%)	1(0.8%)	
	ST-segment sag during cath	1(3.7%)	0(0.0%)	0(0.0%)	
	VPCs	0(0.0%)	0(0.0%)	1(0.8%)	
	Dislodged/retrieved, external iliac torn, laparotomy, sepsis, ICH	0(0.0%)	0(0.0%)	1(0.8%)	
	Blood transfusion after cath	0(0.0%)	0(0.0%)	1(0.8%)	
	Tamponade	0(0.0%)	1(0.8%)	0(0.0%)	
	Residual leak	0(0.0%)	3(2.5%)	2(1.6%)	

*Significant at $p<0.5$

Rare procedural complications, including device dislodgement/retrieval, external iliac artery tear, laparotomy, sepsis, and intracranial hemorrhage (ICH), were grouped together due to low individual frequencies. Percentages represent the proportion of patients within each access group experiencing any of these events

of PDA device company also showed significant impact on outcome as Shashma and AGA devices were mostly used in CAA group and LifeTech and MFO devices used in FAA group. This effect was due to shape memory of individual devices. Liu *et al*., evaluated 686 children using a single-venous approach under echocardiography and angiography, achieving successful closure in the majority and no serious complications.[10] Consistent with these results, our study demonstrated that venous-only or simplified approaches are effective across a broad pediatric age and weight range, with low complication rates.

Garg *et al*., in 2021 reported,[11] the usage of Piccolo ADO II devices in infants that is done solely by SVA and depends largely on echocardiographic images and MR angiography images for device placement which was a limitation in the study. As comparison, our study depended on echocardiography and angiography for size, morphology, and device selection during the intervention. The significant effect on procedure time was noted as less time was required in FAA and SVA groups. Kanwal *et al*.[12] reported favorable safety and efficacy in 212 children undergoing venous-only PDA closure confirming that this approach remains reliable even in older pediatric populations, which aligns with our findings of similar baseline characteristics and procedural outcomes across groups.

A study by Murshid and Elassal in 2021 showed that the process of surgical closure of PDA is being reserved in cases of large PDAs with child being less than 4 kg and showing significant failure to thrive and in our study only 1 patient developed device dislodgment which required surgical intervention. Five patients had technical difficulties while crossing and developing spasm particularly in very small PDAs.[3] Dietrich *et al*., showed 96% procedural success with long-term follow-up (~9.7 years), confirming durable PDA closure.[13] Although our study reports in-hospital outcomes, the high immediate success rates suggest that procedural efficacy is likely to translate into durable closure.

Ön *et al*., observed early closure rates of ~97.5% and emphasized the importance of device selection, duct morphology, and patient selection.[1] Present study supports these conclusions, demonstrating low residual leak/dislodgement rates and providing additional evidence by comparing different access routes. Harinarayanan *et al*., showed that venous-only closure in infants (2–10 kg) was as effective as the standard approach, with no pulse loss and reduced radiation, contrast, and sheath time.[14] The present findings of preserved pulse status and minimal vascular complications in venous approaches mirror these results, highlighting the benefits of less invasive access in smaller patients. Xiong *et a*l., demonstrated that single-venous, echo-guided PDA closure achieved similar success as conventional approaches while eliminating vascular complications and reducing procedural time and contrast use.[15] Present study aligns with these findings.

PDA closure in adult patients remains a unique challenge as reported by Choudary et al, PDA crossing, size estimation as well as catheter maneuverability is challenging,[16] and studies by Ibrahim *et al*., and Yasuhara *et al*., also report similar challenges.[17,18] Present study reported that reducing procedure time and selecting PDA device according to PDA shape adds to better outcome.

This study demonstrates that transcatheter PDA closure in children is safe and effective, with single vessel approach providing minimally invasive alternatives while maintaining low complication rates. These findings support evidence-based selection of access route and device type, highlighting their clinical significance in optimizing pediatric outcomes.

LIMITATIONS OF STUDY

This study is limited by its single-center design and the relatively small sample size in the venous-only group, which may affect the statistical power for detecting rare complications. The inability to evaluate long-term results due to the study measuring only short-term complications is also a limitation. Results may also be impacted due to differences in procedures as a result of operator experience and choice of device. To validate the safety and efficacy of venous-only PDA closure, future investigations should be extended to larger, multicenter cohorts and should include follow-up assessments after extended timeframes.

CONCLUSION

In pediatric patients with transcatheter PDA closure, both techniques, single vessel and standard arteriovenous, show similar rates of success and complication without in hospital complications. There are differences in compression time, pulse, and anticoagulation which are access route specific and reflect the procedural trade-offs. Single vessel techniques in some cases are more preferable than standard access, with the choice of devices and PDA morphology impacting procedural success.

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