PERCUTANEOUS CLOSURE OF PATENT DUCTUS ARTERIOSUS; IMPLICATIONS OF THE KRICHENKO CLASSIFICATION

By

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ABSTRACT

Background: *Despite the revolutionary changes that occurred in percutaneous Patent Ductus Arteriosus (PDA) closure, the classical angiographic Krichenko classification of PDA remained unchanged and its implications on ductal closure has not been frequently studied.*

Aim of the work: *To explore the relative incidence of the different types of PDA based on Krichenko classification and to compare percutaneous closure of the classical type A to the other non- A types.*

Methods: *Retrospective study was conducted on a total of 111 patients who underwent percutaneous closure of PDA in our institution over the period from January 2019 till June 2022.*

Results: *The study included 53 patients with Krichenko type A PDA (47.7 %) and 58 non –type A PDAs (52 %). Patients with type A seemed to have younger age (p= 0.005) and lower weights (p= 0.007) with relatively larger pulmonary end diameters (p=0.000). Duct Occluder I (DO I) was the most commonly used device in group A, while other devices namely Amplatzer Duct Occluder Additional Size (ADO II AS), Flipper coils and PFM coils were more frequently used in the other types (p= 0.004). Non- A PDA seemed to require higher fluoroscopy time (p= 0.32) and radiation exposure (p= 0.006) but no significant difference was observed in the rate of complications (p=0.184).*

Conclusion: *Closure of non-A Krichenko classification PDA is safe and feasible using the readily available devices. The procedure may require higher radiological exposure yet no difference is seen in the rate of complications.*

Keywords: *Patent ductus arteriosus, Percutaneous closure, Krichenko classification.*

INTRODUCTION

Patent ductus arteriosus (PDA) is one of the commonest cardiac lesions in children that results in left ventricular volume overload, hyperdynamic circulation and pulmonary congestion necessitating its closure **(Doyle et al., 2018)**. Surgical or percutaneous interventions are available for its closure. The percutaneous closure has become more popular in recent years because of less invasive manoeuvre, shorter hospital stays and comparable efficacy **(Rodríguez et al., 2018)**.

Different devices are available for percutaneous PDA closure. The most classically used devices are the Amplatzer Duct Occlude I & II as well as the Occulotech PDA occluder which have been shown to be suitable for closure of most morphological types of PDA especially type A &E. However, the large introduction sheaths and the non flexible profile hinder its use in certain configurations and in small infants **(Pepeta et al, 2017)**. The Amplatzer Duct Occluder II AS has solved these problems by a much smaller introducing sheath, different sizes and more delicate profile making it suitable for small infants and certain morphological type like Krichenko type C and D **(Pamukcu et al, 2018)**. Coils has been traditionally used too but require certain configurations for its use to avoid possible residual flow or migration **(Pamukcu et al, 2018)**. Recently new devices have emerged including the Amplatzer vascular plug II which have been shown to be safe and effective in PDA closure especially in preterm neonates **(Greyling A., 2018)**.

Krichenko et al (1989) classified PDA morphology into five different types and recently a sixth class had been suggested type F which is PDA in preterm neonates which is close in configuration to type E but with larger diameter in comparison to descending aorta, more tortuous course and minimal stenosis **(Philip et al, 2017)**.

Although type A PDA is the commonest type of PDA encountered in the catheterization lab, few studies are available on the feasibility of closure of other non-A type PDA and if they pose challenges in percutaneous PDA closure. The main aim of our study was to evaluate the PDA closure in type A and non A type PDA morphology in presence of limited availability of devices.

PATIENTS AND METHODS

I. Ethical considerations:

1. Prior to conducting the study, the ethical approval of Ain

Shams University Ethical Committee was obtained ensuring that the work complies with the principles of the Declaration of Helsinki in 1975.

2. Informed consent was waived because of retrospective nature of the study.
3. All patient's data were kept confidential.
4. No conflict of interests existed regarding the research or the publications.
5. No Funds were received to conduct the research.

II. Sample size:

The sample size estimation was done using the Epi Info7 program for sample size calculation, setting the confidence level at 95% and margins of error at 10% and based on the work done by El-Saiedi et al (2022), a minimum of 50 patients in the each of the two main groups was estimated to be a sufficient sample size to compare variable. Patients were selected by random sampling.

III. Methods:

The current study is a retrospective cohort conducted at Pediatric catheterization unit in Pediatric Cardiology Unit, Ain Shams University Children's Hospital in which data of patients who underwent percutaneous closure of PDA during the period between January 2019 till June 2022 were reviewed.

All patients' records and angiographic films had been viewed. All demographic data of patients were recorded. Recorded angiography have been reviewed for characterization of the morphological type of PDA according to Krichenko classification **(Krichenko et al., 1989)** prior to its closure, the device used, the approach adopted for its delivery, and post deployment angiography. Immediate residual flow was graded if present into trivial when minimal tracing is seen in the pulmonary artery, mild with puffs of dye escaping into the PA and moderate if significant amount of dye were seen in the pulmonary branches **(Liddy et al, 2013)**. Details on type and size of devices used, amount of dye used and total radiation exposure were obtained from files as well as occurrence of complications in the form of vascular occlusion, device migration or protrusion into the aorta. Data on late complications most importantly late residual flow has been obtained from files too.

All procedures were done under general anesthesia. An arterial and venous access were

obtained in patients with an arterial sheath of 5 Fr (except in neonates and small infants where an arterial sheath of 4 Fr had been used). The used venous sheath was usually 5 Fr in size. After obtaining access patients received initial heparinization on 100 units/kg/dose and a single dose of parenteral antibiotic. ACT was usually monitored throughout the procedure and kept ≥200 sec. An appropriate Pigtail catheter was introduced from arterial access and aortography done to delineate PDA morphology. Pulmonary end, aortic end, mid ductal diameter and ductal lengths were all measured. Decision was made on the type and size of device to be used after ensuring normal pulmonary artery pressure. Devices were used when pulmonary end diameter was greater than 2 mm while coils were chosen for ducts with narrowest diameter less than 2 mm. For Duct Occluders I, a MP catheter was passed through venous access to reach pulmonary artery through the PDA and a wire was passed into descending aorta. The catheter was then replaced by an appropriate long sheath through which the device was deployed. For ADO II AS and Flipper coil closure the antegrade approach was used to deploy the device.

IV. Statistical analysis:

Data were statistically described in terms of means ± standard deviation (± SD), median and range, or frequencies (number of cases) and percentages when appropriate. Student t test was used to compare numerical variables. For comparing categorical data, Chi-square (x2) test was performed. Exact test was used instead when the expected frequency is less than 5. Two-sided p values less than 0.05 was considered statistically significant. IBM SPSS (Statistical Package for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows was used for all statistical analyses.

RESULTS

Our results are displayed in the following tables:

Table (1): Different device types and sizes used for PDA closure

Device Type	Device size (mm)	Type A (N=53)	Type B (N=4)	Type C (N=15)	Type D (N=3)	Type E (N=36)	Total
DO I	***4 X6***	2 (1.8%)	1 (0.9%)	1 (0.9%)	2(1.8%)	2 (1.8%)	9 (8%)
	6X8	25 (22.5%)	1 (0.9%)	4(3.6%)	0	17 (15.3%)	47 (42%)
	8X10	18 (16%)	1 (0.9%)	2(1.8%)	0	3 (2.7%)	24 (22%)
	10X12	2 (1.8%)	0	0	0	0	2 (1.8%)
ADO II AS	***4 x 4***	0	0	1(0.9%)	0	1 (0.9%)	2 (1.8%)
	4x5	2 (3.8%)	0	0	0	0	2 (1.8%)
	4 x6	0	0	1(0.9%)	0	4(3.6%)	3 (2.7%)
	5 x6	0	0	2(1.8%)	0	1 (0.9%)	3 (2.7%)
	6 x8	0	0	0	0	1 (0.9%)	1 (0.9%)
	9 x12	0	0	1 (0.9%)	0	0	1 (0.9%)
Flipper coil	***5 x4***	2 (1.8%)	0	0	0	0	2 (1.8%)
	5 x 5	0	0	0	0	1 (0.9%)	1 (0.9%)
	6.5 x 5	0	0	0	0	2(1.8%)	2 (1.8%)
	5x6	0	0	0	1(0.9%)	1 (0.9%)	2 (1.8%)
PFM coil	***5 x6***	0	0	0	0	1 (0.9%)	1 (0.9%)
	6 x7	1 (0.9%)	0	0	0	0	1 (0.9%)
	6 x 9	0	1 (0.9%)	0	0	0	1 (0.9%)

DOI:Duct occlude I, ADO II AS: Amplatzer duct occluder Additional size.

Table (1) shows the different device types and sizes used (Duct Occluder I, Amplatzer Duct Occluder II, Flipper coils and PFM coil).

Table (2): Comparison between group A and non- A PDA regarding clinical data of patients, PDA morphology, procedure and complications

		Type A N=53	Other types N= 58	P value	Signif-icance
Age (years) (x̄± SD)		2.18 ± 2.3	3.67 ±3.05	0.005	**HS**
Sex (Males)		18 (34%)	18 (31%)	0.742	NS
Sex (Females)		35 (66%)	40 (69%)		
Weight (kg) (x̄± SD)		11.28 ± 6.25	15.33 ± 8.64	0.007	**HS**
Height (cm) (x̄± SD)		82.36 ± 19.24	95.43 ± 22.44	0.001	**HS**
BMI (x̄± SD)		15.72 ±3.4	16.41± 4	0.329	NS
BSA(m^2) (x̄± SD)		0.49 ± 0.2	0.80 ± 1.21	0.070	NS
Pulmonary end diameter (mm) (x̄± SD)		2.33± 0.76	1.78 ± 0.83	0.000	**HS**
Mid- ductal diameter (mm) (x̄± SD)		8.89 ± 2.10	2.27 ±0.93	0.000	**HS**
Aortic end diameter (mm) (x̄± SD)		8.89 ± 2.10	6.64 ± 2.9	0.000	**HS**
PDA length (mm) (x̄± SD)		9.48 ± 2.06	11.9 ± 3.08	0.000	**HS**
Device used	**DO I**	47(89%)	35 (60%)	0.004	**HS**
	ADO II	2 (4%)	11 (19%)		
	Flipper Coil	3 (5%)	10 (17%)		
	PFM coil	1(2%)	2 (3 %)		
Long sheath used(Fr.) (median, Range)		6 (5-9)	6 (4-7)	0.002	**HS**
Venous Approach		44 (90%)	44 (76%)	0.050	**S**
Arterial Approach		5 (10 %)	14 (24%)		
Fluoroscopy Time (min) (x̄± SD)		12.320 ±7.7	16.413± 9.32	0.032	**S**
Amount of Dye used (mm) (x̄± SD)		44.2 ± 21	47.8± 32	0.495	NS
Amount of Dye used/ m^2 (mm/m^2) (x̄± SD)		93.1 ± 36.9	72.6 ± 34	0.003	**HS**
Radiation dose (GY cm2) (x̄± SD)		15.58 ± 4.13	18.21± 5.07	0.006	**HS**
Complications					
Immediate residual flow	None	38 (71.7 %)	47 (81 %)	0.184	NS
	Trivial	8 (15 %)	2 (3.4%)		
	Mild	4 (5.7%)	4 (6.9 %)		
	Moderate	3 (5.7%)	5 (8.6%)		
Late Residual flow		51 (96 %)	57 (98 %)	0.111	NS
Embolization / coil breakage		0	1 (1.7 %)	0.523	NS
Vascular complications		6 (11.3 %)	8 (13.8 %)	0.46	NS
Protrusion of aortic disc		0	3 (5.2%)	0.139	NS

Table (2) showing highly significant difference between type A morphology and other types regarding age, weight, height, PDA measurements, amount of dye/m2 and radiation dose.

Table (3): Comparison of the sub-groups of Krichenko non-A PDAs regarding clinical data of patients, PDA morphology, procedure and complications

		Type B N= 4	Type C N= 15	Type D N= 3	Type E N= 36	P value	Sig.
Age (years) (x̄± SD)		5.38 ± 3.22	4.55 ± 3.22	4.43± 3.11	3.05 ± 2.61	0.003	**HS**
Sex (Males)		1(25%)	6 (40%)	2 (66.7 %)	9 (25%)	0.565	**HS**
Sex (Females)		3 (75%)	9 (60 %)	1 (33.3%)	27 (75 %)		
Weight (kg) (x̄± SD)		12.08 ± 12.2	17± 9.3	16.17 ±6.33	14.92 ± 8.3	0.008	**HS**
Height (cm) (x̄± SD)		95.75 ±37.2	102.73 ± 20.84	104 ±20	91.64 ± 21.5	0.005	**HS**
BMI(x̄± SD)		18.7 ±3.89	15± 2.22	13.8 ± 0.68	17±4.5	0.131	NS
BSA (m^2) (x̄± SD)		0.69 ± 0.39	1.29 ± 2.3	0.67± 0.21	0.61± 0.23	0.002	**HS**
Pulmonary end diameter (mm) (x̄± SD)		2.6 ± 0.36	1.95± 1.03	1.193± 0.34	1.67± 0.76	0.000	**HS**
Mid- ductal diameter (mm) (x̄± SD)		3.95 ± 1.48	2.43±0.96	2.78 ± 0.93	1.99 ± 0.62	0.253	NS
Aortic end diameter (mm) (x̄± SD)		5.84 ±1.9	4.37± 2.14	1.58± 1.04	8.09± 2.2	0.000	**HS**
PDA length (mm) (x̄± SD)		7.98 ± 4.8	13.7 ±4.04	11.7 ±1.76	11.67 ± 1.87	0.000	**HS**
Device used	**DO I**	2 (50%)	7 (46.7%)	0	25 (69.4%)	0.004	**HS**
	ADO II AS	2 (50%)	5 (33.3%)	2 (66.7%)	3 (8.3%)		
	Flipper coil	0	2 (13.3%)	1(33.3%)	7 (19.4%)		
	PFM coil	0	1 (6.7%)	0	1 (2.8%)		
Long sheath used (Fr) (median -range)		6(4-7)	5(4-7)	5(4-5)	6(4-10)	0.003	**HS**
Venous Approach		3 (75%)	11 (73.3%)	2(66.7%)	28 (77.8%)	0.415	NS
Arterial Approach		1 (25%)	4 (26.7%)	1 (33.3%)	8 (22.2%)		
Fluoroscopy Time (min) (x̄± SD)		22.75 ± 13	16.15 ± 8.24	17.33 ±10.5	15.5 ±9.33	0.245	NS
Amount of Dye used (mm) (x̄± SD)		65 ±32.4	50.77 ±38.6	37 ±12	45.5 ±30.5	0.795	NS
Amount of Dye used/ m^2 (mm/m^2) (x̄± SD)		73.67± 26.6	70.71±42.7	57.67 ±24.4	74.76±31.9	0.002	**HS**
Radiation dose (GY cm^2) (x̄± SD)		15 ±7.6	8 ±4.27	16 ±5	15.17±2.4	0.000	**HS**
Complications							
Immediate residual flow	None	3 (75%)	12 (80%)	3 (100%)	29 (80.6%)	0.723	NS
	Trivial	0	0	0	2 (5.6%)		
	Mild	1 (25%)	1(6.7%)	0	2 (5.6%)		
	Moderate	0	2 (13.3%)	0	3(8.3%)		
Late Residual flow		4(100%)	15(100%)	3 (100%)	34(97%)	0.139	NS
Embolization / coil breakage		0	0	0	1(2.8%)	0.717	
Vascular complications		1 (25%)	2(13.3%)	0	5 (13.9%)	0.844	NS
Protrusion of aortic disc		3 (75%)	0	0	0	0.000	**HS**

Table (3) showing highly significant difference between the different non-A morphology PDAs regarding age, weight, height, PDA measurements, amount of dye/m2 and radiation dose and protrusion of device into aorta.

DISCUSSION

Since the introduction of transcatheter closure of PDA over fifty years ago, many changes had occurred in the available devices, the procedural techniques and the delivery options **(Rodríguez et al., 2018)**. However, the Krichenko classification of PDA which has been described in 1989 **(Krichenko et al., 1989)** remained unchanged though it is a fundamental aspect in the selection of an appropriate device for ductal closure.

The majority of PDA encountered in the catheterization lab are the classical Krichenko type A PDAs which fits most of the available devices and coils. Non- Krichenko type A PDA are usually thought of as being more challenging and sometimes unfit for closure by the readily available devices. The main aim of our work was to compare Krichenko type A PDA to the non-A type. We aimed at comparing PDA measurements, approach used, devices applied, technical difficulties reflected by Fluoroscopy time and exposure as well as the occurrence of complications.

We have studied a total of 111 patients who underwent percutaneous closure of PDA in our institute. Angiography of patients were reviewed and based on the angiographic shape of PDA they have been grouped into those with Krichenko type A (53 patients) and non Krichenko type A (58 patients). In the non Type A group, the most common type was type E (62%), followed by type C which presented 26 % while type B and D represented 7 % and 5 % consequently. This is comparable to the study of **Liddy et al (2013)** in which 177 patients underwent percutaneous closure of PDA. Among these patients type A was the most frequently encountered PDA in 63.3% of patients followed by type C (22.6%). Type E was seen in 12.4% (22/177), Type D in 1.7% (3/177) of cases. None of their patients was classified as type B. In our study, patients with non A morphology had significantly older age and consequently higher weight, BSA and height. This can be explained in some forms like type E which

usually has a constricted pulmonary end restricting its left to right shunt and causing minimal symptoms to the patients who will be discovered accidently at older ages.

PDA measurements were different between the two groups too. Krichenko type A PDA had wider mean pulmonary end, larger ampulla and significantly shorter length which are intrinsic characteristics in this morphological type. All these three factors (pulmonary end in relation to aortic end diameters and PDA length) makes type A PDA perfectly suitable for closure by DO I devices which have a larger aortic skirt that can fit into the ampulla and the short length preventing over stretching between aortic and pulmonary discs.

The devices available for closure of PDA in our institution include Duct occluders I (DO I), Amplatzer duct occluders II additional sizes (ADO II AS), Flipper coils and PFM coils. Although VSD occluders and vascular plugs are available yet we did not encounter any PDA size or shape that required its use. In our study, the DO I was the most used device. DO I has been used in 89% of the Krichenko type A PDAs and in 60% of the non- A morphology. In the latter, it has been used unexceptionally in all the non- A morphology. On the other hand, the ADO II AS has been a popular choice in type C (tubular) PDAs (27%) especially in small weights and also have been used in type E (19.5%). The Flipper coils have been used in some A morphologies with narrow Pulmonary ends and has been used in type E PDA too, again probably due to the intrinsic constriction of the pulmonary end in this group in relation to aortic ampulla.

The broadest experience in PDA closure has been with the ADO, which seems an appropriate device for most of PDAs morphology, especially for the most common type A and E PDAs. The asymmetrical appearance of the device, the venous approach and the large aortic skirt, all these makes it a good device in the formerly mentioned types of PDA **(Delaney et al., 2013) (Pass et al., 2004)**.

The ADO II AS device is a smaller and more flexible device. This property along with the facts that it is uploaded on a low-profile 4F delivery system either antegradely or retrogradely make its suitable for certain PDA types especially type C and D in small infants. On the other hand, Small PDAs can be readily closed using

the Flipper coils which have small profile and a considerably less cost. However, their deployment can be troublesome to achieve good configuration inside the PDA in addition to higher risk of residual flow and more importantly a significant risk of migration **(Pamukcu et al, 2018)**. In their case series, **liddy et al (2013)** observed the use of ADO in 78.5% of cases while ADO II AS in 5.1% of their cases and flipper coils were used in 14.1% (25/177). In addition to four cases (2.3%) in which "other" devices were used which is comparable to our results.

On comparing the technical aspect of the procedure, total Fluoroscopy time and radiation dose were significantly higher in the Krichenko non- A type morphology which possibly point out to a more challenging procedure. The absolute amount of dye was not different between the two groups yet the amount of dye indexed to BSA appears to be higher in the A group, probably due to small weights and BSAs related to the younger ages observed in this group.

For the incidence of complications, no significant difference was observed between the two groups regarding the incidence of residual flow or vascular complications. There has been a single case of Type E PDA in which proximal breakage of the coil on trial of its detachment occured. However, the coil kept its position with moderate immediate residual flow that was still observed on 3 months follow up after its deployment. Protrusion of the aortic disc into the aorta was seen only in cases of Type B morphology (2 cases closed by DO I and two by ADO II AS). This can be explained probably by the short length of these ducts. However, no significant stenosis across the aorta has been observed on follow up of these patients. In his study **Liddy et al (2013)** described device protrusion in 11.7% of his cases and related this to the used of ADO II which has large retention discs. On the other hand **Baspinar et al. (2013)** and **Agnoletti et al. (2012)** reported no cases of device protrusion with ADO II AS. One must bear in mind that the lower rate of device protrusion with smaller, flexible devices may come at the expense of stability that can be achieved by larger rigid skirts as in ADO I.

CONCLUSIONS

Angiographic morphology of PDA is fundamental for device selection in percutneous DA closure. Non-Krichenko type A morphology can be readily closed by the available devices probably with some technical difficulties but with no

increase in the incidence of complications.

Recommendation

Percutaneous closure should be tried in all morphological types of PDA. New emerging devices should be tried in patients with non A morphology aiming at reaching least radiological exposure, minimal intervention time and no complications.

LIMITATIONS

The current study is limited by retrospective nature of the study in a single institution. Also, the limited availability of devices may have affected the decision of device selection.

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