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To Observe the Residual Leak after Transcatheter Closure of PDA with Different Types of Duct Occluders

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Abstract

Introduction: Patent ductus arteriosus has very diverse morphology and sometimes it becomes challenging at times to occlude along with certain complications. Transcatheter closure of PDA is the procedure of choice and is considered safe. Various devices develop to occlude PDA because of diverse morphology. These devices are usually designed according to the anatomical types of PDA.

Objective: The objective of this study is to observe the residual leak within 24 hours after device occlusion of PDA in the pediatric age group by using different devices in diverse morphology of PDA.

Methods: A cross-sectional observational study with consecutive sampling was conducted in the cardiology department to evaluate the results of PDA device occlusion regarding residual leaks by using different devices at children's hospital and institute of child health Lahore. The data was collected for 6 months after approval of synopsis between 6 months to 16 years of age by developing Performa. All the data was entered in SPSS version 25 software and then analyzed for statistically significant outcomes. Descriptive analysis and the Chi-Square test were applied to measure the association among the different categorical variables.

Results: A total of 79 patients with a male to female ratio of 1:2 selected in the study were admitted for duct occlusion. According to Krinchenko classification, 45 patients had type A, 7 patients had type B, 17 patients had type C, Four patients had type D, and 6 patients had type E PDA. In 50 patients regular shape duct occluder was used. The result revealed 4 patients have a residual leak. In 29 patients reverse shank duct occluder was used, out of which 7 patients have a residual leak. As far as anatomical types of PDA were concerned versus residual leak, in type A 6 patients have a residual leak, in type B and E 1 patient has a residual leak, while in type C PDA 3 patients have a residual leak and in type D no leak was observed.

Keywords: Patent ductus arteriosus; Duct occlude; Standard shank; Reverse shank; Angiography

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Introduction

Patent Ductus Arteriosus (PDA) is a common cardiac defect with an incidence of 6%-11% [1] Symptomatic PDA requires treatment in the form of medicine as well as an intervention [2]. Transcatheter closure of PDA considers being safe and preferable nowadays [3]. Cardiac catheterization was first used to treat PDAs in 1966 [4]. Recently various types of duct occluder devices are available for PDA occlusion [5]. Ductus arteriosus persists in a wide variety of sizes and configurations. Krichenko et al. angiographically classified duct into five types: Type A ''conical'' ductus, with ampulla at the aorta and narrow point at the pulmonary end. Type B ''window'' ductus, with no ampulla and a 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 [6]. The sizes, shapes, and association to other cardiac defects are the main aspect of interventional closure. Various types of devices

for PDA closure are now available. These include ADO device, Rashkind device, SHSMA occlude, and *Gianturco coil* [7]. A lot of studies done on devices effectiveness and complications but few studies done regarding observing normal versus reverse shank outcome spatially focus on residual leak because residual leaks some time challenging to treat because of hemolysis, volume load, increase chance of infective endocarditis, and re-coiling or re-devising.

Methods and Materials

A cross-sectional observational study with consecutive sampling was conducted in the cardiology department to evaluate the results of PDA device occlusion at children hospital and institute of child health Lahore. The data was collected for 6 months after approval of synopsis between 6 months to 16 years of age by developing Performa. Only patients with isolated PDA seem suitable for device occlusion in echocardiography by consultant pediatric cardiologist were selected. Those patients having associated coarctation of the aorta or other cardiac defects, irreversible pulmonary hypertension, neonates, and premature babies were excluded from the study.

Duct occluder classification

Proforma was designed to focus on the angiographic types of PDA and residual leak between standard shank and reverse shank duct occluder used for the different types of PDA. The reverse shank duct occluder has a wider pulmonary end than the aortic end while in normal shank aortic end is wider than the pulmonary end. The devices used for standard shank were Life tech, Amplatzer AGA and Shsma. While for the reverse shank, Occlutech was used.

Device size selection

To date, there is no clear guidance on how to select the size of a duct occluder. Most operators elect to implant devices at least 2 mm larger than the narrowest point of the duct [8,9]. For the selection of the size of duct occluder as standard, 2 mm bigger than the narrow point was preferred in low pulmonary artery pressure while more than 4 mm of the narrow point was preferred in case of moderate to severe pulmonary hypertension [10]. Similarly, duct length measurement from ampulla to narrow point was measured [11]. We repeat angiography always after crossing with the delivery system and re-measured narrow point before selection of the size of the device.

Angiography

PDA device closure was done under universal aseptic condition through the femoral artery and venous approach. Heparin with 100 u/kg was given before the start of the procedure. In children below 7 months procedure was done under general anesthesia. While children above 7 months the procedure is done in local anesthesia with sedation. A full lateral view of Aortic angiogram (90 LAO) was performed to determine the morphology and size of the duct. Sometimes the shape was confirmed at 30 RAO view also. The size of the ampulla, narrow point, and length of the duct was measured at both 90 LAO and 30 RAO angiogram. Both aortic and pulmonary artery pressure was measured before the selection of the device. Device type and size were selected after reviewing the aortogram and pulmonary artery pressure by consensus of two consultant's pediatric cardiologists. The position of the device was reconfirmed before releasing through angiography by contrast media at both 90 LAO and 30 RAO views. The position of the device was also confirmed through angiography by contrast again at 90 LAO and if required then 30 RAO position. Immediate complication like LPA or aortic partial obstruction was confirmed by pullback gradient at ascending and descending aorta and LPA distal to proximal gradient by Cather. The side leak not foaming through the device was labeled as residual leak after 24 hours post-procedure through echocardiography by a consultant pediatric cardiologist. Hemolysis was rule out through clinical status and urine examination before discharge.

Statistical analysis

All the data entered in SPSS version 25 softwares and then analyzed for statistically significant outcomes. Descriptive analysis and the Chi-Square test were applied to measure the association among the different categorical variables.

Results

The male to female ratio was 1:2 **Figure 1**. The mean age of patients in years was ± 4.05 years with a minimum age of 8 months, the mean weight of patients was ± 13.72 kg. The standard deviation of height was ± 27.01 cm. The mean narrow point of the duct was 3.27 mm with a range of ± 1.4 mm to 8.8 mm while the ampulla was ± 1.4 mm to 20 mm. Regarding device selection, the average aortic end diameter of the device to pulmonary end diameter of the device found was ± 3 mm-16 mm to ± 3.5 mm-18 mm. The mean of aortic end to PDA diameter ratio was 2.6 with an average of ± 0.96 mm-7.14 mm. Similarly, the mean of the maximum device to PDA diameter ratio found was ± 1.74 mm to 7.1 mm **Table 1**. Out of 79 patients, according to Krichenko angiographic classification of PDA, 45 patients had Type A shape, 7 patients had Type B, 17 patients had Type C, 4 patients had type D, and 6 patients had Type E angiographic shape **Figure 2**. Regarding the length of the duct, only two patients had a small length (≤ 4 mm) while 46 patients had a medium length (7 mm), and 31 patients had a long length (≥ 7 mm) **Figure 3**. Out of 50 patients in whom regular shape duct occluder devices were used, 4 patients had a residual leak in PDA. While from 29 patients in which reverse shank device was used 7 patients had a residual leak. According to Krinchenko angiographic classification of PDA, 6 patients had a residual leak in type A, 1 patient had a residual leak in type-B, 3 patients had a residual leak in type C. No residual leak was seen in type D shape of PDA and in type E shape 1 patient has a residual

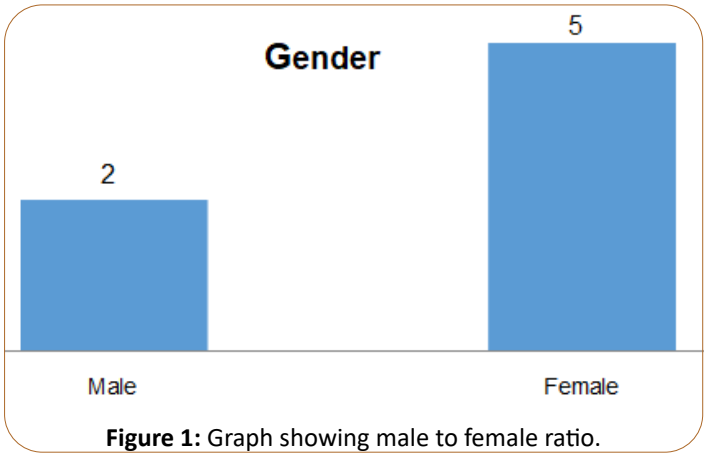

Figure 1: Graph showing male to female ratio.

Table 1: Demographic data of Patients post-duct angiographic measurement (n-79).

Demographics	Mean	Std. Deviation	Range	Minimum	Maximum
Age (year)	4.0544	2.88825	12.2	0.8	13
Weight (kg)	13.7215	7.62144	48.5	2.5	51
Height (cm)	93.0633	27.01156	149	11	160
PDA narrow point (mm)	3.2785	1.4128	7.4	1.4	8.8
PDA ampulla (mm)	11.1814	3.39878	19.4	1.4	20.8
Aortic end diameter of device (mm)	8.0506	2.79605	13	3	16
Pulmonary end diameter of device (mm)	7.6013	2.50305	14.5	3.5	18
Device aortic end to PDA diameter ratio(mm)	2.6484	0.93715	6.18	0.96	7.14
Max device to PDA diameter ratio	2.9119	0.86015	5.36	1.74	7.1

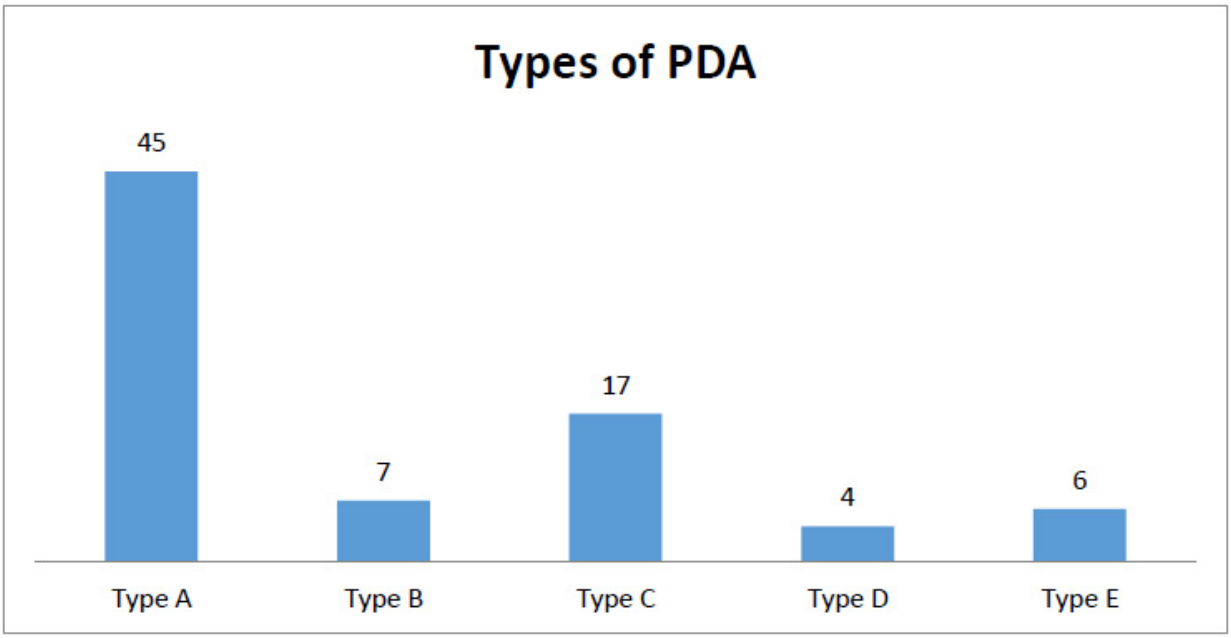

Figure 2: According to Krichenko angiographic classification of PDA.

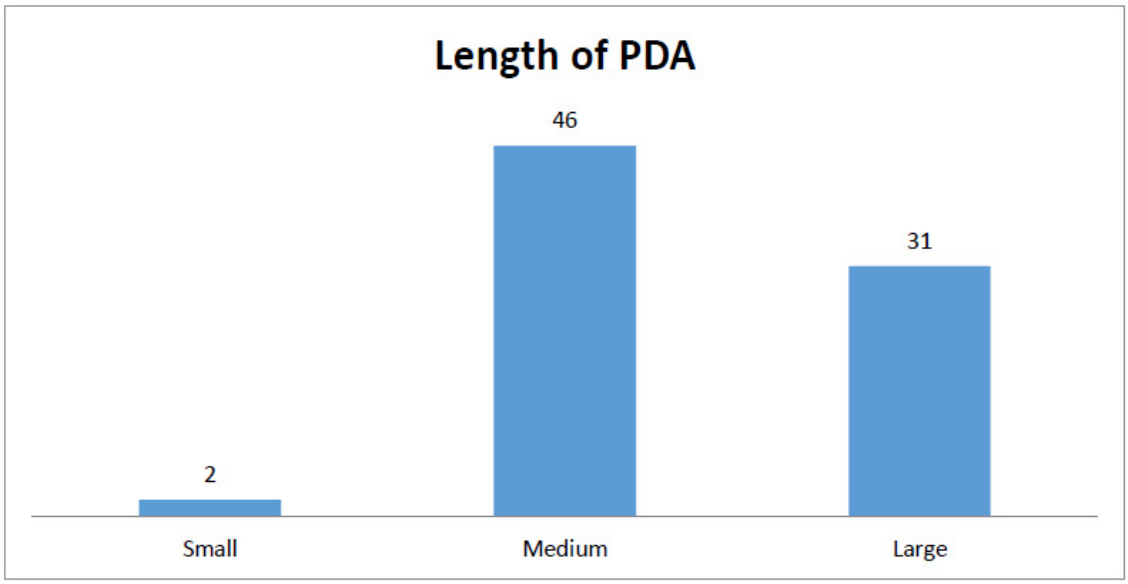

Figure 3: Duct length measurement through angiography.

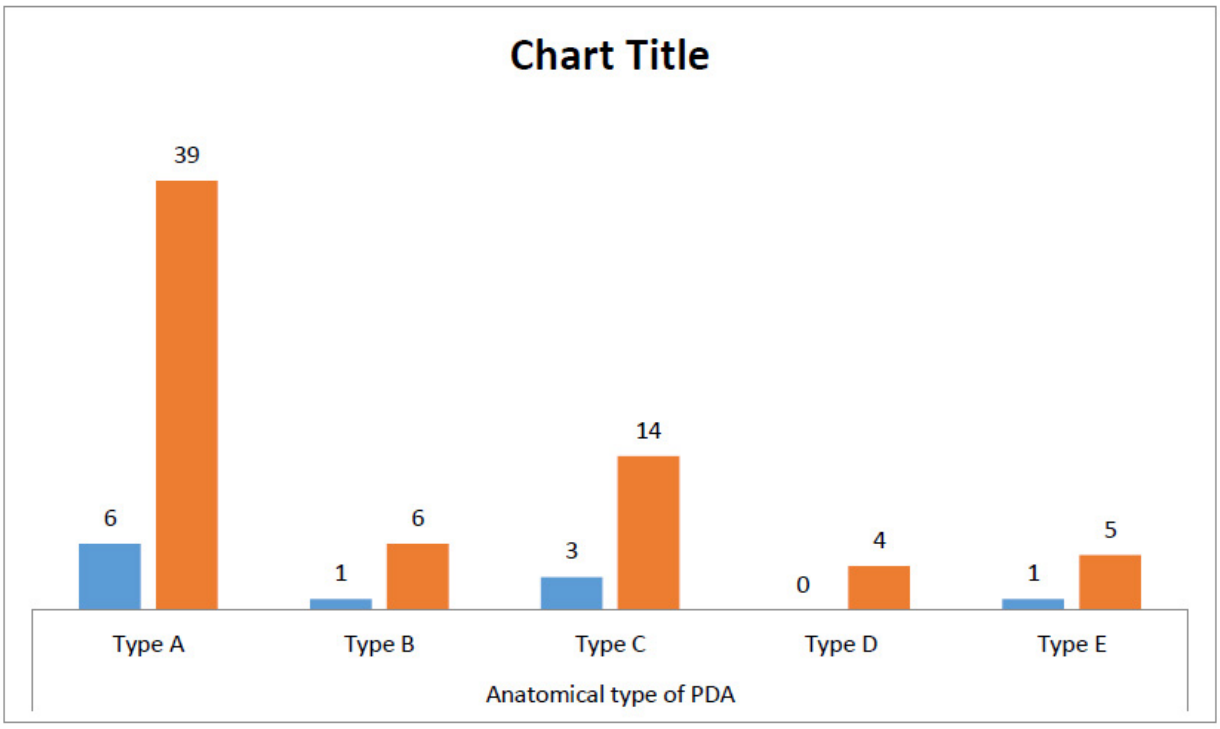

Figure 4 Residual leak according to the angiographic type of shape of duct.

Table 2: Residual leak in normal versus reverse shank duct occluders in different shape of PDA.

Type of Devices	Type-A	Type-B	Type-C	Type-D	Type-E
Normal shank	1	1	1	0	1
Reverse shank	5	0	2	0	0
Total shank	6	1	3	0	1

leak **Figure 4**. Regarding residual leak with reverse shank, the maximum residual leak was seen in type A and type C PDA **Table 2**. Another complication like early embolization, hemolysis, aortic or LPA obstruction was not seen in our case within 24 hours.

Discussion

The reverse shank is designed to enhance the stability of the device in the duct and decrease the risk of embolization. It is present in two different lengths, the standard length and the long shank device made for long ductal ampulla [11]. Residual shunt through the reverse shank device as described in the literature. Excellent occlusion rates have been reported at 1 day (82%-97%), 1 month (96%-100%) and 6 months (96%-100%) follow up [12]. Similarly, reverse shank showed a higher incidence of a residual leak than standard shank devices in our study as 8% found in standard shank device *versus* 24% in reverse shank device, which was supported by Kudumula V study. It was also reported immediate ductal occlusion did not occur by using the ODO [12]. Some studies revealed that there was only a 48.5% complete occlusion rate at 10 minutes post-implant, but in large ducts, complete occlusion occurred till 90 days [13]. But in our study, we found immediate occlusion rate within 10 minutes with all types of devices was 86% while with only ODO it was 76%. A study also documented that immediate complete occlusion with ODO was 63% [14]. We had a better occlusion rate in our study with ODO as mention it was 76%. We have a better implant technique as it may be due to repeat angiography always after crossing with the delivery system and re-measured narrow point before selection of the size of the device. Reyhan et al mentioned that especially in type B and type C oversizing measurement of the device was a better option [14]. We also noticed that in type B and type C only 14% of patients showed residual leak because of the oversizing technique. Regarding complication as early embolization of device, it was documented that chance of embolization in the large duct was always high [15,16]. In our study, there was no embolization seen.

Conclusion

Reverse shank had a higher incidence of a residual leak in type A. However, a regular shank device may be preferable in both Type A and C shape ducts. The result was also comparable of both types of devices in type A, and C patent ductus arteriosus.

Limitations

It was a single-center study. Follow-up was not included regarding hemolysis, volume loaded, residual leak, and infective endocarditis later on. The outcome of re-devising or coiling results not mentions. The fate of pulmonary hypertension after device and co-relation between residual leaks with pulmonary

hypertension not assessed. Similarly, the type of device selection was purely on the subject of availability.

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