Research Article

To study the residual leak within 24 hours after Transcatheter closure of PDA with different types of duct occluder

Khizra Mehmmood [1], Syed Najam Hyder [1], Manawer Ghous [1]

Author's Affiliation:
1- Department of Pediatric Cardiology, The Children hospital and ICH, Lahore.

Correspondence:
Syed Najam Hyder, Email: drnajamhyder@gmail.com

Received on: 30-May-2021 Accepted for Publication: 05-Aug-2021

ABSTRACT

Introduction: Patent ductus arteriosus has very diverse morphology and sometimes challenging to occlude and can cause complications. Various devices have been developed to occlude PDA because of its diverse morphology. These devices are usually designed according to the anatomical types of PDA.

Objective: The objective of this study was to observe the residual leak within 24 hours after device occlusion of PDA in 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 within 24 hours by using different devices at children hospital and institute of child health Lahore. The data of children aged between 6 months to 16 years, was collected for 6 months after approval from ethical committee. The data was entered in SPSS version 25 software and then analyzed for statistically significant outcomes. Descriptive analysis and the Chi-Square test was applied to measure the association among the different categorical variable.

Results: A total of 79 patients with male to female ratio of 1:2 were selected in the study 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 and 4 patients had residual leak in this group. In 29 patients reverse shank duct occluder was used, out of which 7 patients had residual leak. As far as anatomical types of PDA was concerned in regard to residual leak, in type A 6 patients , in type B and E 1 patient each and in type C PDA 3 patients had residual leak while in type D no leak was observed.

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

Key Words: Patent ductus arteriosus, Duct occluder, Standard shank, Reverse shank, Angiography.

Abbrevation: PDA= Patent ductus arteriosus, ODO=Occlutech duct occluder, ADO= Amplatzer duct occluder, RAO= Right anterior oblique, LAO= left anterior oblique, LPA= Left Pulmonary artery

INTRODUCTION

Patent ductus arteriosus (PDA) is common cardiac defect with incidence of 6–11 % [1] Symptomatic PDA requires treatment in the form of medical as well as surgical intervention [2]. Trans catheter closure of PDA is considered to be safe and preferable now a days[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 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 [6].

The size, shape and associated cardiac defects are the main aspects to be considered in interventional closure. Various types of devices for PDA closure are now available. These include ADO device, Rashkind device, SHSMA occlude and Gianturco coil[7]. Lots of studies have been done on effectiveness and complications of various devices but little data is available regarding residual leak in normal versus reverse shank method. Moreover residual leak sometimes may be challenging to treat because of hemolysis, volume load, increase chance of infective endocarditis and re-coiling or re-devising.

METHODS & MATERIALS:

A cross sectional observational study with consecutive sampling was conducted in the cardiology department, Children hospital and Institute of Child Health Lahore, to evaluate the results of PDA device occlusion. The data of patients over last 6 months who underwent duct occlusion, were collected after approval from ethical committee on a pre-designed performa. Age ranged between 6 months to 16 years. Cardiac catheterization was not offered to patients weighing less than 4 kg or patients associated with other cardiac problems required surgery.

Duct Occluder classification:

Performa 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 wider pulmonary end than the aortic end while in normal shank aortic end is wider than pulmonary end. The devices used for standard shank were Life tech, Amplatzer AGA and SHSMA . While for reverse shank, Occlutech was used.

Device size selection:

No clear guideline available for selection of the size of a duct occluder. Most operators select devices at least 2 mm larger than the narrowest point of the duct [8,9]. In selecting size of duct occluder as standard, 2mm bigger than the narrow point was preferred in low pulmonary artery pressure while more than 4mm of the narrow point was preferred in case of moderate to severe pulmonary hypertension[10].Duct length was measured from ampulla to narrow point [11]. We repeated angiography always after crossing with delivery system and re-measured narrow point before selection of size of device. By this technique, our embolization rate was reduced to zero.

Angiography:

PDA device closure was done under universal aseptic condition through femoral artery and venous approach. Heparin with 100 u/kg was given before start of procedure. In children below 7 months procedure was done under general anesthesia. While children above 7 months the procedure was done in local anesthesia and sedation. A full lateral view of Aortic angiogram (90^{o} LAO) was performed to determine the morphology and size of the duct. Sometime the shape was confirmed at 30^{o} RAO view also. The size of ampulla, narrow point, and length of duct was measured at both 90^{0} LAO, 30^{0} RAO angiogram .Initial measurement guided us for selection of size of delivery system .Both aortic, and pulmonary artery pressures were measured before selection of device. After crossing with delivery system, we re-measured the size narrow point. Device type and size was selected after reviewing the aortogram and pulmonary artery pressure by consensus of two-consultant pediatric cardiologist. Position of device was reconfirmed before releasing device through angiography by contrast media at both 90 LAO and if required then at 30 RAO view also. Immediate complication like LPA or aortic partial obstruction was confirmed by pull back gradient at ascending and descending aorta and LPA distal to proximal gradient by cather. The side leak not foaming through device was labelled as residual leak after 24 hours post procedure through echocardiography by consultant pediatric cardiologist.Hemolysis was ruled out by assessing clinical status and urine examination before discharge.

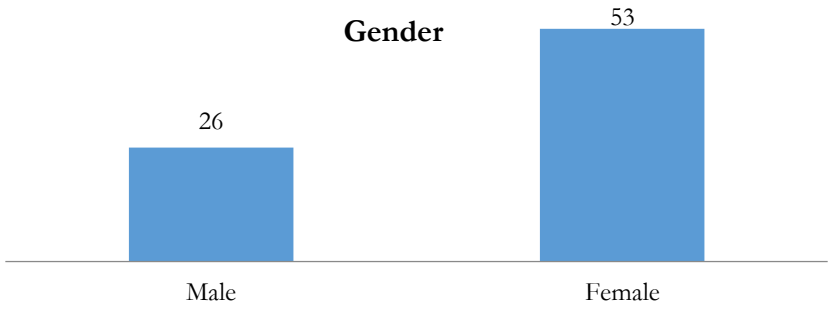
All the data was entered in SPSS version 25 software and then analyzed for statistically significant outcomes. Descriptive analysis and the Chi-Square test was applied to measure the association among the different categorical variable.

RESULTS:

The male to female ratio was 1:2 (Figure-1). The mean age of patients was ± 4.05 years with 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 duct was 3.27mm with minimum range of ±1.4mm to 8.8mm. The minimum size of ampulla was ±1.4 mm to 20 mm. Regarding device selection according to narrow point ,in minimum size of 1.4 mm the average device used was 3.0 mm while with maximum size of ampulla ie 8.8mm ,the average device size used was 16mm. The mean of aortic end to PDA diameter ratio was 2.6 with average of ± 0.96 - 7.14 mm. Similarly, the mean of maximum device to PDA diameter ratio found was ±1.74 to 7.1 mm (Table-1).

Figure-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 length of duct, only two patients had small length (≤4mm) while 46 patients had medium length (7mm) , and 31 patients had long length (≥7 mm) Figure-3.

Table-1: Demographic data of Patients and angiographic duct and device measurement (n-79)

	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

Table-2: Residual leak in normal versus reverse shank duct occluder 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	6	1	3	0	1

Figure-2: The types of duct according to Krichenko angiographic classification (n=79)

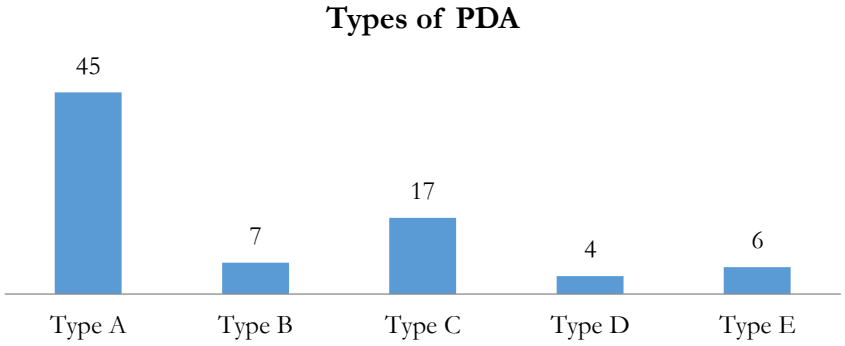
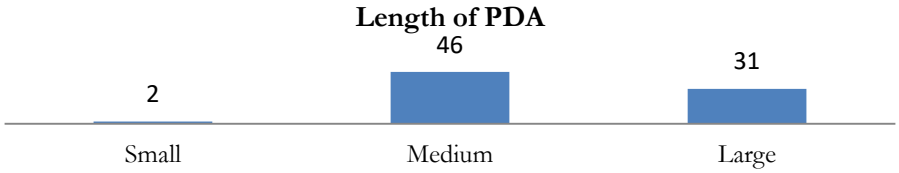
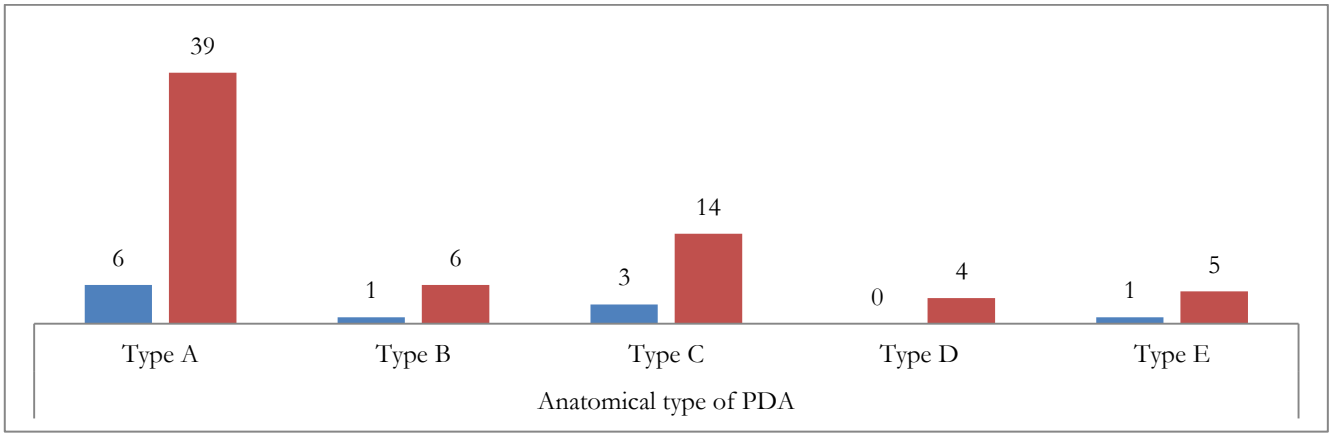


Figure-3: Category of duct length (n-79)



Out of 50 patients in which regular shape duct occluder devices were used, 4 (8%) patients had residual leak in PDA. While out of 29 patients in which reverse shank device was used 7 (24%) patients had residual leak. Therefore, in reverse shank the frequency of leak was found higher than normal shank. According to Krinchenko angiographic classification of PDA, 6 patients had residual leak in type-A, 1 patient had residual leak in type-B, 3 patients had residual leak in type-C. No residual leak was seen in type D shape of PDA and in type -E shape 1 patient has residual leak (Figure-4).

Figure-4. Residual leak in angiographic shape of duct (n=79)



Regarding residual leak with reverse shank, the maximum residual leak was seen in type-A and type-C PDA (Table-2).Similarly, no residual leak in reverse shank was found in PDA type-B, type-D and type-E which indicated that reverse shank duct occluder was good in these shape of duct. Other complications like early embolization, hemolysis, aortic or LPA obstruction were not seen in our patients within 24 hours. The parameters like age, weight, height, minimum PDA diameter , diameter of Ampulla, Aortic end to PDA diameter ratio, the device pulmonary end to PDA diameter ratio and maximum device to PDA diameter ratio all retain the null hypothesis and has no effect on the design of device and with residual PDA used (figure -5).

DISCUSION:

The reverse shank is designed to enhance the stability of device in the duct and decrease the risk of embolization. It is available 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 was 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 higher incidence of 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 that immediate ductal occlusion did not occur by using the ODO[12]. A study revealed that there was only 48.5% complete occlusion rate at 10 minutes post-implant, but in large duct complete occlusion occurred till 90 days[13]. But in our study we found immediate occlusion rate within 10 minutes with all types of devices as 86% while with only ODO it was 76%. Another study also documented that immediate complete occlusion with ODO was 63%[14]. We had better occlusion rate in our study with ODO as mentioned, it was 76%. We had better implant technique possibly due to repeat angiography every time after crossing with delivery system and re-measuring narrow point before selection of size of device. Reyhan et al mentioned that especially in type –B and type-C oversizing measurement of device was better option[14].We also noticed that in type-B and type-C only 14% patients showed residual leak because of oversizing technique.

Figure- 5:

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.	Decision
1	The distribution of Age in years is the same across categories of Residual PDA.	Independent-Samples Mann-Whitney U Test	.350[1]	Retain the null hypothesis.
2	The distribution of Weight (kg) is the same across categories of Residual PDA.	Independent-Samples Mann-Whitney U Test	.204[1]	Retain the null hypothesis.
3	The distribution of Height (cm) is the same across categories of Residual PDA.	Independent-Samples Mann-Whitney U Test	.058[1]	Retain the null hypothesis.
4	The distribution of Minimum PDA diameter (mm) is the same across categories of Residual PDA.	Independent-Samples Mann-Whitney U Test	.807[1]	Retain the null hypothesis.
5	The distribution of Ampulla (mm) is the same across categories of Residual PDA.	Independent-Samples Mann-Whitney U Test	.368[1]	Retain the null hypothesis.
6	The distribution of Device Aortic end to PDA diameter ratio is the same across categories of Residual PDA.	Independent-Samples Mann-Whitney U Test	.568[1]	Retain the null hypothesis.
7	The distribution of Device Pulmonary end to PDA diameter ratio is the same across categories of Residual PDA.	Independent-Samples Mann-Whitney U Test	.858[1]	Retain the null hypothesis.
8	The distribution of Max device to PDA diameter ratio is the same across categories of Residual PDA.	Independent-Samples Mann-Whitney U Test	.708[1]	Retain the null hypothesis.

Regarding complication as early embolization of device it was documented that chance of embolization in large duct was always high[15,16]. In our study there was no embolization seen.

CONCLUSION:

Reverse shank had higher incidence of residual leak in type A. However, regular shank device may be preferable in both Type A and C shape duct. Results were also comparable in both types of devices in type A, and C patent ductus arteriosus.

LIMITATIONS:

It was single center study .Follow up was not included regarding hemolysis, volume loaded, residual leak and infective endocarditis in long run. Outcome of re-devicing or coiling result were not mentioned .Fate of pulmonary hypertension after device and co-relation between residual leaks with pulmonary hypertension were not assessed. Similarly, type of device selection was purely on subject of availability.

ACKNOWLEDGE:

Thanks the support of our angiographer, and other staff members of angiography department.

REFERENCES

1. Mulyadi M. Djer,Dimas Dwi Saputro, Sukman Tulus Putra, et al. Transcatheter Closure of Patent Ductus Arteriosus: 11 Years of Clinical Experience in Cipto Mangunkusumo Hospital, Jakarta,Indonesia. Pediatr Cardiol 2015, 36:1070–1074.
2. Jennifer Y. Lam, MD; Steven R. Lopushinsky, MD; Irene W. Y. et al. Treatment Options for Pediatric Patent Ductus Arteriosus, Systematic Review and Meta-analysis.
3. CHEST 2015; 1 48 (3): 784- 793.
4. Agnetti Aldo, Carano Nicola, Tchana Bertrand,et al. Transcatheter Closure of Patent Ductus Arteriosus: Experience with a New Device. Clin. Cardiol. 2009 .32, 11, E71– E74.
5. Alexi-Meskishvili VV, Böttcher W. The first closure of the persistent ductus arteriosus. Ann Th orac Surg . 2010; 90 (1):349 - 356.
6. Sheridan BJ, Ward CJ, Anderson BW, Justo RN. Transcatheter closure of the patent ductus arteriosus: an intentionto treat analysis. Heart Lung Circ .2013; 22 (6): 428 – 432.
7. Krichenko A, Benson LN, Burrows P, Moes CA,McLaughlin P, Freedon RM. Angiographic classification of the isolated, persistently patent ductus arteriosus and implications for percutaneous catheter occlusion. Am J Cardiol 1989; 63:877–9.
8. Sun W-F, Dong Z-F, Gong K, Zhang G-P, Cui T, Xia Y-D, et al. Transcatheter closure with use of the SHSMA occluder in 180 patients with congenital heart defects: preliminary results. Texas Heart Institute J. 2010; 37 (5):531.
9. Dedeoglu R, Bilici M, Demir F, et al. Short-term outcomes of patent ductus arteriosus closure with new occlutech(R) duct occluder: A multicenter study. J Interv Cardiol. 2016; 29 (3):325-31.
10. Boudjemline Y. The new occlutech((R)) patent ductus arteriosus occluder: single centre experience. Arch Cardiovasc Dis.2016; 109 (6):384-9.
11. Fischer G, Stieh J, Uebing A, Grabitz R, Kramer HH. Transcatheter closure of persistent ductus arteriosus in infants using the Amplatzer duct occluder. Heart 2001; 86:444–7.
12. Abdul Malik Sheikh, Suhair Omar Shebani, Christopher Duke . The occlutech duct occluder :How to choose the correct device size and refine implantation technique to ensure optimal results in small and large arterial duct closure. Interv. Cardiol. 2019 11(6), 113–119 .
13. Kudumula V, Taliotis D, Duke C. The new occlutech duct occluder: immediate results, procedural challenges, and shortterm follow-up. J Invasive Cardiol. 2015 ; 27(5):250-7.
14. Abdelbasit MA, Alwi M, Kandavello G, et al. The new Occlutech PDA occluder: Initial human experience. Catheter Cardiovasc Interv 2015; 86:94–99.
15. Reyhan Dedeoglu,Meki Bilici, Fikri Demir, et al, Short-term outcomes of patent ductus arteriosus closure with new occlutechw duct occluder: a multicenter study. Journal of Interventional Cardiology: 2016, Vol 9999,1-7.
16. Agrawal H, Waller BR 3rd, Surendan S, Sathanandam S. New Pat¬ent Ductus Arteriosus Closure Devices and Techniques. Interv Car¬diol Clin 2019; 8: 23-32.
17. Sinha SK, Razi M, Pandey RN, Kumar P, Krishna V, Jha MJ, et al. Prospective evaluation of the feasibility, safety, and efficacy of Co¬coon Duct Occluder for transcatheter closure of large patent duc¬tus arteriosus: A single-center study with short- and medium-term follow-up results. Anatol J Cardiol 2017; 18: 321-7.