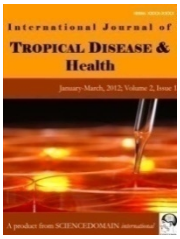

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Clinical Study of Trans-catheter Closure of Patent Ductus Arteriosus with Occluder Devices among Children Aged 9 Months to 18 Years

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Authors' contributions

This work was carried out in collaboration between all authors. Authors JMC, DKA, and IOA designed the study, performed the statistical analysis, wrote the protocol, and wrote the first draft of the manuscript. Authors KSM and VG managed the analyses of the study. Authors JMC, IOA and JCE managed the literature searche. All authors read and approved the final manuscript.

Research Article

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ABSTRACT

Background and Objectives: This study was aimed at determining our experience with occluder devices over last 5 years. The objective of this study is to compare the complication rates and efficacy of different devices used for the closure of PDA.
Methods: A cross-sectional retrospective study in which a review of the records of all children who had PDA surgery in a paediatric cardiac center, Innova Childrens' Heart Hospital, Hyderabad, India over a five year period (June 2007 and July 2011) was undertaken. The hospital records showed that from June 2007 to July 2011, a total of 456 children aged 9 months to 18 years had trans-catheter closure over the study period, of

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these, 159 underwent trans-catheter device closure of PDA. A team of experienced paediatric cardiologist performed all the procedures.
Results: Out of the 159 cases, 134 (84.2%) were successful while 25 (15.7%) were complicated. Five (5) {20.0%} cases had temporary residual leak, 3 (12.0%) had failure of the procedure that required surgical intervention, 9 (36.0%) had protrusion of the device into the aorta without significant Doppler pressure gradient.
There exist a relation between success, complication and device used for the procedure.The type of occluder device used for the procedure significantly affect the outcome (χ^2 = 16.37; p = 0.02) *Chinese* occlude devise had the highest success rate. Twenty five (25.0) {15.7%} patients had complications in all.
The commonest complication (protrusion of the device into the aorta) was seen in 3 (1.8%) cases with Chinese duct occluder, 3(1.8%) with Sear Heart ^{R} and 3 (1.8%) cases with ADOs. Non died from the procedure.
Conclusion: The commonest complication is (protrusion of the device into the aorta) with *Chinese* occludes devise showing the highest success rate. The learning curve and accumulating experience play an indispensable role in choosing the proper device and its size.

Keywords: Patent ductus arteriosus; Trans-catheter closure; Duct occluder; coil closure; complications.

1. INTRODUCTION

The patent ductus arteriosus (PDA) is a vascular structure that connects the proximal descending aorta to the roof of the main pulmonary artery near the origin of the left branch pulmonary artery. This essential fetal structure normally closes spontaneously after birth. After the first few weeks of life, persistence of ductal patency is abnormal. The physiological impact and clinical significance of the PDA depend largely on its size and the underlying cardiovascular status of the patient [1].

In children who were born at term, the incidence of PDA has been reported to be ≈1 in 2000 births [2]. This accounts for ≈5% to 10% of all congenital heart disease. The incidence of patent ductus arteriosus (PDA) in preterm neonates varies from 40% to 60% on the third day of life, depending on estimated gestational age [3]. Therefore, it continues to be one of the commonest problems in preterm neonates. However, if we include children with “silent” patent ductus (those discovered incidentally by echocardiography performed for another purpose), the incidence has been estimated to be as high as 1 in 500 [4]. The female to male ratio is ≈2:1 in most reports [4].

The incidence is inversely related to gestation, but may be reduced by use of antenatal steroids, lower volume fluid regimen and judicious use of phototherapy [4]. However, there continue to be controversy as to the appropriate indications for treatment, varying from prophylaxis on the basis of gestation to treatment only when a PDA is demonstrably significant [5]. The situation is further complicated by differing diagnostic criteria for ductal patency or significance [5]. Complications of PDA include congestive heart failure, repeated chest infections, pulmonary hypertension, and an increased risk of infective endocarditis [6].Trans-catheter closure of PDA is now recommended as a replacement for surgical ligation in different age groups [6,7]. In infancy, congestive heart failure is an indication for closure of the PDA. If medical therapy is ineffective, urgent intervention to close the structure should be undertaken. Repair may be delayed in the patient who is asymptomatic or well

controlled on medical therapy. All PDAs should be closed because of the risk of bacterial endocarditis associated with the open structure [8]. Over time, the increased pulmonary blood flow precipitates pulmonary vascular obstructive disease, which is ultimately fatal [8]. Common complications of trans-catheter closure of PDA include residual shunt, left pulmonary artery (LPA) obstruction bleeding at the catheterization site, rupture of blood vessels , vascular occlusion, inappropriate deployment of the device, migration of the device, and incomplete closure of the ductus [9,10].

Incidence of complication increases with large size ducts and with the use of multiple coils for occlusion [11]. There are only a few reports correlating outcome and complications with the learning curve and experience [12]. In this study, we are reporting our initial experience with PDA device closure using detachable coils and Amplatzer duct occluder (ADO), as well as other duct occluders. Our focus was on reporting the complications of trans-catheter closure of PDA using different PDA closure devices and comparing outcome amongst them. We also evaluated the influence of the learning curve and experience of the cardiologist on the outcome and complications.

2. MATERIALS AND METHODS

A cross-sectional retrospective study in which a review of the records of all children who had PDA surgery in a paediatric cardiac center, Innova Childrens' Heart Hospital, Hyderabad, India over a five year period (June 2007 and July 2011) was undertaken. The folders (case files) of these children were retrieved from the hospital records department and examined individually by the investigators. Data collection was done with structured forms designed for the study. The study was approved by the Research and Ethics committee of the hospital. The hospital records showed that from June 2007 to July 2011, a total of 456 children aged 9 months to 18 years had trans-catheter closure over the study period, of these, 159 underwent trans-catheter device closure of PDA. A team of experienced paediatric cardiologist performed all the procedures.

The occluder devices which were: 1. detachable coils, 2. Amplatzer duct occluders (ADOs) and other duct occluders among which were 3. Chinese duct occluder manufactured by Shanghai Shape Memory Alloy Material Co., Ltd, [13] which consist of metal mesh woven by nitinol wires with shape memory function, supper elasticity and polyethylene filled mesh. The occluder device has specifications of 4/6, 6/8, 8/10, 10/12, 12/14, 14/16 and 16/18 mm (diameter of "waist" pulmonary arterial end/diameter of aortic end), with lengths between 7 and 8 mm. The delivery system consists of loading sheath, delivery sheath and control wire, on the top of which there are screw threads. There is a spiral shank at the tail end. The diameter of outer sheath is 6-10F. 4. Cardiofix, 5. Searcare Heart^{R} 5. Lifetech and 6. Occlutech.

The Gianturco coil,[14] also referred to as the Cook embolization coil, is an arterial and venous occlusive device that was marketed prior to 1976, when the U.S. Food and Drug Administration (FDA) formally acquired regulatory authority over devices. (Please note that the Gianturco coil is entirely different from the Gianturco stent, which is used in coronary arteries). This Gianturco device has never undergone formal FDA approval but is however available for clinical use as the Gianturco coil has been investigated for PDA closure.

In 2003, the Amplatzer Duct Occluder [14] received FDA approval with the specific indication for non-surgical closure of patent ductus arteriosus. This device is a self-expandable device made from a Nitnol wire mesh and polyester fabric. As the occluder is implanted, it expands

outward, and the wires push against the wall of the ductus. The polyester fabric induces thrombosis, which closes the communication.

All patients had clinical evaluation and echocardiographic confirmation of the diagnosis. Cardiac catheterization was done for hemodynamic assessment and shunt estimation. The operation was performed after puncture and systemic heparinization (100 IU/kg). Intra operation, intravenous administration of antibiotics was started and continued for 24 hours to prevent infection. For infants, the operation was performed under general anesthesia, while for older children; it was done under conscious sedation.

During operation, right cardiac catheter examination was first performed, followed by descending aortic side imaging (angiography) to observe and measure PDA location, morphology, size (narrowest diameter, largest diameter and length) and its relative position to the anterior wall of trachea. In 23 cases, 260 cm exchange wire was delivered to descending aorta through PDA along right cardiac catheter to establish femoral vein-pulmonary artery-PDA-descending aorta delivery path. Appropriate sized occluders were selected (3-6 mm larger than the narrowest PDA diameter), and delivered along delivery long sheath to descending aorta.

The front end of the occluder was opened in the descending aorta. The delivery long sheath and delivery cable were fixed and pulled back together to PDA. Still fixed delivery cable and gradually pulling out the long sheath over the occluder opened the body (or waist) of occluder. Detachable coils were used for patients with small PDAs of ≤ 3.0 mm at the narrowest diameter. ADOs were used for PDAs that were >3.0 mm. However, some exceptions to this rule had to be made due to non-availability of the devices at the time of the procedure. The length and diameter of the coils used were double the length and diameter of the PDA. The decision regarding using multiple coils was made after documenting the residual shunt following the deployment of the first coil.

After device deployment, descending aorta imaging (angiogram) was immediately performed for a second time to determine the location of the occluder released and the closure efficacy (no residual shunt or minor shunt, no jet efflux, and only passed through the central part of the occluder). If above conditions are satisfactory, the occluder was released by unscrewing the delivery cable and the closure therapy was done. After operation, pulmonary arterial pressure was measured.

Since this is a retrospective study, all those who had PDA surgery and properly filled data were included in the study, while those with improperly filled data and patients whose clinical diagnosis of PDA was not confirmed with 2 D Echo were excluded.

2.1 Post-operative Monitoring

Chest x-ray (CXR) and two-dimensional echocardiography (2D ECHO) were re-examined for occluder location, residual shunt condition, pulmonary arterial pressure and heart size were observed 24 hours, one month, three months and six months after operation. Oral administration of low dose Aspirin (2-3 mg/kg/day) to a maximum of 100mg/day was given for 4-6 months.

This study was aimed at determining our experience with occluder devices over last 5 years". The objective of this study is to compare the complication rates and efficacy of different devices used for the closure of PDA.

2.2 Statistic Analysis

Statistic analysis was performed using SPSS 18 software packet. Measurement of data was expressed as both mean and standard deviation (SD). Student's t-test was used for inter-group comparison. Level of significance was taken at p- value of < 0.05.

Multiple variables were evaluated to assess their effect on the outcome of the procedure. The stepwise multiple regression analysis was used to reduce the independent variables to the minimum number of effective variables to determine the predictors of the outcomes. The dependent variables were the complications encountered. The independent variables were age and weight of the patient, diameter of the PDA, and the cardiologist's experience.

3. RESULTS

One hundred and fifty nine (159) patients underwent trans-catheter closure of PDA during the study period. Ninety four (94) {59.1%} patients were females while 65 (40.9%) patients were males, giving a male to female ratio of 1: 1.5. Age ranged from 6 months to 16.0 years (mean 3.1 ± 3.4 years), weight from 2.7-42.0 kg (mean 10.5 ± 6.2 kg), PDA diameter was between 2.0-10.0 mm (mean 4.2 ± 3.6 mm). Procedures lasted 60-180 minutes (mean 130 ± 20 minutes). Fluoroscopy time ranged between 5-36 minutes (mean 22 ± 10minutes). Shunt calculations revealed Qp/Qs of 1.2-3.1 (mean 2.1± 0.5).

The majority of patients 70 (44.0%) had moderate size PDA, while small PDA accounted for 40 (25.2%) cases. Table 1 summarizes the PDA sizes among the study population.

Table 1. Classification of patent ductus arteriosus (PDA) sizes among patients

PDA size category	Numerical frequency (n)	Percentage frequency (%)
Small PDA	40.0	25.2
Moderate PDA	70.0	44.0
Large PDA	49.0	30.8

Chinese duct occluder was used in 46 (28.9%) cases, followed by detachable coils in 41 (25.8%) cases and Searcare Heart^{R} in 36 (22.6%) cases. Other duct occluders used were ADOs, Cardiofix, Lifetech and Occlutech in 14 (8.8%), 6 (3.8%), 5 (3.1%) and 5 (3.1%) patients respectively as shown in Table 2.

Table 2. Summary of the PDA device type used among the study population

Device Type	Numerical Frequency (n)	Percentage Frequency (%)
Amplatzer	14.0	8.8
Embolisation coil	41.0	25.8
Cardiofix	6.0	3.8
Chinese duct occluder	46.0	28.9
Sear care Ht^{R}	36.0	22.6
Lifetech	5.0	3.1
Occlutech	5.0	3.1
Total	159.0	100.0

The size and anatomy of the PDA significantly affected the outcome of the procedure (χ^2 = 7.79; p = 0.04), with more complications noted with occlusion of small and large PDAs compared to moderate sized PDA as shown in Table 3.

Table 3. Effect of PDA size on outcome in the study population

	Patent Ductus Arteriosus (PDA) Size		
PDA Size	**Successful**	**Complicated**	**Percentage complication**
Small	32	8.0	20
Moderate	63	7.0	10
Large	40.0	9.0	18.4

χ^2 = 7.79; df = 3; p = 0.04.

The type of occluder device used for the procedure was further shown to significantly affect the outcome (χ^2 = 16.37; p = 0.02) as shown in Table 4.

Table 4. Effect of Occluder Device Type on Procedure Outcome

Outcome	**Type of Occluder Device used**						
	Amplatzer	***Embo. Coil***	**Cardiofix**	**Chinese**	**Sear Heart ^{R}**	**Life-tech**	**Occlutech**
Successful	12.0	29.0	6.0	45.0	35.0	3.0	4.0
Complicated	4.0	12.0	0.0	3.0	3.0	2.0	1.0
Percentage Complication (%)	2.5	7.6	0.0	1.9	1.9	1.3	0.6

x^2 = 16.37; df 7, p = 0.02

Twenty five (25.0) {15.7%} patients had complications in all. Of these, 12 (7.6%) patients underwent PDA closure with detachable coils and 4 (2.5%) patients had their PDAs closed with ADOs as in Table 4.

Table 5 shows the distribution of complications encountered during the study period. The commonest complication was protrusion of the device into the aorta, seen in 9 (5.6%) of all cases and was seen in all the 3 (1.8%) cases with Chinese duct occluder, Sear Heart ^{R} and ADOs.

Partial hemodynamically insignificant LPA obstruction complicated 5 (3.21%) cases of which 1 (0.6%) cases had ADOs and 4 (2.5%) cases with embolisation coil. None of them had a baseline LPA stenosis.

Temporary loss of peripheral pulse was noted in 3 (1.8%) cases with Embolisation coil. Again, none of the patients had a major blood loss requiring blood transfusion.

Residual leak was noted in five cases with coils and none with Amplatzer device. Within 24 hours, it disappeared in three of them. At one-month follow-up, none had any residual leak.

Three had failure of the procedure that required surgical intervention for closure, the entire cases used embolisation coil. Haemolysis, wire fractures, arrhythmias or death were not encountered in any of the patients studied.

Most complications occurred in the first two years of our experience after establishing the new interventional pediatric program. Incidence of complications was minimal in the remaining three years of the study period as shown in Table 6. This improvement in outcome over the study period, likened to the paediatric cardiologist experience, was significant $\chi^2 = 15.69$; $p < 0.01$.

Table 5. Distribution of complications encountered during the study period

Complications Encountered	Study Period				
	1st year	2nd year	3rd year	4th year	5th year
Residual leak	3	1	1	0	0
Device Embolisation	0	0	0	0	0
Protrusion into Aorta	3	3	2	1	0
LPA obstruction	2	2	1	0	0
Total number of complications	11	8	5	1	0
Number of patients	20	45	40	25	29
Percentage (%) Complication	**55.0%**	**17.7%**	**12.5%**	**4.0%**	**0.0%**

Fig. 1 shows a progressively increasing percentage improvement in the procedural outcome as earlier evidenced by a progressive decline in the incidence of complications in relation to the number of patients over the five-year study period. This percentage improvement curve could be likened to as the cardiologist's learning curve over the period of study.

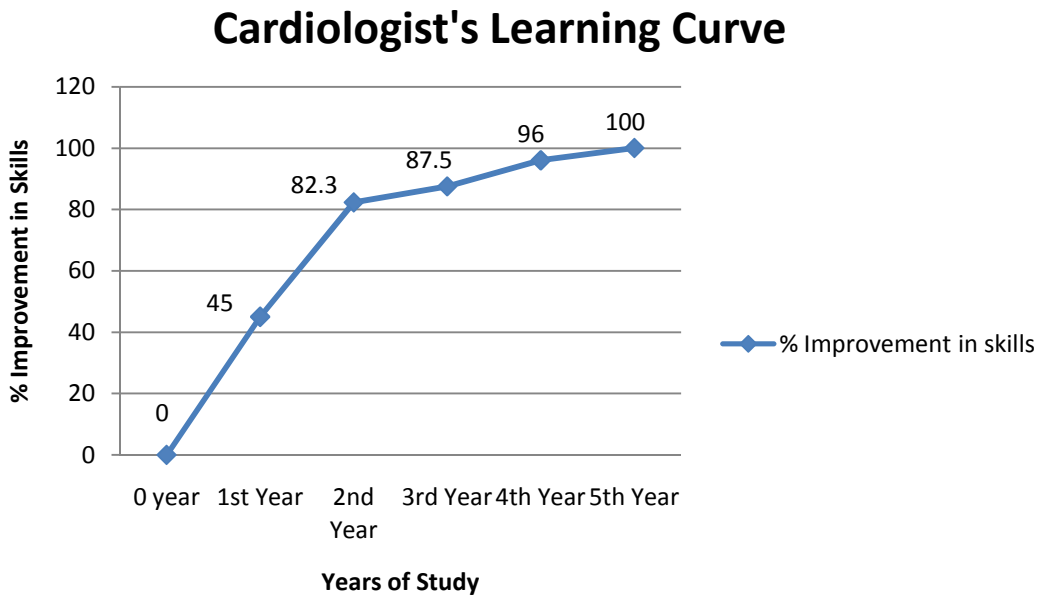

Fig. 1. Cardiologist's Learning Curve

Table 6. Successive Outcome during the five-year study period

Outcome	Years of Study Period					
	2007 (1st year)	2008 2nd year	2009 3rd year	2010 4th year	2011 5th year	Total
Successful	9.0	37.0	35.0	24.0	29.0	134.0
Complicated	11.0	8.0	5.0	1.0	0.0	25.0
No of cases seen per year	20.0	45.0	40.0	25.0	29.0	159.0
Percentage Complication per year (%)	**55.0**	**17.7**	**12.5**	**4.0**	**0.0**	**15.7**

$\chi^2 = 15.69$; df 4, $p < 0.003$.

Correlation analysis was performed to determine the effect of four independent factors (age, weight of the patient, diameter of the duct, and cardiologist's experience) on the occurrence of complications (the dependent factor) and shown in Table 7. Two of the independent variables (cardiologist's experience and duct diameter) showed significant regression coefficients. The coefficient for cardiologist's experience was −0.56 indicating a significant negative relationship between experience and the occurrence of complications. On the other hand, duct diameter showed a coefficient of 0.49 indicating a significantly positive relationship between increasing duct size and increasing incidence of the encountered complications.

Table 7. Correlations values of occurrence of complication and various parameters in the study patients

Factor	Pearson' correlation (r)	p-value
Age (years)	0.32	0.08
Weight (kg)	0.19	0.31
Size of duct	0.49	0.02*
Cardiologist experience	-0.56	0.01*

** Statistically significant*

Table 8 shows a stepwise multiple linear regressions of factors that correlate significantly with occurrence of complication in the subjects. It shows that size of the duct and the experience of the cardiologist was the best predictor of occurrence of complication in the subjects. (r = 0.396, t = 2.186, p = 0.038; r = -0.212, t = - 1.170, p = – 0.252).

Figs. 2 and 3 shows the scatter diagrams, lines of best fit and regression equation for the relationship between the two variables tested and occurrence of complication. The strong linear relationship between occurrence of complication and experience of the cardiologist is clearly depicted.

R square was 0.86 for the effect of experience alone, and 0.88 for the combined effect of experience and PDA diameter on the outcome.

Table 8. Stepwise multiple linear regressions of factors that correlates with occurrence of complication[a] in the subjects

Model	Unstandardized Coefficients		Standardized Coefficients (r)	t	p-value	95% Confidence Interval for B	
	B	Std. Error	Beta			B	Std. Error
(Constant)	1.282	277		4.627	.000	.714	1.851
Size of the duct	-.005	.005	-.212	-1.170	.252	-.015	.004
Experience of cardiologist	.034	.016	.396	2.186	.038*	.002	.066

[a]*Dependent Variable: Occurrence of complication*
**Significant*

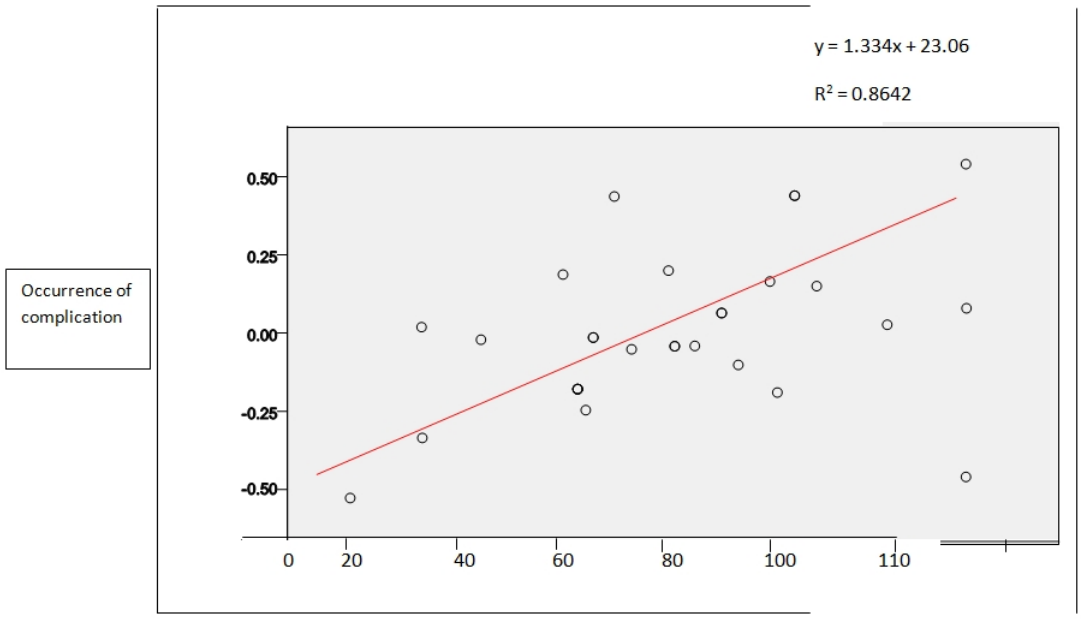

Fig. 2. Partial Regression Plot of occurrence of complication against cardiologist experience

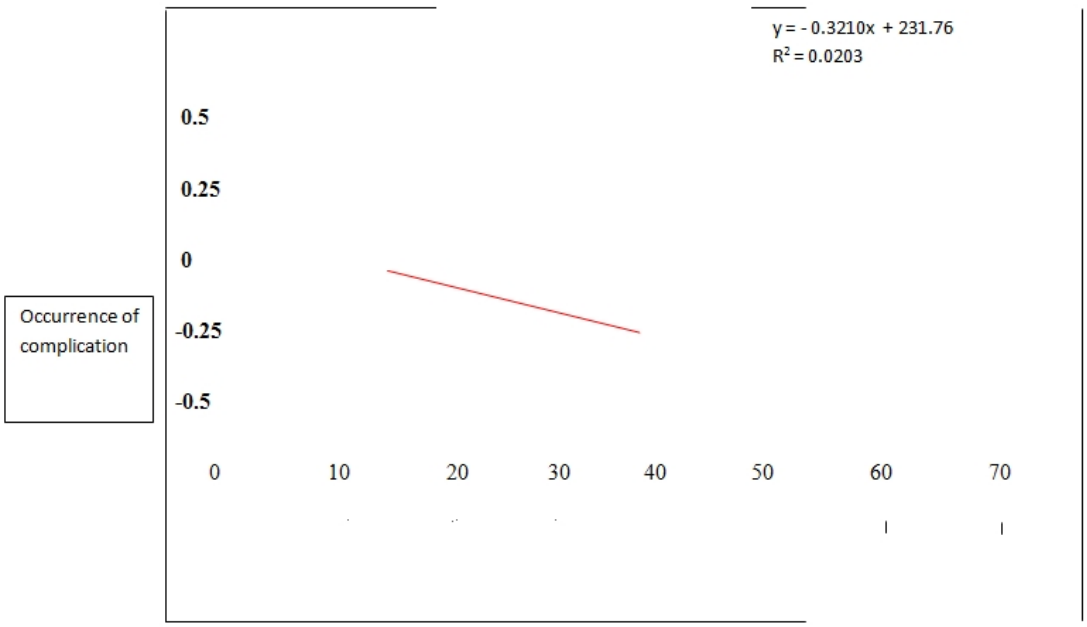

Fig. 3. Partial Regression Plot of occurrence of complication against size of duct

4. DISCUSSION

Trans-catheter closure of PDA is a very effective alternative therapeutic modality to surgical intervention [5,15-17]. We report our experience with 159 cases performed over a period of five years with specific emphasis on complications and their relationship to cardiologist's experience.

Three out of the twenty five complicated cases required surgical intervention, following failure of the procedure. In all the cases, multiple coils were used to close these large PDAs .The reason for this is due to the fact that ADOs were not yet available at the time of the procedure. In retrospect we believe that the cardiologist underestimated the size of the PDA and used smaller sized coils. This shows the importance of the learning curve and the necessity of experience in reducing the incidence of such a complication [7]. Only a few cases may require surgical intervention [18]. This occurred in three out of 159 cases (1.8%) in this study. Still, backup surgical service remains an important life-saving precaution. It is expedient this be available in all interventional pediatric cardiac centers [11].

In this study, we had aortic occlusion in nine cases (5.7%). In three of these cases ADO was used to close the PDA. The main reason was related to the size of the Amplatzer retention disc, which was larger than the size of the ductus ampulla. It is noted in other studies that Protrusion of the occlusion device into the aorta is a common complication of trans-catheter closure of PDA [8, 9]. We observed that large ducts and ducts with small ampulla are more prone to developing protrusion into the descending aorta. A specially designed device is recently used to reduce the incidence of device protrusion into the aorta [18].

Obstruction to the LPA is another common complication of the procedure [8,9]. In our series, five cases (3.1%) developed this complication. One of them had Amplatzer devices and four had coils. None of them had clinical symptoms nor significant Doppler MPA gradient.

We deduced from this study, the occurence of residual leak post operation, it was found in four cases with coils and only one case with Amplatzer device. Within a day, it disappeared in three of them. When we followed them up for one month, none had any residual leak. Thus, this particular complication was minimal in this study. Post-operative residual shunt is a main factor influencing PDA interventional therapeutic efficacy. Its incidences in previous interventional methods are 3%-38% [18]. In our patients, the incidence of residual shunt immediately after operation was 1.8%. The incidence was lower than that reported in other studies [8,17,18]. The occluder is returnable, if the closure efficacy is found to be unfavorable or the location is not good after implantation, the occluder can be pulled back and replaced with another one or the location can be adjusted, so as to ensure success rate and satisfactory efficacy and reduce operative complications [18]. Elimination of the residual leak is very important to prevent haemolysis [19-21] .The Multicenter USA Amplatzer patent ductus arteriosus device trial reported periprocedural and 1-year outcomes in 484 patients from 25 U.S. centers [19] .Of the 484 patients enrolled, the Amplatzer device implantation was not attempted in 45; due to the size of the PDA or the morphology of the PDA was more suited for treatment with a coil. Of the 439 patients in whom implantation was attempted, the device was successfully implanted in 435 patients (99%). Immediate post procedure occlusion was reported in 76% of patients, which increased to 89% on post procedure day 1 and to 99% at 1 year. At last evaluation, PDA occlusion was documented in 98% of patients. At 1-year follow-up patients have no evidence of a left to right shunt on echocardiography. Complications were uncommon, with one peri-procedural death and major events reported in 2.3% of patients. Examples major events include device embolization, partial obstruction of the pulmonary artery and bleeding requiring transfusion. Minor events occurred in 7.1% (31/439) of patients [22].

Other case series of both the Amplatzer device and the Gianturco coils report similar outcomes [10,23-25]. This study varies in terms of patient selection, types of device, and outcomes reported. However, it is consistent in reporting a high rate of procedural success, a high rate of successful closure of the PDA, and a low rate of serious complications.

Some number of non randomized comparative trials has been documented; for instance, Wang et al. [12] compared outcomes among 214 patients undergoing percutaneous closure with coils and 134 patients undergoing closure by an occluder device. Patients were selected for either group by the size of the PDA, with coils utilized for small to moderate PDAs and the occluder device utilized for larger PDAs. The procedural success rate was high for both the coils and the occluder with no significant difference between groups. There were higher complication rates reported for the coil group. Distal embolization occurred in 8.9% of patients in the coil group compared with 1.5% patients in the occluder group. Pulmonary artery stenosis occurred in 4.2% patients in the coil group compared with zero in the occluder group.

The results documented in our series are in line with the results reported in many other interventional paediatric cardiac centers around the world [7,13,15].

It is noted from our series that there exists a significant negative relationship between experience and complications. The effect of the learning curve was responsible for 93% improvement in the procedure outcome. Experience gained throughout the five-year study

period was reflected on better case selection, accurate sizing of the duct length and diameter, better choice of closure device type and size, and confirming the position of the device before releasing and deployment. This is highly indicative of the importance of experience and the rising learning curve in reducing the incidence of complications during trans-catheter PDA closure. The results also underline the importance of surgical backup to safeguard against certain complications.

5. CONCLUSION

The use of percutaneous closure devices has become the procedure of choice for closure of patent ductus arteriosus in suitable patients. The learning curve and accumulating experience play an indispensable role in choosing the proper device and its size. This is necessary to minimize the complications.

CONSENT

All authors declare that 'written informed consent was obtained from the patient for publication of this case report and accompanying images.

ETHICAL APPROVAL

All authors hereby declare that all experiments have been examined and approved by the appropriate ethics committee.

COMPETING INTERESTS

The authors hereby declare that no competing interests exist.

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