# CLINICAL, ECHOCARDIOGRAPHIC, HAEMODYNAMIC AND ANGIOCARDIOGRAPHIC DETERMINANTS OF THE SIZE AND NUMBER OF COILS FOR TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS USING MULTIPLE COILS

*Thesis submitted*
*in partial fulfillment of the requirements*
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*By*

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# DECLARATION

I, Dr.Sajeev.C.G, hereby declare that this thesis "CLINICAL, ECHOCARDIOGRAPHIC, HAEMODYNAMIC AND ANGIOGRAPHIC DETERMINANTS OF THE SIZE AND NUMBER OF COILS FOR TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS USING MULTIPLE COILS" has not been previously submitted by me for the award of any degree, diploma, title or recognition.

**Calicut** **Dr.Sajeev.C.G.**

## CERTIFICATE

This is to certify that this report is an authentic work carried out by Dr.SAJEEV.C.G. under my supervision and guidance and that thereof no part of it has been previously submitted anywhere for any other degree.

**Calicut**

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**Dr.C.G.Sajeev**

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# INTRODUCTION

## Introduction

Congenital cardiovascular disease is defined as an abnormality in cardiocirculatory structure or function that is present at birth, even if it is discovered much later. Congenital cardiovascular malformation usually results from altered embryonic development of a normal structure or failure of such structure to progress beyond an early stage of fetal development. The true incidence of congenital cardiovascular malformation is difficult to determine accurately, however it is estimated that about 0.8 percent of live births are complicated by a cardiovascular malformation[1,2]. Cardiac catheterization is found to be very useful in diagnosis and surgical decision making. With the advent of echocardiography, magnetic resonance imaging (MRI) and fast computed tomographic (CT) methods truly diagnostic cardiac catheterization have become rare[3]. However, therapeutic catheterization has become popular. Balloon atrial septostomy[4] was the first catheter intervention that proved useful in treating CHD (congenital heart disease) and it remains the standard initial palliation in many infants with D-TGA (D-Transposition of great arteries) unless the arterial switch operation is performed immediately. Many transcatheter techniques are now used successfully to treat CHD : blade atrial septostomy, device or coil closure of patent ductus arteriosus (PDA), closure of atrial septal defect(ASD) and patent foramen ovale, transluminal balloon dilation of pulmonary and aortic valve stenosis, radiofrequency perforation of pulmonary valve atresia, balloon expandable intravascular stents for right ventricular outflow tract,

pulmonary artery, aortic coarctation, other vascular stenosis and device occlusion of unwanted collateral vessel and arteriovenous fistula. These all have become treatment of choice in some centres with their capabilities. Patent ductus arteriosus represents the persistent patency of the vessel that normally connects the pulmonary arterial system and the aorta in the fetus. Surgical ligation or division of the PDA was the initial mode of management of these patients. Transcatheter closure of PDA has been performed for more than 30 years[5]. This method is now widely accepted as safe and effective alternative to surgery in many cardiology centres[6,7]. Transcatheter closure can be done either using devices or coils. Devices are quite expensive and in many developing countries device closure costs far more than surgical closure. Transcatheter closure of PDA using Gianturco coil is now a common practice in many cardiology centers as this is a simple and inexpensive technique. Hence this method is of particular interest to developing country like India. Minimally invasive surgery for the closure of a large patent ductus arteriosus using an extra pleural technique has been suggested as an alternative to interventional cardiology procedures[8]. However they have not been popular. Selection of the appropriate size of the coil needed is the most important aspect of this technique. There is no universally accepted criterion for the selection of the coils. In the present study we analysed the clinical, echocardiographic, hemodynamic and angiocardiographic parameters of the patients who underwent successful coil closure to find out the determinants of selection of the size and number of coils.

2.A

# REVIEW OF LITERATURE

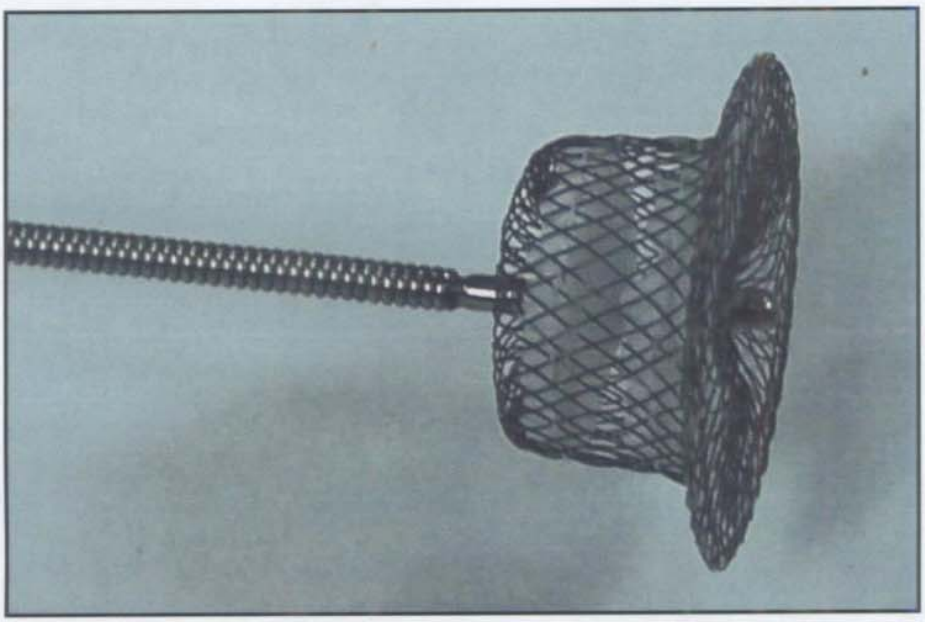
## Review of literature

In 1593, Giambattista Carano described the ductus arteriosus in a book on the great cardiac vessels of the fetus[9]. The name of Leo Bottali nevertheless came to be associated with the arterial duct even though Bottali applied the term ductus to the foramen ovale[9]. It was not until Rokitansky's hand book (1844) and his beautifully illustrated monograph (1852) that patent ductus arteriosus came to be well recognized as an isolated congenital malformation[10]. The incidence of isolated patent ductus is approximately 1 in 2000 live births[10]. The ductus is derived from the 6th aortic arch. From the 6th week of fetal life onwards, the ductus is responsible for most of right ventricular outflow. It contributes to 60% of total cardiac output throughout fetal life. The ductus arteriosus usually closes within 2 or 3 days after birth and becomes the ligamentum arteriosum. Persistence of this fetal structure beyond 10 days of life is considered abnormal[11]. The pulmonary orifice of the ductus is located immediately to the left of the bifurcation of pulmonary trunk. The aortic end of the duct lies immediately beyond the origin of the left subclavian artery. The patent ductus is usually largest at its aortic insertion and may have the shape of a truncated cone. This is so because the closure begin at the pulmonary artery end[12,13,14,15]. On rare occasion, the course of the ductus is from a right aortic arch above to the right pulmonary artery below[16].

**Transcatheter Closure of PDA:**

Transcatheter interventional procedures for the treatment of congenital heart defects have become increasingly popular. The patent ductus arteriosus is a common congenital defect that is amenable to transcatheter occlusion. Transcatheter closure of a PDA and other cardiovascular defects has many advantages over surgical closure, including avoiding general anaesthesia and a thoracotomy procedure, less need for blood transfusions, decreased morbidity, less psychological trauma (especially in children) shorter length of hospitalization and decreased total hospital cost. Many patients who would benefit from transcatheter device occlusion have other cardiovascular defects, which require additional surgery. Trans-catheter closure of defects avoids the adhesions from surgical closure. These adhesions complicate subsequent surgeries and may preclude other procedures.

The devices and techniques for transcatheter occlusion of the patent ductus arteriosus date from the efforts of Porstman[5] who introduced the transcatheter approach in 1967 using Porstman ductal occluder device. They were followed by Rashkind and Cuso[17] later by Sideris[18] and recently by Amplatzer[19]. Several devices have been used to close the PDA; the clamshell device was available during limited investigational trials[20]. The first device was more of a plug; the later devices were of the shape of a double umbrella.



*Amplatzer Duct Occluder*

The Amplatzer device is a combination of a plug and a double umbrella. The youngest of the new generation of closure materials and most commonly in use, are the different types of coils as well as Amplatzer PDA device. Good results were obtained with Amplatzer device. Wang et al [21] studied the acute and follow-up results of transcatheter closure of moderate to large patent ductus arteriosus with the Amplatzer duct occluder. Two hundred and thirty seven of their patients underwent attempted transcatheter closure of PDA, of whom Amplatzer duct occluder was used in 68 patients with moderate-to-large-sized PDA. They defined moderate sized ductus as ductus diameter > or =2.5 mm (> or =3 mm in early phase of their study) in infants and young children, or > or =4 mm in adolescents and adults. The device selected was generally at least 1-2 mm larger than ductus diameter. The ductus diameter ranged

from 2.5 to 8.5 mm (4.1 $\pm$ 1.3 mm).They successfully implanted Amplatzer ductus occluder in 66 out of 68 patients. The size of device deployed ranged from 4 to 12 mm (6.3 $\pm$ 1.6 mm). The causes of failure in 2 of their patients included calcification of ductus resulting, in failure in advancing a sheath to descending aorta in one patient and kinking of a Cook sheath in the other. Distal embolization of the device occurred in one of their patients. No other significant complications occurred in their patients. Complete occlusion was achieved in all patients during three months follow up. They did not observe left pulmonary artery stenosis in any of their patients. They concluded that transcatheter closure of moderate-to-large-sized ductus with Amplatzer ductus occluder is effective and safe. However Amplatzer device is expensive. The large size of the delivery systems necessary for these devices, the relatively frequent residual shunting following placement and the expensive nature of these devices led to the popularity of alternative technique for transcatheter closure of PDA using stainless steel coils. Gianturco coils[19] were introduced in the 1970s and were used by radiologists for occlusion of tumour vascular supplies. During the 1980s, pediatric cardiologists began employing Gianturco coils for occlusion of aortopulmonary collateral vessels in patients with complex Tetralogy of Fallot.[23] Experience with collateral occlusions included successful closures of some vessels anatomically similar to PDAs. In this setting small PDA was first closed using Gianturco coils by Cambier et al[24]. In 1993 Lloyd et al[25]

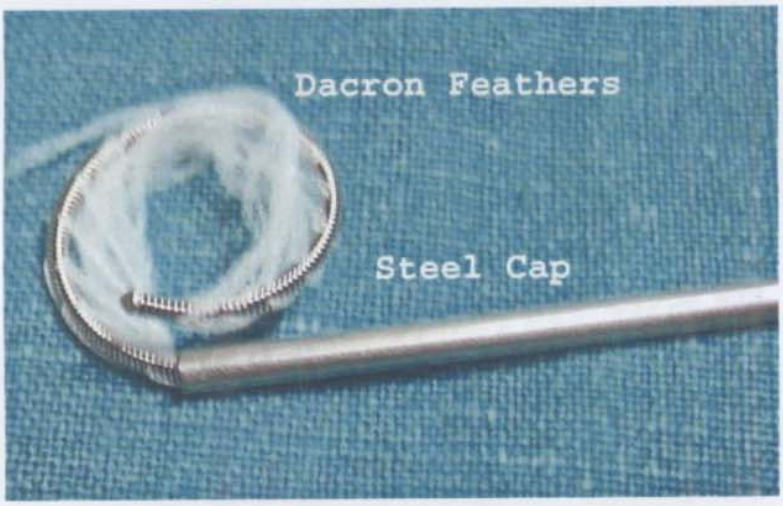
reported the use of Gianturco coils in patients with larger ductus diameters. Gianturco coils became widely used to close small and moderate size PDA by the middle of the 1990s[25] .By the end of the decade, Gianturco coil occlusion of restrictive PDA has become the standard treatment[26]. Moderate to large PDA in selected infants and small children can also be closed using bioptome assisted technique[27]. PDA coil closure can be combined with other transcatheter procedures like atrial septal closure using Amplatzer septal occluder[26].Coil occlusion has been found to be successful for closure of residual shunts after surgical closure of PDA in experimental studies[27].Zou et al[28] compared the results of transcatheter closure for patent ductus arteriosus by different devices in children. Seventy-eight cases of PDA in children (7 months to 14 years old), were included in their study. They used conventional technique of PDA closure. Among these patients, 16 were treated with coils, 9 with Amplatzer duct occluder (ADO), and 53 with native produced PDA occluders. TTE (Transthorasic echocardiography) examination on the next day of the procedure showed that PDAs were completely occluded in 76 cases, while the other 2 cases treated by coil had minimal residual shunt. Sixty-four patients, who had enlargement of the left ventricle before the operation, showed obvious decrease of the cardiac size. At 3 months, TTE examination showed that the closure of PDA was complete, and the left ventricle size was normal in 77 cases, while one case treated with coil had minimal residual shunt, which persisted for more than 4 years. The 3 - 80

months follow-up showed that the closure of PDA was complete in 77 cases. They concluded that the usual procedures of transcatheter closure for PDA are effective and safe with ADO, native produced occluders and coil in children.

**Coil closure of PDA**

There are three types of spiral coil available for transcatheter occlusion procedures (1) Duct occlude coils (PFM, Cologne, Germany) have been specifically designed for closure of PDA; (2) Target coils (Target therapeutics, San Jose, CA) have been designed primarily for neuroradiologic procedure and they are too small and/or too flexible for closure of most PDAs. (3) Gianturco reported the first spiral coils, designed for vascular occlusion in 1975. The design of these coils has changed little since the modification of 1979 and 1980, and the coils have become to be known as Gianturco coils.[30,31] Gianturco coils(Cook incorporated, Bloomington,IN) are made from very small diameter stainless steel wire and Dacron (Dupont, Wilmington, DE) fiber. The wire (diameters: 0.004, 0.006 or 0.008 in) is tightly wound into coils forming a straight length of wire-like or primary coils. These primary coils have diameters (0.0.15, 0.021, 0.028 and 0.043 in). Coil loops or secondary coils with diameters ranging from 2 to 20mm are made by a mechanical process using lengths of the primary coils. A steel cap with a diameter equal to the primary coil diameter is placed on the end of each coil. Dacron feathers are embedded at regular intervals between primary coils

to increase thrombogenicity[32].After the implantation of the Gianturco coil, occlusion occurs as a result of thrombus formation and subsequent organization. The completed coils have nominal diameters (0.025, 0.035, 0.038 and 0.052 in), which are the diameters of the combined masses of the primary coils and dacron feathers. The nominal diameters are the minimum catheter lumen diameters necessary to implant the coils.




*Gianturco coil*

**Size of the coils:**

On the packages of the Gianturco coils, the manufacturer includes the following information in this order: core diameter of the coil, the extended length of the coil in centimeters, and finally the loop diameter in mllimetres. This information is very important while selecting the right size of the coil for a specific PDA. There are at least 15 different loop sizes and lengths of the Gianturco coils, from the smallest diameter of 1mm to the largest of 15mm. These coils can be pushed out of its cases by a normal 0.038 inch wire before deployment.

**Number of loops:**

When the ductal ampulla is not long enough, it is important to know the final number of loops, before selecting the right coil. The number of loops can be calculated from the diameter of the loop and extended length of the coil. Number of loops = coil length/circumference of each loop. The circumference of each loop can be calculated from the coil diameter.

**Detachable Coils:**

A detachable Gianturco coil delivery system is also available (Flipper Cook or Cook detachable coil) that can facilitate some occlusion procedures because the coil can be withdrawn, if it is not in optimal position[33]. There are less than 10 different sizes. The smallest is a coil with 5mm diameter and three loops and the largest coil have 8mm diameter and five loops. Detachable coils have a screwing mechanism and have the advantage over Gianturco coil in that it can be retrieved and repositioned in case it was not properly positioned in the first attempt. Galal et al[34] in their study of 272 children comparing the safety profile and clinical results of cook detachable coils and Gianturco coils have concluded that large ductus can be treated earlier in life safely with detachable coils. Short-term complete occlusion rate was lower in the Cook detachable coil group. Bravo et al [35] studied the success rate and safety of percutaneous closure of patent ductus arteriosus with a detachable coil in forty-one children with small- to moderate-size PDA

(maximum diameter < or = 4 mm).They assessed their results by angiography and echocardiography. The mean age was 2.0 ± 1.3 years (range 0.6 to 5.6 years); mean weight was 10.0 ± 3.4 kg (range 4.5 to 18.0 kg). The mean minimum diameter of the PDA was 1.7 ± 0.6 mm (range, 0.5 to 4.0 mm). The coil was deployed in 39 of 41 patients (95%). The mean coil/PDA ratio was 3.41 ± 1.1. They observed angiographic cessation of blood flow through the PDA after coil insertion in 18 patients; 18 patients had residual shunt, 3 mild shunt and 2 moderate shunt. No complications were observed during the procedure. Thirty-five of thier patients showed absence of blood flow through PDA 24 hours after coil occlusion by echocardiography. The other four patients with residual shunt showed flow cessation after 2 months in two patients and after 6 months in the other two. Two of their patients had detachment of the pulmonary edge of the coil resulting in failure of the procedure. Mean follow-up at 29.5 ± 16.5 months showed no residual blood flow through the occluded PDA, except for one patient. They concluded that PDA coil occlusion is a safe, effective, and cheap procedure. They recommend that PDA coil occlusion should be the elective method for PDA closure in patients older than 6 months of age with small- to moderate size PDA (< or = 4 mm). They were of the opinion that procedure in newborn infants and patients with larger PDA must be made with a different type of occlusive device.

**Costs:**

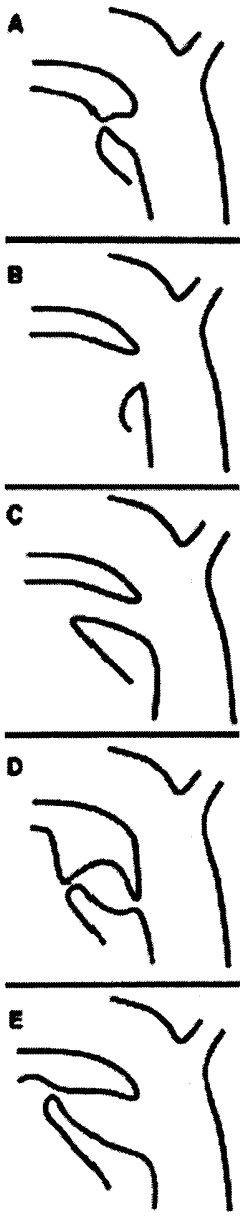
The Gianturco coil is relatively inexpensive. The procedure of using a detachable Cook coil costs about two times the price of Gianturco coils as the access set makes up half of the price of the materials used. The Amplatzer device is almost 10 times as expensive as the detachable coils. The cost of Gianturco coil occlusion is comparable to surgical ligation. Prieto et[36] al in their study of 36 patients comparing the cost and clinical outcome between the transcatheter coil occlusion and surgical closure of isolated PDA have concluded that transcatheter coil occlusion is as effective and less costly than surgical closure[30]. Similar observations were noted by Janokar et al [37] in their study of transcatheter closure of patent ductus arteriosus with the use of Rashkind occluders and/or Gianturco coils. They noted the long-term follow-up of transcatheter closure of patent ductus arteriosus with 2 different modalities in 123 patients of diverse ages.In their study123 patients underwent transcatheter PDA (1.9 to 7.5 mm) closure at a mean age of 6.8 $\pm$ 8.9 years (range 0.06 to 52) and mean weight of 20.9 $\pm$ 17. 6 kg (range 2.7 to 83). They used Rashkind device in 60 patients, the Gianturco coil(s) in 60, and the Rashkind device with a coil in 3 patients. At six months closure rate for the Rashkind group was 77% versus 90% for the coil group. They had to do second procedure for residual shunt in 19 (14 in the Rashkind group and 5 in the coil group) and a third procedure in 1 patient from the Rashkind group. A balloon wedge catheter was used in 50 of 78 coil

procedures to prevent coil embolization. They had embolization of one device and11 coils to the pulmonary arteries. They could retrive the device and all coils except 2 successfully. Overall, 122 (99%) patients showed complete PDA closure. They concluded that transcatheter closure of PDA is feasible in infants as well as in patients >50 years of age without significant complications. The coils are easy to implant, less expensive, and multiple coils may be used in moderately large (>3.5 mm) ducts more effectively than with the Rashkind device. The use of a balloon wedge catheter prevents immediate coil embolization. Multiple procedures are feasible and safe to achieve complete closure.

**PDA types and transcatheter closure:**

The anatomy of PDA is very important in those patients undergoing transcatheter closure. This is more so when coils are used compared to the Amplatzer device. Krichenko et al [38] attempted to present the classification of the PDA and study its implication for the transcatheter closure of the duct in the era of the Rashkind double-umbrella device. According to the evaluation of 79 angiograms, the authors stated that the most suitable type of PDA for the Rashkind device is of type A or type B (conical and window-like short conical). The type C (tubular) was regarded as more problematic. Type D (multiple constrictions) can be safely occluded. Type E (Very large conical type) was also difficult for device closure. Later angiographic studies have revealed that there is marked variability in the anatomy of the duct. The

important factors to be considered during the angiographic study of the ductus include the narrowest diameter, the length of the duct and the largest diameter of the ampulla from the aortic end. Therefore, the different types of PDA vary between the following extremes. There is the window-like PDA, the tubular-shaped PDA, the convex PDA, the conical PDA and the needle like PDA. In general, it is thought that the tubular PDA window-like PDA, and convex PDA with very large ampulla are not safe for closing using a coil. Coil deployment needs a long ampulla and hence the conical type PDA, which is the most common type encountered, qualifies very well for coil occlusion. Moore et al[40] in their study found that type B ductus was associated with development or persistence of residual shunt at intermediate follow up.




Type A(conical) ductus with well defined aortic ampulla and constriction near pulmonary artery end

Type B.(window like) very large ductus with very short length

Type C (tubular )ductus without constrictions

Type D (complex) ductus which has multiple constrictions

TypeE (elongated) ductus with the constriction remote from anterior edge of trachea

Variatations in PDA configuration-Classification of Krichenko et al

**PDA closure in small infants.** The procedure can be technically more difficult in infants < 10 kg. They have larger PDA relative to their overall size which my lead to more complications or failure to close. The infants requiring early closure may have congestive heart failure, pulmonary hypertension or failure to thrive and all these complicate the procedure.

**COIL SELECTION AND DELIVERY**

There is no universally accepted method for coil selection. Coil selection is based on measurements made from a lateral aortogram, hemodynamic significance and patient size. The following are the general guidelines[40].

(1) Loop diameter must be at least twice the minimum PDA angiographic diameter.

(2) The dimension (maximum diameter and length) of the aortic ampulla guide selection of the upper limits of coil loop diameter and number of coil loops.

(3) Maximum coil loop diameter should be less than or equal to the maximum dimension of aortic ampulla.

(4) Minimum of two loops should be placed in the aortic ampulla distal to the narrowest part of PDA. More than three aortic side loops are not necessary and may result in protrusion into the aortic lumen.

(5) Coils should have a total of three to four loops. Most of one loop should be placed on the pulmonary side and remaining loops

should be positioned on aortic side of the ductal narrowing. In summary, loop diameter should be greater than twice the minimum PDA diameter and less than the maximum diameter of the aortic ampulla.

There is general agreement that the coil diameter should be at least twice the size of the narrowest diameter of the PDA. The ductal ampulla should be filled with as large and as many loops as possible. The length of the duct, diameter of the duct from the aortic ampulla end and shape of the duct also influences the decision making. The conical type which makes about 70% of all PDAs are good for coils, while the convex type (very large ductal ampulla in relation to the narrowest diameter and length of the PDA) do not always qualify for the coils. In addition tubular type of PDA does not qualify for coil occlusion.The following approximate guidelines was followed for coil size selection by Kumar et al [29].

**Coil size selection**

(1) 3 to 3.5 mm duct : Single 0.52" - 6mm x 8cm

(2) 3.5 to 4 : Single 0.052" – 8mm x 8cm

(3) 4 to 4.5 : Two 0.52" – 8mm x 8cm or
6mm x 8cm
+ 8mm x 8cm

(4) >4.5 : Two 10mm x 10cm (or 8mm, 10mm)

Combination of 0.052" and 0.038"

**Procedure for catheter based deployment of coils:**

**1) Free Gianturco coils**

1) Direct deployment – Anterograde

- Arterial approach

2) Bioptome assisted or snare assisted delivery

**2) Detachable coils:**

**Direct delivery of free Gianturco coils:**

In this procedure, aortogram is done by a 4F/5F pigtail introduced through the arterial access. A 5F MPA catheter (tapering tip) is used for delivery of coils through the venous access. The catheter is placed across the duct into the descending thoracic aorta. The coil is introduced into the catheter and pushed forward using the soft end of a Teflon wire. One to one and a half loops are pushed out of the catheter tip placed in the descending aorta. The catheter with coil is then withdrawn into the duct ampulla. The catheter tip is then slowly withdrawn to the pulmonary artery with less than half a loop of the coil deployed in the pulmonary artery. A check angiogram is done at the end of five minutes. Additional coils if required are deployed from arterial side. Because of poor stearability and the relatively high rate of embolization in early phase of using this technique, different approaches were proposed. The retrograde approach was propagated by Cambier et al[24,41]. The anterograde deployment was introduced by Hijazi et al[42].The deployment using a nitinol snare to hold the extruded end of the coil in position during the

procedure was introduced by Sommer et al[43].Hayes et al[44]suggested holding the coil by biopsy forceps during deployment. Other suggested methods include use of tapered tip delivery catheter [45] and use of temporary balloon occlusion during the delivery .Moore et al [46] used temporary balloon occlusion during coil delivery in all PDAs, which will accommodate simultaneous passage of two catheters. This technique involves the passage of a balloon wedge catheter pro-grade across the ductus. A straight wire stabilizes this catheter. A Judkins right coronary catheter is passed retrograde across the ductus until its end hole is in the main pulmonary Artery. The balloon is inflated with carbon dioxide and it is pulled into the aortic ampulla with moderate tension on the catheter. With the PDA occluded by the balloon, the coil is advanced through the delivery catheter. One half to two thirds of a loop is pushed out of the catheter. Catheter and loop are pulled towards the ductus. While maintaining the half to two thirds loop on the pulmonary side, the coil is delivered across the ductus and released into the aorta. The balloon holds the coil in place preventing "advancement" of loops into the pulmonary artery as well as pulling of the coil out of the pulmonary side of the PDA. Most of the coil loops are thus delivered into the aorta. These loops gather along the aortic side of the balloon. The balloon stabilizing wire is removed and the balloon is slowly deflated. Gradual deflation allows the balloon settling into the aortic ampulla. This technique facilitates consistent controlled placement of coils using the

catheters needed for the simple diagnostic study performed prior to coil occlusion. Additional specialized catheters or devices are not required. Delivery of all coils from the arterial side has also been reported[47].Liang et al [48] reported use of retrograde approach without heparinization using the Gianturco coil (Cook Cardiology, Bloomington, Indiana) to close patent ductus arteriosus .In their study forty consecutive patients (30 females, 10 males) underwent transcatheter closure of a PDA via the right femoral artery approach without heparinization. Patients ages ranged from 7 months to 55 years (median, 6.8 years); weights ranged from 7.8 to 65 kg (median, 18.3 kg). Twenty-one patients had cardiomegaly (n = 21), congestive heart failure (n = 10), or both (n = 10). The PDA size measured 0.8 to 4.5 mm (median, 2.6 mm) at the narrowest diameter; the mean Qp/Qs ranged from 1.0 to 2.6 (1.4 $\pm$0.4). They used coil diameter 1.7 times the narrowest PDA diameter and the length of the coil was sufficient to produce 4 or 5 loops. In their study successful coil placement was accomplished in all 40 patients. Thirty-five patients (87.5%) underwent single coil implantation, 2 patients (5%) had 2 coils, and 3 patients (7.5%) had 3 coils. Complete ductus occlusion was achieved in 80% of cases at the end of the procedure, while 8 patients had minimal shunt detected by aortography or echocardiography. During follow up, occlusion rate increased to 87.5% by the next day, 90% by 1 month, 92.5% by 3 months, 95% by 6 months, and 97.5% by 9 and 12 months. Minimal residual shunt was present in only one patient at 12

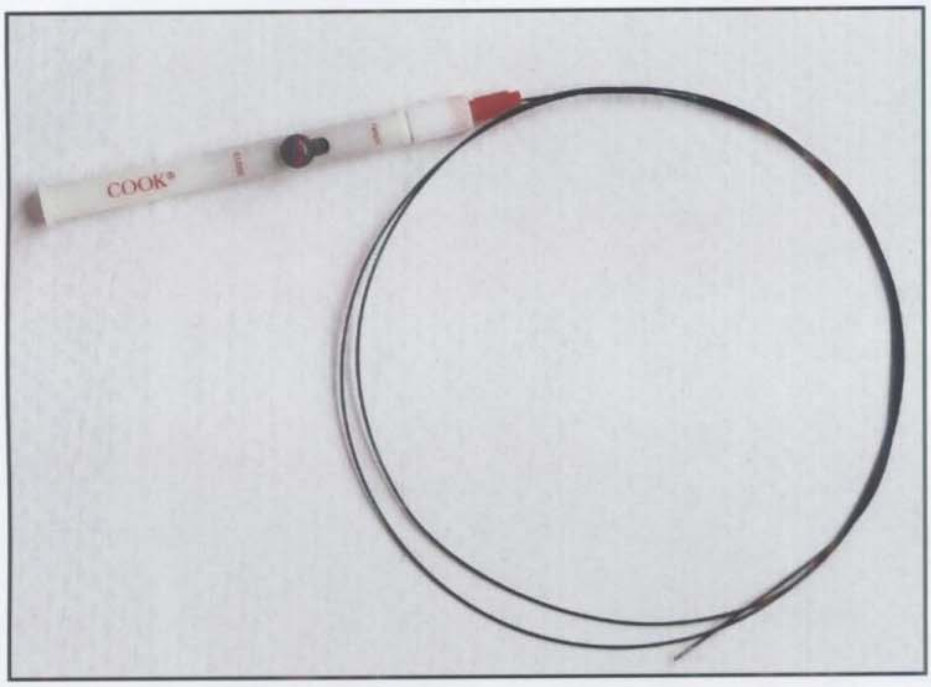
months follow-up. No patient had thromboembolism, endocarditis, coil migration, diminished femoral pulse or hemolysis. Their preliminary results suggested that retrograde transcatheter closure of PDA with the Gianturco coil without heparinization is feasible, safe and efficacious. A single coil allowed complete occlusion of 3mm PDA. However most of the later studies used heparinization. Anil et al [49] used venous access alone in their selected patients with small PDA. They attempted coil occlusion of patent arterial ducts in 104 patients without arterial access. The patients were aged from 3 months to 14 years. The median age was 2 years and weighed 3-35 kg. The median weight was 9.8 kg. The duct diameter at pulmonary artery insertion was 1.8-3.5 mm. The patients were selected on basis of echocardiographic evaluation of duct diameter at pulmonary artery insertion and morphology of the ampulla. Doppler color flow imaging was used in the catheterization laboratory to confirm duct closure. However in their study arterial access was required in 21 patients. The reasons cited were accidental puncture, failure to obtain venous access in 1 patient, aortic embolization in 3 patients, poor echocardiographic images in 2 patients, requirement for additional coils in 8 patients and, failure to cross the duct from pulmonary artery in 2 patients. The fluoroscopic time in their study ranged from 2.2 to 20 min with a mean of $5.3 \pm 3.8$ min. They could obtain immediate closure in 98 patients and this included 79 of the 83 patients in whom arterial access was avoided. Color Doppler evaluation done 3-24 h later showed residual

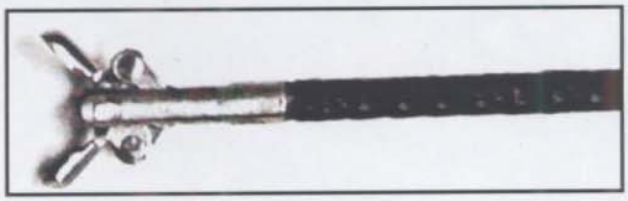
flow in 2 patients. Four of their patients had new-onset left pulmonary artery turbulence with peak gradients below 5 mm of mercury. In their study coil embolization occurred in 6 patients and they could retrieve all coils. At three-month follow up, of 78 patients, small residual ductal leaks were seen in 4 patients, 2 of whom had leaks at 24 h. Two of their patients had recanalization of the ducts. They concluded that it is feasible to occlude small patent arterial ducts with coils using venous access alone in carefully selected patients with excellent immediate and short-term results.

**Bioptome Assisted Delivery of Gianturco coils:**

Direct delivery of free Gianturco coils is technically more challenging and is associated with longer learning curve. The lack of control over the coils may lead to embolization of the coil into the pulmonary arteries or aorta. In large ducti, more often multiple coils may be necessary, which can be technically more demanding. Hence bioptome or snare assisted methods of delivery of the coils were introduced. This method is safer since there in control over the coils till the end of the procedure and coils can be easily retrieved if the deployment is suboptimal. Bioptome can also be reused. Bioptome assisted simultaneous delivery of multiple coils intertwined at the ends of the coil has been reported [50, 51]. Wang et al [52] in their study of transcatheter closure of PDA in adolescents using gianturco coils concluded that the procedure was safe and feasible in majority of adolescents and adults.

However high embolization rate was noted in duct diameter >4mm. They were of the opinion that controlled release coils or Amplatzer duct occluder may be a better choice in that group of patients. Bioptome assisted technique is an alternative to Amplatzer duct occluder in these group of patients as it provides good control over the coils.



*Bioptome with jaws open*

In this procedure a long sheath is positioned across the duct into the descending aorta through venous access. Heparinization with 50 units/kg of intravenous heparin is used.

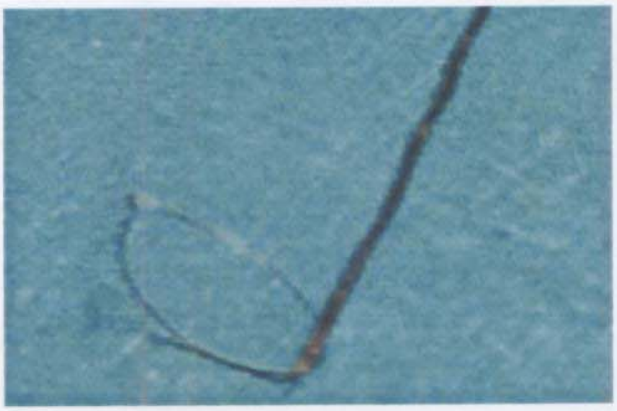
Appropriate coils are selected. If two or more coils are needed they are stretched at the tip and the ends are intertwined securely with a

hemostat. The intertwined coils are held by 3F or 5.2F bioptome (Cook Inc). The coils are then loaded into a short sheath. The assembly is then pushed all the way through the long sheath into the aorta, so that the tip of the bioptome was at the tip of the sheath and the whole coil length dangling in the aorta. The assembly is then pulled back towards the pulmonary artery. The positioning of the coils is guided by the tracheal air shadow that served as a landmark. The compaction of the coils and the loss of oscillatory movement suggest that the coil is positioned satisfactorily. At this time a resistance is felt. The sheath is withdrawn into PA and bioptome is carefully pulled till ½ turn of coil came into pulmonary artery. The delivery method essentially uses the coil mass as a plug to occlude the duct. Aortogram is done to check for residual flow. If the deployment was unsatisfactory the coils are withdrawn into the sheath and redeployed. If the closure is complete, the jaws of the bioptome are opened, releasing the coil. If the closure was incomplete, the duct was re crossed from arterial or venous route and more coils are deployed till complete closure. Attempts to hold the coils for longer period are typically avoided, because this often results in one or more coil turns being inadvertently pulled into Pulmonary artery. Additional 0.038 coils can be delivered from the arterial side using a 4F right coronary catheter if a well defined jet of residual flow is demonstrable. Small diffuse whiffs of flow can be accepted.

**Snare Assisted Technique:**

This technique is essentially same as that of bioptome assisted methods, except that in this technique a nitinol snare is used to "hold" the coil during its delivery[53]. The advantage of the technique is also similar to that of bioptome assisted technique: improved control of the coil throughout the procedure, ability to make fine adjustments in coil position, the ability to test coil stability before release, and the ability to remove a sub-optionally placed coil without releasing it into the circulation. Using a cardiomarker catheter (USCI, Billerica, Massachusetts) or a magic guide wire (Medi-tech, Watertown, Massachusetts) as a measurement reference, the minimum PDA diameter, aortic ampulla dimension, and ductal length are measured. A Berenstein catheter (Medi-tech) is advanced in retrograde fashion through PDA into the main pulmonary artery and is snared with a 4F,10mm diameter nitinol snare (microvena Cor, White bear lake, Minnesota) advanced from the femoral vein. A Gianturco coil (Cook, loomington, Indiana) is selected with a helical diameter 1.6 to 2 times the minimum PDA diameter and with length sufficient to form at least three loops and is advanced through the Berenstein catheter. Approximately ¼ loop of coil is extruded out of the catheter. The snare is loosened and withdrawn slowly to grab the distal 2 to 3 mm of the extruded coil tip which is devoid of dacron fibers. Snaring more than this length risks entangling the snare in dacron fibers of the coil and may make subsequent coil release difficult. The Berenstein-coil –snare unit is adjusted as a single

unit so that only the snare and extruded coil segment remain in the main pulmonary artery. The remaining coil loops are then delivered into the aortic ampulla. By placing gentle traction on the snare, the coil position is adjusted so that only 1/3 loop and no more than one loop is pulled into the main pulmonary artery. This action often results in wedging of coil loops further into the aortic ampulla, which improves ductal occlusion and minimizes coil protrusion into aortic flow. By minimizing the amount of coil in the main pulmonary artery the risk of branch pulmonary artery impingement is also minimized. A hand injection of contrast is performed through the Berenstein catheter at aortic ampulla before the snare release. If the coil appears to be in good position with no residual shunting, the snare is opened to release the coil. If the coil appears to protrude into the aortic flow, the snare can pull additional coil into the main pulmonary artery. If there is residual shunting more than trace to small the Berenstein can be manipulated back through the PDA while the snare is still holding the implanted coil to prevent inadvertent embolization. Once the Berenstein is safely through the PDA the initial coil is released, the Berenstein is resnared and second coil is delivered in a similar fashion. The second coil should have a smaller diameter than the first, so that it can "nest" inside the larger coil where most shunts occur. A repeat right heart sweep is performed to rule out residual left to right shunting and left pulmonary artery impingement. A final descending aortogram is performed 10 to 15 min after coil delivery.



*Nitinol snare*

**The Cook Detachable Coils:**

The Cook detachable coils were introduced to improve the safety of the delivery. This type of coil is attached by two mechanisms. First, there is a central mandrill holding the coil straight, while it is pushed. Then the delivery wire is attached to the coil through a screw mechanism. The stretched coil along with the delivery system is introduced into the catheter and the whole system is advanced until the leading tip of the coil reaches the tip of the catheter, which is positioned (in case of anterograde approach) in the descending aorta. One loop after another is deployed by advancing the coil and at the same time pulling back the mandrill from the tip of the coil, allowing a loop to form, when about one loop is left in the catheter, the catheter and coil delivery system, in total, are pulled back to allow the positioning of the deployed loops into the ductal ampulla. When the last loop is delivered in the pulmonary artery, the release mechanism can be activated by unscrewing the delivery system from the coil and pulling the mandrill completely out of the coil,

one may prefer to leave the tip of the mandrill inside the coil while activating the unscrewing mechanism this will stabilize the coil while being detached from the delivery system. In case the mandrill is withdrawn prematurely, unscrewing can occasionally lead to a kinking and sometimes breakage of the last part of the coil. In the European Registry for catheter closure of PDA (ERCOAD), Cook detachable coils were utilized in over 80% patients undergoing coil occlusion of their PDA [54]. Mallah et al [55] in their study of comparison between Rashkind umbrella occluder and Cook detachable coil concluded that outcome in terms of complete duct closure using the Cook coil is comparable with figures obtained using the Rashkind umbrella. According to them both devices have a good safety profile in the short and medium-terms.

**Efficacy:**

Transcatheter closure of PDA utilizing coils has been used worldwide in thousands of patients. In general, the success rate of deployment in most series is very high (90 to 100%).[56,57] In addition, the rate of complete occlusion approaches 98% in many series.[58, 59] In the European study[54], a total of 576 patients were reviewed from different European centres. In this report, Cook detachable coils were utilized in over 80% of cases. The complete occlusion rate at discharge was 82% but after 8 month of follow-up, it reached 98%. These data confirm the effectiveness of coil occlusion of small duct. Closing larger PDA (>4mm) with Gianturco coils have also been successful as shown in another

study[60]. The procedure was successful in 18 of 19 patients (one patient with a short duct was not closed). There was complete closure in 16 of 18 patients. Eighteen of nineteen patients were treated as outpatients. In a German study[61], a total of 317 patients were included. In these patients, detachable coils were utilized. Successful placement of the coils was possible in 89% of cases.The complete occlusion rate at late follow up 95%. It may be noted that mean fluoroscopy time was 10.7 min, with hemolysis in 3 (1.2%) and embolization in 7 (2.3%). Bioptome assisted coil occlusion of moderate to large PDA in selected infants and small children is also feasible[29].

**Residual Shunts:**

Residual shunts were common after the Rashkind double umbrella, but very uncommon after the Porstmann devices. Immediately after coil occlusion of PDA, residual shunting can occur in over 15% of patients [50]. Shim et al[62] demonstrated that at follow-up residual shunts immediately after coil implantation often resolve spontaneously. Similar observations were also noted by Bravo et al [63].In their study of 41 cases of PDA coil closure in children, noted residual shunts in 18 patients immediately following closure. However only 7 patients had residual shunting at 24 hours. Half of these patients showed flow cessation at 2 months and remaining half at I6 month's .This explain why in most studies on long-term follow up, there are only rare patients with residual shunting[64]. All these studies demonstrate the efficacy of coil occlusion especially in small-to- moderate PDAs.

**Complications:**

Complication related to PDA coil occlusion includes a persistent residual shunt in 5 to 10% of cases. Embolization of coil to pulmonary or systemic circulation, femoral artery injury following cannulation and rarely hemolysis associated with residual shunt. Left pulmonary artery stenosis and late recanalization of the duct have also been reported.

**Coil Embolization:**

Coil embolization is the most common complication, which can prolong the procedure. It occurs with a frequency between 0 to 16% in studies including more than 1000 patients [65,66]. According to a comparative study between Gianturco and the Cook detachable coil from one centre, embolization occurred more often with Gianturco coils than with Cook detachable coils. In addition, this occurs more often when the PDA narrowest diameter is larger than 3.5mm[67].

**Left pulmonary artery stenosis:**

Some LPA impingement by the coil with stenosis and/or increased flow rates by Doppler have been noted in some patients[68], especially when multiple coils are deployed. But significant left pulmonary artery stenosis caused by coil is extremely rare. Soares et al [69] suggested that determination of DVI (Doppler flow velocity integral) may be useful in predicting altered lung perfusion.

**Hemolysis after coil implantation:**

Severe intravascular hemolysis is a rare complication of

transcatheter closure of patent ductus arteriosus [70]. It is thought to be secondary to red blood cell damage from a high-velocity jet from a residual shunt. However, only a small minority of patients with a residual shunt develop this complication. Gupta et al [70] reported a case of intravascular hemolysis after partial coil occlusion of a PDA in which the dacron strands were stripped off the coils during bioptome-assisted deployment. They were of the opinion that exposure of the blood flow jet to bare metallic coils may have contributed to the occurrence of the severe hemolysis. Hemolysis was detected by evaluation of urine samples. Hemolysis subsides after closure of the residual leak either by coil or at surgery. Some cases may resolve spontaneously. Other methods like temporary balloon occlusion of the residual leak from the aortic end of the duct have also been tried[8]. Hemolysis seems to be more common after coil occlusion than after using any other device. Some authors recommend that the patients should leave the cardiac catheterization laboratory with no residual shunt at all[71]. Tomita et al[72] noted that hemolysis was more frequent in adults than in children even though the residual shunt was trivial. Long term complications are rare. Patel et al [73] in their study of 149 patients followed for median of three years reported no episodes of delayed coil migration, recanalization, thrombotic episodes or bacterial endocarditis. Marasini et al[74] reported a case of giant aneurysm following coil occlusion of patent ductus arteriosus in a three month old child with Marfan syndrome. However this is a very rare complication. Non patent spontaneous ductal aneurysm related to

premature closure of pulmonary end of the ductus can rarely occur in normal infants[75].In their patient presumably the aneurysm developed due to progressive dilatation of the aortic bump as a consequence of the increased radial forces after closure of pulmonary end of the ductus on an inherently weak wall or some minimal and unapparent damage in the wall of the ductus might have occurred during coil implantation and together with vascular fragility, may have played a role in aneurysm formation. However aneurysmal dilatation of PDA has been rarely reported as a cause of sudden and unexpected death in infants with Marfan syndrome or other connective tissue disease [75,76] They suggested that transcatheter occlusion of PDA in infants and children with Marfan syndrome should be carefully evaluated and that these patients must be monitored more closely during first month after PDA closure. Overall the complications related to PDA coil occlusion are rare.

There are reports of iantrogenic cardiocaval syndrome following transcatheter closure of PDA[77].Hwang et al reported [77] two infants who developed hoarseness unexpectedly the day after transcatheter coil closure of a slender patent ductus arteriosus. The pathogenesis of this complication appears to be similar to that of the classic cardiovocal syndrome. During the intervention, the inappropriately implanted coil might have distorted the slender PDA, thereby causing angulation of the pliable PDA itself and precipitating impingement on the left recurrent laryngeal nerve. Both their infants recovered spontaneously from the hoarseness within several weeks. At present, the definite underlying

neuropathology of this complication is unknown as they have not yet confirmed recovery of the left vocal cord movement by follow-up fibreoptic bronchoscopy. They concluded that iatrogenic cardiovocal syndrome could occur in infants after transcatheter coil closure of a slender PDA, using the then popular 0.038-inch coil. They were of the opinion that coil with a smaller diameter might prevent the occurrence of this syndrome. Femoral artery thrombosis is an uncommon but potentially serious complication following pediatric cardiac catheterization. Management options include heparin infusion, thrombolytic therapy, and surgical thrombectomy. Carlson et al[78] used tissue plasminogen activator for femoral artery thrombosis following transcatheter coil occlusion of patent ductus arteriosus. Rare complications like new onset aortic regurgitation have also been reported .Yu CH et al [79] found that the larger the PDA and larger the shunt, the greater the likelihood of developing aortic regurgitation after coil occlusion.

**Advantages of Coil Occlusion of PDA:**

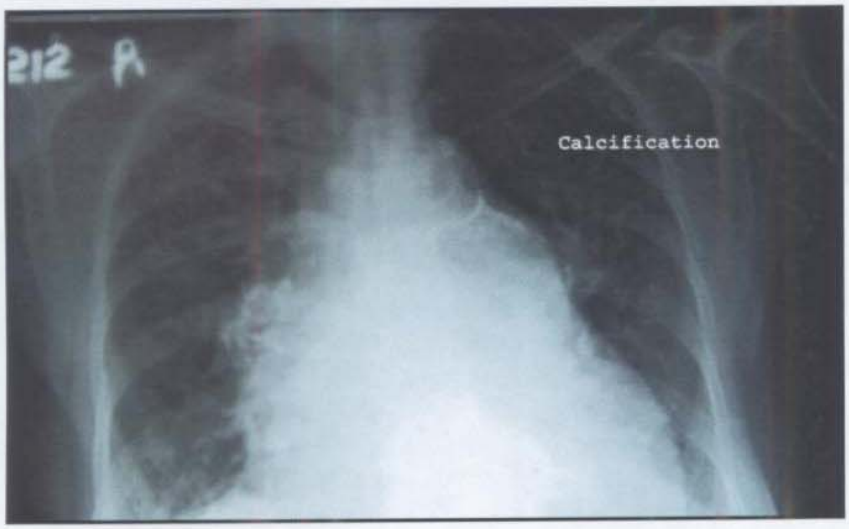
1) The rate of successful occlusion is high
2) Rate of complications is low
3) It is inexpensive
4) Technique is easy
5) Detachable coils, bioptome or snare assisted coils can be easily repositioned and retrieved.
6) It has short procedure and fluoroscopy time.

**Disadvantages:**

1) Complications like embolization or risk of left pulmonary stenosis can occur.
2) Limitation of the procedure in very large PDA.

**PDA in adults**. The anatomic changes of the patent ductus arteriosus in adult patients, such as aortic aneurysm, calcification, or being short and sometimes friable, could complicate treatment. Calcified duct may be a relative contraindication for transcatheter closure. Surgical management also is complicated by a fragile aortic wall due to atheromatous lesions, the presence of friable tissue at the surgical site, and calcification of the ductus. An anterior approach through a median sternotomy with cardiopulmonary bypass is often used [80,81,82]. In a study of transcatheter closure of PDA using Amplatzer device Wang et al [21] reported that calcified ductus was a cause of failure in one of their cases, they had difficulty in advancing the sheath into descending aorta. This is applicable to transcatheter closure using coils also. However Montes et al [83] in their study of Patent ductus arteriosus in the adult, reported good results in 53 of their cases. In their study 53 adult patients (47 women and 6 men) with PDA were treated by means of percutaneous procedures. Average age was 25.3 years (Range, 16 to 54.7 years). Three different devices were used, 39 patients with Amplatzer duct occluder for ductus arteriosus, 1 patient with Amplatzer for muscular interventricular communication, 11 with Gianturco coils, and 1 patient with Nit-Occlud. All

devices were implanted successfully. Immediate complete closure was achieved in 31 patients (58.4%), in 20 patients (37.7%) with minimal leakage, and in 2 patients (3.89%) with moderate leak.They noted changes in the hemodynamic parameters. Before the procedure average systolic pulmonary pressure was 37.08 $\pm$ 22.8. mm Hg (Range: 12-138 mm Hg) and went down to 28.75 $\pm$ 10.25 mm Hg (Range: 16-57 mm Hg). At average follow up of 18.8 months the occlusion was completed in all patients. In none of the patient complications related to implant of the devices were observed. They concluded that transcatheter closure of PDA in adult patients with different devices is safe and feasible. Mesia et al[84] reported a case of a 75 year old woman who had complete occlusion of her PDA with a single Gianturco coil after recurrence of her ductus 3 years post surgical ligation.




*PDA Calcification*

**New advances**: Hayauchio et al[85] reported use virtual endoscopy using multidetector-row CT (MDCT) for coil occlusion of patent ductus

arteriosus. They studied 10 consecutive patients with PDA undergoing cardiac catheterization and coil occlusion. All patients had previously undergone MDCT, and subsequently underwent transcatheter closure of ductus. MDCT evaluations were performed again in 1-3 months after occlusion. Virtual endoscopy showed the anatomy of the orifice of the ductus and spatial relations of adjacent structures from both the aortic and pulmonary sides in all patients. They were able to observe the inner space, and fly through the PDA. This approach is the virtual view of the catheter advancing during coil occlusion. Following occlusion, visualization of the coil can also be established by viewing from inside. Coil protrusion into the aortic and pulmonary sides was clearly observed. Virtual endoscopy provides unique information regarding the ductal lumen that is of use for the coil occlusion of PDA.

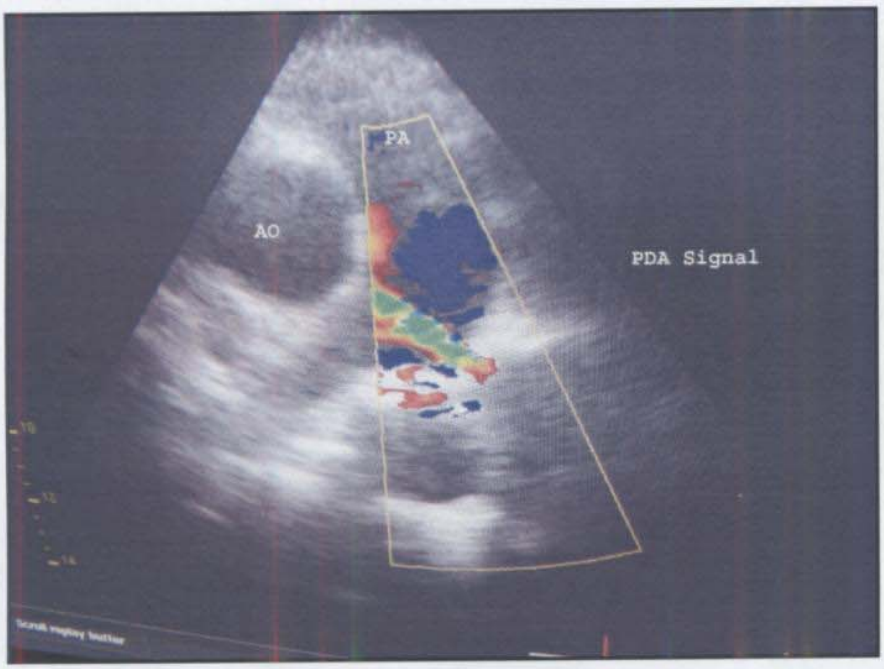
**Combined procedures**; Zhanget al [86] reported the use of combined procedures interventional catheterization for combined congenital heart disease in children. Fifteen of their cases (6 boys, 9 girls) underwent transcatheter intervention for combined congenital heart diseases at their centre. They used the following procedure of transcatheter intervention: for pulmonary stenosis (PS) and atrial septal defect (ASD) or patent ductus arteriosus (PDA), PBPV first, occlusion of ASD or PDA later; for coarctation of aorta (COA) and PDA, dilation of COA first, occlusion of PDA 4-15 months later; for aortic stenosis (AS) and PDA, PBAV first, occlusion of PDA later; for ventricular septal defect (VSD) and PDA, all

occlusions with detachable coils. Transcatheter intervention for combined congenital heart diseases was successful in all patients. There was no residual shunt after occlusion immediately apart from 2 cases of PDA which showed little residual shunt immediately after occlusion. On follow-up for (3.57$\pm$ 2.61) years, the systolic pressure gradients across pulmonary valve and coarctation were normal. Three of their cases had postoperative complications: one with haemolysis, one with migration of the coil and one with systemic embolism, respectively. They concluded that transcatheter intervention for combined congenital heart diseases could obtain satisfactory results with appropriate indications and procedure manipulations.

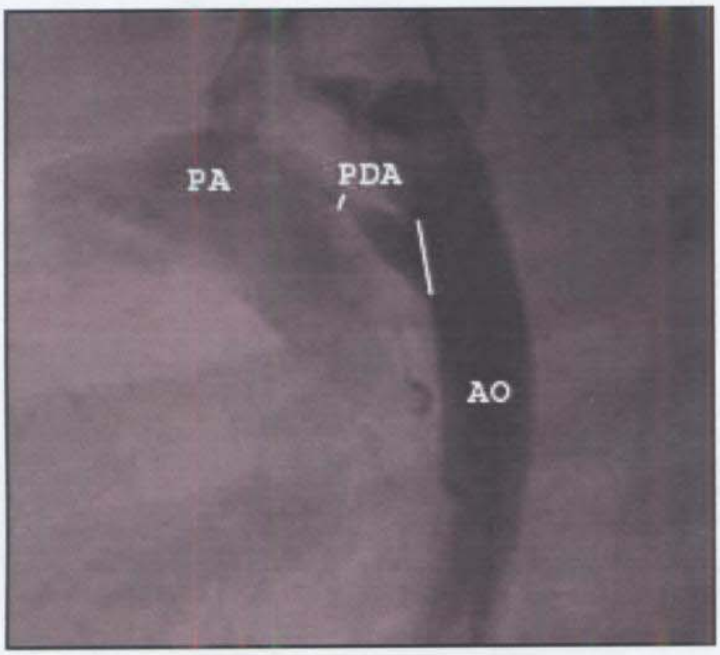
# MATERIALS &METHODS

## MATERIALS & METHODS

All patients undergoing transcatheter closure of PDA using bioptome during the period from February 2003 to august 2006 were enrolled in the study. These patients underwent a thorough clinical evaluation. Colour Doppler echocardiography was done to confirm the diagnosis with particular emphysis on measurement of chamber dimensions and size of the duct and ampulla. A combination of high parasternal,ductal and suprasternal views were used to measure the size of the ductus. The minimum duct diameter and size of the ampulla were noted.




*Color Doppler Echocardiogram showing the flow across the duct*

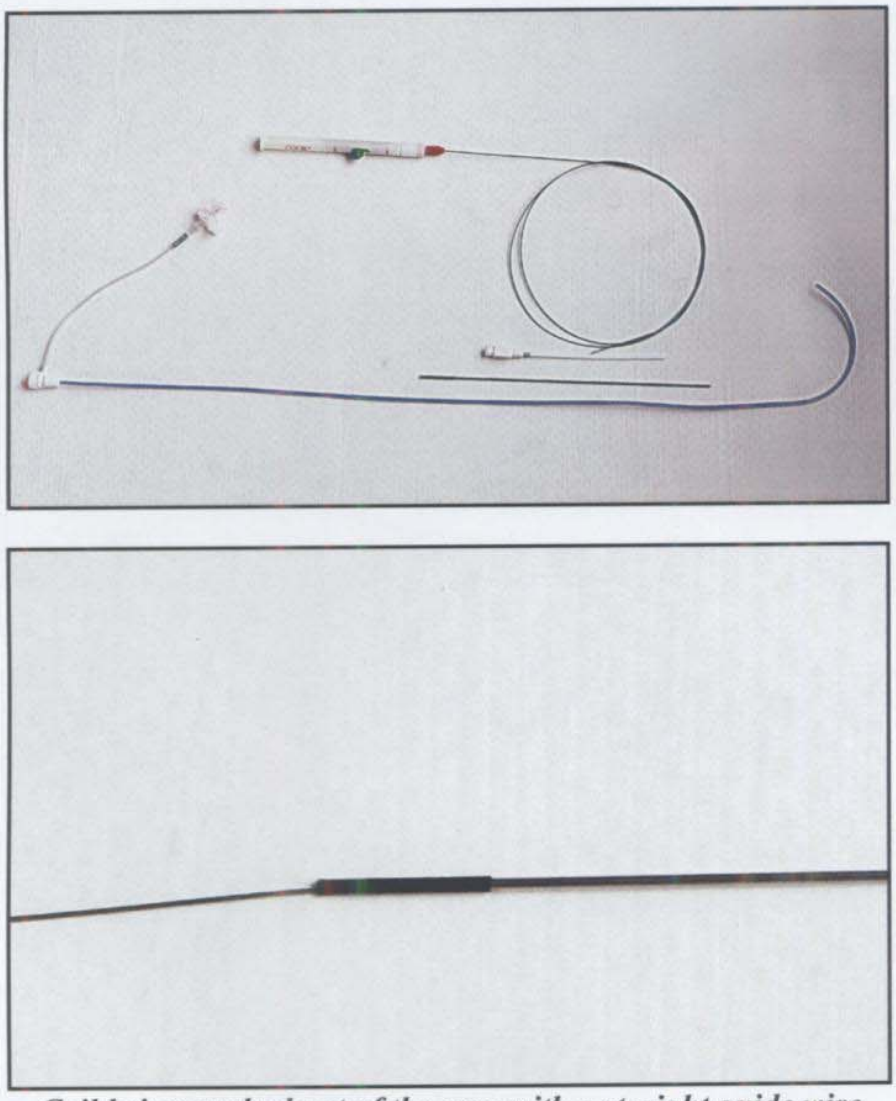



***Aortogram in lateral view showing measurement of duct diameter and ampulla diameter.***

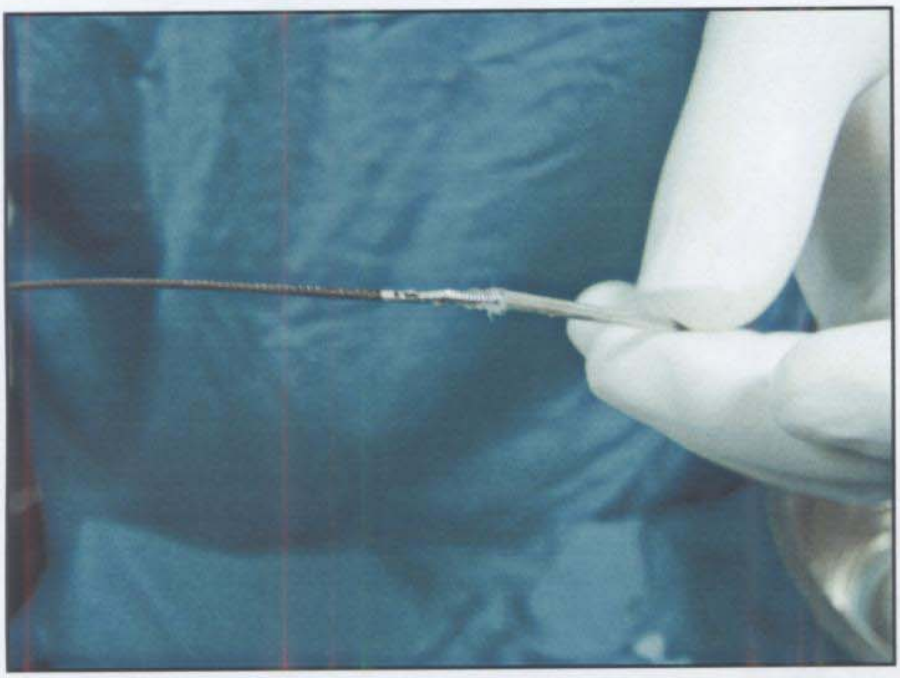
Presence of coarctation was excluded. Skiagram of the chest, 12 lead electrocardiogram and blood investigations required for cardiac catheterization were also obtained. Informed written consent was obtained from patients or from the parents in case of minor children. All patients were brought to the catheterization laboratory. The procedure was accomplished with conscious sedation in adults and general anaesthesia children. Antibiotic (cefazolin 25 mg/kg) was administered and continued for two doses. A 5 French sheath was placed in right femoral vein and another 5 French sheath was placed in the right femoral artery. A 5 French pigtail catheter (Cook Inc) was used to perform a retrograde left heart catheterization. All Patients received 50 units / kg intravenous heparin after insertion of a femoral arterial sheath to avoid the risk of femoral arterial thrombosis. Hemodynamic data were collected

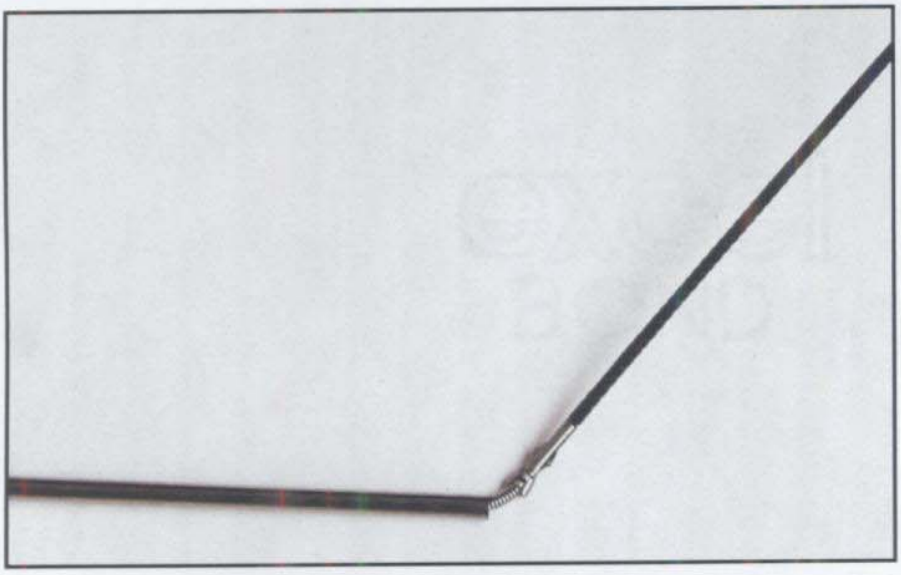
first. Using the pigtail catheter, an aortogram was performed in the descending aorta in the lateral view. The views were adjusted whenever necessary to profile the duct as much as possible. The following dimensions were measured: PDA minimum diameter, aortic ampulla diameter and PDA length. The end hole catheter from the venous side was advanced from the main pulmonary artery, across the PDA into the descending aorta. A 0.025" Teflon exchange wire was advanced through the catheter into the descending thoracic aorta; the catheter was removed. A long sheath with radiopaque marker at the tip was placed across the duct into the descending aorta. The selection of coils was based on the measurements of the size of the duct and ampulla on the lateral aortogram. The loop diameter selected is at least twice the minimum PDA angiographic diameter and as the loops have to fit into the ampulla it should be less than or equal to the maximum diameter of the ampulla. In addition coil should be long enough to produce at least four complete loops. If the ampulla is large additional coils were used. The second coil should have smaller than the first, so that it can "nest" inside the larger coil where most residual shunts seem to occur. In duct of size 3 to 3.5 mm a single 0.52" 6mm, 8cm coil was generally used. The 0.052" coil is selected whenever possible due assumed poor stability of 0.038" coils. If the duct is larger than 4 mm two coils are generally used. The use of thicker 0.052"coils offers greater stability. Selection of coils still involve some amount of guess work. To prevent the coil from becoming entangled with the catheter, before coil implant, the pigtail catheter was

repositioned several centimeters caudal to the PDA. Once the coil is selected the round ball at one of the ends of the coils was stretched out by about 2mm. If multiple coils were used, the stretched out ends were intertwined using a hemostat. The rounded ball at the stretched out end of the coil was held by the bioptome and the coils(s) was pulled into the short sheath (5F or 6 F) by the bioptome. The short sheath loaded with the coil-bioptome, was inserted into the hemostasis valve of the long sheath placed across the duct.

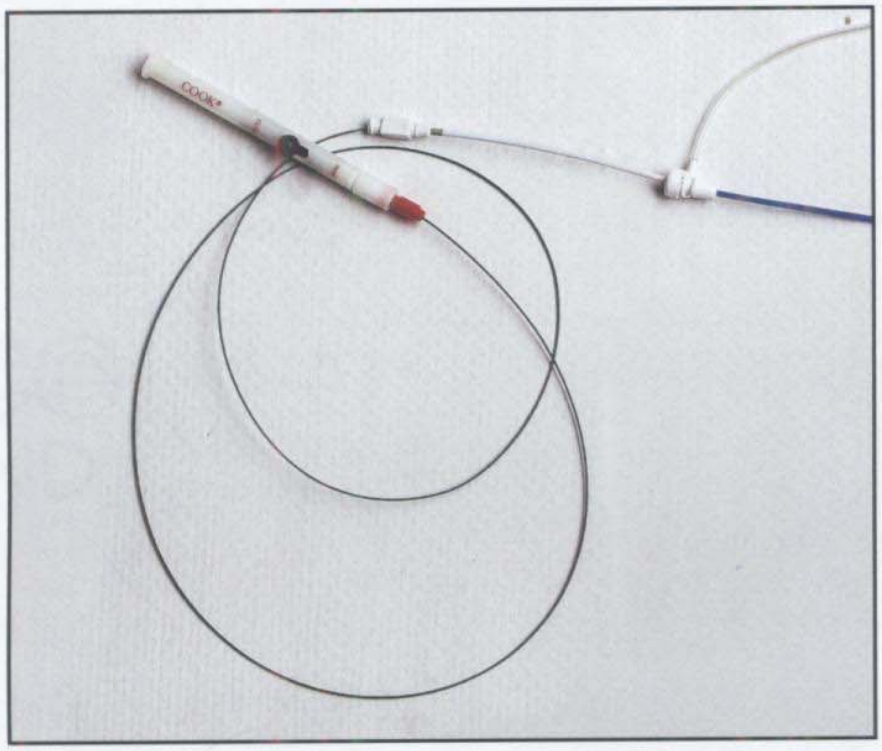


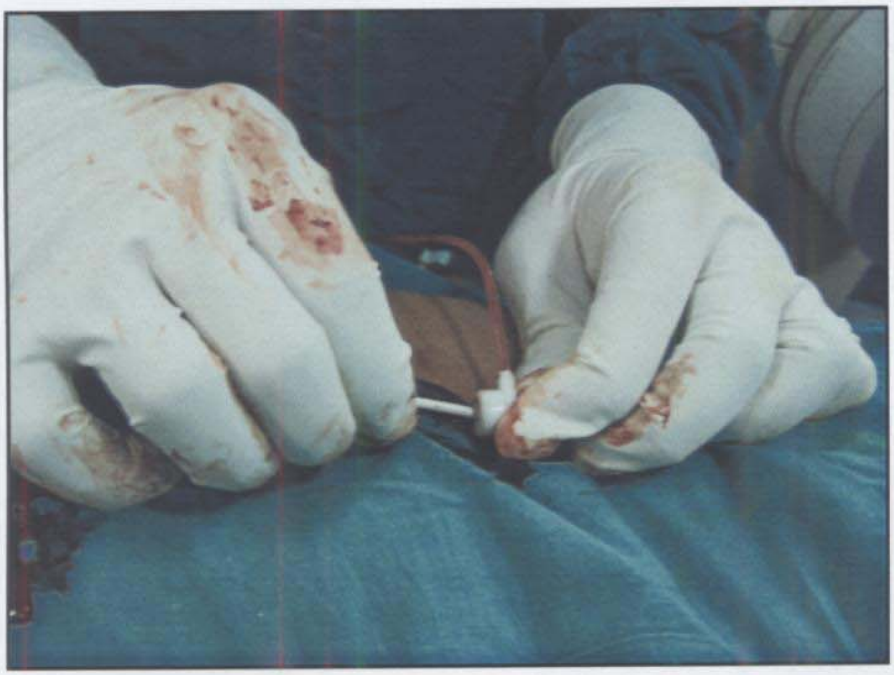
***Coil being pushed out of the case with a straight guide wire***





***Rounded ball at the end of the coil held by bioptome***

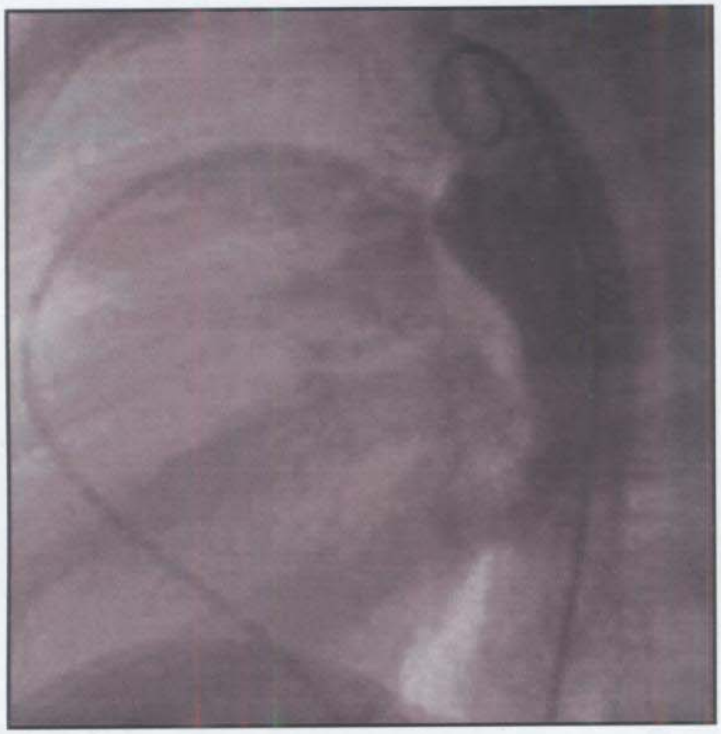


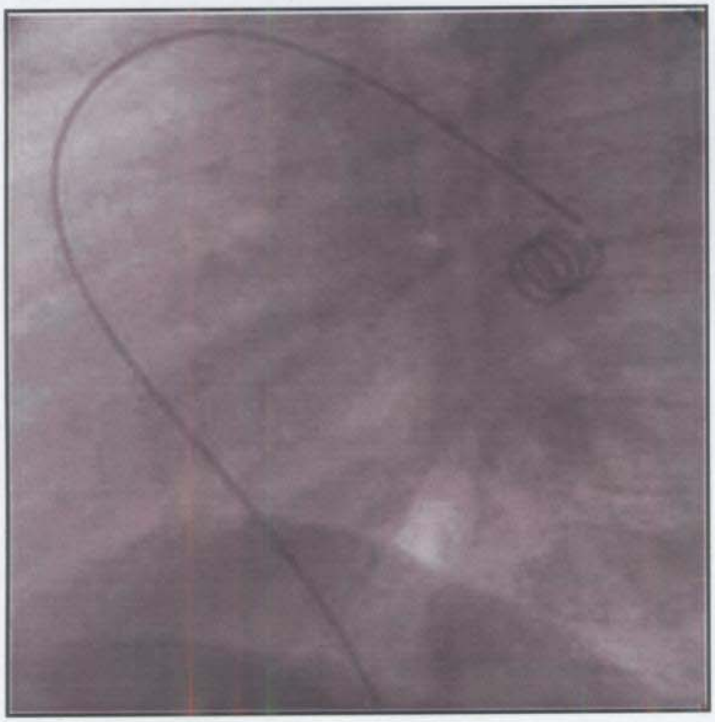
***The short sheath loaded with the coil-bioptome being inserted into the hemostasis valve of long sheath.***

The bioptome is then pushed so that the coils enter the long sheath. The entire coils held with bioptome were then pushed all the way out of the sheath in the descending aorta. The assembly was then pulled back toward the pulmonary artery. This allows the compaction of the coils in the ampulla. The positioning of the coils was guided by the tracheal air shadow that served as a landmark. As the coils enter the duct ampulla, it becomes more compact and there is loss of oscillatory movements. Resistance is also felt at that time. The sheath was withdrawn into the pulmonary artery and the bioptome was carefully pulled till < ½ coil turn came into the pulmonary artery. As the sheath is pulled back from the aorta into the main pulmonary artery (MPA) (just before releasing the coil) 1/4-1/2 loop of coil can be pulled across the PDA into the MPA. To avoid having excessive coil in the MPA, most of the coil is deployed in the aortic ampulla, keeping just enough coils in the sheath to form ½ loop. Then as the sheath is pulled back (to release the coil) an additional1/4-1/2 loop coil comes into the pulmonary artery. This will ensure ideal amount of coil on both sides of the PDA. If more than half a coil turn was withdrawn into the pulmonary artery or if the position of the coils in the ampulla was deemed unsatisfactory, the sheath was advanced over the coil(while also pulling back the coil),through the PDA, into the ampulla ,then the coil was redeployed. More than three aortic side loops are not necessary and may result in protrusion into aortic lumen. Thus the coils should have a total of three to four loops with most of the loops

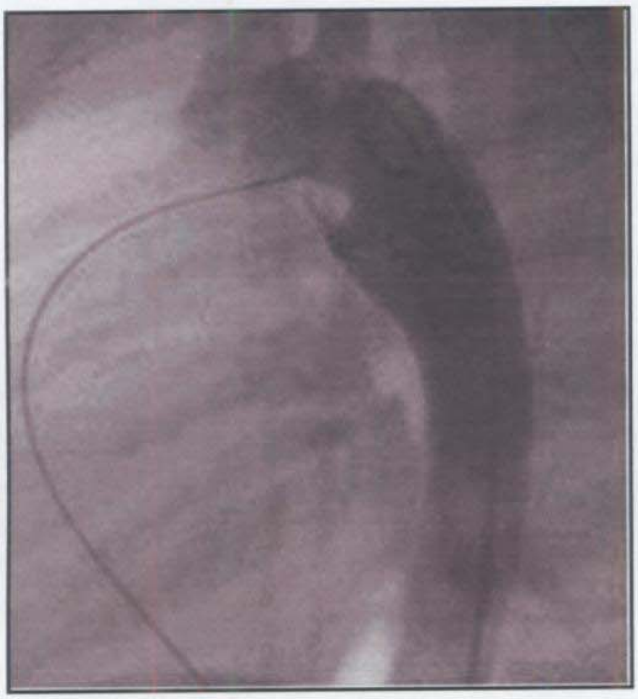
positioned on the aortic side of the ductal narrowing. An angiogram was performed to confirm optimal coil position. To release the coil, the sheath was pulled back over the bioptome (keeping the coil in position), exposing the bioptome jaws. The jaws of the bioptome were released immediately after a satisfactory position was obtained. If the coils achieve compact position the first proximal loop will be oriented parallel to the segment of the ductus that contains the minimum diameter as it enters the pulmonary artery. The horizontal alignment of the proximal coil loop to the ductus increases its occlusive abilities. The most distal coil loop maintains a perpendicular alignment to the ductus inside the aortic ampulla and will prevent the coil from embolizing through the ductus into the main pulmonary artery. After 10 min an angiogram was carried out. In the cases where a residual shunt was present, using the retrograde approach, a 4French snare catheter (microvena corporation, White Bear Lake, MN) and 0.035 Terumo wire ( Medi-Tech Inc, watertown, MA) was used to traverse the implanted 0.052" coil. One or two 0.038" Gianturco embolization coils (smaller diameter than the 0.052"coil) were implanted, coiling tightly inside the larger diameter 0.052 coil. The procedure was considered successful (a) if the coil was positioned properly across the ductus arteriosus; (b) Complete PDA occlusion or no more than a trivial angiographic leak was present on the post angiogram. Small diffuse whiffs of flow were accepted. The total number and the type of coils used were noted.



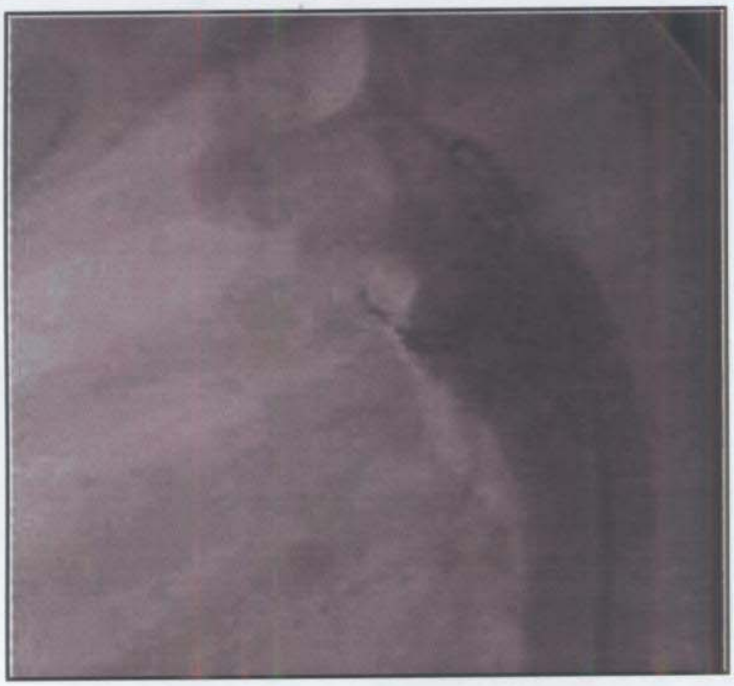
*Long sheath positioned across the duct into descending aorta through venous access*



*Coil dangling in the aorta*



*Coil mass occluding the duct*



*Final angiogram – no flow across the duct*

**Retrieval of Embolized Coils:**

When the coils embolized into the aorta, the duct was immediately re-crossed with a 5 Fr multipurpose catheter via venous access from the pulmonary arterial side. A 10 mm gooseneck snare (Microvena, MN) was used to hold the stretched out end of the coils and the same coils were deployed in the duct if found suitable. Coils that embolized into pulmonary artery were retrieved via the long sheath in the pulmonary artery.

**Discharge:**

Overnight urine samples were inspected for hemolysis in all patients with residual flows. A colour Doppler evaluation at 24 hrs was performed for all patients. Left pulmonary artery (LPA) origin was evaluated for anatomic narrowing, colour flow turbulence and Doppler gradients. New onset LPA stenosis was defined as appearance of color flow turbulence for the first time with gradient >5mmHg at LPA origin.

**Statistical Methods:**

Data are expressed as mean $\pm$ standard deviation and percentage. Paired t test is used for comparing two groups and one way ANOVA as appropriate. Correlation between continuous variables and categorical variables were assessed with Pearson or Spearmans method as appropriate. Independent predictor of coil length, coil diameter and duct size were examined with linear regression. Predictor of number of coils with the duct size were analysed by t test.

# RESULTS

## RESULTS

**Patient profile** .Successful coil occlusion was achieved in 67 of the 68 patients (98.5%).The data of these 67 patients were reviewed. The study group had a mean age of 8.4 ± 10.4 years range (10 months to 58 years),mean weight of 18 ± 12.5 kg ( range 4 kg to 60 kg) Majority of the patients were asmptomatic. Cardiomegaly on physical examination was found in 13(19%) of the patients, while 16(24%) showed left ventricular hypertrophy on electrocardiogram. Skiagram of the chest showed plethora in 18(27%) of the patients. The mean minimum PDA diameter by echocardiogram was 2.98 ± 0.84 mm(range 0.3 to 5 mm, median 3mm ).The mean ampulla diameter by echocardiogram was 8.4 ± 2.2 mm( range 5 to 13 mm, median 8 mm).The mean minimum angiographic duct diameter was 3.19 ± 0.83 mm( range 1.8 to 5.2mm, median 3mm). The mean minimum angiographic ampulla size was 8.39 ± 1.38 mm (range 5 to 12mm, median 8mm).The mean pulmonary artery systolic pressure was 28.73 ± 10.01 mm Hg( range 20 to 90 mm Hg, median 26 mm Hg), The mean pulmonary artery diastolic pressure was 13.85 ± 5.38 mmHg( range 8 t0 50 mmHg, median 13 mm Hg).The mean pulmonary artery pressure was 19 ± 6.46 mm Hg ,range 10 to 35 mm Hg, median 18 mm Hg). The mean aortic systolic pressure was 114.31 ± 14.69(range 85 -160 mm Hg, median 70 mm Hg)

## Table – I

## Descriptive Statistics of the 67 patients studied

| | |
|---|---|
| Age (Years) | 8.4 ± 10.4 |
| Male-Female (N) | 21-46 |
| Weight (Kg) | 18 ± 12.5 |
| Symptoms (No.& %) | 7 ( 10 %) |
| Cardiomegaly (No & %) | 13 ( 19 %) |
| LVH (No & %) | 16 ( 24 %) |
| Plethora (No & %) | 18 ( 27 %) |
| Duct size echo (mm) | 2.98 ± 0.84 |
| Ampulla Diameter (Echo) mm | 8.4 ± 2.1 |
| Pulmonary artery systolic pressure (mmHg) | 28.73 ± 10.01 |
| Pulmonary artery diastolic pressure(mmHg) | 13.85 ± 5.38 |
| Pulmonary artery mean pressure (mmHg) | 19.66 ± 6.46 |
| Aortic systolic pressure(mmHg) | 114.31 ± 14.69 |
| Aortic diastolic pressure(mmHg) | 67.18 ± 8.55 |
| Aortic mean pressure(mmHg) | 90.76 ± 10.95 |
| Duct size (angio) mm | 3.19 ± 0.83 |
| Ampulla size(angio) mm | 8.39 ± 1.98 |

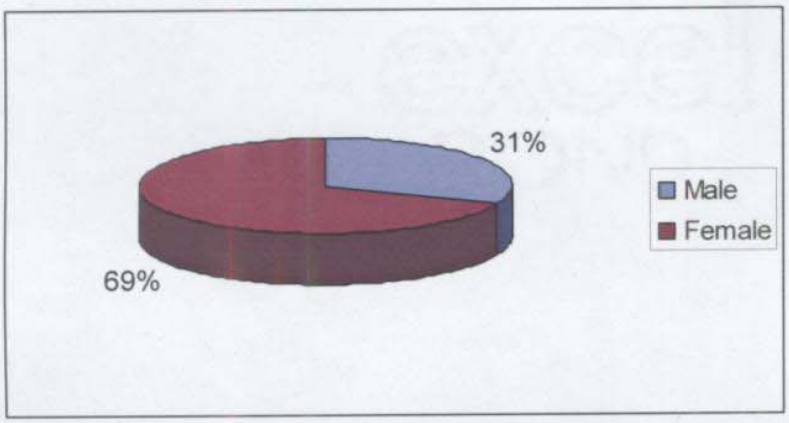
## PATIENT CHARACTERISTICS

Total Patients : 67

Males : 21
Females : 46

Mean age : 8.4 ± 10.4 years

Mean weight : 18 ± 12.5kg




## Clinical Profile:

Majority of patients were asymptomatic

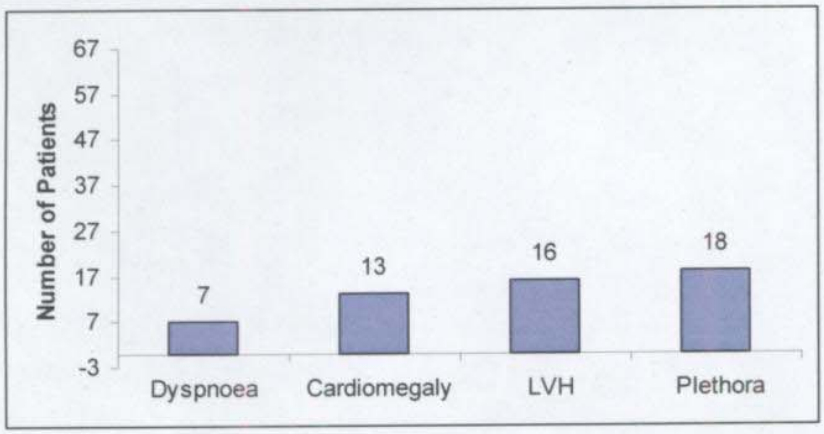
7 patients had NYHA class II dyspnoea

Cardiomegaly was present in 13 patients

All patients had continuous murmur

LVH by ECG was present in 16 patients

Plethora on X-ray chest 18 patients



**Echocardiographic Features:**

Duct size : 2.98 ± 0.84mm

Range : 0.3 to 0.5mm

Median : 3mm

Ampulla diameter: 8.4 ± 2.1mm

Range 5 to 13

Median : 8

**Pulmonary Artery Systolic Pressure:**

28,73 ± 10.01 mmHg

Range : 20-90mmHg

Median: 26mmHg

**Pulmonary Artery Diastolic Pressure**

13.85 ± 5.38mmHg

Range : 8-50mmHg

Median: 13mmHg

**Pulmonary Artery Mean Pressure**

19.66 ± 6.46 mmHg

Range : 10 – 35mmHg

Median : 18mmHg

**Aortic Systolic Pressure:**

114.31 ± 14.69mmHg

Range : 85 – 160mmHg

Median : 70mmHg

**Angiographic Features:**

Angiographic duct size : 3.19 ± 0.83mm

Range : 1.8 to 5.2mm

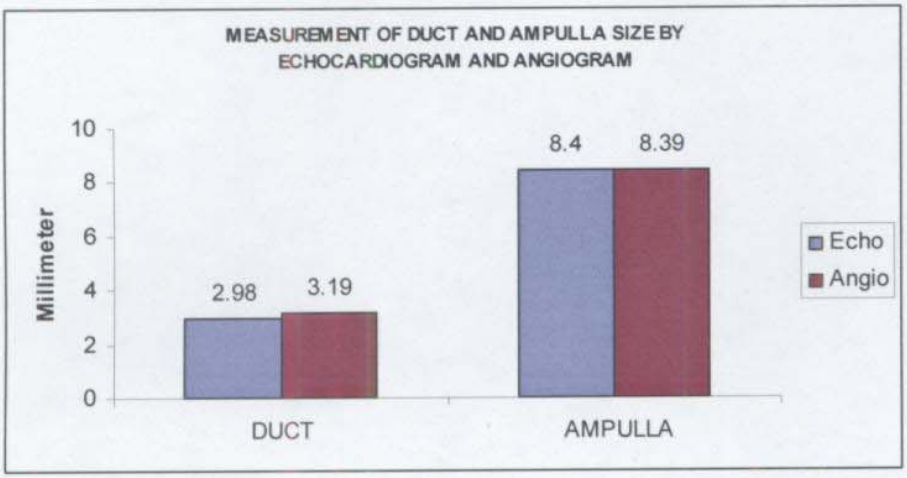
Median : 3mm

## Angiographic Ampulla Size

8.39 ± 1.98mm

Range 5 to 12mm

Median 8mm




**Angiographic type of ductus.**

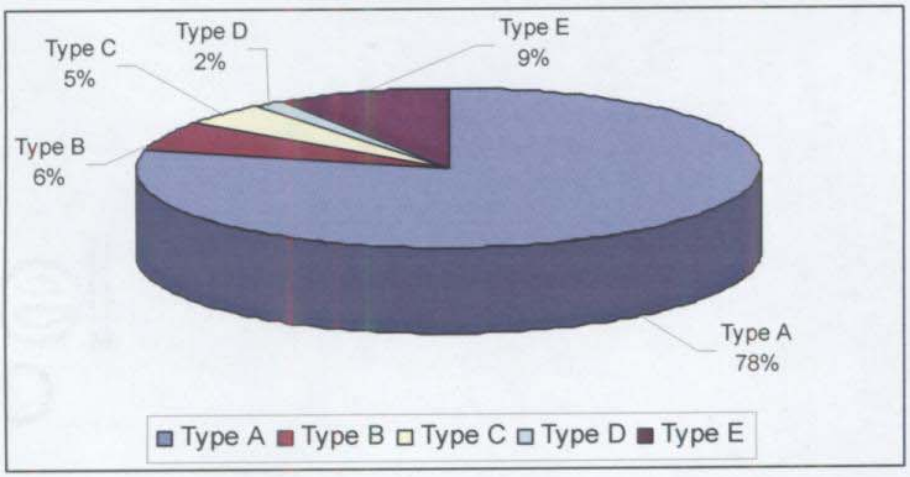
Type A 53(79%)

Type B 4(6%)

Type C 3(4.5%)

Type D1(1.5%)

Type E 6(9%)



**Coil implantation.** Coil implantation was successful in 67 of the 68 patients. The procedure was abandoned in one patient as there was significant residual shunt after the coil was positioned. This patient had PDA diameter of 5mm and the shunt persisted after repeated attempts at coil implantation. It was also difficult to profile the duct in any of the conventional views. It is possible that the duct size in this patient might have been larger than what was measured.

**Coil embolization.** Coil embolization occurred in 3 of the 67(4.47%). Two patients had embolization of coils into the pulmonary artery and one patient had embolization into the aorta. Of the two cases of embolization into the pulmonary artery, in one patient stable coil position was obtained initially and the angiogram showed complete closure. But the bioptome was not released immediately and during this period the coil embolized into the pulmonary artery. A long sheath was passed into the pulmonary artery and 10mm gooseneck snare (Microvena, MN) was passed through the sheath. The coil was retrieved using the snare. Even though the procedure appeared simple it was difficult to exactly locate the site of the coil and it took lot of time in retrieving the coil. In subsequent cases attempts to hold the coils for longer periods were avoided after obtaining a stable position. The problem is more often seen with 5 F stiffer bioptome, which results in inadvertent pull on the coil. In the second case coils embolized into the pulmonary artery as the bioptome was pulled back. In this case there was poor compaction of the coils in the ampulla and the coils got stretched as it was being pulled

back. The coils were larger than what was necessary to form a compact mass in the ampulla. This problem is more commonly seen with more tubular ducts. One patient had embolization of the coils into the aorta. This patient had excess coil in the ampulla and it was protruding into the aorta which later embolized. In this case a long sheath was passed into the descending thoracic aorta. The gooseneck snare (Microvena, MN) passed through the sheath. The coils were retrieved using the snare. Subsequently the duct was closed using a smaller sized coil.

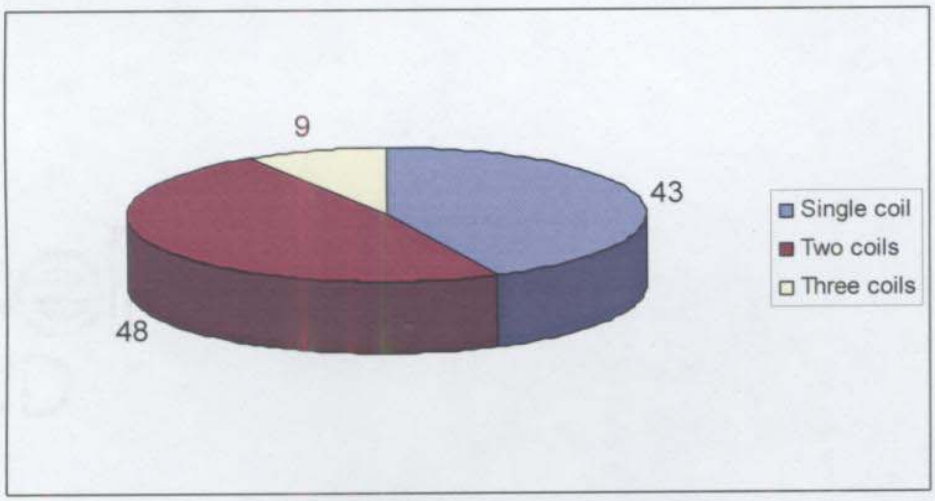
**Complications** Most complications that occurred in our study were minor fever 3(4.4%), groin haematoma 1(1.5 %). Most common minor complication was transient loss of pulse in 10 patients (15%).This was more often seen in children. One patient developed loss of pulse with ultrasound evidence of thrombus at the puncture site. The pulse reappeared after heparinization for 48 hours .No patient suffered permanent loss of the arterial pulse. None of our patients had more important complications like hemolysis, contrast allergy or transfusion requirement.

**Use of single or multiple coils.** Multiple coils were implanted in 38(57%) of patients in our study group. Two coils were used in 32(48%) patients while three coils were used in 6(9%) patients. If the duct size is between 2.4 and 2.7single coil is used at 95% confidence interval. If the duct size duct size is between 3.3 and 3.7 two coils are used at 95% confidence interval. For the duct size between 3.7 and 4.7 three coils are used at 95% confidence interval.

**Table II**

**Number of Coils Used**

| Number of coils used | Number of patients | Percentage |
|---|---|---|
| Single coil | 29 | 43 |
| Two coils | 32 | 48 |
| Three coils | 6 | 9 |




There was a significant relationship of multiple coil use with increasing PDA size.

Among the clinical parameters only the presence of plethora and cardiomegaly showed significant correlation with the number of coils used (Table IV). This is expected as these parameters indicate large left to right shunt and large size of the duct.

**Table IV**

**Correlation between number of coils and patient characteristics**

| Parameter | Correlation coefficient | P value |
|---|---|---|
| Age | -0.15 | NS |
| Weight | -0.149 | NS |
| Symptoms | -0.21 | NS |
| Cardiomegaly | 0.32 | 0.007 |
| LVH | 0.12 | NS |
| Plethora | 0.28 | 0.018 |

**Measurement of PDA size**

PDA size was measured by colour Doppler echocardiogram prior to the procedure or during the procedure from a lateral aortogram. The minimum diameter from these measurements was obtained.The mean duct size measured by echocardiogram was 2.98$\pm$ 0.84mm while angiographic measurement of the duct size was 3.1 $\pm$ 08. Both these measurements showed significant correlation.($p<0.001$).

**Measurement of Ampulla size.**

Ampulla size was measured by colour Doppler echocardiogram prior to the procedure or during the procedure from a lateral aortogram. The mean ampulla size measured by echocardiogram was 8.4 $\pm$ 2.1 mm while the mean angiographic size was 8.39 $\pm$ 1.98mm. Measurement of ampulla size by both these measurements showed significant ($p<0.001$) correlation (Table III).

## Table – III

### Correlation between echocardiographic and angiocardiographic measurements

| N = 67 | Echocardio graphic parameters | Angiocardio graphic parameters | Correlation coefficient ($\gamma$) | P value |
|---|---|---|---|---|
| Duct size (mm) | 2.98 $\pm$ 0.85 | 3.2 $\pm$ 0.83 | 0.71 | < 0.001 |
| Ampulla size (mm) | 8.4 + 2.1 | 8.3 $\pm$ 1.99 | 0.57 | <0.001 |

### Correlation between the number of coils and hemodynamic parameters

Hemodynamic parameters like pulmonary artery systolic pressure, pulmonary artery diastolic pressure, pulmonary artery mean pressure, aortic systolic pressure, aortic diastolic pressure and aortic mean pressure did not correlate with the size and number of coils used.

### Correlation between the number of coils and angiogram parameters

The duct size and ampulla size measured by angiogram showed significant correlation with the number of coils used. (Table V).If the duct size is between 2.4 and 2.7 single coil is used at 95% confidence interval. If the duct size is between 3 and 3.7mm two coils were used at 95% confidence interval. For duct size between 3.7 and 4.7(fig 1) three coils are used at 95% confidence interval.

**Table V**

**Correlation between the number of coils and angiogram parameters**

| Parameter | Correlation coefficient | P |
|---|---|---|
| Duct size | 0.67 | < 0.001 |
| Ampulla size | 0.41 | 0.001 |

The duct size and number of coils used are correlated and significant.

The duct size and ampulla size measured by angiogram showed Significant correlation with the number of coils used (Table V) (Fig.1)

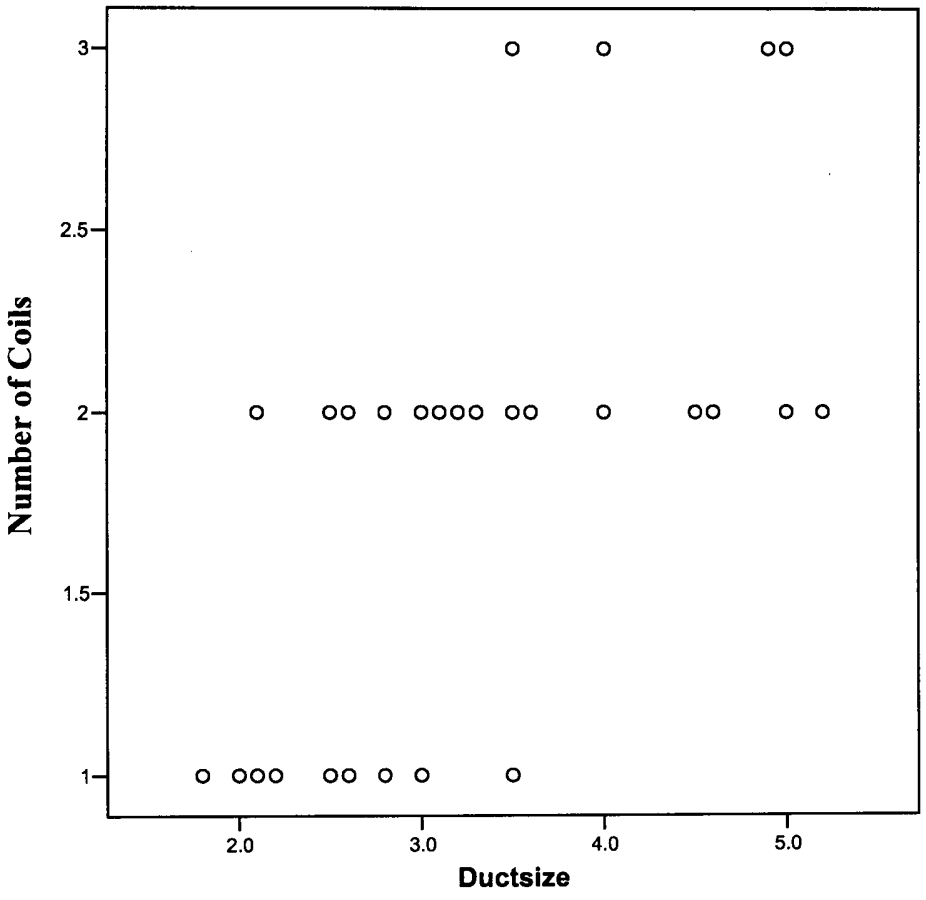



**Figure 1**

If the duct size is between 2.4 and 2.7single coil is used at 95% confidence interval. If the duct size duct size is between 3.3 and 3.7 two coils are used at 95% confidence interval. For the duct size is between 3.7 and 4.7 three coils are used at 95%confidenceinterval

Majority of patients in our study group had angiographic type A duct. We found no significant corelation between multiple coil use and angiographic type of the duct.

**Left pulmonary artery (LPA)/ aortic impingement secondary to coil placement**

Colour Doppler evaluation at the time of discharge from the hospital showed increase in Doppler flow velocity at the origin of LPA (<10 mmHg) in 4 patients.This was not considered significant. There was no Doppler evidence of aortic impingement in any patient.

**Coil removal before release for suboptimal placement.** Coil was pulled back into the bioptome before release in 12/67(20%) of the patients. The indication for coil removal included: excessive coil loops slipping through the PDA into the MPA, aortic lumen or lack of proper compaction of the coils or presence of significant residual shunt. Within the study group there was no statistically significant relationship of coil removal and increasing PDA size, although removal tended to occur more often in larger PDAs. There was no statistically significant relationship between the need for coil removal and angiographic PDA type. This was an important limitation of the technique. This also emphasizes the need for proper guidelines for proper coil selection.

## Correlation between the length of the coil and angiographic parameters

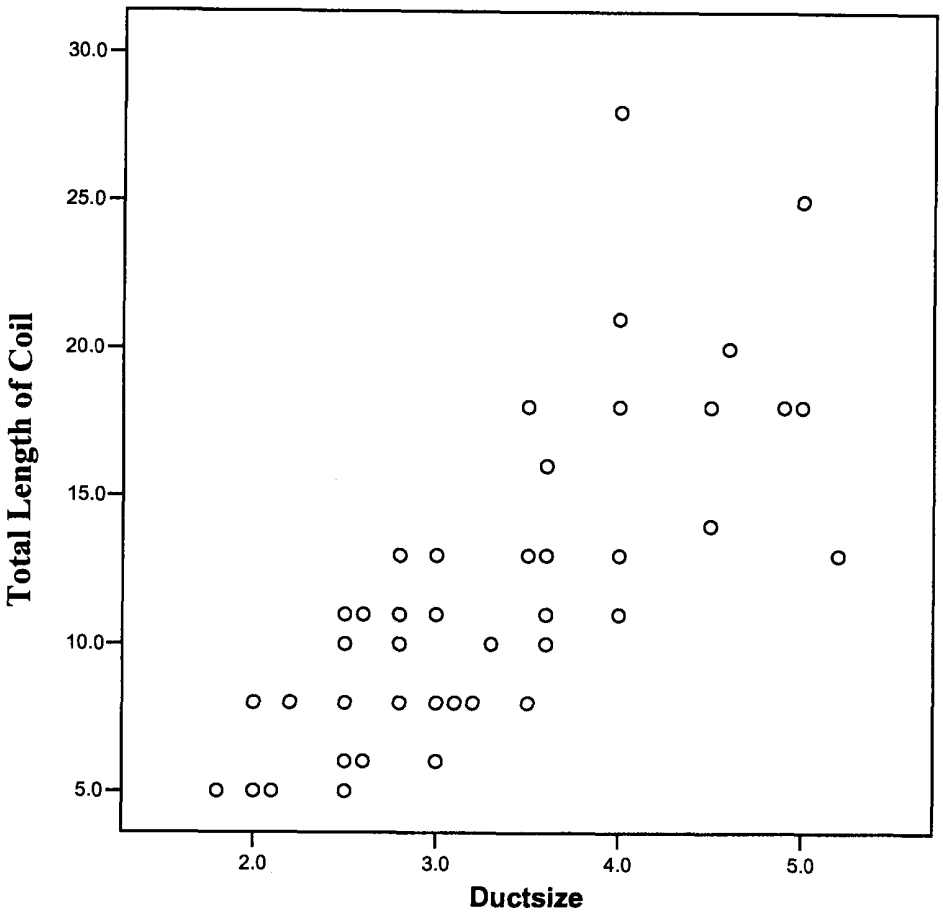
**Length of the coil:**

If single coil is used the length of that coil was used for calculation. If multiple coils were used, total length of the coils were added to obtain the total length of the coil. The duct size showed significant correlation ($p<0.001$) with the length of the coil used (Table VI). For larger duct longer coils were necessary. As also the ampulla size showed significant correlation with the length of the coil used ($P<0.001$). Although duct size and ampulla size showed significant correlation with the length of the coil used the duct size and the coil length showed high degree of linear correlation (Fig.2).

**Table – VI**

**Correlation between the length of the coil and angiographic parameters**

| Parameters | Correlation coefficient ($\gamma$) | P value |
|---|---|---|
| Duct size | 0.77 | < 0.001 |
| Ampulla size | 0.54 | < 0.001 |




**Correlation between diameter of the coil and angiocardiographic parameters**

Diameter of each loop is an important aspect of the selection of the correct size of the coil. Generally the loop diameter must be at least twice the minimum PDA angiographic diameter and the maximum loop diameter should be less than or equal to the maximum dimension of the aortic ampulla. In the present study the duct size and ampulla size showed significant correlation with the diameter of the coil used.

## Table VII

**Correlation between diameter of the coil and angiocardiographic parameters**

| Parameter | Correlation coefficient | P value |
|---|---|---|
| Duct size | 0.54 | < 0.001 |
| Ampulla size | 0.58 | < 0.001 |

Duct size and ampulla size showed significant correlation with the diameter of the coil used.

**Prediction of the coil length from the duct size**

The length of the coil used showed high degree of linear correlation with the diameter of the duct measured on angiogram. The total length of the coil required can be predicted from the diameter of the PDA measured on the angiogram. ( Table VIII).Y=4.8x - 4.3( Y is the total length of the coil and X is the duct size)

## Table VIII

**Univariate predictor of coil length and duct size**

| Predictor | β | P value |
|---|---|---|
| Duct size | 0.55 | < 0.001 |

**$R^2$ = 0.302**

Total length of the coil is related to the duct size ($\beta$ = 0.55, $p < 0.001$) and the total length of coils needed can be predicted from the duct size.

**Prediction of the diameter of the coil from the duct size**

The diameter of the coil required showed significant correlation with the size of the duct. It is possible to predict the coil diameter from the duct size.( Table IX). Y=1.2X+2.91(Y is the coil diameter and X is the duct size)

**Table IX**

**Univariate Predictor of Coil Diameter with Duct Size**

| Predictor | β | P value |
|---|---|---|
| Duct size | 6.54 | < 0.001 |

$R^2$ = 0.291

Coil diameter can be predicted from the duct sizeβ = 6.54, p< 0.001

64-A D

# DISCUSSION

## DISCUSSION

Transcatheter closure of PDA is an established alternative to surgical ligation there by avoiding lateral thoracotomy, shortening hospital stay and reducing costs[59].There are several reports using various devices and novel techniques for occlusion of PDAs [87,88,89,90,91]. Numerous reports confirm the safety and efficacy of Gianturco coil occlusion of PDA. Santoro et al [92] in their study of percutaneous treatment of moderate-to-large patent ductus arteriosus with different devices in 57 patients concluded that by tailoring the device choice to the patient size and ductal morphology the multiple coil option revealed as effective as the ADO (Amplatzer duct occluder) device over a mid-term follow-up. After the first case reports [24] demonstrated efficacy, the procedure was adopted at many centers and started to be widely employed. Individual centers reported success in patient series throughout the remainder of 1990s.The size of the series ranged from 24 Michigan patients [93] reported in 1993 to 149 Boston patients[54] reported in 1999 .Recent reports include 86 patients in whom bioptome assisted coils occlusion was used in moderate to large PDAs in infants and children by kumar et al[29].Even the earliest reports demonstrated high rates of successful implantation (92% to 97%), no mortality and little significant morbidity. Reports from the end of 1990s in larger patient groups have extended the range of this procedure to larger PDAs and to smaller younger patients. They demonstrate successful implantation in up to 98% of patients, no mortality and little significant morbidity.

## The Technique

Transcatheter closure can be achieved by either coils or devices. However, devices are quite expensive and in many developing countries, device closure costs far more than surgical closure. Moreover multiple coil deployment has been shown to be equally effective as Amplatzer duct occluder[92]. Transcatheter PDA closure using Gianturco coils has been very successful, safe and cost effective[68, 94]. Nevertheless coil implantation was difficult for large PDA due to lack of stability and easy coil migration[95].Due to large amount and high velocity of blood flow through a large PDA, two problems are associated with coil occlusion procedures:1) An excessive amount of coil positioned in the pulmonary artery 2) coil embolization .Modified catheters and snare devices have been used to hold the coil during placement, affording some control during positioning the coil, or coil removal if necessary. Although these techniques improve the procedure results, they complicate the procedure, and if the coils are not in the optimal position, the coil must be pulled out of the patent. When pulling the coil out of the patient, the coil can become entangled in the tricuspid valve or iliofemoral vein. Once the coil is removed, to implant another coil, the procedure must be restarted from the beginning. An ideal system for occluding large PDAs would allow for easy repositioning of the coil in the PDA, and simple coil removal if a different size of the coils is needed. Bioptome assisted coil occlusion overcomes many of the difficulties of coil closure of larger PDAs by ensuring much better control

of the delivery process[96] If too many loops of coil are positioned in the MPA, or the coil is not positioned optimally in the PDA, the coil-bioptome can be pulled back into the sheath and the same coil can be redeployed. If the coil diameter is too large or too small, the coil is removed easily by pulling it back into the sheath, as the sheath is advanced into the PDA, then a different size coil can be implanted through the same sheath. If desired, the coil can be held with the bioptome during angiography, or while crossing the PDA with a catheter to place additional coils. Long sheath with a radio opaque band on the distal end is useful for accurate positioning. The only drawback of the system is the additional cost of the bioptome. The minor cost of the bioptome may be overweighed, however, by shorter fluroscopy and catheterization time and most importantly, improved clinical results. For large ductus a single coil is often not sufficient. This techinique allows more than one coil to be deployed simultaneously. This method has potential for closing large ductus that would otherwise require occlusive devices or surgical operation. In this technique coils of different sizes can be used simultaneously, the smaller diameter coils are likely to turn inside the larger coils. This technique also allows simultaneous retrieval and redepyloyment of all the coils if the initial position is not satisfactory. We found that the delivery sequence described by kumar et al[29] to be useful. This technique is different from previous descriptions of bioptome assisted PDA coil closure[96]. In this techinique the entire coil is brought out

into the descending thoracic aorta and then pulled back allowing its compaction in the ampulla, thereby acting as a plug with very little or no protrusion into pulmonary artery. Apart from the ratio of coil diameter to the narrowest duct diameter coil stability is largely determined by whether or not the coil mass is entirely in the ampulla. Ducts with small ampulla may not be suitable for coil occlusion. We also found that flexible 3 Fr bioptome to be more useful than the stiff 5 Fr bioptome. Attempts to hold the coil for longer periods using a stiffer 5 Fr bioptome often resulted in inadvertent dislodgement of one or more coils. Lorber et al [97] used a new catheter that combines good angiographic properties, easy manipulation across the duct, documentation of aortic and pulmonary artery pressure, and coil delivery for percutaneous transaortic ductal occlusion. Only one catheter and one guide wire were used per procedure, with no need for exchange wires or the establishment of an arteriovenous loop. They could significantly decrease the procedure and screening time.

**Coil embolization**

Early reports had embolization rates upto 8%[98] whereas recent rates have been only 3.5 or 4 %. Hijazi et al[99] reported coil embolization as a complication in 7 out of 24 infants. However this study was in infants with technically difficult procedures. The current low embolization rates are especially remarkable because larger technically more challenging PDAs have been included in the recent series. We had only 3(4.5%)

patients who developed embolization. Low rates in our series might have been due to the the use of bioptome. Embolization in our series was unrelated to PDA size or angiographic PDA type. Kumar et al [29] in their study of bioptome assisted coil occlusion of moderate to large PDA in infants and children reported embolization in 14/86(16.2%) patients. They noted that two of the four instances of aortic embolization were related to attempts to deploy the coils entirely in relatively small ampulla and two cases it was during attempts to recross the duct for additional coil deployment. Snare retrieval and redeployment of the same coil was accomplished in all four patients who had aortic embolization in their study. They also noted that 10 instances of pulmonary artery embolization were because of underestimation of the duct size (n=8), failure of the jaws to open satisfactorily to release the coil and embolization of additional coil during deployment. They could reterive the coils in all their 14 patients. These are the usual problems related to coil embolization noted in most series

**Closure results**

The early series reported high residual shunt rates at the time of hospital discharge (17% to32%) [93] .These shunts were usually trivial and many resolve completely during follow up. Kumar et al[29] in their study of bioptome assisted coil occlusion of moderate to large PDA in infants and children reported complete flow occlusion in the catheterization laboratory in 63/86 (73%) patients. Ten of the 23 patients with residual flows

demonstrated in the catheterization laboratory continued to have demonstrable flows on 24 hr Doppler examination. On follow up small residual flows were demonstrable in 11 patients (12.7%) at 3 months that disappeared at one year in two patients. Residual flows were associated with murmur in two of their patients who underwent repeat coil deployment with flow elimination. Daniels et al [100] in their study of 25 patients undergoing trascatheter coil occlusion of PDA, 4 out of 7 (57%) had evidence of residual left to right shunt. They also noted that these patients had length/diameter of the PDA < 3. whereas only 2 out 16 ( 12.5%) with a length/diameter ratio> 3 had residual shunt at intermediate follow up. Similar findings were reported by Forbes et al [101]. With additional operator experience, modification of the implantation technique, use of larger coil loops, coils with more loops, and in many cases more than one coil, residual shunt rates at the time of hospital discharge have been reduced to as low as 3%. With the use of bioptome and improved techniques present day residual shunt are much less. In our study we had only two patients with trivial shunt at the time of at the time of hospital discharge. Early reopening and recanalization after successful coil occlusion of PDA was reported by some authors. Daniels et al [100] found 25 % incidence of PDA reopening 2 to 12 months after procedure. Other investigators have reported a 3 % to 9 % risk of PDA reopening with follow up periods ranging from 9 to 20 months.[102,103].Patel et al [73] reported no PDA recanalization in a large series of patients with a

median follow up of period of 3 years . Turner et al[104] in their review of early reopening and recanalization after successful coil occlusion of PDA noted that early PDA reopening after initial complete coil occlusion occurs uncommonly within 6 months of coil placement. Patients with normal echocardiogram 6 months after coil placement did not develop PDA recanalization, LPA stenosis, or aortic obstruction at intermediate follow up. Interestingly guidewire and catheter manipulation without coil placement has been shown to close minimal patent ductus arteriosus (<1 mm) [105]. Thirty eight patients with minimal PDA were enrolled in their study between

April 2000 and September 2004, They classified their patients into two groups. Group A consisted of 11 patients (age range 0.7

to 3.5 years; mean age 1.6 years) who underwent guidewire and catheter manipulation. Group B consisted of 27 patients (age range 0.5 to 2.7 years; mean age 1.3 years) who underwent transcatheter closure of PDA. They found that in group A (PDA 0.4-0.9 mm), 9 (82%) patients had successful closure, and two (18%) patients failed the manipulation. No patient had complications during the procedure or follow-up. In group B (PDA 0.5-0.9 mm), 26 (96%) patients had successful closure and 1 (4%) patient failed the attempt at transcatheter coil closure. No adverse events of coil closure were found during follow-up. Compared to the patients in group B, those in group A differed significantly in terms of procedure time. There were no significant differences in age, sex, body weight, PDA

size, fluoroscopy time, success rate, and complication rate. They concluded that the catheter manipulation is safe and effective for patients with minimal PDA. The manipulation technique can be tried before transcatheter coil closure in patients with minimal PDA.

**Selection of Coils**

Selection of the type and number of coils is very important in the success of this procedure. However, there is no universally accepted method for coil selection. Coil selection is usually made from measurements from a lateral aortogram, hemodynamic significance, patient size and age of the patient[39]. The most important measurements include the duct size, anatomy and size of the ampulla. Kumar et al [29] suggested echocardiographic measurement to guide coil selection unless the duct diameter by angiography was larger than the echocardiographic measurement. This was done to avoid being misguided by duct spasm. What coil sizes are most likely to achieve duct closure continues to involve some guess work. Coil loops must be large enough to prevent embolization through the PDA and coil loops should also be small enough and few enough to avoid causing obstruction to either the descending thoracic aorta or left pulmonary artery. Excluding neonates, Gianturco coils are capable of occluding most PDAs. PDA with minimum angiographic diameter upto 10mm have been closed .PDAs that are short are more difficult to close with coils especially if they are larger than3mm in diameter. Moore et al [102] in their review of PDA closure in their hospital

between found that the ratio of the minimunm PDA diameter to the diameter of the descending thoracic aorta below the ductal diverticulum was the most important descriminator between patients who underwent PDA coil closure vs those who under went surgery. If the ratio was 0.3 or less 94% of the patients had successful coil occlusion. Various authors have used different criteria for selection of coils. In order to prevent coil embolization the loop diameter must be at least twice the minimum PDA angiographic diameter[40].The maximum coil loop diameter should be less than or equal to the maximum dimension of the ampulla[40].The coil length should allow for 4 loops of coil: ½ to 1 loop in pulmonary artery,3 to 3 ½ loops in the ampulla. Only few studies are available on the selection of appropriate size coils for PDA closure. Lertsapcharoeon et al [95] reported the results in transcatheter coil occlusion of patent ductus arteriosus less than 4 mm, based on a policy in selection of the appropriate type and number of coils for size of PDA. The authors used one 0.035 inch detachable coil, 5 mm in diameter, in PDA less than or equal to 2 mm, and two 0.035 inch detachable coils or one controlled release 0.052 inch Gianturco coil in PDA larger than 2 mm. Their study included 32 pediatric patients. There were 31 cases of successful coil implantation and 1 case failed. Of the 31 successful cases, PDA size varied from 1.4 to 4.0 mm (mean of 2.7 $\pm$ 0.9 mm).The patients were classified into group A and B. Group A included ten patients with a PDA size of less than or equal to 2 mm, while group B included the other 21 patients with a PDA size of

larger than 2 mm. In group A, 9 cases had single-detachable-coil occlusion and one case had double-detachable-coil occlusion. In group B, double-detachable-coil occlusion was performed in 17 cases and controlled release 0.052 inch coil in 4 cases. In their study there were no cases of coil migration or other serious complications. The immediate complete occlusion rate was 58 per cent (18 of 31 cases), which rose to 97 per cent (30 of 31 cases) at the mean follow-up of 2.6 + 2.5 months (range from 1 day to 9 months).They concluded that transcatheter coil occlusion is an alternative to surgical closure of small PDA (less than 4 mm). Kumar et al[33] in their study of bioptome assisted coil occlusion of moderate to large PDA used different criteria as mentioned previously in review of literature. They also suggested to cut the coils if it was anticipated that the coil turns would not fit into the ampulla. The cut end of the coils was carefully inspected. If the cut end had sharp edge a few millimeters of the coil was cut to ensure smoothness. This also indicates how important it is to accurately size the coils. Measurement of the duct size is crucial in the selection of coils. Coils are available with a core diameter of either 0.52" or 0.32".In the present study we used 0.52" coils whenever possible. The 0.052" Gianturco embolization coils (Cook Inc ) are constructed from a heavier gauge wire than the more commonly used 0.38" Gianturco coils. During the implant, the 0.052" coils maintain their tightly wound loop size and configuration: they do not have the longitudinal stretch (ie the accordion effect) as do 0.038" coils. The

sturdier 0.052 coils provides improved positioning during implantation[96]. Because the 0,052 "Gianturco coil is larger in diameter and it requires a larger catheter to implant. 7 Fr catheters may be required which may be too large for small infant. Another disadvantage is that the stiffness of the 0.052" coil might stretch the PDA and change shape of the ductus. Because the contour of the PDA is distorted shunt may become significant if the coil occlusion is not complete in patients having PDAs with significant shunts (Qp/Qs>1:4). Tomita et al [106] reported good results with the use of 0.052"coil. They used used a Gianturco coil (0.052-inch coil) to close PDA >or=2.5 mm. In a retrospective survey of the outcome of coil occlusions for PDA >or=2.5 mm before and after the 0.052-inch coil became available found that (1) the frequency of PDA >or=2.5 mm among all candidates for coil occlusion significantly increased after the availability of a 0.052-inch coil ($p<0.01$); (2) deployment complicated by migration ($p<0.01$), and prolonged procedure time ($p<0.05$) were significantly decreased after the introduction of the 0.052-inch coil. In a multivariate logistic regression model for uneventful deployment adjusted for age, pulmonary to systemic flow ratio, and use of a 0.052-inch coil, use of the 0.052-inch coil significantly decreased eventful deployment ($p<0.05$); and (3) successful deployment of a coil for PDA >or=4 mm significantly increased with the 0.052-inch coil ($p<0.01$). Complete occlusion was achieved once deployment was successful. They concluded that Introduction of the 0.052-inch coil decreased complicated coil

occlusion deployment for PDA >or=2.5 mm, and contributed to a better likelihood of coil occlusion for PDA >or=4 mm.

**Multiple coils**

In the present study 29(43%) of patients required single coil, 32patients (48%) required two coils and only 6(9%) required three coils. In the PDA coil registry[107] sponsored by the university of Michigan and children hospital San Diego CA, involving 64 centres and 1365 Gianturco coil occlusions procedures in 1336 patients most patients most patients (66%) had one coil implantation via the arterial route. However upto nine coils were implanted in individual patients (mean 1.6 coils per patient) About 5% of patients had PDAs that were too large to occlude. Haung et al [108] in their study of safety and efficacy of using 0.052 –inch Gianturco coils for closure of large patent ductus arteriosus found that single 0.052" coil implantation was rarely able to close large PDAs. In their study transcatheter closure of PDA was successful in 13/15(86.7%) o f their patients. Successful single 0.052" coil occlusion of PDA was achieved in 4 patients. The other eight patients received at least two coils. One patient needed three coils. They reported that the 'multiple coil no residual shunt strategy' previously proposed by Zellers et al[71] to be very effective. Lee et al [109] studied the outcome of percutaneous trans-arterial coil occlusion in patients with isolated patent ductus arteriosus using an upstream-and-push maneuver. This study evaluated the 2-year outcome of 52 patients with isolated PDA who received percutaneous transarterial coil occlusion

by an upstream-and-push maneuver.They included a total of 52 patients (25 infants, 27 children) who underwent occlusion of PDA with standard Gianturco coils. There were 39 females and 13 males. Patient age ranged between 7 days and 14 years, and weight was between 3 and 45 kg. Percutaneous transarterial coil occlusion was performed by an upstream-and-push maneuver. Doppler echocardiography were performed in all patients within 24 hours, and 1, 3, 6, 12 and 24 months after coil occlusion. Mean PDA diameter at the pulmonary end was 2.34 $\pm$1.00 mm (range, 1.00-4.80 mm). Angiographicaly they classified PDA into megaphone type in 32 patients, window type in seven, tubular type in six, aneurysmal type in three, and elongated conical type in four. Complete PDA occlusion was performed with a single coil in 41 (79%) patients and with multiple coils in 11 (21%). The mean ratio of pulmonary to systemic blood flow in their study was 1.95 $\pm$ 0.95 (range, 1.10-5.80) before the procedure, and 1.02 $\pm$ 0.04 (range, 1.00-1.20) after the procedure ($p < 0.001$). They could achieve immediate occlusion of the ductus in 15 minutes after the procedure in 44 (85%) patients. 92% of their patients achieved occlusion within 24 hours and in 100% of patients by the 1-month follow-up. There were no complications on follow-up at 24 months after the procedure. Percutaneous transarterial coil occlusion with 5-loop Gianturco coils can be effectively and safely achieved in patients with a PDA minimum diameter <5mm.

**Coil impingement on adjacent structures.**

Use of multiple coils may be a risk factor for coil impingement on adjacent structures and for coil embolization. Most authors screened prospectively for impingement of the coils on adjacent structures as a result of prior experience with the Rashkind occluder [110,111,]. To date, there has been no significant problem with aortic arch obstruction secondary to coil position in any series. Some LPA impingement by the coil with either frank stenosis and/or increased flow rates by Doppler, have been noted in some patients by most authors. Moore et al[40] found Doppler evidence of LPA impingement in 10/29 patients. In the study by Forbes et al[101] two patients developed mild LPA stenosis which in one patient persisted at 43 month follow up. Hijazi et al [99] also noted LPA stenosis in two infants where multiple coils were required. Later studies have confirmed that the pulmonary branch and aortic obstruction induced by coils have not been clinically important .Zellers et al[114] found that complete closure of PDA by multiple coils is feasible and poses no danger to the adjacent vessels. They also stated that the use of even two 0.052" Gianturco coils does not jeopardize the left pulmonary artery or the adjacent aorta.

**Measurement of duct size**

The duct size can be measured by either echocardiography prior to the procedure or by angiogram during the procedure. In the present study both measurements showed good correlation. Hence

echocardiographic measurement of the duct size can be used as a guide to coil selection prior to the procedure; however final coil selection is made from the angiogram. This information from the echocardiogram prior the procedures enable us to make sure the availability of the appropriate coils. Kumar et al[29] in their study also found echocardiogram very useful in selection of coils. In most infants and small children, excellent echocardiographic assessment of duct diameter at PA insertion and adequacy of its ampulla can be obtained using a combination of high parasternal or ductal views and suprasternal views[114,115]. In their study, all patients were selected for coil occlusion after echocardiographic assessment alone and they did not change their strategy in any patient after angiography. In the present study ampulla size measured by echocardiogram and angiogram showed significant correlation. Saunders et al [116] in their study in dogs compared echocardiographic and angiographic ductual dimensions. PDA dimensions were obtained with angiography, 2D and colour Doppler transthoracic echocardiogram, 2D and colour Doppler transoesophageal echocardiogram from the right and left views were prospectively evaluated. They found that PDA dimension measured by using TEE most closely approximated angiographic measures. TEE provided accurate anatomic information regarding PDA morphology and closely approximated angiographic ductal dimensions while aiding in both coil deployment and confirmation of intra-operative ductal closure.

**Clinical profile and number of coils**

In our study we did not find correlation between the number of coils and presence of symptoms, weight or the presence of left ventricular hypertrophy by electrocardiogram. However there was significant correlation between the presence of cardiomegaly and plethora and the number of coils used. Those patients with cardiomegaly and plethora on X ray chest required more number of coils. These parameters usually indicate that the duct is large. However we could not quantify the shunt in these patients due to technical difficulties. Haung et al [108] in their study of 25 patients assessing the safety and efficacy of using 0.052 inch Giantuco coil for closure of large patent ductus arteriosus noted mean QP/Qs of 2.4 (range 1.5 to 3.5); however this was not a significant criteria for selection of coils. The only study which used QP/Qs for selection of coil was that of Moore et al [40] .They used coils with larger nominal diameter (0.052") in larger patients having PDA with significant shunts (Qp/Qs>1:4).Forbes et al [101] in their study of angiographic and hemodynamic predictors for successful outcome of transcatheter occlusion of PDA in infants less than 8 Kg did not find any significant difference between successful versus unsuccessful groups regarding age, weight, or technique used to deliver the coils.

**Haemodynamic parameters and number of coils**

In the present study hemodynamic parameters like pulmonary artery systolic pressure, pulmonary artery diastolic pressure, pulmonary

artery mean pressure, aortic systolic pressure, aortic diastolic pressure and aortic mean pressure did not correlate with the size and number of coils used. Forbes et al [101] in their study of angiographic and hemodynamic predictors for successful outcome of transcatheter occlusion of PDA in infants less than 8 kg found that lower preocclusion systolic, diastolic, and mean pulmonary artery pressures to predictors of successful outcome.

**Duct size and number of coils.**

Moore et al[40] used 0.052 coils in patients having PDA with significant left to right shunt. In our study there was significant relationship of multiple coil use and increasing PDA size ($p< 0.001$). Patients with duct size between2.4 and 2.7mm need only a single coil at 95% confidence interval. Two coils were used when the duct size is between3.3 and 3.7mm at 95% confidence interval. Three coils were used when the duct size is between 3.7 and 4.7mm at 95 % confidence interval. Our observations are in agreement with that published by Kumar et al[29]. This information is very useful in guiding the coil selection. Forbes et al[101] analysed angiographic and hemodynamic predictors for successful outcome of transcatheter occlusion of patent ductus arteriosus in infants less than 8 kilograms The hemodynamic and angiographic data evaluated included the length/diameter (L/D) ratio, defined as the length divided by the narrowest diameter of the ductus arteriosus, and preocclusion pulmonary artery pressures. In their study The L/D ratio was the strongest predictor of successful outcome, with an L/D ratio greater than

3.0 being more amenable to transcatheter occlusion (odds ratio of 4.6). Other predictors for success included lower preocclusion systolic, diastolic, and mean pulmonary artery pressure and smaller ductal diameter. They concluded that infants less than 8 kg with an L/D ratio > 3.0 can safely and successfully undergo transcatheter occlusion of their PDA. Hijazi et al[99] found that larger ductal diameter may make a ductus less amenable to trancatheter occlusion. Others have found that ductus with shorter length was difficult to close. Ing et al[53] used multiple coils in 27 % (28/104) of their patients. In their study of 104 patients two coils were used in 23 patients, 3 coils in 2 patients and 4 coils in one patient with 6.8 mm PDA. They also found significant relationship of multiple coil use with increasing PDA size. In the small PDA group multiple coils were used in only 2.6 % of patients. They classified their patients into three groups according to minimum PDA diameter. Group 1(2.1 -3mm),group II( 3.1 - 4) and group III >4mm. Group I patients received multiple coils in only 9.7% (6/62)of procedures ($p<0.03$,compared with the study group as a whole);both group II(40.7%,11/27;$p<0.02$) and group III (73.3%,11/15;$p<0.001$) patients received multiple coils more frequently than group I. In their study group, the mean PDA minimum diameter in which single coil was implanted was $2.8 \pm 0.6$ compared with $3.8 \pm 1.1$ mm in patients with multiple coil closure ($p<0.001$).The largest PDA in their study to have immediate complete closure with single coil was 4.9 mm in diameter.

**Number of coils and ampulla size.**

In the present study we found significant correlation between the number of coils used and the ampulla size (P=0.001). More number of coils was necessary when the ampulla is large.

**Duct size and total length of the coils.**

The duct size and the total length of the coils showed high degree of linear correlation ($p<0.001$). It is possible to predict the total length of the coil required from the duct size from the formula $Y= 4.8x-4.3$ (Y is the total length of the coil and x is the duct size).This information is also useful to select the appropriate size of the coils. If the length of the coil is known the number of loops can be calculated. (number of loops= coil length/circumference of each loop)

**Duct size and coil diameter.**

In the present study the duct size and the coil diameter also showed significant correlation ($p<o.001$). It is possible to predict the coil diameter required from the duct size using the formula $Y=1.2x+2.91$(Y is the coil diameter and x the duct size).Similarly ampulla size and coil length are highly correlated and correlation is significant. The coil length can be predicted from the diameter of the ampulla using the equation $y=0.43\ x+3.396$(Y is the coil length and x ampulla diameter). In addition angiographic type of the ductus is important in determining the success of the procedure. The PDA coil registry[107] and other series demonstrated a significant relationship between failure of coil implantation and

angiographic type B. However in the present study majority of the ducts were of Type A (79%) and the number of patients in other type of ductus were small to draw any definite conclusion. However Ing et al[53] did not find any relation of the angiographic type of ductus to procedure failure, incomplete closure or to use of multiple coils. The tremendous effectiveness of the Gianturco coil, along with the low cost and widespread availability of this coil, however make it the preferred method for transcatheter PDA occlusion. Selection of appropriate size coils is very important for success of the procedure. To the best of our knowledge no previous studies are available to predict the length of the coils needed from the duct and ampulla size.

# SUMMARY & CONCLUSION

## Summary

Congenital cardiovascular disease is defined as an abnormality in cardiocirculatory structure or function that is present at birth, even if it is discovered much later. Patent ductus arteriosus is a congenital heart disease where there is patency of the vessel that normally connects the pulmonary arterial system and the aorta in the fetus. Surgical ligation or division of the patent ductus arteriosus was the initial mode of management of these patients. With the advent of transcatheter closure of Patent ductus arteriosus this method is now widely accepted as safe and effective alternative to surgery. Transcatheter closure can be done either using devices or coils. However devices are quite expensive and in many developing countries the devices cost far more than surgical ligation. Transcatheter closure using coils is cheap and effective. Selection of the type and the number of coils is very important in the success of transcatheter closure using coils. However there is no universally accepted method for selection of coils. In the present study we analysed the clinical, echocardiographic, hemodynamic and angiocardiographic parameters of the patients who underwent successful coil closure to find out the determinants of selection of the size and number of coils. Our data show that size of the duct and ampulla measured on echocardiogram correlated well with those measured on angiogram. We did not find correlation between number of coils and presence of symptoms, weight and the presence of left ventricular hypertrophy on electrocardiogram.

However there was correlation between the number of coils used and presence of cardiomegaly and the presence of plethora. Our study also showed that the size of the ampulla and duct measured on angiogram was the most important parameter for selection of the coils. It is also possible to predict the number of coils, the total length of coils, and the diameter of the coils needed from these measurements. This information is very important in the success of the trascatheter closure of Patent ductus arteriosus using coils. Transcatheter closure of patent ductus arteriosus using coils is a safe and effective method and the measurements made from the angiogram is the most important criteria for selection of coils.

## Conclusions

Bioptome assisted transcatheter closure of patent ductus arteriosus using coils is a safe and effective alternative to surgical ligation or division. Selection of the appropriate size of the coils is very important in the success of the procedure. Measurement of the duct size from the lateral aortogram is the most important parameter for selection of the coils. These measurements help us to predict the number of coils, the total length of the coils and the diameter of the coils

## Abbreviations

| | | |
|---|---|---|
| ADO | : | Amplatzer duct occluder |
| ASD | : | Atrial septal defect |
| AS | : | Aortic stenosis |
| BPV | : | Balloon pulmonary valvuloplasty |
| CHD | : | Congenital heart disease |
| COA | : | Coarctation of aorta |
| CT | : | Computed tomography |
| D-TGA | : | D transposition of great arteries |
| DVI | : | Doppler flow velocity integral |
| ECG | : | Electrocardiogram |
| LPA | : | Left pulmonary artery |
| LVH | : | Left ventricular hypertrophy |
| MDCT | : | Multidectector row computed tomography |
| MPA | : | Main pulmonary artery |
| MRI | : | Magnetic resonance imaging |
| NYHA | : | New York heart association |
| PDA | : | Patent ductus arteriosus |
| PS | : | Pulmonary stenosis |
| TTE | : | Transthorasic echocardiography |
| TTE | : | Transoesophageal echocardiography |
| VSD | : | Ventricular septal defect |

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