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# Transcatheter closure of patent ductus arterious at Chris Hani Baragwanath hospital and the importance of the shape and size of the patent ductus

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# TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS AT CHRIS HANI BARAGWANATH HOSPITAL AND THE IMPORTANCE OF THE SHAPE AND SIZE OF THE PATENT DUCTUS

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg in partial fulfilment of the requirements for the degree in Master of Medicine in Paediatrics

Johannesburg 2016

## Declaration

I, Paul Ernest Adams declare that this research report is my own work. It is being submitted for the degree of Master of Medicine Paediatrics in the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other University.

Dr Paul Ernest Adams

On the Twenty ninth day of February 2016 in Johannesburg

## Dedication

This work is dedicated to my wonderful wife Jill, and children Matthew, Nina and Christopher, without their love, happiness, encouragement, endless patience and sacrifice it would never have been completed.

## Acknowledgements

I would like to thank and acknowledge Professor Antoinette Cilliers, my supervisor for her role, and who over the years has taught me all I know about Paediatric Cardiology.

I would also like to thank and acknowledge all the cardiologists and fellows I have worked with at Chris Hani Baragwanath Academic hospital for their roles in the procedures and patient care discussed in this report, and my continued education in this field.

Prof MF Chersich deserves a special mention for his tireless and thankless encouragement and advice over the many years it took me to complete this work, in a field very foreign to him, a true labour of friendship.

Finally I would like to acknowledge my Parents who enabled me to start this journey many years ago with boundless support and encouragement.

# Abstract

## Objectives

Review outcomes of transcatheter closure of patent ductus arteriosus (PDA), role of PDA shape and changes in practice over time.

## Methods

Retrospective analysis of patient files and clinic database performed on children who had transcatheter PDA closure at Chris Hani Baragwanath Hospital between 01/01/1993 and 30/06/2008.

## Results

Over 15 years, 1254 PDAs were diagnosed, of which 293 required closure (167 with surgery and 139 transcatheter). Median age at transcatheter closure was 1.8 years (IQR=1-4.5years); 66.2% were female (92/139). Mean PDA diameter was 3.2mm (sd=1.6mm), with an average 2:1 shunt. Transcatheter closure was performed using COOK® Flipper coils (n= 93; 18 required multiple coils) or Amplatzer™ devices (n=46: 37 with ADO1, 8 AVP and 1 ADO2). Repeat procedures were needed in 20 children: Early occlusion rates for coils were 52% (39/75); late occlusion occurred in 90.6% (68/75). Amplatzer™ devices, available since 2003, are now overwhelmingly used. For ADOs, early occlusion rates were 94.3% (33/35) with 100% late occlusion. Successful closures were associated with PDA shape, with 88% closed with type A and E, 50% type B, 28% type C and 0% type D. Surgical closure reduced over time: from 94 weeks (1993–1997), to 40 weeks (1998–2002) and 32 weeks(2003–2008).

## Conclusion

Transcatheter PDA occlusion is safe and effective in this setting, with outcomes similar to reports elsewhere. Shape and size of PDAs are important determinants of device selection and procedure outcome. Transcatheter occlusion helps minimise surgical waiting lists. Overall findings support more widespread use of this procedure in similar settings.

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## List of Publications arising from this Research Report

- Presented as a poster at the World congress of Paediatric Cardiology and Cardiac Surgery in Cairns Australia 2009
- Presented data as an oral presentation at the South African Heart Association congress in 2008

## List of Abbreviations

| | |
|---|---|
| PDA: | Patent Ductus Arteriosus |
| DA: | Ductus Arteriosus |
| ADO: | Amplatzer™ Duct Occluder |
| LA: | Left Atrium |
| AO: | Aorta |
| LA:Ao : | Left Atrium to Aortic ratio |
| SVT: | Supraventricular tachycardia |
| CHBAH: | Chris Hani Baragwanath Academic Hospital |

# Chapter 1 - Introduction

The patent ductus arteriosus (PDA) is a common congenital heart lesion with isolated PDAs accounting for between 6-11% of all congenital heart defects[1]. PDAs are relatively easy to diagnose, and as new devices become available the majority can be effectively and safely closed without surgery, preventing not only the complications of the PDA itself but also some of the morbidity associated with surgery[1]. Surgical closure has been the standard management of PDAs. However more recently, transcatheter closure methods have superseded surgery for most PDAs, and increasingly so.

The ductus arteriosus (DA) is a large vessel that is an essential part of the foetal circulation. The DA allows blood leaving the right ventricle to bypass the lungs and flow directly from the pulmonary trunk into the descending aorta[2]. Shortly after birth, constriction of the DA, results in functional closure. Functional closure is usually complete within hours of birth; complete anatomical closure is achieved by two-to three weeks. Failure of the DA to close results in a PDA.

Prematurity predisposes to persistent patency of the ductus; the shorter the gestation the higher the incidence of PDA. According to A. Rudolph: “More than 80% of infants weighing less than 750 grams have patency of the ductus arteriosus beyond the third day after birth.” [3] Numerous factors underlie the high incidence of PDA in premature infants, including immaturity of ductal tissue, increased circulating prostaglandins and hypoxia, to which these infants are predisposed[3].

Persistent PDA in term infants, who are not hypoxic after birth, is likely a result of structural or biochemical abnormalities of the ductus arteriosus, which interfere with physiological constriction. There are a number of theories as to the possible biochemical and structural reasons for persistent patency of the DA. Congenital rubella has been shown

to result in an increased incidence of PDA. There is also a possible genetic basis with some families showing recurrences[3].

Persistent patency of the DA results in left to right shunting of blood from the aorta to the pulmonary arteries. This results in increased pulmonary blood flow, which is the first step to the resulting morbidity and mortality caused by the PDA. The size of the left to right shunt determines the severity of the symptoms and the progression (if untreated) to irreversible pulmonary hypertension, Eisenmengers Syndrome and death. The size of the shunt is firstly dependant on the size of the PDA, however the relationship between the pulmonary and systemic vascular resistances also play an important role in determining the volume of blood shunted[3]. Together, these factors determine the clinical presentation and progression.

The initial effect of increased pulmonary flow is volume overload of the left atrium and left ventricle resulting in left-sided cardiac failure. This manifests as failure to thrive, excessive sweating while feeding, poor feeding, recurrent chest infections and decreased effort tolerance. The increased flow leads to changes in the pulmonary vasculature, which together with the increased left atrial pressure, results in increased pulmonary pressures. The pulmonary pressures continue to rise and eventually become equal to systemic pressures. At this point, the shunting stops and the child is seen to improve. The pulmonary pressures continue to increase and right to left shunting begins. Changes in the pulmonary vasculature become irreversible – once this point is reached it is known as Eisenmengers Syndrome. For children with Eisenmengers syndrome, closure of the PDA is contraindicated and treatment becomes predominately supportive. Progression of a child with a PDA to Eisenmengers Syndrome is completely unacceptable, and reflects several failures in child health services.

Large PDAs tend to result in more severe symptoms and signs with rapid progression of

the disease, small PDAs may remain undiagnosed, even lifelong. The small PDA however, despite not causing pulmonary hypertension, can have devastating consequences in the form of infective endocarditis.

Early recognition and treatment of the PDA is critical for preventing these disastrous and avoidable outcomes.

Broadly, there are two options for closure of PDAs: surgical or transcatheter occlusion. Transcatheter closure involves the insertion of a device, through a catheter into the PDA from peripheral vessels such as the femoral artery or vein. The indications for closure are the same for both treatment options. There are factors that would make one method more appropriate than the other,[1, 4] for example; the shape of the PDA, the size of the PDA, pulmonary pressures and pulmonary resistance. Since the introduction of echocardiography with colour Doppler the entity of a 'silent' DA has been described[5]. This is a PDA that, in the absence of colour Doppler, would have remained undiagnosed. The current expert recommendations are that a 'silent' ductus does not require closure[1, 5].

Surgical closure of the PDA has been available for many years, with the first report of surgical ligation by Gross and Hubbard in 1939[6]. This method then became the standard management[7]. Only in the last few decades has this been challenged by transcatheter options. More recently transcatheter PDA closure has become the preferred alternative to surgery[8, 9].

The first transcatheter options for closure of the PDA were described by Porstmann and co-workers in 1967[10]. Since then several devices have been designed for transcatheter closure of the PDA. At the time of the study available devices were coils e.g. detachable MReye® Flipper® PDA coils, Gianturco coils, pfm medical PDA coil, Nit-Occlud® PDA coils, the Gianturco-Grifka vascular occlusion device, and the range of Amplatzer™

devices (Amplatzer™ Duct Occluders, Amplatzer™ Vascular Plug and the Amplatzer™ ASD and VSD occluders). In the last few years the number of available devices has grown significantly. They range from close copies of the Amplatzer™ design, to devices with different shapes and release mechanisms (Ceraflex and Occlutec). In addition to these new devices the Amplatzer™ range has expanded offering devices with different shapes and even a range to close very small PDA's[11].

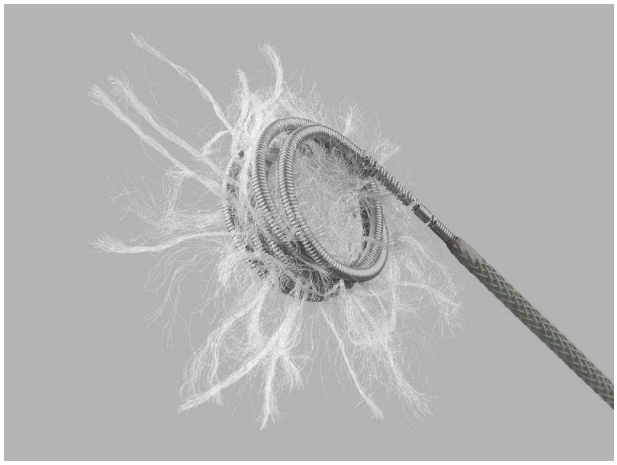


Figure 1.1: MReye Flipper PDA coil[12]



Figure 1.2: Amplatzer Duct Occluder 1[13]



Figure 1.3: Amplatzer Vascular Plug 1[14]



Figure 1.4: Amplatzer Duct Occluder II[15]

At the time of the study the detachable COOK® PDA coils were widely used in small PDAs (<2.5 mm)[8, 9, 16, 17]. The Amplatzer™ Devices have become increasingly popular for moderate to large PDAs (>2.5 mm)[8, 9]. These were first implanted in 1996 [16] and have since been shown to be safe, effective and relatively easy to use[9, 18-20]. The spectrum of PDAs amenable to transcatheter closure also continues to increase. With advances in closure technologies, only very small infants with large symptomatic PDAs, and PDAs

with unfavourable anatomy or failed device closure are candidates for surgical closure[4, 9].

In this study I review the transcatheter closure of the PDA's at Chris Hani Baragwanath Academic hospital over a fifteen-year period which includes the introduction of the Amplatzer™ range of devices to our setting.

# Chapter 2 - Methodology

## *2.1 Objectives*

The objectives of this research report are:

- To assess transcatheter management of PDA at Chris Hani Baragwanath Academic Hospital, over a fifteen year period.
- To assess the effects of the size and shape on the transcatheter management of the PDA.
- Compare outcome of transcatheter procedures in our setting with outcomes recorded in the literature by other centres.
- Describe the demographic profile of patients with PDAs in our setting.

Hypothesis

1. Shape and size are both important factors determining which device is selected for closing a particular PDA, and for closure outcome.

2. Transcatheter occlusion of PDAs is safe and effective in our setting

## *2.2 Study design and population*

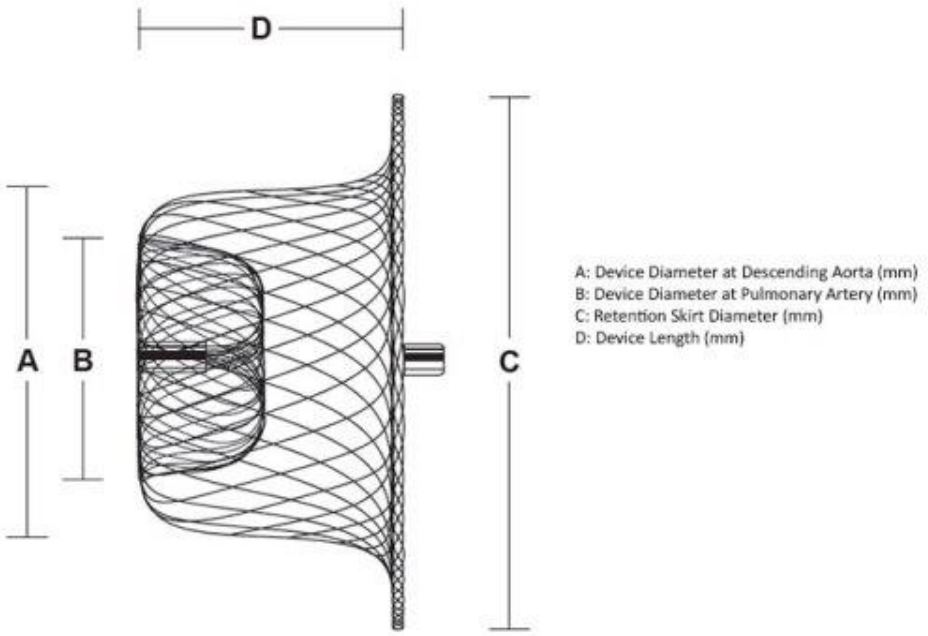
A retrospective analysis was conducted of the paediatric cardiology database (Microsoft Access 2003) and patient records at the Chris Hani Baragwanath Academic Hospital. All children who had transcatheter PDA closure at Chris Hani Baragwanath Hospital between January 1993 and July 2008 were included (a fifteen year period).

## *2.3 Procedure*

### 2.3.1 Implantation details

After obtaining informed consent, the children were sedated, and femoral arterial and

venous access was obtained. Transcatheter PDA closure was undertaken following standardised procedures, outlined below and described in full elsewhere[16]. A descending aortogram in the lateral position was performed at the start of each catheterisation in order to measure the dimensions of the PDA. This was done to prevent any interference with the PDA that may cause constriction and inaccurate measurements. A full diagnostic catheterisation was performed in all patients prior to attempted PDA occlusion, and the shunt and pulmonary vascular resistance were calculated. The narrowest point and ampulla were routinely measured and these factors were used to select an appropriate device. With experience, and particularly for Amplatzer™ devices, additional measurements were added; these usually included the length of duct and diameter of the aorta just proximal to the duct (in smaller children). The size of device was based on the manufacturer's recommendation of at least 2 mm greater than the narrowest point[21], other factors were considered including, PDA shape, ampulla size, and the size of the aorta. For sizing of the coils the narrowest point is also used and a coil with a diameter twice the narrowest measurement is chosen. Coils also have a variable number of loops, the number of loops chosen depends on the space available in the ampulla of the PDA to pack the coils[22].




| Reorder Number | Device Diameter at Descending Aorta (mm) | Device Diameter at Pulmonary Artery (mm) | Retention Skirt Diameter (mm) | Device Length (mm) | Min. Recommended Sheath Size (AMPLATZER™™ TorqVue™ Delivery System) |
|---|---|---|---|---|---|
| 9-PDA-003 | 5 | 4 | 9 | 5 | 5 F; 180° Curve |
| 9-PDA-004 | 6 | 4 | 10 | 7 | 6 F; 180° Curve |
| 9-PDA-005 | 8 | 6 | 12 | 7 | 6 F; 180° Curve |
| 9-PDA-006 | 10 | 8 | 16 | 8 | 6 F; 180° Curve |
| 9-PDA-007 | 12 | 10 | 18 | 8 | 7 F; 180° Curve |

Figure 2.1:Amplatzer Duct Occluder 1 Dimensions and sizing chart[23]

Amplatzer™ devices were routinely delivered from the pulmonary side, except in one patient with an interrupted inferior vena cava, where an Amplatzer™ Duct Occluder II was placed from the aortic side. The majority of coils were delivered from the aortic side; however, if multiple coils were placed in a duct they were sometimes placed from the pulmonary side or even using a combination of aortic and pulmonary routes.

Following device placement and prior to release we performed a number of checks to assess the correct placement of the device. A descending aortogram was performed on each patient. Pressure gradients in the aorta across the newly closed PDA were performed to ensure there was no significant obstruction to flow in the descending aorta. Once sure that

the device was correctly positioned it was released. A repeat angiogram was done and a gradient measured to assess any change in position during release. Following the procedure the patients were observed in the ward. Depending on the day the catheterisation was performed the follow up echocardiography took place 24 – 48 hours after the procedure. If there were no significant problems the children were discharged after the echocardiogram.

## *2.4 Data / Study variables:*

### 2.4.1 Data collection:

Data was collected from patient files and the electronic Paediatric Cardiology database (Microsoft Access 2003) at the Chris Hani Baragwanath Academic Hospital. Data collection included reviewing all available angiograms and classifying the shape of the PDA using the Krichenko classification[24] as this had not been routinely done.

A numbered, data collection sheet (Appendix) was completed for each patient. Data was then entered into a Microsoft Excel spread sheet and, for statistical analysis this was exported into Intercooled Stata 8.0 (Stata Corporation, College Station, TX, USA).

### 2.4.2 Study variables

Age, gender and anthropometric data were used to describe the demographic profile of patients with PDAs in our setting. Clinical details, haemodynamic data, anatomical details including PDA shape and dimensions at echocardiogram and angiography were used to fully describe the PDA and resultant haemodynamics. In order to assess the time taken to close the PDA the fluoroscopy time for each procedure was captured where possible.

The shape of each PDA was assessed angiographically by reviewing each angiogram and classifying them according to the Krichenco classification (A1-3, B1-3,C1-3,D,E )[24].

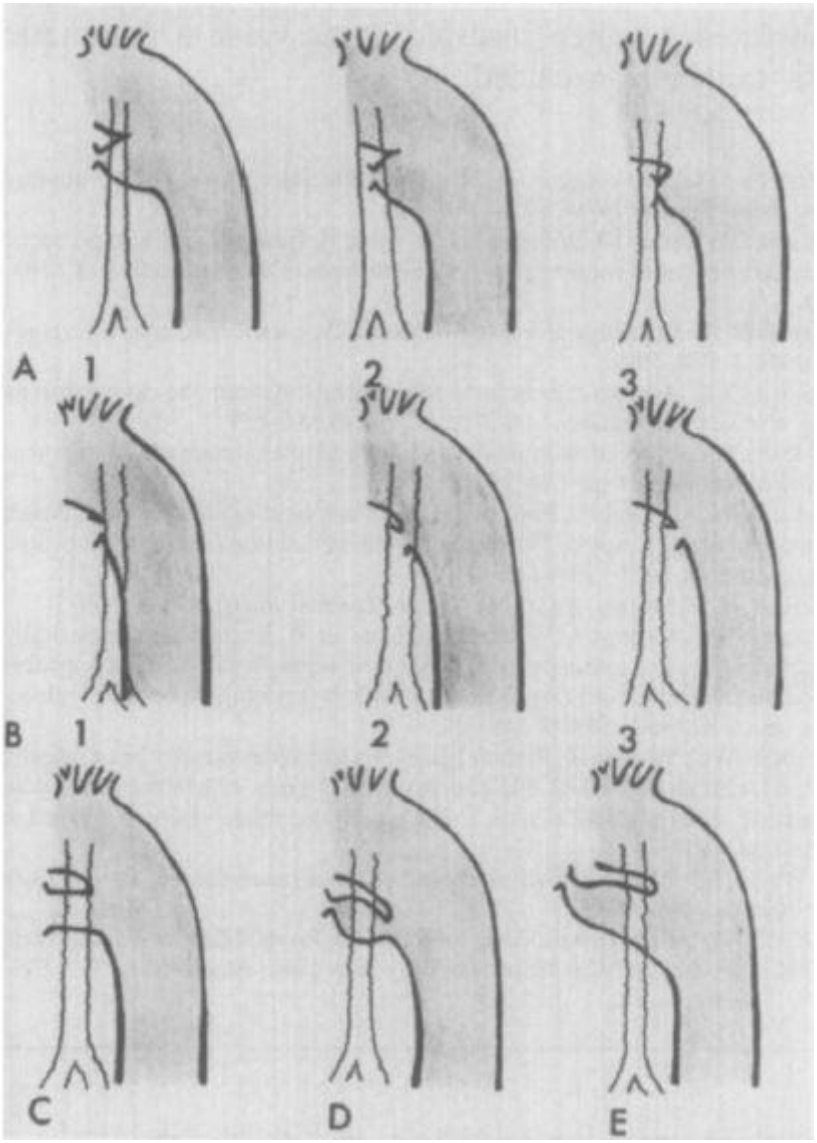


Figure 2.2: Krichenko Classification of PDA shape[24]

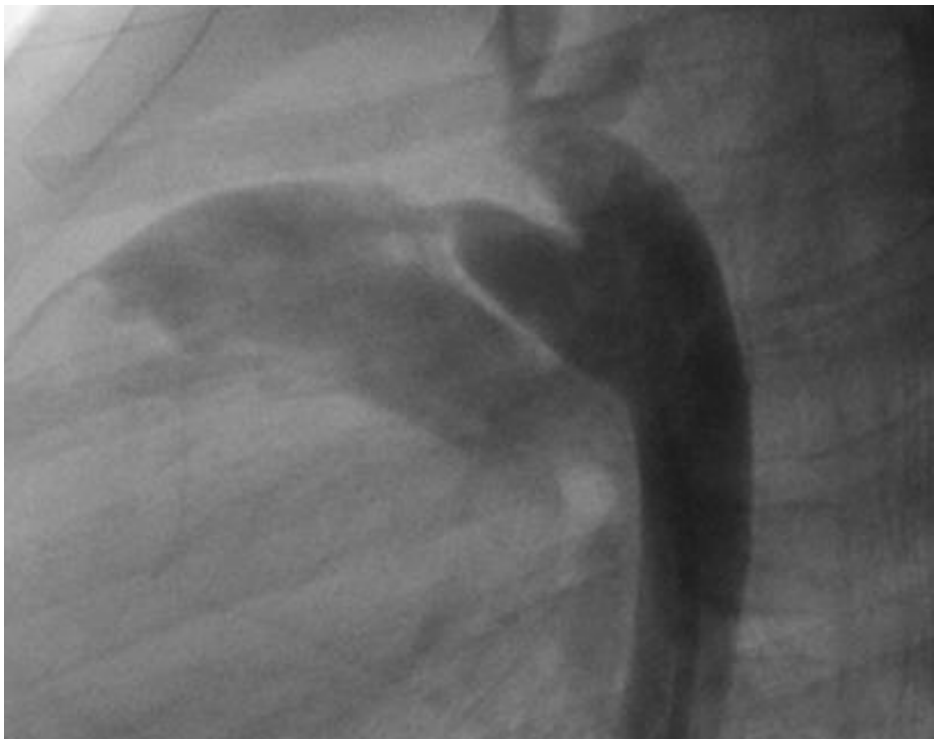


Figure 2.2: Lateral angiogram of type E PDA connecting descending aorta and pulmonary arteries.

A successful procedure was defined as one where the PDA was closed immediately or one where closure occurred within one year after the procedure without any further intervention or procedure to effect closure. The inclusion of PDAs that close later is due to the fact that complete closure of the PDA by a device relies in part on thrombosis and formation of an intimal layer over the device that can take several months. Most are expected to close by one year. Failure of closure after implantation of a device implies that a second procedure was needed to effect closure such as a second device, another type of device or surgery.

An abandoned procedure is one where a catheterisation is performed with the intention to close but the PDA is deemed unsuitable and the patient is sent for surgical closure without further attempt made to close the PDA percutaneously.

Complications of the procedure are divided into major or minor. The division into these

groups was guided by the work of Vitello R et al [25]. Major complications include device embolization, obstruction of the aorta and/or pulmonary arteries by a device requiring any intervention or resulting in long-term morbidity. Minor complications are defined as mild obstruction of the aorta or pulmonary arteries not requiring intervention, problems at the access site such as bleeding, need for a transfusion, haematoma formation or diminished perfusion to the limb requiring a heparin infusion, but which have no long term sequelae.

## *2.5 Statistics and Data analysis*

Data is described using mean and $\pm$SD, and where necessary median and inter quartile range. The $\chi^2$ test was used to compare categorical variables and the Student's t-test was used to compare nominal variables. A *P* value of 0.05 was used to determine whether findings could have resulted by chance, with values <0.05 being interpreted as significant. The statistical program, Intercooled Stata 8.0 (Stata Corporation, College Station, TX, USA) was used.

## *2.6 Ethics Approval*

Ethics approval for this study was obtained from the Ethics Committee of the University of the Witwatersrand, Johannesburg, South Africa (Protocol number – M070470).

# Chapter 3 - Results

## *3.1 Patient Characteristics*

Over the 15 year study period, 1254 PDAs were diagnosed, of which 293 required an intervention to effect closure. Surgical ligation was performed on 167 children and 139 children underwent transcatheter closure. The demographics of the children who had transcatheter PDA closure are detailed in table 3.1 below.

No differences were detected in patient characteristics between the patients who had their PDA closed with an Amplatzer™ device and those who had coiling of their PDA. Two thirds of the study patients were female, which concurs with what is commonly found in isolated PDA[26]. The majority of patients who had PDA closures were more than six kilograms. The anthropometric variables between those who had an Amplatzer™ device or Coils to close their PDA were similar. Amplatzer™ devices were occasionally used in children less than six kilograms even though the product guidelines recommend use only in children above this weight[21].

Table 3.1: Patient Characteristics

| | **Variable** | **Total Patients** (n=139) | **Coils** (n=101) | **Amplatzer™ Devices**(n=49) | ***P*** |
|---|---|---|---|---|---|
| **Demographics** | **Age**: median years (IQR) | 1.8 (1-4.5) | 1.8(1.0-4.4) | 2.1(1.1-4.5) | 0.47 |
| | **Sex:** %(*n*/*N*) Female | 66.2%(92/139) | 68.3%(69/101) | 63.3% (31/49) | 0.54 |
| | Male | 33.8%(47/139) | 31.7%(32/101) | 36.7% (18/49) | |
| | **Weight** (kg): mean (SD) | 12.8 ± 7 | 13.1± 8.1 | 12.9± 9.6 | 0.87 |
| | < 6kg | 5.4% (7/130) | 5.3% (5/95) | 4.4% (2/45) | |
| | >6kg | 94.6%(123/130) | 94.7% (90/95 | 95.6% (43/45) | 0.84 |
| | **Height** (cm): mean (SD) | 87.4 ± 22.9 | 87.0±23 | 89.2±24.3 | 0.62 |

Footnote: Where N in the cells is lower than the N in the header it is due to missing data. Also the total of coils and Amplatzer devices is more than the number of patients as in some instances more than one device in a particular patient.

## *3.2 Patent ductus arteriosus characteristics*

### 3.2.1 Size and shape:

The average PDA size at its narrowest point was 3.2 mm (Standard deviation = 1.6). There is a difference in the mean size of coiled PDAs (2.6 ± 1.1) when compared to those closed with the Amplatzer™ device (4.0±1.9: mean difference=1.3, 95% CI=0.8-1.8). The majority of PDAs less than 2.5 mm were closed with Coils and the PDAs larger than 2.5 mm were more likely to be closed with the Amplatzer™ device.

Krichenco type A PDAs dominated, accounting for 72.8%, with type E the next most frequent at 17.6%. In contrast to Krichenco's description where type B was the second commonest shape[24], it was the least common type in our population. The table below describes the size and shapes of the PDA's in detail.

Table 3.2: Characteristics of Patent Ductus Arteriosus in study population

| Var. cat | Variable | Total Patients (n=139) | Coils (n=101) | Amplatzer™ Devices (n=49) | *P* |
|---|---|---|---|---|---|
| PDA Size | **Narrowest point** mean (sd) | 3.2 ± 1.6 | 2.6 ± 1.1 | 4.0±1.9 | <0.001 |
| | **<2.5 mm** % (n/N) | 37.5% (42/112) | 47.8% (33/69) | 21.7% (10/46) | |
| | **≥2.5 mm** % (n/N) | 62.5% (70/112) | 52.2% (36/69) | 78.3% (36/46) | 0.005 |
| PDA Shape | **A** % (n/N) | 72.8% (91/125) | 74.1% (63/85) | 72.9% (35/48) | |
| | **B** % (n/N) | 1.6% (2/125) | 2.4% (2/85) | 2.1% (1/48) | |
| | **C** % (n/N) | 5.6% (7/125) | 3.5% (3/85) | 8.3% (4/48) | |
| | **D** % (n/N) | 2.4% (3/125) | 2.4% (2/85) | 2.1% (1/48) | |
| | **E** % (n/N) | 17.6% (22/125) | 17.7% (15/85) | 14.6% (7/48) | 0.82 |

Var. cat variable category. Sd standard deviation

Footnote: Where N in the cells is lower than the N in the header it is due to missing data. Also the total of coils and Amplatzer devices is more than the number of patients as in some instances more than one device in a particular patient.

### 3.2.2 Haemodynamics and Fluoroscopy time:

The haemodynamic measurements of these PDA's revealed a significant mean left to right shunt with a Qp:Qs of 2:1 (SD± 1.2). The mean pulmonary vascular resistance was 2.1 Woods Units (SD ± 1.8), with a pulmonary to systemic pressure ratio of 0.39±0.2. The chest x-rays showed cardiomegaly in 85.4% of the patients with plethoric lung fields noted on only 66.2% of the x-rays. Significant differences were noted when the haemodynamic factors between those closed with coils and those closed with Amplatzer™ devices were compared. The details are described in the table below, in summary the PDA's where Amplatzer™ devices were used were bigger with larger shunts and higher pulmonary: systemic pressure ratios. Interestingly the differences in pulmonary vascular resistance and left atrium to aorta ratio were not significant.

Table 3.3: Haemodynamic measurements and comparison between coil and Amplatzer group

| Var. cat | Variable | Total Patients (N=139) | Coils (N=101) | Amplatzer™ Devices (N=47) | *P* |
|---|---|---|---|---|---|
| CXR | **Cardiomegaly** % (n/N) | 85.4% (111/130) | 80.2% (73/91) | 93.6% (44/47) | 0.04 |
| | **Plethora** % (n/N) | 66.2% (86/130) | 56.0% (51/91) | 83.0% (39/47) | 0.002 |
| Haemodynamics | **Pulse Pressure** (mmHg):* | 46.6±9.6 | 44.9±10 | 48.8±8.5 | 0.03 |
| | **LA:AO**:* | 1.6±0.4 | 1.6±0.4 | 1.7±0.4 | 0.5 |
| | **Shunt (Qp:Qs):*** | 2.0±1.2 | 1.8±0.8 | 2.5±1.6 | 0.0003 |
| | **Pulmonary Resistance** (Woods units):* | 2.1±1.8 | 2±1.9 | 2.2±1.6 | 0.5 |
| | **Pulmonary Pressure: Systemic Pressure Ratio*** | 0.39±0.2 | 0.4±0.1 | 0.5±0.2 | 0.0005 |

Var. cat variable category, * mean (SD)
Footnote: Where N in the cells is lower than the N in the header it is due to missing data. Also the total of coils and Amplatzer devices is more than the number of patients as in some instances more than one device in a particular patient.

Fluroscopy time was recorded for each procedure where possible. Unfortunately in about one third of the patients it was not recorded. The mean fluoroscopy time was 27.6 minutes

for the procedures where it was recorded. With the shortest procedure taking eight and a half minutes and the longest two hours and 27 minutes.

## *3.3 Procedure and patient outcomes*

### 3.3.1 Combined outcome

During the period under study two groups of transcatheter devices were available in our setting, the COOK® Coils and the Amplatzer™ duct occluders. A total of 150 transcatheter procedures were performed on 139 patients with the intention of closing their PDAs.

The procedure success rate for closing PDA's at the first procedure over the fifteen years was 82% (114/139), with 15.8% (22/139) requiring further intervention and 2.2% (3/139) no data/unknown.

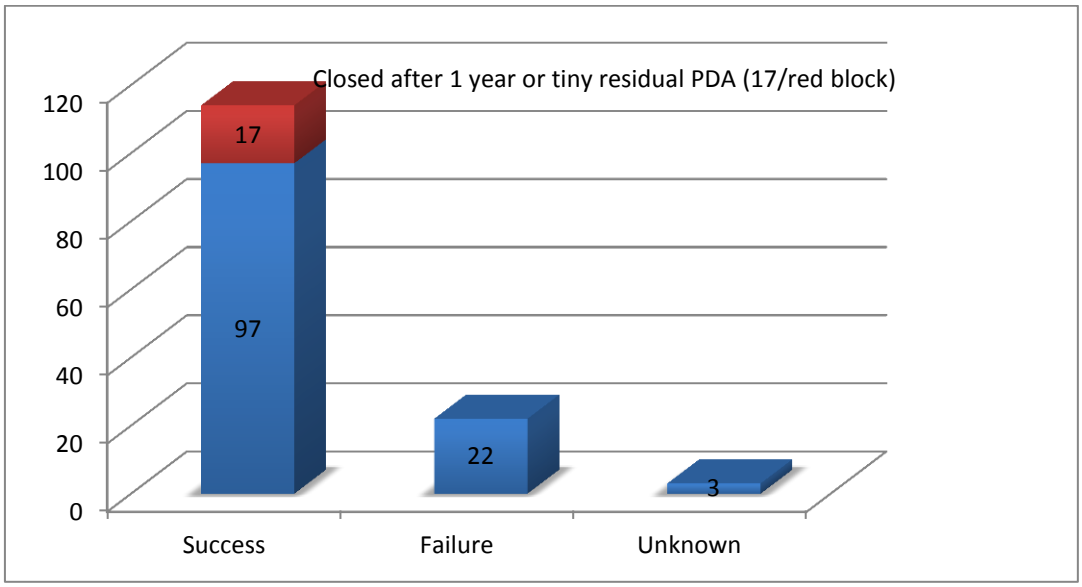



Figure 3.1: Graph describing outcome of first procedure

Footnote: The red block (n=17)on top of the success column indicates those PDAs where the ultimate result was a success for the patient – but they did not fit the definition of success defined by this study.

Breakdown of failures:

Failure was defined as any patient requiring a second procedure to effect closure. However these patients went on to receive further treatment. Of the twenty two patients who had a failed initial procedure, two were lost to follow up, in six patients coil occlusion was not possible at catheterisation and they were sent for surgical closure, two Amplatzer™

patients had a similar fate. Twelve of the 22 had a second catheterisation to try to close the PDA, eight were successfully closed with a device at that catheterisation and the other four were haemodynamically insignificant and it was decided to watch them.

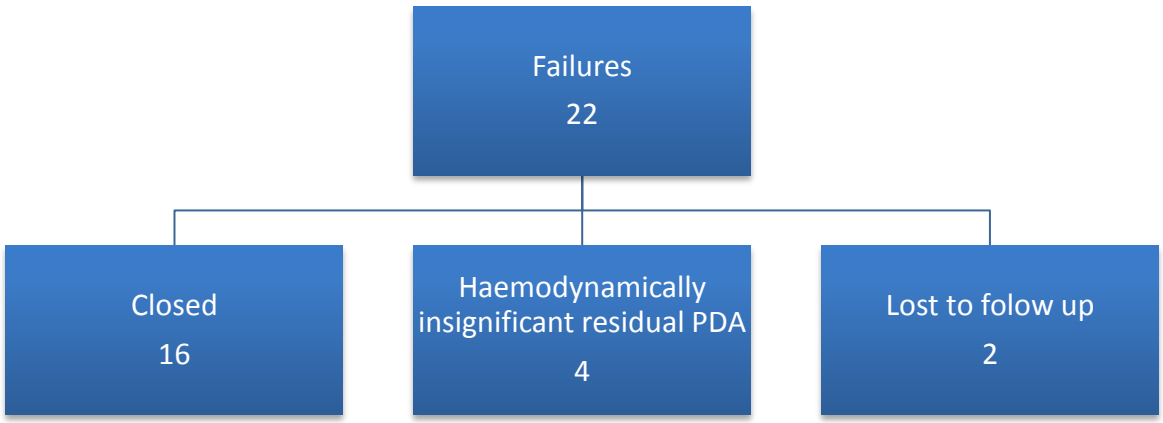



Figure 3.2: Outcome of initially failed procedures

Overall success rate if patients final outcome is considered is 92,67% (139/150), with the other 11 having unknown outcomes. No patients, where closure was attempted, were knowingly left with a significant residual PDA.

### 3.3.2 COOK® Coils:

One hundred and one COOK® coils were placed in 93 patients that underwent transcatheter PDA closure. In the majority of patients a single coil was used to close the PDA, however in larger PDA's (before the Amplatzer™ devices were available) more than one coil was sometimes required to occlude the PDA. The outcomes of the patients who had their PDA coiled are detailed in figure 3.3 below.

In 74 of these a single coil was used and 18 required more than one coil at their initial procedure. (13 patients had two coils placed at the initial procedure; four patients had three coils at their first procedure and in one patient four coils were used to close the PDA).

There was a residual PDA that required further intervention in 7 patients, 6 of these required one further procedure and one required two further procedures.

In 78% of patients the PDA was successfully closed with one or more coils. 7% required surgical closure, 5% had a small residual PDA that did not require surgical closure, one PDA was noted to have closed spontaneously at follow up, and eight patients were lost to follow up.

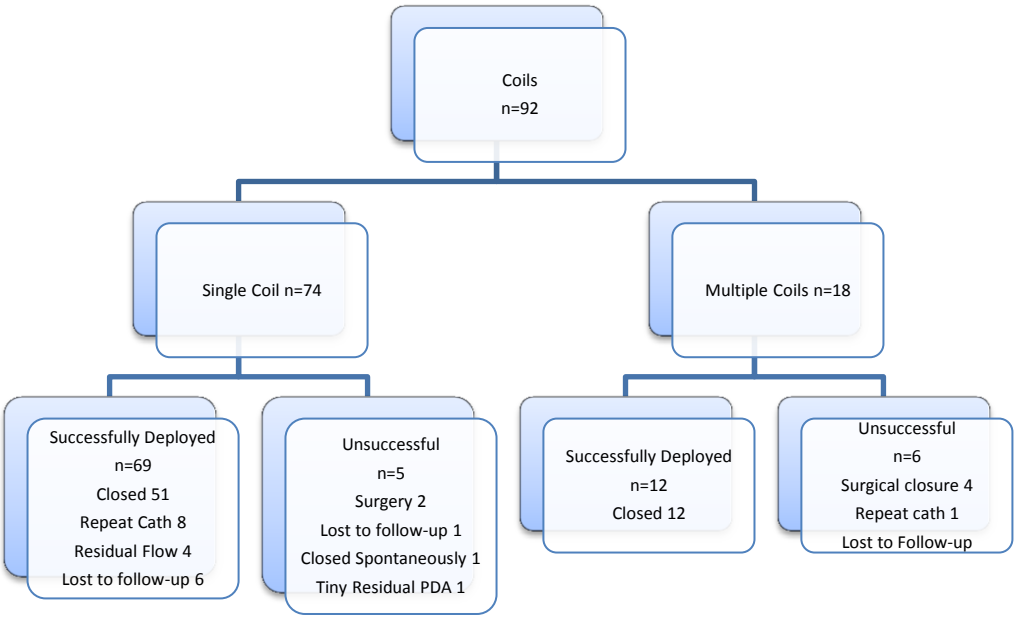



Figure 3.3: Flow chart describing the patients who had PDA coiling and their outcome

### 3.3.3 Amplatzer™ devices:

A total of 49 Amplatzer™ devices were used in 46 patients. Three different Amplatzer™ occlusion devices were used during the study period. The Amplatzer™ devices used comprised of the Amplatzer™ Duct Occluder 1 which was used in 37 patients with the Amplatzer™ Vascular plug being used in eight patients, and a device that only became available towards the end of the study period, the Amplatzer™ Duct Occluder 2 being used in one patient.

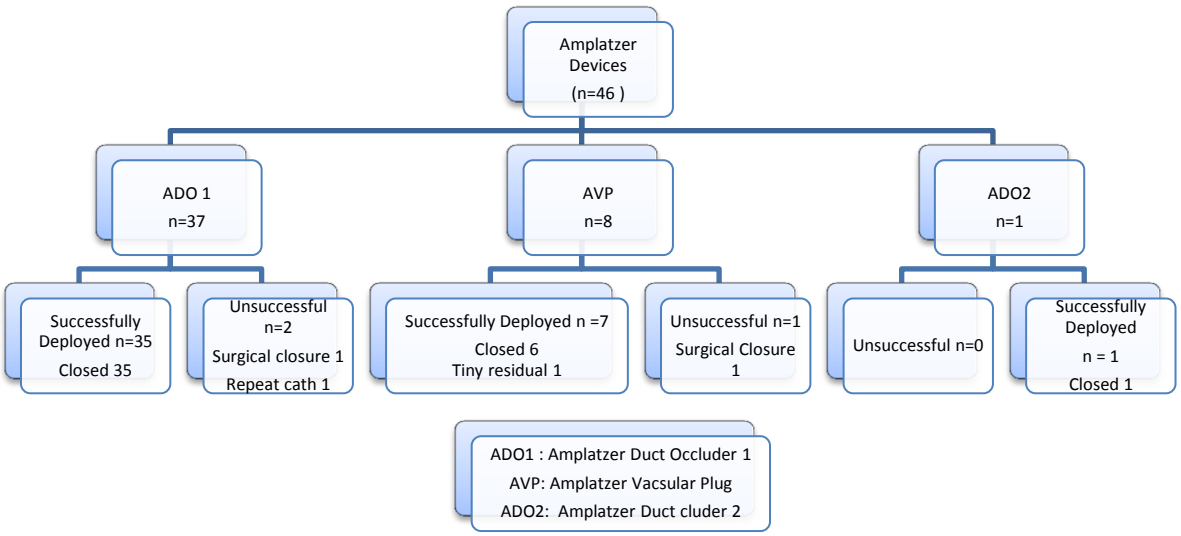



Figure 3.4: Algorithm describing patients who had PDA closure with an Amplatzer device

Transcatheter closure was successful in 91% of the patients where an Amplatzer™ device was used. In 2 patients surgical closure was needed and in one patient a tiny residual PDA was present that did not require closure.

The outcomes for the PDA's closed with the Amplatzer devices were better than those in which the Coils were used. We achieved a success rate of 91.84% with the Amplatzer™ devices and 79.35% with Coils.

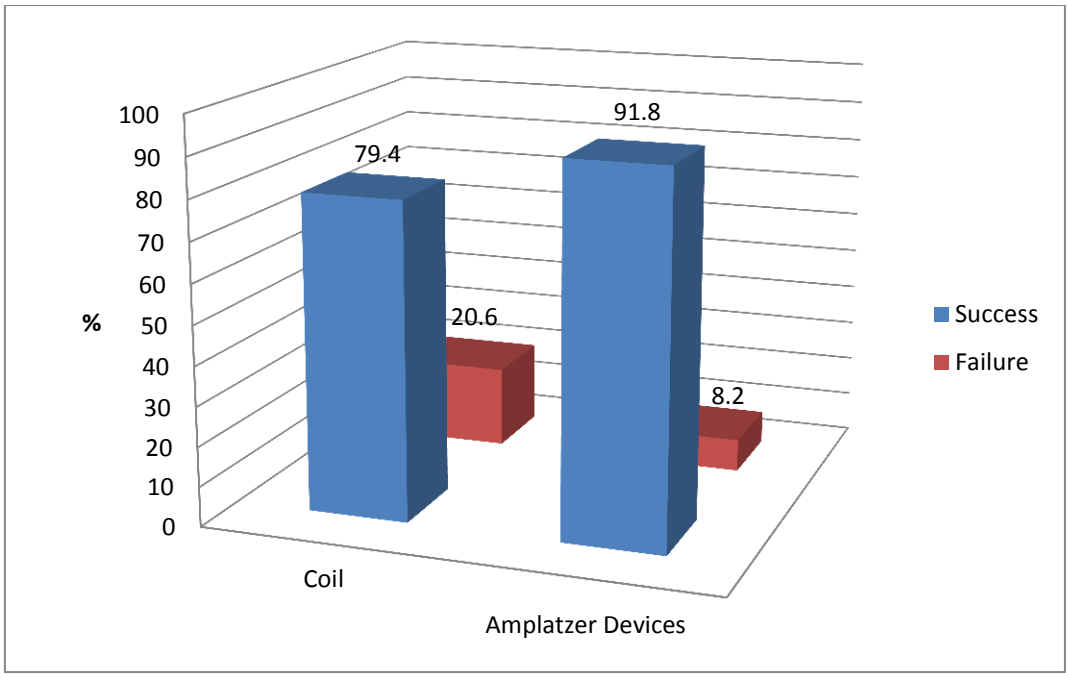



Figure 3.5: Outcomes - Coil vs Amplatzer devices at first procedure

### 3.3.4 Outcome and shape

The shape of the PDA was important in determining the outcome (p=<0.0001). The Type A and Type E PDA's had closure rates of over 88% (88.5% and 88.9% respectively). Half of Type B PDA's attempted were closed. Closure rates for the type C ducts were 28.6%, and No type D PDA's were successfully closed percutaneously.

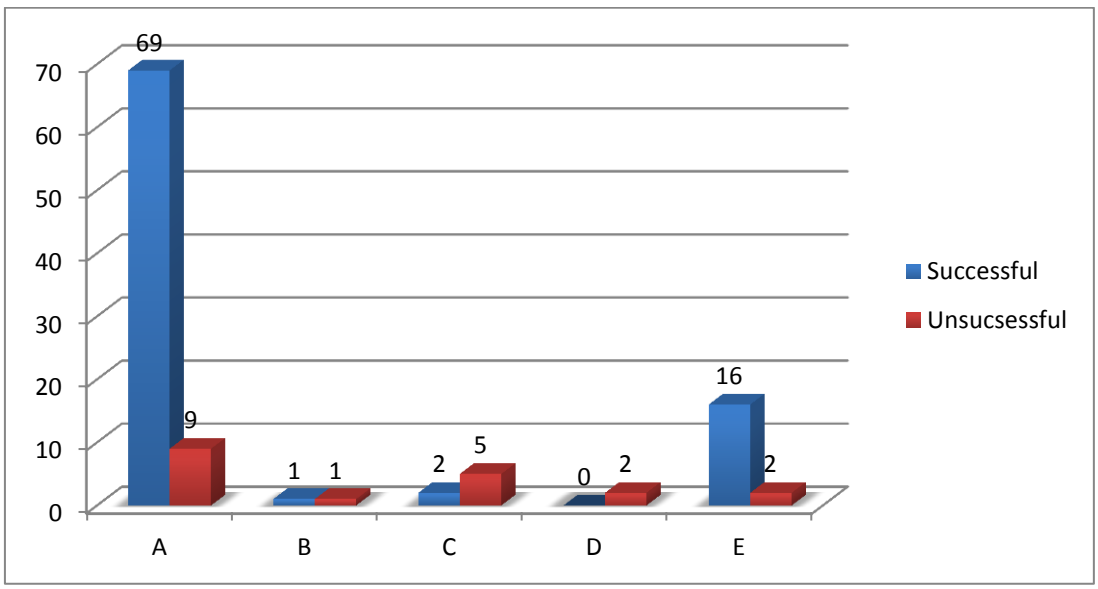



Figure 3.6: Effect of PDA shape on outcome at first procedure

The relationship between the type of closure device chosen and the PDA shape is described in the table below. The majority of PDA's closed were either Type A or Type E, The Type A PDA's were closed with either coils or the ADO1. In the Type E PDA's all available devices were tried at least once during the study period. The Amplatzer Vascular Plug was used in a large proportion of the Type C PDA's (43%). After the Amplatzer devices became available coils were no longer used in the Type C PDA's. To few Type B, C and D PDA's were closed to comment on their outcomes.

Table 3.4: Device usage for each PDA shape at initial procedure

| | **A** | **B** | **C** | **D** | **E** | ***P*** |
|---|---|---|---|---|---|---|
| **Coil** n/N (%) | 59/91 (65%) | 1/2 (50%) | 3/7 (43%) | 2/3 (66.6%) | 15/22 (68%) | |
| **ADO 1** n/N (%) | 32/91 (35%) | 1/2 (50%) | 1/7 (14%) | - | 2/22 (9%) | |
| **AVP** n/N (%) | - | - | 3/7 (43%) | 1/3 (33.3%) | 4/22 (18%) | |
| **ADO 2** n/N (%) | - | - | - | - | 1/22 (5%) | 0.003 |

### 3.3.5 Time to complete closure

Over ninety per cent of the Amplatzer™ devices had completely closed the PDA within 1 week of placement, compared to just over fifty per cent closure for coils in the first week (p= <0.0001). This graph only includes the PDA's that were documented on echocardiography to be completely closed.

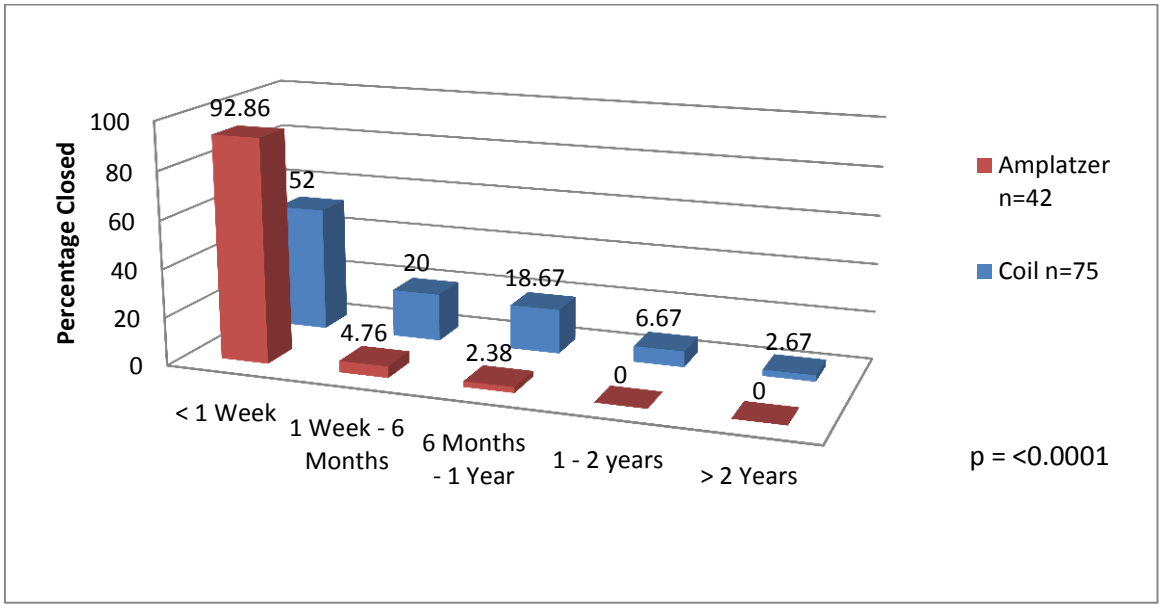



Figure 3.7: Time to complete closure

Footnote: Only PDA's in which closure was confirmed on echocardiography are included.

### 3.3.6 Changes over time

The Amplatzer™ device as an option to close the PDA at Chris Hani Baragwanath Academic Hospital rapidly became the preferred device with the drop in number of coils used mirroring the increase in Amplatzer™ devices.

These changes were noted in a number of different ways that are described below.

Device Usage:

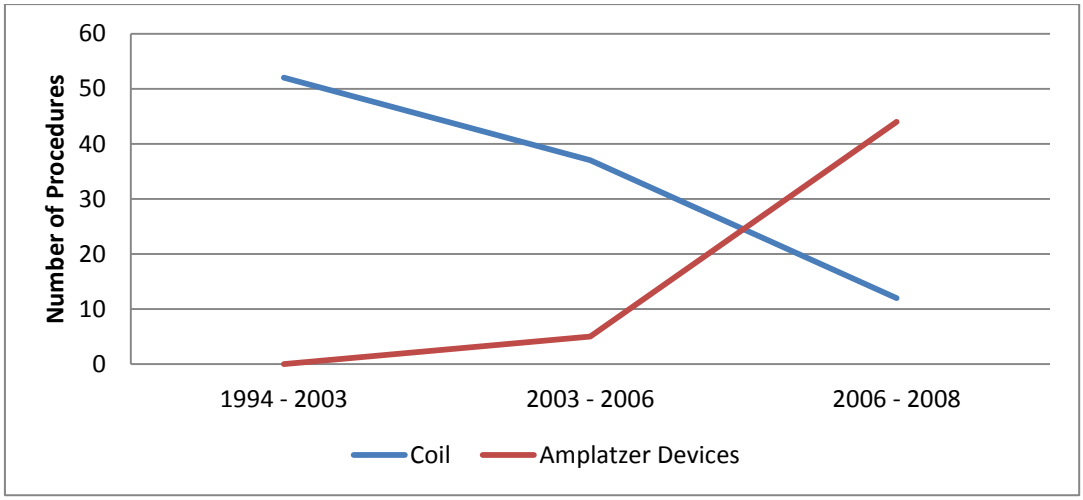



Figure 3.8: Device usage changes over time

A repeat procedure was required when the first procedure was unsuccessful, this could be that percutaneous closure failed, or there was a residual shunt requiring further intervention. The graph below includes all patients who had repeat procedures, including those who initially had surgery and then went for transcatheter closure. The number of patients who had to undergo a second procedure decreased steadily over the fifteen years except for a slight increase following the introduction of the Amplatzer™ device. The increase was short lived, and likely due to the learning curve related to the introduction of a new device. The downward trend was soon resumed.

Repeat Procedures:

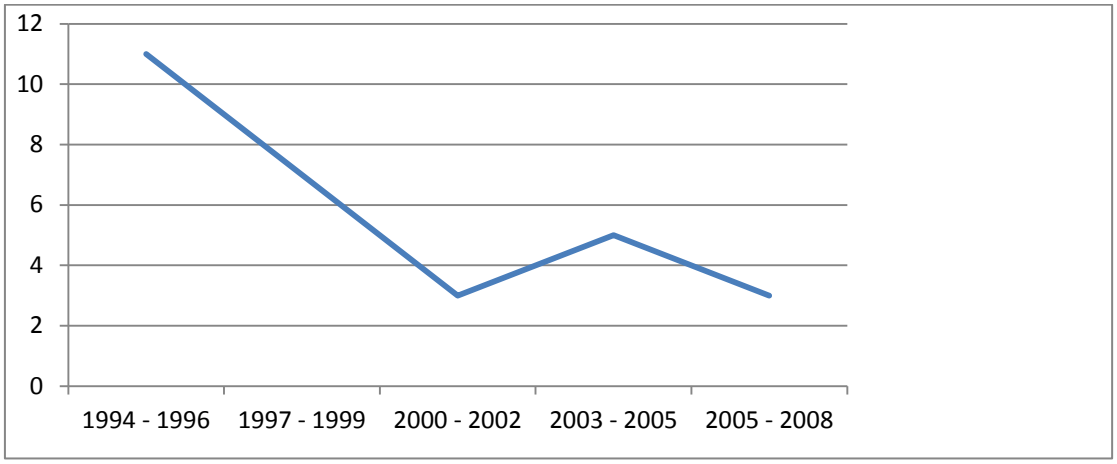



Figure 3.9: Number of patients requiring a repeat procedure to close the PDA

Footnote: This graph includes patients who initially had surgery and then went for transcatheter closure.

There were a total of twenty-eight repeat procedures. Eight patients had had surgery and then underwent cardiac catheterisation to close a residual PDA. Six patients after failed transcatheter coil placement were sent for surgical ligation. Two patients where an Amplatzer device closure was attempted were subsequently sent for surgery.

Twelve patients had a repeat catheterisation to close the PDA. Ten of these patients had coils placed initially and needed a repeat catheterisation to close the PDA, six of these were closed with another coil, two with an ADO, one was left with a tiny PDA, and one was lost to follow up. The other two patients had Amplatzer™ devices and required another catheterisation. The first was a child in whom an Amplatzer Vascular Plug (AVP) was placed and there was a tiny residual shunt – we attempted to put a coil inside the AVP, this was unsuccessful but as the residual PDA was so small and insignificant no further intervention was undertaken. In one patient there was a gradient in the DAO pre release and the procedure was abandoned, it was later successfully closed with a smaller device.

Waiting Times:

The waiting time from diagnosis to closure procedure is illustrated in the graph below, the median waiting time was between twenty to thirty weeks up until the time the Amplatzer

devices were introduced. Following their introduction the waiting time dropped to a median of less than ten weeks.

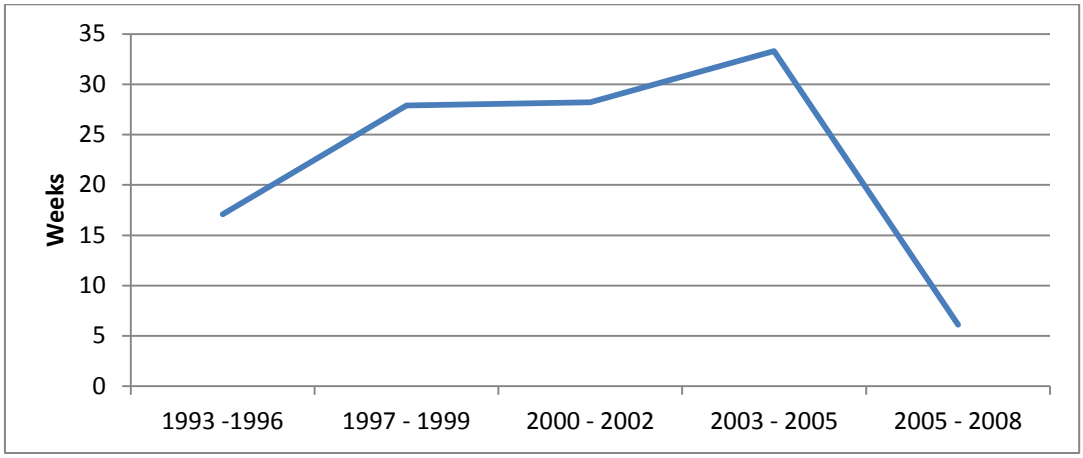



Figure 3.10: Median waiting time in weeks over the study period

Footnote: Waiting time is defined as time from diagnosis to first procedure.

Surgical PDA ligation:

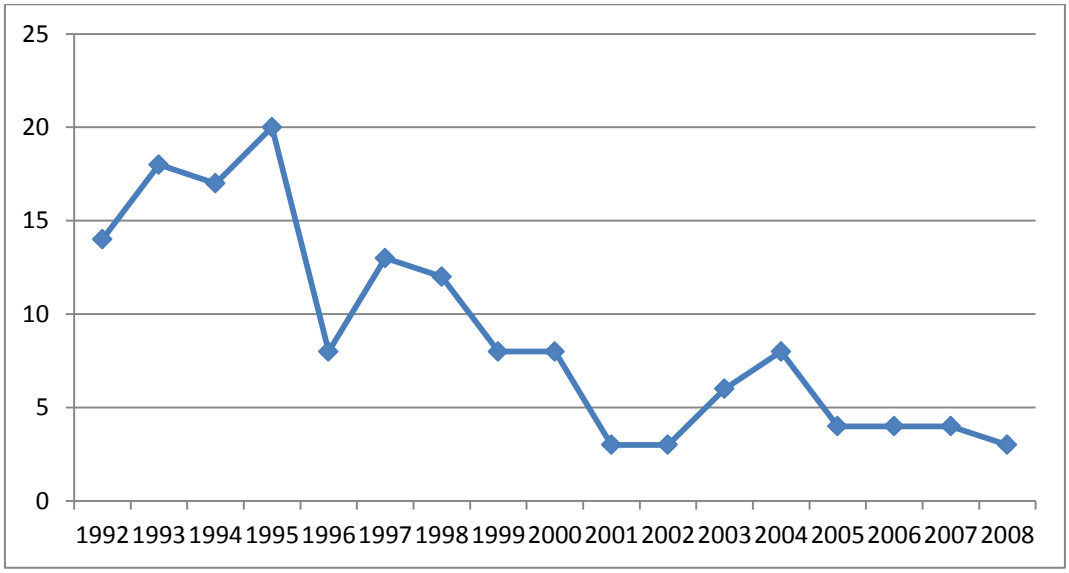



Figure 3.11: Number of PDA's ligated per year over the study period

The number of patients having their PDA ligated decreased over the fifteen-year period.

### 3.3.7 Complications:

Three out of one hundred and forty five patients had a major complication (2%). All three have done well and at last follow up have no problems related to the complication.

The first case was noted to have a significant left pulmonary artery obstruction post PDA occlusion. The patient was sent for surgery, the PDA was ligated and the device removed.

The second patient developed complete heart block during the procedure following a burst Berman balloon. Atropine was given, a supraventricular tachycardia (SVT) followed which did not respond to atropine but following DC cardioversion sinus rhythm resumed. The PDA was then successfully closed.

The final patient had unusual PDA anatomy with a Kommeral diverticulum, the PDA was closed successfully but on a CT angiogram done after the closure a vascular ring was noted. At last follow up the child was well and asymptomatic.

Minor complications were noted in twenty-seven of one hundred and forty five patients (18.6%). None of these resulted in any permanent problems.

Minor Complications:
LV Dysfunction n = 8
Diminished Leg perfusion n=2
Arrythmias n =3
Haemolysis
Embolisation
Coils n=6
Amplatzer n=1
Obstruction
Aorta n=2
Coil n=1 - mild gradient to watch
Amplatzer n=1 – removed smaller device placed
Pulmonary Arteries n=6
Coils n=1 – coil removed
Amplatzer n=5– mild gradients to watch

Major Complications: n=3/145 (2%)
LPA obstruction -
50mmHg
PDA 10mm
ADO1 16/14
Surgically removed
**PDA Ligated – No long term sequelae**

Complete Heart Block –
Burst Berman Balloon
Required Atropine – SVT –
Adenosine – cardioversion
**PDA closed –no long term sequelae**

PDA successfully closed
Abnormal aortic arch and vascular ring (diagnosed post procedure on CT angio).
**Remains asymptomatic**

Figure 3.12: Details of complications

Table 3.5: Complications at first procedure relating to PDA shape

| | **Minor Complications** n/N(%) | **Major Complications** n/N(%) |
|---|---|---|
| **A** | 13/90 (14.44%) | 2/90(2.22%) |
| **B** | 0 /2(0%) | 0/2 (0%) |
| **C** | 1/7 (14.29%) | 1/7(14.29%) |
| **D** | 0/3 (0%) | 0/3(0%) |
| **E** | 5/22 (22.73%) | 0/22 (0%) |
| | *P*=0.755 | *P*=0.302 |

There is no significant difference in the occurrence of either minor or major complications when related to the PDA shape.

## Chapter 4 - Discussion

This study shows that Transcatheter occlusion of PDA is safe and effective in our setting. The introduction of the Amplatzer™ devices at Chris Hani Baragwanath Academic Hospital has increased the potential for the safe and effective closure of a wider spectrum of PDAs at the facility. This has diminished markedly the need for surgical closure of the patent ductus arteriosus. The study also demonstrates that the size and shape of the PDA are both important considerations in choosing the appropriate closure device.

The findings of our study are compared to a large review of PDA closure in general, and then to a review of closure using only Amplatzer devices. In 2006 Galal et al presented a review of original work on PDA occlusion between 1995 and 2004 found in an extensive online search – "We reviewed a total of 21 manuscripts, which described more than 2796 patients."[4] Comparing our results to those reported in this review by Galal et al, our early closure rates are below those reported elsewhere, but late closure approximates their reported range. It is important to note that, Galal et al noted immediate complete occlusion at angiography ten minutes after implantation. This is different to the definition we used. The definition of early complete occlusion in our study was based on the echocardiogram done within 48 hours of the procedure. The echocardiogram could be either done within 24 hours if the procedure was done on our Thursday list or within 48 hours if done on the Monday list. There are likely differences in the sensitivity of the different techniques and the extra time to assessment in our patients gives the duct longer to close. However from a practical point of view, the extra 24 – 48 hours is unlikely to make any real difference to the patient. The "late occlusion" is a more important factor as failure to close may result in further procedures to close the PDA and an on going risk of endocarditis[27]. The rate of device embolization in our facility is also acceptable, falling between the highest and lowest rates reported in the Galal review. Notably however, our fluoroscopy time is longer

than all the results they report. This is likely due to multiple reasons. Firstly, we perform a full diagnostic catheterisation prior to closing the PDA, while in some other settings a more focused catheterisation is done to just close the duct. Secondly, the introduction of a new device (Amplatzer) also required a considerable learning curve of the catheterization team, prolonging the procedure for the initial patients. Finally Chris Hani Baragwanath Academic Hospital is a nationally accredited Paediatric Cardiac training centre, with a high turnover of trainees who each need to perform several procedures in order to become proficient, and complete their sub-speciality. As a result, these procedures almost always actively involved supervising and teaching trainees with little or no experience. To do this safely takes considerably longer.

These results of the comparison between our site and the Galal review are shown in the graph below.

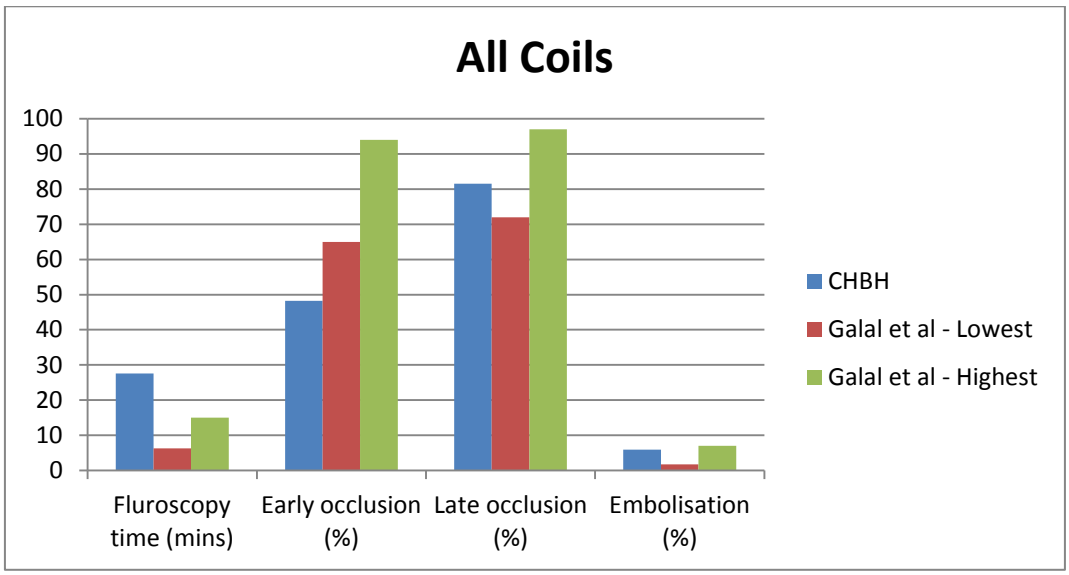



Figure 4.1: Comparison of PDA closure with coils between our results and the review reported by Galal et al

Footnote: Lowest – refers to lowest values in studies reviewed, and highest refers to highest values in studies reviewed

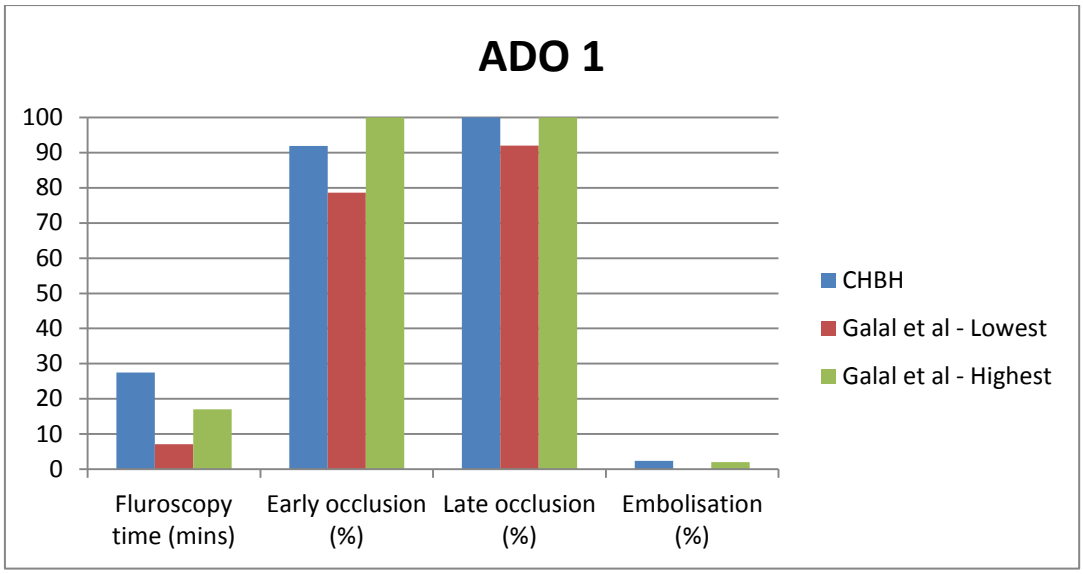



Figure 4.2: Comparison of PDA closure with ADO between our results and the review reported by Galal et al

Footnote: Lowest – refers to lowest values in studies reviewed, and highest refers to highest values in studies reviewed

In 2004, Pass published a multicentre review of closure of PDA's with the Amplatzer™ Duct Occluder in the Journal of the American College of Cardiology, covering 484 patients from 25 centres[28]. The findings reported in his review are compared to those obtained in our study in the graphs below. Our results are very similar to those of the review, with our early closure rates being 92.1% and theirs 89%. Total closure rates of 97.4% were found in in our study, this is almost identical to the 98% in the Pass review.

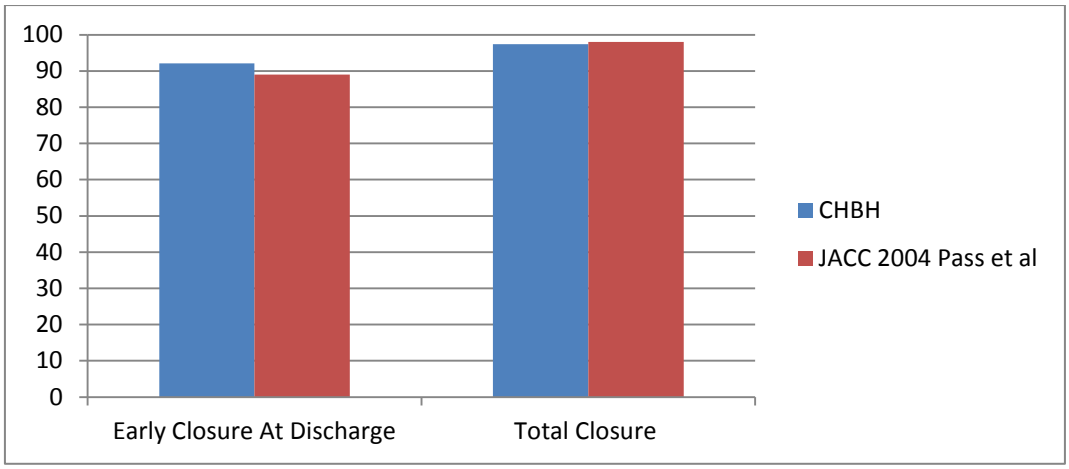



Figure 4.3: Comparison of closure rates with the ADO between our centre and the results as reported by Pass et al

The characteristics of our population and that of the Pass review are similar (e.g. age and weight), as are the PDA sizes and shunt ratios. Of note, as above, our fluoroscopy time is considerably longer, as much as three fold. The long fluoroscopy times are an important factor and result in increased radiation exposure to both patients and staff. Clearly, attention needs to be paid to strategies to reduce radiation exposure in out setting.

Uses of these devices have also been assessed in other middle-income countries.[8, 9] A study in Bloemfontein, confirmed the effectiveness of coils in thirty-six patients a southern African environment.[17]

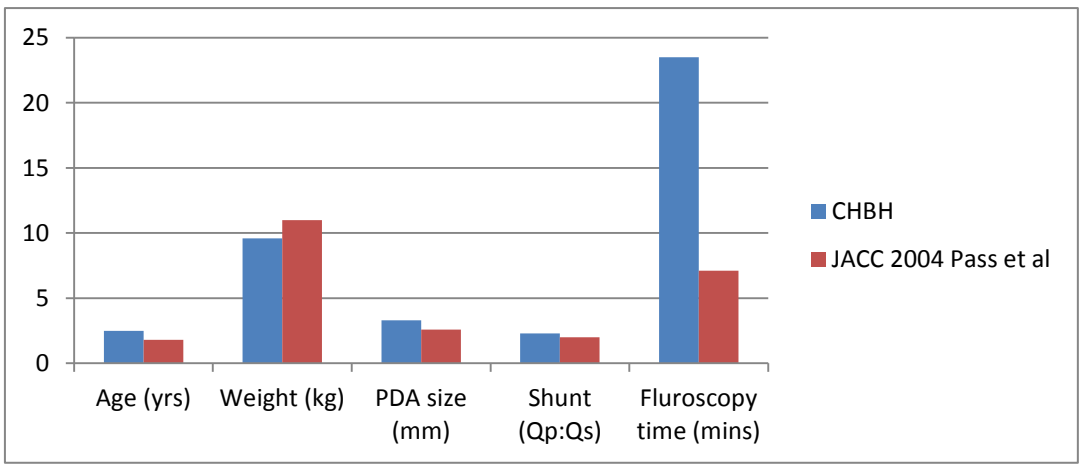



Figure 4.4: Comparison of PDA closure with the ADO between our centre and the results as reported by Pass et al

Shape and size of PDA are both important factors for selecting the optimal device for closing a particular PDA, and for closure outcome. Neither the shape nor size can be ignored but each PDA must be assessed individually and the most appropriate device chosen. To assist in the choice of correct device, a detailed angiographic assessment of the PDA is a necessity in preparation for transcatheter closure and has afforded the interventionalist the opportunity to investigate the anatomy of PDAs, which show remarkable variations in size and shape. These factors play an important role in deciding whether the PDA is amenable to transcatheter closure,[4, 24] as well as in determining the success or failure of the intervention. Where the size of the PDA or anatomical variations in the shape of the PDA made successful closure unlikely, due to the lack of a suitable device the procedure was abandoned because the PDA was deemed unsuitable for transcatheter closure. It is these cases that drive the search for new devices. Careful measurement and assessment of the PDAs shape and size and matching the correct type and size of device to the individual PDA is thus essential to maximise safety and effectiveness as well as to minimize cost incurred by the failure of device placement or use of multiple devices. The practice of placing more than one coil was common in larger PDA's before the availability of the Amplatzer™ devices. Bioptome assisted multiple coil delivery had been described during the study period but due to the availability of the Amplatzer devices we have not employed this technique[29].

Circumstances at Chris Hani Baragwanath Hospital differ in several important ways from those in high-income countries, where most studies of these devices are done. While much care is required in all settings to adequately allocate resources, more severe resource constraints in our setting make resource allocation decisions even harder. During the period under study our options were restricted to the detachable COOK® Flipper PDA coil (the device used in the early parts of the study) and the Amplatzer™ range. The use of

Amplatzer™ devices was first described in 1996[30], but they only became available at Chris Hani Baragwanath Academic Hospital in 2003. The numbers of devices that can be used are limited at Chris Hani Baragwanath Academic Hospital, and thus much care is needed in choosing the correct device, as it is not always possible to deploy a second or third device. In most cases failure to close the PDA at the initial procedure, necessitates surgical closure. This increases pressure on our already long surgical waiting list. In addition, the time from diagnosis to treatment of a PDA is reduced because there is no cardiac catheterisation waiting list at our institution. The costs incurred by the health care system from recurrent admissions due to complications of large PDAs in untreated children waiting for surgery are also likely to be reduced, but this has not been studied or documented. A major advantage of percutaneous closure of PDAs in our setting is that it removes cases from the surgical waiting list, thereby decreasing the time patients with other congenital heart diseases spend waiting for surgery.

### *Limitations of the study*

The number of Amplatzer™ devices used is relatively small compared to other case series, making it difficult to draw definitive comparisons and conclusions for future practice at our site. Most of the patients undergoing surgery prior to the era of device closure did not undergo cardiac catheterisation so the data relating to PDA size and shape were not available for these patients, limiting the ability to compare these and later patients over time.

This study is a limited in that it is a retrospective record review. While much effort was made to capture all data on all patients, there is still missing data.

# Chapter 5 - Conclusions

Transcatheter closure of the patent ductus arteriosus at Chris Hani Baragwanath Academic Hospital is both safe and effective. The treatment outcomes are similar to those in high-income countries, which have considerably more resources for treating their patient populations. The introduction of a new device has broadened the range of PDA's that could be closed and improved the closure rates over time. The size and shape of the PDA as noted on angiography are important to consider when choosing a device. As more devices become available the possibility to close a wider range of PDA's increases. Even though introducing a new device is associated with a learning curve and prolonged fluoroscopy times, careful consideration of device shape and size and the PDA's shape and size can allow for safer procedures overall and ultimately a closure of a wider range of PDA's in the catheterisation laboratory.

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# Appendix

## DATA Sheet

| | |
|---|---|
| Study Number | |
| Name (First Surname) | |
| Hospital number | |
| Sex (M or F or Unknown) | |
| DOB (dd/mm/yyyy) | |
| Weight (kg–2 decimals) | |
| Height (cm 1 decimal place) | |
| Date of Diagnosis | |
| Date of intervention | |
| Date of complete closure | |
| Date of discharge | |
| Birth weight (kg 2 decimal places) | |

| (mm – 2 decimal places) | Actual – smallest (or PA end) | Ampulla | Length |
|---|---|---|---|
| PDA size - echo | | | |
| PDA size - cath | | | |

| | A1-3 | B1-3 | C | D | E |
|---|---|---|---|---|---|
| PDA classification | | | | | |

| | Systolic | Diastolic | Mean |
|---|---|---|---|
| Systemic pressure (Asc Ao at cath) | | | |
| Pulse Pressure (mmHg) Asc Ao at cath | | | |
| LA:Ao (2 decimal places) | | | |
| Pulmonary Pressure Echo (TR Grad mmHg) | | | |
| Pulmonary Resistance R/A(2 decimal places) | | | |
| Shunt (2 decimal places) | | | |

| | Systolic | Diastolic | Mean |
|---|---|---|---|
| Pulmonary pressures Cath (MPA mmHg) | | | |

| AR post closure if Y – Trivial, Mild, Mod, Severe | Yes | No | Unknown | Resolved -Y | No | Unk |
|---|---|---|---|---|---|---|
| | | | | | | |

| | AMC | DN | LP | FM | PA | HN | KVDD | KN | MD | Other |
|---|---|---|---|---|---|---|---|---|---|---|
| Operator/Surgeon | | | | | | | | | | |

Data extraction form – PDA transcatheter occlusion & Shape and Size

| | Surgery | Coil | Coils>1 | ADO 1 | ADO 2 | AVP | Unk |
|---|---|---|---|---|---|---|---|
| Intervention (tick all that apply) | | | | | | | |
| Combinations – and description | | | | | | | |
| Device size | | | | | | | |
| Fluroscopy time (mins) | | | | | | | |

| | Success | Failure | Other | Description of other |
|---|---|---|---|---|
| Outcome | | | | |

| | | | | |
|---|---|---|---|---|
| Complications Major (tick) | Yes | No | Unknown | |
| | | | | |
| Complications Minor (tick) | Yes | No | Unknown | |
| | | | | |
| Complications - Details | | | | |
| Associated lesions Cardiac | | | | |
| Presenting Features | | | | |
| Genetic syndrome | | | | |
| CXR (Yes/No/Unknown) | Cardiomegaly | CTR (%) | Plethora | |
| | | | | |
| ECG (Yes/No/Unknown) | RAH | LAH | RVH | LVH |
| | | | | |
| Indication for closure | | | | |

| Follow up | Date | Other |
|---|---|---|
| | | |
| | | |
| | | |

**Turnitin Report**

**Ethics Clearance**