# Transcatheter Closure of Patent Ductus Arteriosus Using Detachable Spring Coils

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#### **ABSTRACT**

<u>Objective</u>: To report our experience with transcatheter PDA closure using detachable spring coils.

Methods: Suitable patients who presented between March 1996 to July 1997 were selected for coil occlusion of PDA after the diagnosis is confirmed on colour doppler echocardiography. Twenty-seven patients underwent an attempt at transcatheter closure of PDA with coils. Twenty-one were native ducts while 6 were residual ductal leaks following surgical ligation (4) and Rashkind umbrella occlusion (2).

Results: The patients' age ranged from 20 months to 39 years (median 5.5 years) and weighed from 10.5 kg to 49 kg (median 21 kg). The PDA diameter ranged from 1.3 mm to 5 mm (mean 2.4 mm). Twenty-four patients had coils successfully deployed (one coil in each patient) and all had PDA diameter of  $\leq$  3.5 mm. Seventeen had complete occlusion on echocardiographic colour doppler assessment within 24 hrs. Follow-up colour doppler assessment showed complete occlusion in all 24 patients by 6 months. There were no cases of coil embolisation or any other complications. Unsuccessful coil deployment was encountered in 3 patients with PDA diameter of  $\geq$  4 mm.

<u>Conclusion</u>: The detachable coil system allows for complete control over coil release and therefore deployment is precise and complications are minimised. Transcatheter closure of PDA with the detachable coil is a safe and effective method especially for small ducts ( $\leq$  3.5 mm).

Keywords: patent ductus arteriosus, coil occlusion, detachable coil, transcatheter occlusion

**INTRODUCTION** 

Non-surgical closure of patent ductus arteriosus (PDA) was first reported by Porstmann et al in 1971 using the Ivalon plug<sup>(1)</sup>. Since then there have been many reports using various devices in the transcatheter occlusion of PDA. These devices include the Silicon double balloon<sup>(2)</sup>, Rashkind umbrella<sup>(3-6)</sup>, buttoned device<sup>(7,8)</sup> and more recently, the occluding spring coils<sup>(9-20)</sup>. Occlusion of PDA with coils was first reported by Camber et al in 1992<sup>(9)</sup> and since then this method has generated

much interest, with many centres reporting on their experiences. The advantages of coils are: 1) smaller delivery catheters (as small as 4F), which reduces the risk of injury to femoral vessels and allows transcatheter occlusion in smaller patients; 2) ease of delivery, and 3) relatively lower cost compared to other occluding devices and surgery. There are 2 major drawbacks with coils. Firstly, coils are generally limited to occlusion of small ducts(11,19,21) (< 3.5 mm). Secondly, there is difficulty in retrieving or adjusting the coil when placed in an unsuitable position. Embolisation is a significant risk which may be minimised with increased experience. The introduction of controlled release coil is aimed at reducing embolisation risk and to achieve better control in coil positioning and deployment. These controlled release coils are mainly being used in Europe and there are few reports on their experiences (14-16).

This paper reports on our experience with the Cook detachable PDA coils in occluding the small PDA.

## **METHOD**

# Patient selection

Between March 1996 and July 1997, all patients who presented to our institution with a PDA, had an echocardiographic and colour doppler examination done to assess the size of the duct. The ultrasound machines used are the Hewlett Packard Sonos 2000 and the Acuson 128XP10. The size of the duct was defined by the narrowest colour flow width of the ductal flow in the high parasternal view. Patients with PDA measuring less than 5 mm and weighing at least 10 kg were offered transcatheter occlusion. Informed consent was obtained from adult patients or from parents of younger patients.

# Coil occluding system and procedure

We used the detachable coil and delivery system for PDA closure manufactured by Cook. Three sizes of coil diameters (3, 5 and 8 mm) with a range of loop numbers (from 3 to 5) are available. The proximal end of the coil is screwed on to the delivery wire and then passed through a 5F or 4F non-tapered end-hole catheter with a 0.038" lumen. We used Cook's 5F multipurpose or the Microvena 4F multipurpose catheter. The

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Table I – Clinical data of patients who underwent an attempt at coil occlusion of  $\mbox{PDA}$ 

Patient	Age (mths)	Weight (kg)	PDA diameter (mm)	Qp/Qs	Coil used	FT (min)	Complete occlusion (wks)
1	108	36.7	2	1.1	5-PDA3	17.7	0
2	59	13	2	1.2	5-PDA5	25.8	8
3	57	26.9	2	1.6	5-PDA5	14.5	0
4	117	29.9	3.5	1.5	8-PDA4	30.7	24
5	33	12.4	2	1.3	5-PDA5	23.5	0
6	83	25.3	2.5	0.9	5-PDA5	10.3	0
7	117	37.7	2	1.2	5-PDA5	10.8	23
8	44	13.1	2.5	1.1	5-PDA5	23.4	0
9	22	10.5	3	1.0	5-PDA5	8.7	0
10	27	12.2	1.6	1.2	5-PDA5	9.7	0
11	100	19.5	2	2.0	5-PDA5	11.5	0
12	90	25.9	1.8	1.5	5-PDA5	7.2	0
13	158	34.9	5	2.9	Fail	14.9	-
14	106	27.3	2	1.1	5-PDA5	8.4	0
15	71	20.9	4	1.8	Fail	19.1	-
16	20	11.9	3	1.9	5-PDA5	7.6	8
17	251	41	2	1.4	5-PDA5	27.8	2
18	45	16.2	2	1.3	5-PDA5	11.1	0
19	68	15.8	4.5	2.8	Fail	14.8	-
20	465	49	2	1.5	5-PDA5	18.9	0
21	65	25.4	2	1.4	5-PDA5	23.1	0
22	49	14.7	1.5	0.9	5-PDA5	15.0	0
23	55	14.2	2	1.2	5-PDA5	9.2	0
24	32	12.4	1.5	1.0	5-PDA5	8.5	0
25	88	28.8	1.3	1.0	5-PDA3	11.1	9
26	51	21.2	2	1.4	5-PDA5	13	0
27	413	47	2	1.1	5-PDA5	12.8	0

Qp/Qs is calculated by measuring saturation in the superior vena cava, mid-left pulmonary artery and aorta. The detachable coil is denoted by 2 numbers, the first being the coil diameter and the second is the number of loops, eg 5-PDA3 = coil with 5 mm diameter and 3 loops. FT = fluoroscopy time. The last column shows the duration taken for complete occlusion as determined by colour doppler; 0 denotes occlusion within 24 hours

Microvena catheter is used when the 8 mm diameter coil is required or if we estimate the size of the PDA to be smaller than 2 mm. Although smaller, we find that the Microvena 4F multipurpose catheter offers a smoother passage of the larger coil through its lumen. We have had access to this catheter since early 1997.

All children had a cardiac cocktail that consisted of pethidine, chlorpromazine and promethazine given <sup>1</sup>/<sub>2</sub> hour before the procedure. In addition, intravenous midazolam was given in the catheter laboratory if further sedation was needed. The adult patients were given oral diazepam.

The femoral vein and artery were percutaneously punctured and a right heart study done. A 5F pigtail or NIH catheter was used for an aortogram to delineate the PDA in the lateral and/or the right anterior oblique view. The narrowest width of the duct was then estimated comparing it with the 6F catheter placed in the main pulmonary artery as a guide. At this juncture, intravenous antibiotics (cloxacillin 25 mg/kg and gentamicin 2 mg/kg) and heparin (10-

20 units/kg) were given. The PDA was then crossed retrogradely from the aortic side using the 5F or 4F catheter. An appropriate coil was selected and then attached (screw-on) to the delivery wire and passed along the catheter. Selection of the coil is based on the angiographic appearance of the PDA, the narrowest width and the size of the ampulla. The narrowest width will determine the coil diameter and the ampulla size the number of loops necessary. In our experience, the coil diameter must be at least 2 mm more than the narrowest width of the duct. For ducts with large ampullae, coils with more loops are used for better occlusion. Conversely, a shallow ampulla will necessitate the use of fewer loops so that the coil will not protrude excessively into the aortic lumen. One to 2 loops of coil were extruded out of the catheter tip into the pulmonary artery and the catheter was then withdrawn into the aorta. The remaining loops of coil were then packed into the ampulla. The coil was then released from the delivery system (by unscrewing) once it is in a stable and acceptable position. We allow a time lapse of 10 minutes before repeating the aortogram to look for any significant residual leak, which may necessitate a second coil.

Post-procedure, the patient was observed in the ward. Intravenous antibiotics (cloxacillin 50 mg/kg/day 6 hourly and gentamicin 2 mg/kg/dose 8 hourly) were continued till the following day. CXR and echocardiographic/colour doppler assessment and urine microscopy were done before patient was due for discharge. Patients are usually discharged 24 hours after the procedure. At follow-up, repeat colour doppler is done at 3 and 6 months, and at 1-year post-occlusion. Endocarditis precaution is stopped at 6 months after complete occlusion.

## **RESULTS**

Coil occlusion of PDA was attempted in 27 patients (Table I), ranging in age from 20 months to 39 years (median 5.5 years) and weighed from 10.5 kg to 49 kg (median 21 kg). Twenty-one patients had a native PDA. Six had residual ductal leaks of which 4 had previous surgical ligation (patients 1, 13, 17 & 25) and 2 following Rashkind umbrella occlusion (patients 6 & 21). All patients were asymptomatic but had a cardiac murmur. Twenty patients had a typical continuous murmur while the rest had a soft systolic murmur. Only 2 out of the 6 with residual ductal leak had a continuous murmur. There were 28 catheterisation procedures in total. One of the patients, an 8-year-old child, had a repeat procedure under general anaesthesia (the only case) because of inadequate sedation with the usual cardiac cocktail.

The PDA diameter ranged from 1.3 mm to 5 mm, with a mean of 2.4 mm. Eighteen patients had a small shunt with Qp/Qs of less than 1.5. Six patients had a moderate shunt with Qp/Qs of between 1.5 to 1.9 and 3 patients had shunts of 2 and greater. The fluoroscopy time ranged from 7.2 mins to

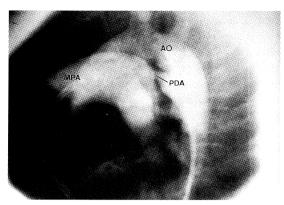


Fig I – Aortogram pulmonary artery is opacified via the patent ductus arteriosus (AO, aorta; MPA, main pulmonary artery; PDA, patent ductus arteriosus)

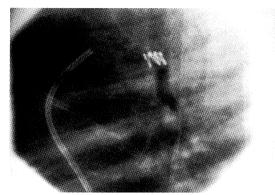


Fig 2 - Detachable coil deployed in the ductus

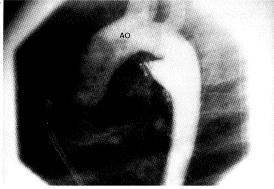


Fig 3 – Aortogram showing complete occlusion of the ductus

30.7 mins (mean 15.2 mins). In the beginning of our series, the fluoroscopy time tended to be longer.

The PDA coil was successfully deployed in 24 out of 27 patients. The sizes of their ducts ranged from 1.3 mm to 3.5 mm (mean 2.1 mm). Only one coil was used in each of the 24 patients. In 21 patients, the 5-PDA5 coils (5 mm coil diameter and 5 loops) were used. The 5-PDA3 coils were used in 2 patients with residual ductal leaks following surgical ligation. The ampullae here were small and shallow and hence the 3-loop coils were chosen. One patient with a 3.5 mm duct required an 8 mm diameter coil.

In the 24 patients with coils successfully deployed, post-coil aortogram showed complete occlusion in 13 patients with the remainder 11 having trivial or small leak. Colour doppler assessment 24 hours later showed complete occlusion in another 4 out of the 11 patients. Seven patients had a persistent small leak on colour doppler at 24 hours. Follow-up assessment with colour doppler showed complete occlusion in all patients. The longest duration between coil implantation and complete colour doppler occlusion was 24 weeks. Except for one patient, doppler study did not show any turbulent flow across the left pulmonary artery or descending aorta after coil implantation. In this patient, turbulence across the left pulmonary artery was already present because of a previous umbrella device and this did not worsen (velocity of 2 m/s).

In the 3 unsuccessful patients, the first had a previous surgical ligation of the PDA (patient 13). This 13-year-old patient had a large residual shunt (Qp/Qs of 2.9) clinically, and chest X-ray showed pulmonary plethora and cardiomegaly. At catheterisation, the PDA was estimated at about 5 mm with an aneurysmal dilatation at the aortic side. Occlusion was attempted with the largest available coil, an 8-PDA5 coil, but was unsuccessful because the large flow kept dislodging the coil into the pulmonary artery. The same problem was encountered in patient 19, who had a PDA of 4.5 mm. Patient 15 had a 4 mm duct, and a 5 mm diameter coil with 5 loops (5-PDA5) was used initially. This was found to be inadequate because the coil slipped into the pulmonary artery before release. An 8-PDA5 coil was then used. However, we encountered difficulty in pushing the 8 mm coil through the Cook's 5F multipurpose catheter and the procedure was abandoned. Since then we have elected to use the 4F Microvena catheter for the 8 mm coil. All three patients subsequently had their PDA successfully ligated.

There were no instances of coil migration or embolisation. All patients had good lower limb pulses after the procedure. No patient required blood transfusion. There was no case of post-procedure haemolysis or coil infection.

## **DISCUSSION**

Surgical ligation is a well-established method for closure of PDA. However, transcatheter methods are being increasingly used in many centres. The Rashkind umbrella device has been extensively used and studied but recent published literature seem to indicate that the spring coil may be superior to the Rashkind device in occluding smaller ducts<sup>(17,19)</sup>. Using multiple coils to occlude large ducts have also been described<sup>(18,20)</sup>. Compared to the Rashkind umbrella device, coil occlusion is a simpler procedure and requires a smaller size catheter for delivery. The Rashkind umbrella device needs a minimum 8F catheter for delivery and is therefore not suitable for smaller ducts or small infants. In

contrast, coils can be delivered in as small as a 4F catheter. The Rashkind device is also more costly and not readily available currently.

The majority of the studies to date on coil occlusion of PDA has been on the use of the uncontrolled release coils, namely the Gianturco coils. The main disadvantage with these coils is the lack of deployment precision and difficult retrieval, and once extruded from the catheter, it cannot be withdrawn. Coil embolisation is therefore a major concern with a reported incidence ranging from 3% to 25%<sup>(10-13)</sup>. This is reduced with increased operator experience. Detachable coils have been introduced to overcome this problem.

Besides coil embolisation, another potential complication of coil occlusion of PDA is that of left pulmonary artery impingement. Mild left pulmonary stenosis has been reported to be ranging from 2% to 6%<sup>(15,20)</sup>. It has been postulated that flow disturbances may compromise vascular growth but the results of a study by Carey et al have not been conclusive<sup>(22)</sup>. Lung perfusion scans have also shown normal blood flow distribution in most patients with multiple coil closure for PDA<sup>(23)</sup>. Haemolysis following coil occlusion is rare<sup>(16)</sup>. Coil infection has not been reported.

Coils can be deployed either anterogradely or retrogradely. The debate on which is the better route has not been resolved and is probably more a matter of preference<sup>(12,13,16,19)</sup>. We have elected to deploy the detachable coil through the retrograde route. This allows us to manipulate and pack the detachable coil into the ampulla with the arterial catheter before release. The anterograde route may be useful when simultaneous deployment of multiple coils are attempted<sup>(20)</sup>.

Our study has shown that the detachable PDA coils are safe and effective in closing small ducts up to 3.5 mm in diameter. We have no case of coil embolisation even though this was our first experience in using these coils for occluding PDA. In the 3 unsuccessful patients, the initial attempts all resulted in loops of the coil slipping into the pulmonary arteries because of the large duct (mean Qp/Qs of 2.5). If Gianturco coils had been used, it may have resulted in embolisation of these coils. With the detachable coils, these were all safely withdrawn. Centres in the United Kingdom have reported the low incidence of coil embolisation associated with detachable coils. This low incidence has been attributed to the controlled release mechanism<sup>(15)</sup>. Although technically feasible, we did not attempt to use multiple coils in our 3 unsuccessful patients with slightly larger ducts. The 3 were in our initial learning curve of the first 19 patients. We also felt that if we were to use multiple coils, the children would need general anaesthesia as the cardiac cocktail given to these patients may not be adequate for the longer procedural time.

In all our procedures, the number of coil loops in the pulmonary artery as well as in the aortic ampulla were carefully adjusted and positioned before release. Unsightly loops of coil protruding into the vascular lumen were therefore avoided. This is important as turbulent flow or obstruction may result from protruding coils. With better control, we were able to select smaller coils for use knowing that the risk of embolisation is low. Our experience shows that a coil diameter of 2 mm more than the minimum PDA diameter (for ducts 3 mm and smaller) is sufficient compared to the recommendation of a coil diameter of 2 to 2.5 times the duct diameter when using the Gianturco coils<sup>(10,12)</sup>.

Occlusion rates reported ranged from 95% to 100% with different types of  $\operatorname{coil}^{(16)}$ . Our own experience shows an occlusion rate of 100% by 6 months in our cohort of ducts that were  $\leq 3.5$  mm. Even with large PDA ( $\geq 4$  mm), good occlusion rate of 94% has been reported with multiple  $\operatorname{coils}^{(18)}$ . We plan to use multiple coils in suitable cases following our experience in this study.

### CONCLUSION

This is the first experience in Singapore of PDA occlusion using detachable coils. We have shown in this small group of selected patients, that the method is safe and effective in occluding small PDA. There was no case of coil embolisation despite our initial learning curve. This attests to the increased safety margin provided by detachable coils. Coil occlusion has the advantage of less hospitalisation days and no physical scarring. We will recommend that this method be offered as an alternative to surgery in selected patients.

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