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# The Results of Transcatheter Occlusion of Patent Ductus Arteriosus: Success Rate and Complications Over 12 Years in a Single Center

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## ABSTRACT

**Background and Objectives:** Percutaneous occlusion of patent ductus arteriosus (PDA) has become increasingly attractive with the evolution of devices and techniques. We reviewed results for percutaneous occlusion of PDA using various devices in a single center. **Subjects and Methods:** A retrospective review was done for 118 consecutive procedures performed in 111 patients with PDA between January 1996 and December 2007. **Results:** The median age of the patients was 4.5 years (0.9 to 60.3 years); body weight was 16.9 kg (6.8 to 74.7 kg). The median PDA diameter at the pulmonic end was 3.8 mm (0.7 to 10 mm); mean pulmonary artery pressure was 21.0 mmHg (7 to 60 mmHg). Complete occlusion occurred in 76/111 (68.4%) immediately after implantation and in 100/111 (90.0%) at one year of follow-up. Second procedures for residual shunts were done in 7 patients. After the year 2001, the complete closure rate was 95.2% compared to 71.4% before 2001. Complications associated with the procedure were left pulmonary artery narrowing (all <20 mmHg) in 14, arrhythmia in 2, and death in 1. **Conclusion:** Evolution of devices, cumulative experience, and health insurance covering the cost of devices have contributed to good outcomes in our center for percutaneous occlusion of PDA. Our results have improved over the years, particularly with the use of the Amplatzer duct occluder. (*Korean Circ J* 2010;40:230-234)

**KEY WORD:** Ductus arteriosus, patent.

## Introduction

Since Rao et al.<sup>1)</sup> first reported transcatheter occlusion (TCO) of a patent ductus arteriosus (PDA) with an Iv-alon plug, several other devices have been developed including Rashkind double-umbrella (umbrella),<sup>2)</sup> Sideris buttoned device (SBD),<sup>3)</sup> Gianturco coil<sup>4)</sup> or Duct-occlud<sup>5)</sup> device (coil), and an Amplatzer Duct Occluder (ADO).<sup>6)</sup> We reviewed our experience with TCO of PDA using various devices to determine the efficacy and safety of TCO

with regard to rates of success and complications.

## Subjects and Methods

### Subjects

A retrospective review was done for 118 consecutive procedures performed in 111 patients (31 males, 80 females) for PDA during the 12 years from January 1996 to December 2007. Associated anomalies were ventricular septal defect (n=4), atrial septal defect (2), pulmonary valve stenosis (1), anomalous origin of the left coronary artery from the pulmonary artery (1), and Down syndrome (3). For TCO of PDA, we used a SBD (Custom Medical Devices, Athens, Greece; TX, USA), an umbrella (USCI, Billerica, MA, USA), coils such as a Gianturco coil (Cook, Inc., Bloomington, IN, USA), a Duct-occlud device (PFM, Cologne, Germany), and an ADO (AGA, MN, USA). Patients were divided into four groups based on the devices that were used: SBD, umbrella, coil, and ADO. In our center, SBD was used by the year 1997 and umbrella by 1999, both for some-

Received: July 2, 2009

Accepted: October 10, 2009

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what large ductus with big shunts. After 1996, coils were favored in cases of a rather small ductus (ductal diameter  $\leq 2.5$  mm) with one or more coils. For secondary occlusion, we mostly used a coil. ADO has been used for ductus  $>2.5$  mm (ductal diameter) since 1999 (Table 1).

### Procedures and follow up

The procedure for each device has been reported.<sup>2)3)5)7)</sup> The ductal diameter was measured at the pulmonic end in the lateral aortogram.<sup>8)</sup> The residual shunt was identified by aortogram, 10 to 15 minutes after the implantation of devices. The catheterization data and angiograms were reviewed by one examiner (NY Kim). Two-dimensional echocardiography and Doppler studies were performed on the next day, and 3, 6, and 12 months following the procedure. Attention was paid to the residual ductal flow and stenosis of the left pulmonary artery and the aortic arch.<sup>9)10)</sup>

### Statistical analysis

Statistical Package for the Social Sciences (SPSS) for Windows (version 12.0, SPSS Inc., Chicago, IL, USA) was used for analysis. Comparisons among the four groups were done with the Kruskal-Wallis test. Comparisons between two groups were done using the Mann-Whitney U-method. A  $p < 0.05$  was considered significant.

## Results

### Comparisons between groups

SBD (n=7 cases), umbrella (n=5), coil (n=41), and ADO (n=58) were used. The patients' mean age was  $12.5 \pm 15.4$  years (0.9 to 60.3 years: SBD  $14.0 \pm 18.7$  years, umbrella  $8.9 \pm 7.1$  years, coil  $5.1 \pm 6.5$  years, ADO  $17.9 \pm 17.8$  years). Mean weight was  $27.0 \pm 20.0$  kg (6.8 to 74.7 kg: SBD  $26.4 \pm 16$  kg, umbrella  $34.0 \pm 27.5$  kg, coil  $18.0 \pm 13.9$  kg, ADO  $32.8 \pm 21.3$  kg). There was no difference between groups in age and weight. The mean ductal diameter was  $3.81 \pm 1.72$  mm (0.7 to 10 mm: SBD  $3.99 \pm 1.21$  mm, umbrella  $4.62 \pm 1.10$  mm, coil 2.18

$\pm 0.82$  mm, ADO  $4.80 \pm 1.41$  mm). The ADO group had the biggest ductus and the coil group the smallest ( $p < 0.01$ ). The ratio of pulmonary blood flow to systemic flow (Qp/Qs) in each group was SBD  $2.00 \pm 0.94$ , umbrella  $1.77 \pm 0.82$ , coil  $1.30 \pm 0.37$ , and ADO  $1.95 \pm 0.71$ . The mean pulmonary arterial pressure (m-PAP) was  $22.6 \pm 10.6$  mmHg (7 to 60 mmHg: SBD  $20.2 \pm 9.79$  mmHg, umbrella  $18.2 \pm 4.23$  mmHg, coil  $19.5 \pm 8.34$  mmHg, and ADO  $25.6 \pm 11.8$  mmHg). There was a significant difference in m-PAP only between coil and ADO ( $p < 0.01$ ). A total of 24 patients (21.6%) had pulmonary hypertension (m-PAP  $>25$  mmHg) (Table 1).

### Results of the procedures

Complete occlusion occurred in 76 of 111 patients (68.4%) at the first trial. Of 35 patients with residual shunt, 25 (71.4%) showed spontaneous occlusion at 1 year of follow up. Reopening developed during follow up in 6 who had an immediate complete closure with a coil. Secondary procedures were performed in 7 using coils and one underwent an additional operation. The final occlusion rate at 1 year of follow up was 90.0% (100/111) (Fig. 1).

### Sideris buttoned device

Only 1 of 7 SBDs was implanted successfully. Two showed spontaneous occlusion at follow up, 3 had successful second procedures with a coil but one of the three developed reopening. One was lost to follow up.

### Rashkind double umbrella

Of 5 umbrellas, 1 was inserted uneventfully; 1 patient had spontaneous occlusion, 2 had a secondary procedure with success.

### Coil

Coils were used in 41 patients, leading to immediate complete occlusion in 27 patients: 5 patients had two coils at the first trial; 10 of 14 who had residual shunt showed spontaneous occlusion at follow up, and two

**Table 1.** Demographic and catheterization data for each device group

Devices	SBD	Umbrella	Coil	ADO	p
No. patient	7	5	41	58	
Sex ratio (M : F)	1 : 6	1 : 4	13 : 28	16 : 42	
Mean age (year)	$14.0 \pm 18.7$ (1.5-54.2)	$8.9 \pm 7.1$ (3.1-16.8)	$5.0 \pm 6.4$ (0.9-33.7)	$17.9 \pm 17.8$ (0.9-60.3)	NS
Mean weight (kg)	$26.4 \pm 16.5$ (10.1-51.0)	$34.0 \pm 27.5$ (13.3-74.7)	$18.0 \pm 13.9$ (7.4-68.7)	$32.8 \pm 21.3$ (6.8-70.0)	NS
Ductal diameter (mm)	$3.99 \pm 1.21$	$4.62 \pm 1.10$	$2.18 \pm 0.82$	$4.80 \pm 1.41$	$<0.001^*$
Qp/Qs	$2.00 \pm 0.94$	$1.77 \pm 0.82$	$1.30 \pm 0.37$	$1.95 \pm 0.71$	$<0.001^*$
Mean PAP (mmHg)	$20.2 \pm 9.79$	$18.2 \pm 4.23$	$19.5 \pm 8.34$	$25.6 \pm 11.8$	$0.018^\dagger$
Immediate occlusion rate (%)	1/7 (14.3)	1/5 (20.0)	27/41 (63.4)	47/58 (81.0)	
Spontaneous occlusion rate (%)	2/6 (33.3)	2/4 (50.0)	10/14 (71.4)	11/11 (100.0)	
Occlusion rate at 1 year of F/U (%)	3/7 (42.9)	3/5 (60.0)	33/41 (80.5)	58/58 (100.0)	

\*Significant differences between coil and other device groups,  $^\dagger$ Significant difference between coil and ADO groups. Qp/Qs: determination of the pulmonary to systemic blood flow ratio, PAP: pulmonary arterial pressure, NS: no significant difference between groups, SBD: Sideris buttoned device, ADO: Amplatzer duct occluder, F/U: follow up

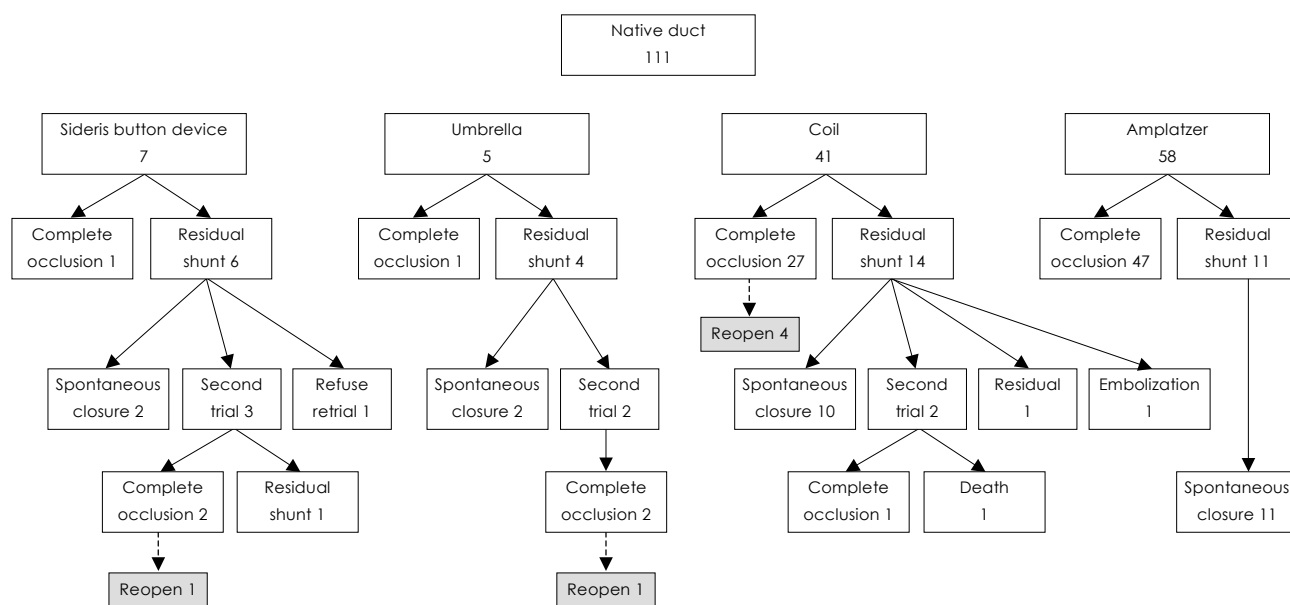


Fig. 1. Outcomes of transcatheter occlusion of PDA cases with different devices. PDA: patent ductus arteriosus.

Table 2. Procedural complications

	No.
<b>Major complications</b>	
Death	1
Anemia requiring transfusion	2
Significant hemolysis	1
<b>Minor complications</b>	
Mild narrowing of left pulmonary artery (<20 mmHg)	14
Mild narrowing of descending aorta (<20 mmHg)	2
Transient bradycardia	1
Embolization of radio-opaque marker	1

were lost to follow up.

**Amplatzer duct occluder**

ADO was implanted in 58 patients: 81% (47/58) had complete occlusion immediately after implantation and 11 with residual shunt showed spontaneous occlusion at follow up. Hence, complete occlusion was achieved in all cases.

**Complications**

There was left pulmonary artery narrowing of less than 20 mmHg in 14 cases, arch obstruction in 2, transient bradycardia in 1, anemia requiring transfusion in 2, embolization of the device in 1, and death in 1 who had coil occlusion for ductus with a 2.5 mm of diameter but a residual shunt developed immediately after implantation and progressed to significant hemolytic anemia. A second procedure using ADO was planned but sudden uncontrollable arrhythmia developed during the procedure, and eventually led to the death of the patient (Table 2).

**The impact of health insurance**

Health insurance has been applied to the use of ADO since 2001, which has resulted in the lessening of cost and a greater use of ADO. This has caused increase in the occlusion rate of PDA from 71.4% to 95.2% (Fig. 2).

**Discussion**

PDA is a common congenital heart disease accounting for 10% of all cases of congenital heart disease. Surgical closure of a PDA was a conventional treatment and has a negligible mortality rate. However, the morbidity of general anesthesia and thoracotomy such as phrenic nerve injury, scar formation, and bleeding, has driven the search for treatment options that are nonsurgical.<sup>10)13-16)</sup> In 1967, Porstmann and colleagues introduced a non-surgical closure of PDA with the use of a preshaped Iv-alon plug, delivered through the femoral artery and requiring an 18 F sheath for implantation. In 1979, Rash-kind and Cuaso developed a polyurethane foam disc umbrella requiring an 8 F or an 11 F sheath. But it is hardly applicable in infancy. Furthermore, the device induces a high residual leak and fracture of arm discs, and is not suitable for tubular shaped or short ductus or ductus >7 mm in diameter.<sup>9)11-13)17)</sup> In 1991, Sideris et al. developed an adjustable buttoned device that can be delivered via a 7 F sheath, but the device also shows a high residual leak and a significant failure rate, especially when the ductus has a long conical shape or is large.<sup>1)9)11)18-20)</sup> Thereafter, Lloyd and Moore and their coworkers reported coil occlusion of PDAs from the arterial side using a 5 F or a 6 F sheath.<sup>4)7)21)</sup> Single or multiple coils are useful for small or tubular shaped ductus. Several modifications such as retrievable, detachable coils, or use of a nitinol

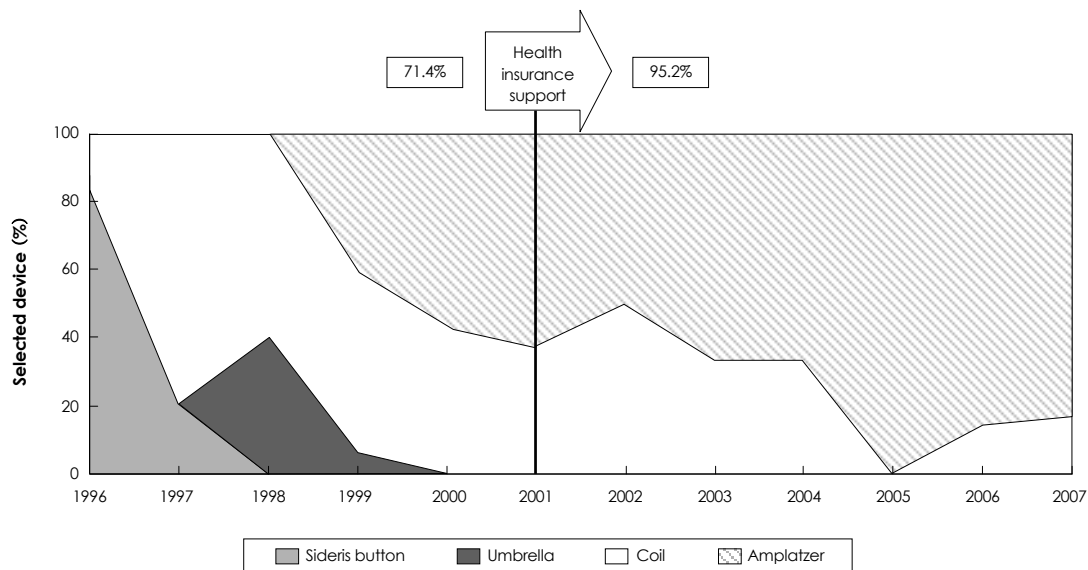


Fig. 2. Overall complete occlusion rate over several years.

snare or forcep, has been tried to decrease the rate of embolization, a common complication.<sup>9)16)22)23)</sup> A Duct-occlud device was designed to better match the shape and configuration of the PDA so that high stability on delivery and higher complete closure rates could be achieved with a single device.<sup>5)9)</sup> Multiple coils sometimes cause protrusion of the coil into the left pulmonary artery or aorta. In 1998, Masura et al.<sup>9)</sup> reported the use of ADO for TCO of moderate to large sized PDAs. The device has the benefit of less embolization, easier implantation, and a 98% to 100% occlusion rate.<sup>9)24)</sup> Our country also has spent considerable effort in developing a better device and the technology to increase the success rate.<sup>25)</sup> The results of our study show that the coil group had a low Qp/Qs ratio and worked for small ductus but the ADO was mostly used for large ductus with higher PAP. TCO with an umbrella double disc or a SBD produced a low occlusion rate and were discarded, which demonstrates that those devices were less effective (the reason might be that our center had little experience performing these procedures in the early stages of TCO). In the coil group, a well designed strategy for determining coil number according to ductal diameter would have given a better outcome. For instance, two or more coils for a ductus >2 mm or an immediate trial of a second coil in case of a residual shunt. The problems of reopening of a shunt and formation of a central residual shunt in coil TCO remain to be solved. Since public health insurance in Korea covers the cost of the ADO procedure, the performers have favored ADO for a ductus >2.5 mm and eventually the occlusion rate reached 100%, although the overall complete occlusion rate is 95.2%. Our study reveals that the success of TCO depends on the availability of safe, effective devices and an experienced interventionist. Health insurance support has also greatly affected outcomes.

## Acknowledgments

This study was presented as a poster at the 2nd Asia-Pacific Congress of Pediatric Cardiology and Cardiac Surgery (PCCS 2008).

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