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Long-Term Outcome of Coil Occlusion in Patients With Patent Ductus Arteriosus

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Background: Coil occlusion has been widely indicated for the closure of patent ductus arteriosus (PDA). Although many reports have shown the efficacy and safety of coil occlusion, the long-term outcome in patients remains controversial. Here, we analyzed the long-term outcome of coil occlusion in patients with PDA in Japan.

Methods and Results: We collected the longitudinal data of patients who underwent coil occlusion between 1995 and 2009. A total of 310 coil occlusions were performed in 298 patients with PDA. The median minimum duct diameter was 1.4 mm. Successful coil occlusion was achieved in 286 patients (96.0%), and total adverse events were seen in only 28 cases (9.0%). The median follow-up period was 50 months. The occlusion rates at 1 month, 6 months, 1 year, 2 years and 5 years were 90.1%, 94.4%, 97.4%, 97.8% and 97.8%, respectively. Patients with a large PDA (≥4 mm) showed a higher rate of residual leakage than those with a small (<2 mm) or moderate (2–4 mm) PDA (P=0.004). Patients who underwent this procedure in the early study period also showed a higher rate of residual leakage than those in the late study period.

Conclusions: Coil occlusion is an effective procedure for patients with PDA. Our data indicate that the long-term outcome is promising without any adverse events. (*Circ J* 2011; **75:** 407–412)

Key Words: Catheter intervention; Coil occlusion; Long-term outcome; Patent ductus arteriosus

Coil occlusion for patent ductus arteriosus (PDA), which was first described in 1992,[1] has now become an established therapy as a transcatheter closure technique. In Japan, coil occlusion for PDA has been used since 1995.[2–4] Various techniques for coil occlusion have been developed,[5–9] and other types of occlusion systems, especially the Amplatzer duct occluder, have been accepted as a safe and effective device worldwide.[10–14] However, this device was not available in Japan until 2009.

Although the efficacy and safety of coil occlusion have been reported in many patients with PDA,[15–19] there are only a few reports on the long-term outcome of coil occlusion. Here, we analyzed the long-term outcome of patients with PDA who underwent coil occlusion in 3 pediatric institutions in Japan.

Methods

From January 1995 to December 2009, a total of 310 transcatheter occlusions were performed in 298 patients with PDA at the Ehime University Hospital, Ehime Prefectural Central Hospital, and National Cardiovascular Center. In accordance with the Declaration of Helsinki, all procedures were performed after written informed consent was obtained from each patient or family. The 0.038-inch and 0.052-inch Gianturco coils and/or detachable PDA coils were used for implantation. Patients with transcatheter occlusions for which the Redel device[20] should be used were excluded, because most pediatric cardiologists have no experience using this device and it is no longer available in Japan. The characteristics of each patient were obtained from their medical records. The duct shape was categorized according to the angiographic classification by Krichenko et al.[21] The

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Table. Patient Demographics

	Median (range)
Sex (M/F)	90/196
Age (years)	5.0 (0.7–74)
Height (cm)	106.0 (60.0–181.3)
Body weight (kg)	18.1 (5.9–99.1)
PDA minimum diameter (mm)	2.0 (0.3–5.6)
Cardiac index	3.9 (1.4–8.9)
Qp/Qs	1.2 (1.0–10.6)
Krichenko classification (A/B/C/D/E/Others)	197/8/13/8/28/32

PDA, patent ductus arteriosus.

minimum duct diameter of the PDA was measured on the lateral projection of the aortogram. Adverse events were defined as follows: failure to implant the coils, coil migration, accidental detachment of the coil, deformity of the delivery cable, difficulty in retrieving the device, coil fracture, hemolysis, peripheral pulmonary stenosis (Doppler velocity >2.0 m/s), coarctation associated with the coils, residual leakage and recanalization. All patients were followed up at 1 month, 6 months, 12 months and every year after the procedure. Echocardiography was performed using several types of machines, mainly Vivid 5, Vivid 7 (General Electric, Vingmed Ultrasound, Horten, Norway), Sonos 5500 (Philips Technology, Andover, MA, USA), Prosound 5500 and Prosound 6500 (ALOKA, Tokyo, Japan) with several types of probes. Residual leakage of the PDA was evaluated by using color-coded Doppler echocardiography. To evaluate the effects of left ventricular volume reduction, the index of left ventricular end diastolic diameter index (LVEDDI: left ventricular end diastolic diameter divided by body surface area) and cardiothoracic ratio (CTR) was estimated using echocardiography and chest X-ray, respectively, before and after 1 year after the procedure and compared using the paired t-test. Long-term occlusion rates after coil implantation were analyzed by the Kaplan-Meier method. The PDAs were categorized according to their size as small (<2 mm), moderate (2–4 mm), and large (≥4 mm).

Results

A total of 310 cardiac catheterizations were performed in 298 patients between 1995 and 2009. The characteristics of these 310 catheterizations are summarized in Table. Coil occlusion was performed in 103 patients from 1995 to 2000 (early study period), whereas 207 patients underwent catheterization from 2001 to 2009 (late study period). The angiographic appearance of the ductus was type A in 197 patients, type B in 8 patients, type C in 13 patients, type D in 8 patients, type E in 28 patients and unknown or unclassified in 32 patients. A majority of the patients had an isolated duct (n=276), but 22 had other cardiac defects, namely, aortic valve disease (n=7), atrial septal defect (n=5), ventricular septal defect (n=3), pulmonary valve stenosis (n=2), mitral regurgitation (n=2), atrioventricular septal defect (n=1), double outlet right ventricle (n=1) and coronary artery fistula (n=1). Twenty-one patients had chromosomal anomalies: 19 patients on chromosome 21 (trisomy 21), 1 patient on chromosome 4 (4q-) and 1 patient on chromosome 22 (del 22.q.11.2).

The coil occlusion was performed under general anesthesia in 73 patients (30%) and under mild sedation or while awake in the other patients. The catheter approach was arterial in 181 procedures (58%), venous in 43 procedures (14%), a combination of arterial and venous in 71 procedures (23%) and unknown in 15 procedures (4%). Implantation was attempted using the detachable PDA coil in 165 procedures (53%), the Gianturco coil in 75 procedures (24%) and a combination of both coils in 35 procedures (11%), while the type of coil used was not reported for 35 proce-

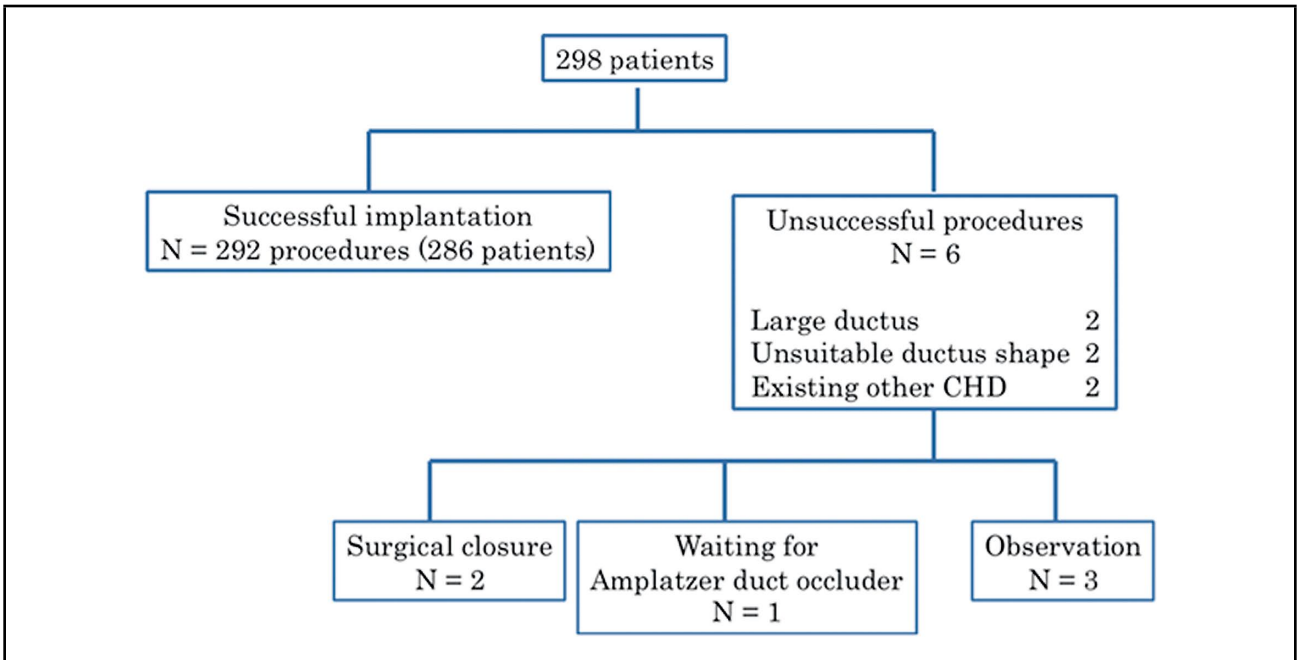

Figure 1. Outcome of 298 patients receiving coil occlusion for patent ductus arteriosus.

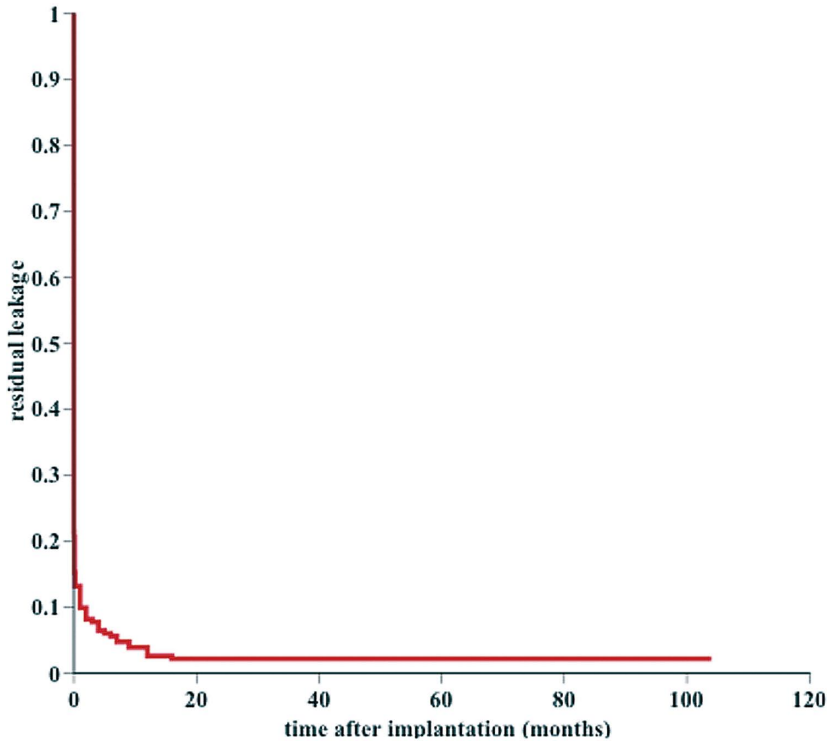

Figure 2. Rate of residual leakage after coil implantation for patent ductus arteriosus in 298 patients. The rate of residual leakage was calculated with the Kaplan-Meier method.

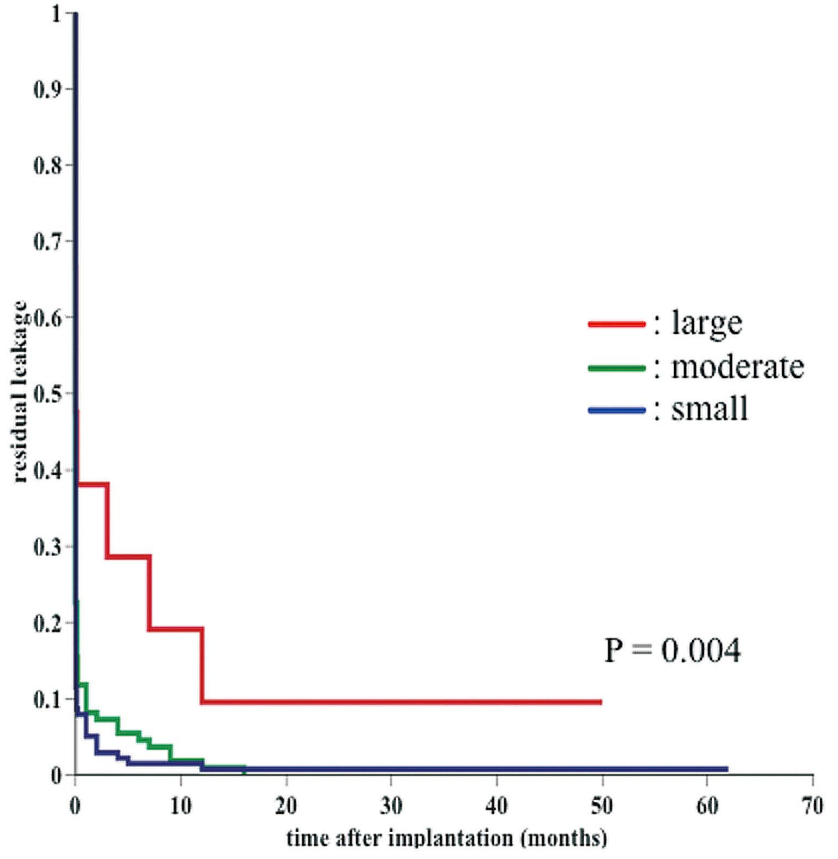

Figure 3. Rates of residual leakage in 3 groups with different sized patent ductus arteriosus (PDA). The rate of residual leakage was significantly associated with the size of the PDA (small, <2 mm; moderate, 2–4 mm; large, ≥4 mm).

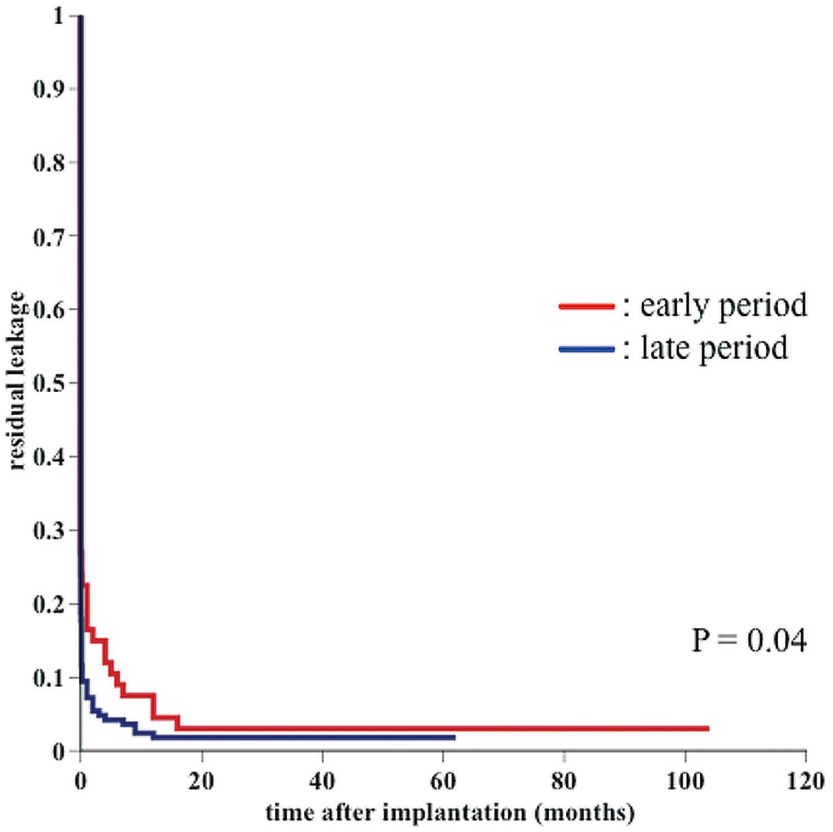

Figure 4. Rate of residual leakage and the timing of coil implantation in 298 patients. The rate of residual leakage was associated with the timing of coil implantation.

dures. The number of coils implanted in each procedure was 1 in 174 patients, 2 in 84 patients, 3 in 23 patients, ≥4 in 7 patients and unknown in 4 patients.

Figure 1 shows the outcome of implantation in 298 patients. The procedure was successful in 286 patients (96.0%) and unsuccessful in 6 (2%); implantation failed in 2 procedures, and the remaining 4 patients did not undergo implantation because the size or shape of the duct was unsuitable. Among the patients who did not undergo coil implantation, 2 underwent surgical closure, 1 received further intervention with the Amplatzer duct occluder and 1 did not receive further therapy and was only observed because the size of the ductus was too small to insert a guidewire. Two patients with other congenital heart disease were observed because it was difficult to implant the coil due to the size or shape of the PDA.

Adverse events were seen in 27 patients (9%) during (n=10) or after (n=17) the procedure. No death and emergent surgical intervention was reported. During the procedure, migration was observed in 3 cases, accidental detachment of the coils in 2 cases, deformity of the coil in 1 case, coil fracture in 1 case and difficulties in retrieving the device in 3 cases. There was no relationship between the frequency of adverse events and the size of the PDA. All migrated coils were retrieved, but 1 coil was partially fractured and parts of the fractured coil remained in the peripheral pulmonary artery. All patients in whom the coils accidentally detached or were difficult to retrieve recovered without complications. Adverse events after the procedure consisted of hemolysis in 3 patients, coarctation of the aorta in 1, peripheral pulmonary stenosis (PPS) in 6, transient atrial flutter in 1, coil fracture (as seen on the roentgenogram) in 1 and residual leakage of the PDA in 5. No recanalization was reported in any patient. Among the patients who did not received coil occlusion therapy, only 1 developed infective endocarditis, whereas no infective endocarditis was observed among the patients who did not receive coil occlusion therapy.

The incidence rate of residual leakage after implantation is shown in Figure 2. The median follow-up period was 50 months, and the occlusion rate at 1 month, 6 months, 1 year, 2 years and 5 years was 90.1%, 94.4%, 97.4%, 97.8% and 97.8%, respectively. Analysis of risk factors revealed that the incidence of final occlusion was significantly higher in patients with a small PDA than in those with a moderate or large PDA (P=0.004) (Figure 3). The occlusion rate in patients who received coil implantation was also higher in patients who underwent the procedure in the late study period (from 2001 to 2009) than in those in the early study period (from 1995 to 2000) (P=0.04), although the final occlusion rate was similar (97.0% vs. 98.0%) (Figure 4). The LVEDDI and CTR were significantly diminished (43.4 [1.5] vs. 35.3 [1.5]; P=0.0002 and 49.5 [0.3%] vs. 47.0 [0.4%]; P<0.0001, respectively).

Discussion

Coil occlusions have been used for patients with PDA since 1992.[1] Various types of devices have been developed; however, the detachable PDA coil and Gianturco coil have been widely accepted.[5–8] Since the Amplatzer duct occluder was

not available during this study period in Japan, coil implantation was a standard therapy of transcatheter occlusion of PDA. Many reports have demonstrated the efficacy and safety of coil implantation for PDA with limited results because of the short-term observation.[15–19] There are only a few reports on the long-term outcome of coil occlusion for PDA.[22–24]

Our study demonstrated that coil occlusion shows long-term efficacy and safety for patients with PDA. The final occlusion rate was 97.8% without any severe adverse events. A large PDA was associated with a higher rate of residual leakage, but we did not observe a relationship between the frequency of adverse events and PDA size. Patients in whom coil implantation was performed in the late study period showed a better occlusion rate than those in the early study period, although the final occlusion rate was similar in the 2 study periods. In addition, the incidence of adverse events during and after the procedure was not high (9%). Although this study was retrospective and the indication or techniques for the procedure varied among institutions, the results of the occlusion rates were similar among them. Therefore, our data can be used to evaluate the long-term outcome of coil occlusion in patients with PDA.

In our study, the mean follow-up period was 4.2 years and 137 patients were followed up for over 5 years. No adverse events occurred 5 years after coil implantation. Patel et al[22] and Hofbeck et al[23] reported long-term results in PDA coil occlusion with different procedures; the former used only the Gianturco coils and the latter used detachable coils. We demonstrated the long-term outcome of the procedures with both coils, which can be considered as a generally accepted therapy. Magee et al[24] demonstrated that the incidence rate of residual leakage was 5% and 4% at 1 and 2 years after the procedure, respectively. The incidence rate of residual leakage in our study was 3.6% and 2.4% at 1 and 2 years after the procedure, respectively. Moreover, the follow-up period was only 24 months in the study by Magee et al compared with our long-term period of 50 months.

The rate of adverse events was 8.7% in our study, which is similar to that reported in previous studies (3–10%).[16,22–24] The most frequent adverse event was PPS, but PPS is not an indication for further intervention in all patients. No patients with adverse events needed an emergency operation or intensive care unit admission in our study. Appropriate procedures and therapy after adverse events probably resulted in a favorable outcome for the patients.

In patients with successful implantation, the rate of residual leakage was very low. However, a higher rate of residual leakage was observed in patients with a moderate or large PDA. In moderate or large PDAs, other methods such as the insertion of an alternative device or surgical closure could be recommended to prevent further residual leakage. Among them, the Amplatzer duct occluder, which has been available in Japan since 2009, has already been used in patients with a large PDA.[10–14]

Study Limitations

Our study has some limitations. This was a retrospective study and had no definite protocol. The indication and techniques used for coil occlusion varied among institutions. However, because of the large sample size and good outcome, our study provides data that can help to determine the optimal choice between the 2 devices, namely coils or duct occluder for closure of large PDAs.

Conclusion

In conclusion, coil occlusion is an effective and safe procedure for PDA; however, we recommend using devices other than coils for closure of a moderate or large PDA. The long-term outcome is favorable. Further studies are required to define the indications that determine which device should be used in patients with larger PDAs.

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