Influence of Ductal Size on the Results of Transcatheter Closure of Patent Ductus Arteriosus with Coils

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SUMMARY

To assess the influence of ductal size on the results of transcatheter closure of patent ductus arteriosus (PDA) with coils, 154 consecutive patients were studied prospectively. Ductal size was defined as the narrowest diameter of ductus measured on aortography. All patients were divided into 5 groups according to ductal size: < 1 mm, 1-1.9 mm, 2-2.9 mm, 3-3.9 mm, and ≥ 4 mm. The occlusion of PDA with coils was performed through a transarterial approach. The results were evaluated by angiography at 10 minutes and by color Doppler echocardiography at 1 day, 2 days, 1 week, 1 month, 3 months, 6 months, and 12 months after the procedure. The immediate occlusion rates for ductal sizes < 1 mm, 1-1.9 mm, 2-2.9 mm, 3-3.9 mm, and ≥ 4 mm were 89.7%, 75.4%, 51.4%, 30.8%, and 40%, respectively; whereas the occlusion rates at 12-months follow-up were 100%, 98.5%, 97.3%, 69.2%, and 80%, respectively. There were no significant differences in occlusion rate at 12-months follow-up among the groups with ductal sizes < 3 mm or among the groups with ductal sizes ≥ 3 mm. The occlusion rate for ductal size < 3 mm at each follow-up time was significantly higher than that for ductal size ≥ 3 mm (10 minutes: 71.8% vs 34.8%, P = 0.001; 12-months: 98.5% vs 73.9%, P < 0.001). The occlusion rate of residual shuntings at 12-months follow-up for ductal size < 3 mm was also significantly higher than that for ductal size ≥ 3 mm (94.6% vs 60%, P = 0.007). The results of the present study demonstrate that ductal size < 3 mm had a higher occlusion rate than that for a size ≥ 3 mm. PDA with a size ≥ 3 mm may need other treatment strategies or other devices to achieve better results. (Jpn Heart J 2003; 44: 395-401)

Key words: Catheterization, Patent ductus arteriosus, Embolization, Congenital heart defects

TRANSCATHETER closure of a patent ductus arteriosus (PDA) was initially introduced by Porstmann, et al in 1967.1) Since then, different devices and techniques have been proposed. A transarterial approach to close PDA with coils was
first described by Cambier, *et al* in 1992. Thereafter, this technique was found to be safe and effective in many reports and has increased in popularity. However, there may be some residual shuntages following this procedure. The factors that influence the results have not been adequately investigated thus far. The purpose of this study was to assess the influence of ductal size on the results of transcatheter closure with coils.

**METHODS**

**Patients:** Between November 1995 and May 1998, all patients with PDA undergoing coil occlusion at our respective institutes were enrolled in this prospective study. Patients aged less than 5 months, with a ductal size larger than 5.5 mm, or with other cardiovascular defects requiring surgery were excluded. Before the procedure, informed consent was obtained from all patients themselves or their parents.

**Ductal size:** Ductal size was defined as the narrowest diameter of the ductus measured on the lateral projection of an aortogram using catheter size as a reference. Patients were divided into 5 groups according to ductal size: <1 mm, 1-1.9 mm, 2-2.9 mm, 3-3.9 mm, and ≥4 mm.

**Materials:** The coil used was a 0.038-inch Gianturco spring coil (Cook Inc., Bloomington, USA) made of stainless steel. Thrombogenic Dacron strands were attached to the coil. The length was sufficient to form 5 loops.

**Standard closure procedure:** Premedication included a prophylactic antibiotic (intravenous cefazolin 25-50 mg/kg or oxacillin 50 mg/kg) and a chloral hydrate enema 50-100 mg/kg for children weighing less than 20 Kg. During the procedure, midazolam 0.2 mg/kg was given intravenously if the patient was crying or was uncooperative. After femoral arterial and venous sheathes were placed, heparin (50 U/kg; maximum 2500 U) was administered intravenously. Routine right and left heart pressure and oxygen saturation were measured. Pulmonary to systemic flow ratio was calculated using Fick's principle. A 5F NIH catheter (Bard Inc., Corington, USA) was placed in the descending aorta for aortography. Coil occlusion of a PDA was performed through a retrograde transarterial approach as described in our previous report. A 4F or 5F right Judkins catheter (Terumo Inc., Tokyo, Japan) was advanced into the pulmonary artery through the ductus from the aortic end. The initial coil had an extruded helical diameter about 2 to 2.5 times the narrowest diameter of the ductus. The coil was loaded into the Judkins catheter and then advanced with a 0.038-inch Teflon coated straight guidewire to the catheter tip. Under lateral fluoroscopic monitoring, one and a half loops of the coil were extruded into the pulmonary artery. The Judkins catheter was then pulled back to the descending aorta and the remainder of the coil was extruded
into the aortic end of the ductus. After the coil was implanted, manual injection of 5 mL urografin was performed at the mouth of the ductus. If significant residual shunting was observed, the ductus was crossed with a 0.018-0.025 inch flexible tipped wire (Terumo Co.). Then, the 4F right Judkins catheter was again placed into the pulmonary artery through the guide wire. The second coil was implanted using the same procedure as for the first coil, except it was smaller in size. Manual injection of contrast medium into the aorta was repeated. If significant residual shunting was noted, a third and subsequent coils were deployed like the second one until there was no more significant shunting.

**Snare-assisted procedure:** If the ductus was so small that a 4F right Judkins catheter could not cross it directly, a 0.018-0.025 inch flexible tipped wire (Terumo Co.) was used to cross the ductus first. A 10-mm diameter snare (Microvena Co., White Bear Lake, USA), delivered through a femoral venous approach, caught the Terumo guidewire, and then pulled the Judkins catheter to the pulmonary artery via the ductus. When the Judkins catheter was at the main pulmonary artery, the coil was deployed using the standard procedure.

**Balloon-assisted procedure:** Since May 1997, the balloon-assisted procedure modified from Berdjis, et al has been used in cases with a ductal size larger than 3.5 mm or coil embolization in the peripheral pulmonary artery during the standard closure procedure. A 5F or 6F pulmonary wedge balloon catheter, guided by a 0.021-inch long wire, was advanced through the femoral vein into the pulmonary artery and then into the descending aorta. Two 4F right Judkins catheters were placed in the pulmonary arteries through both femoral arteries. The balloon was inflated in the descending aorta and then pulled back to engage with the ductus. Thereafter, two coils were deployed simultaneously from both Judkins catheters. After deployment of the coils, the balloon was slowly deflated and the balloon catheter was withdrawn. Manual injection of 5 mL urografin was performed at the mouth of the ductus after the procedure. If significant residual shunting was observed, a third and subsequent coils were implanted according to standard procedure.

**Follow-up:** Repeat descending aortography was performed 10 minutes after implantation of the last coil. The patients underwent follow-up physical examination and color Doppler echocardiography 1 day, 2 days, 1 week, 1 month, 3 months, 6 months, and 12 months after the procedure. The ductus was considered completely closed if no residual shunting was visualized on angiography or echocardiography.

**Statistical analysis:** Descriptive data included patient age, body weight, pulmonary to systemic flow ratio, and ductal size. The occlusion rates of different ductal sizes were evaluated using the proportion z-test. \( P < 0.05 \) indicated statistical significance.
RESULTS

Patient data: A total of 154 consecutive patients were enrolled. There were 102 females and 52 males. Their ages ranged from 5 months to 77 years (median, 2.88 years) and weights ranged from 4.5 to 74 Kg (median, 14 Kg). The pulmonary to systemic flow ratio ranged from 1.01 to 3.73 (mean ± SD = 1.59 ± 0.51). Among the patients, 129 presented with native isolated PDA, 7 with residual PDA after surgical ligation, and 18 with native PDA and associated cardiac lesions including small diminished perimembranous ventricular septal defect in 9, small atrial septal defect in 3, mild aortic stenosis in 2, pulmonary stenosis in 1, asymptomatic double aortic arch in 1, coronary artery fistula in 1, and Kawasaki disease in 1.

Ductal size: Ductal size ranged from 0.24 to 5.1 mm (mean ± SD = 1.42 ± 0.73 mm). The most common ductal size was 1-1.9 mm (65 patients (42.2%)), followed by 2-2.9 mm (37 patients (24%)), < 1 mm (29 patients (18.8%)), 3-3.9 mm (13 patients (8.5%)), and ≥ 4 mm (10 patients (6.5%)).

Closure procedure: The snare-assisted procedure was used in 5 patients with a ductal size less than 1 mm. The balloon-assisted procedure was used in 12 patients (6 patients with ductal size 3-3.9 mm and 6 patients with ductal size ≥ 4 mm). In the group with a ductal size 3-3.9 mm, 6 of 13 patients needed balloon assistance, whereas in the group with a ductal size ≥ 4mm, 6 of 10 needed this procedure.

Coil data: A total of 15 coils were embolized to the left or right pulmonary arteries in 8 patients during the procedure. All of them were retrieved with a snare catheter during catheterization. Among the 8 patients, there were 5 patients with a ductal size 2-2.9 mm, 1 patient with 1-1.9 mm, 1 patient with 3-3.9 mm, and 1 patient with ≥ 4 mm. A total of 218 coils were successfully implanted in the 154 patients. The mean number of coils used in each patient was 1.42, ranging from 1 to 4 with a standard deviation of 0.73.

Occlusion results: The overall occlusion rates at different follow-up times were 66.2% (10 minutes), 77.3% (1 day), 78.6% (2 days), 83.1% (1 week), 87.7% (1 month), 90.9% (3 months), 92.2% (6 months), and 95.5% (12 months). The Table shows the occlusion rates of ductus arteriosus by coils at different follow-up times according to the ductal size. The immediate occlusion rates for ductal sizes < 1 mm, 1-1.9 mm, 2-2.9 mm, 3-3.9 mm, and ≥ 4 mm were 89.7%, 75.4%, 51.4%, 30.8%, and 40%, respectively; whereas the occlusion rates at 12-months follow-up were 100%, 98.5%, 97.3%, 69.2%, and 80%, respectively. There were no significant differences in the occlusion rate at 12-months follow-up among the groups with ductal sizes < 3 mm and among the groups with ductal sizes ≥ 3 mm. The occlusion rate for a ductal size < 3 mm at each follow-up time was signifi-
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Significantly higher than that for a ductal size ≥3 mm (10 minutes: 71.8% vs 34.8%, $P = 0.001$; 12-months: 98.5% vs 73.9%, $P < 0.001$) (Figure).

**Follow-up of residual shunting:** Most of the residual shuntings would be spontaneously closed during follow-up. The occlusion rate of residual shuntings at 12-

**Table.** Occlusion Rates of Ductus Arteriosus by Coils According to Ductal Size

<table>
<thead>
<tr>
<th>Ductal Size (mm)</th>
<th>Follow-up Period</th>
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<tbody>
<tr>
<td></td>
<td>10 minutes</td>
</tr>
<tr>
<td>&lt; 1</td>
<td>N = 29</td>
</tr>
<tr>
<td></td>
<td>(26/29)</td>
</tr>
<tr>
<td>1-1.9</td>
<td>N = 65</td>
</tr>
<tr>
<td></td>
<td>(49/65)</td>
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<td>2-2.9</td>
<td>N = 37</td>
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<td></td>
<td>(19/37)</td>
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<tr>
<td>3-3.9</td>
<td>N = 13</td>
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<td></td>
<td>(4/13)</td>
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<tr>
<td>≥4</td>
<td>N = 10</td>
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<td>(4/10)</td>
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**Figure.** The occlusion rates of patients with ductal sizes < 3 mm and ≥3 mm at different follow-up times.
months follow-up for ductal sizes < 1 mm, 1-1.9 mm, 2-2.9 mm, 3-3.9 mm, and ≥ 4 mm were 100% (3/3), 93.8% (15/16), 94.4% (17/18), 55.6% (5/9), and 66.7% (4/6), respectively. The occlusion rate for residual shuntings at 12-months follow-up for a ductal size < 3 mm was significantly higher than that for a ductal size ≥ 3 mm (94.6% vs 60%, P = 0.007).

Complications: A total of 15 coils were embolized to the peripheral pulmonary arteries in 8 patients during the procedure. Coil embolization mostly occurred in the initial stage of the study. Other complications included 8 instances of diminished femoral pulse, which recovered after the administration of heparin and aspirin, and one instance of hemolysis in a 72 year-old patient due to residual shunting. There were no deaths or instances of endocarditis, delayed coil migration, recanalization of successfully coil-occluded PDA, acquired aortic coarctation, or left pulmonary artery stenosis during the follow-up period.

DISCUSSION

The occlusion rates for a ductal size < 3 mm at different follow-up times were significantly higher than those for a ductal size ≥ 3 mm. The occlusion rates at 12 month follow-up were 98.5% and 73.9% for ductal sizes < 3 mm and ≥ 3 mm, respectively. The result was similar to that of Owada, et al who reported an occlusion rate for ductal size ≥ 3.5 mm of 69%.10) Sanatani, et al concluded that the maximal ductal diameter suitable for coil occlusion is approximately 3 mm.11) We agree that modification of the materials or methods is needed for a relatively large ductus. Owada, et al suggested that the use of 0.052-inch coils could reduce the incidence of embolization and the number of coils needed for closure.10) Hijazi, et al proposed that anterograde transcatheter closure with multiple coils is an effective treatment for most patients with large PDA of diameters up to 7 mm.12) Zellers and Hijazi, et al suggested the use of a “multiple coil-no residual shunt” strategy to improve the results.13,14)

Our findings showed that most of the residual shunting would resolve spontaneously. The occlusion rate of residual shunting at 12-months follow-up for ductal sizes < 3 mm was significantly higher than that for ductal sizes ≥ 3 mm (94.6% vs 60%, P = 0.007). Therefore, in patients with a ductal size < 3 mm, if only a trivial amount of residual shunting is observed as smoke-like jet on angiography, no more coils are needed to minimize the coil number and exposure to radiation. Nevertheless, if ductal size is ≥ 3 mm or the residual shunting is larger than trivial, the strategy of “multiple coil-no residual shunt” is recommended.13,14)
Conclusions: Ductal size $< 3$ mm had a higher occlusion rate than that of sizes $\geq 3$ mm. PDA with a size $\geq 3$ mm may need other treatment strategies or other devices to achieve better results.

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References