Transcatheter Closure of Large Patent Ductus Arteriosus Using the Amplatzer Ductal Occluder

Ming-Chih Lin, Yun-Ching Fu, Sheng-Ling Jan, Chi-Lin Ho, Ching-Shiang Chi, and Betau Hwang

Background: Coils are suitable for the closure of a small patent ductus arteriosus (PDA) but are not recommended for a large PDA. We reported our initial experience of transcatheter closure of a large PDA using the Amplatzer ductal occluder (ADO).

Methods: From April 2002 to October 2006, all patients with ductal size greater than 3.5 mm undergoing transcatheter closure of PDA using the ADO were collected. The results were evaluated by aortography at 10 minutes and by color Doppler echocardiography at 24 hours, 1 month, 3 months, 6 months and 12 months after the procedure.

Results: There were 9 females and 7 males. The median age was 25.4 years (0.9-72.6 years). The median body weight was 54.2 kg (7.8-85.0 kg). The median ductal size was 4.3 mm (3.6-10.5 mm). The median Qp/Qs was 1.98 (1.23-2.44). Three patients had tiny residual shunt immediately after the procedures. All patients had achieved complete closure at 3 months of follow-up. There were no significant left pulmonary artery stenosis, coarctation of the aorta or other complications.

Conclusion: From our limited experience, ADO is safe and effective for the closure of a large PDA.

Key Words: Amplatzer ductal occluder, Heart catheterization, Patent ductus arteriosus

INTRODUCTION

Several kinds of devices have been developed for the transcatheter closure of a patent ductus arteriosus (PDA). Among them, the Gianturco coil is the most popular, safe and effective for the closure of a small to moderate-sized PDA. However it is not suitable for a large PDA due to a high failure rate, high embolization rate, and cumbersome technique. Our previous report showed that the one-year occlusion rate was only 73.9% for ductal size > 3 mm, which was significantly lower than that (98%) for ductal size < 3 mm. To overcome these drawbacks, the Amplatzer ductal occluder (ADO, AGA Medical, Golden Valley, MN) has been developed for the large PDA. It is a self-expandable, mushroom-shaped device made from a 0.004-inch thick Nitinol wire mesh. In this article, we reported our initial experience of transcatheter closure of the large PDA using the ADO.

METHODS

Study patients

From April 2002 to October 2006, after informed consent was obtained from patients themselves or their direct guardians, all patients with angiographic evidence of ductal size greater than 3.5 mm underwent attempted closure of their ductus using the ADO. Patients who had body weights less than 5 kg, severe pulmonary hyperten-
sion, associated cardiac anomalies requiring surgery, bleeding tendency, pelvic vein thrombosis, or inferior vena cava thrombosis were excluded from this study.

**Closure protocol**

The closure procedure is detailed in a previous publication and briefly described here. Patients received detailed physical examination, chest x-ray and blood tests including blood routines and coagulation tests before the procedures. Patients were sedated with local anesthesia or intravenous sedation according to operator-specific decisions. Cefazoline 25 mg/kg was administered intravenously 30 minutes before the procedure. Vascular accesses were established at the right femoral vein and artery. Routine right and left heart catheterizations were performed and pulmonary to systemic flow ratio (Qp/Qs) was determined by Fick’s principle. An aortogram was taken to determine the ductal size and type (Figure 1A). The ductal type was determined according to Krichenko’s classifications. The ductal size was defined as the narrowest diameter of the ductus measured on the lateral or the 30-degree right anterior oblique/15-degree cranial projection, using the catheter size as a reference. Device size chosen was 0-5 mm larger than the ductal size depending on the patient’s size. Although the AGA company recommends the device size be 2 mm larger than the ductus diameter, we would try smaller device for small children under concern of iatrogenic coarctation of the descending aorta by the protruding disc. After that, we advanced an end-hole or multipurpose catheter from the pulmonary artery through the PDA to the descending aorta. By exchanging over a 0.035-inch guidewire, a long 180-degree angled delivery sheath was passed to the descending aorta (Figure 1B). Then the device was advanced inside the long sheath to the descending aorta. After retraction of the long sheath, the retention disc was deployed in the descending aorta. After the device was gently pulled against the orifice (Figure 1C), the sheath was further retracted and the conical part was deployed (Figure 1D). Good ADO position was confirmed by a repeated aortogram, then the device was released by counterclockwise rotation of the vise pin in the delivery cable (Figure 1E). According to the manufacturer’s recommendation, there is no need for anti-platelet medication after the procedure.

**Follow-up**

The results were evaluated by aortography at 10 minutes (Figure 1F) and by color Doppler echocardiography at 24 hours, 1 month, 3 months, 6 months and 12 months after the procedure.

**RESULTS**

The demographic data of 16 consecutive patients are summarized in Table 1. There were 9 females and 7 males. The median age was 25.4 years (0.9-72.6 years). The median body weight was 54.2 kg (7.8-85.0). The median ductal size was 4.3 mm (3.6-10.5 mm). The me-

![Figure 1. (A) Aortogram in lateral projection shows a type A1 PDA. (B) A long 180-degree angled delivery sheath was passed to the descending aorta. (C) The left retention disc was deployed in the descending aorta and gently pulled against the ductal orifice. (D) The conical part of the ADO was deployed. (E) ADO was released by counterclockwise rotation of the vise pin in the delivery cable. (F) Final aortogram shows a complete closure of PDA.](image-url)
dian Qp/Qs was 1.98 (1.23-2.44). The results were summarized in Figure 2. All patients had achieved complete closure at 3 months of follow-up. There were no significant left pulmonary artery stenosis, coarctation of the aorta or other major complications. No patients showed evidences of microembolization or distal embolization during the follow-up period.

**DISCUSSION**

An ideal device for transcatheter closure of PDA should have the following features: First, ease of implantation with simple mechanics, including total control and ability to retract or reposition if misplacement occurs prior to release. Second, complete closure with low residual shunt rate. Third, economic competitiveness with other devices. Fourth, durability until full endothelialization.\(^\text{15,18}\) We believed that the ADO has most of these features. It requires only 5-7 Fr sheaths from the venous side. It achieves complete closure by both a physical barrier (stenting of the ductus) and thrombus formation. In our series, it achieved complete closure in all patients. Comparing with 3 to 38% residual shunting rate,\(^\text{8,10,19}\) the ADO demonstrated its perfect complete closure rate in the long-term follow-up report.\(^\text{20}\) Furthermore, recanalization is not infrequent in patients who have undergone coil closure. The need for second intervention ranged from 3 to 11% in different reports.\(^\text{21,22}\) The only limitation for ADO here in Taiwan is that it is still not covered by the national health insurance. Wang et al. suggested a strategic approach, using Gianturco coil for small-to-moderate sized ductus and ADO for large ductus.\(^\text{23}\) That may be a reasonable strategy when considering the balance between risk and cost for patients.

Some reports and the manufacturer’s recommendation suggest that the implantation of ADO in infants < 5

<table>
<thead>
<tr>
<th>No.</th>
<th>Sex</th>
<th>Age (yr)</th>
<th>Weight (kg)</th>
<th>Ductal size (mm)</th>
<th>Ductal type</th>
<th>Device size (mm)</th>
<th>Qp/Qs</th>
<th>Follow-up time (yr)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>M</td>
<td>50.5</td>
<td>58.0</td>
<td>6.1</td>
<td>A2</td>
<td>10</td>
<td>2.44</td>
<td>4.5</td>
</tr>
<tr>
<td>2</td>
<td>F</td>
<td>34.9</td>
<td>65.0</td>
<td>5.9</td>
<td>A1</td>
<td>10</td>
<td>2.10</td>
<td>3.0</td>
</tr>
<tr>
<td>3</td>
<td>F</td>
<td>21.6</td>
<td>46.0</td>
<td>4.0</td>
<td>A1</td>
<td>6</td>
<td>3.00</td>
<td>3.8</td>
</tr>
<tr>
<td>4</td>
<td>F</td>
<td>3.9</td>
<td>14.0</td>
<td>4.2</td>
<td>A1</td>
<td>6</td>
<td>2.40</td>
<td>2.6</td>
</tr>
<tr>
<td>5</td>
<td>F</td>
<td>2.2</td>
<td>11.0</td>
<td>10.5</td>
<td>A2</td>
<td>12</td>
<td>1.80</td>
<td>2.6</td>
</tr>
<tr>
<td>6</td>
<td>M</td>
<td>28.1</td>
<td>84.0</td>
<td>4.0</td>
<td>A2</td>
<td>7</td>
<td>1.60</td>
<td>2.5</td>
</tr>
<tr>
<td>7</td>
<td>M</td>
<td>46.2</td>
<td>80.0</td>
<td>5.0</td>
<td>A1</td>
<td>10</td>
<td>1.50</td>
<td>2.4</td>
</tr>
<tr>
<td>8</td>
<td>M</td>
<td>28.2</td>
<td>85.0</td>
<td>5.5</td>
<td>A2</td>
<td>7</td>
<td>1.60</td>
<td>2.4</td>
</tr>
<tr>
<td>9</td>
<td>M</td>
<td>38.0</td>
<td>64.0</td>
<td>6.0</td>
<td>A1</td>
<td>10</td>
<td>1.66</td>
<td>1.8</td>
</tr>
<tr>
<td>10</td>
<td>F</td>
<td>22.8</td>
<td>54.0</td>
<td>3.8</td>
<td>A2</td>
<td>8</td>
<td>1.23</td>
<td>1.5</td>
</tr>
<tr>
<td>11</td>
<td>M</td>
<td>0.9</td>
<td>7.8</td>
<td>4.1</td>
<td>A2</td>
<td>8</td>
<td>2.30</td>
<td>1.0</td>
</tr>
<tr>
<td>12</td>
<td>F</td>
<td>1.9</td>
<td>12.0</td>
<td>4.0</td>
<td>A1</td>
<td>6</td>
<td>1.70</td>
<td>1.0</td>
</tr>
<tr>
<td>13</td>
<td>F</td>
<td>36.9</td>
<td>73.0</td>
<td>4.7</td>
<td>A2</td>
<td>8</td>
<td>3.56</td>
<td>1.0</td>
</tr>
<tr>
<td>14</td>
<td>F</td>
<td>72.6</td>
<td>54.4</td>
<td>4.4</td>
<td>A1</td>
<td>6</td>
<td>1.95</td>
<td>0.5</td>
</tr>
<tr>
<td>15</td>
<td>M</td>
<td>1.4</td>
<td>9.1</td>
<td>3.6</td>
<td>A1</td>
<td>6</td>
<td>2.26</td>
<td>0.4</td>
</tr>
<tr>
<td>16</td>
<td>F</td>
<td>2.1</td>
<td>10.0</td>
<td>4.0</td>
<td>A1</td>
<td>4</td>
<td>2.00</td>
<td>0.3</td>
</tr>
<tr>
<td>Median</td>
<td>25.4</td>
<td>54.2</td>
<td>4.3</td>
<td>8</td>
<td>1.98</td>
<td>2.4</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>0.9-72.6</td>
<td>7.8-85.0</td>
<td>3.6-10.5</td>
<td>4-12</td>
<td>1.23-2.44</td>
<td>0.3-4.5</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Qp/Qs = pulmonary to systemic flow ratio

![Figure 2. Complete closure rate during follow-up.](image-url)
kg should be limited because of both higher complication rate and technical difficulties. In addition, technical difficulties were more frequently encountered in small children or infants with large ductus, even when body weight was greater than 5 kg. Kinking of long technical difficulties were more frequently encountered in small children or infants with large ductus, even when body weight was greater than 5 kg. Kinking of long procedure in young infants has been reported. In a long-term follow-up report, all three patients with iatrogenic stenosis of the left pulmonary artery or descending aorta were of a relative low body weight. Although Butera et al. reported a series of implantation of ADO in symptomatic young children with very few complications and a large device has been successfully implanted in a small child in our center, the use of the device in relatively small children should only be with caution and experienced hands. Under the concern of possible aortic obstruction caused by protruding device disc in small children, we would try device smaller than that recommended by the manufacturer.

According to Krichenko’s classification, type A PDA has its narrowest segment at pulmonary insertion with a well-defined ampulla at the aortic end. Type B PDA is short, with its narrowest part at the aortic insertion. Because the PDA is a remnant of the 6th aortic arch, it forms naturally a 30-degree angle with the descending aorta. The retention disc of ADO is at a right angle. As a result, the retention disc may protrude partially into the aorta, especially in patients with type B morphology or type A morphology with a small ampulla. In adults, it may not be of hemodynamic significance, but it may cause partial aortic obstruction in small babies. A modification of the device with angled retention disc may eliminate this drawback. However, protruding into the left pulmonary artery may only cause redistribution of pulmonary blood flow with no pressure gradient. With the growth of a child, the pulmonary artery will enlarge considerably. As a result, the partial obstruction is expected to be self-limited. But further clinical observation should be carried out to prove it. For patients with type B morphology, some authors suggested that ADO should be reserved for those who weigh more than 15 kg. Thanopoulos et al. reported a successful closure of a type B ductus in a 12-kg child using ADO in their series. So, short ductus might not be a major limitation for ADO, but measurement of aortic pressure after releasing the device should be routinely performed.

In conclusion, from our limited experience, the ADO is safe and effective for the closure of a large PDA.

REFERENCES


經心導管使用安普拉茲封堵器關閉大型存開性動脈導管

林明志 1 傅雲慶 1,2 詹聖霖 1, 何季麟 1,3 遲景上 1 黃碧桃 2
台中市 台中榮民總醫院 兒童醫學部 兒童心臟科 1
台北市 國立陽明大學 醫學系 小兒學科 2
台中澄清綜合醫院 小兒科 3

背景 鈕簧圈適合用來關閉小的存開性動脈導管，但不建議用於大型的動脈導管。本文報告我們使用安普拉茲封堵器經心導管關閉大型存開性動脈導管的初期經驗。

方法 從 2002 年 4 月到 2006 年 10 月，我們收集所有使用安普拉茲封堵器經心導管關閉大於 3.5 mm 的存開性動脈導管的病人。放置後十分鐘以血管攝影評估成果，並於 24 小時，1 個月，3 個月，6 個月，及 12 個月後以彩色多普勒超音波追蹤。

結果 總共 9 個女性及 7 個男性。年齡中位數為 25.4 歲 (0.9-72.6 歲)，體重中位數為 54.2 公斤 (7.8-85.0 公斤)，存開性動脈導管直徑中位數為 4.3 mm (3.6-10.5 mm)，肺血流量與主動脈血流量比值中位數為 1.98 (1.23-2.44)。其中三個病人術後十分鐘有輕微殘餘分流，所有病人於術後三個月均達到完全關閉。無顯著左肺動脈狹窄、主動脈弓縮窄或其他併發症。

結論 由我們有限之經驗，使用安普拉茲封堵器治療大型存開性動脈導管是安全且有效的。

關鍵詞：安普拉茲封堵器、心導管、存開性動脈導管。