Transcatheter Closure of Moderate-to-Large Patent Ductus Arteriosus in Infants Using Amplatzer Duct Occluder

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Background: There are difficulties in transcatheter closure of patent ductus arteriosus (PDA) in infants.

Methods and Results: The 46 infants (mean age 6.2±2.7 months; mean body weight 6.3±1.6 kg) who underwent PDA closure using the Amplatzer duct occluder (ADO). The indication for using an ADO was a ductus diameter ≥2.5 or 3 mm. Device diameter selected was 1–3 mm larger than ductal diameter. The mean systolic pulmonary artery pressure was 40.9±18.2 mmHg. The mean Qp/Qs ratio was 3.1±1.2. The mean ductus diameter was 3.3±0.8 mm. ADO was successfully deployed in 45 patients. Failure occurred in 1 case. The mean diameter of device used was 5.4±1.1 mm. No severe complications occurred. At the 1-month echocardiographic follow-up, a small residual shunt was present in 4 of 45 patients and had disappeared in all 4 patients at the 3-month follow-up. One patient developed a moderate degree of left ventricular outflow tract obstruction 2.3 years after the procedure.

Conclusions: Transcatheter closure of PDA in infants using the ADO is a safe and effective method. (Circ J 2010; 74: 361–364)

Key Words: Amplatzer duct occluder; Infants; Patent ductus arteriosus; Transcatheter closure

Transcatheter closure of patent ductus arteriosus (PDA) is increasingly performed worldwide,1–7 and generally surgery is now reserved for those in whom transcatheter closure is either not possible or fails.8 Several different devices have been developed to close the ductus, with variable results, and among them, the coil has been the most popular device because of ease of use, low sheath profile requirement and a high success rate.1–7 However, there are limitations in the use of coils for closure of a large ductus where distal embolization has occurred frequently.4,5,7,9 In the past decade, the Amplatzer duct occluder (ADO) has been successfully used in moderate-to-large PDA, with a high success rate and low complication rate,10–14 but difficulties in using the ADO for occlusion of a large ductus in infants have been reported.15,16 We present our results of catheter closure of moderate-to-large PDA in infants using the ADO.

Methods

Patients

Between January 2002 and September 2008, 46 infants (33 females, 13 males) with a moderate-to-large PDA underwent attempted transcatheter closure using an ADO (AGA Medical Corp, Golden Valley, MN, USA). The age range was 2–12 months, with a mean of 6.2±2.7 months, and body weight ranged from 3.5 to 8.1 kg (mean 6.3±1.6 kg); 18 patients weighed less than 6 kg. Of the 46 infants, 39 had symptoms of heart failure or failure to thrive, and 7 had cardiomegaly on echocardiography or recurrent respiratory tract infections. Two patients were intubated because of tachypnea and retractions. Two had associated Down syndrome. One had multiple congenital anomalies, including severe valvular pulmonary stenosis and non-compaction of left ventricle. One had a moderate degree of mitral regurgitation. In total, 41 patients were taking medications to prevent heart failure. The indication for using an ADO was a minimal PDA dimension ≥3 mm (before September 2007) and ≥2.5 mm afterwards.

During this period of time, 5 symptomatic infants with PDA were sent for surgery because the duct was considered too large (ductus diameter ≥5 mm and body weight <5 kg) as demonstrated by echocardiography or angiography.

Methods

All patients underwent clinical evaluation, chest X-ray and echocardiography upon admission. The left ventricular end-diastolic dimension (LVEDD) was measured in each patient on the M-mode echocardiogram. Informed consent was obtained from the parents of each patient. In patients older than 2 months, premedication with a combination of promethazine and chlorpromazine was given 30 min prior to
the procedure. One dose of antibiotics was administered. During the procedure, ketamine or midazolam was given as required for sedation. After local anesthesia, the femoral vein and artery were accessed and cannulated with a 4 or 5Fr sheath. Hemodynamic studies were performed, and the Qp/Qs ratio was obtained in each patient. Aortograms were obtained in the right anterior oblique 30° and lateral views. The minimal diameter of the ductus was measured on a frozen image. Generally, the catheter diameter was used as the reference. No heparin was used before the procedure. Normal saline containing heparin (10 units/ml) was used to flush the sheath throughout the procedure. The device size selected was usually 1–3 mm larger than the ductus diameter. Generally, a 6Fr AGA sheath (AGA Medical Corporation, Golden Valley, MN, USA) was used to deliver the device, but if not available, a Cook sheath was used (Cook, Bloomington, IN, USA). The technique of device deployment was similar to that reported in the literature, following by aortography to evaluate the device position and presence of residual shunt. One patient who had multiple anomalies underwent valvuloplasty for pulmonary stenosis prior to PDA closure. Following the procedure, 3 doses of antibiotics were given. Patients were discharged the next day after clinical evaluation.

Follow-up
After the procedure, patients underwent clinical evaluation and echocardiography at 1, 3, 6 and 12 months and then annually. A turbulent flow (≥ 1.5 m/s) across the origin of the left pulmonary artery or descending aorta was considered as acquired stenosis. The difference in the LVEDD before and at 1 month after PDA closure was evaluated.

Statistical Analysis
All data are expressed as mean±standard deviation. The paired-t test was used to evaluate the difference in LVEDD before and 1 month after PDA closure. A P value <0.05 was defined as significance.

Results

Acute Results
For the 46 infants, the mean Qp/Qs ratio was 3.1±1.2. The mean systolic pulmonary artery pressure was 40.9±18.2 mmHg. The ductus diameter ranged from 2.5 to 6 mm, with a mean of 3.3±0.8 mm. There were 42 patients with a morphological type A ductus, 1 with a type B ductus and 3 with a type C ductus. The device was successfully deployed in 45 infants. The mean diameter of device deployed was 5.4±1.1 mm (4–8 mm). Failure occurred in a 2.5-month-old infant weighing 4.2 kg with a 2.6 mm ductus and the cause was kinking of the 6Fr sheath (Cook) during advancement of a 4-mm device through the right ventricular outflow tract. The procedure was...

Figure. (A, B) Aortograms in the right anterior oblique 30° and lateral views show the large ductus (arrows). (C, D) Repeat aortograms following deployment of an Amplatzer duct occluder show a moderate residual shunt.
abandoned because no other 6 or 7Fr long sheath was available. Two patients required a one-size-larger device to achieve success, because of repeated pull-through of the device. The mean fluoroscopic time was 10.3±3.6 min. Of the 45 patients with successful deployment of a device, residual shunt was noted in 13 patients on the repeat aortogram obtained 10 min after the procedure; the residual shunt was small or trivial in 11 patients and moderate in 2 (Figure). Two infants who were intubated before the procedure were extubated and weaned from respirator on the next day. All except 7 patients were discharged the next day. Of the 7 patients, 2 had mild fever, 2 had been intubated before the procedure and 3 had loss of a femoral pulse.

**Complications**

Transient bradycardia (<60 beats/min) occurred in 5 patients during the procedure: while the long sheath was being advanced through the right ventricular outflow tract or descending aorta in 4 and after pulling through the device in 1; all spontaneously recovered normal heart rate within a few minutes. Kinking of the sheath occurred in 3 cases, of which the procedure was abandoned in 1 and a new AGA sheath and an Amplatzer vascular plug pushing cable were used in 2. A hematoma was found in 2 patients. Three patients had loss of the femoral artery pulse, which was managed by continuous infusion of heparin and all 3 recovered femoral artery pulse tension the next day. No one had hemolysis and no other serious complication occurred.

**Follow-up**

All patients were available for the 1-month echocardiographic follow-up: 4 patients had mild residual shunt, and 7 had left pulmonary artery stenosis (Vmax >1.5 m/s and <2.5 m/s) at the 1-month echocardiographic follow-up. The LVEDD had decreased from a mean of 3.1±0.5 to 2.7±0.4 cm at the 1-month follow-up (P<0.001). No one had coarctation of the aorta. For the 3-month follow-up 40 patients, including the 4 patients with residual shunt, were available, and none had a persistent residual shunt. Three of the previous 7 patients still had mild stenosis (Vmax <2.5 m/s) at the left pulmonary artery and 4 patients had resolution. All symptomatic patients showed improvement in symptoms during follow-up. Those with recurrent respiratory tract infections had no significant recurrences. One who had moderate degree of mitral regurgitation prior to intervention had improvement in mitral valve function and a significant reduction in left ventricular dimensions during follow-up. Another procedure to close the ductus was performed 3 weeks later in the infant with the failed attempt. Aortography showed a significant decrease in ductus diameter from 2.6 to 1.6 mm and the PDA was closed with a Gianturco coil. One patient developed significant left ventricular outflow tract obstruction, with a peak-to-peak pressure gradient of 65 mmHg derived from catheterization 2.3 years later, but her parents did not accept the recommendation for operation. All patients showed improvement in symptoms during follow-up. Pulmonary hypertension, as evaluated with Doppler echocardiography, regressed in all during follow-up.

**Discussion**

**Advantages of Using the ADO for Closing a Large PDA in Infants**

Transcatheter closure is now considered as the mainstay of treatment for PDA and coils (Gianturco coil or detachable coil) are the most common device used. However, their use in patients with a large ductus is technically difficult and may result in distal embolization of the coils or procedural failure.2-7,9 Although a modified delivery technique or the use of 0.052-inch coils may increase the success rate, embolization or failure to close a ductus ≥3.5 mm with coils remains high.2,4-7,9,18 The ADO, developed to close moderate-to-large-sized PDA, has a high success rate and low complication rate.10-14 We previously proposed a strategic approach to the closure of the ductus: use coils for small-size PDA and the ADO for moderate-to-large ones.9 There are many reports regarding closure of the ductus using the ADO, but the majority of patients included were over 1 year of age, and reports of ductal closure using the ADO in infants are few and the case numbers rather limited.10,16-18-20

PDA may be an isolated anomaly or associated with some other cardiovascular anomalies.21 Infants with a large ductus are usually symptomatic with tachypnea, tachycardia and difficulty in feeding. Failure to thrive and recurrent respiratory tract infections are also quite common. Early closure is generally required to relieve the symptoms. Although coil closure is effective, procedural failure is not uncommon in infants with a large ductus, and using large and multiple coils in infants frequently results in left pulmonary artery stenosis.2,5-7,9,22 Meanwhile, residual shunt is more common in infants undergoing closure with coils than with the ADO.18,21 The mean fluoroscopic and procedural times are shorter with ADO closure than with coil closure for large ductus, so the ADO seems to be the ideal device to use in infants with a moderate-to-large PDA. However, difficulties in the deployment of the ADO in young children have been reported:12,16,19,20,24 for example, kinking of the sheath may occur while advancing the device to the right ventricular outflow tract, although this can be solved by snaring the sheath from the descending aorta15 or using an Amplatzer vascular plug pushing cable. Left pulmonary artery stenosis is not uncommon following deployment of ADO, but is usually mild (Vmax <2.5 m/s).10-14 Avoiding using an excessively over-sized device in infants may decrease the incidence of this complication. Coarctation of the aorta following implantation of an ADO is not rare,10-12,25 but occurs mostly in young infant, in whom an excessively oversized device is implanted, resulting in protrusion of the retention flange into the aorta. An angled device can be useful in infants with a relatively short ductus to minimize protrusion of the upper part of the retention flange.26 Recently, a swivel-disk device has been developed to diminish the possibility of developing a pressure gradient in the aorta.27 In the present series, progressive left ventricular outflow tract obstruction because of a fibromuscular ridge occurred in 1 patient and the cause of an acquired subaortic ridge in this patient remains unclear.

**Considerations of the Morphology of the Ductus During Catheter Closure**

In addition to diameter, the morphology of the ductus should be considered during catheter closure with a device.19,22,27 Failure of coil closure occurs more frequently in infants with a short, large ductus.22 Distal embolization of coils occurs more frequently with a type B or C morphology than with other types of ductus.3,4 The ADO is quite effective in closing both type A and type C ductus,10,12 but it can be cumbersome in the closure of type D and type E ductus in which the new ADO and plug occluder can be useful.27,28 For a window-type (type B) ductus, the ADO could be effective, but a body weight >15 kg is preferred to achieve success.12
Timing and Indications for PDA Closure in Infants

The timing of catheter closure of a PDA in infants should be carefully evaluated in each individual, because technical difficulties are frequently encountered during catheter closure with an ADO. The natural history of the PDA should also be considered, because spontaneous closure or a decrease in ductus diameter may occur. In symptomatic infants, anti-congestive treatment is generally administered to control symptoms and postpone the timing of the procedure if possible. In asymptomatic infants, there is no hurry in closing the ductus, and catheter closure is best performed when the body weight is >10 kg. In this study, transcatheter closure was not attempted in infants weighing <5 kg with a large ductus ≥5 mm because we consider the risk of catheter closure can be higher than that of surgery in such patients.

Conclusions

Using the ADO for transcatheter closure of a PDA in infants is effective and safe and should be considered the procedure of choice.

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References