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Original Articles

Midterm Results of Transcatheter Closure of Moderate to Large-sized Patent Ductus Arteriosus Using the Amplatzer Duct Occluder

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Abstract Transcatheter closure is an established form of treatment for most patients with patent ductus arteriosus (PDA). The design of previously used devices has been associated with several drawbacks for closing moderate to large PDAs. The aim of this study was to examine the midterm results of transcatheter closure of moderate to large-sized PDA using the Amplatzer Duct Occluder (ADO). Ninety patients, aged 2.9 months to 16.5 years with a moderate to large-sized PDA, underwent successful transcatheter closure using the ADO. The median PDA diameter was 2.8 mm (range 1.5 to 5.0 mm). Complete immediate angiographic closure was seen in 34 of 90 patients (37.7%; 95% CI 27.7% to 47.7%). On colour Doppler interrogation, the closure rates at 1 day, 1 month and 3 months after implant were 81.1% (95% CI 73.0% to 89.2%), 88.9% (95% CI 82.5% to 95.3%) and 93.3% (95% CI 88.1% to 98.5%) respectively. At 12 months, all patients had complete closure. The median fluoroscopy time was 11.5 minutes (range 3 to 49.5 minutes) and the median procedure time was 68 minutes (range 32 to 180 minutes). Mild device-related turbulent blood flow but with no significant obstruction occurred in the left pulmonary artery of two patients and the descending aorta of another patient who had pre-existing isthmal hypoplasia. No device embolisation was encountered. Therefore transcatheter closure of moderate to large-sided PDA using the ADO is an effective and safe therapy. Further studies are required to establish long-term results in a larger patient population.

Key words Amplatzer duct occluder; Children; Patent ductus arteriosus; Transcatheter closure

Introduction

In the past two decades, transcatheter closure has become an established form of treatment for the majority of patients with patent ductus arteriosus (PDA). Since the initial experience of transcatheter closure with the Porstmann plug in the 1967,[1] various devices have been used previously with variable degree of success.[2-7] Limitations of previous technique included large delivery sheaths, cumbersome implantation technique, device embolisation and a high rate of residual shunting.[2-5,8-11] Whilst small PDAs can conveniently be closed with a single spring coil,[6,7,12] moderate to large ductus often necessitate implantation of multiple coils which is technically challenging and difficult in young infants. Residual shunting is also common. The Amplatzer Duct Occluder (ADO) is a self-expandable device designed to occlude moderate to large-sized PDA. In this study, we report the midterm results and our experience of transcatheter closure of moderate to large-sized patent ductus arteriosus with the ADO.

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Methods

Patients

From April 1998 to February 2005, ninety patients underwent transcatheter occlusion of PDA using the ADO. All patients had echocardiographic evidence of significant left-to-right shunting through the PDA with left atrial enlargement and ventricular volume overload. Our institutional protocol is as follows: a ductal diameter greater than 2 mm were closed by ADO whereas a ductal diameter less than 1.5 mm were closed by coil occlusion, arterial duct between 1.5 mm to 2 mm in diameter might be closed by either method, depending on patient's specific conditions and the operator's choice. Young infants with symptomatic PDA and a body weight less than 4 kg were sent for surgical ligation.

The Device

The AMPLATZER Duct Occluder (AGA Medical Corporation, Golden Valley, MN) is a self-expandable cone-shaped device made from a 0.004-inch thick Nitinol wire mesh. A retention disc 2 mm large than the diameter ensures secure positioning of the device at the aortic orifice of the PDA. Polyester patches, which are sewn into the device, induce thrombosis that closes the ductus (Figure 1).

Procedure

The procedure was performed with standard technique described previously.[13,14] In brief, under general anaesthesia and fluoroscopic guidance, all patients underwent routine right heart catheterisation through a 6 French sheath in the femoral vein. The pulmonary to systemic blood flow ratio was calculated and pulmonary hypertension was noted. Pulmonary hypertension was defined as systolic pulmonary arterial (PA) to aortic pressure ratio of more than 0.5. A biplane descending aortogram in anteroposterior and lateral projection was performed via a 4 or 5 French sheath in the femoral artery to determine the diameter and anatomy of the ductus. The diameter of the ductus was taken as the narrowest point along the course of the duct on angiography. A 5 French end-hole catheter was then advanced antegradely through the PDA into the descending aorta and was exchanged with a 6 French long sheath over a 0.035 inch guide-wire. The diameter of the occluder was chosen to be at least 1 to 2 mm larger than that measured on angiography. The occluder was screwed to the delivery cable and introduced into the long sheath through a loader. Under fluoroscopic guidance, the ADO was advanced into the descending aorta, where the retention disc was deployed. The disc was pulled gently against the aortic orifice of the PDA. Using gentle traction on the delivery cable, the sheath was pulled back to deploy the conical part of the device into the ductus (Figure 2). Once optimal position was confirmed, the ADO was released by counterclockwise rotation of the delivery cable. An aortogram was performed at five minutes after release of the occluder to check for residual shunts. At 24 hours, chest radiographs in the posteroanterior and lateral positions were obtained to assess device position.

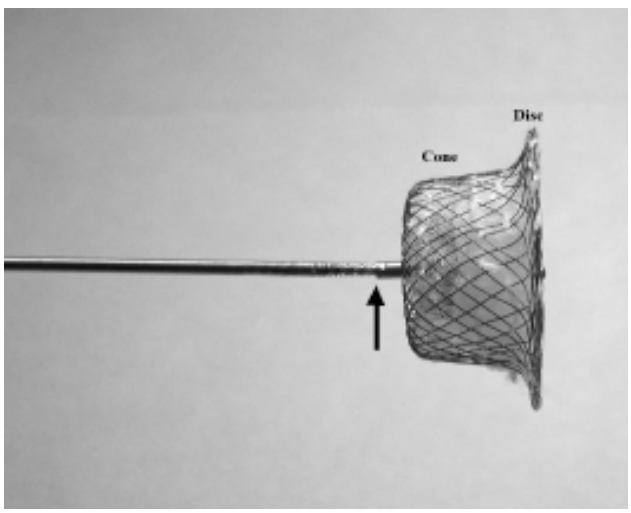

Figure 1 Close-up view of the Amplatzer Duct Occluder and delivery system. Note the cone shaped device with the retention disc. Arrow indicates the microscrew for release.

Follow-up

Follow-up evaluation was performed with 2D echocardiogram, colour-flow mapping and Doppler measurement to look for residual ductal flow in the main pulmonary artery, left pulmonary artery stenosis or aortic obstruction within 24 hours and at 1, 3, 6, 12 months after the procedure and at 6-month intervals thereafter. Significant left pulmonary artery stenosis or aortic obstruction was defined as Doppler-derived pressure gradient of 20 mmHg or more.[15,16] Particular attention was made to look for occurrence of late complications.

Statistical Analysis

Results are expressed as median and range. The percentages with 95% confidence intervals [95% CI] for PDA closure at subsequent follow-up were calculated. Kaplan-Meier method is utilised to analyse the prevalence of residual shunt with time.

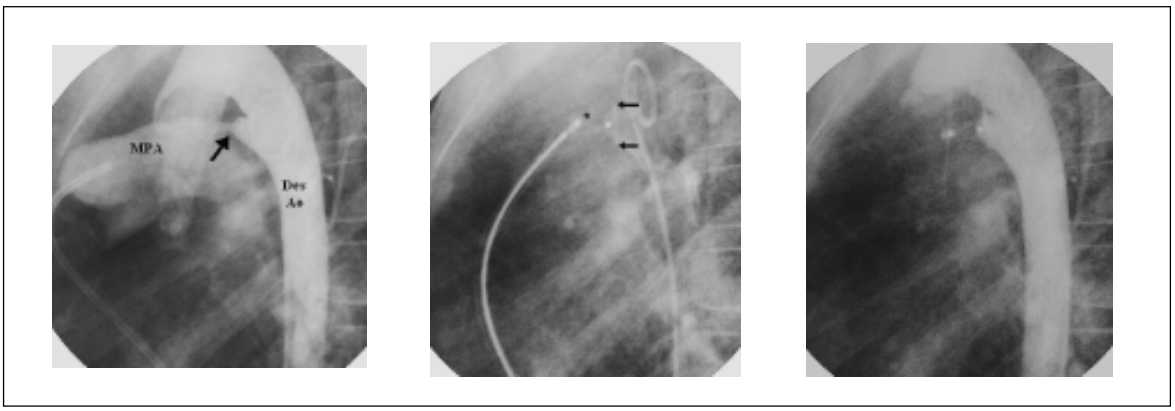

Figure 2 Angiogram in lateral projection demonstrating the deployment of Amplatzer Ductal Occluder. (A) Descending aortogram revealed a moderate-sized PDA (arrow). (B) The retention disc (small arrows) was positioned at the ampulla while the cone (*) was opened in the PDA. The device was still attached to the delivery cable. (C) Descending aortogram after release of the device, revealing a good device position with complete closure of PDA.
Des Ao = descending aorta, MPA = main pulmonary artery.

Results

Ninety patients underwent transcatheter occlusion of PDA using the ADO device. Eighteen were male and seventy-two were female. The median age at the time of the procedure was 3.9 years (range=0.2 to 16.5 years). The median weight was 14.3 kg (range=4.0 to 77.5 kg). Five (5.6%) patients weighed below 5 kg. Twenty-six patients (28.9%) had symptoms of heart failure.

The data of ductal sizes in different age groups was shown in Table 1. Seventeen (18.9%) of the patients were infants and more than 60% were below five years of age. Up to 87.7% of them were less than 10 years old when they underwent the procedure. The median PDA size was 2.8 mm (range 1.5 to 5.0 mm). The largest PDAs were all found in the three younger age groups.

None of our patients had aortic obstruction or left pulmonary artery stenosis before PDA occlusion. Ten (11.1%) patients had concomitant heart lesions as listed in Table 2. PDA in these patients was the dominant lesion whereas other associated lesions were considered to be either not causing significant haemodynamic disturbance or did not require intervention at the time of occlusion.

According to the classification adopted by Krichenko et al,[17] 80 (88.9%) had type A PDA; five (5.6%) had type C and one (1.1%) had type D. The median pulmonary to systemic flow ratio was 2.4 (range 1.2 to 14.9). Fifteen subjects (16.7%) had pulmonary hypertension and one of them had pulmonary hypertension of systemic level. The median mean PA pressure was 23 mm Hg (range 6 to 60 mmHg), and the median systolic PA to aortic pressure ratio was 0.30 (range 0.13 to 1.0). The median fluoroscopy time was 11.5 minutes (range 3 to 49.5 minutes) and the median procedure time was 68 minutes (range 32-180 minutes). In our early experience, one infant weighing 4.8 kg with a PDA of 1.5 mm in diameter was initially treated with coil occlusion (3 mm diameter). The coil embolised to the left pulmonary artery. It was retrieved uneventfully, and subsequently an ADO device of 6/4 mm in size was implanted successfully.

Table 1 Statistical data of ductal size of different age groups

Age group(years)	Number of patients	Percent	PDA size (mm)	
			Median	Range
< 1	17	18.9	3.5	1.5 - 5.0
1-5	40	44.4	2.6	1.5 - 4.5
5-10	22	24.4	2.9	1.7 - 5.0
10-15	8	8.9	3.0	2.0 - 3.8
> 15	3	3.3	2.6	2.1 - 3.0

Table 2 Summary of associated lesions in the patients

Associated lesions	Number
Primum atrial septal defect	1
Secundum atrial septal defect	2
Subaortic stenosis	2
Bicuspid aortic valve	2
Ventricular septal defect	2
Isthmal hypoplasia	1

All 90 patients had successful PDA occlusion using the ADO. Thirty-four patients (37.7%; 95% CI 27.7% to 47.7%) of our subjects achieved immediate complete occlusion. On colour Doppler interrogation, the complete closure rate at 1 day, 1 month and 3 months after implant were 81.1% (95% CI 73.0% to 89.2%), 88.9% (95% CI 82.5% to 95.3%) and 93.3% (95% CI 88.1% to 98.5%) respectively. At 12 months, all patients had complete closure. From the Kaplan-Meier method, the mean time to complete closure was 0.72 months with a standard error of 0.22 months (Figure 3).

Immediate Complications

No major complications were encountered in the procedures. Loss of femoral pulses after the procedure occurred in three infants with body weight less than 5 kg. All femoral pulses returned normal after heparin infusion for two days. One infant had significant blood loss during the procedure and required transfusion.

Follow-up

The median follow-up time was 40.7 months (range 1.1 to 82.4 months). There was no ductal recanalisation in all patients. Major late complications such as device migration, wire fracture, thromboembolism, endocarditis and haemolysis did not occur.

None of the patients developed device-related aortic obstruction or left pulmonary artery stenosis. Only two patients were detected to have turbulent flow in the left pulmonary artery on colour flow mapping but the Doppler-derived gradient was only 9 mmHg and 7 mmHg respectively, and no intervention was required.

Mild device-related turbulent flow on colour Doppler in

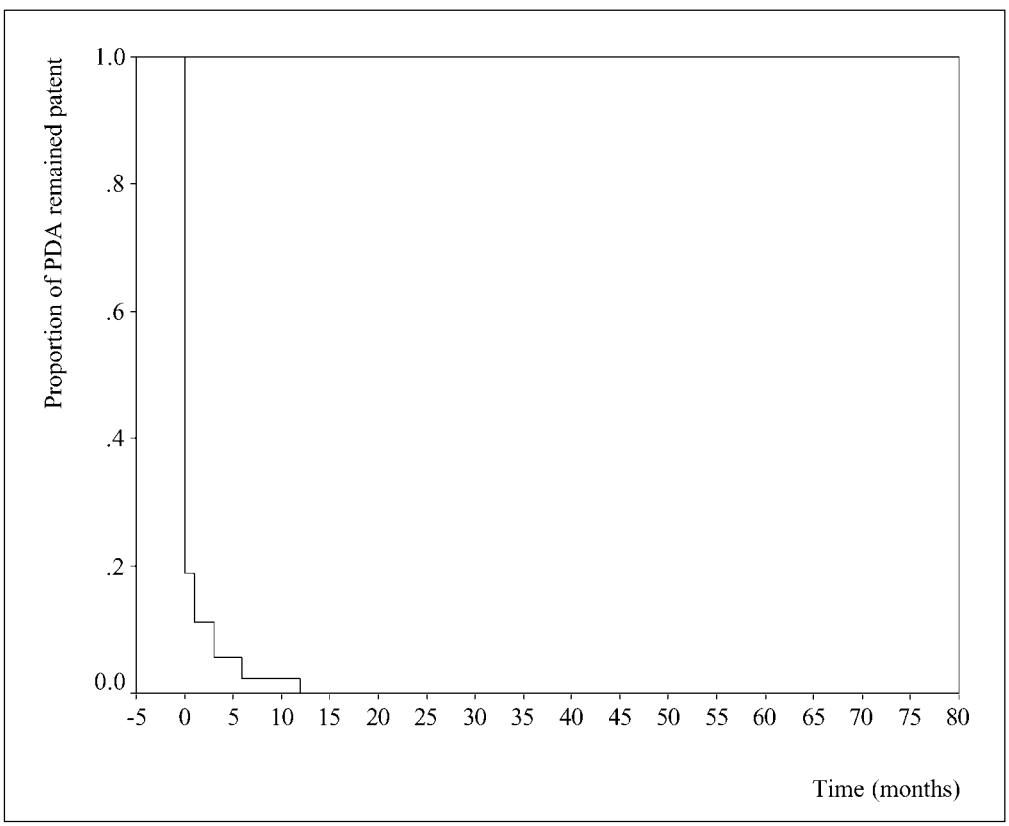

Figure 3 Kaplan-Meier analysis of residual shunting after closure of PDA with ADO.

the descending aorta was detected in one patient who had pre-existing isthmal hypoplasia and received a 6/4 mm ADO implantation for closure of a 1.9 mm PDA at 3 months of age. There were no clinical signs of significant aortic obstruction on subsequent follow-up. However, serial Doppler-derived pressure gradient on echocardiogram was up to 30 mmHg at the descending aorta. Elective cardiac catheterisation performed under general anaesthesia two years later showed a peak to peak pressure gradient of 11 mmHg. The descending aortogram showed only mild protrusion of the ADO into the descending aorta (Figure 4). A mild intrinsic coarctation of aorta that might have developed from the previous isthmal hypoplasia was the main contributing factor to the flow turbulence and pressure gradient detected earlier. Balloon angioplasty was performed with partial angiographic improvement. Subsequently he remained asymptomatic with a small upper and lower limb blood pressure difference of only 10 mmHg.

Discussion

Over the past decade, transcatheter closure of patent ductus arteriosus (PDA) has become a well-established standard procedure to replace surgery in closing the majority of PDA.[2-13] Surgical ligation is generally reserved for infants with body weight less than 4 kg or in symptomatic preterm infants. Transcatheter closure of PDA is a less traumatic procedure that requires shorter hospital stay and causes less pain and discomfort. A permanent thoracotomy scar can also be avoided. Its cost-effectiveness has also been well-demonstrated.[18]

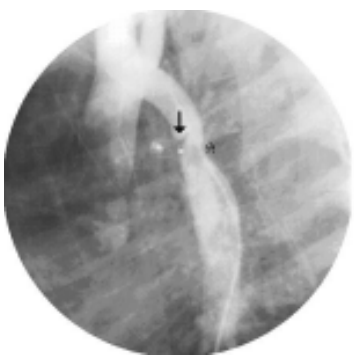

Figure 4 Angiogram in lateral projection illustrating the mild intrinsic coarctation(*) and protrusion of the retention disc (arrow) into the descending aorta.

While small PDA can usually be closed with one or two spring coils, closure of moderate to large PDA with multiple coils is technically challenging, particularly in young infants. High rates of residual shunts and complications like coil embolisation or haemolysis may occur.[19] Our study has shown that transcatheter closure of moderate to large PDA with the Amplatzer Ductal Occluder (ADO) is safe and highly effective (100% closure rate at 12 months). Our result is similar to previous reports.[13,14,20,21] In contrast to previous technique which often requires large delivery system, delivery of the ADO through a small sheath (5-6 French) allows its use in young infants as demonstrated in our study. Its simple implantation technique as compared with previous technique also significantly reduces fluoroscopy time and shortens learning time. Furthermore, the ability to retrieve and reposition the device, which is not available in previous designs, helps ensure optimal device position and reduce the risk of embolisation. The supply of ADO in a wide range of sizes from 4 mm to 16 mm allows closure of very large PDA. Although not all angiographic types of PDA are encountered in our study, a previous multi-centre trial of closing PDA with the ADO in China showed that all angiographic types of PDA can be closed successfully.[22]

Our results showed that midterm results are excellent and the procedure is safe as no major immediate and late complications occurred. However, the use of a large ADO in a young infant may pose a potential risk of causing obstruction of the left pulmonary artery and descending aorta in the long term. Device-related turbulent flow in the left pulmonary artery in two young infants and in the descending aorta in another did not result in significant obstruction in these vessels on mid-term follow-up. The mild coarctation of aorta that developed in the infant with turbulent flow in the descending aorta was thought to be unrelated to the device implantation. We believe that this type of device-related turbulent flow in both the left pulmonary artery and descending aorta would eventually resolve with somatic growth.

Conclusion

Our study confirms that transcatheter closure of moderate to large PDA in children with the ADO is safe and efficacious. The very high success rate and safety of the technique is related to the novel design of the device and the simplicity of deployment. It is particularly useful in

closing relatively large PDA in symptomatic infants and small children as small delivery sheaths can be used. Excellent midterm results have been achieved but long term follow-up is necessary to look for possible late complications.

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