

Long-Term Follow-up of Patent Ductus Arteriosus Closure with the Amplatzer Duct Occluder in Children

Mostafa Behjati-Ardakani, MD^{1*}, Mohammad Amin Behjati-Ardakani, MD²,
Mohammad Hassan Abdollahi, MD¹

¹Yazd Cardiovascular Research Center, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.

²Baqiyatallah University of Medical Sciences, Tehran, Iran.

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Abstract

Background: Transcatheter closure of patent ductus arteriosus (PDA) has become an alternative treatment to surgery. We evaluated the long-term results of the transcatheter closure of PDA with the Amplatzer Duct Occluder (ADO) in children.

Methods: Between May 2004 and October 2012, 138 children with PDA (43 males and 95 females) underwent transcatheter PDA closure. Clinical, electrocardiographic, echocardiographic, and hemodynamic data were assessed pre and postprocedurally and at follow-up.

Results: The mean age of the patients at procedure was 3.53 ± 2.43 years (range = 1.1 to 9.5 years), mean weight was 11.9 ± 4.6 kg (range = 6 to 29 kg), median pulmonary end diameter of the PDA was 5 mm (range = 4 to 15 mm), and median diameter of the ADO was 8 mm (range = 6 to 16 mm). The mean follow-up time was 43.4 ± 23.5 months (range = 13.5 to 98 months). The devices were successfully deployed in 136 (98.5%) patients. Device embolization occurred in 2 patients, immediately in one patient and during the first postprocedural night in the other patient. The first patient had percutaneous device retrieval, followed by implantation of a larger device. The second patient had surgical device removal and PDA ligation. Immediately after device implantation, trivial to mild residual shunts were detected in 112 (80%) patients; all the shunts, however, disappeared 24 hours after the procedure. One patient had left pulmonary artery stenosis with a gradient of 25 mm Hg at 24 hours', 40 mmHg at one month's, and 64 mmHg at 6 months' follow-up. There were no cases of late embolization, aortic obstruction, late hemolysis, infective endocarditis, or death.

Conclusion: Transcatheter PDA closure with the ADO was safe and effective, with a high success rate at long-term follow-up.

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Keywords: Ductus arteriosus, patent • Septal occluder device • Prosthesis and implants • Cardiac catheterization • Treatment outcome

Introduction

Patent ductus arteriosus (PAD) is one of the most frequent congenital heart diseases in children and accounts for 5-10%

of all congenital heart defects. PAD has an incidence rate of one in 2000 in full-term infants and is more common in females than in males.¹ Transcatheter PDA closure with the Amplatzer Duct Occluder (ADO) was first described

*Corresponding Author: Mostafa Behjati-Ardakani, Associate Professor of Pediatric Cardiology, Yazd Cardiovascular Research Center, Afshar Hospital, Jomhoury Boulevard, Yazd, Iran. 8917945556. Tel: +98 351 5231421. Fax: +98 351 5253335. E-mail: dr_behjati@yahoo.com.



in pediatric patients in 1998.² Transcatheter PDA closure is now regarded as a routine procedure for children with low periprocedural complications and it has improved immediate, short, and long-term outcomes according to the results of several studies.³⁻⁷

We investigated the long-term results of transcatheter PDA closure with the ADO at Afshar Cardiovascular Center.

Methods

Between May 2004 and October 2012, a total of 138 patients diagnosed with PDA underwent transcatheter closure procedures with the ADO in our medical center. Of the 138 patients, 2 patients were lost to follow-up. The study population, therefore, comprised 136 patients (93 females and 43 males). All the patients had physical examinations, electrocardiography, chest radiography, and echocardiography prior to the procedure.

The ADO is a self-expanding Nitinol stent, composed of a flat retention flange that is placed on the aortic wall and a tube containing thrombogenic material (a polyester patch sewn to the Nitinol stent) that is placed in the PDA itself. The diameter of the retention flange is 4 mm larger than the tube sheath, which is conical in shape. The pulmonary end of the cone is 2 mm smaller than the end that is attached to the retention flange. The difference in ADO models results from to the variety in the size in millimeters of the two ends of the tube: 6/4, 8/6, 10/8, 12/10, 14/12, 16/14, and 18/16. The total length of the device is 7 mm in the 6/4 and 8/6 models, and 8 mm in the remaining models (Figure 1).

In our study, USA-made (AGA Medical Corporation, Golden Valley, Minnesota, USA, n = 57) and China-made (Starway Medical Supplies Ltd., n = 81) ADOs were used.

Informed written consent was obtained from the parents of all the patients, and the study protocol was approved by the institutional Ethics Committee.

Right and left heart catheterization was performed under local and general anesthesia. Prophylactic antibiotic with Cefazolin (30 mg/kg) was administered intravenously 30 minutes before the procedure, followed by two subsequent doses 8 hours apart. Heparin (100 IU/kg/dose) was administered intravenously after femoral artery access and prior to the procedure. A left anteroposterior or lateral descending aortogram was done to locate the PDA and obtain the diameter at the narrowest part, the aortic ampulla, and the center of the PDA (Figure 2). The device was chosen to be at least 1 to 2 mm larger than the narrowest diameter of the PDA.

Standard technical delivery of the device over a guide wire through the PDA was performed, as was previously described.^{5, 9} A repeat descending aortogram was done prior to the release of the device to check for residual shunt and aortic obstruction (Figure 3).

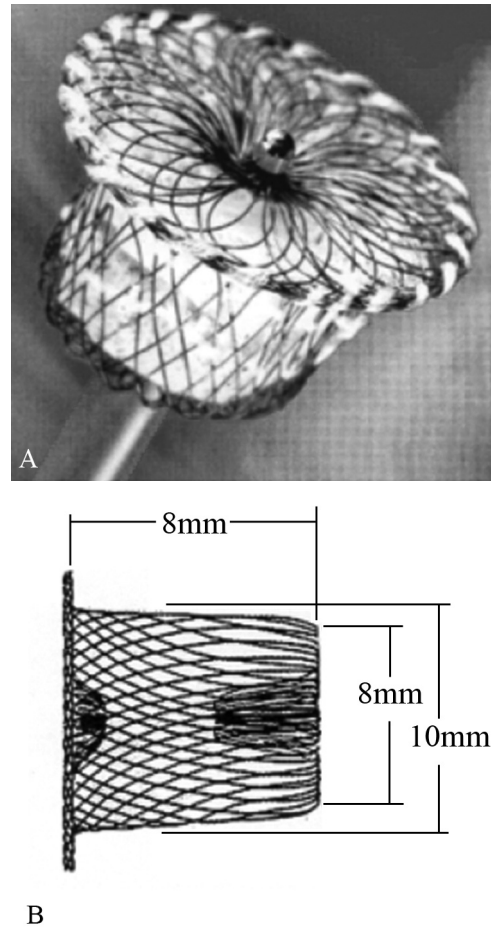


Figure 1. A) The Amplatzer duct occluder for patent ductus arteriosus. B) Drawing of the dimensions of a 10/8 Amplatzer duct occluder (published with the permission of the publisher)⁸

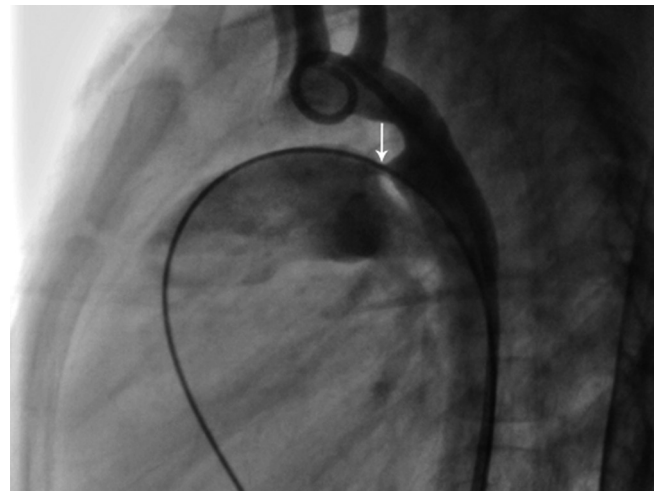


Figure 2. Descending aortogram in the lateral position, showing medium-sized patent ductus arteriosus (arrow)

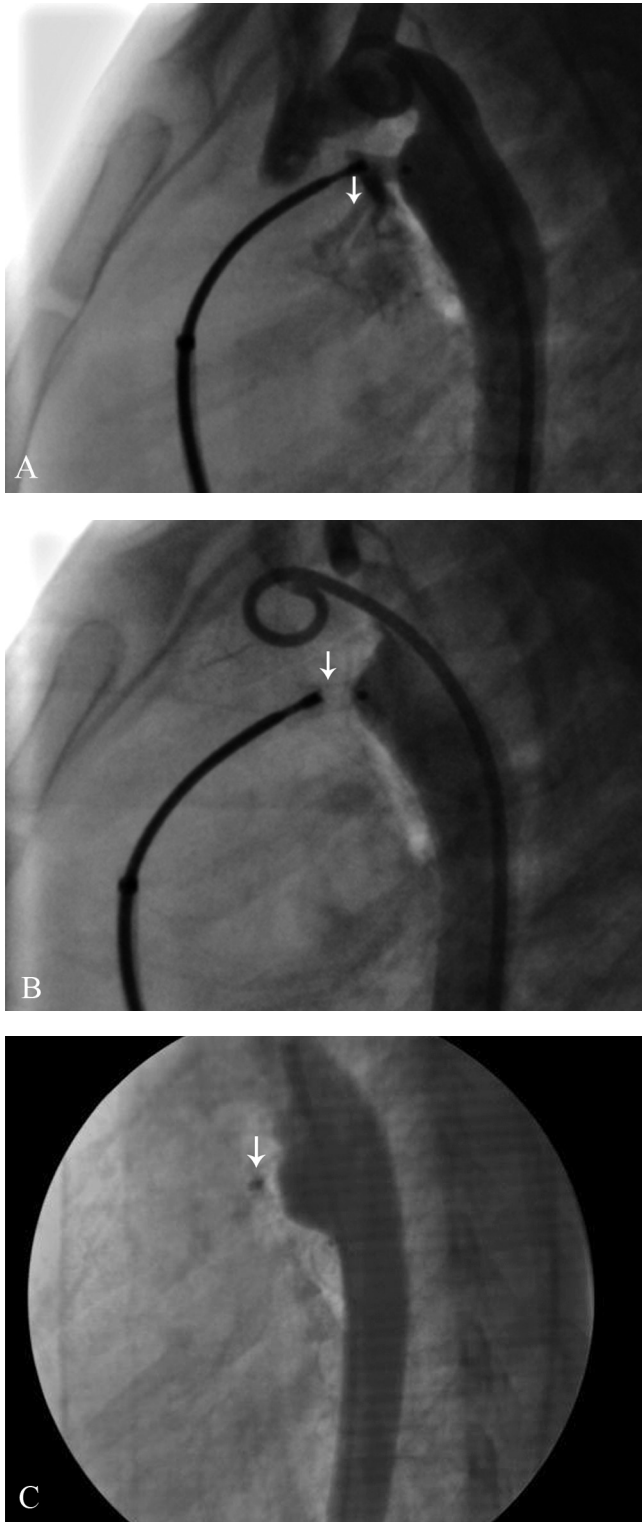


Figure 3. A) Descending aortogram in the lateral position, illustrating trivial mesh leak shunt (arrow). B) Descending aortogram in the lateral position before the release of the device, demonstrating the complete occlusion of the patent ductus arteriosus and appropriate device position (arrow). C) Descending aortogram in the lateral position immediately after the release of the device, depicting the complete occlusion of the patent ductus arteriosus and absence of aortic obstruction (arrow)

All the patients were discharged one day after device implantation. All the patients had complete transthoracic echocardiographic studies at 24 hours', one month's, and 12 months' follow-up and annually thereafter. Special attention was paid to residual shunt, left pulmonary stenosis, and descending aorta obstruction. Endocarditis prophylaxis was discontinued at 6 months' follow-up if the PDA was completely occluded.

The data are presented as mean value \pm standard deviation, percentage, median, and range. The data were analyzed using the SPSS statistical package for Windows (version 15.0.0).

Results

The demographic, echocardiographic, and catheterization data of the patients with PDA are shown in Table 1.

The device was successfully deployed in 136 (98.5%) patients. Device embolization occurred immediately after the release of the device in 2 patients: distal embolization in the descending aorta in one patient and distal embolization in the main pulmonary artery in the other one. The device embolized in the descending aorta was retrieved percutaneously, and repeat implantation was performed with a large device. The device embolized in the main pulmonary artery was retrieved surgically, and surgical ligation of the PDA was performed. In 5 patients, the devices were too small to occlude the defect; consequently, larger ADOs were implanted. Thrombosis of the right femoral artery occurred in 3 patients and left femoral artery in one patient. Continuous intravenous infusion of Heparin (20 unit/kg/hr) was administered successfully in the 3 patients. Intravenous infusion of Streptokinase (loading dose = 10,000 unit/kg) over 60 minutes, followed by 10,000 unit/kg for 6 three hours, produced a successful and complete pulse return in the other patient. Mild right inguinal hematoma occurred in one patient; this minor complication was resolved one week after the procedure. One patient had left pulmonary artery obstruction with a gradient of 25 mmHg at 24 hours' and 64 mmHg at 6 months' follow-up. Surgical removal was recommended, but the patient refused surgery.

The mean follow-up time was 43.4 ± 23.5 months (range = 13.5 to 98 months). All the patients had echocardiographic evaluations at 24 hours', one month's, 6 months', and 12 months' follow-up and annually thereafter. Two patients were lost to follow-up. Immediately after the procedure, trivial or small residual shunts were observed in 112 (80%) patients. However, after 24 hours, transthoracic echocardiography revealed no residual shunts and PDA was completely closed in all the patients.

Left pulmonary artery stenosis occurred in one case, one month after the procedure, with a gradient of 40 mmHg. Via echocardiography 6 months after transcatheter PDA closure, the narrowing of the left pulmonary artery



stenosis was re-evaluated. The pressure gradient by Doppler echocardiography in the left pulmonary artery had increased from 40 mmHg to 64 mmHg.

At intermediate (between 6 and 12 months) and long-term (> 12 months) follow-up, there were no late complications such as device migration, hemolysis, infective endocarditis, recanalization, or device-related obstruction of the descending aorta.

Table 1. Catheterization and demographic data of the patients

	Mean	SD	Median	Range
Age (y)	3.53	2.43	2.75	1.1 - 9.5
Weight (kg)	11.9	4.6	10	6.0 - 29.0
Mean PAP (mmHg)	24.9	14.7	20	6.0 - 84.0
QP/QS	2.26	0.7	2.1	1.3 - 4.5
PDA size (mm)	6.1	1.87	5	4.0 - 15.0
ADO (mm)	7.4/5.5	1.9/1.66	8	6/4 - 16/14
FT (min)	6.2	6.1	4.6	2.1 - 15.2
PT (min)	40.5	10.1	41	20.0 - 70.0
FU (mo)	43.4	23.5	42	14.5 - 98.0

SD, Standard deviation; Qp/QS, Pulmonary-to-systemic flow; PDA, Patent ductus arteriosus; ADO, Amplatzer duct occluder; FT, Fluoroscopy time; PT, Procedure time; F/U, Follow-up

Discussion

Our results demonstrated that the use of the ADO had a high (98.5%) success rate of complete PDA occlusion. Although the majority of our patients had trivial or small residual shunts immediately at the end of the procedure, none had a detectable residual shunt by color-Doppler flow mapping at 24 hours after the procedure. Unlike residual shunts after surgical PDA ligation, which tend to persist if left untreated, the residual shunts detected immediately after the ADO closure of PDA disappeared spontaneously during the follow-up of our study population. This may be partially attributed to the plug type design of the ADO or clot formation.^{2, 10}

Compared with surgical procedures, transcatheter closure of PDA has the advantage of avoiding cardiopulmonary bypass, reducing blood transfusion, relieving discomfort, and shortening hospital stay. Although transcatheter PDA closure has been proven safe and effective, the literature contains such complications as embolization, hemolysis, aortic obstruction, and left pulmonary artery stenosis.^{5, 11, 12}

Embolization of the ADO has a reported incidence of 0.3 to 4.9% in previous studies.^{3, 6, 12-15} In the current study, device embolization occurred in 2 (1.5%) patients. The first patient had percutaneous device retrieval in the Catheterization Laboratory, followed by successful implantation of a larger ADO. In the second patient, a large 10/8 ADO had embolized to the left pulmonary artery and caused obstruction. Percutaneous retrieval was not possible, so the patient

underwent surgical removal of the device and ligation of the duct.

Probably, the most serious morbidity of the ADO is left pulmonary artery and aortic arch obstruction. In our study, there was only a single patient who developed a pressure gradient across the left pulmonary artery of 40 mmHg at one month's and 64 mmHg at 6 months' follow-up. Surgical removal of the device was recommended, but the patient refused because of fear of open cardiac surgery.

Acute major complications such as left pulmonary artery obstruction have a reported incidence of 0 - 4%.^{6-9, 15-17} Hemolysis complicating device implantation is rare, but it can occur with the malposition of the device.¹⁸ Eradication of residual shunts is of vital importance for the prevention of hemolysis.^{18, 19} Hemolysis was not detected in our study, and nor were there other late major complications such as infective endocarditis, device integrity problem, and deformation in our study population. Trivial to small residual shunts were noted in 112 (80%) patients immediately after the procedure; the shunts, however, disappeared within 24 hours in all of these patients. These rates compare favorably with those reported in some other studies.^{7, 11, 16}

Overall, the complete PDA occlusion rate in the current study was as high as 98.5% at our short, mid, and long-term follow-up periods.

Conclusion

Our results showed that transcatheter PDA closure with the ADO was a highly effective and safe procedure in our pediatric patients at short, intermediate, and long-term follow-up.

Accordingly, we believe that transcatheter PDA closure with the ADO should be deemed first option in children.

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