

# Long-term Results of Transcatheter Closure of Patent Ductus Arteriosus in Adolescents and Adults with Amplatzer Duct Occluder

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## Abstract

**Background:** Transcatheter closure of patent ductus arteriosus (PDA) with the Amplatzer ductal occluder (ADO) has become a standard procedure in most pediatric patients. However, experience in adults and adolescents is limited. Our experience of transcatheter closure of PDA with ADO in adolescents and adults is presented in this study. **Aims:** The aim of this study was to investigate long-term outcomes of transcatheter closure of PDA in adolescents and adults with ADO. **Materials and Methods:** In this study, 69 patients (52 females and 17 males) with PDA underwent transcatheter closure between May 2004 and October 2012. The procedure was performed under fluoroscopic guidance. Chest radiograph, electrocardiogram, transthoracic echocardiography (TTE), and clinical assessment of the patients were conducted before the procedure. Clinical and echocardiographic follow-ups were performed on day 1 of the 1st month, 6<sup>th</sup> month, and 12<sup>th</sup> month and then yearly after the procedure. **Results:** The mean and standard deviation age of the patients was  $18.08 \pm 7.25$  years (ranging 10-38 years). The mean and standard deviation angiographic diameter of PDA was  $7.78 \pm 2.78$  mm. The mean and standard deviation size of the implanted device was  $9.3 \pm 2.9$ . The mean and standard deviation average pulmonary artery pressure was  $32.1 \pm 14.2$  mmHg. The mean pulmonary flow/systemic flow ratio was  $2.2 \pm 0.61$ . The devices were successfully implanted in all patients (100%). Immediately after device implantation, 47 patients had residual shunts. The residual shunts disappeared in all the patients, except for one that lingered until 24 h after the procedure. No severe complication occurred at the immediate and long-term follow-ups. **Conclusions:** The long-term results suggested that transcatheter closure of PDA with ADO is a safe and effective treatment for adolescents and adults with PDA. Low complication rates and short hospital stays make this procedure the treatment of choice in most cardiovascular centers worldwide.

**Keywords:** Adolescents, Adults, Amplatzer ductal occluder (ADO), Patent ductus arteriosus (PDA)

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## Introduction

Patent ductus arteriosus (PDA) is an abnormally persistent arterial connection after birth between the descending aorta distal to the subclavian artery and the junction of the main and left pulmonary artery (LPA) branch. PDA accounts for approximately

9-12% of all congenital heart diseases.<sup>[1]</sup> It is not infrequent for PDA to be diagnosed in adulthood on physical examination or as an incidental finding on transthoracic echocardiography (TTE). Additional problems associated with PDA include pulmonary hypertension, left ventricular volume overload, infective endocarditis, calcification, aneurysm formation, and, rarely, rupture.<sup>[2]</sup> The mortality rate in adults with untreated PDA is estimated to be 1.8% per year.<sup>[3]</sup> Therefore, PDA with a significant left-to-right shunt or with an audible murmur should be closed to reduce complications.

Transcatheter closure of PDA has been done for >25 years using various generations of devices including the Amplatzer ductal occluder (ADO) and coils. Currently,

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the ADO is the most commonly used device for adults with PDA.<sup>[4]</sup> In the current study, the long-term results of transcatheter closure of PDA with ADO in adult and adolescent patients are described.

## Materials and Methods

The study was approved by the Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd, Iran. The informed written consent was obtained from the patients or their parents prior to the procedure.

A total of 69 (52 female and 17 male) adolescent and adult patients with PDA undergoing the transcatheter closure of PDA were included in the study between May 2004 and October 2012. Electrocardiography, chest radiography, TTE, and clinical assessment were conducted prior to the procedure. Associated anomalies included bicuspid aortic valve with mild stenosis (two cases) and perimembranous ventricular septal defect (VSD) (one case). One of the patients had residual PDA with a moderate shunt after surgical ligation. Right and left heart catheterization was performed under local or general anesthesia. All patients received bacterial prophylactic antibiotic with 30 mg/kg cefazolin (maximum 1 g) 30 min prior to catheterization; two subsequent doses were repeated at 8 h and 16 h after the procedure, and 100 international units (IU)/kg (maximum 5,000 IU) of sodium heparin was administered after catheterization of the femoral artery. A monoplane left anteroposterior or lateral descending aortogram was performed to outline the ductus and obtain the shape, length, aortic ampulla, and diameter at the narrowest part and the center of the PDA [Figure 1].

## Statistical study

The data were analyzed using statistical software of SPSS version 15.0.0 for Windows (SPSS, Chicago, IL, USA). Using descriptive statistics, the results are expressed as mean  $\pm$  SD, percentage, median, and range.

## Results

Demographic and catheterization data of the patients are summarized in Table 1. All patients were successfully implanted with the ADO devices (ADO I: Nitinol plug device). Angiography at the end of the procedure showed complete occlusion in 16 patients (30.8%) and residual shunt in 47 patients (68.1%). Among these 47 patients, 36 had a trivial residual shunt with foaming through the device and with contrast jet <1 mm, 10 had a small residual shunt (left-to-right shunt with contrast jet >1 mm and <2 mm in diameter), and one had moderate shunt (left-to-right shunt with contrast jet >2 mm and <4 mm in diameter). On physical examination, the

continuous murmur disappeared completely, except in the case of one patient [Table 1].

At 24 h after the procedure, transthoracic color Doppler echocardiography showed complete occlusion in all patients, but one patient had 98% moderate residual shunt. In this patient, the residual shunt was not resolved at 3 months, 6 months, and 12 months of follow-up, and, therefore, the patient was referred for reinterventional treatment. The patient refused retranscatheter therapy because of pregnancy.

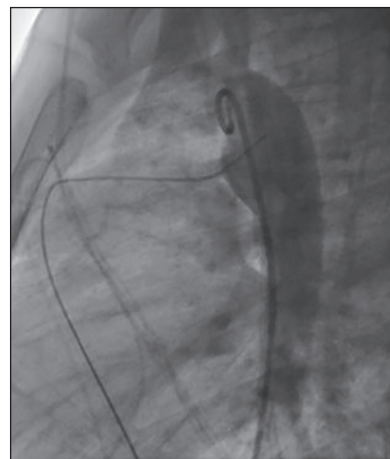
During the  $41.9 \pm 36.3$ -month period of follow-up (ranging 17-101 months), no late complication or abnormality, such as device migration, recanalization, hemolysis, endocarditis, or device-related obstruction of LPA or the descending aorta was observed.

The ADO chosen was 1-2 mm larger than the narrowest diameter of the PDA and was deployed through a venous

**Table 1: Clinical and hemodynamic data in patients with PDA**

Variable	Mean	Median	SD	Range
Age (years)	18.08	17	7.25	10-38
Weight (kg)	44.3	45	15.15	17-85
PDA size (mm)	7.78	7	2.78	4-16
ADO size (mm)	9.3/7.3	8/6	2.93/2.89	6/4-18/16
QP/QS	2.2	2	.61	1.4-4.1
Sys PAP (mmHg)	43.92	39	23.91	10.5-136
Dia PAP (mmHg)	22.2	18	14.5	9-90
Average PAP (mmHg)	29.2	25	17.25	12-106
FT (min)	5.97	4.2	4.28	2.1-25
PT (min)	40.2	40	12.37	21-85
FU (month)	46.1	36.2	36.3	17.6-101

SD = Standard deviation, QP/QS = Pulmonary flow/systemic flow, Sys PAP = Systolic pulmonary artery pressure, Dia PAP = Diastolic PAP pressure, PT = Procedure time, FT = Fluoroscopy time, FU = Follow-up



**Figure 1:** Descending aortogram in the lateral projection showing large sized PDA

approach. The technique of transcatheter closure of PDA with ADO was previously described by Thanopoulos *et al.*<sup>[5]</sup> Before and immediately after release of the ADO, an aortogram was performed to evaluate the position of the device, residual shunt, and aortic obstruction [Figure 2].

Pressure pullback from the ascending aorta and LPA was obtained to exclude a significant pressure gradient. All the patients had complete transthoracic echocardiographic evaluations prior to discharge. The evaluations were performed at 1 month, 6 months, and 12 months after the procedure and yearly thereafter.

Special attention was paid to residual shunt, LPA stenosis, and aortic obstruction. Bacterial endocarditis prophylaxis would be discontinued at a 6-month follow-up if the ductus was completely occluded.

## Discussion

The current study evaluated transcatheter closure of PDA in adults and adolescents during a period of 46 months of follow-up. The PDA should be closed when diagnosed during childhood or adulthood, or it leads to left atrial and ventricular volume overload, pulmonary hypertension, infective endocarditis, aneurysm formation, calcification, and, rarely, rupture. In adults, the treatment of silent PDA with trivial shunting remains controversial.<sup>[2]</sup> Surgical closure of PDA has been the gold standard since 1939, especially for a large PDA.<sup>[6,7]</sup>

Transcatheter occlusion of PDA has greatly changed to surgical ligation in the management of adult

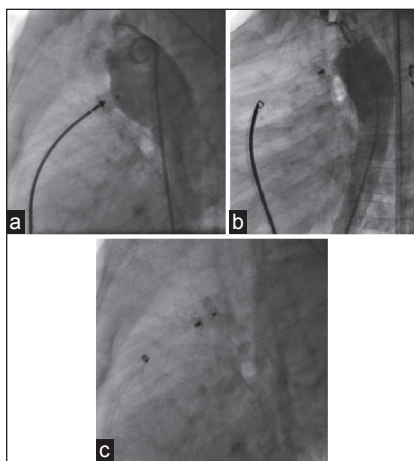
patients with PDA. In case of calcified ductus arteriosus with pulmonary hypertension, transcatheter closure is a low-risk procedure frequently offered over surgical repair, which frequently involves cardiopulmonary bypass with an anterior approach through a median sternotomy.<sup>[8]</sup> Currently, transcatheter closure of PDA has been established to be the technique of choice for managing PDA in adults and adolescents with excellent outcome. However, surgical closure is still the technique of choice for treating very large PDAs or PDAs not curable with transcatheter intervention.<sup>[8]</sup>

The transcatheter closure with ADO has significantly improved the outcome of the percutaneous closure of medium- and large-sized ducts.<sup>[9-12]</sup> The major advantages of ADO are easy implantation technique, small delivery sheath (6-8 Fr), possibility of retrieval, ability to reposition before release of the device, low complication rate, and high closure rate.<sup>[11-13]</sup>

Although the transcatheter closure of PDA has been proven to be effective and safe, several complications, such as embolization, narrowing of the LPA, aortic obstruction, hemolysis, and infective endocarditis have been reported.<sup>[14-16]</sup> In general, the complication rate of transcatheter closure of PDA is low.<sup>[17-19]</sup> In our study, no severe complication occurred. The incidence of residual shunts at short-term, mid-term, and long-term follow-ups was 1.9%. The incidence of residual shunts in late follow-up was reported to be 0-5%.<sup>[14,17,18]</sup>

Device embolization occasionally occurs, necessitating surgical removal or transcatheter retrieval. Device embolization is one of the most important complications of transcatheter occlusion of PDA.<sup>[14]</sup> The embolization rate varies between 0% and 3.1%.<sup>[14-18]</sup> In the present study, no device embolization occurred. The other complication of transcatheter closure of PDA with ADO is LPA obstruction in children.<sup>[19-21]</sup>

Although LPA obstruction is one of the most significant complications, it is not a concern in adults because of the large diameter of pulmonary artery branches.<sup>[2]</sup> In our study, LPA obstruction was not found. Hemolysis and infective endocarditis following transcatheter device closure are rare complications.<sup>[4]</sup> Other late complications associated with ADO were not observed in our study. Overall, the PDA occlusion rate in our study was as high as 98.1% after the short-term, mid-term, and long-term follow-ups. However, our study demonstrated the feasibility of and success in the treatment of PDA with the transcatheter interventional approach in adolescent and adult patients.



**Figure 2:** (a) Descending aortogram in the lateral view before the release of ADO showing trivial mesh leak shunt (b) Immediately after the release of ADO, showing the absence of residual shunt (c) Appearance of ADO after release

**Figure 2c:** Lateral chest radiograph showing radiologic appearance of ADO after release

## Conclusion

The findings from our study showed that transcatheter closure of PDA with ADO was very efficient and safe when used in adolescents and adults, with excellent and satisfied short-term, mid-term, and long-term results. The minimal incidence of complications and residual shunts makes this device ideal for the transcatheter closure of PDA in adolescents and adults. Transcatheter closure of PDA with ADO should be the first choice for treating PDA in adolescents and adults.

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