Do we need a femoral artery route for transvenous PDA closure in children with ADO-I?

Ali Baykan, Nazmi Narin, Abdullah Özyurt, Mustafa Argun, Özge Pamukçu, Sertaç H. Onan, Sadettin Sezer, Zeynep Baykan, Kazım Üzüm*

Department of Peadiatric Cardiology and *Medical Education, Faculty of Medicine, Erciyes University; Kayseri-*Turkey*

Abstract

Objective: The standard procedure in percutaneous closure of patent ductus arteriosus (PDA) with Amplatzer duct occluder-I (ADO-I) is transvenous closure guided by aortic access through femoral artery. The current study aims to compare the procedures for PDA closure with ADO-I: only transvenous access with the standard procedure.

Methods: This study was designed retrospectively and 101 pediatric patients were included. PDA closure was done by only femoral venous access in 19 of them (group 1), arterial and venous access used in 92 patients (group 2) between 2004 to 2012 years. The position of the device and residual shunt in group1 was evaluated by the guidance of the aortogram obtained during the return phase of the pulmonary artery injection and guidance of transthoracic echocardiography. Shapiro-Wilk's test, Mann-Whitney U, chi-squared tests were used for statistical comparison.

Results: The procedure was successful in 18 (95%) patients in group 1 and 90 (98%) patients in group 2. Complications including the pulmonary artery embolization (n=1), protrusion to pulmonary artery (n=1), inguinal hematoma (n=3), bleeding (n=2) were only detected in group 2. In other words, while complications were observed in 7 (7.2%) patients in group 2, no minor/major complication was observed in group 1. Complete closure in group 1 was: in catheterization room 14 (77.8%), at 24th hour in 2 (11.1%), at first month in 2 (11.1%). Complete closure in group 2 was: 66 (73.4%) patients in the catheterization room, 21 (23.3%) at 24th hour, 3 (3.3%) at first month, complete closure occurred at the end of first month.

Conclusion: In percutaneouse PDA closure via ADO-I, this technique can be a choice for patients whose femoral artery could not be accessed, or access is impossible/contraindicated. But for the reliability and validity of this method, randomized multicenter clinical studies are necessary. *(Anatol J Cardiol 2015; 15: 242-7)*

Keywords: amplatzer device, children, echocardiography, patent ductus arteriosus, transcatheter closure, transvenous

Introduction

The transcatheter closure of patent ductus arteriosus (PDA) was first described by Porstmann et al. (1) in 1967. Since then, numerous devices and methods have been introduced, and the applicability of the technique has been extended to various ductal characteristics, sizes and expanding shapes. Recently, transcatheter closure of the PDA with Amplatzer duct occluder-I (ADO-I; AGA Medical Corporation) and other several devices has become an accepted alternative to surgical ligation (2-6).

The standard method in transcatheter closure of PDA with ADO-I is transvenous procedure through the femoral vein under the guidance of aortic catheter accessed from femoral artery route (2). It is rarely hard to access femoral artery or entering into the femoral artery may be contraindicated in patients who planned duct closure. So we need to develop an alternative method for such patients. To the best of our knowledge, there is no study reported in the literature in which ductus occlusion has been used as a technique on humans for PDA closure intravenously only. In this study: standard percutaneous closure method and transvenous PDA closure through only femoral venous route were compared (without access to femoral artery, under the guidance of transthoracic echocardiography and aortogram obtained during the return phase of the pulmonary artery injection) and the applicability of the subsequent method is questioned.

This study was presented as oral presentation in 28th National Cardiology Congress, October 2012, Antalya-Turkey and it was rewarded with the best interventional pediatric studies. Also, this study was presented as oral presentation in "9. Internetional Congress of Update in Cardiology and Cardiovascular Surgery, 21-24 March 2013" and published in the Interventional Journal of Cardiology.

Address for Correspondence: Dr. Abdullah Özyurt, Erciyes Üniversitesi Tıp Fakültesi, Pediyatrik Kardiyoloji Bölümü; Kayseri-*Türkiye*
Phone: +90 505 745 66 21 Fax: +90 352 437 58 25 E-mail: duruozyurt@yahoo.com.tr

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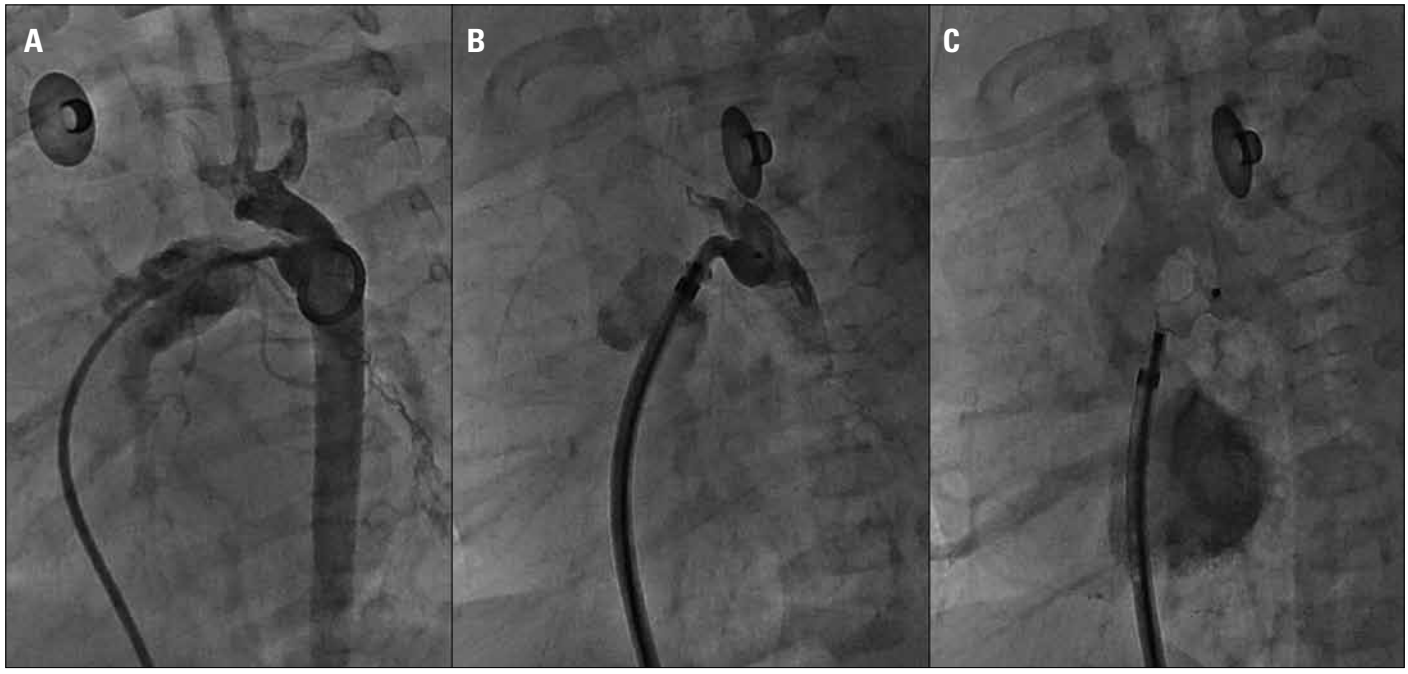

Figure 1. (A). a contrast was injected into the descending aorta at 70 degrees left laterally by pig-tail catheter and conic type patent ductus arteriosus was shown, (B) first disc of ADO I device (6x4 mm) was opened in the descending aorta. (C) device position was checked with a contrast injected into the long sheath. The device position and absence of residual shunt were checked in the return phase by injecting a contrast into the pulmonary artery
ADO-I - amplatzer duct occluder-I

Methods

Patients

This is a clinical retrospective study, performed on patients whose PDAs were closed with ADO-I by only femoral venous access technique (group 1) or standard procedure (group 2). This study was approved by the local Ethical Committee of our University. Diagnosis of PDA was made by echocardiography in all patients. Patients with continuous murmur on physical examination, PDA diameter greater than 1 mm on echocardiography, symptomatic ones because of left to right shunt, and those with signs of left ventricular-atrial volume overload were enrolled. Two patients who had undergone atrial septal defect (ASD)+PDA closure at same session and one patient who had undergone VSD (ventricular septal defect)+PDA, i.e. a total of 3 patients were not included in the study. In addition, 4 patients were excluded from the study in which arteriovenous (AV) loop was formed with noodle guidewire since their PDA could not be reached through the venous route. Thus, of the 99 patients in group2 who had been closed with the standard method using ADO-I, 92 were included in the study. Of the 22 patients in group1 whose PDAs closed without using the arterial route, 3 had used devices other than ADO-I [Cook® detachable coil (n=1), ADO-II additional size (n=2)] were excluded, and therefore, 19 of them included in the study. Informed consent had been obtained from the parents of patients before the intervention. The demographical data, echocardiographic findings before and after the procedure, and the angiocardiography-procedure data were evaluated and recorded retrospectively.

Catheter intervention-procedure

The procedures were performed under general anesthesia. The sheaths with appropriate sizes were placed in the femoral vessels before 100 U/kg heparin was administered to the patients. Blood samples for oxygen saturation and pressures were recorded for the calculation of Qp/Qs ratio and vascular resistance. Patients with pulmonary vascular resistance below than 6 U/m^2 were prepared for PDA closure. In group 1, the shape and size of PDA was evaluated during the aortogram obtained in the return phase of the pulmonary artery injection and transthoracic echocardiography. From the patients in group 2, an angiogram was obtained by a pigtail catheter into the descending aorta near the PDA at 70-90 degrees left lateral and 40 degrees right anterior oblique positions for imaging the shape and measuring the size of PDA. The size of the ADO-I device was selected as approximately 2 mm larger than the narrowest PDA size. The PDA classifications were made according to Kirchenko classification (7). Thus, there were mostly type A (conical) in both groups, followed by type E (atypical, elongated), and type C (tubuler) in order of frequency. The distribution of PDA types was similar in both groups.

Before releasing the device, pulmonary angiography was performed in group 1. During the aortic phase of this angiography device position and residual shunt near the device were checked (Fig. 1 and Video 1. See corresponding video/movie images at www.anakarder.com). Also, stenosis due to the protrusion of the device into the left pulmonary artery and descending aorta was checked with transthoracic echocardiography. All applications done to the patients of group 2 were as described

Table 1. Demographic characteristics, properties of the angiographic and technique data of 19 patients in group 1

Patient no	Age, months	Weight, kg	Assoc. anomaly (mean)	PAP mm Hg	Qp/Qs	PVR	PDA Type	PDA size (narrowest)	Scopy-procedure time (minute)	Follow up, month	Totally occlusion time
1	6	9.8	None	37	1.8	1.6	A	3	9-42	41	Immediately
2	42	13.5	None	32	1.5	1.5	A	3	8-41	40	Immediately
3	10	7.4	AVSD	48	2.9	3.4	C	2	14.3-36	38	Immediately
4	15	6.8	None	19	1.3	1	A	2.7	10.1-44	32	Immediately
5	118	26	None	22	1.5	1	C	3.2	11.7-37	31	After 1 month
6	102	27	None	25	1.2	1.1	A	3	9-43	31	Immediately
7	5	4.4	VSD, ASD	64	4.4	3.1	E	2.8	19-46	30	-
8	16	9	None	19	1.2	1	A	2.5	6.9-35	30	Immediately
9	11	6.5	None	28	1.9	1.3	E	3.1	13.8-49	29	Immediately
10	10	8.7	None	53	1.8	2.9	A	5.4	7.6-43	29	After 1 day
11	9	6.8	VSD, ASD	55	6.6	1.9	A	3.2	9.1-32	28	Immediately
12	4	7.3	None	20	1.3	1	A	1.8	11.4-29	28	Immediately
13	7	4.5	VSD, ASD	50	5.9	1.9	E	2.8	16.4-62	27	After 1 month
14	4	5	None	44	2.4	1.7	A	3	8.4-41	25	Immediately
15	5.5	6	MVI	20	1.2	1	A	2.5	9.7-37	24	Immediately
16	12	9.6	None	31	1.3	1.2	A	2.8	8.9-44	24	Immediately
17	2.5	4.2	VSD	49	1.6	2.7	A	2.3	9.5-49	23	Immediately
18	12	6	VSD, ASD, Pulmonary banding	48	1.9	5.6	A	2.2	12.8-51	19	Immediately
19	9	8	None	19	1.2	1	A	2.1	7.9-36	17	Immediately

ASD - atrial septal defect; PAP - pulmonary artery pressure; PDA - patent ductus arteriosus; PVR - pulmonary vascular resistance; VSD - ventricular septal defect

in earlier studies (2-4). During the procedure, the vital signs and peripheral oxygen saturations were monitored for early detection of hemodynamic deterioration before releasing the device. After eliminating all possible side effects and complications, the device was released and the procedure was terminated successfully. Residual shunt was assessed by transthoracic echocardiography in both groups 15 minutes after the procedure in the catheterization room for the standardization of the assessment.

Follow-up

Twenty-four hours after the procedure, complications like arrhythmia, embolization, left pulmonary artery stenosis or iatrogenic coarctation of the aorta due to device migration, and residual shunt were controlled by physical examination, electrocardiography, telecardiography and echocardiography. Transthoracic echocardiography was repeated at 1st month, 3rd month, 6th month and finally at 1st year after the procedure.

Statistical analysis

To assess the data normality, histogram and q-q plots were examined, also Shapiro-Wilk's test was performed. To compare the differences between groups, independent samples t test and Mann-Whitney U tests were used for continuous variables and chi-squared analysis were used for categorical variables. Values are expressed as frequencies and percentages, mean and standard deviation or median and interquartile range. Analysis were performed using IBM Statistics 20.0 (IBM Inc., Chicago, Illinois, USA) and a p value of <0.05 was considered statistically significant.

Results

In our center, percutaneous PDA closure has been performed on 329 patients since 2001. ADO-I has been used in 118 (35.8%) of these patients. Standard transvenous route has been used in 99 of the patients who have undergone PDA occlusion with ADO-I (92 of them were included in current study). In the remaining 22 patients percutaneous closure was applied by using only femoral vein access (19 of them were included in current study). One of these patients had femoral artery occlusion which was detected during a previous percutaneous intervention. In six patients the femoral artery could not be accessed. We did not want to enter in femoral artery in the remaining 12 patients, because we preferred to make only antegrade approach for PDA closure. Demographic characteristics of 19 patients in

Table 2. The demographic features, follow-up findings, hemodynamic and angiocardiographic data of patients in both groups

Variables		Group 1 (n=19) (Only venous route)	Group 2 (n=92) (Standard procedure)	*P*
Age, months		10.0 (5.5-15.0)	17.0 (6.0-52.0)	0.062
Weight, kg		7.3 (6.0-9.0)	10.7 (7.0-16.5)	0.019
Gender, male, (n%)		8/ 19 (42.1%)	49/92 (52.2%)	0.420
Narrowest diameter of duct, mm		2.8 (2.0.3-3)	2.9 (2.1-3.6)	0.760
Device size, mm		5.0 (5.0-5.0)	5.0 (5.0-6.0)	0.027
Mean PAP, mm Hg		32.0 (20.0-49.0)	25.0 (21.0-36.5)	0.140
Qp/Qs		1.6 (1.3-2.4)	1.7 (1.35-2.4)	0.698
PVR, WoodU/m^2		1.5 (1.0-2.7)	1.9 (1.4-2.4)	0.070
Procedure time, min		43.6± 9.5	48.2 ± 9.1	0.715
Fluoroscopy time, min		11.0 (9.0-17.0)	8.2 (6.8-11.2)	0.001
Quantity of scopy, cGy/cm^2		1367±873	1347±930	0.403
Follow-up time, month		29.0 (24.0-31.0)	44.0 (33.5-55.5)	<0.001
Successful procedure (n%)		18/19 (94.7%)	90/92 (97.8%)	0.434
Major complication (n%)		0/18 (0%)	1/92 (1%)	0.999
Minor complication (n%)		0/18 (0%)	6/92 (6.5%)	0.587
Closure time (n%)	In cath. room	15/18 (83.3%)	66/90 (73.3%)	0.553
	1. day	1/18 (5.6%)	21/90 (23.3%)	0.114
	1. month	2/18 (11.1%)	3/90 (4.6%)	0.193

Values are expressed as n (%), mean±SD or median (25th and 75th percentiles)

group 1, properties of the angiocardiographic and technical data were summarized in Table 1.

Success of the procedure was defined as absence of death due to the procedure, serious complications requiring hospital stay (arrhythmia, bleeding, vascular complications, etc), absence of significant residual shunt, device embolization or protrusion which results in peripheral pulmonary stenosis or coarctation. Thus, the procedure was successful in 18/19 (95%) patients in group1 and 90/92 (98%) patients in group 2 with no statistically significant difference in the success rate of the procedure between the groups. While complication was observed in 7 (7.2%) in group 2 as: pulmonary artery embolization of the device (n=1), protrusion to the pulmonary artery (n=1), groin hematoma (n=3), and bleeding of the femoral artery (n=2), no complications, minor or major were observed in group 1.

Severe pulmonary hypertension was detected during the catheterization of the case number 7, which the procedure was not successful in group1 (Table 1). This was a 5-month-old patient with ventricular septal defect and atrial septal defect, had pulmonary artery pressures as 83/40 mean value of 64 mm Hg, aorta pressures as 92/46 mean value of 65 mmHg. The Qp/Qs was 4.4 and pulmonary vascular resistance was 3.1U/m^2. An ADO-I device was stabilized in the PDA, but before releasing the device during controlling the position, the patient had bradycardia and systemic hypotension. Echocardiography revealed no narrowing at pulmonary and aortic flow. But bradycardia did not resolve. It was thought that the patient could not tolerate PDA occlusion, so the device was taken out without releasing. Also, the procedure failed in two other cases in group 2: one with device embolization to the pulmonary artery, and the other with device related pulmonary artery stenosis and retrieved without releasing. The first patient was 1 year old and had a conical PDA of 4 mm. During the procedure an 8x6 mm device was embolized to the pulmonary artery. After the removal of the device with a snare catheter, the patient underwent to surgical PDA ligation. The second patient was 3 years old and had short conical PDA of window type. The device having been determined to have protruded to the pulmonary artery and caused stenosis in the left pulmonary artery detected by transthoracic echocardiography, the procedure was terminated without releasing the device. This patient also underwent surgical ligation.

The demographic features, follow-up findings, hemodynamic and angiocardiographic data of both groups have been summarized in Table 2.

Six patients had additional accompanying cardiac anomalies in group 1. Surgical repair was done in the case number 18, who was 12 months old and had ventricular septal defect (VSD)-atrial septal defect (ASD) and pulmonary hypertension. In two patients with small VSD-ASD, the defects closed spontaneously during the follow-up. Patients with atrioventricular septal defect (AVSD), VSD and two patients with both VSD and ASD underwent surgical correction at an appropriate time. In group 2, there were additional cardiac anomalies in 12 patients (VSD:4, ASD:5, VSD+ASD:1, AVSD:1, coarctation of aorta (CoA):1).

Discussion

In this study we compared the two methods for percutaneouse PDA closure in pediatric patients with ADO I: by venous access versus standard method (arterial and venous route). No statistical difference is found between procedure times, major-minor complications, totally closure rate, fluoroscopy time. In conclusion percutaneouse PDA closure can be done using venous access with transthoracic echocardiography and aortogram (in pulmonary arterial return phase) in the patients whose arterial route cannot be accessed or contradictory.

Over the past three decades, a number of coils/devices with different delivery techniques have been used for transcatheter closure of PDA, and over the past two decades, transcatheter occlusion of PDA has evolved to be the procedure of choice. Recently developed Amplatzer devices have provided a solution for large PDAs and residual shunts in young patients, which are the major problems in transcatheter closure of PDA (3, 8, 9). Therefore, transcatheter closure has become the first line of treatment in many centers except in the newborn period. With these new devices, the success rate of the procedure is above 95% even in difficult patient groups such as premature and adult

patients. Although complete closure of the PDA can change in some studies depending on patient's age, PDA size and the device used, the highest closure rates have been observed with Amplatzer devices (2-4, 8-10).

Till 2001 various devices such as Cook® coil, ADO-I, ADO-II and ADO-II additional size and PFM coils have been used in our center. As is known, ADO-I devices permits only transvenous closure. In patients whose femoral artery cannot be achievable during the intervention, the possibility of duct closure via only femoral venous access with the guidance of echocardiography and angiography has been wondered. In this retrospective, comparative study, the success of the procedure in group 1 has been found similar to that of the patients in group 2. Complete closure has been detected at the end of the first month in all patients of both groups. The long-term complete closure rates with ADO devices detected with transthoracic echocardiography have been reported between 94.6% and 97% (2, 3).

In many studies using an antegrade procedure in the transcatheter closure of PDA, an additional arterial approach was used for pressure monitoring and contrast substance injection. In these studies, transcatheter closure was carried out only via the venous approach in a few patients with occluded femoral arteries or in cases of failure to use the femoral artery route. When the literature was reviewed, there were no large human studies using only venous closure without using the arterial approach. However, in studies using coils and various devices via a transvenous procedure without using the arterial approach in dogs and sheep, the success rates and complication rates of the procedure were shown to be similar to those in human studies (11-13).

Only one procedure failed which was a pulmonary hypertensive case with additional VSD and ASD in group 1. After closing the PDA with the device, vital signs of the patient worsened and bradycardia did not respond to adrenaline/atropine. With the removal of the device, hypotension and bradycardia resolved spontaneously.

In group 2, two devices had been retrieved, because in 1 (1%) patient owing to partial left pulmonary artery stenosis and in another patient owing to pulmonary artery embolization. Incidence of partial left pulmonary artery stenosis due to device has been reported as 0.5-0.7% for Amplatzer devices (2, 10). Embolization of Amplatzer duct occluder device has been reported as single case reports in the literature (2, 14). Although Amplatzer device embolization risk is very low, if they migrate to pulmonary system or aorta they can be retrievable. These two cases had been carried out in the early periods of our experience on these devices.

Amplatzer devices, in particular, can protrude into the aorta with a mass effect because they are relatively long devices (15-17). Furthermore, using the arterial approach provides visualization of the location of the device by aortogram at every stage of the procedure. In the PDA closure procedure carried out with these devices, the return phase of the contrast substance administered from the pulmonary artery allows visualization of the descending aorta in cases where the arterial route is not used. The problem of device related coarctation in the descending aorta can be eliminated by echocardiography performed by a second hand during the procedure. Similarly, before completing the procedure, we checked the patency of the descending aorta during the return phase of the pulmonary angiogram and the presence of a Doppler gradient at this level with transthoracic echocardiography before releasing the device.

Since the descending aorta is imaged during the return phase of pulmonary artery injection, the scopy time and scopy quantity was greater in group 1, but there was no statistically significant difference in terms of scopy time and scopy quantity (p=0.08 and 0.4, respectively). In addition, there was no statistically significant difference in overall procedure time between the groups (p=0.71).

In our study, the peripheral artery complication has been determined to be 5.4% in group 2, which is consistent with the literature (2, 10, 18-20). Because femoral artery route has not been used in group 1 peripheral artery complication has not been encountered. The design of ADO-I device is suitable for only transvenous PDA closure and ADO-I Amplatzer devices need for relatively greater delivery sheaths, whereas Amplatzer devices such as ADO-II and additional size devices which are recently developed, can be transported via small delivery sheats and allow transvenous and transarterial closure. They decreased peripheral arterial complication rates, but could not eliminate it completely. Apart from major complications, such as significant injuries requiring surgical repair, iatrogenic arteriovenous fistulae and uncontrolled bleeding, there may also be simple minor complications like pulselessness in an extremity, thrombosis or groin hematoma which can be resolved with medical therapy. In a retrospective study by Ghasemi et al. (3) conducted on 546 pediatric patients undergoing closure with Amplatzer, groin hematoma was reported in 2.7% of patients and transient pulselessness was reported in 6% of cases. In their multicenter PDA closure experience including 439 patients, Pass et al. (10) reported femoral artery fistula requiring surgery in one patient, femoral artery bleeding requiring transfusion in two patients, pulse loss in the femoral artery in one patient, groin hematoma in seven patients (1.6%) and peripheral pulse loss in six patients (1.5%). The similar peripheral artery complications rate associated with the procedure have been reported from various centers (19, 20).

Study limitations

Device selection could be affected due to the changes in duct width when PDA was accessed through femoral venous route. Inappropriate device selection may lead to residual defects and migration of the device. The method that we have described can be used as an alternative to the standard method especially in difficult situations by the experienced interventionalists. Since the data regarding the patients and procedures were obtained from the hospital records, the reliability of the

data were related with the accuracy of the hospital records. Transvenous approach was preferred because arterial route could not be used in some of the patients. However, the other patients on whom the procedure was used had been selected randomly, with no criteria. Although both groups were homogenous in terms of age, gender, PDA diameter, PDA shape and the used devices, the number of patients in group 1 where the alternative method assessed was rather inadequate. So, the high success rate with no complication of group 1 should be attributable to the inadequacy of patient number of that group.

Conclusion

Transvenous PDA closure in children with ADO-I without using femoral artery, under the guidance of transthoracic echocardiography and aortogram in the return phase is an effective and reliable method for selected patients. This technique can be a choice for patients whose femoral artery could not be accessed, or access is impossible/contraindicated. But for the reliability and validity of this method, randomized multicenter clinical studies are necessary.

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Video 1. Pulmonary angiography was performed in each step of the procedure in some patients in group 1. Therefore during the aortic phase of this angiography device position and residual shunt near the device were checked. Also transtoracic echocardiography guidance is used during the procedure

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