Original Article

When Can We Release the Amplatzer Ductal Occluder (ADO) Safely?

Mehdi Ghaderian, MD[1, 2*], Mahmood Merajie, MD[2], Hodjjat Mortezaeian, MD[2], Mohammad Yoosef Aarabi Moghadam, MD[2]

[1]*Emam Hosein Medical, Educational and Research Center, Esfahan University of Medical Sciences, Esfahan, Iran.*
[2]*Rajaie Cardiovascular, Medical and Research Center, Iran University of Medical Sciences, Tehran, Iran.*

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Abstract

Background: *The ductus arteriosus connects the main pulmonary trunk to the descending aorta. The incidence of isolated patent ductus arteriosus (PDA) in full-term infants is about 1 in 2000. The Amplatzer Ductal Occluder (ADO) is recommended for PDAs with sizes larger than 2 mm. In this procedure, we must confirm the ADO position in PDA by aortogram from the arterial line. The purpose of this study was to determine the optimal release time of the ADO in the PDA closure procedure, especially in the absence of an arterial line for post-PDA aortography.*

Methods: *This study recruited all patients scheduled to undergo PDA transcatheter closure with the ADO between September 2009 and September 2012 in our center. Age, weight, PDA diameter, systolic and diastolic pulmonic pressures, fluoroscopy time, and total angiographic time were studied. Major complications such as mortality and vascular complications were considered.*

Results: *We studied 237 patients in our investigation. We had 130 female and 107 male patients at a mean age of 34.3 ± 40.6 months and mean weight of 14.2 ± 7.8 kg. PDA sizes ranged from 2.1 to 6.2 mm and its mean was 3.7 ± 1.8 mm. Mean of fluoroscopy time was 11.4 ± 9.7 min and mean of total angiographic time was 42.0 ± 12.3 min. There were no significant complications.*

Conclusion: *We herein describe a new sign, which proved extremely helpful during our PDA closure procedures with the ADO. By considering the angle between the ADO and the cable during the procedure, the operator can release the ADO safely.*

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Introduction

The ductus arteriosus develops from the distal portion of the left sixth aortic arch and connects the main pulmonary trunk to the descending aorta. It runs in a posterior-anterior, inferior-superior, and leftward direction from the aorta to the pulmonary artery. Patent ductus arteriosus (PDA) is a common congenital heart defect, and the incidence of isolated

[*]**Corresponding Author:** ***Mehdi Ghaderian,*** *Assistant Professor of Pediatric Cardiology, Esfahan University of Medical Sciences, Child Growth and Development Research Center, Emam Khomeini St., Esfahan, Iran. 8195100000. Tel: +98 311 3876006. Fax: +98 311 3875998. E-mail: ghader_45@yahoo.co.uk.*

PDA in full-term infants is about 1 in 2000, accounting for approximately 5% to 10% of all types of congenital heart disease.[1] PDA can be closed via such different modalities as video-assisted thoracoscopic surgery, conventional surgery with division and suture, and transcatheter closure by interventional catheterization. Porstmann et al.[2] (1968) described PDA transcatheter for the first time.[2] Small PDAs (< 1-2 mm) can be closed safely with Cook detachable (Flipper) coils or Gianturco with minimal mortality and morbidity and excellent results.[3-5] The Amplatzer Ductal Occluder (ADO), which was introduced in 1997, is recommended for PDAs with sizes larger than 2 mm.[6] PDA occlusion with the ADO can be performed under general anesthesia or deep sedation.

An antegrade approach via venous line is required for the occlusion of PDA using the ADO. Rates of complete closure are as high as 99.7%, as was confirmed during a long-term follow-up study.[7, 8] During the procedure, the device is pushed with a delivery cable until it reaches the tip of the delivery sheath in the descending aorta under fluoroscopy. The sheath is gently pulled to deploy the aortic disk, and the cable delivery sheath and device are subsequently pulled as one unit under lateral fluoroscopy until the retention disk is positioned at the ductal ampulla. At this stage by using fluoroscopy, the tracheal air column can be used as a landmark from the previous aortogram to position the device. Also, a tugging sensation can be felt with the pulse of the aorta. By comparing the tracheal air column and the narrowest diameter of the PDA from the diagnostic aortogram, the operator can retract the delivery sheath with only a slight tension on the cable and deploy the device. After the confirmation of the correct deployment of the ADO by aortography, the device can be released by screwing the cable.

Some complications such as device embolization, narrowing of the aortic artery area, and left pulmonary stenosis have been previously described.[9, 10] One of the most critical complications of PDA closure by ADO is device embolization, frequently seen due to the undersizing of the ADO or incorrect positioning of the ADO in the PDA. Accordingly, having a practical landmark for the correct positioning of the device into the PDA could reduce complications after device deployment. One of the best guides for the correct positioning of the ADO is aortography after ADO deployment in the descending aorta. Be that as it may, in some procedures, there is no arterial line and aortography cannot be performed until the ADO is released. So the question remains as to when we can release the ADO safely.

In this article, we describe for the first time a sign that was extremely helpful during our use of the ADO for the closure of PDA.

Methods

The study protocol was approved by the Ethics Committee of Iran University of Medical Sciences. This retrospective study recruited all patients scheduled to undergo PDA transcatheter closure between September 2009 and September 2012 in Rajaie Cardiovascular, Medical and Research Center. The inclusion criteria were comprised of age < 15 years, body weight > 5 kg, conical PDA, and narrowest size of the pulmonary end of the PDA ≥ 2 mm in lateral view aortograms. The exclusion criteria consisted of other complex diseases requiring surgery, other PDA shapes rendering it suitable for coiling, very small PDAs, and near or systemic pulmonary hypertension.

The clinical characteristics of the patients – including age, sex, and weight – were recorded. During cardiac catheterization, angiographic and catheterization data such as the size of the narrowest diameter of the PDA and the type of the PDA in lateral view aortograms, pulmonary artery pressure, and fluoroscopy time were obtained. The antegrade procedure via venous line under general anesthesia was recommended for all the patients. The course of the venous catheter was from the inferior vena cava to the right atrium, right ventricle, and pulmonary artery. The venous catheter finally reached the descending aorta via the PDA. After the estimation of the size of the PDA via lateral view aortography, a device size at least 2 mm greater than the narrowest size of the PDA at the pulmonary end was chosen. An appropriate sheath was positioned in the descending aorta, and the ADO reached the tip of the delivery sheath by pushing the delivery cable. Thereafter, the aortic disk was deployed by gently pulling the sheath. Next, all of the sheath, delivery cable, and ADO were pulled together in order to position the retention disk at the ductal ampulla. In some patients, there was no arterial line and the ADO was positioned in the PDA by pulling the sheath and tensing the cable. At this time in some of our patients, the continuity between the cable, sheath and ADO was broken – signifying the correct deployment of the ADO. The complications that arose from the procedure were also recorded. Echocardiography was done during the procedure before releasing the ADO and the day after the procedure as well as one month and six months postprocedurally by using a GE Vivid 3 echocardiographic machine. The patients were assessed for residual PDA, left pulmonary artery stenosis, and descending aorta stenosis intraprocedurally via echocardiography. In the case of the presence of significant complications, other methods were considered. Angiography was performed with Zee2 Philips angiographic machine.

All the data are expressed as mean ± standard deviation (SD). The analyses were carried out using SPSS Statistics 18.0. Statistical significance was defined as a p value < 0.05.

Results

Two hundred thirty-seven patients underwent PDA transcatheter closure between September 2009 and

September 2012. The study population comprised 130 female and 107 male patients. The demographic data of the patients are depicted in Table 1.

There were no significant major complications such as mortality or vascular complications. Two of our patients were twins and had similar-sized PDA. Two patients had protrusion of the ADO into the aortic artery but had no significant stenosis; these patients did not have coarctation of the aorta on follow-up. In one of our patients, the ADO protruded into the left pulmonary artery; this artery had no obstruction on follow-up. Six patients had bleeding during the procedure and received blood. There were no cases of device embolization.

Discussion

Transcatheter closure of PDA is an established and safe method of treatment with no mortality and significant morbidity. In our study, transcatheter closure was performed in 237 patients under general anesthesia and the PDA size ranged from 2.1 mm to 6.2 mm. There was no mortality, and there were minimal intraprocedural complications inasmuch as none of the patients had device embolization or vascular complications.[9-12] The closure rate in our patients was greater than 99.7%, which is comparable to the rates reported in some other studies.[7, 8, 13]

Two of our patients had ADO protrusion into the aortic artery. On follow-up, however, there was no significant stenosis or other complications. If the ADO protrudes into the descending aorta without significant coarctation of the aorta or if less than 50% of the aortic area is obstructed, long follow-up without other procedures is needed. As the patient grows older and the aortic surface increases, the need to follow-up is reduced. Left pulmonary stenosis was not seen in our patients. This complication necessitates long follow-up periods, but this type of stenosis tends to diminish as the patient grows older. Nonetheless, if left pulmonary stenosis leads to the reduction or obstruction of the left pulmonary artery flow, other alternative treatment modalities such as surgery and use of other devices should be taken into consideration.

We herein introduce a sign, which can be useful for the correct deployment of the ADO. Figure 1 illustrates a normal conical PDA in a lateral view aortogram. As is shown in Figure 2, during the procedure and before complete deployment (i.e. when the device is pulled into the ductal ampulla), the device, delivery cable, and delivery sheath have continuity with each other in a curved line. The retention disk of the ADO is placed in the ductal ampulla, and the other segments of the ADO are positioned in the narrow segment of the PDA. After pulling the cable delivery sheath and the device as one unit under lateral fluoroscopy, the delivery sheath is pulled into the pulmonary artery and the distal end of the ADO is placed in the pulmonary artery at the narrowest part of the PDA. When there is correct deployment, only the delivery sheath is pulled into the pulmonary artery and the continuity between the cable and the device is broken. This angulation is created by the angle between the PDA and the pulmonary artery (Figure 3). This figure shows an ADO positioned in the PDA with its retention disk placed in the ductal ampulla. The narrow segment of the device is also positioned in the junction between the PDA and the pulmonary artery, and the distal end of the device is in the pulmonary artery. The continuity between the cable and the delivery sheath is broken by a sharp angle between the ADO and the cable. During the procedure and before the release of the ADO, echocardiography is performed to investigate the possible presence of coarctation of the aorta and left pulmonary artery stenosis. At this point in time, the operator knows that the ADO is positioned in the correct site (especially in the absence of an arterial line) and he can release the ADO safely. If the ADO is positioned in other sites, the sign described herein cannot be observed.

In our study, more than 85% of the patients, who underwent PDA closure by ADO, had a positive sign, which denotes the reliability of this sign. The relatively small sample size and duration may be the major limitations of the present study. In addition, we did not use and compare other devices in this study. Nevertheless, we hope that this report prompts more research in this interventional field.

Table 1. Demographic data of the patients

	Total (mean±SD)	Male (mean±SD)	Female (mean±SD)	Range (total)
Age (mo)	34.3±40.6	33.2±41.7	35.4±39.8	6.0 - 78.0
Weight (kg)	14.2±7.8	16.3±8.2	13.2±6.2	8.2 - 23.4
Patent ductus arteriosus size (mm)	3.7±1.8	3.6±1.6	3.9±1.8	2.1 - 6.2
Pulmonary artery pressure (mmHg)				
Systolic	31.3±14.2	34.2±16.1	30.2±12.1	20.0 - 57.0
Diastolic	16.2±8.4	17.8±9.2	15.3±7.1	10.0 - 40.0
Fluoroscopy time (min)	11.4±9.7	11.1±10.1	11.6±9.4	2.2 - 32.0
Total angiography time (min)	42.0±12.3	41.5±12.7	42.1±1.9	21.3 – 60.5

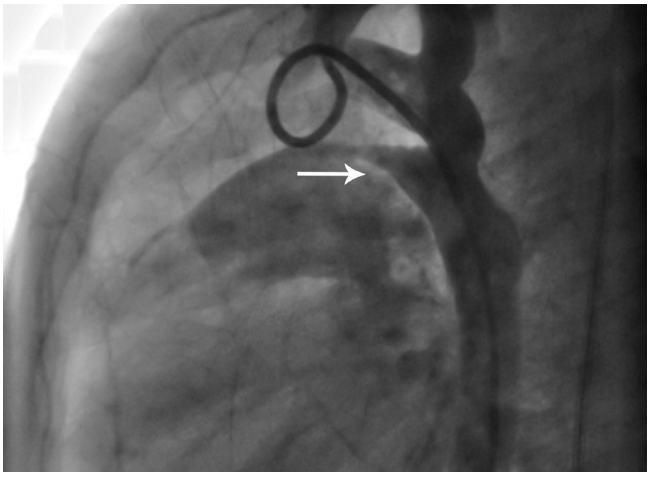

Figure 1. A conical patent ductus arteriosus is shown in lateral view aortogram (arrow)

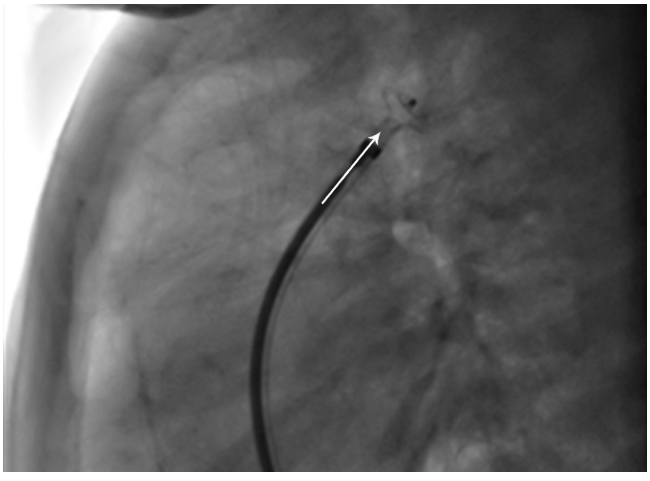

Figure 2. Continuity is demonstrated between the Amplatzer Ductal Occluder and the cable (arrow)

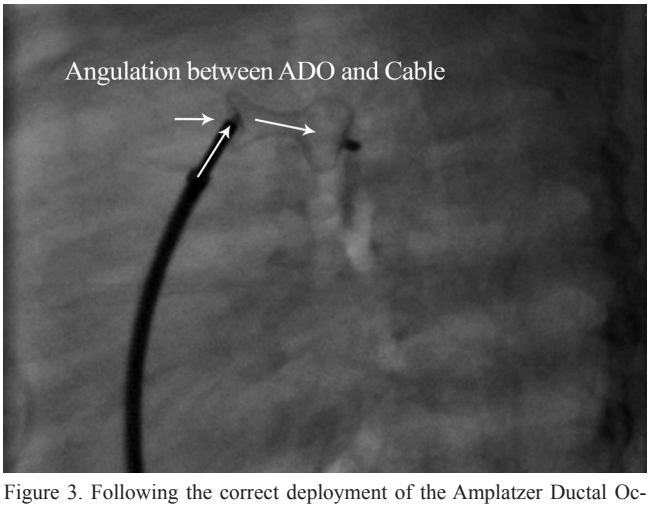

Figure 3. Following the correct deployment of the Amplatzer Ductal Occluder, the continuity between the device and the cable is broken. The angle can be seen in this view (arrows). Compared to Figure 2, in this figure, the two arrows in the cable and the Amplatzer Ductal Occluder are positioned at an angle with each other, as is demonstrated by the arrows

Conclusion

We herein introduced a new sign, which can assist in the correct deployment of the ADO during PDA closure. To our knowledge, the existing literature lacks signs similar to what we describe here. This sign, especially in the absence of an arterial line for post-PDA aortography, can help the operator release the ADO safely.

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