

STRUCTURAL HEART DISEASE

Use of the Amplatzer Vascular Plug II Device to Occlude Different Types of Patent Ductus Arteriosus in Pediatric Patients

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Introduction: Transcatheter patent ductus arteriosus (PDA) closure is difficult in small patients in part due to the diverse PDA morphology. We describe a multicenter pediatric experience using the Amplatzer Vascular Plug II device (AVP II) to occlude PDA.

Methods: All patients undergoing transcatheter closure of PDA with AVP II from April 2008 until May 2012 were included. Clinical, angiographic, and echocardiographic data were collected.

Results: One hundred and seventy-seven procedures were performed. Median age was 14 months (2–180) with median weight 9.7 kg (4.7–68). The morphological PDA classification was Type A in 66 (37.1%), Type C in 27 (15.3%), Type D in 17 (9.6%), and Type E in 67 (37.9%). The median minimum PDA diameter was 2.6 mm (1.2–7.7 mm). The implanted device sizes were: 4 mm in 17 patients (9.6%), 6 mm in 81 (45.8%), 8 mm in 56 (31.6%), 10 mm in 18 (10.2%), and 12 mm in 5 (2.8%). The implanted device was mean of $2.6 + 0.7$ times the ductus narrowest diameter and mean of $1 + 0.5$ times the ductus largest diameter. Complications included: one severe left pulmonary artery stenosis and one device embolization. No aortic obstruction occurred. Closure was complete in the 175 remaining patients.

Conclusions: The AVP II is an effective and safe device for PDA closure. It is particularly useful when dealing with nontypical PDA shapes and in small infants where it eliminated the risk of device-related aortic obstruction. The AVPII is an addition to the PDA device closure armamentarium in pediatric patients. (J Intervent Cardiol 2015;28:198–204)

Introduction

Transcatheter closure has evolved as an established treatment modality for patent ductus arteriosus (PDA). Since the first report of transcatheter PDA closure by Porstmann et al.¹ there have been huge improvements in this procedure, mainly due to the development of more simple, safe, and effective devices. This has lead operators to attempt closure of larger PDAs in smaller patients.^{2,3}

The Amplatzer Duct Occluder device has been designed for this purpose with a high closure and low complications rates.^{4,5} The Amplatzer Duct Occluder

(ADO) device has been demonstrated to be useful closing the usual conical shape PDA (Krichenko A),⁶ even for large size PDA. However, when implanted in low-weight infants, aortic obstruction has been described from the retention disc protruding into the aortic lumen^{7–9} and left pulmonary artery stenosis has also been reported due to protrusion of the device into the left pulmonary artery.^{4,5,9} Additionally, when dealing with an unusual angiographic PDA type (Krichenko C, D, and E), the ADO device may adapt a disposition leading to protrusion or excessive distortion of the ductal tissue.⁸ The second generation of the ADO device (ADO II) was developed in an attempt to overcome these problems; however, there have been pulmonary and aortic obstruction cases reported using it, resulting in less use of this device in small infants due to its large retention discs.^{10–12} The Amplatzer Vascular Plug is a device designed for

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generic vascular occlusion that was also anecdotally used for PDA occlusion.^{13,14} Using the first generation of the Amplatzer Vascular Plugs for PDA closure, residual shunts were usually reported so its use was not widely advisable.^{15,16} A second generation of Vascular Plug device (AVP II) was developed improving its capabilities for occlusion and position stability. The US FDA approved its use in 2007 for closure of vascular malformations.¹⁷ The device has been used off-label to close PDAs; however, the experience was limited.^{18–20}

In this article, we report the largest multicenter experience using AVP II for PDA occlusion in pediatric patients, emphasizing its utility closing different angiographic PDA types.

Methods

All patients referred to us between April 2008 and May 2012 for percutaneous PDA closure in whom AVPII device was used were included in this study. Patients were selected to receive an AVP II device when their PDA was considered to be not ideal to be closed using a regular ADO or ADO II devices, because its morphology (Krichenko C, D, or E).

Other reason to prefer AVPII device was in small infants where the transverse arch was close to the PDA as evaluated in the lateral aortic angiogram and the retention disc of the required ADO I device (4 mm larger than the main body) would be excessively large with a risk to protrude beyond the margin the transverse arch (see as an example the patient at Fig. 2). The procedures were performed in pediatric catheterization facilities from three pediatric cardiovascular centers in Santiago, Chile (Hospital de Niños Dr. Roberto del Río, Hospital de Niños Dr. Luis Calvo Mackenna and Hospital Clínico de la Universidad Católica de Chile). Use of sedation or general anesthesia for the procedures was left up to the operator's choice. Hemodynamic assessment prior to closure of the PDA was up to the operator's preference; otherwise, PDA closure was performed without hemodynamic assessment. The demographics, the available hemodynamic data and the angiographic information were retrospectively obtained from the patient charts. The study was approved by the local Institutional Review Board at each participating institutions. Informed consent was routinely obtained from the parents for all the patients.

The AVP II device is a generic vascular occlusion device made of a dense braided Nitinol double wire

mesh (Fig. 1). The device has three same diameter components in a cylindrical shape, a central component, and two lateral discs. It is available in diameters of 3 and 4 mm, and then with 2 mm increments up to 22 mm. The device length may go from 7 to 11 mm. Similar to other Amplatzer devices it has a proximal microscrew to permit the attachment to a delivery cable. The devices can be implanted through a 4 Fr long sheath for 3–8 mm devices, through a 5 Fr long sheath for 10 and 12 mm devices, through a 6 Fr sheath for 14 and 16 mm devices and through a 7 Fr long sheath for larger devices.

The PDA angiographic morphology was defined on aortic angiogram (usually 90° LAO) according to the Krichenko classification.⁶ The narrowest and largest diameters of the PDA were measured. The procedures were conducted as previously described for routine PDA closure with Amplatzer devices.²¹ All the patients received heparin 100 U/kg IV at the beginning of the procedure. The ductus arteriosus was usually crossed from the venous side into the descending aorta, but implantation from a retrograde approach through the femoral artery was also considered due the symmetric shape of the device. Soon after the first cases at the initial part of our experience we adopted a deployment routine: the device was selected to be twice the narrowest PDA diameter or even larger if the aortic ampulla was large enough to accommodate the device

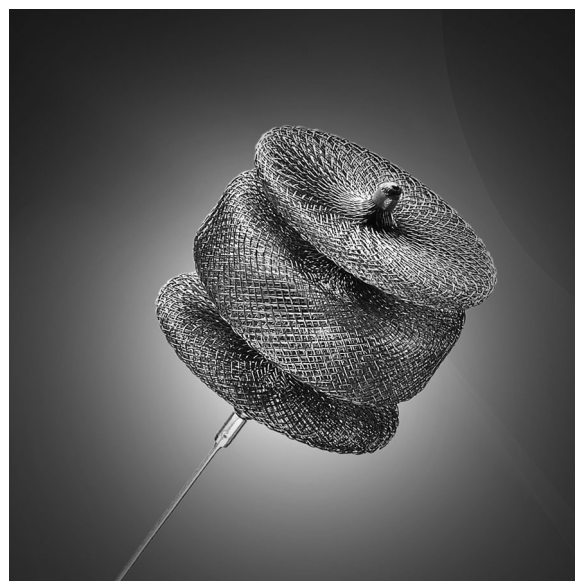


Figure 1. Amplatzer Vascular Plug II (AVPII).

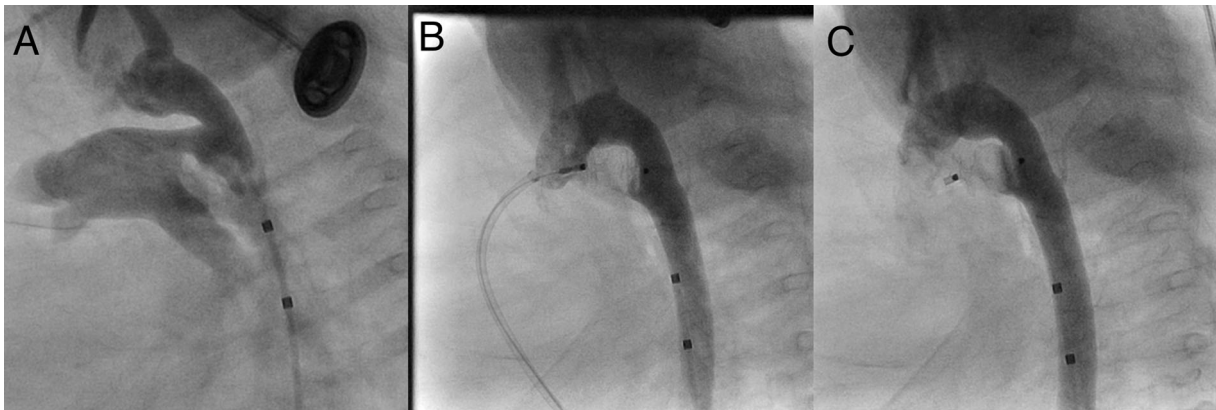


Figure 2. Aortic angiogram in lateral projection in a 3-month infant (weight 5.2 kg) demonstrating a type A conical patent ductus arteriosus (A) with a narrowest diameter of 3.6 mm and aortic ampula of 7 mm. (B) Aortic angiogram with an 8-mm AVP II device deployed in the patent ductus arteriosus still attached to its delivery cable. Immediately postdeployment angiogram demonstrates device position related to the left pulmonary artery. (C) AVP II device after being released and demonstrating complete occlusion of the ductus arteriosus.

trying to fill the aortic ampula with a device equal or 1 mm larger than the diameter of the ampula. For the implantation we usually deployed the distal disc and central component of the device in the descending aorta before pulling the device back into the aortic ampulla. This way demonstrated to be more stable and avoid the device prolapse into the pulmonary artery during the deployment. Excessive pulling was avoided since the AVP II is softer than the regular ADO device and prolapse into the pulmonary arteries can easily occur. When the two distal components of the device seemed to be inside of the aortic ampulla, the proximal disc was deployed in the pulmonic part of the ductus, always avoiding excessive tension on the device. With the device still attached to the delivery cable an aortic angiogram usually 90° LAO was performed to assess device position prior to release. Since contrast usually passes through the device mesh when just implanted it permits to precisely visualize the device position inside the ductus arteriosus and its relation to the left pulmonary artery. A 30° RAO projection can also be useful for this purpose when lateral projection is not conclusive demonstrating these relations properly. At this point the device could be recaptured if considered not to be in an appropriate position; otherwise, the device was finally released. A final 90° LAO aortic angiogram was performed to demonstrate the ductus occlusion after 5–10 minutes from the release.

Patients remained overnight in the hospital and were evaluated with transthoracic echocardiogram the

morning after the procedure. Follow-up frequency using echocardiographic assessment was at the discretion of the patient's cardiologists.

Results

During the study period, 635 procedures for PDA closure were performed and AVPII device was used in 177 (27.9%) of those patients. One hundred and twenty-five patients (70.6%) were female. The median age at catheterization in the patient group was 14 months (range 2–180 months), and the median weight was 9.7 kg (range 4.7–68 kg). Of the patients, 84 (47.5%) were younger than 12 months of age. Preimplantation hemodynamic data were obtained from 38 patients (21.5%). The mean Qp/Qs ratio was 2.4:1 (range 1.3–4.3). Based on angiographic classification by Krichenko our patients had Type A PDA in 66 (37.1%) patients (Fig. 2), Type C PDA in 27 (15.3%) patients (Fig. 3), Type D PDA in 17 patients (9.6%) (Fig. 4), and Type E PDA in 67 patients (37.9%) (Fig. 5). The median smallest (usually the pulmonic end) diameter was 2.6 mm (range 1.2–7.7 mm), and the median largest diameter was 7 mm (range 2.3–12.8 mm). Of 170, 64 (37.7%) were larger than 3 mm at their smallest diameter. The median weight for Type A PDA patients was 9.1 kg (range 4–62.8 kg), for Type C PDA patients was 8.6 kg (range 4.8–13 kg), for

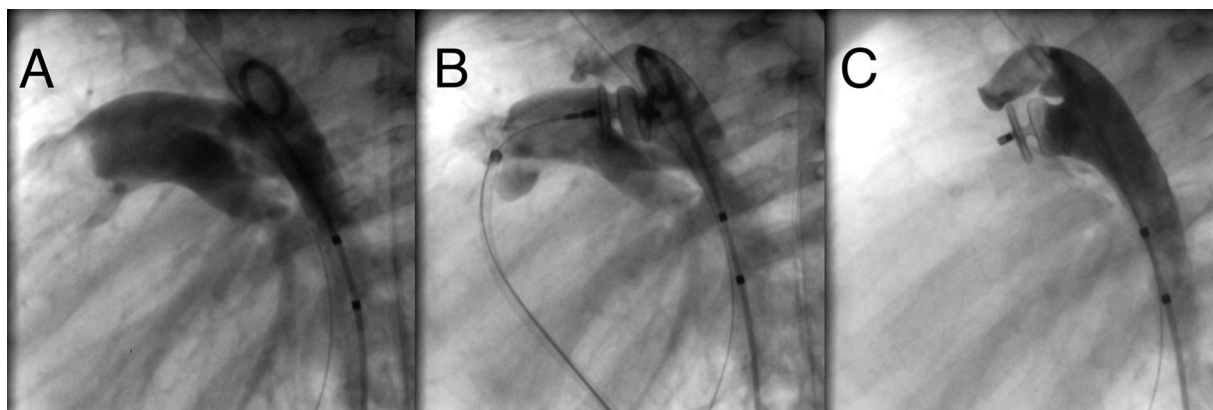


Figure 3. Aortic angiogram in lateral projection in a 5-month infant (weight 6.2 kg) demonstrating a type C tubular patent ductus arteriosus (A) with a diameter of 6 mm. (B) Aortic angiogram with a 10-mm AVP II device deployed in the patent ductus arteriosus still attached to its delivery cable. Immediately postdeployment angiogram demonstrates device position inside the ductus arteriosus and its position related to the left pulmonary artery. (C) AVP II device after being released and demonstrating complete occlusion of the ductus arteriosus.

Type D patients was 10.4 kg (range 6.4–24 kg), and for the Type E patients was 9.6 kg (range 4.7–68 kg).

The implanted device sizes were: 4 mm in 17 patients (9.6%), 6 mm in 81 patients (45.8%), 8 mm in 56 patients (31.6%), 10 mm in 18 patients (10.2%), and 12 mm in 5 patients (2.8%). The size of the implanted device was mean of 2.6 ± 0.7 times the ductus narrowest diameter and mean of 1 ± 0.5 times the ductus largest diameter. In 115 cases (65%), the device was implanted using a 4 Fr delivery long sheath. In the remaining 62 cases, a 5 Fr long sheath was used. The mean fluoroscopy time was 14 minutes

(range 2–49 minutes). Complete angiographic closure was documented at the end of the procedure in all the patients before leaving the catheterization laboratory. There was no device-related aortic obstruction demonstrated. One 4-kg infant with a 4.7-mm PDA had severe left pulmonary artery stenosis evident in the first transthoracic echocardiogram and the 10 mm device was uneventfully percutaneously retrieved the morning after the procedure. In one 7-kg infant with a 4-mm PDA the device embolized into the left pulmonary artery, this was percutaneously retrieved too. Both patients were sent for surgical PDA ligation.

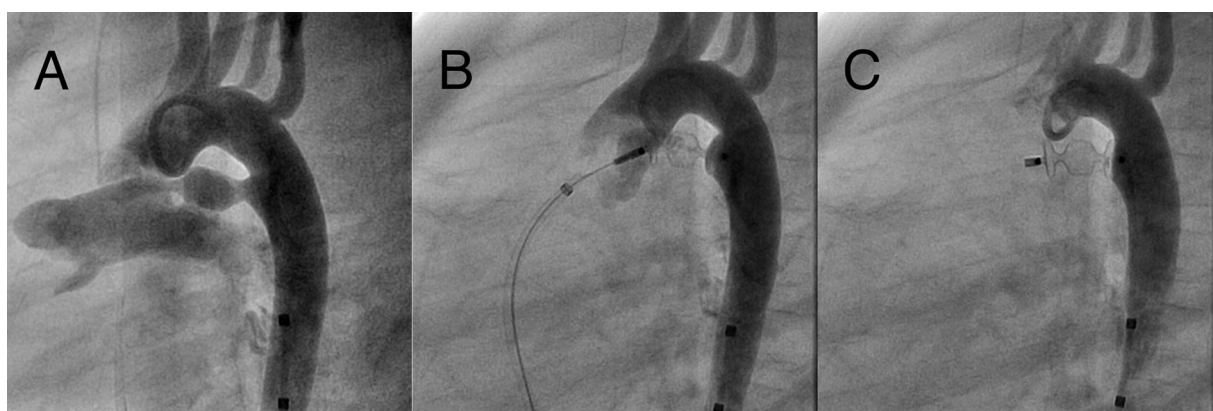


Figure 4. Aortic angiogram in lateral projection in a 11-month infant (weight 8.2 kg) demonstrating a type D patent ductus arteriosus with multiple constrictions (A) with a narrow diameter of 2 mm and aortic ampula of 6 mm. (B) Aortic angiogram with an implanted 6-mm AVP II device deployed in the patent ductus arteriosus still attached to its delivery cable. (C) Aortic angiogram after device release demonstrating complete occlusion of the ductus arteriosus with the device not protruding into the aortic lumen.

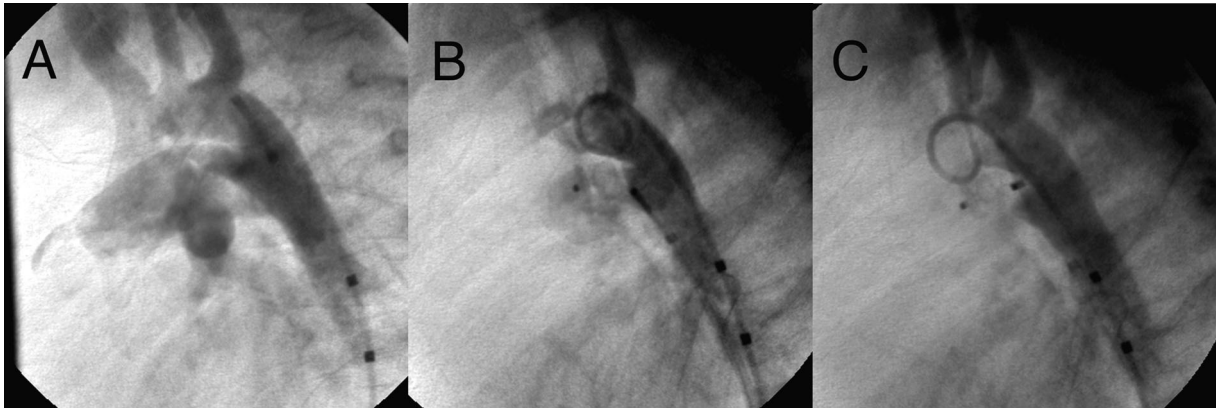


Figure 5. Aortic angiogram in lateral projection in a 5-month infant (weight 8.5 kg) demonstrating a type E elongated patent ductus arteriosus (A) with a narrow diameter of 2 mm and aortic ampulla of 4.3 mm. (B) Aortic angiogram with a 6-mm AVP II device deployed in the ductus arteriosus still attached to its delivery cable via an aortic retrograde approach. Immediately postdeployment angiogram demonstrates device position inside the ductus arteriosus and its position related to the left pulmonary artery. (C) A 6-mm AVP II device after being released and demonstrating complete occlusion of the ductus arteriosus.

In another case (4 kg), loss of pulse was evident during the inpatient observation period and it resolved after heparin infusion during 24 hours. The closure was complete in all patients with the implanted device on echocardiographic evaluation 24 hours after the procedure. Echocardiographic follow up of 11.3 ± 4.5 months (range 1–26 months) has been uneventful with no evidences of aortic or pulmonary artery obstruction, neither residual shunt.

Discussion

This experience demonstrates that the AVPII is an effective and safe device to be used for PDA closure. The closure rate was as higher or better as reported for the regular ADO device^{2,5} and this has also been reported by others using the AVPII.^{19,20} In our own experience, the closure was routinely demonstrated before the patients leave the catheterization laboratory. The dense multilayer wire mesh compared to the original Vascular Plug design seems to have improved the closure since no case of shunt through the device mesh was observed in the echocardiographic evaluation 24 hours after the implantation as reported with the original plug.¹⁶ The structural modifications introduced to the original Vascular Plug design seem to have improved the device stability too since device embolization was observed in just one patient in our series (0.6%). The morphological PDA type distribu-

tion we report are unusual when compared to most of other reported PDA closure series where Type A PDA are clearly dominant.^{4,5} This is because most of our patients were obviously selected because of their PDA morphology; since a Tubular Type C (Fig. 3), multiple constrictions Type D (Fig. 4) and elongated Type E (Fig. 5) were considered to be not ideal to be closed using a regular ADO or ADO II devices. Implantation of AVP II device demonstrated to be particularly useful when addressing the closure of PDA with these nonclassic morphologies and that has been also recently reported by others.²⁰ It seems to us that this device fits remarkably well inside the ductal ampulla particularly in tubular or elongated shape PDA filling it to obtain the occlusion. In this way, the AVP II avoids excessive distortion of the ductal tissue.⁸ The AVP II fitted particularly well too in PDA with multiple constrictions (Fig. 3). For cases of short PDA (Aorto pulmonary window or type B) certainly AVP II is not an adequate device to use and we did not include any patient of these in our experience. For this kind of PDA probably a short double disc design device like ADO II would be useful. It seems to us that it is necessary to consider the PDA morphology in order to select the proper occluder device to use for PDA occlusion.

In addition, this experience demonstrates that the AVP II device permits to occlude large PDA even in small infants avoiding the potential problem of device-related aortic obstruction since this situation did not occur in the patients in our series. However, there was

an isolated patient in whom we demonstrated device-related left pulmonary artery obstruction. This raises our concerns about the excessive length of this device when dealing with large PDA in small infants with an infrequently but real risk to occlude the left pulmonary artery take off with the device proximal disc. Recently, a report was published on the long-term pulmonary blood flow in patients who underwent PDA device closure with the ADO devices,^{22,23} suggesting this would not be a problem exclusively related to the AVP II device but related to the procedure itself when using devices for PDA closure. This complication seems to be anyway unusual and was reported to resolve on its own in the majority of cases,²⁴ therefore, it is not contraindicated to use it for closure of large PDAs in small infants.

The reported initial experiences with a modified Amplatzer PDA closure device named ADO II Additional Sizes (ADO II-AS) has been encouraging with no reported LPA obstruction^{25,26} and particularly useful in small infants and even in preterm babies.²⁷ The ADOII-AS device is a three-lobed cylindrical device with lateral discs just 1–1.5 mm larger than the central body making its shape closer to an AVP II than an ADO II. This supports this experience that a cylindrical device can be effectively used to perform PDA closure procedures. Some of our reported patients could have been done with an ADOII-AS device but it was not available to us at the time we started this experience. In addition, ADOII-AS is indicated to PDA up to 4 mm in diameter and in our report 23.8% of the patients younger than 6 months (5 of 21) had PDA larger than 4 mm, making these patients not suitable for the new ADOII-AS device demonstrating that there are still not a single PDA closure device good enough for all PDA patients.

In summary, the AVP II device was demonstrated to be an effective and safe device to be used for PDA device closure. It is particularly useful when dealing with the nontypical PDA shapes even when performing cases in small infants where it eliminates the risk of device-related aortic obstruction. The AVPII must be considered a new addition to the PDA device closure armamentarium in pediatric patients.

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