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Utility of the Amplatzer Vascular Plug Type II™ for transcatheter closure of patent ductus arteriosus in adults

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ABSTRACT

The Amplatzer Vascular Plug Type II™ (AVPII) has been considered and used for the percutaneous closure of certain cases of persistent patent ductus arteriosus. Certain institutions use this device preferentially over the Amplatzer Duct Occluder Type I (ADOI). We present a series of three cases that highlight the versatility and applicability of this device, particularly in cases of adult congenital heart disease. This device is particularly useful when ductal anatomy cannot be precisely elucidated, or in adults with abnormal or difficult to define ductal anatomy. Two of the three cases presented were percutaneous interventions that were performed in Leon, Nicaragua, highlighting the use of the AVPII in resource-limited settings where device adaptability and cost are paramount.

1. Introduction

Persistent patency of the ductus arteriosus may result in late morbidity due to pulmonary over-circulation, left heart volume overload, and potential for endocarditis. Preemptive closure is generally recommended in all but the smallest ducts. Percutaneous transcatheter closure of the patent ductus arteriosus is a routine and highly efficacious interventional procedure. When this endovascular approach began to replace surgical repair via thoracotomy, the morphologic diversity of ducts became more apparent and important, and the Krichenko angiographic nomenclature came to be widely used [1]. Various occlusive devices have been used to achieve ductal closure but the Amplatzer Duct Occluder Type I™ (ADOI) (Abbott) was designed for the most common angiographic morphology, the Type A conical ductus, and is the first and only implant to receive FDA approval for “on-label” transcatheter closure of the ductus [2–4]. The ADOI is a nitinol mesh plug comprised of a larger aortic retention flange and smaller tapered body with polyester Dacron patches sewn onto the framework. It is designed for transvenous delivery. For some anatomic variants, the aortic retention flange is too bulky or limits secure seating of the body of the occluder across the narrower pulmonary end of the ductus. Proper size selection for the ADOI requires accurate angiographic definition and measurements.

The Amplatzer Vascular Plug Type II (AVPII) (Abbott) is a tri-lobed self-expanding nitinol occlusion device comprised of finer gauge tightly woven nitinol without polyester Dacron (Fig. 1). It is approved for transcatheter closure of peripheral arteries or veins but has been used off-label for closure of the patent ductus arteriosus in selected cases, mostly in infants and children [5–11].

Numerous other occlusion devices have been used to achieve closure, usually Gianturco coils are used for smaller ducts and the ADOI is used for larger ducts. However, some anatomic variants can be challenging to close with these standard occlusion devices. In selected pediatric cases, particularly for small infants, the AVPII has been used preferentially over the ADOI. The AVPII and its included delivery system are significantly less costly than the ADOI and its separate delivery system. For our hospital's purchasing department, the cost difference between the ADOI and the AVPII for a single device is about $5000. In this series, we describe three cases of adult patients undergoing transcatheter closure of the patent ductus arteriosus in whom the AVPII was selected.

2. Case Series

Case 1 was diagnosed at the UNC Adult Congenital Heart clinic and the transcatheter closure was performed at UNC Hospitals in Chapel Hill, North Carolina. Cases 2 and 3 were performed at the Hospital Escuela Oscar Danilo Rosales in Leon, Nicaragua, as a joint effort between Project Health for Leon and an interventional cardiology team from the University of North Carolina School of Medicine. Project

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[1] Dr. Blount was the primary investigator, conceptualized and designed the project, drafted initial manuscript and approved the final manuscript as submitted.
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Fig. 1. Diagram illustrating the design of the AVPII.

Health for Leon is a long-established non-profit organization that has provided outpatient diagnostic cardiology services to several hundred patients annually over the past 30 years. More recently this has expanded to include surgical services. Approximately 10 patients annually have undergone surgical repairs over the past 12 years, mostly valve replacements. The UNC interventional team performed the first four percutaneous balloon valvuloplasties for rheumatic mitral stenosis in January 2017 and six congenital catheter interventions (including cases 2 and 3) in January 2018. The hospital in Leon is a resource-limited environment with no dedicated cardiac catheterization laboratory. An operating room equipped with an aging portable C-arm fluoroscopy unit (Philips BV Pulsera) and a bedside hemodynamic monitor was used. Only limited hand injections of contrast material were used for angiography, as no power injector was available. Intra-procedural transthoracic echocardiography was used for confirmatory imaging (GE Vivid i). All catheters and supplies were brought from the U.S. after approval by the Nicaraguan Ministry of Health.

Patient 1 is a 24-year-old obese woman with a 6-year history of systemic hypertension controlled with hydrochlorothiazide and labetalol. On routine primary care follow-up she was noted to have a systolic murmur, and an echocardiogram showed a diastolic flow signal in the pulmonary artery consistent with a ductus arteriosus or collateral vessel (Fig. 2A). On referral to the Adult Congenital Heart clinic in Chapel Hill, NC, she was noted to have a continuous murmur at the upper left sternal border, and an echocardiogram confirmed a patent ductus arteriosus with mildly dilated left atrium and left ventricle. She was referred for transcatheter closure of the ductus, and at cardiac catheterization, pulmonary artery and left ventricular end-diastolic pressures were found to be mildly elevated. Aortography near the ductus showed modest opacification of the pulmonary trunk but failed to show the morphology and size of the ductus. An intra-ductal angiogram with a transvenous high-flow Pigtail catheter showed a Type D ductus measuring 8.5 mm at the aortic end, 3.5 mm at the pulmonary end, a saccular mid-portion, and length of 22 mm (Fig. 2B). Because of the length of the ductus, an Amplatzer Duct Occluder Type I was not expected to engage the pulmonary end without significantly distorting the ductus, so a 10 mm Amplatzer Vascular Plug Type II was chosen, anticipating that the constrained plug would elongate and occupy the entire length of the ductus. The plug was delivered transvenously via a 5 Fr 75 cm Cook sheath and ideal position was confirmed by a test angiogram in the pulmonary artery via the delivery sheath (Fig. 2C) and transthoracic echocardiography. Doppler echocardiography showed complete closure.

Patient 2 is a 24-year-old woman who was evaluated at the Project Health for Leon outpatient cardiology clinic in September 2017 for a murmur, fatigue and orthopnea. Cardiac exam was notable for a grade 5/6 coarse continuous murmur, and trans-thoracic echocardiography showed a patent ductus arteriosus, measuring 12–14 mm at the aortic end, 4–5 mm at the pulmonary end, and 12 mm in length (Fig. 3A). The Doppler velocity through the ductus was > 4 m/s. In preparation for the medical trip to Nicaragua, a 12 mm Amplatzer Vascular Plug II was pre-selected and favored over an Amplatzer Duct Occluder Type I. The advantage in this case was related to the difference in cost between the two devices, and uncertainty predicting the appropriate sized Amplatzer Duct Occluder Type I. At cardiac catheterization in January 2018, the ductus could not be crossed from the pulmonary artery despite trials of multiple catheters and wires over 1 h. Ultimately, a 5 Fr Cook 75 cm sheath was placed percutaneously in the right femoral artery and the ductus was crossed quickly from the aorta. The 12 mm Amplatzer Vascular Plug II was implanted delivering only the distal disk in the pulmonary artery, which placed the middle lobe and proximal disk of the plug in the ductal ampulla. Test angiography through the sheath (Fig. 3B) and by echocardiography, which confirmed the proper position of the device and demonstrated a small residual shunt. Echocardiography the next morning showed complete closure.

Patient 3 is a 35-year-old woman who was also referred to the Project Health for Leon clinic in September 2017 for evaluation of a murmur, fatigue and orthopnea. A grade 5/6 continuous murmur was noted on exam and an echocardiogram confirmed a patent ductus arteriosus measuring 10–12 mm on the aortic end and 4 mm at the pulmonary end. The length and morphologic type were not well-delineated by echo (Fig. 4A). The peak Doppler velocity through the ductus was 5 m/s. Left atrial and left ventricular dilation were noted. Again, a 12 mm Amplatzer Vascular Plug II had been pre-selected due to the incomplete morphologic characterization of the ductus. At cardiac catheterization in January 2018, the ductus was crossed easily via the pulmonary artery and a 5 Fr Cook 75 cm delivery sheath was exchanged over an Amplatz extra-stiff wire with the tip positioned in the thoracic aorta. The 12 mm Amplatzer Vascular Plug Type II was implanted into the ductus, delivering the distal disk and middle lobe in the aortic ampulla and the proximal disk in the pulmonary artery (Fig. 4B). Proper position was confirmed by test angiography through the sheath and complete closure was noted by echocardiography.

3. Discussion

The three cases in this report highlight the utility of the AVPII in adult patients with patent ductus arteriosus given unique technical considerations in adults, particularly when the full array of occlusion devices are not available, for example in resource-limited settings. These cases illustrate the utility of the AVPII in adults where anatomic variability of the ductus is greater and routine angiography is often suboptimal in defining the anatomic features.

Because routine aortography in adults often yields insufficient imaging of the ductal anatomy [12], some authors have proposed supplementary balloon sizing methods [13]. Case 1 illustrates the inadequacy of aortography, although intraductal power angiography was sufficient. In this case, the length of the ductus led us to favor the AVPII to avoid oversizing and fore-shortening the ductus with an ADOI; we expected an AVPII to conform to the length and shape of the ductus when constrained. In adults, the ductus is often longer than in infants

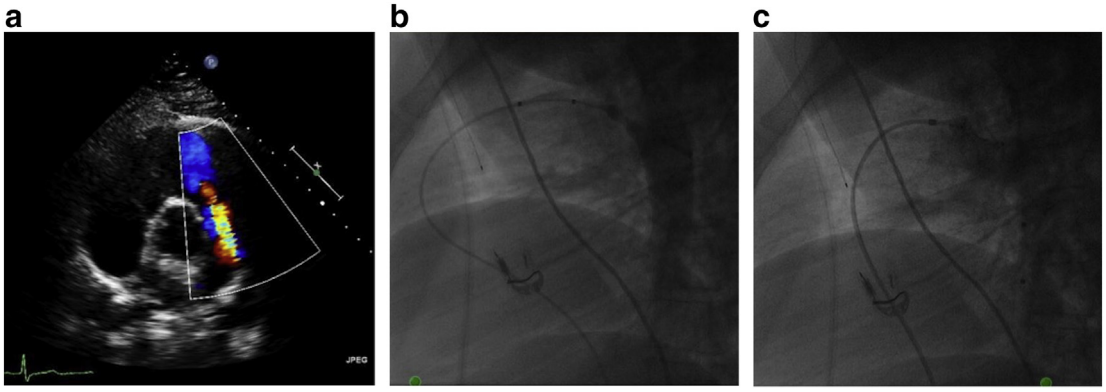

Fig. 2. A: Trans-thoracic echocardiogram showing reversal of flow consistent with patent ductus arteriosus.
B: Intraductal angiogram showing saccular Type D ductus.
C: Post-deployment angiography showing complete occlusion of ductus.

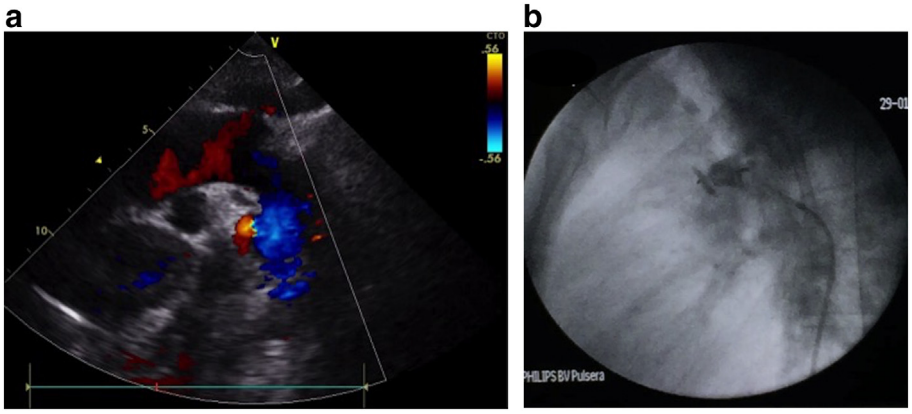

Fig. 3. A: Trans-thoracic echocardiography showing patent ductus arteriosus.
B: Post-placement hand-angiography from aortic end of ductus showing complete occlusion.

and children, so the 7 or 8 mm length of the ADOI is often too short to cover the aortic ampulla and still be securely constrained by the pulmonary end of the ductus. Cases 2 and 3 were performed without the availability of power-injection aortography or the equipment necessary for proper balloon sizing and, because the occluders were chosen in advance based on transthoracic echocardiography, 12 mm AVPIIs were selected to be approximately equal to the aortic ampulla diameter and at least twice the smallest diameter of the ductus. The use of the AVPII occluders allowed for secure positioning without the luxury of detailed morphologic characterization of the ducts.

Although none of our patients had significantly calcified ducts, this is a common anatomic feature especially in older adults and it may produce technical challenges. A recent report highlights the difficulty in traversing the ductus transvenously, requiring creation of an arteriovenous loop after crossing retrograde to deliver an occluder transvenously [14]. Our case 2 highlights the ease of delivering the AVPII retrograde, representing a significant advantage of the AVPII over the ADOI in adults with patent ductus arteriosus. When delivering the AVPII retrograde, only the distal disk is deployed in the pulmonary artery, and thus the middle lobe and proximal disk are deployed into

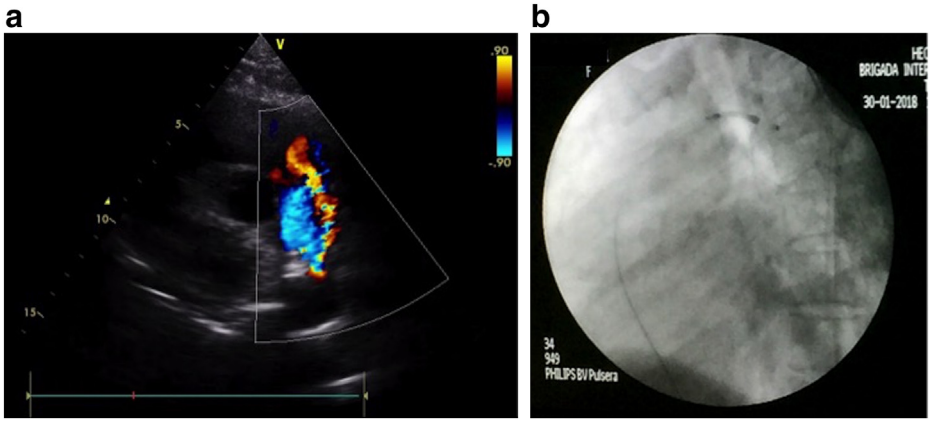

Fig. 4. A: Trans-thoracic echocardiography showing long, thin, patent ductus arteriosus.
B: Post-deployment fluoroscopy showing placement of ductal occlude, which was deployed from the venous side of the ductus arteriosus.

the aortic ampulla. Small hand angiograms through the delivery sheath show the anatomy well after the large ductal flow has been reduced and confirm that the occluder is properly positioned. When delivering the AVPII transvenously (as in case 3) the distal disk and middle lobe are deployed in the aorta and "snugged in" and the proximal disk is deployed in the pulmonary artery. A hand angiogram through the delivery sheath demonstrated capture of the pulmonary end of the ductus by the occluder, and transthoracic echocardiography confirms that the occluder is free from the lumen of the aorta.

When percutaneous closures are performed in a resource-constrained environment and cost is to be minimized, a single occluder is often pre-selected for each patient based on transthoracic echocardiography. In these cases, the AVPII can be preferentially selected over other devices due to its versatility. For our cases performed in Leon, Nicaragua, the use of the AVPII produced excellent results and maximized stewardship. This cost savings may also be advantageous for treating adults with patent ductus arteriosus in domestic hospitals where maintaining and inventory of the full range of ADOI occluders may not be justifiable, given their infrequent use.

4. Conclusion

Adults with patent ductus arteriosus have unique anatomic and technical features. This case series illustrates these features and demonstrates the utility of the AVPII to overcome some the challenges of percutaneous transcatheter closure of the patent ductus arteriosus in adult patients.

Declarations of Interest

None.

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