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Results of the Transcatheter Closure of Various Vascular Anomalies and Cardiovascular Shunt with the Amplatzer Vascular Plugs 2 And 4

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Abstract

Background: A wide variety of abnormal congenital or acquired vascular connections, which may lead to intra/extracardiac shunts, heart failure, and cyanosis, require closure. This study aims to evaluate the safety and efficacy of Amplatzer vascular plugs (AVPs) 2 and 4 in the closure of these connections.

Methods: This is a retrospective analysis of 0.6 to 21-year-old 16 patients treated with AVP2 and AVP4 between 2015 and 2019 in a tertiary heart care centre. The target vessels were demonstrated by angiograms. The diameters of the narrowest segments were chosen as the reference. The ratio of device size to the vessel diameter was calculated. Devices were selected to be 30-50% larger in size for the complete occlusion. The size and number of devices were recorded. The diameters of the vessels were ranging between 2.3 and 14.7 mm while those of the devices were between 4 and 22 mm.

Results: A total of 25 AVPs were successfully implanted, 18 of them with AVP2 (72%) and 7 of them with AVP4 (28%), in 16 patients. APCA (52%), PAVM (20%), pulmonary ante grade flow (8%), venovenous communication after Norwood stage 2 (4%), scimitar vein (4%), excluded hepatic vein (right atria-hepatic vein communication) after Fontan completion (4%), PDA (4%) and residual VSD (4%) were totally occluded. The device-to-vessel ratio was a median of 1.55 for AVP4 and 1.46 For AVP2 devices. Neither complication nor residual shunt was experienced during and after the occlusion procedures.

Conclusion: Because of the excellent design of AVP2 and AVP4 devices, vascular anomalies of various sizes and structures, as well as cardiovascular shunts can be closed safely and efficiently as an alternative to surgery. Complete occlusion can be achieved by a single AVP2 device even in large, high flow abnormally-shaped vessels and AVP4 for tortious, elongated, and small vessels.

Keywords: Vascular plugs; cardiovascular shunt; Vascular malformation; Vascular occlusion

Introduction

A wide variety of abnormal congenital or acquired vascular connections, which may lead to intra/extracardiac shunts, heart failure, and cyanosis, require closure. These are natural

communications such as patent ductus arteriosus (PDA), aortopulmonary collateral artery (APCA), pulmonary arteriovenous malformations (PAVM), ventricular septal defect (VSD), atrial septal defect (ASD), or unwanted shunt or communications created or developed after surgery [1-8]. The number of surgically treated congenital heart disease (CHD) cases, some of which require recurrent surgical or angiographic procedures, has been increasing every day. Patients with single ventricle physiology or major APCA dependent pulmonary circulation are more prone to develop vascular anomalies. Fontan and Glenn shunt surgeries may result in abnormal vascular connections or pulmonary arterial flow leading to increased pulmonary pressure. Transcatheter closure may be applied to these patients as an alternative to surgery [2]. Since the first interventional closure of PDA by Porstmann in 1967, occluder devices have been substantially improved. These advanced devices have enabled the closure of various congenital and acquired vascular abnormalities, shunts, abnormal venovenous connections, surgical shunts, and other miscellaneous lesions. Many centres have preferred AVP2 and AVP4 for the closure of abnormal vascular structures since CE-mark approved their clinical use in 2007 and 2009. They are of self-expanding and low profile nature comprising two (AVP4) and three (AVP2) fine mesh lobes of Nitinol wire. Platinum marker bands at the ends make the device highly visible under fluoroscopy [7]. The AVP4 is available in 4-8 mm diameters (1-mm increments) and AVP2 in 3-22 mm (>4 mm diameter, 2-mm increments). The AVP4's profile is slim enough to require a 5F diagnostic catheter. However, having a limited available size up to 4-8mm is a big disadvantage of this device. It can only be used for vessels smaller than 6 mm. AVP2 devices can be deployed through 5Fr guide for sizes 3-8 mm, and 6-9Fr guide for the largest sizes 18-22 m [4].

Material and Methods

We conducted a retrospective analysis of 0.6 to 21-year-old (median: 7.5years) 16 patients, 6 males and 10 female patients, who underwent vascular occlusion procedure with AVP2 and AVP4 in our institution between 2015 and 2019. 18 AVP2 and 7 AVP4 devices were used in 25 target vessels. Urgent closure was required for three of them, whereas the other 22 were elective procedures. Target blood vessels were demonstrated by angiograms. The diameters of the narrowest segments were chosen as the reference. The ratio of device size to the vessel diameter was calculated. Devices were selected to be 30-50% larger in size for the complete occlusion. The size and number of devices were recorded. The mean device-to-vessel ratio was also recorded. AVP2 was used to occlude extracardiac shunt, large PAVM, and medium to large high flow tubular vascular structures, and AVP4 for tortious, elongated, and small vessels. All the interventions were performed under deep sedation or general anaesthesia. Patients received 50-100 IU/kg heparin throughout the procedure. Standard antibiotic prophylaxis was administered to all patients. The primary occlusion rate was checked for every implanted device. The pulmonary arterial pressures, cutaneous oxygen saturation of the patients were recorded before and after closure. Besides, the urinary output and the dosage of inotropic support of the patients followed in the intensive care unit were recorded. Any device or procedure-related complaints or complications were also documented. The study was approved by the Institute's Ethics Committee. Informed, written consent was obtained from all participants/parents.

Results

A total of 25 AVPs were successfully implanted, 18 of them with AVP2 (72%) and 7 of them with AVP4 (28%), in 16 patients. The mean device-to-vessel ratio was 1.46 for AVP2 and 1.55 for AVP4. Patients' characteristics, diagnoses, and details about the closure with AVP's were listed in Tables 1 and 2. Most of the patients had biventricular physiology. The major indications for AVP use included the closure of APCA (52%), PAVM (20%), pulmonary antegrade flow (8%) and venovenous communication after Norwood stage 2 (4%), Scimitar vein (4%), excluded hepatic vein (right atria-hepatic vein communication) after Fontan completion (4%), PDA (4%) and residual VSD (4%) (Table 1,2).

Table 1: *Patient's characteristics.*

Age Of The Patients (Years)	Gender (F/M)	Diagnosis of closure	Type of the Closed Vessel	Closure Indication	Outcome
4	F	Corrective surgery VSD-APCA-PA	Residual APCA	CHF, RF	Inotropic support decreased and extubated
5	F	Corrective surgery VSD-APCA-PA	Residual APCA	Pulmonary haemorrhage, CHF, RF	Inotropic support decreased and extubated
4	M	VSD -PA-APCA	APCA	Preparation corrective surgery	Operated

1	M	Tetralogy of Fallot	APCA		Operated
2	M	Glenn operation, functional single ventricle	Pulmonary antegrade flow	Head and neck edema	Mean pulmonary pressure decreased 19mmHg to 12mmHg
10	F	Fontan surgery	Pulmonary antegrade flow	Dyspnea, fatigue	Increased effort capacity
13	F	Fontan surgery	RA-HV communication	Cyanosis	sO_2 increased from 80% to 92%
3	F	Glenn shunt- Single Ventricle	APCA	Preparation Fontan	Fontan completed
4	M	Norwood Stage 2, HLHS	APCA	Preparation Fontan	Fontan completed
2	M	Norwood Stage 2, HLHS	APCA	Preparation Fontan	Fontan completed
21	F	Kawashima operation, functional single ventricle	PAVM	Deep cyanosis	sO_2 increased from 60% to 90%
12,16*	F	Congenital PAVM	PAVM	Cyanosis, Clubbing	sO_2 increased from 80% to 98%
16	M	MVR, residual Swiss cheese VSD	VSD	Dyspnoea, fatigue	Increased effort capacity
7	F	PAH-MAPCA	APCA	Dyspnoea, fatigue	Increased effort capacity
3	F	Scimitar Syndrome	Scimitar vein and artery-	Effort dyspnoea	Increased effort capacity
17	F	PDA	PDA	Effort dyspnoea	Increased effort capacity

CHF: congestive heart failure, HLHS: hypoplastic left heart syndrome, F: Female. M: Male, APCA: aorto-opulmonary collateral artery, MVR: mitral valve replacement, PA: pulmonary atresia, PAVM: pulmonary arteriovenous malformation, PDA: patent ductus arteriosus, PAH: pulmonary arterial hypertension, RF: renal failure, VSD: ventricular septal defect
*closed twice for the 12 and 16 years old (3 devices)

Table 2: *Types of AVP devices and the indications of plug choice.*

Site Intervention	No. of vessel	Type of device	No. Of devices	Device size (mm)	Closure dimater (mm)	Device /vessel Ratio (mm)
APCA	13(52%)	AVP 2 AVP 4	9 4	6-14 4, 5, 6 and 8	6.5 (4.1-9,6) 3.8 (2.3-5.3)	1,50 (1.39-1.71) 1.48 (1,31-1.67)
PAVM	5 (20%)	AVP 2 AVP 4	3 2	10, 12 and 22 7 and 8	11.4(8.2-14.7) 4.7(4.2-5.3)	1.47(1.46-1.49 1.58(.151-1.66)
Pulmonary Valve	2(8%)	AVP 2	2	8 and 9	5.8(5.2-6.4)	1.45(1.40-1.53)
Scimiter Vein	1(4%)	AVP 2	1	14	9.1	1.53
Azygos Vein	1(4%)	AVP 4	1	7	4.7	1.60
Exluded Hepatic Vein	1(4%)	AVP2	1	12	9	1.33
PDA	1(4%)	AVP2	1	4	2.65	1.50
Residual apical VSD	1(4%)	AVP 2	1	20	13	1.53

APCA: aorto-pulmonary collateral artery PAVM: pulmonary arteriovenous malformation, PDA: patent ductus arteriosus, VSD: ventricular septal defect.

APCA

APCA closure was performed by placing 14 devices (10 AVP2 and 4 AVP4) into 13 vessels in seven patients. Three of them had VSD with pulmonary atresia, two patients had Tetralogy of Fallot, one patient had normal intracardiac anatomy with pulmonary arterial hypertension (PAH), and one patient had scimitar syndrome. All 13 vessels were completely occluded by angiography. Two patients underwent emergency intervention. Pulmonary hemorrhage, renal insufficiency, and heart failure resistant to inotropic agents developed in two patients following the corrective surgery of pulmonary atresia-VSD-major APCA. Large residual APCAs were detected and occluded totally by AVP2 devices. The hemodynamic parameters of the patients improved after the closure. 2 large APCAs were detected in the angiography of another case which we followed in our outpatient clinic due to PAH without congenital heart disease. The mPAP decreased from 78 mmHg to 46 mmHg after the occlusion of these vessels by two AVP4 devices. There was no change in mPAP in the control angiography performed four years after the closure. The patient had been receiving both iloprost inhalation and bosentan treatment before the procedure. She has been followed asymptomatically by only bosentan treatment since the closure.

PAVM

Two patients underwent occlusion of PAVM. A total of four devices were placed in four PAVMs and all of them were successfully occluded. One patient had a normal cardiac structure, but a large PAVM was detected in the right pulmonary middle lobe. After the occlusion of this PAVM by a 22mm AVP2 device, an extra PAVM was detected at the proximal side of the occluded vessel in the control injection. The device was recaptured three times successfully and repositioned until the two PAVMs were occluded. The oxygen saturation was raised from 80% to 99% by the closure. However, this patient was admitted to the hospital with a complaint of cyanosis 4 years after the procedure. In the pulmonary angiography, enlargement of the PAVMs that were previously small and new PAVMs were observed. The oxygen saturation increased after the closure of the right lung lower lobe fistulas by 12mm and 10mm AVP2 and 10mm devices (Figure 1,2).

In another case, who developed cyanosis after the Kawashima operation, two PAVMs detected in the catheter angiography were occluded by 8 and 7mm AVP 4 devices. Her oxygen saturation raised from 66% to 85% after the occlusion. The hepatic veins of the patient were anastomosed surgically to the pulmonary system after her physical condition improved.

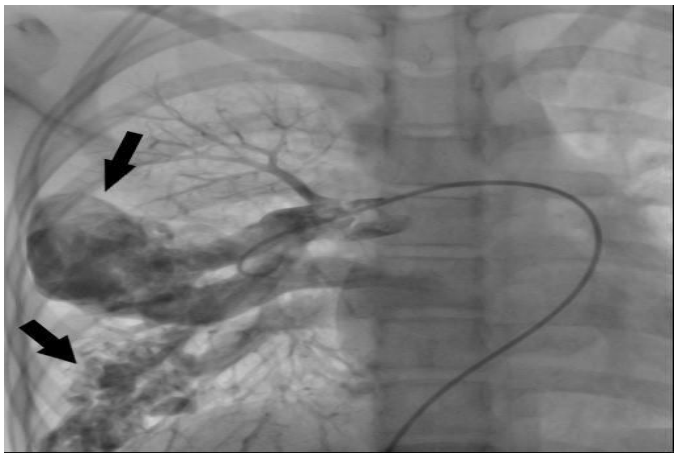

Figure 1: *Multiple arteriovenous malformations in the middle (giant) and lower lobes (black arrows) were detected in the right pulmonary artery injection to a 12- year-old patient.*

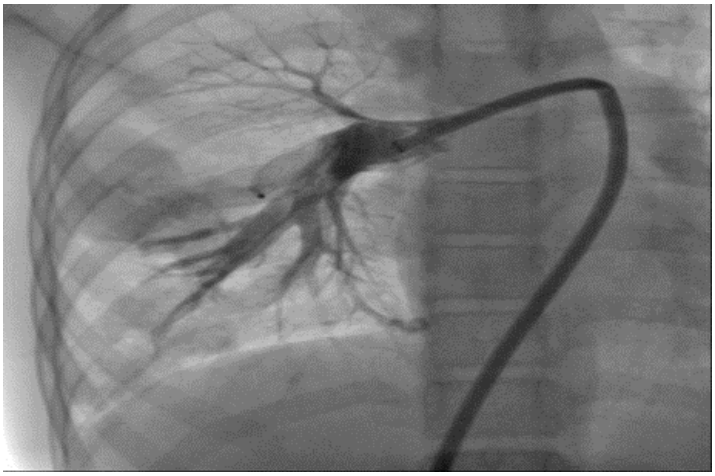

Figure 2: *Angiocardiography performed 4 years later, because of an increase in the patient's cyanosis, showed enlargement in the previously small aneurysms.*

Pulmonary Ante grade Flow

Two patients underwent pulmonary ante grade flow closure with AVP2 devices. One of these cases had developed superior vena cava syndrome while being followed in the intensive care unit after the Glenn shunt operation. The pulmonary ante grade flow was closed by 8mm AVP 2, thereby decreasing the mean pulmonary arterial pressure (mPAP) from 19 mmHg to 12 mmHg. The other case with the pulmonary ante grade flow after Fontan circulation was closed by a 9mm AVP2 device (Figure 3,4).

Miscellaneous

In a 6-year-old patient with Scimitar Syndrome with impaired right pulmonary artery peripheric perfusion, a 14mm AVP2 device was used to close the Scimitar vein. The patient has had no symptoms for the last 5 years. Azygos vein-inferior vena cava communication was detected in the catheter angiography of another patient, 3-year-old with Norwood stage 2 operation, before the Fontan operation.

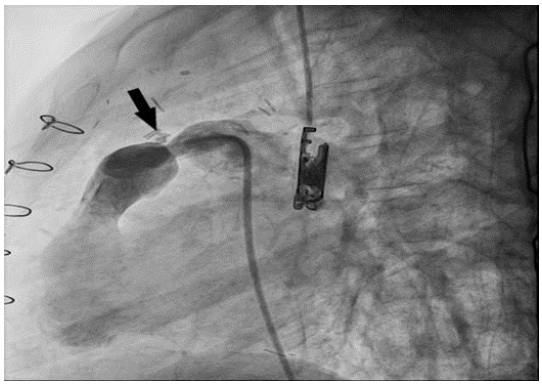

Figure 3: *Pulmonary antegrade flow before closure.*

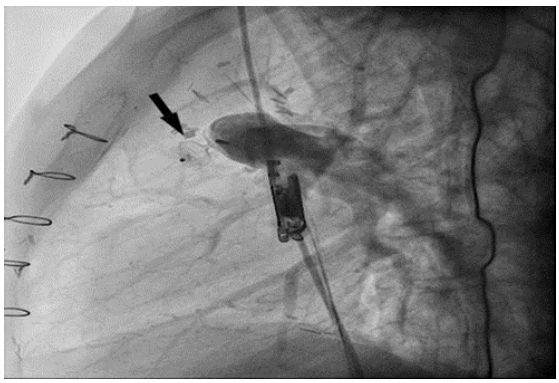

Figure 4: *Pulmonary antegrade flow after closure.*

This vein was closed by 7 mm AVP4. As no increase was detected in the PA pressure in the control angiography of the patient, Fontan operation could be performed 6 months later from the closure. A 10-year-old girl presented with fatigue and oxygen saturation of 80% following the Fontan completion surgery. Direct transhepatic access into the excluded hepatic vein by angiography demonstrated a large right to left shunt from the left side of the liver, as well as left middle collateral veins entering into the right atrium. After the test balloon occlusion, a 12-mm AVP2 was delivered inside the excluded vein, the first lob was seated on the floor of the right atrium, and the other two lobs were situated by pulling towards the hepatic veins. Control angiogram demonstrated complete occlusion of the excluded vein. After this communication was completely closed by 12mm AVP2, the oxygen saturation increased from 80% to 92%. The large residual Swiss cheese apical muscular VSD of a 14-year-old patient was closed by 20 mm AVP2. The echocardiography performed a week later from the closure showed an improvement in the left ventricular functions and the effort capacity of the patient (ejection fraction increased from 55% to 65%). A patient's long tubular PDA was closed with 4mm AVP2. We observed no inadvertent device-related obstruction of neighboring vessels, nor any device embolization, vascular disruption, or any other procedure-related complication. Angiographic evidence of mild residual shunt was observed in three patients after the closure with AVP4, which disappeared in the control contrast agent injection performed after 10 minutes (Figure 5,6).

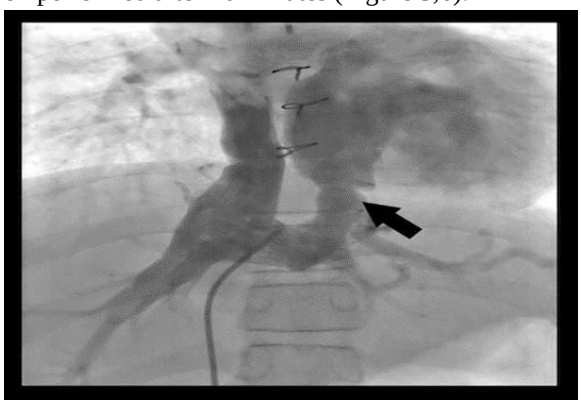

Figure 5: *10-year-old girls, the inferior cava vein angiography demonstrated hepatic vein-right atria communication (black arrow).*

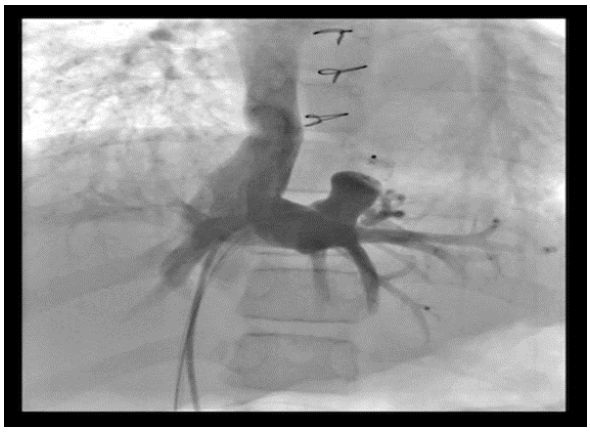

Figure 6: *Control angiography after the closure by12mm AVP2. Black arrow indicated AVP2 devices.*

Technical Details

The device was placed through the femoral venous or arterial access. In three patients, a jugular approach and carotid artery were used. In two of these patients, with modified Glenn shunt, the right jugular vein was preferred to close the ante grade flow. As it was not possible to reach the APCA's, developed after the surgical correction of pulmonary atresia-VSD-major APCA, of the third patient through the femoral artery, the right carotid artery was used to reach the target vessel. The most common catheter used for plug delivery was the 5Fr guiding catheter, 6, 7, 9Fr flexor sheath (cook), and Amplatzer duct occlude delivery. In cases where the position was not suitable after the opening of the

device, it was recaptured and placed repeatedly. We didn't observe any deformity or problem with the configuration of AVP devices during repeated applications. The radiopaque band on both sides of the device provided us a better view of the device. After 10 minutes of deployment, no residual flow was observed. Successful deployment of the device and complete flow occlusion across the vessel could be achieved in all patients.

Discussion

Transcatheter closure may be preferred as an alternative to surgery in native, postoperatively developed, or surgically created vascular malformations. The experiences of AVPs have been increasing since its first introduction [5,6]. One of the first studies about the use of AVP devices was a multicenter study. The indications for the use of AVP1 in this study were collaterals, fistulas, transhepatic tracts, central shunts, PDA, and excluded hepatic vein. AVP1 was the most common device used before AVP 2 became available for clinical use. Then AVP2 has become the most commonly used type due to its better occlusive properties. A study about the use of AVP1 and AVP2 devices for closure of PDA, venous collateral, APCA, Modified BT shunt, portosystemic communication, and miscellaneous. Their institution preferred AVP 2 for occlusion procedures due to its occlusive properties and lower profile design. In another study where AVPs were mostly used for the closure of extracardiac (pulmonary or systemic circulation and aortopulmonary collaterals) and intracardiac (coronary AVM and pulmonary valve closure) shunts, AVP 2 was preferred more. There are some unusual indications, such as the closure of left pulmonary artery pseudoaneurysm, pulmonary antegrade flow, and baffle leak after Fontan completion, partially ligated vertical veins of the patients with the diagnosis of supracardiac total anomalous pulmonary venous connection and post-infarct VSD, where AVP1 and AVP2 were successfully used for closure rather than surgery [9-11]. Unusual indication that they used a 16mm AVP 1 device for the closure of excluded hepatic vein after Fontan completion and then experienced 16-14 ADO device upon the maintenance of a residual shunt. We closed an excluded hepatic vein-right atria communication using a single 12mm AVP 2 device without residual shunt or protrusion into the surrounding tissues. Scimitar syndrome is a rare congenital anomaly treated surgically by ligation or occlusion of the aberrant vascular supply after changing the route of the scimitar vein to the left atrium. A patient in whom they used transcatheter route to occlude the isolated scimitar vein, camouflaged by dual pulmonary venous drainage of the right lung, by an Amplatzer ductal occlude in an ante grade way [12]. An interventional treatment via complete rerouting of anomalous venous drainage to the left atrium using AVP and embolization of aberrant vascular supply [13]. Our Scimitar syndrome case had no right pulmonary arterial perfusion as a rare presentation and her Scimitar vein and abnormal vascular supply were occluded by AVP 2 device, without surgery. Residual APCA, which may rarely be seen following the corrective surgery of pulmonary atresia-VSD-major APCA, should be remembered if the heart failure symptoms are refractory to aggressive cardiac support, including epinephrine infusion, in the early post-surgical period [14]. Hemodynamic instability developed in 2 of our patients in the early postoperative period of unifocalization. We urgently closed their large aortopulmonary collateral arteries by AVP2 device. Although APCA's usually accompany congenital heart diseases, they may rarely be seen as isolated cases and cause pulmonary hypertension. One of our rare presentations was pulmonary hypertension due to the isolated APCA's without a CHD. The mean PAP decreased after the closure of APCA's by AVP4 and the dual (inhaled iloprost and bosentan) treatment of this patient was maintained only by bosentan. It is very important to close the PAVMs completely. The shape (simple or complex), diameter (>3mm, small or large), the neck, and triplet regions of the malformed vessels should be very carefully determined to achieve a complete closure [15-18]. As the recanalization of the large vessels after the coil application is a well-known phenomenon, used AVP1 and coil together for the complete closure of the PAVM's >5mm. They didn't experience recanalization in any of the patients by this technique. AVPs have rapidly become the preferred device for embolization compared with a coil. Advantages include the ability to occlude large-diameter feeding arteries with single plugs, with less procedure time and radiation exposure, easier occlusion at the neck of the sack, and occlusion over a shorter length of the vessel, thereby reducing the risk of occluding vessels supplying normal lung. In our case, three feeding arteries were closed completely by using only a single AVP 2 device to the neck region of the giant and complex PAVM. AVP2 may be preferred to achieve complete closure of the cases with large and complex vascular structures. However, it was observed that there were a large number of PAVMs in pulmonary angiography performed due to an increase in cyanosis 4 years later. The biggest PAVM was closed. Therefore, we suggest a close follow up of these patients for the development of new PAVMs. As already recommended to minimize the risk of residual shunting and AVP closure, it is important to use 30-50% larger plugs concerning the target vessel. Our device/vessel ratio was a median of 1.55 for AVP4 and 1.46 for AVP2, both resulting in an occlusion rate of 100% in the catheter laboratory. These differences may be explained by the AVP's architecture: the AVP 4 has a multi-layered, double-lobed design, whereas the AVP 2 is multi-layered and three-lobed, which enables faster vessel occlusion due to more wire mesh.

Conclusion

In this study, we wanted to share our experiences about the use of different forms of excellently designed AVP devices in various clinical manifestations. AVP2 consists of a nitinol meshwork that allows the closure of intracardiac shunts and large, high flow vascular structures, a trilobate structure allowing faster occlusion with a single device, and minimizing migration and recanalization. A single device can achieve complete occlusion in large, abnormally shaped vessels, residual ventricular septal defects, and pulmonary antegrade flow and excluded hepatic veins. AVP4 requires only a 5F diagnostic catheter and easy deliverability makes it suitable for tortuous and small vessels. As the AVPs are simple, effective, and easy to apply devices, they provide exact, reliable, and cost-effective occlusion of targeted vessels in various clinical situations in selected cases without a significant complication.

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