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Original Article

Early experience on peripheral vascular application of the vascular plugs

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ABSTRACT

Background: Transcatheter closure of various congenital and acquired vascular malformations with Amplatzer Vascular plugs I and II has been established. Here we present our experience with device closure.

Materials and methods: Between October 2006 and August 2012, nine (three males and six females) patients aged between 11 months and 62 years (mean age 19 years) underwent percutaneous device closure with AVP I and II vascular plugs for congenital and acquired arteriovenous malformation and cardiac diverticulum are presented here.

Results: One case of coronary cameral fistula, four cases of pulmonary arteriovenous fistula, one case of large major aortopulmonary collaterals (in tetralogy of Fallot closed before intracardiac repair), one case of congenital cardiac diverticulum, one case of fistula between external carotid artery and internal jugular vein and one case of iatrogenic carotid jugular fistula were successfully closed with AVP I and II plugs. Overall in nine cases, 16 AVP I and II plugs were deployed to occlude feeding vessels and one cardiac diverticulum. The technical success rate was 100%. No major complications were observed.

Conclusion: Amplatzer vascular plugs can be used successfully for closure of various congenital and acquired vascular malformations with good result.

1. Introduction

Portsmann was the first to report transcatheter blood vessel closure in 1967. He had closed patent ductus arteriosus by using Ivalon plug.[1] Advancements in technology have resulted in development of new devices to the interventionist's armamentarium. Amplatzer vascular plugs (AVP; AGA Medical, Golden Valley, MN, USA) have emerged as the new tools for transcatheter embolizations in the peripheral vasculature, occlusion of abnormal vessel communications and congenital cardiac defects. The AVP is a self-expanding cylindrical device, similar to the Amplatzer septal and ductal occluding devices.

2. The Amplatzer vascular plug

The AVP is a self-expandable cylindrical device made of nitinol mesh wires. Its structure allows the device to be compressed inside the catheter, which returns to its intended

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shape when it comes out of the catheter and occlude the vessel. Platinum markers are present on both ends of the device. A stainless steel micro screw is welded to one of the platinum marker bands, which allows attachment to the 135 cm long delivery cable. The available device size ranges from 4 mm to 16 mm in AVP I and 4 to 22 mm in AVP II, with increments of 2 mm. It is preloaded in a loader and delivered through guiding catheters ranging in size from 5 F to 10 F.[2,3] Once positioned by holding the delivery shaft steady and pulling the outer guiding catheter back, it is released by rotating the delivery cable counter clockwise. Device is selected 30%–50% larger than the vessel diameter. Its flexibility allows it to adjust to the vessel shape and over sizing prevents the migration of the device after deployment. Amplatzer vascular plug II (AVP II) and more recently AVP III and AVP IV were designed for better occlusive properties. It contains a finer, more densely woven nitinol, braided in two layers in the smaller devices and three layers in devices bigger than 10 mm.[4] AVP I and IV are single layered, and AVP II and III are multilayered. The use of vascular plug I in patients with congenital and acquired cardiovascular disease had been reported,[2] more recently there was increasing use of vascular plug II in patients with congenital and acquired defects.[4–6] AVP I used for short landing zones, AVP II used for variable landing zones with shorter occlusion time, AVP III for high-flow embolization and AVP IV used for tortuous vessel and rapid embolization.

We describe here our experience with AVP for occluding various peripheral and central arteries and veins, including occlusion of pulmonary arteriovenous malformations (PAVMs) and cardiac diverticulum.

2.1. *Materials and methods*

Between October 2006 and August 2012, nine patients (3 males, 6 females) aged between 11 months and 62 years (mean age, 19 years) underwent percutaneous vessel closure with the AVP. Transfemoral approach was the preferred vascular access and intravenous conscious sedation given for all the procedures.

2.2. *Results*

Patient characteristics and treatment details are described in Table 1. AVP was used for occluding various peripheral and central arteries and veins, including occlusion of coronary arteriovenous fistulas, PAVMs and cardiac diverticulum.

3. Coronary arteriovenous fistula

An eleven-month-old male child with history of failure to thrive and poor weight gain had continuous murmur in right precordial region. Echocardiography showed right coronary artery (RCA) fistula opening into right ventricle. Angiography revealed a large fistula opening from RCA into right ventricle (Fig. 1a). Judkin's right (JR) catheter 5 F was used to hook RCA through the 6 F carotid shuttle sheath (Cook, USA). Terumo wire was passed from fistula to right ventricle and pulmonary artery. Over this JR, 6 F Carotid shuttle sheath was passed up to the point of delivery. Amplatzer vascular plug (AVP I) was deployed. There was partial occlusion of the fistula and clearly visible right coronary artery at end of the procedure (Fig. 1b). There were no signs of RCA territory ischemia post-intervention. Echocardiogram done 24 h later showed no residual flow across the fistula. On follow-up, the child had a grade II systolic murmur and a weight gain of four and half kilograms.

4. Large pulmonary arteriovenous fistulas (cases 2–5 Table 1)

4.1. *Case 2*

A 62-year-old male with history of headache and breathlessness had central cyanosis and clubbing on examination. Echocardiography showed structurally normal heart.

Table 1 – Patient characteristics and procedures done.

Case no	Sex	Age (years)	Indication	Location	Delivery system	Device for total occlusion
1	Male	11 month	Coronary cameral fistula	Right coronary artery	Carotid shuttle sheath 6 F	AVP I plug
2	Male	62	Large PAVM	Both lungs	Cook sheath 6 F	2 AVP II plugs
3	Female	34	Large PAVM	Right lower lobe segment	Cook sheath 10 F	AVP I plug
4	Female	35	Large PAVM	Right lower lobe segment	Cook sheath 11 F	AVP II
5	Male	12	Large PAVM and paradoxical embolism	Left upper lobe segment	Cook sheath 7 F	5 AVP I plugs
6	Female	12	Large MAPCA in tetralogy Fallot	Right upper lobe segment	Judkins right 4 6 F	AVP II plug
7	Female	12	Cardiac diverticulum	Left ventricle	Cook sheath 9 F	2 ADO devices and AVP I plug
8	Male	15	Large neck swelling	Common carotid to internal jugular vein	Carotid shuttle sheath 6 F	AVP II plug
9	Female	13	Large arteriovenous fistula	External carotid to external jugular vein	Carotid shuttle sheath 6 F	AVP II plug

AVP – Amplatzer vascular plug, PAVM – Pulmonary arteriovenous malformation, MAPCA – Major aortopulmonary collateral arteries.

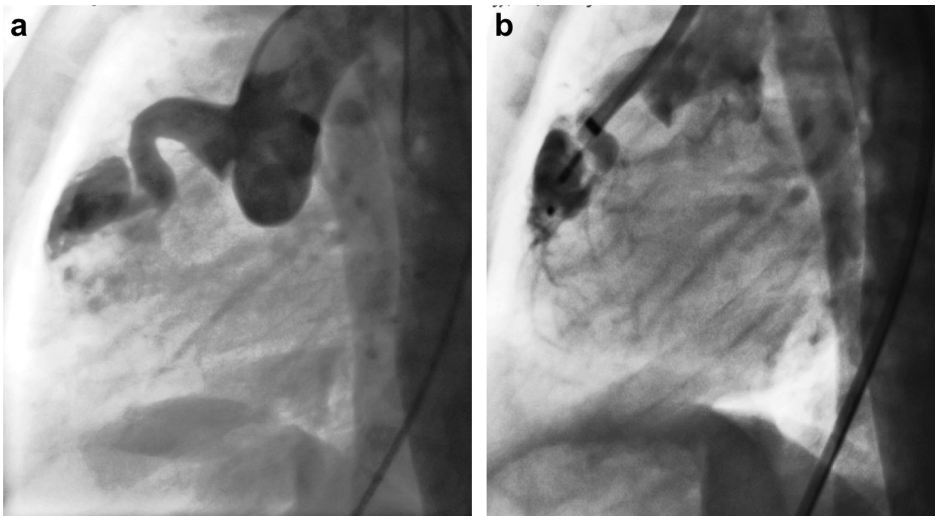

Fig. 1 – a. Coronary cameral fistula into right ventricle. b. Fistula closed by Amplatzer vascular plug I.

Systemic oxygen saturation was 72%. CT pulmonary angiography revealed two pulmonary arteriovenous fistulas, one large fistula in the left posterior basal segment (12 mm) (Fig. 2a) and other small fistula in right basal segment (6 mm) (Fig. 2b). First the left lung fistula was hooked with 6 F Cooks delivery sheath. AVP II 16 mm was deployed. Angiography done 15 min later, revealed complete occlusion of the fistula (Fig. 2c). Saturation improved to 92%. Thereafter, right lung

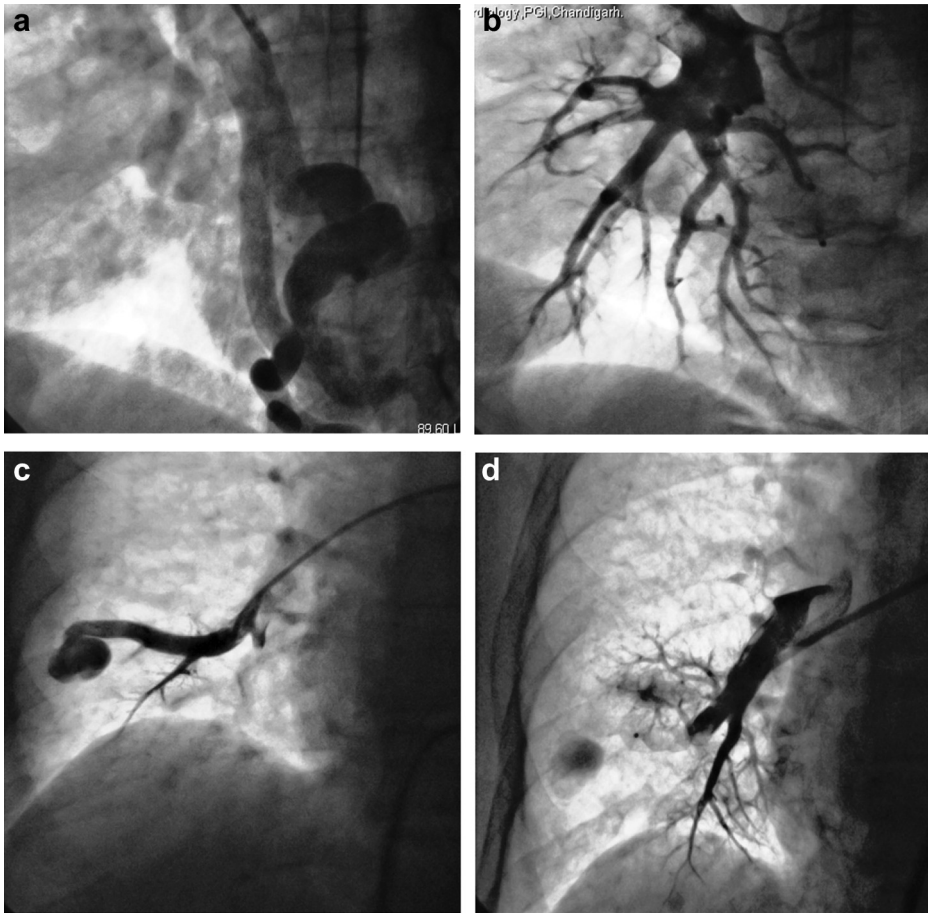

Fig. 2 – a. Left lower lobe pulmonary arteriovenous malformation. b. Right lower lobe pulmonary arteriovenous malformation. c. Left lower lobe pulmonary arteriovenous malformation closed by AVP II 16 mm plug. d. Right lower lobe pulmonary arteriovenous malformation closed by AVP II 8 mm plug.

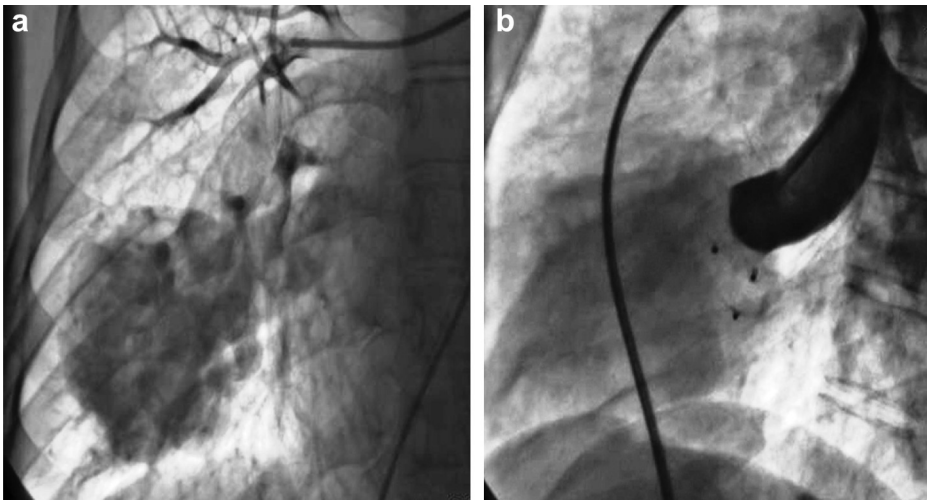

Fig. 3 – a. Right lower lobe arteriovenous malformation. b. Right lower lobe arteriovenous malformation closed by two AVP I plugs.

fistula was hooked with same 6 F Cooks sheath. AVP II 8 mm was deployed with complete occlusion of the fistula (Fig. 2d). At end of procedure, systemic saturation improved to 96%. Six months on follow-up, patient was asymptomatic with systemic oxygen saturation of 97%.

4.2. *Case 3, 4*

A 34-year-old female with cyanosis and clubbing, structurally normal heart having systemic desaturation of 84%. CT pulmonary angiography showed arteriovenous fistula in right basal posterior segment of lung. Right sided arteriovenous fistula was demonstrated on angiography (Fig. 3a) with two feeding arteries, one of 14 mm size and the other of 10 mm size in the right lower lung. Site of feeder vessel was hooked with 10 F Cooks delivery sheath. Two AVP I sized 18 mm and 12 mm were deployed in the fistula. Angiography done 15 min later revealed complete occlusion of the fistula (Fig. 3b). Systemic saturation improved to 98%.

A 35-year-old female with breathlessness and cyanosis, and structurally normal heart had systemic oxygen saturation of 70%. Angiography revealed a 15 mm arteriovenous fistula in the right lung (Fig. 4a). Arterial feeder vessel was hooked with 11 F Cooks delivery sheath and AVP II 22 mm was deployed in the fistula. Angiography done 15 min later revealed complete closure of the fistula (Fig. 4b). Her saturation improved to 95% with relief of dyspnea.

4.3. *Case 5. Large PAVM with paradoxical embolism*

A 12-year-old child with progressive cyanosis for five years presented with headache, fever, single episode of right focal seizure and weakness in his right half of body. On examination, he was drowsy with central cyanosis, clubbing and tachypnea with systemic desaturation of 65%. He had structurally normal heart. Neurological examination revealed loss of power in right upper and lower extremities. Chest X-ray showed normal cardiac size and inhomogeneous opacity with fewer linear channels in left upper lung fields. Electrocardiogram and echocardiography were normal. Contrast echocardiography suggested the presence of intrapulmonary arteriovenous malformation with significant right-to-left

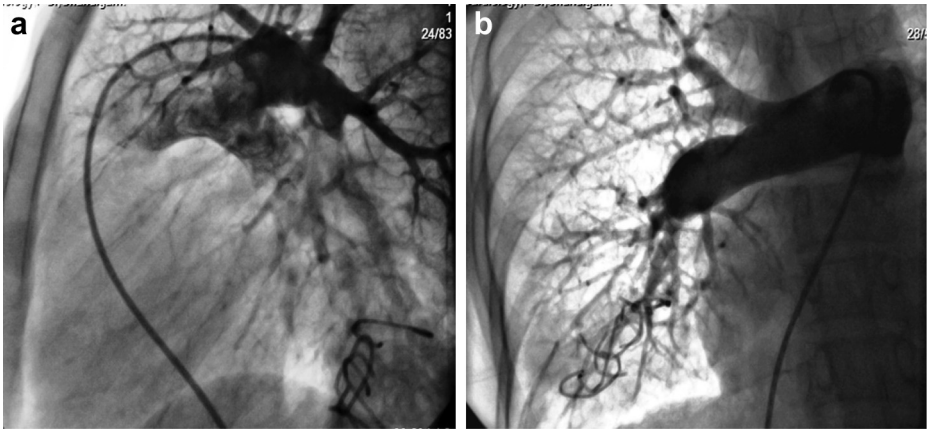

Fig. 4 – a. Right lower lobe arteriovenous malformation. b. Right lower lobe arteriovenous malformation closed by AVP II plug.

shunt. Computer tomography (CT) chest revealed large arteriovenous malformation in the left upper lobe (Fig. 5a). Pulmonary angiography confirmed the presence of large left intrapulmonary arteriovenous malformation with multiple feeder vessels. The boy underwent percutaneous closure of the PAVM with five Amplatzer vascular plugs using Cook 7 F delivery sheath. It was done as a staged procedure. At first stage, three AVP I plugs 14 mm, 12 mm and 10 mm were deployed and oxygen saturation improved to 75%. After the deployment of two more AVP I plugs 16 mm and 14 mm, oxygen saturation improved further to 92% on room air (Fig. 5b). Repeat chest X-ray showed marked reduction of opacity.

A contrast enhanced CT scan (Fig. 5c) of his head revealed a left-sided hypo-dense parietal lesion (5 × 4 cm) with cystic, contrast ring enhancement and peri-lesional edema exerting a significant mass effect. A left-sided osteoplastic craniotomy was performed and white-yellowish pus was aspirated from the encapsulated mass. The histopathology revealed a brain abscess. He was put on empirical broad spectrum antibiotics. Actinomycosis species were identified. Follow-up CT scan of his head 7 weeks after surgery showed resolution of his brain abscess lesion (Fig. 5d). At six months on follow-up, the patient was asymptomatic with a saturation of 96% with small residual opacity on chest X-ray (Fig. 5b).

5. Major aortopulmonary collaterals

5.1. *Case 6. Closure of large aortopulmonary collateral in tetralogy of Fallot*

A 12-year-old male diagnosed case of tetralogy of Fallot with large aortopulmonary collateral to the right upper lobe of lung. He was planned for percutaneous closure of collateral prior to total intracardiac repair of the defect. He had systemic desaturation of 84%. Aortogram with 6 F pigtail revealed large aortopulmonary collateral to the right lung of size 8 mm (Fig. 6a). In view of large collateral, our institute policy is to deploy an Amplatzer vascular plug instead of multiple coils. Judkins right 4 was used to hook the aortopulmonary collateral and AVP II 9 mm was used to occlude the collateral. Angiography done post device deployment revealed complete occlusion of the collateral (Fig. 6b). Post procedure systemic saturation was 78%. The patient was taken up for intracardiac repair post procedure.

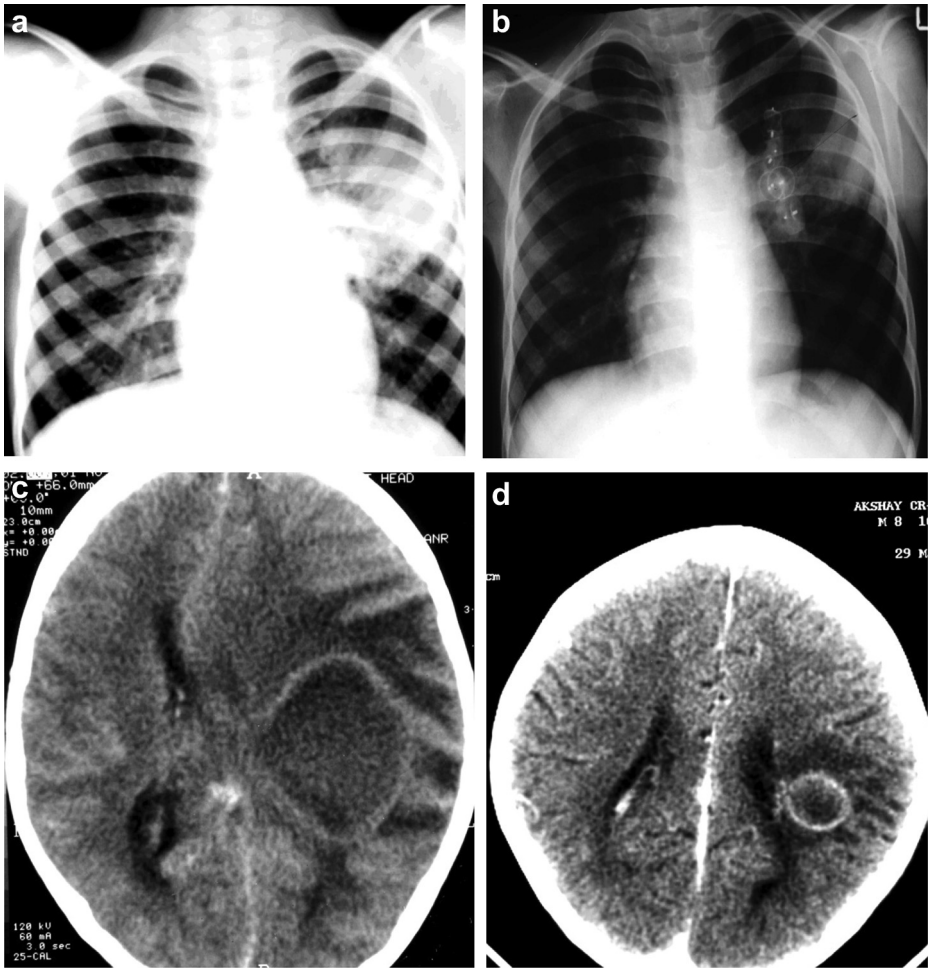

Fig. 5 – a. CT chest of large PAVM in left upper lobe. b. Angiographic image of post device closure of fistulae with AVP I plugs. c. Left parietal-occipital abscess on CT head. d. CT head after surgery and antibiotics.

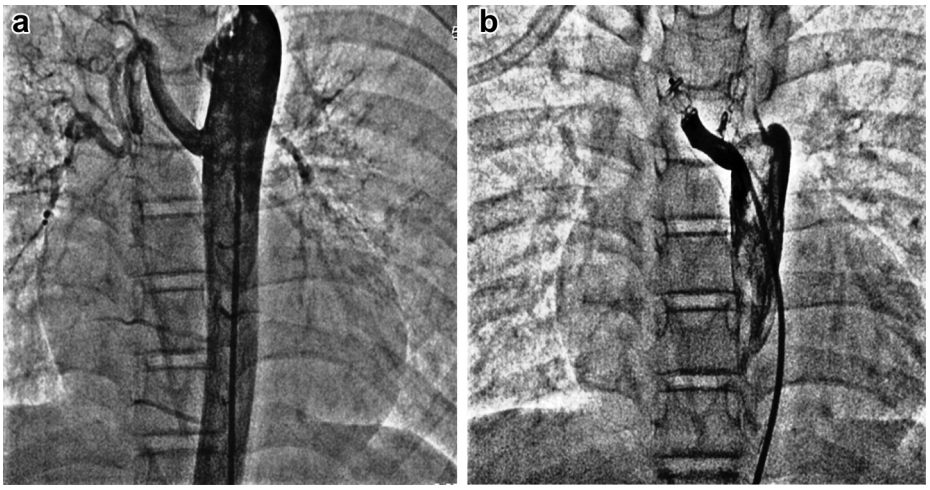

Fig. 6 – a. Large aortopulmonary collateral to right lung. b. Occlusion of collateral with AVP II plug.

6. Cardiac diverticulum[7]

A 12-year-old girl presented with palpitations and two episodes of syncope. Holter monitoring did not reveal any ventricular tachycardia or sinus pause. Echocardiography revealed a suspicious defect in left ventricular outflow tract. Transesophageal echocardiography revealed a thick muscular wall diverticulum in left ventricular outflow tract with dimension of 15 × 17 mm. Device closure of the diverticulum was taken through right femoral arterial access. Angiogram showed cardiac diverticulum anterior to left ventricle attached to the left ventricular outflow tract via 8 mm shaft (Fig. 7a). Diverticulum was hooked with 5 F Judkins right diagnostic catheter and it was exchanged with 9 F Cooks delivery sheath. Initial attempt was made to close with 10 mm Amplatzer duct occluder I. But on release the device prolapsed into the diverticulum. Thereafter 8 mm, AVP I was used to fill the diverticulum which had also prolapsed and finally another 10 × 12 mm Amplatzer duct occluder I was placed at the neck of diverticulum. Finally, the diverticulum was completely occluded. Left ventricular angiography repeated two days later showed complete occlusion of the diverticulum (Fig. 7b). Presently, she is asymptomatic at one and half years of follow-up.

7. Iatrogenic carotido-jugular arteriovenous fistula

A 15-year-old male with neuroblastoma and obstructive hydrocephalus underwent emergency shunt surgery, during which central venous catheter was placed in right internal jugular vein by the anesthetist. Two weeks later, patient noticed right neck swelling. Clinical examination revealed the presence of thrill over the swelling. CT angiography of neck vessels showed a large fistulous tract from right common carotid artery to right internal jugular vein. In view of difficult and high risk vascular access surgically, he was referred for device closure. Angiography confirmed fistulous tract between brachiocephalic trunk and right internal jugular vein (Fig. 8a). Judkins right catheter 6 F was placed in the

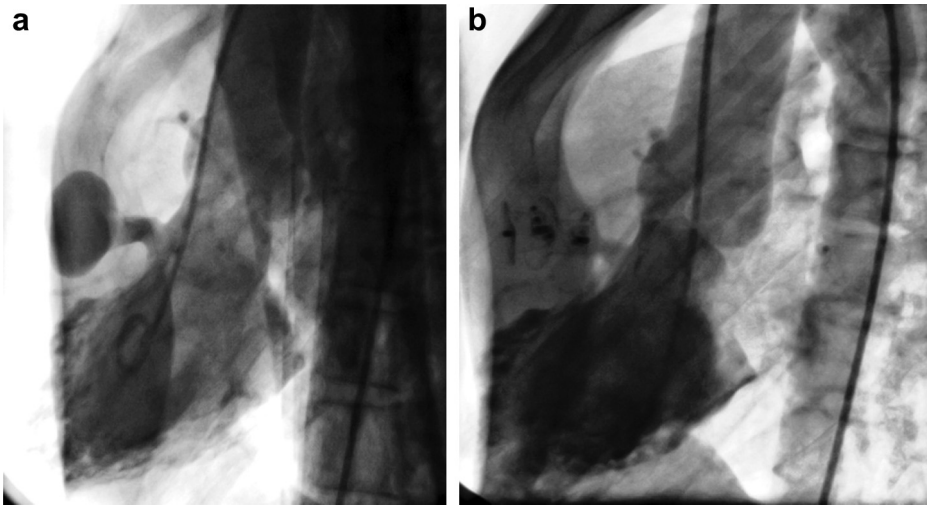

Fig. 7 – a. Left ventriculogram showing cardiac diverticulum anterior to left ventricular outflow tract. b. Diverticulum completely occluded by AVP I plug and ADO I devices.

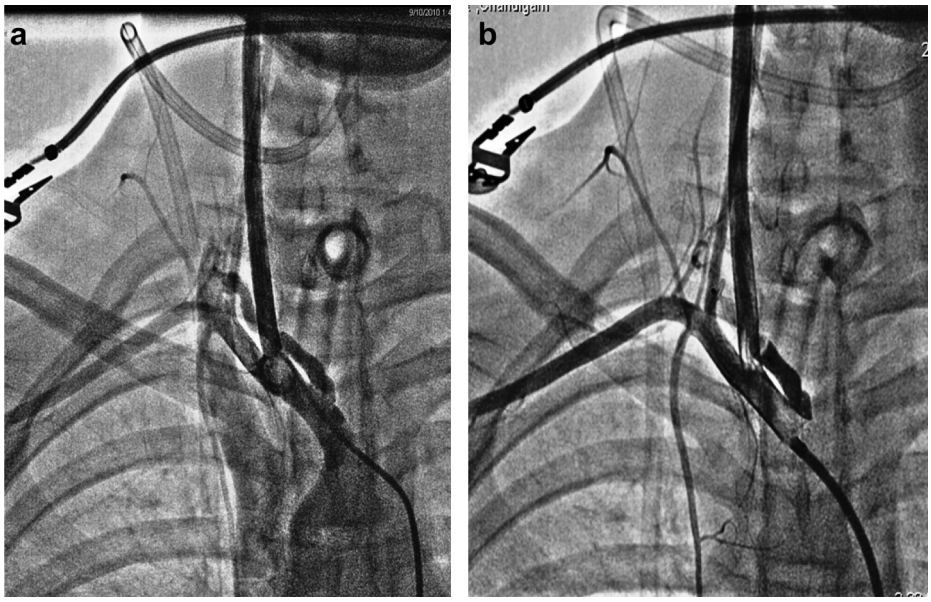

Fig. 8 – a. Iatrogenic right carotido-jugular arteriovenous fistula. b. Fistula closed by AVP II.

brachiocephalic trunk. Terumo wire was passed through the fistulous tract into the internal jugular vein. Carotid shuttle sheath 6 F was advanced into the internal jugular vein through the fistula. AVP II 8 mm was deployed to occlude the fistula. Angiography done after 15 min showed complete occlusion of the fistula (Fig. 2b). Repeat CT angiography after two months showed complete occlusion of the fistulous tract.

8. Carotido-jugular fistula: arteriovenous fistula of left external carotid artery to left internal jugular vein

A 13-year-old girl presented with increasing neck swelling on the left side of mandible for two years. Clinical examination revealed a continuous murmur over the swelling. CT angiography of neck vessels revealed a fistulous communication between left external carotid artery and left internal jugular vein. Selective angiography with multipurpose catheter confirmed the fistulous tract (Fig. 9a). Carotid shuttle sheath 6 F was advanced over the left external carotid artery. AVP II 12 mm was deployed across the fistulous tract. Angiography after 15 min did not reveal any residual flow but the left external carotid artery was completely occluded (Fig. 9b). Post procedure she had recurrent vomiting that stabilized over 48 h with anti-emetics. At one year of clinical follow-up, only mild symptoms of jaw claudication existed.

9. Discussion

Use of AVP I and II was approved by FDA in May 2004 and September 2007, respectively. Their use had been reported for various conditions, like peripheral vessel malformations,[3] pulmonary AVMs,[8–10] venous collaterals,[11] aortopulmonary collaterals,[12] coronary fistulae,[13–15] patent ductus

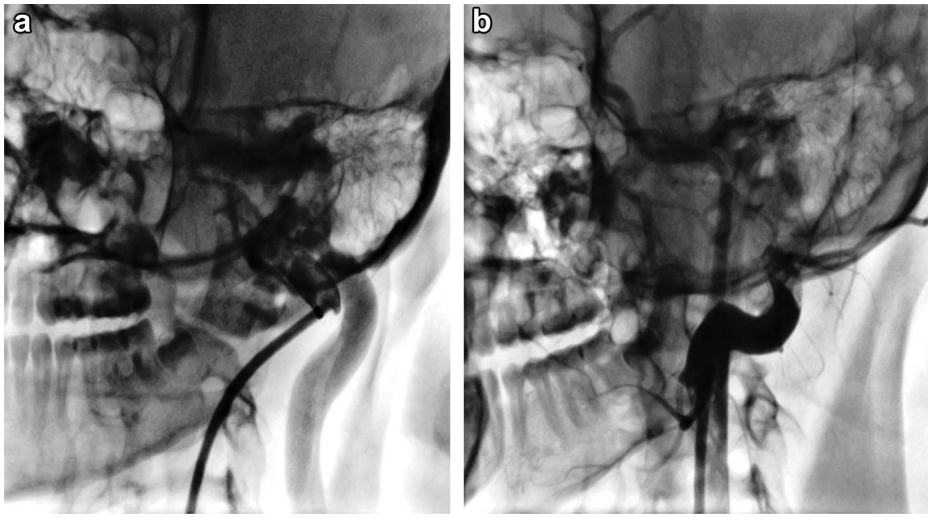

Fig. 9 – a. Carotid jugular arteriovenous fistula. b. Fistula closed by Amplatzer vascular plug II.

ateriosus,[16,17] modified Blalock–Taussig shunts,[18] Fontan fenestrations,[19] ventriculo-pulmonary connections,[20] vena cava aneurysms,[21] perivalvular leaks,[22] and porto-systemic connections.[23] AVP I device use was reported in many studies which were mostly small series with lesser number of reports on use of AVP II.[4–6] Occlusion is not achieved immediately after the deployment of the device. Due to this, the risk of distal embolization during slow thrombosis of the device in the vessels at risk like carotids remains with subsequent neurological complications.[24,25]

Hill et al described the use of AVP I in patients with congenital heart disease in United States across 11 centers.[2] Fifty-two patients were included in that series. The most commonly occluded vessels were aortopulmonary collaterals (42%) and pulmonary AVM's (32%). Venous collateral vessels, trans-hepatic tracts, surgical shunts, PDA and coronary artery fistulae were also treated. 94% complete occlusion rate at the time of catheterization was noted with AVP I. No major complications were reported. One device had to be electively removed from a PDA due to significant residual flow.

Schwartz et al[26] reported AVO I and II for occlusion of various congenital heart diseases. AVP II had taken over AVP I for occlusion procedures because of its better occlusive properties and lower profile design. It had been particularly useful for occlusion of high-flow tubular lesions (type C–E PDA's, aortopulmonary collaterals, AVMs). In our study, a case of TOF who was being taken up for corrective surgery underwent successful closure of major aortopulmonary collateral by AVP II device just prior to surgery.

In our study, transcatheter embolization with vascular plugs was performed for pulmonary arteriovenous malformations, coronary arteriovenous malformation, major aortopulmonary collateral, iatrogenic carotido-jugular fistula, external carotid artery to internal jugular vein fistula and congenital cardiac diverticulum. AVP I was used in three patients and AVP II was used in six patients. No complications were seen secondary to AVP closure of the pulmonary artery feeders. Sixteen AVP I and II vascular plugs of 6–22 mm in diameter were used in nine patients to occlude nine vessels and one diverticulum. 5 F guiding sheaths were used for 4-, 6-, and 8 mm size plugs, 6 F guiding sheaths were used for 10- and 12 mm plugs, 8 F guiding sheath was used for a 16 mm plug and 11 F guiding sheath was used for 22 mm plug. The diameter of the AVP was chosen to be approximately 30%–50% greater than that of the blood vessel, as recommended by the manufacturer. The radio-opacity of the device was sufficient, allowing easy visualization under fluoroscopy. In each case, the final localization of the AVP was confirmed with angiography before its release. The technical success rate was 100%, with total occlusion of all the target vessels. There was no incident of device embolization, or vascular disruption. There was device dislodgement in the case with cardiac diverticulum, which was managed with additional device occlusion. Patency of the embolized vessel was checked with serial contrast injections from the guiding catheter and occlusion of the embolized vessel was confirmed by final angiography. Target vessel occlusion time after deployment of the AVP was 6–10 min (mean, 7.5) in pulmonary arteries, 10–35 min (mean, 24.4) in systemic arteries. Follow-up imaging (range, 1–6 months) was obtained with contrast enhanced computed tomography (CT) in four patients and conventional angiography in five patients all of which showed complete occlusion of the embolized vessels. Clinical follow-up was done in all the patients.

Pulmonary AVMs with afferent arteries more than 3 mm in diameter are known to cause serious neurological symptoms, and its treatment is advocated to prevent paradoxical embolization.[27] Embolization with coils or detachable balloons was the preferred treatment for PAVMs in the past era. Coil embolization of PAVMs had certain shortcomings, such as the need for multiple coils to occlude a single vessel, incomplete occlusion of the vessel, systemic embolization and reflux of coils, and recanalization rates ranging from 5% to as high as 57%.[28–30] The AVP developed as a new tool for the treatment of PAVMs.[2,8,9,12,27,31] Additionally, the risk of embolic device migration and dislodgement was reduced. In our study, we achieved a 100% occlusion rate of PAVMs with no device embolization or migration. In this study in low-pressure venous systems like PAVMs, complete occlusion was achieved in 6–10 min (mean: 7.5 min). The time required for total occlusion of a particular vessel increased with the increase in both vessel diameter and size of the AVP used. Our results are similar to those of Hill et al, who reported complete occlusion within 10 min in 94% of targeted vessels compared to mean occlusion time of 15 min in our study.[6] In our study, four cases of PAVM were closed with total of nine plugs.

Duraisamy et al[32] reported the first the use of AVP to occlude a coronary fistula. AVP has many advantages over other devices previously used for coronary fistula occlusion. The AVP allows for precise deployment due to its complete control of the device until its release and allows the operator to confirm position with hand-injection angiograms via the side-arm of a Tuohy-Borst connection. This is important during occlusion of coronary fistula with branches arising from proximal part of the fistula. Proximal migration can result in occlusion of coronary artery branches which can have fatal clinical consequences.[33] While considering the possibility of proximal migration of an oversized device in a lesion that has wider proximal end, appropriate sizing of the AVP needs to be understood. Due to the possibility of residual shunts, it is good to plan in advance to ensure complete occlusion, especially in locations that appear poorly suited for placing a second plug or another device. In our study, a case of coronary AV fistula was closed through the retrograde approach which had less number of case reports as compared to the more common antegrade approach. In this case, though we had poor visualization of the anatomy of the right coronary artery due the huge coronary cameral fistula, we observed for ischemic changes on electrocardiogram and blood pressure for 30 min before deploying the vascular plug. AVP I was used in the case.

Kelly et al[34] first reported case of successful closure of a subclavian artery to innominate vein malformation by nonsurgical approach in a newborn infant. Sapire et al described a neonate with a left subclavian artery to innominate vein fistulae who presented in congestive heart failure.[35] A subclavian artery to subclavian vein fistula also presenting in a neonate in heart failure was described by Dogan et al.[36] In both of these cases, the fistula was closed by surgical ligation. In our study, a fistulous tract from left

external carotid artery to left internal jugular vein was closed successfully by AVP II vascular plug.

Connie et al[37] reported the successful use of an Amplatzer vascular plug to close an iatrogenic complication of subclavian arteriovenous fistula created during ICD implantation. Subclavian arteriovenous fistula is an uncommon complication of central vein cannulation like pacemaker, ICD implantation and central venous lines. Small subclavian arteriovenous fistula may be asymptomatic and may go unnoticed. Larger subclavian AVF may result in upper extremity pain and swelling or decompensated congestive heart failure. The AVP is approved for use in arterial and venous embolization in the peripheral vasculature,[4] and successful reports of its use in treatment of congenital and iatrogenic vascular disease have been published.[26,38] In our study we closed an iatrogenic arteriovenous fistula formed between brachiocephalic artery and internal jugular vein after central line insertion.

In this study, the AVP were used for achieving the total occlusion of 16 vessels and a cardiac diverticulum[7] in nine patients. The AVP allowed targeted delivery, enabling more precise placement within the artery. The position of the device was easily be verified with a test injection through the guiding catheter prior to release. If device position was unsatisfactory, it was repositioned or removed, which is an important advantage of the AVP. The additional advantages of this device over coil embolization are less risk of device migration, a one-step easy procedure resulting in total occlusion of the target vessel (quicker and less cost than deploying multiple coils), the ability to be repositioned, and MRI compatibility. Moreover, for lesions requiring multiple coils to achieve occlusion, the average cost with the AVP occlusion can be significantly lower than the coil embolization.

The use of the AVP also has some limitations. First, it requires distal placement of a 5–8 F guiding catheter or sheath, depending on the diameter of the vessel to be occluded. Second, it is a cylindrical device and needs a short segment of vessel (1.5–2 cm) with a constant diameter. Tapered vessels may cause poor apposition of the device. Lastly, the AVP is not suitable for occlusion of small vessels in which total occlusion can be achieved with 1 or 2 coils. In such small vessels, coil embolization is less expensive and does not require distal placement of a 5 F guiding catheter.

10. Conclusion

AVP is a simple and effective device, which allows precise, reliable, and cost-effective occlusion of targeted vessels in various vascular territories in selected cases without significant complications. Although long-term results are not yet available, due to the reported advantages of this device, worldwide use is rapidly growing. More research is required in larger series to determine the long-term role of the AVP as a vessel occluder.

Conflicts of interest

All authors have none to declare.

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