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C3 - Core Curriculum in Cardiology

# Vascular plugs – A key companion to Interventionists – '*Just Plug it*'

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ABSTRACT

Vascular plugs are ideally suited to close extra-cardiac, high flowing vascular communications. The family of vascular plugs has expanded. Vascular plugs in general have a lower profile and the newer variants can be delivered even through a diagnostic catheter. These features make them versatile and easy to use. The Amplatzer vascular plugs are also used for closing intracardiac defects including coronary arterio-venous fistula and paravalvular leakage in an off-label fashion. In this review, the features of currently available vascular plugs are reviewed along with tips and tricks of using them in the cardiac catheterization laboratory.



## 1. Introduction

Closure of abnormal natural or artificial vascular communications is frequently performed in the catheterization laboratory. Commonly, 2 types of materials are used for closure of vascular communications, which include materials for embolization like coils, gel foam or particles and the various septal/duct occluders. Embolization materials like coils are relatively inexpensive, have a low profile and are easy to deliver; but the release of these materials cannot be secure and the rates of embolism is higher. The occluder devices are expensive, need a relatively larger sheath for delivery and are difficult to deliver in tortuous structures due to their bulkier profiles. However, the duct/septal occluders can be released in a controlled fashion. The vascular plugs have features of both embolic materials and occluder devices. They have a relatively lower profile and can be released in a controlled fashion. Almost all the published literature with the vascular plugs is with Amplatzer vascular plugs (AVP) [St. Jude Medical, Inc.; Minnesota, USA].[1–5] AVP have evolved over years and are available in four different forms now – AVP I–AVP IV. All these forms of AVPs have been used for the embolization of medium to large vascular communications. Recently, Cera™ series of plugs from Lifetech [Lifetech Scientific Corp., China] became available.[6] Cardiac plugs for the closure of left atrial appendage and microplugs are the latest additions[7,8] to the series of vascular plugs. In this article, the various forms of plugs and technical aspects of their use in cardiac catheterization laboratory are reviewed.

## 2. Types of vascular plugs

AVP are established embolic devices manufactured by St. Jude Medical [St. Jude Medical, Inc.; St. Paul, Minnesota, USA]. The

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initial AVP was approved by the US FDA (Food and Drug Administration) in May 2004, for peripheral vascular embolizations. The indication for AVP and their usage have expanded significantly. The AVP II was introduced in 2007. All these plugs are self-expanding devices made of nitinol wire mesh which can be cylinderlized into a sheath. Upon release they assume the pre-specified shape due to the property of thermal memory. The differences among the series of AVPs are presented in Table 1 and Fig. 1. AVP I has single lobe and AVP II has 3 lobes, whereas AVP III and IV are bilobed. AVP I and IV are single layered, and AVP II and III are multilayered.[1,3] All these devices are complimentary additions and are not a replacement of earlier version. Each of them has a unique feature that is useful in a specific clinical situation.

The initial AVP, (also known as AVP I), made of finely braided Nitinol wire, had a single-layer mesh and a single-lobe design. It has a high radial force and is ideal for structures with short landing zone. However, choosing the appropriate length and diameter of the device is very critical as there are no rims on either side. AVP requires a longer time for complete occlusion. The AVP II is designed to improve the occlusive properties and has a finer and more densely woven nitinol braided in two or 3 layers. It has a central lobe and 2 discs on each side. The multi-layered, multi-segmented design reduces the time to occlusion and offers full cross-sectional vessel coverage. Thus, AVP II has lower migration and recanalization chances. The multi-layered mesh lobes create six occlusive planes, which enable faster vessel occlusion.[1,3]

AVP III is designed for embolization of structures with a very high flow. AVP III has an oblong cross-sectional shape made of multiple Nitinol mesh layers and has extended rims. It has the fastest occlusion properties. Device rims extending beyond device body enables full wall apposition and enhances stability in high-flow vessels. AVP III fits elliptical shaped vascular structures. AVP IV has the best profile among all the AVPs. In fact AVP IV can be delivered through a 0.038 compatible diagnostic catheter (5F diagnostic catheters). This eliminates the need for catheter exchange. Flexible mesh and the floppy distal section of the delivery wire make AVP IV attain a very low-profile, which improves the reach to distal vasculature and across tortuous and angulated structures. The multi-layered, double-lobed design also enables rapid embolization. However, AVP IV is only available up to a size of 8 mm.[3]

Cera™ is a new brand of plugs manufactured by Lifetech [Lifetech Scientific Corp., China]. The manufacturers claim that the Titanium Nitride (TiN) coating prevents thrombosis and improves endothelialization. It has a single lobe and has PTFE material for faster occlusion. Initial clinical data on other forms of this device is published recently.[6]

### 2.1. *Amplatzer cardiac plug*

The Amplatzer cardiac plug-2 (ACP 2) is a self-expanding device specifically designed for left atrial appendage (LAA) closure. ACP 2 has a distal lobe along with a proximal disc connected by a short waist. The ACP 2 is deployed through a septal puncture using a transfemoral route.[7]

### 2.2. *Micro plugs*

The micro-plugs are latest addition to the plug family, which can be delivered through a micro catheter. These micro plugs are available in 3 mm and 5 mm sizes that enables super-selective embolization of distal vessels.[8]

## 3. Indications for vascular plugs

Indications for the use of vascular plugs have expanded and it is said that there are no contraindications.[1] However, their use is approved for extra-cardiac vascular structures only in some countries. Most of the existing literature regarding vascular plugs is with the AVP family and pertains to its use in peripheral vascular malformations. Excellent reviews are available that summarizes the use of AVP in closing peripheral vascular structures ranging from arterial malformations, aneurysms, Arterio-Venous (AV) malformations, for venous occlusion including portal vein embolization, and even endoleak associated with EAVR. AVP have been used to occlude arteries including internal iliac, carotid, splenic, renal and gastroduodenal artery embolizations. They are also useful to close the various man-made shunts including AV fistula for hemodialysis, and transjugular intrahepatic portosystemic shunt (TIPS) occlusion.[1,9]

The ease of use, lower profile and precise deliverability make it ideally suited to close congenital malformations in even smaller children. Recently, a few case series have described the use of AVPs in various congenital malformations.[3,10,11] Shwartz's et al, initially described the use of AVP I and II in congenital heart disease, mostly in patients with PDA

**Table 1 – Device characteristics of various generations of vascular plug family.**

| | AVP I | AVP II | AVP III | AVP 4 | Amplatzer cardiac plug (ACP 2)[a] | Cera™ |
|---|---|---|---|---|---|---|
| Structural details | Single lobe | 3 lobes plug – one central and 2 peripheral | Oblong plug with extended rims | Two lobes (lower profile) | Distal lobe with proximal disc with a waist | Single lobe |
| Available diametric sizes (mm) | 4–16 | 3–22 | Long axis, 4–14 | 4–8 | 16–34 | 4–24 |
| Length of plug (mm) | 7–8 | 6–18 | Short axis, 2–5 | 10–13.5 | 13–18 | 7–14 |
| Guide catheter (Fr) | 5–8 | 5–9 | 6–9 | 5F diagnostic | 12–14 | 4–9 |

Modified from Wang W, et al 2012.[1]
[a] Only useful for left atrial appendage (LAA) occlusion.

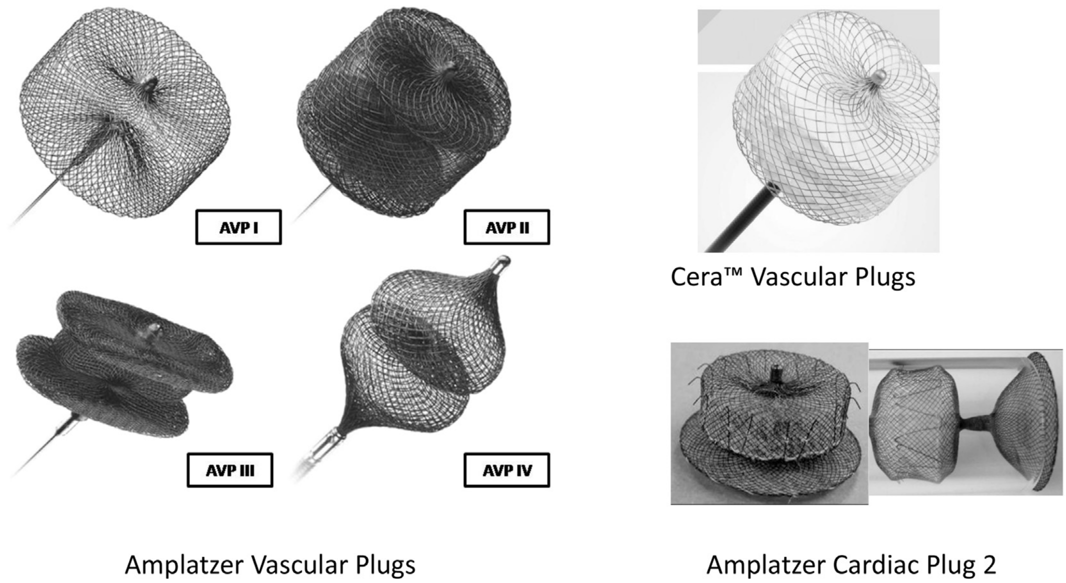


**Fig. 1 – Family of Amplatzer vascular plugs left panel shows the configuration of Type I to type IV – Amplatzer vascular plugs (AVP) right upper panel shows the Cera™ vascular plug from Lifetech Corporation right lower panel shows the Amplatzer Cardiac Plug (ACP) 2, which is designed for left atrial appendage occlusion.**

(persistent ductus arteriosus).[4] A few good series have come from India describing the use of AVP in various congenital malformations.[3,10] AVP may be considered the embolic material of choice for closing coronary AV malformations, pulmonary AV malformations, closure of BT (Blalock-Taussig) shunt, occluding large aorto-pulmonary collaterals, arteriovenous communications, surgically created fenestrations, antegrade flow across the pulmonary valve following Glenn shunt and veno-venous communications in a patient with Fontan surgery. AVP seems to be ideally suited for the closure of whatever extra-cardiac 'extra' vascular channel.

AVP is emerging as an alternative to surgery in patients with a tubular PDA. A few small case series have described the successful use of AVP II for small and moderate PDA.[12,13] An initial series[4] described the use of AVP in 20 small children with tubular PDA and documented complete occlusion in all the patients. The authors used a mean plug to duct diameter ratio of $1.46 \pm 0.42$. Recently, AVP IV has been successfully used in closing tubular PDA. In a series of 47 patients, including 39 infants, AVP IV alone was sufficient to achieve complete closure of PDA in all except one patient who had late embolization. They oversized the device by $1.9 \pm 0.1$ mm more than the measured vessel diameter.[13] However, late migration of a successfully deployed AVP is reported in an adult patient with PDA.[14] Hence, the use of these devices for PDA should be reserved for experienced operators. A few case reports have also described the use of AVP for closing ruptured sinus of Valsalva aneurysms.[15]

Another indication that seems to ideally require a plug is transcatheter paravalvular leak closure. In most of the case series an AVP III has been successfully used through either an ante- or retrograde access for mitral and retrograde approach for aortic paravalvular leaks. It is nearly successful in all patients with aortic paravalvular leak and is successful in 89.7% patients with mitral paravalvular leak.[16,17]

## 4. Procedural details and tips for use

### 4.1. *Choosing the correct type and size of AVP*

The choice of AVP depends on vessel type to be embolized, size of the vessel, quantum of blood flow, approach to the intended site of occlusion and the available landing zone. Fig. 2 highlights the ideal indications for different forms of AVPs. In most of the series, AVP I was the most common type used before AVP II became available for clinical use. Since AVP II became available, it is the most commonly used plug due to better and rapid occlusive properties and wide availability of sizes. AVP I is still useful for vascular structures with short landing zones. Type III is preferred for medium sized high flow tubular/elliptical structures, where faster occlusion is desired. Type III seems particularly suitable for closing the paravalvular leaks. AVP IV is suitable for closing smaller structures (<6 mm diameter) that have a tortuous or angulated course. Deployment of different forms of AVPs in different clinical scenarios is presented in Fig. 3.

We measure the most restrictive diameter along the length of the vascular channel to be closed. It is recommended that a device is chosen that is at least 30–50% larger than the size of the native vessel. The mean device to vessel ratio was 1.4–1.5 in most of the published series. For instance, for a vessel size of 4 mm diameter, a plug with a diameter of 6 mm, and for a vessel of 5 mm a plug with a diameter of 8 mm is generally chosen. The length of the vessel and the available landing zone is also an important determinant of the plug size. An oversized AVP tend to lengthen significantly across the vessel. Hence, a plug must be chosen that is large enough to ensure complete occlusion, but at the same time does not elongate and protrude into nearby structures.

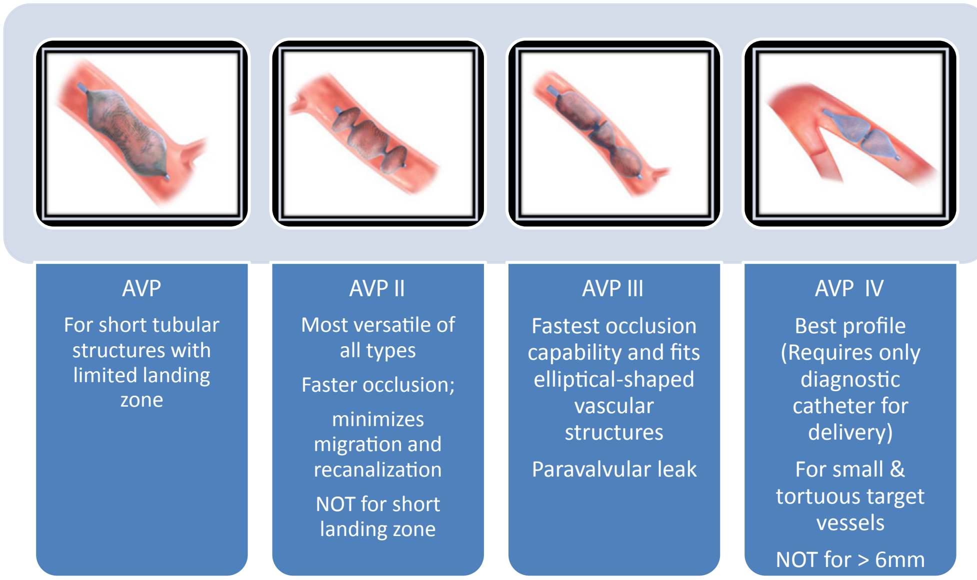


**Fig. 2 – Choice of AVP The in vivo deployment shape of all forms of Amplatzer vascular plugs (AVP) is presented with their salient features and important indications.**

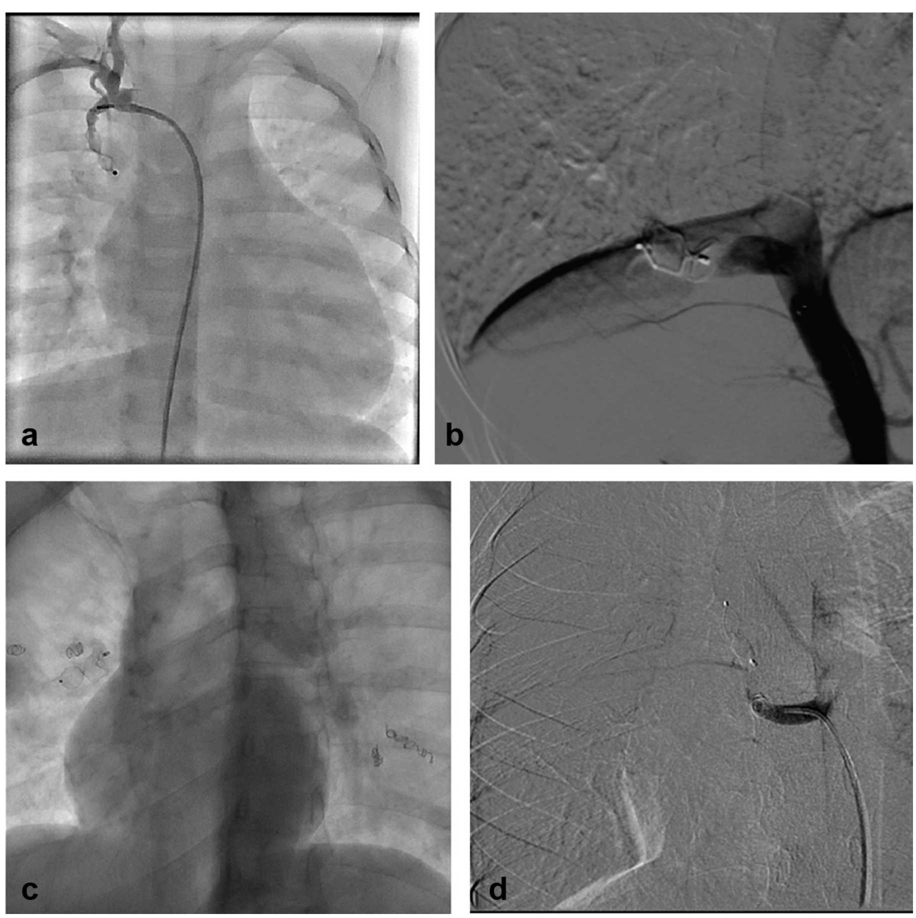


**Fig. 3 – Examples of deployment of AVP I–IV The panel shows the configuration of AVP after deployment in various vascular structures: (a). AVP type I across a modified Blalock Taussig (BT) shunt, (b). AVP II across a large aorto-pulmonary collateral (APC), (c). AVP III across an APC and (d). AVP IV across an APC (Reproduced with permission from ref no 3).**

### 4.2. Procedural details

The procedure may be done under local anesthesia even in infants. Commonly femoral arterial or venous route is preferred as needed. However, the plug can be easily delivered using jugular venous or unconventional routes if needed.[18] We commonly use the Judkin's right (JR) guide catheter (Cordis Corporation, Miami, FL, USA) 5–7F for most of the plug delivery. The other catheters that are often useful depending on the vascular anatomy include Multipurpose (MP), Amplatzer duct occluder (ADO) delivery sheath (St Jude Inc, MN, USA), Cook delivery sheaths (Cook, Bloomington, USA), carotid shudder sheath, renal guide, Amplatz left (AL) and Amplatz right (AR) guide catheters.

In most instances, a Judkin's right coronary, Picard or Conard catheter is used to hook the vessel and cross the site of interest using a J tipped Terumo wire (Terumo Medical Corporation, Somerset, NJ, USA). An exchange length Terumo or ordinary guidewire is advanced and is parked distally. Then over that wire, a guide catheter of choice is taken across the intended site of closure. It may be preferable to take a one size larger bore catheter than recommended especially across tortuous structures. In some instances, there could be difficulty in adequately advancing the guide catheter. Then a catheter in catheter (mother and child) technique may be useful.[19] At times we start with the catheter in catheter system so that exchanging with a stiffer wire could be avoided. A 4F or 5F diagnostic catheter with sufficient length to protrude outside a 6F or 7F guide catheter is taken along with a Terumo wire. In most of the difficult situations, this technique commonly succeeds. At times de-airing becomes difficult once the guide is placed distally. De airing is extremely important when air embolism could lead to systemic events like in pulmonary AV malformations. It may be preferable to use a coronary Tohue Bosht system and deair the system before advancing. The chosen AVP is taken and deployed across the intended site using less traction on the assembly. Due to its lower profile the device may be recaptured and redeployed with ease if needed. A good quality angiogram may be obtained with the same guide catheter or additional diagnostic catheters. Once total occlusion is demonstrated, AVP is released by unscrewing in counter-clockwise rotation. Then a final angiogram is obtained commonly after 10 min of deployment of AVP, when most of the minor residual flow generally disappears. An excellent example of a procedure that was simplified due to the use of AVP, closure of a pulmonary AV malformation, is presented in Fig. 4.

## 5. Advantages of vascular plugs

Vascular plugs are ideal for embolization of medium to large vessels with high flow. These vascular structures are often closed using a single AVP that otherwise would have required many coils. Thus, AVPs are efficient and a cost-effective alternative to coils and other occlusion devices. The family of AVP offers a wide flexibility to select the correct vascular plug for the type of vessel. Use of AVP reduces the procedure times and results in low radiation exposure. The lower profile of these devices enables a technically simpler procedure. The technical success is achieved in nearly all patients. The device visibility is excellent under fluoroscopy with limited imaging artifacts. Screwing with a delivery cable allows for precise delivery and secure positioning of AVP. Accurate placement even in large high-flowing vascular structures can be readily achieved with AVP as compared to coils. Hence, AVPs are associated with a very low device embolism risk. Multi-layered Nitinol mesh makes the plug faster to occlude and AVPs have a lower recanalization rates. Thus, most of the properties of AVP resemble that of duct/septal occluders. However, AVP has a lower profile generally as compared to the same size of duct/septal occluders. In our series also, AVP was successfully deployed when occlusion with septal/duct occluder failed[20] (Fig. 5).

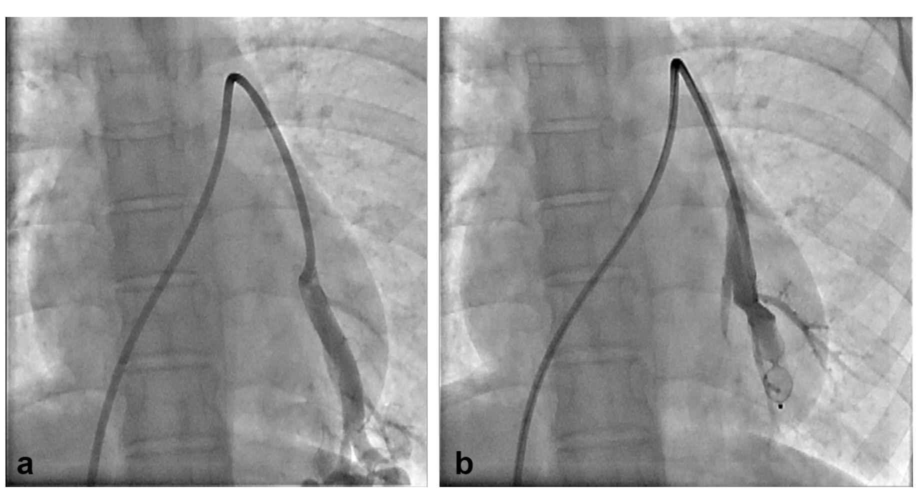


**Fig. 4 – Use of an AVP for closure of a pulmonary arterio-venous (AV) malformation. (a). Pulmonary angiogram showing a large pulmonary AV malformation from the left lower pulmonary artery. (b). Successful and precise deployment of an AVP 2 across the feeding vessel showing complete abolition of flow.**

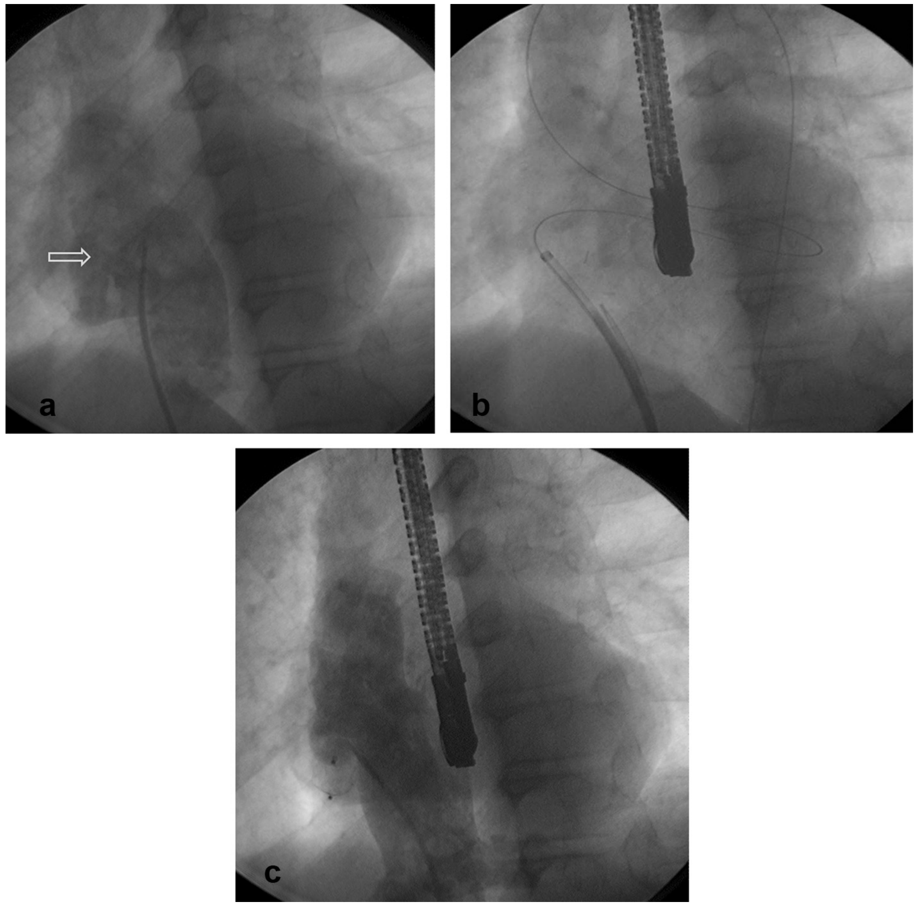


**Fig. 5 – Successful use of an Amplatzer vascular plug (AVP) for closure of a Fontan fenestration, where septal/duct occluders failed. (a). Angiogram showing baffle leak (arrow) following lateral tunnel Fontan leading to significant desturation. (b). Initially, an veno-arterial loop was created, but the duct occluder sheath could not be advanced due to difficult angulation. (c). An AVP I was successfully deployed across the baffle leak through jugular approach. (These figures were published in Ref no. 20. Ramakrishnan S, Kothari SS, Singh N, Singh S. Baffle leak following lateral tunnel Fontan–treated with a vascular plug. Indian Heart J 2009; 61:285–7. Copyright Cardiological society of India").**

## 6. Procedural issues to consider

### 6.1. *Technical success*

The technical success could be achieved in most of the patients using an AVP. Various series have reported a technical success rate of 92–100%. The variation is mostly due to the definition of technical success.[1–5]

### 6.2. *Residual flow*

The rate of residual flow is variable depending on the time of final angiogram. Demonstration of complete flow occlusion is essential at the end of the procedure. An adequate oversizing of the device, proper deployment, and better occlusion properties of newer plugs reduces the chance of residual flow. However, the newer plugs have a variable time of occlusion. It is reported that higher flow, large vessel size and coagulopathy are predictors of residual flow associated with AVPs.[1] Most of such residual flow may be abolished with the use of additional plugs, coils or gel foam.

### 6.3. *Recanalization*

Recanalization after successful deployment with AVP is extremely rare. A review estimated that there were only 5 reports of recanalization among more than 1200 AVP placements.[1]

### 6.4. *Device migration and embolization*

Device migration and embolization following successful deployment is also very rare in experienced hands. Self expanding nature of the device with a good radial force prevents migration even in a high flowing structure. The embolized device may be retrieved percutaneously.

### 6.5. *Reconfiguration*

An oversized device often lengthens significantly. However, a few reports identified that nearly half of the AVPs reconfigure to the original shape due to nitinol memory, but the clinical importance of reconfiguration is not clear.[21]

## 7. Conclusions

Amplatzer vascular plugs are versatile occlusion devices that are useful in a wide spectrum of clinical situations. The use of AVP is associated with a very high technical success rate with fewer complications. The indications for AVP are expanding. Although initially used only for closing extra-cardiac high flowing vascular structures, they now are used to close intra-cardiac defects also. Adequate knowledge of various plugs is essential for the appropriate use of these devices.

## Conflicts of interest

The author has none to declare.

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