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ORIGINAL ARTICLE

Peripheral vascular applications of the Amplatzer® vascular plug

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PURPOSE
To present our experience using the Amplatzer® vascular plug in various arterial and venous systems, and follow-up results.

MATERIALS AND METHODS
Between May 2005 and October 2006, 20 Amplatzer® vascular plugs were used to achieve occlusion in 20 vessels in 12 patients (10 male, 2 female) aged between 24 and 80 years (mean age, 55 years). Localization and indications for embolotherapy were as follows: pulmonary arteriovenous malformations (n = 3; 9 vessels), internal iliac artery embolization before stent-graft repair for aortoiliac aneurysms (n = 4; 4 vessels), preoperative (right hemipelvectomy) embolization of bilateral internal iliac arteries (n = 1), bilateral internal iliac aneurysms (n = 1), large thoracic side branch of the left internal mammary artery coronary by-pass graft causing coronary steal syndrome (n = 1), closure of a transjugular intrahepatic portosystemic shunt (n = 1), and testicular vein embolization for a varicocele (n = 1).

RESULTS
The technical success rate was 100%, with total occlusion of all the targeted vessels. Only one device was used to achieve total occlusion of the targeted vessel in all patients (device size range, 6–16 mm in diameter). No major complications occurred. Target vessel occlusion time after deployment of the Amplatzer® vascular plug was 6–10 min in pulmonary arteries (mean, 7.5 min) and 10–35 min (mean, 24.4 min) in systemic arteries. Mean follow-up was 6.7 months (range, 1–18 months).

CONCLUSION
Embolization with the Amplatzer® vascular plug is safe, feasible, and technically simple with appropriate patient selection in various vascular territories.

Key words: • *Amplatzer vascular plug* • *embolization, therapeutic* • *vascular malformations, pulmonary* • *aneurysm*

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The Amplatzer® vascular plug (AVP; AGA Medical, Golden Valley, MN, USA) is a new occluding device, which is increasingly being used for transcatheter embolizations in the peripheral vasculature and occlusion of abnormal vessel communications (1–14). The AVP is a self-expanding cylindrical device made of nitinol wires, similar to the Amplatzer® septal and ductal occluding devices. The purpose of this study was to present our initial clinical experience with the AVP for occluding various peripheral and visceral arteries and veins, including occlusion of pulmonary arteriovenous malformations (PAVMs), internal iliac arteries, and a testicular vein.

Materials and methods

Between May 2005 and October 2006, 12 patients (10 male, 2 female) aged between 24 and 80 years (mean age, 55 years) who underwent percutaneous embolotherapy with the AVP were retrospectively evaluated. A transfemoral approach was used in 10 of the 12 cases by contralateral arterial puncture for internal iliac arteries, and by right femoral venous access for the pulmonary arteries and testicular vein. Transjugular and left transbrachial approaches were used for occlusion of a transjugular intrahepatic portosystemic shunt (TIPS) and a large thoracic side branch of left internal mammary artery (LIMA) coronary by-pass graft, respectively. Intravenous conscious sedation was used for 11 of the procedures. One patient with bilateral PAVM was treated under general anesthesia (requested by the patient). Only patients who underwent AVP embolization for PAVMs received heparin (70 IU/kg) during the procedure. Patient characteristics and treatment details are given in Table.

The Amplatzer® vascular plug

The AVP is a self-expandable cylindrical device made of 144 nitinol mesh wires that allow the device to compress inside a catheter, and then when released from the catheter, return to its intended shape to occlude the target vessel. The device has platinum markers on both ends. 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 AVP is available in diameters ranging from 4 mm to 16 mm, in 2-mm increments. It is preloaded in a loader and delivered through currently available guiding catheters in sizes ranging from 5F to 8F. 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. It is recommended to select a device approximately 30%–50% larger than the vessel diameter. Since the AVP is a flexible nitinol wire mesh, it adjusts to the shape of the vessel and thus, oversizing prevents device migration after deployment.

Results

The technical success rate was 100%, with total occlusion of all the target vessels. In all, 20 AVP devices 6–16 mm in diameter were used in 12 patients to occlude 20 vessels; 5F guiding sheaths were used for 4-, 6-, and 8-mm AVPs, 6F guiding sheaths were used for 10- and 12-mm AVPs, and an 8F guiding sheath was used for a 16-mm AVP. The diameter of the AVP was chosen to be approximately 30%–50% greater than that of the blood vessel, as recommended by the manufacturer. In each case, the final localization of the AVP was confirmed with angiography before its release. The radioopacity of the device was sufficient, allowing easy visualization under fluoroscopy. There was no incident of dislodging, device embolization, or vascular disruption. We had a minor asymptomatic pulmonary artery dissection secondary to guiding catheter manipulations, which recovered spontaneously. 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 min) in pulmonary arteries, 10–35 min (mean, 24.4 min) in systemic arteries, and 15 min in TIPS (Table). Follow-up imaging (range, 1–18 months; mean, 6.7 months) was obtained with contrast-enhanced computed tomography (CT) in 8 patients (16 vessels), with magnetic resonance imaging (MRI) in 1 patient, and with Doppler ultrasonography in 1 patient, all of which showed complete occlusion of the AVP-embolized vessels (Table). Among the 12 patients, 2 had only clinical follow-up (patients 5 and 11). At the 6-month clinical follow-up, the patient who underwent varicocele embolization was asymptomatic, with resolution of pre-embolization fullness and pain (patient 5). At the 8-month clinical follow-up, the patient who underwent thoracic large side branch of LIMA embolization was asymptomatic (patient 11).

Transcatheter embolization was performed for PAVMs in 3 patients, for bilateral IIA aneurysm in 1 (Fig. 1), for preoperative bilateral IIA embolization before a hemipelvectomy for pelvic angiosarcoma in 1, for IIA emboliza-

Patient characteristics and treatment details

Case no.	Sex	Age	Indication	Location	Device and time for total occlusion	Follow-up (months)
1	F	53	Pelvic angiosarcoma, preoperative embolization	Bilateral internal iliac artery	Left 10-mm AVP, 15 min Right 12-mm AVP, 25 min	1, CTA
2	M	60	Pulmonary AVM	Right upper lobe segment pulmonary artery	8-mm AVP, 6 min	11, CTA
3	M	38	Pulmonary AVM	Left upper lobe segment pulmonary artery	12-mm AVP, 6 min	6, CTA
4	F	62	Pulmonary AVM	Bilateral multiple pulmonary artery (7 feeder vessels)	6-mm, 8-mm, 8-mm, 10-mm, 10-mm, 12-mm, and 16-mm AVP, 6-10 min	18, CTA
5	M	24	Varicocele	Left testicular vein	8-mm AVP and 10 coils, 2 ml NBCA	6, clinical
6	M	80	Bilateral internal iliac artery aneurysms	Bilateral internal iliac artery	Bilateral 16-mm AVP, 35 min	6, CTA
7	M	57	RCIA aneurysm + AAA	Right internal iliac artery	16-mm AVP, 30 min	6, CTA
8	M	72	RCIA aneurysm + AAA	Right internal iliac artery	12-mm AVP, 20 min	6, MRA
9	M	60	LCIA aneurysm + AAA	Left internal iliac artery	12-mm AVP, 30 minutes	6, CTA
10	M	71	RCIA and RIIA aneurysm + AAA	Right internal iliac artery	12-mm AVP and 24 coils, 20 min	6, CTA
11	M	37	LIMA thoracic side branch coronary steal syndrome	Left internal mammary artery	6-mm AVP, 10 minutes	8, clinical
12	M	46	Hepatic ensephalopathy and heart failure after the TIPS	TIPS tract	14-mm AVP, 15 min	1, Doppler

F: female; M: male; AVM: arteriovenous malformation; RCIA: right common iliac artery; RIIA: right internal iliac artery; LCIA: left common iliac artery; AAA: abdominal aortic aneurysm; NBCA: N-butyl 2-cyanoacrylate, LIMA: left internal mammary artery, TIPS: transjugular intrahepatic portosystemic shunt; CTA: computed tomography angiography; MRA: magnetic resonance angiography.

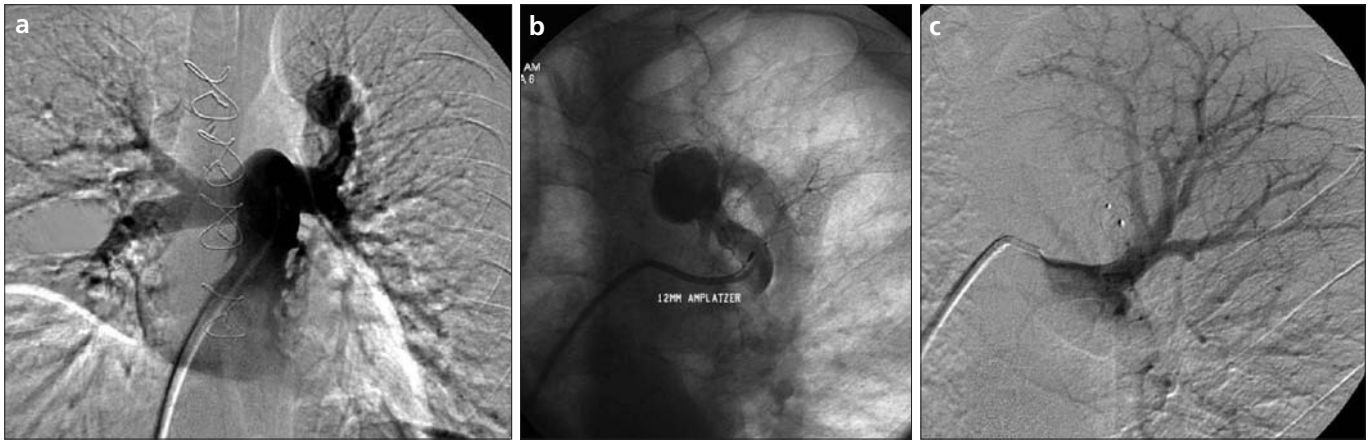

Figure 1. a–c. Main pulmonary artery injection **(a)** shows a simple pulmonary arteriovenous malformation at the left upper lobe. Selective catheterization and placement of a 12-mm Amplatzer® vascular plug (AVP) into the feeding artery **(b)**. Contrast injection 6 min after the deployment of the AVP shows total occlusion of the feeding artery **(c)**.

Figure 2. a–c. Pelvic arteriogram **(a)** of a patient with aortoiliac *(arrows)* and right internal iliac artery aneurysms. Contrast injection to confirm position before deployment of a 12-mm Amplatzer® vascular plug *(arrows)* in the main trunk of the internal iliac artery after partial embolization of the aneurysm with coils **(b)**. Completion angiography obtained 20 min after deployment of the device **(c)** shows occluded internal iliac artery.

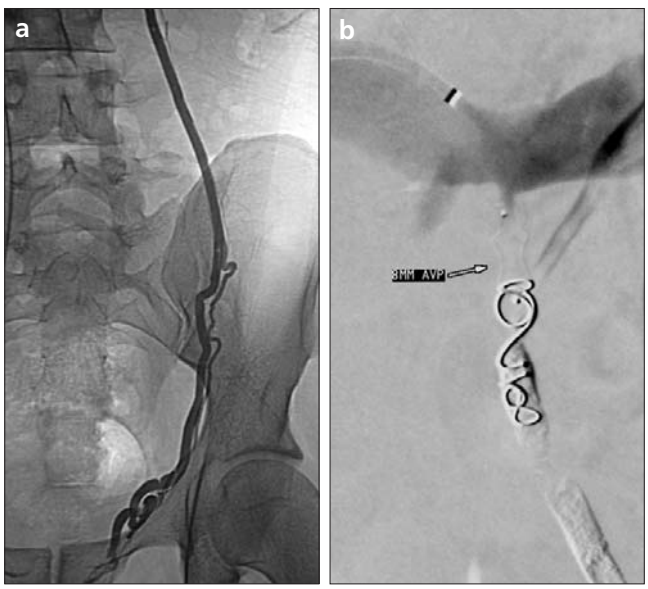

Figure 3. a, b. Selective left testicular venogram **(a)** shows retrograde flow in the left testicular vein consistent with insufficiency. Left renal vein injection **(b)** shows occluded left testicular vein and an 8-mm Amplatzer® vascular plug *(arrow)* in the very central part of the vessel.

tion as an adjunct procedure before endovascular aortic repair (EVAR) in 4 (Fig. 2), for LIMA thoracic side branch coronary steal syndrome in 1, for closure of TIPS causing hepatic encephalopathy and congestive heart failure in 1, and for occlusion of the very proximal part of the left testicular vein in 1 patient (Fig. 3).

In 10 of the 12 patients, embolization was performed only with the AVP device. In the remaining 2 patients, the AVP was used as an additional embolizing device. In one patient undergoing endograft repair for the aortoiliac and 3-cm right internal iliac artery aneurysms, (patient 10), prior to right IIA trunk occlusion with the AVP proximally, the distal half of the an-

eurysm was embolized with multiple fibered coils (Topaz Micro Coils, Dendron GmbH, Bochum, Germany) to prevent continuous filling of the IIA aneurysm via the contralateral IIA collaterals after stent-graft repair of the aortoiliac aneurysm. In total, 24 coils were used to fill the distal half of the IIA aneurysm and the AVP was used proximally instead of continuing with the coils in order to decrease the total cost and duration of the embolization procedure. In another patient who had grade IV varicocele (patient 5), the left testicular vein was embolized with n-butyl 2-cyanoacrylate (NBCA; Hystoacryl, B. Braun, Tuttlingen, Germany) and multiple 0.035-inch fibered coils (Vortex, Fibered platinum coils, Vortex-18, Boston Scientific/Target Vascular, Cork, Ireland); the AVP was placed at the very proximal part of the gonadal vein just below the renal vein entrance, where precise embolization is crucial.

In 3 patients with PAVMs, 1 AVP was used for each feeding artery and no coil was used. AVMs with feeding arteries < 3 mm were not treated. No complications were seen secondary to AVP embolization of the pulmonary artery feeders.

Discussion

Various applications of the AVP have been previously reported, including treatment of PAVMs, anomalous venous connections (left-sided hepatic vein-coronary sinus, coronary fistula, coronary saphenous vein graft aneurysm, patent ductus arteriosus, patent ductus venosus, aorticopulmonary collaterals, azygous and hemiazygous veins, and left superior vena cava), and internal iliac artery (IIA) aneurysms with or without abdominal aortic aneurysm (AAA) (1–14).

If a common iliac artery (CIA) aneurysm extends to the CIA bifurcation in a patient with AAA, as in 4 of our cases, simply extending the endograft into the external iliac artery (EIA) beyond the IIA orifice could potentially result in a type-2 endoleak. In such cases, occlusion of the IIA before endograft placement is necessary (11). In 4 of our patients with aortoiliac aneurysms extending to the IIA and EIA bifurcation, the IIA was occluded with an AVP. Angiography at the completion of the procedure showed no type-2 endoleak; however, in one patient there was a distal type-1 endoleak originating from the contralateral side. Six months later, control CT angiography in 3 patients and MR angiography in 1 patient was performed, which demonstrated occluded IIAs.

Pulmonary AVMs with afferent arteries > 3 mm in diameter have been reported to cause serious neurological symptoms, and treatment of pulmonary AVMs with feeding vessels ≥ 3 mm is recommended in order to prevent paradoxical embolization during the patient's lifetime (1). Embolization with coils or detachable balloons is currently the preferred treatment for PAVMs. Coil embolization of PAVMs has certain disadvantages, 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% (15–17). The AVP is a new alternative for the treatment of PAVMs (1, 6, 8, 12–14).

Varicocele is a well-known cause of male infertility in which the decision to treat should be based primarily on whether it is symptomatic or associated with subfertility, and the choice is between surgical and endovascular treatment (18). Endovascular embolization should be the first-line therapy, with surgery reserved for the small proportion of patients who have failed catheterizations (19). However, the decision is often based on local bias and availability of local expertise (18). Endovascular approaches involve selective catheterization of the spermatic vein and subsequent embolization with a sclerosing agent or embolization with glue and/or coils. When coiling, extreme care is taken while placing the coils proximally to ensure that they do not dislodge into the renal vein. The utility of the AVP in this part of the procedure not only provides an accurate occlusion of the central testicular vein, but also helps to safely protect the renal vein. We think the AVP is safer, in terms of dislodgement into the renal vein, compared to coil embolization, at the very central part of the testicular vein. To the best of our knowledge the utility of the AVP in varicocele embolization has not been previously reported in the English language literature.

Numerous procedures have been described to treat hepatic encephalopathy after TIPS, including occlusion or reduction of the diameter of the TIPS. Definitive occlusion of TIPS can be achieved with large metallic coils or detachable balloons (20). We think the use of the AVP instead of coils or detachable balloons for the occlusion of the TIPS is easier, quicker, and less expensive than the other embolic devices. Additionally, the risk of embolic device migration and dislodgement is reduced.

In our study, in low-pressure venous systems like PAVMs, complete occlusion was achieved in 6–10 min (mean: 7.5 min), whereas in high-pressure arterial circulations it was achieved in 10–35 min (mean: 24.4 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 (6). As vessel occlusion after deployment of the AVP is not instantaneous, there is a possibility of distal embolization and resultant neurological complications during slow thrombosis of the device in vulnerable vessels, like carotids and PAVMs (21–22); however, to date no such complication has been reported in the English language literature.

The AVP can be used alone for vascular occlusion (1, 2, 4, 5, 7–10, 12–14) as well as together with the other embolizing agents (3). In this study, the AVP was used alone for achieving the total occlusion of 18 vessels in 10 patients. In one of the remaining 2 patients, to avoid retrograde filling of the aneurysm, coils were used distally in addition to a proximal AVP since he had a fusiform aneurysm of the right IIA in addition to an aortoiliac aneurysm. In the other patient with varicocele, coils and NBCA were used together throughout the left testicular vein, starting from the inguinal ring level in order to prevent recanalization of the left testicular vein, and then the AVP was placed at the very proximal part of the left testicular vein, just caudal to the renal vein entry.

The AVP allows targeted delivery, enabling more precise placement within the artery. The position of the device can easily be verified with a test injection through the guiding catheter prior to release. If device position is unsatisfactory, it can be 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 than deploying multiple coils), the ability to be repositioned, and it is MRI compatible. Moreover, for lesions requiring multiple coils to achieve occlusion, the average cost of the AVP embolization can be significantly lower than coil embolization. In a recent study by Ha and Calcagno, the estimated average cost to occlude one internal iliac artery in patients undergoing endograft repair of aortoiliac aneurysms was $375 for the AVP versus $3500 for conventional coils (11). 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 (11). 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 5F guiding catheter.

In conclusion, the 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.

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