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INTERVENTIONAL RADIOLOGY

TECHNICAL NOTE

Applications of the Amplatzer Vascular Plug 4

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ABSTRACT

The purpose of this study was to present our initial experience with the Amplatzer® Vascular Plug (AVP) 4 in various arterial environments. This material was designed for the embolization of peripheral small vessels using a diagnostic catheter. Herein, the following three procedures using the AVP 4 were described: hemodialysis fistula occlusion as a treatment for the steal phenomenon, gastroduodenal artery embolization prior to liver radioembolization, and vertebral artery embolization for the treatment of subclavian artery pseudoaneurysm and arteriovenous fistula. All of the treated vessels were successfully occluded, and the devices remained in the original locations and configurations during the follow-up period. When compared with the previous generation of vascular plugs, the AVP 4 allows faster and safer procedures with less radiation exposure to the patients and angiography team.

Key words: • *Amplatzer® Vascular Plug 4* • *embolization* • *angiography*

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In daily practice, transcatheter approaches have evolved and become the first choice treatment for different types of vascular pathologies, including aneurysm treatments and oncological interventions. There are various embolizing materials (gel foam, coils, polyvinyl alcohol, glue microspheres, and occlusion balloons) for this purpose. As the most frequently used material, coils have some limitations; multiple coils are needed for complete occlusion, and it is difficult to perform an embolization at the vessel branching point because of the dislocation risk. To overcome these shortcomings, a new closure device called the Amplatzer® Vascular Plug (AVP) was designed. Reports in the literature examined the utility of different generations of this device.

The AVP 4 (AGA Medical Corporation, Plymouth, Minnesota, USA) is a new generation of AVP, which is increasingly being used for transcatheter embolization in peripheral small vessels. The device is self-expandable and cylindrical shaped, and composed of two nitinol mesh wire lobes that allow the device to compress inside a catheter and then return to its intended shape when released. It has platinum marker bands at each end of the device, rendering it clearly visible under fluoroscopy. The AVP 4 can be deployed through a diagnostic catheter without the need for exchange of a vascular sheath or a guiding catheter. It can be delivered through a 0.038 inch guidewire-compatible diagnostic catheter. The position of the device can be verified with a test injection through the diagnostic catheter prior to release, and the device can be recaptured and repositioned if necessary. When the device is positioned in the correct location, it can easily be released by turning the delivery wire in a counterclockwise direction. The AVP 4 is available in 11-mm lengths with diameters ranging from 4 to 8 mm in 1-mm increments. It is recommended to select a device approximately 30%–50% larger than the vessel diameter (1–3).

Because the AVP 4 is the latest generation of the plugs, limited experiences have been reported to date. The English literature describes the utility of the AVP 4 in renal pseudoaneurysm, postsurgical peritoneal bleeding, posttraumatic gluteal hemorrhage, intercostal pseudoaneurysm, and arteriovenous fistula after in situ saphenous vein bypass grafts (1–8).

Herein, we report our experience with the AVP 4, which was used for hemodialysis fistula occlusion, gastroduodenal artery occlusion, and vertebral artery occlusion.

Case reports

Three different patients (one female and two male) between the ages of 18 and 64 years old (mean age, 40 years) who were treated with an AVP 4 closure device within a two-month period were described in this study.

All of the procedures were performed in the angiography suite under intravenous sedation and local anesthesia. Neither periprocedural antibiotics nor heparin was used.

Case 1

A 38-year-old woman with autogenous brachial-basilic hemodialysis fistula of the left upper limb presented with progressive severe left upper limb edema. Diagnostic venography of the left upper limb and the fistulography suggested venous hypertension as a result of venous strictures and several collaterals competing for fistula outflow (Fig. 1a). The main reason for the limb swelling in this particular patient was the steal phenomenon. Additional venous stenosis was also detected at the dialysis puncture site, and unsuccessful repeated balloon angioplasties were attempted to relieve the limb swelling. Although surgical ligation is a treatment choice for closure of the fistula, endovascular occlusion was preferred because of the extensive edema and the minimally invasive nature of the technique. A 4 Fr introducer sheath (Terumo® Medical Corporation, Elkton, Maryland, USA) was placed under ultrasonography guidance, which was followed by contrast injection via a 4 Fr Burn (Imager™ II, Boston Scientific, Natick, Massachusetts, USA) diagnostic catheter positioned very close to the anastomosis. Because this was a short outflow vein segment of relatively small caliber, embolization was performed with an 8-mm AVP 4 closure device delivered through the diagnostic catheter under fluoroscopy guidance (Fig. 1b). The thrill diminished within seconds, which was also confirmed using a color Doppler ultrasonographic evaluation. Injections through the sheath confirmed the cessation of arterial flow at the site of the outflow vein (Fig. 1c). Because the color Doppler ultrasonography exam confirmed the occlusion with appropriate positioning of the plug (Fig. 1d), the procedure was terminated. The entire procedure was completed within a few steps without any complications. One-week follow-up of the patient included a physical examination and color Doppler ultrasonography, and revealed full restoration of the venous drainage of the left upper

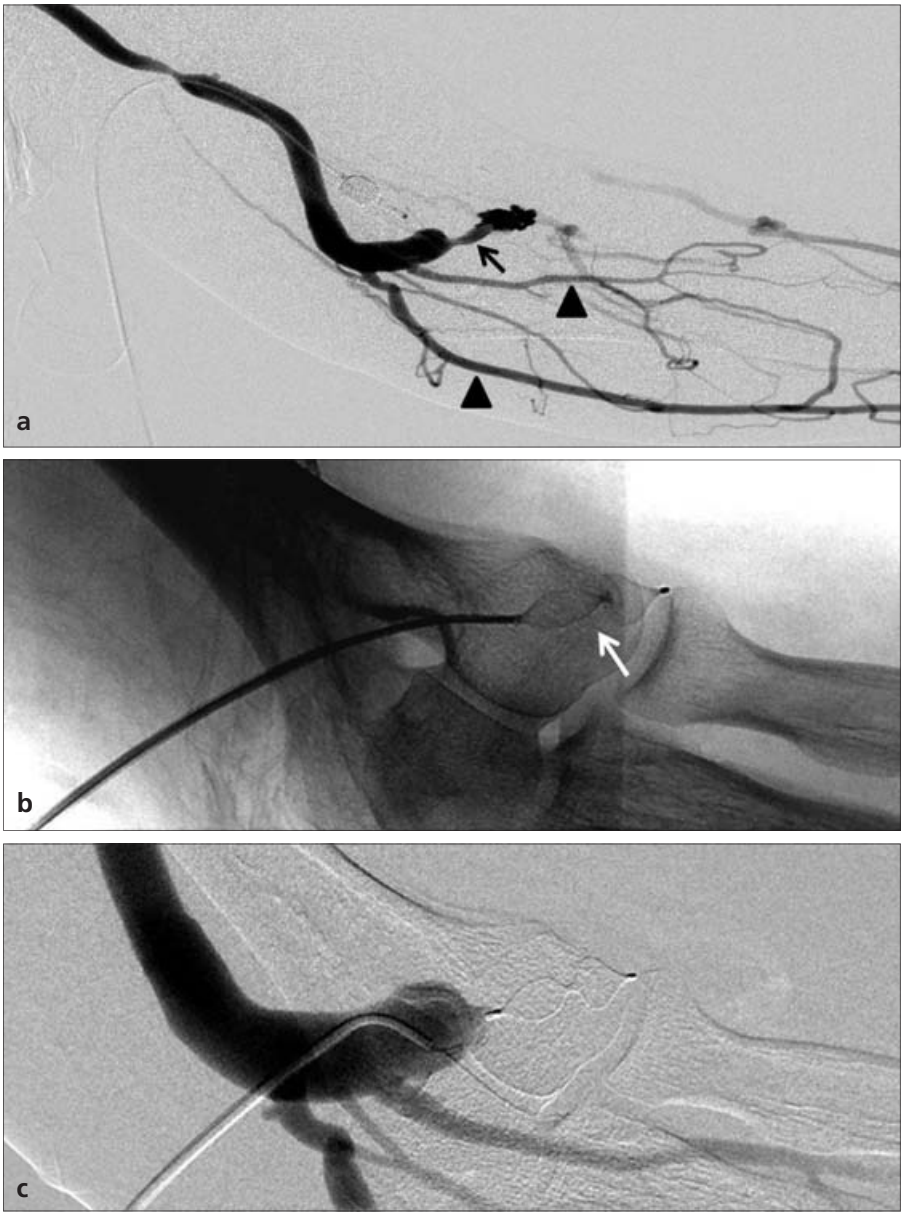

Figure 1. a–d. Fistulography **(a)** of a left autogenous brachial-basilic hemodialysis fistula demonstrated a tight stenosis at the main outflow vein of the fistula, which is the main draining vein of the forearm as well *(arrow)*. Several competing collaterals *(arrowheads)* of the fistula and the inability to visualize the brachial and cephalic veins should be noted. Placement of one 8-mm AVP 4 through the 4 Fr diagnostic catheter **(b,** *arrow***)** into the venous site of the anastomosis is seen. Angiography **(c)** control immediately after deployment showed decreased inflow from the brachial artery with normal venous flow throughout the opacified veins. Color Doppler US **(d)** after the procedure confirmed appropriate positioning of the plug *(arrow)* with no arterial flow signal.

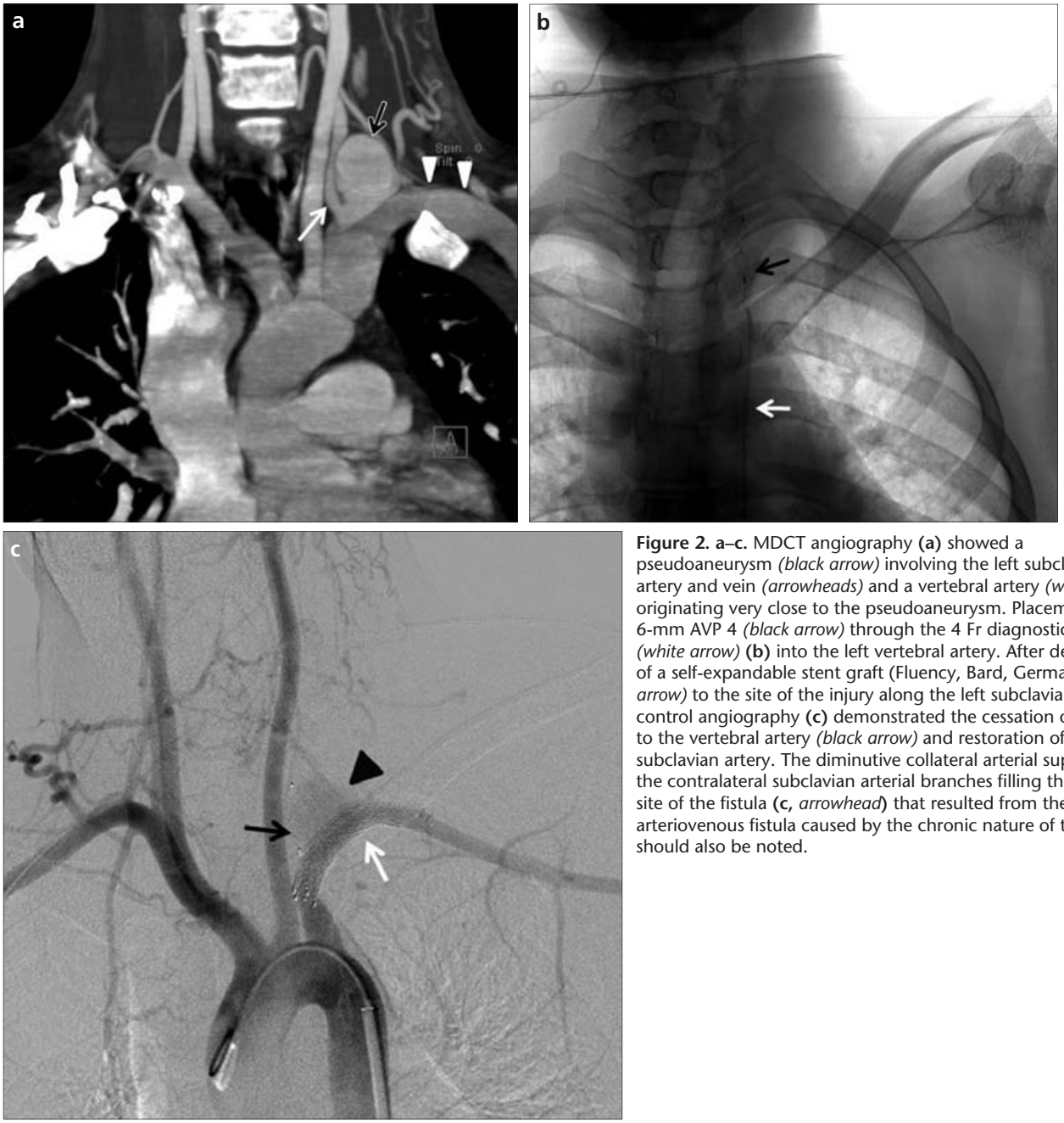

Figure 2. a–c. MDCT angiography **(a)** showed a pseudoaneurysm *(black arrow)* involving the left subclavian artery and vein *(arrowheads)* and a vertebral artery *(white arrow)* originating very close to the pseudoaneurysm. Placement of one 6-mm AVP 4 *(black arrow)* through the 4 Fr diagnostic catheter *(white arrow)* **(b)** into the left vertebral artery. After deployment of a self-expandable stent graft (Fluency, Bard, Germany) *(white arrow)* to the site of the injury along the left subclavian artery, control angiography **(c)** demonstrated the cessation of flow to the vertebral artery *(black arrow)* and restoration of the left subclavian artery. The diminutive collateral arterial supply from the contralateral subclavian arterial branches filling the venous site of the fistula **(c,** *arrowhead***)** that resulted from the complex arteriovenous fistula caused by the chronic nature of the injury should also be noted.

limb and total occlusion of the fistula with stable localization of the AVP 4.

Case 2

An 18-year-old man presented with left upper limb ischemia and vertebra-basillary insufficiency symptoms caused by subclavian arteriovenous fistula and pseudoaneurysm after incurring a gunshot wound. There was a prominent thrill upon physical examination. The multidedector computed tomography (MDCT) angiography images showed a large-caliber arteriovenous fistula and pseudoaneurysm involving the left subclavian artery and vein (Fig. 2a). The left vertebral artery originated very close to the pseudoaneurysm and fistula; thus, the flow was retrograde, filling the fistula (steal phenomenon), which was also confirmed by diagnostic transcatheter angiography. The decision was made to embolize the vertebral artery in order to prevent subsequent type 2-like endoleak into the aneurysm sac and fistula after stent-graft treatment of the subclavian artery. The left vertebral artery was first occluded with a 6-mm AVP 4 closure device at the origin, through a 4 Fr Burn diagnostic catheter (Imager™ II, Boston Scientific, Natick, Massachusetts, USA) (Fig. 2b). Then, a self-expandable Fluency Plus 9×60 mm stent-graft (Bard, Vascular Stent-graft, Angiomed GmbH & Co., Karlsruhe, Germany) was deployed to the site of the injury along the left subclavian artery (Fig. 2c). At the one-month follow-up visit examination, the MDCT angiography images showed total occlusion of the distal left vertebral artery with stable location of the AVP 4 and restoration of the subclavian artery.

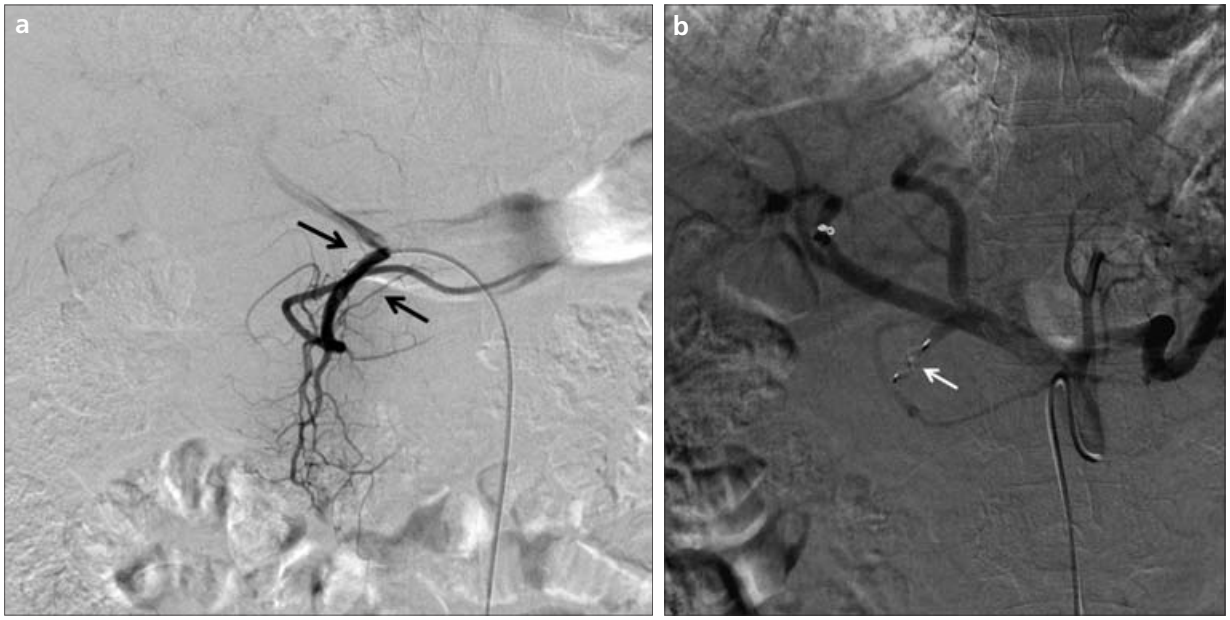

Figure 3. a, b. In an hepatocellular cancer patient with impaired renal functions, selective hepatic arteriography **(a)** revealed a gastroduodenal artery with small early branches *(black arrows)* off the proximal portion as a potential extrahepatic shunt for liver radioembolization. Control main hepatic artery injection **(b)** shows the desired position of the plug *(white arrow)*; an extremely limited amount of contrast media was used for the entire procedure.

Case 3

A 64-year-old man who presented with hepatocellular carcinoma was referred to vascular interventional radiology for locoregional therapy. Radioembolization was planned, and a diagnostic arteriogram performed to isolate the hepatic arterial circulation showed that the gastroduodenal artery was embolized prior to actual Y90 treatment. This isolation was necessary to prevent reflux complications. Instead of our routine embolization procedure, which involves coiling with a microcatheter, the use of an AVP 4 plug was preferred, as there were multiple small extrahepatic branches splitting off from the very proximal part of the gastroduodenal artery (Fig. 3a). We preferred to use an AVP 4, as pushable coils might cause nontarget embolization in such conditions, increasing the number of procedural steps necessary and the time required to complete the operation. A 6-mm AVP 4 closure device was successfully delivered through a 4 Fr Simmons 1 (Optitorque™ Terumo Medical Corporation, Leuven, Belgium) diagnostic catheter to the desired portion of the gastroduodenal artery (GDA) in one step (Fig. 3b). In this way, limited contrast medium can be used in a patient with impaired renal function. More than two weeks after the subsequent radioembolization procedure, hepatic arteriography demonstrated that the GDA was completely occluded and that the AVP 4 closure device was in its correct location. The radioembolization procedure was performed uneventfully.

Discussion

The technical success rate was 100%, with total occlusion of all target vessels and without the need to recapture the device. There were no major complications, such as rupture, perforation or dissection of the treated vessels. A total of three AVP 4 devices, each 6–8 mm in diameter and 11 mm in length, were used in three patients to occlude three vessels. No additional embolic agent was used for the complete embolization of the target vessels. No guiding sheath or microcatheter was used, as the diagnostic catheter was sufficient for deployment. The angiographic occlusion time was less than 5 min for all cases. Follow-up images showed all implanted AVP 4 devices in their original locations; no recanalization was identified.

Hemodialysis access-related complications are being seen more frequently in the clinic because of the increased life expectancy of hemodialysis patients. Central venous obstruction and dialysis-associated steal syndrome are two common complications that cause severe damage to the extremity if not treated. There are percutaneous (transluminal angioplasty, stent application) and surgical treatment options available to overcome these complications. However, if these treatment options fail, the only alternative for treatment is access closure. Surgery is not always easy to perform because of ulcerations, extensive swelling of the extremity and comorbidities, as in our case. In these instances, percutaneous embolotherapy has become the treatment of choice. Coils, n-butyl 2-cyanoacrylate (NBCA), and detachable balloons have been used for occlusion. Previous generations of AVPs have also been used to occlude dialysis access (3). Use of the AVP 4 for fistula closure was very fast, accurate, and easy when performed via a diagnostic catheter as performed in this case series. The relatively small caliber of the venous portion immediately after the anastomosis allowed safe and easy deployment of the AVP 4 for fistula occlusion.

Gastroduodenal artery embolization is considered to be essential before radioembolization to prevent radiation-induced peptic ulcerations due to nontarget embolization of Yttrium-90 microspheres. As mentioned in the discussion of severe side effects of

embolization failure, the success and efficiency of the embolization and material used is critical for the success of radioembolization. Coils are the most preferred embolic materials for gastroduodenal artery embolization. In most cases, to achieve optimal closure of the gastroduodenal artery, the very proximal part of the GDA must be coiled to the level of the origin, as there may be smaller branches splitting off from the GDA supplying the small intestine. This procedure is challenging for many reasons: it is difficult to place a pushable coil without having it migrate distally to the hepatic artery, and detachable coil systems are quite expensive. AVPs are seemingly a good alternative that can be placed safely at the very proximal part of the GDA (5). However, older generations of AVPs require 6 Fr guiding catheters to be placed far into the GDA, which is not desirable because of the risk of vasospasm or dissection of the hepatic artery, which would require treatment later on. In most patients, a 4 Fr diagnostic catheter can safely be placed in the GDA, and thus, the AVP 4 is a good embolic agent to use in this patient group, as described above.

Several neurointerventional applications of previous generations of the AVP have been published, including carotid and vertebral artery occlusions. The vertebral artery originating from a subclavian arteriovenous fistula and pseudoaneurysm requires occlusion before endovascular treatment for total occlusion of the pseudoaneurysm. Before occlusion of the vertebral artery at the side of the pseudoaneurysm, another vertebral artery has to be identified as open and able to effectively feed the posterior cerebrovascular system. Coils, NBCA, and detachable balloons can be used for occlusion. Distal migration risk is the most important shortcoming of coils and glue because of the arterial blood flow. For this reason, we preferred the AVP 4 for vertabral artery occlusion in our case (9).

Our experience showed that the AVP 4 device has many advantages over coils and previous generations of vascular plugs. The AVP 4 can be deployed through a diagnostic catheter without the need for a vascular sheath or a guiding catheter, which is needed for coils and previous generations of AVPs. The loading mechanism is the same as with the previous generations of AVPs. The ability to use a diagnostic catheter as small as 4 Fr, which is flexible enough to cross tortuous vessels or acute angles for peripheral small vessel embolizations, is another advantage over previous generations of AVPs. The AVP 4 can also be positioned easily, and a test injection with contrast medium can be performed using the delivery catheter before deployment (1, 3).

Usually, more than one coil is recommended for total occlusion of a vessel. However, the nitinol mesh wires of an AVP 4 occlude the entire diameter of the treated vessel. Therefore, in most cases, a single plug is sufficient for complete vessel occlusion. The use of one plug results in a significant reduction in the number of procedural steps, which in turn results in lower radiation exposure, reduced procedure time, and lower complication rates (1–8).

Although coils are the embolizing material used most commonly to occlude different types and sizes of vessels, conventional coils have several disadvantages, including the risk of nontarget embolization and thrombosis. The nontarget embolization risk of coils is reported to be 9%–23% (10, 11). Three-dimensional volumetric coils with controlled release are an alternative in these cases; however, the cost of the procedure is higher (approximately $1,200), and electrolytic detachment is more time consuming (6). In contrast, theoretically, there is minimal risk of distal embolization or migration with the AVP 4. Firm vessel attachment can be obtained by selecting a device approximately 30%–50% larger than the vessel diameter (1, 3). Furthermore, placing a plug through a diagnostic catheter takes significantly less time for the operator, thus significantly reducing the radiation dose for both the patient and angio team. However, even placement of a 4 Fr diagnostic catheter in certain vascular territories carries a higher risk of spasm, dissection or thrombosis; pushable or detachable coil systems that are delivered through microcatheters do not have these problems. Therefore, the AVP 4 devices are not suitable for the occlusion of distal small vessels. Furthermore, tapered vessels may cause poor apposition of the device (1, 2).

Coils yield prominent beam hardening metallic artifacts on CT imaging, whereas the AVP 4 results in fewer artifacts. It is therefore easier to precisely determine the configuration and location of the device and the occlusion of the vessel during control CT imaging. The AVP 4 can be visualized clearly using ultrasonography and is magnetic resonance imaging compatible (6).

Moreover, for vessels requiring multiple coils to achieve occlusion, the average cost of the AVP 4 embolization can be significantly lower than coil embolization in some cases. Although the costs vary in different countries, considering the need to use detachable coil systems together with the microcatheter and microwires, plug costs may be much lower. If one considers the entire procedure, including the costs for treatment of possible complications (e.g., thrombolysis, recapturing coils), the cost is increased for each case treated with coils. Therefore, the use of an AVP 4 plug in select cases would certainly decrease the procedure time, complication rate, and cost involved (3).

In conclusion, the AVP 4 is a practical, safe, and effective vascular closure device that can be used in selected cases. Use of the AVP 4 can decrease the procedure time, the radiation exposure time, complication rates, and cost of embolization.

Conflict of interest disclosure

The authors declared no conflict of interest.

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