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Advancing the Standard of Care in Peripheral Embolization

Benefits, clinical applications, and case presentations of the AMPLATZER Vascular Plug 4.

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The AMPLATZER™ vascular plugs (AVPs) (St. Jude Medical, Inc., St. Paul, MN) are a family of well-established embolization devices with multiple models, including the AVP, AVP II, and AVP 4 (Figure 1). Most recently, the AVP 4 was cleared by the US Food and Drug Administration and offers a variety of clinical applications. In this article, we discuss the characteristics of the newest vascular plug, as well as its clinical applications and selection criteria.

The AVP 4 makeup is a double layer of nitinol braiding. The plug has a radiopaque marker at each end, which allows for easy visibility during fluoroscopic deployment. The proximal end has a stainless-steel screw attached to the delivery cable, and the deployment mechanism is the same as each of the other vascular plug models and is released by turning the cable counterclockwise. The AVP 4 also retains the benefits of the earlier models with the ability to reposition and retrieve the plug before deployment due to the intact screw mechanism, which allows for controlled, accurate delivery.

The AVP 4 offers a new bilobed design (Figure 1) that differs from the AVP, which only has a single cylindrical lobe. The bilobed design aids in embolization of smaller, distal, more tortuous vessels with improved vessel wall opposition. The device is available in 4- to 8-mm diameters. More importantly, the AVP 4 is the only model that can be deployed via a standard 0.038-inch diagnostic catheter (4 or 5 F), whereas other plugs require a larger vascular sheath or guiding catheter.

As an embolic device, the vascular plug's occlusive mechanism is largely mechanical and does not boast additional intrinsic thrombogenic properties. Nevertheless, thrombosis after placement is relatively rapid and generally requires only a single device. Occlusion time should be taken into consideration when choosing the type of plug to use, as the AVP II has two layers of nitinol braiding, potentially reducing occlusion time. If more instantaneous occlusion is needed, then adjunctive embolic agents, such as coils or gelfoam, can be considered to seal off the vessel.[1,2] When used in this clinical situation, the AVP 4 may be used as an anchoring scaffold to prevent coil mass migration and improve coil-packing density.[1,3] Overall, however, occlusion time with all vascular plug models is highly variable and depends not only on the material and design, but also the high-flow status of the vasculature, vessel diameter, and underlying coagulopathy. Early reports of embolization with the AVP 4 demonstrate occlusion times averaging 4.5 minutes.[4]

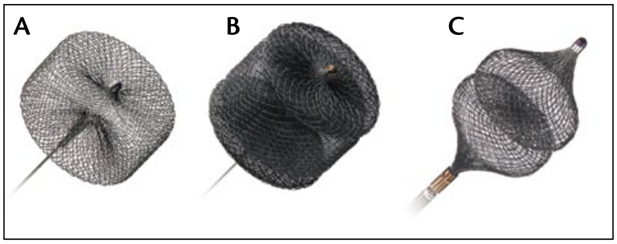
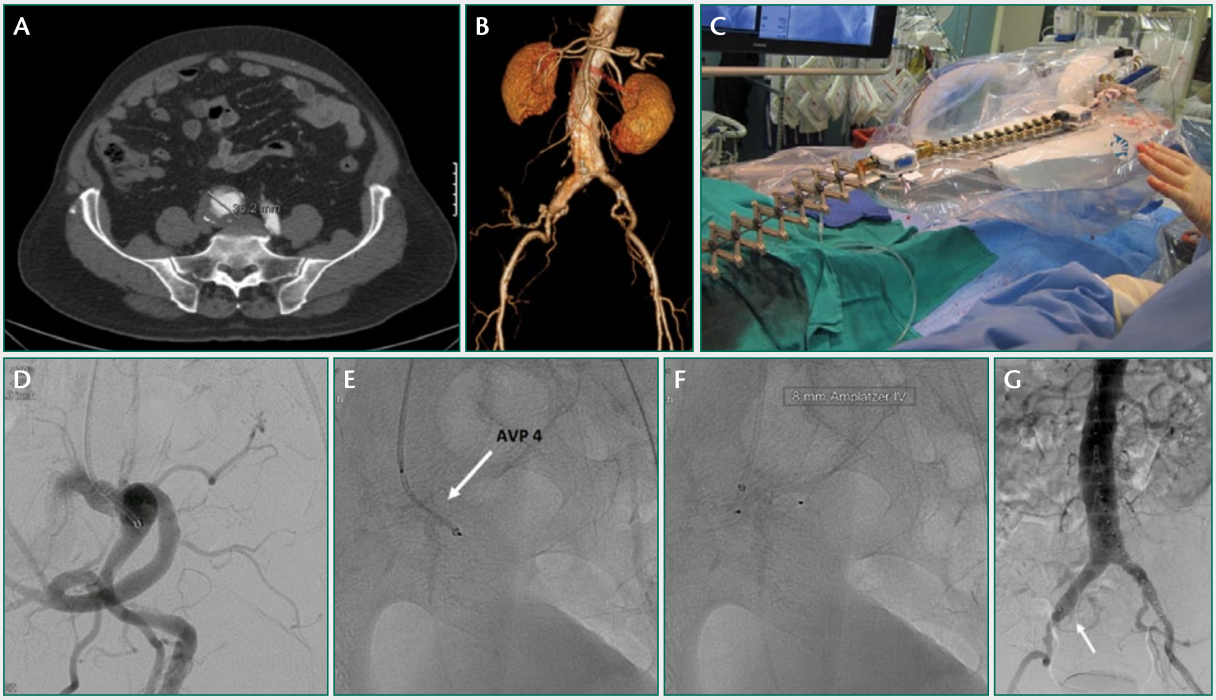


Figure 1. The AMPLATZER vascular plugs: AVP (A), AVP II (B), and AVP 4 (C). AMPLATZER and St. Jude Medical are trademarks of St. Jude Medical, Inc. or its related companies. Reprinted with permission from St. Jude Medical, ©2014. All rights reserved.

CASE REPORT 1. HYPOGASTRIC ARTERY EMBOLIZATION



A 74-year-old man presented with a right common iliac artery aneurysm and required right hypogastric artery embolization before endovascular repair. An axial image from a CT angiogram (A) and volume-rendered image (B) showed a 3.6-cm right common iliac artery aneurysm that extended to the right hypogastric artery. A Magellan robotic catheter (Hansen Medical, Mountain View, CA) was used to catheterize the right hypogastric artery via a crossover approach (C). A selective right hypogastric angiogram was obtained (D), followed by placement of an AVP 4 (E, F) at the origin of the vessel. Completion angiography showed successful occlusion of the hypogastric artery (G).

Finally, the AVP 4 is magnetic resonance conditional and is safe within magnetic resonance imaging fields of up to 3-Tesla. The nitinol mesh material is nonferromagnetic and is therefore compatible with follow-up magnetic resonance imaging when evaluating results of vascular embolization.

BENEFITS

The AMPLATZER vascular plugs have also shown their true value and cost-effectiveness in embolization. Pellerin et al demonstrated significant cost savings using the AVP in internal iliac artery (IIA) embolization when compared to coil embolization of €485 versus €1,745, respectively.[5] They also describe an average of seven endovascular coils used to embolize the IIA compared to a single AVP device, allowing for a shorter procedural time and easier technical success. Another separate independent study corroborated these results, showing that on average, 7.53 coils were required versus 1.35 AVPs in embolization of the IIA, again resulting in a significant cost reduction.[6] Although these results were seen in larger, high-flow vessels and the AVP, similar results could also be expected when using the AVP 4 in smaller vasculature, such as the gastroduodenal artery (GDA). Pech et al demonstrated cost savings in smaller-vessel GDA embolization (average vessel diameter, 3.7 mm) using the AVP II as compared with microcoils (€898 vs €1,268).[7] In these smaller-vessel sizes, the AVP II was also associated with shorter embolization times (23.1 vs 8.8 minutes), reduced embolic material used, and reduced radiation exposure (7.8 vs 2.6 minutes) to both the patient and medical personnel. In slow-flow venous structures, the embolic effect of vascular plugs is theoretically superior to coils in their ability to embolize large vessels where slow flow would promote thrombogenesis and shorter occlusion times.

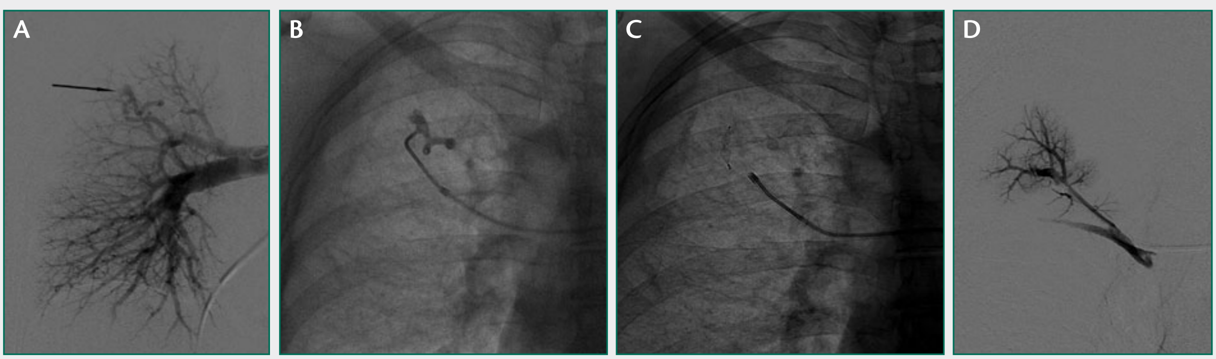
Most recently, Bulla et al demonstrated a superior proximal embolization effect when using AVP 4 when compared to coil embolization of the GDA. The residual perfused GDA stump was significantly shorter with AVP 4 than with coils (3.89 vs 5.78 mm, respectively), which led to reduced collateralization and side branch reperfusion (3.0% vs 26.9%, respectively).[8]

CASE REPORT 2. GASTRIC ARTERY EMBOLIZATION BEFORE YTTRIUM-90 RADIOEMBOLIZATION

A 68-year-old man with stage IV colon cancer with metastatic disease to the liver presented for mapping before yttrium-90 radioembolization. Hepatic angiography via a left radial approach showed a prominent right gastric artery communicating with the left gastric artery (A). A single AVP 4 was placed into the right gastric artery origin via a 0.035-inch diagnostic catheter (B). Angiography after embolization showed occlusion of the right gastric artery (C).

(Images courtesy of Dr. Rahul Patel.)

CASE REPORT 3. PAVM EMBOLIZATION



A 53-year-old woman with a history of Osler-Weber-Rendu syndrome (or hereditary hemorrhagic telangiectasia) presented with a cerebral abscess due to paradoxical embolization through a PAVM. A selective right pulmonary angiogram showed a PAVM in the right upper lobe (A). A 0.035-inch diagnostic catheter was positioned in the neck of the PAVM (B), and an AVP 4 was released in this location (C). Postembolization contrast injection showed complete occlusion of the PAVM with preservation of blood flow to the normal pulmonary branches (D).

(Images courtesy of Dr. James Jackson.)

ENDOVASCULAR CONCERNS

One of the main concerns regarding embolization complication is migration. Although the manufacturer recommends oversizing the plug by 30% to 50% of the target vessel diameter, migration is extremely rare with vascular plugs due to their self-expanding mechanism and adequate radial force, minimizing movement.[1,2,8,9] Furthermore, the bilobed design of the AVP 4 increases the surface area in contact with the vascular wall. This is unlike coil embolization, where migration complications have been reported in up to 3% of cases of pulmonary arteriovenous malformation (PAVM).[10]

Another concern is in reference to recanalization rates after embolization. Typically, vascular plugs seem to be very effective in vessel occlusion. After successful occlusion, there have only been five reports of recanalization described in the literature;[2] the majority were after PAVM embolization. With coil embolics, PAVM recanalization rates are reported from 8% to 15%.[11,12]

CLINICAL APPLICATIONS

The AMPLATZER vascular plugs have been described in a number of clinical situations and have diverse applications, including arterial high-flow embolization, arteriovenous fistula occlusion, venous occlusion, and portal vein embolization.[2] Selected clinical cases presented here include a hypogastric artery embolization prior to endovascular aneurysm repair (Case Report 1), a right gastric artery embolization for yttrium-90 radioembolization mapping study (Case Report 2), and PAVM embolization (Case Report 3).

CONCLUSION

The AMPLATZER vascular plugs have shown to be cost-effective, efficient, embolic devices, and the AVP 4 promises to expand the scope of vascular plug usage, increasing its value in vascular disease management. Its market value exceeds that of other devices, with diverse clinical applications, shorter procedure times, and potentially decreased occlusion times. Its deployment mechanism is precise and easy to use, allowing for accurate placement that can be adjusted or even resheathed before deployment. With the device's trackable delivery system and ability to deploy from standard diagnostic catheters, distal tortuous vasculature is accessible, which has been either not possible or more difficult with earlier models and techniques.

In conclusion, the AVP 4 is a safe and effective vascular embolic device that adapts the benefits from its earlier counterparts while integrating novel features to make the AMPLATZER vascular plugs more diverse and encompass the full range of vascular embolization. ■

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