Original Article

Neuroapplication of Amplatzer Vascular Plug for Therapeutic Sacrifice of Major Craniocerebral Arteries: An Initial Clinical Experience

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Abstract

Introduction: Clinical use of the Amplatzer vascular plug in the cardiopulmonary and peripheral vasculatures has been described extensively in the literature. We present our initial experience in adapting this device for therapeutic sacrifice of major craniocerebral arteries. Materials and Methods: Between July 2007 and November 2008, 8 patients (mean age 59.1 years; range 18 to 82 years) underwent therapeutic occlusion of major craniocerebral arteries using the device, for direct caroticocavernous fistula (1 patient), symptomatic unruptured giant cavernous internal carotid aneurysms (2 patients), and preoperative embolisation before surgical resections of skull base tumours that had encroached upon the internal carotid or vertebral artery (5 patients). The plugs were used alone or in conjunction with detachable platinum coils. The applications of the device, as well as the angiographic and clinical results of the procedures were evaluated. Results: Applications of the plugs were straightforward and successful in all cases, with hermetic occlusions of all target arteries. When used without additional coils, several plugs were deployed in tandem to achieve complete occlusion of the artery. No migration of the device was seen. No patient developed untoward neurological deficits following the procedures, and the 3- and/or 6-month follow-up showed stable results. Conclusion: The Amplatzer vascular plug could be a valuable addition to the neurointerventional armamentarium, particularly in therapeutic occlusion of major craniocerebral arteries. Rigidity of the delivery system limits its current use to vessels below the skull base. The potential risk of distal thromboembolism also requires further evaluation.

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Key words: Amplatzer vascular plug, Craniocerebral artery, Direct caroticocavernous fistula therapeutic sacrifice, Giant aneurysms, Skull base tumours

Introduction

Therapeutic sacrifice of major craniocervical arteries is a common and well-established neurointerventional procedure in the treatment of fusiform giant cerebral aneurysms, direct caroticocavernous fistulae and the control of torrential head and neck haemorrhage from a variety of causes, including carotid artery blowout.[1-6] The procedure is also indicated preoperatively in patients with advanced head and neck or skull base tumours, when surgery may potentially damage the carotid or vertebral arteries.[7,8] Detachable balloons and coils have historically been the conventional embolic devices that are used for these purposes.

The Amplatzer Vascular Plug (AVP) (AGA Medical Corporation, Minnesota, USA) is a self-expanding cylindrical nitinol mesh cage derived from the Amplatzer Septal Occluder and the Amplatzer Duct Occluder, used for closure of atrial septal defects and patent arterial ducts.[9] It has been extensively used for cardiopulmonary and peripheral vascular occlusions.[9,10] Gradual transfer of this technology to the field of neurointervention has occurred over the last 2 to 3 years, with a handful of case reports and small case series (of up to 5 patients) documented in the literature.[11-15] Due to the limited data available on the neuroapplication

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of AVP, scepticism remains on the long-term efficacy of the device and its potential thromboembolic complications.

In this article, we present our initial clinical experience in using the AVP for therapeutic occlusion of major craniocerebral arteries in 8 patients.

Materials and Methods

Device

The AVP is composed primarily of expandable nitinol wire mesh, with platinum marker bands at both ends (Fig. 1). A stainless steel micro-screw is welded to one of the markers, allowing the device to be attached to a 135 cm delivery wire, which can be navigated through a 5- to 8-French guide catheter, depending on the diameter of the AVP. The plugs are available in various sizes ranging from 4 to 16 mm, in 2 mm increments.[16] The entire system is pre-assembled within a loader to be introduced into the guiding catheter through a rotating haemostatic valve.

Deployment of the AVP is similar to an endovascular stent. Once it is correctly positioned, the device is unsheathed by fixing the delivery cable while gently withdrawing the guide catheter. Upon deployment, the plug expands and the outward radial force anchors the device onto the vessel wall and prevents flow-induced migration. If the positioning is suboptimal, the plug may be re-sheathed and redeployed. The AVP is detached through counterclockwise rotation of the pusher wire using a torque device, thus unscrewing the wire from the plug.[11] It is recommended that the AVP should be oversized by 30% to 50% relative to the target vessel, to ensure adequate grip of the device on the vessel wall. When appropriately sized, the deployed plug has an "hourglass" configuration (Fig. 1).[14]

Note that the AVP was designed for arterial or venous embolisations in the peripheral vasculature and at present, its use in the neurovasculature is "off-label".

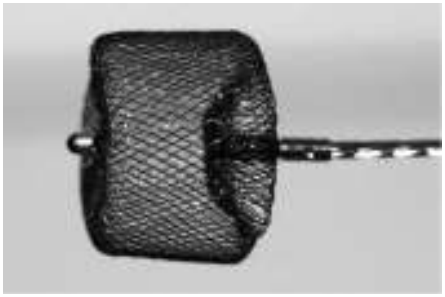


Fig. 1a.

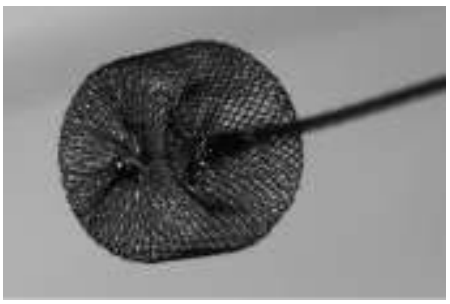


Fig. 1b.

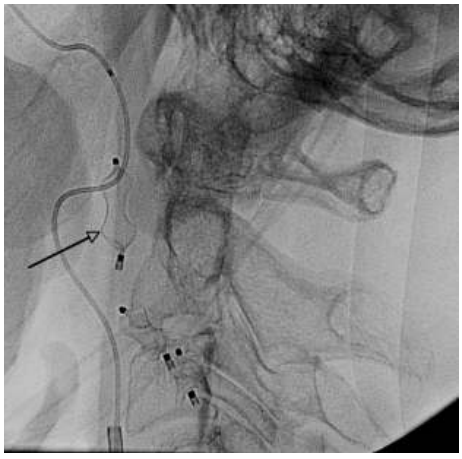


Fig. 1c.

Fig. 1. (a) Lateral and (b) anterior oblique views of the AVP attached to its delivery cable. (c) Unsubtracted fluoroscopic image shows 3 AVPs deployed along the ICA. Note the "hourglass" configuration of the plug (arrow).

Subjects

Between July 2007 and November 2008, 8 patients (3 males and 5 females, mean age 59.1 years, range 18 to 82 years) underwent therapeutic occlusion of major craniocerebral arteries in our department using the AVP (Table 1). One patient presented with a direct caroticocavernous fistula (CCF) following rupture of an underlying cavernous internal carotid aneurysm. Two patients presented with symptomatic unruptured giant aneurysms of the cavernous internal carotid arteries (ICA). In the other 5 patients, the procedures were performed preoperatively before surgical resections of extensive skull base tumours that had encroached upon the ICA or vertebral arteries (VA).

The procedures were carried out using a high-resolution biplane angiography system (Integris Bi-plane, Philips, Amsterdam, Netherlands). Under monitored anaesthetic care and systemic heparinisation (target activated clotting time >250 s), each patient underwent a successful balloon test occlusion of the target vessel with hypotensive challenge.

A 6 French Envoy MPD guide catheter (Cordis Neurovascular, Miami Lakes, FL) with continuous flush of heparinised sodium chloride solution (5 IU/mL) was positioned in the target vessel (ICA or VA), through which the AVP was deployed. In the first 5 of our patients (patients 1-5, Table 1), the plugs were used in conjunction with bare platinum coils. An additional 3 coils and 6 to 8 coils were deployed proximal to the plugs in the vertebral

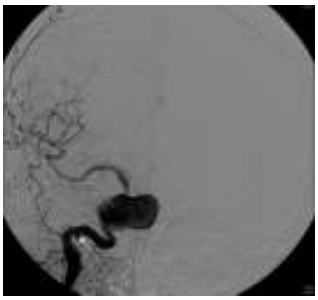
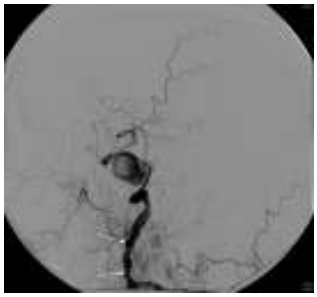


Fig. 2a.



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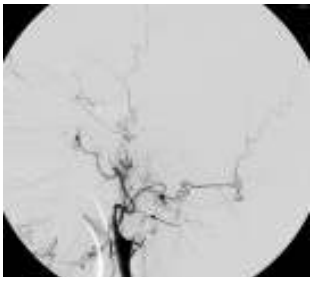

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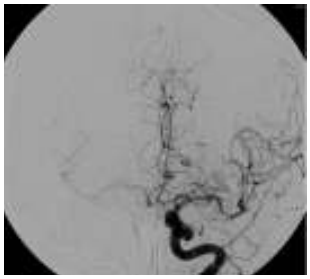

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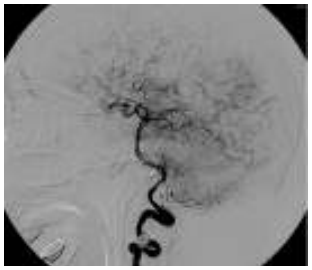


Fig. 2e.

Fig. 2. A 71-year-old female presented with right retro-orbital pain and diplopia. (a) Frontal projection of right internal carotid angiogram shows a giant aneurysm of the cavernous ICA. A small aneurysm is also seen in the horizontal segment of the petrous ICA (arrow). (b) Lateral projection of right internal carotid angiogram reveals severe underlying fibromuscular dysplasia (arrows). (c) Lateral projection of right common carotid angiogram shows complete occlusion of the right ICA, following the use of an 8 mm AVP (arrow) to anchor the subsequently deployed platinum coils. (d) Frontal projection of left common carotid angiogram and (e) lateral projection of left vertebral angiogram at 6-month follow-up show excellent collateral flow into the right cerebral circulation via the anterior communicating artery and a prominent right posterior communicating artery. No retrograde filling of the aneurysm is demonstrated.

and internal carotid arteries, respectively. The AVP acted as an anchoring scaffold to facilitate coil embolisation of the parent artery and prevent coil mass migration[11] (Fig. 2). In the 3 subsequent patients (patients 6-8, Table 1), several AVPs were placed in tandem along the parent vessel without using any additional coils (Fig. 3).

In the patient with direct CCF (patient 2, Table 1) and 1 of the other 2 patients with giant cavernous ICA aneurysms (patient 1, Table 1), the cavernous sinus/aneurysms and the adjacent cavernous ICA were loosely packed with bare platinum coils before occlusion of the cervical ICA proximally. In the other patient with giant cavernous ICA aneurysm (patient 5, Table 1), we decided not to pack the aneurysm with coils due to her severe underlying fibromuscular dysplasia and the associated risk of arterial dissection in navigating a catheter into the aneurysm (Fig. 2). The decision was further supported by the fact that no retrograde filling of the aneurysm was evident during balloon occlusion of the ipsilateral ICA.

Postoperatively, all patients were nursed on flat bed rest for 24 hours with progressive increase in activity as clinically tolerated. The blood pressure was controlled meticulously (target systolic blood pressure >110 mm Hg) for the first 24 to 48 hours. For patients with cavernous ICA aneurysms and/or CCF, they were maintained on systemic heparinisation for 24 hours (target activated prothrombin time, APTT of 50-60 s). For patients who underwent pre-surgical parent artery embolisations, no additional heparin was given apart from the initial dose just prior to the balloon occlusion test, in view of their subsequent operations in the following 1 to 4 days. No periprocedural oral anti-platelet therapy was prescribed for any of our patients. Routine post-procedural imaging was not part of our protocol for uneventful balloon

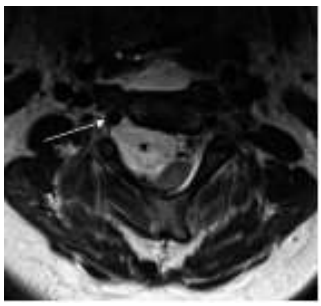
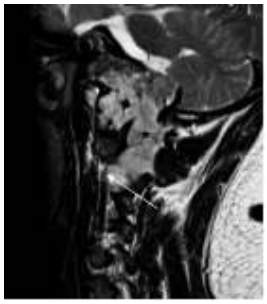


Fig. 3a.



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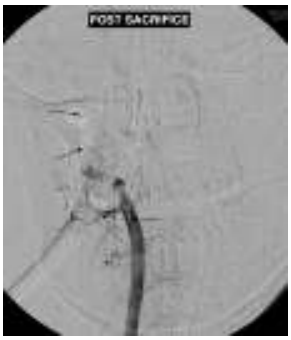

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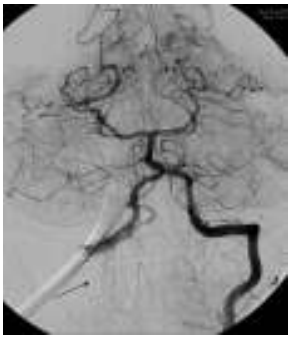

Fig. 3d.

Fig. 3. An 18-year-old male with clival chordoma. (a) Axial and (b) sagittal T2-weighted MR images show the chordoma (asterisks) encroaching upon the right VA (arrows) at the C2/C3 level. (c) Lateral projection of right vertebral angiogram shows complete occlusion of the artery following deployment of 4 AVP (arrows) in quick succession along the artery between C2 and C4 levels. (d) Frontal projection of left vertebral angiogram reveals good retrograde filling of the right posterior inferior cerebellar artery. The plugs are again noted (arrow). The patient underwent a successful surgical resection of the tumour a day after the procedure.

Table 1. Patient Data

Patient	Age (y)	Gender	Underlying lesion	Vessel	No. & (diameter) of AVP occluded	Additional coils
1	62	F	L ICA giant aneurysm	L ICA	1 (8 mm)	Yes
2	82	F	L direct CCF	L ICA	2 (8 & 6 mm)	Yes
3	57	M	Cervical vertebral sarcoma	R VA	2 (8 & 6 mm)	Yes
4	57	F	Cavernous sinus meningioma	R ICA	1 (6 mm)	Yes
5	71	F	R ICA giant aneurysm	R ICA	1 (8 mm)	Yes
6	64	F	Recurrent haemangioblastoma invading L cavernous sinus	L ICA	3 (8, 6 & 6 mm)	No
7	18	M	Clival chordoma infiltrating the upper cervical spine	R VA	4 (10, 8, 6 & 6 mm)	No
8	62	M	Skull base adenoid cystic carcinoma invading right cavernous sinus	R ICA	3 (8, 6 & 6 mm)	No

CCF: caroticocavernous fistula; ICA: internal carotid artery; L: left; R: right; VA: vertebral artery

test occlusion or therapeutic parent artery sacrifice, as it would be unlikely to alter patient management. The patients were followed-up in 3 and/or 6 months.

Results

All the AVPs were deployed through a 6 French Envoy MPD guide catheter. The deployment and detachment of the device were straightforward and uneventful. As noted earlier, additional coils were used in our initial 5 cases but not in the last 3 (Table 1). The procedures were successful in all 8 patients, with hermetic occlusion of the parent vessel documented angiographically in each case. No migration of the AVP was detected. None of the patients developed new neurological deficits in the post-interventional course.

Two complications, not directly related to the procedure were encountered. One patient (patient 1, Table 1) received an erroneous dose of intravenous heparin (10-fold the intended dose) during the procedure. She developed a massive retroperitoneal haemorrhage and eventually died.

Another patient (patient 8, Table 1) had advanced recurrent adenoid cystic carcinoma of the central skull base infiltrating the right cavernous sinus, right orbit and right temporal lobe. The preoperative therapeutic embolisation of his right ICA was successful with no evidence of any neurological complications. He underwent an extensive surgery 4 days later to debulk the tumour, which included right temporal lobectomy, enucleation of the right globe with the optic nerve, exenteration of the right cavernous sinus with tumour resection and sacrifice of the third, fourth, fifth and sixth cranial nerves. He made a poor recovery following his major surgery with persistent increased intracranial pressure and eventual bilateral hemispheric infarcts, especially on the right side. He died 7 days after his surgery, 11 days after therapeutic sacrifice of his right ICA.

The 3-month and/or 6-month follow-up in the other 6 patients showed stable occlusion of the parent artery, with persistent exclusion of the CCF (in patient 2, Table 1) and cavernous ICA aneurysm (in patient 5, Table 1). Other than the expected cranial nerve palsies secondary to the intended surgical sacrifice of particular cranial nerves, all patients were clinically well with no untoward neurological deficits.

Discussion

When therapeutic sacrifice of a major craniocerebral artery is indicated, endovascular occlusion offers clear advantages over direct surgical ligation as it is less invasive and allows assessment of collateral circulation, both clinically and angiographically, during the procedure.[1,17] Conventionally, this has been performed using detachable latex and silicone balloons, pioneered by Serbinenko and Debrun, which allow rapid occlusion of the parent artery and thus minimise the potential risk of distal thromboembolism.[11,18-20] A detachable balloon may be used to perform the test occlusion and (if appropriate) subsequently deployed for therapeutic occlusion of the particular artery. However, using a detachable balloon would preclude stump pressure measurement and more importantly, continuous flushing of the parent artery distal to the inflated balloon during the test occlusion. Should the test fail, there would be no way of clearing the column of stagnant blood with possible thrombi distal to the balloon prior to deflation. Another major drawback of this device is the risk of premature unintended detachment.[15] Moreover, detachable balloons have been withdrawn from the market and are unavailable

or difficult to obtain in certain countries, including the United States of America.

As a result, many neuro-interventionists have resorted to using coils for parent artery embolisation. However, coils provide a much less stable anchorage on the vessel wall, especially in a large compliant artery with a high flow rate, and are therefore prone to migration. In addition, coil embolisation of a major craniocerebral artery is a step-wise, time-consuming procedure, which inevitably requires multiple coils. The duration between deployment of the first coil and complete occlusion of the parent artery allows generation of thromboembolic complications.[15] The risk of these complications may be reduced by deploying the coils while maintaining proximal flow arrest in the parent artery with the test occlusion balloon inflated.[21,22] However, when using proximal flow control, it may be difficult to know for certain when the coil mass is sufficiently stable. In our experience, this often leads to over-packing of the artery. Fibred coils and hydrogel-coated coils have also been used to enhance the thrombogenic effect and increase the volumetric filling of the coils, in order to accelerate occlusion and reduce the number of coils required.[23-25] Regardless of the type of coils, many would consider therapeutic sacrifice of a major craniocerebral artery using coils alone as a relatively expensive procedure that is not cost-effective.

The AVP, on the other hand, offers a unique combination of some of the advantages of the balloons and coils.[15] The device is easy and straightforward to use. As per its product guidelines, the AVP has been shown to be MR conditional and is safe within a static magnetic field of 3 Tesla or less, and a spatial gradient magnetic field of 720 G/cm or less. The ability to resheath and reposition the device enables very precise placement within the target artery. Once deployed, the high radial force anchors the plug securely onto the vessel wall and prevents any distal migration.

The AVP is available to us at a cost of approximately 20% to 30% more expensive than a microcoil or detachable balloon (including the microcatheter to which it is attached). The AVP may be used alone or in conjunction with coils, either way it is more time-effective and cost-effective than using coils alone. Our current practice is to use AVPs only (usually 3 to 4 pieces), as they could be delivered rapidly to achieve total occlusion of the vessel.

The intrinsic thrombogenic effect of the nitinol mesh and the flow turbulence induced by the mesh cage stimulate clot formation within the plug.[14] If only a single plug is deployed, complete cessation of flow through the vessel may be delayed for up to 35 minutes.[26] This presents a possible window for distal thromboembolism into the eloquent cerebral circulation, due to flow through the porous body of the device, until total occlusion of the artery. In addition, prompt occlusion of the parent artery proximally is particularly important when coils are also deployed distally (often in the cavernous ICA to discourage retrograde recanalisation of a giant cavernous ICA aneurysm), to minimise the duration of antegrade flow through any coils in the parent artery to reduce the risk of thromboembolism. In our experience, several AVPs could be deployed in tandem and in quick succession to achieve rapid parent artery occlusion with no evidence of neurological deficits from thromboembolic complications. Admittedly, the data available is limited and routine follow-up MRI with diffusion-weighted sequence was not performed to evaluate for possible clinically silent thromboembolic events. A larger scale of study would be necessary to address this issue, including the appropriate anticoagulation and/or antiplatelet regimes for these patients. In our case series, all patients were under full heparinisation during the procedures, and other than the pre-surgical patients, they also received intravenous heparin for the next 24 hours.

Another major drawback of the AVP is that it is mounted on a fairly stiff delivery wire, which compromises its navigability, especially through tortuous vascular segments.[11] In addition, the plug has to be deployed directly from a relatively large guide catheter of at least 5 French in size. As a result, this device is currently limited to use in vessels below the skull base, and is unsuitable for intracranial vessels. We do not have any experience using the AVP in patients with torrential head and neck haemorrhage. Its use in such cases would obviously be limited by the anatomy and tortuousity of the vessels concerned. Theoretically, it should be feasible to use the device to trap a bleeding point arising from the mid cervical ICA.

These limitations highlight the need for adaptation of the AVP, which is meant for cardiopulmonary and peripheral vascular usage, to meet the stringent demands of neurointerventional procedures.[15] A lower-profile plug with a more delicate delivery system would improve the navigability of the device and enable its placement in the smaller-calibre intracranial vessels.[27] A plug with a denser nitinol mesh, or covered with an impermeable membrane may result in total occlusion of the parent artery much more rapidly with the use of a single device, and thus reduce any potential risk of thromboembolism.[14,15,27]

Conclusion

From our initial clinical experience in using the AVP for therapeutic sacrifice of major craniocerebral arteries, we have found that the use of this device is uncomplicated, safe and effective. With further modifications to circumvent its limitations, this device would be an even more valuable addition to the neurointerventional armamentarium, particularly in parent artery occlusion.

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