CASE REPORT

Retrograde trans-anterior communicating artery rescue of unopened Pipeline Embolization Device with balloon dilation: complication management

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SUMMARY

As the use of the Pipeline Embolization Device (PED) for the treatment of complex intracranial aneurysms rises, knowledge about complications continues to accumulate amidst a paucity of reports on techniques and rescue strategies. We describe the case of a 70-year-old woman who presented with worsening retro-orbital left-sided pain and a large cavernous aneurysm. The patient underwent endovascular treatment with PED, and there was difficulty delivering the device due to significant vascular tortuosity. This resulted in poor PED deployment as the proximal end failed to open. Increasingly aggressive strategies were attempted to open the device, which resulted in an iatrogenic carotid cavernous fistula. We were finally able to rescue the device and open its proximal end with balloon inflation after using a contralateral trans-anterior communicating artery approach and crossing the PED in a retrograde fashion. Excessive vascular tortuosity poses a genuine risk of PED malfunction and poor deployment. Although we were able to rescue the device and our patient had no permanent morbidity, difficult vascular anatomy rendered the procedure extremely complicated with dreaded complications.

BACKGROUND

The Pipeline Embolization Device (PED) was initially approved in Europe in 2009 after the Pipeline Intracranial Treatment of Aneurysms (PITA) trial^{1 2} and in 2011 in the USA after the Pipeline for Uncoilable or Failed Aneurysms (PUFS) trial for treatment of intracranial aneurysms.^{2 3} Since its approval, the use of flow diversion for endoluminal repair of large or giant aneurysms has increased significantly. Current Food and Drug Administration regulations limit its on-label use to adults aged >22 years with large or giant wide-necked aneurysms located on the internal carotid artery (ICA) from the petrous to the superior hypophyseal segments.^{2 4 5} As with any new technology, operators face technical difficulties and complications while using these devices, and sharing experiences is important.

The PED (ev3, Irvine, California, USA) is an unsheathable self-expanding stent with a high metal surface area which is designed to divert flow away from the aneurysm sac and promote its obliteration. It also serves as a scaffold for endothelial neointimal reconstruction across the aneurysm neck.^{2 5} Although postoperative morbidity and mortality have been reported, less attention has been paid to intraoperative technical complications

and their rescue strategies. We report an intraoperative rescue strategy for malfunction and failure of Pipeline deployment during the treatment of a large ICA aneurysm.

CASE PRESENTATION

A 70-year-old woman presented with worsening of left retro-orbital pain and was diagnosed with a 10 mm left cavernous aneurysm with a 4.7 mm neck (figure 1A,B). Management options were

Figure 1 (A) Anteroposterior view and (B) lateral view of the left cavernous carotid aneurysm.

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Figure 2 (A) Aortic arch, (B) left common carotid artery and (C) right common carotid artery angiograms showing significant tortuosity and looping of the vessels.

discussed with the patient and, given her recent changes in headaches, the decision was made to proceed with endovascular treatment using the PED. The procedure was performed with conscious sedation using a right femoral access. A 5 Fr DAV catheter (Cook Inc, USA) was advanced into the aortic arch, which had a bovine configuration (figure 2A). Intravenous heparin was given to maintain activated coagulation time at 250–350 s. The catheter was subsequently navigated to the left ICA, which was found with significant tortuosity (figure 2B), and exchanged over a TAD II wire (Covidien, Mansfield, Massachusetts, USA) for a long 6 Fr Arrow Flex (Arrow International, Reading, Pennsylvania, USA) armored sheath that was positioned in the left proximal ICA. A ReFlex 0.058 guiding catheter (Reverse Medical Corporation, Irvine, California, USA) was then advanced through the armored sheath all the way to the petrous segment of the ICA. Using the roadmap technique, a Marksman microcatheter (ev3) was advanced over a Synchro 2 Soft microwire (Boston Scientific Corporation, Fremont, California, USA) into the left middle cerebral artery. Some difficulty was encountered during this

process due to the marked tortuosity of the ICA. A 5×16 mm PED was then advanced with some difficulty due to tortuosity, and unsheathing of the device was started at the ICA terminus. Opening of the distal end of the PED was challenging and required repeated manipulation and rotation of the wire (fewer than 10 clockwise turns, as stated in the product's Instructions for Use). This was followed by a progressive deployment of the device with satisfactory coverage of the aneurysm neck until the beginning of the proximal horizontal portion of the carotid siphon. At this point, the PED failed to open progressively with unsheathing despite repetitive manipulation of the microcatheter and the delivery microwire (figure 3).

TREATMENT

Fully unsheathed, the proximal part of the device did not open despite manipulation of the microwire and microcatheter both separately and together as one unit. We initially attempted pushing the microcatheter forward to mobilize the proximal end to try to traverse the PED which was also ineffective.

Figure 3 Lateral view of the left cavernous carotid after deployment of the Pipeline Embolization Device (PED). Proximal beaking of the PED can be seen secondary to proximal device failure to open (black lines).

Figure 4 Carotid-cavernous arteriovenous fistula seen after repeated manipulation of the proximal end of the Pipeline Embolization Device to promote opening of the device.

Figure 5 Demonstration of (A) anterior communicating artery patency and (B) trans-anterior communicating access from the right to the left intracranial carotid artery.

Manipulation of the PED delivery microwire was attempted with no success. We then tried to access the constricted proximal end of the PED with a Prowler Plus microcatheter (Cordis Corporation, Miami Lakes, Florida, USA) over a microwire, followed by a further attempt to push forward the proximal device with the microcatheter. After failure of these maneuvers, we unsuccessfully tried to use a Hyperform balloon (Micro Therapeutics, Irvine, California, USA) to push the PED distally and force its opening. We then attempted to retrieve the PED using a microsnare followed by an Alligator retrieval device (Chestnut Medical Technologies, Menlo Park, California, USA) without success. At this point, after repeated manipulation of the endovascular tools within the ICA, we noted a carotid-cavernous fistula (CCF) (figure 4). The options of leaving the device constrained at its inflow zone with a possible negative outcome versus further attempts to reopen it were considered, and the decision was made to try accessing the PED from its distal open end in a retrograde fashion and to attempt to open it using a contralateral approach through the anterior communicating artery. Cross-compression of the right ICA with left ICA injection revealed cross-filling with a sizeable anterior communicating artery (figure 5A). Left groin access was achieved, and a DAV catheter was navigated into the right ICA through the bovine arch. A Neuron 070 guiding catheter (Penumbra, Alameda, California, USA) was advanced into a very tortuous right ICA (figure 2C) with the help of an intermediate size catheter. An Excelsior SL-10 microcatheter (Boston Scientific) was navigated over a Synchro 2 Soft microwire. The Neuron catheter was unstable initially, and a V-18 buddy wire was used to

provide stability to the construct. This helped to stabilize the system and rendered advancement of the microcatheter easier until crossing the anterior communicating complex to the left A1 segment. The left ICA was traversed in a retrograde fashion followed by traversing the distal open end of the PED towards the constrained proximal end until reaching the left ICA at the level of the skull base (figure 5B). During this part of the procedure the patient became agitated with urinary urgency and could not cooperate any further, and the procedure was converted to general anesthesia. An X-Celerator 0.010 microwire (ev3) was used to exchange the Excelsior SL-10 for a Hyperform balloon. Given the tortuosity, there was difficulty advancing the balloon to the contralateral side and the tip of the microwire was unstable. In order to maintain stability of the system, a microsnare was advanced through the right groin into the left ICA to capture, straighten and stabilize the distal end of the microwire in a flossing fashion. Following this, the balloon was advanced over the X-Celerator microwire through the open distal end of the PED into the constricted proximal end (see video 1 of flossing technique). After three balloon inflations, the PED opened appropriately with satisfactory apposition to the vessel wall. We made a few additional attempts to find the fistula point for potential treatment. This proved difficult and the procedure was terminated.

OUTCOME AND FOLLOW-UP

Postoperatively, the patient had no neurological deficit and no clinical evidence of a CCF. Ophthalmological evaluation showed no conjunctival erythema and the intraocular pressure was

Video 1 Flossing technique: stabilization of the micro-balloon microwire with a snare and inflation of the balloon across the constrained proximal end of the PED.

Figure 6 Complete obliteration of the aneurysm and resolution of the carotid-cavernous fistula 7 months after initial treatment. Note the anatomy of the carotid siphon with an acute angle (thin white lines) at the transition from the lacerum to the cavernous segment of the carotid and the markedly higher position of the posterior genu of the cavernous carotid compared with the anterior genu (thick white lines).

within the normal range. A second angiogram was performed after 24 h and showed a stable position of the PED and no radiographic changes of the fistula. The patient was followed with serial ophthalmology evaluations, and she remained at baseline with normal intraocular pressure. Her follow-up angiogram at 7 months showed complete obliteration of the aneurysm as well as the fistula (figure 6).

DISCUSSION

Endoluminal reconstruction of intracranial aneurysms with flow diversion is gaining popularity as a reliable method for treatment of large and giant intracranial aneurysms.^{2 5-7} The PED is a flexible, self-expanding, microcatheter-delivered, stent-like device with high metal surface coverage which is used with increasing frequency.² Compared with intracranial self-expanding stents, adequate PED deployment can be very challenging and the final result in terms of its position in relation to the aneurysm neck and adjacent vessels, wall apposition and degree of opening can be quite unpredictable. For example, owing to its flexibility, the device can foreshorten up to 50%. Furthermore, the distal tip coil should be recaptured with need to recross the whole length of the device with the microcatheter after successful deployment. Problems with recapturing the coil have already been reported,^{8 9} and these events will probably be addressed with the anticipated development of newer generations of the PED. Foreshortening of the device has also been implicated with migration of the proximal end of the device inside a giant aneurysm and loss of distal access.⁷ Based on the PUFs study, the intraoperative performance of the PED was very high and only one of 108 PEDs could not be successfully placed due to impossibility of catheterization of the vessel distal to the aneurysm neck.^{2 3} In an excellent review paper of the current status of the use of the PED for intracranial aneurysm treatment, Mona *et al* have identified a total of eight deployment failures.^{1 10} As the use of this new technology continues to increase, we are learning

more about the device malfunction and the methods to circumvent and manage these procedural complications with potential for negative outcomes. As in our patient, most of these failures occur in patients with very tortuous vessels and are probably related to excessive friction and the need for increased force to push the device.

As removal of the microcatheter and delivery system is clearly recommended and outlined in the PED instructions for use, the option of the so-called 'corking technique' (removal of the device by bringing the partially opened PED to the tip of the delivery microcatheter) was considered while deploying the device. Although not recommended, the PED can be recaptured at very early stages of its deployment. However, we had already unsheathed a significant portion of the flow diverter, precluding safe recapture of the device. Indeed, the microcatheter had an excessively tortuous course, which was even worse than the tortuous course of the ICA as it was pushed forward, and excessive friction was encountered during delivery of the PED. Although we cannot be completely sure, we believe that the excessive force that was required to deliver the PED led to its damage by jamming the mesh network at the interface with the delivery system (pushing the coil), preventing it from adequate deployment. We have observed that navigation of the device through tortuous vessels can be associated with difficulty in deployment and can result in device malfunction. We especially consider a higher risk anatomical configuration when the transition from the lacerum segment of the carotid to the cavernous segment is close to 45° and the posterior genu of the cavernous carotid is higher than the anterior genu (on lateral projection) of the ICA cavernous segment (figure 6).

Once the PED was delivered satisfactorily to the desired position, deployment of the distal PED was tedious and required several manipulations to the microcatheter and delivery microwire. Then, deployment did progress satisfactorily for the middle portion with repetition of pushing and pulling the microcatheter and delivery microwire together, referred to as the 'wagging the tail' maneuver. Deployment of the proximal portion was not progressing satisfactorily, and we considered retrieving the device by pulling the microwire backwards to grasp and secure the PED between the tip of the microcatheter and the distal coil, preventing it from slipping and inadequate deployment. However, we decided to proceed with deployment, as we had in similar events, and the proximal end opened when pushing the wire forward to generate pressure against the proximal mesh or with advancement of the microcatheter to generate a forward pressure on the proximal end and opening the device. We also had similar instances where a balloon was used to push the proximal PED to help it to open. However, all these maneuvers did not succeed in opening the device, and repeated manipulation of the device caused damage to the ICA and resulted in an iatrogenic CCF.

We could have avoided the use of a large long device and instead used two or three shorter devices in a telescoped fashion to cover the aneurysm neck satisfactorily. From a mechanical perspective, and compared with a long PED delivered through the same microcatheter curvatures, a shorter device would be exposed to a smaller surface, would be less curvaceous (relative to its length) and would have less friction against the microcatheter, so it can be delivered more easily for the same degree of vascular tortuosity. In retrospect, this might have helped in the correct opening of the device by avoiding too much tension created by the sharp turns of the ICA of the patient on a single flow diverter. However, this might also represent an increased risk of foreshortening and displacement of

the device as it would have to be penetrated again with a microcatheter to deliver the additional PEDs. In spite of using a triaxial system to provide additional support and improve the transmission of fine microcatheter and microwire movements, we still experienced significant difficulties. Simple rescue strategies that we have previously used to promote the opening of the proximal PED end, such as 'push and shake' of the proximal end of the PED with a microcatheter and a balloon, did not work in this case. We also tried to capture the PED using a snare and an Alligator retrieving device (Covidien). However, the working angle prevented proper contact of the devices, which impeded the catchment and retrieval of the PED after multiple manipulations. This caused a CCF. After the failure of all these strategies, we decided not to leave the device unopened as we were unsure about the prognosis in similar cases, given the paucity of reports on complications with the PED. We therefore elected not to leave an unopened PED, which could pose the potential risk of ICA thrombosis and a major left hemispheric stroke.

We then decided to salvage the device by gaining access into the constricted proximal end of the PED in a retrograde fashion through the contralateral ICA via the anterior communicating artery. The PED was crossed satisfactorily, passing the balloon was very challenging and angioplasties were performed in the constricted proximal PED. Before and after angioplasty of the device, a snare was used to pull on the tip of the microwire to straighten and improve the stability of the system. A similar flossing or pull-down technique has previously been described by Hauck *et al*⁷ as a rescue strategy for repositioning a PED after intra-aneurysmal migration of its proximal end. The posterior circulation was used to gain proximal access through the posterior communicating artery in a retrograde fashion. As in our case, the patient had a CCF during the procedure, in addition to a subarachnoid hemorrhage and a transient motor deficit. In our case, the fistula did resolve spontaneously with no negative clinical outcomes, and this resolution was shown on her angiogram 7 months later.

Another bailout strategy we considered—namely, performing a balloon test occlusion (BTO) with ICA occlusion—might have been our next step if we could not salvage the device and the ICA. We do not routinely perform the BTO before flow diversion procedures for ICA aneurysms; however, this might be worth considering in cases with similar tortuosity. When feasible, we attempt local anesthesia with sedation. Nevertheless, the procedure became complex and the patient became agitated and required intubation, which rendered the BTO unreliable in the absence of good clinical feedback and without neuromonitoring, as stroke has been reported following carotid sacrifice despite long duration BTOs.¹¹ Another rescue strategy in similar cases would be to consider a high-flow bypass with endovascular or open ICA occlusion. In our patient, these options were not discussed elaborately prior to the procedure and the risk of complications with emergency high-flow bypass with the patient on dual anti-aggregation is certainly high.

Learning points

- ▶ Excessive vascular tortuosity increases friction between the Pipeline Embolization Device (PED) and the microcatheter and can damage the device and cause its malfunction and improper deployment.
- ▶ As is the case with any new device, it is important to realize the limitations of unestablished technology to prevent similar complications. In our opinion, it is equally important to report success and failure of new technologies and to communicate with peers about rescue strategies in the event of similar occurrences to prevent undesired patient outcome. In this case, we were able to use retrograde access through the anterior communicating artery to rescue the PED and obtain satisfactory deployment.

Contributors RN: conception and design, acquisition of data, drafting the article, review of submitted version of manuscript. JY: critical revision of the article and review of submitted version of the manuscript. TD: acquisition of data, critical revision of the article and review of submitted version of the manuscript. DAM, RAH: critical revision of the article and review of submitted version of the manuscript. RGT: conception and design, critical revision of the article, review of submitted version of the manuscript, approval of the final version on behalf of all authors and supervision of the study.

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