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Review

Flow diverters for treatment of intracranial aneurysms: Current status and ongoing clinical trials ☆

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ABSTRACT

The ultimate treatment goal for intracranial aneurysms is to reconstruct the vessel wall and correct the hemodynamic disturbance. A flow diverter is a stent placed in the parent artery to reduce blood flow in the aneurysm sac to the point of stagnation, gradual thrombosis, and neointimal remodeling to maintain outflow in the side branches and perforators. Here, we review the two commercially available flow diverters, the Pipeline Embolization Device (PED) and the SILK flow diverter (SFD). The rates of severe hemorrhagic complications have been reported to be 2% for the PED and 0.8% for the SFD. The results of studies completed thus far show that endovascular reconstruction with flow diverters is an effective treatment of wide-necked, fusiform, large, and giant unruptured intracranial aneurysms, with 5% to 10% of patients experiencing permanent major morbidity and mortality. The results of ongoing studies may resolve whether flow diverters can replace coil embolization for the treatment of all, or selected, intracranial aneurysms.

1. Background

Aneurysmal subarachnoid hemorrhage remains an important cause of stroke mortality and morbidity.[1,2] Securing aneurysms to prevent rebleeding is one of the major goals in patient management. Endovascular aneurysm treatment was revolutionized by the introduction of endovascular detachable balloon occlusion in 1974 and Guglielmi detachable coil (Boston Scientific, Target, Fremont, CA, USA) embolization in 1991.[3] In the mid-1990s, balloon-assisted techniques enhanced the capacity to treat intracranial aneurysms endovascularly. Another similar solution using a stent-assisted technique was popularized in the early 2000s. These intracranial stents typically required less than 10% metallic coverage of the parent vessel and aneurysm orifice to act as a scaffold for coil embolization, thereby minimizing the amount of foreign material and reducing the likelihood of thromboembolic complications. With these advances, increasing numbers of ruptured intracranial aneurysms are now being treated with endovascular coil embolization.[4] But endovascular coil embolization has a unique form of recurrence and complications, which has inspired creative pioneers to invent new tools. The use of overlapping intracranial stents to treat uncoilable intracranial aneurysms has been promising and has encouraged further research into flow diversion as a treatment for intracranial aneurysms.[5–11] Here, we review the flow-diverting stent, which has been a groundbreaking invention in intracranial aneurysm treatment.

2. The principle of flow diverters

Hemodynamic factors are considered to be a major factor in the progression and rupture of intracranial aneurysms.[12–15] Accordingly, the ultimate treatment goal is to reconstruct the vessel wall and correct the hemodynamic disturbance. The flow diverter is a stent placed in the parent artery to reduce blood flow in the aneurysm sac to the point of stagnation, gradual thrombosis, and neointimal remodeling to maintain outflow in the side branches and perforators.[16] Additionally, flow diverter implantation may change the configuration of the parent vessel, thereby changing the anatomy of the parent vessel–aneurysm complex and the aneurysm inflow zone.

Computation hemodynamics suggests that a stent with an overall porosity of 50–70% (30–50% metallic coverage) will significantly reduce the inflow rate into an aneurysm.[17] Evaluation in rabbit elastase-induced aneurysm models showed that a device with a porosity of 70% and pore density of 18 pores/mm^3 performed better in occluding aneurysms at six months than devices with 70% porosity and 12 pores/mm^3, or 65% porosity and 14 pores/mm^3.[18] Again, in rabbit elastase-induced aneurysm models, a Pipeline

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Embolization Device (PED) (eV3, Irvine, CA, USA) providing 35% area coverage showed a higher aneurysm occlusion rate than a PED providing 30% area coverage.[19,20] As no branch occlusion was observed, this suggests that a tighter mesh is essential for flow diversion and aneurysm occlusion.

3. Description of flow diverters

The PED is a mesh tube of woven wire, made of 25% platinum and 75% cobalt–nickel alloy, designed to provide 30–35% metal coverage of the inner surface of the target vessel, with a pore size of 0.02–0.05 mm^2 at a nominal diameter.[21,22] The area of coverage provided by the PED is around three times more than other commonly employed intracranial stents, such as the Neuroform stent (Boston Scientific, Target, Fremont, CA, USA) which provides 6.5–9.5% metallic surface area coverage. The PED is attached to a pusher wire, compatible with a 3-F (0.027-inch internal diameter [ID]) microcatheter (Renegrade High Flow, Boston Scientific, Natrick, MA, USA; Mass Transit, Cordis, Miami Lakes, FL, USA; Marksman, eV3, Irvine, CA, USA), which has a platinum coil tip that extends 15 mm beyond the distal edge of the device. The PED is delivered via a 0.027-inch ID microcatheter that requires a 6-F guide catheter support. Once positioned across the aneurysmal segment, the delivery wire is held while the distal one-third to one-half of the PED is carefully unsheathed. Once the unsheathed segment begins to expand, the distal end is released by clockwise rotation of the delivery wire. The proximal segment of the PED can then be deployed, mainly through the application of forward pressure on the delivery wire (supplemented by unsheathing during curves). "Jailing" of another microcatheter is required for secondary coiling, if planned. By August 2010, 1178 aneurysms had been treated with PED.

Another dedicated flow-modifying device, the SILK flow diverter (SFD, Balt Extrusion, Montmorency, France), has also been made available recently for clinical use. The SFD is a flexible, self-expanding device specifically designed to produce hemodynamic flow diversion and to reconstruct laminar flow in the parent artery. The device is a braided mesh cylinder with flared ends, composed of 48 nickel–titanium (nitinol) alloy and platinum microfilaments of around 35 μm, designed to provide 35–55% metal coverage of the ID of the target vessel, with a pore size of 110–250 μm^2.[23,24] The usual insertion technique involves deploying the distal tip of a delivery microcatheter (Vasco 21, Balt, Montmorency, France) to the aneurysm and then pushing the SFD to the tip of the delivery wire to which it is attached. The system is then aligned with the aneurysm under X-ray fluoroscopy and the SFD is deployed by unsheathing it from the constraint of the microcatheter. This involves a combination of pushing the delivery wire and retrieving the microcatheter, to allow the SFD to expand and to compensate for any resulting foreshortening. The SFD can be retrieved into the microcatheter and removed or repositioned when less than 80% of its length has been extruded. No retrieval is possible thereafter. Jailing of another microcatheter is required for secondary coiling, if planned. Around 1500 aneurysms had been treated with SFD by l March 2010.

4. Completed studies[25]

Data are available for three completed studies (the Pipeline Embolization Device in the Intracranial Treatment of Aneurysm Trial [PITA], the Budapest single center study, and the SILK registry) and two large international series conducted by the Buenos Aires Group and the Ankara Group. A SILK retrospective subgroup series has also been reported recently.

4.1. Pipeline Embolization Device

The PED in the PITA trial was an industry-sponsored safety trial for CE mark approval (Conformité Européenne, certifying compliance with the European Community) of the PED.[25] The results have been presented, but not published. The trial comprised a prospective four-center, single arm study with core laboratory image analysis. Thirty-one patients with unruptured wide-necked intracranial aneurysms in whom treatment with coil embolization had failed were included. The mean neck diameter was 5.8 mm and the mean aneurysm diameter was 11.5 mm. PED alone was used in 48% of patients and PED plus coils was used in 52% of patients. Six-month imaging follow-up was conducted in 96% of patients. Complete occlusion at six months was achieved in 93.3% of patients. At six months, the mortality and permanent morbidity rates were 0% and 6.5%, respectively.

The Budapest single center study, which was a continuation of PITA, confirmed the findings of the PITA study.[21] A total of 19 large or giant wide-necked aneurysms were treated in 18 patients. Angiography at six months demonstrated complete occlusion in 17 aneurysms. Four neurological complications resulted in one patient (5.5%) with permanent morbidity and one (5.5%) mortality. Of the 17 ophthalmic arteries that were covered by a PED, one (5.9%) was occluded acutely, with visual deficit and two (11.8%) were occluded in a delayed fashion, with no clinically detectable deficit. No other side branch occlusions were documented.

The results of the Buenos Aires study were reported recently.[22] This prospective single-center registry, which comprised 53 patients with 63 intracranial aneurysms, also expanded on the PITA study and, again, confirmed the findings of the foregoing two studies. Thirty-three (52.4%) were small wide-necked aneurysms. Complete angiographic occlusion was achieved in 56%, 93%, and 95% of aneurysms at 3 months ($n = 42$), 6 months ($n = 28$), and 12 months ($n = 18$), respectively. There was no mortality and three patients (5%) with giant aneurysms experienced transient exacerbation of pre-existing cranial neuropathies or headache. Five patients developed hematomas at the femoral puncture site.

The Ankara (Hacettepe University) Group's experience with the PED was presented recently.[26] The study comprised 129 patients with intracranial aneurysms treated with PED. The 12-month occlusion rate was 95%. There was one (0.8%) symptomatic parent artery stenosis, four (3.2%) permanent morbidities, and one (0.8%) mortality. Again, the outcomes were similar to the other three reported studies.

There are also case reports with encouraging results for use of the PED for large or giant fusiform aneurysms in the internal carotid artery and basilar artery.[27–29]

4.2. SILK flow diverter

The international industry-sponsored, university-regulated SILK registry collected standardized clinical and angiographic data on 70 patients treated with SFD in 18 centers.[23] Fusiform aneurysms comprised 37% and 74% were large or giant aneurysms. Sixty-seven (96%) primary treatments were completed and 50 (71%) patients had follow-up reports returned. Difficulties in SFD deployment occurred in 15 (21%) procedures and procedural parent artery thrombosis occurred in seven (10%). Significant extracranial bleeding occurred in three (4%) patients. One patient (1%) experienced immediate procedure-related permanent morbidity and two (3%) mortalities occurred. At a mean radiological follow-up of 4 months, complete aneurysm occlusion had been achieved in 24 patients (48%) and subtotal occlusion with neck remnant only occurred in 13 patients (26%), similar to the 3-month result of the Buenos Aires PED experience. Follow-up imaging showed parent artery occlusion in seven (14%) patients and arterial narrowing in three (6%) patients. In patients

with returned follow-up reports, two (4%) had overall permanent neurological morbidity and mortalities occurred in four (8%).

A retrospective study of SFD implantation in the basilar artery included the first 12 consecutive patients from five neurovascular centers who had been treated for an aneurysm at the basilar artery with an SFD during an 18-month period.[24] There were two patients with aneurysms with previous hemorrhage, one was treated at day 20 and one was treated at 14 months. During a mean follow-up of 16 weeks, total occlusion was achieved in seven (58%) aneurysms and subtotal occlusion with neck remnant was achieved in two (17%) aneurysms. After SFD placement, the P1 segment of the posterior cerebral artery was no longer opacified by vertebral artery injection in one of nine patients (11%) but the P2 segment was then opacified by carotid artery injection through the posterior communicating artery. There were four (33%) patients with neurological worsening (one with extensive brainstem edema, two with thalamic ischemic lesions, and one with a pontine ischemic lesion), resulting in one patient (8%) with minor and one patient (8%) with major permanent neurological morbidity. The authors proposed that neointimal overgrowth and progressive narrowing of the perforator orifice was the culprit of ischemic lesions, as only 55% of the perforator orifice would be covered by the stent strut in the worst case scenario. Obviously, an embolic event cannot be excluded.

The Ankara (Hacettepe University) Group's experience with the SFD has also been briefly presented.[26] In 20 anterior circulation aneurysms, the occlusion rate was 75%. Parent artery occlusion occurred in 5% and transient exacerbation of mass effect occurred in 10%. Details of their case series await subsequent publication.

In addition, a small successful case series on SFD treatment for recently ruptured, very small uncoilable aneurysms has been recently reported.[30] Three female patients presented with acute subarachnoid hemorrhage and aneurysms smaller than 2 mm were identified as the cause of hemorrhage. In two patients the aneurysms were located at the internal carotid artery and the aneurysm was at the basilar bifurcation for the third patient, SFD were successfully deployed. One aneurysm was excluded from contrast material visualization immediately after stent deployment. The other two aneurysms demonstrated complete occlusion at 3-month and 4-month follow-up angiographies respectively. No rebleeding occurred after SFD placement during the follow-ups between 4 months and 10 months.

5. Hemorrhagic complications of flow diverters

Severe hemorrhagic complications for PED were estimated to be 1.75%, resulting in 0.75% of patients with permanent morbidity and 1% mortality.[25] Most complications were delayed ipsilateral parenchymal hemorrhage or subarachnoid hemorrhage.

Severe hemorrhagic complications for SFD were estimated to be 0.8%.[31] The complications arose 2–135 days after implantation and the mean aneurysm diameter was reported to have been 22 mm – all were larger than 15 mm. A post-implantation inflow jet was proposed to be a risk factor. One case report suggested that, due to the leucocytes contained within the red thrombus, the activity of the lytic enzymes, such as elastase, is higher in the red thrombus than the white thrombus and the lack of formation of an organized thrombus was the reason for the rupture.[32] Whether secondary coiling to convert the red thrombus to white thrombus, or periprocedural dexamethasone treatment, can prevent this complication remains unknown.

6. Side branch and perforator occlusion

Side branch and perforator patency has been the main concern regarding flow diverters. In rabbit aorta models using stainless steel stents, the lumbar arteries were patent in normal rabbits but demonstrated ostial narrowing and thrombotic occlusion in the atherosclerotic aorta.[33,34] Published clinical studies now confirm that flow diverters have a mid-term safety profile comparable to other intracranial stents in regard to ischemic complications, when adequate antiplatelet treatment is given. What remains uncertain is the long-term effects of flow diverters on major branch vessels that lack significant collateral supply, as well as the clinical consequences.

7. Ongoing or planned studies

At least six multi-center and two single-center ongoing or planned flow diverter studies have been reported.[25]

The Pipeline for Uncoilable or Failed Aneurysms Study (PUFS) was a United States Investigational Device Exemption (IDE), non-randomized, single-arm, multi-center Premarket Approval study using historical control.[25] PUFS enrolled 120 patients with large or giant (paraclinoid or cavernous) internal carotid artery aneurysms and six-month data were available in 107 (89%) patients. The data are under review with the United States Food and Drug Administration.

The Complete Occlusion of Coilable Aneurysms Study is an ongoing United States IDE randomized, multi-center study comparing coiling to the PED for treating small paraclinoid aneurysms (aneurysm diameter < 10 mm and neck diameter < 4 mm). The safety endpoint is death and ipsilateral stroke, and the effectiveness endpoint is assessed with six-month complete aneurysmal occlusion.

Two more multi-center randomized clinical trials have been planned to compare coiling and flow diverters. One is the industry-sponsored MARCO POLO trial – the Multi-center rAndomized tRial on seleCtive endOvascular aneurysm occlusion with Coils *versus* Parent vessel recOnstruction using the SiLk flOwdiverter. The other is the government-sponsored endovascular treatment of intracranial aneurysm with Pipeline *versus* coils with or without stents (EVIDENCE) trial. Both the MARCO POLO and the EVIDENCE trials aim to recruit patients with intracranial aneurysms between 7 mm and 15 mm and the study protocol details have not yet been published.

The other two multi-center studies are the UK flow diverter audit and the Hong Kong PED registry for safety and effectiveness, which are both ongoing.

Two single center (Geneva and Budapest) studies aim to assess high frame rate digital subtraction angiography before and after treatment as well as periodic MRI following intra-aneurysmal thrombus. The Geneva study will also assess flow simulation before and after flow diverter treatment.

8. Limitations

The use of flow diverters after acute subarachnoid hemorrhage has raised practical issues among clinicians.[23] For instance, there is a natural reluctance to prescribe full double antiplatelet agents before the aneurysm is secured, which does not occur until a few months afterwards. During this period, the patient is at risk of more severe and fatal bleeding if the aneurysm re-ruptures. Reversal of the antiplatelet effect is difficult. One alternative would be to pack the inflow zone and the aneurysm sac with additional coils, which may prove impossible or difficult in some instances. There is insufficient evidence to recommend on this issue, although encouraging results were recently reported for very small uncoilable ruptured intracranial aneurysms.

The advantage of the flow diverter technique alone is that the aneurysm does not need to be catheterized and multiple coil

manipulations can be avoided, thereby reducing the associated complications. However, due to its small pore size, placement of the flow diverter prevents catheterization and embolization of the aneurysm through the flow diverter. Also, there is a lack of understanding of the effect the flow diverter has on bifurcation. Another major deficiency is the lack of long-term clinical and radiological data. Delayed thrombosis of a PED at 23 months has been reported recently.[35] There is also a lack of data available to clarify the optimal medical treatment to prevent these delayed thromboembolic complications.

For future flow diverter studies, the following five-point angiographic outcome grading schema has been suggested.[36] The outcomes include: 0, no change in the endoluminal flow; 1, residual contrast filling greater than 50% volume or length or width; 2, residual contrast filling less than 50% volume or length or width; 3, residual aneurysm neck filling, or less than 50% filling in length and width; and 4, no residual contrast filling. The schema has been validated with high interobserver agreement.

9. Conclusions

Endovascular reconstruction using a flow diverter represents an effective treatment for wide-necked, fusiform, large, and giant unruptured intracranial aneurysms, with 5–10% permanent major morbidity and mortality. The results of ongoing studies may answer the question of whether flow diverters can replace coil embolization for the treatment of all, or selected, intracranial aneurysms.

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