Current Status of Pipeline Embolization Device in the Treatment of Intracranial Aneurysms: A Review

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Key words
- Intracranial aneurysms
- Pipeline embolization device

Abbreviations and Acronyms
DSA: Digital Subtraction Angiography
OKM: O'Kelly—Marotta
PED: Pipeline embolization device

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OBJECTIVE: **Pipeline embolization device (PED) implantation is a novel endovascular treatment option for the treatment of intracranial aneurysms. It is emerging as a useful alternative to coiling and to open surgery, and its use is increasing worldwide. We performed a literature review to examine its efficacy, technical challenges, and safety.**

METHODS: **PubMed database was used to identify all articles relating to PED.**

RESULTS: **The review outlines the indications for PED, its technical aspects, complications, and clinical outcomes.**

CONCLUSIONS: **PED offers an alternative to endovascular coiling for aneurysms with complex morphology. The indication for its use has evolved from the limited scope of treatment of giant aneurysms with wide necks to the inclusion of smaller aneurysms. The procedural safety profile of PED is comparable with or possibly superior to balloon-remodeling or stent-assisted coil embolization in specific circumstances. However, questions remain regarding the incidence of post-procedural subarachnoid hemorrhage. Ongoing monitoring and meticulous documentation of PED postimplantation safety is strongly recommended.**

INTRODUCTION

The treatment of endovascular aneurysm has evolved considerably during the past two decades, with coiling emerging as the treatment of choice for a significant proportion of saccular aneurysms (17). The International Study of Subarachnoid Aneurysm Treatment (24) and the Barrow Ruptured Aneurysm Trial (23) have established the advantages of endovascular treatment in selected clinical scenarios. However, a considerable number of aneurysms are not amendable to coiling.

Balloon remodeling and stent-assisted techniques were developed in mid-1990s and early 2000, rendering more feasible the treatment of aneurysms with more complex morphology (17).

Despite the technological advances, wide-neck and giant saccular or fusiform aneurysms present considerable challenges for the operator (13). Parent artery occlusion is one of the earliest endovascular techniques that showed efficacy treatment for unclippable giant aneurysms. However, parent artery occlusion depends on patient tolerance to occlusion, and reliable predictors for ischemic events are lacking. (13) Furthermore, successful balloon occlusion test does not preclude delayed ischemic complications that occur between 4% and 15% of cases. (13) Endovascular treatments frequently fail to produce complete occlusion in such aneurysms (1).

Recurrence of the treated aneurysm postendovascular treatment occurs in 9% to 34% cases (1, 3-5, 25, 30). Incomplete occlusion, larger (>10 mm) aneurysm size, and neck size are risk factors for recurrence (1, 3-5, 25, 30). These aneurysms are prone to coil compaction and recanalization, even when complete or near-complete occlusion has been achieved after the initial embolization, and require extended imaging surveillance and the possibility of retreatment (12, 24, 25, 35). Failure of endovascular techniques to achieve a complete and durable occlusion of aneurysms has been attributed to several factors, including limitations with respect to the volumetric packing of the aneurysm sac with coils, inherent difficulties associated with achieving a continuous reconstruction of large complex aneurysm neck defects with coils, and finally a fundamental failure of the endovascular strategy to address the underlying diseased parent vessel (9).

MATERIALS AND METHODS

Literature Review

A search for published articles on pipeline embolization devices (PED) in PubMed between 2000 and February 2012 was performed. A total of 210 patients with 241 aneurysms treated with PED were identified in five reported case series. A detail review on the indications, therapeutic results, and technical and safety issues of PED was performed.

Principle of Flow Diversion

Flow diversion offers a fundamentally novel treatment approach. This approach potentially represents a more physiologic treatment of intracranial aneurysms in comparison with coil embolization. Flow-diversion devices produce both haemodynamic and biological effects, namely (1) flow redirection promoting flow stasis

and thrombosis in the aneurysm and (2) tissue overgrowth where the stent provides a scaffolding for the development of endothelial and neointimal tissue across the aneurysmal neck (29). By redirecting blood flow along the normal course of the parent artery, flow-diversion devices markedly alter dynamic fluid exchange across the aneurysm/ parent vessel interface, creating an intra-aneurysmal environment that is conducive to thrombosis (14, 15, 31). After successful aneurysm thrombosis, the construct becomes progressively incorporated into the parent artery through a process of neointimal overgrowth, and a continuous, homogeneous layer of tissue unites the normal parent artery segments proximal and distal to the aneurysm neck defect, completing the process of endoluminal reconstruction (14, 15, 31). This step ultimately results in the anatomic exclusion of the aneurysm from the circulation and promotes final involution of the aneurysmal mass as the intrasaccular thrombus is resorbed.

PED

PED (ev3, Irvine, California, USA) is a flexible self-expanding, microcatheter-delivered, high-metal-surface-area coverage, stent-like device designed to achieve aneurysm occlusion through the endoluminal reconstruction of the diseased segment of the parent artery that gives rise to the aneurysm (Figure 1). Composed of 48 individual cobalt chromium and platinum strands, it provides 30% to 35% metal surface area coverage when fully deployed (10), in comparison with only 6% to 9.5% coverage with conventional bare metal stents (e.g., Neuroform stent; Boston Scientific/Target Therapeutics, Fremont, California, USA) and 12% to 16% with balloon-mounted stents (21).

Figure 1. Pipeline embolization device (Ev3, Irvine, California, USA).

Devices are available with a nominal diameter from 2.5 to 5 mm with 0.25-mm increments. The nominal length of the implants is in the range from 10 to 35 mm in 2-mm increments. At the nominal diameter, the pore size is 0.02 to 0.05 mm^2, and the radial force is approximately 2.0 mN/mm (3.0 mm vessel diameter). PED is premounted on a stainless-steel wire with a radiopaque 15-mm platinum tip extends beyond the end of the PED and is delivered via a 0.027-inch ID microcatheter.

PED has received the Conformité Européene mark of approval on the basis of the Pipeline Embolization Device for the Intracranial Treatment of Aneurysms (PITA) trial (27) and has been sold outside the United States since July 2009. On the basis of the results of the Pipeline for Uncoilable or Failed Aneurysms (PUFS) clinical study that included safety and efficacy data on 108 patients, in April 2012, PED received premarket approval from the U.S. Food and Administration for the endovascular treatment of adults (>22 years of age) with large or giant, wide-necked intracranial aneurysms of the internal carotid artery from the petrous to the superior hypophyseal segments. Compassionate use of PED is allowed in patients who meet the criteria for treatment but do not qualify for the inclusion criteria in PUFS study because of their age or the location of the aneurysm and for whom there are no other reasonable alternative treatments.

RESULTS

Aneurysm Selection and Limitations

With larger patient series being published recently, confirming the efficacy of the device and its safety profile, the use of PED has transformed during the past few years from a novel, investigational device reserved for otherwise-untreatable lesions to a more established alternative technique that is being integrated into routine cerebrovascular practice (6). A transition in the use of PED in treating large and giant aneurysms to include small- to medium-sized aneurysms has been observed.

Large to giant, broad-necked aneurysms comprised the majority of aneurysms treated in previous studies. In these studies, mean diameter and neck size of treated aneurysms was between 11.1 to 16 mm and 5.8 to 7.4 mm, respectively (21, 27, 33); 48% to 73.3% of these aneurysms were greater than 10 mm compared with mean aneurysm sizes of 3.8 to 5.13 in later studies (Table 1) (11, 19). In more recent studies, small- to medium-sized aneurysms were the target aneurysm size. Lubicz et al. (19) and Fischer et al. (11) each recruited patients with aneurysms greater than 10 mm in only 11.1% and 2.9%, respectively, with 59% and 48.5%, respectively, less than 5 mm. Forty-four to 66% were recurring aneurysms (Table 1) (11, 19). The differences in these aforementioned studies highlight a gradual transition of PED from being an investigational device in treating large and giant aneurysms to a standard treatment options for recurring or de novo aneurysms in the size range encountered more commonly in clinical practice.

Very small or blister aneurysms (<2 mm) pose a different challenge for conventional endovascular coiling because both catheterization and the need of endovascular coil placement have increased risk of procedural rupture, especially in curved vessels. Martin et al. (22) reported a patient with aneurysms smaller than 2 mm who presented with acute subarachnoid hemorrhage and was successfully treated with PED. PED may offer an attractive alternative method in treating these patients with very small or blister aneurysms, potentially reducing risk of periprocedural rupture.

Despite the fact the size range of aneurysms treated with PED has increased dramatically during the past 2 years, the clinical indications remains largely unchanged, that is, (1) for wide neck aneurysms with high likelihood of failure with conventional endovascular therapy or microsurgery; (2) to treat remnants of aneurysms after clips and coiling treatment; (3) fusiform aneurysms; and (4) dissecting aneurysms. PED has two major limitations in its application. First, because it originally was designed for sidewall aneurysms, its use in bifurcation aneurysms has been limited. The potential use with a "kissing" implantation of two PEDs or in combination with conventional stents to create a bidirectional flow diversions has not been fully evaluated. Second, the associated delayed aneurysm

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