

Carotid Stent-Supported Angioplasty Using Different Distal Protection Devices

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LI ET AL.: Carotid Stent-Supported Angioplasty Using Different Distal Protection Devices. Stroke is an important cause of morbidity and mortality in Hong Kong. Extra-cranial carotid stenosis is a common cause of thrombotic stroke, although its incidence is less in Chinese compared with Caucasians. Carotid endarterectomy is the conventional revascularization procedure for carotid stenosis. In the past decade, carotid angioplasty has been emerging as a treatment option for patients with significant carotid stenosis. Due to the intrinsic mechanism of angioplasty, distal embolization causing thromboembolic stroke has been one of the most important complications of carotid stenosis. Distal protection has been shown to be safe and effective in preventing distal embolization during the procedure. According to their mechanism, distal protection devices can be categorized into two major types, namely distal occlusion balloon and filters. Distal occlusion balloon system is of lower crossing profile but it causes temporary cessation of blood flow during the procedure, which may not be well tolerated in all patients. Filters, on the other hand, allow continuous blood flow during the procedure but are of much higher crossing profile, which may make their passage through tight and angulated lesions difficult and traumatic. The choice of the different distal protection devices depends on the characteristics of the lesions and the status of contralateral carotid artery and collateral supply. Local experience reported similar feasibility and efficacy as in the literature. Although the ideal distal protection device is yet to be developed, the use of distal protection devices would become, wherever feasible, a standard during carotid stent-supported angioplasty. (*J HK Coll Cardiol* 2002;10:179-183)

Carotid angioplasty, carotid stenosis, distal cerebral protection

摘要

在香港，中風是致死和致殘的重要原因。頸外動脈狹窄是血栓形成性中風中最常見的病因。頸動脈內膜剝脫術是頸動脈狹窄傳統的血運重建方法。在過去的十年，頸動脈成型術已經成為嚴重頸動脈狹窄的一種治療選擇。由於血管成型術的一些內在機制，遠端血栓栓塞導致的血栓栓塞性中風已經成為頸動脈狹窄最嚴重的併發症。在操作期間應用遠端保護裝置已經顯示在防止遠端栓塞方面是安全有效的。根據它們的作用機制，遠端保護性裝置可以分為兩種類型，分別稱為遠端阻塞球囊和篩檢程式。遠端阻塞球囊裝置系統有著較小的橫截面積，可在操作過程中使血流一過性中斷，但並不是所有患者均可耐受。相反，篩檢程式在操作過程中允許血流持續通過，但它們有著較大的橫截面積，有可能使它們在通過窄的或成角的病變時困難和造成損傷。不同遠端保護裝置的選擇依賴病變的特點和對側頸動脈和側枝迴圈的供血狀態。本市的經驗和文獻報道一樣，是可行和有效的。儘管理想的遠端保護裝置仍需要發展完善，但遠端保護性裝置的應用將成為行頸動脈支撐性支架成型術的常規。

關鍵詞：頸動脈血管成型術 頸動脈狹窄 遠端腦動脈保護

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Stroke is an important cause of morbidity and mortality in Hong Kong. Extra-cranial carotid stenosis is a common cause of thrombotic stroke. The therapy of carotid stenosis may be either medical or revascularizational. Carotid endarterectomy is the gold standard of surgical revascularization of carotid stenosis and has been shown to be superior to medical therapy by several large randomized trials.¹⁻³ However, in the recent few years, with more and more published data regarding its efficacy and safety, carotid stenosis has been emerging as a treatment option for the treatment of carotid stenosis.⁴⁻⁷

Due to the intrinsic mechanism of angioplasty, distal embolization is an inevitable phenomenon. Plaque disruption may occur during engagement of guiding catheter, wire and balloon passage, balloon expansion and stent deployment at the site of atherosclerotic lesion. The clinical significance of the generation of embolic particles depends on the number released and the size of the particles. Ohki demonstrated in his ex-vivo model that echolucent plaques and plaques with a degree of stenosis greater than 90% produced a higher number of embolic particles.⁸

There may be a number of ways to minimize the cerebral embolization during carotid angioplasty. Premedication with aspirin and Clopidogrel is important. Selection of patients is also important. Advanced age, lesion severity, long or multiple stenoses are independent predictors of procedural stroke and are associated with increased risk of stroke.⁹ Proper technique during the angioplasty procedure with the least traumatic way to engage the guiding catheter and to cross the lesion with low profile wires and balloons should minimize the risks of distal embolization. Finally, cerebral distal protection devices should mechanically catch the maximal number of embolic particles released.

The ideal protection device should be simple and easy to use, and yet low profile and atraumatic. It should effectively eliminate embolic particles and be well tolerated without any cerebral ischemic phenomenon. The current commonly available distal protection systems may be divided into two main categories, namely the occlusion balloon system and filters. The distal occlusion balloon system occludes the internal carotid artery above the lesion with the balloon inflated at 1-2 atmosphere. The debris released by the dilatation and stent placement is then eliminated by aspiration. Filters, on the other hand, trap dislodged particles without interrupting the blood flow to the distal vascular bed.

Currently, the occlusion balloon systems include the PercuSurge Guardwire system (Medtronic, USA) and the PARODI system (ArteriA Medical Science, Inc) whereas the filters include the Angioguard (Cordis, USA), NeuroShield (Mednova, UK) and EPI (Boston Scientific Cooperation, USA) filter systems (Table 1).

The PercuSurge GuardWire distal protection system (Figures 1a and 1b) composed of three major components: the GuardWire temporary occlusion balloon, the inflation/deflation kit (consisting of the Microseal Adaptor and EZ Flator) and the Export Aspiration Catheter. The GuardWire has a dual role by acting as a primary angioplasty wire and the temporary occlusion balloon. It has a crossing profile of 0.014" at its tip and 0.036" at the site of un-inflated occlusion balloon. The wire itself has a 2.5 cm shapeable tip and a working length of 200 and 300 cm. The distal occlusion balloon has a working length of 4.5 mm and an inflatable diameter range of 3.0 to 6.0 mm. The Export Aspiration catheter has a working length of 145 cm with a rapid exchange design and an aspiration lumen of 1 mm.

During the intervention procedure, the Guardwire

Table 1. Comparison of different distal protection devices

	GuardWire Plus	Angioguard XP	NeuroShield	EPI Filter Wire
Wire	0.014"	0.014"	0.014" with a 0.018" tip	0.014"
Shapeable tip length (cm)	2.5	3.5	3	3
Length of wire(cm)	300	300	300	300
Crossing profile	0.036" at balloon site	3.2-3.9 F	3.5 F	3.9 F
Sizes of devices (mm)	3.0-6.0 mm inflatable range	4-8	4-6	3.5-5.5

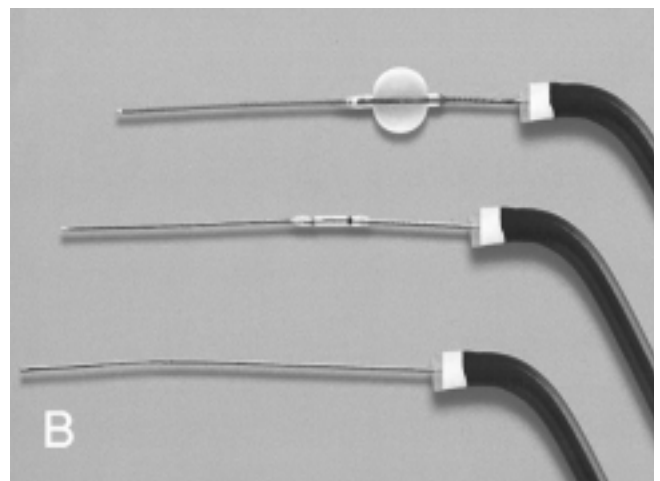
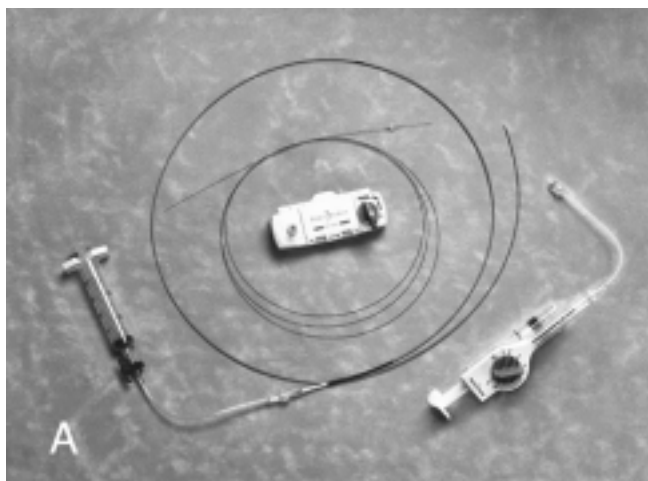
is first advanced carefully beyond the lesion. The distal occlusion balloon is then inflated to a size about 0.5 mm larger than the reference vessel diameter. When the balloon is optimally inflated, it becomes square shaped and complete occlusion is confirmed by a test of contrast injection. With the occlusion balloon inflated, the lesion is pre-dilated, stented and post-dilated as usual. Due to the presence of vertebrae as bony landmarks, positioning of the balloon and stent without contrast injection is rarely a problem. Aspiration is then performed with the Export catheter. The occlusion balloon is then deflated and flow is restored.

The PARODI system is a 'flow reversal' system. It consists of two units: one is a small balloon catheter that is used to occlude the external carotid artery; the other is a large sheath that is used to occlude the common carotid artery. Reverse flow is established by connecting the arterial sheath with a venous sheath placed into the femoral vein. Any debris generated during the angioplasty procedure would be directed away from the cerebral circulation. A filter located in the arteriovenous shunt prevents embolic particles to enter the venous system.

The filters in general consist of a basket or net-shaped device mounted or delivered on a steerable 0.014" wire. The filters have a porous membrane that can block the passage of particles greater than 80 microns or above, while allowing blood to pass through.

The device is delivered across the lesion within a delivery sheath. For tight lesions, they may be first pre-dilated with a 2.5 mm balloon. When positioned at the desired distal site, the delivery sheath is withdrawn and the filter is released in a self-expanding manner. The angioplasty procedure is then proceeded as usual with the filter protection. After the angioplasty procedure, the filter is then withdrawn with a capture sheath with all the debris retrieved within the device. Angioguard XP (Figure 1c) has a crossing profile from 3.2 to 3.9 F (depending on the size of the filter which ranges from 4-8 mm) and can be used to treat vessels of diameters ranging from 3-7 mm. The filter basket with 100-micron pores is mounted on a 0.014" wire, which has a 3.5 cm shapeable tip. The Mednova III NeuroShield (Figure 1d) device uses a floating filter on a bare wire design that has a 3 cm long 0.018" shapeable wire tip and a 0.014" wire shaft. The delivery catheter has a catheter profile of 3 F and a crossing profile of 3.5 F. The filter diameters range from 4.0 to 6.0 mm and are compatible for vessel sizes of 3.5 to 6.2 mm diameters. The EPI Filter Wire (Figure 1e) has a crossing profile of 3.9 F and has a one-size-fits-all and monorail design that can treat vessels from 3.5 to 5.5 mm. The filter consists of a 1.5 cm long polyurethane membrane basket with 80-100 micron pores, which is mounted on a 0.014" wire with a 3 cm long shapeable tip.

Due to the different mechanism of protection, the choice of the distal protection devices depends very



Figures 1a and 1b. *GuardWire Plus system.*

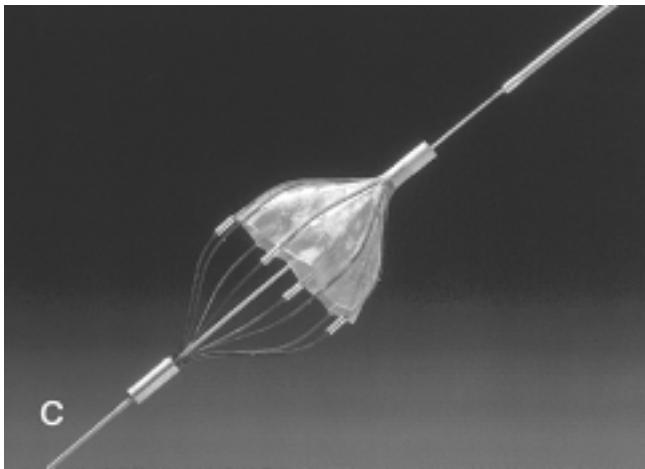


Figure 1c. *Angioguard XP.*

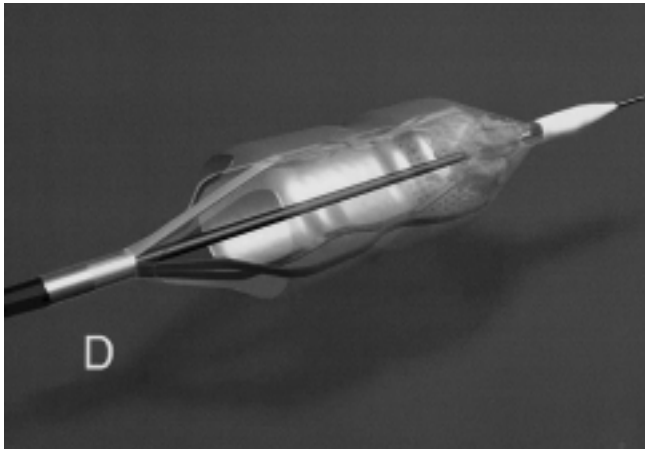


Figure 1d. *NeuroShield.*

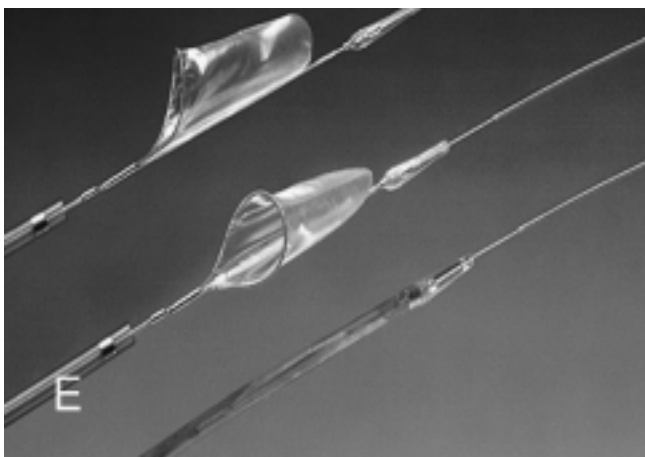


Figure 1e. *EPI Filter Wire.*

much on the lesion characteristics, status of collateral circulation and the experience of the operator. Due to its smaller crossing profile, the PercuSurge Guardwire system is useful in crossing tight, tortuous, long or angulated lesions. However, since the mechanism of protection involves temporary cessation of blood flow during the procedure, it should be avoided in patients with contralateral carotid artery stenosis or occlusion, or when the collateral blood supply through the circle of Willis is deemed inadequate. On the other hand, the filters allow antegrade blood flow during the procedure; they are not contraindicated even in patients with contralateral carotid artery occlusion. Nevertheless, due to their higher crossing profile (>3 F), the filters may not be indicated in those tight or angulated lesions or tortuous blood vessels because forceful passage of the device itself through the stenosis may cause significant local disruption to the plaque, which may in turn, induce dissection or distal embolization.

With the favorable results of distal protection,¹⁰⁻¹⁴ the use of distal protection devices has become a routine, wherever feasible, during carotid angioplasty at the author's institution. From August 2000 to January 2002, 13 patients underwent carotid angioplasty at our institution with distal protection. The age of the patients ranged from 52-79 years (mean 69.3 ± 8.8 years). The reference internal carotid artery diameters, lesion length, pre-procedural stenosis and residual stenosis were 3.15-6.0 mm (mean 4.07 ± 0.87 mm), 10-35mm (mean 20.3 ± 7.5 mm), 70-99% (mean $88.7 \pm 9.9\%$) and 0-30% (mean $11.2 \pm 12.5\%$) respectively. PercuSurge GuardWire Plus system was used in 8 patients, Angioguard filter was used in 2 patients, NeuroShield filter was used in 2 patients and EPI filter wire was used in 1 patient. All procedures were successful with no peri-operative neurological event. No pre-dilatation was needed in all cases with the GuardWire system and the GuardWire was able to cross the lesion at the first attempt in all cases. In the case using the EPI filter wire, in view of the kinking morphology of the lesion, pre-dilatation of lesion was done before it was crossed with the filter. In other cases using the filters, no pre-dilatation was done. The mean balloon occlusion time in the cases using the GuardWire system was 10.2 minutes. In those patients undergoing the distal protection of the GuardWire Plus system, one patient could not tolerate the distal protection balloon occlusion

and early deflation of the occlusion balloon was needed. Another patient suffered from acute stent thrombosis, which was successfully treated with abciximab. No peri-operative neurological event was observed. At 30 days after the procedures, no neurological event or procedure related death was observed. No local injury to the distal vessel was observed apart from some reversible local spasm in three cases (one with Angioguard, one with NeuroShield and one with GuardWire Plus system). In all cases, macroscopically visible debris was retrieved from the protective devices, but the amount was only mild in all cases.

Although the distal protection devices have undergone repeated improvement and miniaturization, the ideal device is yet to be developed. We are still waiting for a device that has the best characteristics of the currently available systems, i.e. having the low profile of the distal occlusion balloon while allowing continuous blood flow as in the filters. While proper selection of patients and matching of the devices to different lesions would minimize the distal embolization phenomenon, no current distal protection device may safely protect, for example, a long, irregular and angulated 99% stenosis with contralateral carotid occlusion. Though effective in preventing distal embolization, distal protective devices are costly and are marketed at the price of the stents. Although further studies on the health-economics of these devices are needed before we can draw any conclusion on their cost-effectiveness, the decrease in the incidence of major stroke during carotid angioplasty as shown in many published series might already make their cost justified.

In conclusion, distal embolization is the most important complication of carotid angioplasty. Distal protection devices have been shown to reduce the distal embolization phenomenon. Although the ideal protection device is yet to be developed, the currently available protective devices appear to be useful adjunct in carotid angioplasty.

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