Carotid Intervention 3: The Evidence for Cerebral Protection

**Fabrizio Fanelli, M.D.,¹ Mario Bezzi, M.D.,¹ Emanuele Boatta, M.D.,¹
and Roberto Passariello, M.D.¹**

ABSTRACT

Carotid stenting is a safe alternative option to conventional carotid endarterectomy in the treatment of carotid artery stenosis in patients considered poor candidates for surgery or who choose not to have open surgery. During the stenting procedure, however, distal embolization may occur with neurological sequelae. To reduce the incidence of this, several cerebral-protection devices (CPDs) have been developed. Different types of CPDs are now commercially available: distal occlusion balloons, distal filters, and proximal protection devices—+ with or without reversal of flow. But complications can occur with their use and are usually associated with an inability to cross the lesion, failure to capture the emboli, vasospasm, and vessel wall injury. Because protection devices are currently the focus of interest by manufacturers and physicians, several trials are going on worldwide to analyze the characteristics of each of them and to evaluate their efficacy in reducing the rate of distal embolization.

KEYWORDS: Cerebral embolization, balloon occlusion, filters, flow reversal

Objectives: Upon completion of this article, the readers should understand (1) the evidence for the use of protected carotid artery stenting, (2) the different technical aspects of protection devices, and (3) techniques now available on the market.

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Carotid angioplasty and stenting (CAS) can be considered a valid therapeutic option for the treatment of the stenoses of the extracranial carotid artery. However, the initial results of this procedure have showed an incidence of neurological complications ranging from 3.2 to 10.9% due to distal embolization.¹ To reduce the rate of periprocedural neurological complications, various systems of cerebral-protection devices (CPDs) have been proposed. The purpose of these systems is

to capture the plaque debris before they reach the brain, avoiding neurological ischemic complications. The first CPD system was described by Theron² in 1990, who introduced the concept of prevention of cerebral embolization by temporary balloon occlusion of the distal internal carotid artery (ICA) during percutaneous transluminal angioplasty. After this initial experience, several authors reported a significant reduction in neurological complications for procedures performed

¹Department of Radiological Sciences, Interventional Radiology Unit, University of Rome "La Sapienza," Rome, Italy.

Address for correspondence and reprint requests: Fabrizio Fanelli, M.D., Department of Radiological Sciences, Interventional Radiology Unit, University of Rome "La Sapienza," 324 Viale Regina Elena, 00161 Rome, Italy.

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Table 1 Protected versus Unprotected Carotid Artery Stenting

	Total no. of cases	Rate of Neurological Events without Protection	Rate of Neurological Events with Protection
Cremonesi ⁵	590	3.2%	0.67%
Wholey ⁴	10,693	5.3%	2.3%
German Registry ¹	1353	2.8%	2.0

with cerebral protection compared with those patients treated without (Table 1).³ The “global carotid artery stent registry” described a perioperative stroke and death cumulative rate of 5.9 and 2.23%, respectively, in those procedures performed without and with a CPD.⁴ Boltuch et al⁶ evaluated 651 patients treated with (n = 180) and without (n = 471) cerebral protection and claimed technical success in 99% versus 95%; a complication rate of 10% versus 18.3%; a transient ischemic attack (TIA) rate of 2.8% versus 3.2%, and a major adverse events (MAE) rate of 0.6% versus 2.1%. This and other studies have promoted the opinion that CPDs should be routinely used during CAS to prevent embolic events.^{7,8} However the indications to the use of CPD are not yet standardized. There are still some authors who prefer to perform CAS procedures without cerebral protection with claimed results that are equivalent. Perona et al reported a series of 400 patients treated without CPD with a major complication rate of 2% (8/400 patients, 5 minor and 3 major strokes).⁹

CPDs can be divided into three different types on the basis of their technical aspects: filters, distal occlusion balloons, and proximal protection systems. Using filter systems, the blood flow is maintained through the ICA and emboli are captured and removed together with the device. Balloon occlusion devices and proximal protection systems completely occlude the flow into the ICA, and emboli must be aspirated before balloon deflation or catheter removal.

CEREBRAL PROTECTION DEVICES

Distal Occlusion Balloons

Distal occlusion balloons represent the first type of CPD routinely used in clinical practice. They consist of a 0.014-inch guidewire equipped with a distal balloon inflated through a small channel present within the wire. Once the lesion is crossed with the guidewire, the balloon is positioned above the lesion and inflated to completely occlude the ICA, thus avoiding the passage of microemboli into the intracranial circulation. After stenting over the wire, a guiding catheter is advanced up to the balloon to aspirate the blood containing the debris dislodged from the atheroma. After complete aspiration the balloon is deflated and the guidewire is removed.

The advantages of this system are the low profile of the balloon wire crossing the lesion ($\leq 2.2F$) associated with very high flexibility and torquability of the system.¹⁰ However, this system produces complete occlusion of the ICA, a hemodynamic condition not well tolerated by 6 to 10% of patients.¹¹ Moreover, it is not possible to obtain continuous visualization of the target lesion during the procedure because the blood flow is completely stopped.

THERON TRIPLE COAXIAL CATHETER

This system is based on three different components: a 9 F/100-cm-long catheter with a lateral flushing system; a 120-cm/5F angioplasty catheter with a 15-mm balloon that can be dilated from 5 to 7 mm; a 250 cm/3F Teflon catheter with a latex balloon attached to the distal end. The system was used in 13 patients and none had neurological complications. But this system was very difficult to steer and had also a large crossing profile.^{3,12}

PERCUSURGE GUARDWIRE

The PercuSurge Guardwire (Medtronic, Minneapolis, MN) is system that provides temporary occlusion of the ICA and aspiration of particles after CAS. The device has three components: an exchange guidewire, a micro-seal adapter, and a monorail aspiration catheter. The distal segment of the wire is shapable, radiopaque, and steerable. Proximal to the distal segment is a balloon that can be dilated from 3 to 6 mm to occlude the ICA blood flow. Once the wire is advanced beyond the target lesion, the predilation balloon is passed over the wire into the distal guiding catheter. After balloon inflation, contrast media injection is performed to confirm the complete occlusion of the blood flow. At the end of the procedure the aspiration catheter is inserted up to the level of the distal occlusion balloon, and 15 to 45 mL of blood are aspirated from the working area. The aspiration catheter is then removed and the occlusion balloon is deflated, restoring the normal antegrade flow. Henry et al used the Guardwire in 184 procedures with a technical success rate of 99.5%. Three periprocedural complications occurred: one major stroke and two transient ischemic attacks (TIAs). Intolerance to balloon occlusion was observed in 5% of patients with a 30-day stroke and death rate of 2.7%.¹³

Filters

Filters are metallic “baskets” coated by a membrane made of polyethylene. The membrane of the filter has pores with a diameter ranging from 80 to 220 μm . Filters are mounted on a 0.014-inch guidewire, generally 30 mm proximal to a flexible tip and are delivered through a very small profile catheter ($\leq 3\text{F}$). Once the lesion is crossed, the filter should be opened in a straight portion of the ICA, at least 2 cm above the target lesion. At the end of the stenting procedure a retrieval catheter is inserted to recapture the filter and remove it (Fig. 1). Where the stenosis is very tight or the anatomy very tortuous, the passage of the delivery catheter through the lesion may be difficult or impossible. In such cases predilation of the stenosis must be performed using a very small (2 to 3 mm) balloon to neither fracture the plaque nor stimulate the vagal sinus reflex. The diameter of the filter must be selected on the basis of the caliber of

the ICA segment where the filter is to be placed. Generally 1 mm oversize is required to get a correct wall apposition of the filter, reducing the possibility of failure to capture the emboli. Because filters produce a marked reduction of the blood flow within the ICA, they should not be left in place for > 15 minutes. Different types of distal filters are available on the market and others will appear in the future. They differ in their metallic structure rigidity, the diameters of the pores, and the supporting wire stiffness (Fig. 2). A detailed knowledge of their technical characteristics is essential to select the correct device suitable for the anatomy and degree of stenosis if complications are to be avoided (Table 2).

RX ACCUNET EMBOLIC PROTECTION SYSTEM

The RX ACCUNET Embolic Protection System (Guidant, Indianapolis, IN) is designed to provide

Figure 1 (A) Digital subtraction angiogram of 71-year-old patient shows preocclusive stenosis of the internal carotid artery. (B) The very low profile of the cerebral-protection device (CPD) (Filter Wire EZ/EX Embolic Protection System [EPI]; Boston Scientific, Natick, MA) easily crossed the lesion avoiding predilation. After deployment of the CPD, however, angiogram showed no flow at the level of the lesion. (C) The procedure was completed very rapidly with the deployment of a self-expandable stent (Carotid Wallstent; Boston Scientific, Natick, MA) at the level of the lesion to the common carotid artery. Angiography performed immediately after stent deployment showed normal blood flow into the internal carotid artery (ICA). The final angiogram shows correct position of the stent, normal blood flow, and no more evidence of ICA stenosis.

Figure 2 AngioGuard XP (Cordis, J&J, Miami Lakes, FL). Specimen photograph showed that at the end of a stenting procedure a great deal of plaque debris is clearly evident inside the filter. No neurological complications occurred in this procedure.

improved capture capabilities and easy filter control. The nickel-titanium filter has 115- μ m pores, is available in different size from 4.5 to 7.5 mm, and is compatible with a 6F guiding catheter. The wire can be torqued independently from the filter basket to facilitate the navigation in tortuous anatomy. For proper positioning of the filter, the vessel distal to the lesion should not be excessively tortuous and must be sufficiently long. The recovery catheter has a formable tip to allow deflection during the advancements. The Acculink Revascularization of Carotid in High-Risk Patients (ARCHer) 1, 2, and 3 trials showed a 10% death, stroke, or myocardial infarction cumulative rate within 30 days compared with a surgery complication rate of 15%. On the basis of these results, the Food and Drug Administration (FDA) approved the use in the United States of the Acculink and the ACCUNET system for the treatment of carotid artery disease.¹⁴

ANGIOGUARD XP

The structure of the AngioGuard XP filter (Cordis-Johnson & Johnson, Miami Lakes, FL) filter is based on eight nitinol struts covered, in the upper portion, by a polyurethane membrane with pore size of 100 μ m. Four of these struts have a radiopaque marker to facilitate the visualization of the filter during the procedure. To prevent injury of the intimal layer of the vessel, the distal end of the device consists of an atraumatic flexible tip (3.5 cm in length). The filter is available in different diameters ranging between 4 and 8 mm. It is preloaded in a catheter with a different crossing profile depending on the filter diameter: 3.2F to 4F. At the end of the procedure the filter is only partially encapsulated into the retrieval catheter (5.1F), reducing the possibility of squeezing the material captured by the filter.¹⁵

FILTERWIRE EZ/EX EMBOLIC PROTECTION SYSTEM

The FilterWire EZ/EX Embolic Protection System (EPI) (Boston Scientific, Natick, MA) features a “suspended nitinol loop” design that supports the filter, allowing for complete vessel wall apposition and for placement in both straight and curved vessels. A porous polyurethane membrane with pore size of 85 μ m is attached to the loop. Once the collapsed device is placed over the lesion, it is deployed by retracting the delivering sheath. After the procedure the filter is closed using a covering sheath and then retrieved. It is available in one size that adapts to vessel diameters ranging between 3.5 and 5.5 mm; moreover it is compatible with a 6F guiding catheter and is deployed with a 3.2F delivery system. Several authors described different series using the FilterWire EX: Grube et al reported the use of this filter in 35 patients with a 30-day rate of stroke and death of 0%. In 74% of cases, debris was found into the filter, and the only two patients who experienced TIAs recovered within 30 minutes.¹⁶ Bosiers et al reported a series of 93 patients treated using the FilterWire EX during a CAS procedure with a technical success rate of 93%. TIA was observed in one patient with a complete resolution of the symptoms after 6 hours, and embolic material was found in 57% of cases.¹⁷

Table 2 Filter Protection Devices

Protection Device	Crossing Profile (F)	Guiding Catheter (F)	Size (mm)	Pores (μ m)
AngioGuard XP	3.2–4	6–7	4–8	100
Filter Wire (EPI)	3.2	6	Self-adaptable	80
SpiderRX	2.9	6–7	3–7	500–200
RX ACCUNET	3.5–3.7	7	4.5–7.5	115
Rubicon	2.1–2.7	6	4–6	100
EmboShield	2.9–3.3	7–8	3–6	140
Interceptor	NA	6	5.5–6.5	100
E-Trap	2.9	6	2.5–7	100

INTERCEPTOR

The Interceptor (Medtronic, Minneapolis, MN) consists of a nitinol basket attached to a 0.014-inch steerable guidewire. The basket ranges between 5.5 and 6.5 mm with 100- μ m pores. The proximal segment of the basket contains four large holes (>1800 microns for the 5.5-mm filter size and >2100 for the 6-5-mm filter size) to allow particulate to enter and be captured by the filter. The filter is opened and closed using an "Actuator Handle," and no delivery catheter is needed. Moreover, to recapture and retrieve the filter, at the end of the procedure, it is possible to use a recovery catheter instead of the Actuator Handle.

MEDNOVA EMBOSHIELD CEREBRAL PROTECTION SYSTEM

The fourth generation of the MedNova EmboShield Cerebral Protection System (Abbott Laboratories, Abbott Park, IL) is now available on the market. It consists of a guidewire, a delivery catheter (3.7 to 3.9 mm in diameter), a filter basket, and a retrieval catheter (6F). The system has a mobile polyurethane filter supported by a nitinol frame work. The filter basket ranges from 3 to 6 mm, with a pore-free zone that helps prevent embolic extrusion and a helical staggered pore design to optimize the capture efficacy. The filter presents a hydrophilic coating to minimize platelet, fibrin, or red blood cells adhesion.

RUBICON FILTER

No delivery catheter is needed to deploy the Rubicon Filter (Rubicon, Salt Lake City, UT). The long tapered cone design of the filter should increase the volume of the filter. It has a retrieval system actuator that shows the exact status of the filter as it is being captured for removal. This CPD is mounted on a 0.014-inch wire and has a very small profile (2.0 to 2.4F). The filter presents 100- μ m pores and is available in different sizes between 4 and 6 mm. To minimize the filter movement during the retrieval phase, there are telescopes over the filter basket.

SPIDERX

The SpiderX (EV3, Plymouth, MN) filter consists of a nitinol basket placed at the top of a 0.014-inch wire. The diameter of the basket ranges between 3 mm and 7 mm, with pores size ranging from 50 to 200 μ m. The basket is attached on a gold radiopaque ring. To allow better stability of the filter during the procedure, the wire can move with an excursion of some millimeters through the basket that is firm inside the vessel lumen. A clasp at the entrance of this device ensures a better vessel wall apposition of the opened filter. The recovery catheter presents a different size, from 4.2 to 4.9F, depending on the filter diameter. The "ProCar" study enrolled 77 patients who underwent protected CAS using the Spi-

derX filter with a technical success rate of 99%. Two patients experienced major strokes and one patient had a minor stroke. No death occurred before discharge.

TRAP FILTER

The trap filter (Microvena, White Bear Lake, MN) is made of a nitinol net at the distal end of a polytetrafluoroethylene-coated 0.014-inch wire. The filter is mounted on a 2.9F catheter and is available in different diameters ranging between 2.5 and 7 mm. The retrieval catheter presents different diameters depending on filter size: 5F (4-mm filter) or 6F (5-mm filter). A proprietary heparin coating of the filter and funnel (Heprotec) allows the instruments to remain inside the vessel for 60 minutes without thrombin or fibrin adhesion on the nitinol net.

PROXIMAL PROTECTION SYSTEMS

Distal occlusion balloons and filters have the disadvantage that the stenotic lesion must be crossed to place the device. These maneuvers carry the risk of complete lumen occlusion and distal embolization, especially where plaque is complex and unstable. Proximal protection systems provide cerebral protection without the need to advance any type of device across the stenosis, reducing the risk of distal embolization. The inflation of an occlusion balloon at the level of the common carotid artery (CCA) and at the origin of the external carotid artery (ECA) causes reversal of flow (Parodi system) or complete cessation of flow (MO.MA) within the ICA. They therefore rely on the vascular anastomoses of the circle of Willis. The advantages of these systems are that the entire procedure can be performed under flow reversal or stagnation, reducing the risk of distal embolization. However, at the present time flow reversal devices are large and complicated and cannot be used in all cases because complete flow occlusion is not tolerated by 6 to 10% of patients.⁶

Parodi Anti Emboli System

In the Parodi Anti Emboli System (PAES) (W.L. Gore, Flagstaff, AZ), an 8F guiding catheter is inserted in the CCA where an occlusion balloon is inflated. To prevent blood flow from the ECA to the ICA, a second occlusion balloon is inflated at the origin of the ECA, thus obtaining ICA. Flow reversal down the ICA from the circle of Willis will then occur. The proximal hub of the guiding catheter is connected to a 10F introducing sheath placed on the contralateral femoral vein. Due to the pressure gradient between the ICA and the femoral vein, a continuous blood flow through the system is maintained. A filter placed at the level of the arterial-venous shunt prevents debris passing into the venous system.

Other than not having to cross the target lesion, the major advantage of flow reversal is the ability to capture any size of particles. Moreover the lesion is crossed only when the blood flow is inverted, avoiding any possible debris. However this technique presents some disadvantages: Diversion of ICA flow from one cerebral hemisphere is not always tolerated, particularly if the circle of Willis is inadequate or there is a carotid stenosis on the contralateral. There is the potential to cause dissection or spasm in the ECA or CCA during balloon inflation. In addition, the Parodi Anti Emboli System requires a large puncture site hole in the groin due to a somewhat bulky sheath (10F outer diameter) and the guide catheter size may also make insertion in the CCA a challenging task in cases of complex arch morphology.

MO.MA

The MO.MA (Invatec, Roncadelle, Italy) device causes proximal flow occlusion. A single device with two independent occlusion balloons is advanced in the CCA. One balloon occludes the CCA while the other occludes the ECA, with complete interruption of the antegrade blood flow from the CCA and potential retrograde blood flow through the ECA. Distal embolization is avoided by complete cessation of flow in the ipsilateral ICA. After stenting, blood is aspirated with a syringe through the working channel of the guiding catheter. It is not possible to visualize the ICA during the stenting procedure because no injection of contrast medium can be used.

COMPLICATIONS

CPDs have been used in clinical practice for several years, but they are still considered “young devices” subject to continuous refinement and improvement. Complications may be summarized as an inability to cross the lesion, a failure to capture the emboli, and vasospasm or injury to the vessel wall.

Failure to Cross a Lesion

Deployment of a CPD may not be considered a problem in straight vessels, but in patients with very tortuous anatomy and tight stenosis it is often a technical challenge to cross the lesion. In tight strictures, one problem may be created by the crossing profile of the device. Predilation with a very low-profile balloon (≤ 3 mm) has been used to overcome this problem, but this maneuver makes the procedure more complicated and increases the risk of distal embolization, especially in those patients with complex plaque morphology (ulcer, friable plaque). Another cause of failure to cross the lesion is the abrupt change in stiffness between the floppy tip of the guide-

wire and the device. This abrupt change may negatively affect catheterization of a tortuous ICA and has been responsible for some failures. To solve this a buddy wire (a second wire placed into the same artery parallel to a previous one) can be used to straighten the vessel, giving more support and facilitating the catheterization.

Failure to Capture the Emboli

Capture efficiency is the most important aspect of any CPD. However it is clear that despite their use, emboli still occur although they are often subclinical.^{18,19} Capture efficiency can be hindered by several different mechanisms and depends on which type of device is used. Distal balloon occlusion systems accomplish brain protection by occluding the ICA. A rare but possible complication is gradual deflation of the balloon during the procedure and the inadvertent reestablishment of blood flow toward the brain before all particles have been removed. This phenomenon can be prevented by constantly monitoring the size of the balloon under fluoroscopy and by injecting contrast medium during the procedure. However, excessive inflation of the balloon will increase the risk of vessel spasm or dissection.¹⁰ Tubler et al, in their experience with the PercuSurge GuardWire, have reported a 5.2% periprocedural neurological complication rate. The authors speculated that “suction shadow” may have been responsible for this phenomenon.²⁰ It occurs when the aspiration catheter fails to remove all the emboli due to some material being too large or the blood column adjacent to the balloon is not always effectively aspirated. Another potential source of neurological complications is embolization of the ECA territory and, via collaterals, the brain. An identical situation may occur when a filter, which supposedly should not block the ICA flow, behaves like a balloon and occludes the ICA lumen. Balloon occlusion closer to the bifurcation reduces the volume of the blood containing emboli, but it may also lead to even more frequent embolization into the ECA.²¹

Both distal occlusion balloons and filters have to cross the lesion without protection, increasing the risk of distal embolization especially where plaque is unstable and complex. Particles are released during the initial phase of the procedure when no protection has been established. The major difference between balloons and filters is that filtration devices should preserve flow into the ICA during the procedure. This not only maintains flow to the brain but allows angiography to be performed. However, small emboli may pass through the filter mesh. Several authors have evaluated the efficacy of filters using different models, and all the filters were able to capture the vast majority of particles, especially the large ones.^{10,20–23} Experience with the PercuSurge GuardWire suggests that 50% of the emboli released during CAS are $< 100 \mu\text{m}$.²⁴ Smaller pore size

may decrease the chances of microembolization, but it also results in a higher incidence of filter thrombosis. Filter thrombosis is related to filter plugging as a result of capturing too many particles and/or fibrin deposition.²⁵ The selection of pore size is a compromise between the risk of filter thrombosis and the risk of microembolization. Incomplete adherence of the filter to the vessel wall may also result in microembolization. The filter should be the right size for the ICA, but poor apposition mainly occurs in tortuous vessels where the filter is not aligned with the long axis of the ICA and particles may flow around the device. For these reasons, whenever possible, filters should be deployed in a straight portion of the ICA and 1-mm filter diameter oversize considered. However too large a filter may also fail to make good wall contact.

Embolization can also occur during the retrieval phase. This happens because filters have limited volume and the material filling the filter could be squeezed when the filter is recaptured into the retrieval catheter. Filters should be partially recaptured into the catheter to prevent this squeeze effect. The use of distal protection devices (balloon and filters) can be associated with a 12% rate of embolic events due to the emboli generated crossing the lesion.^{18,19,26} To avoid this complication in patients with very unstable plaque, Parodi et al²⁷ have introduced the “*seat belt and air bag technique*.” The Parodi antiemboli system and the E-Trap filter are used together: The lesion is crossed with the filter device under reverse flow control to prevent migration of particles during the catheterization phase, and then the procedure is completed using both cerebral protections. The drawback as previously stated is that patients with an aberrant or nonfunctioning circle of Willis or contralateral ICA occlusion may be intolerant to balloon occlusion, which manifests as loss of consciousness, paresis, aphasia, and seizures.

Technical Complications

The ICA is a relatively delicate vessel with regard to dissection and spasm. Because any distal protection device exerts some degree of force on the vessel wall to achieve complete apposition, it will irritate the arterial wall causing spasm (Fig. 3A–C). The degree of irritation increases with frequent movement of the protection device, which happens even in experienced hands. Although most episodes of spasm are self-limiting and do not result in clinical sequelae, the long-term effect of such spasm in the development of intimal hyperplasia unfortunately is still unknown.²² If spasm does cause immediate problems, in the majority of the cases it can be easily solved by intra-arterial injection of vasodilators (Fig. 3D). Damage to the intimal layer may occur due to unexpected movement of the inflated balloon or deployed filter basket by the operator or neck movement by

the patient. This may result in dissection of the ICA.²⁸ Although extremely rare, detachment of the filter from the guidewire has also been reported, occurring when the filter is caught on the stent during retrieval. Similar events have been observed with other components of CPD systems, including a retrieval catheter that detached and embolized. Complications can also occur during the retrieval phase of distal filters due to difficulties in getting the recovery catheter to cross the stent. In these cases filter capture requires several different maneuvers such as external neck compression, advancing the guiding catheter into the proximal stent, or moving the patient's head in different positions to straighten the stent.^{29–32}

EVIDENCE

Kastrup et al³⁰ performed a review of the most relevant publications published between 1990 and 2002 comparing 2537 unprotected CAS procedures with 896 CAS procedures performed using cerebral protection devices. The combined stroke and death rate within 30 days was, in both symptomatic and asymptomatic patients, higher in the group of patients treated without cerebral protection device (5.5%) compared with 1.8% of the protected group ($p < 0.001\%$). CPDs cannot prevent all embolic events that may occur during the different steps of CAS procedures^{18,19} with an increased risk of distal embolization during the unprotected phases of the procedure. Moreover, distal filter devices may have limitations to the debris capture efficiency. Studies performed in animals that included evaluations of cerebral blood flow indicated that the maximum size of particles that can be flushed to the distal arteriolar system in to the brain is $< 15 \mu\text{m}$.¹¹ Coggia et al,³¹ in an ex vivo model, demonstrated that 40,000 microemboli ($< 100 \mu\text{m}$) are generated by the passage of a guidewire through the lesion and that thousands of microemboli are released during angioplasty. It has been observed that the effects of microemboli released during CAS cannot be assessed accurately with the use of NIHSS (National Institute of Health Stroke Scale) because patients may have subtle changes in neurocognitive functions rather than gross motor or sensory manifestation. Autopsy studies of brain from patients with neurocognitive dysfunctions developed after cardiopulmonary bypasses revealed that the most common size of particles responsible for occult cerebral injury was 10 to $70 \mu\text{m}$.³² Similarly, patients having > 10 particulate emboli on transcranial Doppler (TCD) after CEA may have no evidence of stroke on a clinical evaluation but still have marked postoperative deterioration in cognitive functions.

Another potential cause of embolic complications could be the presence of atheroma protruding through stent mesh. “Washing” the stent with saline or contrast

Figure 3 (A) Digital subtraction angiogram in 75-year-old patient shows severe stenosis of the internal carotid artery (>90%). Duplex ultrasound (not shown) demonstrated an increased velocity of the blood flow at the level of the bifurcation (>280 cm). (B) The lesion was easily crossed with a 7-mm cerebral-protection device (CPD) (AngioGuard XP; Cordis, J&J, Miami Lakes, FL). Fluoroscopic image shows a Nitinol self-expanding stent (Precise; Cordis, J&J, Miami Lakes, FL) deployed at the level of the lesion. (C) Digital subtraction angiogram of the common carotid artery shows spasm (arrow) of the internal carotid artery that was observed at the level of the CPD. (D) Angiogram obtained after CPD removal shows no residual spasm after administration of intra-arterial nitroglycerine (0.25 mg).

media injection before CPD removal may be of some value.

Cerebrovascular complication can also occur in the early period after the procedure. Sztrihai et al³³ reported cerebrovascular complications in 14/245 patients (5.4%) most of which (9/14, 64.3%) occurred in the periprocedural phase, and Qureshi et al³⁴ observed a similar postprocedure neurological complication rate (71.4%). These events cannot be completely explained by the passage of atherosclerotic debris through the mesh of the stent. Hemodynamic changes after cerebral reperfusion could cause the detachment of debris from intracranial artery stenoses. Postprocedural hypotension may result in hypoperfusion in poststenotic arteries leading to hemodynamic strokes. Up-to-date data on device effectiveness are still limited, and the results of clinical studies and experimental evaluations of protection devices are controversial.⁹⁻¹³ Several studies, performed using magnetic resonance (MR) images of the brain with diffusion- and perfusion-weighted sequences (DW-MRI) have shown a higher incidence of new ischemic lesions after CAS.^{19,35} Diffusion-weighted MRI appears to be a sensitive method in assessing patients at high risk for subclinical stroke.³⁴

Jaeger et al³⁶ analyzed 70 patients who underwent CAS. He found no changes of neurological status in observations of 69/70 patients, but diffusion MRI performed at 24 hours showed 29% new ipsilateral lesions and 9% contralateral lesions.

CONCLUSIONS

Distal embolization remains the "Achilles' heel" of carotid artery stenting. Several international trials have shown the introduction of CPDs resulted in a drastic reduction in periprocedural neurological adverse events with a significant improvement in results. However, no level-one evidence exists for their use at the time of writing. The choice of the most suitable cerebral protection system includes an imaging preevaluation of the vessels anatomy and detailed plaque characterization. Although cerebral protection devices represent a further step in the development of endovascular treatment of carotid disease, cerebrovascular complications, due to late embolization or cerebral hemodynamic changes, can occur in the early period after the procedure.

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