Cerebral Protection With Filter Devices During Carotid Artery Stenting

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Background—Distal embolization of debris during percutaneous carotid artery stenting may result in neurological deficit. Filter devices for cerebral protection potentially reduce the risk of embolization.

Methods and Results—Elective carotid stent implantation using 3 different types of distal filter protection devices was attempted in 88 consecutive lesions (84 patients) in the internal carotid artery that had >70% diameter stenosis (mean, 78.7 ± 10.7%). Procedures were performed in 3 different centers. The mean age of the patients was 69 ± 8 years, 75% were men, and 35.7% had neurological symptoms. In 86 lesions, a stent was successfully implanted (97.7%). In 83 of these 86 procedures (96.5%), it was possible to position a filter device. In 53% of filters, there was macroscopic evidence of debris. Collected material consisted of lipid-rich macrophages, fibrin material, and cholesterol clefts. Neurological complications during the procedure, in the hospital, and at 30 days of clinical follow-up occurred in only one patient (1.2%). This patient suffered a minor stroke that resolved within 1 week. Two major adverse cardiac events (2.3%) occurred during the 30 days of follow-up.

Conclusions—Filter protection during carotid artery stenting seems feasible and safe. In the present series, the incidence of neurological complications was low. (Circulation. 2001;104:12-15.)

Key Words: carotid arteries • angioplasty • stents • embolism

Stent placement for extracranial carotid artery disease has emerged as a potential alternative to carotid endarterectomy.1,2 As shown by transcranial Doppler monitoring, percutaneous carotid stenting is accomplished with increased dislocation of microemboli compared with the surgical approach.3 Emboli have been associated with a higher neurological complication rate4 and are a potential cause of periprocedural stroke after endarterectomy.5–7 Protection devices have the potential to reduce the incidence of intracranial particulate debris embolization and render carotid artery revascularization safer.8–11 The present, prospective, multicenter registry was designed to evaluate the feasibility and safety of recently available filter protection devices.

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Methods

Patient and Lesion Characteristics

Between January 2000 and January 2001, elective carotid artery stent implantation using a distal emboli protection filter was attempted in 88 consecutive lesions in 84 patients (42 patients at Columbus Hospital, 10 at San Raffaele Hospital, 32 at Mirano Hospital). These lesions were 39.8% of the total 221 lesions treated overall in the 3 study centers. All patients presented with a significant (>70%) stenosis of the internal or common carotid artery. Clinical and angiographic characteristics are listed in Table 1.

All patients were taking aspirin (100 to 325 mg). Ticlopidine (500 mg) was started at least 48 hours before the procedure, and heparin (70 to 100 U/kg) was given intra-arterially. Arterial blood pressure was monitored during the procedure and, if needed, modulated with nitrates or dopamine. All patients were awake during the procedure. After the procedure, patients received aspirin indefinitely and ticlopidine for 1 month.

Careful neurological examination, including the NIH Stroke Scale, was performed before and after the procedure, at discharge, and at 30-day follow-up by a board-certified neurologist or by a board-certified internist. In 23 cases (26%), 1-month follow-up information was obtained by telephone call. Neurological complications were previously defined by Mathur et al.12

Carotid Stenting Procedure

Procedures were performed by following a strict protocol that was developed in collaboration by the first operators (A.C., C.D.M., and B.R.). Percutaneous access was gained through the femoral (2.3%) or brachial (2.3%) artery. Long sheaths (80 to 90 cm long; 6 or 7 French in diameter) or coronary guiding catheters (8 French) were advanced into the common carotid artery using diagnostic catheters and long 0.035 or 0.038 inch support wires placed in the external carotid artery. Stenoses were crossed with a filter device with a diameter matching the distal cervical internal carotid artery (Figure 1). Three different filter designs were used; they included 48 Angioguard filters (55.8%; J&J Cordis), 30 NeuroShield filters (34.9%; MedNova), and 8 FilterWire EX filters (9.3%; Embolic Protection, Inc; Figure 2). All filters were released recently, and data on their clinical efficacy are not available. The present study was not designed to detect differences between filters but to evaluate the clinical feasi-
bility and safety of protection devices during cardiovascular intervention. After positioning of the filter, predilation with coronary balloons was performed in 83.7% of cases. Self-expandable stents (82.3% Carotid Wallstent, Boston Scientific-Schneider; 12.8% X-act, MedNova; and 4.7% SMART stent, Cordis) were implanted, and all but one stent was postdilated at a medium-high pressure (8 to 12 atm).

**Filter Device Description**

The filter consists of a nitinol skeleton or supporting wire with a polyurethane membrane that has pores with a diameter ranging from 80 to 130 μm. The diameter of the filters ranged from 5.0 to 7.0 mm. The filters are connected to the distal end of a 0.014-inch wire with a floppy tip, which was used as a guidewire during the interventional procedure. The closed filter is advanced through the lesion and opened in the internal carotid artery distal to the lesion. At the end of the procedure, a retrieval sheath is advanced, and the filter is closed and removed from the artery.

Histopathological analysis was performed on 25 filters (30.1%) by light microscopy after staining with hematoxylin-eosin and Azan-Mallory.

### Results

In 2 lesions (2.3%), it was impossible to advance a long sheath or a coronary guiding catheter in the common carotid artery. In the remaining 86 procedures (97.7%), a stent was positioned at the lesion site. In 83 of these 86 cases (95.5%), the filter device crossed the lesion. In 6 of these cases (6.9%), the filter could be advanced through the lesion only after gentle predilation with 2.0-mm diameter coronary balloons. In 3 lesions (3.5%), the filter did not cross the stenosis. Crossing success occurred in 46 of the 48 Angioguard filters (95.8%), 29 of the 30 Neuroshield filters (96.6%), and 8 of 8 FilterWire EX filters (100%). In one case, an occlusive balloon protection system was adopted (Guardwire, Percusurge Inc), and 2 lesions (2.3%) were treated without protection. Spasm of the distal internal carotid artery, which resolved after intra-arterial nitrate administration, was observed in 3 cases (3.6%). Flow impairment resistant to nitrates, without angiographic signs of vessel spasm and resolving after filter removal, occurred in 6 procedures (7.2%). At the angiographic control vessel, alterations of the segment of the internal carotid artery where the filter was positioned were not observed. Difficult retrieval of the closed or partially closed filter through the stent requiring repeat rotation of the device occurred in 7 cases (8.4%). Macroscopic visible debris was seen in 44 filters (53%). Procedural data and results are shown in Table 2.

One patient (1.2%) experienced a category 1 minor stroke with partial upper limb paralysis, which resolved completely within 1 week. Four patients (4.6%) required intravenous dopamine infusion for prolonged hypotension. There were no procedural deaths and no vascular access complications.

The 30-day clinical follow-up did not reveal any further neurological events. Two major adverse cardiac events (2.3%) occurred. One patient with severe coronary artery disease suffered a massive anterior myocardial infarction 4 days after carotid stent implantation and died 3 days later with heart failure. A second patient underwent coronary angioplasty the day before carotid stenting and experienced a nonfatal, acute Q-wave myocardial infarction from subacute stent thrombosis.
The histological analysis detected particulate, atheromatous material characterized by lipid-rich macrophages, fibrin material, and cholesterol clefts.

**Discussion**

This is, to our knowledge, the largest consecutive series of carotid stent implantation using filter devices for cerebral protection. Previously reported series of cerebral protection with occlusive balloon systems report similar favorable results in terms of a low incidence of neurological complications. After comparing occlusive balloons with filter systems, we determined that balloons have a favorable, lower crossing profile but do not permit flow and are not tolerated by all patients. With filter devices, antegrade flow is maintained, allowing visualization and more precise stent placement (Figure 1). In this study, filter devices were well tolerated by all patients.

The presence of particulate detected at microscopic analysis shows that filters could collect debris that otherwise would have embolized in cerebral vessels. It is impossible to postulate the clinical impact collected debris might have had. However, most complications during surgical endarterectomy have been related to the presence of distal embolism. The histological findings confirm earlier studies suggesting that material is dislocated from the atheromatous plaque during the intravascular procedure.

The major cardiac events occurring in 2 patients (2.3%) underline the importance of considering the hemodynamic consequences of the procedure.

**Limitations of the Study**

One limitation of the study is the absence of transcranial Doppler monitoring during the stent procedure. Therefore, the study does not provide any information on the degree of embolization occurring while crossing the lesion with the device, nor does it provide data on the efficiency of the filter in capturing all particles dislocated during angioplasty and stenting. A recent ex vivo study reported that 88% of embolized particles were captured in the filter. Whatever the degree of Doppler-detectable embolization was, we should acknowledge the low incidence of associated neurological events.

In 26% of the procedures, 1-month follow-up evaluation was obtained by telephone contact only. Therefore, minor neurological events may be under-reported.

**Conclusions**

Cerebral protection with filter devices during carotid artery stent implantation seemed feasible and safe. Protection de-
vices reduce the cerebral embolization of plaque debris during carotid artery stent implantation. The incidence of associated neurological events was low; however, the clinical efficacy of protection filters requires further confirmation.

References
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