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Routine Use of Cerebral Protection (Filter Wire) During Carotid Artery Stenting: Results of a Single Center Registry of 37 Patients

Objective/Background: To evaluate the short-term outcome of patients who underwent carotid stenting with the routine use of cerebral protection devices.

Patients and methods: In our center, 36 successful carotid stenting procedures (of 38 attempted) were performed in 37 patients (23 men; aged 66±7 years). Cerebral protection involved distal filter devices (n= 36) of which 12 were Accunet and 24 were EZ filter wires.

Results: The protection devices were positioned successfully in 36 of the 38 attempted vessels. The 30-day incidence of stroke and neurological death was three. Neurological complications included one major stroke, and one minor stroke. There was also one (sudden cardiac death on the first day). The proportion of stroke or death was two for symptomatic lesions and one for asymptomatic lesions, and two in patients aged <80 years and one in those aged ≥80 years. Protection device-related vascular complications included mild spasm, which occurred after three procedures (8%), none of which led to neurological symptoms. There were another four cardiogenic deaths in 30-day follow-up.

Conclusion: In this uncontrolled study, routine cerebral protection during carotid artery stenting was technically feasible and clinically safe. The incidence of major neurological complications in this study was lower than in previous reports of carotid artery stenting without cerebral protection.

Keywords: carotid angioplasty, stenting, protection device, filter wire

Introduction

Carotid artery stenting is under investigation as an alternative to surgical of endarterectomy.[1] The goal of both procedures is to prevent stroke, and their efficacy depends on the rates of periprocedural complications. A randomized trial of carotid angioplasty versus surgical endarterectomy showed that the early and 3-year outcomes were similar.[2]

Despite advances in stenting techniques and the use of combined antiplatelet therapy (aspirin plus clopidogrel or ticlopidine), embolic neurological events are inevitable during carotid artery stenting.[1,3] Obstructive carotid artery lesions contain friable, ulcerated, and thrombotic material[4] that can embolize during the intervention. [5,6] To minimize the risk of embolic events, several protection strategies have been introduced.[7] Preliminary results indicate that the refinement of stenting techniques, the higher experience of the interventionalist, and the routine use of cerebral protection, can produce results similar to the best surgical series . [8-15]

We report the results of 38 attempts of carotid stenting, designed to evaluate procedural and 30-day outcomes of a consecutive series of carotid stent implantations with routine use of cerebral protection devices (Figure 1).

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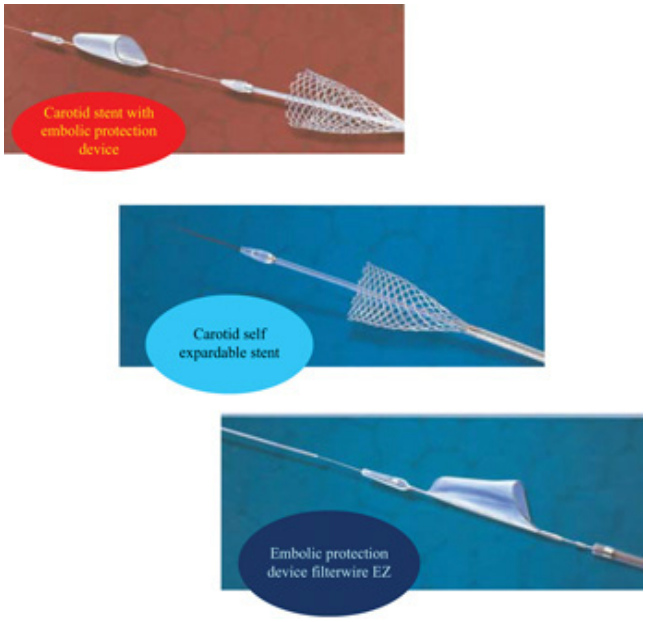


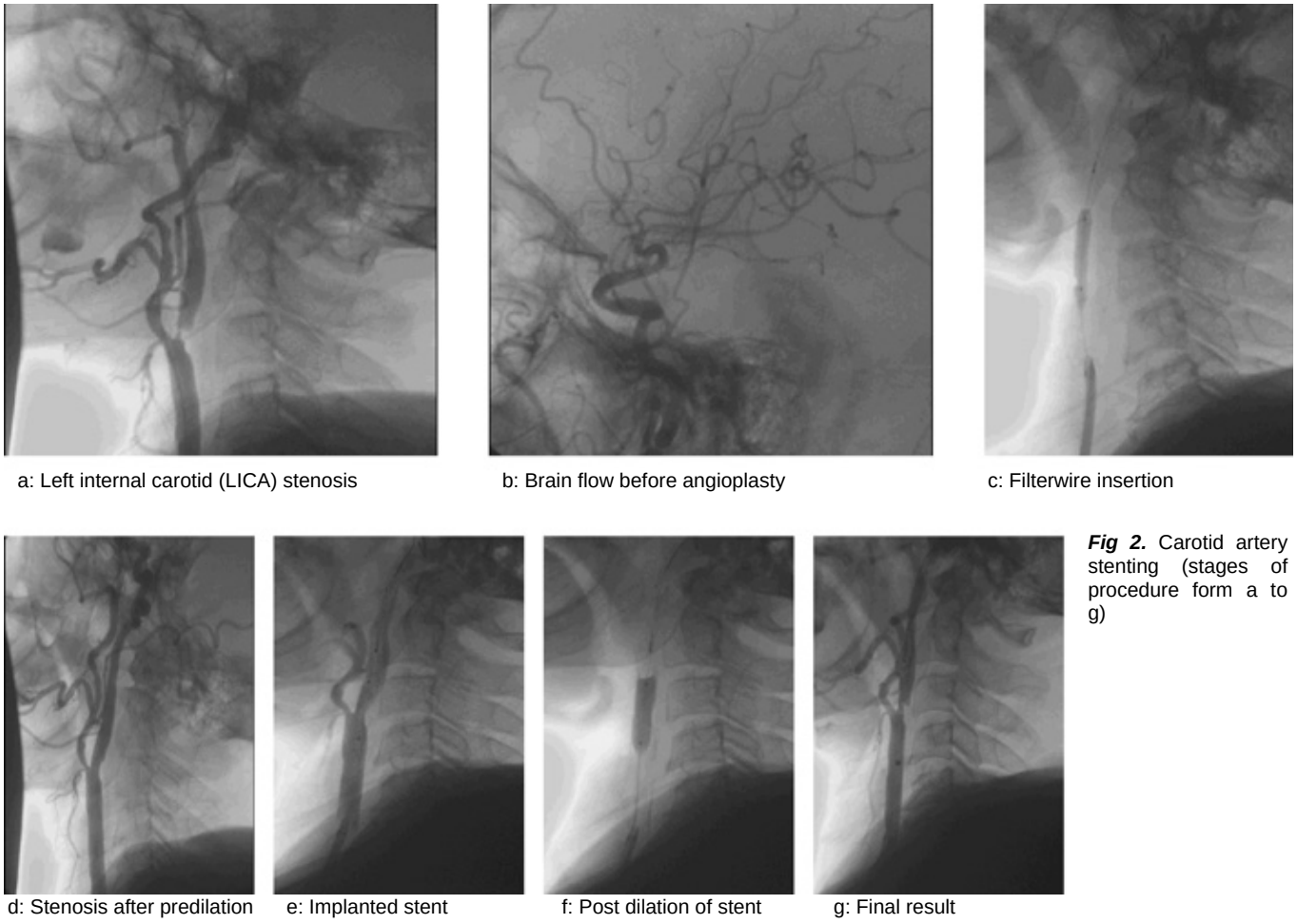
Fig 1. Embolic protection devices (filter wire) and stent

Patients and Methods

Between Jan 2003 and Jan 2005, elective carotid artery stenting using cerebral protection devices were attempted on 38 vessels in 37 consecutive patients (23 male; mean age [±SD] 66±7 years) with 38 lesions. Experienced interventionalists using similar stenting techniques performed the procedures. All patients had a ≥70% diameter stenosis of the internal or the common carotid arteries, measured according to the North American Symptomatic Carotid Endarterctomy Trial (NASCET) criteria using the distal, nontapering portion of the internal carotid artery as the reference segment. [11,16,17] The patients were selected based on a carotid Doppler screening. The patients with stenosis more than 70% were candidates for stenting. All patients had prestenting plain brain CT.

Stenting Procedure (Figure 2)

Percutaneous access was gained through the femoral artery using guiding catheters (7 or 8 French), which were advanced into the common carotid artery. Cerebral protection was attempted using distal filter devices (38 procedures) EZ filter wire, Boston Scientific (17 cases); Angiogaurd, Cordis (1 cases); Acculink, Guidant (20 cases). The choice of protec-



a: Left internal carotid (LICA) stenosis
b: Brain flow before angioplasty
c: Filterwire insertion
d: Stenosis after predilation
e: Implanted stent
f: Post dilation of stent
g: Final result

Fig 2. Carotid artery stenting (stages of procedure form a to g)

tion device was at the discretion of the operator and the availability of the device. Filter protection devices were 0.5 to 1.0 mm larger than the vessel diameter. If it was difficult to advance the distal protection device, a 0.014-inch support wire ("buddy wire") was positioned in the internal carotid artery to facilitate deployment. Two procedures were not continued because of severe proximal tortisity and cross failure of the filter wire.

After deployment of the protection devices (12 Accunet filter wires and 24 EZ filter wires and balloon predilatation, self-expandable mesh stents (Wallstent, Boston Scientific, Natick, Massachusetts; or Nitinol stents, Acculink, Guidant, Temecula, California) were implanted. The majority of stents were balloon postdilated based on the CAVATAS study recommendation. Arterial sheaths were removed the same day. After the procedure, patients underwent continuous electrocardiographic monitoring and noninvasive blood pressure measurements every 3 hours for at least 12 hours.

All patients were treated with aspirin (100 to 325 mg/d). Clopidogrel (75 mg/d) was started at least 3 days before the procedure. Heparin (70 to 100 IU/kg) was given just before the procedure to achieve an activated clotting time >250 seconds. Patients were discharged on a regimen of aspirin (indefinitely), and ticlopidine or clopidogrel for 1 month.

Neurological examination including the National Institutes of Health (NIH) Stroke Scale was performed before and after the procedure.[18] and on day 30 of follow-up by a board-certified neurologist.

Complications

Procedure-related complications from the beginning of the procedure through 30-day follow-up were recorded. Neurological complications were defined using standard criteria.[1] A transient ischemic attack was defined as a hemispheric event from which the patient would make a complete recovery within 24 hours. A minor stroke was defined as a new neurological deficit that would either resolve completely within 30 days or would increase the NIH Stroke Scale by ≤3. A major stroke was defined as a new neurological deficit that persists for >30 days and increases the NIH Stroke Scale by ≥4. A fatal stroke was defined as death attributed to an ischemic stroke or intracerebral hemorrhagic stroke. Amaurosis fugax was defined as transient loss of vision. The references of these definitions are the American National Institute of Health Stroke Scale, which is discussed at the Roubin et al.'s study in Circulation 2001.[1] Cerebral events related to intracerebral hemorrhages were classified according to the neurological problems such as transient ischemic attacks, minor strokes, or major strokes.

The proportion of single complications and cumulative complications were calculated as the number of complications divided by the total number of 36 successful procedures.

Results

Of 38 selected lesions, all were de novo (Table 1). In one patient, both carotid arteries were treated during staged procedures. Eight of the lesions were associated with neurological symptoms (stroke or transient ischemic attack in the ipsilateral hemisphere) within 6 months before the procedure.

Cerebral Protection

Of the 38 interventions, procedural success was achieved in 36 cases (Table 2). In addition, placement

Table 1. Characteristics of 37 patients

Characteristic	Number
Patients	37
Age (±SD)	66±7 years
≥80 years old	2
Male	23 (65%)
Diabetes	15 (40%)
High cholesterol level	18 (50%)
Hypertension	15 (40%)
Coronary artery disease	35 (95%)
Contralateral carotid artery stenosis ≥50%	3 (10%)
Contralateral carotid artery occlusion	1 (3%)
Lesions	
De novo	38 (100%)
Restenosis after endarterectomy	0
Restenosis after carotid artery stenting	0
Angiographic evaluation	
Diameter stenosis (%)	85%±10
Lesion length (mm)	20±5

Table 2. Results of the procedures

	Number
Protection device attempted (filter wire)	38
Successful protection device placement	36
Accunet filter wire (Guidant)	12
EZ filter wire (Boston)	24
Protection device-related compliaions	3
Predilation of lesion	34
Stent placed	36
Self-expandable stents	36
Wall stent (Boston scientific)	17
Acculink (Guidant)	18
Precise (Cordis)	1
Postdilation of placed stent	35

of the protection devices prior to the stenting procedures was carried out in 36 procedures. In two procedures, the filter protection device could not be advanced beyond the lesion due to the lesion severity (one EZ filter wire and one Accunet filter wire).

Protection device-related vessel complications (spasm) occurred during 3 procedures, without causing neurological symptoms.

Flow-limiting vessel spasm that resolved with intra-arterial administration of nitrates occurred in two filter procedures. Flow impairment due to filter obstruction occurred in one procedure; this resolved after filter removal.

Stenting

Procedural stenting was done in 36 lesions (Table 2). This resulted in a decrease in stenosis diameter from 75–95% to a residual stenosis <30%. One stent was placed in every vessel in 36 lesions.

Neurological Complications, Deaths, and Myocardial Infarctions within 30 Days

Of the three neurological complications (Table 3), none occurred during the procedure, but all of them occurred during the hospital stay. There was one major stroke that none involved retinal infarction. There was one minor stroke, which presented with localized ischemia and cognitive dysfunction. A plain brain CT with standard protocol was used for evaluation of post stenting stroke. Both patients had complete regression of clinical symptoms, and CT scans within 30 days showed no evidence of persistent hemorrhage. One patient had sudden cardiac death

Table 3. Neurologic Complications, Death, and Cardiogenic Death within 30 Days

Outcome	Number
Transient ischemic attack	0
Minor stroke, nonfatal	1
Major stroke, nonfatal	1
Major stroke, fatal	0
Sudden cardiac death	1
Total	3
30_ day cardiogenic death	4
Post CABG death	1
Fatal myocardial infarction	2
CHF	1
Total	4

(SCD) on the first day. No transient ischemic attacks or amaurosis fugax was encountered.

During the 30 days of follow-up, four cardiogenic deaths were seen, of which two patients died because of myocardial infarction, one patient after CABG, and one patient of CHF. One major vascular access complication required blood transfusion and surgical repair.

In evaluation of device related complication, EZ filter wire was used in all the three cases with neurological complication, two had Wall stent and one SCD patient had Acculink stent. In four cardiac mortality in one month, the stent that used were two Acculink (Guidant), two Wall stent (Boston), two Accunet filter wire, and two EZ filter wire.

Discussion

Our findings show that the routine use of cerebral protection during carotid stenting is technically feasible, with a 95% success rate in positioning a protective device. Based on the feasibility and safety of protection-device handling, and the ability of protection devices to reduce embolization of debris into the cerebral circulation, we opted for cerebral protection during carotid artery stenting.

The potential benefits of procedures to treat stenotic carotid artery disease depend on the incidence of complications associated with that procedure.[19] Because surgical endarterectomy has been performed for many years, we applied the same safety criteria

accepted for endarterectomy, to stenting as well. The American Heart Association has set guidelines for the performance of surgery, according to which the treatment of severe extracranial carotid stenosis should only be performed if the cumulative perioperative stroke and death rate can be kept ≤6% in symptomatic and ≤3% in asymptomatic patients. [19,20]

In our study, the cumulative 30-day rate of stroke among patients was 2.36 (%6), and thus, fell near the figures on guidelines. In less selected groups of patients, less favorable results of endarterectomy have been reported. For instance, in the Veterans Affairs Cooperative Study, the rate in surgically treated asymptomatic patients was 4.7% .[21,22] Thus, the 30-day clinical outcomes observed in our registry appear similar to the best results obtained with carotid endarterectomy particularly if we consider that many patients in our study would have been ineligible for NASCET because of comorbid medical conditions.

Roubin et al. observed a 7.3% cumulative 30-day stroke/death rate, and Wholey et al reported a 5.9% rate without cerebral protection.[1,3] During unprotected stent implantation, the incidence of stroke and death was even higher in symptomatic patients (8.2%) and in patients aged >80 years (16.0%).[1] In our study, the incidence of stroke/death was not significantly different for symptomatic and asymptomatic lesions, and also among patients aged ≤80 or >80 years, suggesting that protected stent treatment of high-risk patients does not increase the risk of complications.

In our registry, stenting was performed electively as an alternative to endarterectomy.[23] Thus, the indications were not limited to patients at high surgical risk, such as those with contralateral carotid occlusion, restenosis after endarterectomy, age >80 years, or patients who had severe concomitant cardiovascular or pulmonary disease. Our registry included patients who were suitable candidates for endarterectomy, as well as patients who were at high risk for endarterectomy. Nevertheless, the risk of periprocedural complications was low, and similar to results in surgical registries with more stringent inclusion criteria. [16, 21, 22]

The clinical equipoise of the surgical and percutaneous approaches has been addressed in two randomized trials comparing endarterctomy with carotid artery stenting and in the preliminary results from the SAPPHIRE trial.[2,8,24] None of the three trials found significant differences in the periprocedural risk of death and stroke. In SAPPHIRE, 156 patients were randomly assigned to stent implantation with cerebral protection and 151 patients were assigned to endarterectomy. The cumulative 30-day incidence of death/stroke was lower, but was not statistically significant in the stent group (4.5% vs. 6.6%). However, the cumulative 30-day rate of stroke, death, and myocardial infarction was significantly lower in the stent group (5.8% vs. 12.6%). Other randomized trials of endarterectomy versus neuroprotected carotid artery stenting are ongoing, although enrollment has been slow.

In two complicated cases, a CT scan showed ipsilateral, localized ischemia that resolved within one month. Subarachnoid bleeding was not observed. [25,26] Careful intraprocedural anticoagulation with reduced administration of heparin (≤70 IU/kg) and control of the activated clotting time (>250 seconds and ≤300 seconds) has been adopted by the participating centers. In addition, we did not use glycoprotein IIb/IIIa inhibitors. [27, 28]

The four myocardial infarctions that occurred in one month follow-up in this study underline the importance of monitoring hemodynamic consequences of the procedure and thereafter, particularly in patients with unstable coronary syndromes.[29] This incidence of infarctions was not surprising, since more than 95% of our patients had known coronary artery disease.

The main limitation of this registry is that it was not a randomized comparison of carotid artery stenting versus endarterctomy. In addition, outcomes were not ascertained blindly, and we do not have data on long-term outcomes. Furthermore, we did not compare different protection devices.

Conclusion

In conclusion, routine distal cerebral protection with filter wire during carotid artery stenting is technically feasible and clinically safe. In this prospective registry of carotid artery stenting, the incidence of periprocedural neurological complications was lower than in registries of carotid artery stenting without

cerebral protection. Our results were comparable to the results reported for carotid endarterectomy. [30, 31, 32]

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