

ROUTINE USE OF CEREBRAL PROTECTION (FILTER WIRE) DURING CAROTID ARTERY STENTING

A. M. Haji-Zeinali*, M. Alidosti, S. E. Kassaian and M. Salarifar

Department of Interventional Cardiology, School of Medicine, Medical Sciences/University of Tehran, Tehran, Iran

Abstract- To minimize the risk of embolic events, several protection strategies have been introduced. We have evaluated the short-term outcome of patients who underwent carotid stenting with the routine use of cerebral protection devices. In our center, 36 successful carotid stenting procedures (of 38 attempted) were performed in 37 patients (23 men; age mean [\pm SD] 66 \pm 7 years). Cerebral protection involved distal filter devices (n = 36). The protection device was positioned successfully in 36 of the 38 attempted vessels. Neurologic complications included 1 major stroke and 1 minor stroke and there was 1 sudden cardiac death. The rate of stroke or death was 2 for symptomatic lesions and 1 for asymptomatic lesions, and 2 in patients aged < 80 years and 1 in those aged \geq 80 years. Protection device-related vascular complications were mild spasm occurring after 3 procedures (8%) but none led to neurologic complications. There were another four cardiogenic deaths in 30 day follow up. In this uncontrolled study, routine cerebral protection during carotid artery stenting was technically feasible and clinically safe. The incidence of major neurologic complications in this study was lower than in previous reports of carotid artery stenting without cerebral protection.

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Key words: Cerebral protection, carotid artery, filter devices

INTRODUCTION

Carotid artery stenting is under investigation as an alternative to surgical treatment for endarterectomy (1). The goal of both procedures is the prevention of stroke, and the efficacy of these procedures 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, increasing experience of the interventionalists, and the routine use of cerebral protection produce results similar to the best surgical series (8-15).

We report the results of a 38 attempts for carotid stenting that was designed to evaluate procedural and 30-day outcomes of a consecutive series of carotid stent implantations with routine use of cerebral protection devices.

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* Corresponding Author:

A. M. Haji-Zeinali, Department of Interventional Cardiology, Shariati Hospital, School of Medicine, Medical Sciences/University of Tehran, Tehran, Iran
Tel: +98 21 88029650
Fax: +98 21 88029724
E-mail: ali_zeinali_cardio@yahoo.com

MATERIALS AND METHODS

Between Jan 2003 and Jan 2005, elective carotid artery stenting using cerebral protection devices was attempted at 38 vessels in 37 consecutive patients (23 men; age mean [\pm SD] 66 \pm 7 years) with a total of 38 lesions. The procedures were performed by experienced physicians using similar stenting techniques. All patients had \geq 70% diameter stenosis of the internal or the common carotid artery, measured according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria using the distal, nontapering portion of the internal carotid artery as the reference segment (11, 16, 17).

Stenting Procedure

Percutaneous access was gained through the femoral artery guiding catheters (7 or 8 French) advanced into the common carotid artery. Cerebral protection was attempted using distal filter devices (38 procedures) Filter Wire EZ, Boston Scientific (17 cases) Angioguard, cordis (1 cases) acculink, Guidant (20 cases). The choice of the protection device was at the discretion of the operator and the availability of the devices. 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.

After deployment of the protection device and balloon predilatation, self-expandable mesh stent (Wallstent; Boston Scientific, Natick, Massachusetts) or nitinol stents (Acculink, Guidant, Temecula, California) were implanted. The majority of stents were balloon postdilated. Arterial sheaths were removed the same day. After the procedure, patients had 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 treatment. 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.

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

Complications

Procedure-related complications from the beginning of the procedure through 30-day follow-up were recorded. Neurologic complications were defined using standard criteria (1). A transient ischemic attack was defined as hemispheric event from which the patient made complete recovery within 24 hours. A minor stroke was defined as a new neurologic deficit that either resolved completely within 30 days or increased the NIH Stroke Scale by \leq 3. A major stroke was defined as a new neurologic deficit that persisted for $>$ 30 days and increased the NIH Stroke Scale by \geq 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. Cerebral events related to intracerebral hemorrhages were classified according to the neurologic symptoms as transient ischemic attacks, minor strokes, or major strokes. The rate of single complications and of cumulative complications was calculated as the number of complications divided by the total number of procedures.

RESULTS

Of the 38 lesions, 100% were de novo (Table 1). In 1 patient, both carotid arteries were treated during staged procedures. neurologic symptoms (stroke or transient ischemic attack of the ipsilateral hemisphere) within 6 months before the procedure occurred in 18% of the lesions.

Cerebral Protection

Of the 38 interventions, procedural success was achieved in 36 cases (Table 2). Placement of the protection device prior of the stenting procedure was achieved in 36 of these 38 procedures. In 2 procedures, the filter protection device could not be

Table 1. Characteristics of the 37 patients

Characteristic	Number (%) or
	Mean \pm SD
Patients	
Age (years) (\pm SD)	66 \pm 7
\geq 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 \geq 50%	3 (10%)
Contralateral carotid artery occlusion	1 (3%)
Lesions	
De novo	38 (100%)
Restenosis after endarterectomy	---
Restenosis after carotid artery stenting	---
Symptomatic	8 (20%)
Angiographic evaluation	
Diameter stenosis (%)	85% \pm 10
Lesion length (mm)	20 \pm 5

advanced beyond the lesion because of lesions severity. Protection device-related vessel complications (spasm) occurred during 3 procedures, without causing neurologic symptoms.

Flow limiting vessel spasm that resolved with intra-arterial administration of nitrates occurred in 2 filter procedures. Flow impairment due to filter obstruction occurred in 1 procedure; this resolved after filter removal.

Table 2. Results of the 36 successful procedures*

Procedure	Number (%)
Protection device attempted (filter wire)	38 (100%)
Protection device successful	36 (95%)
Protection device-related complications (spasm)	3 (10%)
Predilation of lesion	34 (92%)
Stent placed	36 (100%)
Self-expandable stents	36 (100%)
Wall stent (Boston scientific)	17
Acculink (Guidant)	20
Precise (cordis)	1
Postdilation of placed stent	35 (95%)

* Of 38 attempted; see text for details.

Stenting

Procedural success was achieved in 36 of the 38 lesions (Table 2). This resulted in a decrease in diameter stenosis from 75%–95% to residual stenosis $<$ 30%. A stent was placed in 36 of these lesions.

Neurologic Complications, Deaths, and Myocardial Infarctions within 30 Days

Of the 2 neurologic complications (Table 3), none occurred during the procedure, but all of them during the hospital stay. One major stroke occurred that did not involve retinal infarction. The 1 minor stroke occurred in one patients with localized ischemia and cognition disorder. All two patients had complete regression of clinical symptoms, and computed tomographic (CT) scans within 30 days showed no evidence of persistent hemorrhage. One patient had sudden cardiac death (SCD) on the first day. No transient ischemic attack occurred during the procedure. No amaurosis fugax was seen. In 30 days follow up 4 patients had cardiogenic death. Four patients had myocardial infarctions and 2 of them died. One patient died after coronary artery bypass graft (CABG) and one patient died because of congestive heart failure (CHF). There was one major vascular access complication that required blood transfusion and surgical repair.

Table 3. Neurologic complications, deaths, and myocardial infarctions within 30 days

Outcome	Number (%)
All strokes and transient ischemic attack	2
Transient ischemic attacks	---
Minor strokes, nonfatal	1
Major strokes, nonfatal	1
Major strokes, fatal	---
Sudden cardiac death	1
30 day cardiogenic death	4
Post CABG death	1
Fatal myocardial infarctions	2
CHF	1

Abbreviations: CABG, coronary artery bypass graft; CHF, congestive heart failure.

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 and low incidence of device-related complications. 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 (6), we recommend 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 used the same safety criteria for stenting as have been accepted for endarterectomy. The American Heart Association has set guidelines for the performance of surgery, according to which treatment of severe extracranial carotid stenosis be performed if the cumulative perioperative stroke and death rate can be kept $\leq 6\%$ in symptomatic and $\leq 3\%$ in asymptomatic patients (19, 20, 21). In our study, the cumulative 30-day rate of stroke and neurological death among patients was 3 and thus fell within the 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% (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. Our results were better than those seen when stenting is performed without cerebral protection. Roubin et al (1) observed a 7.3% cumulative 30-day stroke/death rate, and Wholey et al (3) reported a 5.9% rate. Major strokes and death were also less common in our study. 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 contrast, in our study, the incidence of stroke/death was not significantly different for symptomatic or asymptomatic lesions, and 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 who have severe concomitant cardiovascular or pulmonary disease. Our registry includes patients who were good candidates for endarterectomy, as well as patients who were at high risk from 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 endarterectomy with carotid artery stenting (2, 8) and in preliminary results from the SAPPHIRE trial (24). None of the three trials found significant differences in the periprocedural risk of death and stroke. In SAPPHIRE, 156 patients were assigned randomly to stent implantation with cerebral protection and 151 patients were assigned to endarterectomy. The cumulative 30-day incidence of death/stroke was lower, but not statistically so, 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%, $P < 0.05$). 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 1 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 4 myocardial infarctions that occurred in this study underline the importance of monitoring the hemodynamic consequences of the procedure,

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 endarterectomy. In addition, outcomes were not ascertained blindly, and we do not have data on long-term outcomes. Furthermore, we did not compare the different protection devices. 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 neurologic complications was lower than in registries of carotid artery stenting without cerebral protection and similar to the best results reported for carotid endarterectomy.

Conflict of interests

We have no conflict of interests.

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