Procedural Outcome and Midterm Result of Carotid Stenting in High-Risk Patients

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ORIGINAL CONTRIBUTION

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ABSTRACT

Carotid endarterectomy is the standard treatment for carotid stenosis, but carotid artery stenting has emerged as a potential alternative. Elective carotid artery stenting was performed in 42 patients aged 42 to 79 years (mean, 67.05 ± 8.67 years) after ultrasonography, computed tomography, magnetic resonance angiography and a neurological evaluation. There was bilateral carotid stenosis in 23 patients (55%), with > 90% stenosis in 18 vessels. All patients had significant associated coronary lesions. An emboli protection device and self-expanding stents were used. One year later, the patients were evaluated by Doppler sonography and selective angiography. Technical success was achieved in all procedures. During follow-up, 1 (2.4%) patient died from myocardial infarction, 1 underwent coronary artery bypass and 14 (40%) had minor complaints including occasional dizziness. No other neurological events were noted. Restenosis was found in one case, but selective angiography ruled out a significant lesion. One patient suffered embolization, but recovered completely within 24 hours. In 7 (17%) patients with type C arch interruption and a tortuous carotid course, stenting was successful and they had no embolization or restenosis. Carotid artery stenting is recommended in high-risk patients.

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INTRODUCTION

Stroke is one of the leading causes of death worldwide. More than 500,000 new strokes occur annually in United States, and it has been estimated that carotid artery disease may be responsible for 20% to 30% of these.[1] Asymptomatic carotid artery stenosis can progress to occlusion, and disabling strokes may occur in 20% of patients, and thereafter in 1.5% to 5% annually.[2] As demonstrated in multicenter randomized trials, carotid endarterectomy (CEA) is the most effective treatment to reduce strokes in symptomatic and asymptomatic patients with significant carotid stenosis.[3,4] Carotid artery stenting has recently emerged as an alternative to CEA, offering less invasiveness and a shorter hospitalization, which might benefit older and high-risk patients.[5] In a randomized trial, the result of stenting was not inferior to that of CEA, and the mortality rate was 39% lower.[6] The number of carotid stenting procedures has steadily increased in last few years but is still limited because of concerns about long-term results and neurological complications.[7] Although it has been shown to be safe and effective, with lower incidences of death, stroke and myocardial infarction than CEA, there is a perceived risk of vessel restenosis.[6,8] A study of high-risk patients reported a 5% to 14% rate of carotid restenosis or occlusion.[9] However, restenosis occurs in up to 24% of patients after CEA.[10] Because of a lack of data on carotid stenting in Iran, this prospective study aimed to assess early and midterm results to evaluate the efficacy of the procedure.

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Patients and Methods

From April 2004 to March 2005, 42 patients aged 42 to 79 years underwent elective carotid stenting in Shiraz Medical Centers. The risks and benefits of carotid stenting compared to CEA were explained in details to each patient before the procedure by the medical team. Preoperative Doppler ultrasonography, computed tomography and magnetic resonance angiography with complete evaluation by a radiologist were performed to determine the degree of carotid artery stenosis and any calcification, thrombus or tortuosity. All patients were known to have coronary artery disease, and carotid angiography was carried out along with coronary angiography to confirm the findings. Criteria for carotid stenting were symptomatic stenosis > 50% or asymptomatic stenosis > 70%, as defined by NASCET (North American Symptomatic Carotid Endarterectomy Trial).[11] A neurologist evaluated each patient's neurological status before and after the procedure. All patients were given aspirin 325 mg and clopidogrel 75 mg daily at least 72 hours before the procedure and for at least 1 month afterwards. Aspirin was continued indefinitely, and those who had complex anatomy or bilateral stenosis had dual antiplatelet therapy for at least 6 months.

Carotid stenting was performed using emboli protection devices and 1 of 3 available types of stent: Wallstent (Boston Scientific, Natick, MA, USA) in 25 (60%) patients, Acculink (Guidant, Indianapolis, IN, USA) in 12 (29%), and Protégé (ev3, Plymouth, MN, USA) in 5 (12%). A Wallstent was used for complex lesions (thrombotic, soft or calcified); Protégé and Acculink stents were used for less complex lesions or arteries with a tortuous course. The stents were 40–80 mm in length and 6–8 mm in diameter. The protection devices were FilterWire EZ (Boston Scientific, Natick, MA, USA) in 52%, Spider (ev3, Plymouth, MN, USA) in 24%, and MoMa (Invatec s.r.l, Ronacadelle, Italy) in 24%. MoMa devices were used in patients with complex anatomy (severely narrowed with thrombus) and without significant tortuosity, Spider filters were used in those with severe stenosis or a tortuous coarse of the carotid artery, which prohibited passage of common filters, and the FilterWire EZ was used in less complex lesions. The carotid artery lesion was dilated with a 4–6-mm balloon before stent placement in 9 (21%) patients, after stenting in 27 (64%), and both before and after in 6 (14%). Technical success was defined as the ability to access the carotid artery and stent the lesion with < 20% residual stenosis. All patients were clinically assessed by a cardiologist and a neurologist postoperatively. Electrocardiograms and plasma troponin I levels were checked daily for 3 days to detect any cardiac events.

Of the 42 patients treated, 7 could not be contacted for follow-up. The others were examined during follow-up of 6–18 months (mean, 14 months) after stenting. A neurological assessment and color Doppler sonography of the stented carotid artery were performed every 6 months. Restenosis of the stented artery was defined as > 50% narrowing on Doppler sonography, confirmed later by carotid angiography. A questionnaire was designed to assess the patients' carotid disease risk factors, complications during the procedure and condition 1 year after the procedure. Major stroke was defined as a new neurologic event lasting longer than 24 hours, with an increase in the National Institute of Health stroke scale of more than 3. Minor stroke was defined as a new neurologic event that lasted longer than 24 hours with an increase in the stroke scale of less than 3. A transient ischemic attack was defined as a new neurologic deficit for < 24 hours.

All data are expressed as mean ± standard deviation. The data were analyzed by Student's *t* test using SPSS version 13.3 software (SPSS, Inc., Chicago, IL, USA). Multivariate analysis was performed using logistic regression, which remains statistically valid even with small numbers of individuals. A p value < 0.05 was considered significant.

Results

Demographic, clinical and angiographic characteristics of the patients are given in Table 1. All had angiographically confirmed coronary disease (stenosis > 70%). Bilateral carotid stenosis was present in 23 patients. Stenosis of > 90% was found in 18 (43%) carotid arteries. Technical success was achieved in all procedures. During the procedure, 8 (19%) patients developed bradycardia and hypotension, and 1 (2.4%) developed hypotension only. One had an embolism during the procedure, with slurred speech and hypotension. Emergency magnetic resonance imaging showed no significant new ischemic event, so the neurologist decided to follow the patient clinically, without repeat angiography or thrombolytic therapy. All neurologic deficits resolved completely within 24 hours.

Follow-up data of the 35 patients who could be contacted are given in Table 2. There were 14 (40%) patients with minor complaints including occasional dizziness. One complained of paresthesia in his left extremities contralateral to the stented carotid artery, and another suffered from occasional ataxia; these symptoms were considered to be due to strokes prior to carotid stenting. There were no other neurological events 1 year after stenting. Restenosis (defined as > 50% narrowing) was found in one of 34 patients who were evaluated by Doppler ultrasonography of the epiaortic vessels 1 year after stenting. It was reported as 90%, but

Table 1. **Profile of 42 Patients with Carotid Artery Stenosis**

Variable	No. of Patients	%
Mean age (years)	67.05 ± 8.67	
Male/female	30/12	71%:29%
Bilateral stenosis	23	55%
Mean degree of stenosis	87.88% ± 7.86%	
Carotid artery involvement		
Right	23	55%
Left	19	45%
Prior ipsilateral stroke	7	17%
Prior TIA	13	31%
Coronary artery disease	42	100%
Diabetes mellitus	10	24%
Hypertension	26	62%
Hyperlipidemia	25	60%
Smoker	12	29%
Mean body mass index	23.97 ± 2.64	
Family history of stroke		
< 60 years of age	5	12%
≥= 60 years of age	5	12%
Family history of MI	20	48%

MI = myocardial infarction, TIA = transient ischemic attack.

Table 2. **Follow-up Data of 35 Patients**

Variable	No. of Patients	%	Comments
Restenosis*	1	2.9%	Not confirmed by carotid angiography
TIA/minor or major stroke	0		
Death	1	2.9%	Myocardial infarction after 6 months
Hospitalization	1	2.9%	Coronary artery bypass after 10 months
Clinical follow-up only	32	91.4%	Asymptomatic or minor complaints only

*Detected by color Doppler ultrasonography. TIA = transient ischemic attack.

carotid angiography revealed 45% narrowing, which did not fulfill our criteria for restenosis.[11] The mean degree of stenosis was reduced from 87.88% to 7.2% ($p < 0.005$) 1 year after carotid stenting, according to NASCET criteria.

DISCUSSION

Percutaneous transluminal balloon angiography was described in 1980, and numerous reports have proclaimed high success rates for this procedure.[12,13] Despite some controversy regarding the indications for carotid stenting, the feasibility and safety are no longer questioned. Although a previous study suggested that vessel tortuosity is a relative contraindication to stenting, 7 (17%) patients in our study who had significant tortuosity (type C arch interruption and a tortuous carotid artery course) were successfully stented.[14] As observed in other studies, there was a high incidence of concomitant coronary artery disease in our patients.[15,16] This was because they visited cardiologists initially and carotid stenosis was noted during examinations. Although all of our patients had some degree of coronary disease, no peri-procedural heart-related complication was observed. Considering their cardiac condition, age and outcome after 1 year, it seems that carotid stenting is suitable in these high-risk patients treated at Iranian centers. It should be noted that major adverse events (stroke, myocardial infarction or death) have been reported in 8.8% – 10% of patients with severe coronary disease undergoing CEA.[17] Stent over-sizing and cerebral protection with filters prevent distal embolism and are associated with lower rates of restenosis.[18–20] Our combined stroke and mortality rate of 2.9% is close to that of large multicenter trials.

Carotid sinus compression syndrome has been observed after carotid stenting. It is thought to be due to stimulation of carotid sinus baroreceptors by the angioplasty balloon and endovascular stent, leading to hypotension and bradycardia. Our incidence of hypotension and/or bradycardia of 23.8% might be due to the fact that pre or post-stenting dilation is a risk factor for carotid sinus compression syndrome, along with patient factors such as advanced age, coronary disease and myocardial infarction.[20] Prophylactic atropine may decrease the incidence of carotid sinus compression syndrome and cardiac morbidity in patients undergoing carotid stenting. However, the major concern is restenosis which has been reported to occur in 5% to 14% of patients.[9] We observed restenosis using Doppler sonography in one patient, but further angiography of the lesion revealed < 50% narrowing. The difference in compliance between the stent and the native arterial wall could cause an increase in peak systolic volume, leading to overestimation by sonography of the degree of stenosis in a stented artery. However, we noted a very low rate of restenosis, which might be due to the small size of our study population. Therefore, more studies with a larger population from other Iranian vascular centers are suggested, to provide more information about the outcome of this technique. The results of several ongoing randomized trials comparing CEA with carotid stenting, and more long-term follow-up, will help to define the role of stenting in the treatment of carotid occlusive disease.

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