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Carotid Artery Stenting in Patients with Symptomatic Coronary Artery Disease

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Abstract

Carotid artery stenting has been accepted as a potential alternative to carotid endarterectomy in patients with significant carotid artery stenosis. The objective of this study was to evaluate the feasibility, safety and long-term outcome of percutaneous stenting of carotid artery stenosis in patients with coexisting symptomatic coronary disease. Between May 1996 and May 1999, we performed carotid artery stenting at 48 lesions in 36 patients with carotid stenosis of 60% and symptomatic coronary artery stenosis. Twenty-one patients (58%) had neurologic symptoms. Carotid stenting was performed in 43 internal, 2 external and 3 common carotid lesions. We used Wallstent in 46 lesions, Palmaz stent in 2 lesions and Microstent II in 1 lesion. Staged or combined coronary intervention was performed in 18 patients (50%) and staged coronary artery bypass surgery was performed in 6 patients (17%). In the other 12 patients (33%), medical treatments were performed. Carotid stenting was successful in all lesions. Simultaneous bilateral carotid stenting was performed in 11 patients (31%). One major and 1 minor stroke developed during the procedure. There were no deaths during the procedures and within 30 days post-procedure. During the follow-up of 14±7 (3 to 40) months, there were no deaths or neurological events. On follow-up (6±1 months) angiography and/or duplex sonography of 44 eligible lesions in 32 patients, there were 2 cases of asymptomatic restenosis (4.5%) which developed in Palmaz stents implanted at the external carotid artery and the common carotid artery, respectively. In conclusion, carotid artery stenting in patients with coexistent carotid and coronary artery disease is feasible, safe and shows favorable follow-up outcomes.

Key Words: Carotid, stenosis, stent, coronary

INTRODUCTION

Prospective randomized studies such as the North American Symptomatic Carotid Endarterectomy Trial (NASCET),[1] European Carotid Surgery Trial (ECST)[2] and the Asymptomatic Carotid Atherosclerosis Study (ACAS)[3] proved the superiority of carotid endarterectomy (CEA) over medical treatment for carotid stenosis greater than 60%, with or without symptoms. The risk of stroke and/or death was 5.8% in the NASCET, 7.5% in the ECST and 2.3% in the ACAS. Rothwell et al. reported a 7.7% incidence of stroke and/or death in a review of 126 surgical published series when the follow-up was performed by a neurologist.[4] However, in high risk patients with significant coronary artery disease, morbidity and mortality of carotid endarterectomy reached as high as 18%[5-10] On the other hand, the perioperative stroke rate for coronary artery bypass surgery in the presence of severe carotid artery disease has been reported to be 4−20%.[11,12] The current evidence suggests that asymptomatic carotid disease is not a contraindication to coronary artery bypass surgery, although Brener et al. reported that the operative mortality rate after cardiac surgery was three times higher in patients with carotid disease than in those with normal carotid arteries.[13] A combined operation addressing both the carotid and coronary disease is a riskier alternative than either operative procedure alone.[7,14] This clinical dilemma, especially for cardiologists responsible for such patients, is still controversial.

Percutaneous techniques have the potential for being safer, less traumatic, more cost effective, and usable in patients at high surgical risk. Percutaneous balloon angioplasty of the carotid arteries was first performed in the early 1980s,[15,16] but concern about

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the potential risk of embolization to the central nervous system has slowed its development. Ongoing technical refinements, powerful new anti-platelet agents, and the addition of stent implantation have made the percutaneous approach an attractive alternative to conventional endarterectomy.[17-20] Recent multicenter experience reported that the procedural risks for major and minor strokes and death are acceptable for the early stage of development, with a minor stroke rate of 4.8%, a major stroke rate of 1.3%, and a 30-day post-procedure mortality rate of 1.4%.[21]

We performed this study to determine the feasibility of percutaneous stenting of carotid artery stenosis in such high risk patients with angiographically-documented combined carotid and coronary disease who had angina symptoms.

MATERIALS AND METHODS

Patient selection

Between May 1996 and July 1999, carotid angioplasty with stenting was performed at 48 lesions in 36 patients with symptomatic coronary artery disease at Yonsei Cardiovascular Center. To be eligible for the study, patients must have had angina symptoms within one month of presentation with angiographic coronary artery stenosis of 50% during admission, as well as angiographic documentation of carotid artery stenosis of 60%. Patients were included whether neurologic symptoms were present or not. Patients were excluded if any of the following were present: inability to give informed consent; presence of severe disability due to previous stroke or dementia; presence of an intracranial tumor or arteriovenous malformation; presence of intracranial stenosis that exceeded the severity of extracranial stenosis; or if the predicted life expectancy was less than 3 years due to terminal disease state.

Clinical and imaging protocol

A complete independent neurologic evaluation was performed on all patients by an experienced neurologist before and after the procedure. Ultrasound duplex scanning, computed tomography of the head, complete four-vessel (carotids and vertebrals) angiography, cerebral angiography (including intracranial views and assessment of collateral circulation) and coronary angiography were performed in all patients. If patients had neurological deterioration after carotid stenting, computed tomography was repeated. All patients were asked to have follow-up angiography and/or duplex sonography at 6 month. Quantitative analysis was performed on all vessels before angioplasty, after stenting, and at follow-up angiography using an on-line system (Siemens AG, Erlangen, Germany). Diameter stenosis was determined using the NASCET criteria,[1] with the distal non-tapering portion of the internal carotid artery serving as the reference segment. Minimum lumen diameter was measured after calibration of the system with the known diameter of the sheath.

Data collection and end points

Baseline clinical data and laboratory results were prospectively recorded on standard forms throughout the hospitalization.

The primary clinical end points were as follows: (1) any minor or major stroke, myocardial infarction or death within the first 30 days; and (2) any minor or major stroke, myocardial infarction or death during the follow-up period.

Imaging end points were as follows: (1) angiographic minimal lumen diameter (MLD) and percent stenosis after stenting; (2) angiographic success rate, defined as achieving a less than 30% residual stenosis; and (3) binary restenosis (50% diameter stenosis) on follow-up angiogram and/or duplex sonography.

A transient ischemic attack was defined as a new neurologic deficit that resolved within 24 hours. A minor stroke was defined as a new neurological deficit that either resolved completely within 7 days or increased NIH Stroke Scale score by 3 or less.[13] A major stroke was defined as a new neurological deficit that persisted after 7 days and increased the NIH Stroke Scale score by 4 or more. Myocardial infarction was defined as the development of new pathological Q waves or the elevation of creatine kinase to more than twice the normal range with an elevated MB fraction. Target lesion revascularization was defined as all surgical or percutaneous revascularization involving the target lesion, including repeat angioplasty or stenting and carotid endarterectomy.

Carotid angioplasty and stenting protocol

All patients were administered with aspirin (100 mg a day) and ticlopidine (250 mg twice daily) or cilostazol (100 mg twice daily) for at least two days prior to carotid stenting. Those patients with symptomatic coronary disease who were scheduled for a combined or staged intervention underwent percutaneous coronary angioplasty first. Carotid artery stenting was first performed only in patients going for coronary artery bypass surgery. Carotid artery stenting was performed using coaxial catheterization techniques adopted from coronary and other endovascular interventions. Arterial access was obtained using the modified Seldinger technique and inserting a 90-cm-long 7 Fr/8 Fr sheath (Cook Cardiology, Inc., Bloomington, IN, USA) in the femoral artery. Heparin (5000 IU) was administered intravenously and was then titrated to maintain an activated clotting time between 250 and 350 seconds. A 5 Fr temporary transvenous pacemaker was advanced to the right ventricle, which was immediately available to prevent symptomatic bradycardia related to excessive stretching of the carotid sinus.

Access to the common carotid artery was accomplished in the majority of cases using a 5 Fr VTK (Cook Cardiology, Inc., Bloomington, IN, USA), Headhunter (Meditech, Watertown, MA, USA) or Newton (Mallinckrodt Medical Inc., St Louis, MO, USA) catheter and an 0.035"/0.038" hydrophiclic guide wire (glidewire M) (Terumo, Tokyo, Japan). The tip of the catheter was selectively positioned at the origin of the carotid artery just proximal to the segment to be treated. Contrast angiography was performed in multiple orthogonal views to fully assess the degree of stenosis. The glide wire was then carefully advanced distally in the external carotid artery. The 5 Fr diagnostic catheter was advanced into the external carotid artery over the glide wire and it served as an exchange catheter for placement of a 0.038" extra stiff exchange wire (Cook Inc, Bloomington, IN, USA). After removal of the diagnostic catheter, a 7 Fr sheath was advanced over the extra stiff exchange wire into the common carotid artery just proximal to the carotid bifurcation. Contrast injections were again performed and on-line quantitative angiography was used to accurately determine the distal (internal carotid cephalad to the lesion) and proximal (common carotid artery caudal to the lesion) reference dimensions. With the use of a standard coaxial system, the stenosis was carefully passed with a 0.014" flexible coronary guide wire, which was positioned in the distal intracranial internal carotid artery. Prior to dilation, intravenous atropine (1.0 mg) was given prophylactically to prevent hypotension and bradycardia. Predilation was performed using a low profile, 3.5 mm to 4.0 mm coronary balloon with low atmospheric pressure to completely expand the balloon. After predilation, the stent-balloon assembly was advanced into the carotid sheath and across the lesion site, making certain that the distal margin of the stent was placed beyond the most distal portion of the lesion. Adjunct ballooning with a larger balloon was performed using high pressure (12−16 atm) inflation to firmly embed the stent into the vessel wall. Neurological status was continuously monitored both during and after balloon inflation by simple contralateral hand gripping. Follow-up intracerebral angiography was performed using the same orthogonal views that were used before stent placement to confirm the patency of the intracerebral vessels. At the end of the procedure, the sheath was carefully removed from the common carotid artery under fluoroscopic guidance down to the abdominal aorta. No additional heparin was given and vascular sheaths were removed the same day. Patients were monitored on a cardiac care unit to facilitate frequent neurologic assessments. Patients were generally discharged within 2 days after stent implantation, on aspirin 100 mg daily and ticlopidine 250 mg or cilostazol 100 mg twice a day for at least 4 weeks, with the aspirin continued indefinitely.

RESULTS

Patient characteristics

The demographic and clinical characteristics of the 36 eligible patients are shown in Table 1. We treated 32 men and 4 women with a mean age of 65±7 (47−79) years. Neurologic symptoms were present in 21 patients (58%). Eight patients (22%) had previous myocardial infarction. Multi-vessel coronary involvement was found in 23 patients (64%). Before presentation with carotid stenosis, six patients (17%) had undergone coronary artery bypass surgery due to multi-vessel coronary stenosis and 4 patients (11%)

Table 1. Baseline Clinical Characteristics of Patients

Patients	36
Male	32 (89%)
Mean age (range), years	65 (52−79)
Cardiovascular risk factors	
Hypertension	23 (64%)
Diabetes	12 (33%)
Smoker	27 (75%)
Hypercholesterolemia (T-chol ≥ 220 mg/dL)	16 (44%)
Peripheral artery disease	24 (67%)
Coronary artery disease	
Vessel disease	
One vessel	13 (36%)
Two vessels	8 (22%)
Three vessels	15 (42%)
Left main disease	6 (17%)
Previous myocardial infarction	8 (22%)
Prior coronary artery bypass surgery	5 (14%)
Prior percutaneous coronary intervention	4 (11%)
Percutaneous coronary intervention	18 (50%)
Combined	5 (14%)
Staged	13 (36%)
Staged coronary artery bypass surgery	6 (17%)
Left ventricular dysfunction*	5 (14%)
Carotid artery disease	
Contralateral occlusion	4 (11%)
Contralateral stenosis ≥ 60%	13 (36%)
Asymptomatic	15 (42%)
Symptomatic	21 (58%)
Transient ischemic attacks	14 (39%)
Stroke	7 (19%)
Cardiac rhythm disorder	4 (11%)

* Left ventricular ejection fraction < 35%.

had undergone percutaneous coronary angioplasty (PTCA). Fifteen patients (55%) had symptomatic carotid disease; 4 (11%) patients had contralateral carotid occlusions and 13 patients (36%) had contralateral stenosis of 60%. Combined revascularization procedures involving either both carotid arteries (n=11), carotid and coronary artery (n=5) or the carotid and another artery (n=4) were performed in a total of 18 patients (50%). Staged coronary artery bypass surgery and PTCA were performed in 6 (17%) and 13 (36%) patients respectively. Overall, coronary revascularization was performed in 24 patients (67%). Medical treatments were performed in the other patients. Two patients (6%) had diffuse coronary disease which was inoperable or non-interventionable.

Table 2. Procedural Features

Carotid arteries stented	
Internal carotid artery	43
External carotid artery	2
Common carotid artery	3
Right side lesion	23
Left side lesion	26
Stents used	
Wall	46
Palmaz	2
AVE Micro stent II	1
Simultaneous bilateral carotid stents	11

Procedural characteristics

In 36 patients, 49 stents were successfully implanted in 48 vessels. We implanted 2 Wallstents in a lesion which was slightly uncovered by single Wallstent due to stent migration. One patient required 2 procedures because an extremely tortuous aortic arch made it impossible to engage the carotid artery by the carotid sheath in the initial procedure; on the second attempt, carotid stenting was successfully performed by transseptal approach. Stents used are shown in Table 2. Wallstents (Schneider, Bülach, Switzerland) were used for all internal carotid stenoses and 1 external carotid stenosis. Palmaz stents (Johnson & Johnson company, Warren, NJ, USA) were used in 2 common carotid arteries and 1 external carotid artery. AVE Microstent II (Applied Vascular Engineering, Santa Clara, CA, USA) was used in 1 common carotid artery. The mean stenosis before the procedure was reduced from 79±13% (range 60% to 99) to 7±9% after stenting (range, −23% to 26%). The mean reference artery diameter was 4.8±0.9 mm. The MLD increased from 1.0±0.8 mm (before intervention) to 4.5±1.2 mm (after stenting). The mean lesion length was 12.2±6.6 mm. The final mean inflation pressure was 14.8±2.7 atmosphere. Typical angiographic results are shown in Fig. 1.

Procedure results and complications

The post-procedural clinical events are shown in Table 3. There were no deaths. There was 1 major stroke and 1 minor stroke. The single major stroke developed immediately after high-pressure post-stenting balloon dilation. Immediate intracerebral angiography

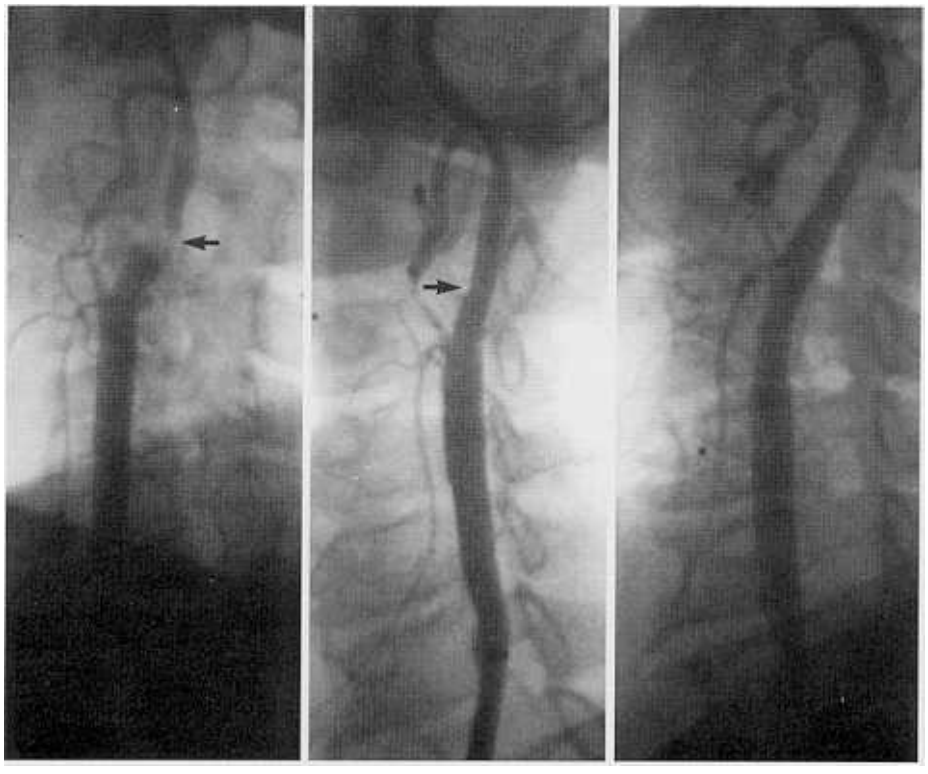

Fig. 1. Angiograms of severe left internal carotid artery stenosis before (pre) and after (post) balloon dilation and stenting, and at 6-month follow-up (FU). In the preprocedure angiogram, the arrow points to a severe stenosis at the proximal left internal carotid artery. In the postprocedure angiogram, a Wallstent was implanted well over the common-to-internal carotid artery and the arrow points to minimal residual stenosis. In the follow-up angiogram at 6 months after the procedure, the stent is intact and the internal carotid artery is patent with minimal luminal narrowing at the previous stenotic site.

Table 3. Post-procedure Clinical Events within 30 Days

Major stroke	
Minor stroke	1
Myocardial infarction	0
Death	0

Table 4. Follow-up Results

Restenosis*	2
Stent deformation†	1*
Major stroke	0
Minor stroke	0
Myocardial infarction	0
Death	0

* Occurred in Palmaz stent at common and external carotid artery.
† Occurred in Palmaz stent at common carotid artery.

revealed no significant obstruction or hemorrhage. Magnetic resonance imaging taken 24 hours later revealed a large cerebral infarction. The patient recovered gradually and was discharged with some motor and speech disturbances remaining. There was 1 minor stroke which developed immediately after post-stenting dilation. Immediate intracerebral angiography revealed no significant abnormal findings. After an injection of urokinase 100,000 units via the carotid sheath, the signs of minor stroke disappeared within 5 minutes. Twenty-four patients (67%) experienced transient sinus bradycardia with balloon inflation in the carotid sinus. There were no cases of prolonged or permanent second- or third- degree AV block.

Follow-up results

Among 32 patients (44 lesions) eligible for follow-up imaging studies, all patients had either follow-up angiography (30 patients, 42 lesions) and/or ultrasonography (34 patients, 44 lesions). On the follow-up angiography at 6 ± 1 months, mean diameter stenosis was $16\pm15\%$ and the MLD was 4.0 ± 1.3 mm by QCA. Two patients (2 stents) showed restenosis (Table 4). One (65% diameter stenosis) developed at the common carotid artery stented with

a Palmaz stent, which showed stent deformation. The other (79% diameter stenosis) developed at the external carotid artery stented with a Palmaz stent. We did not perform additional procedures at the restenotic lesions because they did not cause any neurologic symptoms and the distal flow was prompt. Clinical follow-up was available in all patients over a mean of 14 ± 7 months (3 to 40 months). There were no strokes, myocardial infarctions or deaths during the follow-up period.

DISCUSSION

This study demonstrated the safety and favorable follow-up results of carotid artery stenting in patients with severe coexisting occlusive disease in both the coronary and carotid systems. We undertook this study because the natural course of carotid stenting in patients with concomitant coronary and carotid stenosis has not been systematically investigated before. Significant preoperative risk was notable in the study population, highlighted by the increased number of patients with multi-vessel coronary artery disease, left ventricular dysfunction and multiple comorbidities, as well as carotid artery disease.

Carotid and coronary artery stenosis frequently coexists as part of the systemic atherosclerotic process.[5,22,23] Historically, more than 50% of patients undergoing CEA have significant coronary artery disease with previous angina, myocardial infarction or ischemic electrocardiographic changes.[5,7,22] Conversely, 10−20% of patients with symptomatic coronary artery disease have severe carotid artery obstructive disease (stenosis $\geq$ 70%).[7,22] Staged surgical procedures, either coronary artery bypass surgery first, followed by carotid endarterectomy or vice versa, appear to be associated with an increased risk of ischemic perioperative complications. Currently, there are no guidelines based on prospective trials indicating how such patients are best managed. Although simultaneous carotid endarterectomy and coronary bypass surgery have been advocated as a safe surgical alternative, recent reports have shown that this approach resulted in combined postoperative stroke and death rates ranging from 8−18%.[5,8-12,24,25]

Percutaneous alternative treatment options in this high-risk population have been explored with the rationale that minimizing the hemodynamic instability during revascularization might improve the ultimate outcome. In this regard, carotid stenting has potential advantages over surgery. In contrast to carotid endarterectomy, the antiplatelet regimen can be continued and abrupt changes in blood pressure can be avoided. When acute myocardial ischemia occurs during the procedure, intraarterial access is provided and immediate angioplasty can be performed. Carotid stenting provided an acceptable therapeutic alternative for complex, inoperable lesions in patients with multiple medical problems.[19] It does not require a neck incision and iatrogenic nerve palsy can be avoided.[26-28] In addition, the need for general anesthesia and blood transfusion is nearly nonexistent and the low risk of protracted immobility may reduce surgical complications such as wound infection, septicemia, pulmonary embolism, congestive heart failure, and myocardial infarction. The end result may be reduced median hospital stay, cost reduction, diminished patient discomfort, and increased patient acceptance. Carotid stenting series have reported various complication rates. Diethrich et al., in their initial experience of 110 patients, reported 7.3% periprocedural stroke and death rate.[17] In a series of 174 carotid arteries at high surgical risk, Henry et al. reported 2.9% periprocedural stroke and death rate.[18] Yadav et al. at the University of Alabama in their initial high risk series of 116 carotid stents reported on combined periprocedural stroke and a death rate of 8.5%.[19] Mathur et al. in the extended cases at the University of Alabama reported an acceptably low periprocedural complication rate in a group of high risk patients.[20] In that series of 231 patients with 271 carotid arteries stented, half of the patients were $\geq$70 years, 71% of the patients had concomitant coronary artery disease, and only 14% of the lesions would have been eligible for inclusion in NASCET. Technical success was 99% and the combined rate of major stroke and death was 1.1%. Babatasi et al. performed carotid balloon angioplasty/stenting in 10 patients with severe carotid artery disease prior to undergoing successful coronary bypass surgery for severe coronary artery disease with no mortality and no neurologic events.[29] Moreover, cases of combined percutaneous approach have been reported. Even cases of simultaneous coronary angioplasty and bilateral carotid artery stenting have been reported.[30] Shawl reported successful simultaneous

coronary angioplasty and carotid stenting in 4 patients who presented with acute neurological and coronary events, and staged the procedure in a fifth.[31] No complications occurred in these patients. In another case report, successful combined carotid and coronary stenting was performed in a patient with unstable angina and coexistent severe asymptomatic carotid disease with no complications.[32]

In this study, 17% of patients underwent staged coronary artery bypass surgery, 50% of the patients received either simultaneous or staged coronary artery stenting and 6% were inoperable and non-interventionable cases. In other words, at least 73% of the cases had profound coronary risks for general anesthesia and major surgery. In our study population, the rate of 30-day major event (death, major stroke, acute myocardial infarction) was 2.8%. This figure compares favorably with any surgical series having such significant coronary risks. All our patients were pre-treated with an aggressive antiplatelet regimen prior to carotid stenting. This careful preparation of patients in our series with aspirin and either ticlopidine or cilostazol may have been responsible for a lower complication rate. Another factor related to this encouraging result may have been proper care of vital signs during and after interventions. Although not performed simultaneously, our staged revascularization procedure appears to be safe and unassociated with an increased risk of ischemic complications from either vascular bed. We treated a small number of patients with generalized arteriosclerosis, left ventricular dysfunction after coronary artery bypass surgery, or rhythm disorder. These patients with an underlying disease likely to be associated with embolic stroke and general symptoms of carotid disease fulfilled the NASCET exclusion criteria and were not candidates for carotid endarterectomy. This study confirmed the reported safety of carotid stenting in treating severe coexisting carotid and coronary artery disease.

We are aware of the concern about the safety of carotid stenting. This new therapy has to be evaluated critically by means of prospective randomized clinical trials as a combined effort of neurologists, interventional neuroradiologists, vascular surgeons and cardiologists. Although we fully agree with the call for a randomized prospective trial, we believe that the patients treated here might not qualify for the randomization because of their concomitant medical problems. We attempted to meet at least some of the issues they raised by providing independent qualified neurological assessment, adequate carotid imaging, interdisciplinary peer review, and careful follow-up. Moreover, in a recent international survey of 24 centers performing carotid stent placement,[21] 2,048 cases were reported with a technical success of 98.9%. The complication rate was 1.3% for major stroke and the mortality rate at 30 days post-procedure compared favorably with CEA, particularly considering the complexity of the cases undergoing a percutaneous procedure. In order for CEA to achieve the benefit observed in major randomized trials, the combined perioperative rates of major stroke and death must not exceed 6% in symptomatic or 3% in asymptomatic patients.[33] The multicenter results and our stenting results are within the acceptable safety standards reported in major surgical trials, as well as the European and US guidelines. However, as the reported morbidity and mortality rates of surgical revascularization in patients with severe coexisting carotid and coronary artery disease are higher than the recommended surgical guidelines, it seems that there are strong indications that a safer alternative treatment should be recommended. Carotid artery stenting has reproducibly shown encouraging results in treating severe carotid artery stenoses, especially in patients at high operative risk. This report suggests that carotid artery stenting in patients with symptomatic coronary disease is feasible and safe. Moreover, proper simultaneous or staged revascularization of significant coronary disease with carotid artery stenting resulted in favorable immediate and long-term outcomes. This strategy offers a reasonable alternative treatment option in this high-risk population.

This study has several limitations. As all the symptomatic coronary lesions were not candidates for percutaneous intervention or coronary artery bypass surgery, some of the patients may have had lower risks than the populations of previous studies using coronary bypass candidates. However, most (92%) of our patients were compatible with the exclusion criteria of NASCET due to severe left ventricular dysfunction, rhythm disorder, other associated medical diseases. The lesion locations and stents used were heterogenous, so that the procedure-related risks, follow-up clinical events and restenosis rate must be interpreted on the basis of these procedural charac-

teristics.

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