Original Article -

A NOVEL SCORING SYSTEM FOR IDENTIFYING HIGH-RISK PATIENTS UNDERGOING CAROTID STENTING

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Background/Objective: In patients with severe concurrent coronary and carotid artery disease, two different treatment strategies may be used: simultaneous endarterectomy and coronary bypass surgery, and carotid stenting with delayed coronary bypass surgery after a few weeks. To evaluate the safety and efficacy of carotid stenting with delayed coronary bypass surgery after a few weeks in patients referred to Tehran Heart Center, Tehran, Iran and to determine the independent predictors that may be used to identify the appropriate treatment plan for such patients.

Methods: This prospective study was performed from December 2003 through October 2004. Symptomatic patients with >60% stenosis and asymptomatic patients with >80% stenosis were included in this study. The risks and benefits of carotid stenting were explained. Patients were excluded from the study if any of the following was applicable: age ≥85 years, history of a major stroke within the last week, pregnancy, intracranial tumor or arteriovenous malformation, severely disabled as a result of stroke or dementia, and intracranial stenosis that exceeded the severity of the extracranial stenosis. Thirty consecutive patients who underwent carotid stenting were enrolled in this study.

Results: The mean \pm SD age of patients was 66.3 \pm 8 years. The procedural success rate was 96.7%. During a mean \pm SD follow-up period of 5.6 \pm 3.2 months, 4 (17%) deaths occurred; none of which were attributed to a neurologic causes. Moreover, 1 (3%) patient developed a minor nonfatal stroke with transient cognitive disorder. Most of patients (80%) with major complications acquired a score of \geq 26.

Conclusion: To reduce the rate of carotid stenting complications in high-risk patients with heart disease, to optimize the patient selections, and to determine the best treatment strategy, based on the clinical and lesion characteristics of patients, we proposed a new scoring system.

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Keywords: Carotid arteries • carotid endarterectomy • carotid stenting • scoring system

Introduction

arotid and coronary artery occlusive disease frequently coexists as part of the systemic atherosclerotic process.^{1, 2} Carotid artery stenosis increases the risk of perioperative stroke in patients undergoing coronary artery bypass grafting (CABG). The management of severe coexisting disease poses a major dilemma. Surgical revascularization of one vessel is associated with an increased rate of complication in the others.³⁻⁶ Staged and simultaneous surgeries of both vascular territories in these patients have been practiced at the expense of significant morbidity and mortality, mainly due to myocardial infarction and/or stroke.³⁻⁶ Percutaneous elective carotid artery stenting (CAS) has been shown to be effective in treating severe occlusive carotid artery disease and may have its greatest benefit in patients with a high preoperative risk.^{7, 8} However, the clinical and anatomic heterogeneity

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of patients with carotid disease might expectedly lead to differences in outcomes with this procedure.9 Thus, selection and postprocedural care of very high-risk stenting candidates are very important in prevention of later complications. In patients with severe concurrent coronary and carotid artery disease, two treatment strategies may be used: simultaneous endarterectomy and coronary bypass surgery, or carotid stenting with delayed coronary bypass surgery after a few weeks. We sought to evaluate the safety and efficacy of the latter in patients of Tehran Heart Center. Based on observations made in this study and previous lesion-typing studies, we aimed to determine the independent predictors, which could be used to correctly select the appropriate treatment plan for such patients.

Patients and Methods

Patient selection

From December 2003 through October 2004, thirty consecutive patients underwent carotid stenting at the Tehran Heart Center, Tehran, Iran. Symptomatic patients with >60% stenosis and asymptomatic patients with >80% stenosis were included in this study. The risks and benefits of carotid stenting were explained. The operator informed patients that they were undergoing an investigational procedure, told them about the proven efficacy of carotid endarterectomy (CEA), and offered them this treatment as an alternative. Patients were excluded from the study if any of the following was applicable: age \geq 85 years, history of a major stroke within the last week, pregnancy, intracranial tumor or arteriovenous malformation, severely disabled as a result of stroke or dementia, and intracranial stenosis that exceeded the severity of the extracranial stenosis.

Definition

Transient ischemic attack (TIA) was defined as a local retinal or hemispheric event from which the patient made complete recovery within 24 hours.¹⁰

Minor nonfatal stroke was defined as a new neurologic deficit that either resolved completely within 30 days or increased the National Institute of Health (NIH) stroke scale by ≤ 3 .¹⁰

Major nonfatal stroke was defined as a new neurologic deficit that persisted >30 days and increased the NIH stroke scale by ≥ 4 .¹⁰

Fatal stroke was defined as death attributed to an ischemic or intracerebral hemorrhagic stroke. It did not include brain tumors or death resulting from head trauma.¹⁰

Myocardial infarction (**MI**) was defined as the development of new Q waves on the ECG or a creatine kinase (CK) elevation to at least twice the normal level, accompanied by above normal elevation of CK MB.¹¹

Eccentric lesion was defined as angiographic appearance of the stenotic lumen in the outer onequarter diameter of the apparent normal lumen.¹²

Lesion calcification was defined as radiologic densities readily seen within the apparent vascular wall of the artery at the site of the stenosis.¹²

Ulcerated lesion: A plaque was classified as ulcerated if it fulfilled radiographic criteria of ulcer niche, observed in the profile as a crater from the lumen into a stenotic plaque and (when visible) a double density on face view.¹³

Long/multiple lesions: Lesion length (measured with calipers as distance from proximal to distal shoulder of lesion in a projection that best elongates the stenosis) >10 mm and/or the presence of >1 lesion separated by a normal vessel wall.¹⁴

Bilateral carotid disease: Presence of $\geq 60\%$ diameter narrowing in internal and/or common carotid arteries on both sides, or presence of $\geq 60\%$ diameter narrowing in left internal and/or common carotid arteries with $\geq 60\%$ diameter narrowing of the innominate artery.⁹

Types of lesions were defined as explained in Table 1.¹⁵

Procedure success was defined as improvement of stenosis by >20%, with a final residual stenosis of <50%.¹⁶

Clinical and imaging protocol: A complete neurologic history was taken and physical examination was performed on all patients by an experienced neurologist. The study protocol assigned an independent neurologist, not involved in the interventional procedures, for evaluation of patients, using the NIH stroke scale,¹⁷ before the procedure and 24 hours, one month, and 6 months after the procedure. Carotid duplex (based on the Washington criteria), magnetic resonance imaging (MRI) or computed tomography (CT) scan of the head and complete diagnostic angiography, including intracranial views and assessment of the collateral circulation, were performed for all patients. If a patient had neurologic deterioration

Parameter	Type A, Score = 1 (% of patients)		Type B, Score = 2 (% of patients)		Type C, Score=3 (% of patients)	
Age (years)	<60	(17)	60 - 79	(77)	≥ 80	(6)
Length (mm)	<10	(47)	10 - 20	(43)	>20	(10)
Stenosis (%)	<80	(33)	80 - 95	(43)	95 – 99	(24)
Ulceration	Smooth	(57)	Niche	(30)	Large crater	(13)
Thrombus	None	(87)	Mild	(13)	Significant	(0)
Eccentricity	Non	(20)	Yes	(80)	_	
Calcification	None	(47)	Mild	(33)	Dense	(20)
Number of lesions	One	(77)	Two	(20)	>2	(3)
Plaque echogenicity	Homogeneous	(87)	Hypoechoic	(10)	Heterogeneous	(3)
Proximal tortuosity	None	(80)	Mild-moderat	(17)	Severe	(3)
Angulation	<45	(73)	45 - 60	(20)	>60	(7)
Hemispheric dominance	Recessive	(50)	Balanced	(0)	Dominant	(50)
Bilateral stenosis	No	(53)	Yes	(43)	Both >90%	(4)
Contralateral occlusion	No	(97)	Yes	(3)	-	

Table 1. Lesion typing and scoring (n = 8).

after stenting, MRI or CT scan of the head was repeated.

Carotid stenting protocol: No sedation was given before the procedure. All patients received aspirin (325 mg/day) and clopidogrel (75 mg/day) for at least four days prior to CAS or 300 mg clopidogrel once a day before CAS, and 75 mg in the morning of the procedure. Hemodynamic parameters were continuously monitored. Nitroglycerin, atropine, and dopamine were administered, as required to manage hypertension. bradycardia, and hypotension. Femoral venous access was gained in all patients and a transvenous pace-maker was immediately available. Percutaneous access was gained from the femoral artery. Heparin (5000 - 10000 units) was given by intravenous boluses to maintain the activated clotting time during the procedure at 250 - 300seconds. Arterial sheath (7F [arrow], or 8F) guiding catheter was placed in the carotid artery just proximal to the segment to be treated. Vessel diameter measurements were performed by biplane four-vessel and cerebral angiography to facilitate sizing of balloons and stents. Stenoses were crossed with a 0.014-inch filter wire, which was placed at the site of internal carotid artery distal to the lesion. In most cases, predilation (low profile, 3.5 - 4 mm coronary balloon, and low pressure) was performed before the stent placement. Balloon inflations were routinely performed within the stents, after placement. Continuous intravenous heparin was given during the night and vascular sheaths were removed in the morning, after the procedure. The patients were usually discharged two days after the procedure and prescribed clopidogrel (75 mg/day) and aspirin (100 mg/day) for four weeks and aspirin life-long thereafter.

Data collection and statistical analyses: All the clinical, angiographic, and stenting data were prospectively recorded by a physician. Clinical and laboratory details were continuously recorded during the hospitalization. The clinical end-points were any major or minor stroke, MI, and death during the follow-up period. Clinical end-points were critically reviewed by the neurologists of the study group. Morphologic data were recorded retrospectively by reviewing the angiographic films. All the values were expressed as mean \pm SD. Categorical variables were expressed 28 percentage.

Results

Patient characteristics

The demographic and clinical characteristics of the 30 patients who took part in this study are shown in Table 2. The mean \pm SD age of patients was 66.3 \pm 8 years. All patients had significant coronary artery disease and 90% (n = 27) were

Table 2. Frequency of base line characteristics of the patients (n = 30).

01 the patients (n = 50).	
Characteristics	n (%)
Male	18 (60)
Asymptomatic	22 (73)
History of TIA or CVA	8 (26)
Angina class III or IV	22 (73)
Previous MI	7 (23)
Significant coronary artery disease	30 (100)
Three-vessel disease	25 (83)
Left main disease	7 (23)
Diabetes mellitus	14 (47)
Hypertension	18 (60)
Hyperlipidemia	20 (75)
Current smoker or past history of smoking	15 (50)
Left ventricular ejection fraction ≤ 40	5 (20)
Significant valvular heart disease	3 (10)
Referred by cardiac surgeon	27 (90)

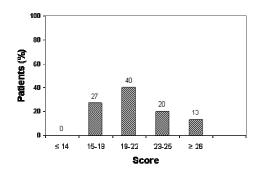


Figure 1. Lesion scoring of the patients (n = 30).

referred by cardiac surgeons. Our patients had predominantly grade 3 or 4 of the Mayo Clinic Carotid Endarterectomy Risk Classification scheme.¹⁸

Angiographic and stenting results

Based on previous studies, the patients were classified into type A, B, or C, if any of the characteristics attributed to a higher class was present.¹⁵ Guidelines for stratifying patients on the basis of clinical, lesion, and affected vessel characteristics are proposed in Table 1. Based on the above classification, we designed a new scoring system: point 1 for type A, point 2 for type B, and point 3 for type C. Seventy-six percent of patients had type C lesions, 23% had type B lesions, and none had type A lesion. The mean \pm SD score of lesions was 21.2 ± 3.5 (Figure 1). The mean \pm SD stenosis before and after stenting was $83.6 \pm 9.7\%$ and $15.2 \pm 3.5\%$, respectively. Twenty-three percent of patients had subtotal occlusion (≥95% stenosis). The procedural success rate was 97%. In one patient the procedure was unsuccessful due to the failure to pass the guide wire. Thirty stents were implanted in 29 vessels: 20 (66%) Acculink (Guidant, Santa Clara, CA, USA) and 10 (34%) Wallstent (Boston Scientific

Procedural events	
TIA, n (%)	0 (0)
Minor nonfatal stroke, n (%)	0 (0)
Major nonfatal stroke, n (%)	0 (0)
Fatal stroke, n (%)	0 (0)
MI, <i>n</i> (%)	0 (0)
Postprocedural events	
Transient ischemic attack, n (%)	0 (0)
Minor nonfatal stroke, n (%)	1 (3)
Major nonfatal stroke, n (%)	0 (0)
Fatal stroke, n (%)	0 (0)
MI, <i>n</i> (%)	2 (7)
Total death, n (%)	4 (14)

Table 3. Clinical events in 29 patients.

Corp., Water Town, MA, USA). Protective devices were used in all patients—17 (59%) EZ (Boston Scientific-EPI, Santa Clara, CA, USA) and 12 (41%) AccuNet (Guidant, Indianapolis, IN, USA). In all patients, postdilation was performed. The mean \pm SD poststent balloon inflation pressure was 7.14 \pm 1.38 atm. After stent deployment, the control cerebral angiogram was normal in all patients. Neurologic assessment showed no transient neurologic deficit, nor any minor or major stroke during the procedure was reported.

Procedural outcomes

At a mean \pm SD follow-up period of 5.6 \pm 3.2 (range: 1 - 11) months, four (17%) deaths occurred, none of which were attributed to a neurologic cause. One of them expired 12 hours after the procedure with cardiovascular collapse and asystole due to MI. The second patient died in the CCU after three days of pulmonary edema and cardiogenic shock. Another death occurred one day after CABG (eight days after the procedure), with bradycardia and electromechanical dissociation. The last death was noted five days after discharge with MI. Also, one (3%) patient had a minor nonfatal stroke (transient cognitive disorder) (Table 3). Clinical and lesion characteristics of

Characteristics	Complicated n (%)	Uncomplicated a (0/)	
Clinical	Complicated <i>n</i> (%)	Uncomplicated n (%)	
Age ≥70 years	5 (100)	7 (29)	
Three-vessel disease	5 (100)	16 (67)	
Left main disease	3 (60)	4 (17)	
Diabetes mellitus	2 (40)	12 (50)	
Hypertension	5 (100)	14 (58)	
Significant valvular heart disease	2 (40)	1 (4)	
Lesion			
Stenosis ≥95%	4 (80)	3 (12)	
Ulceration (niche or large crater)	5 (100)	8 (33)	
Bilateral (both $\geq 60\%$)	4 (80)	10 (42)	
Гуре C lesion	5 (100)	13 (54)	
Score ≥22	5 (100)	5 (21)	
Score ≥25	4 (80)	0(0)	

Table 4. Clinical and lesion characteristics in complicated and uncomplicated patients.

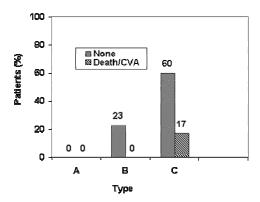


Figure 2. Lesion typing and complications (n = 29).

patients with and without complications are shown in Table 4. Discrimination of patients based on morphologic characteristics of their carotid lesions is summarized in Figures 2 and 3.

Predictors of events

As it can be seen in Figure 3, all the neurologic and other important complications had type C lesions. Nonetheless, 18 patients (62%) with type C lesion did not have any complications during the procedure and within the follow-up period. The sensitivity, specificity, and positive and negative predictive values of lesion-typing system for primary end-points of the study were, thus, 100%, 28%, 22%, and 100%, respectively. Table 1 shows that our new proposed scoring system considers each parameter as a numeric value. Most of patients (80%) with major complications had a score of ≥ 26 , and all of them had a score of ≥ 22 (Figure 3). All patients with a score of ≥ 26 had major complications. The sensitivity, specificity, and positive and negative predictive values of the system (score ≥ 26) for scoring major complications were, thus, 80%, 100%, 100%, and 96%, respectively. Excluding one patient who died after CABG (score = 22), all patients with major complications during the waiting period for CABG had a point score of ≥ 26 .

Discussion

CEA has been the gold-standard treatment for carotid occlusive disease for decades. Several randomized clinical trials have reported combined stroke/death rates ranging from 2.3% to 7.1%.^{19–21} Over the past few years, CAS has proven to be a satisfactory alternative to CEA.^{22–25} Carotid stent-

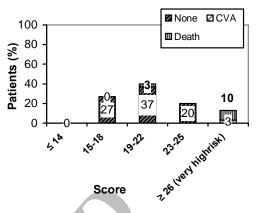


Figure 3. Lesion scoring and complications (n = 29).

ing offers the potential of nonsurgical treatment of carotid stenosis, with possibly lower morbidity than surgery in those patients in high surgical risk categories.¹⁶ The rapidly evolving technique of carotid stenting is currently undergoing investigation in many centers as an alternative to surgical endarterectomy.⁹

Our study is one of the few studies to critically analyze the neurologic and clinical complications of CAS in high-risk patients with severe coronary artery disease, who are candidates for open heart surgery. This study also examines the abovementioned complications for their clinical, morphologic, and procedural descriptions. Our findings suggest that a new scoring system, which considers all the previously-mentioned factors in the classical lesion typing model and values all of them by numerical points, is a valuable predictor of procedural and postprocedural major complications with a reasonable predictive value for CABG candidates.

It has been suggested that if the neurologic complication and mortality are higher than that observed in the recent CEA trials (4% to 8%), the overall benefit of the procedure would be eliminated.^{22 - 24, 26} When the safety of carotid stenting is evaluated, it is important to note that our patient population have more significant cardiac comorbidity than those included in the reported randomized endarterectomy trials.²⁷ Our patients also had more severe clinical and cardiac problems, as compared to many other important stenting registries or randomized trials.^{13, 22, 24} As it is shown in Table 5, the present study includes the presence of a greater number of patients with highrisk coronary anatomies, such as significant left main coronary artery lesion or severe three-vessel

Table J. Dase line characteristics of the	e into registry vs. the roubin et al	registry (r = 0).
Characteristics	THC registry	Roubin et al registry
Mean age (mean \pm SD) (yr)	66.28 ± 8.06	69 ± 10
Females, n (%)	12 (40)	172 (32)
Diabetes mellitus, n (%)	14 (47)	167 (32)
History of TIA, <i>n</i> (%)	4 (13)	183 (30)
History of stroke, n (%)	4 (13)	134 (22)
Asymptomatic, n (%)	22 (73)	287 (48)
Three vessel disease, n (%)	25 (83)	NA^{\dagger}
Left main disease, n (%)	7 (23)	NA
Total coronary artery disease, n (%)	30 (100)	372 (71)

Table 5. Base line characteristics of the THC^{*} registry vs. the Roubin et al^{10} registry (n = 8).

*THC = Tehran Heart Center; $^{\dagger}NA = not available$.

disease. Despite the unfavorable risk profile, the overall incidence of procedural stroke was only 3% of the treated vessels, whereas in other important studies it was around 6% (Figure 4).^{22, 23, 28, 29} However, when we consider other important endpoints, such as MI or any mortality within a month after the procedure, the incidence is around 14%, which is about twice as much as the average of other four important studies (Figure 4).

It is important that a realistic and comprehensive definition of complications be used to evaluate the technique. The definition of minor and major strokes used in the present study incorporates both the extent of neurologic deficit and the degree of functional disability produced. Minor strokes are essentially nondisabling, and in this study we included those minimal neurologic deficits that are only detected by detailed neurologic examination, often not noted by the patient, and resolved within a week. In the present study, there was no major

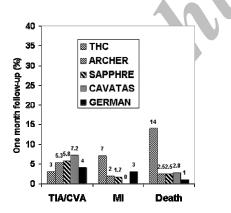


Figure 4. Long-term complications: THC study vs. other studies. THC: Tehran Heart Center, Acculink for revascularization of carotids in highrisk patients (ARCHER),²⁹ stenting and angioplasty with protection in patients at high-risk for endarterectomy (SAPPHIRE),²³ the carotid and vertebral artery transluminal angioplasty study (CAVATAS),²² and GERMAN²⁸ (n = 29).

disabling stroke. Minor nondisabling stroke occurred in 3% of the vessels treated, which represented a rapidly resolving minimal cognitive disorder that was probably due to small amounts of embolic debris. Comparing the results obtained with those of previous endarterectomy or stenting series, the stroke rate seems to be quite low.^{22,23,28,29}

Other end-points, except major or minor stroke, are MI and death within or after the procedure (1 month). Our study protocol is carotid stenting with a delayed coronary bypass surgery after a few weeks (at least 1 month) due to the probability of stent occlusion and clopidogrel consumption. Thus, even if we did not have any periprocedural complications, MI or death in the waiting period for CABG are complications of delayed CABG.

In our registry, there were two (7%) MI, one of them after 12 hours and the other after discharge. Also, we had 4 (14%) deaths, one of them one day after CABG, and the other three patients during the waiting period before CABG. There was no clinical or paraclinical clue in favor of a neurologic sequel, as the primary cause of mortality in patients. Compared with previously reported studies, MI and mortality rate are far higher than usual.

The importance of independent neurologic oversight, when the incidence of neurologic complications is assessed, cannot be overemphasized. In a comprehensive review, Rothwell et al³⁰ documented the increased incidence of neurologic complications of CEA from about 2.3% to >7.5%, when a neurologist coauthored the report. Each patient in the present study was closely evaluated by a neurologist at frequent intervals for recording and classifying the neurologic complications. Hence, it is unlikely that the stroke rate has been underestimated in the present report.

Mathur et al retrospectively analyzed clinical data of 231 high-risk patients, who underwent

elective stenting of 271 extracranial carotid arteries and correlated it with neurologic complications.⁹ Significant predictors of adverse events in that study were advanced age and the presence of long or multiple stenosis. In the present study, we correlated various clinical, morphologic, and procedural factors with not only neurologic adverse events but also with MI and death in the periprocedural period, the waiting period before CABG, and afterwards. At first glance, it may be unclear as to why this evaluation system, which is mostly based on the characteristics of carotid lesion, would determine the occurrence of cardiac events. Indeed, patients with atherosclerosis of the peripheral arteries are likely to have pathologically similar lesions in other vascular beds.³¹ Commonalties also exist, that link the fundamental mechanisms of stenosis formation, plaque instability, and thrombosis in the coronary and peripheral arteries.³² Importantly, inflammation appears to occur in disrupted plaques within the carotid, as it does so in the coronary circulations.

Ninety percent of the patients were referred by surgeons. Our patients had an average score of 3.23 on the Mayo Clinic Carotid Endarterectomy Risk Scale. In the Mayo Clinic series, the incidence of major complications (permanent stroke, MI, or death) was 3.1% for grade 3 patients and 8.1% for grade 4 patients.¹⁸

Classic guidelines for stratifying patients undergoing percutaneous carotid revascularization on the basis of clinical, lesion, and affected vessel characteristics are proposed in Table 1. Based on available data and current techniques, the patients are classified into type A, B, and C, if any of the characteristics attributed to a higher class is present. The risk of procedure-related stroke/death is expected to be <1% for type A, between 2% and 3% in type B, and >3% in type C patients. Therefore, the choice of procedure needs serious consideration, based on the presence or absence of significant symptoms and prior strokes.¹⁵

Most (76%) of our patients had type C lesions, and as shown in Figure 2, although all type B and A patients had no complication during the procedure or in the follow-up period (very high sensitivity), we cannot accurately predict which patient with type C lesion is really at risk of a complicated course after carotid stenting (low specificity).

Considering the clinical and lesion characteristics in complicated and uncomplicated patients (Table 4), it could be seen that all the complicated patients had an age \geq 70 years, three-vessel disease, hypertension, plaque ulceration, type C lesion, and a score of \geq 22. Although all these six factors are highly sensitive to predict complications, absence of none of them allows for sufficient specificity to rule out the probability of major complications.

As shown in Table 1, based on the abovementioned typing classification, a numeric point score has been considered for each characteristic and it was found that the total score is an invaluable index for prediction of major complications after carotid stenting. Especially, the very high specificity of a total score ≥ 26 (Table 4 and Figure 3) may help the physician to make an appropriate decision as to whether stent the vessel or refer the patient for endarterectomy (before or simultaneous with CABG). It is also suggested that if a decision has been made for carotid intervention in patients with a total sore of ≥ 26 , the physician should closely observe the patient (perhaps in the hospital) during the waiting period before CABG.

Study limitations

The major limitation of this study was the small sample size used which results in low statistical power. Validation of these risk factors requires larger prospective studies. Also this study could not be compared with the reported clinical trials and the CEA series, due to the confounding factors which could place patients at higher risk. This would ultimately be tested in randomized trials.

This study carefully defined the demographic, clinical, and lesion characteristics of patients undergoing carotid stenting in Tehran Heart Center. Our study showed that the complications of carotid stenting depend on patient selection. On the basis of our suggested scoring system, it appears that patients who have a score of ≥ 26 before the procedure, should be considered as very high-risk patients. Great care should be taken when decision is going to be made regarding the treatment of these patients. To determine whether the best treatment strategy for these patients is carotid stenting with delayed coronary bypass surgery after one month or a simultaneous endarterectomy and CABG surgery, commencement of a prospective randomized clinical trial is required. However, we did not have any procedural complications with these patients, thus it seems that CAS is feasible and safe, even when they have a significant coronary artery disease and are CABG candidates.

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