Original Article

Carotid artery stenting: Results and long-term follow-up

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Background and Purpose: The role of carotid artery stenting (CAS) as an alternative to carotid endarterectomy in the treatment of for symptomatic carotid artery stenosis is investigated. **Materials and Methods:** Forty-seven patients underwent CAS over 10-year period. Forty-nine vessels were treated. Stenosis quantification was done using North American symptomatic carotid endarterectomy trial method. The mean follow-up period by clinical and Duplex examination ranged is 5.6 years. **Results:** The technical success rate was 100%. There were four deaths (8.1%) and two (4.1%) minor strokes within thirty days of procedure. There was no major strokes. All patients with minor stroke achieved complete recovery at 1-month follow up. Two deaths occurred probably due to hyperperfusion syndrome (HS) and two due to cardiac arrest. **Conclusion:** CAS is an effective treatment modality of symptomatic carotid artery disease but should be carefully done in high-risk groups having severe medical ailments and those having severe bilateral stenosis of the carotid arteries.

Key words: Carotid artery stenting; interventional radiology; stroke.

Surgical carotid endarterectomy (CEA) is currently the accepted standard mode of treatment for revascularization of extracranial carotid occlusive disease.[1-5] Carotid artery stenting (CAS) is currently being investigated as an alternative treatment to CEA.[6-11] The purpose of the present study is to analyze our experience, determine the therapeutic benefits of CAS in preventing stroke and to describe the technical details of the procedure.

Materials and Methods

CAS was performed on 47 patients (35 males and 12 females) at our institution between January 1995 and June 2005. These cases were analyzed retrospectively. To be considered suitable for stenting, symptomatic patients had at least 50% stenosis and asymptomatic patients had at least 70% diameter narrowing. This is as per the criteria laid down by North American symptomatic carotid endarterectomy trial (NASCET).[4,5,12] Forty-five patients had recurrent transient ischemic attacks or stroke ipsilateral to the side of carotid stenosis, which was resistant to medical treatment. Two patients had high-grade asymptomatic carotid stenosis.

Clinical protocol

Carotid Doppler study, CT or MR imaging, routine blood investigations, cardiological and neurological evaluation was performed by a team of consensual staff. National Institutes of Health Stroke Scale (NIHSS) was recorded before the procedure and at 24 h, 30 days and subsequently at 3 month interval. Antiplatelet therapy was started 2-4 days before the procedure. Follow-up Doppler study was obtained at first month and then every 3 months.

Definitions of clinical terms

Technical success was defined as the ability to access the carotid artery and successfully stent the lesion with residual stenosis of no more than 20%. Study end points were defined as an occurrence within 30 days of minor stroke, major stroke, death, or myocardial infarction (MI). Myocardial infarction was assessed clinically and ECG evidence of ischaemia. Minor stroke was defined as an increase in the NIHSS score of less than 3, with complete resolution or no significant disability at 30 days. Major stroke was defined as an increase in the NIHSS score of 3 or more, with significant disability at 30 days. Severe coronary artery disease was defined as angiographic evidence of triple vessel disease with stenosis of more than 70%.

Technique of carotid artery angioplasty and stenting

The procedure was performed under sedation and local anesthesia. A baseline activated clotting time was obtained.

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Preprocedure diagnostic angiography of neck vessels and intracranial circulation was performed. Stenosis was quantified according to NASCET criteria. The patients activated clotting time was kept 2-2.5 times the baseline. Initially stenosis was traversed under digital road map guidance with a 300 cm, 0.014 in. exchange-length guide wire. Protection devices were used in six patients. If patient affords, we intend to use protection devices routinely. After predilation, the stent was placed across the lesion referenced by bony landmarks and postprocedure angiograms were obtained. Postdeployment angioplasty was done in cases where the stent opening was thought to be inadequate after deployment. Postprocedure mean arterial pressure was kept 10-20% below baseline to prevent cerebral reperfusion injury.

Results

Demographic, clinical and morphological characteristics

A total of 49 vessels were treated during 48 procedures [Table 1]. The mean age of the patients was 61.2 years. Significant coronary artery disease (angiographically proved triple vessel disease with stenosis greater then 70%) was present in 21 patients (44.68%). Significant disease in both carotid arteries was present in 18 patients (38.29%) and contralateral carotid artery occlusion was present in 3 (6.38%) patients. Lesion severity of >90% was present in 17 vessels (34.69%). A bilateral carotid procedure was undertaken in two patients (4.25%) [Figure 1]. These two patients were symptomatic on both sides with stenosis >70% (NASCET criteria). Of the 45 patients (95.74%) with symptomatic carotid stenosis in this series who met the angiographic criteria, only 26 (57.7%) would have been eligible for inclusion in NASCET. Protection devices were used in six patients (six procedures). Wall stents (Boston Scientific Corporation, USA) were used in all. The length and the diameter of the stents ranged from 40-80 to 6-8 mm, respectively. Technical success was achieved in 100% of procedures.

Angiographic characteristics before and after stent placement

Angiographic morphology indicated 34 concentric lesions of ICA and 15 eccentric plaques [Figure 2]. The lengths of the stenoses were 7-36 mm (mean: 15 mm). Twenty-nine plaques showed the typical niches of ulcerations. Calcification was seen in

Table 1: Patients' demography with postprocedural events

	Patients	Minor stroke	Major stroke	Death
Age (years)				
<60	20 (42.55%)	0	0	0
60-69	13 (27.65%)	0	0	0
>69	14 (29.78%)	2	0	4
Sex				
Male	35	2	0	4
Female	12	0	0	0
Symptomatic	45	2	0	4
Asymptomatic	2	0	0	0
Coronary artery disease				
Yes	21	2	0	4
No	26	0	0	0
Hypertension				
Yes	43	2	0	4
No	4	0	0	0
Smoking				
Yes	29	1	0	4
No	16	1	0	0
Bilateral disease				
Yes	18	2	0	4
No	29	0	0	0
Contralateral occlusion				
Yes	3	0	0	2
No	44	2	0	2
ASCET eligible				
Yes	26	0	0	0
No	21	2	0	4
Prior CEA				
Yes	1	0	0	0
No	46	2	0	4

CEA, carotid endarterectomy; NASCET, North American symptomatic carotid endarterectomy trial; ASCET, American symptomatic carotid endarterectomy trial

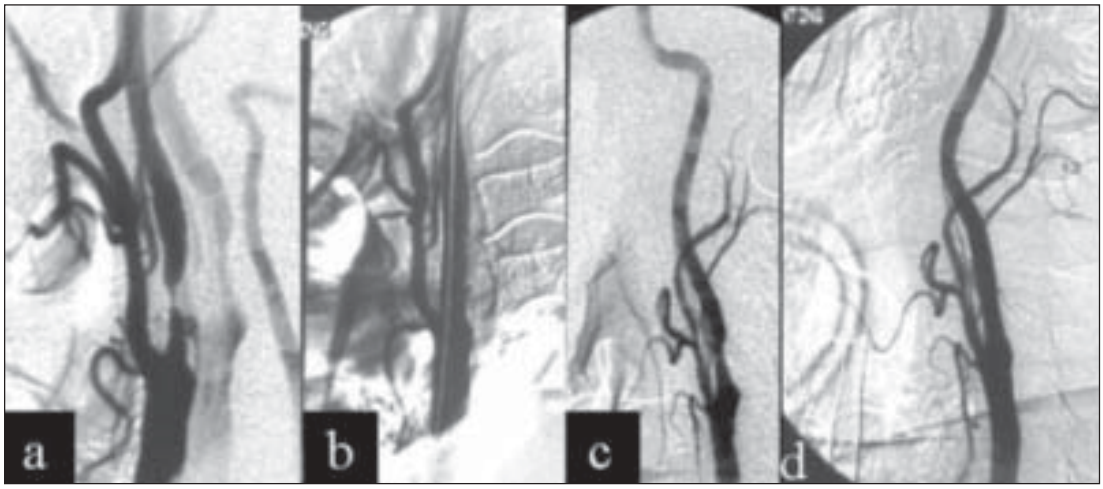

Figure 1: (a) Right CCA angiogram lateral view shows critical stenosis at ICA origin. (c) Left CCA angiogram oblique view shows high-grade stenosis at ICA origin. Patient was symptomatic on both sides. (b, d) Bilateral stenting was done on the same sitting with good result

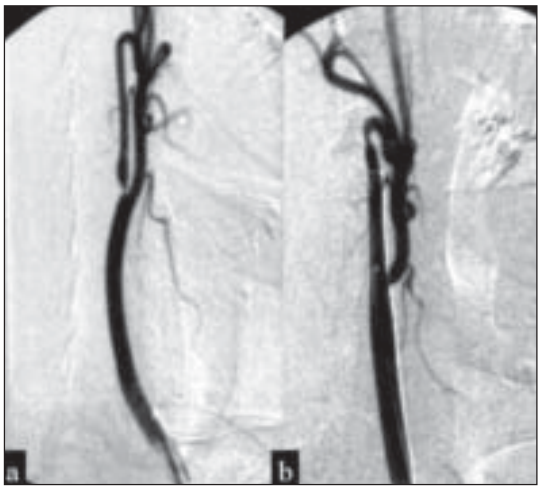

Figure 2: (a) Right common carotid artery (CCA) lateral view shows eccentric plaque in the origin of internal carotid artery (ICA). (b) Poststenting CCA angiogram shows normal contour of the artery

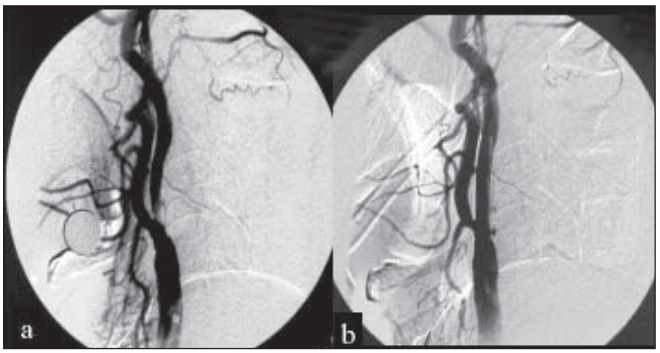

Figure 3: (a) Left CCA angiogram oblique view shows ulcerated plaque with critical stenosis at the origin of ICA and CCA. (b) Poststenting CCA angiogram shows normal contour of the ICA. Residual ulceration seen. The stenting was done without protection devices. The procedure was uneventful

15 lesions. Stent implantation reduced the mean percentage of stenosis (according to the NASCET criteria) from 83.8 to 6.3%, which is highly significant ($P < 0.001$, Wilcoxon test). In one case there was a residual small ulceration after the stent placement [Figure 3]. Due to the small size of the ulcer,it is being observed on antiplatelet therapy. In this patient at 1-month follow up no ulcer crater was visible on Duplex and the patient remained asymptomatic till his last follow up at 3 years. Wallstent implantation induced kinking of the ICA above the distal end of the stent in two cases. The kinks were associated with moderate (5-10%) stenoses. This was due to severe tortuosity of the vessel, however, there was no flow limitation. Due to this reason a second stent was not put to rectify the kink.

Sonographic characteristics before and after stent placement

All stenoses were 70% or greater, according to Doppler criteria (acoustic evaluation, peak systolic velocity and duplex measurement of local luminal narrowing). Sonographic plaque morphology confirmed 16 echolucent smooth plaques, six

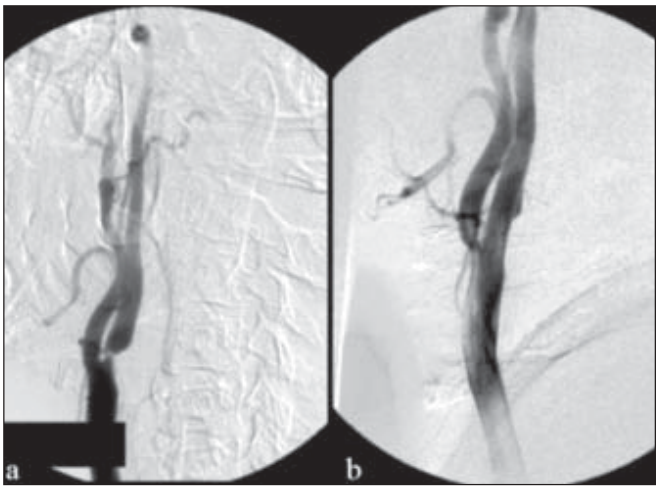

Figure 4: (a) Left CCA angiogram oblique view shows critical stenosis in the bulb of the internal carotid artery. (b) Poststenting CCA angiogram shows normal contour of the ICA with good distal flow. Other ICA was occluded (not shown)

Table 2: Shows plaque morphology with postprocedure neurological events

		No. of vessels	Minor stroke	Major stroke	Death
Lesion severity	<70%	0	0	0	0
	70-89%	32	0	0	0
	<90%	17	2	0	4
Fibro fatty smooth plaque		16	1	0	0
Calcified plaque		15	0	0	1
Ulcerated plaque		29	1	0	3

echodense plaques and 26 lesions of mixed echodensity with ulcerations. Duplex sonograms depicted an irregular surface in 26 plaques and showed coincident findings in 26 of 29 angiographically proved irregularities. Sonograms depicted three further plaques that were incompletely covered by the proximal end of the stent. As the plaques were thin and were situated in mid-CCA, second stents were not put in them. High-resolution sonograms (obtained in power mode) depicted two cases of ulcer niche that persisted immediately after stent placement but no ulcer was seen at 1-month follow up and the patients remained asymptomatic. Mild in-stent intimal thickening was noted in three patients on follow-up Doppler study at 6 months, but they were stable up to latest follow up at 48 months.

Procedural outcomes

Cinical characteristics and procedural outcome of the patients are given in Table 1. A total of two neurological events were noted within 30 days of stenting in 49 carotid arteries. These included two minor strokes after the procedure (4.1%) and they recovered completely. These were thought to be of embolic origin and happened in patients where no protection devices were used. There were four deaths within 7 days of procedure, two related to hyperperfusion and two due to cardiac arrest. One patient with bilateral carotid stenoses and the other with one side carotid occlusion and other side having 98% stenosis had hyperperfusion

syndrome despite strictly controlling the blood pressure below baseline [Figure 4]. One patient died within 24 h and the other within 4 days of the procedure. The third patient having prior history of MI and had undergone bilateral stenting died of cardiac arrest after 2 days of the procedure. The fourth patient had severe triple vessel coronary artery disease and one side carotid occlusion also died of cardiac arrest. The relation between plaque morphology and procedural outcome are given in [Table 2]. Most of the complications were seen in high-grade stenosis with ulcerated plaques ($P = 0.011$, Fisher's exact test).

Predictors of neurological events

All the complications are seen with patients older than 70 years of age ($P = 0.006$, Fisher's exact test). Presence of bilateral carotid lesions ($P = 0.017$), contralateral carotid occlusion ($P = 0.016$) and severe coronary artery disease ($P = 0.034$) had significant influence on risk of stroke and death. Lesion severity (>70%) was also associated with the risk of stroke and death ($P = 0.011$, Fisher's exact test).

Clinical outcome and follow up

The follow-up ranged from 6 months to 9 years. One minor ipsilateral stroke (2.04%) occurred 15 months after stent placement in a 78-year-old patient and she had total recovery with patent stent. One patient stopped antiplatelet medication 3 years after the procedure and she had a fainting attack. Her Doppler showed total stent occlusion, but she was neurologically normal. On follow-up Doppler study all the patient stents were covered well by intima and were patent. Only two vessels showed (4.08%) mild (10-15%) restenosis inside the stent with any flow restriction and neurological event. All other patients were symptom free on last follow up (mean 5.6 years).

Discussion

Percutaneous transluminal balloon angioplasty was first reported in 1980 and since then a number of reports are available in the literature detailing high success rate of the procedure.[13-18] The concept for stent placement has come from successful trials in the coronary arteries.[15,16]

Yadav et al. reported their result in 77% of NASCET ineligible patients.[9] In our series 57.77% of patients did not fulfill NASCET inclusion criteria and all our complications were encountered in this group of patients.

Stent oversizing and cerebral protection is theoretically advantageous in preventing distal embolism and in reducing tissue prolapse and is associated with a lower rate of restenosis.[19-22] So, we choose stents 3-5 mm larger then the vessel diameter to avoid these problems. Theron et al. reported good result with distal balloon protection and depends on the emboli size.[6,23-25] We have not encountered any embolic episode since we started using the protection devices.

Large series of extracranial carotid angioplasty and stenting have revealed the incidence of stroke and death to be in the range of 3.6-7.9%.[9,26] In the present series the combined stroke and mortality rate is 12% and the patients had either bilateral critical carotid stenoses or unilateral carotid occlusion with contralateral critical stenosis and the patients had a prior coronary artery bypass grafting for critical triple vessel disease. This high rate of stroke is also due to lack of usage of protection devices in most of our cases. Recent report from the data of SAPPHIRE trial clearly showed the advantages of protection devices in preventing the periprocedural stroke in CAS.[27] Postprocedural hyperperfusion intracerebral hemorrhage been reported as a rare complication of CEA and stenting, with an incidence upto 5%.[28-33] We have seen two deaths (4.2%) related to HS. Severe (>90%) ipsilateral stenosis, contralateral occlusion, increased age, impaired collateral blood flow or an incomplete circle of Willis, perioperative and postoperative hypertension and use of antiplatelet agents or other anticoagulants are risk factors for the development of postCEA intracerebral hemorrhage.[34-36] Our experience suggests that bilateral procedures should not be done in the same sitting to reduce the chances of HS. When this treatment is required for such patients, extreme postprocedural care must be taken. Protection devices appear to play a role in avoiding this problem.[37,38]

Lack of cerebral protection, poor patient selection and the relatively small size of the series adversely affected the result. The stroke recurrence rate was 2.04%, which was significantly low when compared to the natural history of the patients with atherosclerotic carotid artery disease which can be as high as 26.5%.[39,40]

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