

Outcome of Ischemic Stroke Patients After Carotid Stenting without a Protection Device

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Abstract:

Background: Carotid angioplasty and stenting are treatment options for ischemic stroke patients who have carotid stenosis. Previous studies showed mixed results about its efficacy and functional outcome. **Objective:** The purpose of the study was to observe the functional outcome of ischemic stroke patients after carotid stenting without a protection device. **Methodology:** This prospective hospital-based longitudinal study was conducted at BSMMU during October 2022 to September 2023 on patients with >50% extracranial ICA stenosis, measured by NASCET. Imaging (Doppler/MRA/DSA) confirmed stenosis. Stenting was performed, followed by MRI (DWI) within 48 hours. Functional outcome was assessed using mRS before and 1 month after stenting. **Result:** A Total of 39 patients were analyzed in the study. The mean age of the respondents was 59.8 ± 9.4 years. About 79.5% participants were male and 20.5% were female. Hypertension was found most common among the patients (76.9%) followed by DM (51.3%), Smoking (38.5%), dyslipidemia (38.5%), and CKD (12.8%). Before stenting, 97.4% patients had DWI lesions on MRI. Severe carotid stenosis was found among 89.7% patients and 69.2% lesions were ulcerated. Calcification was present in 17.9% lesions and 33.3 % lesions were more than 15 mm in length. Carotid stenting without any distal protection device was done on the left side in 64.1% of the patients and 35.9 % had right-sided carotid stenting. Within 48 hours after stenting, MRI of the Brain showed a new DWI lesion in 7.7 % patients. Before stenting, only 9 (23.1%) patients had mRS 0-2, whereas one month after stenting, 38(97.4%) patients achieved a good functional outcome, which was statistically significant (p value < 0.001). **Conclusion:** Carotid stenting without protection devices is a safe and effective treatment, yielding significantly improved functional outcomes.

Key words: Ischemic Stroke, Outcome of Stroke, Carotid Stenting, Carotid Angioplasty, Protection Devices

Introduction

Carotid stenting with or without angioplasty is currently widely performed for carotid artery stenosis. However, the benefit of carotid stenting is highly dependent on a low risk of procedural neurological complications. The benefit is eliminated when the combined 30-day stroke and death rates exceed approximately 5% to 7% for symptomatic and 3% for asymptomatic patients, respectively.^{1, 2} Carotid endarterectomy is an alternative for the treatment of severe carotid stenosis. Because higher morbidity and mortality rates have been reported when carotid endarterectomy is

used in everyday clinical practice, carotid angioplasty and stenting (CAS) might become an attractive alternative treatment strategy.³ Although evidence is accumulating that CAS can be performed with acceptable complication rates, fear of distal embolization of plaque fragments to the brain has generated a great concern regarding the safety of this technique.^{4,5} Therefore, recent efforts have focused on the development of cerebral protection devices aimed at preventing the passage of embolic material into the cerebral vasculature. The concept of cerebral protection during CAS is appealing and has indirectly been supported by several

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case series and stent registries.^{4, 5} But, the use of cerebral protection devices increases the intervention time, the complexity and cost of the procedure, and may also have a negative influence on embolization rates themselves.^{6, 7} Because clinical events after CAS are relatively uncommon, additional surrogate markers for clinical stroke that occur at a greater frequency would be of considerable use to evaluate the efficacy of protection devices. Against the background of a high incidence of clinically silent emboli occurring during CAS detected by diffusion-weighted imaging (DWI),^{8–14} this imaging modality could become a useful tool in this scenario. In fact, DWI is currently the most sensitive tool to detect early cerebral ischemia¹⁵ and offers the possibility of making even small and thus asymptomatic lesions visible shortly after their emergence.¹⁶ One study published recently has directly compared the frequency of new DWI lesions in unprotected CAS.¹⁷ Moreover, the clinical significance of these lesions has not yet been established in a larger patient population. Therefore, the goals of the study were to assess the frequency, number, and size of new DWI lesions after carotid stenting (after 48 hours), and to assess the clinical outcome of stroke and death within 30 days.

Methods

This longitudinal prospective observational cohort study was conducted in the Indoor Department of Neurology, BSMMU, Dhaka, from October 2022 to September 2023. Ischemic stroke patients aged more than 18 years who had carotid stenosis of more than 50% were selected. Extra-cranial vascular imaging in the form of CT angiogram, MR angiogram, or duplex study of neck vessels was done to identify carotid stenosis and NASCET criteria were used to determine the degree of stenosis.

A total of 39 patients were selected who had a recent ischemic stroke and more than 50% stenosis in the symptomatic side of the carotid artery. Ischemic stroke patients of the posterior circulation and who had complete occlusion of the internal carotid artery were excluded from the study. Every patient underwent carotid stenting without using a protection device, and after 48 hours, a DWI MRI was performed to identify new cerebral lesions. If any patient history and clinical examination suggest a new occurrence of stroke during follow-up time, then one or both of the following were used as evidence of stroke: a one-point increase on the mRS score or an appropriate new or extended abnormality on MRI of the Brain. Periprocedural outcome events were grouped into TIA, nondisabling stroke, disabling stroke, fatal stroke, MI and death. After one month of stenting, all the patients were followed up over the phone or in person. Follow-up outcome events were grouped into TIA, nondisabling stroke, disabling stroke, fatal stroke and death from any other cause. Any of the events were noted in the data sheet.

Results

The majority of participants were between 60 and 69 years of age (43.6%), followed by those aged 50–59 years (25.6%). The mean age of the study population was 59.8 ± 9.4 years, with an overall range of 40 to 75 years. Comorbidities and vascular risk factors were common.

Table-1
Characteristics of study population (n=39)

Variables	Number (%)
Age mean (range) 59.8 ± 9.4 (40-75)	
Age in years	
≤49	5 (12.8%)
50-59	10 (25.6%)
60-69	17 (43.6%)
≥70	07 (17.9%)
Sex category	
Men	31(79.5)
Women	8 (20.5)
Risk factors	
Hypertension	30 (76.9%)
DM	20 (51.3%)
Dyslipidemia	15(38.5%)
Smoking	15 (38.5%)
Ischemic heart disease	12 (30.8%)
Family history	09 (23.1%)
CKD	05 (12.8%)
Site of Stenosis	
Only Left	11 (28.2%)
Only Right	09 (23.1%)
Both Arteries	19 (48.7%)
Site of Stenting	
Left	25 (964.1%)
Right	14 (35.9%)
Angioplasty	10 (25.6%)
Severity of Stenosis	
Moderate	4 (10.3%)
Severe	35 (89.7%)
Contralateral Occlusion	24 (61.5%)
H/O of stroke	17 (43.6%)
Lesion Characteristics	
Length of the Lesion > 15 mm	13 (33.3%)
Lesion of calcification	07 (17.9%)
Ulceration	27 (17.9%)
Procedural events	
Technical success	38 (97.4%)
Hemodynamic instability	12 (30.8%)
Bradycardia	3 (9.7%)
Hypotension	3 (9.7%)
MRI abnormality	
Before CAS	
Lesion Present	38 (97.4%)
Lesion Absent	01 (2.6%)
After CAS	
Previous lesion	33 (84.6%)
New lesion	3 (7.7%)
Lesion absent	3 (7.7%)

CAS (carotid angioplasty and stenting)

Hypertension was present in 76.9% of cases, diabetes mellitus in 51.3%, smoking in 38.5%, and dyslipidemia in 38.5%. Ipsilateral carotid lesion characteristics revealed severe stenosis in 89.7% of cases and moderate stenosis in 10.3%. Calcification was observed in 17.9% of lesions, while ulceration was present in 69.2%. Lesion length greater than 15 mm was documented in 33.3% of cases. Post-stenting diffusion-weighted imaging (DWI) on MRI demonstrated new ischemic lesions in 7.7% of patients (Table 1).

Table-2

Distribution of new lesions (n=3)

New lesions	Number (%)
Symptomatic	
Yes	1 (33.3%)
No	2 (66.7%)
Number of lesions	
Single lesion	3 (100.0%)
Location of lesions	
Contralateral	1 (33.3%)
Ipsilateral	2 (66.7%)
Arterial territory	
MCA	1 (33.3%)
Watershed	2 (66.7%)
Location	
Parietal	3 (100.0%)

We encountered three cases that experienced new lesions. Among these three cases, all were in a single location. Most of the new DWI lesions were on the ipsilateral side than the contralateral side, which was 2 (66.7%) cases and 1 (33.3%) case, respectively. Considering arterial territory, all 3 (100.0%) new cases were in the watershed area (Table 2).

The distribution of the study population according to the modified Rankin Scale (mRS) was assessed before stenting and at 30 days post-procedure. Prior to stenting, 30 patients (76.9%) had poor functional outcomes (mRS 3–5). At 30 days after stenting, only 1 patient (2.6%) remained in the poor outcome category (Figure 1). Of the 30 patients with poor outcomes before stenting, 29 (96.7%) demonstrated

Table-3

Comparison of functional outcome before and after carotid stenting (n=39)

Functional Status Before Carotid Stenting	Functional Outcome After Carotid Stenting		p value
	Good	Poor	
Good	9 (100.0)	0 (.0)	<0.001
Poor	29 (96.7)	1 (3.3)	
Total	38 (97.4)	1 (2.6)	

McNemar test was done to measure the level of significance

improvement to good functional status (mRS 0–2) following the procedure. Overall, the majority of patients achieved good functional outcomes after stenting, and this improvement was statistically significant ($p < 0.001$) (Table 3).

Discussion

A total of 39 patients were recruited after fulfilling the inclusion and exclusion criteria. The majority of participants were aged 60–69 years (17 cases, 43.6%), followed by those aged 50–59 years (10 cases, 25.6%). The mean age of the study population was 59.8 ± 9.4 years. In comparison, a retrospective observational study from Bangladesh reported a mean age of 55 ± 5.5 years among patients undergoing carotid artery stenting (CAS). Another CAS registry comprising 2,878 patients from 31 hospitals documented a mean age of 70.0 ± 8.6 years, while the mean age among the US Medicare population in 2013–2014 was 75.2 ± 7.6 years.^{9, 20} The higher mean age observed in Western populations undergoing carotid stenting may reflect differences in life expectancy between Asian and Western populations. Regarding gender distribution, males predominated with 31 cases (79.5%), compared to 8 cases (20.5%) among females, yielding a male-to-female ratio of 3.87:1. Similar male predominance has been reported in previous studies.^{21, 22}

Comorbid conditions and vascular risk factors were documented among the study population. Hypertension was the most prevalent, observed in 30 patients (76.9%). Diabetes mellitus was present in 20 patients (51.3%). A history of smoking was reported in 15 patients (38.5%), and dyslipidemia was identified in 15 patients (38.5%). In comparison, Pinero et al. (2006) reported similar findings, with hypertension in 78.4% of cases, diabetes mellitus in 48.8%, hyperlipidemia in 61.1%, and smoking in 50%.²³

Diffusion-weighted imaging (DWI) lesions on brain MRI prior to stenting were documented. Among the 39 patients who underwent carotid stenting, 38 (97.4%) demonstrated DWI lesions before the procedure. The distribution of carotid artery stenosis by side was also assessed. Bilateral carotid artery stenosis was the most common, observed in 19

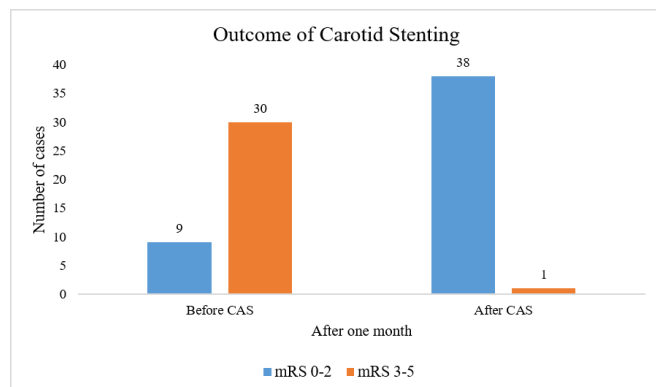


Figure 1: Bar diagram showing outcome of study population after carotid stenting (n=39).

patients (48.7%). Right-sided stenosis was present in 9 patients (23.1%), while left-sided stenosis was identified in 11 patients (28.2%). Ipsilateral carotid lesion characteristics revealed that severe stenosis was more frequent than moderate stenosis, reported in 27 patients (87.9%) and 4 patients (12.1%), respectively. Calcification of the lesion was observed in 7 patients (22.6%), whereas ulceration was present in 27 patients (69.2%).

In this study, all three patients who developed new diffusion-weighted imaging (DWI) lesions following carotid stenting had ulcerated carotid lesions. Lesion length exceeded 15 mm in 13 patients (33.3%). A previous study reported that carotid lesion length >15 mm was associated with recurrent stroke after stenting.²⁴ In contrast, no recurrence of stroke was observed among patients with lesion length >15 mm in the present study. The distribution of carotid stenting by side was also recorded. Left-sided carotid stenting was more common, performed in 25 patients (64.1%), whereas right-sided stenting was performed in 14 patients (35.9%). Angioplasty with stenting was carried out in 10 patients (25.6%).

In this study, carotid angioplasty and stenting were performed without the use of distal embolic protection devices. The role of such devices in influencing outcomes of carotid stenting has been well documented. Previous studies demonstrated that omission of embolic protection during carotid artery stent placement was associated with a fourfold increase in perioperative stroke risk.²⁵ Nazari et al. reported a stroke rate of 2.1% with protection devices compared to 6.5% without.²⁵ Large multicenter trials also highlighted the impact of protection devices. The International Carotid Stenting Study (ICSS) and the SPACE trial, both conducted with protection devices, reported stroke rates of 7.4% and 7.2%, respectively.^{26, 27} In the present study, the stroke rate was 7.7% despite the absence of protection devices, which is comparable to those trials. Similarly, Schreiber et al. observed a stroke rate of 5.4% in procedures performed without protection devices.²⁸

Distribution of study population according to new DWI lesion after stenting was recorded. This study showed among the total 39 patients, no patient suffering from symptomatic stroke. Binning et al. showed that stroke rate was 0% without protection device.³⁰ One study found new DWI lesion in 17.3% cases.³¹ Another study got new DWI lesion in 23% cases.³² Bjuklic found new DWI lesion in 32.8% cases.³³ Among these 39 cases, after carotid stenting new DWI lesion was found in 3 (7.7%) cases which were asymptomatic. This study recorded mRS before and after 1 month (at day 30) of stenting procedure. Before stenting, 30 (76.9%) patients had mRS 3-5, whereas one month after stenting, only 1 (2.6%) patients had mRS 3-5. This study showed improvement of disability after carotid stenting in symptomatic stroke patient those had carotid stenosis.

The distribution of new diffusion-weighted imaging (DWI) lesions after stenting was assessed. Among the 39 patients included in this study, no patient experienced a symptomatic stroke. Binning et al. similarly reported a stroke rate of 0% in procedures performed without protection devices.²⁹ Other studies have documented variable rates of new DWI lesions: 17.3%, 23%, and 32.8%.³⁰⁻³³ In the present cohort, new DWI lesions were observed in 3 patients (7.7%), all of whom were asymptomatic. Functional outcomes were evaluated using the modified Rankin Scale (mRS). Prior to stenting, 30 patients (76.9%) had an mRS score of 3-5. At 30 days post-stenting, only 1 patient (2.6%) remained in this range. These findings indicate a marked improvement in disability following carotid stenting among patients with symptomatic carotid stenosis.

Conclusion

Carotid stenting in indicated patients without distal embolic protection devices resulted in a reduced stroke rate, comparable to major trials where protection devices were used. New diffusion-weighted imaging (DWI) lesions occurred in very few of cases, all asymptomatic, and no patient experienced a symptomatic stroke. Functional outcomes improved markedly. These findings suggest carotid stenting can be performed safely and effectively in selected patients, even without protection devices.

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Conflicts of Interest

The authors declare that they have no conflicts of interest related to this work.

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