

Carotid artery stenting for symptomatic carotid artery stenosis: A single centre experience of 150 cases

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Abstract

Objective: Carotid artery stenting is presently universally adopted for treatment of carotid artery stenosis. The objective of this study was to analyze the outcomes of carotid artery stenting (CAS) performed in a single institution.

Materials and Method: We retrospectively studied on 150 cases, who presented in our Hospital from January 2015 to January 2024. All patients were symptomatic including 66 cases performed with distal embolic protection device (DEPD) and 84 cases without distal embolic protection device. Procedure – related morbidity and mortality as well as influencing factors for outcomes were assessed. Modified Rankin scale (mRS) score was applied to evaluate outcome. Mean, median and t/Chi-square test were used to analyze data.

Results: There were 99 males and 51 females with mean age of 64.2 (ranged 20-81) years. The maximum incidence was noted in age group of 50-70 years (62%) with more case with symptoms of transient ischemic attack (TIA) (65.3%). Hyperlipidemia was significantly higher in DEPD group compared to non-DEPD group (p=0.03). Ulcerated plaque was significantly higher in DEPD group compared to non-DEPD (p<0.0001). Co-morbidities (HTN, DM, hyperlipidemia, smoker, and previous stroke history), age as well as pre/post stenting degrees of stenosis were significantly correlated with outcomes. One case with distal embolic stroke was noted in non-DEPD group, but no mortality and re-stenosis were reported at mean follow up period of 11.2±6.7 Months.

Conclusions: Carotid artery stenting for sever stenosis is found to be safe and successful strategy. However, appropriate precaution should be reimbursed to the patients who have ulcerated plaque.

Keywords: Internal carotid artery, stenosis, angioplasty, stenting, outcome

INTRODUCTION

Carotid atherosclerosis is one of the undermined and lethal factors for stroke[1]. Atherosclerosis can lead to carotid artery stenosis which reports almost 20 % of all ischemic stroke cases [2]. Carotid Endarterectomy (CEA) has been believed to be standard and effective treatment strategy for carotid artery stenosis in both symptomatic and asymptomatic patients[3].But, with the development minimal invasive tools and technique,

carotid artery stenting has evolved as an alternative treatment method. Therefore carotid angioplasty and stenting is thought to be safe and successful procedure which is broadly utilized to prevent from primary and secondary stroke in patients associated with high risk for CEA due to co-morbidities, anatomic variation or contraindications in severe symptomatic or asymptomatic carotid stenosis [4, 5, 6]. Presence of ulcerated carotid plaque which is leading cause of complications such embolic stroke

after CAS, is still debatable in the world [7, 8]. Even though the use of DEPD in carotid artery stenosis is safe-guarded in patients with severe stenosis and ulcerated plaque [9]. The purpose of this study was to evaluate the risk factors and clinical outcomes of patients as well as determine safety of CAS in both DEPD/non-DEPD group with symptomatic patients who underwent angioplasty and carotid artery stenting in a single institution.

MATERIALS and METHODS

We performed a descriptive and retrospective study on a total of 150 patients who underwent CAS in our Hospital in the period from January 2015 to January 2024. Among 150 cases, there were 66 cases performed with embolic protection device and 84 cases without embolic protection device. Symptomatic patients were defined as those who had a history of TIA and previous stroke history within two months. Symptomatic patients with stenosis of more than 50% according to North Symptomatic Carotid Endarterectomy Trial (NASCET) were included. Age less than 20 year and asymptomatic patients as well as simultaneous stenting following mechanical thrombectomy in acute ischemic stroke or coiling were also excluded. The degree of carotid artery stenosis with 50%-70%, 70%-90% and more than 90% were defined as mild, moderate and severe stenosis respectively according to digital subtraction cerebral angiography. Patient's demographic, angiographic, procedure details and clinical follow up data were collected and influencing factors for outcome were analyzed. We assessed procedure related morbidities and mortality. Procedural mortality was defined as death within 30-day following carotid stenting. Peri-procedural stroke was defined as stroke that occurred within 24 hours and post procedural stroke was defined as stroke that occurred within 30 day of CAS. The outcomes were measured by mRS grading

score. It was mentioned as Good outcome if mRS was 0, 1 and poor outcome if mRS was ≥ 2 at follow up period. Pre-operative imaging studies included carotid ultrasonography, brain and neck magnetic resonance angiography (MRI) and digital subtraction angiography (DSA). Dual antiplatelets of aspirin 100mg and clopidogrel 75mg were routinely taken for at least 7 days prior to CAS. All patients were routinely evaluated by cardiologist to confirm risk of myocardial infarction. Oxygen saturation, electrocardiogram and blood pressure were monitored during procedure. When the pulse rate falls below 50, it was controlled using atropine.

Procedure of Carotid Artery Angioplasty and Stenting

All procedures were performed under local anesthesia via trans-femoral route. After placement of short arterial introducer (6F) on femoral artery, blood sampling for activated clotting time (ACT) measurement was done. Intravenous bolus injection of 50 IU to 60 IU/kg heparin was done depending on ACT level on all cases. For all procedures, a 7 F long sheath (guiding sheath, 7 x 90 cm; Cook medical) was navigated in common carotid artery with support of 5F, 0.038 inch diagnostic catheter (Vert; Cook medical) and 0.035 inch gliding wire (Terumo; Cook) via femoral approach. 1000ml normal saline with 1000 IU Heparin +10ml Nimodipine was administered through guiding long sheath continuously throughout the procedure. Viatrac plus, peripheral dilation catheter (Abbott, 5mm x 20mm, 135cm) was advanced over 0.014 inch microwire (Asahi Cikai, Asahi Intecc medical) and angioplasty was done. Balloon catheter was removed and closed cell stent, Xact stent 8mm-6mm x 40mm (Abbott) was placed over carotid stenosis in all cases. Post-stenting angioplasty was also done for all cases (**Figure 1**). All cases were discharged well on aspirin 100mg and clopidogrel 75 mg daily

for at least 3 months then Clopidogrel was discontinued after 3 month and aspirin was maintained lifelong. Patients were counseled to follow up at 1, 3, 6 and 12 months following discharge from hospital. Carotid Doppler was done for all case to evaluate stenosis at the period of follow up. Clinical and duplex ultrasound imaging outcome at follow up period were evaluated.

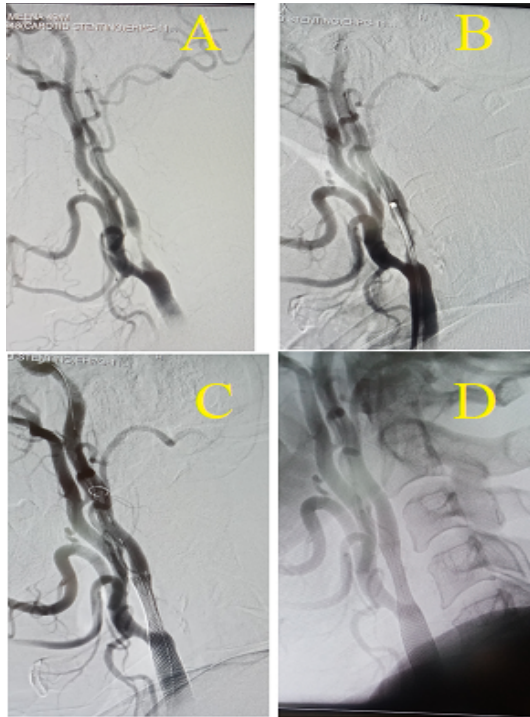


Figure 1
Figure.1, A: Cerebral Digital Subtraction Angiography (DSA) showing severe carotid stenosis with calcified plaque, B: DSA showing placement of distal embolic protection device with balloon angioplasty, C: showing initial deployment of carotid stent with balloon angioplasty, D: Fluoroscopic image showing post operative improvement in carotid stenosis.

Statistical Analysis

Statistical analyses were performed using SPSS 26.0 for windows (SPSS Inc; Chicago, IL, USA). Continuous variables are expressed as mean \pm SD. The significant difference between groups was examined using independent samples t- test for continuous variable or Chi-square test for

categorical variables. A p-value of less than 0.05 was considered statistically significant.

RESULTS

The study population consisted of 150 symptomatic CAS patients. The mean age was 64.2 ± 10.03 years. Male to female ratio was 1.9:1. The maximum incidence (62%) was noted in age group of 50-70 years with more (64%) carotid stenosis cases located in right side. 73.3% of patients having procedure within 14 days after symptoms where as duration of symptoms to stenting was noted significant correlation with DEPD and non-DEPD group. Modified Rankin scale score 0, 1 (<2) was found in 44.6 % cases and mRS scale score ≥ 2 was found in 55.4% cases at the time of admission. The most common clinical presentation was TIA 65.3% followed by previous stroke history previous stroke history was 50%. The most common risk factor of carotid artery stenosis was hyperlipidemia 82.5 % followed by smoking history 60%, hypertension 55.3%, DM 23.3% and CAD 11.4%. **Table 1** summarizes the baseline characteristics of CAS patients. 44.6% cases had ulcerated plaque and which was significantly associated with DEPD (64.2%) and non-DEPD (35.8%) group. Most of CAS cases had moderate stenosis in 75.3% cases followed by mild stenosis in 13.3 % and severe stenosis in 11.4%. Post stenting degree of stenosis was found mild stenosis in 81.3% cases and moderate stenosis in 18.7% cases and was significantly associated with DEPD and non-DEPD group (**Table 2**). Good and poor outcome were defined as according to mRS at the follow up period. Good outcome was defined when the mRS grade was 0, 1 and poor outcome was defined when the mRS grade was ≥ 2 .

Variables	Totals	DEPD group	Non-DEPD group	P value
Age, mean \pmSD (years)	64.2 \pm 10.03(Year)			
<50	12	6	6	0.6114
50-70	93	38	55	
>70	45	22	23	
Sex				
Male	99	39	60	0.1133
Female	51	27	24	
Duration of symptoms to stenting				
<14days	110	40	70	0.0018
>14days	40	26	14	
mRS scale at admission				
<2	67	21	46	0.0050
\geq 2	83	45	38	
Clinical presentations				
Headache	56	43	13	0.0011
Previous Stroke history	75	41	34	
TIA	98	64	34	
Decreased in Vision	47	19	28	
Co- morbidities				
HTN	83	37	46	0.0315
DM	35	21	14	
CAD	17	12	5	
Hyperlipidemia	124	75	49	
Smoking History	90	40	50	
Side of stenosis				
Right	96	45	51	0.344
Left	54	21	33	
Follow up, mean \pmSD(month)	11.2 \pm 6.7(Month)			

Table 1. Patient's baseline characteristics

Age more than 70 years had more poor outcome compared to age less than 70 years ($p < 0.0001$). The following co-morbidities such as HTN, DM, hyperlipidemia, previous stroke and smoking history were significantly associated with outcome scale (modified Rankin scale) ($p = 0.0002$). Hyperlipidemia was found as most influencing factors and directly correlated with poor outcome followed by smoking and previous stroke history. mRS grade at admission was found significantly correlated with outcomes at the period of follow up ($p < 0.0001$). Pre-stenting and post

stenting degree of stenosis were significantly associated with outcomes ($p < 0.0001$) (Table 3). But duration of symptoms and use of DEPD were not found significant association with good and poor outcome at the period of follow up. There was one case of stroke found within 24 hour of procedure in non-DEPD group but no mortality was observed within mean follow up period of 11.2 Months.

Variables	Totals	DEPD group	Non-DEDP group	P value
Ulcerated plaque				
Yes	77	53	24	<0.0001
No	73	23	50	
Pre-stenting degree of stenosis (%)				
Mild (<70)	20	6	14	0.3320
Moderate(70-90)	113	50	63	
Severe(>90)	17	10	7	
Post-stenting degree of stenosis (%)				
Mild(<50)	122	48	74	0.0165
Moderate(50-70)	28	18	10	

Table 2. Patient's imaging characteristics

Variables	Good outcome (mRS < 2)	Poor outcome (mRS ≥ 2)	P value
Age, years			
<70 year	88	17	<0.0001
>70 year	16	29	
Co-morbidities			
HTN	54	29	0.0002
DM	22	13	
Hyperlipidemia	49	75	
Previous Stroke history	26	49	
Smoking history	41	49	
mRS score at admission			
<2	47	20	<0.0001
≥2	27	56	
Ulcerated plaque			
Yes	53	14	0.2004
No	58	25	
Pre-stenting degree of stenosis (%)			
Mild (<70)	16	4	0.0003
Moderate(70-90)	85	28	
Severe(>90)	5	12	
Post-stenting degree of stenosis (%)			
Mild(<50)	112	10	0.0028
Moderate(50-70)	20	8	
Duration of symptoms to stenting			
<14 days	74	36	0.7515
>14days	28	12	
Use of DEPD			
Yes	49	18	0.5182
No	57	26	

Table 3. Outcome of the patient following carotid artery stenting**DISCUSSION**

Carotid artery stenosis is one of the major disabling factors by buildup of atherosclerosis plaque within carotid artery leading to wide range of symptoms, from mild symptoms including blurred vision and confusion to life threatening presentation including paralysis due to stroke. CEA has been suggested as standard treatment method. But, with the development of technique and tools, CAS is being widely used for the treatment of carotid stenosis in both symptomatic and asymptomatic cases. Our study might be one of few studies to investigate long term outcomes as good and poor outcome following uniform 8mm-6mm x 40mm, CAS for the management of carotid artery stenosis. Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST) is well designed study among randomized controlled studies in terms of patient's selection, procedure, management and follow up, where incidence of periprocedural stroke was 4.1% [6]. Periprocedural stroke was found in 0.6% cases in our study which is comparatively lower rate than other studies reported as 4.5%-5.1% [10, 1, 12]. Post procedural stroke was not noted in our study, similar to other study [10].

Closed-cell stents are known to be effective in confirming atheroma to the blood vessels wall, thus reducing the rate of visible debris capture in DEPD [13]. For this reason, patients treated with closed cell stents have a lower risk of intraoperative stroke than patients treated with Open –cell stents[14, 15]. Therefore we used Closed-cell stent in all cases. Ulcerated plaque at presentation was noted significantly higher in DEPD group compared to non-DEPD group in our study ($p < 0.0001$). However, a multicentre randomized prospective study have described 139 patients with DEPD among 279 patients

where it reported that 22.3 % embolic complication in DEPD group[16], another large systemic review, the use of DEPD was found to reduce thromboembolic complications during CAS[17]. Only one case of distal embolus was noted in non deployed DEPD group in our study. However, use of DEPD was not significantly associated with outcomes in our study.

Patients equal to or greater than 70 years of age were more likely poor outcomes (64.4%) as compared to age less than 70 years (16.2%) ($p < 0.0001$), which is similar to results of other studies [10,18,19]. The following co-morbidities were directly significantly associated with poor outcomes: hyperlipidemia, smoking history and previous stroke history ($p = 0.0002$) in our retrospective study, which is in contrast to other studies[10,19]. Duration of symptoms to stenting less than 14days was significantly higher in non-DEPD group and more than 14days was significantly higher in DEPD group ($p = 0.0018$). However, no significant association of duration of symptoms to procedure with outcomes was reported ($p = 0.7515$). Modified Rankin scale score at the admission was significantly association with outcomes ($p < 0.0001$). Score less than 2 had more good outcome (70.1%) and less poor outcome (29.9%) in contrast to score more than 2 at the time of presentation had less good outcome 32.5%) and more poor outcome (67.5%) in our study.

In our study, all cases were performed with balloon angioplasty by Viatrac plus (Abbott, 5 x 20mm) before and after procedures. Pre and post stenting degree of stenosis were found to be associated with outcomes ($p < 0.05$). There was poorer outcome noted as degree of stenosis increased before stenting. Severe degree of stenosis before stenting had 70.6% poor outcome and 29.4% good outcome in our study, which is in contrast to

a study where it reported that pre and post angioplasty as well as pre and post stenting degree of stenosis was not significantly associated with outcome as complications[10]. Post stenting re-stenosis after 3 years was described in some studies due to recurrent arteriosclerosis [20, 21]. The closed-cell stent is rigid, it can be induce straightening of the carotid artery and stimulate neointimal hyperplasia and stent restenosis within 3 year causing vessels wall stress [22, 23]. But, we did not report case of stent restenosis in our study, which is in contrast to some study, SPACE trail where 5.8% stent restenosis on follow up was found[5]. This study has some limitations such as retrospective study, not long term follow up period and not enough number of cases.

CONCLUSIONS

This study concludes that CAS, closed –cell stent is safe and effective for management for carotid stenosis and does not result in stent restenosis. Though rate of complications is minor following stenting for stenosis with plaque, use of distal embolic protection device may provide protection from inducing secondary stroke. Larger number of symptomatic cases with longer follows up period should be carried out to validate results of this study.

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