Carotid Stenting Results and Short Term Follow up

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Abstract

Background

Aim of work: to assess the value and consequences of carotid artery stenting immediate and during short term follow-up.

Methods: This prospective study was carried out in vascular surgery department at 6 October insurance hospital on 30 patients (22 males, 8 females) with a mean age of 65.5 years (45-81years) suffered from carotid artery stenosis and were high risk patients. Subjects were scheduled to carotid artery stenting (CAS) during the period between August 2015 and December 2016 and followed up for one year Nearly all carotid lesions were in internal carotid artery (28 patients, 93.3%) and only 2 patients (6.7%) had common carotid artery lesions. 20/30 patients were symptomatic carotid stenosis while 10/30 patients were asymptomatic and refereed from cardiac unit before coronary artery bypass graft (CABG). The commonest clinical presentation was stroke(40%) followed by transient ischemic attack (TIA) (26.7%).

Results: Technical success was achieved in all patients and all the procedures were performed using embolic protection devices. 3 patients (10%) developed stroke; one had intra operative stroke after stent deployment, one developed stroke at 6 month follow up by cerebral hemorrhage due to uncontrolled hypertension, the 3rd one stoke occurred during the 12th month follow up. Six cases (20%) developed TIA. Acute myocardial infarction (MI) occurred in 3 patients (10%); one was admitted to cardiac care and underwent coronary angiography while the other two cases died after massive MI. Two cases had intraoperative bradycardia and relived by atropine. Death occurred in one case 6 months after CABG.

Conclusion: The management of carotid stenosis is complicated and has been studied for a long time. Stroke prevention without complications is the main goal of successful treatment. Risk–benefit assessment should be discussed with individual patients, and should be based on patient status, plaque characteristics and procedural risk, rather than on the argument between CEA and CAS. Although the data show CEA to be associated with fewer stroke events, there have been advancements in technology and training for CAS, resulting in comparable outcomes between the 2 procedures with considering that CAS is preferable than CEA in high surgical risk patients.

Keywords: Carotid Stenting, High Surgical Risk Patients.

INTRODUCTION

Cerebrovascular disease is one of the commonest causes of death and a major source of permanent neurological and physical impairment in adults. In United States, cerebrovascular disease represents the 5th most common cause of death with approximately 795,000 stokes per year. Ischemic stroke is the most prevalent, with approximately 15–20% of these ischemic strokes occurred from atherosclerotic carotid artery stenosis. [(1)] Because of this fact, carotid artery stenosis should be accused in any patient with ischemic stroke or TIA and it can be diagnosed easily by duplex US imaging and is also useful in decision making. [(2)]

Symptomatic carotid artery stenosis is defined as stenosis in internal carotid artery (ICA) with cerebral

manifestations associated with ipsilateral carotid lesions. [3]

Carotid endarterectomy (CEA) remains the golden standard treatment of carotid artery stenosis. Carotid artery stenting (CAS) is another method of carotid revascularization which has developed rapidly over the last 30 years due to the perceived benefits of less invasiveness of the procedure, less morbidity and faster convalescence when compared to CEA. Randomized studies comparing carotid angioplasty and CEA showed comparable results. Restenosis is fortunately rare after CAS (3% - 5%) and the long-term results are encouraging.[4]

CAS should be the first treatment in the near future. In comparison to other endovascular peripheral arterial interventions, CAS is a more challenging procedure requiring complex catheter based skills and continuing learning curve. [5]

CAS may be a substitute for surgery especially in high-risk patients. However, embolic stroke, even with a meticulous technique and experienced operators, represents the major drawback of the procedure. The majority of neurological complications are due to intracerebral embolism of plaque fragments or thrombosis during different procedural steps. [6] Careful selection of patients, improvements in endovascular tools and proper medication may reduce the embolic risks. Embolic protection devices (EPD) retain fragments and debris generated during the procedure aiming to decrease the incidence of neurological complications. [7] Several studies suggest that CAS even without cerebral protection can be performed with an acceptable perioperative stroke and death rate of 2.9−8.2 %. [8]

Patients and Methods

This prospective study was carried out in vascular surgery department at 6 October insurance hospital on 30 patients suffered from carotid artery stenosis. Percutaneous transluminal angioplasty was done during the period between August 2015 and December 2016. 20/30 patients were symptomatic carotid stenosis while 10/30 patients were asymptomatic and referred from cardiac unit before CABG.

Inclusion criteria were (1) symptomatic stenosis >50% associated with one or more of the high surgical risks; elder patients ≥ 80 years, congestive heart failure (class III/IV) and/or ejection fraction less than 30%, unstable angina (CCS class III/IV), recent myocardial infarction (within 30 days), open heart surgery needed within 6 weeks or contralateral carotid occlusion. (2) Stenosis more than 70% in asymptomatic carotid lesions requiring CABG. Exclusion criteria were acute ischemic neurologic event within the last 48 hours or total occlusion of the target carotid artery.

After discussing the procedure, its possible complications, benefits, risks and other alternative interventions with patients, an informed written consent was obtained. This study was approved by hospital ethics committee.

All patients were subjected to clinical assessment regarding identification of risk factors e.g. age, smoking, DM, hypertension, hyperlipidemia and family history of related ischemic diseases or similar conditions. Neurological assessment was done by a neurologist with stress on the recent cerebral ischemia whether transient or persistent, weakness, tremors, sensory manifestations, numbness, cranial nerves affection, speech disturbances, visual symptoms and cognitive functions disturbances. All patients were evaluated by full laboratory investigations with concern to kidney functions, coagulation and lipid profile. Carotid duplex was done for all cases to determine the degree of stenosis, plaque morphology and systolic velocity of the internal carotid artery, CT angiography for aortic arch and carotid arteries and CT brain were performed to assess any brain infarction and exclude any hemorrhagic events before intervention.

Procedure:

Preoperative medications with dual antiplatlet therapy in the form of loading dose of clopidogrel 300 mg and aspirin 150 mg were given the night of the procedure. The procedure was performed with local anesthesia by a retrograde transfemoral access using 6F sheath. 5000 IU heparin was injected immediately after insertion of the sheath. Selective bilateral carotid angiography was performed to assess the lesion prior to intervention. A 0.035 stiff-angled guide wire is then advanced into one of the main branches of the external carotid artery (ECA). Replacing this wire by long stiff Amplatz wire

followed by long sheath 6F 90 cm length (Cook Medical Inc., Bloomington, IN) and positioned at common carotid artery (CCA) below the target lesion. Amplatz wire was removed.

The filter (embolic protection device; EPD) 0.014 guide wire (FilterWire EX™, Boston Scientific Corp, Santa Clara, CA or SpideRX™, ev3, Irvine, CA) was slowly advanced across the stenosis till the petrous portion of ICA and then, the filter basket was deployed in the straight portion of the cervical ICA. After deployment, an angiogram was performed to ensure that the basket is well opposed to the vessel wall.

Balloon pre-dilatation for the carotid stenosis was performed using a 0.014 coronary angioplasty balloon with a smaller diameter e.g. 1.5- 2 mm, especially for severe tight lesions or calcified lesions.

Self expandable stent (Wallstent, Boston Scientific Scimed or Precise stent, Cordis Neurovascular, USA) was deployed. The length of the stent was determined according to the lesion length (usually 20–40 mm) with avoidance of unnecessary excess lengths. When carotid stenosis involves the ostium of the ICA, stent positioning should involve the distal CCA& proximal ICA. In such cases, the diameter of the stent should match the distal CCA (most commonly using an 8 mm diameter straight stent or a 7–10 mm tapered stent). Post stent dilatation was performed by 5-6 mm diameter; 20 mm length balloon if significant residual stenosis was observed. Any residual stenosis up to 30% was as an acceptable result. Post-dilatation should be omitted in cases of mild residual stenosis, especially in symptomatic patients, bulky atherosclerotic or non-calcified plaques to decrease the high risk of distal embolization. Also, high pressure inflation should be kept away to avoid the risk of carotid dissection, perforation, and distal embolization.

After Retrieval of EPD, completion angiography of carotid bifurcation and intracranial circulation was performed to assess technical success, cerebral flow and collateral circulation.

Post-operative management:

Patients were closely monitored in intensive care units for 24 hours especially for blood pressure, heart rate and neurological deficits. MRI or CT brain was performed if the neurological status of the patient changed. Post procedure medications were prescribed for patients as enoxaparin every 12 hours for 2 days, Aspirin 150 mg daily for life, clopidogrel 75 mg/ day for at least 3 months and statins.

After discharge, patients were followed up at 1,6,12 months in outpatient clinic and assessed neurologically especially for the cognitive functions, motor and sensory system affection. Duplex examination was performed routinely at one, six and 12 months after procedure.

Study outcome: stroke, death, myocardial infarction were the study outcome if occurred immediately within first 30 days postoperative or through 1, 6, 12 months follow up.

Statistical analysis:

All statistical analyses were performed using SPSS statistical software. Descriptive statistics were done for parametric quantitative data by mean ± standard deviations.

Analysis was done by Chi square test between different groups and McNemar test between different times.

A b

Fig. (1) Right CCA& ICA stenosis ,a: before treatment, b:after stent deployment.

a b

Fig. (2) Left ICA stenosis ,a: before treatment, b:after stent deployment.

Results

This study included 30 patients presented to the vascular surgery department at 6 October insurance hospital with carotid artery stenosis for whom CAS was done during the period between August 2015 and December 2016. Patient's criteria and demographic data were summarized in table (1)

Table (1): Patients criteria and risk factors:

	(No.=30)
Age	**65.5 (45-81)**
Male / Female	**22 / 8 (73.3% / 26.7%)**
Risk Factors:	
DM	**23 (76.7%)**
Hypertension	**30 (100%)**
Smoking	**16 (53.3%)**
Hyperlipidemia	**30 (100%)**
Renal impairment	**5 (16.7%)**
Cardiovascular disease	**20 (66.7%)**

The main presentations were stroke 17/30 (56.6%), TIA 8/30 (26.7%) and asymptomatic patients 5/30 (16.7%). All asymptomatic patients were referred from cardiac surgery unit who were prepared for CABG and discovered accidentally by routine preoperative carotid duplex. All patients were investigated by duplex study and CT angiography of the aortic arch and its branches including carotid arteries. Only 5 patients that had renal impairment (creatinine >1.6) were diagnosed by duplex US. Twenty- five patients (83.3%) were symptomatic (14 patients of them with stenosis 50-70% and the

other 11 patients with stenosis >70%). The remaining 5 patients (16.7%) who were asymptomatic had stenosis >70%.

Table (2): Patients presentation, diagnostic tools and lesion criteria:

Patients presentations:	
Symptomatic	
Previous stroke	**12 (40%)**
TIA	**8 (26.7%)**
Asymptomatic	**10 (33.3%)**
Diagnostic Tools	
Both duplex US & CTA	**25 (83.3%)**
Duplex US only	**5 (16.7%)**
Lesion criteria	
Site of lesion	
ICA	**28 (93.3%)**
CCA	**2 (6.7%)**
Severity of lesion	
50-70%	**10(33.3%)**
>70%	**20 (66.7%)**

Balloon pre dilatation was done in 3 cases (10%) due to very tight lesions using coronary balloons 2mm in diameter. Filter EPD was deployed in all cases. Post stent balloon dilatation was done in 5 cases due to significant residual stenosis.

Regarding the complications; 3 patients (10%) developed stroke; one had intra operative stroke after stent deployment in spite of using the filter, the 2nd patient developed stroke at 6 month follow up by cerebral hemorrhage due to uncontrolled hypertension, the 3rd one stoke occurred during the 12th month follow up; CT brain showed patent stent & contralateral carotid stenosis 50%. Six cases developed TIA, their carotid duplex showed patent stent and CT brain show no recent infarction. Acute MI occurred in 3 patients; one was admitted to cardiac care and underwent coronary angiography while the other two cases died from massive MI. Two cases had intraoperative bradycardia either during stent deployment or balloon pre-dilatation and relived by immediate administration of atropine. Death in one case occurred 6 months postoperatively after CABG.

Table (3): Complications:

	Immediately (30 days) (n=30)	**6 months (n=30)**	**12 months (n=29)**	**P value**		
				Immediately versus 6m	**Immediately versus 12m**	**6m versus 12m**
Death	**0 (0%)**	**1 (3.3%)**	**2 (6.9%)**	**1**	**0.5**	**0.5**
Stroke	**1 (3.3%)**	**1 (3.3%)**	**1 (3.4%)**	**1**	**1**	**1**
TIA	**2 (6.7%)**	**2 (6.7%)**	**4 (13.8%)**	**1**	**0.687**	**0.687**
MI	**0 (0%)**	**1 (3.3%)**	**2 (6.9%)**	**1**	**0.5**	**0.5**

– **McNemar test for repeated measure qualitative data**

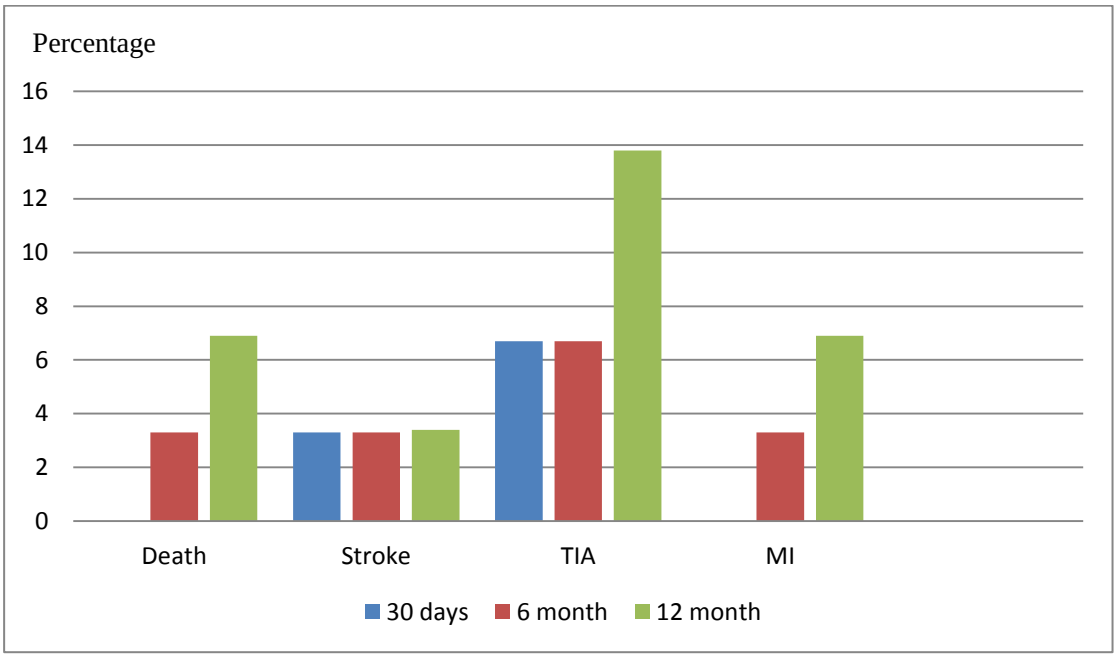

Figure (3): complications of the procedure.

Discussion:

Carotid endarterectomy has been established in late 20th century as the preferred method for prevention of stroke for symptomatic patients suffered from carotid stenosis >50% and asymptomatic patients with >60% carotid stenosis compared with medical therapy.(9) Moreover, broad-based guidelines support CAS for treatment of carotid artery disease in symptomatic and asymptomatic patients with high or average surgical risk features.(10) Also, recent evidences from randomized controlled trials and meta-analyses appreciated CAS with EPD for management of carotid artery stenosis as it offered better periprocedural outcomes comparable to CEA in patients with high risk for surgical approach.(11)

Patients included in this series were either symptomatic stenosis >50% or asymptomatic stenosis >70% and both had high surgical risks. They were diagnosed by CT angiography or duplex US. Brott et al,.(12) had recorded that the eligibility for CAS was extended to include asymptomatic patients with stenosis ≥60% by angiography or ≥ 70% by duplex US. International Carotid Stenting Study (ICSS) (13) had changed the inclusion criteria to enroll patients older than 40 years and had asymptomatic carotid artery stenosis ≥50%.

Regarding risk factors in patients of this study, the incidence of hypertension and hyperlipidemia were (100%) followed by DM (76.7%). ICSS trial had noticed similar results apart from decreased incidence of hyperlipidemia (61%). (13)

Male to female ratio in carotid artery stenosis is now widely accepted and can be attributed by the effect of female sex hormones that seem to play a protective role on vascular endothelial function, lipid homeostasis, and cardiovascular risk factors. (14) Also, Mathur et al (15) claim that estrogens might have a plaque stabilization effect and its role in inflammatory status. De Weerd et al., (16) found that prevalence of moderate stenosis increases with age in either men and women but men at all ages have higher prevalence estimates. In this study male to female ratio was 73.3% / 26.7%. Nearly similar results were obtained by sapphire study (17) in which the prevalence of males was 66.9% and females was 33.1%.

Duplex US is a widely available as a first-line imaging modality that can evaluate hemodynamic status of carotid vessels as well as its usefulness in decision making. Significant carotid artery stenosis is considered when peak systolic velocity is greater than 250 cm/sec or if the end diastolic velocity is greater than 120 cm/sec. Also, lipid-rich or heterogeneous hemodynamic profile indicates the presence of high-risk plaques. (18) Other modalities of investigations include CT angiography and MRI. Either CTA or MRI are useful when carotid stenosis is far from the carotid bifurcation and cannot be

detected by duplex US. Their benefits are in evaluation of aortic arch anatomy as well as carotid morphology. [19] In this series, all cases were diagnosed firstly by duplex US followed by CT angiography. Five patients (16.7%) were diagnosed by duplex US only because of presence of renal impairment.

Routine use of cerebral protection can achieve similar or even comparable results to surgery particularly in high surgical risk group, so the indications of CAS could be extended, especially for lesions with high embolic risks. [20] On the contrary, Reimers et al, [21] had reported in his series that Pro-Cas study; prospective comperative registry reported that 4709 patients were treated with EPDs and 3543 patients without use of EPDs. The conclusion revealed no difference in stroke and death rates between the 2 groups. International Carotid Stenting Study (ICSS) looked at patients who underwent (MRI) before and after CAS and CEA & for patients who underwent stenting with and without EPDs. They noticed that patients who had new ischemic lesions were more in patients treated with stenting and cerebral protection devices than without. Also, rate of stroke was higher in the EPD group (5.1%) than the unprotected group (2.4%). [22] They can be attributed by the following; use of EPDs can be worsened by tortuous vascular anatomy which need for pre-deployment ballooning angioplasty to cross through stenosis. Carotid lesion has to be crossed with the wire and filter; a step that is not protected and may end by dissections and possible embolic complications. Filter devices do not have ideal wall apposition, allowing material to embolize around the filter. Also, thrombus can be formed on the filter itself and then embolize around. Finally, EPDs add expense to the CAS procedure. [23]

In this series, the type of stent was closed cell stent design; precise stent and Wallstent. Sahin et al. [24] reported in his study that he used the two types of stents; open cell stent and closed cell stent randomly into 2 patient's groups and concluded that closed cell type are associated with low rate of ischemic stroke as a procedure related complication.

In this study, 10 patients (33.3%) were asymptomatic and referred to CAS because of their high surgical risk and immediate need for CABG. There are still questions about the management of asymptomatic carotid artery stenosis as they have low annual stroke incidence, and there are complications and costs associated with surgery. However, new era of pharmacologic agents such as antiplatelet agents, statins, and angiotensin-converting-enzyme inhibitors can stabilize atherosclerotic plaque and reduce the incidence of ischemic stroke.[25] Kamran and his colleagues[26] had reported in their series that the guidelines 2018 of Eueopean society of vascular surgery (ESVS) recommend that patients with asymptomatic carotid artery stenosis of 60–99% and average surgical risk should be considered for CEA only on condition where there is increased risk of late ipsilateral stroke. Aboyans et al, [19] had reported that symptomatic patients > 60% have an annual risk of ischemic stroke greater than 10% and thus reperfusion is recommended and becomes more beneficial when performed within 14 days while in asymptomatic stenosis, the need for reperfusion is limited because the annual risk of stroke recurrence is about 2% and concluded that, it is preferable to limit the use of reperfusion therapy in asymptomatic carotid artery stenosis to the following indications; presence of occlusion of the contralateral carotid artery, rapid progression of stenosis by clinical follow-up, presence of a silent brain infarction in CT brain and vulnerable plaque found on Duplex US.

In this study, patients were discharged on drug regimen as enoxaparin every 12 hours for 2 days, Aspirin 150 mg/ day for life, Clopidogrel 75 mg/ day for at least 3 months and Atorvastatin according to the presence or absence of dyslipidemia. This drug regimen protocol was recorded in ICSS trial [13] but with little difference in clopidogrel duration which was continued for 4-6 weeks only in asymptomatic patients and for 3 months in symptomatic patients.

Regarding to the 30-day stroke rate, stroke occurred in 3.3% (one patient), TIA in 6.7% (2 patients) with no deaths or MI. Both stoke and TIA incidences were observed in patients with carotid stenosis $\geq$ 70% while no complications have been occurred in patients with carotid stenosis less than this percentage. These results were consistent with Mathur et al, [15] who found that CAS performed in lesions with

angiographic severity > 90% stenosis were associated with higher 30-day stroke rate of 14.9% compared with lower rate of 3.5% in patients with lesion severity < 90% stenosis. Nearly similar results were obtained by CAVATAS study [27] and Angelini et al., [28]. Wallstent study [29] reported 12.1% stroke in symptomatic carotid stenosis (60 % - 99%). They attributed this high incidence as they didn't use EPD during CAS and thus, the neurological complications were due to embolization of atheromatous materials.

In this study, stent patency rate was 100% during the whole 12 months follow up period. In CAVATAS study, one-year patency rate was 86%. [27]

Stroke occurred in 3 cases (10%); one of them intraoperative mostly due to embolization in spite of using EPD, another one was due to cerebral hemorrhage at 6th month and the 3rd one occurred in the 12th month postoperative. Death occurred in 3 patients (10%); two of them after extensive myocardial infarction and the other died after CABG by 6-month duration. In Caress study [30], one-year death and stroke rate was 10% and the combined end point of death, stroke, or MI was 10.9%. In sapphire trial [17] the combined endpoint of the death, stroke or myocardial infarction rate at one year was 11.9%.

CAS is characterized by better quality of life (QOL) especially during the early recovery period when compared to CEA regarding to physical limitations. These differences diminished over time and were not evident after 1 year. [31]

The International Carotid Stenting Study (ICSS) investigators compared CAS and CEA in prevention of stroke, death, and procedure-related heart attacks in 1713 patients suffered from symptomatic carotid stenosis. Findings concluded that patients in CAS group had a significantly greater risk of stroke, death, or procedure-related heart attack. [32]

A recent and novel technique for management of carotid artery stenosis is transcarotid artery revascularization (TCAR) which provides an alternative to carotid endarterectomy (CEA) and (CAS) for high-risk patients. This hybrid technology approached carotid arteries directly with cerebral blood flow reversal for embolic protection during stent deployment. It is characterized by its minimally invasiveness and low risk of stroke. [33] This procedure reported less stroke rates in comparison to CEA 1.8% versus 2.4% at 30 days and 1.8% versus 3.6% at one year (P ¼ NS). Regarding the complications, it was noted that cranial nerve injury, and myocardial infarction rates were similar with a decreased rate of mortality at 30 days (p ¼ .026). [34]

Conclusion:

Management of carotid stenosis is challenging in high risk patients. Stroke prevention is the main goal of successful treatment. Risk–benefit assessment should be based on patient status, plaque characteristics and procedural risk, rather than on the argument between CEA and CAS.

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