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Assessment of Endovascular Management of Extracranial Internal Carotid Artery Stenosis

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ABSTRACT

Background: carotid artery stenting (CAS) had become widely used as an alternative to carotid endarterectomy (CEA) in revascularization therapy of carotid artery stenosis, especially in some high risk patients for surgical intervention**.**

Objective: the purpose of this study was to evaluate the outcome and follow up of cases that undergo extracranial CAS at the Neuroendovascular Unit of Ain Shams University Hospital.

Methods: during a 30 month period, 50 cases were enrolled and underwent carotid artery stenting with open cell (Protégé® - EV3) or closed cell (Wall stent® - Boston scientific) stents. A filter device for embolic protection (Spider filter® - EV3) was used. Clinical assessment with the National Institute of Health Stroke Scale (NIHSS) together with post procedural diffusion-weighted magnetic resonance imaging (DW-MRI) was used to determine cerebral embolization.

Results: CAS was performed in 50 cases; 40 (80%) symptomatic and 10 (20%) asymptomatic . A similar number of open-cell and closed-cell stents were used. New acute cerebral emboli were detected with DW-MRI in 12% (6/50) of cases after the procedure. Three (3/50) cases (6%) showed corresponding clinical deterioration in NIHSS; two cases developed minor stroke and the third case developed a major stroke.

Conclusion: CAS at Ain Shams Neuroendovascular Unit showed a high technical success rate and good short term clinical outcome.

Keywords: Carotid artery stenting (CAS), brain DW-MRI, NIHSS.

INTRODUCTION

Carotid interventions are effective measures in preventing stroke and death among patients with significant carotid stenosis[1]. Although carotid endarterectomy (CEA) has been the primary treatment option for carotid stenosis, carotid artery stenting (CAS) is currently an equivalent alternative especially in patients with a high risk for CEA[2]. The Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) did not reveal any significant differences between CAS and CEA among standard risk patients based on a composite primary end point of peri-procedural stroke, myocardial infarction, or death and ipsilateral stroke thereafter, although a higher risk of stroke with CAS and a higher risk of myocardial infarction with CEA were observed during the peri-procedural period[3]. Diffusion weighted magnetic resonance imaging (DW-MRI) is an imaging technique frequently used to detect cerebral microembolization during carotid interventions. Because adverse neurologic events after CAS are rare events in high-volume practices, quantification of microembolization using DW-MRI may be used as surrogate end-points of cerebral embolization during CAS[4]. The goal of this study is to evaluate the outcome and follow up of cases with symptomatic and asymptomatic extracranial carotid stenosis undergoing CAS at the Neuroendovascular Unit, Ain Shams University Hospital.

PATIENTS AND METHODS

During a 30 month period, 44 patients with significant carotid stenosis were enrolled and underwent CAS with open-cell or closed-cell stents. Indications for CAS were either symptomatic (50% or greater) or asymptomatic (80% or greater) carotid stenosis. This was determined with duplex ultrasound scan and confirmed during the procedure with digital subtraction angiography. Measurement of angiographic carotid stenosis (percentage by diameter) was performed according to North American Symptomatic Carotid Endarterectomy

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(NASCET) methodology. Exclusion criteria included the presence of anticipated or potential sources of cardiac embolization, total occlusion of the ipsilateral carotid artery, sever stroke with sever disability that makes the patient inappropriate for study participation, intramural carotid thrombus and history of contrast nephropathy.

This study was reviewed and approved by the Local Ethics Committee at Ain Shams University. After eligible patients agreed to participate in the study and signed informed consent, patients underwent stenting with either an open-cell stent (Protégé® - EV3) or a closed-cell stent(Wall stent® - Boston scientific). A filter device for embolic protection (Spider filter® - EV3) was used.

Neurologic evaluation was performed using the NIHSS by trained and certified neurologist before the procedure, immediately after and at 30-day follow-up visit. All CAS procedures were performed under local anesthesia through retrograde access from the common femoral artery. All patients received dual anti platelet therapy with aspirin 150 mg once daily and clopidogrel 75mg once daily, one week before the procedure or aspirin 150 mg and cloipidogrel 300 mg, one day before the procedure and continue on them postoperatively. All procedures were completely performed by an interventional neurologist at the Interventional Neurology Unit **(Siemens machine)**, Ain Shams University Hospital. Pre-dilatation was selectively performed using 2.5 mm in diameter balloons. Post-dilatation was also selectively performed using (5-6) mm balloons if residual stenosis after stent placement was 20% to 30%. Completion angiograms, including cervical and cerebral views, were routinely obtained; before intervention and after embolic protection devices deployment.

All patients had brain DW-MRI obtained before CAS, within 48 hours after the procedure and whenever necessary within the one month follow up period. DW-MRI was obtained using standard head coils on 1.5-Tesla. On the post-procedural MRI, acute embolic lesions were defined as focal hyperintense areas with restricted diffusion signal, which were confirmed by apparent diffusion coefficient mapping to rule out artifacts. New post-procedural cerebral lesions consistent with microemboli were recorded in terms of location and number for all DW-MRI examinations performed. The DW-MRI studies were assessed by readers blinded to the clinical status, stent design, and outcomes of the patients. Secondary endpoints included technical success, major or minor stroke, transient ischemic attacks, death, and stent thrombosis.

Statistical Analysis

Statistical analysis of the results was done using the mean, standard deviation (± SD) and range for parametric numerical data, the median and interquartile range (IQR) for non-parametric numerical data, and frequency and percentage of non-numerical data.

RESULTS

The study included 44 patients who underwent 50 CAS as 6 patients underwent bilateral stenting. Base-line characteristics of the study group are shown in table (1). All cases were assessed by brain MRI and carotid duplex. The findings are illustrated in tables (2) and (3). All cases underwent DSA to confirm the carotid duplex findings before stenting. The degree of stenosis by DSA ranged from 55% to 97% with a mean of 82.58%±11.27. All patients underwent CAS. Twenty five cases (50%) with closed cell design stents and 25 cases (50%) with open cell design stents. Twenty six cases (52%) underwent right CAS and 24 cases (48%) underwent left CAS. Forty cases (80%) were symptomatic. Among them, 15 cases (30%) underwent CAS within two weeks of symptoms (early) and 25 cases (50%) underwent CAS after two weeks of symptoms (delayed).

Table (1): Base-line characteristics of the population study.

Age (Mean ±SD)	63.92 ± 5.14	
Males (n ,%)	36	72%
Females (n ,%)	14	28%
Symptomatic (n ,%)	40	80%
Asymptomatic (n,%)	10	20%
Smoking (n ,%)	25	50%
Diabetes (n ,%)	39	78%
Hypertension (n ,%)	36	72%
Ischemic heart disease (n ,%)	23	46%
Dyslipidemia (n ,%)	32	64%

n= number

Table (2): Initial brain DW-MRI findings of all cases.

Findings	**Number**	**%**
Carotid infarction	29	58.0%
Carotid **territory** infarction	12	24.0%
Carotid **watershed** infarction	8	16.0%
Carotid **lacunar** infarction	9	18.0%
Vertebrobasilar infarction	1	2.0%
No recent infarction	20	40.0%

Table (3): Carotid duplex findings of all cases.

		Number	**%**
Type of carotid stenosis	Unilateral stenosis	33	66.0%
	Bilateral stenosis	12	24.0%
	Unilateral stenosis with contralateral occlusion	5	10.0%
Degree of carotid stenosis	stenosis <70%	9	18.0%
	stenosis ≥70%	41	82.0%

Fourteen cases (28%) with tight carotid stenosis underwent pre-dilatation angioplasty with 2.5 x 20 mm balloon. While all cases underwent post-dilatation angioplasty. Among them, 47 cases (94%) with 5.5 x 20 mm balloon, 2 cases (4%) with 6 x 20 mm balloon and one case (2%) with 5 x 20 mm balloon.

All cases were assessed using NIHSS as a base line before CAS, immediately after and at one month follow up visit. Changes in the NIHSS are illustrated in table (4). Six cases (12%) showed new lesions at brain DW-MRI. Among them, three cases (6%) showed corresponding clinical deterioration and the other three were asymptomatic. Among cases with new brain lesions, one case (1/26) underwent right CAS and five cases (5/24) underwent left CAS. Four cases (4/40) were symptomatic and 2 cases (2/10) were asymptomatic. The three cases that showed clinical deterioration were symptomatic and underwent left CAS.

Table (4): NIHSS changes of all cases from baseline value to one month follow up.

		Number	**%**
NIHSS change after intervention	No change	47	94.0%
	Mild deterioration	2	4.0%
	Moderate deterioration	0	0.0%
	Severe deterioration	1	2.0%
NIHSS change at one month Follow up	No change	31	62.0%
	Improvement	18	36.0%
	Deterioration	1	2.0%

Mild deterioration = (1-4 scores change of the initial NIHSS).

Moderate deterioration = (5-15 scores change of the initial NIHSS).

Severe deterioration = (> 15 scores change of the initial NIHSS).

DISCUSSION

This clinical study was designed as a prospective single center trial to evaluate the outcome and follow up of cases that undergo extracranial CAS at the Neuroendovascular Unit, Ain Shams University Hospital. The study was conducted over 2.5 years (between 2013 and 2016).

Forty four patients were enrolled and underwent fifty CAS procedures. Out of them, six patients underwent bilateral ICA stenting. Males were more frequent in our sample (36/50) which is similar to what is reported in previous studies [5]. The mean age of our patients was 63.92(±5.14) years**.** Age and multiplicity of risk factors are thought to be the determinant of carotid artery disease [6]. The mean age of the present study is younger than other previous studies such as SAPPHIRE and CAVATAS; 72.6 and 67 years respectively [7,8]. The presence of patients with younger age in the current study may be explained by the difference in vascular risk factors between the current study and the other studies. Diabetes mellitus was more frequent in this study than in other studies. Other factors were similar. Diabetes

mellitus helps in early atherosclerosis of the vessels especially when combined with other risk factors, and subsequent early occurrence of carotid stenosis in younger age. Diabetes Mellitus was the most prevalent risk factor in our sample (39/50). Diabetics are at higher risk to develop carotid stenosis than the non-diabetics [9]. Hypertension was the second most prevalent risk factor (36/50). Hypertension accelerates the progression of atherosclerosis. Systolic hypertension is an independent predictor of carotid artery stenosis [10]. Thirty two patients had dyslipidemia (32/50); this is in line with the fact that there is a strong relationship between total cholesterol, low-density lipoprotein cholesterol, and the extent of extracranial carotid artery atherosclerosis and wall thickness.

Cerebral embolization is considered one of the main limitations of CAS. Brain DW-MRI had been extensively used to detect periprocedural subclinical brain ischemic injury after carotid interventions [11]. In this study, brain DW-MRI was used to delineate ischemic brain events during and after CAS. Because several neurologic events occur after removal of the embolic protection device and completion of the CAS procedure, it is presumed that a high proportion of stented carotid lesions continue to release embolic material after the carotid intervention [12]. In the current study, we observed that new brain DWI lesions occur after carotid stent placement with the use of protective devices in six of our cases. This is in agreement with the previous studies [13,14].

The lesion load in our study was low, new ischemic lesions were noted only in 6 cases (6/50). Among the explanation for this, is the use of better tools nowadays concerning the exchange system and the use of flexible guiding catheters instead of the long sheath together with the most important factor in our opinion which is the avoidance of pre-stenting balloon dilatation which was not routinely done. It was selectively done in 14 of our cases with tight stenotic lesions, to allow passage of the stent across the lesion under filter protection device. Another explanation might be the younger age range of our sample.

In our study the clinical neurological event rate was (3/50). This result was in keeping with previously reported series CAVATAS [15]. There was a subclinical injury rate of (3/50), as detected by DWI scanning which was significantly lower than Jaeger and his colleagues who found DWI detected infarcts at 22% of patients undergoing CAS [13]. Again this is due to the better tools available nowadays and the fact that either DWI is too sensitive and identifies lesions that are not clinically significant or that standard neurological examination is too crude to pick up subtle changes associated with these lesions and more complex tests of higher cerebral function are necessary .

In the current study, the frequency of periprocedureal clinical strokes occur more among patients with symptomatic carotid stenosis than asymptomatic carotid stenosis (one month stroke rate was 3/40 and 0/10 respectively). This finding is similar to the CREST study (one month stroke and death rate 6.0% in symptomatic versus 3.2% in asymptomatic patients). A pooled analysis of 2104 patients derived from four major studies (SAPPHIRE, CASES, CNC, and ADVANCE) of which 24.2% patients were symptomatic found that asymptomatic patients had a 30-day stroke and/or death rate of 3.8% compared to 5.3% in symptomatic patients [16]. The higher rate of ischemic events among symptomatic patients may be due to plaque characteristics, which is characterized by fissure, intramural microthrombi, inflammation and higher embolic load. This is the cause for recurrent strokes in patients with carotid artery diseases and may be a cause of cerebral embolization during the procedure [17].

In this study, three cases with new DWI lesions associated with clinical deterioration (i.e. occurrence of stroke). Two of them rapidly improved within one week after the procedure. The third case was initially ok. After one week, the patient came with recent left middle cerebral artery (MCA-M1) occlusion and marked deterioration of the NIHSS. At one month follow up visit, the NIHSS partially improved but still more than the base line value. No cases with transient ischemic attacks, death or stent thrombosis were recorded within the one month follow up period.

CONCLUSION

CAS at Ain Shams Neuroendovascular Unit showed a high technical success rate and a good short term clinical outcome.CAS is a safe and efficacious procedure specially with the availability of proper materials and experienced staff.

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