

Evaluation of Carotid Stenting in the Treatment of Symptomatic Carotid Stenosis

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Abstract: Background: Extracranial carotid artery stenosis, is usually caused by an atherosclerotic process and is one of the major causes of stroke and transient ischemic attack. Carotid artery stenting was initially positioned as a good alternative to carotid endarterectomy in high risk patients. The benefits of carotid artery stenting include minimal incision, limited potential for complications, short hospitalization, and rapid recovery. **Aim of the work:** to evaluate carotid stenting in the treatment of symptomatic carotid stenosis. **Patients and methods:** The patients were subjected to detailed medical history, general and neurological examination, laboratory investigations, electrocardiography and imaging including vascular images of the brain and carotid arteries. Carotid stenting was done to all the studied patients. **Results:** There was a significant difference between patients presented with transient ischemic attack (TIA) and patients with stroke (p value = 0.008); all patients presented with (TIA) showed improvement with no restenosis or recurrence and all patients presented with stroke had a stationary course with no restenosis or recurrence. There was a significant difference between the eccentric and concentric stenosis on carotid stenting outcome; all the concentric stenosis showed improvement with no restenosis or recurrence and all the eccentric stenosis showed a stationary course with no restenosis or recurrence (p value = 0.008). **Conclusion:** Carotid angioplasty and stenting is an option for higher risk symptomatic patients and patients with health risks precluding surgery. The presenting symptoms; TIA or stroke; have a significant effect on the carotid stenting outcome. Intra-operative angiography is very important in early diagnosis of distal filter occlusion Hyperperfusion syndrome must be expected in cases of severe carotid stenosis especially with the use of heparin.

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1. Introduction

Stroke is one of the leading causes of death in the world and carotid artery stenosis is a major cause of ischemic strokes.¹ Ischemic stroke is the most common serious neurological problem worldwide and is anticipated to become an epidemic.^{2,3} Sixteen percent of ischemic strokes are due to a carotid atherothrombotic disease. Early detection is key to avoiding a potential stroke.³ Atherosclerotic plaques ultimately cause narrowing or thrombosis of the vessel segment that may result in the reduction of flow in the vessel and impede vascular flow to the brain. Alternatively, recent discoveries have identified that certain types of plaques may contain areas with potential for rupture, which may lead to small blood clots, emboli, or fragments that propagate into the cerebrovascular circulation. This leads to occlusion of a distal cerebral vessel, causing a stroke.^{4,5}

Carotid artery stenosis can result in wide-ranging stroke syndromes or transient ischemic attack (TIA) symptoms.⁶ Conventional angiography has been considered the standard method for evaluating carotid stenosis. However, the introduction and development of

ultrasound doppler, CT angiography (CTA), and MRI angiography (MRA) have been replacing angiography for diagnostic purposes, essentially reserving it for endovascular treatment.⁷ Carotid angioplasty and stenting is an option for higher risk symptomatic patients who have other health risks precluding surgery.⁸ The aim of the work is to evaluate carotid stenting in the treatment of symptomatic carotid stenosis.

2. Patients and Methods

This study is a prospective intervention study. It was conducted on 10 patients with symptomatic carotid artery stenosis presented to the Neurosurgery Department, Tanta University Hospital, Tanta University, Egypt during the period between 10/ 2020 and 10/ 2021. The study was approved by the scientific and ethical committee of medicine. An informed consent was obtained from all patients. The inclusion criteria included patients with symptomatic carotid artery stenosis (60-99%). The excluded criteria were patients with symptomatic carotid artery closure (100, unfavorable aortic arch anatomy (a heavily calcified

aortic arch), inaccessible endovascular techniques such as severely tortuous vessels, patients with a contraindication to radiation or dye injection, pregnancy and coagulation profile disturbance.

Methods:

All Patients in the study were subjected to clinical evaluation, laboratory investigations and imaging. Imaging included vascular imaging of the brain; CT, CTA, MRI and MRA brain and vascular imaging of the carotid arteries including duplex ultrasonography with high-frequency probes [B-mode duplex ultrasound, estimation of Peak Systolic Velocity (PSV), End Diastolic Velocity (EDV), ICC/CCA PSV ratio and diagnosis of ICA stenosis using doppler criteria (table 1)⁷], maximum intensity projection (MIP) of 3D-CT angiography and Time-of-Flight (TOF) Magnetic Resonance Angiography with or without contrast. Electrocardiography (ECG) as done for a studied patients. All patients were given Acetylsalicylic Acid (Aspidol -75) [2 tablets /day after meal for 7 days prior to operation] and oral anti-platelets; Ticagrelor; (Brilique-90 mg film coated tablets) [one tablet/12 hours 2 days before operation]. Pre-operative x ray pictures of the carotid artery were done. The diagnostic phase of the endovascular intervention included insertion of 5Fr catheter, intravenous anticoagulation (a bolus dose of 100 unit/kg unfractionated heparin), injection of contrast material into the carotid artery through the catheter, antero-posterior, lateral and sometimes oblique projections to optimally visualize the stenosis and angiographic measurement of the stenosis by the North American Symptomatic Carotid Endarterectomy Trial (NASCET) criteria.⁹ If the stenosis failed to meet criteria, the procedure was terminated. If not the diagnostic 5Fr catheter was replaced with guiding catheter 8Fr. The therapeutic phase of the endovascular intervention is angioplasty and stenting procedures which included distal filter placement in which a Spider FX filter [embolic protection device] was inserted beyond the narrowing to catch any debris that may break off from the narrowed area of artery during the procedure. The filter was deployed in the straight terminal segment of the cervical carotid artery with enough distance from the stenosis to allow sufficient space to deliver the stent. Once deployed, adequate apposition to the carotid arterial wall needed to be ensured by angiography because if the device is too small, emboli may not be captured, and if too large the embolic protection device (EPD) may cause arterial injury or induce vasospasm. Special attention was made to minimize cranial-caudal motion of the EPD once deployed, as excess motion may also lead to dissection or, more commonly, vasospasm. In cases of severe stenosis, predilation of the stenosis after distal filter placement and before the stent placement

was done. The balloon tip was threaded into the narrowed area and inflated to push the plaque to the side and widen the vessel. Atropine 0.5 to 1 mg was prepared to give it immediately if bradycardia occurred. Stent Placement: Closed-cell stent [Carotid WALLSTENT or Casper Stent] or Open-cell stent [Protégé™ RX GPS™ self-expanding peripheral and carotid stent system] was used. The suitable stents regarding the length and diameter were used to cover the stenosis and to achieve optimal wall apposition respectively. After placing the stent, postdilation was done using balloon angioplasty inflator, inflated angioplasty balloon and deflated angioplasty balloon. After the stent placement and post-dilation, the distal filter was observed for trapped embolic material before recaptured. An aspiration catheter was used to clear any trapped debris. Once the distal filter is recaptured, removal under fluoroscopic observation was done as the EPD may engage the stent margin because it is withdrawn through the stent. After its successful removal, a completion angiogram including both the cervical ICA and the intracranial circulation was performed to evaluate for residual stenosis, exclude vasospasm or dissection, and evaluate intracranial blood flow. The completion angiogram was compared with the pre-procedure angiogram. After removal of the balloon, filter, catheter and sheath, pressure was applied to the small catheter insertion site to prevent bleeding. Intra-operative difficulties and complications were reported. When the procedure was done, the patient lied still in one position while pressure was applied to the site to stop bleeding, a dressing was applied to cover the small incision site and clinical focusing on post-operative occurrence of any complication or neurological deficits. All patients were given Aspidol -75 (Acetylsalicylic Acid) [2 tablets /day after meal] and Brilique-90 mg film coated tablets (Ticagrelor) [one tablet morning and evening] up to 3 months post-operative. CT-Brain immediately after procedure to exclude any intra-cranial hematomas. MRI-Brain with diffusion one day after procedure to exclude ischemic infarctions. Duplex Ultrasonography is done monthly in the first 3 months. MR-Angiography is done after 3 months and 1 year. DSA if needed. Monthly clinical follow up in the first 6 months then a visit every 3 months in the next 6 months, focusing on post-operative occurrence of any complications or neurological deficits.

Statistical Analysis:

The collected data were organized, tabulated and statistically analyzed using SPSS version 19 (Statistical Package for Social Studies) created by IBM, Illinois, Chicago, USA. For each variable, the number and percentage were calculated and differences between subcategories were tested by Fisher's exact test. The level of significant was adopted at $p < 0.05$.

3. Results

This study was conducted on 10 patients with symptomatic carotid artery stenosis presented to the Neurosurgery Department, Tanta University Hospital, Egypt in the period between 10/ 2020 and 10/ 2021.

Five patients out of ten (50%) presented with transient ischemic attack and the other five (50%) with stroke as shown in table (2). As shown in table (3), there is a significant difference between patients presented with transient ischemic attack (TIA) and patients with stroke (p value 0.008); all patients presented with (TIA) showed improvement with no restenosis or recurrence and all patients presented with stroke had a stationary course with no restenosis or recurrence.

Regarding the side of carotid stenosis (table 4), Fifty percent of the right sided and left sided patients showed improvement with no restenosis and the other 50% had a stationary course with no restenosis with no significant difference. Also, the laterality of the stenosis had no significant difference on the stent outcome (p value 1.000). As shown in (table 4) and , 57.1% of the patients with ICA stenosis of 60-80% had improvement with no stenosis and only 33.3% of the patients with ICA stenosis of 60-80% had a stationary course with no significant difference (p value 1.000). Regarding the shape of the stenosis, there is a significant difference between the eccentric and concentric stenosis; all the concentric stenosis showed improvement with no restenosis and all the eccentric stenosis showed a stationary course with no restenosis with a significant difference (p value 0.008). The presence or absence of plaque ulceration had insignificant difference on the stent outcome; the presence of plaque ulceration

increased the incidence of improvement. Also, there was no significant difference between the presence or absence of the plaque calcification on the stent outcome; the absence of plaque calcification increased the incidence of improvement with no restenosis[table 4].

As regards the effect of operative factors on the stent outcome (table 5), the use of general or local anesthesia had no significant difference on the stent outcome (p value 1.000). The pre dilatation was used in only 3 cases having severe carotid stenosis. There was a statistically significant difference between the use of carotid protégé (open) and other stents [carotid casper stent (closed) and carotid wall stent (closed)] (p value 0.048); all patients with closed stents showed improvement with no restenosis and only one out of 6 patients with open stent had improvement with no restenosis. As shown in table 5, distal filter was used in 9 patients; 4 out of 9 (44.4%) showed improvement with no restenosis and 5 patients (55.6%) had a stationary course with no restenosis. Intra-operative distal filter occlusion occurred in 2 cases out of 10 (20%) after stent placement and immediately retrieved by the filter retrieval catheter. The latter case showed improvement with no restenosis or recurrence.

Only one case out of ten (10%) suffered from delayed recovery, headache and altered conscious level (hyperperfusion syndrome) for 3 days and gradually improved and discharged from the hospital after 1 week. Carotid stent complications as carotid artery dissection, carotid artery perforation, acute stent thrombosis, contrast agent encephalopathy, sustained hypotension / bradycardia, post-operative intra-cranial hemorrhage and post-operative infarction were not encountered in this study.

Table 1: Doppler criteria for diagnosis of ICA stenosis⁷

Diameter stenosis (%)	PSV (cm/sec)	EDV (cm/sec)	ICA/CCA PSV ratio
Normal	<125	<40	<2.0
<50	<125	<40	<2.0
50-69	125-230	40-100	2.0-4.0
≥70	>230	>100	>4.0
Near total occlusion	Variable	Variable	Variable
Total occlusion	Undetectable	Undetectable	Not applicable

ICA, internal carotid artery; PSV, peak systolic velocity; EDV, end diastolic velocity; CCA, common carotid artery.

Table (2): Clinical presentation of studied patients

Variables	Number	%
Transient ischemic attacks	5	50.0
Stroke	5	50.0

Table (3): Clinical presentations and stent outcome in the studied patients

Variables	Outcome				p
	Improved with no restenosis or recurrence		Stationary with no restenosis or recurrence		
	n	%	n	%	
Vascular accidents					0.008*
Transient ischemic attacks	5	83.3	0	16.7	
Stroke	0	0.0	5	100.0	

*Significant

Table (4): Factors related to the ICA stenosis and stent outcome in the studied patients

Variables	Outcome				p
	Improved with no restenosis or recurrence		Stationary with no restenosis or recurrence		
	n	%	n	%	
Side of stenosis:					1.000
Right	2	50.0	2	50.0	
Left	3	50.0	3	50.0	
Laterality of stenosis:					1.000
Unilateral	4	50.0	4	50.0	
Bilateral	1	50.0	1	50.0	
Degree of stenosis:					1.000
60-80	4	57.1	3	42.9	
81-100	1	33.3	2	66.7	
Shape of stenosis:					0.008*
Eccentric	0	0.0	5	100.0	
Concentric	5	100.0	0	0.0	
Plaque ulceration					0.524
Absent	2	33.3	4	66.7	
Present	3	50.0	1	50.0	
Plaque calcification					0.206
Absent	4	80.0	1	20.0	
Present	1	20.0	4	80.0	

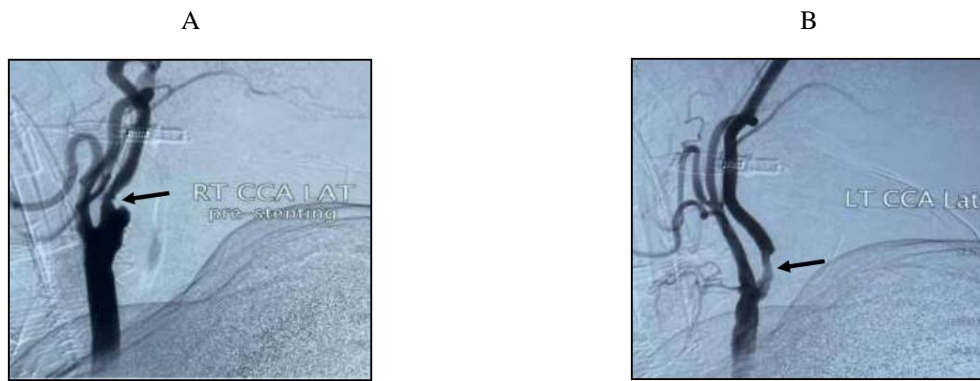
*Significant

Table (5): Operative factors and stent outcome in the studied patients

Variables	Outcome				p
	Improved with no restenosis or recurrence		Stationary with no restenosis or recurrence		
	n	%	n	%	
Type of anesthesia:					1.000
General	4	50.0	4	50.0	
Local	1	50.0	1	50.0	
Pre dilatation					1.000
Absent	4	57.1	3	42.9	
Present	1	33.3	2	66.7	
Stent type:					0.048*
Carotid protégé (open)	1	16.7	5	83.3	
Closed stents	4	100.0	0	0.0	
Distal filter					1.000
Absent	1	100.0	0	0.0	
Present	4	44.4	5	55.6	

*Significant

Case 1



Pre-stenting Rt CCA angiogram (lateral view). The arrow points to the Rt CCA stenosis

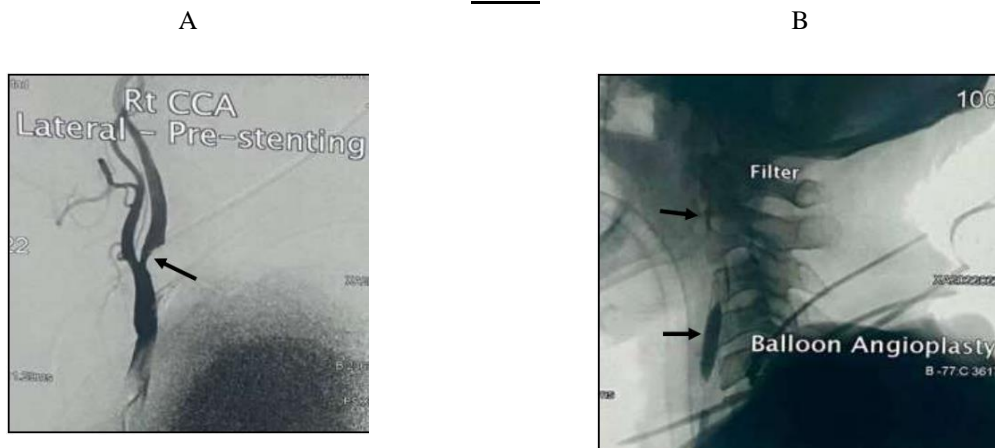
Pre-stenting Lt CCA angiogram (lateral view). The arrow points to the Lt CCA stenosis (ulcerated plaque)



Balloon dilation (arrow)

Post-stenting Rt CCA angiogram (lateral view). The arrow points to stent in place

Figure 1 (A-B-C-D): A 76-year-old male patient, known to be diabetic, hypertensive, cardiac, smoker & hyperlipidemic, presented with recurrent transient ischemic attacks. carotid duplex & CTA showed bilateral ICA stenosis, more on the left side. Carotid artery stenting on the right side using Carotid WALLSTENT™ & SpiderFX Embolic Protection Device was done. Stenting of left ICA is rescheduled later on. In this case, intraoperative distal filter occlusion occurred after stent placement and immediately retrieved by the filter retrieval catheter. Patient follow up showed no further TIAS occurred.

Case2

Pre stenting Rt CCA angiogram. The arrow points to Rt CCA stenosis

Balloon Angioplasty with distal filter in place. Upper arrow points to distal filter and lower arrow points to balloon angioplasty

Post-stenting Rt CCA angiogram (lateral view). The arrow points to stent in place

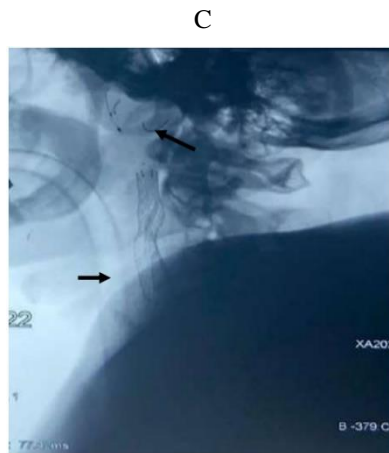
Stent in place (arrow)

Figure 2 (A-B-C-D): A 65-year-old male, known to be diabetic and hypertensive presented with dysphasia and right side weakness with a history of stroke 3 years ago. Preoperative carotid duplex & CTA showed Rt ICA stenosis. Carotid artery stenting on the right side using Protégé RX Carotid Stent & SpiderFX Embolic Protection Device was done. Post-operative, this patient suffered from delayed recovery, headache and altered conscious level (Hyperperfusion syndrome) for 3 days and gradually improved and discharged from hospital after 1 week. Patient follow up showed no further deterioration or further stroke events

Case 3

Pre-stenting right ICA angiogram showing right ICA high grade stenosis. The arrow points to Rt ICA high-grade stenosis.

Post-stenting right ICA angiogram with stent in place. The arrow points to stent in place



Stent in place with distal filter. Upper arrow points to distal filter and lower arrow points to stent in place

Figure 3 (A, B, C): A 56 year old female, known to be diabetic, hypertensive and hyperlipidemic presented with right side weakness and dysphasia with history of previous 2 strokes. Preoperative carotid duplex & CTA showed Rt ICA stenosis (99%). Carotid artery stenting on the right side using Protégé RX Carotid Stent & SpiderFX Embolic Protection Device was done. Patient follow up showed no further deterioration or further stroke events

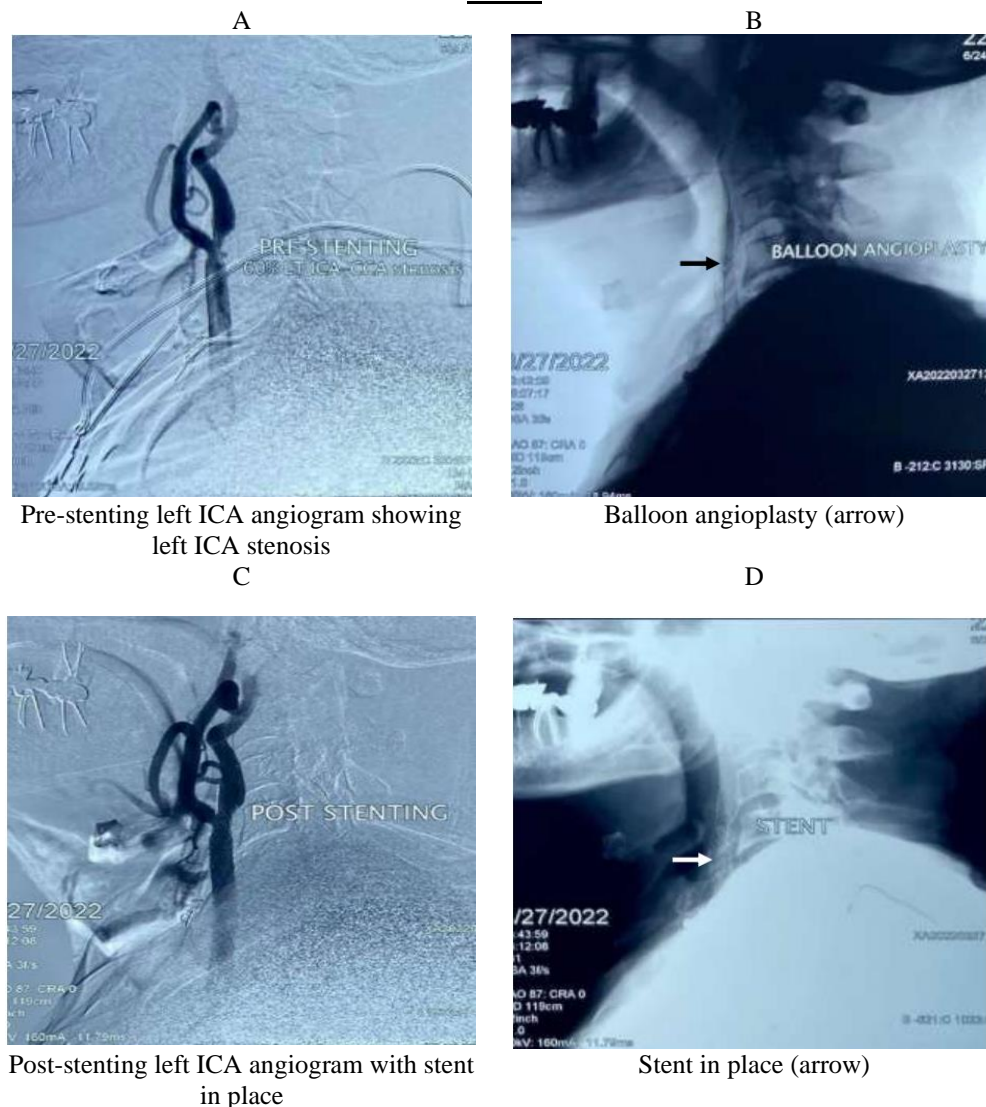
Case 4

Figure 4 (A, B, C, D): Eighty one year old male, known to be diabetic, hypertensive and hyperlipidemic presented with recurrent TIAs. Preoperative carotid duplex & CTA showed LT ICA stenosis. Carotid artery stenting on the left side using CASPER™ carotid stent. Distal protection device wasn't used in this case due to unfavorable anatomy. Patient follow up showed no further TIAs occurred.

4. Discussion

Carotid artery stenosis is a major contributor to ischemic stroke, found to be responsible for 15–20% of all strokes. Appropriate medical and/or revascularization management of these patients may provide a significant reduction in stroke burden in the future. Symptomatic carotid stenosis is commonly defined as stenosis in the internal carotid artery, either intracranial or extracranial, leading to symptoms of amaurosis fugax, transient ischemic attacks, or ischemic stroke ipsilateral to the lesion. Severe stenosis (70–99%) has been demonstrated to confer the highest risk for recurrent stroke or TIA. Current treatment options for

symptomatic carotid stenosis vary based on location of the stenosis - extracranial vs. intracranial.¹⁰

Extracranial carotid atherosclerosis is typically seen at the carotid bifurcation extending to the intracranial internal carotid artery in a portion referred to as the cervical segment. The patients with severe symptomatic extracranial atherosclerosis benefit from revascularization in addition to medical management. Revascularization techniques for extracranial carotid atherosclerosis include carotid endarterectomy (CEA) or carotid angioplasty and stenting (CAS).¹¹

CAS is an endovascular revascularization procedure performed utilizing balloon angioplasty and deployment of a stent over the culprit plaque to increase

the size of the lumen and reduce recurrent stroke risk.¹² Typically, patients who are felt to be particularly favorable for CAS are those who are high risk for surgery, such as those with contralateral occlusion, anatomical variations making surgical access technically difficult (radiation injury, history of prior neck dissection, presence of tracheostomy), or those with severe medical comorbidities making them high-risk for open surgery.¹³ Patients with symptomatic >70% carotid stenosis are thought to be at high risk of complications from CEA.¹⁰

In the present study, fifty percent of the patients were presented with transient ischemic attack and fifty percent with stroke. Only one patient who presented with stroke had a past history of transient ischemic attack. Wabnitz AM et al also stated that symptomatic carotid stenosis either intra-cranially or extra-cranial leading to transient ischemic attack or ischemic stroke ipsilateral to the lesion.¹⁰ The current study showed a significant difference between patients presented with transient ischemic attack and patients with stroke regarding the stent outcome (p value=0.008); all cases presented with transient ischemic attack showed improvement with no deterioration or recurrence and all patients presented with stroke showed a stationary course with no deterioration or recurrence that is logical.

In this study, the left internal carotid artery stenosis occurred in sixty percent of the studied patients, this is matched with Selwaness M et al study which reported that ischemic stroke is more often diagnosed in the left hemisphere than in the right.¹⁴ Luo X et al explained this fact by the difference of the hemodynamic and biochemical effects on the right and left carotid and their effects on the carotid artery intima-media thickness (CIMT) which is more thicker in the left carotid.¹⁵

Regarding the laterality of stenosis, eighty percent were unilateral and twenty percent were bilateral. The less symptomatic fellow eyes in bilateral cases rescheduled.

In this study, 43% of patients with 60-80% ICA stenosis presented with stroke with no improvement but with no deterioration or recurrence after CAS, 50% of patients with 81-90% closure stenosis presented with stroke with no improvement but with no deterioration or recurrence after CAS and the only one patient with 91-99% closure (100%) presented with stroke with no deterioration or recurrence after CAS that is logical. Mughal MM et al study explains the occurrence of ischemic stroke in cases of carotid artery stenosis by pieces of plaque break free and travel to the brain and block blood vessels that supply blood to the brain.¹⁶ According to the shape of stenosis, 50% of the studied patients had eccentric stenosis and the other 50% had concentric. There is a significant difference (p value=0.008) between cases with eccentric plaque and cases with concentric regarding the carotid stent

outcome; All cases with eccentric stenosis presented with stroke and showed no improvement after CAS with no restenosis or recurrence in the follow up period. On the other side all cases with concentric stenosis presented with transient ischemic attack and showed improvement after CAS with no restenosis or recurrence. This is aligned with Ohara T et al study which reported that eccentric plaque was associated with a significantly increased incidence of ipsilateral cerebrovascular events compared with patients with concentric stenosis.¹⁷

Concerning with plaque ulceration, 40% of the studied patients had plaque ulceration. 75% of them presented in the left side and 25% in the right. This is consistent with Sary HC et al study which referred the pathogenesis of plaque ulceration to the local hemodynamic factors; which have more effect on the left carotid than the right; and other factors.^{15,18} The presence or absence of the plaque ulceration had no significant difference on the carotid stent outcome. Fifty percent of the patients with plaque ulceration showed improvement after carotid stent and one third of the patient without plaque ulceration showed improvement. This can be explained by Kohyama et al study which conclude that persistent ulceration after CAS improves spontaneously and is not a risk factor for cerebral embolism.¹⁹

Plaque calcification in this study was present in fifty percent of the studied patients, 60% of them present in the right side and 40% in the left. This is aligned with Selwaness M et al study which stated that right sided carotid plaques are more liable for calcification.¹⁴ The presence or absence of the plaque calcification had no significant difference on the carotid stent outcome. Twenty percent of the patients with plaque calcification showed improvement after carotid stent and eighty percent of the patient without plaque calcification showed improvement. The less percentage of improvement of the patients with plaque calcification explained by the fact that the circumferential complexity of calcified plaques elicits a non-homogeneous circumferential stretch response whereby lumen gain is predominantly attained by stretching of the non-calcified portion.²⁰

. In the present study 80% of the carotid artery stent procedures were done under general anesthesia and 20% under local. The later was done in medically high risk patients. There was no significant difference between the two types of anesthesia on the carotid artery stent outcomes (p value =1.000). Aridi HD et al prefer the use of local anesthesia in general especially in medically high risk patients because general anesthesia seems to be associated with increased cardiac complications, length of stay and consequently hospitalization costs.²¹

Pre-dilatation procedure was done in 3 cases; 2 with 81-90% carotid artery stenosis and one case with 91-99% closure. Also Sahin et al do this procedure prior to stenting in cases of severe carotid artery stenosis.²² In this study the absence or presence of pre dilatation had no significant difference on the carotid stent outcome (p value=1.000).

Regarding the stent type, carotid protégé (open) was used in cases with tortuosity in the carotid artery (60% of cases). Carotid wall stent (closed) was used in 20% of cases and carotid casper stent (closed) in 20%. There is a significant difference between the outcome in patients with open stent type and the closed type (p value= 0.048); only one case with the open stent showed improvement and the other five showed no deterioration or recurrence, on the other side all cases with closed stent showed improvement. This can be referred to the clinical presentation of the cases; five cases out of six with open stent clinically presented with stroke and all cases with closed stent with transient ischemic attack. In this study all cases with open and closed carotid stent showed no deterioration or recurrence. This is not matched with Texakalidis et al study which stated that the cases with open cell stent design is associated with a decreased risk for restenosis when compared to the closed cell stent without significant differences.²³ Also Vries et al study concluded that open cell stenting resulted in a significantly higher number of sub-clinical post procedural new ischemic lesions compared with closed cell stenting²⁴ that is not recorded in the current study. These differences can be referred to the short period of follow up and the small number of the patients in this study.

Concerning with the use of distal filter in this study, distal filter was used in nine patients and could not be used in only one case because of the unfavorable anatomy. The occurrence of distal filter occlusion in 2 cases out of 10 (20%) give the importance of frequent angiogram during the CAS procedure.

Hyperperfusion syndrome occurred only in one case (10%) suffered from severe carotid stenosis and this is matched with Naylor AR et al study which stated that the syndrome typically occurs in patients with severe carotid stenosis.²⁵ In Cremonesi et al study, hyperperfusion syndrome occurred in 0.5% of cases.²⁶ The increased incidence in the present study can be referred to the use of heparin during the procedure.²⁷ Many of minor and major complications of CAS were not encountered in this study and this can be referred to the small number of the studied patients.

Conclusion:

Carotid angioplasty and stenting is an option for higher risk symptomatic patients and patients with health risks precluding surgery. The presenting symptoms; TIA or stroke; have a significant effect on the carotid stenting outcome. The eccentric type of

stenosis has a bad prognosis compared with the concentric type. Intra-operative angiography is very important in early diagnosis of distal filter occlusion. Hyperperfusion syndrome must be expected in cases of severe carotid stenosis especially with the use of heparin.

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