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Safety and Efficacy of Carotid Artery Stenting without the use of Protective Embolic Devices

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Abstract

Background: It is reported that the second most common cause of death worldwide is stroke. 15 to 20% of cerebral ischemia are due to extracranial carotid stenosis.

Aim of Study: The study aims at evaluating the efficiency and safety of carotid artery stenting. The chosen patients are those diagnosed with high risk carotid artery stenosis which will be delt by using non protective embolic devices.

Patients and Methods: Eighty patients eligible for the inclusion and exclusion requirements and referred to NIR unit as candidates for the procedure through 6 months period were included and underwent Carotid artery stenting (CAS) without Embolic protective device.

Results: In the present study, to evaluate the reliable and efficacy of CAS not protected by device, all the cases were assessed by the National Institutes of Health Stroke Scale (NIHSS) prior to the CAS. The immediate results after the intervention were as follows:

Seventy eight cases (97.5%) did not show change from their initial NIHSS. Two cases only underwent mild deterioration in their NIHSS. No cases experienced major disability strokes, as well as no related death occurred from neurological affection.

That was recorded during the procedure and in the follow -up duration.

Conclusion: Satisfactory safety and efficacy can be obtained during carotid stenting without protection devices when done by expert hands. This can be realized as we depend on tailored approach for patient choice especially in dealing with financial low resources.

Key Words: Carotid artery stenting – Protective embolic.

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Introduction

Stroke is classified as the commonest third source of man disability and second highest detectable one of death throughout the world *[1]*.

15 to 20% of cerebral ischemic accidents are due to extra cranial carotid stenosis *[2]*.

Asymptomatic carotid artery stenosis less than 75% carries a risk of stroke of 1.3% per year. When the stenosis exceeds 75%, both TIA and stroke rate is 10.5%. In symptomatic stenosis over 70%, the annual risk for stroke can reach up to 15% *[3]*.

In patients suffering severe symptomatic or asymptomatic carotid artery stenosis, the revascularization of the artery is obviously superior to aggressive medical treatment to avoid complicating stroke *[2]*.

Stenting of the carotid artery with protected devices can be accepted as less invasive and equal alternative to the traditional carotid endarterectomy (CEA). This procedure became widely applied in critical cases, although the role of protective devices is still in debate *[4]* ASA/AHA (American Stroke Association/American Heart Association) has suggested using CAS as a substitution to CEA in cases with symptoms with acceptable or non harmful adverse effects by minimal procedure inside the vessels. If the stenosis accounts to >70% detected by non invasive image or >50% by angiography, and when the predicted death estimate is less then 6%, CAS can be proceeded.

Asymptomatic patients with carotid stenosis >70% can also benefit from CAS. Moreover it can help in unfavourable neck anatomy due to previous

CEA of same side, vocal cord paralysis, tracheostomy, radical surgery or irradiation [5].

The neurology department at Ain Shams University Hospitals approved a recent study on Carotid Stenting without the use of cerebral protection device (CPD) [6].

The study was conducted upon 91 patients who underwent CAS without EPDs (embolic protection devices) concluding CAS was done safely [6].

As a result, by correlating profit with expenses, EPD is not be applied as a routine [6].

The purpose of cerebral protection devices (CPDs) is debatable, and their use might not be mandatory. A meta-analysis of 30 day stroke in random patients subjected to CAS and using EVA-35, SPACE and ICSS (n $^{1}/_{4}$ 1557) revealed that no evidence CPDs reduced perioperative stroke rates (OR 0.95, 95% Cl 0.38 – 2.41, p=0.92) [7].

In addition, a CSTC meta-analysis of three RCTs (n = 1557) mentioned that CPDs did not reduce the 20 day stroke/death (RR 1.1; 95% CI 0.71 – 1.70, p = 0.67) [8]

On the above assumption, the European society for vascular surgery (ESVS) 2023 recommended the use of CPD during CAS not as a solid routine indication but on a low level of evidence (level C) [9]. This is to be applied in the guidelines for management of atherosclerotic carotid and vertebral diseases.

Frequently, stenting can be complicated by distant thrombi, leading to cerebral ischemic outcomes. Various protecting measures are used, most commonly the filter protection device.

However, it is still doubtful about their efficacy. The success of their protection depends upon factors related to the filter itself such as capacity to control the system, the diameter, the length, pore size of the open filter. Moreover extrinsic factors can have their impact as the capability of the filter to work in sinuous carotid axes or in case of spasm, and problems in filter withdrawal. Some reports revealed intimal and subintimal histological damage from the protection filter device which could affect the number of intracerebral embolic complications [10].

Distal protection systems present some hazards due to the necessity of the appliance to penetrate through the narrowing. That is the cause of using devices which do not cross the stenosis. However ,being unsafe at times, they are not always utilized due to their interference to blood circulation,.as well as they need larger catheters liable to induce complications.

In many cases, embolism can happen when the procedure terminates and the device removed. The percentage of embolic accidents in relation to the procedure that benefit from the protection device does not exceed 25%.

The routine utilization of protective devices in elderly population is not justified as they are liable to clot formation and complications due to vessels tortuosity. Therefore the EPD add their risk to embolism [11].

Many reviews reported a decreasing number of patients who can suffer ipsilateral cerebral accidents or death if they undergo treatment with CAS and CPD [12,13]. However unchecked investigations related impressive outcomes in cases treated without protection appliances [14,15].

It was reported in a Meta-analysis that the use of protective devices can lower the incidence of stroke following carotid stenting; but still its efficiency was not clear, and therefore as a routine with patients having symptomatic lesions it is better to assess its mandatory use [16].

The use of balloon occlusion techniques and filter system is known to alter the duration, complexity and costs of the intervention; therefore it is of no need for CAS [12].

The literature compared the rates of periprocedural outcomes in patients operated with and without cerebral protection in the published stent-protected angioplasty, versus carotid endarterectomy in patients with symptoms (SPACE) trial [12].

The goal of the present work was to assess the safety and efficiency of CAS without the utilization of protective devices in patients suffering carotid artery stenosis, and facing high cost, and rarity of such devices.

Aim of the work:

The study aimed on evaluating the efficacy and the safe stenting of the internal carotid artery in absence of cerebral protective appliance in cases revealing symptoms of high risk stenosis of the internal carotid artery.

Patients and Methods

Eighty patients eligible for the inclusion and exclusion requirements and referred to NIR (Neurointerventional unit) unit as candidates for the procedure through 6 months period (from January 2023 to June 2023) were included and underwent CAS without protective devices.

The study was approved by the Ethical Committee of Faculty of Medicine Ain Shams University.

Inclusion criteria:

Symptomatic carotid stenosis (SCS) 70% or more by duplex or CT angiography as well as SCS of 50% or more by diagnostic phase of the digital subtraction angiography. North American Carotid Endarterectomy trial (NASCET) methodology was used to measure the degree of angiographic carotid stenosis. There was no sex, neither age predilection.

Exclusion criteria:

Contraindication to anticoagulants, antiplatelet therapy, bleeding diathesis, cardiac embolization as well as left ventricular aneurysm, cardiomyopathy, mitral or aortic heart values, calcified aortic stenosis, endocarditis, mitral stenosis, left atrial thrombus, any DVT(deep venous thrombosis), PE (pulmonary embolism), cardiac mass treated within the last 12 months, in addition to non-atherosclerotic carotid stenosis, intraluminal carotid thrombus. Disabling stroke as well as non stroke neurological deficits.

Study tools and procedures:

Patients were admitted the same day of operation and signed a consent after explanation of the details of procedure. Its benefits and risks were explained if needing brachiocephalic angiograply and possible stent application. That was applied in case of marked severity and when anatomically suitable.

Full history was taken, in addition to the neurological assessment using the National Institutes of Health Stroke Scale (NIHSS) by well trained personnel before and immediately after the procedure, and 24 hours later before discharge.

Symptomatic patients, and those with history of stroke or transient ischemic attacks or showed abnormal CT or MRI received dual antiplatelet therapy (aspirin 150mg once per day and clopidogrel 75mg also once daily). This regimen was applied one week before the procedure. Otherwise aspirin 150mg and clopidogrel 300mg was given the day before or 6 hours before the procedure if rapid intervention or in emergency cases. Post operative aspirin 150mg day was given for life and clopidogrel 75mg every day for six months. All procedure were done under local anesthesia and through right femoral artery approach.

Two well-trained interventional radiologists (with 13 and 19 years of experience) did the procedure at the Department of Neurointerventional radiology of hospital of Ain Shams University by monoplane neurovascular machine.

Cerebral and Cervical angiography were performed to all patients before stenting. Predilatation was selectively done by balloons 2.5 x 20mm. If after stent deployment there was residual stenosis higher than thirty per cent, then post dilatation was done using 5.5 x 20mm balloons. Control angiography was done for all cases at the end of the procedure to make sure of patency of the cerebral circulation and no distal embolism. Technically success was determined by the capacity to reach the carotid artery and stent the lesion effectively with no more residual stenosis than 30%. The procedure timing ranged from 30 minutes up to 2 hours depending on the difficulty to access the target artery to be stented.

Following the procedure: The femoral sheath was removed, then haemostasis was accomplished by manual compression.

All patients stayed hospital one night under close monitoring of their vital signs. Attention was paid keep their legs immobilized several hours to avoid bleeding from site of puncture.

Moreover neurological reassessment was obligatory done to detect any post procedure deficit. It was done immediately and 24 hours later before discharge of patient. Referring to neurological consultation was needed to detect any complications or if further intervention was needed.

Postprocedural medications:

Long life Aspirin 150mg per day was given and 75mg per day of clopidogrel for six months.

Neurological outcome was based upon examinations by a trained person preprocedural at day of admission, intraprocedural 24 hours and for 30 days after the procedure.

Patients who developed periprocedural stroke were subjected to formal neurological examinations and received NIHSS scores as well as brain DW-MRI obtained by using standard head coils.

Follow-up of all patients was achieved through telephonic contact and through referring to physi-

cians. The study end points were the development of stroke whether trivial or considerable and the occurrence of heart infarction or death within 30 days.

Minor stroke: Was defined as rise of the NIHSS score of less <3 with complete resolution and no impairment at 30 days.

Major stroke: It is an increase in the NIHSS score of 3 or more, with great disability at 30 days.

Results

Data management and analysis: The data of the patients were collected revised, put in tables and studied on a PC using SPSS25 (Statistical Package for Social Science). Data was presented and analysed according to the data obtained for each parameter.

Descriptive statistics: These are mean, standard deviation (+SD) and range for parametric numerical data, whereas Median and Interquartile range (IQR) for non-parametric numerical data.

Frequency and percentage of non numerical data are done.

Table (1): Demographic data for the study group.

	Mean / N	SD / %	Median (IQR)	Range
Age (years)	59.33	7.58		
Gender:				
Female	33	41.3%	58 (52 – 66)	(48 – 76)
Male	47	58.8%		

Table (2): Risk factors for the study group.

	N	%
Hypertension	29	36.3
Diabetes	53	66.3
Dyslipidemia	32	40.0
ISHD	20	25.0

Table (3): Interval between symptoms and stenting for the whole study group.

	N	%
Interval between symptoms and stenting:		
<2 weeks	8	10.0
>2 weeks	72	90.0

Table (4): Duplex finding and clinical presentation for the grouped studied.

	Mean / N	SD / %	Median (IQR)	Range
Percent of carotid stenosis by angiography (%)	80.74%	9.46%	85% (72.5% - 88%)	(60% - 98%)
Carotid duplex findings:				
Left	38	47.5%		
Right	38	47.5%		
Bilateral	2	2.5%		
Bilateral more on the left	1	1.3%		
Bilateral more on the right	1	1.3%		
Clinical presentation:				
Stroke	50	62.5%		
TIA	30	37.5%		

Table (5): Peri-procedural complications and need to angioplasty for the study group.

	N	%
Peri-procedural stroke:		
Negative	78	97.5%
Positive	2	2.5%
Peri-procedural death:		
Negative	80	100.0%
Angioplasty:		
Post procedural angioplasty only	75	93.8%
Pre and post procedural angioplasty	5	6.3%

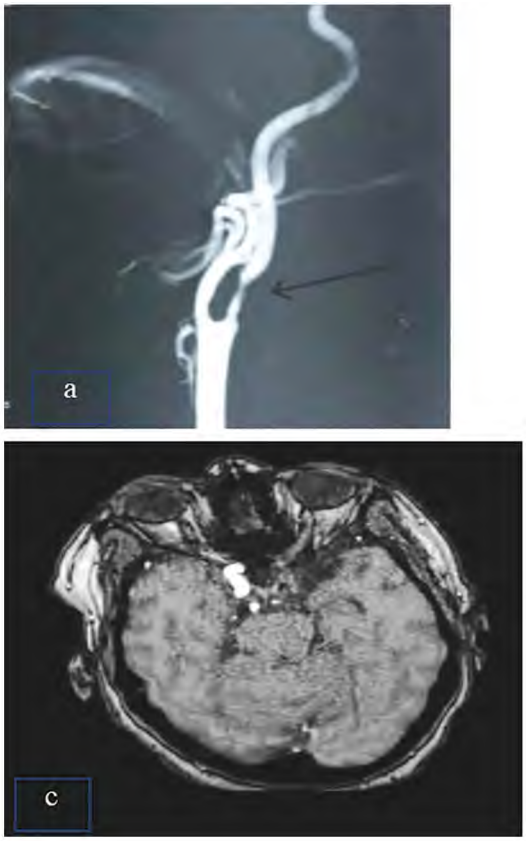

Fig. (1): 63 years old female hypertensive, hyperlipidenic, diabetic patient with history of passive smoker complaining from two previous transient ischemic attacks the last one was one month before stenting. The complaint was paresthesia on the right side of both upper and lower limbs. Mild dysarthria was present NIMSS = zero. (A) Intracranial angiography shows proximal ICA stenosis about 85% (by NASCT method). (B) Delayed carotid stenting without protection was applied one month after the onset of symptoms with pre and post stenting angioplasty. Post stenting greatly improved the intracranial flow. The residual stenosis was less than 30%. The NIHSS changed to eight one hour after the procedure. (C) Follow-up brain MRI stroke protocol revealed scattered areas of lacunar infarctions in the periventricular and occipital regions and total occlusion of left ICA. The patient NIHSS improved to two, one week later and he left the hospital. Physiotherapy to the affected right arm was advised. On one month follow-up the NIHSS became zero with regaining of the full motor power.

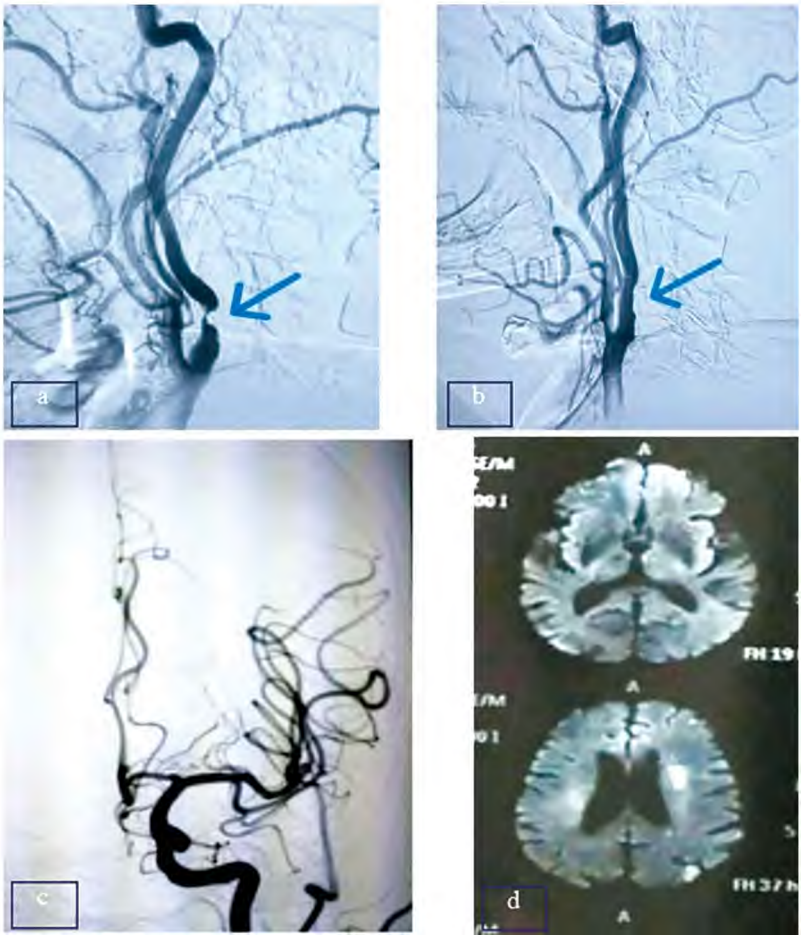

Fig. (2): 75 years old smoker, hypertensive, hyperlipidemic male patient with history of ISHD on medical treatment complaining of previous several TIA of the left MCA distribution, 3 months before stenting. Baseline NIHSS before the procedure = zero. (A) Intracranial angiography before stenting revealed stenosis of the internal carotid artery on the left side up to 90%. He was subjected to delayed unprotected carotid stenting with pre and post dilatation angioplasty. (B) The extracranial part of the left internal carotid artery after stenting with marked improvement of the intracranial flow was observed with less than 30% residual stenosis. (C) The intracranial portion of the left internal carotid artery after intervention. The NIHSS after the intervention became three immediately. (D) Brain DW-MRI follow-up, 2 small embolic points were discovered. The NIHSS of this patient was reestablished to the base level in the following 7 days.

Discussion

Stroke is the most serious complication of carotid artery stenosis. It can result from hemorrhage, thromboembolism, hypoperfusion, hyper perfusion syndrome.

Generally speaking, the percentage of cerebral accidents (stroke) for Transfemoral-CAS (TF-CAS) is 3 to 4%. Improvement in device technology and experience of the operator has decreased this percentage.

Complications as bleeding, blood collection, remote thrombi, pseudoaneurysm can be associated to CAS. Moreover it can result in related renal failure, heart infarction, fracture of stent or restenosis [17]. Several protective devices are present and are targeting to prevent complications during stent insertion. In most percutaneous CAS procedure, filter devices are used, although benefit for EPDs is not definitely established.

The new recommendations from the European Society for Vascular Surgery (ESVS) reported absence of better information to approve using protective devices. Even though, practitioners of carotid stenting usually advocate utilizing EPDs while dealing with CAS (class 11 a level b) **[9].**

In addition, numerous studies favor the use of proximal or distal EPDs, although still the probability of cerebral accidents or embolism is present. [18].

Concomitant, researches on unprotected carotid stents are fewer in the present times or they were done mostly as subanalysis of other studies **[19].**

It is reported in some investigations that EPDs were not efficacious in dealing with brain lesions with ischemia, or due to stroke **[20,21].**

Two trials by meta-analysis were done and proved that the final result whether stroke or death was the same for CAS (protected) when compared to those unprotected. The trial was stent protected Angioplasty versus carotid Endarterectomy (SPACE) and the other, Endarterectomy versus Angioplasty in severe carotid stenosis (EVA-3S) **[22].**

Moreover it is reported that unprotected techniques can decrease the neurological risk of periprocedural complications. Theoretically severe atherosclerosis and vascular tortuosity might increase the prevalence of embolism or thrombosis in situ. Although protection devices aim to minimize the emboli, yet they require some maneuvers that can facilitate their release or can cause vasospasm or dissection **[23].** In high risk lesions emboli can be dislodged during passage of the device through the lesion ("unprotected" lesion crossing).

Other troubles include misplacement of the filter basket, inexact handling of the lumen and liberation of trash materials **[23].**

The problem of the distal protection systems is the need for the device to pass through the stenosed segment. Therefore other devices were created and were not intended to cross the stenosed part. Yet these proximal devices are not suitable for all patients and necessitate larger catheters liable also to complications **[24,25].**

At times, embolization can arise near the end of the maneuver, after the removal of all devices due to plaque displacement adjacent to the common carotid itself or aortic arch. Only 25% of the embolism related to the maneuver can be avoided by the protection devices.

The Evidence-based using the EPDs as a routine in elderly peoples is not justified as such population would suffer added danger of embolus formation and other problems related to the tortuous aspect of the vessels **[26].**

Good comprehension of the vessels anatomy during CAS procedures is a must.

Therefore planning a successful CAS, necessitate well knowledge of brain anatomy.

Safe and fast catheterization can be limited by a severe tortuous carotid artery. The aortic arches type and length might vary from patient to another and become more tortuous and elongated with senility. As a result, the origins of the major branches become more difficult to reach. Severe tortuosity of the ICA may hinder the correct placement of a distal EPD far from the stent deployment, and serious vessel spasm can occur. Consequently the vessel morphology will determine the selecting device for CAS **[27].**

A decrease in the complication percentage was noticed on studying the EPDs. This fact was attributed to the better progress in instrumentation and better skill of the practitioner rather than to the EPD itself. In agreement to this assumption, a single-center series dealing with CAS without protection noticed a remarkable decrease in the thirty days minor stroke rate in the 5^{th} year, as compared to the 1^{st} year (3.1 versus 7.1, respectively). This study included 528 patients **[28].**

The related neurological impairments to the procedure and the new cerebral ischemic lesions involved only two cases in our study which represent a low lesion load (2/80) denoting a 30 day risk of stroke/death of 2.5% in symptomatic patients.

This percentage is much lower than the accepted risk during achieving carotid artery stenting in symptomatic patients with carotid artery stenosis (50-99%). The guidelines in the recent ESVS 2023 reaches up to 6%. The result was in agreement with former investigations [29,30].

In the present study, before dealing with CAS, all cases were assessed clinically by the NIHSS. Seventy eight cases (representing 97.5%) preserved their initial NIHSS. Only in two cases (2.5%) the NIHSS mildly declined.

The first patient studied, an old man 75 years, suffered stenosis of internal carotid artery up to 90%, with NIHSS base level zero. He underwent pre and post dilatation angioplasty in conjunction to a stent for the carotid artery. Instantly after the procedure, the NIHSS rised to three. The brain DW-MRI in the follow-up revealed two recent small embolic foci. One week later, the patient reached the initial NIHSS.

The second case in our study, a female aged 63 years, was diagnosed as near total occlusion of internal carotid artery on the left side. NIHSS was zero before the procedure. Delayed carotid stenting was done with pre and post dilatation angioplasty. One hour after procedure the NIHSS rised to eight. Brain MRI stroke protocol revealed on the left-side dispersed areas of acute lacunar infarctions in the periventricular and occipital areas as well as total occlusion of left ICA. This might be the result of exaggerated manipulations through the stenosed artery. The NIHSS dropped to two, one week later. The patient left the hospital with advice of physiotherapy to the affected right arm. After follow-up for one month, the NIHSS dropped to zero and full motor power was regained.

In the present study, the only case who clinically deteriorated, occurred while stenting a left internal carotid artery. Similar complication was reported previously by Naggara and colleagues. They observed such fact that CAS for left sided stenosis was associated with cerebral stroke on the same left side rather than a stent done to a right side occluded artery [31].

Difficulty to reach the left common carotid might speculate the higher rate of complications of the stenting. It would take more time to reach the stenotic segment which open the way to more complications.

Moreover, as the right hemisphere is the non eloquent one, strokes might pass asymptomatic in case of stenting the right common carotid artery.

Regarding time of revascularization of the two cases in our study, it was noticed a delay resulting from periprocedural neurological events which have evolved from the delayed stenting (more than 2 weeks after the last symptoms).

This is in agreement with data of the North American Symptomatic Carotid Endarterectomy Trial (NASCET) and European Carotid Surgery Trial (ECST). These trials approved that a revascularization of a non disabiling stroke due to transient ischemic attack is found to markedly improve the results if done in a period not longer than 2 weeks [32].

In 2016, a meta-analysis was done for evaluation of pooled data from patients complaining of symptoms of carotid impairment by the trials of SPACE, EVA-3S, Carotid Revascularization Endarterectomy versus Stent trial (CREST) and European Carotid Surgery Trial (ICSS)trials. [33]. They mentioned that for cases designed to TF-CAS (Transfemoral carotid artery stenting), a global danger of cerebral accident or death from the procedure would increase with age as follows:

In comparison to cases below sixty years, the danger was elevated for those aged 65 to 69 (relative risk ratio [HR] 2.2, 95% CI 1.1-4.1); for patients 70 to 74 years (HR 4, 95% (I 2.2-7.3), for patients 75 to 79 years (HR 3.9, 95% CI 2.1-7.3) and for patients aged more than 80 (HR 4.2, 95% CI 2.2-7.8) [33].

In our study no difference was recognized in the outcome of periprocedural risk of stroke and death in patients aged below sixty nine years or older than seventy years, as the two cases belonged to two different age group.

This result denote that our practice is a safe one depending on the most recent international guidelines, which are associated to ameliorated stent technology over the years, increased practitioners performance, accurate patient selection and preoperative evaluation.

The good results of our study could be due to (a) better choice of materials regarding the exchange system, by using pliable conducting catheters better than the long sheath, (b) reducing the appliances which passover the obstruction before stenting; this can be achieved by discontinuing use of filter and

limiting the use of balloon dilatation before stenting unless in very tight stenotic lesion so that the stent could pass (was done only in five cases) (c) focusing our study and evaluation of the complications of the procedure that can evolve upon not the EPD. This is a distinction from other studies which neglect the assessment of the effectiveness of the EPD.

Conclusion:

Stenting of the carotid arteries can be performed in the absence of protective devices, achieved by expert hands that can realize security and efficient consequences.

Moreover the outcome is almost satisfactory so long as we depend on tailored approach for patient choice, especially in dealing with financial low resources.

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سلامة وفاعلية استخدام دعامات الشريان السباتي بدون استخدام اجهزة الحماية من الصمات

الخلفية: تعتبر السكتة الدماغية هى ثانى أكثر أسباب الوفاة شيوعاً فى جميع أنحاء العالم. ١٥ إلى ٢٠ ٪ من حالات نقص التروية الدماغية ناتجة عن ضيق الشريان السباتى خارج الجمجمة.

الهدف من العمل: تهدف الدراسة إلى تقييم كفاءة وسلامة دعامات الشريان السباتى. المرضى الذين تم اختيارهم هم المرضى الذين تم تشخيص إصابتهم بضيق الشريان السباتي عالى الخطورة والذى سيتم علاجه باستخدام الدعامة دون استخدام أجهزة وقائية للانسداد.

المرضى والطرق: خلال فترة الدراسة تم تضمين ٨٠ مريض من المعرضين للخطر.

النتائج: فى هذه الدراسة، تم تقييم مدى موثوقية وفعالية دعامة الشريان السباتى بدون استخدام اجهزة الوقاية. وكانت النتائج المباشرة بعد التدخل على النحو التالي ثماني وسبعون حالة (٩٧,٥ ٪) لم يحدث تغيير فى مؤشر تحديد شدة الجلطة كما كان قبل العملية حالتان فقط تم تغيير فى مؤشر تحديد شدة الجلطات وكان هذا التغيير بسيط. لم يحدث اى اعاقة كبيرة او وفيات نتيجة جلطات بالمخ تم تسجيل ذلك أثناء الإجراء وفى مدة المتابعة.

الخلاصة: يمكن الحصول على سلامة وفعالية مرضية أثناء إجراء دعامة الشريان السباتى بدون أجهزة حماية عند إجرائها بأيدي خبراء. يمكن تحقيق ذلك من خلال الاعتماد على نهج مصمم خصيصًا لاختيار المريض خاصة فى التعامل مع الموارد المالية المنخفضة.