Carotid endarterectomy versus carotid artery stenting without protection devices for the management of carotid artery stenosis

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Background
Ischemic stroke represents a major health problem and it is an important cause of long-term disability. The aim of this study was to compare short-term results of carotid endarterectomy and stenting without the use of cerebral protection device.

Patients and methods
During a 2-year period, we enrolled 40 patients with carotid artery stenosis and performed 18 carotid endarterectomy operations and 22 carotid artery stenting procedures without distal protection devices.

Results
Mortality was zero. The main postoperative results after endarterectomy were as follows: one patient developed hemorrhagic stroke and another one developed myocardial infarction. With carotid artery stenting, one patient developed minor stroke and two patients developed restenosis.

Conclusion
No superiority of certain procedure over the other was found. Proper patient selection is the key to successful outcomes when deciding the optimal treatment for carotid artery stenosis. Carotid stent placement without the use of distal protection devices was found to be a safe and effective procedure with a relatively low incidence of periprocedural complications.

Keywords:
endarterectomy, stenting, stroke

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Introduction

Carotid endarterectomy (CEA) is one of the most commonly performed peripheral vascular procedures for the prevention of stroke in patients with high-grade symptomatic or asymptomatic carotid artery stenosis. However, in the past few years, evidence has accumulated that carotid artery stenting (CAS) might become an alternative to CEA for the treatment of these disorders [1]. Prior studies comparing CEA and CAS were confused with the use or nonuse of cerebral protection devices (CPDs) that are presumed to offer protection from microemboli during CAS. However due to their bulky profiles, the use of these devices has been shown in some studies to actually increase the risk for cerebral emboli and stroke [2,3]. Accordingly, the most important plan for CAS with or without cerebral protection remains unresolved. In this trial, we aimed to compare CEA versus CAS with minimal touch approach aiming to avoid stroke.

Patients and methods

After approval of the ethical committee in our faculty, 40 patients with carotid artery stenosis from July 2012 to December 2014. All patients were subjected to the following: medical history taking; physical examination; laboratory investigations such as complete blood count, prothrombin time and concentration, lipid profile, liver function tests, and kidney functions tests; radiological investigations (carotid duplex ultrasound assessment and computed tomography angiography), neurological consultation, and cardiac consultation. After the procedure, patients were followed up weekly for 1 month and then monthly for 1 year with clinical evaluation and carotid duplex assessment. Our 40 patients were divided into two groups. In group A (surgical treatment) (18 patients), CEA was performed with carotid shunt for four patients and without shunt for 14 patients (according to the stump pressure, six patients underwent right carotid artery stenosis and 12 patients underwent left carotid artery stenosis). In group B (endovascular treatment) (22 patients), CAS was performed with primary stenting and balloon dilatation for 14 patients and without balloon dilatation with self-expanding stenting for eight patients.

CEA

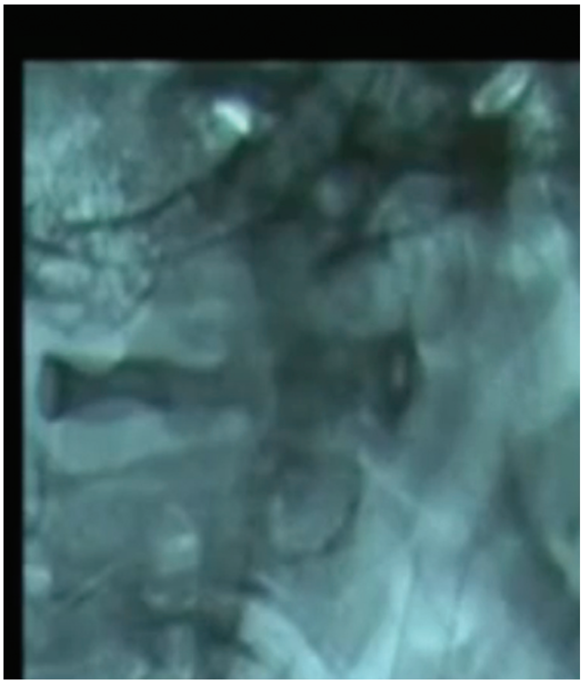
Inclusion criteria	Exclusion criteria
Asymptomatic carotid artery stenosis more than 70%	*Medical criteria*: Severe cardiac disease [congestive heart failure, need for coronary bypass surgery, recent cardiac operation, or recent myocardial infarction (MI)], severe pulmonary disease, dialysis-dependent renal failure, or age greater than 80 years
Symptomatic carotid artery stenosis more than 60%	*Anatomic criteria*: Prior ipsilateral endarterectomy, prior radical neck surgery or radiation, contralateral carotid occlusion, permanent tracheal stoma, stenosis secondary to arterial dissection, and contralateral laryngeal nerve palsy

Timing: CEA was performed in symptomatic carotid artery stenosis after 2 weeks from clinical presentation date of cerebral ischemia.

CAS

Inclusion criteria	Exclusion criteria
Asymptomatic carotid artery stenosis more than 70% or symptomatic carotid artery stenosis 60% or more with high-risk criteria	These include conditions that would make sheath placement difficult: Aortic arch angulation or atheromatous disease, tortuosity of the innominate or common carotid artery (CCA), tandem lesions within these access vessels, and either disease involving the distal CCA or an external carotid artery (ECA) occlusion since the ECA is typically cannulated with a stiff wire to deliver the sheath into the distal CCA

Figure 1

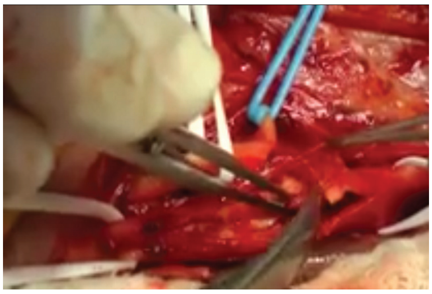


Carotid endarterectomy.

In CEA, control of the CCA is obtained proximal to the level of disease by surrounding the vessel with an umbilical tape. Once proximal control is obtained, dissection is continued distally around the ECA and its first branch, the superior thyroid artery. Subsequently, control is obtained distally at the internal carotid artery (ICA). Heparin (5000–7000 U) is administered intravenously. The ICA, the CCA, and the ECA are occluded, in that order. An arteriotomy is made with a no. 11 blade, starting anteriorly on the CCA proximal to the lesion and extending cephalad through the plaque opposite the flow divider, and then continued into the ICA with Potts scissors. Distal to the plaque, the arteriotomy is extended until it reaches a point where the ICA is relatively normal. Under general anesthesia, a shunt is placed by inserting the distal end of the shunt into the normal ICA distal to the lesion. Back-bleeding the shunt clears any air or debris, and the proximal end of the shunt is then placed well into the CCA, proximal to the plaque. The endarterectomy proper is begun with a Penfield elevator. The optimal endarterectomy plane is that between the inner and outer medial layers (Fig. 1). The proximal endpoint is obtained by sharply dividing the plaque in the CCA. The plaque can be elevated under full vision while the endarterectomy is continued into the carotid bulb. Carotid plaque that extends a short distance into the ICA may be teased medially toward the origin of the ECA to achieve an adequate endpoint. The plaque can also be divided in the bulb so that the ICA and ECA endarterectomies can be conducted independently. Once the plaque is divided, the device (clamp or loop) used to control the ECA is loosened, and an eversion endarterectomy is performed. In the ICA, the divided plaque is feathered so that a smooth taper is achieved in the transition to the normal distal intima. If a smooth distal taper is not achieved, placement of interrupted 7–0 monofilament tacking sutures may be necessary to secure the endpoint.

In CAS through femoral approach, the patient is placed in a supine position. Both femoral regions are

Figure 2



Carotid angioplasty and stenting.

prepared and draped in a standard manner. Anatomic landmarks are marked on the patient (i.e. the anterior superior iliac spine and pubic tubercle). The femoral pulsation is palpated, and a puncture needle is inserted one fingerbreadth below the inguinal ligament. Upon entry into the artery, a hydrophilic wire is inserted through the needle by means of the Seldinger technique. The needle is removed and is replaced by a 6 Fr sheath. A guide wire is advanced into the aorta under direct fluoroscopy. Diagnostic catheter is placed over the guide wire and positioned in the aortic arch. Heparin 80 IU/kg is administered. An aortogram is obtained in the left anterior oblique position at 45° of angulation. The aortic arch, innominate artery, left CCA, and left subclavian artery are identified. Selective catheterization of the left or right CCA is performed. The guide wire is placed in the ECA, and the diagnostic catheter is then placed in the ECA. The guide wire is replaced with a stiffer wire. A carotid arteriogram is obtained (in anteroposterior, lateral, and intracerebral views). The lesion is crossed with 0.014-inch wire. Predilatation is performed with a 2–3 mm balloon. The stent is placed across the lesion and deployed. A repeat arteriogram is performed. Any residual stenosis exceeding 30% is treated with balloon angioplasty (Fig. 2).

Results

The present study included 40 cases, of whom 28 (70%) were male and 12 (30%) were female with male-to-female ratio of 2.3: 1, with no statistically significant difference between male and female patients. As regards clinical presentation, 28 (70%) cases were presented with different neurological symptoms, whereas 12 (30%) cases were discovered accidentally. The percentage of carotid artery stenosis was 50–70% in 10 (25%) cases and 71–90% in 30 (75%) cases; unilateral complete occlusion was seen in four cases (Tables 1 and 2).

Table 1 Sex and presentation

	N (%)
Sex	
Male	12 (30.0)
Female	28 (70.0)
Presentation	
Symptomatic	28 (70.0)
Accidentally	12 (30.0)
Carotid artery stenosis (%)	
50–70	10 (25.0)
71–90	30 (75.0)
Unilateral 100[a]	4 (10.0)

Table 2 Sex, presentation, and the technique

	CEA [*N* (%)]	CAS [*N* (%)]	χ^2	*P*
Sex				
Male	5 (27.7)	7 (31.8)	0.07	0.78
Female	13 (70.0)	15 (68.2)		
Presentation				
Symptomatic	14 (77.7)	14 (63.6)	0.94	0.33
Accidentally	4 (22.3)	8 (36.4)		

CAS, carotid angioplasty and stenting; CEA, carotid endarterectomy.

Table 3 Carotid endarterectomy procedures

	N (%)
Side	
Right	6 (33.3)
Left	12 (66.7)
Shunt	
With shunt	4 (22.2)
Without shunt	14 (77.8)

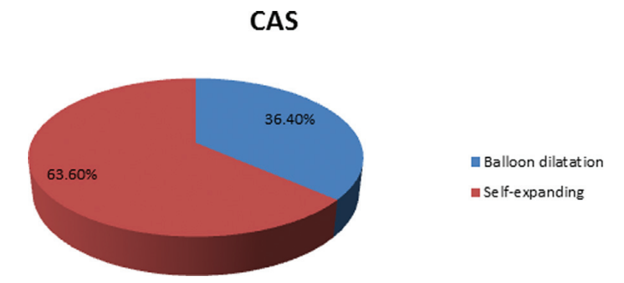
CEA was performed in 18 cases, six (33.3%) on the right side and 12 (66.7%) on the left side. In addition, shunt was performed in four (22.2%) cases, with a statistically nonsignificant difference as regards side of procedure or shunt (Table 3).

CAS was performed in 22 cases; eight (36.4%) of them were subjected to primary stenting and balloon dilatation, whereas 14 (63.6%) cases were subjected to stenting alone without postdilatation, with a statistically nonsignificant difference. No CPDs were used. In cases of CAS, one patient developed minor stroke (Table 4 and Fig. 3).

Table 4 Carotid angioplasty and stenting procedures (Fig. 3)

	N (%)
Stent	
Balloon dilatation (postdilatation)	8 (36.4)
Without (postdilatation)	14 (63.6)

Figure 3



CAS Procedures.

During the follow-up period, two patients with stent developed restenosis after 1 year. Following successful CEA operation, one patient developed major hemorrhagic stroke. This is caused by a high dose of heparin and clopidogrel in the postoperative period. During 1-year follow-up, one patient developed MI. He was a 66-year-old male, diabetic, and smoker with hyperlipidemia who presented with recurrent transient ischemic attacks (TIAs). He had been documented with coronary artery disease (frequently three vessel). In cases of CAS, one patient developed minor stroke, probably due to excessive preinflation and postinflation of the balloon. This patient was a 64-year-old female, diabetic, hypertensive who had coronary heart disease associated with hyperlipidemia. ICU stay was recommended for 3 days. Complete resolution was achieved within 1 month. During the follow-up period, two patients with stent developed restenosis after 1 year. One patient was treated for stenosis with re-entry and dilatation of stent. Another patient with bilateral carotid stenting had developed left carotid stent occlusion after 3 months of the procedure, which was defined through duplex follow-up and was not associated with neurological symptoms and remained asymptomatic (Table 5).

The low intraprocedural complication rate in our study may be related to several factors. Low-profile devices were used. The stents were not over expanded during postdilatation.

Discussion

Ischemic stroke is the leading cause of permanent disability in the developed world. Up to 20% of ischemic strokes result from atherosclerotic stenosis of the ICA [4].

Table 5 Early and late complication

	CEA [*N* (%)]	CAS [*N* (%)]	χ^2	*P*
Early				
Free	17 (94.5)	21 (95.5)	0.02	0.88
Stroke	1 (5.5)	1 (4.5)		
Late				
Free	17 (94.5)	20 (91.0)	2.8	0.23
MI	1 (5.5)	0 (0.0)		
Restenosis	0 (0.0)	2 (9.0)		

CAS, carotid angioplasty and stenting; CEA, carotid endarterectomy.

The prevalence rate of nonfatal cerebrovascular stroke in Egypt was 5.08/1000. Both the prevalence and incidence rates of cerebrovascular stroke were higher among male than among female patients [5]. It is estimated that ~700 000 incidents are reported annually in the USA [6]. Carotid revascularization with CEA has been shown to be superior to medical therapy for stroke prevention in symptomatic and asymptomatic patients with moderate-to-severe stenosis who meet well-defined medical and surgical selection criteria. The benefit of CEA is significantly higher in symptomatic compared with asymptomatic patients. CAS has emerged as an alternative in patients who are considered as having high surgical risk due to coexistent medical comorbidities or anatomical high-risk features [7].

Thus, the present study was designed to review the safety and efficacy of CEA and endovascular therapy of carotid artery stenosis after careful patient selection and to determine which therapeutic approach is suitable for everyone. Our results indicate that stents may safely and efficiently reduce neurological complications due to embolization.

The Brooks randomized trials comparing CAS with CEA were published in 2001 and 2004. The first publication focused on symptomatic patients; the latter focused on asymptomatic patients. Both studies reported low complication rates for either treatment and challenged the 'gold standard' of CEA [8].

The SAPPHIRE study tested the hypothesis that CAS was noninferior to CEA in high-risk patients. Most patients (~70%) in both treatment arms had asymptomatic carotid artery stenosis. The 30-day incidence of stroke or death was 3.7 and 5.3% for CAS-treated and CEA-treated patients, respectively. At 1 year, the incidence of stroke or death was 12.8 and 20.1% in CAS-treated and CEA-treated patients, respectively [9].

Subsequently, the SAPPHIRE investigators reported long-term results, and no difference between CAS and CEA was evident. The major secondary endpoint was any periprocedural stroke, death, or MI. At 3 years, the cumulative evidence for that endpoint was 24.6% for CAS-treated patients and 26.9% for CEA-treated patients ($P=0.71$) [10].

Shabaneh *et al.* [11] reported that CAS has significantly evolved over the last decade as techniques and equipment have continued to improve. CAS is being performed more frequently in community hospitals with reasonable results, as seen in multiple registries. The most recent randomized trials that have compared CAS versus CEA have shed considerable light on the safety and efficacy of stenting. The results of the most recent trial, carotid revascularization endarterectomy versus stenting, confirmed the safety and efficacy of stenting [11]. In addition, Guay [12] at the end of meta-analysis reported that, compared with stenting, CEA decreases the risk for stroke at 30 days, increases the risk for MI, and does not affect the risk for death.

Although early results of the treatment of carotid artery stenosis with CAS have been promising, comparison with a retrospective group of patients undergoing CEA indicates that CEA is the safer procedure. Furthermore, long-term follow-up will be necessary to determine whether CAS may be a useful alternative treatment for carotid artery stenosis in selective high-risk patients with significant carotid stenosis [13].

The incidence rate of TIA within 30 days was relatively higher in CAS than in CEA. It is presumed that the complications are relevant to the procedure, in which the wire must pass through the atherosclerotic lesion with severe stenosis or total occlusion. Besides, the complications might be associated with the stent design. Carotid stents are now made of nitinol and available in closed-cell and open-cell designs. Although the closed-cell design has better plaque coverage compared with the open-cell design, it still incises the plaque and causes many small emboli. The incidence rate of TIA is in accordance with the stroke/death rate within 30 days. Recent studies have demonstrated that overall survival is significantly lower in patients with postoperative TIA, which is an independent predictor of decreased survival at the 5-year follow-up [14]. Results from these studies demonstrate CEA and CAS to be associated with equivalent major stroke incidence and death, whereas carotid percutaneous transluminal angioplasty is associated with a significantly higher incidence of minor strokes [15].

Our results are in agreement with a meta-analysis of three of the recent trials that found that the perioperative risk for stroke or death was significantly higher with CAS (8.9%; 153/1725) than with CEA (5.8%; 99/1708). The investigators concluded that CAS for the treatment of people with symptomatic carotid artery stenosis should be avoided among people older than 70 years [16].

In their study, Hiyama *et al.*[17] included 36 men and five women, aged 61–83 years (mean: 72.3 years), who underwent CEA for the treatment of carotid artery stenosis. These results are in agreement with the present work as regards the increased prevalence of carotid artery stenosis in male in comparison with female patients and in old age than in younger age, although the percentages are quite different. This difference may be attributed to different inclusion criteria, different samples sizes, and different risk factors between populations in both studies.

A major concern during carotid artery stent placement is the potential for cerebral embolism. Diminishing the number of device manipulations across the lesion might reduce procedural stroke risk. For this purpose, we report our experience with carotid stent placement without the use of distal protection device. Timler *et al.*[18] reported that no randomized trials have compared CAS with CPDs versus CAS without CPDs. However, the availability of CPDs seems to decrease the risk for embolic complications as described by the carotid artery stent registries [19].

Although all distal CPDs are able to capture and remove embolic debris, this does not eradicate embolic complications. Inability to deliver or deploy the CPD, CPD-induced vessel injury, ischemia caused by occlusion, and incomplete embolic debris removal may all result in embolic cerebral complications. Stents used are mostly self-expanding, but balloon-expandable stents can be used when treating the ostium of the CCA [20]. In accordance with these results, Tang *et al.*[21] reported that no significant differences were found between the two groups at 30-day follow-up. Two strokes occurred in the CAS group, both in patients who had distal embolic protection.

Conclusion

From all results reported in the present study, it can be said that, there is no superiority of certain procedure over the other. It may be attributed to the fact that we carefully selected our patients depending on the results of previous trials. Thus, every patient was managed separately according to their clinical data and it may be a reasonable explanation for nonsignificant difference between the two procedures as regards efficacy and safety. The treatment must be individualized, and a specific risk–benefit ratio must be formulated for CEA and CAS, as proper patient selection is the key to successful outcomes when deciding the optimal treatment for carotid stenosis. Carotid stent placement without the use of distal protection devices was found to be a safe and effective procedure with a relatively low incidence of complications.

Conflicts of interest

There are no conflict of interest.

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