

Convenience of carotid artery stenting in management of carotid artery stenosis in surgically high-risk patients: periprocedural results and early outcome

Osama A. Ismail^a, Mohamed T.M. Eldien^b, Khaled M.Abdo Elhindawy^c

^aDepartment of Vascular Surgery, Sohag University, Sohag, ^b6 October Insurance Hospital, Cairo, ^cDepartment of Vascular Surgery, Cairo University, Cairo, Egypt

Correspondence to Osama A. Ismail, MD, Department of Vascular Surgery, Sohag University, Sohag, 82524, Egypt.
Tel: +201005452782;
e-mail: oelnahaas@yahoo.com

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Aim

The aim was to review the value of carotid artery stenting (CAS) in management of carotid artery stenosis in surgically high-risk patients.

Patients and methods

This prospective study was carried out in Vascular Surgery Department at 6 October Insurance Hospital and Mahmoud Mosque Specialized Hospital on 45 patients (33 males and 12 females), with a mean age of 68 years (54–82 years), who had carotid artery stenosis and were at high risk for surgery. Patients were subjected to CAS during the period between December 2015 and March 2019 and followed up for 1 year. Nearly all carotid lesions were in internal carotid artery (41 patients, 91.1%) and only four (8.9%) patients had common carotid artery lesions. Of 45 patients, 39 had symptomatic carotid stenosis whereas 6/45 patients were asymptomatic and were referred from cardiothoracic surgery unit before coronary artery bypass graft. The commonest clinical presentation was stroke (55.6%) followed by transient ischemic attack (TIA) (31.1%).

Results

Technical success was achieved in all patients, and all the procedures were performed using embolic protection devices. Periprocedural (within 30 days) complication included stroke in 6.7% (three patients) and TIA in 8.9% (four patients), with no deaths or MI. Regarding the overall 1-year complications, five (11.1%) patients developed stroke, where two cases had intraoperative stroke after stent deployment whereas the other cases occurred during 6th–12th month follow-up. One patient developed cerebral hemorrhage and eight (17.8%) cases developed TIA. Acute MI occurred in five (11.1%) patients. A total of six (13.3%) cases had intraoperative bradycardia. Death occurred in three (6.7%) patients.

Conclusion

Management of carotid stenosis in surgically high risk patients is debatable. The main task is prevention of stroke. CAS is an effective and convenient procedure for management of carotid artery stenosis in surgically high-risk patients. Whatever the used technique, proper patient selection and preprocedural planning are necessary in achieving success.

Keywords:

carotid artery stenosis, carotid artery stenting, outcome, periprocedural, surgically high-risk patients

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Introduction

Carotid artery stenosis is one of the commonest causes of mortality and a major source of permanent neurological deficit [1]. In the USA, stroke is the fourth leading cause of death and the first cause of long-term disability [2]. In 2020, it is reported to affect ~800 000 persons per year [3]. It remains an unresolved medical problem with a substantial socioeconomic effect [1]. Carotid artery stenosis should be suspected in all patients with cerebral stroke until it is easily proved or excluded [3]. Optimal management has been studied extensively over the past 3 decades. It can be managed medically, surgically, and with minimally invasive interventional procedures [4].

Recently, various prospective and retrospective clinical trials have compared the ideal treatment options, for example, carotid endarterectomy (CEA) and carotid artery stenting (CAS). Results of these series are relatively constant. CEA is the preferred and the golden standard treatment over CAS unless patients had surgical risk [5]. However, most of the trials which established CEA effectiveness intended to exclude patients with significant comorbidity [6]. CAS

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procedure has developed rapidly over the last decades because of its benefits of less invasiveness, less morbidity, and faster convalescence when compared with CEA [7]. Moreover, stenting and angioplasty with protection in patients at high risk for endarterectomy (sapphire) trial reported that CAS is noninferior to CEA in high surgical risk patients [8].

Although CAS may be a substitute for surgery, especially in high-risk patients, it represents a more challenging procedure, requiring complex catheter-based skills, continued learning curve [9], and careful patient selection and procedural planning [1]. However, the intracerebral embolization of plaque fragments even with a meticulous technique, experienced operators, and improvement in endovascular tools technology represents the major drawback of this procedure [10].

Embolic protection devices (EPD) retain fragments and debris generated during the procedure aiming to decrease the incidence of neurological complications [11]. Several studies suggest that CAS even without cerebral protection can be performed with an acceptable perioperative stroke/death rate of 2.9–8.2% [12].

In this decade, the American Heart Association/American Stroke Association released guidelines for treatment of symptomatic carotid artery stenosis. For patients with stenosis 50–99%, CEA is recommended and best to be performed within 2 weeks from onset of attack on condition that the perioperative morbidity and mortality risk is estimated to be less than 6%. CAS is indicated as an alternative for patients who had anatomical or medical considerations that increase the risk for surgery [5]. Although recent trials offer evident guidelines for treating patients with carotid artery stenosis, these trials do not include the varieties of risk factors seen in the real world [13].

Patients and methods

This prospective study was carried out in Vascular Surgery Department at 6 October Insurance Hospital and Mahmoud Mosque Specialized Hospital on 45 patients with carotid artery stenosis. The study was performed during the period between December 2015 and March 2019. Of 45 patients, 39 had symptomatic carotid stenosis, whereas 6 patients were asymptomatic and referred from cardiothoracic surgery unit before coronary artery bypass graft (CABG).

Inclusion criteria were symptomatic stenosis greater than 55% and asymptomatic carotid stenosis greater

than 70% associated with one or more of the following surgical risks: congestive heart failure (class III/IV), ejection fraction less than 30%, unstable angina (CCS class III/IV), recent myocardial infarction (within the last 4 weeks), or contralateral carotid occlusion. Exclusion criteria were acute ischemic neurologic event within the last 2 days, total occlusion of the target carotid artery, excessive tortuosity of internal carotid artery (ICA), and significant atherosclerosis of the aortic arch. After discussing the procedure, its possible complications, benefits-risk values, and other alternative interventions with patients and their relatives, an informed written consent was obtained. This study was approved by Hospital Ethical Committee.

Demographic data were collected, and clinical characteristics were recorded including history of diabetes mellitus, hypertension, smoking, and hypercholesterolemia. Thorough neurological examination was essential before starting the procedure, with stress on recent cerebral manifestations whether transient or persistent, weakness or sensory manifestations, speech disturbances, visual symptoms, and cognitive function disturbances.

All patients were evaluated by full laboratory investigations, with concern on kidney functions, coagulation, and lipid profiles. Carotid duplex was done for all cases to determine the degree of stenosis, plaque morphology, and systolic velocity of ICA. Computed tomography (CT) angiography for aortic arch and carotid arteries, beside CT brain, was also performed in all cases.

Procedure

Preoperative medications were started by dual antiplatelet therapy in the form of clopidogrel 75 mg/day and aspirin 100 mg daily at least 5 days before the intervention or receive 300 mg clopidogrel as a loading dose 6 h before the procedure. Baseline neurological examination should be performed and documented. The procedure was performed under local anesthesia by a retrograde transfemoral access. Overall, 100 IU/kg unfractionated heparin was injected immediately after insertion of the sheath. A 0.035 stiff-angled guide wire (Radifocus, Terumo, Japan) combined with vertebral catheter 5 F was advanced up toward the aortic arch. Aortic arch angiogram with left anterior oblique projection was done for visualization and cannulation of the ostium of common carotid artery (CCA). Road-map technique was used in cannulation. Caution was kept in mind not to cross the carotid lesion unintentionally and wire

should be passed to one of branches of the external carotid artery (ECA). Wire exchange was done by replacing this wire by another super stiff Amplatz wire, and afterward, a long sheath 6 F 90 cm length (Cook Medical Inc., Bloomington, Indiana, USA) was inserted and positioned at CCA few centimeters below carotid bifurcation. Multiple images were taken to visualize the lesion and the best exposure angle that allows the origins of ICA and ECA to be distinguished during the intervention.

EPD 0.014 guide wire (Filter Wire EZ; Boston Scientific, Massachusetts, USA) was slowly advanced across the stenosis. Its advancement was performed under road-map imaging technique to avoid blind traversing of the lesion especially in severe stenosis. It should be deployed in a straight segment of ICA with enough distance above the lesion to permit sufficient space to deploy the stent. After deployment, an angiogram was performed to ensure that the basket was well opposed to the vessel wall. Care should be taken to minimize upward downward movement of the filter to avoid dissection or vasospasm.

Self-expandable stent (Wall stent; Boston Scientific) was deployed. The length of the stent was 30 or 40 mm with avoidance of unnecessary excess lengths. When carotid stenosis involved the ostium of ICA, stent positioning should involve the distal CCA and proximal ICA. In such cases, the diameter of the

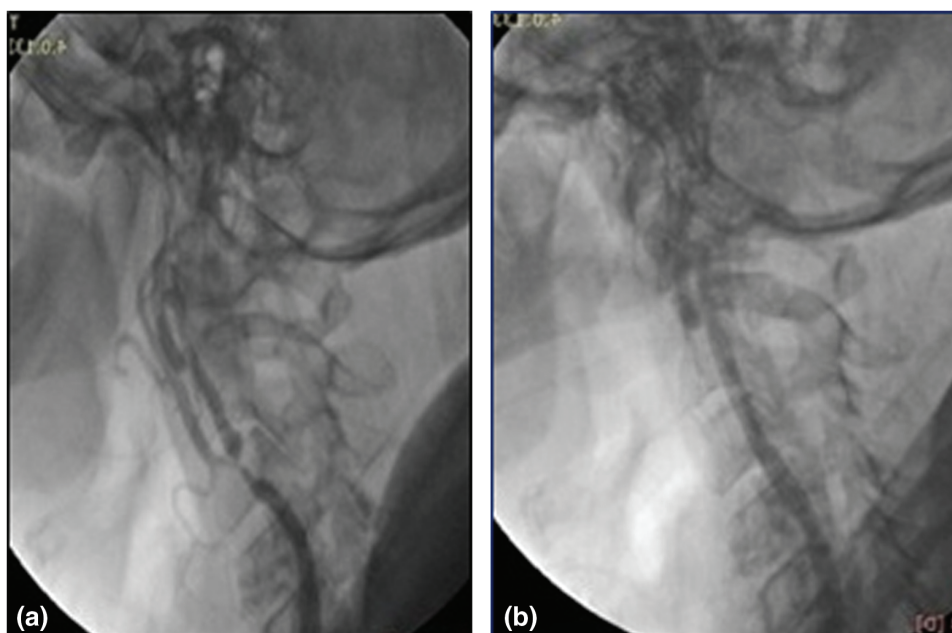
stent should match the distal CCA diameter (most commonly 7 mm). Another angiogram was performed after stent deployment to evaluate if there was inadequate stent expansion. In such cases, balloon dilatation was performed with 5-mm balloon (Figs 1 and 2). Any residual stenosis up to 30% was an acceptable result, and therefore, post-stent dilatation should be omitted, especially in symptomatic patients, as well as in bulky atherosclerotic or non-calcified plaques. Thorough monitoring of heart rate and blood pressure should be done during stenting and after stent dilatation. If hemodynamic changes were observed, immediate injection of 0.5–1 mg atropine should be performed.

Completion angiogram including both cervical part of ICA and the intracranial circulation was performed to evaluate the technical success, exclude vasospasm, dissection, as well as the intracranial blood flow. The filter was then recaptured using its retrieval catheter followed by another confirmative angiography. Patients should be reassessed neurologically, for example, functionality of each limb, cognitive function, simple tests, and answering simple questions or performing simple tasks.

Postoperative management

Patients were closely monitored in intensive care units for 24 h, especially for hemodynamic changes such as blood pressure and heart rate. Frequent neurological examination should be performed and documented.

Figure 1



Left CCA and ICA stenosis. (a) Before treatment; (b) after stent deployment. CCA, common carotid artery; ICA, internal carotid artery.

Figure 2



Right ICA stenosis. (a) Before treatment; (b) after stent deployment. ICA, internal carotid artery.

Brain imaging studies, for example, MRI, was required if patient developed any neurological deficit.

Postprocedure medications were prescribed as enoxaparin every 12 h for 2 days, aspirin 150 mg daily for life, clopidogrel 75 mg/day for at least 3 months, and statins according to the lipogram profile.

After discharge, patients were followed up at 1, 3, 6, 9, and 12 months in the outpatient clinic and assessed neurologically, especially for the cognitive functions, as well as motor and sensory system affection. Duplex examination was performed routinely in each visit.

Definitions

Periprocedural period was defined as 30-day period starting from the day of CAS procedure.

Periprocedural stroke was defined as occurrence of any stroke intraoperatively and within 30 days postoperatively.

Study outcome included stroke, death, and MI if occurred immediately, within the first 30 days postoperatively or throughout the 12-month follow-up.

Statistical analysis

The statistical analyses were performed using SPSS (USA) statistical software. Quantitative variables were described as mean±SD and qualitative variables were described as number and percentages.

Table 1 Patients' criteria and risk factors

	N=45 [n (%)]
Age (years)	68 (54–82)
Male/female	33/12 (73.3%/26.7%)
Risk factors	
Hypertension	45 (100)
Hyperlipidemia	45 (100)
Smoking	25 (55.6)
Diabetes mellitus	35 (77.8)
Renal impairment	8 (17.8)
Cardiovascular disease	31 (68.9)

Results

This study included 45 patients presented to the Vascular Surgery Department at 6 October Insurance Hospital and Mahmoud Mosque Specialized Hospital with significant carotid artery stenosis and were at high risk for surgery, for whom CAS was performed during the period between December 2015 and March 2019. Patients' criteria and demographic data are summarized in Table 1.

The main presentations were stroke in 25/45 (55.6%), transient ischemic attack (TIA) in 14/45 (31.1%), and asymptomatic patients representing 6/45 (13.3%). All asymptomatic patients were discovered accidentally during routine preoperative preparation for CABAG by carotid Duplex US. All patients were investigated by Duplex study firstly, followed by CT angiography of the aortic arch and its branches including carotid arteries. A total of 39 (86.7%) patients were symptomatic (15 patients of

Table 2 Patients' presentation and lesion characteristics

	<i>n</i> (%)
Patients' presentations	
Symptomatic	25 (55.6)
Previous stroke (TIA)	14 (31.1)
Asymptomatic	6 (13.3)
Lesion characteristics	
Site of lesion	
ICA	41 (91.1)
CCA	4 (8.9)
Degree of stenosis	
50–70%	15 (33.3)
>70%	30 (66.7)

CCA, common carotid artery; ICA, internal carotid artery; TIA, transient ischemic attack.

them with stenosis 55–70% and 24 patients with stenosis >70%). The remaining six patients who were asymptomatic had stenosis greater than 70% (Table 2).

Filter was used in all cases. Balloon predilatation was done in four cases because of tight lesions using coronary balloons 2 mm in diameter. Poststent balloon dilatation was performed in seven cases owing to significant residual stenosis.

Periprocedural (within 30 days) complication were as follows: stroke occurred in 6.7% (three patients) and TIA in 8.9% (four patients), with no deaths or MI. Both stroke and TIA incidences were observed in patients with carotid stenosis greater than or equal to 70%, whereas no complications occurred in patients with carotid stenosis less than this percentage (Table 3).

Regarding the overall 1-year complications, five (11.1%) patients developed stroke: three cases had intraoperative stroke after stent deployment, whereas the other cases occurred during 6th–12th month follow-up. All patients who had stroke complication were from the symptomatic carotid stenosis group and had stenosis more than 70%. One patient developed cerebral hemorrhage owing to uncontrolled hypertension. A total of eight (17.8%) cases developed TIA. Their carotid Duplex showed patent stent, and CT brain shows no recent infarction. Acute MI occurred in five (11.1%) patients: three of them were admitted to coronary catheter unit and underwent coronary angiography, whereas the other cases died because of massive myocardial infarction. Six (13.3%) cases had intraoperative bradycardia either during stent deployment or poststent dilatation and relieved by immediate administration of atropine. Death occurred in three (6.7%) patients: two of them after

Table 3 Procedure-related complications

	Immediately (30 days) [<i>n</i> (%)]	1st–12th month complications [<i>n</i> (%)]	Total [<i>n</i> (%)]
Stroke	3 (6.7)	2 (4.4)	5 (11.1)
TIA	4 (8.9)	4 (8.9)	8 (17.8)
MI	0	5 (11.1)	5 (11.1)
Cerebral hemorrhage	0	1 (2.2)	1 (2.2)
Bradycardia	6 (13.3)	0	6 (13.3)
Death	0	3 (6.7)	3 (6.7)

TIA, transient ischemic attack.

extensive myocardial infarction and the other died after CABG at 6-month duration.

Discussion

Carotid artery bifurcation is the most common site for stenosis secondary to atherosclerosis. Atheromatous plaque is composed of fibrous cap embedded in matrix of collagen fibers and a core rich in cellular debris and cholesterol crystals [14].

CE has been established in late century as the preferred method for prevention of stroke for symptomatic patients with carotid stenosis greater than 55% and asymptomatic patients with carotid stenosis greater than 60% compared with medical therapy [15]. Carotid Revascularization Endarterectomy versus Stenting Trial (CREST) showed that CAS was equivalent to CEA in absence of high surgical risk. It also reported that regarding the periprocedural complications, CAS patients had more stroke incidence than CEA patients, whereas CEA patients had more MI incidence [16]. Moreover, recent evidence from randomized controlled trials and meta-analyses appreciated CAS with EPD for management of carotid artery stenosis, as it offered better periprocedural outcomes comparable to CEA in patients with high risk for surgical approach [17].

Patients included in this series were either symptomatic stenosis greater than 55% or asymptomatic stenosis greater than 70% with high surgical risk. Brott *et al.* [16] had recorded that the eligibility for CAS was extended to include asymptomatic patients with stenosis greater than or equal to 60% by angiography or greater than or equal to 70% by Duplex ultrasound (US).

Regarding risk factors, the incidence of hypertension and hyperlipidemia was 100% followed by DM

(77.8%). International Carotid Stenting Study (ICSS) trial had noticed similar results apart from decreased incidence of hyperlipidemia [18].

In this study, most of the patients presented with symptomatic carotid stenosis and only six (13.3%) patients were asymptomatic. There are still questions about the management of patients with asymptomatic carotid artery stenosis, as they have low annual stroke incidence. Medical therapy such as antiplatelet agents, statins, and angiotensin-converting-enzyme inhibitors maintaining long-term blood pressure less than 140/90 can stabilize atherosclerotic plaque and reduce the incidence of ischemic stroke [6]. Aboyans *et al.* [19] had reported that symptomatic patients greater than 60% have an annual risk of ischemic stroke greater than 10% and thus reperfusion is recommended, whereas in asymptomatic stenosis, the annual risk of stroke is ~2%, and therefore, the effect of reperfusion is limited. It is preferable to limit the need for reperfusion therapy in asymptomatic carotid artery stenosis to certain circumstances: presence of contralateral carotid artery occlusion, contralateral TIA or stroke, rapid progression of stenosis by duplex US follow-up, vulnerable and lucent plaque by duplex US, silent brain infarction in CT, and presence of intraplaque hemorrhage on MRI.

Male to female ratio in carotid artery stenosis is now widely accepted and can be attributed by the effect of female sex hormones that seem to play a protective role on vascular endothelial function [20]. Moreover, Mathur *et al.* [21] claim that estrogens had a plaque stabilization effect. In this study, male to female ratio was 73.3%/26.7%. Nearly similar results were obtained by Sapphire study [22], in which the prevalence of males was 66.9% and females was 33.1%.

Duplex US is widely available and accepted tool for investigation that can evaluate the stenotic lesion of carotid vessels as well as its usefulness in decision making. Significant stenosis is confirmed when peak systolic velocity is greater than 250 cm/s or if the end diastolic velocity is greater than 120 cm/s [23]. Other modalities of investigations include CT angiography, which is more effective and sensitive especially when the carotid lesion is far away from the carotid bifurcation and cannot be detected accurately by duplex US. Its benefit extends to evaluate the aortic arch anatomy [19]. In this series, patients were diagnosed firstly by duplex US and then CT angiography for all cases.

In this series, only the distal filter type was used as an EPD. Generally, there are three types of EPD: distal

filter device, distal occlusion balloon, and proximal occlusion with flow reversal. All of these varieties have their own advantages and disadvantages [2]. The filter type to be efficient, it must be deployed in a straight segment of ICA to achieve optimum opposition to the vessel wall, and thus, tortuous ICA is not a candidate for the filter type as well as it may induce complications in its advancement. Advancement of the filter in tight calcified lesion is another concern. It required predilatation with 2-mm balloon. In such circumstances, CEA should be considered better than the unprotected dilatation or using a flow reversal system instead of the filter. It is advisable to limit the unintentionally motion of the filter after its deployment as it may lead to its malposition or pull it back out of the carotid lesion [1]. The proximal protection device, for example, Mo. Ma device (Medtronic, Minneapolis, Minnesota, USA), has the advantages of that the stenosis will not be crossed with any device until protection is obtained. The distal occlusion balloon has additional disadvantages beside the lack of protection during advancement: patients may not tolerate the occlusion due to insufficient collateral circulation and suffered from transient neurologic intolerance [2]. Binning *et al.* [24] had reported that routine use of cerebral protection devices achieved comparable results to surgery particularly in high surgical risk group. On the contrary, Reimers *et al.* [25] had commented in their series upon Pro-Cas study which is a prospective comparative registry used EPDs that there was no difference in stroke and death rates between patients performed with or without EPD. Moreover, ICSS trial noticed that patients who had new ischemic lesions were more of stenting with cerebral protection devices than without (5.1 vs 2.4%) [26]. They attributed their opinion by the following: carotid lesion has to be crossed with the wire and filter, a step that is not protected and may end by possible embolic complications. Use of EPDs may not be easy in case of tortuous vascular anatomy. Filter devices do not have ideal wall apposition allowing material to embolize around the filter, and thrombus can be formed on the filter itself and then embolize around the filter [27].

After completion of the procedure, the EPD should be retrieved safely with its retrieval catheter. Caution should be taken as the filter may engage the stent struts. If these difficulties were noticed, the patient is asked to turn his head, to cough, or to do Valsalva maneuver. This may help in solving the problem [2].

In this series, balloon predilatation was done in 4 cases because of tight lesions. Predilatation of the stenosis

before stent deployment is controversial. Theoretically, it makes the stent delivery less traumatic. However, its disadvantages include liability for plaque rupture and more risk of distal embolization before stent deployment. Therefore, it is not favored and becomes limited to cases when the stent cannot be safely advanced. If predilation is performed, 2–3 mm balloon will be sufficient [2].

In this series, the type of stent was closed cell stent design, wall stent. Sahin *et al.* [28] reported in their series that they used two types of stents (open cell stent and closed cell stent) randomly into two patients cohorts and concluded that closed cell type is associated with low rate of ischemic stroke as a procedure-related complication. The length of stent should cover the lesion completely. It should be extended from CCA to ICA and match the diameter of CCA. Another stent may be needed if there is incomplete coverage of the stenosis. Prophylactic atropine should be injected or be ready to be used immediately in case of bradycardia caused by stimulation of carotid baroreceptors. In this study, the stent patency rate was 100% during the whole year of follow-up period. The study by Cavatas investigators [29] had reported one-year patency rate of 86%.

Post-stent dilatation may be indicated when it is not expanded adequately. However, complete and optimum expansion of stent is not recommended. Maynar *et al.* [30] had reported that successful outcomes with CAS was achieved with avoidance of post-stent dilatation routinely. They attributed their opinion as carotid stent was observed to expand spontaneously with time. Moreover, stent after dilation may increase undesired embolic complications, and therefore, it should be limited to heavily calcified stenosis with poststent carotid diameter less than 5 mm. When indicated, postdilation was performed using 5 mm balloon.

Choosing the proper timing for carotid revascularization is very crucial. Rantner *et al.* [31] had assessed the correlation of time between onset of symptoms and the risk of periprocedural stroke and death. The investigators found that the risk of periprocedural stroke was high in the first 7 days, (9.4%) and decreased to 8.1% if CAS was performed between 8 and 14 days and 7.3% if performed after 14 days [6].

Regarding periprocedural complication rate, it was noticed that stroke occurred in 6.7% (three patients). All of these patients were from the symptomatic

carotid stenosis group and had stenosis more than 70%. TIA developed in 8.9% (four patients), with no deaths or MI. Nearly similar results were obtained by the study by Cavatas investigators [29] and Angelini *et al.* [32] Mathur *et al.* [21] found that CAS performed in lesions severity greater than 90% stenosis associated with higher stroke rate than those with less lesion stenosis (14.9 vs 3.5%). Moreover, Wiesmann *et al.* [33] reported 12.1% stroke in symptomatic carotid stenosis (60–99%). They attributed this high incidence as they did not use EPD, and then, more embolization from the atheromatous plaques.

In 2018, a recent meta-analysis composed of five studies comparing CEA and CAS, including CREST trial, and involved 3901 patients (1585 subjected to CEA and 2316 subjected to CAS). It demonstrated significantly increased risk of periprocedural stroke following CAS than those with CEA (2.6 vs 1.3%) [34]. Perioperative administration of dual antiplatelet therapy (aspirin and clopidogrel) and use of the EPD may decrease the incidence of periprocedural risk [35]. Death occurred in three (6.7%) patients: two of them owing to extensive MI and the other died after CABG at 6-month duration. Brott *et al.* [36] published the long-term results of CREST and reported that CAS has equivalent outcomes compared with CEA in composite periprocedural stroke, death, and MI (11.8 vs 9.9%). Therefore, the higher periprocedural stroke rates after CAS were offset by higher rates of MI after CEA. On the contrary, ICSS investigators [37] concluded that patients in CAS group had a significantly greater risk of stroke, death, and procedure-related heart attack.

Bradycardia and hypotension are also common drawbacks associated with CAS procedure. They were noticed in ~68% of cases. Bradycardia may be caused by stimulation of carotid baroreceptors during stenting or poststent dilatation. Both hypotension and bradycardia are more common in patients with contralateral tight carotid stenosis. These drawbacks are usually self-limited [38].

CAS has the advantages of better quality of life and rapid return to physical activity, especially in the early postoperative period, compared with CEA. These advantages diminished over time and were not evident after 1 year [39].

A recent advancement for management of carotid artery stenosis is transcarotid artery revascularization, which provides an alternative technique to CEA and CAS for high-risk patients. This hybrid technology

approached carotid arteries directly with cerebral blood flow reversal during stent deployment. It is characterized by its minimally invasive approach and low risk of stroke [40]. This procedure reported less stroke rates in comparison with CEA vs at 30 days (1.8 vs 2.4%) and vs at 1 year (1.8 vs 3.6%). It was noted that cranial nerve injury and MI rates were similar between transcrotid artery revascularization technique and CEA, with the advantages of decreased mortality rate at the periprocedural period ($P=0.026$) [41].

Conclusion

Management of carotid stenosis in surgically high-risk patients is debatable. The main task is prevention of stroke. CAS is an effective and convenient procedure for management of carotid artery stenosis in surgically high-risk patients. Whatever the used technique, proper patient selection and preprocedural planning are necessary in achieving success.

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Conflicts of interest

There are no conflicts of interest.

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