Carotid angioplasty as an alternative to carotid endarterectomy for management of extracranial atherosclerotic carotid stenosis

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Introduction
Endoluminal treatment of carotid stenosis is gaining increasing popularity owing to its perceived less invasiveness. However, the outcome of carotid angioplasty-stenting (CAS) should be verified in each center before considering CAS a valid alternative to carotid endarterectomy (CEA). The aim of this study was to compare the safety and efficacy of CAS and CEA (considered as the gold standard treatment for carotid stenosis) in a concurrent series of patients.
Patients and methods
This is a retrospective study of prospectively collected data comprising all consecutive patients who underwent CAS for atherosclerotic carotid artery stenosis from March 2014 to May 2018 in the Division of Vascular and Endovascular Surgery, University of Perugia, Perugia, Italy, and Department of Vascular and Endovascular Surgery, Assiut University Hospital, Assiut, Egypt. Both asymptomatic and symptomatic patients with carotid artery stenosis were included. Indications for CAS were high-risk patients, recurrent carotid disease, and irradiated neck. All cases of CAS cases were performed under local anesthesia in a hybrid operating room using cerebral protection devices. CEA cases were performed either under local or general anesthesia based on anesthesiologist and patient choice. Transcranial Doppler monitoring was always used when feasible.
Results
Symptomatic stenosis was more frequent in the CEA group (50 vs. 39%, respectively). Severe heart disease was more frequent in the CAS group when compare with the CEA group (62 vs. 30%, respectively). The inability to complete CAS occurred in five (4.2%) patients with immediate conversion to CEA. At 30 days, four major strokes (3.3%; one of them was fatal) occurred in the CAS group, and two (0.6%) major strokes occurred in the CEA group (P=0.04; odds ratio=5.9, 95% confidence interval=1.1–31.2).
The endovascular group showed a higher incidence of minor neurological complications compared with the CEA group (13/119 vs. 3/344, respectively; $P<0.0001$).
Conclusions
Our early experience showed that CAS has a 30-day neurological outcome worse than CEA. This may be owing to a higher cerebral embolic risk of endovascular procedure. Currently, CEA remains the gold standard for carotid stenosis. CAS should be performed in selected patients.

Keywords:
carotid stent, CAS, CEA

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Introduction

Carotid endarterectomy (CEA) provides excellent protection against ipsilateral ischemic stroke in patients with severe internal carotid artery stenosis as many randomized trials have largely shown [1–4].

Carotid angioplasty-stenting (CAS), first described 20 years ago, represents an alternative to the surgical approach for carotid stenosis. It was slow to gain acceptance until recently as a true valid alternative to CEA because of the excellent results and the low risk of neurological complications (<2% in the experienced canters) [5–9] of CEA. However, CAS represents an evolving technique and many complications have been described in the early phases of the evolving technique, but now the incidence has reduced because of the introduction of advanced technologies (distal cerebral protection systems, floppy and thin guide wires, etc.) and improvement of the level of experience of the operators [10,11]. Some authors suggested that CAS may be considered a valid alternative to CEA, with comparable results with a reduction of patient discomfort as the procedure is minimally invasive, in

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high-risk patients unsuitable for surgery [12]. Other authors thought that CAS may expose the patient to higher risk of perioperative cerebral embolism, but on the contrary, CAS has low incidence of late restenosis [13–17].

The results of CAS are far to be proven by large randomized trials. The purpose of this study was to compare early and middle term results of CAS with CEA in a concurrent series of patients treated in our center.

Patients and methods

During a period of 48 months (from March 2014 to May 2018) in the Division of Vascular and Endovascular Surgery, University of Perugia, Perugia, Italy, and Department of Vascular and Endovascular Surgery, Assiut University Hospital, Assiut, Egypt, 463 cases of carotid stenosis have been treated in 440 patients: 119 CAS procedures were performed in 112 (26%) patients and 344 CEA procedures in 328 (74%) patients. The Institutional Review Board of the University of Perugia, Assiut University Hospital, waived the need for ethics approval or informed consent for the use of anonymized and retrospectively analyzed data.Endovascular treatment was principally reserved for patients with carotid restenosis and for de novo stenosis in patients with hostile neck (irradiated neck and tracheostomy) or severe comorbidities [North American Symptomatic Carotid Endarterectomy Trial (NASCET) and Asymptomatic Carotid Atherosclerosis Study (ACAS) ineligibility] [12]. Exclusion criteria for endovascular treatment were considered creatinine blood levels more than 2 mg%, allergy to contrast medium, calcified or an echogenic plaque on Duplex scan, and excessive anatomic tortuosity of the vessels.

Preoperative evaluation was based on Duplex scan with 12.5 MHz linear probe. All the examinations were performed by two vascular surgeons who established site of stenosis, as well as severity and morphology of the carotid lesion. In patients candidate for CAS, length of stenosis and size of vessel were also detected on Duplex scan in order to planning proper balloon and stent size. Preoperative angiography with study of aortic arch, selective injection of the supraaortic vessels, and intracranial circulation was required selectively. Cerebral computed tomographic scan was performed selectively in symptomatic patients. Regarding indication for intervention, symptomatic carotid stenosis was found in 46 (39%) patients of CAS group and 171 (50%) patients of CEA group.

Operative techniques

All patients undergoing CAS were pretreated with dual antiplatelet therapy with aspirin and clopidogrel starting 2 days before the procedure and for 30 days after. On the contrary, patients undergoing CEA were pretreated with only aspirin.

All endovascular procedures were performed by a multidisciplinary team in the same operating room equipped with high-quality fixed imaging system. Cerebral monitoring with transcranial Doppler (Nicolet Pioneer TC 4040, EME, Uberlingen, Germany) was used when feasible. All procedures were performed under systemic heparinization (100 UI/kg).

The procedure started with diagnostic angiogram of aortic arch and supraaortic vessels using pig-tail 5-F catheter introduced by femoral percutaneous access under local anesthesia using Seldinger technique. Selective cannulation of common carotid artery was than performed using a guide catheter 8–9 F (MP1, MP2, HS Lyber Scimed; Boston Scientific, Marlborough, Massachusetts, USA) placed few centimeters far from common carotid bifurcation. Continuous washing flow (heparinized solution 2 ml/min) was maintained during all the procedure. Cerebral distal protection was routinely used in all procedures. Two types of filters were employed: EPI (Boston Scientific) and FilterWire EZ (Boston Scientific), both supported by monorail system and guidewire 0.014 inch. Generally, primary stenting was performed after proper placing of the filter in the internal distal carotid artery. Predilatation with angioplasty balloon of 2–3 mm diameter was used selectively in preocclusive stenosis. One or more self-expandable stent (Carotid Wallstent; Boston Scientific) according to length and the size of the lesion were used in all cases. Aviator balloons inflated for pressure less than 14 atm were used to dilate the stent.

CEA procedures were performed under local or general anesthesia based on anesthesiologist preference and the patient choice. Intraoperative monitoring was based on clinical monitoring (when possible), TCD (4040 Pyoneer Eme) when feasible, or stump pressure measurements. CEA was performed with selective shunting. The need for intraoperative shunting are the following: awake deficit within 60 s, carotid stump back pressure more than 50 mmHg ,TCD: decrease MCAV 0–15% of preclamp. Eversion or standard techniques were used for CEA, based on surgeon choice and anatomical findings.

Neurological status of the patient was assessed preoperatively, at discharge, and during follow-up. When a neurological deficit was detected, neurologist' evaluation was required.

(1) End points: primary end points of the study were perioperative death and major stroke.
(2) Secondary end points were minor stroke, transient ischemic attack systemic perioperative complications, and recurrent stenosis.
(3) Transient ischemic attack was defined as retinal or hemispheric focal events completely regressed in 24 h.
(4) Minor stroke was considered a new neurological event completely solved in 30 days or with minimal residual disability (<3).
(5) Major stroke was defined as a new neurological event persisting after 30 days or with disability (minimal residual disability>3)
(6) Restenosis was defined stenosis more than 50% after intervention of CEA or percutaneous transluminal angioplasty at Duplex examination.

Follow-up

Clinical evaluation and duplex examination were scheduled at 1, 3, and 6 months and every year after procedure.

Statistical analysis

Primary analysis of data was by intention to treat. Software SPSS (SPSS Inc., Chicago, Illinois, USA) was used for all the analyses. *t* test, χ^2 test (Mantel–Henzel, Yates corrected), and exact Fisher test with odds ratio and confidence intervals were used for comparisons. Multivariate analysis with logistic regression and backward stepwise LR method was performed using any postoperative stroke (every type) as dependent variable. Fourteen independent variables were tested in the model: age, sex, smoking, hypertension, diabetes, coronary heart disease, atrial fibrillation, contralateral occlusion, hyperlipidemia, vascular peripheral disease, symptoms, restenosis, degree of stenosis, and length of plaque. To search adverse predictors of postprocedural stroke in the CAS subgroup, multivariate analysis with method back ward stepwise LR was performed to test eight variables (age, sex, diabetes, restenosis, symptoms, contralateral occlusion, >90% stenosis, irregular plaque, and length >2 cm) as independent predictors of postoperative stroke in this specific group of patients. Significant values were considered with *P* value less than 0.05.

Results

Clinical indications of patients for surgical and endovascular treatment are displayed in Table 1. Demographics and risk factors are displayed in Table 2. Preoperative angiography was performed in 37 (31%) patients undergoing CAS and in 62 (18%) patients undergoing CEA. Cerebral monitoring with TCD was feasible in 70 (59%) patients in CAS group and in 134 (39%) patients in the CEA group. In 79 (23%) CEA cases, stump pressure was used for monitoring patients. Other patients of CEA group were performed under local anesthesia.

In CAS group, predilatation before stent deployment was employed in nine (7.5%) patients. In six (5%) patients, an adjunctive stent was used. EPI filter was used in 83 (73%) cases, and Filter Wire EZ (Boston Scientific, Natick, Massachusetts, USA) in 30 (26%) cases. In 33 (28%) patients, there were macroscopic particles in the filters. In one patient, cerebral protection devices were not used for impossibility to cross the lesion with filter.

Technical failure occurred in 5/119 (4.2%) CAS procedures. In case of failed passage of the lesion,

Table 1 Treatment indications in 463 procedures

	CAS (*N*=119) [*n* (%)]	CEA (*N*=344) [*n* (%)]	*P* value
Symptomatics	46 (39)	171 (50)	0.04
Ipsilateral symptoms	33 (28)	131 (38)	0.05
TIA	11 (67)	68 (52)	NS
Stroke	22 (33)	63 (48)	NS
Contralateral symptoms	10 (8)	33 (10)	NS
Vertebral-basilar symptoms	3 (3)	9 (3)	NS
Asymptomatics	73 (61)	171 (50)	0.03
Restenosis	25 (21)	3 (1)	<0.0001

CAS, carotid angioplasty-stenting; CEA, carotid endarterectomy; TIA, transient ischemic attack.

Table 2 Demographic and risk factors in 440 patients

	CAS (*N*=112) [*n* (%)]	CEA (*N*=328) [*n* (%)]	*P* value
Mean age (years)	71.3±7.8 (50–86)	70.4±7.9 (47–90)	NS
Male	87 (78)	230 (70)	NS
Smoke	32 (29)	94 (29)	NS
Hypertension	96 (86)	257 (78)	NS
Diabetes	33 (29)	98 (30)	NS
Hyperlipemia	52 (46)	167 (51)	NS
CHD	70 (62)	99 (30)	<0.0001
Peripheral disease	27 (24)	59 (18)	NS
Contralateral occlusion	10 (9)	27 (8)	NS

CAS, carotid angioplasty-stenting; CEA, carotid endarterectomy; CHD, coronary heart disease.

the patients were converted immediately to open surgery with no perioperative complication. In one patient, a residual stenosis more than 30% was detected. In other one patient, complete occlusion of the stent that was completely solved by UK intraarterial infusion occurred after stent release.

Table 3 shows perioperative mortality and morbidity of the two groups. The only death occurred in the CAS group was owing to massive cerebral hemorrhage. In the CEA group, one patient died perioperatively owing to myocardial infarction. One peripheral neurological lesion occurred in the CAS group owing to median nerve injury after percutaneous brachial access in a patient with severe iliac occlusion by PAD. Timing and type of stroke are displayed in Table 4.

Multivariate analysis of the cohort showed that independent predictors of 30-day stroke (major or minor, contralateral ipsilateral) were CAS (P=0.0007, hazard ratio=14.3, 95% confidence interval=3.1–66.8) and age (P=0.03, hazard ratio=1.09, 95% confidence interval=1.006–1.19). None of the eight potential predictors of stroke in the CAS subgroup were found to be statistically associated with adverse event.

In the 8-month follow-up, one (0.8%) restenosis occurred in CAS group and four (1.2%) restenosis in the CEA group.

Discussion

This study showed that CAS can be successful performed (96%) with an acceptable rate of periprocedural complications, especially in high-risk patients for CEA: 3.3% stroke/death was detected. This complication rate in the CAS group appeared worse than that found in the surgical group (0.9%); however, the results did not reach statistically significant difference (P=0.07). Furthermore, the two groups of patients that were analyzed were not matched in different comorbidities distribution, where the majority of the patients treated with CAS (61%) were high-risk surgical patients, unfit for NASCET/ACAS enrollment. In particularly, high incidence of cardiac disease (atrial fibrillation, instable angina, need of coronary artery bypass

Table 3 Incidence of perioperative events in 463 procedures

	CAS (N=119) [n (%)]	CEA (N=344) [n (%)]	P value %	OR	95% CI
Major stroke/death	4 (3.3)	3 (0.9)	NS		
Death	1 (0.8)	1 (0.3)	NS		
Major stroke	4 (3.3)	2 (0.6)	0.04	5.1	1.1–31.2
Ipsilateral	3 (2.5)	2 (0.6)	NS		
Minor stroke	6 (5)	0	0.0002	13.8	
Omolateral	4 (3.3)	0	0.004	8.1	
TIA	7 (5.9)	3 (0.9)	0.003	6.1	1.7–25.7
AMI	2 (1.7)	1 (0.3)	NS		
Hematoma	3 (2.5)	6 (1.7)	NS		
Neurological peripheral lesions	1 (0.8)	6 (1.7)	NS		

AMI, acute myocardial infarction; CAS, carotid angioplasty-stenting; CEA, carotid endarterectomy; CI, confidence interval; OR, odds ratio; TIA, transient ischemic attack.

Table 4 Periprocedural major and minor strokes

Procedure	Stenosis	Symptom	Plaque	Stroke	Side	Timing
CAS	Restenosis	No	Echolucent	Major	IPSI	Dilatation
CAS	Primary	No	Echolucent	Major	IPSI	Catheterization
CAS	Primary	Yes	Calcium	Major	VB	Catheterization
CAS	Primary	No	Calcium	Major	IPSI	Catheterization
CAS	Primary	No	Echolucent	Minor	VB	Dilatation
CAS	Primary	No	Echolucent	Minor	IPSI	Dilatation
CAS	Primary	Yes	Anechoic	Minor	IPSI	Dilatation
CAS	Primary	No	Calcific	Minor	CL	CABG
CAS	Primary	No	Echolucent	Minor	IPSI	Postdilatation
CAS	Primary	No	Echolucent	Minor	IPSI	Postdilatation
CEA	Primary	No	Calcium	Major	IPSI	After 1 week
CEA	Primary	Yes	Calcium	Major	IPSI	Intraoperative

CABG, coronary artery bypass grafting; CAS, carotid angioplasty-stenting; CEA, carotid endarterectomy; CL, contralateral; IPSI, ipsilateral; VB, vertebrobasilar.

grafting or recently done, etc.) was two-fold higher in CAS group in comparison with CAS group (63 vs. 30%, respectively, see Table 2).

Our results of CAS cannot be compared with the results of randomized trials on CEA because populations at study were not matched [18]. In NASCET/ACAS ineligible patients with severe comorbidities, CEA has shown worse results than those reported in low-risk eligible patients from randomized trials [19]. Moreover, some particular anatomic conditions such as distal lesions of the internal carotid artery, restenosis, and hostile necks represent restricting factors that limit large applicability of CEA's results.

Nowadays, CAS is not yet based on enough clinical pieces of evidence than like CEA. Of the three randomized trials (CAVATAS, Wallstent, and Leicester) published on CAS, two were early stopped for the high periprocedural risk of stroke and death (12 vs. 3.6% in Wallstent and 43 vs. 0% in Leicester, CAS vs. CEA, respectively). The only one concluded randomized study (Carotid and Vertebral Artery Transluminal Angioplasty Study: CAVATAS) has not shown significant differences between endovascular and surgical treatment of carotid stenosis, but complication rate was exceptionally high in both treatments (10 vs. 9.9%) [20–22].

Two factors imitate the results of these randomized trials and their applicability:

(1) CAS is a procedure in continuing evolution: both technological (due to use of proper ultrathin materials, filters, cerebral protection system, etc.) and technical (due to major experience of the operators after a learning curve phase) improvements have been expected and are then obtained since the first introduction of the procedure in this concluded RCT [23–27].
(2) Selection of patients is crucial to provide good results.

Cerebral embolism represents the most important risk of supraaortic catheterization: this is a limiting factor for the procedure. Three periprocedural major stroke in our CAS patients occurred because of massive embolization during trial for selective catheterization. One perioperative major stroke and all minor stroke occurred during stent dilatation. In all neurological complications, there were macroscopic particles in the filter (both EZ and EPI). Selective catheterization is a crucial phase of CAS procedure that may expose to high risk of cerebral embolism, especially when diffuse pathology of the arch obstacles the access to carotid vessel. In these cases of difficult cannulation of the supraaortic vessel, it is advised to stop the endovascular procedure rather than an extremely difficult and long catheterization trial which will greatly increase cerebral embolic risks. Accumulated experience suggests that eventual cross-over endovascular procedure for open surgery after diagnostic angiography showing unfavorable anatomy is not to be considered a failure but has to be used for intention to treat.

Embolism occurrence during CAS may be reduced, more than by using cerebral protection systems, by excluding from CAS those patients with unfavorable anatomy of supraaortic vessels. CAS cannot be considered the gold standard for patients with long, diffuse lesions involving common carotid artery and aortic arch, calcified plaques, tortuosity of the vessels, endoluminal thrombosis, instable neurological symptoms, or difficult access.

Some authors suggested to identify low-risk plaques before to plan CAS for patients; however, there are no strong clinical evidence on this issue neither standardized criteria to define true risk plaques.

Cerebral protection systems can minimize embolic risk of CAS; however, there is no evidence that with such procedures the risks are really low. Different distal cerebral protection systems have been introduced: distal balloon (PERCUSURGE) filters (NEUROSHIELD, TRAP, EPI, ANGIOGUARD) or inverted flow (Arteri A) [28–30]. However, none of these devices can be considered perfect and able to be safe at all. In literature, the risk of neurological complications using distal cerebral protection devices vary from 1 to 4.8% [30]. On the contrary, there are other experiences that showed a low risk of neurological complications in CAS, also without cerebral protection devices. Roubin and colleagues [31] in a series of 528 CAS without protection reported a major stroke /death and minor stroke rate of 4.8%. Recently, Criado and colleagues [32] found only one (0.7%) major stroke and two (1.4%) minor strokes in a series of 135 patients treated with CAS without protection. Wholey and colleagues published data of the largest International Registry of more than 8000 CAS (only 15% of these with cerebral protection) and showed stroke/death rate of 4.35%. In particular, the risk reduced from 4.7% in cases without protection to 3.7% in those treated with cerebral protection.

Recently, Roubin using cerebral protection obtained a further reduction of neurological events than in his

previous experience: 2.4% stroke/death in 345 treated cases.

Other risk factors can be relevant for the selection of candidates to CAS. Our data in accordance with other experiences suggested that old age increases stroke risk during CAS. Multivariate analysis confirmed age as an independent predictor of periprocedural stroke. Despite it is considered that CAS is a less durable procedure, CAS should be offered to young patients.

Conclusions

Nowadays, CAS represents an alternative to surgery, being potentially valid in some subgroups of patients affected by carotid stenosis. In our experience, cerebral embolic risk of the procedure is higher than CEA. In our opinion, CEA remains now the gold standard in the treatment of carotid stenosis with indication for surgical treatment. CAS is surely to recommend for patients unfit for surgery. Accurate selection of cases, good technique, and 'knowing when to quit' are some of the essential criteria to ensure success and low risk for the procedure. Further enlargement of clinical indications is not yet justified by our results or by data of actual literature; on-going trials will give a final answer to questions about security and late efficacy of CAS.

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Conflicts of interest

There are no conflicts of interest.

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