Carotid Stenting Versus Endarterectomy for the treatment of carotid artery stenosis: Single center contemporary results

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Abstract:

Background/aim: Although carotid endarterectomy (CEA) has long been considered the preferred intervention for carotid occlusive disease, carotid angioplasty and stenting (CAS) may serve as a minimally invasive alternative with equivalency in providing protection against ipsilateral stroke. The aim of the present study was tocompare the outcomesof both treatment modalities at a single center.

Methods: We retrospectively analyzed patients with carotid artery stenosis admitted to our hospital for carotid revascularization in a 14-year period. Eligibility criteria for revascularization were determined on the basis of symptomatic stenosis over 70% or asymptomatic stenosis over 80%. The primary outcome was a composite of periprocedural death, stroke, and myocardial infarction (MI).

Results: Of the 483 patients admitted for carotid revascularization 283 (58.6%) underwent CEA and 200 (41.4%) CAS. In total 301 CEAand 207 CAS procedures were performed. Symptomatic lesions were similar between the two groups, while no differences in baseline characteristics were found.In the CEA group, 30-day stroke rate was 0.9%. Major complications occurred in 3% of the procedures and cranial nerve injury in 4.3%. In the CAS group, technical success was 98.6%. Thirty-day neurological events included stroke in four patients (2%) and transient ischemic attack in two (1%). None of the patients in both groups died during the first 30 days. Both groups demonstrated similar rates of the composite outcome, MI, and death during the first 30 days after the procedure (p=0.34). During the follow-up period (mean 88±34 months in the CEA and 52±28 months in the CAS group) 15-year cumulative freedom from an ipsilateral stroke was 100% for both groups, while the 15-year cumulative freedom from any stroke was 88.4% for the CEA and 90% for the CAS group (p=0.643). 15-year cumulative freedom from restenosis was 98.3% for the CEA and 98% for the CAS group (p=0.353).

Conclusion: Short-term outcome, including stroke and myocardial infraction, was not differentbetween CEA and CAS in a single center providing both techniques. During follow-up, long-term protection against ipsilateral stroke did not also differ between the two methods.

INTRODUCTION

Atherosclerotic stenosis of the carotid artery is a major cause of ischemic stroke.[1] Carotid endarterectomy (CEA) has been used as tool for stroke prevention for many decades. The beneficial role of CEA in preventing strokes, mostly for symptomatic and to a lesser extent for asymptomatic patients, has been highlighted in all current guidelines.[2] In the era of less invasive procedures carotid artery stenting (CAS) has emerged as an evolving, less invasive, alternative technique that may even be used as first-line treatment in high-risk patients.[3] Randomized controlled trials comparing CEA and CAS have produced diverging results which may be at least partially explained by heterogeneity in patient's cohort, endpoint definition, operator experience and device immaturity.[3-6]

It has been shown that it is possible to achieve acceptable results with CAS at a single center, but not in a wider perspective.[7] Despite the quite inferior results of CAS in randomized, multicenter, prospective trials, the single center results support sufficiently both techniques, with similar event rates.[7,8,9,10] The strict criteria of patients' selection and the high-experience teams working in high-volume centers pro-

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viding both techniques may have probably affected the quality of those results.

The aim of the present study was to analyze all CEA and CAS procedures performed at our institution in a 14-year period with respect to efficacy, safety, and mid-term outcome.

METHODS

Study design

A retrospective study of all patients treated for carotid artery revascularization (CEA and CAS) from March 2001 to March 2015 at the University Hospital of Ioannina was conducted. CAS program was initiated on the January 2007. A dedicated database was established to prospectively collect patients' data, including demographics, preoperative risk factors, operative time, blood loss, contrast media use, patient outcomes, length of stay, and complications. Symptomatic patients included those with previous transient ischemic attacks (TIA) or strokes ipsilateral to the carotid lesion within the last six months. The degree of stenosis was evaluated by color duplex ultrasound imaging according to established NASCET criteria and confirmed by computed tomography angiography (CTA) of the aortic arch and intracranial and extracranial arteries.[11]

Eligibility criteria for carotid revascularization were determined based on symptomatic stenosis over 70% or asymptomatic stenosis over 80% and the presence of significant medical co-morbidities. CAS was contraindicated in case of total ICA occlusion, the presence of free-floating thrombus, severe chronic kidney disease (estimated glomerular filtration rate (e-GFR) < 30 ml/min) or contraindications against the use of dual antiplatelet therapy for at least four weeks.

The choice of revascularization method was at the discretion of the surgeon after a detailed preoperative evaluation. All patients signed an informed consent prior to the intervention and the study was approved by the institutional ethics committee.

CEA: CEA procedures were performed under general anesthesia, and a standard longitudinal incision with patch arteriotomy closure was undertaken in most cases (mostly bovine pericardium as patch material) (Figure 1). ICA stump pressure measurements in all patients and cerebral oximetry whenever available were used for intraprocedural assessment of cerebral collateral circulation to facilitate selective application of carotid shunting.[12] After returning to the ward and if there was no neurologic event as assessed by an independent neurologist or no other major complication, patients were usually discharged on the 2ndpostoperative day with aspirin 100 mg or clopidogrel 75 mg daily without imaging examination.

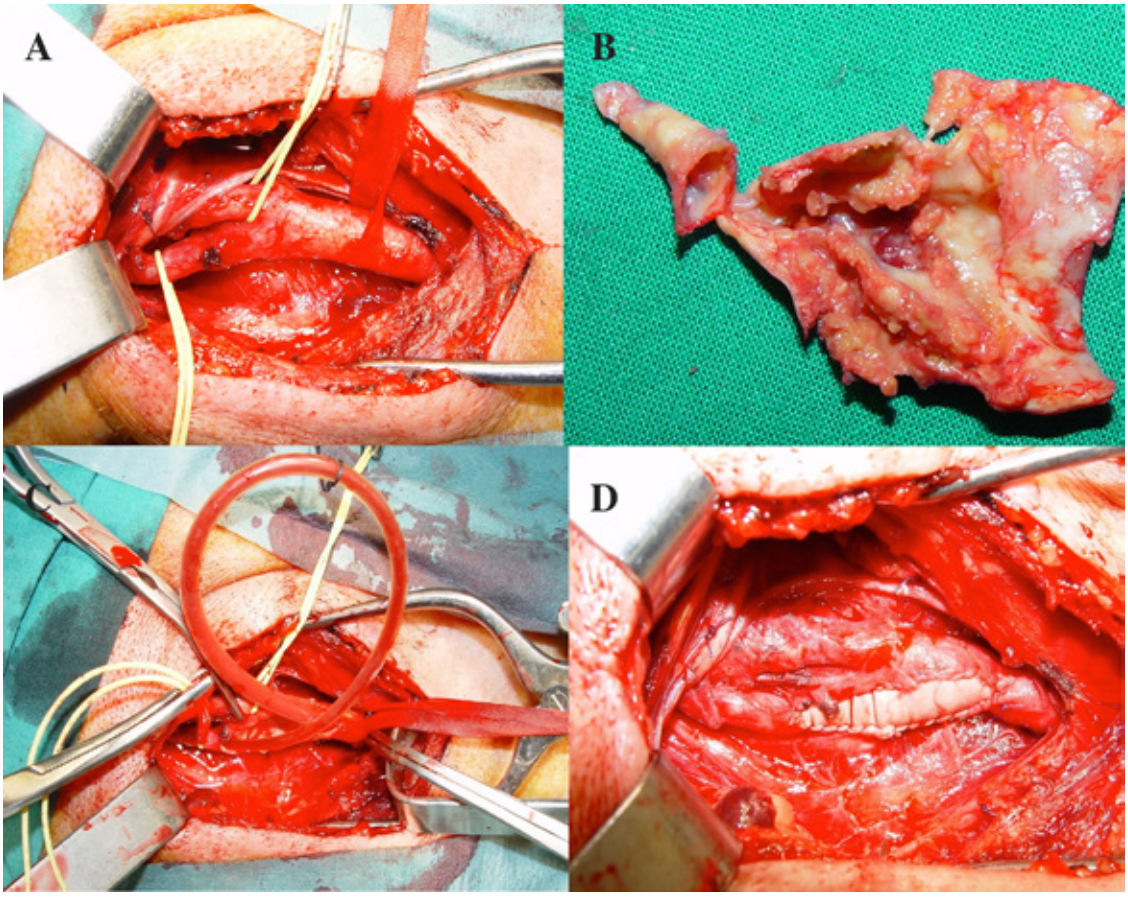

Figure 1. Carotid endarterectomy in a symptomatic patient (Panel A & B). A severe contralateral stenosis set the indication for shunt (Panel C). A bovine patch was used as a standard of care in most cases (Panel D).

CAS: CAS procedures were performed under local anesthesia in an operation theatre with the presence of an anesthesiologist. During the procedure unfractionated heparin was administered (50 IU to 100 IU per kg body weight). Access to the lesion was performed via the femoral artery using an 8F guiding catheter, finally positioned in the mid part of the common carotid artery. Most procedures were performed using distal ICA filters as cerebral protection devices. Following the placement of the protection device, the stent was deployed and post-dilatation performed with a balloon of 5 to 5.5 mm in diameter. In case pre-dilatation was needed, a 2.5-3.5 mm diameter balloon was used. (Figure 2) The choice of the stent was at the discretion of the surgeon (always tapered, open or closed cell design) and there was a preference of close-cell design for symptomatic lesions, according to the anatomy as well. Stenting was intended in every procedure and stent position typically extended from the common to the internal carotid, crossing the origin of the external carotid artery. Before retrieval of the protection device, final biplane angiogram of the stented lesion as well as intracranial views was obtained. Technical success was defined by the coverage of the carotid lesion with a stent in the presence of a residual stenosis < 30% and normal flow. During the CAS-procedure, all patients were monitored neurologically as well as for vital parameters under the care of the anesthesiologic team. After the procedure patients continued to receive dual anti-platelet therapy for at least one month and continued single antiplatelet agent thereafter.

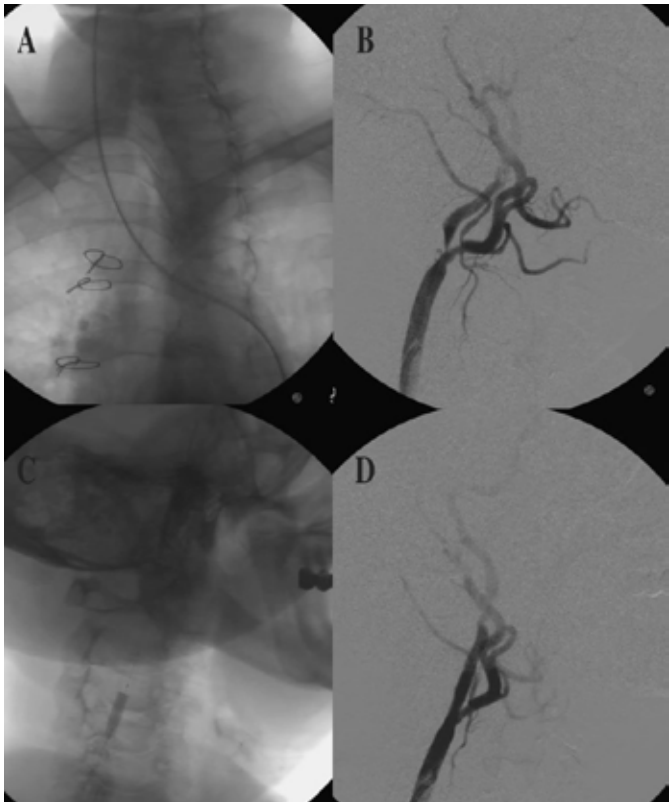

Figure 2. Carotid stenting in an asymptomatic patient with high grade stenosis (Panel A & B). Pre-dilatation was needed in this case (Panel C). Completion angiography confirmed a satisfying result (Panel D).

Outcomes

The primary outcome included 30-day major adverse events, including myocardial infarction (MI), stroke and death. Follow-up outcomes were stroke, myocardial infarction (MI), transient ischemic attack (TIA), death and rate of restenosis. TIA was defined as a new focal, retinal or hemispheric event that persisted for less than 24 h. Minor stroke was defined as focal neurological deficit lasting more than 24 h with Ranking score <2 and National Institutes of Health (NIH) Stroke Score <4, while major stroke was diagnosed in the presence of a Ranking score >3 or NIH score >15.[9] In-hospital surveillance was assessed by the treating therapist while in case of a new-onset adverse event, a consultation from a dedicated neurologist was demanded, According to neurologist evaluation, a CT or MRI (if available) was assessed to set the diagnosis. Clinical and duplex ultrasound follow-up visits to our outpatient clinic were routinely scheduled at 1, 6, and 12 months after the index procedure and yearly thereafter. Restenosis was diagnosed in the presence of a >50% ICA luminal narrowing as assessed by flow velocities using color duplex ultrasonography.[11]

Statistical analysis

Patients were analyzed according to the treatment they received. Data are expressed as mean ± standard deviation except for non-Gaussian parameters that are presented as median and interquartile range (IQR). Categorical data are presented by absolute values and percentages (%). Statistical significance between the groups for continuous variables used the independent t-test for normally distributed data or the Mann-Whitney U test for nonparametric data. The Pearson x^2 test or the Fisher exact test was used for categorical variables, as appropriate. Midterm follow-up data were analyzed by Kaplan-Meier life-table analysis, and results were compared by the log-rank test. Statistical analyses used SPSS 20.0 software (IBM Corp, Armonk, NY). A p value of <.05 was considered statistically significant.

RESULTS

Of the 483 patients admitted for carotid revascularization 283 (58.6%) underwent CEA and 200 (41.4%) CAS. In total 301 CEA and 207 CAS procedures were performed. 160 patients were treated with CEA between 2001 and 2006, and 123 between 2007 and 2015. The lower rate of CEAs after 2007 was due to parallel induction of CAS in our practice; from January 2007, we performed CAS liberally in much more patients, providing they had a suitable aortic arch, carotid lesion, and plaque anatomy, as well as all patients with an absolute contraindication for CEA (Figure 3). In a 9-year period, 207 CAS procedures were performed with an annual rate of more than 20 procedures per year.

	CEA group n=283	CAS group n=200	p
Patient characteristics			
Male gender	227 (81)	164 (81.2)	0.74
Age (years)	71.2±9.2	70.5±8.7	0.34
Risk factors			
Hypertension	170 (60)	130 (65)	0.30
Hyperlipidemia	164 (58)	137 (68.5)	0.09
Diabetes	43 (16)	42 (21)	0.10
CAD	85 (30)	75 (37.5)	0.18
COPD	86 (31)	59 (29.5)	0.32
Smoking	80 (28)	71 (35.5)	0.18
Lesion characteristics			
Side			
Left ICA	144 (48)	90 (44)	0.28
Right ICA	157 (52)	117 (56)	
Symptomatic lesions			
Stroke	60 (32.9)	35 (31)	
TIA	108 (59.3)	63 (55.7)	0.34
Amaurosisfungax	14 (7.8)	15 (13.3)	
Pathology			
Primary stenosis	301 (100)	207 (99)	0.78
Restenosis		2 (1)	

CAD: coronary artery disease, COPD: chronic obstructive pulmonary disease, ICA: internal carotid artery, TIA: transient ischemic attack

Table 1. Patient and lesion characteristics

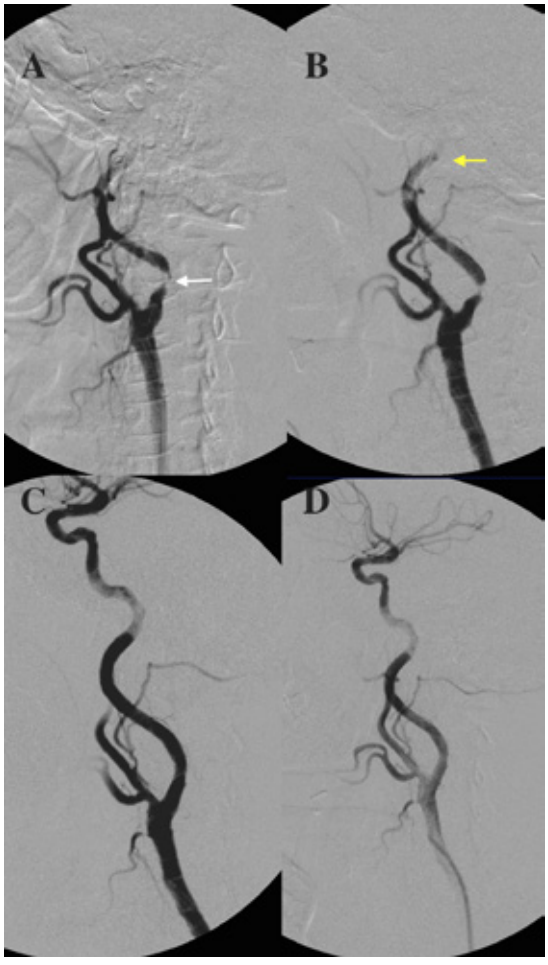

Figure 3. A symptomatic very high-risk patient treated with carotid stenting for a stenosis >90% (Panel A, white arrow). As embolic protection, a filter was used during the procedure (Panel B, yellow arrow). Completion angiography confirmed internal carotid artery patency (Panel C) and the restoration of the intra-cerebral circulation (Panel D).

CEA and CAS procedure data

CEA group: 182 carotid arteries (60.4%) were symptomatic and 119 (40.6%) were asymptomatic. 5 (2.7%) crescendo TIAs were included in the symptomatic group. Preoperative patients' characteristics are listed in Table I. All procedures were accomplished under general anesthesia, while the mean carotid clamp time was 33 ± 6.2 minutes (range 17-60 minutes).270 CEAs with patch closure (262 with bovine and 8 with polytetrafluoroethylene or Dacron patch) and 31 eversion CEAs were performed.

CAS group: Symptomatic stenoses were treated in 113 lesions (56.5%). All procedures were accomplished under local anesthesia, while in all patients' access was achieved through the femoral artery. Successful recanalization of treated vessel was obtained in 204 cases (98.6%). There were three technical failures. In one patient we were unable to deploy the embolic protection device distally to the lesion due to severe ICA kinking, while in another patient common carotid artery catheterization was failed due to the presence of hostile aortic arch. The third patient had a nearly occluded ICA characterized by a calcified irregular plaque and we were not able to cross the lesion. All three patients were converted on site to CEA under general anesthesia with a good clinical result.

	Symptomatic	Asymptomatic	p
CEA group			
Stroke	3 (1.6)	0	<0.001
TIA	0	0	NA
CAS group			
Stroke	4 (3.5)	0	<0.001
TIA	1 (0.8)	1 (1)	0.34

TIA: transient ischemic attack

Table 2. Patients' 30-day outcome according to the presence of symptoms

Embolic protection devices (EPD) were applied in all technically successful procedures (Table 3) CAS. The vast majority (98.5%) included filter devices, while balloon occlusion devices were used in only 3 patients. The lesions were pre-dilated in 37 cases (18.1%) and post-dilated with a balloon in all procedures. Stents were applied in all lesions. One stent per procedure was used in 197 lesions (96.6%), while in 7 lesions the use of two stents was necessary, due to long carotid lesions (4 cases), or extensive jumping of the first stent (3 cases). Stents with an open cell design were deployed in 118 patients, while closed cell stents in 86 patients. Symptomatic patients were more likely to receive a stent of closed cell design (p<0.001).

	n (%)
Type of stent	
Acculink (Abbott)	96 (44.1)
X-act (Abbott)	41 (19.2)
Exponent (Medtronic)	22 (10.3)
Adapt (Boston)	33 (15.5)
Protégé (Covidien)	12 (5.7)
Wallstent (Boston)	7 (3.3)
Crystalloo Id (Invatec, Medtronic)	4 (1.9)
Type of EPD	
Accunet (Abbott)	81 (39.8)
Emboshield (Abbott)	54 (26.7)
Interceptor+ (Medtronic)	29 (14)
Filterwire (Boston)	37 (18)
Moma (Invatec, Medtronic)	3 (1.5)

EPD: embolic protection device

Table 3. Procedural characteristics

Outcome: 30-day stroke rate was 0.9% in the CEA and 2% in the CAS group (p=0.112). Symptomatic patients were more likely to suffer from stroke during the peri-procedural period than asymptomatic patients in both groups (p<0.001). Mortality was null in both groups. ***In the CEA group*** there were 3 strokes. One symptomatic male patient had an acute ICA thrombosis during an episode of paroxysmal atrial fibrillation with hemodynamic instability. Re-exploration was not attempted because of the patient's severe condition and multiple intracranial carotid lesions. The patient recovered from kinetic problems but not from aphasia and died after 28 months due to a cardiac event. The second stroke concerned a symptomatic male patient with contralateral ICA occlusion. The operated ICA remained patent and the CT scan negative, so it was considered a lacunar stroke. The patient recovered completely and remains alive with patent ICA almost 13 years after the procedure. The third stroke occurred in an asymptomatic female patient who suffered an acute ICA thrombosis. Re-exploration revealed an intimal flap at the proximal site of the CEA. The defect was repaired and the ICA successfully recanalized. The patient recovered completely from the stroke and is alive with patent ICA 7 years after the procedure. ***In the CAS group***, four patients, all symptomatic, suffered an ipsilateral stroke. All these strokes were minor and none of them became disabling through the hospitalization period. Two (1%) patients, one symptomatic and one asymptomatic, suffered a TIA, while in two other patients, cognitive dysfunction observed after the operation that completely resolved after 1-3 days. No significant relation was shown between the cerebrovascular event occurrence and the type of stent (stroke, p=0.405; TIA, p=0.624). No access-site pseudoaneurysm was diagnosed in any patient, expect of 5 cases of post-operative mild hematoma with no clinical significance which were treated conservatively.

In the CEA group, rate of complications was 3.6% including 7 cardiac (5 acute coronary syndromes and 2 paroxysmal atrial fibrillation), 1 pulmonary (acute respiratory insufficiency), and 1 renal (acute renal failure); 2 patients experienced neck hematoma, requiring drainage under local anesthesia due to airway compression. Median hospital in-stay was 2 days.12 (4%) postoperative events of cranial nerve injury were observed; 6 were related to the hypoglossal and 6 to the inferior laryngeal nerve. In 11 patients, symptoms were revealed during the first 6 months' follow-up, while in only 1 remained as vocal cord paresis without significant clinical consequences. ***In the CAS group,*** there were no cardiovascular events or major complications within 30 days. Median hospital in-stay was 2 days.

FOLLOW-UP

The mean follow-up time was 88 ± 34 months (range12-168 months) for the CEA and 52±28 months (range 18-98 months) for the CAS group. 52 patients (10.6%) in the CEA and 24 patients (12%) in the CAS group were lost to follow-up. The latest recorded data for all patients were used for the analysis.

Cerebrovascular events: Twenty patients, 12 in the CEA and 8 in the CAS group, experienced a late stroke. All late strokes were contralateral to the operated carotid, and 6 were fatal. The15-year cumulative freedom froman ipsilateral stroke was 100% for both groups, while the 15-year cumulative freedom from any stroke was88.4% for the CEA and 90% for the CAS group (log rank test=0.215, p=0.643, (Figure 4A).

Restenosis: Five carotid arteries, 4 (1.3%) in the CEA and 1 (0.5%) in the CAS group, developed restenosis at 3, 12, 18, 36 and 24 months, respectively. All patients with restenosis remained asymptomatic. In the CEA group, one restenosis progressed to total occlusion and 3 in significant lumen stenosis (> 50%), but only 1 case required an endovascular intervention due to severe (> 90%) narrowing. The other 2 patients remained under surveillance. In the CAS group, there was an in-stent restenosis in the mid portion of the stent that was progressed in >90% after 2 more years. This patient was successfully treated by CAS again, using a balloon expandable short stent this time. 15-year cumulative freedom from restenosis was 98.3% for the CEA and 98% for the CAS group (log rank test=0.862, p=0.353, Fig. 4B).

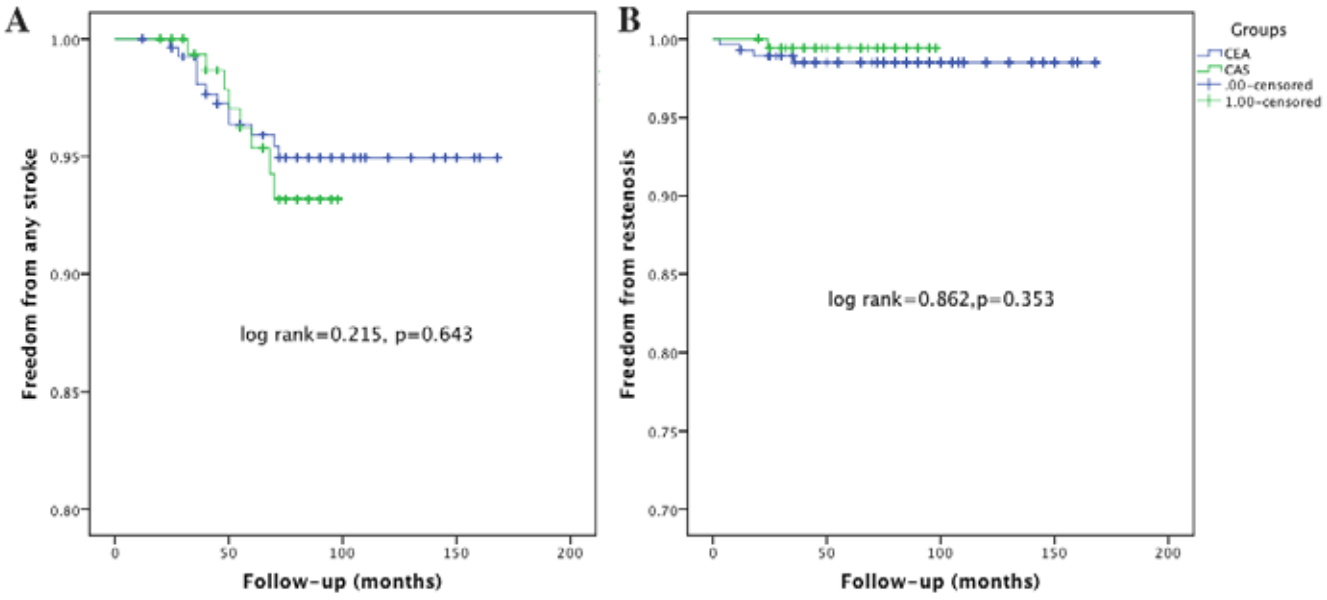

Figure 4. Kaplan-Meier cumulative proportions of freedom from any stroke (A) and for restenosis (B) for both groups of patients.

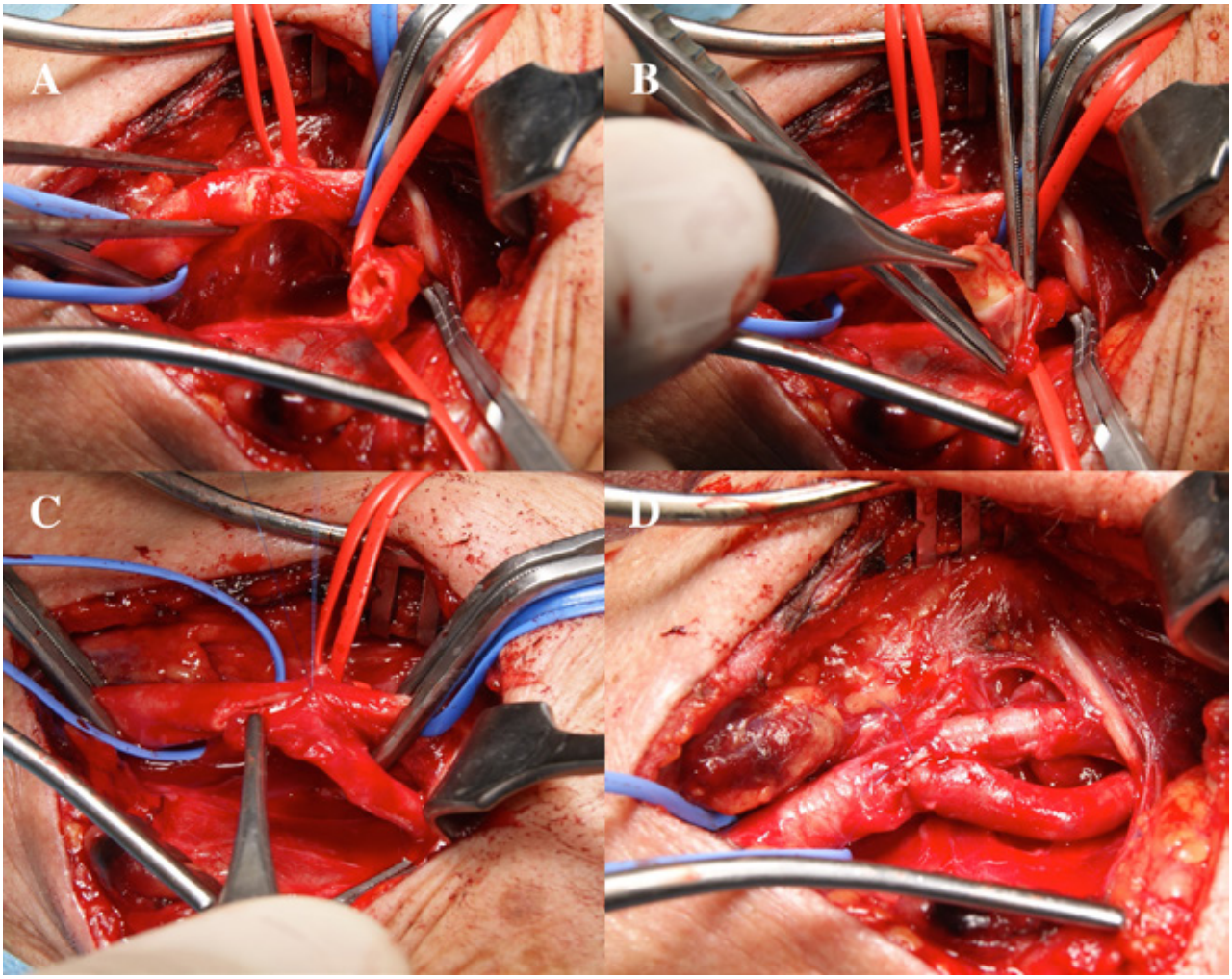

Figure 5. Carotid endarterectomy with the eversion technique (Panel A & B). Eversion technique has analogous results concerning restenosis as patch closure (Panel C & D).

DISCUSSION

In the largest and most reliable randomized trial of CEA vs CAS, CEA conserved its superiority in the prevention of stroke, particularly in symptomatic patients (Figure 5).[6] This study showed a higher rate of stroke in patients treated by CAS during the 30 days after the procedure. Respectively, a higher rate of cardiac events was recorded for patients treated by endarterectomy. Similar to CREST, in our study, there were no significant differences in the occurrence of the composite endpoint, consisting of major stroke, MI, and death but patients undergoing CAS did demonstrate a higher rate of periprocedural stroke, although non statistically significant.[13] This was likely related to the fact that patients undergoing CAS tended to have more baseline medical comorbidities.

In a meta-analysis of 21 published registries and nearly 1.500.000 patients, the stroke and death rate following CAS remained significantly higher than after CEA and remarkably exceeded the threshold referred in current guidelines.[13,14] In 43% of the analyzed registries for asymptomatic and in 72% registries for symptomatic patients, the stroke/death rate was over the 3% and6% AHA/ASA guideline threshold respectively.[14] However, these data included patients even from the first CAS years when EPD were not routinely used while some of them suffered from reporting and selection biases.[14]

On the other hand, data from single center studies offering both CEA and CAS seem promising. In a recent single center report of nearly 500 patients, the incidence of in-hospital stroke and death was below 1%, while in another single vascular surgeon report offering both modalities no differences were noted with low rates of periprocedural stroke (2% CEA vs 1.2% CAS).[8,15] The results of the present study show that in selected patients and in single centers with a high operational experience, there is no significant difference between the two methods. In symptomatic group, we confirmed a higher post-operative stroke rate than asymptomatic patients, with an occurrence rate much less than the 6% guideline benchmark. Equally, in asymptomatic patients the stroke rate was much less than the 3% benchmark, even in patients treated with the CAS technique. These single center results of carotid artery disease treatment could be explained by the factor of operator's competency. In experienced high-volume centers the results seem to be different and much better than those mentioned in multicenter trials. The strict criteria in patients' selection and the high experience of operating teams on both techniques could offer a patient tailored approach that may lead to a better outcome.

Long-term prevention from neurologic events constitutes the hallmark of effective carotid revascularization. During the follow-up period none of our patients sustained any ipsilateral cerebrovascular event. These results are in coherence with those reported in randomized studies that have demonstrated the same low mid-term stroke rate with no significant differences between CAS and CEA.[16,17]

There were several limitations to this study. This study reports data from a single center, is hypothesis generating and due to its retrospective nature lacks power to draw widely applicable conclusions. In addition, the study lacked randomization and cannot account for selection bias. All procedures were performed by the same surgical and anesthesiology team. The results of this study only apply to the population of patients with carotid artery stenosis admitted to our hospital and cannot be generalized across institutions with varied procedural experience. Furthermore, the relatively limited number of patients does not allow a reliable subgroup analysis for detection of patient or lesion's characteristics that may account for a different risk for cerebrovascular events and certainly the possibility for a type II statistical error cannot be excluded.

CONCLUSION

Short-term outcome, including stroke and myocardial infraction, was not different between CEA and CAS in a single center providing both techniques. During follow-up, long-term protection against ipsilateral stroke did not also differ between the two methods. More real-world comparative data outside RCTs and registries are needed to define the role of each technique in treating patients with significant carotid artery stenosis.

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