Original communication

Long-term outcomes of open and endovascular treatment of recurrent carotid artery stenosis – a 16-year retrospective single centre case series

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Summary: *Background:* The aim of this study is to evaluate perioperative as well as long-term outcomes in patients operated with carotid endarterectomy (CEA) or stenting (CAS) due to symptomatic or asymptomatic high-grade restenosis of the internal carotid artery (ICA). *Patients and methods:* In a retrospective analysis of our electronic database including 2980 patients who underwent carotid endarterectomy or stenting due to a symptomatic or asymptomatic high-grade stenosis of the ICA, between 2000 and 2016, we enrolled 111 patients with recurrent ICA stenosis. *Results:* An ipsilateral 2nd time restenosis (> 80 % in the asymptomatic and > 50 % in the symptomatic patients according to NASCET criteria) of ICA was detected in 13 patients (12 %); 3 of them were symptomatic. These patients were managed with either CEA (n = 5/38 %) or CAS (n = 8/62 %) with no perioperative stroke or death. The stroke-free survival rates at 2 and 8 years for CEA were 98 % and 98 % versus 100 % and 100 % for CAS respectively (P = .271). The type of the initial procedure (patch, CAS or interposition) did not play any significant role for the development of a 2nd time restenosis (P = .841). *Conclusions:* Redo-CEA/CAS seem to have similar results as primary procedures (as reported in the literature) with favorable periprocedural and long-term outcomes.

Keywords: Carotid stenosis, endarterectomy, angioplasty

Introduction

The short, mid- and long-term outcomes of carotid surgery as well as the outcomes after carotid endarterectomy (CEA) versus carotid stenting (CAS) have been well studied in randomized controlled trials [1–4]. How to deal with restenosis, though, after CEA and CAS is of debate and no guidelines have been produced on basis of randomized trials.

The incidence of carotid restenosis (or 1st time restenosis after a previous CEA or CAS) has varied between the different studies. A recent report by the International Carotid Stenting Study investigators (ICSS) stated that at a median follow up of 4.0 years (IQR 2·3–5·0) at least a moderate restenosis (≥ 50 %) occurred in 274 patients after stenting (cumulative 5-year risk 40.7 %) and in 217 after endarterectomy (29.6 %) in 1713 patients randomly allocated to receive treatment (855 were assigned stenting and 858 endarterectomy) [5].

In another study, Moore et al. [6] reported an aggregate incidence of residual and recurrent carotid stenosis varying between 12.7 % and 20.4 %. However, the use of patch angioplasty closure reduced the overall risk of restenosis from 21.2 % to 7.1 % in patients in the Asymptomatic Carotid Atherosclerosis Study (ACAS) [7].

Furthermore, Marques de Marino et al. could not find a statistically significant difference between CEA and CAS in their case-series of 44 patients at three years in terms of early and long-term mortality, neurologic morbidity, and overall morbidity. The rate of 2nd time restenosis and freedom from reintervention was similar in both groups during follow-up [8].

The main cause for early restenosis after CEA is hypothesized to be myointimal hyperplasia, whereas later restenosis is generally considered to be a further evolvement of the underlying atherosclerotic disease [9, 10]. Recurrent lesions within four to six weeks after CEA represent residual atherosclerotic lesions and the restenosis due to

neointimal hyperplasia usually begins three to six months postoperatively. The restenosis occurring 24 months after the initial operation represents most likely a recurrent atherosclerotic process. Factors associated with restenosis include smoking, hypertension, female gender, diabetes, small carotid diameter, residual stenosis, and primary closure after CEA [11–13].

Information on the recurrence of carotid restenosis or 2nd time restenosis (after two prior carotid endarterectomy/stenting procedures) as well as the therapeutic modality has not been as well studied as the first-time restenosis.

The aim of the present study was to evaluate the perioperative as well as the long-term outcome in patients operated with CEA and CAS due to a high grade symptomatic or asymptomatic re-stenosis of the internal carotid artery as well as to identify the possible risk factors associated with a high grade > 80 % 2nd time restenosis (severe re-re-stenosis).

Patients and methods

In the retrospective analysis of our electronic database including 2980 patients operated between 2000 and 2016 (between 2000–2008 digitally scanned documents were analyzed), 111 patients, who were initially admitted to our institute due to a restenosis of the internal carotid artery (ICA) and underwent a carotid endarterectomy/stenting, were enrolled. The indication for CEA/CAS was a high-grade asymptomatic restenosis (> 80 % according to North American Symptomatic Carotid Endarterectomy Trial (NASCET)[3]) or a > 50 % symptomatic restenosis.

A carotid artery stenosis was classified as symptomatic when an ipsilateral neurologic deficit had occurred during the six-month period preceding the presentation in the outpatient clinic. The stenosis grading was done using a color-duplex ultrasonography according to the revised national DEGUM (Deutsche Gesellschaft für Ultraschall in der Medizin-German Society for Ultrasound in Medicine) Ultrasound Criteria for Grading Internal Carotid Artery Stenosis [14]. The multi-parametric German "DEGUM ultrasound criteria" consisting of combined Doppler and imaging criteria were revised and transferred to the NASCET definition [15].

A complete neurologic history and examination by an experienced neurologist were performed on all patients with a suspected symptomatic internal carotid artery stenosis prior to the operation, 24 hours after the procedure and at discharge. Thereafter the patients were followed-up every 6 months by clinical examination and color-duplex ultrasonography.

A preoperative magnetic resonance imaging (MRA) or a CT angiography of the cervicoencephalic arteries in addition to brain-MRI was also performed on all symptomatic patients or when CAS was planned in asymptomatic patients. MRA was also done where the duplex ultrasonography was not able to delineate the distal end of the carotid plaque.

Our local standard is to offer a redo CEA in restenosis but also to offer CAS to patients with a carotid restenosis where the distal disease-free carotid artery could not be safely reached or who were at a higher local risk for a CEA due to neck radiation or radical neck dissection. CAS was not performed in the patients with tortuous carotid arteries, highly angulated aortic arch (type III) or in presence of a floating thrombus in the carotid plaque depicted on duplex ultrasonography or CT.

Open repair (CEA)

Our standard protocol is to perform the CEA under locoregional anesthesia to provide a direct neurological monitoring in order to assess the need for shunting according to the neurological status after clamping of the carotid arteries.

A patch angioplasty with Polyethylenterephthalat is used routinely unless the internal carotid artery is angulated or a relative contraindication to the use of prosthetic material (infection, immunosuppression) is present. In such cases an eversion endarterectomy or a venous patch is used. However, eversion endarterectomy is normally not performed in redo patients due to the less pronounced splitting of the wall layers.

Carotid stenting (CAS)

In our institution CAS is performed by the neuroradiologists in the angiographic suite under local anesthesia, supported by intravenous sedation or general anesthesia when required.

Routinely, the common femoral artery is used for access and rarely the brachial artery is used. The carotid artery lesion is then passed with a .014" guide wire. Pre-dilatation and stent-implantation are the next steps after having done a diagnostic angiography. A double antiplatelet therapy (aspirin and clopidogrel) is adopted for 3 months, after which a monotherapy is continued.

Outcomes

The primary outcomes were perioperative stroke/death, perioperative myocardial infarction, cranial nerve injury (CNI) and incidence of 2nd time restenosis.

Perioperative/periinterventional stroke was defined as a newly occurring irreversible neurologic deficit lasting more than 24 hours. The diagnosis of perioperative myocardial infarction was based on clinical complaints and confirmed by electrocardiogram and cardiac enzymes. CNI was defined by occurrence of cranial nerve injury at discharge.

The secondary outcomes were the same but in long-term follow up.

Risk factors in medical history such as smoking habits, history of diabetes, arterial hypertension, hypercholesterolemia (arterial hypertension with a systolic component $\geq$ 140 mmHg and diastolic $\geq$ 90 mmHg, hypercholesterolemia defined as a total cholesterol greater than 190 mg/dL and/or LDL > 130 mg/dl) and the prevalence of cardiovascular diseases (peripheral arterial disease (PAD), coronary artery disease (CAD)) were recorded.

Because of the retrospective single center nature of the present study (review of patients' database) no additional approval of study from Ethic-Committee was required. The informed consent of patients was obtained prior to each procedure.

Statistical analysis

Statistical analysis was performed using the SPSS statistical software package (SPSS Version 25, IBM Corp, Armonk, NY, USA). Test of normality was performed for all numeric data. Data are expressed as mean (standard deviation, SD) or median (interquartile range, IQR) for continuous variables and counts (%) for nominal variables. Non-parametric data was analyzed with the Mann-Whitney and Kruskal-Wallis test and statistical analysis of parametric data was performed with the unpaired t-test. The Chi-square test was used to compare categorical variables. A forward, stepwise, multivariate logistic regression model was used to identify predictors for the developing of 2nd time restenosis including basic demographic characteristics and relevant preoperative comorbidities.

Kaplan-Meier curves were computed for comparison of overall long-term stroke-free survival and treatment groups were compared by the log rank test. A p-value less than 0.05 was considered statistically significant. For multiple testing/comparisons a Bonferroni correction for the level significance has been used. Confidence intervals with 95 % confidence level were used.

Results

Out of the 2980 patients in our database having undergone carotid CEA or CAS, 111 (49 females, 44 %) were operated/intervened due to ICA restenosis and were included. Basic demographic characteristics of the recruited patients are shown in Table I.

In 14 (13 %) patients the restenosis was treated with CAS. The rest of the patients had a CEA using patch angioplasty technique (9–8 % venous patches, 85–77 % Polyethylenterephthalat), whereas a graft interposition was used in 3 (3 %) patients. CEA will be used in this context for both patch and interposition.

11 patients (10 %) were operated due to a symptomatic restenosis of the ICA; 2patients with stroke and 9 (8 %) with a transit ischemic attack (TIA).

7 of the asymptomatic patients (7 %) had a contralateral ICA occlusion and 2 (18 %) of the symptomatic ones (P = .605).

The perioperative all territories stroke rate was 2.7 % (2 patients with an asymptomatic and one patient with a symptomatic stenosis). 2 strokes occurred after CEA and one after CAS (P = .238). No periprocedural death or myocardial infarction occurred.

One patient in the CEA group had CNI (recurrent nerve paresis) vs. none in the CAS group. (P = .704).

No gender difference in term of perioperative stroke risk was detected (P = .653).

35 patients were lost during the follow-up, leaving 76 patients with a median follow-up period of 37 months (IQR: 9–67.5 months) including 9 patients with a follow-up period less than 6 months.

An ipsilateral 2nd time restenosis (> 80 % in the asymptomatic and > 50 % in the symptomatic patients according to NASCET criteria) of the internal carotid artery was detected in 13 patients (12 %) (11 in the CEA and 2 in the CAS group), 3 of them were symptomatic (23 %) (2 presented with TIA and one with a stroke). (P = .562). The

Table I. The basic characteristics of patients who underwent CEA (open redo operation) vs. CAS (carotid artery stenting).

	CEA	CAS	P-Value
Male/female	55/42	7/7	.775*
Age	69.9 ± 9.3	69.4 ± 10.7	0.873‡
Diabetes mellitus	26 (26.8 %)	4 (28.6 %)	.750*
Peripheral arterial disease	37 (38.1 %)	6 (42.9 %)	.764*
Coronary artery disease	33 (34 %)	4 (28.6 %)	1.000*
Smoking	35 (36.1 %)	2 (14.3 %)	.212*
Arterial hypertension	84 (86.6 %)	12 (85.7 %)	1.000*
Hypercholesterolemia	34 (35.1 %)	2 (14.3 %)	.213*
Symptomatic stenosis	11	0	.353*
TIA	9	–	–
Stroke	2	–	–

* Qi square test (Fisher's exact test) was used.
‡Mann-Whitney test was used.

Table II. The basic characteristics of patients who developed a 2nd time restenosis (S-RS) during follow-up

	No S-RS (n = 98)	S-RS (n = 13)	P-Value (2-sided)
Male/female	53/45	9/4	.542*
Age	71 ±9.3	64±9	0.025‡
Diabetes mellitus	25(26 %)	5(38.4 %)	.323*
Peripheral arterial disease	36(37 %)	7(54 %)	.234*
Coronary artery disease	36(37 %)	1(7.7 %)	.055*
Smoking	31(32 %)	6(46 %)	.333*
Arterial hypertension	84(86 %)	11(85 %)	1.000*
Hypercholesterolemia	35(36 %)	1(7.7 %)	.058*
TIA	9	2	.482
Stroke	2	1	.238

* Qi square test (Fisher's exact test) was used.
‡ Mann-Whitney test was used.

basic characteristics of patients who developed a 2nd time restenosis are shown in Table II. The mean estimated time for recurrent re-stenosis to occur was 136 months (95 % CI 109–164) in CEA group and 92months (0–194) in CAS group.

Half of the 2nd time restenosis cases were detected within the first three years of follow-up.

These patients with a 2nd time restenosis were managed with either endarterectomy and patch angioplasty (n = 5/38 %) or carotid stenting (n = 8/62 %) with no perioperative stroke or death. The 2 patients who developed a 2nd time restenosis after a previous CAS were also treated with CAS.

Additionally, of the 111 patients with a restenosis 35 (31.8 %) developed a contralateral high-grade stenosis during the follow-up period.

In the multivariate regression analysis, the male patients showed a higher incidence of 2nd time restenosis. Furthermore, the patients who developed a 2nd time restenosis had a higher prevalence of diabetes mellitus. Table III.

The type of the initial procedure (patch, CAS or interposition) did not play any significant role for the development of a 2nd time restenosis (P = .841).

The estimated mean stroke-free survival was 186 months (95 % CI 177–194) for the CEA group. Because of the occurrence of only one stroke in the CAS group during follow-up (144 months after the initial operation) no 95 % CI for the estimated mean stroke-free survival could be calculated (P = .271). The stroke-free survival comparison between CEA and CAS is shown using a Kaplan-Meier curve in Figure 1 and because of the short follow up for CAS, only for CEA in Figure 2.

The stroke-free survival rates at 2 and 8 years for CEA were 98 % and 98 % versus 100 % and 100 % for CAS respectively (P = .271).

Furthermore, we performed an additional case-matched control group comparison between the 111 patients (group A) operated due to a restenosis and of those (group B) who underwent CEA due to a primary carotid stenosis. Group B was retrospectively analyzed during the same period with the same surgical and radiological team. The matching was based on age, gender, symptomatic/asymptomatic stenosis and co-morbidities and yielded a control group consisting of 104 patients. The mean age of this group was 71.9 ± 8.4 years with 47 female patients.

Table III. The relevant risk factor in the multivariate regression analysis to develop a 2nd time restenosis.

	p-value	OR	95 %CI
Male gender	.019	21.1	1.7–256.1
Diabetes mellitus	.017	13.7	1.6–116.8

CI: Confidence Interval; OR: Odds Ratio.

There was no statistically significant difference between the perioperative stroke rate in group B with 2.9 % vs. the 2.7 % in the restenosis group.

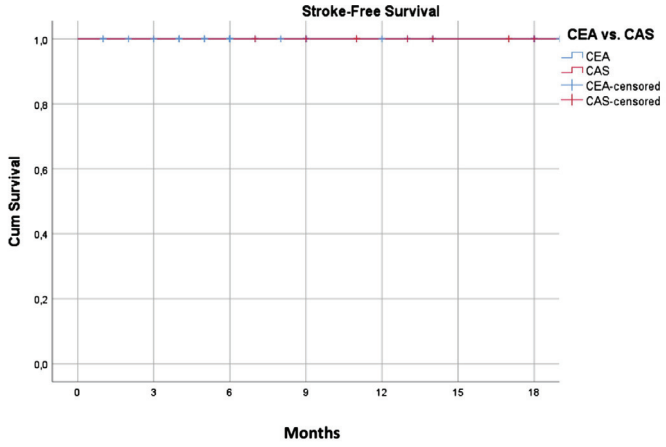
An ipsilateral 2nd time restenosis (> 80 %) was diagnosed in 8 patients (P = .531 in comparison to the restenosis group), but no further strokes were detected in the primary group during the follow-up.

Discussion

The main findings of the present study were the low perioperative/periinterventional stroke rate with a comparable rate of 2nd time restenosis to that reported in the literature.

Additionally, a higher incidence of 2nd time restenosis was found in patients with diabetes mellitus and in male patients. A significant drawback was the relatively large number of patients who dropped-out of the follow-up program leading, possibly, to a selection bias therefore this result found in the in multivariate analysis should be balanced with the low number of patients.

The management of atherosclerotic carotid and vertebral artery disease guidelines of the European Society for Vascular Surgery (ESVS) recommended that the choice of redo endarterectomy or stenting should be based on a multidisciplinary team review, local surgeon/interventionist preference, and patient choice (evidence class I, level C). [13] Among other references, the ESVS-Guidelines also cited the meta-analysis from 2015 done by Fokkema et al. [16], who derived 1132 patients from 13 studies where a redo CEA was compared with CAS. They did not find any statistical difference in the 30-day stroke/death rates between redo CEA and CAS. Neither did they find a difference of recurrent restenosis > 70 %. The 2nd time restenosis rate in the present study was in the same magnitude as that found in the meta-analysis performed by Texakalidis et al. [17]; they reported an estimated proportion of recurrent restenosis rate of 8.5 % among 328 patients who underwent CEA versus 4.2 % among those in the CAS group, with a preponderance for severe restenosis among CEA group. Furthermore, the authors found that CAS was associated with significantly lower risk for long-term recurrent carotid artery restenosis when defined as stenosis > 60 % or > 70 %.

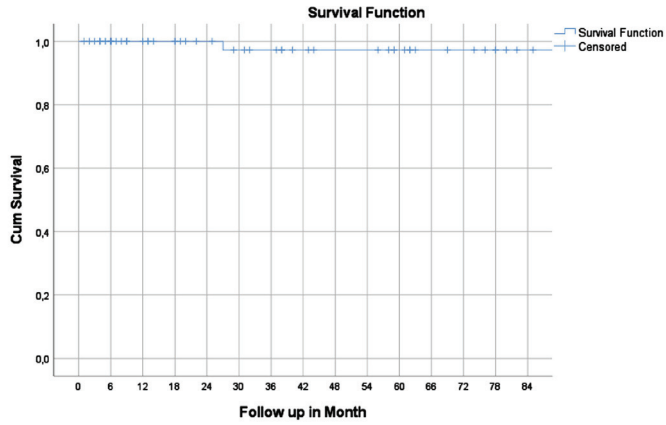


Stroke-free survival (Nr. at risk):

P=.271

Months	0	3	6	9	12	15	18
CEA	97	62	56	49	46	43	42
CAS	14	13	13	13	11	11	10

Figure 1. The stroke-free survival for CEA (carotid endarterectomy) and CAS (carotid stenting) groups shown with Kaplan-Meier curve.



Stroke-free survival (Nr. at risk):

Months	0	6	12	18	24	30	36	42	48	54	60	66	72	78	84
CEA	97	56	46	42	38	34	33	28	26	26	22	18	17	14	11

Figure 2. The stroke-free survival for CEA (carotid endarterectomy) group shown with Kaplan-Meier curve.

However, a 2nd time restenosis rate, similar to our study, was reported by Rockman et al. [18] and Akingba et al. [19] in their 10-year retrospective case series as well as by Dorigo et al., but with no restenosis in the CAS group [20].

The stroke rate seen in the present study (2.7 %) seems to be similar to the one reported in other works: Texakalidis et al. [17] reported a periprocedural stroke rate of 2.3 % in patients with a redo CEA and 1.7 % of patients undergoing CAS, a difference without a statistical significance. On the contrary, the 30-day stroke rate was relatively higher (5 % after CEA and 3 % after CAS group) in the case-series reported by Antonello et al. [21].

In the present study one CEA patient (1 %) developed a recurrent nerve paresis. As expected, none of the CAS patients developed a CNI. Our CNI rate after CEA seems to be lower than that reported by Marques de Marino et al. [8] where 13 % in the CEA-redo group developed a CNI, which is higher than the 5.5 % reported in a per-protocol analysis in the ICSS being more common among females [22]. There is no other obvious cause for our better results than maybe the high volume and standardized protocol.

A quite interesting finding in the present study was that 10 % of patients who underwent a redo intervention due to a carotid restenosis were symptomatic, and that 23 % of the patients in the group of repeated redoes due to the 2nd time restenosis were symptomatic. A possible cause here might be the lower number of patients who developed a 2nd time restenosis and the relatively reduced follow-up duration. Another explanation is that the patients who develop neurologic symptoms would seek medical assistance more than those who stay asymptomatic or that the

tendency to operate asymptomatic patients is lower for redo surgery.

Our finding of more frequent 2nd time restenosis in male patients does not align with the results of other studies where the female gender was associated with a higher rate of recurrent stenosis. Trisal et al. reported that female patients had a slightly higher recurrence rate of restenosis as compared to males [9]. In addition to the female gender, the CREST study reported also diabetes, and dyslipidemia to be independent predictors of restenosis or occlusion after both procedures, but there was no report regarding the 2nd time restenosis [12]. We found diabetes mellitus to be a risk factor for the 2nd time restenosis, but with few patients in this group. When looking into other areas (Percutaneous Transluminal Coronary Artery Angioplasty-PTCA, angioplasty of renal arteries) the female gender as well as the diabetes still play a possible role in developing a recurrent stenosis in patients who had a PTCA [23, 24] but not in patients with a renal artery stent-angioplasty [25], there is only data for the primary restenosis and not for a 2nd time restenosis. There is no really good explanation for the higher restenosis rate in males but the limited number of patients who developed a 2nd time restenosis especially as there was no difference regarding the risk factors (coronary artery disease, peripheral arterial disease, smoking, diabetes mellitus, arterial hypertension or hypercholesterolemia) between the two genders. Although, the limited number of patients included in the regression analysis in the present study would reduce the robustness of results regarding the possible risk factor we found to be associated with a 2nd time restenosis.

Although there was a reduced number of patients who developed a 2nd time restenosis in the present study, both CEA and CAS could be used for re-redoes. However, the lack of studies on the treatment options and absence of mid- and long-term outcomes of patients treated due to 2nd time restenosis make this topic an area of further research.

Limitations

The retrospective and single center design of the present study combined with the relatively low number of patients treated with CAS and the significant number of patients who dropped out of the follow-up in addition to the long duration of the study reduces the robustness of the findings.

Conclusions

Redo-CEA/CAS seem to have similar results as primary procedures (as reported in the literature) with favorable periprocedural and long-term outcomes. Nevertheless, a cohort with a larger number of patients would strengthen the validity of the study and its results.

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