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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Impact of coronary artery disease presence on the long-term follow-up of carotid artery stenting

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Abstract

Background: Carotid artery stenting (CAS) has become an alternative for carotid endarterectomy in the treatment of carotid artery atherosclerosis, due to limited injury and comparable periprocedural risk. The impact of coronary artery disease (CAD) on long-term follow-up after CAS needs to be reconsidered due to the intensification of aggressive pharmacotherapy in CAD in recent years.

Aim: To assess the impact of CAD presence on the long-term follow-up of patients after CAS.

Methods: Data of 130 symptomatic and asymptomatic patients undergoing CAS with cerebral protection systems from December 2002 to December 2010 were divided into two groups: those with and those without CAD. Major adverse cardio- and cerebrovascular events (MACCE) during follow-up were defined as the combination of death (cardiac and non-cardiac), myocardial infarction (MI) and stroke or transient ischaemic attack (TIA). Long-term outcomes of patients were stratified based on the history of CAD.

Results: The mean age of patients was 66 ± 9 years, and the majority of patients were male (80.2%). Long-term follow-up data were available in 86.2% of patients. During mean follow-up of 71.9 ± 31.7 months the all-cause mortality rate was 19.3%. The rates of MI, stroke/TIA, and MACCE were 16.7%, 12.3%, and 36.3%, respectively. The frequency of MACCE during long-term follow-up was higher in patients with CAD vs. without CAD (40.8% vs. 6.7%, p = 0.01), and the mortality rate in the two groups was 22.2% vs. 0%, (p = 0.07), respectively.

Conclusions: Patients with symptomatic or asymptomatic carotid stenosis are high-risk individuals. The presence of CAD increases the risk of MACCE in such patients during long-term follow-up.

Key words: carotid artery stenosis, carotid artery stenting, coronary artery disease, stroke

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INTRODUCTION

Carotid artery atherosclerosis is a significant cause of neurological morbidity and mortality [1]. Among major risk factors for stroke are hypercholesterolaemia, arterial hypertension, diabetes, smoking, atrial fibrillation, coronary artery disease (CAD), and other cardiac and cerebrovascular diseases [2]. Carotid artery stenosis is often associated with advanced CAD. The coexistence of carotid artery disease and CAD varies between 2% and 14% [3] and adds complexity to the treatment decision and aggravates the prognosis.

Surgical carotid endarterectomy (CEA) has for a long time been the standard approach for the treatment of carotid artery stenosis. Carotid artery stenting (CAS), as a less invasive technique, may be non-inferior to CEA in patients with high risk for surgery [4]. Currently, CAS has evolved to be an alternative method in selected patients.

The impact of CAD in patients undergoing CAS needs reconsidering due to the intensification of aggressive pharmacotherapy in CAD in recent years. In addition, most studies focus on cerebral events after CAS, and fewer on cardiovascular events during follow-up.

The purpose of the present study was to assess the impact of CAD presence on the long-term follow-up of patients after CAS.

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METHODS

Study population

The study population consisted of 130 consecutive patients with symptomatic and asymptomatic carotid artery stenosis undergoing CAS from December 2002 to December 2010. Patients were divided into two groups based on the presence or the absence of CAD. The first group consisted of 111 patients with a history of CAD. The second group comprised 19 patients without history of CAD and without significant atheromatosis in coronary arteries.

Patients with a history of myocardial infarction (MI), coronary artery bypass grafting, percutaneous coronary intervention, or at least one ≥ 50% stenosis in coronary arteries were considered to have a history of CAD. Patients with ipsilateral ischaemic stroke or transient ischaemic attack (TIA) within six months before CAS were classified as symptomatic.

Patient selection for revascularisation was based on clinical findings and non-invasive examinations, such as ultrasonographic imaging. CAS was performed in symptomatic patients with ≥ 50% carotid stenosis and in asymptomatic patients with ≥ 80% stenosis by carotid angiography. We measured the carotid stenosis according to North American Symptomatic Carotid Endarterectomy (NASCET) criteria [5]. All patients before CAS had been disqualified for CEA, after neurological and vascular surgeon consultation. CAS was performed in high-risk patients for CEA and in the absence of patient consent to CEA. Neurology evaluation was performed prior to the procedure and 24 h after the procedure.

Procedures

All patients were screened for CAD, and coronary angiogram was performed before CAS. In the case of significant lesions, coronary revascularisation was performed, based on the current guidelines.

CAS was performed through femoral or brachial access, with the use of different kinds of stents (open and closed cell) and proximal or distal embolic protection devices (EPD), according to the "Tailored-CAS" algorithm, which allows the choice of the most suitable EPD and stent type depending on the lesion characteristics and the presence of neurological symptoms [6].

Periprocedural treatment

Prior to intervention, the patients received acetylsalicylic acid (ASA), clopidogrel for at least 2–3 days, or a loading dose of 300 mg of clopidogrel immediately before the procedure. During the period between 2002 and 2005, a number of patients received 500 mg ticlopidine daily for at least three days before CAS. During the procedure the patients received 100 U/kg of unfractionated heparin intra-arterially, followed by boluses so as to maintain activated clotting time at the level of 300–400 s. After the procedure the patients received clopidogrel (75 mg/daily) or ticlopidine (500 mg/daily) for one month and life-long ASA (75 mg/daily). In addition, angiotensin-converting enzyme inhibitors, beta-blockers, and lipid-lowering drugs, such as statins, were used to control the arterial hypertension and hypercholesterolaemia. Recommendations for smoking cessation and weight reduction in obese patients were issued.

Clinical follow-up

Clinical follow-up was performed as control visits to the outpatient facility or as telephone conversations carried out by a physician. Follow-up was performed from hospital discharge, at 1, 6, and 12 months, and yearly thereafter. The major adverse cardio- and cerebrovascular events (MACCE) were defined as the occurrence of death (cardiac and non-cardiac), stroke/TIA, or MI during the periprocedural period or within the time of follow-up. MI was defined as chest pain with concomitant elevation of cardiac creatine kinase (CK-MB) (> three times the upper limit of normal values or ≥ 50% if the value was above normal at baseline) and/or new electrocardiographic (ECG) changes (ST-segment elevation, left bundle branch block, or new Q-waves). Stroke was defined as new neurological deficit lasting for > 24 h and diagnosed by a neurologist. TIA was defined as transient, reversible neurological deficit. The periprocedural period was defined as the period from CAS through 30 days after intervention.

Statistical analysis

Results are presented as percentage or mean ± standard deviation, as applicable. Differences in categorical variables were analysed using the χ^2 test or Fisher's exact test, as appropriate. Continuous variables were compared using the unpaired Student t test. Cumulative survival and MACCE-free survival during follow-up were calculated with the Kaplan-Meier method and compared between groups using the log-rank test. Additionally, multivariate Cox regression analysis was performed to find independent predictors of all cause death and MACCE. The following covariates were tested: age, sex, past medical history (previous CAD, previous MI, previous percutaneous coronary intervention, previous coronary artery bypass grafting, arterial hypertension, diabetes mellitus, dyslipidaemia, smoking status, previous stroke/TIA), and target lesion. Risk of death and MACCE during follow-up was expressed as hazard ratio with 95% confidence interval. All tests were two-tailed, and a p value < 0.05 was considered statistically significant. All statistical analyses were performed using SPSS software, version 15.0 (SPSS Inc., Chicago, Illinois).

RESULTS

The data from 130 consecutive patients with symptomatic and asymptomatic stenosis of carotid arteries undergoing CAS were collected. There were 111 (85.4%) patients with a history of CAD (CAD group), and 19 (14.6%) patients without the history of CAD (no-CAD group). Symptomatic patients

Table 1. Demographic data and medical history of patients after carotid artery stenting

Parameter	CAD (n = 111)	No-CAD (n = 19)	P
Age [years]	65.6 ± 9.1	66.1 ± 8.0	0.82
Male	84.7%	57.9%	0.01
History of myocardial infarction	39.6%	0.0%	< 0.001
Previous percutaneous coronary intervention	34.2%	0.0%	< 0.001
Previous coranory artery bypass graft	9.9%	0.0%	0.22
Arterial hypertension	82.0%	78.9%	0.48
Diabetes mellitus	23.4%	5.3%	0.12
Dyslipidaemia	70.3%	52.6%	0.18
Current smokers	2.7%	5.3%	0.47
Prior stroke or transient ischaemic attack	42.3%	57.9%	0.22
Right carotid artery stenosis	49.5%	42.1%	0.80

CAD — coronary artery disease

constituted 44.6% of the whole group. There were no significant differences between the two groups in terms of age. The prevalence of males was significantly higher in the CAD group (p = 0.01). Demographic data and medical history of patients with carotid artery stenosis are presented in Table 1.

Long-term follow-up data was available in 86.2% of patients (89.2% for the CAD group and 78.9% for the no-CAD group). Carotid interventions were performed in the right internal carotid artery (RICA), left internal carotid artery (LICA), and in the left common carotid artery (LCCA) in 48.5%, 48.5%, and 3.1% patients, respectively. No intracranial haemorrhages, cerebral ischaemic events, MIs, or deaths occurred during the periprocedural period in the studied groups.

During mean follow-up of 71.9 ± 31.7 months the frequency of MACCE was significantly higher in patients with a history of CAD (p = 0.01). Long-term rates of strokes, MI, deaths, and other events are presented in Table 2. For all patients, total MACCE occurred in 55 (36.3%) patients, MI in 19 (16.7%) patients, stroke/TIA in 14 (12.3%), and 22 (19.3%) patients died. Among the deaths, fatal MI occurred in six (27.2%) patients (all of them with a history of CAD), fatal stroke in four (18.1%) patients, cancer in five (22.7%) patients, and seven (31.8%) deaths were from unknown cause. No deaths occurred in the no-CAD group during follow-up.

There were no significant differences in cardiac and cerebrovascular events between symptomatic and asymptomatic patients during follow-up. The rate for combined MACCE was similar for symptomatic and asymptomatic patients (36.7% vs. 35.9%, respectively, p = 0.93). In-stent restenosis was observed in two symptomatic patients at 12 months and in one asymptomatic patient at 36 months follow-up. There was no significant difference in the in-stent restenosis rate between the two groups.

Age and previous MI were the most consistent independent risk factors of all-cause death and MACCE during long-term follow-up (Table 3). In the Kaplan-Meier cumulative survival curve, there were no differences between the two groups (p = 0.07) (Fig. 1). After 11 years follow-up the rate of MACCE-free survival was significantly higher in the patients without CAD (p = 0.02) (Fig. 2).

Table 2. Major adverse cardio- and cerebrovascular events (MACCE) and other events after carotid artery stenting (CAS) stratified by coronary artery disease (CAD) presence

Variable	CAD (n = 111)	No-CAD (n = 19)	P
All-cause death	22.2%	0%	0.07
Myocardial infarction	18.2%	6.7%	0.46
Stroke/TIA	14.1%	0%	0.21
Total MACCE	40.8%	6.7%	0.01
PCI	21.2%	5.3%	0.30
CABG	5.5%	5.3%	0.99
Contralateral CAS	4.0%	0%	0.64

CABG — coronary artery bypass grafting; CAD — coronary artery disease; PCI — percutaneous coronary intervention; TIA — transient ischaemic attack

DISCUSSION

The long-term follow-up results indicate that patients undergoing CAS have a high risk of cardiac and cerebrovascular events. In this study the rate of events among symptomatic and asymptomatic patients was significantly higher in patients with a history of CAD during long-term follow-up.

The majority of patients (85.4%) had a history of CAD; this disproportion between the two groups could be related to the profile of the patients, who were admitted to the cardiology department. Routine coronary angiogram and revascularisation for critical stenosis was performed before CAS, when

Table 3. Independent predictors of all cause death and major adverse cardio- and cerebrovascular events in patients after carotid artery stenting

Variable	HR	95% CI	P
All-cause death			
Age (per 1 year)	1.076	1.021–1.135	0.007
Previous myocardial infarction	2.612	1.113–6.129	0.027
Major adverse cardio- and cerebrovascular events			
Age (per 1 year)	1.041	1.004–1.080	0.031
Previous myocardial infarction	2.241	1.199–4.188	0.011

Values are presented as hazard ratio (HR) with 95% confidence interval (CI)

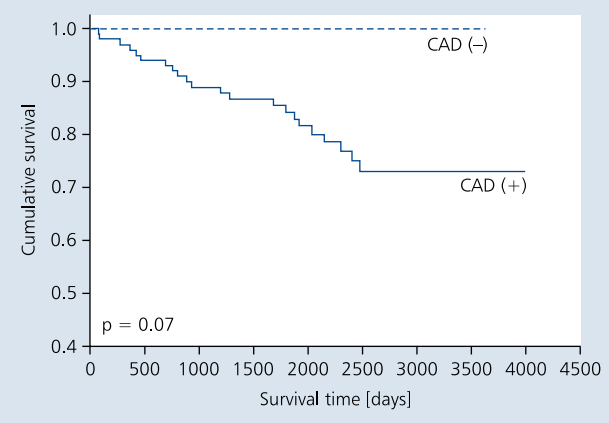

Figure 1. Kaplan-Meier curve. The cumulative survival in patients undergoing carotid artery stenting, stratified by the presence or absence of coronary artery disease

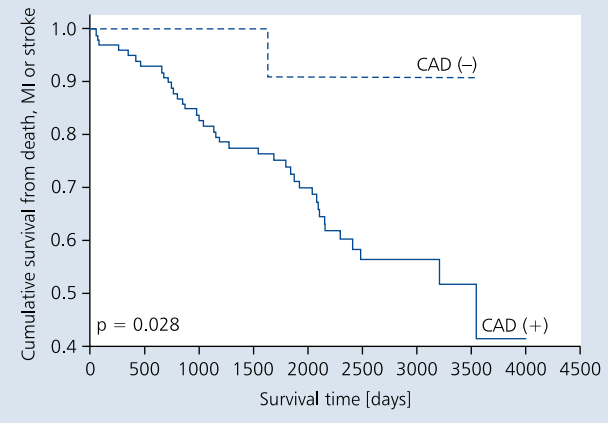

Figure 2. Kaplan-Meier curve. Probability of survival free from death, myocardial infarction (MI), and stroke/transient ischaemic attack in patients undergoing carotid artery stenting, stratified by the presence or absence of coronary artery disease

needed. Cardiac screening should be performed in patients with carotid stenosis before carotid revascularisation, due to the high probability of the coexistence of CAD. In addition, the coexistence of contralateral carotid stenosis seems to be related with higher probability of coexisting CAD [7].

Undergoing CEA in the previous study of 200 patients without history of CAD identified coronary lesions in 86% of patients and severe stenosis (≥ 70%) in 40% [8]. Revascularisation of critical coronary artery stenosis before CAS could play a part in the reduction of cardiac complications during follow-up.

The periprocedural stroke or death rates after CAS in previous trials are varied, with the values ranged between 3.1% and 9.6% [9–12]. Another study of over 1,000 patients found a 2.3% 30-day rate of death, any stroke, or MI [13]. The 30-day stroke and death rates in current studies and trials are varied, probably due to the different use of embolic protection systems, proportion of symptomatic patients [14], and the lack of operator's experience. Low-volume experienced centres are associated with increased 30-day mortality [15].

The CEA vs. CAS trials (EVA-3S, ICSS) in symptomatic patients showed significantly higher rates of stroke or death after CAS at 30-day follow-up [16, 17]. It is remarkable to point out that there were numerous limitations for the EVA-3S study as a high failure rate of CAS, low-volume experienced centres, rates of MI were not assessed, emergency conversion of CAS to CEA and incomplete antiplatelet drug therapy. In ICSS EPD was not mandatory in 72% of patients. Likewise, EPD was not mandatory in 27% of patients in SPACE trial, which reported comparable results between symptomatic CAS and CEA [18]. In the CREST study, the 30-day rate of any stroke or death was significantly higher in CAS for symptomatic patients, but with a higher rate of minor strokes and with no difference for major strokes. MI was more common after CEA in symptomatic and asymptomatic patients, but without significant differences. At four-year follow-up there were no significant differences in the outcomes between CAS and CEA [9, 19].

During the periprocedural period of the study there were no deaths, or cardiac or cerebrovascular events. Symptomatic hyperfusion with blood pressure reduction occurred immediately after CAS in two patients. The absence of events could result from the wide experience of the operators and the use of cerebral protection devices in all patients.

In the CAVATAS study the cumulative eight-year rate of ipsilateral stroke was higher in CAS (11.3%) [20]. Radu et al. [14] reported overall stroke rates of 15.4% after 12 years follow-up. In the present study, after 11 years of follow-up the overall stroke rate was 12.3% and MI occurred in 16.7% of patients. The incidence of in-stent restenosis occurred in two symptomatic patients at 12 months and in one asymptomatic patient at 36 months follow-up. It is important to note that ultrasonographic follow-up was not available to all patients.

Previous studies reported a significantly negative impact of coexisting CAD in patients after CAS on the long-term survival, with a difference of 8.2% ($p = 0.04$), after three years follow-up [6]. Our 11-year follow-up showed a significantly higher MACCE-free survival in the patients without CAD ($p = 0.02$).

Age is an important parameter that should be taken into consideration when selecting patients either for carotid stenting or endarterectomy. A number of studies showed that elderly patients after CAS are associated with a higher number of cerebrovascular events, but mortality is equivalent to that seen in younger patients [21, 22]. CAS could be safely performed in elderly patients if factors such as vascular tortuosity and heavy concentric calcification of the lesion were avoided [23]. Previous studies found that advanced age (> 75 years) was an independent predictor of death after CAS [6]. Also in this study, age and previous MI were independent predictors of death and MACCE.

Finally, the impact of CAD during long-term follow-up needs to be reconsidered, due to the intensification of aggressive pharmacotherapy and primary prevention efforts in CAD in recent years.

Limitations of the study

The study has a number of limitations. First, it has all the limitations inherent to single-centre registries. Second, a disproportion between the two groups (small number of patients without a history of CAD) was observed. Third, follow-up data was not available for all patients. Fourth, because of the absence of ultrasound examination during follow-up in some patients, the restenosis rate may have been underestimated. Fifth, data concerning compliance to guideline-recommended pharmacotherapy was not available. And finally, CAS procedures were performed between 2002 and 2010, which is why carotid revascularisation was performed according to previous guidelines.

CONCLUSIONS

Patients with symptomatic or asymptomatic carotid stenosis are high-risk individuals with many coexisting diseases. Despite more intensive pharmacotherapy in CAD in recent years, the presence of CAD in patients after CAS has an unfavourable prognostic influence during long-term follow-up.

Conflict of interest: *none declared*

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Wpływ choroby niedokrwiennej serca na wyniki odległej obserwacji pacjentów po zabiegu stentowania tętnicy szyjnej

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Streszczenie

Wstęp: Ze względu na ograniczenie urazu i porównywalne ryzyko okołozabiegowe stentowanie tętnic szyjnych (CAS) stało się metodą alternatywną dla endarterektomii w leczeniu miażdżycy tętnic szyjnych. Uwzględniając intensyfikację farmakoterapii u pacjentów z chorobą niedokrwienną serca (CAD) w ostatnich latach, wpływ CAD na obserwację odległą po CAS wymaga ponownego rozpatrzenia.

Cel: Celem badania była ocena wpływu obecności CAD na długoterminową obserwację pacjentów po CAS.

Metody: Zgromadzono dane 130 objawowych i bezobjawowych pacjentów poddanych CAS w okresie od stycznia 2002 do grudnia 2012 r. Chorych podzielono na dwie grupy: z CAD i bez CAD. Niekorzystne incydenty sercowo-naczyniowe (MACCE) w okresie obserwacji zostały zdefiniowane jako zgon, zawał serca i udar niedokrwienny/przemijające niedokrwienie mózgu (TIA) rozpatrywane łącznie. Obserwację odległą oceniono w grupie pacjentów z CAD i bez CAD.

Wyniki: Średni wiek pacjentów wynosił 66 ± 9 lat, a większość chorych stanowili mężczyźni (80,2%). Dane dotyczące obserwacji odległej były dostępne w przypadku 86,2% osób. Podczas obserwacji, trwającej średnio 71,9 ± 31,7 miesiąca, śmiertelność wyniosła 19,3%. Zawał serca, udar niedokrwienny mózgu oraz MACCE stwierdzono odpowiednio u 16,7%, 12,3% i 36,3% pacjentów. Częstość MACCE była znamiennie większa u osób z CAD niż bez CAD (40,8% *vs*. 6,7%; p = 0,01), a śmiertelność podczas obserwacji odległej w obu grupach wynosiła odpowiednio 22,2% *vs*. 0% (p = 0,07).

Wnioski: U pacjentów ze zwężeniem tętnic szyjnych istnieje zwiększone ryzyko zgonu. Współistnienie CAD zwiększa ryzyko MACCE w obserwacji odległej w tej grupie chorych.

Słowa kluczowe: choroba niedokrwienna serca, stentowanie tętnic szyjnych

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