Safety and efficacy assessment of carotid artery stenting in a high-risk population in a single-centre registry

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Postep Kardiol Inter 2014; 10, 4 (38): 258–263
DOI: 10.5114/pwki.2014.46767

Abstract

Introduction: Ischaemic stroke is the primary cause of long-term disability and the third most common cause of death. Internal carotid artery stenosis is an important risk factor for stroke and transient ischaemic attack (TIA). European Society of Cardiology (ESC) and American Heart Association (AHA) guidelines allow carotid artery stenting (CAS) as an alternative to endarterectomy in centres with low rates of death or stroke.

Aim: To assess the safety and efficacy of CAS in a single-centre observation.

Material and methods: We performed a retrospective analysis of all patients treated with CAS between March 2008 and July 2012. Clinical data and outcomes in both asymptomatic and symptomatic patients were analysed.

Results: A total of 214 consecutive patients were included in the registry. Symptomatic patients accounted for 57% of the study group and were more likely to have a history of stroke and/or TIA that occurred more than 6 months before the procedure (50% vs. 8%, $p < 0.001$). Asymptomatic patients were more likely to have a history of coronary artery disease (88% vs. 61%, $p < 0.001$), and the rates of previous acute coronary syndrome and revascularisation were also higher in this group (58% vs. 41% and 71% vs. 52%, respectively, both $p < 0.05$). The symptomatic group had higher incidence of stroke in periprocedural and 30-day observation (4% vs. 0%, $p < 0.05$). There was no difference in incidence of adverse events in long-term observation.

Conclusions: Carotid artery stenting is a safe and efficacious procedure. Every centre performing CAS should monitor the rate of periprocedural complications.

Key words: carotid artery stenting, peripheral artery disease.

Introduction

Cardiovascular diseases are the leading cause of mortality and disability in Europe. Ischaemic stroke is the most common cause of long-term disability and the third most common cause of death [1]. In various analyses, stroke mortality ranges from 10% to 30%. One of the most important risk factors for stroke and transient ischaemic attack (TIA) is internal carotid artery stenosis [2]. In the majority of cases, carotid artery stenosis is caused by atherosclerosis. Some trials, such as NASCET and ACAS, showed benefits of carotid endarterectomy (CEA) over medical therapy [3]. Carotid artery stenting (CAS) is a less invasive method of carotid revascularisation, devoid of some complications that are typical for carotid endarterectomy (e.g. peripheral nerve damage), with a relatively high restenosis rate, and with comparable outcomes [4–6]. European Society of Cardiology (ESC) and American Heart Association (AHA) guidelines state that CAS may be considered as an alternative to CEA in high-volume centres with documented death or stroke rate < 6% in symptomatic patients and < 3% (or "low" according to the AHA guidelines) in asymptomatic patients [7, 8].

Aim

The aim of this registry was to assess the safety and efficacy of CAS procedures performed in our centre in periprocedural, 30-day, and long-term periods.

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Received: 23.09.2014, **accepted:** 4.11.2014.

Material and methods

Study design

This was a single-centre, retrospective, registry-based study. The study protocol was approved by the local ethics committee and was in accordance with the Declaration of Helsinki.

Registry group

In our study we included all consecutive patients who underwent CAS procedures in our centre from March 2008 to July 2012.

In order to assess the significance of artery stenosis every patient had a duplex ultrasound performed. Asymptomatic patients with 70–99% and symptomatic patients with 50–99% carotid artery stenosis were selected for the procedure. According to the European Society of Cardiology guidelines on peripheral artery disease, carotid artery stenosis is considered symptomatic in the presence of TIA or stroke (affecting the corresponding central nervous system territory) within the previous 6 months [7].

All the comorbidities (heart failure, coronary artery disease, hypertension, dyslipidaemia, diabetes mellitus, chronic kidney disease, and peripheral artery disease) were diagnosed according to current guidelines.

Procedure

Every patient was examined by a neurologist before and after the procedure. Each patient was given standard medical pretreatment with antiplatelet agents (aspirin and clopidogrel). Anti-hypertensive drugs were withdrawn 24 h prior to the procedure. Procedure efficacy was defined as a successful stent deployment. All of the patients were discharged home on dual anti-platelet therapy and statins, unless there were contraindications. Every CAS procedure was performed by experienced operators.

Procedures were performed via femoral access. Proximal (Mo.Ma, Medtronic, USA) or distal (FilterWire EZ, Boston Scientific, USA) protection devices were used in every procedure, unless the operator was unable to introduce the device. Each patient was given 5000 IU of unfractionated heparin intravenously with an additional dose dependent on activated clotting time (ACT). Protege RX (ev3 Endovascular, USA), Cristallo Ideale (Medtronic, USA), Wallstent (Boston Scientific, USA), and RX Acculink (Abbott Vascular, USA) stents were used. Pre- and post-dilation were performed if needed. In cases of hypotonia the patient was given intravenous infusion of saline with dopamine when needed; bradycardia was treated with intravenous atropine injection. After the procedure every patient was monitored for 24 h in an Intensive Cardiac Care Unit.

Adverse events

Ischaemic stroke was defined as an acute neurological ischaemic event of at least 24 h duration with focal signs and symptoms, and TIA as temporary focal brain or retinal deficits caused by vascular disease that clear completely in less than 24 h. Diagnosis of myocardial infarction was based on clinical history of chest pain, electrocardiographic changes, and serum cardiac enzymes. Contrast-induced nephropathy (CIN) was defined as either a greater than 25% increase of serum creatinine or an absolute increase in serum creatinine of 0.5 mg/dl.

Statistical analysis

Quantitative values with normal distribution are shown as mean ± standard deviation and were compared using Student's *t*-test. The χ^2 test was used to analyse categorical data. For all tests a value of $p < 0.05$ was considered statistically significant. Statistica 10.0 (StatSoft, USA) package was used to perform all statistical analyses. Separate analyses were done for the symptomatic and asymptomatic patient sub-groups.

Results

Whole studied population

A total of 214 consecutive patients, aged 68 ±9 years, were included in the registry. Women accounted for 33% of the registry population. One hundred twenty-one patients (57%) were symptomatic, according to ESC guidelines criteria. Older patients (≥ 75 years) accounted for 25% of the registry population, 36% of patients had diabetes, 46% dyslipidaemia, 73% a history of coronary artery disease (CAD), 48% were survivors of acute coronary syndrome (ACS), 27% had been diagnosed with heart failure, 20% had peripheral artery disease, 32% had survived a TIA or stroke more than 6 months before the procedure, 82% had arterial hypertension, 16% had chronic kidney disease (CKD), 60% of the registry population underwent coronary revascularisation procedures, and 14% were active smokers (Table I).

Mean internal carotid artery stenosis was 88 ±9%. Left internal carotid artery (LICA) was the target vessel in 53% of procedures, and right internal carotid artery (RICA) in 47% of procedures. Contralateral total occlusion was observed in 4% of cases.

We observed a 96% procedure efficacy. In the vast majority of cases (98%) only one stent was implanted, and 5 patients (2%) required two stents. In 61% of procedures a predilation was performed. Post-dilation was done in 90% of procedures. We used embolic protection devices in 98% of procedures (distal – 86%, proximal – 14%). In 4 cases (2%) the operator was unable to place the embolic protection device in the desired position, so the procedure was terminated.

Median of follow-up was 463 days. Six patients (2%) were lost to follow-up. In periprocedural and 30-day period, stroke occurred in 5 patients (2%), TIA in 10 patients (5%), and acute myocardial infarction in 1 patient (0.5%). There was no case of death during periprocedural and

Table I. Baseline clinical data of the study group

Parameter	All patients (*n* = 214)	Symptomatic patients (*n* = 121) (57%)	Asymptomatic patients (*n* = 93) (43%)
Age, mean ± SD [years]	68 ±9	67 ±9	69 ±9
Age – older (> 75 years), *n* (%)	53 (25)	22 (18)	31 (33)
Sex – female, *n* (%)	70 (33)	38 (31)	32 (34)
DM, *n* (%)	77 (36)	37 (31)	40 (43)
Dyslipidaemia, *n* (%)	99 (46)	55 (45)	44 (47)
CAD, *n* (%)	156 (73)	74 (61)	82 (88)***
Previous ACS, *n* (%)	103 (48)	49 (41)	54 (58)*
Previous PCI or CABG, *n* (%)	129 (60)	63 (52)	66 (71)*
Heart failure, *n* (%)	58 (27)	29 (24)	29 (31)
Peripheral artery disease, *n* (%)	42 (20)	27 (22)	15 (16)
Previous (> 6 months) stroke and/or TIA, *n* (%)	68 (32)	61 (50)***	7 (8)
Hypertension, *n* (%)	175 (82)	102 (84)	73 (78)
CKD, *n* (%)	33 (16)	20 (17)	14 (15)
Active smokers, *n* (%)	30 (14)	13 (11)	17 (18)

*Data are presented as numbers and percentages for categorical variables. Quantitative values with normal distribution are shown as mean ± standard deviation. *p < 0.05, ***p < 0.001. DM – diabetes mellitus, CAD – coronary artery disease, ACS – acute coronary syndrome, TIA – transient ischaemic attack, CKD – chronic kidney disease, PCI – percutaneous coronary intervention, CABG – coronary artery bypass graft*

30-day period; we did not record any case of intracranial haemorrhage either.

In the periprocedural period we observed 7 cases (3%) of CIN, 1 patient (0.5%) required pacemaker implantation due to persistent symptomatic bradycardia, and 3 patients (1%) required dopamine infusion due to hypotonia. There were 2 patients (1%) with haematoma located in the arterial access site, requiring either thrombin injection or surgical treatment (Table II).

In long-term follow-up 8 patients (4%) died (3 patients died from cardiovascular events, 5 patients died from non-cardiovascular related causes 10 patients (5%) suffered a stroke, 11 (5%) had a TIA, and 6 patients (3%) had an acute myocardial infarction (Table III).

Symptomatic vs. asymptomatic patients

Symptomatic patients were more likely to have a history of stroke and/or TIA that occurred more than 6 months before the procedure (50% vs. 8%, $p < 0.001$). Asymptomatic patients were more likely to have had CAD diagnosed previously (88% vs. 61%, $p < 0.001$). The rates of previous ACS and coronary revascularisation (coronary artery bypass graft – CABG or percutaneous coronary intervention – PCI) were also higher in this group (58% vs. 41% and 71% vs. 52%, respectively, both $p < 0.05$). These findings can be related to the fact that patients treated due to ACS or stable angina are also screened for atherosclerosis in other vascular areas and asymptomatic carotid artery stenosis can be found; furthermore, some symptomatic patients are referred for CAS from neurology departments, and their history of cardiovascular diseases is often negative.

We recorded no difference in procedural efficacy or periprocedural complications. The symptomatic group had higher incidence of stroke in periprocedural and 30-day observation (4% vs. 0%, $p < 0.05$). There was no difference in incidence of adverse events in long-term follow-up.

Discussion

Both European and American guidelines recommend CAS as a valuable alternative to CEA, with remarks that such procedures should be done by a team of well-qualified and experienced operators in high-volume centres with documented low rates of death or stroke [7, 8]. European guidelines require periprocedural death or stroke rates to be less than 6% in symptomatic patients (class of recommendation: IIb) and 3% in asymptomatic patients (class of recommendation: IIb). American guidelines are more favourable towards CAS with Class I recommendation for symptomatic patients (with low rate of death or stroke) and with Class IIa recommendation for asymptomatic ones. These recommendations were based on large trials, like CAVATAS, EVA-3S, ICSS, SPACE, SAPPHIRE, and CREST [6, 9–19] and meta-analyses of randomised trials. One of the meta-analyses, done by Economopoulos *et al.*, involving 7484 patients, sum-

Table II. Periprocedural and 30-day results

Parameter	All patients (*n* = 214)	Symptomatic patients (*n* = 121) (57%)	Asymptomatic patients (*n* = 93) (43%)
Internal carotid artery stenosis, mean ± SD (%)	88 ±9	88 ±10	88 ±7
Contralateral total occlusion, *n* (%)	8 (4)	7 (6)	1 (1)
Efficacy, *n* (%)	206 (96)	117 (97)	89 (96)
Any death, *n* (%)	0	0	0
Cardiovascular death, *n* (%)	0	0	0
Stroke, *n* (%)	5 (2)	5 (4)*	0
TIA, *n* (%)	10 (5)	7 (6)	3 (3)
Intracranial haemorrhage, *n* (%)	0	0	0
MI, *n* (%)	1 (0.5)	1 (1)	0
CIN, *n* (%)	7 (3)	4 (3)	3 (3)
Bradycardia requiring PM implantation, *n* (%)	1 (0.5)	1 (1)	0
Hypotonia requiring dopamine infusion, *n* (%)	3 (1)	2 (2)	1 (1)
Access site hematoma requiring intervention, *n* (%)	2 (1)	0	2 (2)

*Data are presented as numbers and percentages for categorical variables. Quantitative values with normal distribution are shown as mean ± standard deviation. *p < 0.05, TIA – transient ischaemic attack, MI – myocardial infarction, CIN – contrast induced nephropathy, PM – pacemaker*

Table III. Long-term results

Parameter	All patients (*n* = 214)	Symptomatic patients (*n* = 121) (57%)	Asymptomatic patients (*n* = 93) (43%)
Any death, *n* (%)	8 (4)	4 (3)	4 (4)
Cardiovascular death, *n* (%)	3 (1)	3 (2)	0
Stroke, *n* (%)	10 (5)	6 (5)	4 (4)
TIA, *n* (%)	11 (5)	7 (6)	4 (5)
Intracranial haemorrhage, *n* (%)	0	0	0
MI, *n* (%)	6 (3)	3 (2)	3 (3)

Data are presented as numbers and percentages for categorical variables. Quantitative values with normal distribution are shown as mean ± standard deviation. TIA – transient ischaemic attack, MI – myocardial infarction

marised that outcomes of CAS compared to CEA were associated with increased risk of any stroke, decreased risk of periprocedural myocardial infarction, and statistically non-significant increase in total mortality [20].

The results of our registry-based analysis show that it is possible to maintain a low rate of periprocedural adverse events and achieve a high efficacy rate due to highly-experienced operators and appropriate patient selection.

In our registry population 57% of patients were symptomatic according to ESC guidelines criteria. Among the trials mentioned above, only the SAPPHIRE and CREST studies enrolled both symptomatic and asymptomatic patients. The SAPPHIRE and CREST populations were quite similar to the one observed in our registry, although there were differences regarding age (older SAPPHIRE population), prevalence of dyslipidaemia (more frequent in CREST and SAPPHIRE populations), diabetes (less frequent in SAPPHIRE population), chronic kidney disease (less frequent in SAPPHIRE population), and coronary artery disease with CABG/PCI (more frequent in SAPPHIRE patients). The meta-analysis by Economopoulos *et al.* analysed data from 13 trials and found that 80% of patients were symptomatic. There was no direct comparison between results in asymptomatic and symptomatic sub-groups. In our registry population, we found higher incidence of stroke in symptomatic patients during the periprocedural period, but the groups did not differ in long-term follow-up.

Some meta-analyses and registries have shown that there is no a great impact of age on complications rate

after CEA [21]; however, older patients were always considered at high surgical risk. The latter opinion was shared by some authors, and their conclusion therefore was that older patients could be good candidates for CAS procedure [22–24]. In our material older patients (> 75 years old) accounted for 25% of the population, with no difference among symptomatic and asymptomatic patients. Contrary to the opinions mentioned above, some authors emphasise that in older patients the procedure can be more challenging and related to higher rates of periprocedural complications caused by severely calcified vessels and vessel tortuosity [25, 26]. To minimise the risk of distal embolisation, guidelines suggest that use of embolic protection devices (EPD) may be considered (class of recommendation: IIb).

A single-centre, randomised study with a small number of patients (36) carried out by Barbato *et al.* showed no reduction of microembolisation during CAS with EPD [27]. In the trial by Macdonald *et al.* CAS with EPD was associated with an increase in new lesions on diffusion-weighted magnetic resonance imaging, and significantly higher rates of microembolisation on transcranial Doppler [28]. In the SPACE and ICSS trials EPD use was not mandatory, and both studies showed no benefit from EPD use [4, 29]. Although the outcomes with use of EPD in the publications mentioned above were controversial, the best results of CAS were observed in trials and registries with mandatory use of EPD (SAPPHIRE, CREST, two large registries by Stabile *et al.* and Zahn *et al.*) [5, 6, 30, 31]. In our registry EPD use was mandatory; in 4 cases when it was impossible to introduce the device, and the procedure was not continued.

Women accounted for 33% of our registry population, which is similar to data from other trials and registries. An increased risk of CEA perioperative complications among women was reported [32, 33]. The impact of sex on outcomes of CAS remains uncertain. In a systematic review of trials by Touzé *et al.* there was no evidence that there was increased risk in women. In our registry group women were less likely to have a history of hypertension and chronic kidney disease, but these differences did not affect outcome – there was no difference in adverse event rates between men and women [34].

Other factors, commonly found in our registry patients, such as a history of CAD (73%), acute coronary syndrome (48%), heart failure (27%), previous stroke and/or TIA (32%), arterial hypertension (82%), chronic kidney disease (16%), and previous PCI or CABG (60%), are widely acknowledged risk factors for any operation, for those high-risk patients the guidelines recommend CAS as an alternative to CEA (class of recommendation: IIa).

In 2007 Ochała *et al.* published the results of a registry-based observation of Polish high-risk patients qualified to CABG surgery, who underwent CAS procedure with mandatory use of EPD due to significant internal carotid artery stenosis. Even though those patients were a selected group of high-risk patients awaiting CABG surgery due to advanced coronary artery disease, the general characteristics of the registry group were similar to our population. The incidence of adverse cardiovascular events, partially connected with elective CABG surgery, was similar to the results of trials and registries involving high-risk patients, as well as to our registry [35].

We could not perform appropriate statistical analyses for each of the sub-groups mentioned above due to the limited number of patients and relatively low rate of adverse events.

Conclusions

Carotid artery stenting, even in a high-risk population, is a relatively safe and efficacious procedure. Every centre performing CAS procedures should constantly monitor the rate of periprocedural complications because outcomes of CAS – like every relatively new method – depend mainly on the experience of the operators and appropriate patient selection.

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