

Carotid artery stenting according to the 'tailored-CAS' algorithm is associated with a low complication rate at 30 days: data from the TARGET-CAS study

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Abstract

Background: The rate of early complications of carotid artery stenting (CAS) should not exceed 3% in asymptomatic and 6% in symptomatic patients. However, some recent studies/registries failed to reach this threshold, fueling a debate on the role of CAS in the treatment of patients with carotid artery stenosis.

Aim: To evaluate 30-day safety of CAS using different embolic protection devices and different stent types according to the 'tailored-CAS' algorithm and to identify risk factors for complications.

Methods: Between 2002 and 2010, we performed 1176 CAS procedures in 1081 patients (age 38–86 years, mean 66.3 ± 8.4 years, 51.5% symptomatic) according to the 'tailored-CAS' algorithm that included extracranial ultrasound and computed tomography angiography to select the most appropriate embolic protection device (EPD) and stent type. Proximal EPD and closed-cell (CC) stents were preferentially used for high-risk lesions (HR — soft/thrombus-containing/tight/ulcerated, 36.14% of all lesions) and in symptomatic patients.

Results: Procedural success rate was 99.8%. In symptomatic patients, proportion of HR lesions was higher (41.1%) than in the asymptomatic group (30.8%, $p = 0.001$) and the usage of CC stents (76.2% vs 71.7%, $p = 0.103$) and proximal EPD (P-EPD, 34.8% vs 27.7% among asymptomatic patients, $p = 0.010$) was more frequent. CC stents were used in 82.4% of CAS procedures involving HR lesions (vs 69.1% for non-HR lesions, $p < 0.01$), and P-EPD were used in 83.1% of procedures involving HR lesions (vs 2.5% for non-HR lesions, $p < 0.001$). In-hospital complications included 6 (0.55%) deaths, 1 (0.08%) major stroke and 19 (1.61%) minor strokes. No myocardial infarctions (MI) were noted. Among 7 (0.59%) cases of hyperperfusion syndrome, 2 were fatal. Thirty-day complication rate (death/any stroke/MI) was 2.38%. Age > 75 years was a predictor of death ($p = 0.015$), and prior neurological symptoms were a predictor of death/stroke ($p = 0.030$). There were 4 cases of periprocedural embolic cerebral artery occlusion, all treated with combined intracranial mechanical and local thrombolytic therapy.

Conclusions: CAS with EPD and stent type selection on the basis of thorough non-invasive diagnostic work-up ('tailored-CAS') is safe. Advanced age was associated with an increased risk of death and the presence of prior neurological symptoms was a predictor of death/stroke at 30 days. With the 'tailored-CAS' approach, 'high-risk' lesion features (soft/thrombus-containing/tight/ulcerated) are eliminated as a risk factor. Hyperperfusion syndrome is a severe CAS complication which may lead to intracranial bleeding and death. Acute, iatrogenic embolic cerebral artery occlusion is rare and may be managed by combined intracranial mechanical and local thrombolytic therapy.

Key words: carotid artery stenting, proximal neuroprotection, hyperperfusion syndrome, intracerebral macroembolisation

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INTRODUCTION

According to the current guidelines, carotid artery stenting (CAS) may be an alternative to surgical carotid endarterectomy (CEA) in selected patients with carotid artery stenosis if periprocedural risk of death/stroke/myocardial infarction (MI) does not exceed 6% in symptomatic and 3% in asymptomatic patients [1]. However, this threshold rate of clinically significant complications was exceeded in at least some CAS studies and registries in which only a single type of stent and embolic protection device was used [2]. In addition, randomised SPACE and EVA-3S studies comparing safety of CAS and CEA did not show equivalence of these approaches due to a high rate of complications in the endovascular arm [3, 4]. It has been noted, however, that in both studies, operators with little or no (EVA-3S) experience in CAS were recruited. These findings are in agreement with the results of a meta-analysis by Lin et al. [5] which showed a significantly higher risk of periprocedural CAS complications in patients treated by unexperienced operators. Effectiveness of distal neuroprotection systems (filters or occlusive balloons) in reducing the risk of distal embolisation during CAS was shown in a retrospective metaanalysis including more than 23,000 of CAS procedures [6]. However, safe use of these systems is not possible in some cases of carotid artery stenosis; a number of published CAS studies using distal neuroprotection showed

a significantly higher complication rate among patients with narrow stenoses (> 90%) [7], lipid-rich [8], thrombus-containing lesions [9], and in symptomatic patients [10–12]. In these cases, an alternative approach involves the use of proximal embolic protection devices (P-EPD) which allow performing CAS during cessation or reversal of blood flow in the internal carotid artery. Despite established safety profile, these systems continue to be used infrequently in the clinical practice.

Currently, CAS procedures are performed only with the use of self-expanding stents of open-cell (OC) or closed-cell (CC) design. Although CC stents may be more effective in preventing plaque protrusion and peripheral embolisation, they have a stiffer structure, limiting their use in tortuous arterial segments.

In November 2002, a CAS program was started in the Department of Cardiac and Vascular Diseases at the Jagiellonian University Medical College (The John Paul II Hospital in Cracow), with the application of an algorithm of selection the most appropriate embolic protection device and stent type based on plaque morphology and the presence of neurological symptoms ('tailored-CAS' algorithm) that had been developed during the preceding 10 months [13]. This algorithm indicates the use of P-EPD and CC stents for high-risk (HR) lesions (> 95% stenosis, thrombus-containing lesions, 'soft' lesions, i.e. with computed tomography [CT] density of < 60 HU) and in symptomatic patients (Fig. 1).

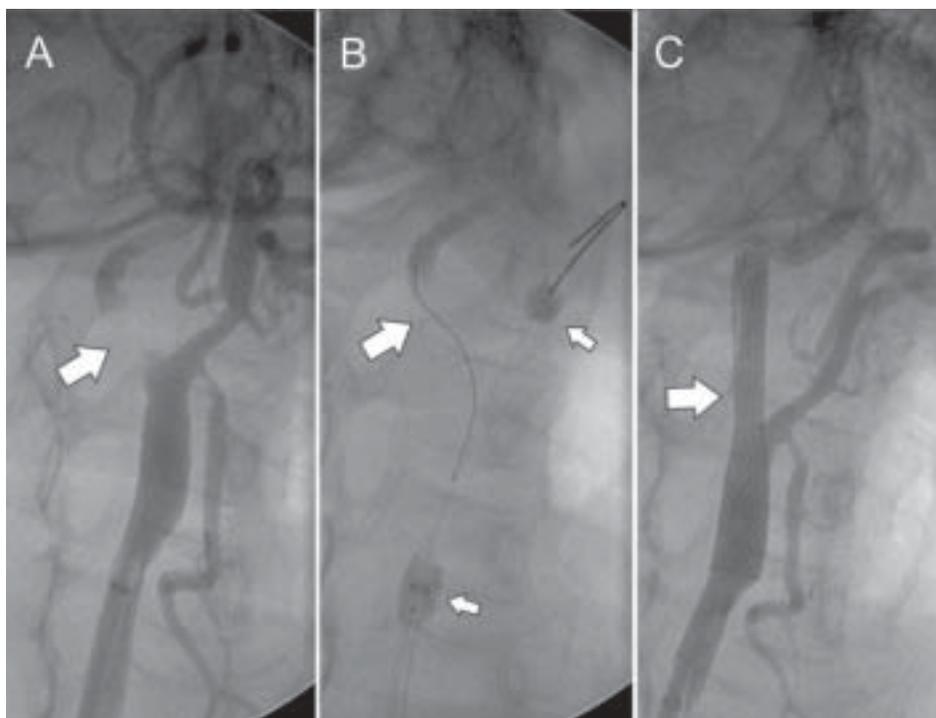


Figure 1. Stenting of the left internal carotid artery (LICA) in a 51-year-old patient with a history of transient ischaemia of the left hemisphere that occurred 7 days earlier; **A.** A massive thrombus seen in the LICA ostium, resulting in a significantly reduced inflow to the distal part of the artery; **B.** Under flow-reversal, the stenotic site was crossed with a HT Whisper MS 0.014' guidewire — large arrow; small arrows — Gore Neuro Protection System occlusion balloons; **C.** Final angiographic result after implantation of a closed-cell Carotid Wallstent 7 × 30 mm (arrow)

The aim of the present study was to evaluate safety of CAS using individually selected embolic protection devices (proximal — flow blockage/reversal in the carotid artery; or distal — filter or occlusive balloon) and stent types (CC, OC, hybrid) according to the 'tailored-CAS' algorithm and to identify risk factors for complications of CAS during a 30-day follow-up.

METHODS

We analysed data from a prospective registry including 1081 consecutive patients who underwent overall 1176 CAS procedures. Patient selection for invasive treatment was based on clinical and neurological examination findings, non-invasive testing (including duplex Doppler and CT angiography performed within 2 months before CAS), and invasive angiography. Symptomatic patients were defined as patients with ipsilateral ischaemic stroke or transient ischaemic attack within preceding 6 months. Patients were selected for CAS if they had symptomatic > 50% stenosis or asymptomatic > 80% stenosis by carotid angiography. CAS technique was at operator's discretion, provided that the 'tailored-CAS' algorithm was applied, allowing for optimal choice of neuroprotection device and stent type depending on lesion morphology and the neurological status of the patient. On the basis of extracranial carotid Doppler ultrasound, CT angiography and invasive angiography HR lesions (tight, lipid-rich, thrombus-containing) were selected. For HR lesions (36.14% of all lesions) and in symptomatic patients, P-EPD and CC stents were preferentially used. The diameter of the stent was 1–2 mm larger than the diameter of carotid artery lumen proximally to the stenosis. Postdilatation was performed using a balloon catheter with the diameter equal to the reference diameter of a distal part of internal carotid artery. Methodology of invasive and noninvasive assessment, the algorithm allowing individual selection of neuroprotection device and stent type, and further details regarding procedural technique were described previously [13].

In all patients, coronary angiography was performed to evaluate the presence and severity of concomitant coronary artery disease (CAD). In case of significant CAD, patients were referred for myocardial revascularisation based on the current guidelines. Neurological examination was performed by an independent neurologist within 24 h after the procedure, on discharge, and at 30 days. In patients with symptoms suggesting acute myocardial ischaemia in the postprocedural period, cardiac markers were evaluated in at least two measurements 6–8 h apart. Major complications of CAS included death, stroke, and MI.

Stroke was defined as a focal neurological deficit of vascular origin lasting for more than 24 h. Major stroke was defined as a stroke resulting in deterioration of the neurological status by more than 3 points in the NIHSS scale.

We analysed the impact of neurological symptoms, HR lesions, demographic characteristics outlined in Table 1, the

Table 1. Demographic and angiographic characteristics of the study group

Total number of patients	1081 (100%)
Age in years (mean \pm SD, range)	66.29 \pm 8.43 (36–88)
Number of patients > 75 years of age	178 (16.47%)
Men	740 (68.45%)
Present neurological symptoms:	557 (51.53%)
Previous ipsilateral stroke	429 (39.69%)
Previous ipsilateral TIA	258 (23.87%)
Previous amaurosis fugax	42 (3.89%)
Cigarette smoking (current or past)	610 (56.43%)
Hypertension	961 (88.90%)
Diabetes	295 (27.29%)
Hypercholesterolaemia	920 (85.11%)
Peripheral arterial disease	216 (19.98%)
Angiographically confirmed CAD	691 (63.92%)
Previous myocardial infarction	295 (27.29%)
Bilateral ICA stenosis	425 (39.31%)
Contralateral ICA occlusion	140 (12.95%)
Atrial fibrillation	64 (5.9%)

Unless noted otherwise, data are shown as patient numbers and proportions. TIA — transient ischaemic attack; CAD — coronary artery disease; ICA — internal carotid artery

type of neuroprotection device (distal vs proximal) and the stent type (OC vs CC) on the risk of complications of CAS. The study was approved by a local ethics committee. All patients gave written informed consent for participating in the study.

Statistical analysis

Categorical variables were compared using χ^2 test or the exact Fisher test, with or without Yates correction. These data are presented as absolute and percentage proportions of patients in the evaluated groups. Continuous variables are presented as arithmetic mean \pm SD and were compared using two-sided Mann-Whitney U test (due to Kolmogorov-Smirnov test findings showing non-normal distribution of the variables). Stepwise logistic regression analysis was performed for demographic and angiographic data, with the threshold of variable entry into the model at the level of $p < 0.1$. Results for independent predictors in the model are shown as odds ratios (OR) and 95% confidence intervals (CI). Statistical significance was defined at $p < 0.05$. Statistical analyses were performed using the STATISTICA 9.0 package (Statsoft Inc., Tulsa, OK, USA).

RESULTS

Four hundred twenty-five (36.14%) lesions were HR, and 274 (23.30%) were associated with > 95% lumen stenosis. Among symptomatic patients, HR lesions were significantly more

Table 2. Neuroprotection systems and stent types used in the study

Neuroprotection system	N (%)	Stent	N (%)
Proximal neuroprotection	369 (31.38)	Closed-cell	729 (61.16)
PAES/GNPS	194 (16.50)	Carotid Wallstent	469 (39.33)
Mo.Ma 9F/8F	175 (14.88)	Xact	239 (20.05)
Distal neuroprotection	807 (68.62)	NexStent	21 (1.76)
FilterWire EZ	325 (27.64)	Hybrid	162 (13.59)
Emboshield	188 (15.99)	Cristallo Ideale	162 (13.59)
Angioguard	105 (8.93)	Open-cell	294 (24.66)
Spider RX/FX	74 (6.29)	Precise	179 (15.01)
Accunet	73 (6.21)	Acculink	107 (8.98)
PercueSurge	26 (2.21)	Exponent	8 (0.67)
FiberNet	9 (0.76)	Others	7 (0.59)
Gore Embolic Filter	4 (0.34)		
Defender	3 (0.25)		

Table 3. Complications at 30 days

Complications at 30 days	CAS procedures (1176)	Patients (1081)	Symptomatic (557)	Asymptomatic (524)	P
	N (%)	N (%)	N (%)	N (%)	
Death	7 (0.59)	7 (0.65)	6 (1.08)	1 (0.19)	0.052
Major stroke	1 (0.08)	1 (0.09)	1 (0.18)	0 (0.0)	0.31
Minor stroke	20 (1.70)	20 (1.85)	13 (2.33)	7 (1.34)	0.14
Any stroke	21 (1.79)	21 (1.94)	14 (2.51)	7 (1.34)	0.10
MI	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	–
Death/major stroke/MI	8 (0.68)	8 (0.74)	7 (1.26)	1 (0.19)	0.03
Death/any stroke/MI	28 (2.38)	28 (2.59)	20 (3.59)	8 (1.53)	0.02
TIA	42 (3.57)	42 (3.88)	25 (4.49)	17 (3.24)	0.17
Hyperperfusion syndrome	7 (0.59)	7 (0.65)	6 (1.08)	1 (0.19)	0.052
Arterial dissection	5 (0.42)	5 (0.46)	3 (0.54)	2 (0.38)	0.26
Anaemia requiring transfusion	4 (0.34)	4 (0.37)	2 (0.36)	2 (0.38)	0.80

TIA — transient ischaemic attack; MI — myocardial infarction

common (41.1%) compared to asymptomatic patients (30.8%, $p = 0.001$). Procedural success rate (introduction of a guiding catheter and the neuroprotection device, stenting, and residual stenosis of $< 30\%$) was 99.8%. Table 2 shows the types and frequencies of stents and neuroprotection devices used. Among symptomatic patients, CC stents (76.2% vs 71.7% in asymptomatic patients, $p = 0.103$) and P-EPD (34.8% vs 27.7% in asymptomatic patients, $p = 0.010$) were used more often. HR lesions were also more commonly treated with CC stents (82.4% vs 69.1% in non-HR lesions, $p < 0.01$) and P-EPD (83.1% vs 2.5% in non-HR lesions, $p < 0.001$). Bilateral two-stage CAS was performed in 88 (8.14%) patients, and two-level stenting of the common carotid artery (ostium) and the internal carotid artery was performed in 7 (0.6%) patients. Direct stenting was performed in 663 (56.38%) patients. In

19 (1.61%) cases, the lesion could not be crossed with the stent during an attempt of direct stenting. In 21 (1.78%) patients, lesion predilatation with a 1.5 mm balloon catheter was necessary before introducing P-EPD (patients with contralateral occlusion of the internal carotid artery without adequate collateral circulation in transcranial Doppler study). Mean time of balloon inflation during stent postdilatation was 22.1 ± 9.5 s (range 8–60), mean inflation pressure was 11.5 ± 2.4 atm (range 6–20), and at least 2 postdilations were performed in 96.4% of cases.

At 30 days, the overall rate of major complications was 2.38%. This rate was higher (3.59%) among symptomatic patients compared to asymptomatic patients (1.53%, $p = 0.017$, Table 3). During hospitalisation, 6 (0.55%) deaths occurred, including 2 (0.19%) due to ischaemic stroke and

4 (0.37%) due to severe intracranial bleeding, which was related to hyperperfusion syndrome in 2 cases (confirmed by ultrasonography). We also noted 1 (0.08%) major stroke and 19 (1.61%) minor strokes. One (0.08%) death occurred at 24 days after CAS (sudden death during sleep), and 1 (0.08%) minor contralateral stroke occurred at 16 days after CAS. Age > 75 years was associated with a significantly increased mortality risk (2.2% vs 0.33% among patients < 75 years of age, $p = 0.015$, OR 1.61; 95% CI 1.13–4.87). Preprocedural presence of neurological symptoms was associated with a significantly increased risk of combined endpoint of death and stroke ($p = 0.030$, OR 2.52; 95% CI 1.09–5.82). Such factors as HR lesions, age, and the use of OC stents or distal embolic protection devices did not affect the probability of complications of CAS. Iatrogenic dissection of the common carotid artery occurred in 5 (0.42%) cases, none associated with new neurological symptoms. In all cases, dissection was successfully treated with implantation of additional stents.

Four cases of intracerebral macroembolisation occurred periprocedurally. Recanalisation was attempted in all cases, using dedicated cerebral 0.014' wires. After crossing the occlusion site with the wire, a perfusion microcatheter was introduced in the immediate vicinity of the embolus, the wire was removed, and the microcatheter was used to administer recombinant tissue plasminogen activator (rt-PA) in 5 mg boluses until a total dose of 20 mg or restoration of blood flow in the occluded artery. In 1 patient, angioplasty of the occluded vessel was performed with good acute results (Fig. 2). This was 1 of the 2 cases of intracerebral macroembolisation in which complete resolution of neurological symptoms was achieved in the periprocedural period. Another two CAS procedures were complicated by stroke (4 points in the NIHSS scale), and fatal intracranial bleeding. No MI was noted. Coexisting CAD was found in 691 (63.92%) patients on coronary angiography. Percutaneous coronary intervention was performed within 15–30 days before CAS in 58 (5.36%) patients, within 15–35 days after CAS in 54 (4.99%) patients, and simultaneously with CAS in 6 (0.55%) patients. Coronary artery bypass grafting (CABG) was elected in 43 (3.98%) patients and performed within 31–93 days after CAS. In 4 (0.37%) patients, a hybrid procedure was undertaken in a surgical room, with CABG performed immediately after CAS.

P-EPD intolerance occurred in 17 (1.44%) patients; all underwent successful CAS, and neurological symptoms resolved within several minutes after restoration of antegrade flow in the carotid artery. Seven (0.59%) CAS procedures were complicated with hyperperfusion syndrome, with 4 cases leading to intracranial bleeding. Of those, two cases were fatal, another two resulted in haemorrhagic stroke and subarachnoid haemorrhage. Ipsilateral > 95% stenosis of the internal carotid artery was identified as a risk factor for hyperperfusion syndrome ($p = 0.033$).

DISCUSSION

Current AHA guidelines modifications were influenced by two large multicentre trials comparing CAS with CEA: CREST and CaRESS. They showed CAS that CAS is not inferior to CEA in the treatment of patients with symptomatic carotid artery stenosis [1, 14, 15]. The CREST study, including more than 2500 patients, showed that combined risk of death, stroke, and MI at 30 days was 6.8% after CEA and 7.2% after CAS ($p = 0.51$). Even stronger evidence indicating equal outcomes with these 2 therapeutic approaches were obtained in the CaRESS study which showed comparable complication rates in the 2 groups both during short-term follow-up and at 4 years (death/stroke/MI rate at 4 years in the CEA and CAS groups: 27.0% vs 21.7%, respectively, $p = 0.273$). Our study showed that individual selection of stent and neuroprotection device type makes CAS safe, also in patients with HR lesions. The use of embolic protection devices is currently a well established practice, although its effectiveness in preventing embolic complication is only supported by observational data. Some authors suggested no difference in the rate of CAS complications between groups treated with or without the use of neuroprotection devices but these results might reflect inadequate operator experience with different neuroprotection systems or selection of low-risk patients [3, 4]. An approach providing for individual selection of the stent type (among 9 different types) and the neuroprotection device (among 9 types of distal embolic protection devices and 2 types of P-EPD) allowed successful and safe CAS in > 99% of patients referred for this procedure. Exclusive use of distal embolic protection devices in all consecutive patients is associated with a significant proportion (12%) of cases requiring predilatation due to inability to cross the stenotic lesion with the neuroprotection system [16]. Attempts to cross narrow, ulcerated, or thrombus-containing lesions with a distal embolic protection device may clearly result in an increased risk of cerebral embolisation.

Similarly to the study by Reimers et al. [17], transient intolerance of P-EPD (in 1.7% patients in our study) was not associated with the need to interrupt the procedure, balloon deflation, or an increased complication risk. Lower rate of P-EPD intolerance in our study was probably related to the use of this method in the treatment of narrow stenoses which are usually associated with a well-developed intracerebral collateral circulation.

Among patients aged > 75 years both mortality and the risk of a combined endpoint of death and stroke was significantly higher compared to younger patients (death/stroke rate 5.0% vs 1.89%, $p = 0.022$). These findings are consistent with the results of the CREST study, in which the complication rate rose with the age of patients undergoing CAS, reaching 12.1% for the combined death and stroke rate among patients > 80 years of age [18]. A similar trend is observed in the general population, with several-fold increase in the risk

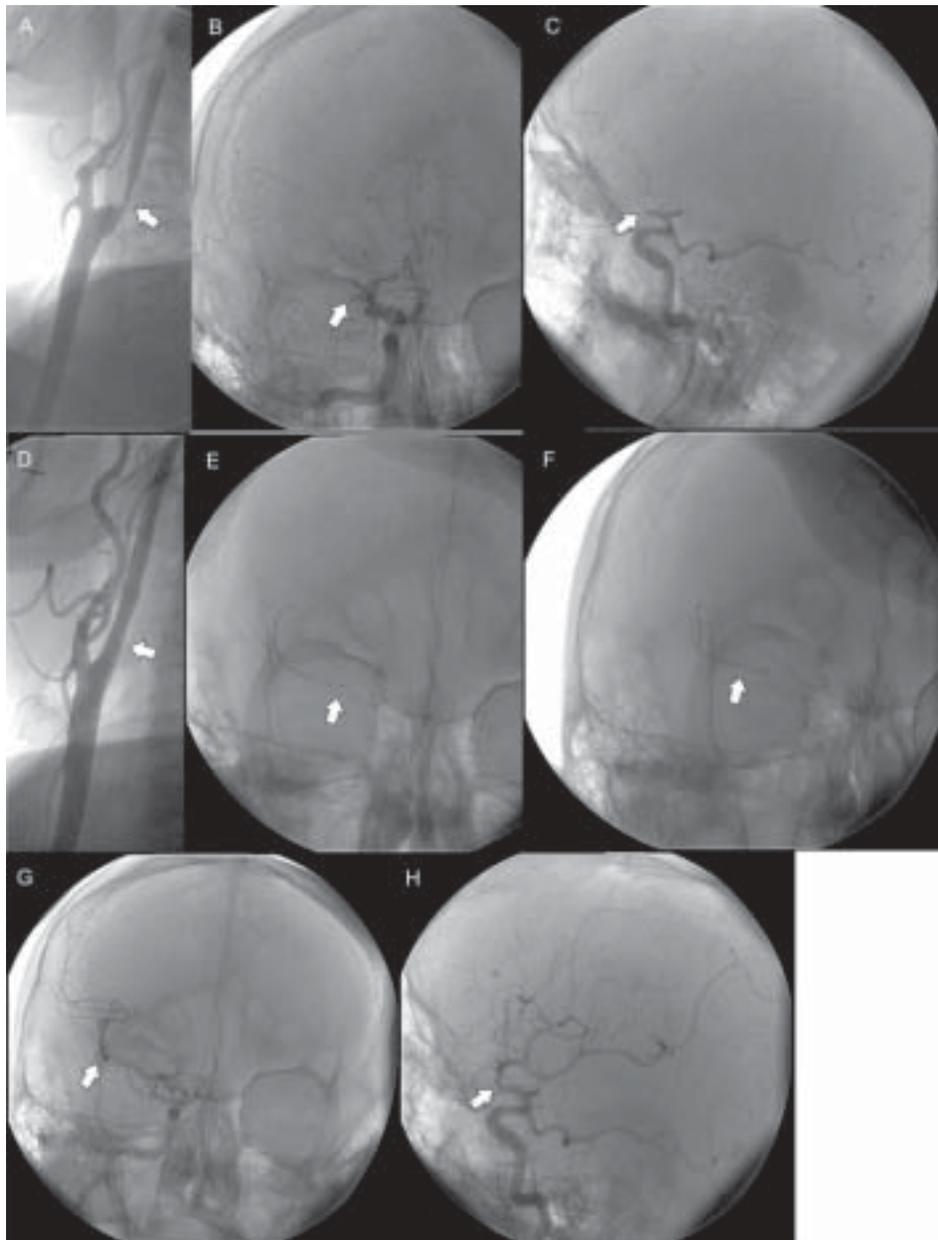


Figure 2. Embolisation of the middle cerebral artery (MCA) during stenting of the right internal carotid artery (RICA), treated successfully with angioplasty and intraarterial administration of 20 mg rt-PA in a 61-year-old patient with a history of stroke involving the right hemisphere that occurred 3 months earlier; **A.** A critical RICA stenosis (arrow); **B, C.** Preprocedural diagnostic cerebral angiography revealed acute embolic occlusion of the right MCA (arrows); **D.** Angiography following successful RICA stenting (Xact 9–7 × 30 mm stent indicated with an arrow); **E.** A microcatheter introduced using a Cirrus 14 0.014' guidewire allowed rt-PA administration near the thrombus (distal catheter marker indicated with an arrow); **F.** Angioplasty using balloon catheters Falcon 1.0 × 10 mm followed by Sprinter Legend 2.0 × 15 mm (arrow); **G, H.** Final angiographic result showing successful recanalisation of the right MCA (arrows)

of stroke among subjects above 75–80 years of age, accompanied by an increased mortality rate among patients who suffer stroke. With increasing age, the incidence and severity of comorbidities also increase, vascular anatomy undergoes unfavourable changes, body adaptive capabilities decrease, and cerebral autoregulation becomes dysfunctional. All the-

se factors, commonly coexisting in elderly subjects, might have contributed to an increased risk of early mortality.

In a recently published Medicare registry including more than 10,000 patients above 65 years of age who underwent CAS or CEA, the risk of periprocedural complications was similar for both approaches (stroke: 1.9% among CAS patients

vs 1.4% among CEA patients, $p = 0.14$; mortality: 0.9% among CAS patients vs 0.6% among CEA patients, $p = 0.2$) but 1-year mortality was significantly higher in the CAS group (9.9% vs 6.1% in the CEA group, $p < 0.001$) [19]. As noted by the authors, this difference probably reflected higher baseline risk in patients undergoing CAS. In this group, prevalence of CAD, previous MI, peripheral arterial disease, and heart failure was significantly higher compared to the CEA group. Indeed, our own observations indicate that coexisting CAD is the major cause of long-term mortality in patients undergoing CAS [13]. Results of large randomised trials that served as the basis for the guidelines on the management of carotid artery stenosis, often indicated an increased periprocedural complication risk in women undergoing CEA. In 2011, Rockman et al. [20] performed a retrospective analysis of CEA and CAS procedures performed in the United States in 2004–2005 (a total of 54,658 procedures) that showed that gender is no longer a risk factor both for CEA and CAS. In our study, we also did not find an increased periprocedural risk among women.

Our observations indicate that most periprocedural embolic strokes (14/20, or 70%) occur at the time of the common carotid artery intubation with diagnostic/guiding catheter. Stroke rate during diagnostic angiography may be as high as 5.4% [21]. It has been shown that direct cannulation of the ipsilateral common carotid artery may reduce duration of the procedure and eliminates the need to manipulate guidewires and catheters within the aortic arch [22].

Our findings indicate that with 'tailored-CAS' algorithm, HR lesions are eliminated as a risk factor for periprocedural complications. We did not find any impact of the presence of neurological symptoms on the risk of periprocedural strokes and deaths as individual endpoints, although the risk of combined endpoint of stroke and death was increased in this patient group. Of note, this risk continued to be acceptably low and below guideline thresholds. Jacobowitz et al. [23] performed a retrospective analysis of a database including more than 1,000 CEA procedures and confirmed that the presence of neurological symptoms was associated with an increased procedural risk. According to these authors, even small particles of the embolic material may result in new neurological symptoms in symptomatic patients. In asymptomatic patients, embolic material of similar size may also result in transient occlusion of intracerebral arterial branches, but it does not lead to neurological symptoms due to efficient collateral circulation.

Coronary angiography performed routinely in all patients allowed identification of patients at an increased risk of death and MI in the periprocedural period. Strategies of early invasive treatment of CAD eliminated MI as a complication of CAS in our study group. In studies of CAS, in which coronary angiography was not performed routinely, the rate of MI was up to 3.0% [24]. This is an important benefit, as reduction in

the rate of MI results in a smaller overall rate of clinically significant complications of CAS.

Clearly, sequelae of intracerebral embolisation were reduced in our study by the use of interventional treatment specifically aimed at this complication. Although there are no guidelines to address therapeutic decisions in this regard, we used a technique combining drug therapy (administration of rt-PA via microcatheter) with mechanical fragmentation of the thrombus using a guidewire. Only in one case it was possible to advance balloon catheter up to the level of occlusion and perform successful angioplasty, although it should be noted that dedicated intracerebral angioplasty catheters were not available at that time. Similar success rate was reported by Lin et al. [25] who used a combination of drug therapy and interventional procedures to treat intracerebral embolisation complicating CAS.

Symptomatic hyperperfusion occurred in 0.59% of cases, at a rate smaller compared to that reported in the literature (3.8–6.9%). In patients with a narrow stenosis of the internal carotid artery, blood pressure reduction was initiated already in the catheterisation laboratory, immediately after CAS. Our findings confirm observations by Abou-Chebl et al. [26] regarding the effectiveness of blood pressure control in preventing hyperperfusion. Of note, 4 of 7 (57%) hyperperfusion episodes in our study were life-threatening or fatal. Dangers of hyperperfusion were confirmed by the results of other studies, in which 50–60% cases of symptomatic hyperperfusion were complicated by cerebral ischaemia or death [26, 27].

Limitations of the study

In our study, we analysed data from a prospective registry in a single academic centre, and thus the strength of the evidence cannot be compared to those obtained in randomised studies. Selection of HR lesion characteristics was based on the previously mentioned studies, but there are no data available in the literature that would indicate an advantage of proximal over distal neuroprotection devices in the treatment of such lesions, and thus it is difficult to compare our findings with previously published data. It seems that our results only suggest the need to use P-EPD in patients with HR lesions. They also indicate that CAS may be safely performed in most patients referred for such treatment.

CONCLUSIONS

CAS with individual embolic protection device and stent type selection on the basis of non-invasive diagnostic testing including ultrasound and CT angiography ('tailored-CAS') is safe. Advanced age was associated with an increased risk of death at 30 days and the presence of prior neurological symptoms was a predictor of a combined endpoint of death and stroke. With the 'tailored-CAS' approach, 'high-risk' lesion features

are eliminated as a risk factor. The most dangerous complication of CAS is hyperperfusion syndrome which may lead to intracranial bleeding and death. Acute, iatrogenic embolic cerebral artery occlusion may be successfully managed invasively by combined intracranial mechanical and local thrombolytic therapy.

Conflict of interest: none declared

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Stentowanie tętnic szyjnych oparte na algorytmie 'tailored-CAS' wiąże się z niskim odsetkiem powikłań w obserwacji 30-dniowej: analiza danych z badania TARGET-CAS

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Streszczenie

Wstęp: Odsetek okołoperacyjnych powikłań zabiegów stentowania tętnic szyjnych (CAS) nie powinien przekraczać 3% u chorych bezobjawowych i 6% u chorych objawowych. Wyniki ostatnio opublikowanych badań wskazują, że często jest to cel trudny do osiągnięcia.

Cel: Celem pracy była ocena bezpieczeństwa CAS opartego na algorytmie indywidualnego doboru systemu neuroprotekcji i stentu oraz próba identyfikacji czynników ryzyka powikłań CAS w obserwacji 30-dniowej.

Metody: Od 2002 r. autorzy przeprowadzili u 1081 pacjentów (w wieku 36–88 lat, średnio $66,3 \pm 8,4$ roku; 51,5% chorych objawowych) 1176 zabiegów CAS, opartych na algorytmie 'tailored-CAS' obejmującym zewnątrzczaszkowe USG oraz angio-TK w celu optymalnego doboru systemu neuroprotekcji i stentu w zależności od cech morfologicznych zwężenia/stanu neurologicznego pacjenta. Dla zmian wysokiego ryzyka (HR, ciasnych, miękkich, ze skrzepliną; 36,14% wszystkich zwężeń) i u chorych objawowych preferencyjnie stosowano systemy neuroprotekcji proksymalnej oraz stenty zamkniętokomórkowe (CC).

Wyniki: Skuteczność zabiegu wyniosła 99,8%. W grupie osób objawowych odsetek zmian HR był wyższy (41,1%) niż w grupie bez objawów (30,8%; $p = 0,001$), także częściej stosowano CC (76,2% v. 71,7%; $p = 0,103$) i systemy neuroprotekcji proksymalnej (P-EPD; 34,8% v. 27,7%; $p = 0,010$). W grupie HR częściej stosowano stenty CC (82,4% v. 69,1% dla non-HR; $p < 0,01$) oraz systemy P-EPD (83,1% v. 2,5% dla non-HR; $p < 0,001$). W trakcie hospitalizacji wystąpiło 6 (0,55%) zgonów, 1 (0,08%) duży i 19 (1,61%) małych udarów mózgu, nie stwierdzono zawału serca. Wystąpiło 7 (0,59%) zespołów hiperperfuzji, z czego 2 były powikłane zgonem. W okresie po hospitalizacji wystąpił 1 (0,08%) zgon i 1 (0,08%) mały, kontralateralny udar mózgu. Trzydziestodniowy odsetek istotnych klinicznie powikłań wyniósł 2,38%. Wiek > 75 lat zwiększał istotnie ryzyko zgonu ($p = 0,015$). Obecność objawów neurologicznych przed zabiegiem zwiększała ryzyko wystąpienia zgonu i udaru mózgu ($p = 0,030$). W okresie okołozabiegowym wystąpiły 4 przypadki makroembolizacji tętnic mózgowych, którą leczono miejscowo mechanicznie i fibrynolitycznie.

Wnioski: Zabiegi CAS oparte na algorytmie indywidualnego doboru systemu neuroprotekcji i stentu na podstawie badań nieinwazyjnych ('tailored-CAS') stanowią metodę bezpieczną. Zaawansowany wiek wiąże się ze zwiększonym ryzykiem zgonu, obecność objawów neurologicznych zwiększa ryzyko zgonu i udaru mózgu w obserwacji 30-dniowej, jednak pozostaje w granicach akceptowanych przez wytyczne. Zastosowanie 'tailored-CAS' eliminuje obecność zmian wysokiego ryzyka jako czynnika ryzyka powikłań CAS. Najgroźniejszym powikłaniem zabiegów CAS jest zespół hiperperfuzji, który może prowadzić do udaru krwotocznego i zgonu. Ostrą, jatrogeną embolizację tętnic krążenia mózgowego można skutecznie leczyć interwencyjnie.

Słowa kluczowe: stentowanie tętnic szyjnych, neuroprotekcja proksymalna, zespół hiperperfuzji, embolizacja tętnic mózgowych
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