The use of a new generation self-expanding stent, Vascuflex SEC, for carotid artery stenting

Zastosowanie nowej generacji samorozprężalnego stentu Vascuflex SEC do zabiegów stentowania tętnic szyjnych

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Abstract

Background: Technological developments in the embolic protection device (EPD) and stent designs contribute significantly to the progress in endovascular management of carotid artery stenosis.

Aim: To evaluate the safety and efficacy of carotid artery stenting (CAS) using a new generation self-expanding nitinol stent, Vascuflex SEC, with different types of embolic protection.

Material and methods: Carotid artery stenting with Vascuflex SEC was performed in 50 consecutive patients (age 66.4 ±7.8 years, men 66%, symptomatic 40%) referred for the procedure after independent neurological consultation. Embolic protection device type was selected on the basis of atherosclerotic plaque morphology by duplex ultrasound and CT angiography. In a subset of patients (n = 20), we tested the feasibility of using intravascular ultrasound with virtual histology (IVUS-VH) to guide the EPD choice and final stent post-dilation. Proximal neuroprotection by flow reversal or temporary flow cessation was applied in 23 procedures (46%). Clinical evaluation was performed at discharge and at 30 days.

Results: Procedural success was 100% and, in all cases, only one stent was implanted per patient/lesion. Direct stenting was performed in 20 patients (40%). Intraprocedural IVUS-VH was feasible and safe. Diameter stenosis was reduced from 84.1 ±7.5% to 9.1 ±7.7% ($p < 0.001$). There were two neurological events: one periprocedural ipsilateral minor stroke and one contralateral major stroke within 30 days. A closure device was used in 80% of patients and no access site complications occurred.

Conclusions: In an unselected population referred for carotid revascularization, CAS with Vascuflex SEC stents is safe and effective. Lesion morphology-guided selection of EPD may contribute to the low complication rate.

Key words: carotid artery stenosis, carotid artery stenting, self-expanding carotid stents, open-cell stent design

Streszczenie

Wstęp: Zwiększenie bezpieczeństwa i stały rozwój zabiegów stentowania tętnic szyjnych (ang. *carotid artery stenting*, CAS) z zastosowaniem systemów protekcyjnych (ang. *embolic protection device*, EPD) jest możliwy dzięki postępowi technologicznemu stosowanych urządzeń.

Cel: Ocena skuteczności i bezpieczeństwa CAS z zastosowaniem nowej generacji samorozprężalnych stentów nitinolowych Vascuflex SEC.

Materiał i metody: Od stycznia do końca kwietnia 2010 r. zabiegi CAS z implantacją stentów samorozprężalnych Vascuflex SEC przeprowadzono u kolejnych 50 chorych (33 mężczyzn i 17 kobiet, średnia wieku 66,4 ±7,8 roku, objawy – 20 osób, tj. 40%). Przed zabiegiem u wszystkich chorych wykonano badanie ultrasonograficzne oraz angio-TK w celu określenia stopnia i morfologii zwężenia. W podgrupie 20 chorych wykonano ultrasonografię wewnątrznaczyniową (ang. *intravascular ultrasound with virtual histology*,

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IVUS-VH) w celu wstępnej selekcji EPD i oceny postdylatacji po CAS. Zabiegi CAS wykonano u wszystkich chorych z zastosowaniem EPD (protekcja proksymalna u 23 chorych – 46%). Chorych poddano ocenie bezpośrednio po zabiegu, w dniu wypisu i po 30 dniach. U 40 osób (80%) po zabiegu zastosowano urządzenia zamykające tętnicę udową w miejscu wkłucia.

Wyniki: Uzyskano 100-procentową skuteczność zabiegów; u wszystkich chorych implantowano jeden stent. Stwierdzono istotne zmniejszenie stopnia zwężenia tętnicy szyjnej z 84,1 ±7,5% do 9,1 ±7,7%, $p < 0,001$. Badanie IVUS-VH wykonano bez powikłań. W trakcie obserwacji szpitalnej i 30-dniowej stwierdzono 2 (4%) incydenty neurologiczne (1 mały udar i 1 konralateralny duży udar). Nie odnotowano istotnych powikłań miejscowych w analizowanej grupie chorych.

Wnioski: Zabiegi stentowania tętnic szyjnych z zastosowaniem nitinolowych stentów Vascuflex SEC są procedurą bezpieczną. Liczba powikłań okołozabiegowych i w 30-dniowej obserwacji nie przekracza wyznaczonych zaleceniami wartości. Na dobre wyniki stosowanych stentów może mieć wpływ odpowiedni dobór różnych czasowych urządzeń protekcyjnych mózgu.

Słowa kluczowe: zwężenie tętnic szyjnych, angioplastyka tętnic szyjnych, samorozprężalne stenty otwartokomórkowe.

Introduction

In the last decade carotid artery stenting with temporary cerebral protection devices has become increasingly adopted in the treatment of patients with atherosclerotic lesions of brain supplying arteries. A randomized controlled trial, CREST, published in 2010 demonstrated similar direct and long-term results of carotid artery stenting (CAS) and carotid endarterectomy (CEA) [1, 2]. Conditions which determine an optimal result of a carotid artery stenting procedure include operator experience and adequate stent and protection device selection tailored to the patient's clinical condition, atherosclerotic plaque morphology and the anatomy of the carotid artery [3-5]. Continuous progress and reduction of periprocedural complications are influenced by progressive modernization of the equipment used and most importantly by the construction of new types of protection devices and stents. Self-expanding stents are routinely used for internal carotid artery stenting (ICA) except stenting of the stenosed ostium of the common carotid artery and brachiocephalic trunk where metal stents mounted on a balloon are used. Self-expanding stents used for CAS procedures may be divided according to design into open-cell and closed-cell, each possessing different construction. Differences in the design and characteristics of self-expanding stents influence the strategy of the CAS procedure. Closed-cell or open-cell stents should be selected during the procedure according to atherosclerotic plaque morphology, the presence of neurological symptoms and the anatomy of the treated carotid artery [3-5]. Based on their own experience, the centres performing CAS should be equipped with stents of different design including hybrid stents. Several large registres suggested that the use of only one stent type and one protection device type (usually filter) in all treated patients and lessions can be associates with a high complication rate.

It should be noted that the criteria of an acceptable complication rate (death, stroke, myocardial infarction) for interventional treatment of carotid artery stenosis with cut-off values of 6% in symptomatic patients and 3% in asymptomatic patients are still valid [6]. Therefore each new device dedicated to carotid artery stenting should be introduced into practice in centres with extensive experience in CAS procedures. We present the treatment results in 50 consecutive patients who underwent internal carotid artery stenting with different temporary cerebral protection devices and a new generation self-expanding, open-cell stent – Vascuflex SEC.

Material and methods

Between January and April 2010 a consecutive group of 50 patients underwent carotid artery stenting with different protection devices according to the "Tailored CAS" algorithm [4] with implantation of a new generation self-expanding stent, Vascuflex SEC. Prior to the procedure all patients had ultrasound Doppler of the carotid arteries and angio-CT of the aortic arch and brain supplying arteries. Duplex examination supplied by colour Doppler study initially estimates the degree of artery stenosis and characterizes atherosclerotic plaque morphology. Angiotomography helps in pre-procedural assessment of the type of aortic arch and in detection of potential anomalies of brain supplying arteries as well as in quantitative assessment of stenosis morphology (from adipose through fibrotic to highly calcified). Both of those non-invasive studies help in initial planning of the carotid artery stenting procedure. Qualification for the procedure included symptomatic patients with > 50% stenosis or asymptomatic patients with ≥ 80% stenosis. All patients were qualified for the procedure by an independent neurologist and underwent neurological assessment by the same neurologist directly after CAS, at discharge and at 30 days after the procedure. All patients received dual antiplatelet therapy (aspirin 75 mg/day + clopidogrel 75 mg/day) once daily for at least 3 days before and after the procedure. Postprocedural antiplatelet therapy included clopidogrel for three months and lifelong aspirin.

A selective coronary angiography was performed in all patients before the carotid artery stenting procedure to determine the risk of periprocedural complications. In cases of severe coronary artery disease patients were qualified for percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG) at later term. All hypotensive, diuretic and anti-arrhythmic drugs were withheld on the day of the procedure and all patients received 500 ml of

isotonic saline before the procedure. In all patients carotid artery stenting was performed with the use of cerebral protection devices. A subgroup of 20 patients was assessed for the feasibility of intraprocedural use of intravascular ultrasound with virtual histology (IVUS-VH) to optimize the selection of neuroprotective device and stent post-dilation. A proximal protection device (MoMa/GNPS system) was used in all symptomatic patients with high risk stenosis (critical, tortuous, long or ulcerated lesion with the presence of thrombus). The type and number of protection devices used in the presented group are shown in table 1.

All patients received a nitinol self-expanding open-cell stent – Vascuflex SEC.

An example of a procedure in a symptomatic, high-risk patient where a proximal cerebral protection device and Vascuflex SEC stent were used is presented in figure 1. During the procedure patients received unfractionated heparin to maintain activated clotting time (ACT) of 250-300 s. All patients, except those with an implanted pacemaker, received 0.5-1.0 mg of atropine before stent implantation. Most patients underwent direct stent implantation. Post-dilation was performed in all patients to maximally optimise the result of the procedure, with residual

Table 1. Devices for temporary cerebral protection (embolic protection device, EPD) used in the study cohort

Tabela 1. *Czasowe urządzenia protekcyjne mózgu (EPD) stosowane w badaniu*

Proximal – NPD	23 (46%)
Mo.Ma 8 F	16 (32%)
Gore NPS	7 (14%)
Distal – EPD	27 (54%)
FilterWire EZ	13 (26%)
Emboshield Pro/NAV	10 (20%)
Spider FX	4 (8%)

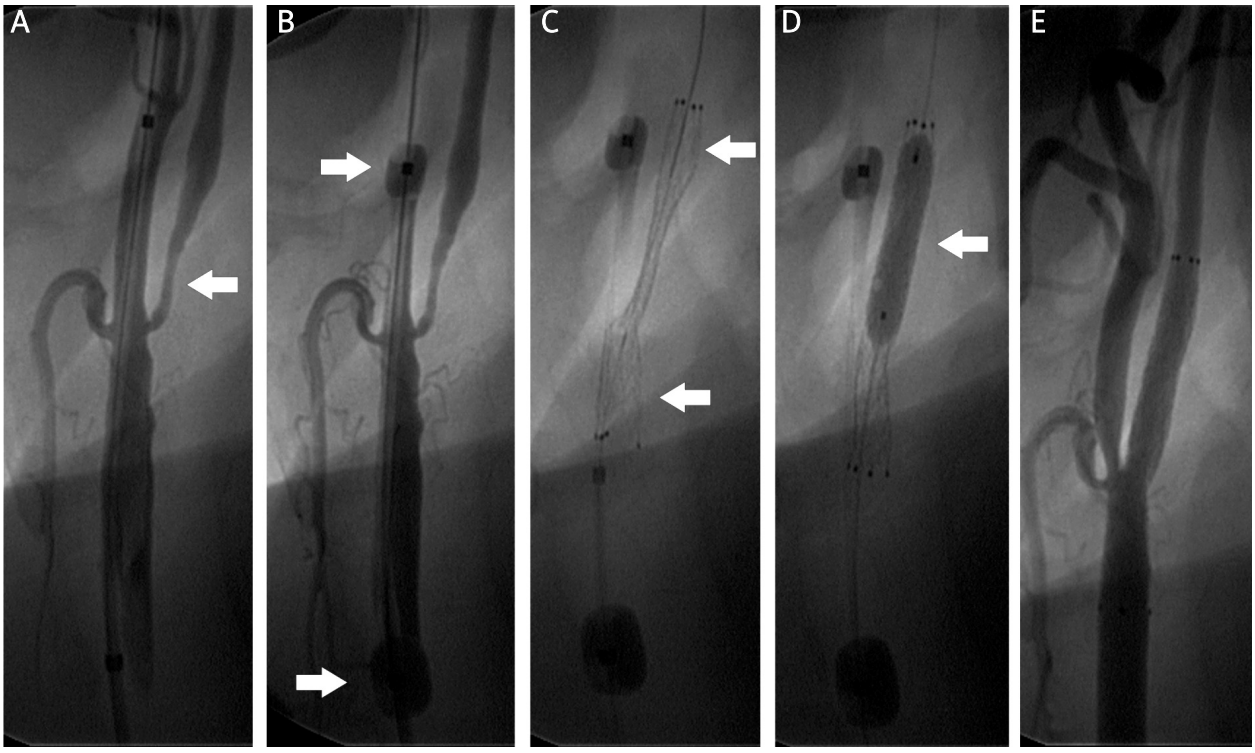

Fig. 1. RICA-CAS with Vasculfex SEC implantation under proximal protection with Mo.Ma 8 F system. **A** – angiographically critical, long lesion in a clinically symptomatic patient (arrow). **B** – RICA flow cessation by inflating the low-pressure ECA and CCA Mo.Ma system balloons (arrows). **C** – optimal aposition of the Vascuflex SEC 7.0 × × 40 mm carotid stent edges (arrows). **D** – stent post-dilatation with Viatrac 5.0 × 20 mm balloon (2 × 12 atm/20 s, arrow). **E** – optimal angiographic result of the procedure

Ryc. 1. *Zabieg stenowania tętnicy szyjnej wewnętrznej prawej z implantacją stentu Vascuflex SEC przy zastosowaniu systemu neuroprotekcji proksymalnej Mo.Ma 8 F. **A** – krytyczne długoodcinkowe, klinicznie objawowe zwężenie tętnicy szyjnej wewnętrznej prawej w odcinku proksymalnym (strzałka). **B** – zahamowanie przepływu w tętnicy szyjnej wspólnej i zewnętrznej prawej niskociśnieniowymi balonami systemu Mo.Ma (strzałki). **C** – optymalna apozycja proksymalnego i dystalnego odcinka stentu Vascuflex SEC 7,0 × 40 mm do ściany naczynia (strzałki). **D** – postdylatacja stentu cewnikiem balonowym Viatrac 5,0 × 20 mm inflacją 2 × 12 atm/20 s (strzałka). **E** – optymalny efekt angiograficzny zabiegu*

stenosis not exceeding 30%. All patients underwent pre- and postprocedural intracranial angiography to exclude periprocedural embolic complications. In most patients (after initial femoral artery angiography) the arterial puncture site was closed using a closure device to allow faster patient mobilization after the procedure. An ultrasound examination was performed before discharge and 30 days after CAS to check the implanted stent. A neurological consultation was done to assess any neurological incidents which occurred during 30 days of follow-up.

Results

Between January and April 2010 a group of 50 consecutive patients with critical internal carotid artery stenosis and mean age of 66.4 ±7.9 years (33 men and 17 women) was included in the registry. Demographic data and clinical characteristics of the studied group are presented in table 2. Twenty patients (40%) had a history of neurological incidents during the 6 months preceding CAS. Eight patients (16%) had an occlusion of the contralateral carotid artery. Routinely performed coronary angiography showed the presence of significant coronary artery disease in 33 (66%) patients (tab. 2).

Mean stenosis was 84 ±7.5% (70-99%) before the procedure and 9.1 ±7.7% (0-30%) after the procedure ($p < 0.001$). Six patients (12%) had pre-procedural stenosis of 95-99%. Intraprocedural assessment of stenosis by means of IVUS-VH was feasible and safe. Proximal protection devices were used in a high percentage of patients (46%). Direct stenting technique was performed in 20 patients (40%). Procedural success of stent implantation was 100% and, in all cases, only one stent was implanted per patient/lesion. In all patients stent implantation was followed by stent post-dilation to obtain residual stenosis not exceeding 30%. An additional stent post-dilation with a 0.5 mm larger balloon was performed in 1 patient (1/20, 5%) after assessment of in-stent minimal lumen area by means of intravascular ultrasound.

There were no cases of major stroke, myocardial infarction or death during CAS, directly after the procedure or throughout the hospitalization period. A minor stroke with complete resolution of symptoms during hospitalization was diagnosed in one patient by the consulting neurologist. There were no signs of intracranial bleeding or acute ischaemic foci in the brain on the CT scan in that patient. A transient ischaemic attack (TIA) occurred in three patients during the procedure. Two of those patients had a contralateral carotid artery occlusion and one had a critical contralateral stenosis. All patients completely recovered before transportation from the cath lab to the ward. There were no cases of death, myocardial infarction or minor stroke between discharge and day 30 of the follow-up. One female patient suffered from major contralateral stroke 5 days after discharge and 7 days after CAS. The stroke occurred in the hemisphere supplied by a chronically occluded carotid artery – contralateral to the stented artery. Ultrasound assessment of the implanted stent showed its good patency and apposition. In-hospital and 30-day complications in symptomatic and asymptomatic patients are presented in table 3. In 40 patients

Table 2. Demographic and clinical characteristics of the studied group
Tabela 2. *Demograficzna i kliniczna charakterystyka chorych*

Number of patients	50 (100%)
Age in years (range)	66.4 ±7.9 (48-78)
> 75 years of age	8 (16%)
Men	33 (66%)
Neurological symptoms present	20 (40%)
Previous ipsilateral stroke	14 (28%)
Previous ipsilateral TIA	9 (18%)
Previous amaurosis fugax	4 (8%)
Cigarette smoking (active or in the past)	23 (46%)
Hypertension	45 (90%)
Diabetes	7 (14%)
Hypercholesterolaemia	47 (94%)
Peripheral arterial disease	5 (10%)
Angiographically proven coronary artery disease	33 (66%)
Previous myocardial infarction	20 (40%)
Bilateral ICA stenosis	15 (30%)
Contralateral ICA occlusion	8 (16%)

Table 3. Periprocedural and 30-day complications of CAS
Tabela 3. *Okołozabiegowe i 30-dniowe powikłania zabiegów CAS*

Complications	Patients ($n = 50$)	Symptomatic ($n = 20$)	Asymptomatic ($n = 30$)	Value of p
Death	0 (0%)			
Major stroke	1 (2%)	1 (5%)	0 (0%)	NS
Minor stroke	1 (2%)	0 (0%)	1 (3%)	NS
Any stroke	2 (4%)			
Myocardial infarction	0 (0%)			
Death/major stroke/myocardial infarction	1 (2%)	1 (5%)	0 (0%)	NS
Death/any stroke/ myocardial infarction	2 (4%)	1 (5%)	1 (3%)	NS
TIA	3 (6%)	1 (5%)	2 (6%)	NS
Hyperperfusion syndrome	0 (0%)			
Artery dissection	0 (0%)			

(80%) the femoral artery was closed using the Angioseal 6 or 8 F closure device. Complications at the puncture site in the form of pseudoaneurysm were observed in only one patient and were successfully treated with local thrombin administration.

Statistical analysis was performed by means of non-parametric Wilcoxon test.

Discussion

The growing number of CAS procedures is a result of new guidelines based on the results of recent randomized trials comparing endovascular and surgical treatment indicated high efficacy of percutaneous treatment of atherosclerotic changes in the brain supplying arteries [8, 9]. Several years of experience in carotid artery stenting and the growing significance of proximal devices used for CAS caused a marked reduction of the periprocedural complication rate and a shift from periprocedural towards postprocedural complications [9].

It is estimated that 2/3 of all complications occur after the CAS procedure and are caused by migration of embolic material through the stent cells. Therefore adequate stent apposition to the atherosclerotic plaque and artery wall is crucial and can be best obtained with the use of open-cell stents. A second key element is to avoid embolic material migration through stent cells in the postprocedural period. In this situation closed-cell stents have a marked advantage. The size of self-expandable stent cells varies greatly and ranges from 1.08 mm^2 for the Carotid Wallstent to 11.48 mm^2 for the Acculink stent. This characteristic can have an influence on the size of embolic material and therefore clinical consequences caused by migration of atherosclerotic plaque parts to the cerebral circulation. Bosiers *et al*. [10] demonstrated in their analysis that the use of open-cell stents is related to higher risk of complications in comparison to closed-cell stents. Our studies did not demonstrate differences in direct and long-term results of CAS for both types of stents if cerebral protection devices and, preferably, closed-cell stents are used in symptomatic patients and in patients with high risk lesions [3].

It should be noted that open-cell stents better adapt to tortuous segments of carotid arteries and therefore they have a well-established position as first choice stents in patients with tortuous and calcified carotid arteries treated with the endovascular method [11]. In a 2-year observation period Muller-Hulsbeck *et al.* found no difference in terms of complications between open- and closed-cell stents implanted in the carotid arteries [12].

In our study using open-cell stents in consecutive patients we registered a very low complication rate of 4%. It should be noted that minor stroke was diagnosed in a patient with partial aphasia which persisted over 24 h following the procedure and resolved without sequelae 5 days after the procedure. A major stroke in the right hemisphere (the third one in 10 years occurring in the presence of ipsilateral carotid artery occlusion) can hardly be related to left internal carotid artery stenting. It should be noted that such good results obtained in a group of 40% of symptomatic patients could have been influenced by the selection of protection devices according to the "Tailored CAS" algorithm. It should also be noted that in 23 patients (46%) a proximal cerebral protection was used (MoMa and GNPS system – tab. 1).

Vascuflex SEC stents have a relatively small area of the cells of 9.3 mm^2, which also could have influenced the favourable results of the procedure in the analysed group. Nowadays it is hard to perform carotid artery stenting solely with the use of closed-cell stents. The properties of nitinol self-expandable stents are sometimes crucial for a correctly conducted CAS procedure. However, the selection of stent used for carotid artery stenting should be best based on the morphology of the atherosclerotic plaque and on the anatomy of the stenosed artery [3, 4, 12].

Conclusions

Carotid artery stenting with nitinol open-cell Vascuflex SEC stents is a safe procedure. The rate of periprocedural and 30-day complications does not exceed the values accepted by the guidelines. The favourable results obtained using the described stents may have been influenced by the selection of protection devices according to the "tailored CAS" algorithm.

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