Perspectives on Carotid Revascularization Decision Making

Prof. Piotr Pieniazek, MD, PhD, shares his thoughts on the ideal applications of CAS procedures and his approach to individualized care.

What is your impression regarding the current status of CAS and CEA in Europe? How does reimbursement affect its status?

The number of carotid artery stenting (CAS) procedures performed in Europe has been increasing for the last 10 years. Carotid endarterectomy (CEA) is a well-known technique that has been used for the treatment of carotid atherosclerosis since the 1950s. CEA has numerous limitations, such as lesions at the C2 or higher, below the clavicle, prior radial neck surgery or radiation, contralateral occlusion, previous CEA, contralateral cranial nerve palsy, tracheostomy, and many other severe comorbidities.

In the early 1990s, CAS was introduced as a minimally invasive endovascular alternative to carotid revascularization. During the last 20 years, many types of new stents, embolic protection devices (EPDs), and increasing operator experience have improved this treatment method.

The fact that carotid revascularization is superior to pharmacotherapy alone was shown many years ago in the NASCET trial. Nowadays, most patients are already on acetylsalicylic acid, statins, ACE inhibitors, and/or other antihypertensive drugs (optimal medical therapy), and they still suffer from myocardial infarct or stroke. We shouldn't overestimate the role of optimal medical therapy in saving lives because it is unfair to the thousands of endovascular specialists and surgeons performing complex procedures to save or prolong these lives.

Today, both CEA and CAS are two alternative (and equal) carotid revascularization methods. The patient should be informed of the advantages and disadvantages of both of them and take part in making the decision. In some cases, surgical revascularization is a better option for the patient. CAS, however, can be safely performed in most cases. The procedure is performed under local anesthesia via femoral puncture, lasts about an hour, and the patient is usually discharged home the next day. The patients recovering after CEA and CAS stay together in one room, and CEA patients are jealous of the fact that CAS patients are on their feet only 4 hours after the procedure. CAS is a minimally invasive method that is most appreciated by the patients.

CAS with EPD usage has full reimbursement in Poland, similarly to other European countries. The CAS procedure is much cheaper than the costs of rehabilitation treatment for patients who suffered from a severe stroke. There's no price to place on the tragedy of the patient who has a severe stroke. I consider any limitations on reimbursement for CAS to be unethical.

What data are needed for CAS to become a more prominent treatment for carotid artery disease?

We now have enough data on CAS safety. Another CAS versus CEA trial would be a waste of time, in my opinion. I would indicate cranial nerve palsy as a severe complication of CEA that has never been included in the analysis of major adverse events, although many neurologists claim that such a complication is equivalent to a minor stroke. Myocardial infarction is more often observed in patients who undergo CEA, but it is a rare complication of CAS, especially when the procedure is performed by interventional cardiologists. If iatrogenic cerebral artery occlusion occurs during CAS, it must be diagnosed and treated immediately, which is impossible if the patient undergoes CEA. Currently, we should focus on the prevention and risk factors of post-CAS hyperperfusion syndrome, restenosis prevention/treatment, and analyzing new (mesh-covered, polyeth-

General direct stenting strategy	Predilate only if very tight or highly calcified lesion according to duplex ultrasound, CTA, and angiography.
Soft/thrombus-containing plaque or a severe string-sign lesion in a symptomatic patient (Fig. 1A1, 1B, 1E)	(1) Use a proximal NPD (flow reversal if (non-critical) ECA stenosis or severe angulation that precludes the use of a (one-piece) proximal flow blockade system); if no ECA stenosis/tortuosity, either of the 2 proximal systems can be used. (2) Use a closed-cell stent (cobalt-alloy braided in a straight segment; nitinol if tortuous).
Soft/thrombus-containing plaque or a severe string-sign lesion in a symptomatic patient with access vessel (severe iliofemoral atherosclerosis) or target vessel anatomy precluding the use of proximal NPD (e.g., severe ECA stenosis or diffuse CCA disease or severe CCA stenosis at the bifurcation)	Use an independent-wire filter with 1.25- to 1.5-mm balloon dilation prior to filter delivery or a 6-F–compatible distal occlusion system.
Severe ICA angulation/tortuosity at bifurcation or severe calcifications (Fig. 1D)	Use an open-cell stent.
Soft/symptomatic lesion coexisting with a severe ICA angulation/tortuosity	Consider a hybrid (open-cell/closed-cell/open-cell) stent.*
Severe calcifications on CT angiography	Consider cutting balloon predilation; avoid aggressive postdilation.
Non-severe echogenic or fibrotic/partly calcified asymptomatic lesion	(1) Use a distal NPD (Fig. 1A2). (2) Use open- or closed-cell stent (depending on the target segment tortuosity).
Bilateral ICA stenosis (Fig. 1A)	(1) Consider treating the less severe lesion with distal NPD first. (2) If the contralateral lesion is tight/soft/symptomatic, treat it under proximal NPD (within a few days).
Severe ICA/CCA diameter mismatch	Consider using a tapered (nitinol) stent.
Lack of optimal landing zone for a filter (Fig. 1B, 1D)	Use a proximal NPD; if not applicable (no femoral access, diffuse iliofemoral atherosclerotic disease, or severely angulated arch), use a distal occlusion system.
Lack of femoral access	Use a transradial or brachial approach with a 6-F–compatible filter or distal occlusion system.
Critical stenosis (particularly if symptomatic) + contralateral ICA/CCA occlusion (Fig. 1C)	(1) Consider proximal NPD (document collateral supply via the basilar and posterior communicating artery(-ies) on TCD). (2) If proximal NPD excluded, use an independent-wire filter with 1.25 to 1.5-mm balloon predilation prior to filter delivery (Fig. 1C). (3) Use a closed-cell stent.

Figure 1. Tailored CAS algorithm for patient- and lesion-specific selection of the neuroprotection system and stent type. Adapted with permission from Pieniazek P, Musialek P, Kablak-Ziembicka A, et al. Carotid artery stenting with patient- and lesion-tailored selection of the neuroprotection system and stent type: early and 5-year results from a prospective academic registry of 535 consecutive procedures (TARGET-CAS). *J Endovasc Ther.* 2008;15:249–262.

ylene terephthalate) carotid stents instead of another stent or EPD device registry.

Could you summarize your tailored CAS algorithm?

I believe adopting a tailored CAS algorithm is the optimal strategy for performing successful CAS procedures. Tailored CAS means fitting a proper EPD (distal or proximal) and stent (open- or closed-cell) to the lesion severity, carotid artery anatomy, and patient symptom status. The tailored CAS algorithm that I use (Figure 1) could guide operators who are new to the procedure on how to avoid unnecessary complications. The high-risk procedures, as shown in Figures 2 and 3, should never be performed with a distal EPD filter. The outcomes of CAS performed according to the tailored CAS algorithm are significantly lower than what is common for CEA (6% for symptomatic and 3% for asymptomatic patients).

What differences have you observed in treating patients with proximal versus distal protection?

Using proximal EPDs definitely makes a difference in CAS safety. Distal EPD filters are the first generation of this technology and have many limitations. As such, they should only be used for simple procedures. The recently published meta-analysis by Bersin et al,[1] which included trials using two proximal EPDs (the Gore Flow Reversal system [Gore & Associates, Flagstaff, AZ] and the Mo.Ma protection device [Medtronic Invatec, Frauenfeld, Switzerland]), has shown a very low 30-day complication rate of 2.25% in 2,397 patients.

In our center, among 1,717 CAS procedures, 36% were performed with proximal EPDs according to the "tailored CAS" algorithm (Figure 1) for patients with high-risk lesions ("string-sign," symptomatic, soft, thrombus-containing, previous radiation therapy). The complication rate in this group was similar to the low-risk group treated with distal EPDs.[2] In Cracow, we have more than 10 years experience in performing CAS with proximal EPDs. Of the 248 CAS procedures performed in 2012, proximal EPDs were utilized in more than 50% of cases, and the 30-day complication rate in this group was as low as 1.5%.

What is your experience with symptomatic versus asymptomatic patients?

There is no doubt that symptomatic patients with transient ischemic attack, amaurosis fugax, or minor

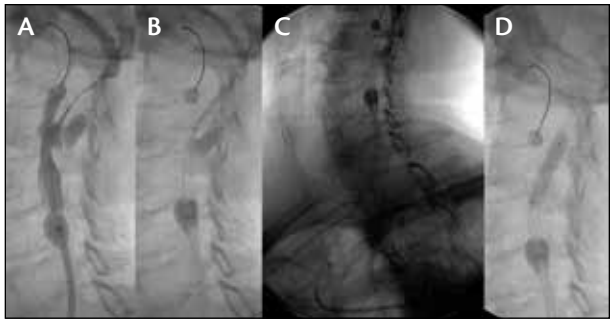

Figure 2. Long narrow (> 95%) left internal carotid artery symptomatic stenosis to the level of the skull associated with aneurysm (A); the proximal EPD (Gore Flow Reversal system) was in place when the lesion was crossed with a Teflon-coated soft coronary wire (Whisper MS, Abbott Vascular, Santa Clara, CA). Predilatation of the lesion with a 2.5- X 20-mm coronary balloon (B). A 5-F, 6- to 9- X 40-mm flexible hybrid stent (Cristallo, Medtronic Invatec) crossing a sharp left common carotid artery takeoff (ostium) (C). Postdilatation with a 5- X 20-mm peripheral balloon (D).

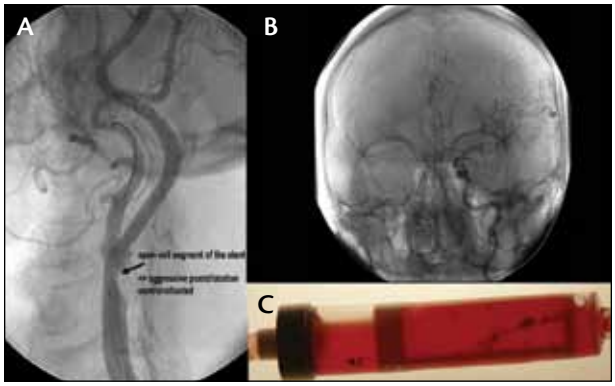

Figure 3. Final result with no residual left internal carotid artery stenosis (A). Intracranial angiography should be routinely performed after all CAS procedures (B). A large amount of embolic material captured with the Gore Flow Reversal system (C).

stroke should be immediately treated, preferably within 14 days from onset of the neurological symptoms. The neurologists should refer the symptomatic patient as soon as possible to have carotid revascularization performed. Patients who have suffered from a severe stroke require an individualized neurological assessment, rehabilitation, and a treatment strategy that weighs the risks of dual-antiplatelet and heparin therapy, which could increase the bleeding risk in the area of the stroke.

The revascularization of neurologically asymptomatic patients is still an unsolved problem. Eighty percent of strokes occur without any symptoms beforehand (a so-called wake-up stroke). From my own experience, an asymptomatic patient with an internal carotid artery lesion and increasing peak systolic and end diastolic velocities on carotid Doppler duplex or soft, echolucent plaque should undergo CAS. Also, a patient who had a stroke a year before, has an occluded internal carotid artery, and a contralateral internal carotid artery stenosis of 75% is still neurologically asymptomatic from the neurologist's point of view and should undergo invasive treatment—either CEA or CAS.

To what degree does clinical experience affect procedural outcomes?

Operator experience is crucial for CAS procedures and has a great influence on the outcome. In the second half of the CREST study, the outcome was much better than in the early years. Brisk device development forces the endovascular operator to keep up with all of the novel techniques and take part in conferences and workshops. The most important thing in the decision-making process is individual patient assessment and cooperation among the multidisciplinary team, which consists of a neurologist, vascular surgeon, and invasive cardiologist. In this team, a physician experienced in performing carotid Doppler imaging and a radiologist acquainted with MRI and CT angiography are also needed. Each center should also have its own CAS registry that would facilitate the systematic assessment of patients after CAS and monitor the complication/restenosis rates.

What do you believe is the role of simulation in CAS training? How can it help to ease the learning curve?

I consider every form of education and exercise that increases operator experience to be positive. Prolonged CAS procedures caused by lack of operator experience could significantly increase the complication rate. I have tutored simulation trainings many times, and they were usually much appreciated by the participants. The great number of questions and comments that surfaced reflects the great need for such training. ■

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2. Leipzig Interventional Course. LINC web site. www.linc2013.com. Accessed January 26, 2013.