

Volume 4 - Issue 2 , 2010 - Cover Story: Cardiovascular Intervention

Carotid Endovascular Interventions: Patient Selection, Devices, Techniques and Tips

The search for a conclusive answer to the optimal treatment of patients with asymptomatic or symptomatic carotid artery disease (CAD) is an ongoing and long-lasting debate. The choice between carotid endarterectomy (CEA), carotid artery stenting (CAS) and/or optimal medical therapy to treat patients with CAD, depends on their risk profile.

Recent data from both the EVA-3S (Endarterectomy versus Stenting in Patients with Symptomatic Severe Carotid Stenosis) and SPACE (Stent-Supported Percutaneous Angioplasty of the Carotid Artery versus Endarterectomy) randomised trials failed to demonstrate non-inferiority for CAS over CEA. However, other publications suggest that with growing experience and the development of dedicated CAS technology, CAS can be performed safely and efficiently.

Success Depends on Selection of Best Device

The success of carotid stenting does not solely depend on the operator's skills and experience, but also on the adequate selection of carotid stents and cerebral protection devices. Currently, CAS practitioners are confronted with a large number of dedicated CAS devices such as stents and embolic protection devices. This wide array of products makes individual treatment strategies difficult to generalise, as no single device possesses all of the optimal features to treat all types of carotid plaques and patients. This article reviews the principles of patient selection and device selection in contemporary CAS practice.

Carotid Treatment Assignment

Based on a systematic literature review, the Society for Vascular Surgery (SVS) stipulated a set of recommendations for the management of carotid artery stenosis. In these guidelines, it states that revascularisation is indicated in patients with a high-grade stenosis, defined as a ≥ 60 percent stenosis for asymptomatic patients according to the European Carotid Surgery Trial (ECST) and a ≥ 50 percent stenosis for symptomatic patients according to the North American Symptomatic Carotid Endarterectomy Trial (NASCET).

Otherwise, the best medical therapy is indicated as the therapy of choice. The choice between carotid endarterectomy (CEA) and carotid artery stenting (CAS) depends on the presumed surgical risk: patients with low risk for surgery are referred for CEA, whereas CAS is reserved for patients considered at high risk for open surgery (see figure 1). Consequently, not only is the population recommended for treatment with CAS very limited according to these SVS guidelines, but, more importantly, potential risk factors for CAS are neglected, possibly increasing the risk of procedure-related neurological events after CAS, which may even exceed the long-term risk of ipsilateral stroke with optimal medical therapy, especially in asymptomatic patients.

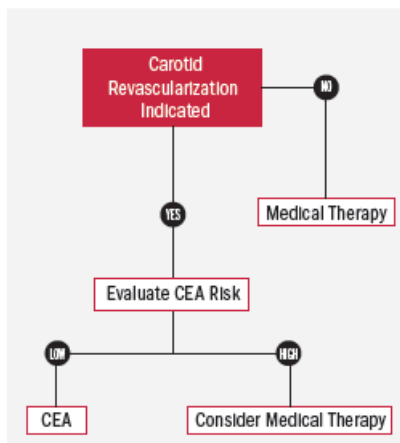
Table 1. Limiting factors for CAS

High risk patient profile for CAS	High risk lesion characteristics for CAS
Advanced age	Filling defects and intraluminal thrombus
Decreased accessibility due to tortuous iliac vessels and/or diseased or elongated aortic arches	Heavy circumferential calcification
Recent stroke	Excessive distal tortuosity
Antiplatelet intolerance	String sign lesions
Cerebral atrophy and dementia	Vulnerable plaque

CAS & CEA are Complementary

Furthermore, SVS recommendations did not see a place for the widespread use of CAS. This conclusion found support in the initial 30-day results from the EVA-3S and SPACE trials. However, both EVA-3S and SPACE report no difference in long-term ipsilateral stroke rates among CAS and CEA patients who were free of stroke within the first 30 days. This means that, by limiting the number of procedure-related CAS complications to a minimum, CAS and CEA are complementary.

Figure 1. Treatment assignment according to presumed surgical risk



This can be achieved by excluding every patient from CAS who presents with any factor that may have a negative influence on the outcome, as shown in table 1, and assign them to CEA (see figure 2).

Using this paradigm, approximately 80 percent of all carotid patients are eligible for both techniques, while the remaining 20 percent require careful attention to be paid to predisposing factors, putting them at increased risk for complications with one of the two techniques. We believe that our paradigm using these potential limiting factors for CAS can lead to optimal CAS outcome, when performed in experienced centres, by skilled operators and using the right materials.

Embolic Protection Selection Guidelines

All embolic protection devices (EPD) can be classified under three main groups, each with its own working principle, advantages and disadvantages:

1. Distal occlusion balloons (DOB);
2. Distal filters (DF), and
3. Proximal occlusion devices (POD).

Screening a patient to decide on which EPD to use, begins with assessing intracerebral circulation. Without sufficient cerebral collateralisation, DFs are recommended as they preserve per-procedural oxygen-delivery to the brain. DOB and POD should not be used because cerebral perfusion might be inadequate during the procedure. Although the protective balloons could be temporarily deflated to guarantee intracerebral circulation, we believe this is a laborious technique, which can potentially increase the risk of distal embolisation and stroke.

Secondly, the selected access site needs to be assessed. Patients presenting with tortuous iliac access or with a type III aortic arch require low-profile, flexible protection systems as the lesion site is difficult to reach. As DOBs have crossing profiles comparable to those of guidewires, they are always steerable and flexible enough to pass tortuous anatomies. Of the DFs, only the smallprofile, flexible ones qualify. Due to the large French sizes of POD systems, they are not recommended in these cases.

Anatomy & Morphology the Key

The anatomy and morphology of the carotid lesion is key in tool selection. Highly stenotic, irregular lesions and near-occlusions can be treated with any EPD. With DFs, though, device selection should be done with caution because only low-profile, soft-tipped, flexible devices should be used to cross the lesion - they are less traumatic and may avoid complications. For cases with a severely angulated ICA, PODs are the most likely candidates to serve as protection during the procedure because they do not have to cross the lesion site. When choosing a DOB or DF system, make sure to opt for a device that is highly steerable and flexible. Another possibility to straighten the ICA is the buddy-wire technique.

When the ICA distal to the lesion is too tortuous or when there is little space between the lesion site and the cerebrum, distal protection systems cannot be used due to the lack of a landing zone for the device. This means only PODs can securely protect during such interventions.

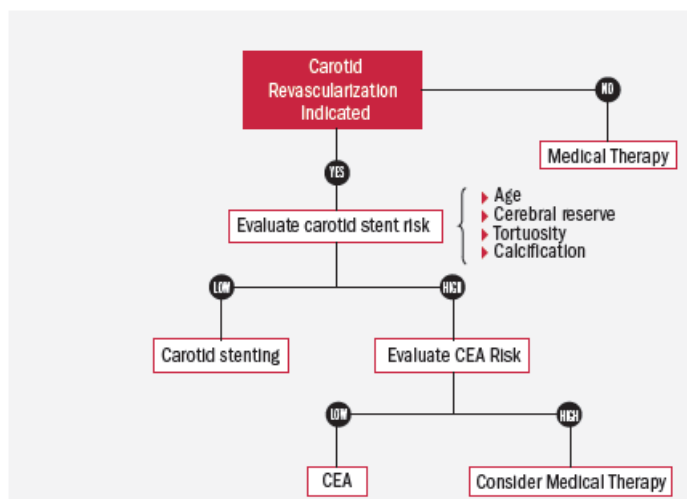
Soft plaque lesions are often more dangerous because they have a greater tendency to embolise. Therefore, stressing the plaque should be avoided at all times. When using a POD this is not an issue. However, when using a DOB or DF, only low-profile, soft-tipped, flexible devices can fulfil this requirement.

Trial Data Inconclusive

Only small variations in complication rates for the different cases can be expected. Thus, hard data from randomised controlled trials is currently not and will probably never become available to prove the presented guidelines. In a recent comparison by El- Koussey et al, they found a non-significant trend toward fewer embolic events after CAS with POD versus DF protection, based on diffusion-weighted magnetic resonance imaging (DW-MRI) outcome.

Both the total number of new lesions, as well as the volume of consistent (relevant) new lesions, was non-significantly lower in the POD group. These DW-MRI differences did not result in a difference in clinical outcome between the two types of EPD. The latter was confirmed in a sub-analysis of the Belgian Italian Carotid (BIC) registry, which concluded that none of the observed differences in 30-day event rates between the different EPDs and EPD types could be explained by the EPD selection itself, but were all largely attributable to the difference in stent type used in conjunction with the EPD.

Figure 2. Treatment assignment according to potential limiting factors for CAS



Carotid Stent Selection Guidelines

During carotid endarterectomy (CEA), plaque is completely removed from the body. By contrast, after CAS, plaque remains in the artery. As the potentially hazardous debris stays in the artery, the brain needs to be continuously protected against embolisation, potentially leading to sometimes devastating neurological complications. After EPD removal, the only protection against brain-embolisation remains the selected carotid stent. Therefore stent scaffolding capacities are of major importance to obtain a stroke-free CAS result.

Self-expanding carotid stents are composed either of a nickel-titanium alloy, known as “nitinol” or a cobalt alloy, often called “stainless steel”. Table two (see below) lists all the specific device characteristics and manufacturing details of the below-mentioned stents. The differences in construction and design between nitinol and cobalt alloy stents provide each stent with unique functional properties. Our clinical experience suggests that proper stent selection can greatly influence the outcome of the CAS procedure, by approximately 20 to 30 percent of cases.

Conclusions

Interventional specialists, who offer both CEA and CAS as part of a unified service, are best placed to treat the CAD population. It has to be understood that both strategies are complementary and not concurrent and that a well-thought treatment allocation is crucial to achieve good results in both CAS and CEA.

The treatment algorithm as currently used in our services and as initially proposed by Roubin et al. allocates patients to CEA or CAS, based on potential risk factors for suboptimal CAS outcome. This same algorithm was introduced in our service at the end of 2006, and led to a resurgence in CEA procedures in symptomatic patients. This resulted in less complications in both the CEA and CAS populations following this approach.

Since all devices have their assets and downsides, it is impossible to acclaim one specific device as being the best, only taking into account product characteristics. In patients presenting with unfavourable anatomy of the carotid region, the choice of protection device lies not entirely in the hands of the interventionalist, but has to depend also on anatomical limitations. However, in all other cases, device selection when performing carotid procedures depends on the preferences of the interventionalist.

Table 2. Stent characteristics

Characteristic	Definition	Acknowledgements
Conformability	The extent to which a stent is resistant to elastic recoil and radial crush without exerting excessive chronic outward force.	- Too much radial force may result in plaque disruption, especially in vulnerable lesions. - Higher radial force is needed in heavily calcified lesions - Nitinol stents have a higher outward force than stainless steel stents - Although CAS often achieves a good outcome in calcified lesions, severely calcified lesions are often better treated with CEA.
Vessel wall adaptability	Ability of a stent to adjust to the tapered anatomy of the carotid region.	- Cobalt-chromium stents taper by foreshortening or elongating during placement. Selection of these stents should be done according to the diameter of the common carotid artery. - Nitinol stents comprised of different rings connected by bridges have a self-tapering effect because the different rings interact independently with the vessel wall. - Tube-form nitinol stents are more rigid and may taper less well. - Tapered stents are pre-shaped for the carotid anatomy, having a wider diameter proximally and a smaller diameter distally.
Scaffolding	The support to the vessel wall counted as the ratio between quantity of stent material to the amount of vessel tissue.	- Higher scaffolding implies better containment of the plaque, which makes it crucial to stent performance in order to prevent post-procedural plaque embolisation through the stent struts. There are three scaffolding parameters: 1) Cell area (mm²) 2) Pore diameter 3) Pore size (mm²)

A full set of references for this article is available on request to the Managing Editor: edi.torial@cardiologymanagement.eu

Published on : Sun, 31 Jan 2010