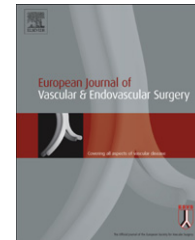




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CAROTID MASTERCLASS

How to Introduce Carotid Angioplasty without Compromising Patient Safety[☆]

Jörn O. Balzer*

Department of Radiology and Nuclear medicine, Catholic Clinic Mainz, An der Goldgrube 11, 55131 Mainz, Germany

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Abstract Carotid angioplasty with stenting (CAS) is increasingly being used in the treatment of extracranial carotid disease and numerous studies have demonstrated its feasibility. However, the exact role of CAS in the treatment of carotid stenosis and its long-term efficacy has not been defined. The assessment of the patient's medical condition, the exact identification of vessel anatomy as well as anomalies of the aortic arch and the cervicocerebral circulation is required for successful and safe performance of CAS. New CAS practitioners would be advised to start their experience in patients with predominantly easier anatomical situation as well as plaque configuration.

The appropriate selection of interventional techniques as well as vascular access for CAS is dependent on the anatomy of the aortic arch and of the CCA proximal to the target lesion. Usually a retrograde femoral artery approach to access the CCA is preferred. In order to treat a patient safely with carotid artery stenting, it essential for interventionalists to appropriately chose a patient suited for endovascular therapy, to identify possible sources of complications prior to the interventional procedure as well as to know the key points for a successful carotid artery intervention. An interdisciplinary evidence-based approach will facilitate the choice of optimal intervention for each patient. Finally, trainee programs for physicians starting with CAS as well as facility certification are absolutely mandatory to ensure high success rates as well as low complication rates.

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Introduction

In 2007 stroke was identified as the third leading cause of death (164,000 deaths/year) in the US (after heart disease

and cancer and approximately 1 million stroke-related events occur each year. According to Bates *et al.* these latter events can be subdivided into 500,000 new strokes, 200,000 recurrent strokes, and 240,000 transient ischemic

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* Tel.: +49 6131 575 1700; fax: +49 6131 575 1709.

E-mail address: balzerjo@t-online.de

attacks (TIAs). Overall, it is likely that carotid artery disease suitable for revascularization accounts for 5% to 12% of new strokes.¹

Carotid angioplasty with stenting (CAS) is increasingly being used in the treatment of extracranial carotid disease and numerous studies have demonstrated its feasibility. In order to replace carotid endarterectomy (CEA) as the standard treatment for carotid artery disease, however, CAS has to be shown to be at least as safe and effective as surgery. However, the exact role of CAS in the treatment of carotid stenosis and its long-term efficacy has not yet been defined.^{2–16} Part of the controversy arises from confusion about which physicians should treat carotid artery disease. With the introduction of CAS, a broad variety of “vascular specialists” have established endovascular treatment of carotid artery disease into their routine practice. This has occurred in parallel with important innovations in the device (stent, protection device), technical refinements and a better knowledge of patient selection.^{17,18}

With the introduction of CAS, vascular surgeons have been challenged to change their attitude regarding the management of severe carotid artery disease.¹⁷ The two most referenced trials in the current clinical decision-making process for carotid stenosis are the North American Symptomatic Carotid Endarterectomy Trial (NASCET) and the Asymptomatic Carotid Atherosclerosis Study (ACAS). Both concluded that there was a clear benefit for CEA in patients with symptomatic and asymptomatic carotid occlusive disease.^{19,20} These landmark trials typically included patients who were considered to be at low or intermediate risk of perioperative events. Patients who were considered ‘high risk for surgery’ were excluded. This became evident when published death rates were found to be significantly higher in post-NASCET and ACAS era of treating patients, even though these audits were undertaken in the same hospitals where NASCET and ACAS had recruited patients.²² Thirty day stroke and death rates of 3 and 6% in asymptomatic and symptomatic patients, respectively, are now considered the benchmark for acceptable results for CEA based on the results of these early trials. It is therefore expected that the outcome of CAS should achieve a similar standard.^{21,23} In current clinical practice, CAS has emerged as a viable alternative for patients who are deemed at ‘high risk for surgery’ or ‘poor’ candidates for CEA, which is now considered the standard of care.²⁴ Several trials have suggested equivalent results for CAS and CEA.^{24–28}

While a number of important issues still need to be resolved, it is likely that an increasing number of clinicians will want to learn how to perform CAS. This paper will review how this can be achieved without compromising patient safety.

Patient Selection

Since the early and mid 1990s, CAS has emerged as an alternative to surgery in patients who are considered ‘high surgical risk’. Over time, the definition of increased surgical risk has been established into two main categories. The first (general) high-risk category includes; patients with medical co morbidities such as New York Heart Association class 3 or 4 congestive heart failure, reduced left ventricular ejection

Table 1 Common increased surgical risk features [modified from 24]

General criteria	Anatomic criteria
<ul style="list-style-type: none"> • Unstable angina • Myocardial infarction within 30 days • NYHA class 3 or 4 congestive heart failure • Multivessel coronary artery disease (non-revascularized) • Reduced left ventricular ejection fraction (<30%) • Cardiac or vascular surgery required within 30 days • Chronic obstructive lung disease (FEV1 < 30% of predicted) • Age greater than 75 years 	<ul style="list-style-type: none"> • Lesions higher than C2 or lower than C6 • Tandem carotid lesions requiring treatment • Restenosis following ipsilateral CEA • Ipsilateral radical neck dissection or irradiation • Tracheostomy • Bilateral severe carotid artery stenosis • Contralateral carotid artery occlusion • Contralateral CEA resulting in cranial nerve injury

NYHA: New York Heart Association; FEV1: Forced expiratory volume in one second; CEA: Carotid endarterectomy.

fraction (<30%), unstable angina, multivessel coronary artery disease (non-revascularized), myocardial infarction within 30 days, cardiac or vascular surgery required within 30 days, chronic obstructive lung disease with forced expiratory volume in one second of <30% predicted, or age older than 75 years.²⁴ The second (anatomical) high-risk category includes; carotid lesions located proximally or distally beyond conventional surgical access (lower than the sixth or higher than second cervical vertebral bodies), tandem carotid lesions requiring treatment, a history of ipsilateral CEA or radical neck dissection, neck irradiation, tracheostomy, bilateral severe carotid artery stenosis requiring treatment, contralateral carotid occlusion, or contralateral CEA which has already caused a cranial nerve injury²⁴ (Table 1).

In addition to the assessment of the patient’s medical condition, the exact identification of vessel anatomy as well as anomalies of the aortic arch and the cervicocerebral circulation is required for successful and safe performance of CAS (Table 2). Arch elongation and calcification and vessel tortuosity are all features that generally increase the difficulty of CAS and thus increase the likelihood of encountering procedural complications. Although more common in the older patient, these characteristics may be found in patients of any age and may be considered as risk factors for perioperative stroke with CAS.²⁹ It is important to recognize the type of aortic arch and the configuration of the great vessels in each patient, since these anatomic features influence procedure complexity.

There are three types of aortic arch, based on the relationship of the innominate artery to the aortic arch.^{1,30,31} The type I aortic arch is characterized by the origin of all 3 great vessels being in the same horizontal plane as the outer curvature of the aortic arch. In the type II aortic arch, the innominate artery originates between the horizontal plane of the outer and inner curvatures of the aortic arch. In the type III aortic arch, the innominate artery originates below the horizontal plane

Table 2 Anatomic and clinical evaluation of favorable and unfavorable arterial characteristics for CAS [modified from 29]

	Favorable	Unfavorable
Arch elongation	Vessel origins off top of the arch (type I)	Origin from ascending or between greater and lesser curvatures (type III), severe posterior rotation
Arch calcification	No or minimal	Luminal irregularity or diffuse calcification
Origin stenosis	<50%	>50%
Carotid tortuosity	<30° angularity	>30° angularity
Lesion stenosis	<99%	>99% or occlusion
Lesion calcification	No or trace shadowing	Severe calcification
Thrombus	None	Presence of fresh thrombus
Lesion length	0–5 mm	>5 mm
Aneurysm	None	Ipsilateral intracranial aneurysms >5 mm
Age	<80 years	>80 years
Cerebral reserve	Sufficient	Reduced (e.g. prior stroke, dementia)

CCA: Common carotid artery; ICA: internal carotid artery.

of the inner curvature of the aortic arch. The more inferior the origin of the target artery (i.e. type II or III aortic arch), the greater the difficulty in gaining access to the carotid artery (Figs. 1–3). Accordingly, new CAS practitioners would be advised to start their experience in patients with predominantly type 1 arches, because the major difficulty lies in the appropriate placement of the guiding catheter or sheath without causing distal emboli or dissection. In either arch, the placement of a stiff guidewire in



Figure 1 CE-MRA of a type I aortic arch with all 3 great vessels in the same horizontal plane as the outer curvature of the aortic arch. In addition, an anatomical variation in the origin of the left vertebral artery was detected (white arrow) as well as a stenosis of the left subclavian artery (yellow arrow).

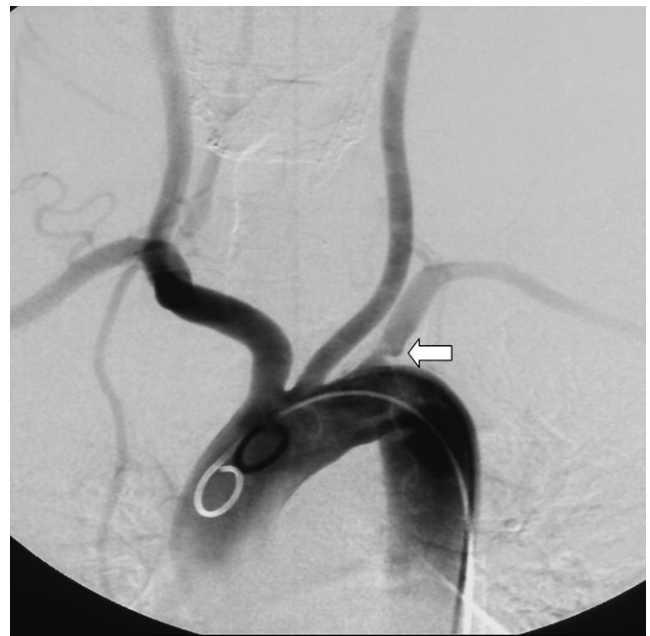


Figure 2 IADSA showing a type II aortic arch. The innominate artery originates between the horizontal planes of the outer and inner curvatures of the aortic arch. Additionally this patient presented with a stenosis of the left subclavian artery (white arrow).

the ipsilateral ECA is necessary in order to prevent distal embolisation through guidewire manipulation at the level of the carotid stenosis.

In addition to the type of arch, the configuration of the great vessels is also important when planning any CAS procedure. In the usual configuration, the innominate



Figure 3 IADSA of the aortic arch with depiction of a type III aortic arch where the innominate artery originates below the horizontal plane of the inner curvature of the aortic arch.

artery, the left common carotid artery (CCA), and the left subclavian artery have separate origins from the arch. Two common anomalies are encountered in clinical practice, both of which have been erroneously termed 'bovine arches'. In fact, neither of these variants bears any resemblance to the actual anatomy seen in cattle! The first variant is where there is a common origin to the innominate artery and the left CCA. The second common anomaly is where the left CCA arises as a branch of the innominate artery. Both of these conditions can cause access difficulties for less experienced CAS practitioners and this should be considered during case selection. Other anatomical variations can occur more distally in the carotid circulation. The distal CCA usually bifurcates into the internal carotid artery (ICA) and the external carotid artery (ECA) at the level of the thyroid cartilage, but an anomalous bifurcation may occur anywhere within 5 cm above or below this level, and there are many variations in the position of the ICA relative to the ECA. There is also considerable variation in length and tortuosity of the ICA, with up to 35% of individuals having some form of coiling or kinking of the ICA, particularly in the older patient.

Even with increasing experience of performing CAS, it is important to continue to remember those factors that make the procedure more difficult or even hazardous. In the elderly patient, the increased susceptibility of the brain to emboli, hypo- or hyperperfusion increases the risk of a suffering a neurologic event after CAS.²⁷ At the time of writing, relatively little reliable information exists regarding which anatomical factors predispose individual elderly patients to increased procedural risk (there is still no known association between plaque calcification and age³²), but the less experienced CAS practitioner might be best advised to develop their practice on a younger cohort of patients before expanding this into an older patient population.

Technique of Carotid Artery Stenting

Historical perspective

Balloon angioplasty of the first carotid artery stenosis was performed in 1979; the first cerebral protection systems were used in the early where a distal balloon occlusion system as used to reduce embolic complications.^{4,11,15,33} The first balloon-expandable stent was deployed in a carotid artery in 1989, however these stents were prone to compression and major adverse events occurred in more than 10% of patients at 30 days follow-up.^{34,35} The introduction of the self-expanding Wallstent, supplemented later by self-expanding nitinol stents solved these problems.^{10,18}

However, the risk of embolic stroke was the main concern that limited early carotid artery PTA. Initial strategies focused on neurological rescue interventions, but then shifted to neurological protection, leading to the development of dedicated embolic protection devices (EPD) to capture and remove embolic debris that were generated during the course of the interventional procedure. Notwithstanding these important technological innovations, that certainly improved outcomes, CAS still careful training of the operator and wide experience in endovascular procedures in order to achieve low complications rates.

Technique

From a clinical standpoint, the main goal of carotid revascularization is to prevent stroke. Since most strokes follow thromboembolism, most interventionalists feel that it is more important to reduce the overall risk of embolisation than completely eliminate the carotid stenosis. From a technical point of view, the main aims of CAS are to enlarge the lumen as well as cover the lesion by placement of a stent. This requires careful imaging of the carotid artery and intracranial circulation before and after CAS. Generally, an angiographic examination of the target lesion in two projections is required, as well as an angiographic examination of the intracranial circulation in anteroposterior and lateral projections.

All patients should be pretreated with acetylsalicylic acid (ASA) at a mean dosage of 100 mg/day and with clopidogrel at a mean dosage of 75 mg/day for at least 6 days prior to intervention. Clopidogrel (75 mg/day) should then be continued for at least one month after the interventional procedure. Thereafter, mono antiplatelet therapy (aspirin or clopidogrel) should be continued on a life-time basis.

Carotid access

Appropriate selection of interventional material for CAS is dependent on the anatomy of the aortic arch and of the CCA proximal to the target lesion. Usually a retrograde femoral artery approach to access the CCA is preferred. Additionally, a right brachial or radial access is required, particularly in cases involving an anomalous left CCA arising from the proximal innominate artery or in cases where transfemoral access is not possible due to severe inflow occlusive disease. Access to the CCA is achieved by using either a guiding catheter or an interventional sheath.

The choice of technique is largely operator dependent, although there are several anatomic factors that might favor one technique over another. When treating patients with a simple arch and carotid anatomy, a 6-F interventional sheath or an 8-F guiding catheter can be employed. The tip is usually positioned in the distal CCA, a few centimeters below the carotid bifurcation. In cases which require a more aggressive guiding catheter shape, the tip of the guide is usually positioned in the proximal (intrathoracic) segment of the CCA, although this generally provides less support for the procedure. Careful placement of the tip of guiding catheter or interventional sheath will help prevent spasm, thrombosis, or dissection. Strict management of catheter flushing and elimination of air is essential to avoid periprocedural emboli. In addition, in order to minimize embolisation, the target lesion should be subjected to as little manipulation as possible.

Carotid artery angioplasty and stenting

After access has been achieved 5000–10000 I.U. of intrarterial heparin should be administered with the aim of achieving an activated clotting time (ACT) of 250 to 300 s. The next step involves placement of the EPD. The choice

of protection device (distal or proximal) is dependent on anatomical as well as haemodynamic factors and predilatation may be necessary in cases where the passage of the lesion with a distal EPD is not possible and proximal protection is not indicated. After placement of the EPD, PTA with undersized balloons (3 to 4 mm in diameter and 15 to 40 mm in length; a balloon to ICA ratio of 0.5 to 0.6) are selected to allow passage of the stent delivery system, if needed. This is especially important in severe stenosis since removal of the stent delivery catheter could become impossible otherwise. Additionally, undersized angioplasty balloons (4.5 to 6 mm in diameter and 15 to 30 mm in length) are used to expand the stent after deployment. The goal of CAS is not to eliminate the stenosis altogether, but to reduce the risk of thromboembolism. Accordingly, a moderate residual stenosis (30% to 40%) is acceptable. Nitinol self-expanding stents show a tendency to continue to expand within the lumen after the procedure, and it is possible that a moderate residual stenosis immediately after intervention may remodel into a milder residual stenosis several few months later. The number of balloon inflations should be kept to the minimum as vasovagal or vasodepressor reactions may increase complications. Most interventionists recommend administering Atropine (0.5 to 1 mg) to the majority of patients just before the post-stenting PTA phase to reduce the risk of bradycardia and hypotension. Atropine should not be administered to patients with tachycardia and uncontrolled systemic hypertension.

Choosing the right stent

The choice of stent (balloon vs self expandable) is relatively straightforward. Balloon expandable stents are generally used for intrathoracic lesions (eg at the origin of the CCA), while for the cervical portion of the distal CCA or proximal ICA, self-expanding stents are recommended. Nitinol self-expanding stents are preferred by most operators over stainless steel stents because of better conformability, lack of shortening, and predictable deployment. However, early and late published results appear to be similar, regardless of stent design. All self-expanding carotid stents have delivery systems that are compatible with 0.014-inch guidewires, which is the most common platform for delivering distal EPDs. Many nitinol stents are now available in tapered designs so as to conform to the tapered transition from the larger CCA (8 to 10 mm in diameter) to the smaller ICA (5 to 7 mm in diameter), although there are no data to suggest better outcomes compared with non-tapered designs. Stent lengths (most commonly 30–40 mm) are usually chosen to achieve complete lesion coverage (normal-to-normal from the distal CCA to the proximal ICA). There is still a lot of debate about whether 'open' or 'closed' stent designs are optimal. Although open cell stents allow a higher degree of stent conformability, it does permit more extrusion of plaque material through the stent interstices. Conversely, closed cell stents offer very good plaque coverage at the expense of greater rigidity and lower conformability. So called 'hybrid' stents (a sandwich of open cell:closed cell:open cell components) could allow optimal plaque coverage with greater conformability.

Discussion

The management of carotid atherosclerosis remains one of the most controversial areas of vascular practice, despite attracting more randomised trials than any other problem in peripheral artery disease. Presently the most hotly debated topic is carotid stenting. Over the last decade there has been an increasing shift towards the endovascular treatment of most vascular beds. In many countries this also applies to the treatment of carotid stenosis.

Luebke and colleagues presented a meta-analysis of trials comparing CAS and CEA for the treatment of carotid stenosis. The main findings were that CAS was associated with increased risk of perioperative stroke, OR 1.50 (95% CI: 1.05-2.16), but a reduced risk of cranial nerve injury, OR 0.15 (95% CI: 0.09-0.26).² No difference in outcome at one year was found, however, few of the studies analyzed have as yet reported at this time point. Based on these findings the authors concluded that CEA remains the "gold standard" in the treatment of carotid stenosis and CAS should only be carried out as part of an on-going randomized trial. It should be noted that the authors finding of a worse perioperative outcome in patients randomised to CAS only held for a fixed effect model and was not demonstrated with the statistically more conservative random effect model.²

The randomized trials of CAS and CEA have not had the same impact as the "surgery versus best medical therapy" trials of the 1980s, failing to show superiority for either modality. Moreover, several of these trials have raised concerns about the procedural risk of CAS, and even the greatest protagonists of CAS would accept that some elements of case selection are absolutely essential in order to achieve clinically acceptable rates of technical success and low rates of stroke and death. With the available data for symptomatic patients, there is little to recommend the routine use of CAS, and patients should continue to be randomized to the ongoing randomized trials. Furthermore, there should be a concerted effort to concentrate resources on treating symptomatic carotid disease as an emergency, with specialized units providing a multidisciplinary team approach, offering expedient imaging, thrombolysis, and appropriate intervention. Loftus *et al.* stated, that there may be a role for CAS in asymptomatic disease, however as with symptomatic disease, there are no trial data to recommend routine intervention in asymptomatic individuals. Ongoing randomized trials may provide clearer guidance in this domain, but in order to demonstrate equivalence for CAS, each individual center will need to demonstrate a 3% periprocedural stroke and death rate. Even with excellent technical results, the clinical benefit will be small for asymptomatic patients.³⁶

However, CAS is now considered a favorable alternative to CEA in 'high-risk' patients. FDA approved carotid stent and embolic protection systems are currently available. Many interventionists predict that CAS will become at least an equal alternative to CEA in the general patient population, pending the results of multiple ongoing prospective randomized trials.²⁴

This author agrees with the guidelines established by the AHA/ASA (American Stroke Association) and these provide a useful 'starting point' for those interested in developing

a CAS practice. Symptomatic patients who would otherwise have a low operative risk with either moderate (50%–69%) or severe (70%–99%) stenosis are recommended to undergo CEA, whereas patients who are symptomatic with severe stenosis (>70%) and who are 'high risk for CEA' are recommended to undergo CAS.³⁷ What should the 'less experienced' CAS practitioner do about asymptomatic patients? For the asymptomatic patient who is likely to face a low operative risk, two areas of controversy exist. First, is intervention really needed in these patients and second, if an intervention is warranted, what should be the threshold stenosis for intervening?.¹ A number of randomized trials are now recruiting 'standard risk' asymptomatic patients and this is the ideal forum to evaluate the respective roles of surgery, CAS and 'best medical therapy'. Although CAS would seem to be an appropriate intervention for patients who would otherwise face a 'high operative risk', no level I data are currently available to support this type of intervention. In this situation, less experienced CAS practitioners should probably avoid becoming embroiled in this controversy!

Conclusion

Carotid artery stenting is a validated, approved, and possibly superior treatment alternative for selected patients with carotid artery stenosis. Improved device technology, operator experience, and adjunctive pharmacotherapy have led to significant improvement in carotid artery stenting outcomes over the past years. The clinical trials published so far demonstrate the advancement of CAS and the likely future in which CAS will become the treatment of choice for carotid artery stenosis, whereas CEA will be reserved for patients with anatomic and clinical contraindications to CAS.^{38–40} This is also reflected by the creation of CAS reimbursement policies by the Center for Medicare and Medicaid Services (CMS) (Table 3), training and credentialing guidelines by multiple societies, creation of reimbursement codes, and the increasing number of CAS procedures performed. Notwithstanding this, patient safety remains the primary goal of physicians involved in the management of patients with carotid artery stenosis and an interdisciplinary evidence-based approach will facilitate the choice of optimal intervention for each patient. Finally, trainee programs for physicians starting with CAS as well as facility certification are absolutely mandatory to ensure high success rates as well as low complication rates.^{41–43}

Table 3 Criteria for CAS according to the Center for Medicare and Medicaid Services (CMS) and FDA decision^{40,41}

	CMS coverage criteria	FDA-labeled criteria
High surgical risk	YES	YES
Symptomatic, Stenosis $\geq 70\%$	YES	NO
Symptomatic, Stenosis 50–70%	NO	NO
Asymptomatic, Stenosis $\geq 80\%$	YES	YES
embolic protection device required	YES	YES

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