

Use of cerebral protection during carotid artery stenting

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Abstract

Carotid artery stenting (CAS) is emerging as a less invasive alternative to carotid endarterectomy, although embolic neurological events occur invariably during CAS. These are often attributable to fragments of atheromatous plaque dislodged during the stenting procedure. Use of a protection device can minimise this risk, and three approaches have been developed: distal occlusive balloons, distal filters and proximal protection by occlusion of common and external carotid arteries. Distal protection devices must cross the lesion for correct positioning and therefore carry a risk of causing embolisation in the absence of cerebral protection. In contrast, proximal systems provide cerebral protection before any device passes the lesion and therefore should enable complete prevention of embolisation. Despite the lack of randomised trials evaluating these devices, available data indicate superiority of protected over unprotected CAS. The capture of debris and prevention of emboli, few device-related complications and technological improvements in newer devices support the use of cerebral protection for CAS.

treatment or carotid surgery were equivalent.²

Despite the routine application of stents, advanced stenting techniques, and combined antiplatelet therapy with aspirin plus clopidogrel or ticlopidine, embolic neurological events occur invariably during CAS. Obstructive carotid artery lesions are known to contain friable, ulcerated and thrombotic material⁴ that can embolise during the intervention as shown in transcranial Doppler, *ex vivo*⁵ and *in vivo*⁶ studies.

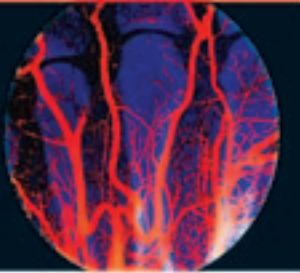
It has also been shown that microembolisation occurs considerably more frequently during CAS than CEA.⁷ In order to minimise the risk of embolic neurological events, a number of protection strategies have been introduced into the carotid stenting procedure. A reduction of the Doppler-defined embolic load by means of a protection device has been demonstrated.⁸ Preliminary results indicate that the refinement of stenting techniques, the increasing experience of the physician, and the routine use of cerebral protection produce results with CAS similar to the best surgical series (Figure 1).^{3,9,10}

Introduction

CAS is emerging as an alternative therapy to surgical carotid endarterectomy (CEA) for the treatment of extracranial carotid stenosis.¹⁻³ The common goal of both procedures is the prevention of stroke and the efficacy of the procedure depends on the periprocedural complication rates. The endovascular stent procedure offers a less invasive approach to achieve this goal by avoiding some of the perioperative complications of surgical treatment. The randomised trial of carotid angioplasty (the Carotid and Vertebral Artery Transluminal Angioplasty Study – CAVATAS) showed that despite the use of sub-optimal interventional techniques the early and 3-year outcomes of endovascular

The first system, a balloon for distal occlusion, was developed and used by Theron in 1990.¹¹ In current practice, three different approaches are used for cerebral protection (Figure 2): two systems of distal protection (distal occlusive balloons and filters), and proximal protection using the occlusion of the common and external carotid arteries. The histopathological analysis of the debris collected using the various systems of protection has demonstrated that this debris comprises fragments of atheromatous plaque dislodged during carotid stenting.⁶ In this article, the three different approaches to cerebral protection are briefly described.

Distal occlusive balloons



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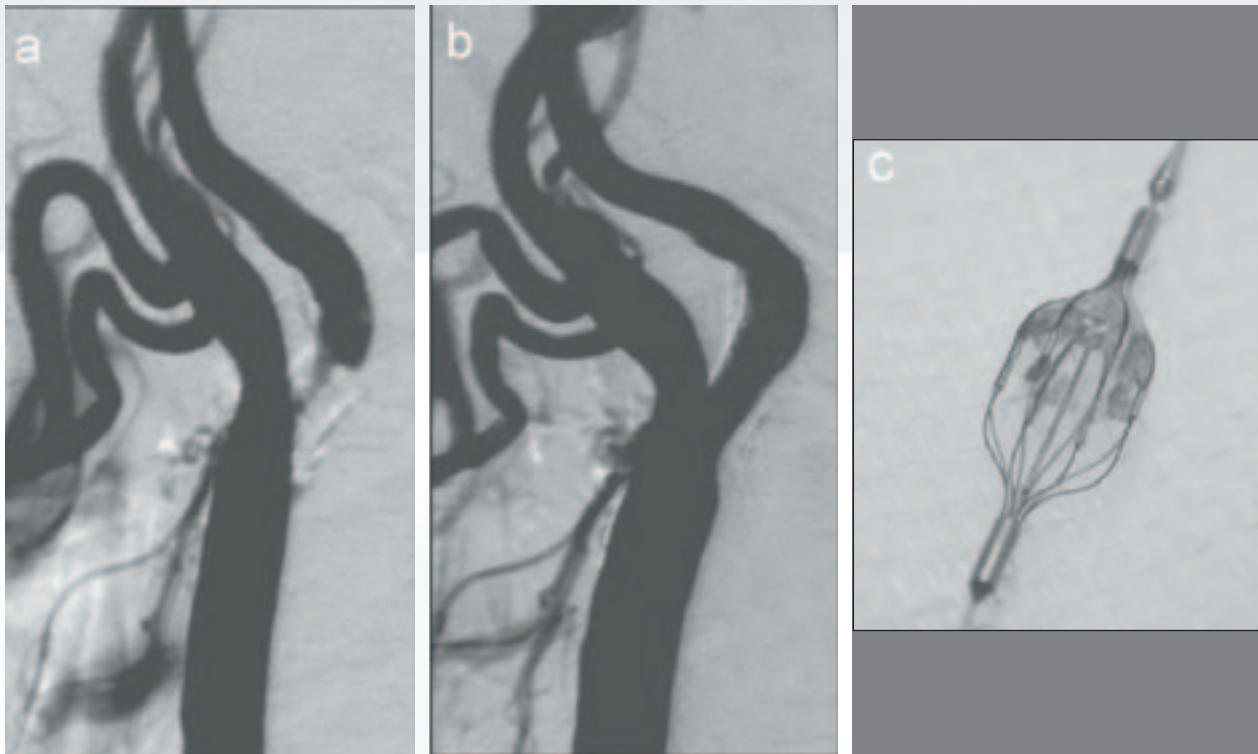


Figure 1. Angiographic images of a tight, calcific stenosis of the proximal internal carotid artery before (a) and after (b) stent implantation. (c) The protection device removed following the procedure.

Distal occlusive balloons constitute the first system of protection used on a large scale.⁸ They consist of a guide of 0.014 inches with a balloon on the distal portion that may be inflated and deflated through a very small channel contained in the guide itself (PercuSurge™/GuardWire™). The lesion is crossed with the guide thereby positioning the balloon distally to the stenosis where it is inflated until the blood flow in the internal carotid artery is blocked. Following this, the angioplasty and stenting procedure is carried out. On completion of the procedure, a catheter is advanced up to the distal balloon and the column of blood contained in the occluded internal carotid artery is aspirated. In this way debris dislodged incidentally during the stent procedure is eliminated. Afterwards the balloon is deflated and the guide is removed. The advantages of

distal occlusive balloons are the small diameter (2.2 French) and the good manoeuvrability and flexibility of the system. Possible disadvantages are that the occlusion is not tolerated by 6–10% of patients⁹ and it is not possible to image the vessel with contrast medium during the inflation.

Distal filter system

The protection filters consist of a metallic structure (or skeleton) coated by a membrane of polyethylene or a net of Nitinol™ wires that contain holes 80–200 µm in diameter.¹² The filters are usually positioned at the distal portion of a 0.014 inch guide. During the procedure, the filters are folded into a delivery catheter with which they are advanced distally to the stenosis. After the lesion is crossed, the filter

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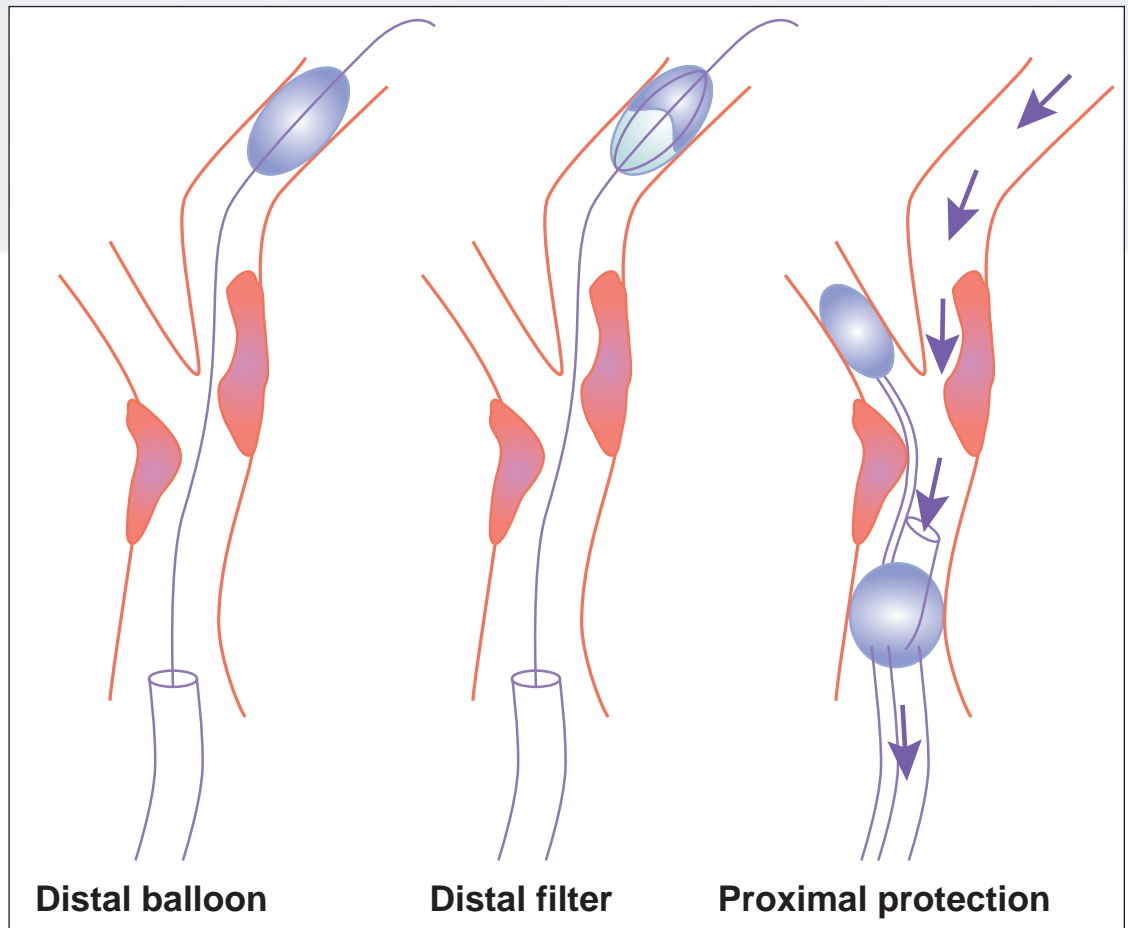
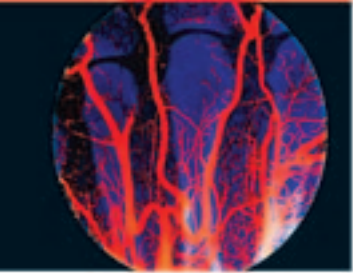


Figure 2. The three different concepts of cerebral protection applied during carotid artery stenting.

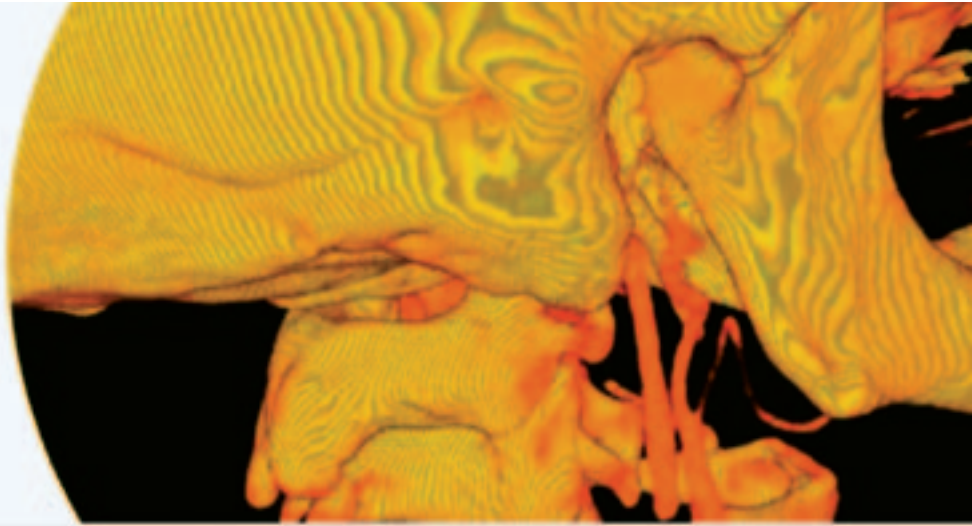
is opened by removing the delivery sheath. At the end of the stenting procedure the filter is closed with a retrieval catheter and is removed from the carotid artery.

Systems of proximal protection

The distal protection devices – occlusive balloons or filters – have the disadvantage that they must cross the lesion before they are inflated or opened.¹³ This passage (or crossing) carries the risk of embolisation during this 'unprotected' step of the procedure. The proximal protection systems, in contrast, provide cerebral

protection before the passage of any type of device through the stenoses.

These systems consist of a long introducer sheath with a balloon that is inflated in the common carotid artery. A second balloon, inflated in the external carotid artery, assures the total blockade of the antegrade blood flow in the internal carotid artery. The proximal protection systems use the cerebral vascular connections of the Willis circuit. After the occlusion of the common and external carotid artery, the collateral flow through the Willis circuit will create so-called 'back-pressure', which



will prevent antegrade flow in the internal carotid artery. After stent positioning, and before the deflation of the balloons in the common and external carotid artery, the blood present in the internal carotid artery – possibly containing dislodged debris – is aspirated and removed.

The advantage of the proximal protection system is the fact that the entire procedure is carried out under protection and, if it is correctly applied, it should completely avoid any type of embolisation.

The disadvantages of the proximal protection system are that it is not tolerated by all patients and that the two systems actually available (Parodi™, Mo.Ma™) require 10 French introducer sheaths.

Clinical results

In the recent Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy trial (SAPPHIRE), 156 patients were randomised to carotid stenting with cerebral protection and 151 patients to endarterectomy.¹⁴ The 30-day incidence of stroke/death in the group of patients treated by CAS was 4.5% and in the group treated by CEA was 6.6% (p =not significant). The SAPPHIRE study clearly shows that both procedures are at least equivalent in high-risk patients. If CAS performs at least as well as CEA in difficult patients, why should it work less well in patients at 'normal' risk? Kastrup *et al.* reviewed data from published single-centre reports of 2537 unprotected and 896 protected CAS procedures.⁹ The 30-day death/stroke rate was 1.8% for patients treated with protection compared with 5.5% in patients treated without protection. However, no randomised trials are available to show the superiority of protected over unprotected CAS and it is difficult to imagine that such a randomised controlled study of protected *versus*

unprotected CAS will ever be carried out. Primarily, such a study would require too many patients to show a difference between groups, considering the low reported complication rates of the procedure. However, the use of these protection devices has some advantages: firstly, a demonstrated capacity to capture debris which otherwise would have embolised; secondly, the reduction of emboli as shown by transcranial Doppler studies;⁸ thirdly, an increase in experience using these devices with a low incidence of device-related complications;³ and finally, the availability of second-generation devices featuring much higher flexibility, lower crossing profile, and easier handling.

Conclusions

Carotid artery stenting is emerging as an alternative, less invasive therapy for the treatment of carotid stenoses. Cerebral protection devices have been used successfully in large series of CAS and low periprocedural complication rates have been obtained. Based on the documented feasibility and safety of protection-device handling³ and the previously shown capacity of protection devices to reduce embolisation of debris into the cerebral circulation,⁶ it appears prudent to consider cerebral protection mandatory for any carotid artery stent procedure.

With respect to the controversy surrounding endovascular *versus* surgical therapy, the results of the first randomised studies and data from the registers of CAS with cerebral protection indicate outcomes similar to those obtained from the best surveys of surgical endarterectomy.

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Key Learning

- Embolic neurological events occur invariably during carotid artery stenting (CAS) despite advances in technique, technology and anti-thrombotic regimens
- The risk of embolic neurological events can be minimised using cerebral protection devices:
 - distal occlusive balloons
 - distal filter systems
 - proximal protection systems (occlusion of the common and external carotid arteries)
- Distal devices have to cross atheromatous plaque before deployment, increasing the risk of embolisation without cerebral protection in place
- A proximal protection system can provide cerebral protection from any type of embolisation throughout the procedure
- Available data support the use of cerebral protection devices during CAS

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