The endovascular management of carotid artery disease is a rapidly developing area currently under evaluation in Europe and the US. The technique is a simple progression of those skills used in peripheral vessels and involves the percutaneous placement of a metallic stent. Current data indicate that it may well offer a similar safety profile and efficacy at stroke prevention as conventional endarterectomy, but as yet there has only been one randomised controlled trial (CAVATAS). Future developments include the identification of a cohort of patients best treated with this technology, the evaluation of cerebral protection systems, and optimisation of pharmacological support.

Carotid endarterectomy combined with best medical treatment is a well validated technique to manage symptomatic high grade carotid disease. Two large randomised trials comparing carotid endarterectomy and best medical therapy against best medical therapy alone have been published and have shown additional benefit from surgery in symptomatic patients with high grade stenoses\(^1,2\). There are, however, significant problems with the technique, in particular the complications and costs associated with surgery of the neck. Thirty-day outcome following surgery in the European Carotid Surgery Trial (ECST) study was associated with a death and major stroke rate of 7.5%. Similarly, the North American Symptomatic Carotid Endarterectomy Trial (NASCET) had a corresponding rate of 5.8%. The NASCET study also highlighted a 7.6% rate of cranial nerve injury, wound complications in 8.9%, myocardial infarction in 0.9%, congestive heart failure in 0.6%, and other cardiovascular problems in 1.2% of patients. For some patients, serious cranial nerve injury is as incapacitating as stroke. Away from randomised trials performed by experienced surgeons in large units, the safety, and therefore the benefit, of surgery is less secure. When the American Heart Association performed an assessment of carotid endarterectomy in the community, the risks were substantially higher (death and major stroke 4.8–9%) than those reported in the American randomised trial\(^3\). Similarly, Rothwell performed a systematic review of carotid endarterectomy studies published since 1980 and demonstrated a risk of stroke and/or death of 5.64% with 95% confidence intervals of 4.4–6.9%\(^4\).
What then has the endovascular management of carotid disease got to offer (Fig. 1)? The value of carotid endarterectomy relies on the balance between the eventual stroke prophylaxis and the major events surrounding surgery. Clearly, any new therapeutic intervention that is not associated with the risks of general anaesthesia or neck incision and involved a short hospital stay would be worth pursuing, so long as it had a good risk benefit ratio and was financially prudent. Carotid angioplasty and stenting is performed from the groin under local anaesthesia. Significant costs are associated with the stent (currently approximately £700 in the UK) and in the future, with use of cerebral protection systems, costs will increase further. Balloon angioplasty and stent
Carotid angioplasty and stenting

placement achieve their aims by converting a high-risk unstable plaque into a smooth, non-embologenic lesion. The end-point of most damage to vessel wall is the production of a smooth area of myointimal hyperplasia. This has been demonstrated both following surgical intervention and endovascular intervention in the arterial system. Stents offer the additional potential to reduce carotid dissection, increase the initial lumen gain, and probably restrict distal embolisation.

Technique

Endovascular intervention for stenoses of the internal carotid artery has gone through a rapid evolution over a short period of time. The first report detailed a cut-down to the common carotid artery. Subsequently, percutaneous femoral access was used with conventional 035 wires and 5 French based balloon angioplasty. With the development of reliable stents, and the involvement of US based cardiologists, carotid stents became the norm despite the absence of any scientific base. Vascular radiologists adopted low profile wires, balloons and guide-catheters and concentrated on appropriate pharmaceutical support. The almost universal technique now involves the following steps:

- Pre-treatment with aggressive antiplatelet agents (usually a combination of aspirin and ticlopidine or clopidogrel)
- A percutaneous femoral approach and 5000 IU heparin
- A stiff wire to the ECA followed by a guide-catheter or long sheath to the CCA
- Atropine to block the carotid baroreceptors
- An 014 or 018 wire placed across the stenosis with the tip below the skull base
- Pre-dilatation with a 3 or 4 mm balloon to facilitate deployment of a stent
- Stent placement
- Stent deployment
- Post dilatation to 5–6 mm
- Closure device to the femoral artery.

Patients are monitored throughout the procedure with ECG and blood pressure monitoring. Combined platelet therapy is maintained for 2–4 weeks followed by life-long aspirin.

As with surgical intervention, the endovascular management of carotid disease is plagued by cerebral embolisation. In our own practise,
Fig. 2 (a) The MedNova NeuroShield cerebral protection system. The 'umbrella' is supported by Nitinol struts and has holes at the apex to allow some blood flow. The hole size is determined by the size of debris that the system is required to capture. The filter is contained within a catheter which is advanced across the carotid stenosis. The catheter is withdrawn to open the filter above the stenosis. The lesion may then be balloon dilated and stented allowing the filter to capture any debris. At the end of the procedure the filter is closed with a retrieval catheter and removed. (b) Close up of the device after removal showing the struts and holes. (c) Debris inside the device after bench-top testing.
transcranial Doppler is used throughout the procedure and embolisation occurs mainly at the time of stent deployment and post-stent balloon dilatation. To combat this, various ingenious devices are starting to appear which provide cerebral protection against embolisation. Theron was the first to suggest such a technique and demonstrated the use of an occlusive balloon placed above the stenosis prior to the key stages of the technique. The emboli are removed proximal to the inflated balloon by aspiration or flushing prior to balloon inflation. This technique has seen commercial refinement with the introduction of the Percusurge® system. Other devices have focused on the placement of a filter above the lesion which allows cerebral perfusion of the hemisphere throughout. The perfusing holes are small enough to collect debris and the whole system is removed at the end of treatment. The MedNova NeuroShield (Fig. 2) is currently undergoing clinical evaluation.

Available data

The 30 day safety of endovascular manoeuvres on symptomatic and asymptomatic carotid plaque has been demonstrated in the literature. A Cochrane review is available and includes all the early, small series. However, the majority of data has emerged since 1996. Gil-Peralta and colleagues treated 87 patients with high grade (> 70%) symptomatic internal carotid artery disease with simple balloon dilatation. They report a 4.9% death and disabling stroke rate with 3.7% of patients suffering a TIA. They failed to cross the lesion in 5% of patients. At 4 years, over 95% of their patients were free of ipsilateral disabling strokes. The Alabama group has published a group of 107 patients, with 126 carotid arteries treated by primary stenting, using a variety of devices, and without cerebral protection. All treatments were completed successfully reducing the stenosis from a mean of 78% (range 53–100%) to 2% (range —10% to 25%). The procedural complications reported include 4.7% minor stroke, 0.8% major stroke and no deaths. At 30 days there was a further major stroke in 1 patient, minor stroke in 1 patient and 1 death. Overall, they report a 30 day major stroke and death rate of 2.4% when 126 carotid arteries were treated; 64% of their patients were symptomatic and all but 2 minor strokes occurred in this group. At short-term follow-up there were no late strokes. Eckert and colleagues treated 58 patients with symptomatic internal carotid artery stenoses of > 70% narrowing according to the NASCET criteria. They had an 81% success rate, with no deaths and only one major stroke (2%). At a mean of 16 months follow-up, there was one stroke death, and a further stroke following restenosis.
At the Sheffield Vascular Institute there has been endovascular intervention in 207 patients\(^1\); 189 carotid interventions occurred in 182 patients with atherosclerotic disease. All were symptomatic apart from 2 who underwent carotid stenting prior to coronary artery by-pass surgery. The carotid artery had a low grade stenosis (NASCET technique) in 19 patients (50–69%), a high grade stenosis in 121 cases (70–95%), and was pre-occlusive in 49 cases (> 95%). The contralateral internal carotid artery was significantly diseased (> 70%) in 55 patients. In the total group (189 interventions), there were 3 deaths (1.6%), 2.6% of cases had a disabling major stroke and 2.6% a non-disabling major stroke. The overall death and disabling major stroke rate was, therefore, 4.2%, with a death and total stroke rate (i.e. including disabling and non-disabling major stroke) of 6.9%. There were, in addition, 2.1% minor strokes, 13% TIA's and 1.5% branch retinal artery occlusions. These 30 day endovascular results are within the 95% CIs reported by Rothwell\(^4\) and include a large number of patients who would have been considered high risk for endarterectomy using the NASCET criteria.

**The CAVATAS trial\(^{12}\)**

The most compelling data regarding comparative safety and long-term effectiveness comes from the CAVATAS trial run by Professor Martin Brown. This was an international multicentre prospective randomised trial that investigated the safety and efficacy of endovascular carotid intervention. Patients with symptomatic carotid disease and greater than a 50% stenosis were randomised to either surgery versus endovascular if they were fit for surgery, or endovascular versus best medical treatment if they were unfit. The last group was too small to provide meaningful data, but 24 active centres recruited a total of 504 patients to surgery versus endovascular treatment (253 surgery and 251 endovascular). The trial was started before the routine use of stents so that only 26% of endovascular patients received a stent and this was largely due to a poor angioplasty result rather than by primary intention. Patients were well matched for demographics, risk factors, presenting symptoms and degree of stenosis.

At 30 days, the principal safety outcomes chosen were death, disabling stroke, and non-disabling stroke and are shown in Table 1. There were

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Patient numbers</th>
<th>Death</th>
<th>Disabling stroke</th>
<th>Non-disabling stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>Endovascular</td>
<td>251</td>
<td>7</td>
<td>9</td>
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<tr>
<td>Surgery</td>
<td>253</td>
<td>4</td>
<td>11</td>
<td>10</td>
</tr>
</tbody>
</table>

"Table 1 The comparative 30 day cerebral complications from CAVATAS"
significantly more cranial nerve palsies (0% \textit{versus} 8.7%) and haematomas requiring intervention (1.2 \textit{versus} 6.7%) in the surgical group.

The procedure is prophylactic with the intention of preventing stroke. At follow-up out to 3 years, there is no difference between the two techniques in preventing either ipsilateral stroke or disabling stroke and death.

There has been some criticism of the trial. The 30 day complication rate is high. To an extent this may reflect the outcome of patients treated outside the strict requirements of a surgical randomised trial when assessed by an independent neurologist. The endovascular complication rate may reflect the learning curves of the centres participating in new treatment, something that needs to be addressed by future trials. CAVATAS was not powered to show a difference in the 30 day complication rate and the confidence intervals surrounding this outcome are too broad to draw absolutely firm conclusions. The trial was also conducted during a period of change involving the technique of endovascular therapy. Future studies will probably involve cerebral protection, primary stent placement with low profile systems, optimised adjuvant pharmacology (particularly antiplatelet therapy) and better attention to post-procedure blood pressure management. Attention has been drawn to the randomisation process. This was performed using the ‘grey area’ principal similar to the ECST trial. Whilst a degree of prior selection was performed this is entirely in keeping with this type of trial involving new therapy.

\section*{Conclusions}

Data are available to suggest that the endovascular management of carotid disease is a technique worthy of attention. Practitioners need to identify exactly where its role lies. Patients at high risk of stroke need to be better defined to reduce the number needed to treat to prevent stroke, and identify those who would most benefit from endovascular intervention. The new technologies need to be adequately assessed and already larger randomised trials are being proposed to address some of these issues. In the US, the NIH are funding a large multicentre randomised trial comparing surgery \textit{versus} carotid stenting (CREST) and, in the UK, CAVATAS II is being developed.

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