Carotid Endarterectomy Without Angiography: a Prospective Randomised Pilot Study


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Objectives: to determine whether duplex ultrasonography alone is an adequate examination prior to carotid endarterectomy.

Design: prospective, randomised, single centre study.

Material and Methods: all patients with carotid bifurcation stenosis greater than 70% – based on duplex scanning – were randomised to arteriography followed by carotid surgery (Group A; n=96) or carotid surgery alone (Group B; n=90). Study endpoints were neurological complications or death occurring between the day of randomisation and until 30 days after surgery.

Results: major neurological complications of death in 1 (1%) vs 3 (3.3%) patients in group A and B, respectively (n.s.). Minor neurological complications (only TIA) were observed in 0 and 3 (3.3%) patients, respectively.

Conclusions: complication rates were low in both groups and within the generally accepted rate after carotid surgery in asymptomatic and symptomatic patients.

Key Words: Atherosclerosis; Carotid endarterectomy; Duplex scanning; Stroke.

Introduction

Carotid duplex is increasingly replacing angiography as the investigation of choice prior to carotid endarterectomy. Duplex scanning showed a sensitivity of 98%, a specificity of 96%, positive predictive value 96%, negative predictive value 98% and accuracy 97% compared with angiography for both symptomatic and asymptomatic carotid disease.1 Duplex scanning also showed a better correlation (r=80, p<0.001) with ex vivo atheroma measurements than angiography (r = 0.56; p<0.05) and magnetic resonance imaging (0.76; p<0.001).2 Several studies,3-5 suggest that carotid endarterectomy can be performed safely without intrarterial digital subtraction angiography (IADSA). However, no randomised trial has compared neurological complications and mortality in patients undergoing CEA with and without angiography.

Materials and Methods

From February 1998 to July 1999, 396 symptomatic and asymptomatic patients underwent CEA. All patients underwent colour-coded duplex scanning (CCDS), performed by the same qualified and experienced personnel using an ESAOTE Idea AU 4, provided with a 7.5 MHz linear probe. B-mode images and pulsed Doppler signals were obtained. The indication to CEA was a greater than 70% carotid stenosis for both symptomatic and asymptomatic patients.9,10 The degree of stenosis was assessed by a combination of velocity reduction in area or diameter on multiple longitudinal- and cross-section scans.11

Patients excluded from the study shared (suspected) thrombosis of one carotid artery, unclear images, and (suspected) associated lesions of the distal and proximal arteries.5,12 Patients provided informed consent.

Patients were randomised into two groups according to whether the last digit of the unique patient admission code, provided by the centralised hospital administration office, was odd (A) or even (B).

Group A patients underwent IADSA via femoral artery puncture and the stenosis was measured according to the NASCET criteria.10 All patients underwent cerebral computed tomography (CT). All CCDS, IADSA and cerebral CT were performed within 14 days of surgery.

Surgery was performed under general anaesthesia.
Carotid Endarterectomy Without Angiography

Table 1. Demographic characteristics and risk factors.

<table>
<thead>
<tr>
<th></th>
<th>Group A (IADSA)</th>
<th>Group B (No-IADSA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>N. pts.</td>
<td>96</td>
<td>90</td>
</tr>
<tr>
<td>Males (%)</td>
<td>69 (72%)</td>
<td>53 (59%)</td>
</tr>
<tr>
<td>Mean age</td>
<td>71 (59–85)</td>
<td>73 (56–84)</td>
</tr>
<tr>
<td>CAD</td>
<td>39%</td>
<td>39%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>69%</td>
<td>59%</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>23%</td>
<td>17%</td>
</tr>
<tr>
<td>Smoking</td>
<td>62%</td>
<td>50%</td>
</tr>
</tbody>
</table>

CAD = coronary artery disease.

with continuous EEG perioperative monitoring, systemic heparinisation, and routine insertion of a Pruitt-Inahara shunt and the routine closure of the arteriotomy with a PTFE patch.

Where there was a significant kinking of the internal carotid artery excision of the internal carotid artery, eversion endarterectomy and proximal reanastomosis on the homolateral common carotid artery was performed.

Total clamp time, the presence of EEG alterations after clamping, the recovery of EEG alterations after shunt insertion, the total shunt time, and the length of the second clamp time from extraction of the shunt to completion of the suture were recorded. Neurological examination was performed upon awakening, every 3 h during the first postoperative day, daily until discharge and finally at day 30 after surgery. Study endpoints were disabling and fatal stroke, non-disabling stroke, TIA, and non-cerebrovascular mortality from the day of randomisation until day 30 after surgery. Results are presented as mean, incidence rate and 95% confidence interval (CI). A local ethical committee approved the trial protocol according to national laws.

Results

CCDS exclusion criteria were met in 14 patients: four subclavian artery stenosis, four contralateral carotid occlusion, one associated proximal lesion, two associated distal lesion (tandem lesion) and three presented heavy calcification. Nine patients refused to enter the protocol, and 185 patients were excluded because they had IADSA or MR angiography prior to admission.

One hundred and eighty-six patients were randomized to group A (96 patients) and B (90 patients). The mean age was 71 (range: 59–85) years in group A, and 73 (range 56–84) years in group B (Table 1). In group A, IADSA always confirmed the CCDS findings.

At admission, 27 (28%) and 17 (19%) patients presented with hemispheric symptoms in group A and B, respectively, 24 (26%), 22 (24%) patients presented non-hemispheric symptoms, and 45 (46%) and 51 (5%) patients were asymptomatic (n.s.).

Preoperative cerebral CT revealed significant lesions in five (5%) and seven (8%) patients in group A and B, respectively.

In either group, 85 patients underwent standard carotid endarterectomy and PTFE patch. An eversion endarterectomy of the internal carotid artery and proximal reanastomosis was performed.

In group A, RNCR was 1%. One asymptomatic patient suffered from a major stroke: a monoparesis of the controlateral limb, partially regressed during the hospital stay.

In group B, RNCR was 3.3%. One asymptomatic patient died as a result of massive cerebral infarct in the contralateral hemisphere (with negative pre- and postoperative CCDS of the controlateral carotid artery and no complications on the operated side) and two symptomatic patients suffered from a major homolateral stroke upon awakening, documented by serial postoperative CT scans (Table 2). No minor stroke was observed in both groups. No postoperative TIA was documented in group A and 3 (3.3%) in group B. Mortality due to noncerebrovascular causes was absent in both groups.

Discussion

Some authors advocated the use of CCDS alone prior to CEA, because IADSA entails risk, because it does not provide haemodynamic or morphological information about the plaque, and is aggressive.

Others believe that there is still no reliable alternative to IADSA because CCDS does not provide information about the supraortic vessels, or the intracranial circulation.

However, associated proximal and distal lesions
Table 2. Results.

<table>
<thead>
<tr>
<th></th>
<th>Group A</th>
<th></th>
<th></th>
<th>Group B</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Symptomatic</td>
<td>Asymptomatic</td>
<td>Total</td>
<td>Symptomatic</td>
<td>Asymptomatic</td>
<td>Total</td>
</tr>
<tr>
<td>N. pts.</td>
<td>51</td>
<td>45</td>
<td>96</td>
<td>39</td>
<td>51</td>
<td>90</td>
</tr>
<tr>
<td>Lethal stroke</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Disabling stroke</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Minor stroke</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>TIA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>% (95% CI)</td>
<td>1.0%</td>
<td>(0.03–5.5%)</td>
<td></td>
<td>3.3%</td>
<td>(0.6–8.5%)</td>
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</table>

Major complication rate.
CI = Confidence Interval.

rarely modify the management of patients with extracranial carotid stenosis. In our experience of more than 3000 patients studied by IADSA, only in 0.3% of cases did the presence of significant intracranial lesions modify the indication to surgery. However, in the present pilot study, two (1%) patients were excluded because of intracranial lesions suspected on CDDS.

The inability of CCDS to distinguish subocclusive and occlusive atherosclerotic lesions in some patients is well known. In our experience, therefore, a carotid thrombosis suspected on CCDS represents an indication for IADSA.

In the evaluation of a stenotic lesion of the carotid bifurcation, the accuracy of CCDS was comparable or superior to IADSA.

Finally, there is concern about increased perioperative CEA risks without IADSA, although several authors have achieved good results.

The results of this pilot study show that the perioperative rate of relevant neurological complication and TIA are comparable in group A and B patients. Complications in both groups for asymptomatic and symptomatic patients are low, and below the general accepted rate for CEA.

If we consider the costs and the reported risks of preoperative angiography, an extended prospective trial based on the protocol and results from this pilot study may be justified. However, the incidence rate of our endpoints is low, and to test the equivalence of these in the two preoperative evaluation groups requires a very large series of patients to draw any statistically significant conclusion.

Acknowledgements

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References


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