

Very Urgent Carotid Endarterectomy is Associated with an Increased Procedural Risk: The Carotid Alarm Study

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WHAT THIS PAPER ADDS

There are diverse results in the literature regarding peri-operative risk in very urgent carotid endarterectomy (CEA). This prospective study adds further evidence in favour of a more careful approach with expedited CEA, in the first 2 days after an ischaemic event.

Objective/Background: The aim of the Carotid Alarm Study was to compare the procedural risk of carotid endarterectomy (CEA) performed within 48 hours with that after 48 hours to 14 days following an ipsilateral cerebrovascular ischaemic event.

Methods: Consecutive patients with symptomatic carotid stenosis undergoing CEA were prospectively recruited. Time to surgery was calculated as time from the most recent ischaemic event preceding surgery. A neurologist examined patients before and, after CEA. The primary endpoint was the composite endpoint of death and/or any stroke within 30 days of the surgical procedure. The study was designed to include 600 patients, with 150 operated on within 48 hours.

Results: From October 2010 to December 2015, 418 patients were included, of whom 75 were operated within 48 hours of an ischaemic event. The study was prematurely terminated owing to the slow recruitment rate in the group operated on within 48 hours. Patients undergoing CEA within 48 hours had a higher risk of reaching the primary endpoint than those operated on later (8.0% vs. 2.9%). Multivariate logistic regression analyses showed that CEA performed within 48 h (odds ratio [OR] 3.07; 95% confidence interval [CI] 1.04–9.09), CEA performed out of office hours (OR 3.65; 95% CI 1.14–11.67), and use of shunt (OR 4.02; 95% CI 1.36–11.93) were all independently associated with an increased risk of reaching the primary endpoint.

Conclusion: CEA performed within 48 hours was associated with a higher risk of complications compared with surgery performed 48 hours–14 days after the most recent ischaemic event.

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INTRODUCTION

Carotid endarterectomy (CEA), in combination with best medical therapy, is the recommended treatment for stroke prevention in patients with symptomatic stenosis of the internal carotid artery. A number of studies have reported a remarkably high risk of early stroke recurrence in patients with a transient ischaemic attack (TIA) or minor stroke due to a > 50% carotid stenosis (North American Symptomatic Carotid Endarterectomy Trial [NASCET] criteria).^{1–3} In a recent review, the stroke risk was estimated to be 6.4%

within the first 2–3 days, 19.5% at 7 days, and 26.1% at 14 days.⁴ In 2004, a meta-analysis of two large interventional studies of symptomatic carotid stenosis showed that surgery is more favourable when done within the first 2 weeks of the ischaemic event versus later surgical intervention.⁵ However, these studies were not powered to determine whether surgery performed in the very early phase (i.e., within 48 hours following symptom onset) was even more beneficial. Given the early risk of a recurrent disabling event, there is reason to believe that CEA performed in the

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very early period following an ischaemic event could improve the benefit of CEA if the risk of per- and post-operative complications remains similar, or only slightly increased, compared with later surgery.

Several studies, with divergent results, have reported on the stroke and mortality risk associated with CEA in the very early period after carotid related ischaemic symptoms.^{6–9} One prospective registry study noted that patients operated on within the first 2 days had increased peri-operative mortality and stroke risk (11.5% within two days versus 3.6% between 3 and 7 days).⁶ In contrast, a number of large retrospective studies found no differences in the risk of stroke and mortality depending on whether surgery was done within the first 2 days, or 3–14 days after an ischaemic event.^{7–9} A recent systematic review and meta-analysis on early carotid intervention concluded that the current evidence for very early CEA was limited, and that randomised controlled trials or prospective observational studies directly comparing acute CEA with subacute surgery were needed to determine the optimal timing of the intervention.¹⁰

Accordingly, the aim of this prospective study was to compare the per- and post-operative outcomes of CEA carried out within 48 hours with the outcome 48 hours–14 days after an ischaemic event. It was hypothesized that very early CEA would not increase, or only slightly increase, the risk of per- or post-operative complications versus CEA performed during the later period.

METHODS

General study design

The Carotid Alarm Study, carried out in the Region Västra Götaland in Sweden, was a prospective study of consecutive patients with symptomatic carotid stenosis undergoing carotid surgery within 14 days of an ipsilateral ischaemic cerebrovascular event. Per- and post-operative complications were compared in patients operated on within 48 hours with those operated on between 48 hours and 14 days.

Patient selection

The two centres that perform CEA in the Region Västra Götaland in the south-west of Sweden are the Sahlgrenska University Hospital and the Södra Älvsborg Hospital. The aim was to recruit all patients undergoing CEA within 14 days of an ischaemic event within the Region. Recruitment started at the Sahlgrenska University Hospital in October 2010 and at Södra Älvsborg Hospital in June 2012. Recruitment continued until December 2015 at both centres.

Patients with retinal ischaemia (amaurosis fugax/retinal stroke), minor ischaemic stroke, TIA, and/or crescendo TIA (at least two episodes within 24 hours or at least three episodes within 7 days) with symptoms compatible with a thromboembolic event in the anterior circulation, an ipsilateral carotid stenosis of 50–99% (NASCET criteria), and carotid surgery within 14 days of an ischaemic event were

eligible for the study. Patients with clinical findings indicating major stroke (National Institutes of Health Stroke Scale > 5, or infarct size exceeding > 3 cm in diameter on diffusion weighted magnetic resonance imaging [DW-MRI]) were excluded, as were patients with stroke in evolution, severe life limiting disease, and patients treated with intravenous thrombolysis due to the ischaemic event.

In hospital organisation

There are nine stroke units in this region and doctors from regional hospitals refer patients to the Carotid Alarm Study units at Sahlgrenska University Hospital or Södra Älvsborg Hospital by telephone or fax. A *fast track* for patients with recent symptoms of cerebrovascular ischaemia was introduced. The purpose of this fast track was to enable CEA within 48 hours for all patients seeking care within 24 hours of an ischaemic event, thus reducing selection bias in the group with very urgent CEA. Patients newly arrived at the hospitals' stroke units were screened twice daily. Eligible patients were investigated with a carotid Doppler ultrasound within 2 hours (daytime, 7 days a week). If a carotid stenosis (> 50%) ipsilateral to the ischaemic event was found, the investigation was supplemented with acute neuro-imaging, which was deemed necessary in order to facilitate a fast treatment decision. Patients seeking medical care later than 24 hours following an ischaemic event were not processed according to the fast track. Doppler ultrasound, imaging, clinical assessment, and, when applicable, carotid surgery were performed as fast as possible, within 14 days.

Definition of qualifying event, time to surgery, referring event, and out of office hours

A qualifying event was defined as the most recent ischaemic event preceding CEA. The time to surgery was the time between the qualifying event and CEA. For multiple events, time to surgery was calculated using the most recent event preceding CEA, also when the event occurred after admission to hospital. In patients with a wake-up stroke, the time when the patient was last known to be free of symptoms was used. The referring event was the ischaemic event that brought the patient to medical care. Out of office hours were defined as hours when the vascular surgeon was on call (i.e., Monday–Thursday 4.00 pm–7.30 am, Friday 2.00 pm–7.30 am, weekends, and public holidays).

Diagnostic work-up and data collection

A neurologist examined the patients before, and 2 and 30 days after CEA. Data were prospectively documented in electronic case record forms and compiled in a predefined database. Duplex ultrasound scanning was used to assess the degree of carotid artery stenosis. Brain computed tomography was performed in all patients with cerebral hemisphere TIA or stroke (i.e., all patients except those with retinal stroke or amaurosis fugax) in order to rule out haemorrhage and other differential diagnoses. In addition, patients with stroke underwent DW-MRI to rule out large infarcts not suitable for early carotid surgery (Fig. 1).

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