The Asymptomatic Carotid Surgery Trial-2 (ACST-2): an ongoing randomised controlled trial comparing carotid endarterectomy with carotid artery stenting to prevent stroke

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Declared competing interests of authors: none

Published October 2017
DOI: 10.3310/hta21570

Scientific summary

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Health Technology Assessment 2017; Vol. 21: No. 57
DOI: 10.3310/hta21570

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

The second Asymptomatic Carotid Surgery Trial (ACST-2) is a randomised controlled trial (RCT) of 3600 patients with tight asymptomatic carotid artery stenosis comparing intervention with carotid endarterectomy (CEA) with carotid stenting (CAS). Patients will be followed up long term (median follow-up of around 10 years) to determine both the short-term hazards of intervention and, more importantly, the long-term durability of protection against stroke.

Atheromatous carotid artery lesions can partially block one or both of the arteries in the neck that supply the brain. Such lesions can rupture suddenly, causing a major or minor stroke. Significant (e.g. 70–90%) carotid artery narrowing that has not yet caused a stroke (asymptomatic stenosis) is an increasingly common incidental finding due to widespread use of vascular imaging for investigating stroke and stroke-like symptoms. Imaging methods include ultrasound, computed tomography or magnetic resonance imaging, and these scans can reveal severe stenoses that indicate an increased future risk of stroke.

In patients with tight carotid stenosis, long-term triple therapy (lipid-lowering, antihypertensive and antithrombotic treatment) lowers the risk of stroke and is widely used. However, when future risk of stroke from carotid stenosis remains, this can be reduced further by surgery (CEA) or stenting (CAS) in patients with an otherwise reasonable life expectancy. The first Asymptomatic Carotid Surgery Trial (ACST-1) (in 3000 asymptomatic patients) compared CEA with no carotid procedure and showed that, even in patients on triple therapy, CEA substantially reduced patients' 10-year stroke risk (*Figure a*).

Our current trial, ACST-2, is an international RCT comparing CEA with CAS in patients thought likely to benefit from preventative carotid intervention. Symptomatic carotid artery lesions are those that have already caused a stroke; they are more dangerous to touch (i.e. associated with a high procedural stroke risk) and are not the subject of this study. Asymptomatic lesions that have not recently caused stroke can, however, be treated fairly safely by CEA or by CAS, thus providing long-term protection against stroke. There may be substantial uncertainty, shared by the doctor and the patient, about whether or not CEA or CAS is the preferred treatment and, in such circumstances, randomisation via ACST-2 is appropriate.

Objectives and outcome measures

The primary objectives of the trial are to compare periprocedural risks, defined as myocardial infarction, stroke and death within 30 days of undertaking the randomised procedure (CEA or CAS), and to follow up patients in the longer term (median follow-up about 10 years) to obtain the rates of disabling or fatal stroke in this cohort during the years after CEA or CAS.

The secondary objectives include comparing health-related quality of life, which is to be assessed as part of our health economic evaluation. Depending on the numbers of participants who are eventually randomised, ACST-2 (and associated individual patient data meta-analyses) may help identify subgroups of patients in whom one of the procedures is clearly preferable.

Trial registration

This trial is registered as ISRCTN21144362.

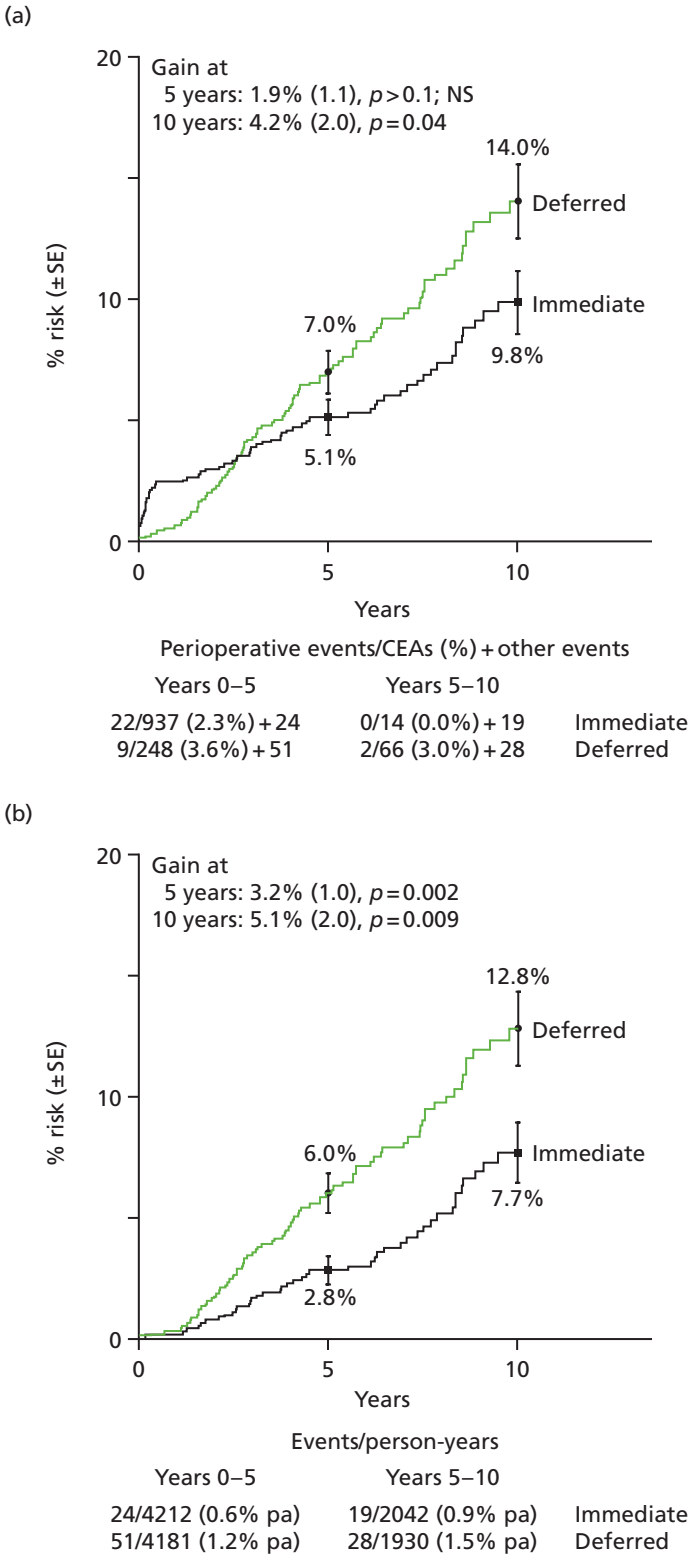

FIGURE a ACST-1, a comparison of immediate vs. deferred CEA: the 10-year stroke risk in patients with tight asymptomatic carotid stenosis who are already on triple medical therapy (statin, antithrombotic and antihypertensive). (a) Any stroke (or perioperative death); and (b) non-perioperative stroke. SE, standard error.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research. Funding was also received from BUPA Foundation [BUPAF/33(a)/05].

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 4.236

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 06/301/233. The contractual start date was in April 2007. The draft report began editorial review in September 2016 and was accepted for publication in July 2017. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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