

Endarterectomy for asymptomatic carotid disease offers sustained stroke protection

ACST-1 results published in *The Lancet* showed that immediate surgery lowers 10-year stroke risk compared with deferred carotid endarterectomy

Successful carotid endarterectomy for asymptomatic patients younger than 75 years of age reduces 10-year stroke risks, the results of the ACST-1 (Asymptomatic carotid surgery trial 1) study have shown. The paper was published in the 25 September 2010 issue of *The Lancet*.

Alison Halliday, principal investigator said "This long-term large study shows that younger men and women who are already on good medical treatment have a separate significant stroke reduction benefit from endarterectomy. Patients on good antithrombotic, blood-pressure-lowering and statin treatment had fewer strokes (13.4% vs. 7.6%, gain 5.8%) after successful endarterectomy. They also had a lower peri-operative risk which is important when considering potential long-term benefits of intervention."

"Half this reduction is in disabling or fatal strokes. Net benefit in future patients will depend on their risks from unoperated carotid lesions (which will be reduced by medication), on future surgical risks (which might differ from those in trials), and on whether life expectancy exceeds 10 years," the authors, led by Alison Halliday, Nuffield Department of Surgical Sciences, John Radcliffe Hospital, Oxford, UK wrote.

The multicentre randomised trial was designed to assess the long-term effect of successful endarterectomy in asymptomatic



Alison Halliday

patients with carotid artery stenosis.

Between 1993 and 2003, 3,120 asymptomatic patients from 126 centres in 30 countries were allocated equally, by blinded minimised randomisation, to immediate endarterectomy (median delay one month, IQR 0.3–2.5) or to indefinite deferral of any carotid procedure, and were followed up until death or for a

median among survivors of nine years (IQR 6–11).

The primary endpoints were peri-operative mortality and morbidity (death or stroke within 30 days) and non-perioperative stroke. Kaplan-Meier percentages and logrank p values are from intention-to-treat analyses.

In the randomisation, 1,560 patients were allocated immediate endarterectomy versus 1,560 allocated deferral of any carotid procedure. The proportions operated on while still asymptomatic were 89.7% versus 4.8% at one year (and 92.1% vs. 16.5% at five years). Peri-operative risk of stroke or death within 30 days was 3% (95% CI 2.4–3.9; 26 non-disabling strokes plus 34 disabling or fatal peri-operative events in 1,979 carotid endarterectomies). Excluding peri-operative events and non-stroke mortality, stroke risks (immediate vs. deferred endarterectomy) were 4.1% versus 10% at five years (gain 5.9%, 95% CI 4.0–7.8) and 10.8% versus 16.9% at 10 years (gain 6.1%, 2.7–9.4); ratio of

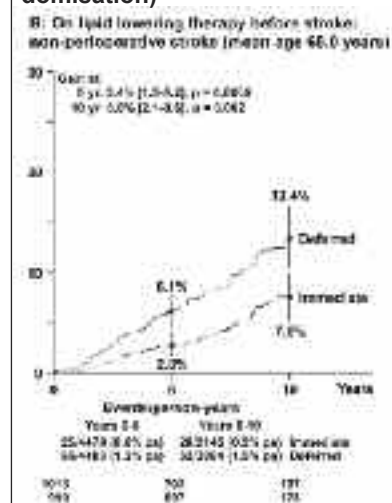
stroke incidence rates 0.54, 95% CI 0.43–0.68, $p < 0.0001$. Sixty two versus 104 had a disabling or fatal stroke, and 37 versus 84 others had a non-disabling stroke. Combining peri-operative events and strokes, net risks were 6.9% versus 10.9% at five years (gain 4.1%, 2.0–6.2) and 13.4% versus 17.9% at 10 years (gain 4.6%, 1.2–7.9). Medication was similar in both groups; throughout the study, most were on antithrombotic and antihypertensive therapy. Net benefits were significant both for those on lipid-lowering therapy and for those not, and both for men and for women up to 75 years of age at entry (although not for older patients).

The study was funded by UK Medical Research Council, BUPA Foundation, and Stroke Association.

Table 1. Long-term outcomes

	Immediate endarterectomy (n=1,560)	Deferred endarterectomy (n=1,560)	p value
Non-perioperative stroke			
Five years	4.1%	10%	<0.000
10 years	10.8%	16.9%	0.0004
Stroke or peri-operative death			
Five years	6.9%	13.4%	0.0001
10 years	10.9%	19.9%	0.009

10-year risks, by current lipid lowering therapy (at or after randomisation)



From stent design to virtual procedure planning

Mathieu De Beule, IBiTech-bioMMeda, Ghent University, Ghent, Belgium, presented the institution's experience in stent design testing at the European Society for Vascular Surgery annual meeting, in a presentation titled "Virtual bench testing of carotid Wallstents: from design tools towards virtual procedure planning".

"The main task of a stent is to re-open and scaffold a stenosed lesion while minimising possible vessel injury. To that extent, the stent requires adequate mechanical properties," De Beule said. "Experimental evidence has shown that these mechanical properties are strongly design-dependent and their assessment generally requires sophisticated and accurate test setups and protocols. Complementary to such experimental methods, we developed a virtual simulation environment to evaluate these mechanical properties and the potential of the developed virtual bench tests is illustrated for the Wallstent."

The virtual bench testing environment is developed by combining the finite element solver Abaqus with the open-source pyFormex design software and allows studying accurately the following stent characteristics: fore-



Mathieu De Beule

shortening, radial strength, flexibility, conformability, stent/catheter and stent/vessel interaction. "The created virtual Wallstent model can easily be adapted in terms of wire diameter, number of wires and pitch angle, which allows assessing the impact of these design parameters on the stents mechanical behavior," added De Beule.

The simulations, De Beule said, showed that reducing the foreshortening in 20%, while maintaining the radial strength, is feasible by increasing the wire diameter, the number of wires and the pitch angle. "These results are in line with the available less shortening Wallstent design. Furthermore, the simulated stent release from the catheter corresponds well with available experimen-

tal data. Finally a novel and stable simulation strategy was developed to virtually insert the Wallstent into patient specific blood vessel models, which allows to assess the conformability and potential vessel injury."

In conclusion, he said, "Complementary to experimental bench tests, we have developed a virtual environment to accurately quantify the mechanical properties of peripheral stents. This novel tool allows us to virtually assess design variants/ideas without the need to actually fabricate prototypes. Currently we are virtually testing other self-expandable stents to provide objective information to the clinical practice that is potentially helpful for a well-considered choice of stent type."