

Update on the only remaining Carotid Multicenter Randomised International Trial in the World:ACST-2

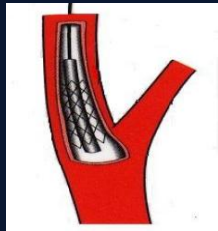
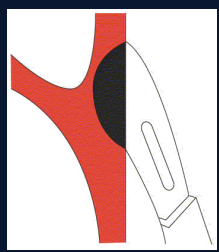
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Disclosure Statement of Financial Interest

I, Alison Halliday, DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.



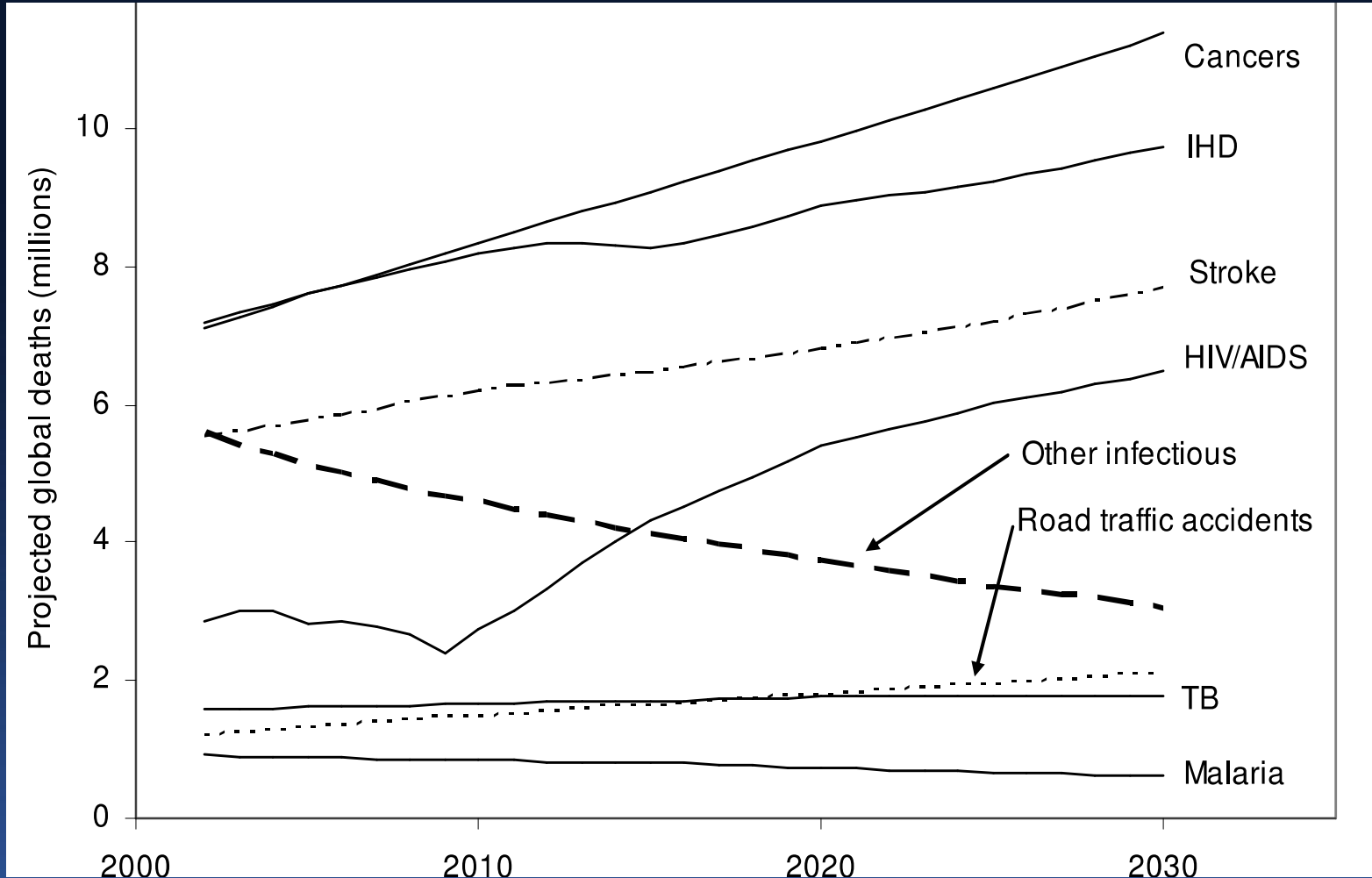
ACST-2 is funded by



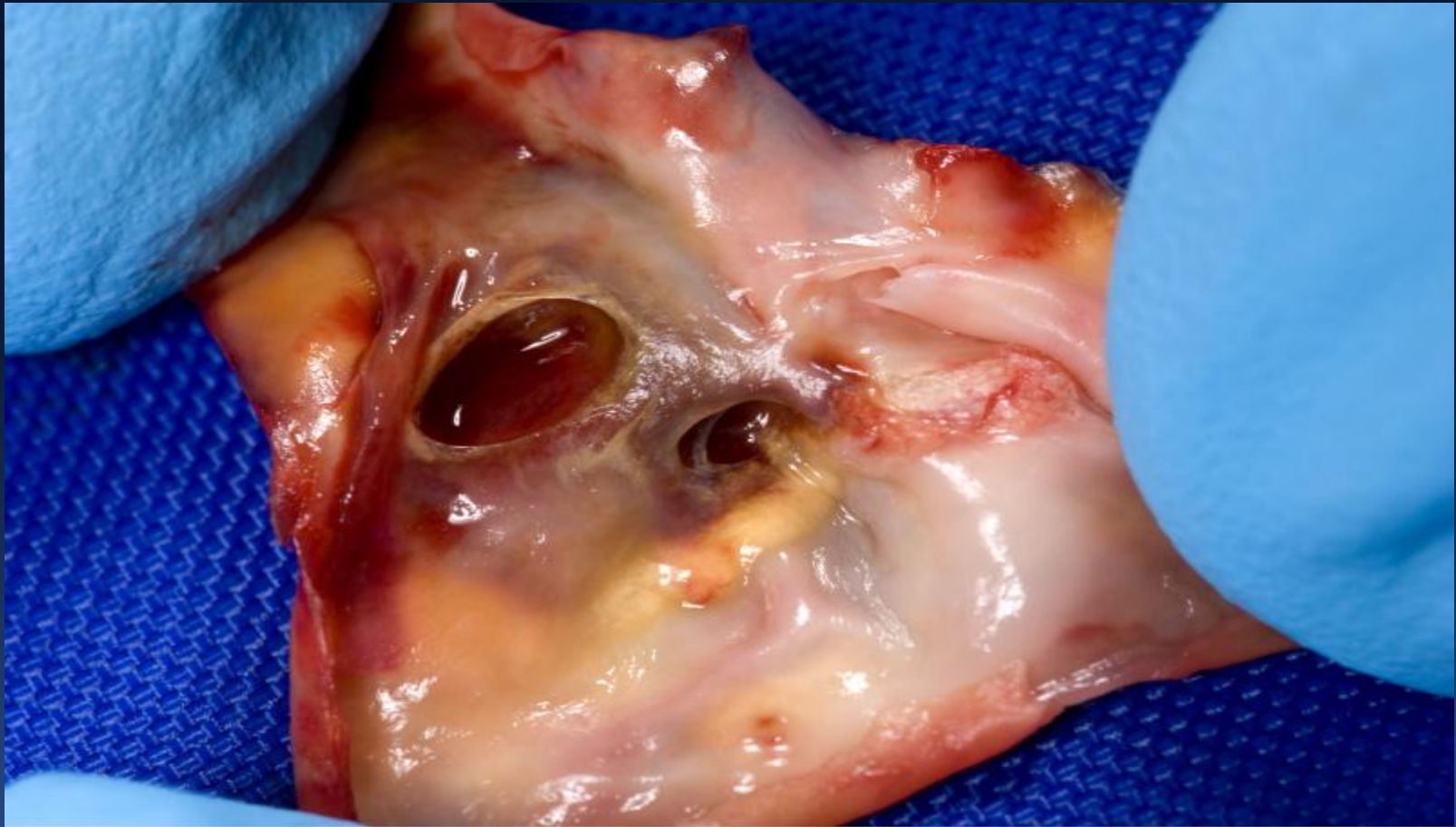
and organised within



Projected Rise in Stroke Mortality Worldwide to 2030 (WHO)



Symptomatic or Asymptomatic?



© OMI 00122410.jpg Date Taken: 2010-11-10

ACST-1 (1993-2008)

Tight asymptomatic carotid stenosis

3120 patients



1560

**medical treatment
alone**

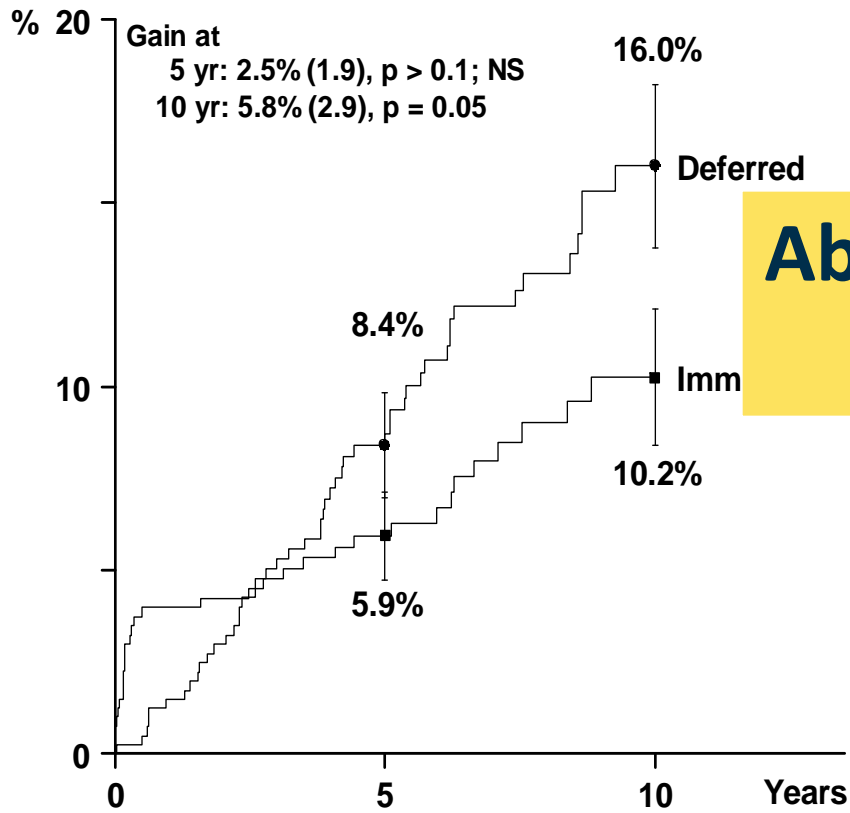
1560

**medical treatment
+CEA**

**CEA reduced subsequent stroke risk by ~50%
Benefit maintained to 10 years**

Surgery for men & women under 75 years reduces 10-year stroke risk

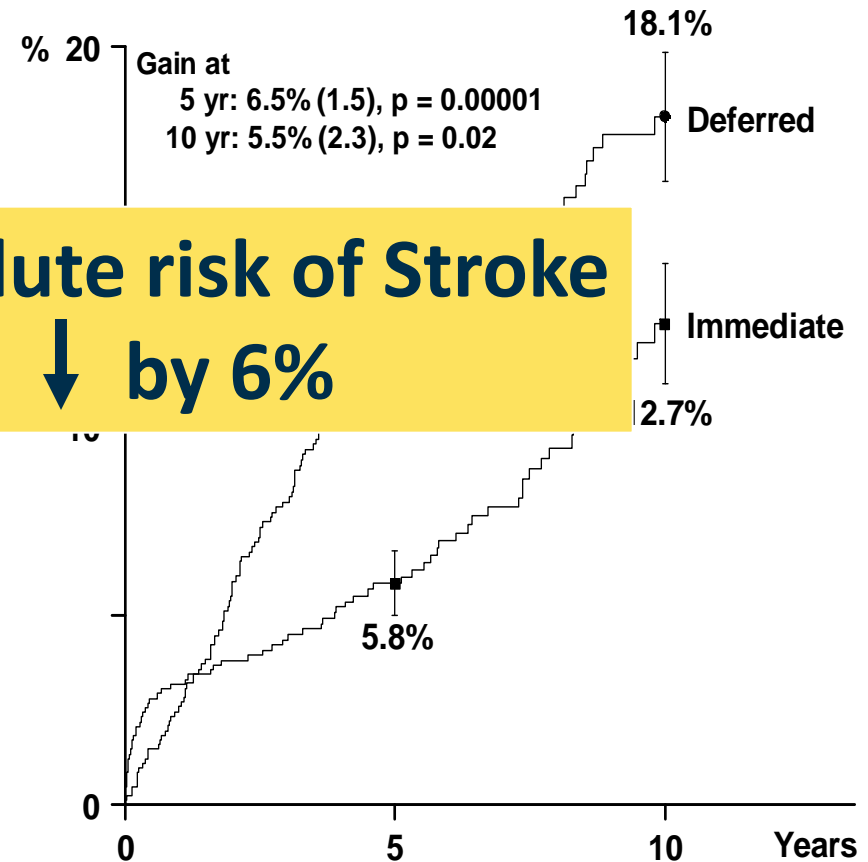
(c) Any type of stroke or perioperative death (Female, Age <75)



Perioperative + other events

Years 0-4	Years 5+	Immediate	Deferred
16 + 7	0 + 9		
4 + 28	1 + 17		

(a) Any type of stroke or perioperative death (Male, Age <75)



Perioperative + other events

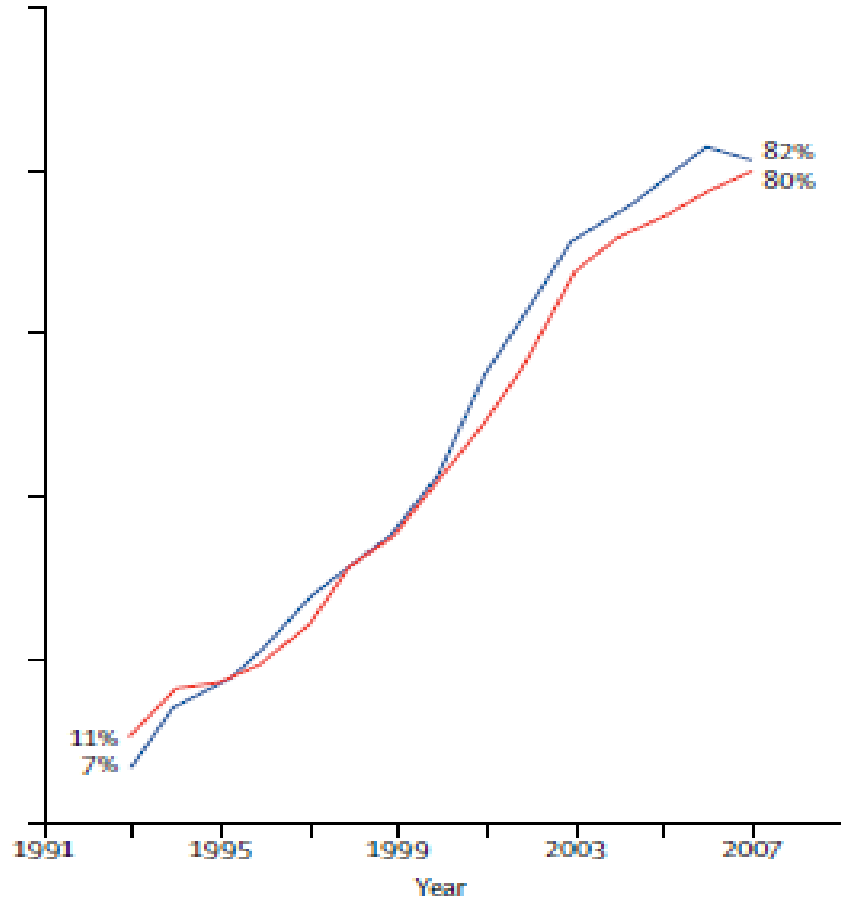
Years 0-4	Years 5+	Immediate	Deferred
17 + 28	0 + 25		
8 + 24	1 + 24		

Absolute risk of Stroke ↓ by 6%



Lipid-lowering treatment at randomisation & during follow up

D Lipid-lowering drug use



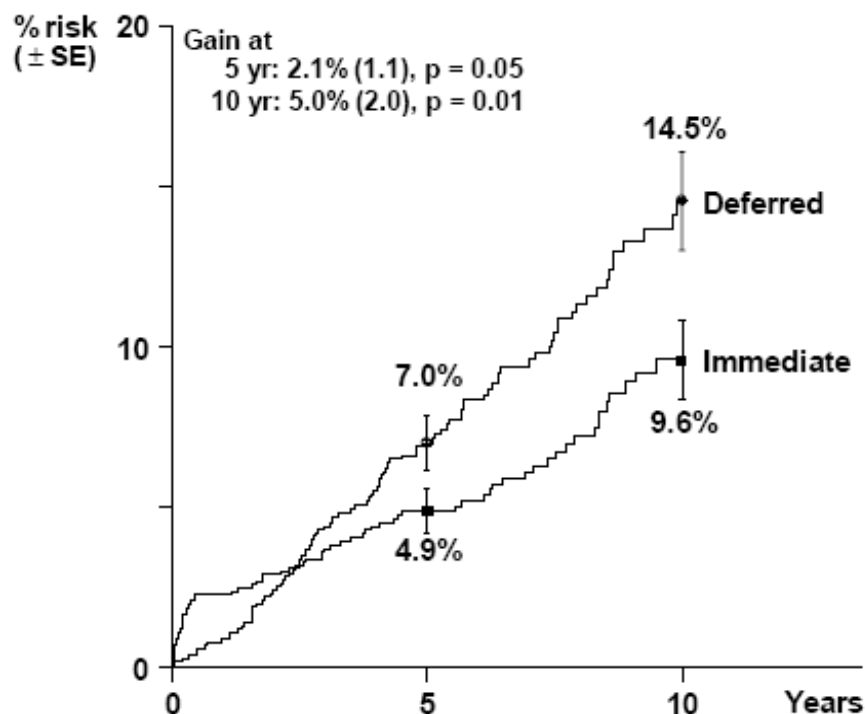
202	956	1316	1436	1434	1380	1188	426
198	964	1356	1448	1456	1390	1198	412

Lipid-lowering Drugs use ↑ during ACST

We analysed effects of this On overall result

Same absolute benefit from surgery (6%↓ in stroke risk) for patients on statins

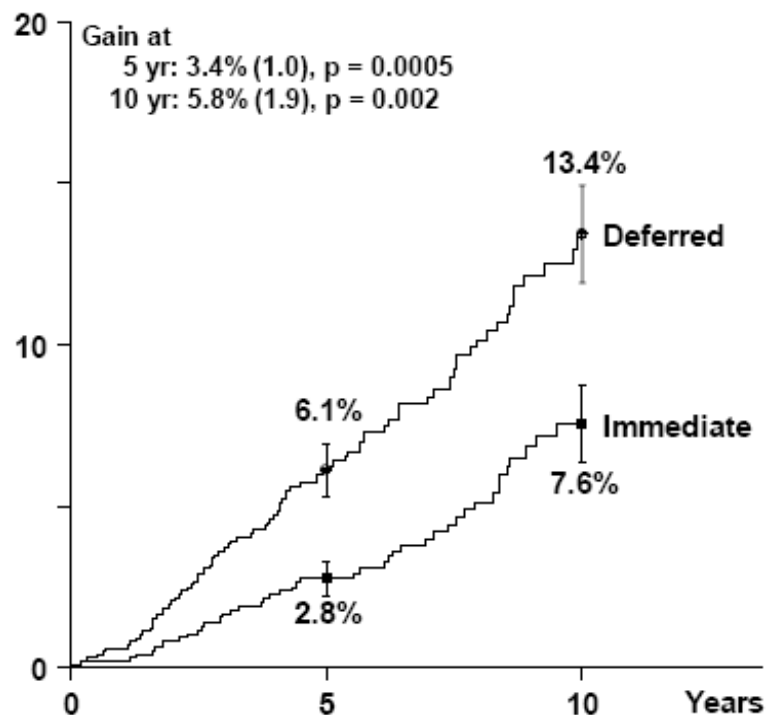
**A: On statin before stroke:
stroke or perioperative death**



Perioperative events/CEAs (%) + other events

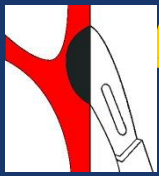
Years 0-5	Years 5-10	
22/993 (2.2%) + 25	0/15 (0.0%) + 20	Immediate
9/259 (3.5%) + 56	2/69 (2.9%) + 32	Deferred

**B: On statin before stroke:
non-perioperative stroke**



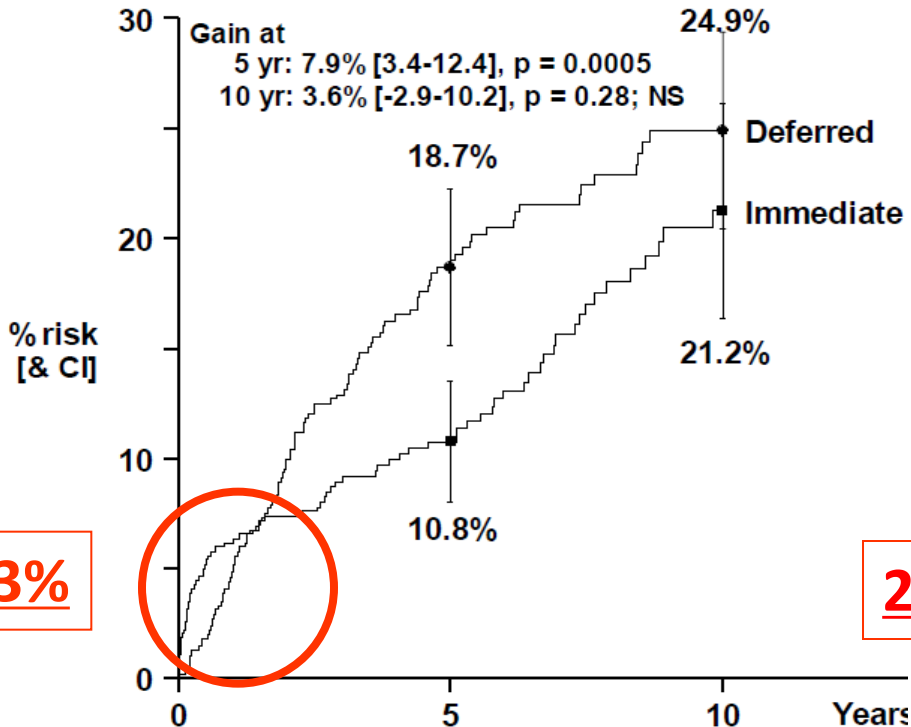
Events/person-years

Years 0-5	Years 5-10	
25/4478 (0.6% pa)	20/2145 (0.9% pa)	Immediate
56/4483 (1.2% pa)	32/2084 (1.5% pa)	Deferred



ACST-1 – peri-operative risk may be reduced by statin therapy

C: Not on lipid lowering therapy before stroke: stroke or perioperative death (mean age 69.6 years)



4.3%

2.2%

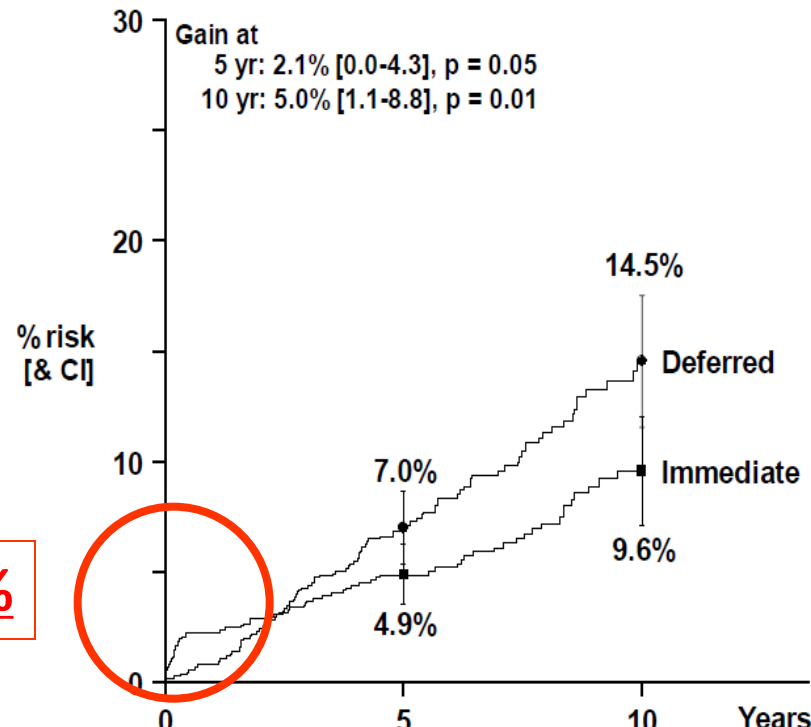
Perioperative events/CEAs (%) + other events

	Years 0-5	Years 5-10	
Immediate	22/516 (4.3%) + 31	0/8 (0.0%) + 23	96
Deferred	5/101 (5.0%) + 84	0/18 (0.0%) + 16	105

Number at risk

	Years 0-5	Years 5-10	10 Years
Immediate	547	301	96
Deferred	561	284	105

A: On lipid lowering therapy before stroke: stroke or perioperative death (mean age 68.0 years)



2.2%

Perioperative events/CEAs (%) + other events

	Years 0-5	Years 5-10	
Immediate	22/993 (2.2%) + 25	0/15 (0.0%) + 20	197
Deferred	9/259 (3.5%) + 56	2/69 (2.9%) + 32	176

Number at risk

	Years 0-5	Years 5-10	10 Years
Immediate	1013	702	197
Deferred	999	697	176

>250,000 Carotid Interventions Worldwide but Wide Variation in Practice

	Asymptomatic (%)	Proportion Stented (%)
US	90	40
Europe	60	40
UK	20	10

Means much Uncertainty
about choosing CEA or CAS

The Rationale for ACST-2

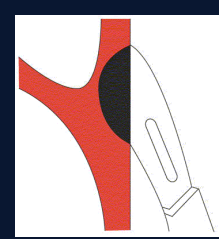
In large asymptomatic carotid stenting registries, in CREST, and in ACST-1 the hazard of intervention is ~3%

Hazards of CEA and stenting may be similar, but long-term benefits are not yet known

4832 US patients. Circ Cardiovasc Intervent 2009; 2: 159

Worldwide during the 2010s, millions of asymptomatic patients will have carotid stenting or surgery

ACST-2 hopes to randomise up to 5000 people to reliably assess the early and long-term efficacy of carotid stenting vs endarterectomy



When intervention seems clearly needed
and both procedures are appropriate

Consider patients for ACST-2

Surgery



Stenting

Begin the randomisation process in the Vascular Lab

Wall Posters

NIHR HTA/BUPA Foundation/University of Oxford

Asymptomatic Carotid Surgery Trial (ACST-2)

Which Intervention for Asymptomatic Carotid Stenosis?

CEA **OR** CAS

Inclusion

- = \geq 70% Stenosis
- = Patient suitable for both CEA & CAS
- = Patient otherwise in good health
- = Patient on good medical treatment and likely to live at least 10 years
- = Patient born on or after **1938**

Criteria:-

For more information, please go to our website: www.acst.org.uk or contact us on: acst@nds.ox.ac.uk

Stickers for Doppler scan reports/notes

NIHR HTA/BUPA Foundation/University of Oxford

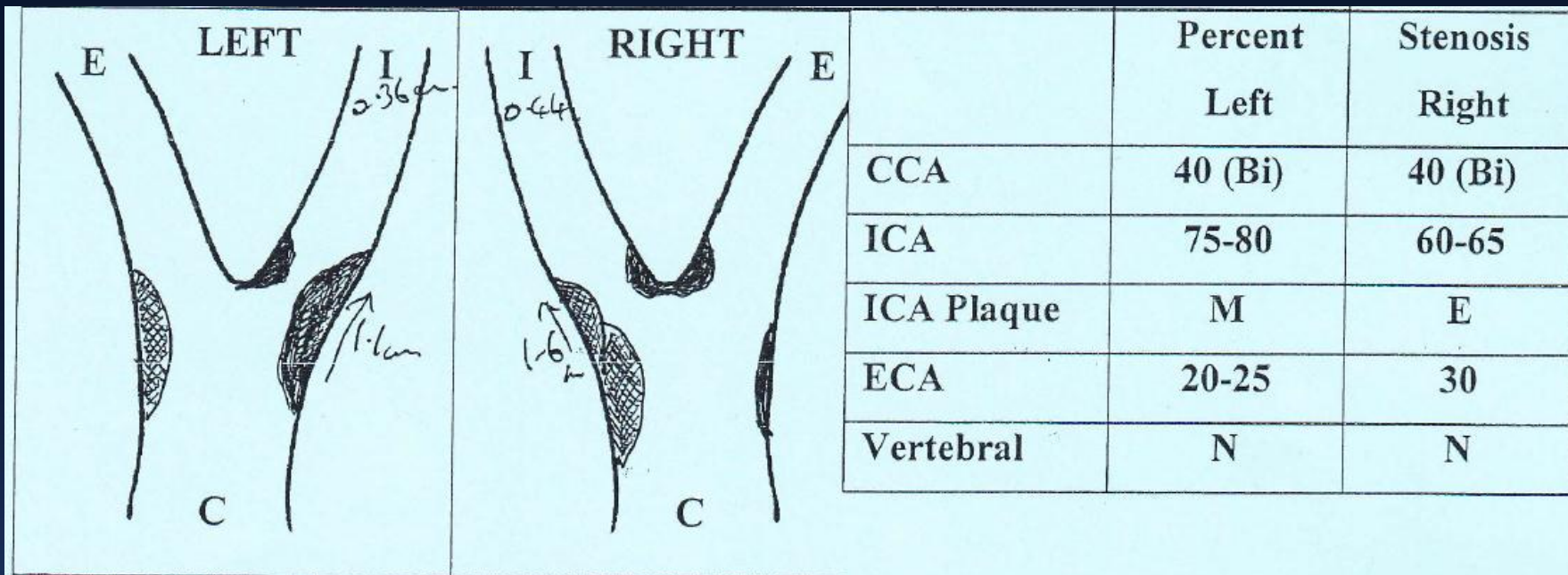
Asymptomatic Carotid Surgery Trial (ACST-2)

Have you considered **ACST-2** for this patient?

Study Coordinator: 01865 221 345

Website: www.acst.org.uk





Have you considered **ACST-2** for this patient?

Study Coordinator: 01865 221 345

Website: www.acst.org.uk

Symptoms: Pre-op CABG. Left carotid bruit. Asymptomatic.

Characteristics of first 1000 patients in ACST-2

Median age	71 (68*)
70-99% stenosis	96%
70-100% contralateral stenosis	20%
Diabetic	30% (20*)
Renal Failure	11%
Atrial Fibrillation	6%
Ischaemic Heart disease	37%

(* ACST-1)

Medical Treatment at Trial Entry

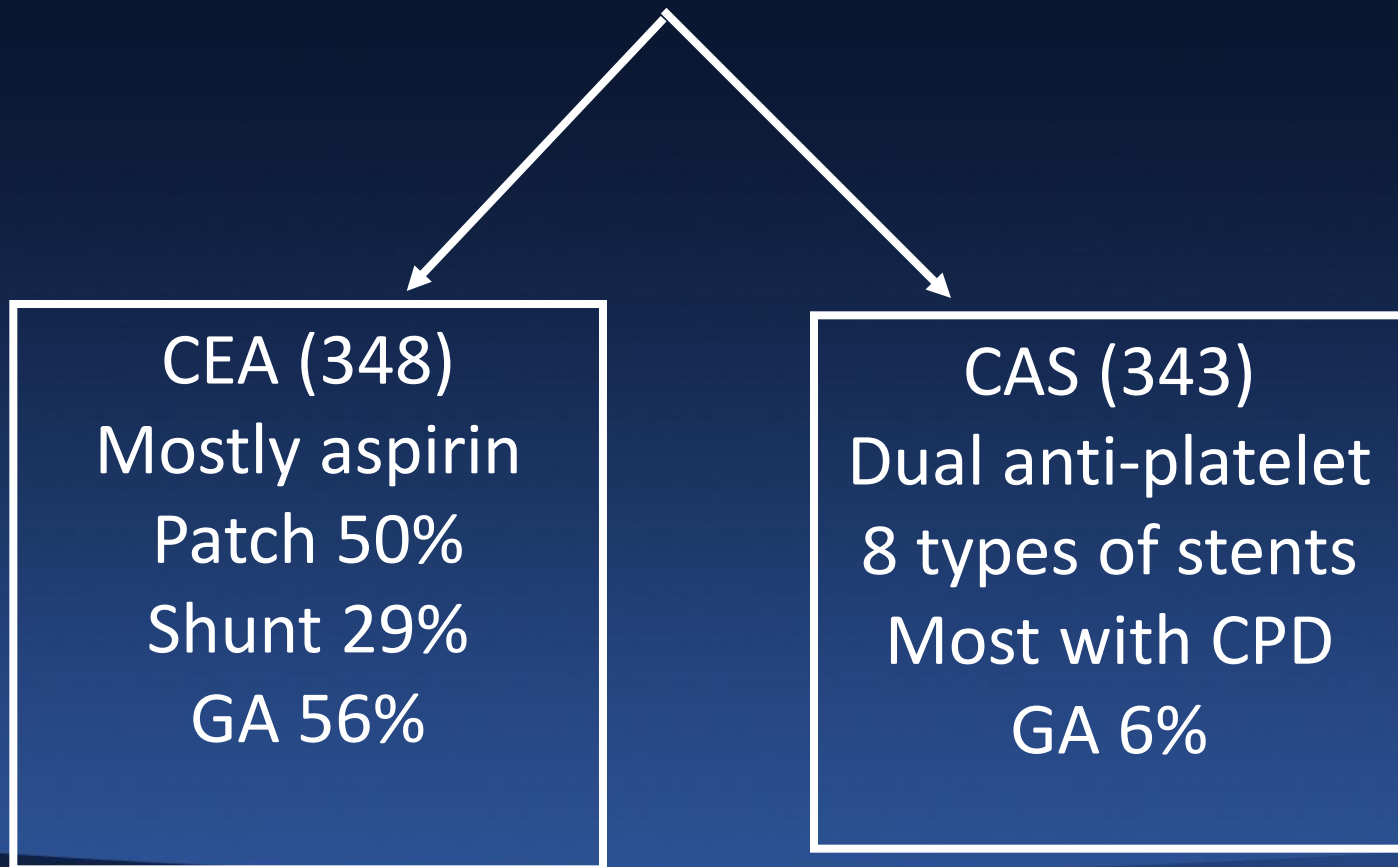
- **Anti-thrombotic** 90%
- **Anti-hypertensive** 79%
- **Lipid-lowering** 75%*

***Higher usage expected in follow-up**

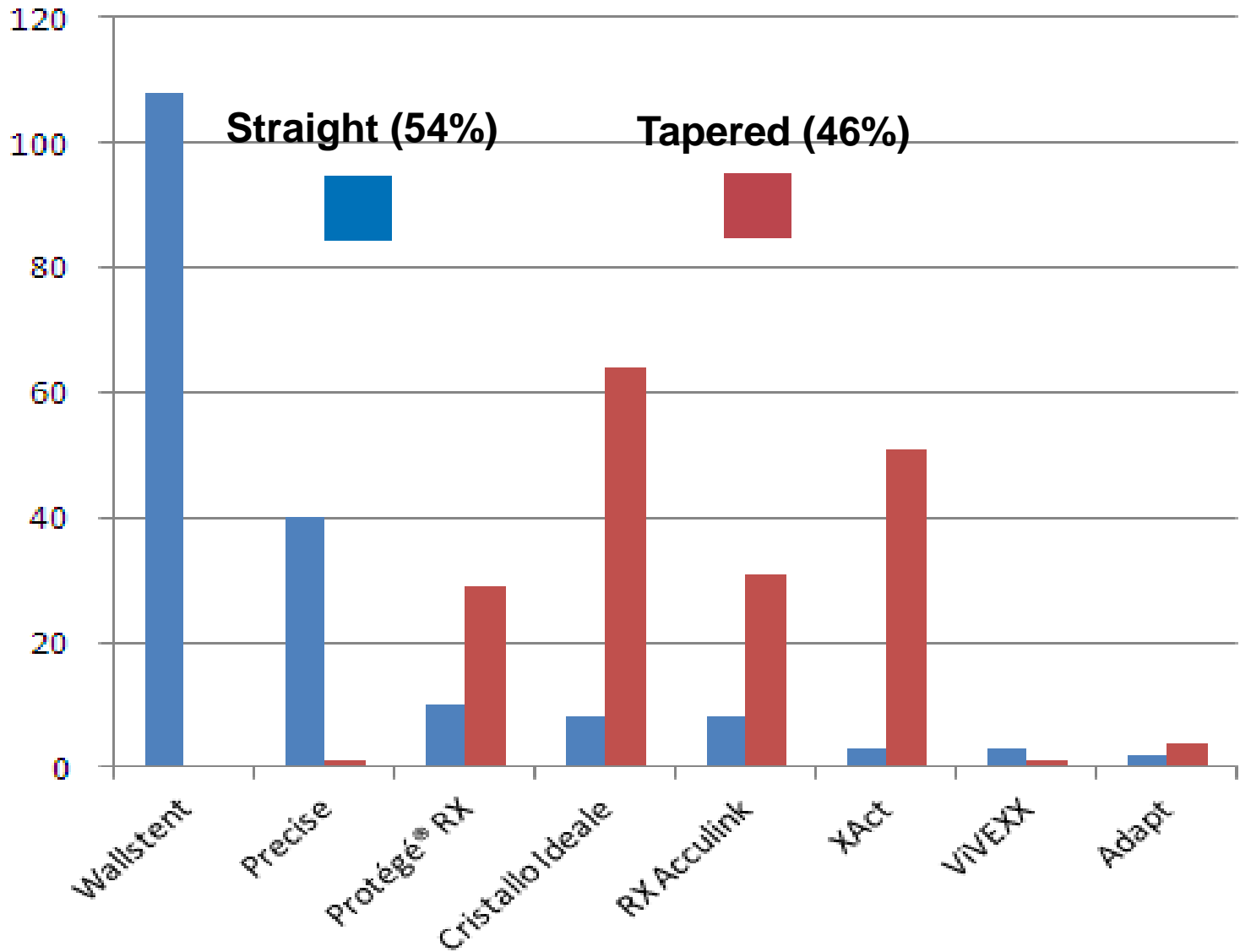
ACST-2: blinded early results

691 patients

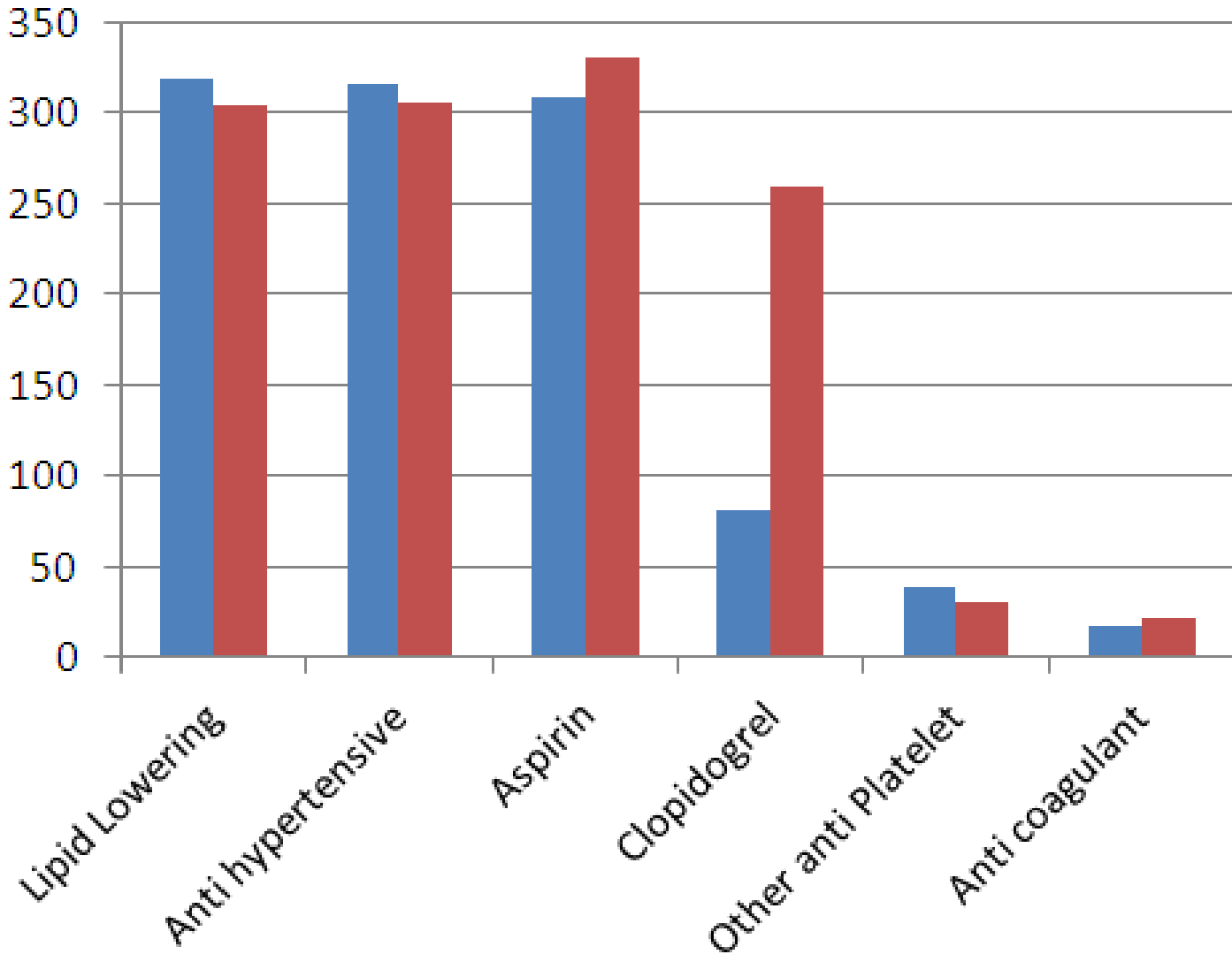
(1 month follow up + 6-month Rankin scoring for any stroke)



ACST-2: STENTS USED IN FIRST 800 PATIENTS



CURRENT THERAPY AT ONE MONTH FOLLOW-UP



CEA



CAS

30-day overall morbidity (691 pts)

Death / disabling stroke 1.0 (7) *

Non-disabling stroke 2.0% (14)

Non-fatal MI 0.4% (3)

* ACST-1 1.7% (for CEA)

Data Monitoring Committee (2012)

Chair, Professor P Sandercock

The DMC had no concerns and saw no reason to modify the protocol or intake to the study

The DMC commends the investigators on progress to date, and on the recent increase in recruitment

We urge the ACST-2 group now substantially to increase the rate of patient recruitment while maintaining close long-term follow-up of all cases in this important trial.

(next review April 2013)

Final UK NICE guidance on carotid stenting for asymptomatic carotid stenosis

“NICE encourages clinicians either to enter patients into the ACST-2 trial or to submit data to the Endovascular Carotid Register”

27 April 2011

NICE (UK National Institute for Clinical Excellence)

ACST-2: simple & efficient (clinicians do it for love, not money)

Randomise online

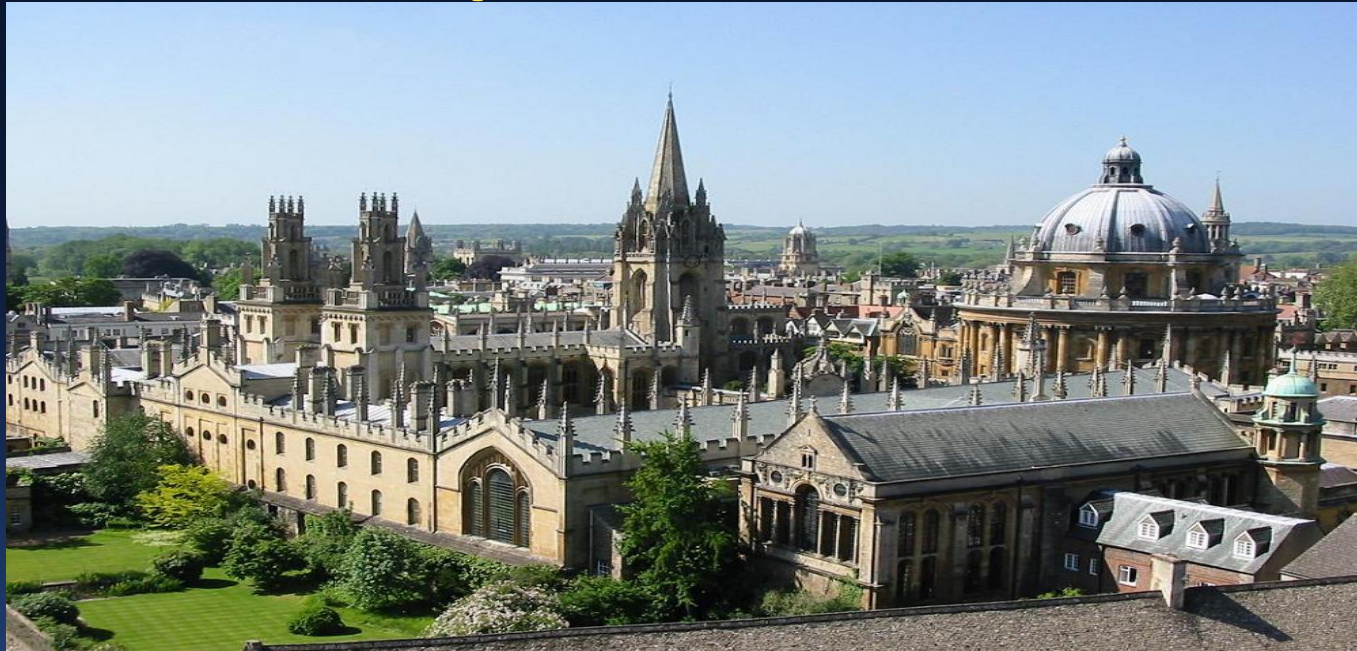
Only 2 x 1-page forms to complete

£100 per patient recruited with follow-up to 1-month completed

Email us at: acst@nds.ox.ac.uk

Website: acst.org.uk

Asymptomatic Carotid Surgery Trial-2 Collaborators' Meeting, Oxford April 2013



CARDIOVASCULAR
RESEARCH FOUNDATION
a passion for innovation

