What is the optimal approach to asymptomatic carotid stenosis?
Intervention or not? We cannot all be correct!

A. Halliday
Professor of Vascular Surgery
University of Oxford, UK
Disclosure

Speaker's name:

Alison Halliday

I do not have any potential conflict of interest
Intervention or not for Carotid Stenosis

- Long-term randomised evidence is very important
ICSS - long-term evidence
...changing the future for CAS
ICSS - why operate for symptoms if stenting works as well or better?
ICSS Early results

In favour of CEA, >minor strokes after CAS
CAS operators much less experienced than CEA

Many centres stopped stenting
Others carried on, results improved, devices changed....

ICSS long-term results published in 2014
.............*a clearer picture*
ICSS 4 year follow up

post-procedure

fatal/ disabling stroke  ipsilateral stroke
ICSS - 4 year follow up in 1700 patients
(Lancet, Oct 2014)
ICSS 4 yr follow up, symptomatic patients: *Lancet (Oct 2014)*

**CEA vs CAS...**

- ‘equivalent long-term disability’
- ‘quality of life is similar (after CAS) compared with endarterectomy’
Interventions for Carotid Stenosis
Or Medical Treatment alone?

- Long-term evidence is of most importance
ACST-1 Immediate vs Deferred CEA

Stroke Risk (%)

% risk (± SE)

0 5 10

0 10 20

Events/person-years

Years 0-5

24/4212 (0.6% pa) 51/4181 (1.2% pa)

Years 5-10

19/2042 (0.9% pa) 28/1930 (1.5% pa)

Immediate Deferred

Immediate

Deferred

Gain at

5 yr: 3.2% (1.0), p = 0.002
10 yr: 5.1% (2.0), p = 0.009

CEA better than Medical treatment alone
Guidelines – really uncertain about the optimal approach

**AHA Carotid Disease Management Guidelines (2011)**
It is reasonable to perform CEA in asymptomatic patients who have > 70% stenosis (Evidence Level: A)
Prophylactic CAS might be considered in highly selected patients with asymptomatic carotid stenosis (Evidence Level: B)

Asymptomatic > 60% stenosis should be considered for CEA (Evidence Level: A)
CAS should not be performed except as part of an on-going clinical trial (Evidence Level: B)

**RCP Stroke Guidelines (2012)**
Surgery or stenting (CEA or CAS) for asymptomatic carotid artery stenosis should not routinely be performed unless as part of a randomised trial.
The CREST-2/ECST2/SPACE-2 Research question

For asymptomatic patients with stenosis which might require intervention:

Which is generally better (in addition to good medical treatment)?

Intervention or Medical treatment alone
the ACST-2 research question..

For asymptomatic patients with tight stenosis requiring intervention:

Which procedure is generally better (in addition to good medical treatment)?

- carotid surgery (CEA)
- carotid stenting (CAS)?
Better procedural outcomes for CEA and CAS since 1990’s
Can we all be correct?

Procedural hazards of CEA and CAS are falling in recent trials and registries.
Techniques, devices, experience have all changed since the symptomatic trials...
Open cell vs closed-cell stent design

Closed-cell safer?
Newer FLOW-reversal systems and direct puncture

Reduce emboli, early results now comparable to CEA
the ACST-2 research question..

For asymptomatic patients with tight stenosis requiring intervention:

Which procedure is generally better (in addition to good medical treatment)?

- carotid surgery (CEA)
- or
- carotid stenting (CAS)?
ACST-2
A very European Trial

www.acst.org.uk
ACST-2 Recruitment – now >1800 patients

Target 3600 by end of 2019

1849
ACST-2 Recruitment increasing
(350-400 patients/year)
**ACST-2 – inclusive, practice-driven**  
*(all CE-marked)*

<table>
<thead>
<tr>
<th>Stent</th>
<th>CP Device</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston Wallstent</td>
<td>Emboshield</td>
<td>Filter</td>
</tr>
<tr>
<td>Cordis Precise</td>
<td>Filterwire</td>
<td>Filter</td>
</tr>
<tr>
<td>Ev3 Protégé® RX</td>
<td>Mo.Ma</td>
<td>Prox occ</td>
</tr>
<tr>
<td>Cristallo Ideale</td>
<td>Spider</td>
<td>Filter</td>
</tr>
<tr>
<td>Abbott RX Acculink</td>
<td>AngioGuard</td>
<td>Filter</td>
</tr>
<tr>
<td>Abbott Xact</td>
<td>Accunet</td>
<td>Filter</td>
</tr>
<tr>
<td>Boston Adapt</td>
<td>Gore Flow Reversal</td>
<td>Prox occ</td>
</tr>
<tr>
<td>Optimed Sinus Carotid RX</td>
<td>Twin One</td>
<td>Dist balloon</td>
</tr>
</tbody>
</table>
ACST-2: Open vs Endovascular treatment

Sex, Age, Co-morbidities:

Men 70%
Mean age 72 years
Ischaemic heart disease 36%
Diabetic 30%
Renal impairment 6%
ACST-2: Open vs Endovascular treatment

Stroke risk factors:

- Atrial Fibrillation: 6%
- Age >75 yrs: 26%
- Previous stroke symptoms or infarct: 43%

Medical Treatments:

- BP drugs: 85%
- Lipid-lowering: 86%
- Anti-thrombotic: 99%
ACST-2: Open vs Endovascular treatment

Blinded procedural outcomes (2015, 1600 patients)

Disabling/fatal stroke, fatal MI 1.0%
Congratulations to San Giovanni Di Dio, Florence; they have recruited their first patient within **5 days of being active:**

“We were in the period of final approval for ACST-2, when a patient was considered. We presented the trial to him; he accepted, signed the patient consent and was randomised to CEA. We thought that the randomisation process was simple and we were pleased to hear that we were the fastest randomisers to date in the ACST-2 study.”

⇒ Dr Emiliano Chisci
Future evidence comes from Trial collaborations. ACST-2 (3600 patients) will provide much of the planned evidence. CREST-2, ECST-2, SPACE-2, ACT-1 will enable 5000+ patient analysis.

We will then be able to determine the impact of:

- current medical treatment (mostly more statins)
- greater operator experience (especially with CAS)
- newer devices and techniques
- on older, but often fitter patients
The optimal approach to asymptomatic carotid stenosis? Intervention or not? We cannot all be correct!

✓ Medical treatment for all
  Tight stenosis, *maybe* intervene?
  Consider CREST-2 or ECST-2 (now recruiting)

✓ Stenosis, expected to live 5+ years?
  Stroke considered likely? *Definitely* intervene...
  CTA/MRA
    – suitable for CEA only?
    – hostile neck, recurrent stenosis? CAS
    – suitable for CEA or CAS? ACST-2

Help form future Guidelines!