STENTING SHOULD BECOME THE DEFAULT STRATEGY FOR CAROTID REVASCULARIZATION

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CONFLICT OF INTEREST
Related to Carotid Stenting

• Financial:
  – Consultant: None
  – SAB member: None
  – Speaker’s Bureau: None
  – Research: None

• Intellectual:
  – PI: BEACH & CABANA Trials (BSC)
  – CARE Steering Committee Chair (NCDR)
  – Past-President of SCAI
  – Angry that my patients are being denied a choice of reasonable therapies by the “politics of medicine”.

“So, I’m the only one who sees a conflict of interest here?”
Carotid Revascularization

Symptomatic

Asymptomatic

★ ICSS
★ SPACE
★ EVA-3S
★ CREST
★ ECST
★ NASCET

★ ACT-1
★ ACAS
★ ACST
★ VA
★ SAPPHIRE

THE MOST STUDIED PROCEDURE IN MEDICINE

CREST SAPPHIRE BEACH ARCHER EXACT CAPTURE
CABERNET CREATE MAVeRIC SECURITY
Maybe CMS needs help weighing the evidence?
High Risk for CEA ≠ CAS

<table>
<thead>
<tr>
<th>Anatomic Criteria</th>
<th>Medical Comorbidity</th>
</tr>
</thead>
<tbody>
<tr>
<td>High cervical or intrathoracic lesion</td>
<td>Age ≥80 yrs</td>
</tr>
<tr>
<td>Prior radical neck surgery or radiation</td>
<td>Class III/IV congestive heart failure</td>
</tr>
<tr>
<td>Contralateral carotid artery occlusion</td>
<td>Class III/IV angina pectoris</td>
</tr>
<tr>
<td>Prior ipsilateral CEA</td>
<td>Left main coronary disease</td>
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<tr>
<td>Contralateral laryngeal nerve palsy</td>
<td>Multivessel coronary artery disease</td>
</tr>
<tr>
<td>Tracheostoma</td>
<td>Urgent (&lt;30-day) heart surgery</td>
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<td></td>
<td>LV ejection fraction ≤30%</td>
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<tr>
<td></td>
<td>Recent (≤30-day) myocardial infarction</td>
</tr>
<tr>
<td></td>
<td>Severe lung disease</td>
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<tr>
<td></td>
<td>Severe renal disease</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Comorbidities</th>
<th>Anatomic Features</th>
<th>Procedural Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age ≥80 yrs</td>
<td>Complex aortic arch</td>
<td>Operator inexperience</td>
</tr>
<tr>
<td>Symptomatic</td>
<td>Tortuosity</td>
<td>No emboli protection device</td>
</tr>
<tr>
<td>Decreased cerebral reserve</td>
<td>Calcification</td>
<td>Time delay from symptom onset</td>
</tr>
<tr>
<td>Hypercoagulable state</td>
<td>Intraluminal thrombus</td>
<td>Open cell stents</td>
</tr>
<tr>
<td>Severe renal disease</td>
<td>Echoluent plaque</td>
<td>Vascular access difficulty</td>
</tr>
<tr>
<td>Increased bleeding risk</td>
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</tr>
</tbody>
</table>
SAPPHIRE: LEVEL I EVIDENCE

TREATMENT RECEIVED: HIGH SURGICAL RISK PATIENTS

At one year, carotid revascularization was repeated in fewer patients who had received stents than in those who had undergone endarterectomy (cumulative incidence, 0.6 percent vs. 4.3 percent; P=0.04).

P = 0.048

**ABSTRACT**

Carotid-artery stenting and carotid endarterectomy are both options for treating carotid-artery stenosis, an important cause of stroke.

We randomly assigned patients with symptomatic or asymptomatic carotid stenosis to undergo carotid-artery stenting or carotid endarterectomy. The primary composite outcome of stroke, myocardial infarction, or death did not differ significantly in the group undergoing carotid-artery stenting and the group undergoing carotid endarterectomy were similarly low (2.0% and 2.4%, respectively; P=0.85). There was no difference in the estimated 4-year rates of the primary end point between the stenting group and the endarterectomy group (7.2% and 6.8%, respectively; hazard ratio with 95% confidence interval, 0.90 to 1.33; P=0.70).

Results Among patients with symptomatic or asymptomatic carotid stenosis, the risk of the composite primary outcome was 4.5% and 2.7% (hazard ratio, 1.86; P=0.01), and for myocardial infarction (1.1% vs. 2.3%, P=0.14), and the rates among symptomatic patients were 8.0% and 6.4% (hazard ratio, 1.37; P=0.07), respectively.

**METHODS**

Patients were randomly assigned to undergo carotid-artery stenting or carotid endarterectomy. The primary composite end point was stroke, myocardial infarction, or death from any cause during the periprocedural period or any ipsilateral stroke within 4 years after randomization.

**CONCLUSIONS**

During the periprocedural period, there was a higher risk of stroke with stenting and a higher risk of myocardial infarction with endarterectomy. Among patients with symptomatic or asymptomatic carotid stenosis, the risk of the composite primary outcome did not differ significantly in the group undergoing carotid-artery stenting and the group undergoing carotid endarterectomy.
**Background**

Carotid-artery stenting and carotid endarterectomy are both options for the treatment of carotid-artery stenosis, an important cause of stroke.

**Methods**

We randomly assigned patients with symptomatic or asymptomatic carotid-artery stenosis who were scheduled to undergo carotid-artery stenting or carotid endarterectomy. The primary endpoint was a composite of stroke, death, or myocardial infarction during the 30-day period after the procedure. The 4-year study period was the period after randomization in which the assigned procedure was performed. Hazard ratios were adjusted for age, symptomatic status, and sex. P values were calculated on the basis of the significance of the hazard ratio (per study period).

**Results**

The 1181 asymptomatic patients consisted of 594 patients in the carotid-artery stenting (CAS) group and 587 in the carotid endarterectomy (CEA) group. The 1321 symptomatic patients consisted of 457 patients in the CAS group and 864 in the CEA group.

**4-Yr Study Period (Including Periprocedural Period)**

<table>
<thead>
<tr>
<th></th>
<th>CAS</th>
<th>CEA</th>
<th>Absolute Treatment Effect of CAS vs. CEA (95% CI)</th>
<th>Hazard Ratio for CAS vs. CEA (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>no. of patients (% ±SE)</strong></td>
<td></td>
<td></td>
<td>percentage points</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Any periprocedural stroke or postprocedural ipsilateral stroke</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Asymptomatic patients</td>
<td>24 (4.5±0.9)</td>
<td>13 (2.7±0.8)</td>
<td>1.9 (−0.5 to 4.3)</td>
<td>1.86 (0.95 to 3.66)</td>
<td>0.07</td>
</tr>
<tr>
<td>Symptomatic patients</td>
<td>48 (7.6±1.1)</td>
<td>37 (6.4±1.1)</td>
<td>1.2 (−1.8 to 4.1)</td>
<td>1.29 (0.84 to 1.98)</td>
<td>0.25</td>
</tr>
</tbody>
</table>

No statistical difference for stroke out to 4 years between CAS and CEA.

Long-term outcomes after stenting versus endarterectomy for treatment of symptomatic carotid stenosis: the International Carotid Stenting Study (ICSS) randomised trial

Leo H Bonati, Joanna Dobson, Roland L Featherstone, Jörg Ederle, H Bart van der Worp, Gert J de Borst, Willem P Th M Mali, Jonathan D Beard, Trevor Cleveland, Stefan T Engelter, Philippe A Lyrer, Gary A Ford, Paul J Dorman, Martin M Brown, for the International Carotid Stenting Study investigators*

Summary

Background Stenting is an alternative to endarterectomy for treatment of carotid artery stenosis, but long-term efficacy is uncertain. We report long-term data from the randomised International Carotid Stenting Study comparison of these treatments.

The International Carotid Stenting Study (ICSS) randomised comparison of stenting with endarterectomy at 50 centres worldwide. Results of ICSS are reported here up to 10 years after initial randomisation.

Methods Patients with symptomatic carotid stenosis were randomly assigned 1:1 to open treatment with stenting or endarterectomy. The number of fatal or disabling strokes (52 vs 49) and cumulative 5-year risk did not differ significantly between the stenting and endarterectomy groups (6·4% vs 6·5%; hazard ratio [HR] 1·06, 95% CI 0·72–1·57, p=0·77). Any stroke was more frequent in the stenting group than in the endarterectomy group (119 vs 72 events; ITT population, 5-year cumulative risk 15·2% vs 9·4%, HR 1·71, 95% CI 1·28–2·30, p<0·001; per-protocol population, 5-year cumulative risk 8·9% vs 5·8%, 1·53, 1·02–2·31, p=0·04), but were mainly non-disabling strokes. The distribution of modified Rankin scale scores at 1 year, 5 years, or final follow-up did not differ significantly between treatment groups.

Interpretation Long-term functional outcome and risk of fatal or disabling stroke are similar for stenting and endarterectomy for symptomatic carotid stenosis.
ICSS: CAS = CEA

1º Endpoint: Fatal or Disabling Stroke

RCT: Level I Evidence
Average Surgical Risk, Symptomatic Pts

HR 1.06 (95% CI 0.72–1.57), p=0.77

Cumulative incidence (%)
20 30
10 25
35 15
85 15
60 15
45 15
30 15
10 15

Number at risk
CAS 853 777 733 651 498 328 163 85
CEA 857 789 750 661 482 310 140 79

Lancet 2015; 385: 529–38
CAS IMPROVEMENT

CAS Results Show an Improving Trend In High Surgical Risk Patients (2003–2012)

Risk of Death, Stroke or Myocardial Infarction Within 30 Days of Procedure (%)

8% 6% 4% 2%


Class I
Symptomatic >50% (angio), >70% (ultrasound) with periprocedural stroke and death risk ≤ 6%.

Class II
Ila = CAS > CEA with unfavorable neck anatomy.
Ilb = Highly selected, asymptomatic >60% (angio), >70% (u/s).
EVIDENCE FAVORS STENTING

Large RCT’s (CREST/ICSS) equipoise for CAS & CEA.

FDA approves 7 devices for both high and avg surgical risk.

Multispeciality guidelines: ACC/AHA/ASA/SVS, etc support.
UNCLE SAM COMMITS MALPRACTICE

Killing Carotid Stenting
Time to add CEA to the list?

Amputation for fractures
Boiling oil on amputation wounds.
Radiation therapy for acne
Collapse therapy for Tuberculosis
Aortic Wrapping for aneurysms
Orchiectomy for mental illness
Vineberg procedure
Thank You