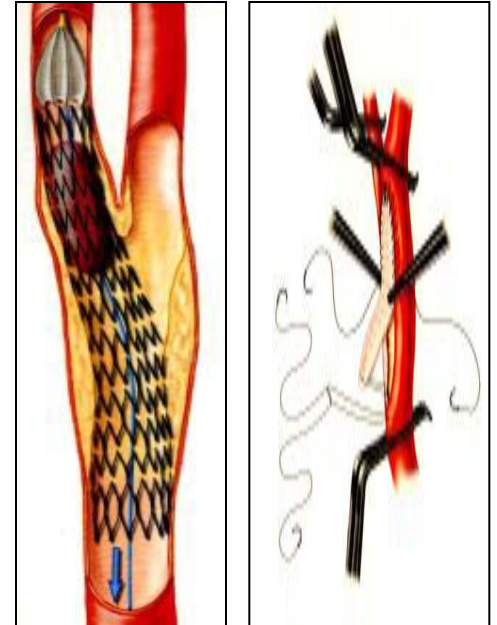
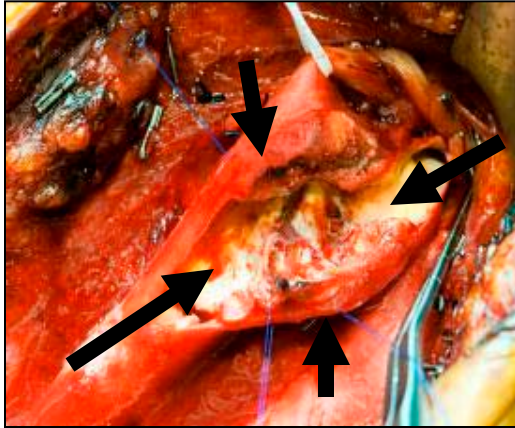


CMS MEDCAC Management of Carotid Atherosclerosis



Richard P. Cambria, M.D.

President, Society for Vascular Surgery

Chief, Division of Vascular and Endovascular Surgery

Massachusetts General Hospital

Professor of Surgery, Harvard Medical School, Boston, MA

- **> 3600 U.S. Vascular/Endovascular Surgeons**
- **SVS (founded 1946) – nation's oldest medical professional Society devoted to non-cardiac vascular disease**
- **Carotid arteriosclerosis core element of Vascular Surgery practice since 1951**
- **Vascular Surgeons uniquely offer all 3 available treatments (Med Rx/CEA/CAS)**
 - ↳ **longitudinal patient F/U**

SVS @ MEDCAC

- **Written detailed document pertaining to the 7 research questions submitted**
- **SVS does not support change NCD for CAS**
- **MEDCAC presentation organized**
 - **RCT data CAS vs. CEA**
 - **“Real world” data CAS vs. CEA**
 - **Clinical decision-making → asymptomatic patients**
 - **Vascular surgeons and CAS**
 - **Implication of Δ NCD for CAS**
 - **Medical Rx ?adequate asymptomatic**

Vascular Surgeons & CAS

- **Vascular Practice 50-70% Endovascular**
- **Similar to other Vascular territories
(AAA/PVD → genuine patient benefit)
SVS members will embrace CAS when/if
it's safety/cost efficacy profile equals
CEA . . . to date this has not occurred**

RECENT META ANALYSIS

SOCIETY FOR VASCULAR SURGERY[®] DOCUMENT

A systematic review and meta-analysis of randomized trials of carotid endarterectomy vs stenting

Mohammad Hassan Murad, MD, MPH,^{a,b,c} Anas Shahrour,^a Nilay D. Shah, PhD,^c
Victor M. Montori, MD, MSc,^{a,c,d} and John J. Ricotta, MD,^c Rochester, Minn; and Washington, DC

Objective: The purpose of this systematic review and meta-analysis was to synthesize the available evidence derived from randomized controlled trials (RCTs) regarding the relative efficacy and safety of endarterectomy vs stenting in patients with carotid artery disease.

Methods: We searched MEDLINE, EMBASE, Current Contents, and Cochrane CENTRAL through July 2010 to update previous systematic reviews. Two reviewers determined trial eligibility and extracted descriptive, methodologic, and outcome data (death, nonfatal stroke, and nonfatal myocardial infarction). Random-effects meta-analysis was used to pool relative risks and the I^2 statistic was used to assess heterogeneity.

Results: Thirteen RCTs proved eligible enrolling 7484 patients, of which 80% had symptomatic disease. Methodological quality was moderate to high, with better quality among RCTs published after 2008. Compared with carotid endarterectomy, stenting was associated with increased risk of any stroke (relative risk [RR], 1.45; 95% confidence interval [CI], 1.06-1.99; $I^2 = 40\%$), decreased risk of periprocedural myocardial infarction (MI; RR, 0.43; 95% CI, 0.26-0.71; $I^2 = 0\%$), and nonsignificant increase in mortality (RR, 1.40; 95% CI, 0.85-2.33; $I^2 = 5\%$). When analysis was restricted to the two most recent trials with the better methodology and more contemporary technique, we found stenting to be associated with a significant increase in the risk of any stroke (RR, 1.82; 95% CI, 1.35-2.45) and mortality (RR, 2.53; 95% CI, 1.27-5.08) and a nonsignificant reduction of the risk of MI (RR, 0.39; 95% CI, 0.12-1.23). For every 1000 patients opting for stenting rather than endarterectomy, 19 more patients would have strokes and 10 fewer would have MIs. Outcome data in asymptomatic patients were sparse and imprecise; hence, these conclusions apply only to symptomatic patients.

Conclusion: Compared with endarterectomy, carotid artery stenting (CAS) significantly increases the risk of any stroke and decreases the risk of MI. (J Vasc Surg 2011;53:792-7.)

J Vasc Surg 2011;53:792

SVS Practice Guidelines

SOCIETY FOR VASCULAR SURGERY[®] DOCUMENT

- “Granular” review of different patient subgroups
- Greatest emphasis on “hard end points” of STROKE/DEATH
- CEA 1st line treatment for symptomatic & selected asymptomatic (60-99%) patients
- CAS
 - symptomatic → unacceptable CEA candidates
 - asymptomatic → not indicated

Peter Faries, MD,^{*} and Brajesh K. Lal, MD,[†] Washington, DC; Charleston, WV; Brooklyn, NY; Chicago, Ill; New York, NY; and Baltimore, Md

J Vasc Surgery 2011;54:832-6

Multispecialty Guidelines

**ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/
SCAI/SIR/SNIS/SVM/SVS Guideline**

**2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/
SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the
Management of Patients With Extracranial Carotid and
Vertebral Artery Disease: Executive Summary**

- Symptomatic patients → CEA first line RX and CAS is “alternative Rx”
- Asymptomatic patients → CEA “reasonable” CAS → insufficient evidence

Gary Friday, MD††; Vicki S. Hertzberg, PhD; E. Bruce McIlff, MD§§;
Wesley S. Moore, MD; Peter D. Panagos, MD§§; Thomas S. Riles, MD|||;
Robert H. Rosenwasser, MD¶¶; Allen J. Taylor, MD##

Circulation 2011;124:489-532

DETAILS OF CREST

Safety of Stenting and Endarterectomy by Symptomatic Status in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST)

Frank L. Silver, MD; Ariane Mackey, MD; Wayne M. Clark, MD; William Brooks, MD;
Carlos H. Timaran, MD; David Chiu, MD; Larry B. Goldstein, MD; James F. Meschia, MD;
Robert D. Ferguson, MD; Wesley S. Moore, MD; George Howard, DrPH; Thomas G. Brott, MD;
for the CREST Investigators

Background and Purpose—The safety of carotid artery stenting (CAS) and carotid endarterectomy (CEA) has varied by symptomatic status in previous trials. The Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST) data were analyzed to determine safety in symptomatic and asymptomatic patients.

Methods—CREST is a randomized trial comparing safety and efficacy of CAS versus CEA in patients with high-grade carotid stenoses. Patients were defined as symptomatic if they had relevant symptoms within 180 days of randomization. The primary end point was stroke, myocardial infarction, or death within the periprocedural period or ipsilateral stroke up to 4 years.

Results—For 1321 symptomatic and 1181 asymptomatic patients, the periprocedural aggregate of stroke, myocardial infarction, and death did not differ between CAS and CEA (5.2% versus 4.5%; hazard ratio, 1.18; 95% CI, 0.82 to 1.68; $P=0.38$). The stroke and death rate was higher for CAS versus CEA (4.4% versus 2.3%; hazard ratio, 1.90; 95% CI, 1.21 to 2.98; $P=0.005$). For symptomatic patients, the periprocedural stroke and death rates were $6.0\% \pm 0.9\%$ for CAS and $3.2\% \pm 0.7\%$ for CEA (hazard ratio, 1.89; 95% CI, 1.11 to 3.21; $P=0.02$). For asymptomatic patients, the stroke and death rates were $2.5\% \pm 0.6\%$ for CAS and $1.4\% \pm 0.5\%$ for CEA (hazard ratio, 1.88; 95% CI, 0.79 to 4.42; $P=0.15$). Rates were lower for those aged <80 years.

Conclusions—There were no significant differences between CAS versus CEA by symptomatic status for the primary CREST end point. Periprocedural stroke and death rates were significantly lower for CEA in symptomatic patients. However, for both CAS and CEA, stroke and death rates were below or comparable to those of previous randomized trials and were within the complication thresholds suggested in current guidelines for asymptomatic patients. (*Stroke*. 2011;42:657-680.)

Stroke 2011;42:657-680

STROKE/DEATH IN SYMPTOMATIC PATIENTS CREST “SAFETY DATA”

		CAS (%)		CEA (%)		HR (p values)
Overall	(2500 pts)	4.4		2.3		1.9 (p .005)
Symptomatic	(1321 pts)	6.0	0.9	3.2	0.7	1.9 (p .02)
Asymptomatic	(1181 pts)	2.5	0.6	1.4	0.5	1.88 (p = .15)

Stroke 2011;42:657-680

CREST Editorial

The NEW ENGLAND JOURNAL of MEDICINE

EDITORIALS

What can we conclude from CREST? It is among the largest of the randomized trials of carotid-artery stenting, with impressively low complication rates, but the results are broadly consistent with those in previous trials. Namely, carotid-artery stenting is associated with a higher periprocedural risk of stroke or death, a difference that was still significant at 4 years. A

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NC100004/32), the results of which are reported by Brott and colleagues in this issue of the Journal.¹

cal question is whether the CREST results — with the headline finding of and endarterectomy rega

N Engl J Med 2010;36380-82



Poor outcomes after endovascular treatment of symptomatic carotid stenosis: time for a moratorium

The long-term outcomes of the CAVATAS trial, years of follow-up were available on the 3248 patients reported in the October issue of *The Lancet Neurology*,^{1,2} who underwent endarterectomy; therefore, the

add substantially to the p on the durability of endo endarterectomy for symptom Endarterectomy versus Stent Trial]],¹³ the routine use of stenting in patients with recent symptoms of carotid stenosis who are suitable for endarterectomy can no longer be justified. In particular, the use of vague and

reduce the long-term risk of stroke. Comparable data in patients with symptomatic carotid stenosis. The on outcomes beyond the immediate post-procedural recently presented International Carotid Stenting period come from the SAPHIRE,³ EVA-3S,⁴ and SPACE⁵ Study (ICSS),⁶ the largest trial of endarterectomy versus

Treatment Guidelines: Asymptomatic

Organization	Year	Guideline
ACC/AHA	2011	CEA "reasonable" >70%, risk low; CAS no data
SVS updated	2011	CEA indicated >60%, longevity; CAS no data
ESC	2011	CEA indicated >60%, longevity; CAS high volume
Australasian	2011	CEA indicated; CAS not indicated
NICE	2011	CAS only in trials

ASYMPTOMATIC STENOSIS:

% ECST Stenosis	# Stroke/TIA	# Patients
50-69	10 (5.1%)	194
70-89	54 (9.1%)	593
90-99	44 (13.4%)	328
% NASCET Stenosis		
50-69	29 (8.2%)	352
70-89	37 (10.7%)	344
90-99	21 (19.3%)	109
Overall, 10% patients had events @ 3 years!		

ASYMPTOMATIC STENOSIS: THE QUEST FOR RISK STRATIFICATION

- **Imaging of Plaque Characteristics**

- **Duplex → GSM**

- SVS has identified study of asymptomatic carotid stenosis as #1 Clinical Research Priority

- ↳ Resources committed – granting mechanism

- **Molecular Imaging**

- **Biomarkers (MMP / CRP) of unstable plaque**

Has Modern Medical Therapy made Intervention for Asymptomatic Stenosis Obsolete?

- **Current (2011) Practice Guidelines
→ NO**
- **Major Transatlantic Differences**
- **What is the evidence?**

BEST MEDICAL THERAPY DATA CRITIQUE

The “extrapolated” data on stroke risk is greatly biased by inclusion of many patients with insignificant carotid stenoses wherein CEA would not be recommended.

(Smart/Oxford/ACSRS)

Late Results - ACST

✦ 10-year stroke prevention after successful carotid endarterectomy for asymptomatic stenosis (ACST-1): a multicentre randomised trial

*Alison Halliday, Michael Harrison, Elizabeth Hayter, Xiangling Kong, Averil Mansfield, Joanna Marra, Hongchao Pan, Richard Peto, John Potter, Karem Rabbani, Anand Rao, Stuart Robertson, Jonathan Smeiley, David Thorne, on behalf of the ACST-1 Group, *Lancet* 2010;376:1008-16*

Stroke risk

5 yr – 4.1% CEA vs 10% medical
CEA reduces long-term stroke risk....in asymptomatic pts.

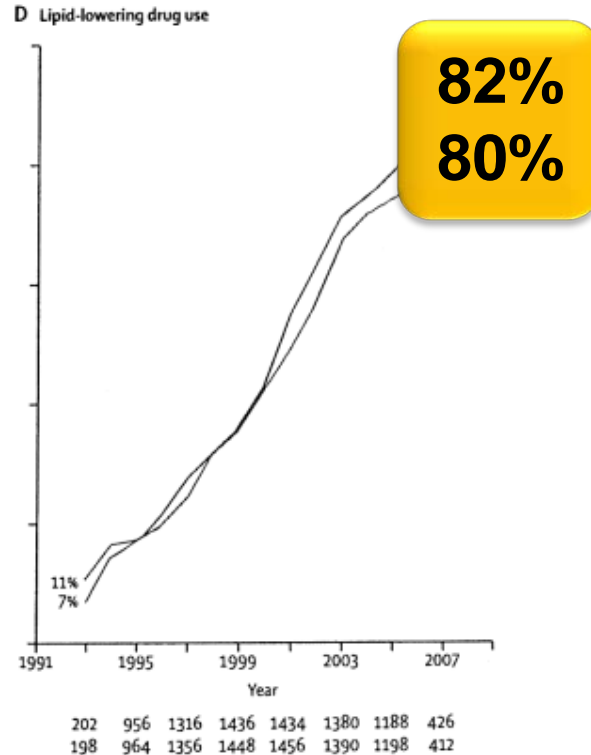
University of London, London, UK (Prof A Halliday, E Hayter); Department of Neurology, University College, London, UK (Prof M Harrison FRCP); Department of Surgery, Imperial College, London, UK (Prof A Mansfield FRCS, Prof D Thomas FRCP); Department of Medical Statistics, London School of Hygiene and Tropical Medicine, London, UK (J Marra MSc).

had a disabling or fatal stroke, and 37 versus 84 others had a non-disabling stroke. Combining perioperative events and strokes, net risks were 6.9% versus 10.9% at 5 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).

Interpretation Successful CEA for asymptomatic patients younger than 75 years of age reduces 10-year stroke risks. Half this reduction is in disabling or fatal strokes. Net benefit in future patients will depend on the prevalence of unoperated carotid lesions (which will be reduced by medication), on future surgical risks (which will be reduced by medical treatment), and on whether life expectancy exceeds 10 years.

The Lancet 2010:376

Statin Use in ACST



OPTIMAL MED Rx BECAME PART OF ACST!

The Lancet 2010:376

ACST – 10 yr Results

BENEFIT OF CEA – DESPITE STATINS

On lipid-lowering therapy before stroke:
non-perioperative stroke (mean age 68.0 years)

Gain at

5 years: 3.4% (95% CI 1.5-5.2), $p=0.0005$

10 years: 5.8% (95% CI 2.1-9.6), $p=0.002$

Not on lipid-lowering therapy before stroke:
non-perioperative stroke (mean age 69.6 years)

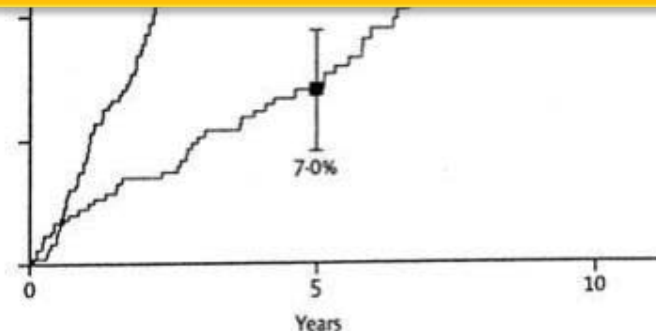
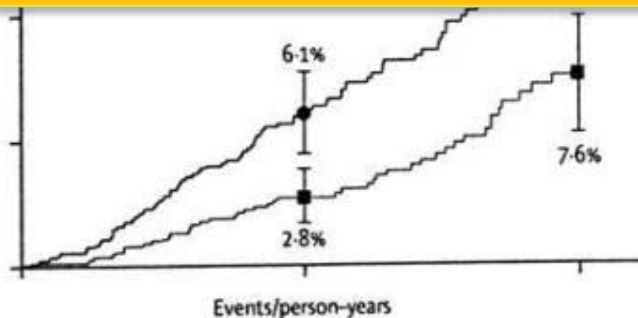
Gain at

5 years: 10.8% (95% CI 6.6 to 15.1), $p<0.0001$

10 years: 6.2% (95% CI -0.4 to 12.8), $p=0.07$

24.1%

“ . . . patients with tight ($\geq 60\%$ NASCET) carotid stenosis cannot have the risk from it completely abolished by medical treatment alone.”



SVS & NCD for CAS

- **SVS (et. al.) recommends no changes in NCD for CAS at this time**
 - **2-fold ↑ in S/D CAS vs CEA (symptomatic)**
 - **No data in asymptomatic vs BMT**
- **Prior position statements (2006/07/08)**
 - ↘ **CAS for anatomic high risk patients**
 - ↘ **NOT for octogenarians**

Future Directions

- **Separate symptomatic vs. asymptomatic**
- **Asymptomatic trials → BMT arm**
- **Research → stroke risk stratification of asymptomatic patients → SVS #1 priority**
 - ↙ at present % stenosis reasonable surrogate
- **Claim that BMT = CEA for stroke prevention in asymptomatic patients is unsubstantiated**