Carotid Artery Disease

How the 2014-2015 Data Will Influence Management
The Symptomatic vs. the Asymptomatic Patient

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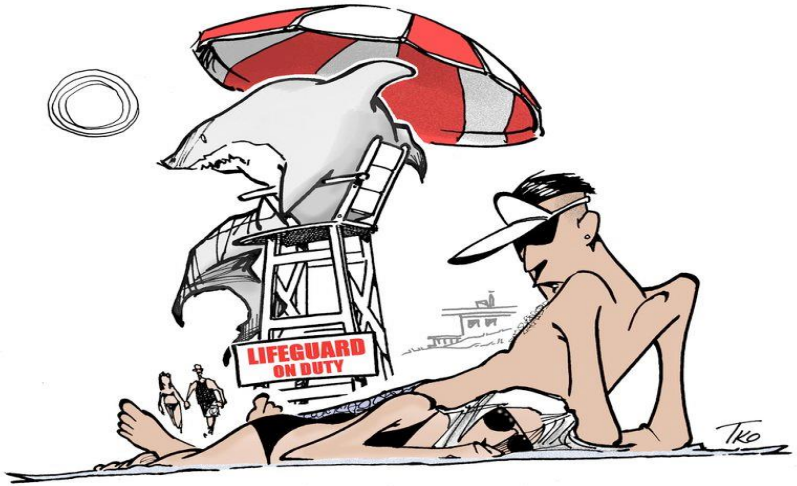
DISCLOSURE

Relevant to Carotid Artery Stenting

- Relationships with industry:
  - Research: None
  - Stock Ownership: None
  - Speakers Bureau: None
  - Consultant: None



"So, I'm the only one who sees a conflict of interest here?"

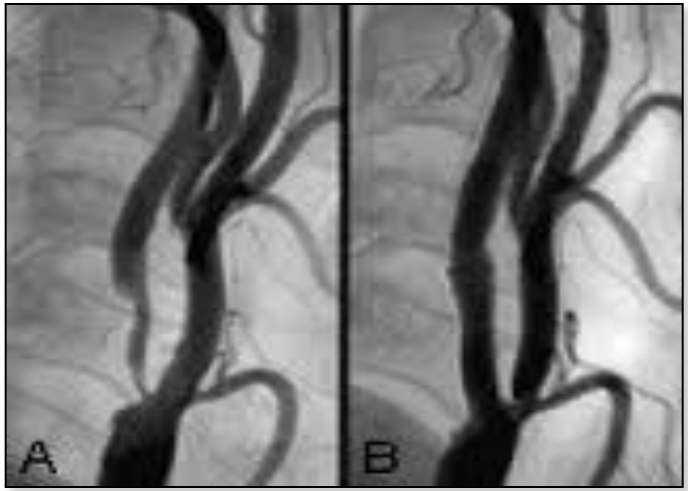
Stroke Prevention

RISK FACTOR
Blood Pressure
Atrial Fibrillation
Smoking
Cholesterol
Diabetes
Exercise
Diet
Stroke in Family

- Carotid plaque most often causes symptoms due to EMBOLIZATION, rather than thrombosis.
- Extracranial carotid OCCLUSION is the source of ischemic stroke in fewer than 20%.
- Symptomatic patients have a much higher stroke rate than asymptomatic patients.
- Asymptomatic patients outnumber symptomatic patients by 4:1.

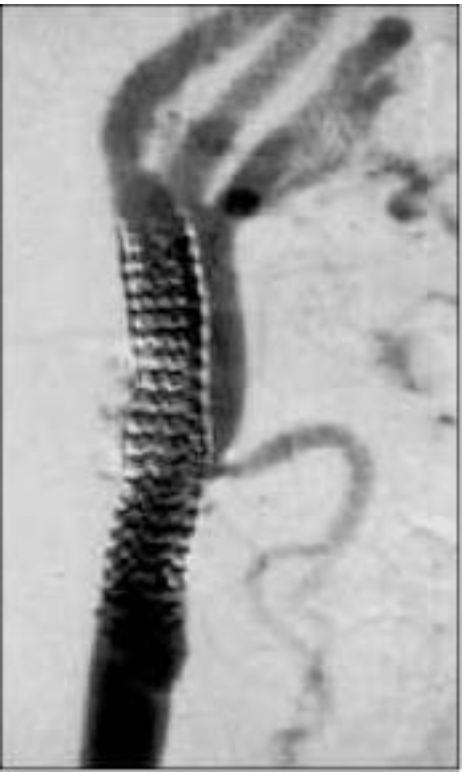
FACT(s)

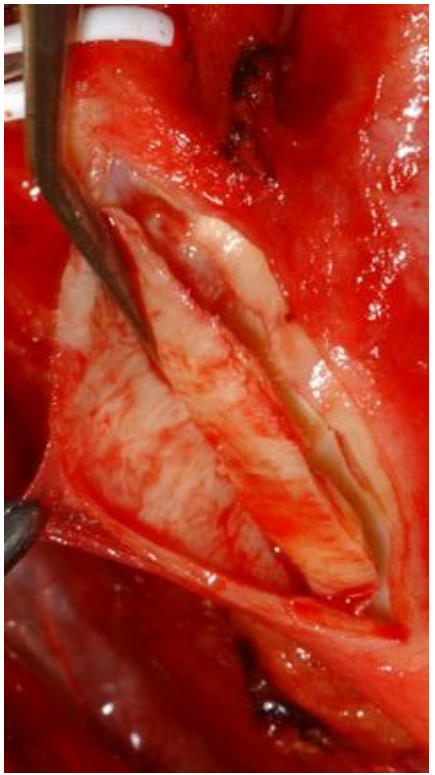
We do **NOT** need more trials to establish equipoise for CAS vs. CEA



- CAS is one of the most studied procedures of all time.
  - 7 systems approved as ***"safe and effective"*** by the FDA, all with "pivotal" and post-approval trials, that account for more than ***10,000 published cases***.
  - 3 poorly executed European trials (SPACE, EVA-3s, & ICSS) tell us "trainees" cannot do CAS as well as experienced surgeons can do CEA.
  - SAPPHIRE, a small RCT in **high surgical risk patients**, showed that CAS is the procedure of choice in those pts.
  - CREST was a very large, well conducted trial in average risk patients with no difference between CEA and CAS.

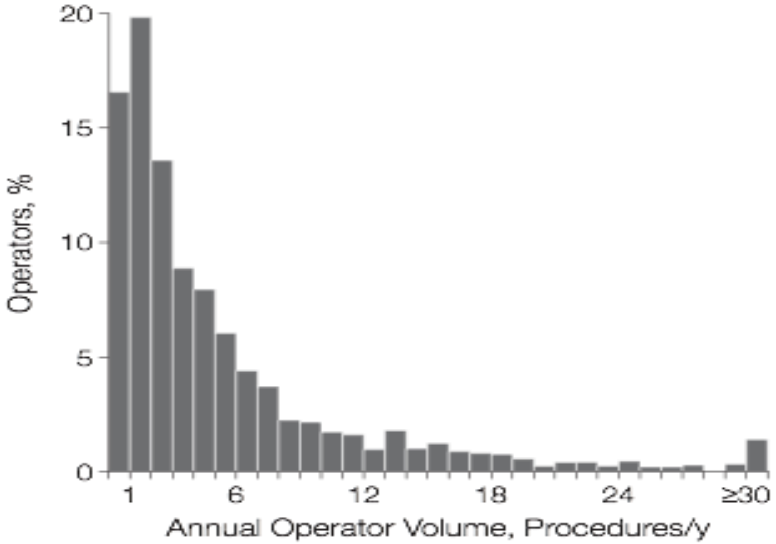
Stroke Prevention





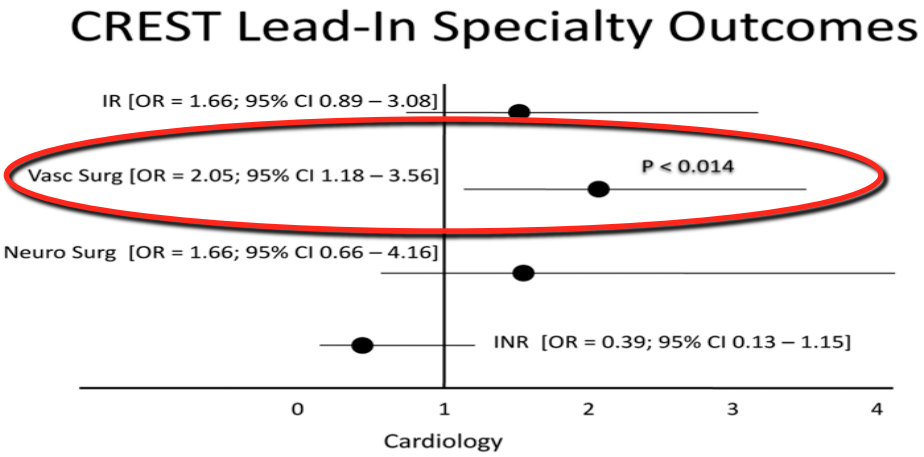
BARRIERS to CAS

- Low volumes.
- No reimbursement.

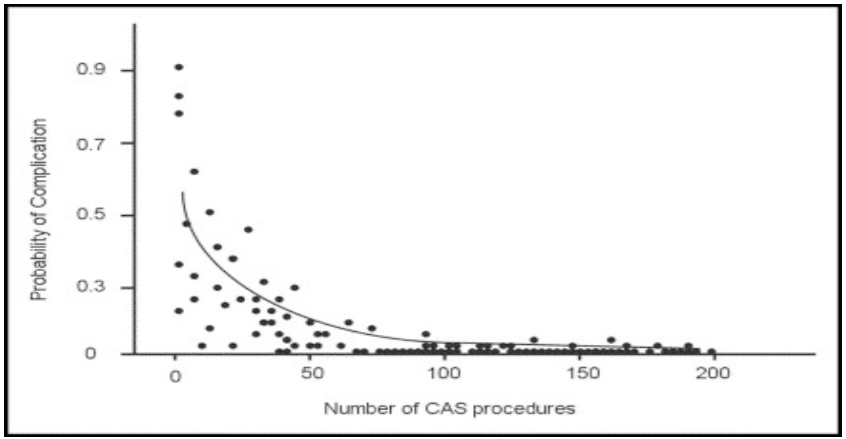


Nallamothu, BK et al JAMA. 2011;306(12):1338-1343

Do I Have to Explain Why Experience Matters ?

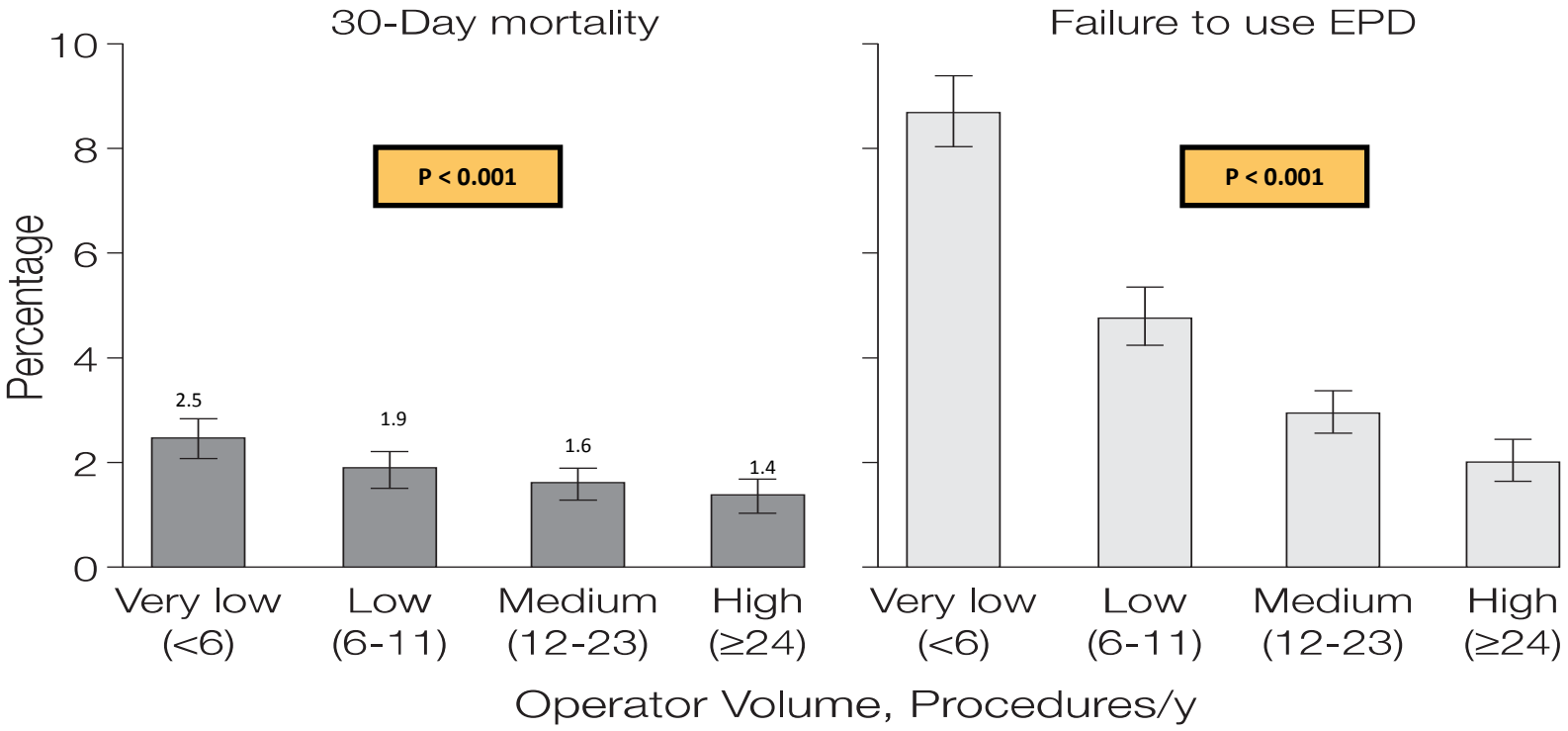


Hopkins LN, et al. J. Stroke and Cerebrovascular Dis. 2010;19:153-162



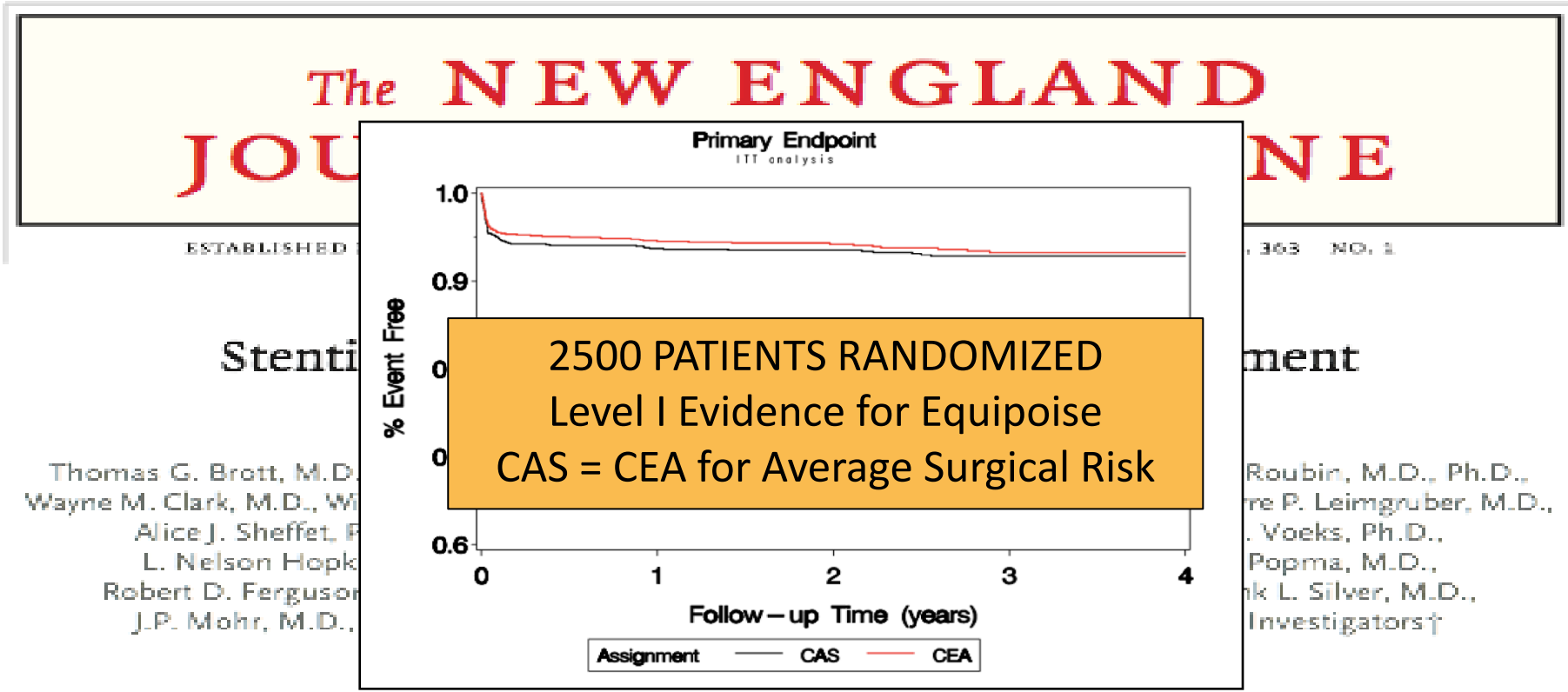
Lin PH, et al. Am J Surg. 2005;190:855-863

Unadjusted Patient Outcomes by Annual Operator Volume



Nallamothu, BK et al JAMA. 2011;306(12):1338-1343

CREST



2500 PATIENTS RANDOMIZED
Level I Evidence for Equipoise
CAS = CEA for Average Surgical Risk

CREST
4-Yr Stroke Events

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 JULY 1, 2010 VOL. 363 NO. 1

Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis

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ABSTRACT

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

METHODS
We randomly assigned patients with symptomatic or asymptomatic car
to undergo carotid-artery stenting or carotid endarterectomy. The prim

stroke (4.1% vs. 2.3%, P=0.01), and for myocardial infarction (1.1% vs. 2.3%, P=0.03). After this period, the incidences of ipsilateral stroke with stenting and with endarterectomy were similarly low (2.0% and 2.4%, respectively; P=0.85).

CONCLUSIONS
Among patients with symptomatic or asymptomatic carotid stenosis, the risk of the composite primary outcome of stroke, myocardial infarction, or death did not differ significantly in the group undergoing carotid-artery stenting and the group undergoing carotid endarterectomy. During the periprocedural period, there was a higher risk of stroke with stenting and a higher risk of myocardial infarction with endarterectomy. (ClinicalTrials.gov number, NCT00004732.)

Table 3. Primary End Point and Its Individual Components among the 1181 Asymptomatic and the 1321 Symptomatic Patients, According to Treatment Group.*

4-Yr Study Period (Including Periprocedural Period)

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

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

*Deceased.
†The Carotid Re... ectomy vs. Sten... tigators and c... listed in the Ap...

This article (10.10... published on Ma... on June 14, 2010...
N Engl J Med 2010...

Brott TG, et. al N Engl J Med. 2010;363:11-23.

John Ochsner Heart & Vascular Institute

EQUIPOISE FOR CAS & CEA

WE DON'T NEED MORE TRIALS....WE NEED TO USE THE DATA WE HAVE TO ALLOW PHYSICIANS AND PATIENTS TO MAKE REASONABLE CHOICES, BASED UPON THE EVIDENCE.

- ★ Patients with CAD.
- ★ Younger age.
- ★ Experienced operator.
- ★ Experienced team.

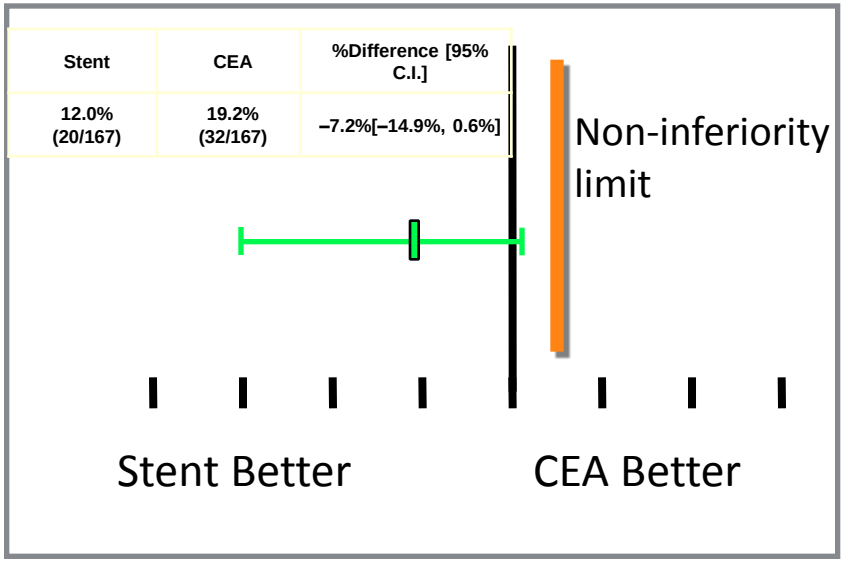
- ★ High CAS risk.
- ★ Older age.
- ★ Experienced operator.
- ★ Experienced team.

FACT(s)

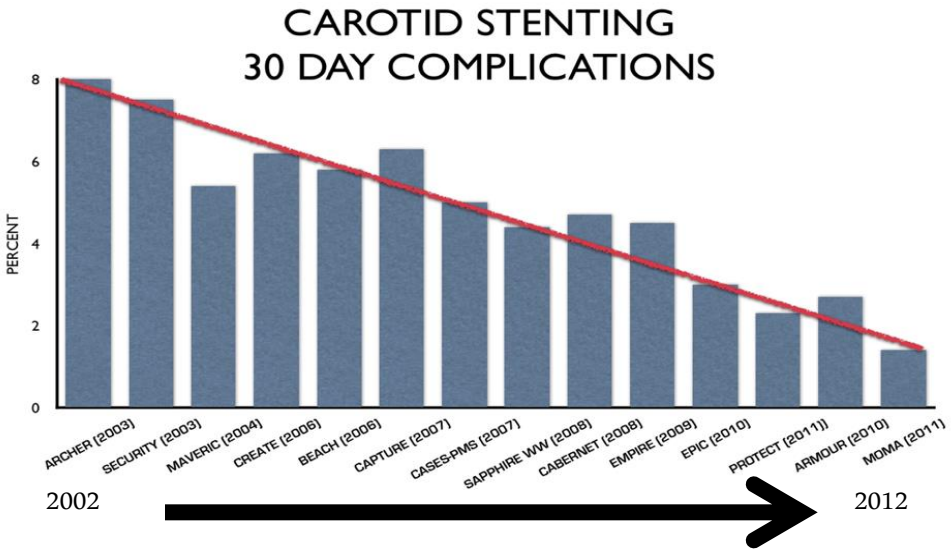
"One size does not fit all"

- There IS overall equipoise for CEA and CAS but….
  - Patient selection for CEA/CAS should be individualized.
  - Operator and Institutional volume matter for outcome quality in both CEA and CAS.
  - Symptomatic patients have more to gain than Asx.
  - Younger patients have more to gain, over the long-term, from revascularization, than do the very elderly.

High Surgical Risk



- Sapphire: Level I evidence supporting equipoise for CAS and CEA.



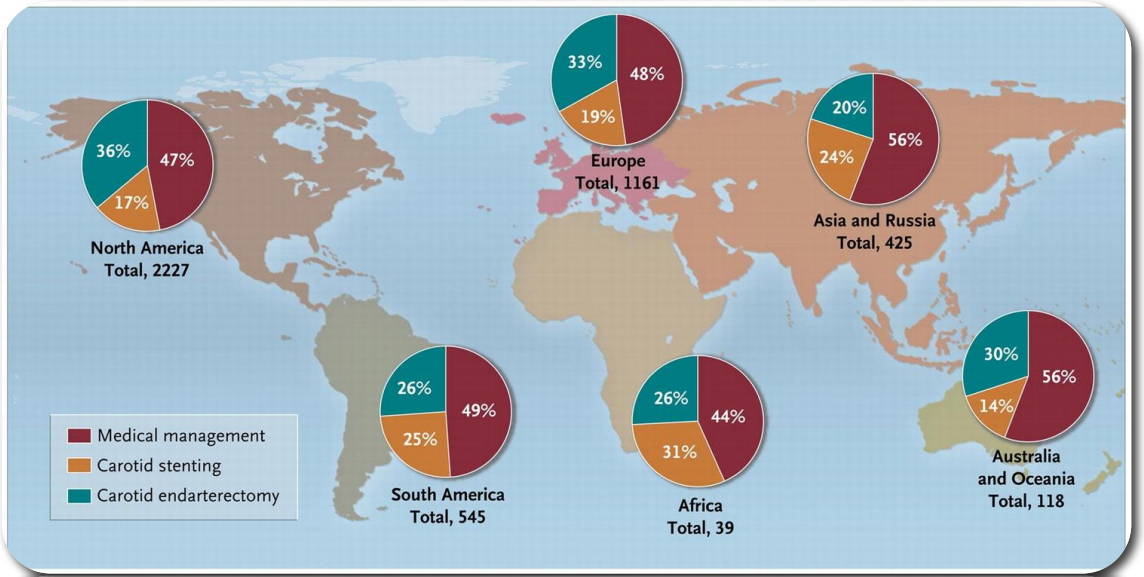
CAS Preferred in High Surgical Risk Patients


Courtesy of David Holmes MD

- Some patients present difficult challenges for CEA, and may be offered CAS as an alternative.
- Some patients who are at increased risk for CEA will strongly prefer CAS.
- Assumes operator and institutional experience and a track record for safety and quality.

Percent Choosing Treatment Options

- 67-year-old man with a carotid bruit and 70%-80% RICA.
  - nonsmoker
  - hypertension
  - hyperlipidemia
  - LICA 20% stenosis.



Klein, A, et al. *New England Journal of Medicine* 358.20 (2008): 1617-1621.

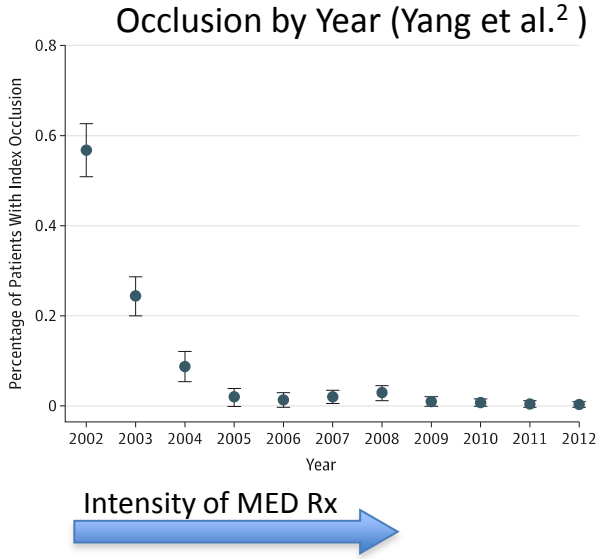
Asymptomatic Carotid Stenosis

- ACAS[1] and ACST[2] in the 1990's:
  - CEA vs. MED
    - 5 yr relative risk reduction for ipsilateral stroke 50%.
    - 1 yr absolute risk reduction of 0.5% to 1.0%.
    - NNT 100-200 to prevent one stroke per year.
    - CEA did not reduce combined stroke and death.
    - CEA did not benefit women.
    - CEA did not benefit men ≥ 75 years.
  - CMS 2004-2006
    - Asx CEA = 88%, Asx CAS = 87%.

1. Barnett HJ, et. al. N Engl J Med 1998; 339:1415–25. 2. Halliday A, et al. Lancet 2010;376: 1074–84.

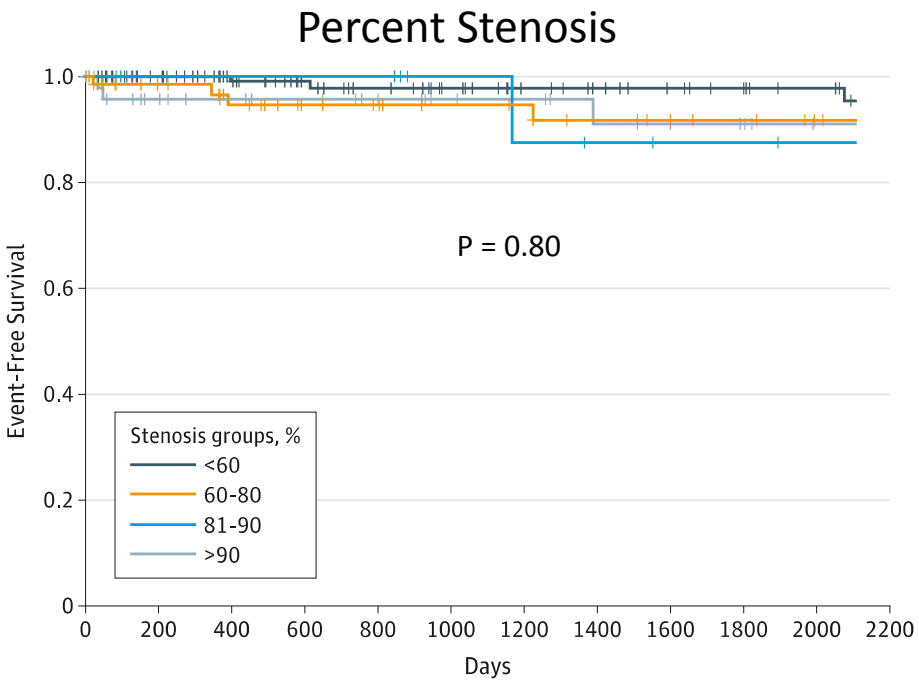
Asymptomatic Carotid Stenosis

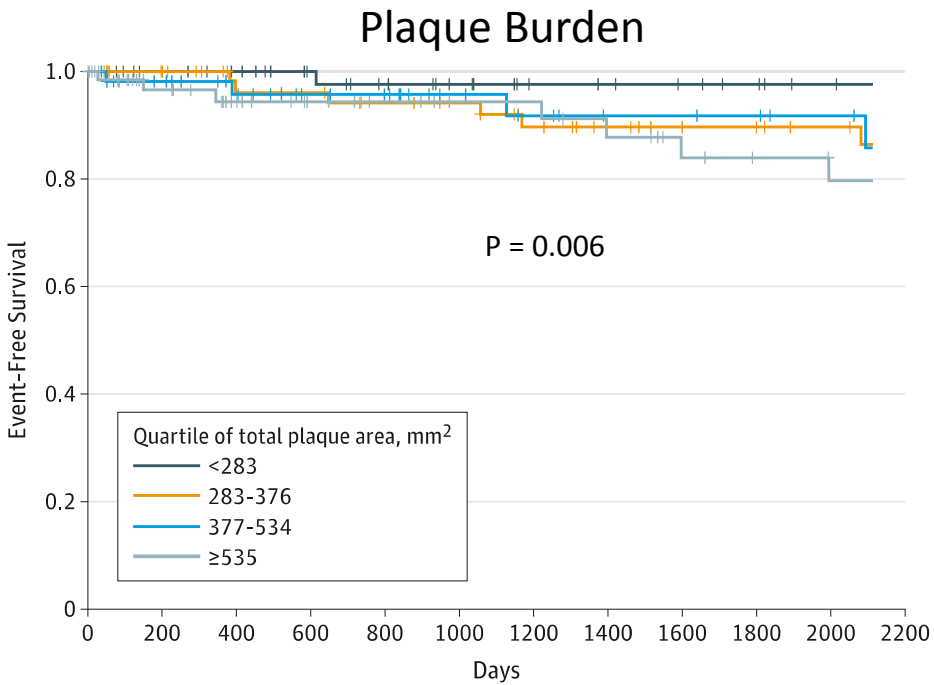
- Risk of progression to occlusion is low.
  - ACST[1]: 1,469 MED Group:
    - 94 progressed to occlusion.
    - 12 with symptoms.
    - 1 with stroke.
  - Yang et al[2].: 3,681 MED for 20 yrs.
    - 254/316 (80%) Occlusions before 2002.
    - Only 1 stroke with occlusion.



1. Halliday A, et al. Lancet 2010;376: 1074–84. 2. Yang, et al. JAMA Neurol. doi:10.1001/jamaneurol.2015.1843

Asymptomatic Carotid Stenosis





Yang, et al. JAMA Neurol. doi:10.1001/jamaneurol.2015.1843

Consensus CAS vs. CEA

Asymptomatic

- Selection of asymptomatic patients for revascularization should be based on comorbid conditions and patient life expectancy (Class I, Level of Evidence: C).
- Highly selected patients may benefit from CEA if the perioperative stroke/death rate is <3% (Class IIa, Level of Evidence: A).
- CAS might be considered in highly selected patients if the perioperative stroke/death rate is <3% (Class IIb, Level of Evidence: B).
- The usefulness of CAS is not well established for patients at high risk for CEA (Class IIb, Level of Evidence: C).

Symptomatic

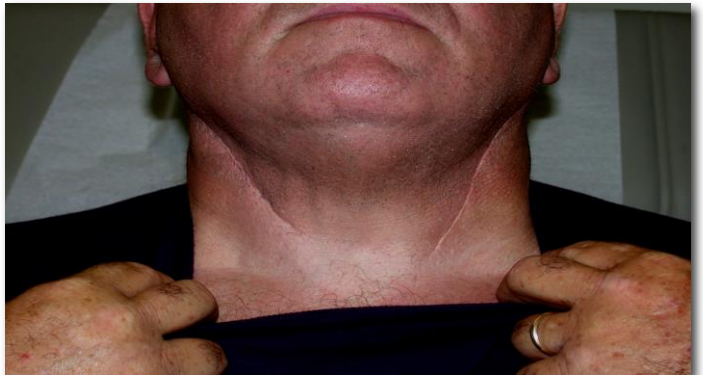
- Patients with a TIA or stroke ≤ 6 months and ipsilateral severe stenosis (70% to 99%), CEA is recommended if the perioperative stroke/death rate is estimated to be <6% (Class I, Level of Evidence: A).
- CAS is indicated as an alternative to CEA if the anticipated perioperative stroke/death rate is <6% (Class IIa, Level of Evidence: B).
- When revascularization is indicated, it is reasonable to perform it within 2 weeks rather than delay (Class IIa, Level of Evidence: B).
- It is reasonable to consider patient age in choosing between CEA and CAS (Class IIa, Level of Evidence: B).

Chaturvedi, S. et al. J Am Coll Cardiol. 2015; 65(11):1134–43.

FACT(s)

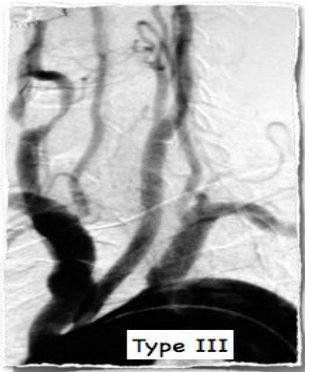
Patients hard to operate on safely.

- Class III/IV angina.
- Class III/IV heart failure.
- Intrathoracic or intracerebral lesions.
- Prior neck surgery or RT.



Patients hard to place stents safely.

- Type III Aortic Arch.
- Tortuous and calcified lesions.
- Unable to use EPD.
- Difficult vascular access.



Stroke Prevention Strategy

Revascularization includes aggressive risk factor modification.

CREST-2

	No Symptoms	Yes Symptoms
Asymptomatic Carotid Stenosis	CAS or MED	CAS
Symptomatic Carotid Stenosis	CAS/CEA or MED	CAS or CEA

Sapphire

CREST

or

Thank You