



HARVARD MEDICAL SCHOOL  
TEACHING HOSPITAL



# When to Intervene in Asymptomatic Carotid Artery Stenosis

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VASCULAR AND STROKE CARE

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## Conflicts of Interest

- **Consultant**

- Abbott Vascular (non-compensated)
- American Genomics, Inc
- Astra Zeneca Pharmaceuticals, Inc
- Biomet Biologics
- Boston Scientific (non-compensated)
- Cordis Corporation (non-compensated)
- Covidien (non-compensated)
- Ekos Corporation (DSMB)
- Medtronic (non-compensated)
- Micell, Inc
- Primacea

- **Board Member**

- VIVA Physicians (Not For Profit 501(c) 3 Organization)
  - [www.vivapvd.com](http://www.vivapvd.com)
- CBSET

- **Equity**

- Access Closure, Inc
- Embolitech, Inc
- Hotspur, Inc
- Icon Interventional, Inc
- I.C.Sciences, Inc
- Janacare, Inc
- MC10
- Northwind Medical, Inc.
- PQ Bypass, Inc
- Primacea
- Sadra Medical
- Sano V, Inc.
- Vascular Therapies, Inc

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# Stroke Stats

- Fourth leading cause of death in the US
  - 134,138 deaths in 2008
  - 1 out of 18 deaths due to stroke in US
    - One American dies of a stroke every 4 minutes
- Most common cause of adult disability
  - 31% of stroke survivors receive outpatient rehabilitation
    - 50% with some hemiparesis
    - 30% unable to walk without some assistance
    - 26% dependent in ADLs
    - 35% depressed
    - 26% institutionalized in a nursing home

# Stroke Costs

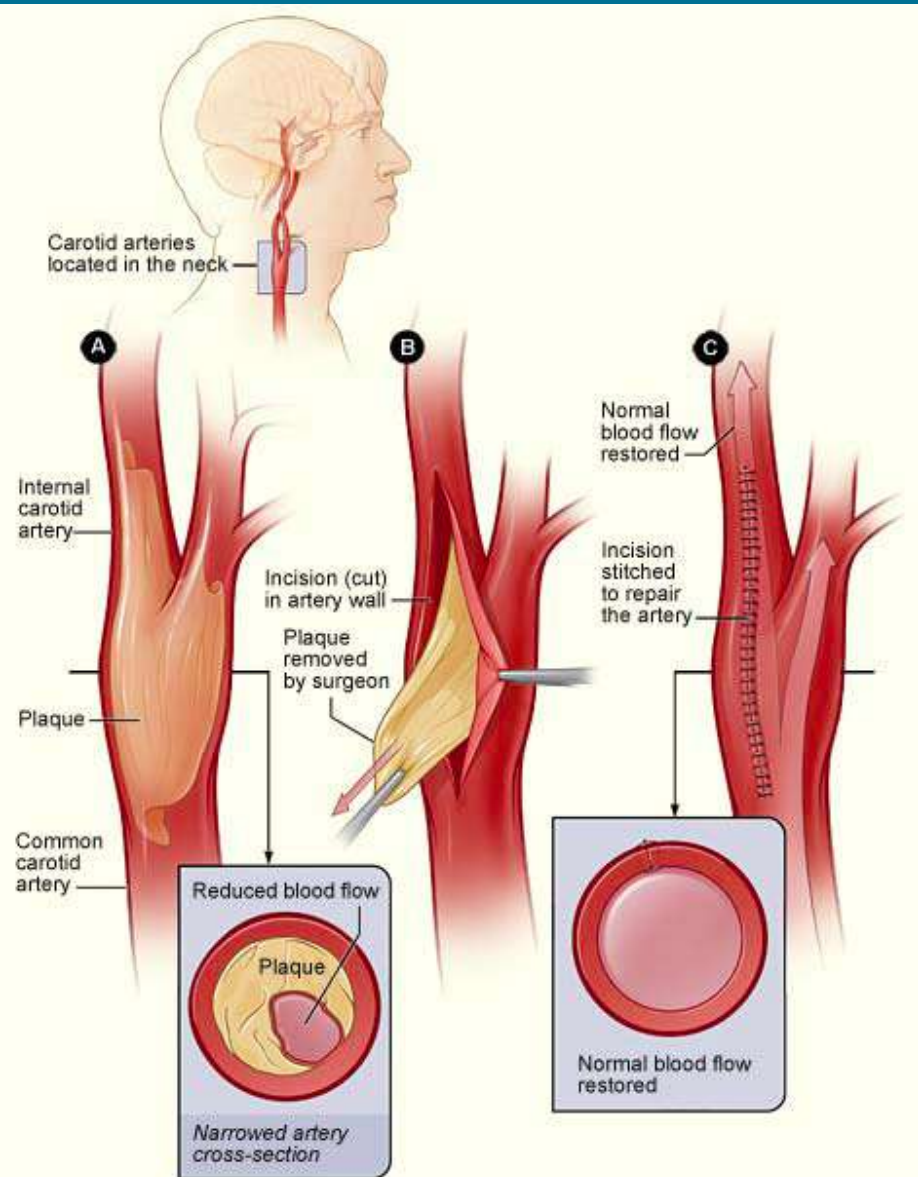
- Total cost of stroke care 2005-2050 (in 2005 dollars)

**\$1.52 Trillion---Non-Hispanic Whites**  
**\$313 Billion---Hispanics**  
**\$379 Billion---Blacks**

# Recommendations for Primary Stroke Prevention

- ASA
- SBP <140 mmHg/DBP <90 mmHg
- Abstinence from cigarette smoking
- Diabetes
- Hypertension
  - JNC VII Blood Pressure Control (ACEI/ARB)
- Hypercholesterolemia
  - Statins for LDL goal NCEP/ATP III Goals

# Carotid Endarterectomy



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# What We Know about CEA vs Medical Therapy

Trial Name	n	Eligible Stenosis, %	Symptom Status	Operative Death or Stroke, %	Ipsilateral Stroke, CEA vs Medical (ARR, <i>P</i> ), %	Death or Stroke, CEA vs Medical (AAR, <i>P</i> ), %
NASCET	2885	30–99	Symptomatic	6.7	9.0 vs 26.0* (17.0, <i>P</i> <0.001) 15.7 vs 22.2† (6.5, <i>P</i> =0.045)	15.8 vs 32.3* (16.5, <i>P</i> <0.001) 33.2 vs 43.3† (10.1, <i>P</i> =0.005)
ECST‡	3018	Any	Symptomatic	7.5	(18.7, <i>P</i> <0.0001)* (2.9, <i>P</i> =0.05)†	(21.2, <i>P</i> <0.0001)* (5.7, <i>P</i> =0.05)†
ACAS§	1662	>60	Asymptomatic	2.3	5.1 vs 11.0 (5.9, <i>P</i> =0.004)	25.6 vs 31.9 (6.3, <i>P</i> =0.08)
ACST	3120	>60	Asymptomatic	2.8	Total not reported	6.4 vs 11.8 (5.4, <i>P</i> <0.0001)
VA Cooperative	444	>50	Asymptomatic	3.8	4.7 vs 9.4 (4.7, <i>P</i> =0.06)	41.2 vs 44.2 (3.0, <i>P</i> >0.05)

Circulation 2012;126:2636-2644



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# Why Carotid Endarterectomy?

- Procedure has been around for a long time (over 50 years)
- Techniques perfected
- Results repeatedly solid
- The gold standard
- Patients often discharged within 24 hours
- Never see the inside of an ICU



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# Are There Patients at High Risk for CEA?

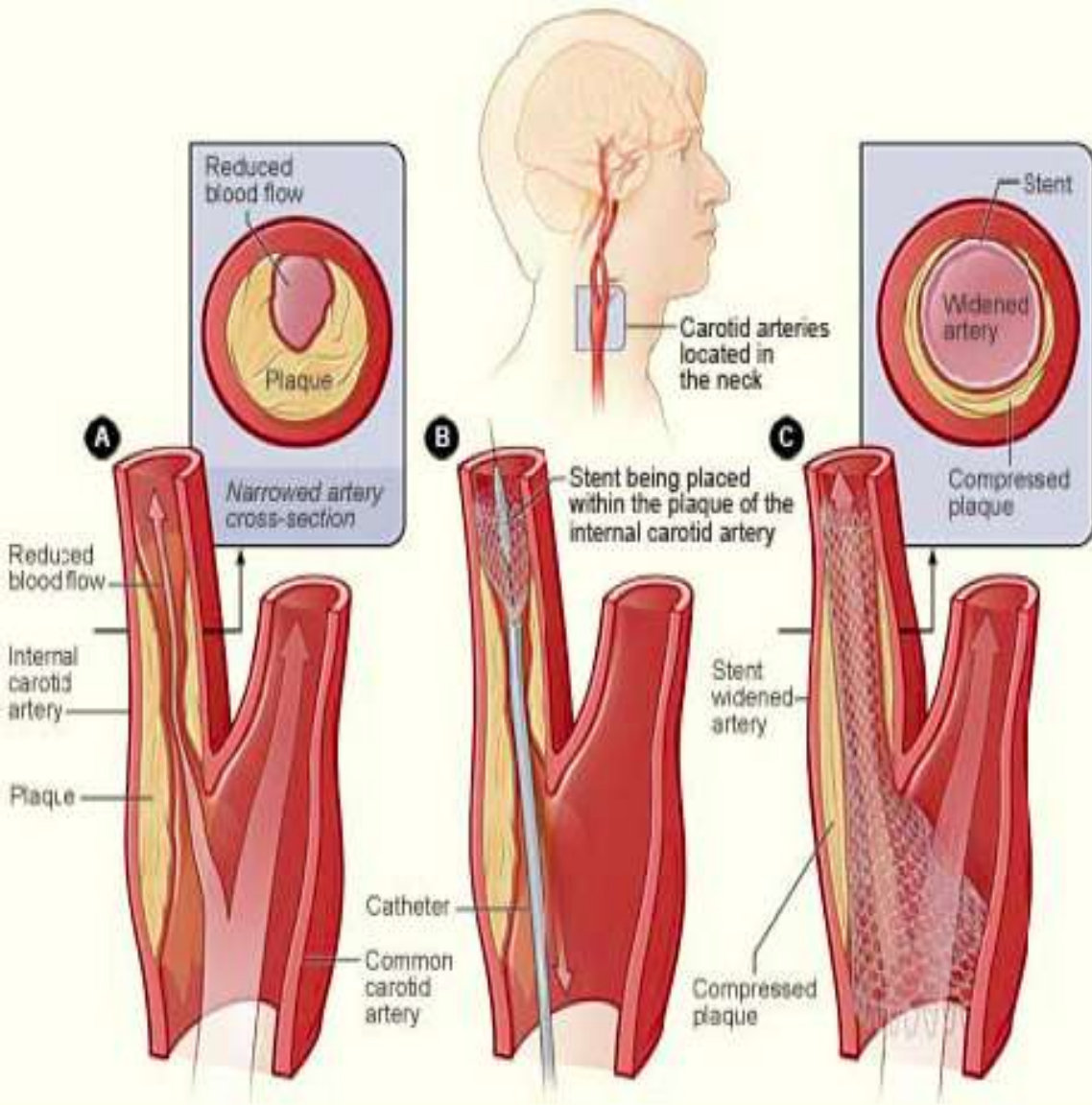
Anatomic (1 Factor From Below)	Comorbid Clinical Conditions (1 Factor From Below)	Comorbid Clinical Conditions ( $\geq 2$ Factors From Below)
Contralateral carotid occlusion*	Age $>80$ y	Age $\geq 75$ y
Previous CEA with recurrent stenosis*	Recent myocardial infarction*	$\geq 2$ Proximal or major diseased coronary arteries with $\geq 70\%$ stenosis that have not been or cannot be revascularized
Prior radiation treatment to the neck* or radical neck surgery	Congestive heart failure class III/IV*	Planned peripheral vascular surgery or other major surgeries after carotid stenting
Surgically inaccessible lesion (eg, lesions above the level of C2 or below the clavicle)	Left ventricular ejection fraction $\leq 30\%$	
Tracheostoma or tracheostomy	Unstable angina*	
Contralateral laryngeal nerve (cranial nerve IX) palsy or laryngectomy	Dialysis-dependent renal failure	
Tandem lesions $\geq 70\%$ stenosis	Severe pulmonary disease FEV <sub>1</sub> $\leq 30\%$ predicted	
At risk for wound infection	Currently on a list for major organ transplantation (ie, heart, lung, liver, kidney) or is being evaluated for such	
Carotid artery dissection	Uncontrolled diabetes mellitus defined as fasting glucose $>400$ mg/dL and ketones $>2+$	
	Spinal immobility: inability to flex neck beyond neutral or kyphotic deformity	
	Concurrent requirement for aortocoronary bypass or cardiac valve surgery	
	History of liver failure with elevated prothrombin time	



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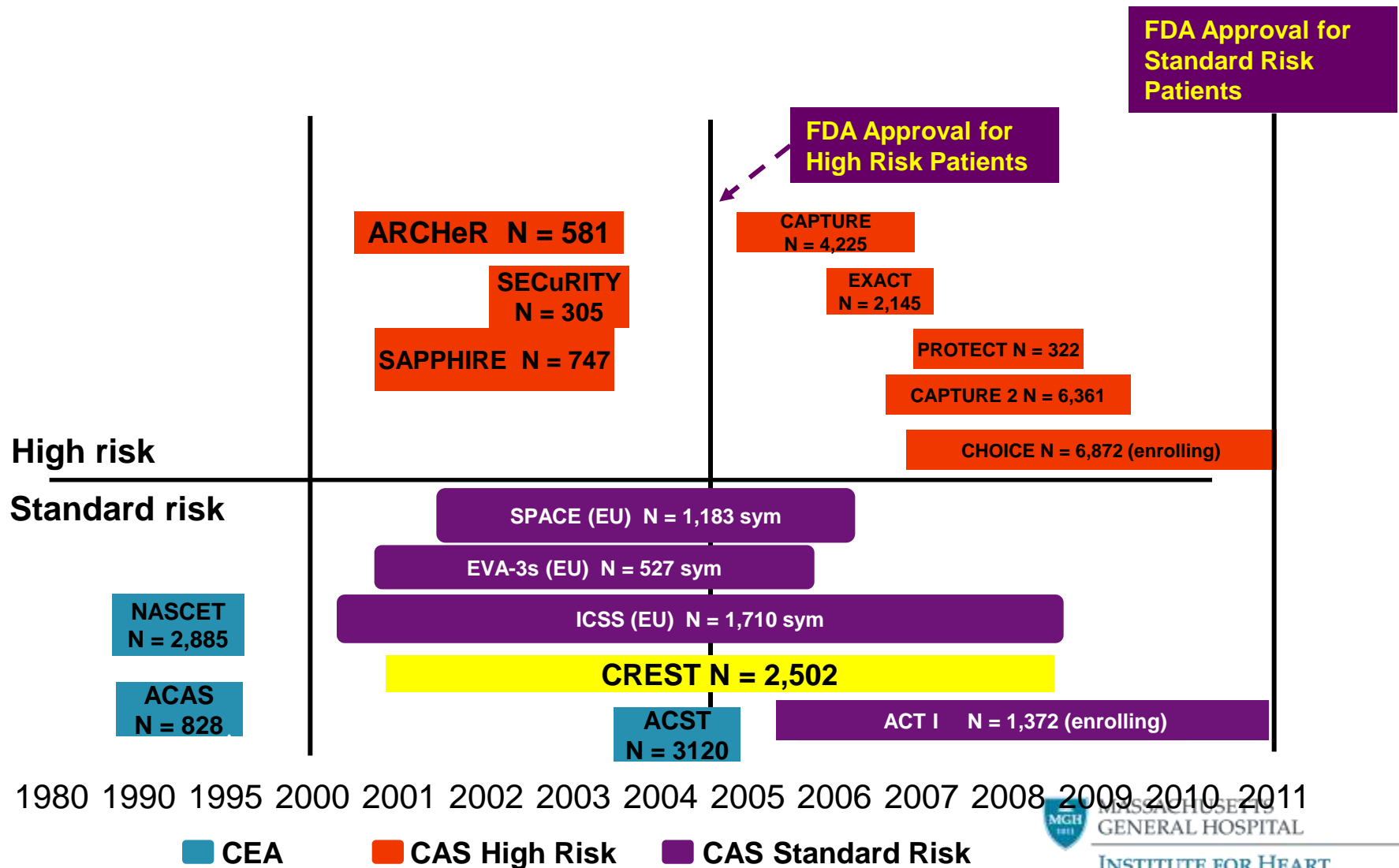
# Carotid Artery Stent



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# Clinical Trials Evaluating CAS



# Why Carotid Stenting?

- No surgical incision
- No need for general anesthesia
  - Conscious Sedation
- Useful in patients at high risk for CEA



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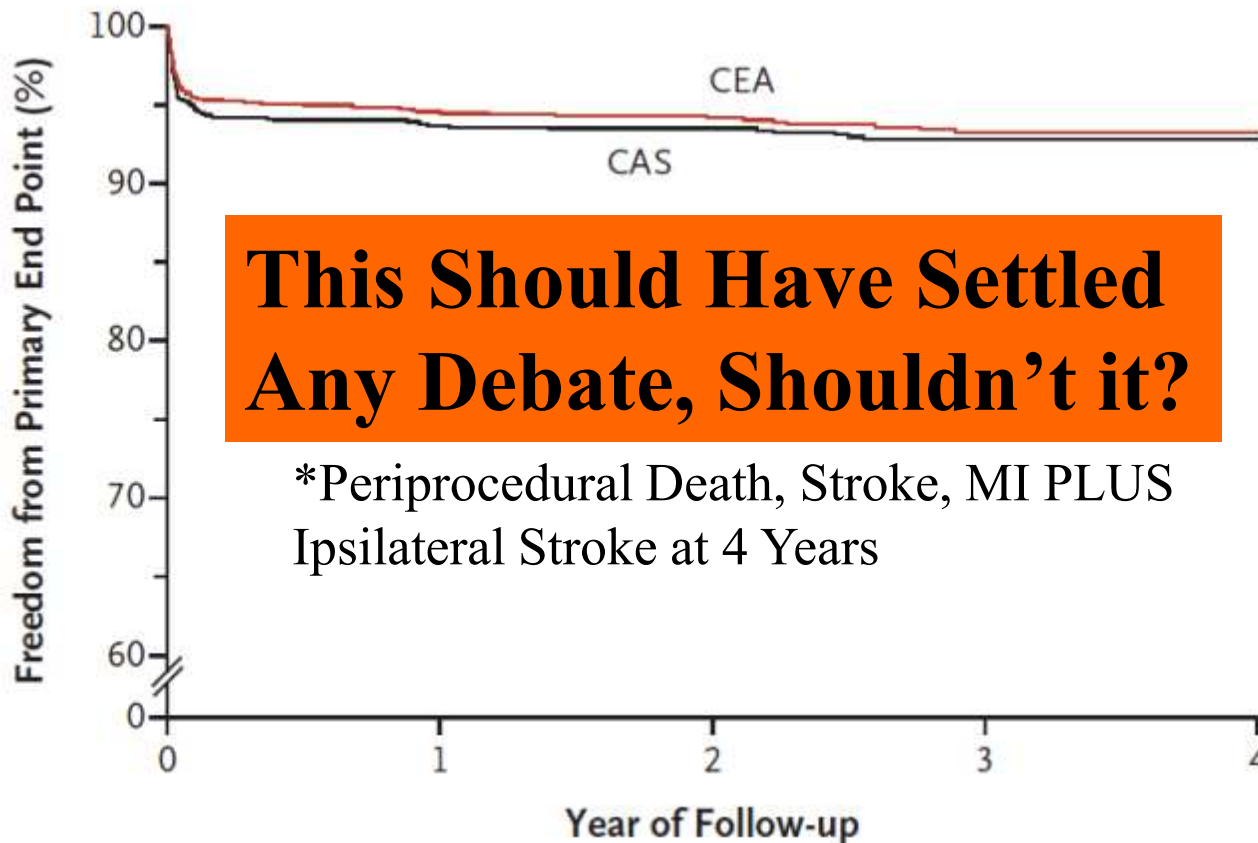
# All Leading Up to the Mother of All Carotid Trials...

## Stenting versus Endarterectomy for Treatment of Carotid-Artery Stenosis

Thomas G. Brott, M.D., Robert W. Hobson, II, M.D.,\* George Howard, Dr.P.H., Gary S. Roubin, M.D., Ph.D., Wayne M. Clark, M.D., William Brooks, M.D., Ariane Mackey, M.D., Michael D. Hill, M.D., Pierre P. Leimgruber, M.D., Alice J. Sheffet, Ph.D., Virginia J. Howard, Ph.D., Wesley S. Moore, M.D., Jenifer H. Voeks, Ph.D., L. Nelson Hopkins, M.D., Donald E. Cutlip, M.D., David J. Cohen, M.D., Jeffrey J. Popma, M.D., Robert D. Ferguson, M.D., Stanley N. Cohen, M.D., Joseph L. Blackshear, M.D., Frank L. Silver, M.D., J.P. Mohr, M.D., Brajesh K. Lal, M.D., and James F. Meschia, M.D.,  
for the CREST Investigators†



# CREST Primary Endpoint\*



**This Should Have Settled  
Any Debate, Shouldn't it?**

\*Periprocedural Death, Stroke, MI PLUS  
Ipsilateral Stroke at 4 Years



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# Why Didn't CREST End the Debate?

- Surgeons feel that carotid revascularization is performed for stroke prevention
  - CEA reduced stroke risk more than CAS
  - Excess MI rate with CEA less of an issue
- Interventionists feel that CAS performed as safely as CEA
  - Excess stroke risk was minor stroke only
  - MI risk of CEA is important
- Neurologists feel that although outcomes were low, medical therapy is more effective than *any* revascularization



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# So, What Do We Know?

## Options for Patients with Carotid Artery Disease

- CEA: Effective when performed by skilled surgeons with excellent track record
- CAS: Effective when performed by skilled interventionists
- Medical Therapy: Still must be tested head-to-head with revascularization, but impact likely improving—

**CREST 2, ACST 2, SPACE 2**



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