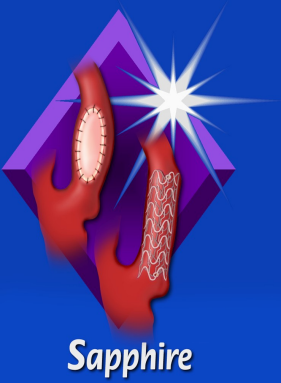


***2006 Considerations for Carotid  
Stenting Credentialing and Practice:  
Training, volume issues, reimbursement***

**Jay S. Yadav MD**

**Cleveland, OH**

**TCT 2006**



# *Disclosures*

- ◆ Inventor of Angioguard
- ◆ Advisory Board: Cordis, Abbott



April 22, 2004

Health & Science

# Stenting to prevent stroke clears early FDA hurdle

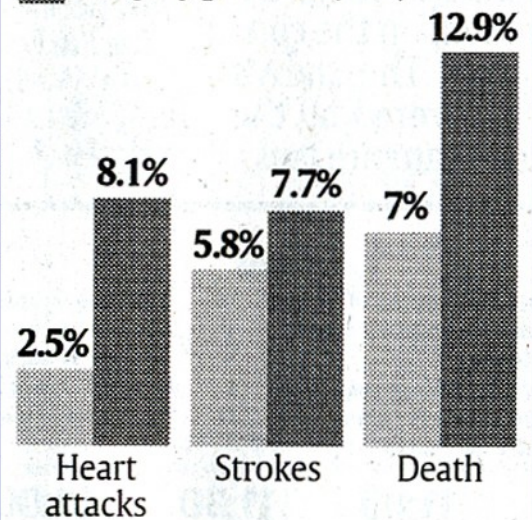
*the new stent for the carotid . . . is expected to put a dent in the need for carotid artery surgery.*

## Stroke prevention without surgery

Of 310 high-risk patients who received treatment in the Sapphire study, the number who suffered:

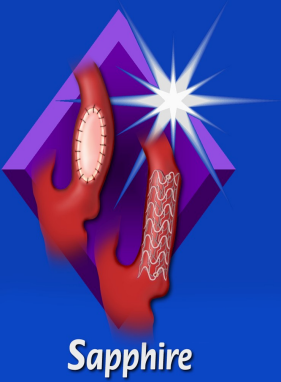
Stent patients (159)

Surgery patients (151)



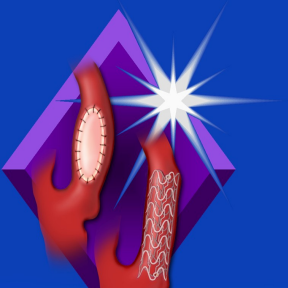
Note: After one year

Source: Sapphire study, Jay Yadav of the Cleveland Clinic



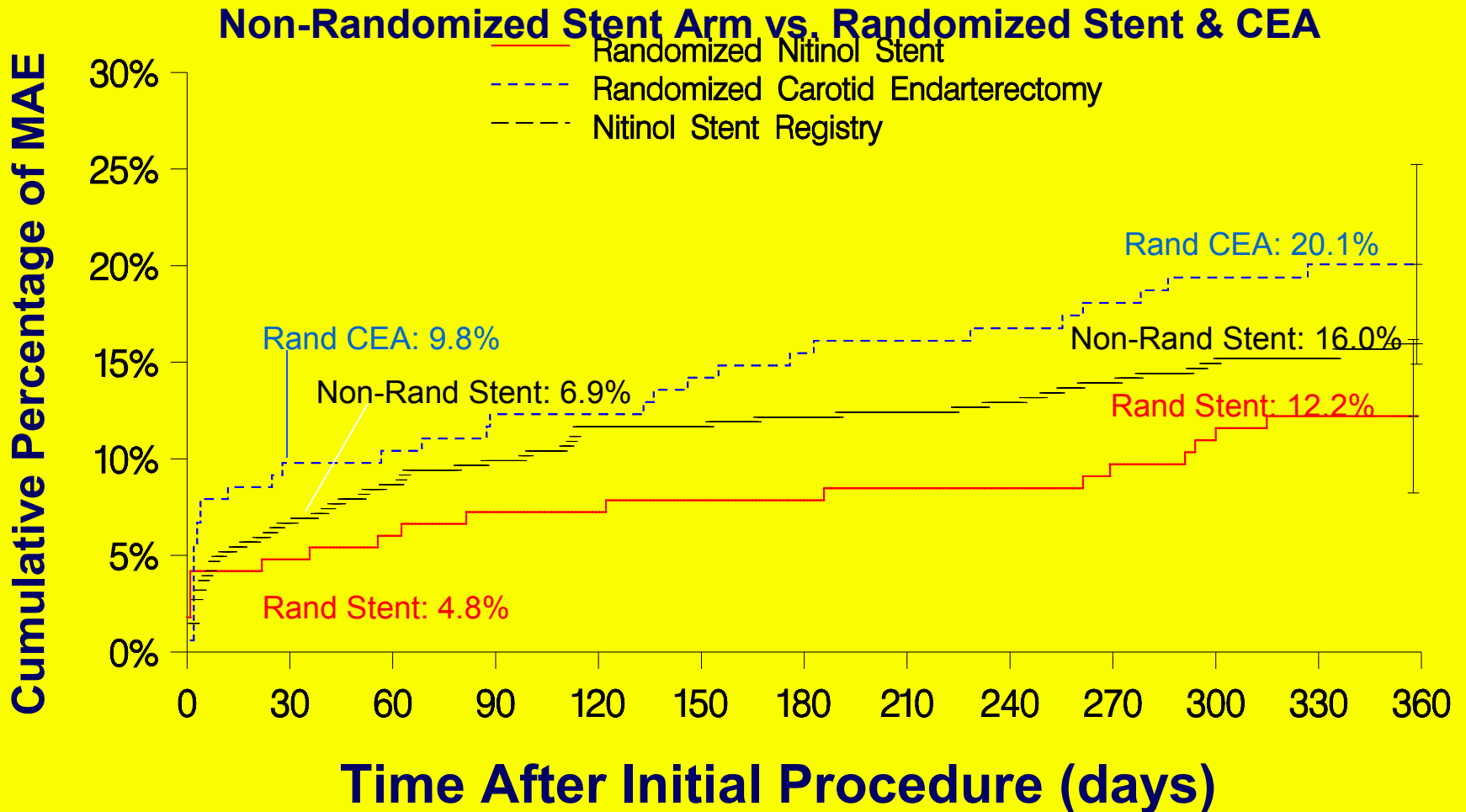
# *High-Risk Patient Trials - Carotid Stenting with Emboli Protection*

- ◆ **Randomized against Surgery**
  - ◆ **SAPPHIRE**
- ◆ **Non-Randomized Registries**
  - ◆ **ARCHER**
  - ◆ **SHELTER / BEACH**
  - ◆ **MAVERICK**
  - ◆ **CABERNET**
  - ◆ **SECURITY**



# SAPPHIRE STUDY

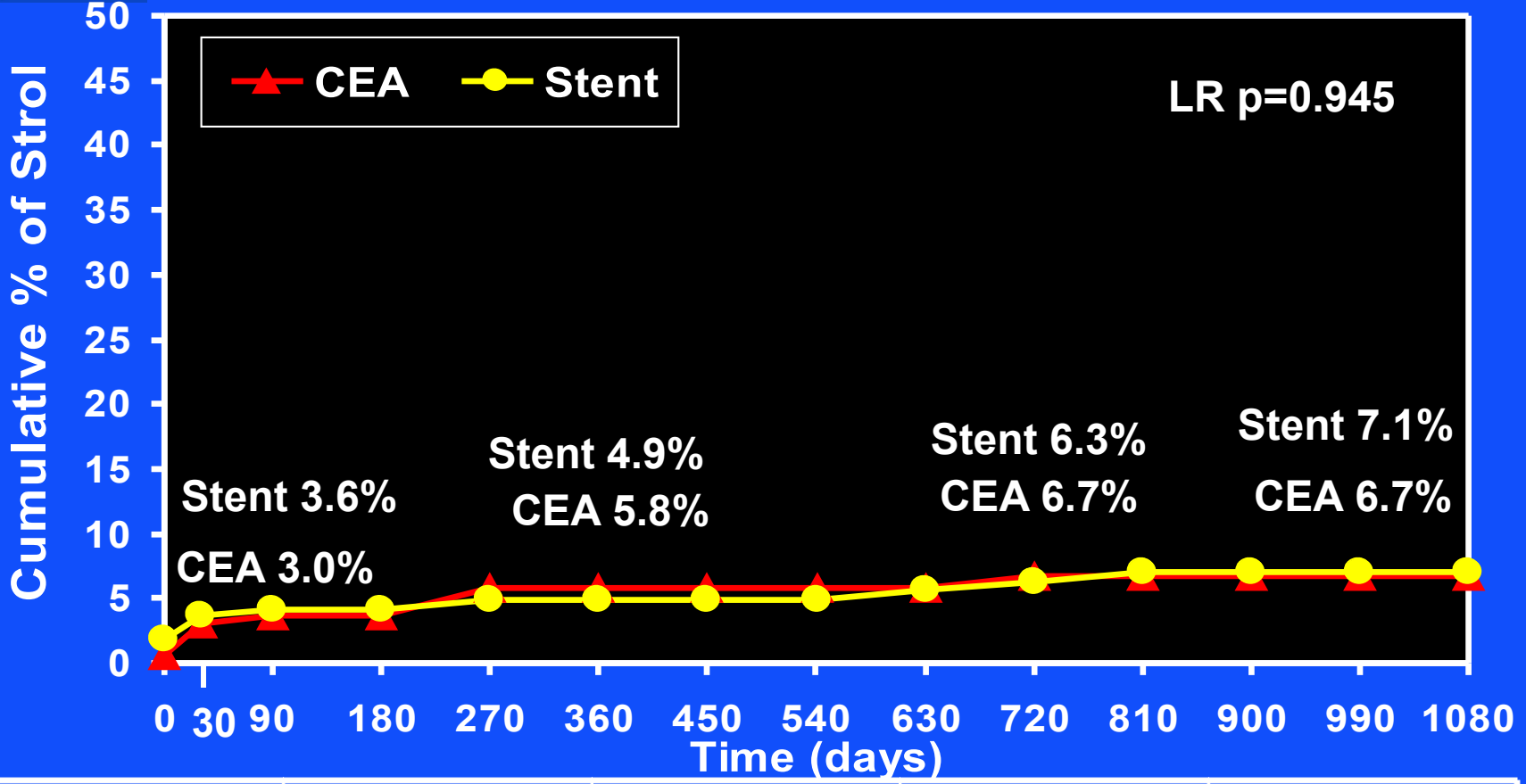
## MAE at 360 Days



# Cumulative Percentage of Stroke to 30 Days and Ipsilateral Stroke from 31 to 1080 Days

Sapphire

Randomized Patients



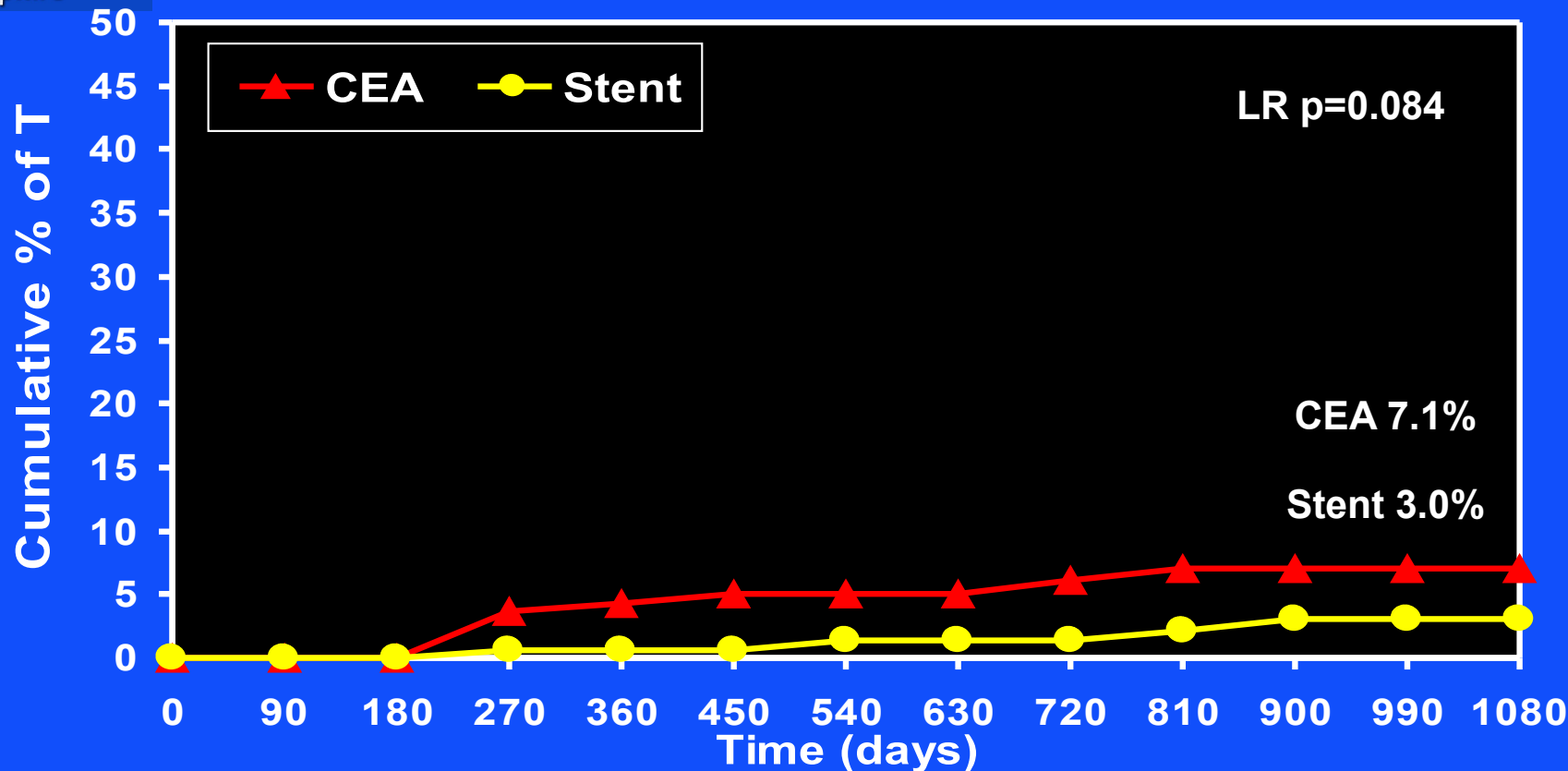
Days:	0	360	720	1080
CEA:	167	150 (90%)	134 (80%)	112 (67%)
Stent:	167	161 (96%)	154 (92%)	139 (83%)



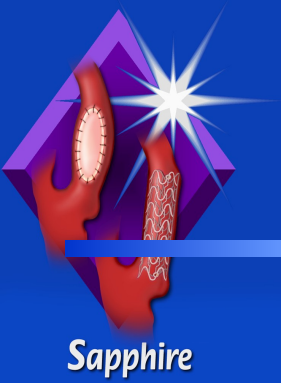
# Cumulative Percentage of Target Lesion Revascularization at 1080 Days

Sapphire

Randomized Patients



Days:	0	360	720	1080
CEA:	167	150 (90%)	134 (80%)	112 (67%)
Stent:	167	161 (96%)	154 (92%)	139 (83%)

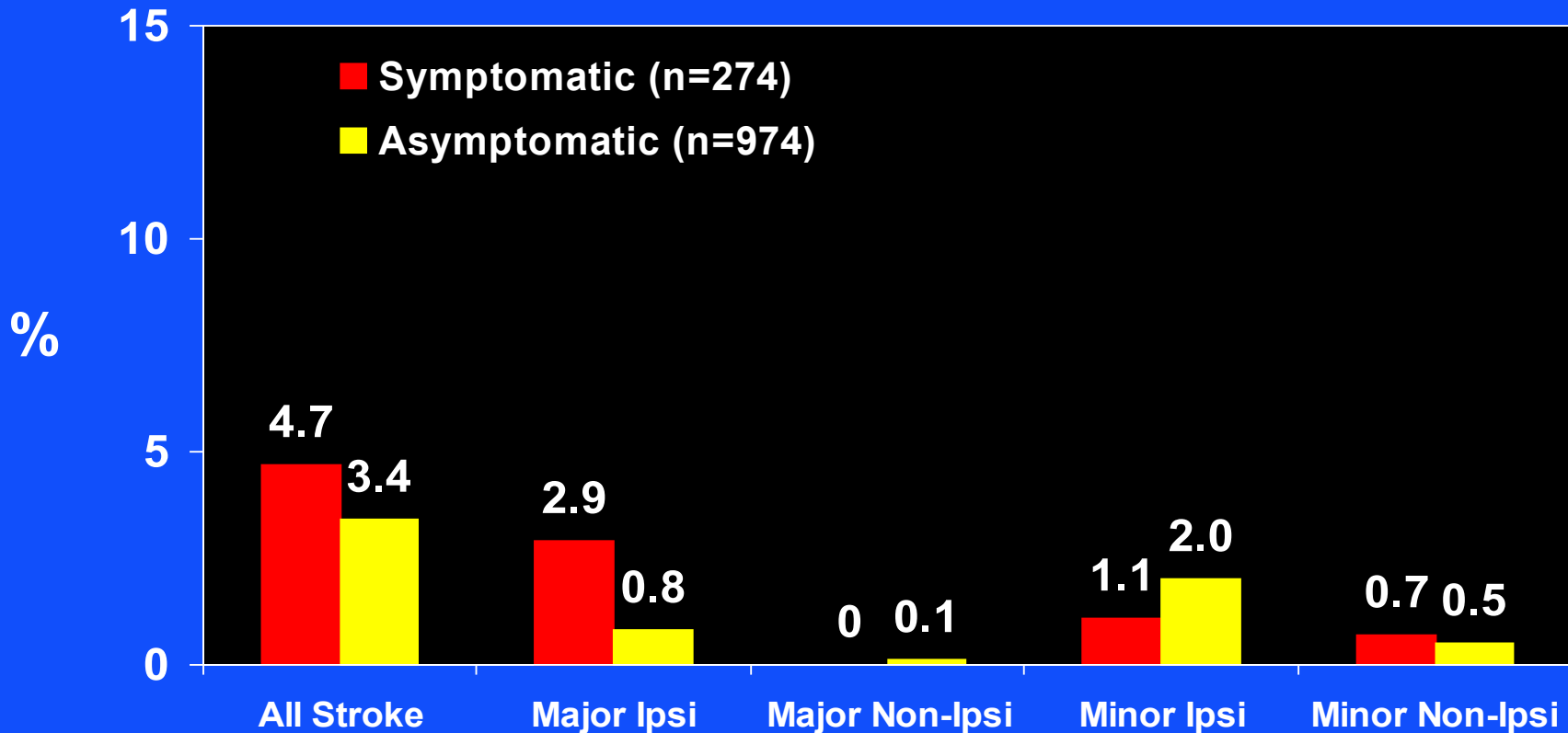


Sapphire

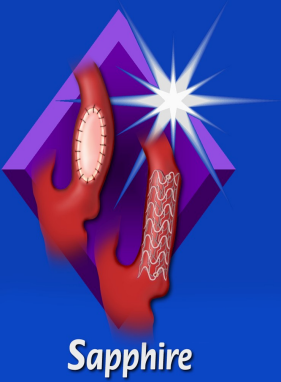
CASES -PMS

# Stroke at 30-Days

## Symptomatic vs. Asymptomatic







# *High Risk Trials/Registries:*

Sapphire  
Archer  
Maveric

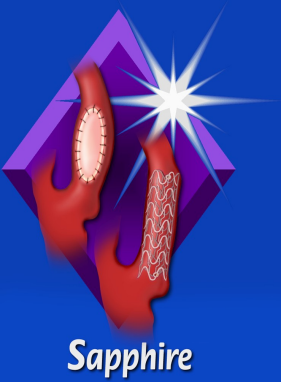
Beach  
Security → 2,400 patients  
Cabernet

World Registry  
Carotid Stenting → 11,035 patients

German Carotid Registry → 2,427 patients  
**16,070 patients**

**How much more data do we need?!?!**

*Low to Moderate Risk  
Patients*

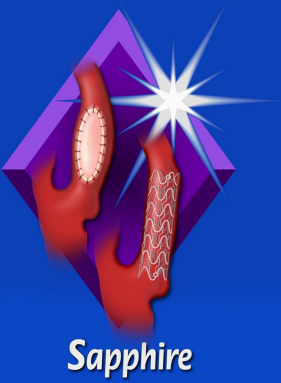


# *Moderate Risk Patients – CREST Lead In*

## 30 day Stroke/Death

◆ 527 Pts	3.4%	
◆ Asx	2.4%	<ACAS
◆ Sx	5.6%	<NASCET
◆ < 60 yrs:	2%	
◆ Lenox Hill 187 pts	1.6%	

Hobson, AHA 2003



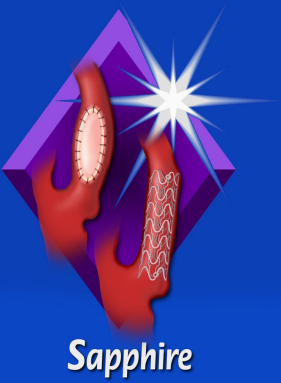
# *CARESS Lead In – Low Risk*

## 30 Day Events

	CEA	Stent
--	-----	-------

Stroke/Death	2%	2%
--------------	----	----

Stroke/Death/MI	3%	2%
-----------------	----	----



# *Who Should Treat Patients with Carotid Disease ?*

- ◆ **Cardiologists**
- ◆ **Radiologists**
- ◆ **Surgeons**
- ◆ **Neurologists**
- ◆ **Vascular Internists**

# Task Force 11: Training in Vascular Medicine and Peripheral Catheter-Based Interventions

MARK A. CREAGER, MD, FACC, CHAIR  
JOHN P. COOKE, MD, PHD, FACC  
JEFFREY W. OLIN, DO, FACC\*  
CHRISTOPHER J. WHITE, MD, FACC

# COCATS

ACC March 2002

Vascular diseases are encountered frequently by cardiovascular physicians. Atherosclerosis and thrombosis, in particular, are systemic disorders with clinical manifestations in most peripheral circulations. These and other diseases account for substantial cardiovascular morbidity and mortality. Moreover, technological advances in diagnostic techniques and catheter-based interventions have improved the management of vascular diseases. However, the training of the cardiovascular specialist in vascular medicine during residency has been inadequate to address the needs of contemporary practice in vascular medicine.

**Level 1—** Fellows should receive training to care for many patients with vascular disease.

**Level 2—** Additional training for fellows who wish to develop special expertise in evaluating and managing patients with vascular disease. This level does not include training in catheter-based interventions.

**Level 3—** Training for noncoronary catheter-based vascular interventions. This level of training is to ensure that the fellow develops both the cognitive and technical skills requisite to making appropriate decisions regarding invasive and interventional treatment of patients with vascular disease.

## **Level 1: Basic Training for Cardiovascular Fellows**

The essentials of vascular medicine should be provided to all fellows. Vascular medicine training should be a core component of the fellowship program and include the essentials of the diagnosis and management of vascular diseases, exposure to noninvasive diagnostic modalities, angiography, and peripheral catheter-based interventions. At least the equivalent of 2 months of the fellowship, either as dedicated rotations or in the aggregate as an integral component of other rotations, should be devoted to vascular medicine. Acquisition of this fundamental knowledge will permit the fellow to recognize a broad array of vascular diseases and common medical disorders associated with vascular disease, to initiate appropriate med-

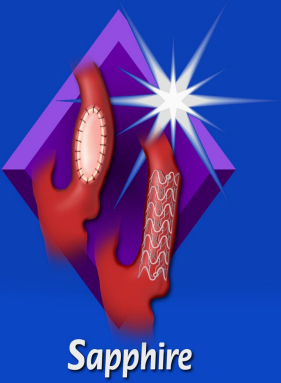
ication, and to refer patients for appropriate medical or surgical intervention. This level of training, however, is not sufficient to qualify the trainee as a vascular specialist capable of managing complex vascular patients.

**Level 1—** Basic training in vascular medicine that all fellows should receive to acquire a sufficient knowledge base to care for many patients with vascular disease.

**Level 2—** Additional training for fellows who wish to develop special expertise in evaluating and managing patients with vascular disease. This level does not include training in catheter-based interventions.

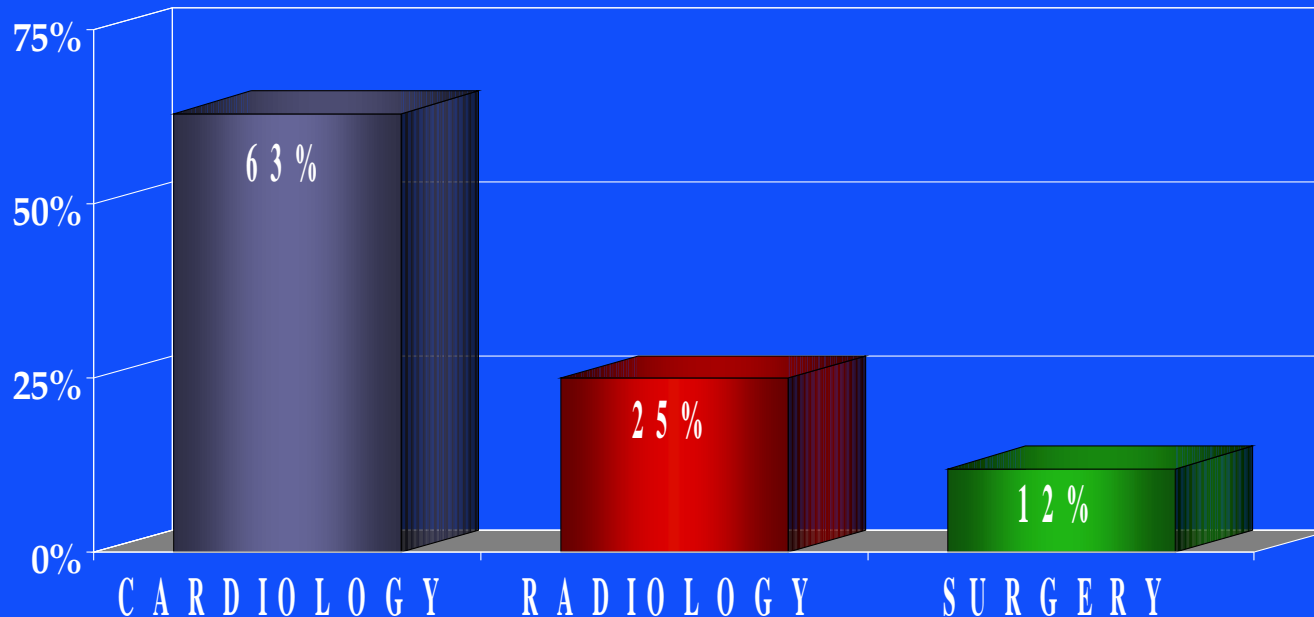
**Level 3—** Training for noncoronary catheter-based vascular interventions. This level of training is to ensure that the fellow develops both the cognitive and technical skills requisite to making appropriate decisions regarding invasive and interventional treatment of patients with vascular disease.

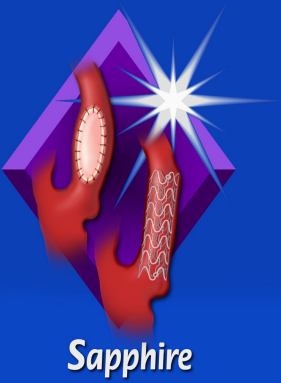
and second-order branch vessels, such as the internal mammary arteries; and pulmonary angiography) in 25 patients with whom they are involved from precatheterization clinical evaluation to final disposition. This training will not qualify the trainee to independently perform noncardiac angiography.



# Worldwide Registry

## Carotid Stent by Physician Specialty

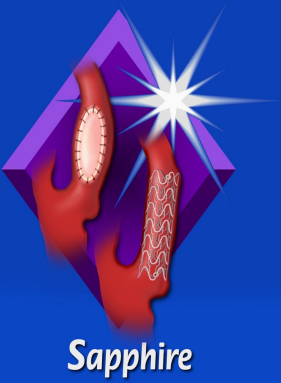




# *Credentials = Privileges*

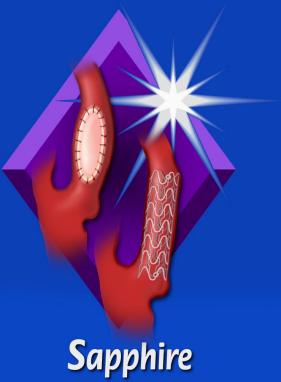
- ◆ Local hospital function.
- ◆ Rules apply equally to all specialties.
- ◆ Quality assurance function.





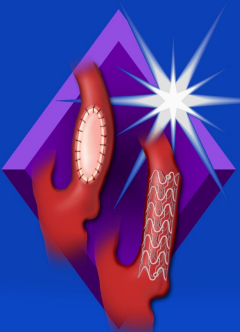
# *Certification = Guidelines*

- ◆ **Professional societies or associations.**
- ◆ **Payers.**
- ◆ **Government agencies.**



# **CERTIFYING ORGANIZATIONS**

- ◆ **ACC/AHA**
- ◆ **SCAI** (Society of Cardiac Angiography and Intervention).
- ◆ **ISCI** (International Society of Cardiovascular Interventionists).
- ◆ **SIR** (Society of Interventional Radiologists).
- ◆ **SVS** (Society of Vascular Surgery).



Sapphire

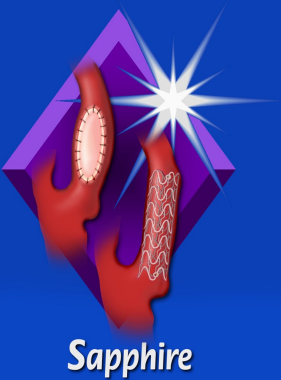
# ***REQUIRED SKILL ELEMENTS***

## **ENDOVASCULAR COMPETENCE**

**Cognitive:** The fund of knowledge for vascular disease, natural history, pathophysiology, diagnostic methods, and treatment alternatives.

**Technical:** Competence in both diagnostic angiography and interventional techniques.

**Clinical:** The ability to manage inpatients, interpret diagnostic tests, obtain consent, admitting privileges, assessment of risk to benefit ratio.

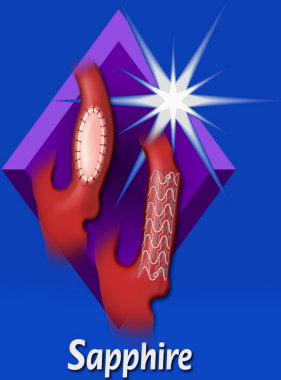


# **Training, competency, and credentialing standards for diagnostic cervicocerebral angiography, carotid stenting, and cerebrovascular intervention**

**A Joint Statement from the American Academy of Neurology, the American Association of Neurological Surgeons, the American Society of Interventional and Therapeutic Neuroradiology, the American Society of Neuroradiology, the Congress of Neurological Surgeons, the AANS/CNS Cerebrovascular Section, and the Society of Interventional Radiology\***

**John J. Connors III, MD; David Sacks, MD; Anthony J. Furlan, MD; Warren R. Selman, MD;  
Eric J. Russell, MD; Philip E. Stieg, PhD, MD; and Mark N. Hadley, MD;  
for the NeuroVascular Coalition Writing Group†**

**200 cerebral angiograms  
5 carotid stents**



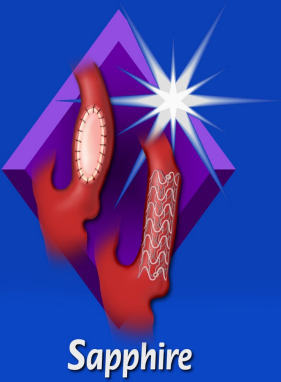
## **SCAI/SVMB/SVS CLINICAL COMPETENCE STATEMENT**

# Clinical Competence Statement on Carotid Stenting: Training and Credentialing for Carotid Stenting— Multispecialty Consensus Recommendations

A Report of the SCAI/SVMB/SVS Writing Committee to Develop a  
Clinical Competence Statement on Carotid Interventions

## **Background of Interventional Experience**

**30 cerebral angiograms - half as primary operator**  
**25 carotid stents - half as primary operator**



# ***AHA/ACC GUIDELINES FOR PTA (1993)***

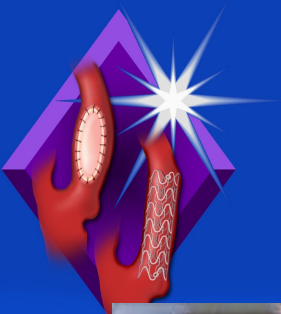
## **◆ AHA/ACC CRITERIA.**

- ◆ 100 diagnostic angiograms with 50 as 1<sup>o</sup> operator.**
- ◆ 50 PTA's with 25 as 1<sup>o</sup> operator.**
- ◆ No distribution requirements.**
- ◆ No threshold event rate.**
- ◆ Not specialty specific.**
- ◆ Completely arbitrary criteria.**



# *Ideal Cardiology Carotid Criteria*

- ◆ Experienced interventional cardiologist ( $\geq 200$  coronary interventions).
- ◆ Skilled with SVG-EPD's ( $\geq 20$  cases).
- ◆ Credentialed to perform non-coronary angiography and angioplasty.
- ◆ Committed to carotid "fund of knowledge".
  - ◆ Neurology/Vascular medicine/surgeon partner.
  - ◆ Attendance at live demonstration course.
- ◆ Carotid angiograms  $\geq 50$  proctored cases with stroke and death rate  $\leq 1\%$ .
  - ◆ 1 month, 6 month, 12 month, and with annual review.
  - ◆ Proctoring/case review for threshold rate achieved.
- ◆ Carotid stents with EPD  $\geq 25$  proctored cases with stroke and death rate  $\leq 5\%$ .
  - ◆ 1 month, 6 month, 12 month, and with annual review.
  - ◆ Proctoring/case review for threshold rate achieved.



# Ranges of simulations

Sap



These \$10MM flight simulators are used to train airline pilots from around the world and they exactly replicate the flight deck of the real aircraft, with sophisticated views of the outside world.

System Report Editor Site: 1			
lect Report		Test Data Options	
By Test Time			
me	Loc.	Report Name	PID
150	603	Ruben P	525
150	x	Lucas P	525

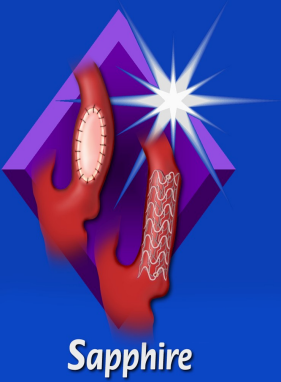
Visual Simulations allow users to interact with virtual representations of types of input/output criteria, with multiple branches.



Manikin-based simulations use a plastic manikin with sophisticated software, dedicated workstations and realistic tactile feedback.

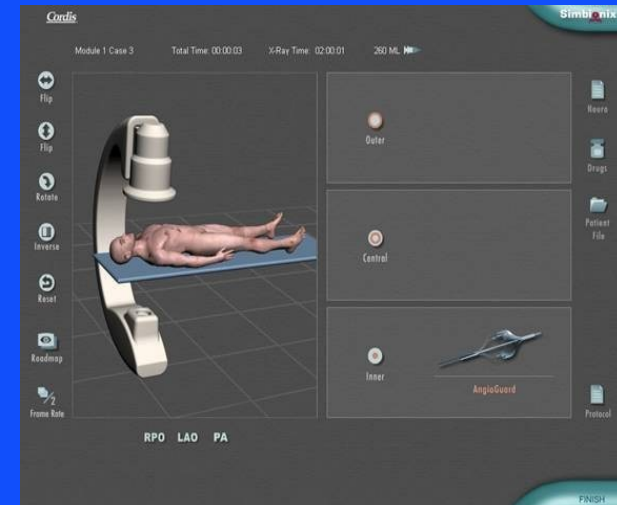


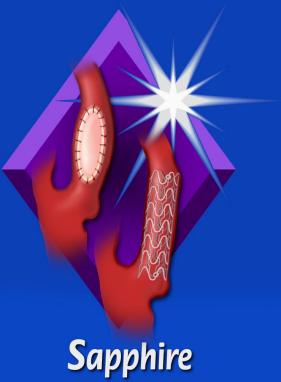




# Education

- ◆ Cardiologists and Surgeons
- ◆ Active Training Program
- ◆ FDA will Mandate Training
- ◆ Medical Simulation
  - ◆ Simbionix, Mentice, SimSuite
  - ◆ Vascular and Coronary
  - ◆ Fellow Education





# CAPTURE: Primary Safety Events by Physician Experience Level

CAPTURE (N=1603)	High N=166	Medium N=1177	Low N=260
Death <sup>a</sup>	0.0%	1.6%	2.3%
Stroke <sup>a</sup>	5.4%	3.7%	4.6%
Major	1.2%	1.7%	2.7%
Minor	4.2%	2.0%	1.9%
MI <sup>a</sup>	0.6%	0.8%	1.2%
S/D/MI <sup>b</sup>	6.0%	4.8%	5.8%
S/D <sup>b</sup>	5.4%	4.3%	5.0%

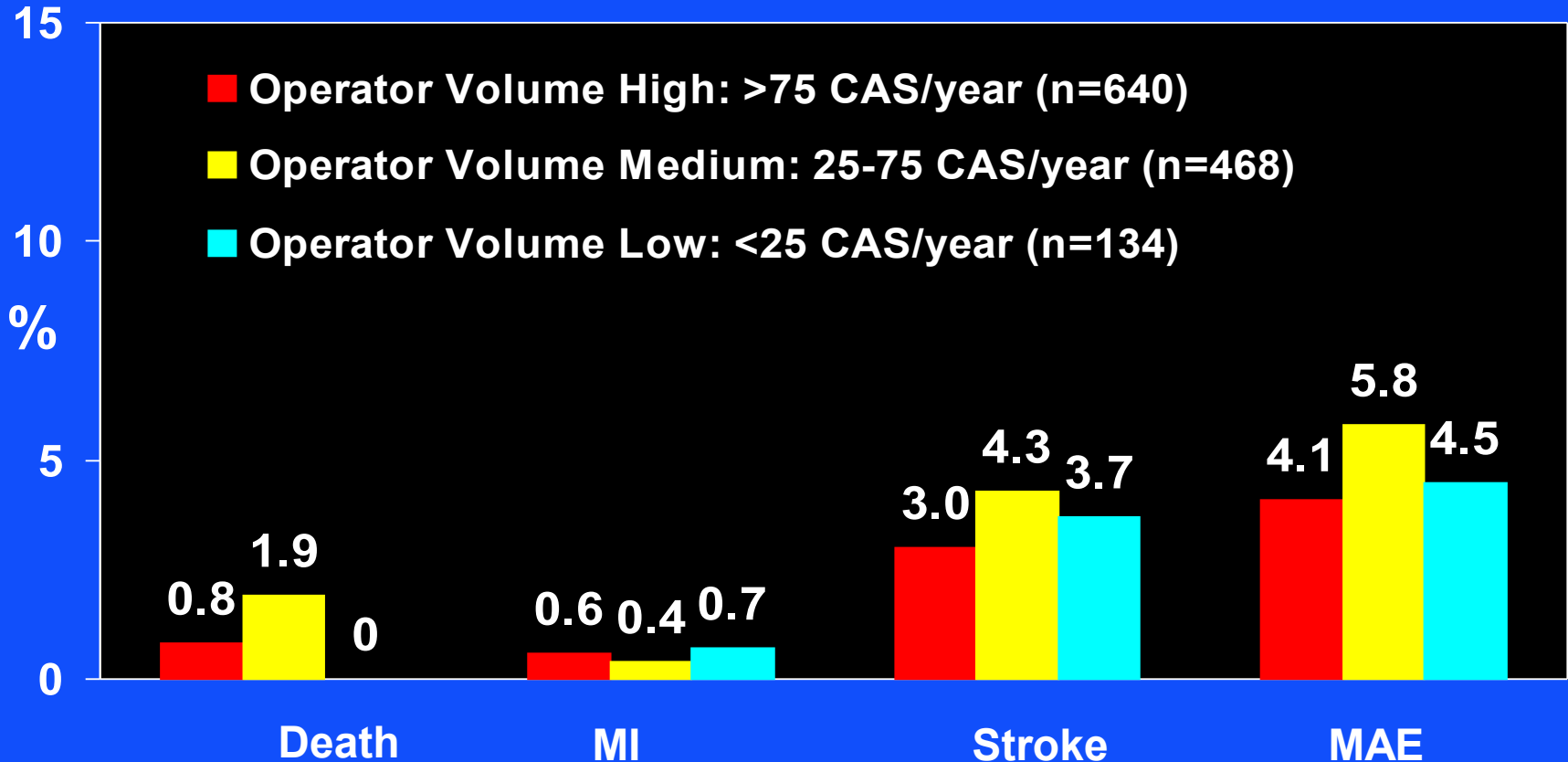
<sup>a</sup>Non-hierarchical

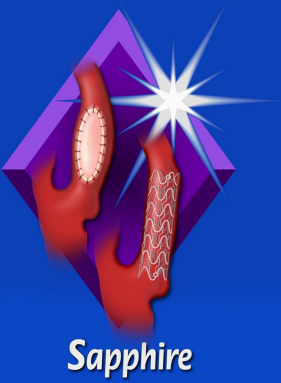
<sup>b</sup>Hierarchical

# Major Adverse Events at 30-Days

## Operator Volume

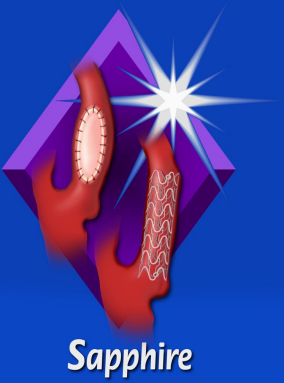
Sapphire





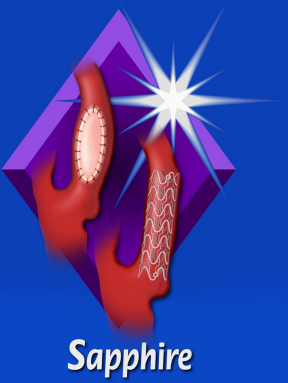
# ***FDA***

- ◆ **SAPPHIRE high risk criteria**
- ◆ **Symptomatic 50% stenosis**
- ◆ **Asymptomatic 80% stenosis**



# *CMS*

- ◆ **SAPPHIRE High Risk**
- ◆ **Symptomatic 70%**

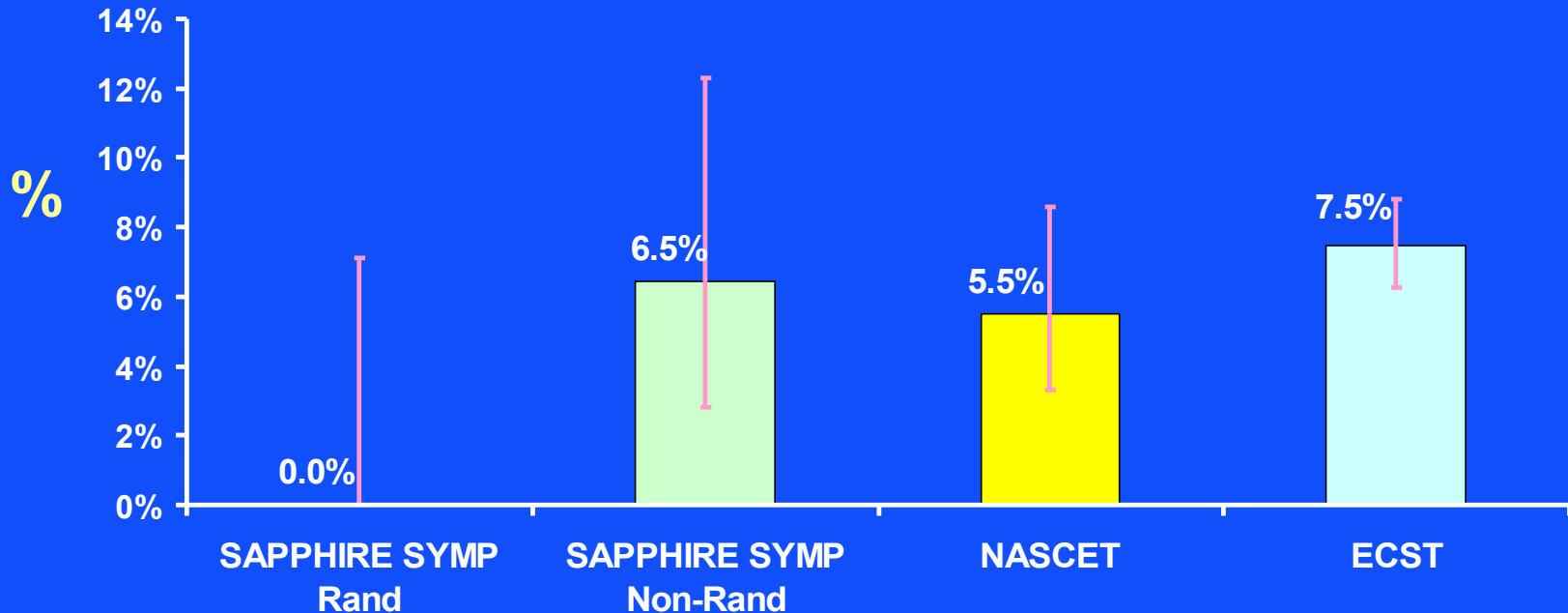


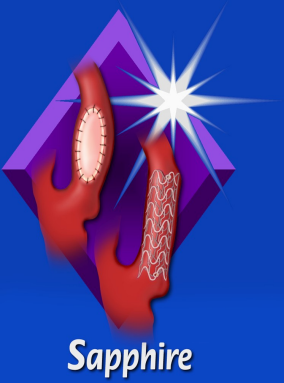
# STENTING vs OTHER SURGICAL TRIALS

## Symptomatic Patients

### 30-Day Ipsilateral Stroke

Error Bar = 95% CI

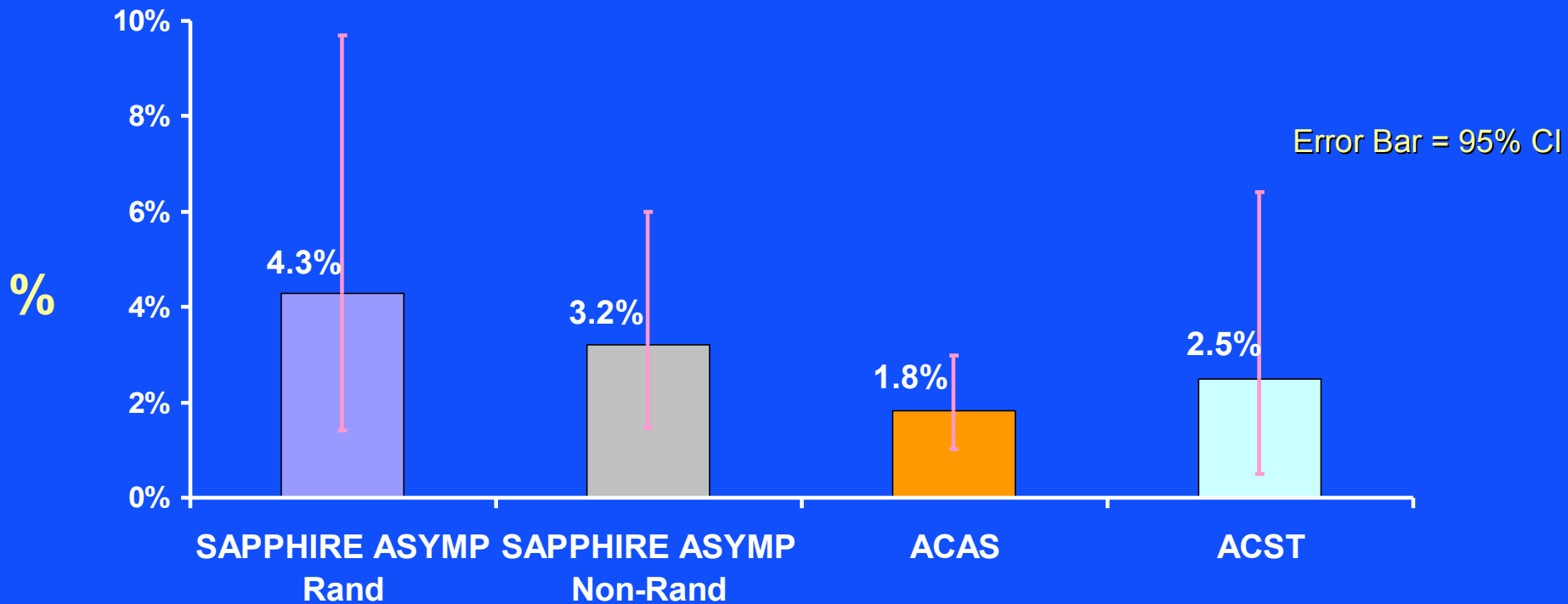


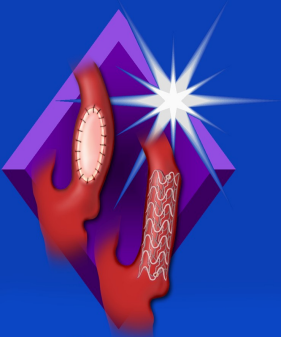


# STENTING vs OTHER SURGICAL TRIALS

## Asymptomatic Patients

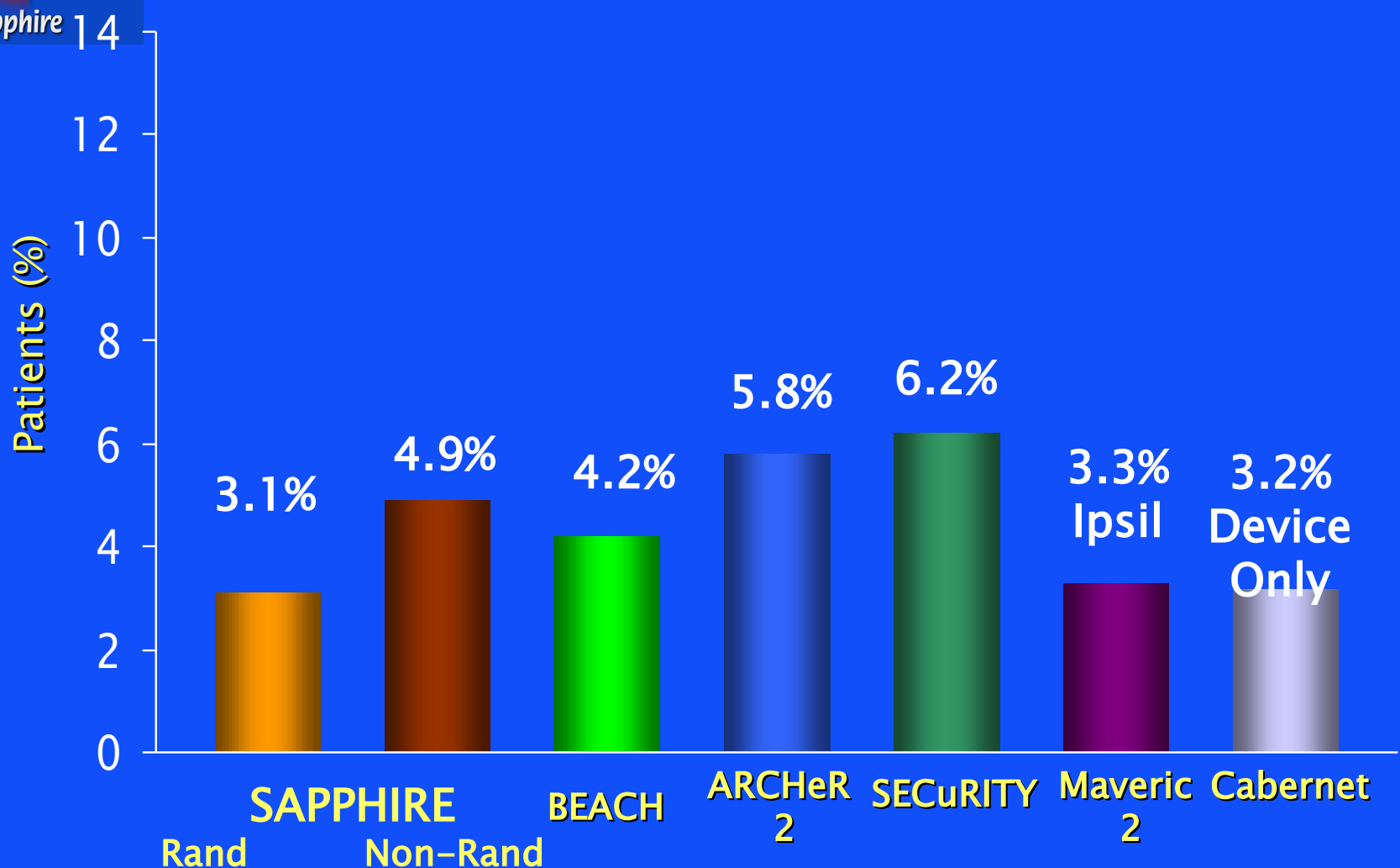
### 30-Day Ipsilateral Stroke



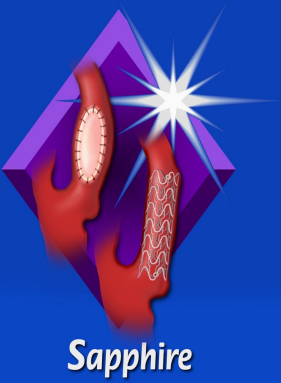


# 30-Day Risk of Stroke in High Risk Carotid Stenting Trials

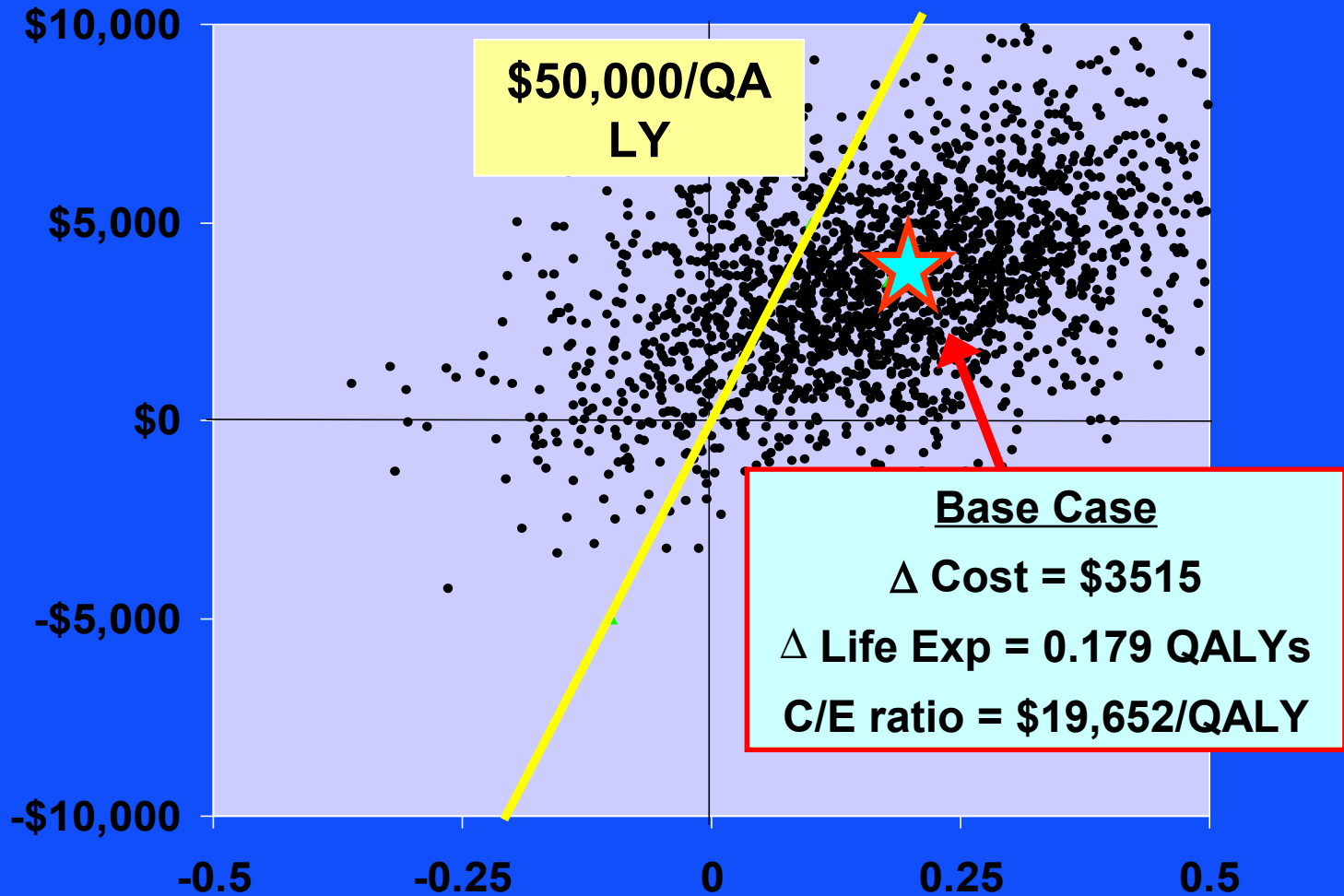
Sapphire



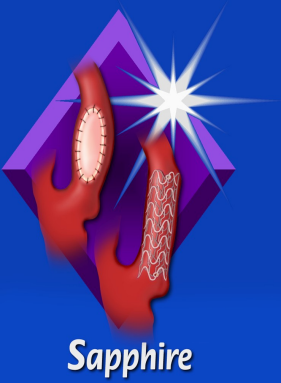




# LIFETIME Cost and QALYs

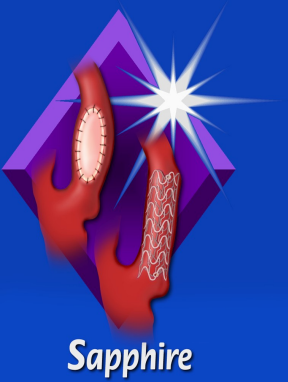


$\Delta$  Quality-Adjusted Life Expectancy (yrs)



# *CMS Position*

- ◆ **CEA Reimbursed:**
  - ◆ Any Patient
  - ◆  $Sx > 50\%$
  - ◆  $Asx > 60\%$
  
- ◆ **CAS Reimbursed:**
  - ◆  $Sx > 70\%$  High Risk

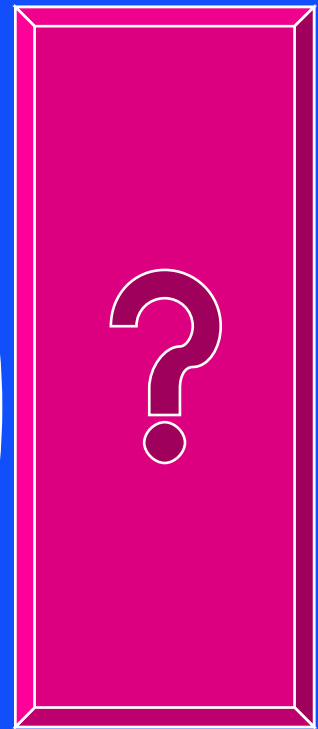


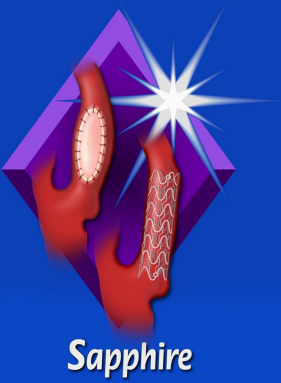
# ***CMS Position***

***CAROTID  
DISEASE***

***More Invasive Procedure (CEA)***

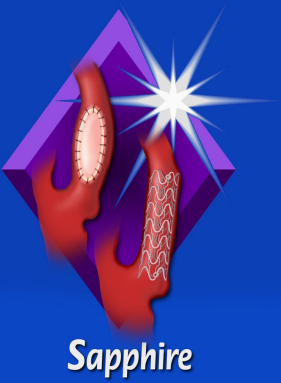
***Less Invasive  
Procedure  
(CAS)***





# *CLINICAL CONSEQUENCE?*

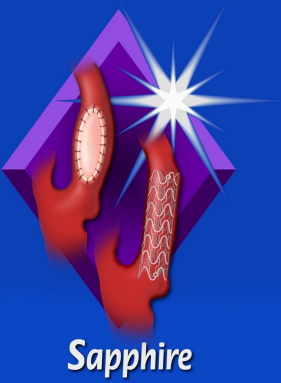
- ◆ Medicare patients will continue to get CEA when they could benefit from a less invasive treatment which is at least as safe as CEA.



Sapphire

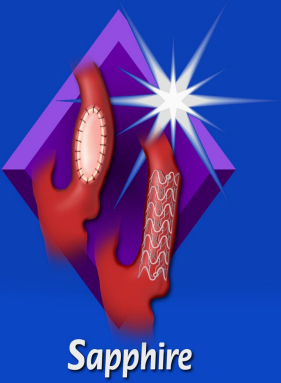
# *More Data?*

- ◆ **Low Risk Asymptomatic and Moderate Stenosis Symptomatic Trials BUT they are randomized to CEA**
- ◆ **CMS is taking the position that CEA is not Proven in these Patients**



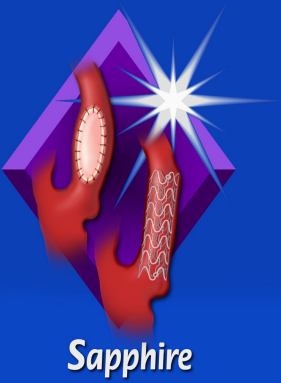
# *What Can You Do?*

- ◆ **Express your opinion**
  - ◆ **[steve.phurrough@cms.hhs.gov](mailto:steve.phurrough@cms.hhs.gov)**
- ◆ **Medical Societies need to speak with one voice**
- ◆ **Educate Your Patients, Congressional Representatives**



# **CONCLUSIONS:** *High Risk Patients*

- ◆ **Protected Carotid Stenting is Superior to CEA in Pts with Co-Morbid Conditions**
- ◆ **Protected Stenting: Lower risk of Major Ipsilateral Stroke, MI, CN Injury and Revascularization**



# *Conclusions*

- ◆ **Credentialing Criteria Have Been Developed**
- ◆ **Training Programs – Industry Sponsored, FDA Mandated**