

# **Carotid Stenting and the Asymptomatic Patient: *Can it be Advocated for the Prevention of Stroke?***

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# Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

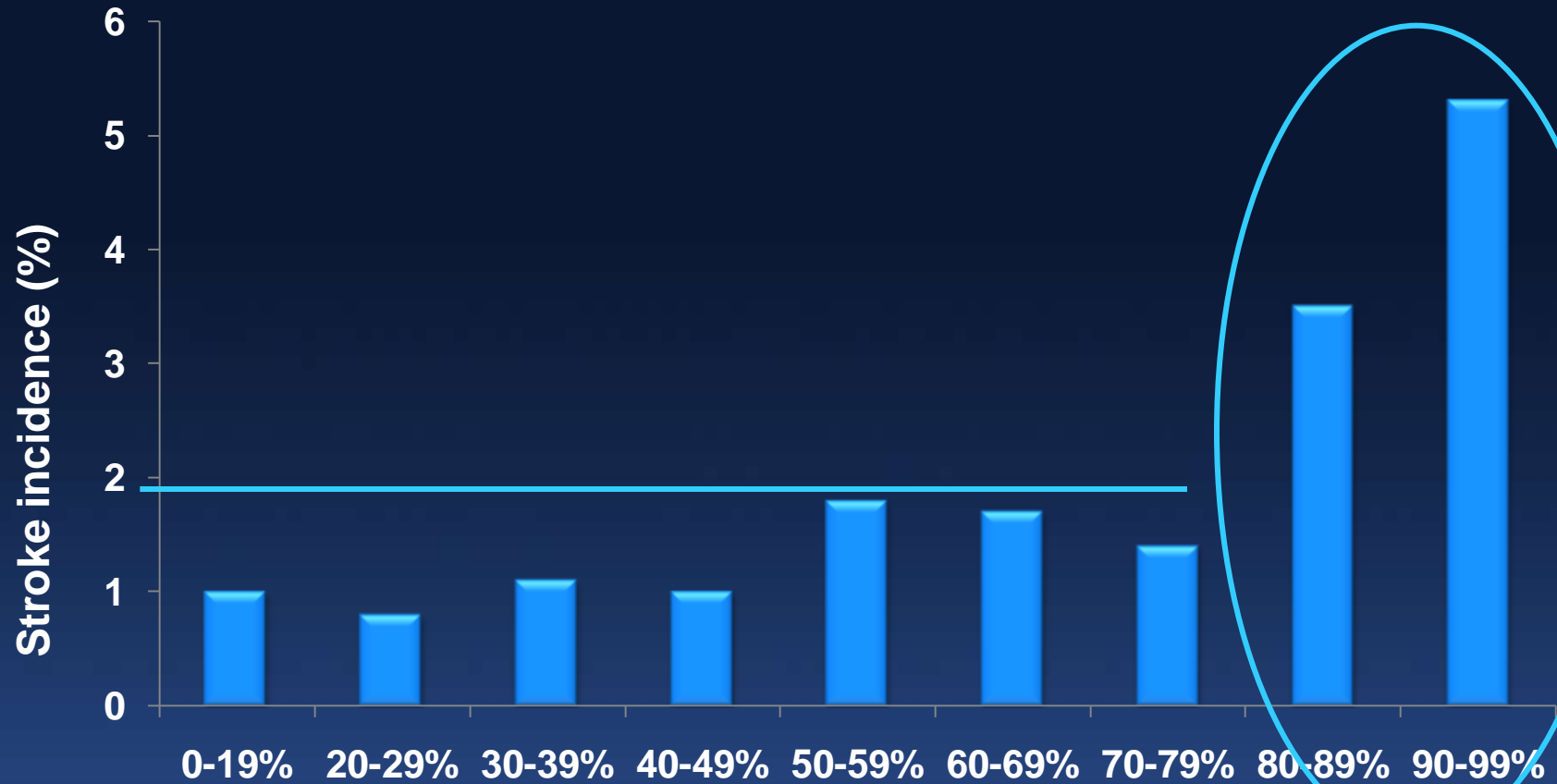
## Affiliation/Financial Relationship

- Grant/Research Support
- Consulting Fees/Honoraria
- Major Stock Shareholder/Equity

## Company

- Abbott Vascular, Cordis
- Abbott Vascular, Cordis, Medtronic, Eli Lilly.
- None

# What Is the Risk of Stroke in Asymptomatic Patients?



*Chambers. NEJM. 315(14):860-5.*

## Carotid Artery Stenosis

*Mendelsohn & Yadav, Management of Atherosclerotic Carotid Disease, Remedica Publishing, 2000.*

*Norris. Stroke. 22(12):1485-90.*

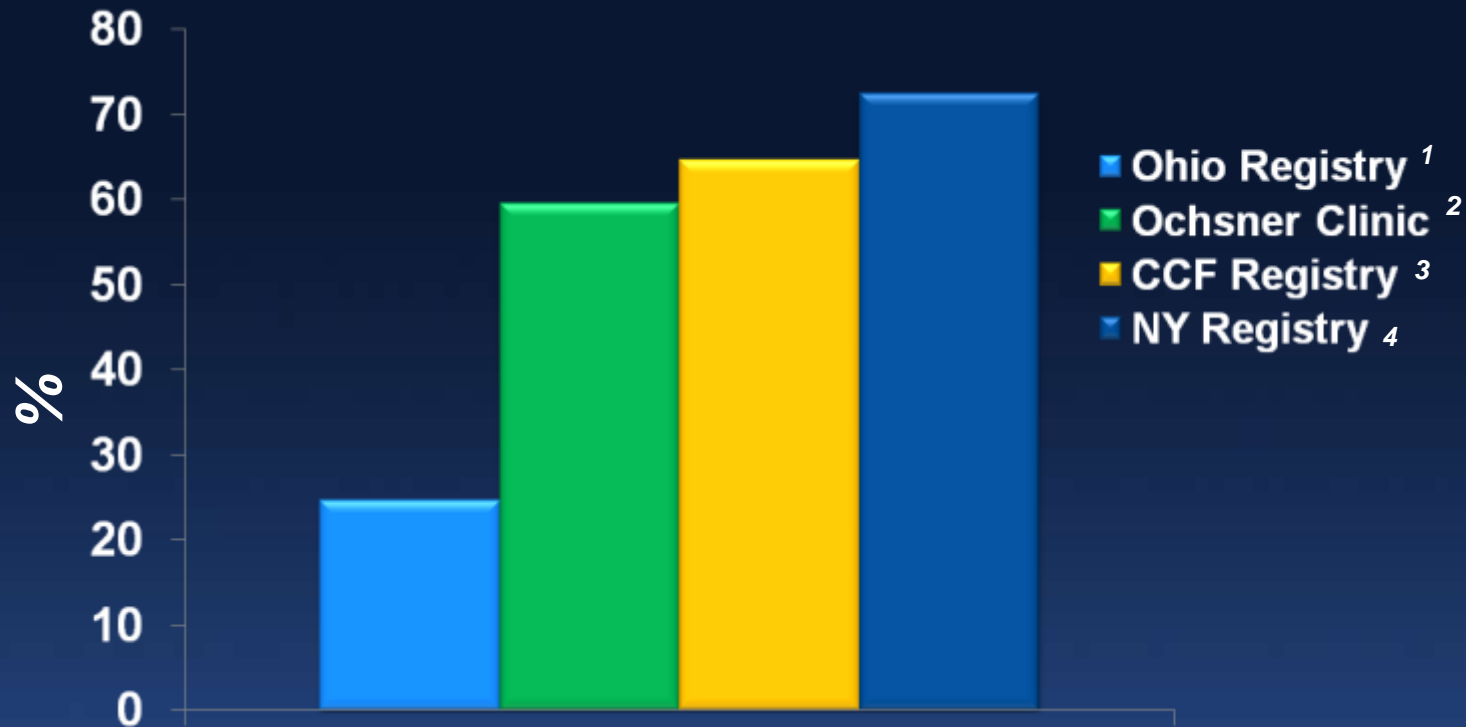
# **Epidemiology:** ***Asymptomatic Carotid Disease***

- **Progression of stenosis increases risk**
- **Severe ulceration - 7.5% stroke/yr**
- **Most asymptomatic carotid stenosis pts progressing to stroke do not have a preceding TIA**

# Asymptomatic Disease: *Revascularization Risk Should be Similar to Annual Stroke Risk with Medical Treatment*

	Peri-op Stoke/Death	Annual Risk of Stroke: Medical Treatment
<b>ACAS</b>	<b>2.3%</b>	<b>2.2%</b>
<b>ACST</b>	<b>3.1%</b>	<b>2.3%</b>

# Up To 75% of CEA Pts Are Asymptomatic

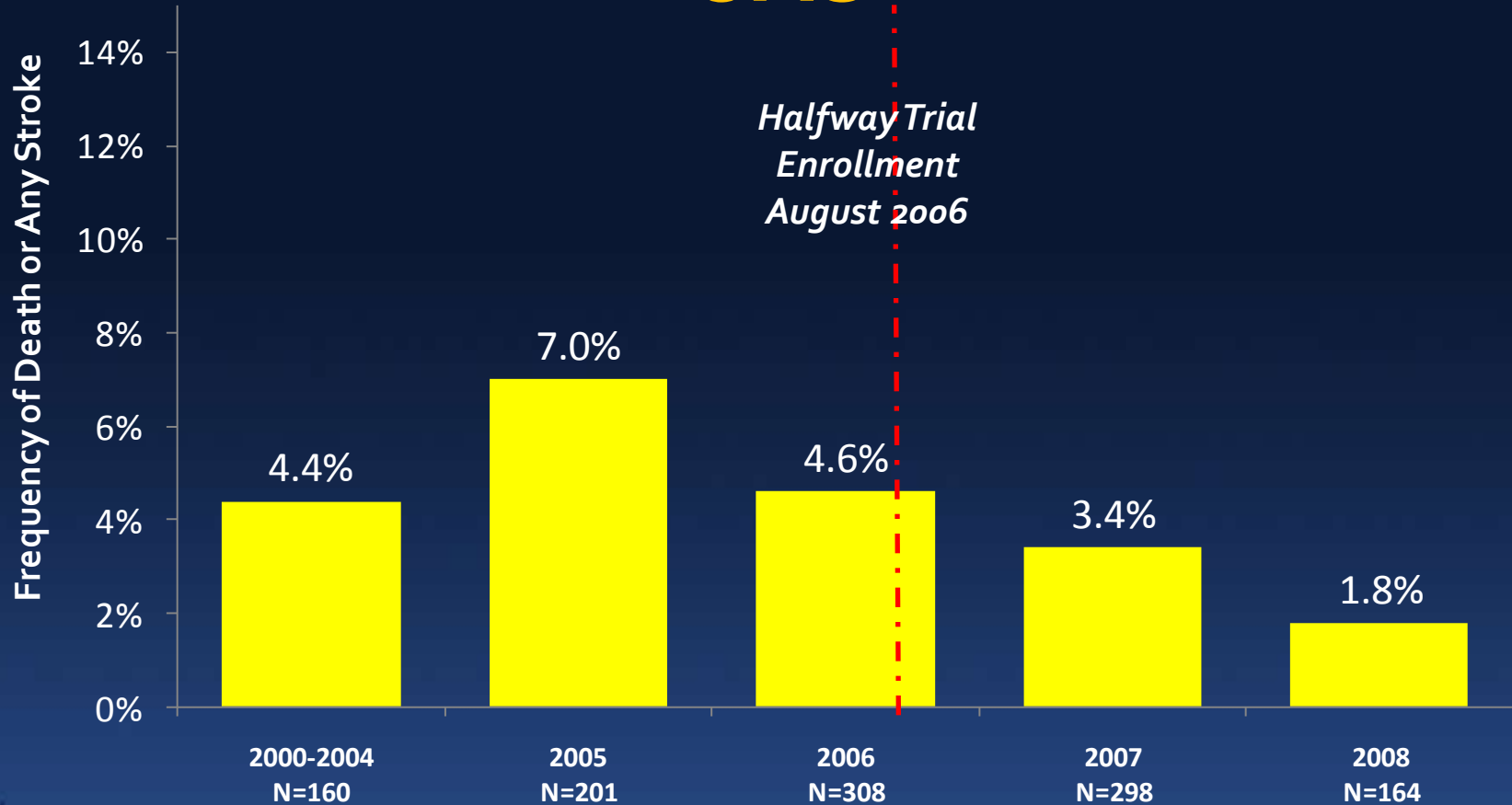


1. *Cebul et al., JAMA 279:1282-1287, 1998*
2. *Leporre et al., J Vasc Surg 34:581-586, 2001*
3. *Ouriel et al., J Vasc Surg 33: 728-732, 2001*
4. *Halm et al., Stroke 34: 14264-1472, 2003*

# Carotid Stent Trials

- **Discrepant results between European and US trials**
  - **Physician experience is important**
  - **Embolic protection is an important factor in CAS results**
  - **Common in US to treat selected asymptomatic patients**
  - **Asymptomatic patients consistently have better CAS outcomes than symptomatic pts**

# Death/Stroke Rates Decrease for CAS



*CREST. Feb, 2011 FDA Panel*

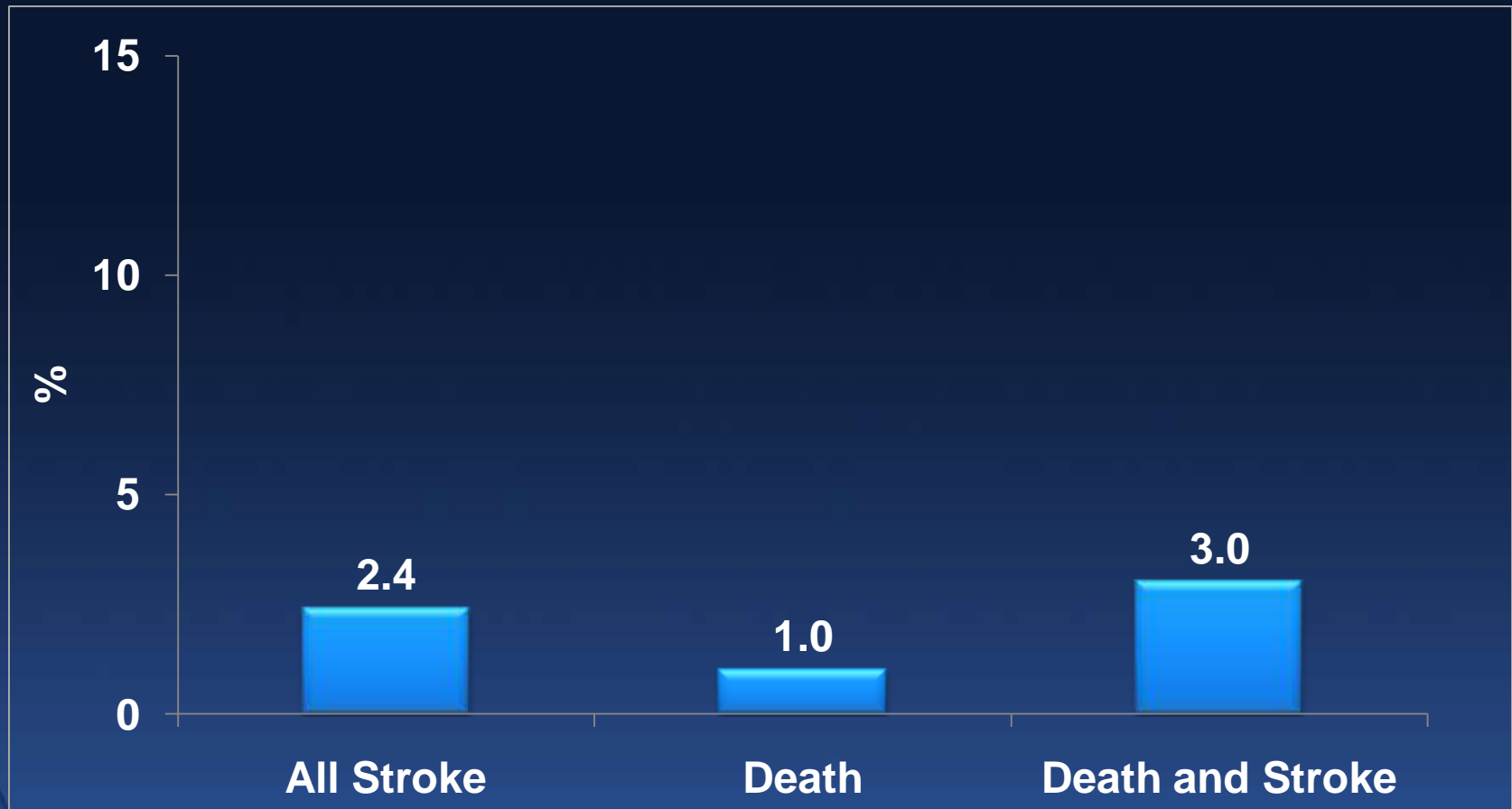


# Large, Post-Market High Surgical Risk Registries

- **CAPTURE: 3500 PTS**
- **CASES: 1492 PTS**
- **Same high-risk criteria as SAPPHIRE / ARCHER**
- **Neurological exam q 24 hrs until D/C**
- **Independent CEC**

# CAPTURE

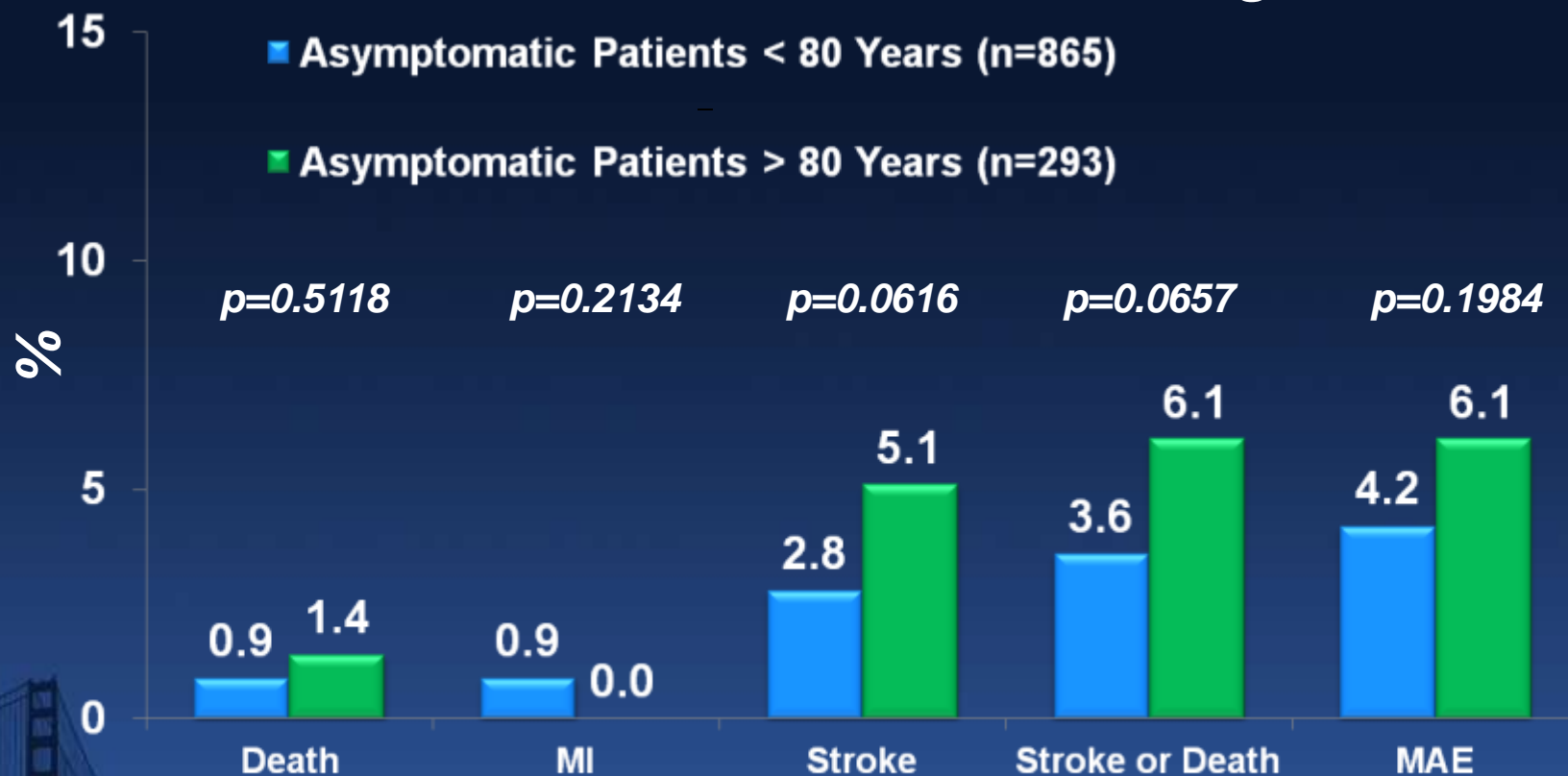
*Asymptomatic,  $\leq$  80 Yrs of Age, N = 1116*



# CASES:

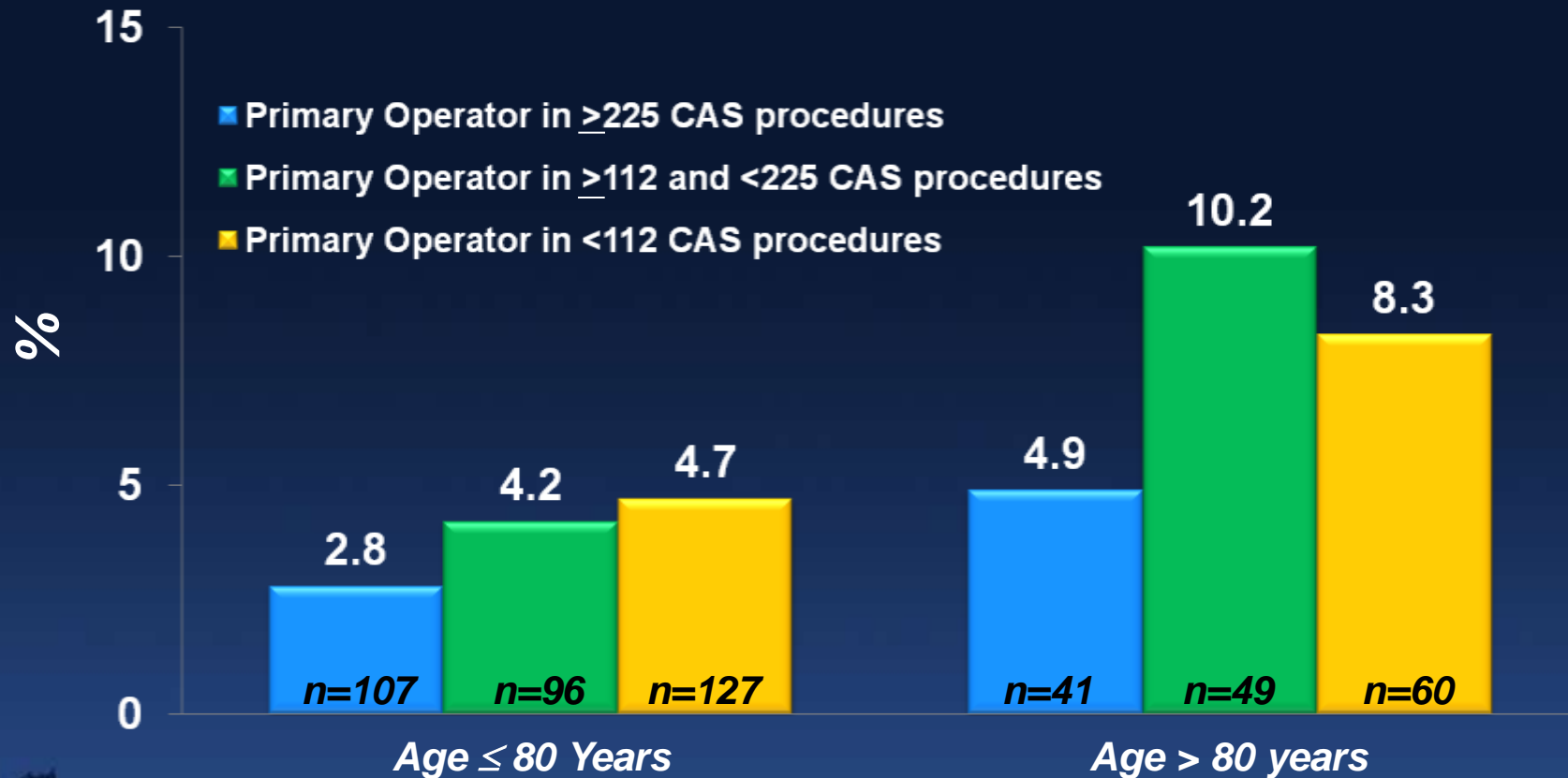
## Asymptomatic Pts 30-Day Outcomes

*Patients  $\leq 80$  vs.  $> 80$  Years of Age*



# CASES: Operator Experience and Outcomes

## 30-Day Stroke or Death



Division of Level 1 operators into subgroups was based on obtaining relatively similar sample sizes  
Level 1: ≥25 CAS procedures as primary operator (≥10 with Cordis devices) – exempt from training

# CREST Asymptomatic Patients

Stenosis  $\geq 60\%$  by angiography

$\geq 70\%$  by ultrasound, or

$>80\%$  by CTA/MRA if ultrasound is 50-69%

<b><i>n=1181</i></b>	<b>Periprocedural Period</b>			<b>4-Yr Study Period (including Periprocedural Period)</b>		
	CAS	CEA	P Value	CAS	CEA	P Value
	No. of patients (% $\pm$ SE)			No. of patients (% $\pm$ SE)		
<b>MI</b>	7 (1.2 $\pm$ 0.4)	13 (2.2 $\pm$ 0.6)	0.20			
Periprocedural stroke or postprocedural ipsilat stroke	15 (2.5 $\pm$ 0.6)	8 (1.4 $\pm$ 0.5)	0.15	24 (4.5 $\pm$ 0.9)	13 (2.7 $\pm$ 0.8)	0.07
Periprocedural stroke, death or postprocedural ipsilat stroke	15 (2.5 $\pm$ 0.6)	8 (1.4 $\pm$ 0.5)	0.15	24 (4.5 $\pm$ 0.9)	13 (2.7 $\pm$ 0.8)	0.07
Primary end point (Periprocedural stroke, MI, death, or post-procedural ipsilat stroke)	21 (3.5 $\pm$ 0.8)	21 (3.6 $\pm$ 0.8)	0.96	30 (5.6 $\pm$ 1.0)	26 (4.9 $\pm$ 1.0)	0.56

# ACT I

Asymptomatic Carotid Trial

- **Asymptomatic**
- **Standard risk for CEA**
- **Single de novo ICA lesion +/- involvement of the common carotid artery**
- **Stenosis  $\geq 70\%$  and  $\leq 99\%$  by angiography or duplex ultrasound**

**Independent neurological exam**

**Annual follow up for 5 years**

**As of August, 2011: >1200 randomized subjects**

**Primary composite endpoint:**  
***Any stroke, MI and death during 30-day post procedural period, plus ipsilateral stroke between 31 and 365 days post procedure***

Confidential: This information is for study participants ONLY. This document contains information and shall not be duplicated, disclosed

# ACT 1 Key Exclusion Criteria

## *Anatomical/angiographic*

- Tortuosity and/or occlusive disease that might preclude the safe introduction of a guiding catheter/sheath, cerebral protection device, or stent. “Severe tortuosity” defined as 2 or more >90 degree bend points within 3cm of the target stenosis. If ICA branches from the CCA as a 90 degree angle, this is considered one “bend”
- Aortic arch anatomy unacceptable for carotid stent placement
- Presence of carotid artery dissection, aneurysm, pseudoaneurysm, arteritis or fibromuscular dysplasia (FMD) in target vessel
- Occlusion or string sign of carotid artery
- Excessive calcification at lesion
- High risk for CEA

# ACT I: Outcomes

## Lead-In Patients

Event	30 days, N=180
Death, Stroke and MI	1.7% (3/180)
All Stroke and Death	1.7%
Major Stroke and Death	0.0%
Death	0.0%
All Stroke	1.7%
Major Stroke	0.0%
Minor Stroke	1.7%
MI	0.0%
	31-365 days, N=157
Ipsilateral Stroke	0.0%



# Asymptomatic Patients: Carotid Stenting and CEA Comparison

## Death / Stroke at 30 days (%)

Surgical Risk	Study	Stenosis	CEA	Stent
High	CAPTURE	≥ 80%		4.6
High	Cases	≥ 80%		3.6
Conventional	ACAS	≥ 60%	2.3	
Conventional	ACST	≥ 60%	3.1	

## Death / MI / Stroke at 30 days (%)

Surgical Risk	Study	Stenosis	CEA	Stent
High	SAPPHIRE	≥ 80%	10.2	5.4
Conventional	CREST	≥ 60%	3.6	3.5
Conventional	ACT I (lead in)	≥ 70%		1.7

# Asymptomatic Patients

- **Conventional Risk**
  - CAS is equivalent to CEA on basis of CREST
- **High Risk**
  - Consider only in stenosis  $\geq 80\%$
  - Carefully weigh risk / benefit
  - Stenting is preferred treatment
- **ACT I**: critical trial for definitively defining the treatment of asymptomatic patients

# Summary : *CAS should be applied selectively*

- **High risk factors for CAS:**
  - Advanced age
  - Recent symptoms
  - Challenging anatomy
- **ACT 1 randomized trial will be revealing:**
  - Excludes octogenarians
  - Excludes high risk for CEA--protocol defined
  - Excludes high risk for CAS--protocol defined
  - Surgeon and interventionalist criteria are strict and verified
  - Standardized protocol: routinely uses embolic protection, optimal medical therapy