

# CASES-PMS Study: Study of Carotid Stenting with Distal Embolic Protection

## Effect of Age > 80 Years on 30-Day Outcomes

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For the CASES-PMS Investigators  
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# Presenter Disclosure Information

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## CASES-PMS Study

Disclosure Information...

The following relationships exist related to this presentation:

Barry Katzen - *No relationships to disclose*

# Background

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- **Treatment of vascular disease in elderly patients is associated with a higher risk for adverse outcomes**
- **In the CASES-PMS study, rates of adverse events were evaluated in patients  $\leq 80$  years old and in patients  $> 80$  years of age**

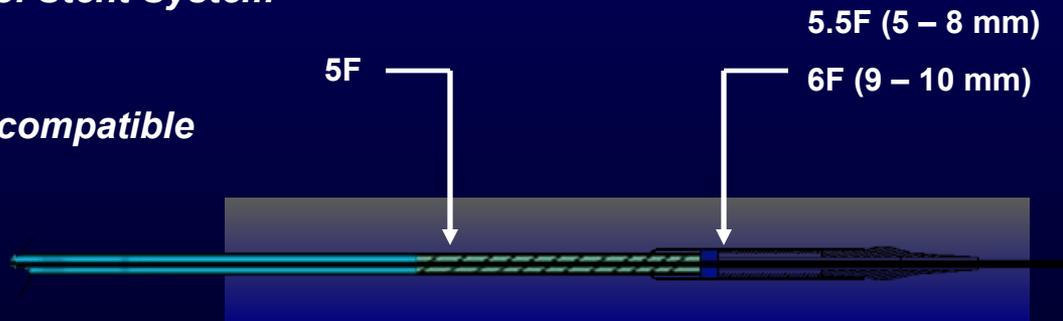
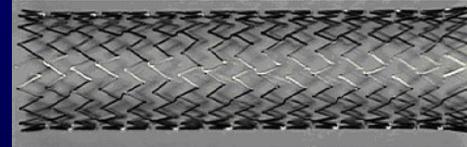
# CASES-PMS: Objective

- This study was undertaken as a condition-of approval study of the Cordis PRECISE® Nitinol Stent and ANGIOGUARD® XP Emboli Capture Guidewire System
- **GOAL:** To assess safety and efficacy outcomes of carotid artery stenting (CAS) with distal emboli protection when performed by physicians with varied experience in CAS utilizing a formal training program
  - **Sites from:**
    - Academic/non-academic centers
    - High/intermediate/low CAS volume centers
    - Geographically diverse centers
    - Experienced → no experience in CAS
  - **CASES training program:**
    - Level 1: Experienced in CAS & with Cordis devices – exempt from training
    - Level 2: Some experience in CAS/no experience with Cordis devices – intermediate training program
    - Level 3: Limited or no experience in CAS – full training program

# PRECISE® Nitinol Stent System and ANGIOGUARD® XP Emboli Capture Guidewire System

## •*Stent Delivery System:*

- 5.5F Cordis PRECISE® Nitinol Stent System*
- 6F Cordis PRECISE® Nitinol Stent System*
- Usable Length: 135 cm*
- Guidewire Lumen: 0.018" compatible*



## *Polyurethane filter on a Nitinol frame:*

- Basket Diameter: 4 - 8 mm*
- Oversize basket : 0.5 – 1.5 mm vs. RVD*
- Filter Pore Size: 100 microns*
- Crossing Profile: 3.5F*
- Wire Diameter: 0.014"*

# Study Design

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- **CASES-PMS**
  - **Condition of approval study for the Cordis Carotid System**
  - **Performed under an IDE from the FDA**
- **All endpoints adjudicated by an independent clinical events committee**
- **Site monitoring performed by CRO independent of sponsor**
- **Data management, analysis, and reported performed by a CRO (Harvard Clinical Research Institute) independent of the sponsor**

# Study Design

Prospective, multicenter (73 sites), single arm, open-label study  
(August 2003 – October 2005)

**Primary Endpoint:**

**30-day composite of major adverse events (MAE) including all death, stroke, and/or myocardial infarction**

**Patients Enrolled  
n = 1,493**

**Patients  $\leq$  80 Years of Age  
n = 1,107 (74.1%)**

**Patients  $>$  80 Years of Age  
n = 386 (25.9%)**

# Key Inclusion Criteria

- Disease of native common or internal carotid artery:
  - Symptomatic  $\geq 50\%$  stenosis by U/S or angiography
  - Asymptomatic  $\geq 80\%$  stenosis by U/S or angiography
- At least 1 co-morbid condition which increases the risk CEA:
  - Anatomic factors:**
    - Contralateral carotid occlusion
    - Contralateral laryngeal nerve palsy
    - Radiation therapy to neck
    - Previous CEA with recurrent stenosis
    - Difficult surgical access
    - Severe tandem lesions
  - Medical Co-morbidities:**
    - CHF (class III/IV) and/or severe LV dysfunction (LVEF  $< 30\%$ )
    - Open heart surgery within 6 weeks
    - Recent MI (1 day to 4 weeks prior)
    - Angina at low workload or unstable angina (CCS class III/IV)
    - Severe pulmonary disease
    - Age  $> 80$  years

# CASES-PMS Patient Demographics: Age $\leq$ 80 Years vs. $>$ 80 Years

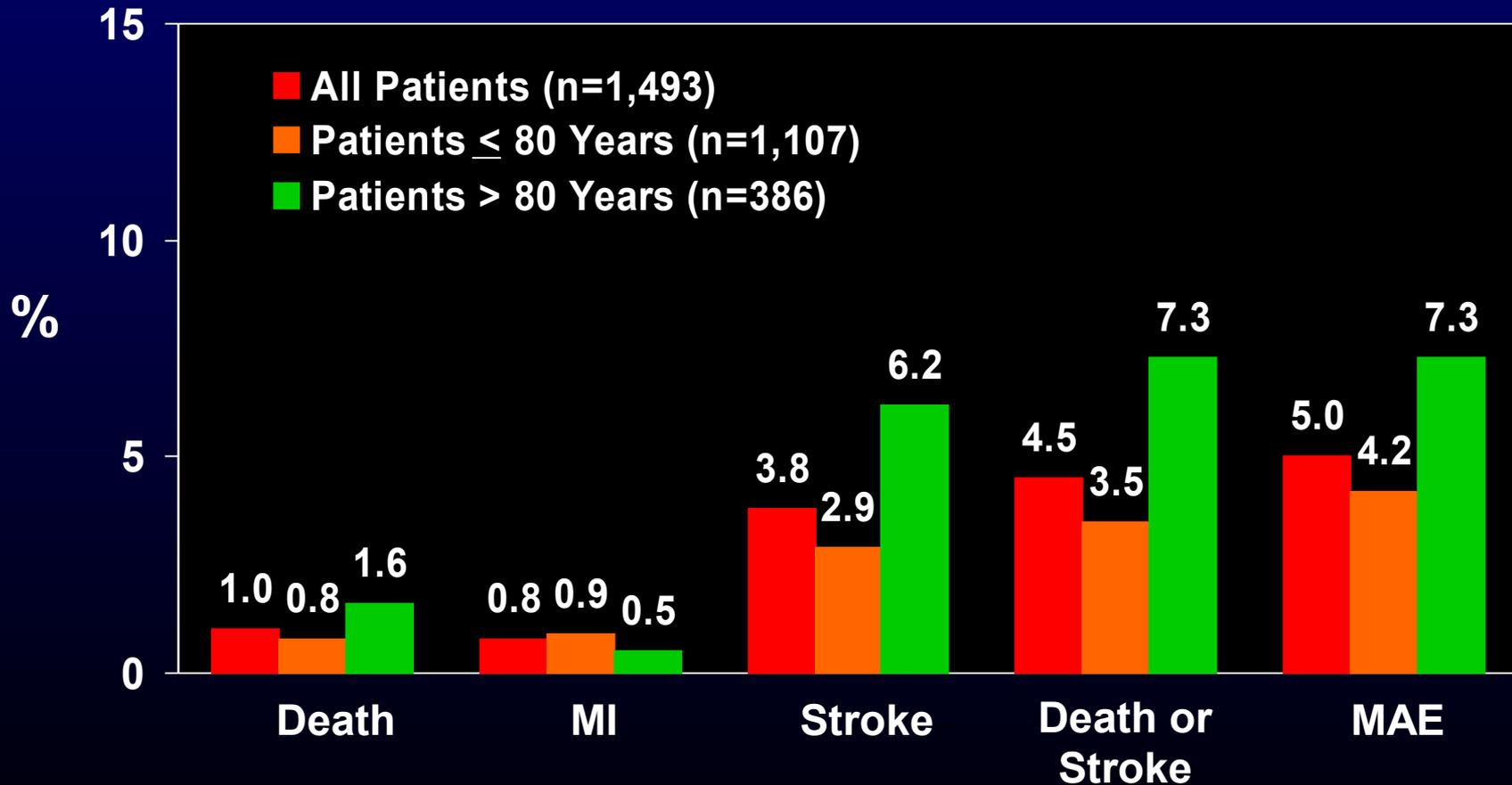
	CASES-PMS (n = 1,493)	Age $\leq$ 80 Years (n = 1,107)	Age $>$ 80 Years (n = 386)
Age (years)	73.4 $\pm$ 9.5	69.5 $\pm$ 7.7	84.7 $\pm$ 3.1
Age $>$ 80 years	25.9%	0%	100.0%
Male	62.7%	63.8%	59.6%
Symptomatic	21.8%	21.1%	23.5%
Renal insufficiency (creatinine $>$ 2.5mg/dl)	6.5%	6.8%	5.7%
History of hypertension	90.3%	91.1%	87.8%
Diabetes mellitus	35.4%	37.5%	29.3%
History of MI	35.6%	37.0%	31.6%
Prior PCI	36.9%	39.5%	29.1%
Previous PTA (carotid)	3.5%	3.9%	2.3%
<b>Prior CEA</b>	<b>29.9%</b>	<b>33.3%</b>	<b>19.9%</b>
History of TIA	27.4%	27.1%	28.3%
History of stroke	26.3%	25.7%	28.0%

# Comparison of High-risk Characteristics

	CASES-PMS (n = 1,493)	Age ≤ 80 Years (n = 1,107)	Age > 80 Years (n = 386)
CHF (class III/IV) &/or known severe LV dysfunction LVEF < 30%	14.7%	17.8%	7.5%
Open heart surgery within 6 weeks	0.5%	0.7%	0%
Recent MI (> 24 hours and < 4 weeks)	1.0%	1.5%	0%
Unstable angina (CCS class III/IV)	7.2%	9.3%	2.2%
Coexistent severe cardiac & carotid disease requiring open heart surgery & carotid revascularization	2.5%	3.4%	0.3%
Severe pulmonary disease	10.4%	13.1%	4.1%
Contralateral carotid occlusion	12.4%	15.4%	5.3%
Contralateral laryngeal palsy	1.7%	2.3%	0.3%
Post radiation treatment	6.5%	8.1%	2.8%
Previous CEA recurrent stenosis	23.7%	27.9%	14.1%
High cervical ICA or CCA lesions below the clavicle	4.9%	6.4%	1.6%
Severe tandem lesions	2.0%	2.4%	0.9%
Abnormal stress test	9.5%	11.8%	4.4%
Age > 80 years as a single risk factor	34.8%	7.0%	98.8%

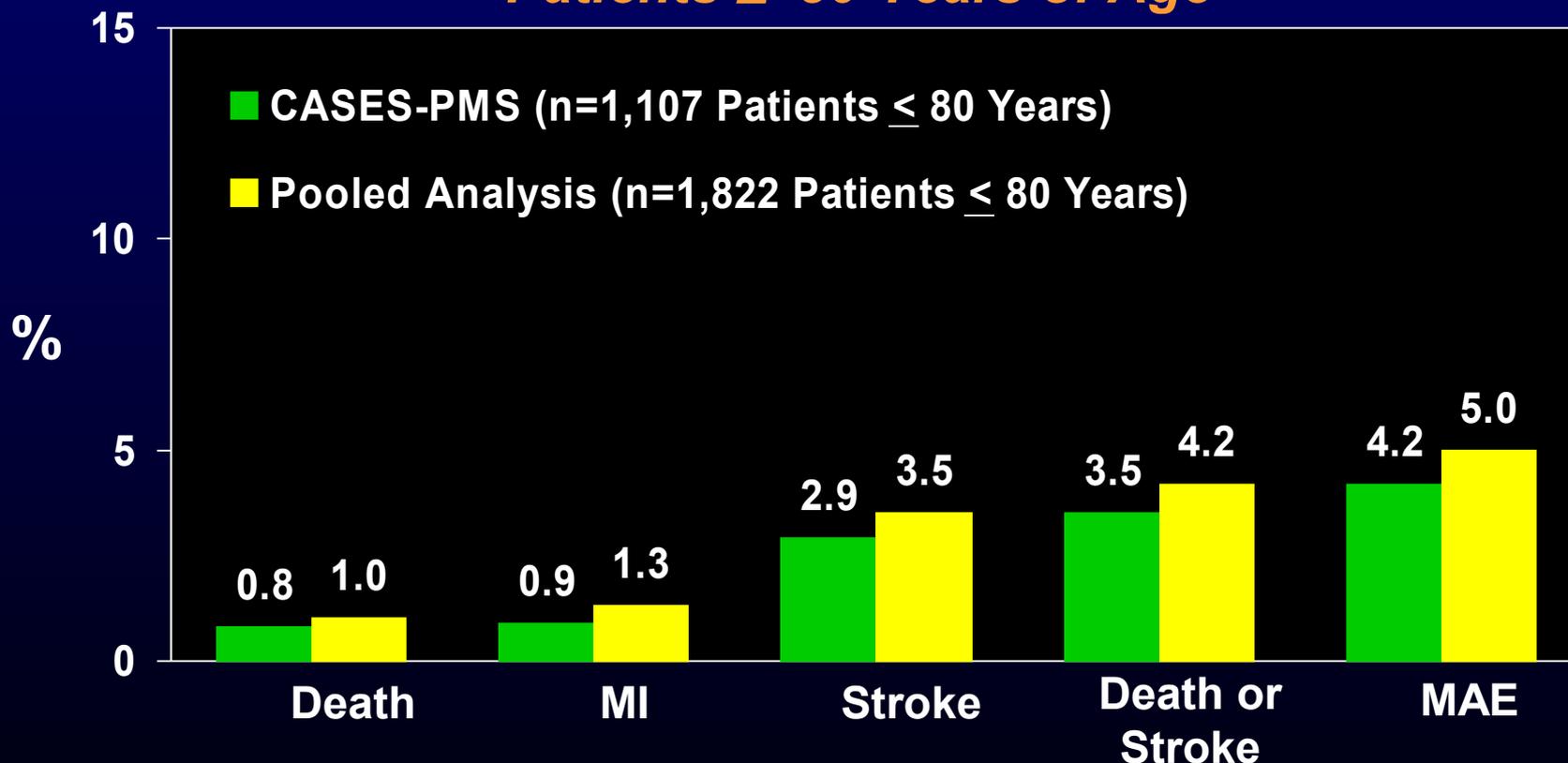
# Major Adverse Events at 30-Days

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



# Major Adverse Events at 30-Days Compared with Pooled Analysis\*

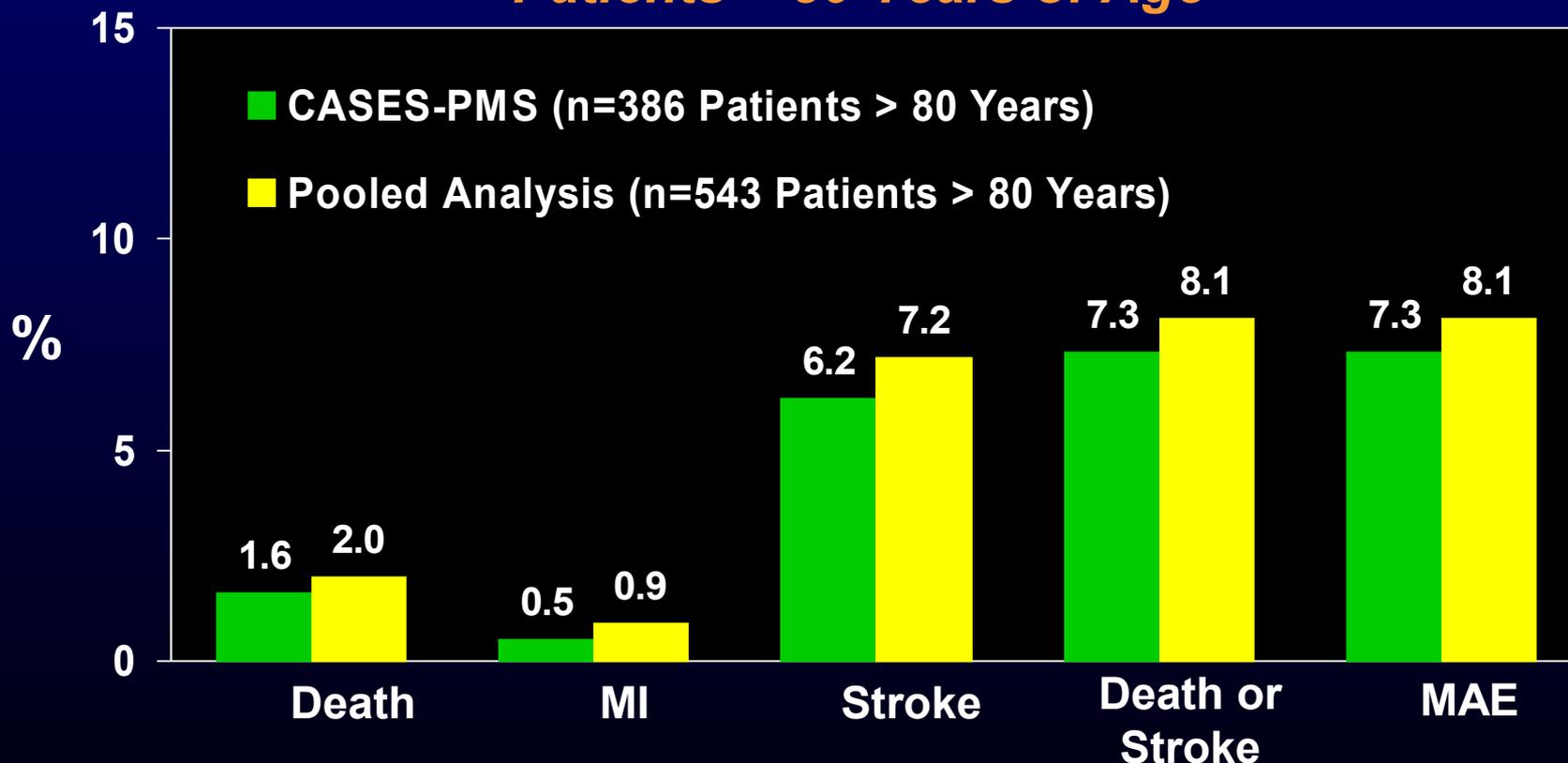
*Patients ≤ 80 Years of Age*



\*Pooled analysis from the ≤ 80 years of age subgroups of the US Feasibility Study, randomized and non-randomized stent arms from SAPPHERE, ADVANCE and CASES-PMS)

# Major Adverse Events at 30-Days Compared with Pooled Analysis\*

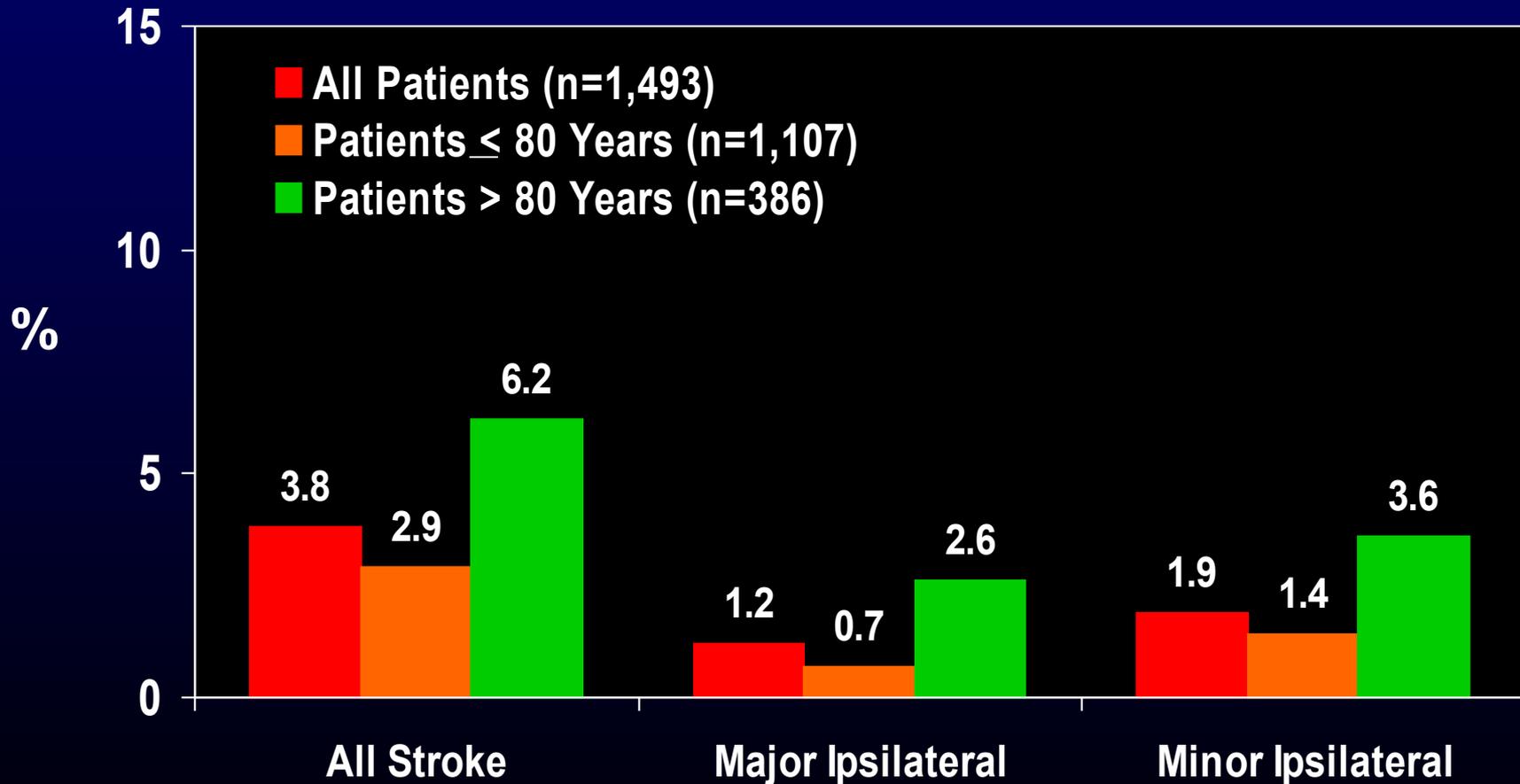
## Patients > 80 Years of Age



\*Pooled analysis from the > 80 years of age subgroups of the US Feasibility Study, randomized and non-randomized stent arms from SAPPHERE, ADVANCE and CASES-PMS)

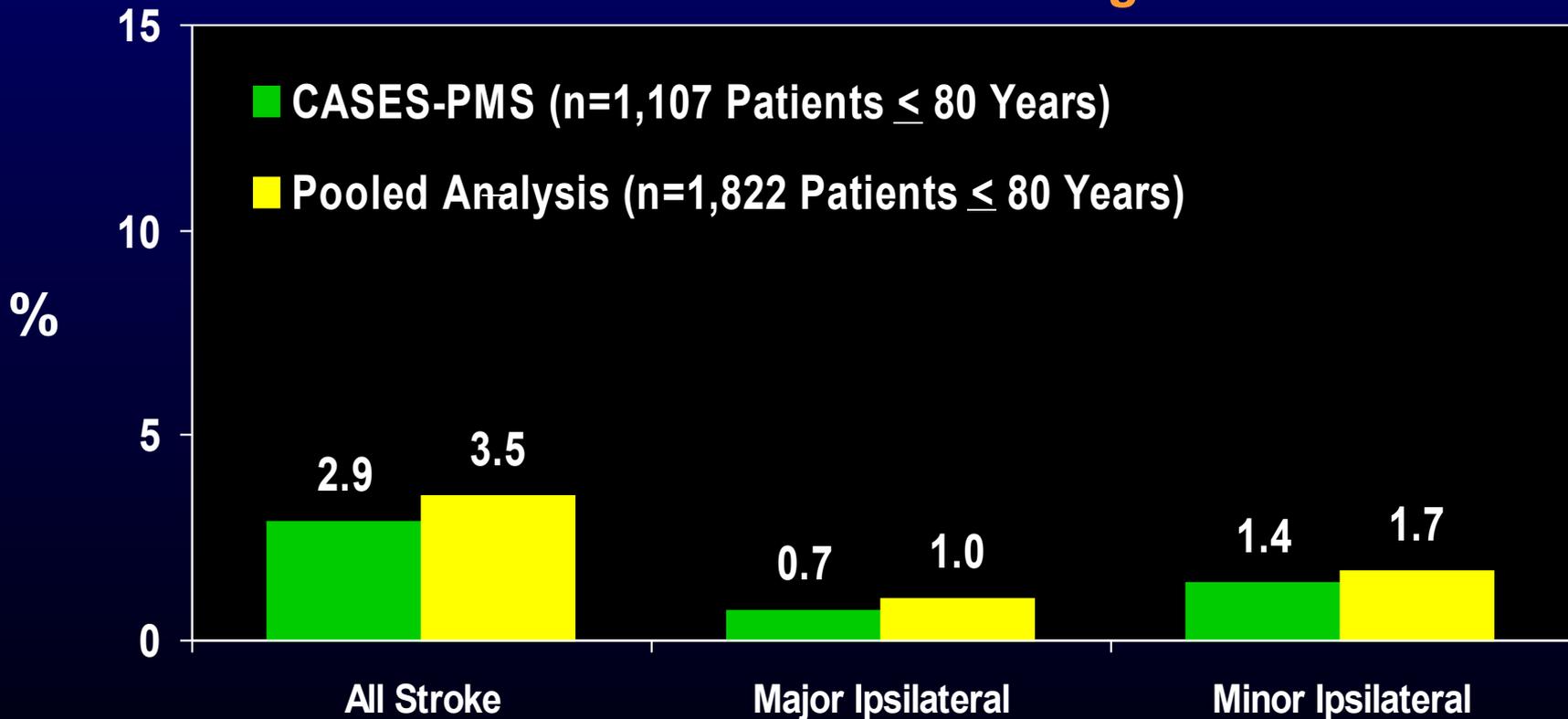
# Stroke at 30-Days

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



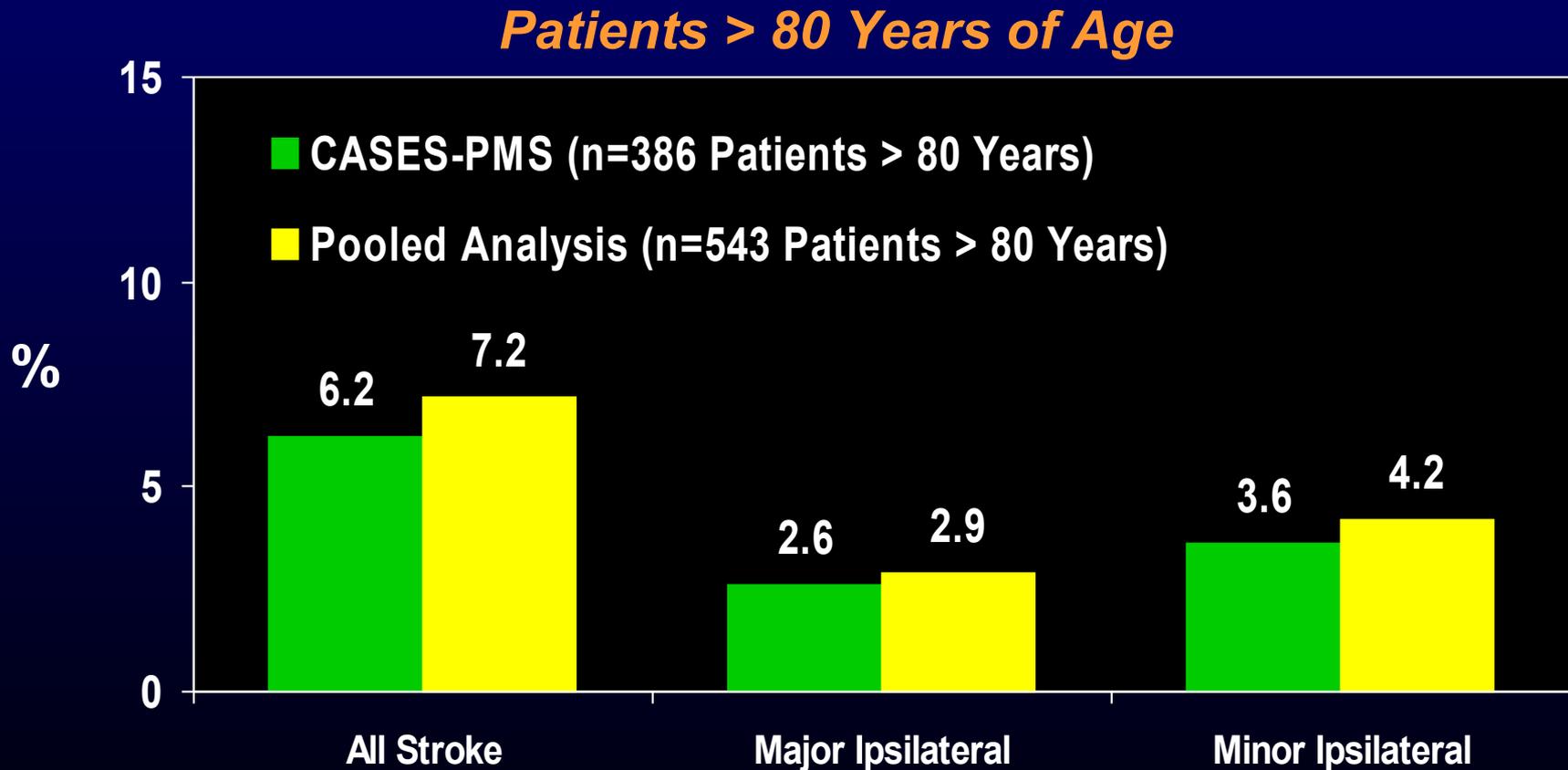
# Stroke at 30-Days Compared with Pooled Analysis\*

## Patients $\leq$ 80 Years of Age



\*Pooled analysis from the  $\leq$  80 years of age subgroups of the SAPHIRE (randomized and registry stent arms), CASES-PMS, ADVANCE, and Carotid Feasibility Trials)

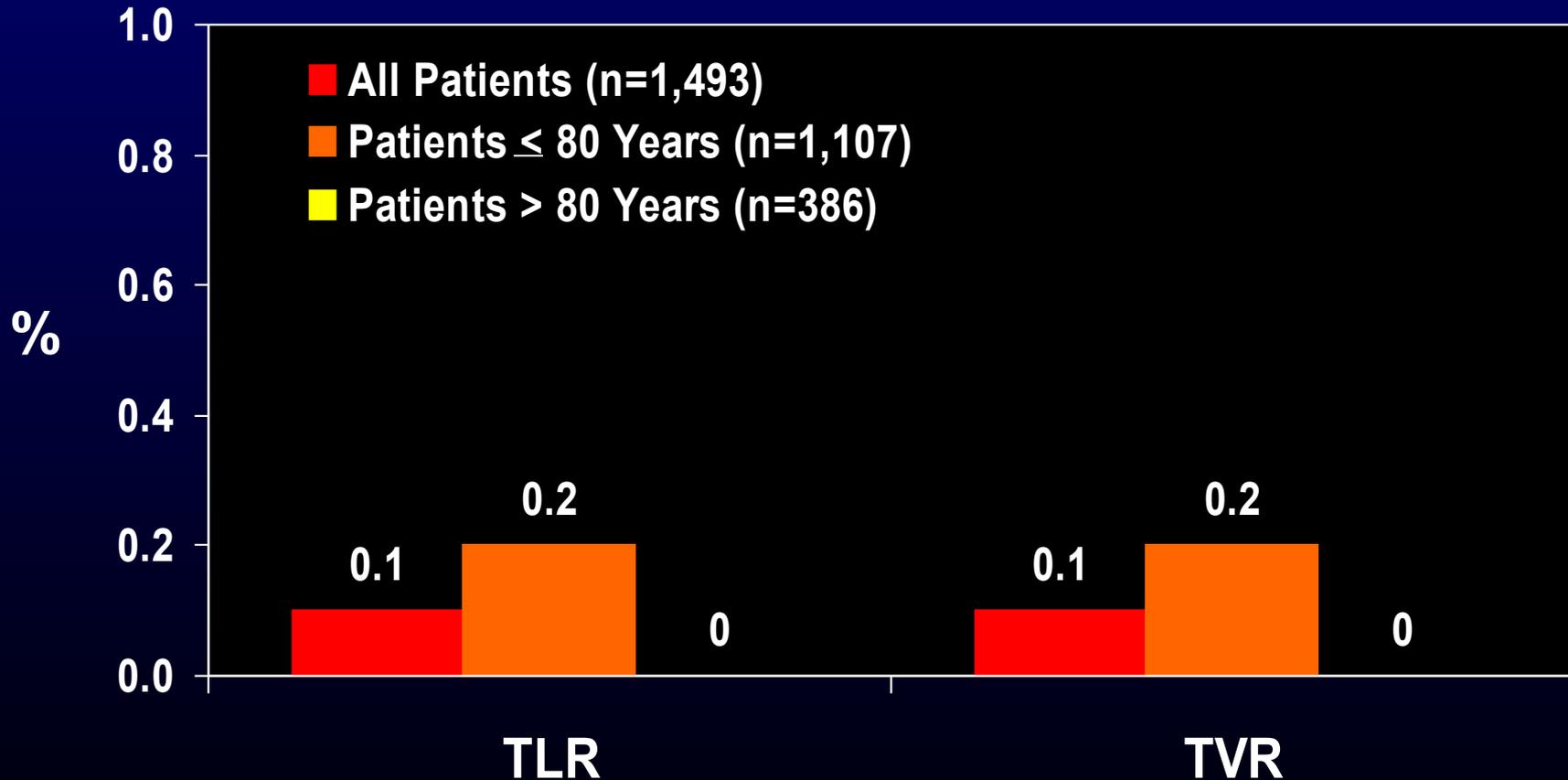
# Stroke at 30-Days Compared with Pooled Analysis\*



\*Pooled analysis from the > 80 years of age subgroups of the SAPPHERE (randomized and registry stent arms), CASES-PMS, ADVANCE, and Carotid Feasibility Trials)

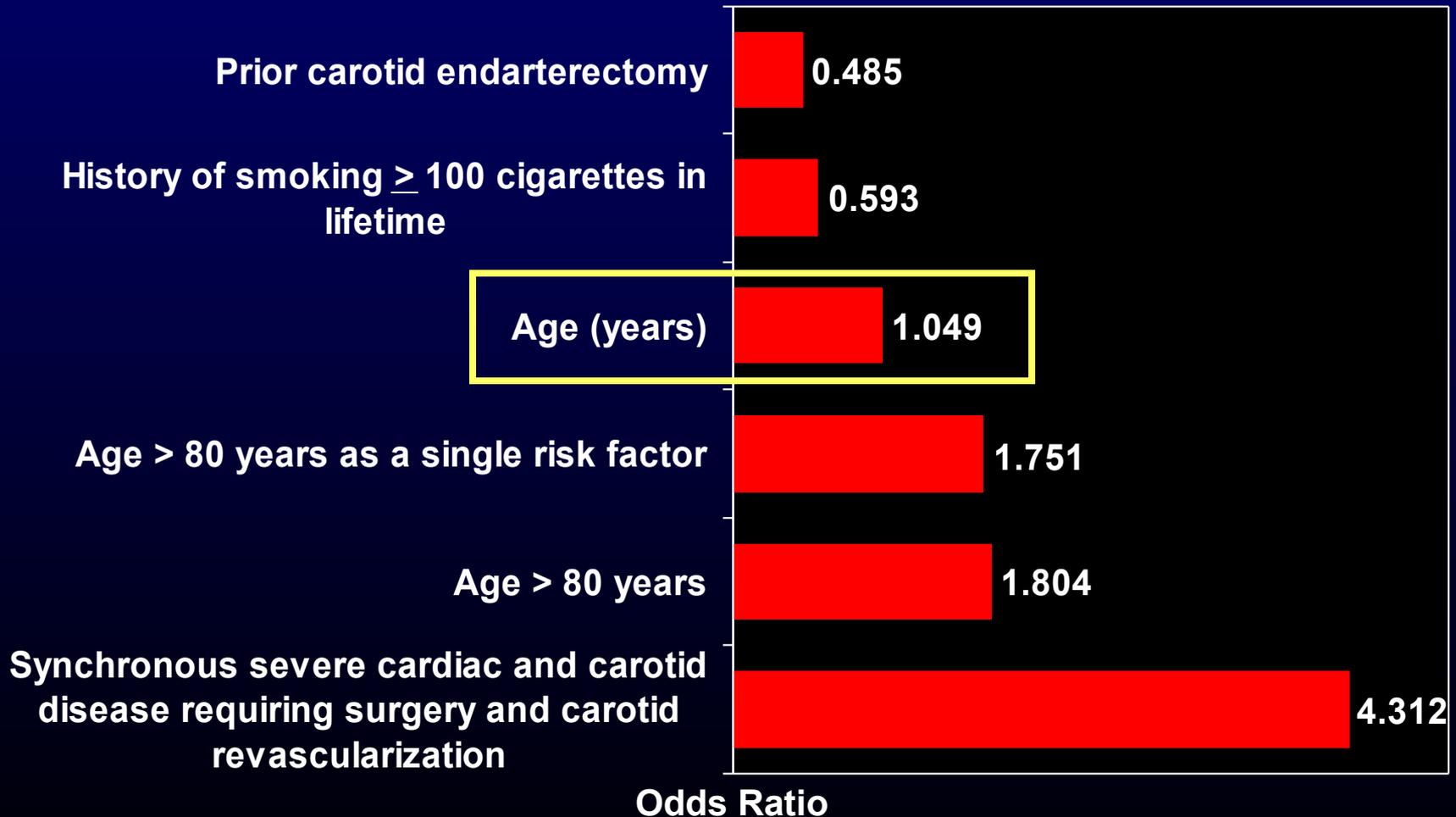
# Revascularization at 30-Days

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



# Univariate Predictors of MAE to 30 Days

## Logistic Regression Analysis



\*Only age and prior CEA remained as a multivariate predictors of MAE

# Univariate Predictors of Stroke to 30 Days

## Logistic Regression Analysis



\*Only age remained as a multivariate predictors of stroke

# Conclusions

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- **Consistent with outcomes in other studies involving vascular interventions, 30-day major adverse events are higher in patients > 80 old age than in younger patients undergoing CAS with distal protection**
- **Octogenarians have been excluded from most major studies of carotid endarterectomy**
- **Correlation of outcomes vs learning curve in these patients has not been done**
- **Direct comparison of safety and efficacy outcomes of carotid stenting and carotid endarterectomy will be required with associated health economic assessment to determine the proper role of carotid intervention in octogenarians**