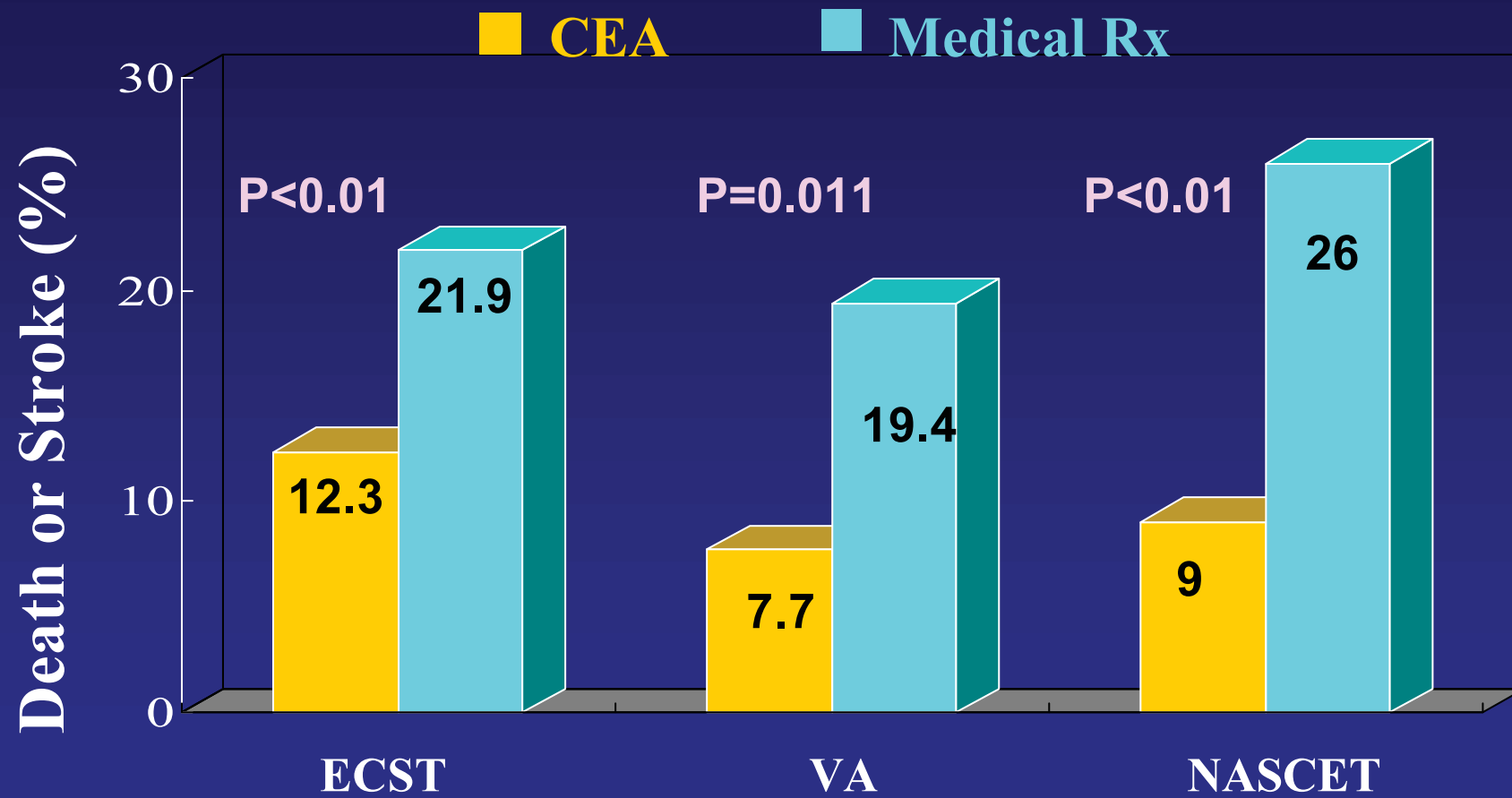


# **Outcomes of Carotid Artery Stenting in High to Extreme Risk Patients**

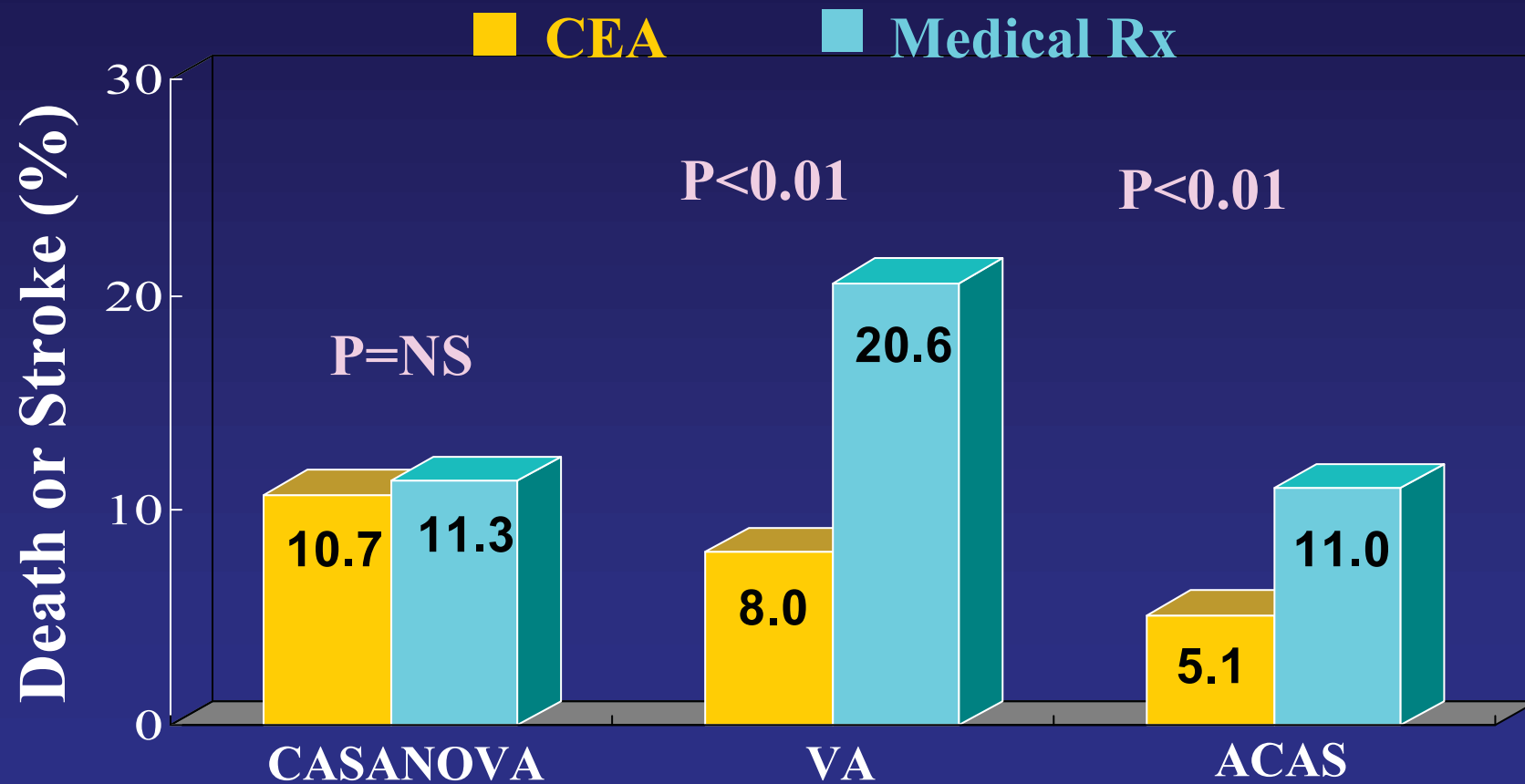
**Seong-Wook Park, MD, PhD, FACC**

**Department of Medicine, Asan Medical Center,  
University of Ulsan College of Medicine,  
*Seoul, Korea***

# Symptomatic Patients



# Asymptomatic Patients



# **BACKGROUND**

Carotid endarterectomy has been shown to be superior to medical treatment in reducing the overall risk of stroke in symptomatic or asymptomatic patients with carotid artery stenosis

NASCET. *N Engl J Med* 1998;339:1415–1421

ACAS. *JAMA* 1995;273:1421–1431

However, in high risk patients, especially those with angina pectoris, mortality rates of 4–18% following carotid endarterectomy have been reported.

*JAMA* 1995; 273: 1421–

# CAVATAS

## Multicenter Randomized Trial: *CEA vs. Angioplasty without protection*

	Angioplasty N=251	CEA N=253
<i>Stenting = only in 26%</i>		
30-day death & stroke	6.4%	5.9 %
Cranial neuropathy	0 %	8.7 %
1-year restenosis *	14 %	4 %

ischemic heart disease; 38%, Prior MI: 18%, Atrial fibrillation; 10%,  
contralateral carotid artery occlusion: 9%

# CEA vs CAS without protection

## Prospective Randomized Trial:

	CAS N=53	CEA N=51
Death/cerebral ischemia, n		
Death	0	1
Stroke	0	0
TIA	1	0
Other, n		
Arterial thrombosis/amputation	1	0
Hematoma	3	1
Cranial/cervical n injury	0	0
Bradycardia	7	7
Hypotension	12	3

Ischemic heart disease: 35%.

Brooks et al. J Am Coll Cardiol 2001;38:1

# **The SAPPHIRE Study**

**In high risk subsets for CEA**

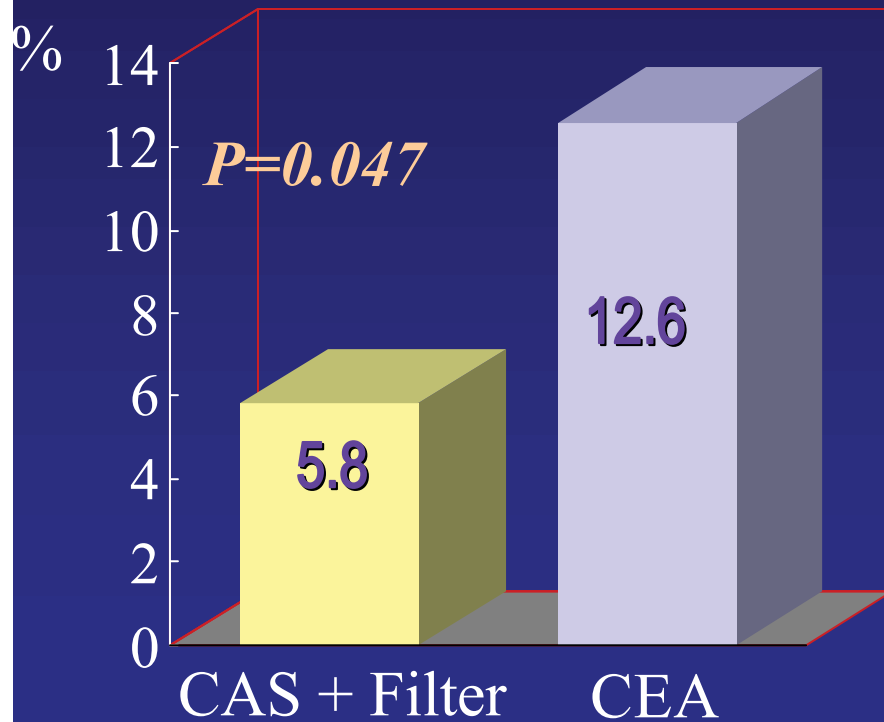
**Stenting with filter device**

**vs. CEA**

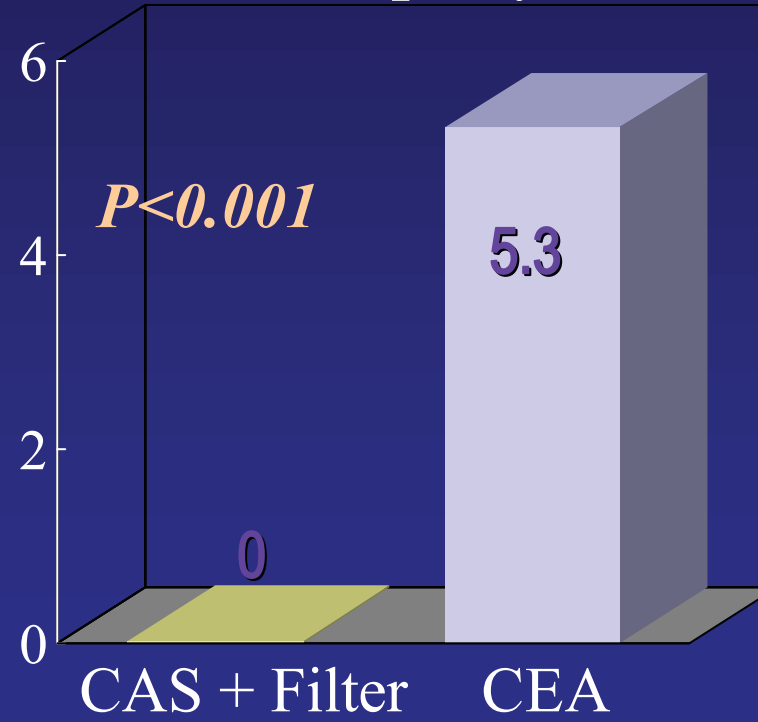
# SAPPHIRE

## 30-Day Events

### Death/MI/Stroke



### Cranial n. palsy





# ***BACKGROUND***

Carotid artery stenting is now widely used as an alternative to CEA, and it may be a reasonable approach to high-risk patients.

However, outcome of high to extreme risk patients undergoing carotid artery stenting has not been sufficiently evaluated.

# ***Purpose***

**We assessed the feasibility, safety, and clinical outcome in high to extreme risk patients undergoing percutaneous carotid interventions.**

# ***Study patients***

**From April 2001 to April 2004**

***Seventy consecutive high risk patients* who  
underwent carotid artery stenting in **74**  
carotid arteries.**

# ***Definition***

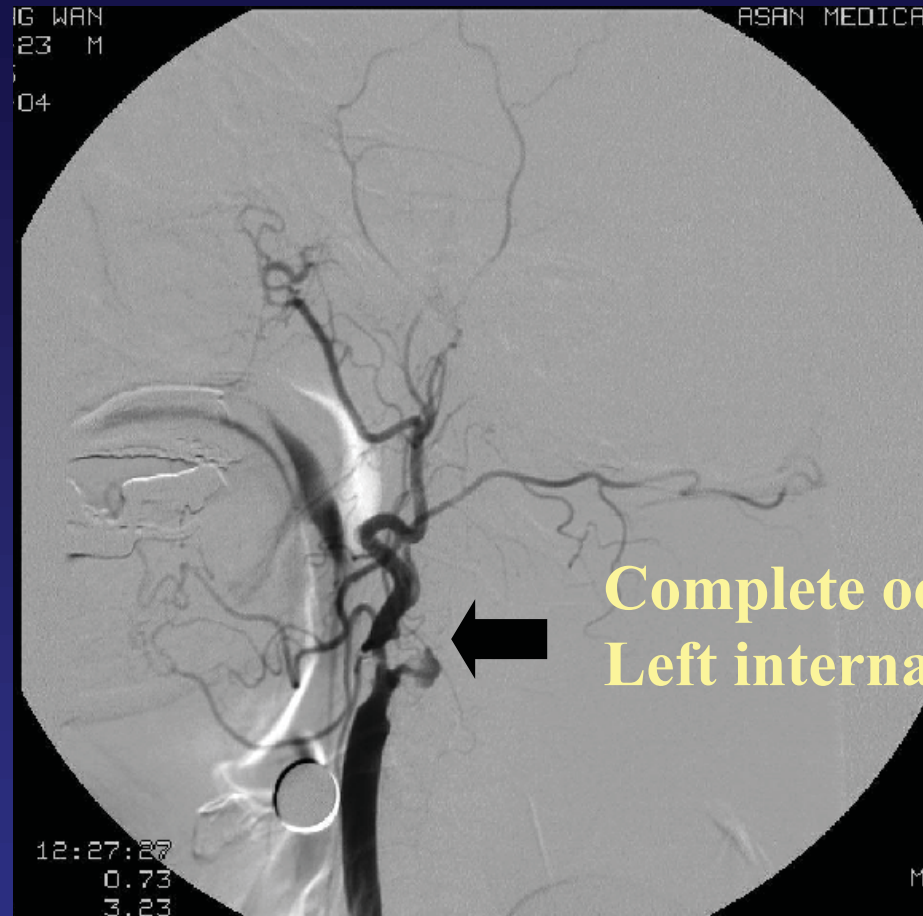
---

**Procedural success:** residual stenosis  $< 30\%$  and absence of major stroke, myocardial infarction or death

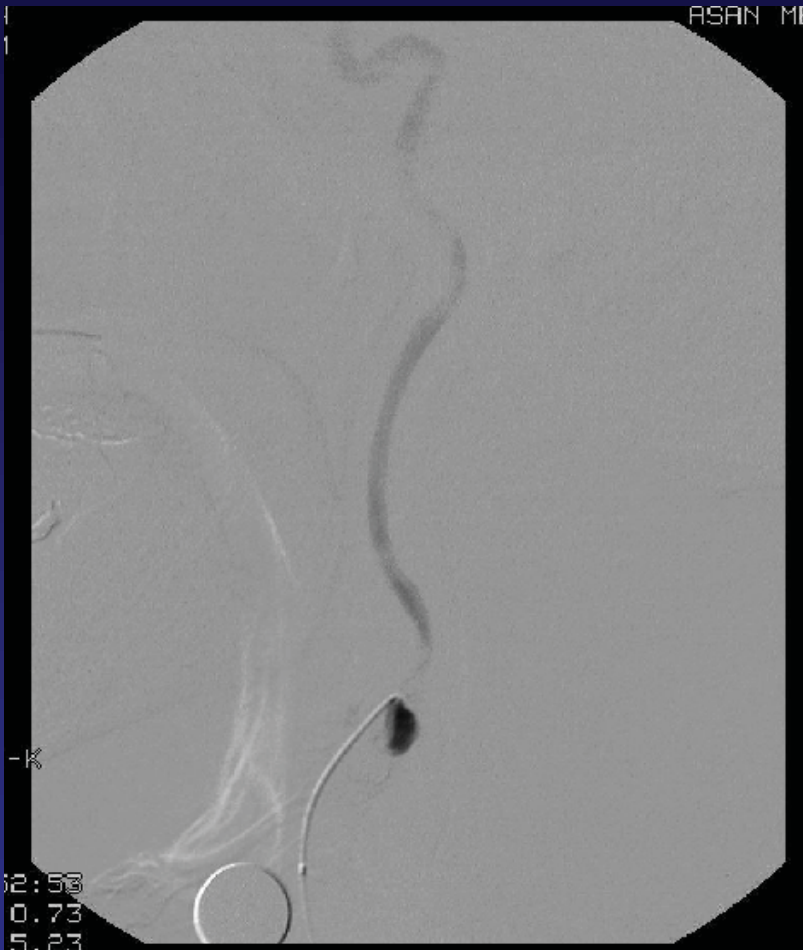
**Minor stroke:** change of NIH stroke scale by 3 and resolved neurological deficit within 30 days

**Major stroke:** change of NIH stroke scale  $\geq 4$  and persisted neurological deficit after 30 days

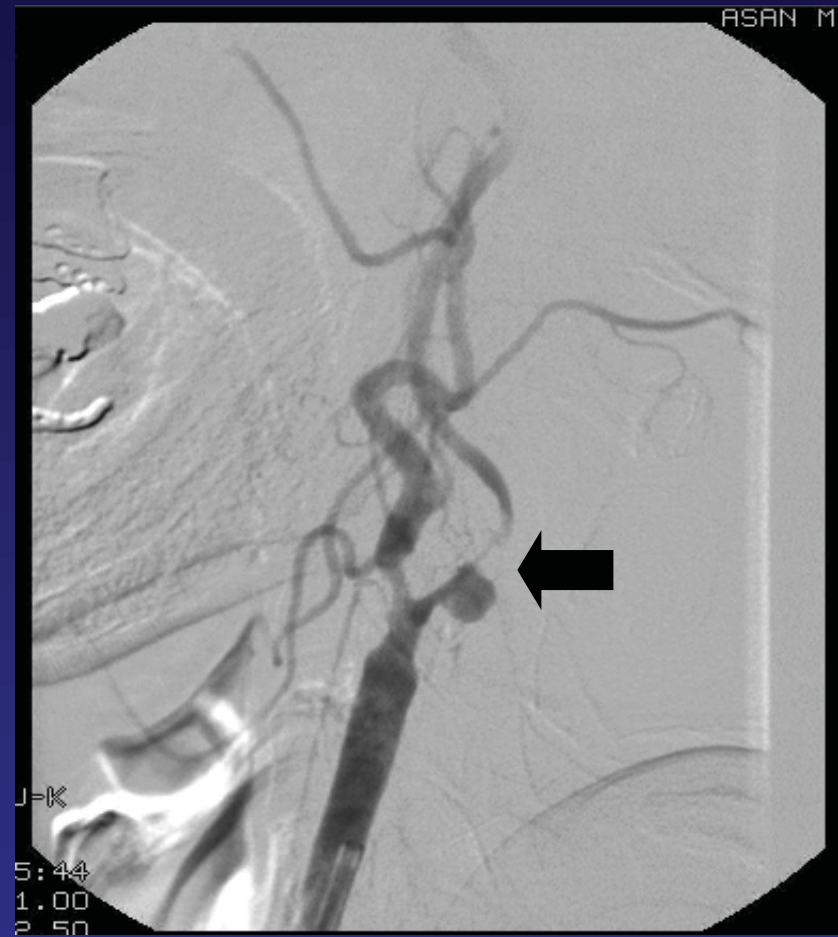
**Myocardial infarction:** CK-MB  $\geq 3$  fold upper normal



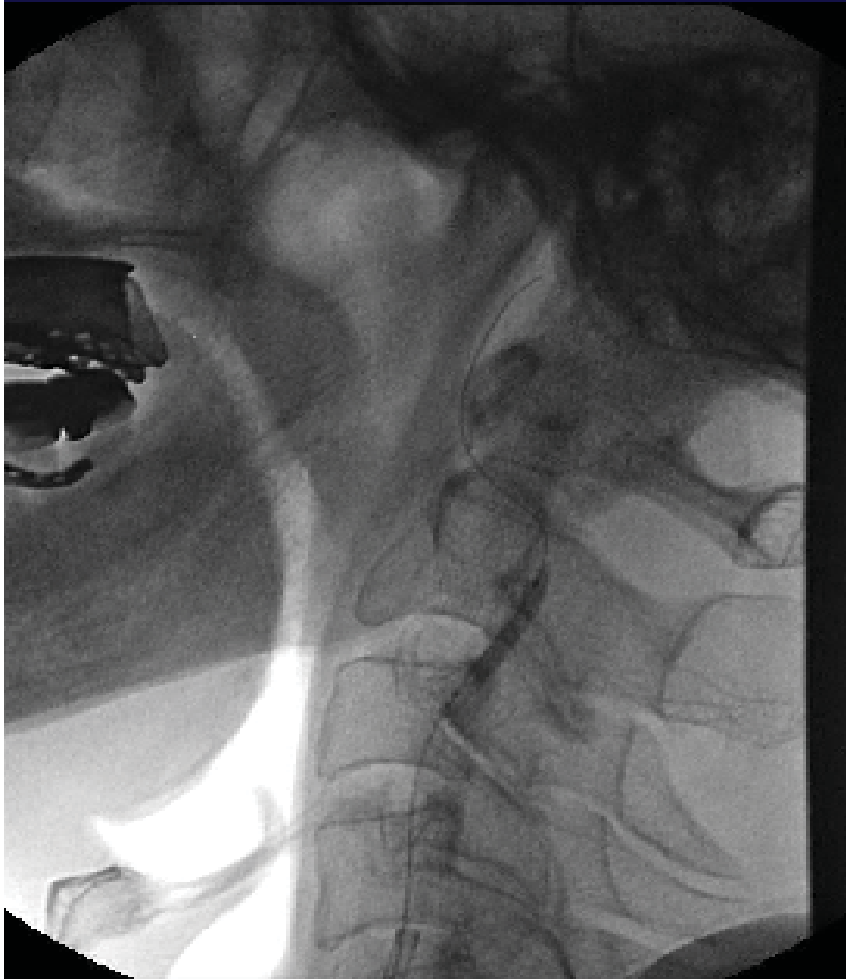
- M/80 years, right hemiplegia for 3 hrs
- Acute hemispheric stroke
- NIH stroke scale 17 at admission



Intra-arterial urokinase  
400,000 unit



Recanalized left internal  
carotid artery



Balloon angioplasty  
with U-pass 3.0x20

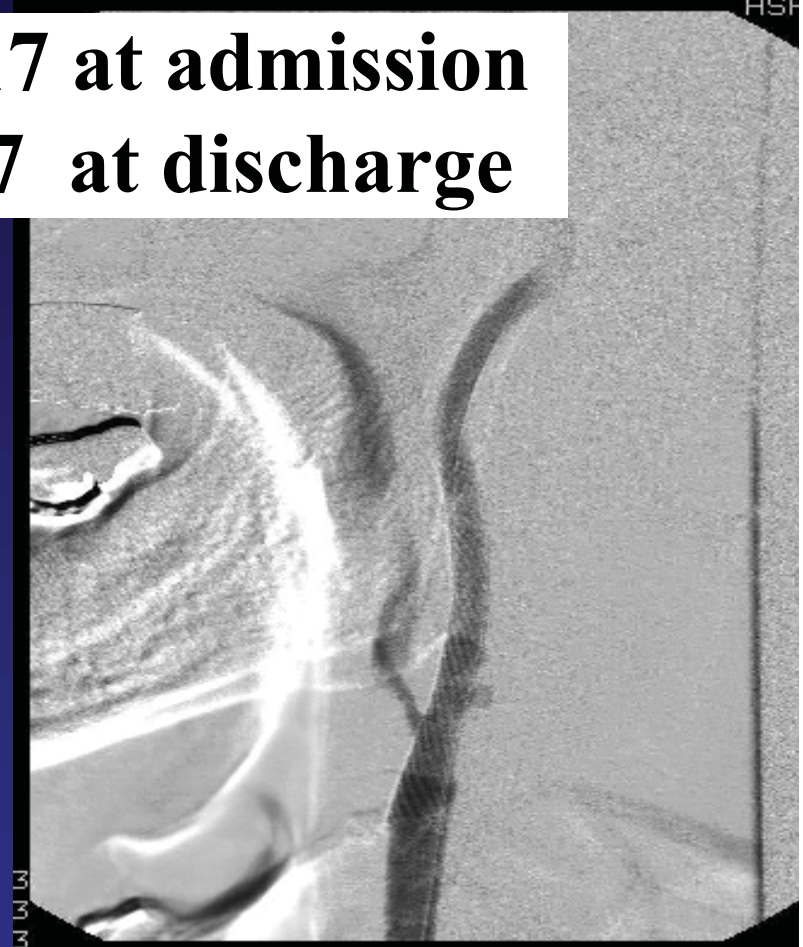


Post-ballooning

**NIH stroke scale 17 at admission**  
**NIH stroke scale 7 at discharge**

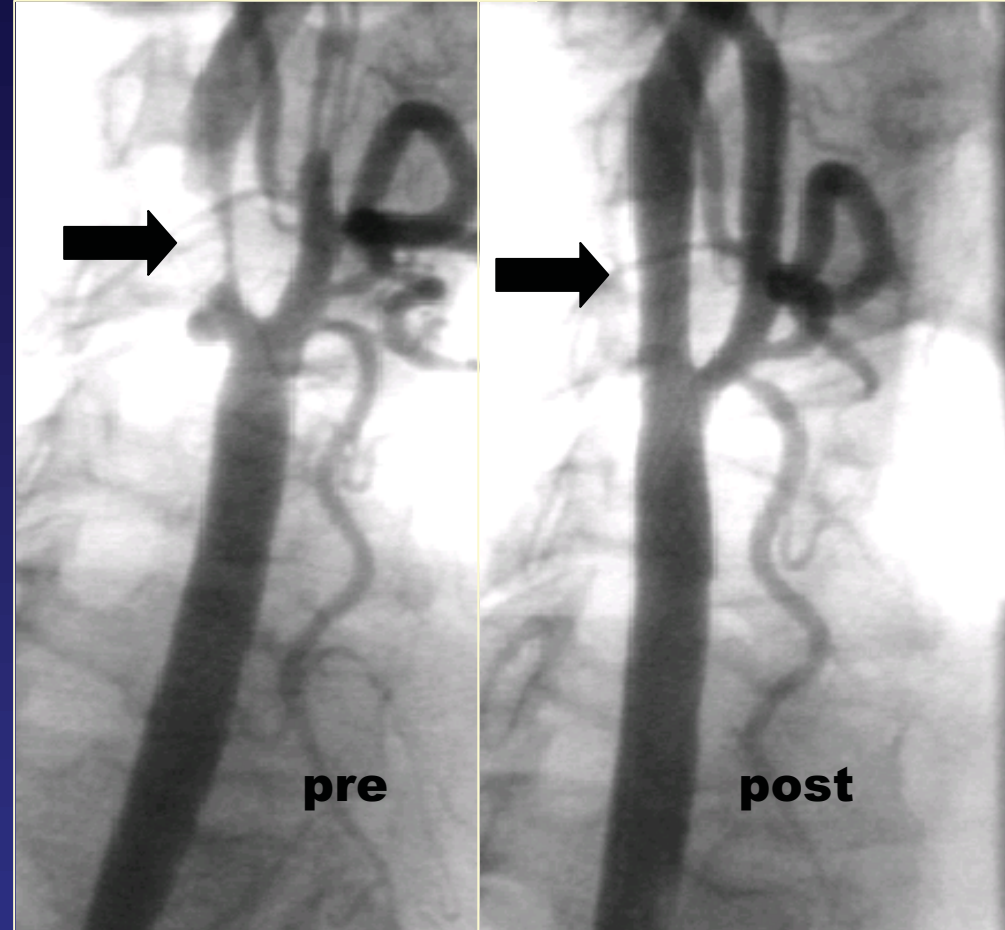
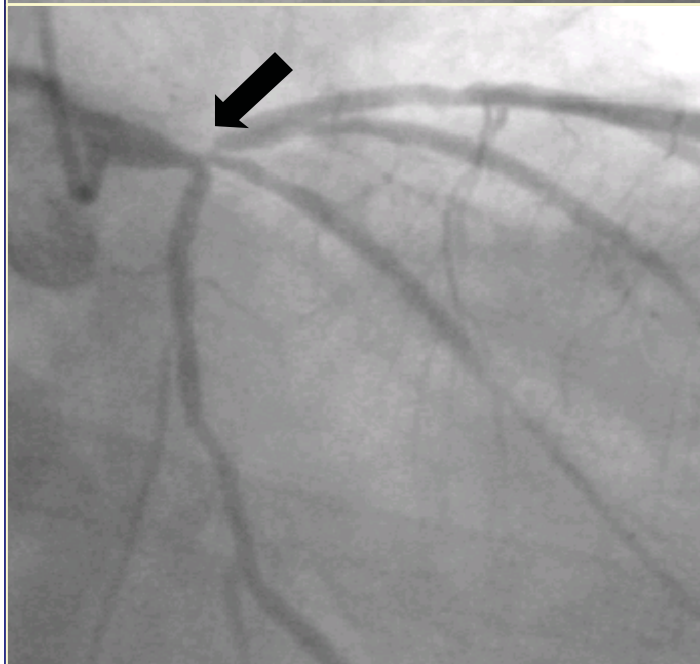
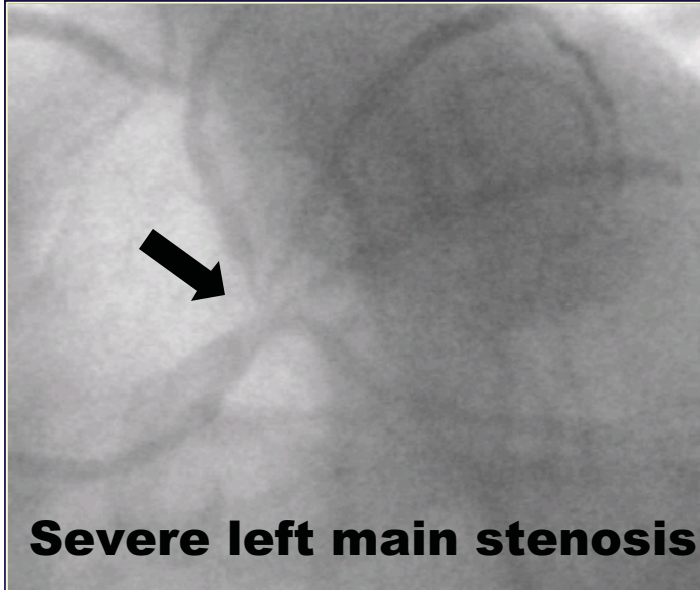


Stenting with Wall stent  
9x40mm

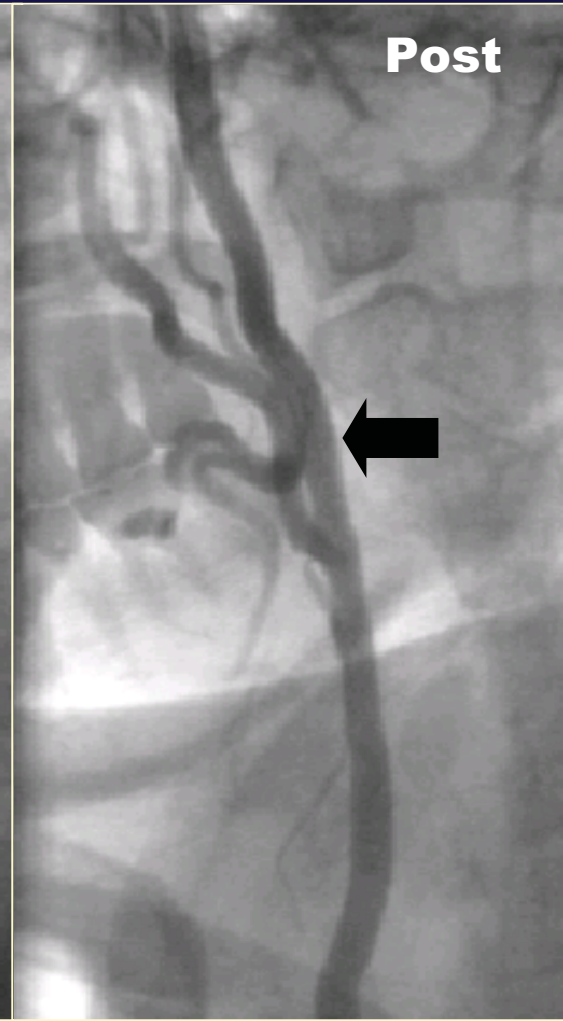
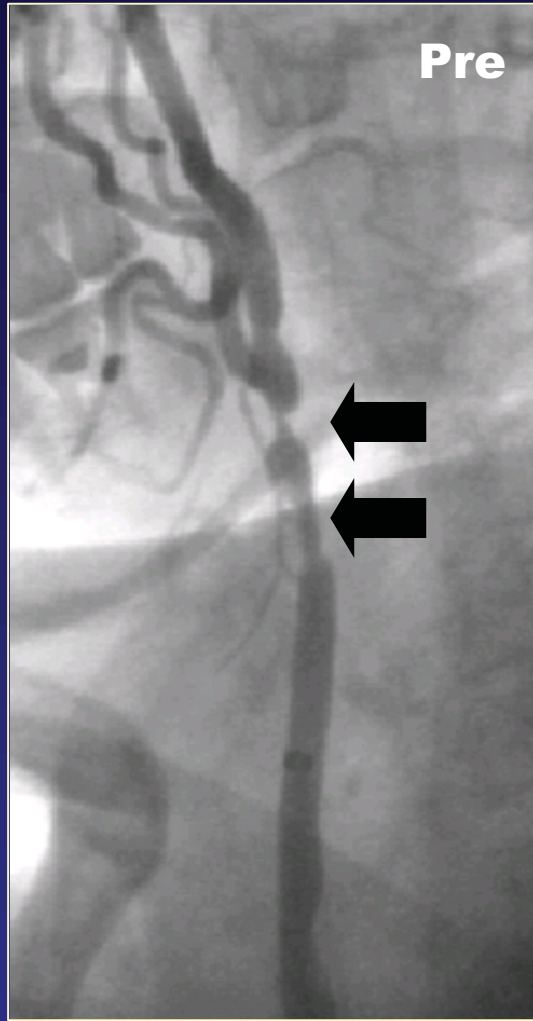
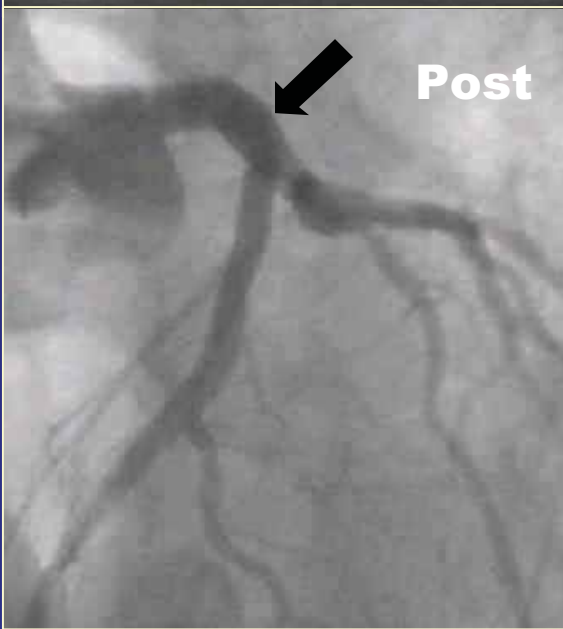
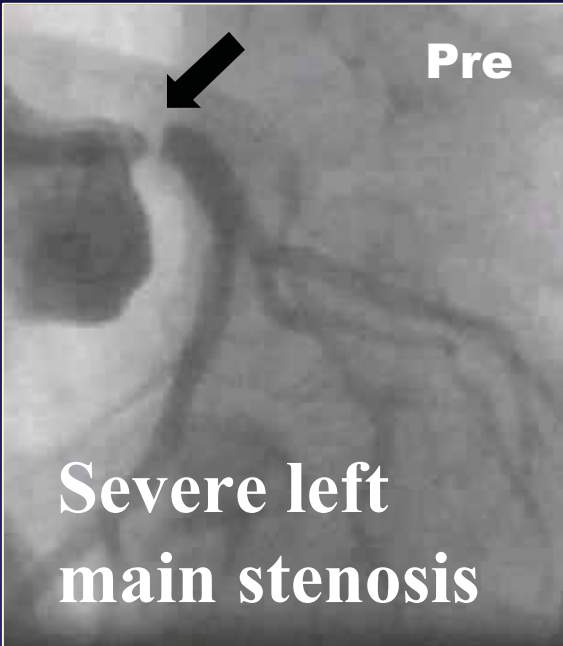


Final results with good  
antegrade flow





- **55YO Man with unstable angina**
- **CAG : LM+3VD**
- **No history of stroke**
- **Pre-CABG CAS was done**



- 60YO woman with stable angina
- CAG : LM disease
- Simultaneous left main coronary artery and carotid artery stenting.



- **67 y man with 3VD waiting for CABG**
- **Presented with acute right hemiparesis with unstable neurological symptoms**
- **Urgent carotid stenting performed**

# Baseline Characteristics

n=70

Age (years)	65±10	33-86
Age > 80 years	7	10%
Male gender	57	81.4%
Treated artery	74	100%
Symptomatic	47	67.1%
Hypertension	47	67.1%
Diabetes mellitus	30	42.9%
Peripheral vascular disease	7	10%

# Reason for High to Extreme Risk

n=70

<b>Neurologically unstable</b>	33	47.1%
Hyperacute hemispheric stroke	13	18.6%
Evolving neurological deficit	20	28.6%
<b>Severe coronary artery disease</b>	40	57.1%
Left main disease	6	8.6%
Unstable angina	25	35.7%
Recent myocardial infarction	2	2.9%
<b>Asymptomatic heart failure</b>	4	5.7%
NYHA III/ IV	4/0	

# Reason for High to Extreme Risk

n=70

Age > 80 years	7	10%
Atrial fibrillation	6	8.6%
Surgically inaccessible	8	11.4%
Contra-lateral occlusion	11	15.7%
Severe co-morbidity	6	8.6%
Renal failure	3	
Myelodysplastic syndrome	1	
Chronic obstructive pulmonary disease	1	
Aortic dissection	1	

# Reason for NASCET exclusion

NASCET: North America Symptomatic Carotid Endarterectomy Trial

n=62

---

Age > 79 years	7	11.3%
Atrial fibrillation	6	9.7%
Unstable angina	25	40.3%
Recent myocardial infarction	2	3.2%
Neurologically unstable	33	53.2%
Symptomatic heart failure	4	6.5%
Severe co-morbidity	5	8.1%

# **Procedural Characteristics**

n=70

(74 lesions)

---

<b>Angiographic success</b>	73	98.6%
<b>Procedural success</b>	65	92.9%
<b>Lesion length, mm</b>	16.5±6.7	
<b>Diameter stenosis, %</b>		
Pre-intervention	87.9±10.0	
Post-intervention	8.7±7.3	
<b>Distal protection device</b>	19	27.1%



# In-Hospital outcome

n=70

Transient ischemic attack	2	2.9%
Minor stroke	1	1.4%
Major stroke	2	2.9%
<b>Death#</b>	2	2.9%
Myocardial infarction	0	0
<b>Combined events*</b>	5	7.1%

morrhagic transformation in patients with hyperacute ipsilateral hemispheric stroke treated with IAUK and stenting on 3<sup>rd</sup> and 11<sup>th</sup> days after index procedure by stroke, myocardial infarction or death

# In-Hospital outcome

acute stroke treated with emergency  
vascularization)

n=13

Intra-arterial urokinase

4

30.8%

NIH stroke scale

Baseline

9.8 ± 5.4

4-17

At discharge

5.3 ± 3.1

0-10

Improved

9

69.2%

Aggravated

2

15.4%

No change

2

15.4%

Hemorrhagic transformation #

2

15.4%

Death #

2

15.4%

Combined events

2

15.4%

hemorrhagic transformation in patients with hyperacute ipsilateral hemispheric stroke treated with IAUK and stenting on 3<sup>rd</sup> and 11<sup>th</sup> days after index procedure

# Clinical Follow-Up Data

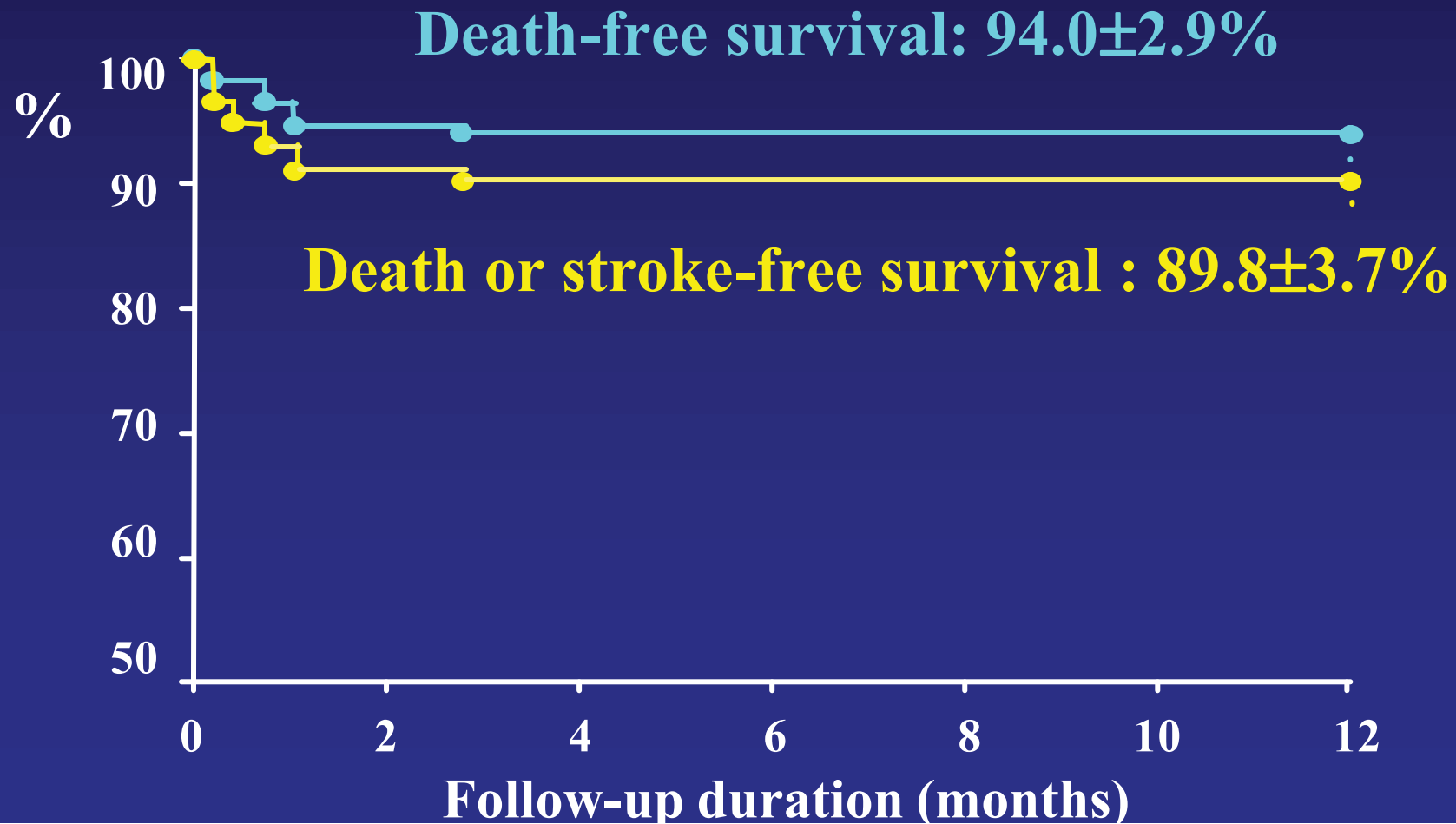
	Discharge to 30 days	At 1 year
Transient ischemic attack	0	0
Minor stroke	0	0
Major stroke	0	0
Death	0	2(3.3%)
Cerebral hemorrhage *	0	1(1.7%)
Unknown cause #	0	1(1.7%)
Combined event	0	2(3.3%)

At 3.5 months after index procedure

At 1.5 months after index procedure

# Event-Free Survival

Mean follow-up duration:  $16.2 \pm 9.5$  months



# **CONCLUSION**

- **Carotid artery stenting** appears to be technically feasible and safe, even in high to extreme risk patients with few major complications.
- **Carotid artery stenting** may be a reasonable alternative to carotid endarterectomy.
- Long-term follow up is necessary to assess the durable effect of carotid artery stenting in these selected high-risk group.