2010 CATH LAB SYMPOSIUM

Carotid Artery Stent: Is it ready for prime time?

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Memorial Regional Hospital

August 2010

CAE and CAS

- CAE 56 yrs old and the most studied vascular operation in history of medicine
- CAS 15 yrs old and the most devated and scrutinized interventional procedure

Stroke

- Third most common cause of death
- 750,000 strokes each year in the US.
- Single most important cause of long term intellectual and physical disability.
- Huge economical burden on society.
- Approx 25% of strokes are related to extracranial carotid artery disease.

INDICATIONS

The ONLY reason for treating bifurcation carotid stenosis is:

to reduce the risk of stroke

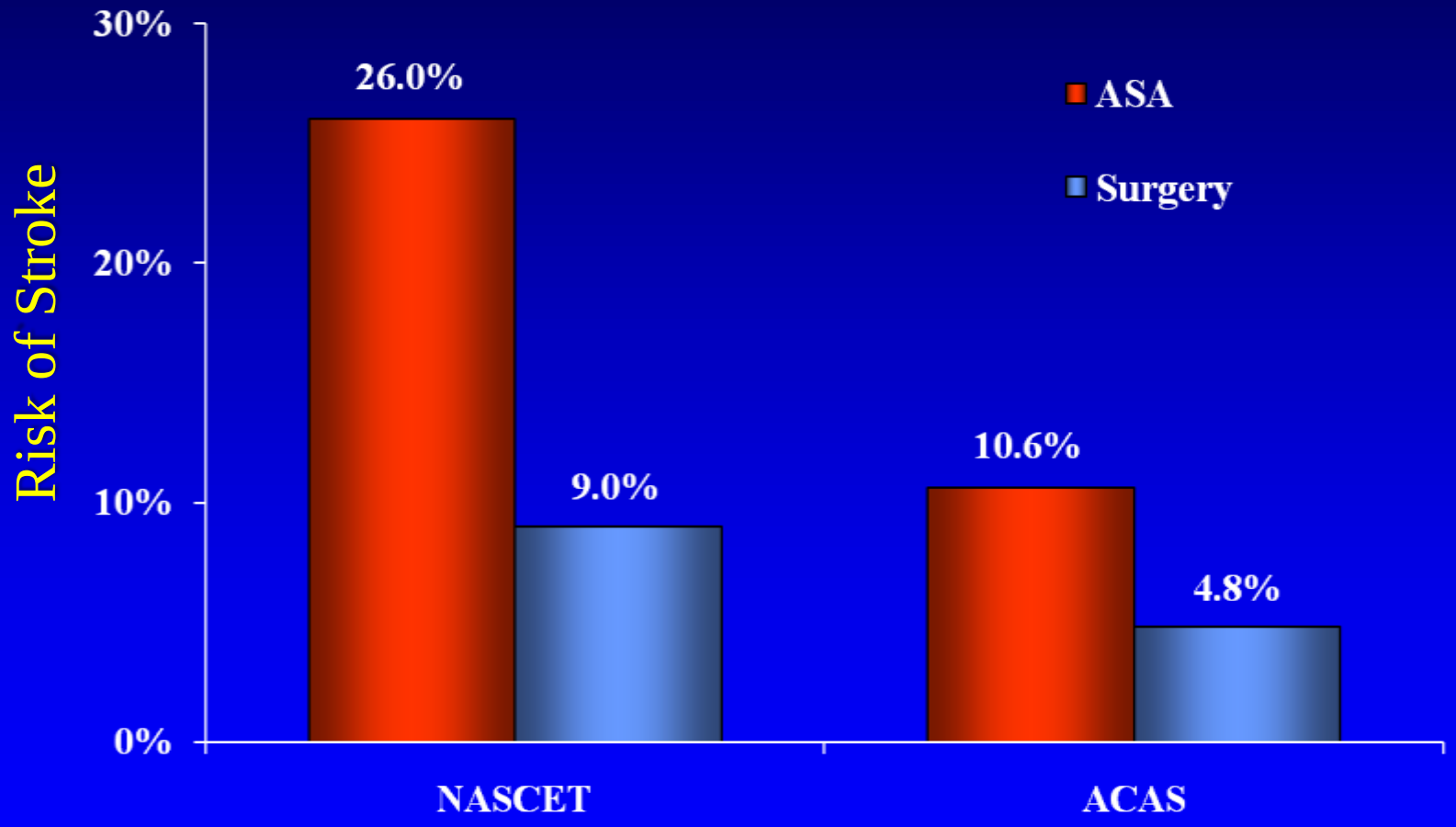
INDICATIONS

The stroke risk associated with the intervention

…..should not exceed the stroke risk related to the natural history of the disease!

- **Symptomatic: 10 –15% next 6-9 months**
- **Asymptomatic: 2-3% per year**

CAE for Carotid Stenosis



CAROTID ENDARTERECTOMY INDICATIONS

GOAL: STROKE PREVENTION (IF BENEFIT > RISK)

SYMPTOMATIC : > 50%

NASCET I and II and ECST

If risk of surgery is less than 6%

ASYMPTOMATIC : >80%

ACAS and ACST

If risk of surgery is less than 3%

Endarterectomy Trials: Exclusions

NASCET and ACAS Exclusions

- Age>79
- Prior ipsilateral CEA
- Unstable coronary syndrome
- Myocardial infarct in previous 6 months
- Cardiac valvular or rhythm abnormality likely to cause embolic cerebrovascular symptoms
- Contralateral occlusion
- A more severe lesion cranial to the surgical lesion
- Contralateral CEA within previous 4 months
- Uncontrolled hypertension or diabetes
- Organ failure likely to cause death within 5 years
- Total occlusion
- Major surgical procedure in previous 30 days
- Prior severe CVA
- Progressing neurologic syndrome

Endarterectomy outcomes in high surgical risk patients

There are no randomized trials in high surgical risk patients

to guide recommendations for therapy

U.S. Food and Drug Administration

Department of Health and Human Services

FDA News

FOR IMMEDIATE RELEASE

August 31, 2004

Media Inquiries: (301) 827-6242

Consumer Inquiries: 888-INFO-FDA

FDA Approves Stent System as an option for patients at high risk for CAE

Carotid Artery Stenting: INDICATIONS

FDA approved CAS as an alternative to CAE in patients at high risk for surgery

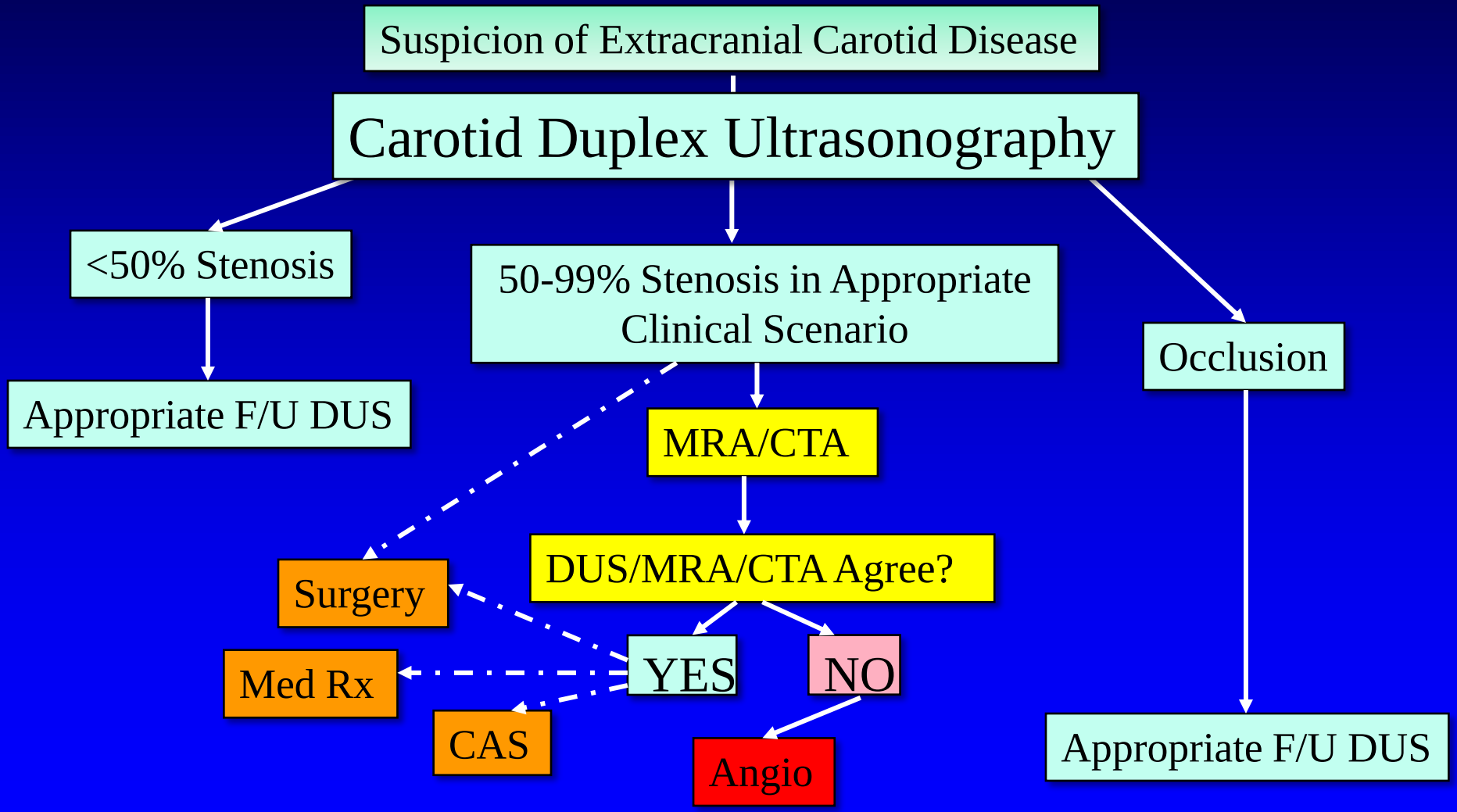
1. **ANATOMICAL**:
   - Lesions too high or too low
   - Tandem lesions
   - Contralateral occlusion or stenosis
   - Restenosis post CAE
   - Post radiation or radical neck surgery
   - Neck too short, C-spine immobility
   - Contralateral laryngeal nerve palsy

Carotid Artery Stenting: INDICATIONS

2. PHYSIOLOGICAL (COMORBIDITIES):

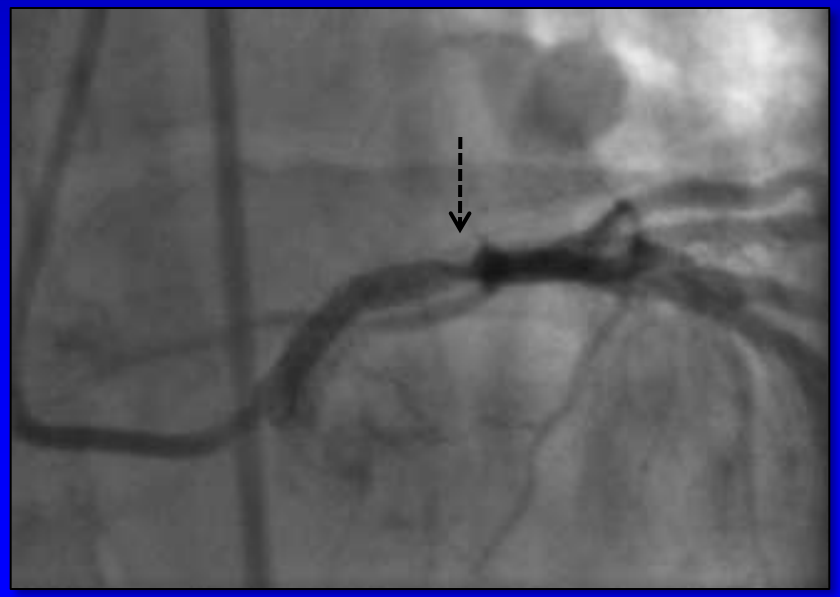
- Older than 75
- CHF class III or IV
- EF less than 30%
- USA or recent MI
- Severe COPD
- Cardiac disease requiring surgery within 6 weeks
- Severe CAD (2 lesions > 70% stenosis or abn. Stress test in 2 territories or large defect)
- Renal failure requiring dialysis.

Diagnostic Algorithm for Extracranial Carotid Disease



CASE: High surgical risk

- 81 yr old, severe CAD with USA and needs CABG.
- Found to have an asymptomatic 90% R ICA stenosis
- Hypertension
- Hypercholesterolemia

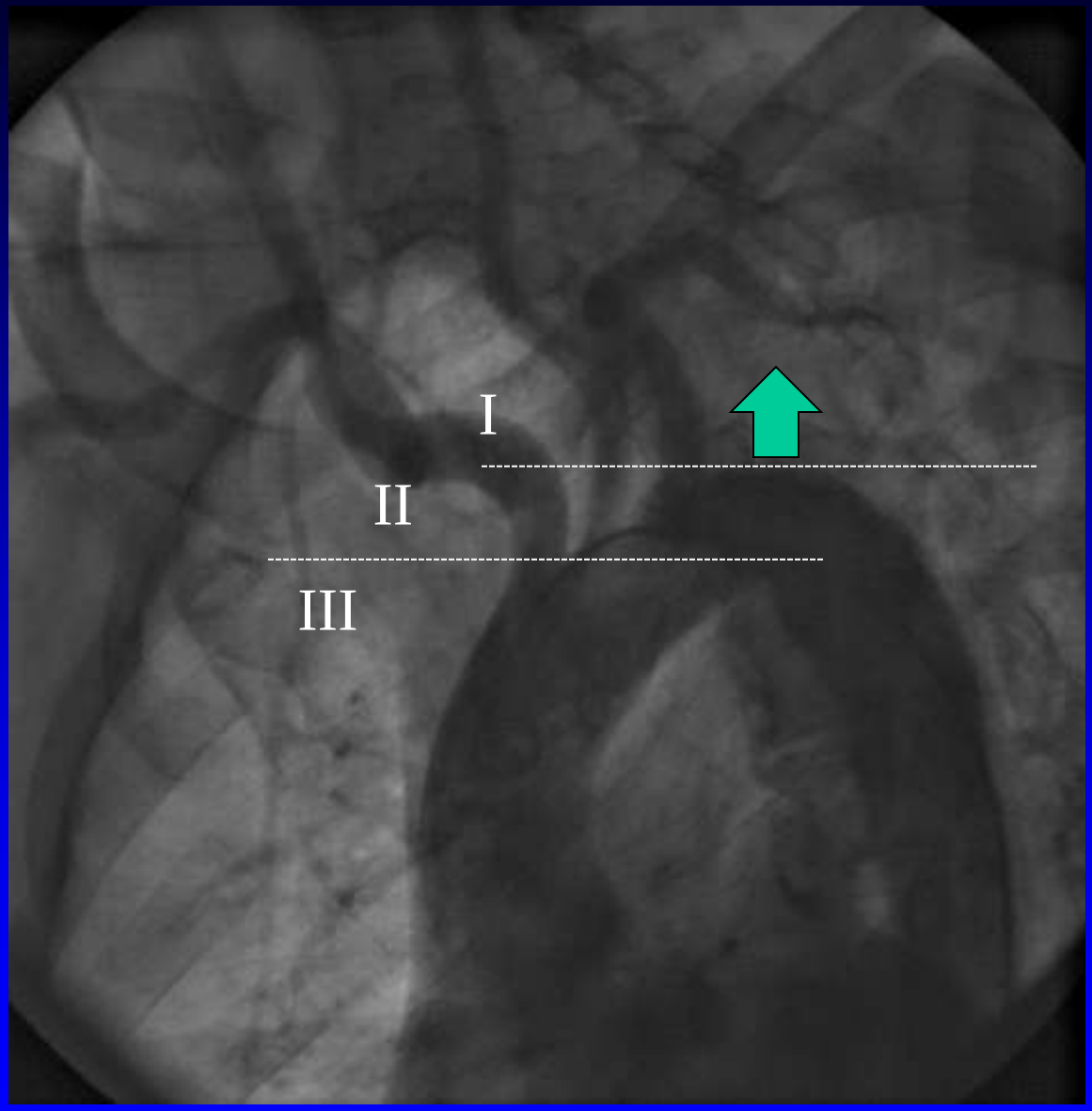


Duplex US

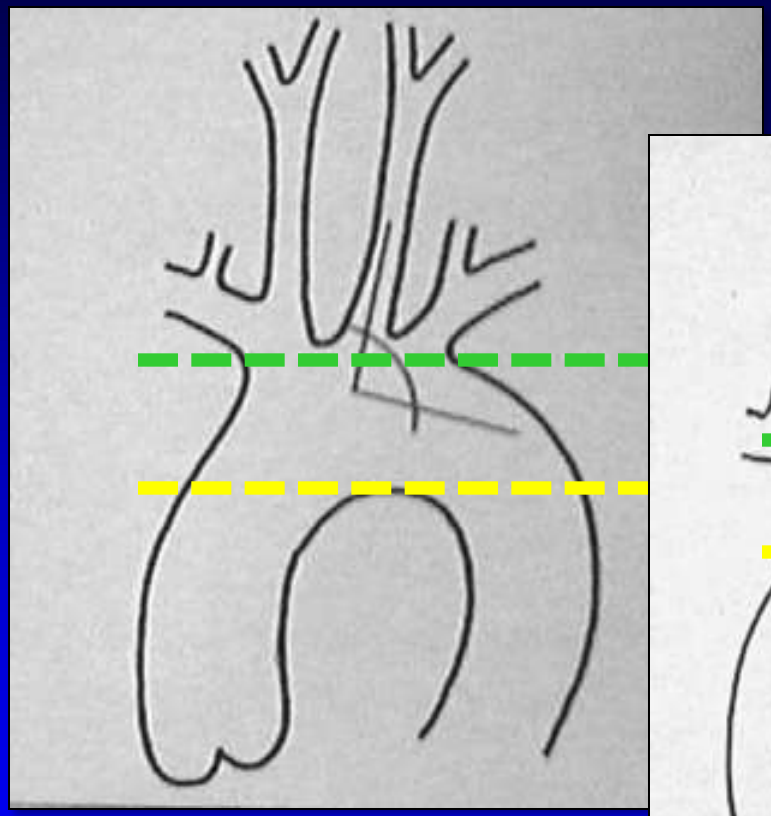

FR 28Hz 42°
R1
2D
60%
C 50
P Low
Gen
CF
74%
3000Hz
WF 165Hz
Med
PW
82%
WF 150Hz
SV1.5mm
M2
3.5MHz
1.8cm
M2 M3
+28.9
-28.9
cm/s
R Prox ICA
PSV -333 cm/s
EDV -86.2 cm/s
3.5
-400
-300
-200
-100
Inv
cm/s
100
RT ICA Prox
3.6sec


28Hz 46°
P Low
Gen
CF
74%
3000Hz
WF 165Hz
Med
PW
70%
WF 70Hz
SV1.5mm
M2
3.5MHz
1.7cm
M2 M3
+28.9
-28.9
cm/s
L Prox ICA
PSV -92.4 cm/s
EDV -23.6 cm/s
3.5
-180
-120
-60
Inv
cm/s
60
LT ICA PROX
3.6sec

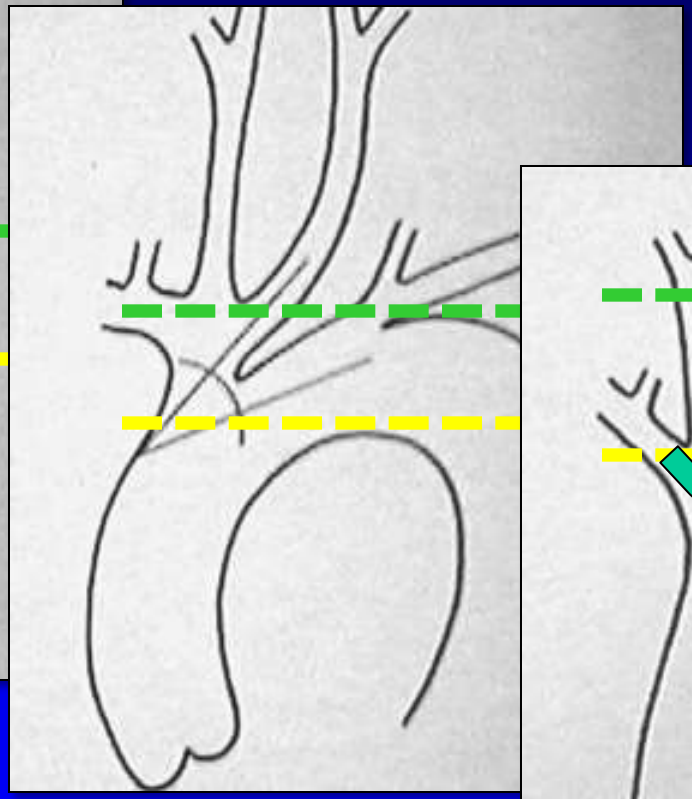
Aortic Arch



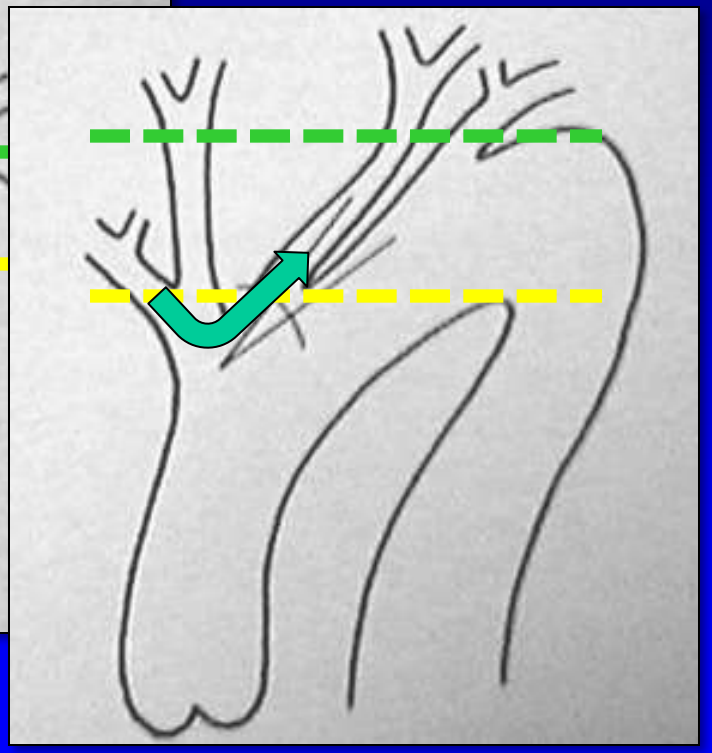
Aortic Arch Types



Type I Arch



Type II Arch



Type III Arch

R ICA

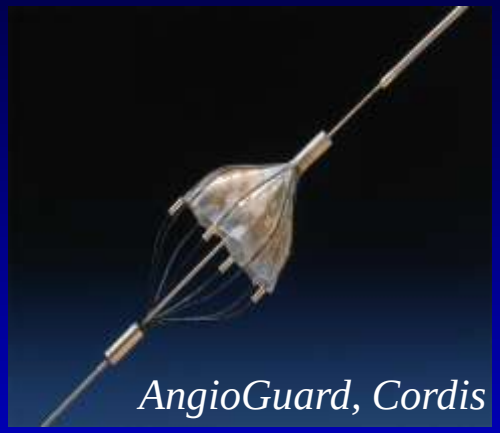
Filter

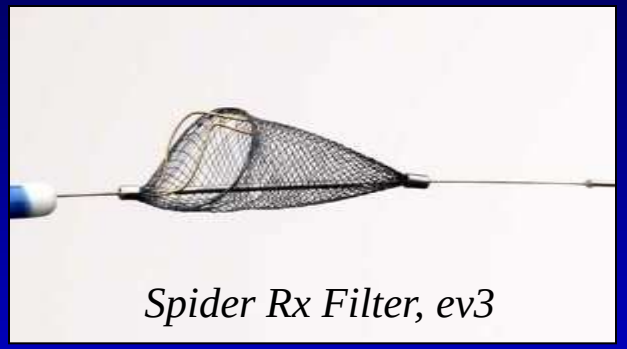
After pre-dilation

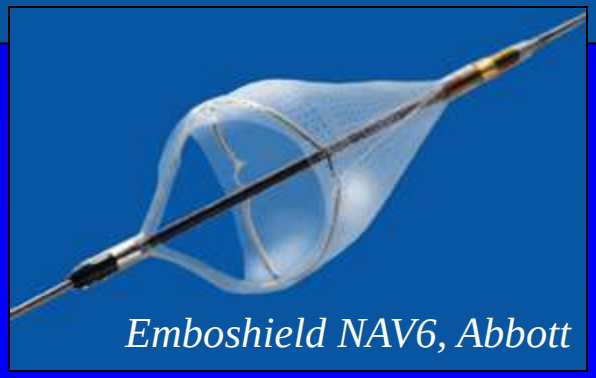
After Stent

Cerebral protection is necessary:

Filters Approved in US





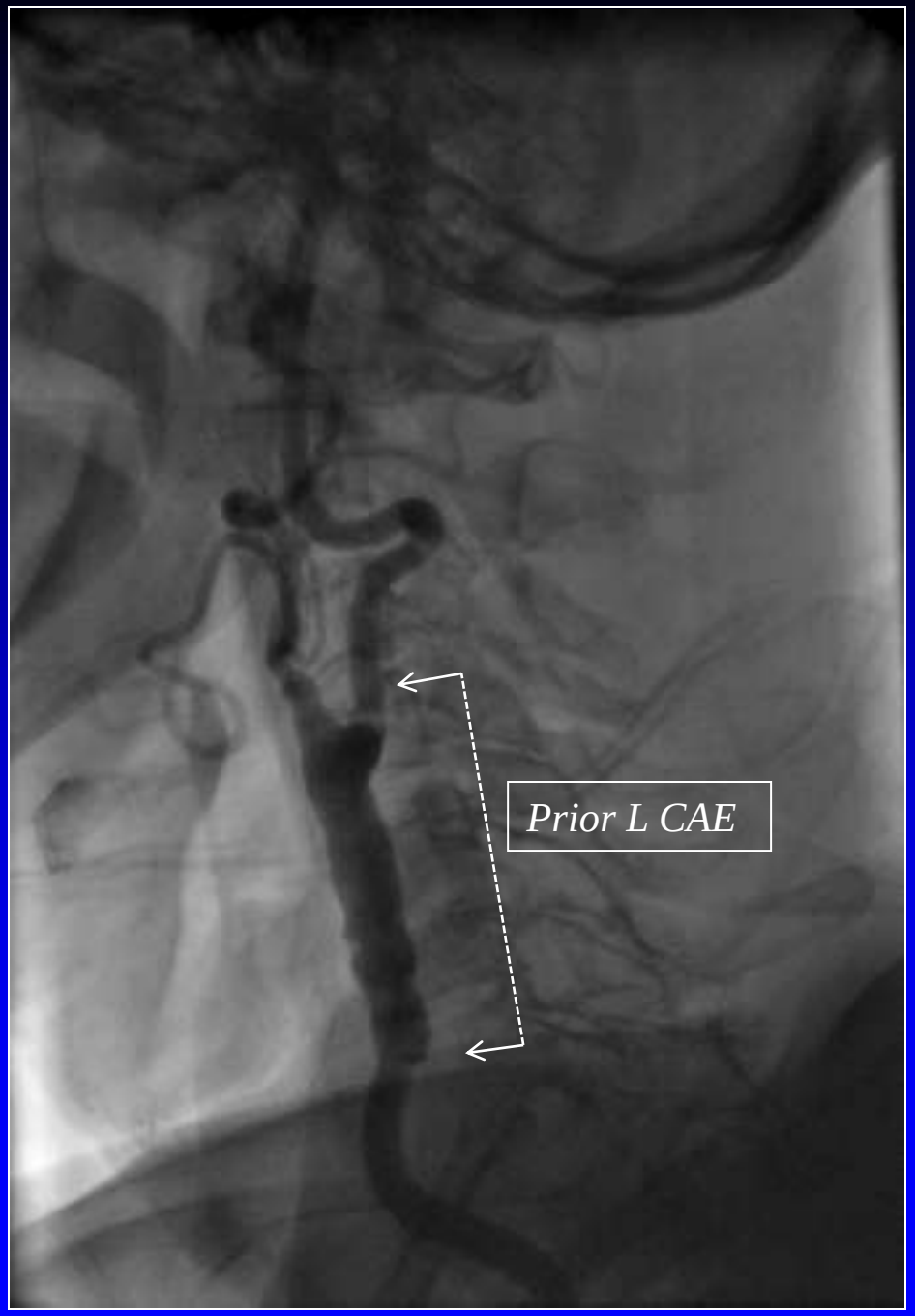


CASE: Multiple high risk features

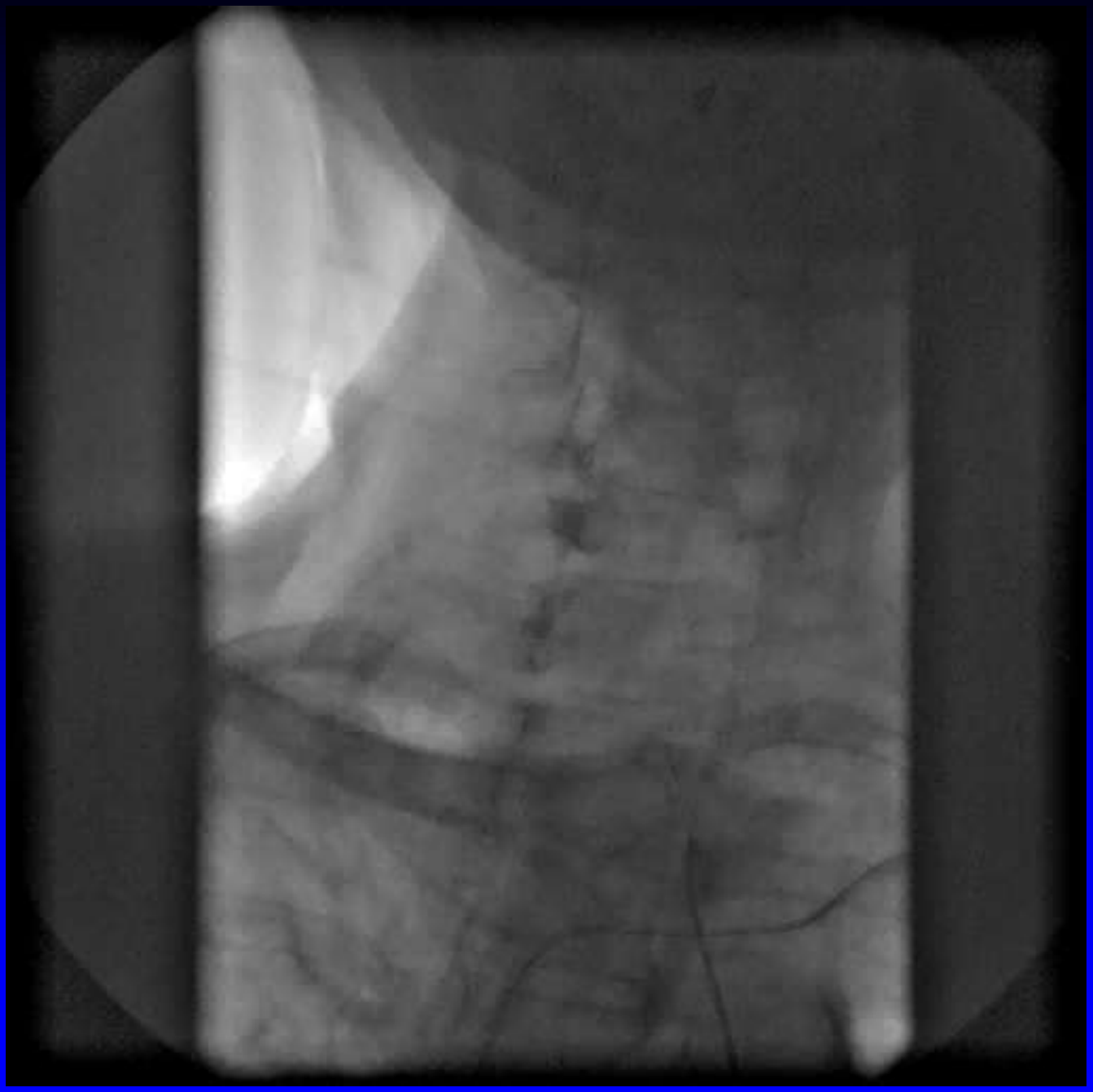
- 80 yr old Tonsillar cancer 1988, s/p R radical neck dissection 1988 and RT
- Bilateral CAE 10 yrs ago
- Cardiomyopathy, ICD

- Asymptomatic, progressive R CCA stenosis by Duplex

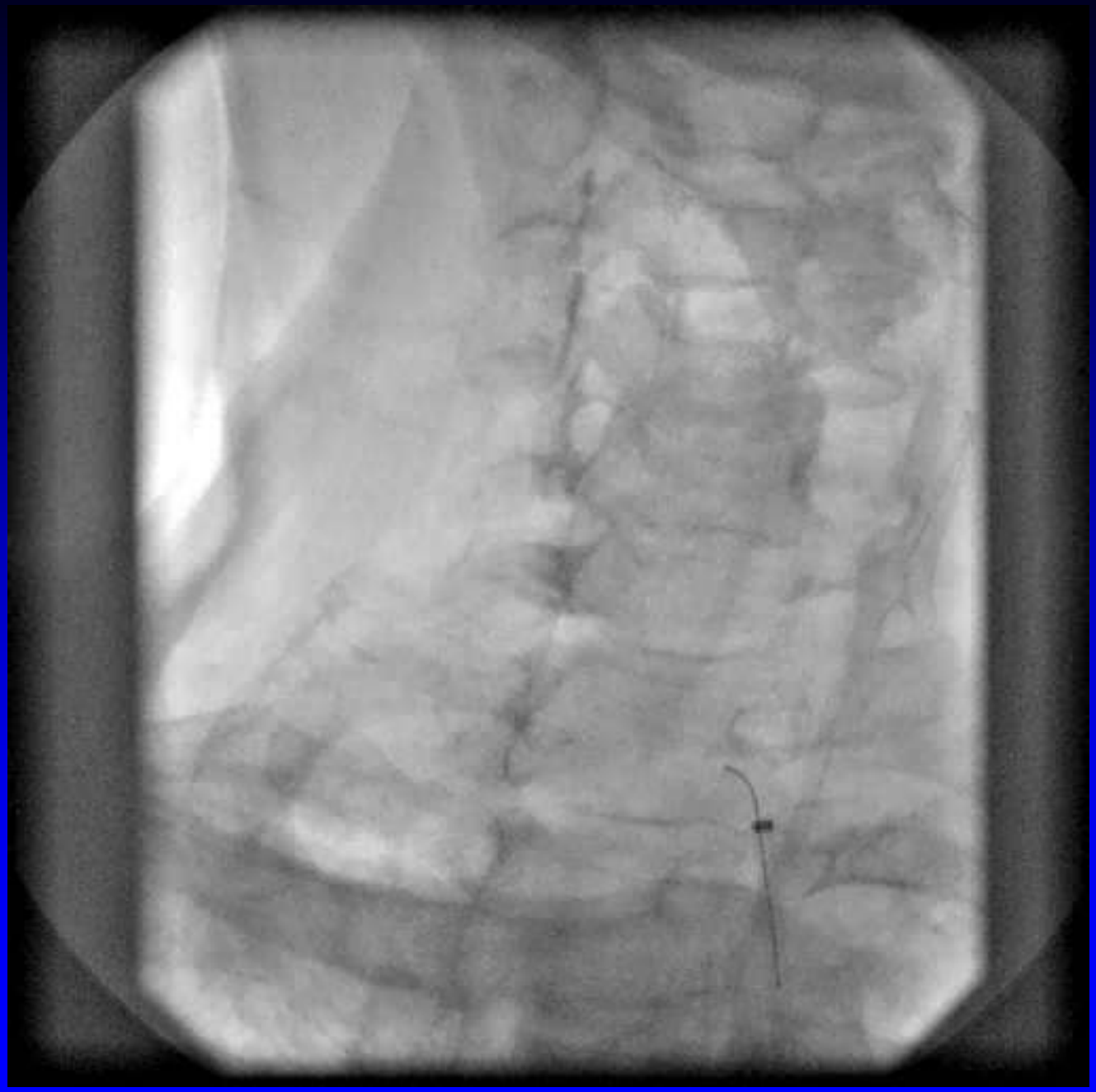
L ICA



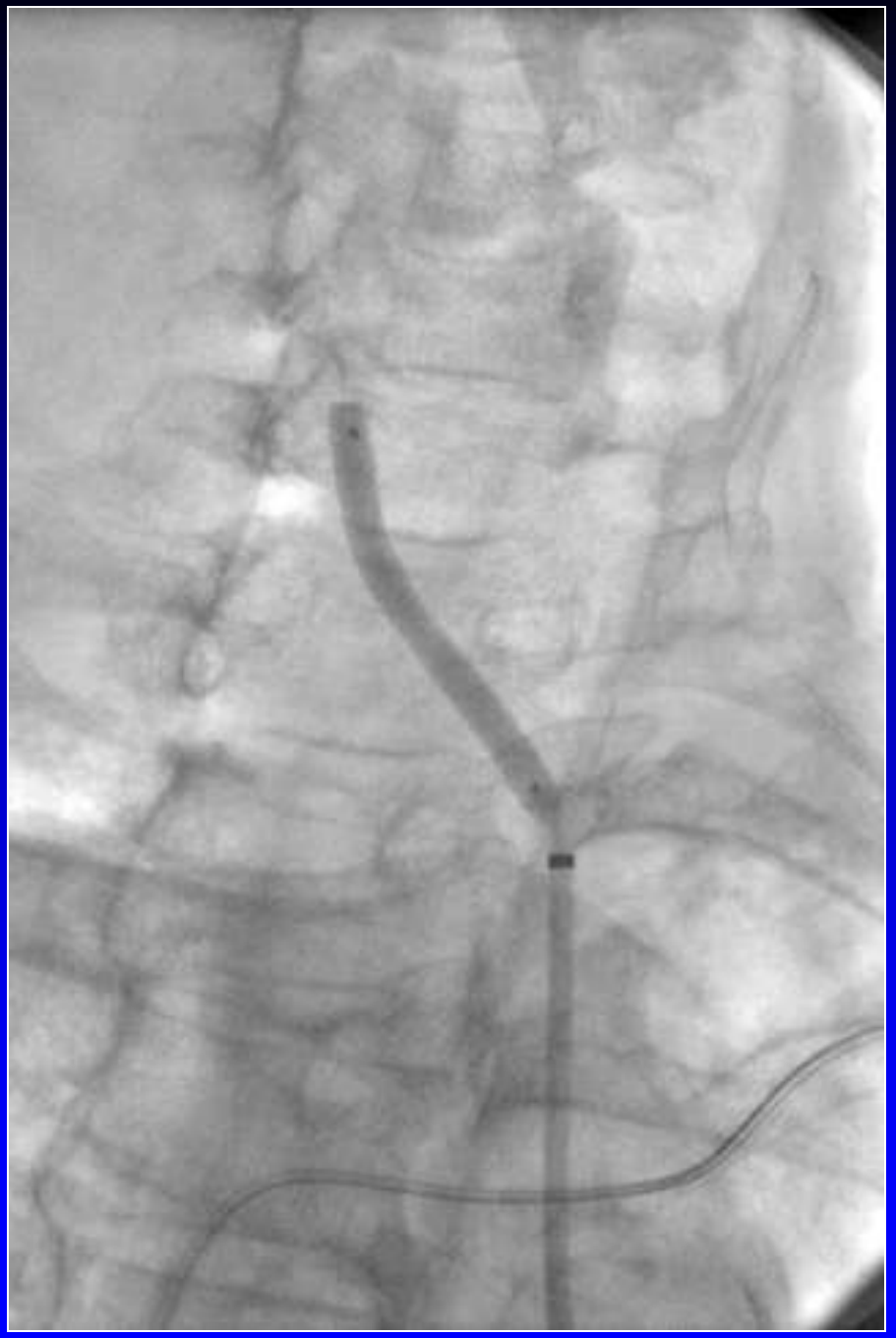
R Carotid Stenosis
Post Neck radiation



Carotid Stenting



Balloon predilatation



Post Stenting

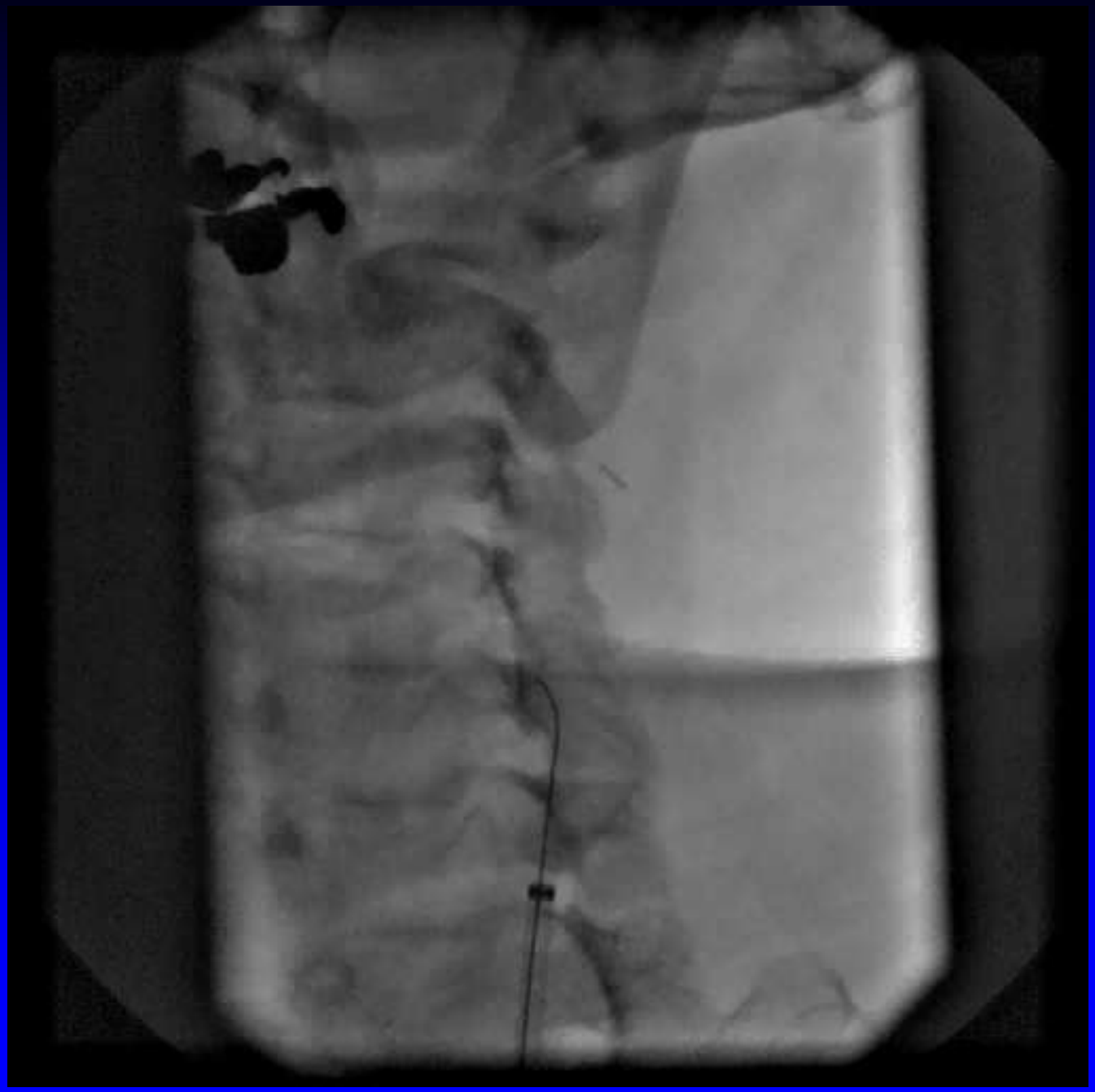
CASE: Post CAE restenosis

liabetic w neur
ypercholesterc
_Sep 2006 afte
with a TIA/mir

vealed critical r

L ICA

Post CAE restenosis



18 months later: Carotid Duplex

What about data?

Modern Randomized Trials

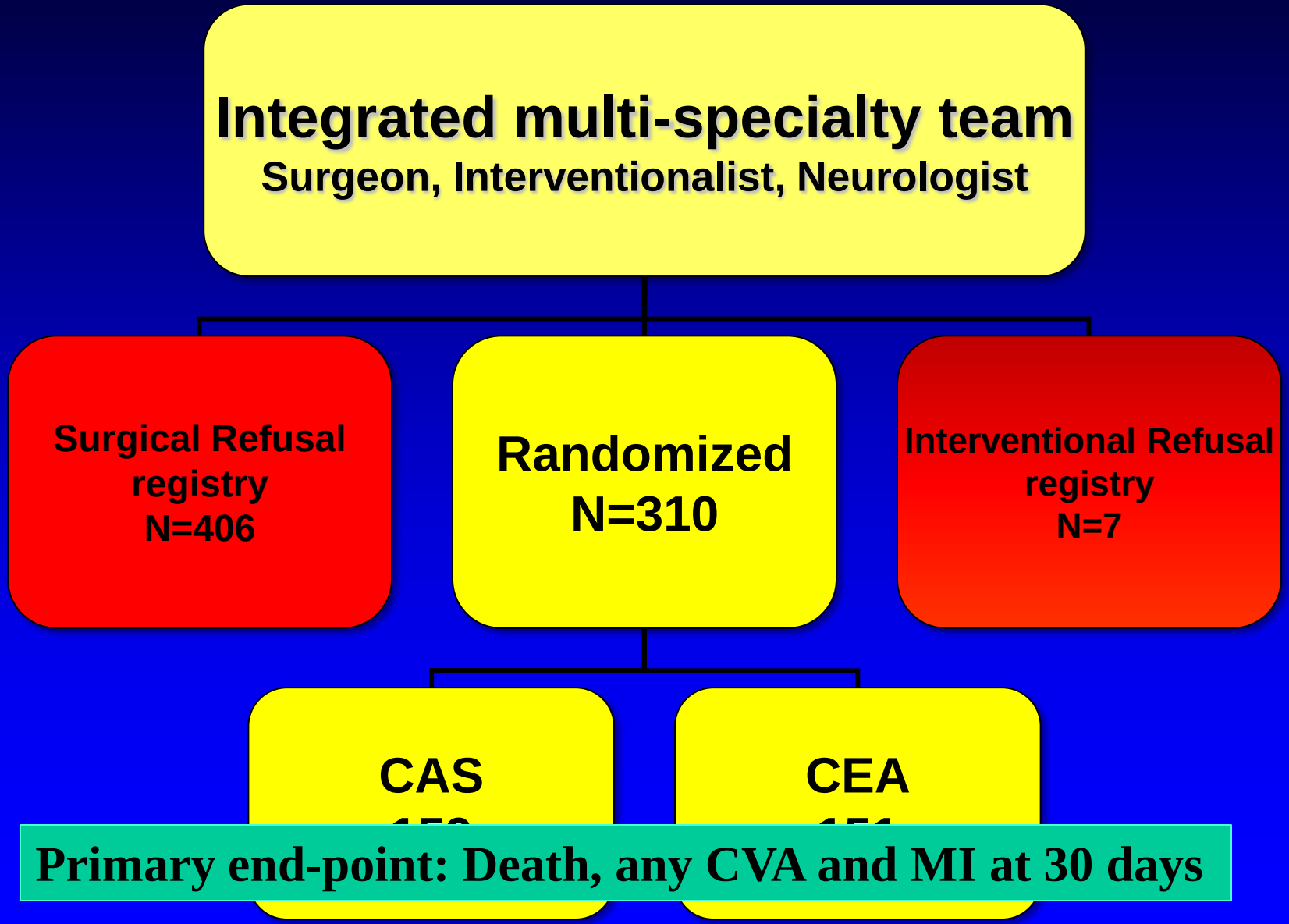
- US TRIALS:
  - Sapphire, NEJM 2004
  - CREST, on line NEJM 5/26/10
- EUROPEAN
  - EVA 3S, NEJM 2006
  - SPACE, Lancet 2006
  - ICSS, Lancet 2010

Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy

The SAPPHIRE Study

- **U.S. Randomized, Multicenter trial in high-risk patients**
- **Symptomatic > 50% or asymptomatic > 80% stenosis**
- **Experienced Operators**

SAPPHIRE: Trial Design



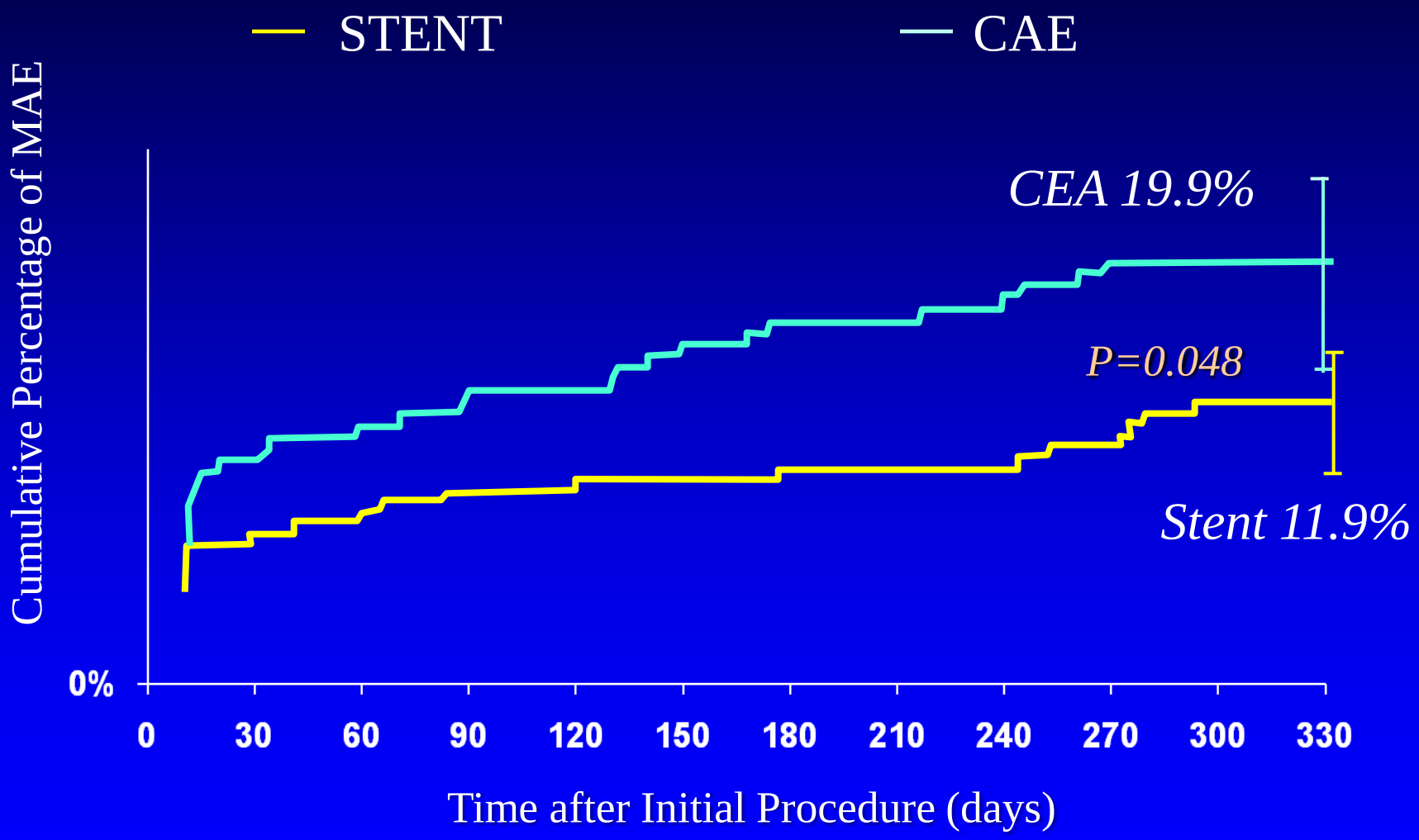
SAPPHIRE

30-Day Events

	STENT (156 pts)	CEA (151 pts)
DEATH	0.6%	2%
CVA: Major:	0.6%	2%
Minor:	3.8%	3.3%
MI	2.6%	7.3%
Death or CVA:	4.5%	6.6%
Death/MI/CVA:	**5.8%**	**12.6%***

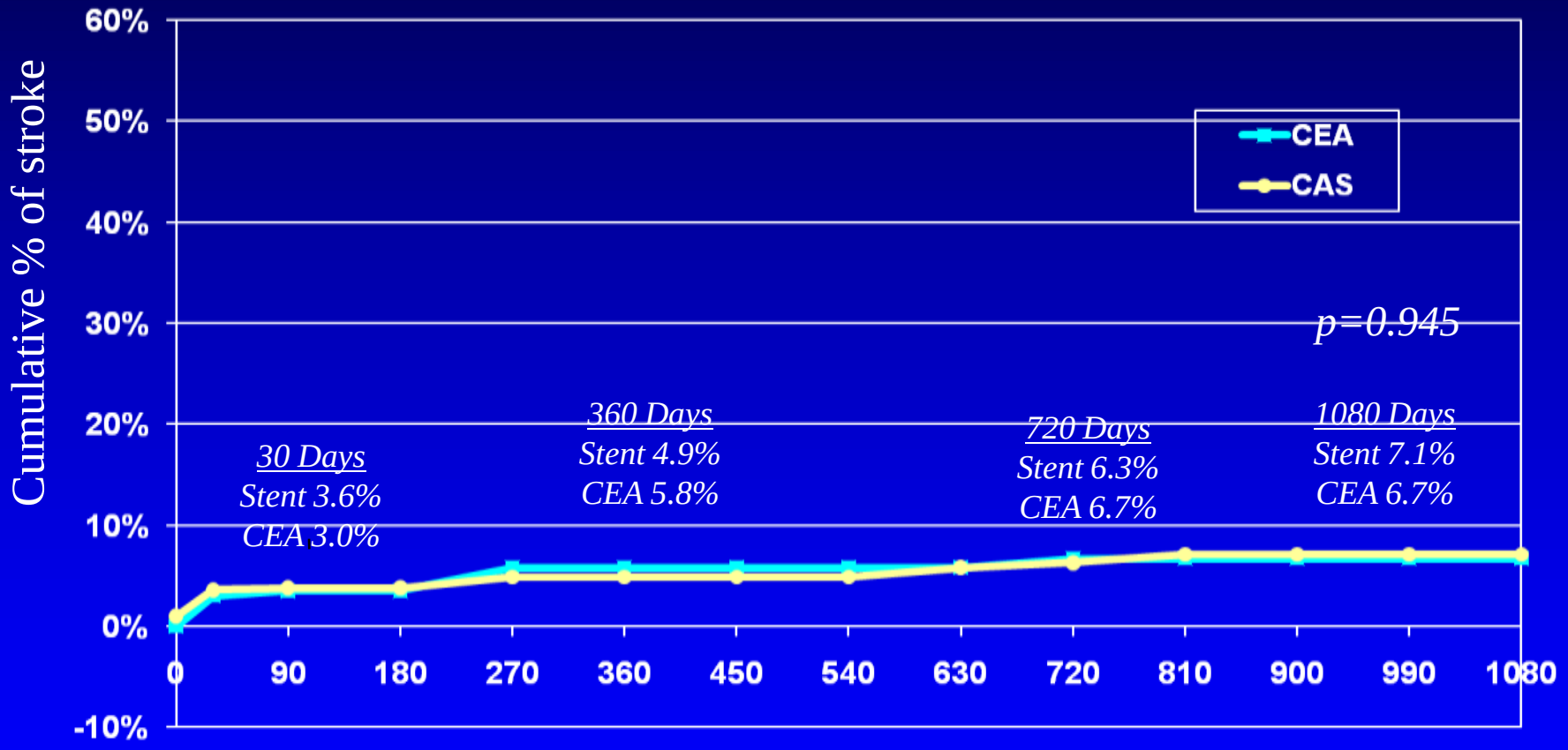
***p= 0.047**

SAPPHIRE: 1 year primary endpoint



SAPPHIRE Randomized Cohorts: CEA and CAS
30 day stroke and ipsilateral stroke 31-1080 days

No advantage of CEA over CAS in efficacy



Time (Days)

SAPPHIRE: Conclusions

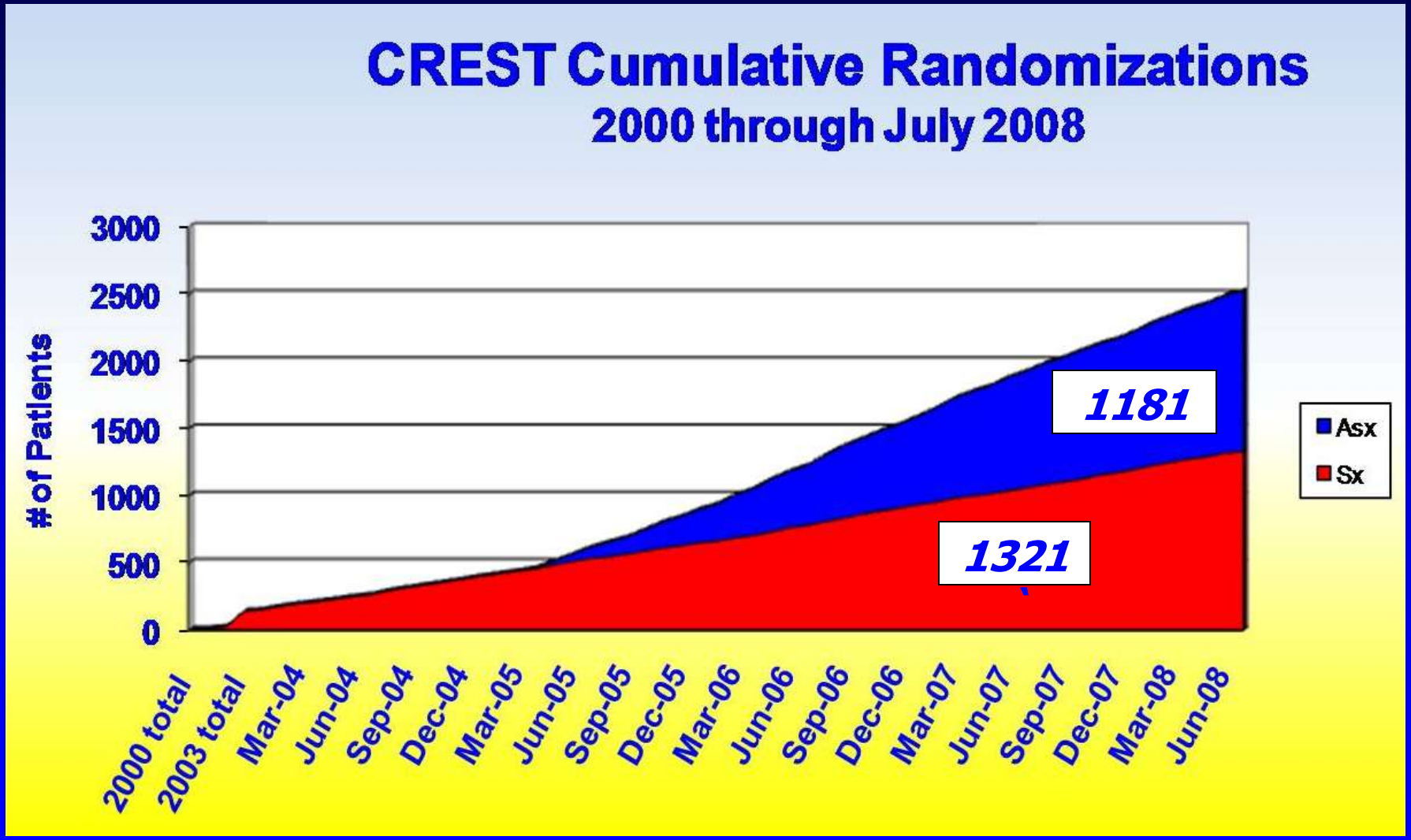
- First randomized study comparing carotid stenting with emboli protection to CAE in high risk patients
- Major adverse cardiac events included MI unlike prior CAE trials
- Carotid artery stenting showed to be an option to CAE in high-risk patients
- Led to FDA approval in that group of patients

Carotid Revascularization Endarterectomy Vs Stenting Trial: CREST

Presented at the Inter national Stroke Conference in San Antonio, Feb 26, 2010

Published on line NEJM on May 26, 2010

CREST: FINAL ENROLLMENT



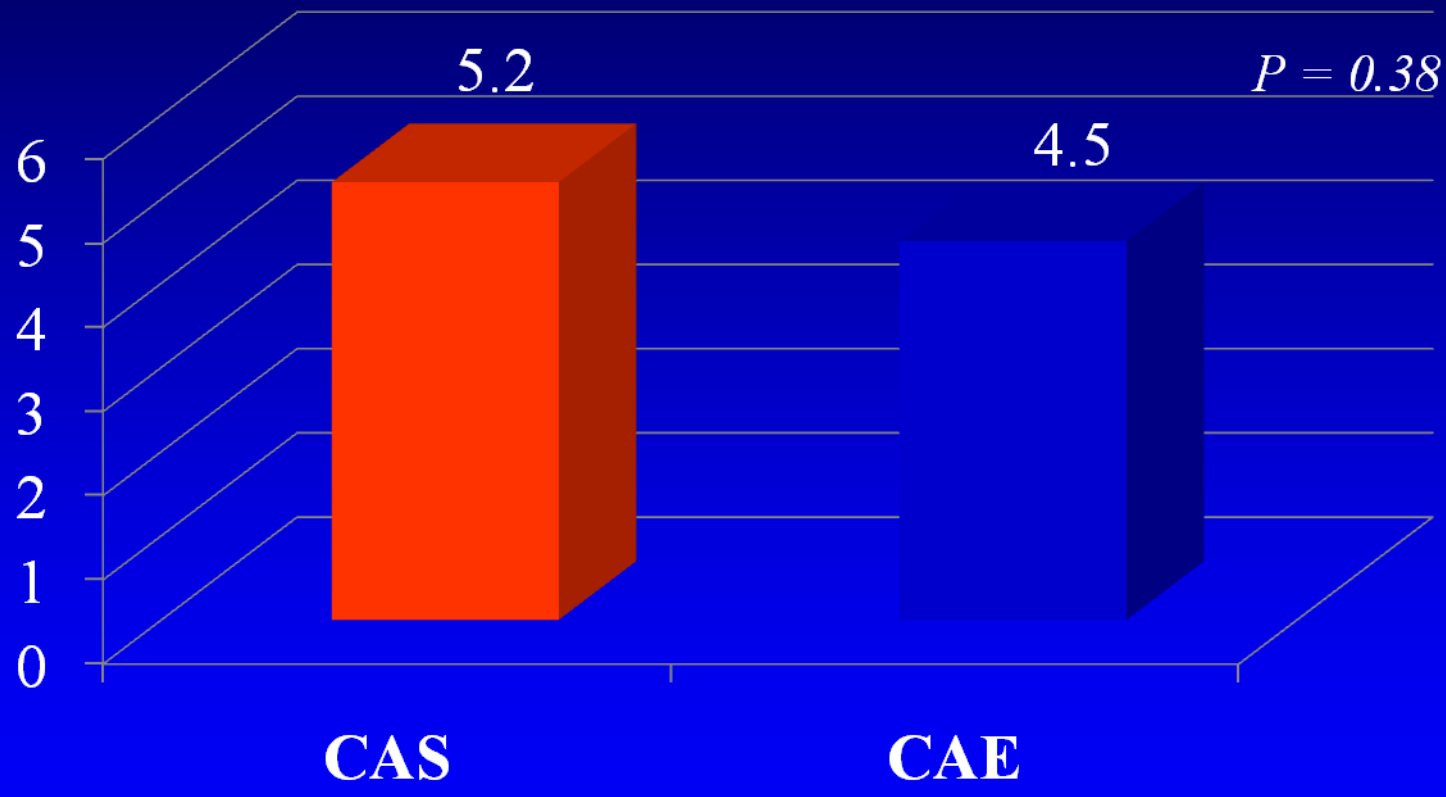
CREST

- CREST is a decade long, multi-million dollar NIH study involving nearly 120 centers and 224 interventionalists

- It is the largest (2500) randomized prospective study of CAS vs. CEA in both symptomatic and asymptomatic as well as low and high surgical risk patients.

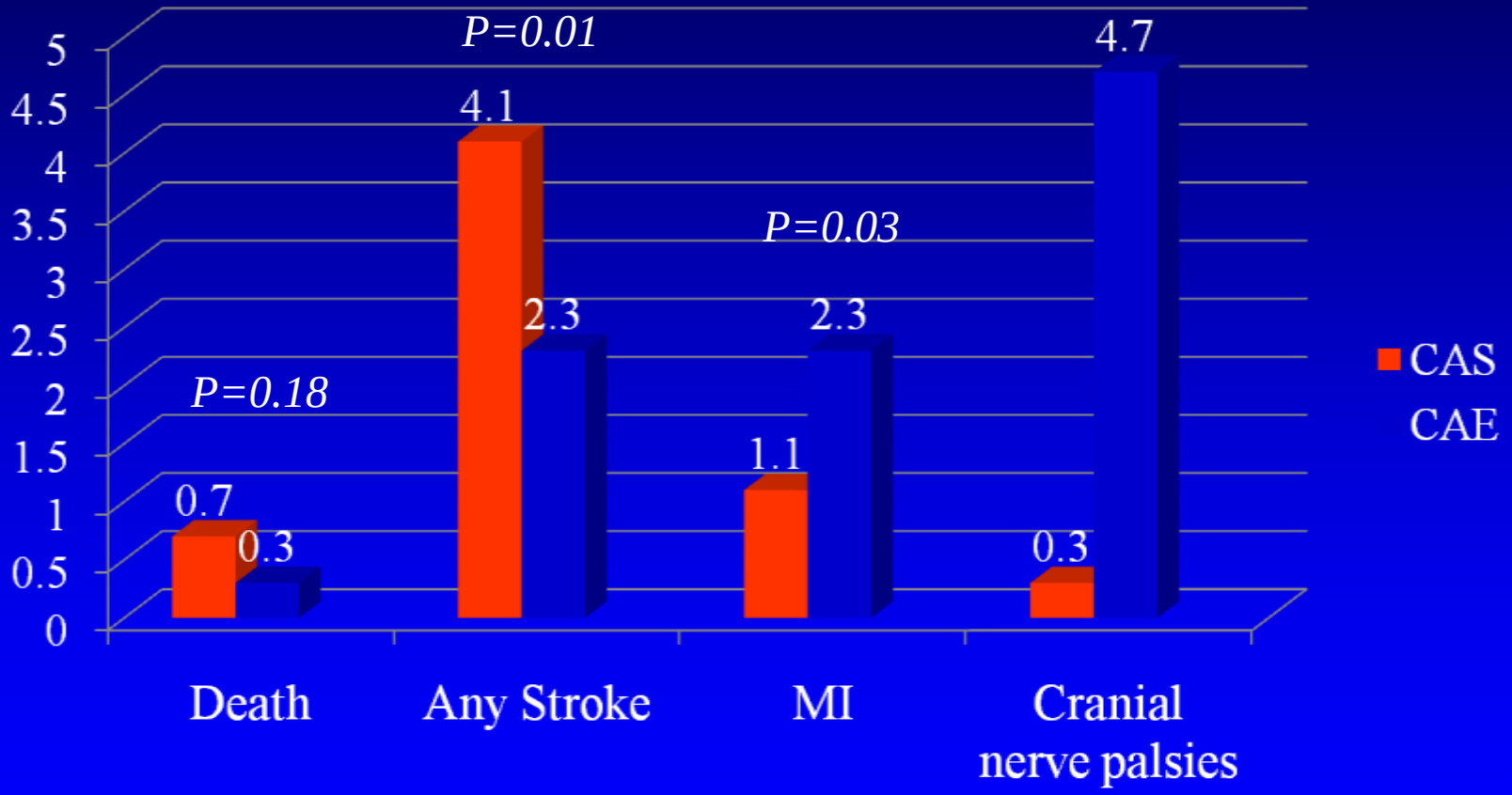
CREST: Primary Endpoint*

Periprocedural period



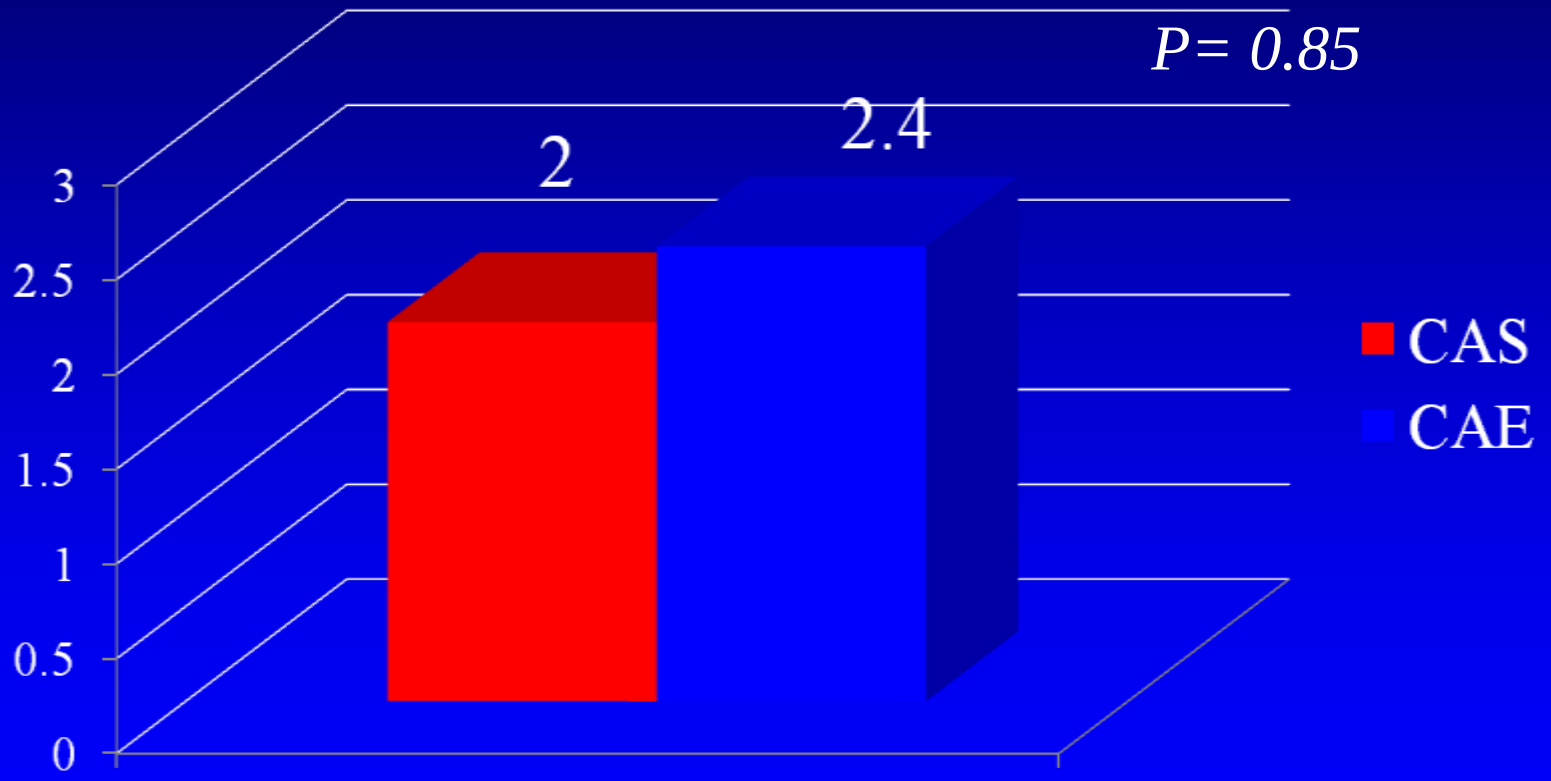
**Death, any Stroke or MI*

CREST: Periprocedural



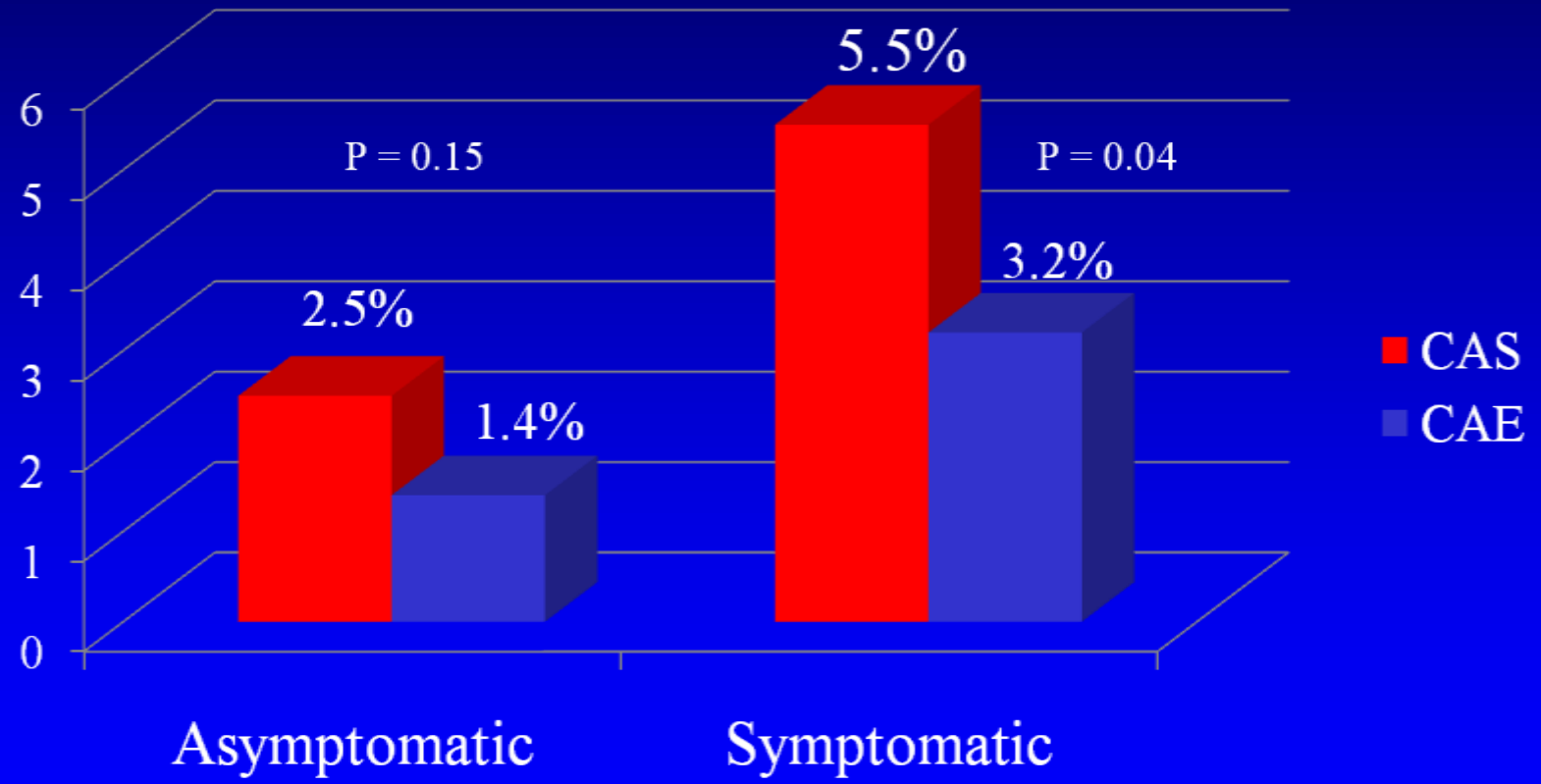
Major CVA: 0.9 vs 0.6%

Ipsilateral Stroke
After 30d and up to 4 yrs

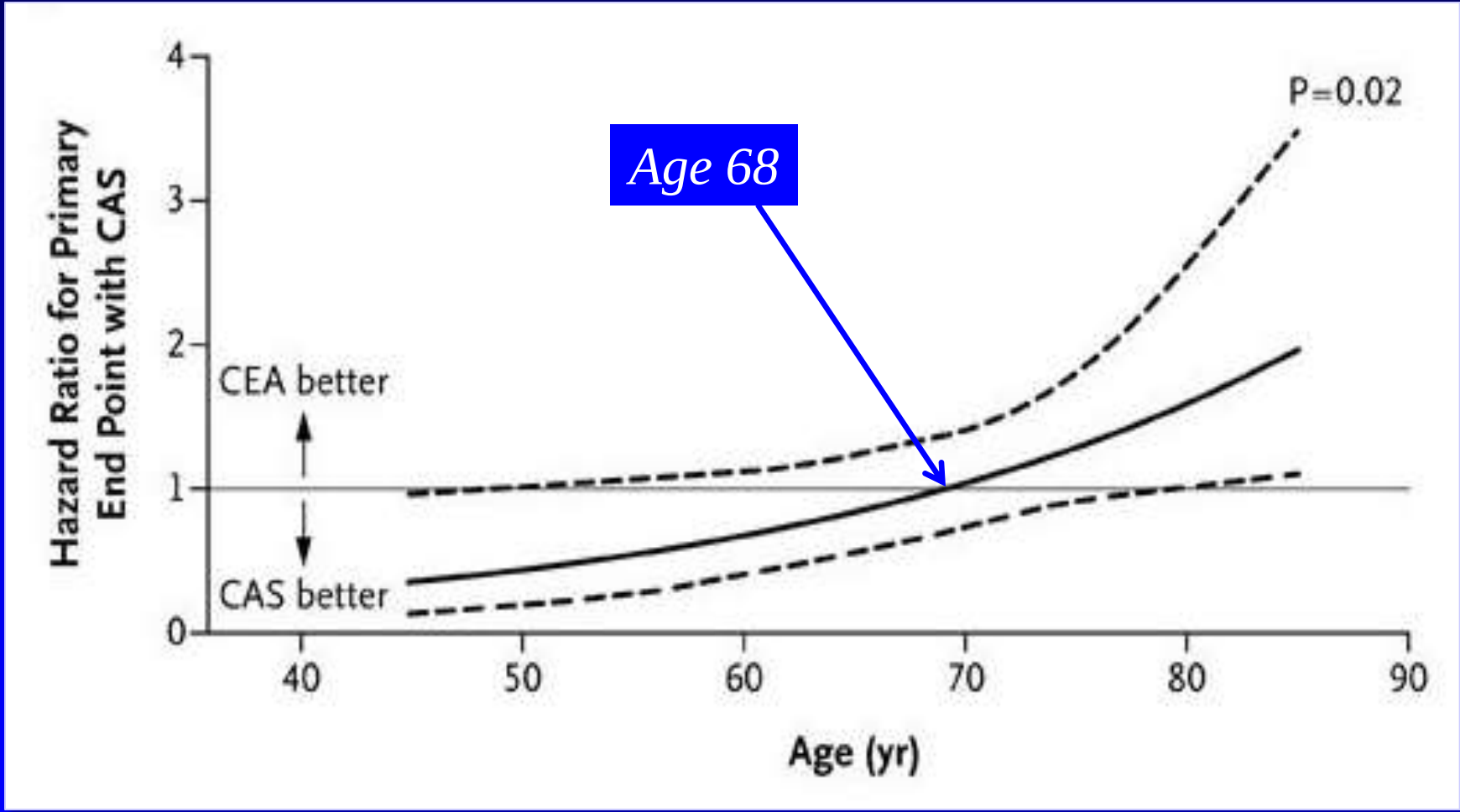


CREST: Symptom status

Any CVA or post procedural ipsilateral CVA



CREST: Age Influence



CREST CONCLUSION

- CAS and CEA have similar global outcomes:
  - CAS caused more minor strokes than CEA
  - CEA caused more MIs and cranial nerve palsies
  - Symptomatic status: little more advantage for CEA
- AGE:
  - Younger patients slightly better with CAS
  - Older patients better with surgery

How about New Technology ?

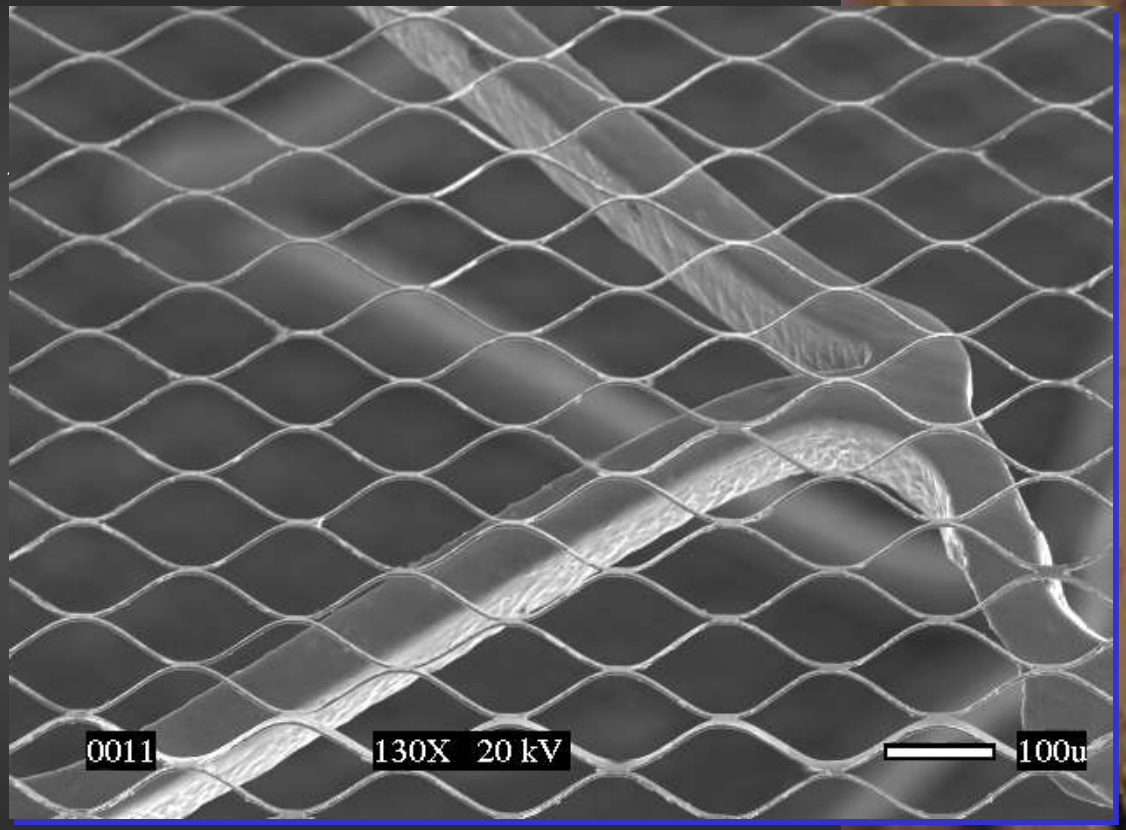
New stents

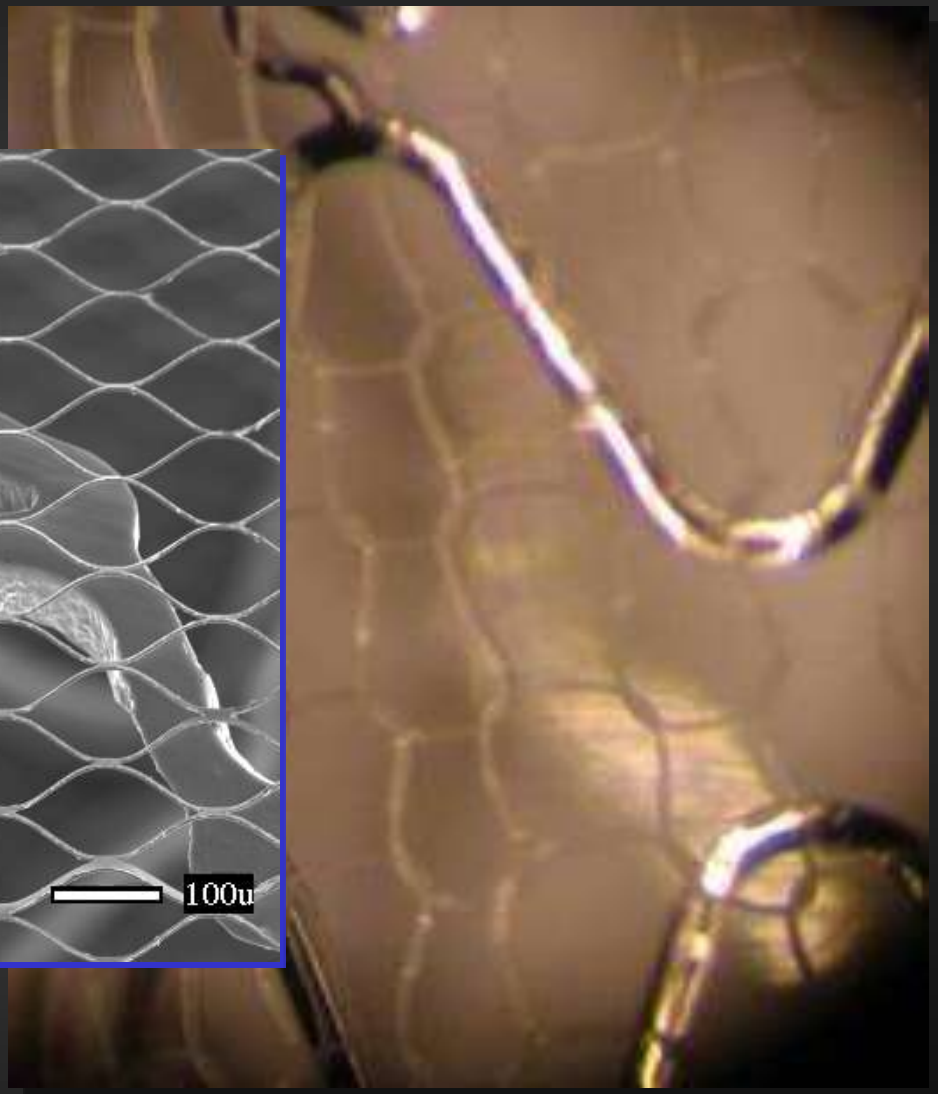
New Embolic Protection Devices:

New Filters

Proximal Protection

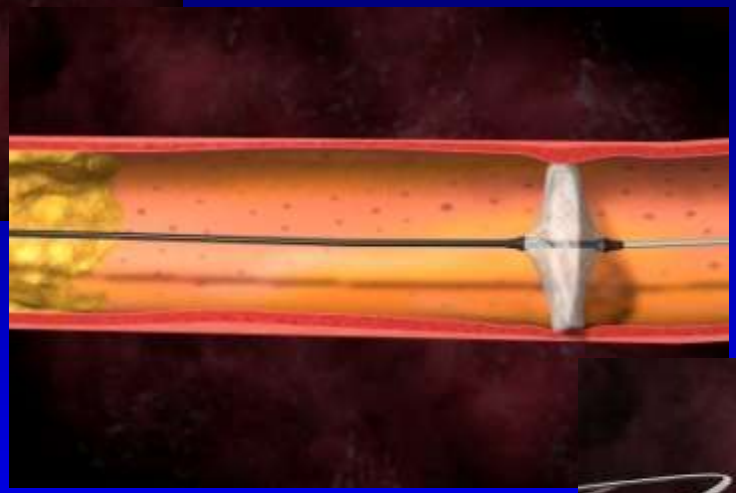
MGuard Stent



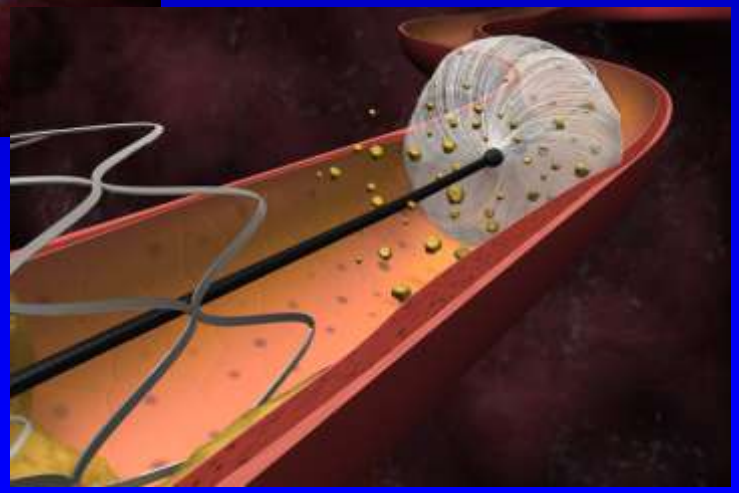


EPIC FiberNet® EPS

No delivery system required with a crossing profile
1.7 to 2.9 F



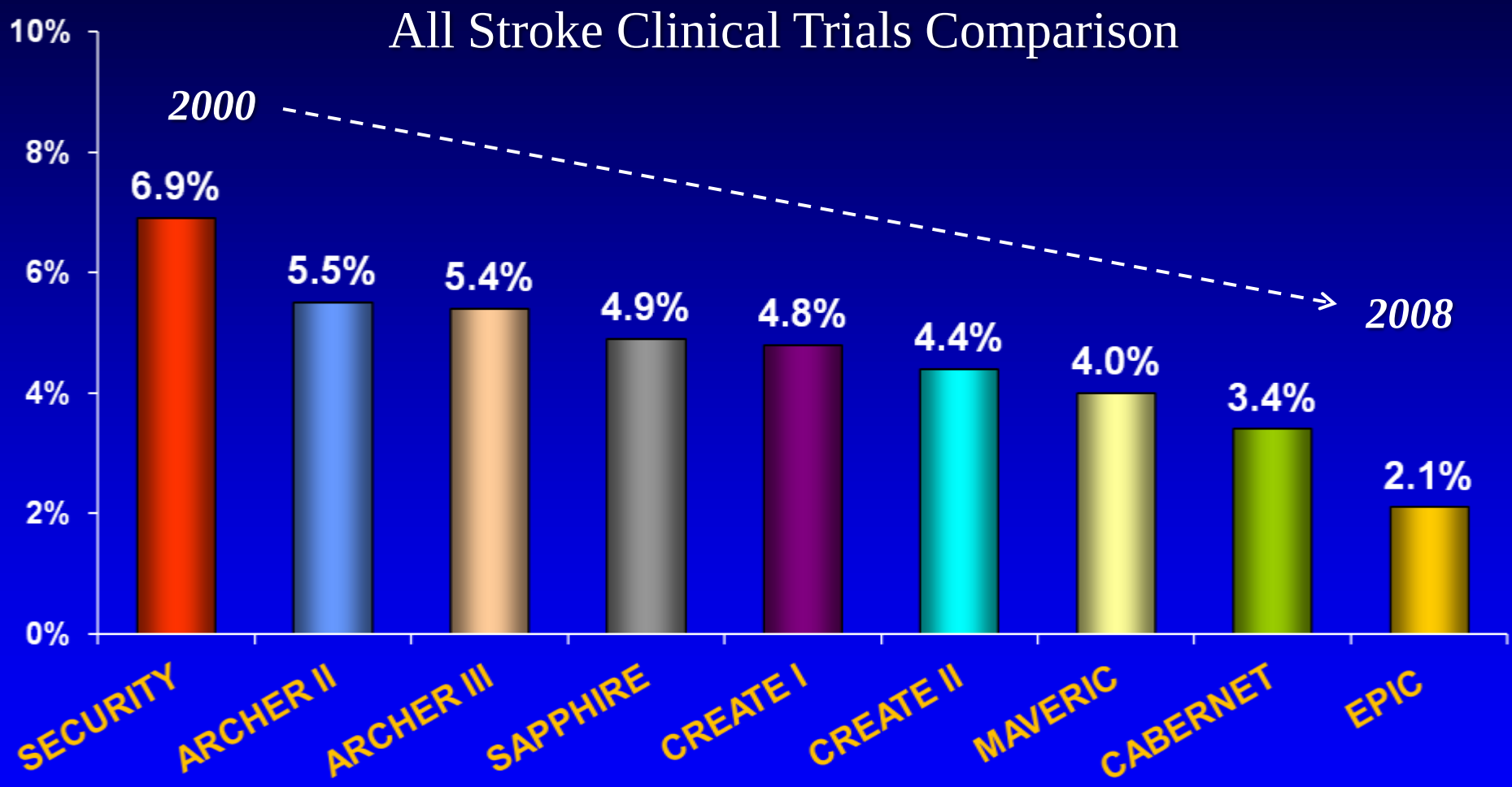
Fiber-based filter conforms to asymmetrical vessels



Particle entrapment as small as 40 µm

EPIC (30 days results)
All CVA: 2.1%
Death 0.4
Mi 0.4%

30 Day Event Rates



Proximal Cerebral Protection

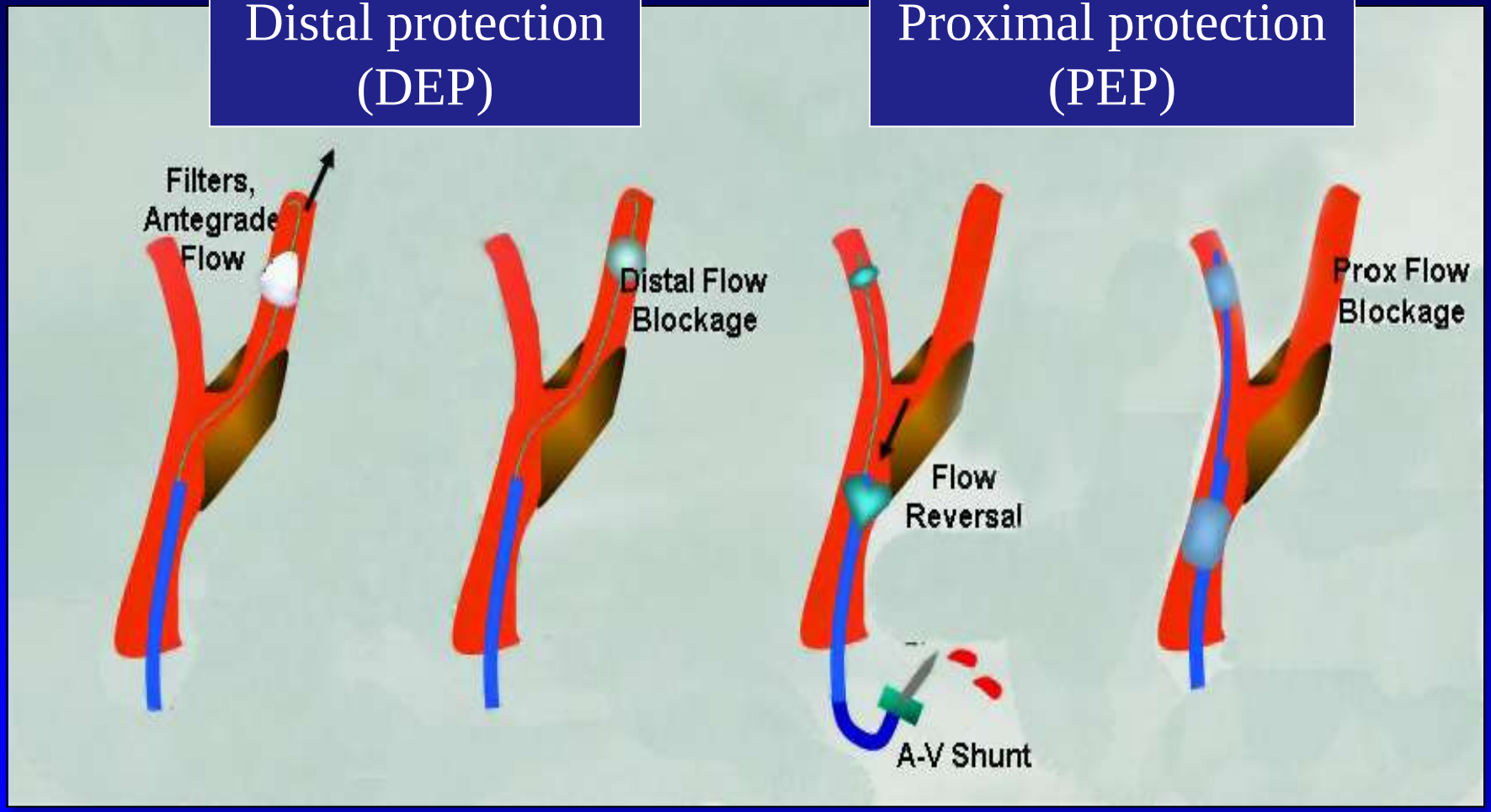
Proximal Protection may be the "game changer" in Carotid Revascularization

Christopher White. Editorial
JACC 2010:55: 1668

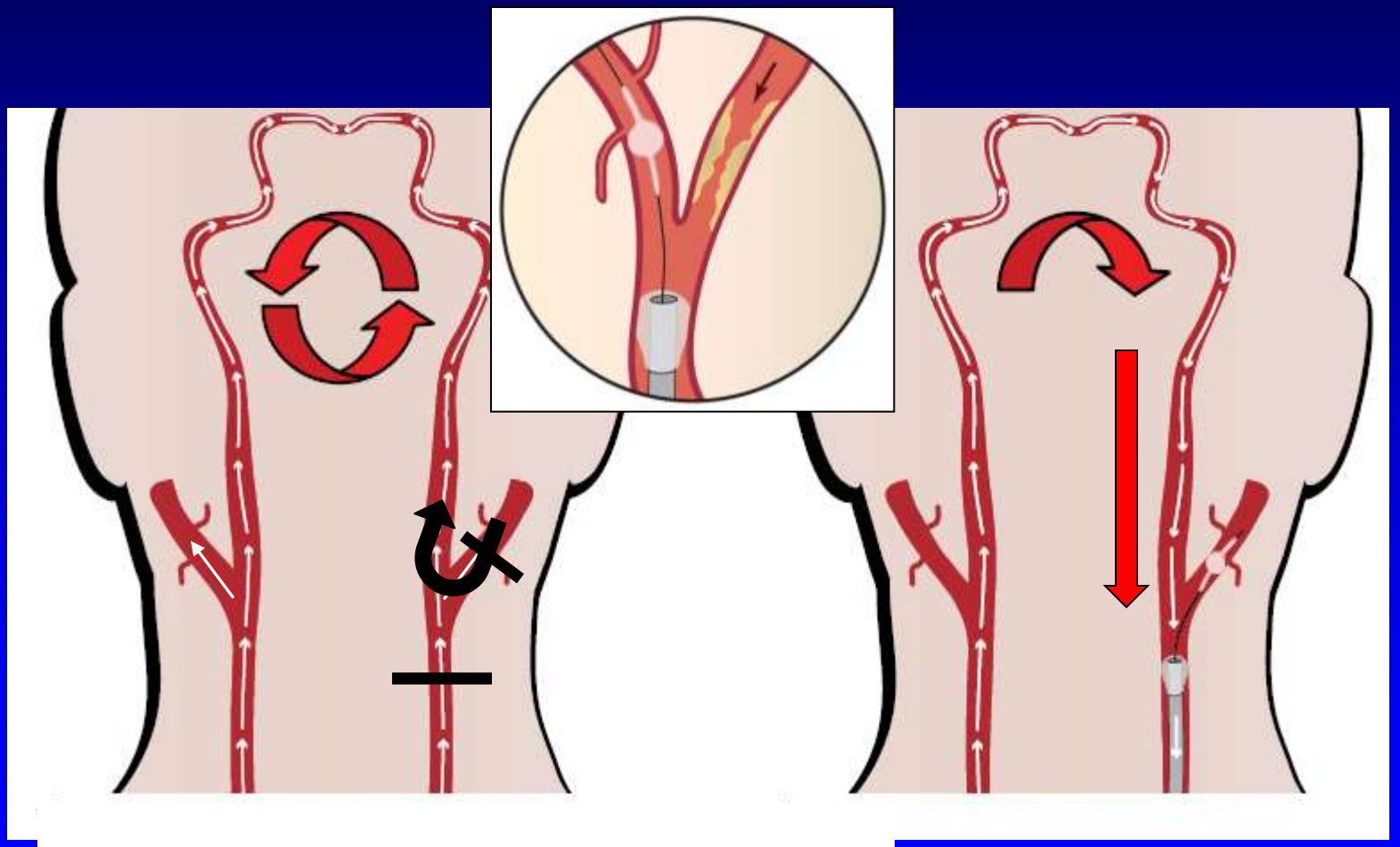
EPD Categories

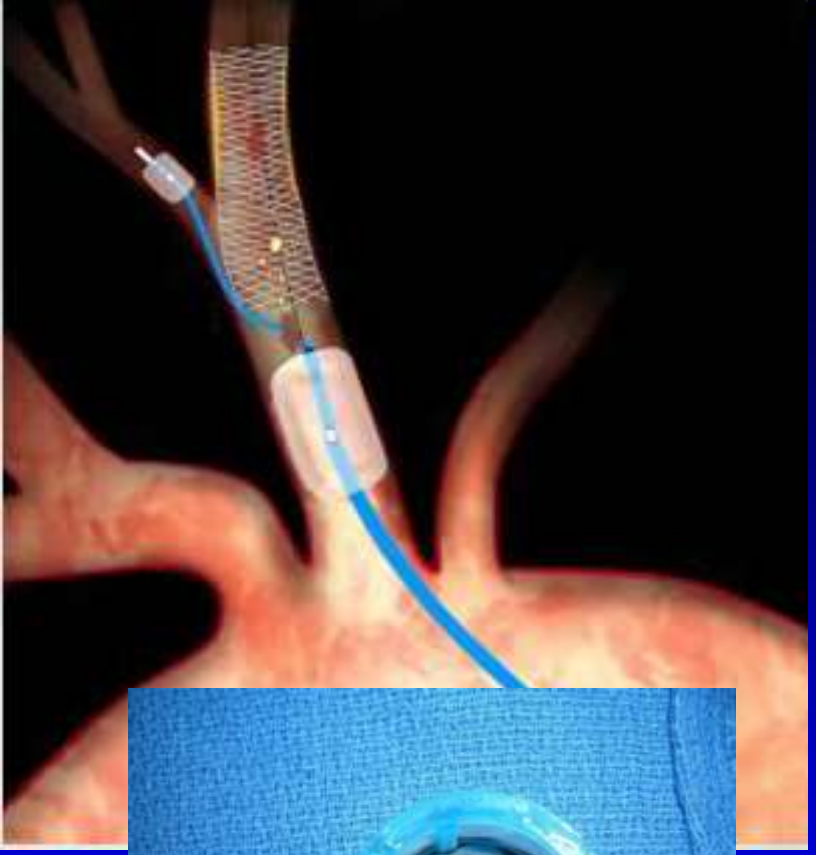
Distal protection (DEP)

Proximal protection (PEP)

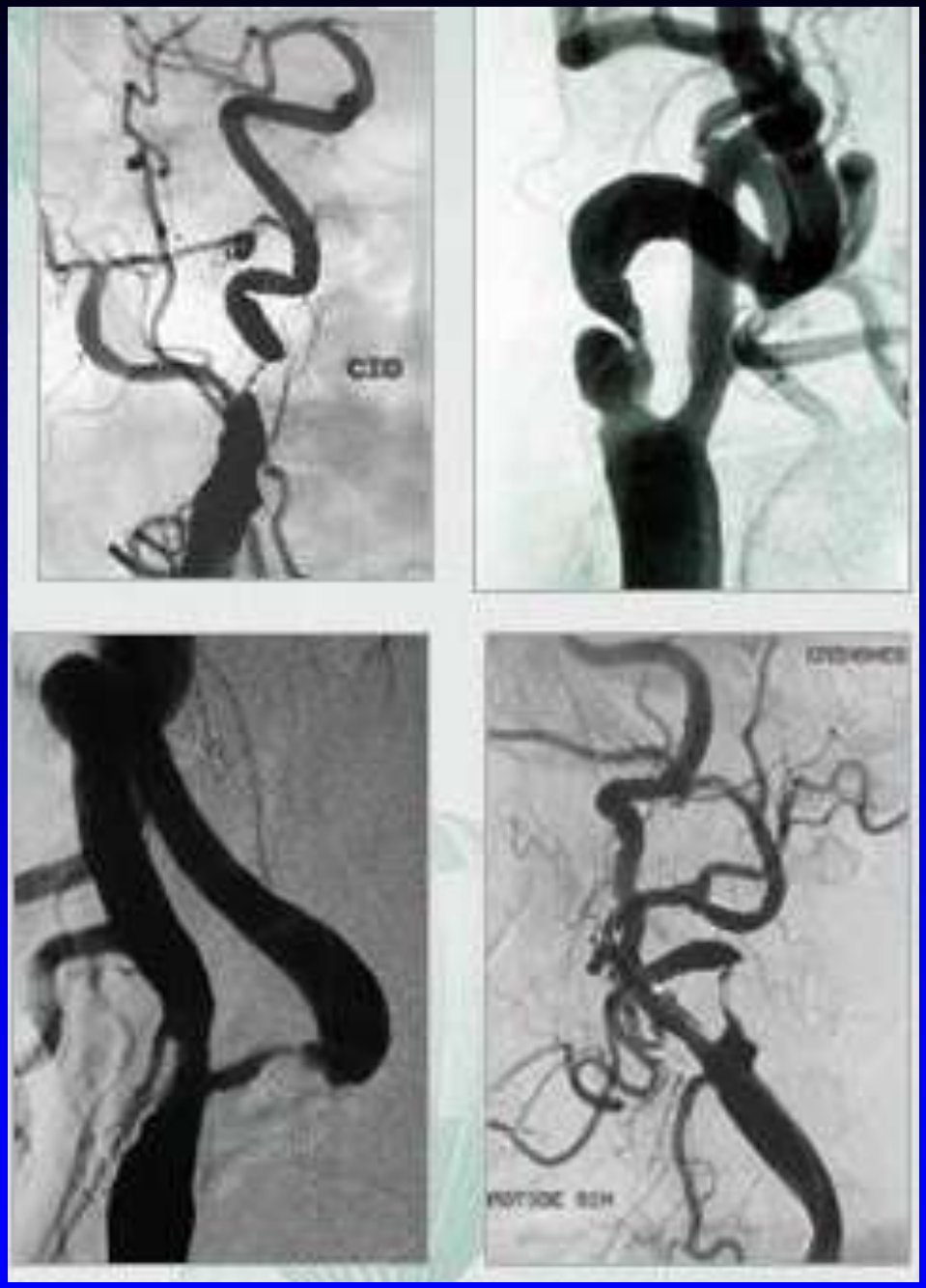


The Concept: Flow Reversal





Applicable to the most complex anatomies



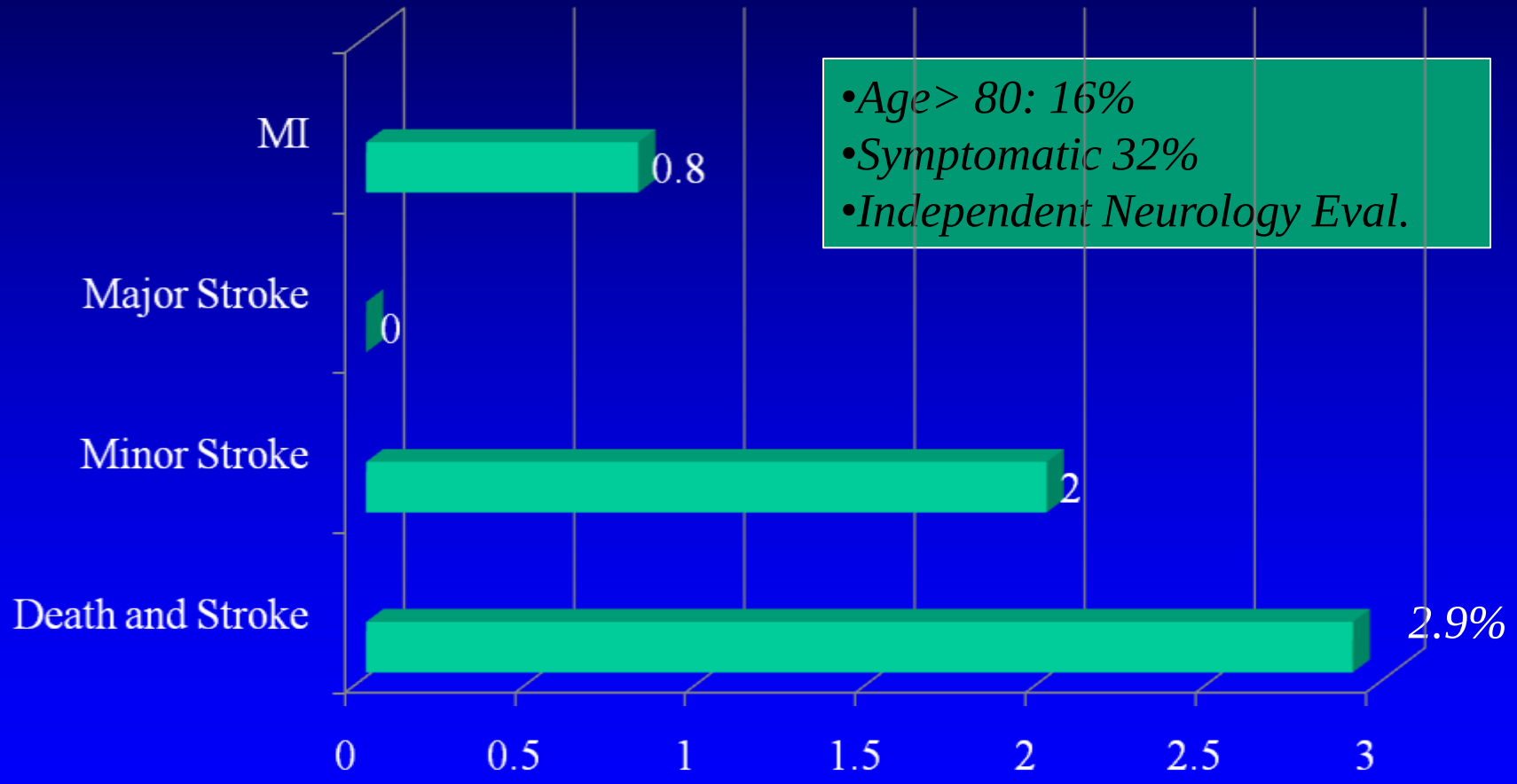
PROXIMAL PROTECTION TRIALS

- EMPIRE : Gore Flow Reversal (WL GORE)
- ARMOUR : Mo.MA Device (InVatec).
- Italian Single Center Experience (1300 patients) using the MoMA Device

EMPIRE

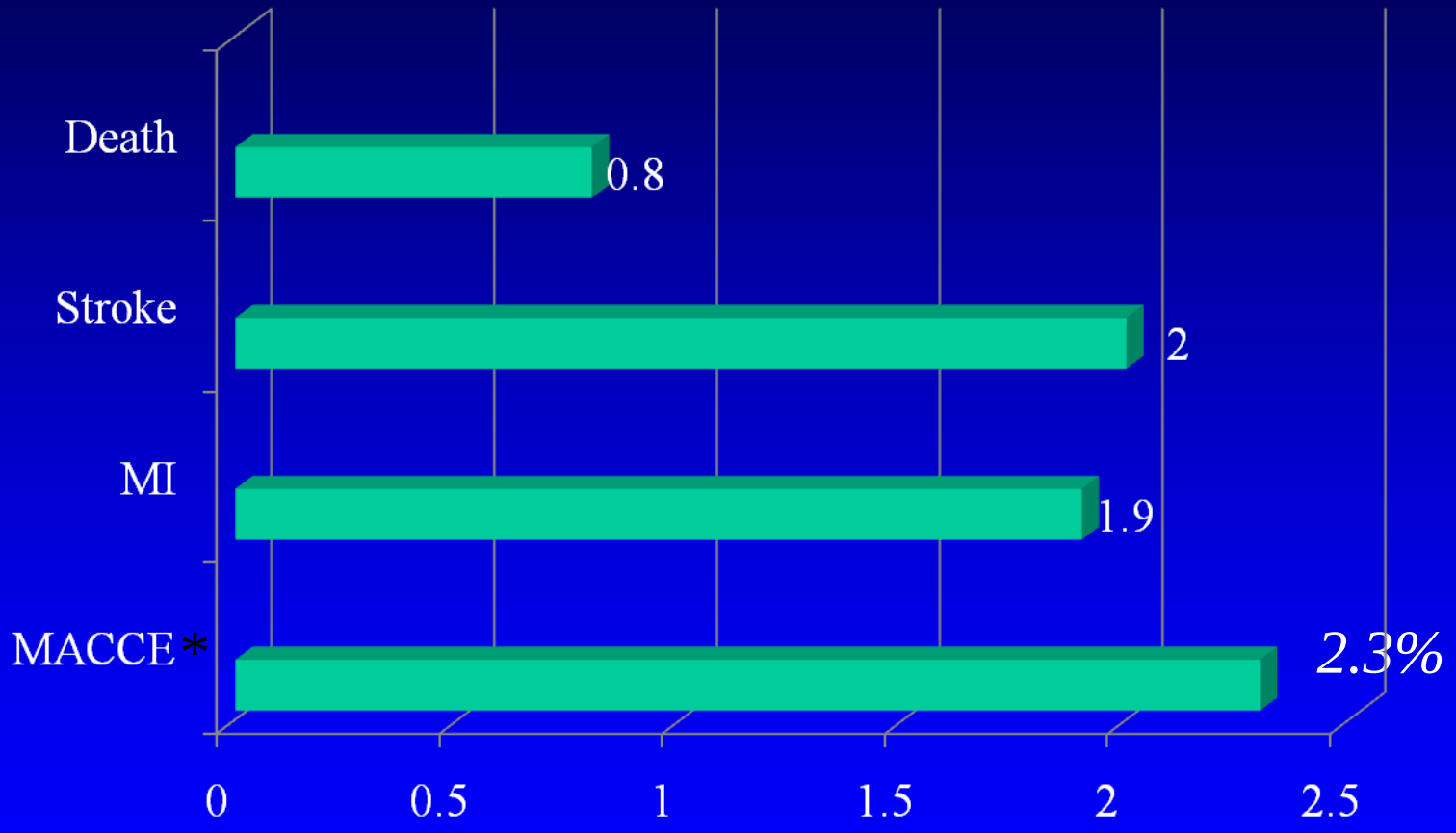
GORE FLOW REVERSAL SYSTEM

MAJOR ADVERSE EVENT RATE AT 30 DAYS (N=245)



ARMOUR TRIAL

USING THE MO.MA PROXIMAL PROTECTION (N=257)

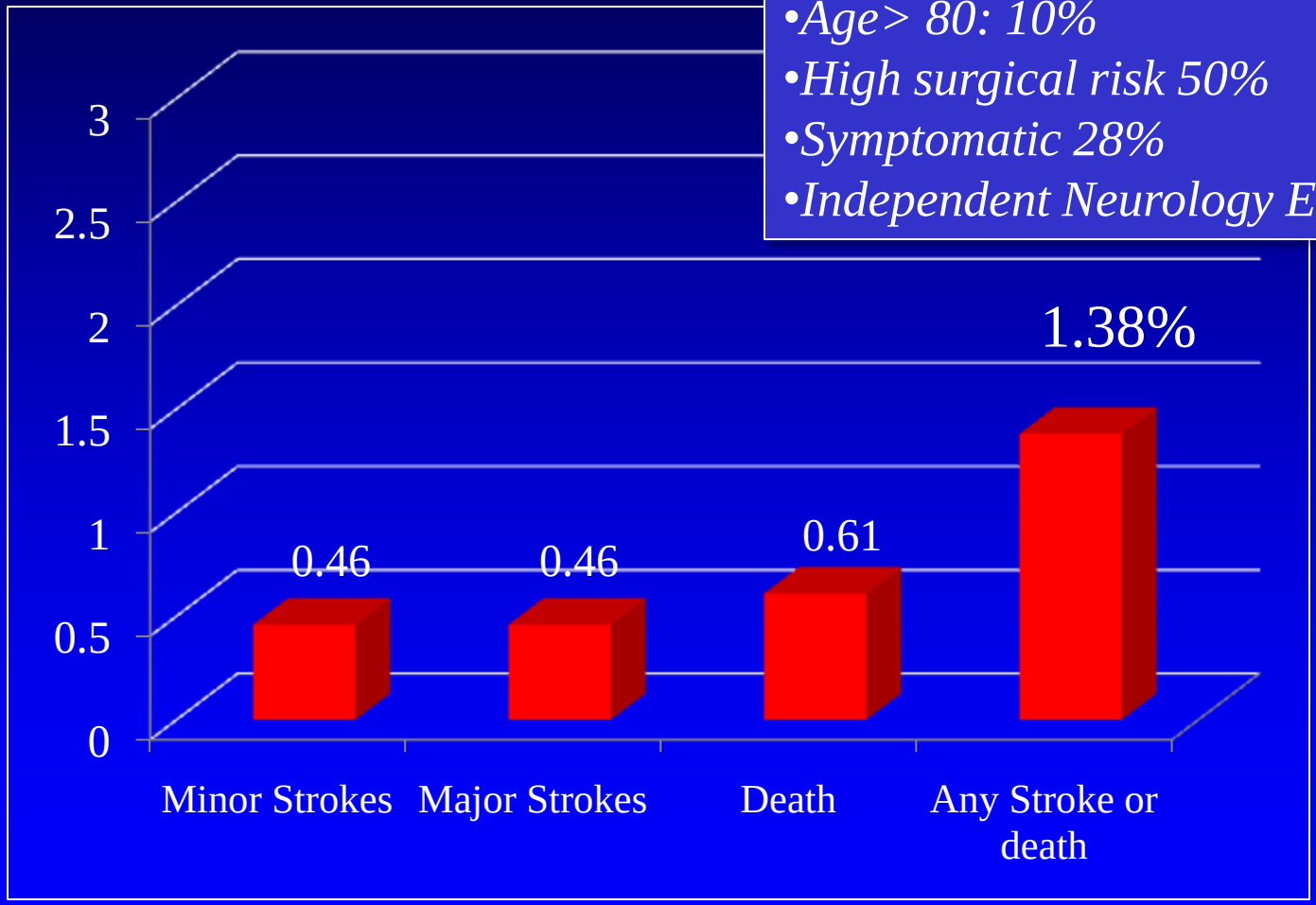


** MACCE = Death + CVA + MI*

ITALIAN REGISTRY: PROXIMAL PROTECTION USING THE MO.MA DEVICE

30-DAY OUTCOMES (N=1300)

- *Age> 80: 10%*
- *High surgical risk 50%*
- *Symptomatic 28%*
- *Independent Neurology Eval.*



Stabile, E. et al. J Am Coll Cardiol 2010;55:1661-1667

CONCLUSION

- Optimal role of CAS Vs CAE continues to be debated…. but they are COMPLEMENTARY
- CAS is the procedure of choice in many high-surgical-risk patients (unstable cardiac disease, post CAE restenosis, post radiation and other anatomical risk factors).
- Favor CAE in elderly patients with symptoms especially with aortic arch disease (difficult access, calcified lesions and complex anatomies)

CONCLUSION

- Although safety of CAS in “low risk” patients (young, asymptomatic with favorable anatomy) is proven by current trials when done by experienced operators, the best approach at a given Institution should be based on a Team Approach
- However, CMS reimbursement, financial and turf issues are currently the major obstacles for adoption of stenting and are some of the most important factors in the decision making today

CONCLUSION

- Technology will continue to improve outcomes in CAS (i.e. new filters, stents, and proximal protection)

Thank you !