PCI for Carotid Artery Stenosis

Natural Incidence of CVA In Carotid Stenosis

- **Asymptomatic 80% carotid stenosis**
  - **6% / year**
- **Symptomatic carotid stenosis**
  - **10% / year**
  - **40% / 5 years**

Why should we open ?

Carotid End-Arterectomy
vs.
Medical Therapy

Carotid End-arterectomy

3,061 CEA during a 10-year period

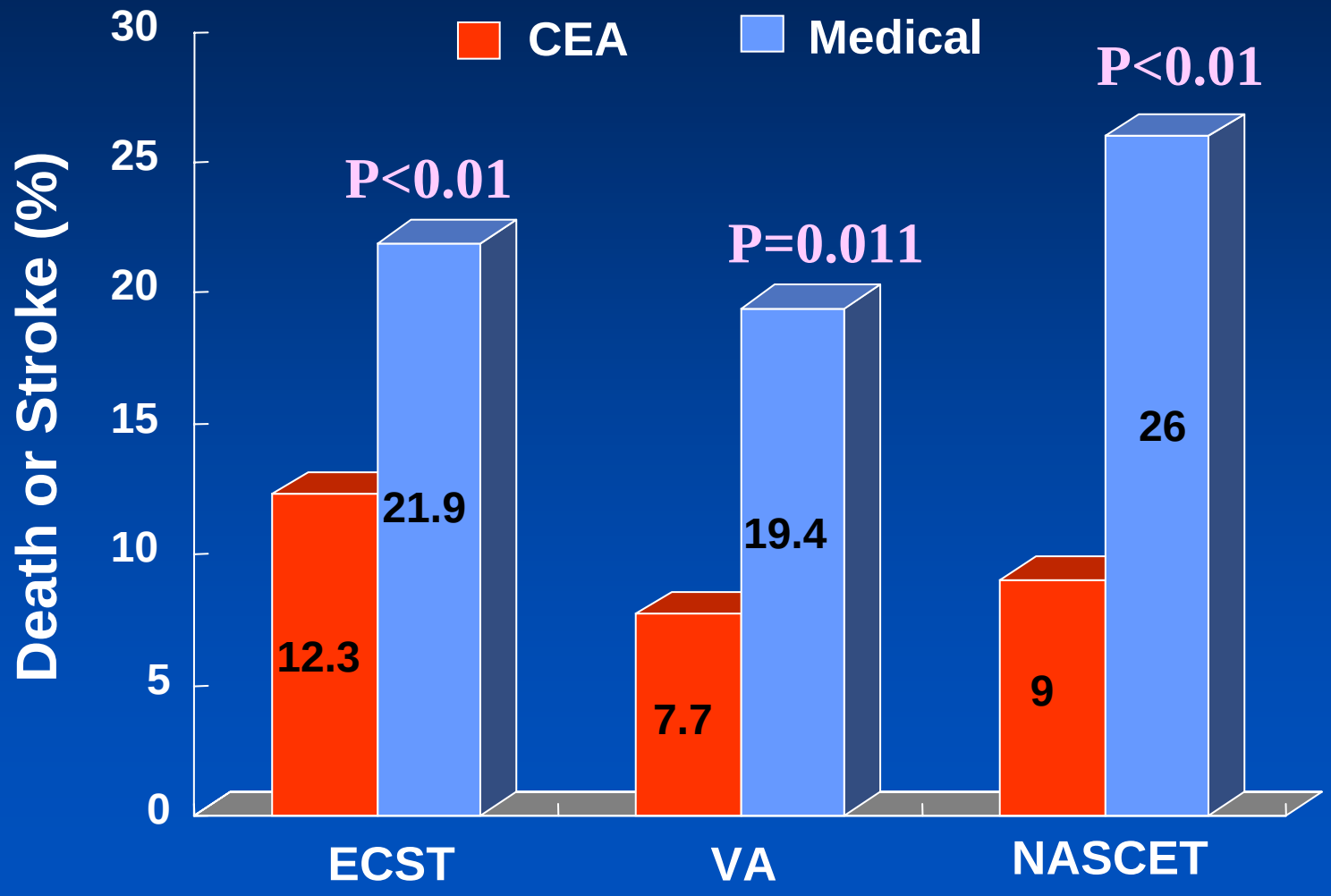
	Stroke	Death	Stroke, MI, Death
High Risk Patients	3.5%	4.4%	7.4%
Low Risk Patients	1.7%	0.3%	2.9%

* **High risk patients**: severe coronary disease, COPD, renal insufficiency

Ouriel K, et al. J Vasc Surg 2001;33:728

Endareterectomy (CEA) vs. Medication

Symptomatic Patients



CEA vs. Medication

Asymptomatic Patients

MRC Asymptomatic Carotid Surgery Trial (ACST)

- Total 3,120 asymptomatic patients
- Randomized to CEA vs medical therapy or deferred surgery
- Inclusion Criteria: ≥ 60% stenosis on ultrasound
- 30 Countries, 126 Hospitals
- In the immediate CEA patients (n=1,560)
  - 2.8% of perioperative stroke or death

Lancet 2004;363:1491

CEA vs. Medication

	Allocated immediate CEA (n=1560)	Allocated deferral of any CEA (n=1560)
Mean F/U during first 5 years (years)	3·4	3·4
Carotid strokes %(fatal+disabling+non-disabling)		
Ipsilateral	13 (3+4+6)	62 (24+11+27)
Contralateral	11 (3+3+5)	35 (9+8+18)
Unknown laterality	6 (5+0+1)	8 (6+0+2)
Subtotal	30 (11+7+12)	105 (39+19+47)
Other strokes %(fatal+disabling+non-disabling)		
Ischaemic vertebrobasilar	8 (1+1+6)	8 (1+0+7)
Haemorrhagic	4 (0+2+2)	7 (4+0+3)
Subtotal	12 (1+3+8)	15 (5+0+10)
Total	42 (12+10+20)	120 (44+19+57)
5-year risk of stroke	3·8%	11·0%

Lancet 2004;363:1491

CEA vs. Medical Rx

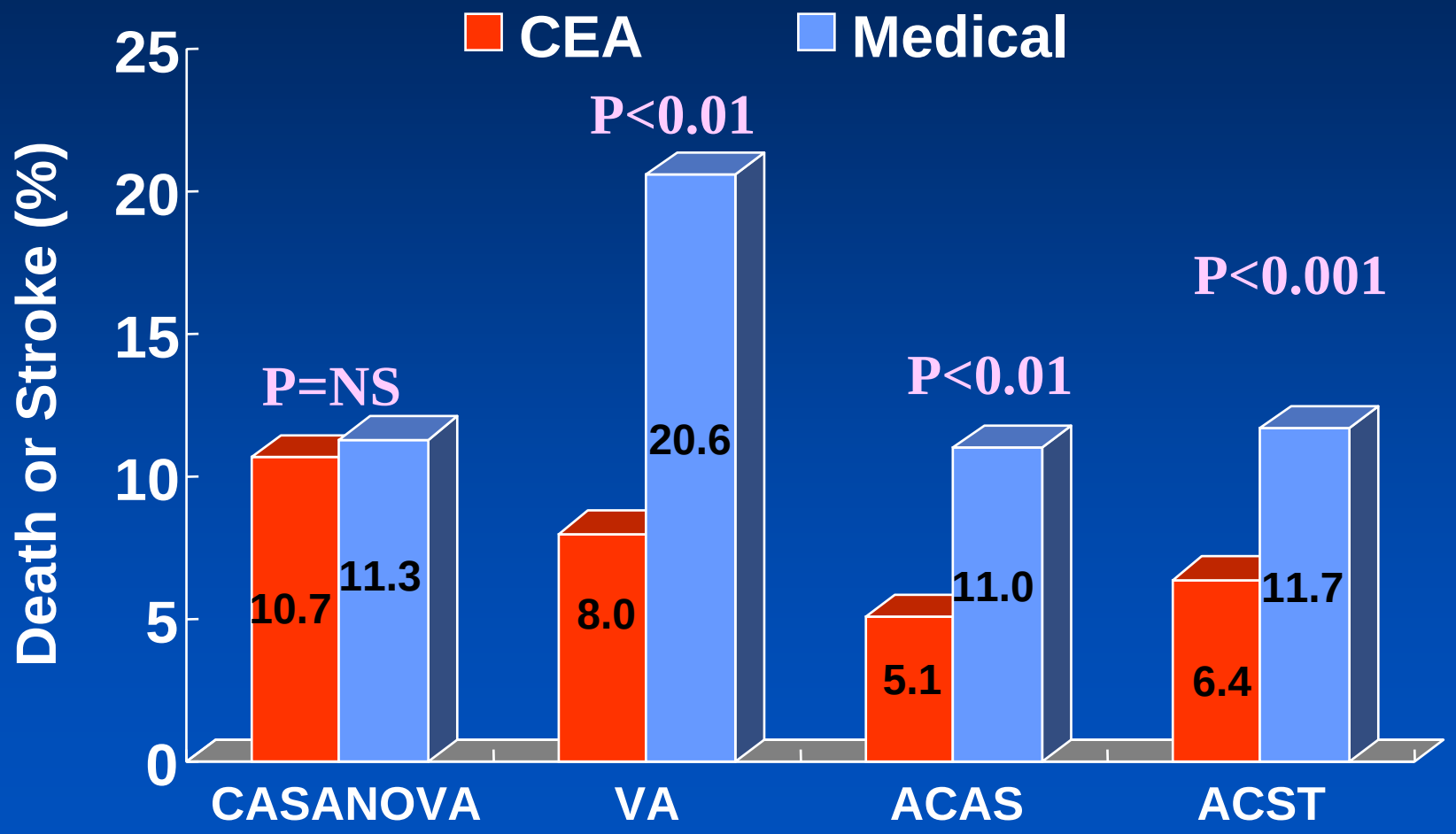
Asymptomatic Patients

	Perioperative Stroke/Death	Annual Risk of Stroke in Medical Rx
ACAS	**2.3%**	**2.2%**
ACST	**2.8%**	**2.3%**

Revascularization risk should be similar to annual stroke risk with medical treatment

CEA vs. Medication

Summary of Asymptomatic Stenosis

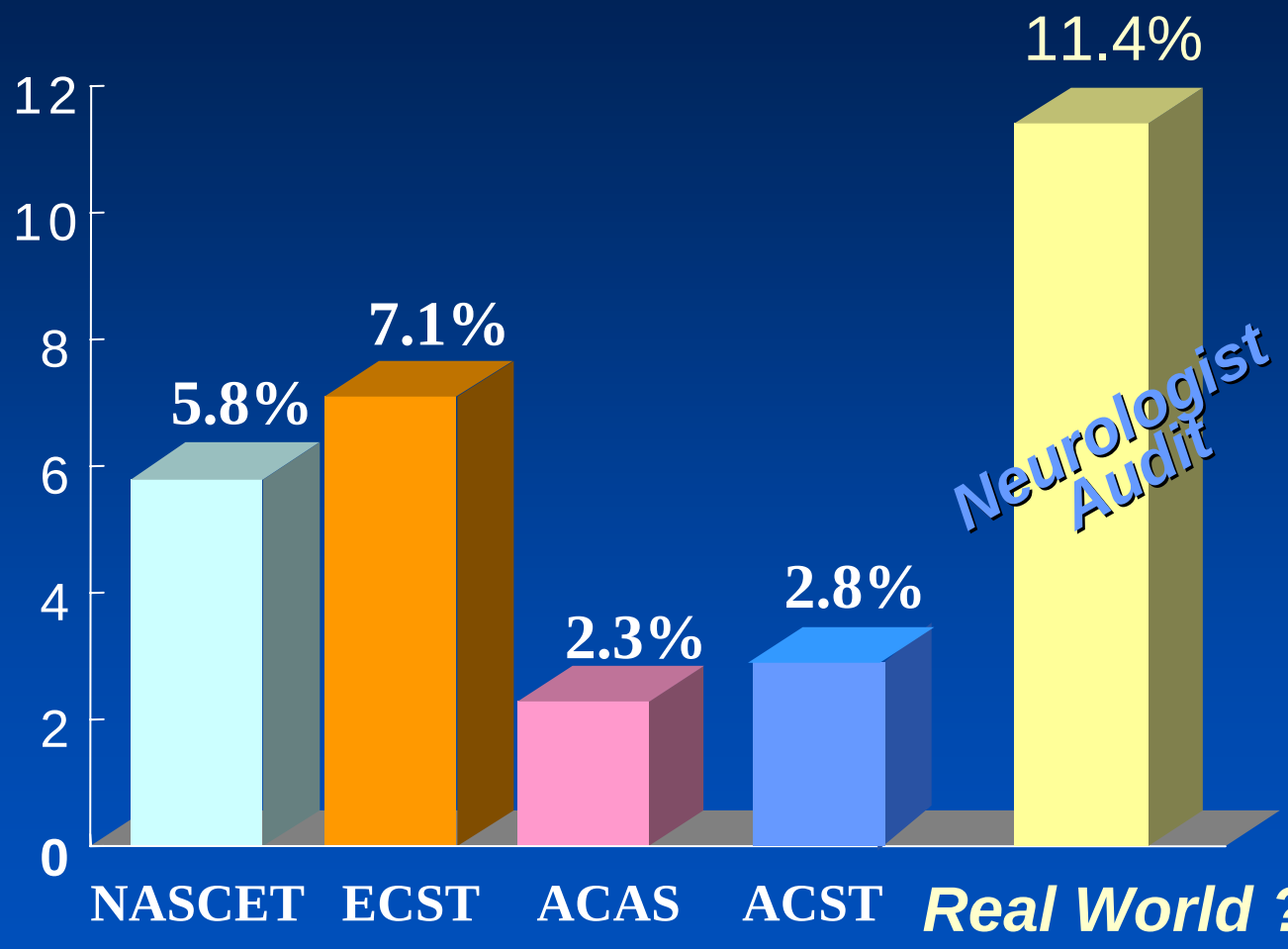


Limitations of CEA

- Perioperative stroke for low risk patients: ~6%
- Anatomic considerations
- Cranial nerve palsies: 7~27%
- Restenosis: ~15%
- > 50% have severe coronary artery disease

Carotid Stenting

Death or Stroke after CEA



Chaturverdi, Neurology 2001 Sep
MRC ACST Collaborative group, Lancet 2004

Carotid Stenting

Potential Benefits

- Reduced complication rates
- Less invasive
- Can reach essentially all blockages
- Very low restenosis rate
- Rapid return to daily life

Current Contraindications of Carotid Stenting

- Severely tortuous, calcified and atheromatous aortic arch vessels
- Pedunculated thrombus at the lesion site
- Recent stroke ≤ 3 weeks
  should be placed on anticoagulants and antiplatelets for 1 month
- Unable to tolerate antiplatelet agents

Carotid Stenting

Without Protection

Success & Complications Rates

Carotid Stenting

Study	Setting	No	Success Rate	Stroke & TIA*	Death
Roubin (1996)	High risk	146	99 %	6.2 %	0.7 %
Shawl (2000)	High risk	170	99 %	2.9 %	0 %
Wholey (2000)	Registry	5129	98.4 %	4.2 %	0.8 %
Roubin (2001)	High risk	428	99 %	4.6 %	0.2 %

** Major stroke < 1%*

Complication Rates

Carotid Stenting

N=4,757 pts, 36 major carotid centers, 1988-1997

TIAs	**2.82 %**
Minor Stroke	**2.72 %**
Major stroke	**1.49 %**
Deaths	**0.86 %**
Total stroke & death	**6.29 %**

6-mo ISR = 1.99%

12-mo ISR = 3.46%

Wholey MH, et al. CCI 2000;50:160

Why distal protection ?

Carotid Stenting

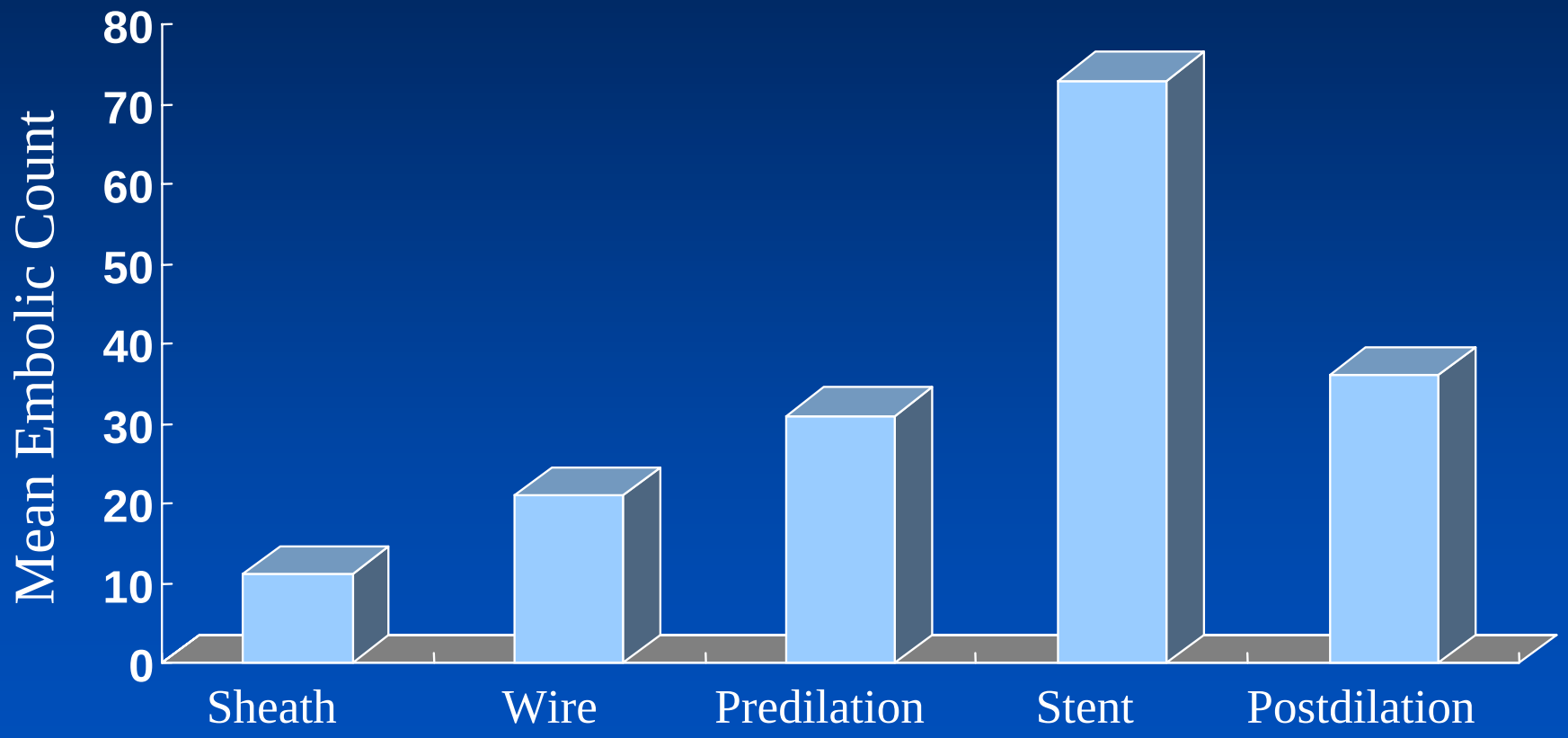
With Protection

Cerebral Embolization

Susceptible High Risk Lesions

- Unstable plaque
  : break down of fibrous cap
- Soft plaque
- Long stenosis string sign
  : contain thrombus

Microembolization Profile



Al-Mubarak N, et al. Circulation 2001;104:1999

Embolic Complications of Stenting

Periprocedural

- Angiography → Rare
- Access → Rare
- Wire Crossing → Rare if coronary wire
- Balloon Dilatation → Rare
- Stent Placement → Potential and unpredictable
- Post Dilatation → Potential and unpredictable

Postprocedural → Rare

Protection of Distal Embolization

- Use cerebral protection device
- No pre-dilatation with a peripheral balloon
- No oversizing of balloon
- Never use high pressures
- Never try to dilate the stent to in ulcerated area external to the stent

Predictors of stroke
Multivariate analysis

30 days outcomes		*P* value
Minor stroke	Protection(-)	0.0182
	Hypertension	0.0216
Major stroke	Protection(-)	0.0892
	Age>80 yrs	<0.0001
Fatal stroke	Protection(-)	0.0892
	Prior TIA	0.0320
All stroke	Protection(-)	0.0009
	Hypertension	0.0102
	Age>80 yrs	0.0081
	Prior CEA	0.0822

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Effect of Cerebral Protection

	Cerebral Protection	
	No (n=102)	Yes (n=142)
TCD-HITS	100%	100%
DW-MRI	29%	7.1%
TIA	8%	2.7%
Stroke	3%	1.3%
TIA + Stroke	11%	4%

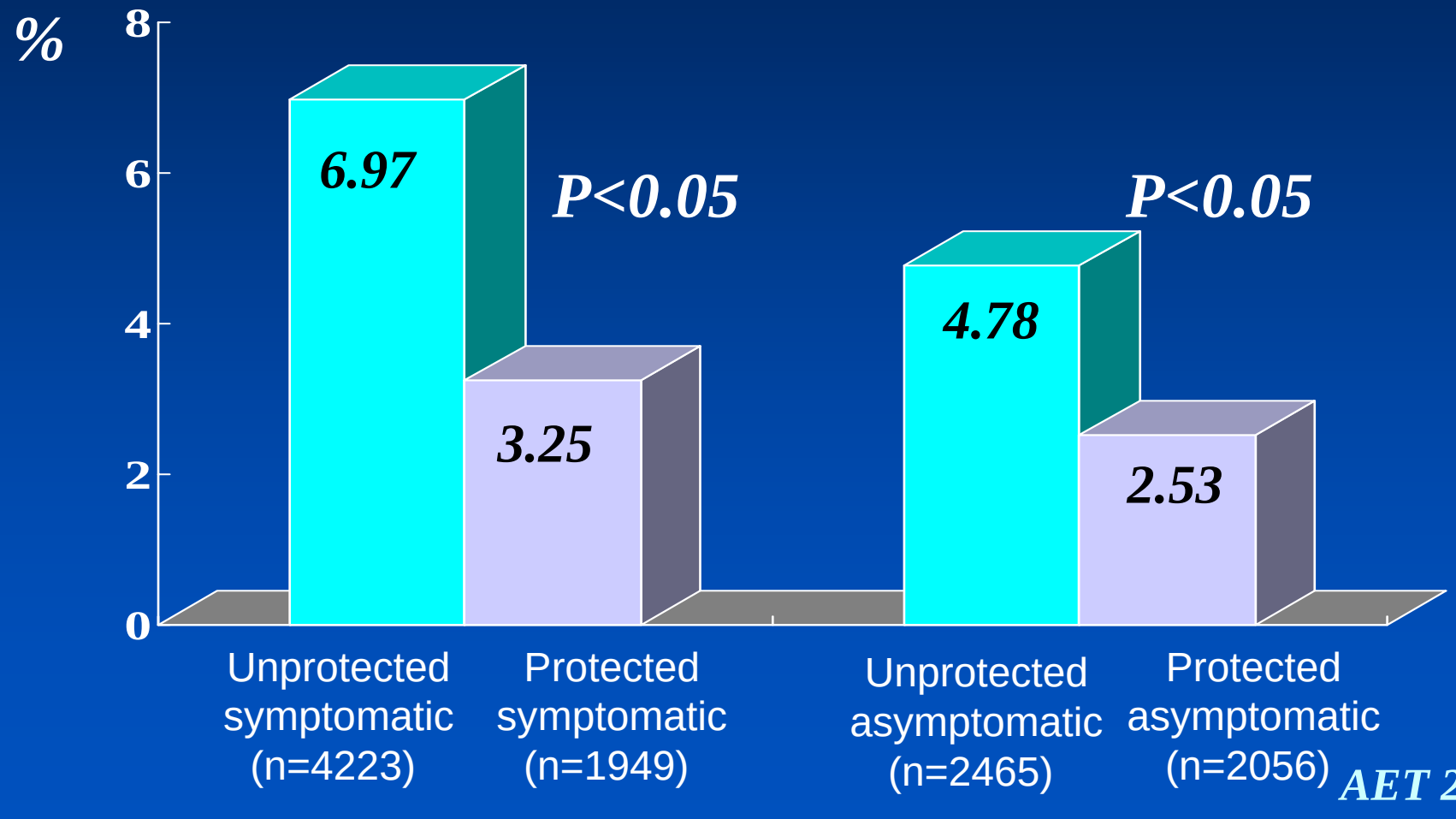
** Protection devices: Angioguard®, PercuSurge® & EPI*

K. Mathias et al, AJNR 2001

Periprocedural Outcomes

With or Without Protection

All events: minor, major stroke, & all cause death



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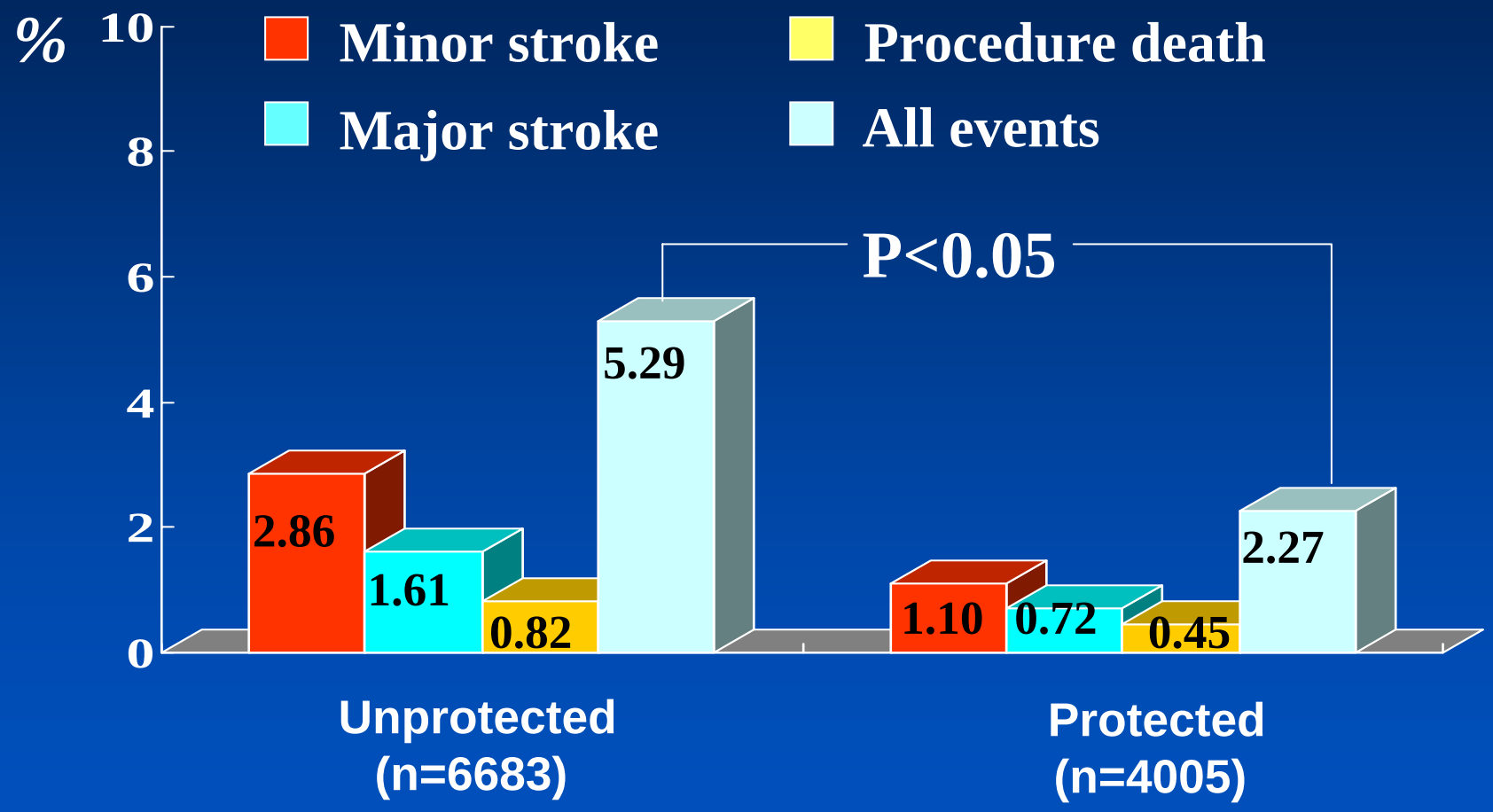
Periprocedural Outcomes

With or Without Protection



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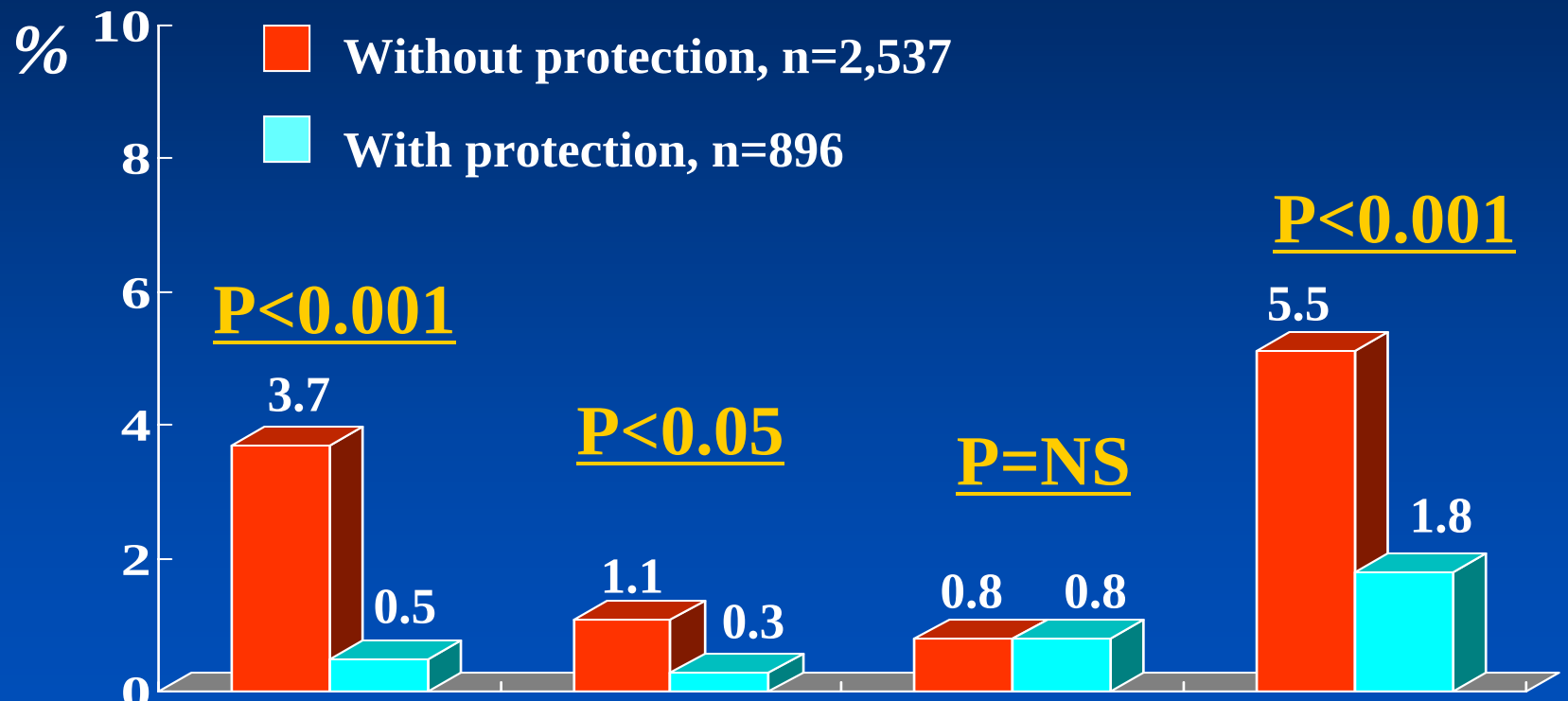
30-Day Outcomes
With or Without Protection
54 studies about carotid stenosis



Stroke 2003;34:813-819

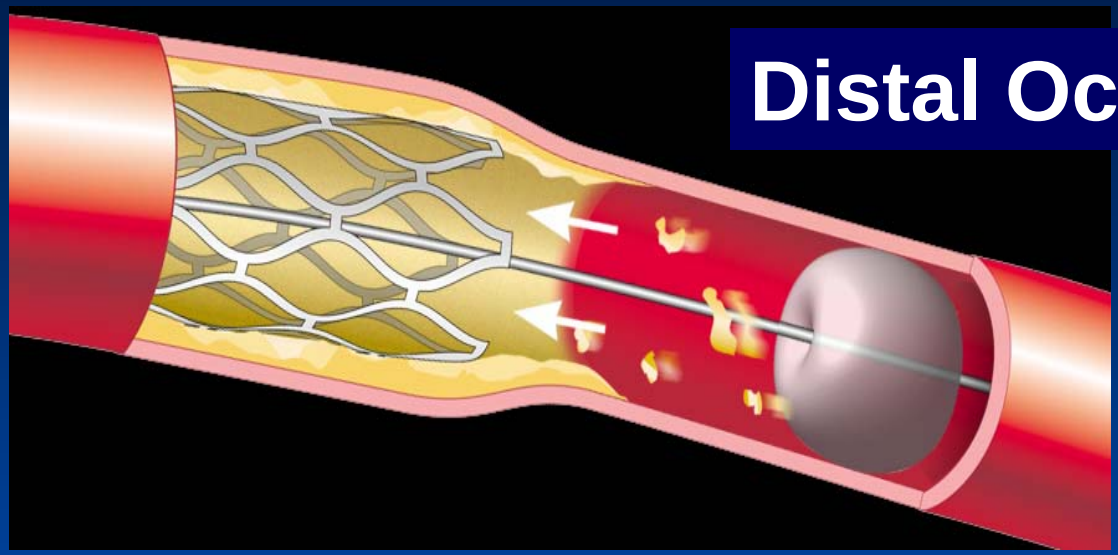
The Ideal Protection System

- Does not cause harm
  - Complete protection
  - Capture efficiency
- Protection at all time for all particles
- Wide applicability
- User friendly

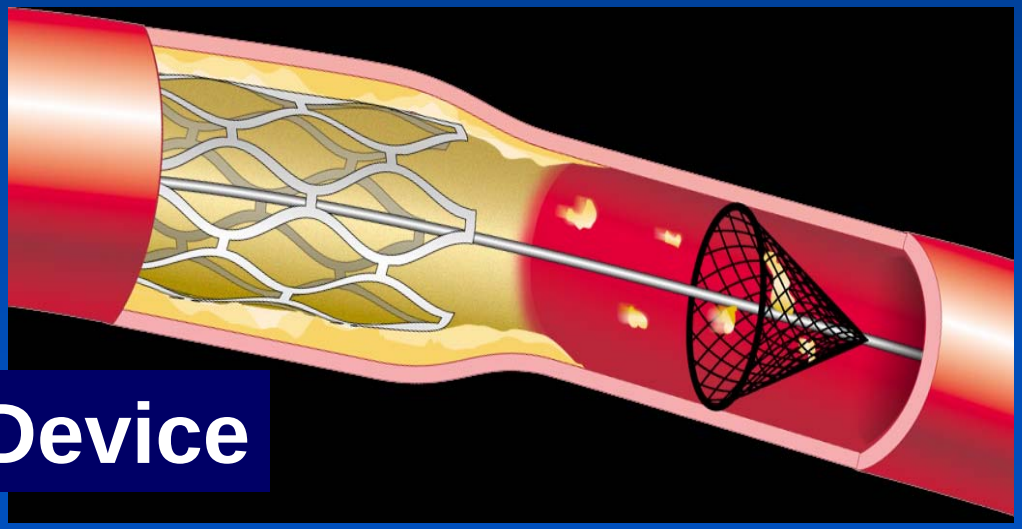
Distal Protection Devices

Distal occlusion	Theron balloon PercuSurge Guardwire
Filter	MedNova NeuroShield EPI filter Angioguard filter Medtronic filter BSC Captura Bate's Floating Filter Accu-Filter E-Trap Microvena Trap
Proximal occlusion	Kachel balloon ArteriA Parodi Catheter

Distal Protection Devices



Distal Occlusion Device



Filter Device

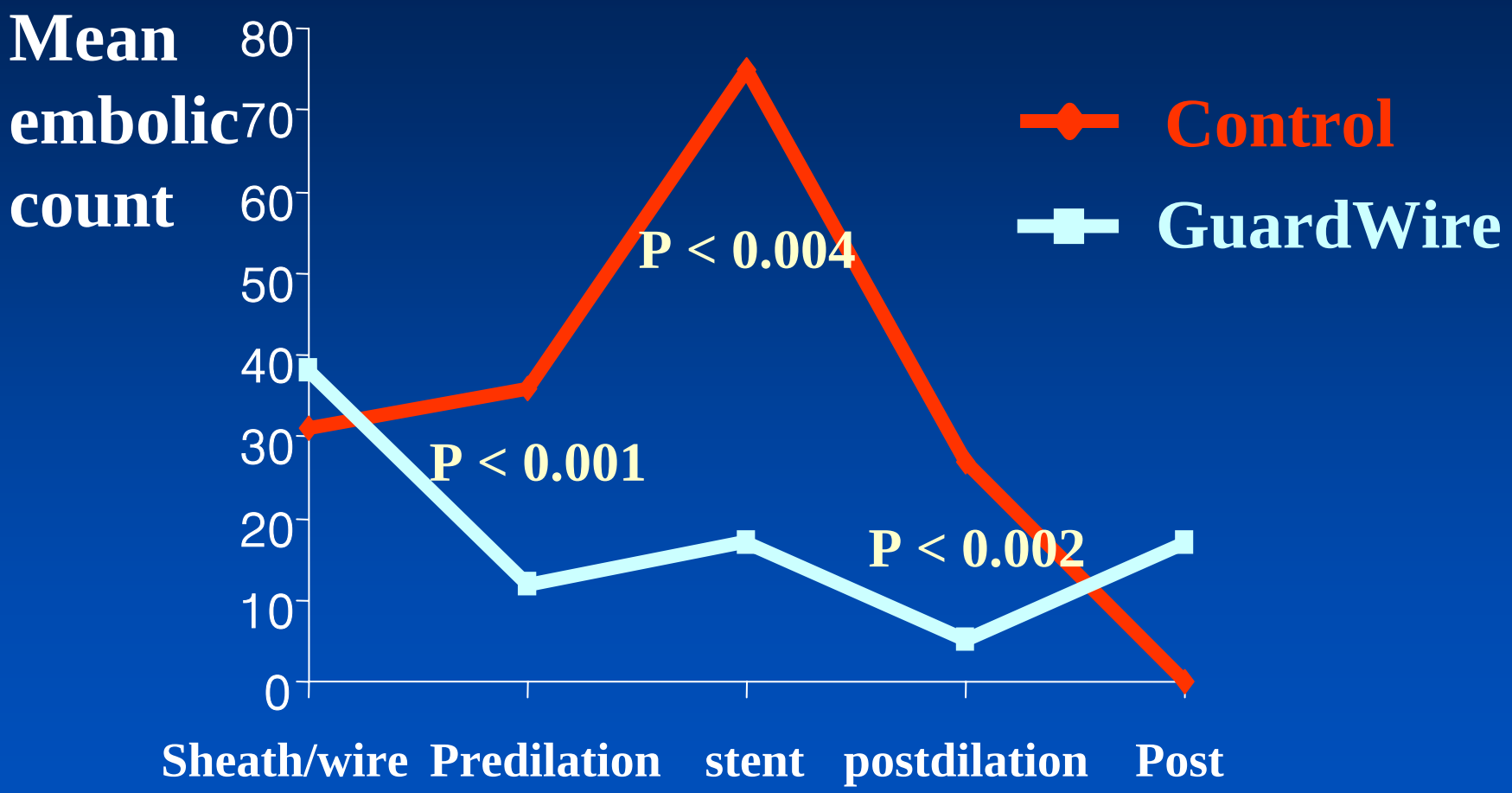
PercuSurge GUARDWIRE™

PercuSurge GUARDWIRE™

GuardWire™	PERCUSURGE, Inc
System	0.014
Crossing Profile	0.036” (3-6mm), 0.028” (2-5mm)

The Export® Aspiration Catheter	PERCUSURGE, Inc
Total Length	137 cm
RX shaft design	3.5 x 4.5F distal OD
Aspiration system	20cc locking syringe

PercuSurge GUARDWIRE™



Al-Mubarak et al, Circulation, 2001

Protection with PercuSurge GuardWire

Number	179
Technical success	99.3 %
Overall mean balloon time (sec)	410 ± 220
30-day stroke rate	6 (2.3 %)
Minor stroke (TIA, retinal embolism)	4 (1.5%)
Major stroke	1 (0.4%)
Death (cardiac)	1 (0.4%)
36-month event (stroke & death)-free survival	97%
Death (AMI, stroke, cancer)	4 (1.5%)

Catheter Cardiovasc interv 2004;61:293-305

Distal Occlusion Balloon

Strength

- Mimics standard guidewire more than any filters
- Ability to cross lesion
- Particles of all sizes can be blocked (ICA)

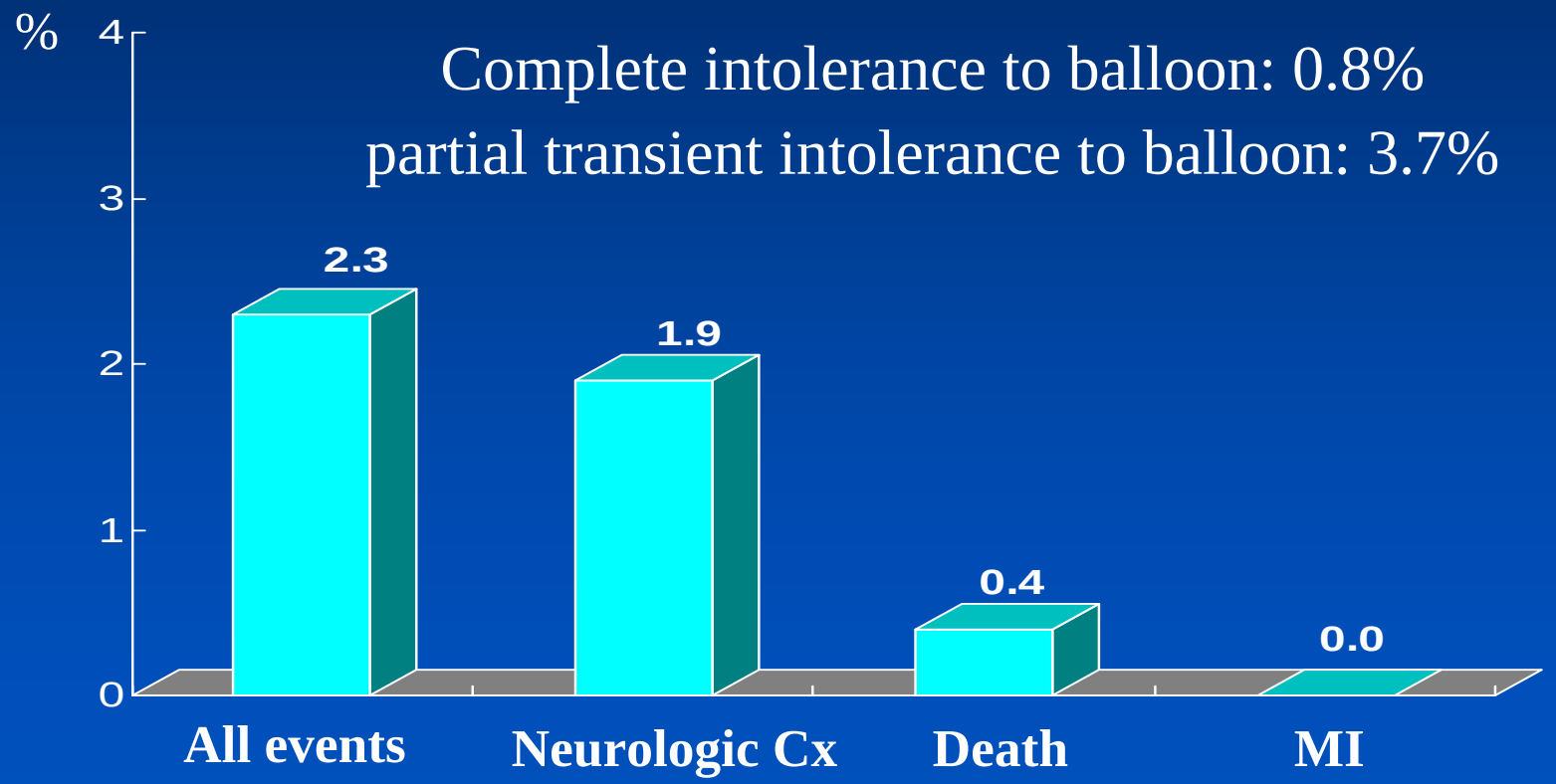
Distal Occlusion balloon

Weakness

- Unprotected
    1) During passage
    2) ECA
    3) Incomplete suction
- Does not preserve ICA flow (can’t be angiogram)
- May cause spasm/dissection in distal ICA
- Cumbersome procedure (cannot move wire during exchange, several added steps, aspiration)

Outcomes at 30 Days

246 patients (272 lesions) with Percusurge GuardWire

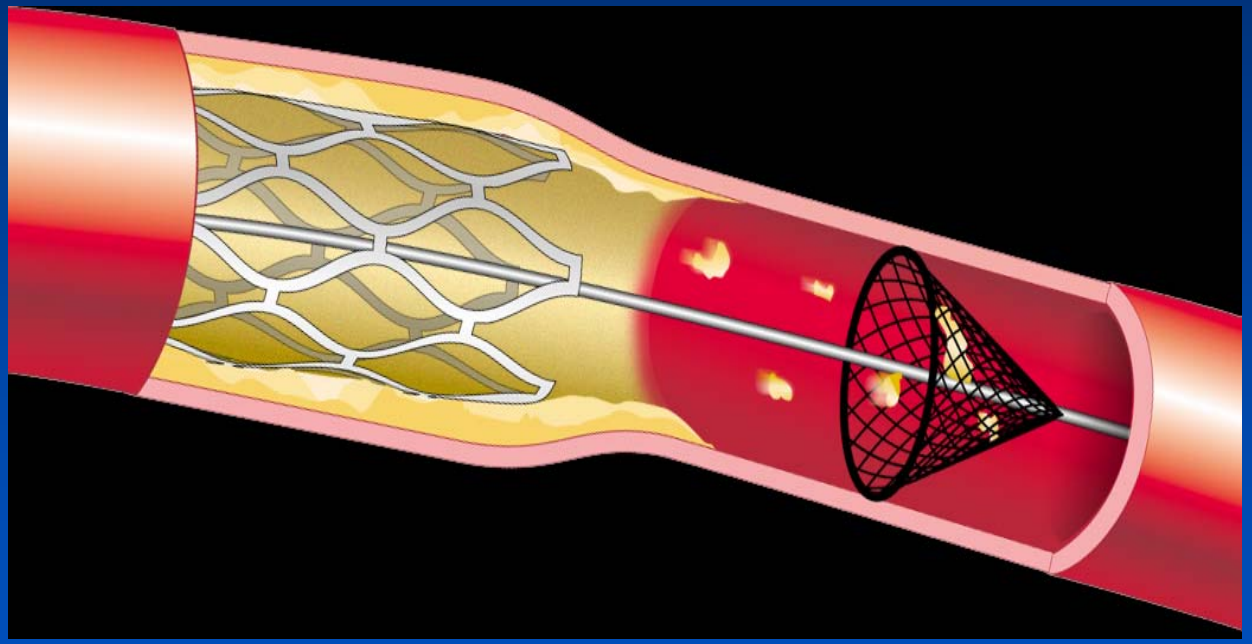


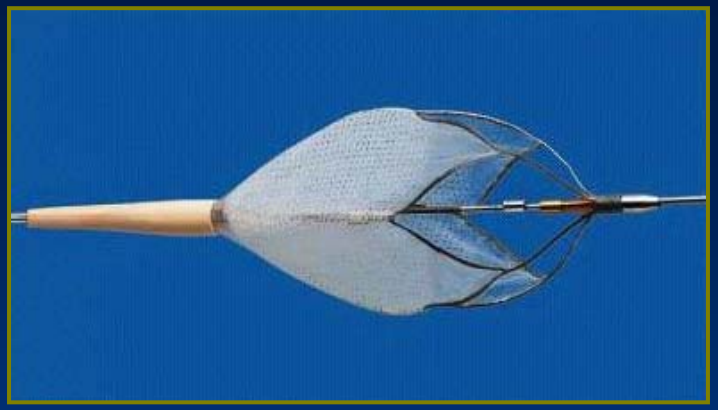
Complete intolerance to balloon: 0.8%
partial transient intolerance to balloon: 3.7%

J Interven Cardiol 2004;61:233-43

Distal Protection Devices

Filter





Guidant - ACCUNET

BSC - EPI

MedNova - Emboshield

Filter Device

Strength

- User-friendly
- Preserves ICA flow

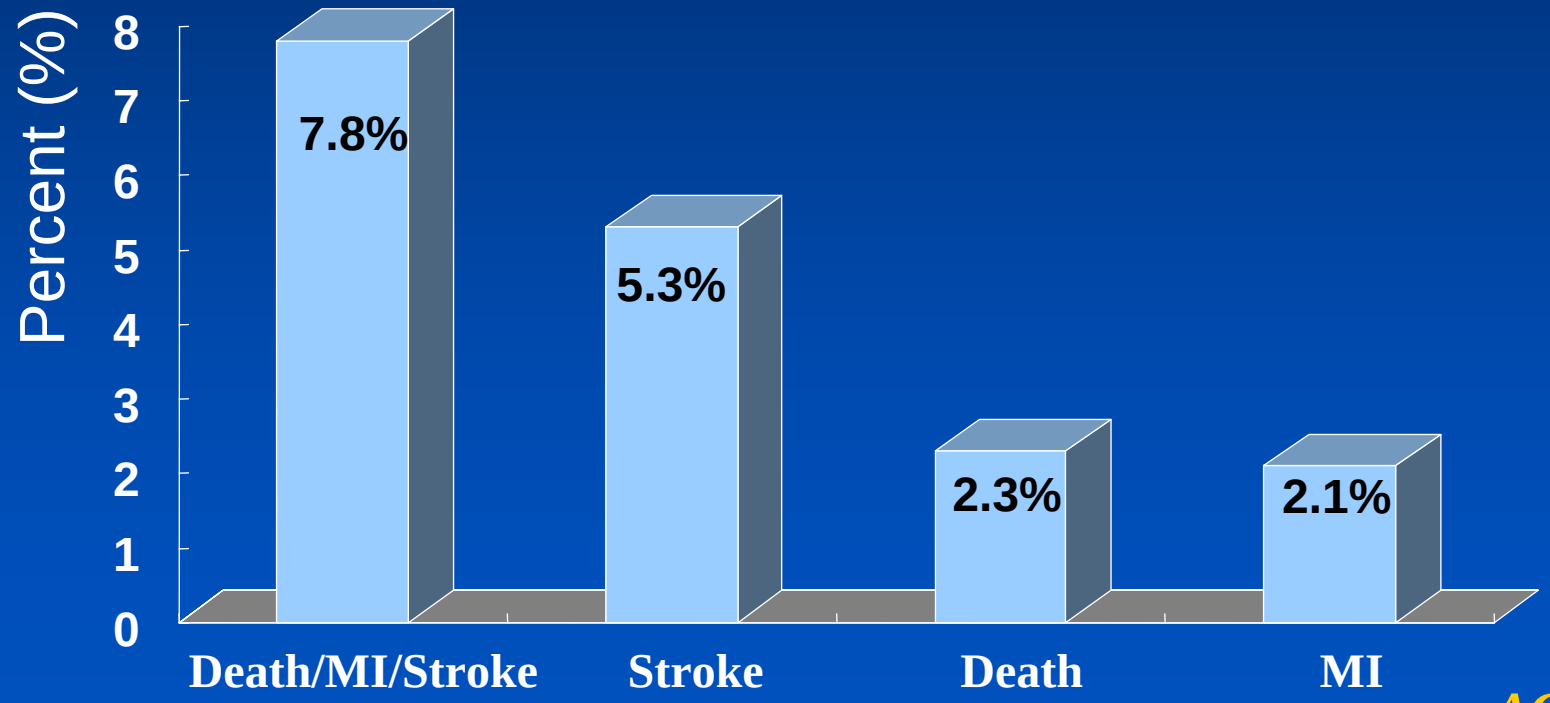
Filter Device
Weakness

- Not same as standard guidewire
- Larger profile, less flexible
- Frequent need to predilate (recross PTA site)
- Unprotected
  1) during passage
  2) small particles
  3) flow around filter
  4) during filter retrieval
- May thrombose
- May cause spasm/dissection in distal ICA
- Cumbersome procedure (cannot move wire during exchange, several added steps)

ARCHER Trial

- With 513 high risk patients
- With Acculink device

Complications at 30-day

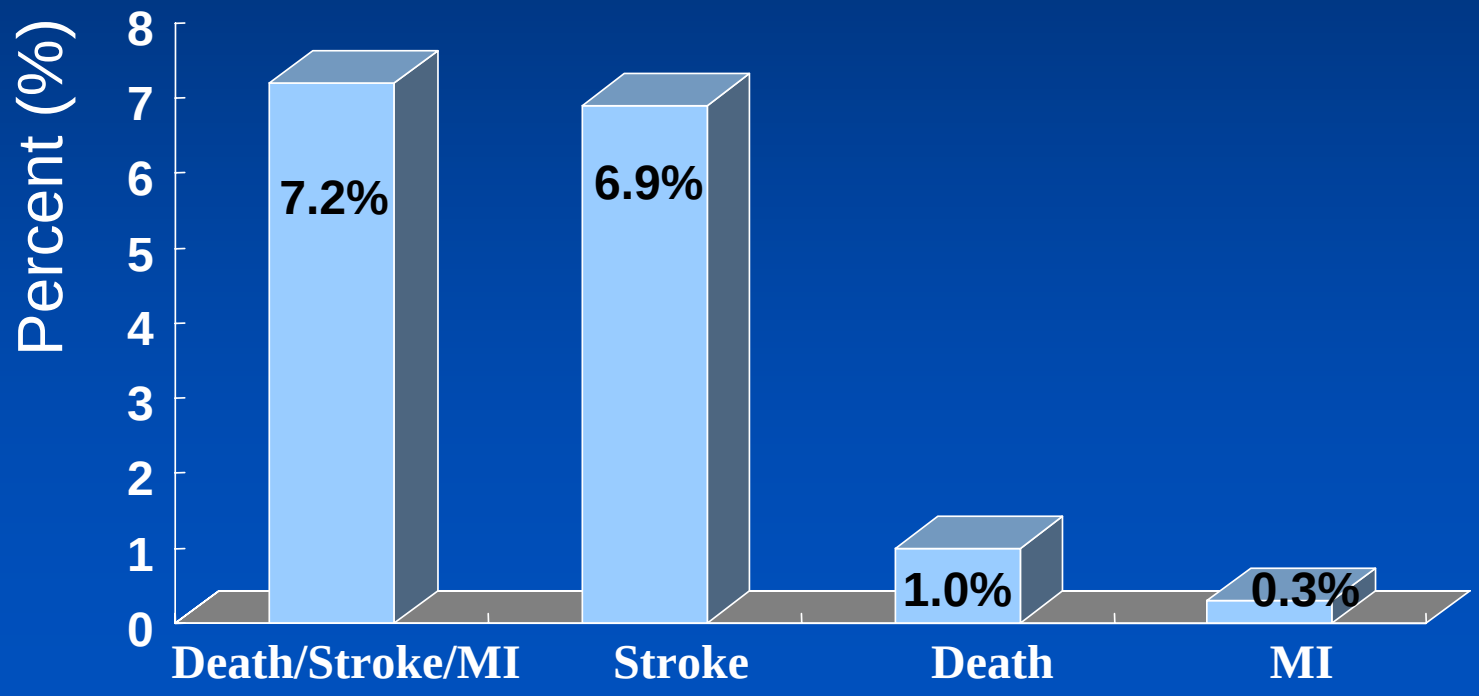


ACC 2003

SECURITY Trial

- With 305 high risk patients
- Mednova filter wire/ X Act stent

Complications at 30-day



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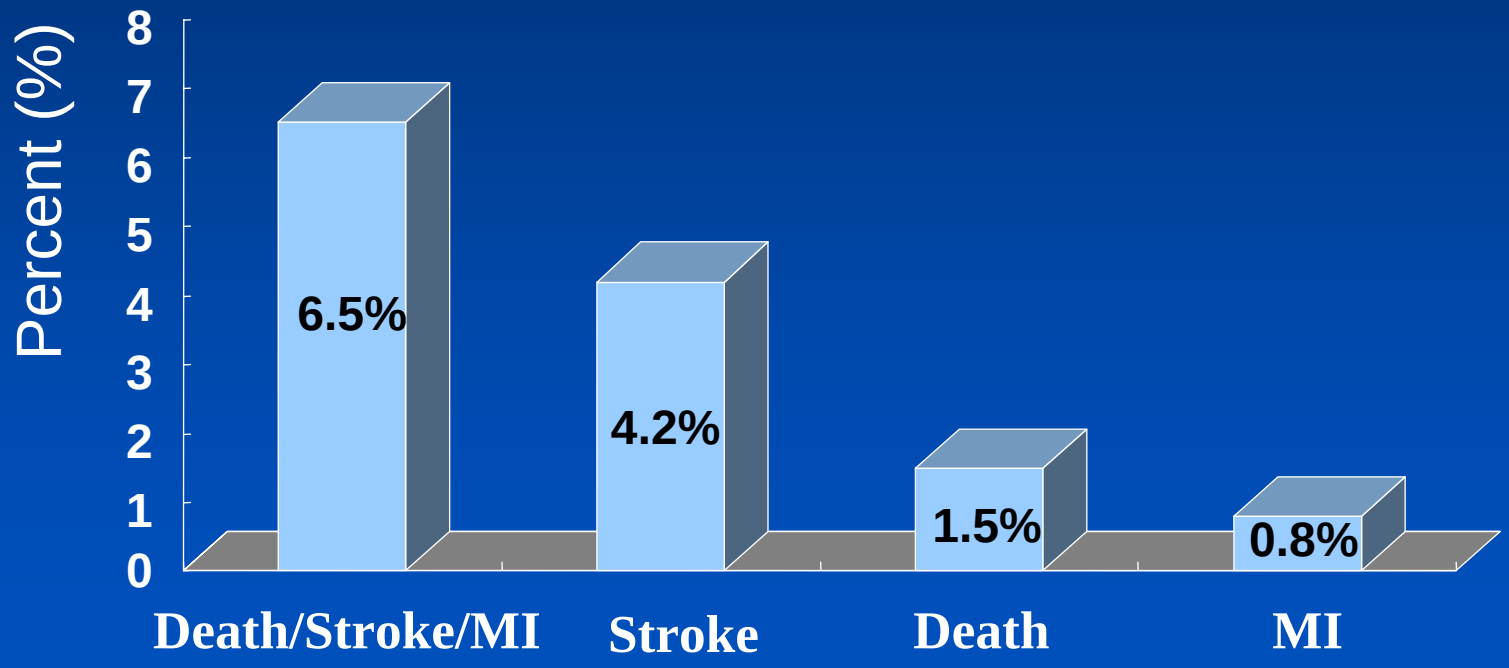
BEACH Trial

- With 747 high risk patients
- Carotid wall stent with filter wire

Complications at 30-day



ACC 2004

BEACH Trial

- With 747 high risk patients
- Symptomatic patients: stenosis ≥50%
- Asymptomatic patients: stenosis ≥80%
- Carotid wall stent with filter wire
- 30 day outcomes
  - Death/Stroke/MI : 6.5%
  - Death : 1.5%
  - Stroke : 4.2%
  - MI : 0.8%

ACC 2004

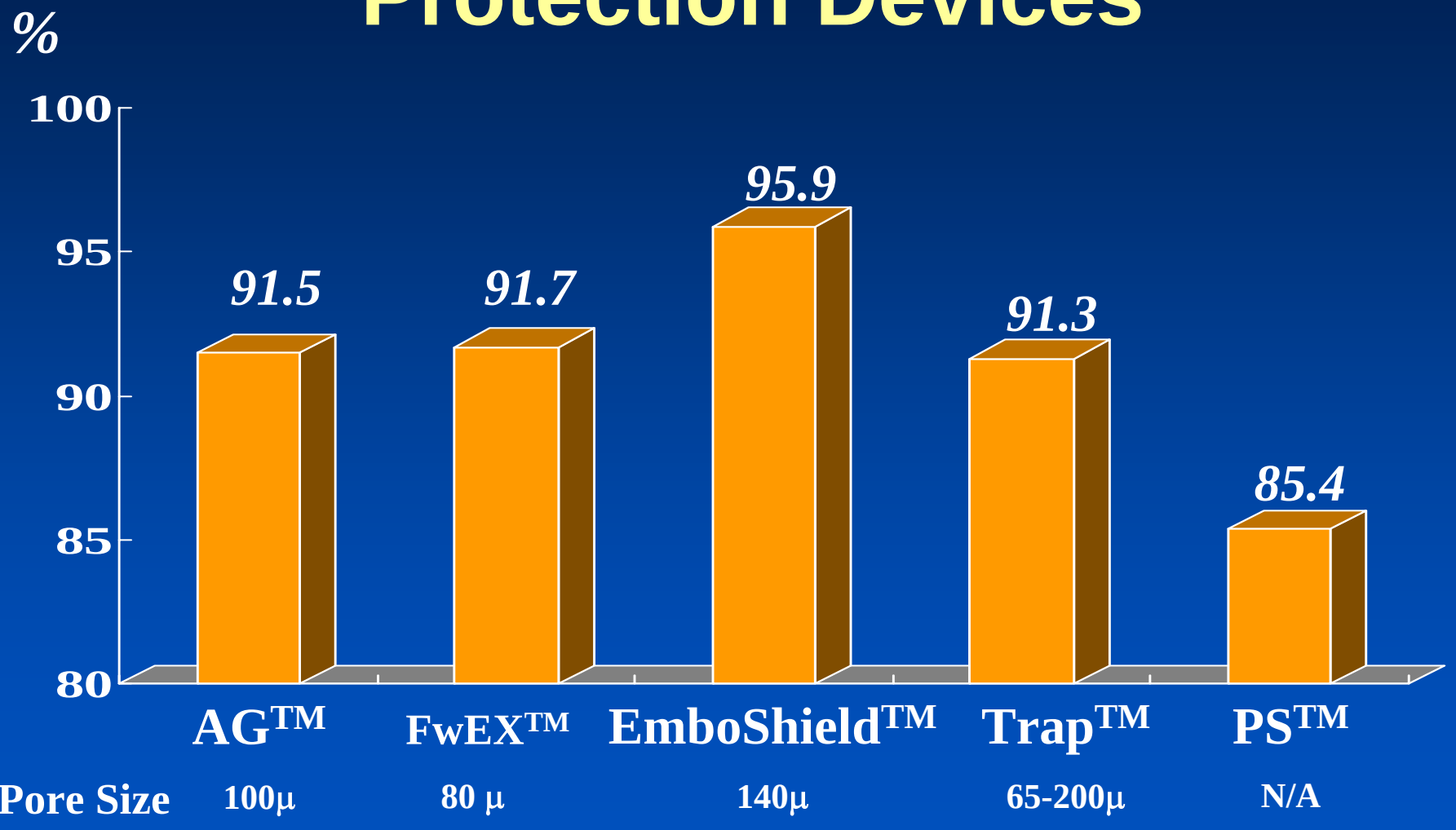
Comparison of Devices Efficiency

Different Protection Devices

Advantages and Disadvantages

	Easy to use	Embolization during lesion crossing	Flow decrease	ICA protection emboli	Ability to perform angiography during protection	Embolization through ECA	Potential spasm/ damage to ICA	Tolerance
Filters	+++	+	+	+	+++	-	+++	+++
Occlusion	++	+	++	++	-	+++	+++	+
Flow reversal	+	-	+++	+++	+++	-	-	+

Capture Efficiency of Protection Devices



JVIR 2003;14:613-620

CAS with protection
Complication at 30 days

	Al-Mubarak 2002 (Neuroshield)	Tubler, 2001 (Percusurge)	ARCHeR (Acculink, Accunet)	SAPPHIRE (Angioguard, Precise)
Patients	N=162	N=58	N=437	N=408
Death	1.0%	0%	2.3%	2.5%
Stroke	1.0%	4%	5.3%	5.6%
Major	0%	2.0%	1.6%	3.1%
Minor	1.0%	2.0%	3.7%	2.7%
MI	0.5%	0%	2.1%	1.7%
Total MAE	2.0%	4%	7.8%	7.8%

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Comparisons at 30 Days

Major Endpoints	N=56 Angioguard filter	N=55 Neuroshield filter
Minor stroke	1(1.78%)	0
Major stroke	0	1(1.8%)
MI	0	0
death	0	0

No difference !!!

AET 2003

Endarterectomy

Vs.

Stenting

CAVATAS

Multicenter Randomized Trial
CEA vs. Angioplasty

	Angioplasty N=251	CEA N=253
30-day death & stroke	**6.4%**	**5.9 %**
Cranial neuropathy	**0 %**	**8.7 %**
1-year restenosis *	**14 %**	**4 %**

**** Stenting = only in 26%***

CAVATAS Investigators, Lancet 2001;357:1729

Procedural Cx of CAS vs. CEA

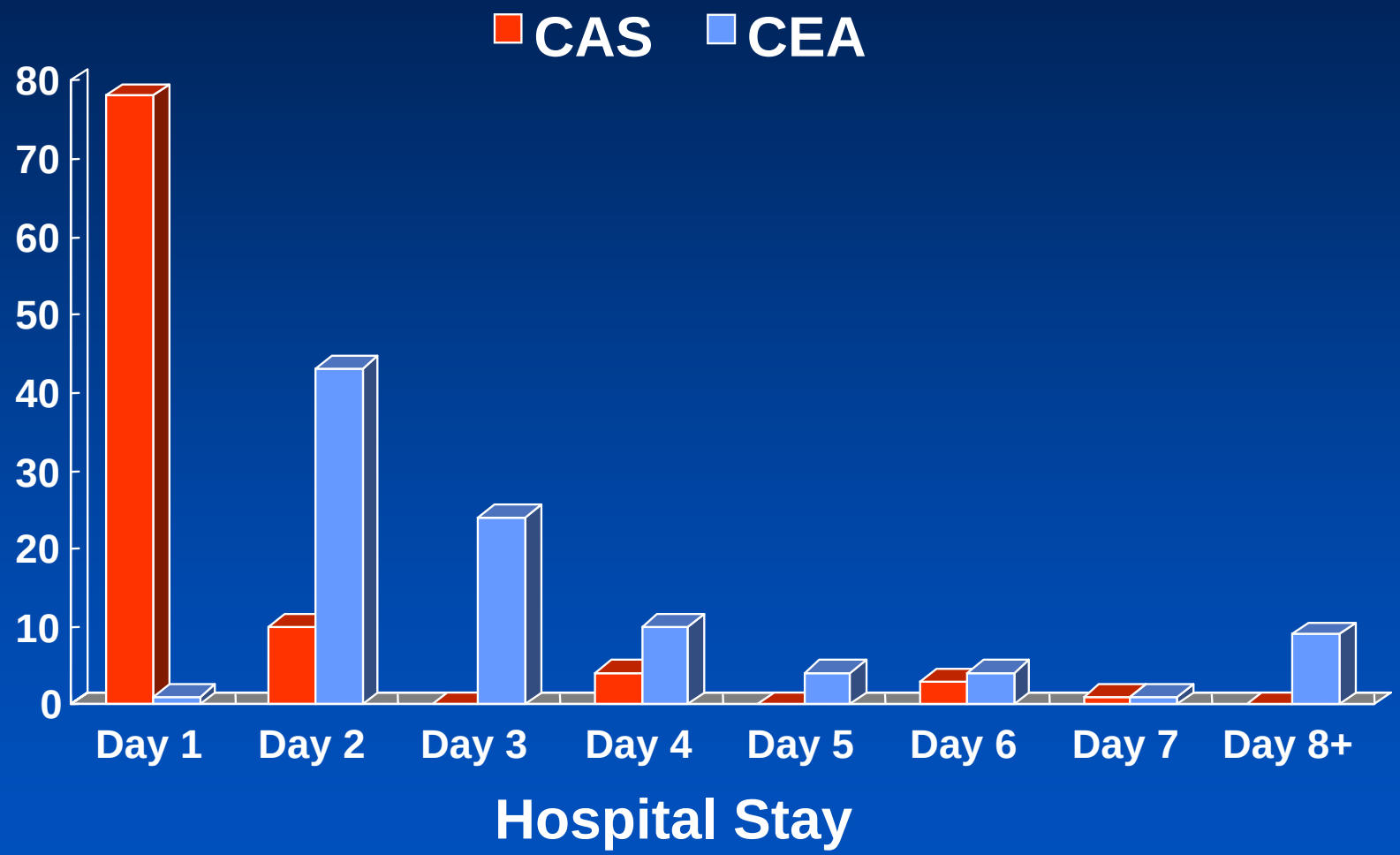
Randomized Trial in a Community Hospital

	CAS N=53	CEA N=51
Death	**0**	**1 (MI)**
Stroke	**0**	**0**
TIA	**1**	**0**

- CAS is equivalent to CEA, Slightly higher cost in CAS
- No increased risk for major complications of death/stroke
- Shortened hospitalization and convalescence

Brooks WH, et al. JACC 2001;38:1589

Hospital Stay of CAS vs. CEA



Ecker RD et al. J Neurosurg 2004;101:904

Cost of CAS vs. CEA

Factor	CAS	CEA	p Value
Duration of hospitalization (days)			
Mean (SD)	**1.6 (1.5)**	**4.1 (5.3)**	**<0.001**
Median	**1.0**	**3.0**	
Median cost (range, $)			
Anesthetic	**315 (285–360)**	**518 (471–621)**	**<0.001**
Hospital	**7671 (5705–10,042)**	**7715 (5950–10,006)**	**0.540**
Physician	**3221 (2090–5000)**	**1760 (1594–2678)**	**<0.001**
Total	**10,628 (8492–14,662)**	**10,148 (8287–13,429)**	**0.495**

The SAPPHIRE Study

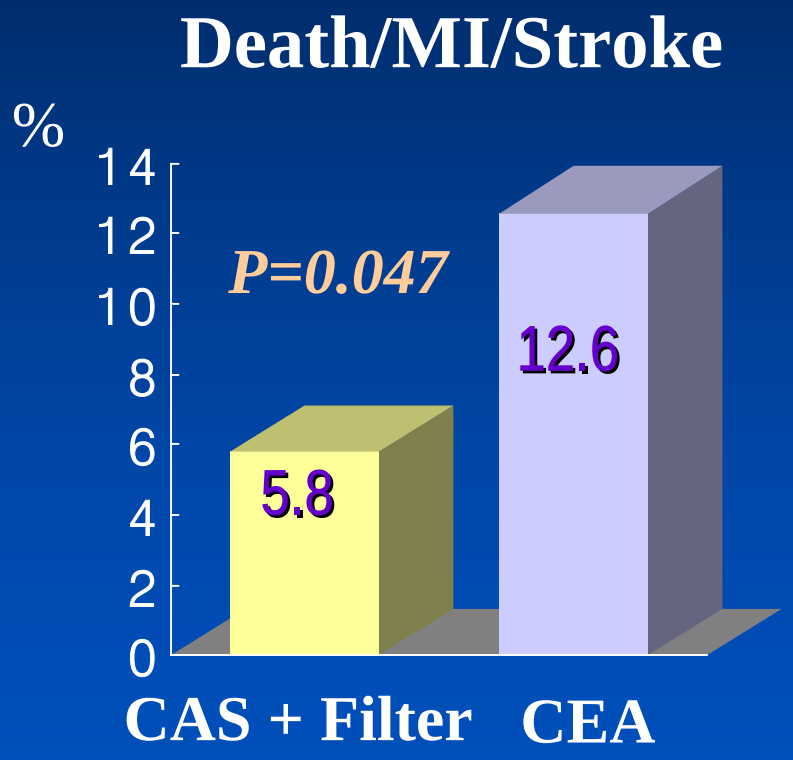
Senting with filter device

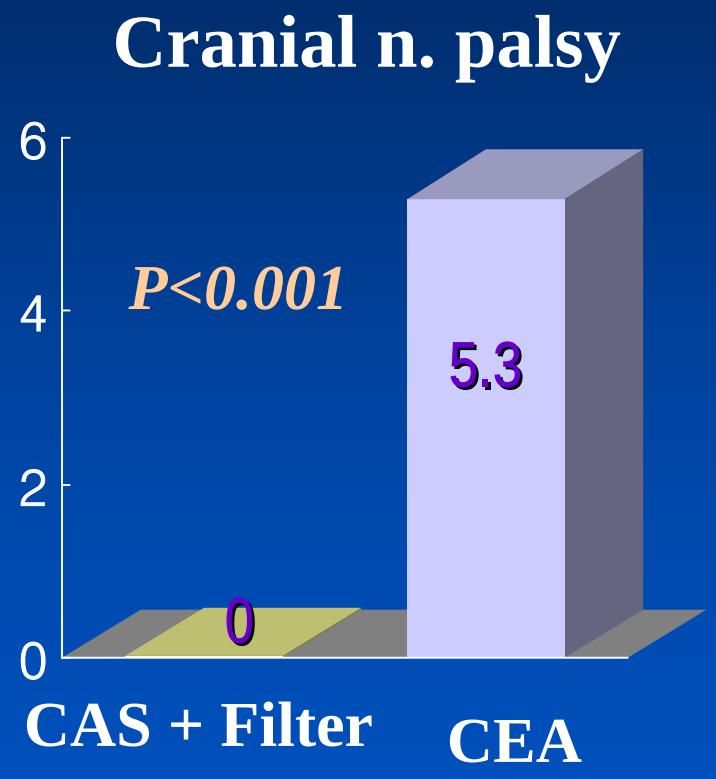
vs.

Endarterectomy

in high risk patients

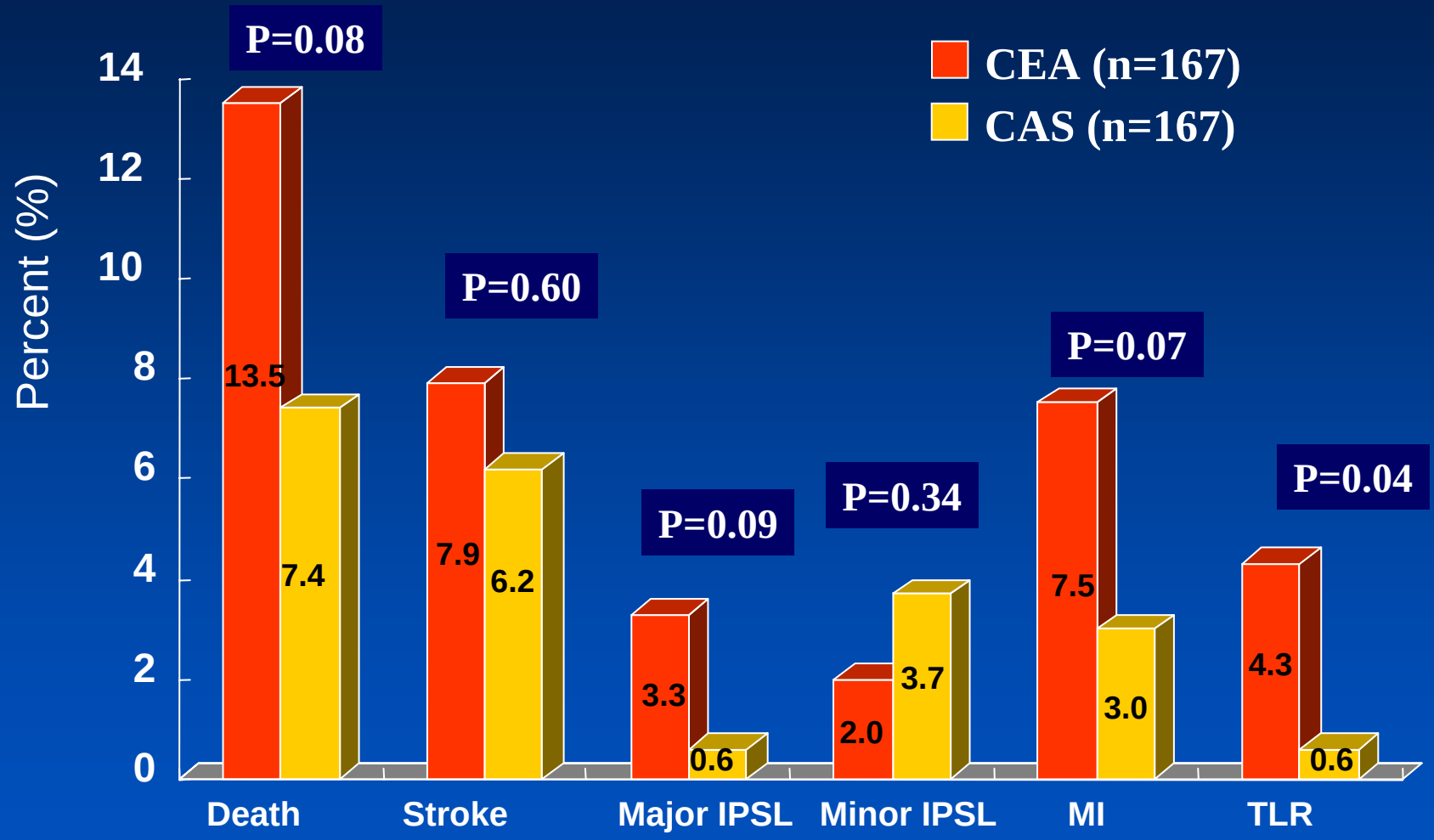
Events Rate at 30 Days





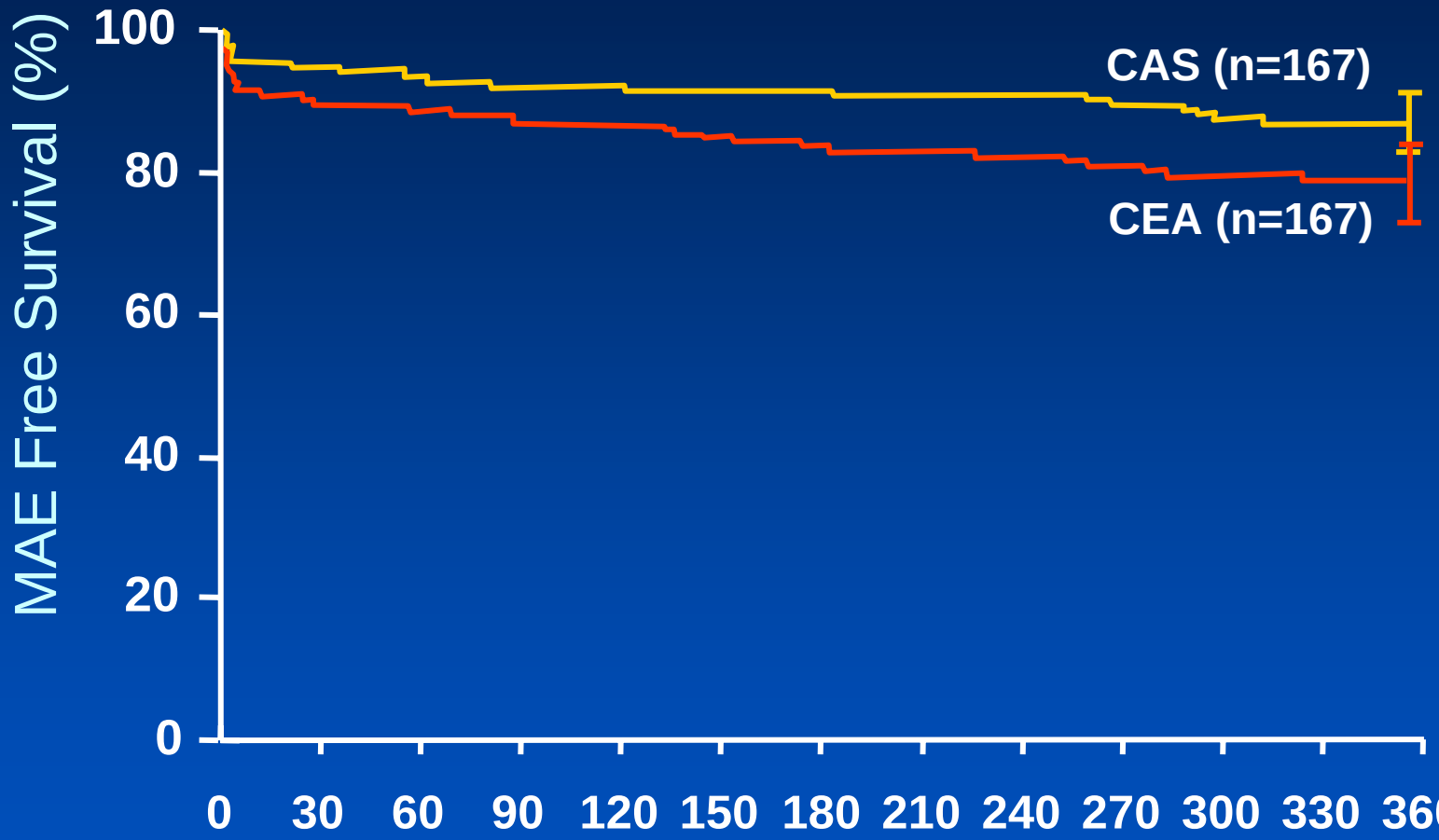
Yadav JS, et al. NEJM 2004;351:1493

Event Rates at 1 Year



Yadav JS, et al. NEJM 2004;351:1493

Event-free Survival



Yadav JS, et al. NEJM 2004;351:1493

SAPPHIRE Trial

- Among patients with severe carotid-artery stenosis and coexisting conditions, CAS with the use of an emboli-protection device is not inferior to CEA.

Yadav JS, et al. NEJM 2004;351:1493

CAS With Protection Devices

- CAS with protection is a safe and efficient procedure

- Protected CAS
  - Lower risk of major ipsilateral stroke, MI, cranial nerve injury and revascularization

CAS With Protection Devices

- Protected CAS was non-inferior regardless of neurologic symptom status
- One year event rates for CAS in asymptomatic patients were significantly lower than with surgery and compared with previous CEA trials

Patient Selection of Carotid Stenting

Only high surgical risk patients

vs.

All patients

High Risk Surgical Criteria

Should be the stenting !

Anatomic high risk

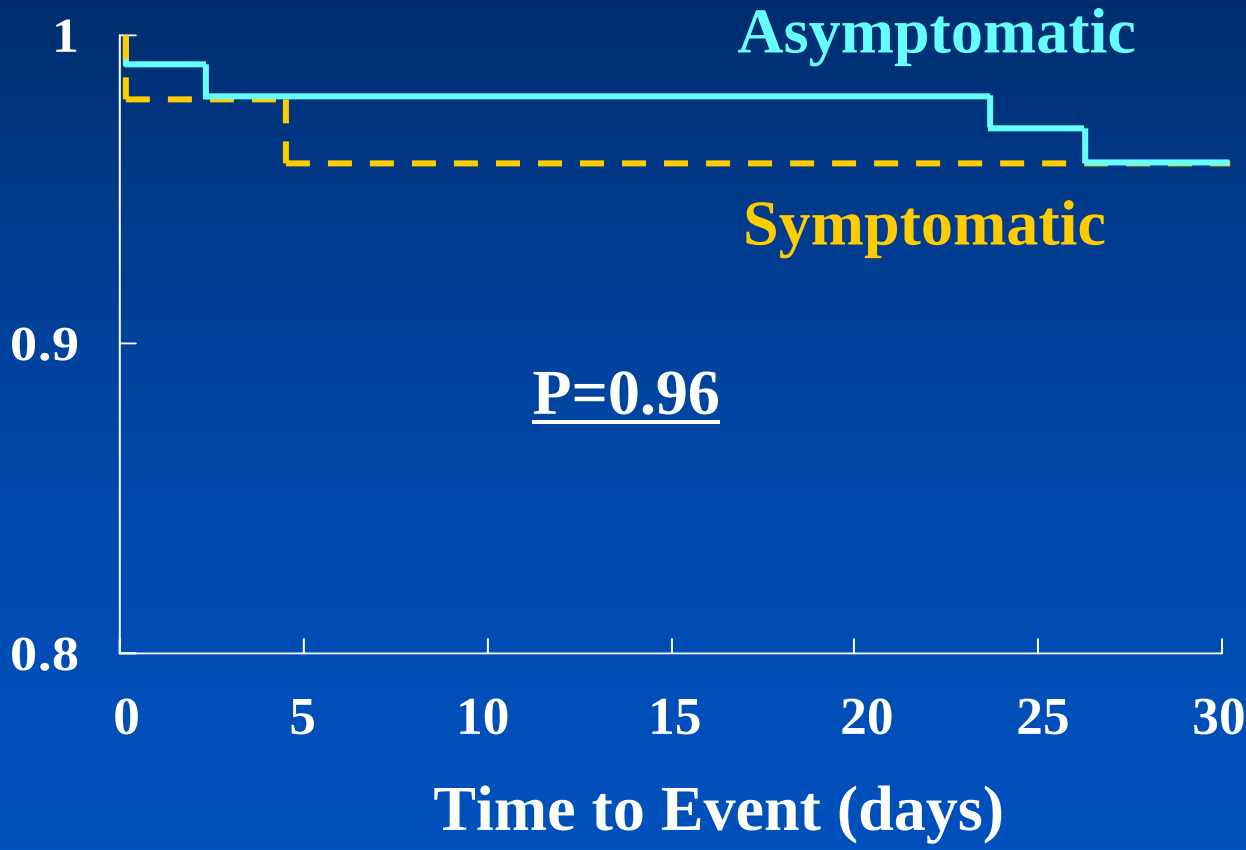
- High(C2) carotid bifurcation
- Prior neck irradiation or radical neck dissection
- Restenosis following prior CEA
- Contralateral occlusion
- Ostial common carotid lesion
- Spine immobility

Surgical high risk

- Severe CAD
  - Not revascularized or awaiting CABG
- Class III or IV CHF
- Severe COPD
- Age > 80

Outcomes of CAS with Protection at 30 Days

Symptomatic vs. Asymptomatic



ACC 2004

Outcomes of CAS with Protection at 30 Days

High vs. low risk

	High risk N=326	Low risk N=262	p
Minor stroke	**4(1.2%)**	**3(1.1%)**	**ns**
Major stroke	**1(0.3%)**	**1(0.4%)**	**ns**
Fatal stroke	**2(0.6%)**	**0**	**ns**
All stroke	**7(2.1%)**	**4(1.5%)**	**ns**
All death	**4(1.2%)**	**1(0.4%)**	**ns**
Death+Stroke	**9(2.8%)**	**5(1.9%)**	**ns**

High risk: age > 80, prior ipsilateral CEA, prior neck surgery or radiation, contralateral occlusion, anatomic low or high lesion, unstable/severe heart disease

ACC 2004

Carotid Stenting

- With the use of the protection device, carotid stenting may be a more preferred therapy to carotid endarterectomy in carotid stenosis.

- The efficacy of carotid stenting may be extended to all patients subsets, such as symptomatic, asymptomatic, high risk, and low risk subgroups.