

Carotid Artery Stenting

**Is it a standard therapy for
carotid stenosis ?**

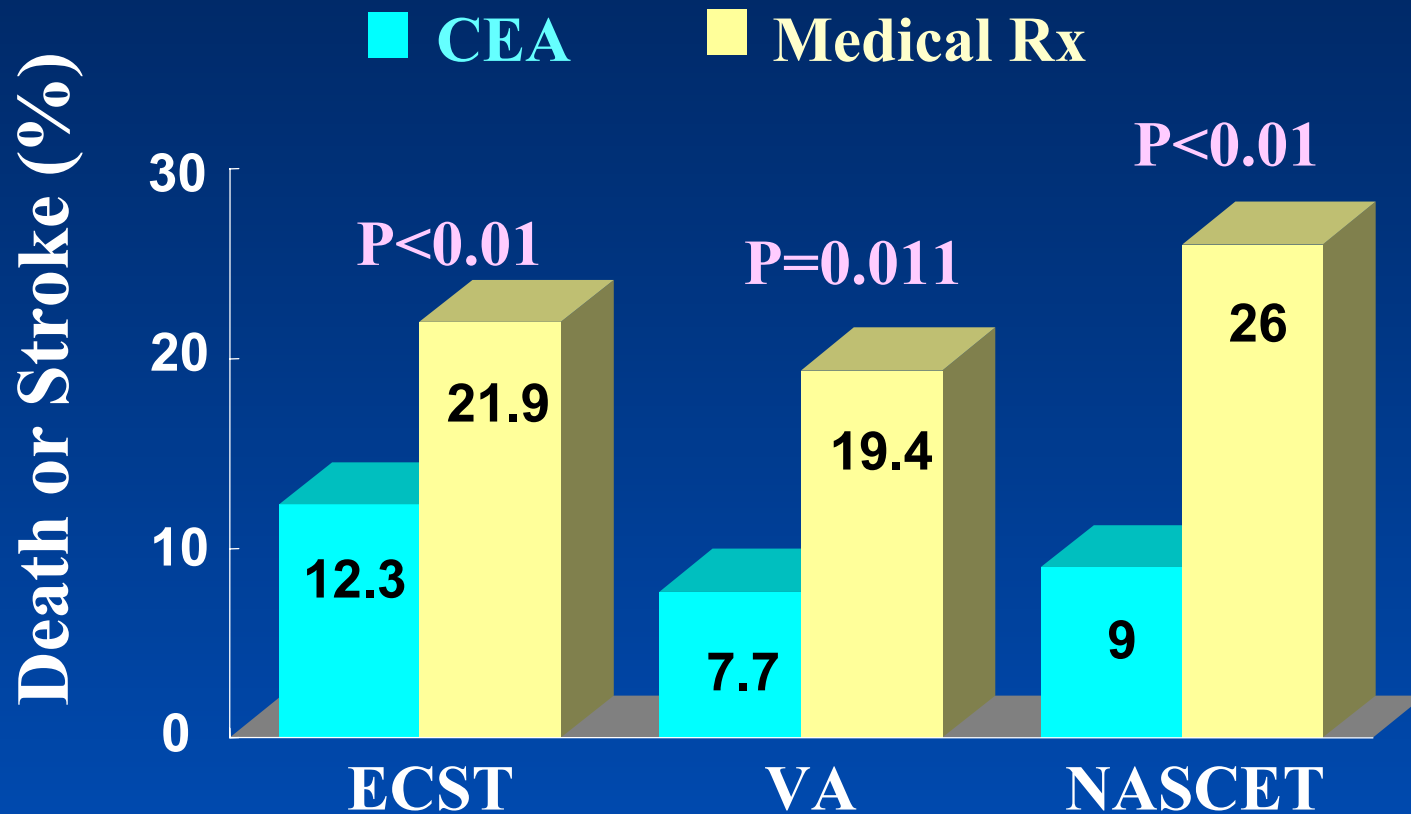
Natural history of the carotid stenosis

- Asymptomatic 80% carotid stenosis
 - 6% risk of stroke / year
- Symptomatic carotid stenosis have
 - 10% risk of CVA at one year and 40% at 5 years

Why should we open ?

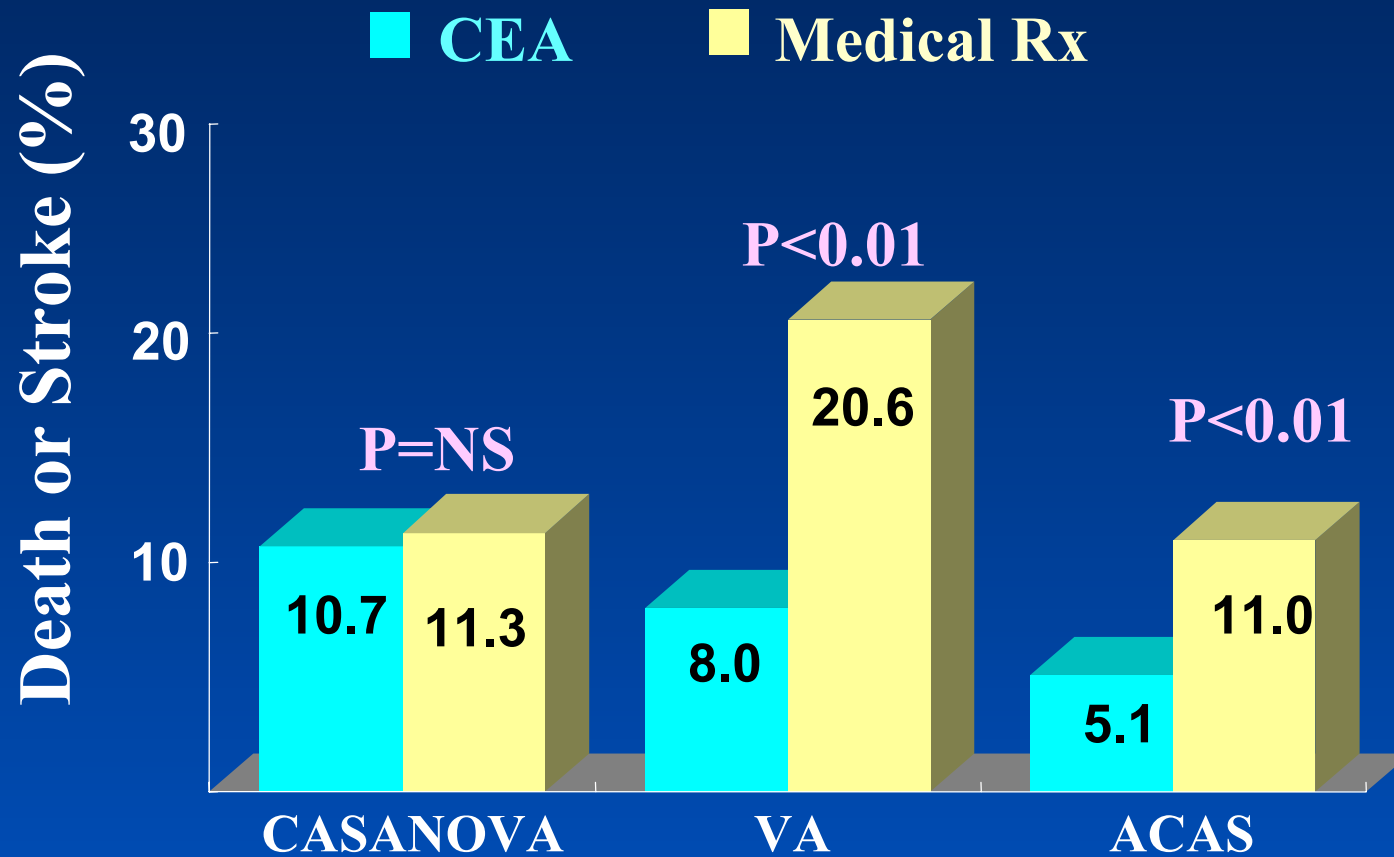
**Carotid end-arterectomy
Vs.
Medical therapy**

CEA vs. Medical Symptomatic Patients



CEA vs. Medical

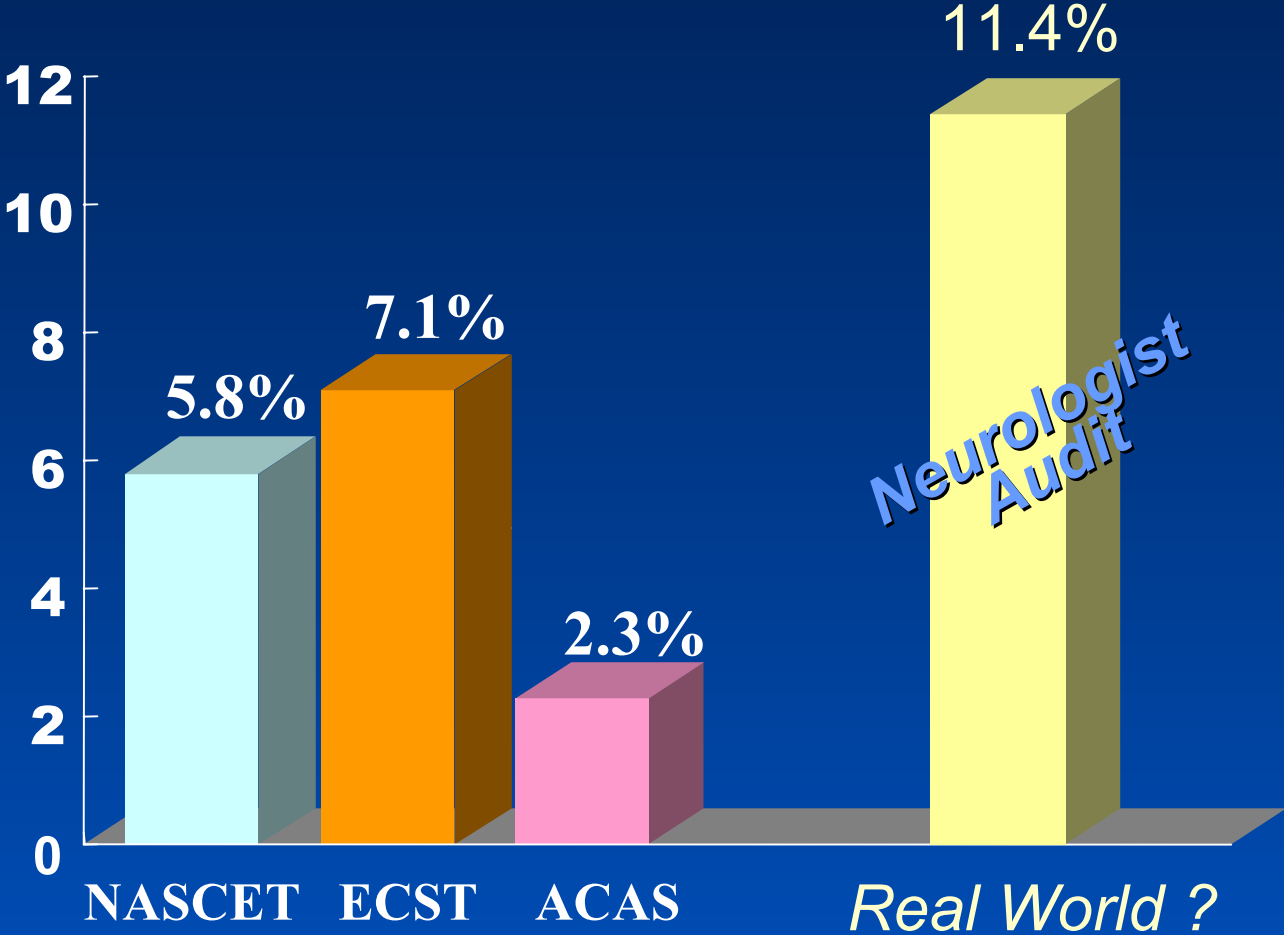
Asymptomatic Stenotic Patients



Limitations of CEA

- Average risk of perioperative stroke for low risk patient is ~6%
- Anatomic considerations
- Cranial nerve palsies (7~27%)
- Restenosis ~15%
- > 50% have severe coronary artery disease

Death or Stroke after CEA



Chaturverdi, Neurology 2001 Sep

Carotid Stenting

Carotid Stenting

Potential Benefits

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

Current Contraindication of Carotid Stenting

- Severely tortuous, calcified and atheromatous aortic arch vessels
- Pedunculated thrombus at the lesion site
- Severe renal impairment
- 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	N	Success	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%*

Complications Rates in Multicenter

Carotid Stenting

N=4757 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;50:160-7

Carotid Stenting With Protection

Embolization during CAS

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

** Protection devices: Angioguard, PercuSurge & EPI*

K. Mathias et al, AJNR 2001

Cerebral Embolization

High Risk Lesions

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

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**

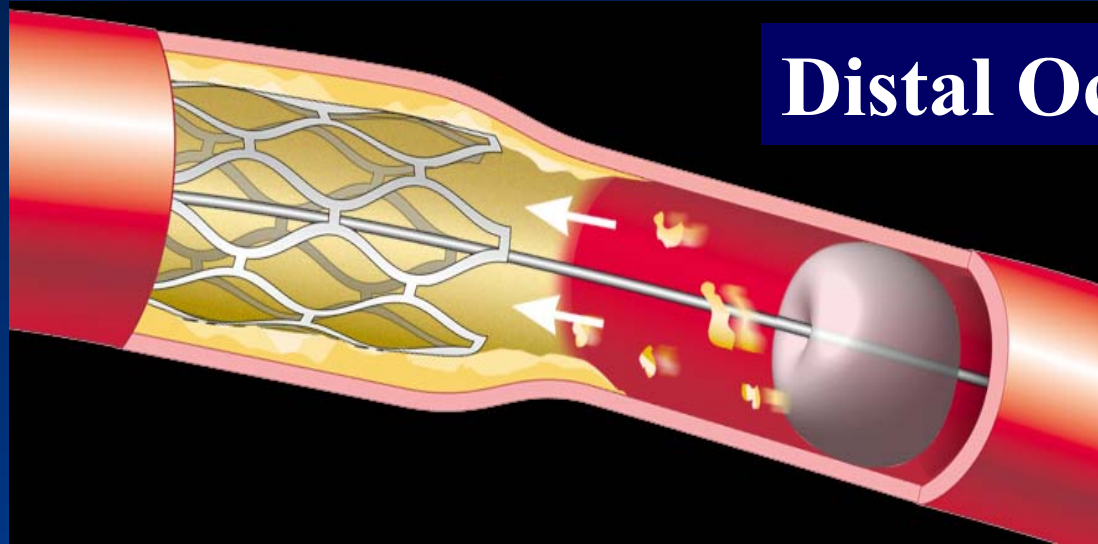
Protection of Distal Embolization

- 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 obliterate contrast filled ulcerated area external to the stent

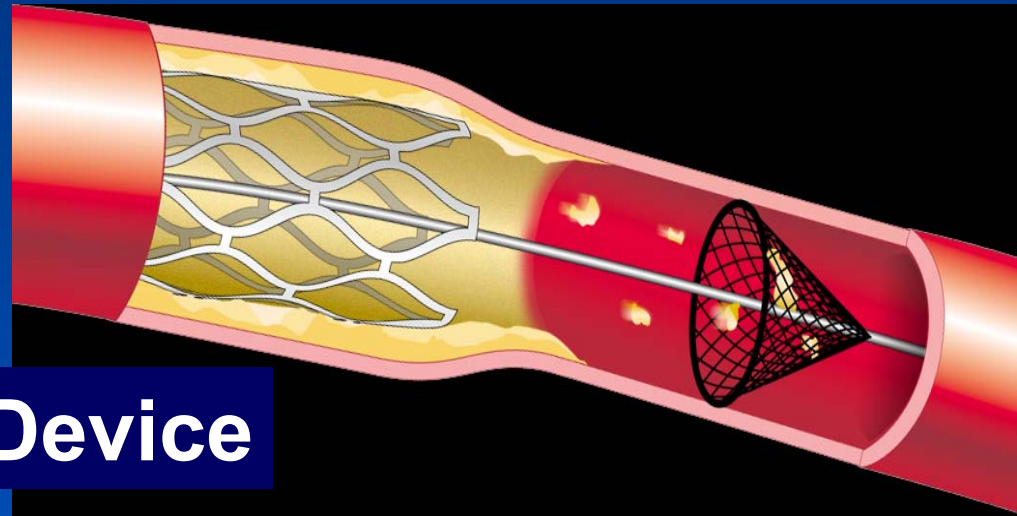
Distal Protection Devices

- **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 - Concepts



Distal Occlusion Device

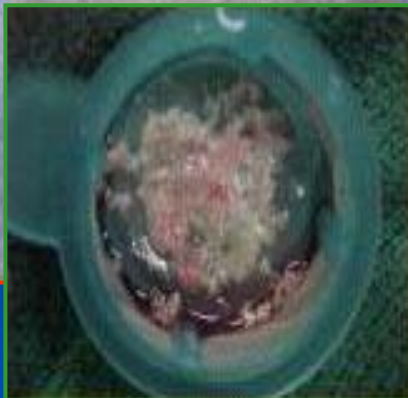
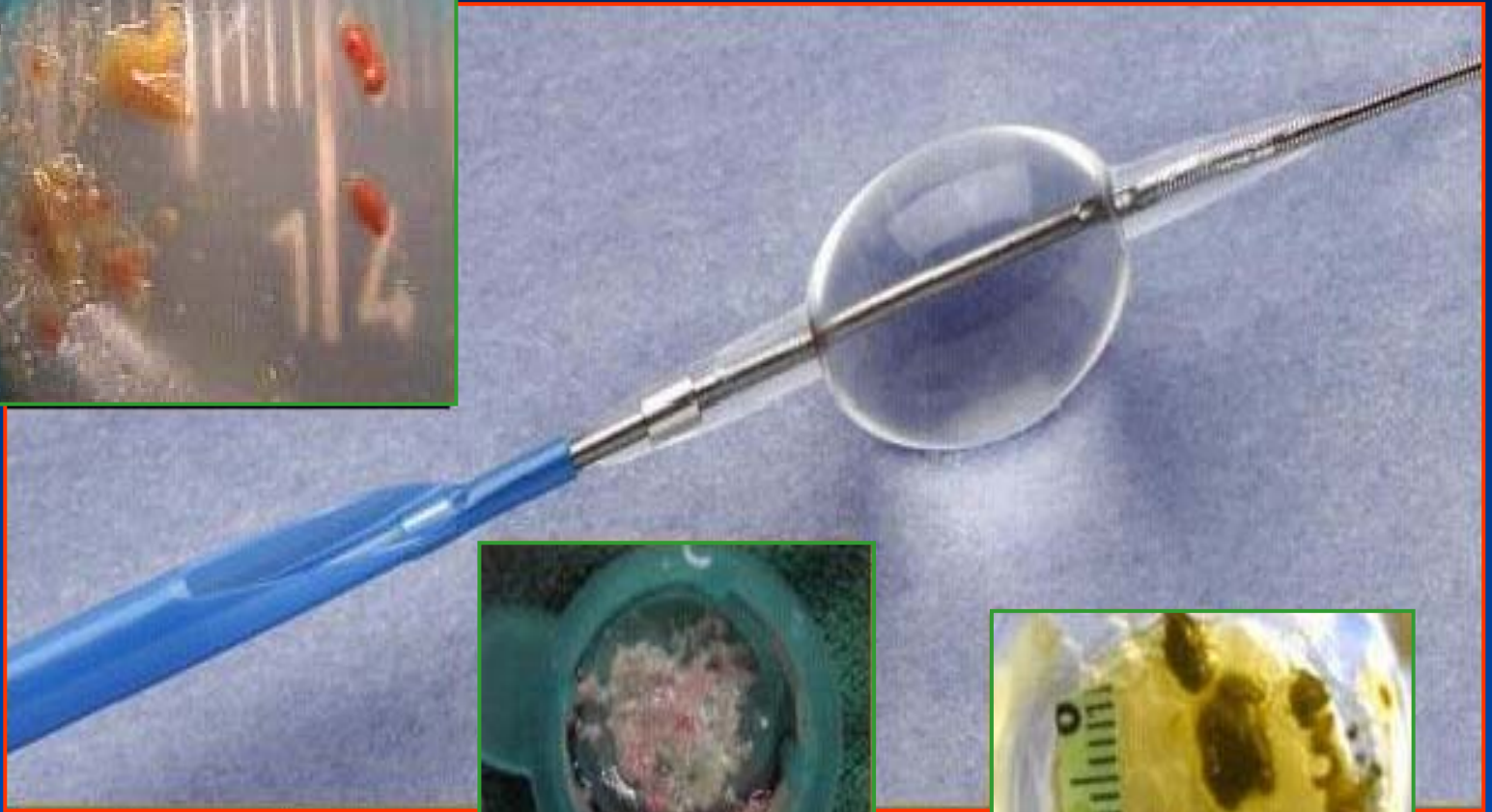


Filter Device

The Ideal Protection System

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

PercuSurge GUARDWIRE™



PercuSurge GUARDWIRE™

GuardWire™	PERCUSURGE, Inc
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System	0.014
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Crossing Profile	0.036”(3-6mm), 0.028”(2-5mm)
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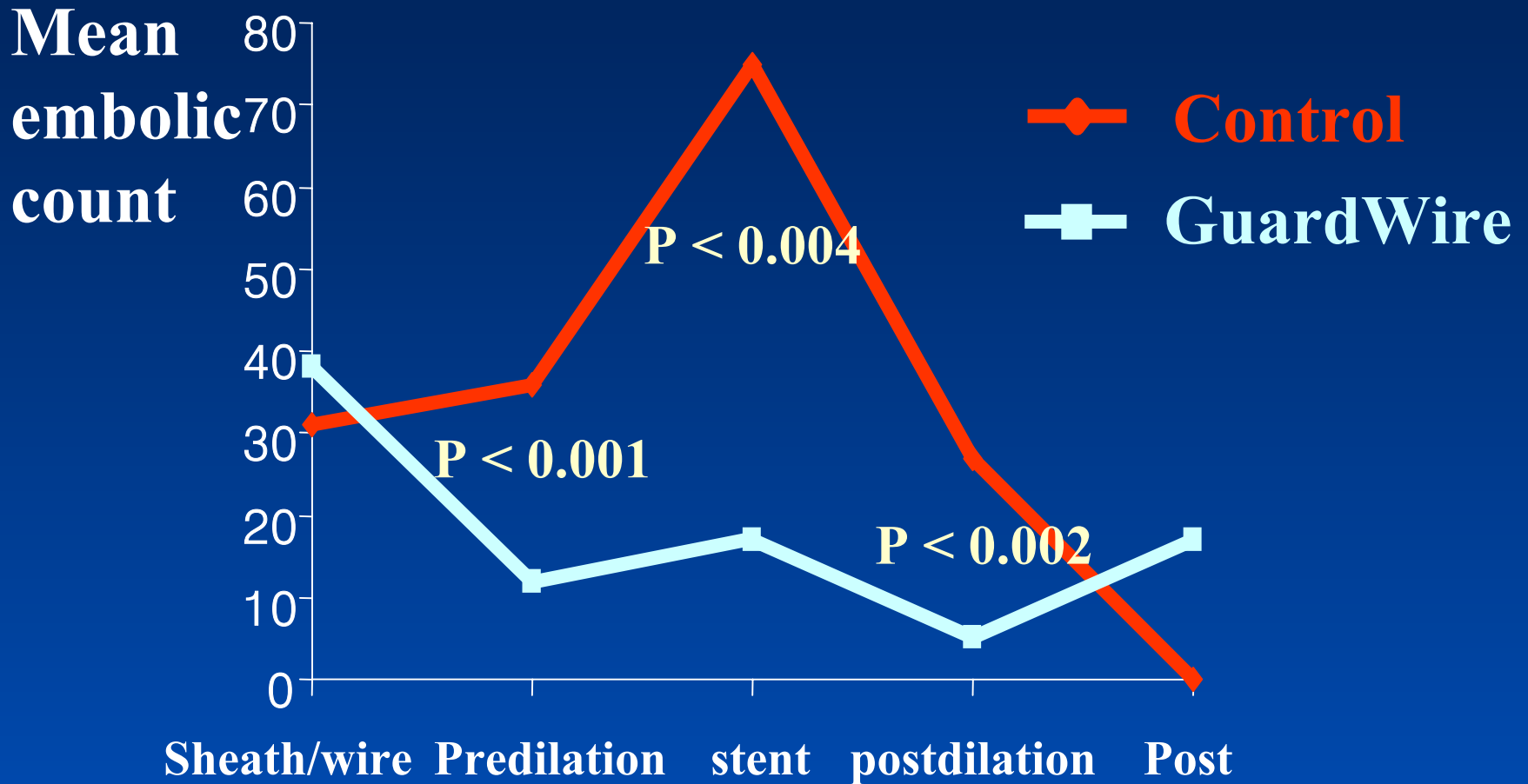
The Export® Aspiration Catheter	PERCUSURGE, Inc
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Total Length	137 cm
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RX shaft design	3.5 x 4.5F distal OD
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Aspiration system	20cc locking syringe
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PercuSurge GUARDWIRE™



Al-Mubarak et al, Circulation, 2001

Protection with Percusurge GuardWire system

- 242 patients with PercuSurge (179, 74% high risk)
- 99.3% Technical Success
- Overall mean balloon protection time = 410 ± 220 sec
- 30 days outcome (2.3%)
 - 3 TIA, 1 retinal embolism 1.5 % (4)
 - Major Stroke 0.4 % (1)
 - Death(cardiac) 0.4 % (1)
 - Total events 2.3 % (6)
- 36-month event-free survival (stroke, death) : 97%
4 death(2 AMI, 1 contralateral stroke, 1 cancer)

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)

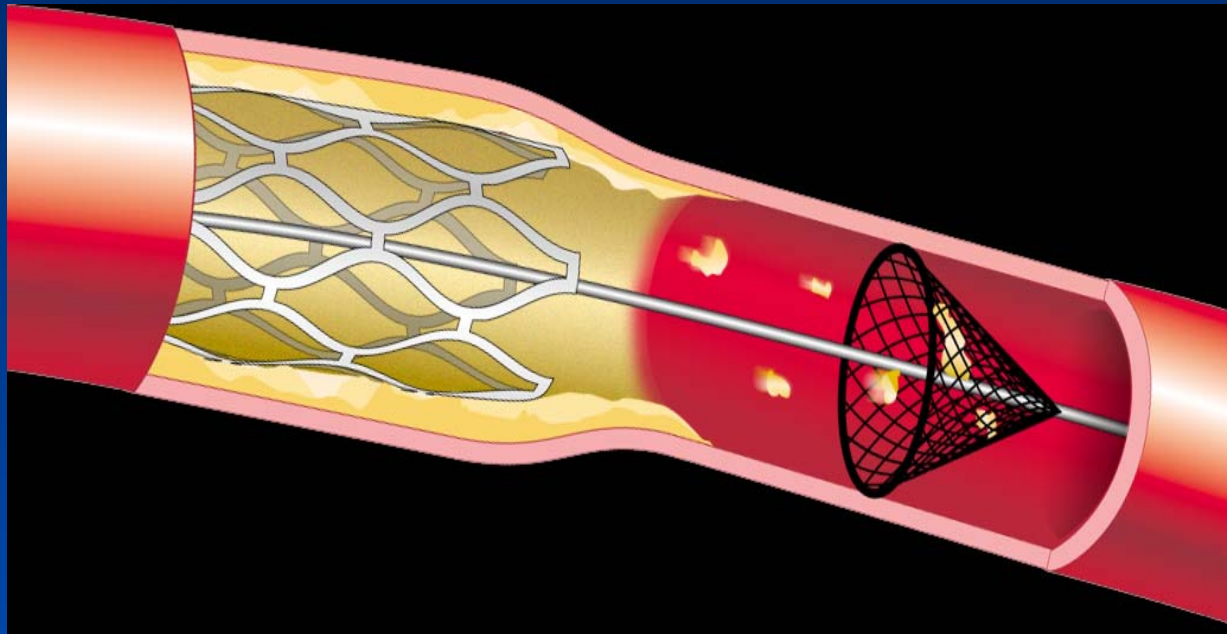
Distal Occlusion balloon

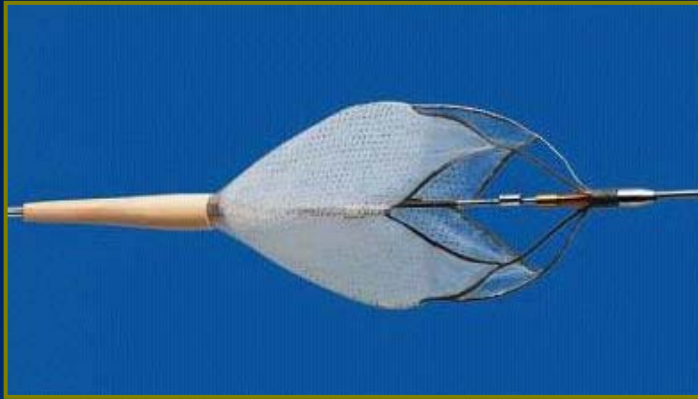
Weakness

- 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)

Distal Protection Devices

Filter

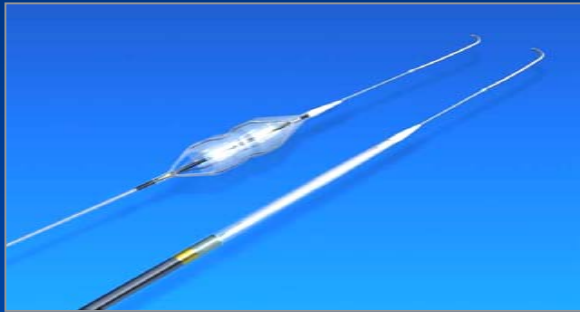




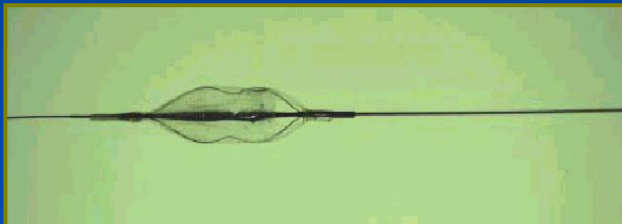
Guidant - ACCUNET



BSC - EPI



MedNova - Emboshield



MedNova – Gen III

Filter Device

Strength

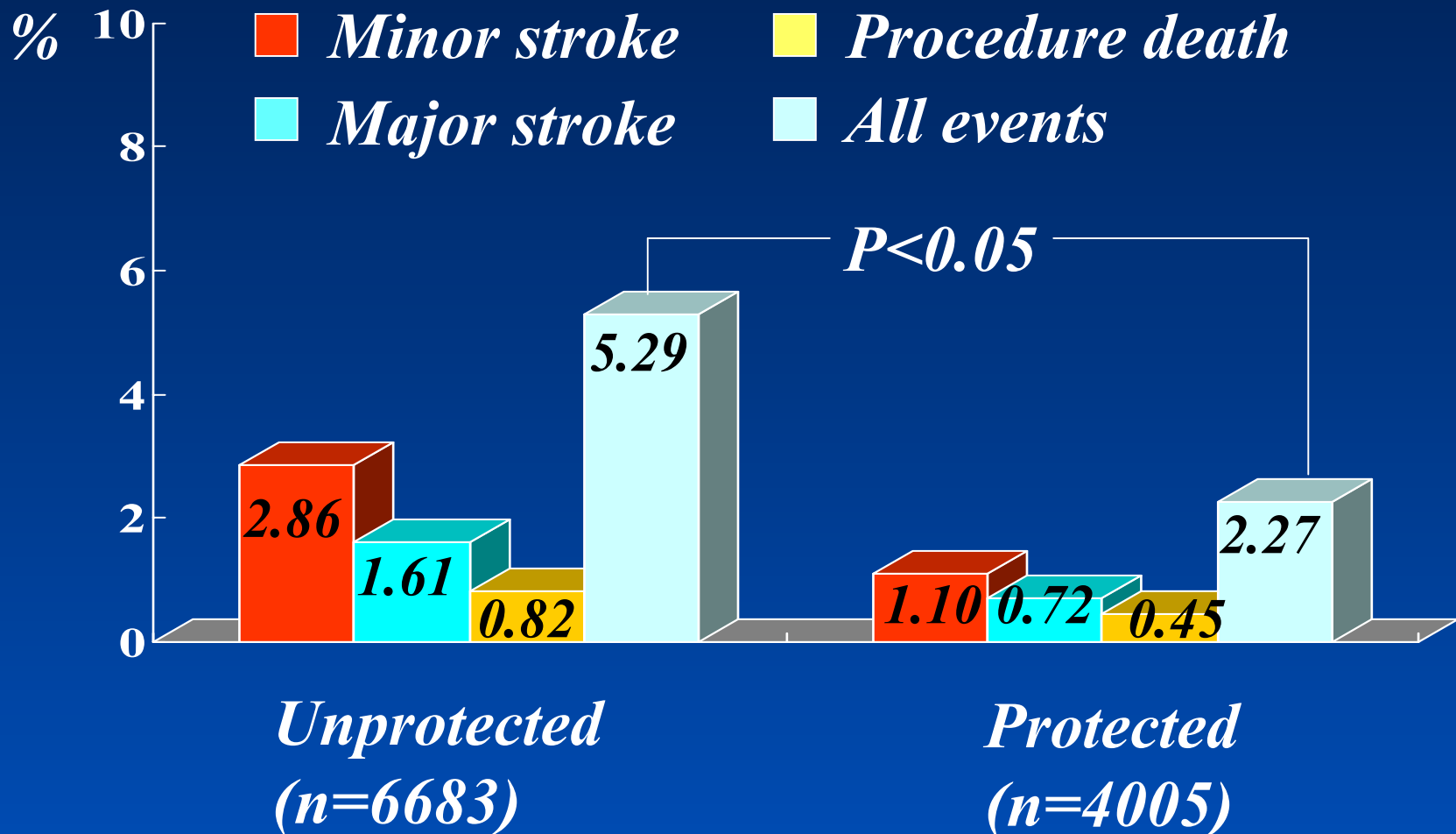
- Intuitive
- Preserves ICA flow

Filter Device

Weakness

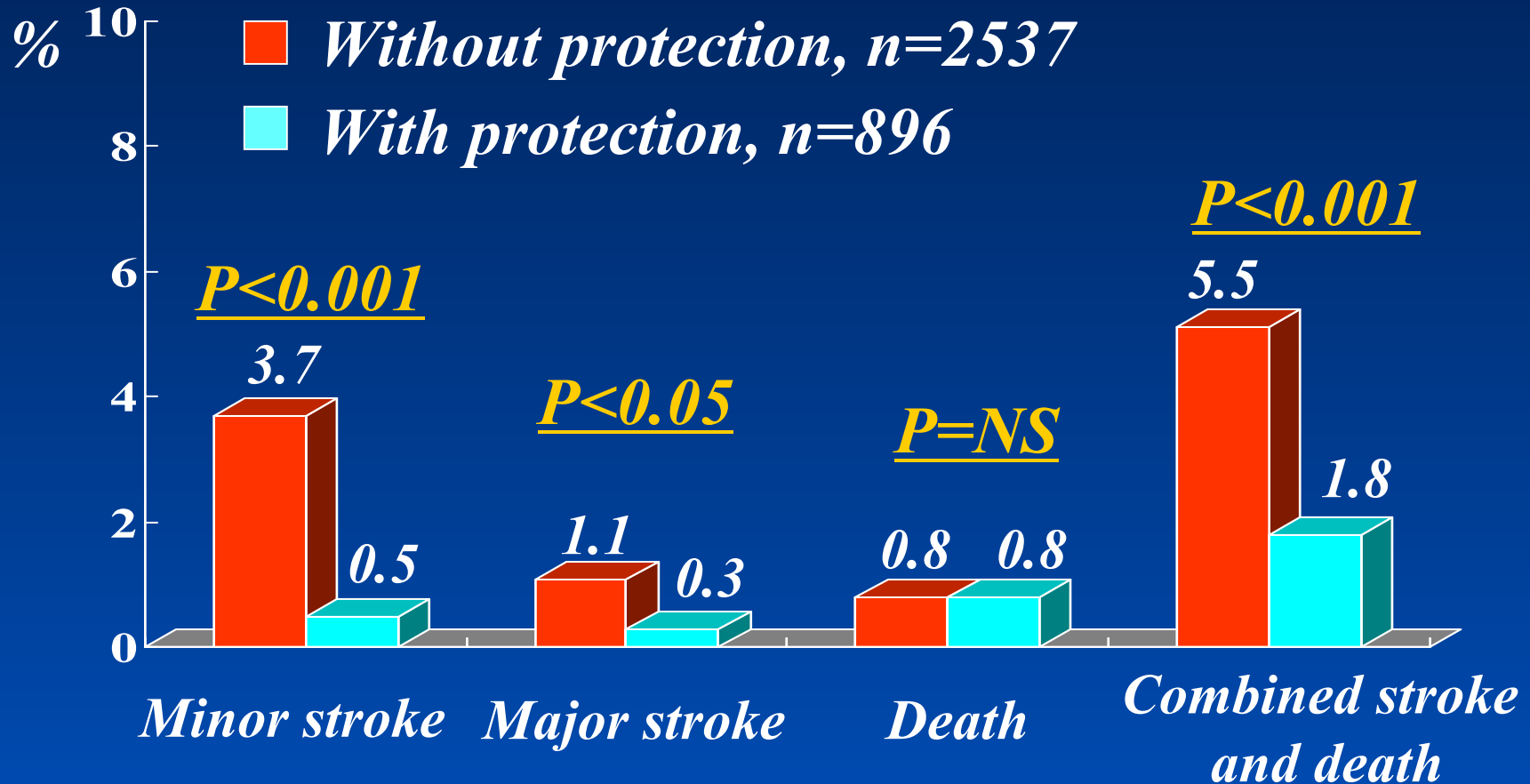
- Not same as standard guidewire
- Larger profile, less flexible
- Frequent need to predilate (recross PTA site)
- Unprotected
 - 1) during passage
 - 2) small particles
 - 3) flow around filter
 - 4) during filter retrieval
- May thrombose
- May cause spasm/dissection in distal ICA
- Cumbersome procedure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

Periprocedural Outcomes with Protection Device



AET 2003

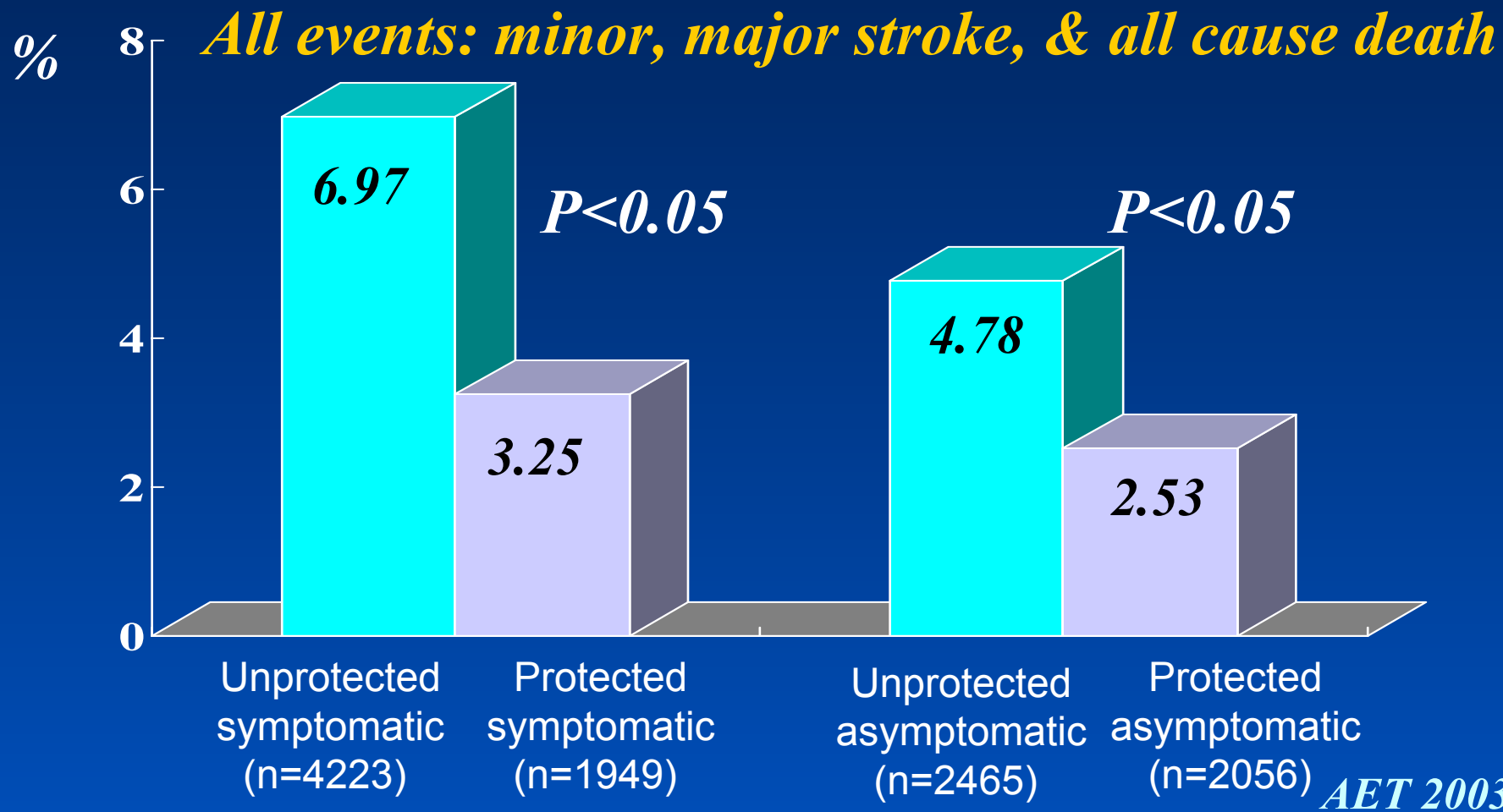
30-Day Outcomes with Protection Device



Stroke 2003;34:813-819

Periprocedural Outcomes

Symptomatic & Asymptomatic



AET 2003

Predictors of stroke

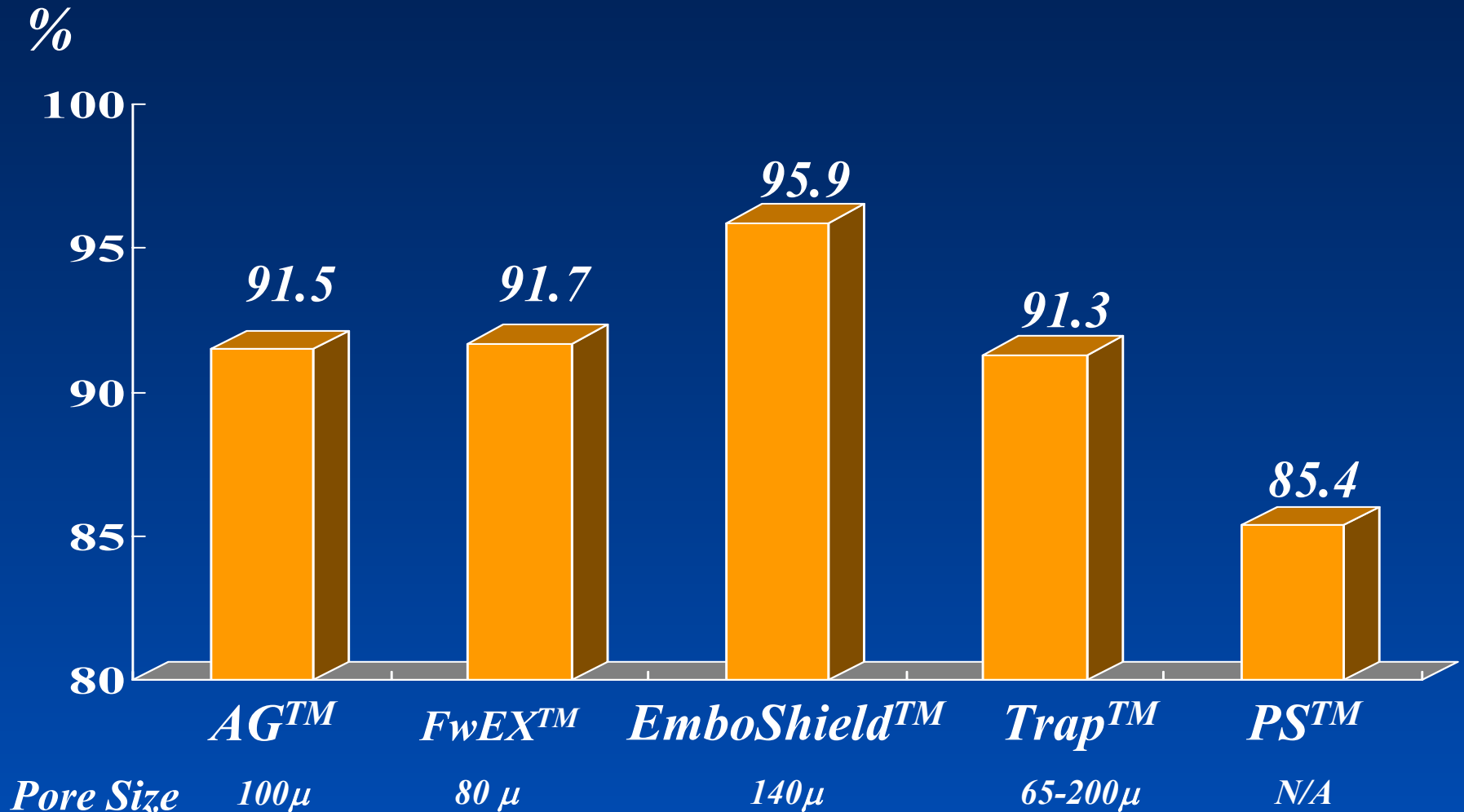
Multivariate analysis

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

AET 2003

Comparison of Devices Efficiency

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%

AET 2003

Comparisons Between Filter Devices *30 days Outcomes*

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

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%*

Lancet 2001;357:1729-37

The SAPPHIRE Study

Senting *with filter device*

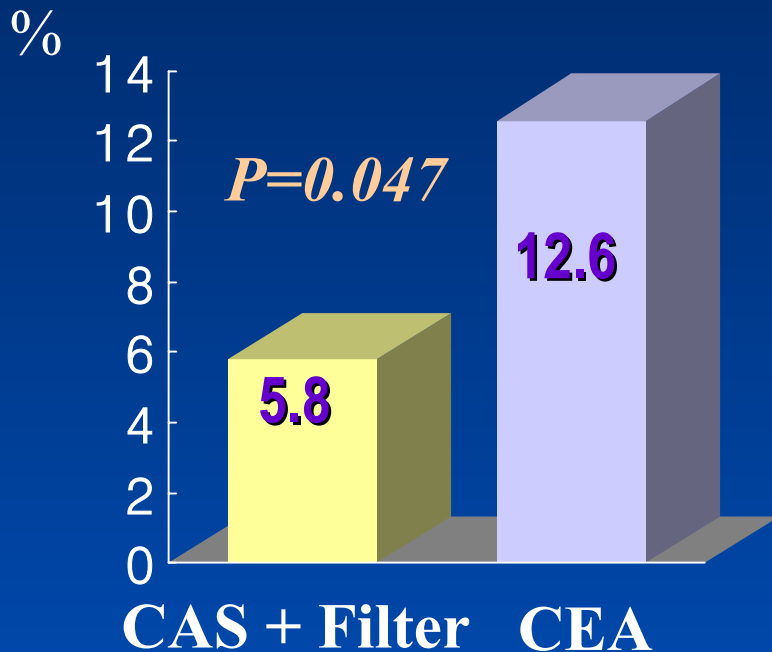
vs. Endarterectomy

in high risk patients

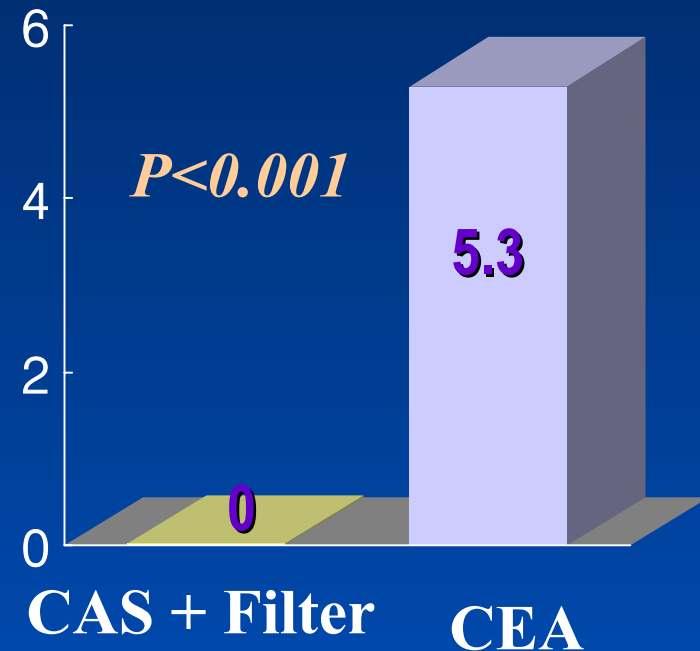
30-Day Events

SAPPHIRE

Death/MI/Stroke



Cranial n. palsy



Patient selection of carotid stenting

Only high surgical risk patients

Vs.

All patients

High Risk Surgical Criteria

Should be the stenting !

Anatomic high risk

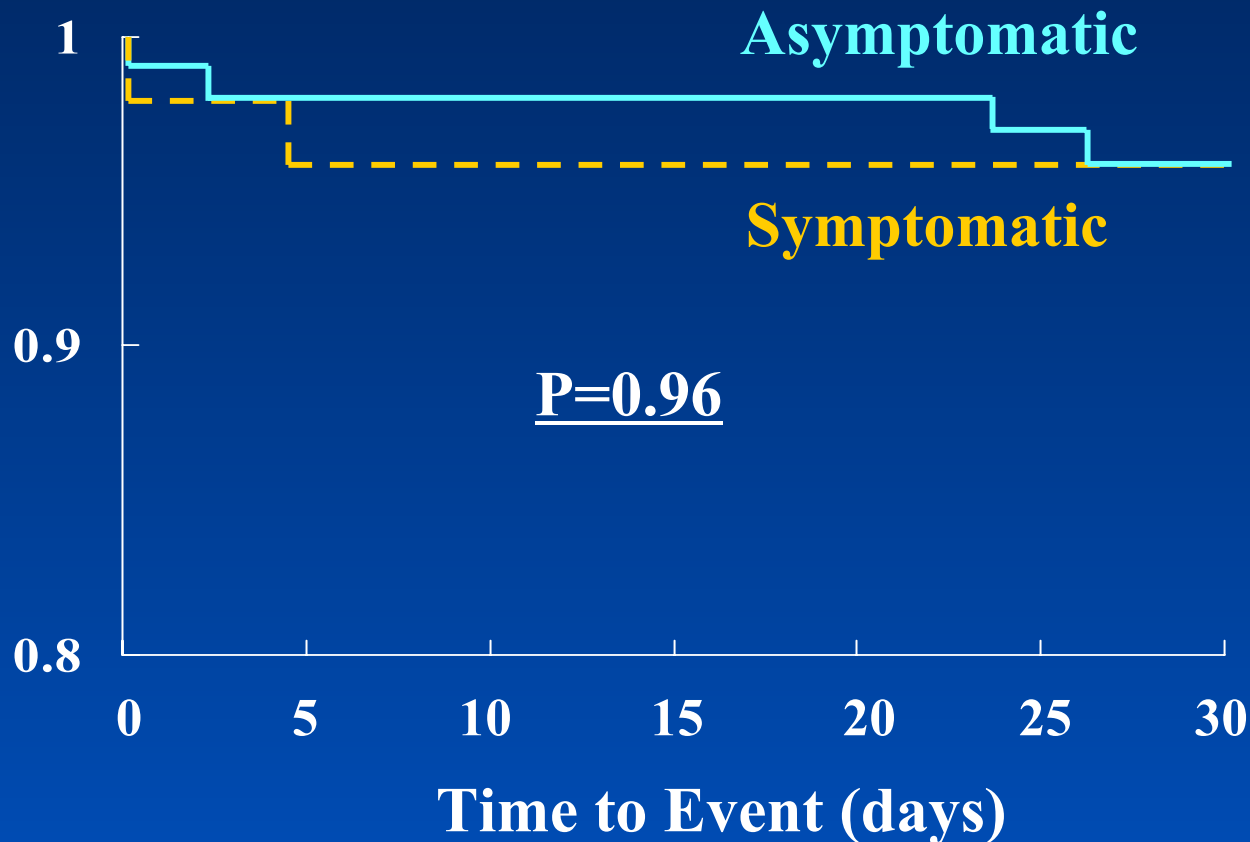
- High(C2) carotid bifurcation
- Prior neck irradiation or radical neck dissection
- Restenosis following prior CEA
- Contralateral occlusion
- Ostial common carotid lesion
- Spine immobility

Surgical high risk

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

30 days Outcomes of CAS with protection

Symptomatic vs. Asymptomatic



ACC 2004

30 days outcomes of CAS with protection

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

Now. 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.