

Carotid Artery Stenting In high risk patients

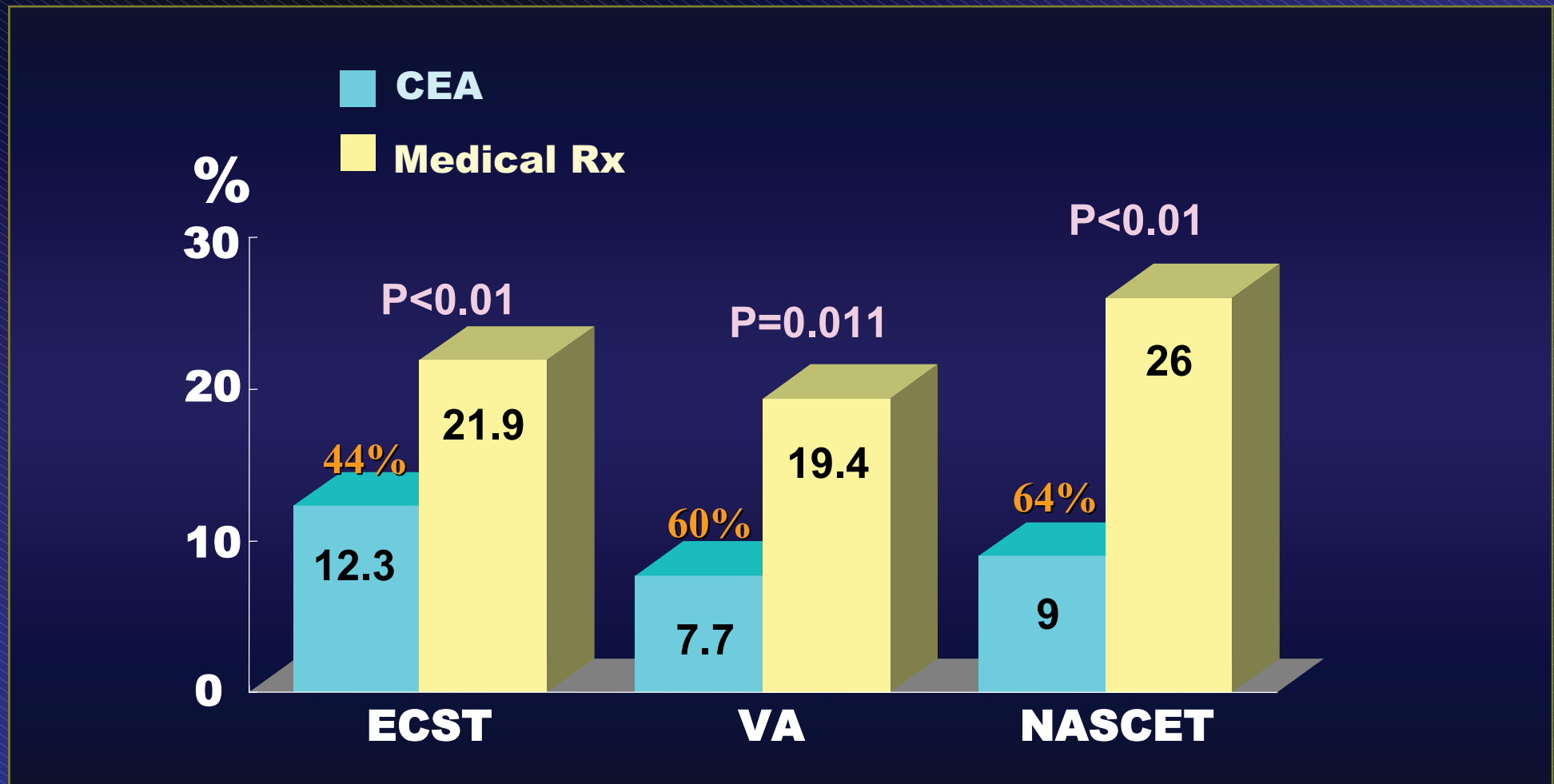
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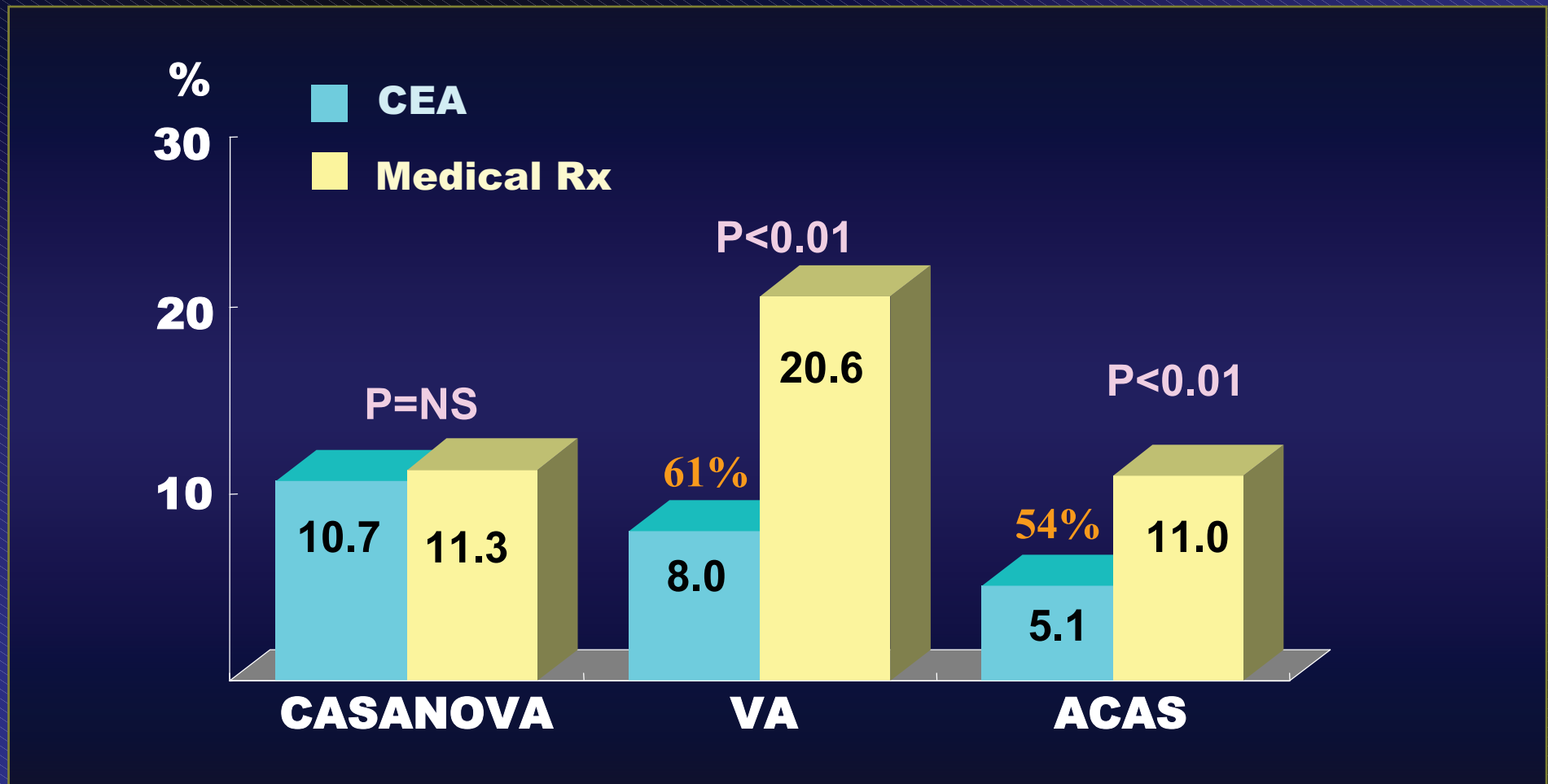
Surgery vs. Medical Management

Primary Endpoint: Symptomatic Patients



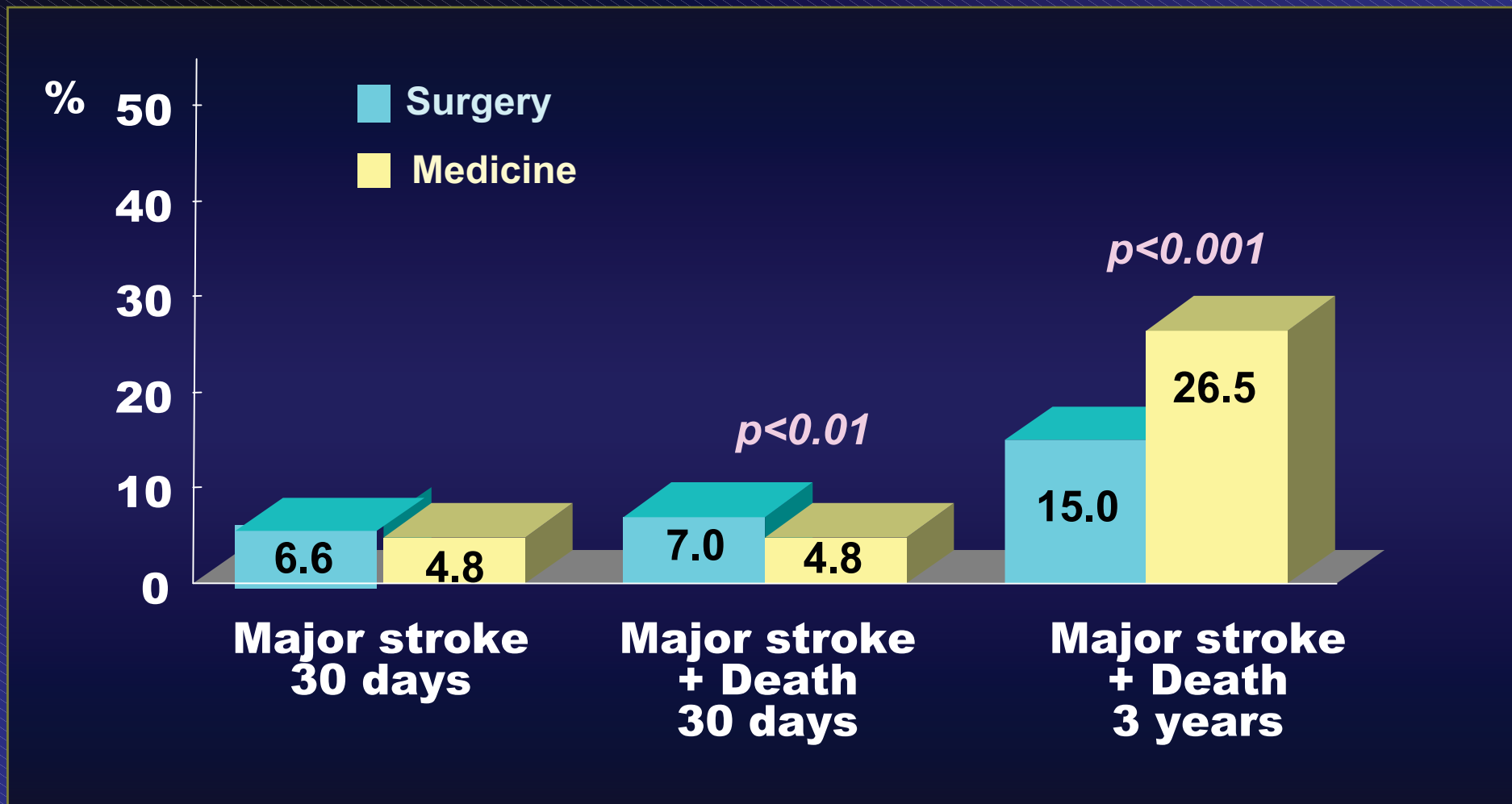
Surgery vs. Medical Management

Primary Endpoint: Asymptomatic Patients



Surgery vs. Medical Management

European Carotid Surgery Trial (n=3024)



Lancet 1998;351:1379-87

Limitations of CEA

- Despite years of experience, national 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

High Anatomical Risk for CEA

- Contralateral occlusion
- High lesion / bifurcations
- Low or ostial common carotid lesions
- Neck radiation
- Prior radical neck dissection
- Prior carotid endarterectomy
- Short obese necks
- Spinal immobility due to congenital/acquired conditions
- Additional stenosis involving the ipsilateral Siphon

Carotid Stenting

Potential Benefits

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

Carotid Stenting

Contraindications

- 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

Success & Complications

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%	4.21%	0.8%
Roubin (2001)	High risk	428	99%	4.6%	0.2%

* Major stroke < 1%

Carotid Stenting

Complication Rate

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 in High Risk Patients

Unfavorable CEA subsets

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

Carotid Stenting

In High Risk Patients

- **Ineligible for CEA trials
or referred by surgeons (n=170 pts)**

Age, yrs	73 ± 8
Success rate	99 %
30-day stroke rate	2.9 %
19 months FU	
Restenosis	2 %
Stroke	0

Is Carotid Stenting Durable?

Long-term Follow-up

6% Restenosis Rate

CAVATAS

Multicenter Randomized Trials: CEA vs. Endovascular treatment

	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 = 26%

Lancet 2001;357:1729-37

Carotid Artery Stenting

The Most serious of Complications Is

**Cerebral
Embolization !!**

Cerebral Embolization

Highest Risk

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

Avoiding 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 Device Protection

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

Guardwire®



PercuSurge

Distal Occlusion balloon

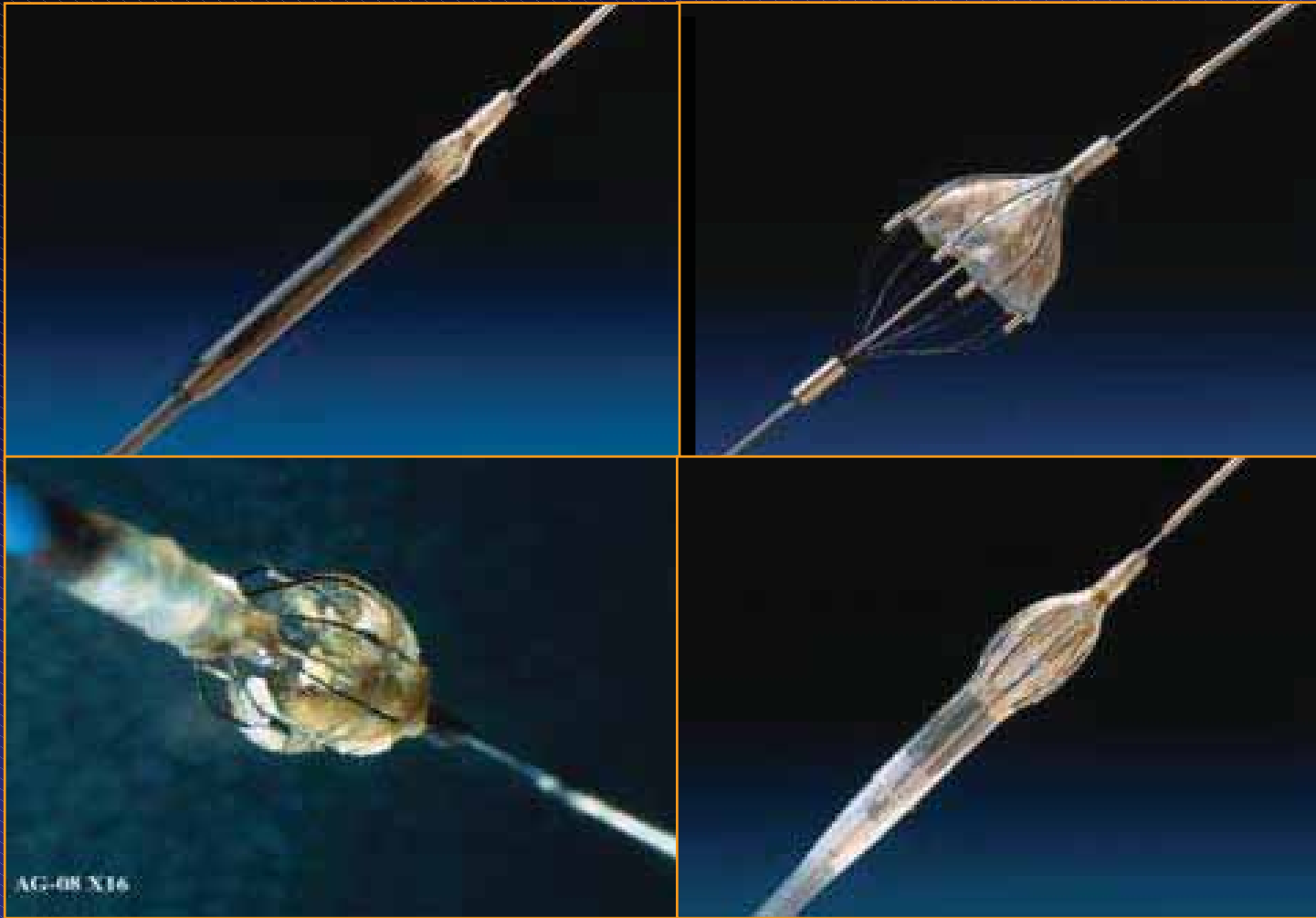
Strength

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

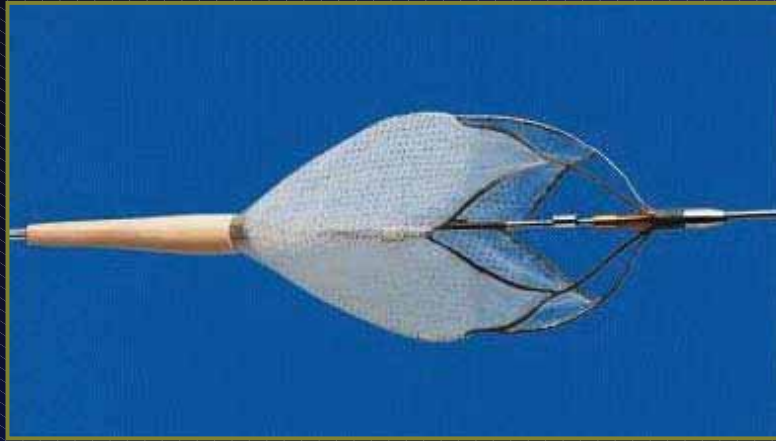
Weakness

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

Angioguard®



MedTronics



Guidant - ACCUNET



BSC - EPI



MedNova - Neuroshield



MedNova - Gen III

Distal Filter

Strength

- Intuitive
- Preserves ICA flow

Weakness

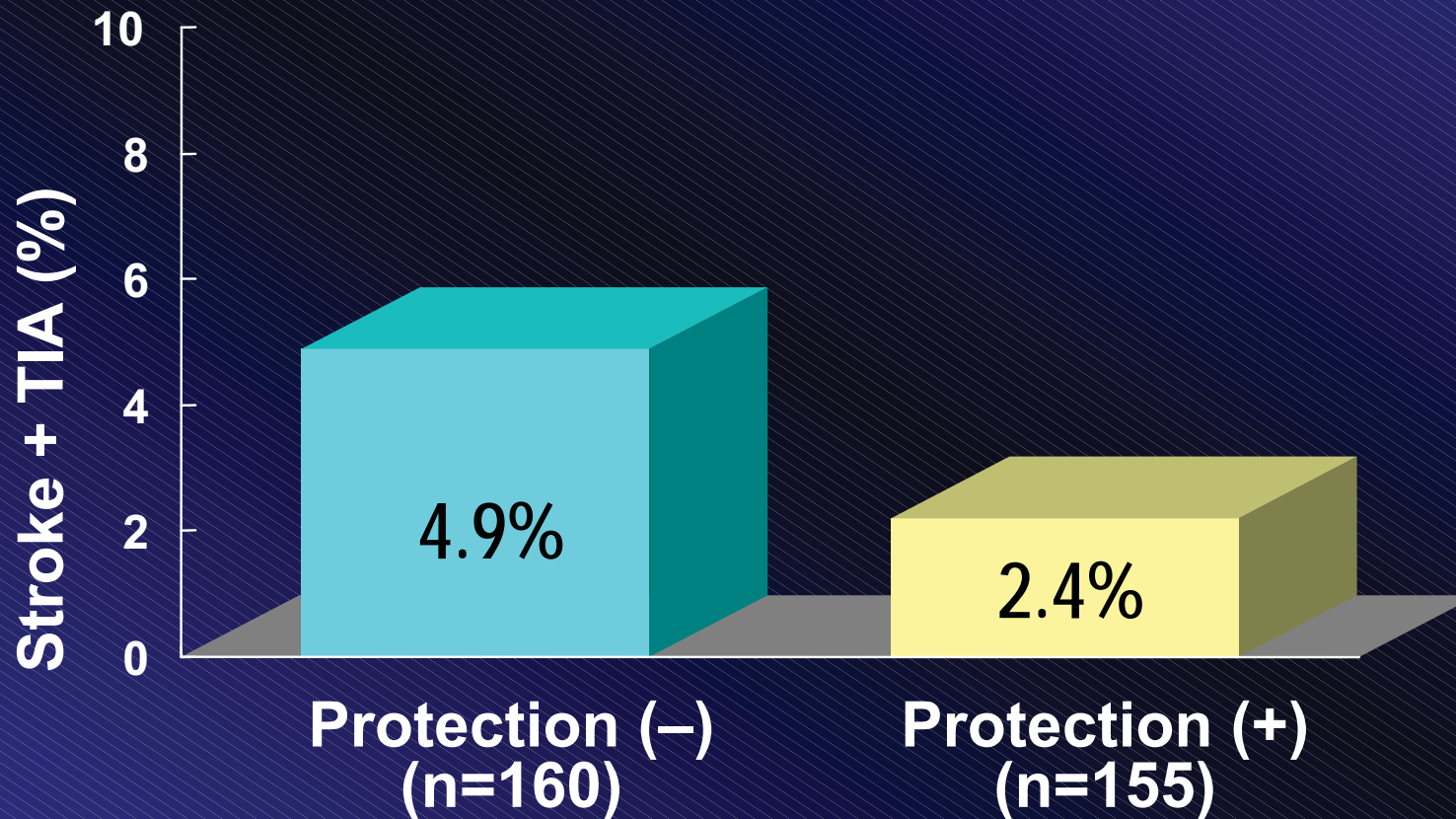
- Not same as standare guidewire
- Larger profile, less flexible
- Frequent need to predilate (recross PTA site)
- Unprotected 1) during passage, 2) small particles, 3) flow around filter, 4) during filter retrieval
- May thrombose
- May cause spasm/dissection in distal ICA
- Cumbersome procedure (cannot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

The Ideal Protection System

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

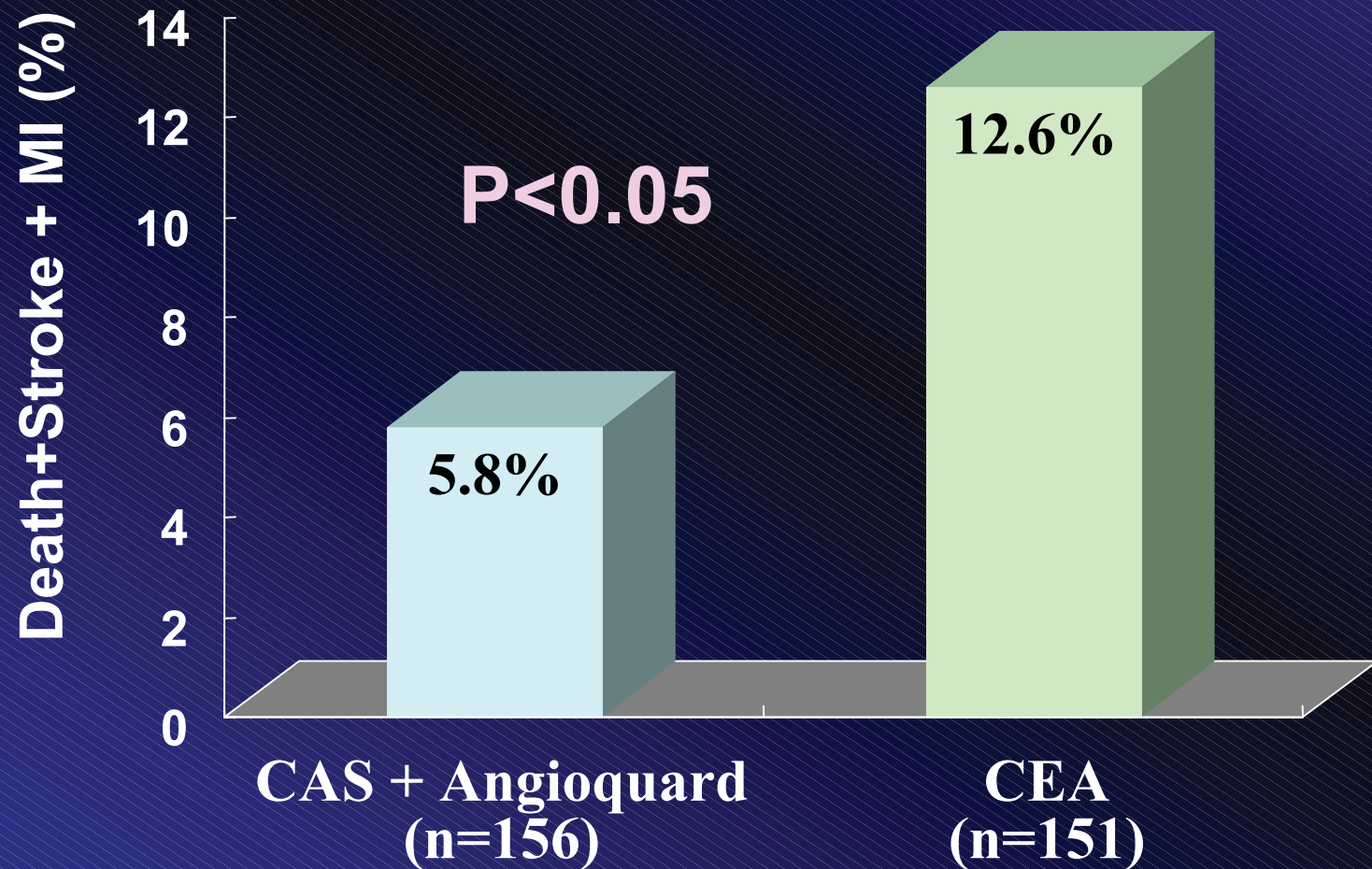
Effect of Protection Device

* Protection devices: Angioguard & PercuSurge



SAPPHIRE-multicenter randomized

CAS+Angioguard vs. CEA, at 30 days



AHA 2002

Effect of Protection Device

* Protection devices: Angioguard, PercuSurge & EPI

	Cerebral Protection	
	No (n=102)	Yes (n=142)
TCD-HITS	100%	100.0%
DW-MRI	29%	7.1%
TIA	8%	2.7%
Stroke	3%	1.3%
TIA + Stroke	11%	4%