

Carotid Interventions: Accepted, Investigational, unethical, or Standard of Care?

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While the use of C-PTA has been used in extraordinary situations, the crucial interrogatory persistently been avoided

“ should C-PTA be limited to only extra-ordinary clinical situations”

or

“should C-PTA be utilized for symptomatic and asymptomatic patients with severe extracranial carotid bifurcation obstructive disease, who are reasonable surgical candidate?”



Crucial Factual Information

Wennberg's 30 day CEA risk of stroke+death among
113,300 Medicare Pts treated at 2699 non-federal
hospitals (1992-3)

86 Trial and 2613 Non-trial institutions

Conclusions:

Trials hospitals had the best results, *but* Procedural
volume directly impacted perioperative mortality.



Goldstein: assessed the impact of potential perioperative risk factors on CEA.

A random sample of 1160 asymptomatic CEA patients had their charts abstracted re: perioperative complications.



The perioperative stroke and death rate was 2.8%:
with a similar risk for PTS with cerebrovascular
symptoms (1.8% vs. 4.2%; $p=0.21$).

However, the postoperative stroke and death rate:

>3X higher in women (5.3% vs. 1.6%; $p=0.02$)

>4X higher in PTS (7.8% vs. 1.8%; $p=0.01$)

4X higher in PTS with CHF (8.6% vs. 2.3%; $p=0.03$)

9X higher in PTS who had undergone

CEA +CABG (18.7% vs.2.1%; $p<0.001$).



Carotid Stenting Results for symptomatic patients





Roubin and Iyer's non-randomized observational data:

528 consecutive patients,
604 hemispheres were treated

Underwent the procedure: mortality of 1.6%,
0.6% fatal stroke
1% non-stroke death rate @ 30 days.

Stroke: Major 1%
Minor 4.8%.

30-day stroke and death rate: 7.4%.

Over the 5-year study period, 30-day minor stroke rate improved

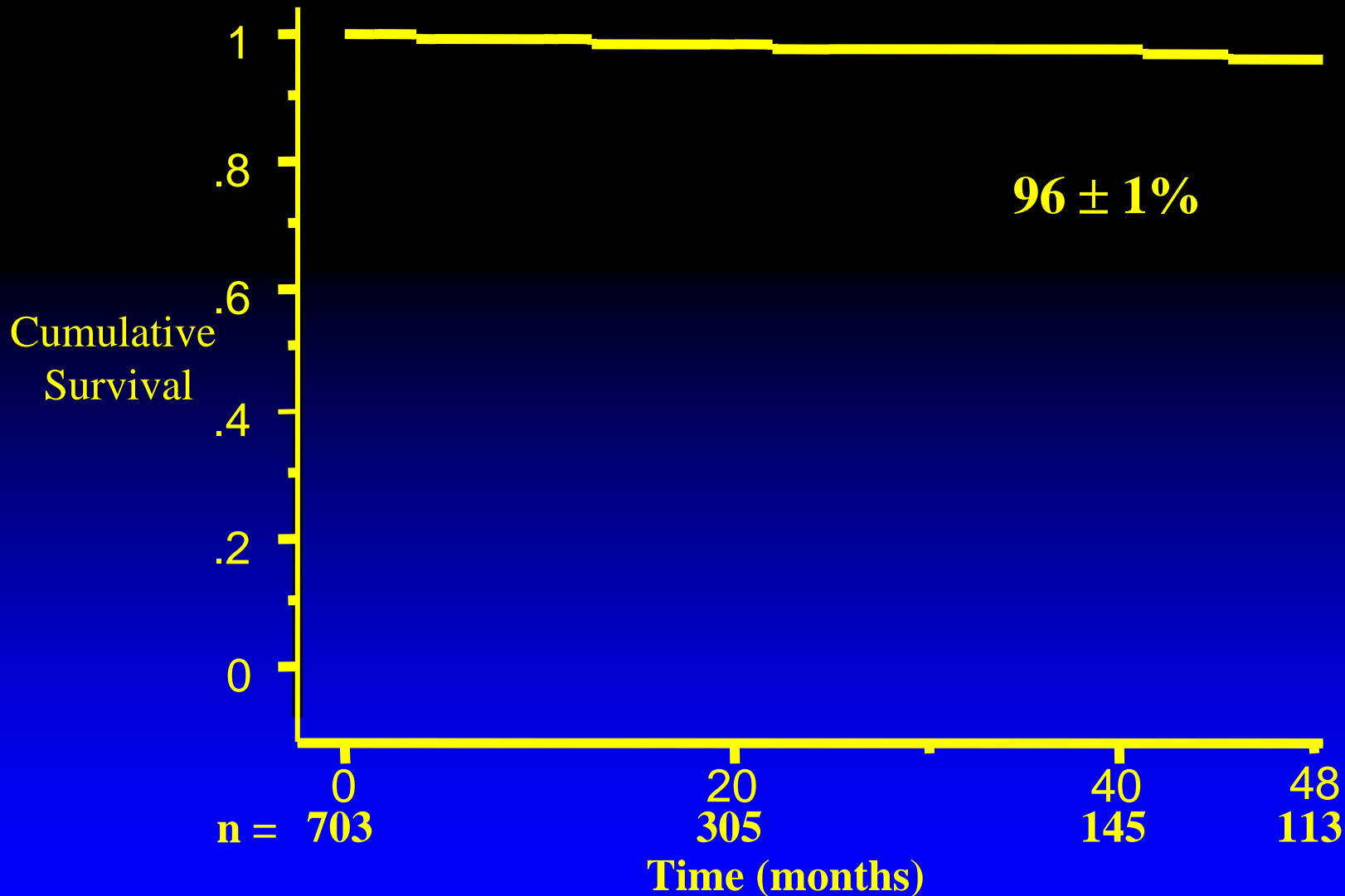
7.1% for the 1st year to
3.1% for the 5th year ($P < 0.05$).

After the 30-day period, the incidence of fatal and nonfatal stroke was 3.2%.

The 3-year freedom from ipsilateral or fatal stroke was $92 \pm 1\%$.



All Ipsilateral Strokes & Deaths > 30 Days



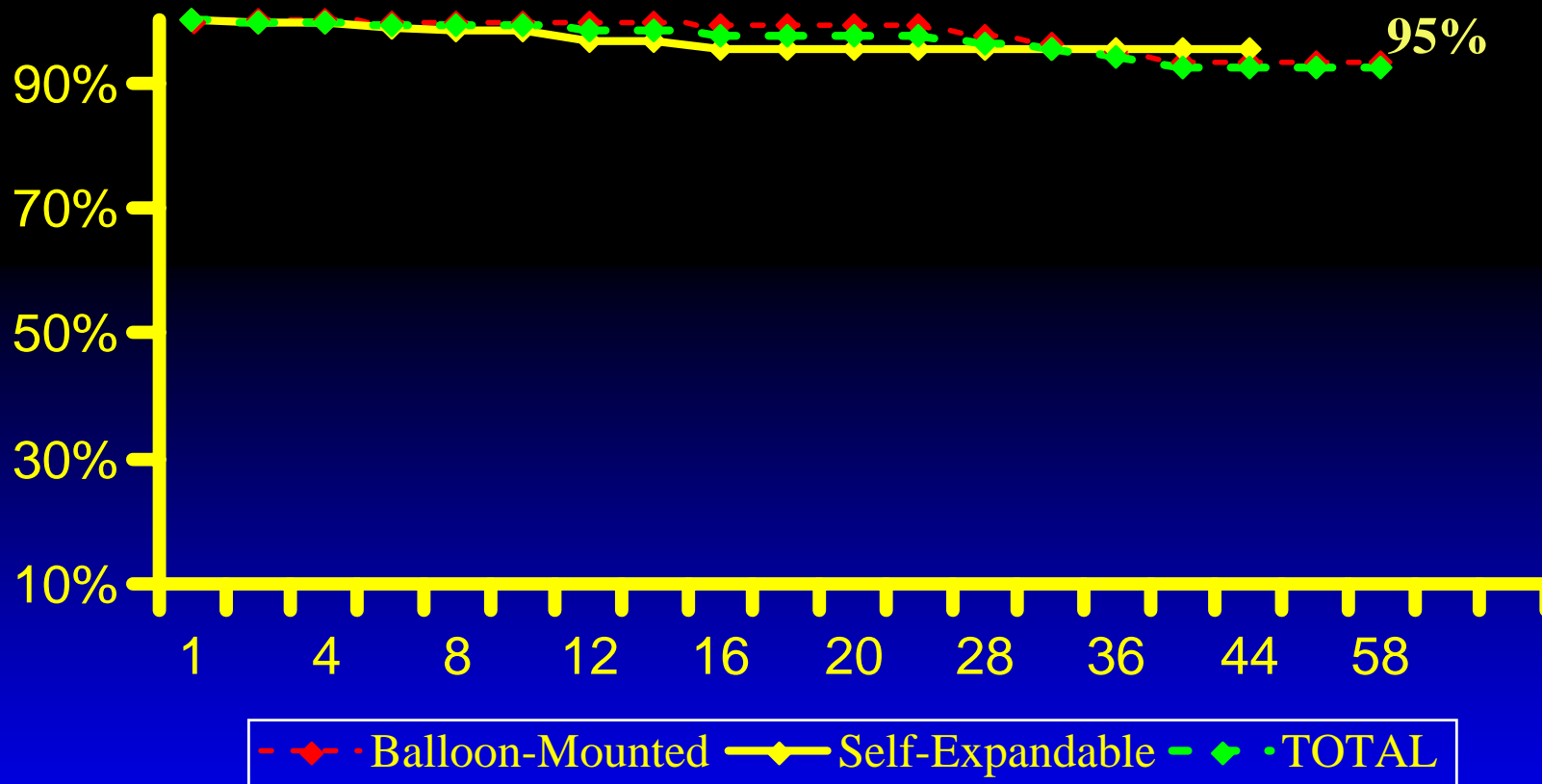
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Circ 2001; 103: 532-537



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Stroke and Neuro Death Free Rate (Wholey's data reproduces Roubin and Iyer's data)



464 patients = 94% F/U @ mean 21-mon (range: 0-5.6 yrs)

(Wholey in press)



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Roubin and Iyer's numerous and carefully monitored studies *all with independent neurologic assessment* never focused upon or included patient assessment of the aforementioned cognitive domains.

However, their meritorious studies included many patients excluded from the major surgical trials (NASCET, ACAS, ECST).



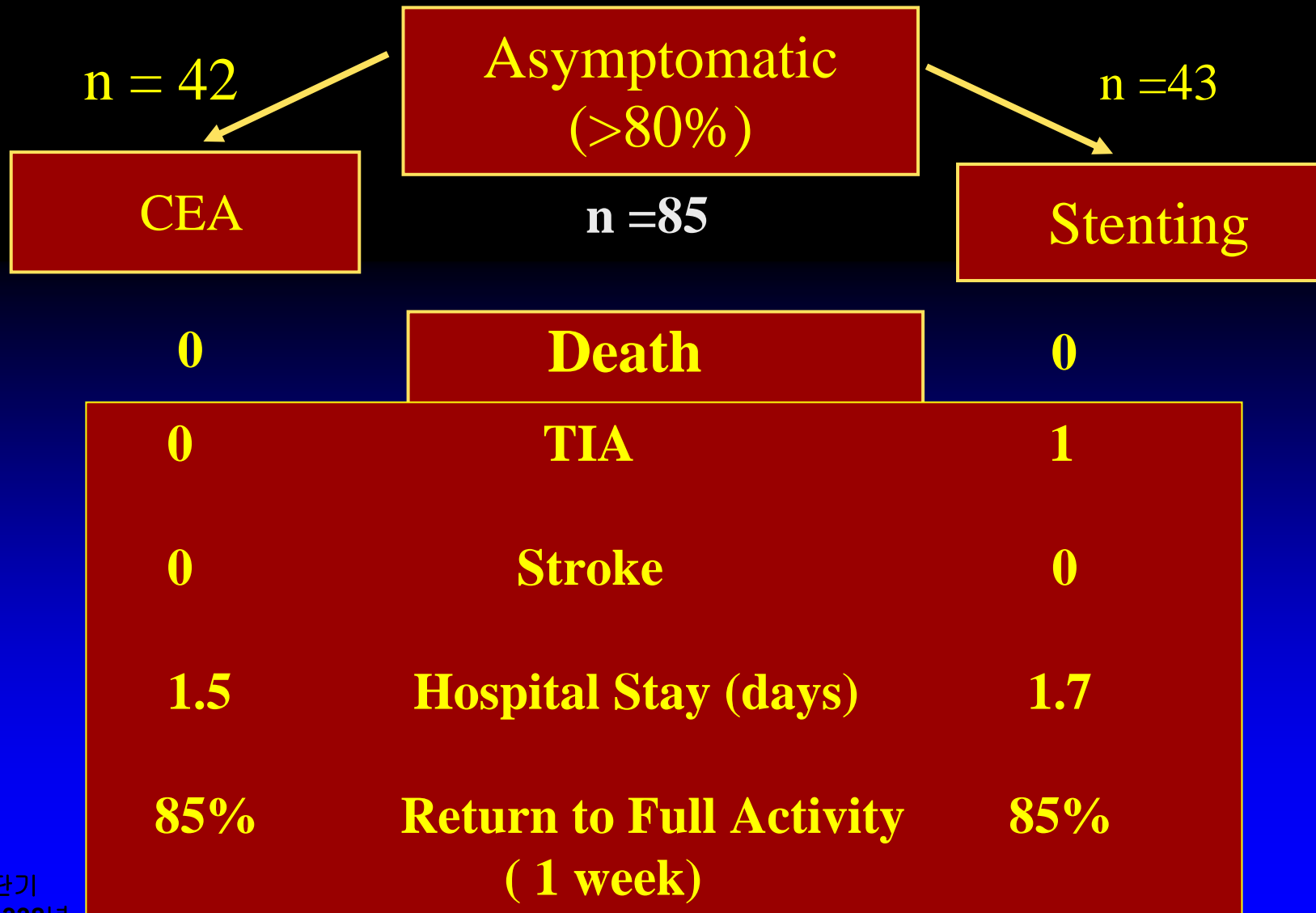
Despite the presence of a larger number of NASCET excluded patients, their data, *with regard to acute procedural outcome and freedom from subsequent neurological events,* were excellent and superior to that of CEA, especially considering their PTS.



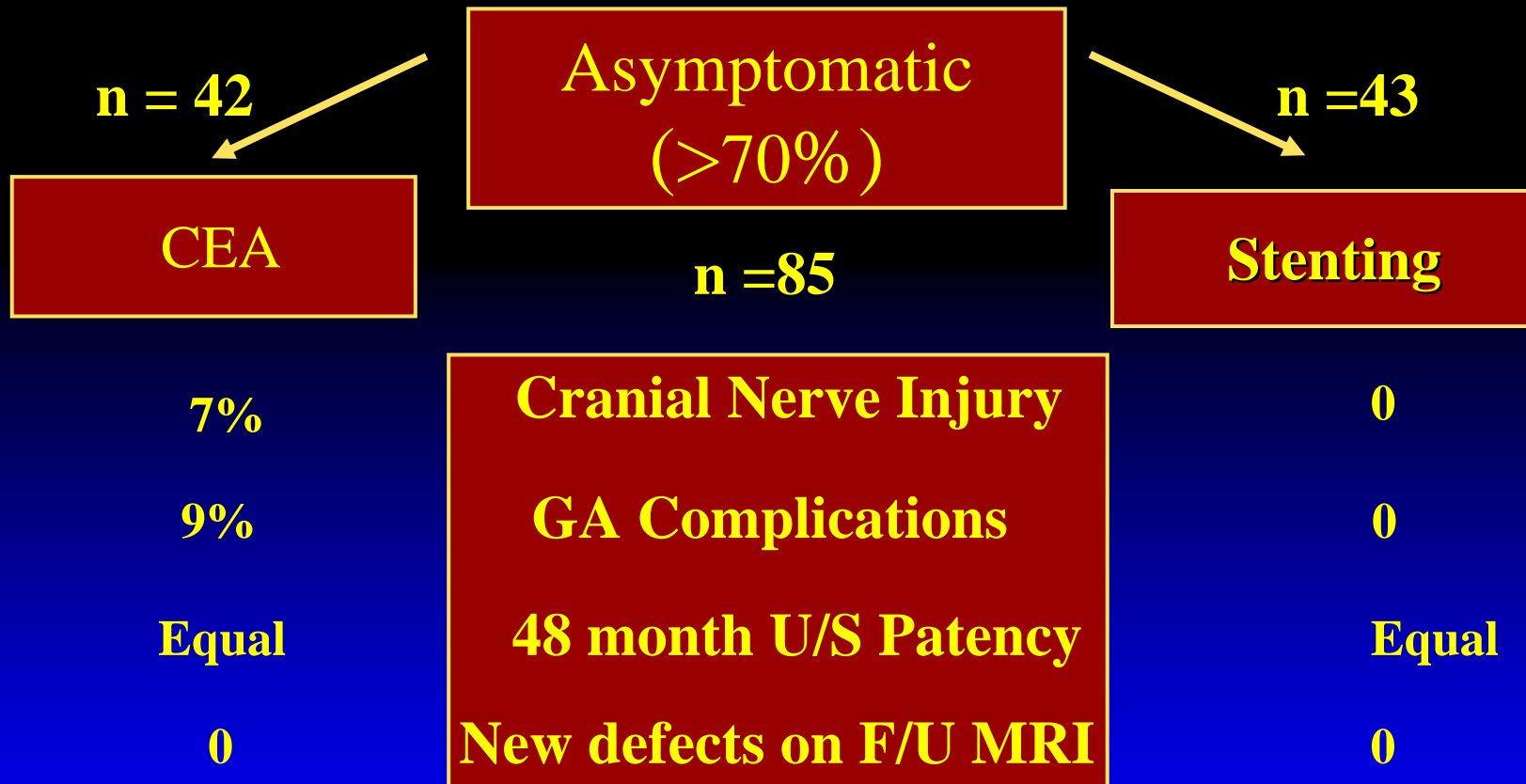
High Risk Carotid Stenting



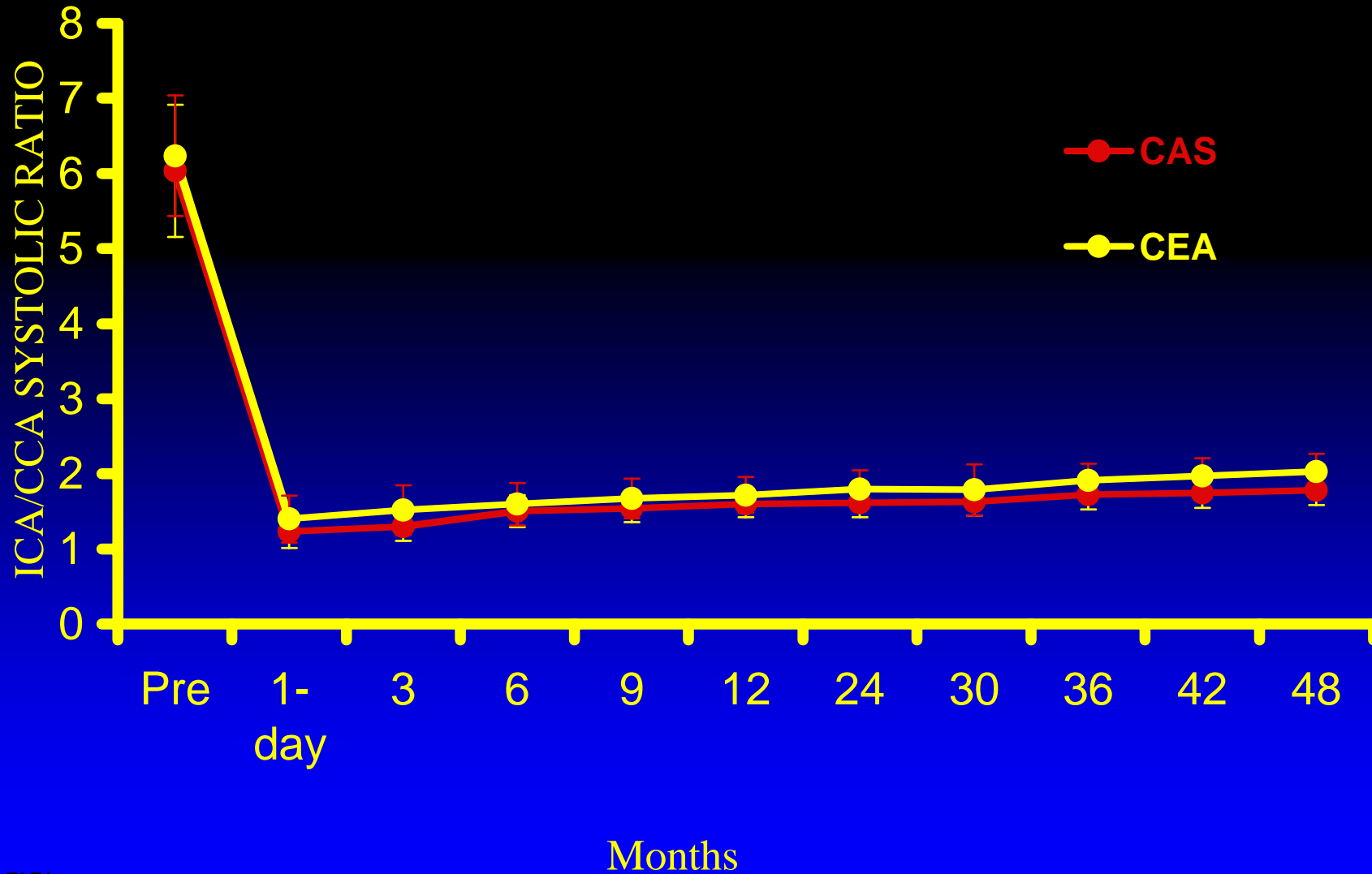
Brooks: Carotid Stenting vs. CEA



Brooks: Carotid Stenting vs. CEA



Brooks: Patency: Follow up Ultra Sound (48 mos.)



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CARESS (Carotid Revascularization Using Endarterectomy or Stenting Systems): Multi-Center Data (14 sites)

1. Between 2001-2002: 254 CEA and 143 CAS Pts
2. Treated; 68% Asymptomatic (>75%)

30-day	CEA (n=254)	CAS (n=143)
Death+Stroke	2%	2%
Death+Stroke+MI	3%	2%

3. Conclusions: equivalent results in broad risk population for CEA and CAS



CAS: routine cerebral protection in high-risk patients

68 Pts with 72 CAS with success in 70 cases (97%)

Devices: PercuSurge (28%), Filterwire (72%)

Results:

No periprocedural mortality or device complications

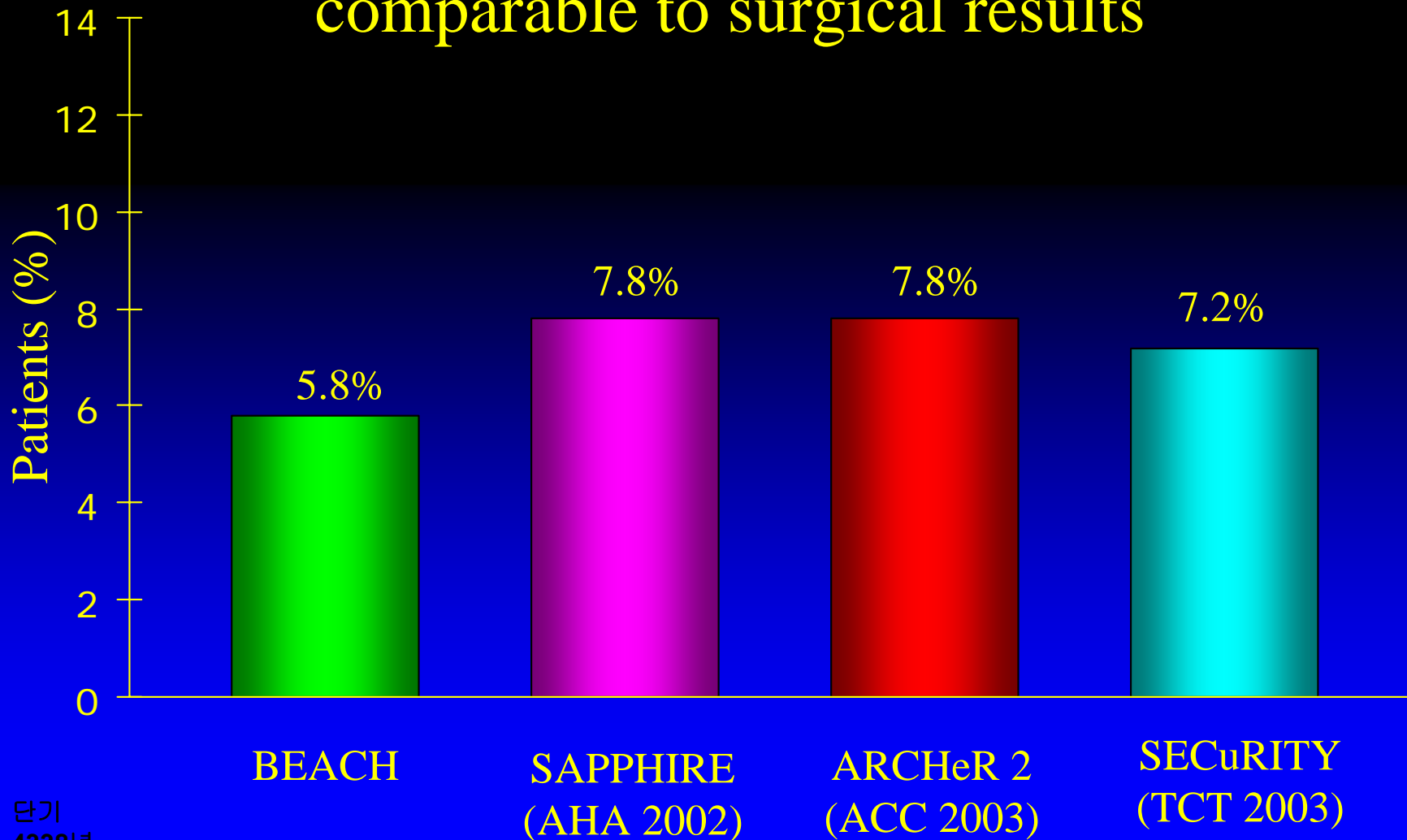
30-day stroke-death rate 2.7%,

Overall complications 6.9%

2 symptomatic restenosis at 6 and 8 mos.
successfully re-intervened



30-Day Composite Endpoint in High Risk Carotid Stenting Trials: clearly comparable to surgical results



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Carotid Stent with Neuroprotection



Carotid Stent with Neuroprotection IDE

(Drs. Roubin and Iyer)

June 2003-Jan 2005

No of Patients:	189
Vessels Treated:	199
Age Range (yrs):	39-92
Mean Age (yrs):	72.3 ± 9.9
≥80 years:	42 (22%)
Females:	78 (41%)

All Patients were seen before and within 24 hours post procedure by a neurologist



Primary Safety End-Points (30 Days): All Pts



6/03-1/05	N=189(199)
Death	0
Major Stroke	2 (1.0%)
Retinal Infarction	1 (0.5%)
Minor Stroke	3 (1.5%)
Death/Stroke/MI	6/199(3.0%)

One Year Follow-up

84 Patients Eligible for follow up

No new strokes or other neurological events at 1-yr

Four deaths - none neurological related



(CAS + protection) vs. CEA

(1997-2001): Pts > 75yrs: 53 CAS vs. CEA

1. Symptomatic : 57% vs. 63%
2. 30-day CVA: 11.3% vs. 1.8%; $p < 0.05$;
but 4 vs. 0 minor CVAs
3. 30-day major CVA: 3.8 vs. 1.8%; ns



CAS with cerebral protection

100 consecutive Pts with 104 lesions, performed by cardiologists

Results: success 99% (103) with cerebral protection applied in 102 (98%)

30-day stroke +death: 4%

1 major stroke, 2 minor strokes, 1 fatal MI

Cernetti Ital Heart J 2003; 4: 695-700



CAS with protection devices (EPI filter and TRAP)

96 Pts with 100 lesions (EPI/TRAP: 67%/28%; with 5% unable to have filter pass)

CAS successful in 95% cases with 86% using primary stenting

Results: 8% homolateral CNS events: 2 major, 1 minor, and 5 TIAs; 4% major complications: 2 major CVAs, 1 MI, 1 lesion of median n.

Conclusions: filter protection works, and EPI easier to use than TRAP



Carotid Artery Stenting in Asymptomatic Patients



CEA for Asymptomatic Carotid Stenosis

Asymptomatic Carotid Surgery Trial (ACST)

Largest prospective CEA study in Asymptomatic Pts

3120 pts, >60% stenosis on U/S

Randomized to immediate (1 mo-1year) or indefinite deferral (4%)

5 year stroke risk (fatal/disabling stroke)

Med Rx: 11.8% (6.1%)

CEA: 6.4% (3.5%)



CEA for Asymptomatic Carotid Stenosis

Periprocedural/30 day stroke and mortality

ACST: 3.1% (50% fatal)

ACAS: 2.3% (0.1% mortality)

Both ACAS and ACST enrolled >60% stenosis

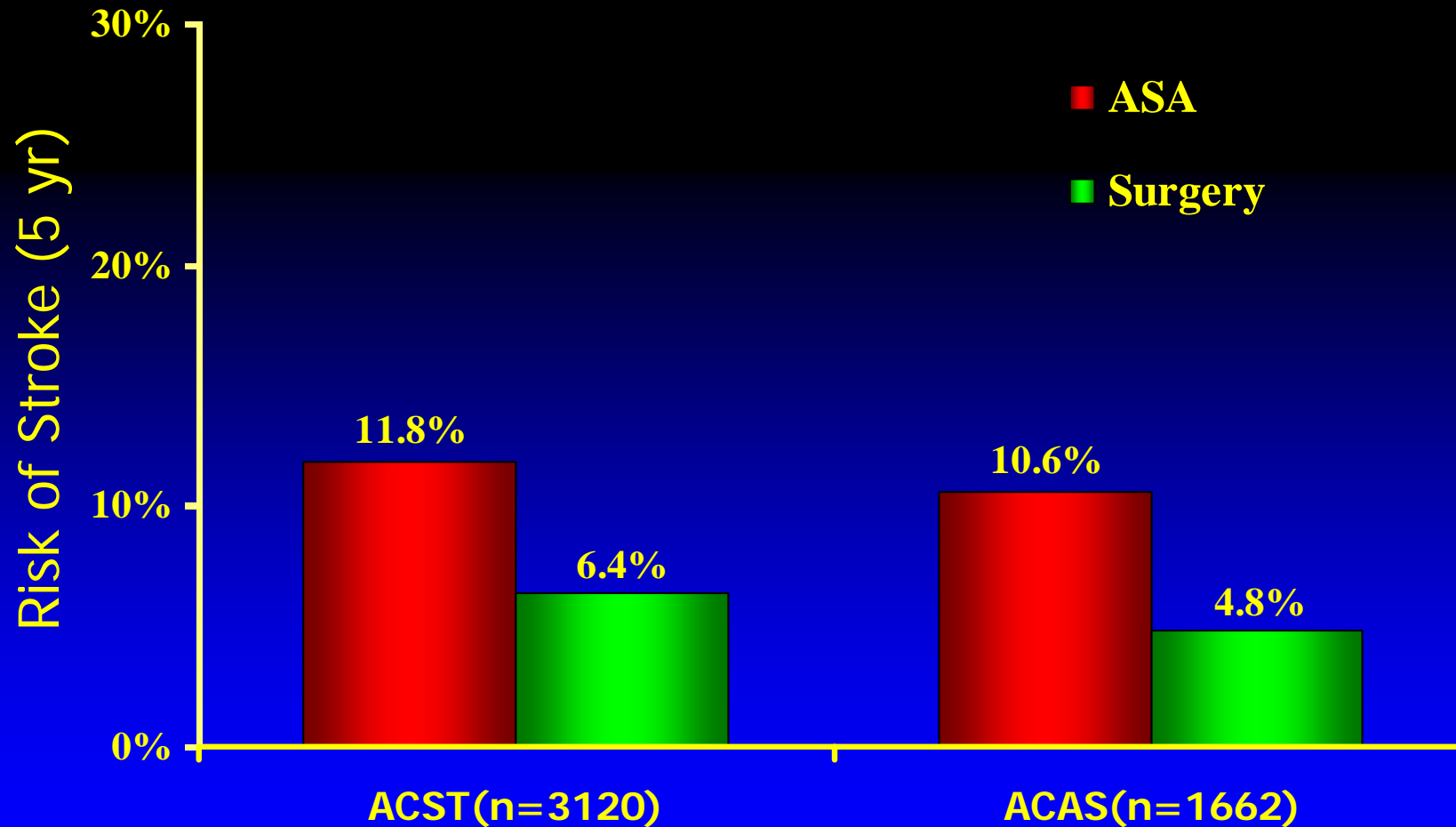
ACST enrollment was on basis of ultrasound

ACAS surgeons were pre selected (<3%)

Benefit of CEA was not seen in females (ACAS)



Surgery for Asymptomatic Carotid Stenosis was beneficial



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Asymptomatic Carotid Stenosis Stenting with Neuroprotection IDE (Drs. Roubin and Iyer)

Since the *only* reason for treating bifurcation
carotid stenosis is to *reduce the risk of stroke*,

The stroke risk associated with this prophylactic
intervention should not exceed the stroke risk
related to the natural hx of the disease (2-3%/yr)



Carotid Stent with Neuroprotection IDE

(Drs. Roubin and Iyer)

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No of Patients:	189
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Mean Age (yrs):	72.3 ± 9.9
≥80 years:	42 (22%)
Females:	78 (41%)

All Patients were seen before and within 24 hours post procedure by a neurologist



Primary Safety End-Points (30 Days): Asymptomatic Carotid Stenosis Stenting with Neuroprotection IDE (Drs. Roubin and Iyer, personnel communications)



6/03-1/05	N=167
Death	0
Major Stroke	1 (1.0%)
Retinal Infarction	1 (0.5%)
Minor Stroke*	3 (1.5%)
Death/Stroke/MI	5/167(3.0%)

* All 3 minor strokes recovered completely by 30 days

One Year Follow-up

84 Patients Eligible for follow up

No new strokes or other neurological events at 1-yr

Four deaths - none neurological related





As this nascent period of endovascular carotid procedures draws to an end, what is clear, crystal clear to me, is that a significant conundrum exists. The Gordian knot to be unraveled, i.e. the interrogative to be answered, is not whether

stent-supported carotid angioplasty is the standard of care, but rather how will physicians adequately develop the cognition and skill to safely perform these procedures.

Presently, some segments of the medical community are

not sufficiently perplexed

as to the equivalency of CEA and C-PTA.

Spokes-persons for each contingent vigorously and passionately detail their perspectives, often referencing their observational experiences as evidence of their unbiased, and logical conclusions.





However,
clinical equipoise,
a genuine state of doubt regarding the
equivalence
of each procedure or the superiority of one
procedure over another, does not exist.
But, in reality, the point of perplexity has
passed.

While some members of the medical community may not share this view, from my vantage, their opposition and disagreement appears more likely to be lack of familiarity with the

a. *extant data,*

b. *obstinacy,*

c. *self-interest, and/or*

d. *an inflexible need for a randomized trial*

to demonstrate the statistical merit of the therapy, rather than an assessment of the data.



**Stent supported carotid angioplasty,
subjects the patient to**

- a. an immediate lower complication rate than CEA,
- b. less trauma,
- c. a minimal postoperative recovery period, and
- d. precludes subsequent ipsilateral neurologic deficit.



While neurologic deficit can and will occur with both procedures, the incidence of such deficits appears significantly less likely to occur with C-PTA, as such,

C-PTA has become the 1^o treatment of extracranial carotid bifurcation obliterative disease

