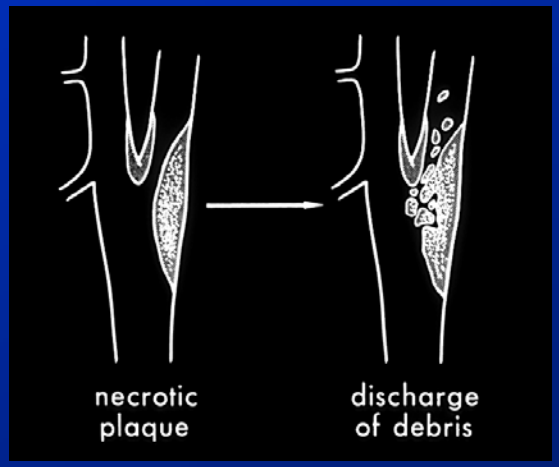
Update on Carotid Stenting

John R. Laird
Cardiovascular Research Institute
Washington Hospital Center

Washington
Hospital Center

Carotid Stenting
What a Crazy Idea!

- **Pathogenesis of stroke**



Does it make sense to think that expansion of luminal diameter with an uncovered stent will produce equivalent stroke prevention to removal of the plaque?

R. Cambria

Guidelines…

CEA: Acceptable morbidity and mortality *

Symptomatic → **< 6%**

Asymptomatic → **< 3%**

Ad Hoc Committee, AHA

Carotid Stenting
The Early Years

- Use of equipment designed for other vascular beds
- Balloon expandable stents
- High profile systems
  - 9 Fr guides or 7Fr or 8Fr sheaths
  - 0.035 inch balloon catheters
- No embolic protection systems

UAB/LHH Total Experience

9/8/94 – 1/16/02

	Patients (N=999)	Vessels (n=1106)
Death	13 (1.3%)	13 (1.2%)
Minor Stroke	41 (4.1%)	41 (3.7%)*
Major Stroke	8 (0.8%)	8 (0.7%)
All Strokes & Deaths	62 (6.2%)	62 (5.6%)

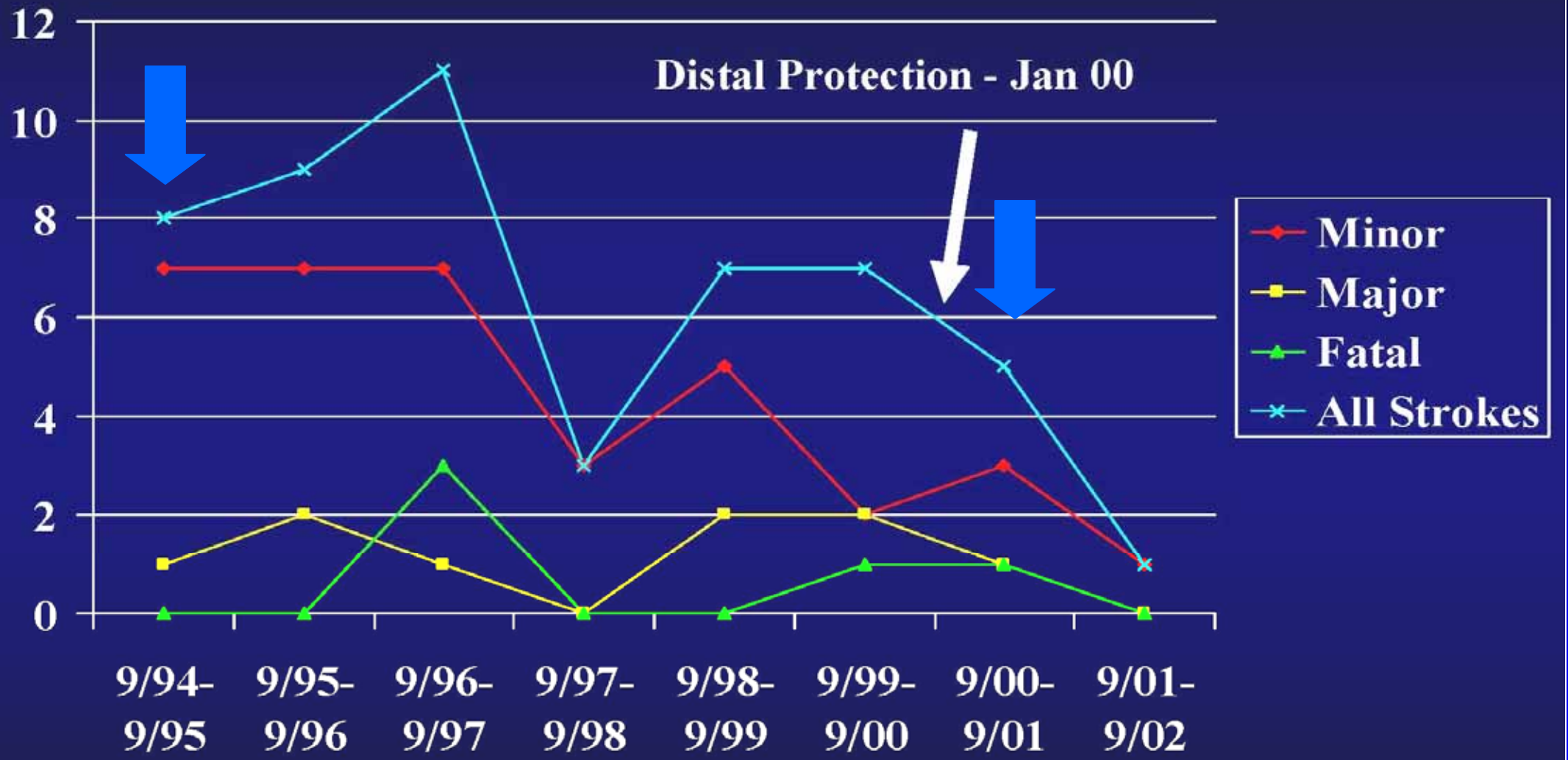
**** Includes: 2 patients with retinal embolus and 2 patients with hyperperfusion syndrome***

Lenox Hill Experience
11/20/97 – 1/16/02

	Patients (N=679)	Vessels (n=730)
Death	3 (0.4%)	3 (0.4%)
Minor Stroke	20 (2.9%)*	20 (2.7%)
Major Stroke	4 (0.6%)	4 (0.5%)
All Strokes & Deaths	27 (4.0%)	27 (3.7%)

**** Includes: 2 patients with retinal embolus and 2 patients with hyperperfusion syndrome***

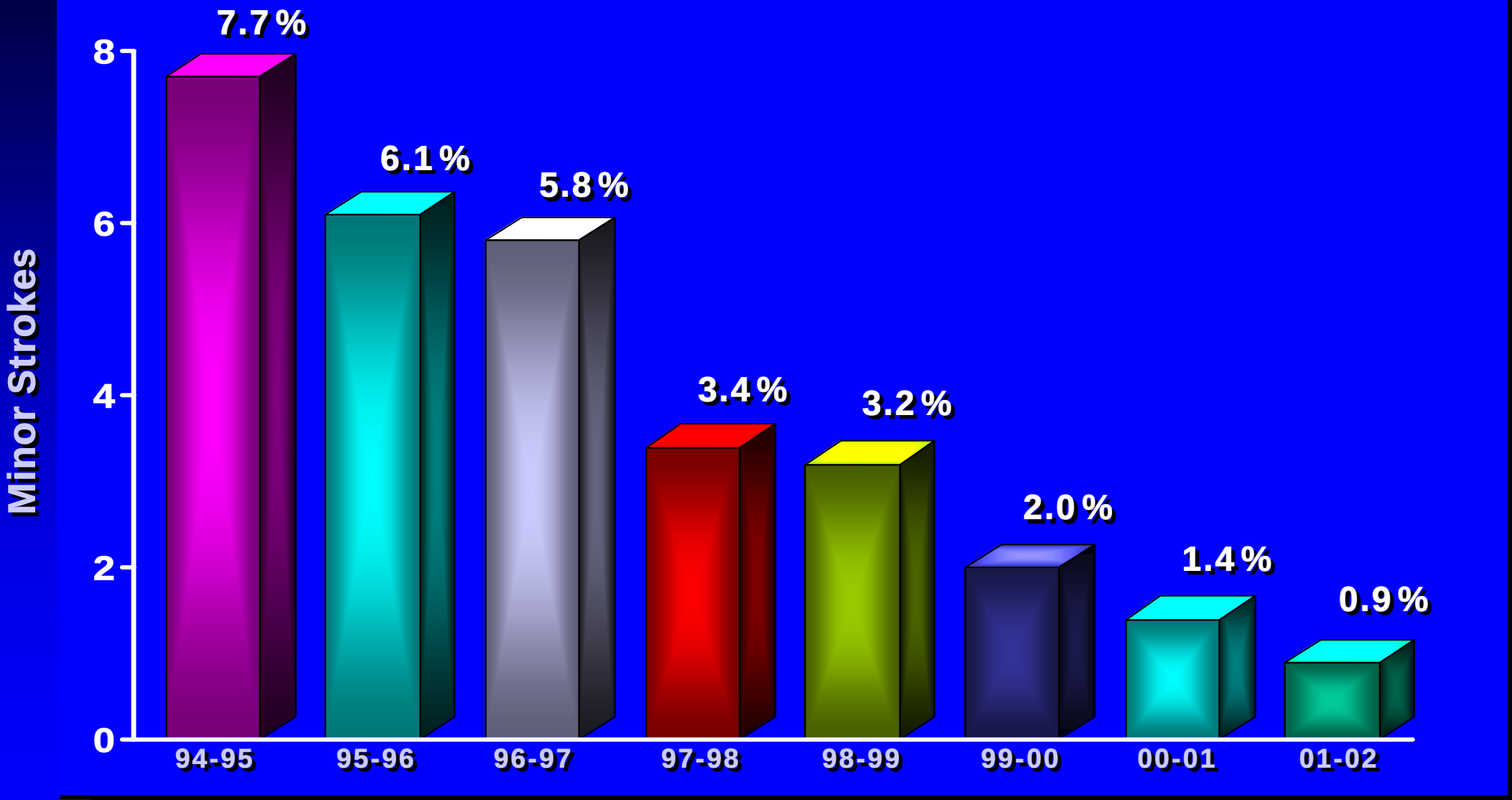
Improving Results of Carotid Stenting



N	=	100	124	126	94	159	207	214	178

New, Roubin JACC Suppl. 41;79a, 2003

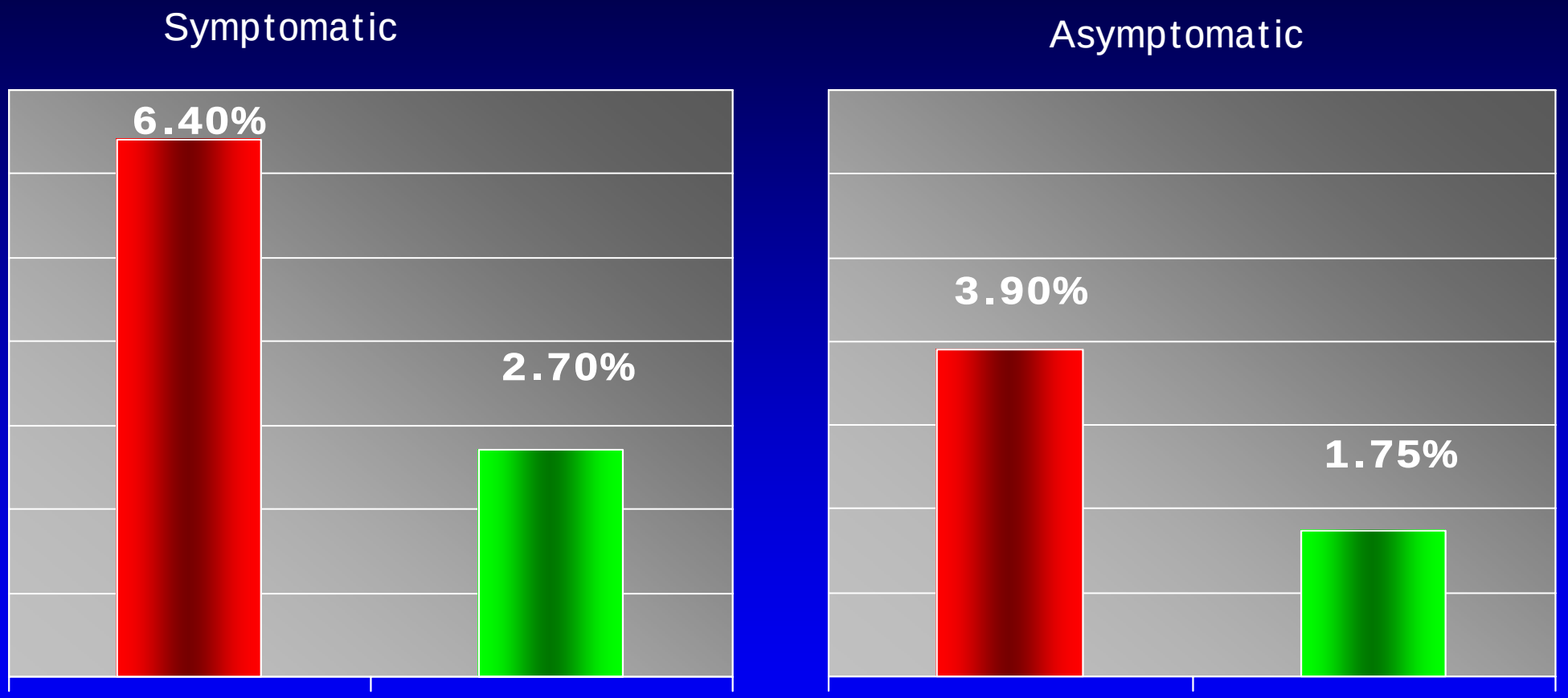
Temporal Trend - Minor Strokes



Carotid Stenting
Improved Results

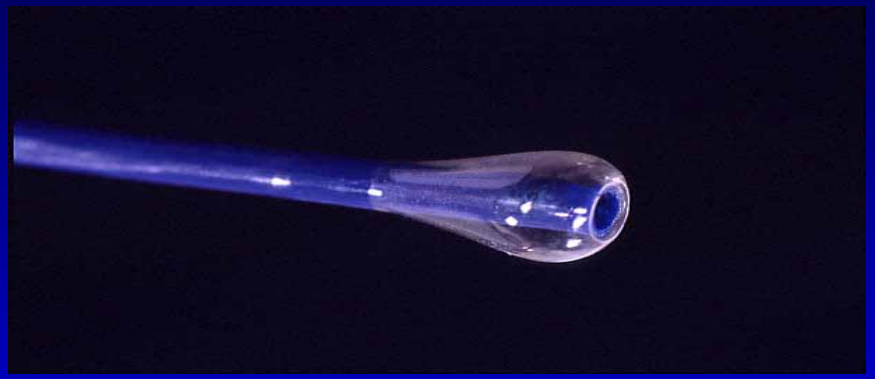
- Better patient selection
- Standardized techniques
- Dedicated carotid stent platforms
- Lower profile systems
  - 6 Fr sheath
  - 0.014 balloons
  - Self-expanding stents (Wallstent, Nitinol stents)
- Emboli protection systems
- Better adjunct pharmacology

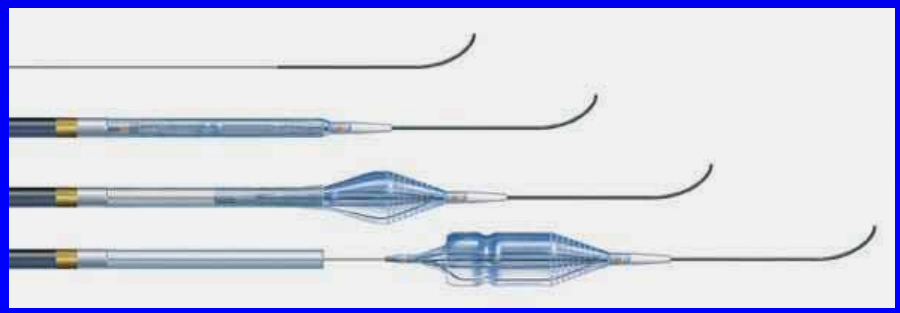
Global Carotid Registry

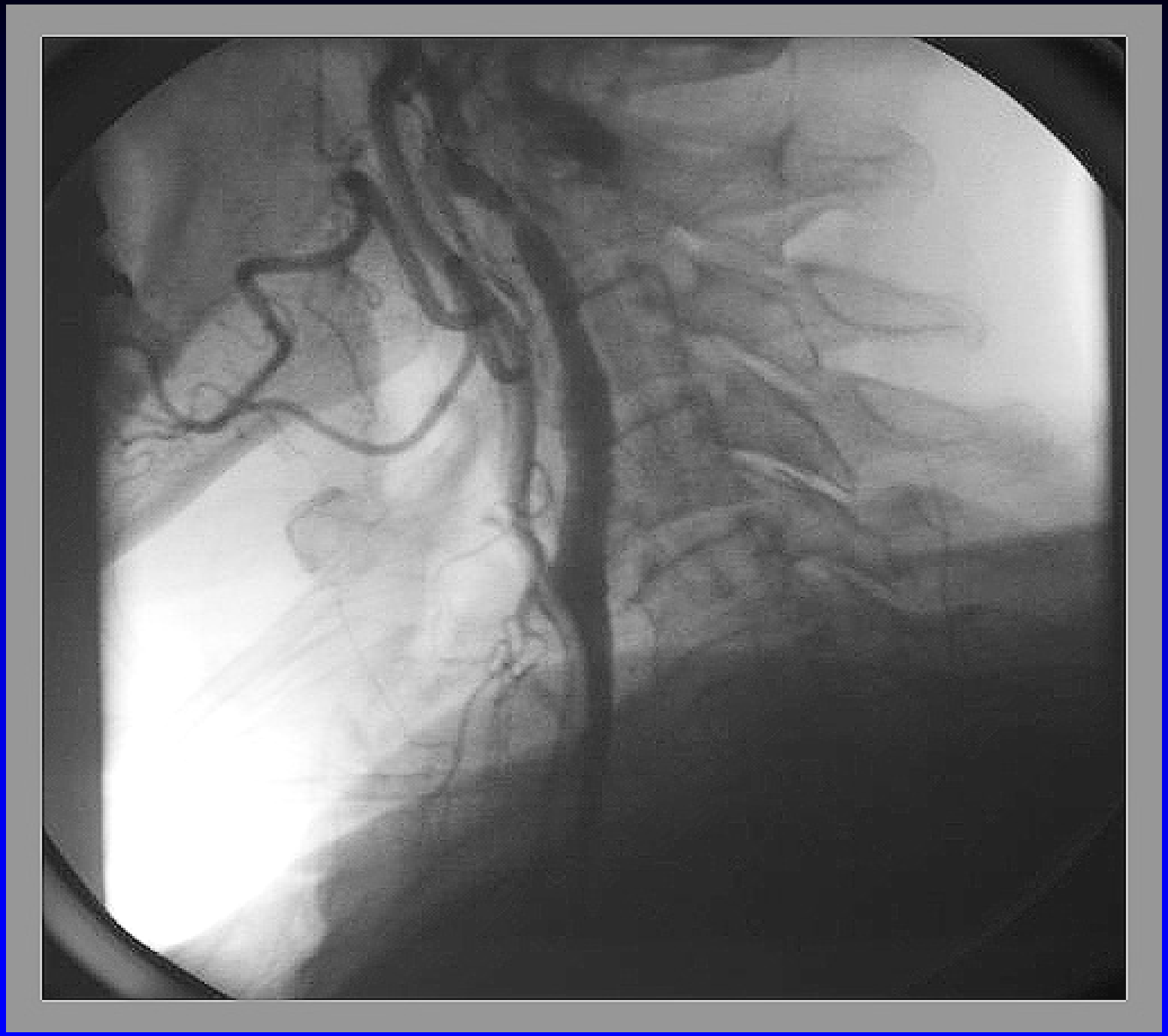


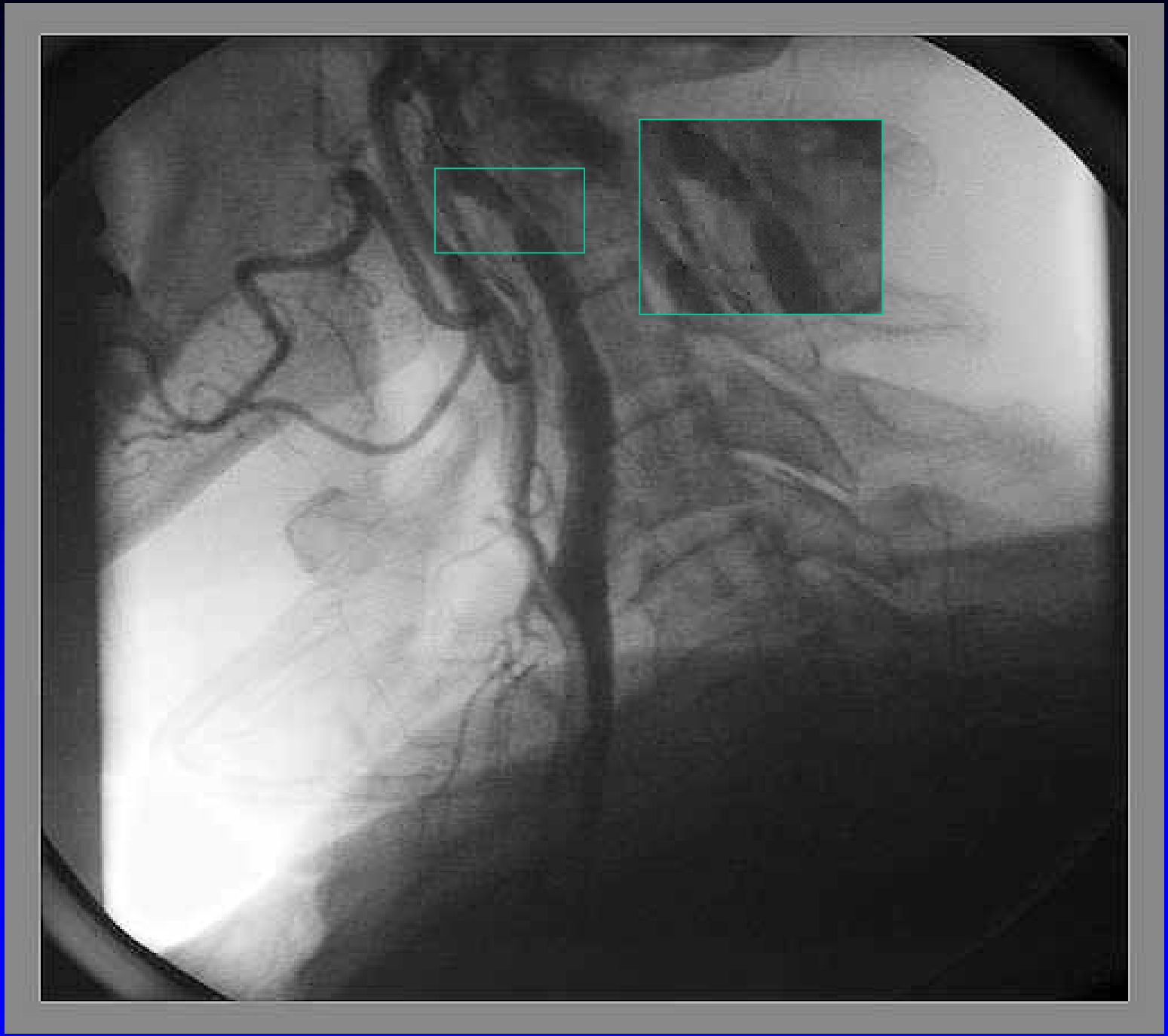
Wholey, Catheter Cardiovasc Interv 2003; 601: 259-266

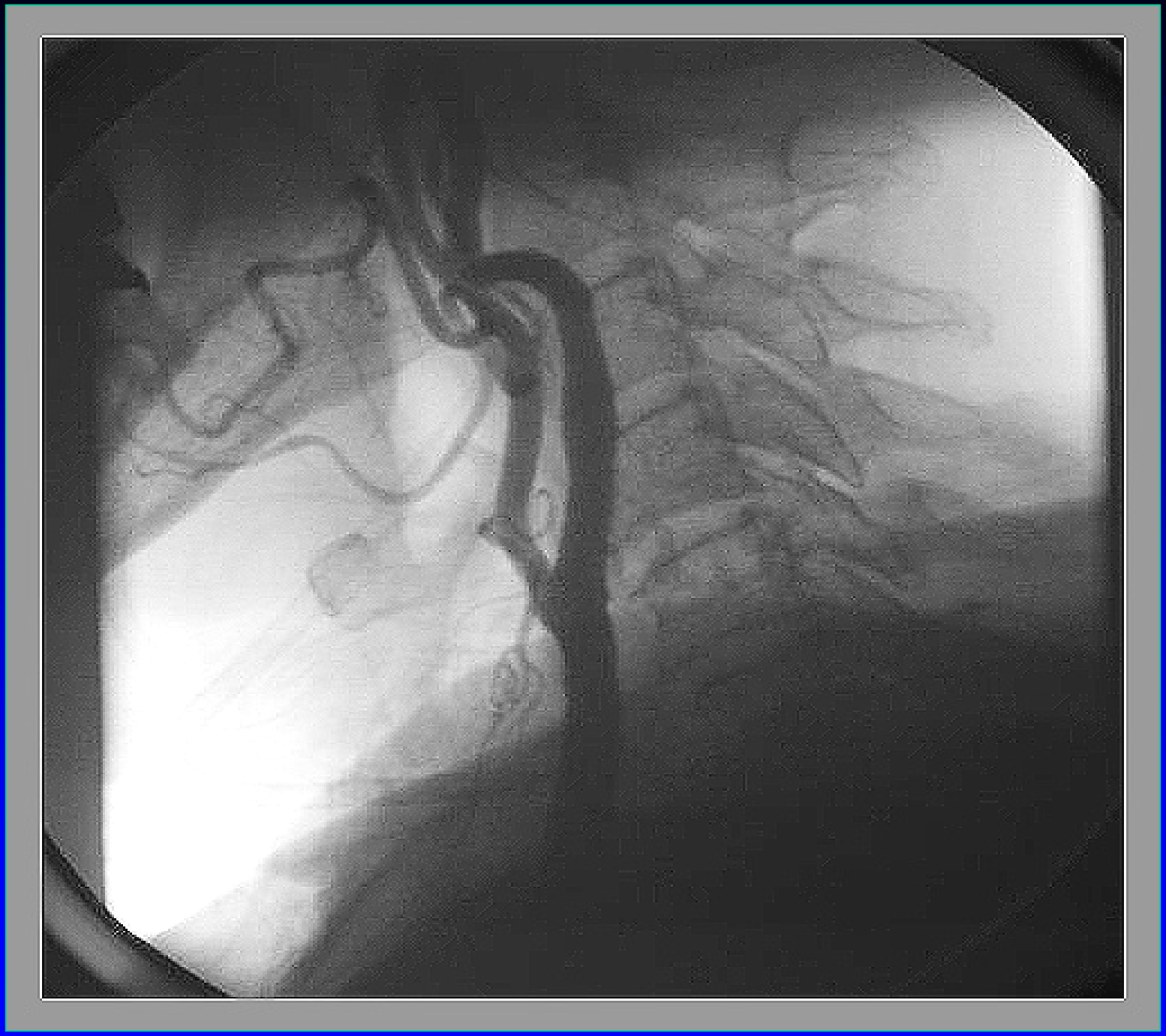
Review of Carotid Stent/Embolic Protection Platforms

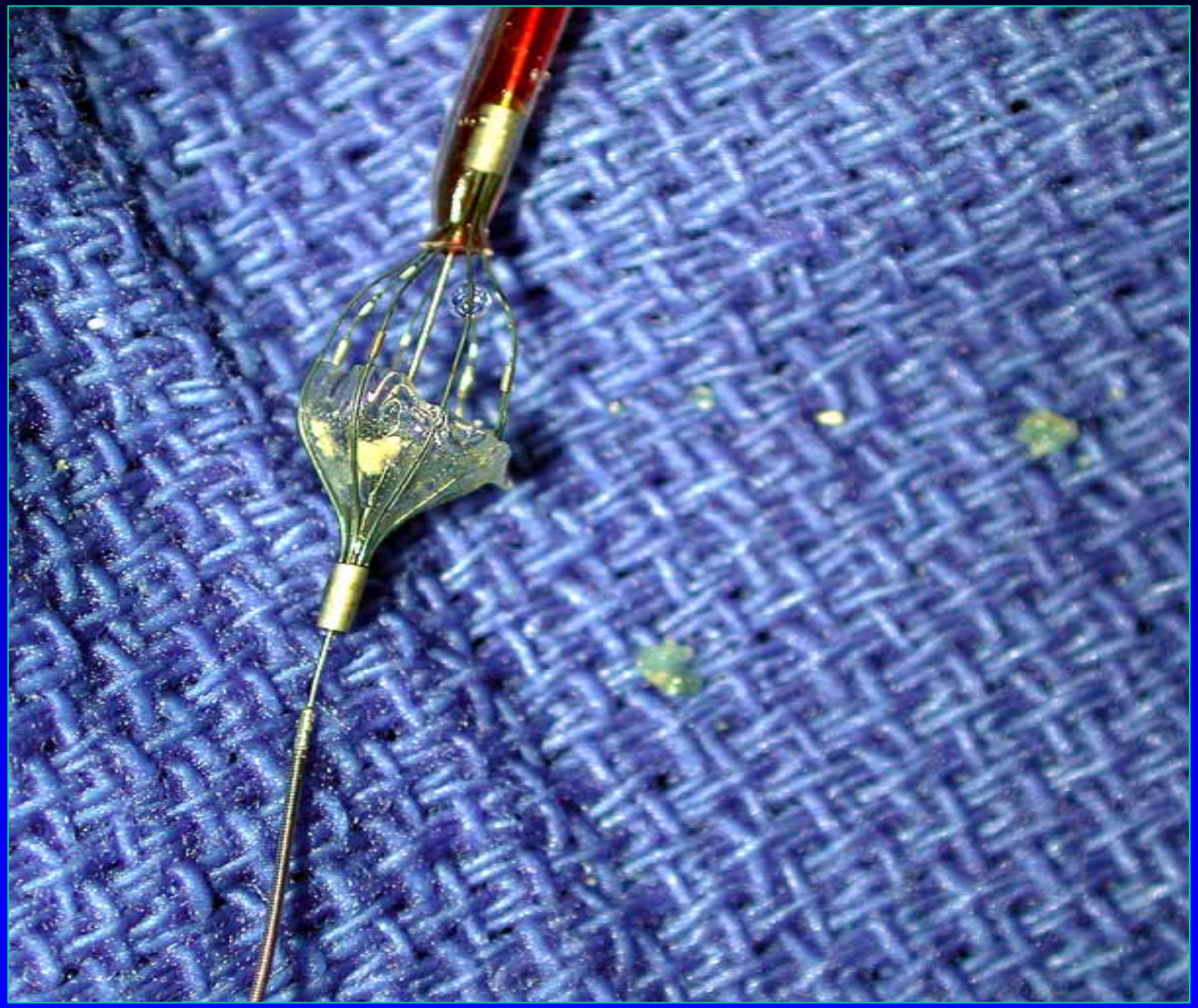








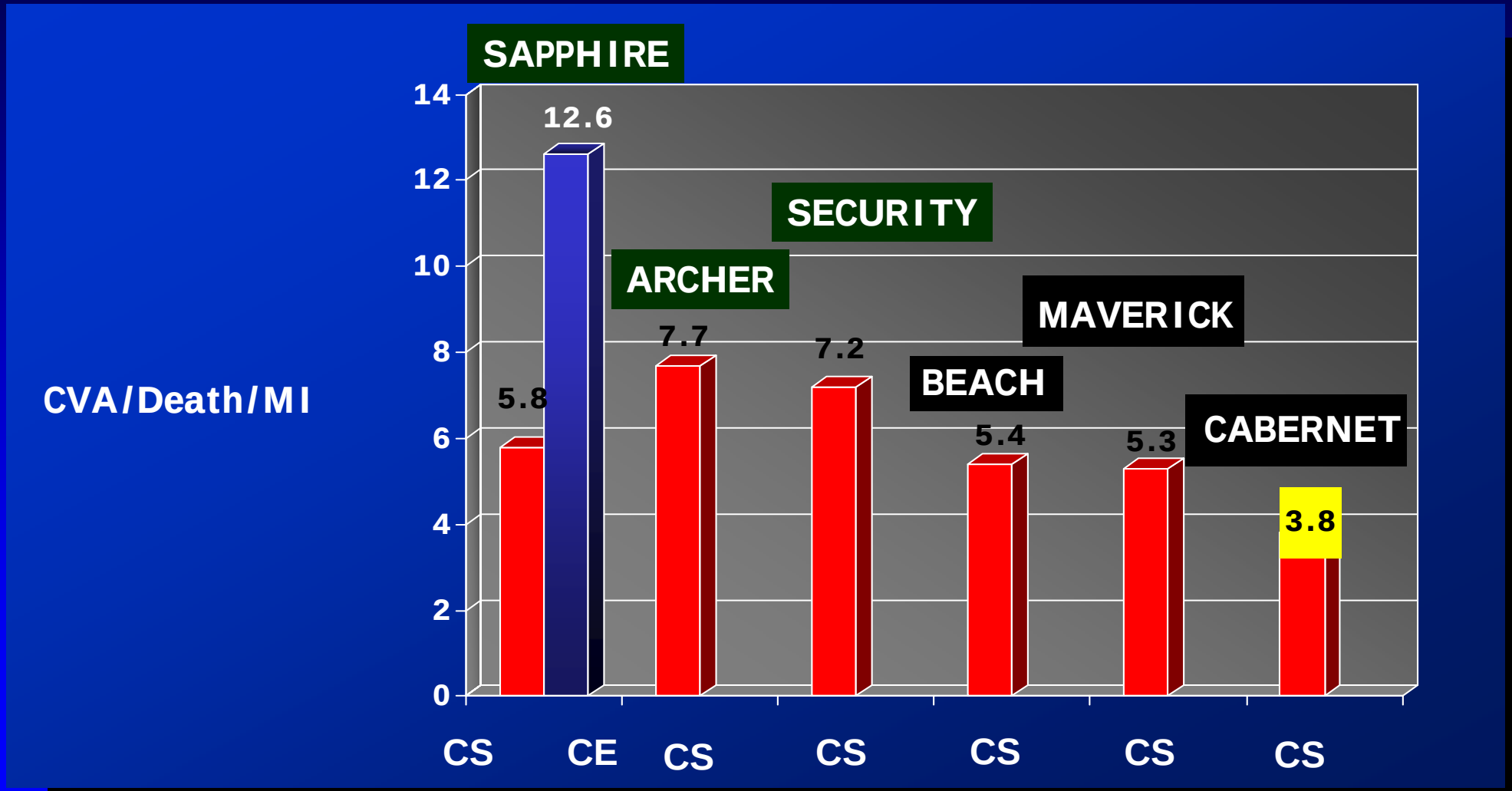




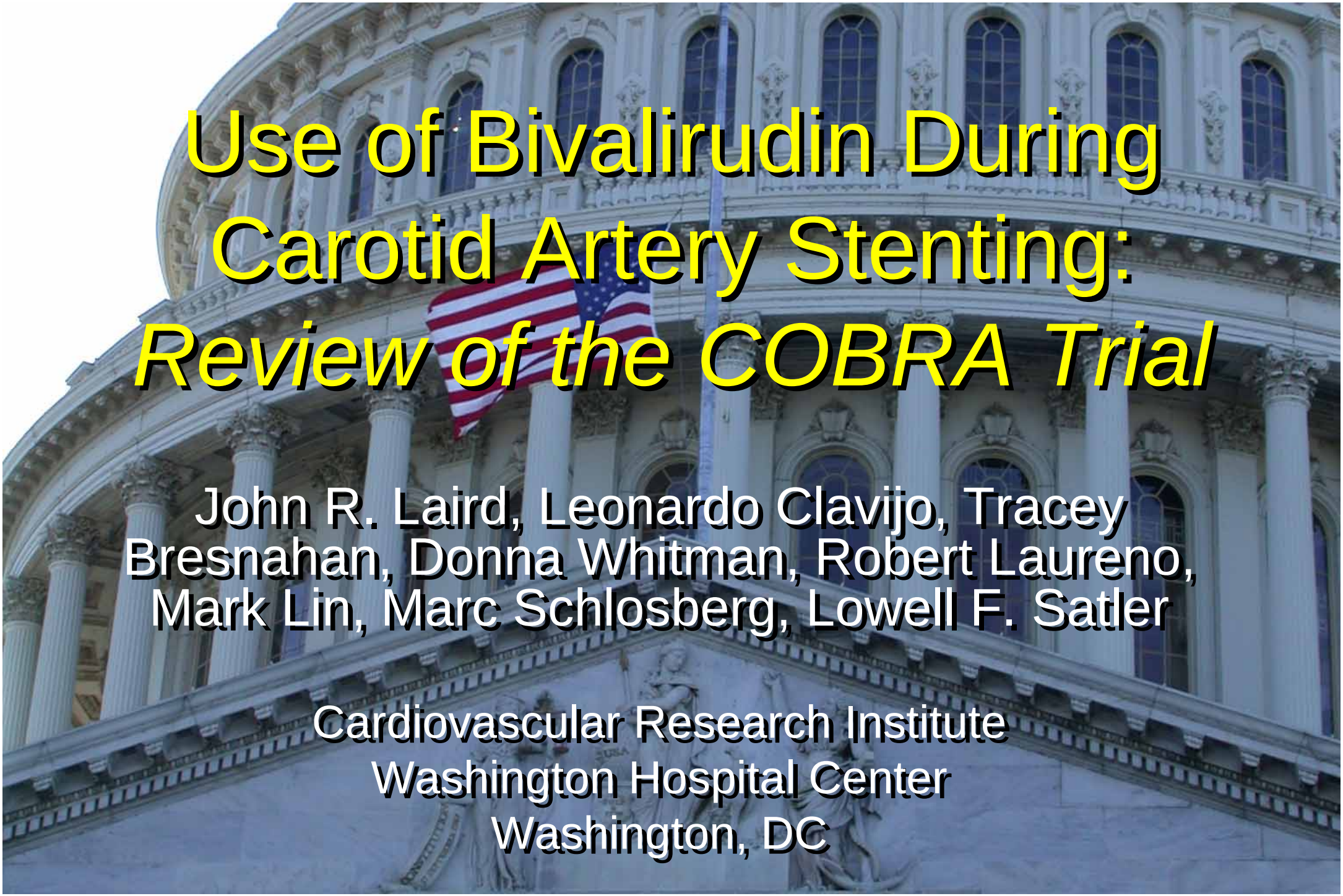
Carotid Stent Clinical Trials

- **Registries**
  - SHELTER (BSC/Percusurg)
  - ARCHER (Guidant)
  - MAVERICK (Medtronic)
  - CARESS (ISES)
  - BEACH (BSC,EPI)
  - SECURITY (Abbot, Mednova)
  - CABERNET (BSC, Endotex)
  - VIVA (Bard)
- **Randomized**
  - CREST (NIH)
  - SAPPHIRE (Cordis)
  - ACT 1 (Abbott)

High Risk Carotid Trials: 30 Day Outcomes



CS =Carotid stent
CE =Carotid endartectomy

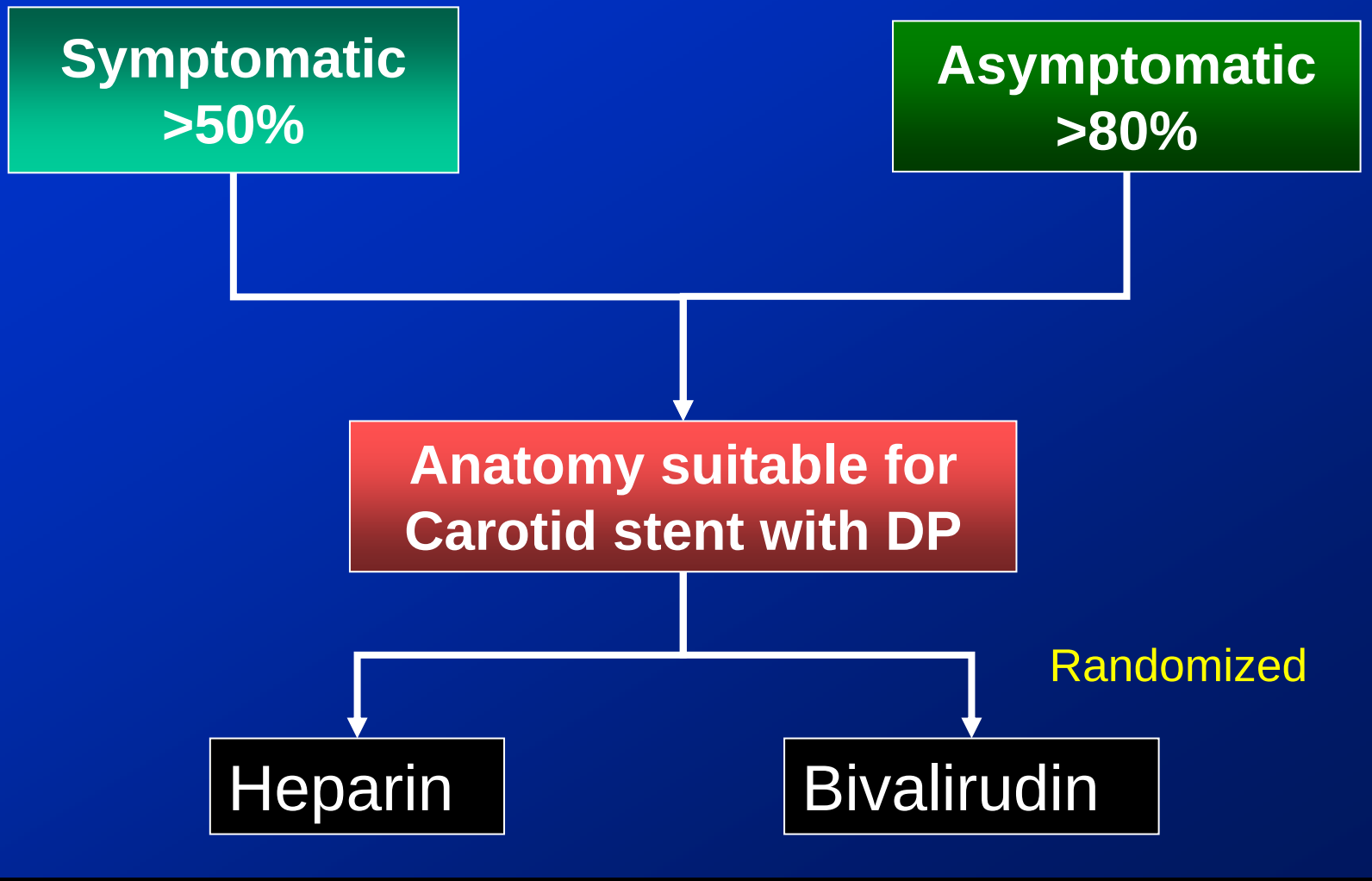


Use of Bivalirudin During Carotid Artery Stenting: *Review of the COBRA Trial*

John R. Laird, Leonardo Clavijo, Tracey Bresnahan, Donna Whitman, Robert Laureno, Mark Lin, Marc Schlosberg, Lowell F. Satler

Cardiovascular Research Institute
Washington Hospital Center
Washington, DC

COBRA


Symptomatic
>50%
Asymptomatic
>80%
Anatomy suitable for
Carotid stent with DP
Randomized
Heparin
Bivalirudin

Pre-Procedure Assessment

- Neurology Evaluation: NIH stroke scale, Rankin scale, Barthel index
- Carotid Duplex study
- CT scan of the head
- Complex arch and carotid study (most often during same procedure)

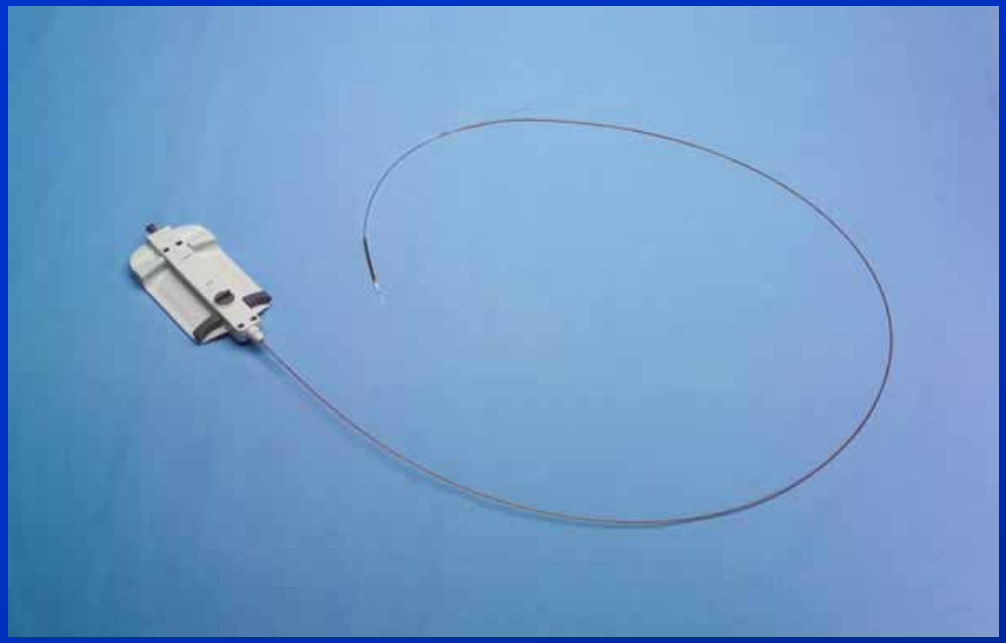
Procedural Technique

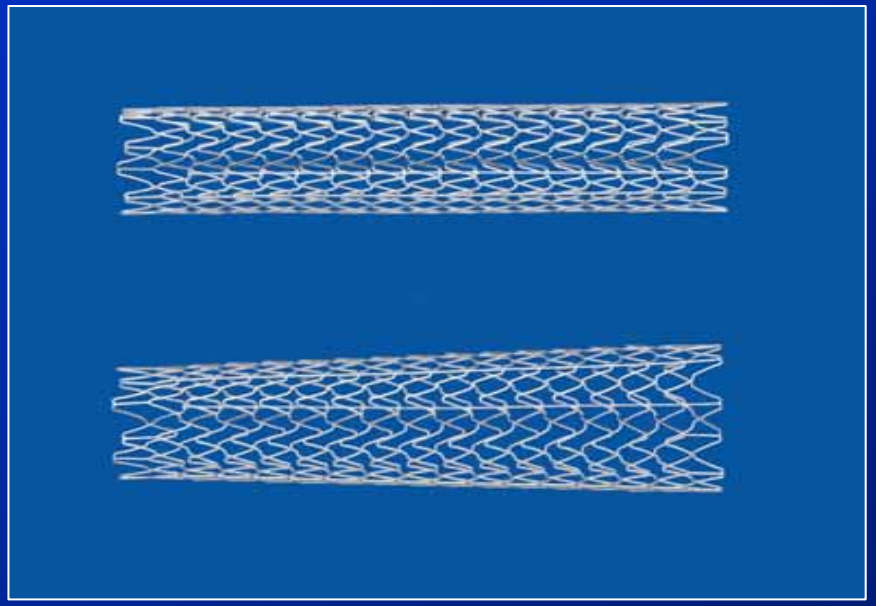
- High volume operators (JL or LS)
- 10 year carotid stenting experience

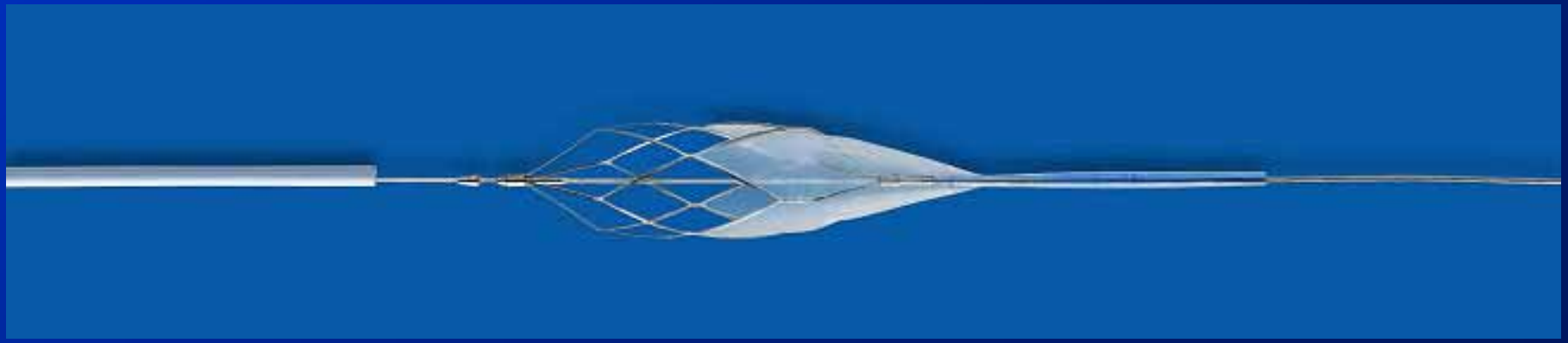
Pharmacologic Treatment Regimen

- Heparin: 4,000 – 5,000 unit IV bolus to achieve an ACT of 250-300 sec
- Bivalirudin: 0.75 mg/kg IV bolus followed by 1.75 mg/kg/hr IV infusion
- Bivalirudin discontinued upon completion of the procedure
- Aspirin 325 mg po
- Plavix 75 mg po (one month minimum)

Guidant Carotid Stenting System

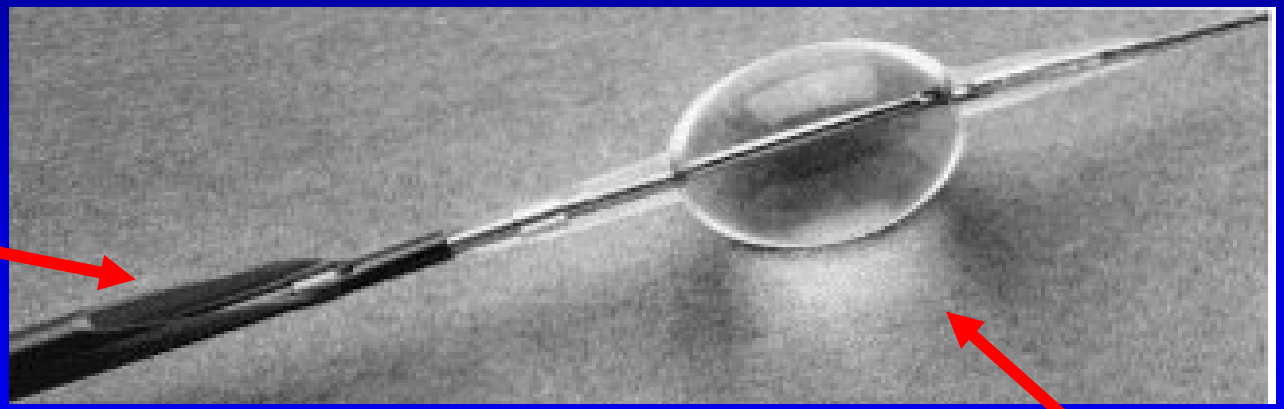






PercuSurge

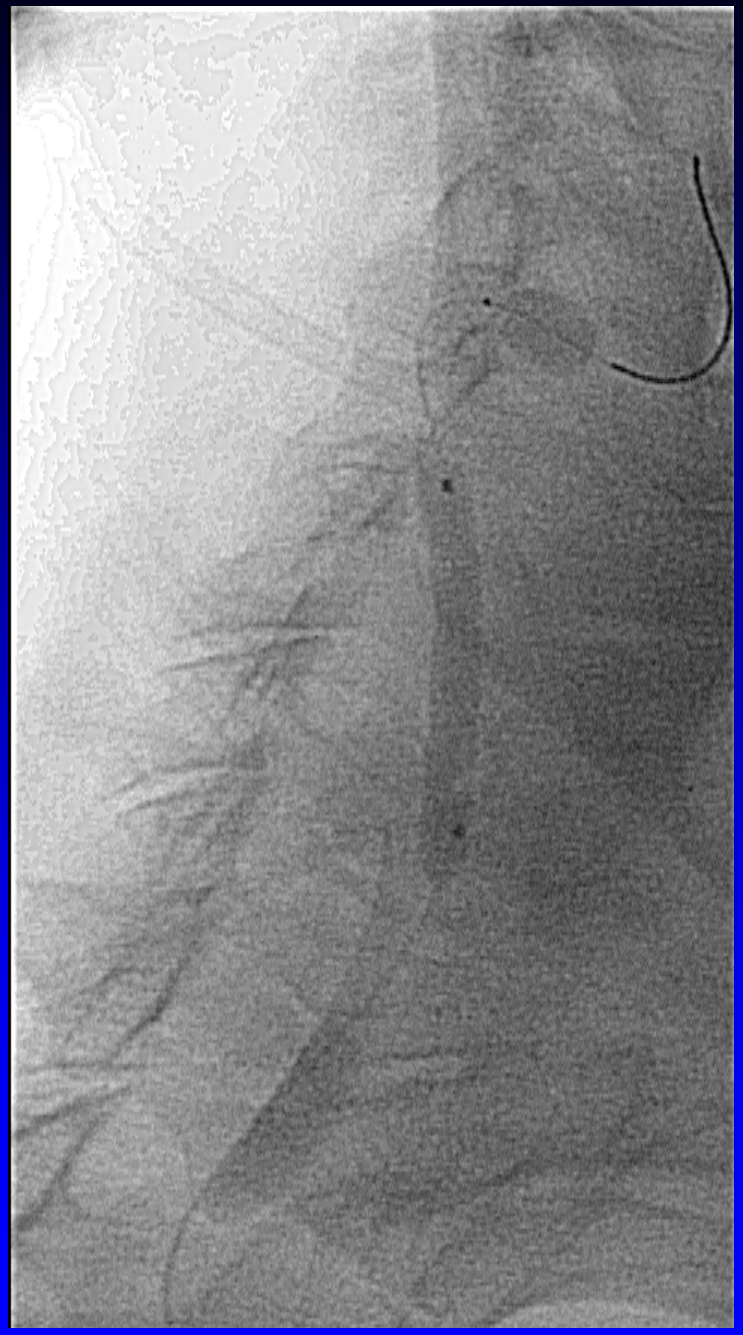
Aspiration catheter

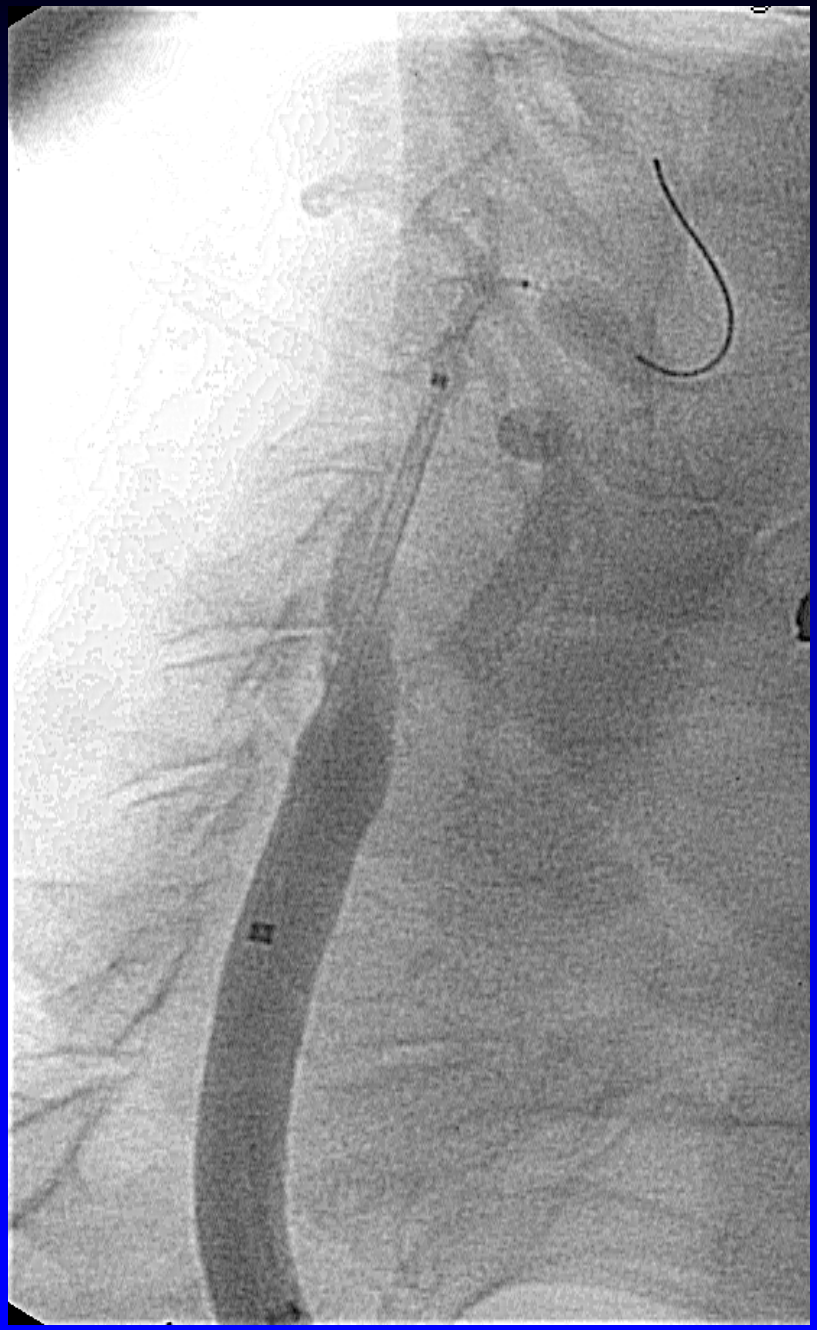


Distal occlusion balloon

Case History

- 81 year old female
- Severe CAD
- Symptomatic right carotid stenosis – small right hemispheric stroke two weeks prior
- Carotid duplex evaluation:
  - 80-99% RICA stenosis
  - 40-59% LICA stenosis

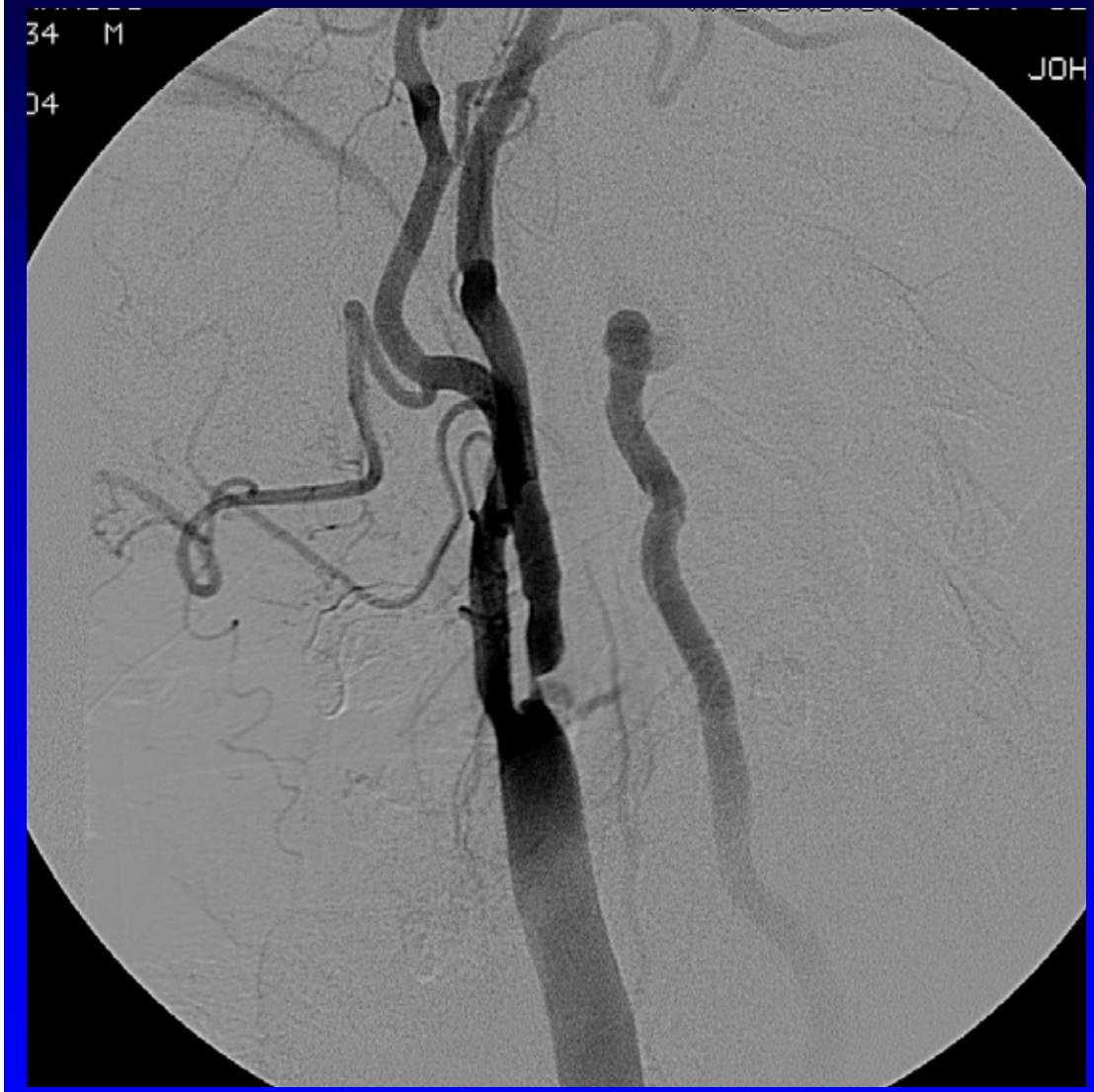




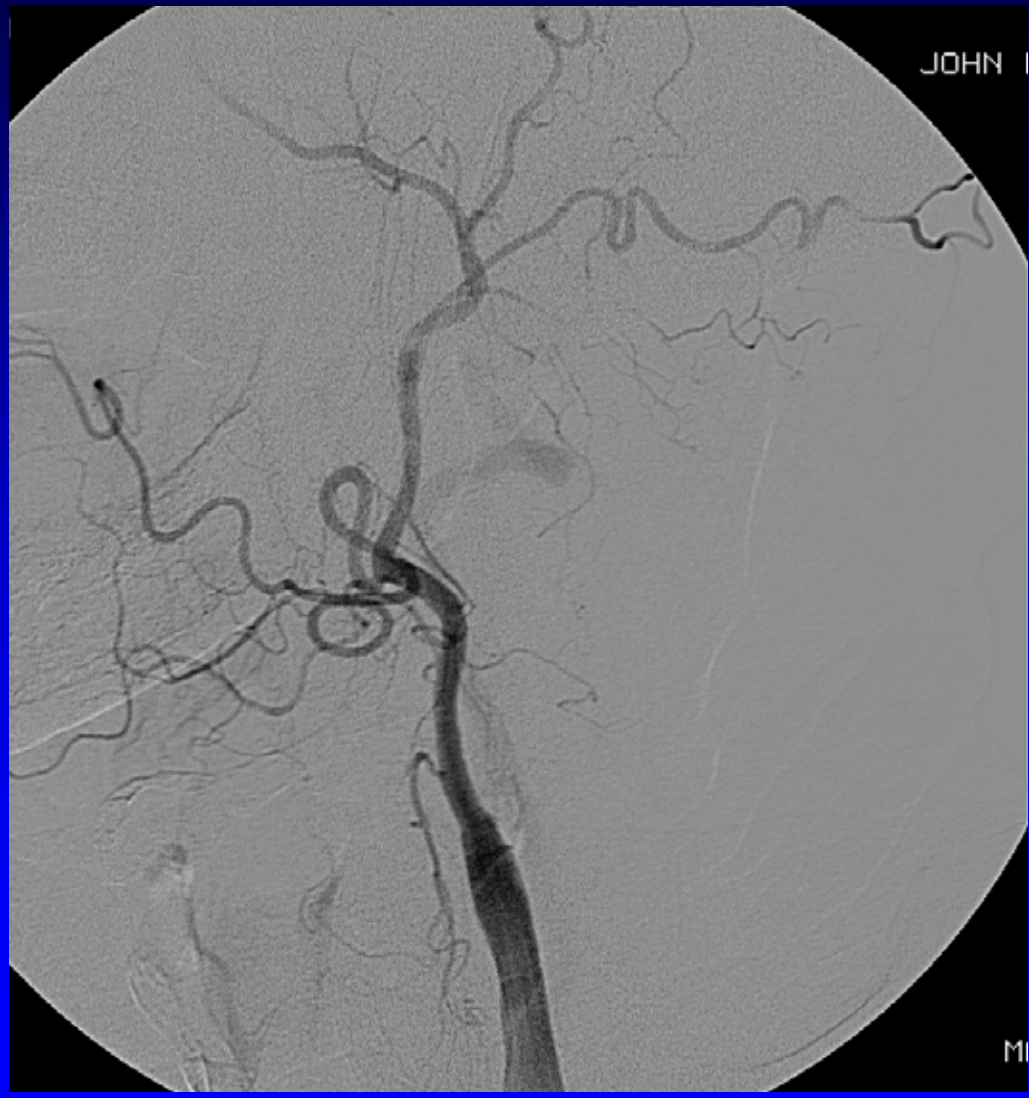

23 F
05


Washington Hospita
JOH

Carotid Angiography

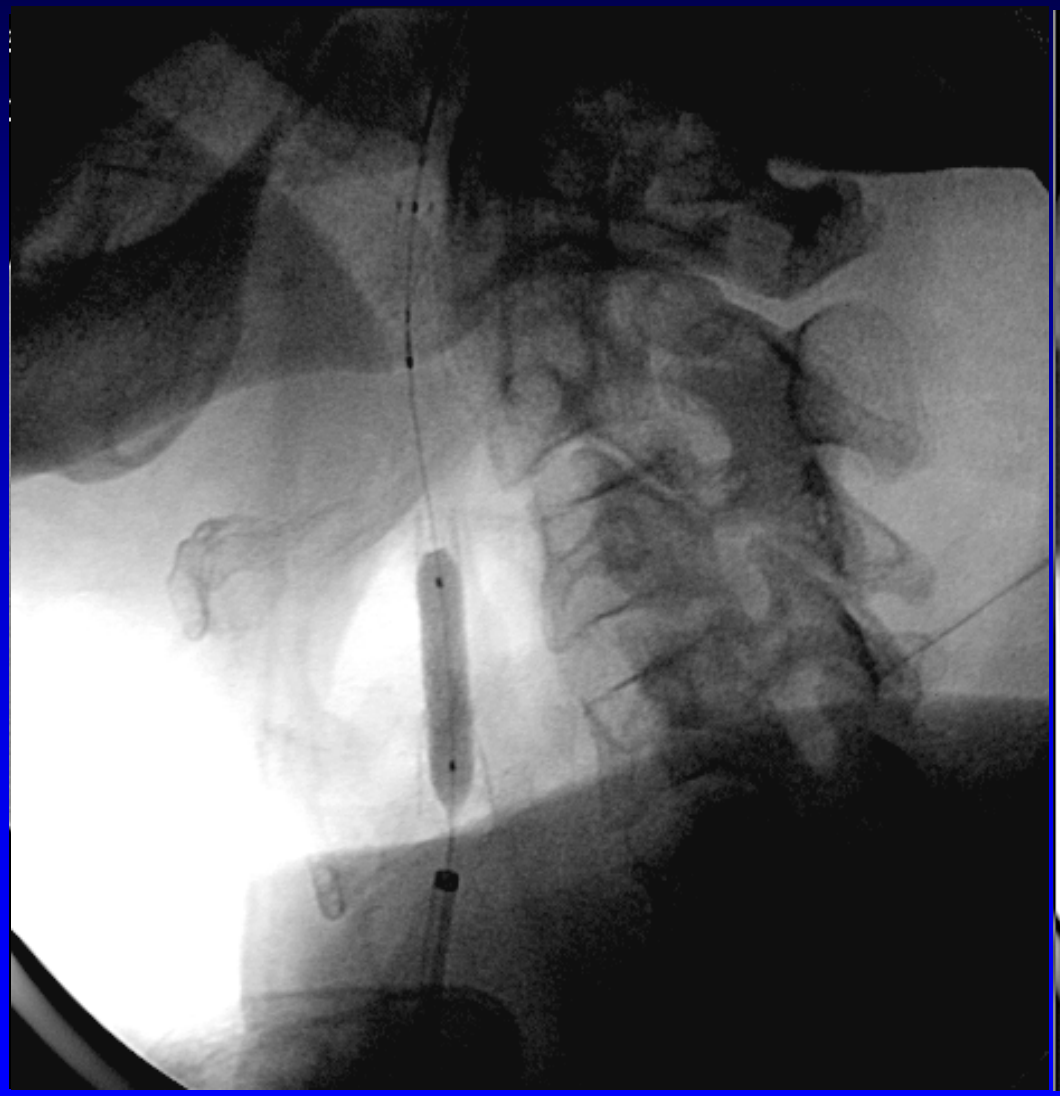


RICA



LICA

Case History



Interim Results

- 220 patients enrolled to date
- 180 patients included in the current analysis
- 92 patients – heparin group
- 88 patients – Bivalirudin group

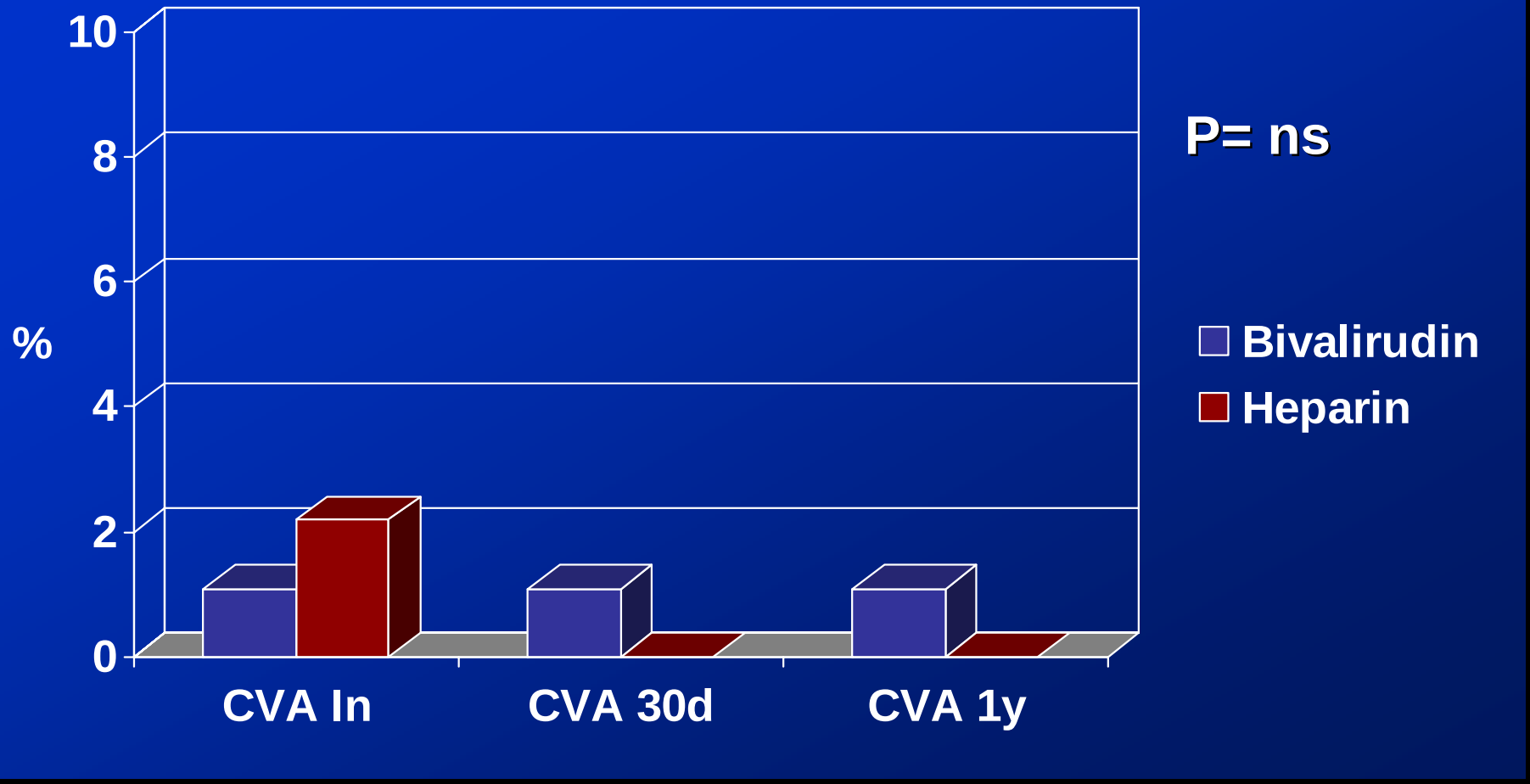
Demographic Characteristics

Variable	Bivalirudin	Heparin	p value
Age	70.1±8.3	71±10.1	0.6
Male,%	61.9	68.9	0.41
HTN, %	84.1	80.3	0.58
DM, %	47.6	42.6	0.57
CRI, %	14.3	11.5	0.64
HLP, %	92.1	85.2	0.06
PAD, %	71.4	85.2	0.23
Symptomatic	32.8	22	0.18

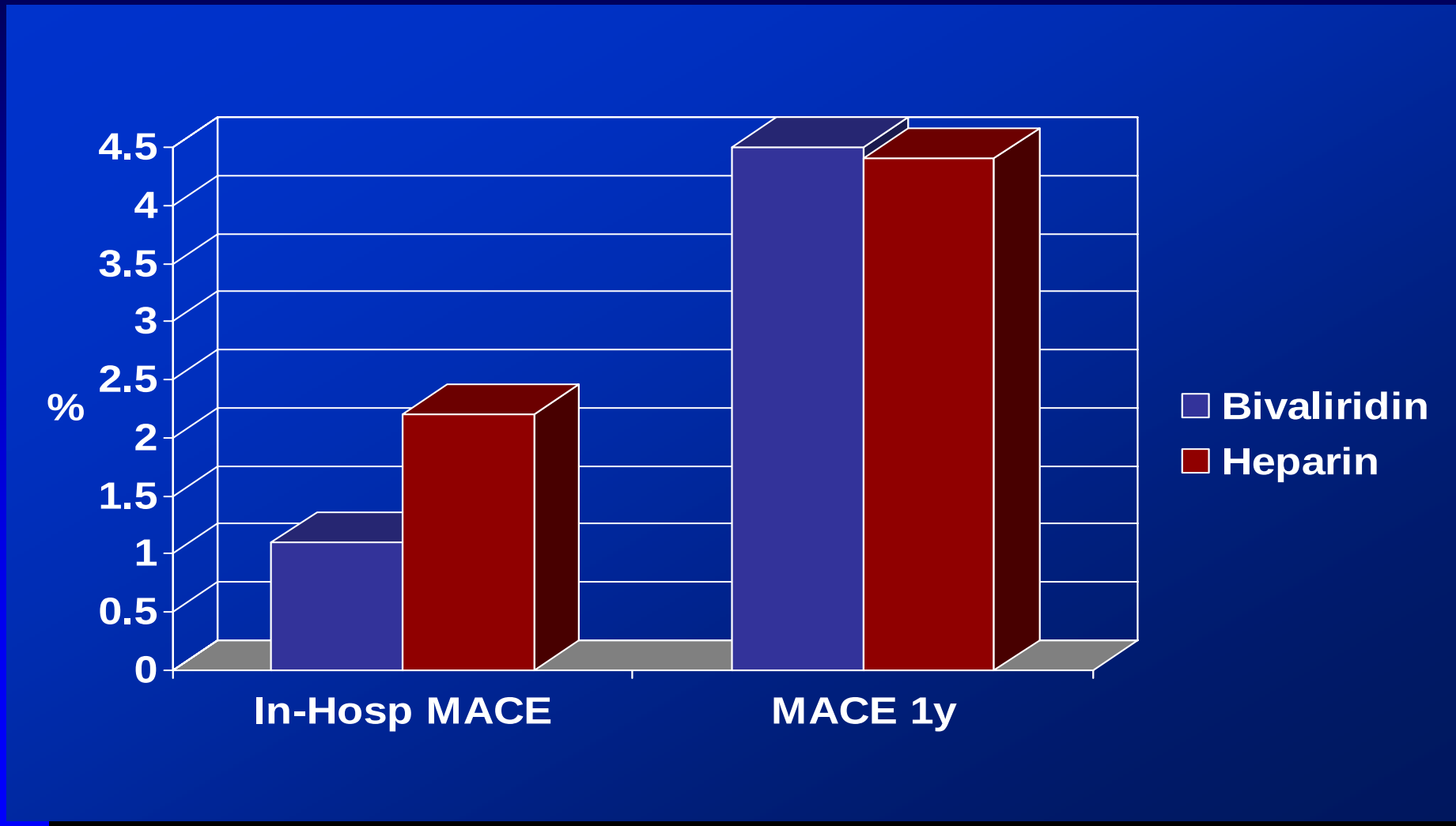
Preliminary Results

Variable %	Bivalirudin	Heparin	p value
Proc. Succ	100	100	1
Hypotension	9	10	0.52
DEP	100	100	1
Debris	10.9	9.1	0.75
Closure	50	57.4	0.43
Hosp. Stay	1.8 ± 1.3	1.9 ±4.9	0.81

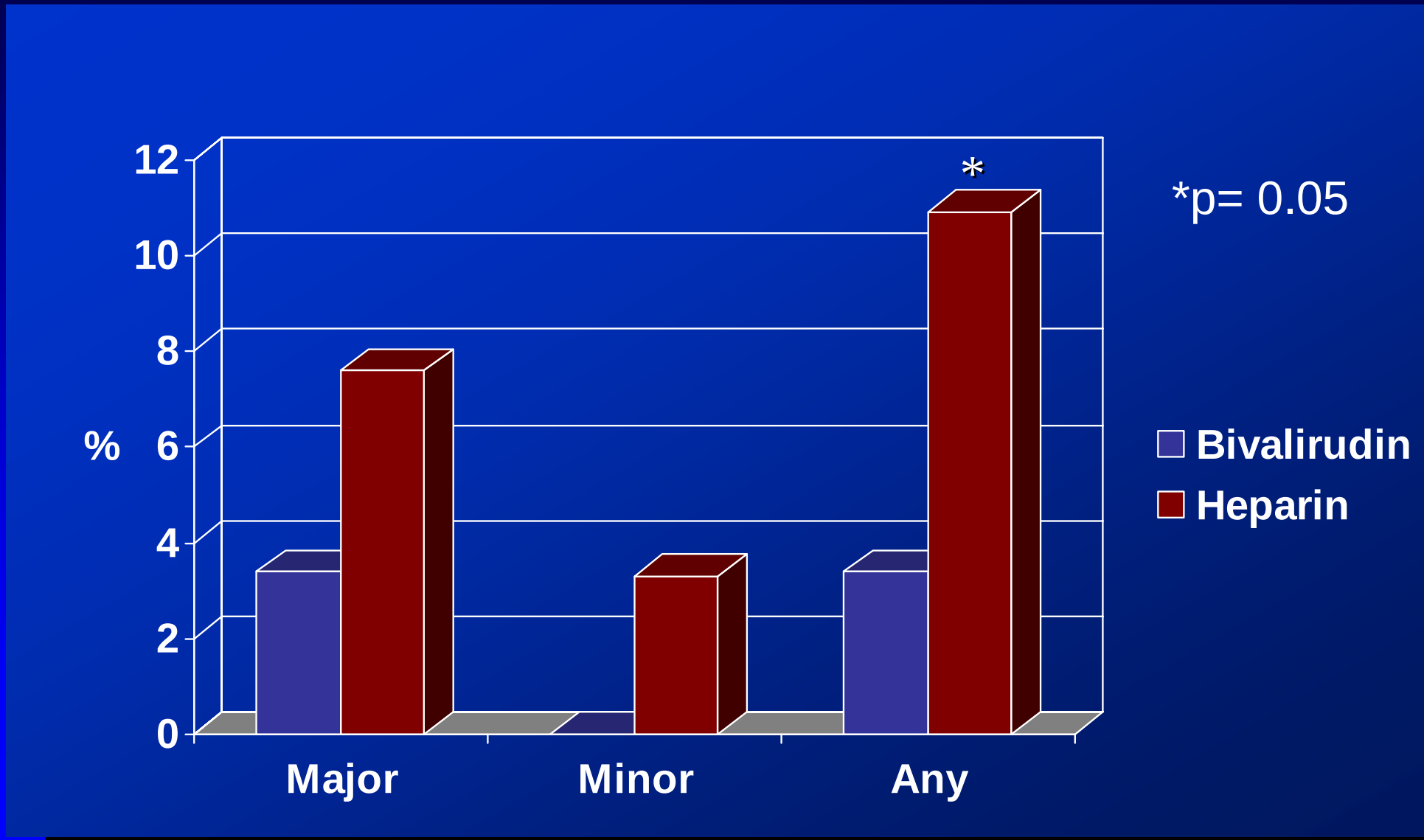
Stroke



MACE



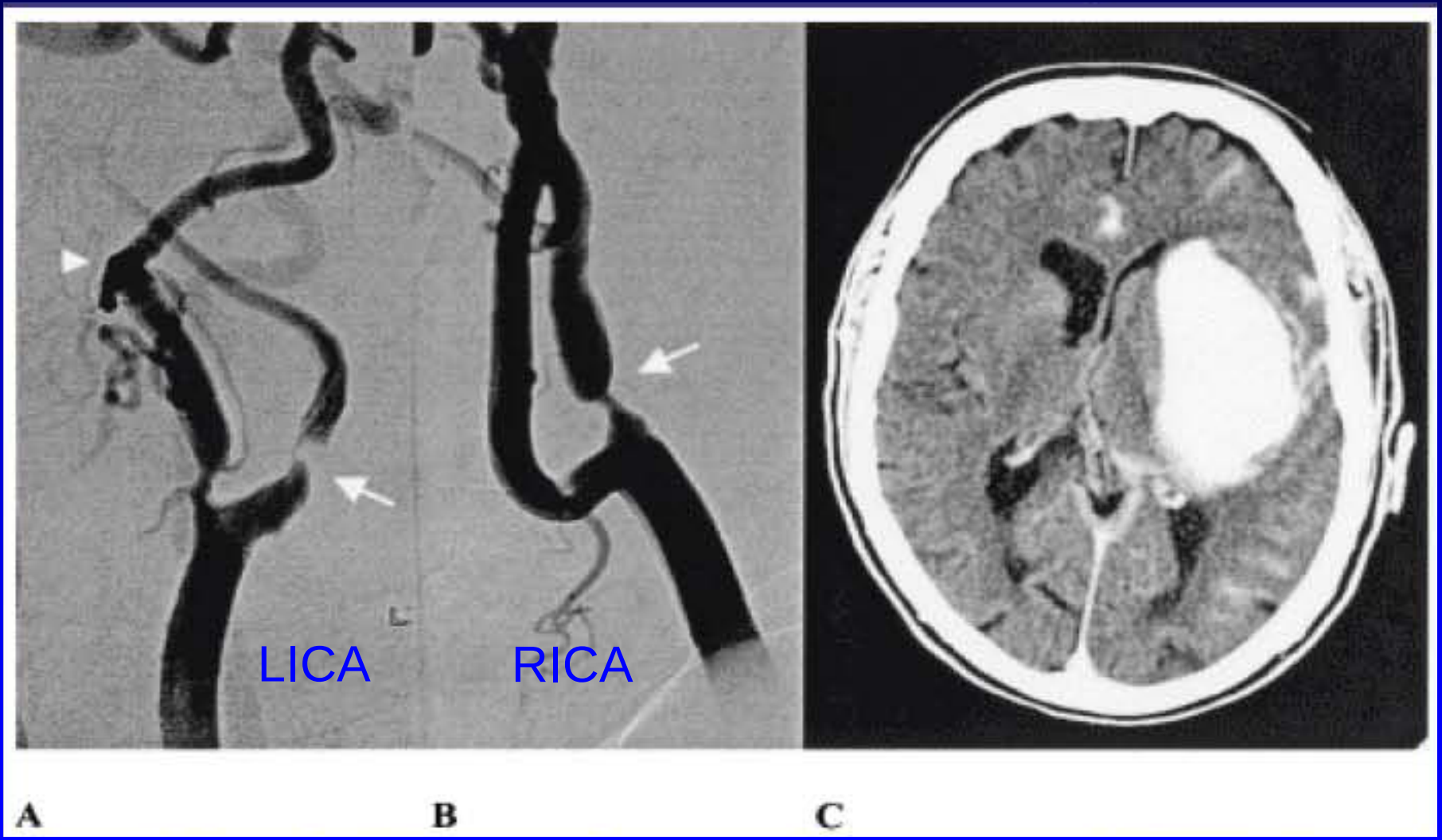
Bleeding Complications



Complications of Carotid Stenting

- Stroke
- Carotid dissection
- Carotid perforation/rupture
- Bradycardia/Hypotension
- Hyperperfusion syndrome – cerebral bleed
- Access site complications

Intracranial Hemorrhage and Hyperperfusion Following CAS



Abou-Chebl A, Yadav JS, et al. J Am Coll Cardiol 2004;43:1596-601.

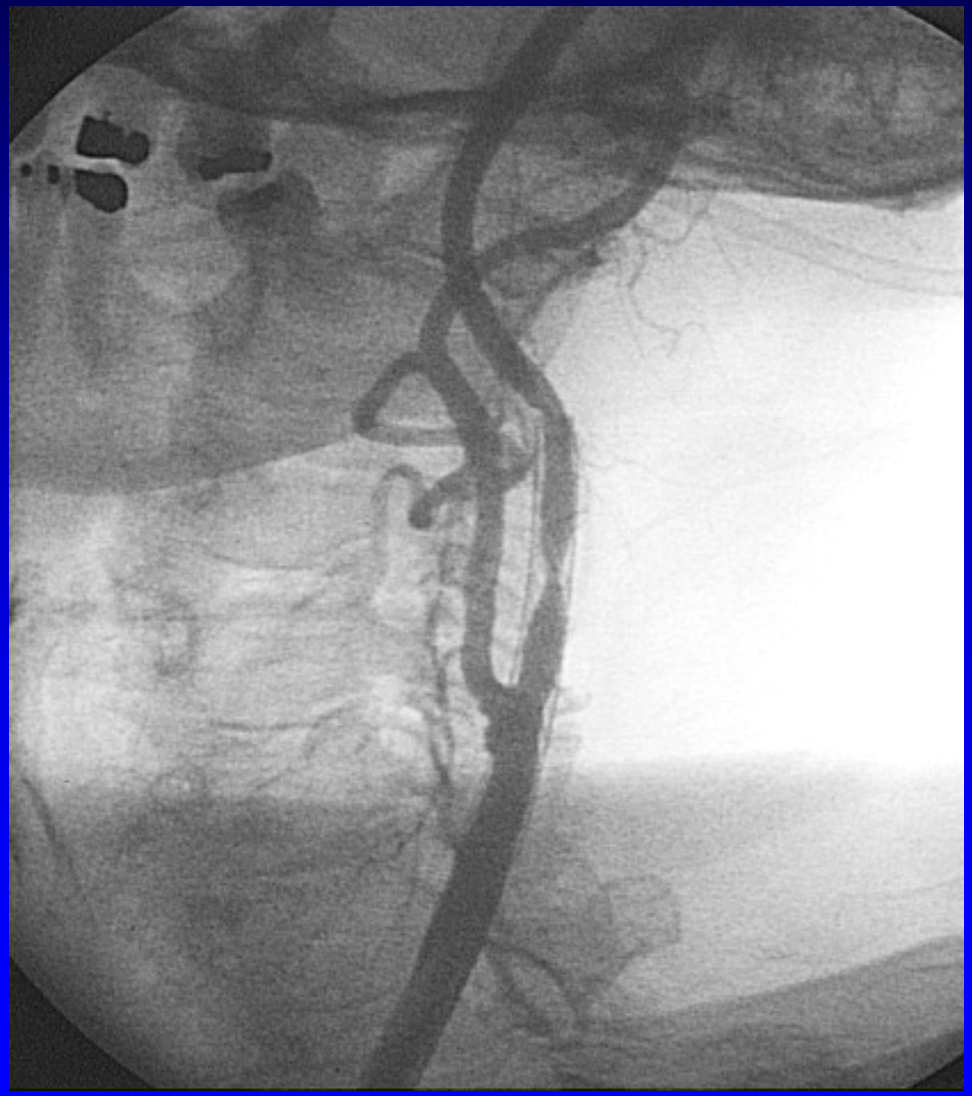
Aphasia & Weakness (left) with Right MCA Occlusion Following CAS

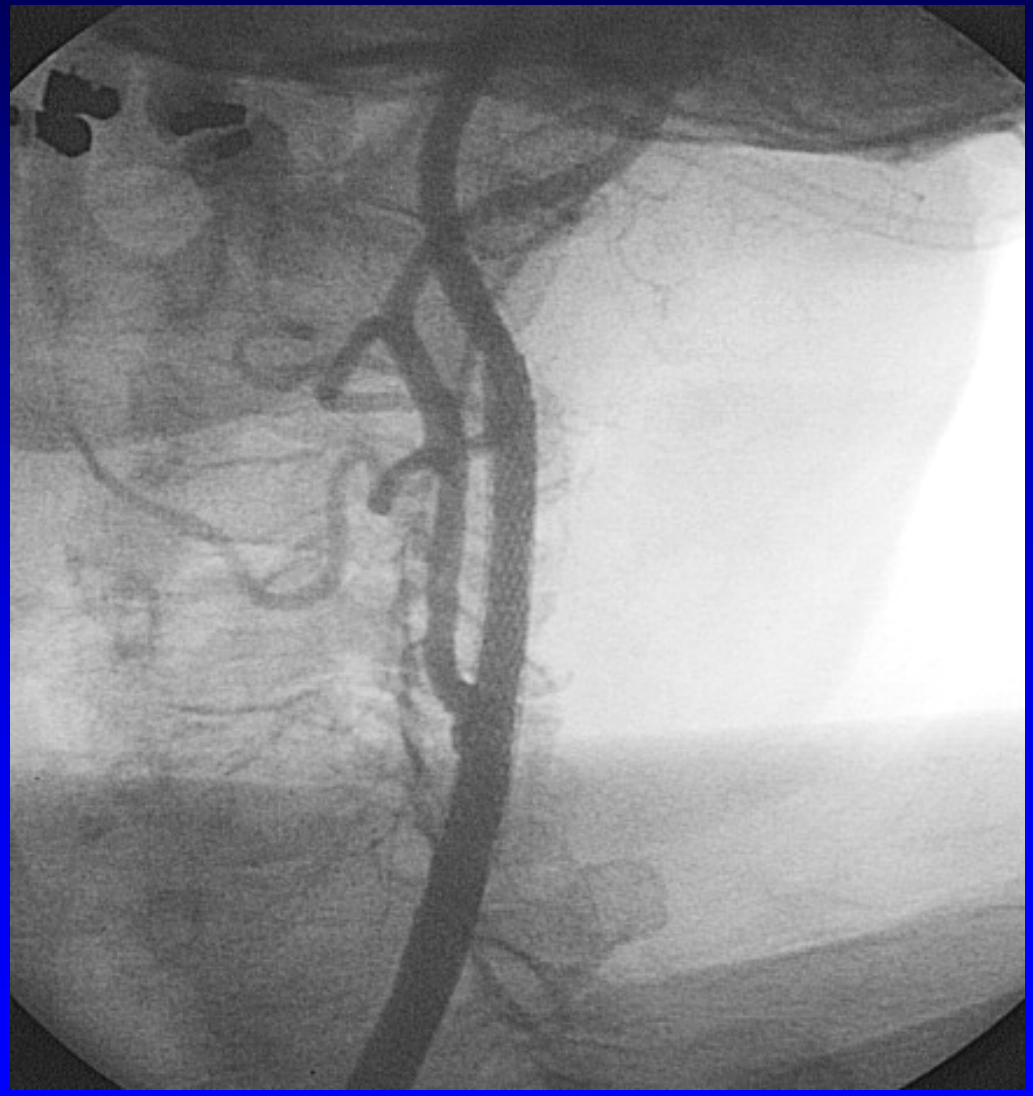
Neurovascular Rescue

- Microcatheter positioned at site of occlusion in M1 segment of MCA
- Low dose thrombolytic infusion initiated

Following Thrombolytic Therapy

Restenosis after Carotid Stenting





Restenosis after Carotid Stenting

- 122 carotid stent procedures in 118 patients from September 1996 – March 2003
- Indications for procedure:
  - Restenosis after CEA: 66%
  - High risk for surgery: 29%
  - Previous radiation: 5%
- Mean follow-up: 18.8 months (1 -74)
- Life table analysis and Kaplan-Meier curves predict restenosis rate (>80%) of 6.4% at 60 months
- Instent restenosis not associated with any neurologic symptoms

J Vasc Surg 2003;38:1162-9

Final Thoughts

- Once a “crazy idea”, carotid stenting is now a viable treatment alternative for the high risk patient
- Future and current studies (CREST and ACT 1) will determine the role of stenting for the low risk and asymptomatic patient
- Your results must be consistent with published guidelines for CEA
  - Patient selection
  - Know the equipment
  - Standardized technique
  - Know when to stop