Impact of Carotid Technique and Device Selection (Stents and Protection Systems) on Clinical Outcomes

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Outline

- **Why Do Carotid Complications Occur?**
- **Does Embolic Protection Make A Difference And What Is The Best Configuration?**
- **Does Carotid Stent Design Make a Difference?**
- **What CAS Patients Should Be Avoided?**

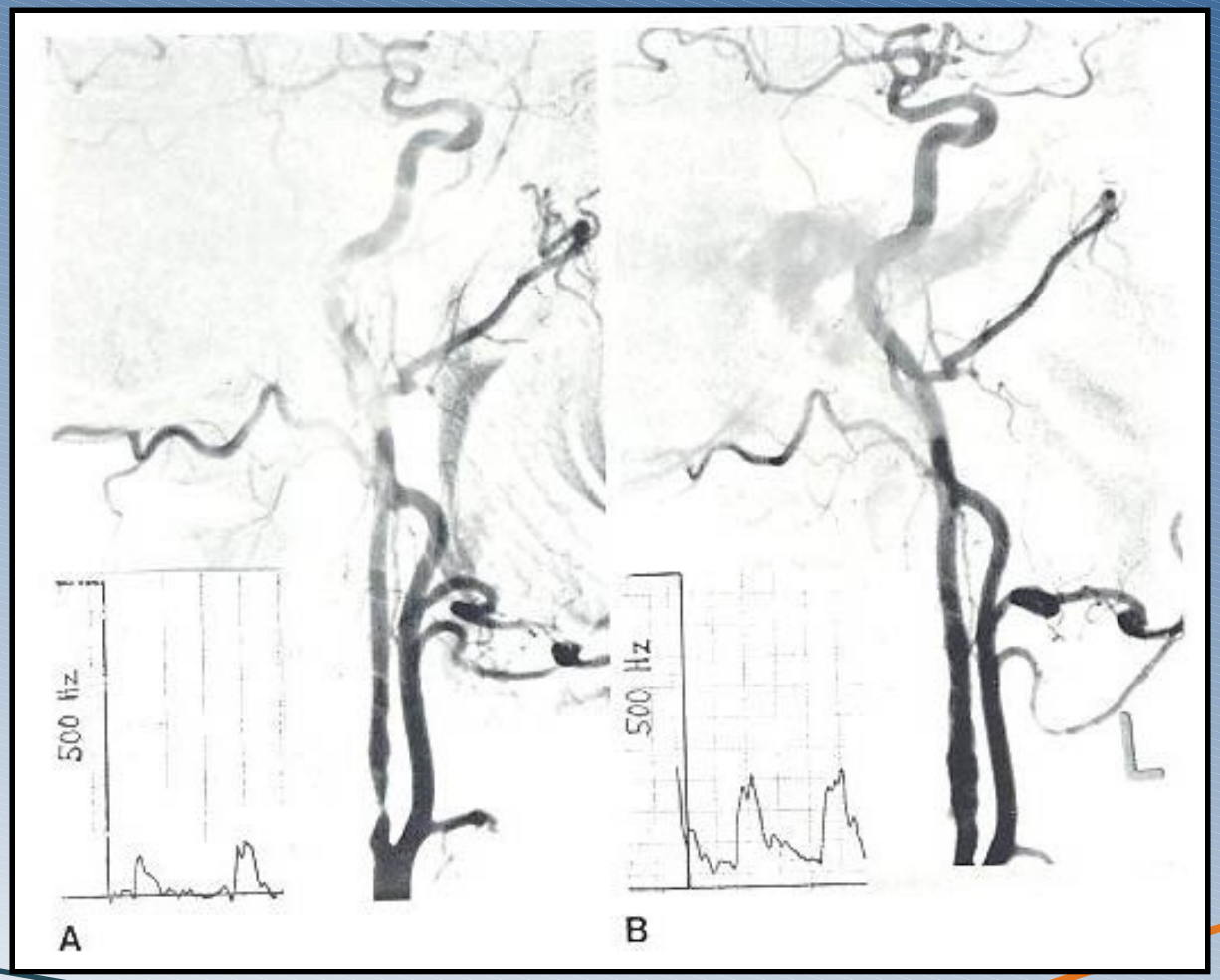
Percutaneous Transluminal Angioplasty in Arteriosclerotic Internal Carotid Artery Stenosis

Stephan A.M. Bokenheimer and Klaus Mathias

First Series of Case Reports

Bokenheimer, S.A.M., AJNR May/June 1983;4;791–792.

Carotid Angioplasty and Doppler Flow: Pre- and Post-PTA



Bokenheimer, S.A.M., AJNR May/June 1983;4;791–792.

Elective Stenting of the Extracranial Carotid Arteries

Jay S. Yadav, MD; Gary S. Roubin, MD, PhD;
Sriram Iyer, MD; Jiri Vitek, MD; Peter King, MD;
William D. Jordan, MD; Winfield S. Fisher, MD

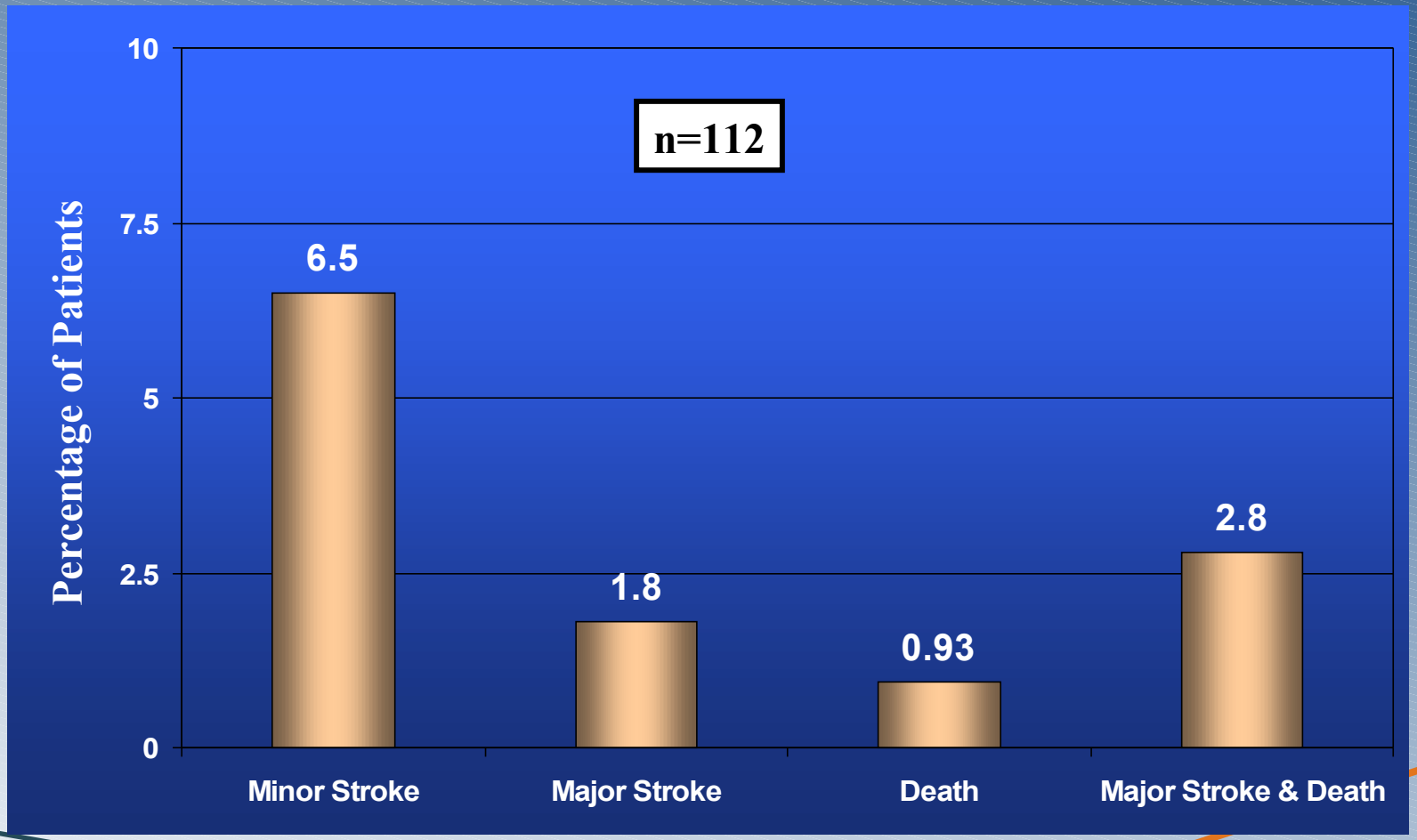
Yadav, J.S., *Circulation* 1997;95:376–381.

Methods

- **March 1994–Nov 1995**
- **77% excluded from NASCET, ACAS**
- **Symptomatic Patients > 70% stenosis**
- **Asymptomatic Patients > 60% (after ACAS)**
- **Stents:**
  - **Palmaz medium biliary stents (J&J) 69%**
  - **Flex-Stents (Cook Inc) 20%**
  - **Wallstents (Schneider) 11%**

Yadav, J.S., *Circulation* 1997;95:376–381.

Results at 30 Days



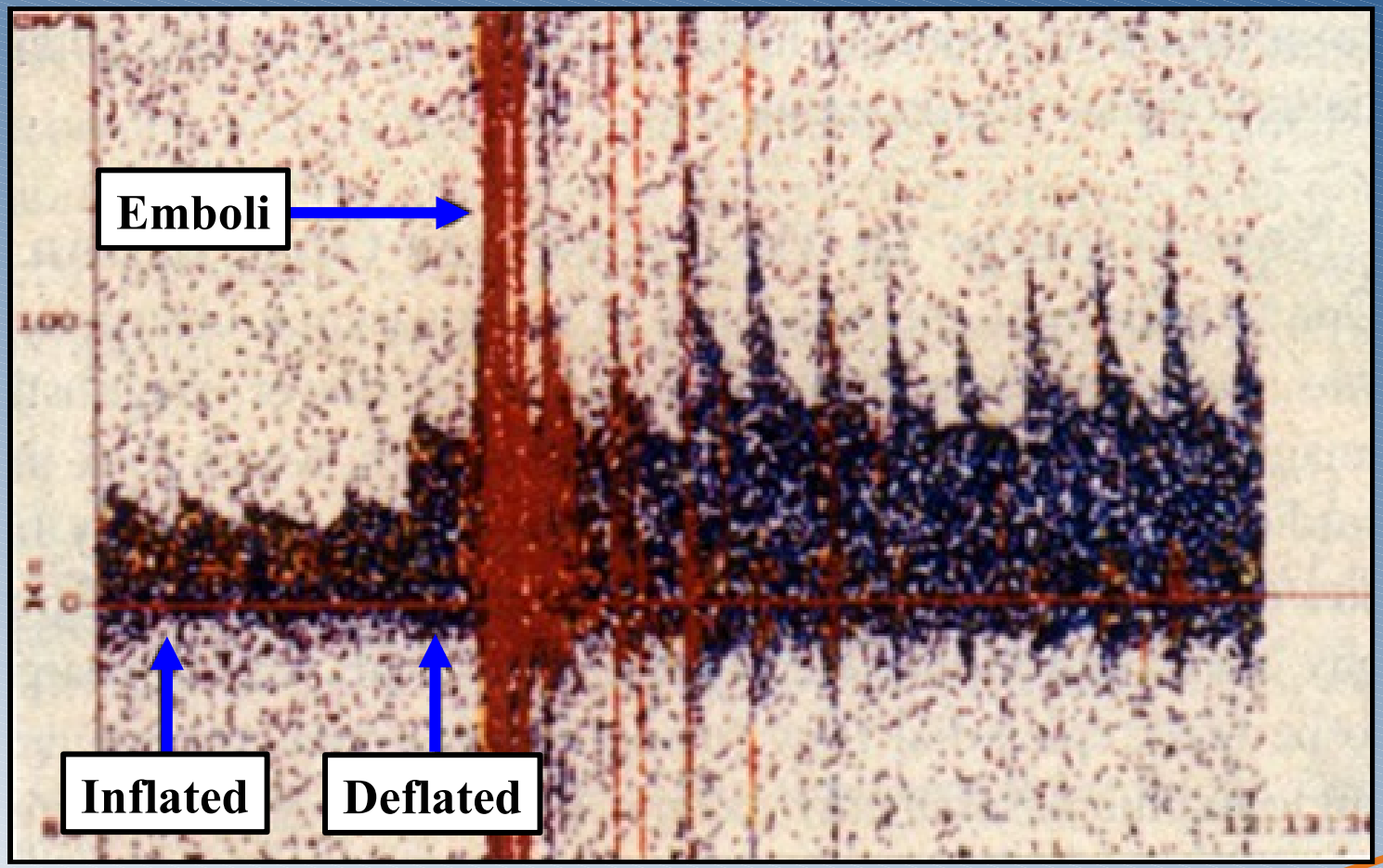
Yadav, J.S., *Circulation* 1997;95:376–381.

Why Use Embolic Protection in Carotid Artery Stenting?

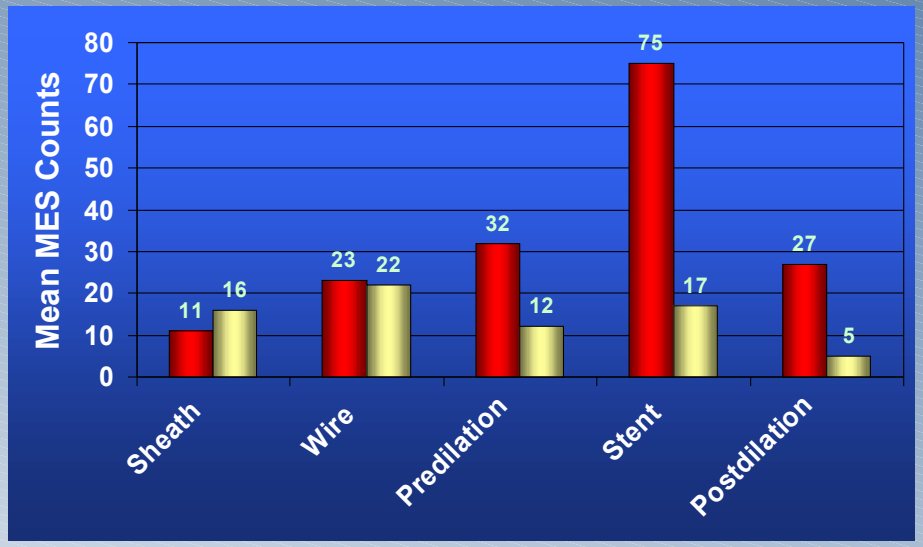
The main cause of complications is . . .

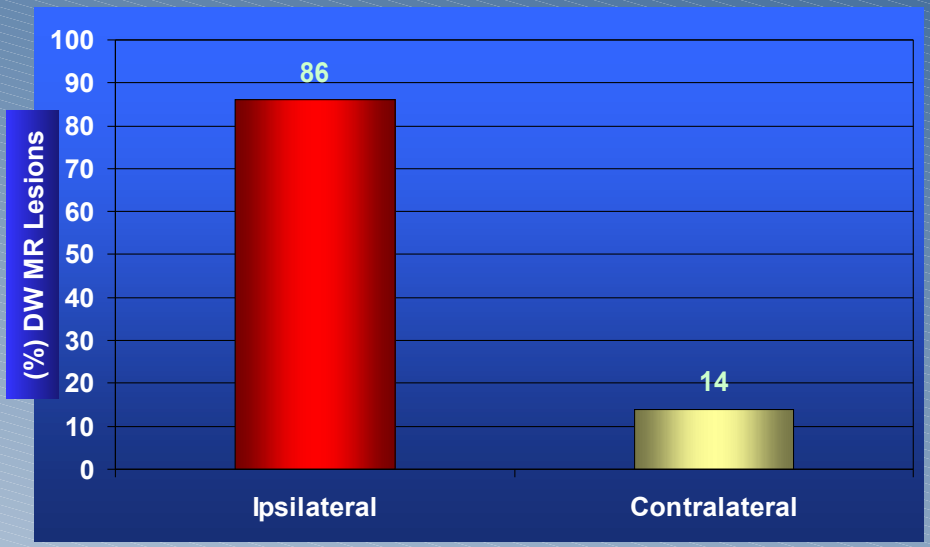
Cerebral Embolization

Transcranial Doppler During CAS



Microembolic Profile During CAS and New (DW) MR Lesions After CAS



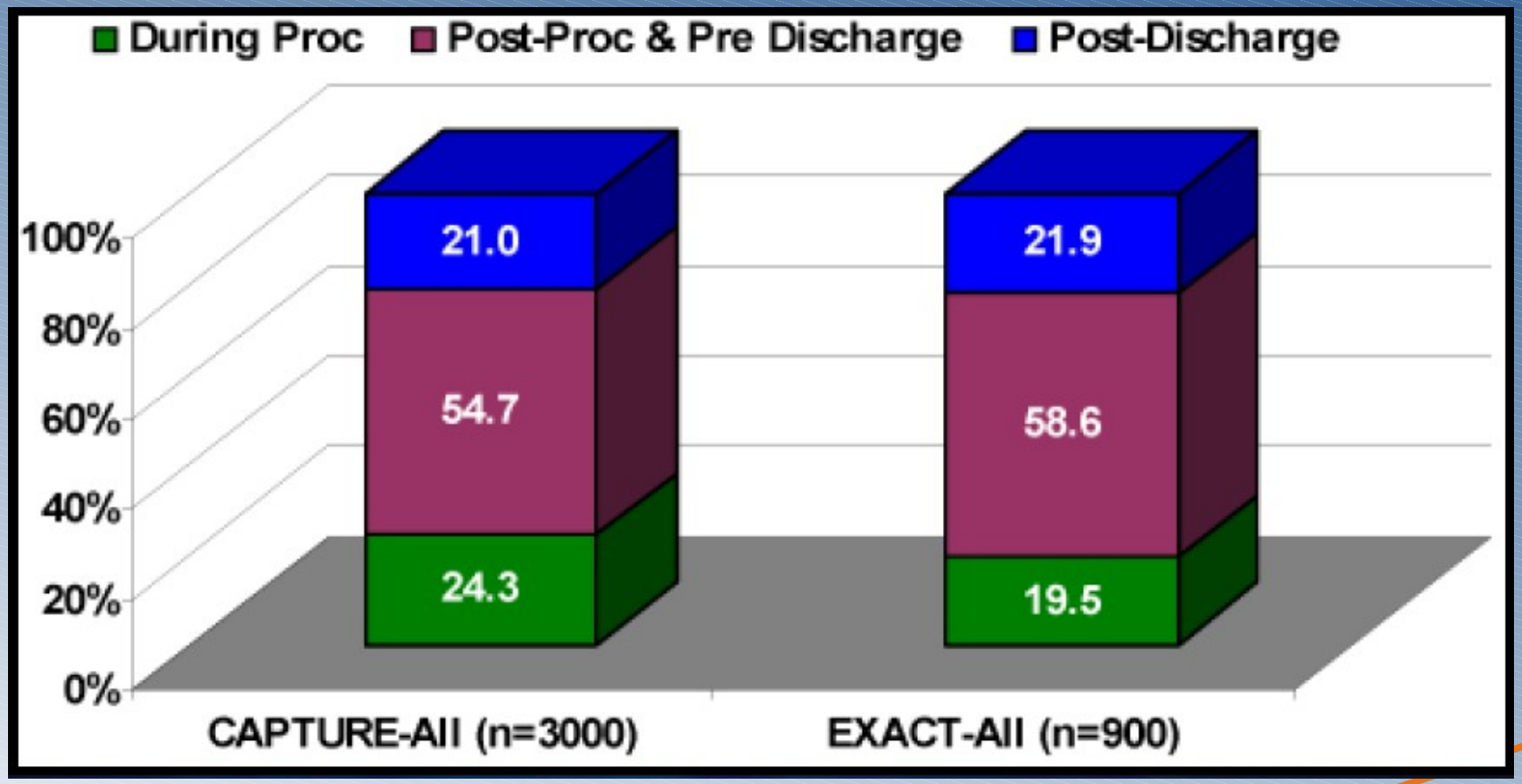


No protection PercuSurge

Al Mubarak, *Circulation* 2001;104:1999–2002.

Mathias, K., AJNR Oct. 2005;26:2336–2341.

CAPTURE 3000 Vs. EXACT 900: Timing of Stroke

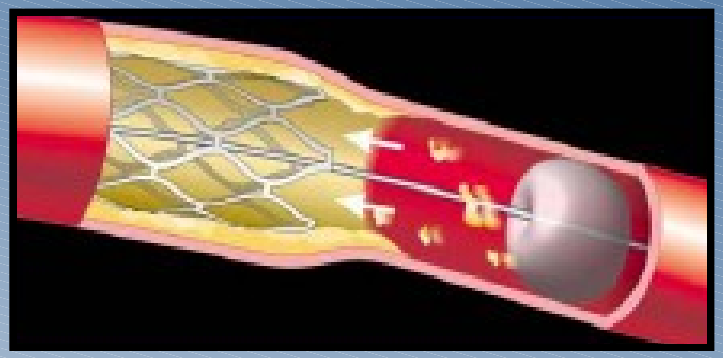


The Majority of Strokes Occur Post-Procedure and Before Discharge

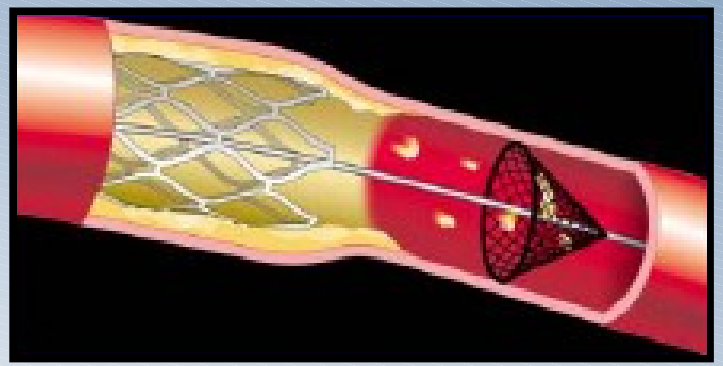
Selection of EPD

- **Filter devices**
- **Distal balloon occlusions**
- **Proximal protection**

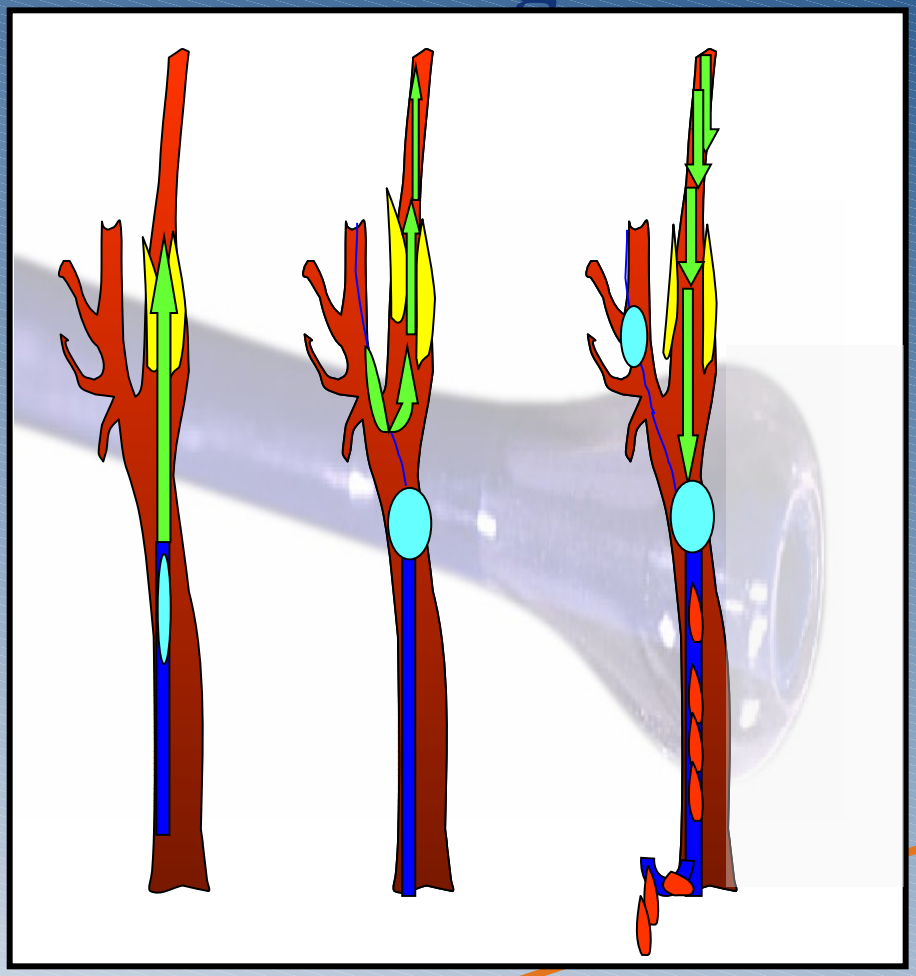
Therapeutic Options: Current Embolic Protection Categories



Distal Occlusive Devices



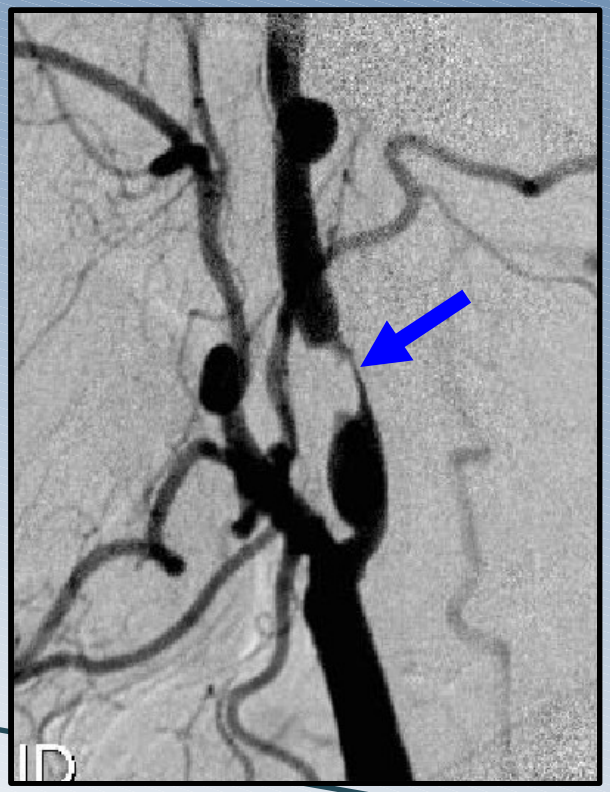
Distal Filters

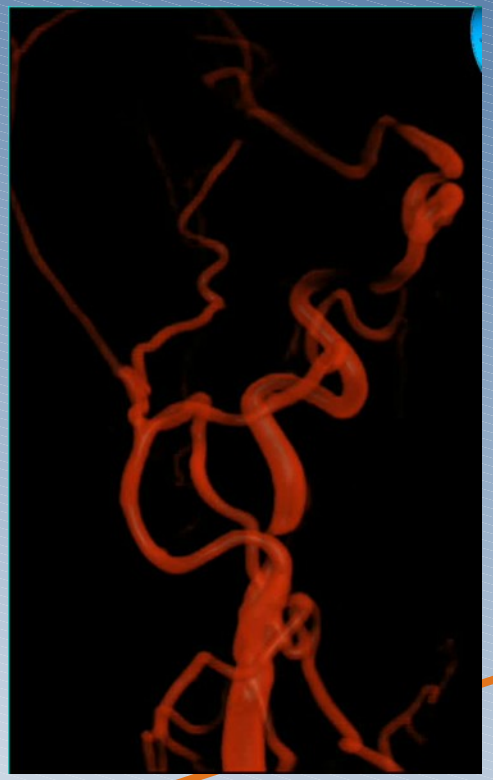


Proximal Occlusion and Flow Reversal

Right ICA

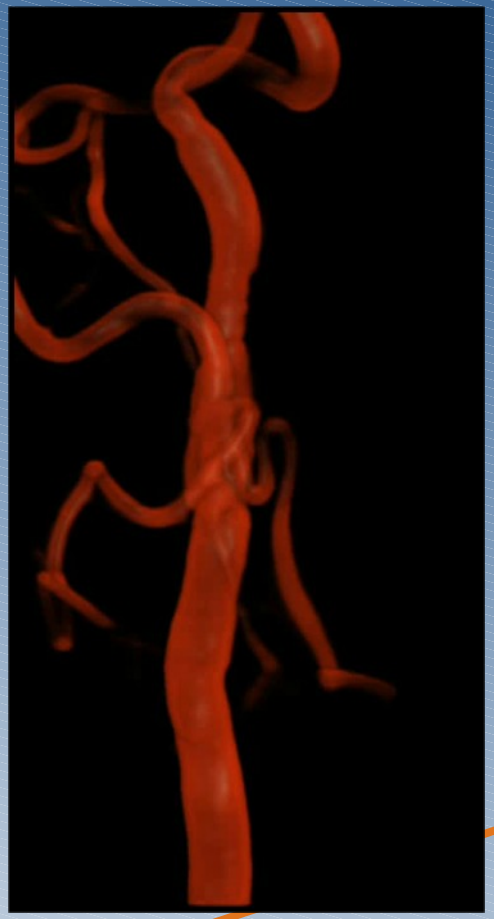
- 59 YO with h/o CABG and St. Jude AVR
- RCEA 6 years ago
- Amaurosis fugax despite therapeutic INRs





McCormick, D.J.

GuardWire — PercuSurge EPD



Embolic Protection Devices

Balloon Occlusion Devices

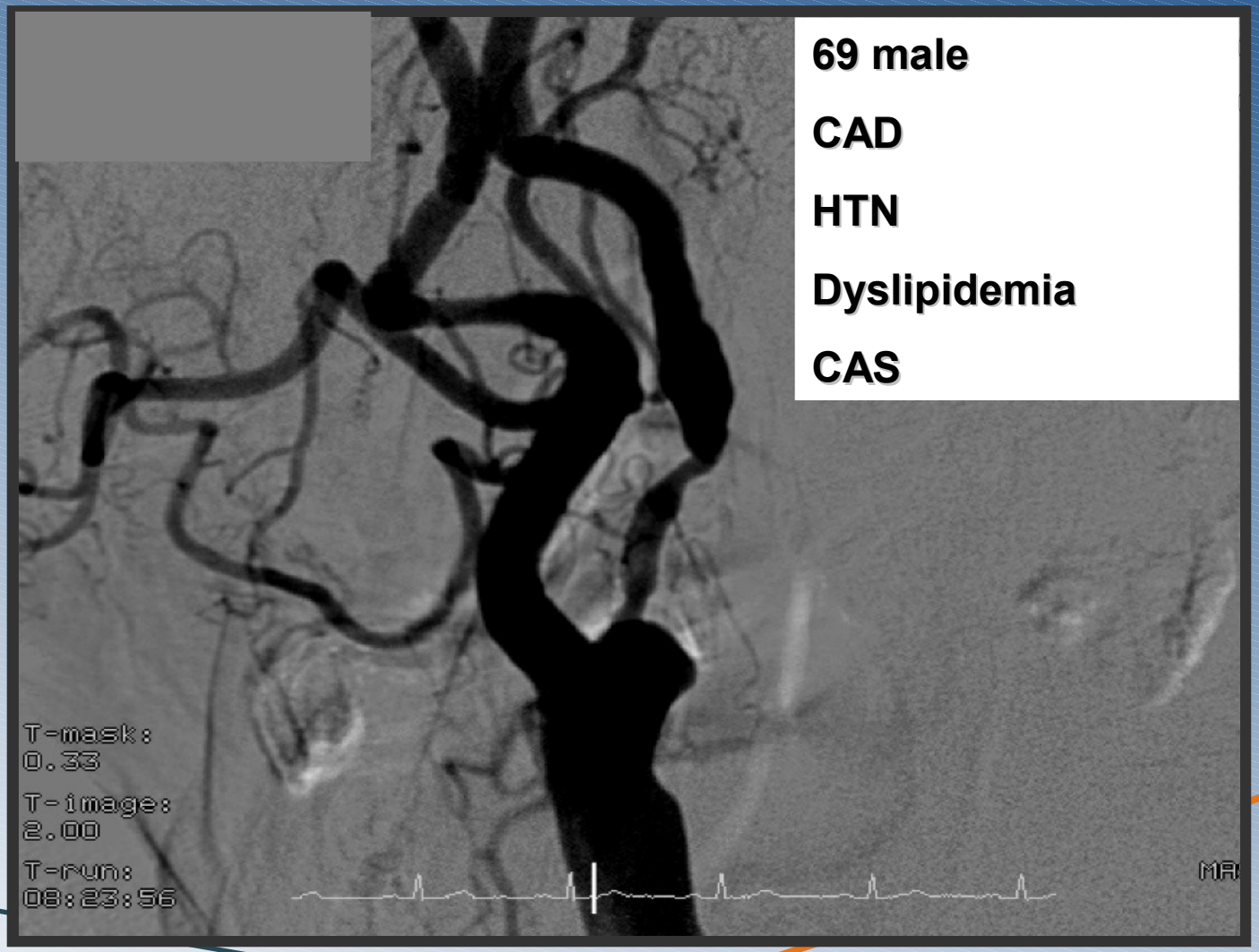
Advantages

- Easy to cross lesion
- Compatible with devices
- Aspirate large and small particles
- Reliably trap debris
- Easy device retrieval

Disadvantages

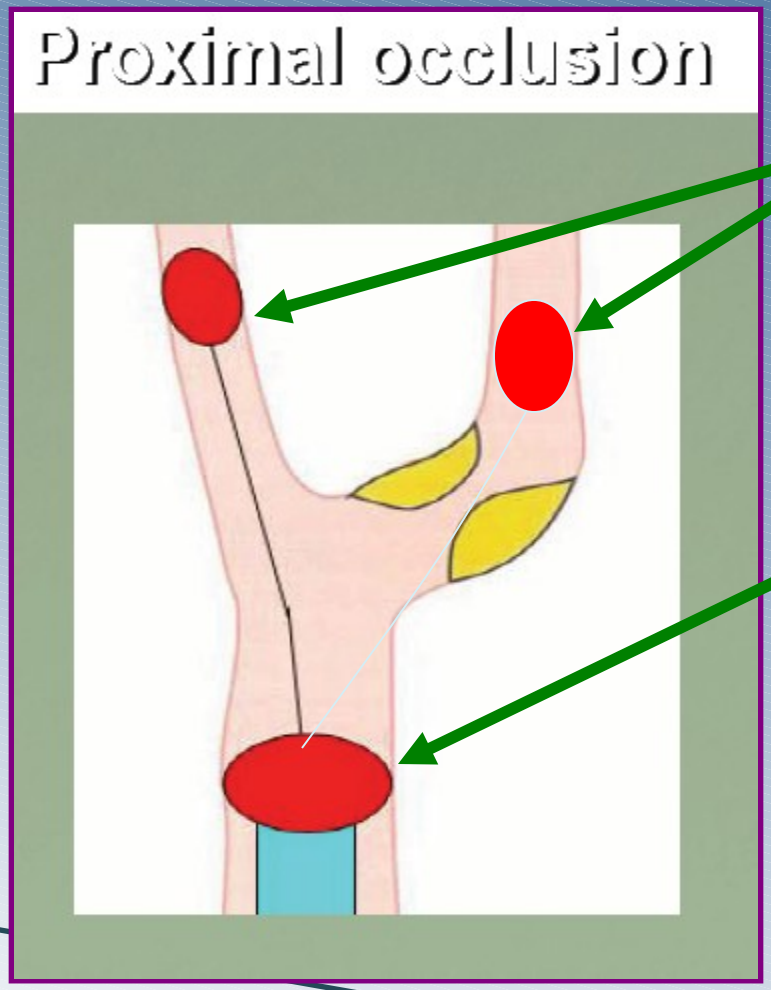
- No antegrade flow
- 5–8% are intolerant
- Balloon-induced injury
- Not as steerable as PTCA wires
- Difficult to image during the procedure

Proximal Protection



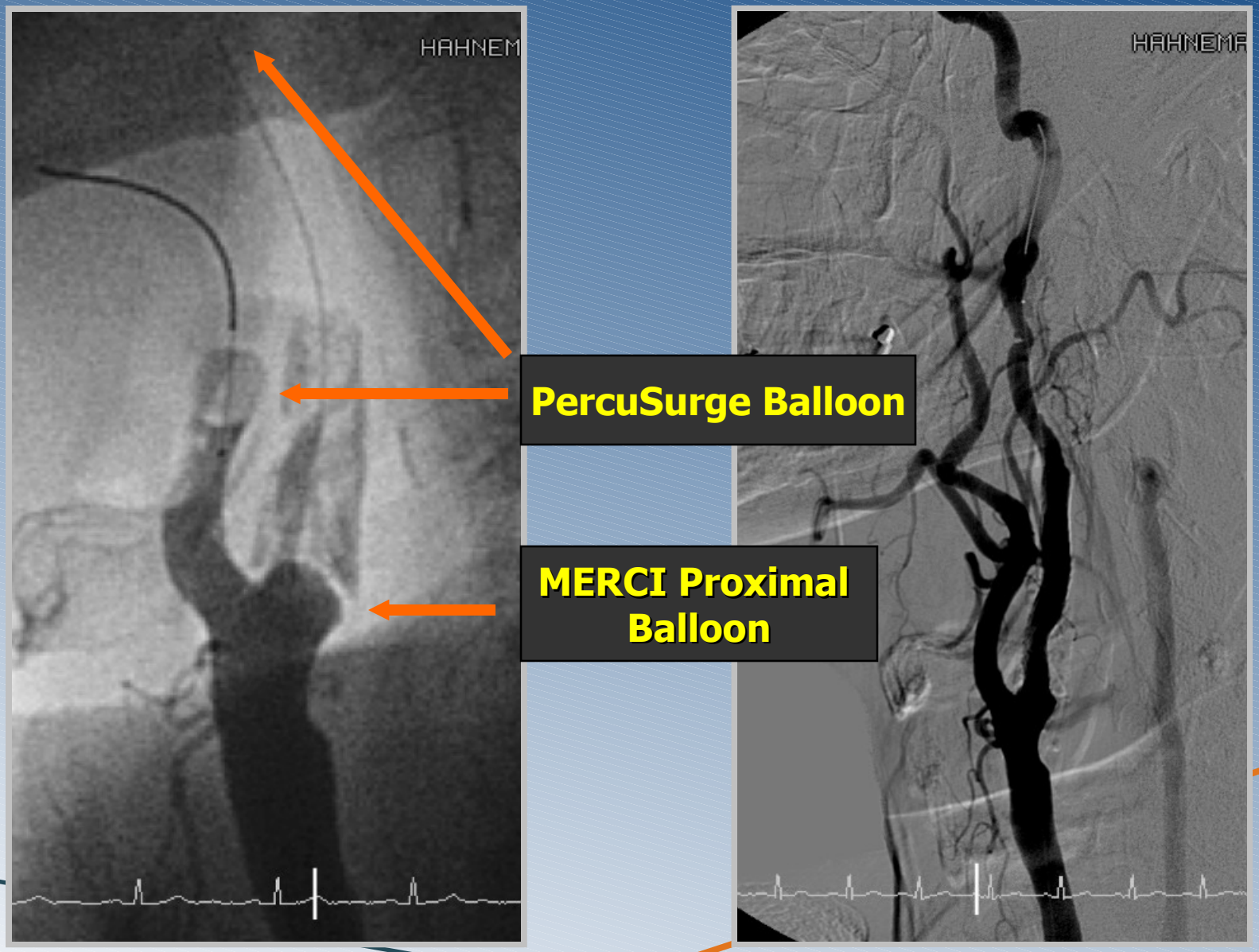
McCormick, DJ TCTmd.com 2006

Merci® Balloon Guide Catheter



PercuSurge Device or FilterWire

Merci® Balloon Guide Catheter 8F or 9F


PercuSurge Balloon
MERCI Proximal Balloon

Distal Embolic Protection Devices

Filter Devices

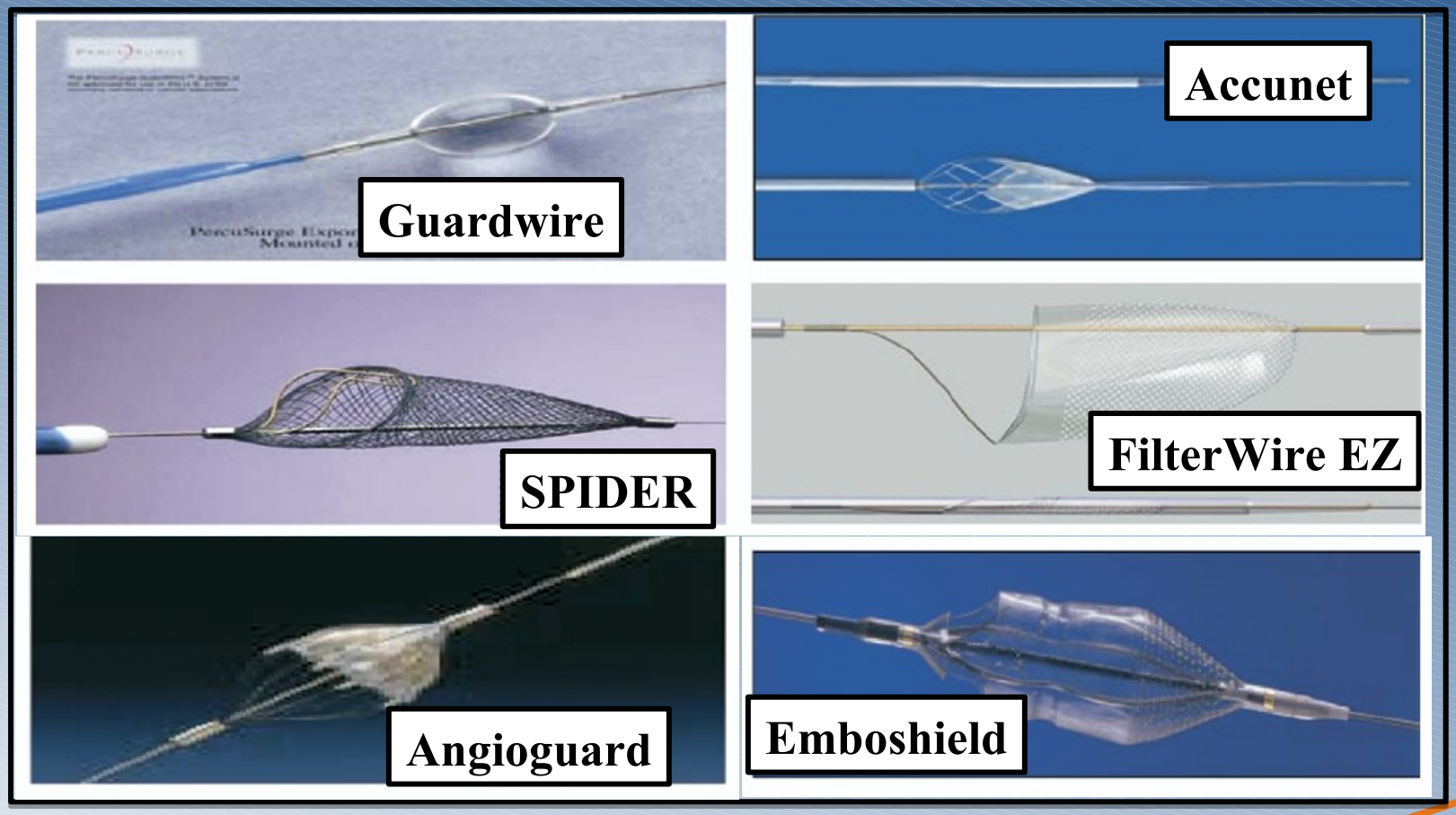
Advantages

- Preserve antegrade flow
- Contrast imaging is possible throughout the procedure

Disadvantages

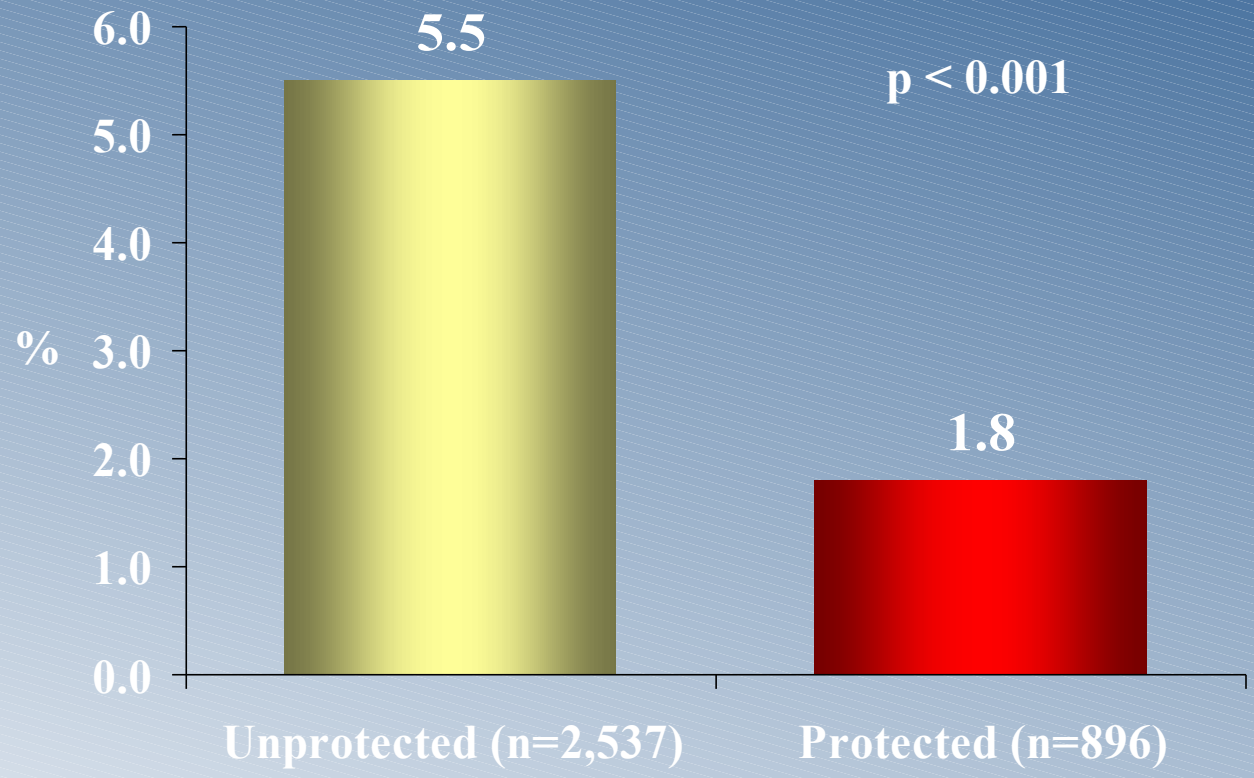
- May not capture all debris
- Filters may clog, cause spasm
- Delivery catheters may cause embolization before filter deployment
- Retrieval sheath may snag on stents

Current DPDs in Use



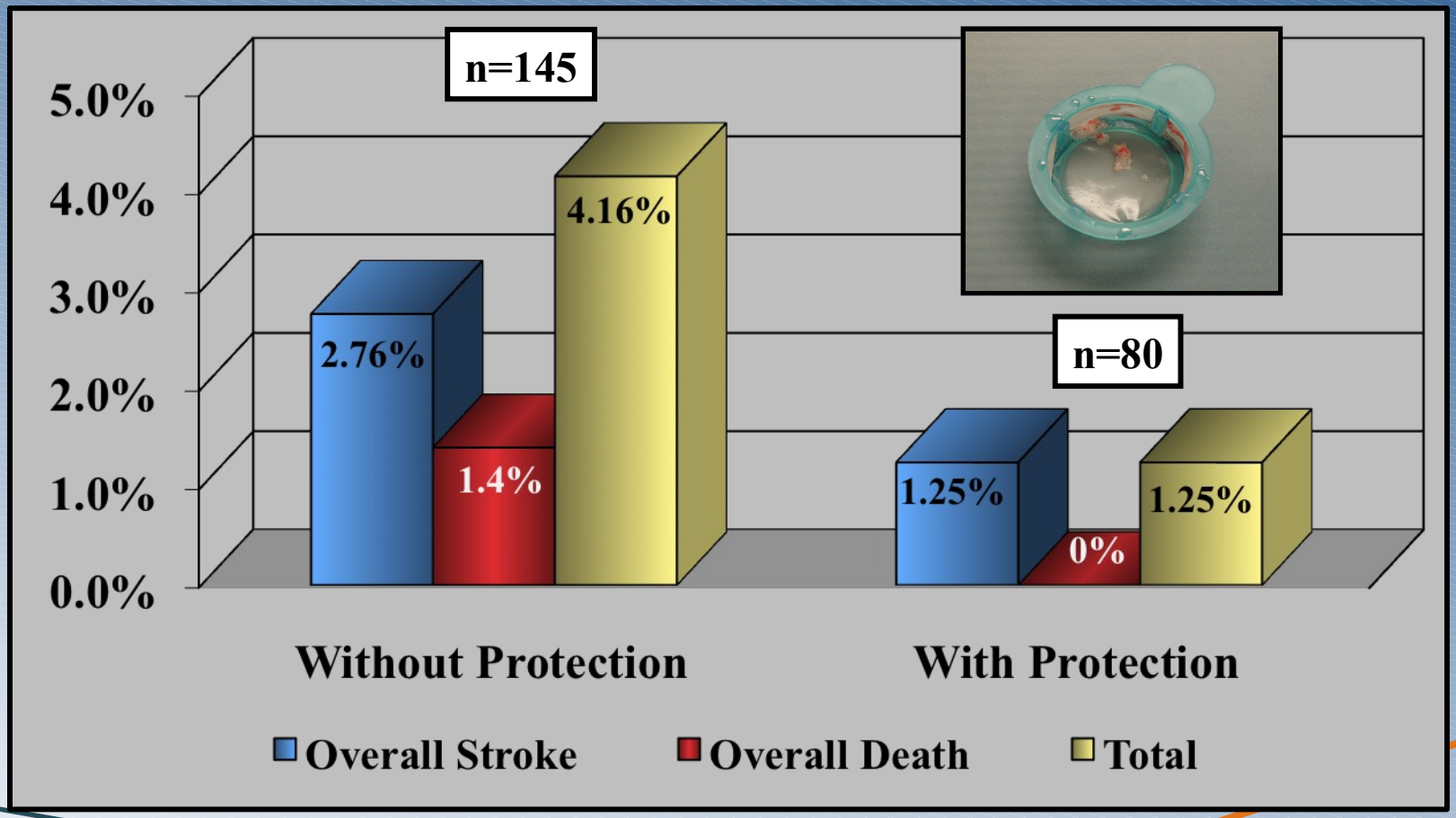
Death and Stroke With and Without CPD

"A Systematic Review of the Literature"



Kastrup, A., et al. *Stroke* 2003;34:813–819.

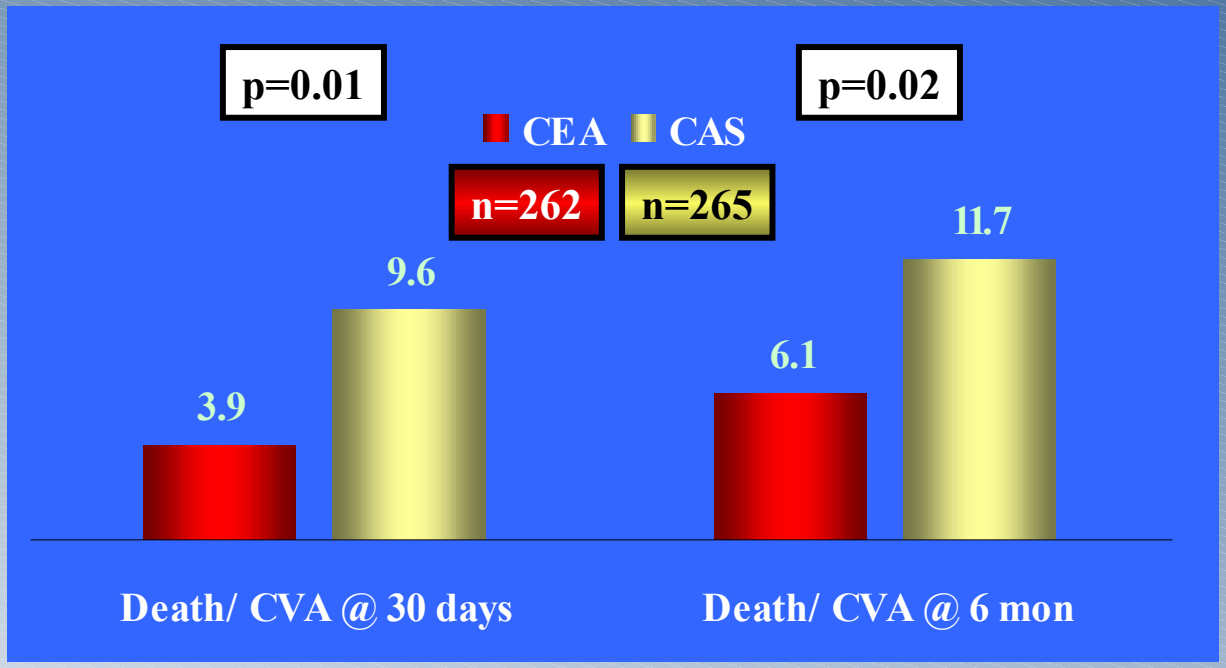
Combined Stroke and Death Outcomes (One Month)



McCormick, D.J., *Catherization and Cardiovascular Interventions* 2003;59:122.

EVA-3S

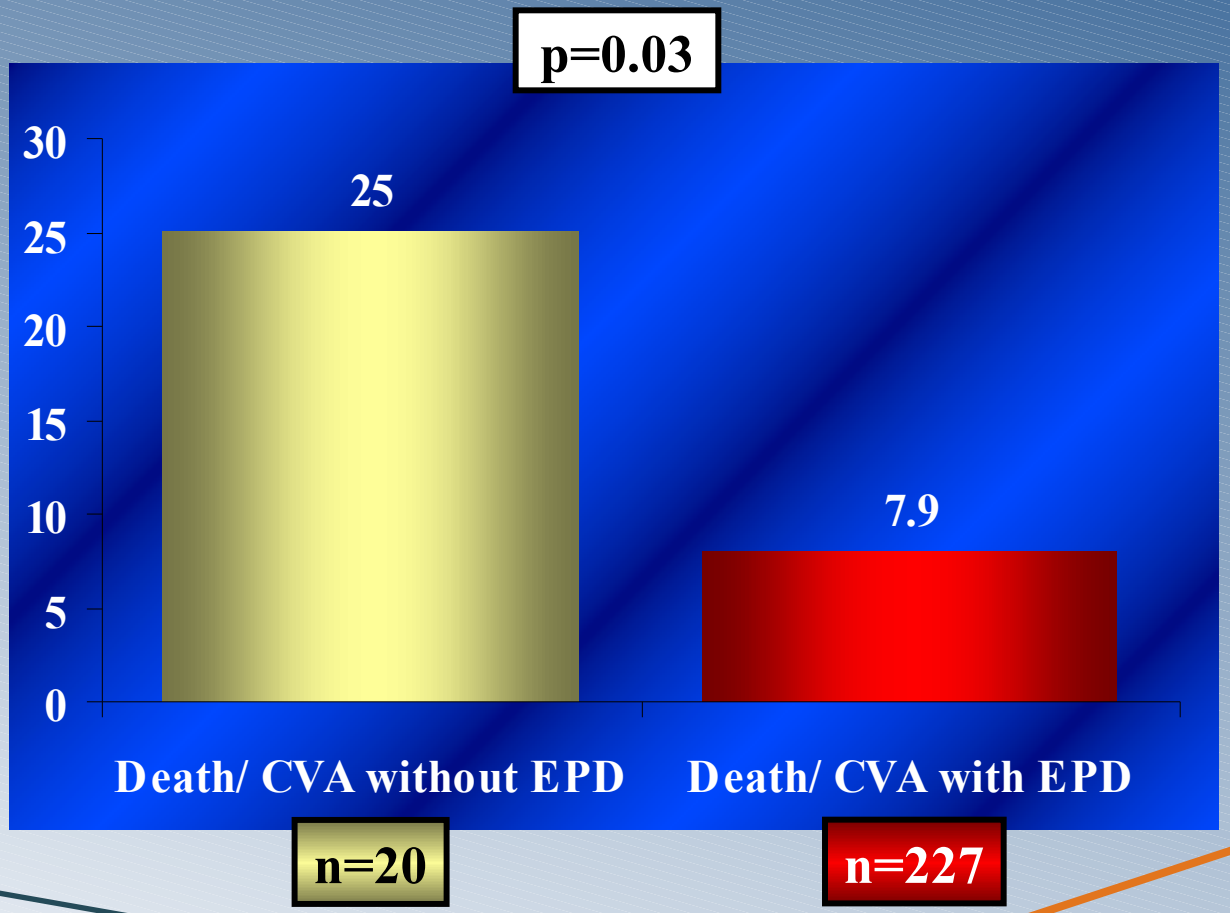
Symptomatic Carotid Stenosis > 60% (n=527)



Mas, J.L., NEJM 2007;355:1660.

EVA-3S

Symptomatic Carotid Stenosis > 60% (n=527)



Mas, J.L., NEJM 2006;355:1660.

EVA-3S: Learning Curve

The Type of Embolic Protection Does Not Influence the Outcome in Carotid Artery Stenting

Vikram Iyer, MD, Gianmarco de Donato, MD, Koen Deloose, MD, Patrick Peeters, MD, Fausto Castriota, MD, Alberto Cremonesi, MD, Carlo Setacci, MD, and Marc Bosiers, MD

Iyer, et al, *J Vasc Surg* 2007;46:251–6.

30-Day Events (TIA, Stroke, and Death)

Comparison	RR	95% CI	*p*
Proximal occlusion vs. filter			
• Unadjusted	1.52	0.75–3.13	1.00
• Adjusted for RF, ST	1.59	0.71–3.10	1.00
Distal occlusion vs. filter			
• Unadjusted	2.72	0.71–10.51	0.96
• Adjusted for RF, ST	3.38	0.55–10.87	0.54
Distal vs. proximal occlusion			
• Unadjusted	1.79	0.40–7.96	1.00
• Adjusted for RF, ST	1.79	0.40–7.96	1.00
Eccentric vs. concentric filter			
• Unadjusted	0.59	0.38–0.92	0.04
• Adjusted for RF, ST	0.76	0.47–1.22	0.51

Iyer, et al, *J Vasc Surg* 2007;46:251–6.

FiberNet®
A New 3-D Filter: (Lumen Biomedical)

- **Ability to allow flow during the procedure (FILTER)**
- **Capability to capture emboli (FILTER)**
- **Captures all small particles (OCCLUSION BALLOON)**
- **Very deliverable as a standard coronary guidewire (0.014)**
- **Capture embolic particles in a “3-dimensional filter”**

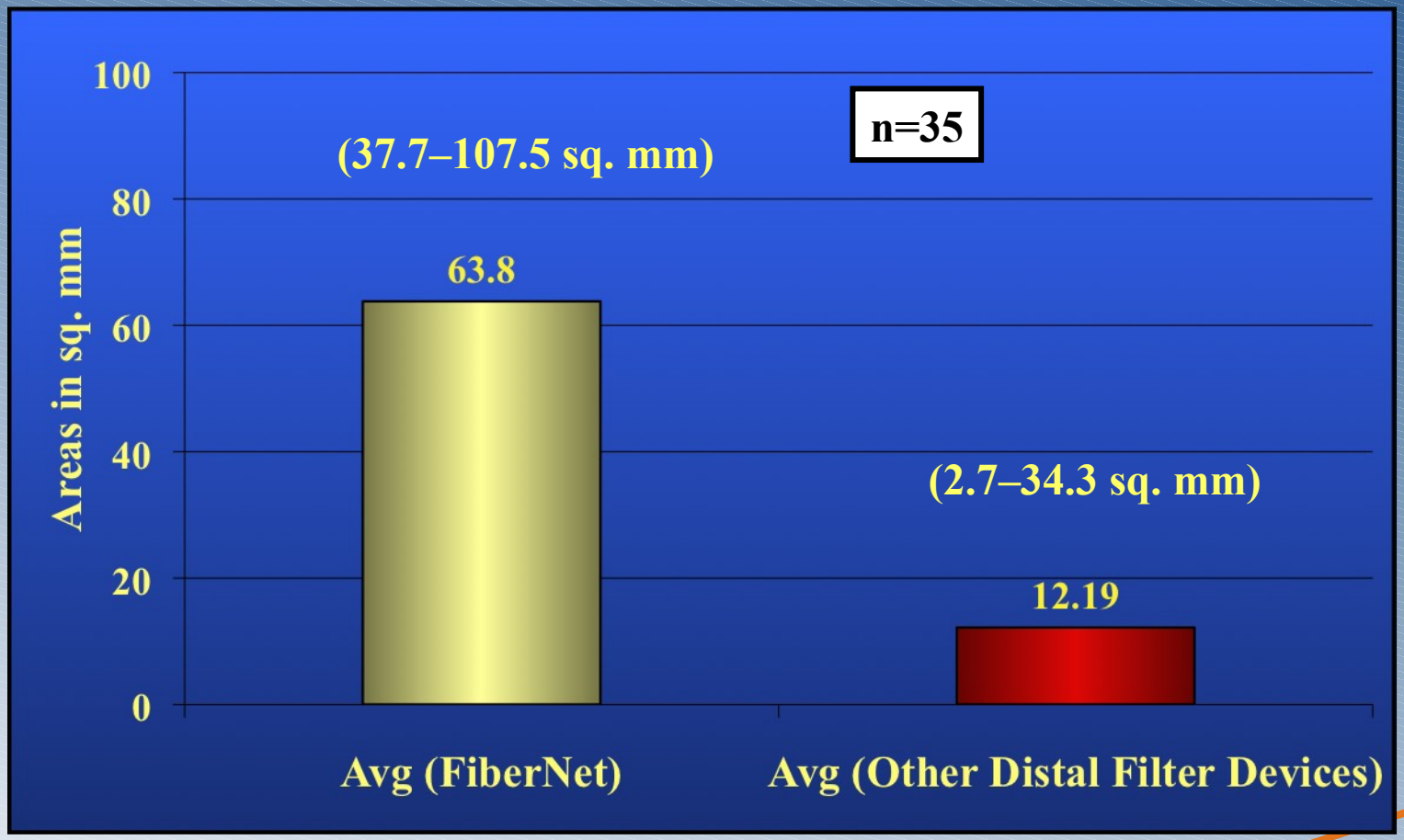
New Distal Embolic Protection Device

The FiberNet® 3 Dimensional Filter: First Carotid Human Study

Michel Henry, Antonios Polydorou, Isabelle Henry, Jerry Sedgewick, and George Ruth

Michel Henry, *Catheterization and Cardiovascular Interventions* 2007;69:1026–1035.

Mean Surface Area of Particulate Caught via FiberNet® System

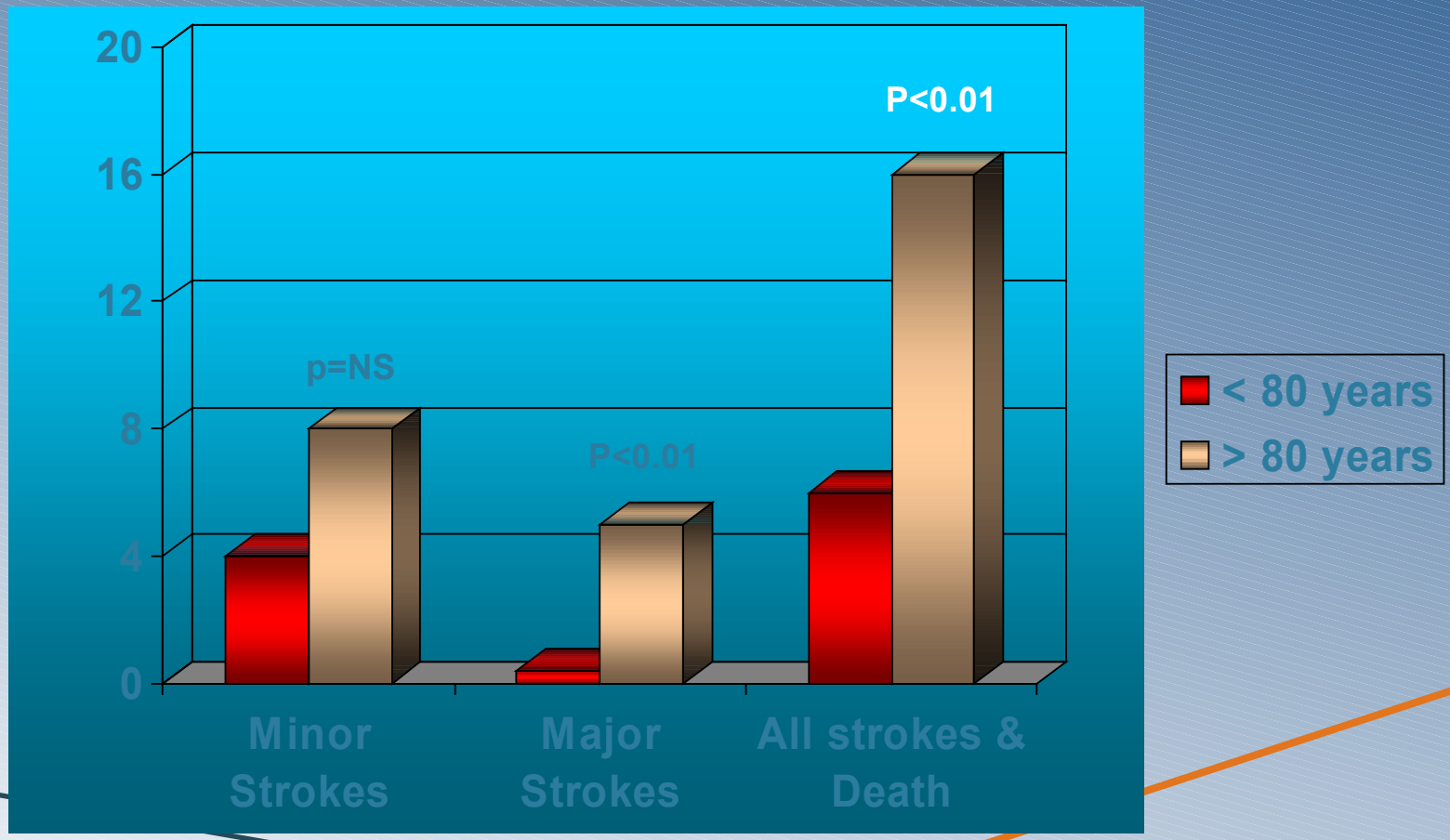


FiberNet System vs. other distal filter devices

Michel Henry, *Catheterization and Cardiovascular Interventions* 2007;69:1026–1035.

Carotid Artery Stenting in the Elderly (Octogenarians)

Thirty-Day Outcomes in Patients <80 Versus >80 yrs of Age



Roubin GS, Circulation 2001;103;532-537

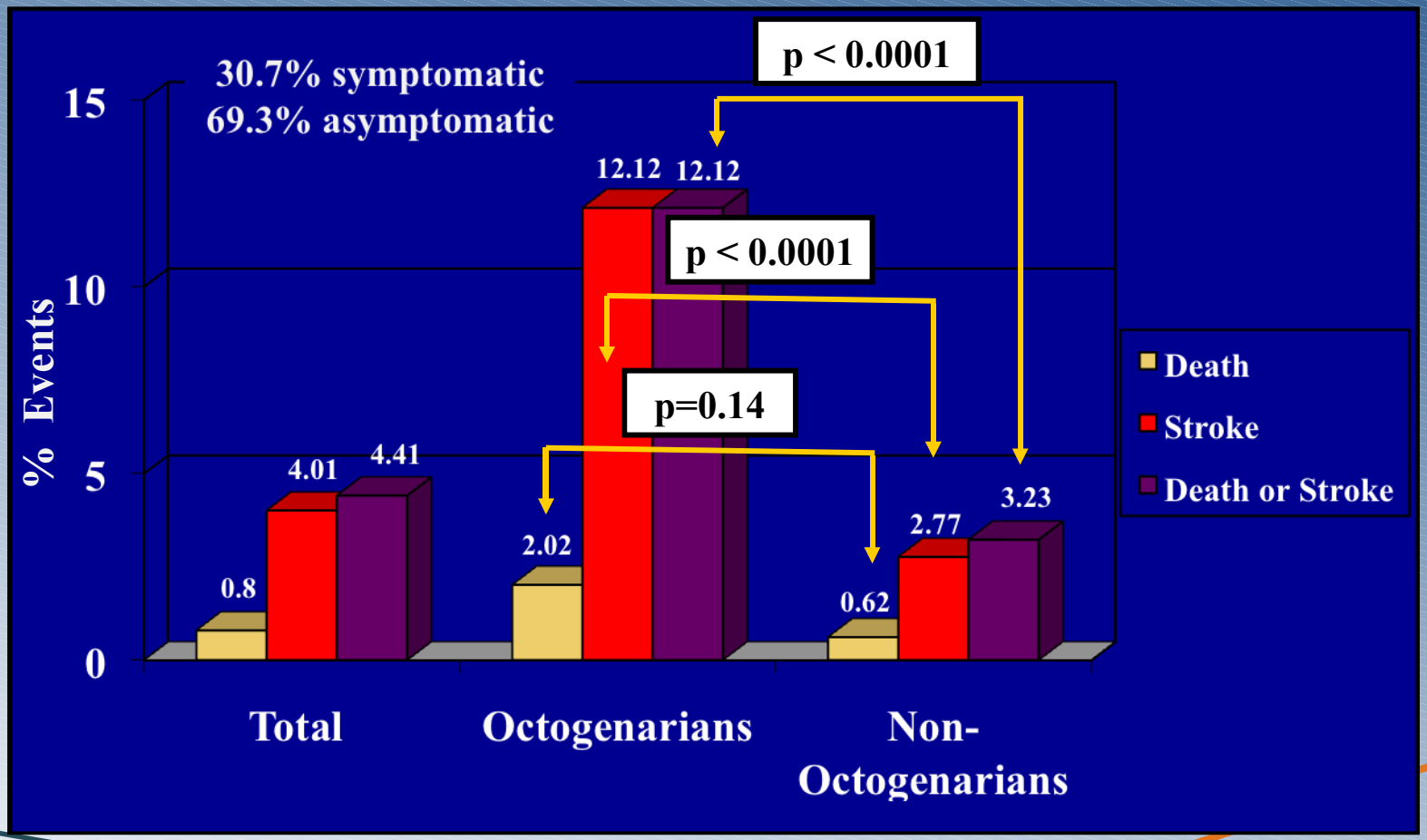
The CREST Lead-In Phase

Carotid artery stenting is associated with increased complications in octogenarians: 30-day stroke and death rates in the CREST lead-in phase

Robert W. Hobson II, MD; Virginia J. Howard, MSPH; Gary S. Roubin, MD, PhD; Thomas G. Brott, MD; Robert D. Ferguson, MD; Jeffrey J. Popma, MD; Darlene L. Graham; and George Howard, MD, PhD; the CREST Investigators

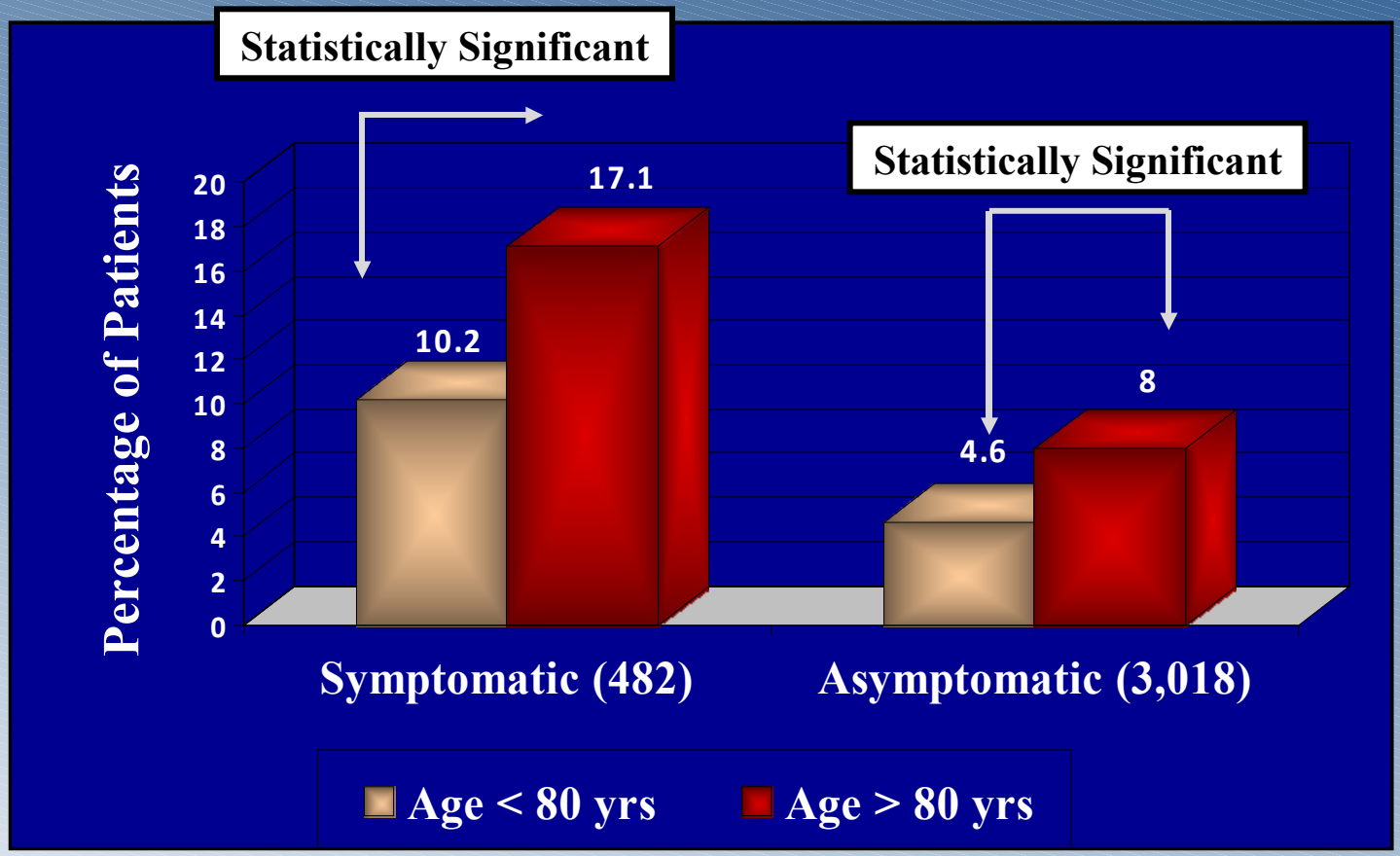
Hobson, R.W., at al, *J Vasc Surg* 2004;40:1106–11.

Death and Stroke Within 30 Days of Stent Procedure — CREST Lead-In Phase



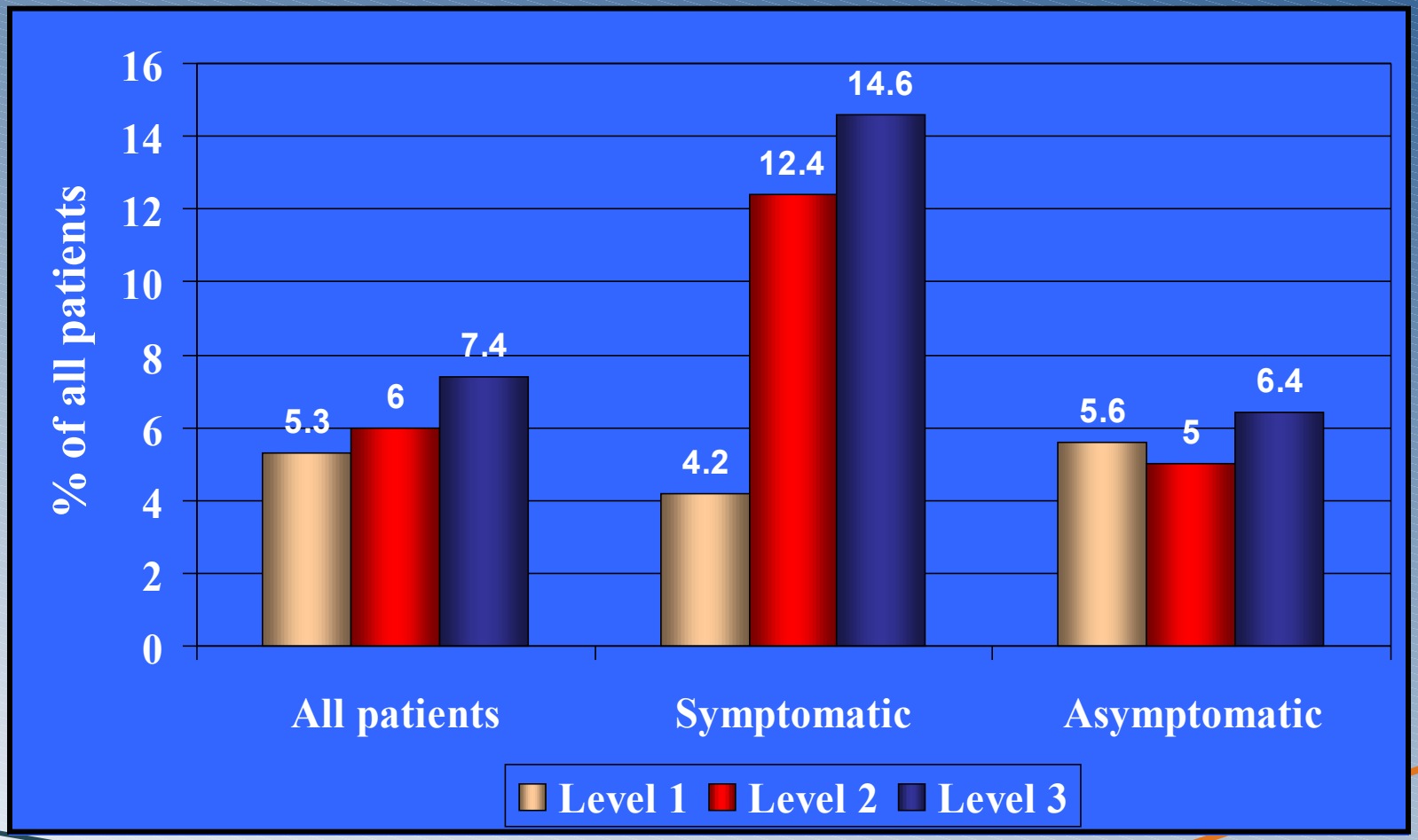
Hobson, R.W., at al, *J Vasc Surg* 2004;40:1106–11.

Death, Stroke, and MI



Gray, W.A., et al, *Catheterization and Cardiovascular Interventions* 2007;70:1025–1033.

DSMI by Physician Level by Symptomatic Status



Gray, W.A., *Catheterization and Cardiovascular Interventions* 2007;69: 341–348.

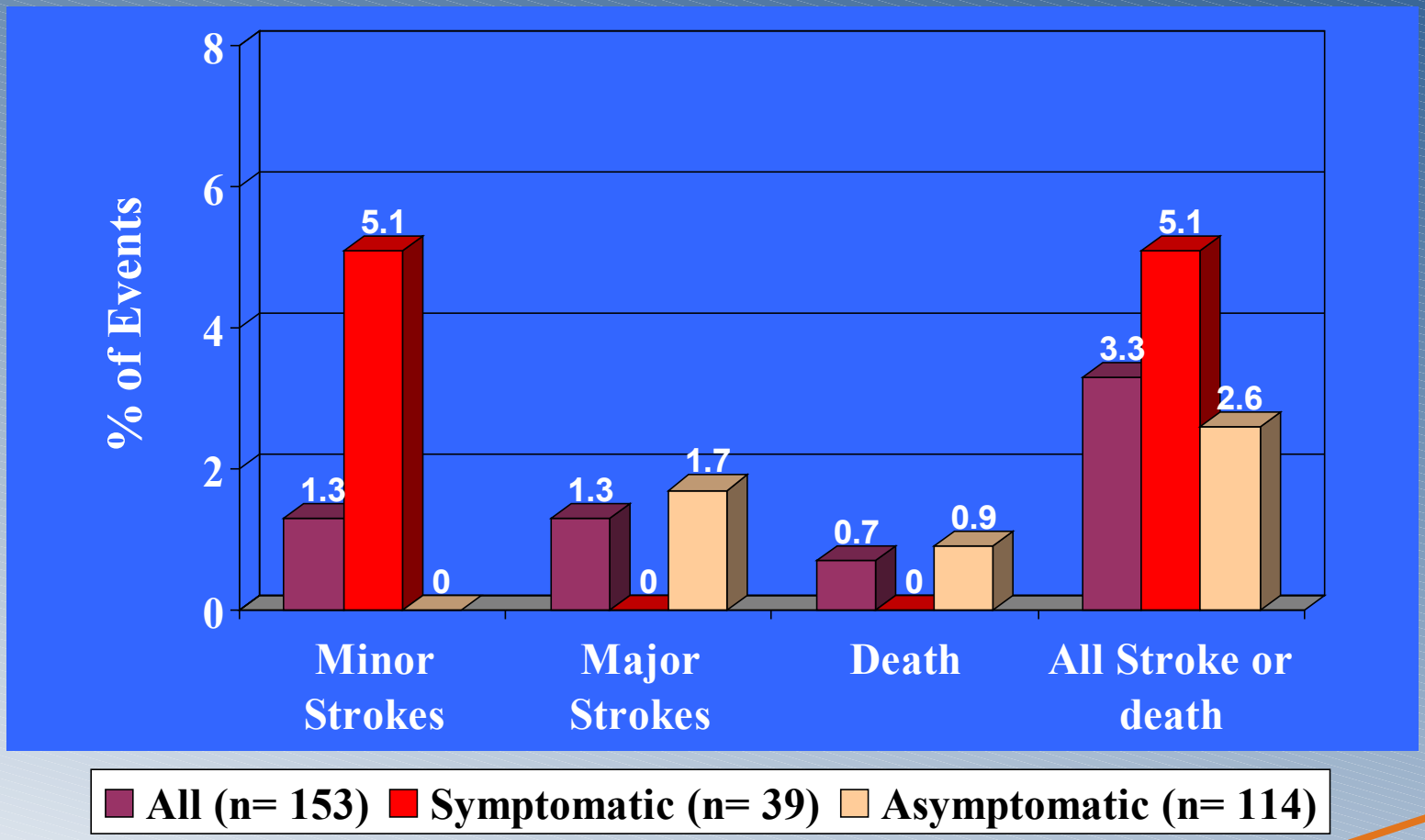
Markers of Increased Risk During Carotid Stenting

	Risk Factor	Features
Clinical	Advanced age	Age ≥ 80 years
	Decreased cerebral reserve	• Prior large stroke • Multiple lacunar infarcts • Intracranial microangiopathy • Dementia
Angiographic	Excessive tortuosity	≥ 2 90° bends within 5 cm of the lesion
	Heavy calcification	Concentric calcification; width ≥ 3 mm

≥ 2 Risk Factors ~ High Risk for Complications

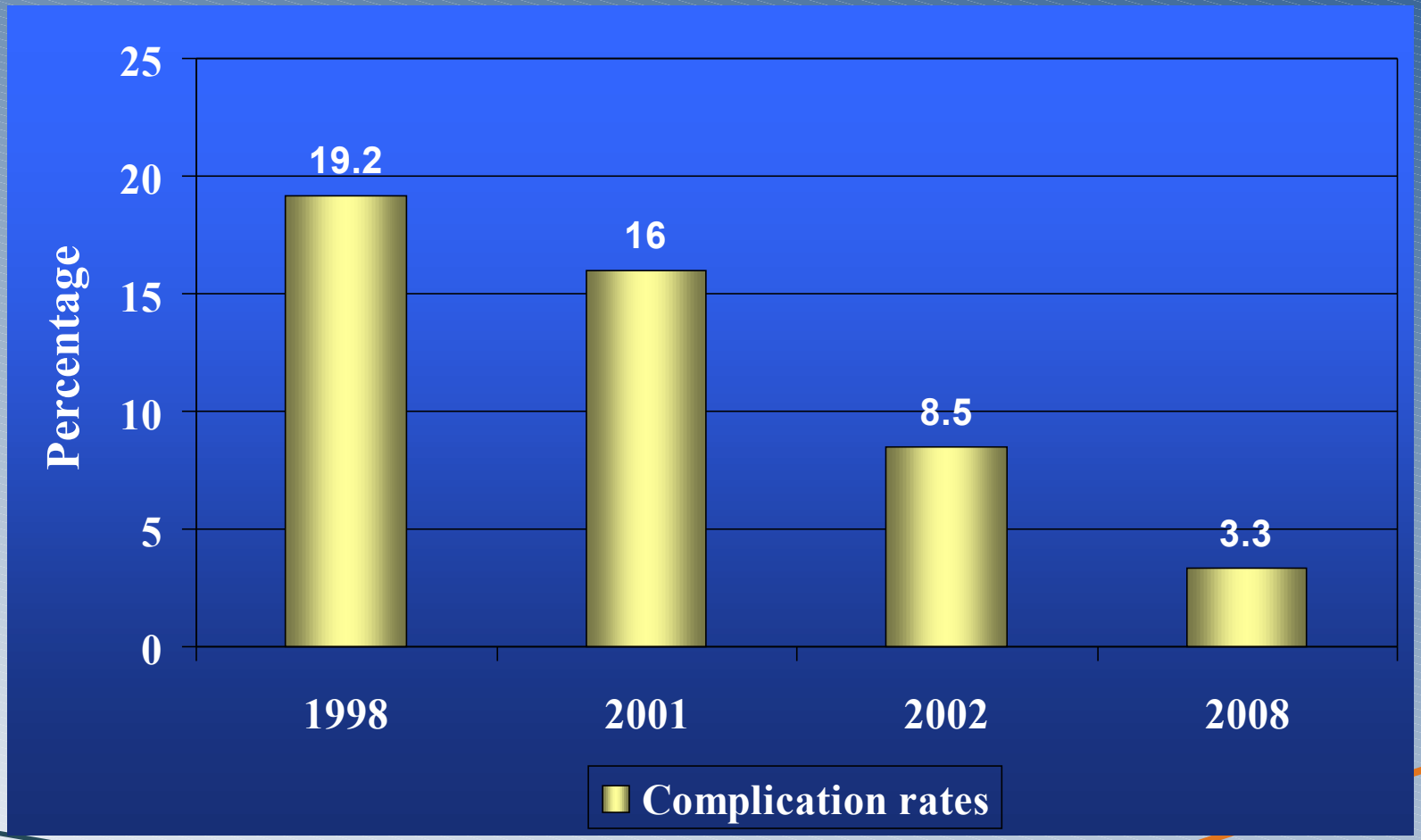
Chiam, P.T.L., Roubin, G.S., *Cath and Cardiovasc Interv* 2008;72: 318–324.

Thirty-Day Event Rates in Octogenarians



Chiam, P.T.L., Roubin, G.S., *Cath and Cardiovasc Interv* 2008;72: 318–324.

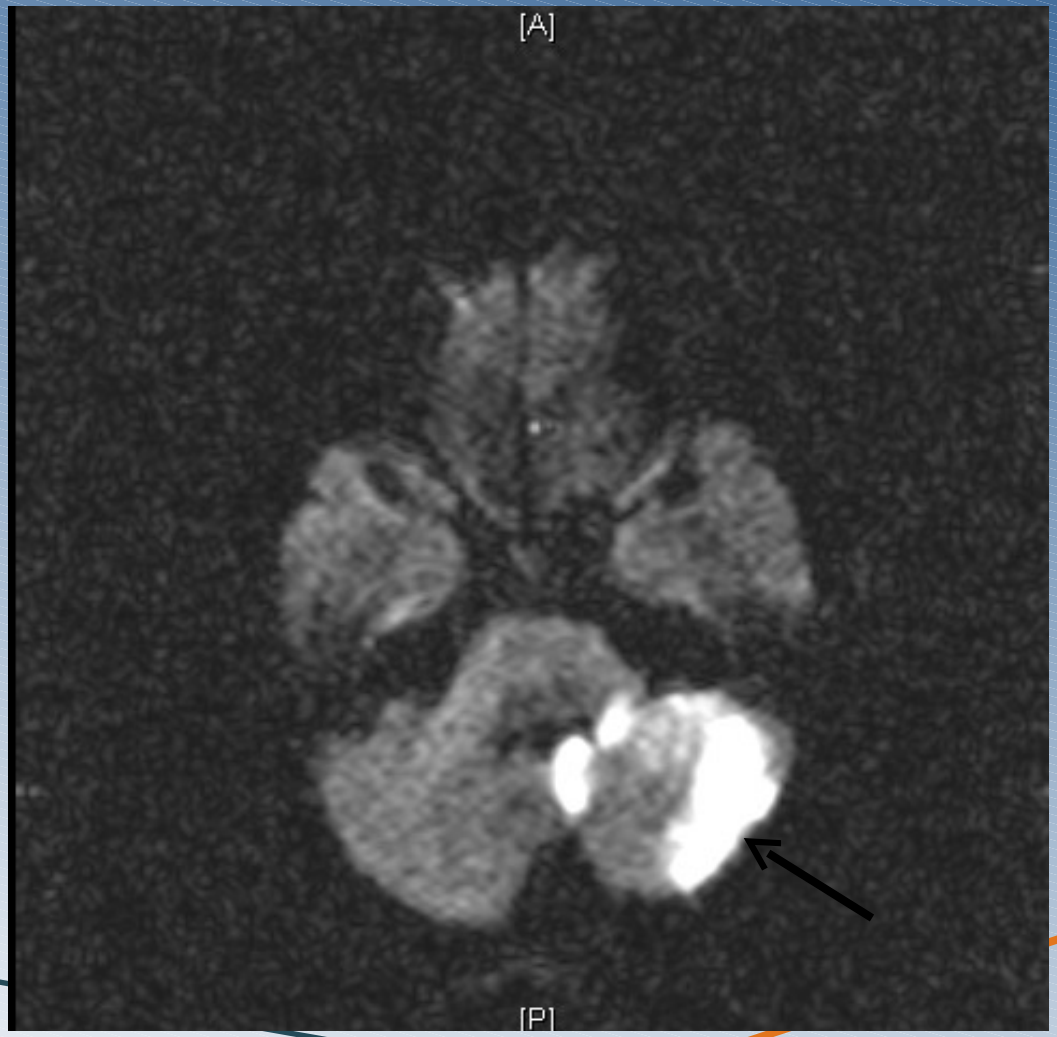
Trend for Complication Rates in Octogenarians



Chiam, P.T.L., Roubin, G.S., *Cath and Cardiovasc Interv* 2008;72: 318–324.

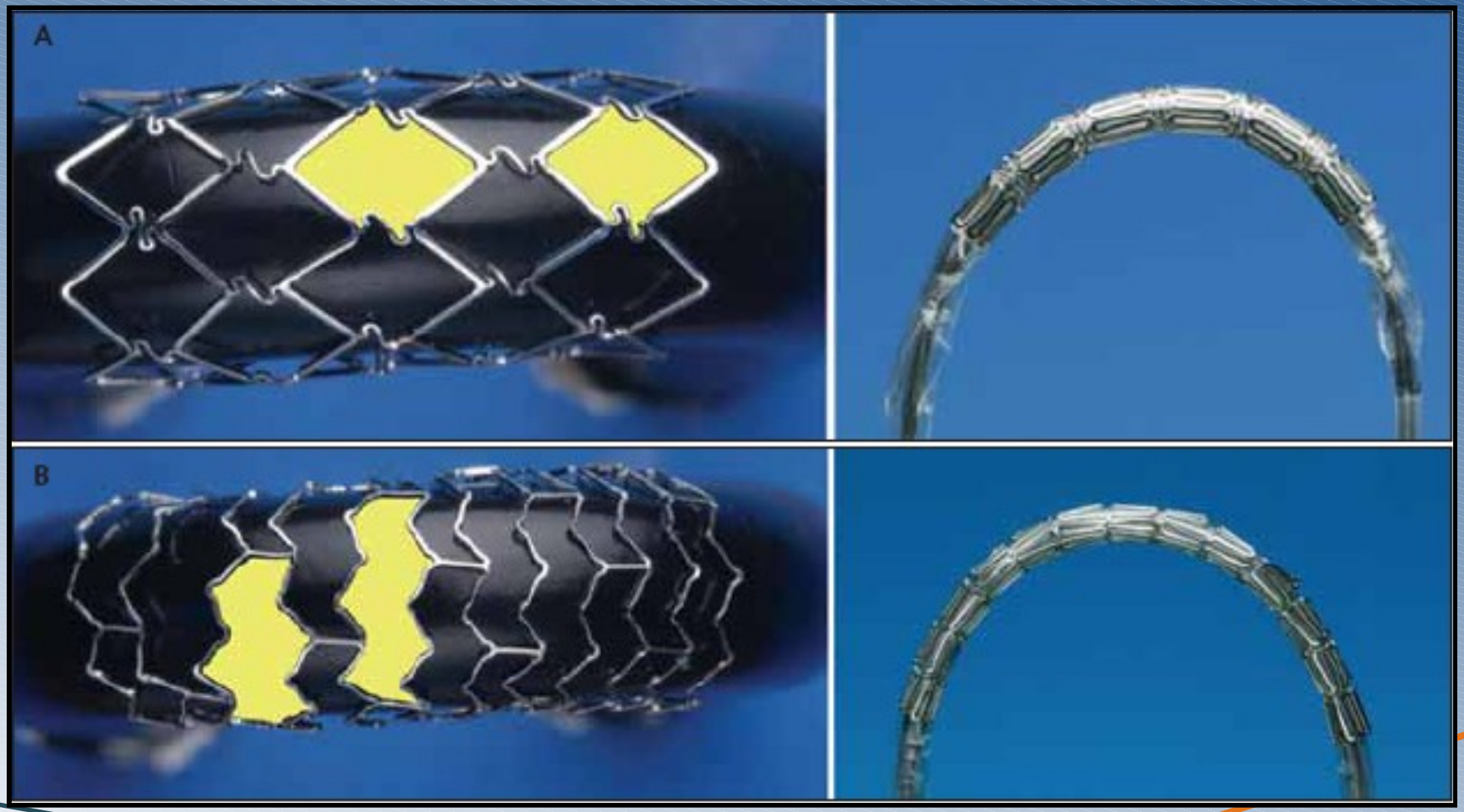
Hostile Aortic Arch

MRI Brain w/o contrast

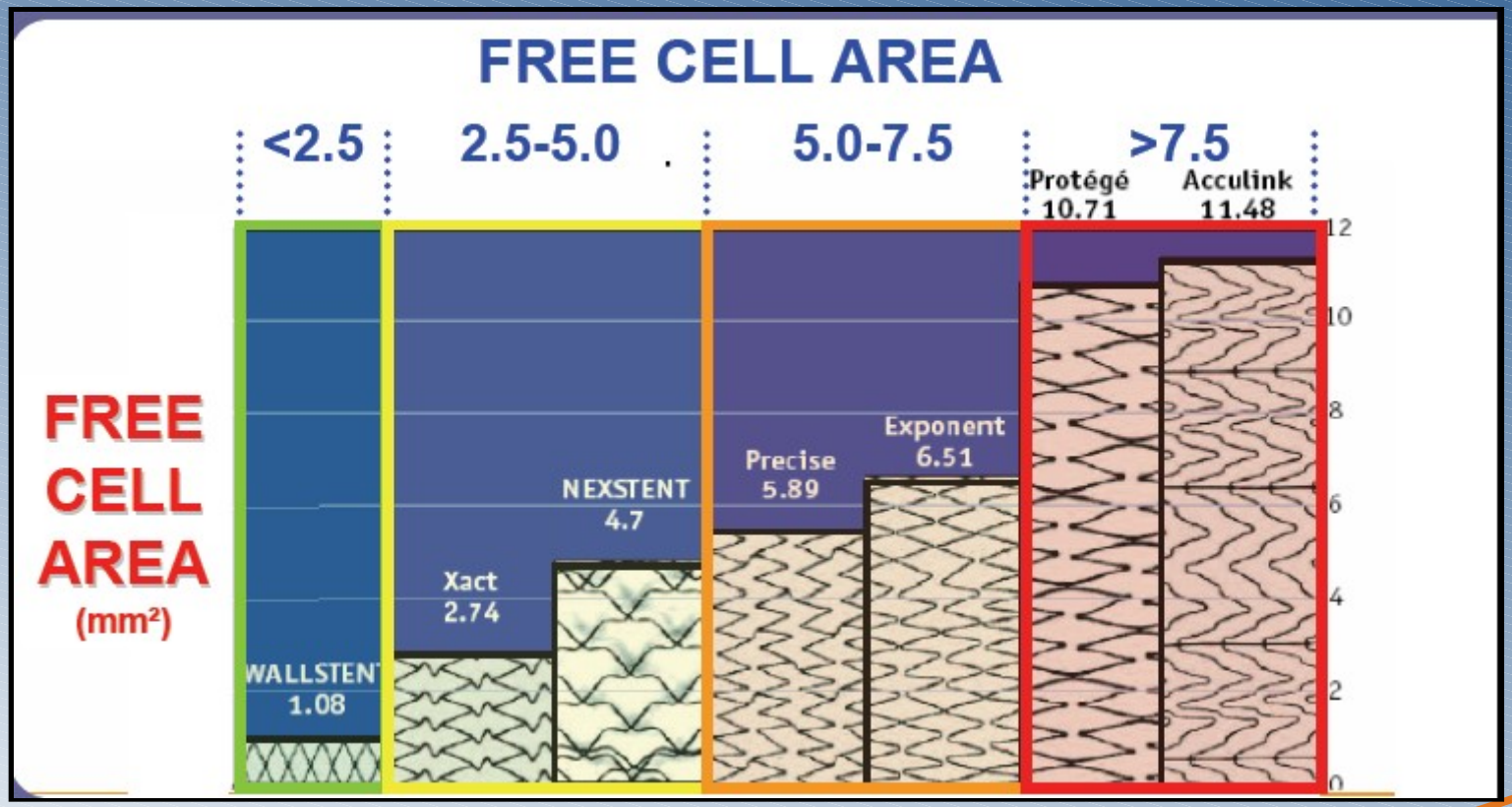


Carotid Stent Design and Lesion Specific Stent Selection

Basic Principle of Open Versus Closed Cell



Free Cell Area of Available Stent Designs . . .



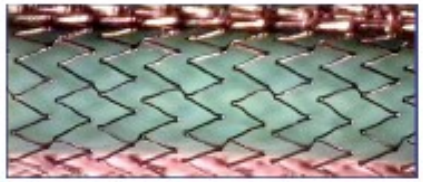
Scaffolding and Plaque Coverage

closed cell elgiloy stent – Wallstent

Plaque Coverage

+++

open cell nitinol stent



+

closed cell nitinol stent

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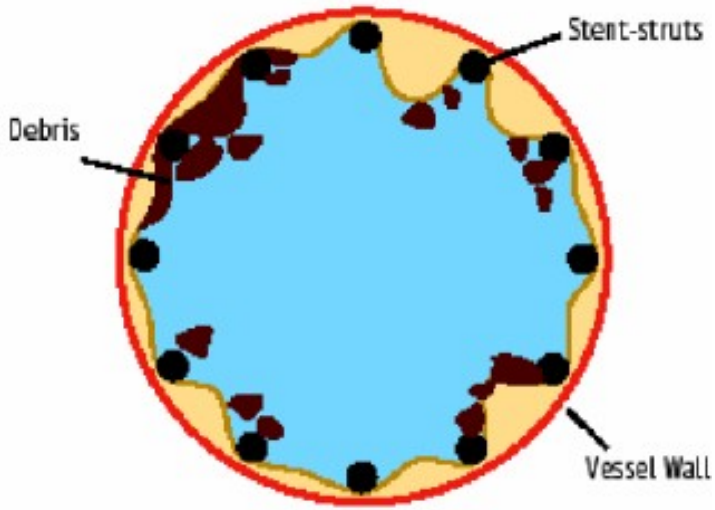
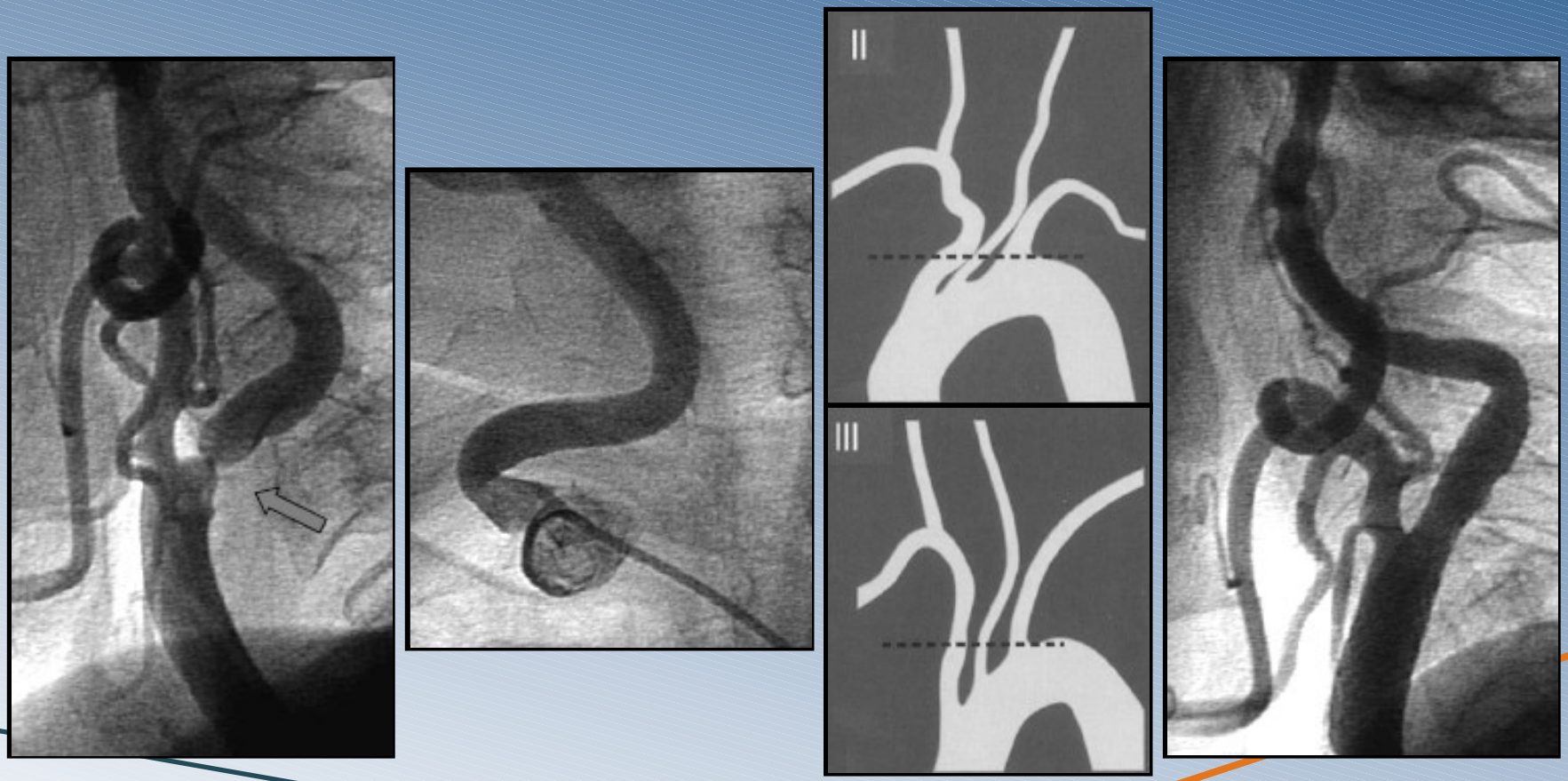
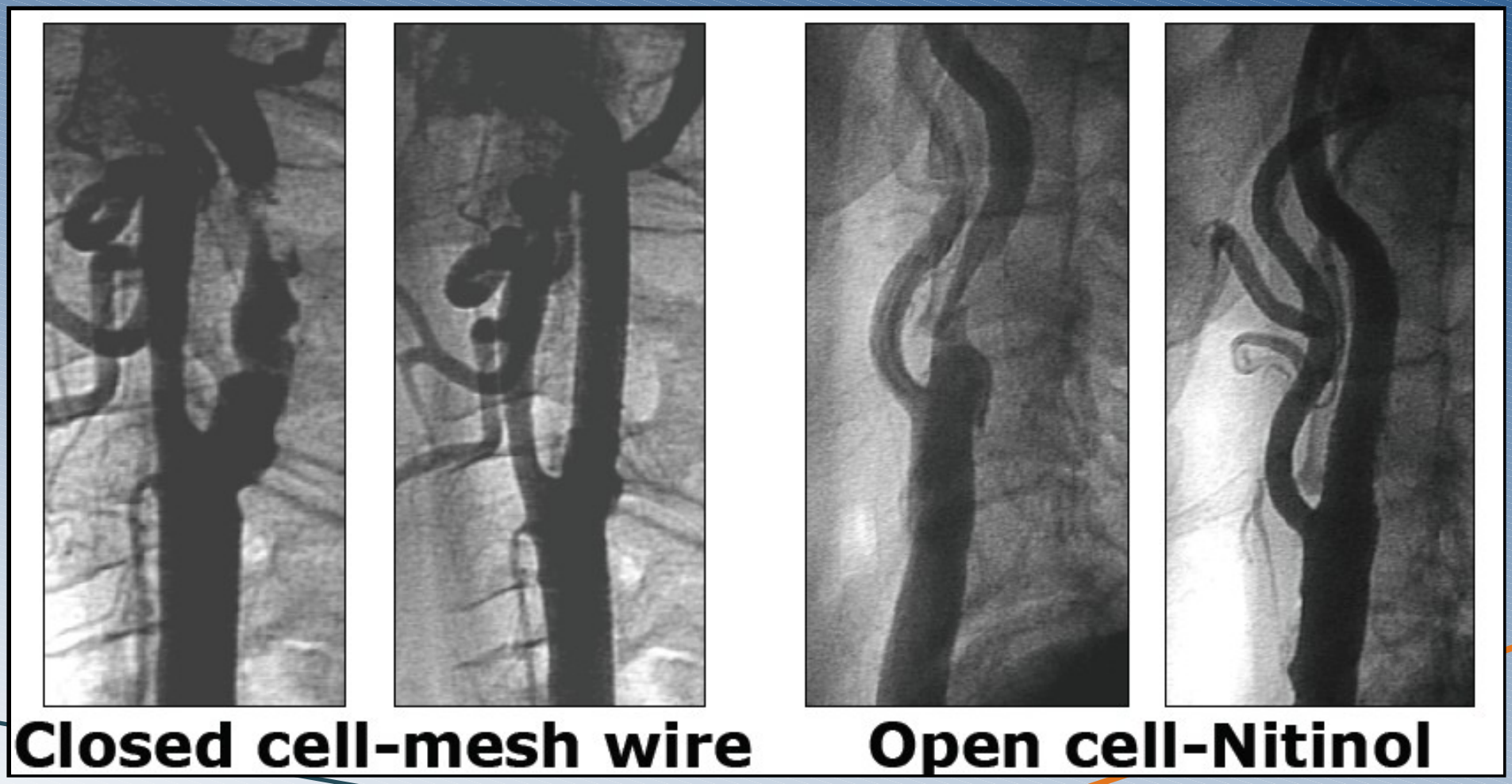


Difficult Access:
High Stent Deliverability Required!

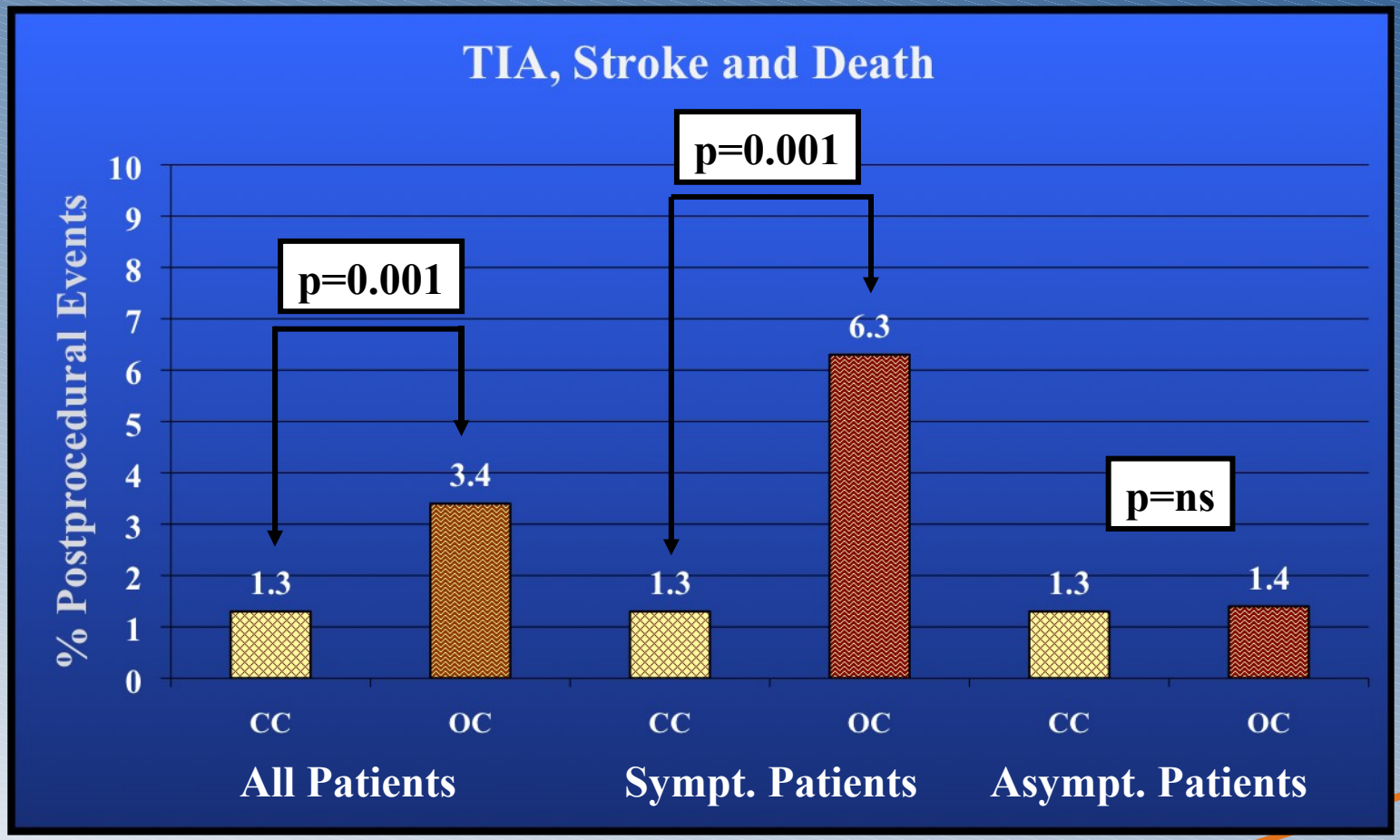
Mesh Wire Stents Superior



Stent Design: Lesion Coverage and Scaffolding

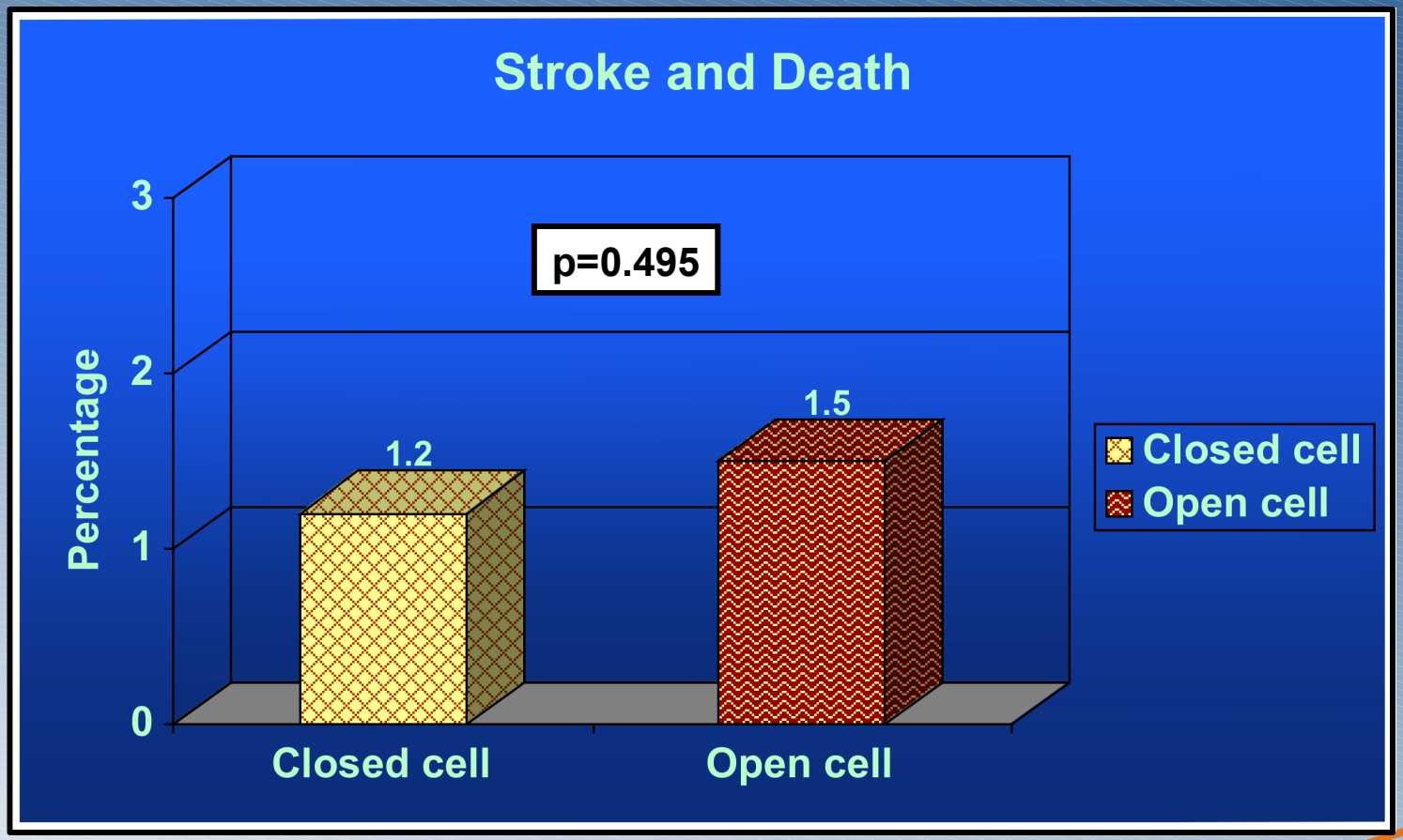


Comparison of Post-Procedural Event Rates by Cell Types



Bosiers, M., et al, *Eur J Vasc Endovasc Surg* 2007;33:135e–141.

30-Day Stroke (As Defined By the Authors) / Death Rates (no TIAs)



Difference: 0.3% (95% CI–0.5% to 1.4%, p=0.495)

Adapted from Table 3 in Bosiers, M., et al, *Eur J Vasc Endovasc Surg* 2007;33:135e–141.

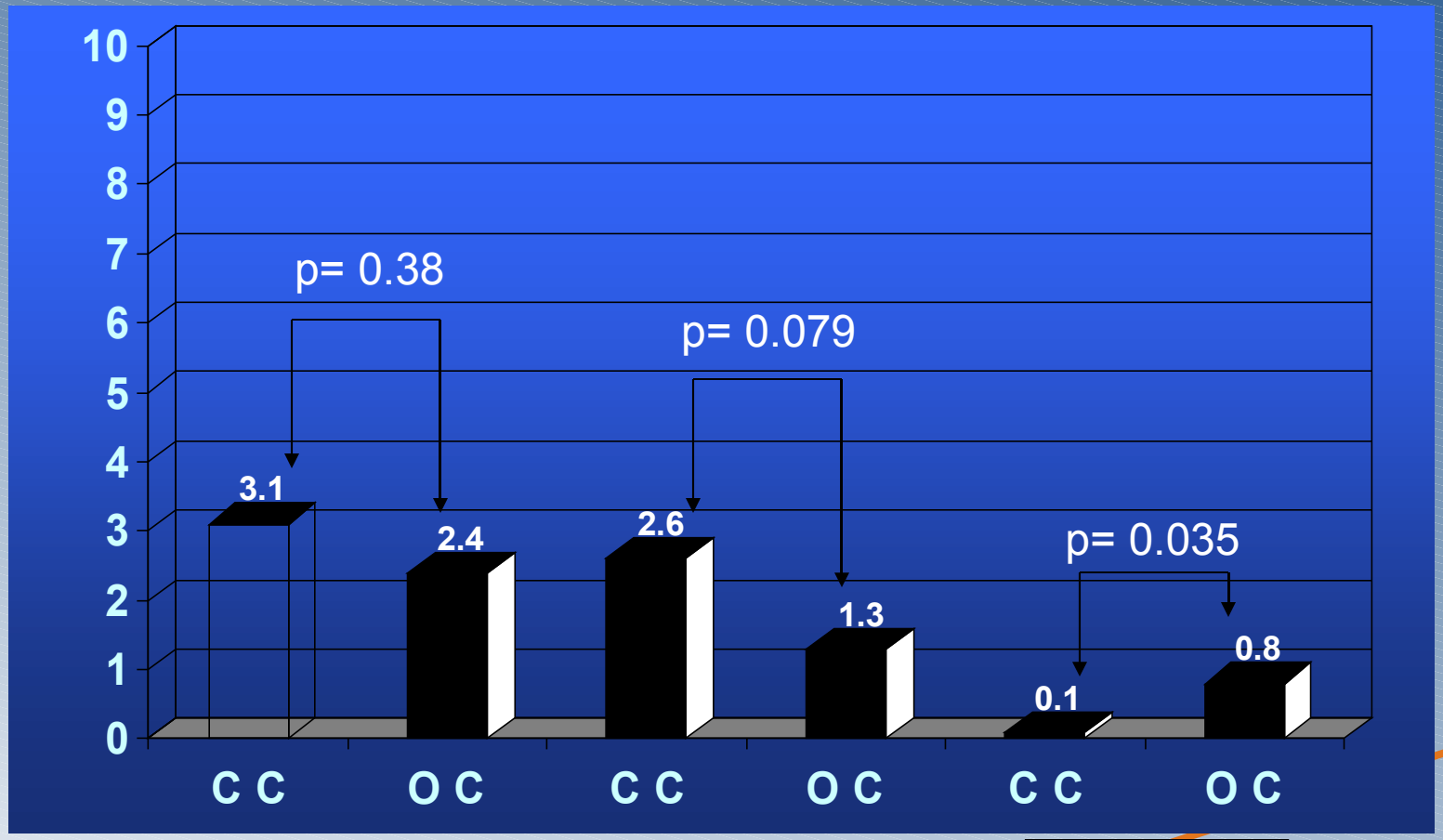
Does Carotid Stent Cell Design Matter?

European Registry

Martin Schillinger, MD; Manfred Gschwendtner, MD; Bernhard Reimers, MD; Johannes Trenkler, MD; Luc Stockx, MD; Johann Mair, MD; Sumaira Macdonald, MD; Franz Karnel, MD; Kurt Huber, MD; Erich Minar, MD

Schillinger, M., *Stroke*, 2008;39:905–909.

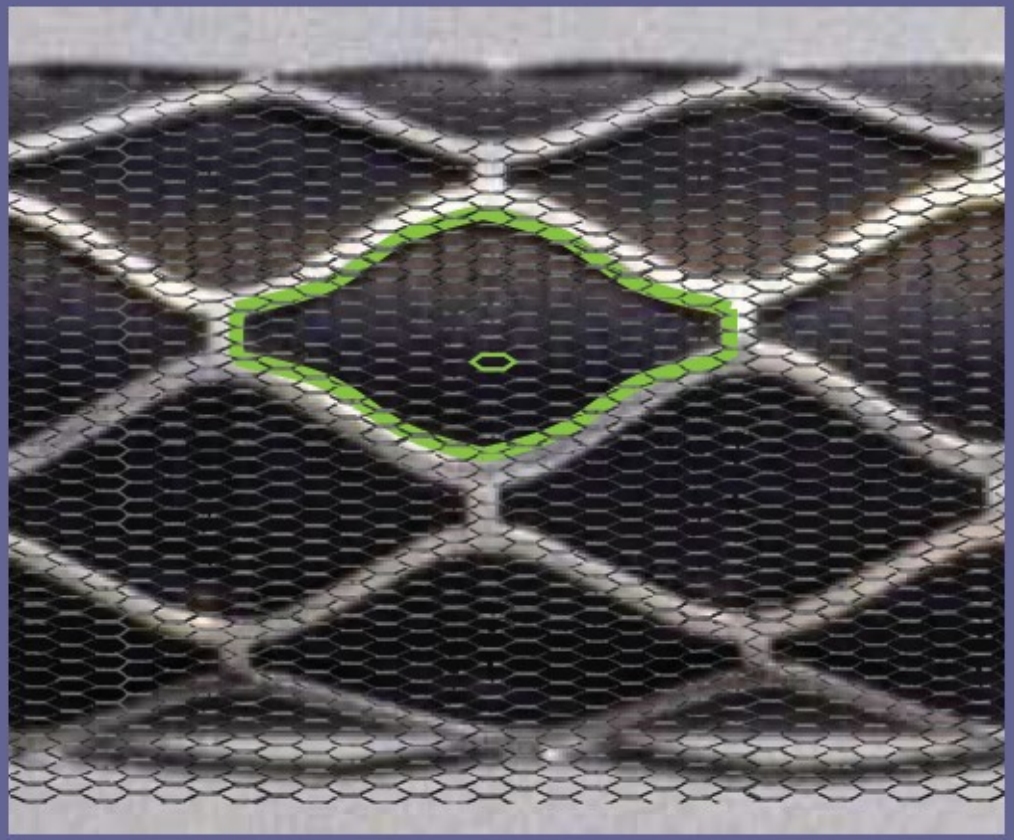
Stroke and Death rates



Schillinger M, Stroke. 2008;39:905-

Addition of stent “mesh”

- Finest mesh stent



Courtesy of Dr. Mark Wholey

CAS Outcomes Tied To . . .

ANATOMY

- Difficult Arch
- CCA/ICA Tortuosity
- Lesion anatomy

PATIENT

- Symptoms
- Octogenarians
- Cerebral Reserve

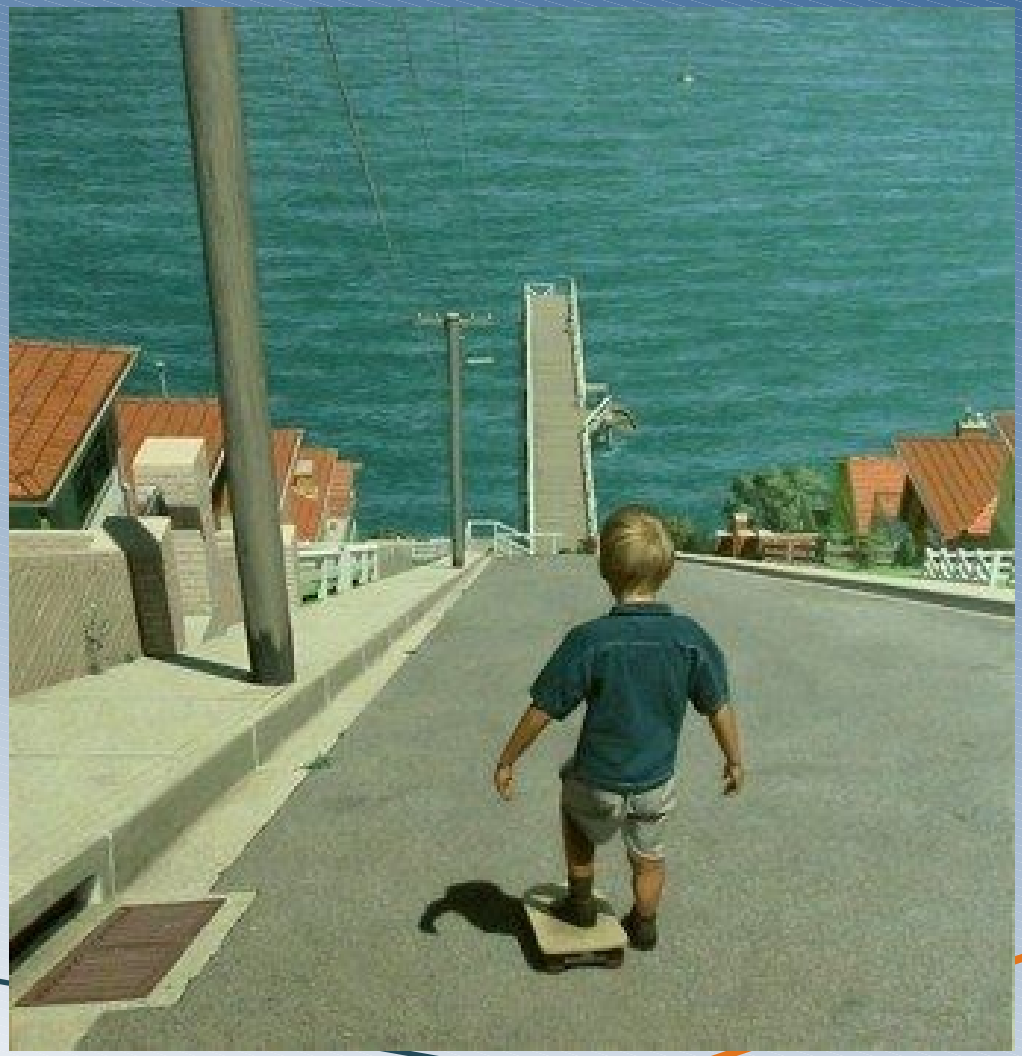
OPERATOR

- Early learning curve
- Case selection
- Stubborn persistence

DEVICE SELECTION TECHNIQUE

- Embolic Protection
- Stent design
- Cerebral protection

Opportunity



Judgment