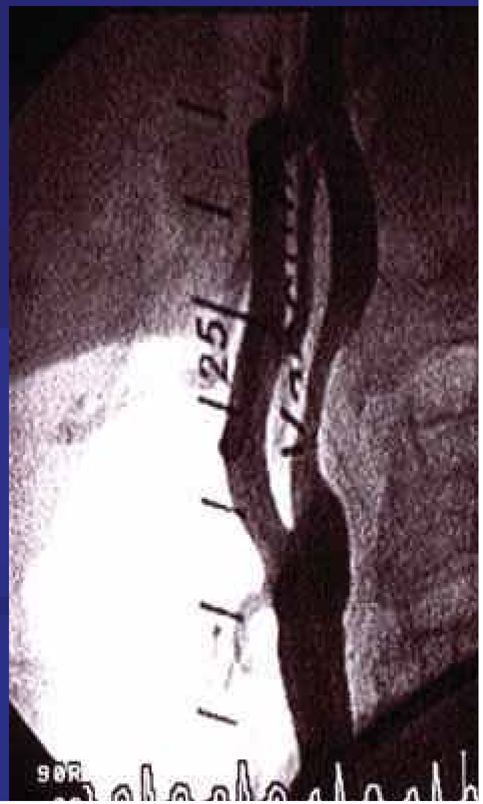
Embolic Protection In Carotid Stenting

Paul Hsien-Li Kao, MD
Assistant Professor, Cardiology
Director, Cardiac Catheterization Lab
National Taiwan University Hospital
Taipei, Taiwan

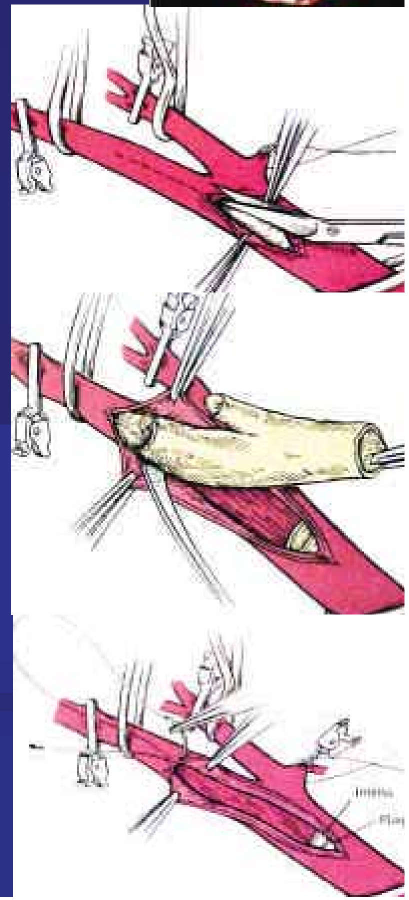
Carotid artery stenosis

- Responsible for 20-30% of ischemic strokes
- Spontaneous distal embolism is the mechanism causing symptoms
  - Transient ischemic attacks
  - Amaurosis fugax
  - Ischemic stroke
- Symptomatic with DS>70%
  - Risk of stroke 12-13% in the first year, 30-37% in 5y
  - 26% stroke rate in the first year if DS>90%
- Treatment options
  - Antiplatelet and risk factor modification
  - Surgical endarterectomy (CE)
  - Endovascular stenting (CS)



Carotid endarterectomy (CE)

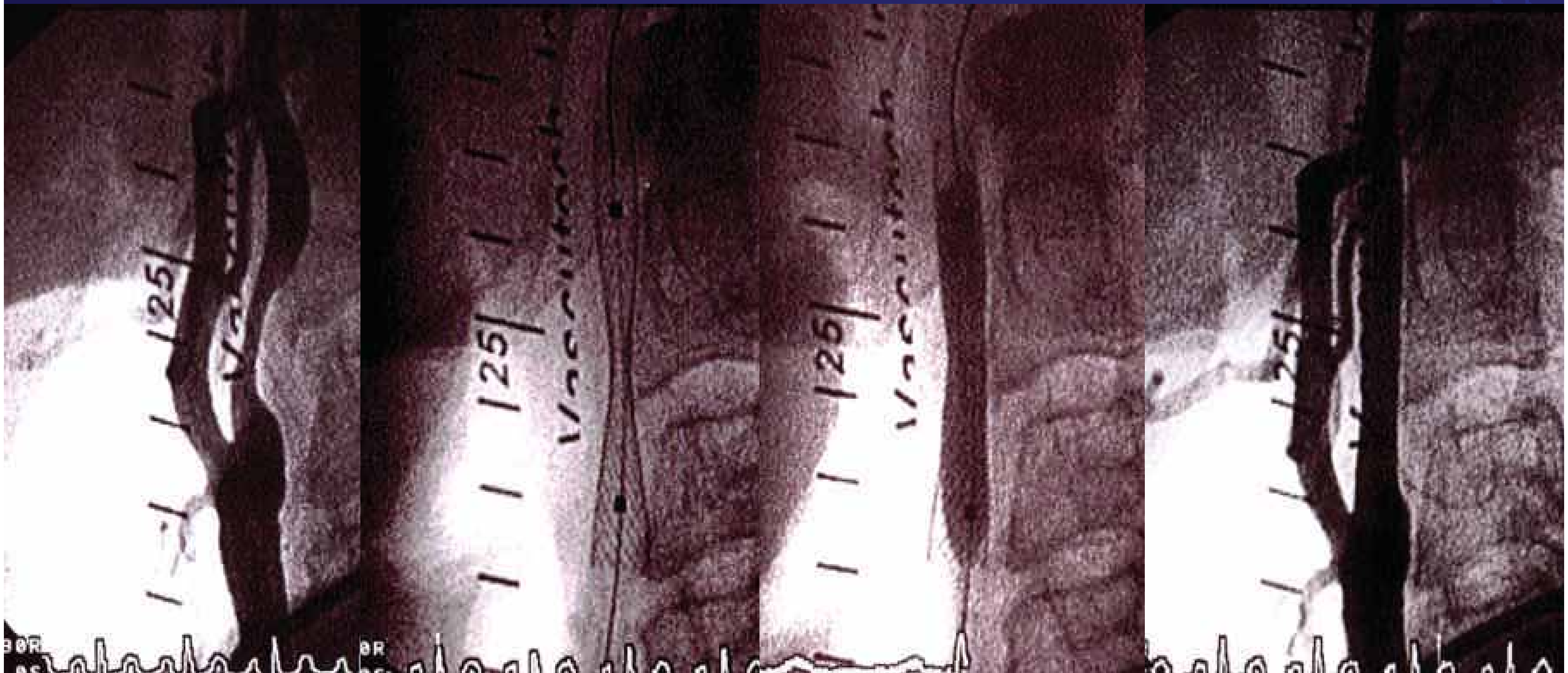
- Proven by NASCET, ACAS, and ECST
  - 30d peri-procedural stroke/death rate 5-8%
  - Stroke risk reduction 60-70% in 3-5y
- 30d peri-operative morbidity is high
  - Cranial nerve palsy 6-8%
  - Hematoma/infection 3-8%
  - CV problems 1-4%
  - Total medical complication 10-20%
- Trial results do not apply to the real world
  - Operator experience
  - Surgical risk profile of patient



Carotid stenting (CS)

- First described in 1987, with rationales of
  - Metallic buttressing maintains vessel patency
  - Meshwork scaffolding the plaque
  - Neointimal formation generates a non-thrombotic surface
  - Although the plaque is not removed from the vessel wall, it is "excluded"
- Despite skeptics from the surgical society, the procedure gained wide popularity among neurologists, interventional radiologists, and cardiologists

Symptomatic left ICAS



73M repeated TIA, CAD, old MI

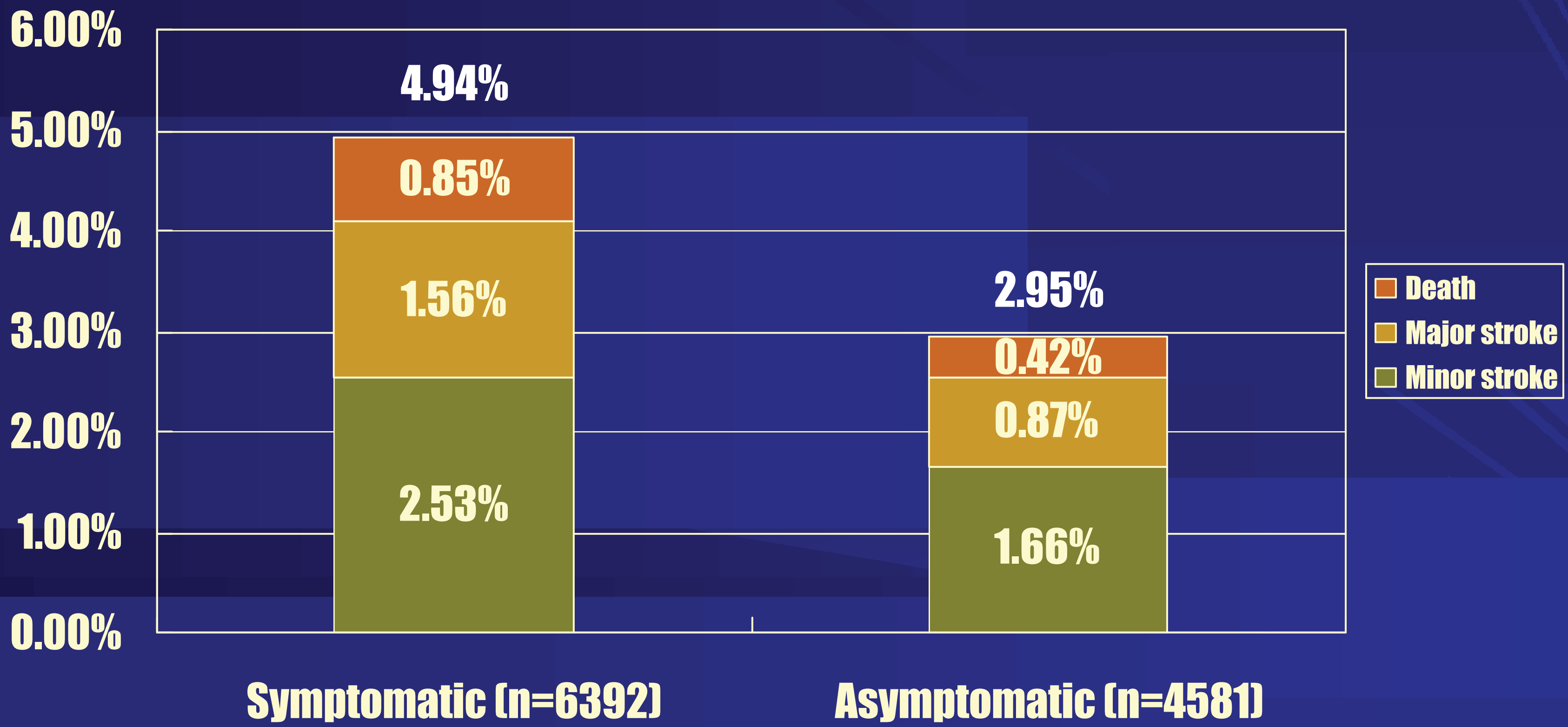
Global experience

Wholey MH, et al. CCI 2003;60:259

- 12,393 CS procedures in 11,243 patients at 53 centers worldwide since 1997
- Registry with "real world" demographics
- Technical success rate 98.9%
- 53.2% lesions symptomatic
- Peri-procedural event (%)
  - Minor stroke 2.14
  - Major stroke 1.20
  - Procedure-related death 0.64
  - Non-related death 0.77
  - Total stroke/death 4.75

30d stroke and procedure-related death

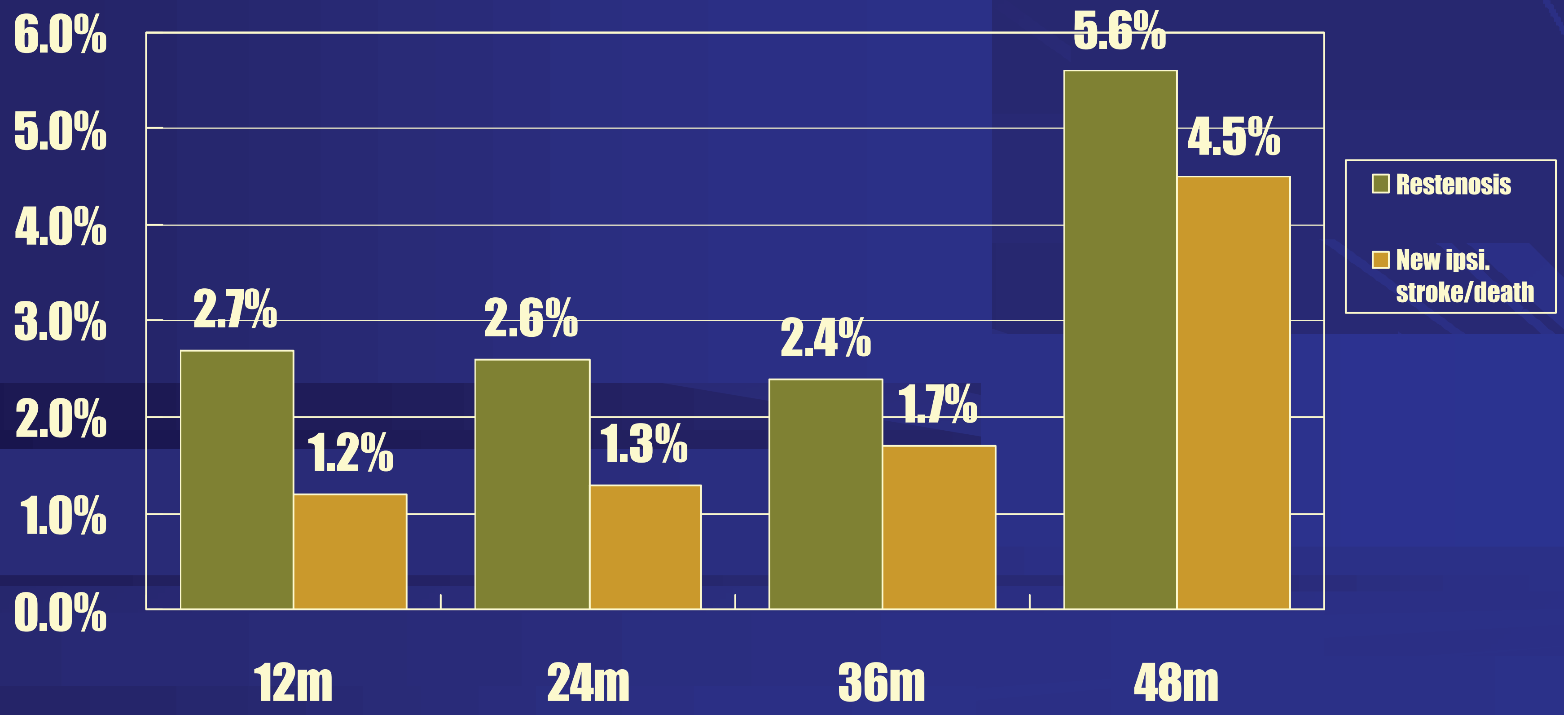
Wholey MH, et al. CCI 2003;60:259



Actual stroke prevention

Wholey MH, et al. CCI 2003;60:259

- 9,419 (85%) of the patients were followed for more than 12m



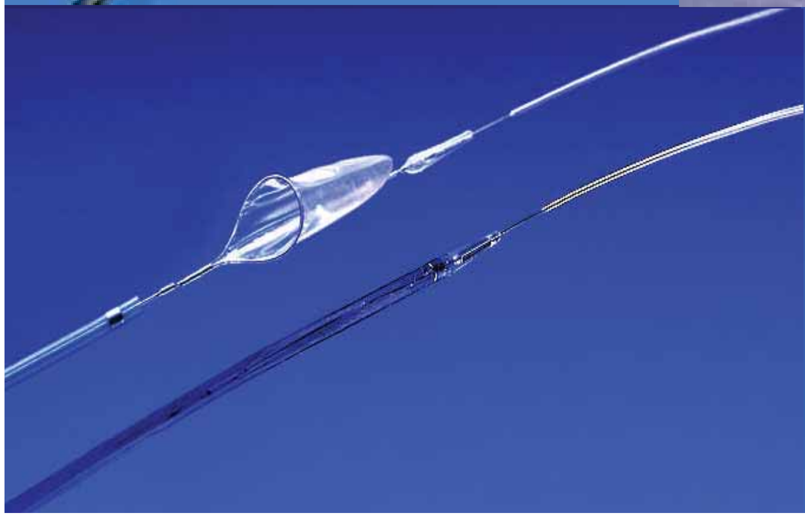
Procedural embolism

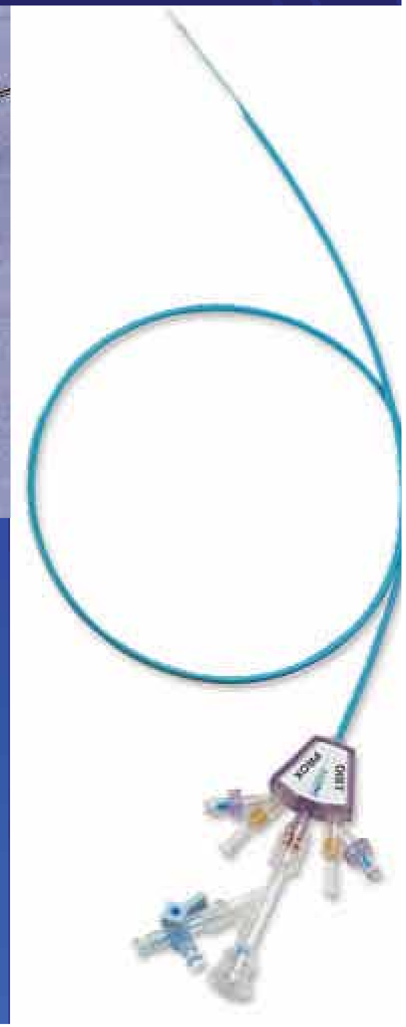
- The most devastating complication of CS
- Embolic materials are released in all steps of the procedure
- Surgeons criticize CS for putting patients at risk for embolism, while CE protects with clamping or shunting

Embolic prevention in CS

- Adjuvant pharmacology
  - Antiplatelet
  - Preocedural anticoagulation
- Procedural technique
  - Delicate wiring
  - Direct stenting
- Device design
  - Dedicated carotid device
- Embolic protection device (EPD)
  - Filter
  - Distal occlusion
  - Proximal occlusion

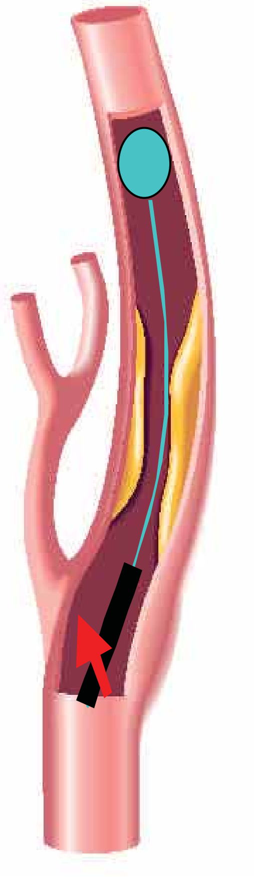
NTUH experience of EPD





Distal occlusion

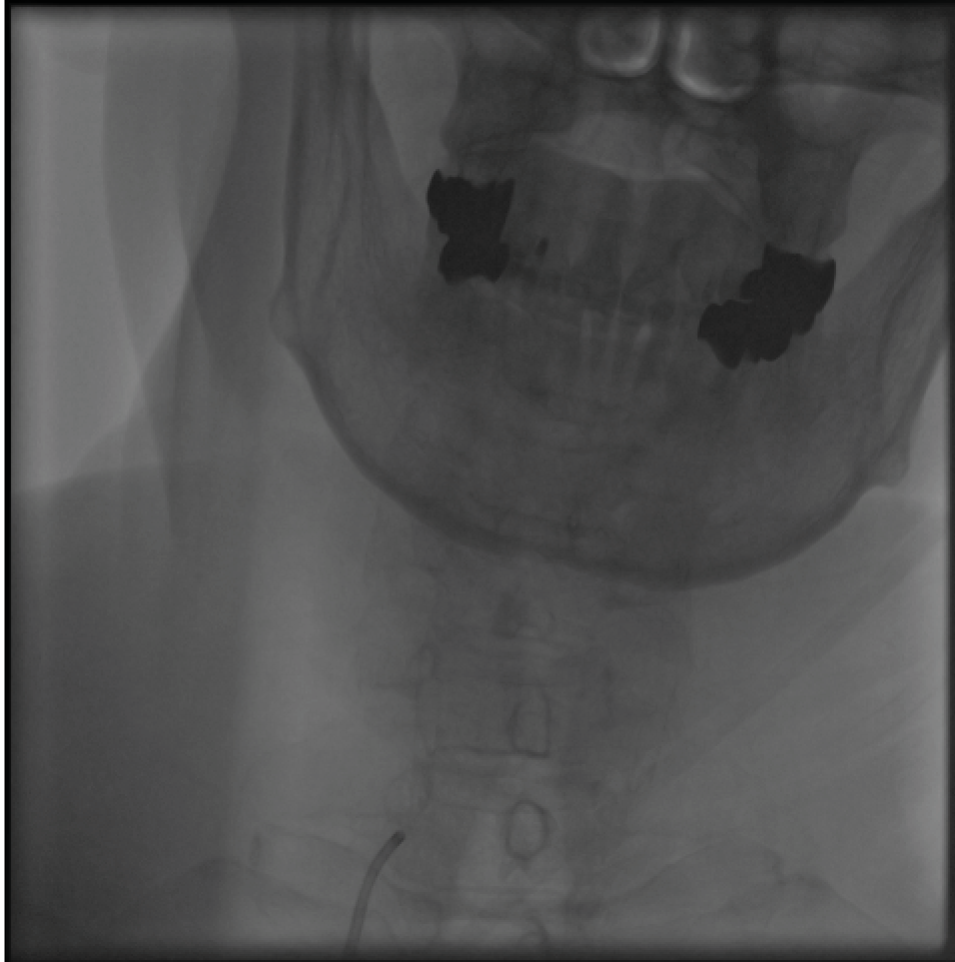
- Balloon on wire crosses lesion
- Inflation before and throughout angioplasty to stop anterograde flow
- The wire shaft serves as angioplasty wire
- Debris released stayed in the stagnant column of blood
- Aspiration to remove debris
- Lesion has to be crossed first
- Patient tolerance
- Potential distal vessel trauma

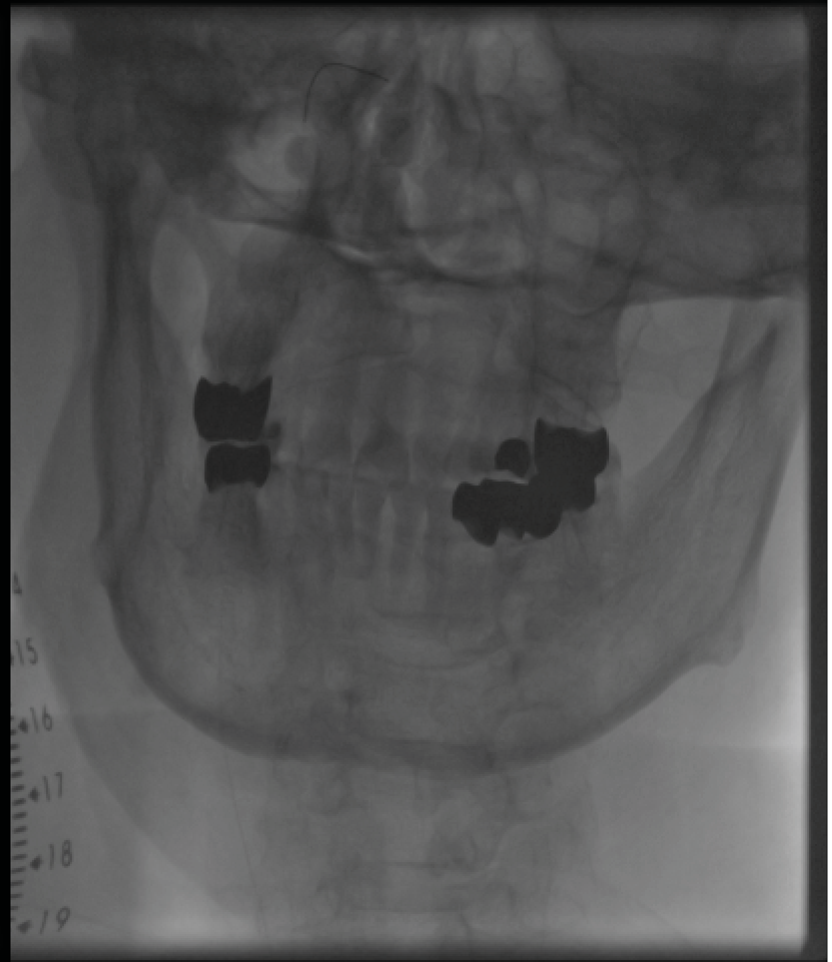


PercuSurge GuardWire Plus

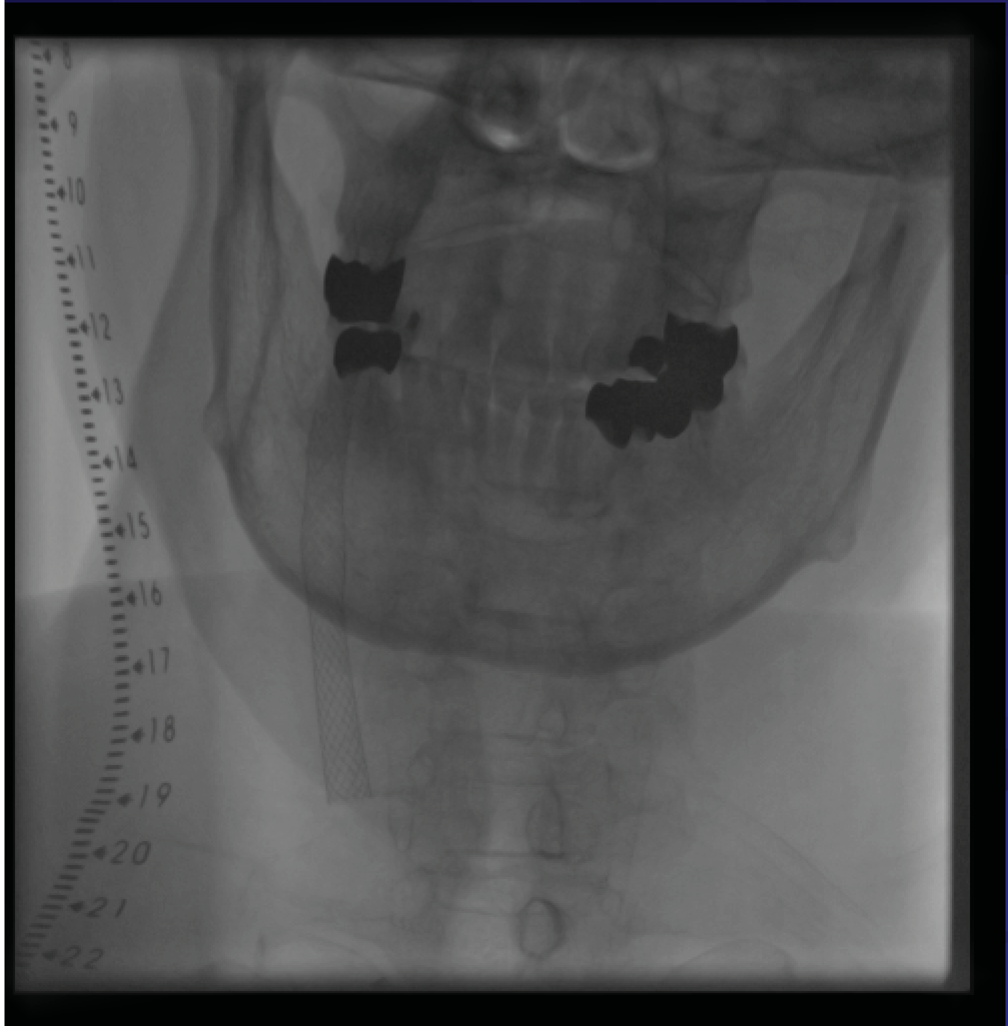
- Better crossing profile than other distal devices
- One size fits all (3-6 mm)
- Emboli particle size irrelevant
- Device handling and preparation is complex

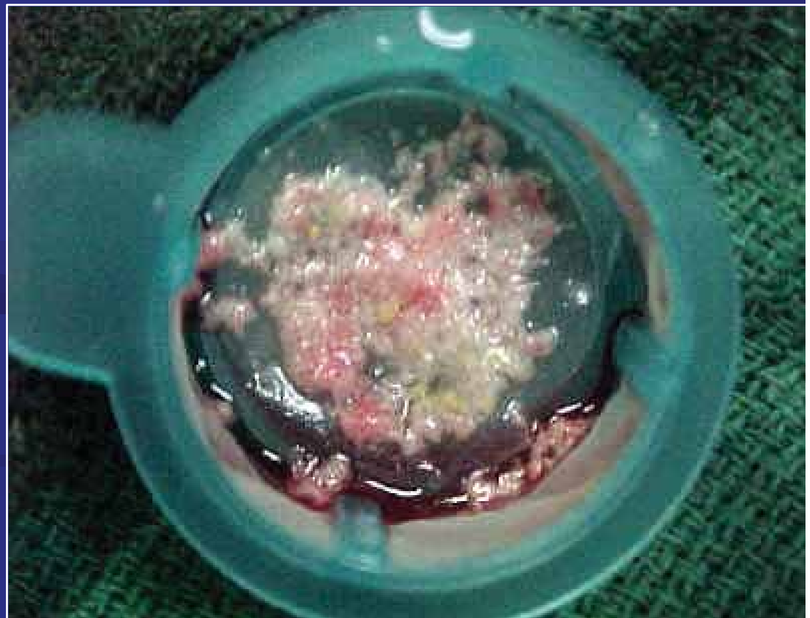
GuardWire Case





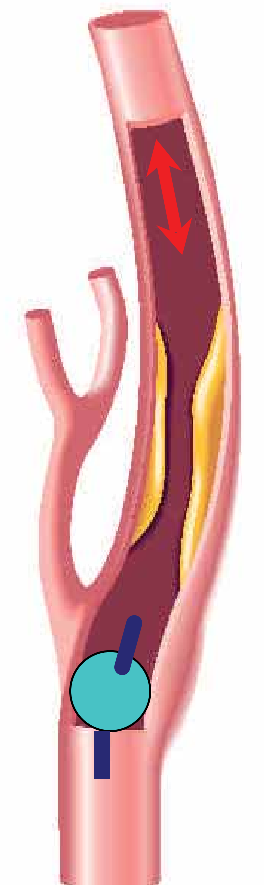
GuardWire Case





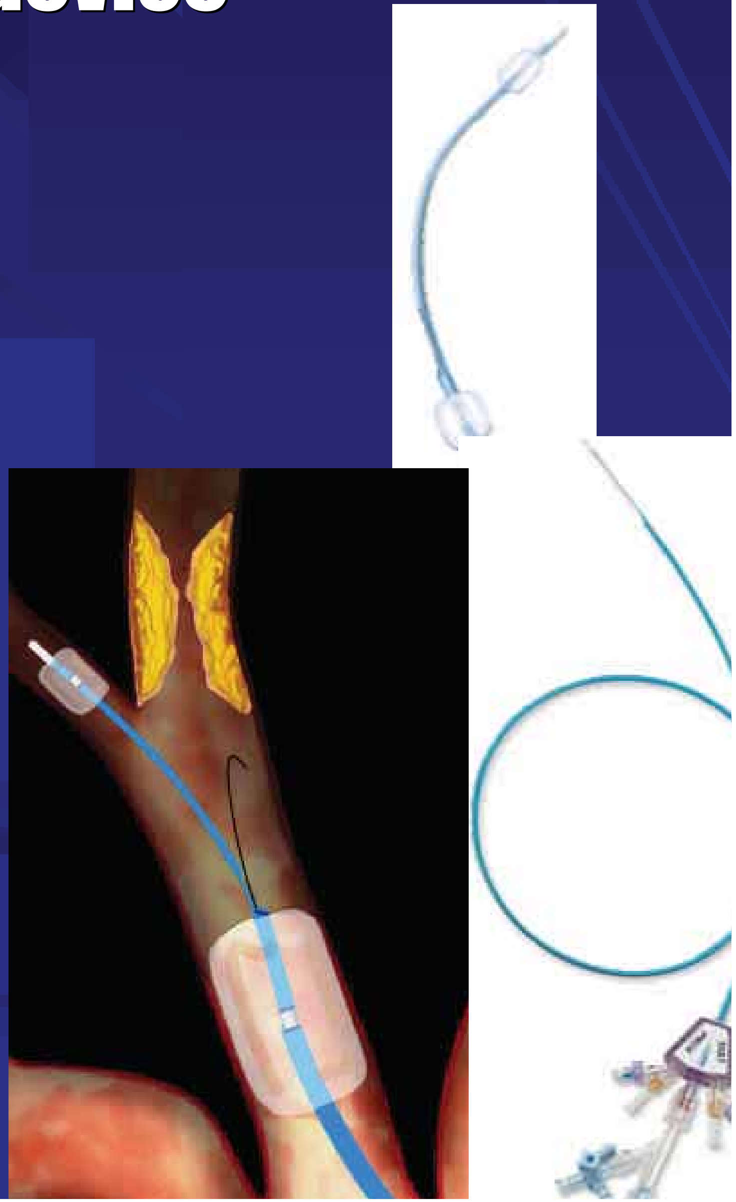
Proximal occlusion

- Balloon-necked catheter placed proximally
- Anterograde flow stopped or diminished before lesion manipulation
- Routine angioplasty instruments through catheter lumen
- Debris released removed by aspiration
- Large groin access
- Patient tolerance

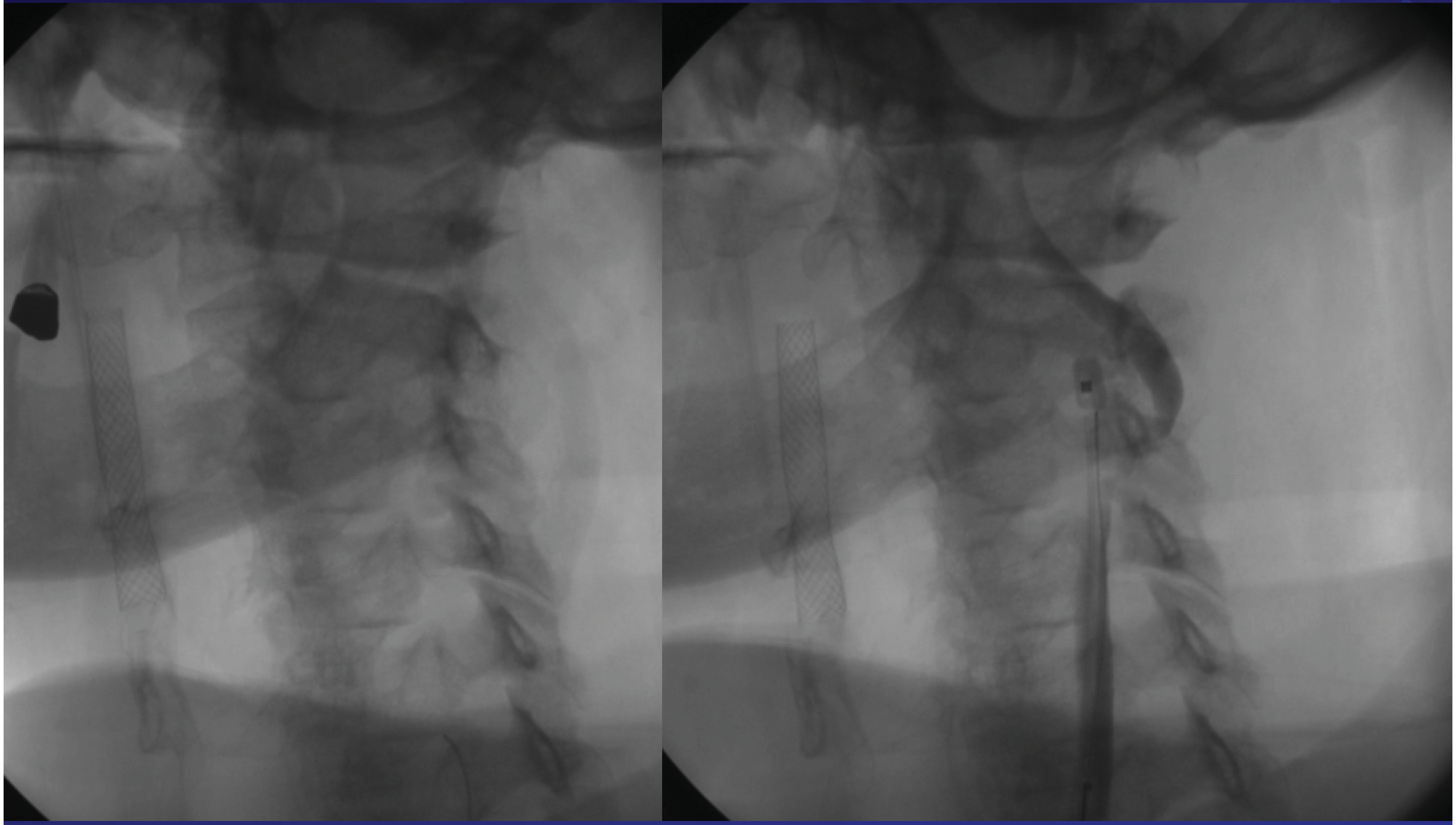


Invatec MoMA device

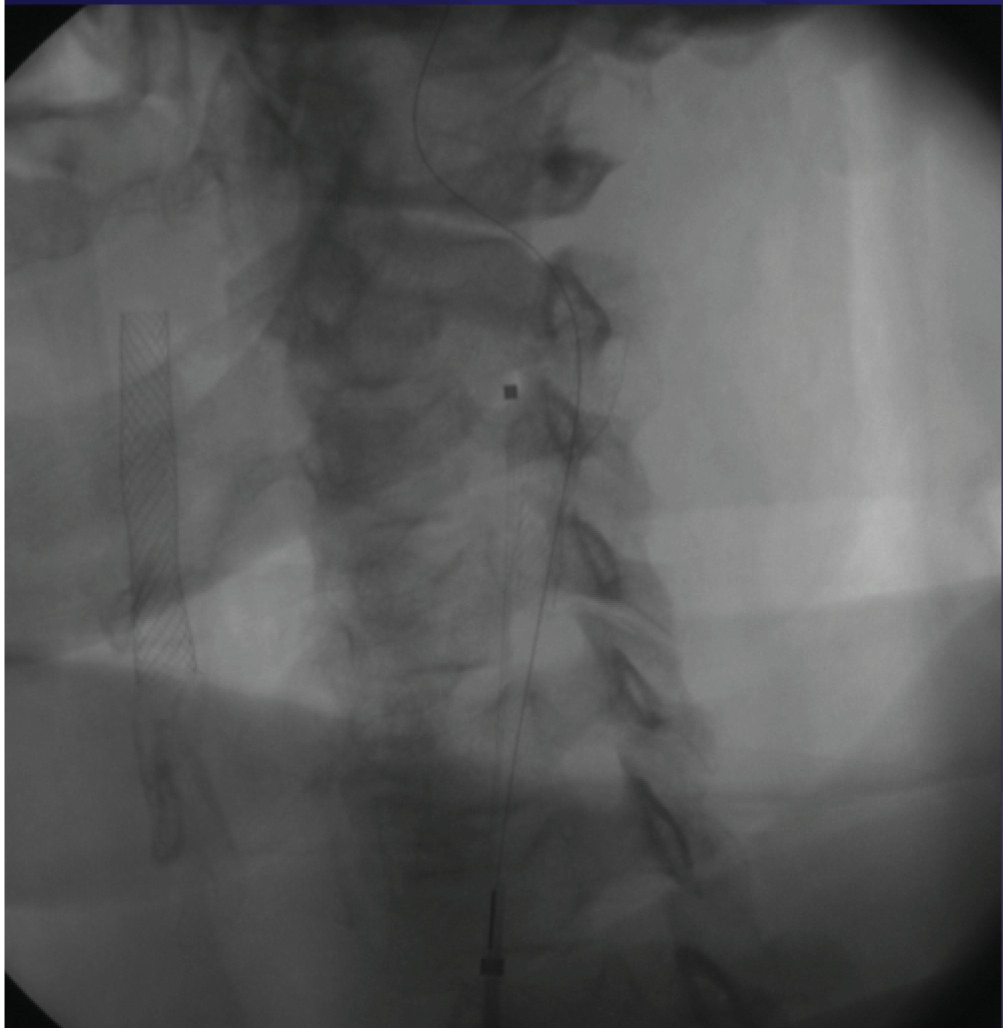
- 10Fr balloon-necked catheter for CCA occlusion
- Extension balloon for ECA occlusion
- Catheter lumen serves as working channel
- Protection before lesion is touched
- Virtually no size limit on the target vessel
- Choice of any wire, balloon, and stent
- Device handling and preparation is complex



MoMA case

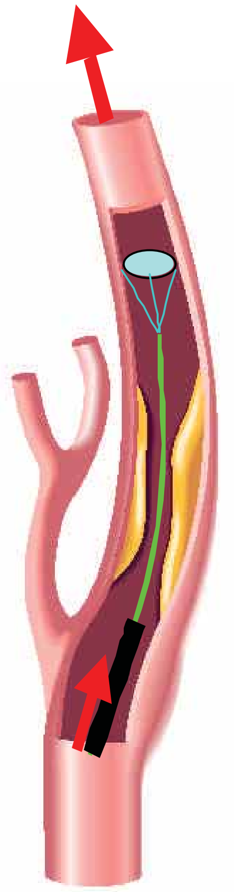


MoMA case



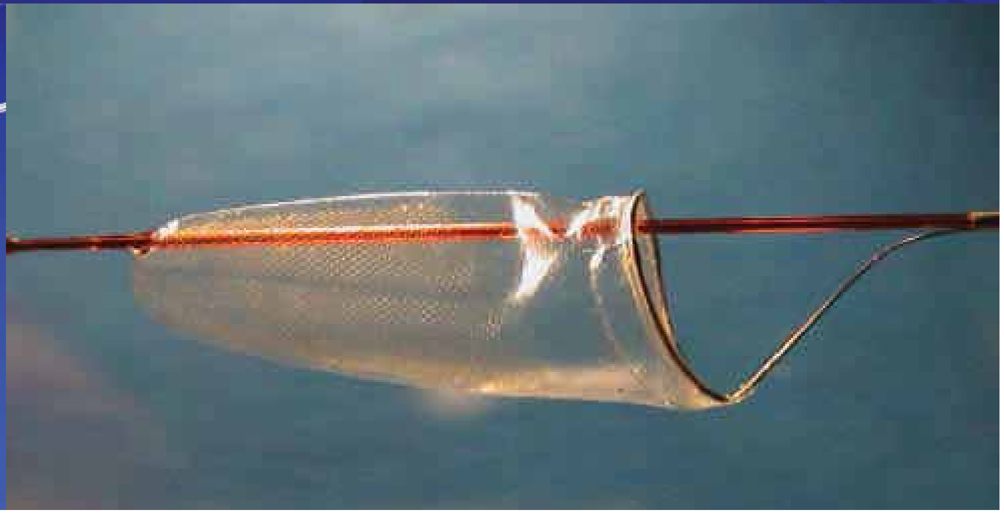
Filter

- Filter crosses the lesion in a constrained fashion
- Deployment before angioplasty
- Wire shaft serves as angioplasty wire
- Anterograde flow maintained while debris captured
- Final filter retrieval
- Lesion has to be crossed first
- Potential distal ICA trauma
- Emboli smaller than pore size escape filtration

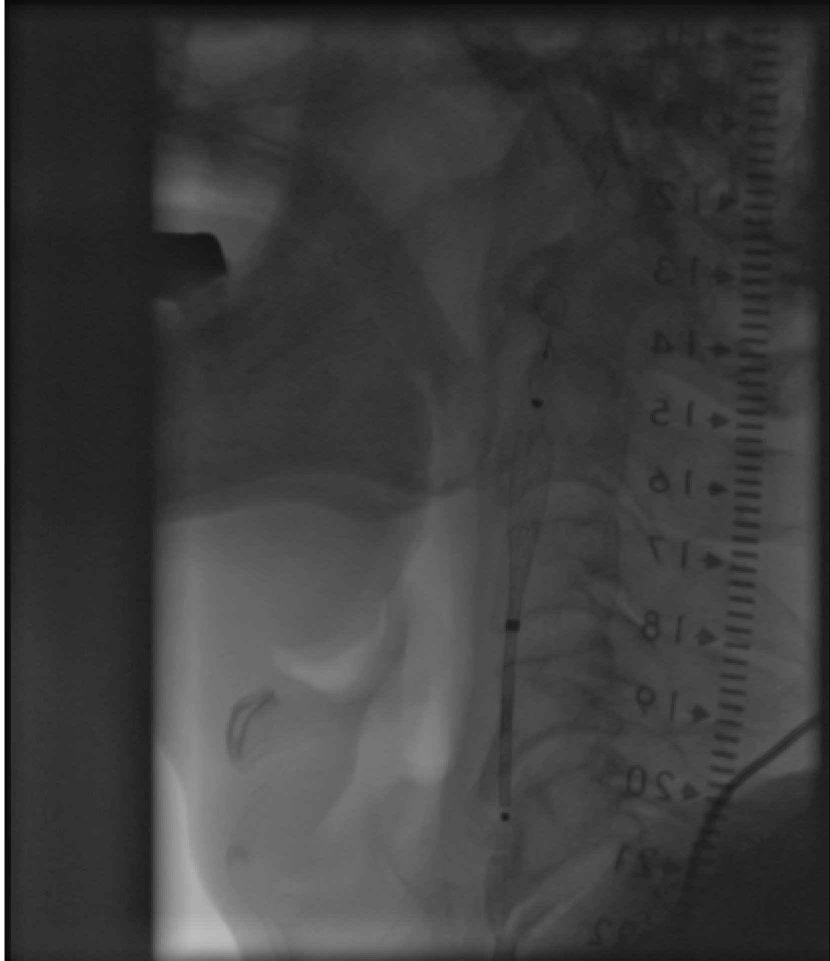


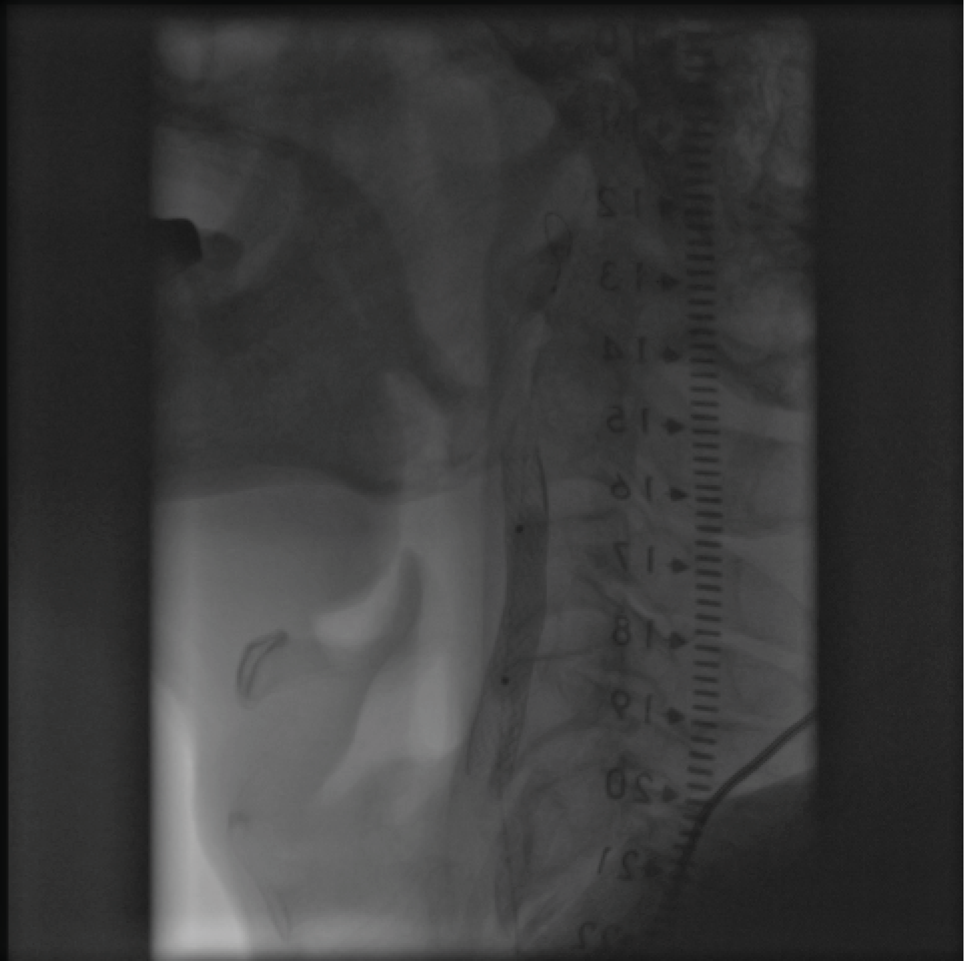
BSc EPI FilterWire

- Fishnet silicon filter membrane with pore size 80 (EX) and 110 micron (EZ) with Nitinol mouth loop
- Same monorail sheath for delivery and capture
- Easy device preparation and handling
- One size fits all (3-5.5mm)
- Coaxiality and pocket capacity

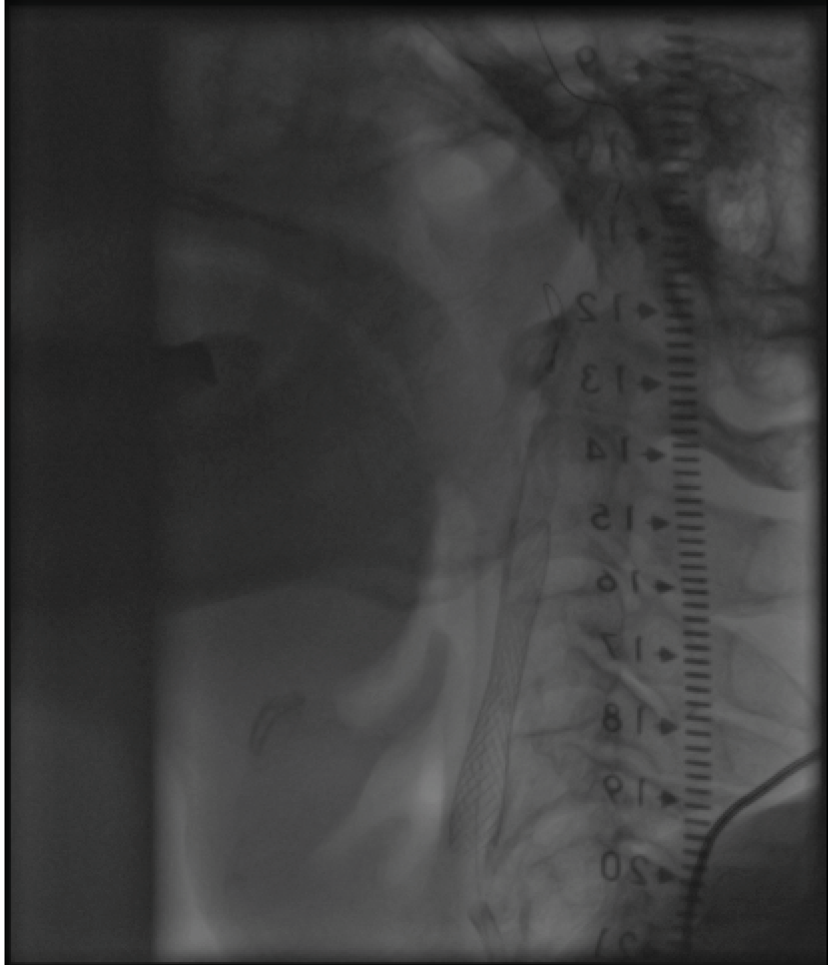


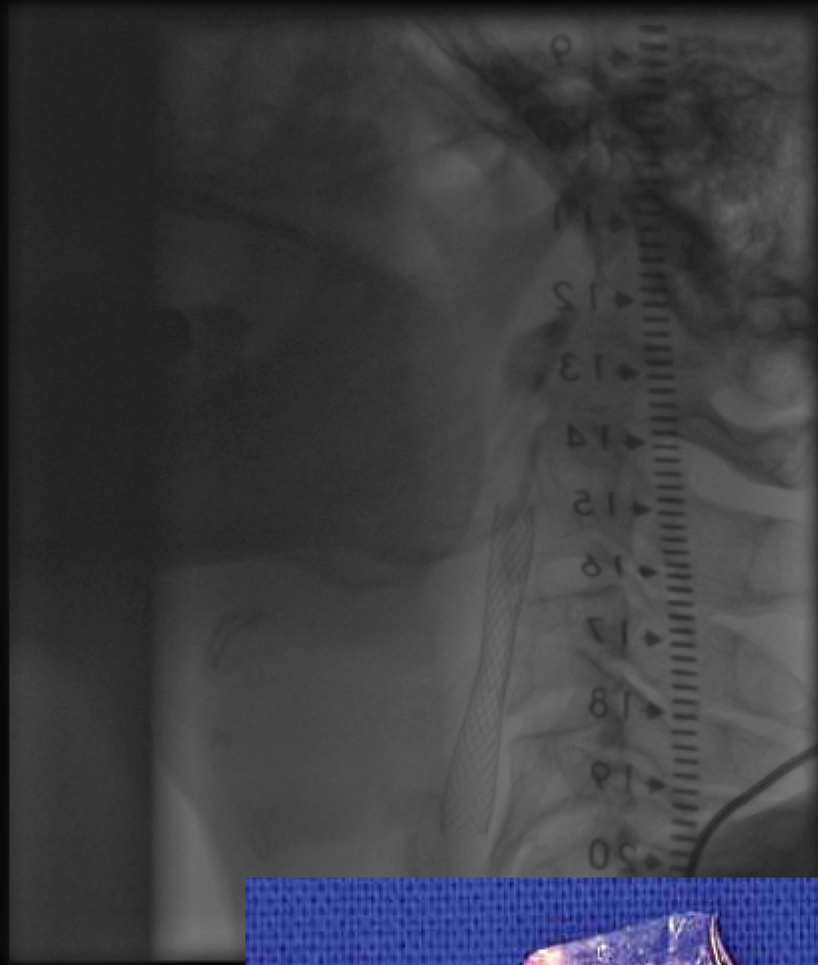
FilterWire case





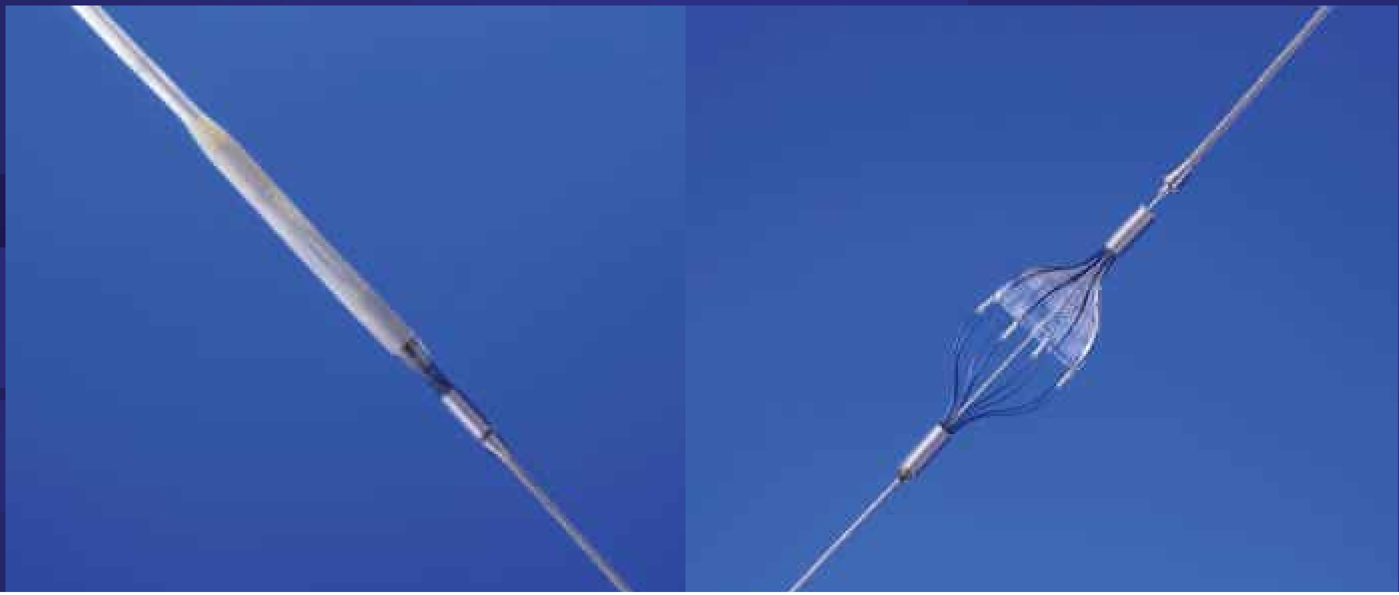
FilterWire case



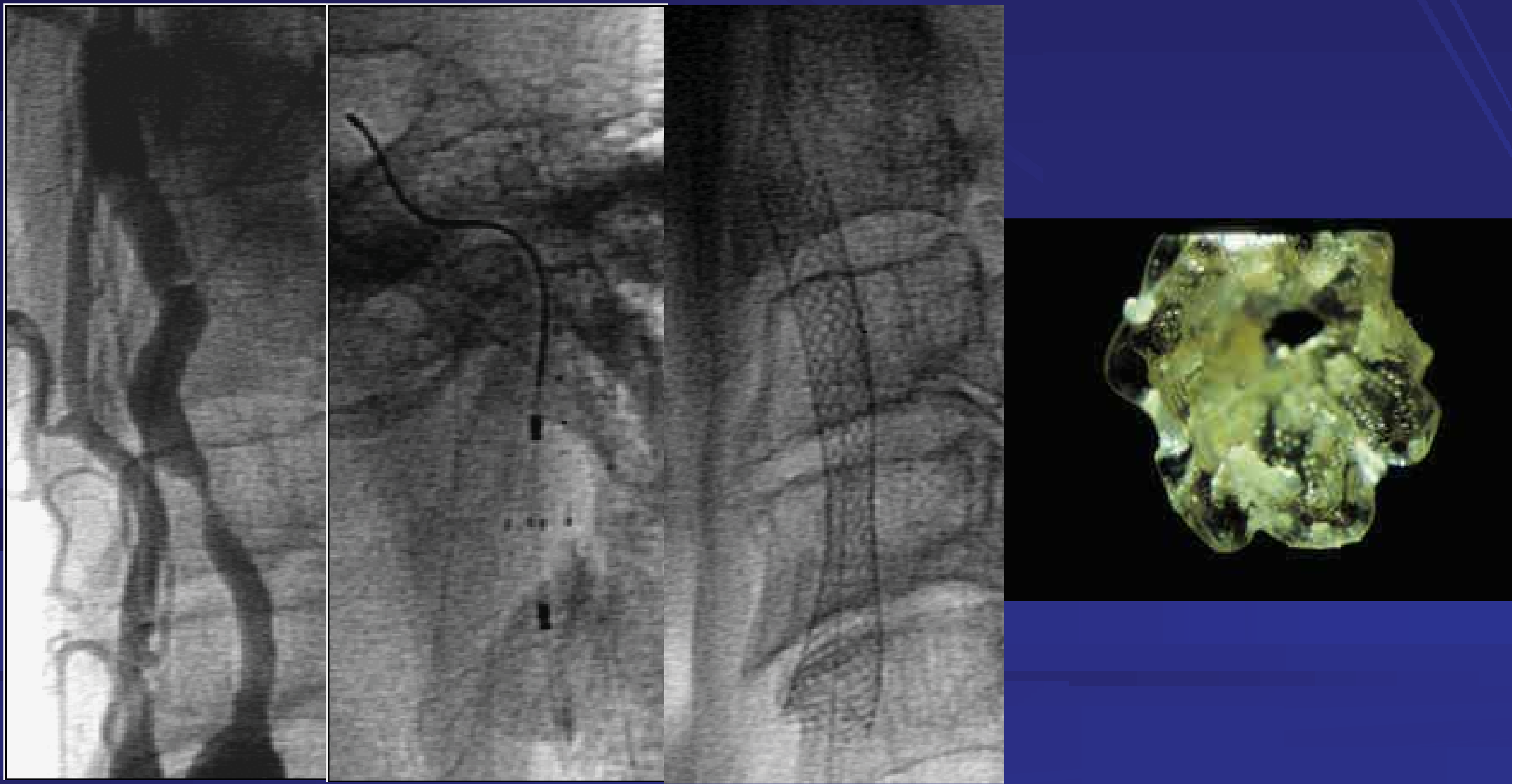


Cordis AngioGuard XP

- Nitinol filter basket with silicon membrane and pore size 100 micron
- Good coaxiality and self-centering ability
- Pocket capacity
- Vessel spasm



AngioGuard case



Abott MedNova EmboShield

- Independent stepped guide wire and detached filter
- Polyurethane filter membrane (pore size 150 micron) and nitinol basket framework
- Better wire maneuverability
- Large pocket capacity
- Rigid filter
- Complex device preparation


NTUH protected CS experience

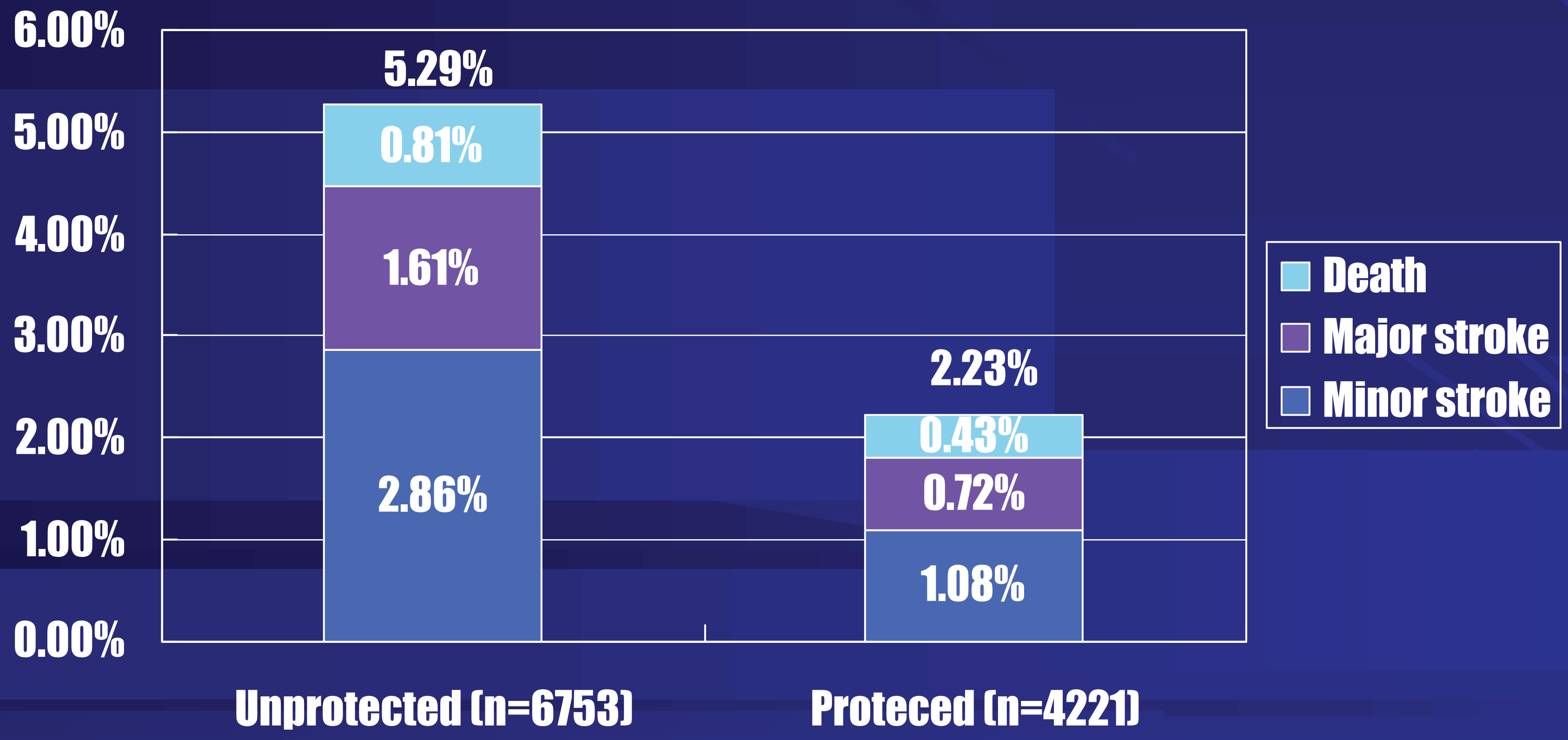
	Non-protected (n=174)	Protected (n=143)
Sex, M/F	123/51	111/32
Age, y	72 ± 8	74 ± 8
HTN, %	71	78
DM, %	28	31
HLP, %	44	48
Smoking, %	46	55
Symptomatic, %	65	66
NASCET exclusion, %	70	67
CCA diameter, mm	7.5 ± 1.2	7.3 ± 1.0
ICA diameter, mm	5.4 ± 0.8	5.4 ± 0.8
Lesion length, mm	21 ± 9	20 ± 7
DS, %	86 ± 10	90 ± 7
Final RS, %	13 ± 8	12 ± 7

NTUH protected CS experience

	Non-protected (n=175)	Protected (n=143)
Tech. success, %	99.4	99.3
Procedural stroke/death, %	4.6	2.1
Ipsi. stroke, %	3.4	0.7
Total stroke, %	4.0	1.4
Death, %	0.6	0
Follow-up, m	42 ± 11	16 ± 12
F/u rate, %	98	99
New stroke/death, %	6.9	2.8
Ipsi. Stroke, %	2.9	0.7
Total stroke, %	4.0	0.7
Death, %	3.4	1.4
Angio. restenosis, %	2.9	1.4

30d stroke and procedure-related death

Wholey MH, et al. CCI 2003;60:259



NTUH EPD selection

	Distal balloon	Proximal balloon	Filter
Isolated ICA	+	+	+
Contr. occlusion	-/+	-/+	+
Diseased CCA	+	-/+	+
Large ICA >6-8 mm	-/+	+	-
String sign	-/+	+	-
Insufficient Willis	-/+	-/+	+
Long tortuous lesion	-/+	+	-
Brachial approach	+	-	+

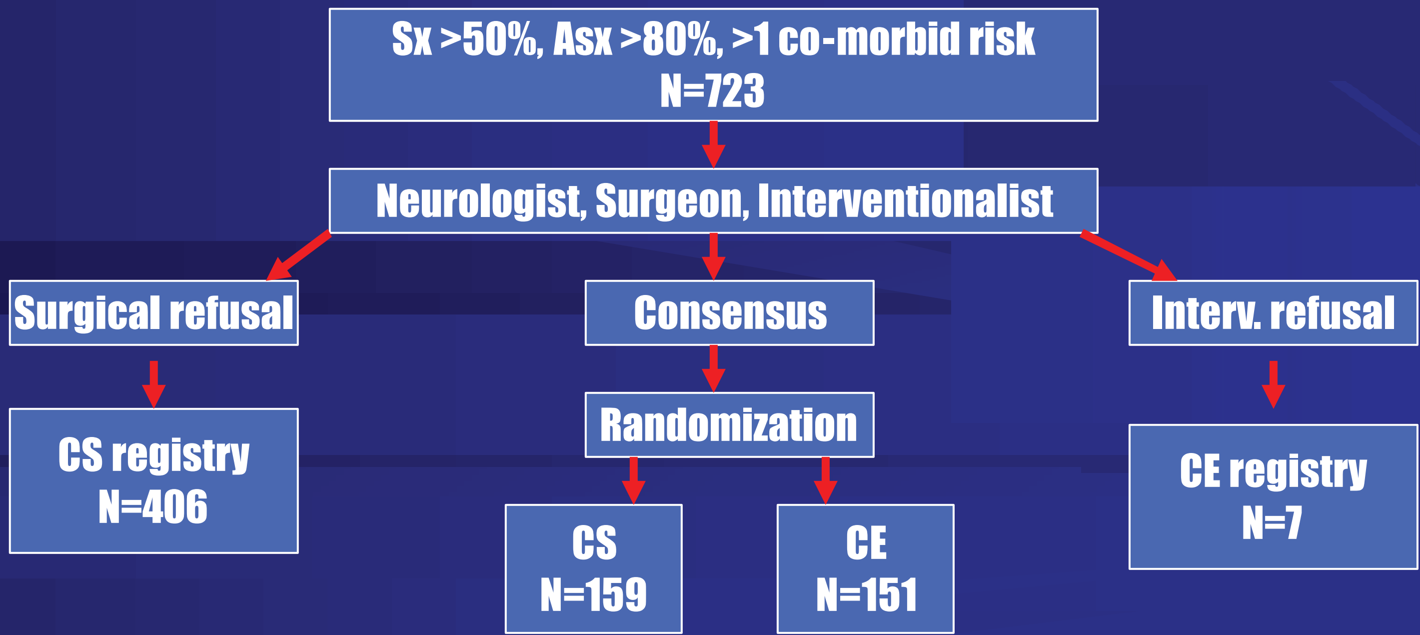
Does EPD really work?

- PercuSurge: Henry M et al CCI 2004;61:293
  - 268 lesions in 242 patients
  - Debris aspirated in all, with mean particle size 250 μm (56-2652 μm) and number 74 (7-145)
  - 30d death/stroke rate 2.3%
- EmboShield: SECuRITY registry TCT 2003
  - 305 high-risk patients with Xact + EmboShield
  - 30d stroke/death/MI 7.2%
- Accunet: ARCHeR 2 registry TCT 2003
  - 278 high-risk patients with OTW Acculink + Accunet
  - 30d major stroke/death rate 2.5%
  - New ipsi. stroke upto 12-month 0.4%

SAPPHIRE trial

Yadav JS. ACC 2003

- Parallel randomized comparison and registries of CS under EPD vs. CE in 29 US sites
- Designed to look at both real-world as well as randomization-eligible patients



SAPPHIRE randomization 30d

Yadav JS. ACC 2003

	CS	CE	P
Death	0.6%	2.0%	0.36
Stroke	3.8%	5.3%	0.59
MI (Q/non-Q)	2.6%	7.3%	0.07
Death/stroke/MI	5.8%	12.6%	<0.05
TIA	3.8%	2.0%	0.5
Major bleeding	8.3%	10.6%	0.56
Cranial nerve injury	0.0%	5.3%	<0.01

SAPPHIRE randomization 1y

Yadav JS. ACC 2003

	CS (N=159)	CE (N=151)	P
Death (%)	11 (6.9)	19 (12.6)	0.12
Stroke	9 (5.7)	11 (7.3)	0.65
Major ipsi.	0	5 (3.3)	0.03
Major non-ipsi.	1 (0.6)	1 (0.7)	1
Minor ipsi.	6 (3.8)	3 (2.0)	0.5
Minor non-ipsi.	3 (1.9)	3 (2.0)	1
MI	4 (2.5)	12 (7.9)	0.04
QMI	0	2 (1.3)	0.24
Non-QMI	4 (2.5)	10 (6.6)	0.1
MAE w/o non-neuro death >30D	9 (5.7)	19 (12.6)	<0.05
MAE w/o non-neuro death or MI >30D	8 (5.0)	11 (7.3)	0.48
Cranial n. palsy	0	7 (4.6)	<0.01
Clinically driven TLR	1 (0.6)	6 (4.0)	0.06

Conclusion

- Procedural embolism of CS can be effectively prevented by various EPD, along with refined equipments and techniques
- EPD is mandatory and essential in the current standard practice
- Vast body of experience demonstrates CS with EPD is safe, effective, and durable in stroke prevention
- SAPPHIRE trial showed CS with EPD is better than CE, with more RCT's coming