

21st CARDIOVASCULAR SUMMIT **TCTAP2016**

April 26-29, 2016

coex, Seoul, Korea

Carotid Artery Stenosis Angiography or Image Guided decision; Medical, CEA or Stent

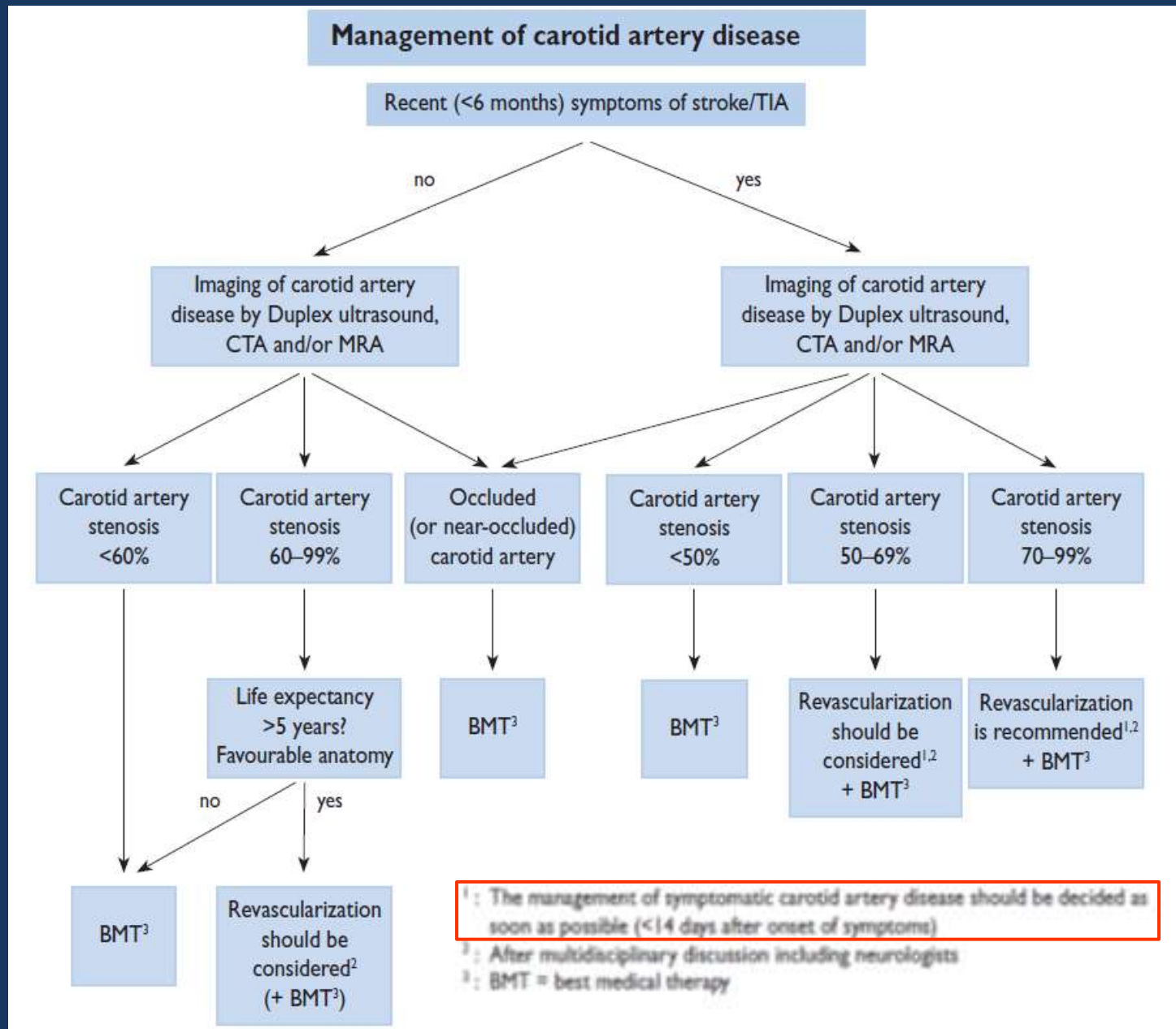
Prof. Piotr Pieniazek MD PhD



John Paul II Hospital in Krakow,
Jagiellonian University Institute of Cardiology,
Krakow, Poland

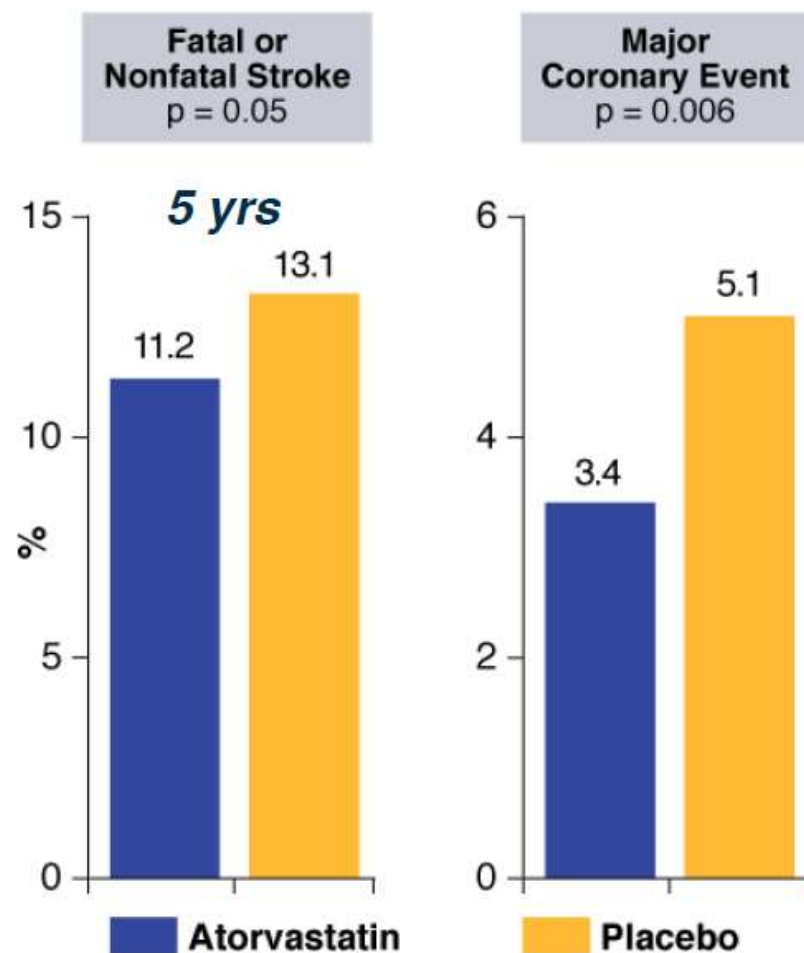


ESC Guidelines 2011



SPARCL

Trial Design: SPARCL was a randomized, double-blind trial of atorvastatin (80 mg daily, n=2365) or placebo (n=2366) in patients with prior stroke or TIA. Primary endpoint was fatal or nonfatal stroke at a median follow-up of 4.9 years.



Results

- At 1 month, LDL levels ↓ from 133 mg/dl at baseline to 61.3 mg/dl in atorvastatin group ($p < 0.0001$) but no change in placebo group (133.5 mg/dl)
- Primary endpoint of stroke ↓ in atorvastatin group vs placebo (Figure)
- Reductions in 2° endpoints of TIA (6.5% vs 8.8%, $p = 0.004$), major coronary event (Figure), major CV event (14.1% vs 17.2%, $p = 0.005$) also ↓ for atorvastatin
- No difference in mortality (9.1% for atorvastatin vs 8.9% for placebo, $p = 0.77$)
- Persistent ALT/AST elevations ↑ in atorvastatin group (2.2% vs 0.5%, $p < 0.001$)

Conclusions

- Among patients with prior stroke or TIA, treatment with atorvastatin was associated with reduction in recurrent stroke compared with placebo, as well as reductions in major coronary events
- Prior studies such as 4S, CARE, and CARDS showed ↓ coronary events with statin in patients with coronary heart disease
- Present trial extends findings to setting of cerebrovascular disease

High-Risk Criteria for CEA

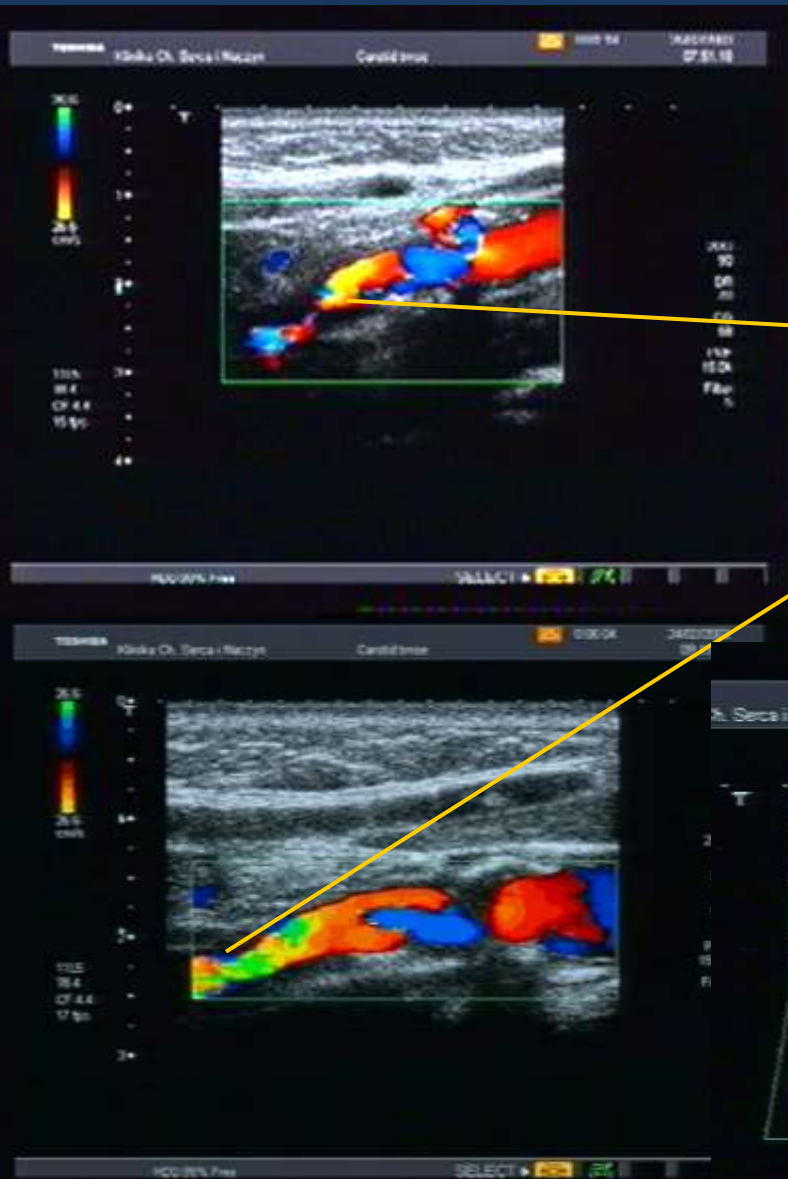
Anatomical Criteria

Lesion at C-2 or higher
Lesion below clavicle
Prior radical neck surgery or radiation
Contralateral carotid occlusion
Prior ipsilateral CEA
Contralateral laryngeal nerve palsy
Tracheostoma

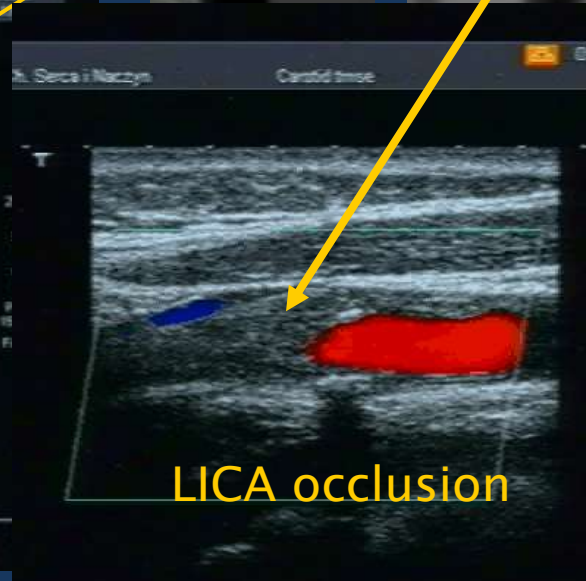
Medical Comorbidities

Age \geq 80 yrs
Class III/IV congestive heart failure
Class III/IV angina pectoris
Left main/ \geq 2 vessel coronary disease
Urgent (<30 days) heart surgery
LV ejection fraction $\leq 30\%$
Recent (<30 days) myocardial infarction
Severe chronic lung disease
Severe renal disease

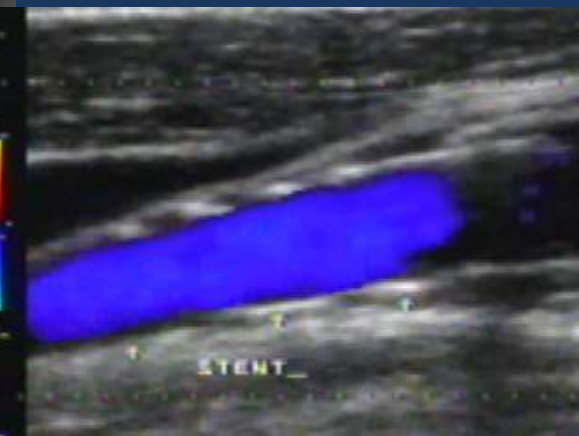
Experienced-operator Duplex Ultrasound: MANDATORY



- screening
- stenosis severity
- plaque morphology
- stent & EPD selection (CAS 'tailoring')
- stent follow-up

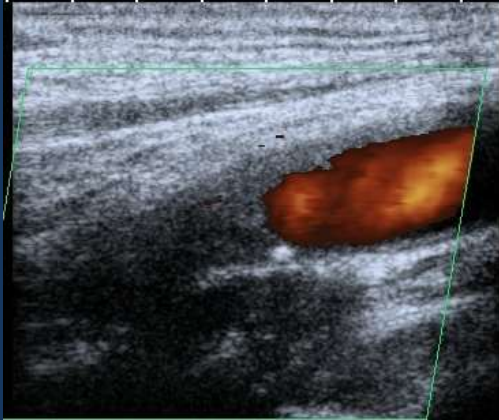


tandem RICA stenosis!!

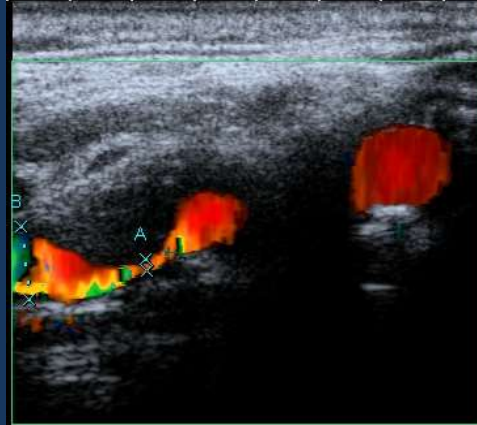


Contralateral ICA occlusion: not an absolute contraindication to CAS with proximal EPD **but** collateral supply from the vertebral arteries needs to be documented on TCD!

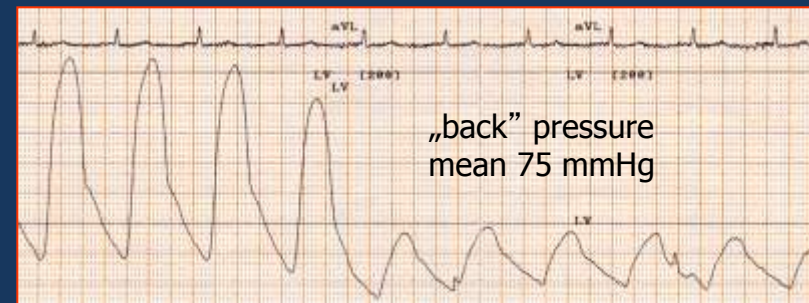
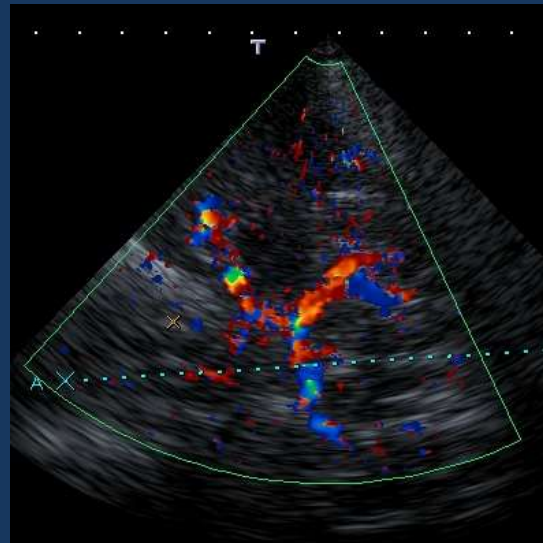
RICA occlusion



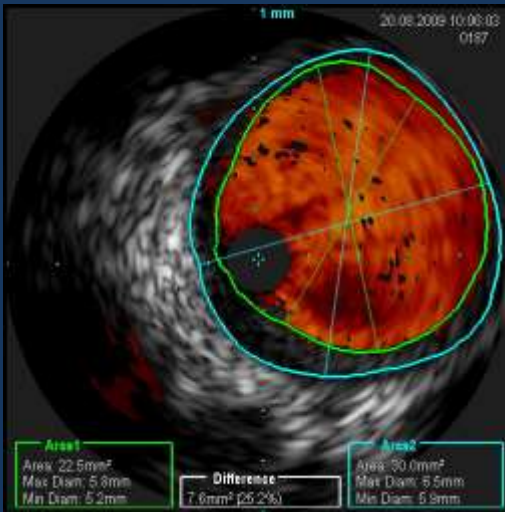
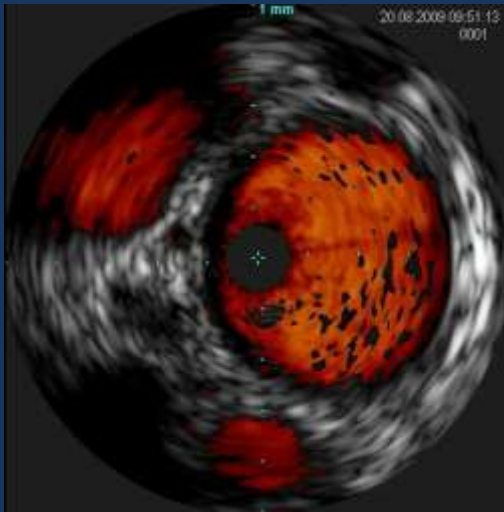
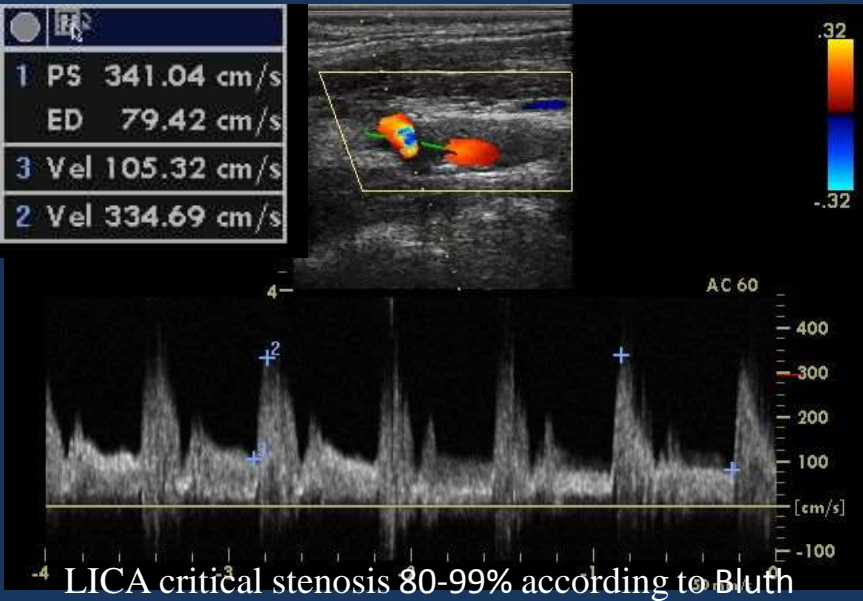
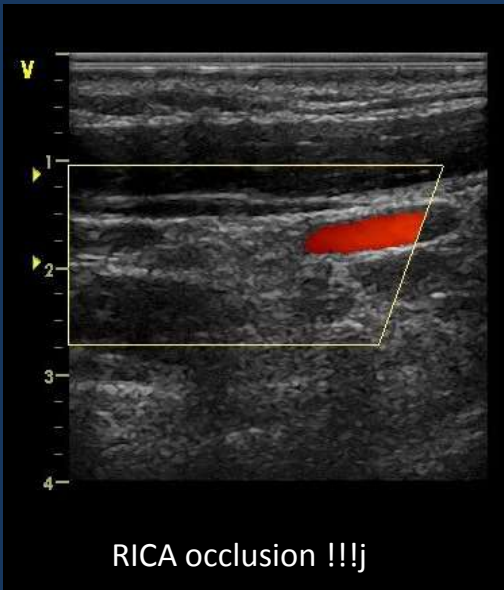
LICA stenosis



Patent collateral flow through the left posterior communicating artery to the left middle cerebral artery, in the patient with occlusion of the right internal carotid artery and tight stenosis of the left internal carotid artery



One in 5 patients referred for CEA on the basis of DUPLEX ULTRASOUND gets operated on IN ABSENCE of SIGNIFICANT ICA stenosis

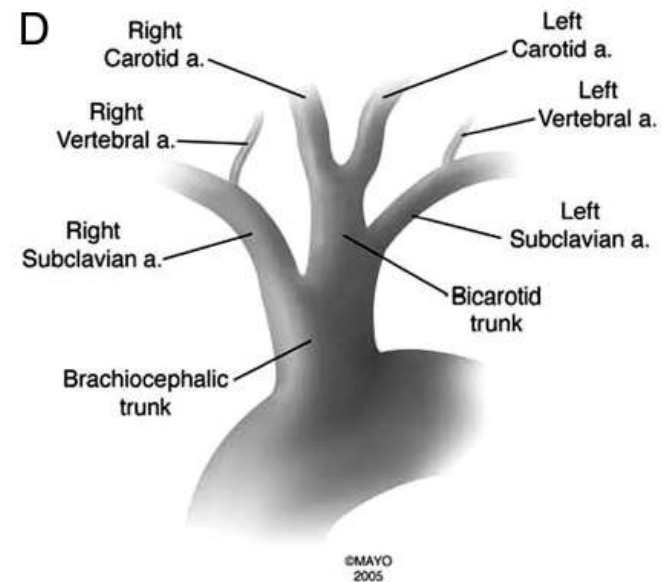
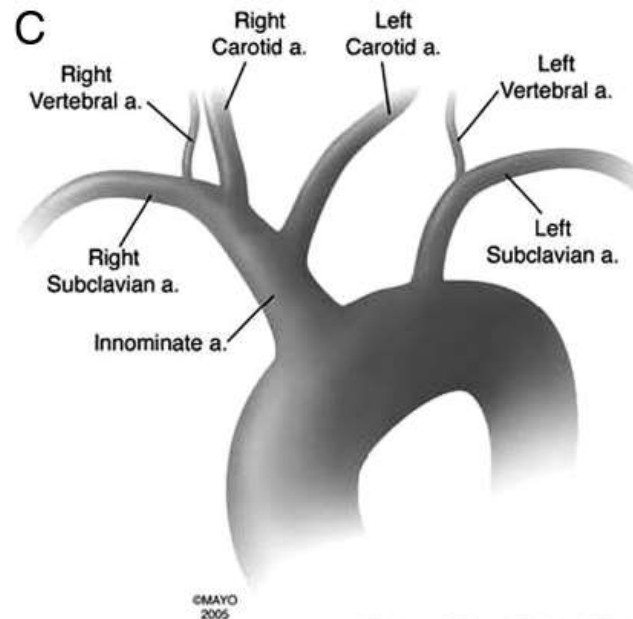
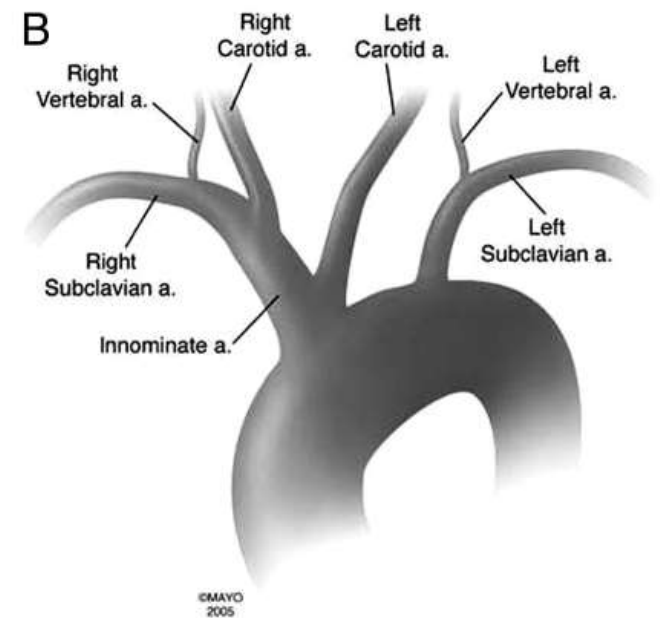
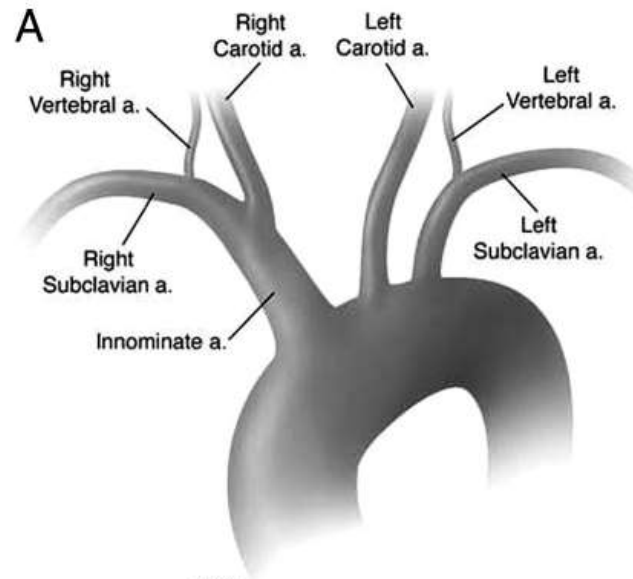


Queshi AI et al.: Stroke 2001; 32, 2287

Target ICA access anatomy:

...can be crucial
in determining
CAS feasibility
& safety

⇒ less contrast
use / less time /
less risk if
access anatomy
defined prior
to CAS!



Normal arch

Normal CCA	
Normal target vessel	Angulated distal ICA
Standard	2.4
lesion	(0.4)
Pinhole	2.9
stenosis	(1.2)

No arch disease		Diseased CCA	
Normal target vessel	Angulated distal ICA	Normal target vessel	Angulated distal ICA
3.5	4.3	3.7	4.5
(1.2)	(1.2)	(1.5)	(1.4)
2.9	4.8	4.1	5.0
(0.9)	(1.0)	(1.7)	(1.3)

Normal CCA	
Normal target vessel	Angulated distal ICA
Standard	4.3
lesion	(1.9)
Pinhole	4.7
stenosis	(1.8)

Arch atheroma	
Normal target vessel	Angulated distal ICA
Standard	5.3
lesion	(1.8)
Pinhole	5.8
stenosis	(1.6)

Diseased CCA	
Normal target vessel	Angulated distal ICA
Standard	5.0
lesion	(2.2)
Pinhole	5.5
stenosis	(2.2)

Bovine

Standard	3.6
lesion	(1.4)
Pinhole	4.1
stenosis	(1.5)

Standard	4.7
lesion	(1.8)
Pinhole	5.1
stenosis	(1.6)

Standard	4.9
lesion	(1.4)
Pinhole	6.3
stenosis	(1.4)

Standard	5.0
lesion	(1.4)
Pinhole	6.4
stenosis	(1.6)

Standard	6.0
lesion	(1.3)
Pinhole	7.4
stenosis	(0.9)

Standard	5.8
lesion	(1.8)
Pinhole	6.3
stenosis	(1.6)

- Arch → Diseased / not diseased
- Arch → Normal / bovine / type III
- CCA → Normal / diseased
- Distal ICA → Normal / tortuous
- Lesion → standard / pinhole

Type III

Standard	4.6
lesion	(1.6)
Pinhole	5.1
stenosis	(1.3)

Standard	5.7
lesion	(1.3)
Pinhole	6.1
stenosis	(1.4)

Standard	6.3
lesion	(1.4)
Pinhole	6.3
stenosis	(1.4)

Standard	6.4
lesion	(1.4)
Pinhole	6.4
stenosis	(1.6)

Standard	7.8
lesion	(0.7)
Pinhole	7.5
stenosis	(1.1)

Standard	6.8
lesion	(1.6)
Pinhole	7.2
stenosis	(1.2)

Bovine + Type III

Standard	5.5
lesion	(1.4)
Pinhole	6.0
stenosis	(1.4)

Standard	6.5
lesion	(1.4)
Pinhole	7.0
stenosis	(1.3)

Standard	6.7
lesion	(1.4)
Pinhole	7.2
stenosis	(1.3)

Standard	6.4
lesion	(1.3)
Pinhole	6.8
stenosis	(1.3)

Standard	7.4
lesion	(1.1)
Pinhole	7.9
stenosis	(0.7)

Standard	7.2
lesion	(1.3)
Pinhole	7.6
stenosis	(1.2)

Straightforward → Difficult

CAS strategy: Non-invasive work-up



Z. Moczulski & M. Irzyk

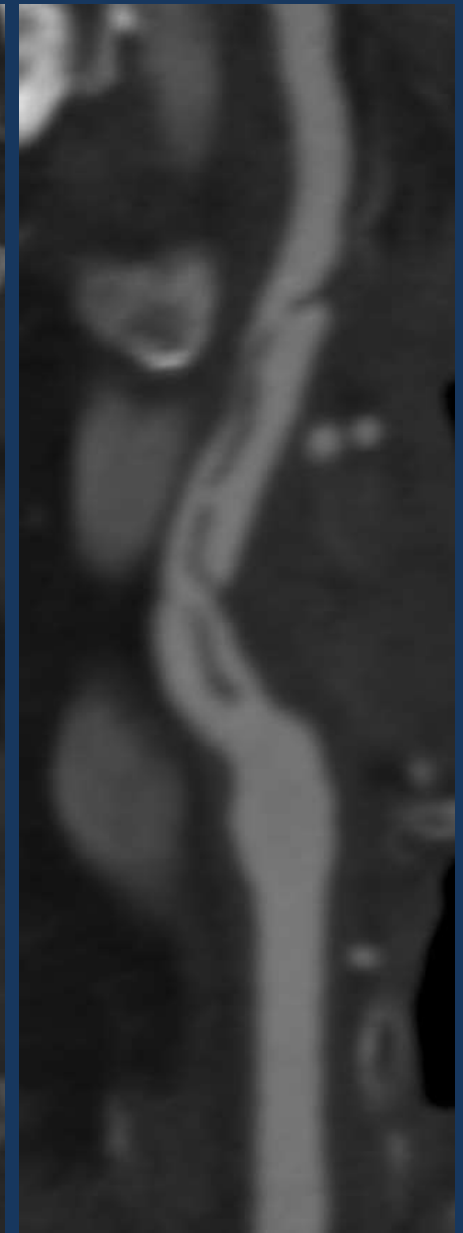
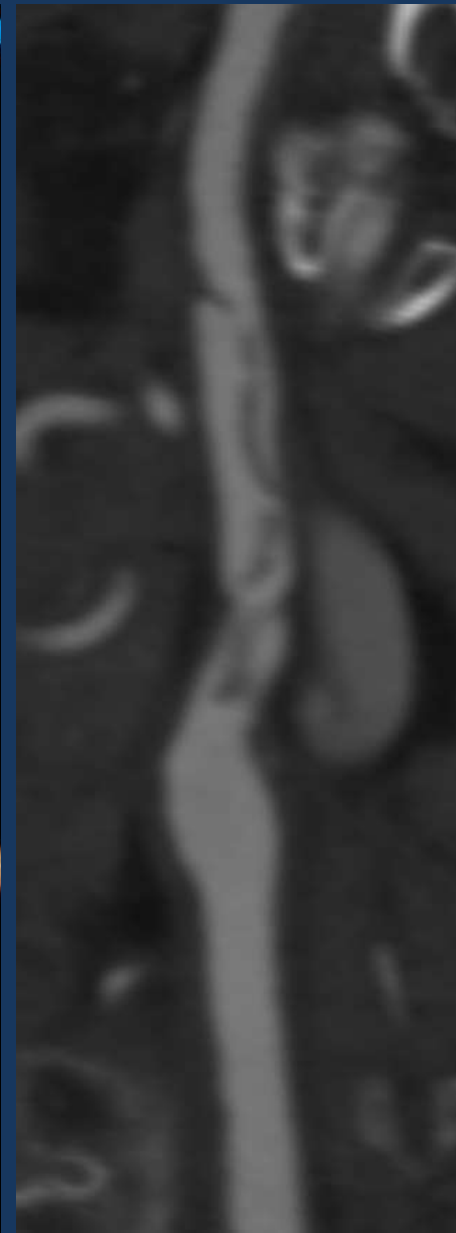
*Centre for Diagnosis and Rehabilitation
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John Paul II Hospital, Krakow*

CT angio can indicate CAS strategy (or CAS vs CEA) options !!!!

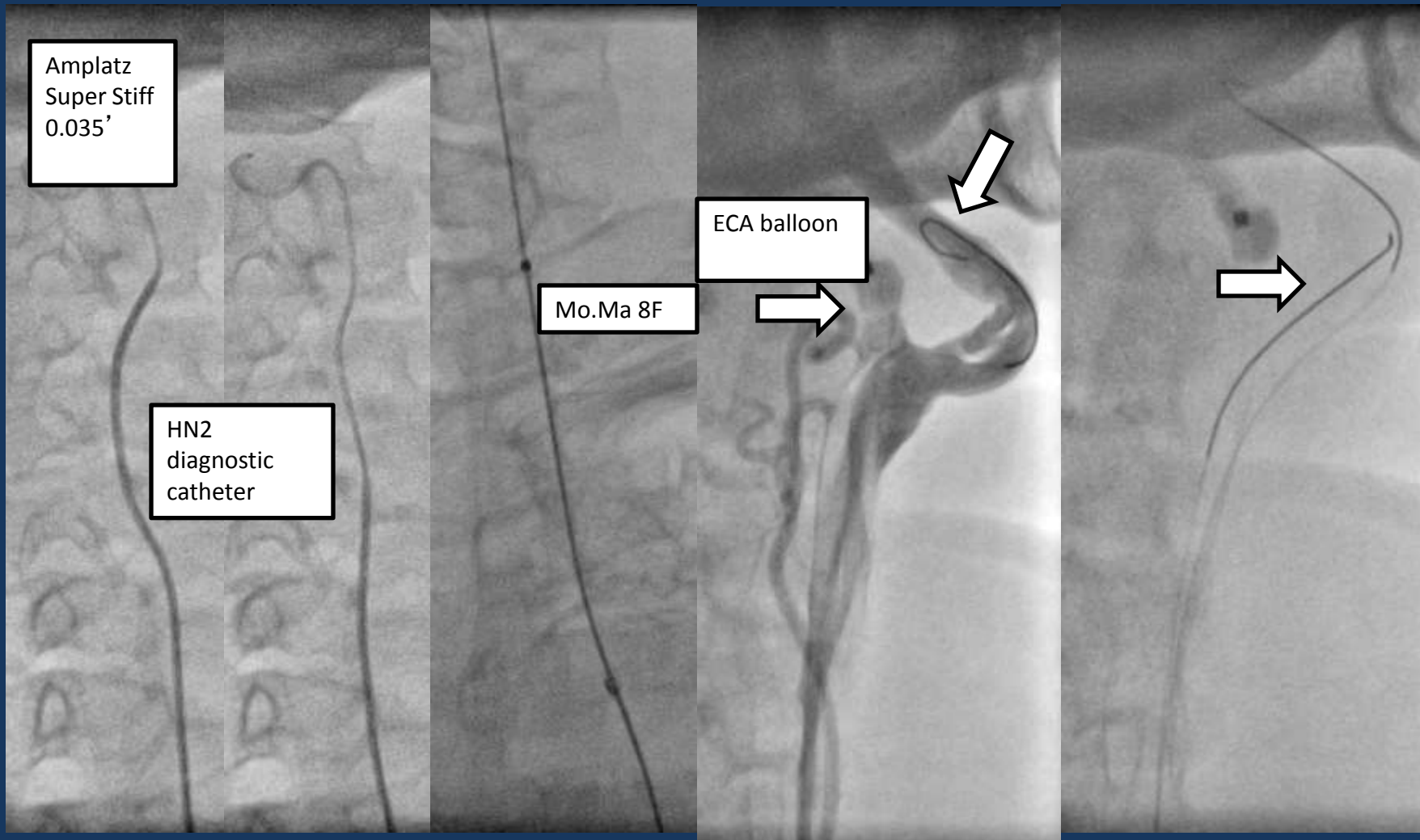




'bovine arch' , stent in RICA



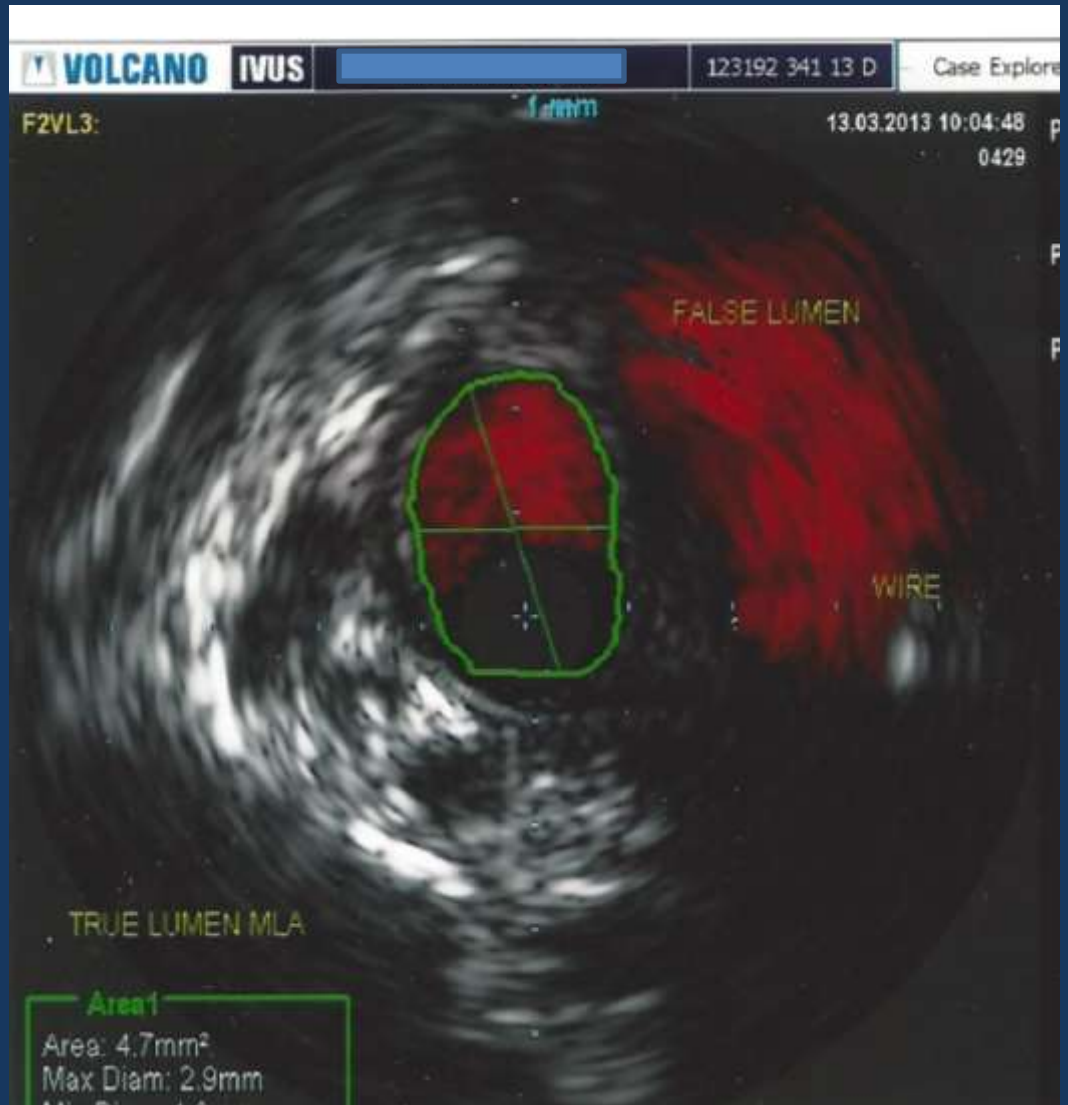
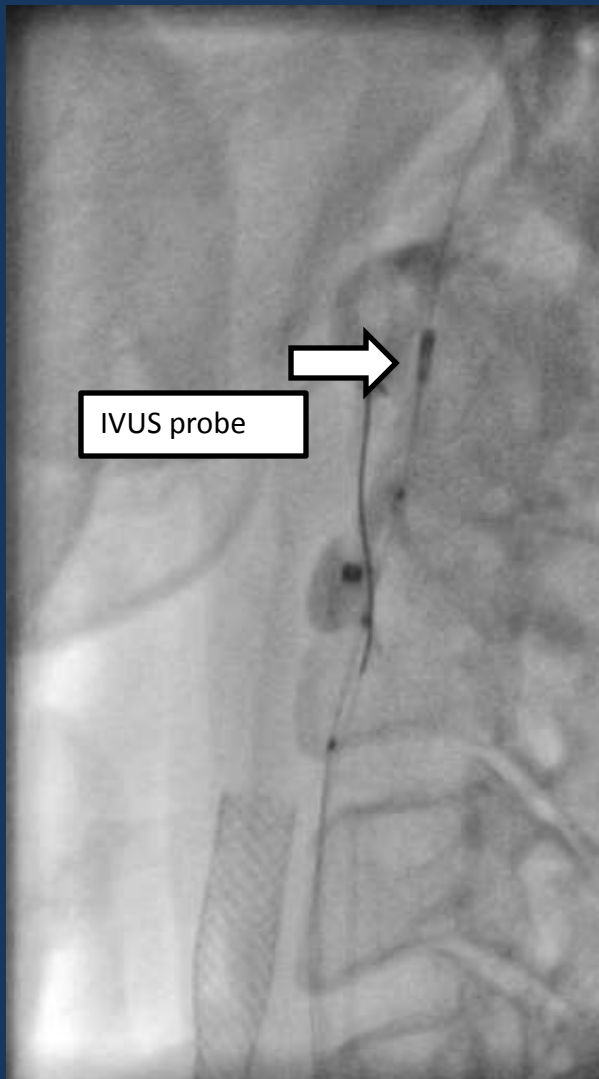
Long iatrogenic LICA dissection
3 months after CEA



Mo.Ma 8F proximal EPD

0.014' guidewire
LICA false lumen

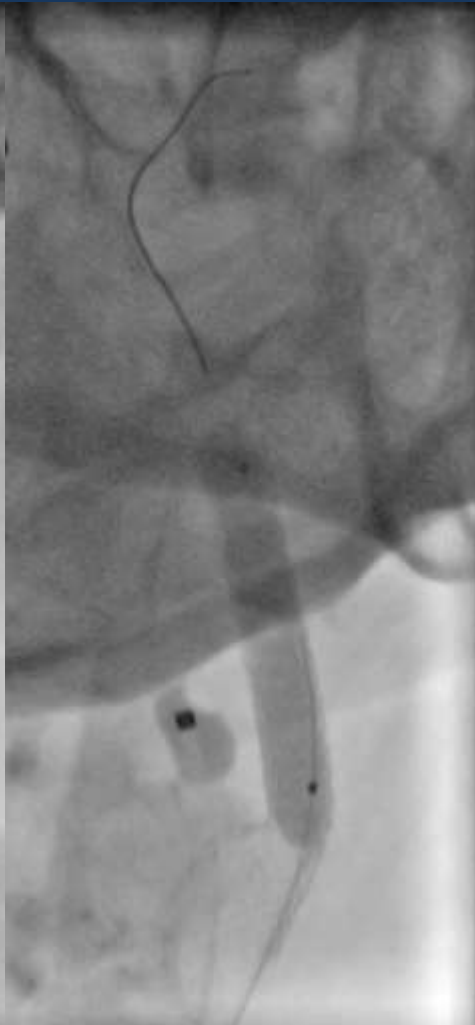
True lumen second
guidewire



IVUS verification of true lumen in LICA



Precise 8x40mm self-expanding stent

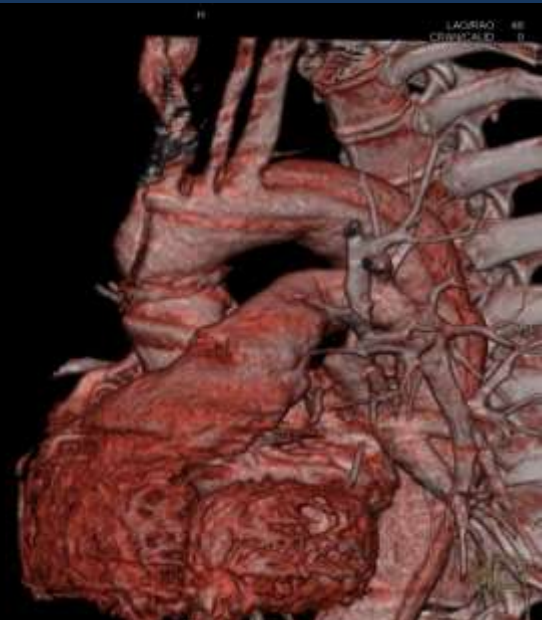
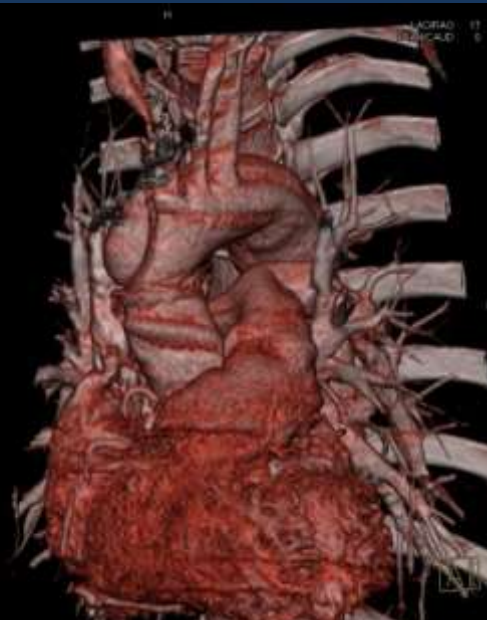
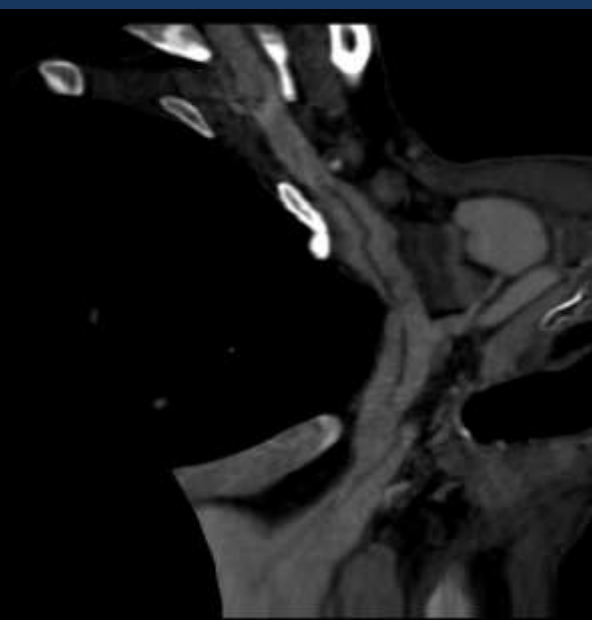


Stent postdilatation with 5,5x30mm balloon



Final angiography

Pts. age 32 with Marfan Syndrome after Bentall deBono surgery with TBC , RCCA & Aorta dissection



Right hemisphere TIA

1 month after cardiac surgery.

CAS procedure of RCCA & TBC via direct surgical approach from RCCA !!!!!

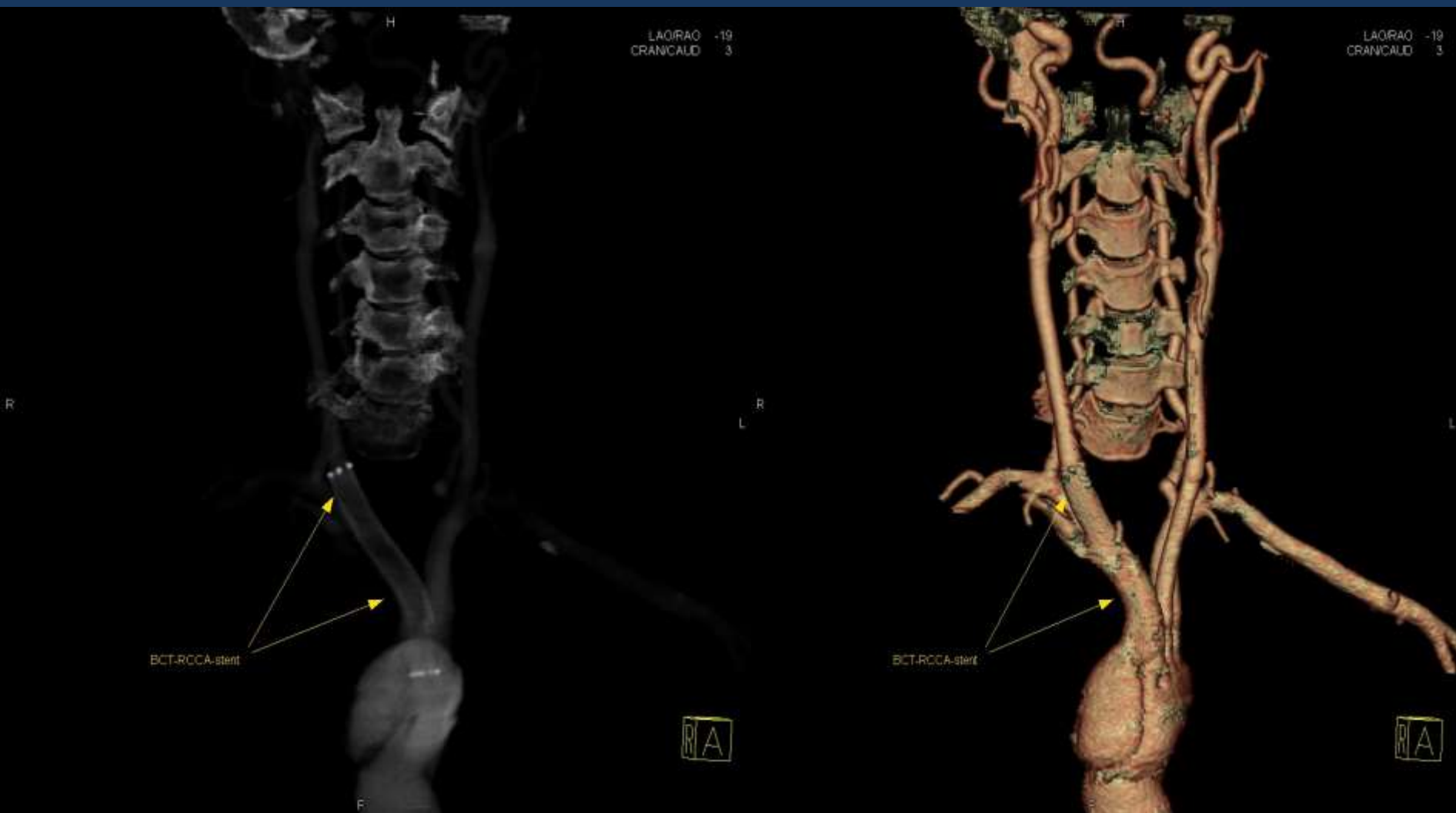


CAS procedure of RCCA & TBC via direct surgical approach from RCCA !!!!



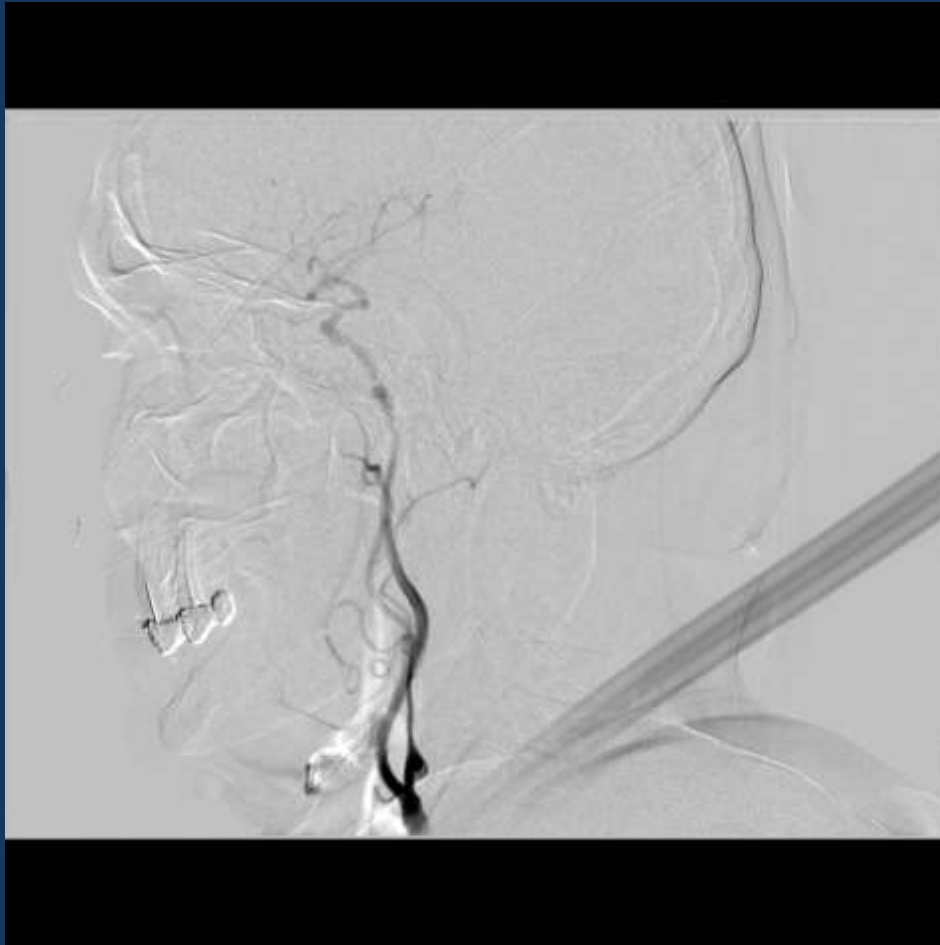
SMART 10/80 selfexpandible stent without postdilatation

CAS procedure of RCCA & TBC via direct surgical approach from RCCA !!!!

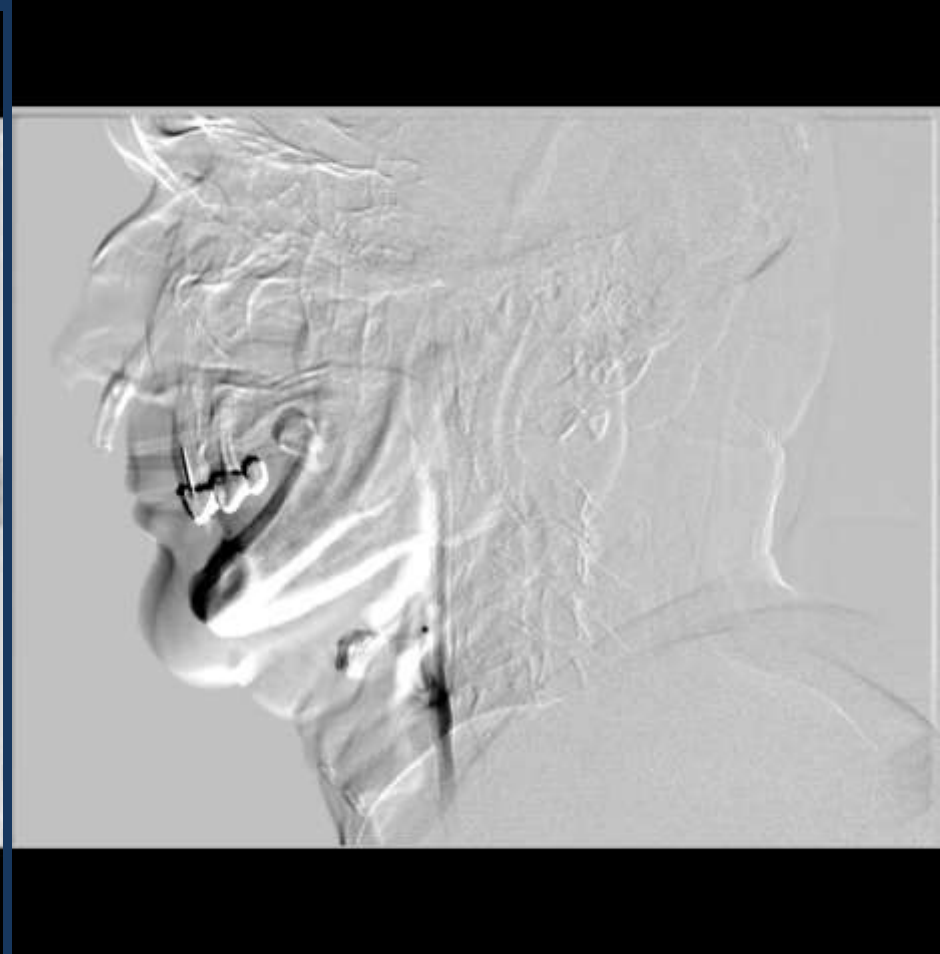


Angio CT optimal angiographic and clinical effect

Hybrid Room in JPII Hospital in Krakow – rotational angiography
CAS procedur is feasible with only less than < 50ML of CM



Before LICA -CAS



After LICA -CAS

6 ml of CM for each angiography !!!!

What does **high risk** lesion mean ????



long filiform
irregural contra
lateral ICA
occlusion



symptomatic
ICA occlusion



thrombus containing
lesion



lesion after
radiotherapy



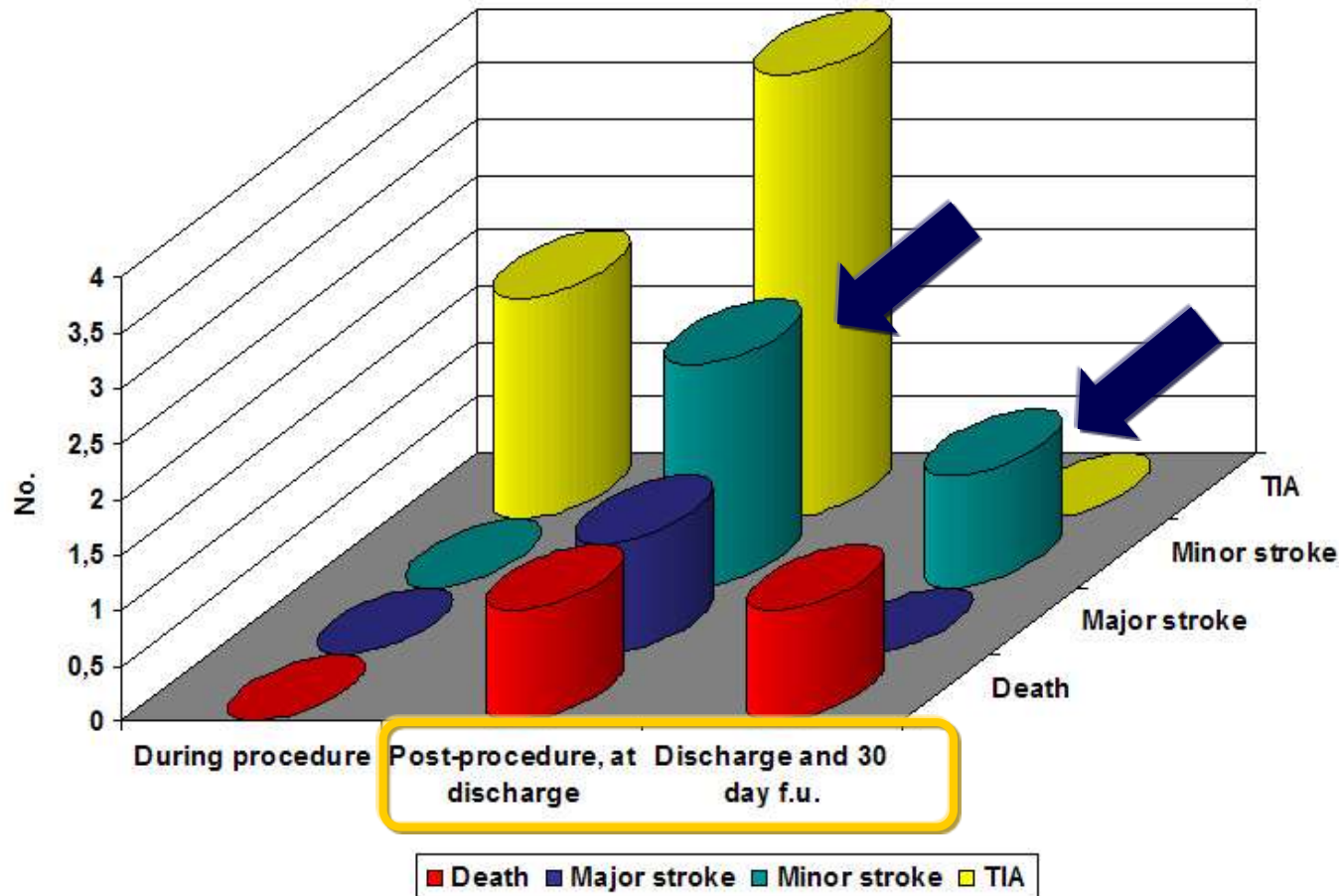
huge plaque
burden



CCA / ICA tight
stenosis

Analysis on 377 consecutive patients

Temporal distribution of embolic events



Tailored CAS: Protocol for Patient- and Lesion-Specific Selection of the Neuroprotection System and Stent Type



General direct stenting strategy

Soft/thrombus-containing plaque or a severe string-sign lesion in a symptomatic patient (Fig. 1A1, 1B, 1E)

Soft/thrombus-containing plaque or a severe string-sign lesion in a symptomatic patient with access vessel (severe iliofemoral atherosclerosis) or target vessel anatomy precluding the use of proximal NPD (e.g., severe ECA stenosis or diffuse CCA disease or severe CCA stenosis at the bifurcation)

Severe ICA angulation/tortuosity at bifurcation or severe calcifications (Fig. 1D)

Soft/symptomatic lesion coexisting with a severe ICA angulation/tortuosity

Severe calcifications on CT angiography

Non-severe echogenic or fibrotic/partly calcified asymptomatic lesion

Bilateral ICA stenosis (Fig. 1A)

Severe ICA/CCA diameter mismatch

Lack of optimal landing zone for a filter (Fig. 1B, 1D)

Lack of femoral access

Critical stenosis (particularly if symptomatic) + contralateral ICA/CCA occlusion (Fig. 1C)

Predilate only if very tight or highly calcified lesion according to duplex ultrasound, CTA, and angiography.

- (1) Use a proximal NPD (flow reversal if (non-critical) ECA stenosis or severe angulation that precludes the use of a (one-piece) proximal flow blockade system); if no ECA stenosis/tortuosity, either of the 2 proximal systems can be used.
- (2) Use a closed-cell stent (cobalt-alloy braided in a straight segment; nitinol if tortuous).

Use an independent-wire filter with 1.25- to 1.5-mm balloon dilation prior to filter delivery or a 6-F-compatible distal occlusion system.

Use an open-cell stent.

Consider a hybrid (open-cell/closed-cell/open-cell) stent.*

Consider cutting balloon predilation; avoid aggressive postdilation.

- (1) Use a distal NPD (Fig. 1A2).
- (2) Use open- or closed-cell stent (depending on the target segment tortuosity).

- (1) Consider treating the less severe lesion with distal NPD first.
- (2) If the contralateral lesion is tight/soft/symptomatic, treat it under proximal NPD (within a few days).

Consider using a tapered (nitinol) stent.

Use a proximal NPD; if not applicable (no femoral access, diffuse iliofemoral atherosclerotic disease, or severely angulated arch), use a distal occlusion system.

Use a transradial or brachial approach with a 6-F-compatible filter or distal occlusion system.

- (1) Consider proximal NPD (document collateral supply via the basilar and posterior communicating artery(-ies) on TCD).
- (2) If proximal NPD excluded, use an independent-wire filter with 1.25 to 1.5-mm balloon predilation prior to filter delivery (Fig. 1C).
- (3) Use a closed-cell stent.

Lesion specific stenting: the solution

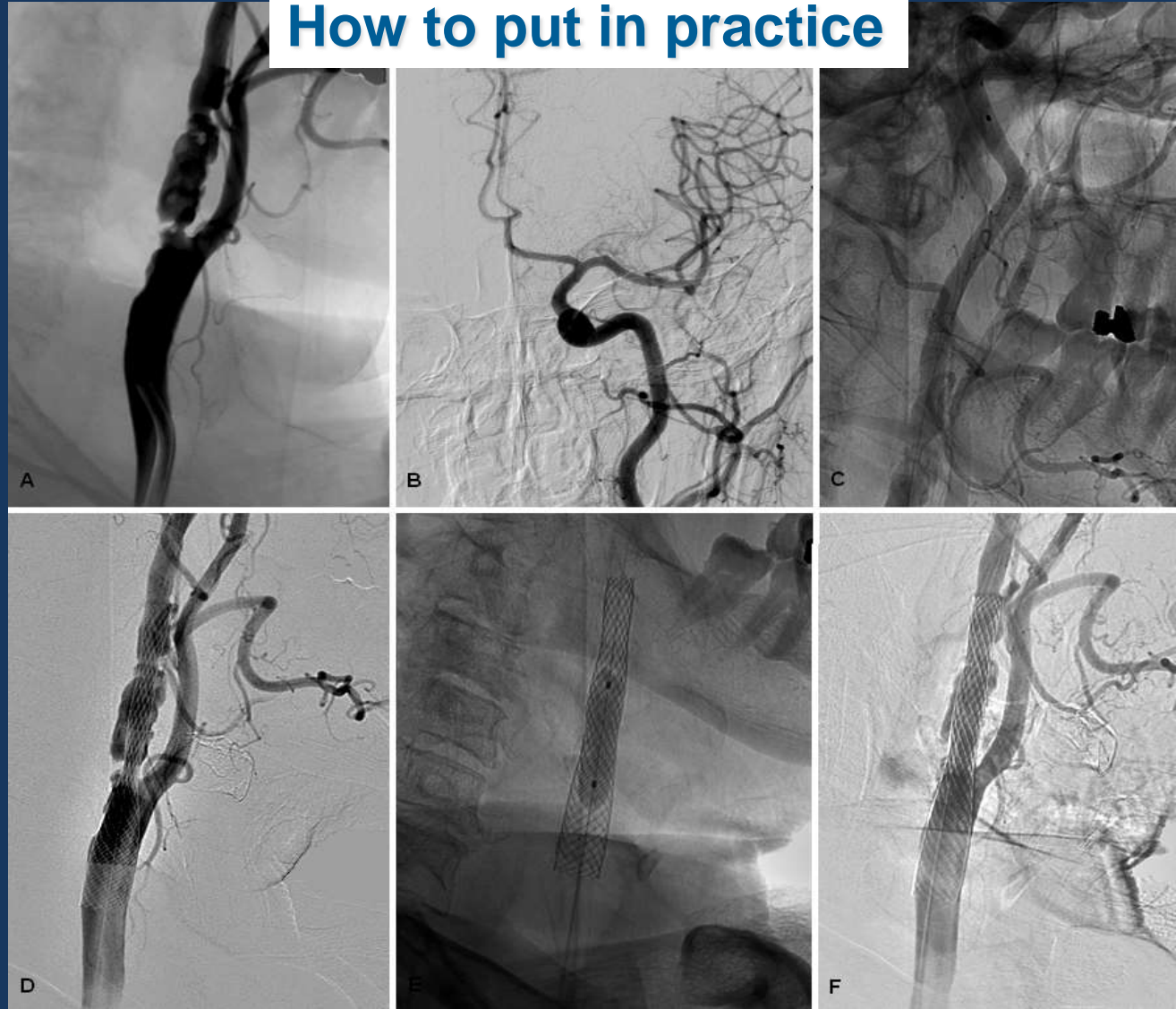
Definition

Lesion specific stenting:

- Tailored procedure which consists in matching **stent biomechanical characteristics** to **carotid lesion features**









- **Main goal:** **sustained anti-embolic protection**

How to put in practice

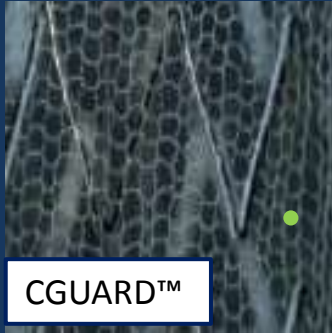


Competition Carotid Stents

"Mesh" Stents

								
Terumo/ Microvention	Inspire MD	W.L. Gore	Abbott Vascular		Boston Scientific	Ev3/ Covidien/ Medtronic	Cordis/ Cardinal Health	Invatec/ Medtronic
Roadsaver	CGuard	Gore Carotid Stent	Acculink	XACT	Carotid Wallstent	Protégé	Precise Pro	Cristallo Ideale
0.38 mm ²	0.15 mm ²	0.44 mm ²	2.36 mm ²	1.89 mm ²	1.397 mm ²	4.93 mm ²	2.36 mm ²	3.23 mm ²
Bench marking by Microvention								
375-500µm	150-180µm	500µm						
Advertising by Inspire MD								

Pore Size

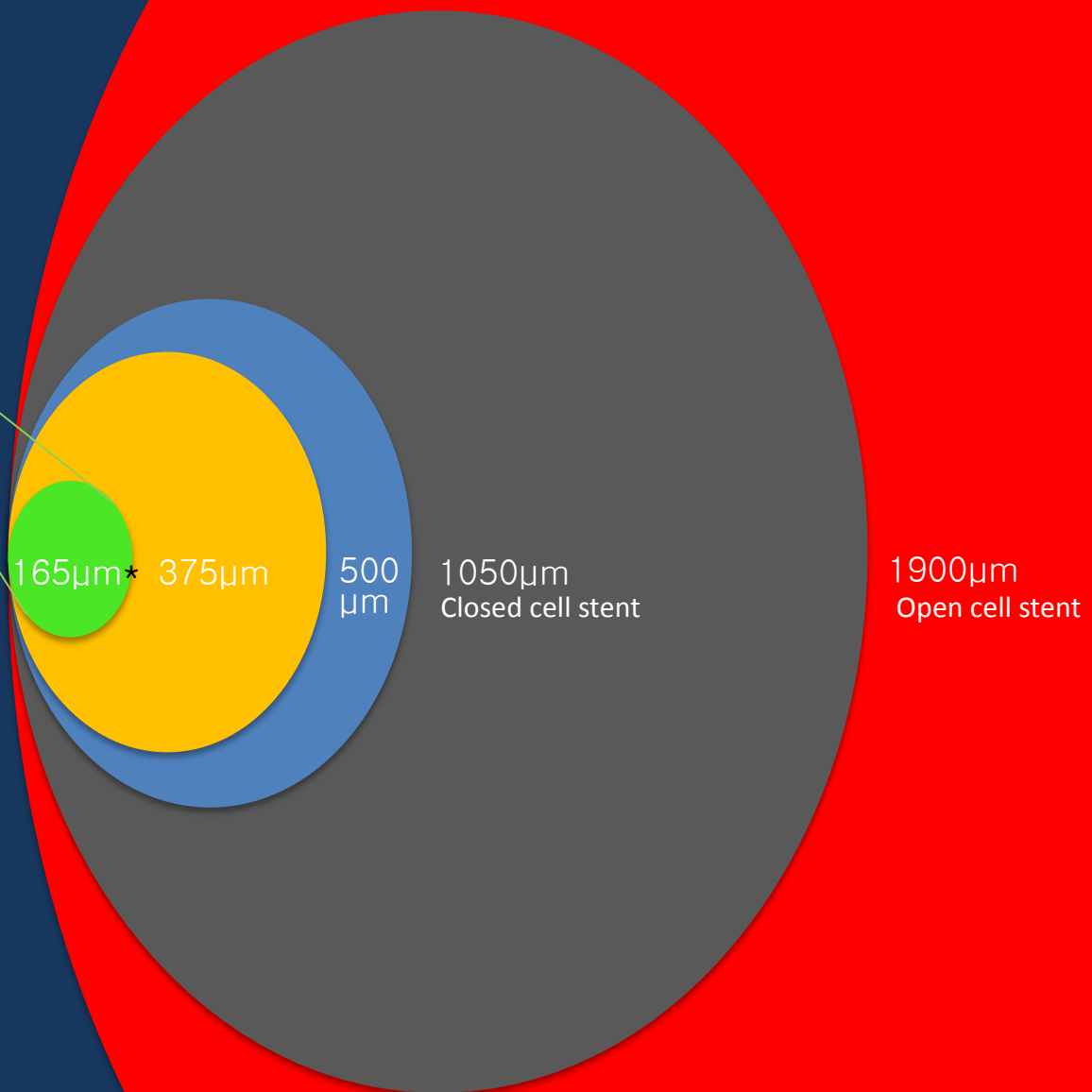
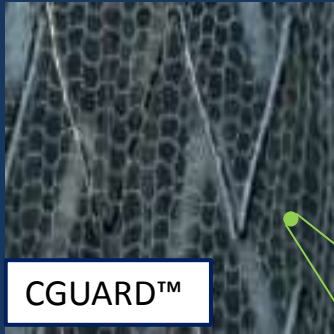


Closed cell stent

Open cell stent

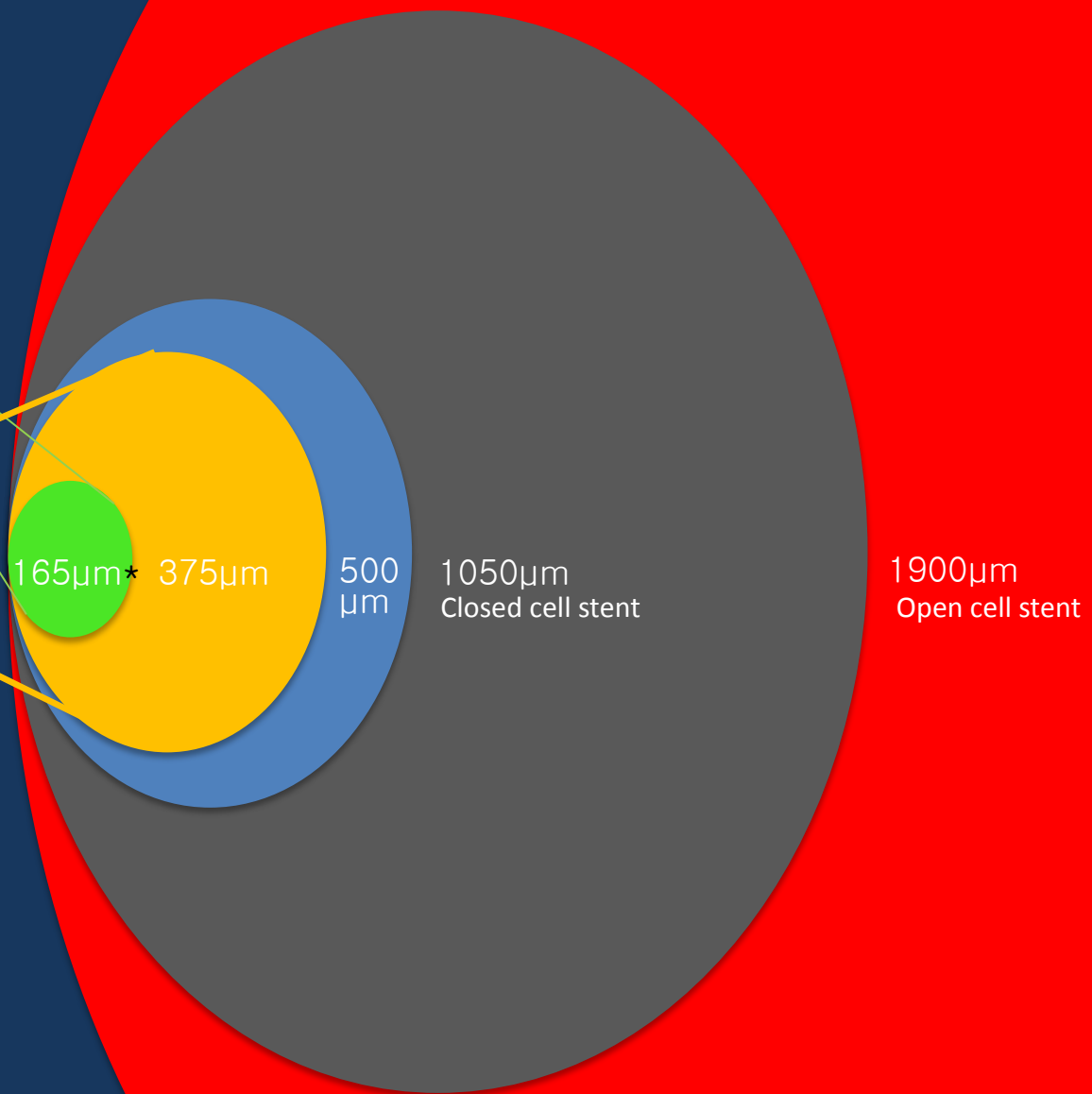
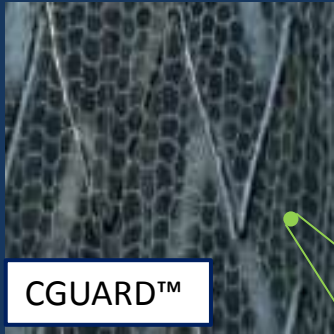
* 150–180μm

Pore Size



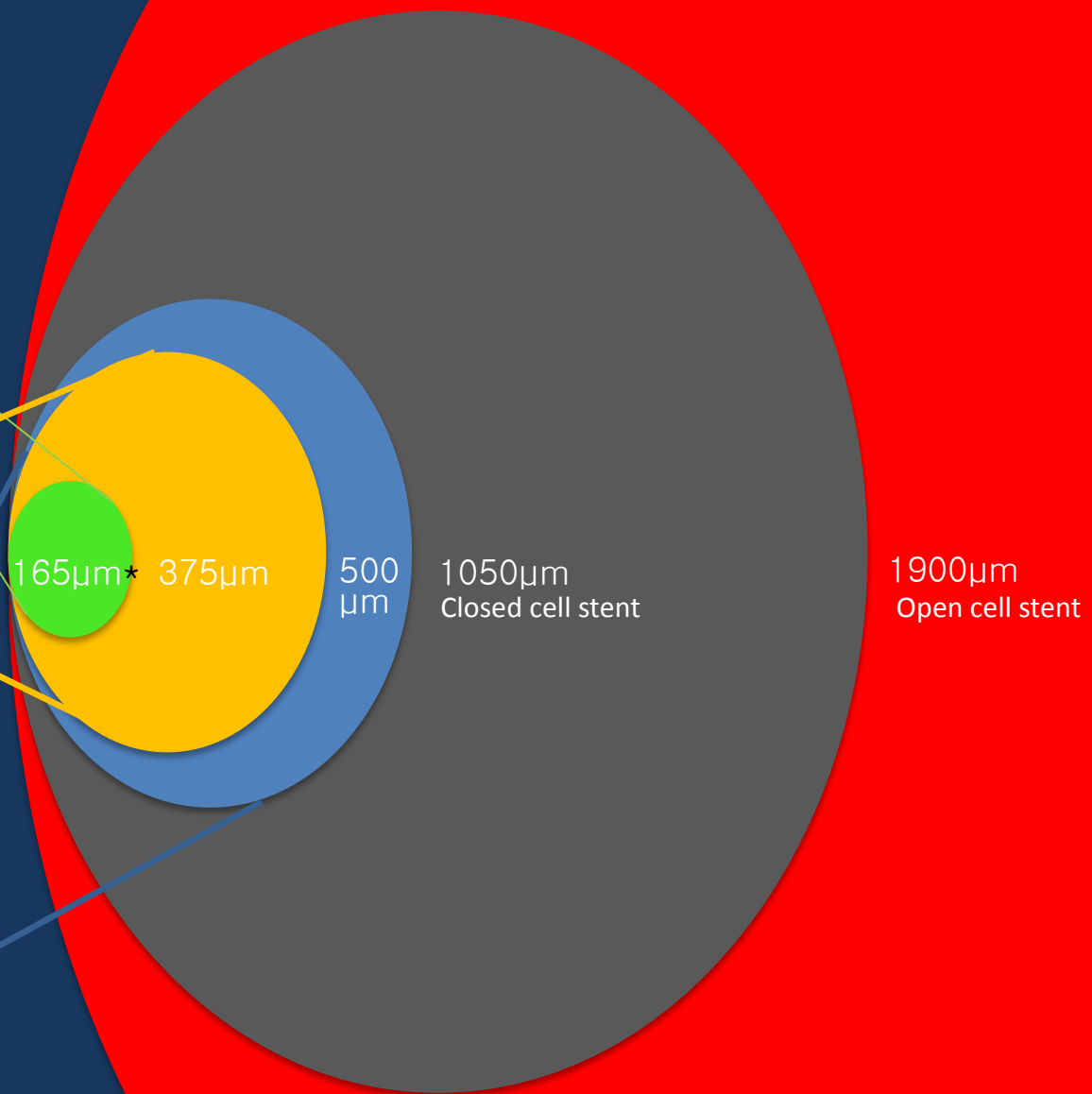
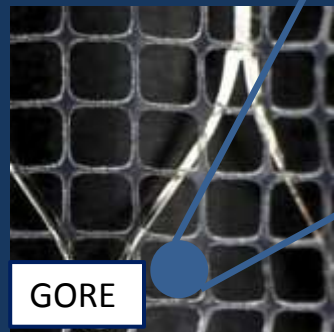
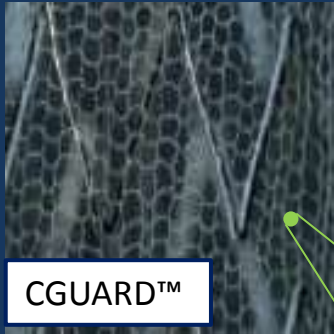
* 150–180μm

Pore Size



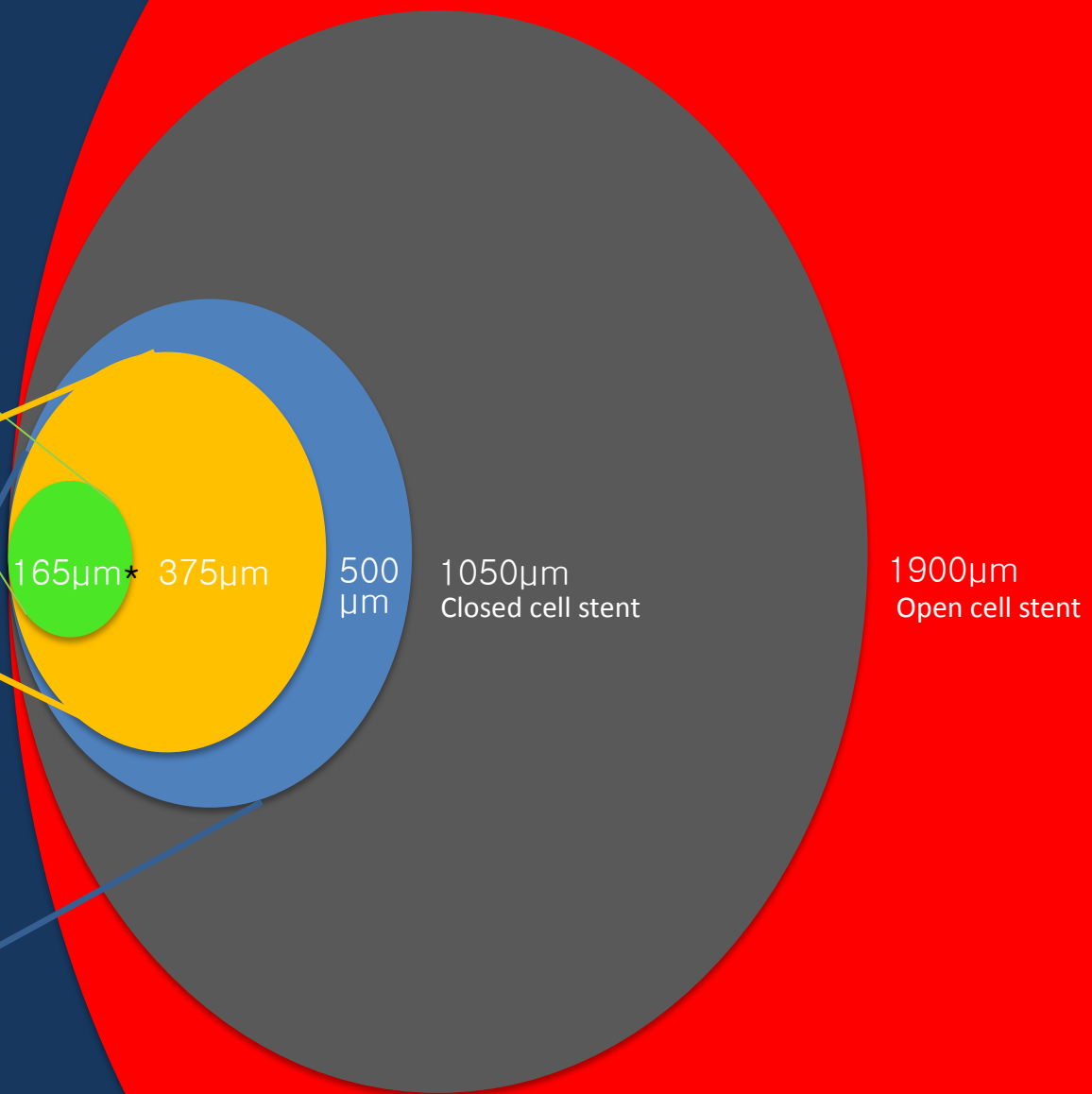
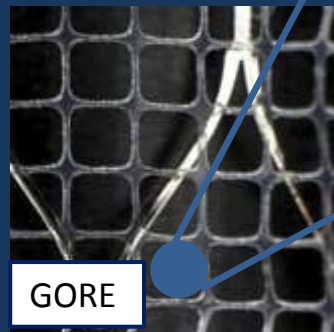
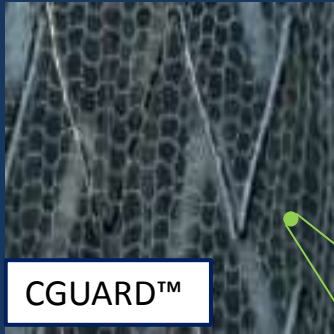
* 150–180μm

Pore Size

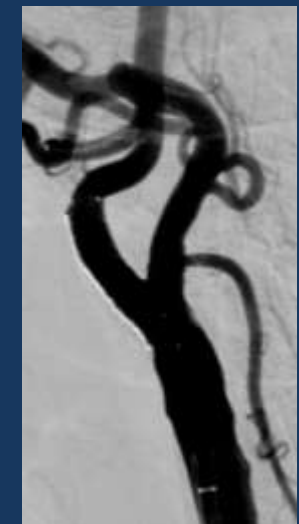
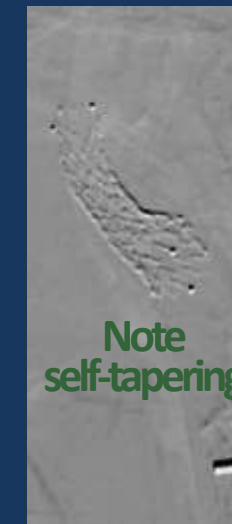
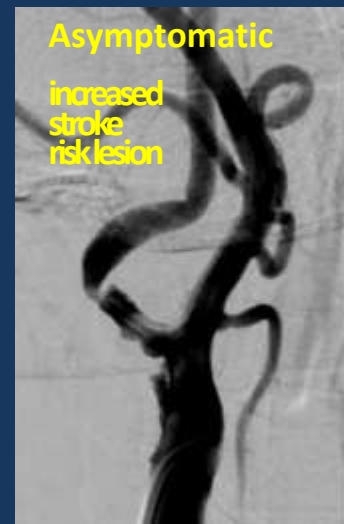
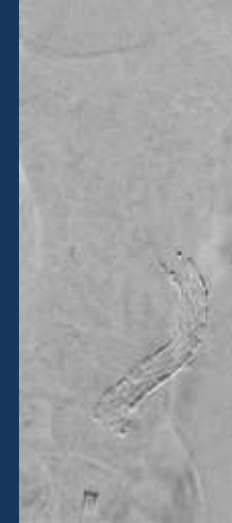
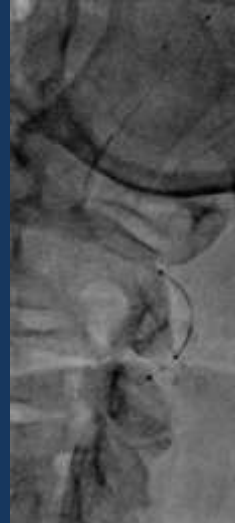
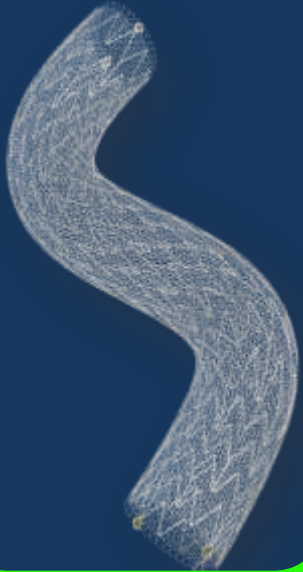


* 150–180µm

Pore Size



* 150–180µm



Endovascular Reconstruction of the Carotid Bifurcation

A Prospective, Multicenter Study of a Novel Mesh-Covered Carotid Stent



The CGuard CARENET Trial (Carotid Embolic Protection Using MicroNet)

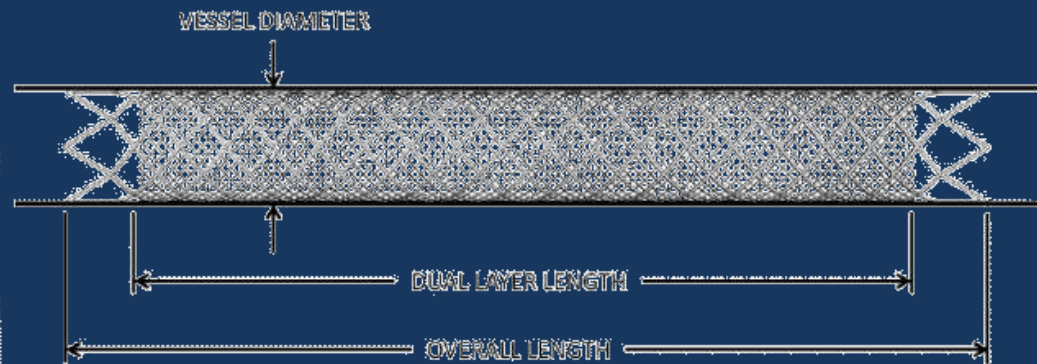
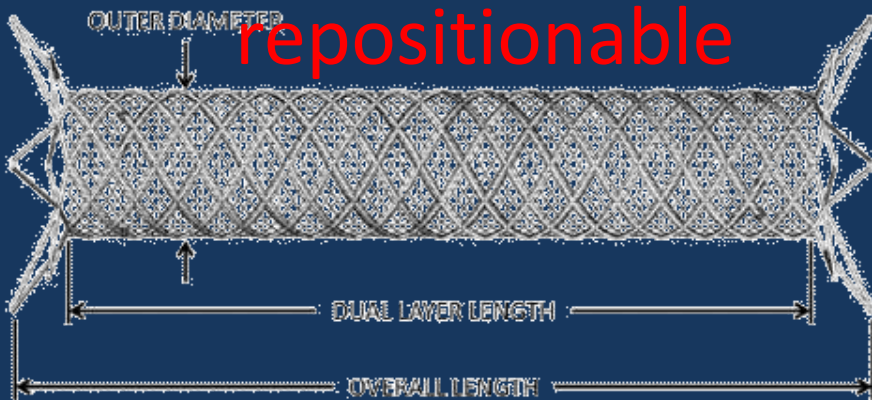
Joachim Schofer, MD,* Piotr Musialek, MD, DPHIL,† Klaudija Bijuklic, MD,* Ralf Kolvenbach, MD,‡
Mariusz Trystula, MD,† Zbigniew Siudak, MD,†§ Horst Sievert, MD||

RESULTS The primary combined endpoint was the procedure success of the CGuard system and the number and volume of new lesions on the ipsilateral side assessed by diffusion-weighted magnetic resonance imaging at 48 h post-procedure and at 30 days. The secondary endpoint was 30-day major adverse cardiac or cerebrovascular events (death, stroke, or myocardial infarction). Protection devices were used in all procedures. Procedure success was 100%, with 0% procedural complications. The 30-day major adverse cardiac or cerebrovascular events rate was 0%. New ipsilateral ischemic lesions at 48 h occurred in 37.0% of patients and the average lesion volume was $0.039 \pm 0.08 \text{ cm}^3$. The 30-day diffusion-weighted magnetic resonance imaging showed complete resolution of all but 1 periprocedural lesion and only 1 new minor (0.116 cm^3) lesion in relation to the 48-h scan.

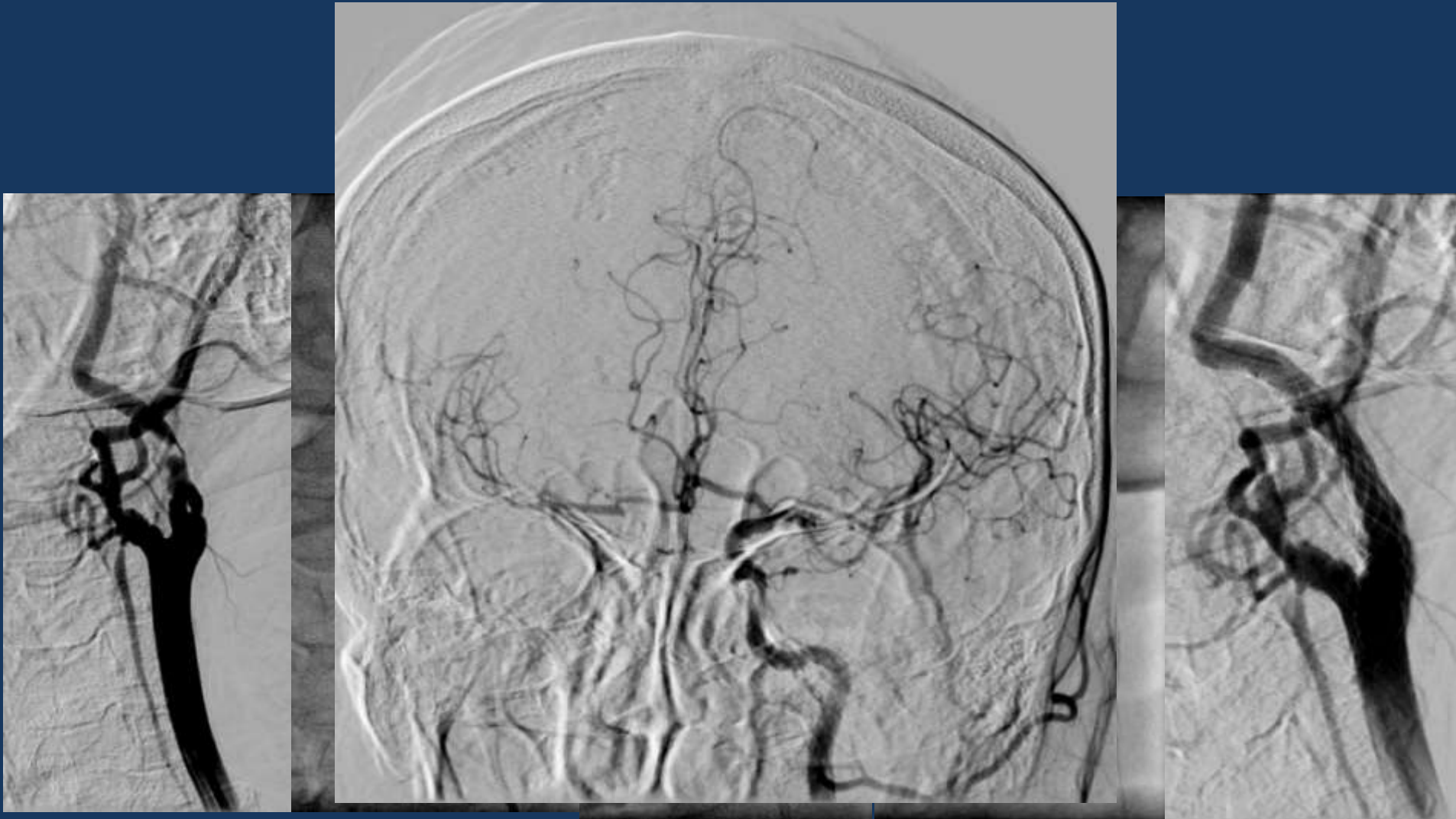
CONCLUSIONS The use of the CGuard system in patients undergoing carotid artery stenting is feasible. In addition, the benefit of using CGuard may extend throughout the stent healing period. (J Am Coll Cardiol Interv 2015;8:1229-34)

RoadSaver Carotid Stent

- double layer micromesh scaffold
- enabling sustained embolic protection by very tight plaque coverage
- embolic protection starts with implantation of the stent into the lesion and continues throughout the process of neointimalization
- up to 50% deployment full re-sheathable and repositionable

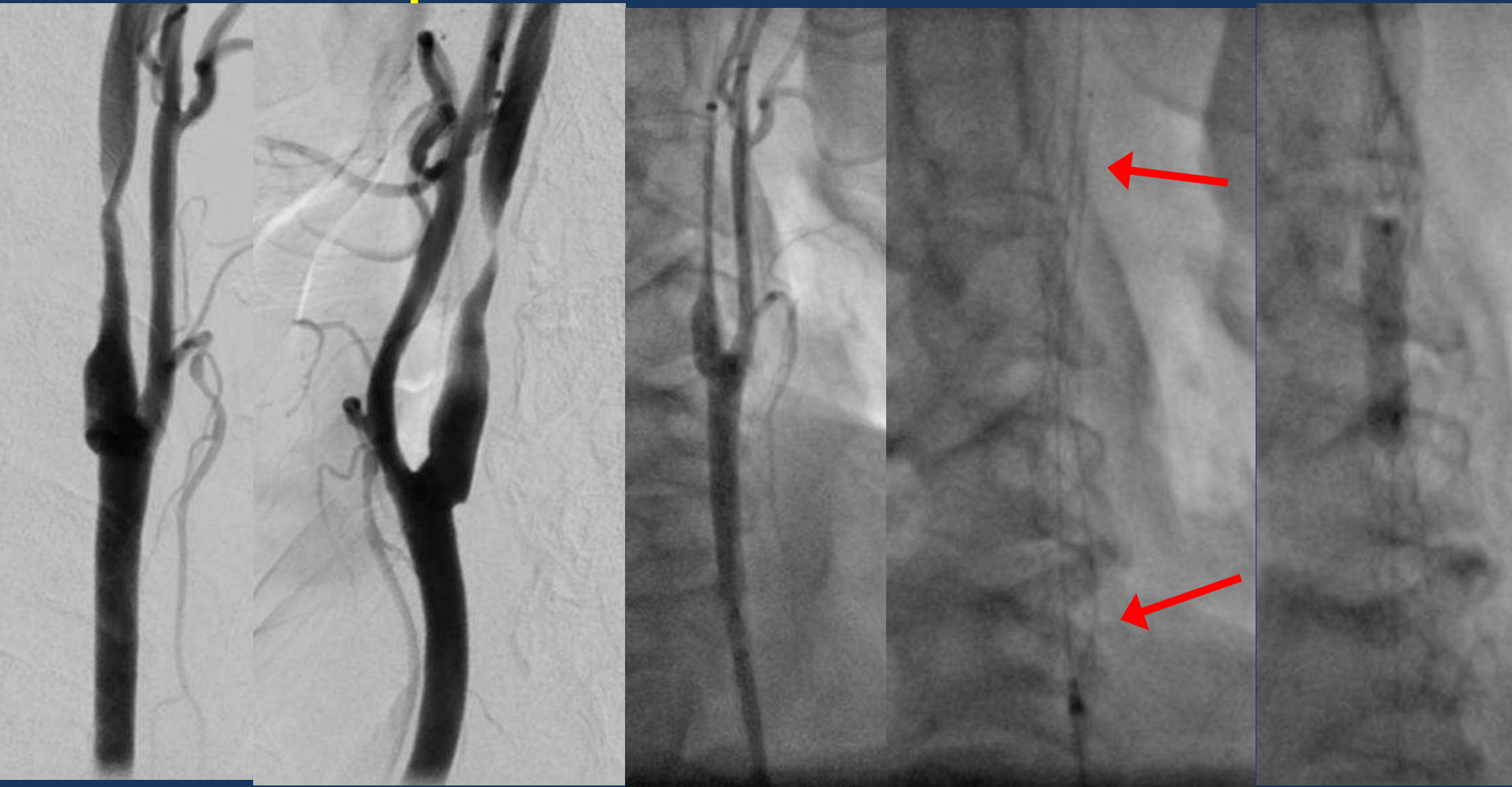


Pt.age 61. RICA occluded , Symptomatic LICA stenosis
95% - dissected : Meshstent technology only option.



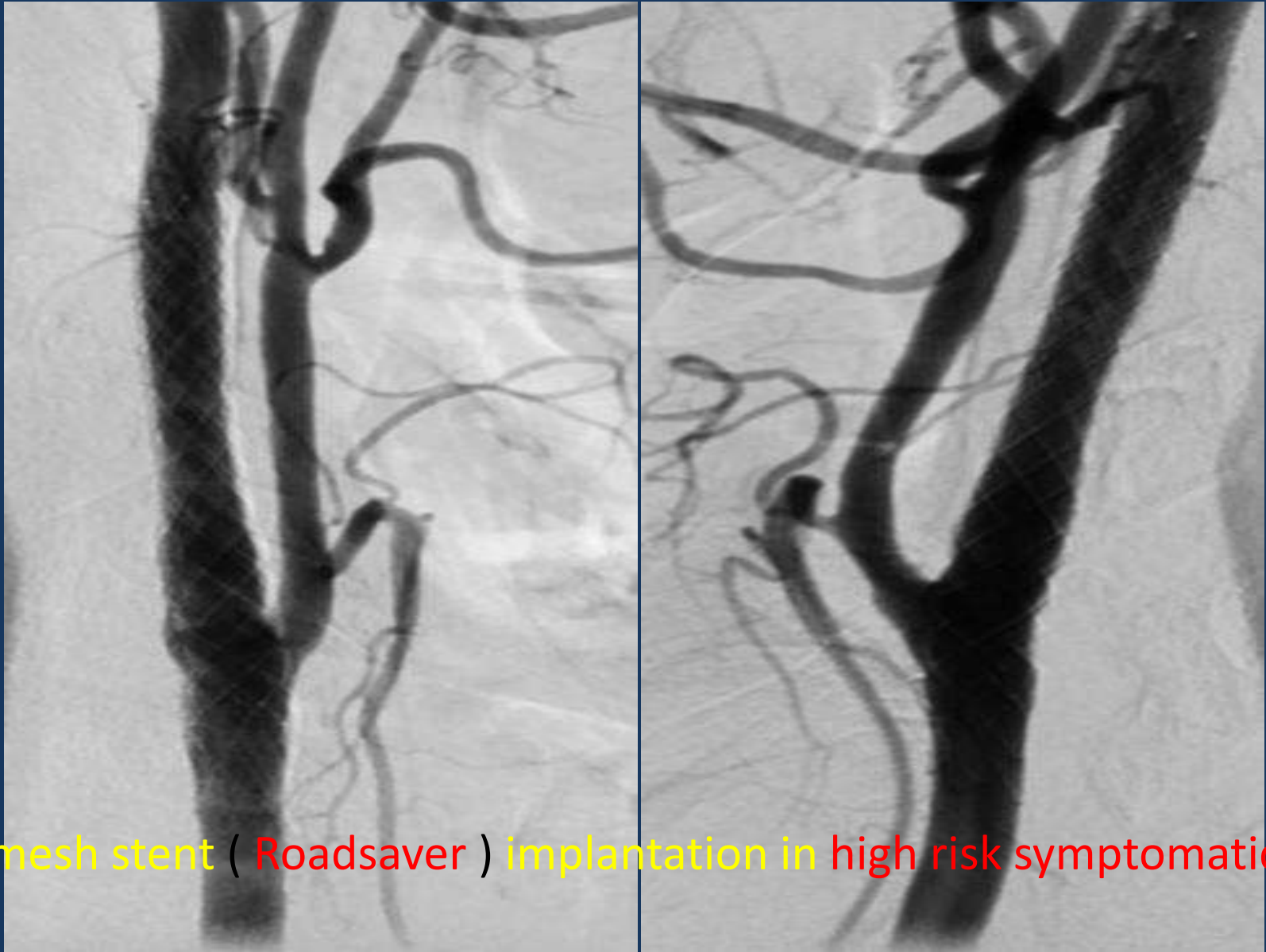
RoadSaver 8.0/25mm with SPIDER RX protection successfully implanted .

Novel technology for better brain protection in 2016



Micromesh stent (Roadsaver) implantation in high risk symptomatic lesion.

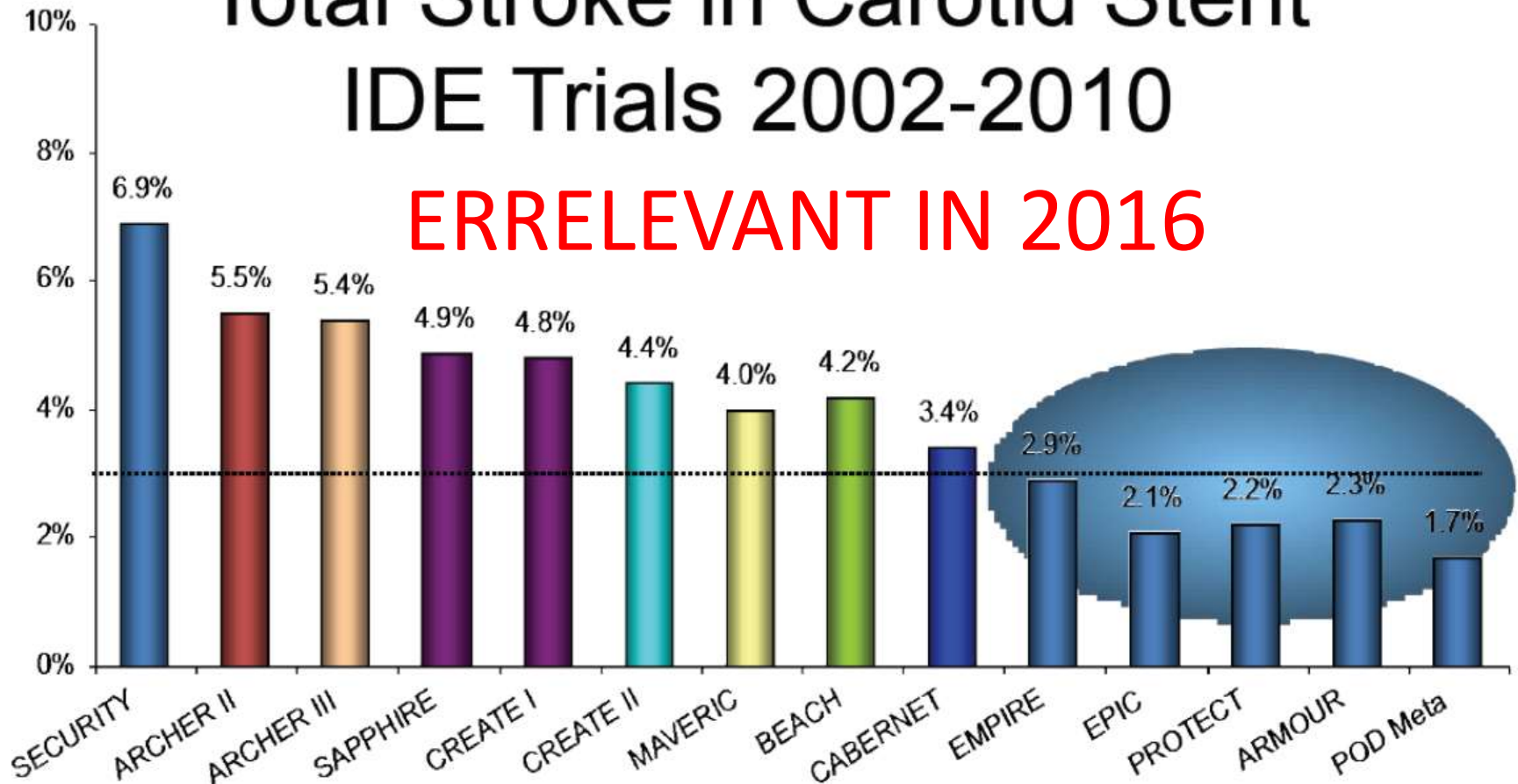
2016 Krakow experience; 40 pts with RoadSaver implantation. All symptomatic High Risk lesions. Periprocedural & 30 days complications rate (1 minor stroke & 1-TIA)



Micromesh stent (Roadsaver) implantation in high risk symptomatic lesion.

Total Stroke in Carotid Stent IDE Trials 2002-2010

ERRELEVANT IN 2016



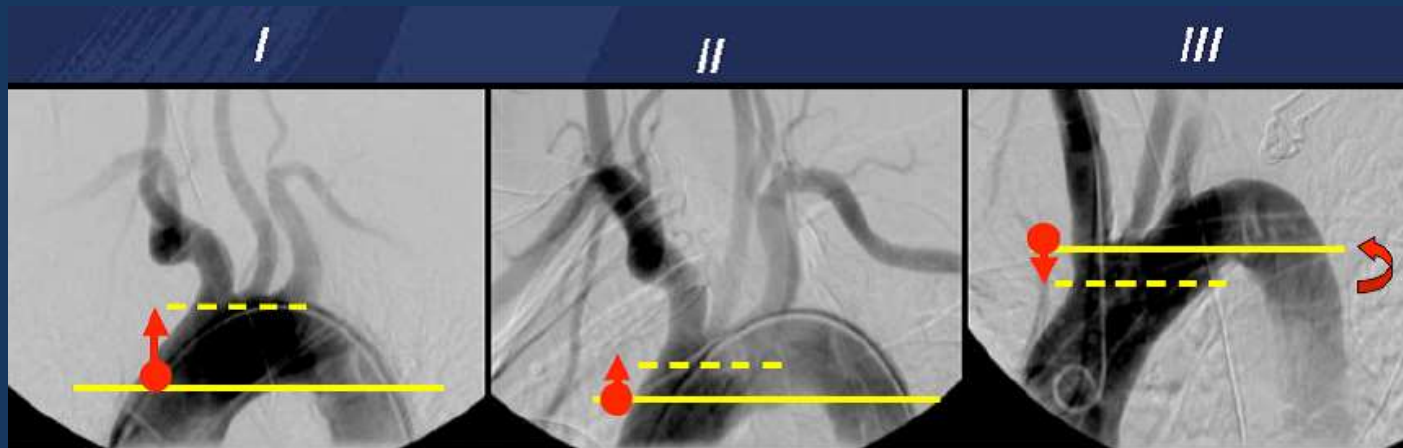
2003

2005

2007

2009

Caniulation difficulties of CCA during CAS

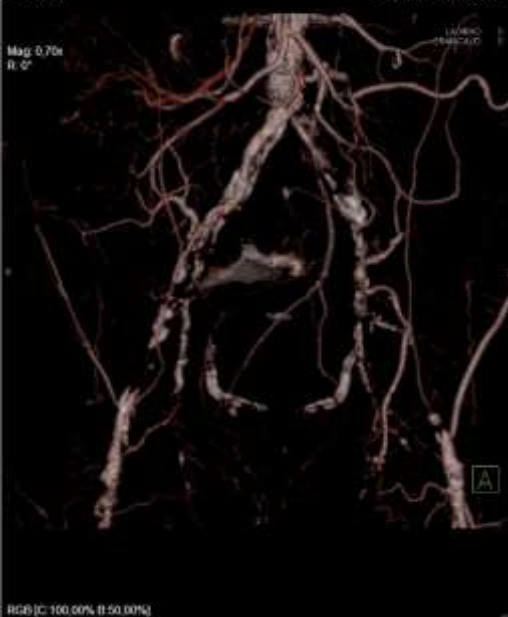


Aortic arch



Bovine arch

CTA WPM0193
SIMD: 131049093S
<VRT Collection>
Se: 502
In: 88
ABDOMEN
Szpital im. Jana Pawła II w Krakowie
KWATEK JOZEF
1947-06-10 M 367343
Acc: 131040093S
2014.01.17
Acq Tm: 00:54:10.000000



CTA WPM0193
SIMD: 131049093S
<VRT Collection>
Se: 503
In: 203
ABDOMEN
Szpital im. Jana Pawła II w Krakowie
KWATEK JOZEF
1947-06-10 M 367343
Acc: 131040093S
2014.01.17
Acq Tm: 00:54:10.000000



Femoral Approach Limitations !!!

Aorto-Iliac disease or occlusion
(Leriche'a Syndrom)

Previous surgical bypass at peripheral field

After stent graft implantation

Significant overweight

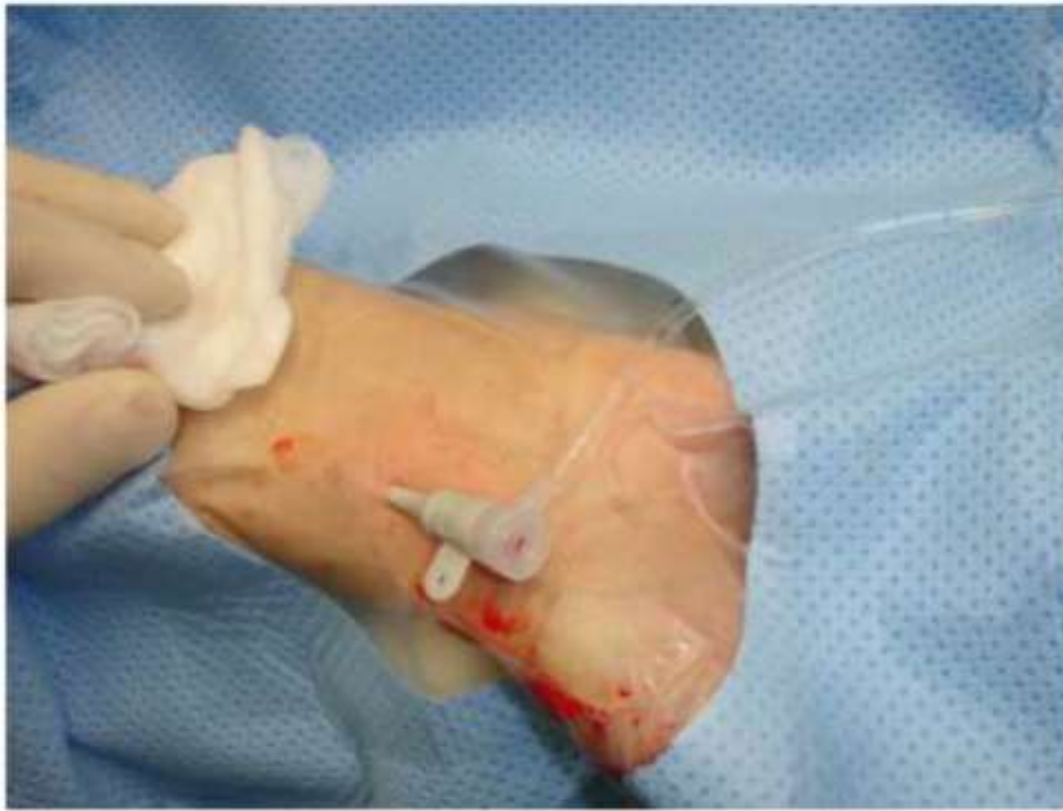
Large hernia

Spine disease difficulty in lying after CAS

Haematological disease or Coumadin therapy

Radial access - special transradial sheath 6F or 7F/11cm

Widespread use by cardiologists (6-8% radial artery occlusion)



Antispasmodic cocktail

2.5mg Verapamil

200ug Nitroglycerin

5000 IU Heparin

In pts with carotid artery stenosis the coexistence of CAD was observed in 69% pts.

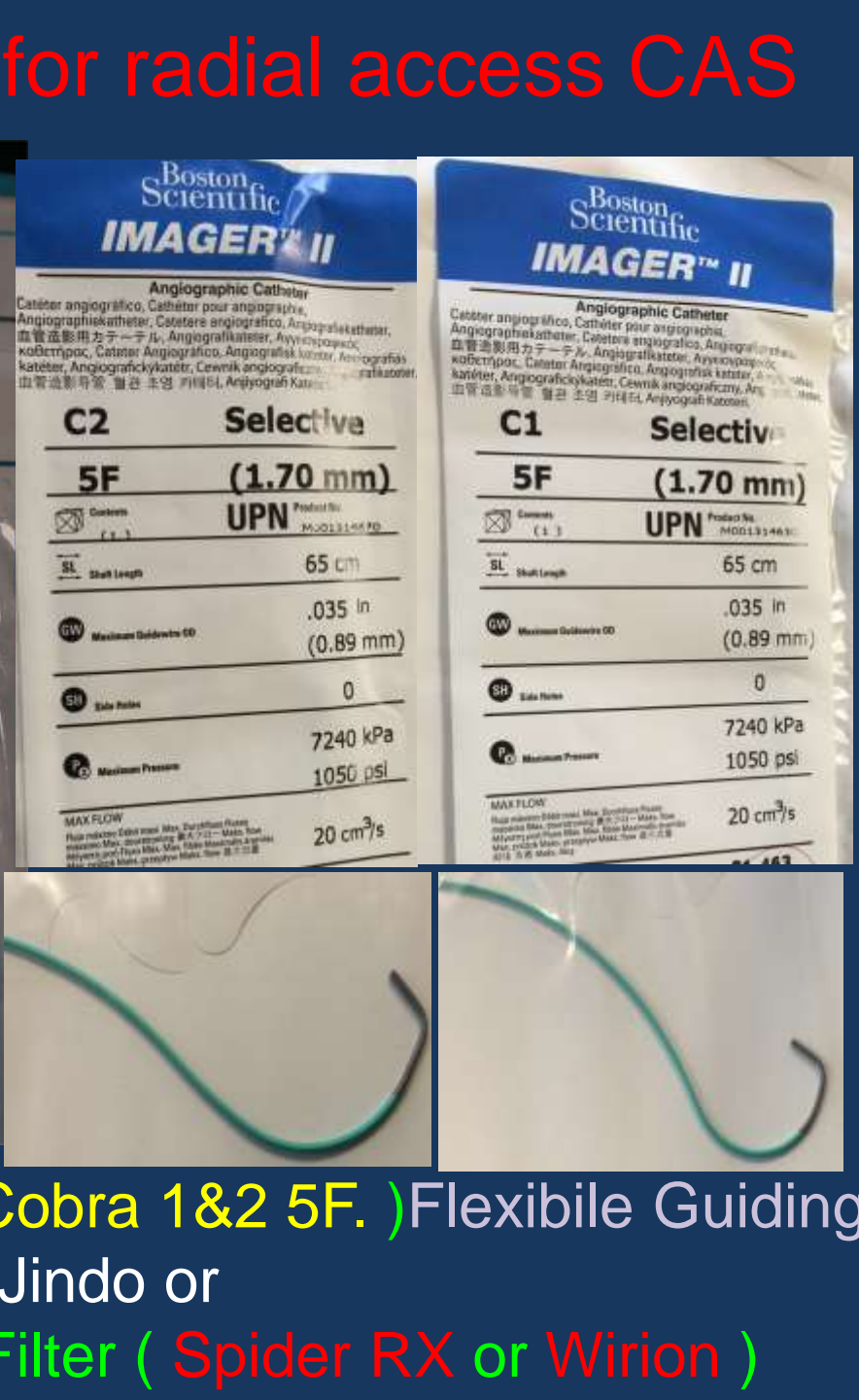
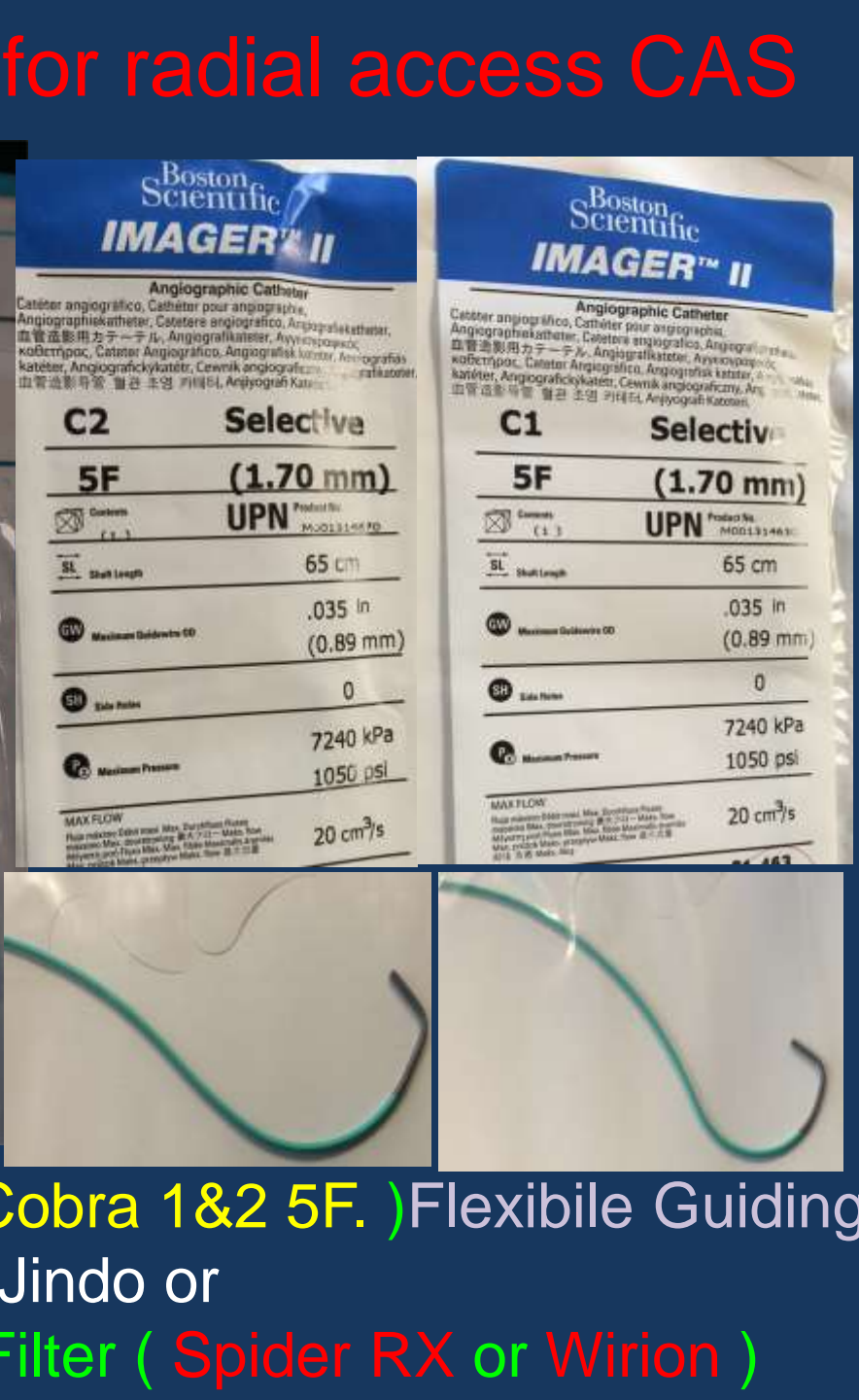
Pieniążek P i wsp. Kardiologia Polska. 2004;61:II-48-56

I do not recommend 8F sheath and proximal protection !

Special devices is crucial for radial access CAS

Special dedicated diagnostic cath (Cobra 1&2 5F.)

Flexible Guiding Cath 6/7F or 5F sheath, Dura Glide Jindo or Glidewire Advantage, Independent Filter (Spider RX or Wirion)

[illegible][illegible]

Special devices is crucial for radial access CAS

Special dedicated diagnostic cath (Cobra 1&2 5F.)

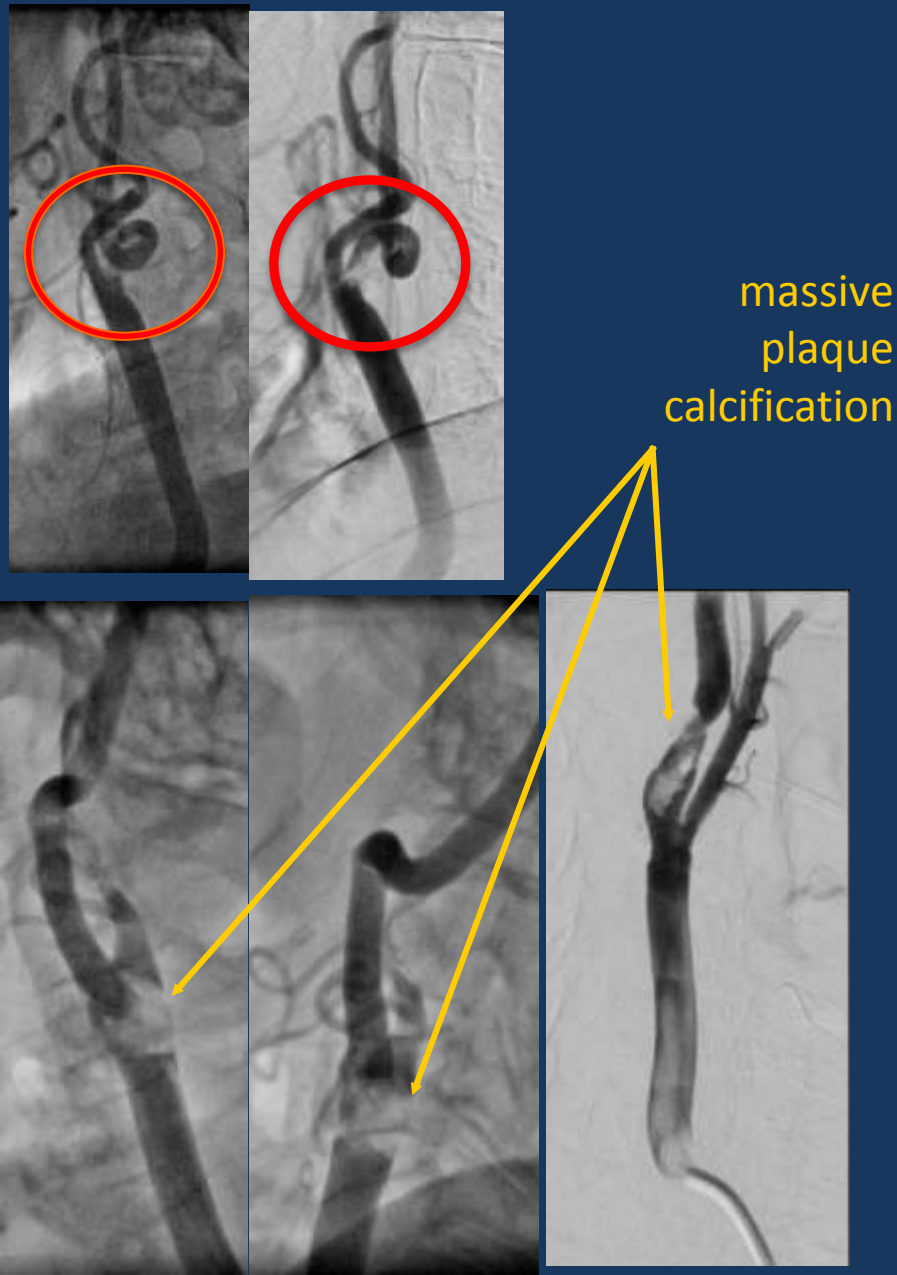
Flexible Guiding Cath 6/7F or 5F sheath, Dura Glide Jindo or Glidewire Advantage, Independent Filter (Spider RX or Wirion)

Unique solution for transradial access intervention !!! Glidesheath SLENDER !



Save radial and ulnar artery to the next intervention

Contraindications to CAS ...are very few



- hostile anatomy / no endovascular access
- thrombocytopenia, leukopenia, neutropenia
- recent (< 3 mo) GI bleeding
- intolerance or resistance of thienopyridines
- fresh thrombus + anatomy precluding the use of proximal protection
- Sharp angulation or massive calcification at stenosis site
- total chronic occlusion

We must be prepared & ready to treat our all complication

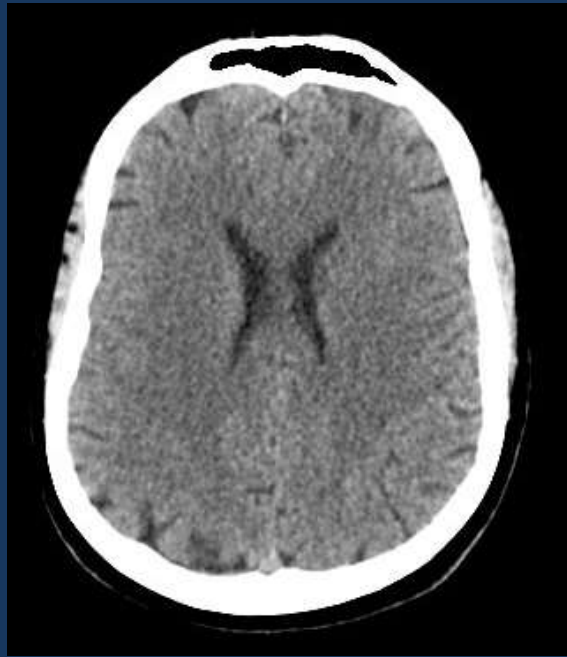
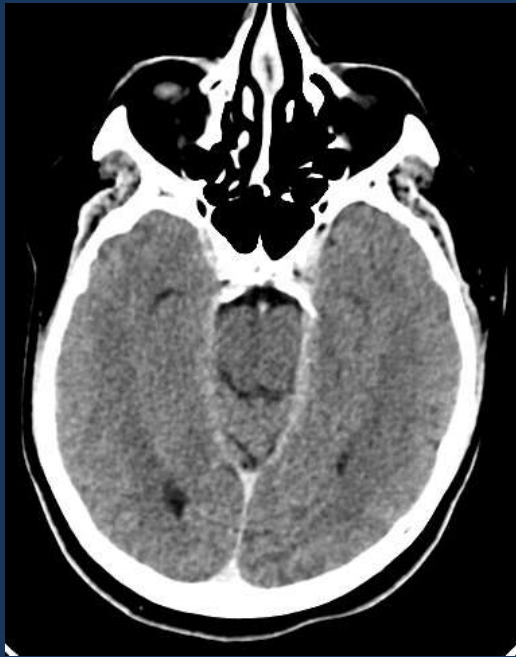
Case# 2562 F. age 61 (5 people from the family died due to ischemic stroke !!) with severe LICA 95% stenosis.



CAS LICA with proximal protection **MoMa + Cristallo** stent **without complications**. Angioseal for femoral artery closure

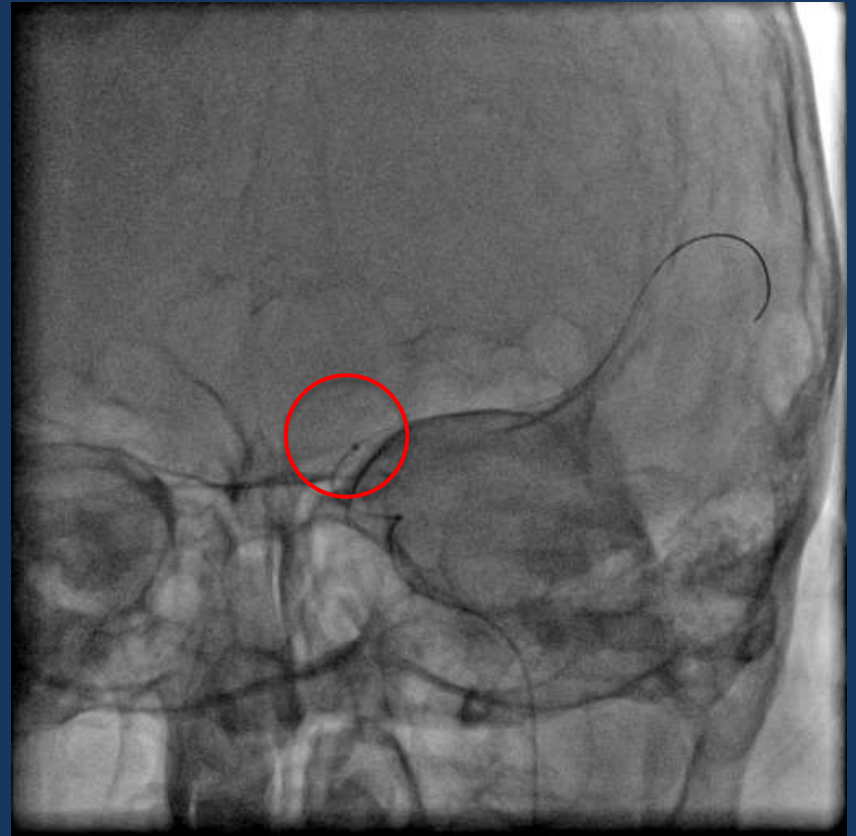
15 min after CAS total loss of consciousness
Left hemisphere stroke symptoms !!

Sent for brain CT + angiography



Excluded intracranial bleeding .Tight stenosis /occlusion of left
MCA segment M1/M2 .. the lack of fulfillment of peripheral artery

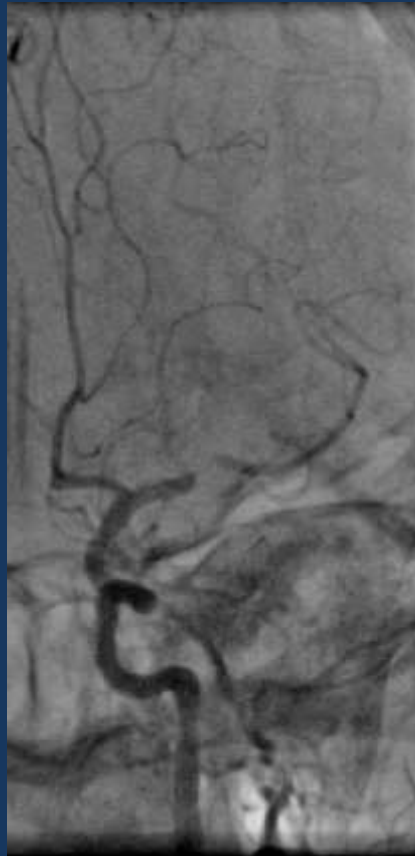
Left femoral access Intracranial angiography of left hemisphere.
Occlusion of left MCA . Patient required general anesthesia
because of severe seizures.



Performed mechanical embolectomy with ERIC
system with proximal protection MoNo MoMa !!!!

2 passages of ERIC thrombectomy

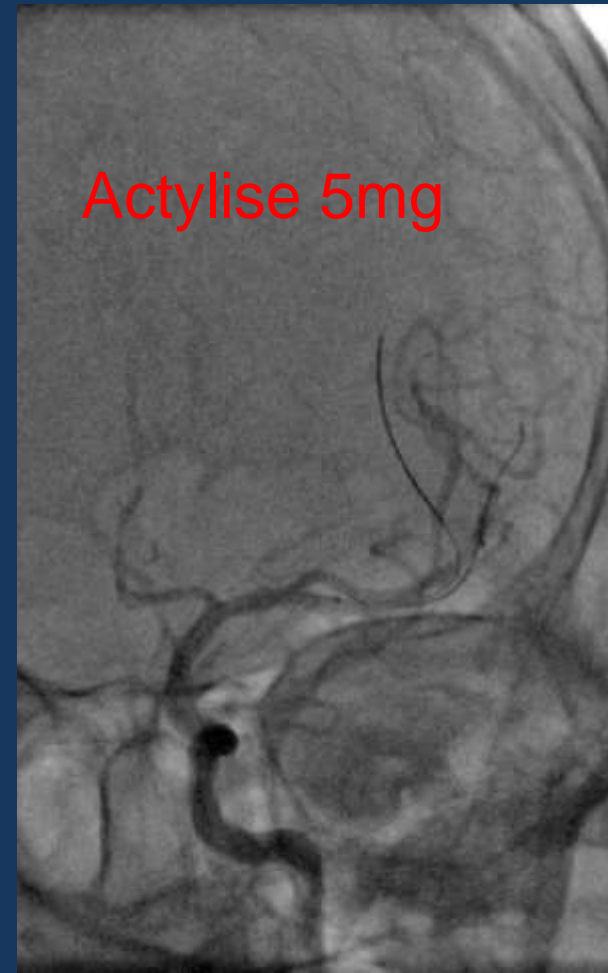
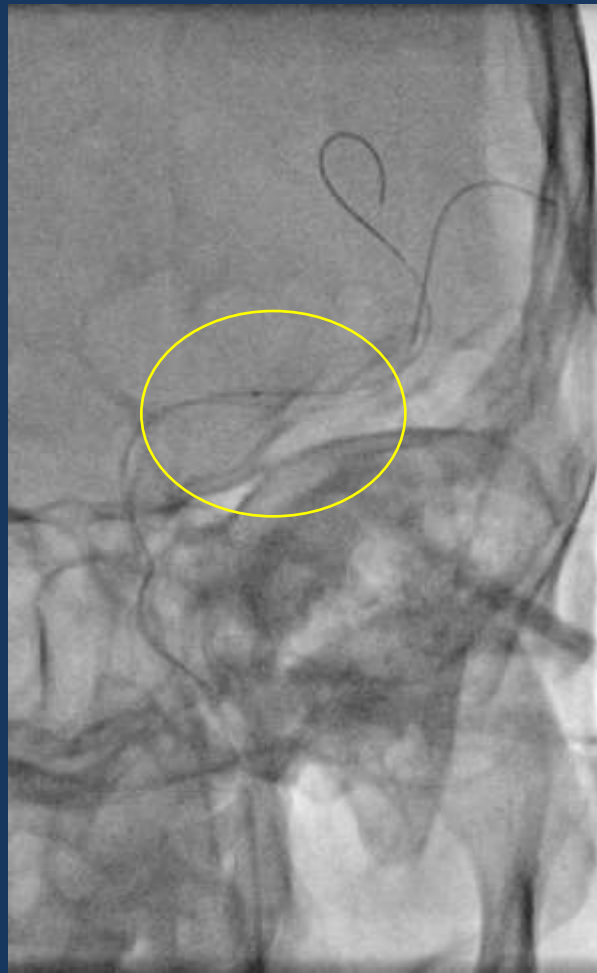
Not satisfactory flow in l. MCA !!



PTA with OTW small 1.5mm coronary balloons .

Kissing technique for both artery recanalization

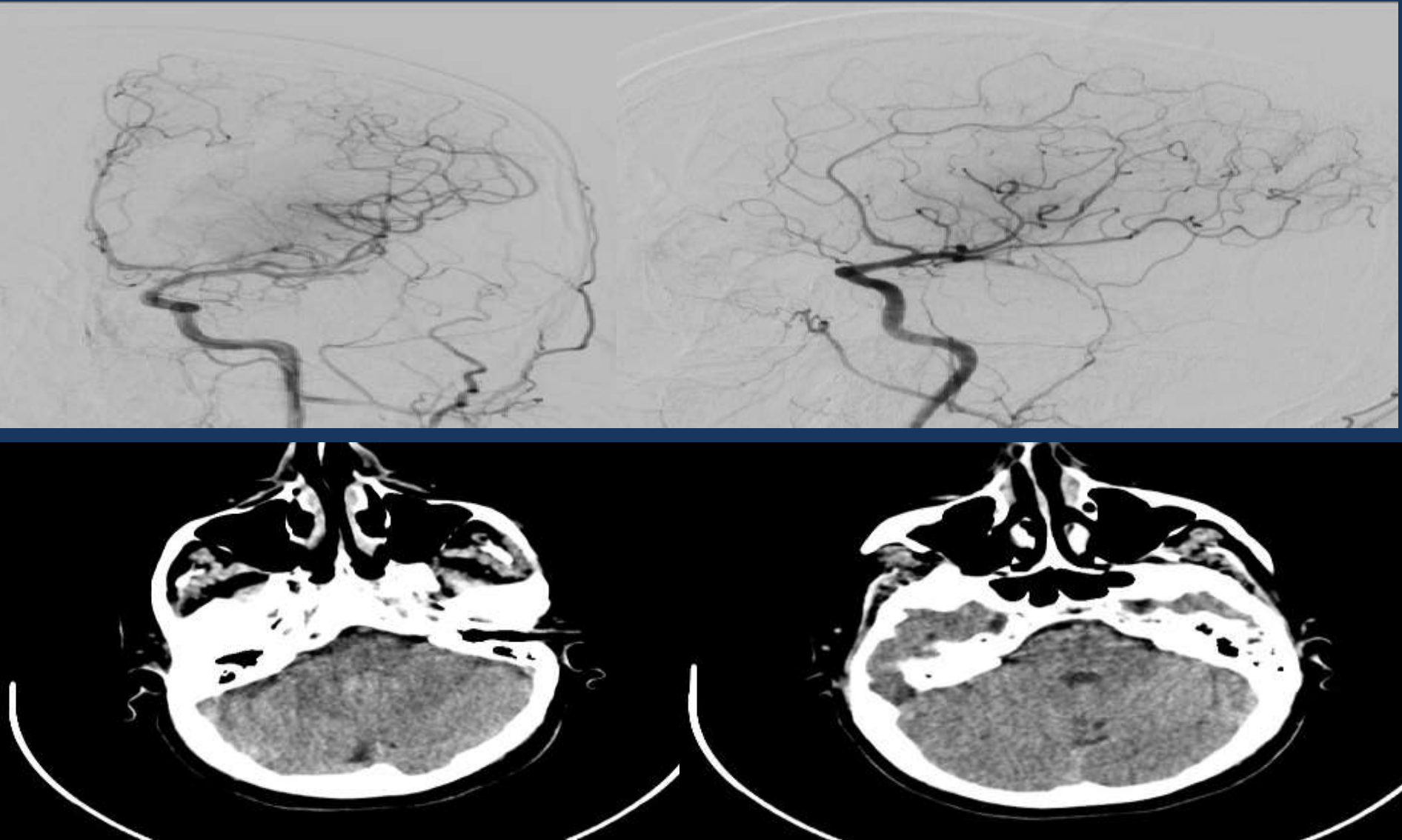
5mg rTPA locally via microcatheter



Actylise 5mg

Final angiography with M1/M2 recanalization

8 mm only new ischemic area on left hemisphere. She left hospital at 5 day with NIHSS 1 after neurology consultation



Learning curve

Survey by Lin et al.

TABLE 1. COMPARISON OF TECHNICAL SUCCESS, PROCEDURAL VARIABLES, AND COMPLICATIONS AMONG PATIENT GROUPS

	Group 1 Cases No. 1 to 50 N=50	Group 2 Cases No. 51 to 100 N=50	Group 3 Cases No. 101 to 150 N=50	Group 4 Cases No. 151 to 200 N=50	Group 5 Cases No. 201 to 246 N=46
Technical success	47 (94%)	49 (98%)	50 (100%)*	50 (100%)*	46 (100%)*
Hospital length of stay (d)	1.6±1.2	1.3±1.1	1.4±0.7	1.5±0.6	1.4±0.8
Procedural variables					
a) Procedural time (min)	58±10	43±11*	39±8†	36±10†	38±12†
b) Contrast used (mL)	98±24	79±19*	55±15†	53±12†	50±15†
Complications					
a) Cardiopulmonary	2 (4%)	2 (4%)	1 (2%)	1 (2%)	1 (2%)
b) Hemorrhagic	3 (6%)	1 (2%)	0*	0*	0*
c) Stroke (TIA)	1 (2%)	0	0	0	0
d) Stroke (minor)	1 (2%)	1 (2%)	0	0	0
e) Stroke (major)	1 (2%)	0	0	0	0
30-day death	1 (2%)	0	0	0	0
30-day stroke/death	4 (8%)	1 (2%)*	0†	0†	0†
Overall complication rate	9 (18%)	4 (8%)*	1 (2%)*	1 (2%)*	1 (2%)*

≤50

>50

number of CAS ↑



procedure time ↓

stroke/death ↓



*Progress cannot be stopped !
Progress in CAS technology is
Enormous in Recent Years
CAS is the beter option for
majority of patients*



Hospitalization time: 48 < 72 hrs.



John Paul II Hospital Krakow PL

Thank you