

19th
CARDIOVASCULAR SUMMIT
TCTAP 2014

TRANSCATHETER
CARDIOVASCULAR THERAPEUTICS
ASIA PACIFIC

April 22-25, 2014 @ COEX, SEOUL, KOREA

Proximal Protection
for
Carotid Stenting in High Risk Lesions

Prof. Piotr Pieniazek MD PhD



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



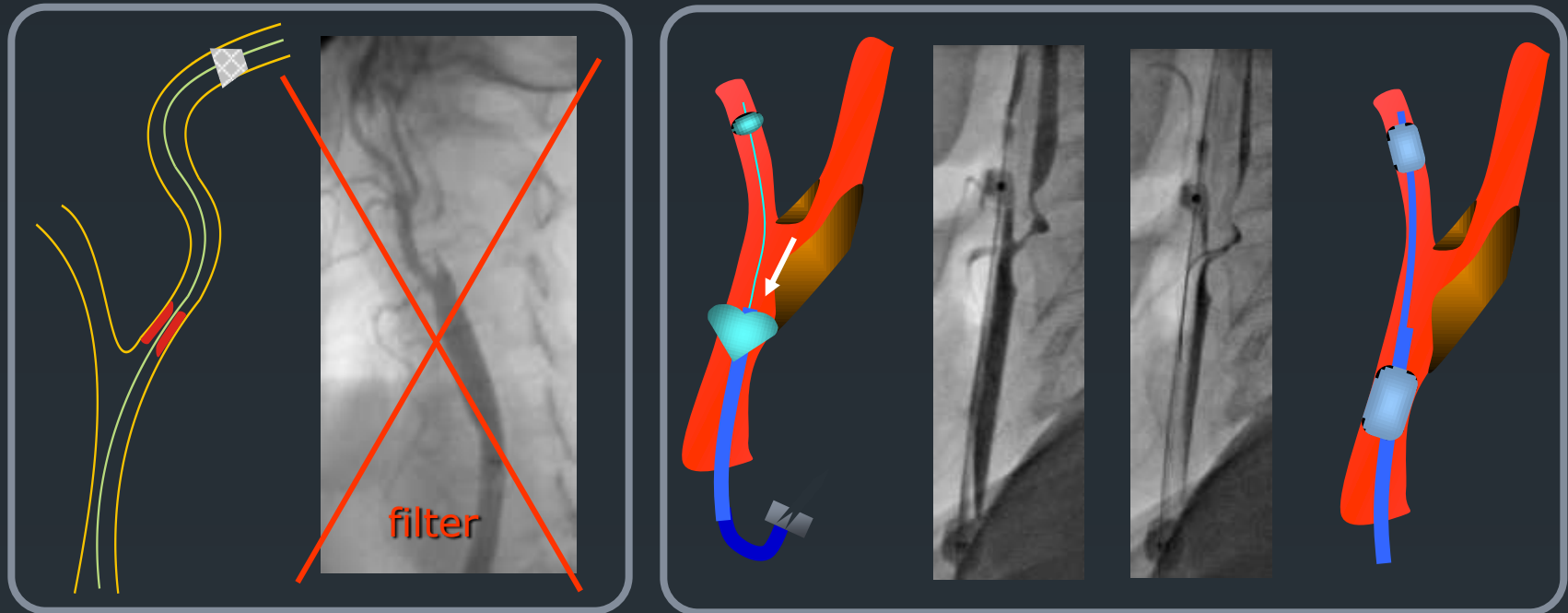
Disclosure

Speaker name: Piotr Pieniazek

I have the following potential conflicts of interest to report:

- Consulting
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)
- I do not have any potential conflict of interest

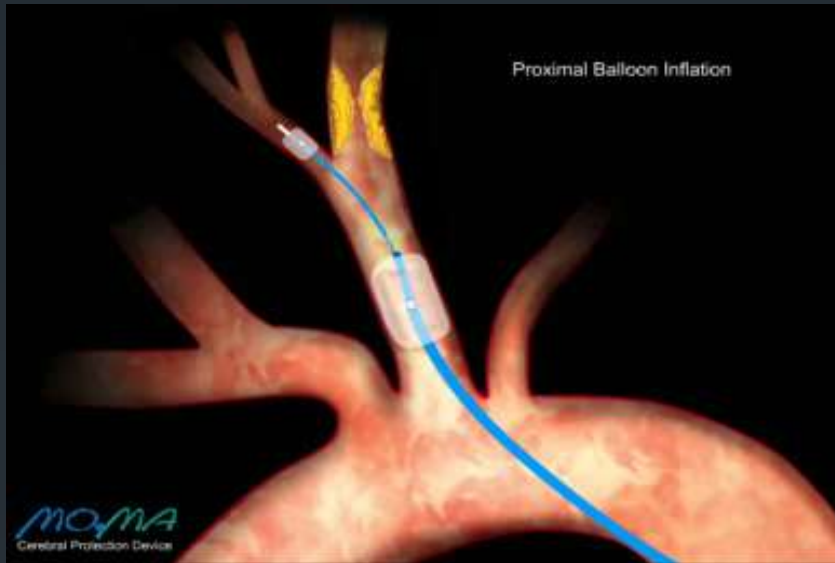
Proximal flow reversal or flow blockage : why so important ?



- Protection works before the lesion is approached
- Backflow or stop flow prevents antegrade escape of debris
- Tight & tortuous lesions can be treated
- Guidewire of choice
- Protection system placed in the CCA & not in ICA (ICA is prone to vasospasm!)
- Proximal protection systems are easy to remove after procedure
- During filter retrieve, however, severe complications do occur

More than 12 years experience with proximal protection in Krakow

Mo.Ma.



Kardiol Pol. 2004 Sep;61 Suppl 2:1148-56.
Carotid artery stenting with proximal or distal brain protection: early outcome
Pieniazek P. et al.

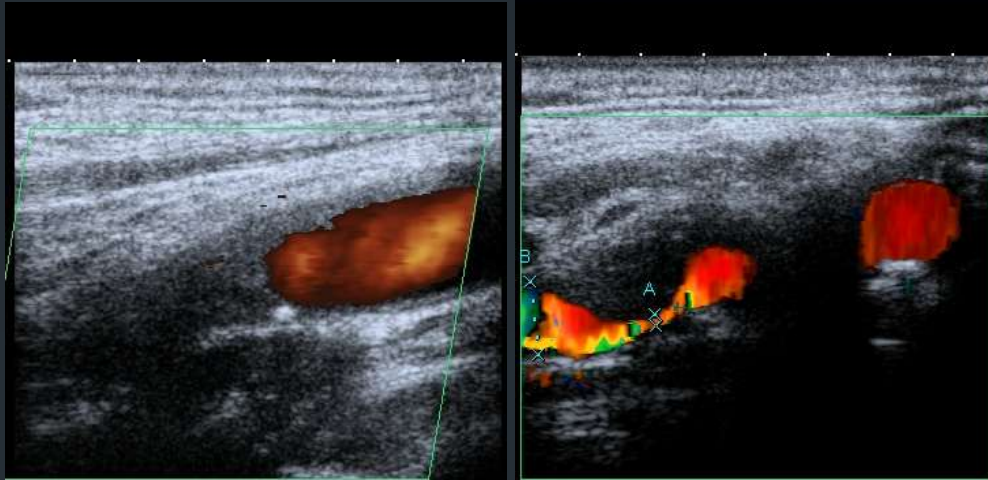
Gore NPS



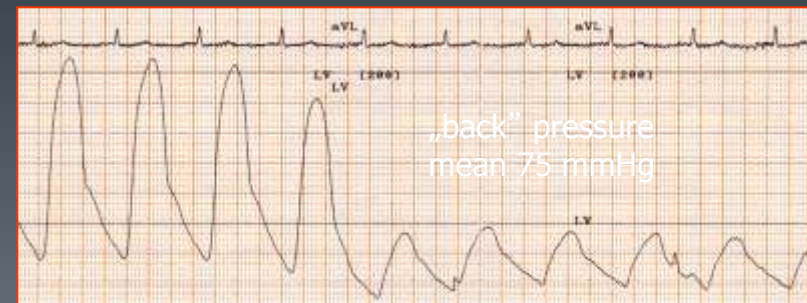
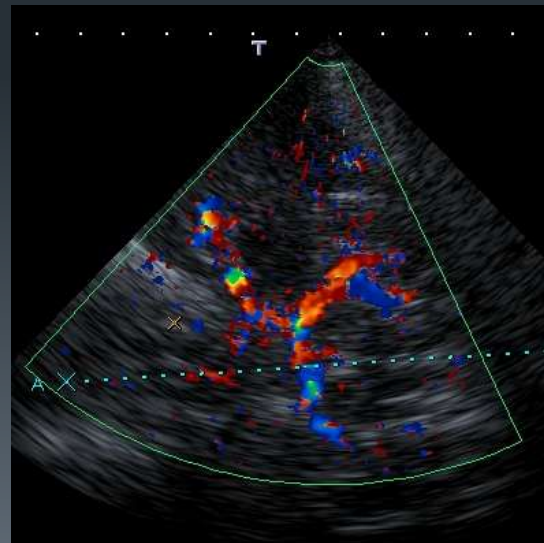
Kardiol Pol. 2002 Oct;57(10):322-30
Reversed blood flow during internal carotid artery stenting using Parodi Anti-Emboli System--progress in protection against cerebral stroke.
Pieniazek P et al.

Proximal protection is routinely used for CAS procedures since 2002 in Krakow: **2085 CAS** (786 with Proximal EPD).

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!



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



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.

Proximal endovascular occlusion for carotid artery stenting: results from a prospective registry of 1,300 patients.

Stabile E et al

Invasive Cardiology Laboratory, Cardiology Division, Clinica Montevergine, Via Mario Malzoni 1, Mercogliano, Italy.
geko50@hotmail.com

RESULTS: The 30-day stroke and death incidence was 1.38% (n = 19). Operator experience, symptomatic status, and hypertension were found to be independent predictors of adverse events.

J Am Coll Cardiol. 2010 Apr 20;55(16):1661-7.

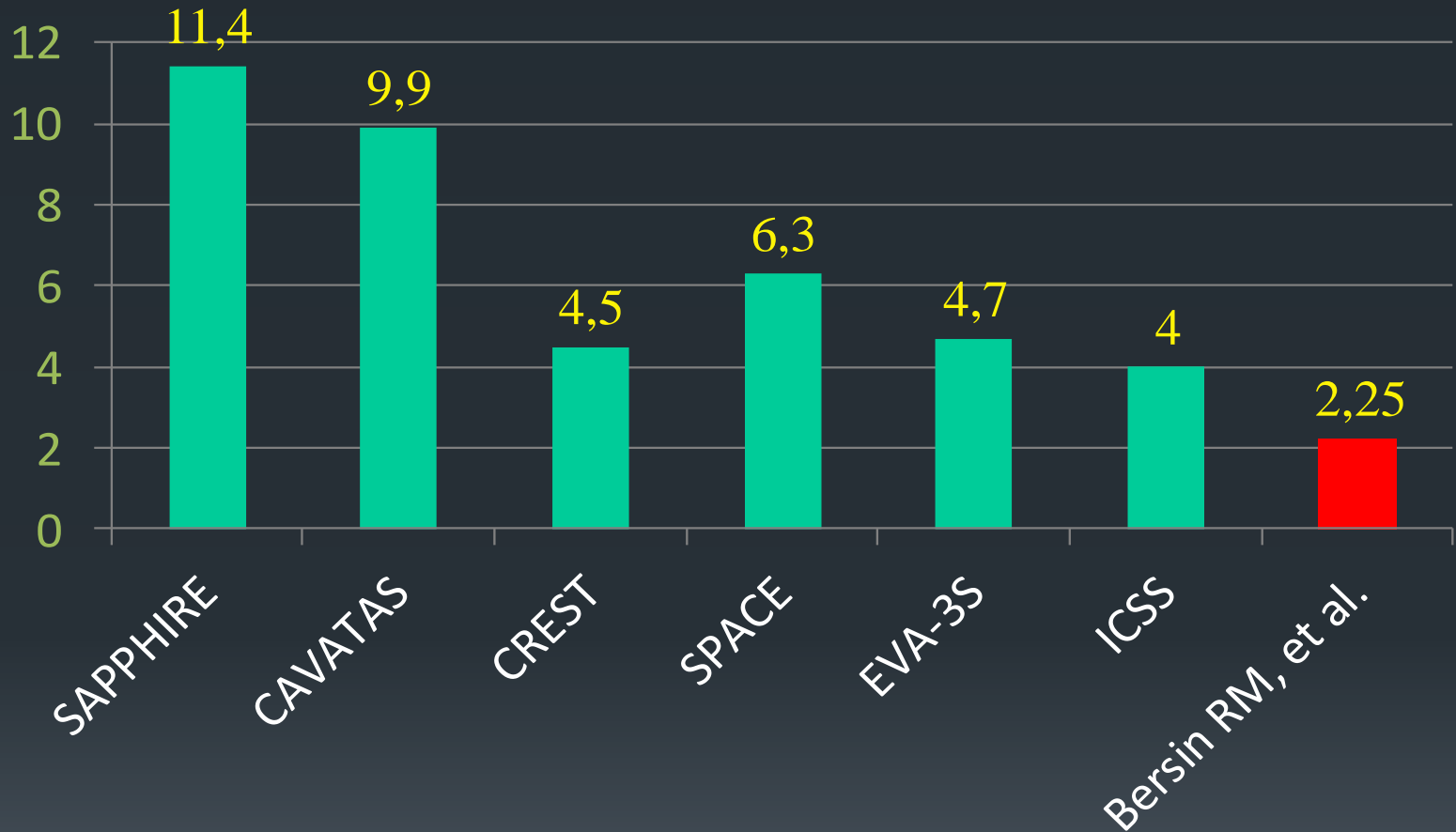
Carotid artery stenting according to 'tailored-CAS' algorithm is associated with low complication rate: data from on-going TARGET-CAS registry.

Materials and methods: Between 2002 and 2010, we performed 1176 CAS in 1081 patients [pts, age 38-86y, mean 66.3 ± 8.4 y, 51.5% symptomatic (S)] according to 'tailored-CAS' algorithm

Results: Thirty-day complications rate (death/any stroke/MI) was 2.38%. Age >75y was a predictor of death ($p=0.015$). The presence of prior neurological symptoms was a predictor of death/stroke ($p=0.030$).

P Pieniazek et al., Kardiol.Pol . 2012;70(4):378

30-day death/stroke/MI rate in RCT (arm CEA)



Bersin RM, et al. A meta-analysis of proximal occlusion device outcomes in carotid artery stenting. Catheter Cardiovasc Interv. 2012;80:1072-1078.

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



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



long filiform
irregural contra
lateral ICA
occlusion



symptomatic
ICA occlusion



thrombus containing
lesion



lesion after
radiotherapy

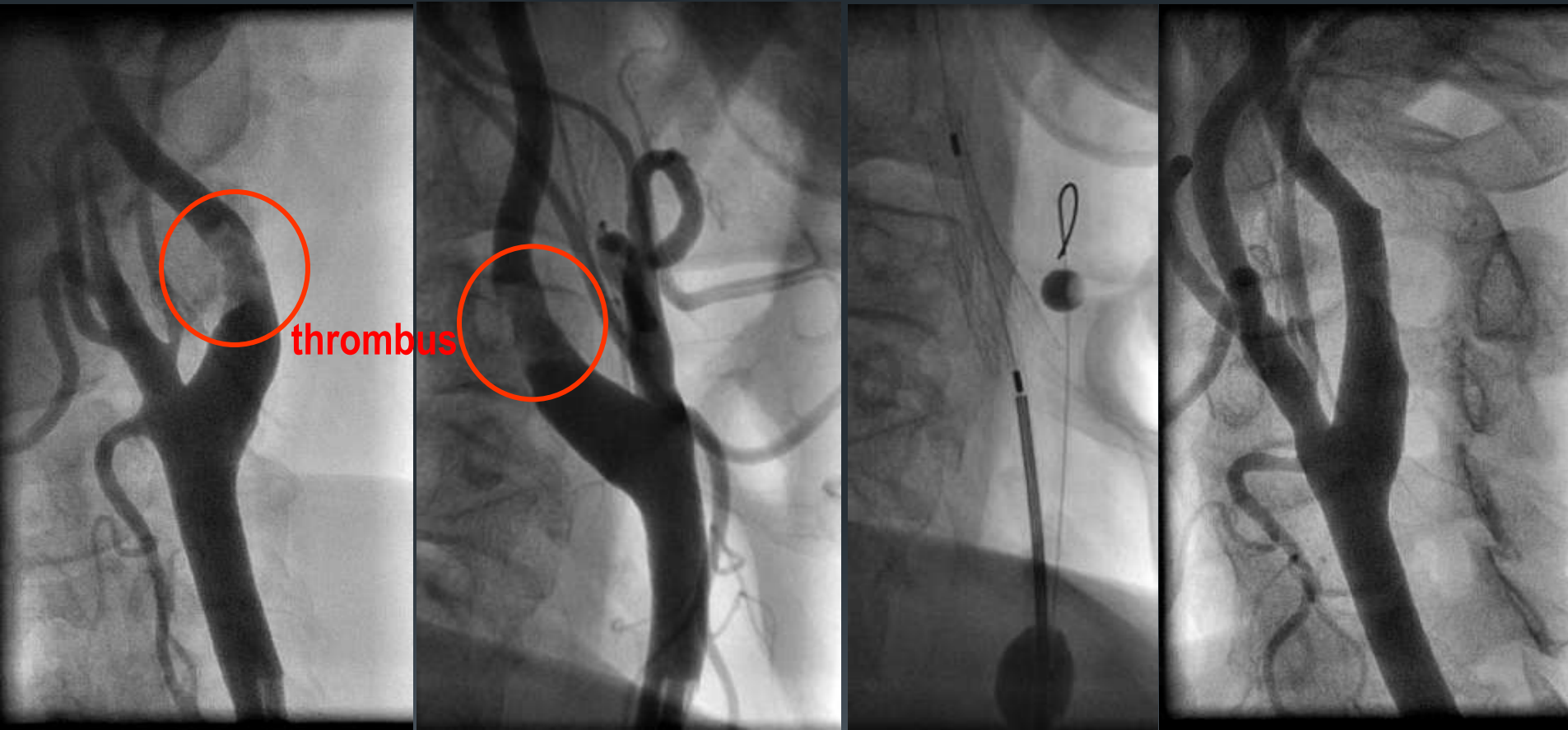


huge plaque
burden



CCA / ICA tight
stenosis

In some situations **CAS** is the **ONLY** option to save the patient's life !!!!



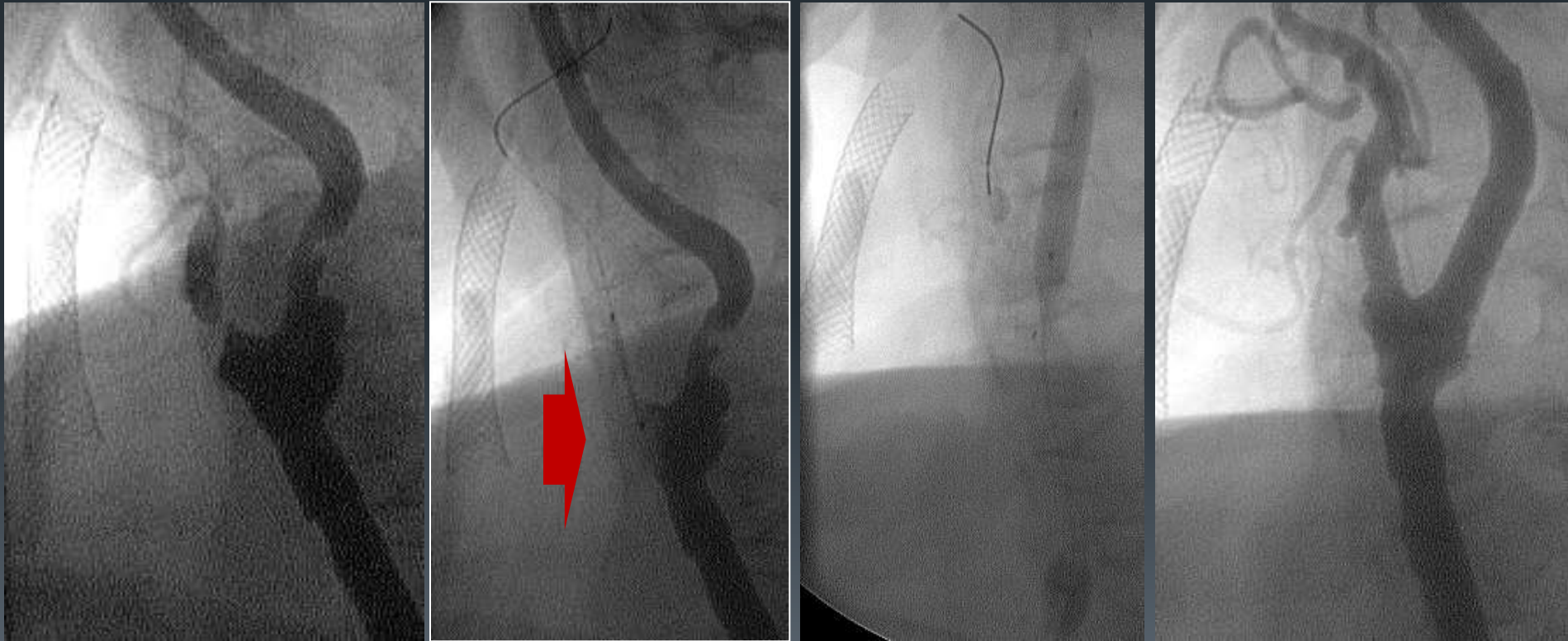
Patient 3 weeks after restrictive surgical mitral valve repair due to severe MR:
Highly-symptomatic, huge fresh thrombus in the LICA causing amaurosis fugax and TIAs !!!

PATIENT-AND-LESION-TAILORED NEUROPROTECTION

!requires! tips and tricks proximal EPD system use

In case of severe ipsilateral ECA stenosis...

ECA stenting (coronary stent implantation) in the first stage- to perform CAS of the symptomatic lesion safely with proximal protection system (GORE NPS)



Introduction of the new Mono Mo.Ma system enables the use of proximal neuroprotection in patients with critical ICA stenosis coexisting with ipsilateral ECA occlusion



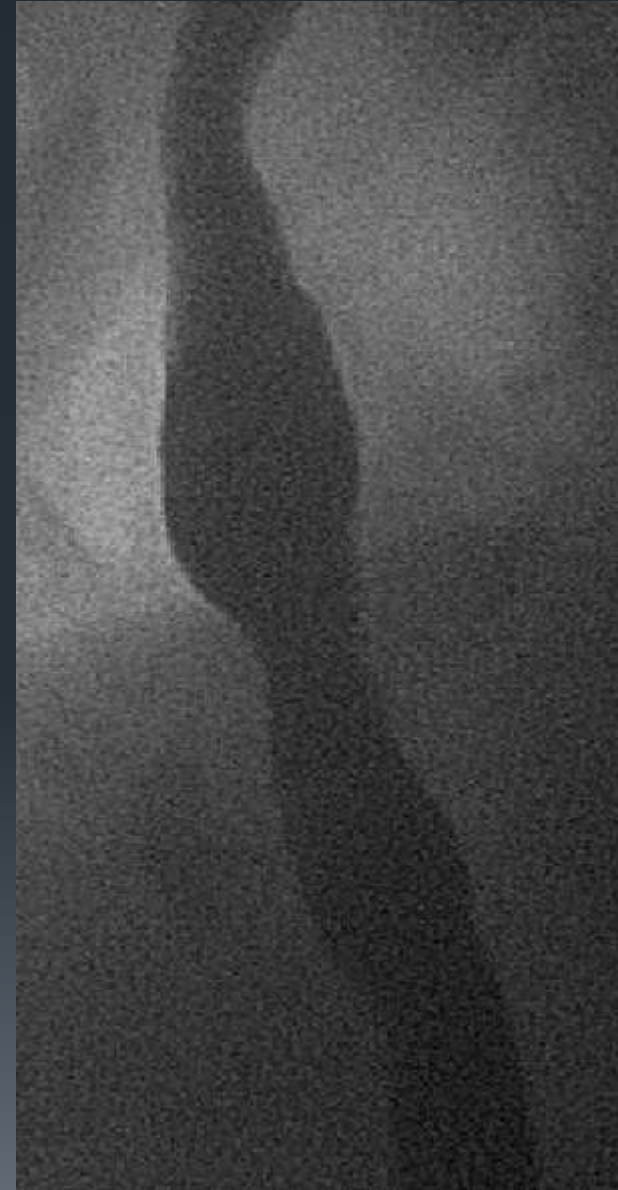
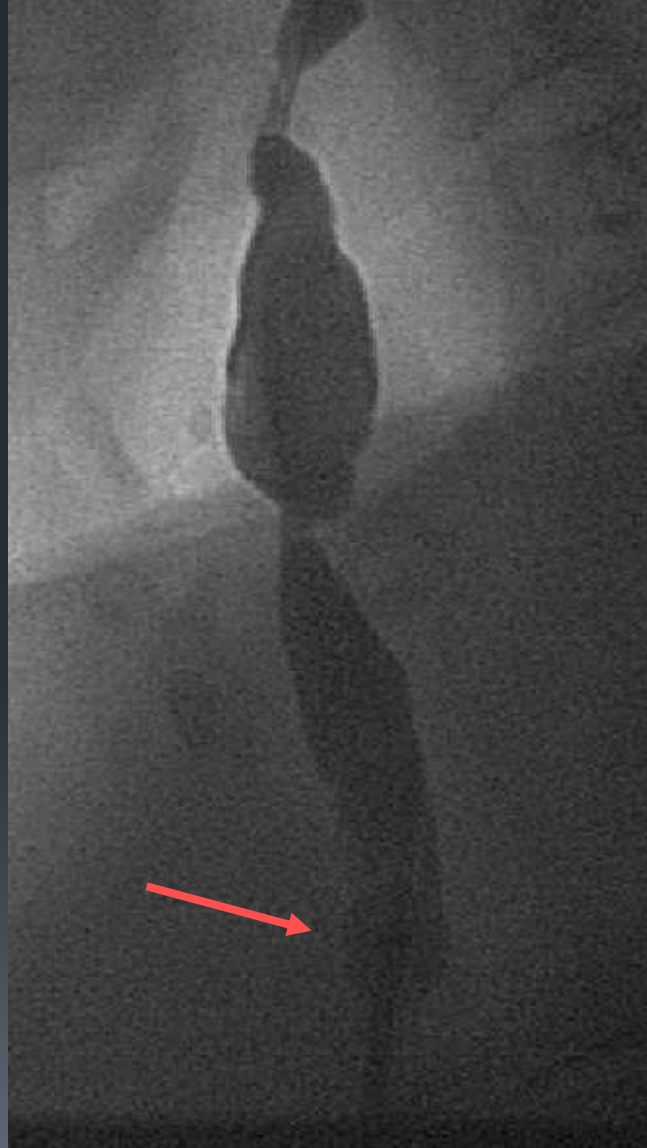
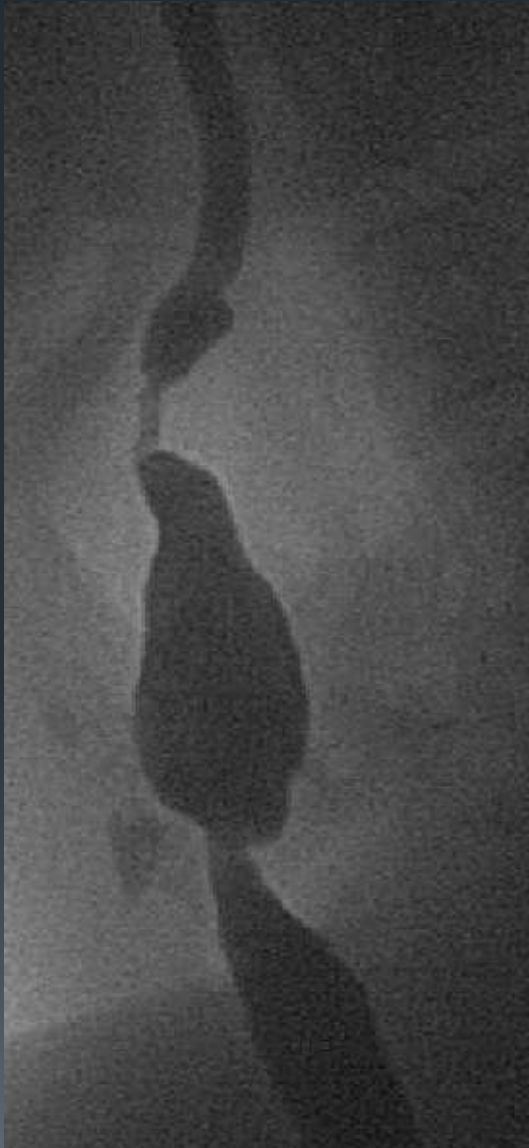
Flow reversal for proximal neuroprotection during endovascular management of critical symptomatic carotid artery stenosis coexisting with ipsilateral external carotid artery occlusion.

Pieniazek P et al..

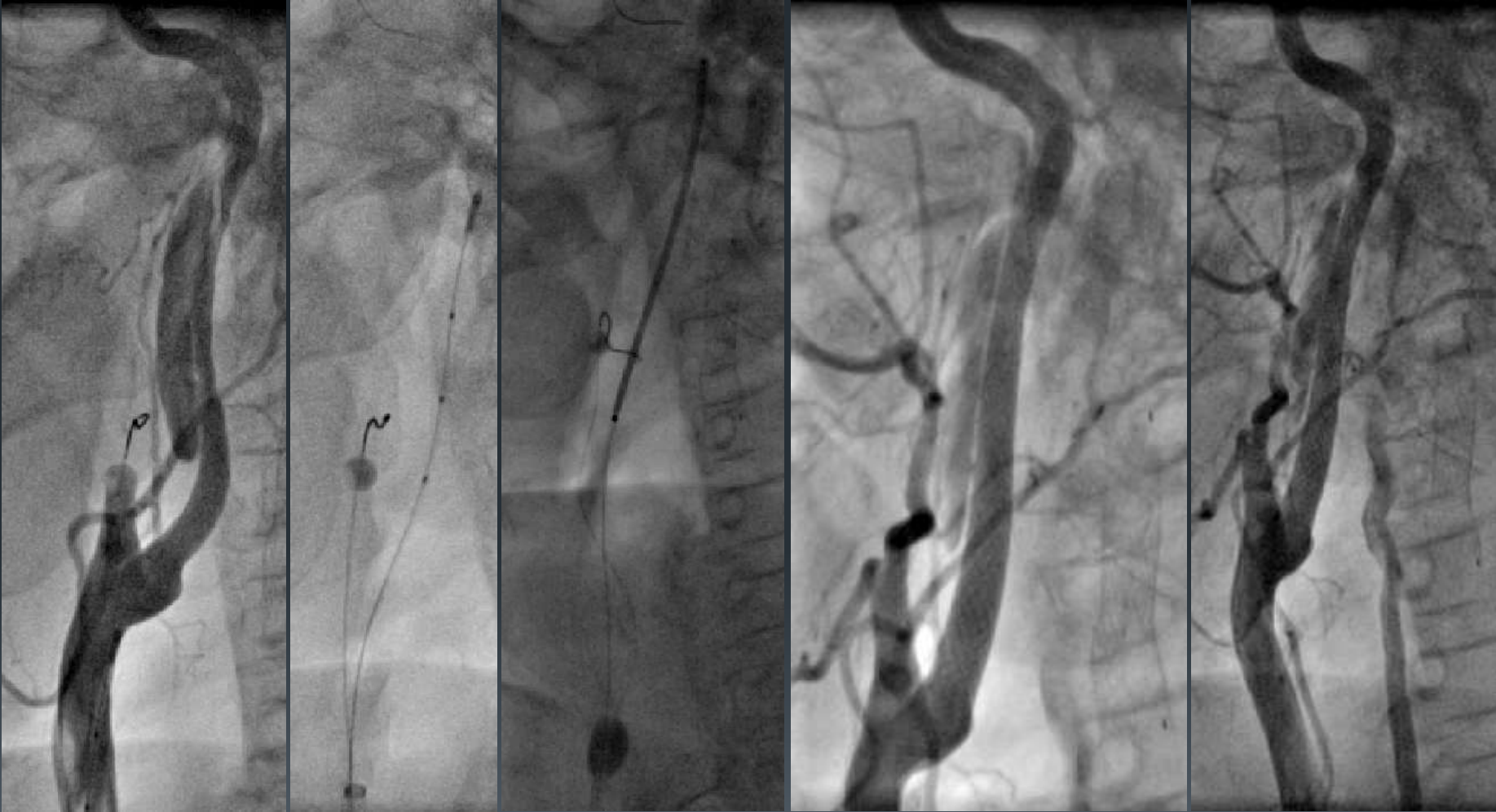
J Endovasc Ther. 2009 Dec;16(6):744-51.

Mono MoMa !!!!!

New proximal protection device.
Restenosis 6m. after CEA with ECA occlusion.



52 yo pt.: Symptomatic spontaneous RICA dyssection



IVUS verification of wire position + proximal protection + close cell stent without postdilatation !!!!!

Proximal EPD= the only option: iatrogenic ICA occlusion



fresh thrombus captured by the FR Filter

bail-out proximal FR-EPD



⇒ the proximal EPD system
should be available in all cath-labs
performing CAS
(at least for bail-out situations!)

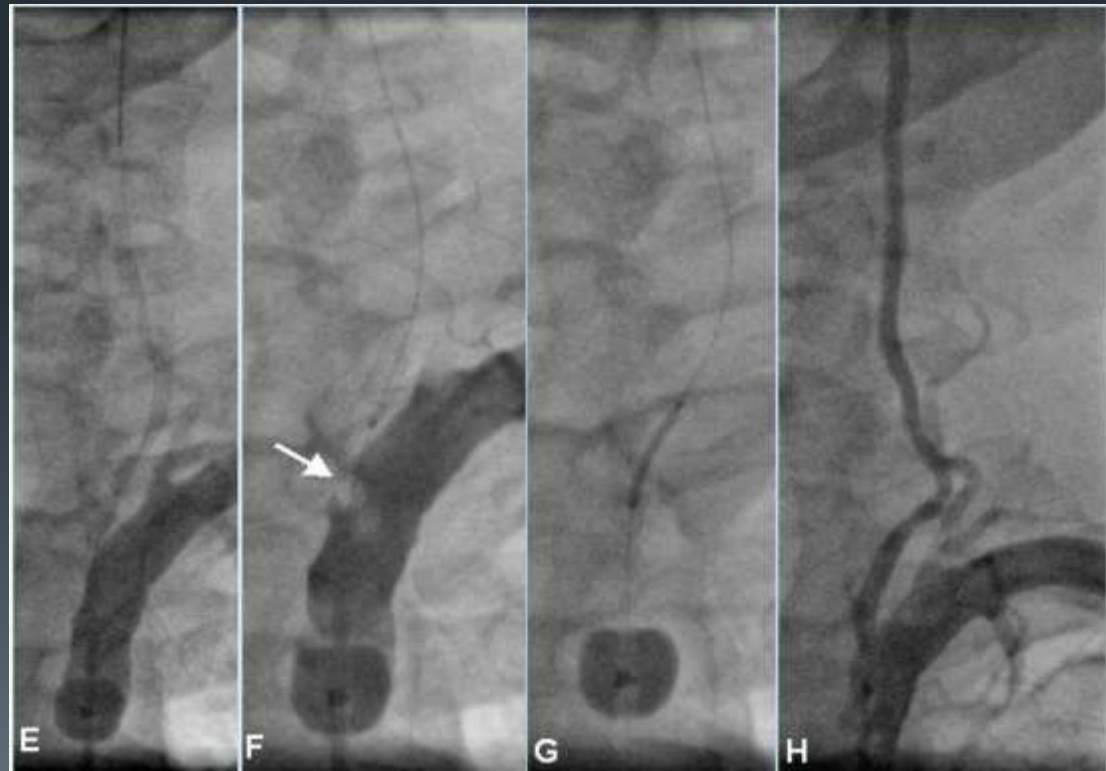
Pt 49y with LICA and LCCA stenosis. **Always** make **angio** also **CCA** before proximal EPD insertion: **First stage** Filter protected LCCA stenting. **Second stage** Mo.Ma protected LICA stenting.



Dont'd believe ultrasographer check always CCA

New indication for
Mono Mo.Ma

Mono Mo.Ma for
vertebral artery
recanalization !!!!



2005 CAS procedures (01.2001 – 12.2013)

1802 pts; 49.6% symptomatic

826 high risk lesion – 41.2%

PROXIMAL EPD in 747 CAS (500 MoMa, 247 Gore; 37.3%)

In 2012 53.0%, In 2013 45.1%

Man: 67.3%; age 67.2 ± 8.9 y.o.

mean FR time 6.15 min; 3.03 – 18.43 min

FR/C intolerance $30/747 = 4.0\%$

FR/C immediate intolerance requiring CCA balloon
deflation $4/747 = 0.5\%$

All completed successful

Patient characteristics

Age, y (range)	67.2±8.9 (36–88)
>75 years	321 (17.8%)
Men	1213 (67.3%)
Smoking – current or past	820 (45.5%)
Symptomatic ICA/CCA stenosis	894 (49.6%)
Ipsilateral stroke*	725 (40.2%)
TIA*	390 (21.6%)
Amaurosis fugax*	51 (4.7%)
Diabetes mellitus	514 (28.5%)
Insulin therapy (% of diabetics)	186 (36.2%)
Arterial hypertension	1648 (91.5%)
Hyperlipidemia	1338 (74.3%)
Significant bilateral ICA disease	593 (32.9%)
Contralateral ICA occlusion	243 (13.5%)
High-risk lesions† (% of all lesions)	826 (41.2%)
CAD by angiography‡	1174 (65.1%)
History of myocardial infarction	475 (26.4%)
History of PCI and/or CABG	724 (40.2%)

Continuous data are presented as means ± standard deviation; categorical data are given as counts (percentages).

CAS: carotid artery stenting, ICA: internal carotid artery, CCA: common carotid artery, TIA: transient ischemic attack, CEA: carotid endarterectomy, CAD: coronary artery disease, CABG: coronary artery bypass graft, PCI: percutaneous coronary intervention.

*Within 6 months prior to CAS.

†By morphology, i.e., echolucent, thrombus-containing, or string-sign lesion (>95% by QCA).

‡Lesion(s) ≥50% by QCA.

2005 CAS procedures (01.2001 - 12.2013) 1802 pts; 49.6% symptomatic

	Proximal NPS (747 CAS)	distal NPS (1258 CAS)	p
Symptomatic pts	377 (50.5%)	545 (43.2%)	0,004
Doppler PSV	3.8 ± 1.3 (1.2-6.5)	3.4 ± 1.3 (1.2-6.1)	NS
EDV	1.6 ± 0.7 (0.2-2.4)	1.1 ± 0.5 (0.4-2.2)	0.042
Stenosis by QCA (%)	90.0 ± 12.0 (60-99)	80.2 ± 9.9 (50-99)	< 0.001

2005 CAS procedures (01.2001 - 12.2013) 1802 pts; 49.6% symptomatic

	Proximal NPS (747 CAS)	distal NPS (1258 CAS)	p
High-risk lesion	712 (95.3%)	115 (9.1%)	p<0,001
Direct stenting	221 (29.6%)	769 (61.1%)	< 0.001
Closed-cell stents	85.8%	69.6%	< 0.001
Residual stenosis by QCA	11 ± 9% (0-40)	11 ± 9 (0-30)	NS
Restenosis >50% (US, CT)	1.7%	2.1%	NS

2005 CAS procedures (01.2001 - 12.2013)

1802 pts; 49.6% symptomatic

RESULTS

	Proximal protection	Distal protection	
No. of CAS	747	1258	
30-day death	0.80% (6/747)	0.64% (8/1258)	p=0.664
30-day major/disabling stroke	0.40% (3/747)	0.32% (4/1258)	p=0.169
30-day any stroke	1.47% (11/747)	1.75% (22/1258)	p=0.638
30-day death/disabling stroke	1.20% (9/747)	0.95% (12/1258)	p=0.594
30-day death/any stroke	2.27% (17/747)	2.38% (30/1258)	p=0.158

There is no MI complication in both group !!

Conclusion

- ❖ ICA stenting with usage of proximal flow blockage systems can have better outcome than those recommended in current guidelines for CEA (3% asympt. and 6% sympt.)
- ❖ The ongoing development and increasing experience in proximal neuroprotection systems use broadens indications for high risk carotid and vertebral artery stenting

Home message...

each operator performing CAS should have a working knowledge and experience of proximal neuroprotection !

Thank You

