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WIST

Short - and long-term results of open cell carotid MER stent.

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DISCLOSURE STATEMENT OF FINANCIAL INTEREST

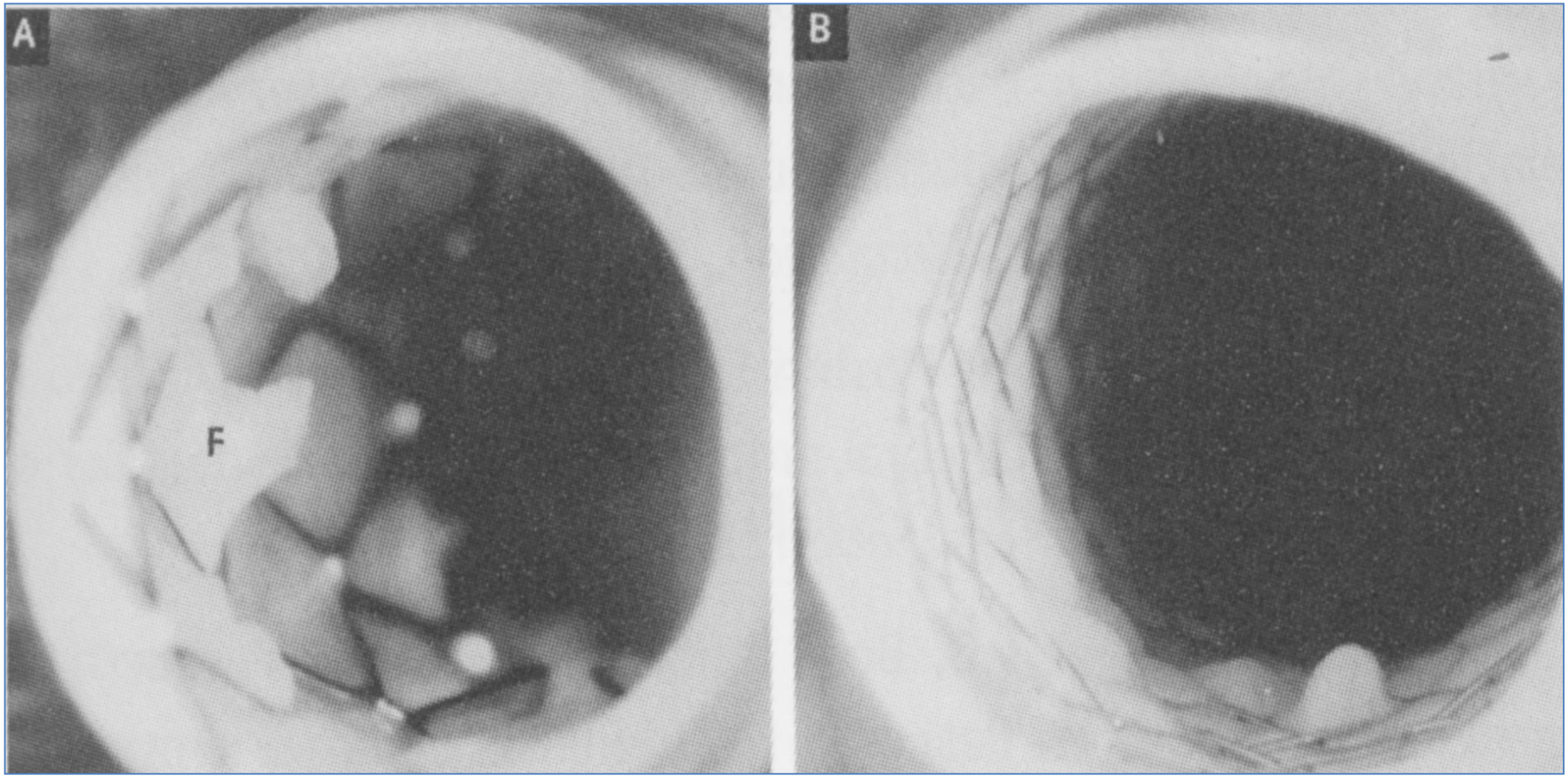
Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below

AFFILIATION/FINANCIAL RELATIONSHIP	COMPANY
• Grant/Research Support	
• **Consulting Fees/Honoraria**	**Balton, Terumo, Boston, Medtronic, Abbot**
• Major Stock Shareholder/Equity	
• Royalty Income	
• Ownership/Founder	
• Intellectual Property Rights	
• Other Financial Benefit	

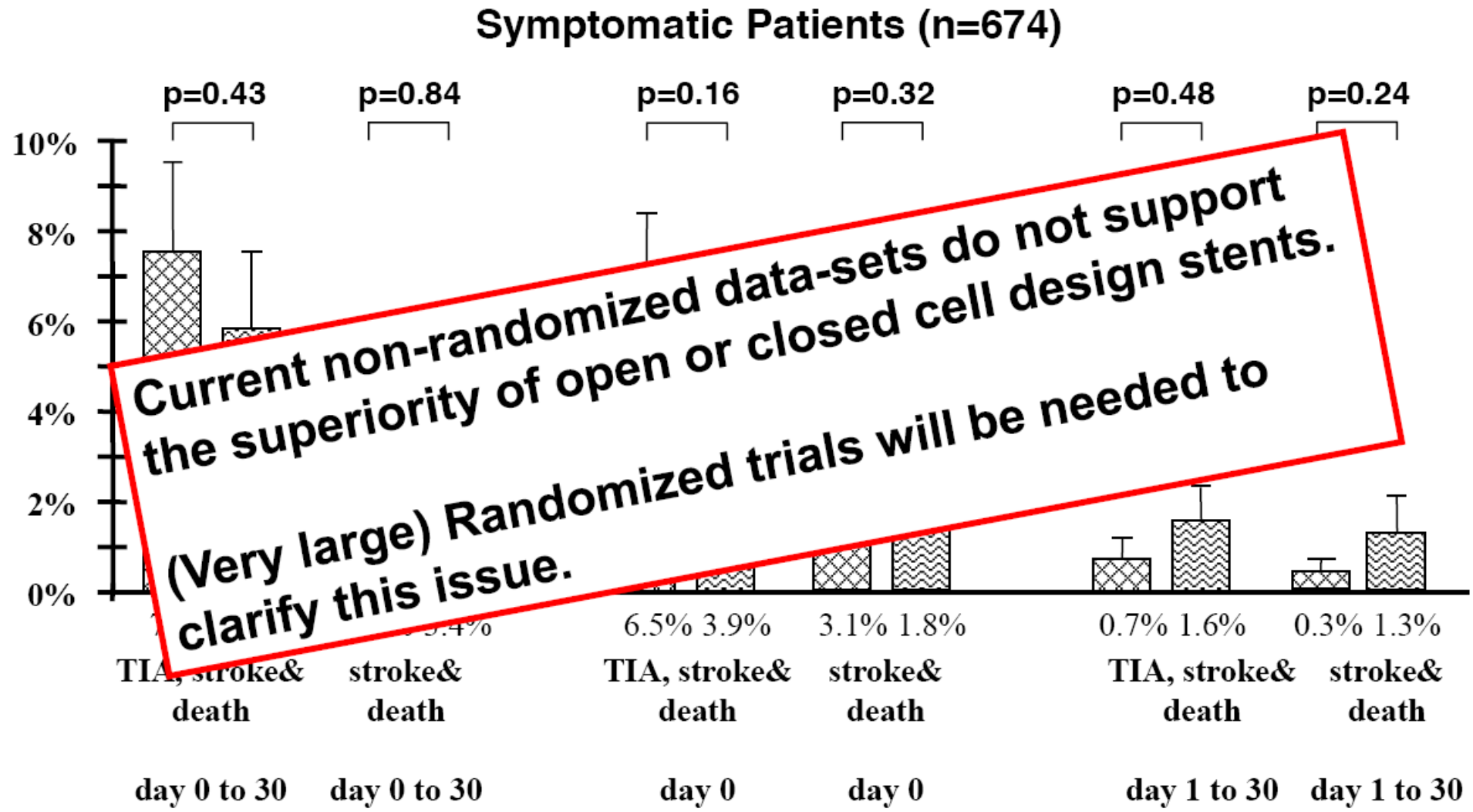
What are the possible causes of stroke in CAS?

- Operator error
  - Technique (balloon sizing, wire misadventure, EPD error, etc.,)
- Patient factors
  - Vulnerable plaque (lesion, carotid, aorta)
  - Vascular anatomy or characteristics (calcium, thrombus, etc.,)
  - Genetics related to thienopyridine metabolism
- Inadequate technology
  - EPD, stent, procedural pharmacology

Open versus close cell design stent
Most ischemic stroke after CAS procedure or during 30 days follow-up



European Registry: no effect of stent type on outcomes



Current non-randomized data-sets do not support the superiority of open or closed cell design stents.

(Very large) Randomized trials will be needed to clarify this issue.

The effect of stent design on clinical and radiological outcome of carotid artery stenting: a systematic review and meta-analysis

EE de Vries[1], AJA Meershoek[1], EJ Vonken[2], HM den Ruijter[3], JC van den Berg[4], Gert J de Borst[1]; ENDORSE study group

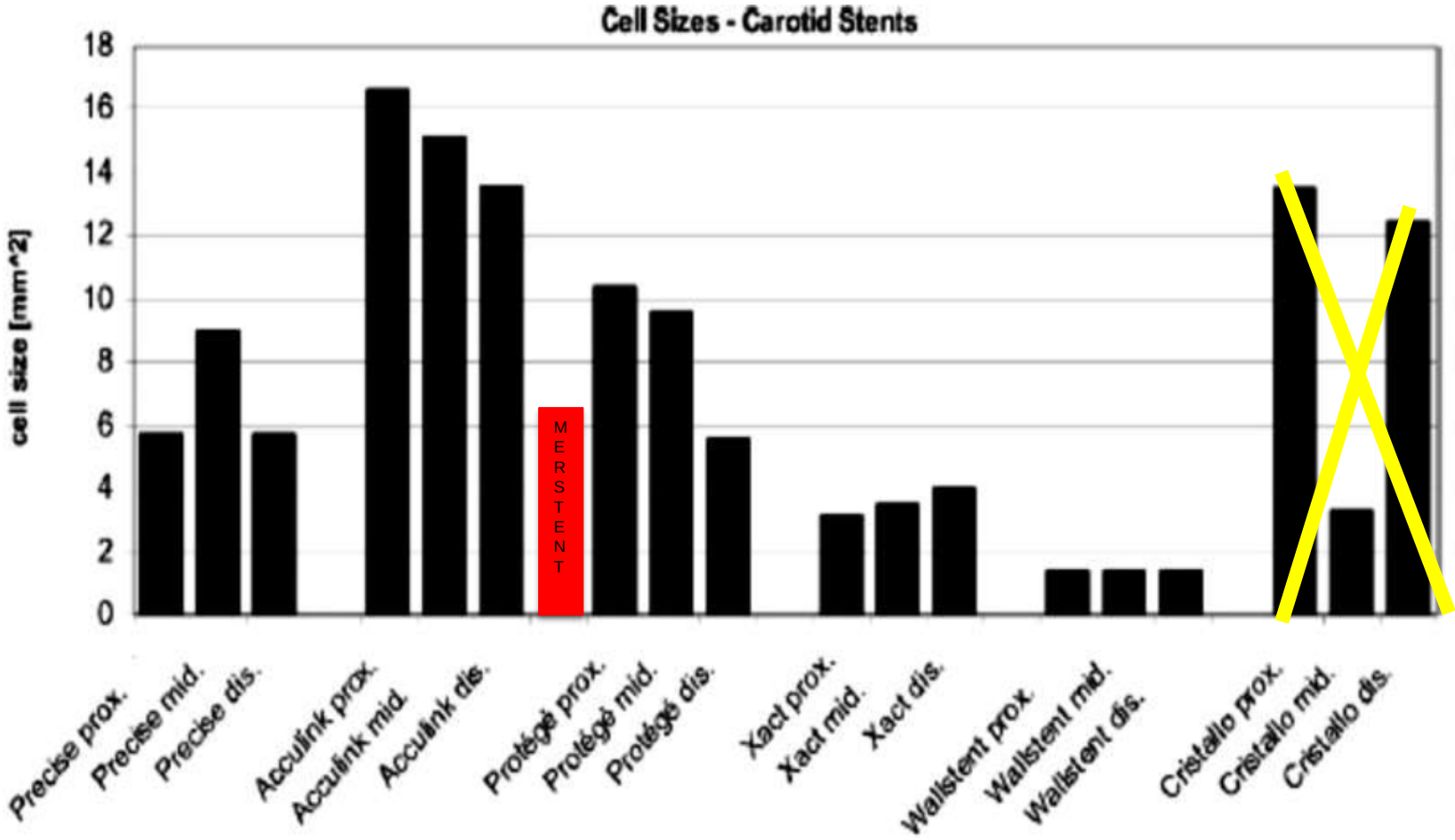
Materials and Methods: A systematic search was conducted in MEDLINE, Embase, and Cochrane databases in January 2017 identifying articles reporting the occurrence of clinical or radiological short- and long-term major adverse events (MAE) in different stent designs used to treat carotid artery stenosis. Random effects models were used to calculate combined overall effect sizes. The lack of specified data precluded the performance of adequate subgroup analyses.

Results: From 2,069 unique identified articles, two randomized controlled trials and 60 cohort studies were eligible for analysis. Short-term clinical MAE rates were similar for patients treated with open cell versus closed cell or hybrid stents. Long-term clinical MAE rates remained similar for open versus closed cell stents. Use of open cell stents predisposed to a 25% higher chance (relative risk, 1.25; p=0.03) of developing postprocedural new ischemic lesions on magnetic resonance diffusion-weighted imaging (MR-DWI).

Discussion: Stent design does not affect short- or long-term clinical MAE rates in patients undergoing CAS. However, open cell stenting resulted in a significantly higher number of MR-DWI–detected subclinical postprocedural new ischemic lesions compared with closed cell stenting.

In press 2019

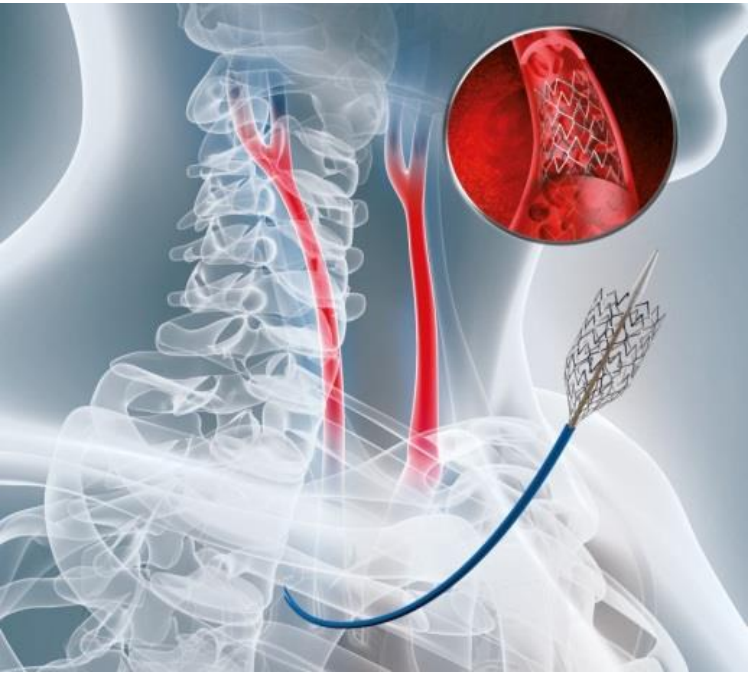
Differences in cell size by stent



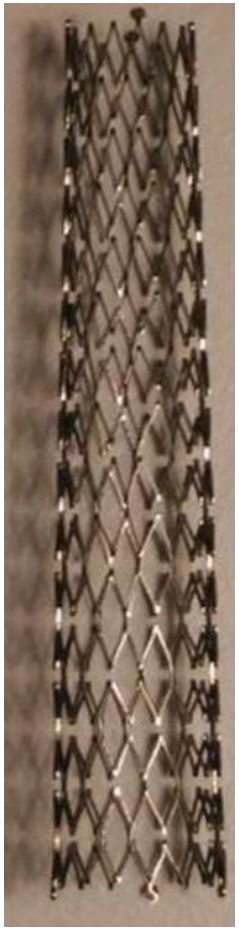
PrOspective multiCentEr study of cArotid artery steNting Usinng mer Stent– OCEANUS study !!!

MER®

BALTON®



Carotid self-expanding stent „MER”
with delivery system (RX)



- Self- expanding stent dedicated to carotid artery made of Nitinol
- Open cells design
- Strut thickness: 0.19 mm
- Cell area: 6.2 mm^2
- Atraumatic, flexible distal tip of the delivery system

Large possibilities of choosing straight or taperated MER stent in the range of length and diameter.

All MER stent 5 F – Delivery system size.

TAPERED STENT / Pull-back system								
Catalog number REF	Nominal stent diameter [mm]		Nominal stent length [mm]	Delivery system working length [cm]	Delivery system size	Minimum Guide Catheter I.D.	Use with introducer	Use with guide wire
	DISTAL	PROXIMAL						
			G					
ZSTS5x7xG14135	5	7	20, 30, 40, 50	135	5F	0.071"	5F	0.014"
ZSTS6x8xG14135	6	8						
ZSTS7x9xG14135	7	9						
ZSTS7x10xG14135	7	10						
ZSTS8x10xG14135	8	10						

STRAIGHT STENT / Pull-back system							
Catalog number REF	Nominal stent diameter [mm]	Nominal stent length [mm]	Delivery system working length [cm]	Delivery system size	Minimum Guide Catheter I.D.	Use with introducer	Use with guide wire
		G					
ZSTS4xG14135	4	20, 30, 40, 50	135	5F	0.071"	5F	0.014"
ZSTS5xG14135	5						
ZSTS6xG14135	6						
ZSTS7xG14135	7						
ZSTS8xG14135	8						
ZSTS9xG14135	9						
ZSTS10xG14135	10						

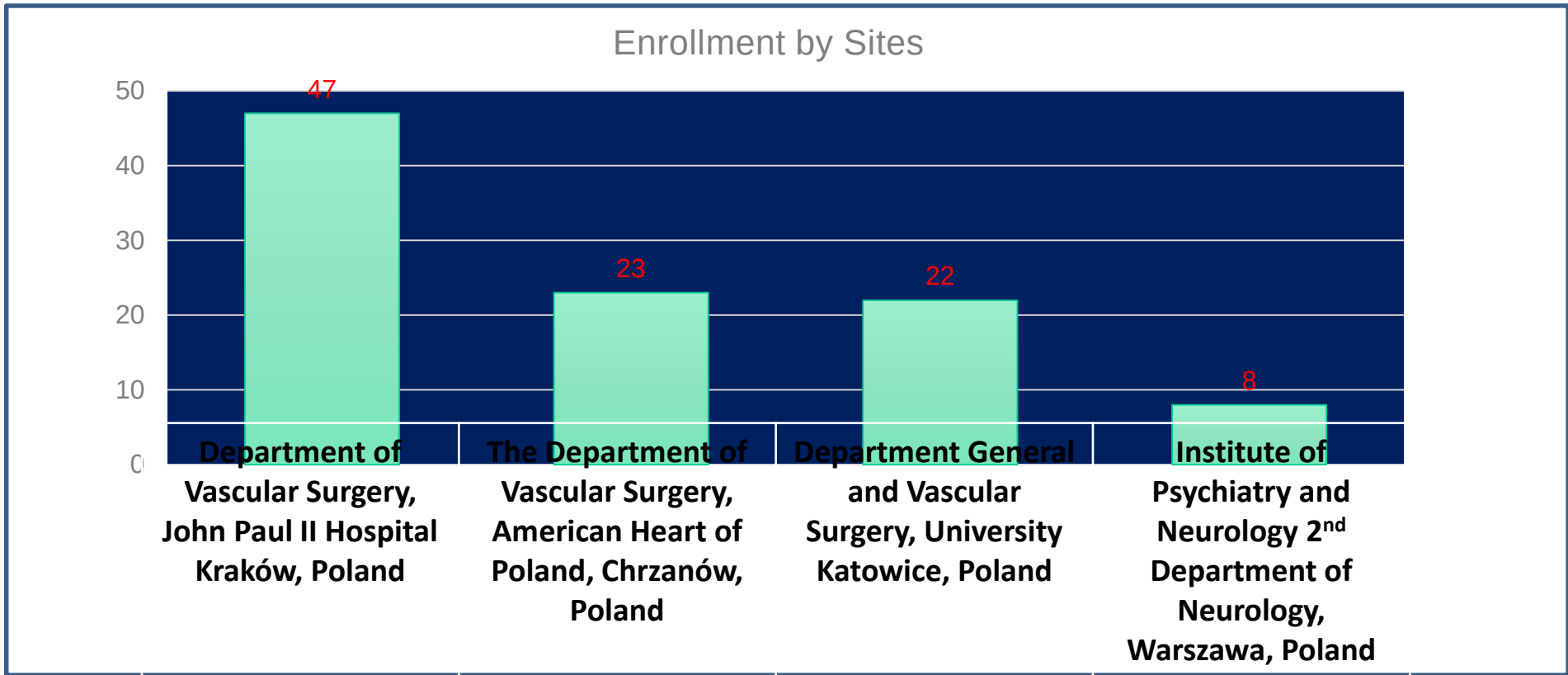
KCRI's Core Laboratory offers independent, standardized and adjudicated data analysis of several imaging study endpoints:

- Angiography: Coronary and Peripheral (including carotid vessels)
- Intravascular Ultrasound (IVUS)
- Virtual Histology (VH)
- Optical Coherence Tomography (OCT)
- Cardiac Magnetic Resonance (CMR)
- Computed Tomography (CT)
- ECG
- ECHO (in cooperation)

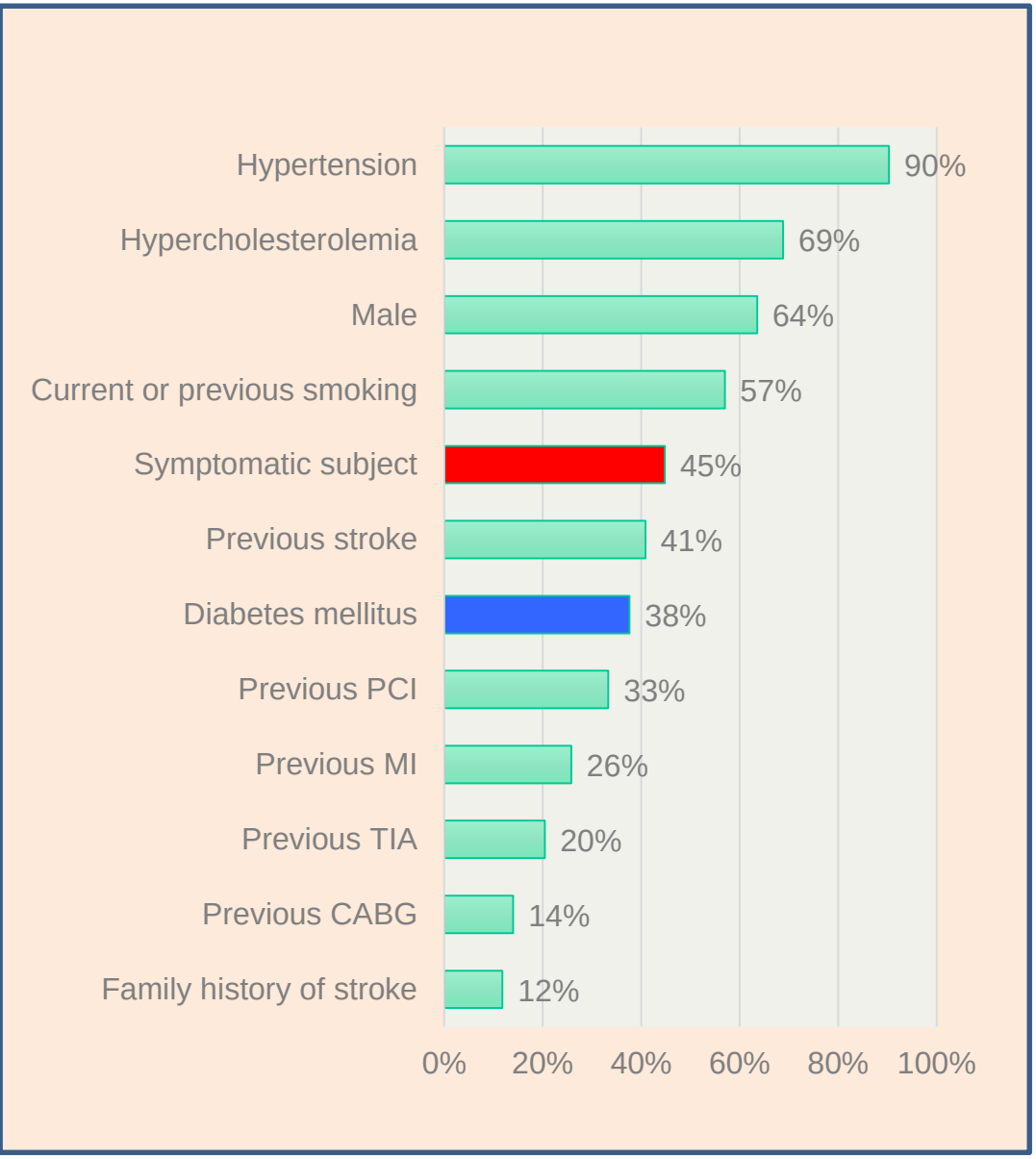
The infrastructure of the Core Laboratory includes state-of-the art and validated analytical workstations with dedicated tools for quantitative data assessment and raw data management.

Enrollment and timelines - OCEANUS - STUDY

- First patient in the study: 10-Oct-2016
- Last patient enrollmend to the study: 23-May-2017
- 1 month FU were completed for all subjects: Jun-2017
- 6 months FU were completed for all subjects: Nov-2017
- 12 months FU were completed for all subjects:June 2018

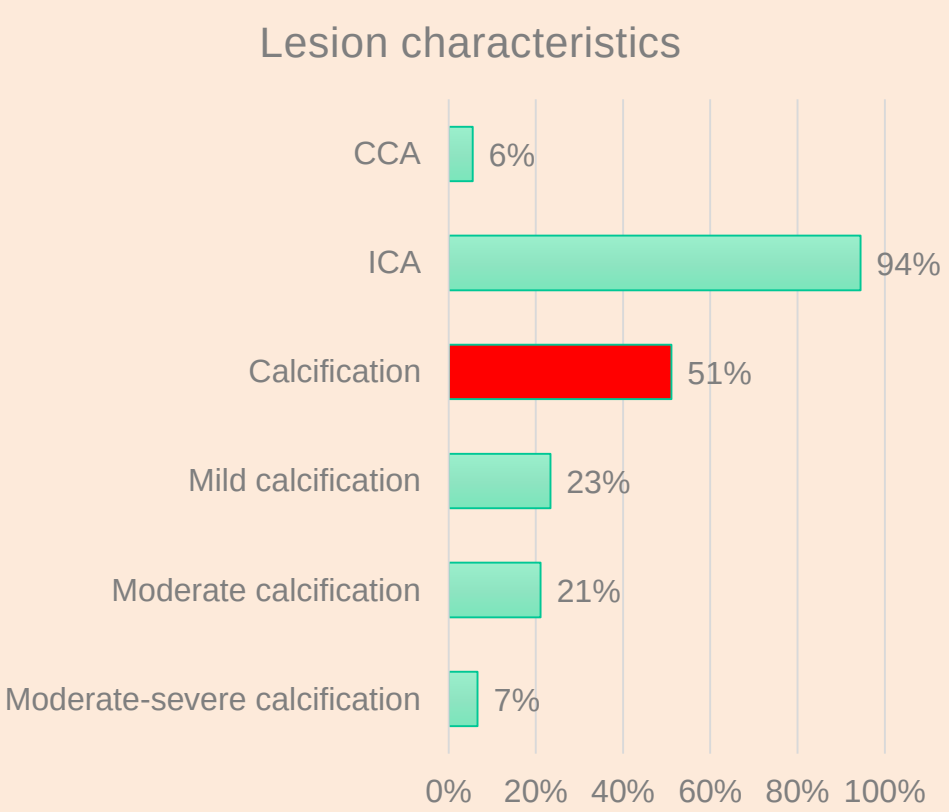


Demographics and baseline data



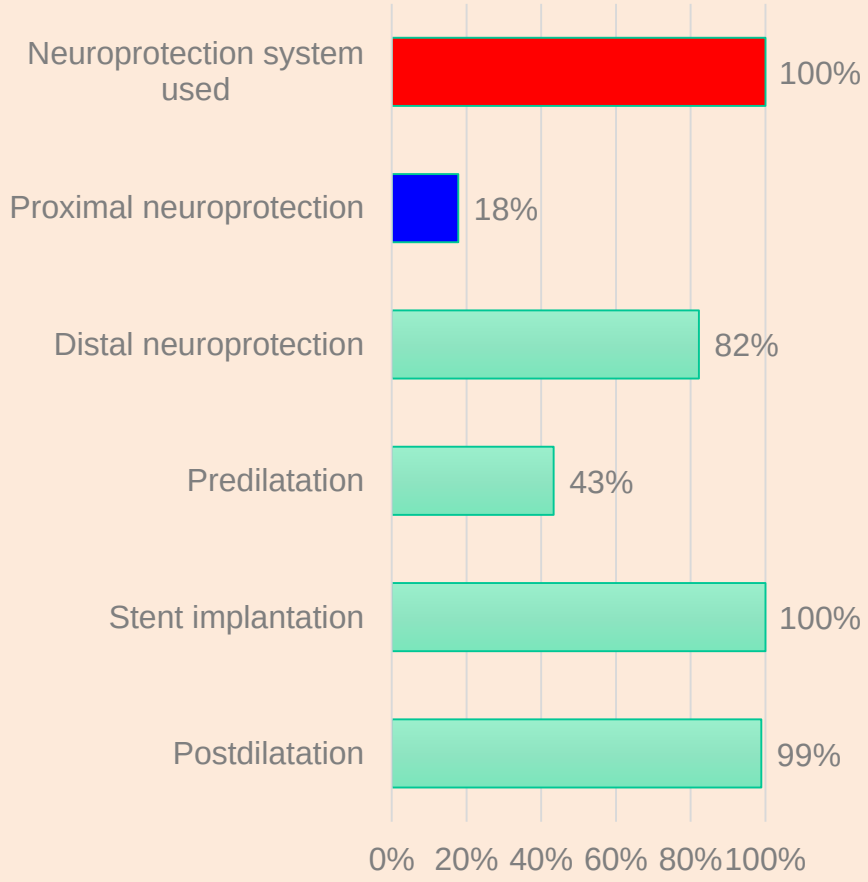
Variable	Measure	Total
Age at enrollment, years	n	95
	Mean (±SD)	68.55 (±8.24)
	Mean 95% CI	(66.87; 70.23)
	Me (Q1; Q3)	68.00 (62.00; 75.00)
	Min/Max	51.00 / 85.00
Systolic blood pressure, mmHg	n	93
	Mean (±SD)	152.39 (±23.68)
	Mean 95% CI	(147.51; 157.26)
	Me (Q1; Q3)	152.00 (135.00; 170.00)
	Min/Max	83.00 / 213.00
Diastolic blood pressure, mmHg	n	93
	Mean (±SD)	78.41 (±11.48)
	Mean 95% CI	(76.04; 80.77)
	Me (Q1; Q3)	80.00 (70.00; 85.00)
	Min/Max	53.00 / 120.00
Diameter stenosis NASCET, %	n	93
	Mean (±SD)	76.42 (±9.79)
	Mean 95% CI	(74.40; 78.43)
	Me (Q1; Q3)	76.00 (72.00; 83.00)
	Min/Max	49.00 / 95.00

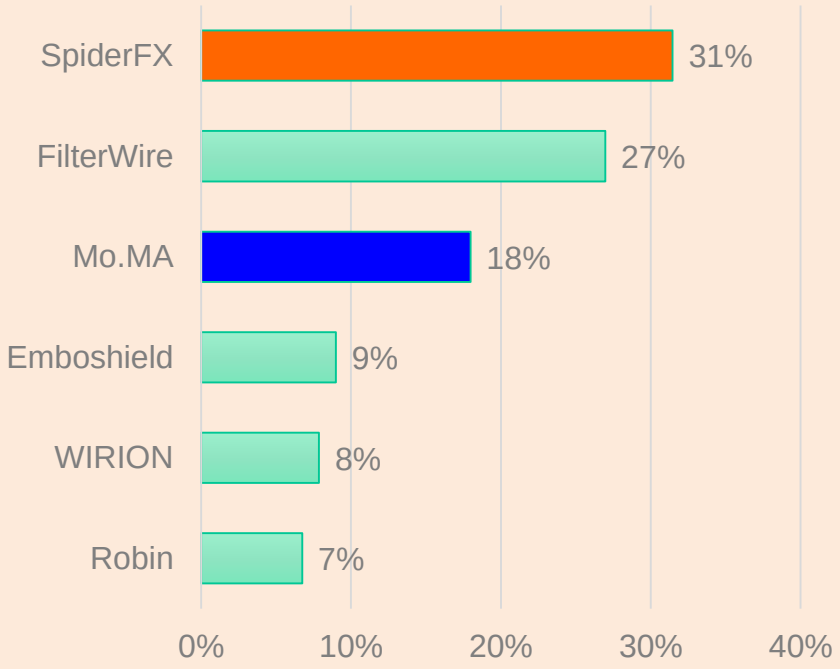
Baseline lesions characteristics



Variable	Measure	Total
Diameter stenosis QCA, %	n	90
	Mean(±SD)	82.10 (±9.23)
	Mean 95% CI	(80.17; 84.03)
	Me(Q1;Q3)	80.00 (77.00; 90.00)
	Min/Max	56.00 / 99.00
Reference vessel diameter, mm	n	89
	Mean(±SD)	5.69 (±0.94)
	Mean 95% CI	(5.49; 5.89)
	Me(Q1;Q3)	5.80 (5.00; 6.00)
	Min/Max	2.60 / 8.00
Lesion length, mm	n	89
	Mean(±SD)	17.04 (±8.34)
	Mean 95% CI	(15.28; 18.79)
	Me(Q1;Q3)	15.00 (10.00; 21.65)
	Min/Max	2.80 / 46.50

Procedural data



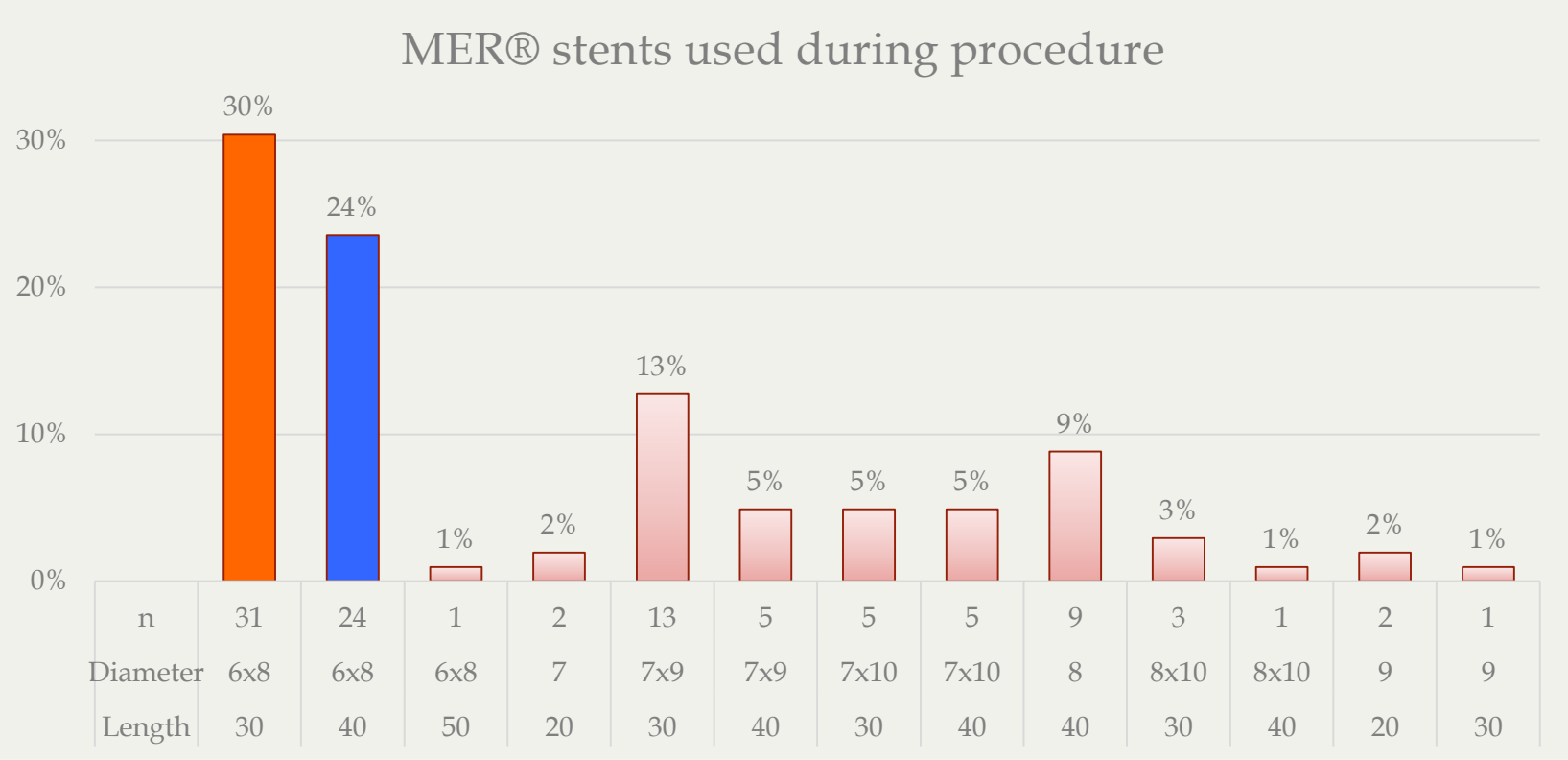


Variable	Measure	Total
Occlusion time for proximal protection, min:sec	n	18
	Mean(±SD)	6:19 (±2:55)
	Mean 95% CI	(4:46; 7:52)
	Me(Q1;Q3)	5:55 (4:45; 7:08)
	Min/Max	3:30 / 16:00

MER® stents used during procedure

Data reported for 100 subjects

Two subjects required 2nd stent implantation (102 stents used)



Procedural data

Carotid Artery stenosis before stenting was 81.9±9.1%, whereas it was 12.5±8.7% after stent implantation ($p<0.0001$)

Direct stenting - 55%

Periprocedural & at dicharge pharmacotherapy:

ASA 75mg - 73% , 150mg -27% (total -100% !!!)

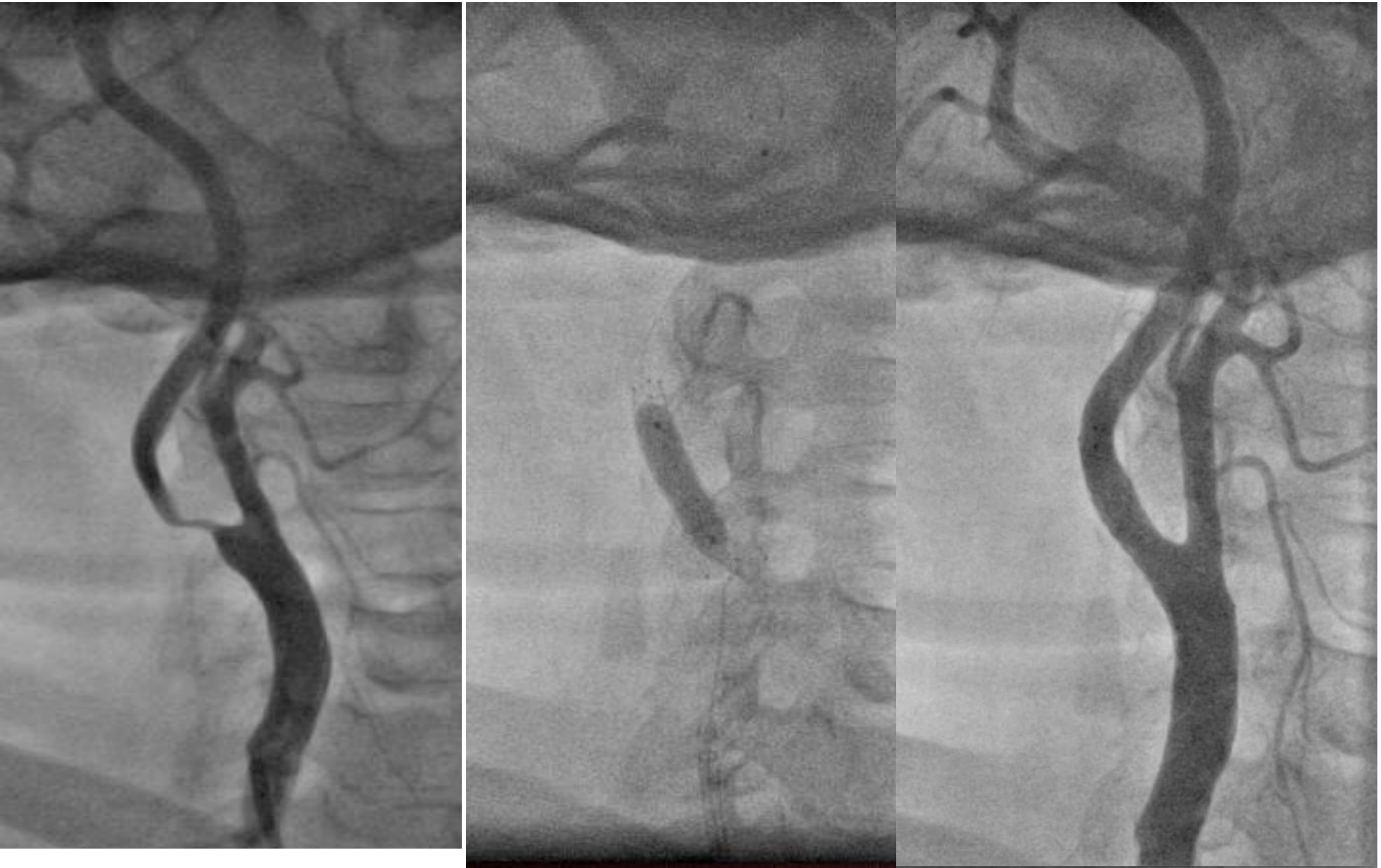
Clopidogrel 75mg – 98%

Ticagrelol 180mg – 2%

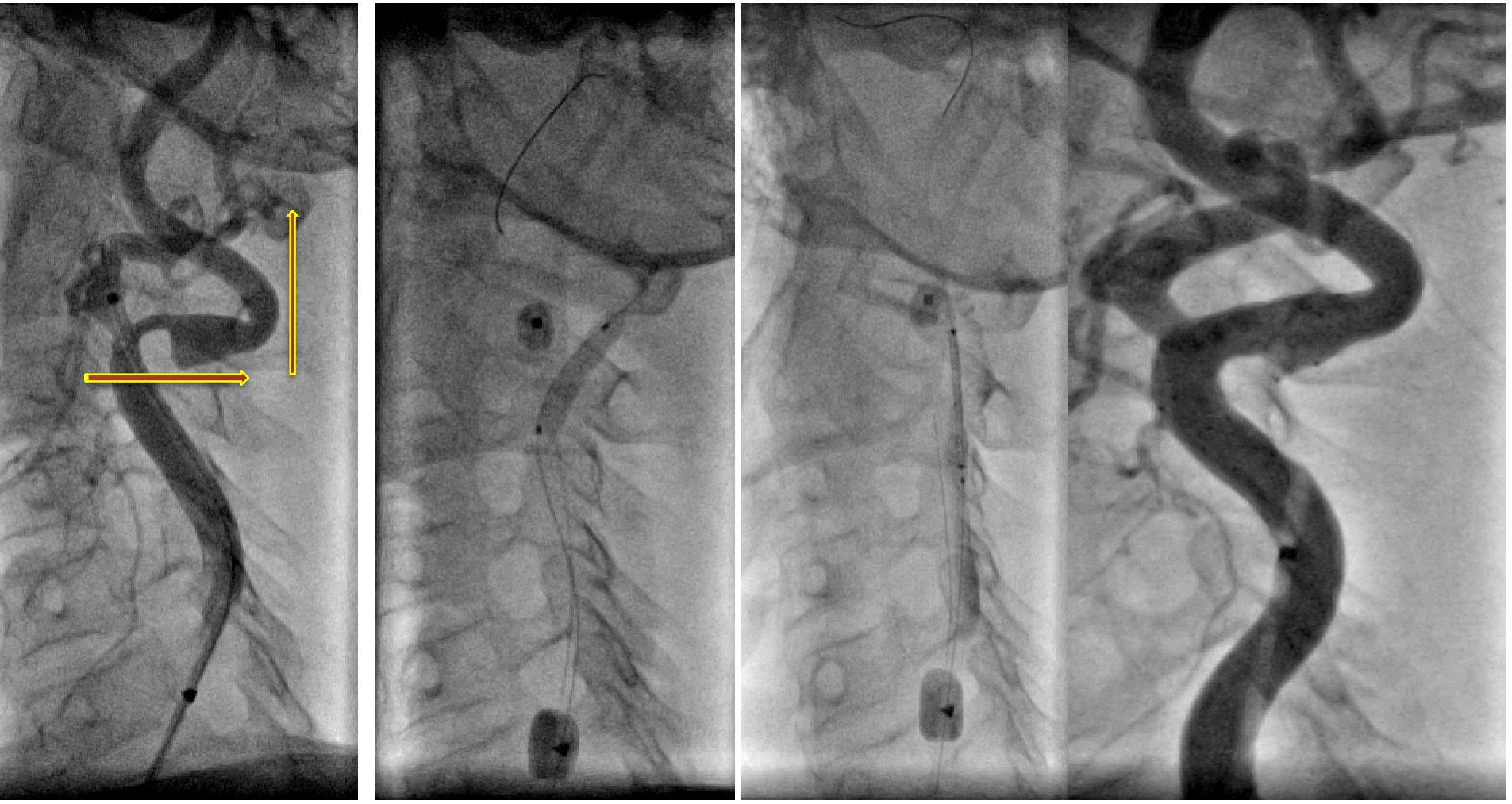
(total – 100% !!!!)

Why we still need open-cell carotid stents

Unique vessel flexibility and adaptability with carotid MER stent



Severe angulation more than 180 degree !!! in pt. with contra-indication to endarterectomy !!!



GRANDSLAM coronary wire 0.014” & Wirion Filter - successful passing and 7.0/20mm MER stent implantation !!!

Symptomatic pt. – angiography of RICA

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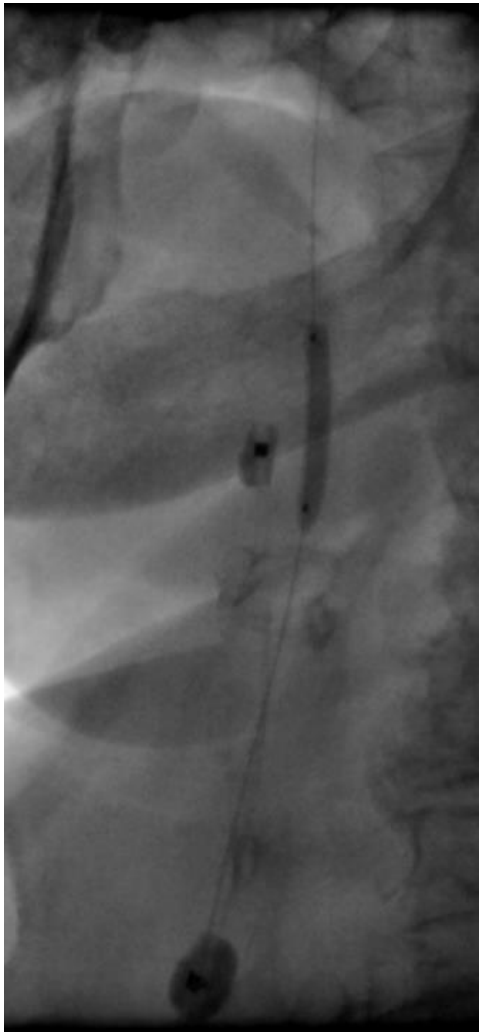


System Mo.Ma Ultra 8F Predilatation with balloon 3.0x20mm – 12 atm.

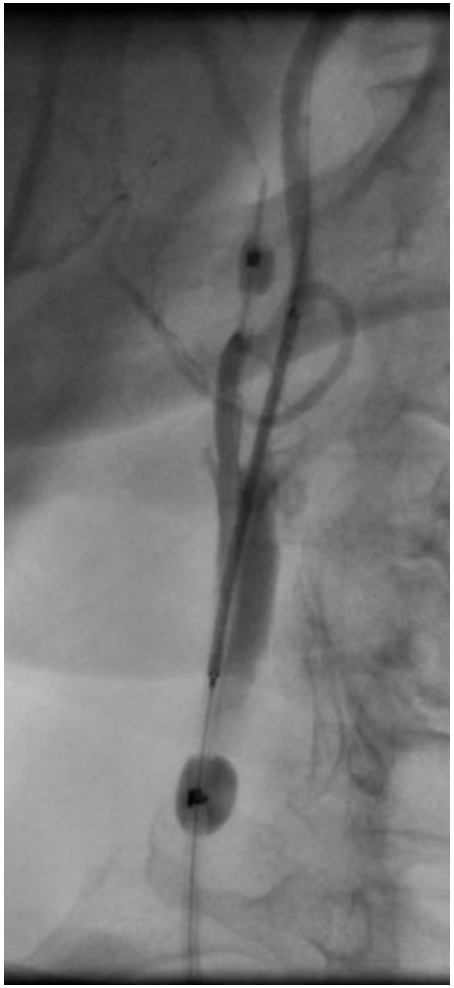
Back pressure – 35/20 mmHg

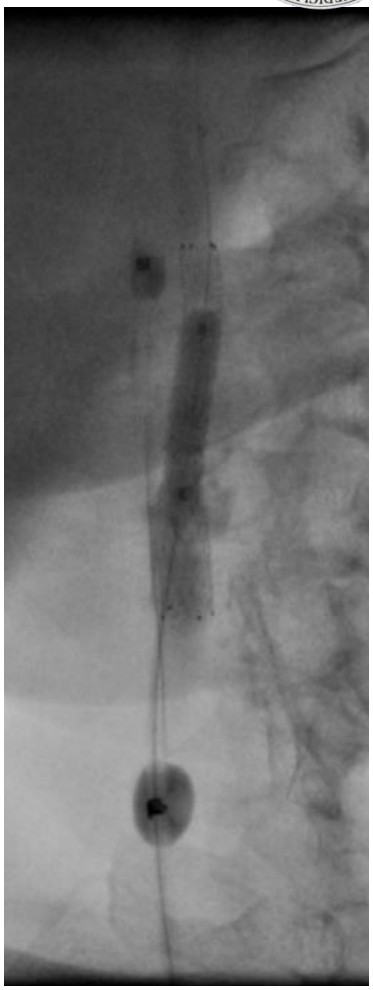
During predilatation symptomatic neurological symptoms due to Proximal EPD intolerance

Required active aspiration and restoration of the flow to release neurological symptoms !!!

After 5 min deflation of proximal balloon of Mo.Ma

back pressure 40/30 mmHg.



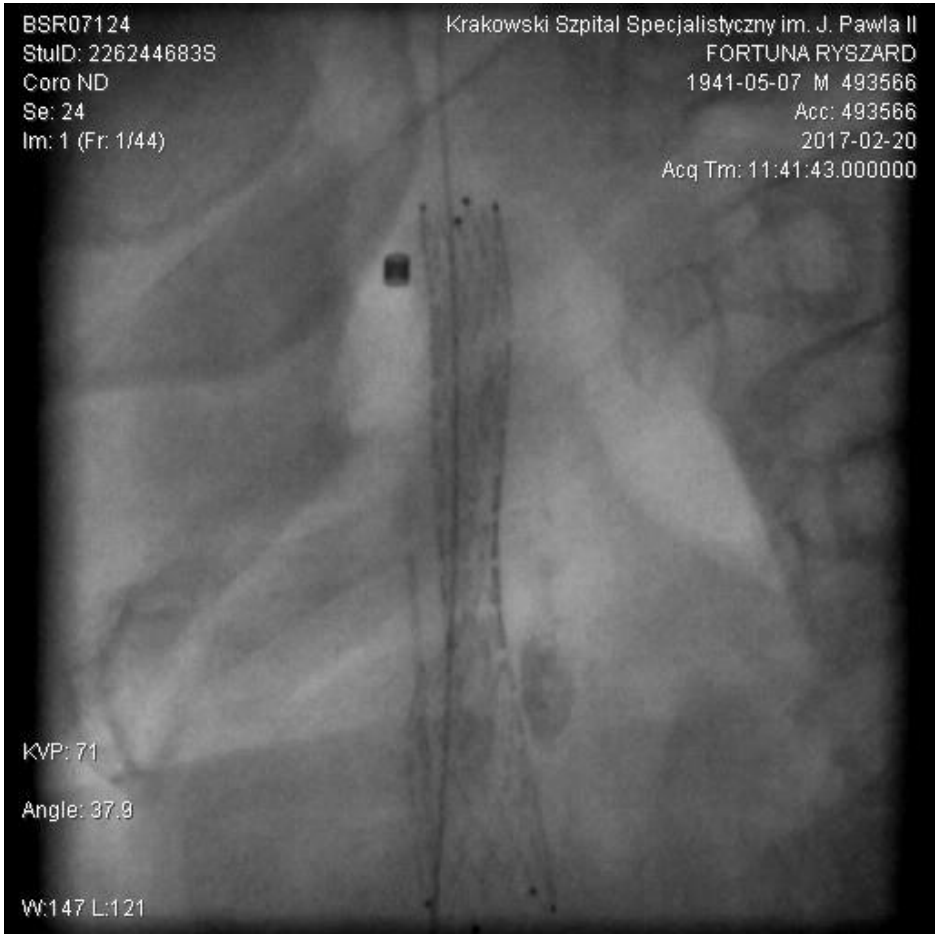


After predilatation stent implantation Postdilatation with balloon

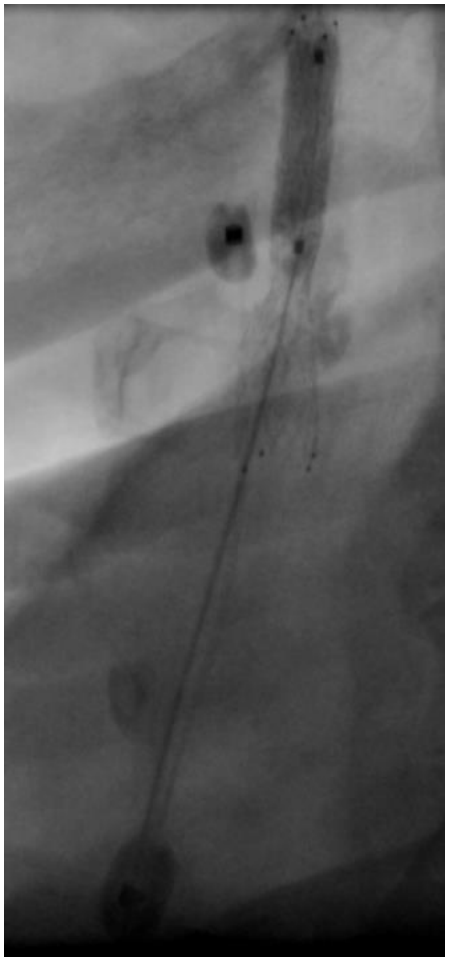
Mer 6-8x40mm Sterling 4.5x20mm – max. 15atm

Aspiration, deflation of Mo.Ma balloons – **many particles and thrombogenic material.**

Angiography after CAS-RICA



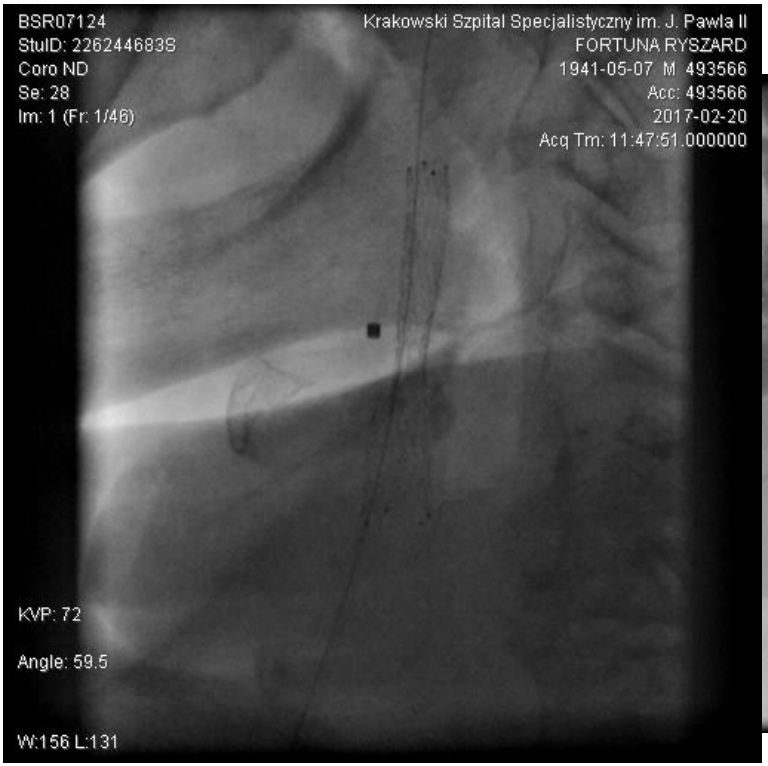
Large plaque protrusion of lesion through the MER – stent.



Third inflation of balloons under Mo.Ma protection
Postdilatation with bigger balloon – Sterling 5.0x20mm – max. 15atm

Control angiography after RICA – CAS !!

Aspiration – **in external filter many particles of atherosclerotic debris.**



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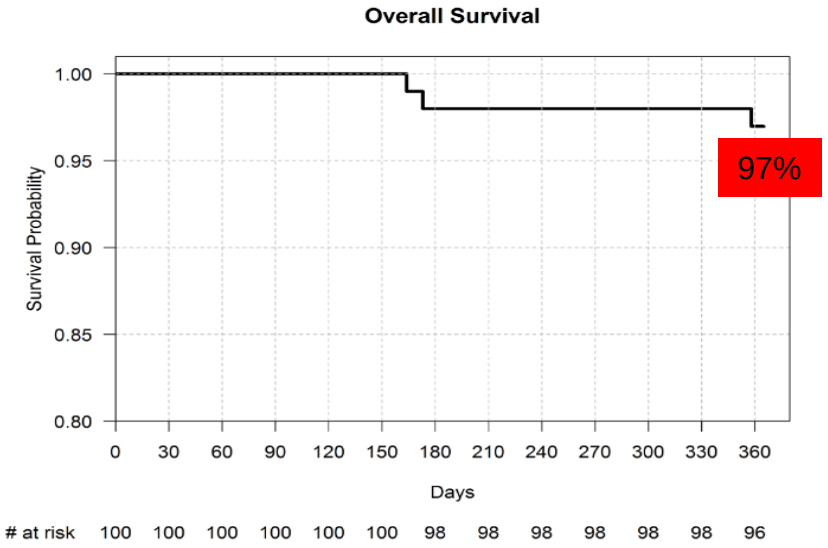
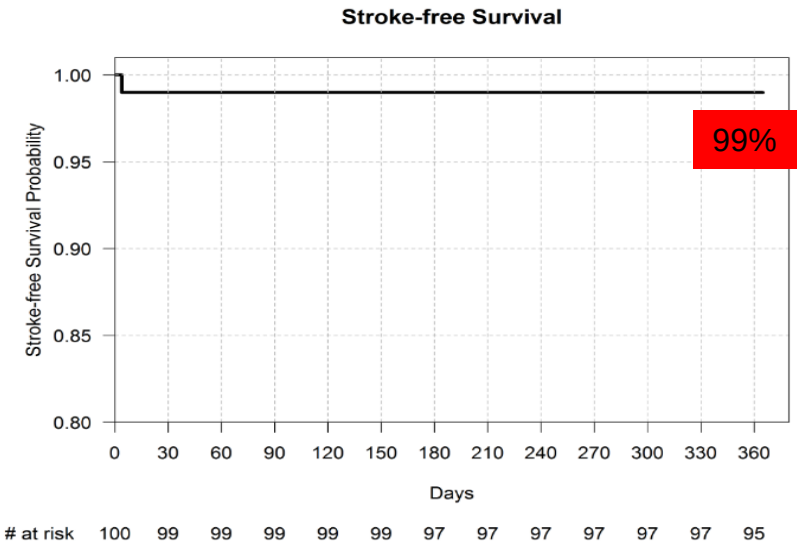
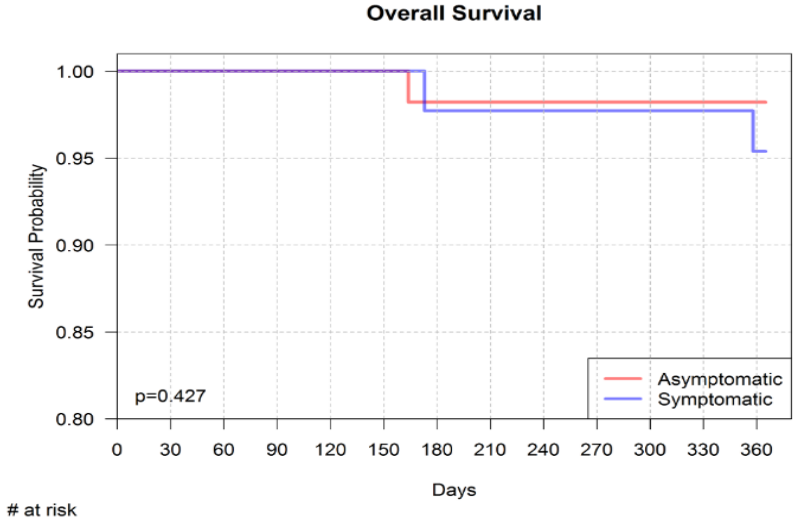
Complication during hospitalization & 30d follow-up !!

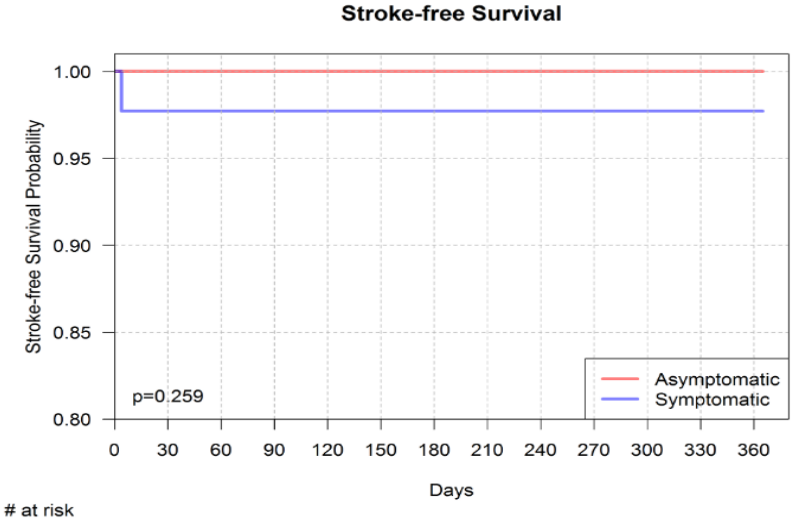
- TIA 0%
- Stroke (ischemic) at day 4 – 1pts 1% !!!!!
- Death 0%
- MI 0%
- Edge dyssection required additional MER stent implantation 1pts – 1%
- Haematoma or bleeding complication 0%
- Renal impairement 0%
- Hypotonia required inotropic agents – 1pts 1%

Excellent 12 months follow-up with MER stent









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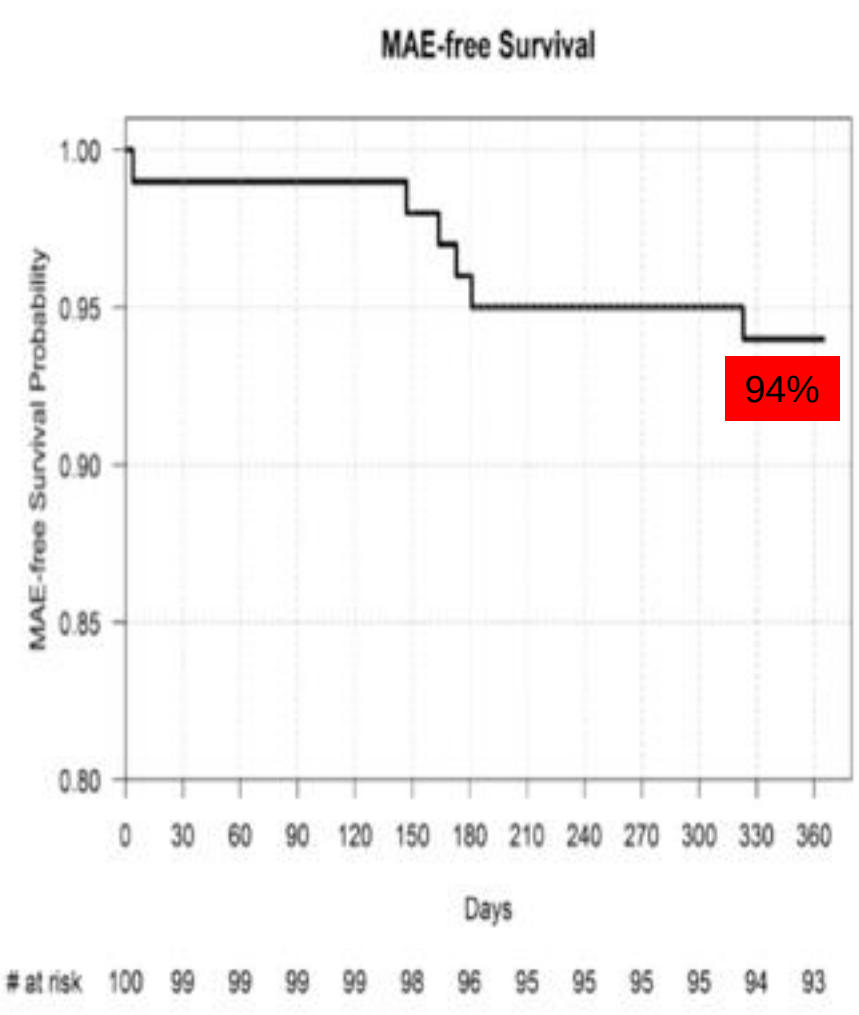
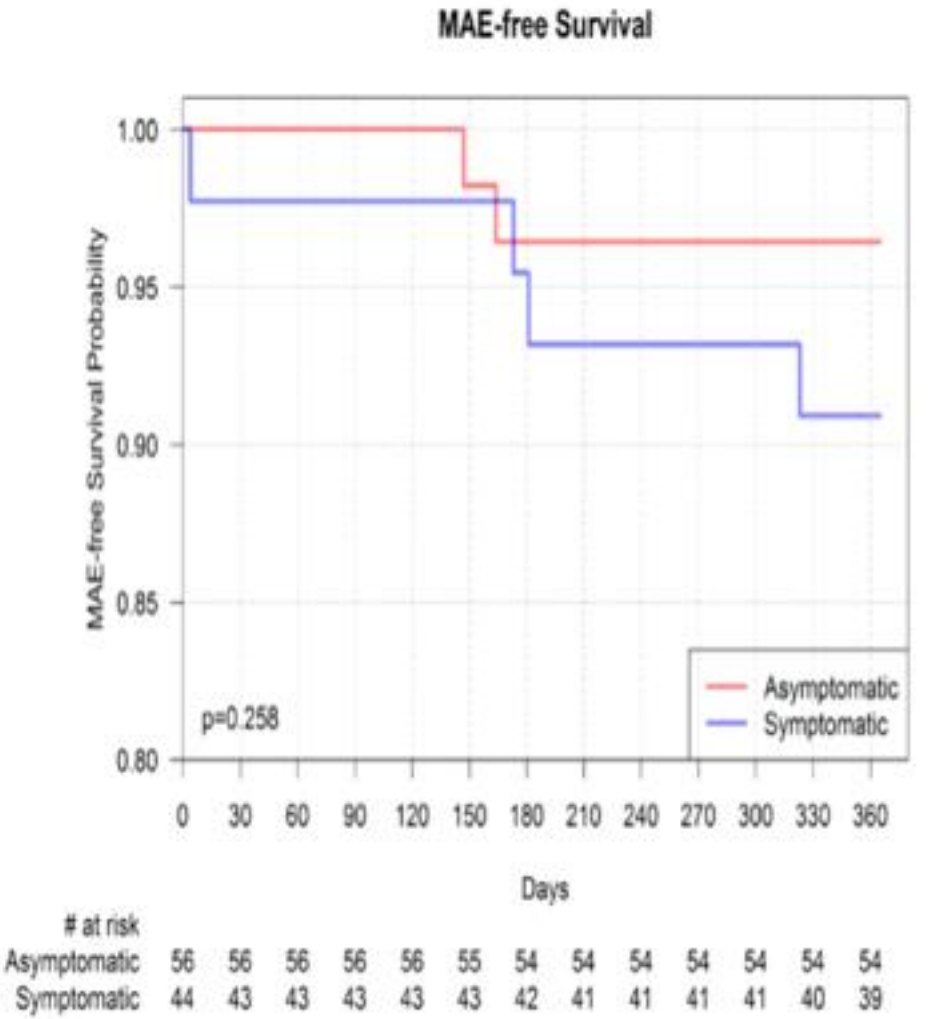
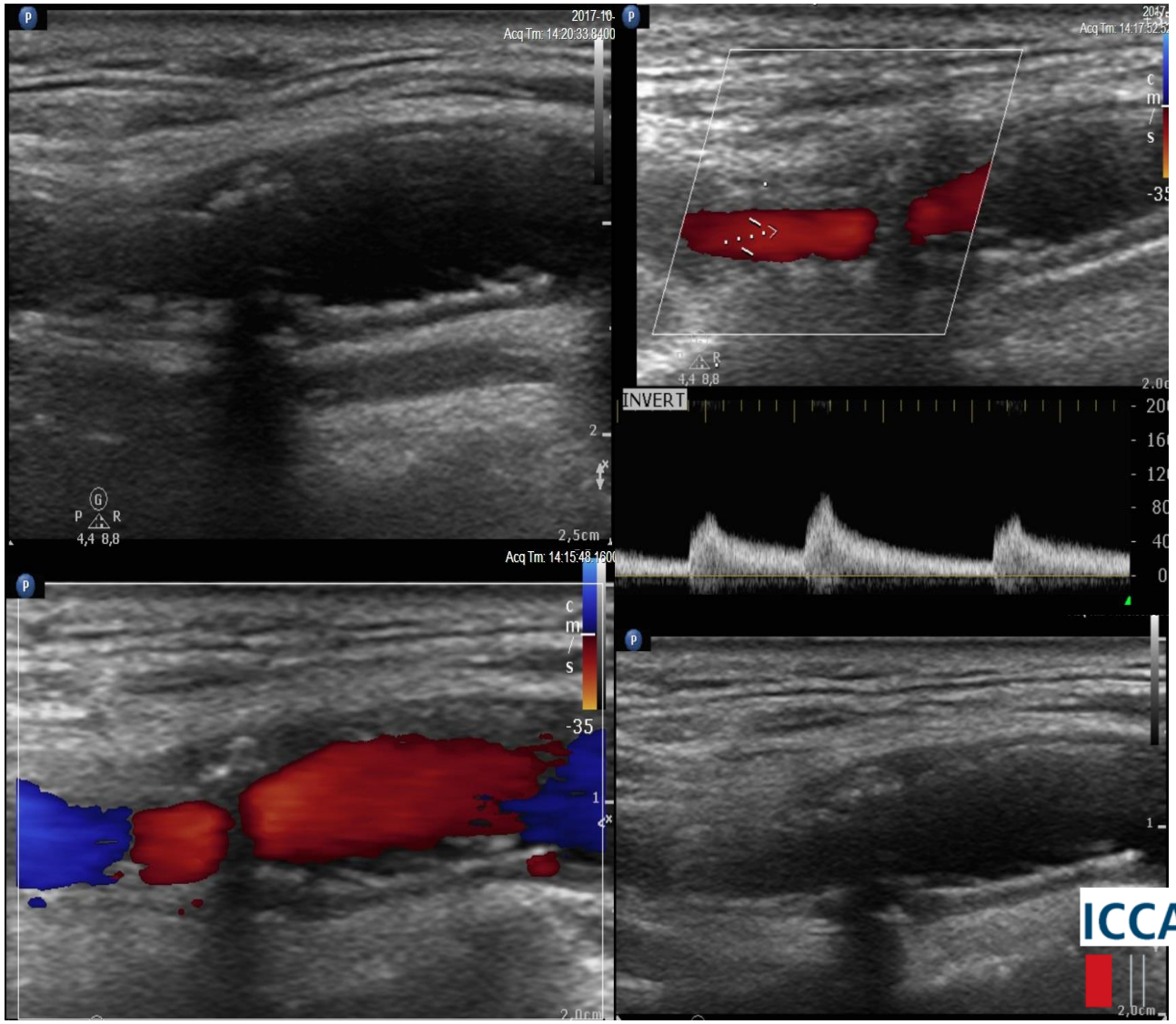
Excellent 12 months follow-up with MER stent





Mer stent – 12 months follow-up Doppler-US investigation .



Laminar flow in MER Stent

PSV 0,9 m/s
EDV 0,3 m/s

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OCEANUS – study

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7 MAE during 12 months follow-up !!! (6 patients)

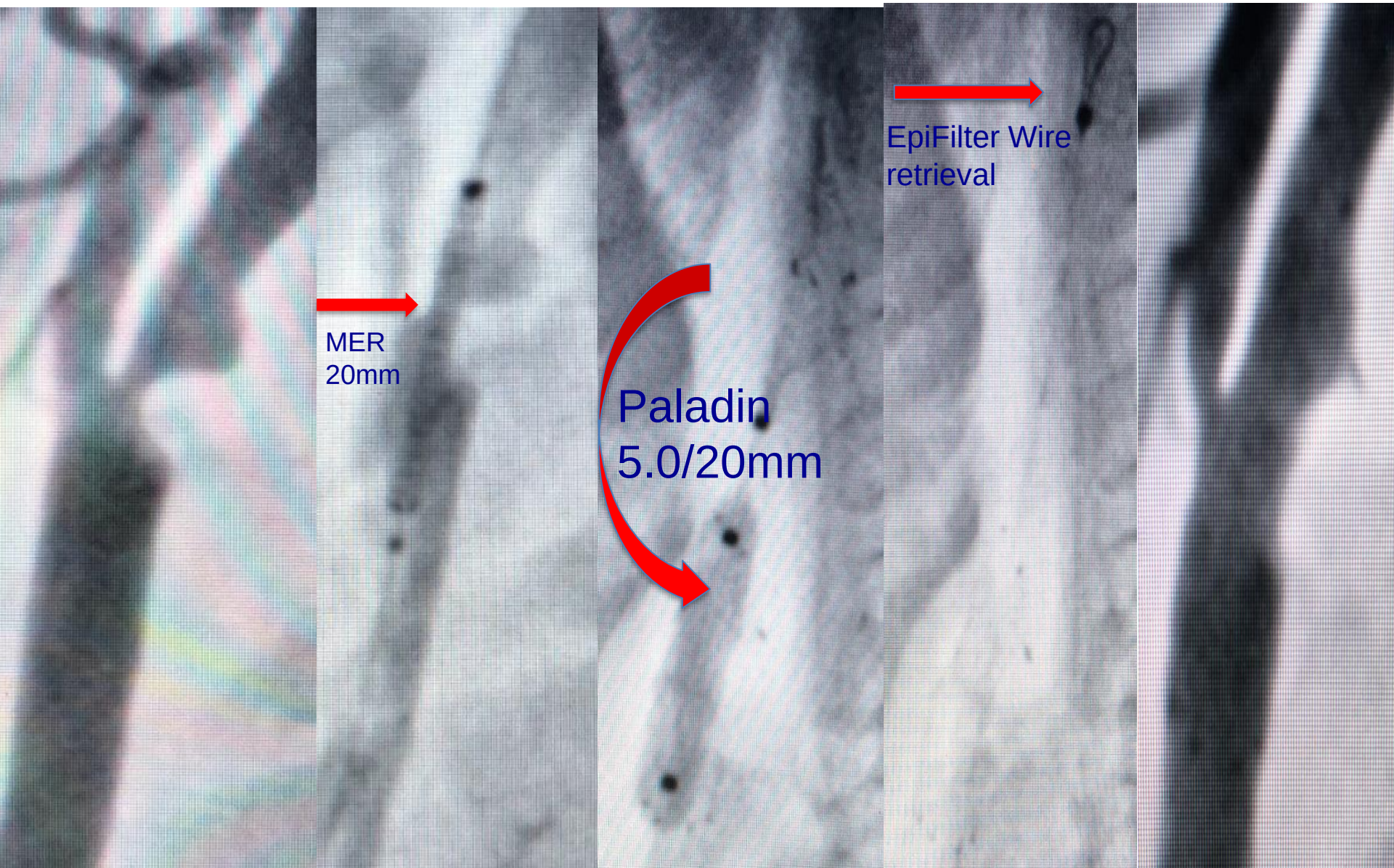
- Stroke (ischemic) at day 4 – 1pt (30 days observation)

- Death : 3 pts – 1pt cardio-pulmonary insufficiency
- 1 pt complication during treatment of
- acute leg ischemia,
- 1 pt died due to suicide !!
- MI – 3 pts – 2pts succesfully treated with pPCI
- 1pt died due to post MI complications.

- ADDITIONAL IMPORTANT EVENT

- 1 pt developed in-stent restenosis required re PTA

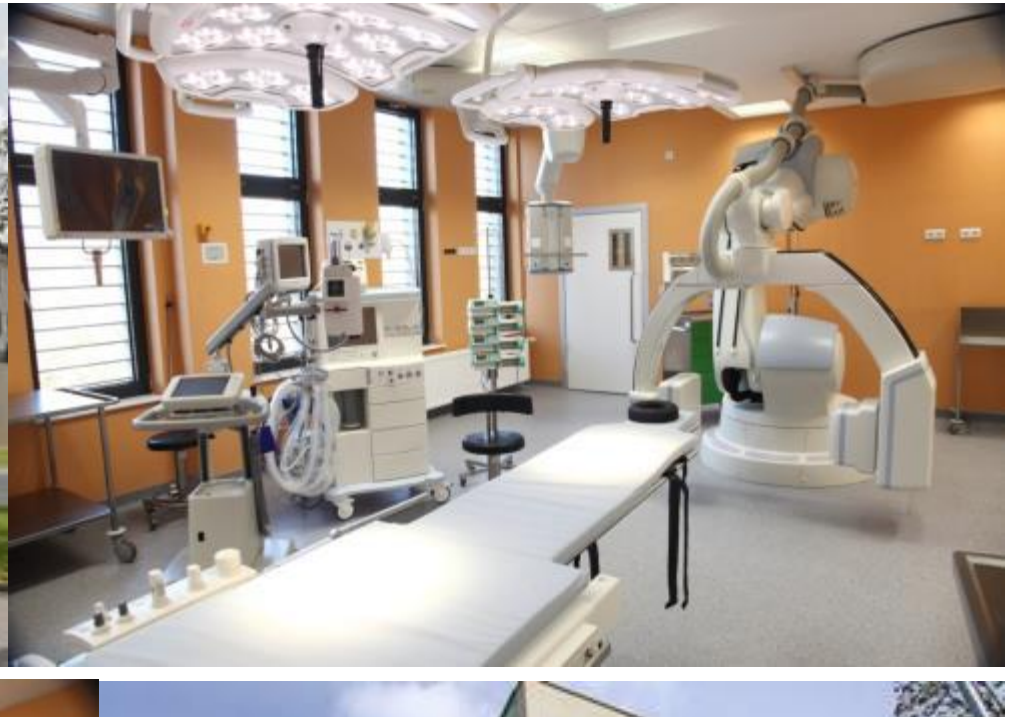
For operator use only dystal protection – short MER stent with double protection Filter plus Paladin system for post dilatation can be very safe option for treatment symptomatic lesion.



Conclusions

- CAS is a fast developing interventional treatment of carotid artery stenosis.
- Great technological progress is observed in the field of devices used for Carotid Artery Stenting. Example a new 5Fr. MER carotid stent!!!
- The 30-day and 12 months clinical outcome of 100 patients treated with a nitinol open-cell carotid self-expandable MER stent shows very good results.
- Our study suggests that the MER stent is safe and effective device for endovascular treatment in both symptomatic and asymptomatic patients.


Thank you




John Paul II Hospital Krakow PL