

The Future Role of the Cardiologist in Extracardiac Intervention: **Carotid and Renal Arteries**

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Clinical and Interventional Angiology

University of Leipzig Heart Center

The Role of the Cardiologist



•Undefined

•Controversial

The Role of the Cardiologist

Undefined

The Expression

„Vascular Interventionalist“

does not exist.

The Role of the Cardiologist

- **Controversial**

- Who should decide when the pat. has to be treated ?
- Who should perform the intervention ?
- Who should take care of the pat. during the follow-up ?

The Role of the Cardiologist

- **Main Question**

Do we really need an extension of cardiologist's interventional activities into the peripheral field ?

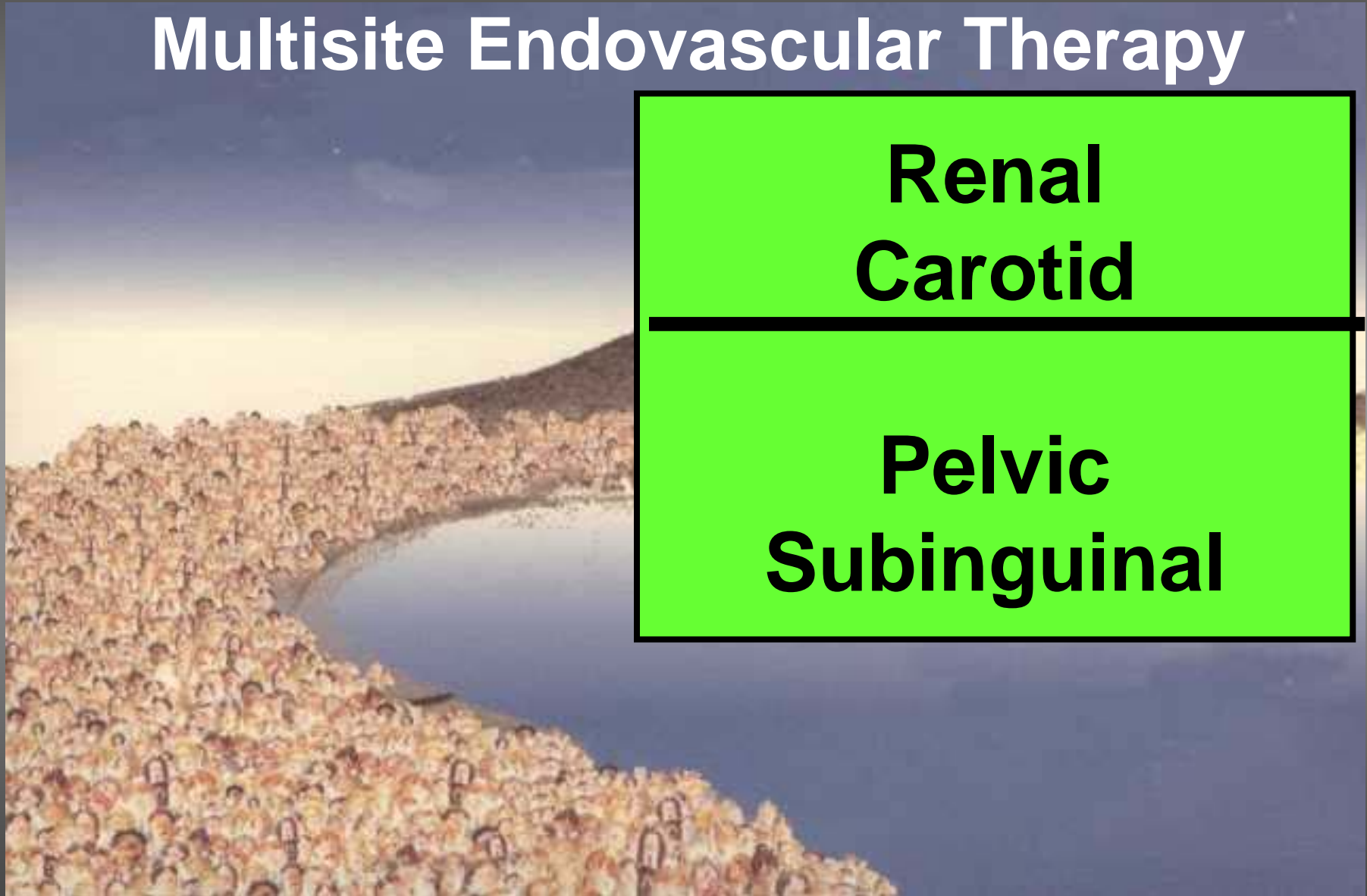
YES !

Interventional Cardiologists beyond PCI:

Multisite Endovascular Therapy

**Renal
Carotid**

**Pelvic
Subinguinal**



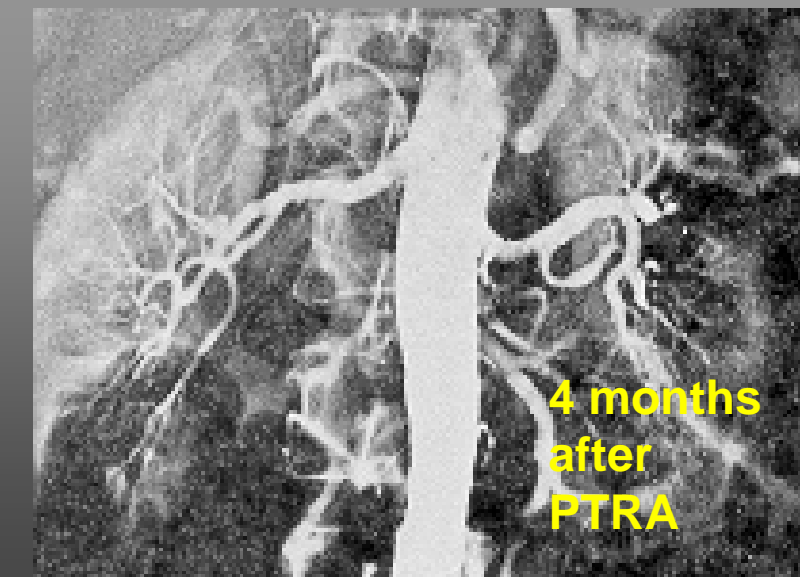
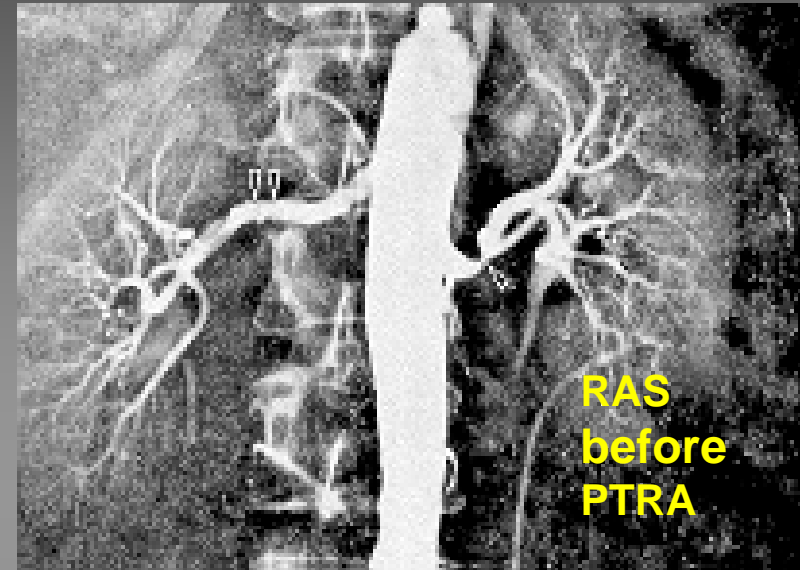
The first PTRA, 07.12. 1977

Treatment of Renovascular Hypertension by Transluminal Renal Artery Dilatation

FELIX MAHLER, M.D.; ALEX KRNETA, M.D.; and MICHAEL HAERTEL, M.D.

Inselspital; Bern, Switzerland

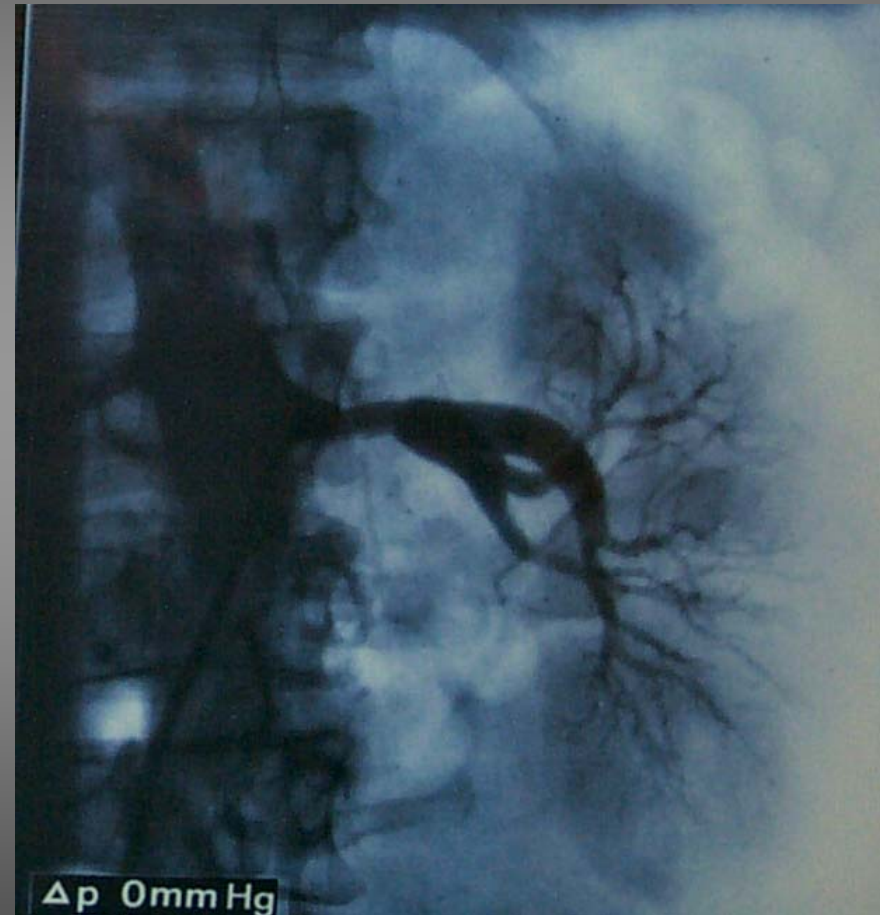
A 50-year-old woman was admitted to hospital in 1977 because of hypertension. In July her blood pressure was 240/120 mm Hg, and methyldopa therapy, 750 mg daily, was started. At examination her blood pressure was 140/100 mm Hg, and a high-pitched bruit was heard in the left upper abdominal quadrant. Arteriography revealed severe stenosis in the middle third of the left renal artery and a string-of-beads appearance of the distal right renal artery, suggesting intimal fibroplasia on the left and medial fibroplasia on the right side (4) (Figure 1a). Peripheral renin activity of 8.1 ng/ml · h was clearly higher than our normal standard (5), and the left-to-right ratio of the selective renal vein renin of 1.90 lateralized the excess renin to the left side. On 7 December transluminal dilatation of the left renal artery was done under general anesthesia at the patient's request (Figure 1b). After dilatation, anticoagulation therapy



Reprinted from ANNALS OF INTERNAL MEDICINE Vol. 90, No. 1 January 1979
Printed in U.S.A.

The Role of the Cardiologist

Renal Stenosis



Andreas Grünzig 1975



**Cosmetic or
Clinically Relevant ?**





**Atherosclerotic Renal Artery
Stenosis--
What are the Facts?**

POOR DATA ON

- **Incidence**
- **Prevalence**
- **Progression**

Incidence of Renal Stenosis in Patients with CHD

15 % of patients undergoing CABG
a significant RAS $> 50\%$ can be found
(Heart Center Leipzig)

19 % of patients (101/534) referred
for coronary angiography with
refractory hypertension ($> 140/90$ on
two drugs) had RAS $> 70\%$.

(Khosla et al., Cath.Card.Interv.2003,58:400-03)

Incidence of Renal Stenosis in Patients with CHD

- In a cohort of 500 consecutive patients showing a relevant coronary disease
 - **20 %** had an undetected renal stenosis
 - in half of these cases the stenosis was considered critical

8-10 %

**P.Rubino et al., Cardiovascular Clinic, Montevergine
Mercogliano (AV)**

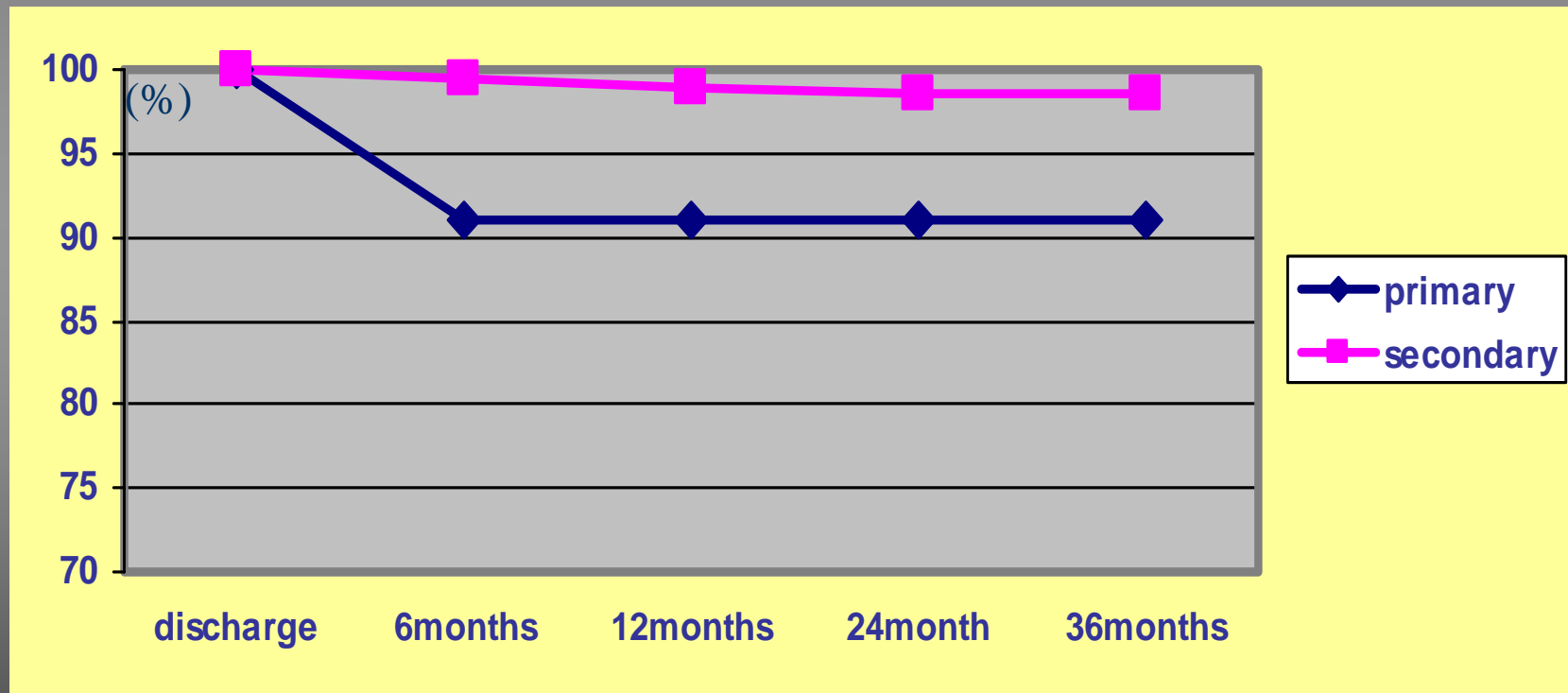
Stent-angioplasty of RAS: Results - randomized trial stent vs PTA

	PTRA	PTRA/Stent
Number of patients	42	43
Primary success rate	57%	88%
Primary patency rate	29%	75%
Restenosis rate	48%	14%

Van den Ven et al.: Lancet 1999; 282-286

Stent-angioplasty of RAS

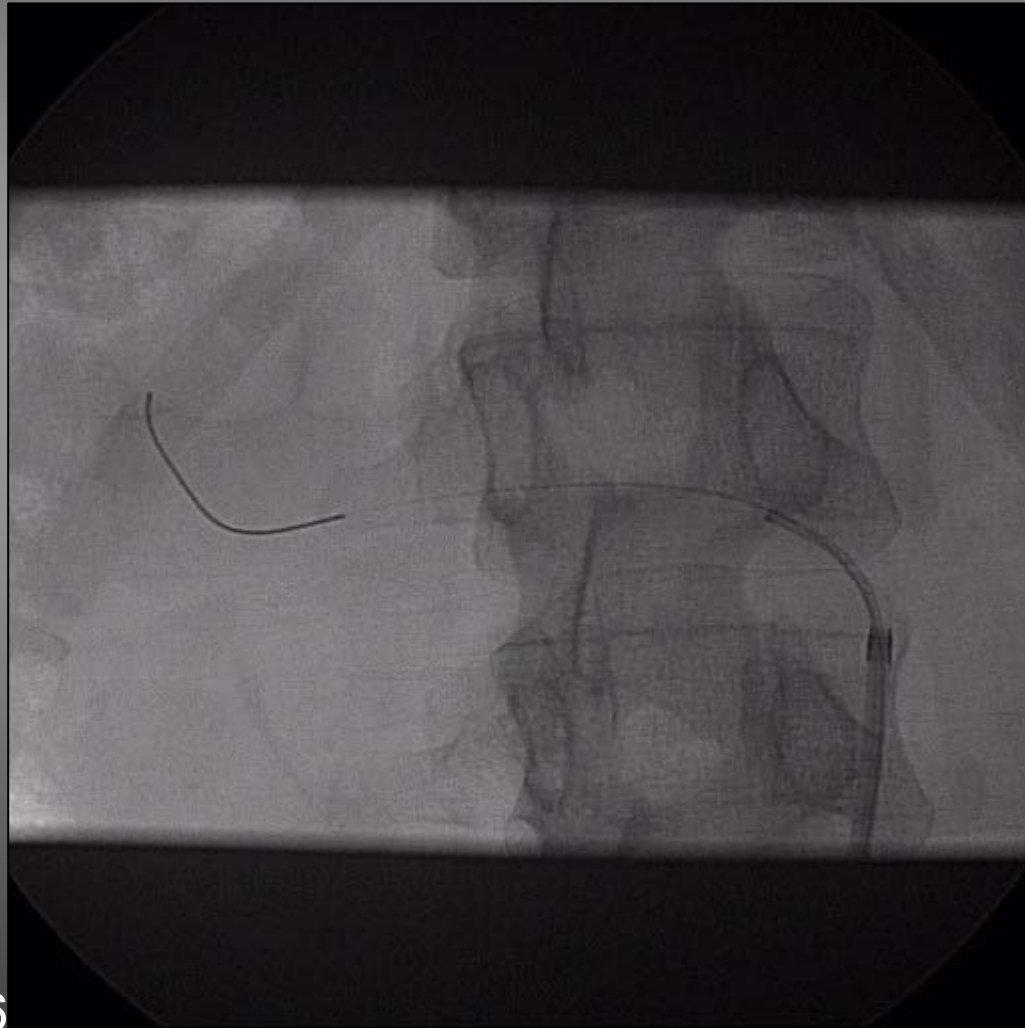
Kaplan-Meier-curve: n = 364



Th. Zeller, 2002

Renal artery stenting

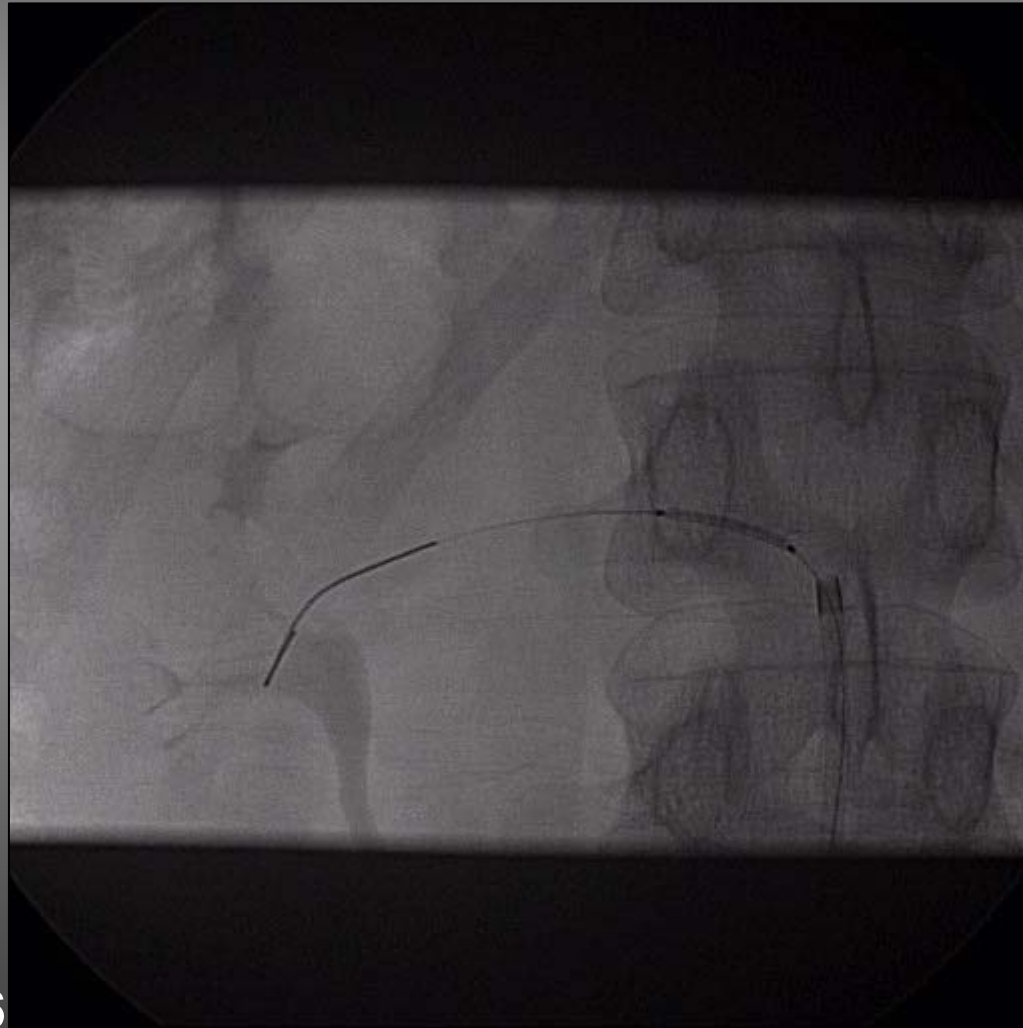
- Ostial stenosis of right renal artery



55726, P01-0446

Renal artery stenting

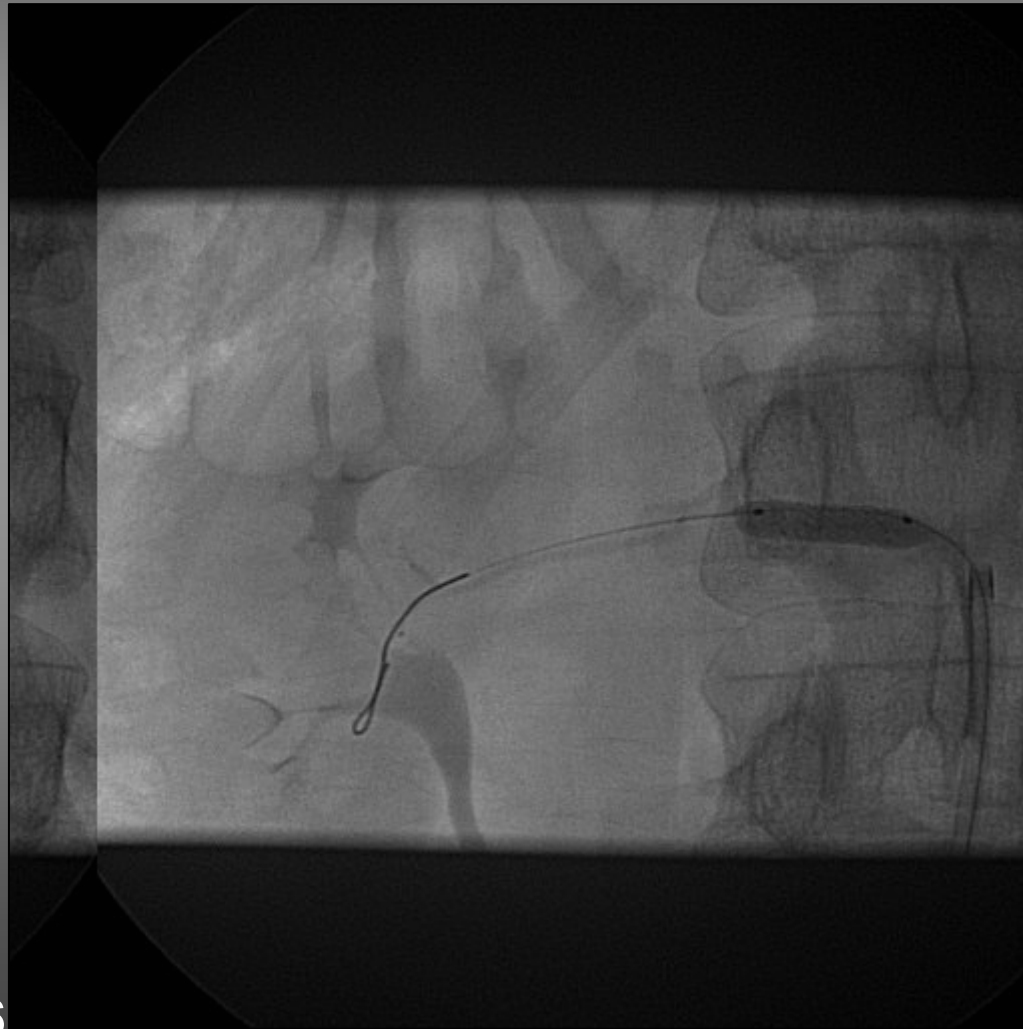
- Ostial stenosis of right renal artery



55726, P01-0446

Renal artery stenting

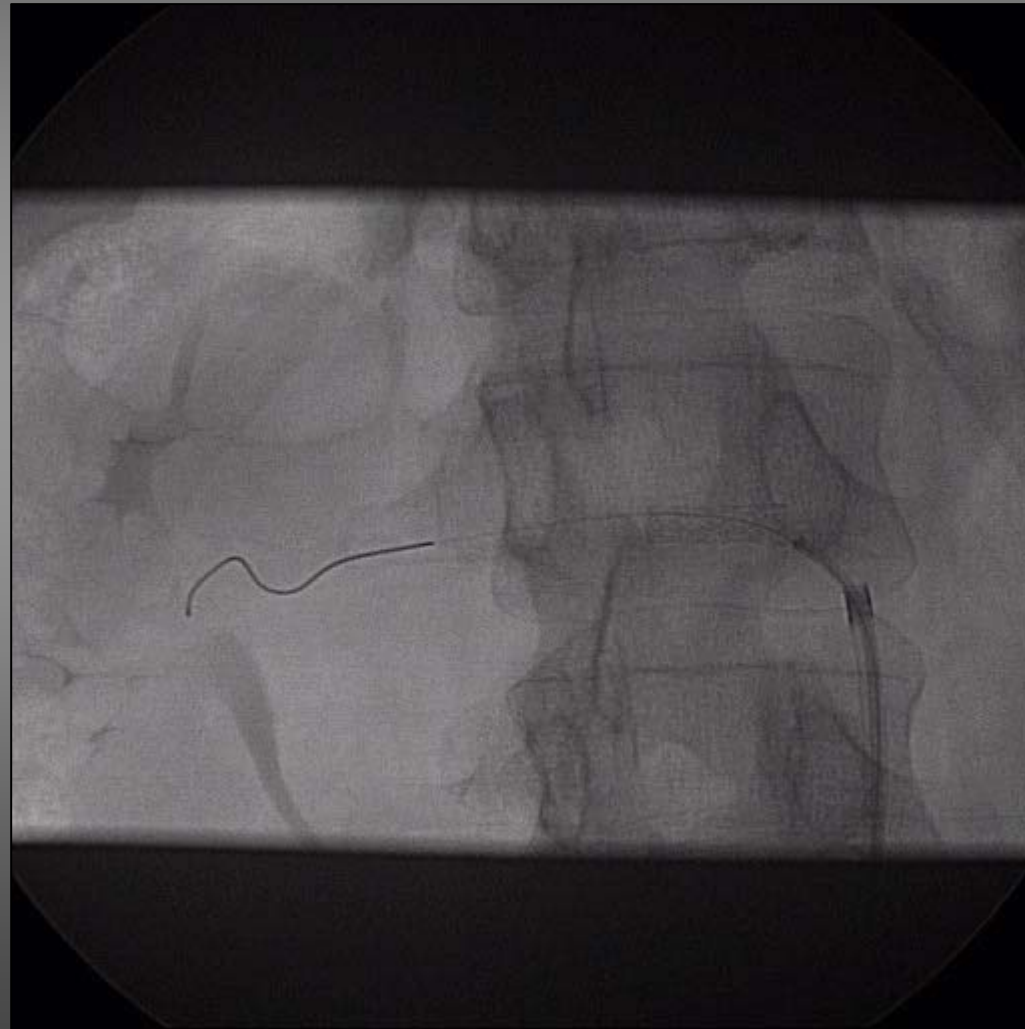
- Ostial stenosis of right renal artery



55726, P01-0446

Renal artery stenting

- Ostial stenosis of right renal artery



55726, P01-0446

What is the Problem Today??

- Primary Success Rate
~100%
- Restenosis Rate < 10%
- Complications rare

INDICATION ???

LET`S DO IT !!

Potential Indication for Renal Artery Revascularization

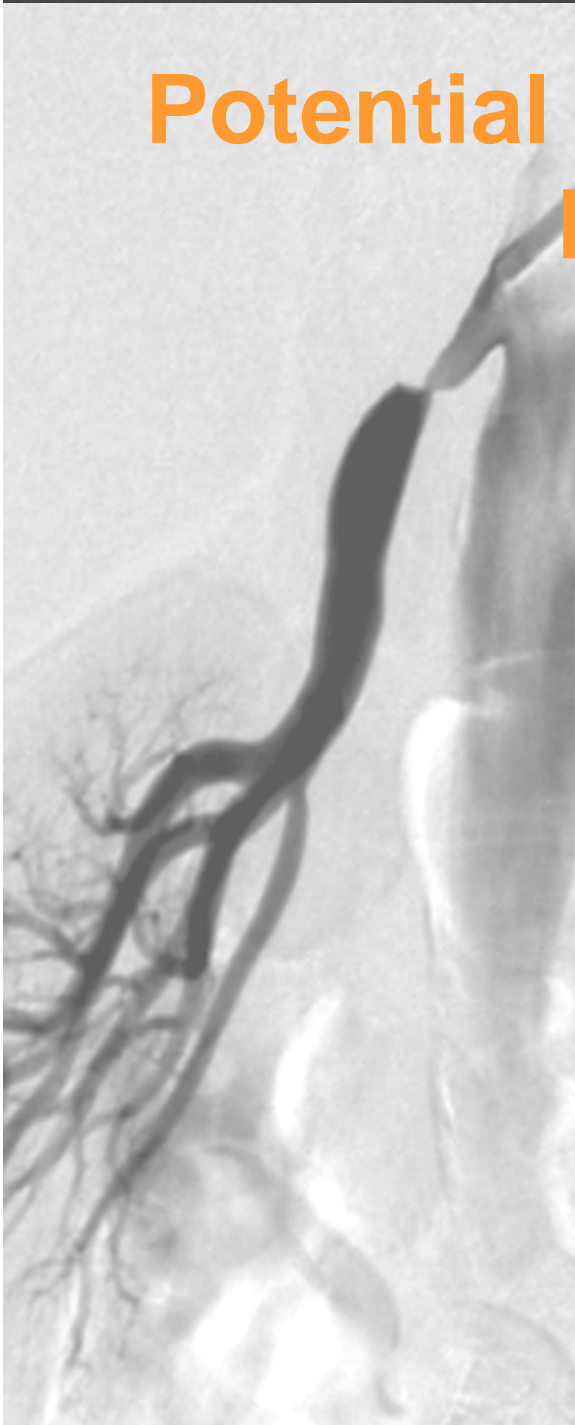
- Refractory/Resistant Hypertension
- Chronic Renal Insufficiency

- Recurrent Flash Pulmonary Edema

FEW DATA

- Need for Use of ACEI
- Unilateral Renal Artery Stenosis

NO DATA





Results of Renal Artery Angioplasty/ Stenting in Hypertensives

- Accumulate data from 8 authors
349 patients with mean follow up
11 months

Hypertension:

Unchanged

44%

Improved

56%

Cure

10%

Endovascular Treatment of RAS in Ischaemic Nephropathy

~~CURED~~

IMPROVED

UNCHANGED

DETERIORATED ??

Acute Deterioration in Renal Function after Angioplasty/ Stenting

- Incidence of 10-20% in patients with ischemic nephropathy
- Possible aetiologies:
 - iodinated contrast nephropathy
 - procedure related arterial trauma(e.g. dissection)
 - cholesterol atheroembolization

NO DATA

GREAT Study 6-Month QCA Data

	Bare	SES	P-value
	Mean \pm SD	Mean \pm SD	
	N=41 (79%)	N=45 (85%)	
Reference vessel diameter	5.58 \pm 0.81 mm	5.52 \pm 0.73	0.74
Diameter stenosis (% DS)	23.9 \pm 22.89 (0.0 - 66.0)	18.7 \pm 15.58 (0.7 - 66.0)	0.39
diameter (MLD)	(0.2 - 6.8)	(1.6 - 6.1)	
In-stent restenosis (> 50%)	6 (14.3%)	3 (6.7%)	0.30
Late Loss	0.92	0.62	0.21

**My conclusion :
NO differences, waste of time and money**

Renal Artery Angioplasty

- No reliable noninvasive test to assess the functional severity of the renal stenosis

- 1/3 improves, 1/3 unchanged, 1/3 further deterioration (BP + Renal function)

- No reliable noninvasive testing to predict which patient might benefit from renal artery

- Very little is known on pathophysiology of renal artery stenosis revascularisation.

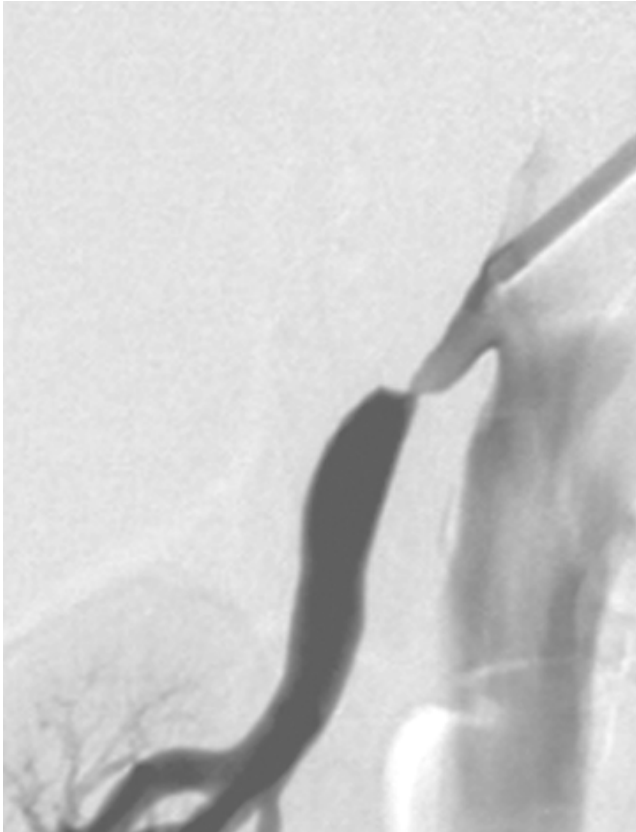
**99 000 procedures,
in 2003 (WW)**

- **US : 60 000**

- **EU : 30 000**

- **ROW: 10 000**

With permission of Bernard De Bruyne



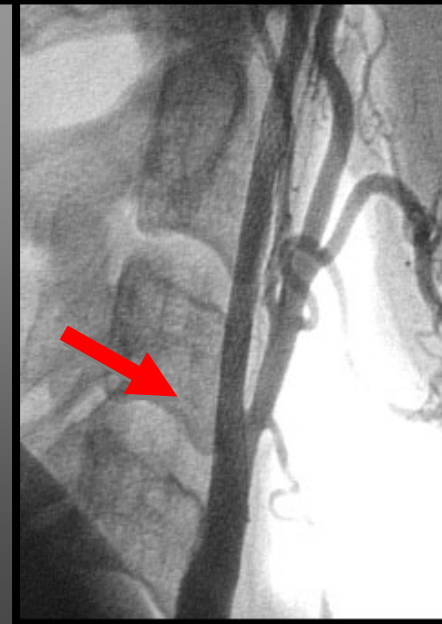
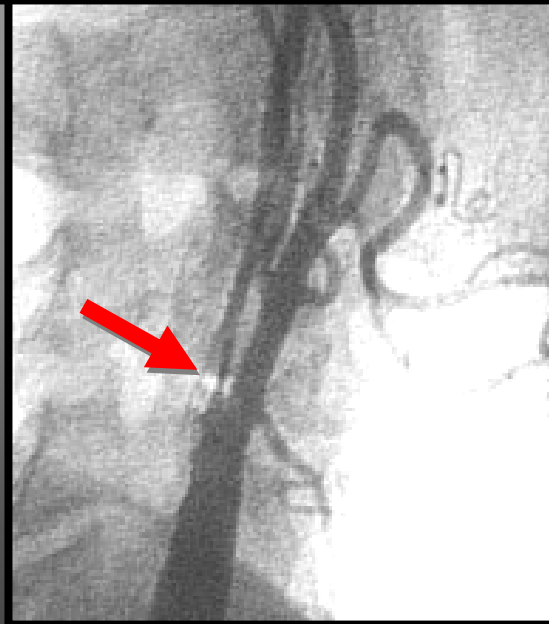
How can we prevent an excess
of

OCULO-STENOTIC REFLEXES IN RAS??

!!! WE NEED EVIDENCE BASED DATA !!!

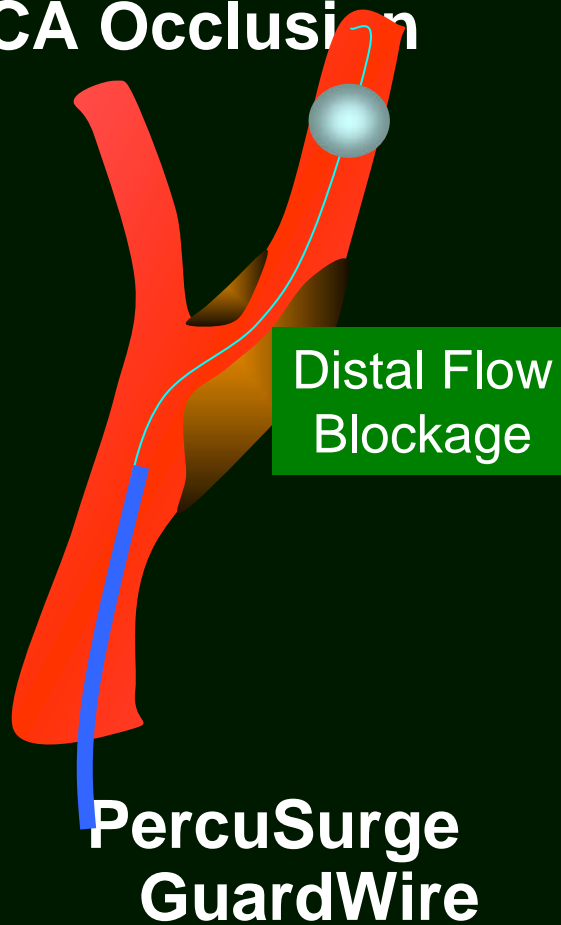
The Role of the Cardiologist in Carotid Artery Stenting (CAS)

**First FDA Approval
Sept. 10th 2004**

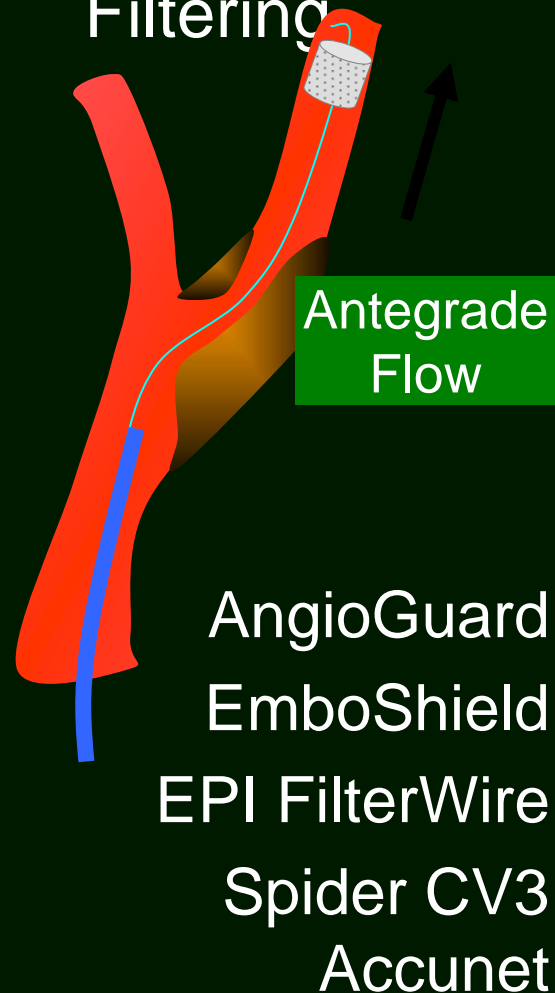


Current principles of neuroprotection

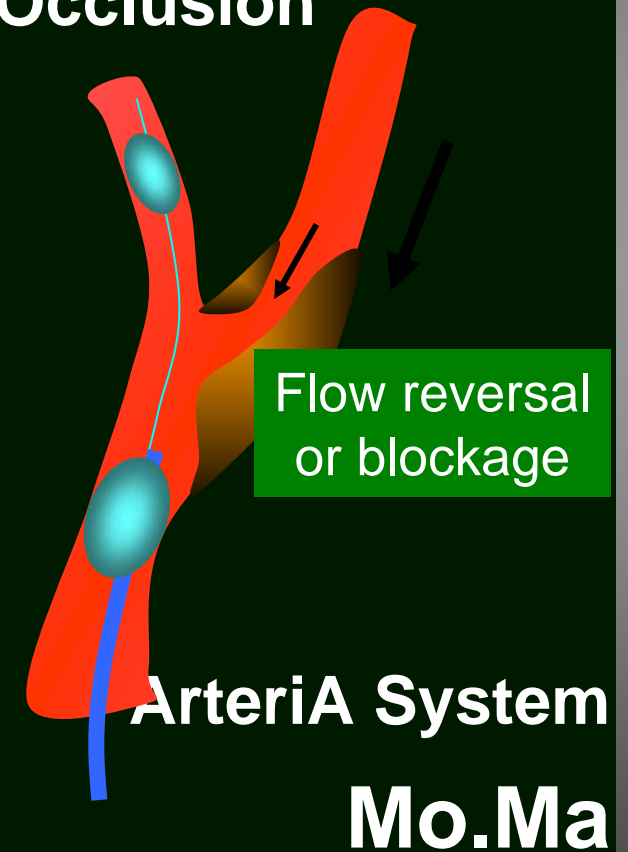
Flow Blockage by distal ICA Occlusion



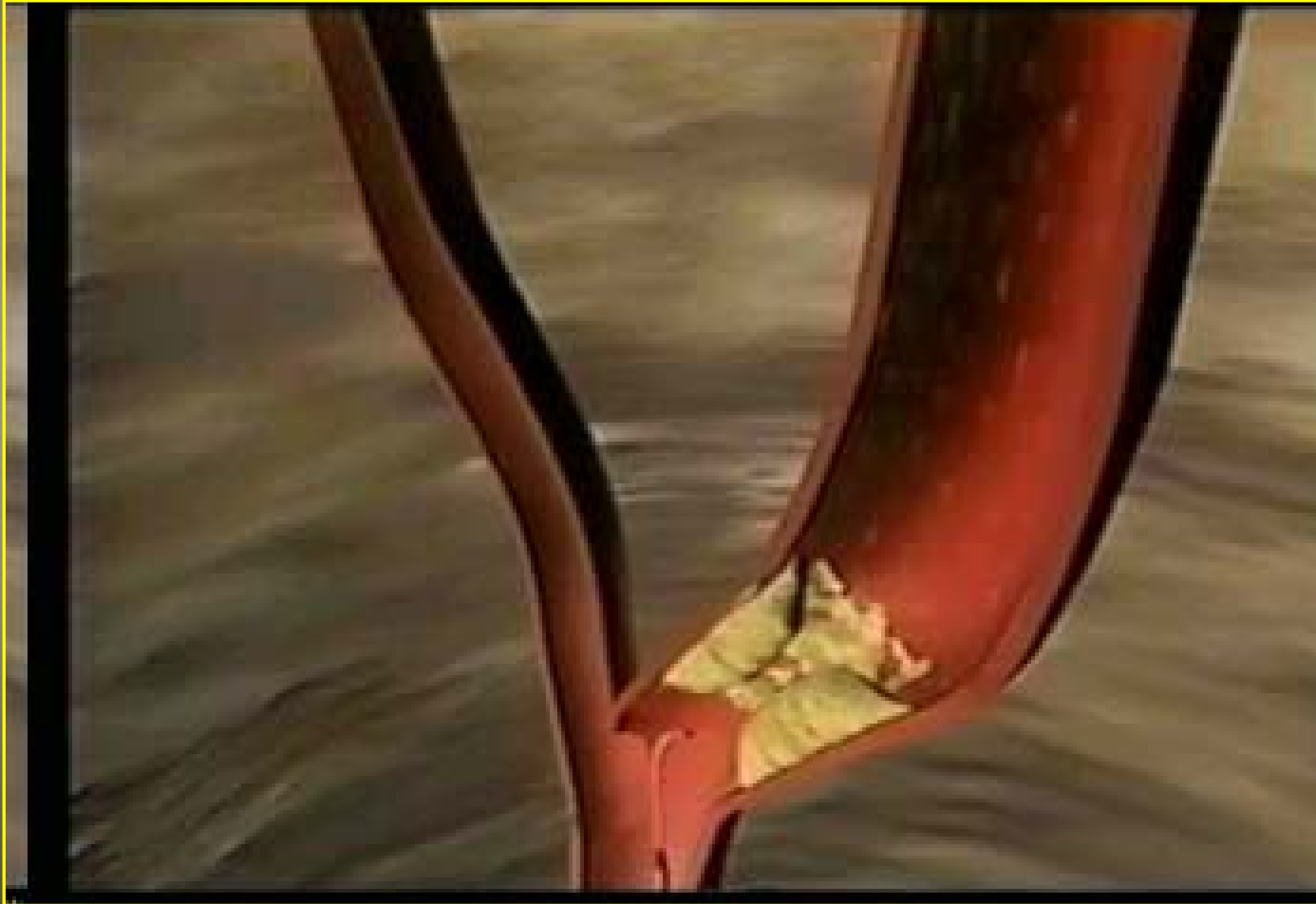
Distal ICA Filtering



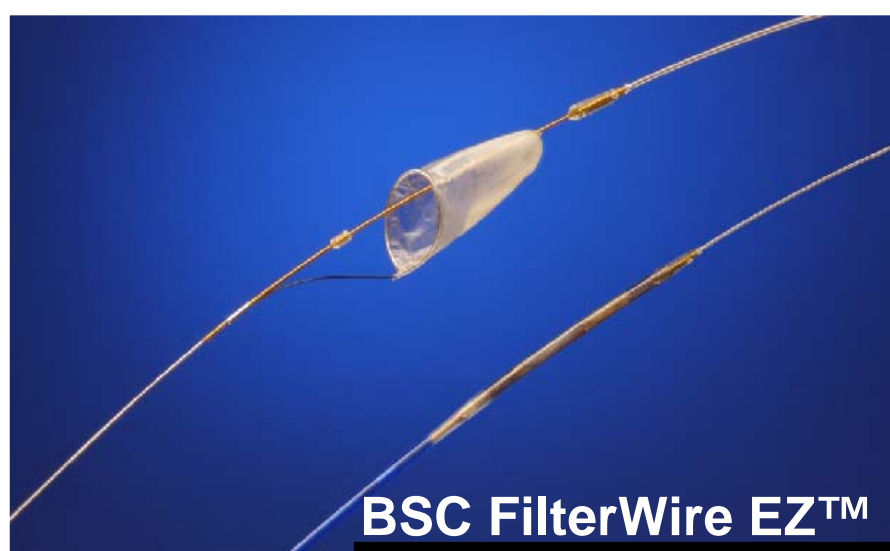
Endovascular Clamping by CCA and ECA Balloon Occlusion



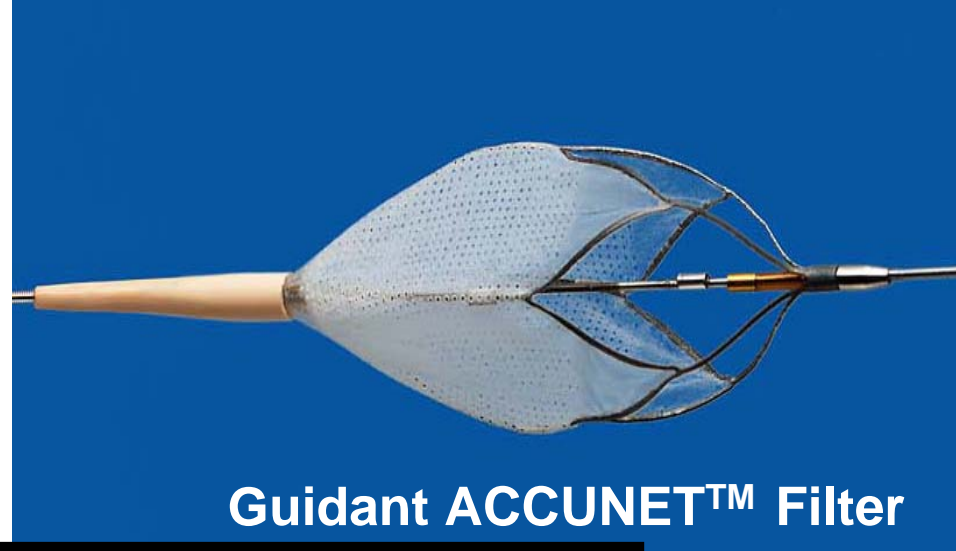
Filter Wire - Animation



Filter Embolic Protection Devices

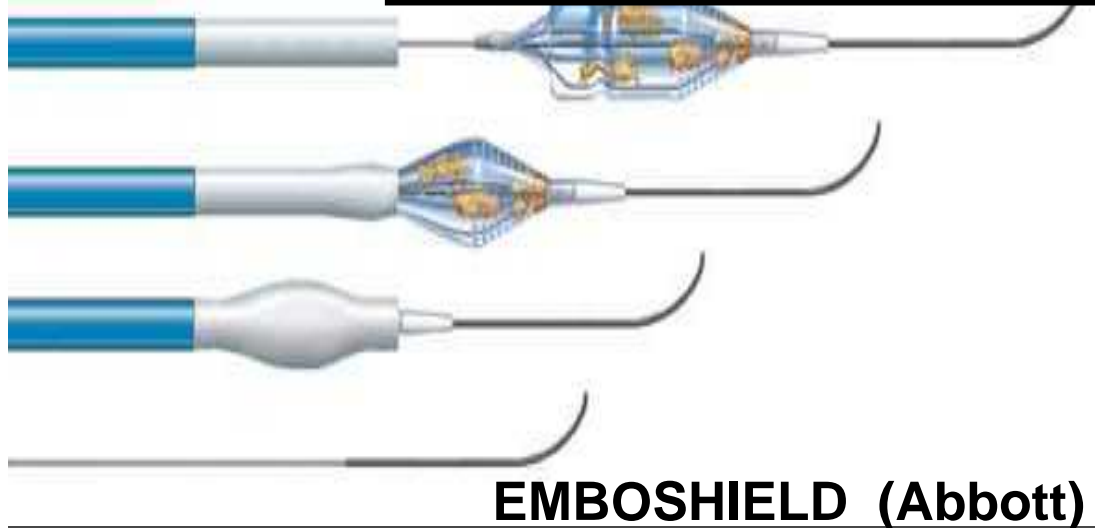


BSC FilterWire EZ™



Guidant ACCUNET™ Filter

NO COMPARATIVE DATA



EMBOSHIELD (Abbott)

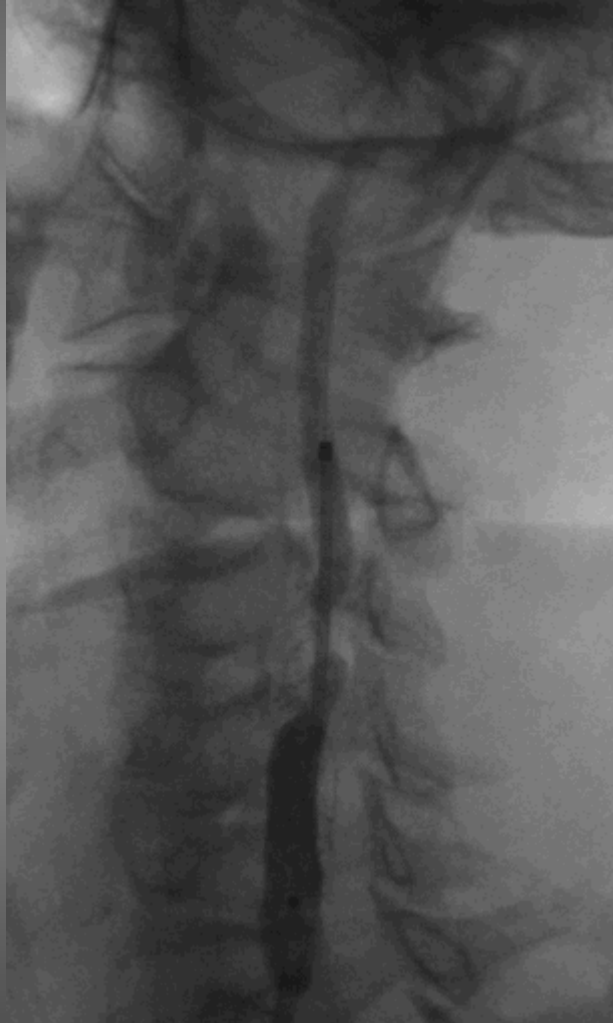


Angioguard Cordis

Restenosis post TEA

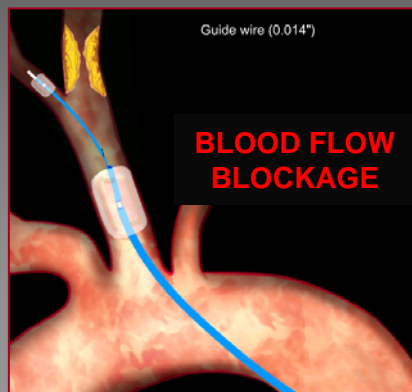


Restenosis post TEA

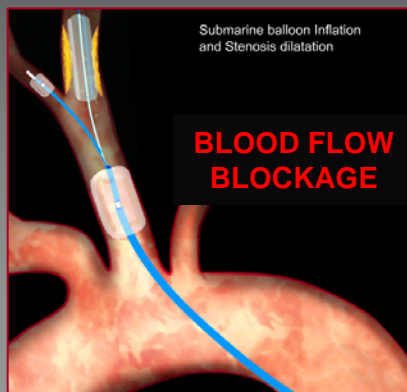


MOMA

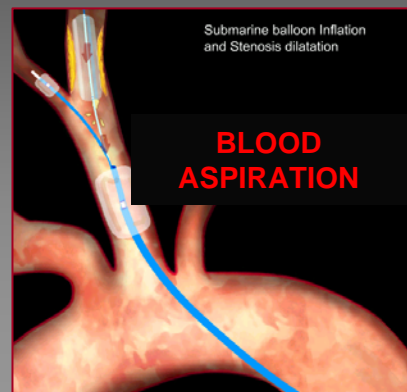
Operational Steps



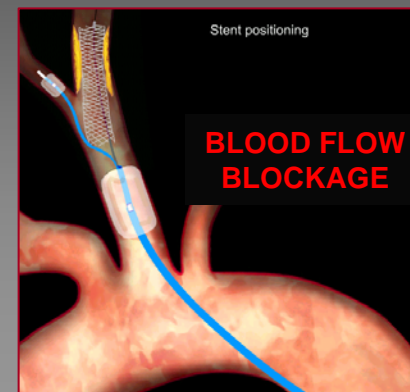
Device introduction, positioning, balloons inflation



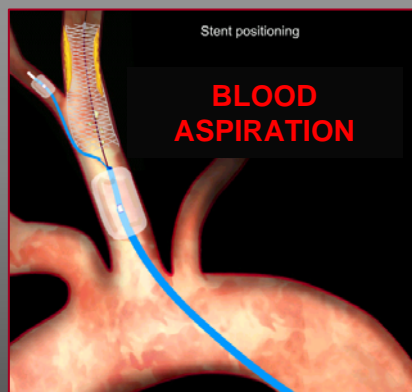
Lesion pre-dilatation



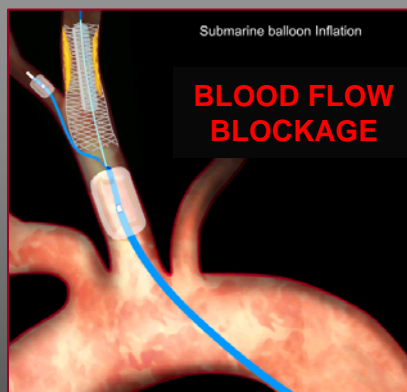
Debris removal by blood aspiration



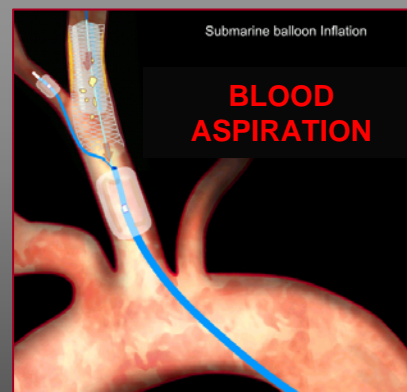
Stent deployment



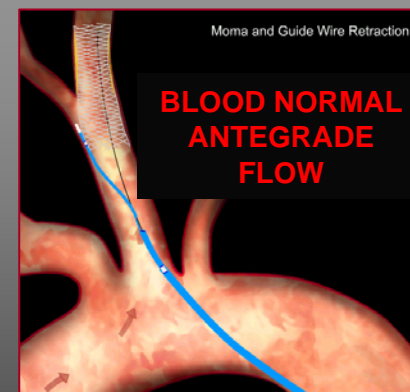
Debris removal by blood aspiration



Stent post-dilatation

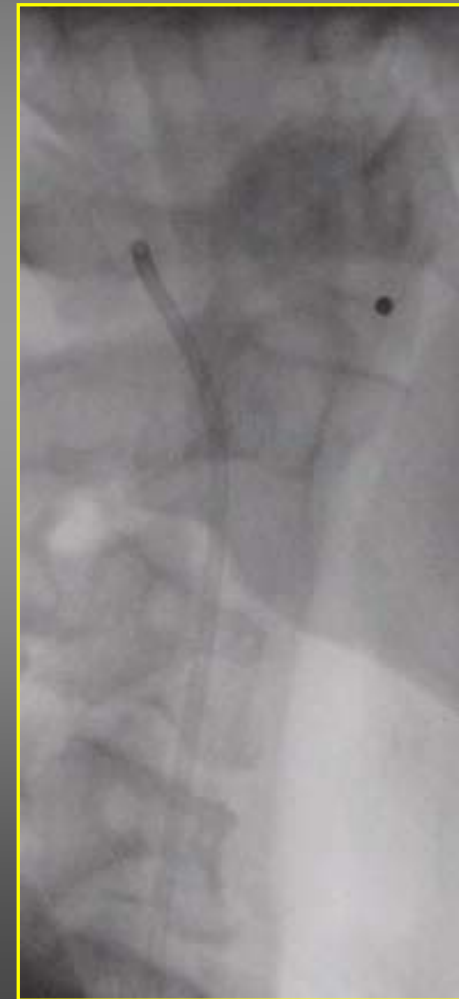


Debris removal by blood aspiration



Device removal

Step by Step Carotid Stenting using the Mo.Ma Protection Device I



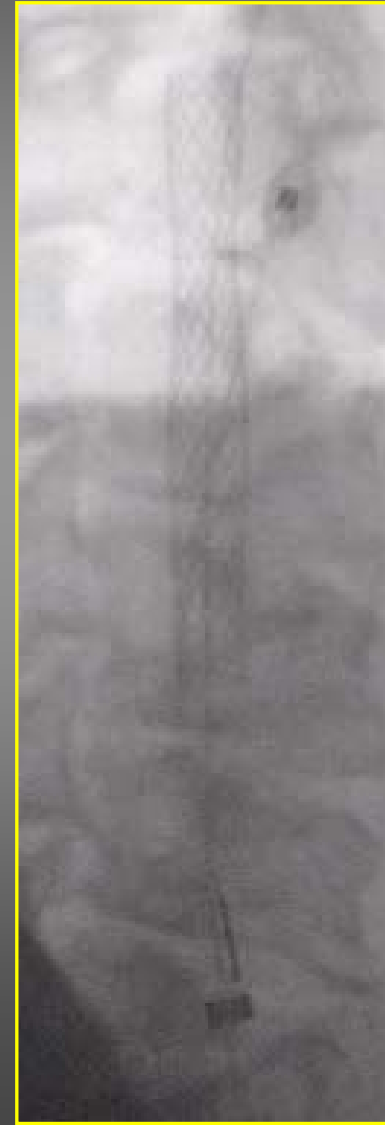
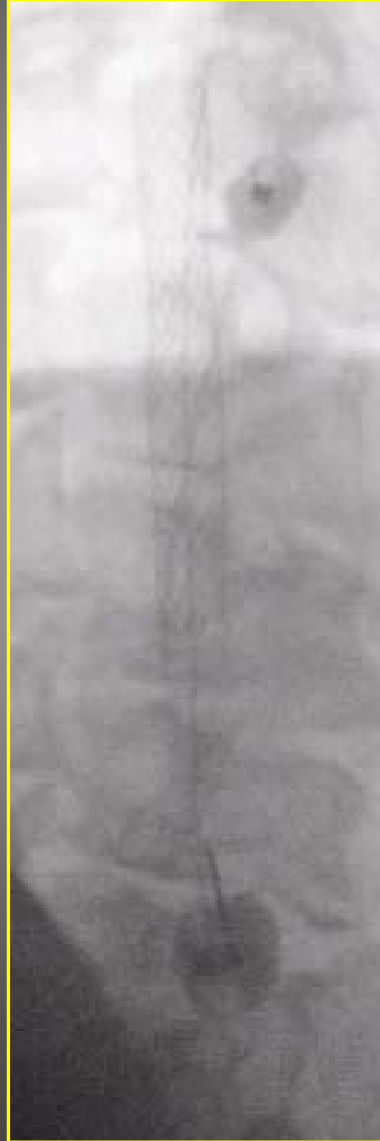
Step by Step Carotid Stenting using the Mo.Ma Protection Device II



Step by Step Carotid Stenting using the Mo.Ma Protection Device III



Step by Step Carotid Stenting using the Mo.Ma Protection Device IV



Step by Step Carotid Stenting using the Mo.Ma Protection Device V



Debris Following Carotid Stenting (MoMa-Device)





In-Hospital Outcome

Death	during procedure	0
	in-hospital	0
Major Stroke	during procedure	0
	in-hospital	0
Minor Stroke	during procedure	2 (1.25%)
	in-hospital	2 (1.25%) 1 (intracr. bleeding)
TIA	during procedure	5 (3.2%)
	in-hospital	3 (1.9%)

Primary Endpoint

(Death, Stroke at discharge)

2.5 %

SAPPHIRE STUDY

Randomized Patients (n : 307)

30-Day Event

DEATH;STROKE AMI	CAS N : 156	CEA N : 151
Global	5.8 %	12.6 %
Symptomatic	4.2 %	15.4 %
Asymptomatic	6.7 %	11.2 %

Personal Summary of CAS-Studies at EuroPCR 2003

- European Carotid High-Risk Study
- Mo.Ma. Registry,
- ARChER,
- SAPPHIRE,

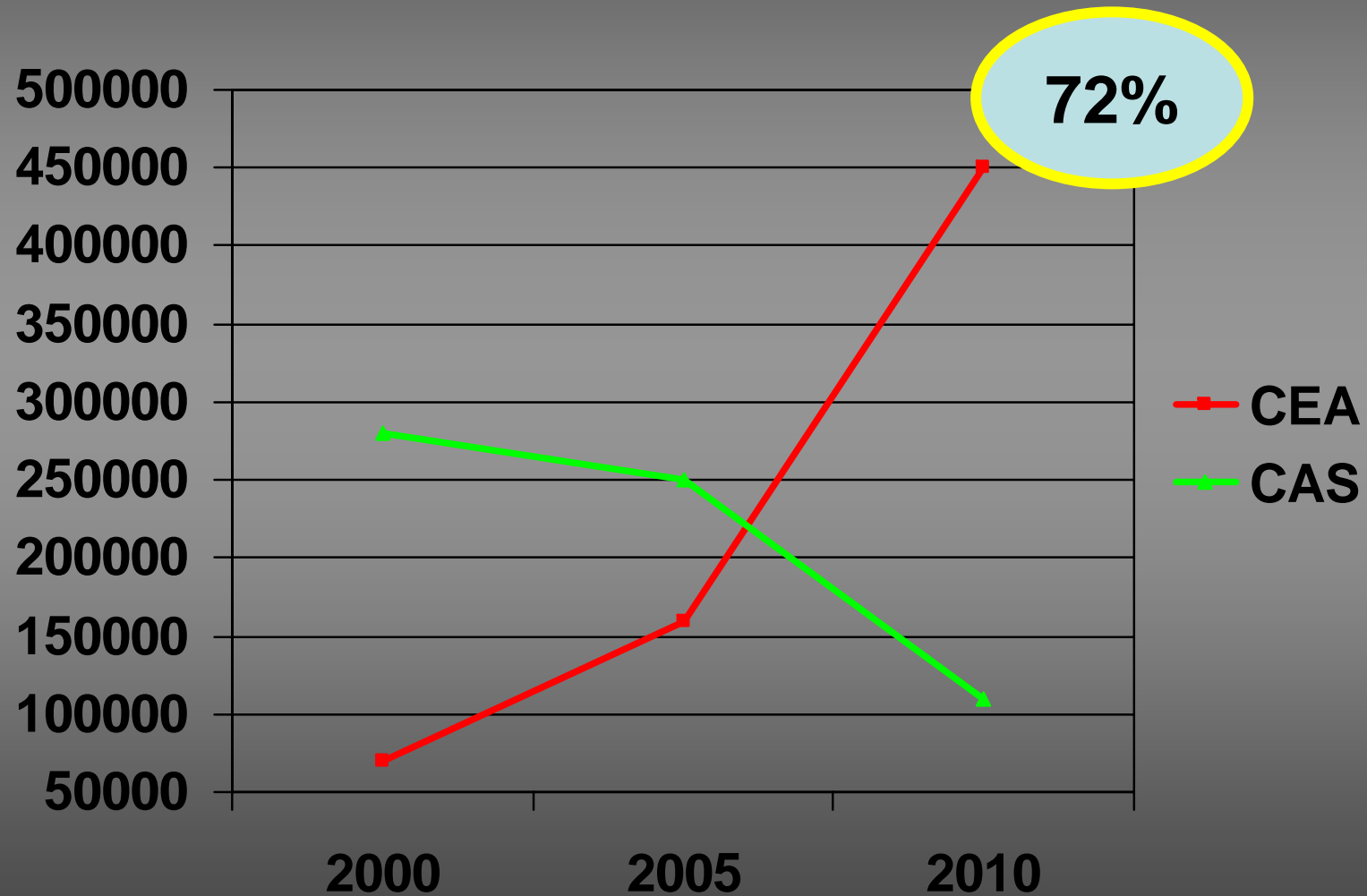
- Bea

- Sec

DEATH	< 0.2%
MAJOR STROKE	< 0.5%
MINOR STROKE	3.5 – 4.0 %

World Wide Carotid Procedures

Morgan Stanley, BSC, estimates



Carotid Artery Stenting (CAS)

Different sources
of data indicate

> 60%

of CAS are
performed by
cardiologists



Carotid Artery Stenting (CAS)

- Prescriptions for a Disaster
 - Just do it
 - Learn by doing
 - Treatment of angiographic pictures



„SENSE OR NON-SENSE“ of PROTECTION DEVICES

- The new nightmare of renal stenting

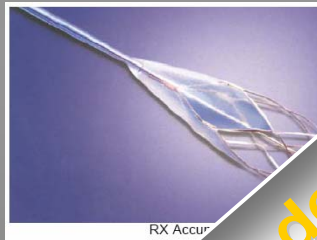
“Nonsense” of filter-wires



Angioguard (Cordis)



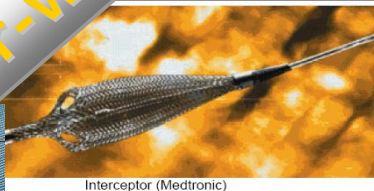
FilterWire EZ (Bostr)



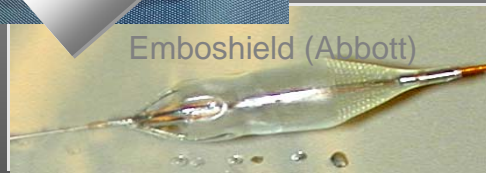
RX Accur



Rubicon

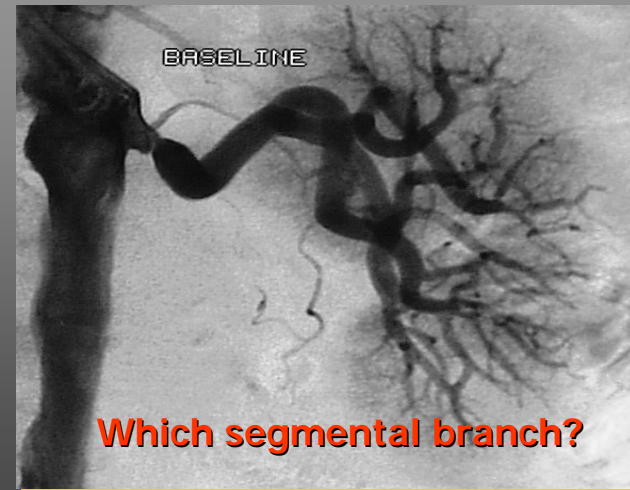
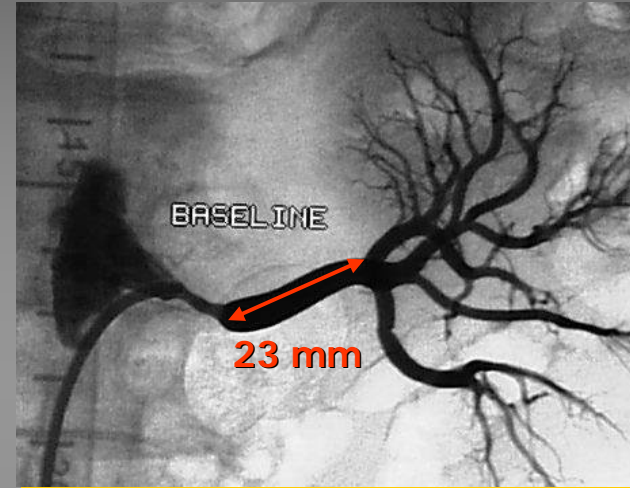


Interceptor (Medtronic)

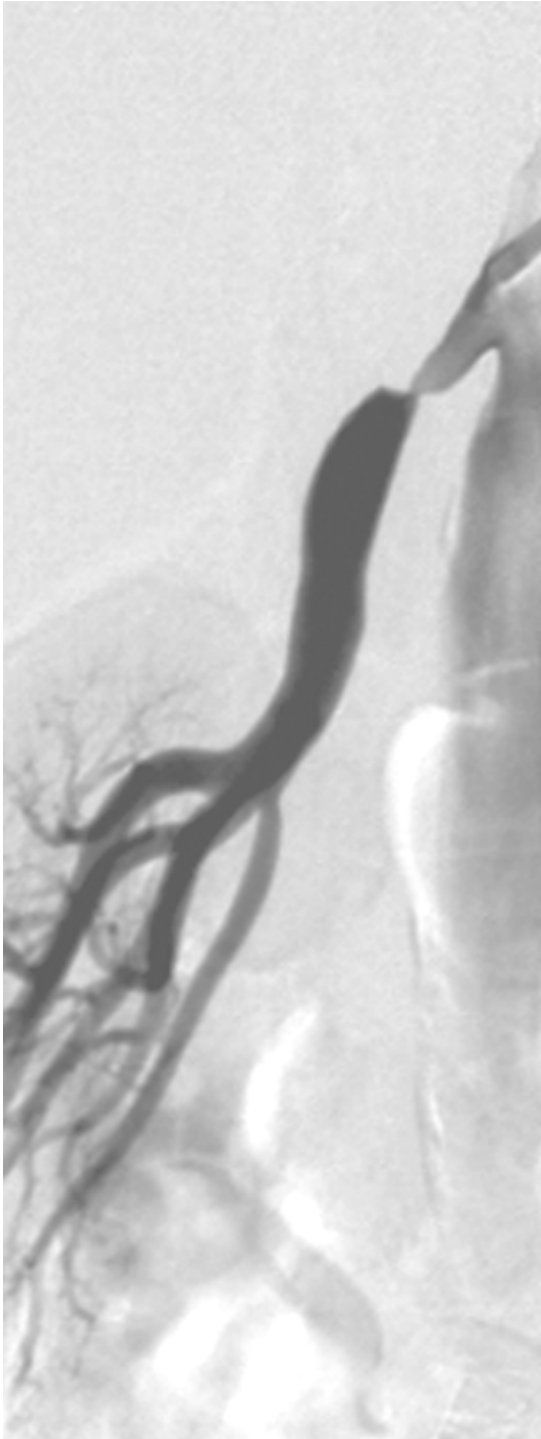


Emboshield (Abbott)

Non-dedicated renal filter-wires



Courtesy of A.Cremonesi



Open Questions

- Wich amount of embolic material may provoke a relevant deterioration of the renal function in pts. with creatinine
 - <1.1 mg/dl
 - 1.1-1.8 mg/dl
 - > 2.0 mg/dl

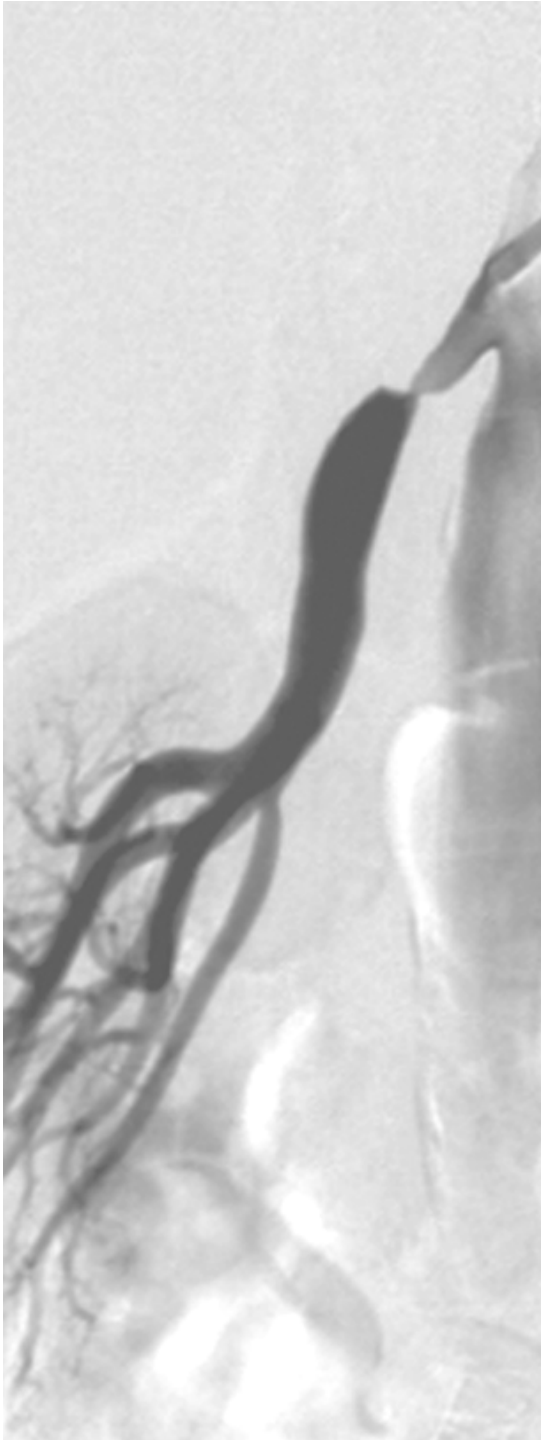
NO DATA

Open Questions

- Within which time frame should we expect a deterioration of the renal function after embolization
 - Hours ?
 - Days ?
 - Months ?

NO ANSWER

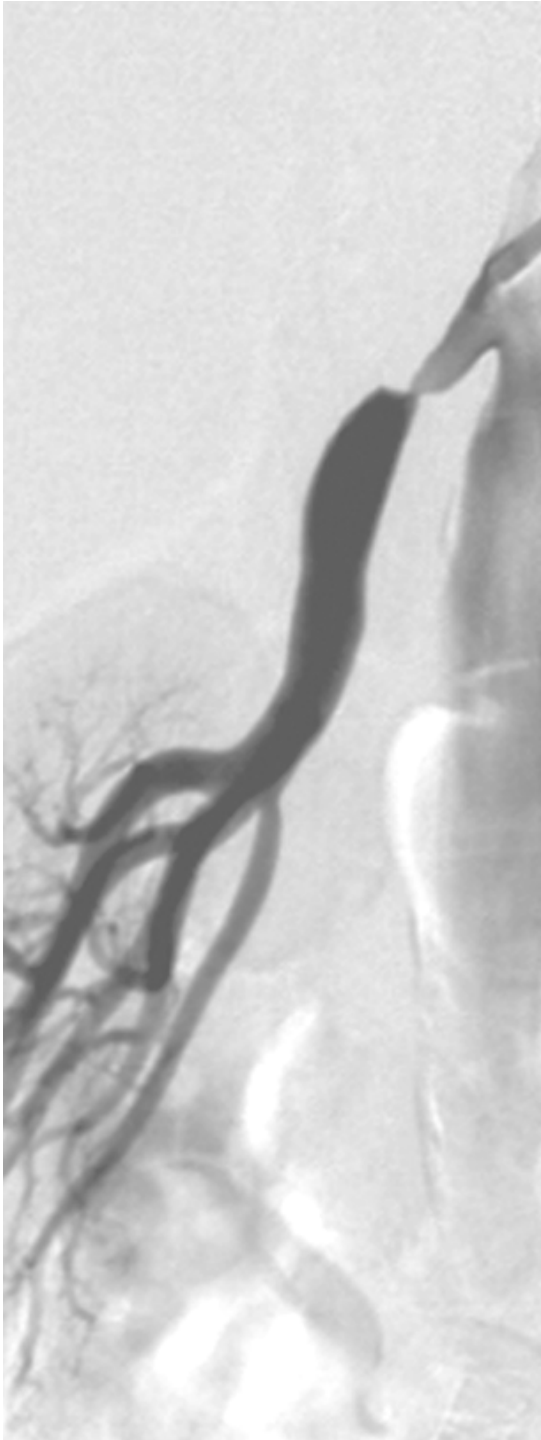
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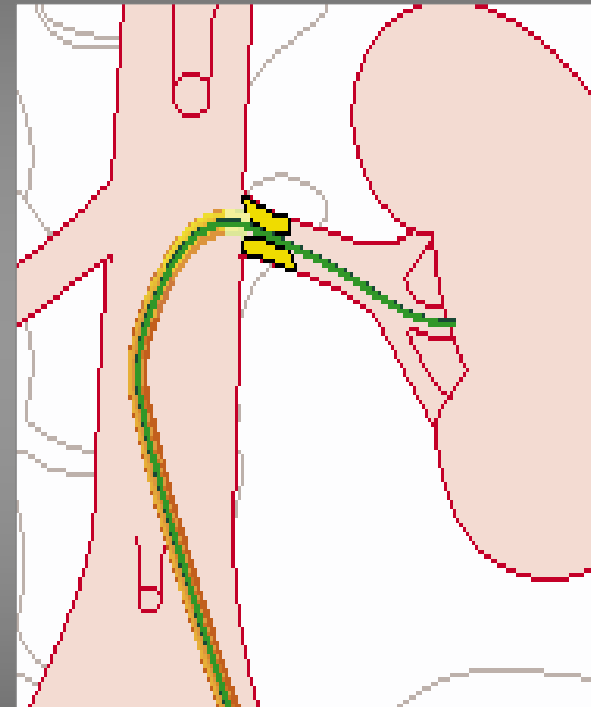
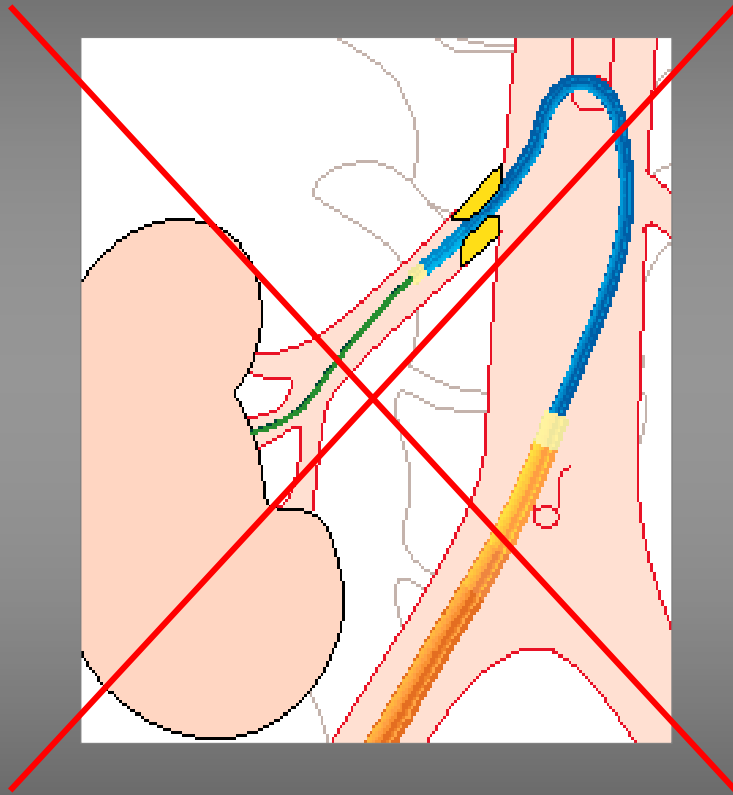
Open Questions

- We do not have any data indicating that using the new low profile systems and direct stenting-technique the amount of collected debris remains constant ?????

NO DATA



Technical Improvement : The Coronary Technique



ENDOVASCULAR CLAMPING

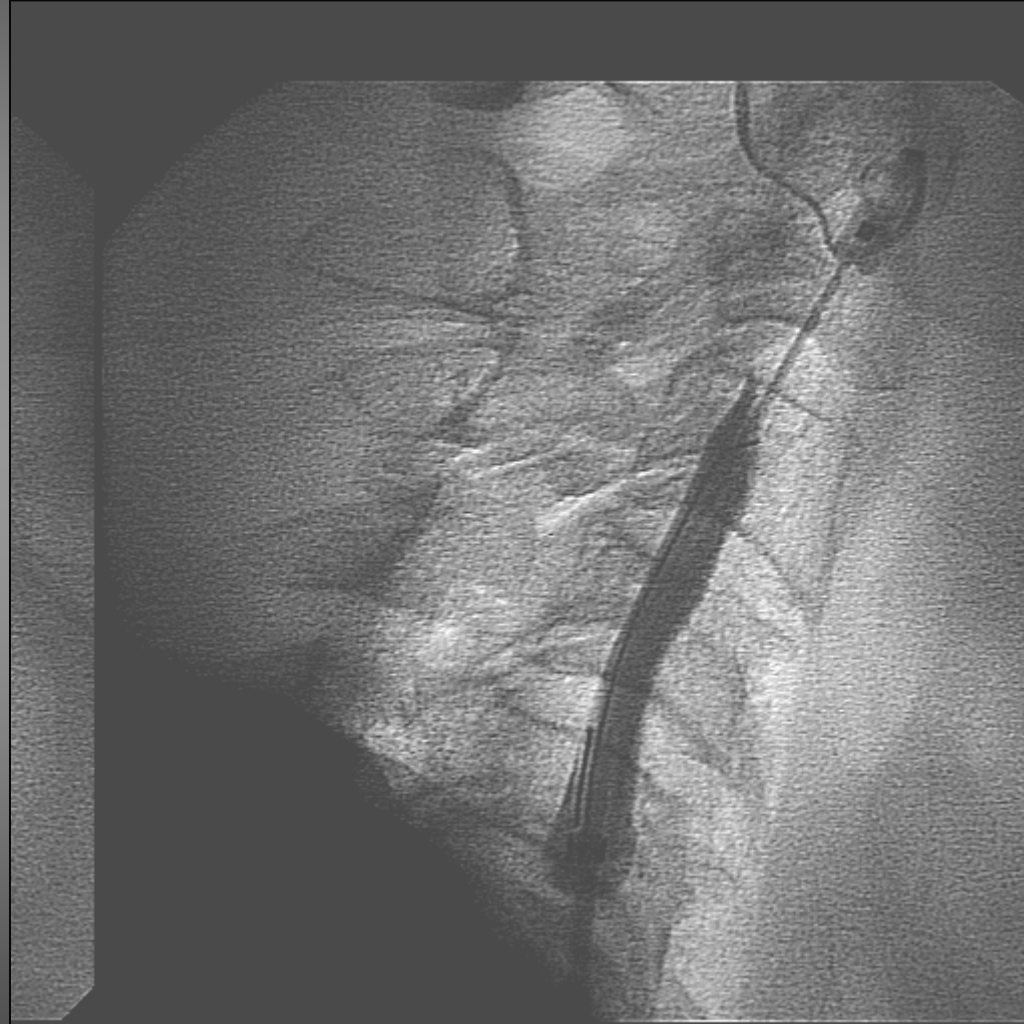
Case Example



V.P. 010518_10

ENDOVASCULAR CLAMPING

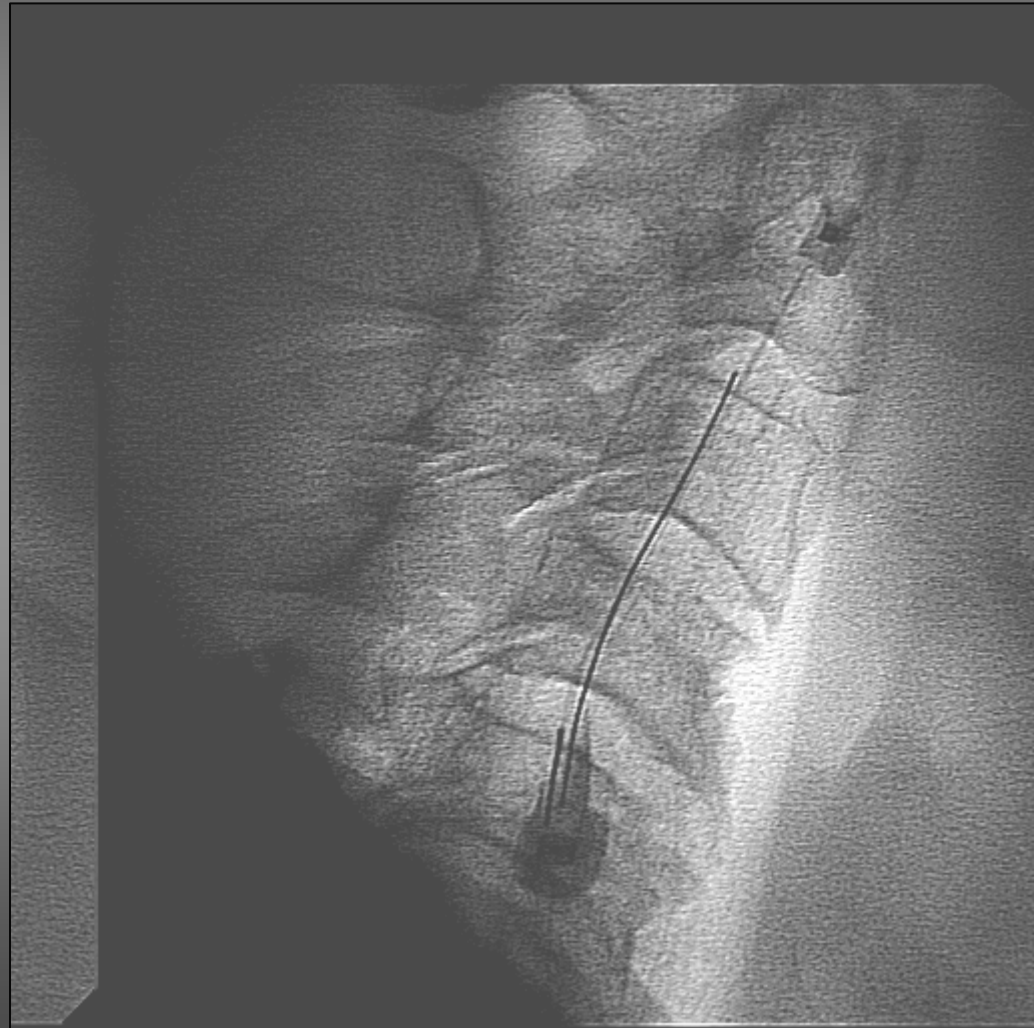
Case Example



V.P. 010518_7

ENDOVASCULAR CLAMPING

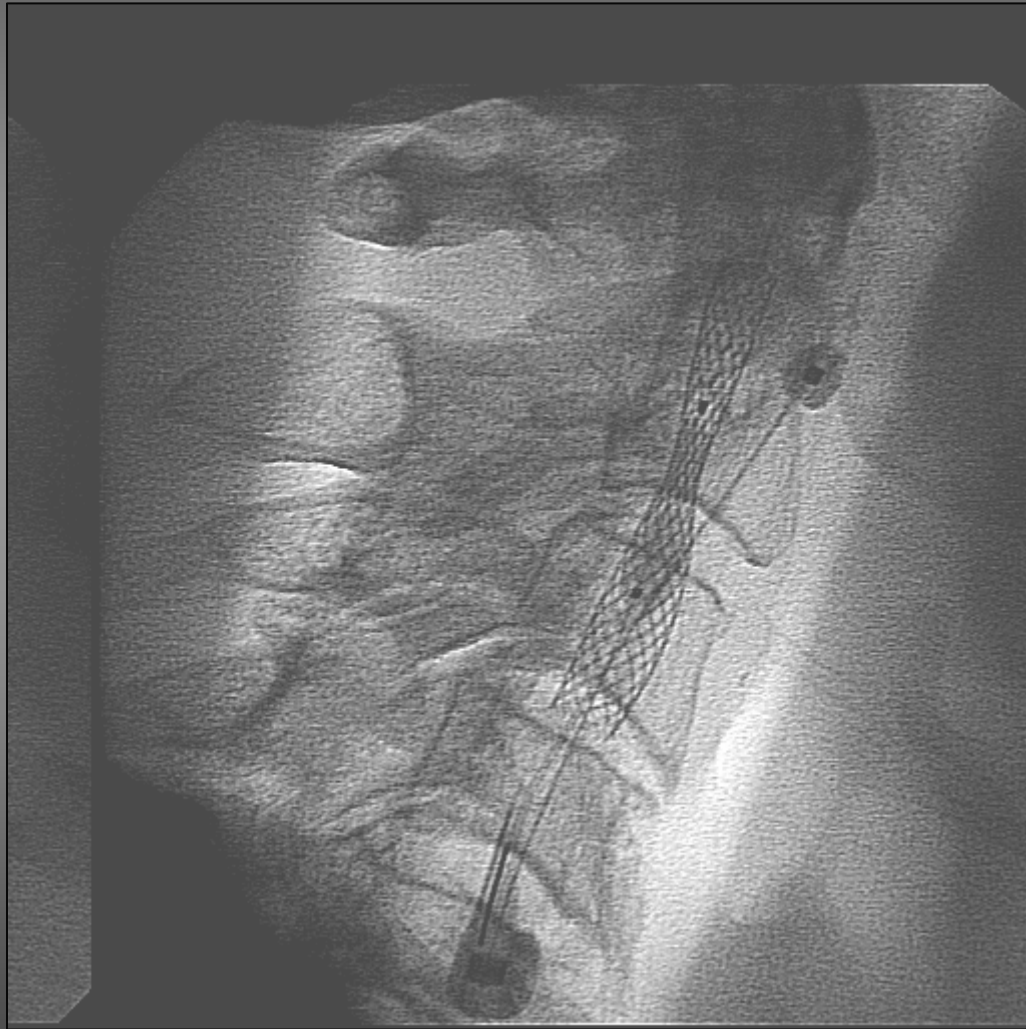
Case Example



V.P. 010518_7.1

ENDOVASCULAR CLAMPING

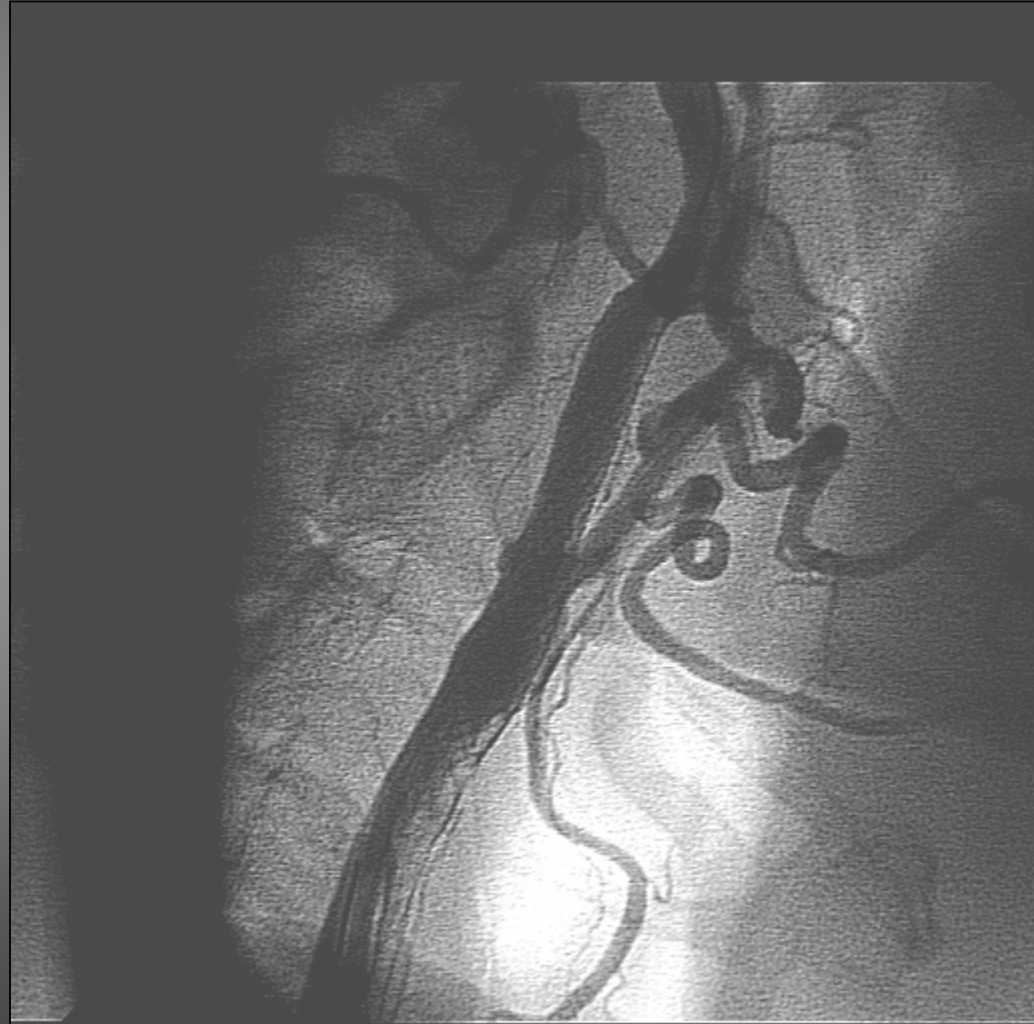
Case Example



V.P. 010518_8

ENDOVASCULAR CLAMPING

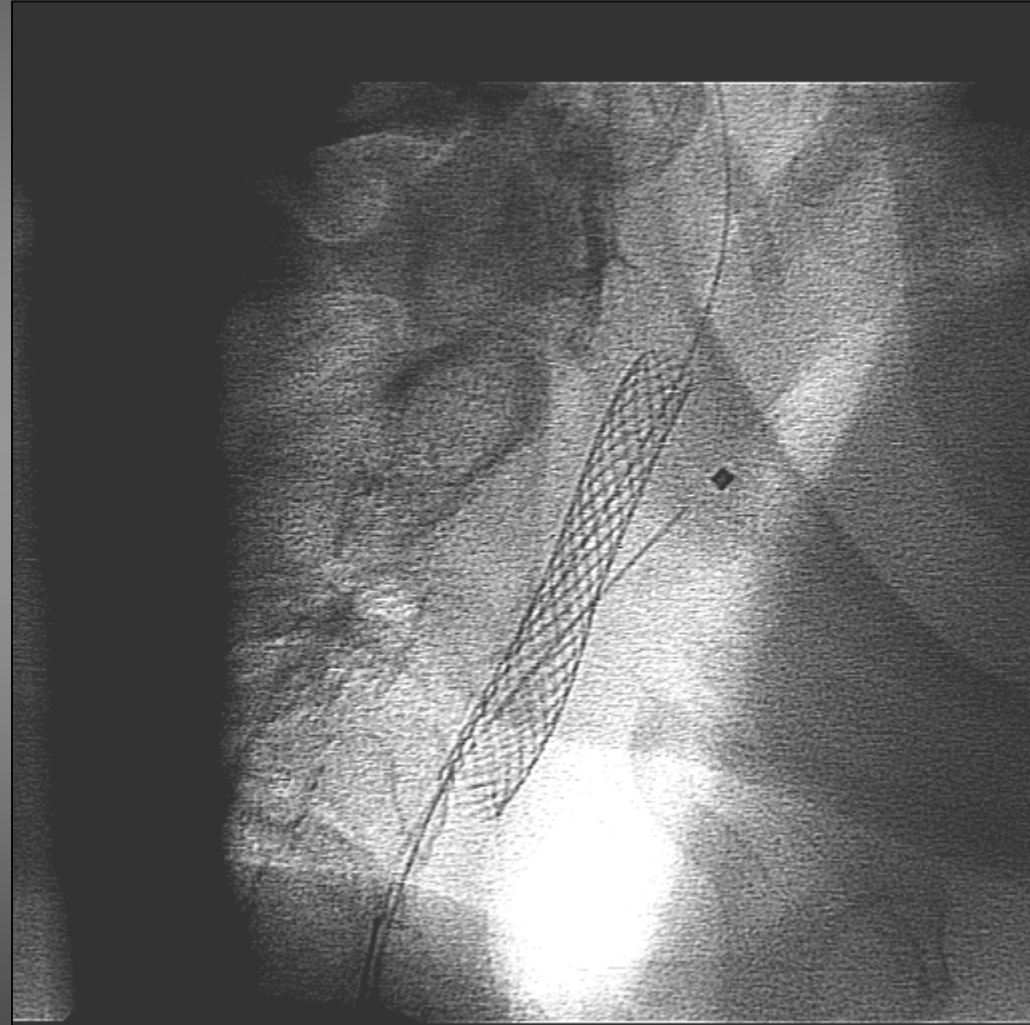
Case Example



V.P. 010518_9

ENDOVASCULAR CLAMPING

Case Example



V.P. 010518_10

Die perkutane transluminale Rekanalisation
chronischer Arterienverschlüsse
mit einer neuen Dilatationstechnik

Andreas Grüntzig



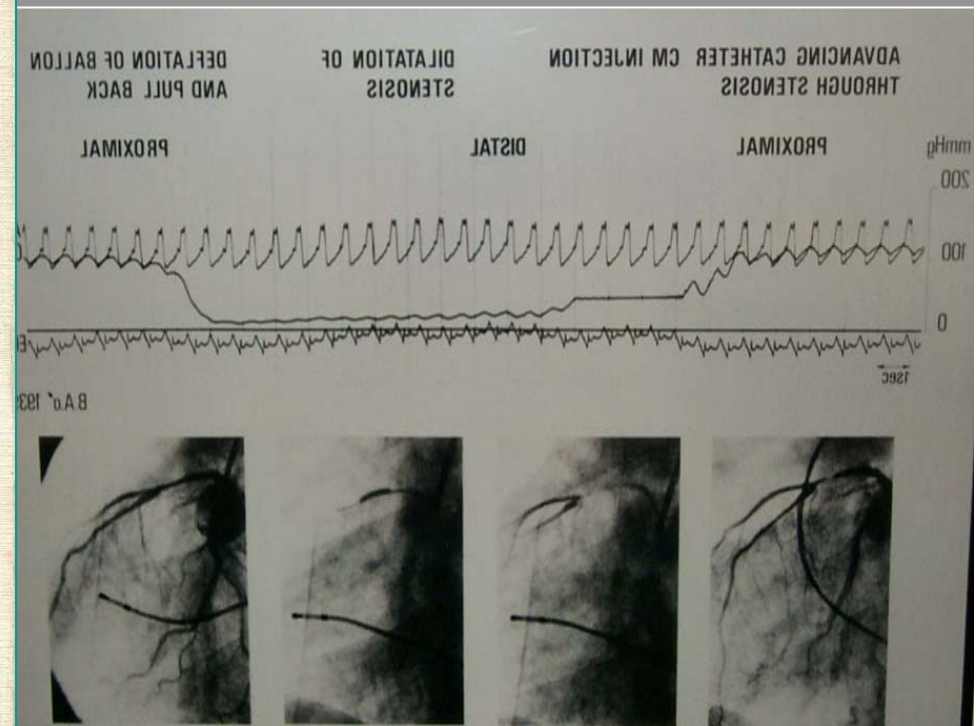
1977



Verlag Gerhard Witzstrock · Baden-Baden · Köln · New York

First Peripheral PTA in Zürich 1971

At this time in 1977 he had already performed nearly 200 peripheral interventions before he abandoned the field starting the coronary adventure.



Die perkutane transluminale Rekanalisation
chronischer Arterienverschlüsse
mit einer neuen Dilatationstechnik

Andreas Grüntzig



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Preface:

„I am convinced that percutaneous transluminal angioplasty represents a real expansion of our therapeutic possibilities.....The advantage of this easy, safe, and cost reducing technique is evident....we have to evidentiate its value on the basis of credible scientific data, analyzing indication, acute and long term results .“

Walter Siegenthaler, Zürich 1977