ST elevation myocardial infarction (STEMI) - aspiration (thrombectomy) & direct stenting

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Reperfusion of myocardium is only achieved in about 50%-60% of pts

How to Optimize Primary PCI ?

Improvement of myocardial reperfusion

- Gp IIb/IIIa – proven efficacy (class IIaA)
- mechanical protection - thrombectomy, distal and proximal protection (class IIb C)

↑ST resolution, ↑ MPG

no MACEs improvement, no ↑EF ?

Reduction of TVR during long term follow up

- DES ?

Thrombectomy - *ESC PCI, march'2005*

Distal embolic protection	Saphenous Vein Grafts	I A
Distal and proximal protection devices (suction, thrombectomy)	ACS with high thrombus load in native coronary arteries	II b C

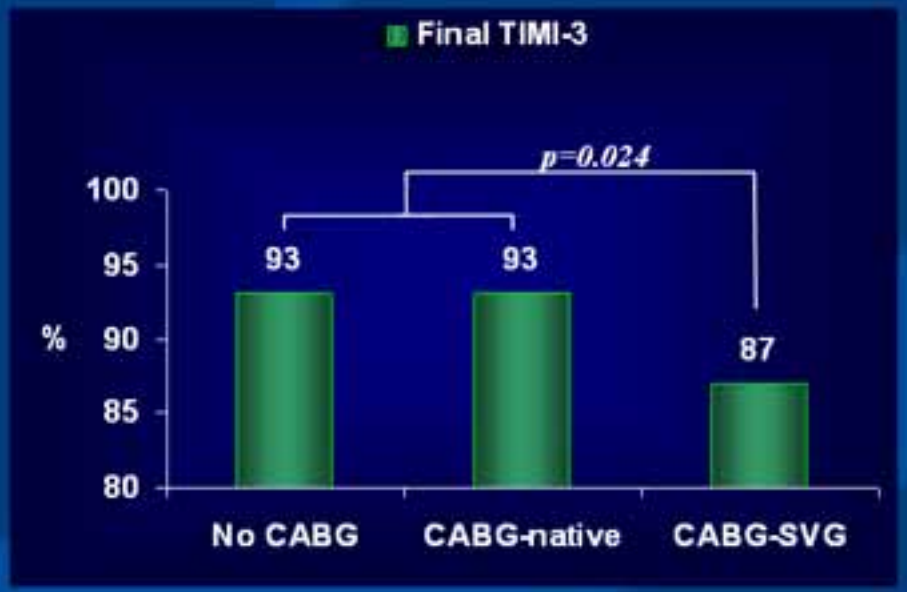
Primary PCI for STEMI in patients after CABG

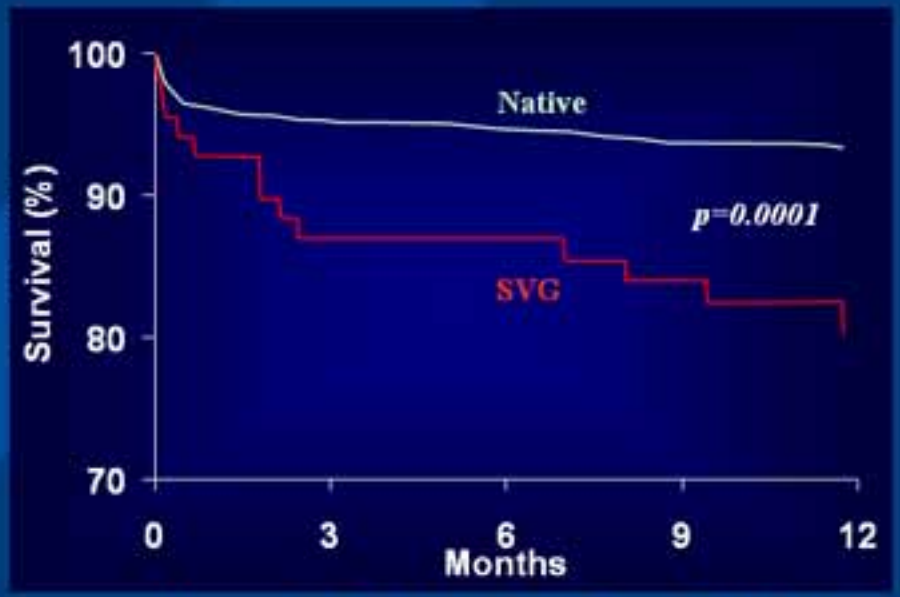
One-Year Survival in Patients With Acute Myocardial Infarction and a Saphenous Vein Graft Culprit Treated With Primary Angioplasty

Thanh T. Nguyen, DO, William W. O'Neill, MD, Cindy L. Grines, MD, Gregg W. Stone, MD, Bruce R. Brodie, MD, David A. Cox, MD, Lorelei L. Grines, PhD, Judith A. Boura, MS, and Simon R. Dixon, MBChB

(PAMI-2, Stent-PAMI Pilot, Stent-PAMI, PAMI No SOS, The Local Med. Pilot Trial)

No CABG, n = 3072 **CABG-native, n = 76** **CABG-SVG, n = 93**





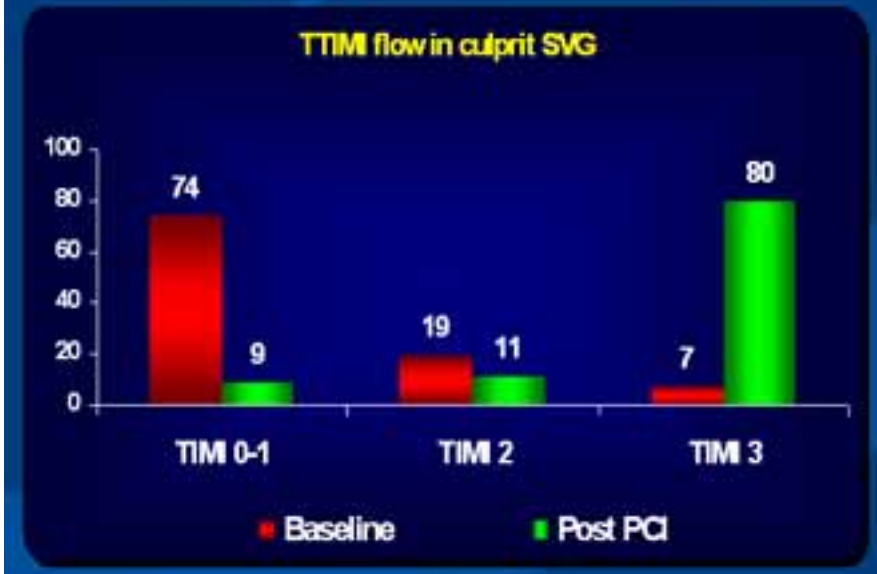
Nguyen T., et al. AJC 2003;91:1250-54

Primary PCI for STEMI in patients after CABG

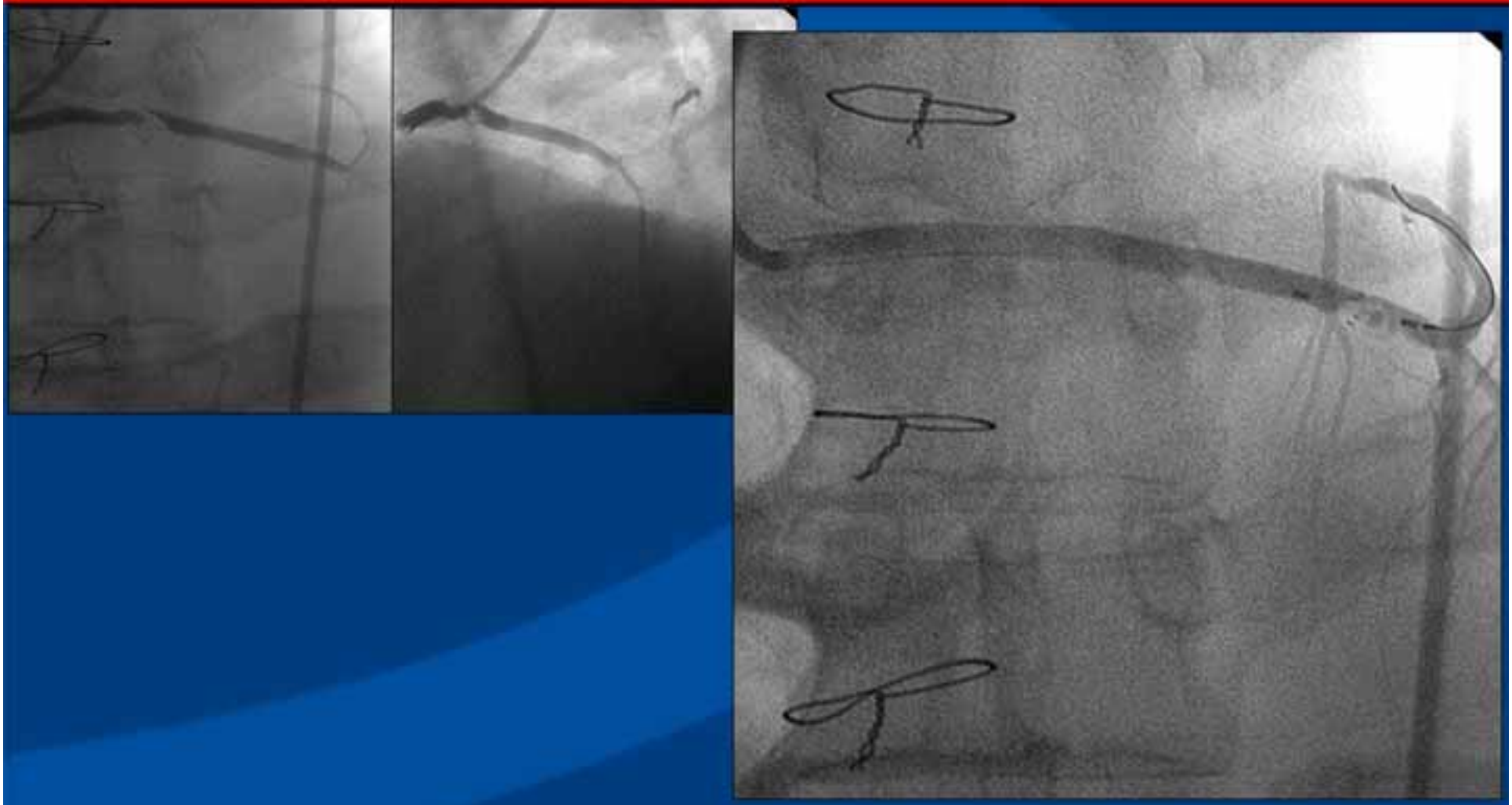
Multicenter Registry of the Working Group on Invasive Cardiology of the Polish Cardiac Society (2003)

n = 70

POBA = 18 (26%) STENT = 52 (74%) [Direct Stenting = 24 (46%)]



PCI in SVG for NSTEMI



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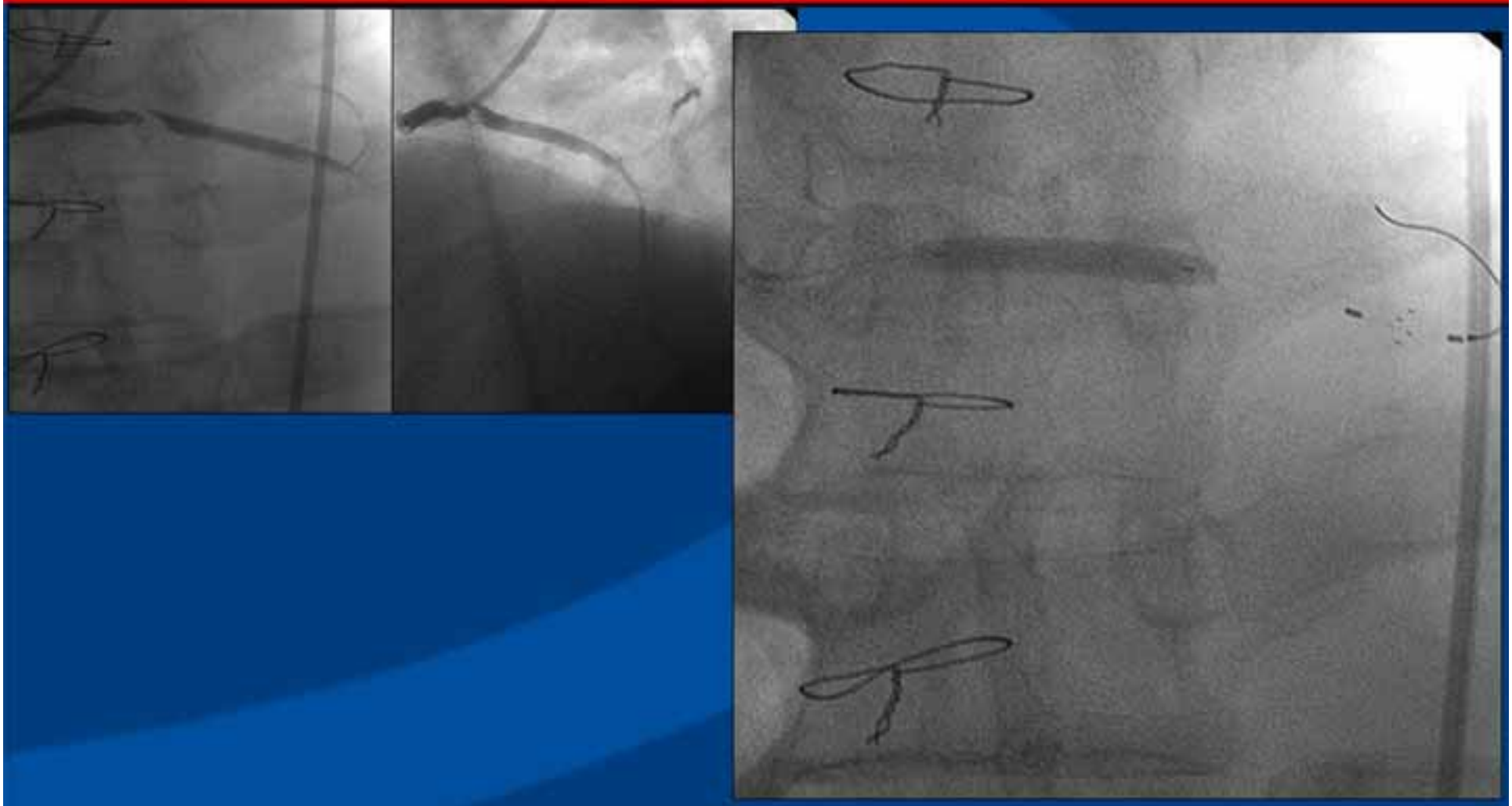

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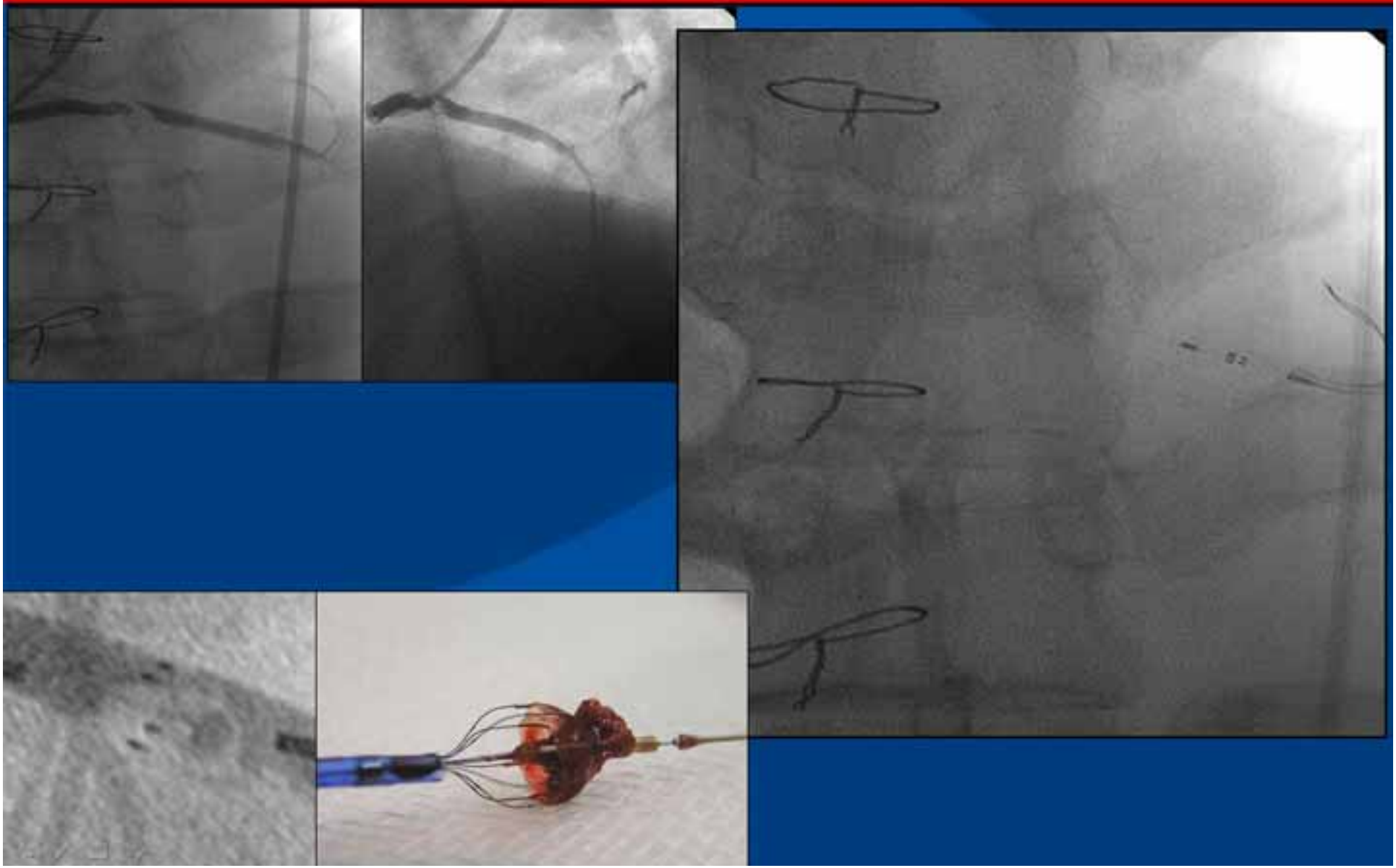

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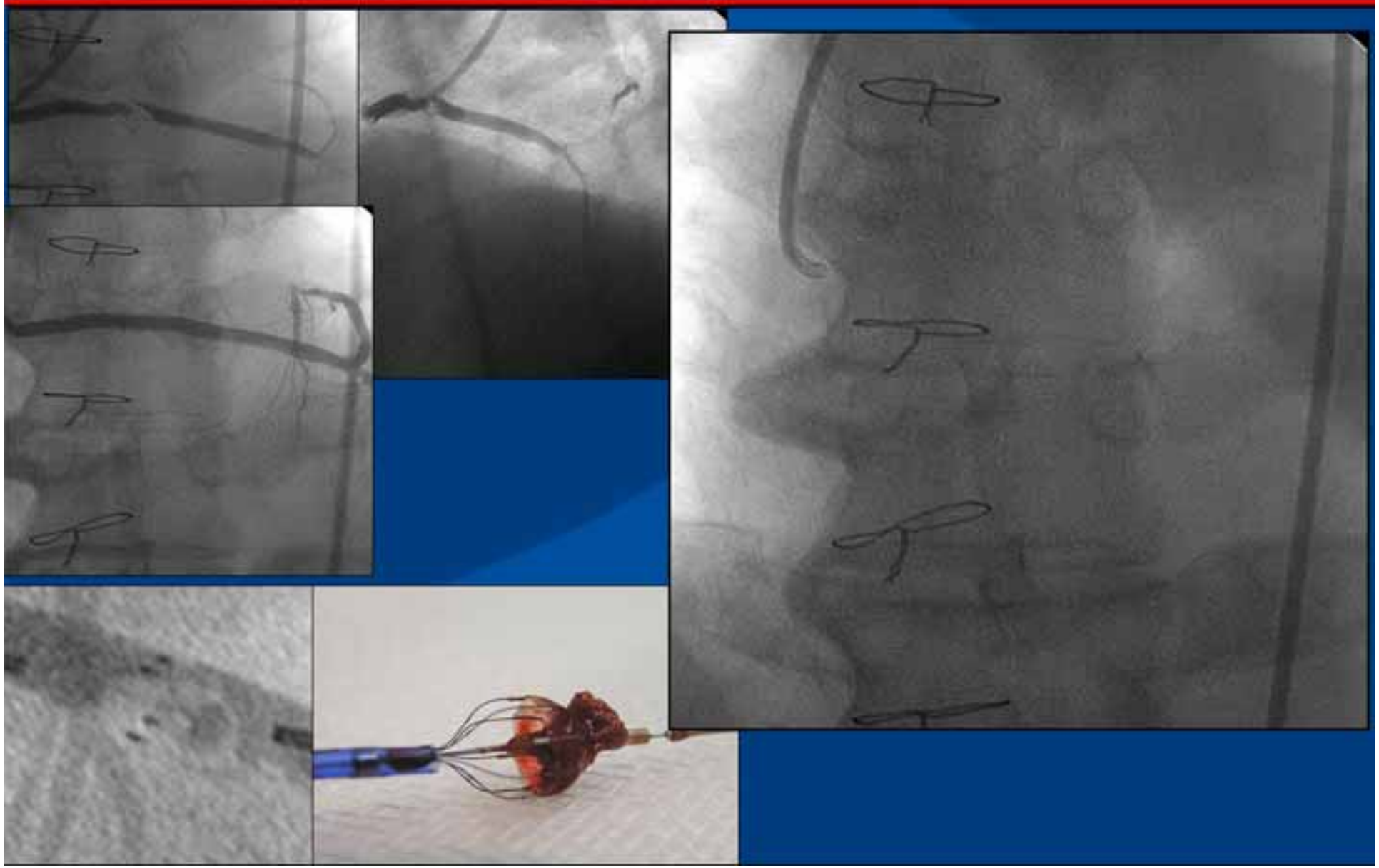

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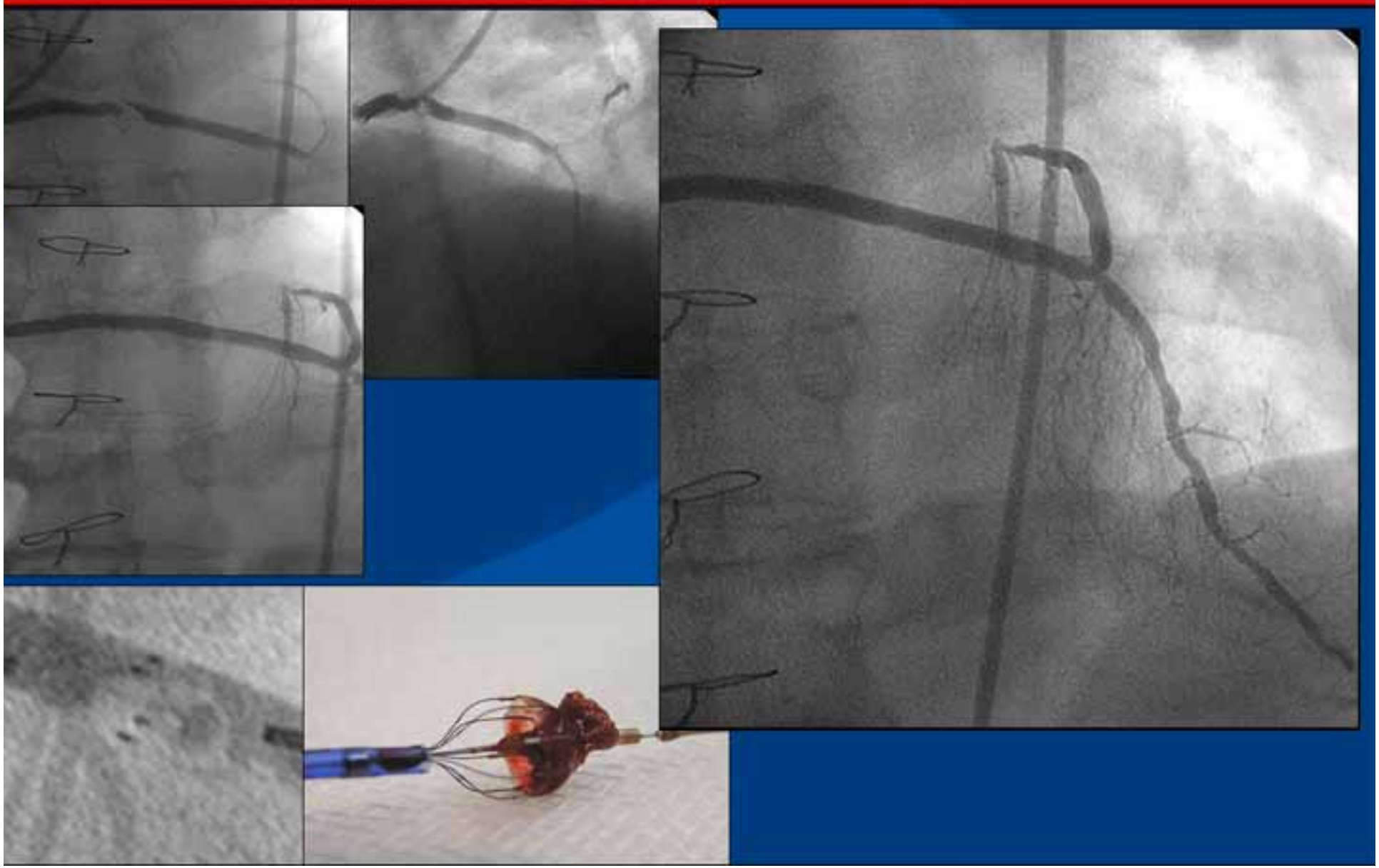

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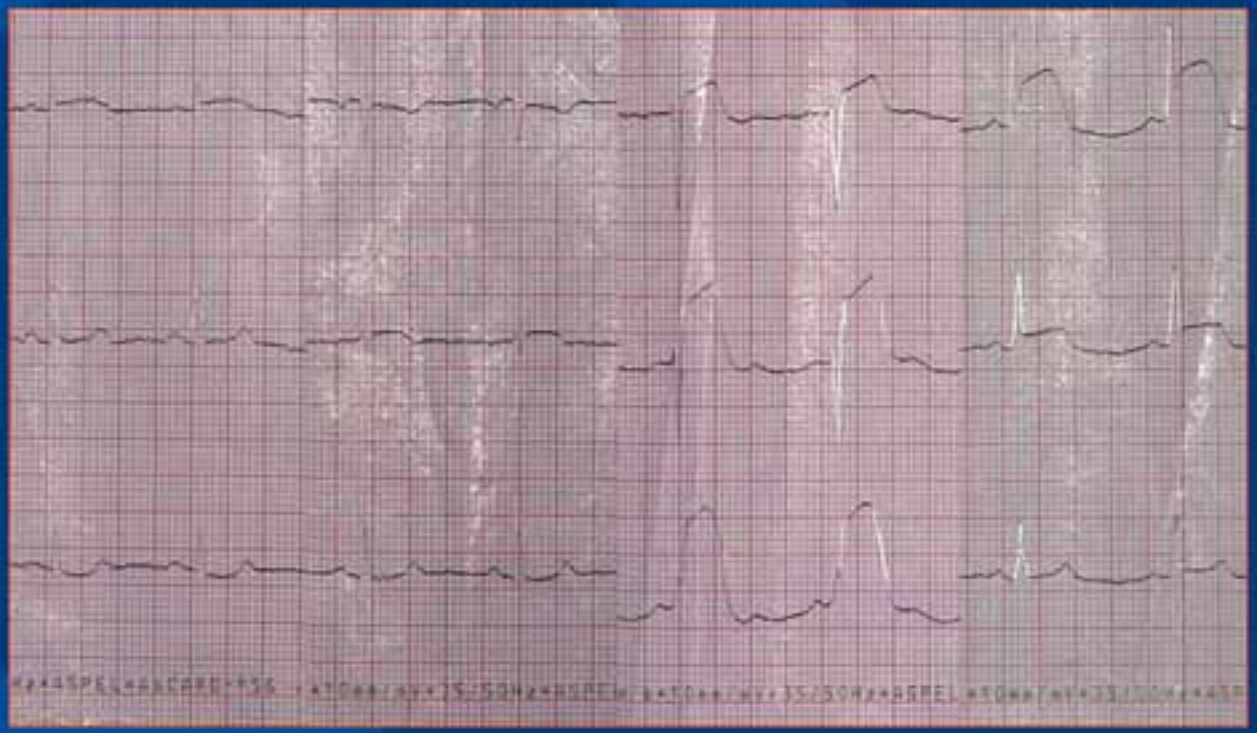

PCI in SVG for STEMI

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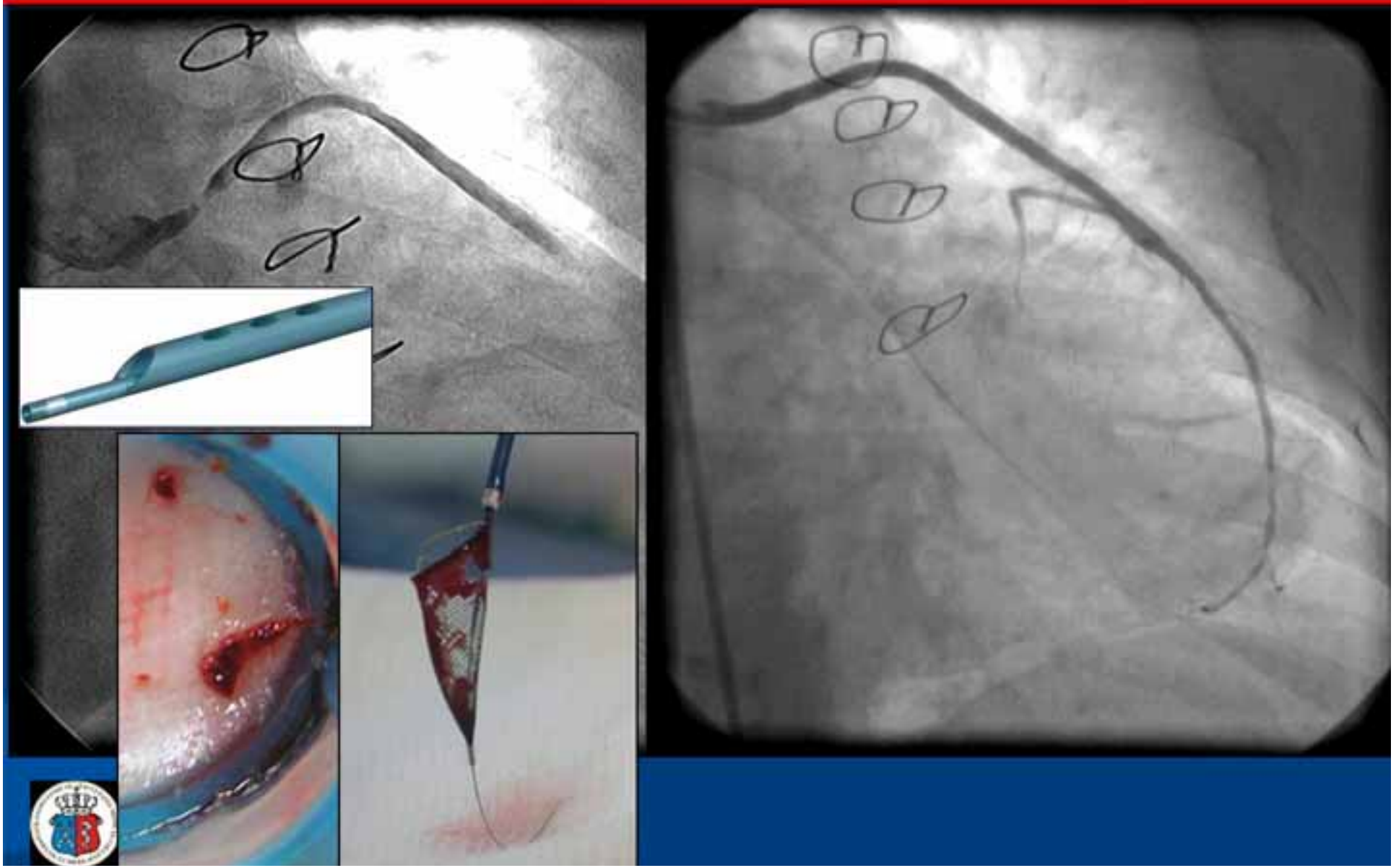

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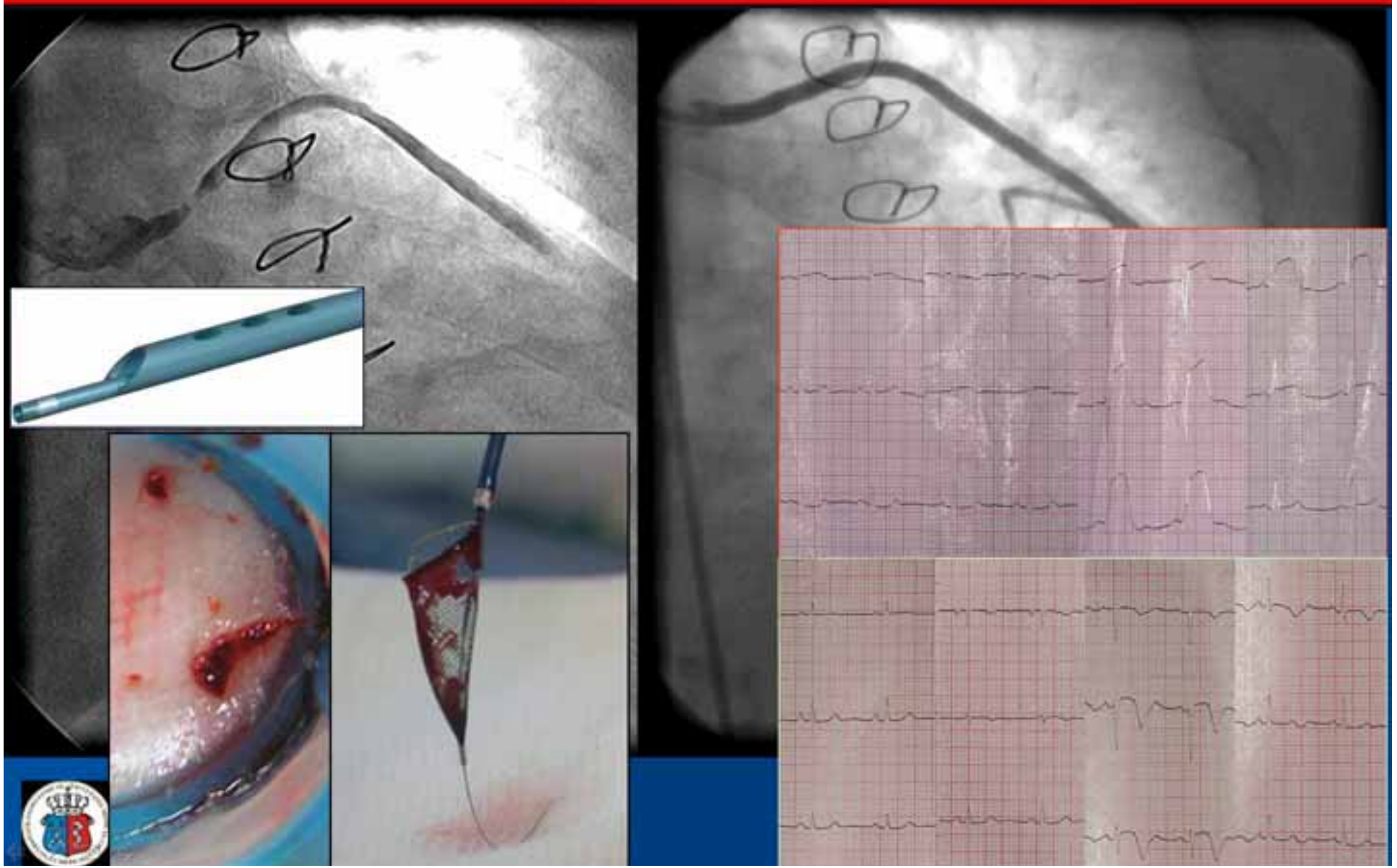


Thrombectomy - *ESC PCI, march'2005*

Distal embolic protection	Saphenous Vein Grafts	I A
Distal and proximal protection devices (suction, thrombectomy)	ACS with high thrombus load in native coronary arteries	II b C

Randomized trials in protection of distal embolization in ACS

Year of publication	First author	Procedure	Device	Category	No. of pts	C	D	Successful, n (%)	TIMI 3 C/D (%)	cTFC C/D (mean)	MBG C/D (%)	ST resolution C/D (%)
2002	Beran [34]	Thrombectomy	X-sizer	ACS	66	31	30	31 (91)	84/90	25/18*	1.6/1.8†	52/83*
2003	Napodano [35]	Thrombectomy	X-sizer	ACS	92	46	46	40 (87)	96/94	NA	37/72*	52/83*
2005	Lefèvre [38]	Thrombectomy	X-sizer	STEMI	201	101	100	87 (87)	89/96	25/23	30/31	53/68*
2004	Antoniucci [37]	Thrombectomy	AngioJet	STEMI	100	50	50	48 (96)	NA	23/18*	NA	72/90*
2005	Ali [39]	Thrombectomy	AngioJet	STEMI	480	240	240	228 (95)	97/92	29/32	37/31	68/60
2004	Dudek [36]	Thrombectomy	RESCUE	STEMI	72	32	40	35 (87)	86/85	19/21	38/54	25/68
2005	Burzotta [42]	Thrombectomy	DiverCE	STEMI	100	50	49	44 (88)	NA	26/23	68/45‡	58/37
2005	Stone [32]	Distal Protection	GuardWire	STEMI	501	249	252	193 (79)	89/92	20/18	53/61	62/63
2005	Gick [31]	Distal Protection	FilterWireEx	AMI	200	100	100	95 (95)	93/93	NA	67/64*‡	NA

Category, Patients included in study, that is, patients with ST elevation myocardial infarction (STEMI), acute coronary syndrome (ACS), and acute myocardial infarction (AMI); C, control group; D, device group; No. of pts, number of patients included in study; Successful, number of interventions in the treatment group that were successful according to definition in respective trials; TIMI 3, Thrombolysis in Myocardial Infarction flow 3 after the procedure; cTFC, corrected TIMI frame count at the end of the procedure; MBG, myocardial blush grade 3 after the procedure; ST resolution, percentage of patients with ST-segment elevation resolution after the procedure according to definition in respective trials; NA, not available.

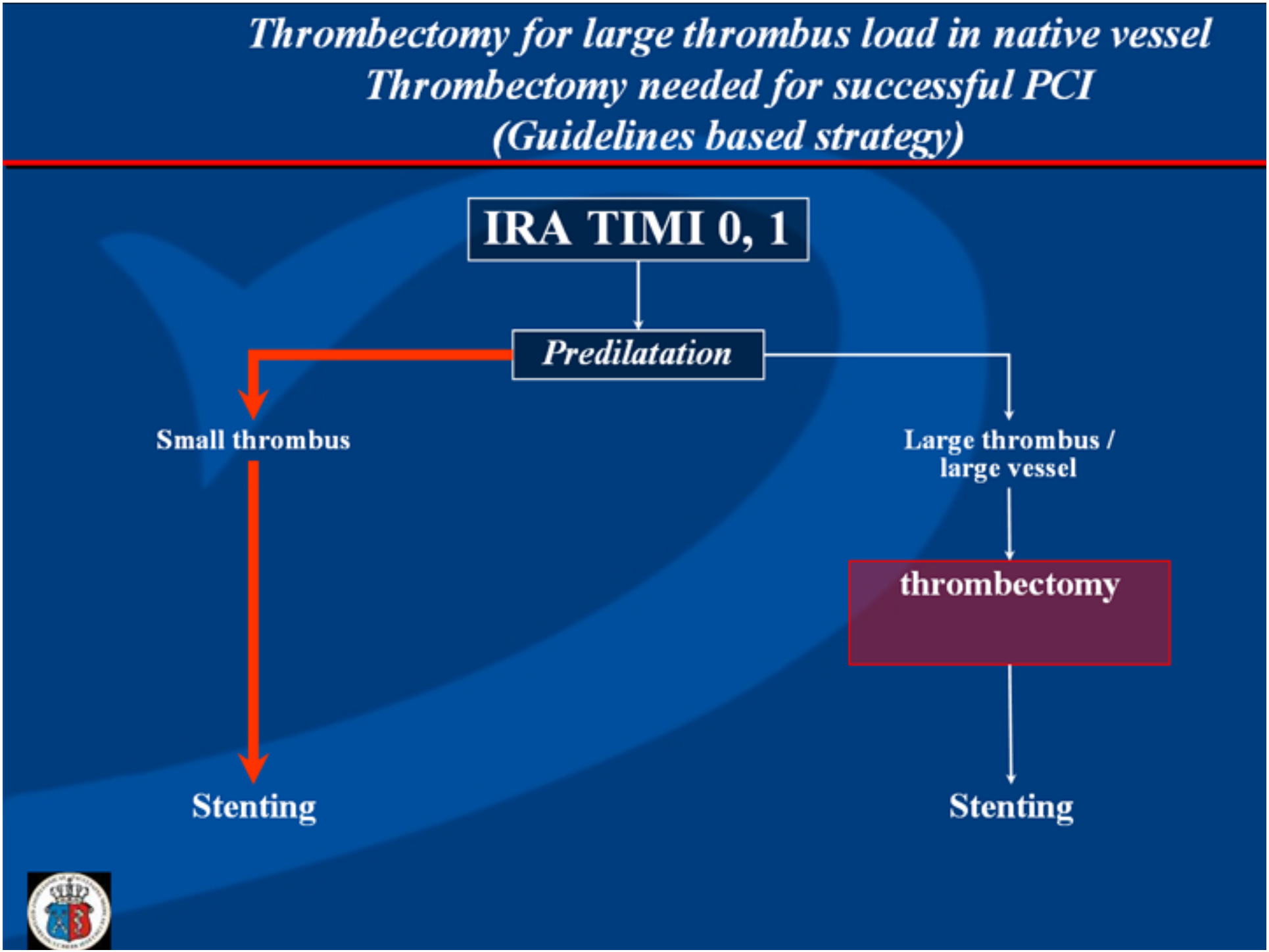
*P <0.05

† Mean MBG.

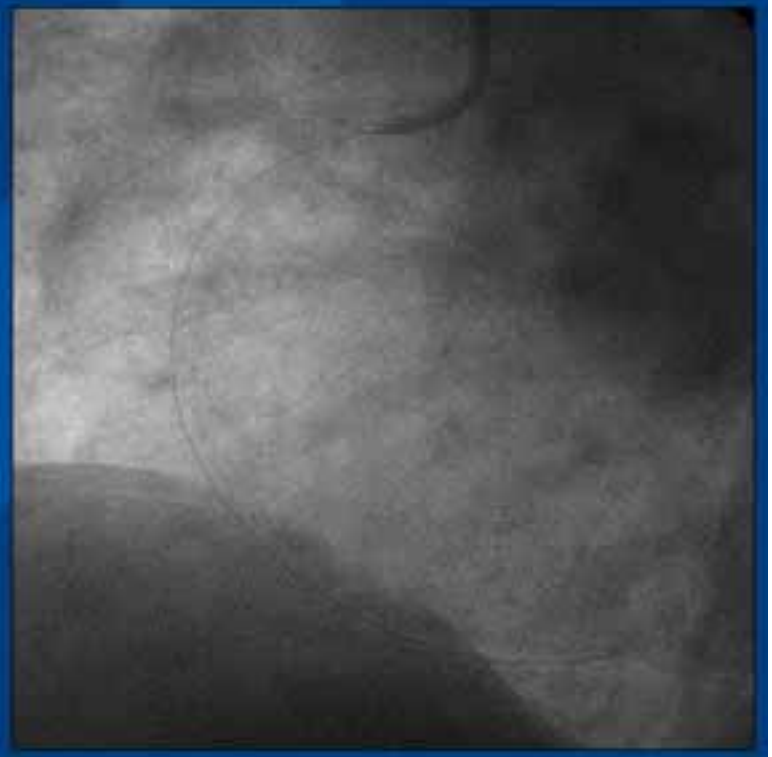
‡ MBG

Tone Svilaas, MD; Am Heart J 2006;151:597.e12597.e7.

Thrombectomy for large thrombus load in native vessel Thrombectomy needed for successful PCI (Guidelines based strategy)



Primary PCI with DIVER CE



D. Dudek et al, EHJ, 2005, 7, Sup I, I15-I20

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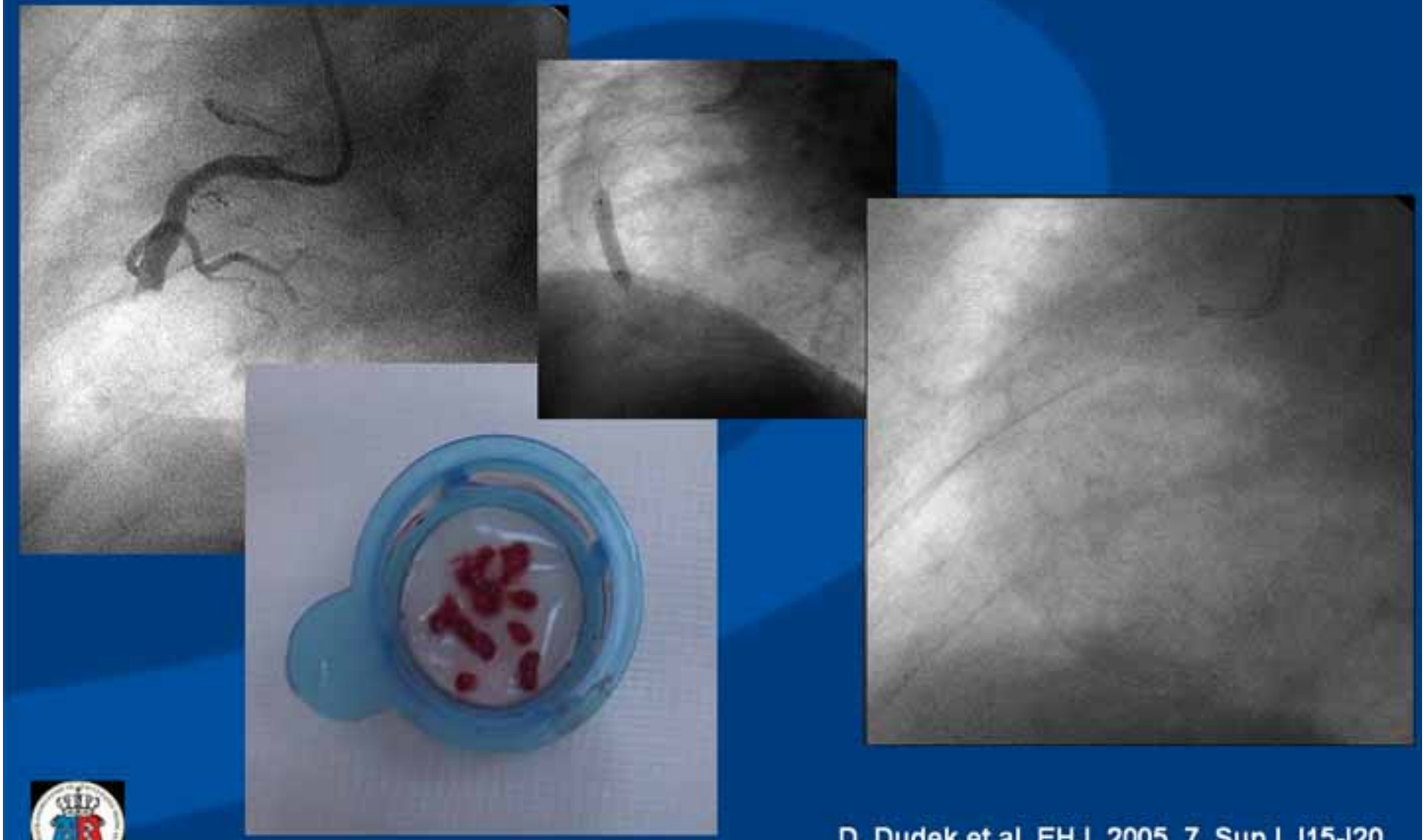

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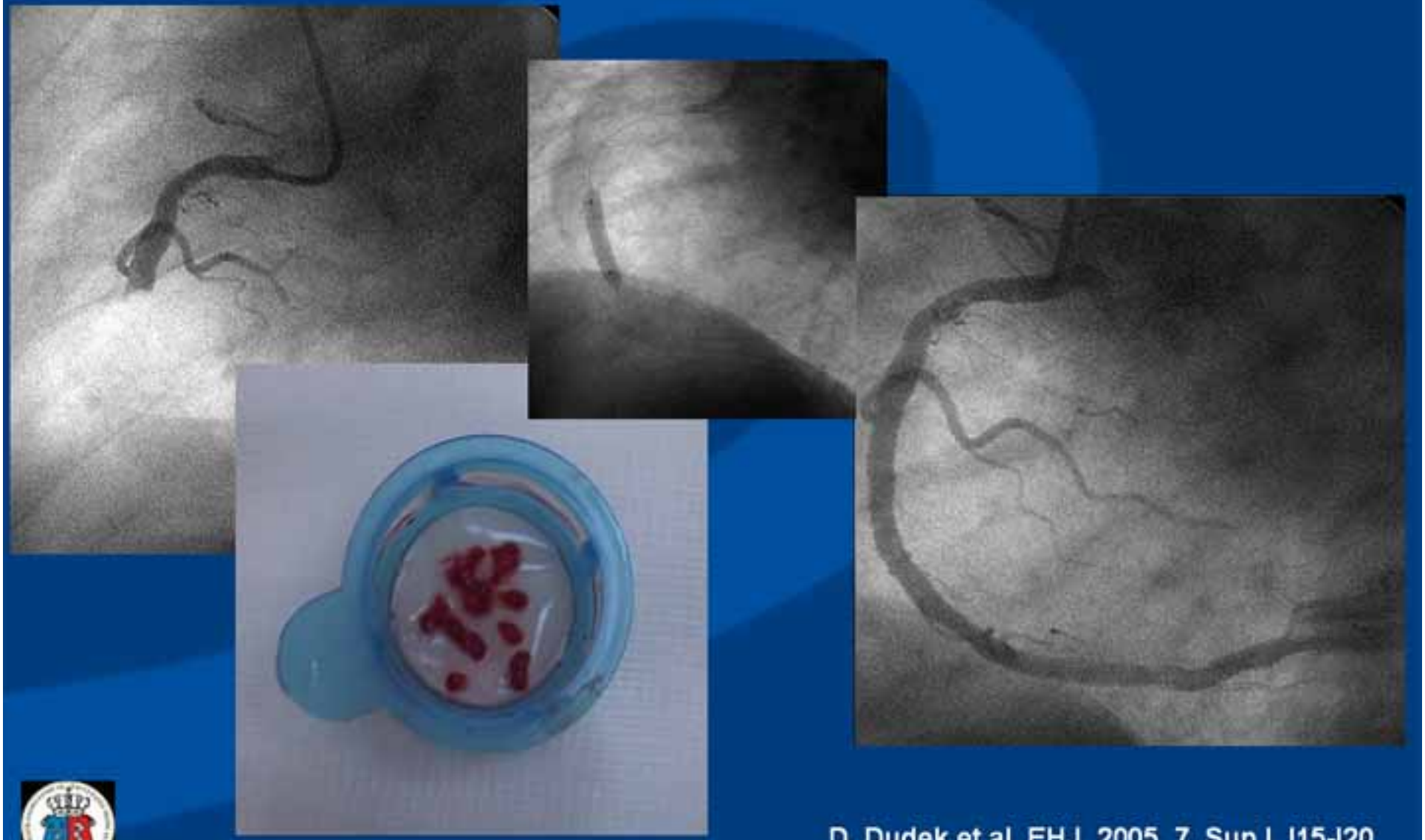
Primary PCI with DIVER CE



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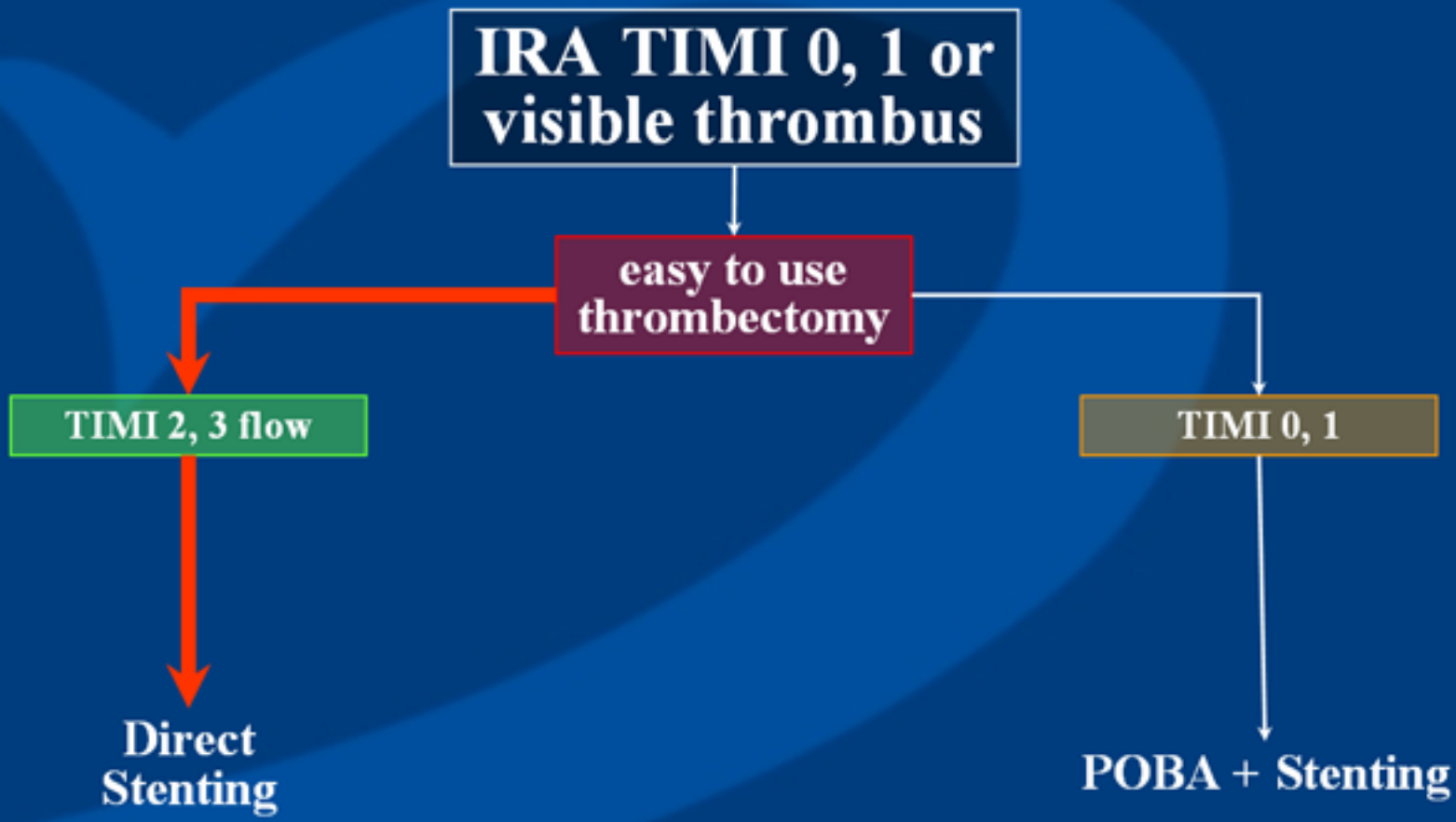
New concept – high risk pts

(TIMI 0 or 1 after passage of wire; visible thrombus)

Thrombectomy to avoid balloon predilatation before stenting



Polish-Italian-Hungarian Randomized ThrombEctomy Trial.

PIHRATE Trial



PIHRATE Trial (n=200 pts)

STEMI <6hr
ST elevation >3 mm in one lead
TIMI 0 or 1

TIMI, eTFC, MBG

RANDOMIZATION

Grup I
THROMBECTOMY

TIMI, eTFC, MBG

TIMI 0 or 1

POBA

STENTING

TIMI 2 or 3

DIRECT STENTING

TIMI, eTFC, MBG

Grup II
PREDILATATION

TIMI, eTFC, MBG

STENT IMPLANTATION

TIMI, eTFC, MBG

ST SEGMENT RESOLUTION 60 MINUTES AFTER PCI

PIHRATE Trial (n=200 pts)

STEMI <6hr
ST elevation >3 mm in one lead
TIMI 0 or 1

RANDOMIZATION

Grup I
THROMBECTOMY

Grup II
PREDILATATION

CK/CK-MB LEAK: every 6 hours for 24 hours

ECHO: EF, ESV, EDV, WMSI predischarge and 6 month follow up

CMR – in the subgroup of patients –
EDV, ESV, mass and ejection fraction, delayed-contrast-enhancement 6 months follow up

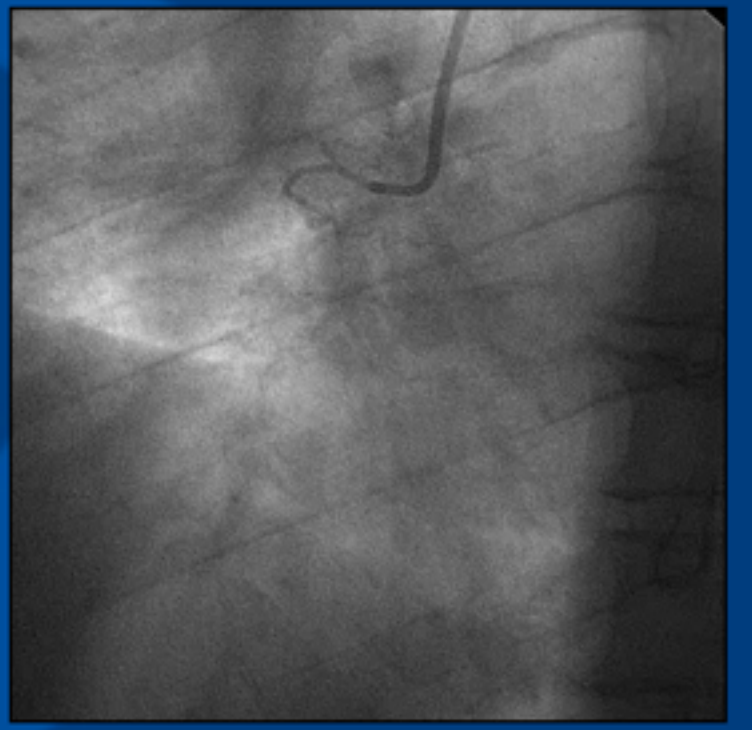
MACE: 30 day and 6 month follow up

Learning curve ought to be taken into account when considering thrombectomy

The catheter must be advanced very slowly down and to thrombus level and aspiration must be initiated proximal to the thrombus in order to avoid pushing and fragmenting it

The system is less effective in large coronary arteries. Distal protection as the additional device could be considered

PIHRATE Trial



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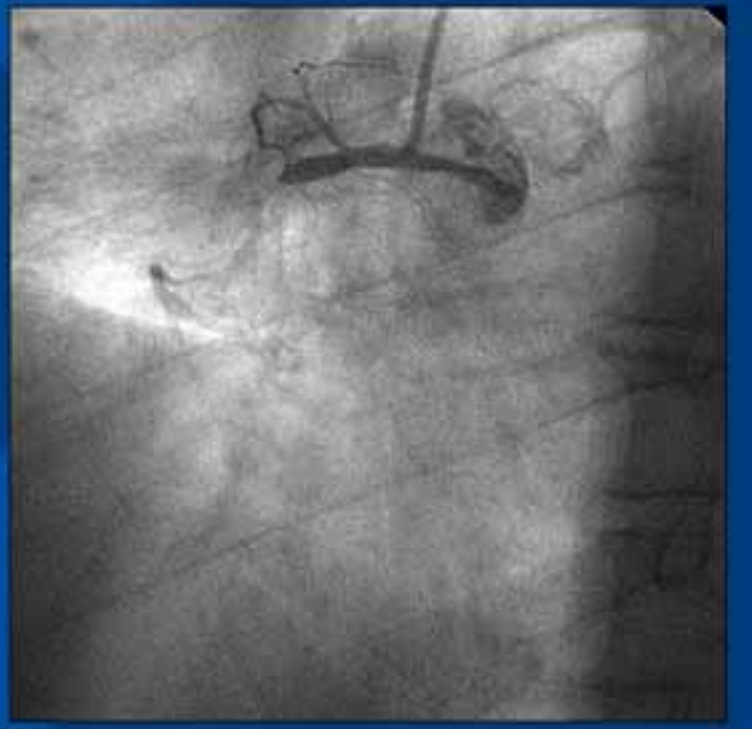

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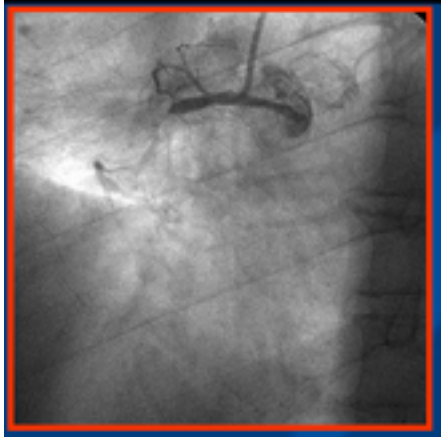

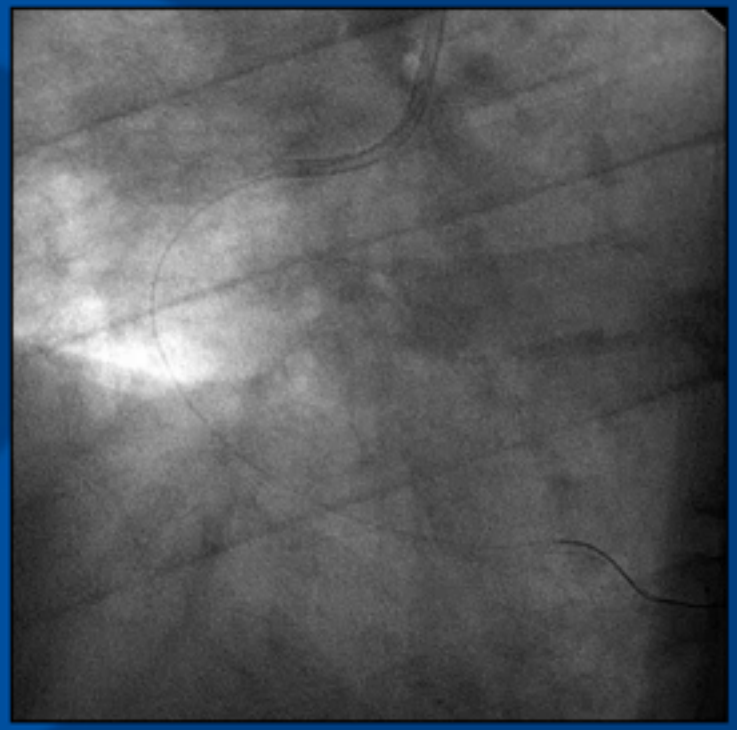

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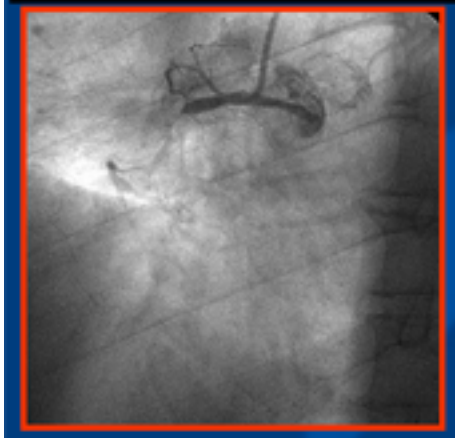
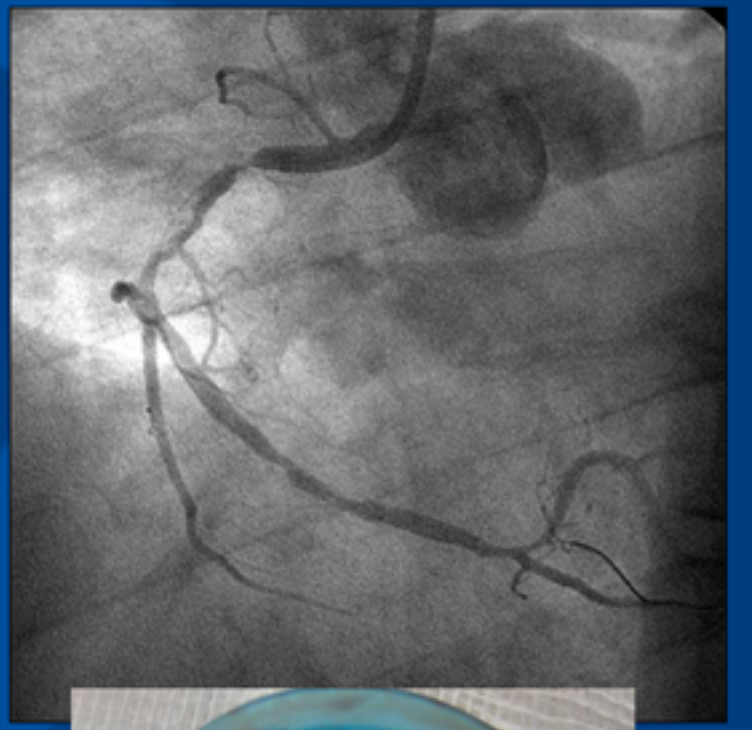
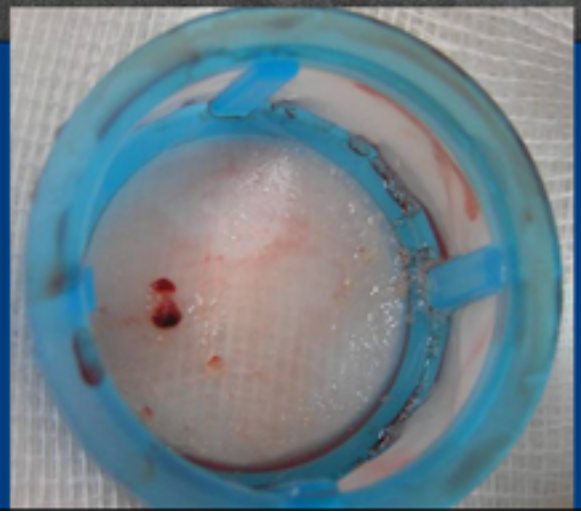
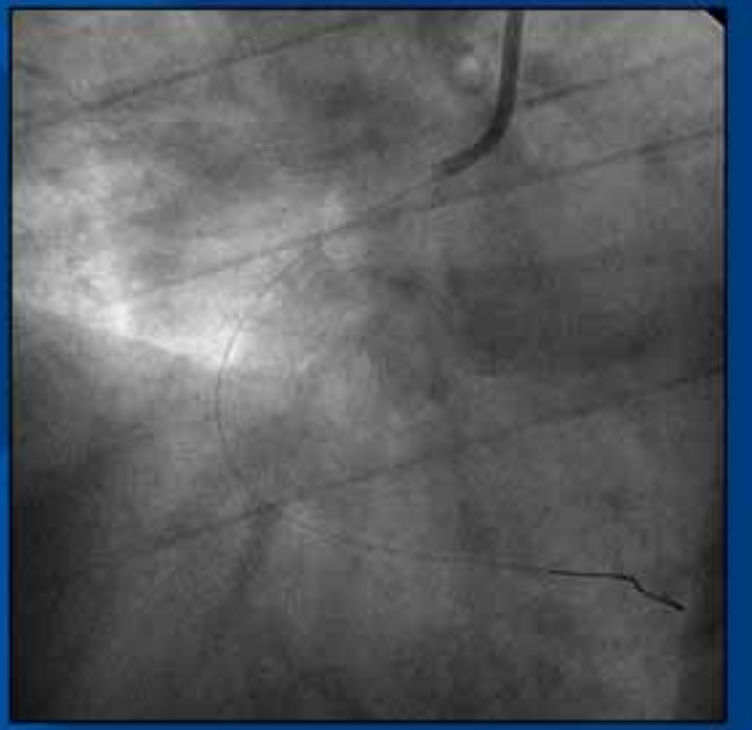






PIHRATE Trial

35cc
syringe



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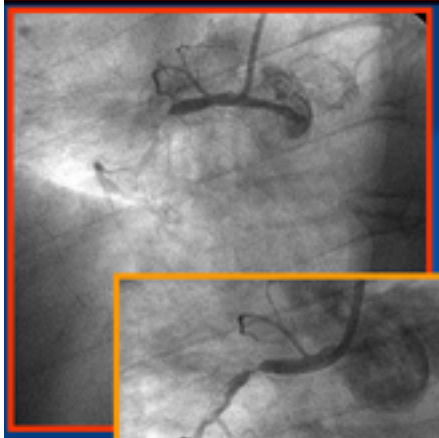
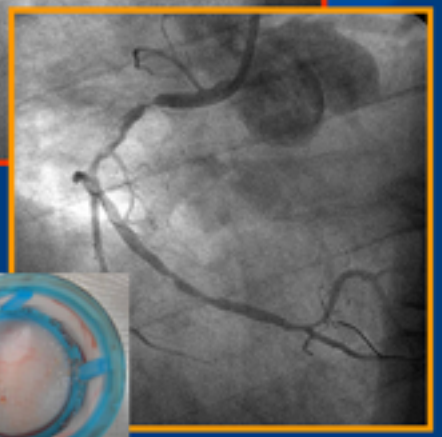
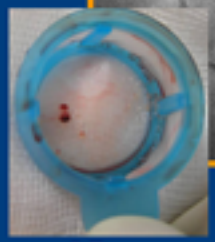
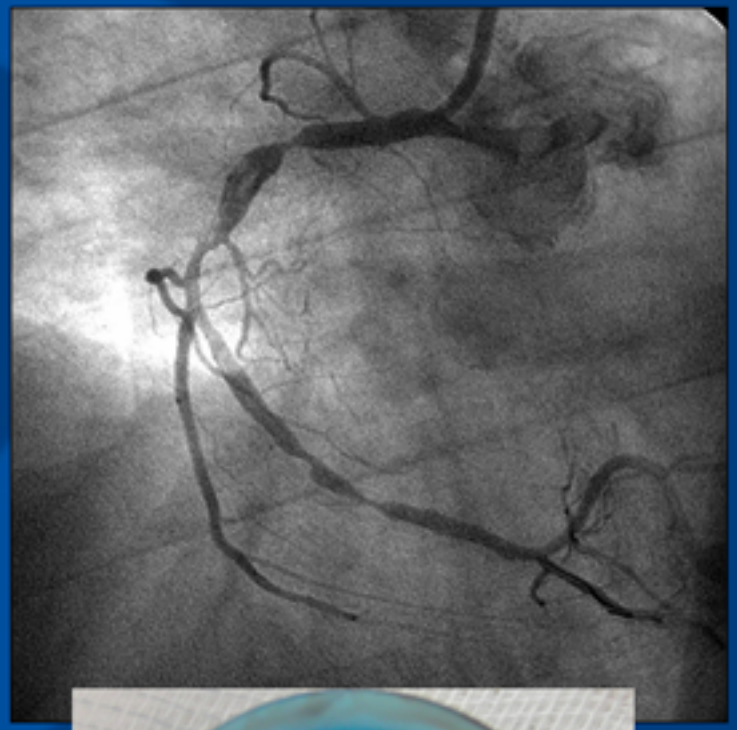
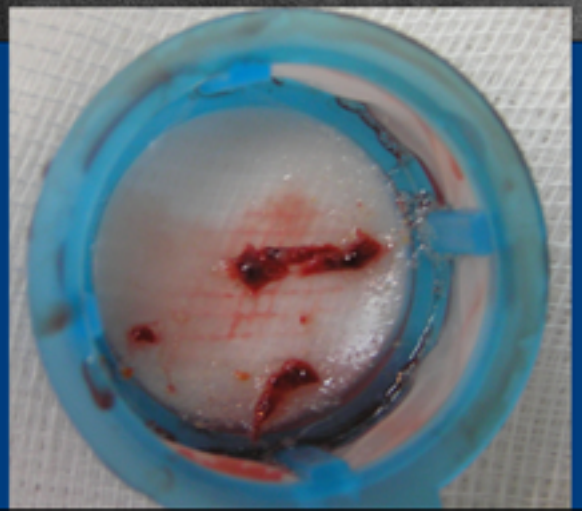






35cc
syringe





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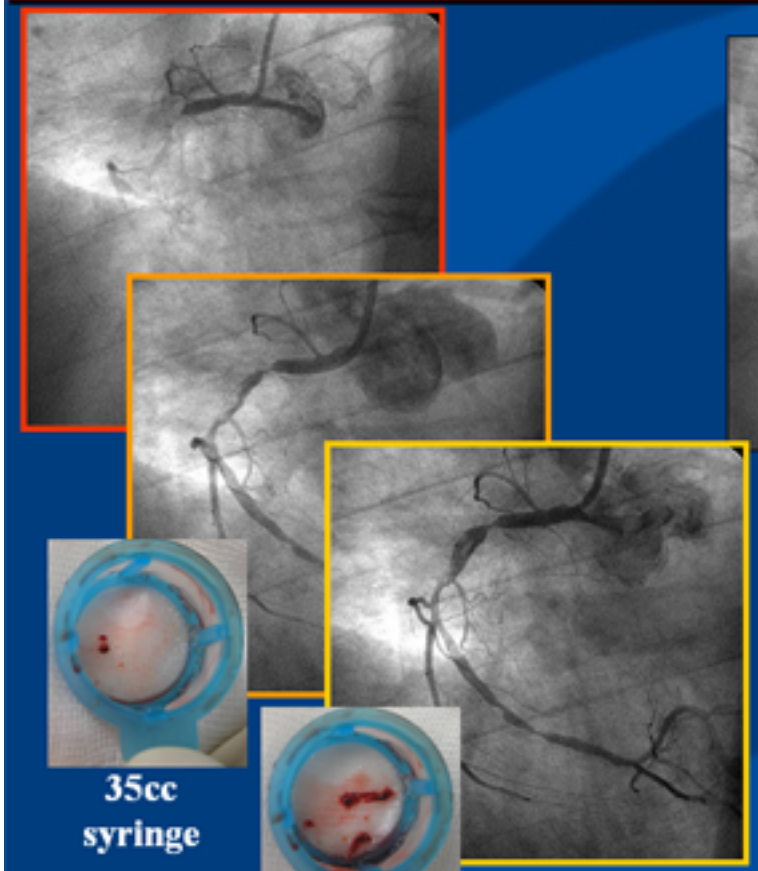
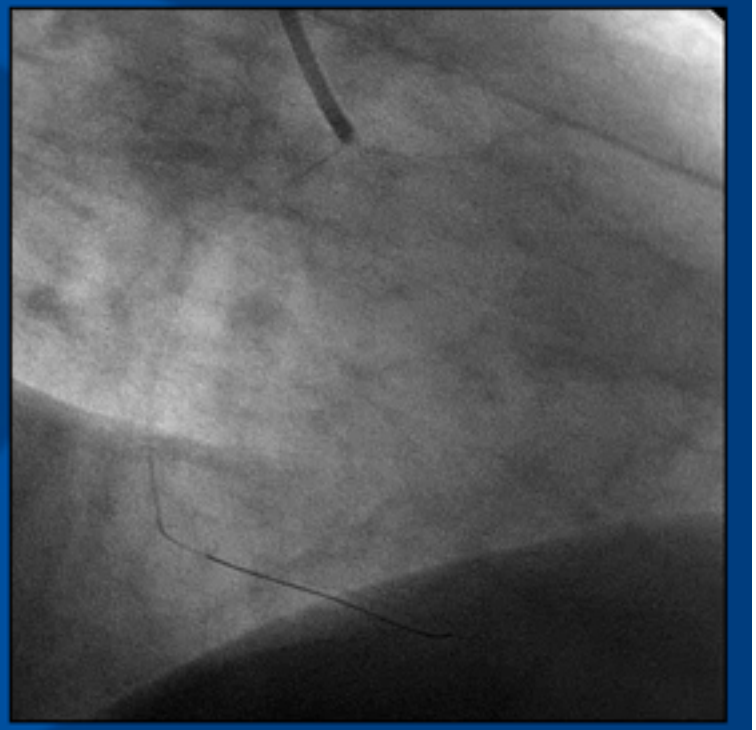


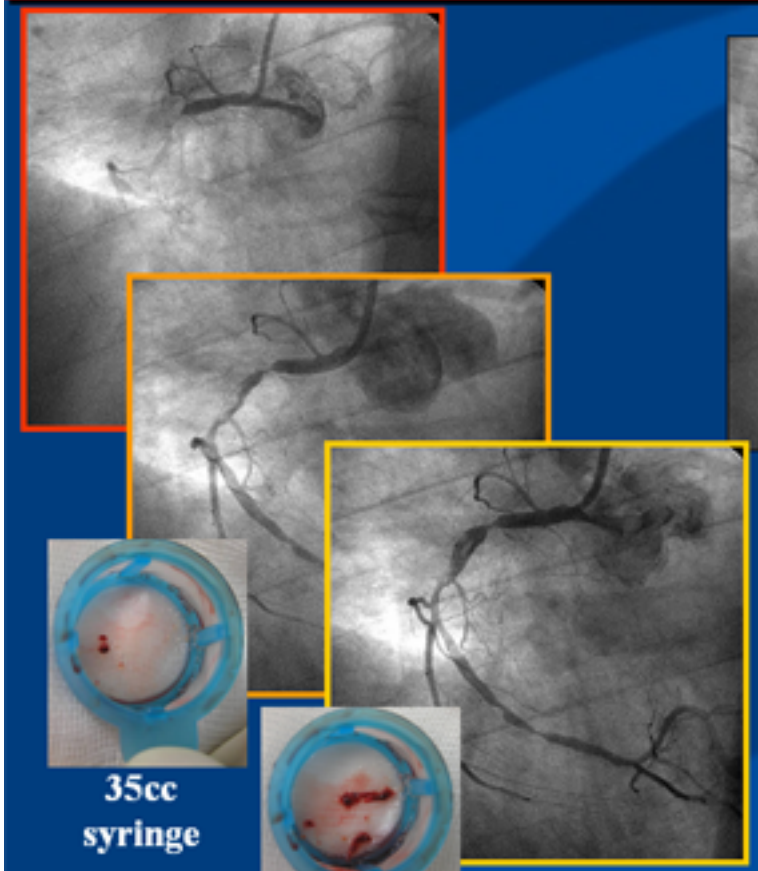
35cc syringe

50cc syringe



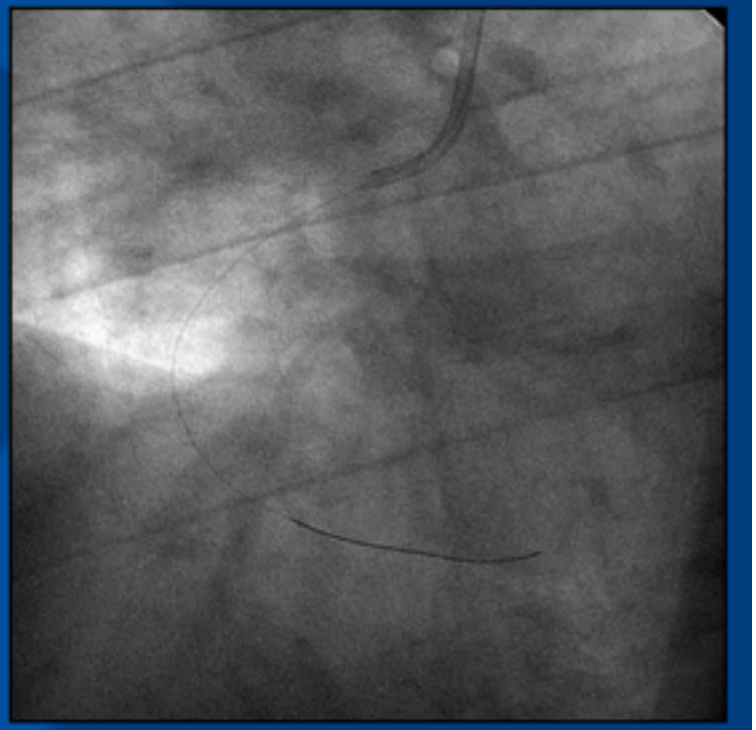
visible residual thrombus
requiring 3rd thrombectomy pass

PIHRATE Trial



35cc syringe

50cc syringe



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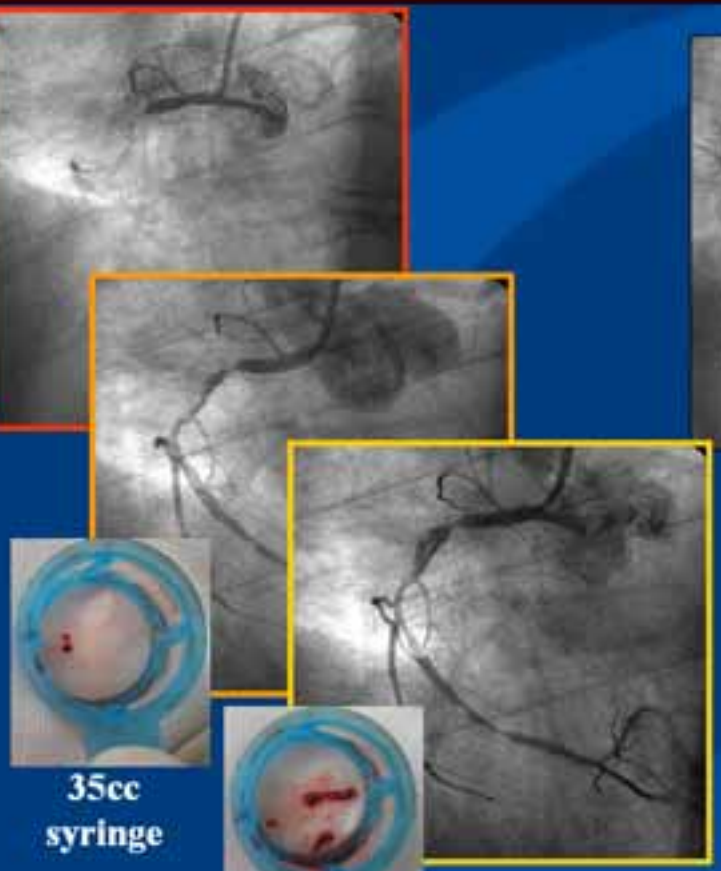

35cc
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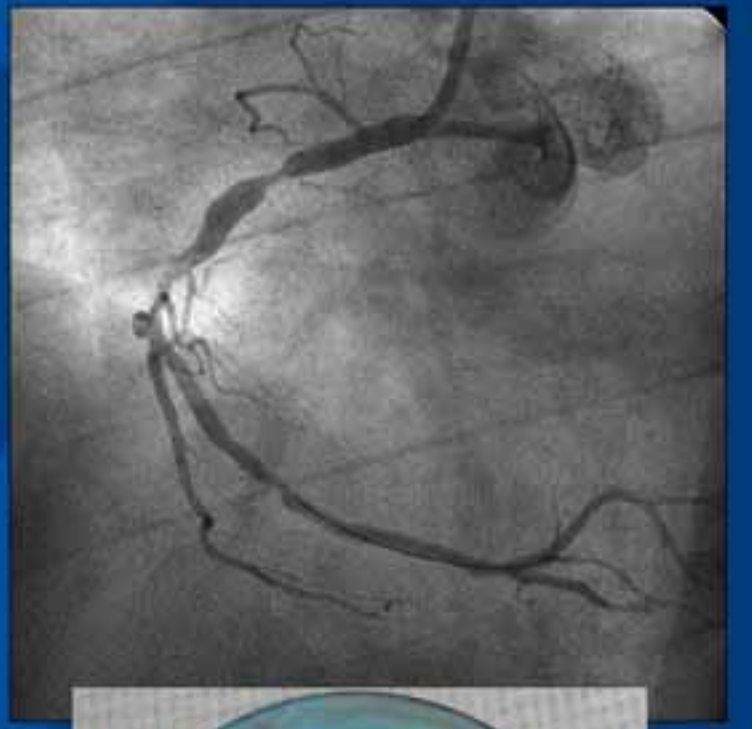

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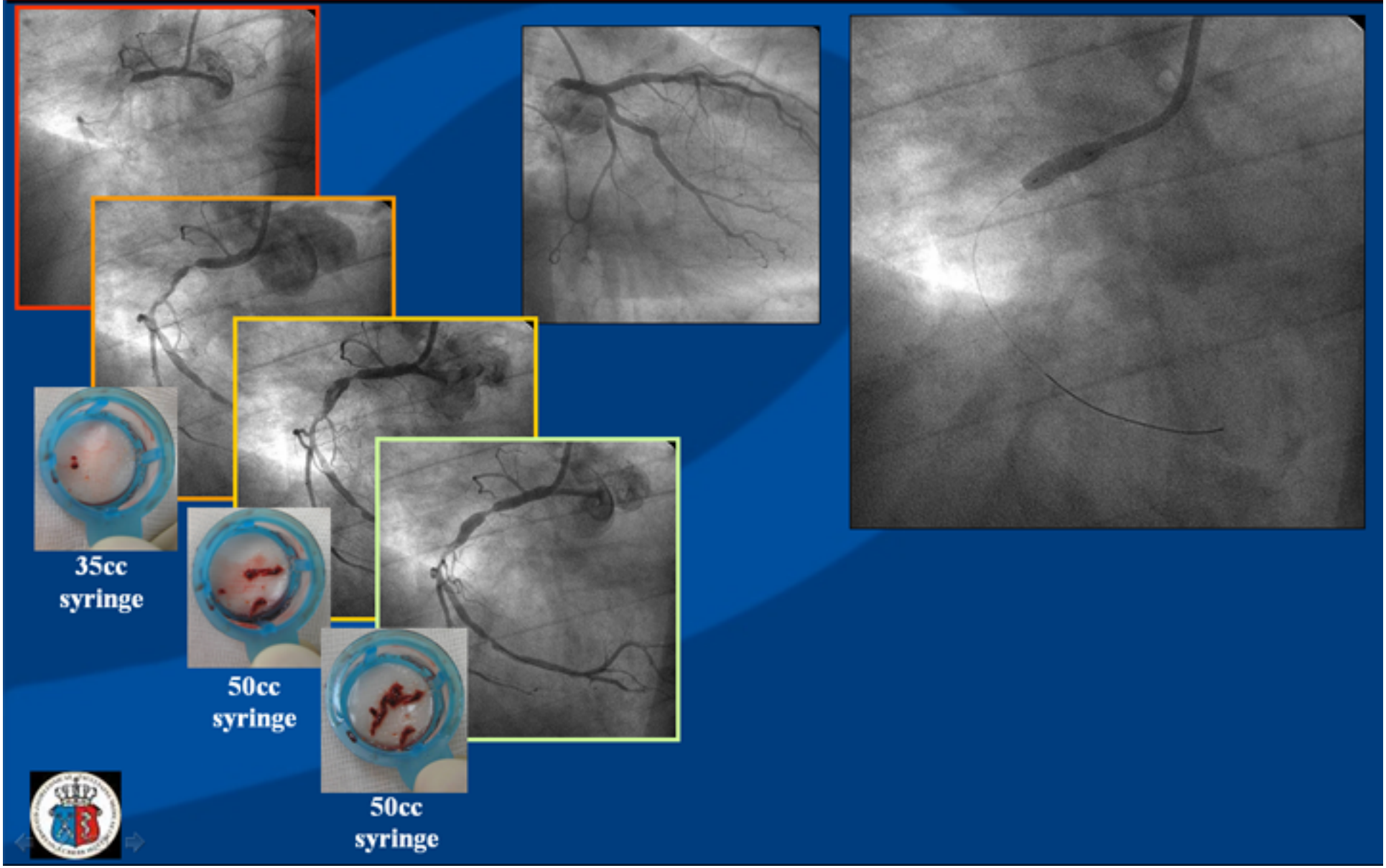

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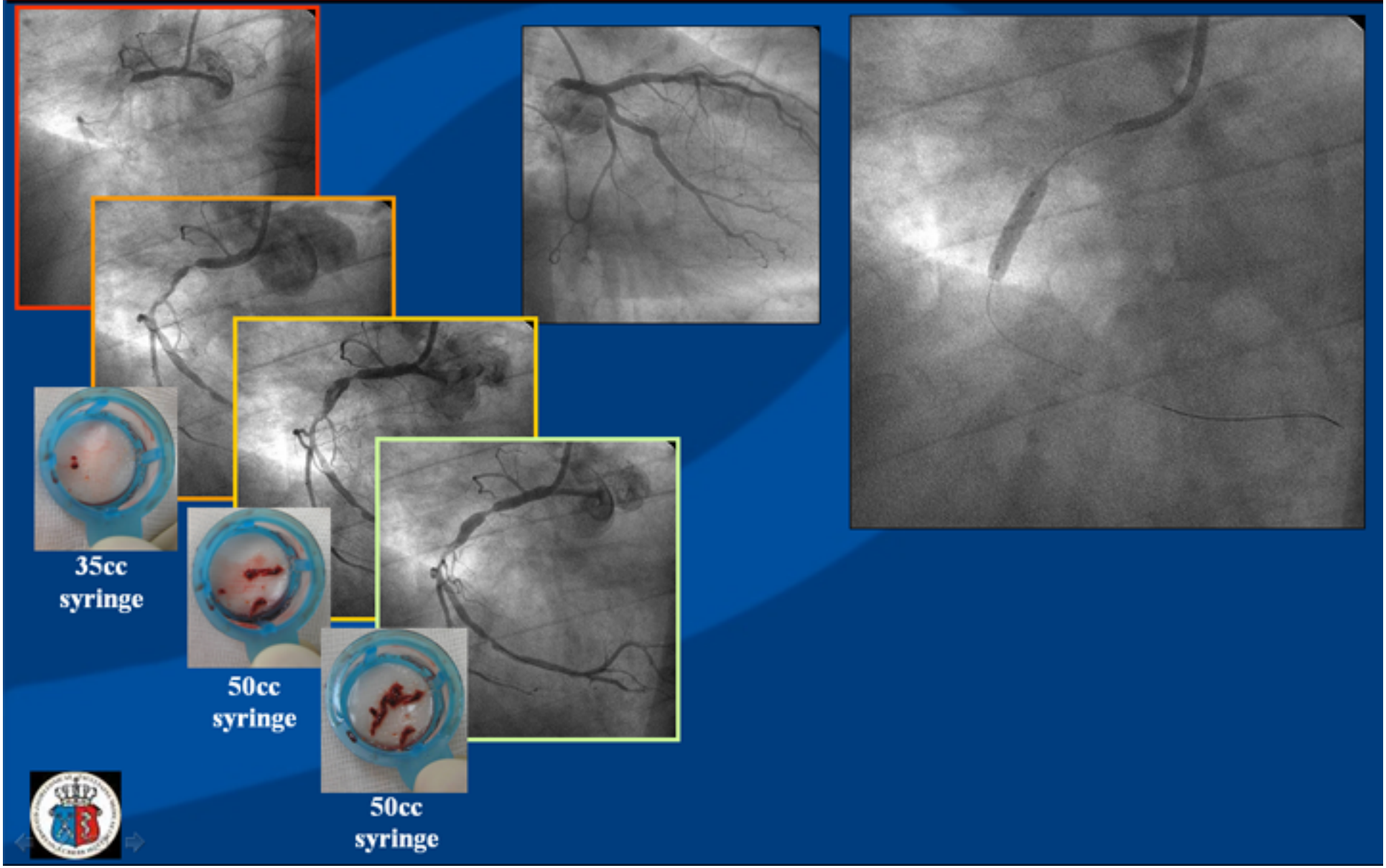

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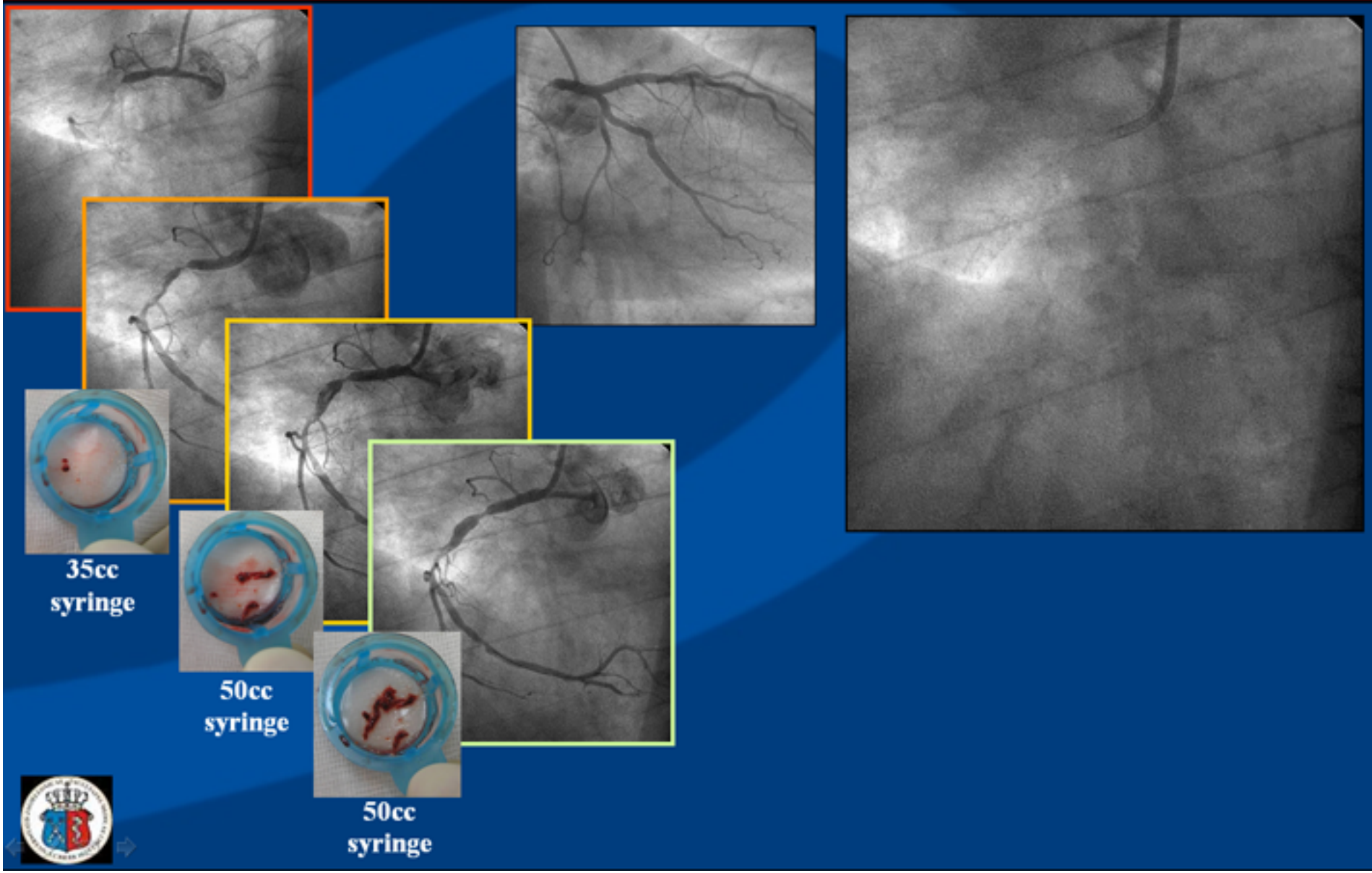

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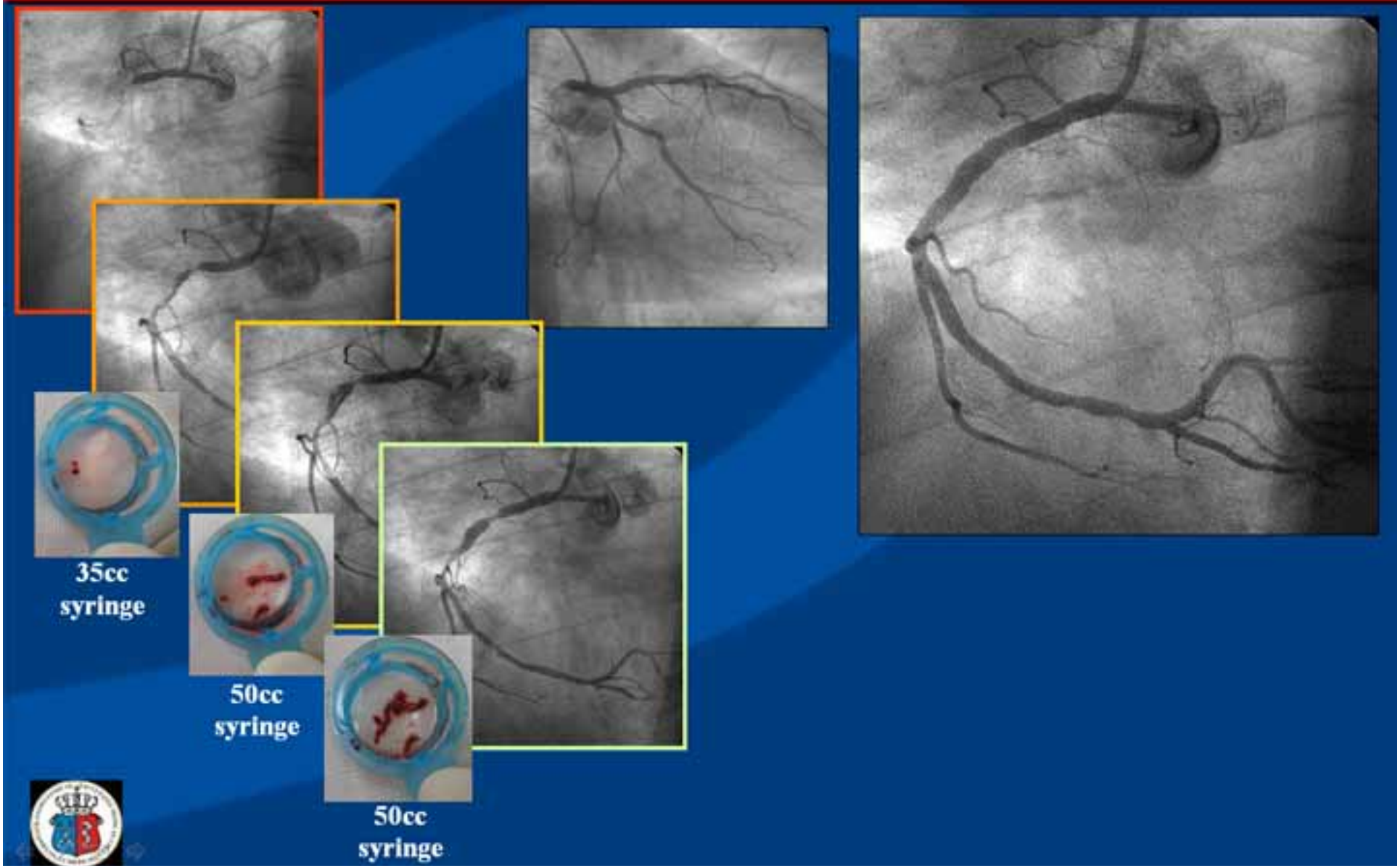

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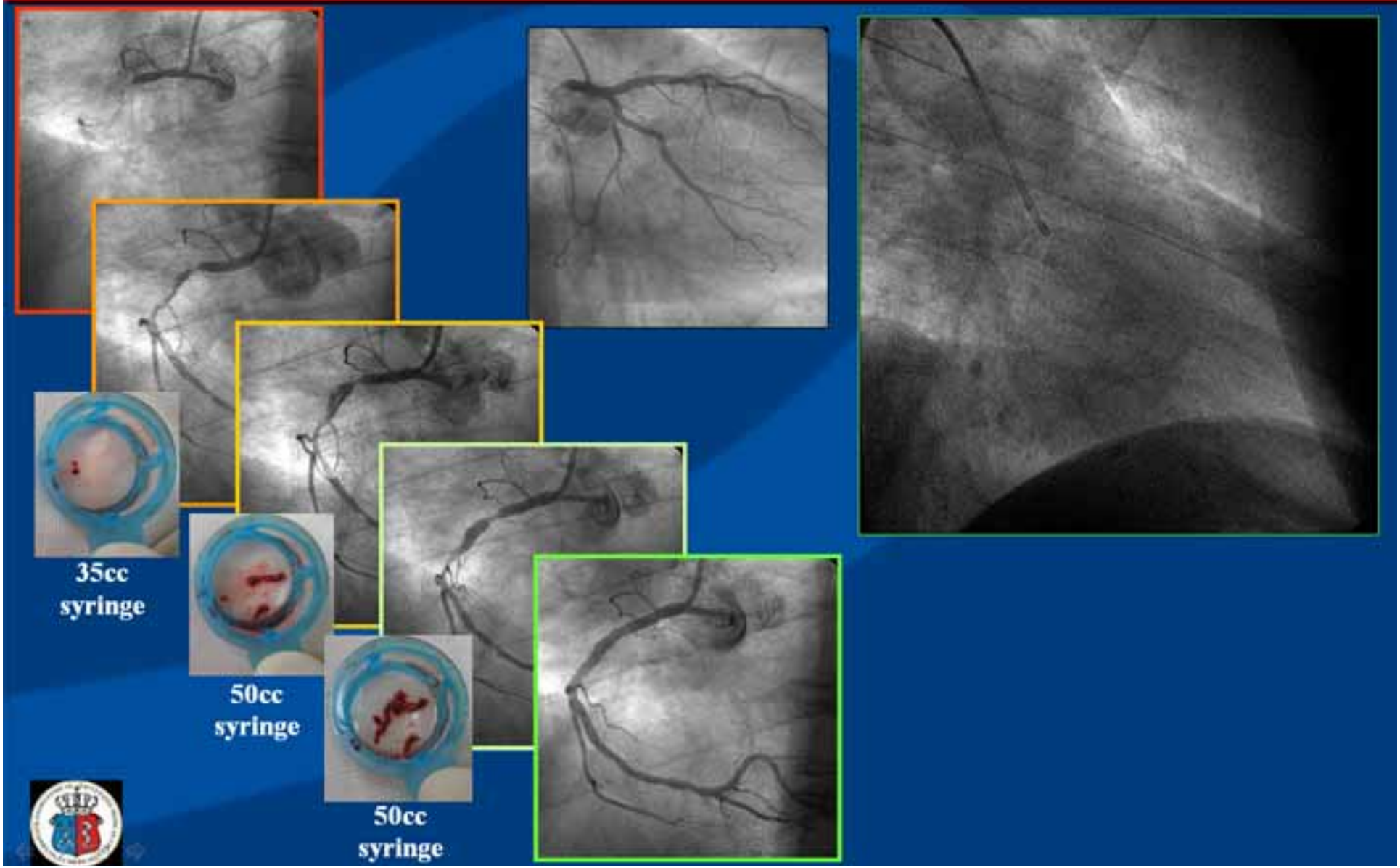

Primary PCI: Filter EZ + DIVER CE for vessel ≥ 4.0 distal thrombus and no reflow phenomenon i.c. nitroprusside + 2nd aspiration + direct stenting

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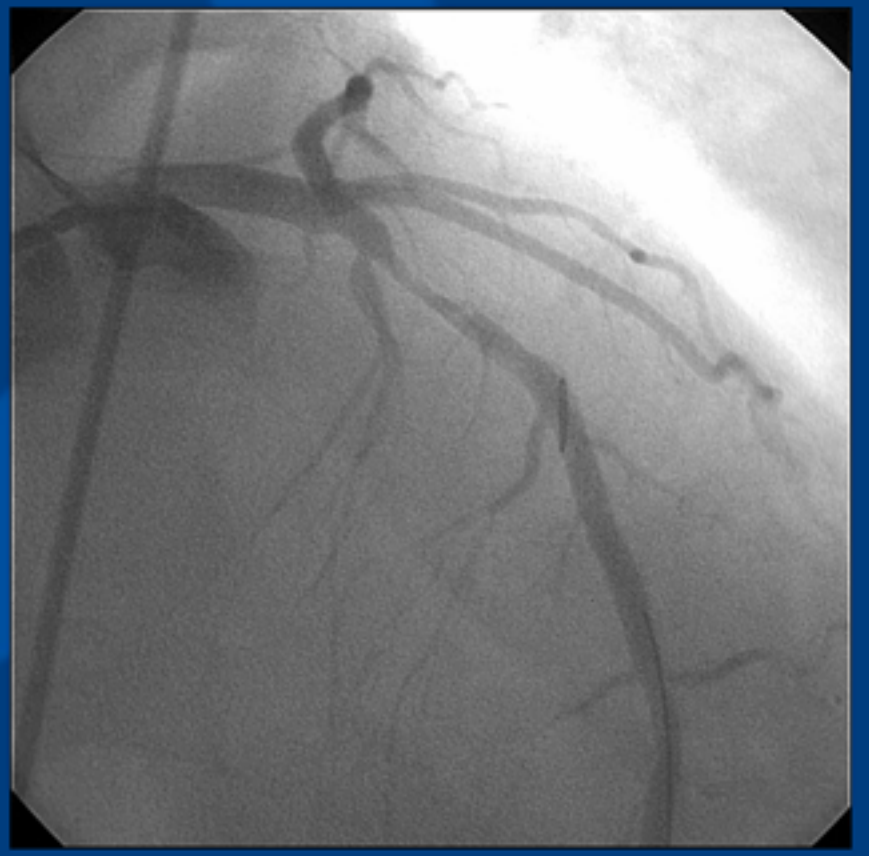

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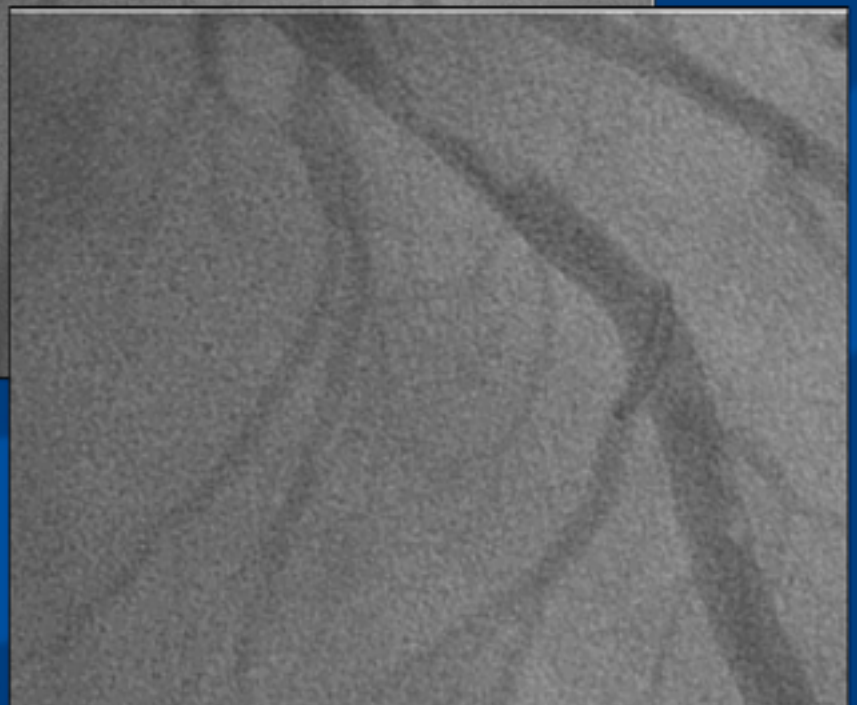

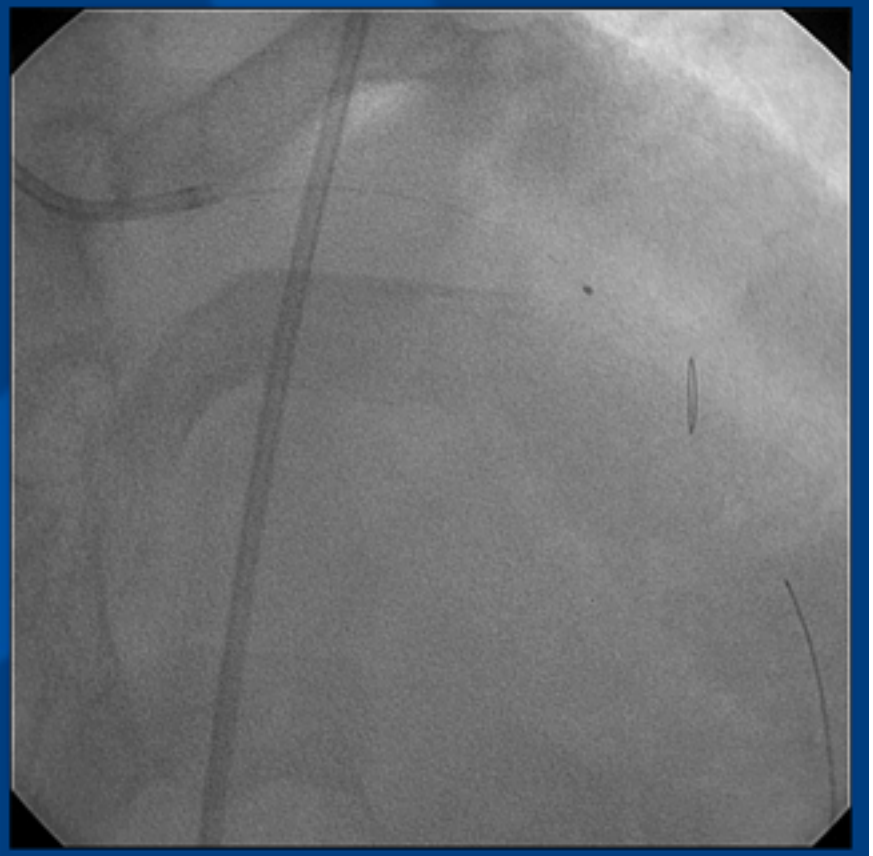

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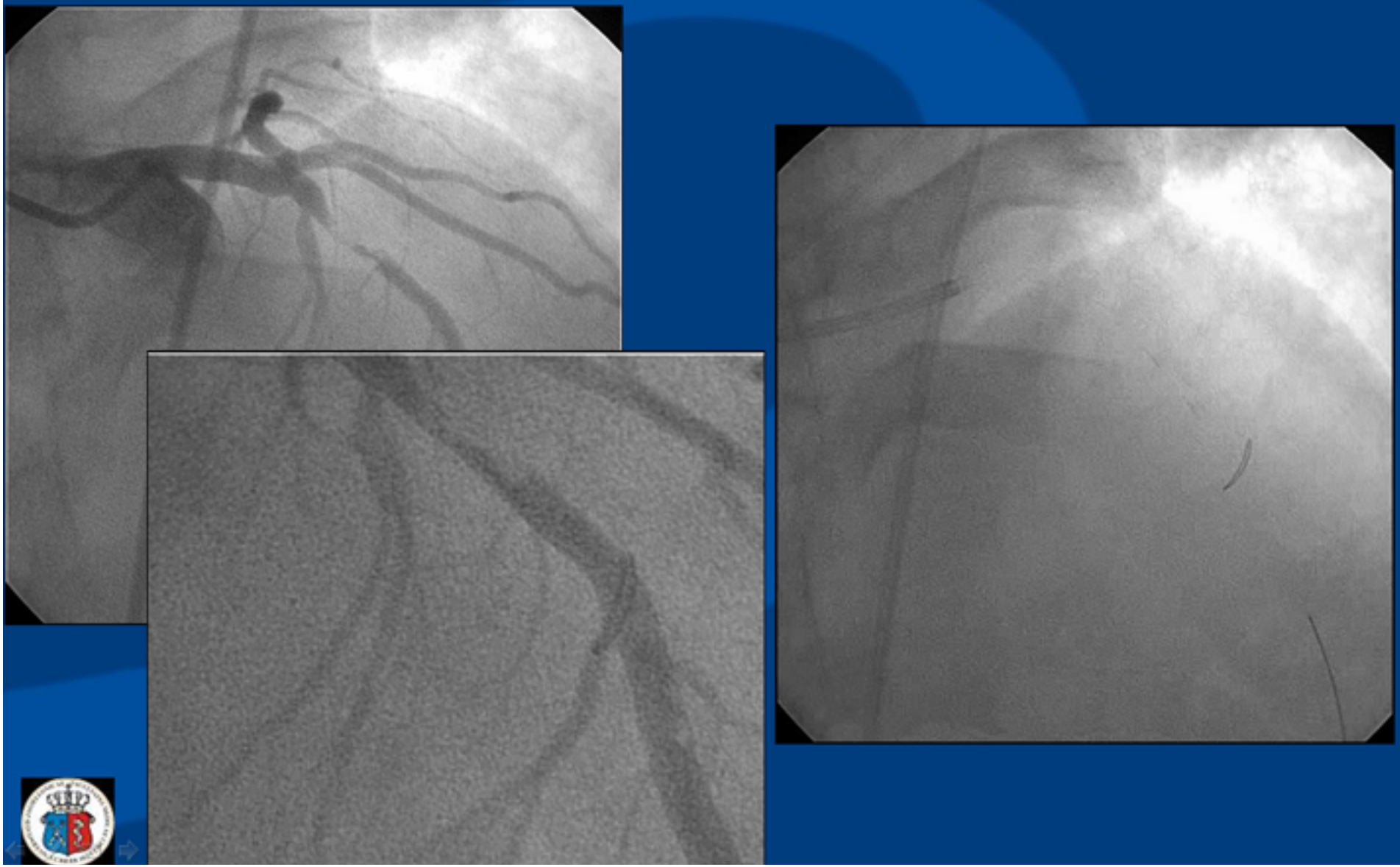

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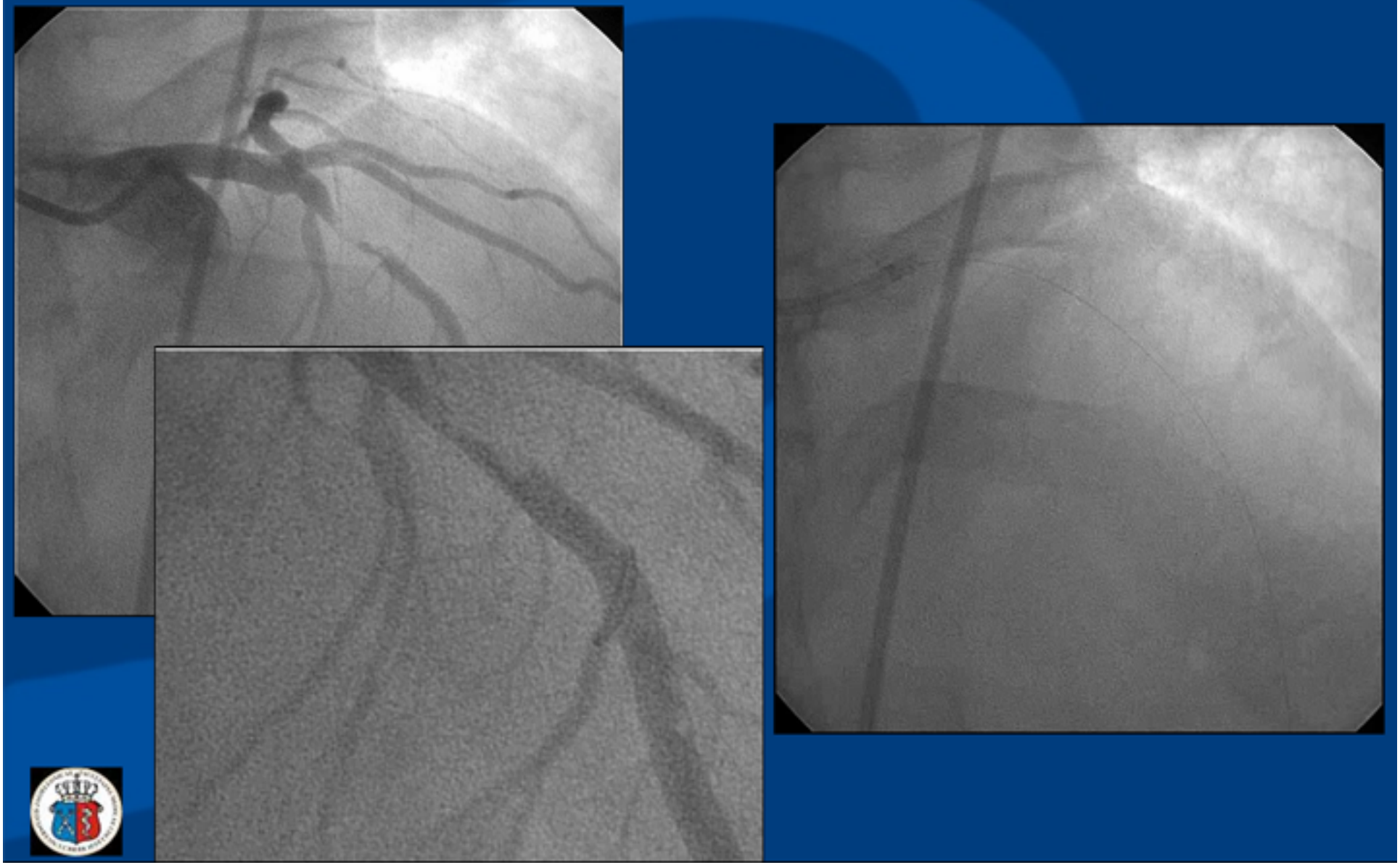

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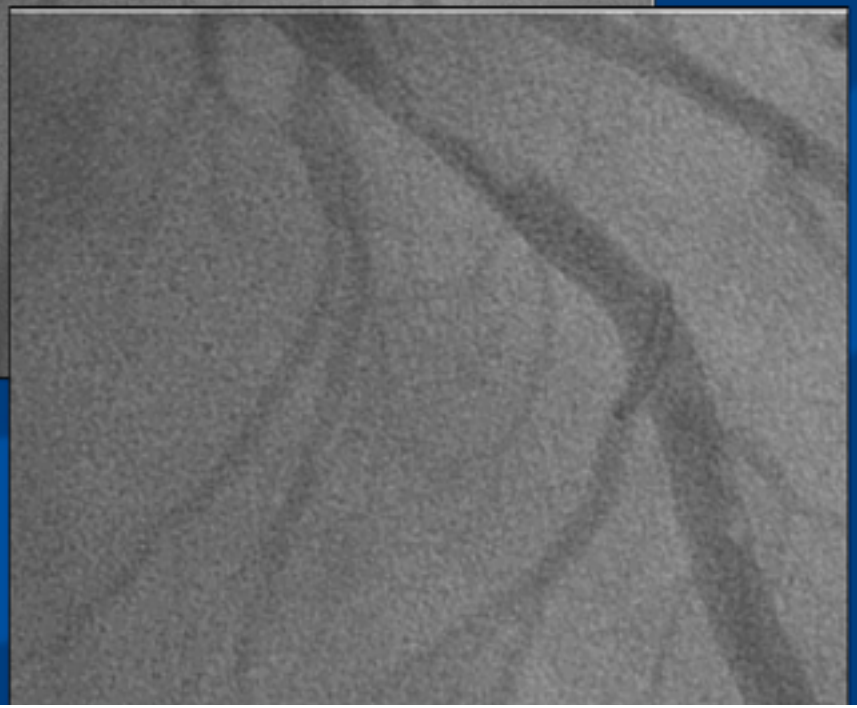

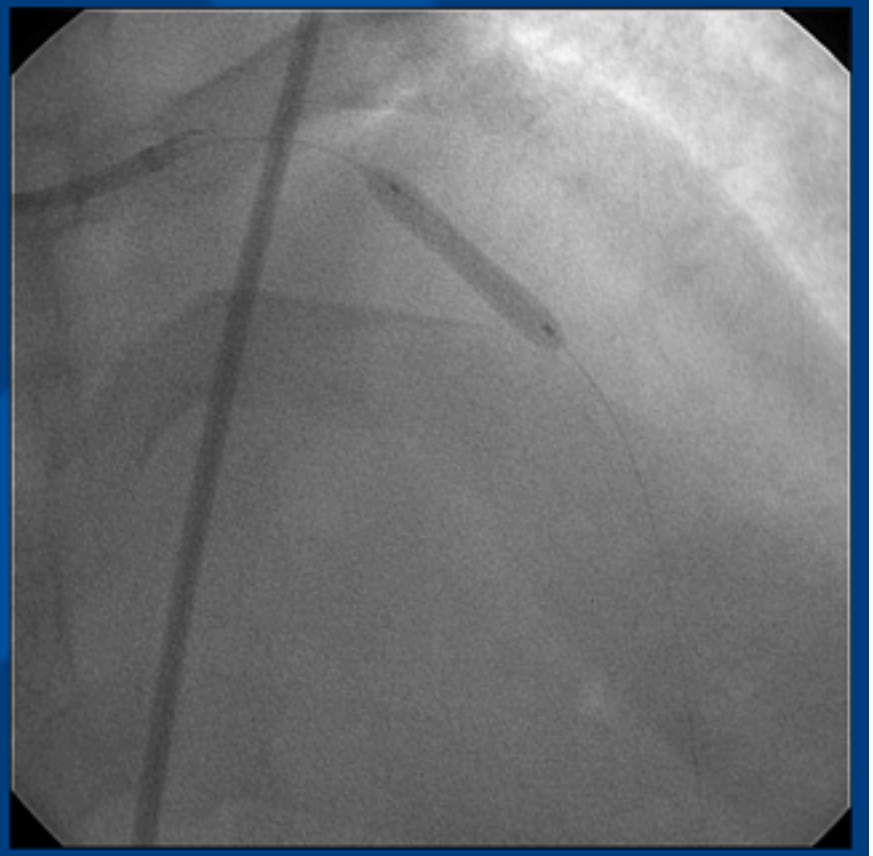

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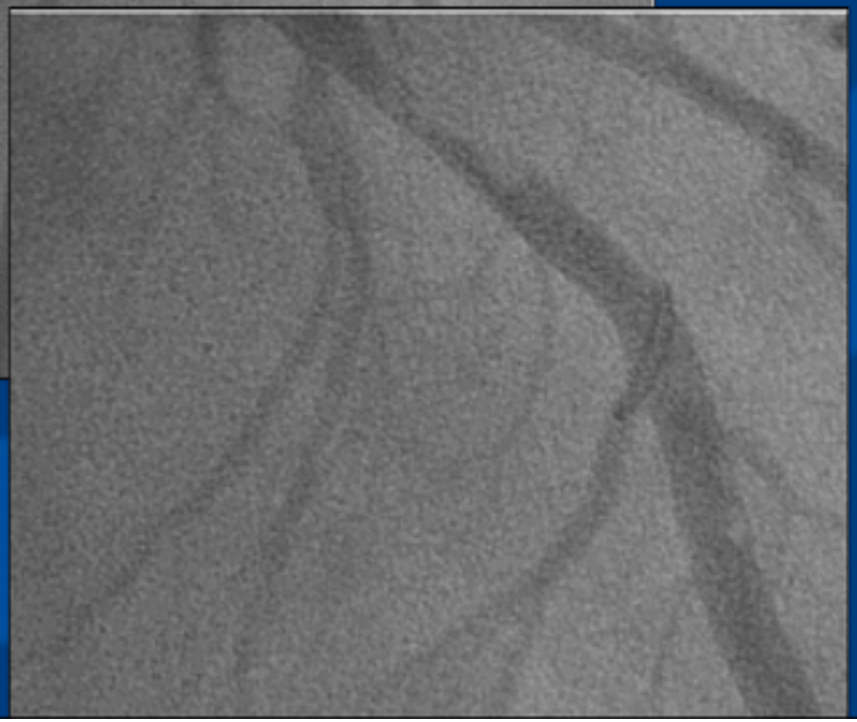

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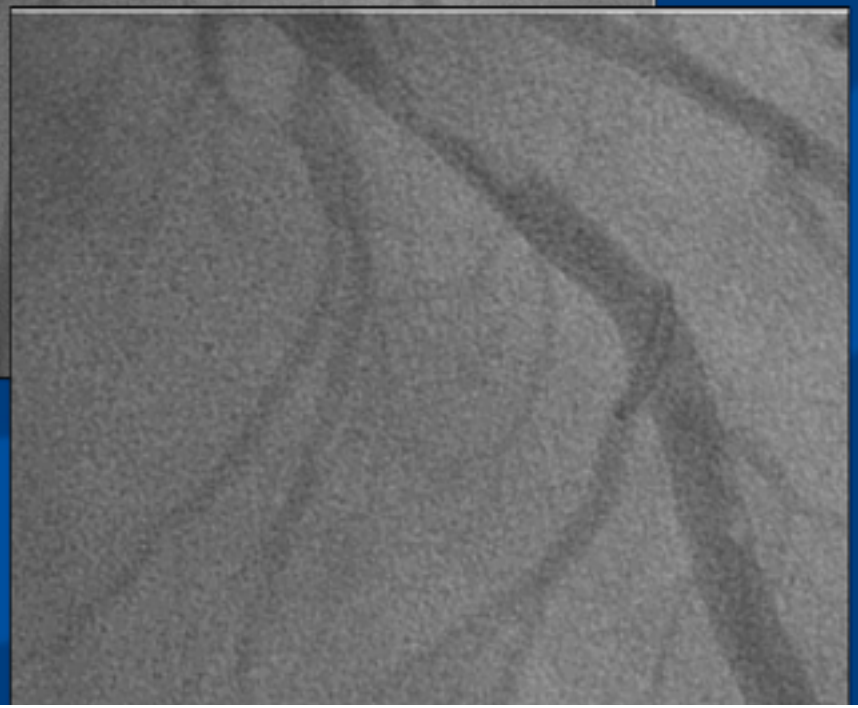

Thrombus Aspiration during Percutaneous coronary intervention in Acute myocardial infarction Study (TAPAS)

Inclusion criteria:
STEMI <12 hours

Exclusion criteria:
rescue PCI after thrombolytic therapy, inability to obtain informed consent, life expectancy of <6 months.

Randomization 1:1 before angiography (1080 pts)

Thrombus aspiration with Export Aspiration Catheter followed by IRA stenting

Balloon angioplasty followed by IRA stenting

Primary Endpoint:
MBG 0 to 1

Secondary Endpoints:
distal embolization;
TIMI after PCI,
ST-seg. resolution;
enzymatic infarct size;
MACE at 30 days, 1 year.

Am Heart J 2006; 151: 597

Conclusions – Take Home Messages

Patients with STEMI due to SVG occlusion treated with primary PCI are sicker, have poor acute procedural results, and higher early and late mortality in comparison to patients with STEMI due to native coronary artery occlusion

Distal embolization has been significantly reduced but not eliminated by mechanical protection devices - USE MECHANICAL PROTECTION WHENEVER POSSIBLE.

Conclusions – Take Home Messages

Intracoronary administration of vasodilators (sodium nitropruside, calcium channel blockers, adenosine) can prevent slow-flow and no-reflow phenomenon – THEY SHOULD BE USED NOT ONLY FOR TREATMENT, BUT FOR PREVENTION

Stents have substantially improved outcomes after PCI in SVG – DO NOT PREDILATE, GO WITH DIRECT STENTING whenever possible

Conclusions – Take Home Messages

Routine use of distal embolic protection and aspiration system during primary PCI for STEMI does not improve microvascular flow, reduce infarct size or enhance event-free survival (the benefit for low risk pts remains uncertain)

Thrombectomy should be considered prior to primary angioplasty in high risk pts (TIMI 0 or 1 after passage of wire; visible thrombus)

Clinical usefulness of different thrombectomy and proximal protection devices during primary PCI for STEMI have to be proven in further, clinical trials