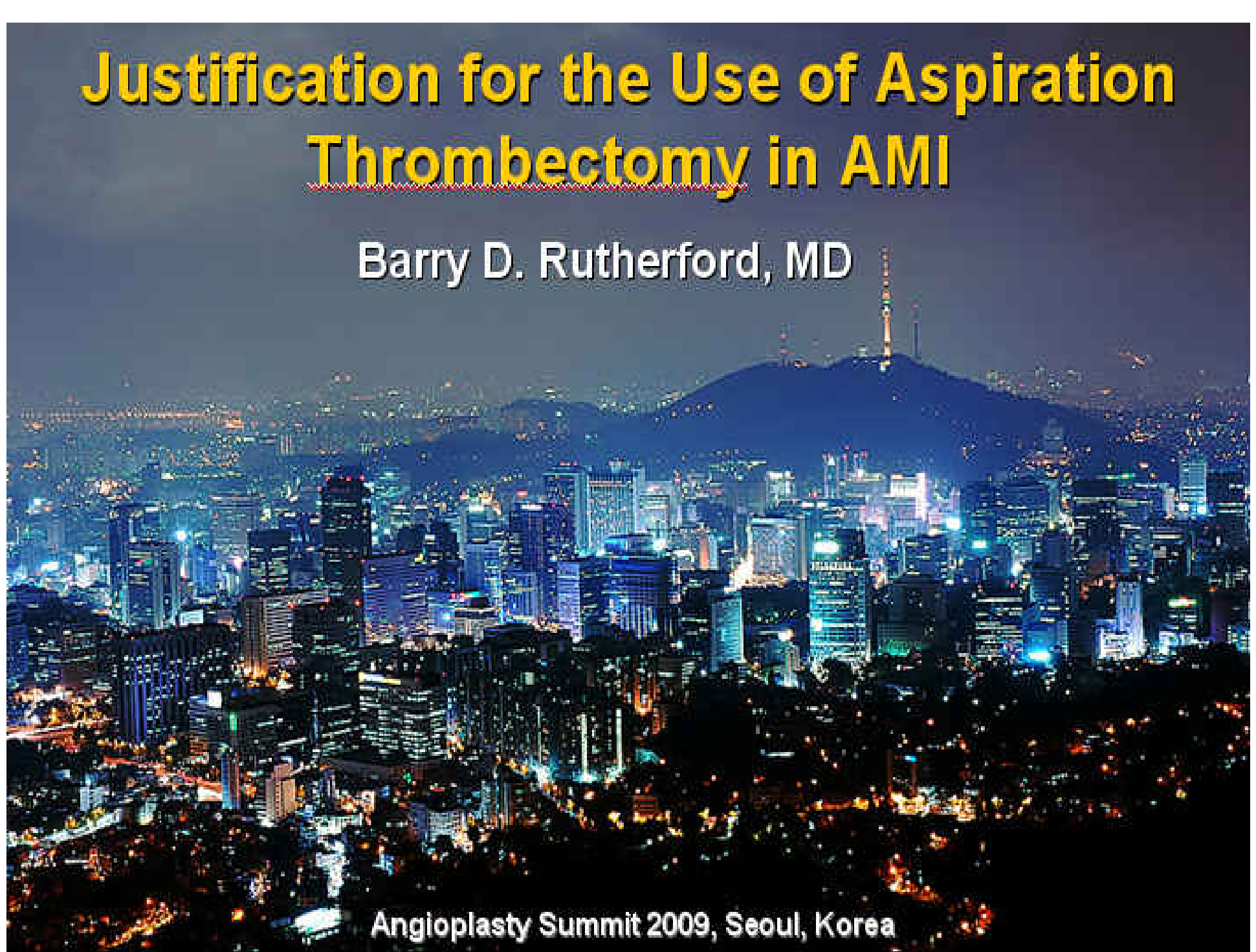


Justification for the Use of Aspiration Thrombectomy in AMI

Barry D. Rutherford, MD

Angioplasty Summit 2009, Seoul, Korea



The New England Journal of Medicine

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Volume 303

OCTOBER 16,

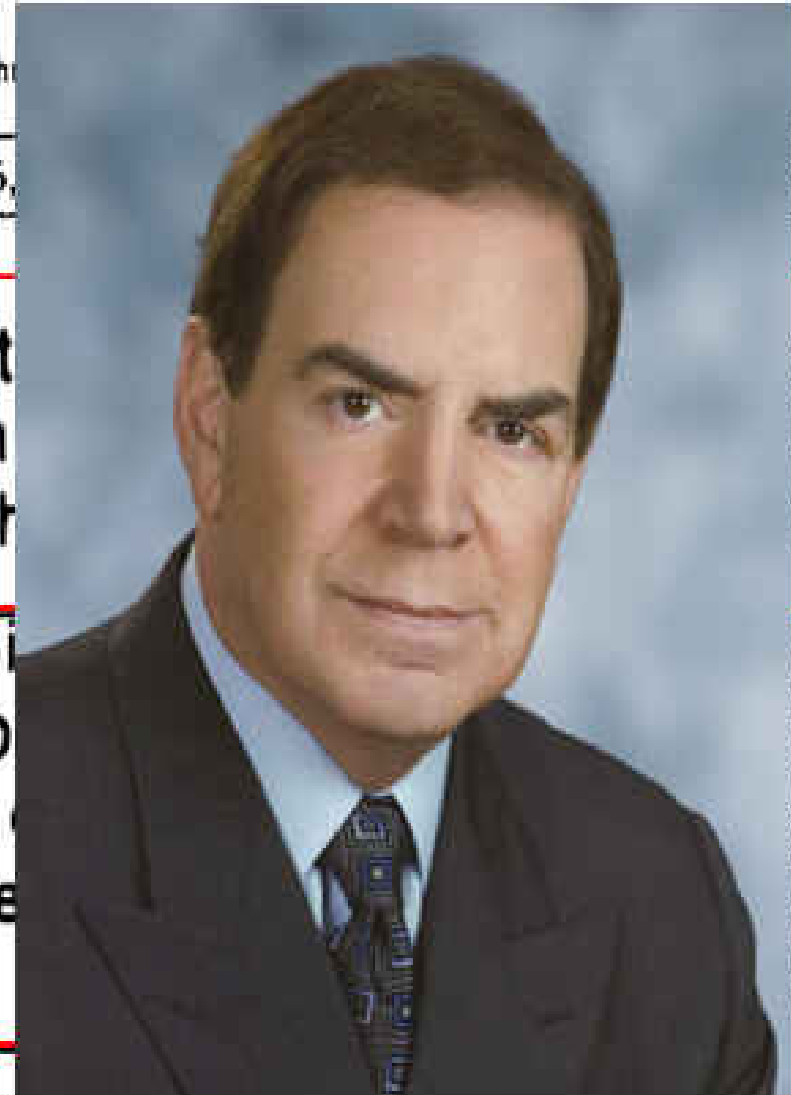
16

PR

Among 59 patient
tures of coronary throm
retrieved by Fogarty cath

clusi

cent) who were evaluated withi
onset of symptoms; this propo
nificantly, to 37 of 57 (65 per
were studied 12 to 24 hours after
toms.



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54-yo Female Acute Inferior Wall STEMI



Distal Emboli, Slow Flow, No Reflow: 15-20%
Microvascular Dysfunction: 30%

Pathophysiology of No-Reflow

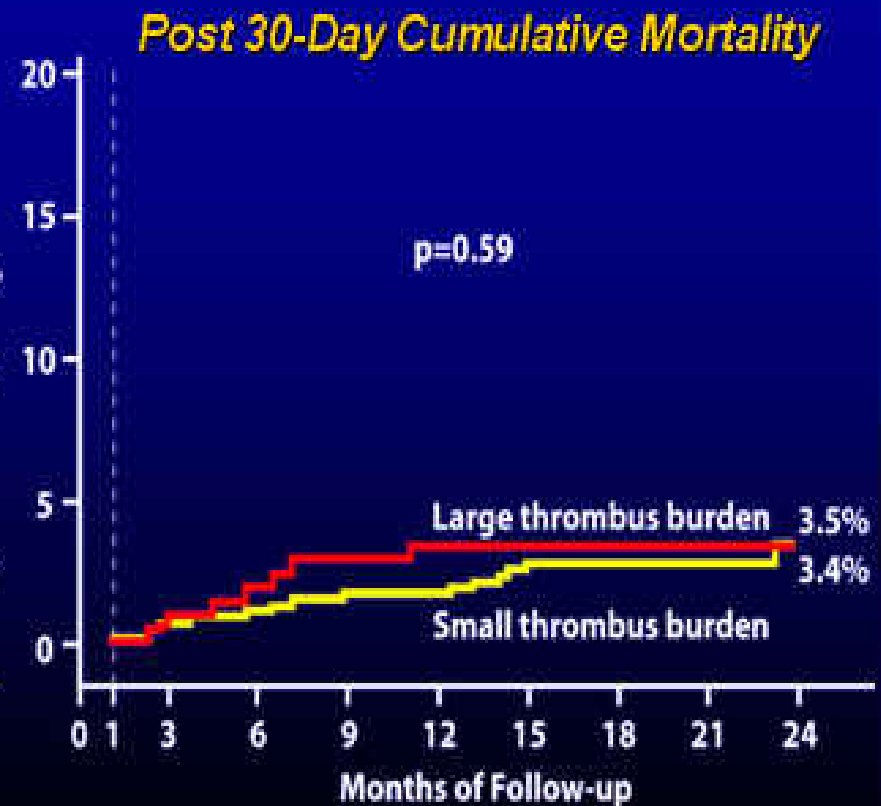
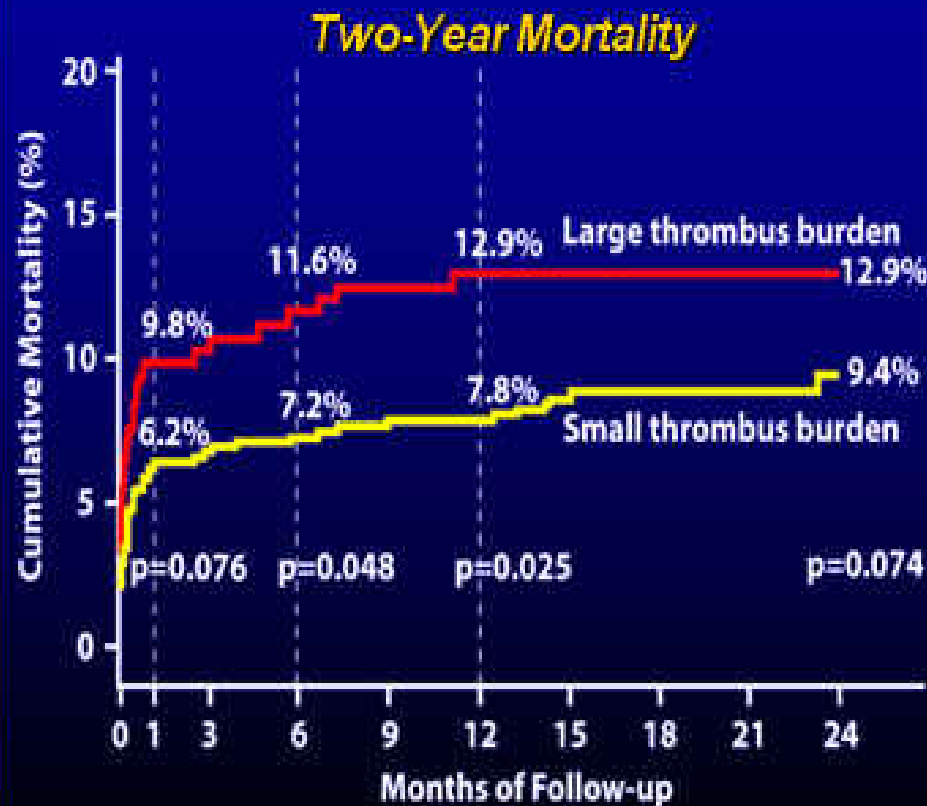
- Thromboembolic / Atheromatous debris
- Coronary spasm
- Microvascular disruption / necrosis
- Endothelial and myocardial edema
- Coagulation / Shedding of Active Tissue Factor
- Hypercholesterolemia – activation of K_{ATP} channels
- Hyperglycemia

Aim: to prevent rather than have to treat

Angiographic Stent Thrombosis After Routine Use of DES in STEMI: The Importance of Thrombus Burden

Impact of Thrombus Burden on Mortality

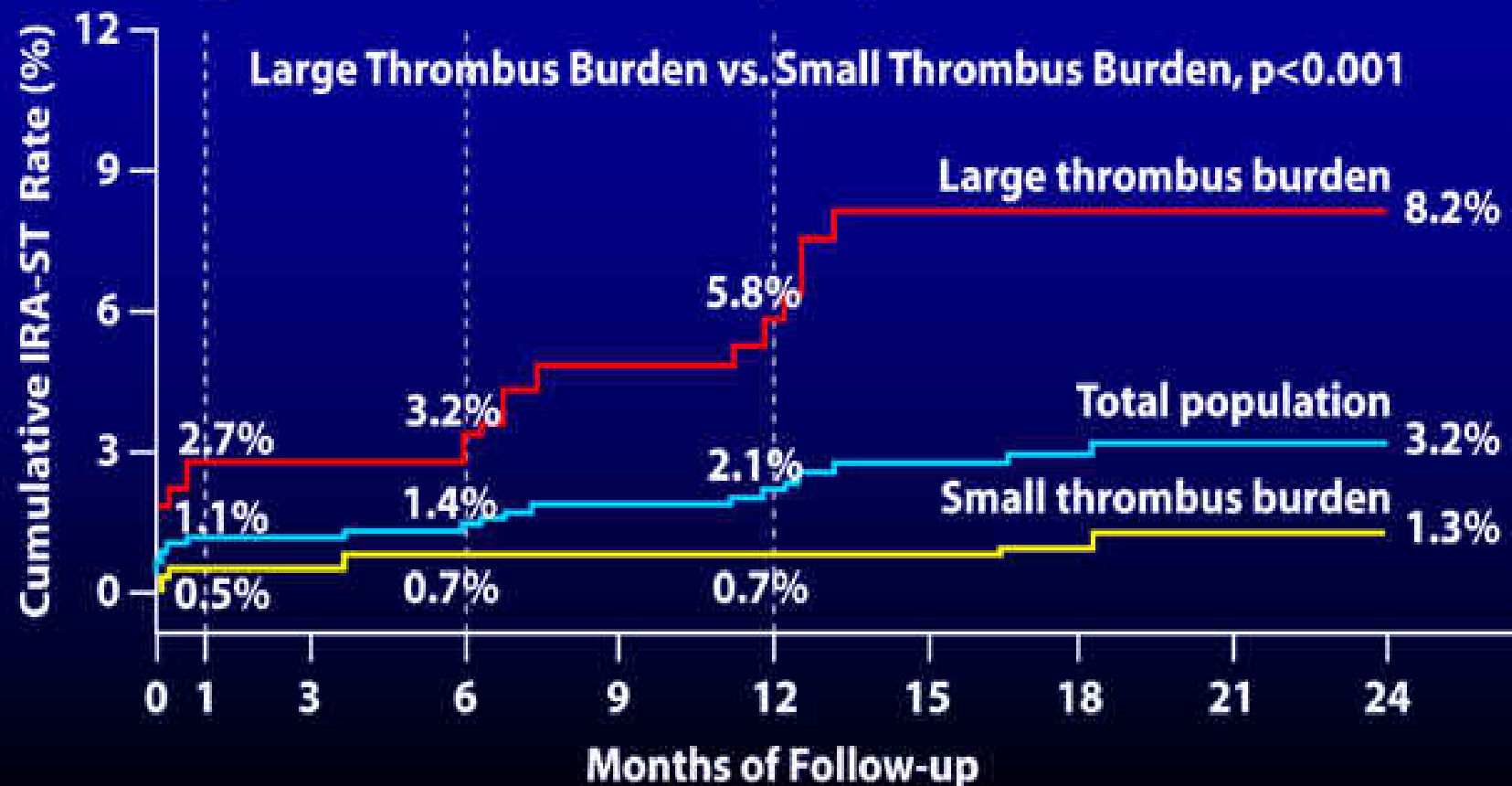
812 pts, Apr 2002-Dec 2004, STEMI ≤ 12 hrs; F/U 18.2 ± 7.8 months
Large Thrombus Burden (LTB) ≥ 2 vessel diameters



Angiographic Stent Thrombosis After Routine Use of DES in STEMI: The Importance of Thrombus Burden

Cumulative Infarct-Related Artery Stent Thrombosis

812 pts, Apr 2002-Dec 2004, STEMI ≤ 12 hrs; F/U 18.2 ± 7.8 months
Large Thrombus Burden (LTB) ≥ 2 vessel diameters



Primary PCI in AMI With or Without Adjunctive Thrombectomy: A Meta Analysis

16 Randomized Trials: 2,944 pts

	OR
Significantly less no-reflow	0.35
More frequent ST <u>seg</u> resolution	2.24
More frequent MPG 3	2.45
No difference in death, Re-MI, stroke	1.16
No significant difference in: Post-procedure TIMI 3 flow Distal <u>embolization</u> or procedure time	0.84

Thrombectomy did not increase LVEF

Aspiration Thrombectomy Catheters

**Export
XT**

**Export
6F**

**Export
7F**

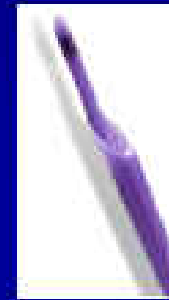
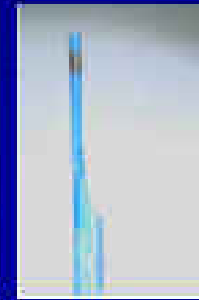
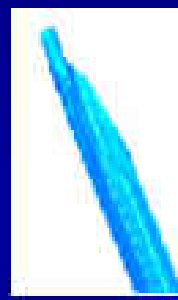
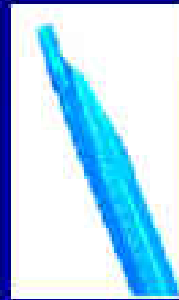
**Pronto
V3**

**Diver
(sideholes)**

QuickCat

Fetch

**Aspiration
Tip**



**Tip
Design**

Soft,
beveled
short tip

Bevel
cut

Bevel
cut

Rounded
"bull-
nose" tip
with slot
cut to
prox tip

Bevel cut
with long
tip and 3
side
holes

Bevel cut
with long
tip

Convex
cut

**Distal
Lumen (in)**

0.041

0.041

0.050

0.047

0.033

0.041

0.044

Lossy Compression - not intended for diagnosis

**65-yo
Male
with
lateral
wall
STEMI**

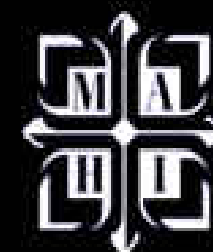


Lossy Compression - not intended for diagnosis

60-yr
Male

Acute
Anterior
STEMI

8-30-05





60-yr Male Acute Anterior STEMI 8-30-05

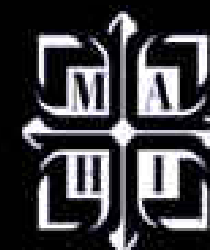


Lossy Compression - not intended for diagnosis

**60-yr
Male**

**Acute
Anterior
STEMI**

**3-yr F/U
2-5-08**



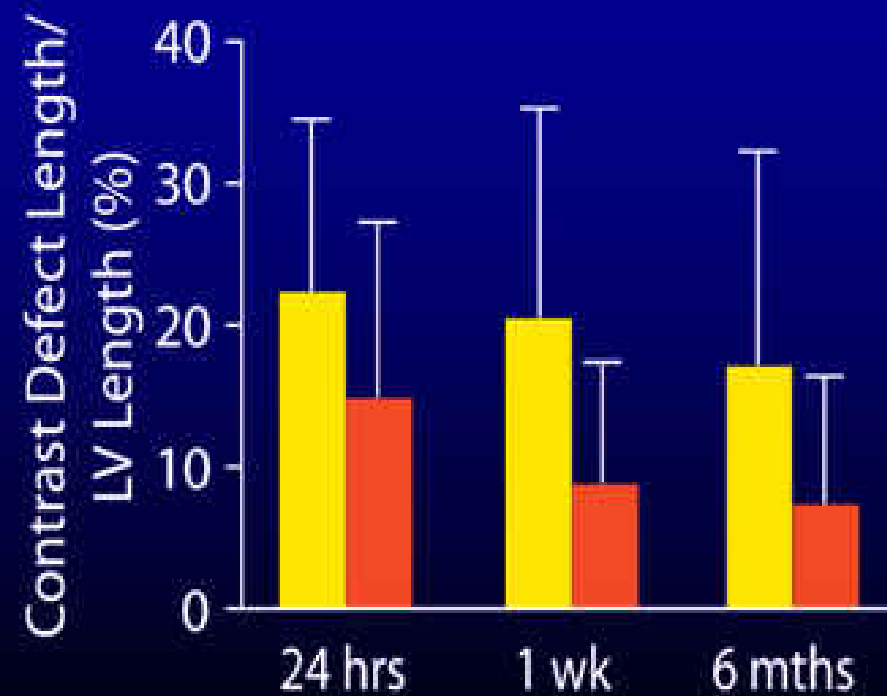
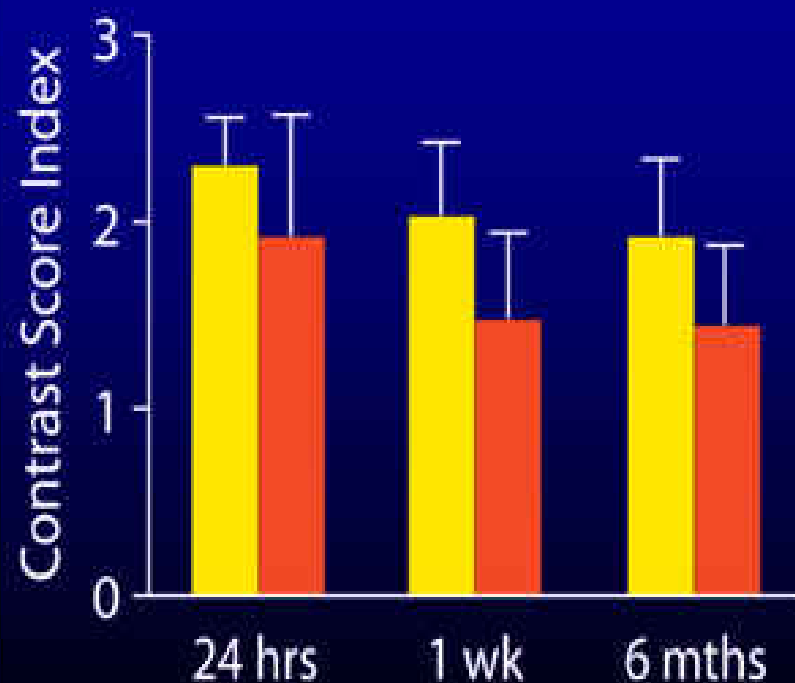
**Thrombus Aspiration Improves Myocardial Reperfusion
(REMEDIA) Trial: STEMI within 12 hours of Onset.
Aspiration Device: Diver CE (Invatec, Brescia, Italy)**

	Thrombus Aspiration N = 50	Standard PCI N = 49	p-value
Post MBG ≥ 2	68.0%	44.9%	0.02
Post STR $\geq 70\%$	58.0%	36.7%	0.03
MBG ≥ 2 + STR $\geq 70\%$	46.0%	24.5%	0.02

Thrombus Aspiration Reduces Microvascular Obstruction After Primary Coronary Intervention: An MCE Substudy of the REMEDIA Trial

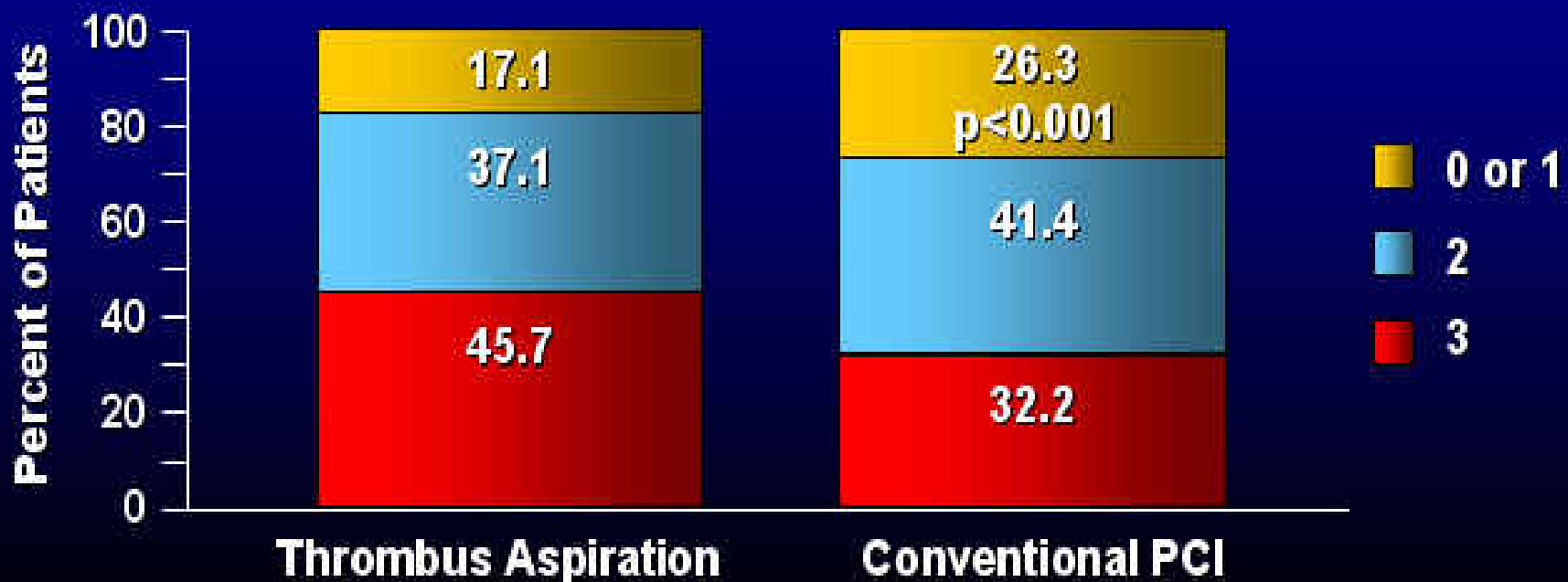
MCE done at 24 hrs, 1 wk & 6 months post PCI. 50 pts, randomized to std PCI vs PCI with thrombus aspiration (Diver CE, Invatec, Italy)

■ Control ■ Thrombus Aspiration



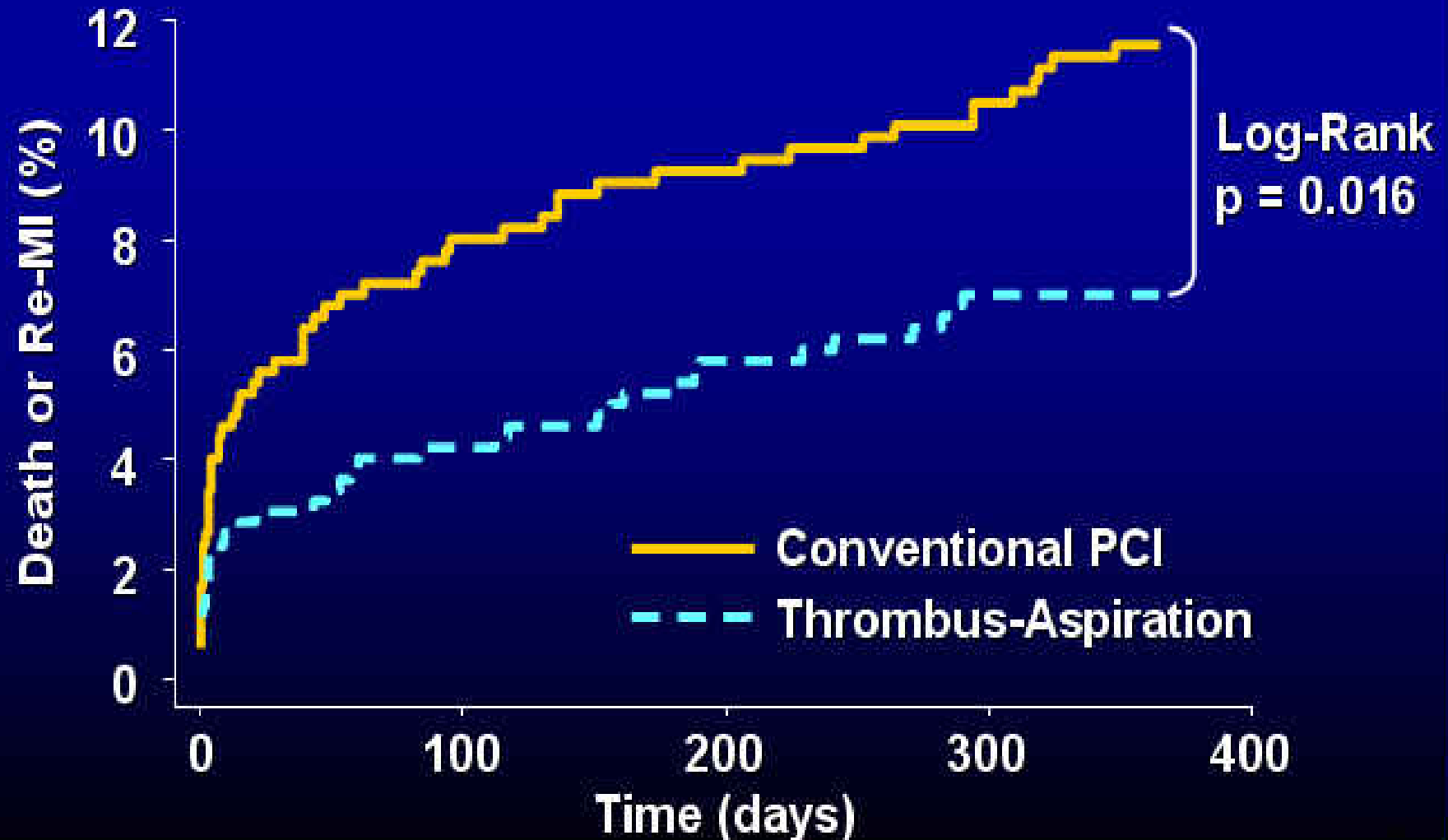
Thrombus Aspiration During Primary Percutaneous Intervention in AMI Study (TAPAS)

- 1071 STEMI pts, randomized (before angio) to Aspiration Thrombectomy with Export Catheter (533 pts) vs. Standard Primary PCI (536 pts)
- **Primary Endpoint:** Myocardial Blush Grade



TAPAS

Mortality or Non-fatal Re-MI at 1 Year



Aspiration Thrombectomy for AMI Improves Myocardial Salvage Index: Single Center Randomized Study

127 pts, 1st STEMI \leq 12 hrs, Std PCI vs AT Rescue or Diver
Salvage index assessed by sestamibi SPECT imaging

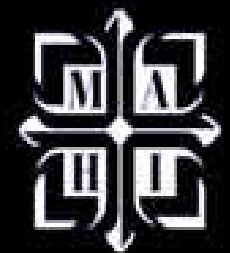
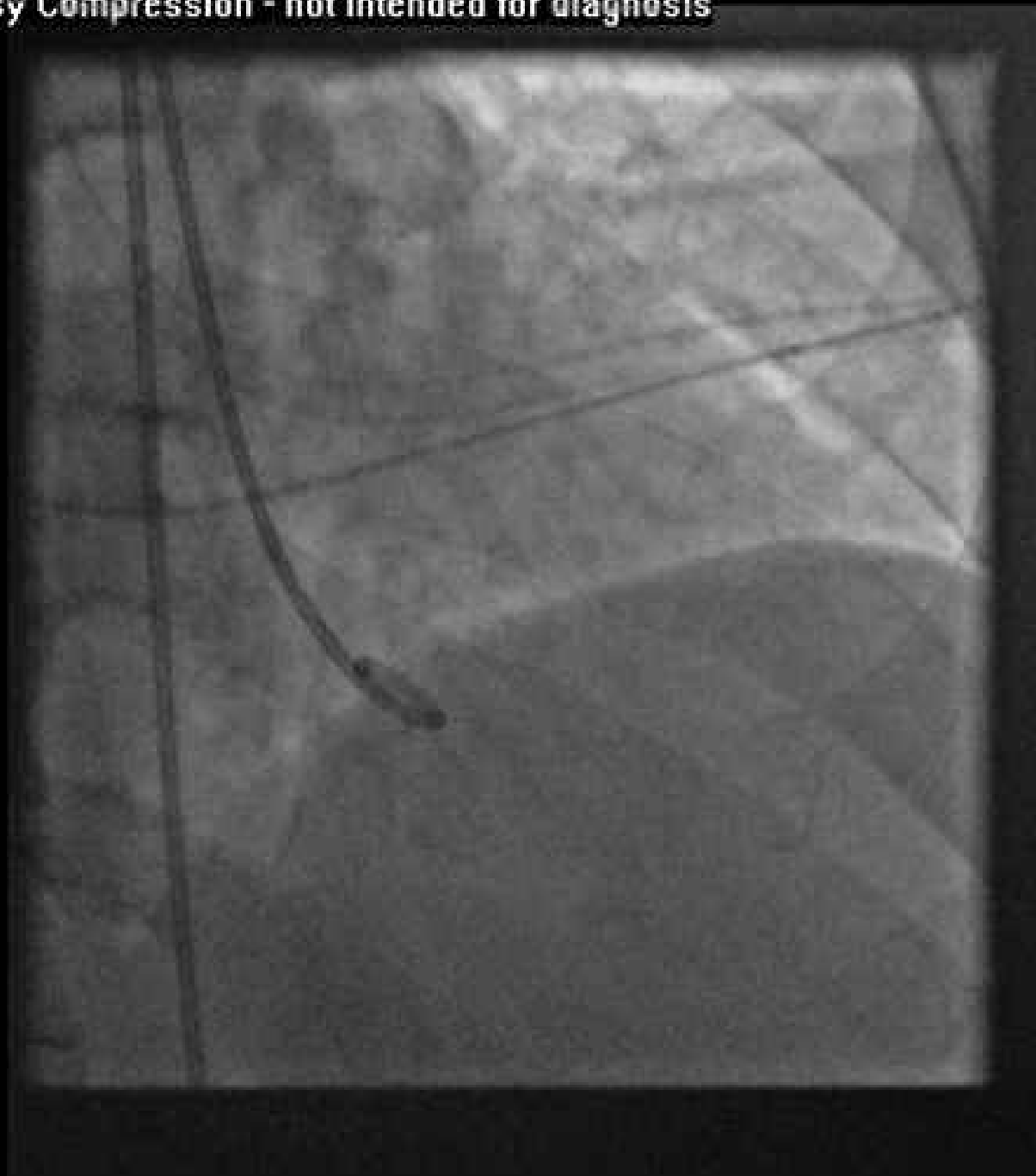
	Aspiration <u>Thrombectomy</u> N = 63	Control N = 64	p-value
Area of Myocardium at Risk	35.0 \pm 12.8%	35.8 \pm 10.9%	NS
Myocardial Salvage Index	0.33 \pm 0.27	0.20 \pm 0.21	0.004
Final Infarct Size	23.9 \pm 13.1%	28.3 \pm 9.6%	0.005

Steps in the Interventional Management of STEMI

1. Wire crossing of the lesion
2. Aspiration thrombectomy
3. IVUS evaluation
4. Direct stenting
5. Repeat IVUS evaluation

Lossy Compression - not intended for diagnosis

**52-yr
Male;
Acute
Inf MI**

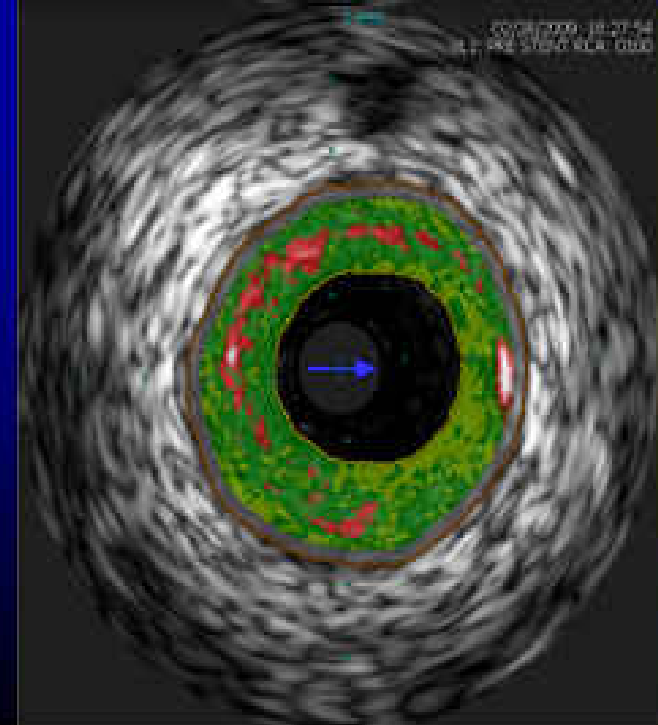
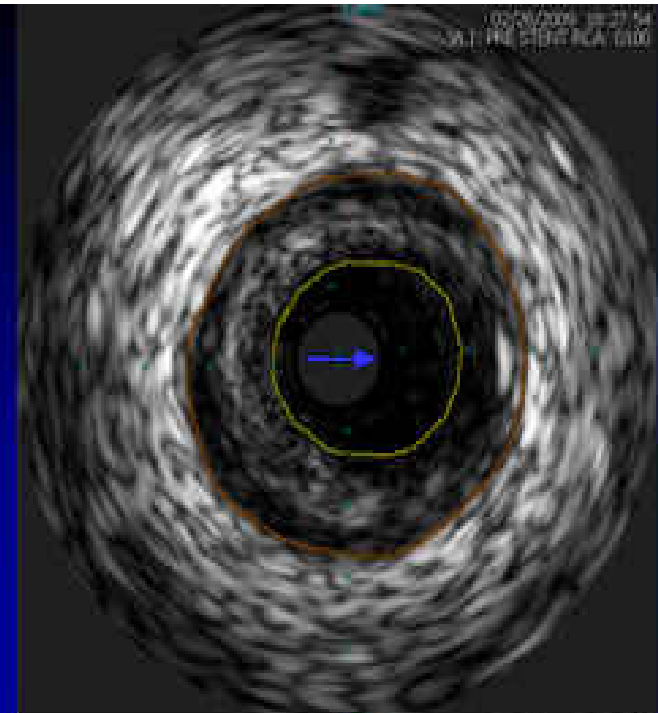
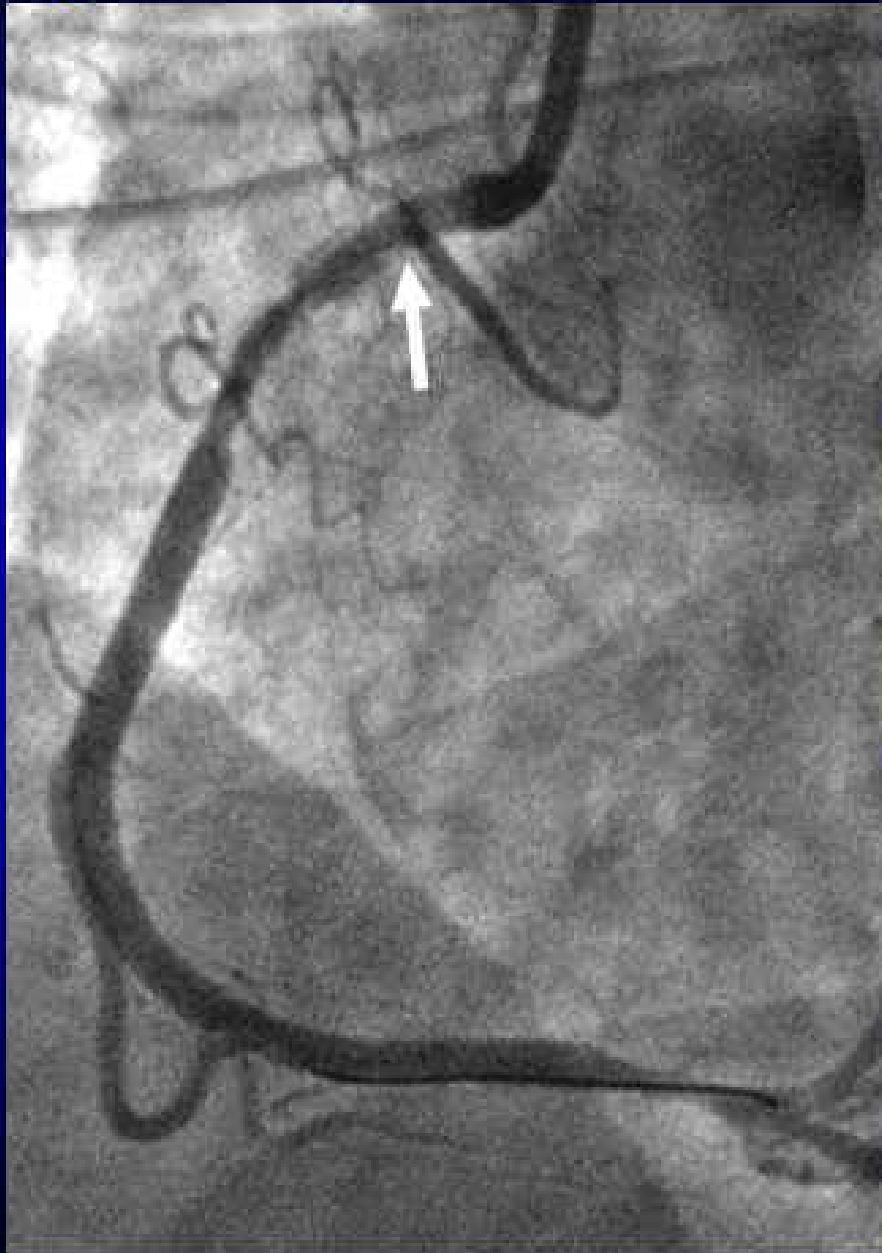


52-yr Male

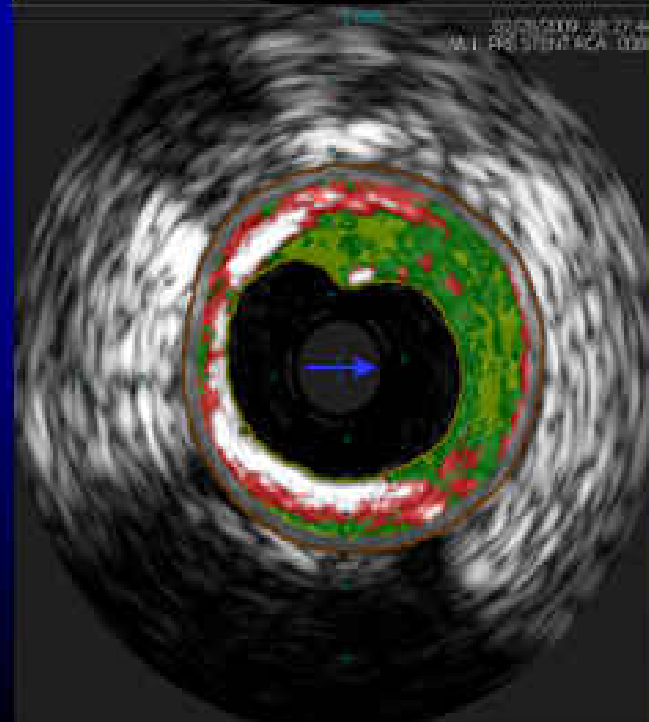
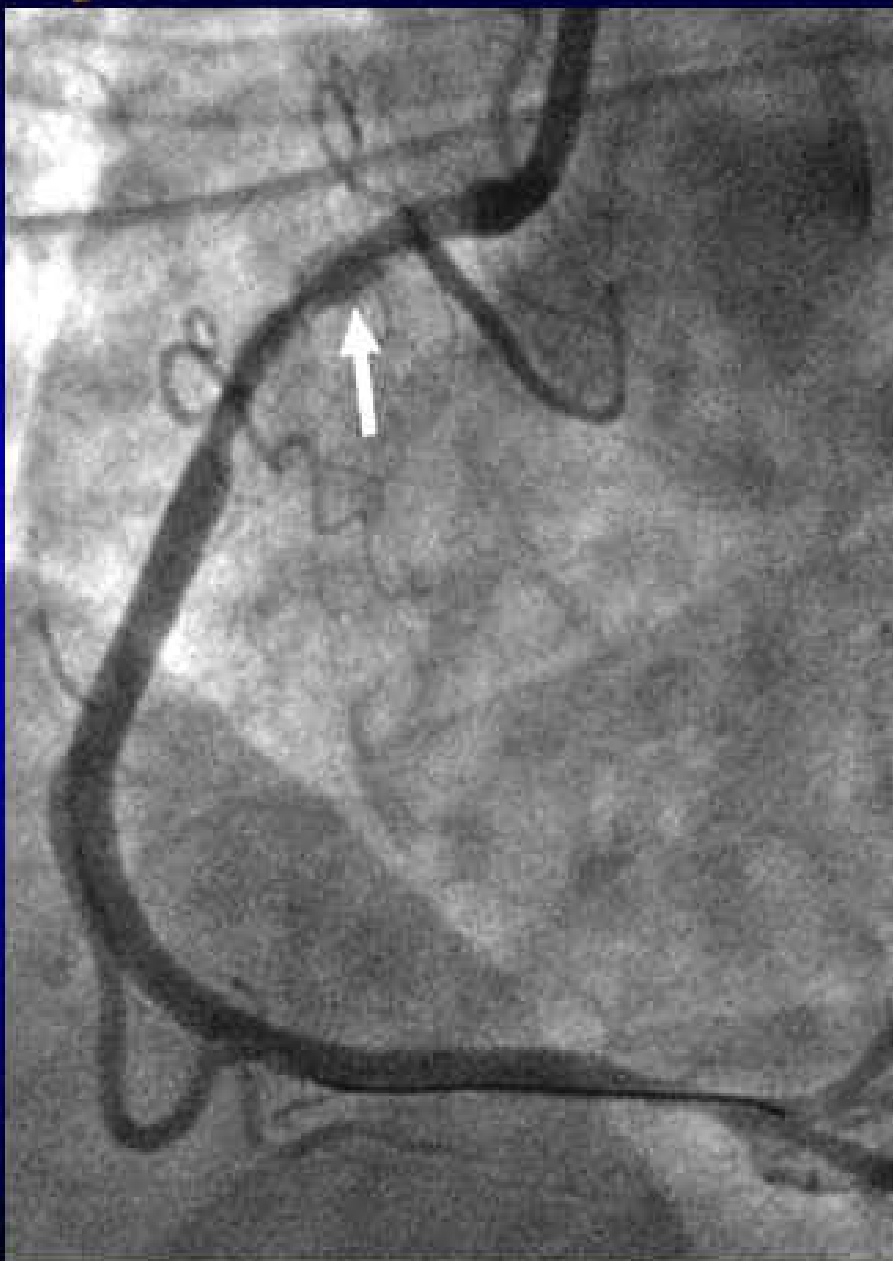
**Acute
Inferior MI**



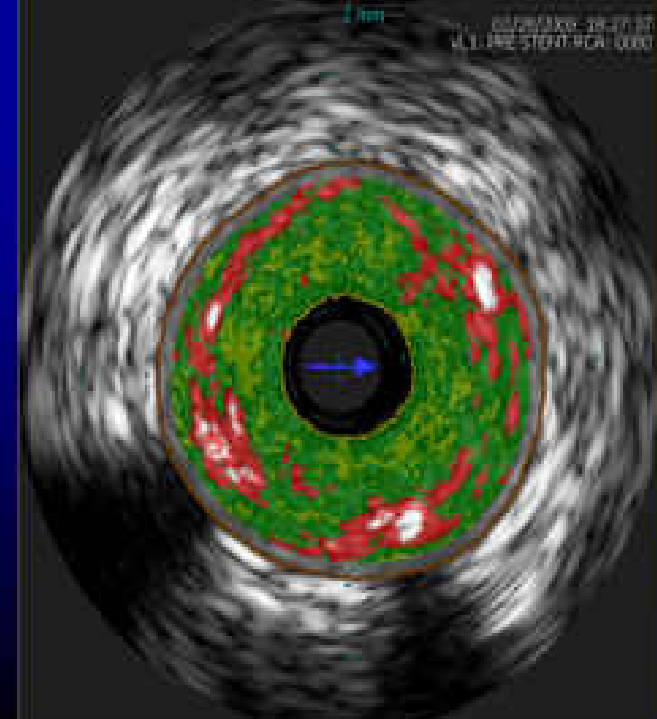
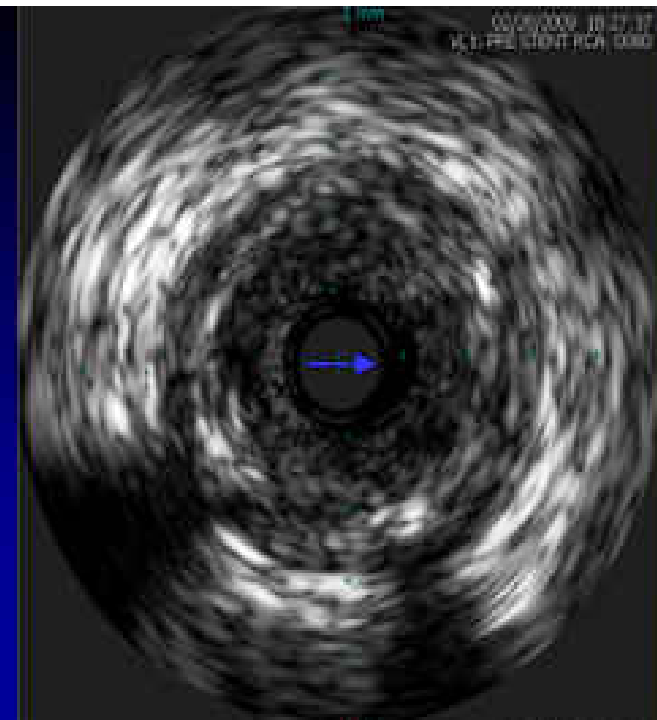
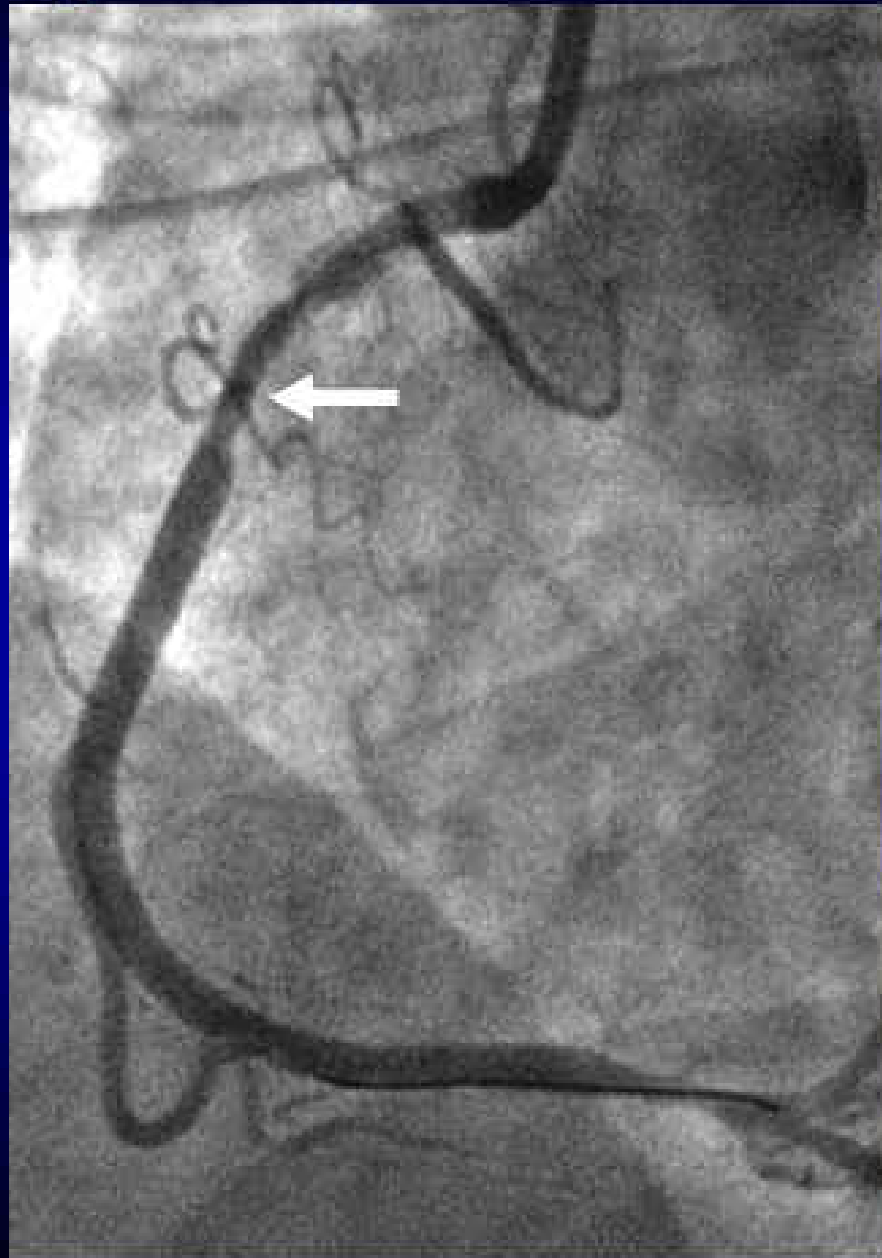
52-yr Male; Acute Inferior MI



52-yr Male; Acute Inferior MI



52-yr Male; Acute Inferior MI



Justification for the Use of Aspiration Thrombectomy in AMI: *Conclusions*

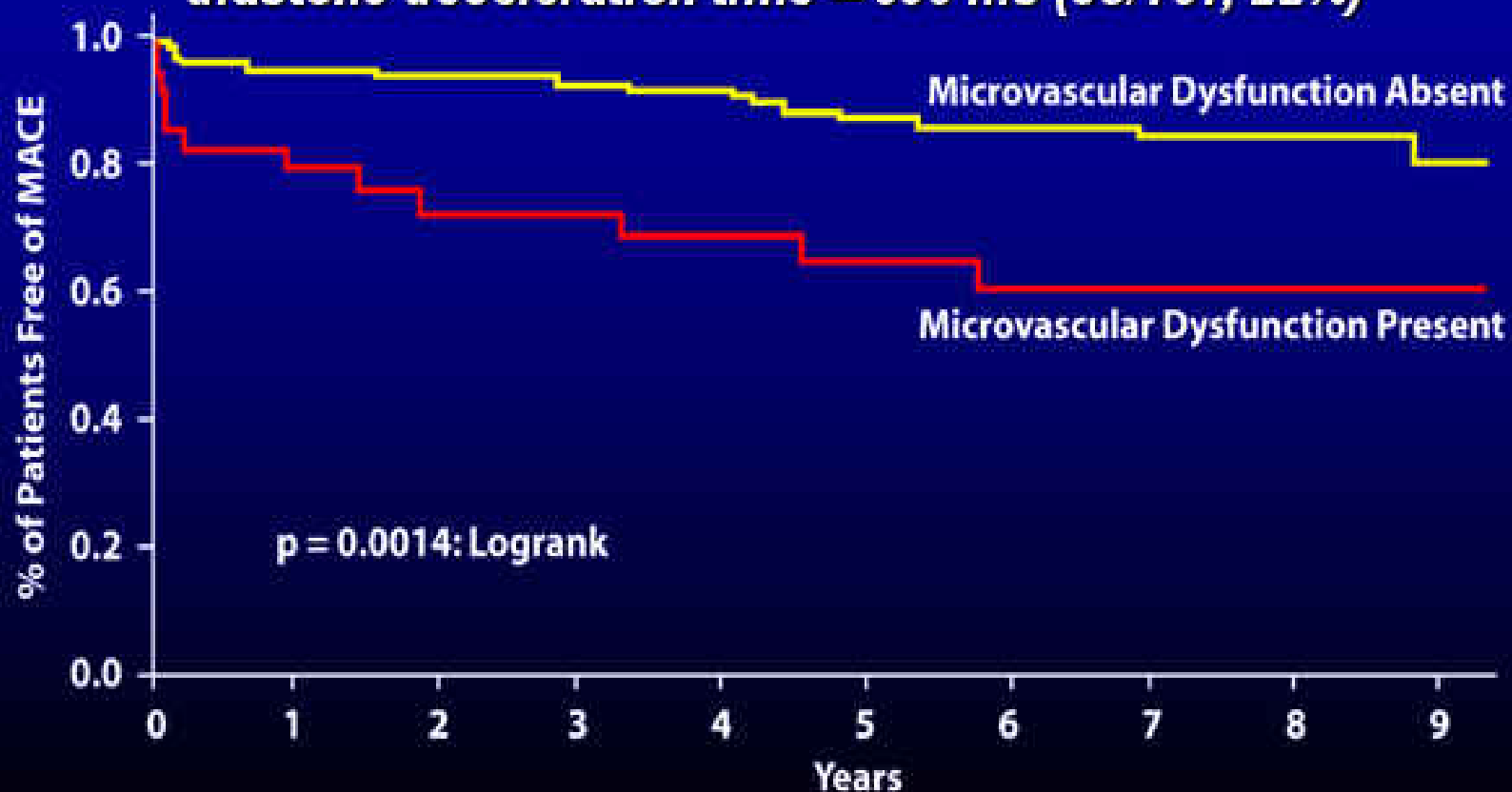
- Distal Protection, Rheolytic Thrombectomy, Filter devices have not been shown to reduce complications or improve microvascular flow
- Aspiration Thrombectomy has been shown to reduce no-reflow and increase microvascular perfusion and improve long-term clinical outcomes
- Therefore, there is justification for routine use of aspiration thrombectomy as a primary device, then IVUS evaluation, followed by direct stenting

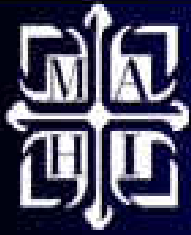


Extra Slides

Impact of Microvascular Dysfunction on Long-Term Cardiovascular Events After Primary PCI for AMI in Patients Achieving TIMI-3 Reperfusion

161 pts, 1st anterior MI, successful reperfusion. Coronary flow velocity assessed by Doppler guidewire, microvascular dysfunction defined as diastolic deceleration time ≤ 600 ms (35/161, 22%)





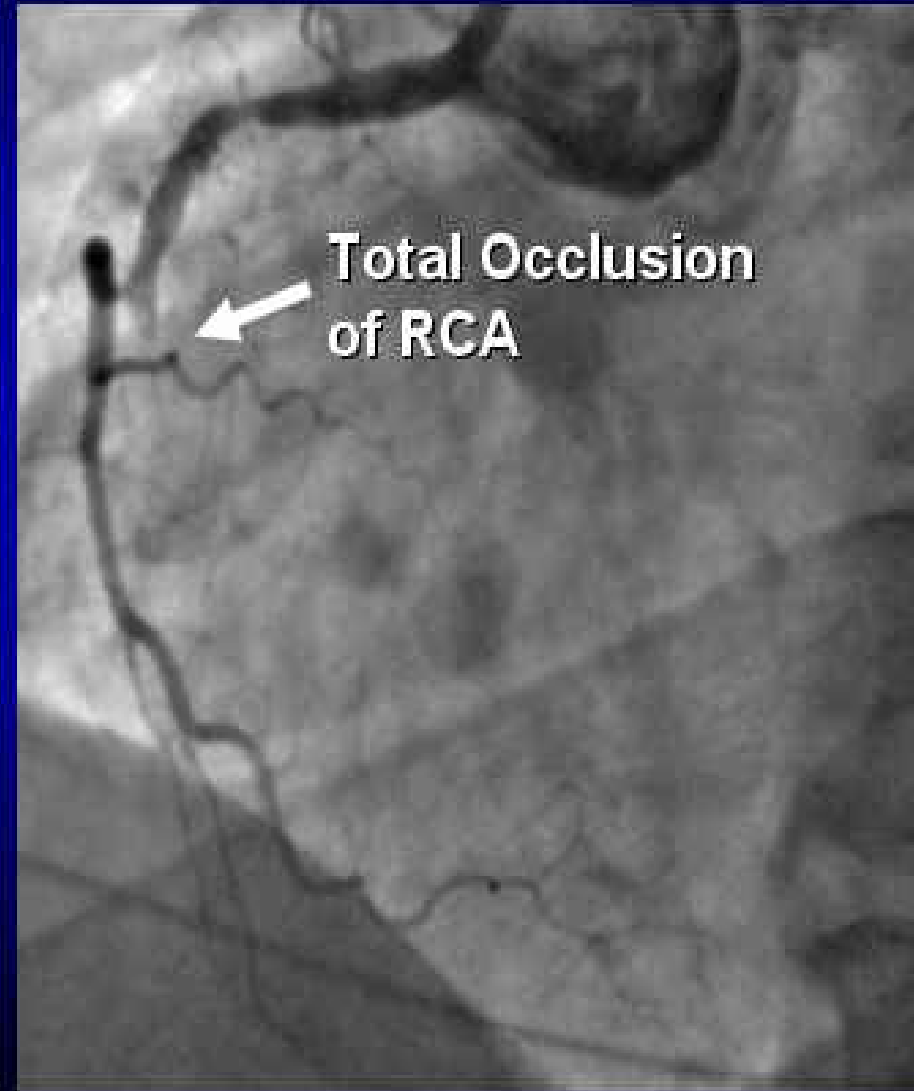
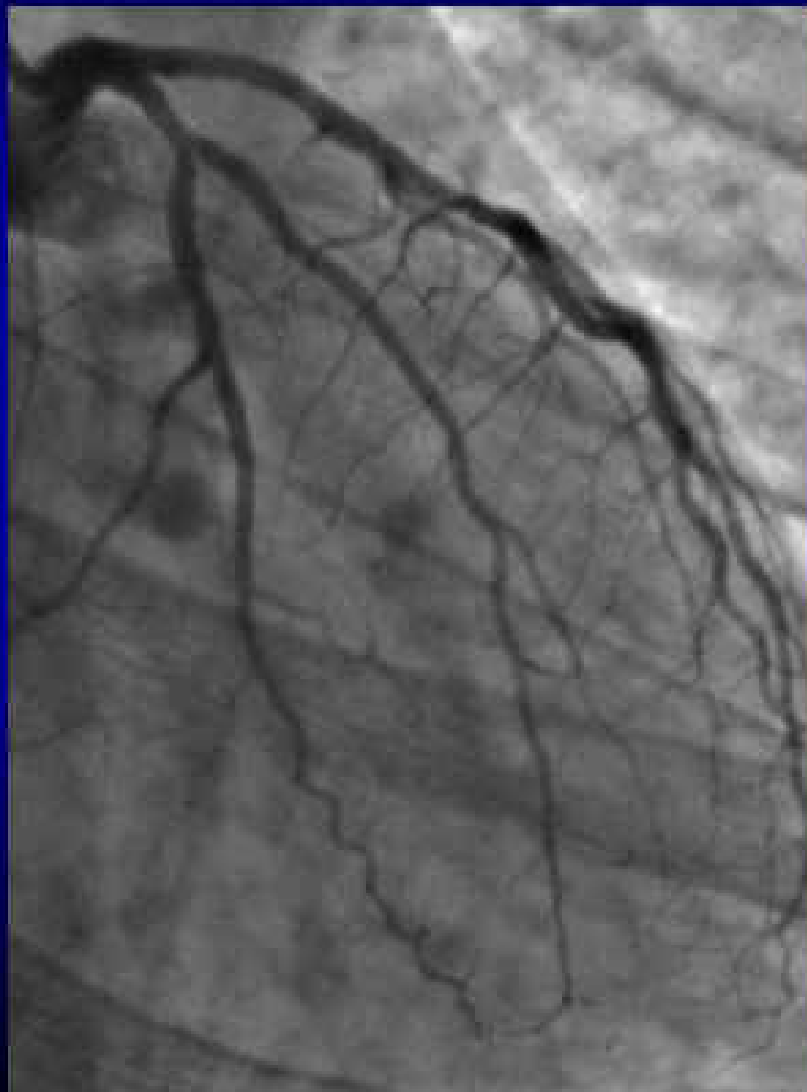
Use of IVUS in the Management of the STEMI Patient

Value of IVUS:

- Infarct vessel size is always underestimated by angiography
- Define the longitudinal limit of disease
- Value of Virtual Histology
- Large necrotic core is associated with distal emboli

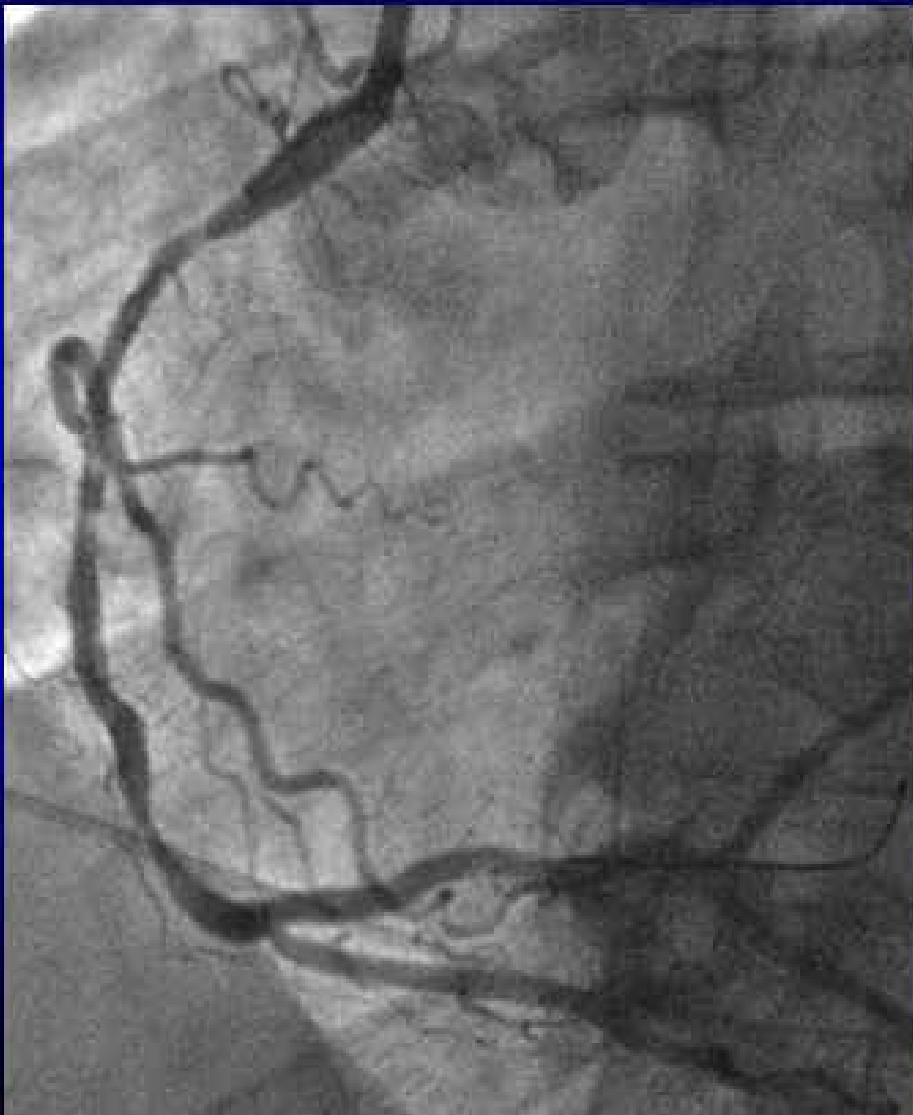


46-Year-Old Male
Acute Inferior STEMI 4-8-2006



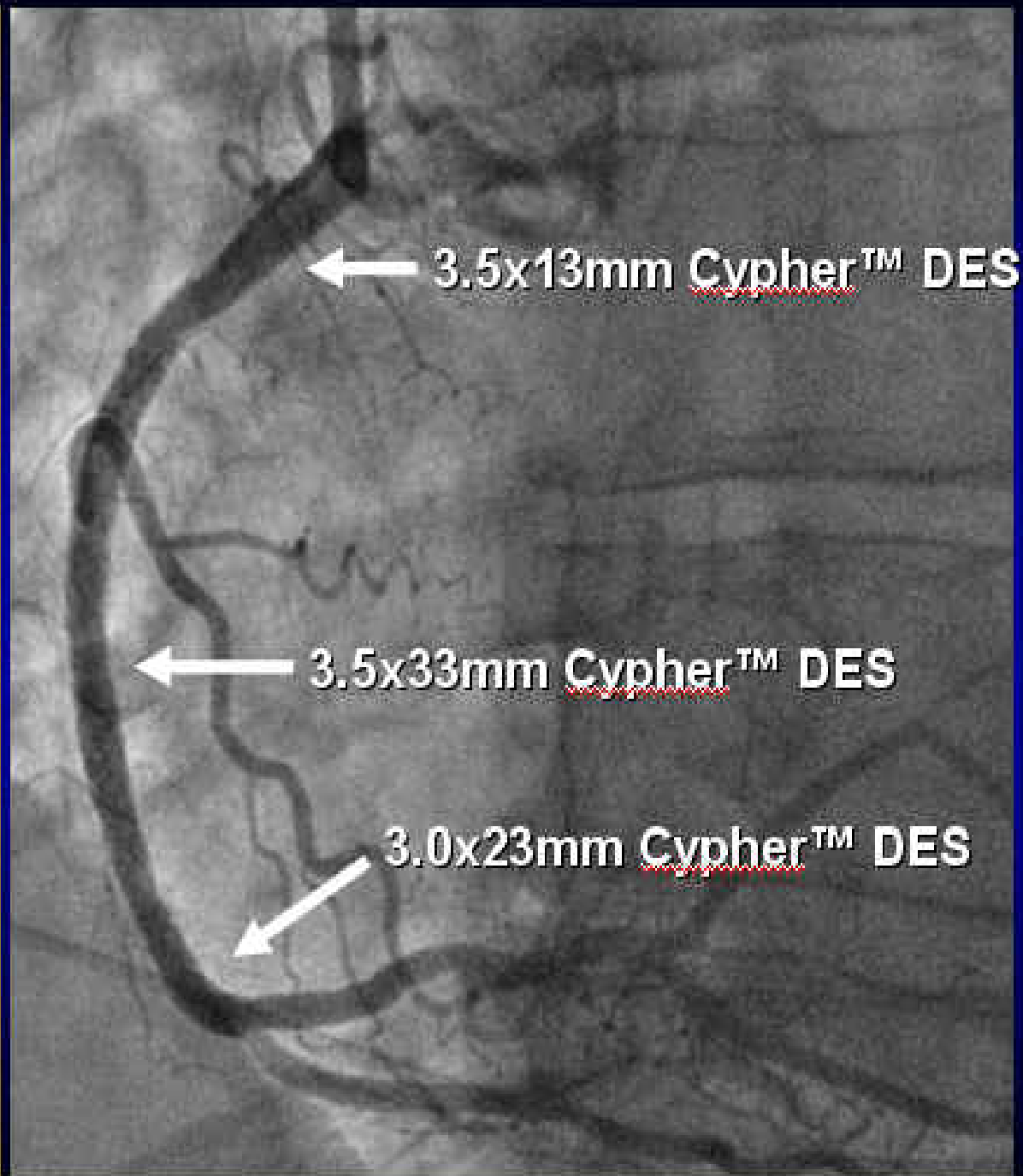


46-y/o Male: Acute Inferior STEMI 4-8-2006
Following PCI and EXPORT™ Catheter



**46-Year-Old Male
Acute Inferior
STEMI 4-8-2006**

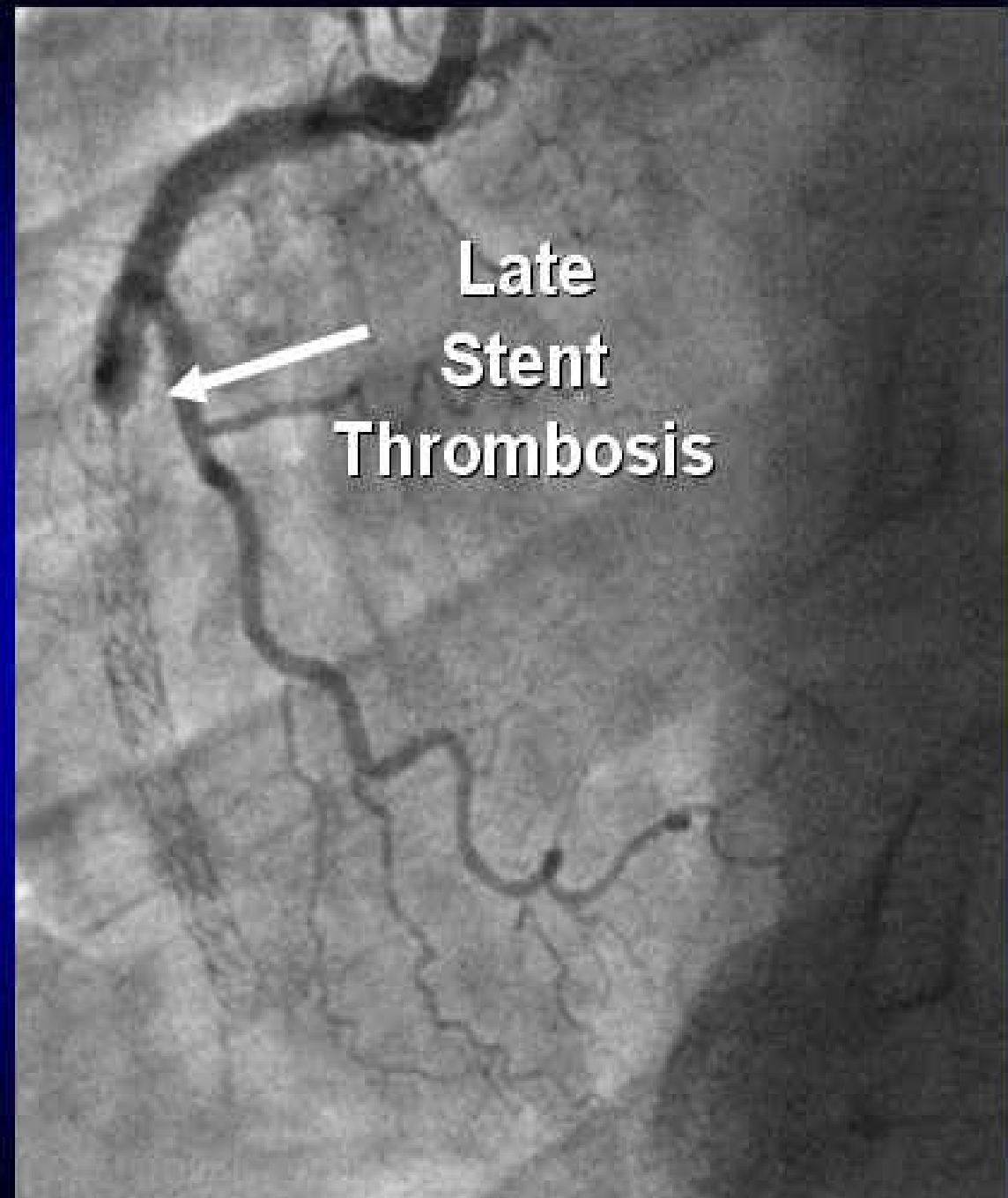
Stents deployed
at 18 atm



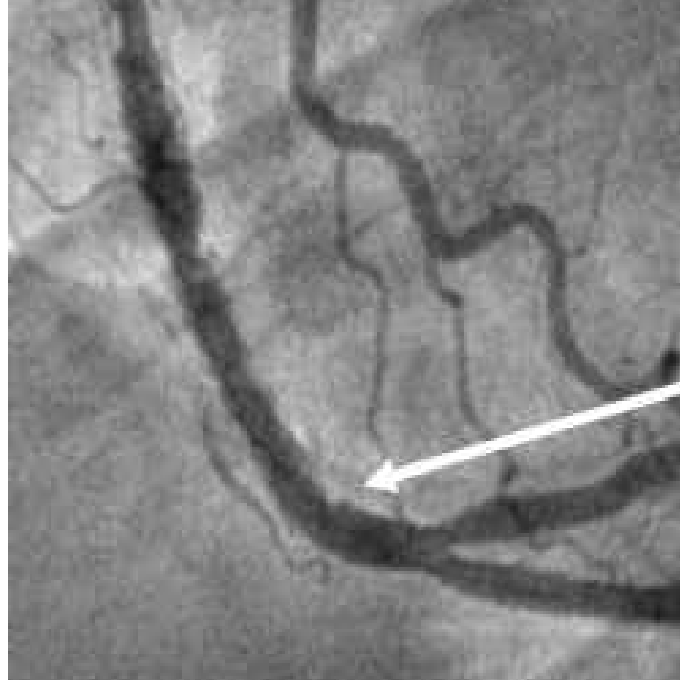
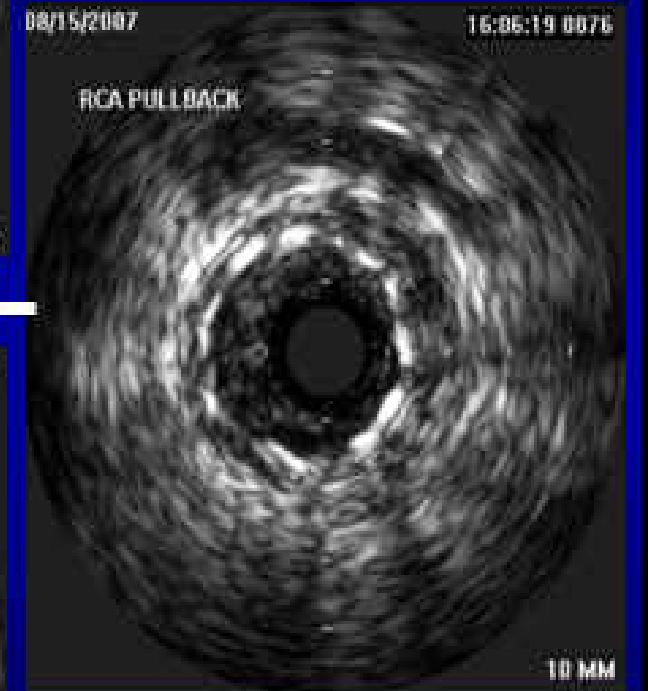
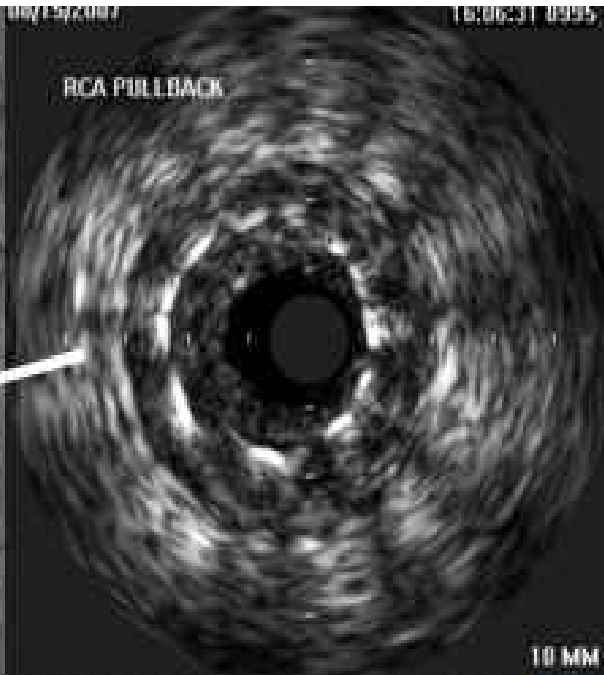
**48-Year-Old
Male**

**Re-Inferior
STEMI**

8-15-2007



**48-yr Male
Re-Inferior
STEMI
8-15-2007**

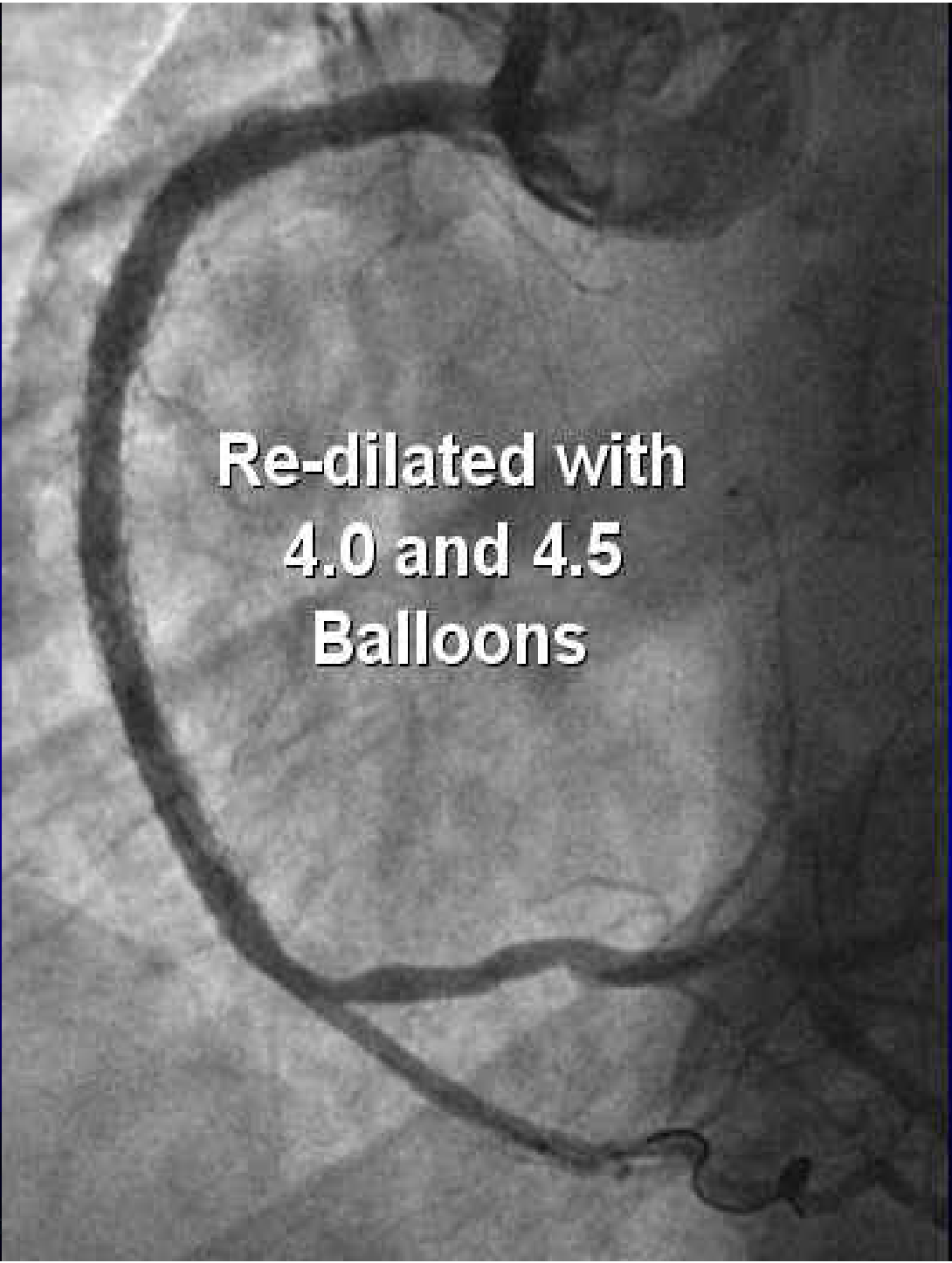


48-Year-Old Male

Re-Inferior STEMI

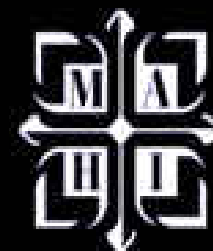
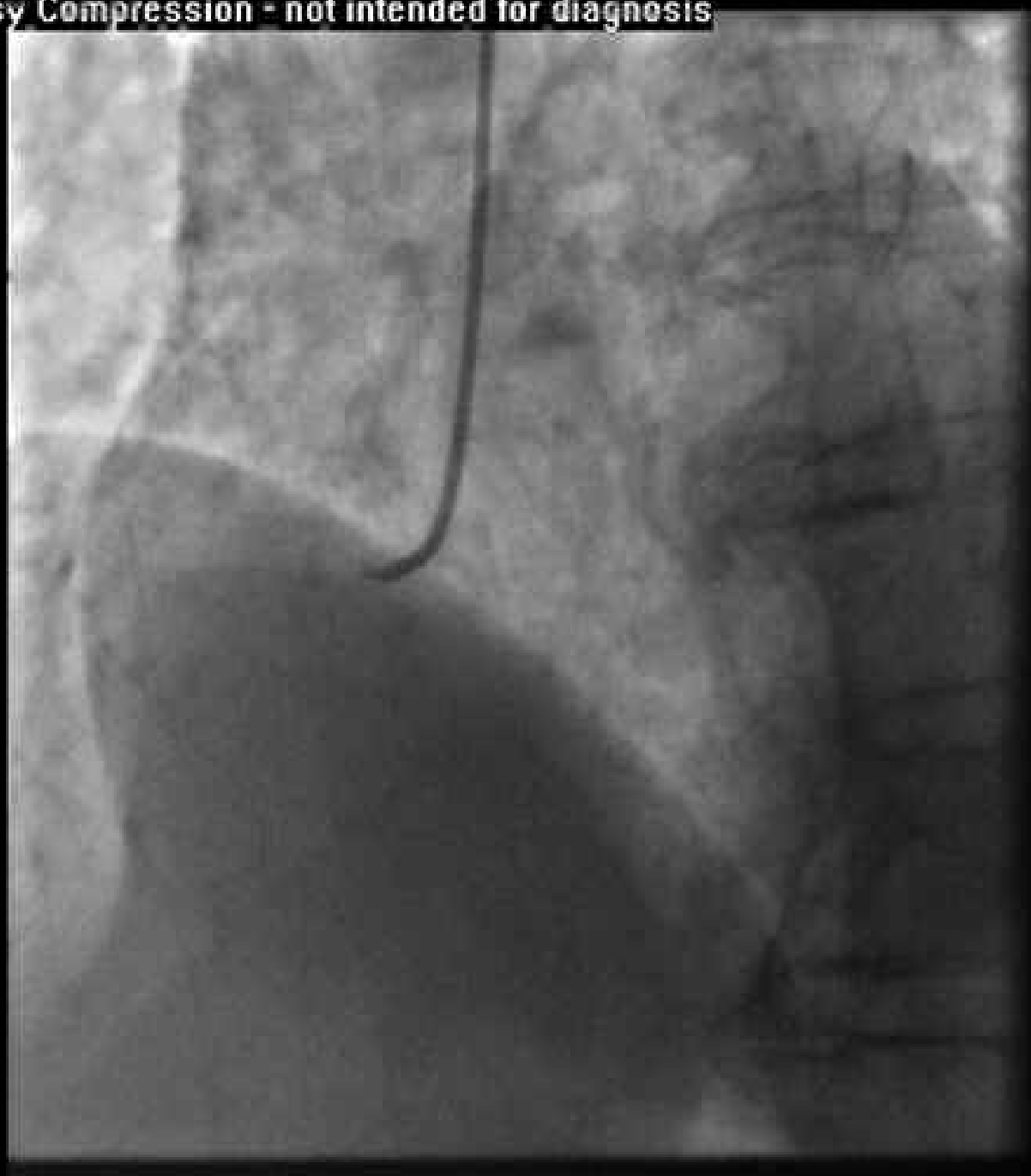
8-15-2007

**Re-dilated with
4.0 and 4.5
Balloons**

A catheter angiogram showing the coronary artery system. The vessel lumen is significantly dilated, indicating successful re-dilation. The text "Re-dilated with 4.0 and 4.5 Balloons" is overlaid on the image.

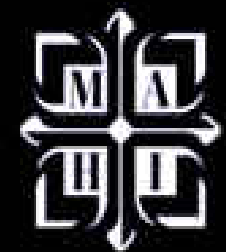
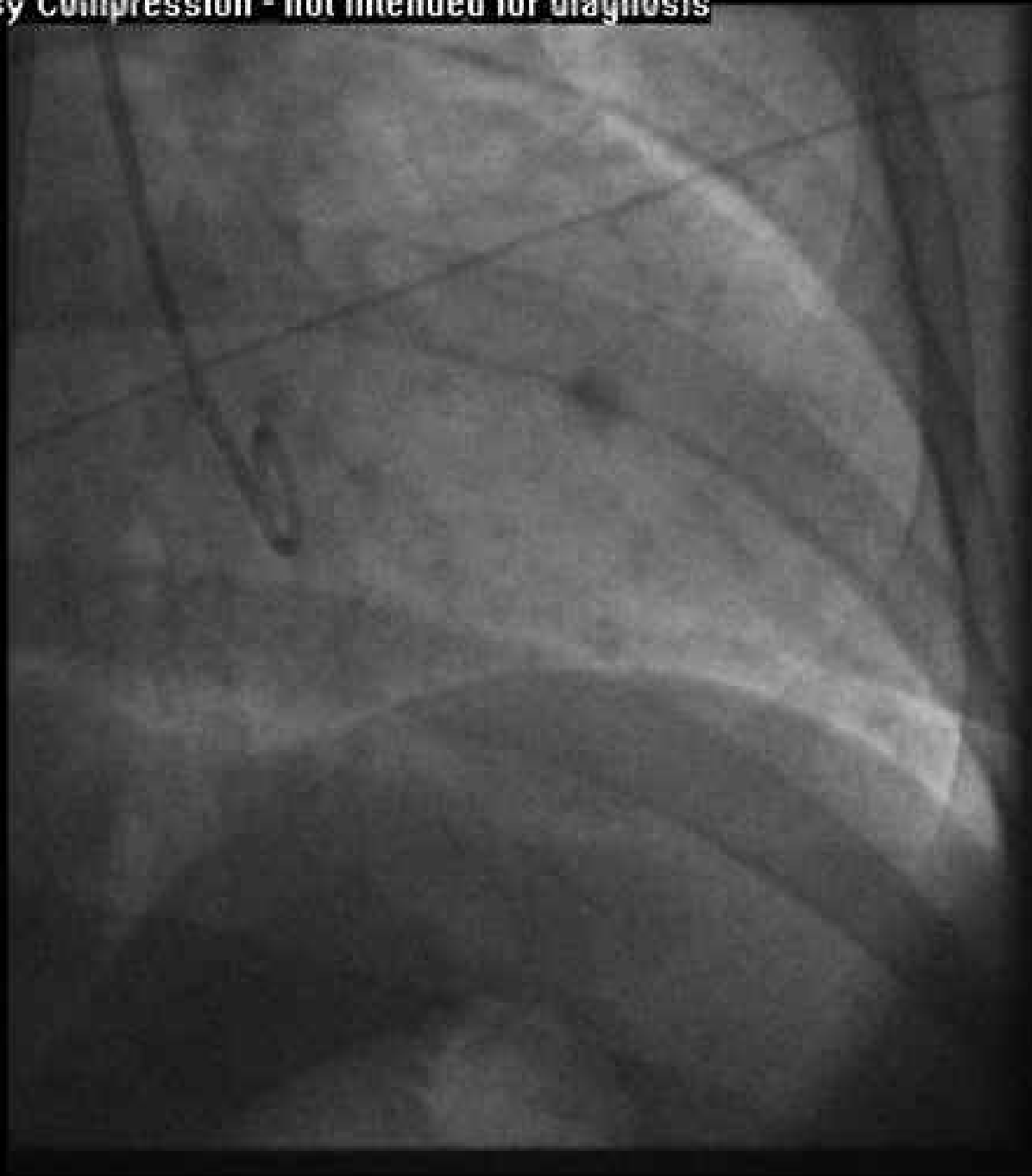
Lossy Compression - not intended for diagnosis

**54-yo
Female
Acute
Inferior
Wall
STEMI**



Lossy Compression - not intended for diagnosis

**40-yr
Female,
Acute
Lateral
Wall
STEMI**



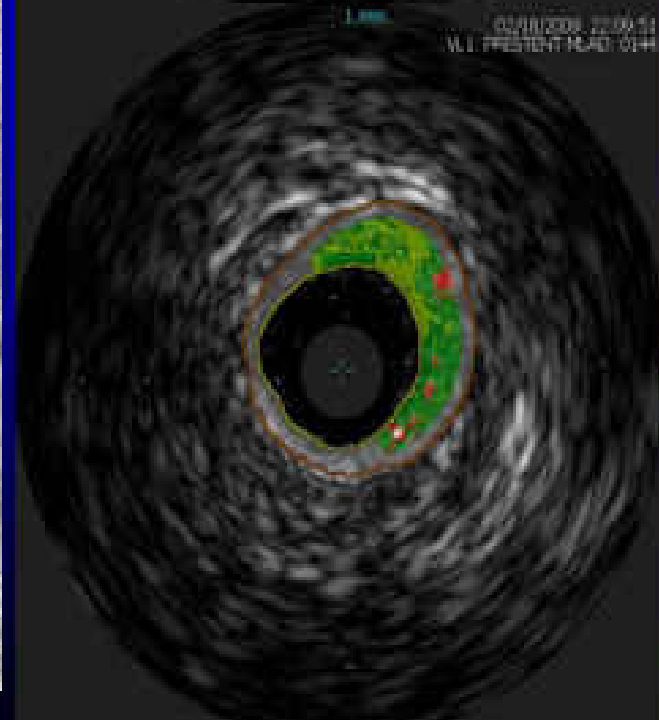
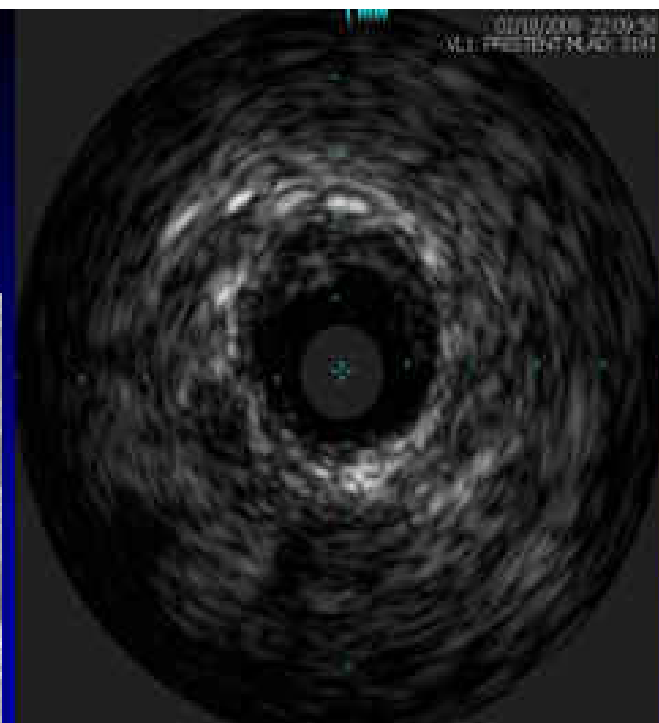


40-yr Female Acute Lateral Wall STEMI



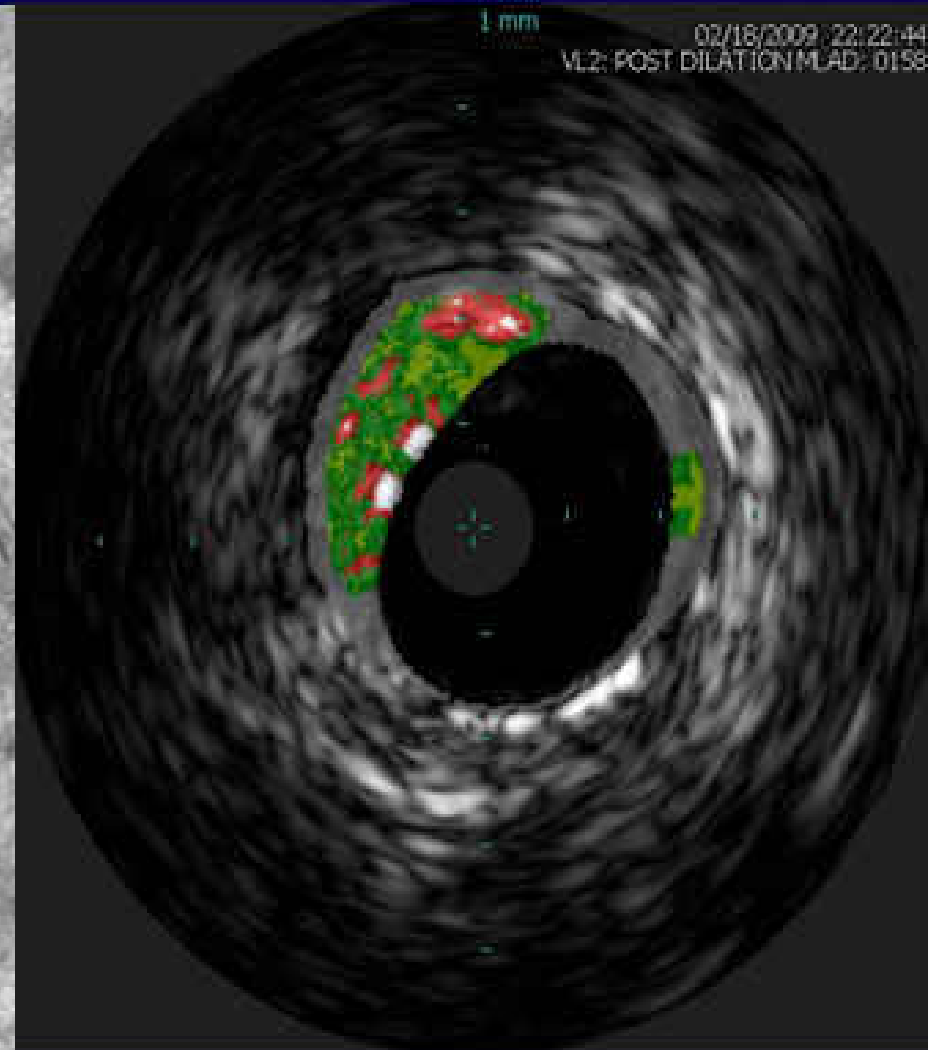


40-yr Female Acute Lateral Wall STEMI



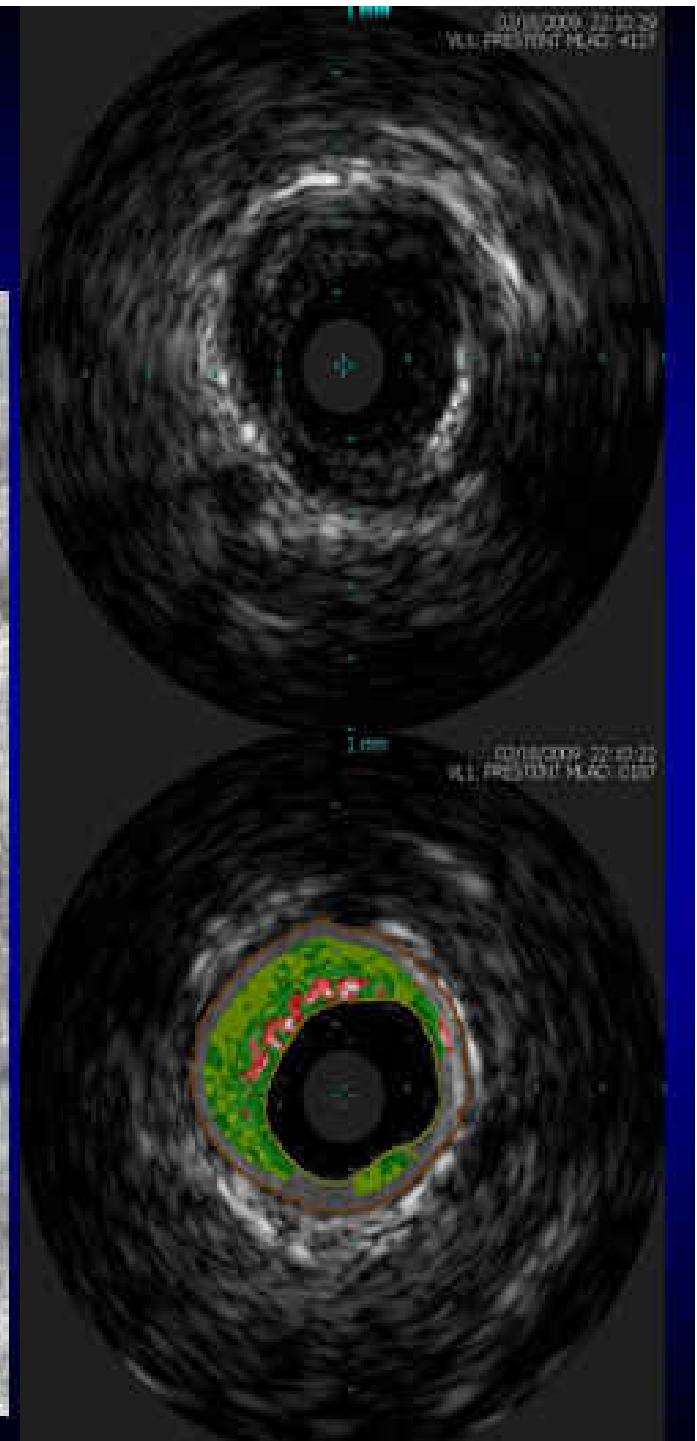
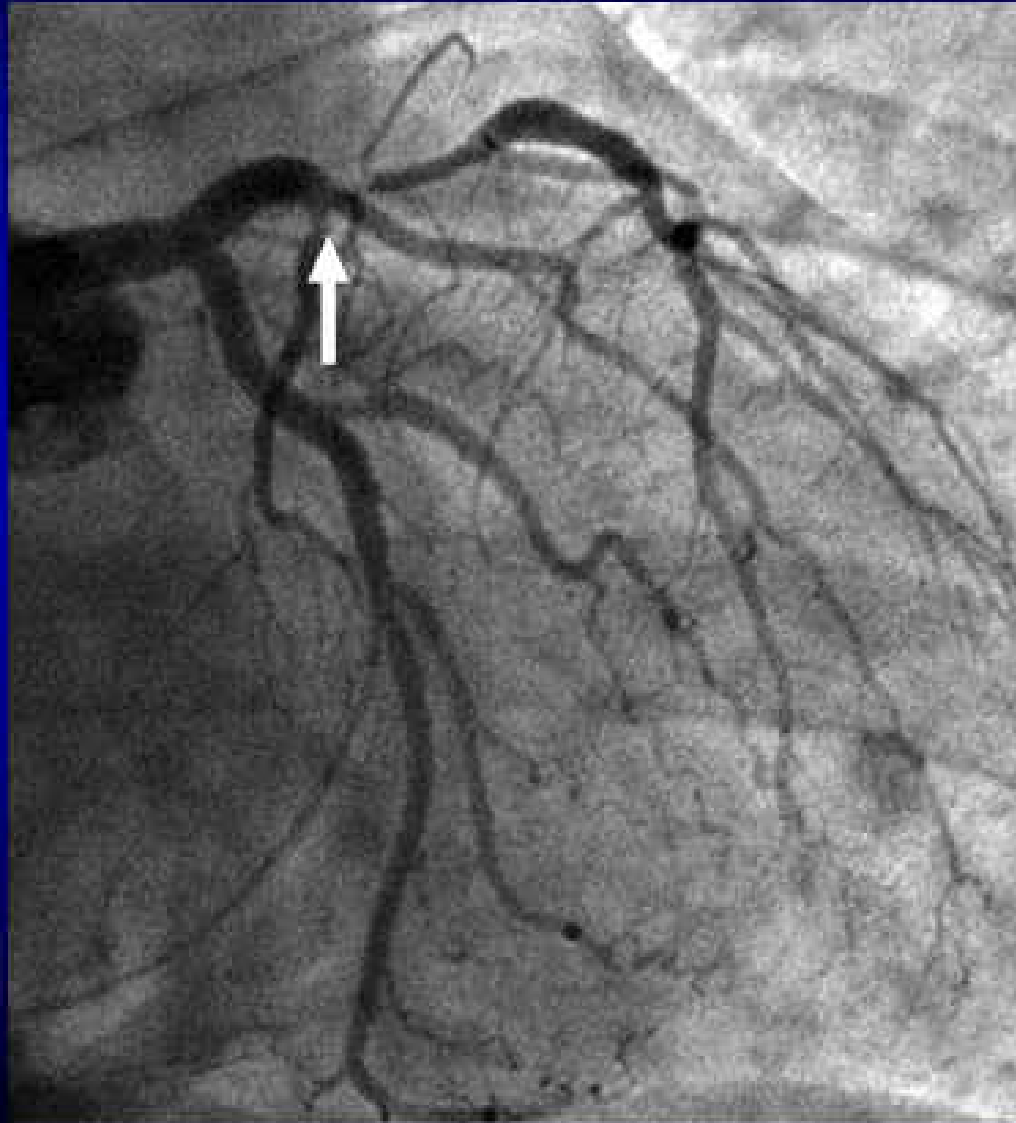


40-yr Female, Acute Lateral Wall STEMI





40-yr Female Acute Lateral Wall STEMI



Thrombus Aspiration During Percutaneous Coronary Intervention in AMI Study (TAPAS)

- 1071 STEMI pts, randomized (before angio) to Aspiration Thrombectomy with Export Catheter (533 pts) vs. Standard Primary PCI (536 pts)
- **Primary Endpoint:** Myocardial Blush Grade
- **Secondary Endpoints:**
 - Death (30d, 1yr)
 - Reinfarction
 - ST-Segment Resolution
 - MACE
 - TVR

Impact of Reversal of No-Reflow Phenomenon on 30-Day Survival After PCI for AMI: A Retrospective Study of 1,141 Pts. National University Hospital, Singapore

Incidence of No-Reflow – 10%

	Group I No NRF N = 1028	Group II NRF, but recovery	Group III NRF, persisted	p-value
30-Day Mortality	4%	3.3%	35.4%	< 0.001 0.006

Group II – TIMI 3 flow restored in 81%: verapamil, adenosine, NP

Predictors of NRF – Intracoronary thrombus,

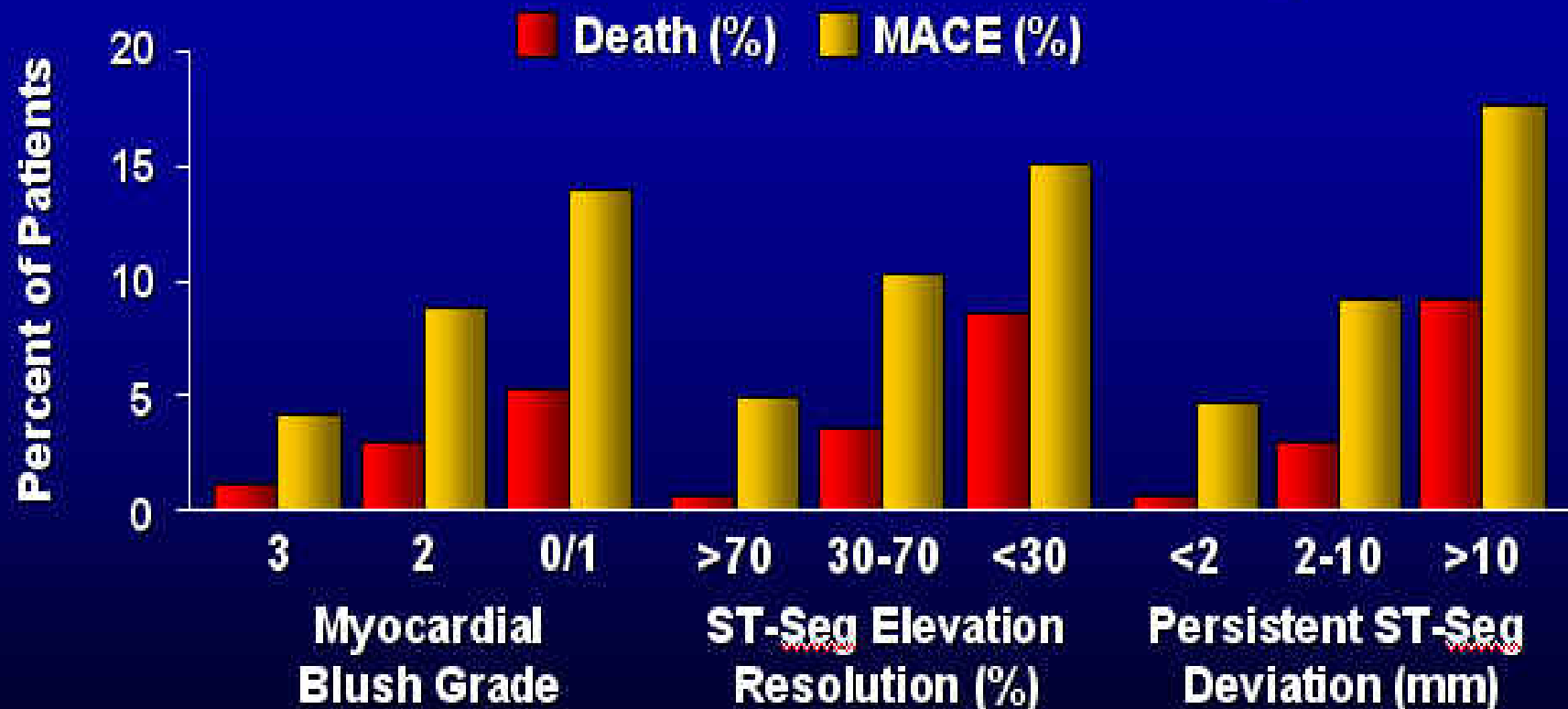
Irregular lesion contour

Baseline TIMI flow < 3

Hypotension, tachycardia

Thrombus Aspiration During Primary Percutaneous Intervention in AMI Study (TAPAS)

Rates of Death and MACE by MBG and ST-Seg Variables



Death (%)	1.0	2.9	5.2	0.7	3.6	8.6	0.6	3.0	9.3
MACE (%)	4.2	8.8	14.1	4.8	10.3	15.2	4.7	9.2	18.0

Assessment of Reperfusion at Microvascular Level in STEMI Patients

- **TIMI Flow Grade**
- **ST-Segment Resolution**
- **Myocardial Blush Grade**
- **Endocardial length of contrast defect (MCE)**
- **Index of Microcirculatory Resistance (IMR)
calculated using a pressure/thermistor wire**
- **Infarct size (SPECT)**

Thrombus Aspiration Improves Myocardial Reperfusion (REMEDIA) Trial. STEMI within 12 hours of onset.
Aspiration Device: Diver CE (Invatec, Brescia, Italy)

Procedural Characteristics	Thrombus Aspiration N = 50	Std. PCI N = 49	p-value
Angio Success (%)	95.8	91.8	NS
Procedural Time (min)	81 ± 43	72 ± 34	NS
Total Stent Length (mm)	27.2 ± 13.5	26.0 ± 9.7	NS
CTFC: Pre	78 ± 22	80 ± 28	NS
Post	23 ± 14	26 ± 19	NS
No Reflow (%)	8.3	12.2	NS
Slow Flow (%)	14.6	24.5	NS
Distal Emboli (%)	8.0	17.8	0.19
Distal Emboli, No Reflow, Slow Flow (%)	22.0	34.7	0.16
Direct Stenting (%)	66.0	24.4	0.0001

Methods to Improve Myocardial Perfusion in Acute MI Treated With Percutaneous Intervention

3. Thrombectomy

- AngioJet (POSSIS, Inc, MN)
- X-Sizer (EndiCOR Medical, Inc.)
- RESCUE (Boston Scientific Scimed, Inc)
- EXPORT Catheter (Medtronic Vascular)
- PRONTO Catheter (Vascular Solutions, MN)
- DIVER Catheter (Invatec Innovative Technologies, Italy)
- QuickCat

4. Pharmaceutical

- GP IIb/IIIa inhibitors
- B-blockers
- Nicorandil
- Adenosine
- Nitroprusside
- Verapamil

Angiographic Stent Thrombosis After Routine Use of DES in STEMI: *The Importance of Thrombus Burden*

812 pts, Apr 2002-Dec 2004, STEMI \leq 12 hrs

Large Thrombus Burden (LTB) \geq 2 vessel diameters

Mean Follow-up 18.2 ± 7.8 months

Classification of Thrombus Burden

Thrombus Score (%)	Reference	G5 Reclassified	Final Classification
G5 – Occluded vessel	57.0	0.4	0.3
G4 – \geq 2 vessel diameter	9.6	32.5	28.2
G3 – $>1/2$ but $<$ 2 vessel diam	7.6	17.6	17.7
G2 – $\leq 1/2$ vessel diam.	11.9	24.8	26.1
G1 – Possible thrombus	8.5	19.1	19.4
G0 – No thrombus	5.3	4.6	7.9

Angiographic Stent Thrombosis After Routine Use of DES in STEMI: *The Importance of Thrombus Burden*

812 pts, Apr 2002-Dec 2004, STEMI \leq 12 hrs
Large Thrombus Burden (LTB) \geq 2 vessel diameters
Mean Follow-up 18.2 \pm 7.8 months

Thrombus Score (%)	2-Year Mortality (%)	2-Year MACE (%)
G4 – \geq 2 vessel diameter	13.0	24.4*
G3 – $>1/2$ but $<$ 2 vessel diam	7.9	12.8
G2 – $\leq 1/2$ vessel diam.	9.6	13.8
G1 – Possible thrombus	7.8	15.0
G0 – No thrombus	14.6	24.9*

*p<0.001

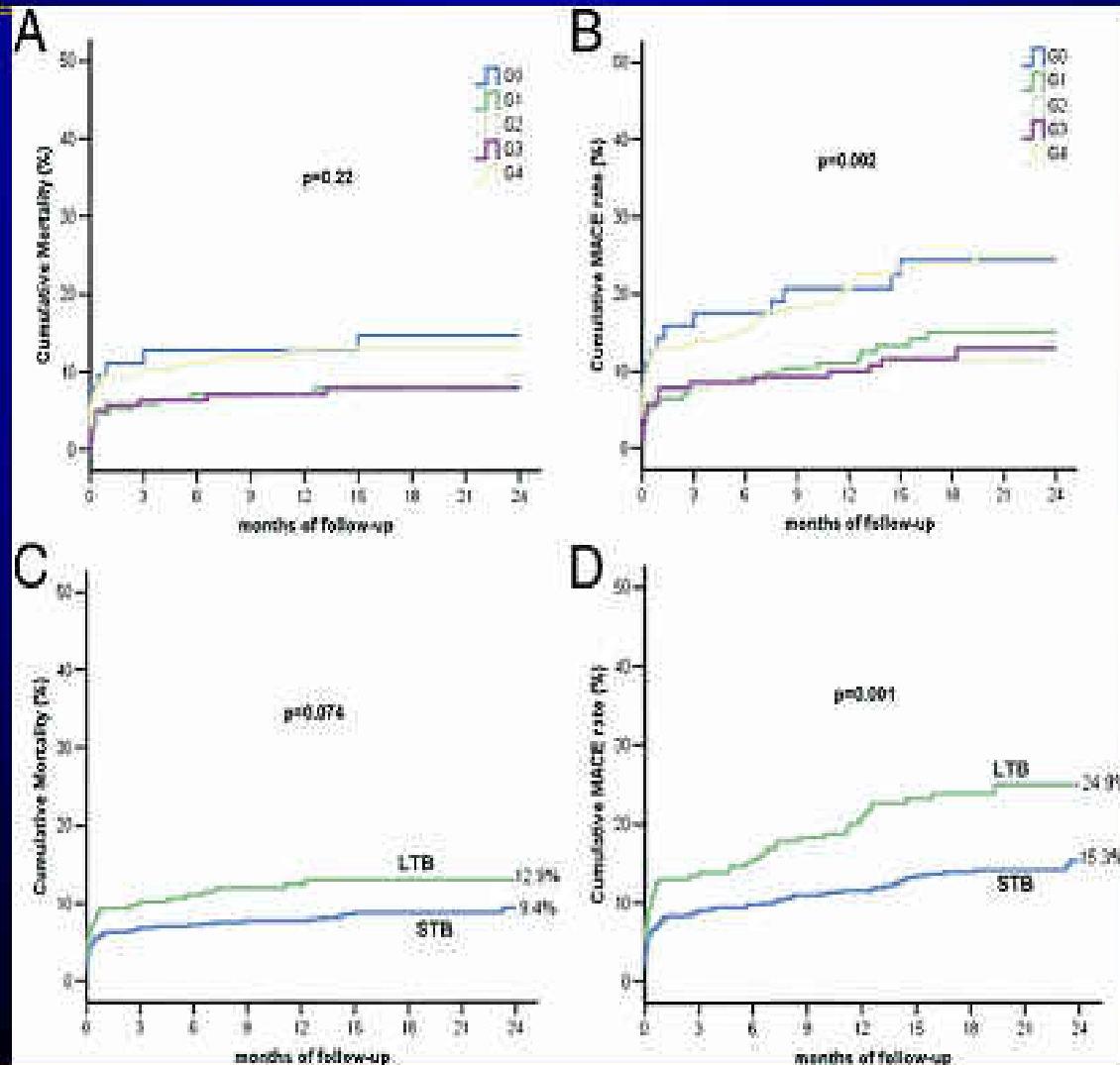
Angiographic Stent Thrombosis After Routine Use of DES in STEMI: *The Importance of Thrombus Burden*

812 pts, Apr 2002-Dec 2004, STEMI \leq 12 hrs
Large Thrombus Burden (LTB) \geq 2 vessel diameters
Mean Follow-up 18.2 \pm 7.8 months

	Total	STB	LTB	p-value
Procedural Outcome	N=792	N=567	N=225	
Final TIMI 3 Flow (%)	91.7	94.9	83.3	<0.001
MBG 3 (%)	47.6	53.2	35.4	<0.001
Complete thrombus removal (%)	95.6	98.1	89.3	<0.001
No Reflow (%)	1.5	0.5	4.0	0.001
Distal Emboli	7.4	3.5	17.3	<0.001

Angiographic Stent Thrombosis After Routine Use of DES in STEMI: *The Importance of Thrombus Burden*

Figure 3: Mortality and MACE According to Thrombus Burden



Angiographic Stent Thrombosis After Routine Use of DES in STEMI: *The Importance of Thrombus Burden*

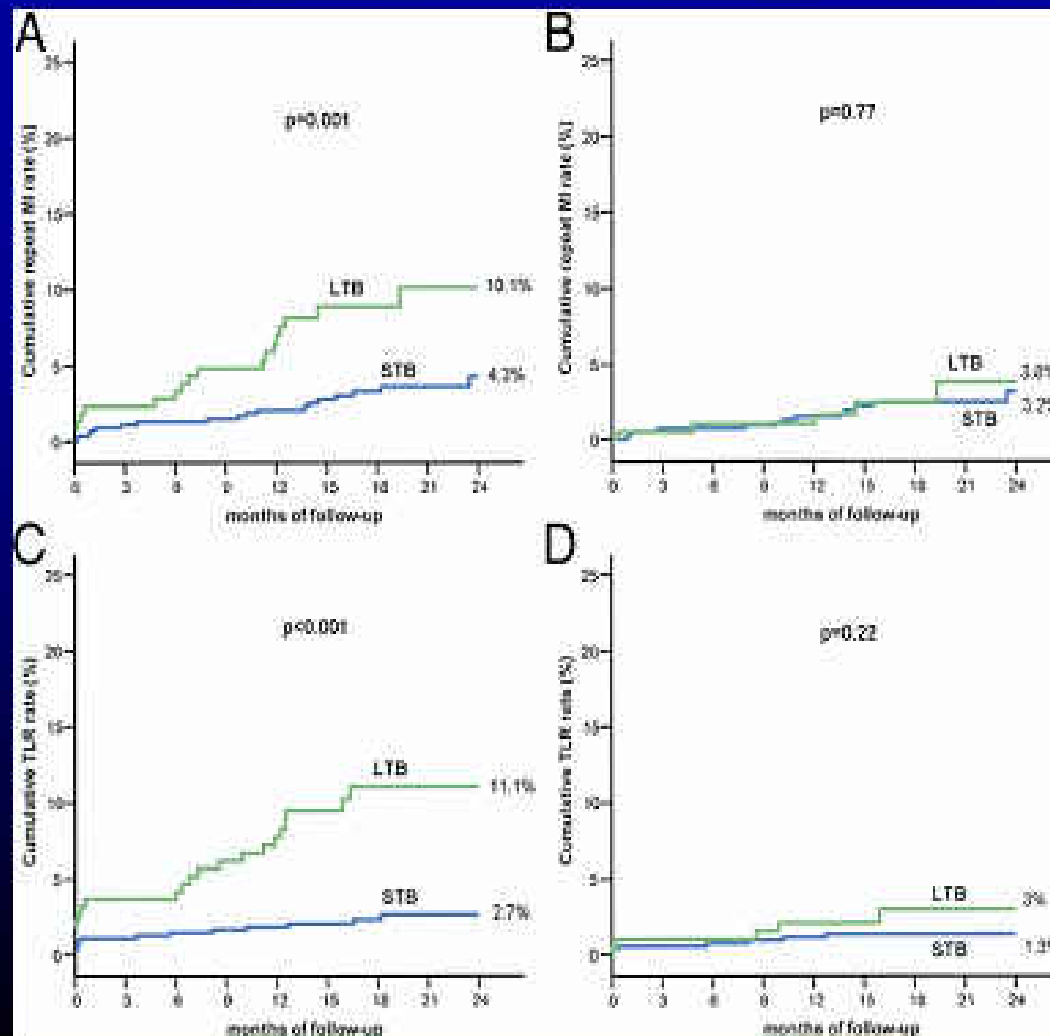
Table 5: Independent Predictors of Infarct-Related Artery Stent Thrombosis

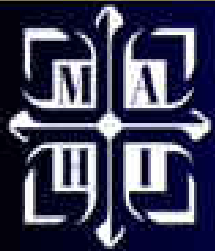
Variable*	Hazard Ratio	95% Confidence Interval	p Value
Age (per 10-yr increase)	0.55	0.37-0.82	0.003
Stent thrombosis at presentation	6.24	2.06-18.92	0.001
Bifurcational stenting	4.06	1.64-10.02	0.002
Rheolytic thrombectomy	0.11	0.01-0.81	0.03
Large thrombus burden	8.73	3.39-22.47	<0.001

*Additional variables entered in the multi-variate model but not found to be significant were diabetes mellitus, previous myocardial infarction, previous percutaneous coronary intervention, and direct stenting.

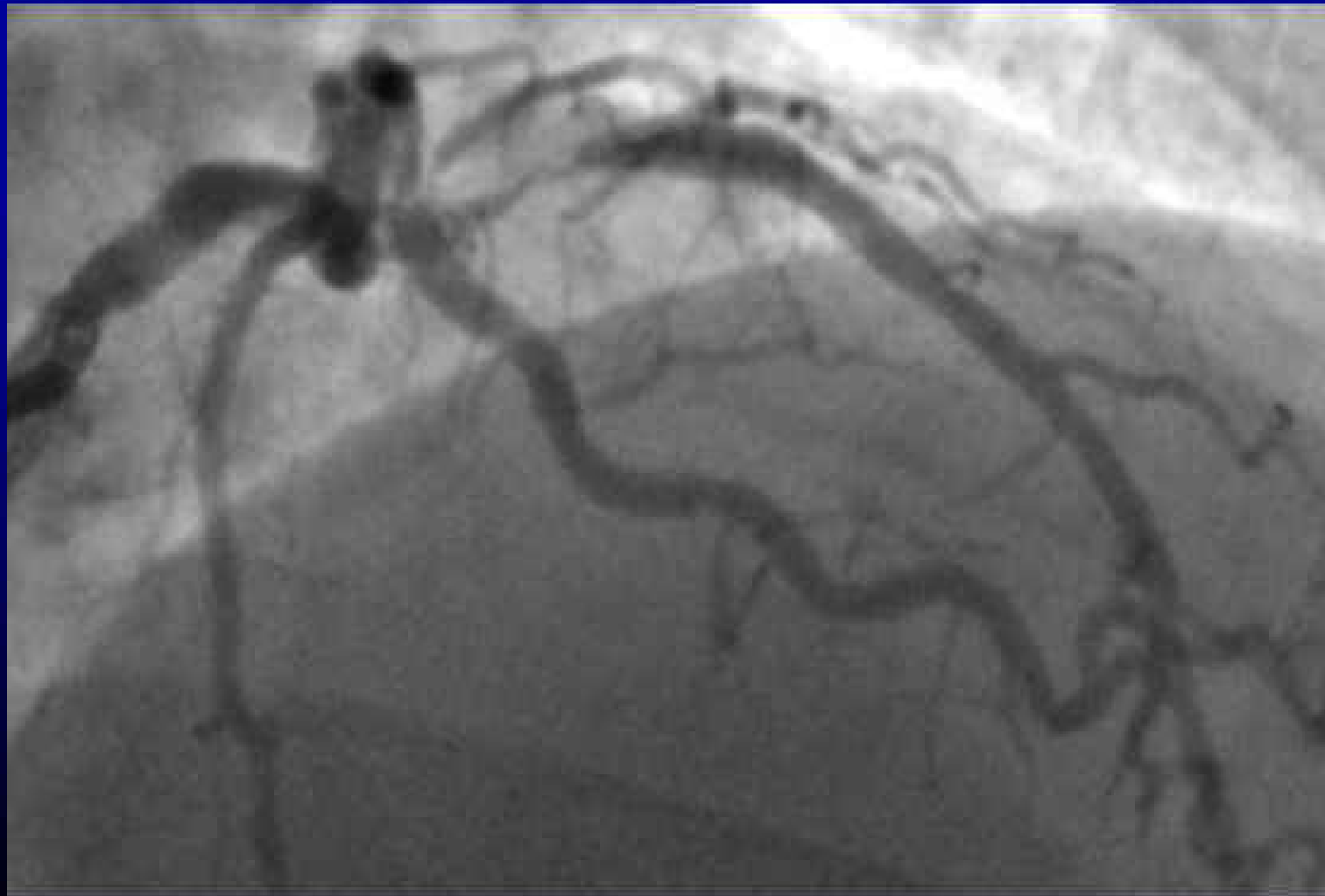
Angiographic Stent Thrombosis After Routine Use of DES in STEMI: The Importance of Thrombus Burden

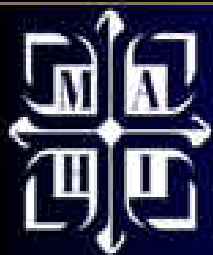
Figure 6: Impact of Thrombus Burden and IRA-ST on Repeat MI and TLR



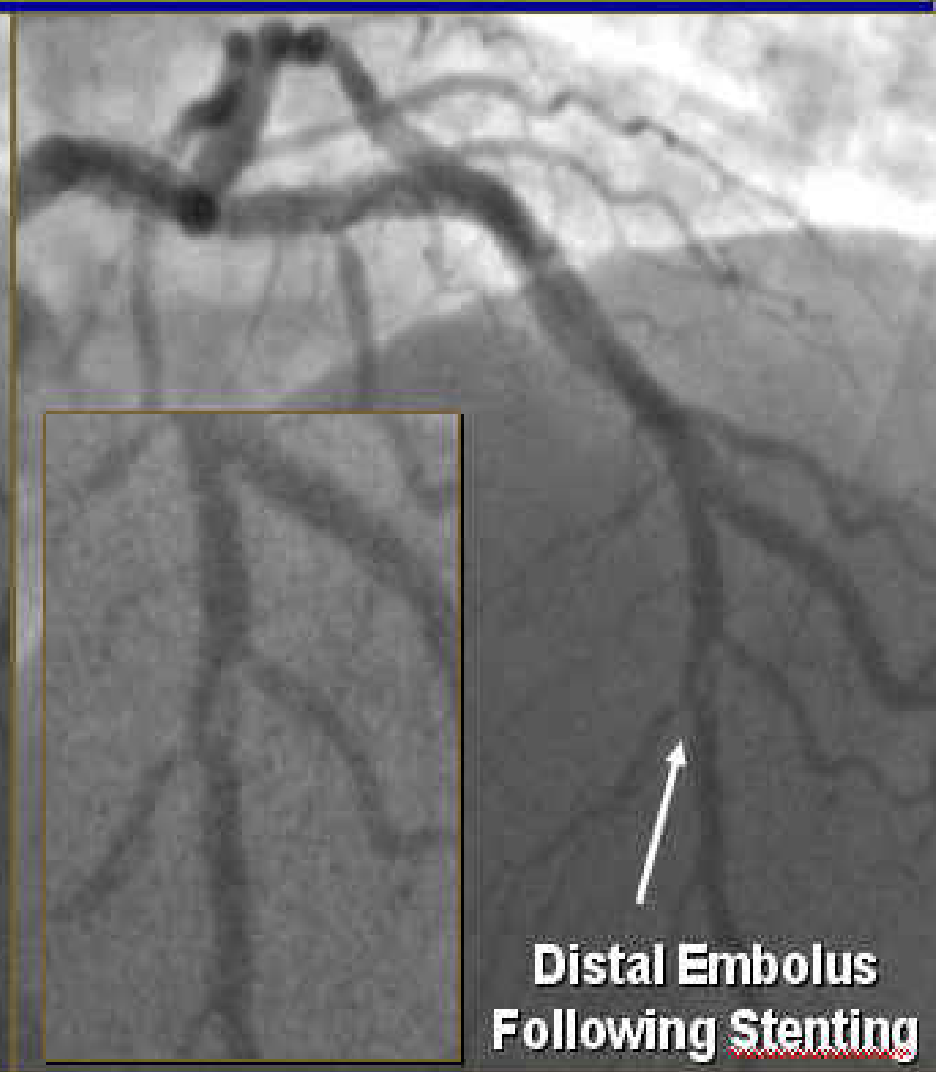
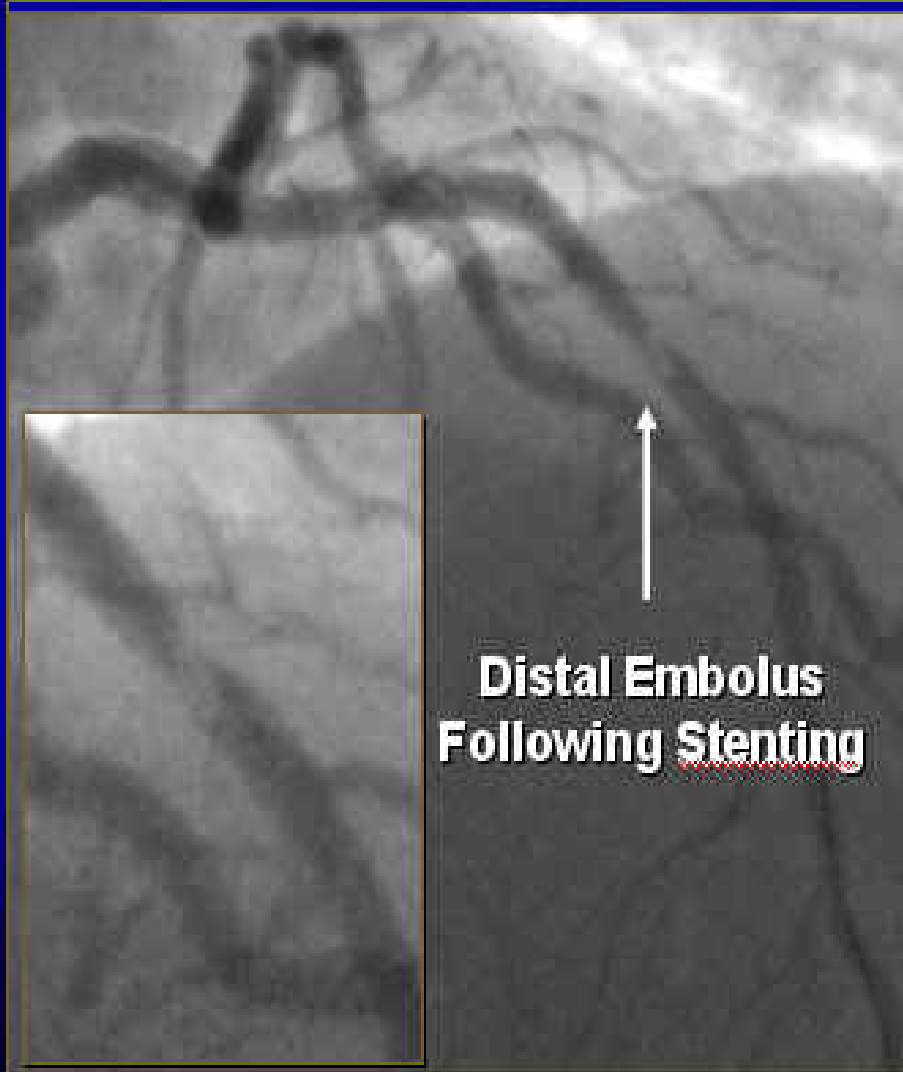


B.B.
Acute Anteroseptal Infarct 2-22-04



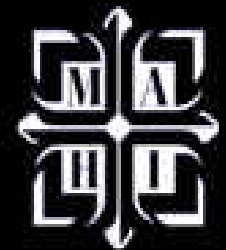


B.B. Acute Anteroseptal Infarct 2-22-04 Direct Stenting of LAD



**45-yo
Male
8-13-04**

**Acute
Inferior
Infarction**





Drug Eluting Stents in AMI

MAHI Experience: 95 pts, ≤ 12 hrs STEMI, 7/03-5/04

Pre-routine Use of Aspiration Thrombectomy

Angiographic Outcome	No.	Percent
TIMI-3 Flow post stent	79	83.2
MBG 3 post stent	51	39.1
Slow flow	9	9.5
No reflow	3	3.1
Branch occlusion	2	2.1
Distal embolization	2	2.1
Edge dissection	2	2.1
Guide induced dissection	1	1.0
No reflow, slow flow, distal emboli	14	14.7

Failed Trials of Distal Protection in AMI

EMERALD; N = 501	GuardWire DP	Control	p-value
ST-seg Resolution	62.2%	60.6%	NS
Infarct Size (% LV)	18.3±19.4	16.2±19.1	NS
ASPARAGUS; N = 341	GuardWire DP	Control	p-value
MBG-3	24.8%	20.3%	NS
MBG-3 (RCA only)	20.5%	6.3%	0.04
AIMI Study; N = 480	Rheo Thrombectomy	Control	p-value
Final Infarct Size	12.5±12.1	9.8±10.9	<0.02
FI Size for Inf. MI	10.2±11.1	6.5±8.9	<0.005
30-Day MACE (%)	6.7	1.7	<0.01
FilterWire EX; N = 200	FilterWire	Control	p-value
Infarct Size (%)	11.8±9.3	10.4±9.4	NS
MBG 0/1 (%)	36	33	NS

Necessity of Balloon Predilatation After Thrombectomy; Influences on Worse Outcome in Comparison to Thrombectomy and Direct Stenting or Standard Angioplasty: PIHRATE Trial

196 pts, Poland, Italy, Hungary

	TD N = 75	TB N = 25	BS N=96	p-value
TIMI-3 Flow	91%	78%	82%	0.08
MBG 3	81%	53%	59%	0.03
TIMI-3 + MBG 3	78%	53%	56%	0.01
STR > 70% + MBG 3	41%	29%	24%	0.01
Distal emboli, No-Reflow Need for NP/Adenosine	8.9%	37%	22.6%	0.003

Thrombus Aspiration During Primary Percutaneous Intervention in AMI Study (TAPAS)

- 1071 STEMI pts, randomized (before angio) to Aspiration Thrombectomy with Export Catheter (533 pts) vs. Standard Primary PCI (536 pts)
- Resolution of ST Segment Elevation

