

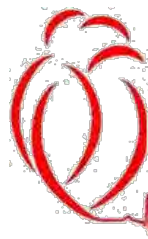


XVIII SOLACI Congress & SOCIME Annual Meeting

SOLACI' 2012 In partnership with TCT

México DF, 8-10 August, 2012

Efficacy of intracoronary IIb/IIIa inhibitor during primary PCI. Standard use or bailout only?



Costantino R. Costantini, M.D., Ph.D., F.A.C.C.
Hospital Cardiológico Costantini
Foundation Francisco Costantini
Curitiba - Brazil

Room Molino del Rey, August 9th, 2012, 16h15 at 17h05 pmc



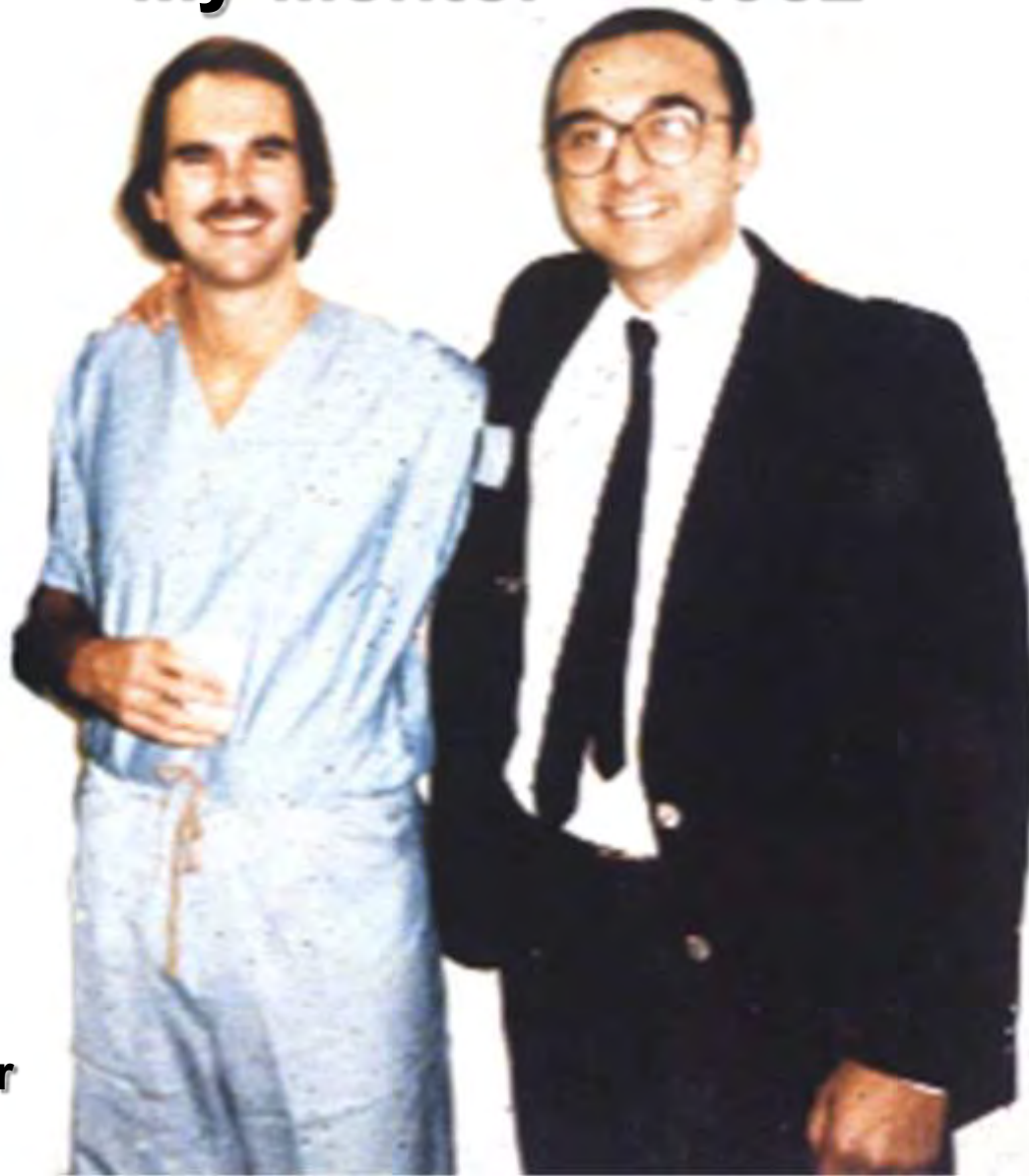
2012 -- Potential conflicts of interest

Speaker's name: Costantino R Costantini, M.D., Ph.D., F.A.A.C.

Acute Myocardial Infarction

❖ MACRUZ et al	ARQ. BRAS. CARD	1970
❖ FAVALORO et al.	AM J CARDIOL	1972
❖ GALEANO et al.	ARQ. BRAS. CARD	1973
❖ RENTROP et al.	CLINIC. CARD	1978
❖ MEYER et al.	CIRCULATION	1982
❖ HARTZLER et al.	AM J CARDIOL	1983

My Mentor --- 1982



Geoffrey Hartzler
† 65 Year Old
(Last April)

Arquivo pessoal: C. Costantini

Acute Myocardial Infarction PTCA Direct Approach

Why ?????

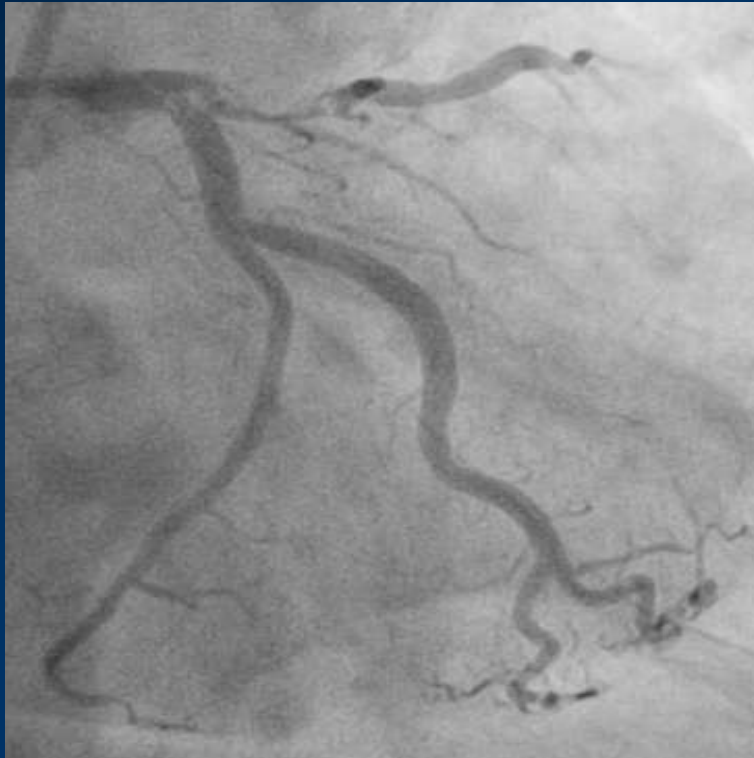


- HIGH RATE OF SUCCESS
- LOW HOSPITAL MORTALITY / MORBIDITY
- LOW LATE MORTALITY
- IMPROVES VENTRICULAR FUNCTION
- HIGH RATE OF ASYMPTOMATIC PATIENTS
- FEW CONTRA INDICATIONS

G. Hartzler 1982

!!!!!!! Thrombus !!!!!!!
This is the Problem !!!!!! (1982 Hartzler)

2012 STILL is THE PROBLEM !!!!



Images Hospital Costantini 2011

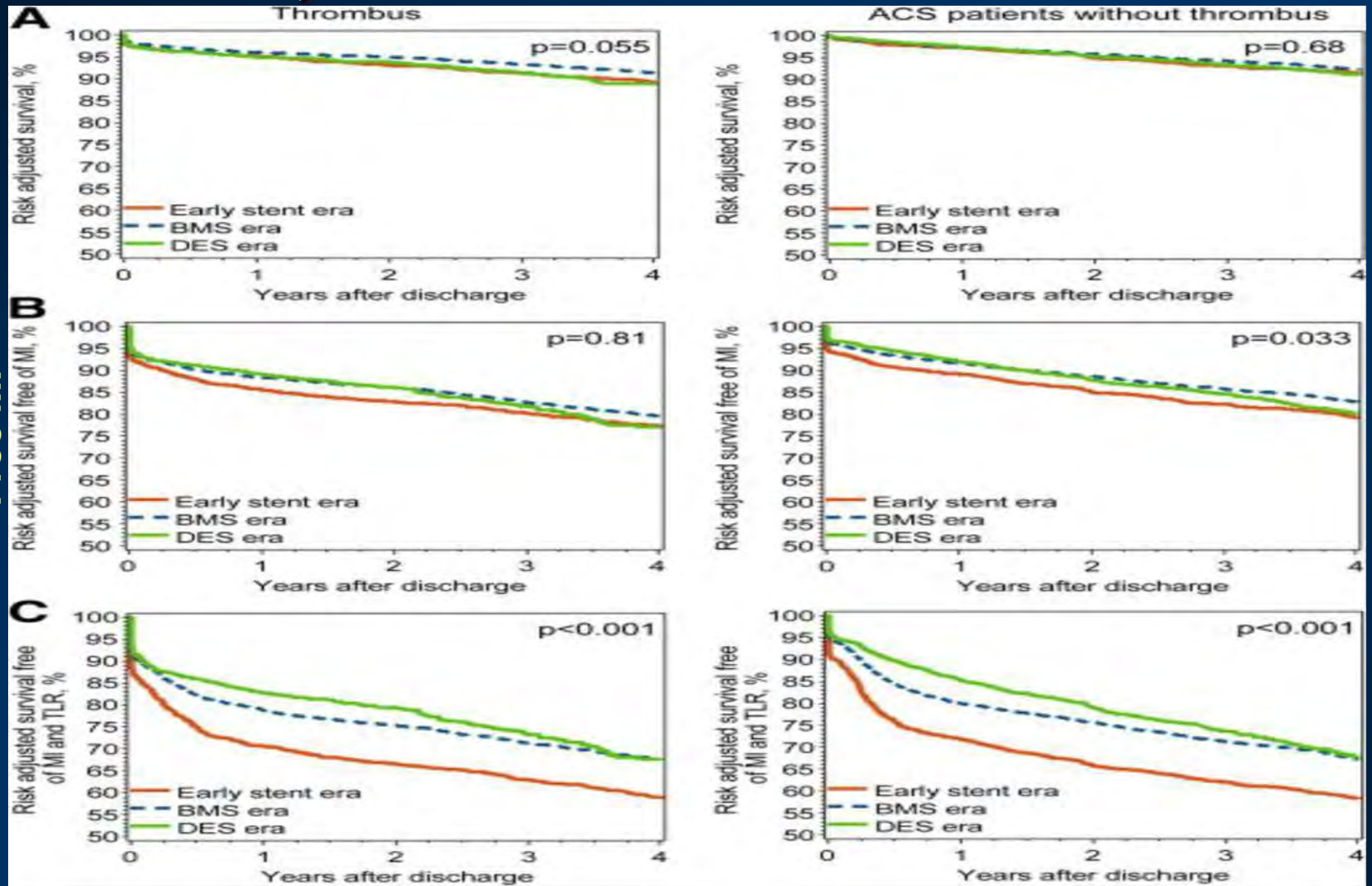
5,000 Patients With Thrombus

7,671 ACS Without Thrombus

Survival

Survival Free MI

Survival Free MI and TLR



Holmes, J Am Coll Cardiol Interv. 2010;3(9):937-946

Acute Myocardial Infarction

Reperfusion Objectives

FAST

TIME IS MUSCLE

EFFECTIVE

TIMI FLOW III / BLUSH III

RECURRENT ISCHEMIA

ELIMINATE THE CULPRIT LESION

Functional Recovery



Life Quality



Early Social Reinsertion

AMI (!!! Thrombus !!!)

What to do ???



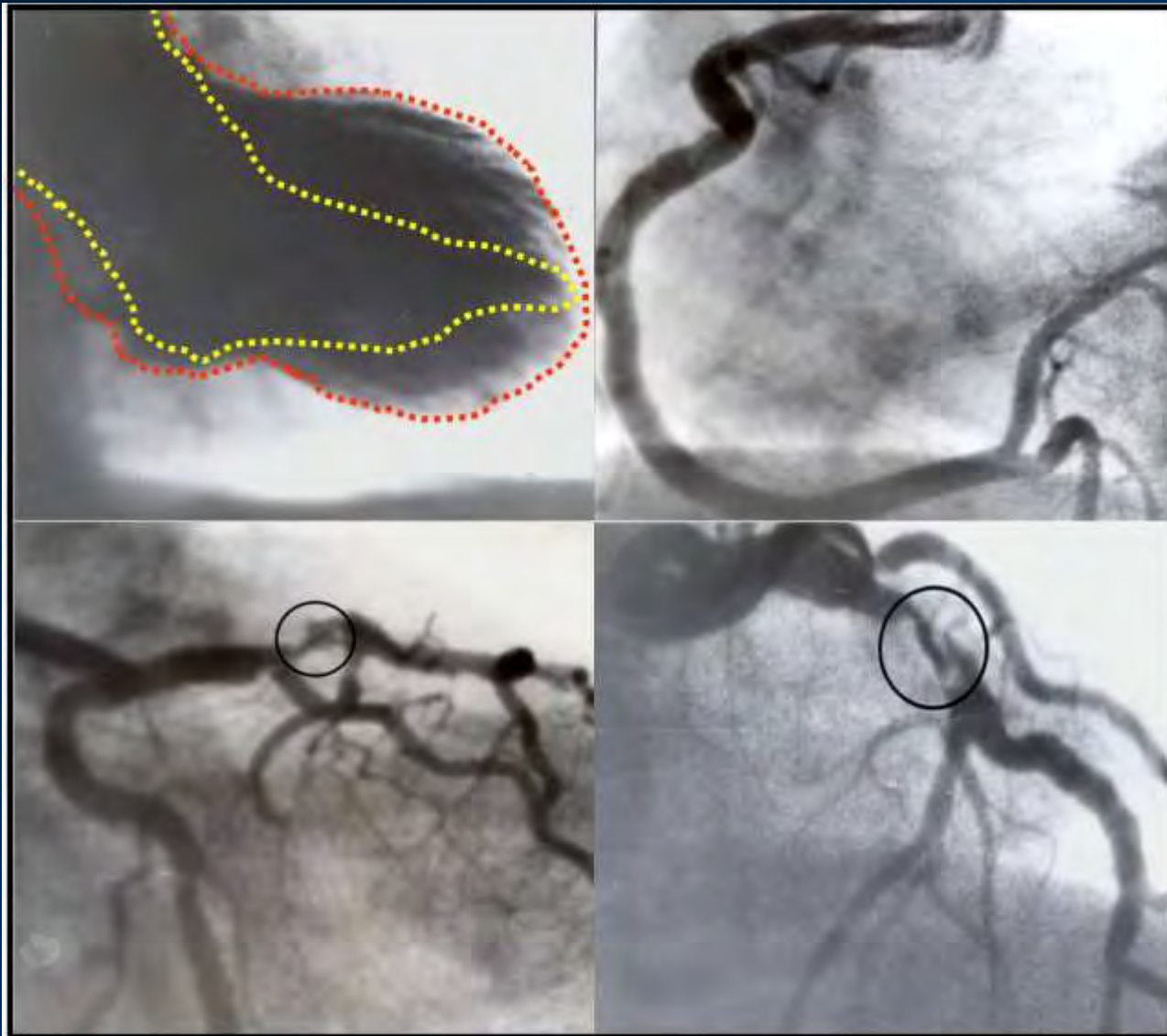
**Medical Approach
?**

**Mechanical Approach
??**

**Or Both
???**

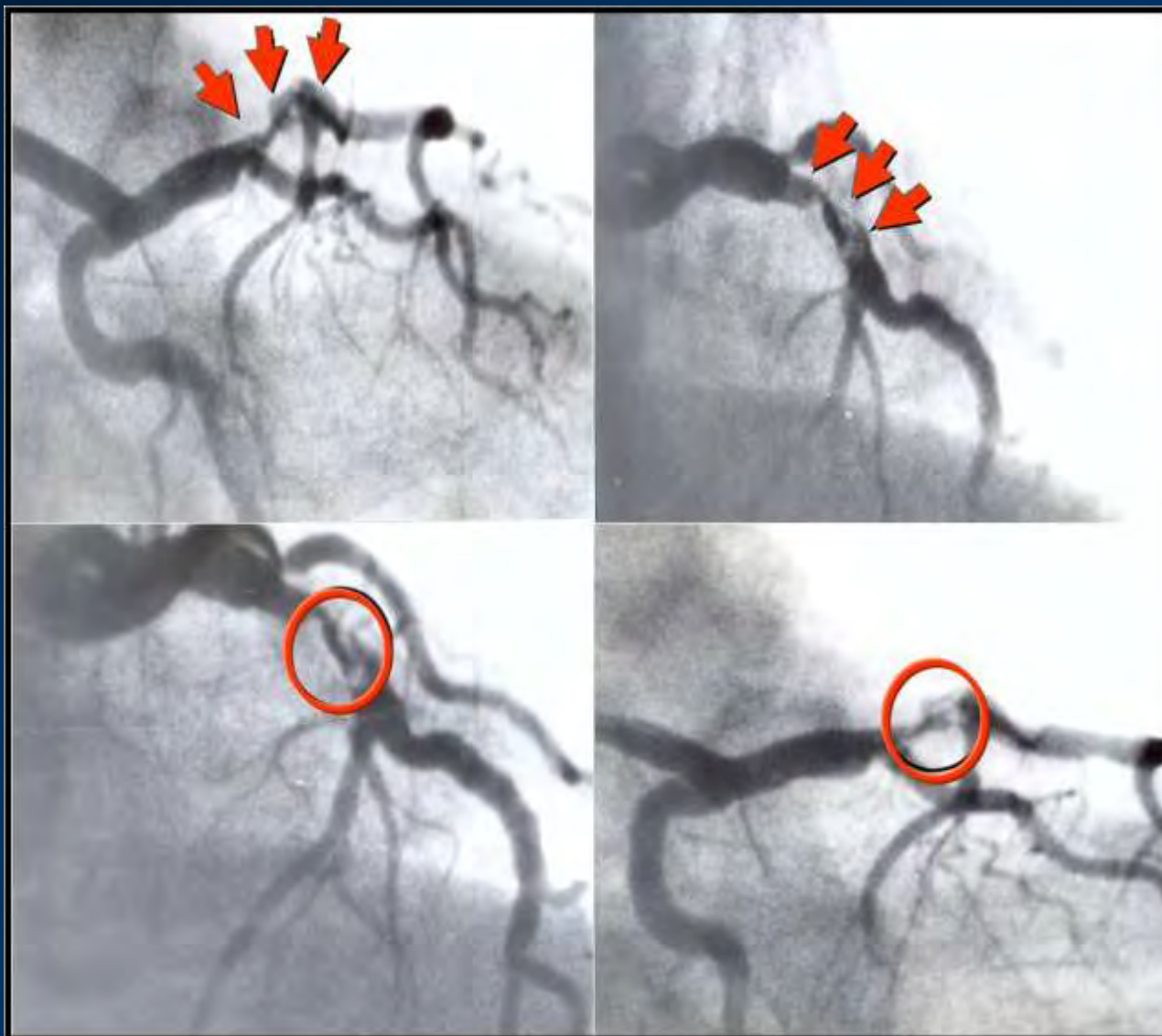
Images Hospital Costantini 2011

ACS -- 1994



ACS -- LAD angiograph with Thrombus

1994



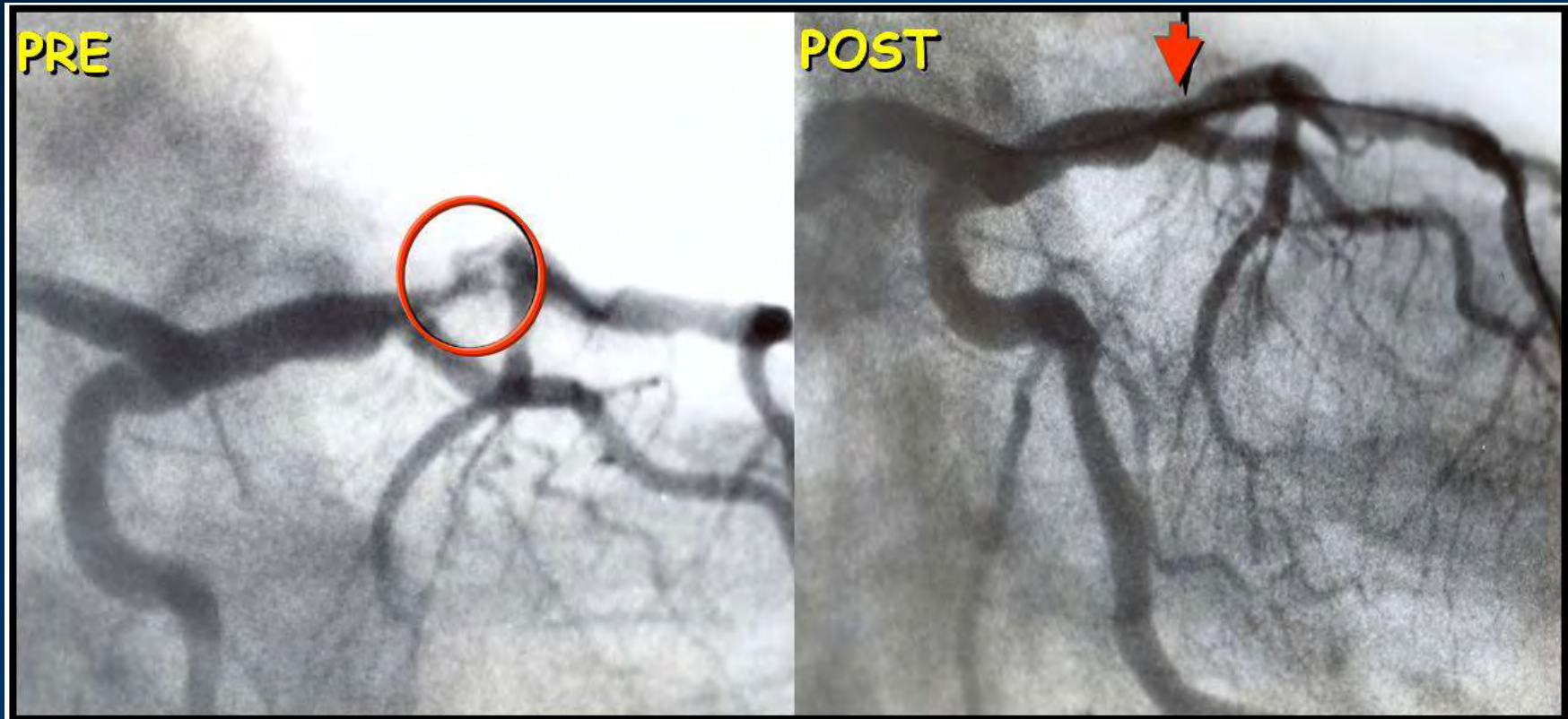
ACS -- LAD angiograph after 5 days Heparin

1994



ACS -- LAD angiogram post ANGIOPLASTY

1994



AMI

PRIMARY PCI LIMITATIONS

**RECURRENT
ISCHEMIA
(10 - 15%)**

**ACUTE OCCLUSION
(5 - 10%)**

**REOCCLUSION AFTER 6 MO
TIMI FLOW I
(10 - 15%)**

**DISSECTION (20 – 25 %)
REESTENOSIS (35 - 40%)**

Circulation. 2000; 102: 2945-51.

The Stent PAMI Pilot Study

Palmaz-Schatz implanted in 236 consecutive pts with STEMI

Mean Follow-Up Duration of 7.4 ± 2.6 Months

	In-Hospital	Post D/C	Cumulative
Death	2 (0.8%)	4 (1.7%)	6 (2.5%)
Reinfarction	4 (1.7%)	5 (2.1%)	9 (3.8%)
TVR	10 (4.2%)	26 (11.1%)	35 (14.8%)
- PCI	5 (2.1%)	20 (8.5%)	24 (10.2%)
- CABG	6 (2.5%)	10 (4.3%)	16 (6.8%)
Death, MI, or TVR	13 (5.5%)	30 (12.8%)	41 (17.4%)

Stone GW et al. JACC 1998;31:23–30.

Stone GW et al. Circulation. 1999;99:1548-1554.

The Stent PAMI Pilot Study

Palmaz-Schatz implanted in 236 consecutive pts with STEMI

FU angio in 176 pts (77.0%) at 7.8 ± 3.2 mos

Late loss = 0.88 ± 0.92

Binary angiographic restenosis = 27.5%

Reocclusion = 6.4%

Stone GW et al. JACC 1998;31:23–30.

Stone GW et al. Circulation. 1999;99:1548-1554.

TIMI Myocardial Perfusion (TMP) Grades



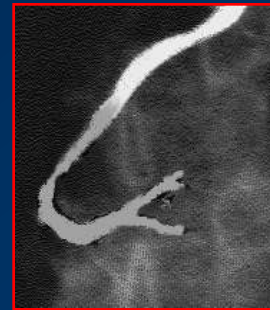
TMP Grade 3

Normal ground-glass appearance of blush. Dye mildly persistent at end of washout.



TMP Grade 2

Dye strongly persistent at end of washout. Gone by next injection.



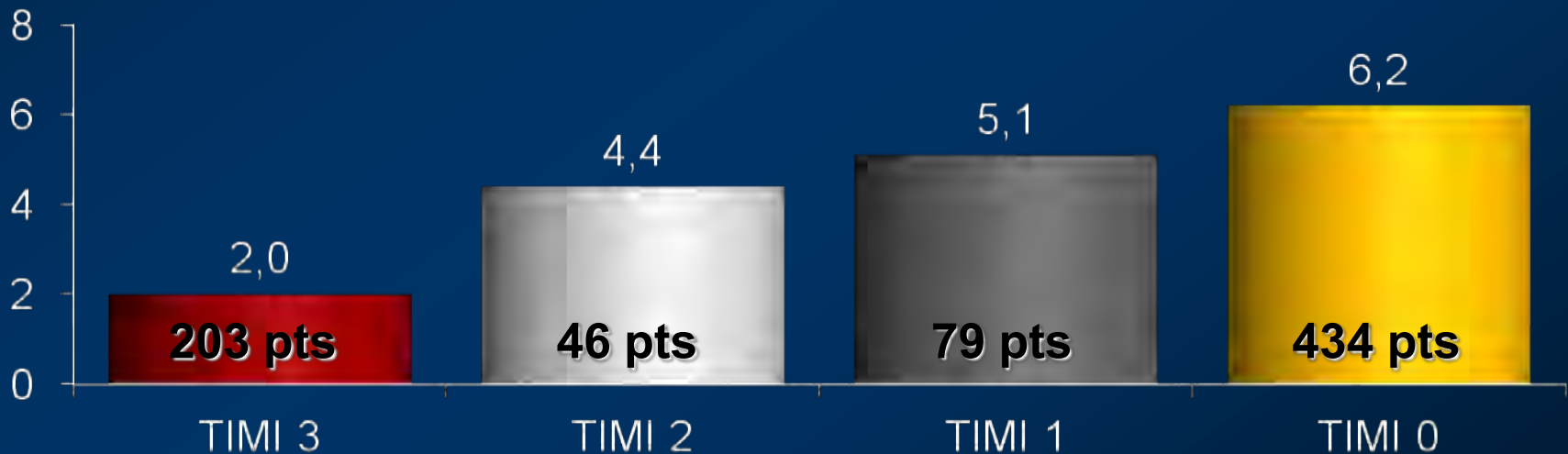
TMP Grade 1

Stain present. Blush persists on next injection.



TMP Grade 0

No or minimal blush.



Adapted from Gibson CM, et al. Circulation. 2000;101:125-130.

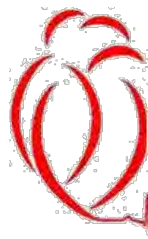


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Efficacy of intracoronary IIb/IIIa inhibitor during primary PCI. Standard use or bailout only?



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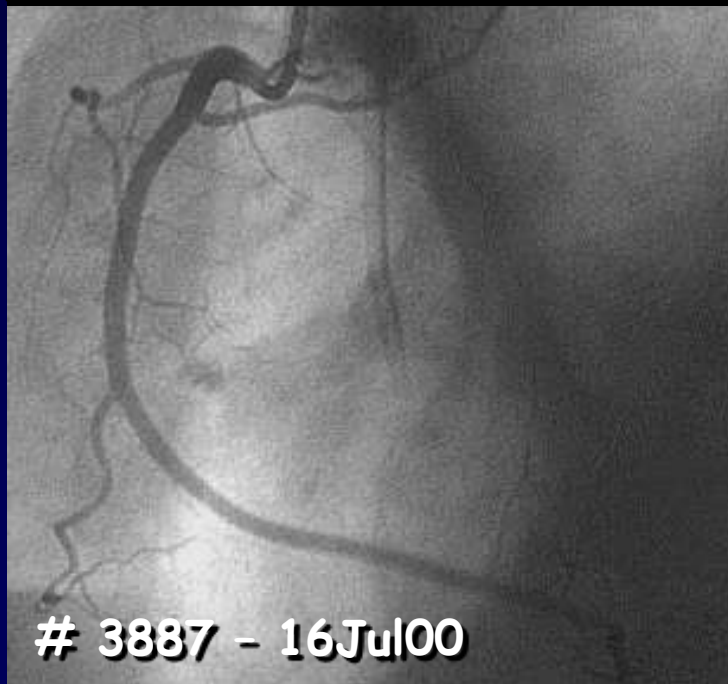
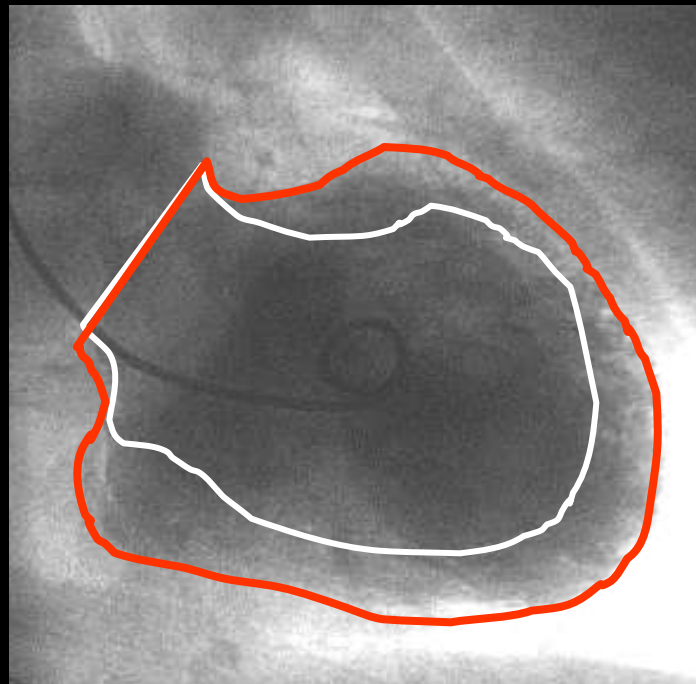
Iib - Iia

The Use of Agents that Block the Platelet Receptor Iib / Iia is the Most Important Pharmacological Therapeutic Advancement as Adjunct PCI , since the Discovery of Action of Aspirin.

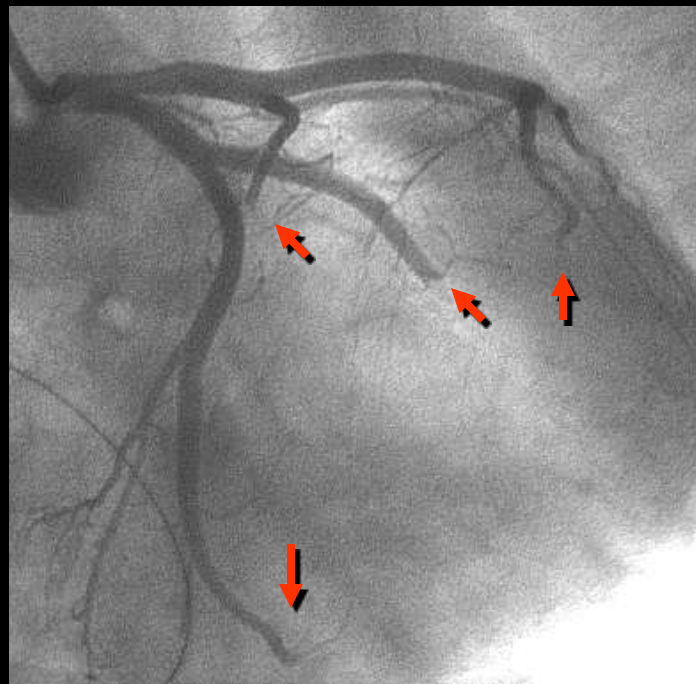
HOLMES. NEJM. 1997 MAYO CLINIC

L.K. 52 Yrs ♀
W/O RISK FACTORS
HORMÔN USE
AMI 3 HOURS
KKIV

DIAGNOSTIC	9:30
HOSP. ADMISSION	10:10
CATH LAB	10:20
1º INFLATION	10:35
END	11:40



3887 - 16Jul00



L.K. 52 Yrs ♀
AMI 3 HOURS
KKIV

BALLOON 2.0mm

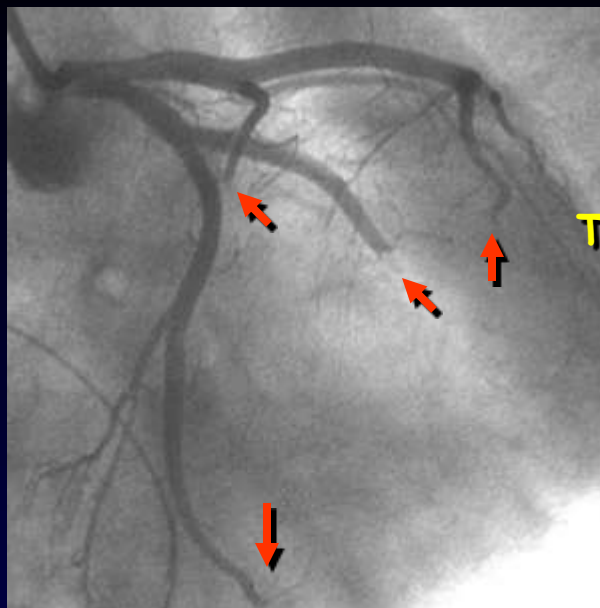
**HEPARIN &
TIROFIBAM
INTRA
CORONARY**

**DOPAMINE
DOBUTAMINE**

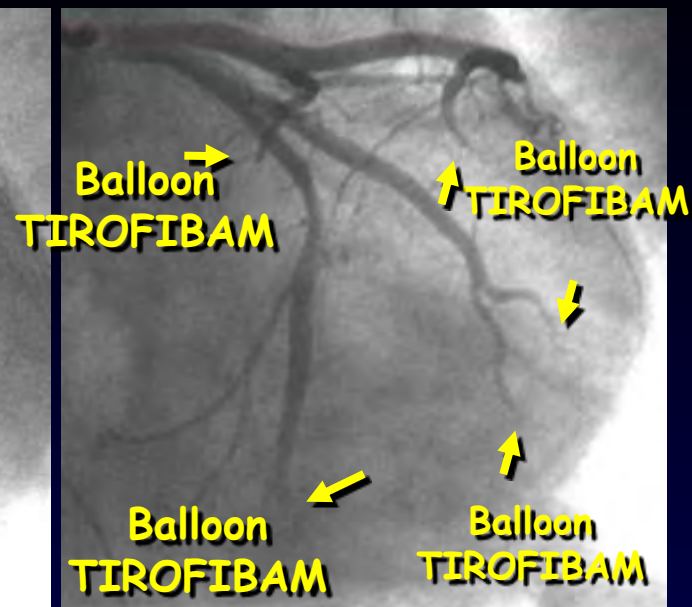
IABP

**PLATELETS
1.190.000**

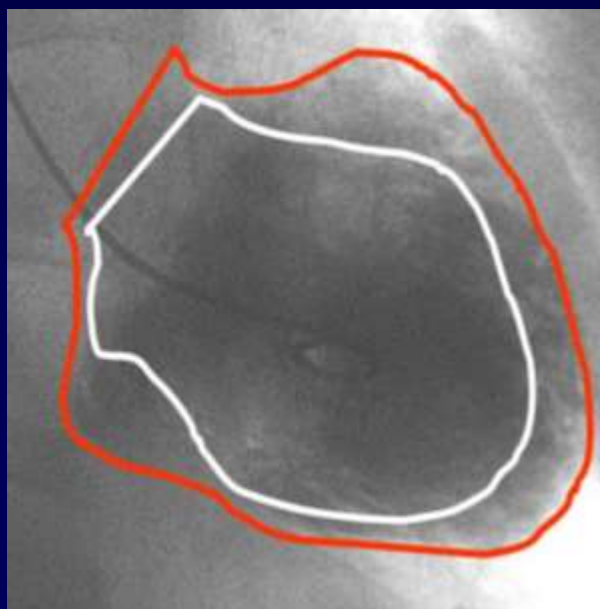
PRE



POST



After 8 days



3940 - 24Jul00

Follow up @ 10 Years Post Tirofiban IC

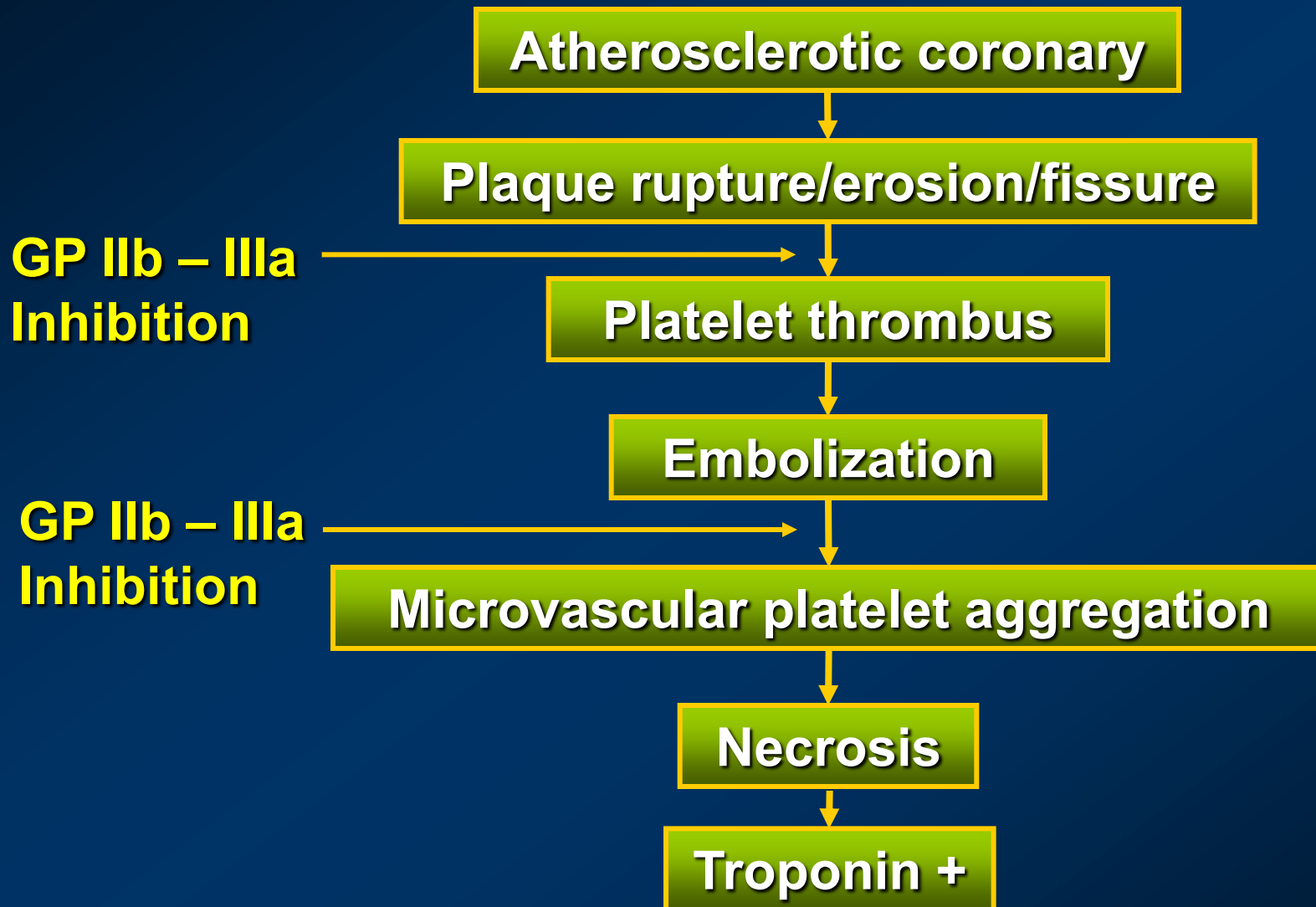


**Trans Thoracic
Echo
Ejection Fraction
41%
(15Sep2010)**

Normal Treadmill Test (11 Mets)

LK ♀ - 65 Yrs
15Sep10

ACS Possible Link Between Platelets and Troponin and Benefit of GP IIb – IIIa Inhibition



Topol EJ. 1997

2001

Comparação dos inibidores das glicoproteínas IIb-IIIa na angina instável em angioplastia coronária: Tirofiban versus abciximab

José Luis LAZARTE*, Sergio Gustavo TARBINE*, Rubens Zenobio DARWICH*, Daniel Anibal ZANUTTINI*, Marcelo Freitas SANTOS*, Marco FRANCHETTI**, Lauro RUBINI**, Mario MARANHÃO**, Marcio MARANHÃO**, Marcio SCORSIN***, Gilson YARED**, Marco BARBOSA**, Costantino Costantini ORTIZ*, Olavo GARCIA**, Costantino Roberto COSTANTINI****

Bolus Intracoronario em Todos os Pacientes

Medicação

O uso do inibidor da glicoproteína IIb-IIIa começou imediatamente durante o procedimento antes da revascularização coronária.

Tirofiban : usou-se 10 ug/k/ em bolus e infusão contínua de 0.15 ug/k/min. durante 36 horas .

Abciximab : de 0.25 mg/k em bolus, seguida de infusão de 0.125 ug/k/min durante 12 horas.

Todos receberam antes do procedimento ac. acetil salicílico 200 mg/d, clopidogrel 300 mg, mantendo com 75mg/d. ou ticlopidina 500 mg/d., durante 30 dias.

Costantini et al; Rev Bras Cardiol Invas 2001; 9 (4):12-17

Different IIb/IIIa Drugs Comparative Analysis In Patients with Unstable Angina Undergoing PCI

Tirofiban vs. Abciximab (Intracoronary Bolus)

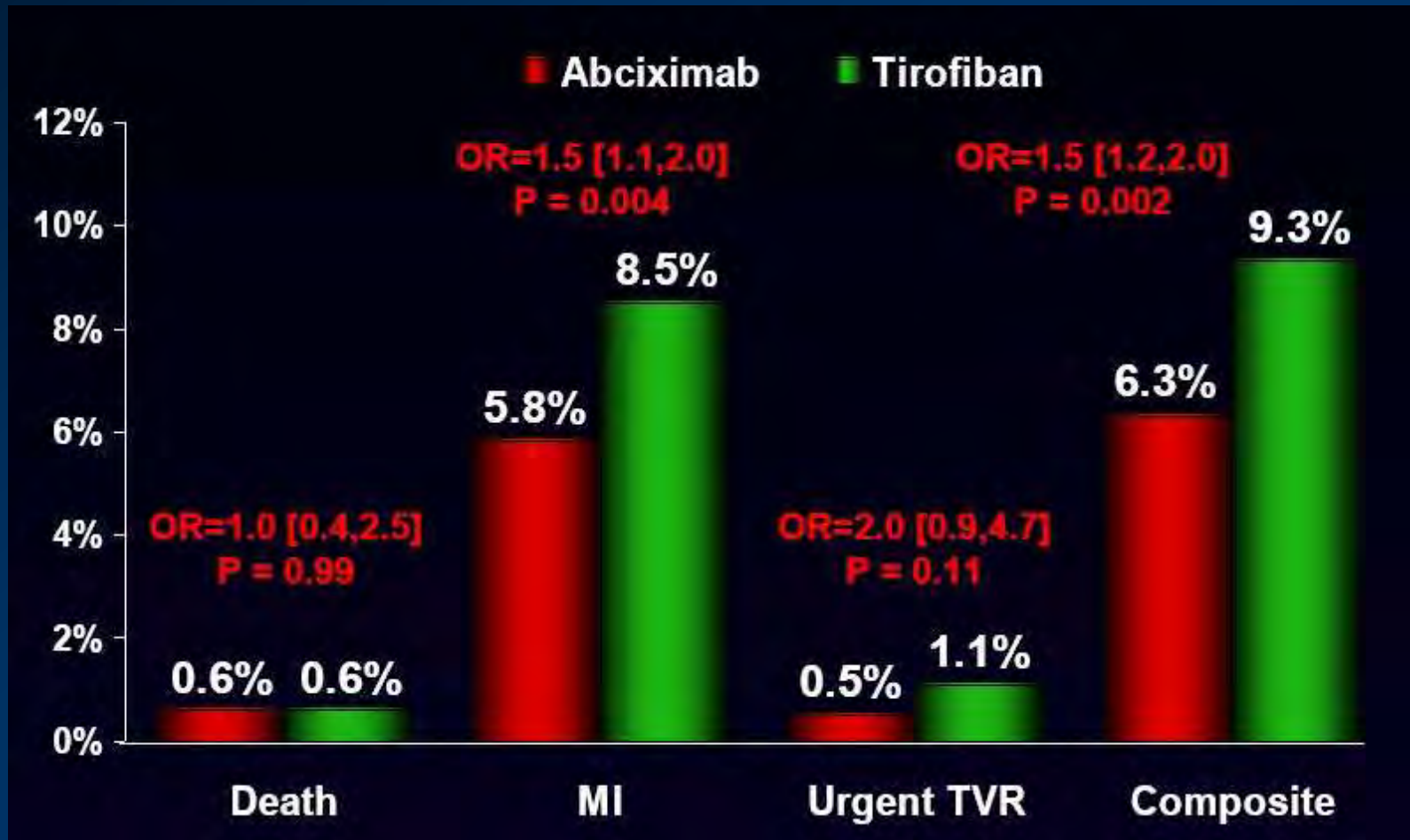
Costantini et al 2001

	*Tirofiban N=72 (IC)	*Abciximab N=198 (IC)	<i>p</i>
<i>Intra Hospitalar Events (%)</i>			
Acute Occlusion	(2,7)	(2,5)	0,984
AMI	(0,0)	(0,5)	1,000
Death	(1,4)	(0,5)	0,462
MACE	(4,1)	(3,5)	NS
Minor Bleeding	(5,5)	(1,5)	-

Costantini et al; Rev Bras Cardiol Invas 2001; 9 (4):12-17

TARGET Trial: 30 Day Events - ACS

Abciximab vs. Tirofiban

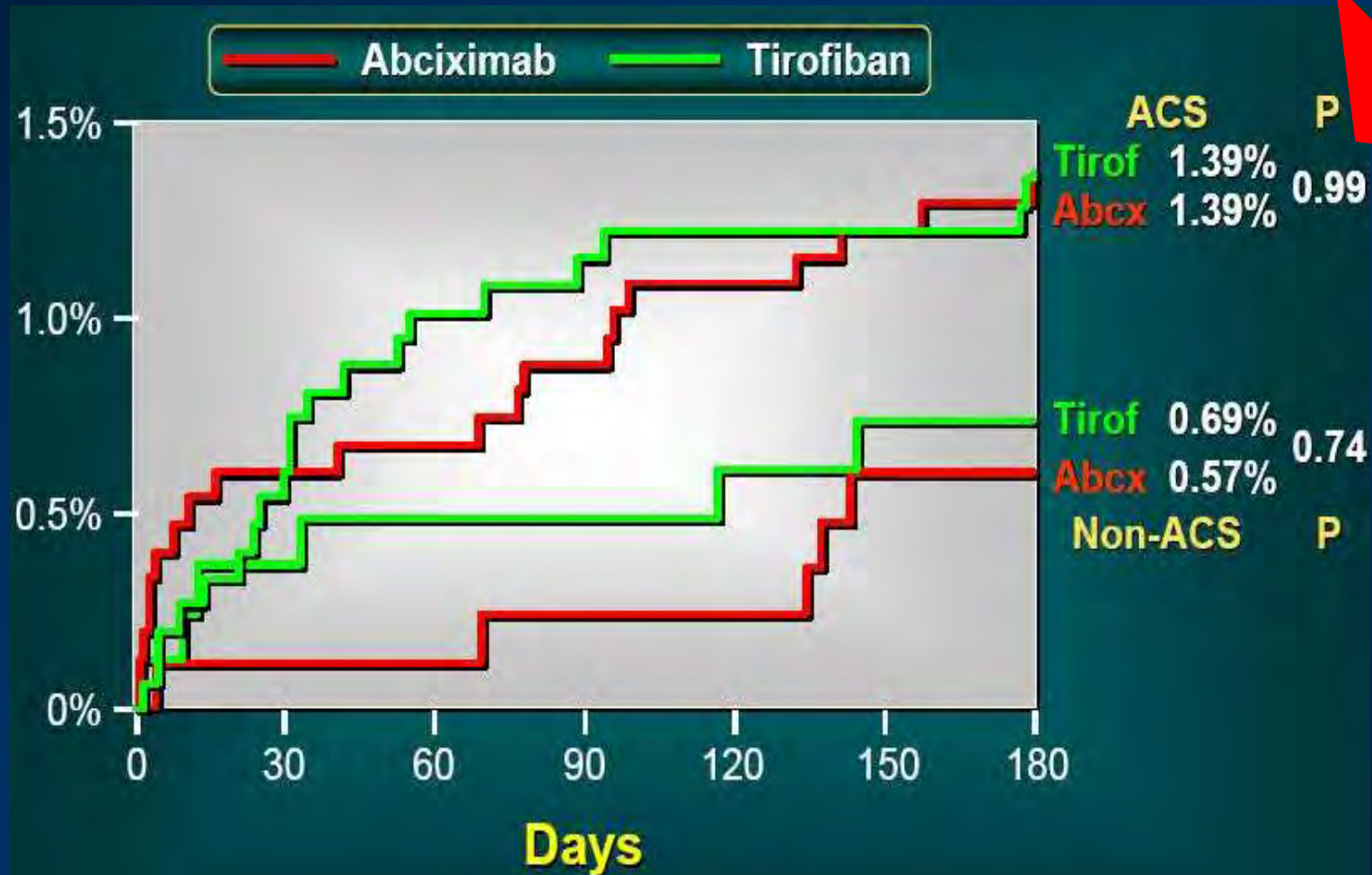


Stone, Moliterno, Bertrand, et al. Circ 2002;105:2347

TARGET Trial: 6 months Death

Abciximab vs. Tirofiban

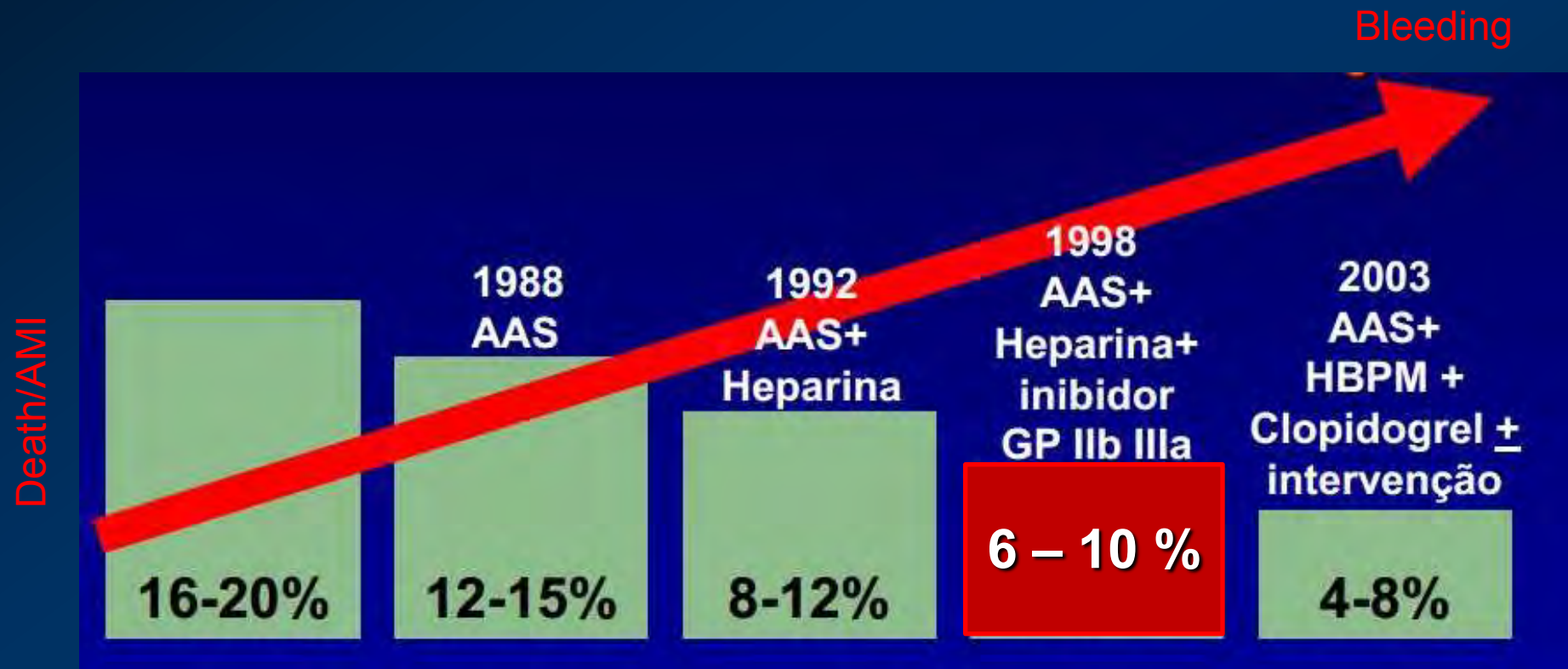
NS



Oral presentaion Stone, TCT 2002

Anti Thrombotic Drugs Risk Benefit in AMI/UA in the last decade:

Improved efficacy, however increased bleeding



RIDKER, P. et al. Are both aspirin and heparin justified as adjuncts to thrombolytic therapy for acute myocardial infarction? The Lancet, 341: 1574-1577, 1993.

Study Design

AMI <12 hours, any age, cardiogenic shock excluded
n=2,665 at 76 centers in N.A., S.A. and Europe

Angiography

Met angiographic criteria
n=2,082 (78%)

no
Registry
n=583 (22%)

yes

Randomize

1° PTCA
(n=516)

1° PTCA
+ Abciximab
(n=529)

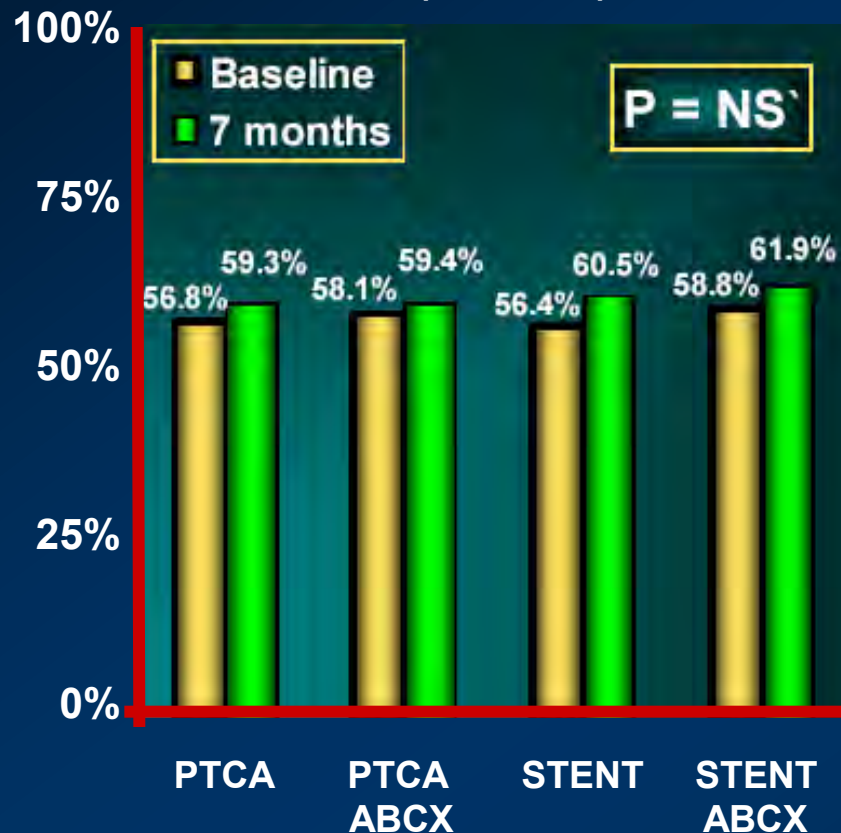
MultiLink stent
(n=512)

MultiLink stent
+ Abciximab
(n=525)

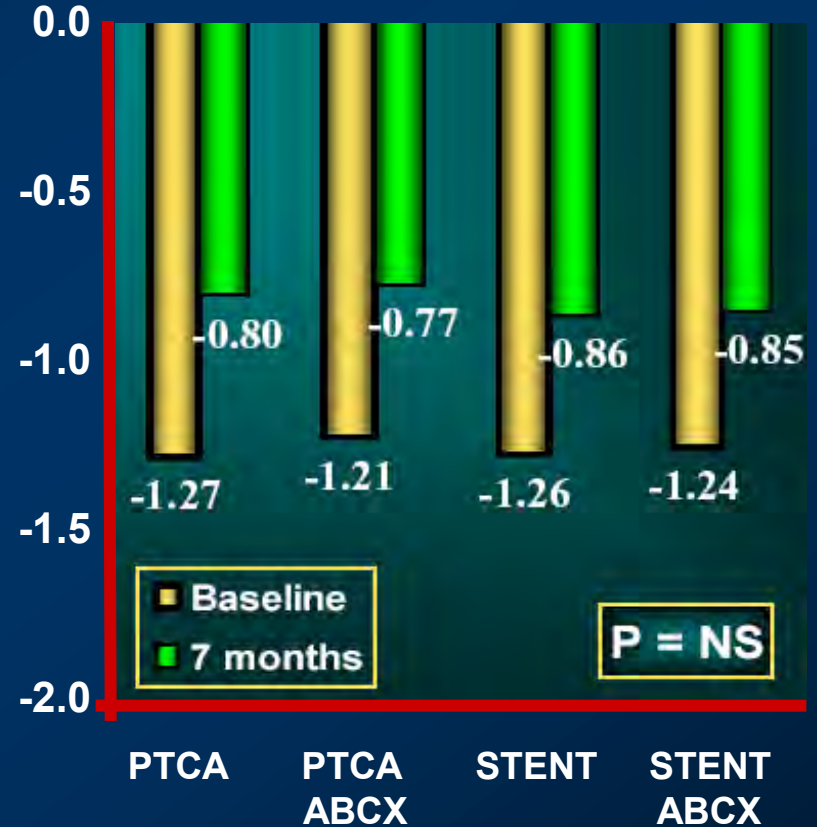
Stone et al.Circulation 2000; 102: II-664

CADILLAC: Myocardial Recovery

LVE (MEDIAN)

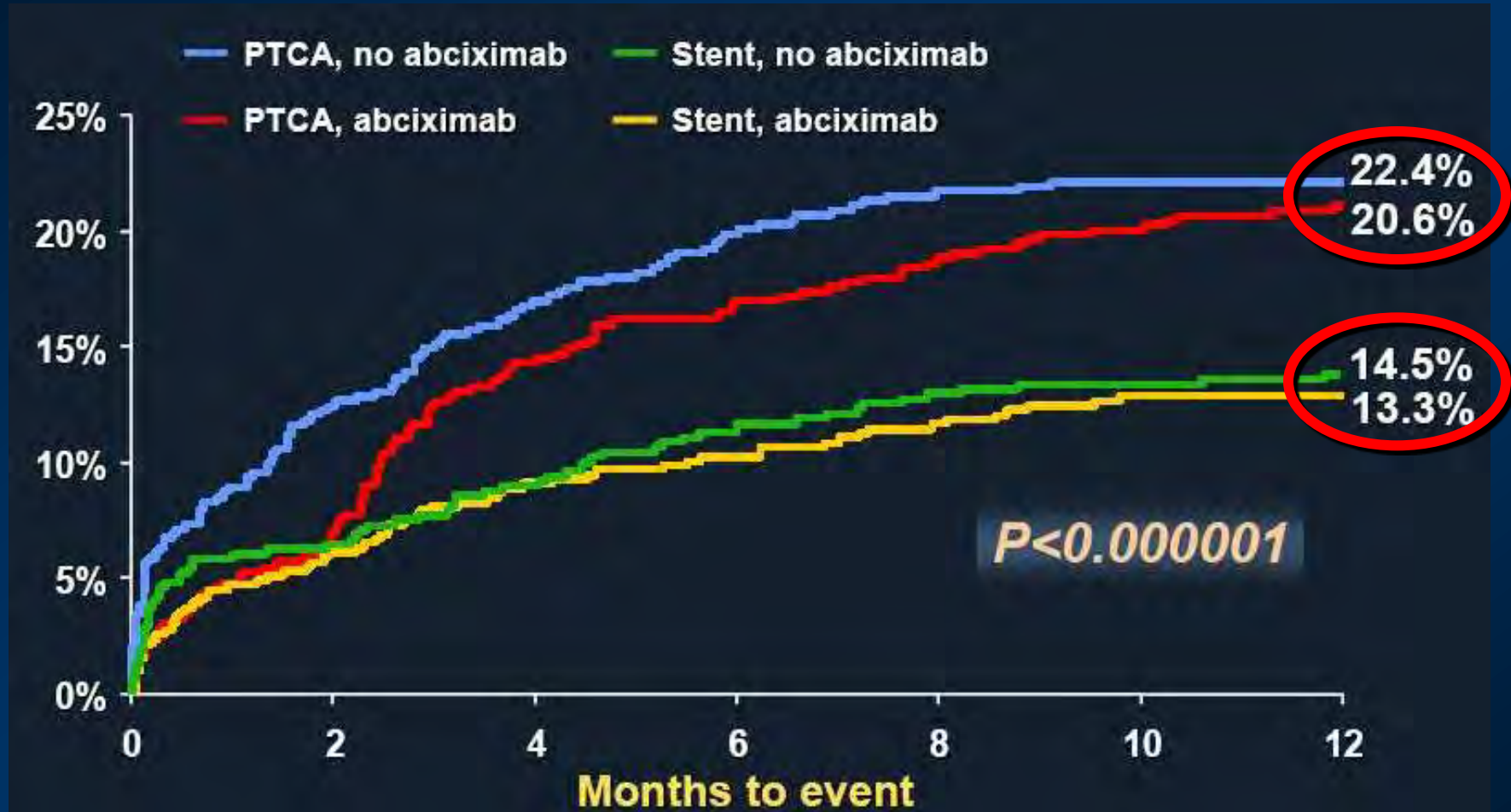


INFARCT ZONE RWM (ST.D/CHORD)



Stone GW et al. NEJM 2002;346:957-66

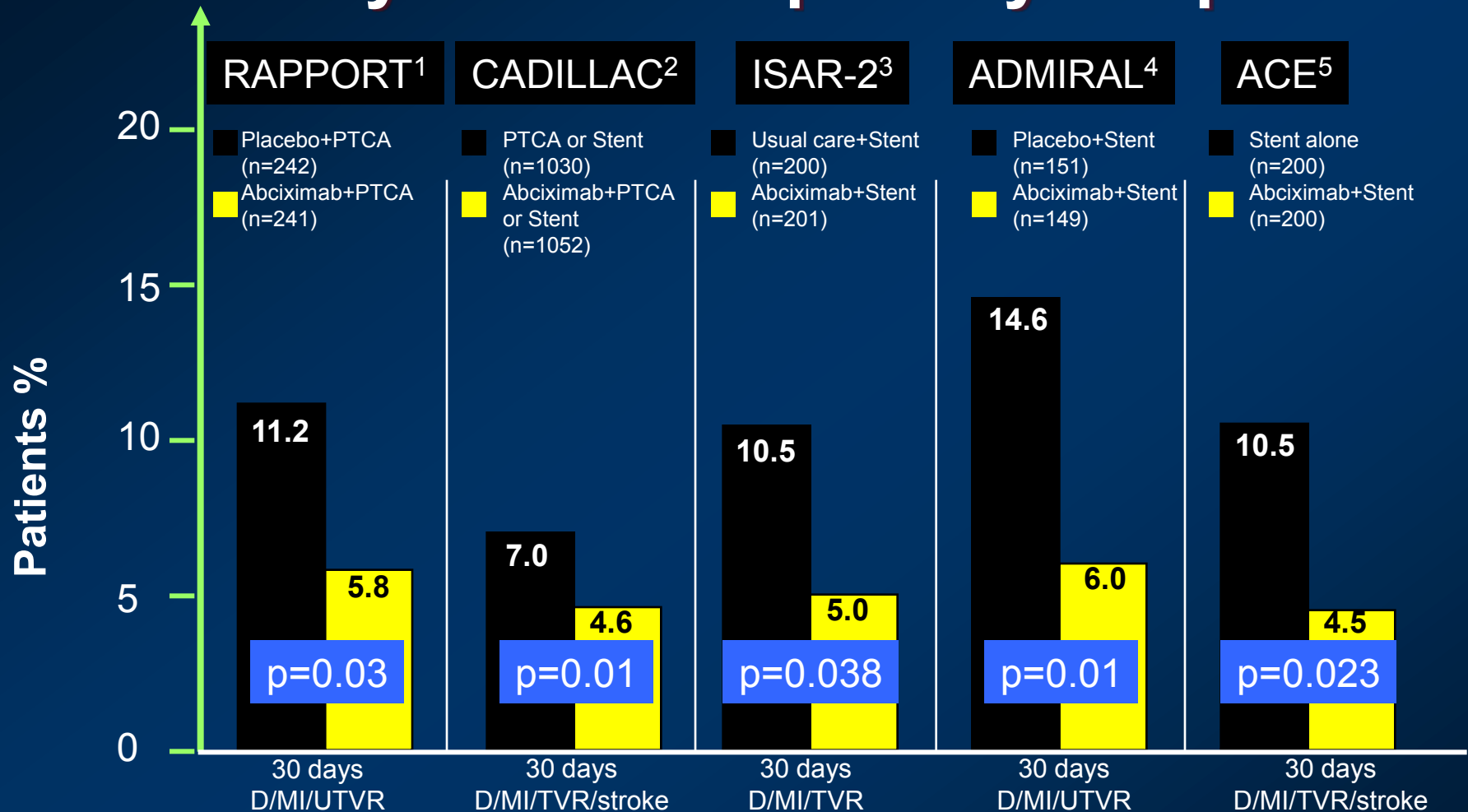
CADILLAC (n=2,082): 12 Month MACE



Stone GW et al. NEJM 2002;346:957-66

ReoPro® in Primary PCI Trials:

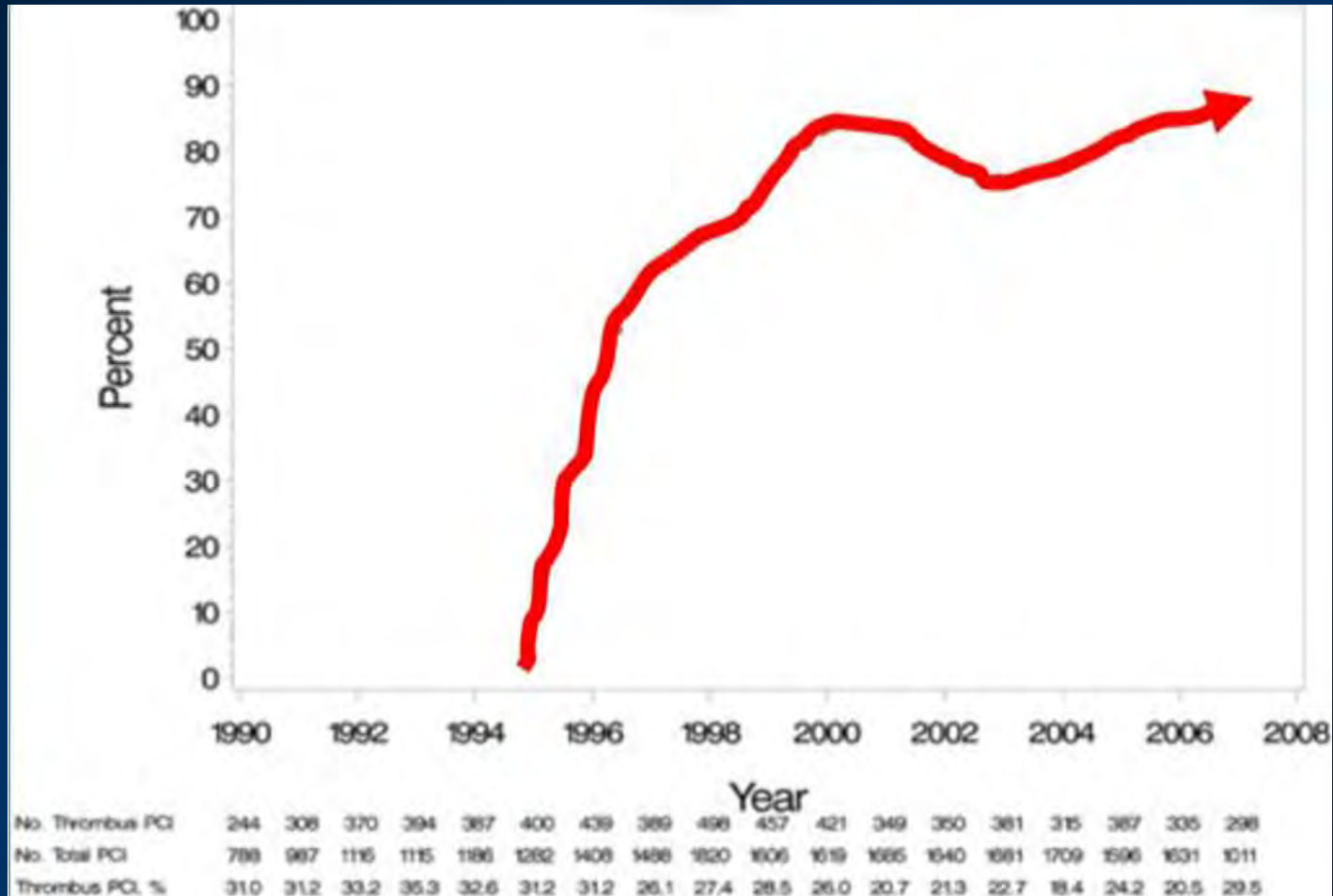
30-Day results for primary Endpoint



Adapted from

1. Brener SJ, et al. *Circulation* 1998;**98**:734–741.
2. Tcheng JE, et al. *Circulation* 2003;**108**:1316–1323
3. Neumann F-J, et al. *J Am Coll Cardiol* 2000;**35**:915–921.
4. Montalescot G, et al. *N Engl J Med* 2001;**344**:1895–1903
5. Antoniucci D, et al. *J Am Coll Cardiol* 2003;**42**:1879–1885

Temporal Trends in the Use of Glycoprotein IIb/IIIa Inhibitors



Adapted Costantino Costantini Solaci 2012; Holmes, J Am Coll Cardiol Interv. 2010;3(9):937-946

Use of Glycoprotein IIb/IIIa Receptor Antagonists in STEMI

BRAVE-3, ON - TIME 2, HORIZONS-AMI, META-ANALYSES GURM & De LUCA, MULTISTRATEGY, FINESSE

Modified Recommendation

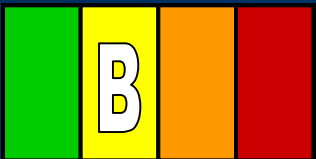
It is reasonable to start treatment with glycoprotein IIb/IIIa receptor antagonists at the time of primary PCI (with or without stenting) in selected patients with STEMI:

I IIa IIb III



abciximab

I IIa IIb III



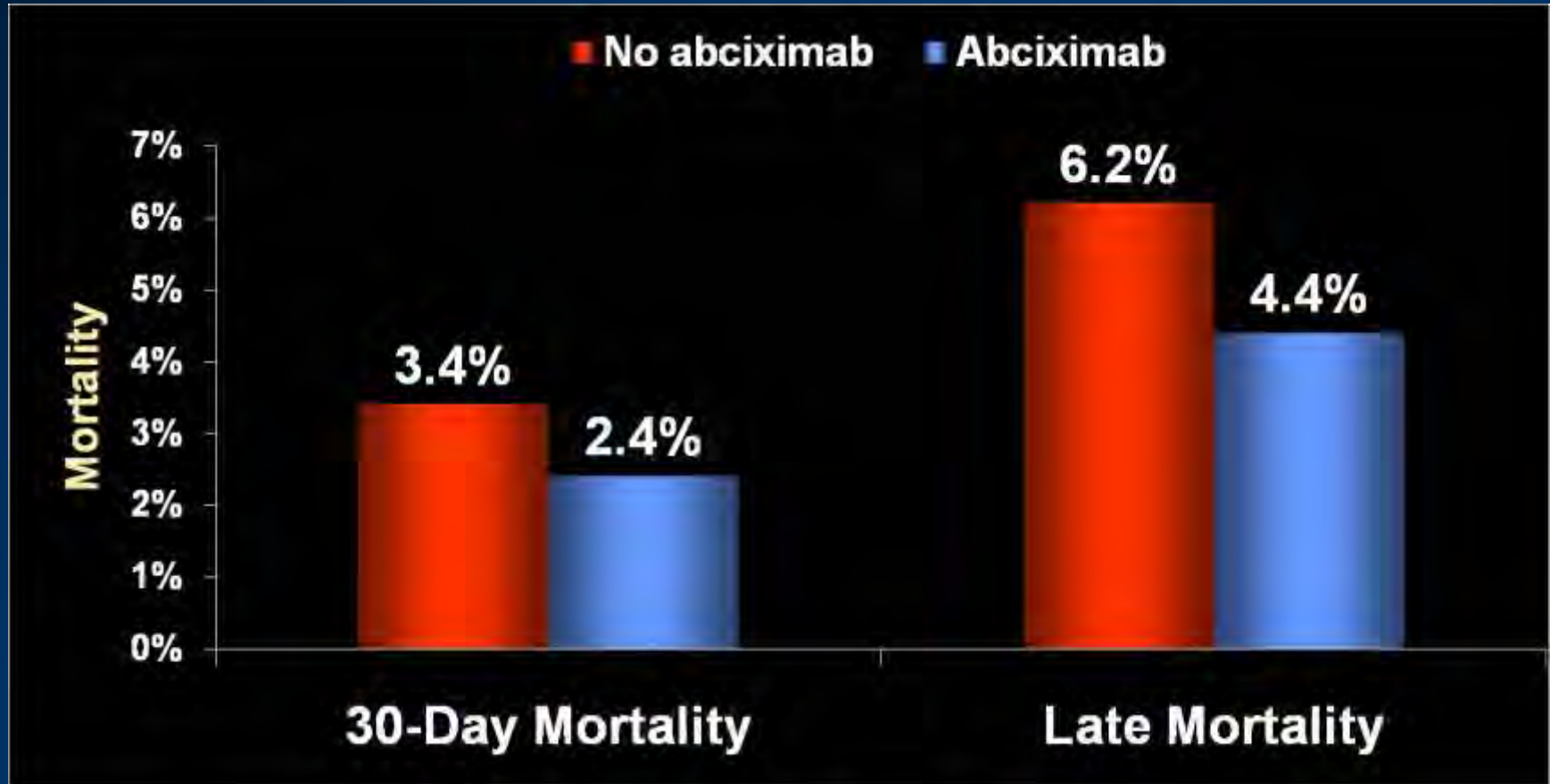
tirofiban and eptifibatide

Given the results of the studies cited above, the writing group concluded that in the setting of dual-antiplatelet therapy with UFH or bivalirudin as the anticoagulant, current evidence indicates that adjunctive use of a GP IIb/IIIa antagonist can be useful at the time of primary PCI but cannot be recommended as routine therapy. These agents might provide more benefit in selective use, for example, for the patient with a large thrombus burden or for patients who have not received adequate thienopyridine loading.

JACC Vol.54, No, 23, 2009; 2205-41., ACC/AHA 2009 Joint STEMI/PCI Guidelines Focused Update

Abciximab in Primary PCI Meta-analysis

8 RCTs – 3,949 pts with AMI w/i 12^o undergoing primary (7) or rescue (1) PCI rand to abciximab vs. placebo or control



De Luca G et al. JAMA 2005;293:1759–1765

Tirofiban as adjunctive therapy for acute coronary syndromes and percutaneous coronary intervention: a meta-analysis of randomized trials

Methods and results

We searched for randomized trials comparing tirofiban vs. placebo or any active control. Odds ratios (OR) were computed from individual studies and pooled with random-effect methods. Thirty-one studies were identified involving 20 006 patients (12 874 comparing tirofiban vs. heparin plus placebo or bivalirudin alone, and 7132 vs. abciximab). When compared with placebo, tirofiban was associated at 30 days with a significant reduction in mortality [OR = 0.68 (0.54–0.86); $P = 0.001$] and death or myocardial infarction (MI) [OR = 0.69 (0.58–0.81); $P < 0.001$]. The treatment benefit persisted at follow-up but came at an increased risk of minor bleedings [OR = 1.42 (1.13, 1.79), $P = 0.002$] or thrombocytopenia. When compared with abciximab, mortality at 30 days did not differ [OR = 0.90 (0.53, 1.54); $P = 0.70$], but in the overall group tirofiban trended to increase the composite of death or MI [OR = 1.18 (0.96, 1.45); $P = 0.11$]. No such trend persisted at medium-term follow-up or when appraising studies testing tirofiban at 25 µg/kg bolus regimen.

Conclusion

Tirofiban administration reduces mortality, the composite of death or MI and increases minor bleedings when compared with placebo. An early ischaemic hazard disfavours tirofiban when compared with abciximab in studies based on 10 but not 25 µg/kg tirofiban bolus regimen.

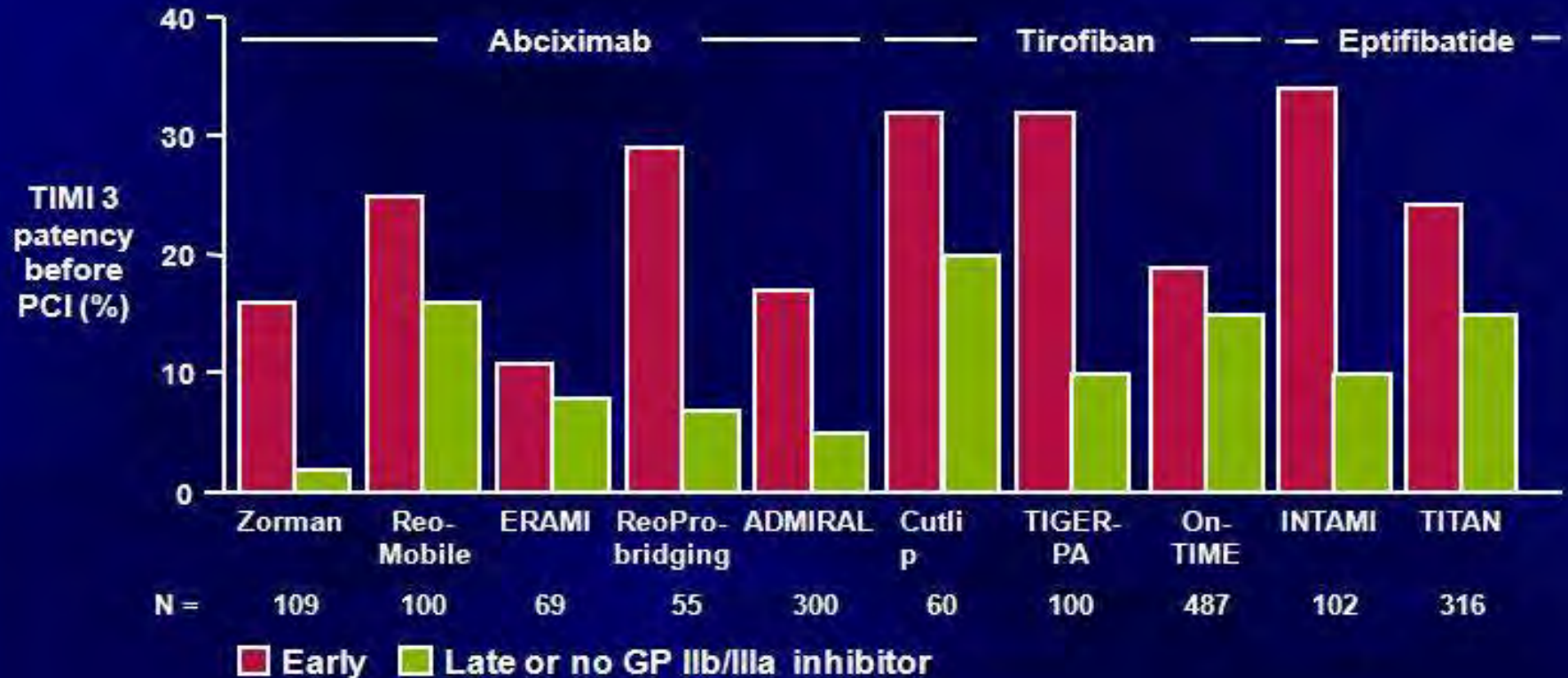
Abciximab vs. Tirofiban (MultiStrategy Trial)

3 Year Outcomes All-Cause Death



Am Heart J. 2012 Jan;163(1):104-11.

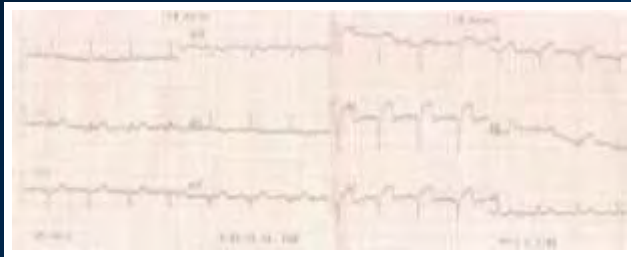
TIMI 3 patency before PCI in trials of early vs late/no GP IIb/IIIa inhibitors in STEMI



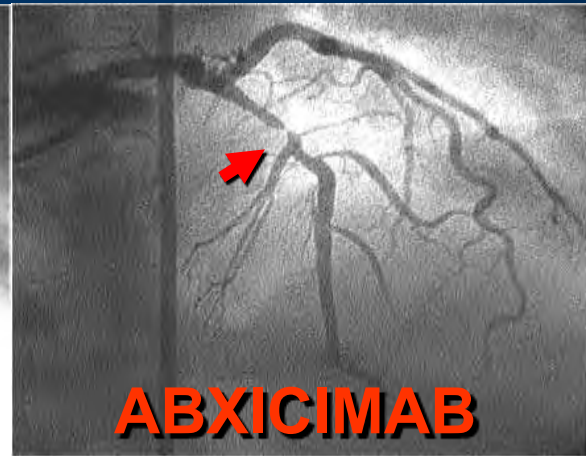
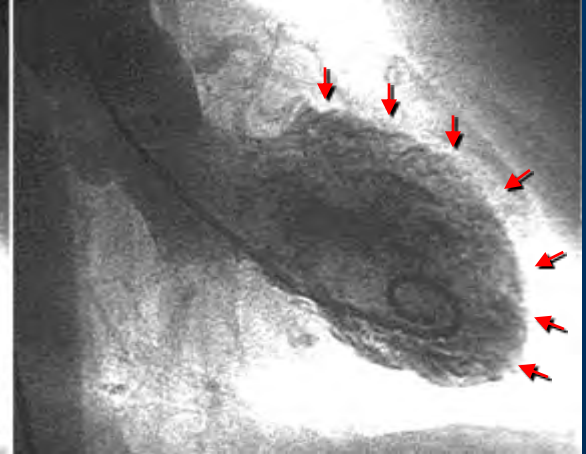
Zeymer U et al. *Eur Heart J*. 2005;26:1971-7.
www.timi.org

IAM & ABXICIMAB (1999)

LVEF= 42 %



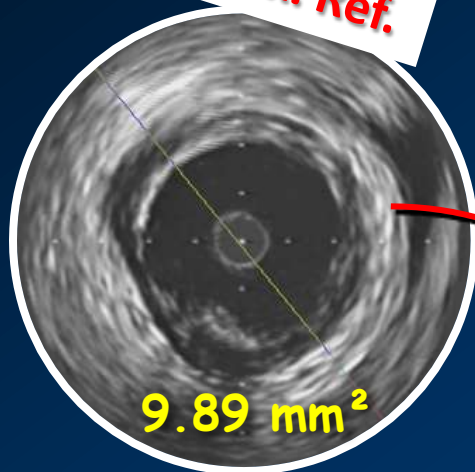
Anterior STEMI , 195'. Onset



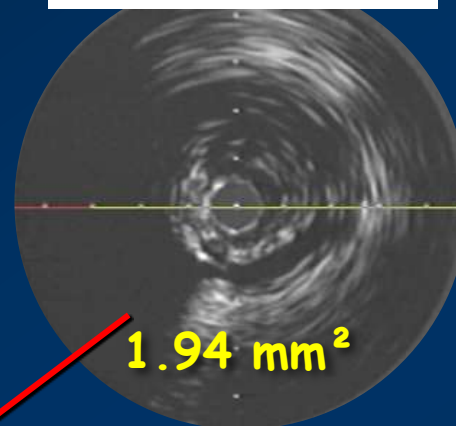
ABXICIMAB

GML ♀
61 Yrs
2239
25Sep99

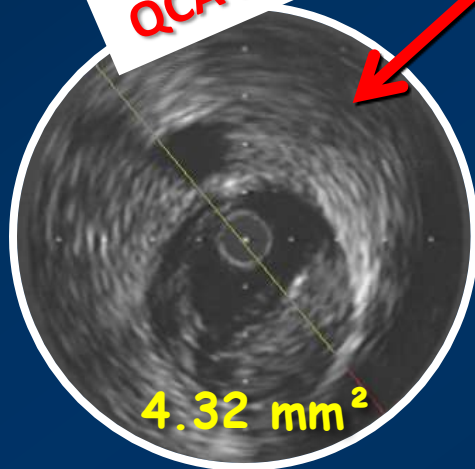
IVUS Prox. Ref.



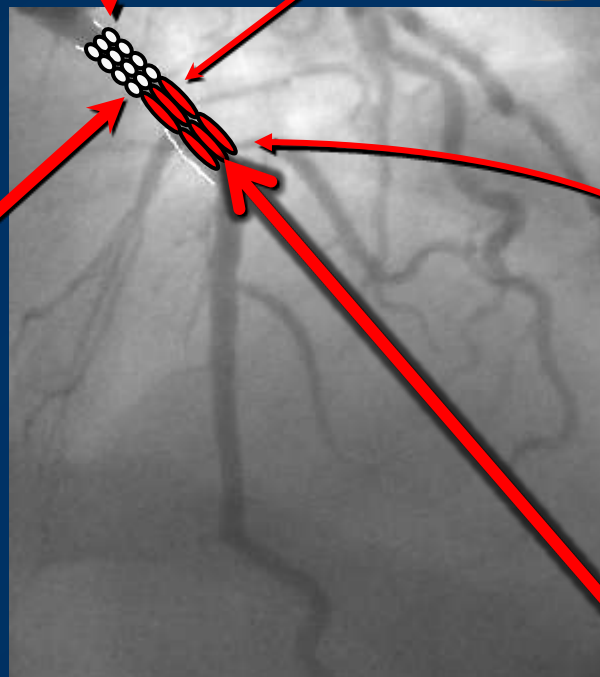
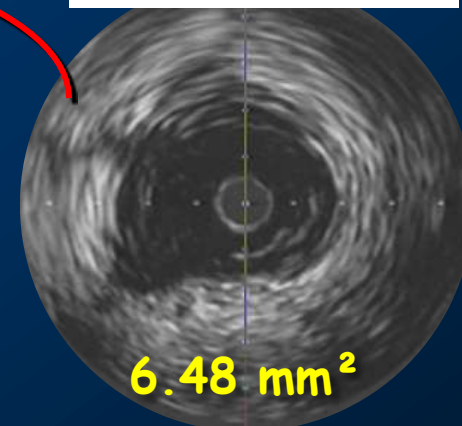
Lesion



QCA Prox. Ref.



Distal Ref.



QCA Length 10.02 mm

IVUS Length
16 mm

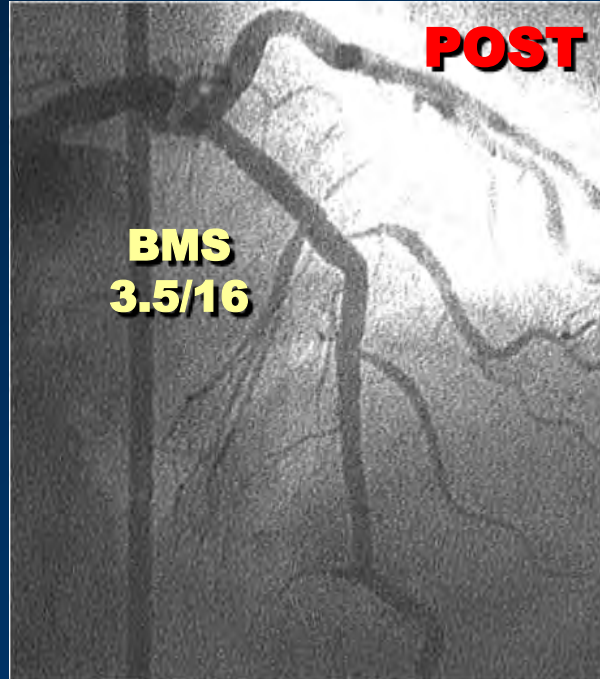
Year 1999 Angiography Pre & Post PCI in STEMI

PRE

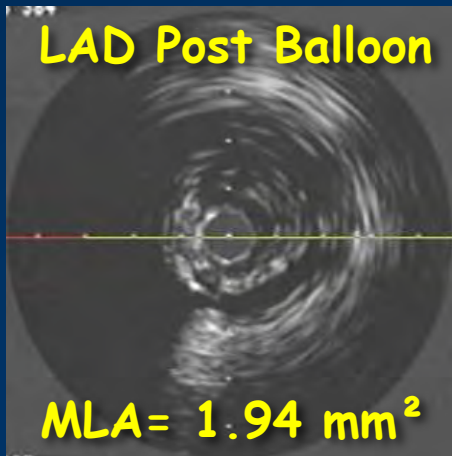


POST

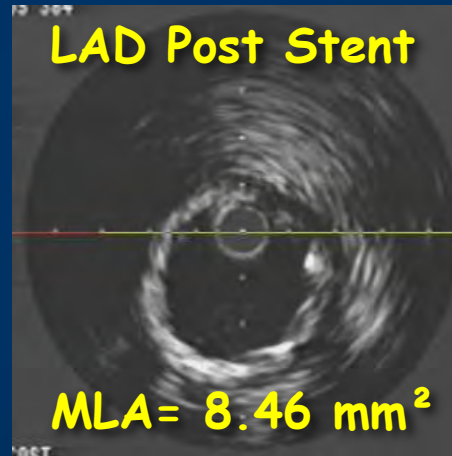
**BMS
3.5/16**



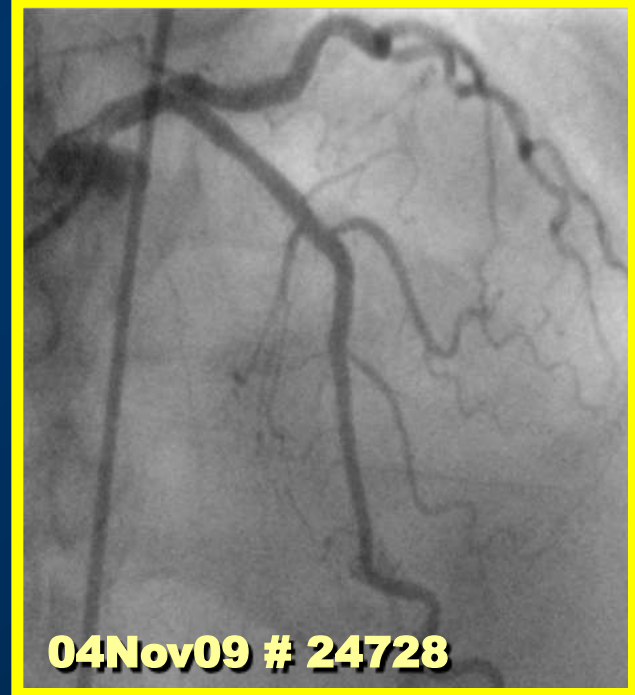
LAD Post Balloon



LAD Post Stent

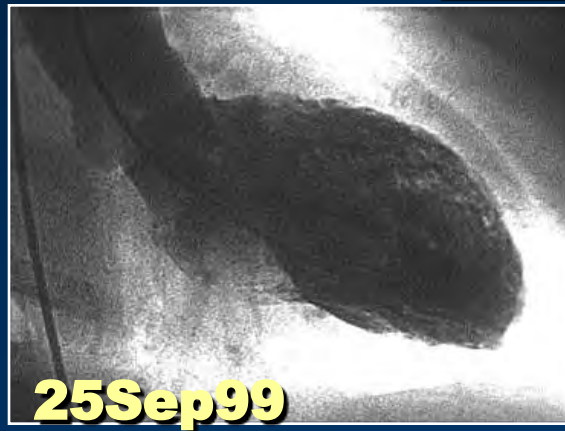
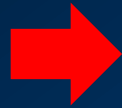


Year 2009
FU @ 10 Yrs

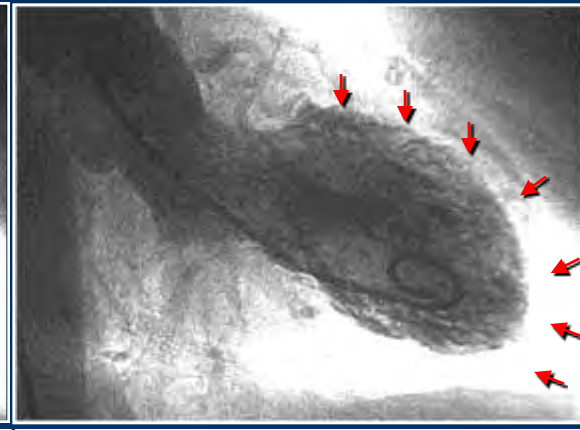


LVEF= 42 %

**Anterior AMI
1999 > 3 hs**



25Sep99



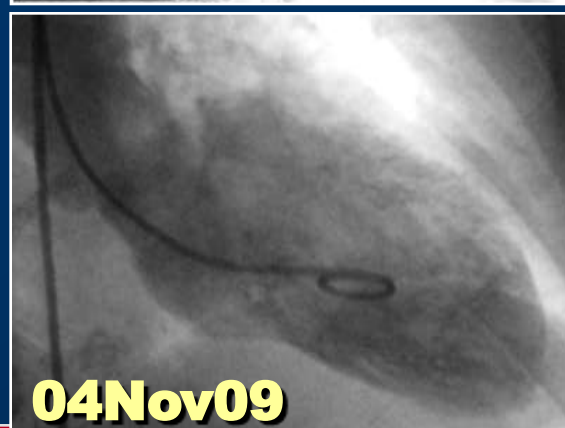
**FU @ 32 Days
After PTCA With
BMS**



27Oct99



**FU @ 10 Yrs
After PTCA With
BMS**



04Nov09



LVEF= 76 %

GML ♀
71 Yrs

IIb/IIIa in STEMI 1998 - 2012

HCC Use vs. No Use

	*IIb/IIIa Used N=409 (51%)	*IIb/IIIa No Used N=389 (49%)	<i>p</i>
<i>Intra Hospitalar Events (%)</i>	92 % IC		
TIMI 3 Flow	(94,7)	(94,4)	0,7123
Death	(5,6)	(6,42)	0,6258
REMI	(0,51)	(1,7)	0,1103
REPCI	(1,02)	(2,2)	0,1875
CABG or repeat PCI	(0,24)	(0,51)	0,5309
Transfusion	(6,1)	(7,45)	0,4476

*HCC MI: Intra Hospitalar Events

Efficacy of intracoronary IIb/IIIa inhibitor during primary PCI.

Standard use or bailout only?

2011 ACC/AHA PCI Guidelines

GP IIb/IIIa Inhibitor Therapy*

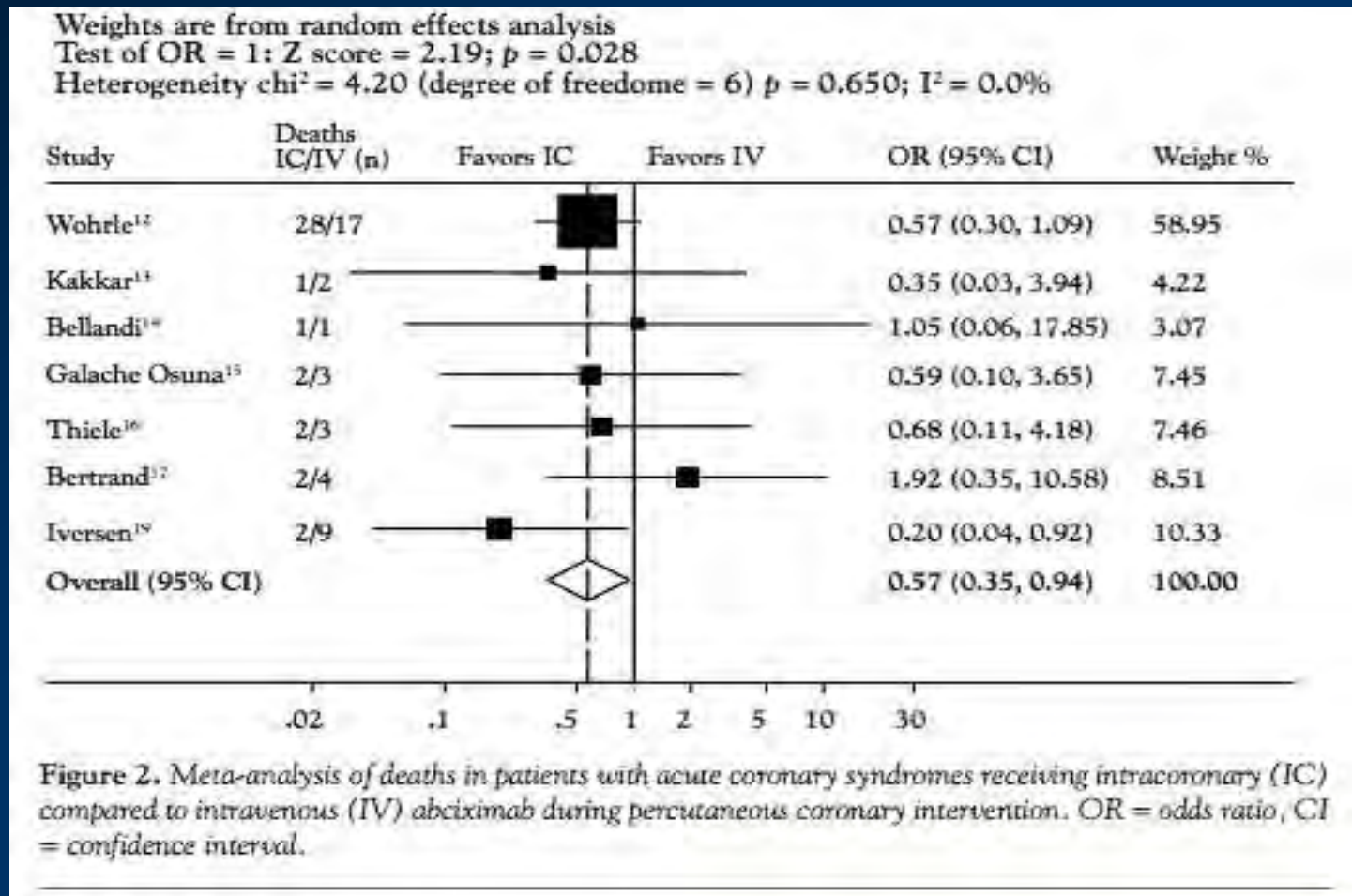
Additional Recommendations	COR	LOE
Administration of <i>intracoronary</i> (versus IV) abciximab administration in patients undergoing primary PCI with abciximab	IIb	B
Routine precatheterization laboratory (e.g., ambulance or emergency room) administration of GP IIb/IIIa inhibitors as part of a upstream strategy for patients with STEMI undergoing PCI	III – No Benefit	B

*Recommendations apply for abciximab, double-bolus eptifibatide, or high-bolus dose tirofiban



2011 ACCF/AHA/SCAI Guideline for PCI and Coronary Revascularization

Meta Analysis of IC Versus IV Abciximab administration of peer reviewed studies 997 STEMI



Hansen et al. Journal of Invasive Cardiology Vol 22; 6. June 2010. 278-282.

Meta-analysis of IV vs IC Bolus Abciximab (+ 12° Infusion) During Primary PCI in STEMI

6 RCTs, 1246 total pts randomized

30-Day Mortality



Navarese EP et al. Platelets 2011;On-line

Meta-analysis of data 1,198 STEMI pts in 5 randomized trials that compared intracoronary and IV Abciximab

30-Day Follow Up

30-day Follow-up	Intracoronary (n = 611)	IV (n = 597)	P Value
Death or Reinfarction	2.9%	5.5%	0.03
Death	1.5%	3.4%	0.04
TVR	2.6%	4.8%	0.045

Conclusion: In a meta-analysis of small, single-center trials, intracoronary vs. IV abciximab was associated with improved short-term survival.

Piccolo R, et al. Heart. 2012: Epub ahead of print.

Comparasion of Abciximab vs. Eptifibatide During PCI in STEMI (from the HORIZONS-AMI Trial)

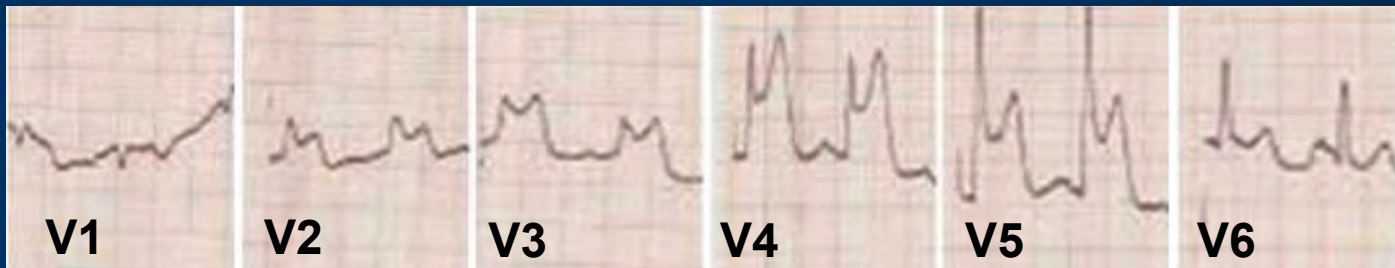
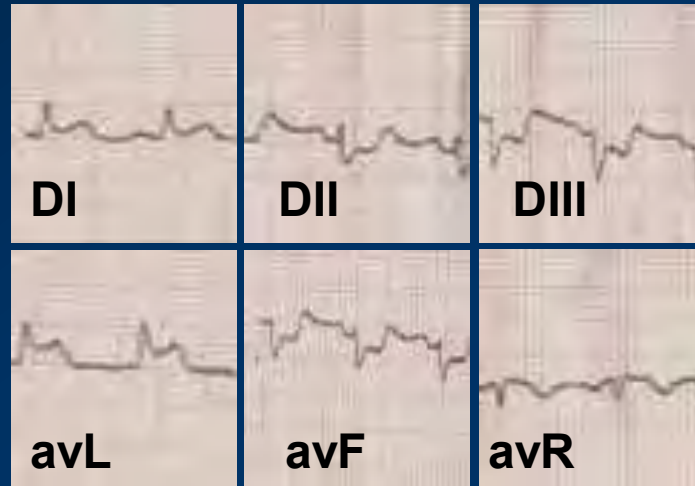
1,710 primary PCI pts in the heparin plus glycoprotein lib/IIla inhibitor arm compared according to GPI choice
3-Year Outcomes

3-Year Outcomes	Abciximab (n = 907)	Eptifibatide (n = 803)	P Value
MACE	21.3%	22.8%	0.47
Major Bleeding (Non-CABG)	10.9%	10.2%	0.68
NACE	27.3%	28.4%	0.64

Implications: In pts with STEMI, use of either abciximab or eptifibatide during primary PCI results in comparable bleeding risks and clinical efficacy at 3 years.

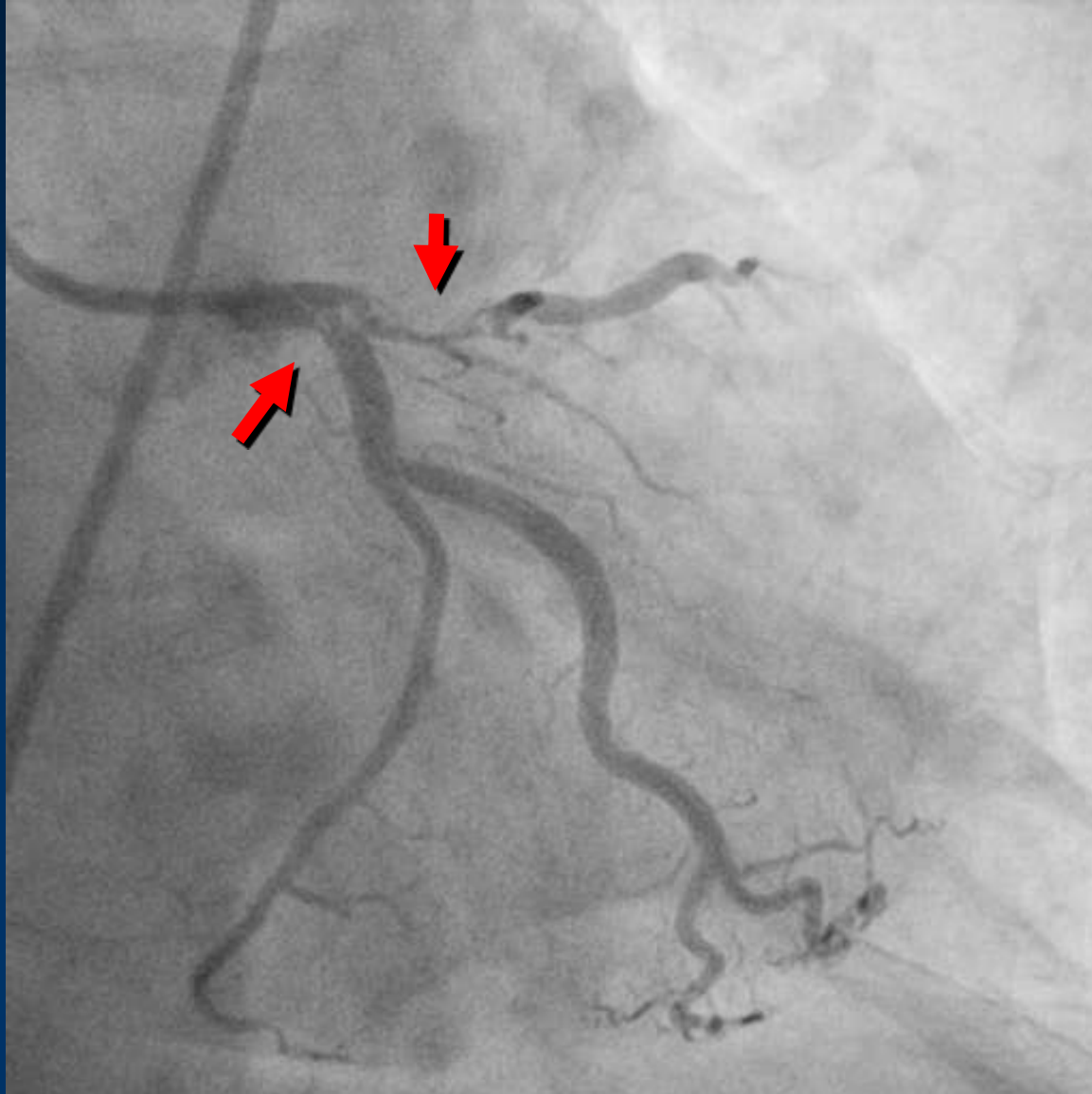
Singh HS, et al. Am J Cardiol. 2012: Epub ahead of

ECG Ambulance, Anterior wall AMI 40 min on set

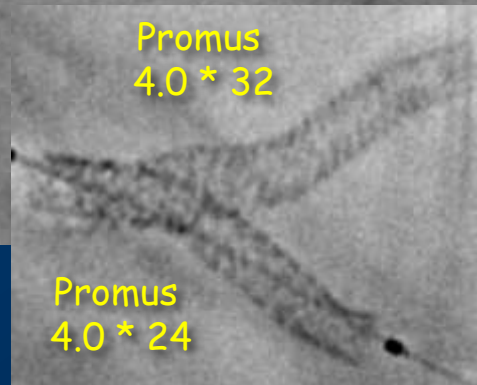
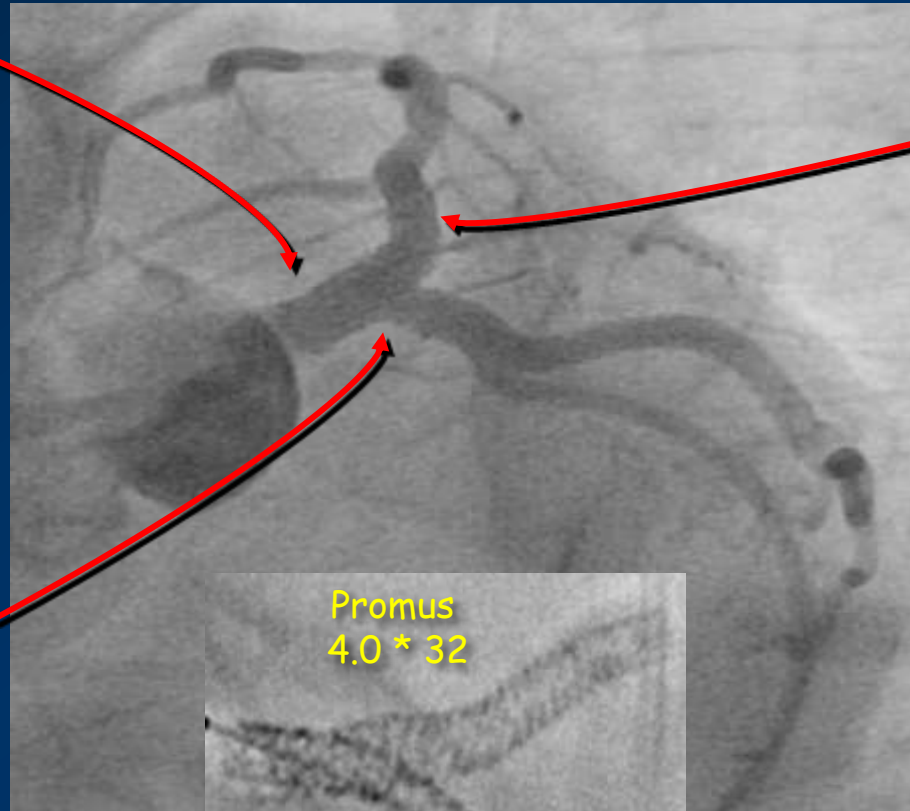
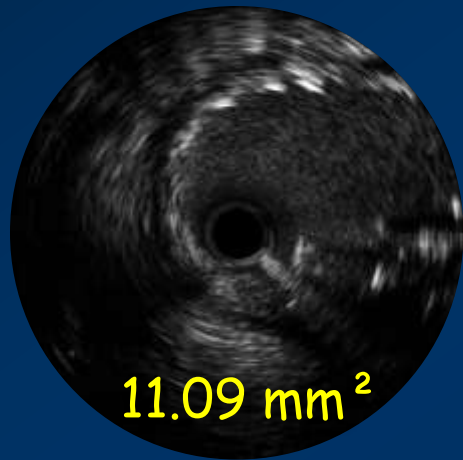
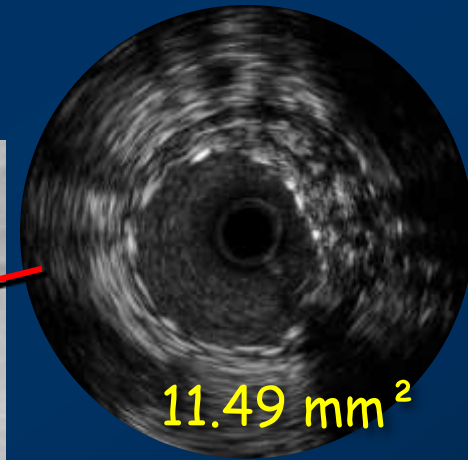
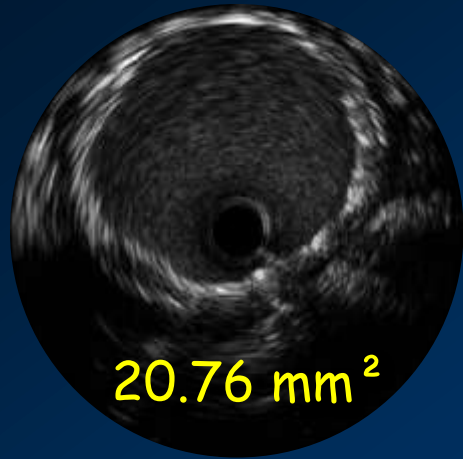


(CARDIAC SURGEON in the FAMILY)

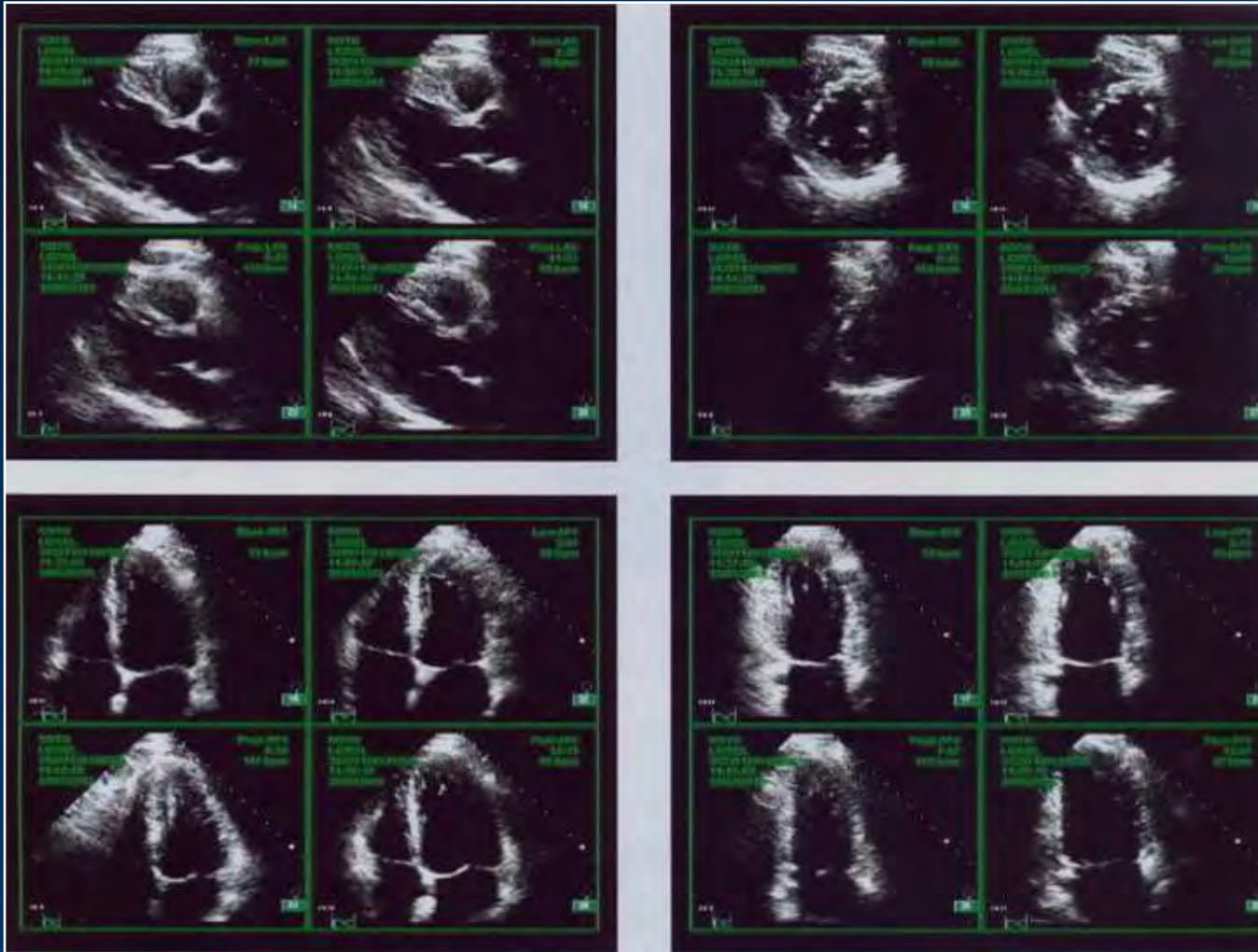
LM > LAD / LCx



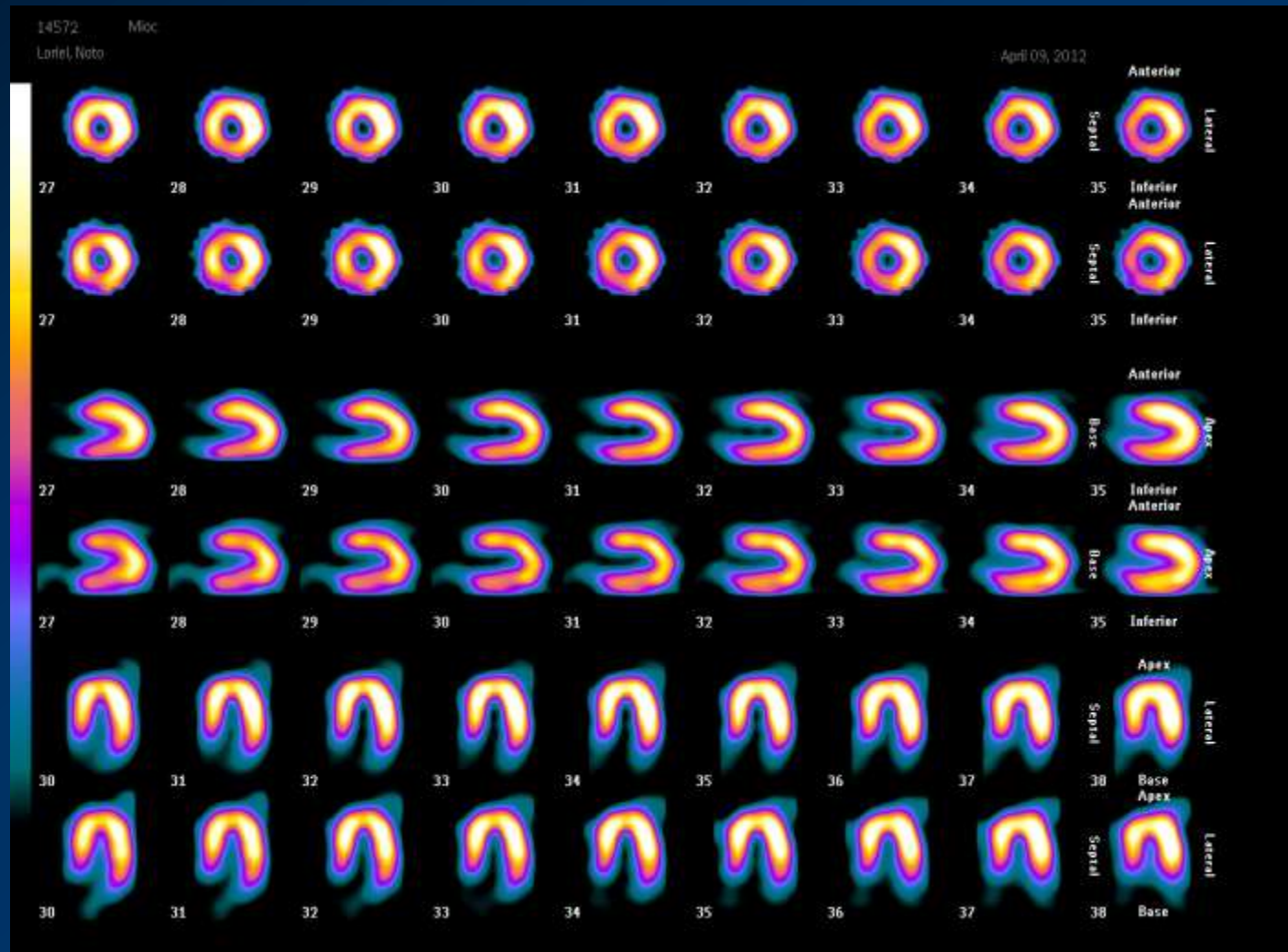
Final Result



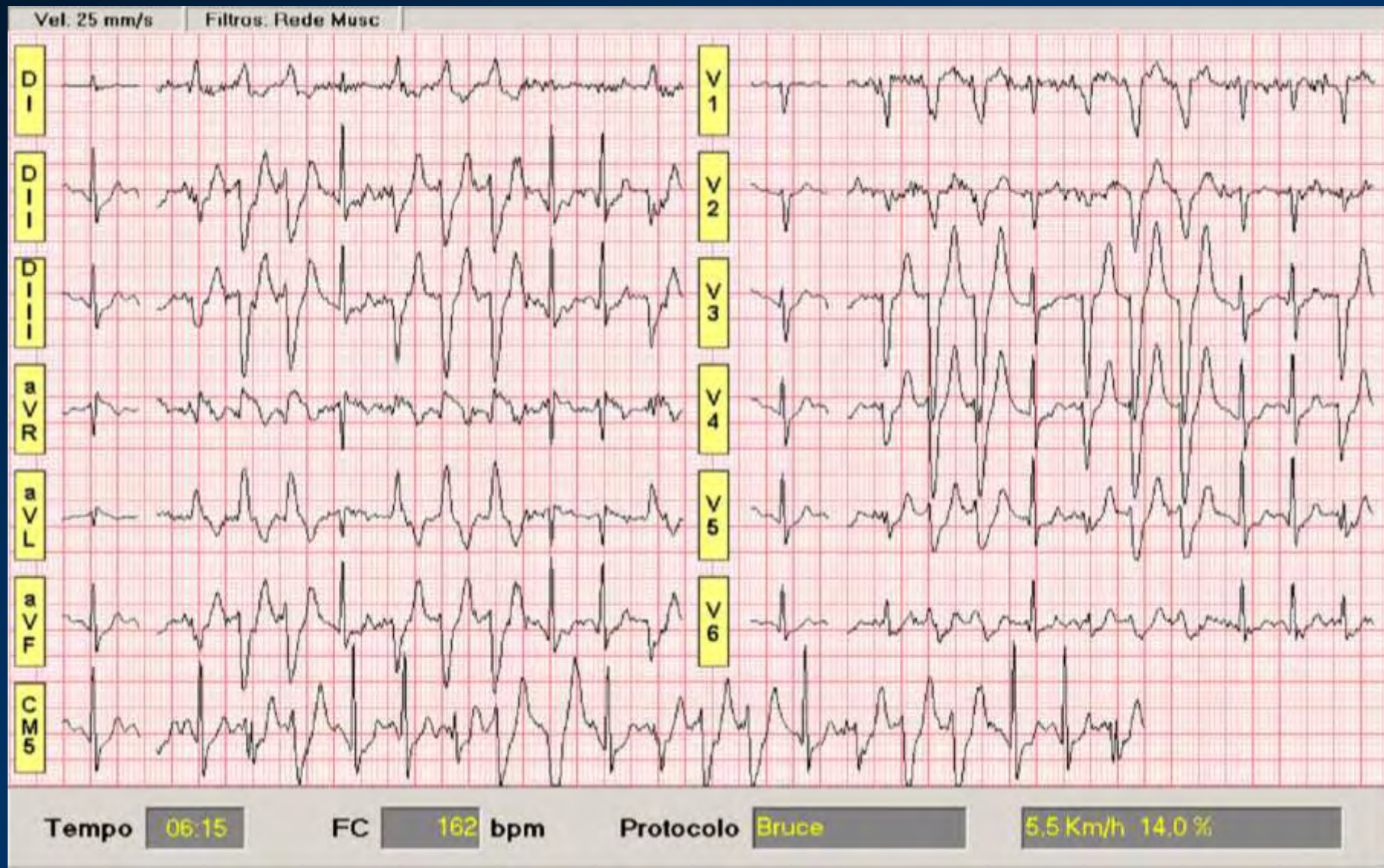
Dobutamine Echo Stress; Normal After 3 months



Thallium Spect; Normal After 3 months

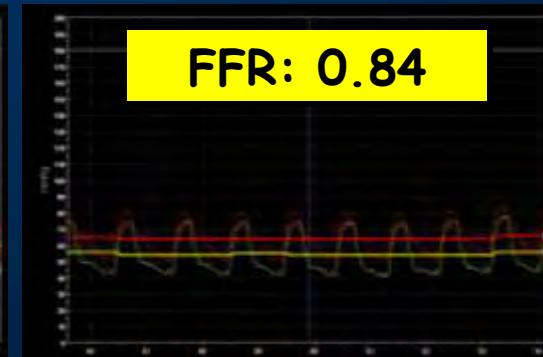
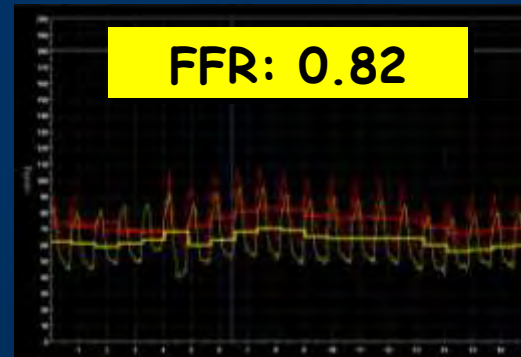
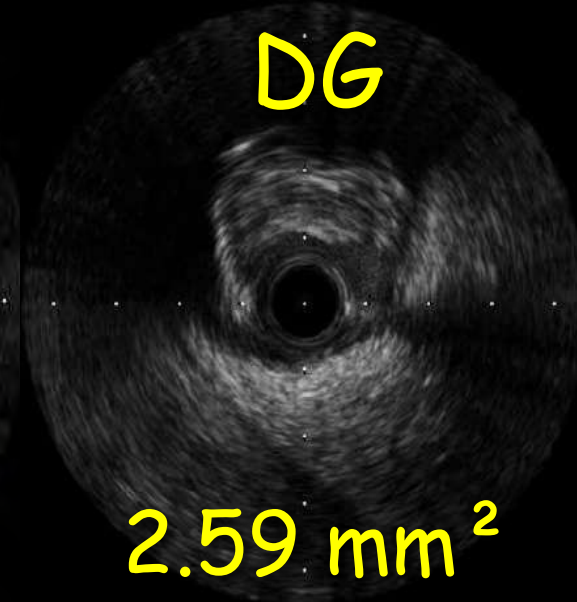
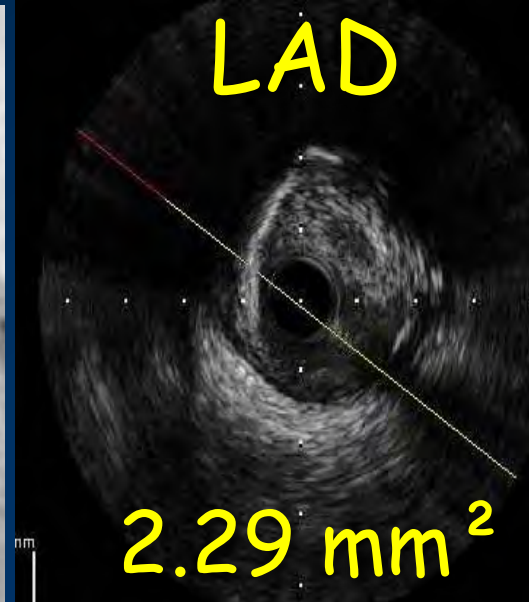
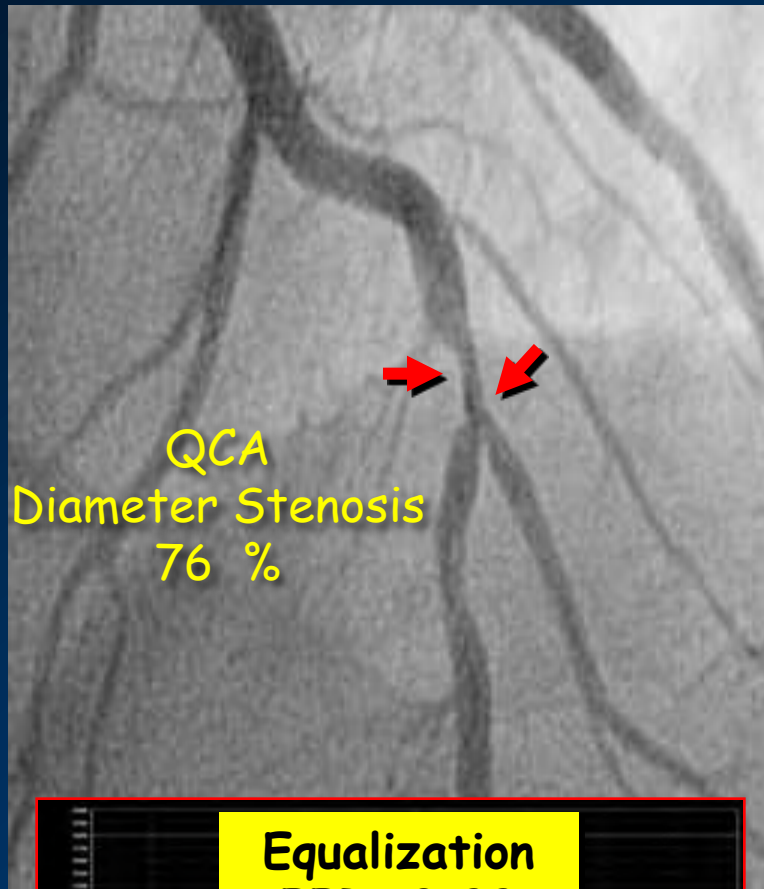


TMT After 3 months



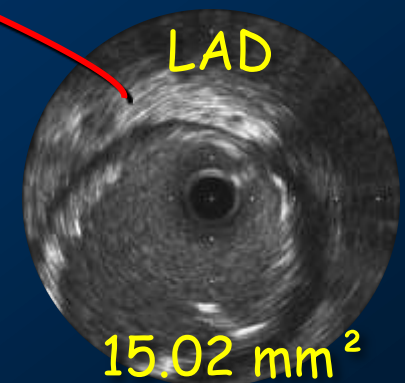
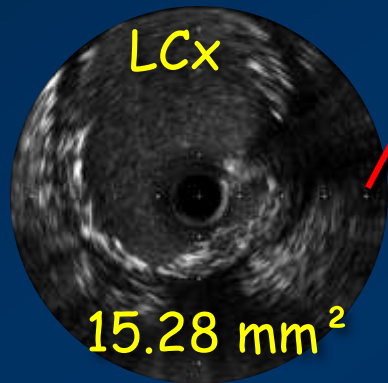
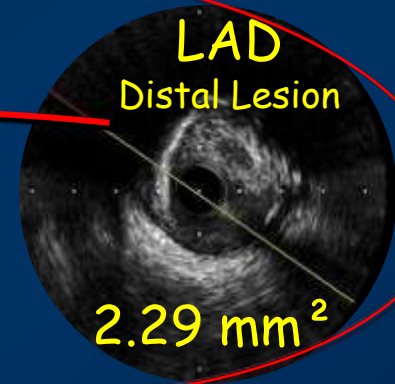
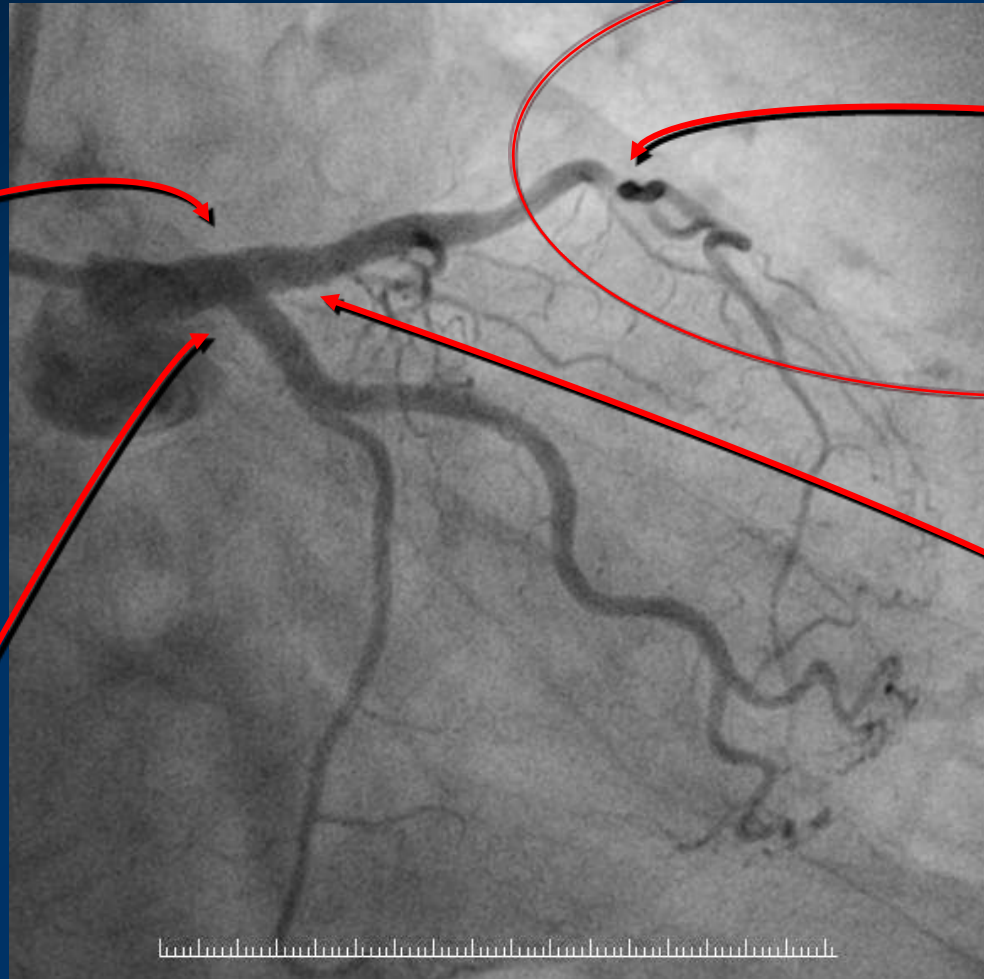
FFR Vs. IVUS Vs. ???

Continuous Intravenous Infusion 180 $\mu\text{g/kg/min}$



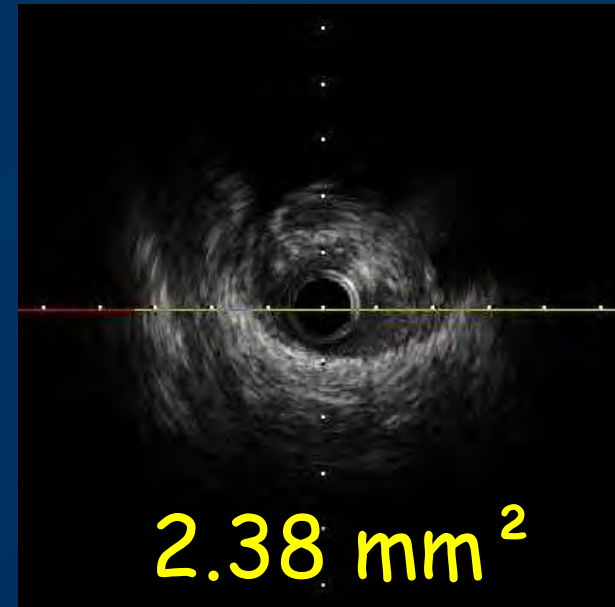
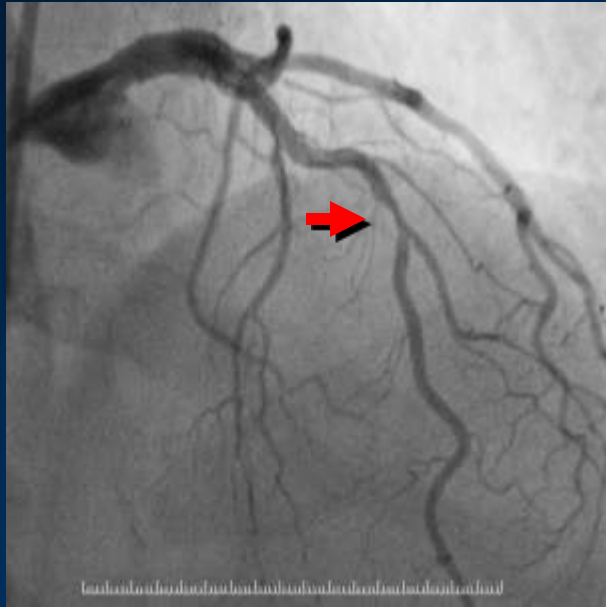
Follow up @ 7 months

ANGIO and IVUS Evaluation



Second Evaluation FFR

0.78

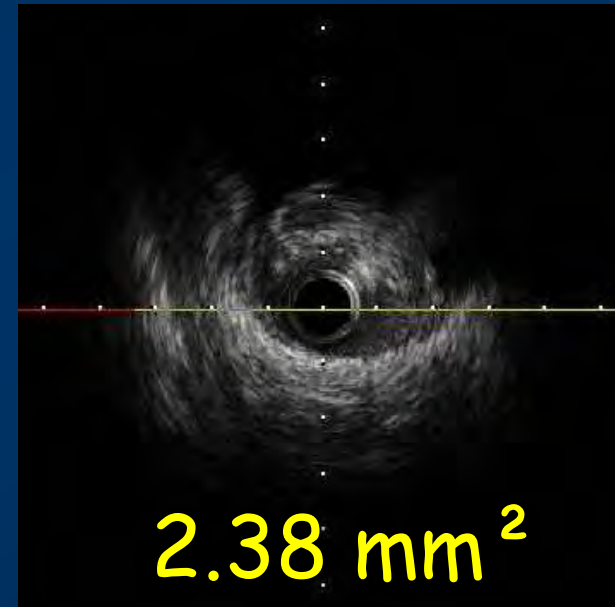
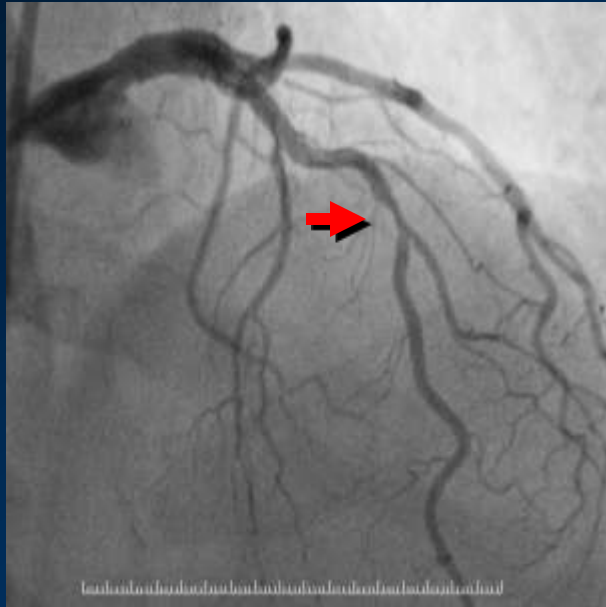


2.38 mm²

FFR was measured with a coronary pressure guidewire (Radi Medical Systems) at maximal hyperemia induced by intravenous adenosine, which was administered at a rate of 140 µg per kilogram of body weight per minute through IV.

Second Evaluation FFR

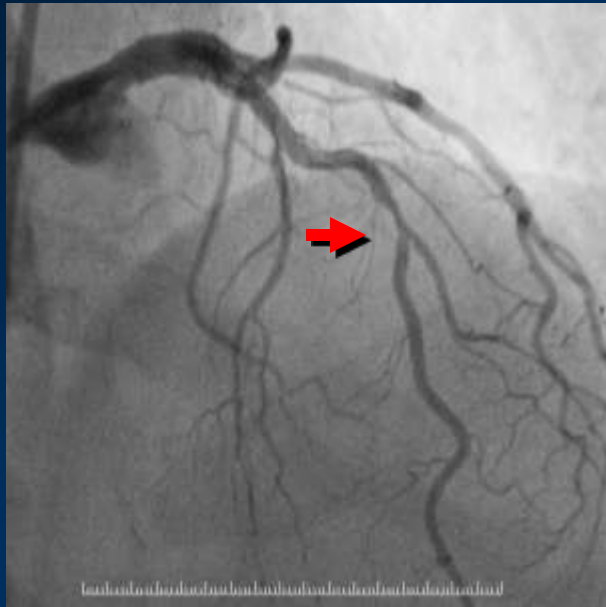
0.78



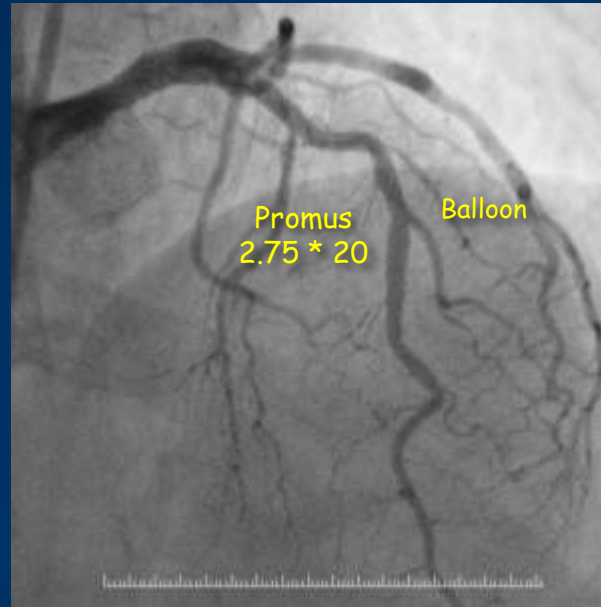
2.38 mm²

FFR was measured with a coronary pressure guidewire (Radi Medical Systems) at maximal hyperemia induced by intravenous adenosine, which was administered at a rate of 140 µg per kilogram of body weight per minute through IV.

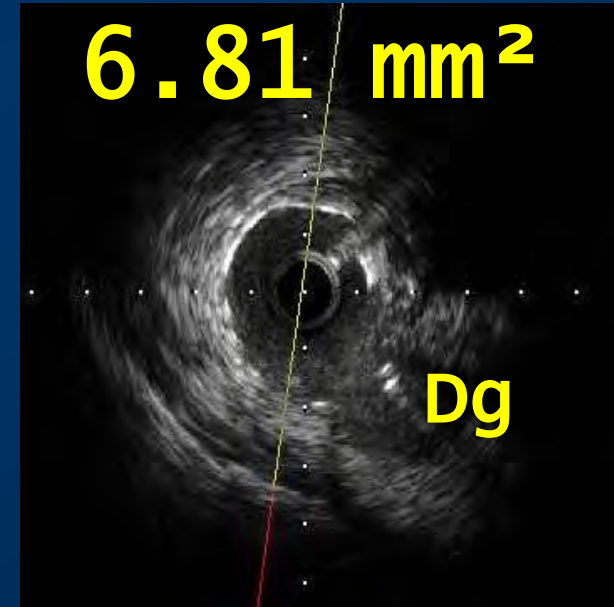
Second Stage LAD / DG



Pre



Post



IVUS

INFUSE-AMI Trial

452 pts with anterior STEMI

Anticipated Sx to PCI <5 hrs, TIMI 0-2 flow in prox or mid LAD
Primary PCI with bivalirudin anticoagulation

Pre-loaded with aspirin and
clopidogrel 600 mg or prasugrel 60 mg

Stratified by symptoms to angio <3 vs ≥3 hrs,
and prox vs mid LAD occlusion

R
1:1

Manual aspiration

No aspiration

R
1:1

IC Abcx

No Abcx

R
1:1

IC Abcx

No Abcx

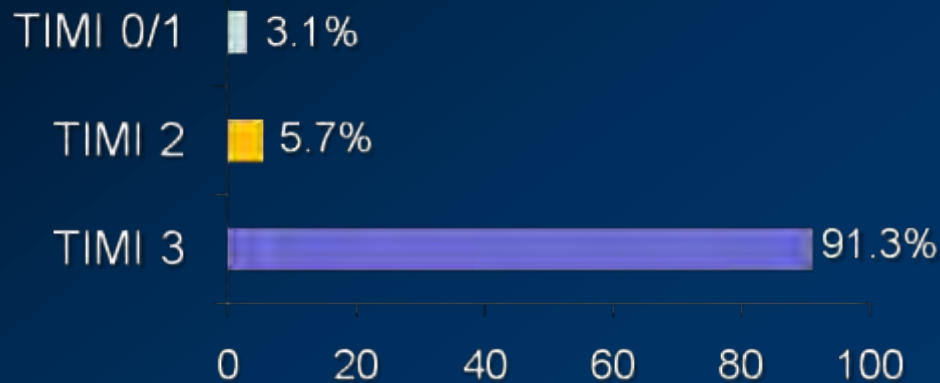
Primary endpoint: Infarct size at 30 days (cMRI)

2° endpoints: TIMI flow, blush, ST-resolution, MACE (30d, 1 yr)

INFUSE-AMI: Reperfusion post-PCI*

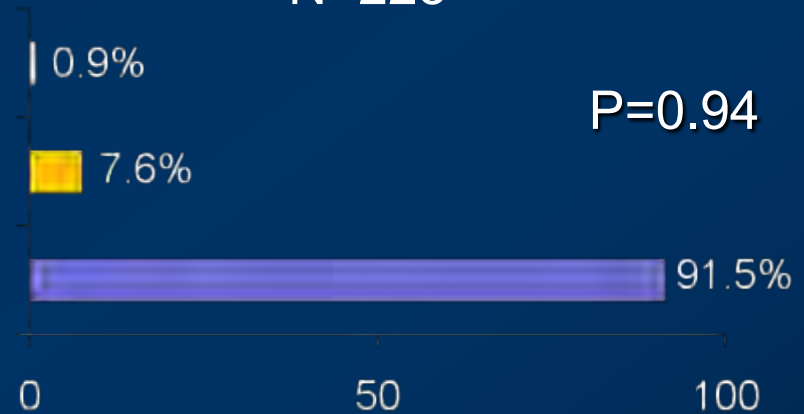
IC abciximab

N=229



No abciximab

N=223



P=0.94

Corrected TIMI
frame counts:

20 [16, 26]

vs.

20 [16, 26]

P=0.62

MBG 0/1



MBG 2/3



0 20 40 60 80 100

MBG 0/1



MBG 2/3



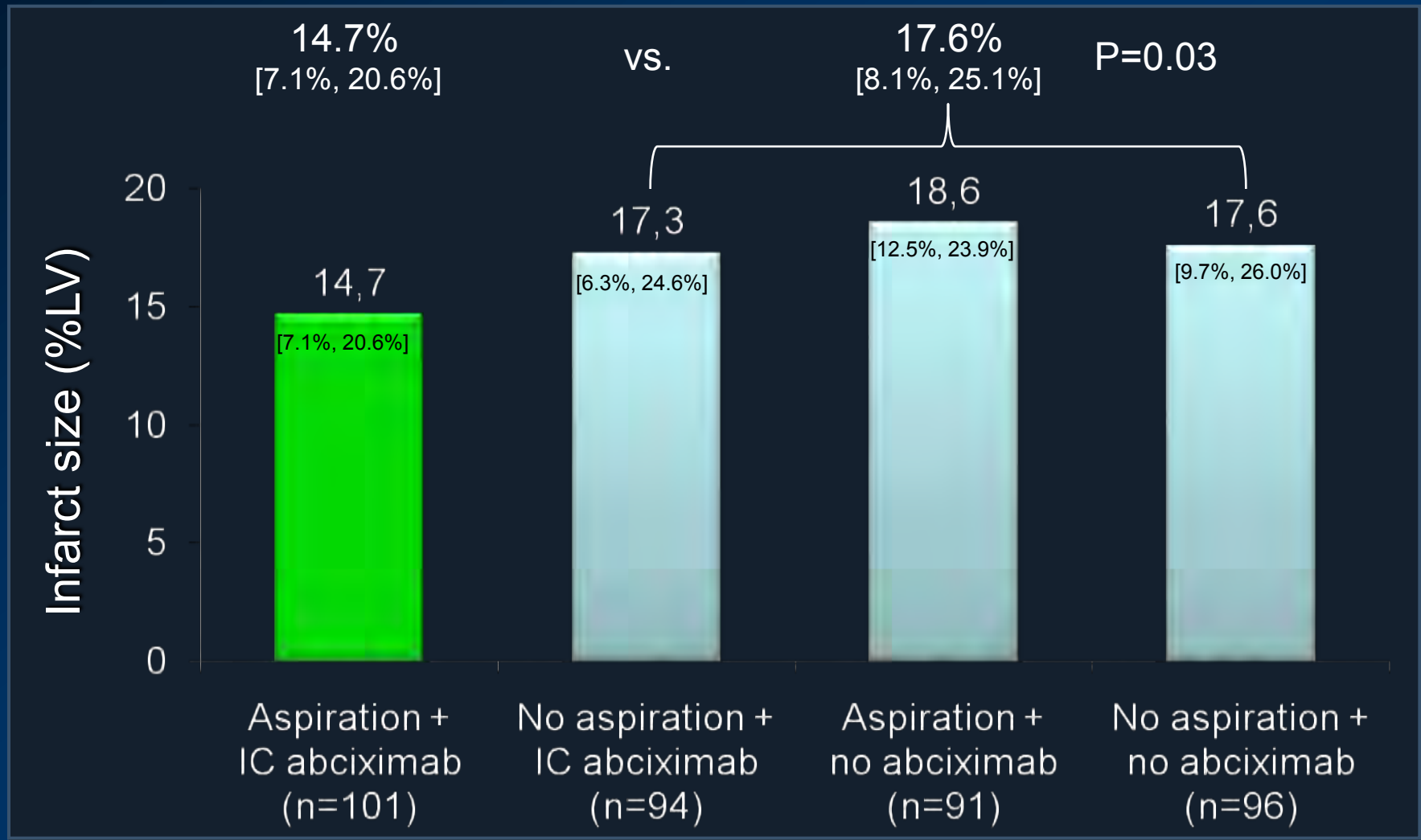
0 50 100

P=0.71

Stone GW et al. JAMA 2012;307:0n-line

INFUSE-AMI: Infarct size at 30 days*

- 4 group analysis -



Stone GW et al. JAMA 2012;307:0n-line

Efficacy of intracoronary IIb/IIIa inhibitor during primary PCI.

Standard use or bailout only?

Summary: Potential Benefits....

- **Faster reduction thrombus burden**
- **Reinfarction** ↓↓
- **Improved TIMI-flow...**
- **No-Reflow** ↓↓
- **Infarct size** ↓↓
- **Mortality** ↓↓
- **MACE** ↓↓

Take Home Message

- Although technological and pharmaceutical evolution, AMI still remains a great challenge looking for improved outcomes.
- Intracoronary thrombus management is one of the most important factors limiting better results.
- IIb/IIIa inhibitors agents are a great allied in order to improve PCI results and clinical outcomes whenever thrombus is present.
- **In Our Catch Lab used IIb/IIIa in 51 % of Patients With SCA.**
- However its usage should be indicated in selective group of patients !!!!!

Muito Obrigado



Arquivo pessoal: C. Costantini

Muito Obrigado





Cardio Interv

2012

**12th INTERNATIONAL INTERVENTIONAL
CARDIOLOGY SYMPOSIUM**

30 Nov - 01 Dec 2012

Curitiba.PR.Brazil

**Conferences, discussions, round tables
and live cases.**

Organization



**Fundação
Francisco Costantini**

Suport





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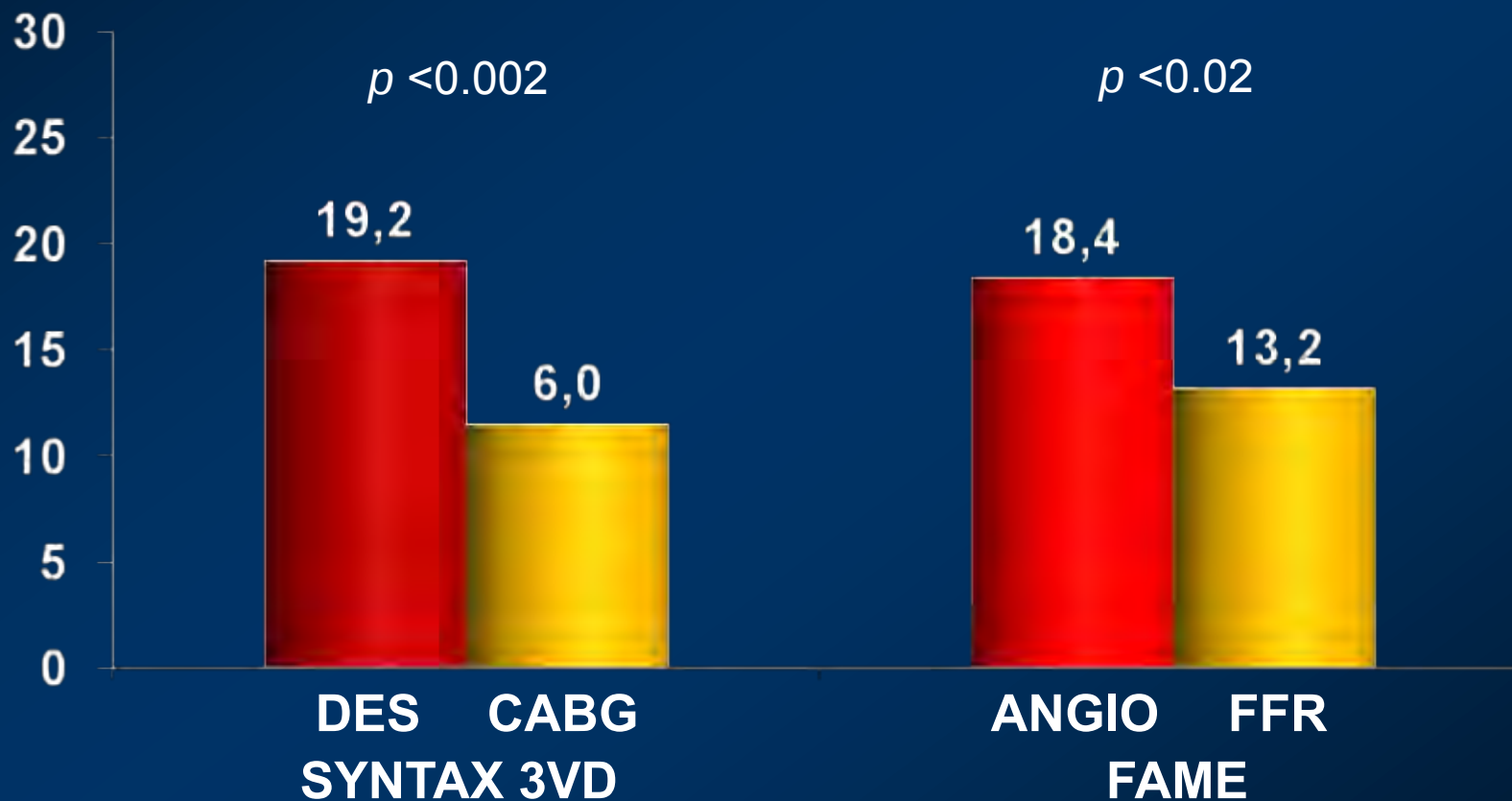
Suport



MACE 1 Year

1 Year Follow-Up

SYNTAX 3VD vs FAME

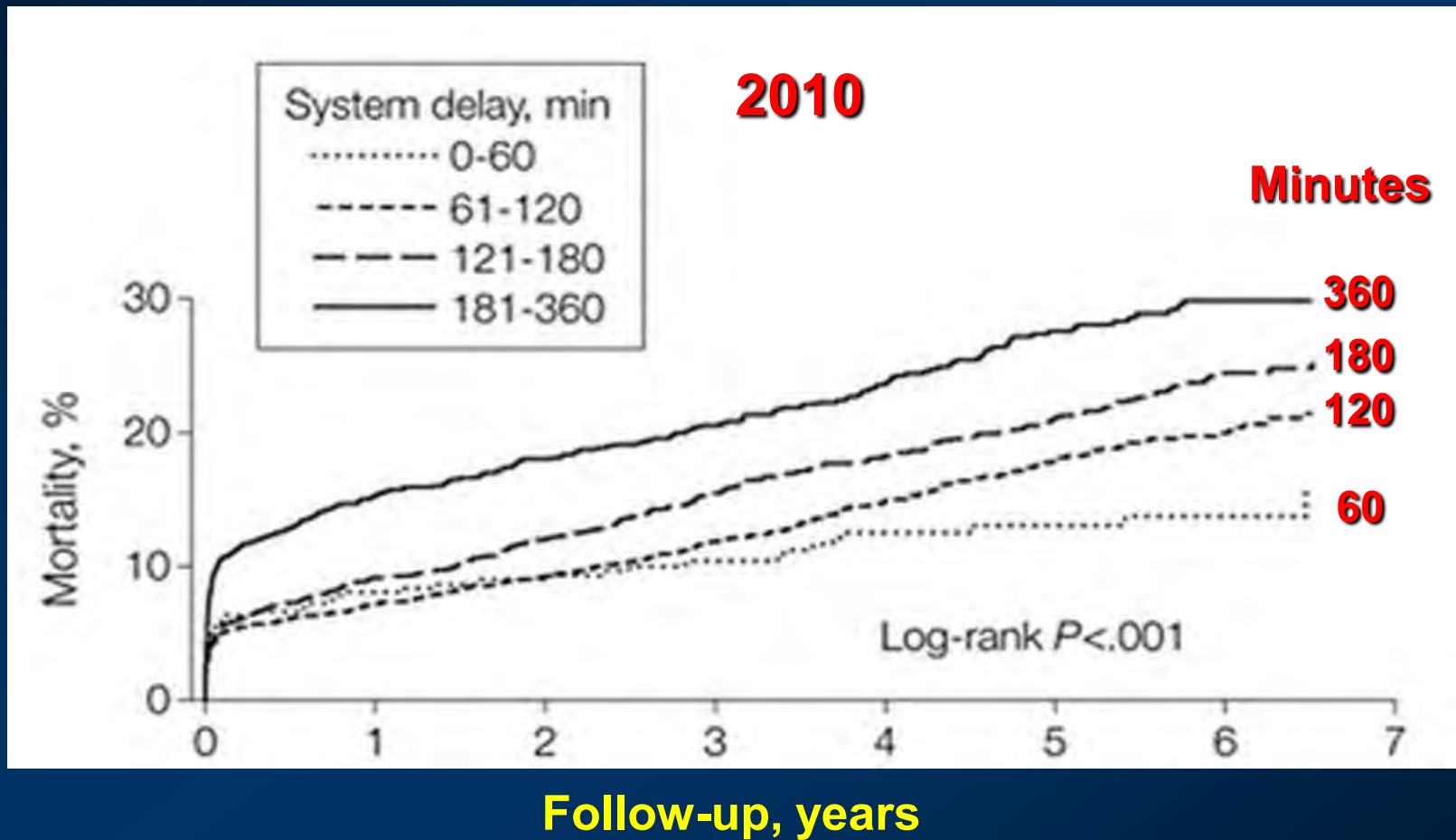


Patient and procedural characteristics from ARTS-II, and FAME

	ARTS-II (100% DES)	FAME (95% DES)	
	N= 607	Angio N= 496	FFR N= 509
Age (yrs)	63	64.2	64.6
Male (%)	77	73	75
Previous MI (%)	34	36.3	36.7
Diabetes mellitus (%)	26	25.2	24.2
Unstable Angina (%)	36	35.5	29.4
Ejection fraction (%)	60	57.1	57.2
SYNTAX score	20.7	14.5	14.5
Lesions per patient	3.6	2.7	2.8
Number of stents	3.7	2.7	1.9
Length of stents (mm)	72.5	51.9	37.9
Procedural duration (mins)	85	70	71
Hospital stay (days)	3.4	3.7	3.4
Oral presentation Serruys; CIT, Beijing, 2009– Adapted Costantini SOLACI 2012			

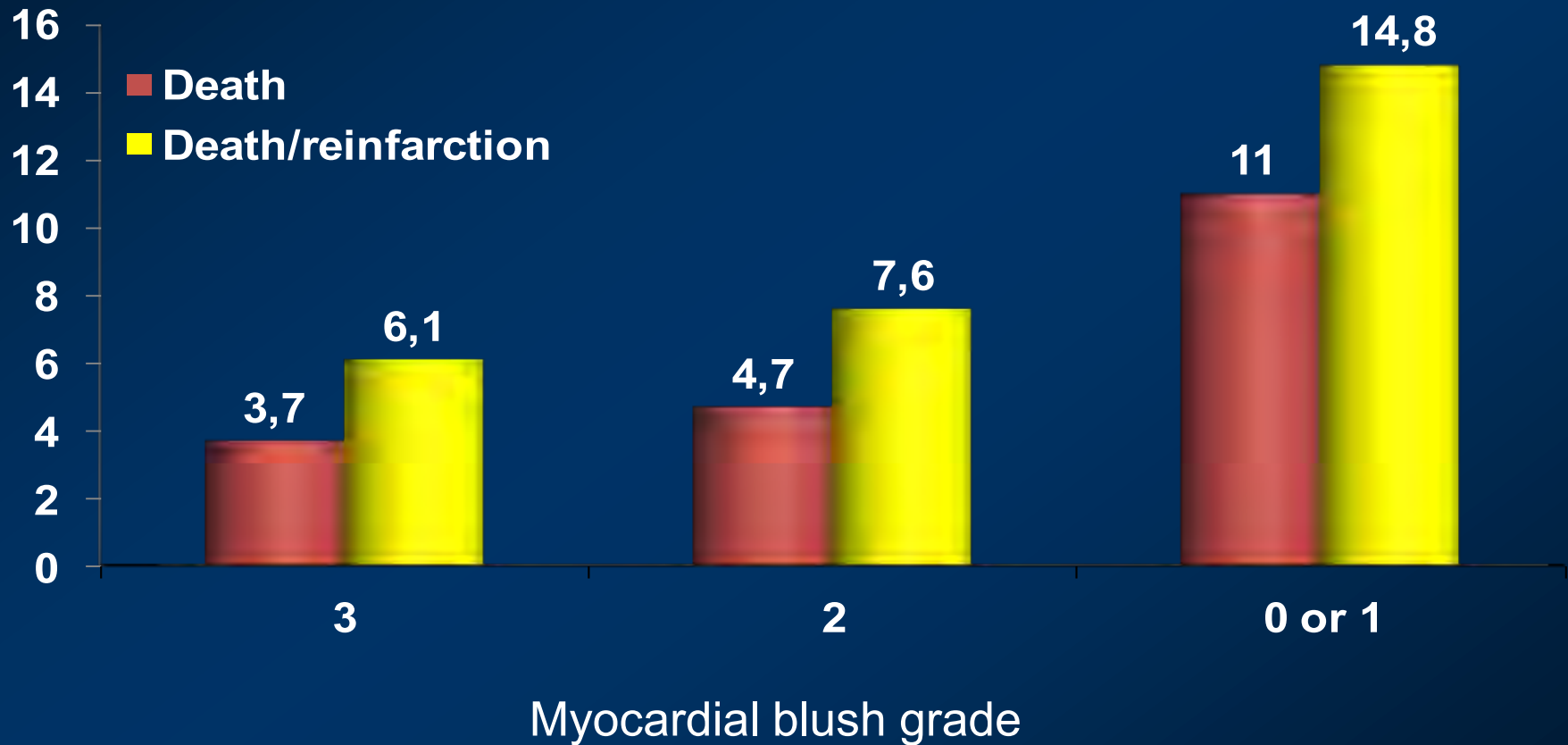
System delay

Time is Muscle



Terkelsen, C.J. et al JAMA 2010;304:763-771

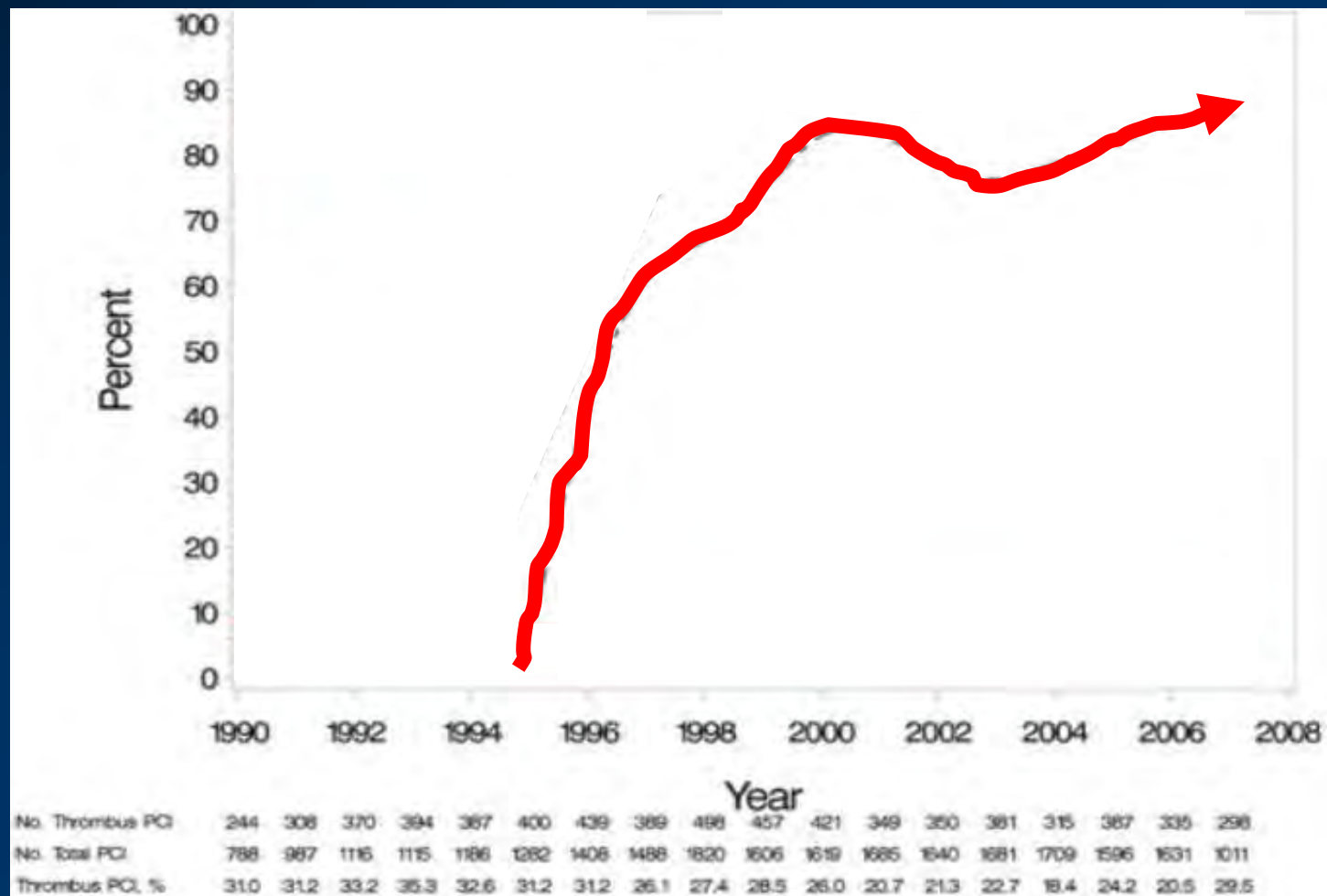
TAPAS one year outcome: Myocardial blush grade and death



Svilaas T et al. NEJM 2008;358-557 .

2011 ACC/AHA PCI Guidelines

GP IIb/IIIa Inhibitor Therapy



J Am Coll Cardiol Interv. 2010;3(9):937-946

Primary Endpoint Analysis

6 months Follow up

