scientific sessions 2008 | American Heart Association

Impact of Thromboaspiration during Primary PCI on infarcted segmental myocardial function: a Tissue Doppler imaging evaluation.
EXPIRA Trial substudy.

GENNARO SARDELLA, MD, FACC ,FESC;

MASSIMO MANCONE, MD; RAFFAELE SCARDALA, MD; ANGELO DI ROMA,MD; LORENZO MARIA ZUCCARO, MD; GIULIA BENEDETTI, MD; GIULIA CONTI,MD ; FRANCESCO FEDELE, MD.

O.U. of Invasive Cardiology,
Dept. of Cardiovascular Sciences
Policlinico Umberto I
"Sapienza " University of ROME

GENNARO SARDELLA MD

Impact of Thromboaspiration during Primary PCI on infarcted segmental myocardial function: a Tissue Doppler imaging evaluation.
EXPIRA Trial substudy.

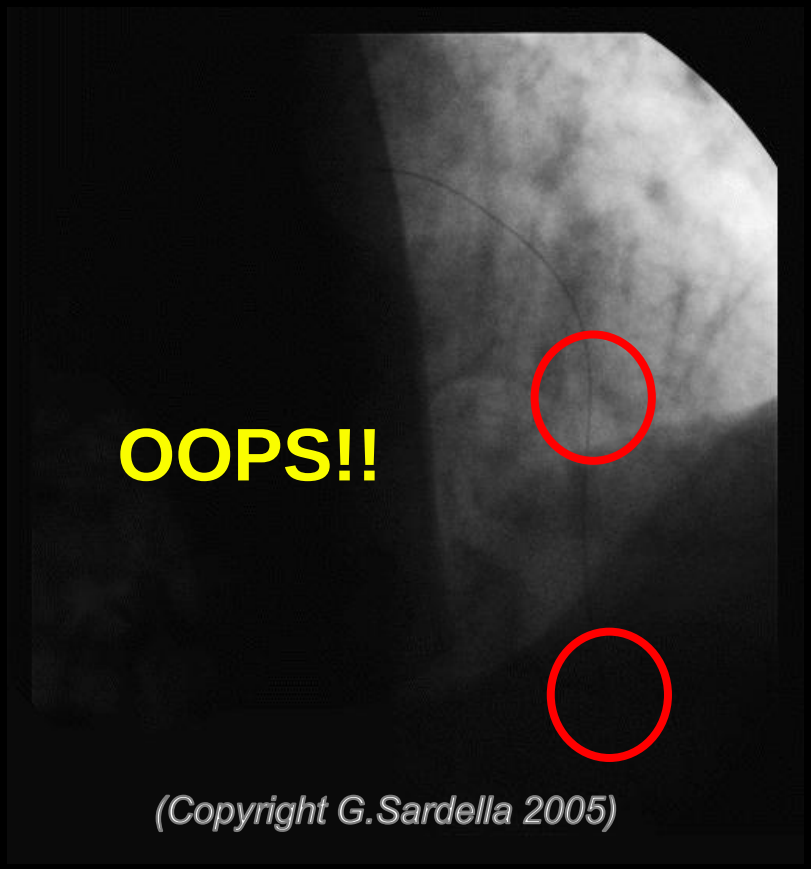
FINANCIAL DISCLOSURE:

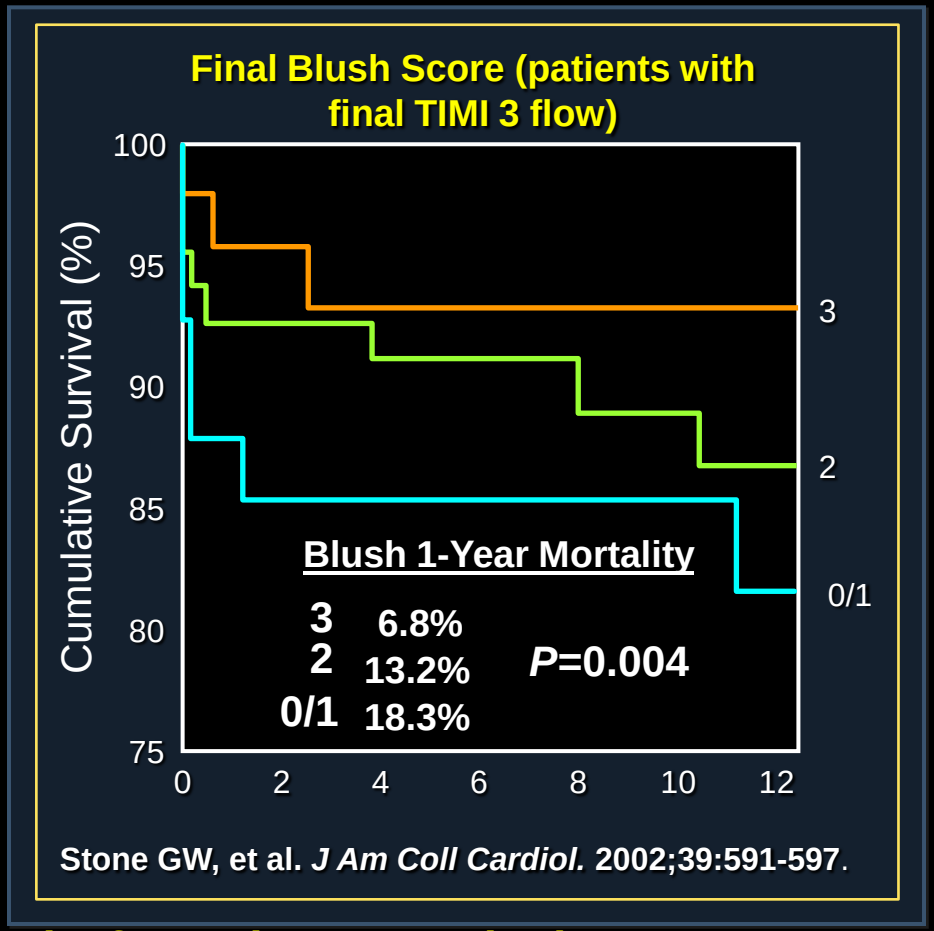
No relationship to disclose

Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

Background

- In the AMI setting the **distal embolization** after the IRA reopening (" no-flow"phenomenon) is associated with poor perfusion and high mortality.

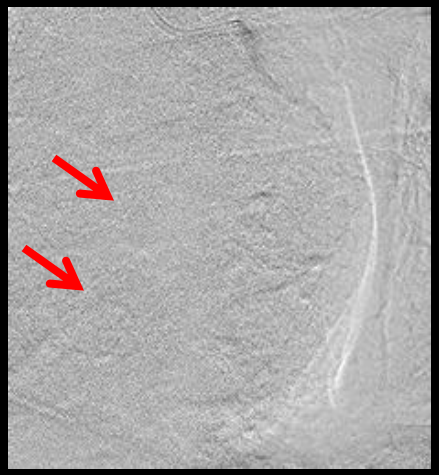




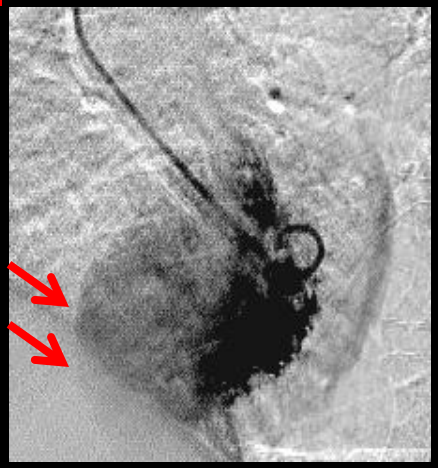
- Myocardial Perfusion (MBG) After Primary PCI is the Strongest Predictor of Mortality independently from IRA reopening

Background

PPCI Hardest point



“ Open Artery ...but Closed Myocardium !!



MBG 3

Study	Manual thrombectomy (n/N)	Cont (n/N
DEAR MI	65/74	32/7
De Luca *et al.*[21]	14/38	5/3
EXPIRA	62/88	25/8
Export	15/24	11/2
Export Study	39/109	29/1
PIHRATE	67/88	68/8
VAMPIRE	82/178	35/1
TAPAS	224/490	158/4
Total (95% CI)	568/1089	343/1

Test for heterogeneity: $\chi^2 = 27.23$, df = 7 ($P = 0.0003$), $I^2 = 74.3\%$
Test for overall effect: $Z = 9.74$ ($P < 0.00001$)

Favours C

30 – Day mortality

Study	Manual thrombectomy (n/N)	Control (n/N)	OR (fixed) 95% CI	Weight (%)	OR (fixed) 95% CI
DEAR MI	0/74	0/74			Not estimable
De Luca *et al.*[21]	0/38	2/38		6.59	0.19 (0.01–4.08)
EXPIRA	0/88	1/87		4.01	0.33 (0.01–8.11)
Export	0/24	1/26		3.78	0.35 (0.01–8.93)
Export Study	3/120	5/129		12.55	0.64 (0.15–2.72)
PIHRATE	3/100	3/94		8.02	0.94 (0.18–4.77)
REMEDIA	3/48	3/48		7.51	1.00 (0.19–5.22)
VAMPIRE	1/179	1/174		2.69	0.97 (0.06–15.66)
TAPAS	11/529	21/531		54.84	0.52 (0.25–1.08)
Total (95% CI)	21/1200	37/1201		100.00	0.58 (0.34–0.98)

Test for heterogeneity: $\chi^2 = 1.73$, df = 7 ($P = 0.97$), $I^2 = 0\%$
Test for overall effect: $Z = 2.03$ ($P = 0.04$)

0.1 0.2 0.5 1 2 5 10

Favours Thrombectomy Favours Control

(De Luca G.,Dudek D. Sardella G. et al EHJ 2008 Sep 5. [Epub ahead of print])

SAPIENZA
UNIVERSITÀ DI ROMA

DIP.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

Impact of thrombectomy with EXPort catheter in Infarct Related Artery on procedural and clinical outcome in patients with AMI.

(EXPIRA Trial) . A Prospective, Randomized Trial of Thromboaspiration during Primary Angioplasty in Acute Myocardial Infarction

Principal Investigator : G. SARDELLA MD, FACC, FESC

Investigators : M.Mancone, A.Di Roma, L.De Luca, G.Conti, R.Colantonio, G.Benedetti.

O.U. of Invasive Cardiology, Dept. of Cardiovascular Sciences
Policlinico Umberto I - University "La Sapienza
ROME

TCT 2007
TRANSCATHETER CARDIOVASCULAR THERAPEUTICS

CARDIOVASCULAR RESEARCH FOUNDATION

Impact of Thrombectomy with EXPort catheter in Infarct Related Artery on procedural and clinical outcome in patients with AMI (EXPIRA Trial).

(G.Sardella et al . TCT 2007)

Design

- Prospective, randomized, double-arm, mono-centric study.
- ***Primary end-point :***
  - *Final MBG ≥ 2 ;*
  - *90′ ST resolution*

  (> 70% decrease of ST segment after PCI)
- ***Secondary end-point :***
  - *MACE at 9 month clinical f-u*
- ***Principal investigator***

  G.Sardella MD

256 pts.

(STEMI, at 6.8 ± 2.3 h from symptoms onset)

(Heparin 7.500 U/I, GPIIb/IIIa, Aspirin, Clopidogrel 300 mg)

175 pts. eligible for 1:1 randomization

81 pts.excluded:

- Cardiogenic shock
- 3-vessel / Left Main
- TIMI >0-1
- TS < 3
- Contra to GPIIb/IIIa

88 pts randomized to Thrombectomy + PCI

87 pts randomized to Standard PCI

Final MBG ≥ 2 ; 90′ ST resolution

9 months clinical f-u

Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

Methods

Inclusion Criteria

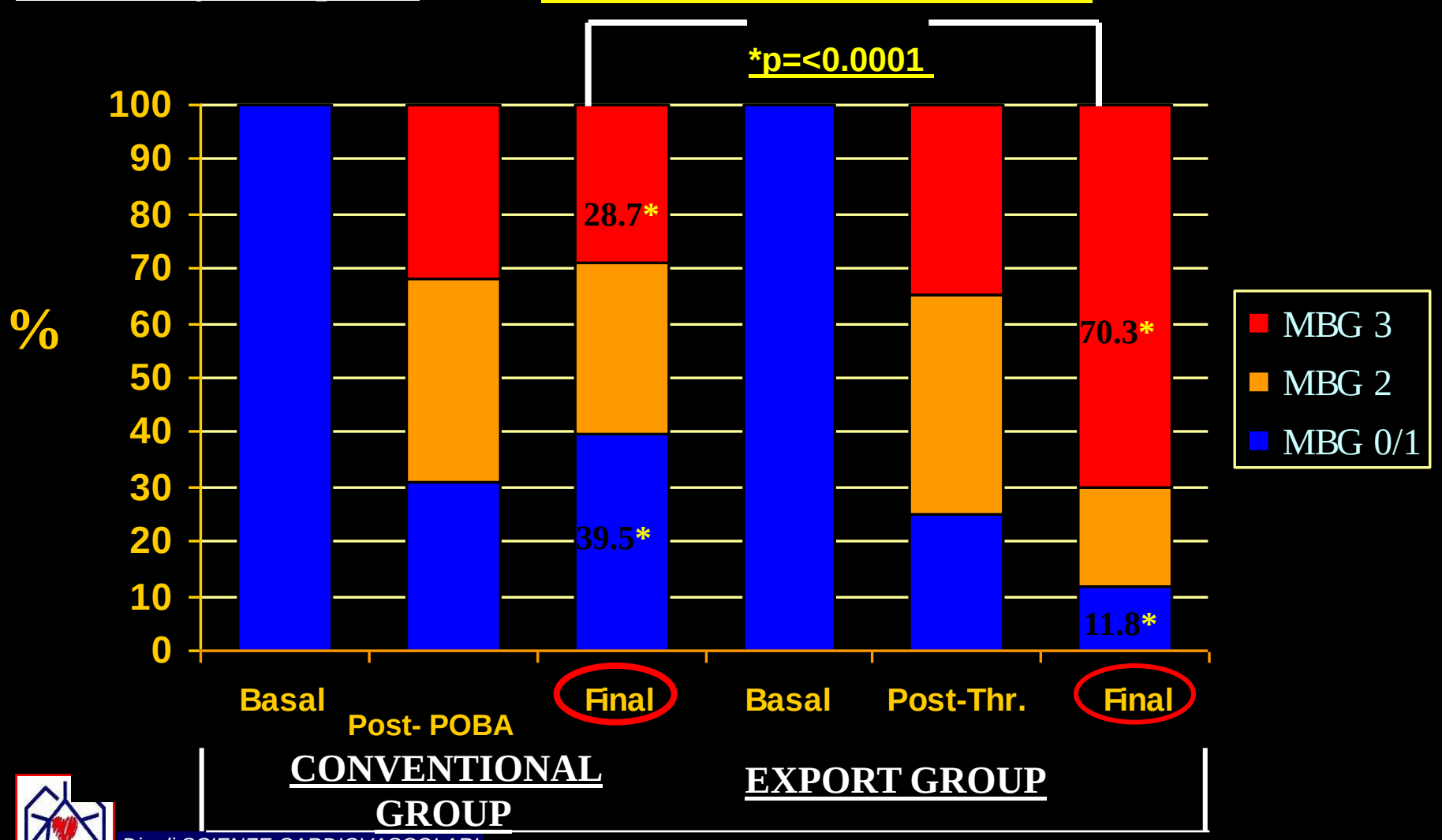
- Age >18 yrs
- STEMI within 9 hrs from symptoms onset
- "*De novo*" coronary artery lesions
- Native IRA ≥2.5 mm diameter
- Angiographically identifiable occlusive thrombus (TS grade ≥ 3)
- TIMI 0-1 at time of initial angiography

Exclusion Criteria

- Previous AMI or CABG
- Cardiogenic shock
- 3-vessel / Left Main CAD
- Severe valvular heart disease
- Unsuccessful PCI (*no antegrade flow or 50% residual stenosis in the IRA)*
- Rescue / Facilitaded PCI
- Contraindication to GP IIb/IIIa inhibitors

Impact of Thrombectomy with EXPort catheter in Infarct Related Artery on procedural and clinical outcome in patients with AMI (EXPIRA Trial).

1° Primary End-point



Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

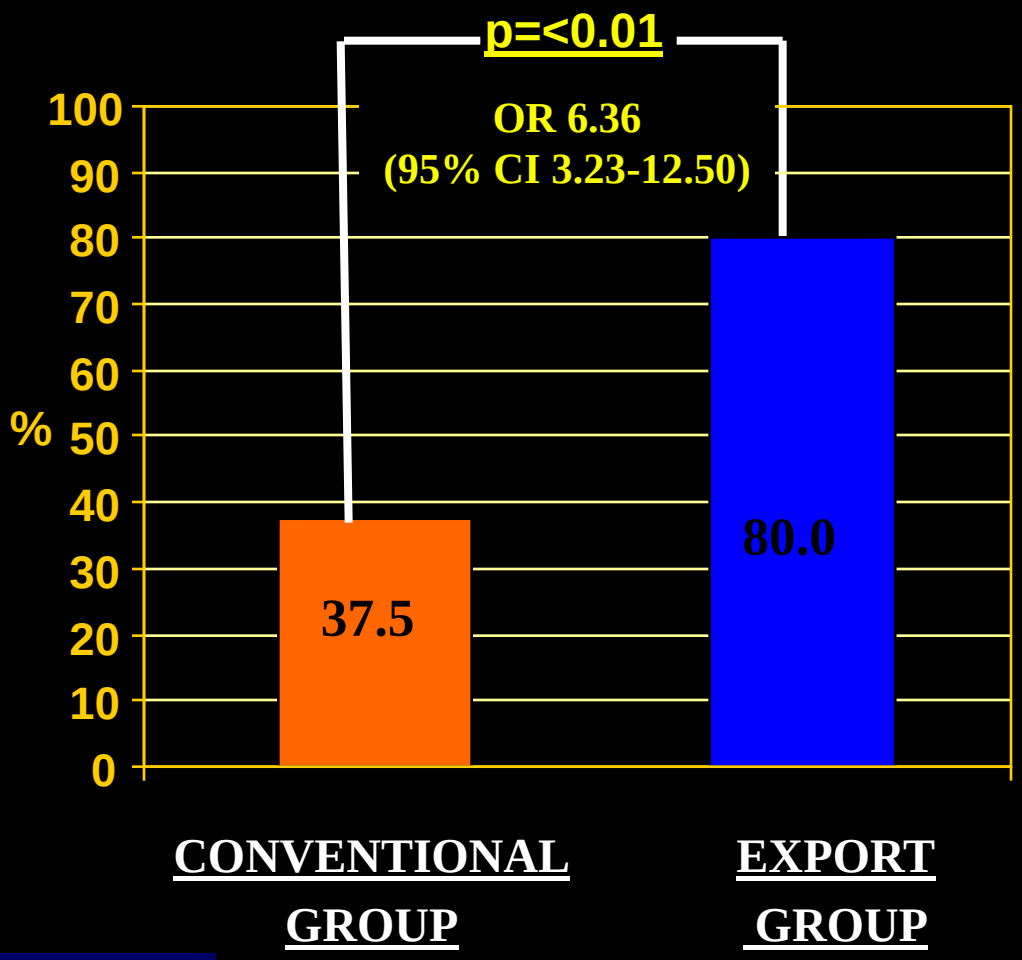
(G.Sardella et al ,TCT 2007)

Impact of Thrombectomy with EXPort catheter in Infarct Related Artery on procedural and clinical outcome in patients with AMI (EXPIRA Trial).

2°Primary End-point

90' ST resolution after PCI (%)

(> 70% decrease of ST segment)

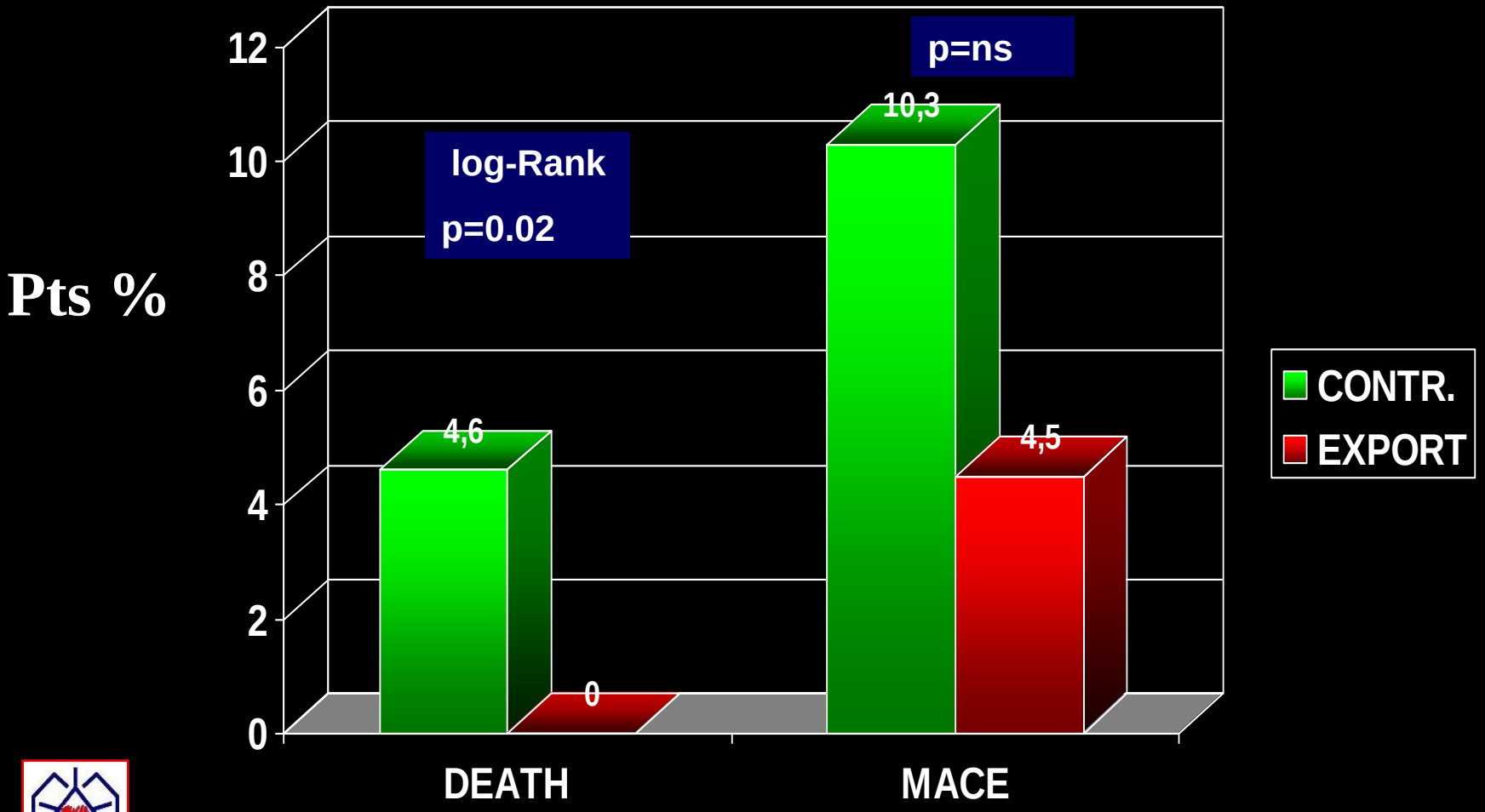


(G.Sardella et al ,TCT 2007)

Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

Impact of Thrombectomy with EXPort catheter in Infarct Related Artery on procedural and clinical outcome in patients with AMI (EXPIRA Trial).

9 months Composite Cardiac Event Rates



Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

(G.Sardella et al ,TCT 2007)

EXPIRA Trial MRI Study

Design

- Prospective, randomized, double-arm, mono-centric study.

❑ *1° End-points (MRI evaluation)*

➢ *Microvascular damage (grams/g) in terms of Hypoenhancement .*

➢ *Infarct size (grams/g) in terms of Hyperenhancement.*

75 patients eligible for 1:1 randomization
(Anterior STEMI, at 6.8 + 2.3 h from symptoms onset)

(Heparin 7.500 U/I, GPIIb/IIIa, Aspirin, Clopidogrel 300 mg)

37 pts randomized to Standard PCI

38 pts randomized to Thrombectomy + PCI

3 – 90 Day MRI follow-up

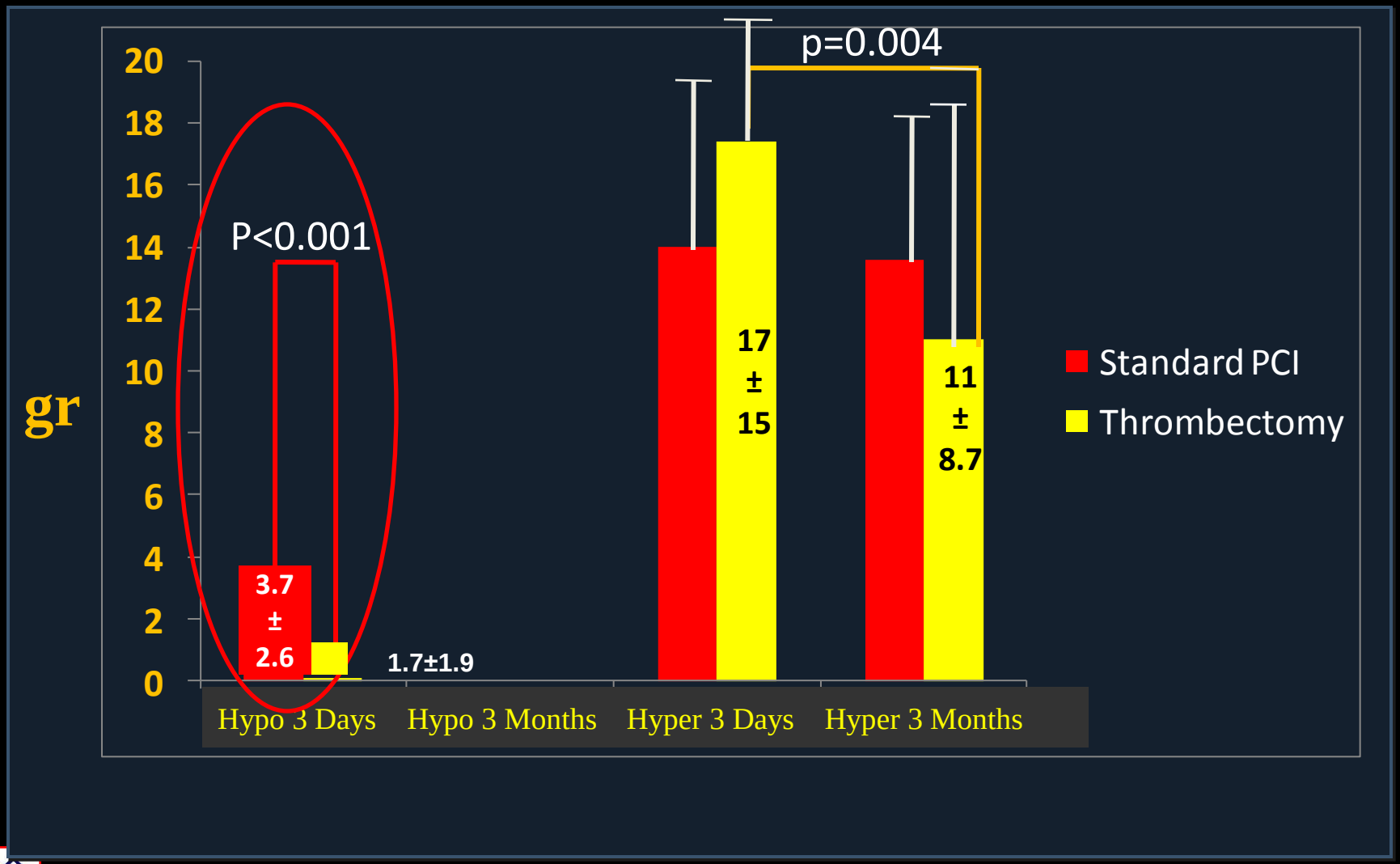
➢ **Microvascular damage**
➢ **Infarct size**

(G.Sardella et al , JACC 2008 in press)

Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

SAPIENZA
UNIVERSITÀ DI ROMA

MRI Results



(G.Sardella et al , JACC 2008 in press)

Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

Myocardial Function

➢**Tissue Doppler imaging (TDI) quantitatively assess regional myocardial function by measuring Systolic Strain, an index reflecting the extent of myocardial fiber deformation.**

Journal of the American College of Cardiology
© 2007 by the American College of Cardiology Foundation
Published by Elsevier Inc.
Vol. 49, No. 16, 2007
ISSN 0735-1097/07/$32.00
doi:10.1016/j.jacc.2006.12.047

Early Prediction of Infarct Size by Strain Doppler Echocardiography After Coronary Reperfusion

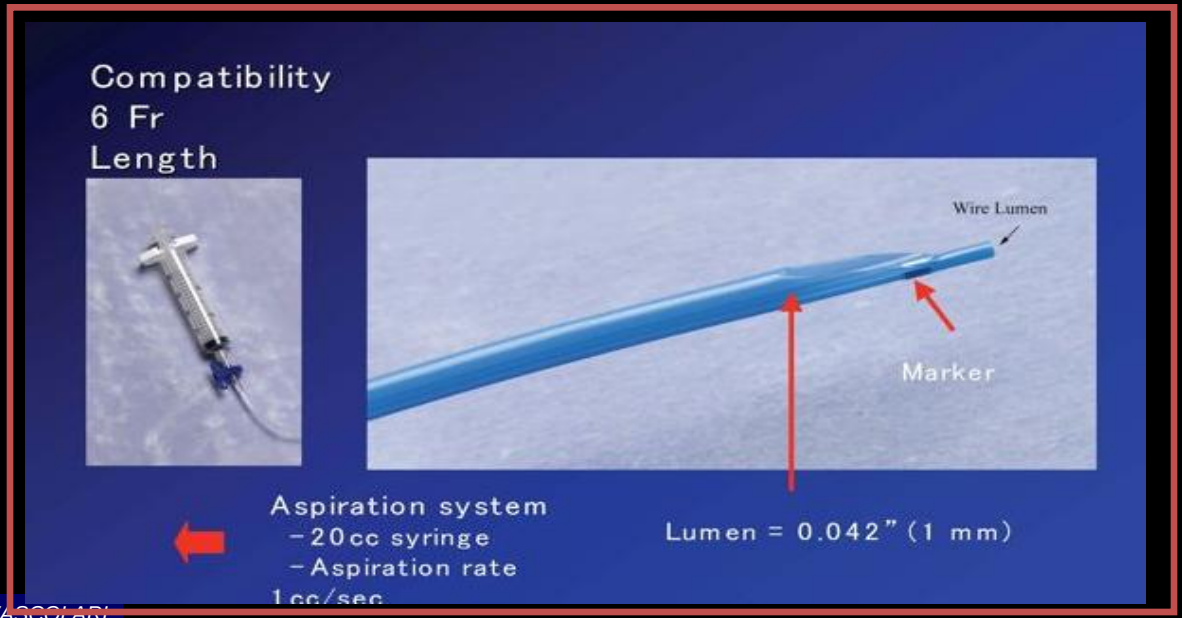
Regional and global strain at 1.5 h after reperfusion therapy correlates with size and transmural extent of myocardial infarction as determined by CE-MRI.

(Vartdal T et al. J Am Coll Cardiol 2007;49:1715–21)

Aim of the Study

➢ **We sought to evaluate the impact of thromboaspiration on procedural outcomes and Systolic Strain by TDI as compared to conventional primary PCI**

Export® aspiration catheter (Medtronic, Minneapolis, Minnesota)



Methods

Design

- Prospective, randomized, double-arm, single-centre study.

❑ ***1° End-point (TDI evaluation):***

➢ ***LV function recovery evaluated in terms of global and segmental Systolic Strain (%) by TDI***

75 patients eligible for 1:1 randomization
(Anterior STEMI, at 6.8 + 2.3 h from symptoms onset)

(Heparin 7.500 U/I, GPIIb/IIIa, Aspirin, Clopidogrel 300 mg)

37 pts randomized to Standard PCI

38 pts randomized to Thrombectomy + PCI

12 pts(16%) were not analyzed because of poor echocardiographic quality

TDI evaluation

16 segments model was applied and regional myocardial function was evaluated, ≤ 90'after primary PCI, by measuring peak systolic myocardial strain by TDI

Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

CLINICAL CHARACTERISTICS

	Total Population (n=75)	Conventional Group (n=37)	Thrombectomy Group (n=38)
Age, yrs±SD	66.3±10.6	65.8±13.1	67.4±14.1
Males (%)	47 (62.7)	24 (64.7)	23 (60.5)
Risk factors			
Hypertension (%)	43 (57.8)	24 (64.9)	19 (50.0)
Diabetes (%)	17 (22.7)	9 (24.3)	8 (21.1)
Smoking (%)	26 (34.7)	11 (29.8)	15 (39.5)
Obesity (%)	2 (2.7)	2 (5.4)	0
Family History of CAD (%)	27 (36.0)	12 (32.4)	15 (39.5)
Cholesterol (mg/dl±SD)	164±13	165±10	163±11
Triglycerides (mg/dl±SD)	120±35	122±23	121±27
Renal Failure (%)	4 (5.3)	3 (8.1)	1 (2.6)
Killip class III (%)	19 (25.3)	12 (32.4)	7 (18.4)
Previous PCI (%)	10 (13.3)	4 (10.8)	6 (15.8)
Symptoms to balloon, (hrs±SD)	7.9±0.7	7.7±1.2	6.5±1.4
LVEF (%±SD)	43.1 ±12	40.8 ±7.5	41.9 ±0.9

P= ns for all characteristics

PROCEDURAL CHARACTERISTICS

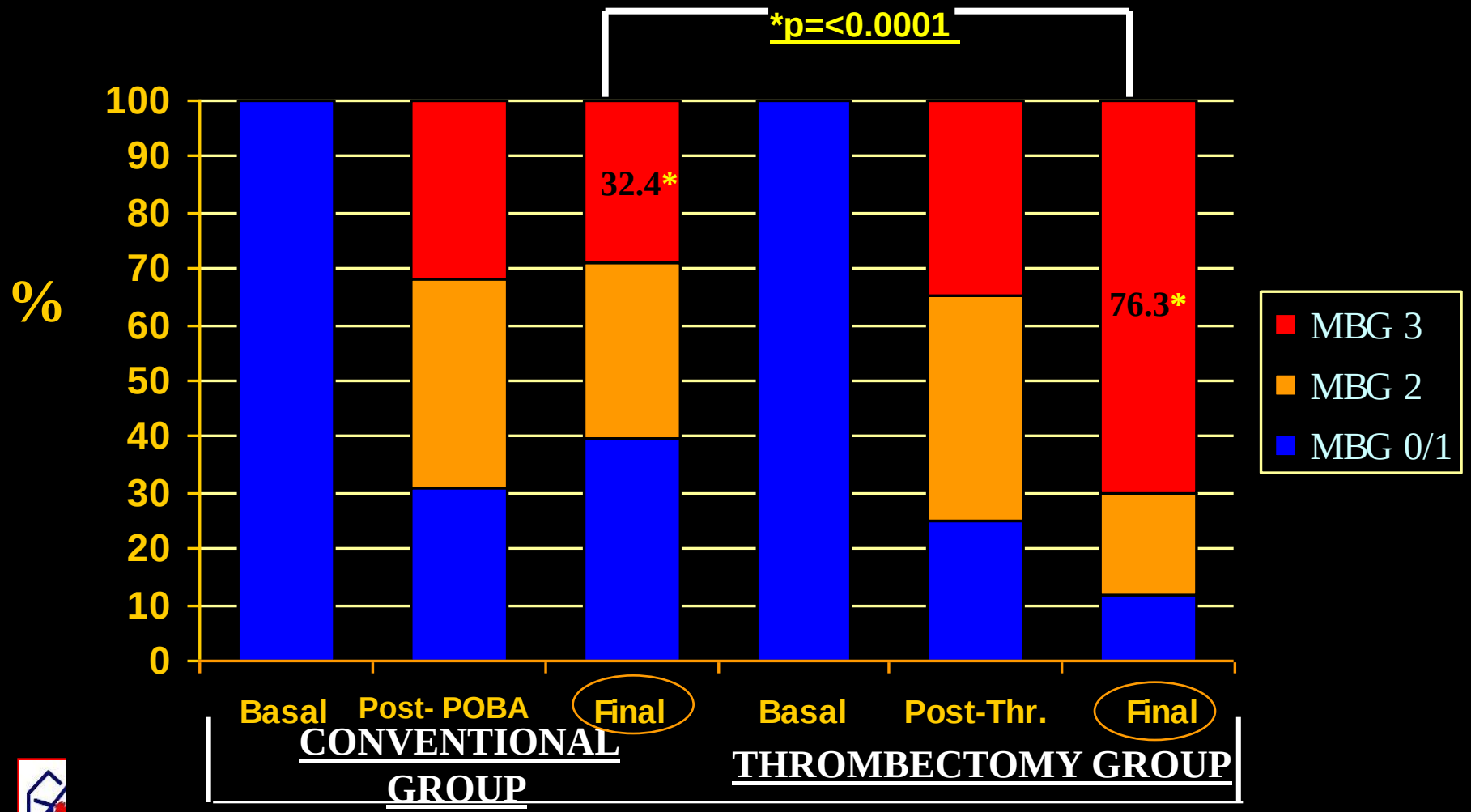
	Total Population (n=75)	Conventional Group (n=37)	Thrombectomy Group (n=38)
IABP (%)	7 (9.3)	4 (10.8)	3 (7.9)
Lesion length, mm±SD	13.8±5.7	14.1±5.6	14.9±4.9
Vessel size, mm±SD	2.9±0.6	2.8±0.5	2.9±0.6
MLD pre, mm±SD	0.8±0.4	0.9±0.4	0.7±0.3
GPIIb/IIIa Inhibhitors	75 (100)	37 (100)	38 (100)
Direct stenting	32 (42.6)	2 (5.4)*§	28 (74.3)§
Post-dilatation	7 (9.3)	3 (8.1)	4 (10.5)
MLD post, mm±SD	2.9±0.7	2.8±0.5	2.9±0.3
Post-PCI diameter stenosis, (%±SD)	3.4±5.2	3.5±3.9	3.4±5.4
Stent Type (%)			
Bare-metal Stent	29 (38.7)	17 (45.9)	12 (31.5)
Drug-eluting Stent	46 (61.3)	20 (54.0)	26 (68.4)

* 2 pts with recanalized IRA after guide-wire placement

§ *p*= <.0001

PROCEDURAL RESULTS

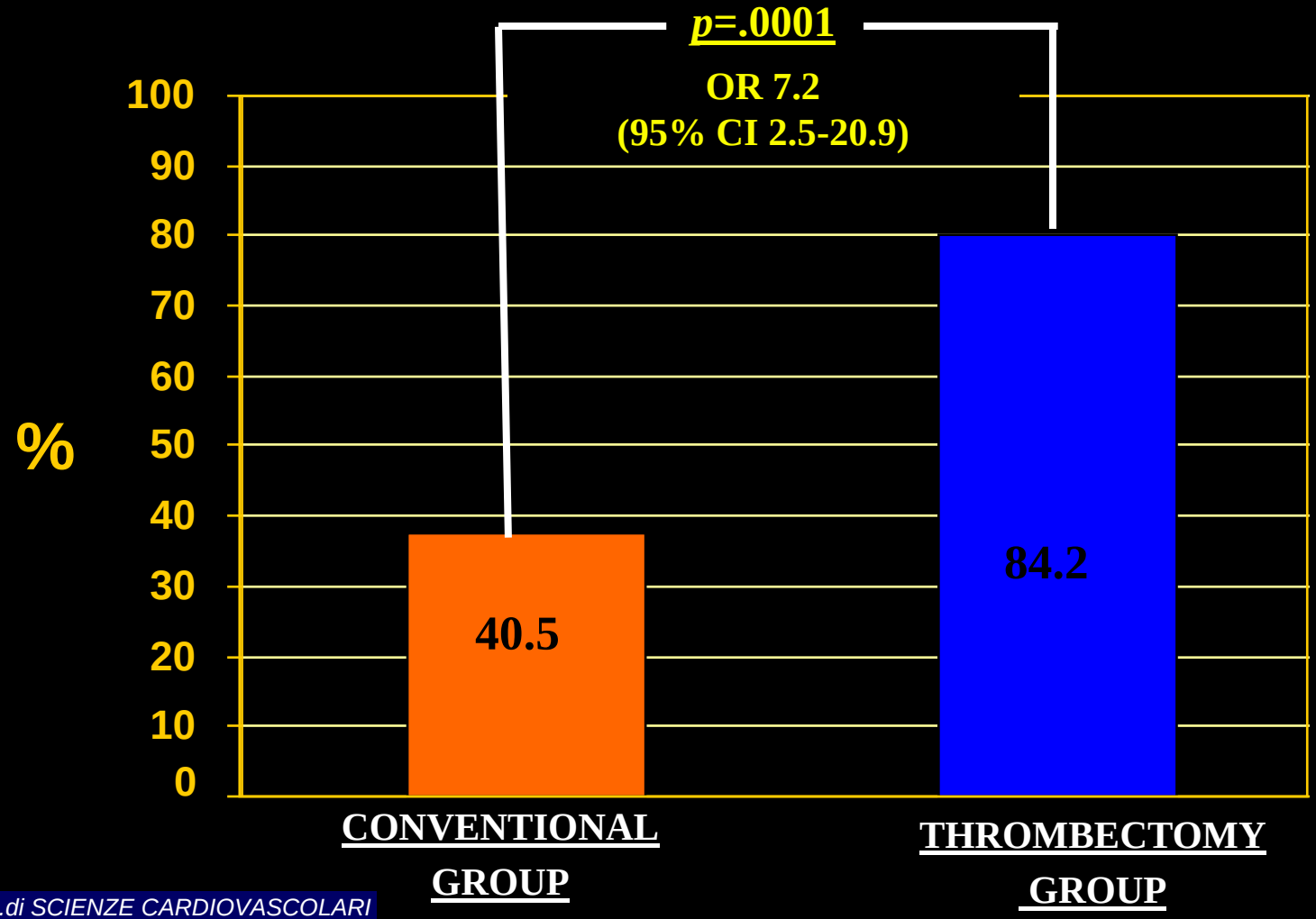
MYOCARDIAL BLUSH GRADE



In-Hospital Outcome

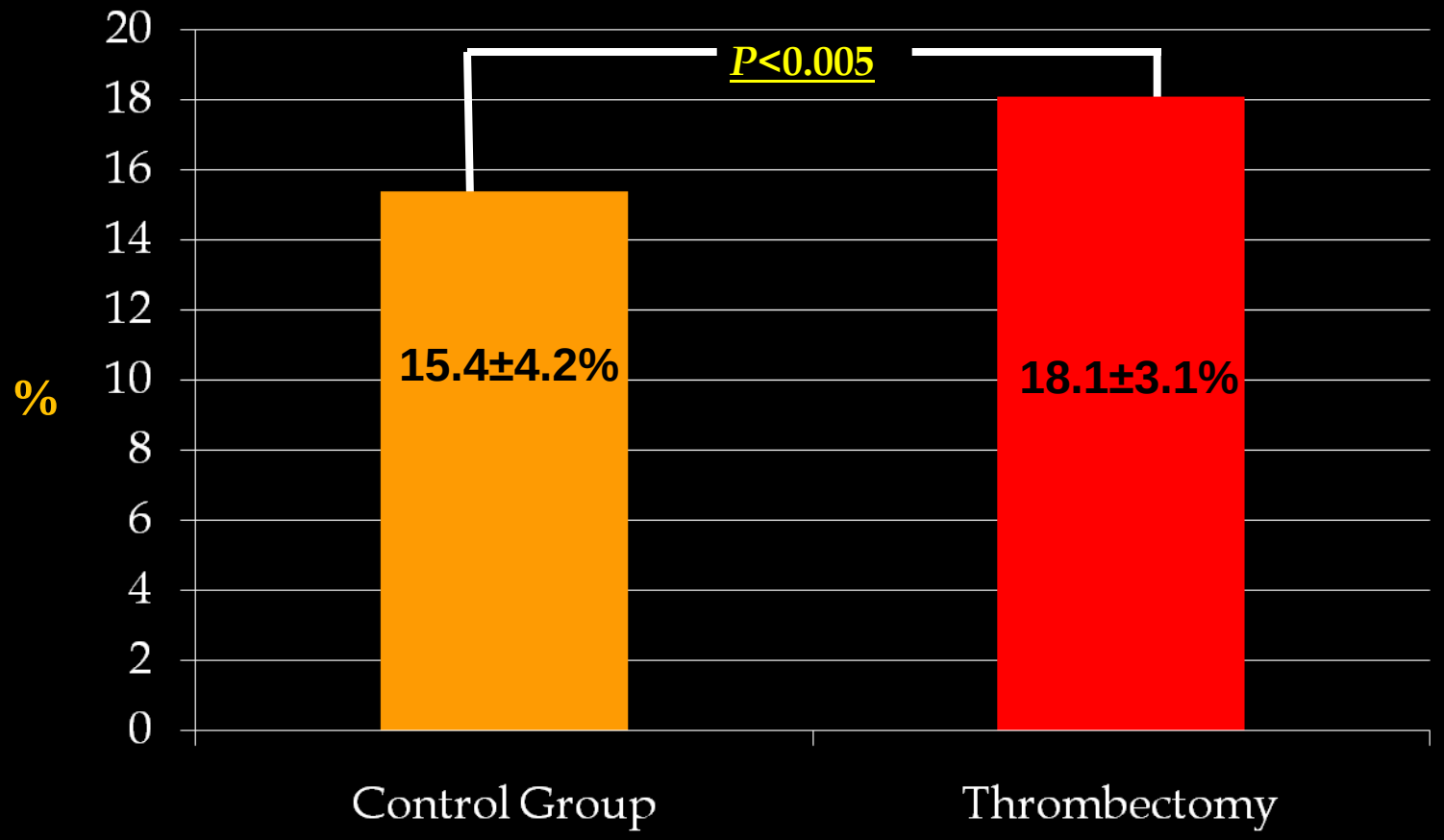
90’ ST resolution after PCI

(> 70% decrease of ST segment)



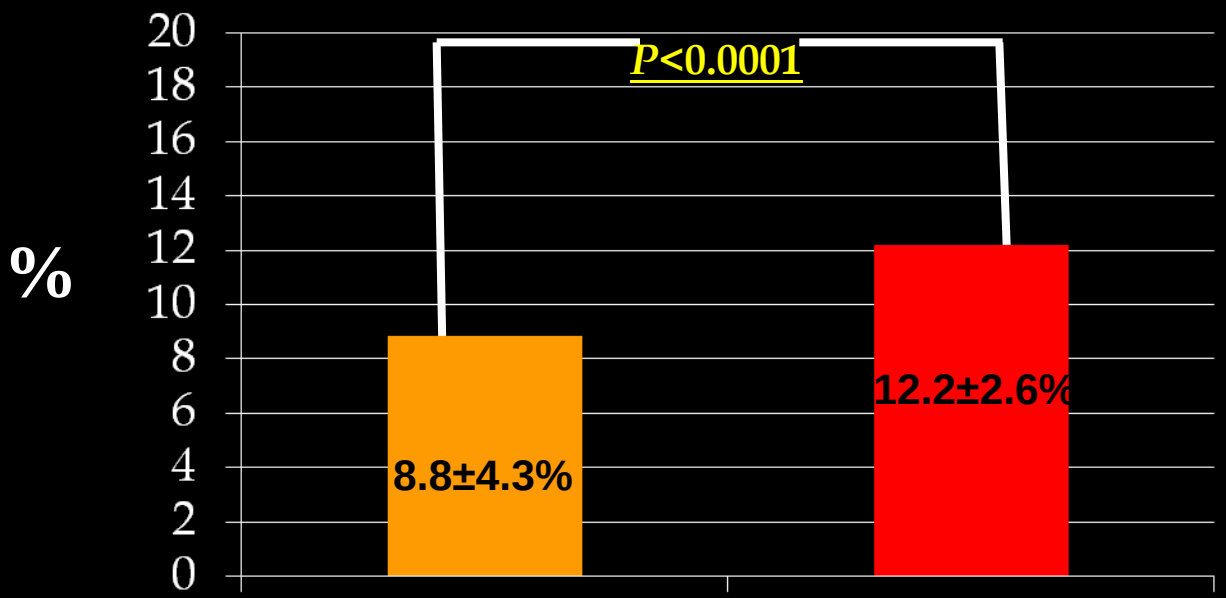
TDI Results

Mean Systolic Strain

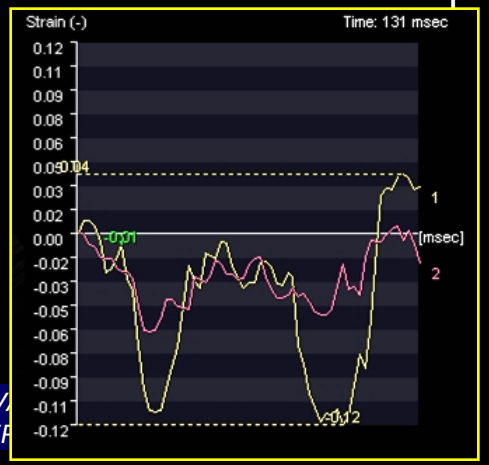


TDI Results

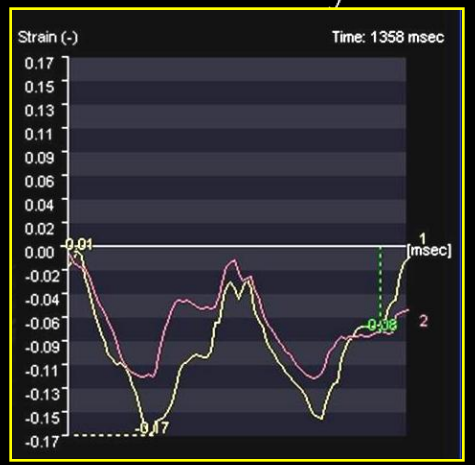
Mean Systolic Strain in Infarcted Area



Control Group



Thrombectomy



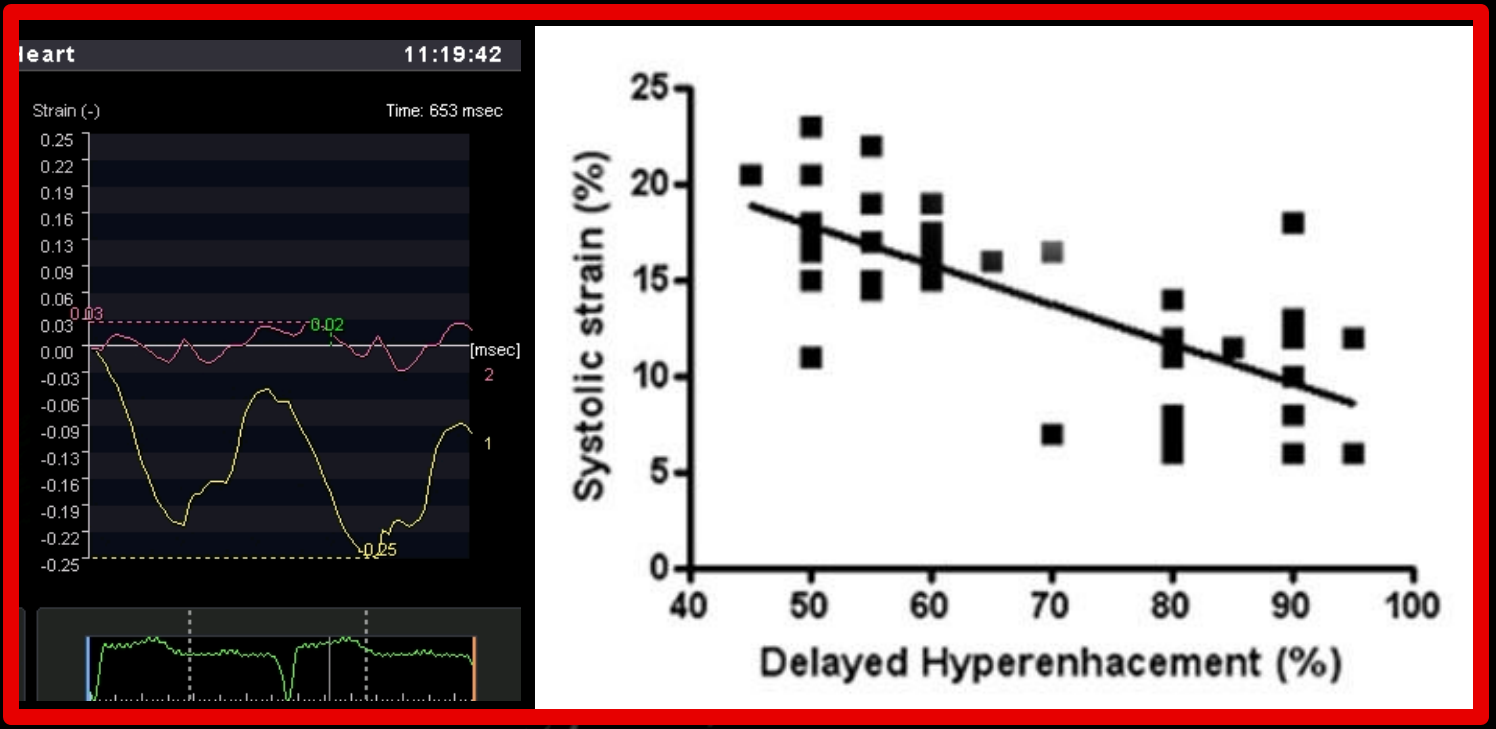
Infarcted Segments

Non-Infarcted Segments

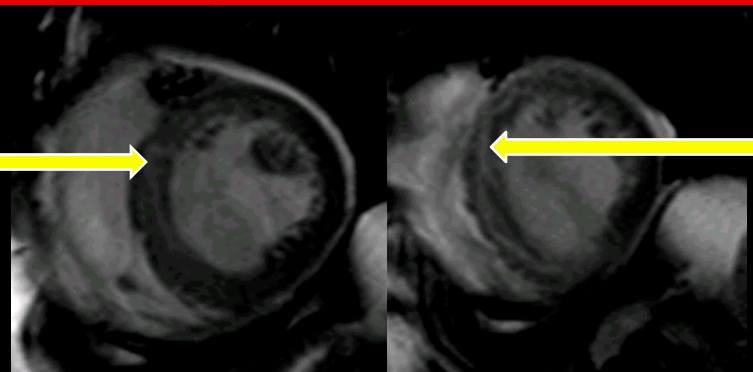
Dip.di SCIENZE CARDIOV
POLICLINICO UMBER

TDI and MRI Correlation

Significant Systolic Strain / Delayed Hyperenhancement correlation (r=0.69; p<0.05)



Low HPRE



High HPRE

Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

Conclusion

❖ In our experience **Thrombectomy** has been demonstrated to be **safe and effective** in AMI setting during Primary PCI.

❖ Compared with conventional stenting, in well selected patients with intracoronary visible and occlusive thrombus, pretreatment with manual aspiration thrombectomy during primary PCI improves acutely the **parameters of myocardial tissue perfusion and ST resolution** with a **reduction of microvascular damage and infarct size** in long term compared with acute evaluation.

❖ The difference observed in term of **Systolic Strain** between the two groups **suggest a rapid and better segmental function recovery** in pts treated with Thrombectomy.

❖ These data also confirm that **Systolic Strain** after primary PCI could be useful **to evaluate if primary percutaneus reperfusion has been effective in terms of function recovery.**

SAPIENZA
UNIVERSITÀ DI ROMA

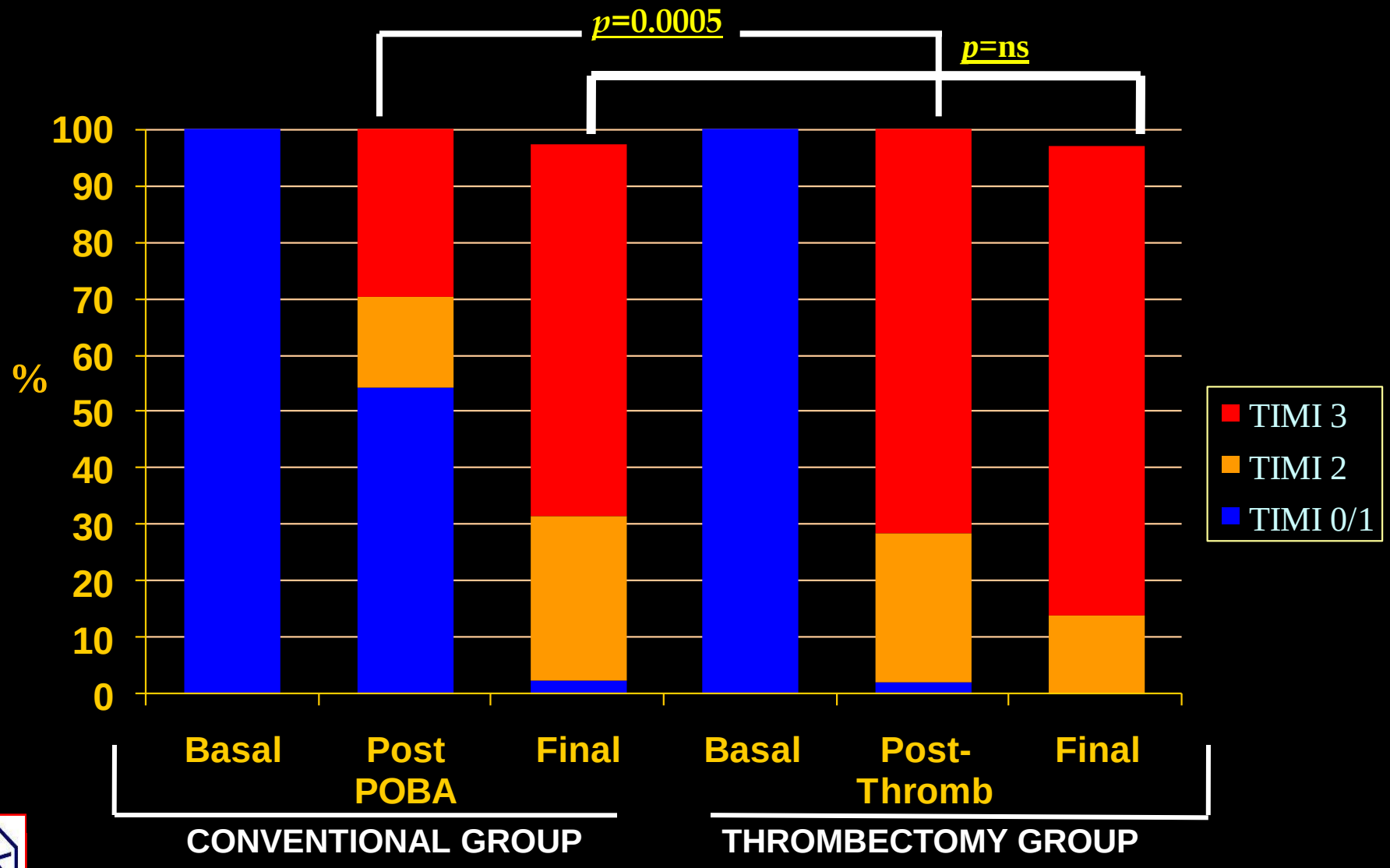
UMBERTO I
POLICLINICO DI ROMA

Thank You !

Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I

PROCEDURAL RESULTS 1

TIMI FLOW GRADE



Dip.di SCIENZE CARDIOVASCOLARI
POLICLINICO UMBERTO I