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Thrombus Aspiration During Primary Percutaneous Coronary Intervention Improves Myocardial Reperfusion and Reduces Infarct Size: The EXPIRA Thrombectomy With Export Catheter in Infarct-Related Artery During Primary Percutaneous Coronary Intervention) Prospective, Randomized Trial

*Gennaro Sardella, Massimo Mancone, Chiara Bucciarelli-Ducci, Luciano Agati,
Raffaele Scardala, Iacopo Carbone, Marco Francone, Angelo Di Roma,
Giulia Benedetti, Giulia Conti, and Francesco Fedele*

O.U. of Invasive Cardiology, Dept. of Cardiovascular Sciences

**Dept. of Radiology*

Policlinico Umberto I - University "La Sapienza

ROME

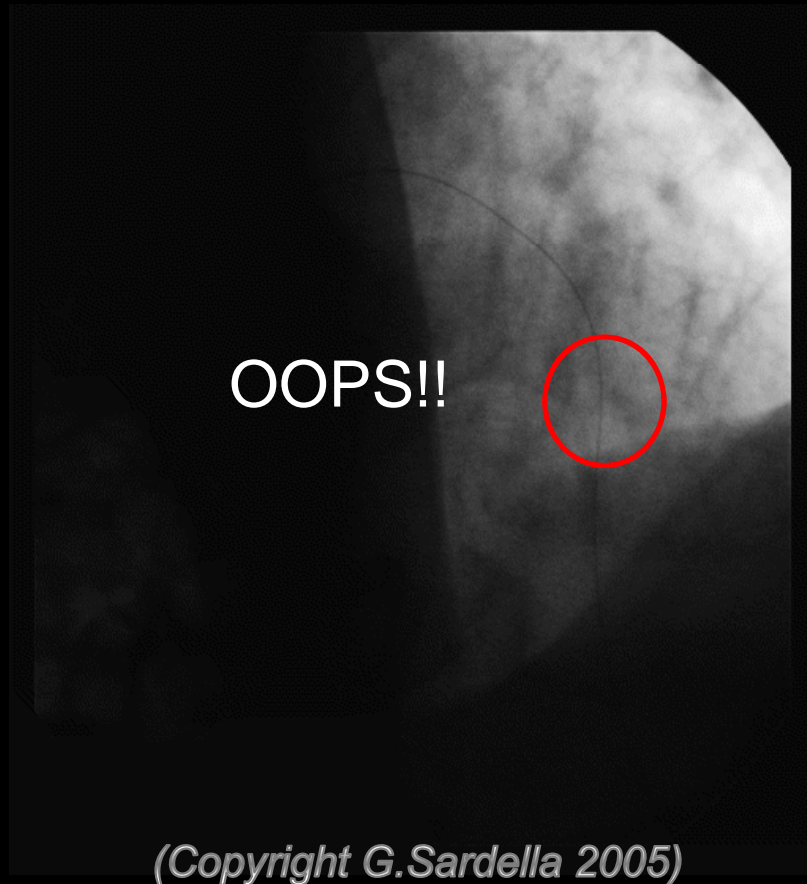


**GENNARO SARDELLA,MD;
MASSIMO MANCONE,MD;
RAFFAELE SCARDALA, MD;
CHIARA BUCCIARELLI DUCCI,MD;
ANGELO DI ROMA,MD;
IACOPO CARBONE,MD*;
GIULIA BENEDETTI MD,
GIULIA CONTI,MD;
FRANCESCO FEDELE, MD.**

✓ **No relationship to disclose**



Microembolization during Primary PCI



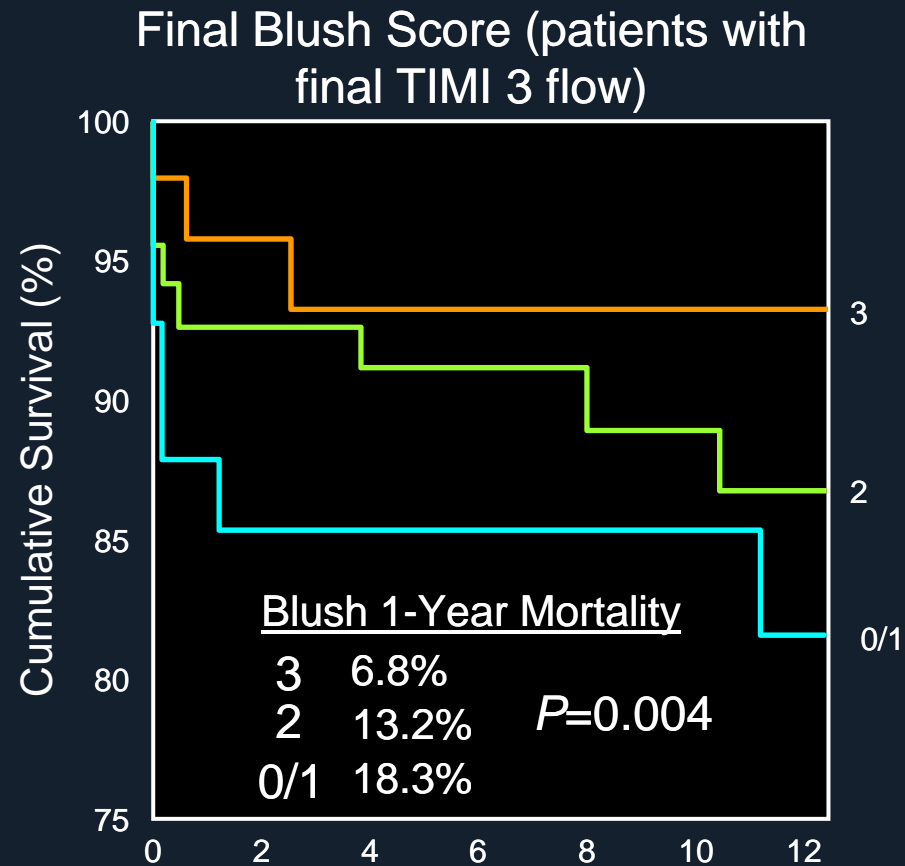
- In the AMI setting the “**no-flow**” phenomenon is caused by the **distal embolization** after the IRA reopening.
- This common complication is associated with **poor perfusion and high mortality**.

Embolism after IRA reopening

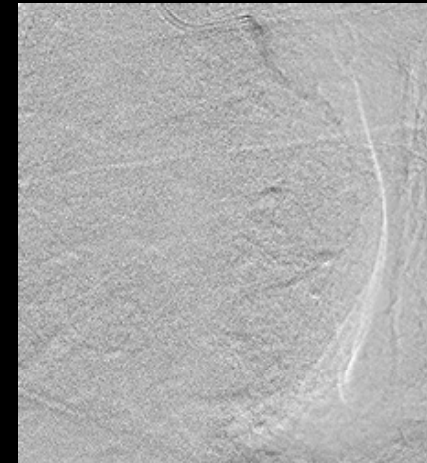


Background

Myocardial Perfusion After Primary PCI is Strongest Predictor of Mortality independently from IRA reopening
PPCI Hardest point



Stone GW, et al. *J Am Coll Cardiol.* 2002;39:591-597.



“Open Artery ...but Closed Myocardium !!”

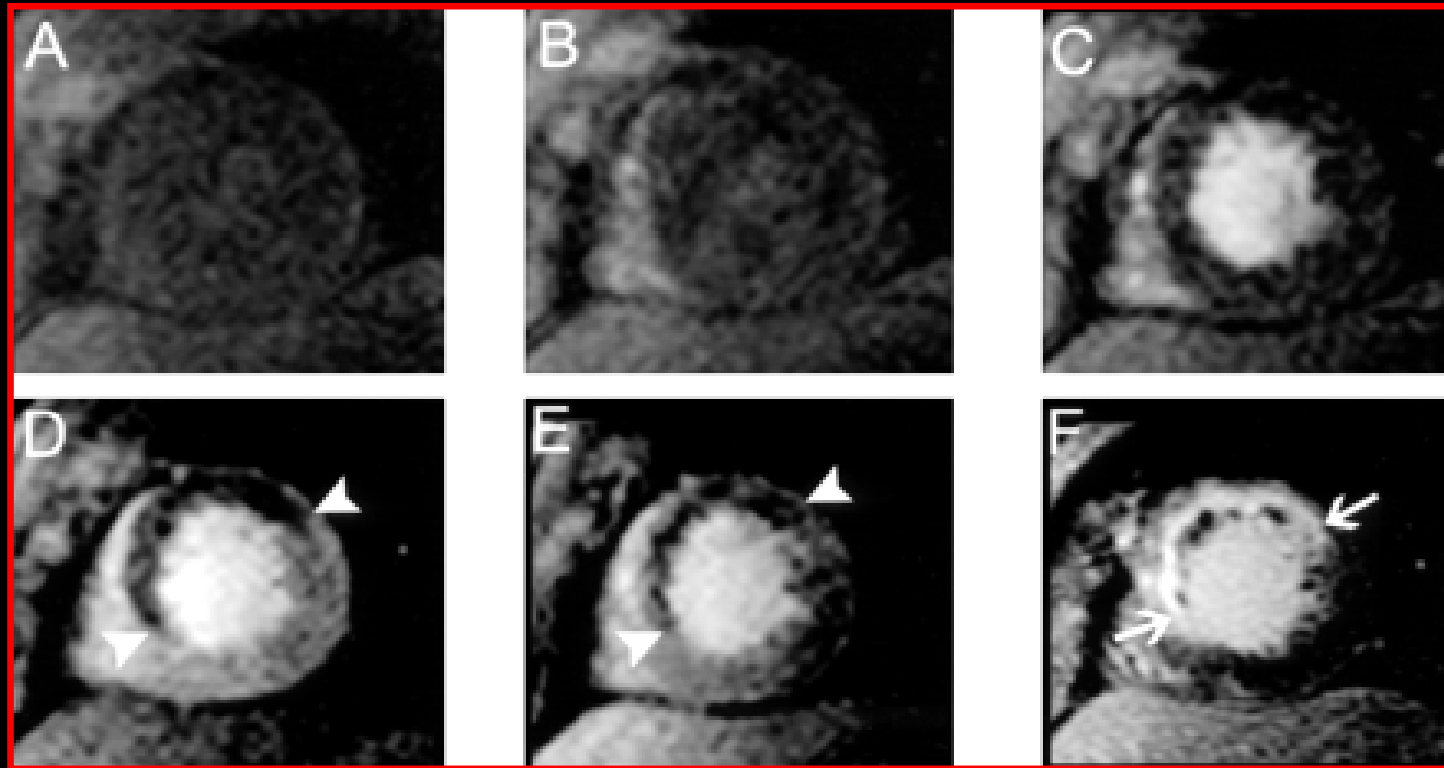


(Courtesy of M.Gibson)



Background

Acute anterior MI post PCI



Microvascular obstruction valued by **Ce-MRI**
predicts significantly increased rate of
cardiovascular adverse events after AMI

(Wu KC, et al. Circulation 1998;97:765)



Impact of Thrombectomy with **EX**Port catheter in **I**nfarct **R**elated **A**rtery on procedural and clinical outcome in patients with AMI (**EXPIRA** Trial).

(G.Sardella et al presented at TCT 2007)

Design

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

□ Primary end-point :

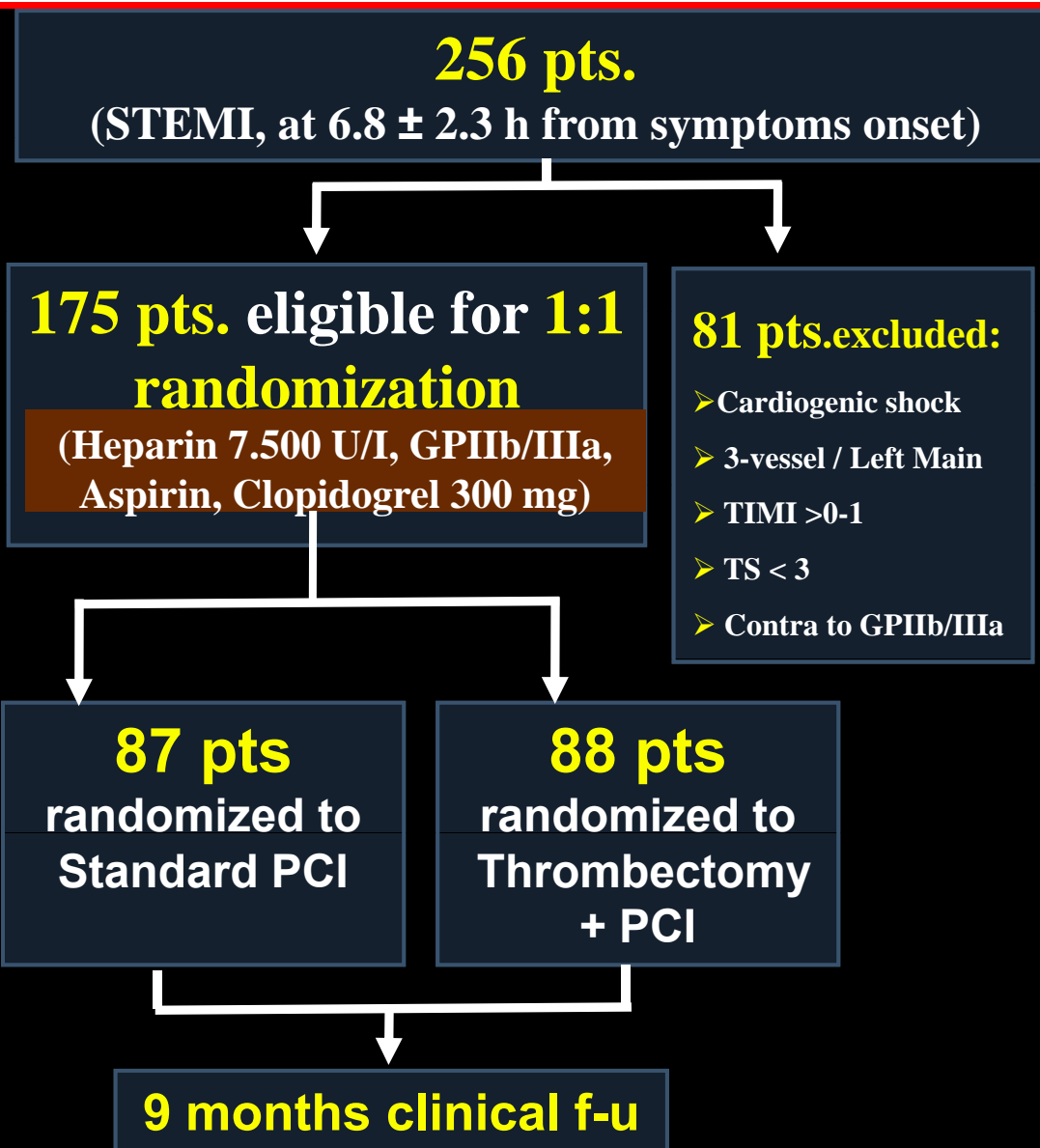
- **Final MBG ≥ 2 ;**
- **90' ST resolution**
(> 70% decrease of ST segment after PCI)

Secondary end-point :

□ **MACE at 9 month clinical f-u**

□ Principal investigator

G.Sardella MD

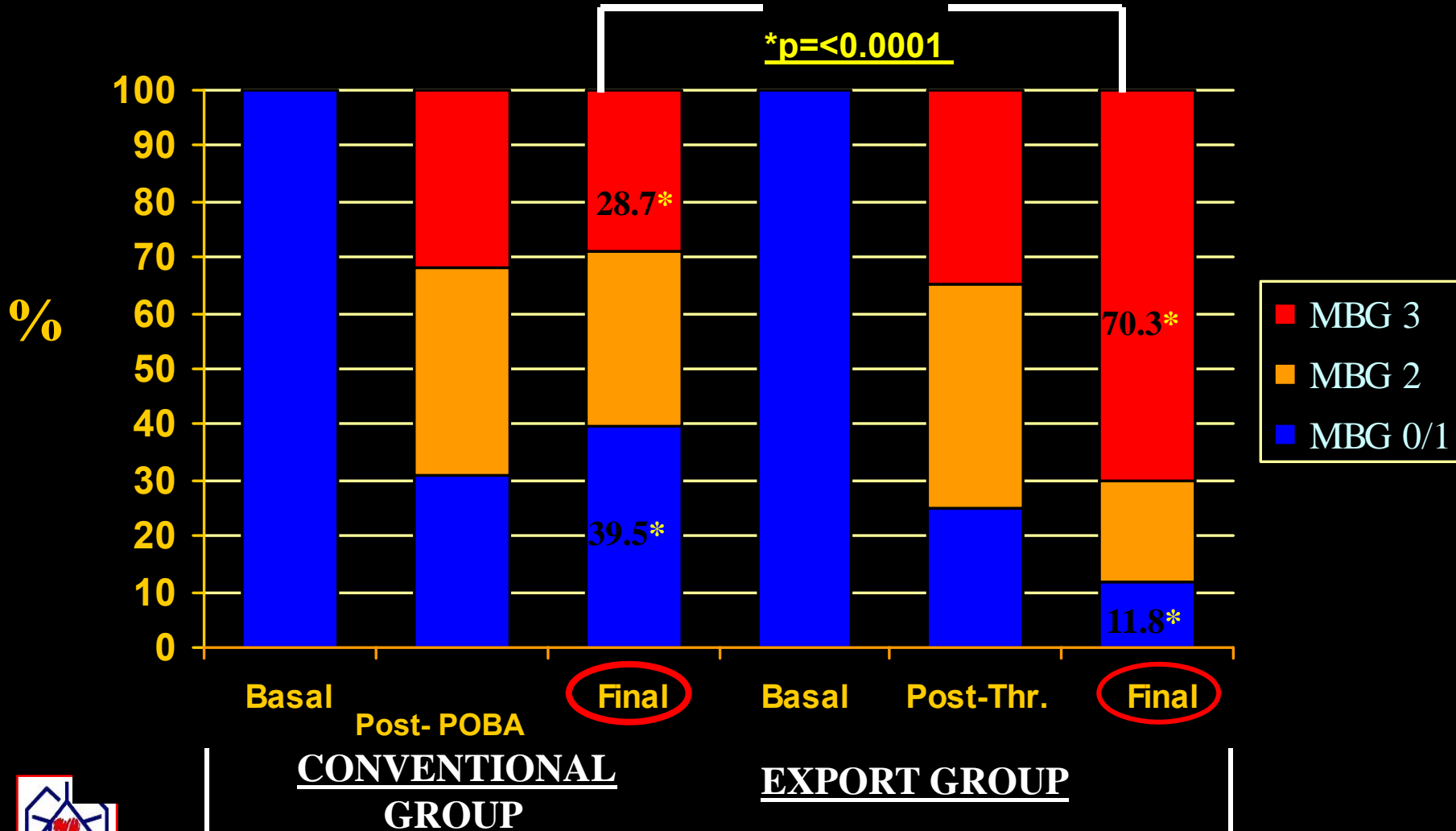




Impact of Thrombectomy with **EXP**ort catheter in **Infarct Related Artery** on procedural and clinical outcome in patients with AMI (**EXPIRA** Trial).

Procedural Results

MYOCARDIAL BLUSH GRADE

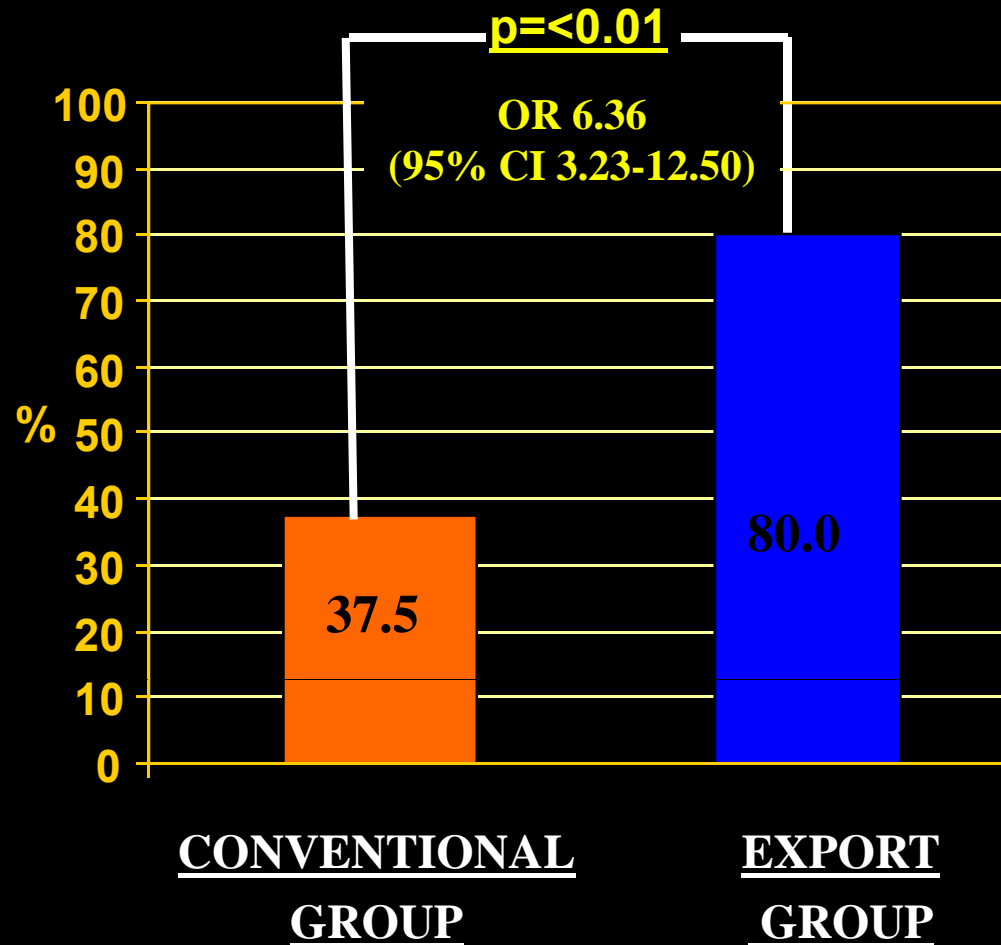




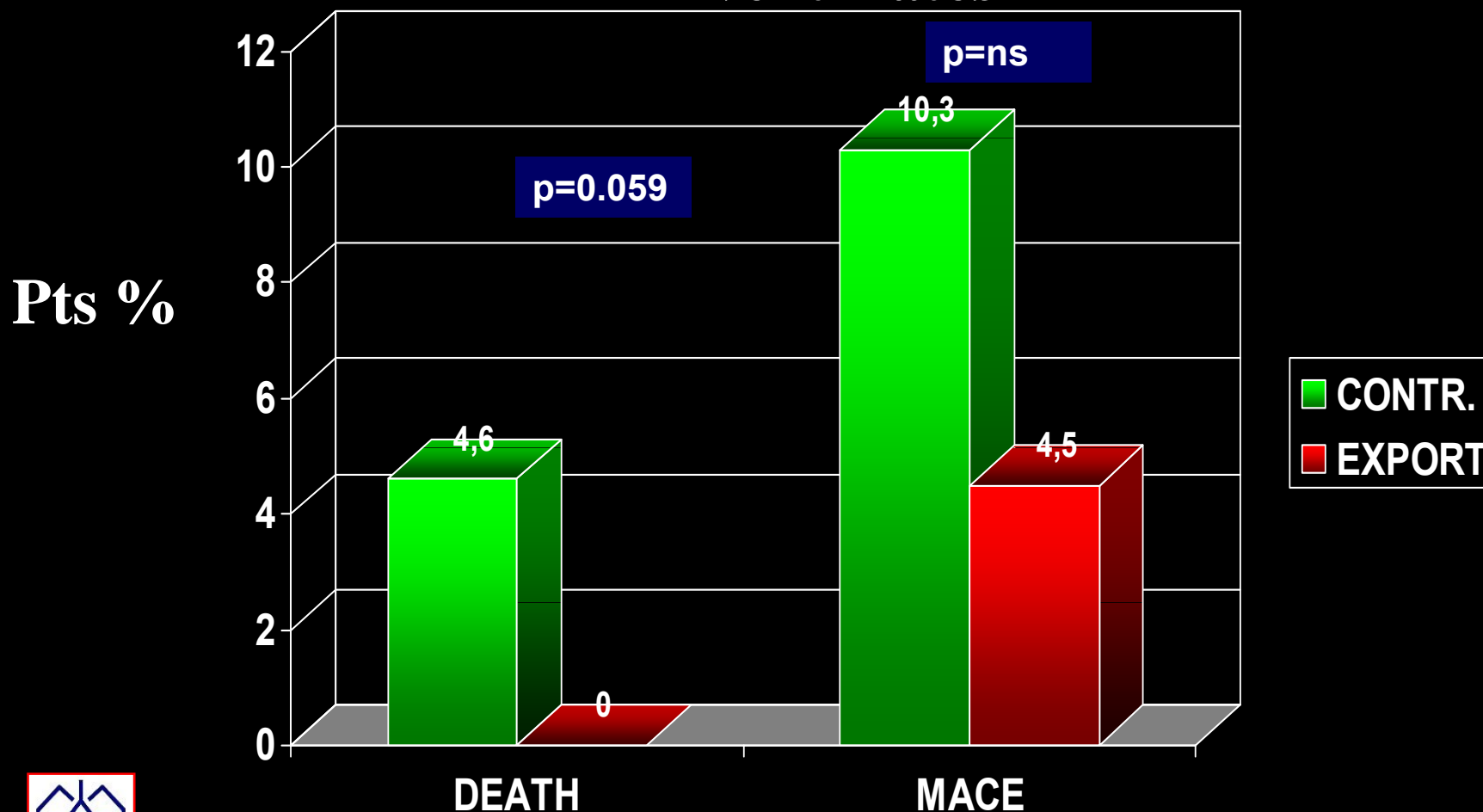
Impact of Thrombectomy with **EX**Port catheter in **I**nfarct **R**elated **A**rtery on procedural and clinical outcome in patients with AMI (**EXPIRA** Trial).

90' ST resolution after PCI (%)

(> 70% decrease of ST segment)



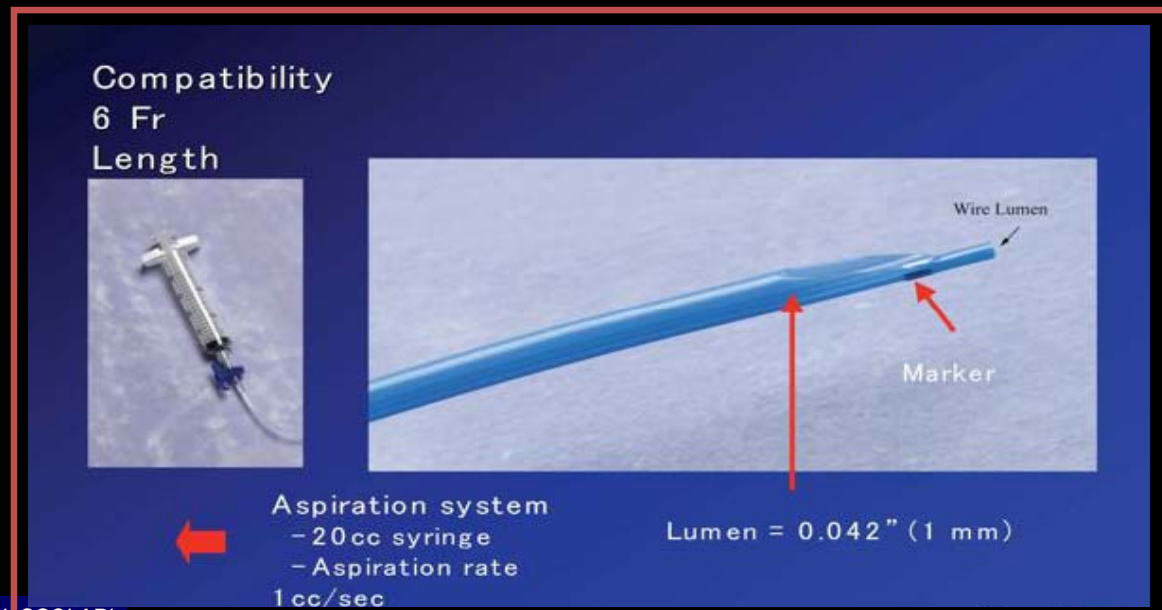
9 months Composite Cardiac Event Rates



Aim of the Study

➤ We sought to evaluate the impact of **thromboaspiration** on procedural and long term outcomes in terms of **microvascular damage and infarct size by contrast enhanced-MRI (ce-MRI)** as compared to conventional primary PCI.

Export® aspiration catheter (Medtronic, Minneapolis, Minnesota)

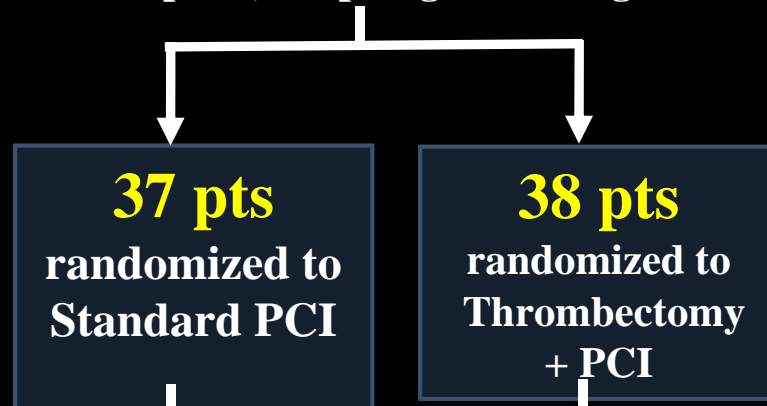


Design

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



3 - 90 Day MRI follow-up

- **Microvascular damage**
- **Infarct size**



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 / Facilitated PCI
- Contraindication to GP IIb/IIIa inhibitors





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)
<u>Risk factors</u>			
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





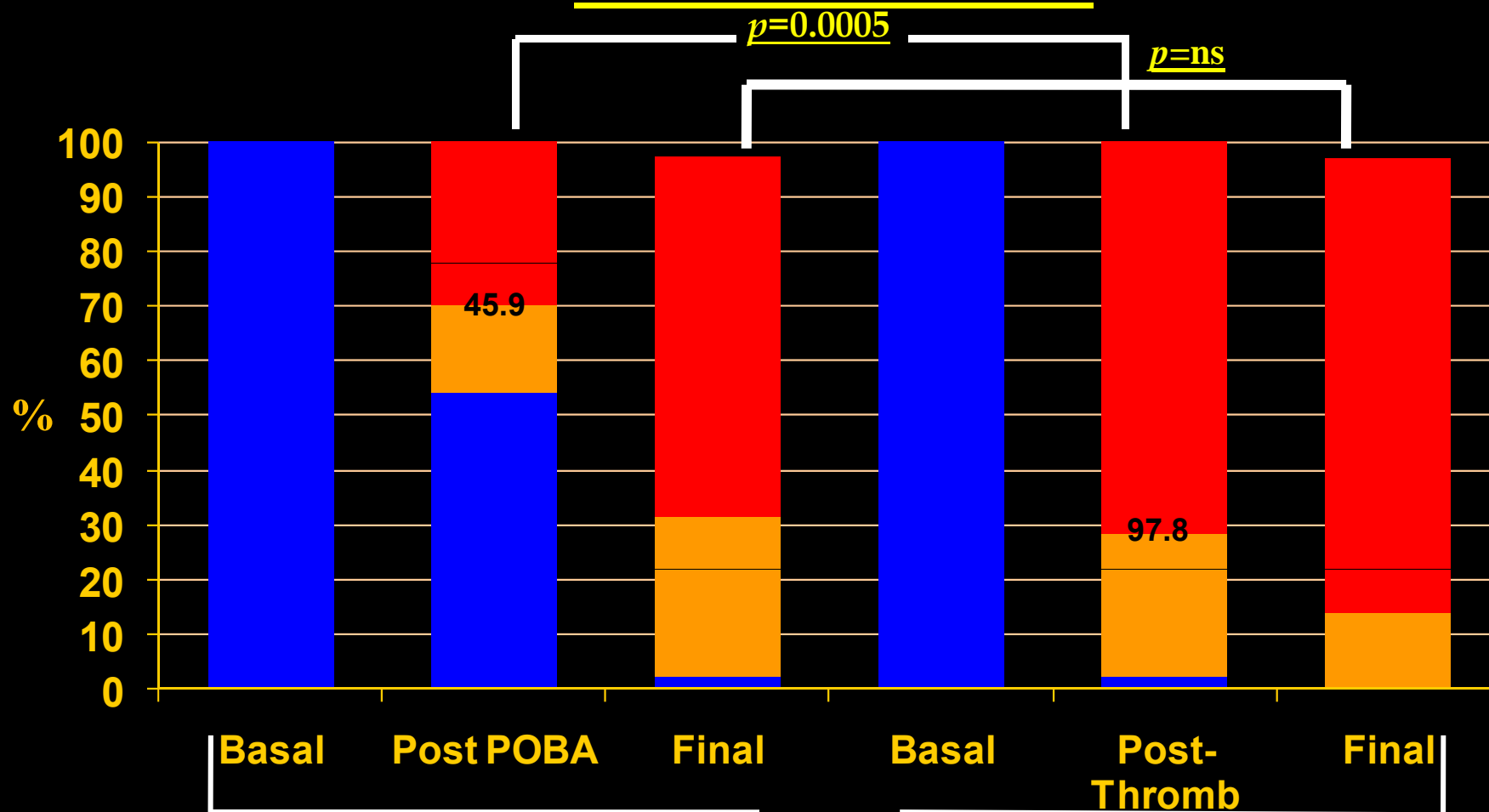
	Total Population (n=75)	Conventional Group (n=37)	Thrombectomy Group (n=38)
IABP (%)	7 (9.3)	4 (10.8)	3 (7.9)
Lesion length, mm±SD	13.8±5.7	14.1±5.6	14.9±4.9
Vessel size, mm±SD	2.9±0.6	2.8±0.5	2.9±0.6
MLD pre, mm±SD	0.8±0.4	0.9±0.4	0.7±0.3
GPIIb/IIIa Inhibitors	75 (100)	37 (100)	38 (100)
Direct stenting	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)





PROCEDURAL RESULTS 1

TIMI FLOW GRADE



CONVENTIONAL GROUP



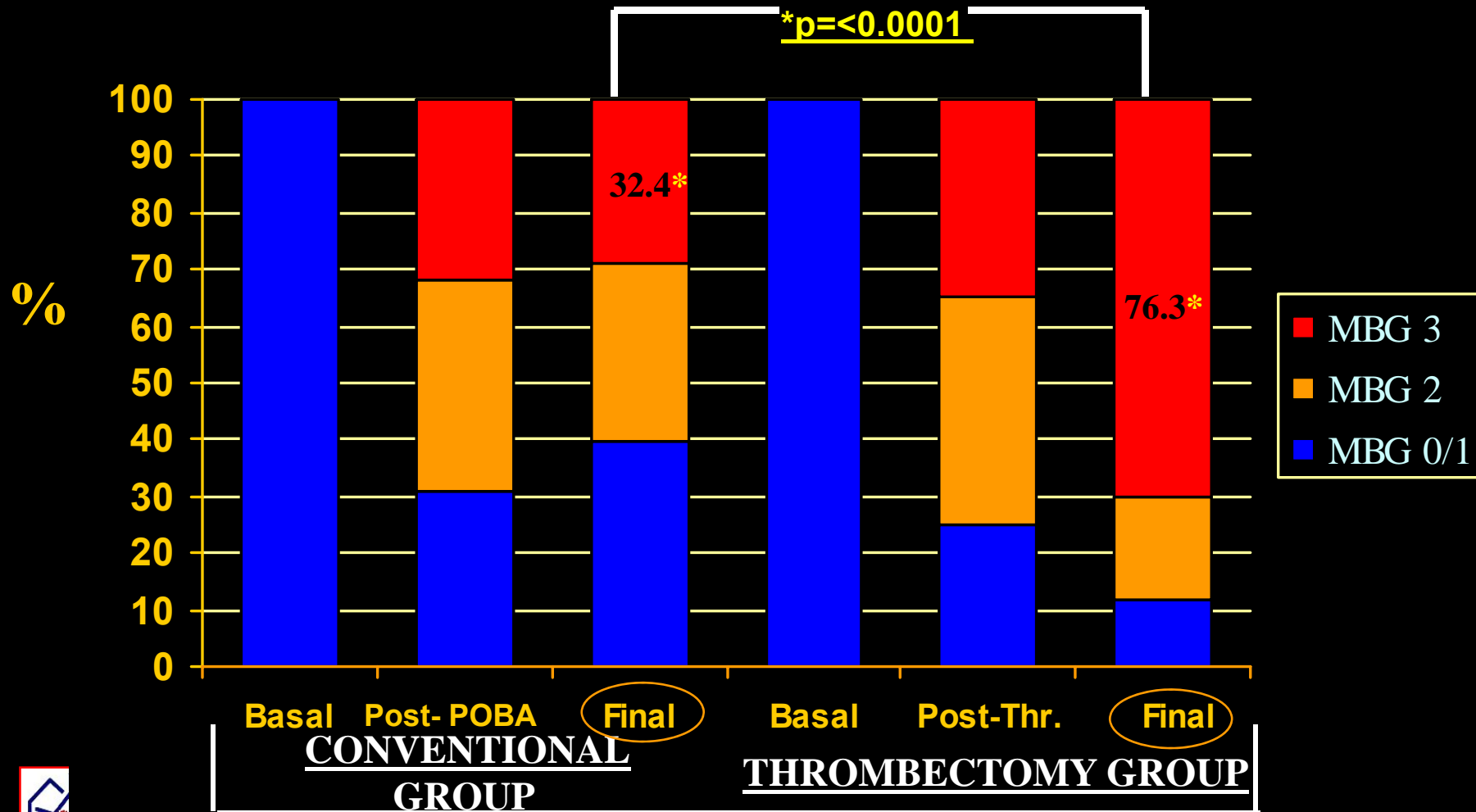
THROMBECTOMY GROUP





PROCEDURAL RESULTS 2

MYOCARDIAL BLUSH GRADE

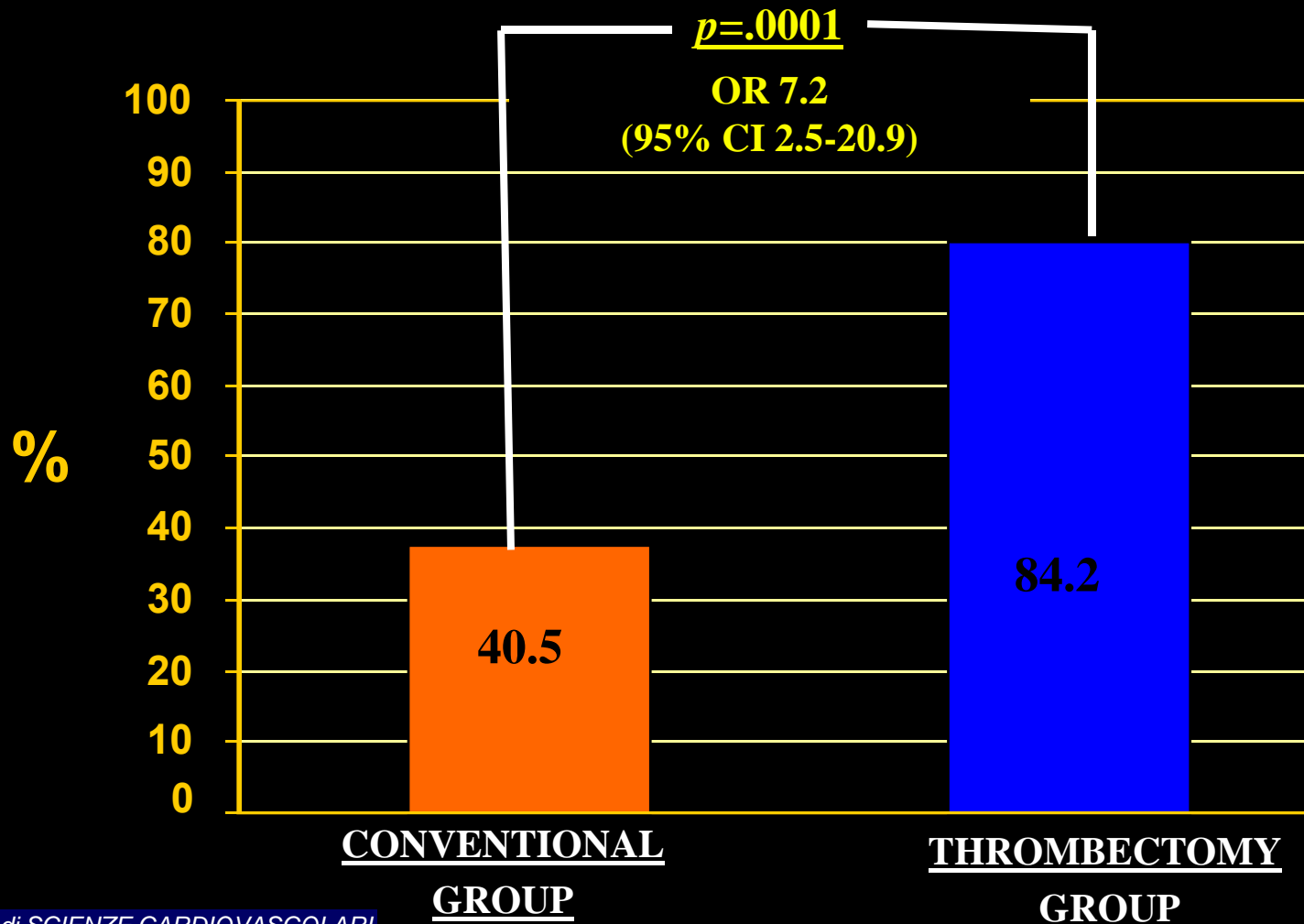




In-Hospital Outcome

90' ST resolution after PCI

(> 70% decrease of ST segment)

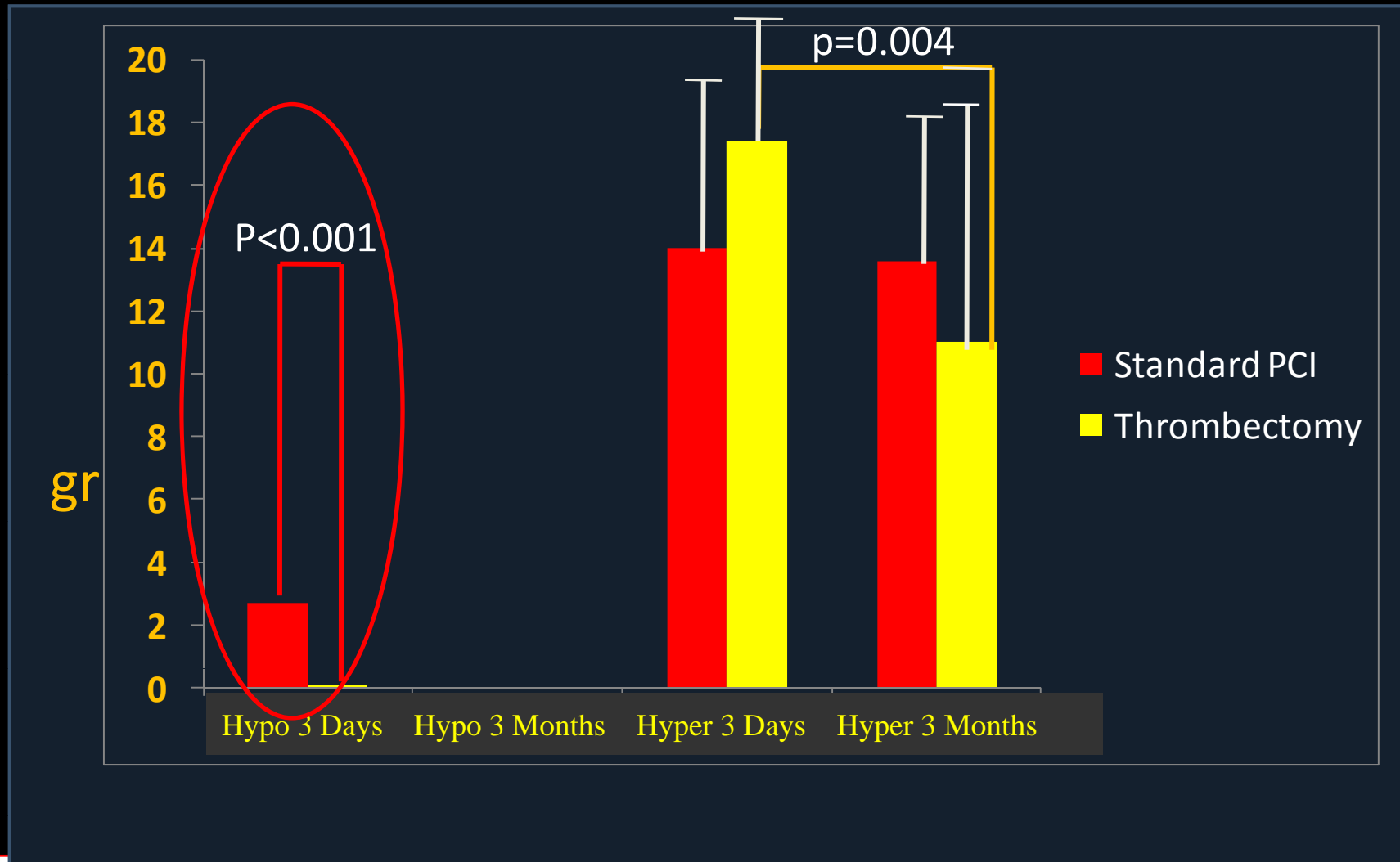


MRI Results-1

	S-PCI (n=37)	EM-PCI (n=38)	P value	S-PCI (n=36)	EM-PCI (n=36)	P value
	Acute Phase 3 d			3-Month Follow-up		
EDV (ml)	137.5±18.6	131.5±14.4	0.1	144.5±20.3	136.2±19.9	0.08
ESV (ml)	77.4±15.4	71.3±17.3	0.1	76.1±16.5	69.3±17.7	0.09
EF (%)	44.3±9.5	46.3±8.6 #	0.3	46.7±10.6	49.0±9.3 #	0.3
IS (%)	13± 6.7	14±12 §	0.6	11± 8.7	9± 4.5§	0.2
IS (gr)	14±7.5	17±15*	0.2	13± 12	11±8.7*	0.4
MVO(n)	27 (72.9%)	9 (31.5%)	0.0005	-	-	-
MVO (gr)	3.7±2.6	1.7±1.9	0.0003	-	-	-

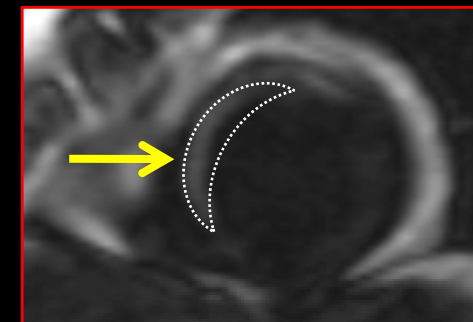
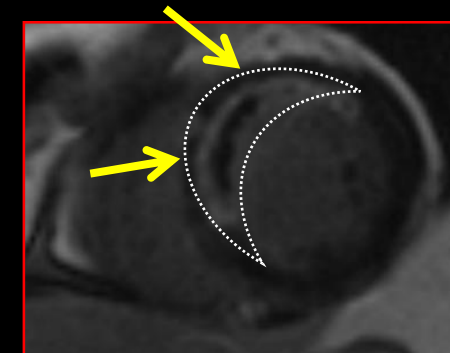
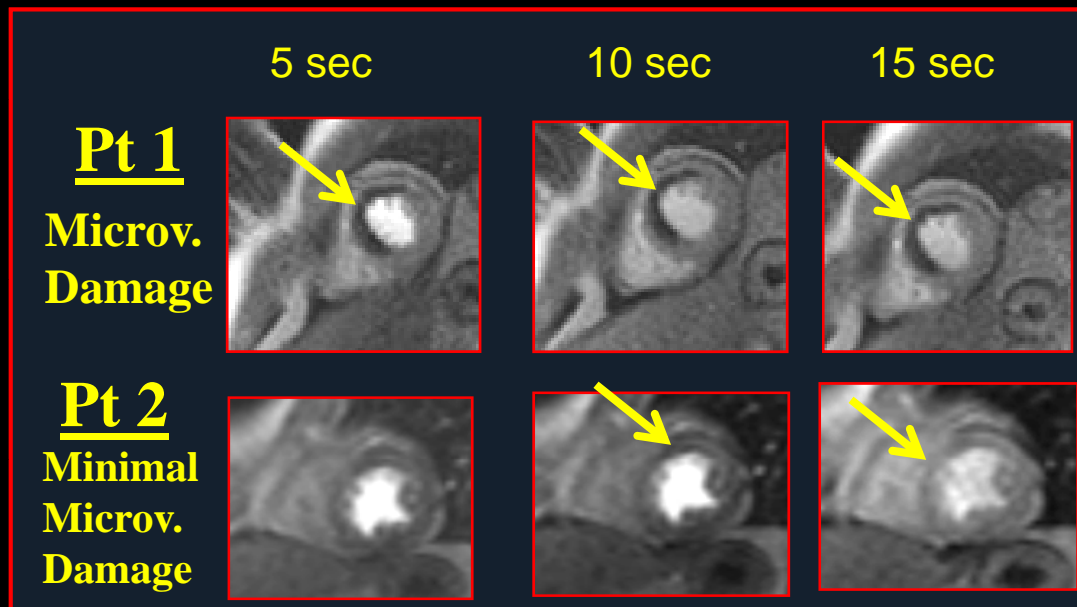


MRI Results-2



Microvascular evaluation (HPO)

Infarct size (HPR)

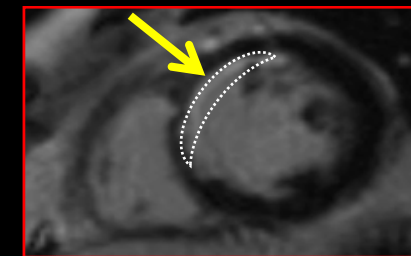
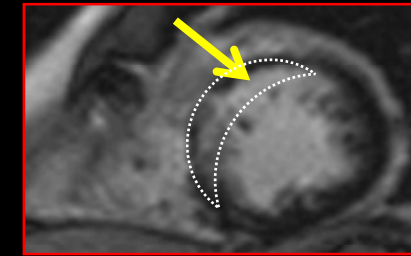
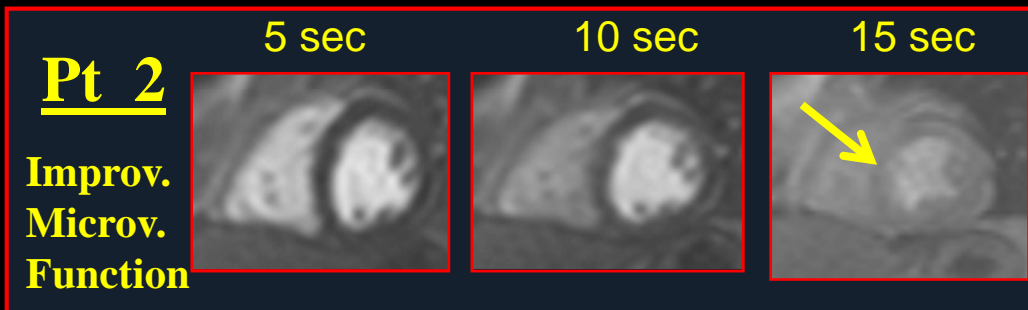
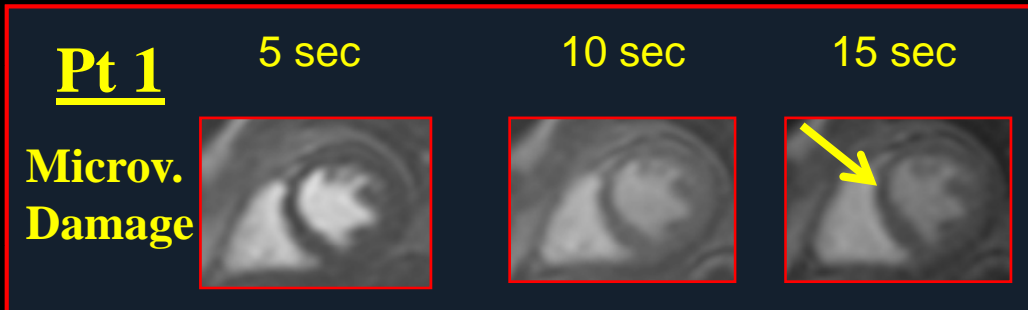


Pt 1 : Control

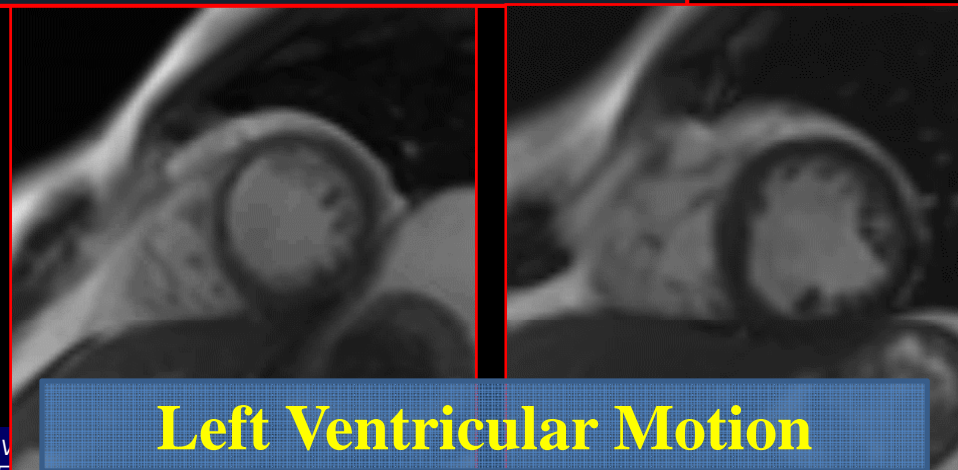
Pt 2 : Thrombectomy

Microvascular evaluation (HPO)

Infarct size (HPR)



Pt 1
Control



Pt 2
Thrombectomy

Left Ventricular Motion



Conclusion

- ❖ In this study **Thrombectomy** has been demonstrated to be **safe and effective** in AMI setting during Primary PCI.
- ❖ Compared with conventional stenting, in 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** in a well selected population.
- ❖ **MRI long term evaluation** showed a **reduction of microvascular damage** in the **Thrombectomy group** compared with the Control group.
- ❖ In the **Thrombectomy group** setting resulted a **reduction of microvascular damage and infarct size** in long term compared with acute evaluation.

