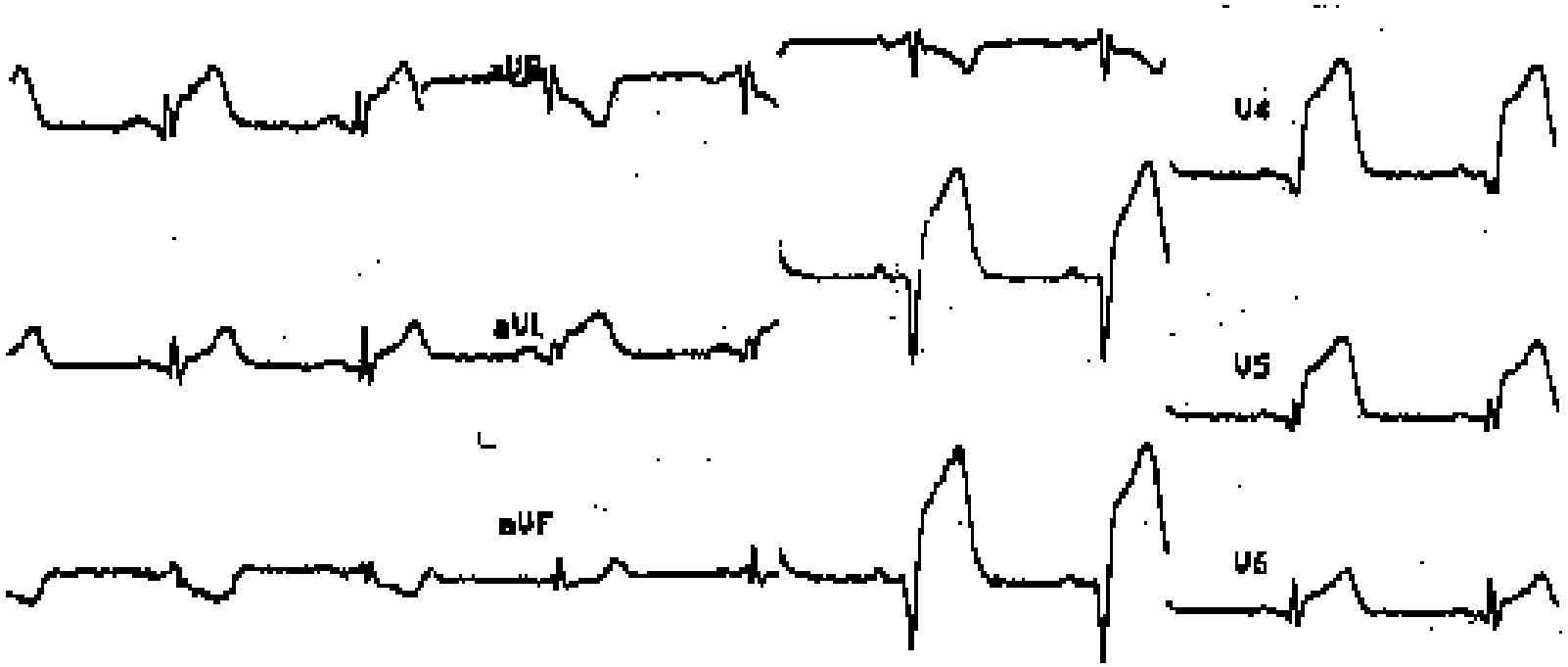
Thrombectomy in Acute MI



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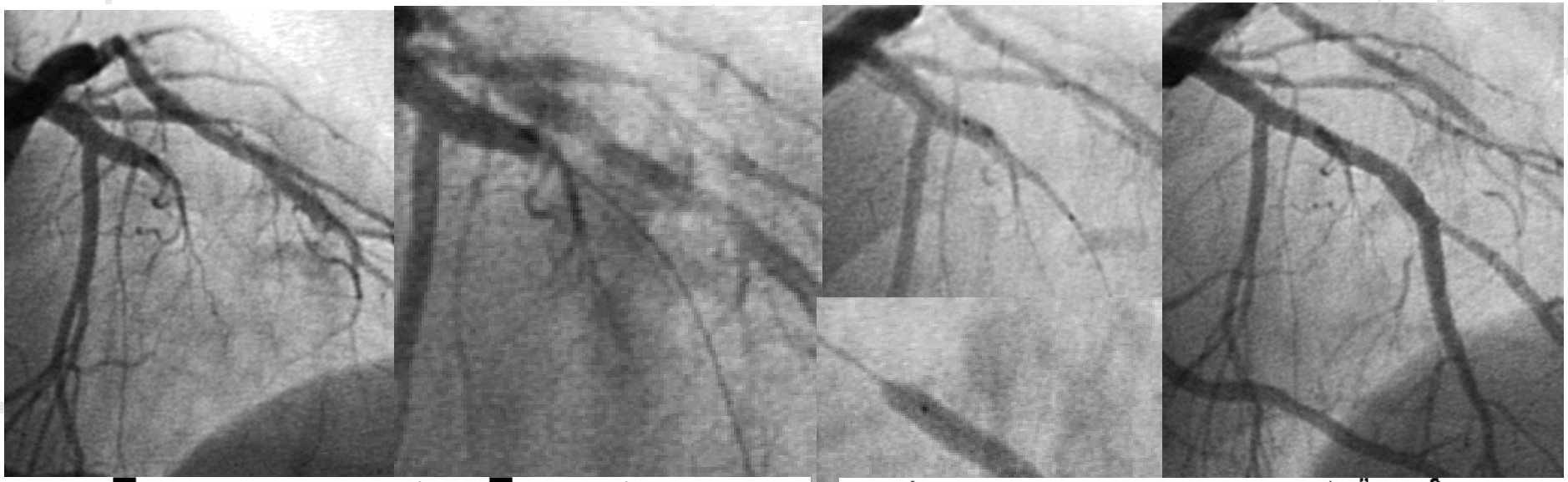
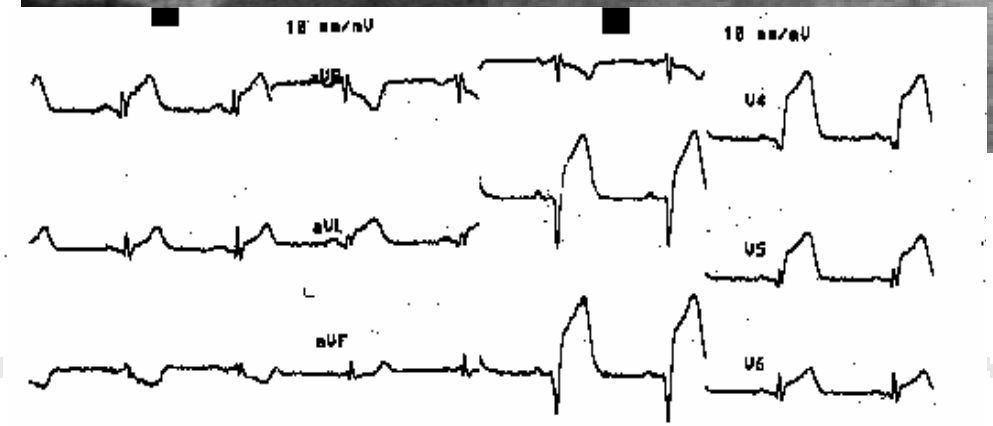
Introduction

- ✓ PCI and Stent is now the gold standard treatment in AMI.
- ✓ Angiographic success rate is high (TIMI 3 > 90%)
- ✓ But true myocardial reperfusion rate is 50-70%

Male, 42 yo. AMI 3 h 30





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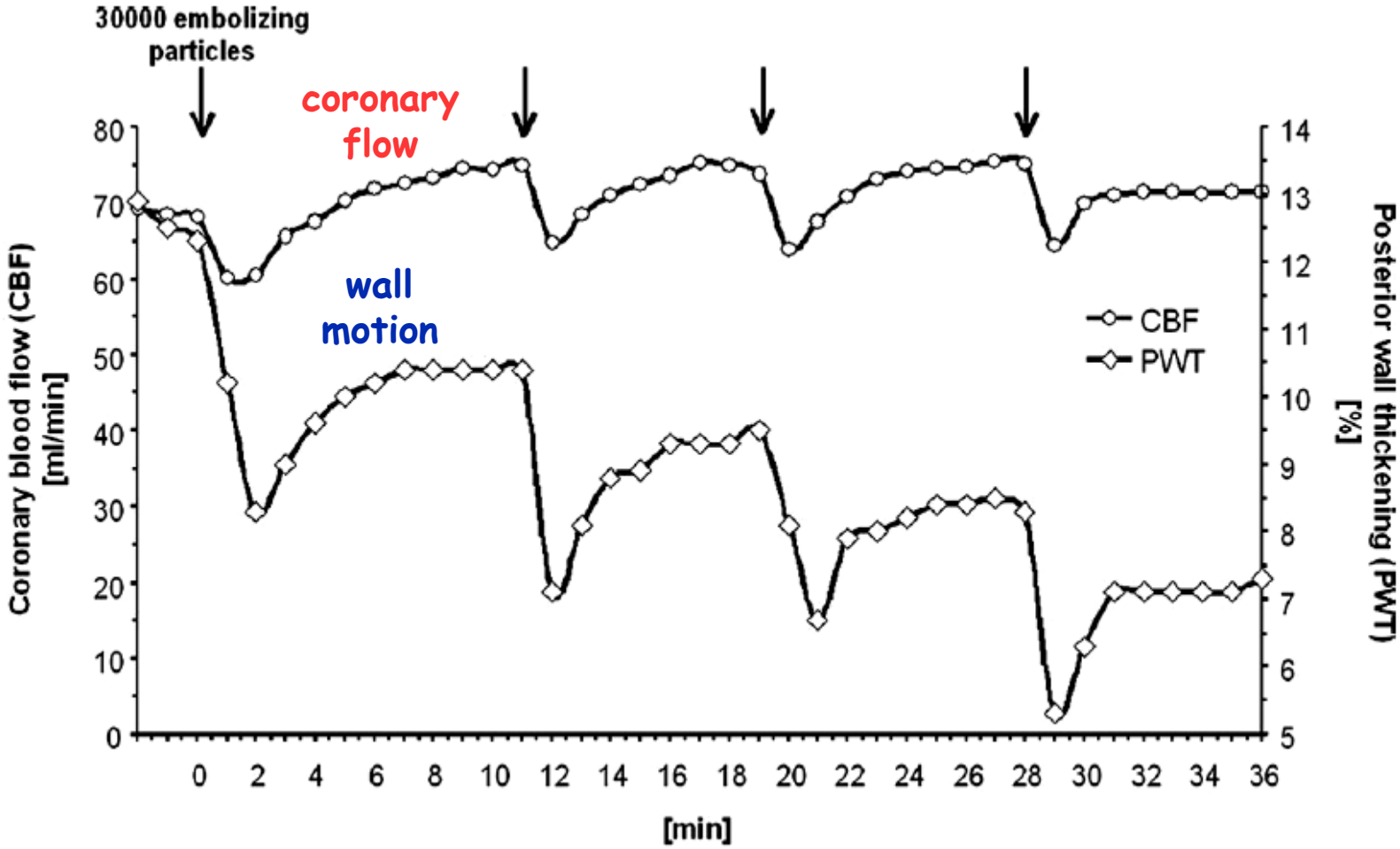
Perfusion-Contraction Mismatch With Coronary Microembolization



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A. Skyschally et al, Am J Circ Physiolo 282:H611-H614, 2002

Thrombectomy in AMI

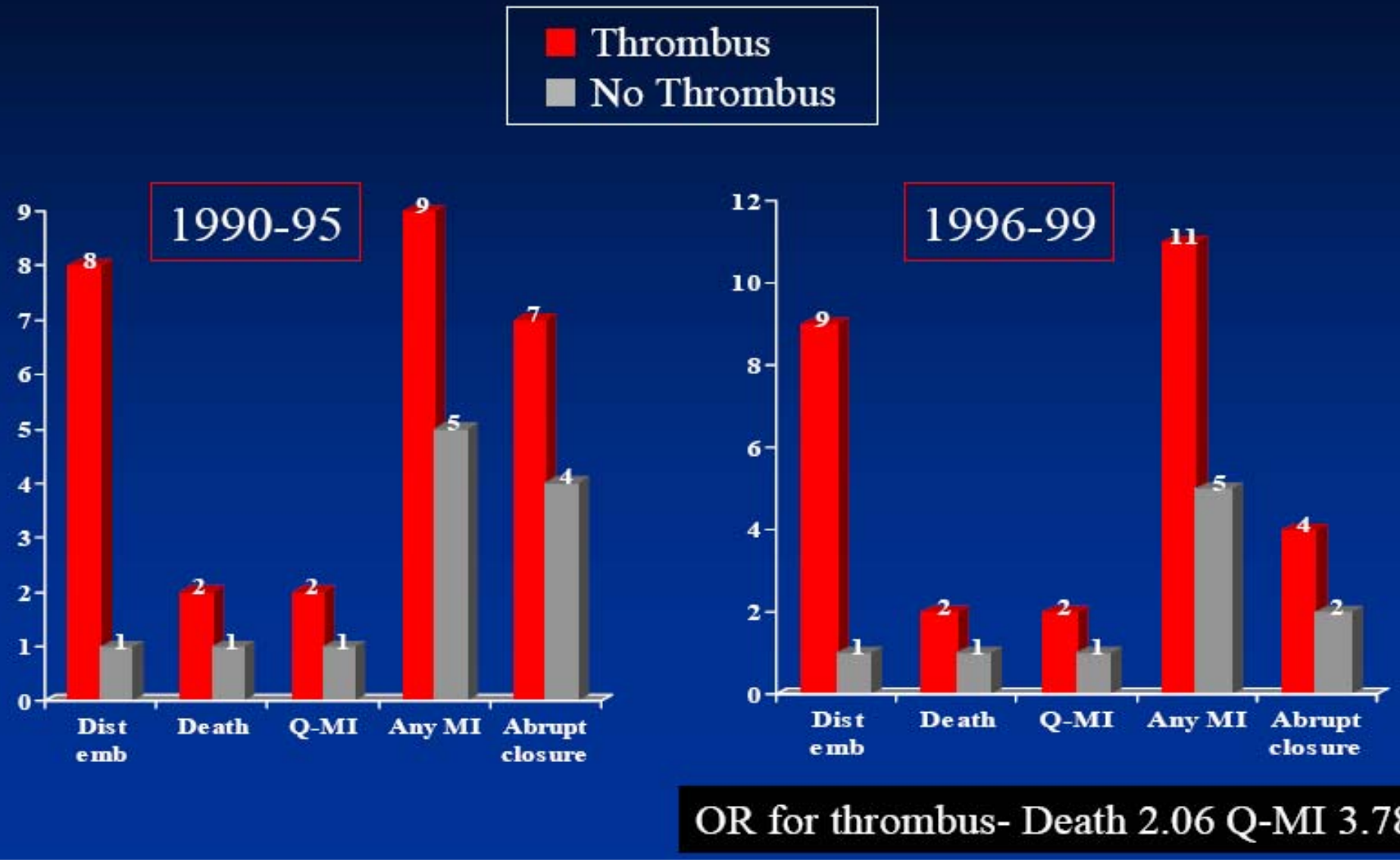
1. What is the Rationale ?

Mechanisms of No Reperfusion in AMI

Leucocytes
Endothelial cells
Platelets
Free radicals
Intersticial Oedema
Distal embolization

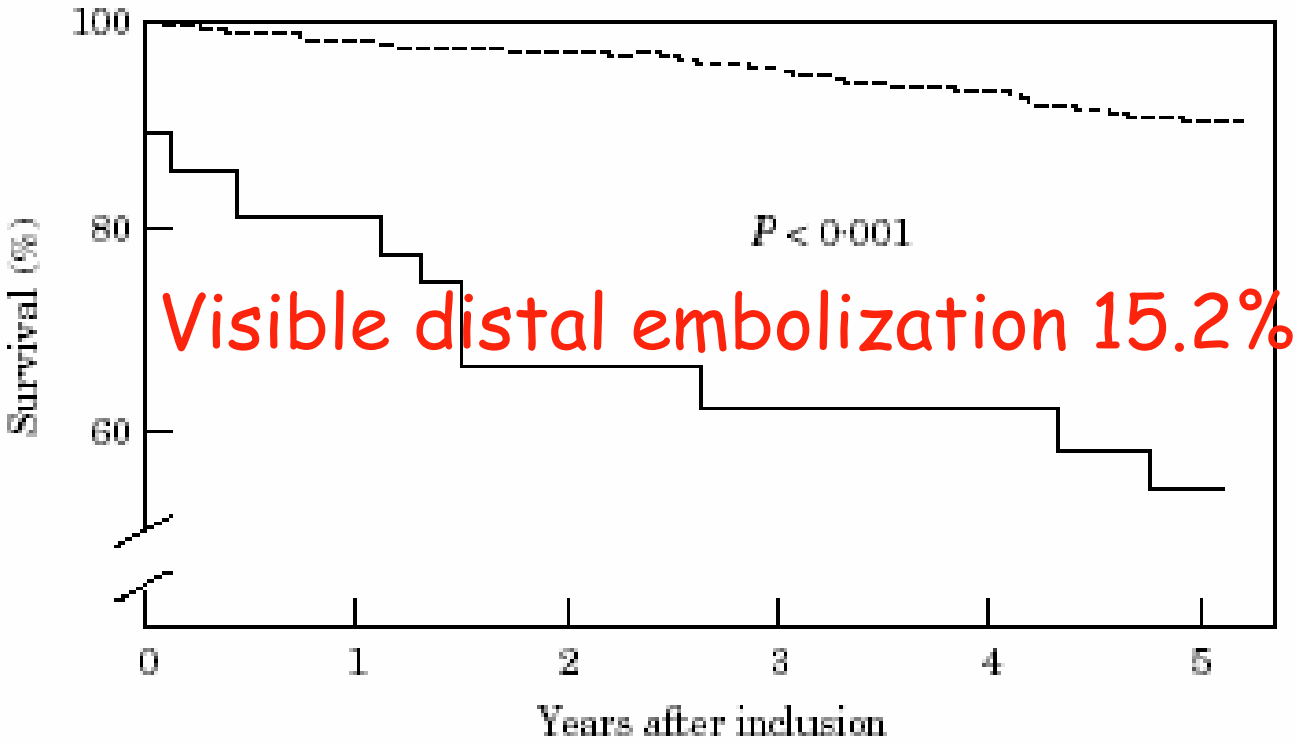
Impact of thrombus on clinical outcome

(Singh et al. Am J Cardiol 2001;88: 1091-96)



OR for thrombus- Death 2.06 Q-MI 3.78

Incidence and Clinical Significance of Distal Embolization during Primary Angioplasty for AMI



Visible distal embolization 15.2%

No Distal embolization

Distal embolization

Henriquez et al Eur J Cardiol 2002; 23: 1112-7

Prevention of Distal Embolisation in AMI

1. Upstream Gp2b3a Inhibitors (Admiral)
2. Direct stenting (Loubeyre et al, JACC 2002)
3. Distal Protection ?
4. **Thrombectomy**

Thrombectomy in AMI

2. Which Kind of Data We Need ?

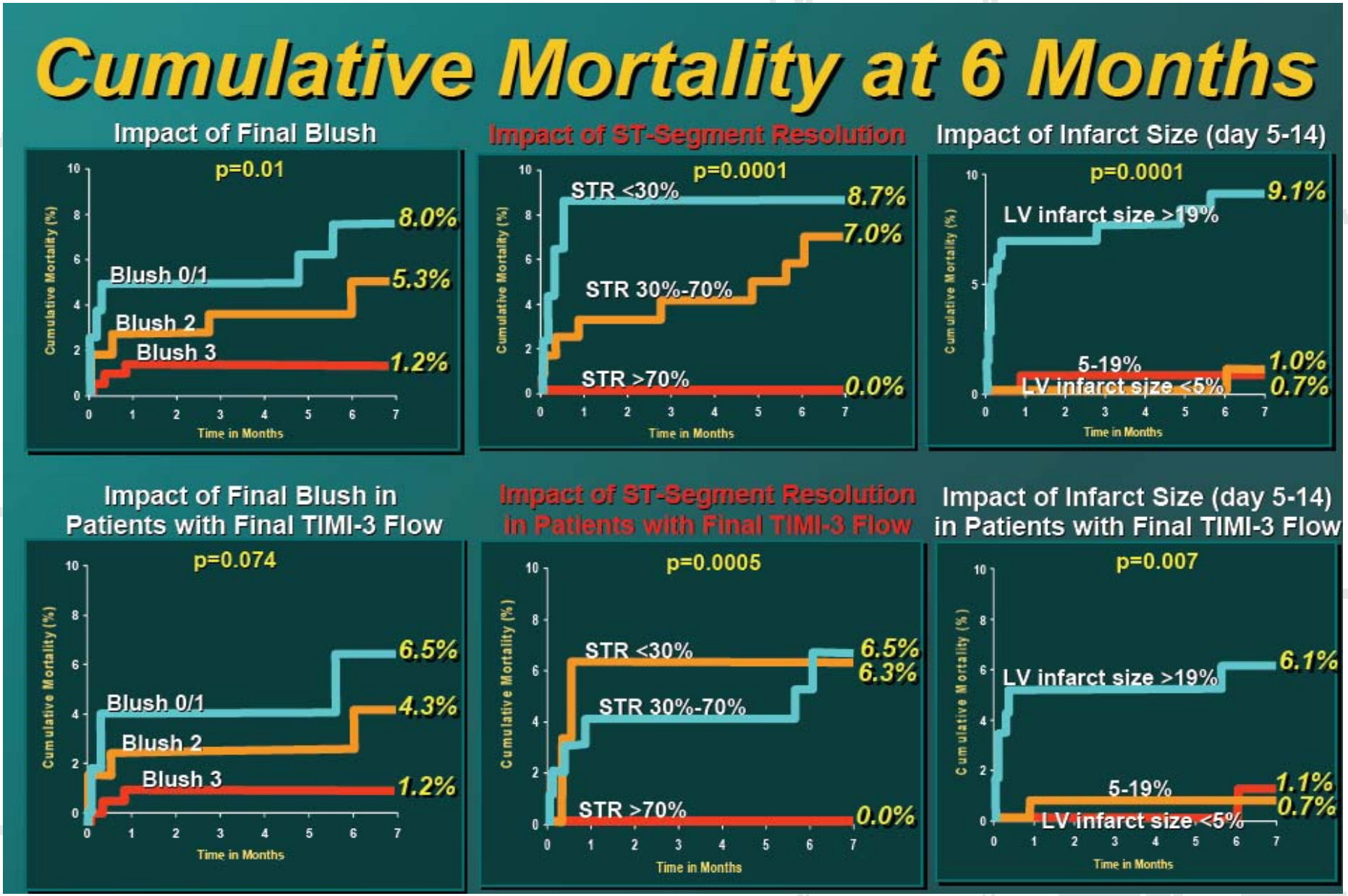
Methodological Problems

- ✓ What is the « good » Primary Endpoint ?
- ✓ How to avoid the learning phase with new devices in multicenter randomized studies ?
- ✓ Which kind of patients we should include ?

Methodological Problems

	Mortality	Surrogate Endpoint
Patients to be included (n)	10,000	30-150
Cost (millions d'Euro)	50 ?	1-5

Cumulative Mortality at 6 Months



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A. Lanski, TCT 2004

TIMI 3 Flow is Only the Tip of the Iceberg

Predictors of MACE after primary PCI

	X^2	*P*	Risk Ratio (95% CI)
%ST	8.4	0.004	3.4 (1.5–7.9)
Shock	3.7	0.06	
Multivessel disease	3.2	0.07	
TIMI grade	2.5	0.11	
Age	2.2	0.14	

Claeys et al. Circulation 1999; 99: 1972-77

Thrombectomy in AMI

3. Which Kind of Data We Have ?

Routine Thrombectomy in Percutaneous Coronary Intervention for Acute ST-Segment–Elevation Myocardial Infarction

A Randomized, Controlled Trial

Anne Kaltoft, MD, PhD; Morten Bøttcher, MD, PhD; Søren Steen Nielsen, MD; Hans-Henrik Tilsted Hansen, MD; Christian Terkelsen, MD, PhD; Michael Mæng, MD, PhD; Jens Kristensen, MD; Leif Thuesen, MD, DMSCi; Lars Romer Krusell, MD; Steen Dalby Kristensen, MD, DMSCi; Henning Rud Andersen, MD, DMSCi; Jens Flensted Lassen, MD, PhD; Klaus Rasmussen, MD, DMSCi; Michael Rehling, MD, DMSCi; Torsten Toftegaard Nielsen, MD, DMSCi; Hans Erik Bøtker, MD, DMSCi

Background—Distal embolization during primary percutaneous coronary intervention (PCI) for ST-elevation myocardial infarction may result in reduced myocardial perfusion, infarct extension, and impaired prognosis.

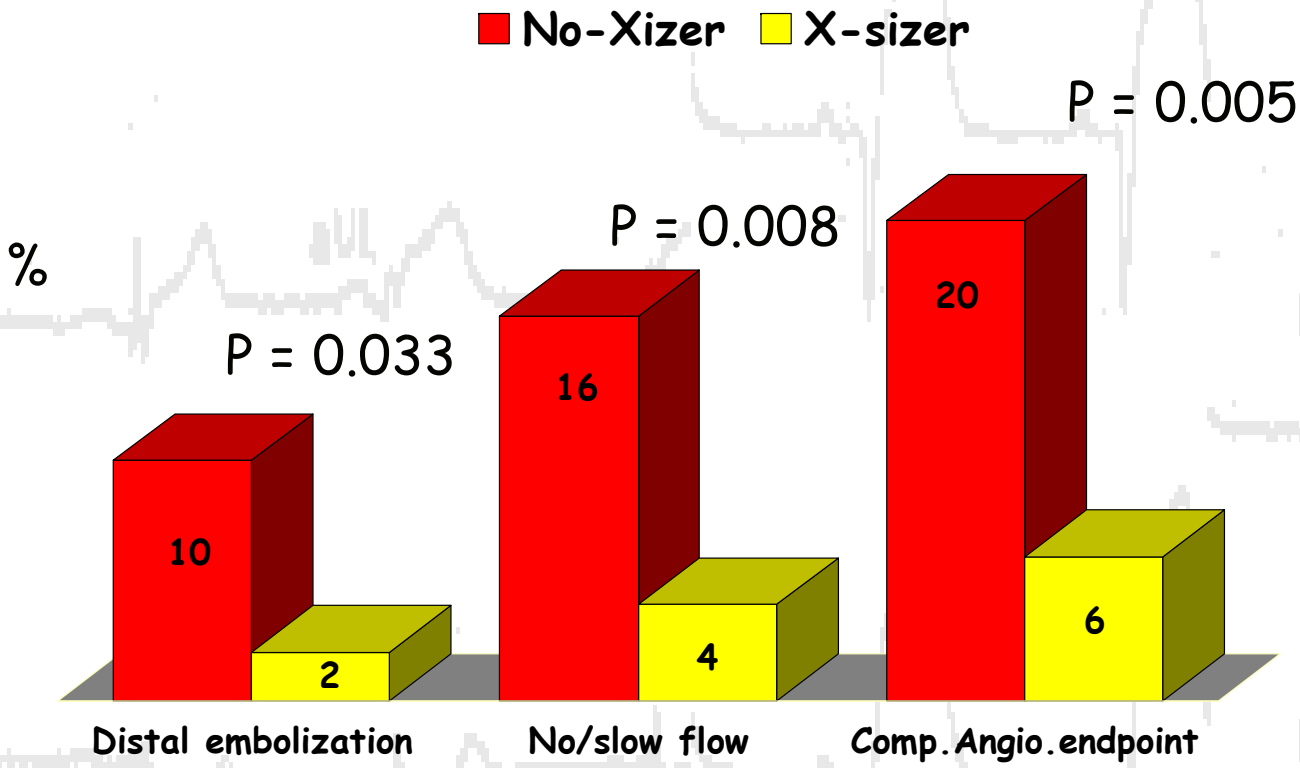
Methods and Results—In a prospective randomized trial, we studied the effect of routine thrombectomy in 215 patients with ST-segment–elevation myocardial infarction lasting <12 hours undergoing primary PCI. Patients were randomized to thrombectomy pretreatment or standard PCI. The primary end point was myocardial salvage measured by sestamibi SPECT, calculated as the difference between area at risk and final infarct size determined after 30 days (percent). Secondary end points included final infarct size, ST-segment resolution, and troponin T release. Baseline variables, including ST-segment elevation and area at risk, were similar. Salvage was not statistically different in the thrombectomy and control groups (median, 13% [interquartile range, 9% to 21%] and 18% [interquartile range, 7% to 25%]; $P=0.12$), but 24 patients in the thrombectomy group and 12 patients in the control group did not have an early SPECT scan, mainly because of poor general or cardiac condition ($P=0.04$). In the thrombectomy group, final infarct size was increased (median, 15%; [interquartile range, 4% to

Conclusions—Thrombectomy performed as routine therapy in primary PCI for ST-elevation myocardial infarction does not increase myocardial salvage. The study suggests a possible deleterious effect of thrombectomy, resulting in an increased final infarct size, and does not support the use of thrombectomy in unselected primary PCI patients.

Thrombectomy in AMI

XAMINE ST

Composite Angiographic Endpoint



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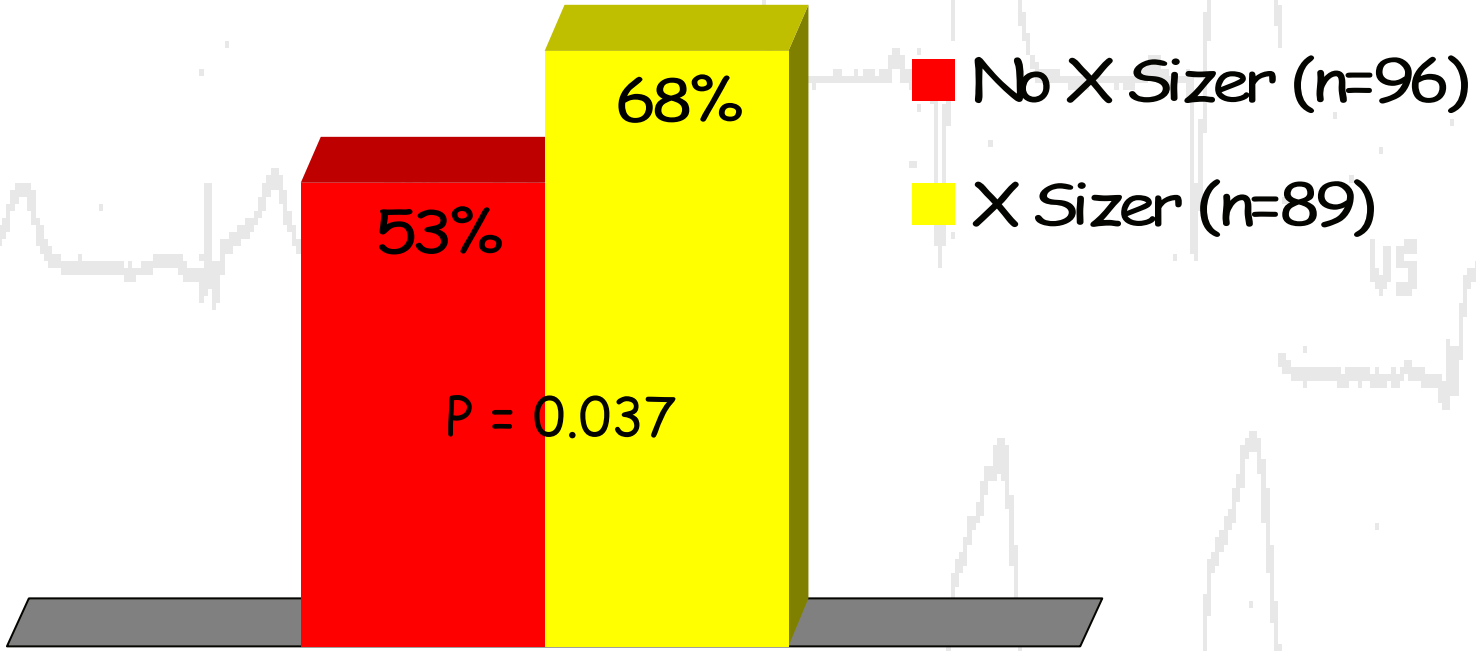
T. Lefèvre. JACC 2005

Thrombectomy in AMI

XAMINE ST

ST Segment Resolution > 50%



Lefèvre et al, JACC 2005

Comparison of Rheolytic Thrombectomy Before Direct Infarct Artery Stenting Versus Direct Stenting Alone in Patients Undergoing Percutaneous Coronary Intervention for Acute Myocardial Infarction

TABLE 2 End Points

Variable	Thrombectomy (n = 50)	Placebo (n = 50)	p Value
Early ST-segment elevation resolution	45 (90%)	36 (72%)	0.022
Corrected TIMI frame count (mean ± SD)	18.2 ± 7.7	22.5 ± 11.0	0.032
Technetium-99m sestamibi infarct size (%) (mean ± SD)	13.0 ± 11.6	21.2 ± 18.0	0.010
Death	0	0	
Reinfarction	0	0	
Target vessel revascularization	0	0	
Major bleeding requiring blood transfusion	0	1 (2%)	0.315
Disabling stroke	1 (2%)	0	0.315

*Mean ± SD.

Antoniucci et al. Am J Cardiol 2004;93:1033-1035

Export Study

Angiographic Results

	Export (N=30)	Control (N=30)	*P*
TIMI III Flow post (%)	97	83	NS
TIMI Frame Count post (fr.)	22 ± 10	32 ± 21	< 0.04
Blush Grade 3 (%)	67	43	< 0.05
Distal embolization (%)	7	10	NS
Composite angio. endpoint (%)	7	27	<0.05
Duration of procedure (min.)	43.0 ± 14.9	37.2 ± 11.3	<0.05
Fluoroscopy time (min.)	13.4 ± 5.0	8.3 ± 4.4	<0.02

B. Noel, PCR 2005

Etude EXport

EKG and In-Hopsital Outcome

		Export (N=30)	Control (N=30)	*P*
ST resolution	> 50%	87	63	<0.04
ST resolution	> 70%	53	10	<0.01
Peak CPK (UI/l)		1545 ± 1230	1987 ± 1013	NS
Death (%)		0	3	NS
Re MI (%)		3	3	NS
Stroke (%)		0	0	NS
MACE (%)		3	7	NS

B. Noel, PCR 2005

Etude EXport

MRI Assessment

	Export (N=24)	Control (N=23)	*P*
EF (%)	50.4 ± 11.3	46.1 ± 12.2	NS
Hypo-enhancement at 1st Pass (% LV)	7.8 ± 7.4	12.9 ± 7.9	0.07
Gad. delayed enhancement (% LV)	12.9 ± 9.6	20.9 ± 7.8	< 0.04
MI Size (gr.)	15.0 ± 11.5	25.6 ± 16.7	< 0.03

Gad. = Gadolinium Diethyltriaminepentaacetic Acid

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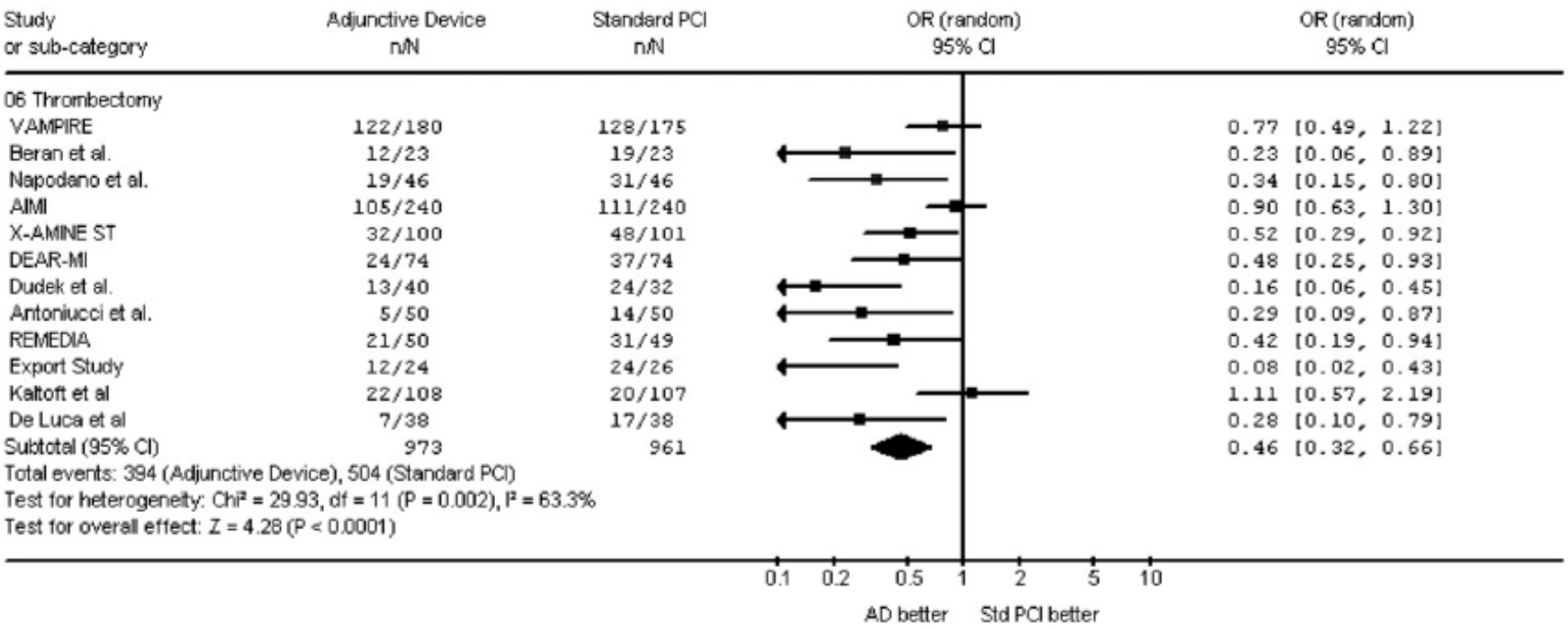
B. Noel, PCR 2005

Thrombectomy in AMI



ST segment resolution

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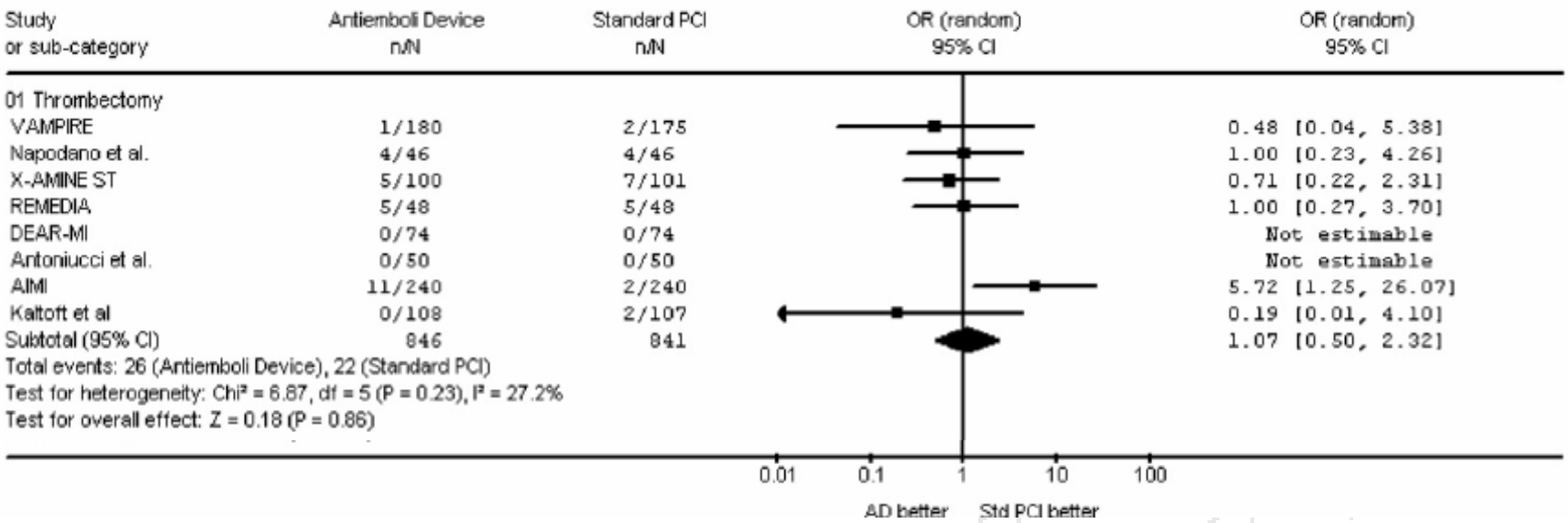
F. Burzotta et al. Int. J Cardiol 2007

Thrombectomy in AMI



Death and MI

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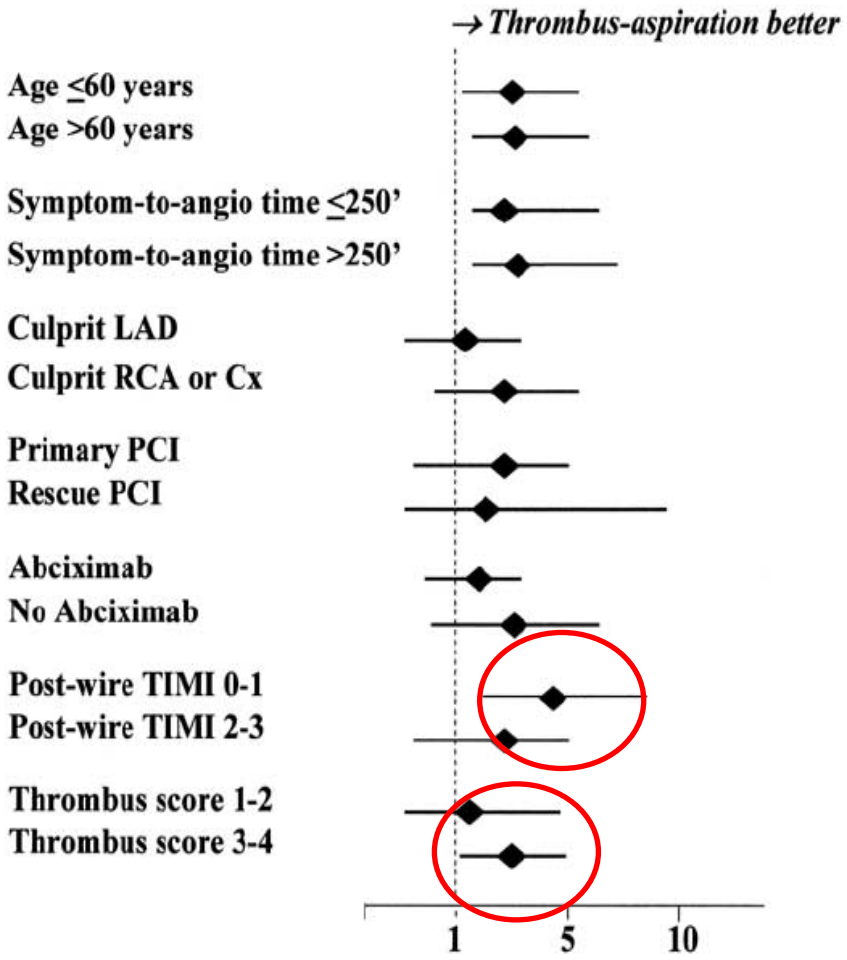
F. Burzotta et al. Int. J Cardiol 2007

Thrombectomy in AMI

4. In Which Kind of Patients ?

Manual Thrombus-Aspiration Improves Myocardial Reperfusion

The Randomized Evaluation of the Effect of Mechanical Reduction of Distal Embolization by Thrombus-Aspiration in Primary and Rescue Angioplasty (REMEDIA) Trial



Burzotta et al, JACC 2005; 46: 371-6

Is Distal Protection Dead in ST Segment Elevation MI ?

✓ Distal embolization is frequent in AMI and significantly associated with poor outcome.

✓ Therefore mechanical approach that decrease the risk of distal embolization remains crucial.

Is Distal Protection Dead in ST Segment Elevation MI ?

Thrombectomy should be used in high risk patients:

- ✓ TIMI 0-1 flow after wiring
- ✓ Visible thrombus

Is Distal Protection Dead in ST Segment Elevation MI ?

✓ To validate definitively the role of thrombectomy in AMI, we need a large prospective randomized study in high risk patients with carefully choosen surrogate endpoints and operators who have passed the learning phase .