



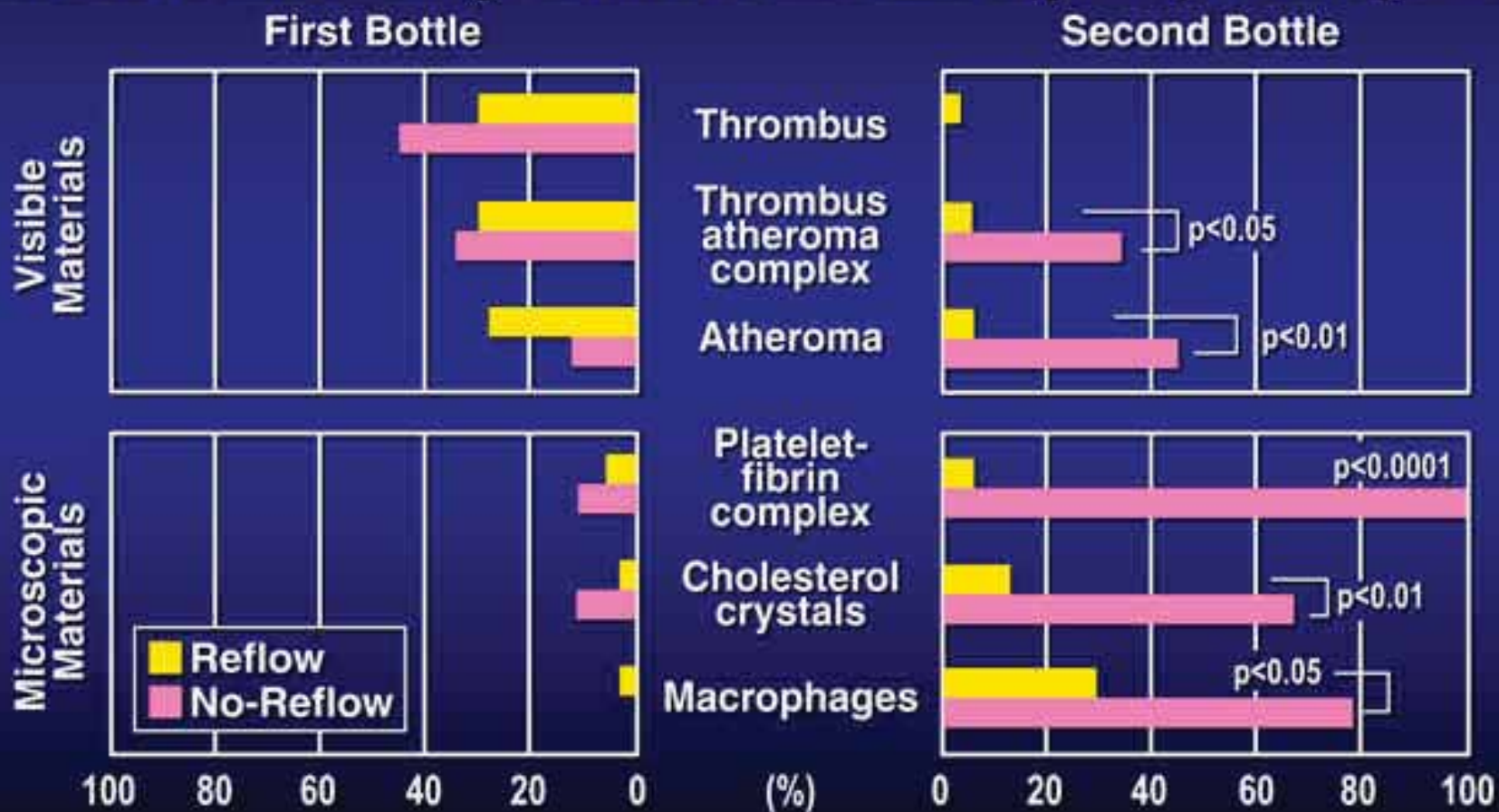
DISTAL PROTECTION IN AMI *– Is the Extra Effort Worth It?*

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Angioplasty Summit, Seoul, Korea 2004

Plaque Gruel of Atheromatous Coronary Lesions May Contribute to the No-Reflow Phenomenon in Patients With ACS

48 Pts, treated with RESCUE thrombectomy catheter. Aspiration before intervention and following each intervention balloon (N = 16) or stent (N = 31)



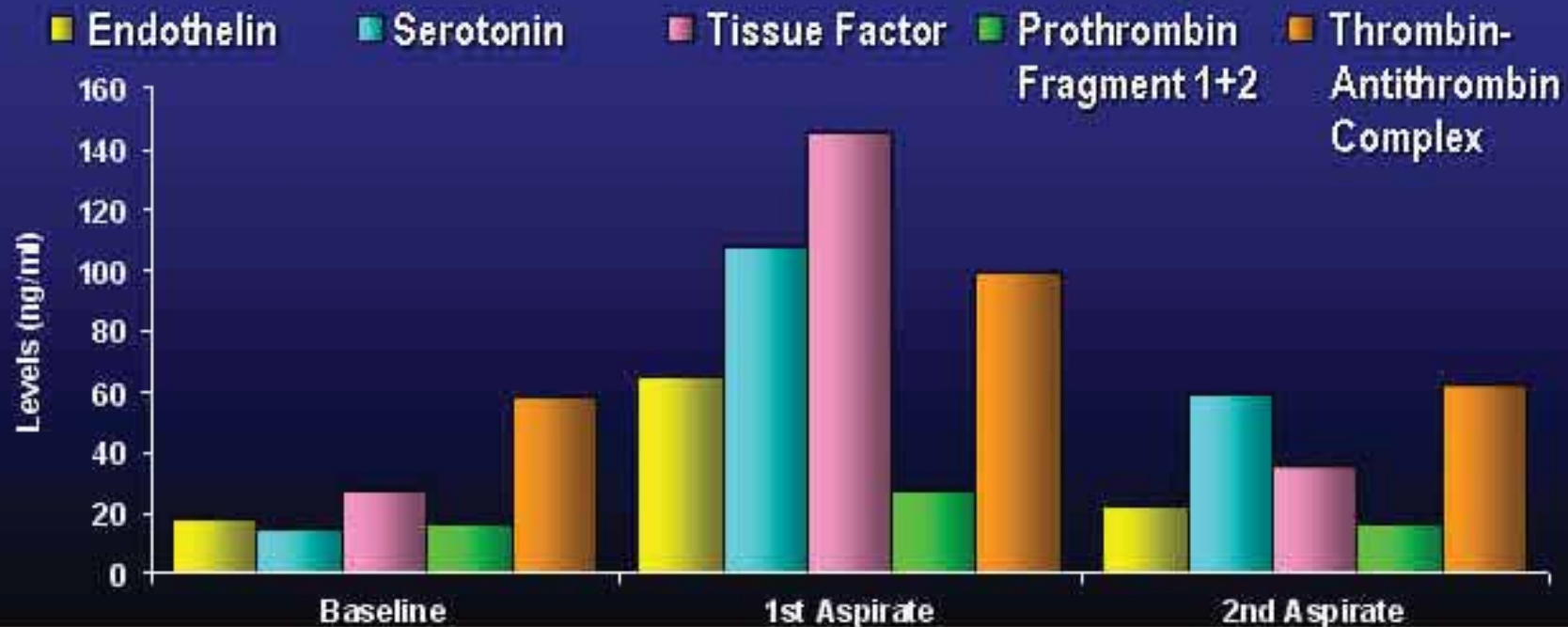
Pathophysiology of No-Reflow

- **Thromboembolic debris**
- **Atheromatous debris**
- **Coronary spasm**
- **Microvascular disruption/necrosis**
- **Endothelial and myocardial edema**

Elimination of Soluble Vasoactive Factors by the PercuSurge GuardWire Distal Protection Device During PCI of SVG

35 pts, blood prior to PCI as baseline, then aspirates after stenting, before deflating distal balloon

Vasoactive Factors Released During SVG PCI



Salloum et al. JACC 2004;43

Rationale for Distal Protection in Acute Myocardial Infarction

- 1.** Reduce the incidence of epicardial coronary No-Reflow, occurs in 10-15% of pts with STEMI
- 2.** Improve microvascular perfusion, only 30% of pts have normal microvascular flow post AMI (despite TIMI-3 flow)
- 3.** Improve LV function
- 4.** Reduce mortality, particularly in high risk groups – MVD, diabetes, elderly, cardiogenic shock
- 5.** Improve long-term outcome

Distal Protection in Acute Myocardial Infarction

Implications of No-Reflow

- **Contrast echocardiography, PET Scan, Nuclear scintigraphy, Doppler flow wire – have shown that microvascular no-reflow is associated with extensive infarction, poor LV recovery and increased mortality**

Distal Protection in Acute Myocardial Infarction

Implications of No-Reflow

- **Myocardial blush grade and ST segment resolution correlate with mortality and myocardial salvage**
- **MBG may reflect mechanical patency of the microvasculature and the integrity of the endothelium**
- **ST-segment resolution may reflect the integrity of the myocardium**

Impact of Normalized Myocardial Perfusion After Successful Angioplasty in AMI

173 patients undergoing PCI within 24 hours of AMI

Post Procedure

TIMI Flow		Blush Score	
0/1	2.9%	0/1	30.2%
2	2.9%	2	41.9%
3	94.2%	3	27.9%

TIMI Flow 0/1 Blush Score 3 (0%)

TIMI Flow 3 Blush Score 3 (29.4%)

ST-Segment Elevation Resolution and Myocardial Blush Grade as Predictors of Mortality in Patients with TIMI-3 Flow: CADILLAC Trial

	Pts	Death (%)	
		30-days	1-Year
ST-Seg Resolution	700		
< 30%	71 (10%)	7.7	9.9
30-70%	193 (27%)	2.8	5.2
> 70%	436 (63%)	1.7	4.2
MBG	856		
0/1	396 (44%)	3.2	5.9
2	300 (35%)	1.3	2.4
3	160 (20%)	0.3	2.3

**TIMI Myocardial Perfusion Grade and ST-Segment Resolution:
Association with Infarct Size as Assessed by Single Photon
Emission Computed Tomography Imaging: LIMIT AMI Trial**

*Association between TMPG, Infarct Size
Stratified by ST-Segment Resolution*

	Median SPECT Infarct Size (% LV)		P-value
	TMPG 0-1	TMPG 2-3	
Overall	13	7	0.004
ST-Res: < 30%	18	13	0.23
30-69%	12	8	0.83
≥ 70%	11	3	0.009

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

1. Thrombectomy

- AngioJet (POSSIS, Inc, MN)
- X-Sizer (EndiCOR Medical, Inc.)
- RESCUE (Boston Scientific Scimed, Inc)
- EXPORT Catheter (Medtronic Vascular)

2. Proximal Protection

- Velocimed Proxis Device
- Rinspirator System, Kerberos Proximal Solutions

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

3. Distal Protection

- PercuSurge, GuardWire (Medtronic Vascular)
- Filter Devices: FilterWire EX, AngioGuard XP

4. Pharmaceutical

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

Intracoronary Abciximab Downstream of Coronary Occlusion May Increase Myocardial Salvage in AMI Treated With PCI

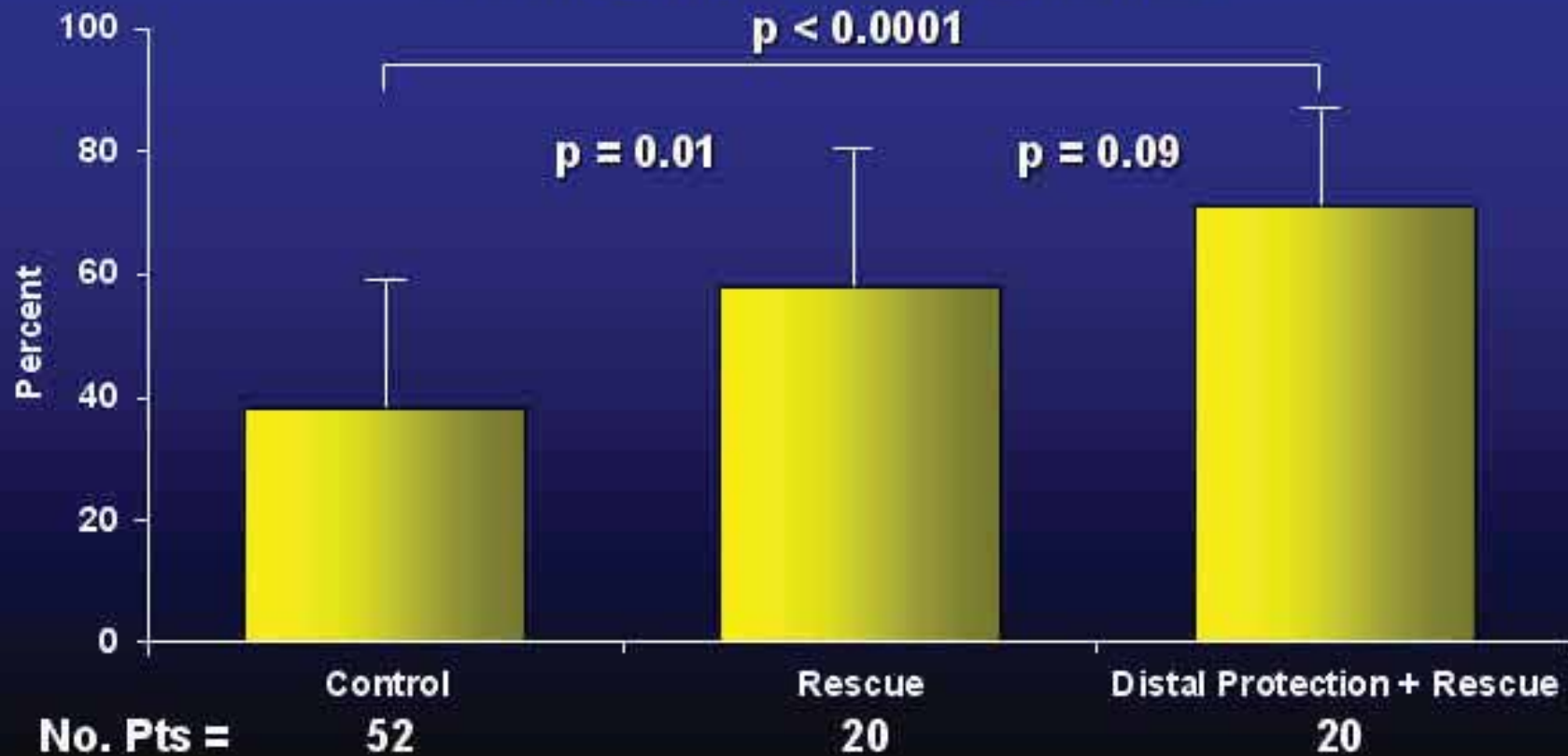
Abc dose 0.25 mg/kg vs. 10 mg I/V + 0.25 mg/kg I/C

	Abciximab Single I/V bolus; N=21	Double Bolus I/V + I/C N=21	P-value
% Initial Perfusion Defect	32 ± 5	34 ± 5	NS
% Infarct Size	14 ± 3	12 ± 3	0.02
% Myocardial Salvage	18.4	21.4	0.02
% Salvage Index	0.56 ± 0.08	0.64 ± 0.07	0.001
LVEF, Baseline	43 ± 4	41 ± 4	0.001
7 days	45 ± 6	47 ± 5	
30 days	48 ± 4	52 ± 4	

Tc99m Sestamibi and Gated SPECT, baseline, 7 d, 30 d.

Thrombectomy With Distal Protection Prior to Stenting Is a Novel Strategy to Obtain Optimal Reperfusion in Patients With Acute Myocardial Infarction

ST Resolution 1 Hour After PCI



N. Ito et al. JACC 2003;41:356A

The EndiCOR X-Sizer in AMI

	X-Sizer Registry N = 216	Madrid Experience N = 71	Milano Italy N = 46	Vienna Experience N = 30
Mean Age (yrs)	58.5	61 ± 11	61.3 ± 10.8	55.9 ± 9.9
Anterior MI (%)	48	49	39	35
Successful Crossing (%)	93.9	-	91.3	93.7
TIMI 3 Flow After Device (%)	82	-	78.3	-
Final TIMI 3 Flow (%)	92.2	94	93.5	90
Myocardial Blush Grade 3 (%)	58	59	71.7	-
≥ 50% ST-Seg Resolution	-	75	82.6	83
30-Day MACE	5.4	5.2	6.5	6.1

D. Cox et al. AJC Sept. 2002
M. Napodano JACC 2003;42:1395

E. Garcia et al. JACC 2003;41:356A
Beran Circ 2002;105:2355

Evaluation of a Distal Protection Filter Device in Pts with AMI: Final Results of the DIPLOMAT Trial

60 pts, AMI < 12 hrs, randomized, prospective trial.

AngioGuard™ XP filter

Primary Endpoint: ST-seg resolution 1 hr post-PCI

	AngioGuard N = 25	Control N = 31	p-value
Successfully deployed	100%	-	
Debris retrieved	82%*	-	
Absolute ST-seg res (mm)	15.8 ± 15.3	9.6 ± 6.7	0.04
Complete ST-seg res.	80%	73%	NS
30-day death	0	4.2%	NS
Death or MI	3.3%	8.3%	NS

*344 ± 306 μm

LeFevre et al. JACC 2004;43:72A

Successful Embolization Protection Using GuardWire System for AMI

Multicenter Registry in Japan
212 pts, macroscopic debris in 93.9%

Anterior MI (%)	54.2
Cardiogenic shock (%)	19.8
Peak CPK (mean)	2010
Procedural success (%)	100
Clinical success (%)	100
No Reflow (%)	0
TIMI 3 Flow, post (%)	100
In-Hospital death (%)	0

Distal Protection Device Was Associated With Better LV Function by Improving Microcirculation After Primary Coronary Intervention

*29 pts, within 12 hours of STEMI, treated with PercuSurge, matched to 30 control pts.
Samsung Medical Center, Korea*

	PercuSurge N = 29	Control N = 30	p-value
Myocardial Blush Gd 3	62%	30%	0.04
Early ST-Seg Resolution	76%	47%	0.02
LVEF	52 ± 9%	45 ± 10%	0.01



The EMERALD Trial

Enhanced Myocardial Efficacy and Removal
by Aspiration of Liberated Debris

AMI <6° (N=501)
Primary or rescue PTCA
Native cor. or SVG

Cath lab →

PercuSurge eligible
2.5 - 6.0 mm vessel
IIb/IIIa inhibitor optional

1° Endpoint - Efficacy
Resolution of ST segment
elevation; Infarct size by
tc-99m-sestamibi

2° Endpoints
Myocardial blush, MACE

252
PCI with 3rd
generation
0.028"
PercuSurge
distal protection

249
PCI
without
protection

Primary Angioplasty in AMI with Distal Protection of the Microcirculation: Results from the Roll-In Phase of the EMERALD Trial

- **102 Patients**

- Final Myocardial Blush Score

- Grade 3 58.5%
 - Grade 2 18.5%
 - Grade 0/1 23.1%

- MACE at 30 Days

- Death 0
 - Reinfarction 1.5%
 - TVR 5.9%



GuardWire Performance

276 lesions in 252 pts

	<u>Per Isn</u>	<u>Per pt</u>
GuardWire crossed the lesion	95%	96%
- as the primary wire	80%	80%
- with a buddy wire, \pm aspiration	12%	13%
- with pre-dilatation	3%	3%
Balloon occlusion ever established	93%	95%
Aspiration ever performed	95%	97%
Visible debris removed	70%	73%



Baseline and Final Myocardial Blush





Primary Endpoint

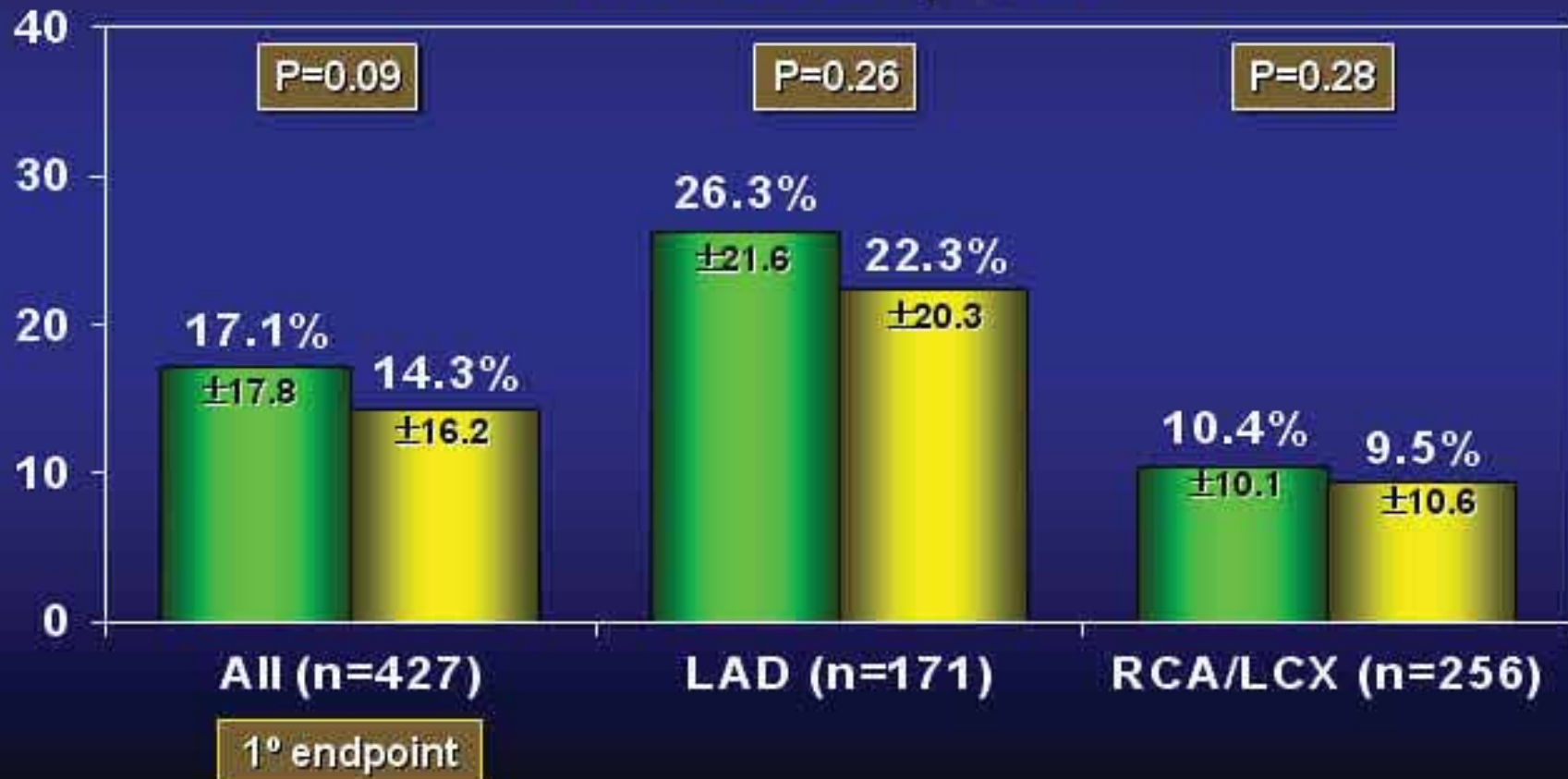
ST-Segment Resolution at 30 Minutes





Infarct Size by Tc-99m-SPECT

Infarct size, %LV



Primary Angioplasty in AMI with Distal Protection of the Microcirculation: *Conclusions*

- Distal protection, with balloon occlusion and aspiration or filter devices is feasible in most patients (technically challenging in complex anatomy)
- Visible debris retrieved in two thirds of lesions
- High rate of normal myocardial blush and ST-Segment resolution compared to historical controls
- Distal protection has been demonstrated to reduce incidence of slow-flow and no-reflow
- Distal protection with GuardWire, however, does not result in improved microvascular flow or reduced infarct size in the EMERALD Trial

Primary Angioplasty in AMI with Distal Protection of the Microcirculation: *Conclusions*

- Distal protection however remains a viable concept and option for the effective treatment of AMI