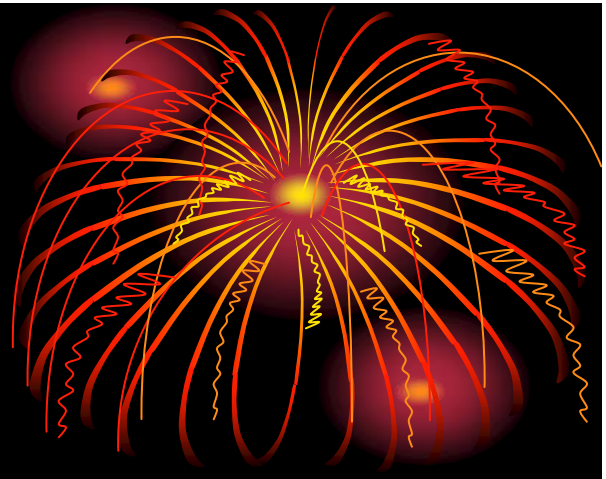


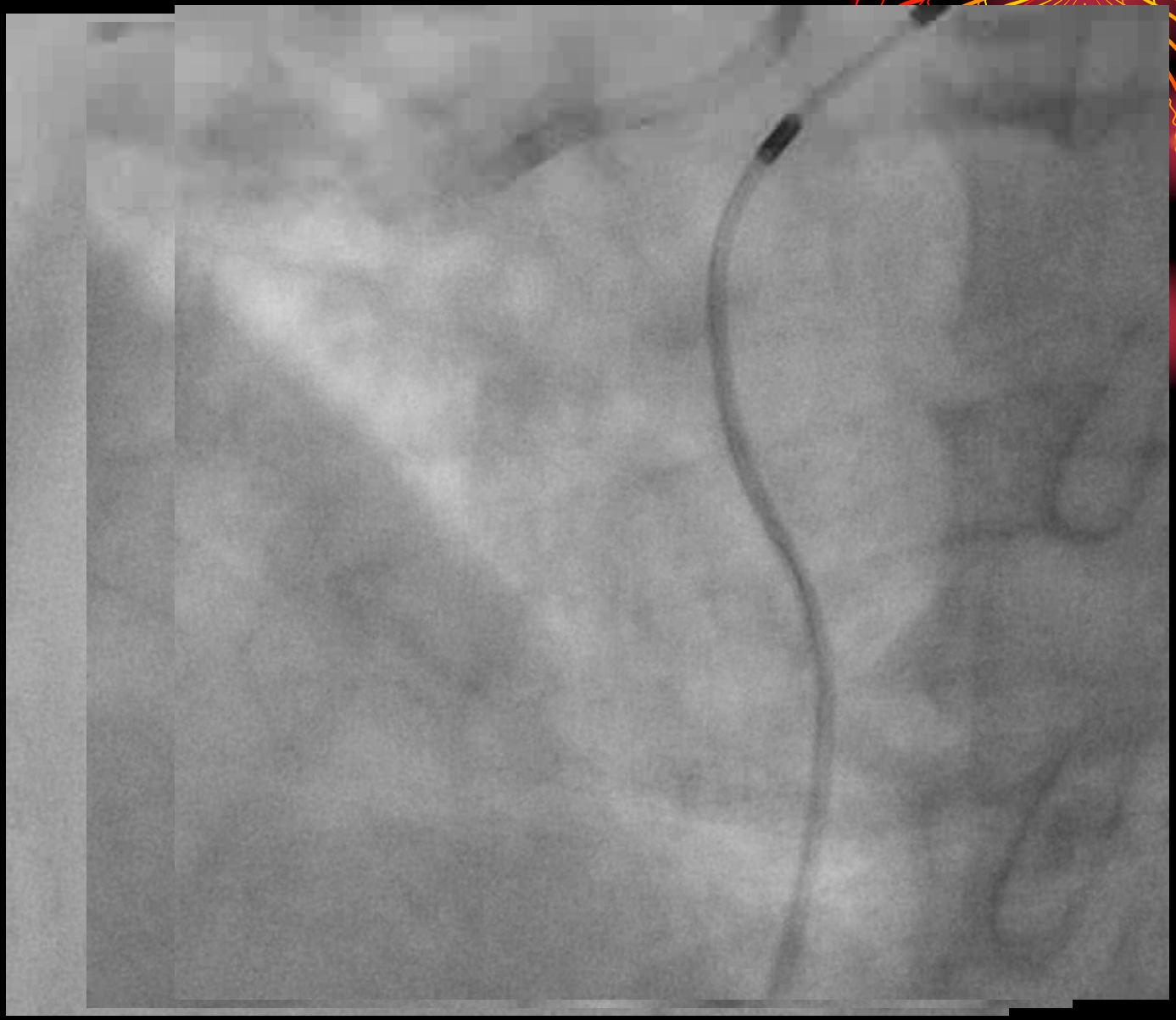
Distal protection for ACS

Toshiya Muramatsu

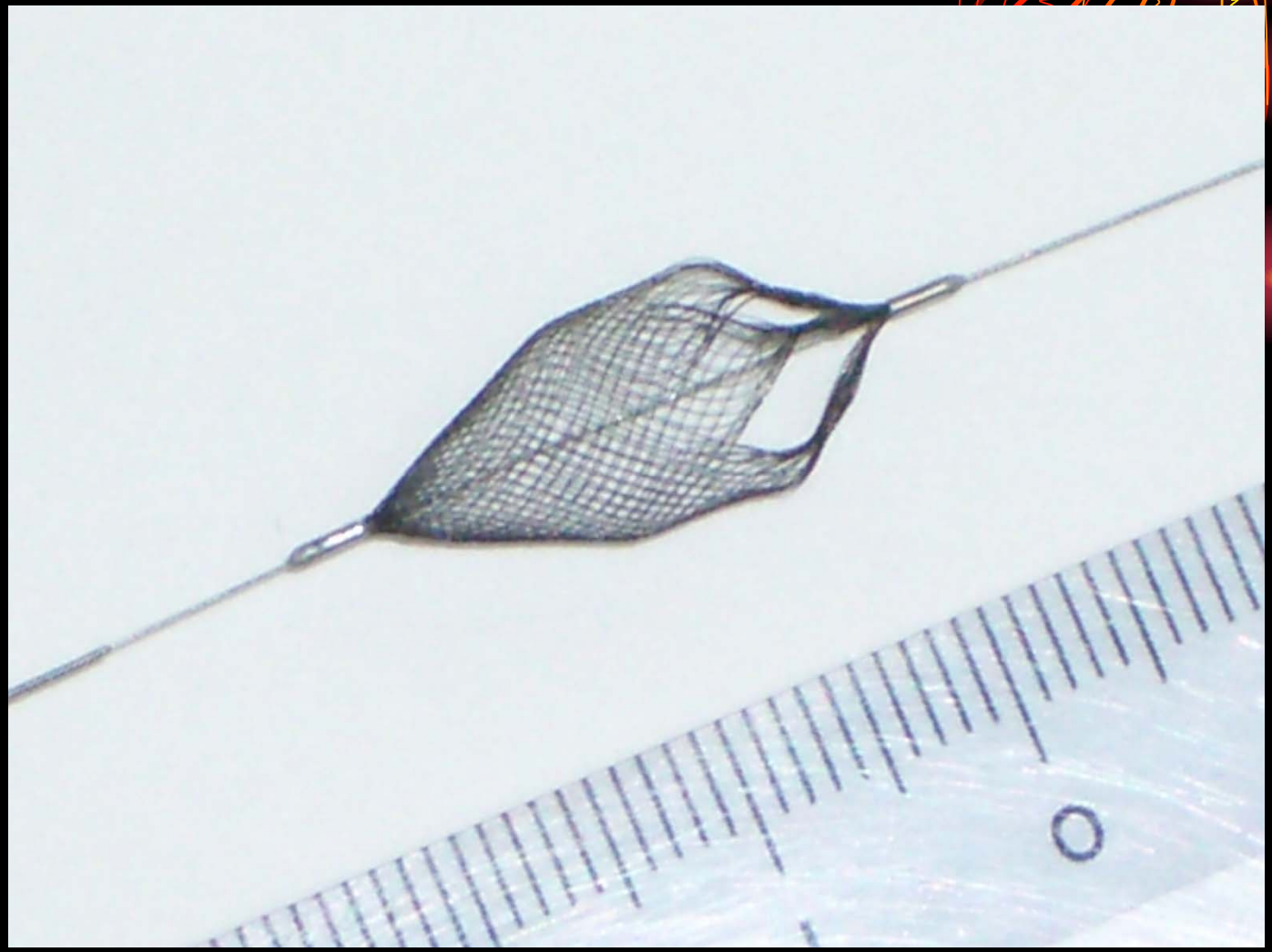
Saiseikai Yokohama-city
Eastern Hospital

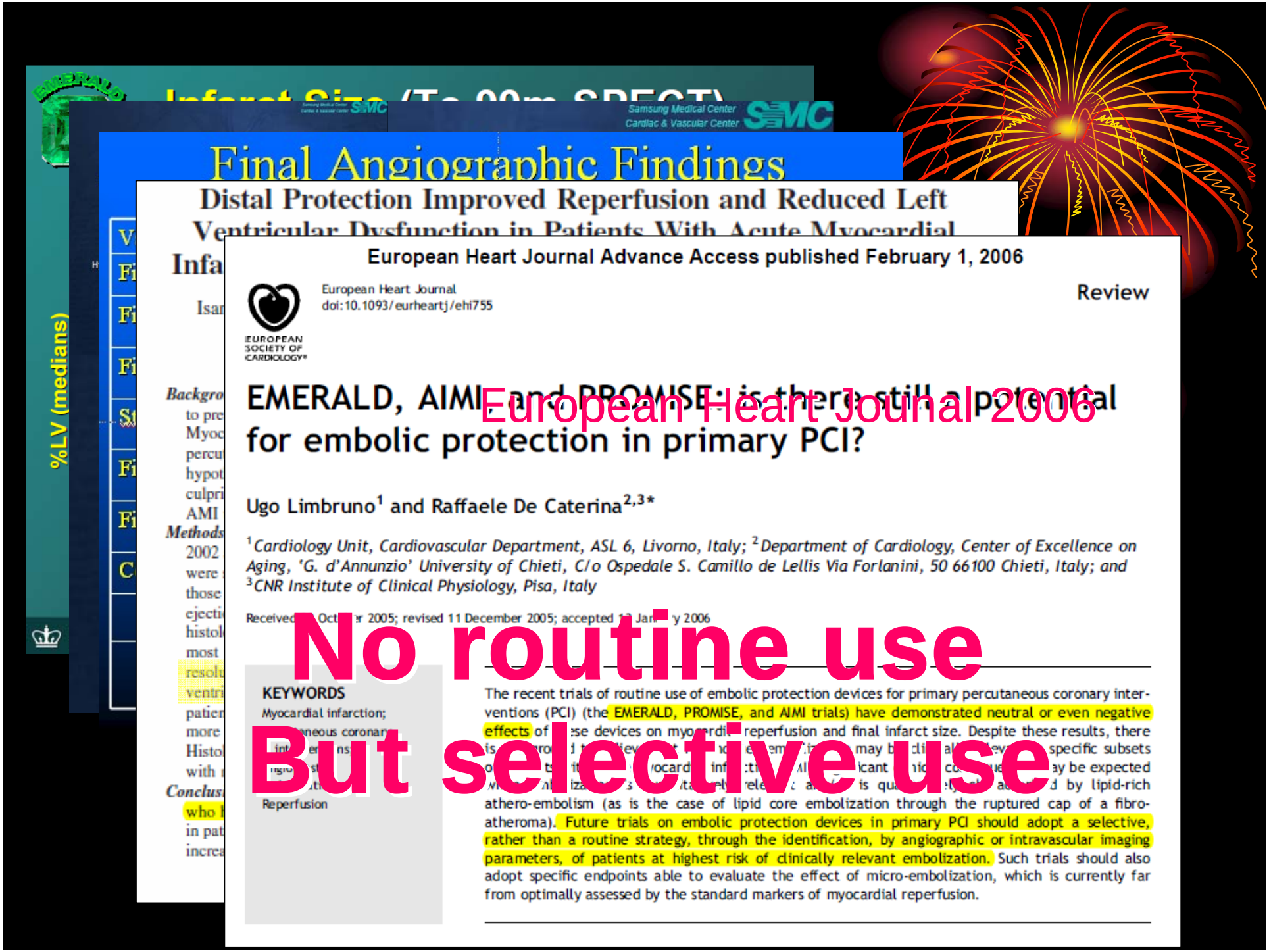
Slow flow after stent

Stenting with filter



Parachute Wire




%LV (medians)
Samsung Medical Center
Cardiac & Vascular Center
Final Angiographic Findings
Distal Protection Improved Reperfusion and Reduced Left
European Heart Journal Advance Access published February 1, 2006
European Heart Journal
doi:10.1093/eurheartj/ehi755
EUROPEAN SOCIETY OF CARDIOLOGY
Review
EMERALD, AIMI and PROMISE: is there still a potential for embolic protection in primary PCI?
European Heart Journal 2006
Ugo Limbruno[1] and Raffaele De Caterina[2,3]*
[1]Cardiology Unit, Cardiovascular Department, ASL 6, Livorno, Italy; [2]Department of Cardiology, Center of Excellence on Aging, 'G. d'Annunzio' University of Chieti, C/o Ospedale S. Camillo de Lellis Via Forlanini, 50 66100 Chieti, Italy; and [3]CNR Institute of Clinical Physiology, Pisa, Italy
KEYWORDS
Myocardial infarction;
Reperfusion
The recent trials of routine use of embolic protection devices for primary percutaneous coronary interventions (PCI) (the EMERALD, PROMISE, and AIMI trials) have demonstrated neutral or even negative effects of
adopt a selective, rather than a routine strategy, through the identification, by angiographic or intravascular imaging parameters, of patients at highest risk of clinically relevant embolization. Such trials should also adopt specific endpoints able to evaluate the effect of micro-embolization, which is currently far from optimally assessed by the standard markers of myocardial reperfusion.
No routine use
But selective use

Catheterization and Cardiovascular Interventions 70:677–682 (2007)

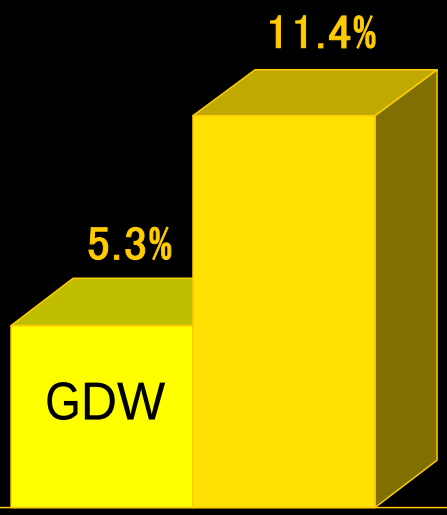
ASPARAGUS

Comparison of Myocardial Perfusion by Distal Protection Before and After Primary Stenting for Acute Myocardial Infarction: Angiographic and Clinical Results of a Randomized Controlled Trial

Toshiya Muramatsu,[1*] MD, Ken Kozuma,[2] MD, Reiko Tsukahara,[1] MD, Yoshiaki Ito,[1] MD, Naoya Fujita,[3] MD, Satoru Suwa,[4] MD, Shiho Koyama,[5] MD, Masahiko Saitoh,[6] MD, Haruo Kamiya,[7] MD, and Masato Nakamura,[8] MD, for the ASPARAGUS Trial Investigators

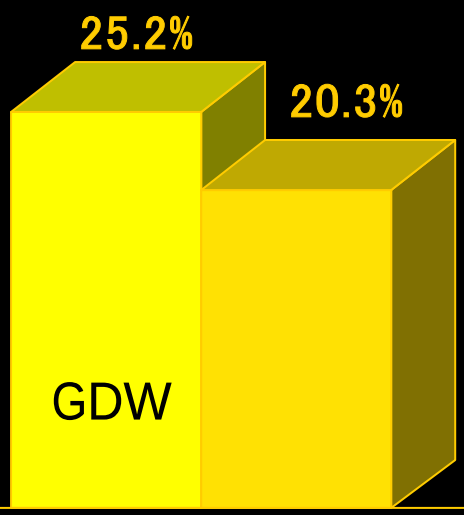
Slow flow & No reflow

P=0.05



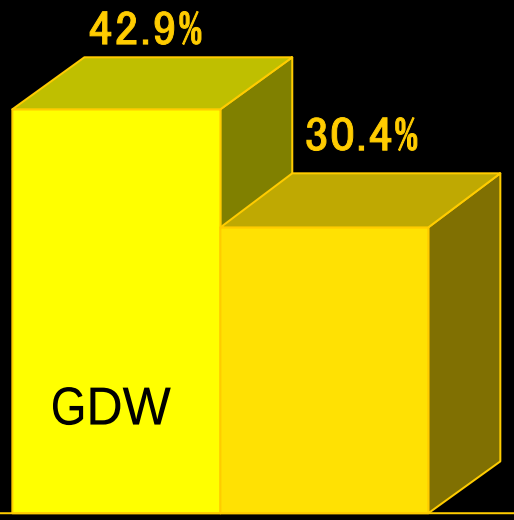
Postprocedural MBG3

P=0.26



30-day MBG3

P=0.035



Adjunctive mechanical devices to prevent distal embolization in patients undergoing mechanical revascularization for acute myocardial infarction: A meta-analysis of randomized trials

Giuseppe De Luca, MD,[a,f] Harry Suryapranata, MD,[b] Gregg W. Stone, MD,[c] David Antoniucci, MD,[d] Franz-Joseph Neumann, MD,[e] and Massimo Chiariello, MD[a] *Novara, Naples, and Florence, Italy; Zwolle, The Netherlands; New York, NY; and Bad Krozingen, Germany*

Background The benefits of adjunctive mechanical devices to prevent distal embolization in patients with acute myocardial infarction (AMI) are still a matter of debate. The aim of this meta-analysis was to combine data from all randomized trials conducted with adjunctive mechanical devices to prevent distal embolization in AMI.

Methods The literature was scanned by formal searches of electronic databases (MEDLINE and Central) from January 1990 to October 2006, scientific session abstracts (from January 1990 to October 2006), and oral presentation and/or expert slide presentations (from January 2002 to October 2006) (on the Transcatheter Cardiovascular Therapeutics, American Heart Association, European Society of Cardiology, American College of Cardiology, and European Percutaneous Revascularization Web sites). We examined all randomized trials on adjunctive mechanical devices to prevent distal embolization in AMI. The following key words were used: randomized trial, myocardial infarction reperfusion, primary angioplasty, rescue angioplasty, thrombectomy, thrombus aspiration, proximal or distal protection device, X-sizer, Diver, Export Catheter, Angiojet, Rescue catheter, Pronto catheter, PercuSurge, GuardWire, FilterWire, and SpideRX. Disagreements were resolved by consensus.

Results A total of 21 trials with 3721 patients were included (1877 patients [50.4%] in the adjunctive mechanical device group and 1844 [49.6%] in the control group); 1502 patients (40.3%) were randomized in trials with distal protection devices, and 2219 patients (59.7%) were randomized in trials with thrombectomy devices. Adjunctive mechanical devices were associated with a higher rate of postprocedural TIMI 3 flow (89.4% vs 87.1%, $P = .03$), a significantly higher rate of postprocedural myocardial blush grade 3 (48.8% vs 36.5%, $P < .0001$), and less distal embolization (6.0% vs 9.3%, $P = .008$), without any benefit in terms of 30-day mortality (2.5% vs 2.6%, $P = .88$). No difference was observed in terms of coronary perforations (0.27% vs 0.07%, $P = .24$).

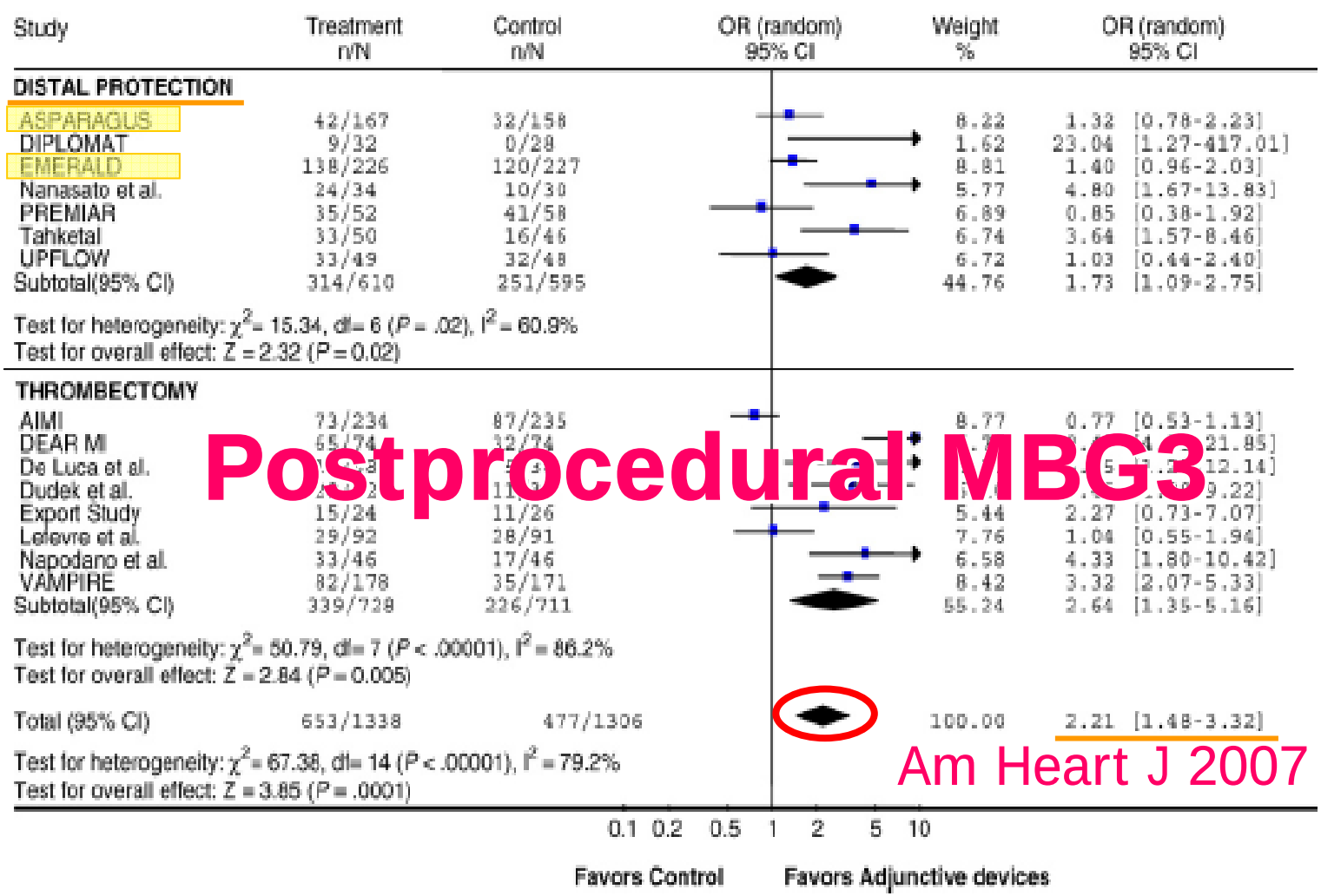
Conclusions This meta-analysis demonstrates that, among patients with AMI treated with percutaneous coronary intervention, the use of adjunctive mechanical devices to prevent distal embolization is associated with better myocardial perfusion and less distal embolization, but without an apparent improvement in survival. (Am Heart J 2007;153:343-53.)

Protection/Thrombectomy

21 randomized trials

Meta–analysis

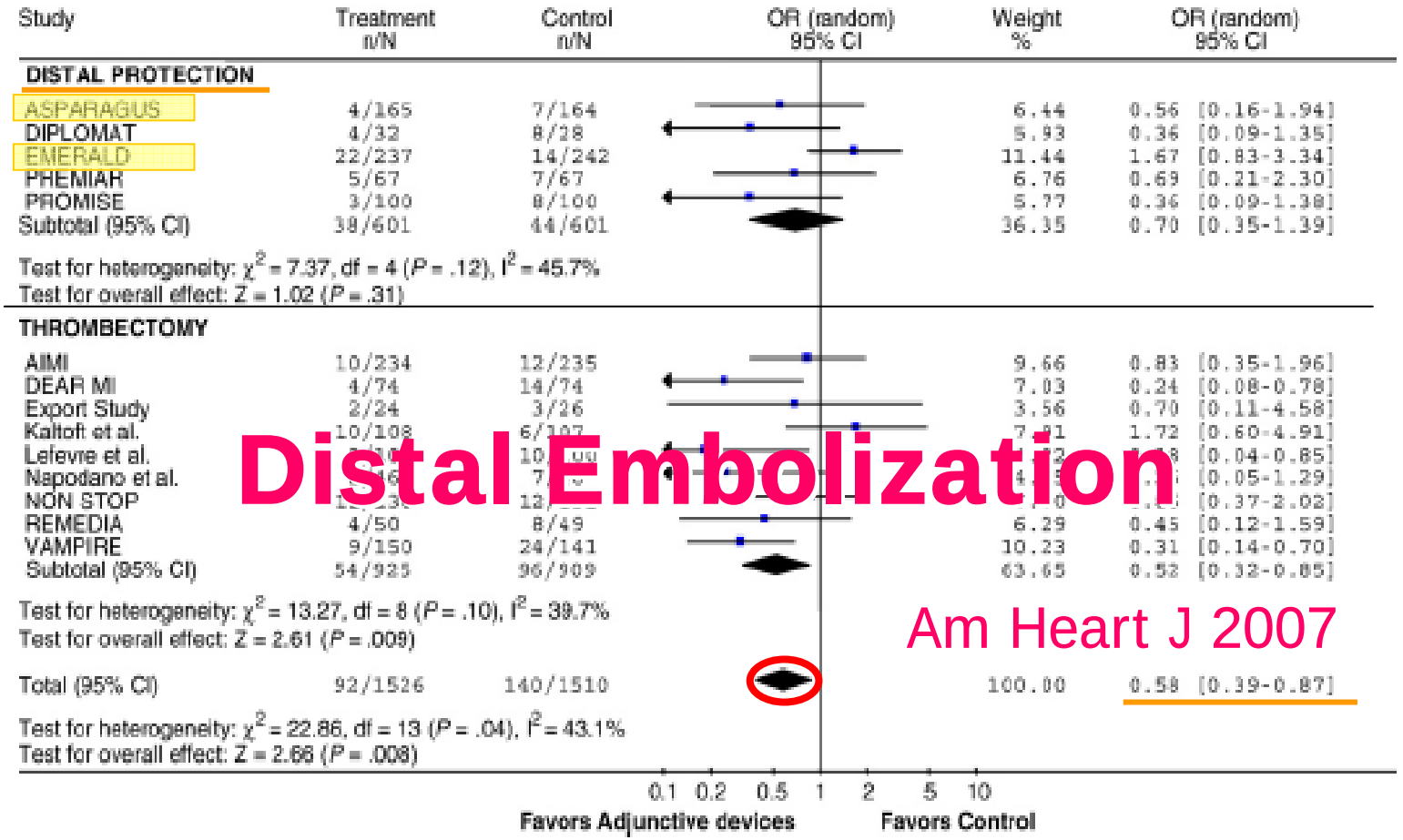
Am Heart J 2007



Postprocedural MBG3

Am Heart J 2007

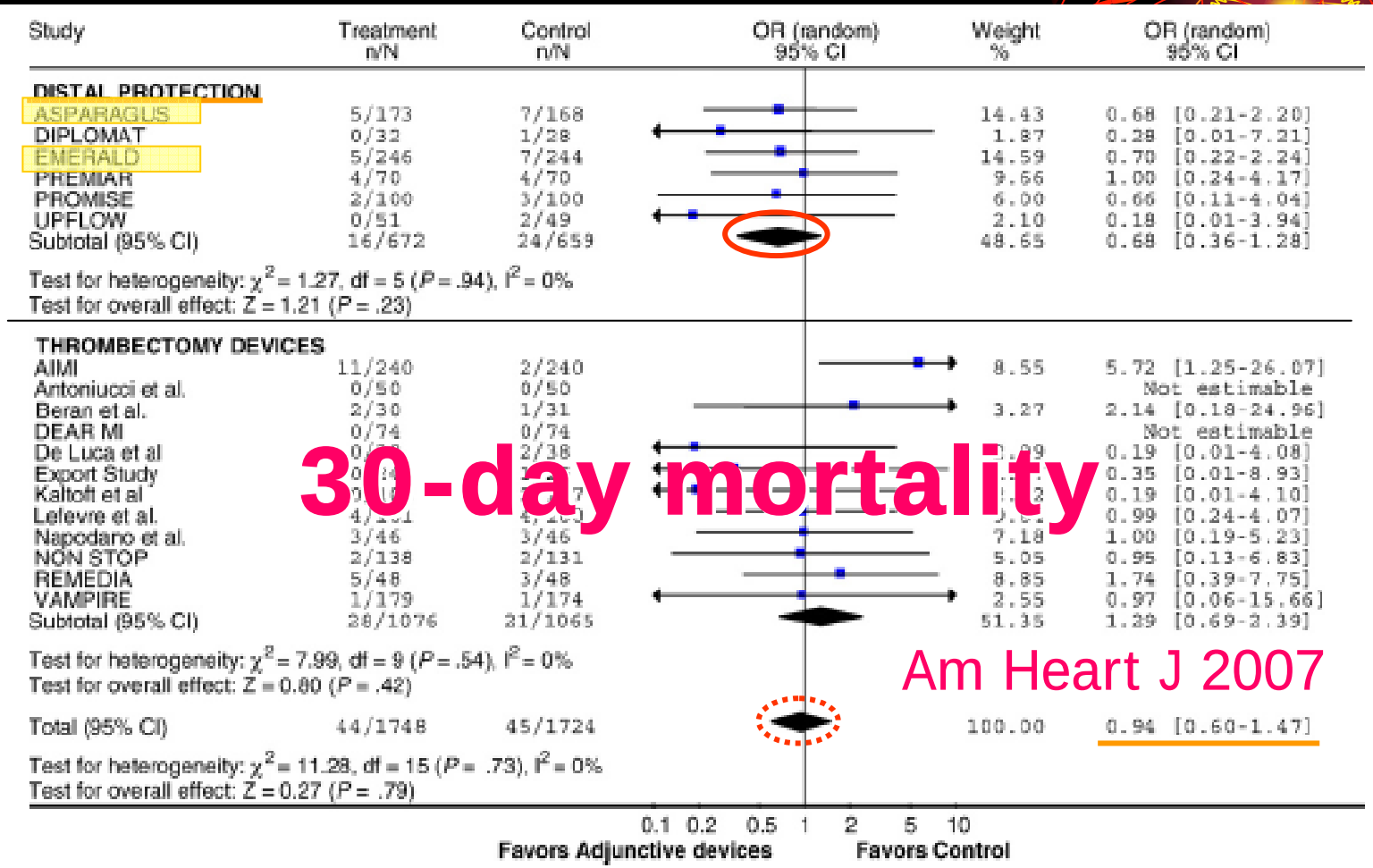
Adjunctive mechanical devices and postprocedural MBG 3, with ORs and 95% CIs. The size of the data markers (squares) is approximately proportional to the statistical weight of each trial.



Distal Embolization

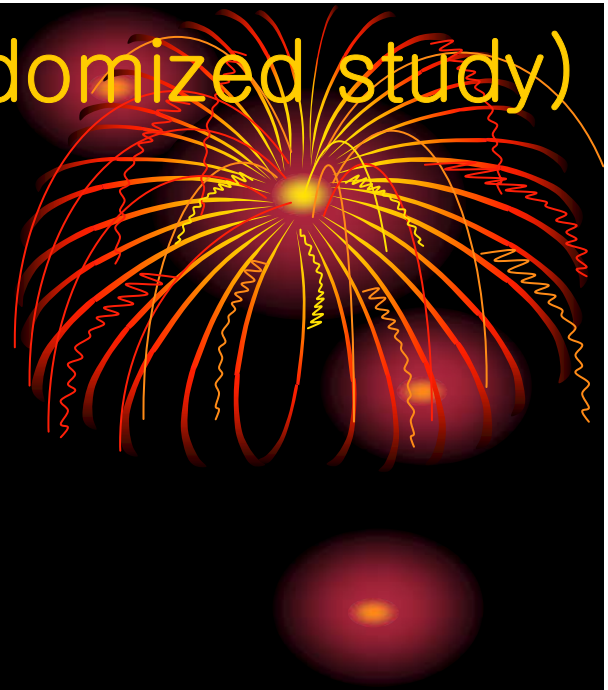
Am Heart J 2007

Adjunctive mechanical devices and distal embolization, with ORs and 95% CIs. The size of the data markers (squares) is approximately proportional to the statistical weight of each trial.



Adjunctive mechanical devices and 30-day mortality, with ORs and 95% CIs. The size of the data markers (squares) is approximately proportional to the statistical weight of each trial.

Summary of Total 21 trials (randomized study)



3721 patients
1877 [50.4%] ; Adjunctive mechanical device group
1844 [49.6%] ; Control group

1502 (40.3%) ; Distal protection devices
2219 (59.7%) ; Thrombectomy devices.

Adjunctive mechanical devices;

Higher rate of postprocedural **TIMI 3 flow** (89.4% vs. 87.1%, P = .03)

Higher rate of postprocedural **myocardial blush grade 3**
(48.8% vs. 36.5%, P < .0001)

Less **distal embolization** (6.0% vs. 9.3%,P = .008)

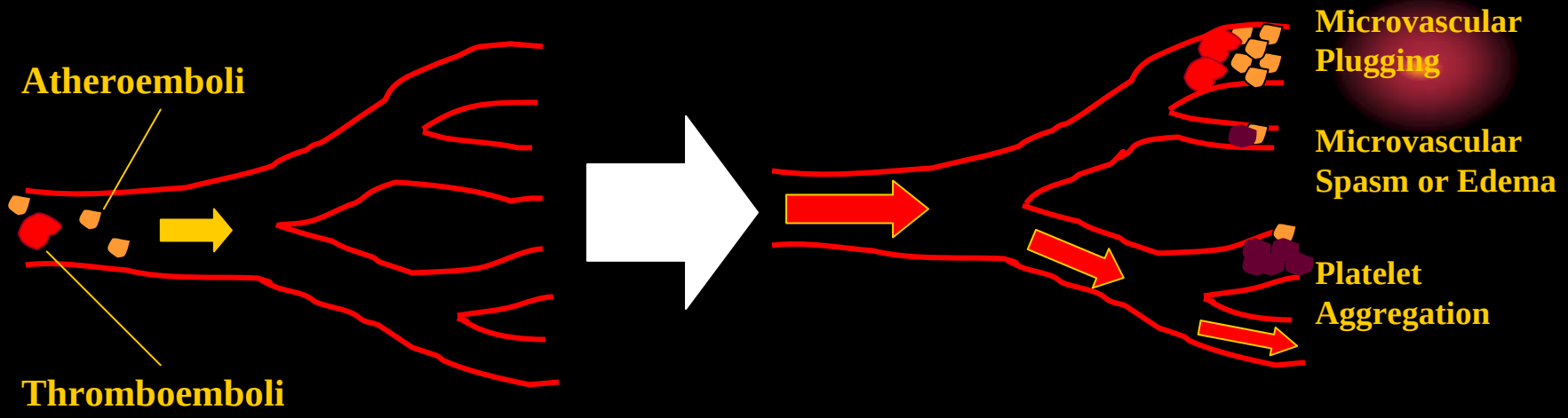
No benefit in terms of **30-day mortality** (2.5% vs. 2.6%, P = .88)

No difference in terms of **coronary perforations** (0.27% vs. 0.07%, P = .24).

Microvascular Obstruction

Pathophysiology

Hori M, et.al. *Am J Physiol* 1986; 250:H509-18.



Epicardial flow is maintained or even enhanced due to an adenosine-related hyperemia of the myocardium surrounding the embolized microregions, with blood shunting around the areas of obstruction

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.

	Aspiration	No Aspiration	Odds	P
N	50	50		
MBG≧2	66%	48.9%	2.6	0.02
STR≧70%	58%	36.7%	2.4	0.034
Opitmal reperfusion	46%	24.5%	2.6	0.025

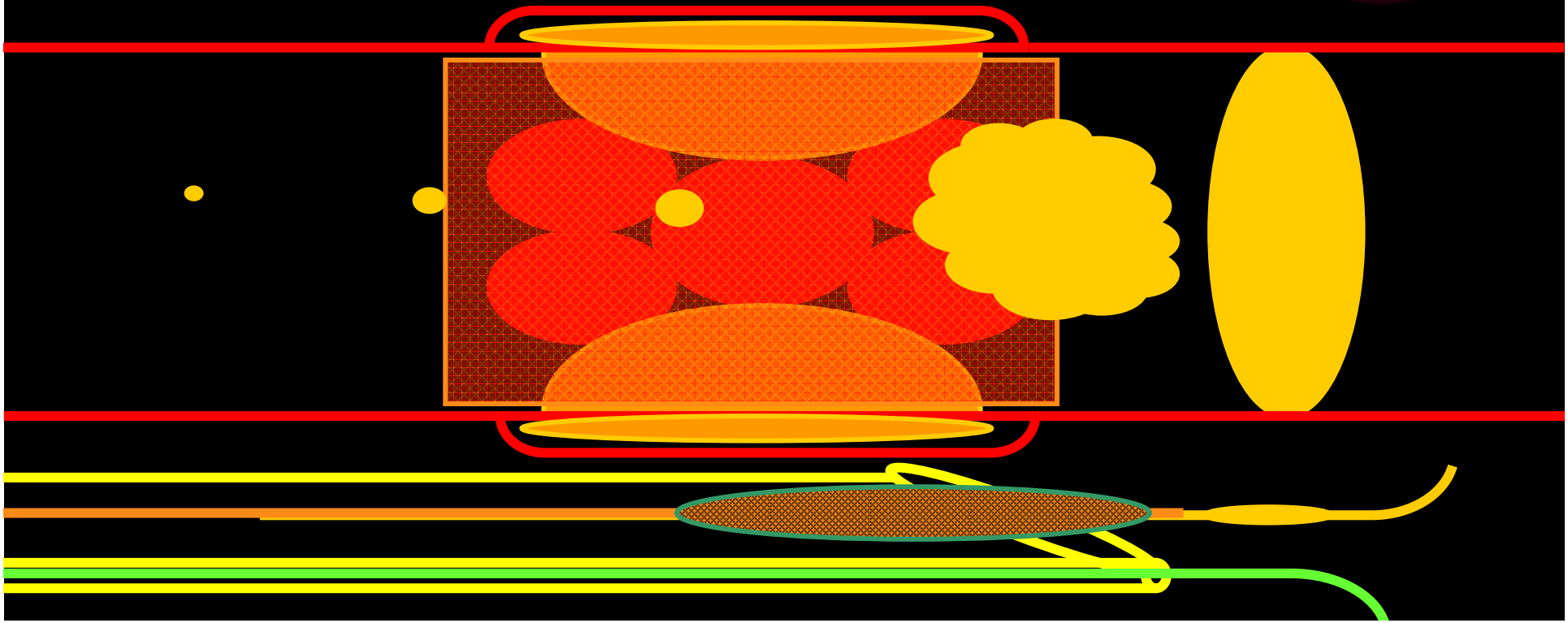
Multivariate analysis :
Thrombus aspiration was a significant independent predictor of achievement of MBG > or =2 and STR > or =70% (p = 0.013).

Burzotta F; J Am Coll Cardiol. 2005 Jul 19;46(2):371-6,

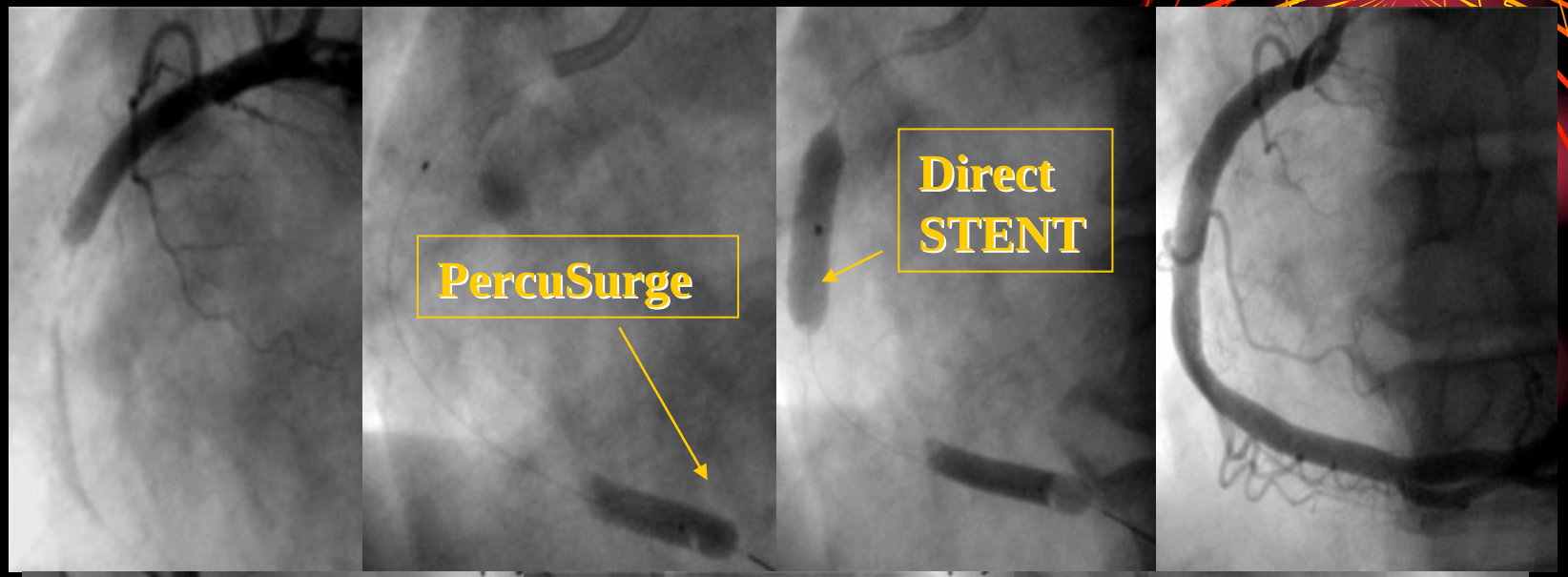
Direct stent with distal Protection in Rebirth

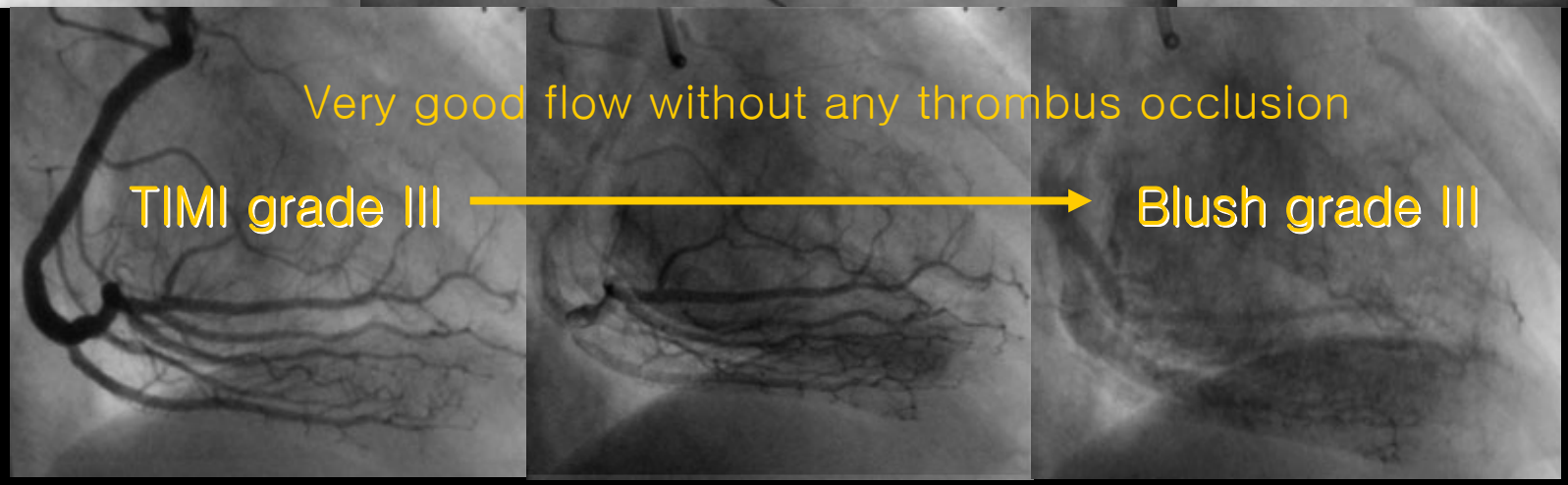
Duraflex　4.0×25mm（Crossing　profile　0.044inch≒1.12mm）

Rebirth　Distal　Shaft



Evaluation of myocardial perfusion Blush grade

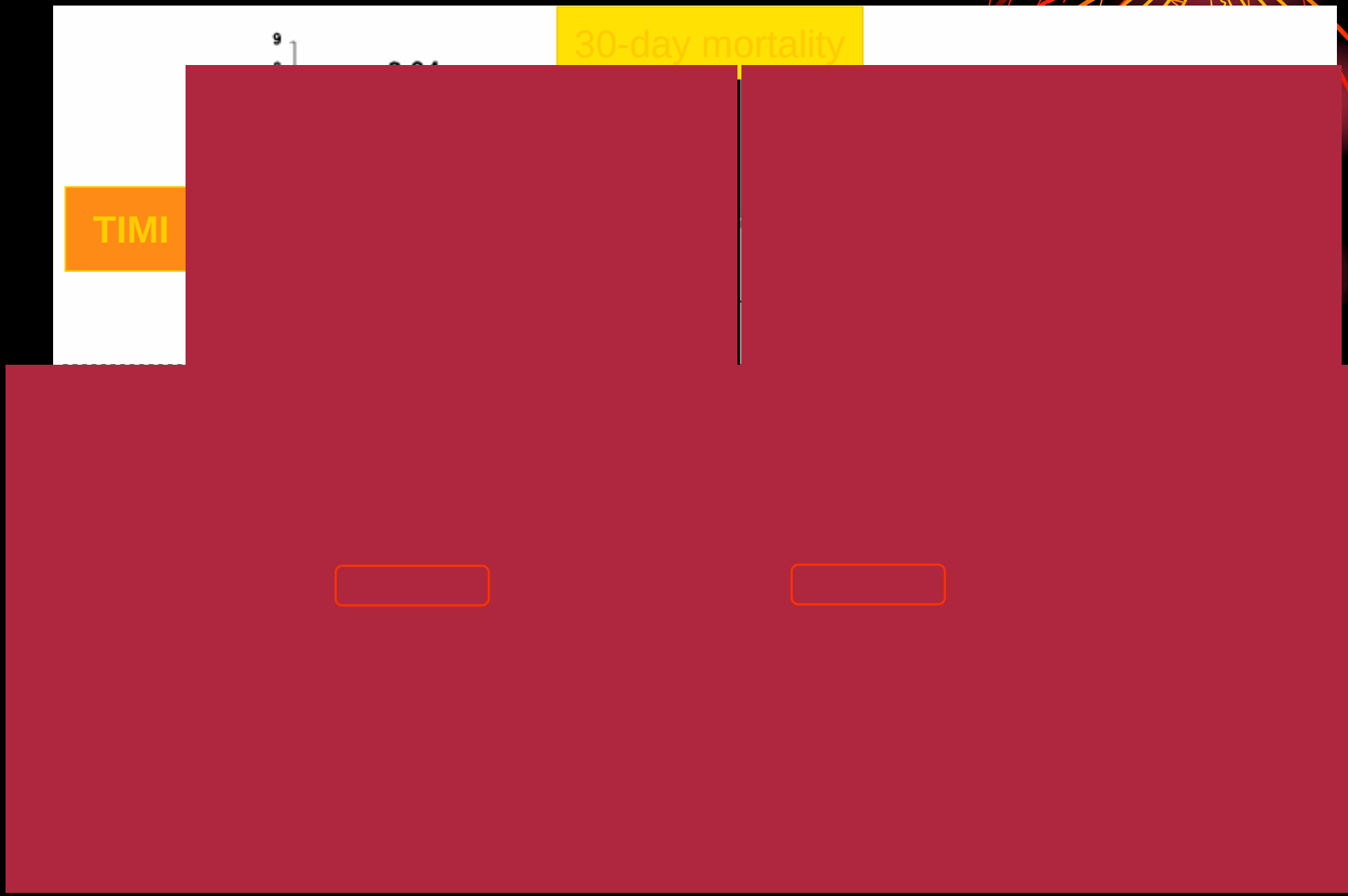




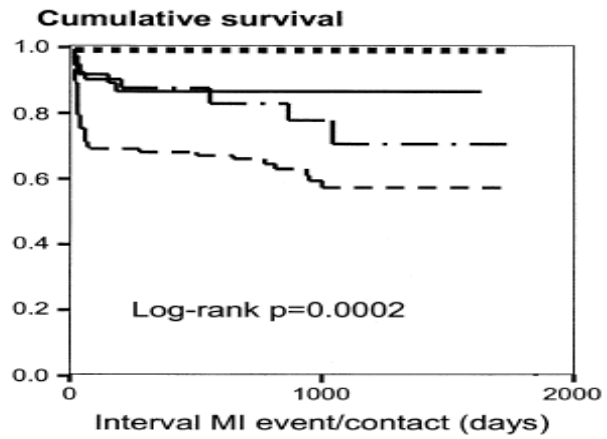
Very good flow without any thrombus occlusion

TIMI grade III → Blush grade III

Blush grade and Prognosis



Gibson et al. Circulation 2000;101;125-130



MBG 3 + persistent ST elevation in ≤2 ECG leads
MBG 0-2 + persistent ST elevation in ≤2 ECG leads
MBG 3 + persistent ST elevation in >2 ECG leads
MBG 0-2 + persistent ST elevation in >2 ECG leads

Table 1. Baseline Clinical and Angiographic Characteristics

	Dead (n = 62)	Alive (n = 191)	p
Age (yrs)	63.6 ± 10.8	58.3 ± 11.7	0.002
Chest pain to hospital (h)	4.8 ± 5.7	3.8 ± 4.5	0.336
Door to needle time (h)	2.0 ± 2.2	1.9 ± 2.0	0.892
Female	17 (27%)	31 (16%)	0.082
Cardiogenic shock	11 (18%)	23 (12%)	0.171
Heart rate before PTCA (beats/min)	90.7 ± 26.5	73.3 ± 16.4	< 0.001
Patient referral	24 (39%)	50 (26%)	0.063
No. of diseased vessels	2.1 ± 0.8	1.7 ± 0.7	0.002
Peak creatine kinase (U/l)	1,492 ± 1,713	914 ± 1,166	0.004
Abciximab	30 (48%)	92 (48%)	1.000
IABP	25 (41%)	11 (6%)	< 0.001
Stent	42 (68%)	151 (79%)	0.058
Target vessel: left anterior descending	24 (39%)	80 (42%)	0.626
Baseline TIMI flow 3	7 (11%)	67 (35%)	< 0.001
Previous myocardial infarction	22 (36%)	67 (35%)	1.000
Left bundle branch block	14 (23%)	11 (6%)	< 0.001
Markers of reperfusion			
Postprocedure TIMI flow 3	50 (80%)	173 (91%)	0.064
MBG 0/1	39 (63%)	61 (32%)	< 0.001
MBG 2	14 (23%)	60 (31%)	0.206
MBG 3	9 (14%)	70 (37%)	0.004
CTFC (frames)	42.6 ± 32.2	32.8 ± 23.9	0.012
ECG leads with ST-segment elevation post PTCA	4.42 ± 1.87	3.20 ± 2.22	0.001

CTFC = corrected TIMI frame count; IABP = intraaortic balloon pump; MBG = myocardial blush grade; PTCA = percutaneous transluminal coronary angioplasty; TIMI = Thrombolysis In Myocardial Infarction

Haager et al.
JACC 2003;41;532-538

Trials in native coronary artery ST–elavated MI

Trial and Treatment	Inclusion Criteria	No.	Primary End Point(s)	Results (Experimental vs Control)	*P*
EMERALD					
GuardWire Plus	ST-elevation myocardial infarction	252	Complete ST-segment resolution at 30 minutes	63.3% vs 61.9%	0.78
Conventional guidewire		249	Infarct size (median)	12.0% vs 9.5%	0.34
PROMISE					
FilterWire EX	ST- or non–ST-elevation myocardial infarction or visible thrombus	100	Maximum adenosine-induced flow velocity	34±17 vs 36±20 cm/s	0.46
Conventional guidewire		100			
ASPARAGUS					
GuardWire Plus	ST-elevation myocardial infarction	165	TIMI grade 3 flow	77% vs 78%	0.73
Conventional guidewire		164			

The reason of discrepancy in outcome?

The reason of negative data

- The timing of intervention: after much of the injury had taken place?
- The Difficulty of measuring benefits: background of large infarction?
- Other reason of injury: reperfusion injury, edema?
- Smaller amount of debris ?
- Selection bias

Myocardial blush grade data in AMI

Author Journal	Van't Hof et al Circulation 1998 (97: 2302-2306)	Gibson et al Circulation 2000 (101: 125-130)	Stone et al JACC 2002 (39: 591-597)	Hagger et al JACC 2003 (41: 532-538)	Henrique et al Circulation 2003 (107: 2115-2119)
No. of Pts.	777	762	173	253	924
Strategy	PCI	Thrombolysis	PCI	PCI	PCI
Blush Grade 0-1	**30%**	**71%**	**30%**	**40%**	**11%**

Henrique et al, Circulation 2003 ; 107: 2115-2119

The CARROT Registry

ClinicAl Result of Registry fOr PaTients with Unstable Plaque

All unstable plaque cases in angiography
STEMI, Non-STEMI, Recent MI, UAP, SVG

↓

Consecutive enrolled ← **·PCI**
·Aspiration
·Aspiration + PCI
·Aspiration + Protection + PCI

↓

TIMI, Blush, QCA, ECG, Complications

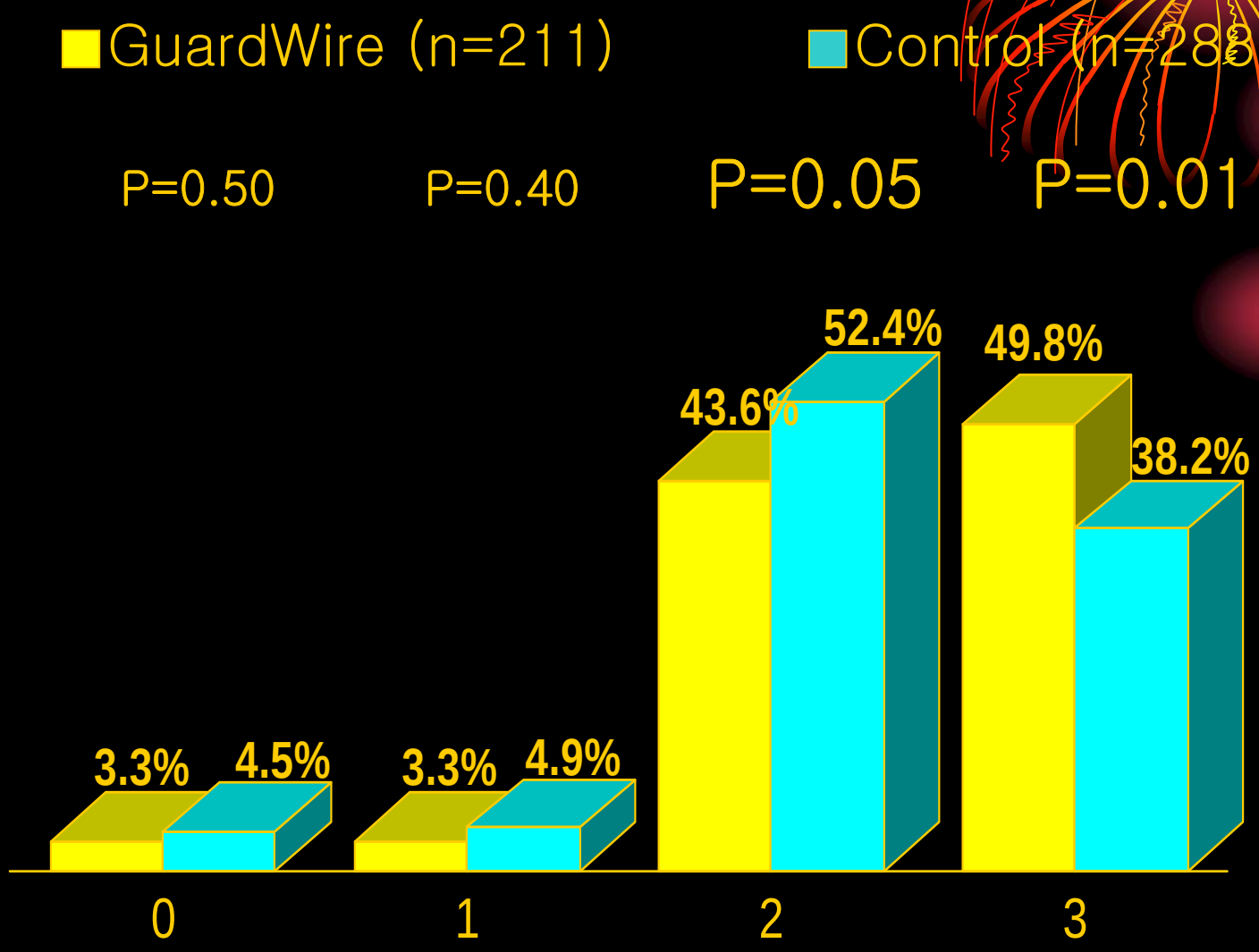
↓

6Mo FU: TIMI, Blush, MACE

↓

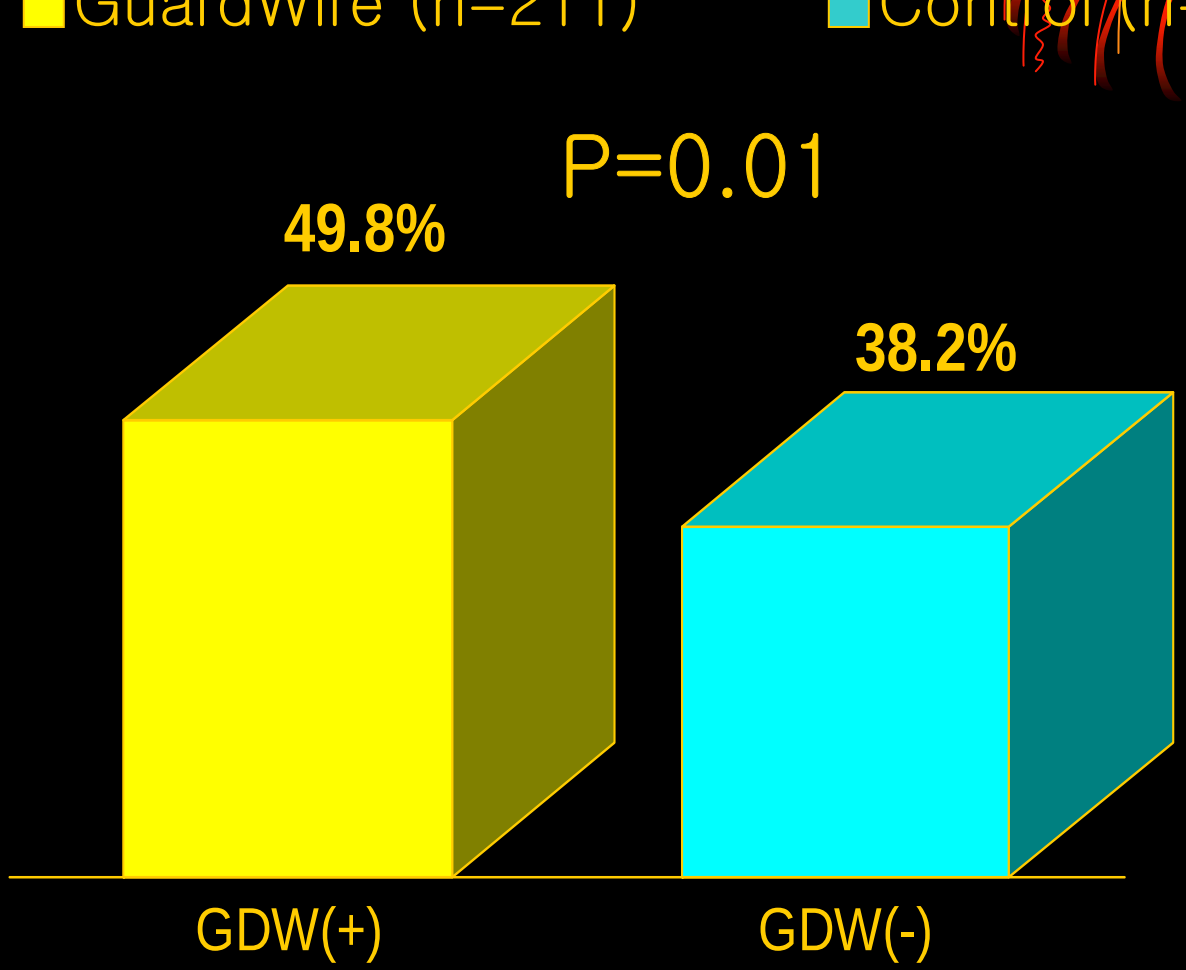
3 years FU: MACE

Final Myocardial Blush (Overall)

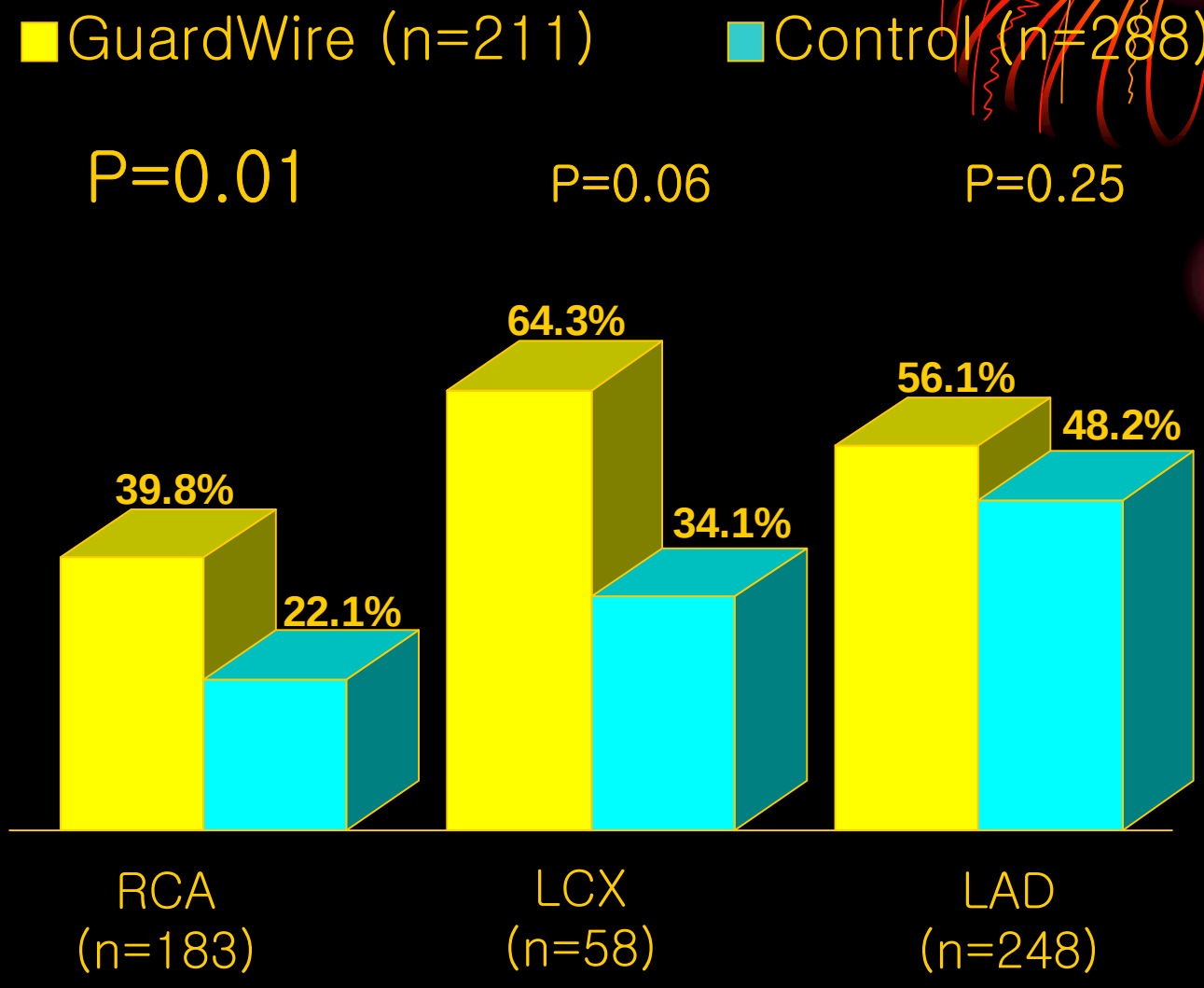


Final Myocardial Blush 3 (Overall)

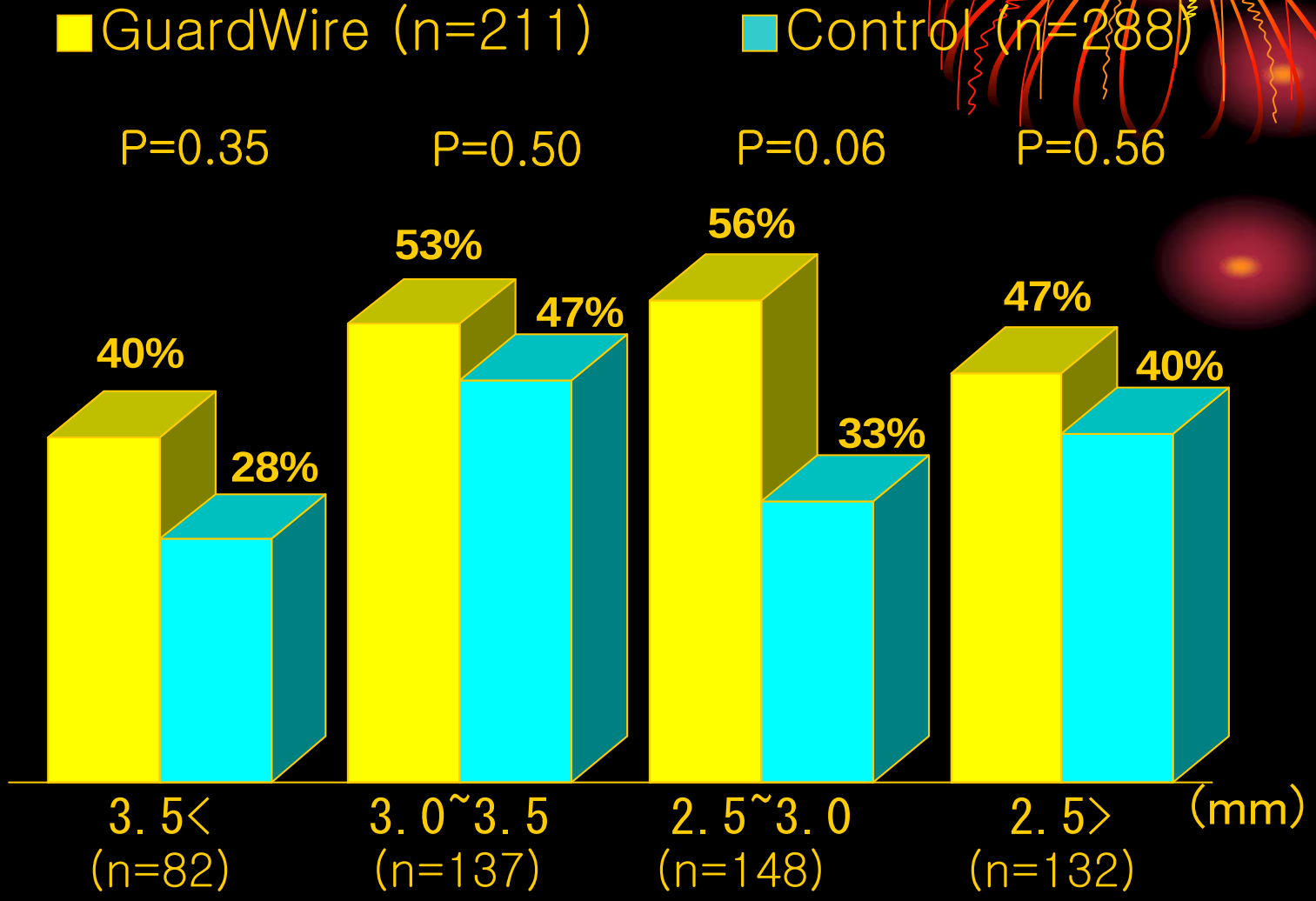
Distal protection



Final Myocardial Blush 3 (Overall)
Target Vessels



Final Myocardial Blush 3 (Overall)
Vessel Diameter

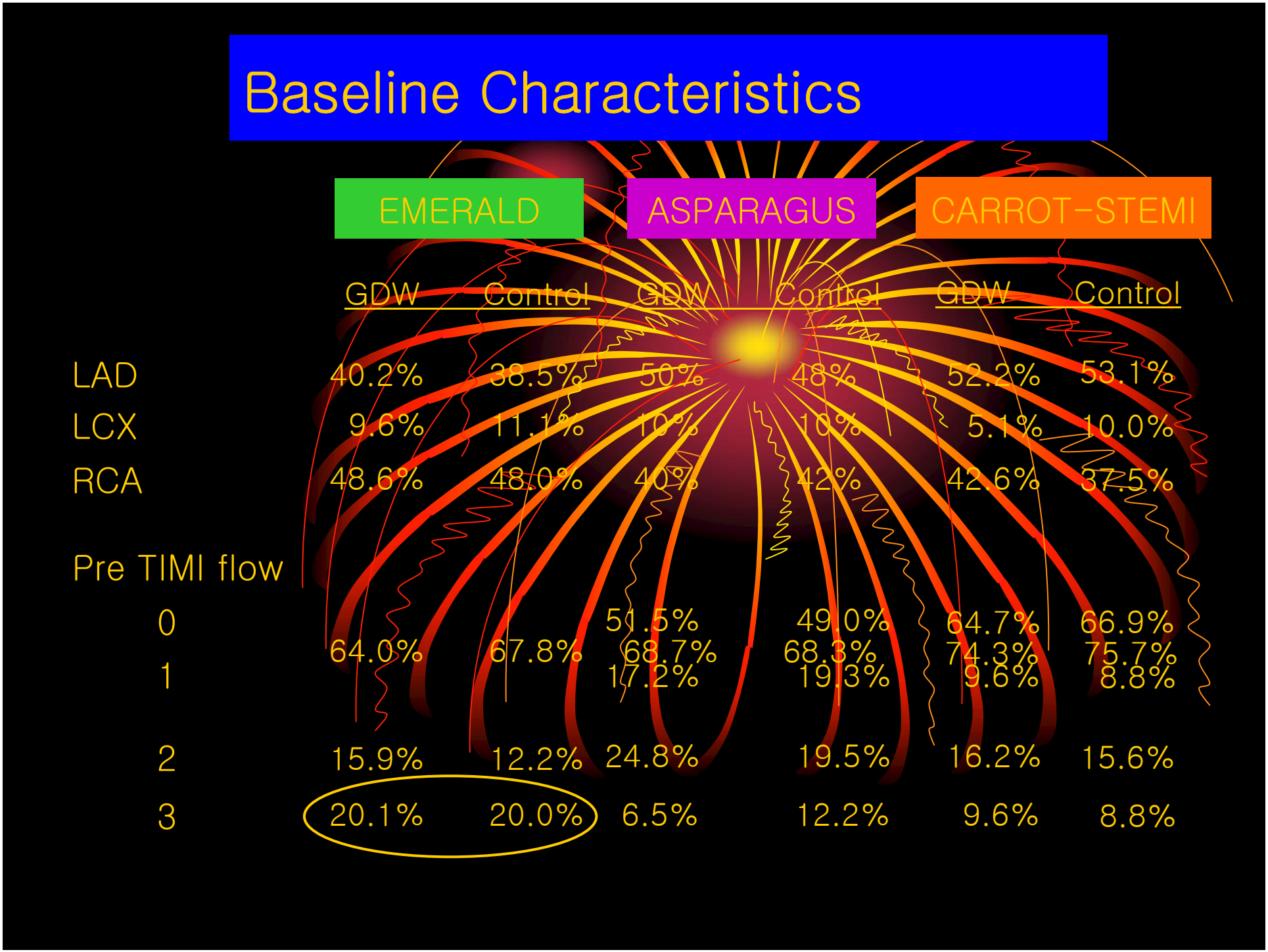



ST Elevation MI

Baseline Characteristics 1-1

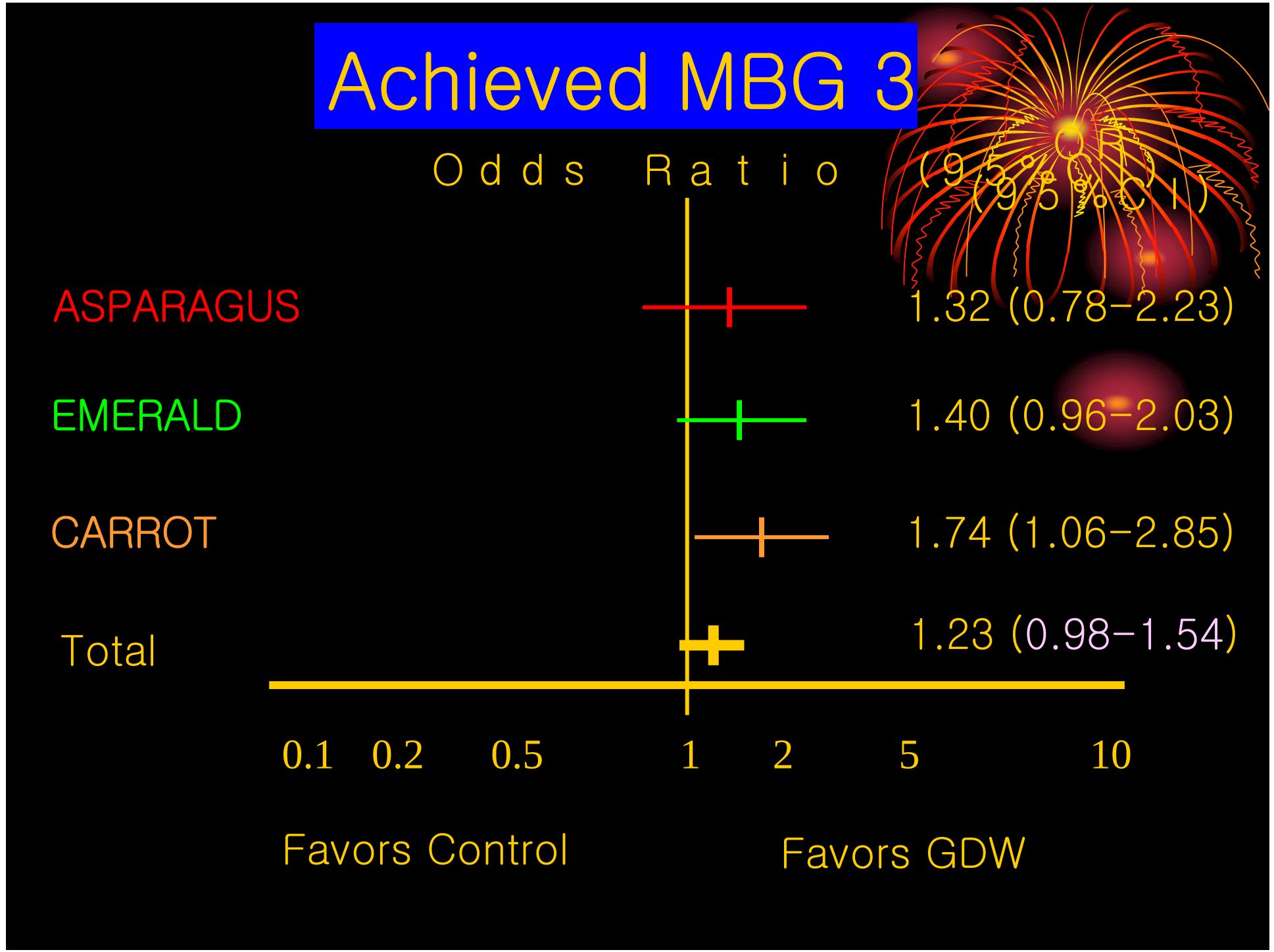
	EMERALD		ASPARAGUS		CARROT-STEMI	
	GDW	Control	GDW	Control	GDW	Control
N	211	288	165	164	136	160
Age (yrs)	58.5	59.8	63.5	64.7	63.9	67.2
Male	76.2%	80.7%	78.6%	72.9%	79.4%	72.5%
Hypertension	35.9%	38.2%	42.2%	44.1%	52.4%	47.6%
Hypercholest.	20.2%	28.5%	32.9%	32.9%	51.1%	48.9%
Smoker	40.5%	44.6%	51.4%	49.4%	51.9%	48.1%
Diabetes	7.5%	17.3%	31.8%	32.3%	40.9%	31.9%
Prior MI	9.5%	12.4%	1.7%	2.9%		
Killip class ≧2	11.7%	13.1%	2.3%	0.0%	7.5%	18.9%

Baseline Characteristics



	EMERALD		ASPARAGUS		CARROT-STEMI	
	GDW	Control	GDW	Control	GDW	Control
LAD	40.2%	38.5%	50%	48%	52.2%	53.1%
LCX	9.6%	11.1%	10%	10%	5.1%	10.0%
RCA	48.6%	48.0%	40%	42%	42.6%	37.5%
Pre TIMI flow						
0	64.0%	67.8%	51.5%	49.0%	64.7%	66.9%
1			17.2%	19.3%	9.6%	8.8%
2	15.9%	12.2%	24.8%	19.5%	16.2%	15.6%
3	20.1%	20.0%	6.5%	12.2%	9.6%	8.8%

Achieved MBG 3



Difference between EMERALD and ASPARAGAS

	EMERALD	ASPARAGAS
N	500	300
Use of GP IIb/IIIainhibitor	+	−
Use of thrombectomy	−	+
Serial angio FU	−	+
Frequency of slow flow	negative	positive
Frequency of distal emboli.	negative	positive
TIMI score	negative	negative
Blush score	negative	negative
Blush score in Prox. RCA	unknown	positive
Blush score in 1 mon. FU	unknown	positive
ST resolution	negative	negative
Infarct size	negative	negative
MACE	negative	negative

What is useful cases for Distal Protection?

Clinical

1. Early onset Acute MI
2. Shock case

Lesion Morphology

1. Non calcified, non tortous vessel
2. Proximal RCA
3. Large LAD (without major SB)
4. Big thromus case
5. Rupture plaque
6. Large plaque area by IVUS
7. Large vessel area by IVUS(>16mm^2)