The Japanese

ASPARAGUS Trial

*ASP*ir*A*tion of Libe*R*ated Debris in *A*cute MI

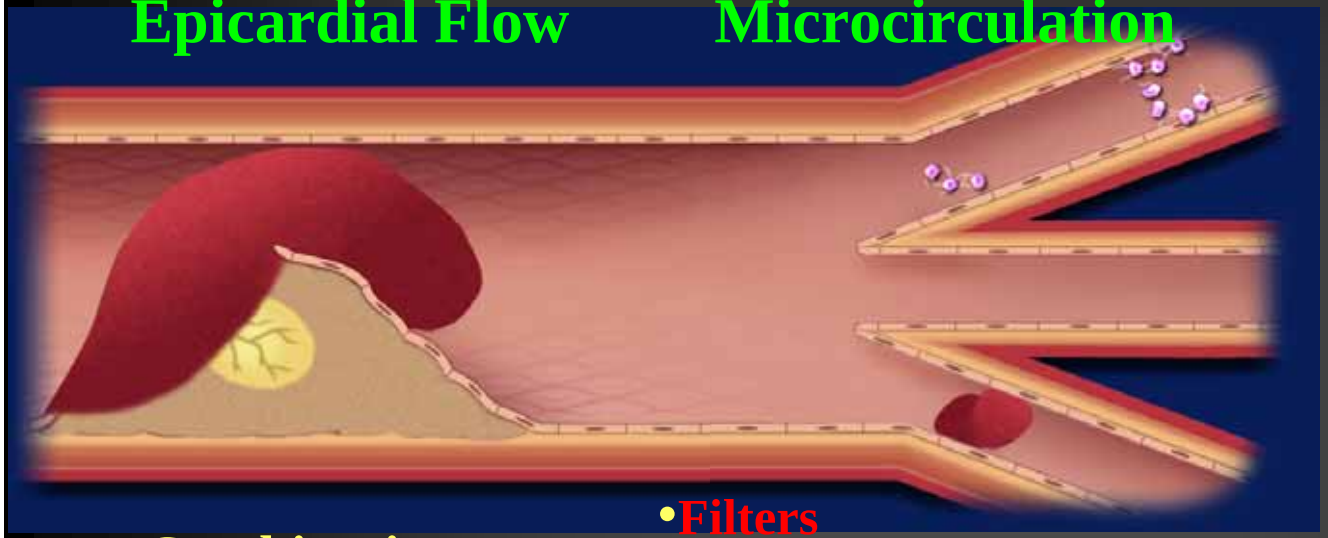
with *GU*ardWire Plus ™ *S*ystem

Toshiya Muramatsu, MD

Kawasaki social Insurance Hospital, Kawasaki, Japan

Reperfusion of the IRA to the Myocardium
Therapeutic Targets and Agents

Epicardial Flow

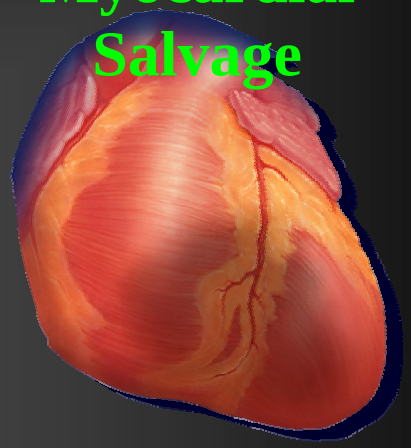


- Combination pharmacotherapy
- PTCA/Stents
- Adjunct Anti-thrombotics
- Facilitated PCI

Microcirculation

- Filters
- Thromboembectomy
- IIb/IIIa inhibitors
- Nicorandil
- Adenosine (vaso-dil)
- Adhesion antagonists (a-CD18)
- Complement inhibitors
- P-selectin inhibitors

Myocardial Salvage



- Aqueous O_2
- Hypothermia
- GIK
- Nicorandil
- Adenosine (pre-cond)
- Na^+/H^+ pump inhib.
- IIb/IIIa inhibitors

Mod from O'Neill and Gersh

Top 10 Enrollers

Investigator	*Site*
Toshiya Muramatsu, MD	Kawasaki social Insurance Hospital
Satoru Suwa, MD	Jyuntendo Univ. Izu-Nagaoka Hospital
Naoya Fujita, MD	Eastern Japan Medical Center
Shiho Koyama, MD	Saiseikai Noe Hospital
Masahiko Saito, MD	Ageo Central General Hospital
Haruo Kamiya, MD	First Nagoya Red Cross Hospital
Akitsugu Oida, MD	Dokkyo University Cardiology
Takeshi Tsuchiya, MD	Kanazawa Cardiovascular Hospital
Yuhki Horita, MD	Ishikawa Prefectural Central Hospital
Shigeo Kawano, MD	Sakurabashi Watanabe Hospital

Total 341 cases randomized at 22 centers

Trial Organization

Principal Investigator:
Toshiya Muramatsu, MD
Kawasaki Social Insurance Hospital

Co-Principal Investigators:
Kinzo Ueda, MD
Koseikai Takeda Hospital

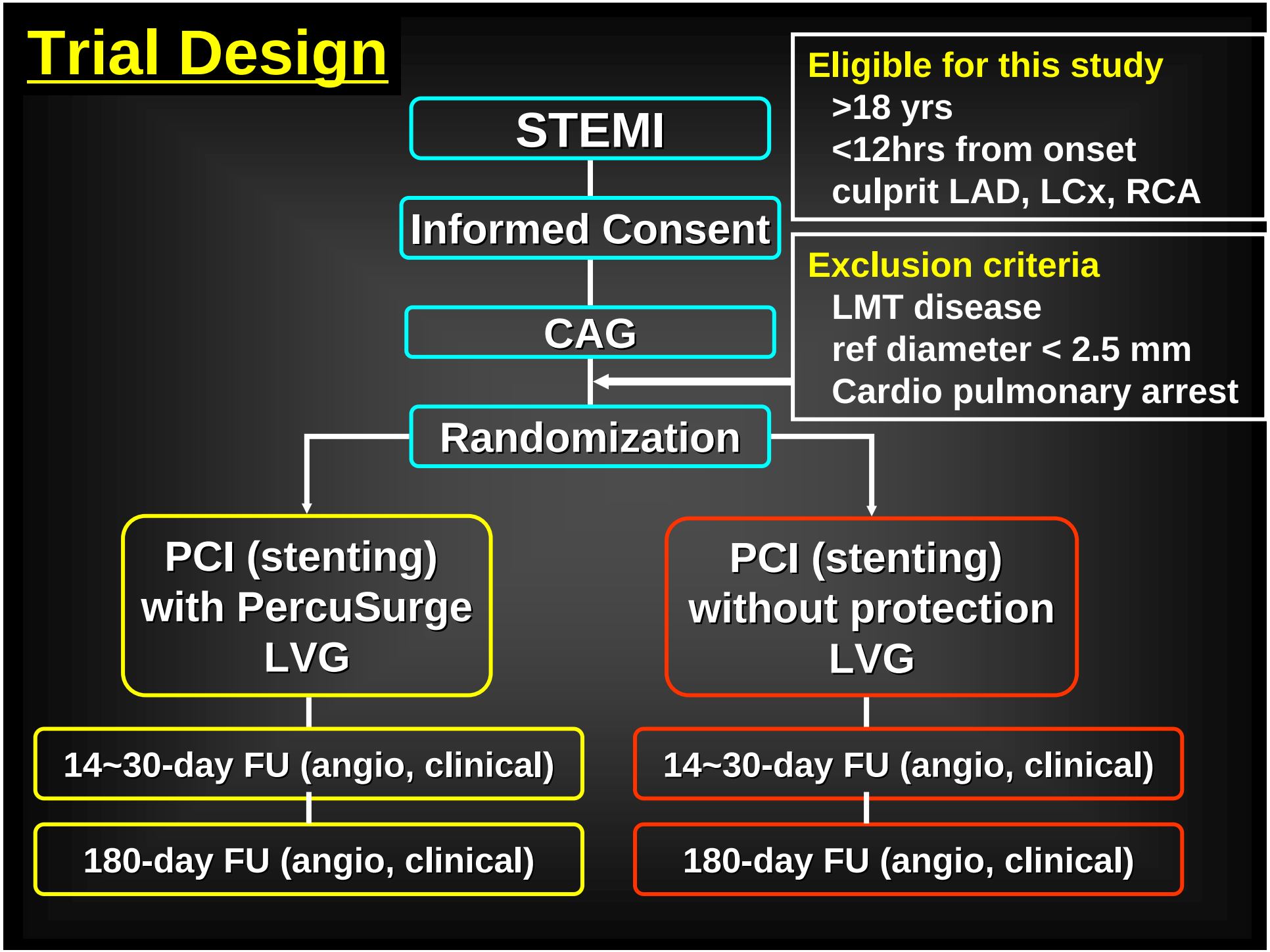
Masato Nakamura, MD
Toho University, Ohashi Hospital

QCA Core Lab:
Ken Kozuma, MD
Cardio Core Japan

QCU Core Lab:
Yoshiaki Ito, MD
Kawasaki Social Insurance Hospital

Data Management Core Lab:
Hideki Hashimoto, MD
Cardio Core Japan

Trial Design



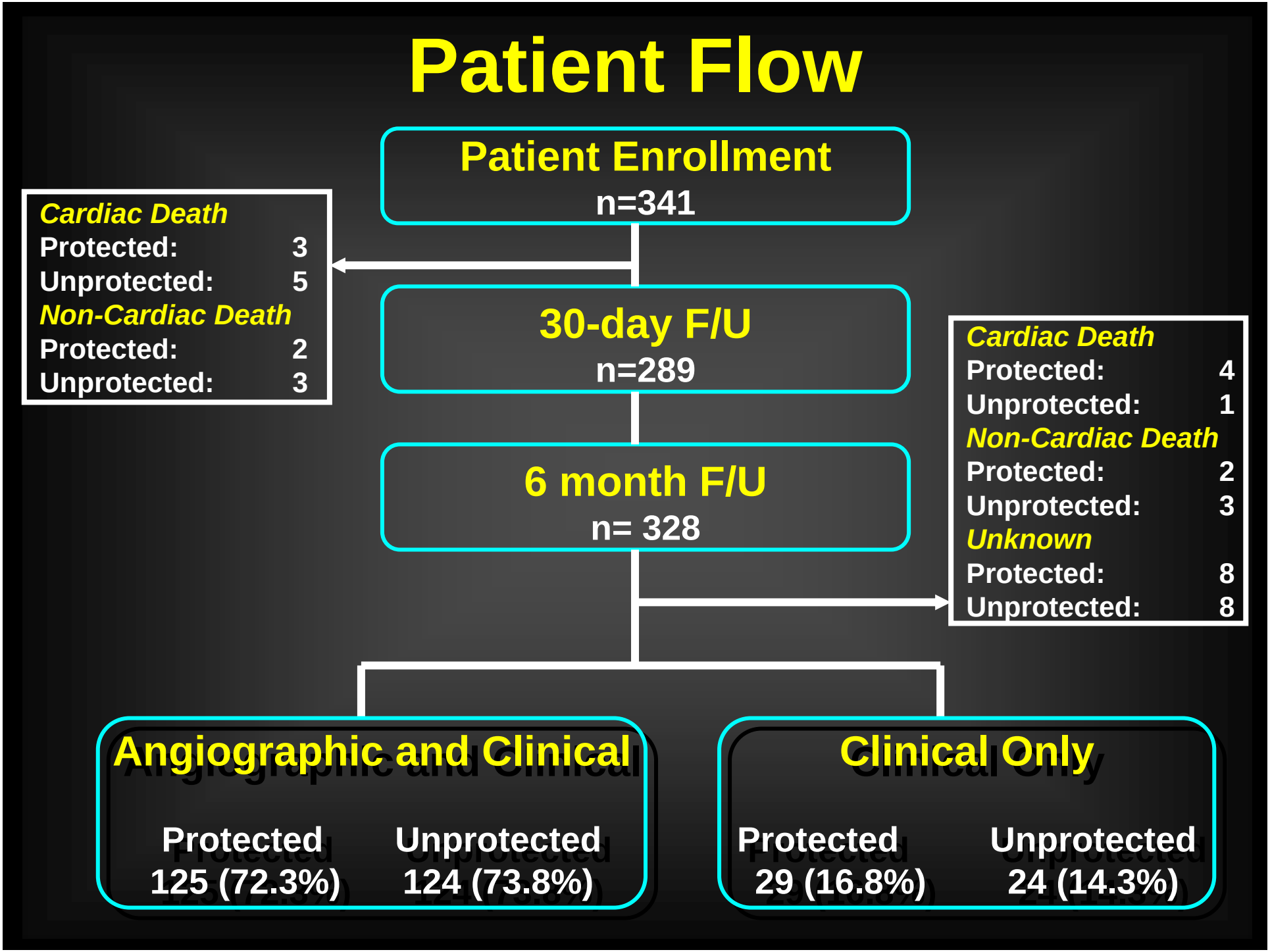
Primary Endpoints

- Final myocardial perfusion after primary PCI
  - TIMI flow
  - CTFC
  - Blush score
- Myocardial damage
  - CK, CK-MB, Troponin T
  - ST resolution
  - LVEF, LVEDV

Secondary Endpoints

- Rate of complications related to protection device
- MACE at 6 months

Patient Flow



Patient Demographics

	Protected (n=165)	Unprotected (n=164)	p value
Age, years	63.5 ± 12.3	64.7 ± 11.1	NS
Male, %	78.6	72.9	NS
Hypertension, %	42.2	44.1	NS
Hyperlipidemia, %	32.9	32.9	NS
Diabetes, %	31.8	32.3	NS
Smoking, %	51.4	49.4	NS
Family history, %	4.6	4.1	NS
History of MI, %	1.7	2.9	NS
Killip class II – IV, %	2.3	0.0	NS
Chest pain to Hosp., hrs	4.2 ± 2.8	4.4 ± 3.4	NS
CK at ER, IU/dl	589	569	NS
CK-MB at ER	46	45	NS

Lesion Demographics

	Protected (n=165)	Unprotected (n=164)	p value
Vessel disease, %			
1	59	58	NS
2	32	27	NS
3	9	15	NS
Target vessel, %			
RCA	40	42	NS
LAD	50	48	NS
LCx	10	10	NS
Pre TIMI flow			
0	44	44	NS
1	17	14	NS
2	21	19	NS
3	5	11	NS

Procedural Results (1)

	Protection (n=165)	Unprotected (n=164)	p value
Procedural success, %	98.9	97.1	NS
Vascular Complications, %	7.0	7.5	NS
Fluorescent time (min)	26.1±11.0	22.9±11.1	0.02
Operation time (min)	29.7±18.3	29.5±18.2	NS

Procedural Results (2)

	Protection (n=165)	Unprotected (n=164)	p value
After stenting			
Slow flow	7 (4.1%)	15 (8.8%)	0.07
No flow	1 (0.6%)	3 (1.7%)	NS
Distal embolization	4 (2.3%)	10 (5.9%)	NS
Post PCI			
Slow flow	7 (4.1%)	13 (7.8%)	0.15
No flow	2 (1.2%)	6 (3.6%)	0.15
Slow flow or No flow	9 (5.3%)	19 (11.4%)	0.05
Distal embolization	4 (2.3%)	7 (4.1%)	0.35
Total incidence	13 (7.6%)	26 (15.5%)	0.027

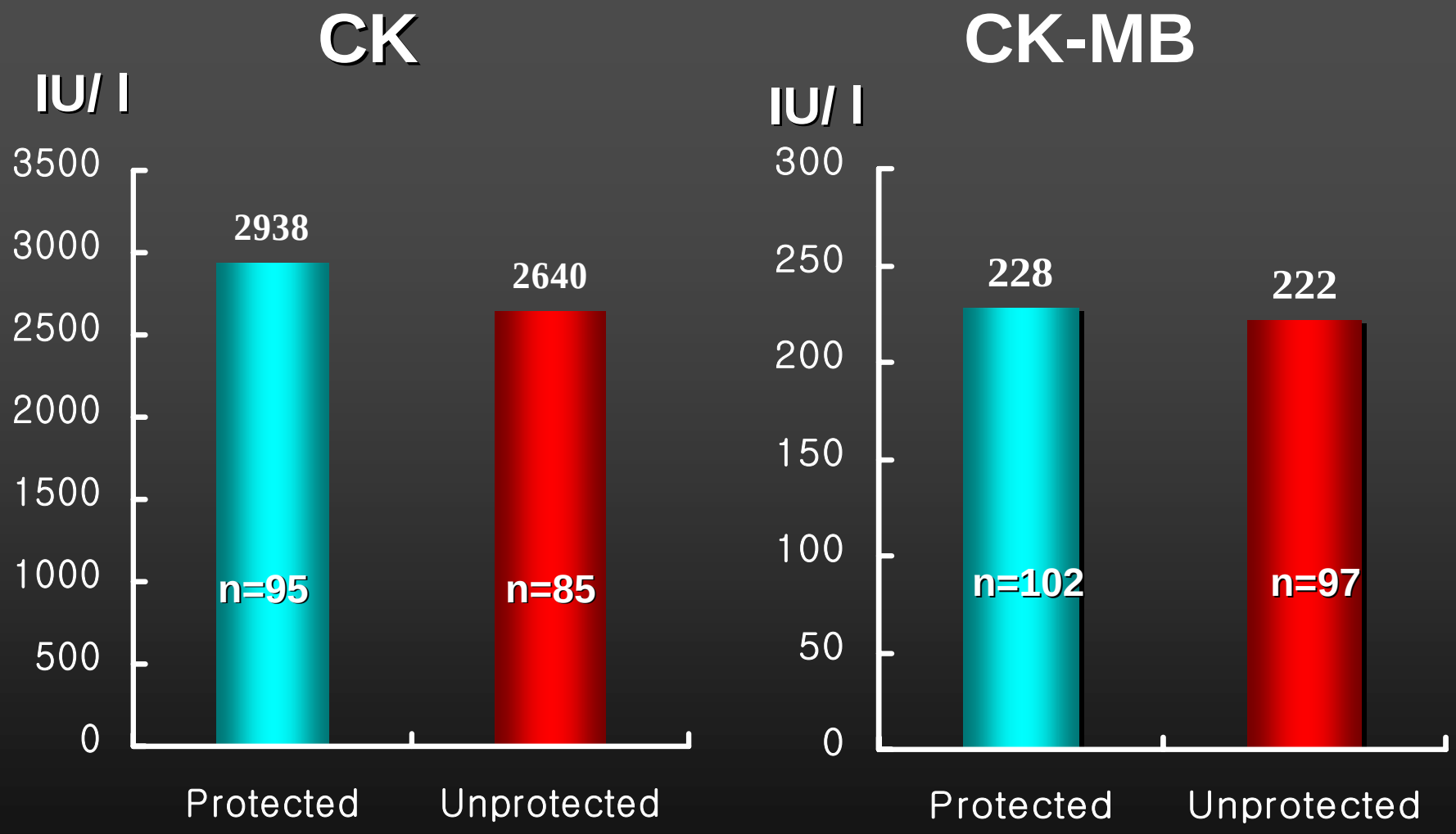
Device Performance Results

	n=173
GuardWire™ crossed the lesion, %	97
Without any procedure, %	41
With buddy wire, %	53
After balloon dilatation, %	4
Unsuccessful for crossing the lesion, %	1.2
Not performed distal protection, %	0.6
Distal embolization after GuardWire™ insertion, %	1.2

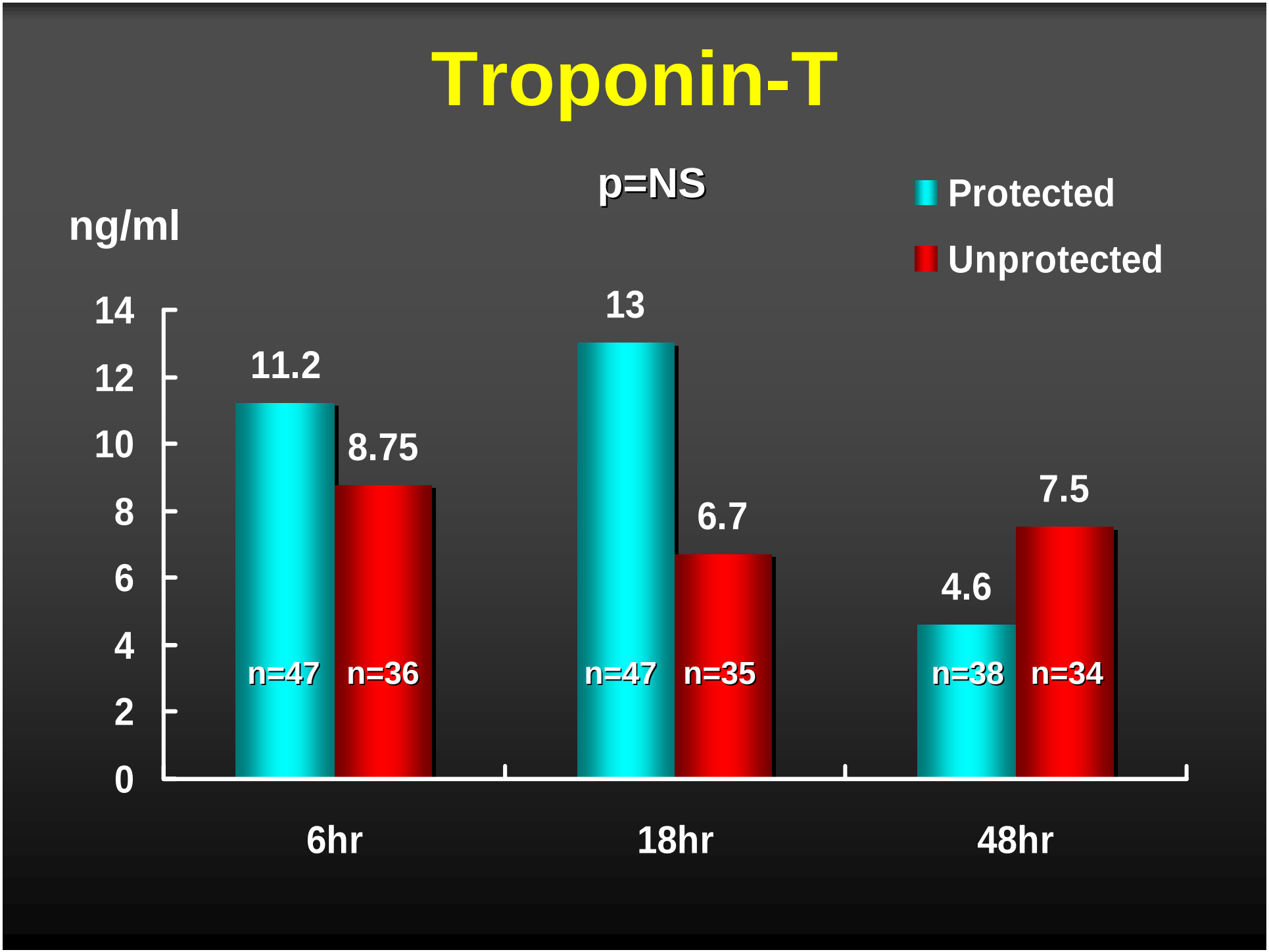
Clinical Outcomes

	Protection (n=173)	Unprotected (n=168)	p Value
In-hospital MACE			
Death	5 (3%)	7 (4.0%)	NS
re-MI	0	1 (0.6%)	NS
TLR/TVR	0	1 (0.6%)	NS
6 month MACE	(n=160)	(n=152)	
Death	6 (3.8%)	4 (2.6%)	NS
re-MI	0	0	NS
TLR/TVR	17 (10.6%)	15 (9.9%)	NS

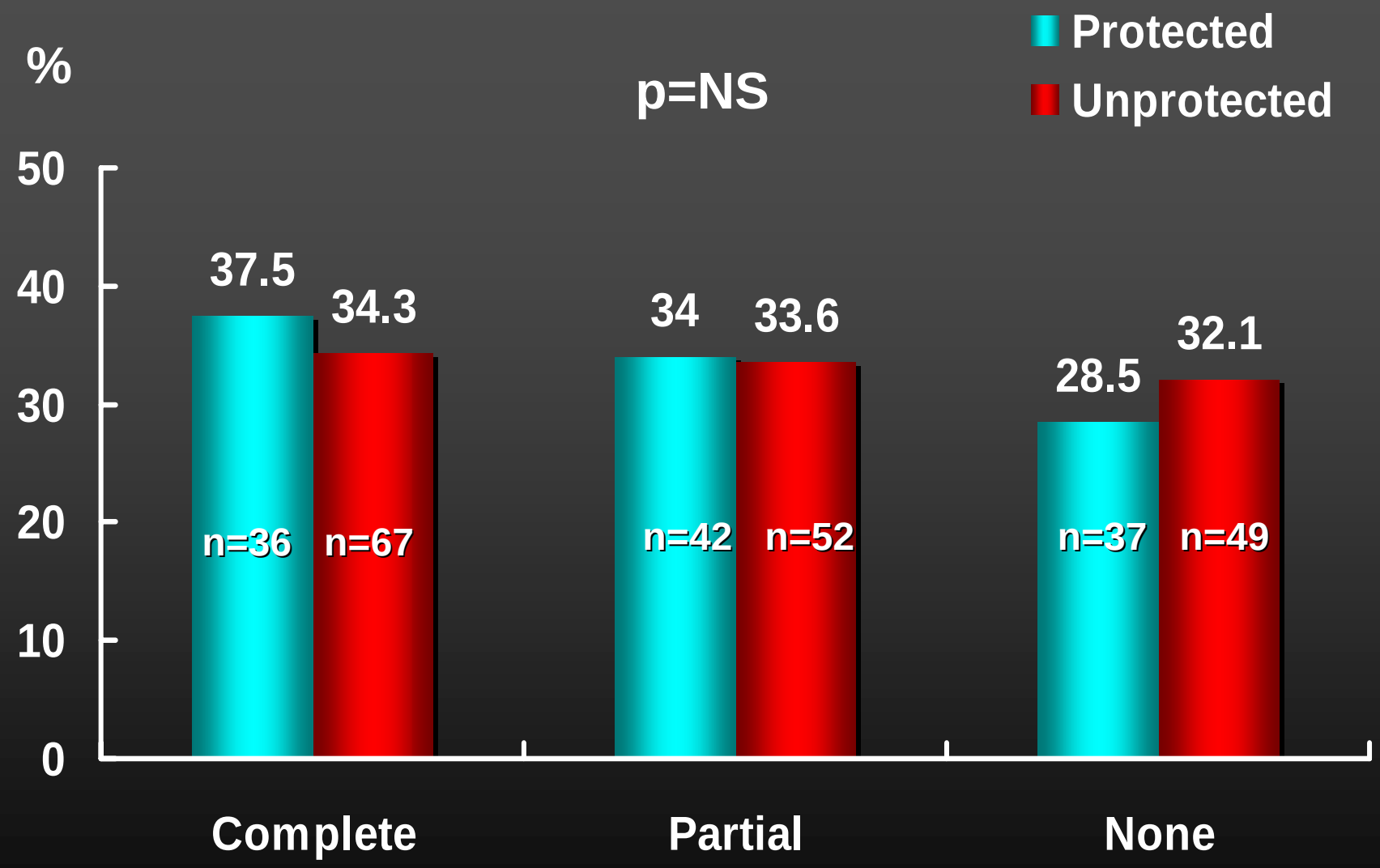
Peak CK / CK-MB


CK
IU/ l
3500
3000
2500
2000
1500
1000
500
0
2938
2640
n=95
n=85
Protected
Unprotected
CK-MB
IU/ l
300
250
200
150
100
50
0
228
222
n=102
n=97
Protected
Unprotected

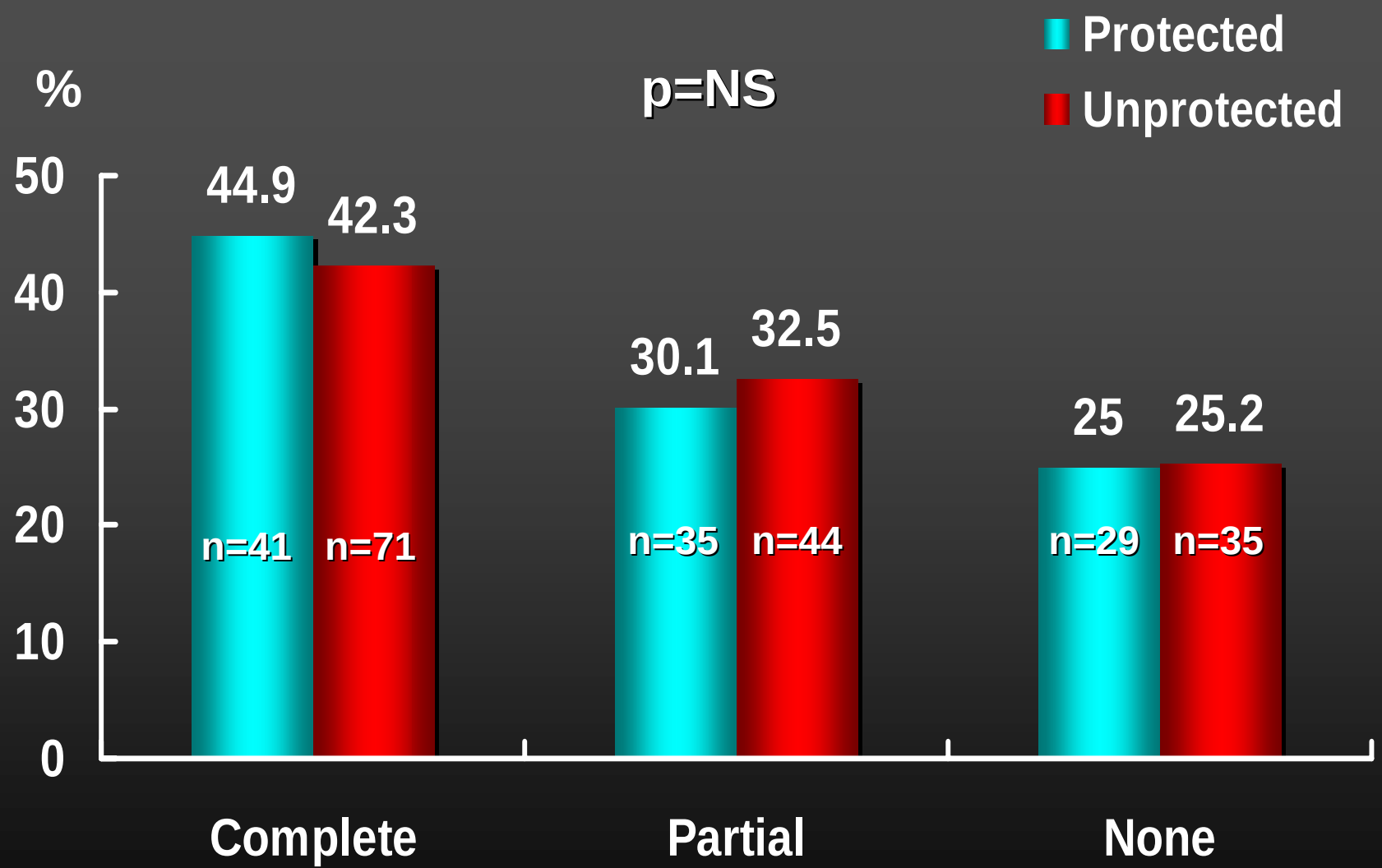
Troponin-T


p=NS
Protected
Unprotected
ng/ml
14
12
10
8
6
4
2
0
11.2
8.75
13
6.7
4.6
7.5
n=47
n=36
n=47
n=35
n=38
n=34
6hr
18hr
48hr

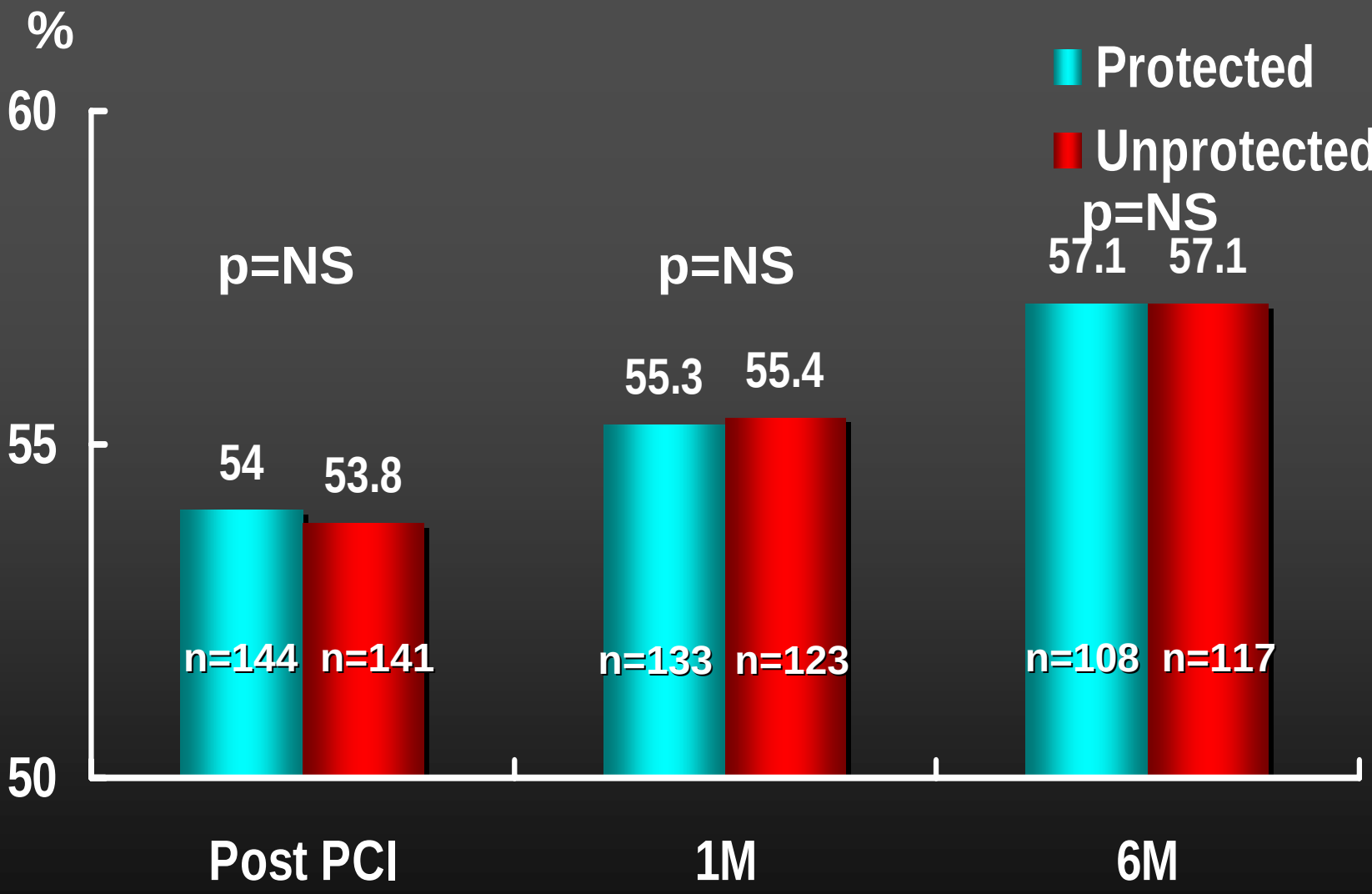
ST Resolution (90min)



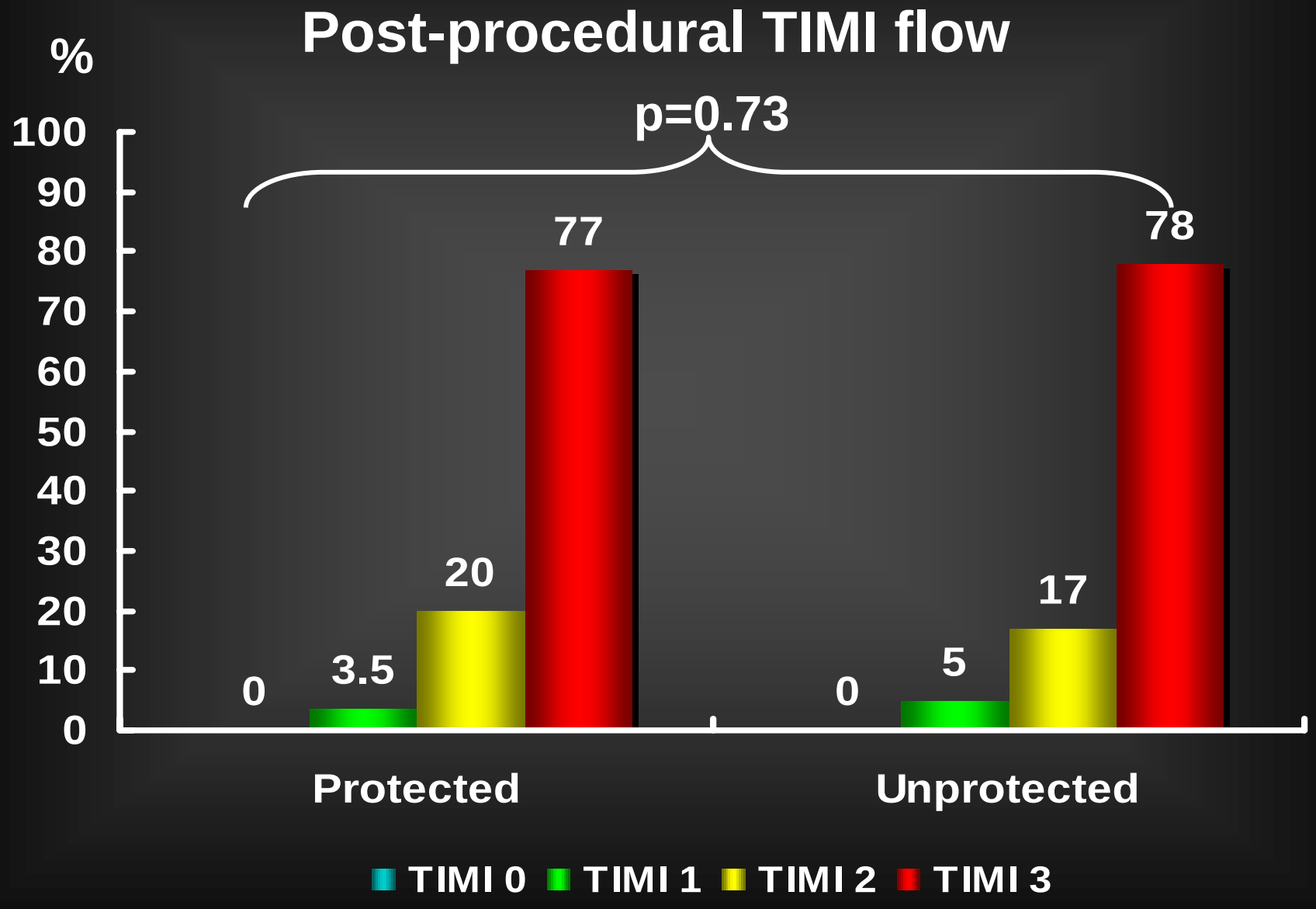
ST Resolution (180min)



LVEF

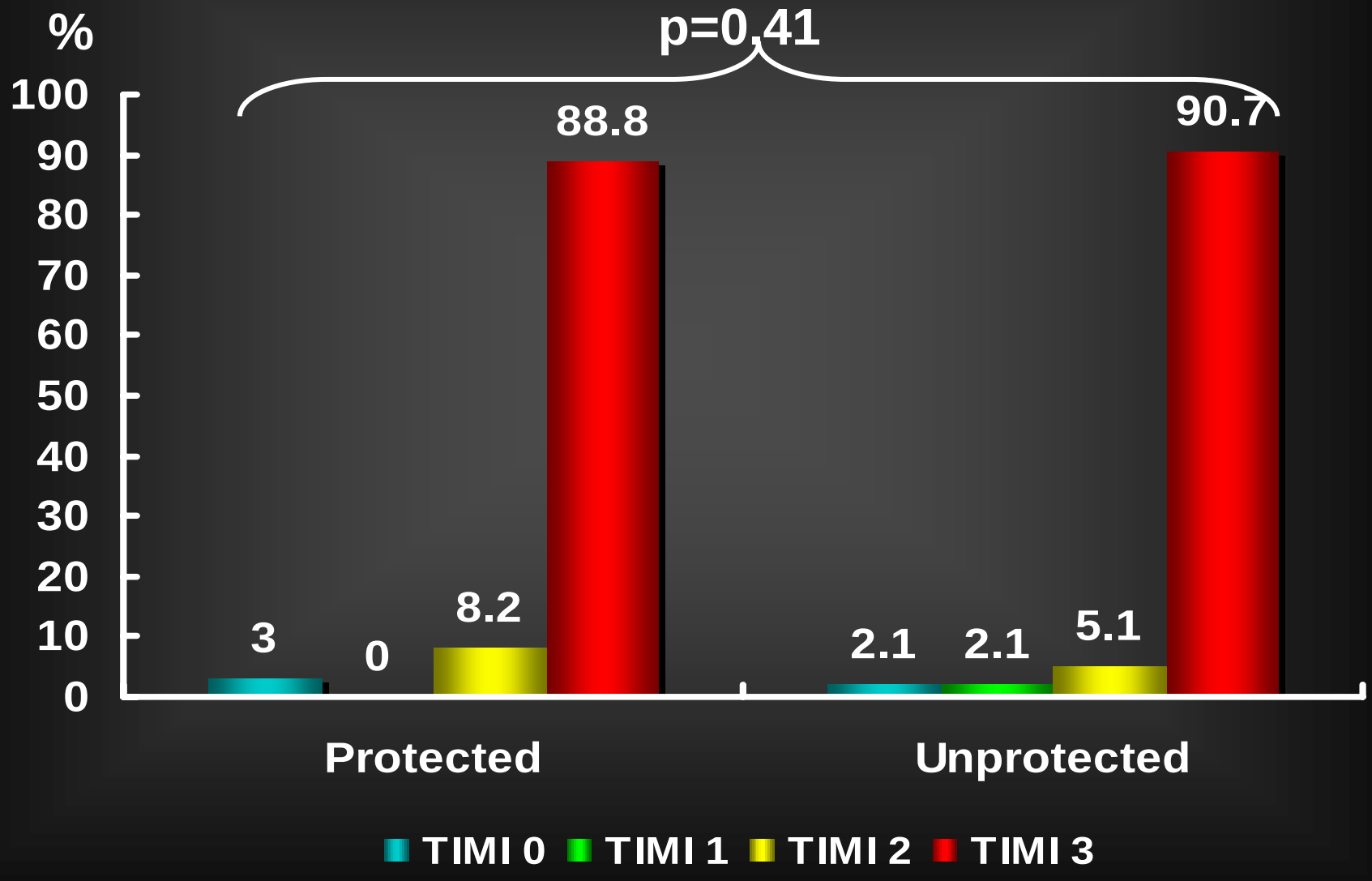

%
60
55
50
Protected
Unprotected
p=NS
p=NS
p=NS
54
53.8
55.3
55.4
57.1
57.1
n=144
n=141
n=133
n=123
n=108
n=117
Post PCI
1M
6M

Angiographic Results

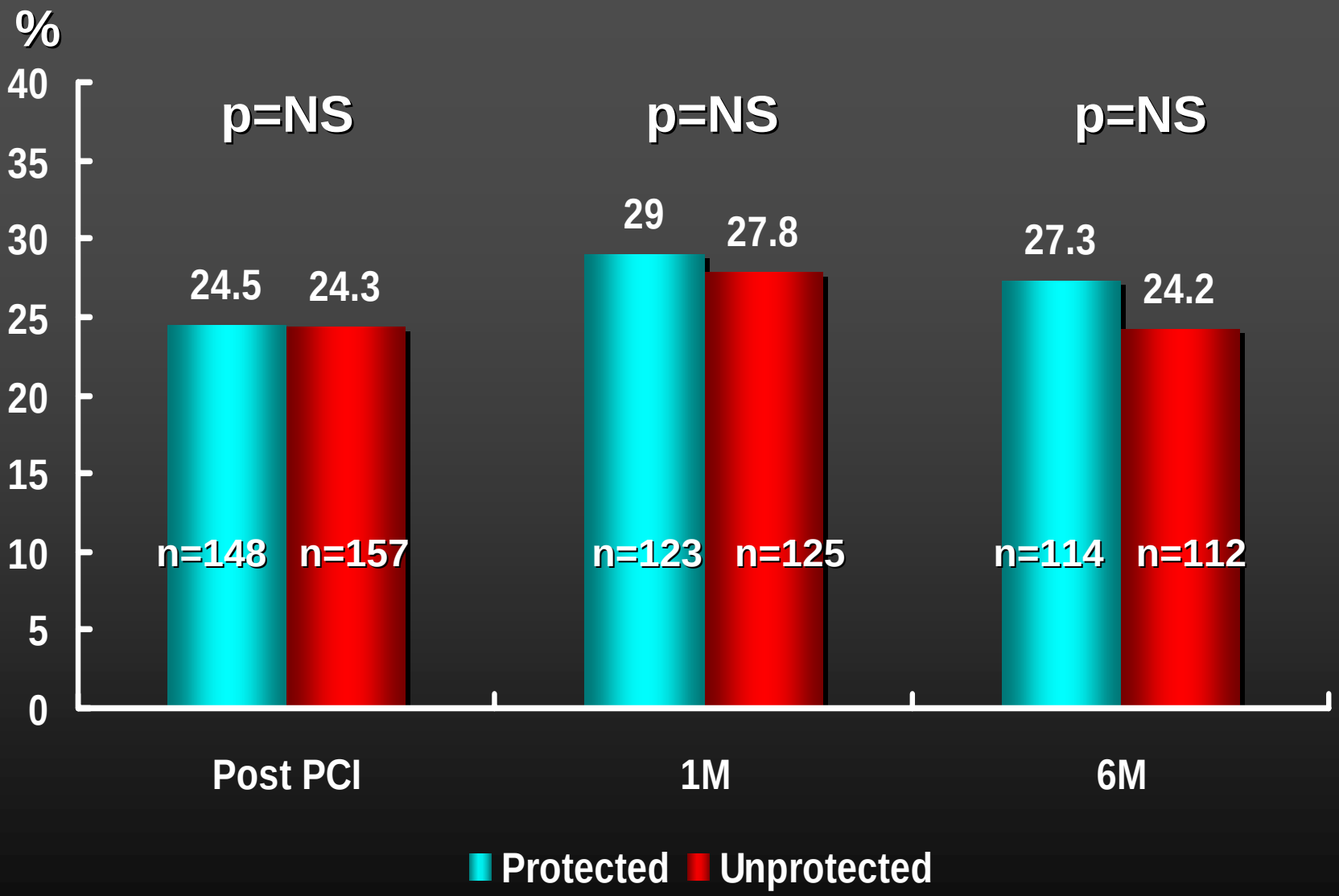


Angiographic Results

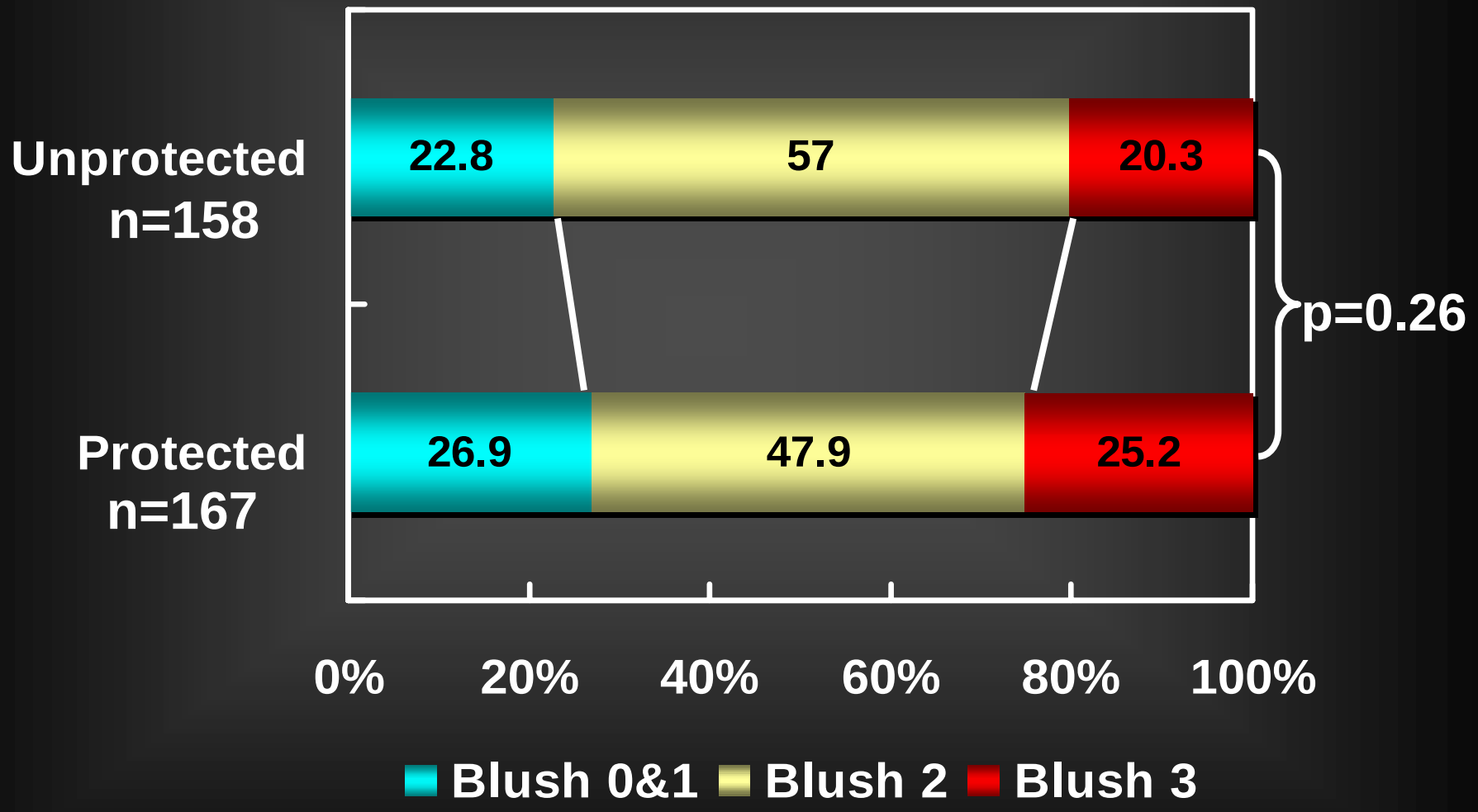
TIMI flow at 6 month



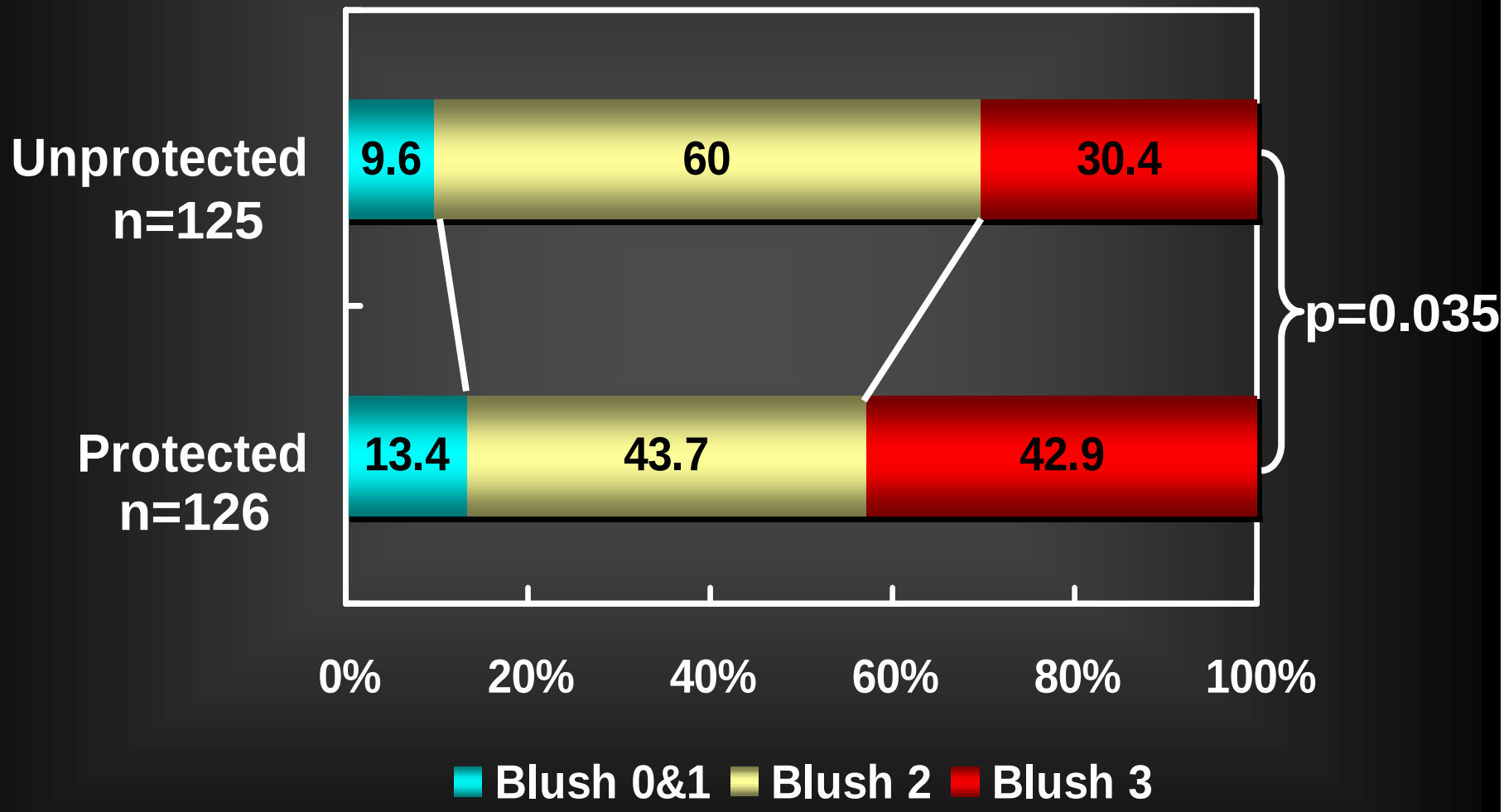
Corrected TIMI Frame Count



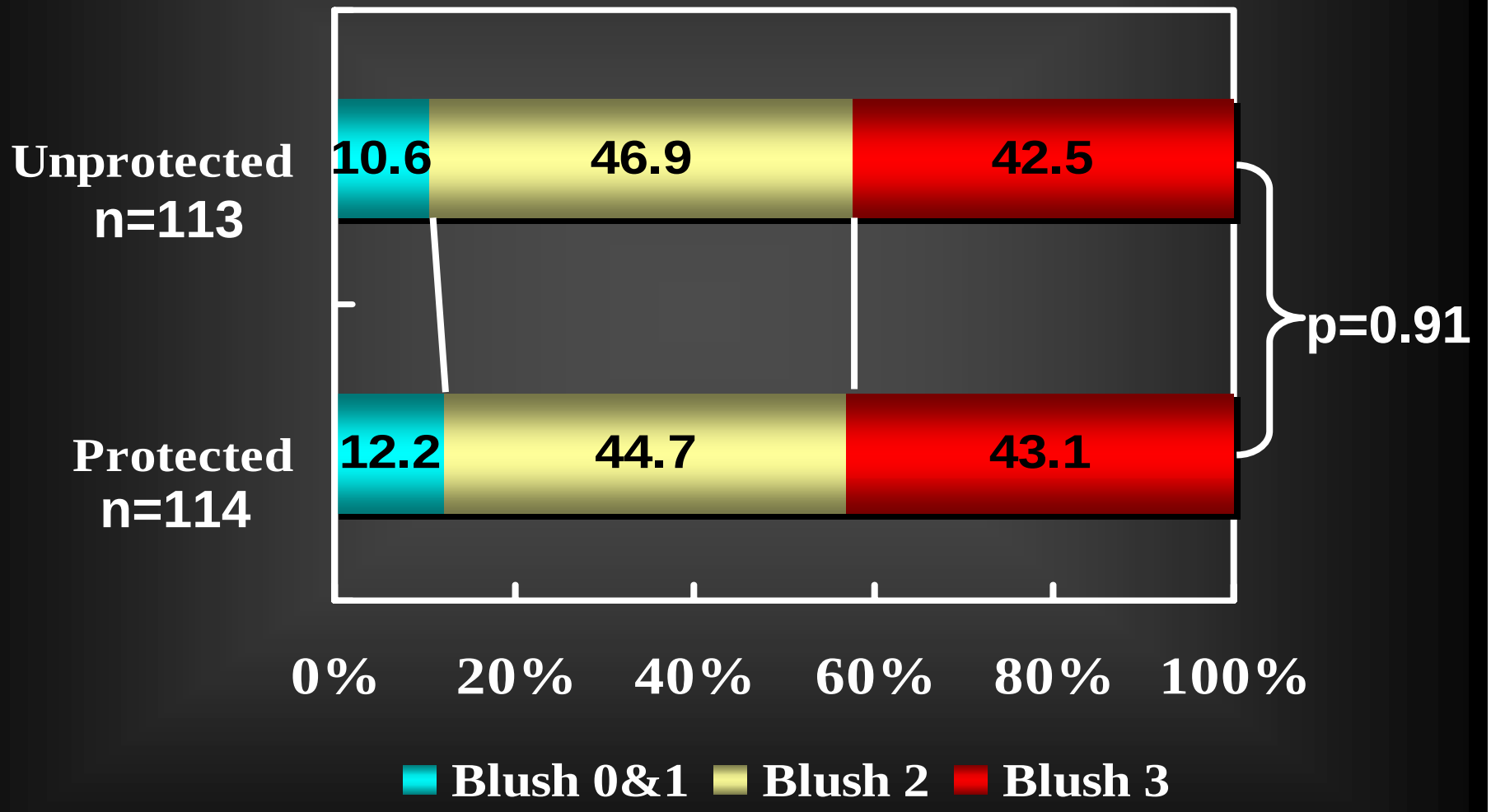
Post-procedural Blush Score



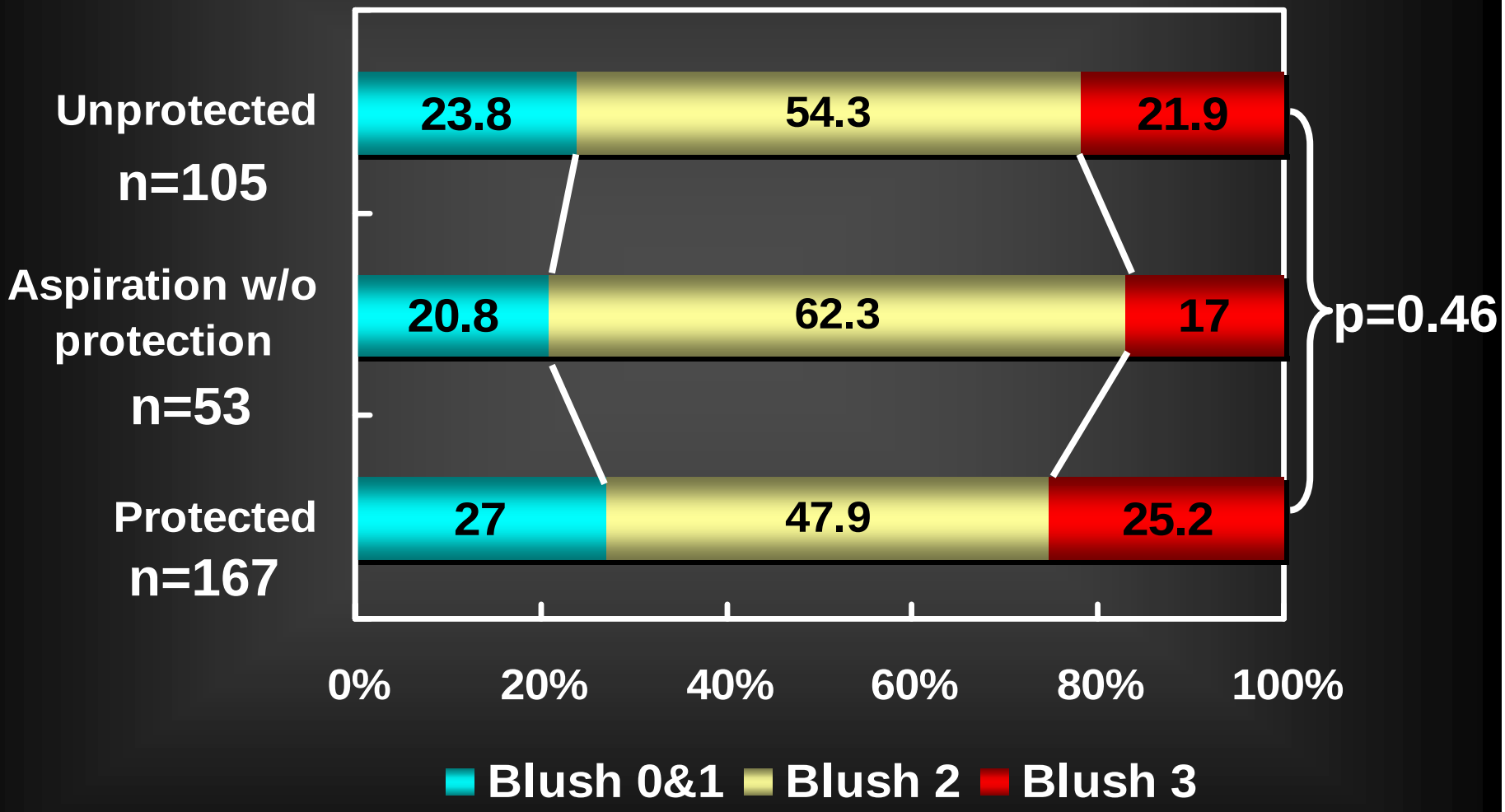
Blush Score at 30-day



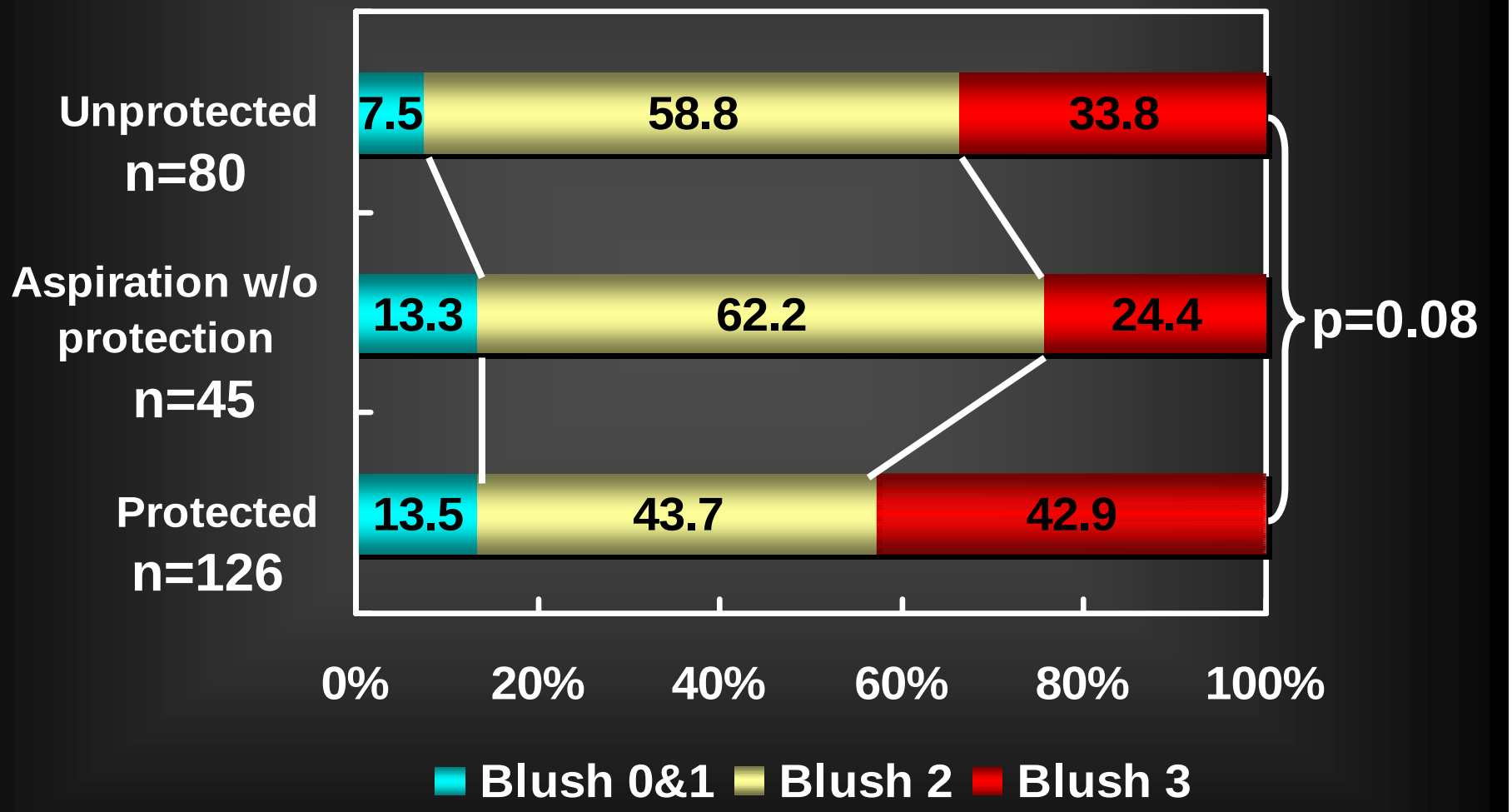
Blush Score at 6 month



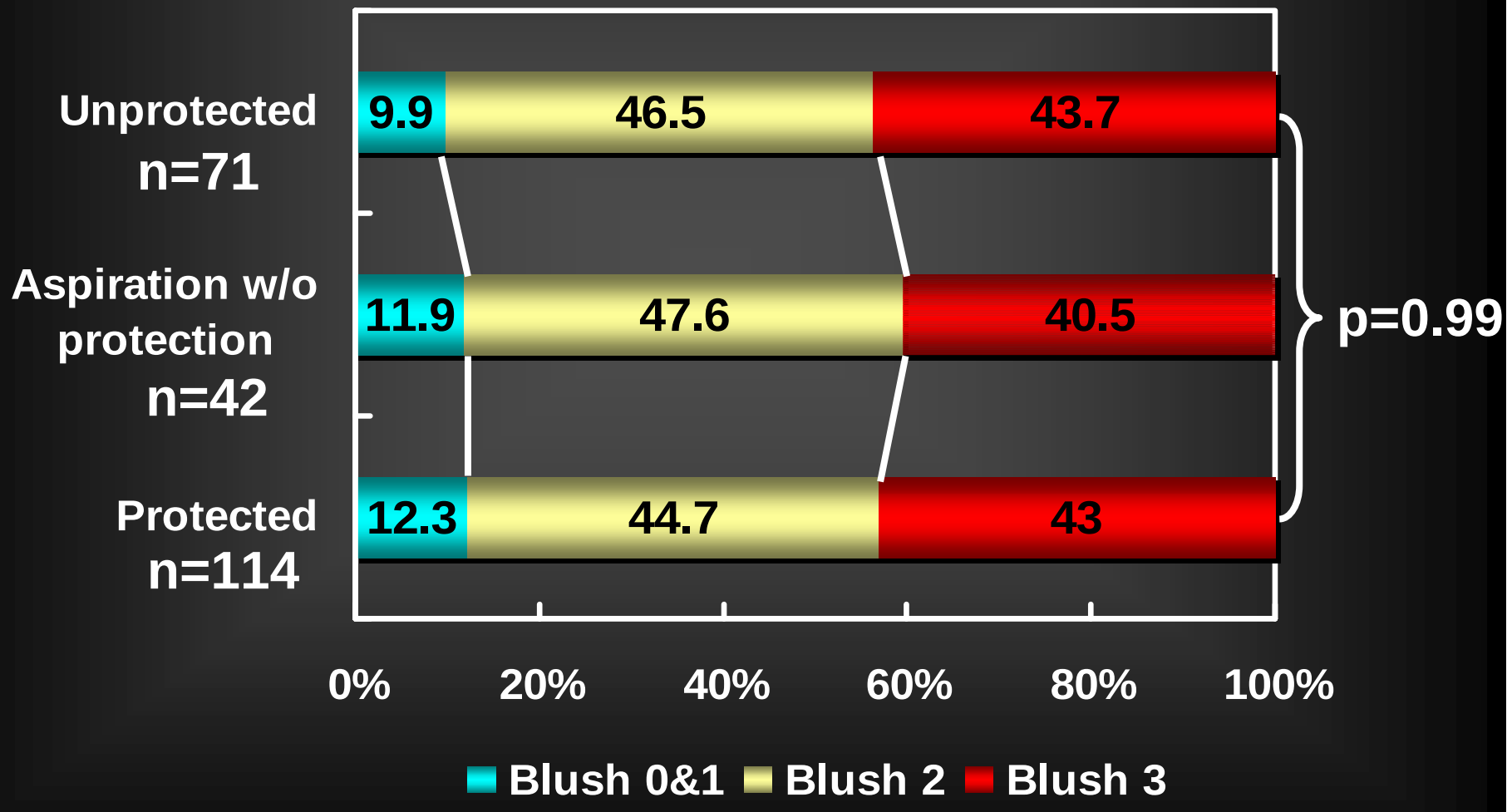
Post-procedural Blush Score



Blush Score at 30-days

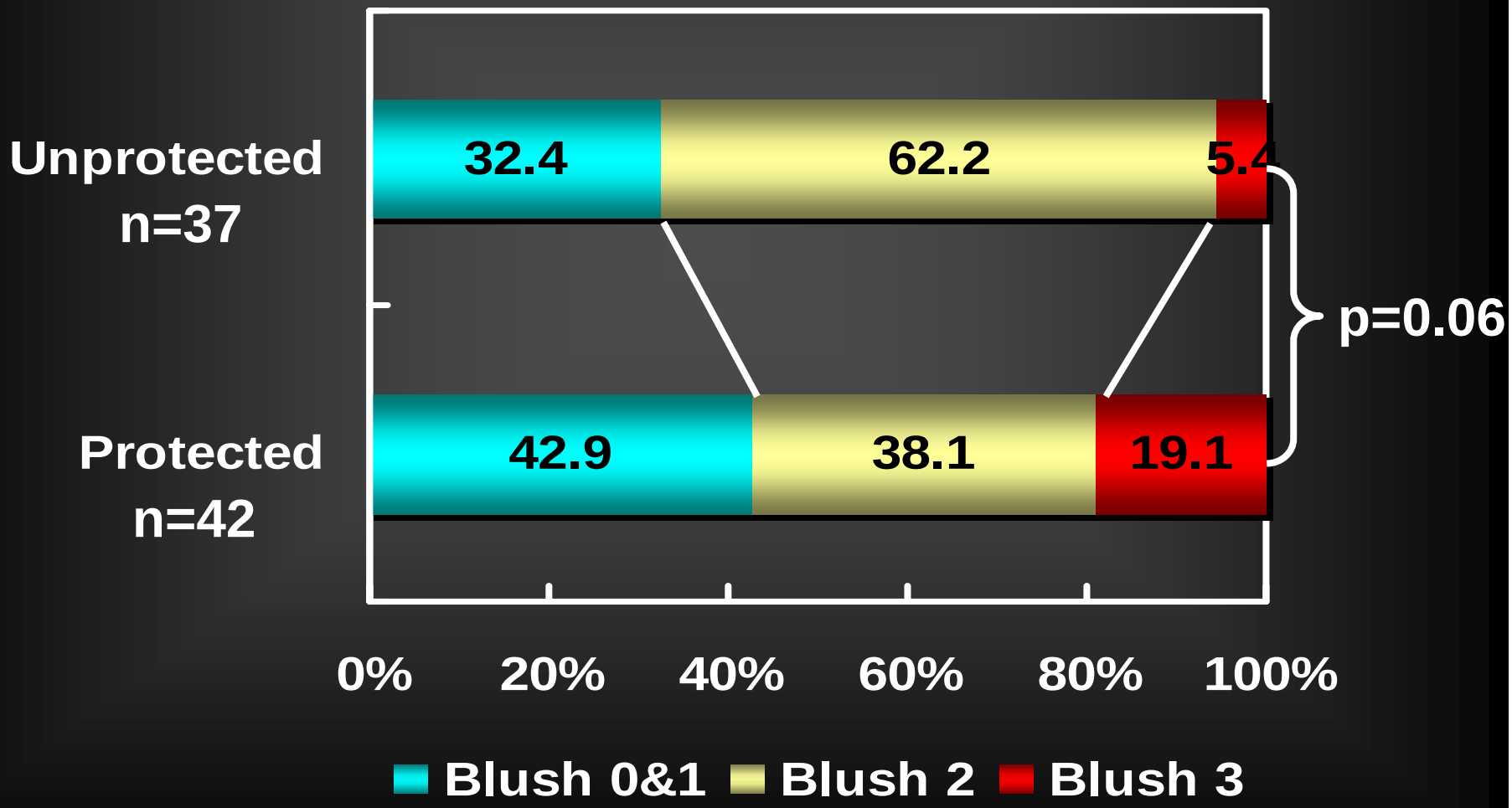


Blush Score at 6 months



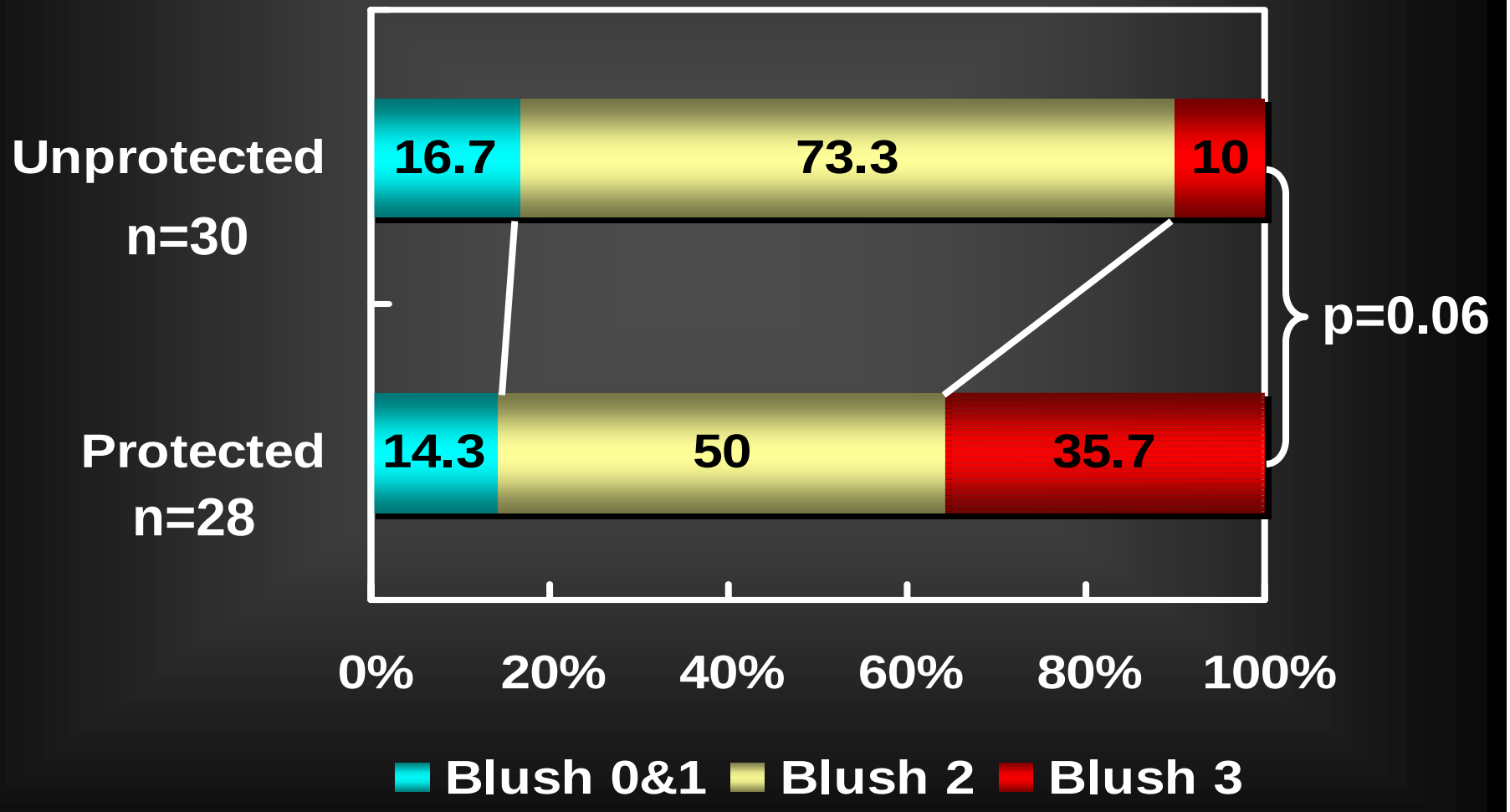
Post-procedural Blush Score

Proximal RCA



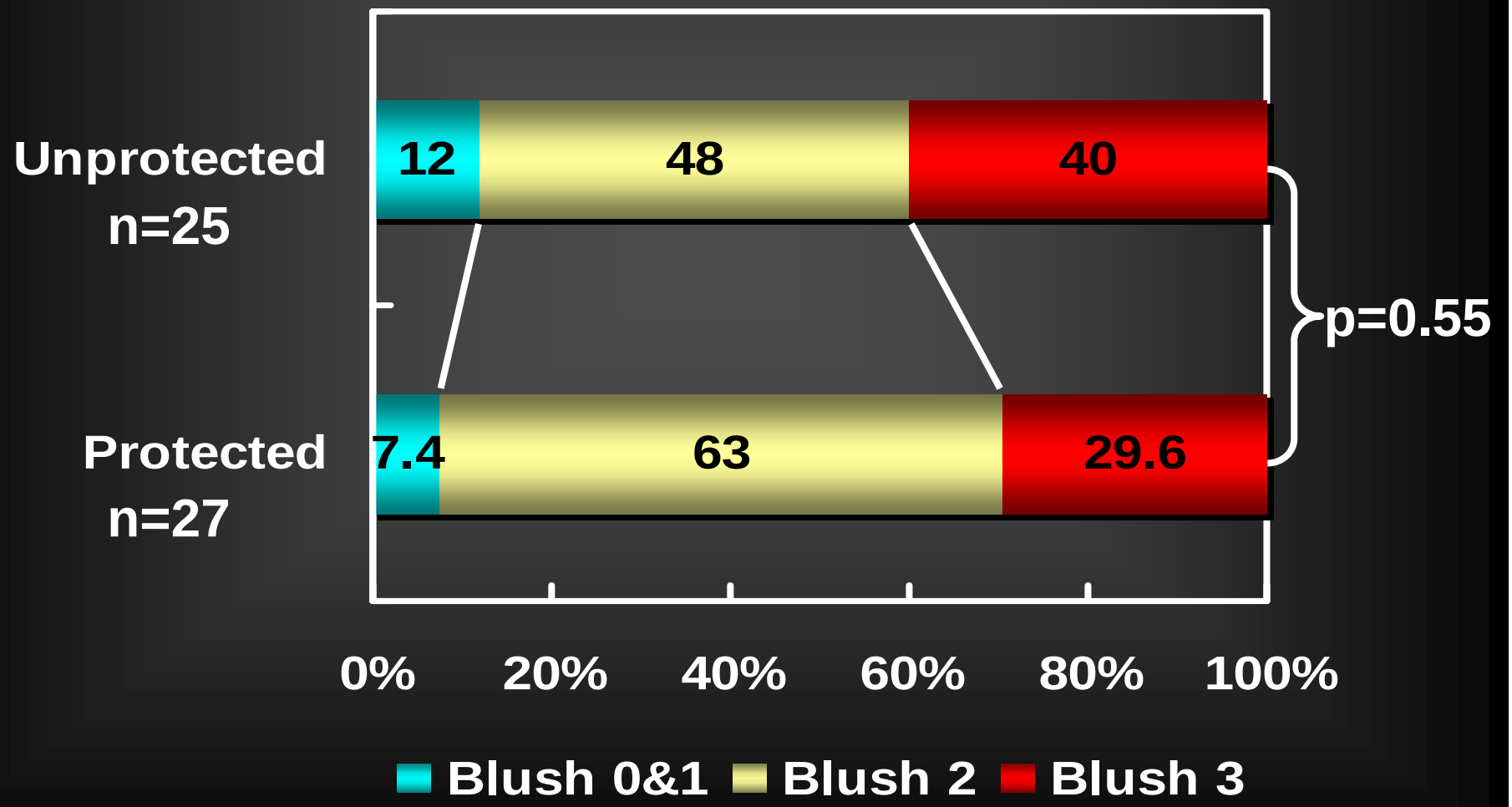
Blush Score at 30-day

Proximal RCA



Blush Score at 6 month

Proximal RCA



Angiographic Results

QCA at 6 month

	Protected (N=173)	Unprotected (N=168)	p value
Post Ref. Vessel Diam. (mm)	3.07±0.62	3.02±0.54	0.39
Diameter stenosis , %			
pre (n= 172, 165)	88±19	89 ±17	0.50
post (n= 173, 168)	19.3 ±11.7	20.2 ±13.1	0.51
1Mo (n= 144, 136)	18.0 ±14.2	18.8 ±13.8	0.64
6Mo (n= 122, 122)	36.3 ±22.3	36.2 ±22.2	0.98
MLD, mm			
pre	0.32 ±0.49	0.27±0.42	0.30
post	2.48 ±0.59	2.40 ±0.53	0.22
1Mo	2.59 ±0.66	2.47 ±0.60	0.10
6Mo	1.79±0.76	1.72 ±0.70	0.44
Binary restenosis, %	21.3	23.8	0.65

Sub-Analysis Data Flow

Trial Total Enroll

341 cases

Eligible Flow Wire analysis

50 cases

CFR: 50 cases

Unroteted:25 cases

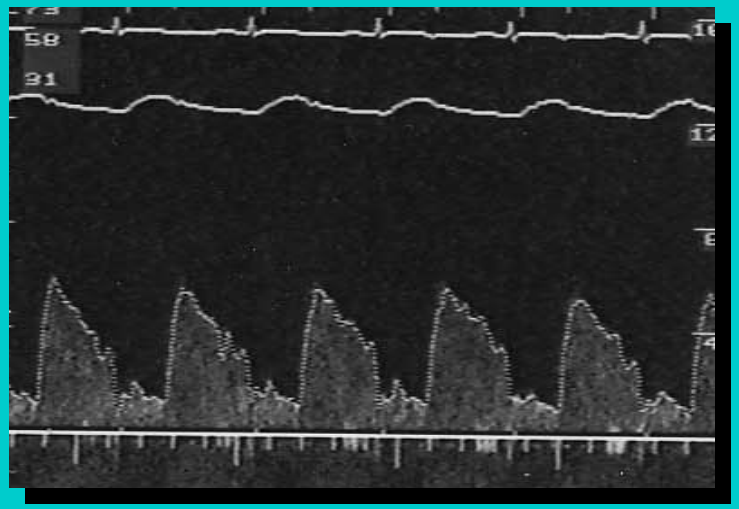
Protected: 25 cases

Pzf: 35 cases

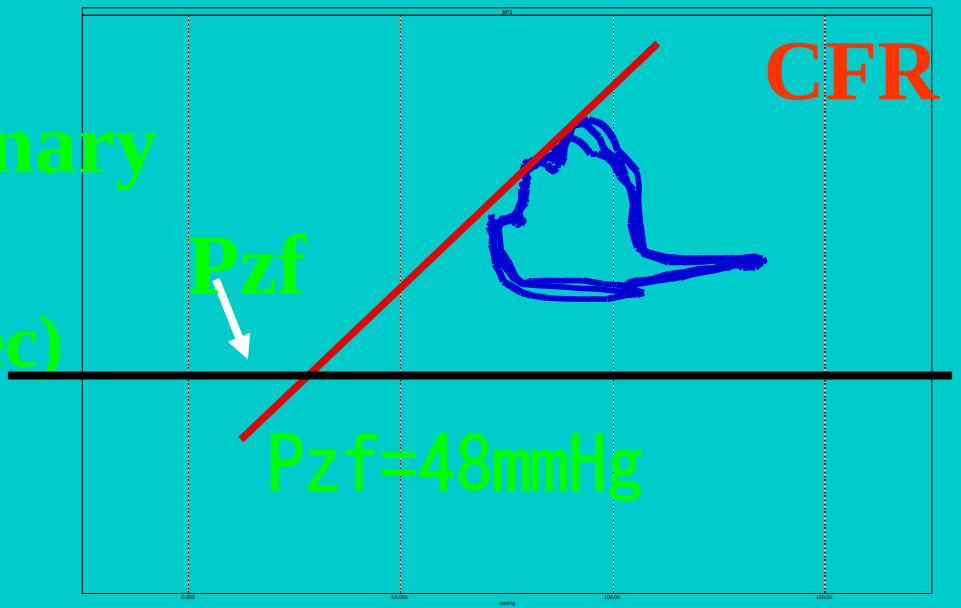
Unroteted:16 cases

Protected: 19 cases

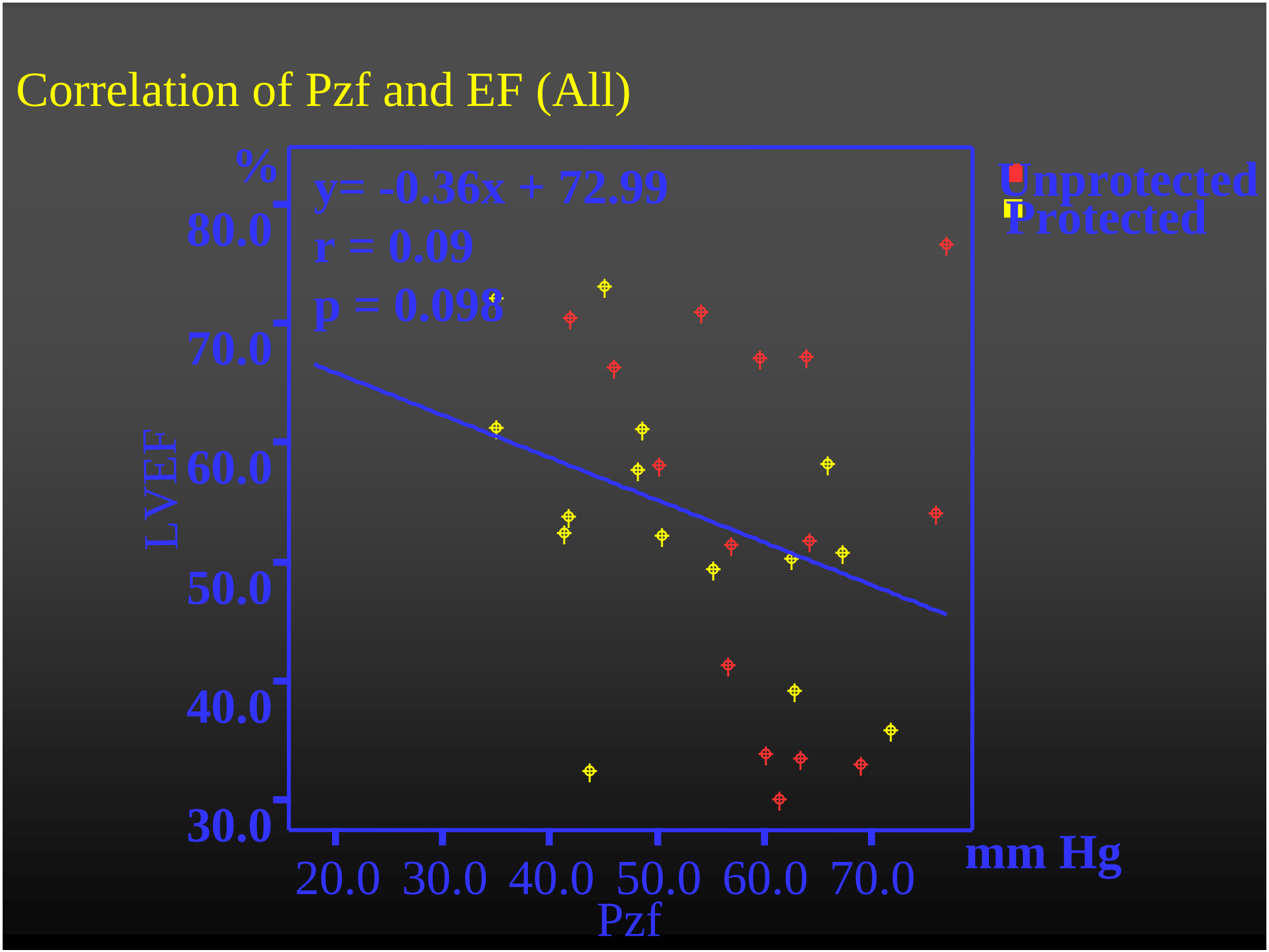
Zero-flow pressure



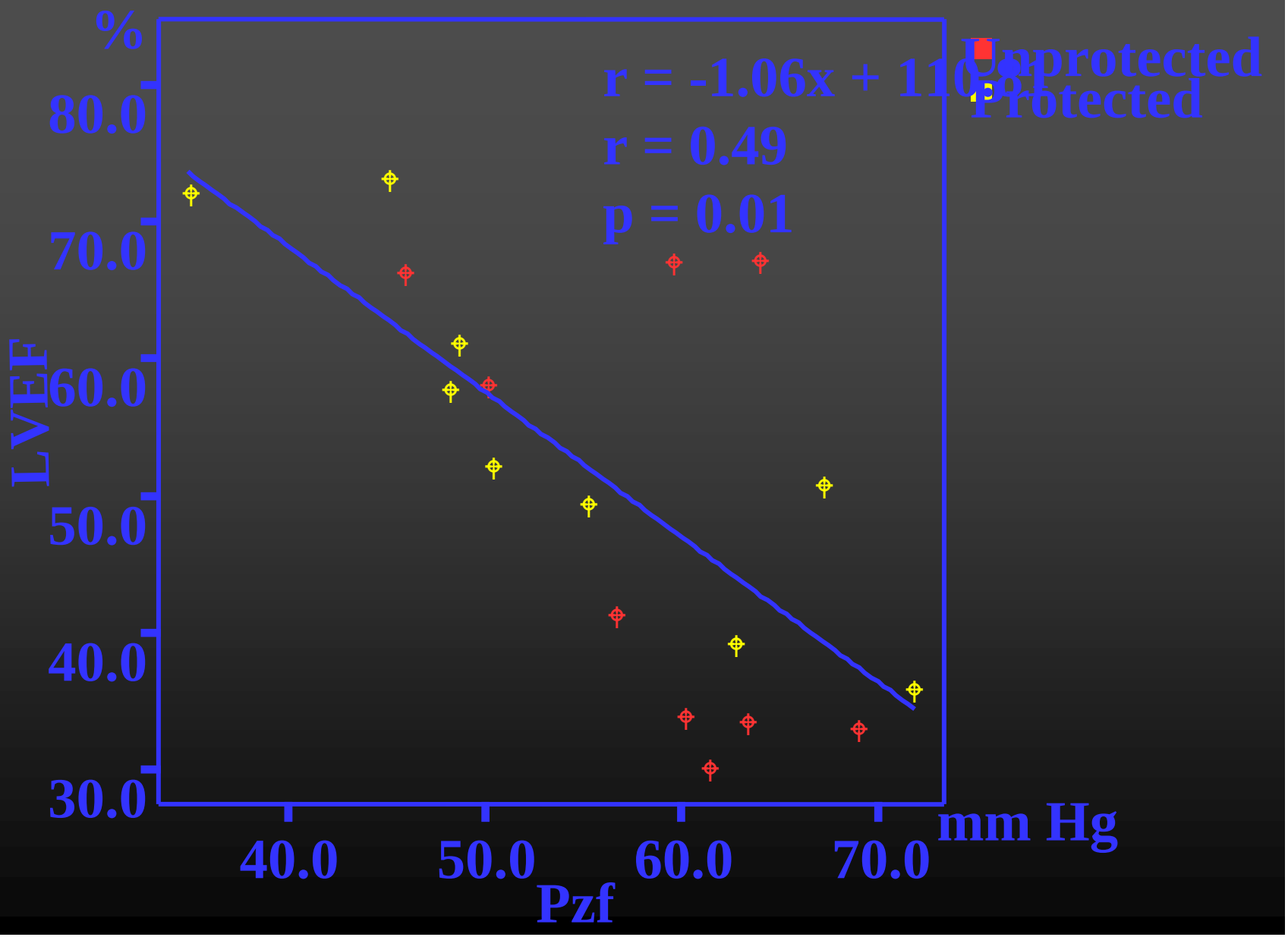
APV 21 cm/s
ADPV 27 cm/s
ASPV 12 cm/s
DVSR 2.2
ESRF (-)
CFR 1.6



Correlation of Pzf and EF (All)



Correlation of Pzf and EF (LAD)



Conclusions (1)

- There was no detrimental effect in patients with AMI regarding the usage of the PercuSurge™ distal protection system.
- The frequency of in-hospital and 6-month MACE was similar among the protected and control groups.
- The incidence of slow flow, no reflow, and distal embolism was lower in the group treated with distal protection than that of unprotected group.

Conclusions (2)

- A higher incidence of Blush 3 post procedure and at 30days has been observed in the group treated with PercuSurge™, especially in the cases with proximal RCA lesions.
- These findings may indicate that distal protection is beneficial in terms of prevention of severe flow disturbance and microvascular myocardial perfusion.
- However, further study is necessary to prove the clinical impact of the distal protection therapy on the AMI patients.