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ASPARAGUS Trial

ASPirAtion of LibeRated Debris in Acute MI with GUardWire+™ System

Early Results From the Japanese Asparagus Trial

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On behalf of the ASPARAGUS investigators

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ASPARAGUS investigators

Enrollment Lists

Kawasaki social Insurance Hp	69	Iseikai Hp	5
Jyuntendo Univ. Izu-Nagaoka HP	57	Toyooka Public Hp	5
Eastern Japan Medical Center	41	Miki City Hp	4
Saiseikai Noe Hp	40	Gifu Social Insurance Hp	3
Ageo Central General Hp	28	Kanto Rosai Hp	2
First Nagoya Red Cross Hp	20	West Tokyo Central Hp	1
Dokkyo University Cardiology	14	Koseikai Takeda Hp	1
Kanazawa Cardiovascular Hp	13	Aichi Medical Univ. Hp	1
Ishikawa Prefectural Central HP	10		
Sakurabashi Watanabe Hp	10		
Kasai Public Hp	8		
Cardiovasc. Center Sakakibara	7		
Toho Univ. Ohashi Hp	6		
Showa Univ. School of Medicine	6		

22 centers

Total 341 cases

Trial Organization

Principal Investigator:	***Toshiya Muramatsu M.D.*** **Kawasaki Social Insurance Hospital**
Co-Principal Investigators:	***Kinzo Ueda M.D.*** **Koseikai Takeda Hospital**
	Masato Nakamura M.D. **Toho University, Ohashi Hospital**
QCA Core Lab	***Ken Kozuma M.D.*** **Cardio Core Japan**
QCU Core Lab	***Yoshiaki Ito M.D.*** **Kawasaki Social Insurance Hospital**
Data Management Core Lab	***Hideki Hashimoto M.D.*** **Cardio Core Japan**

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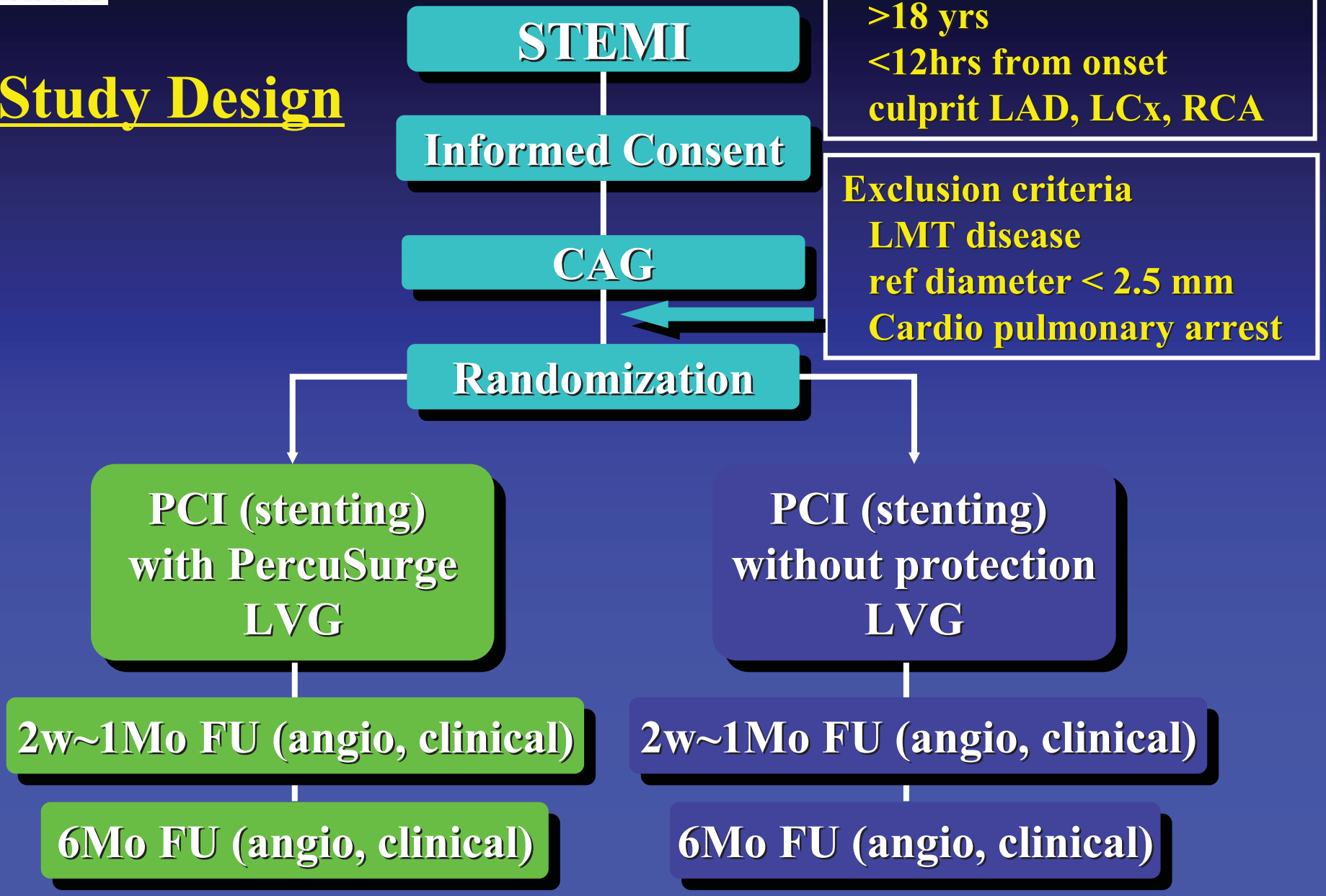
Study Design



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ASPARAGUS Trial

- **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 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

	Protected (n=165)	Unprotected (n=164)	p Value
Procedural success, %	98.9	97.1	NS
Vascular Complications, %	7.0	7.5	NS
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
After post dilatation			
Slow flow	6 (3.5%)	0 (0%)	0.01
No flow	0 (0%)	1 (0.6%)	NS
Distal embolization	1 (0.6%)	1 (0.6%)	NS
In-hospital MACE			
Death	0	1 (0.6%)	NS
re-MI	0	1 (SAT)	NS
TLR/TVR	0	1	NS

PercuSurge Related Procedural 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

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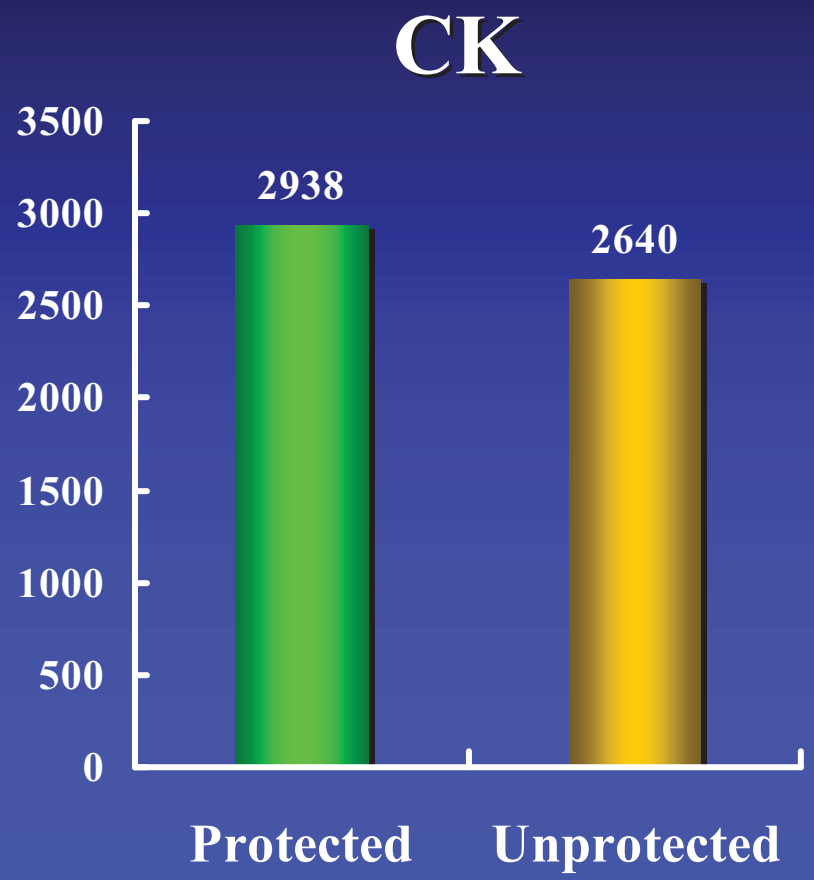
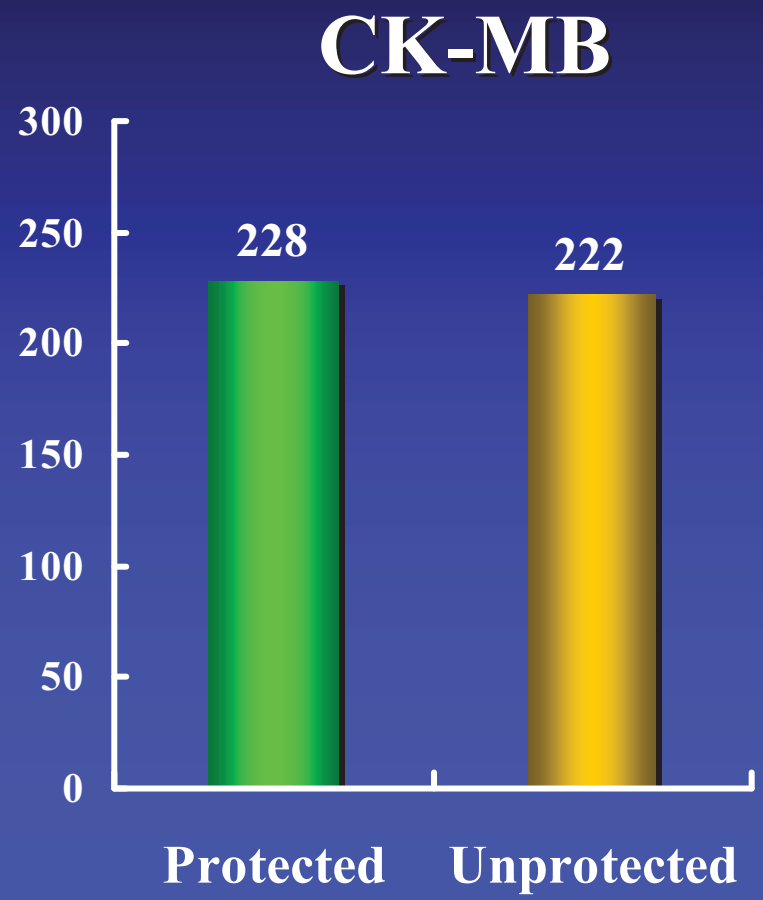
Peak CK / CK-MB





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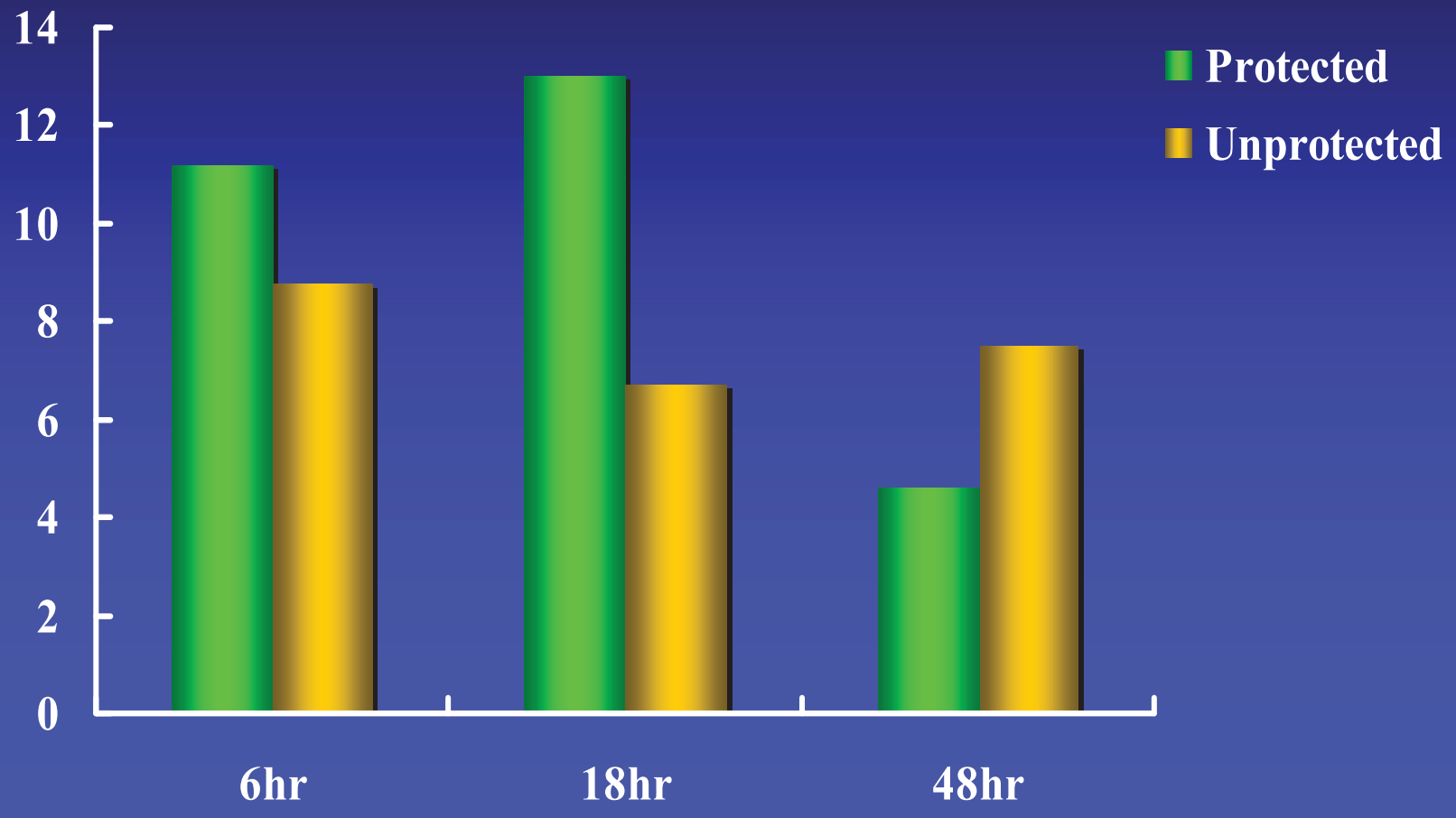
Troponin T



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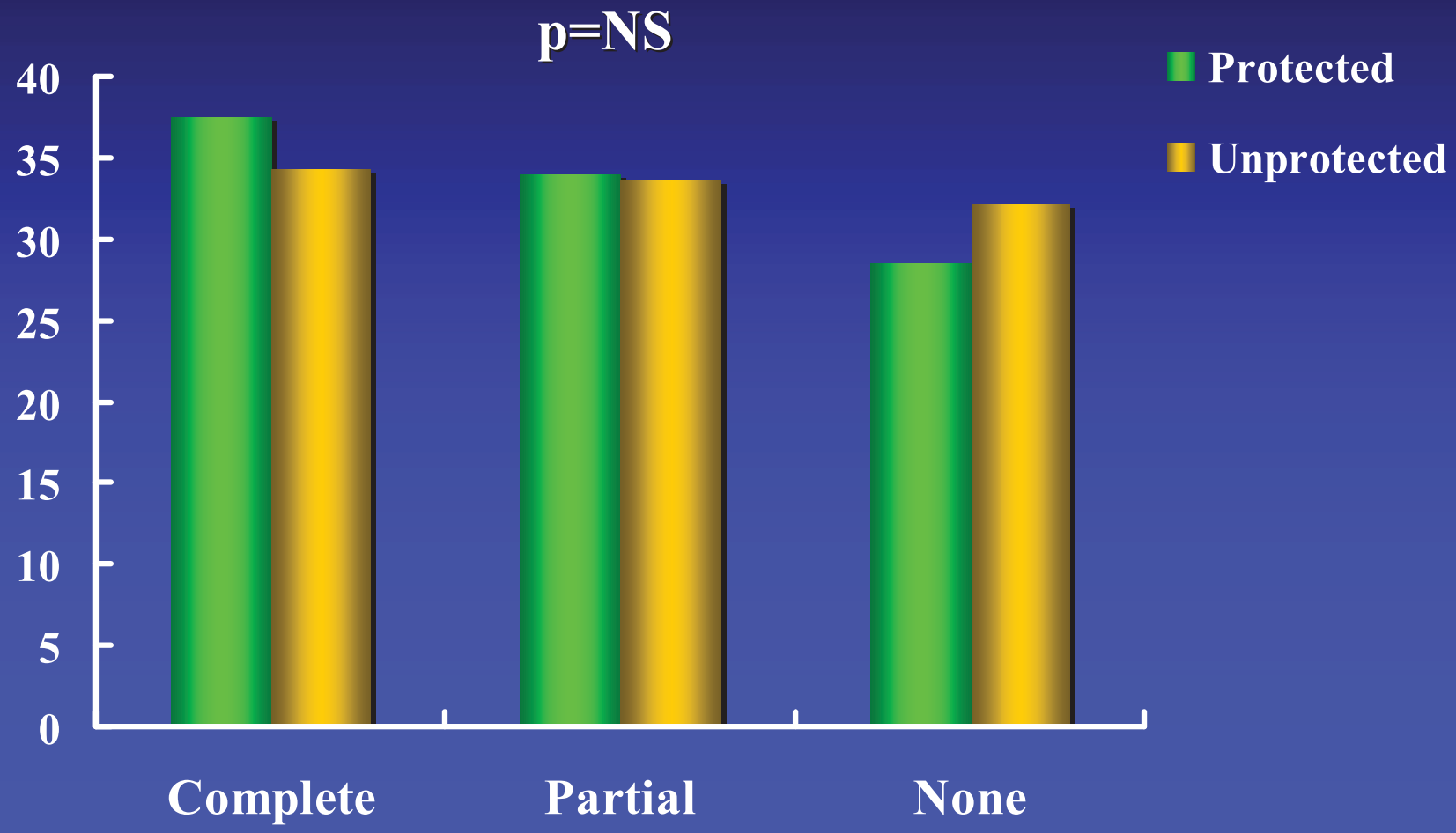
ST Resolution (90min)



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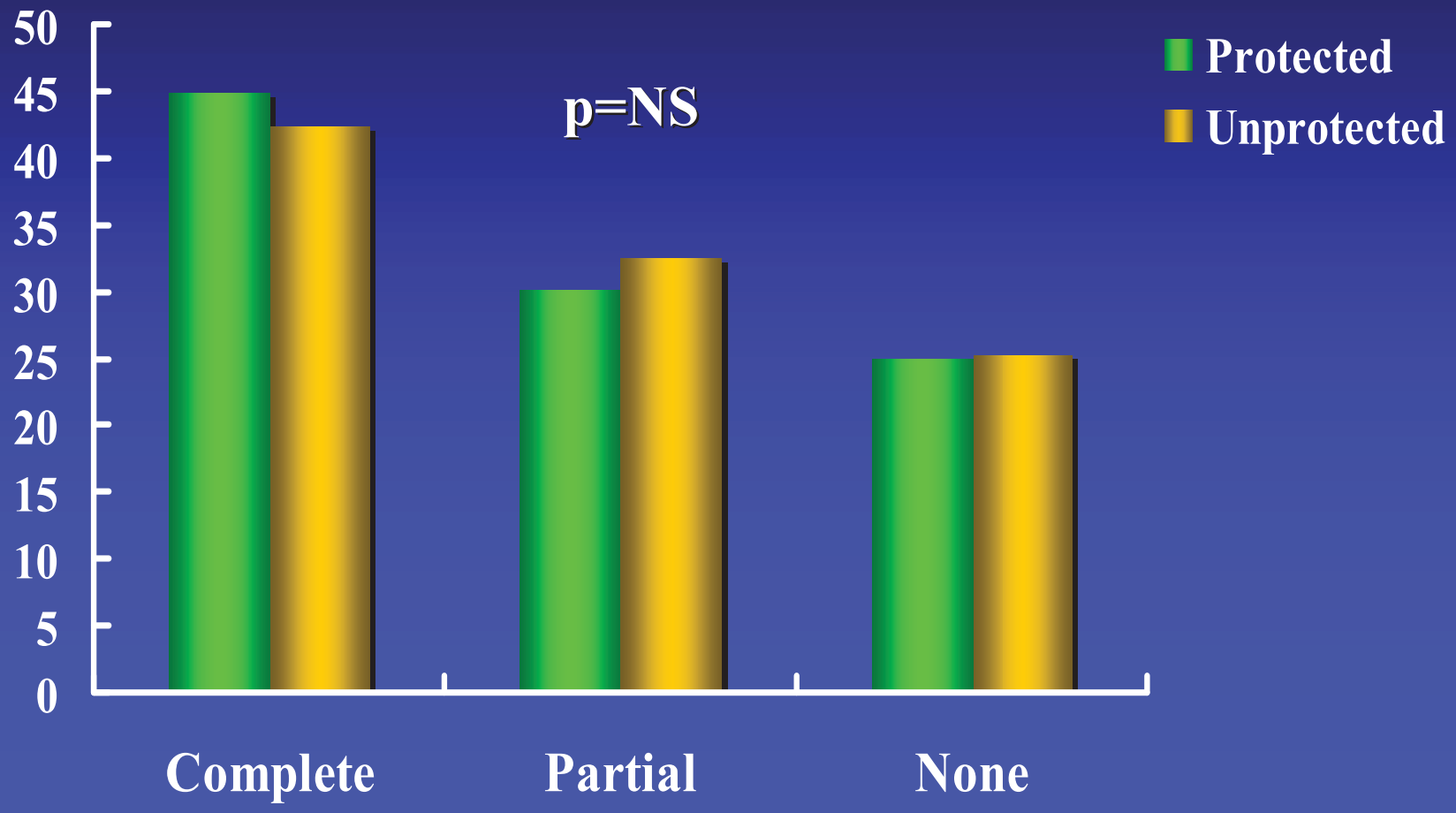
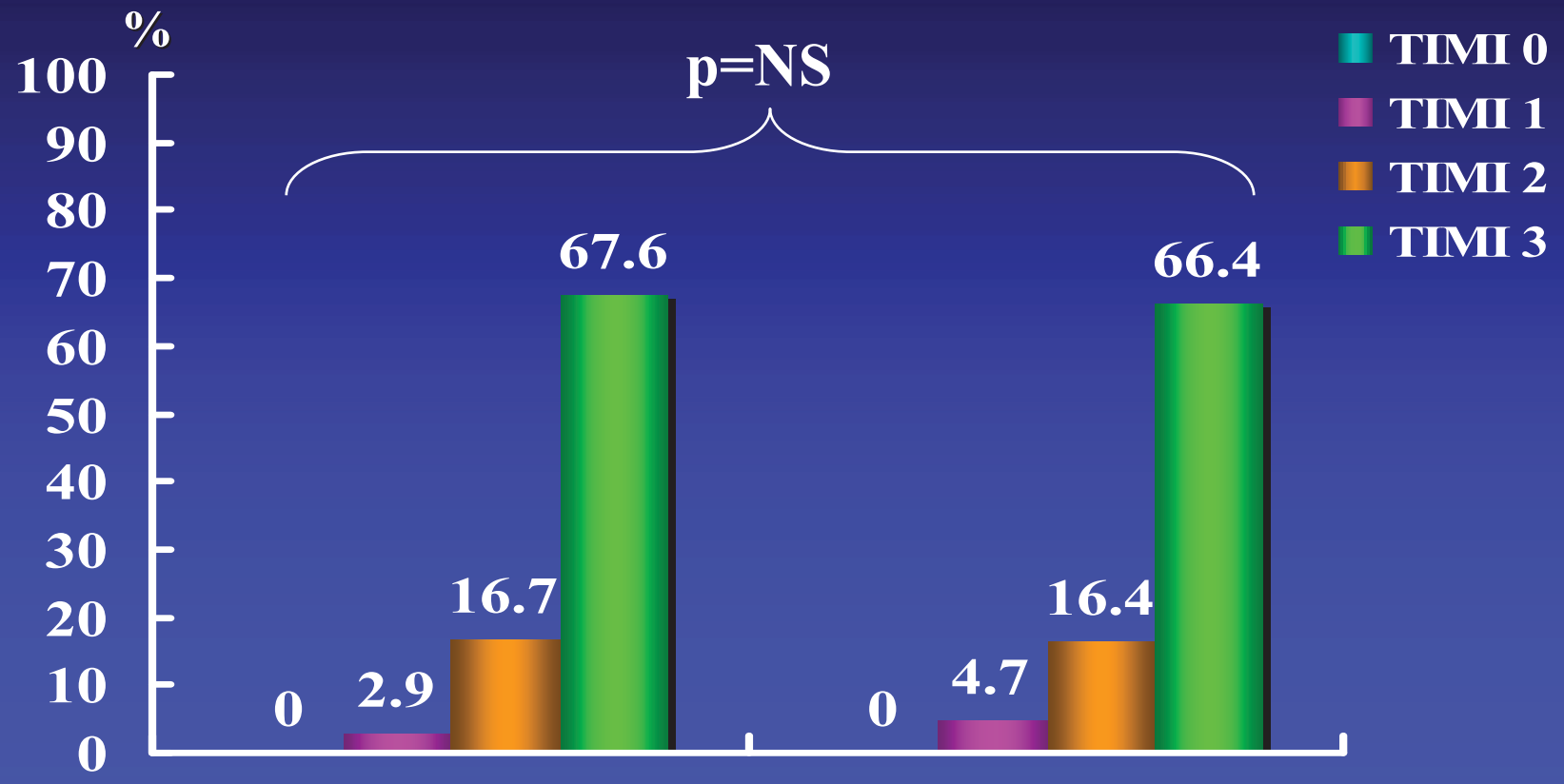
ST Resolution (180min)



Angiographic Results

Post-procedural TIMI flow



CTFC	24.0±12.3	22.6±11.2	p=NS

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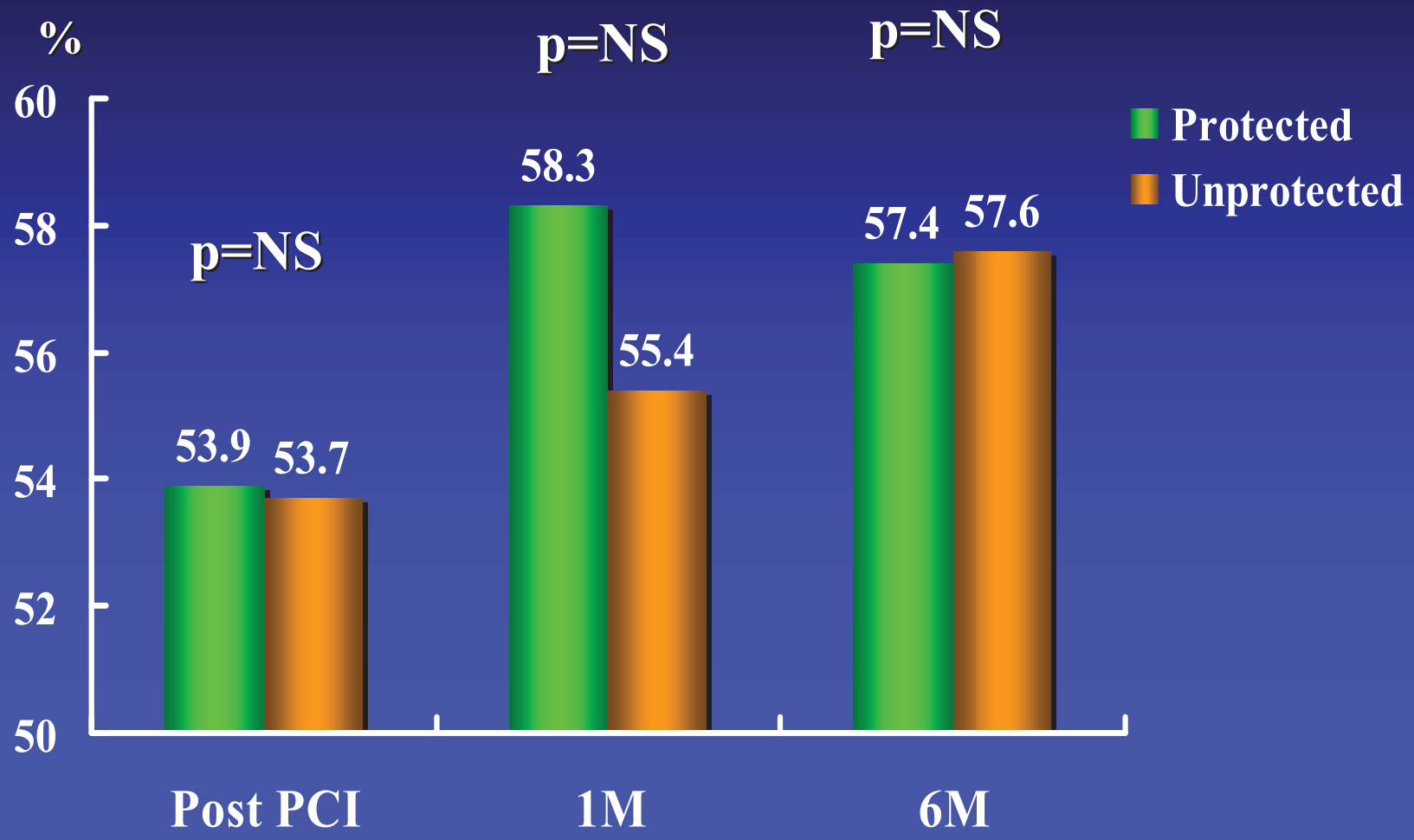
LVEF



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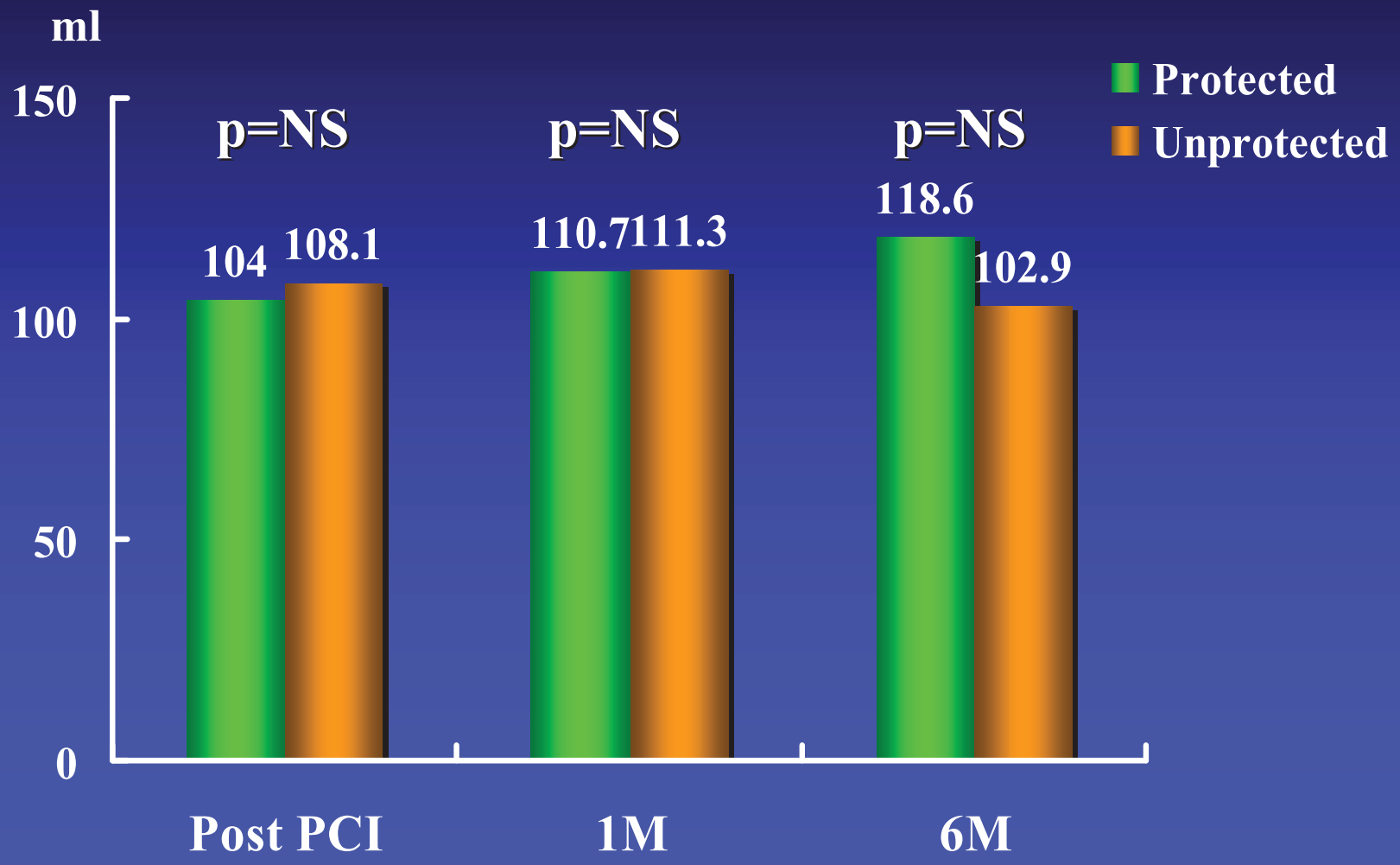
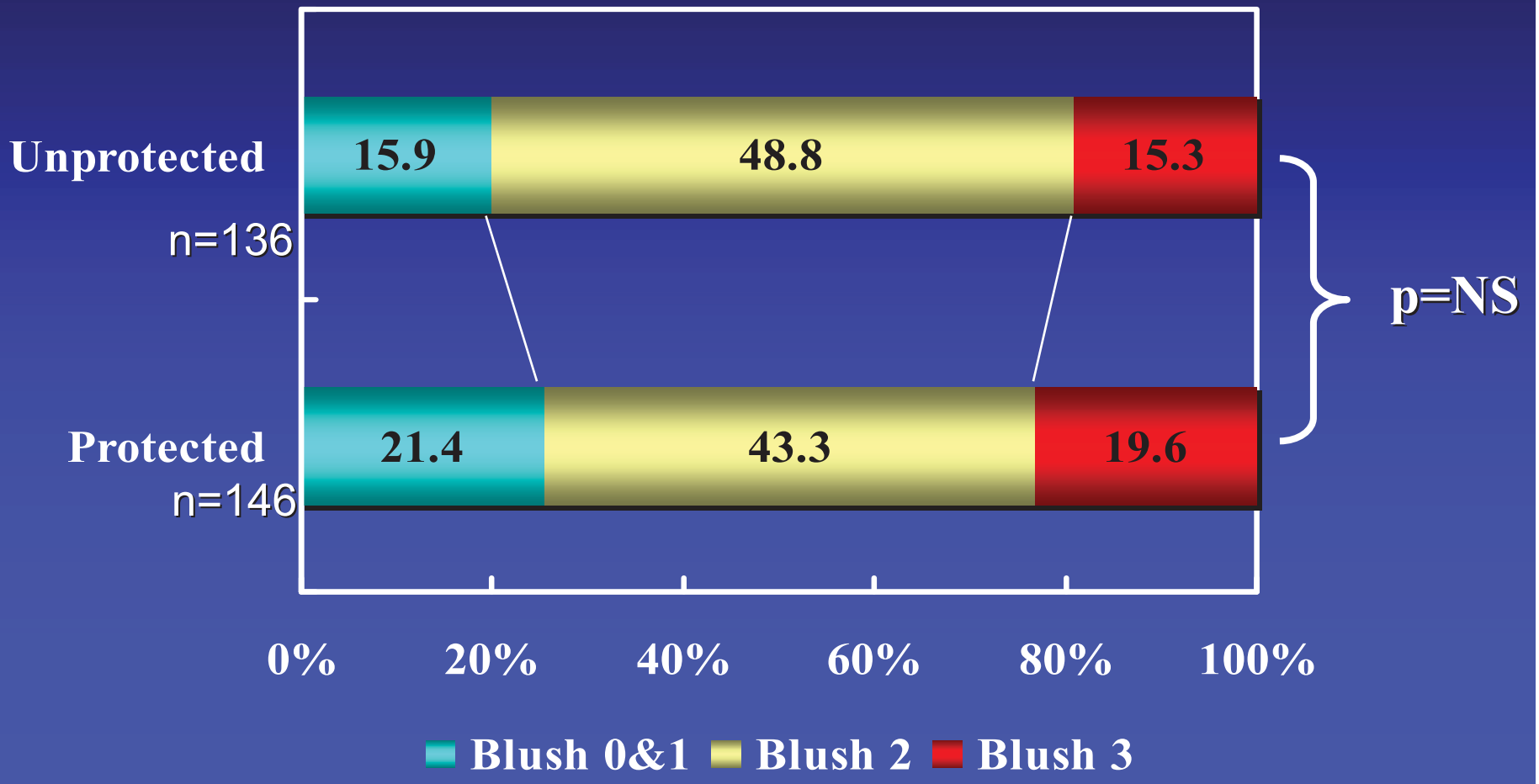
LVEDV



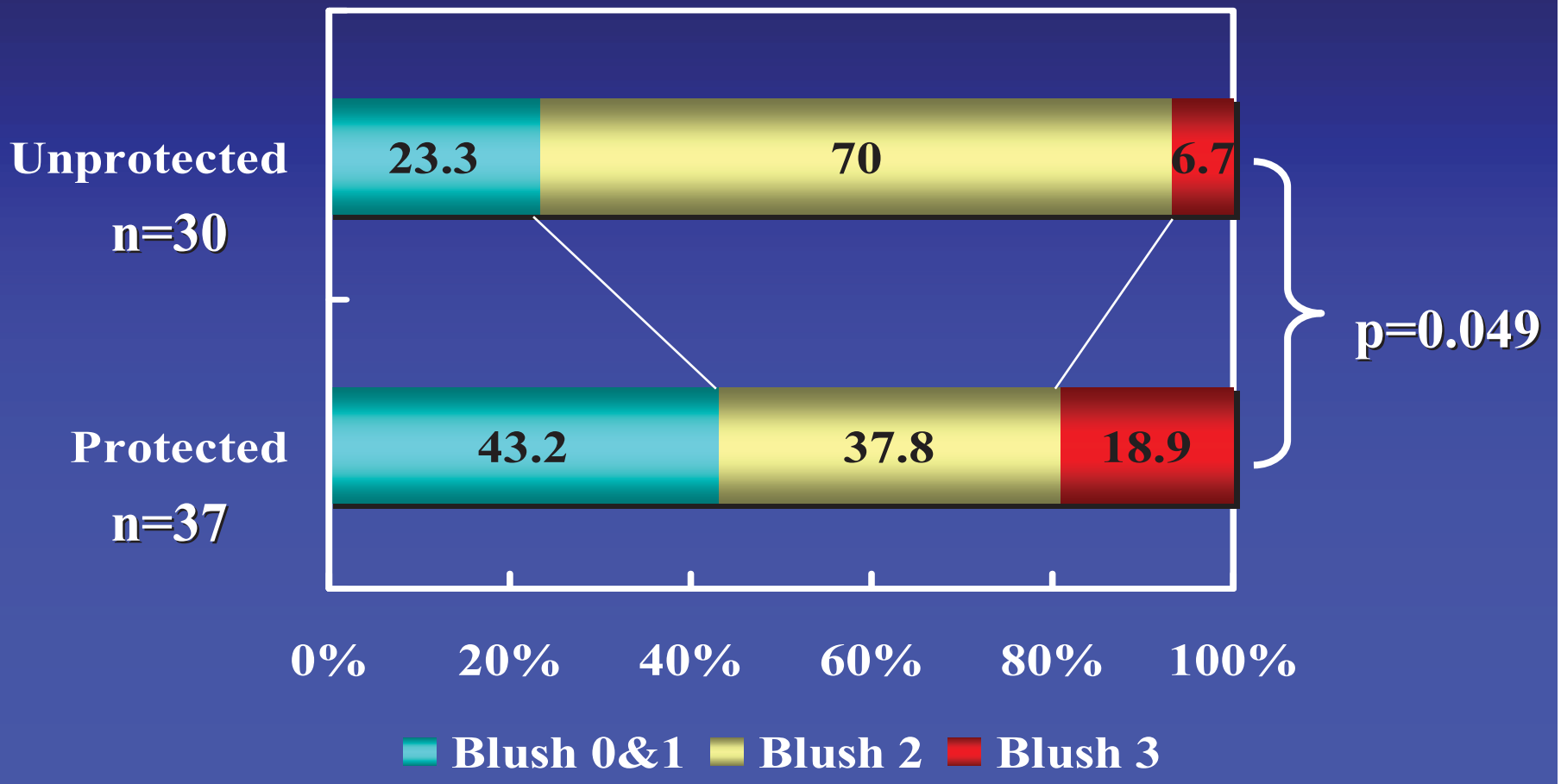
Angiographic Results

Post-procedural Blush Score



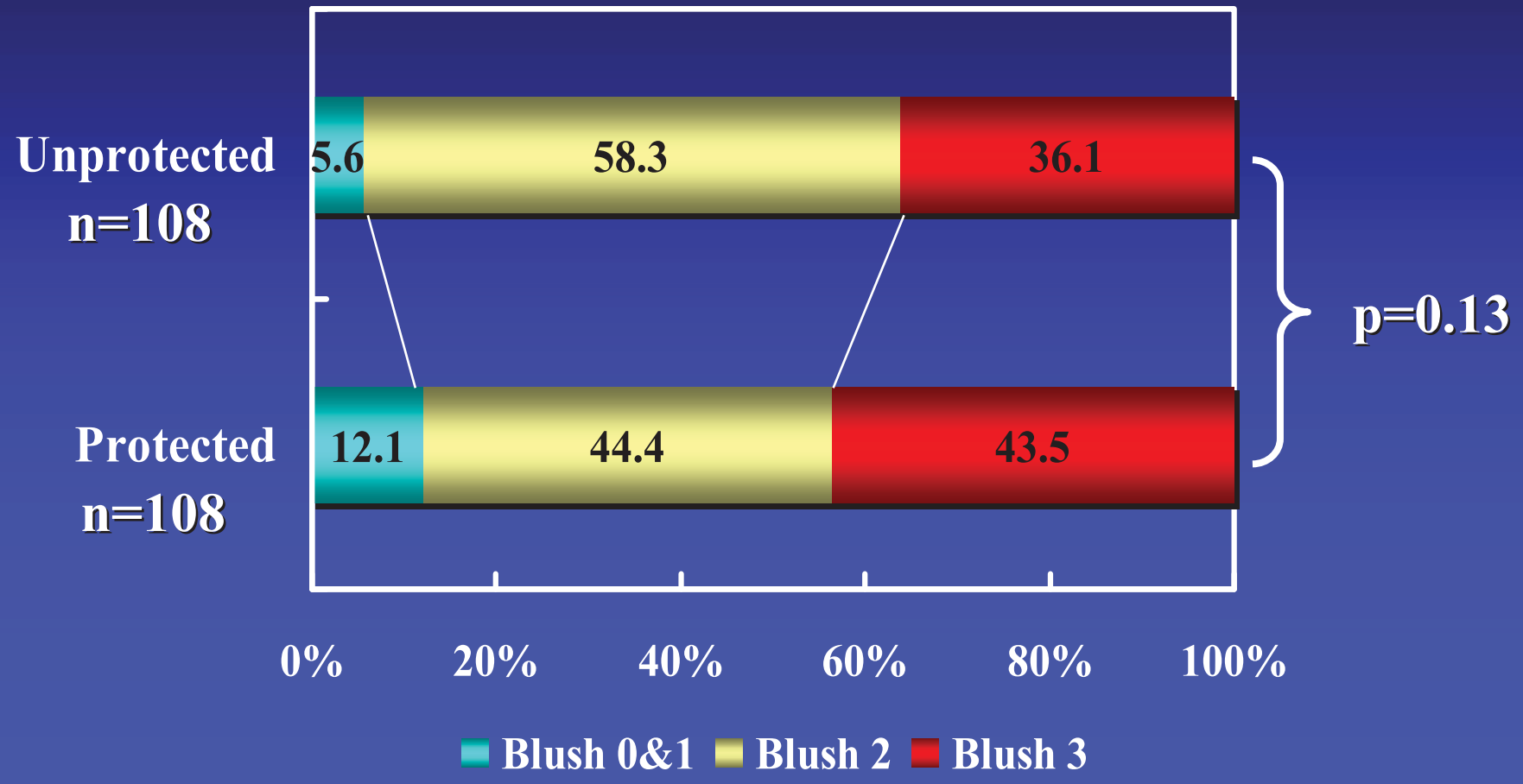
Angiographic Results

Post-procedural Blush Score (Prox. RCA only)



Angiographic Results

Blush Score at 30 days



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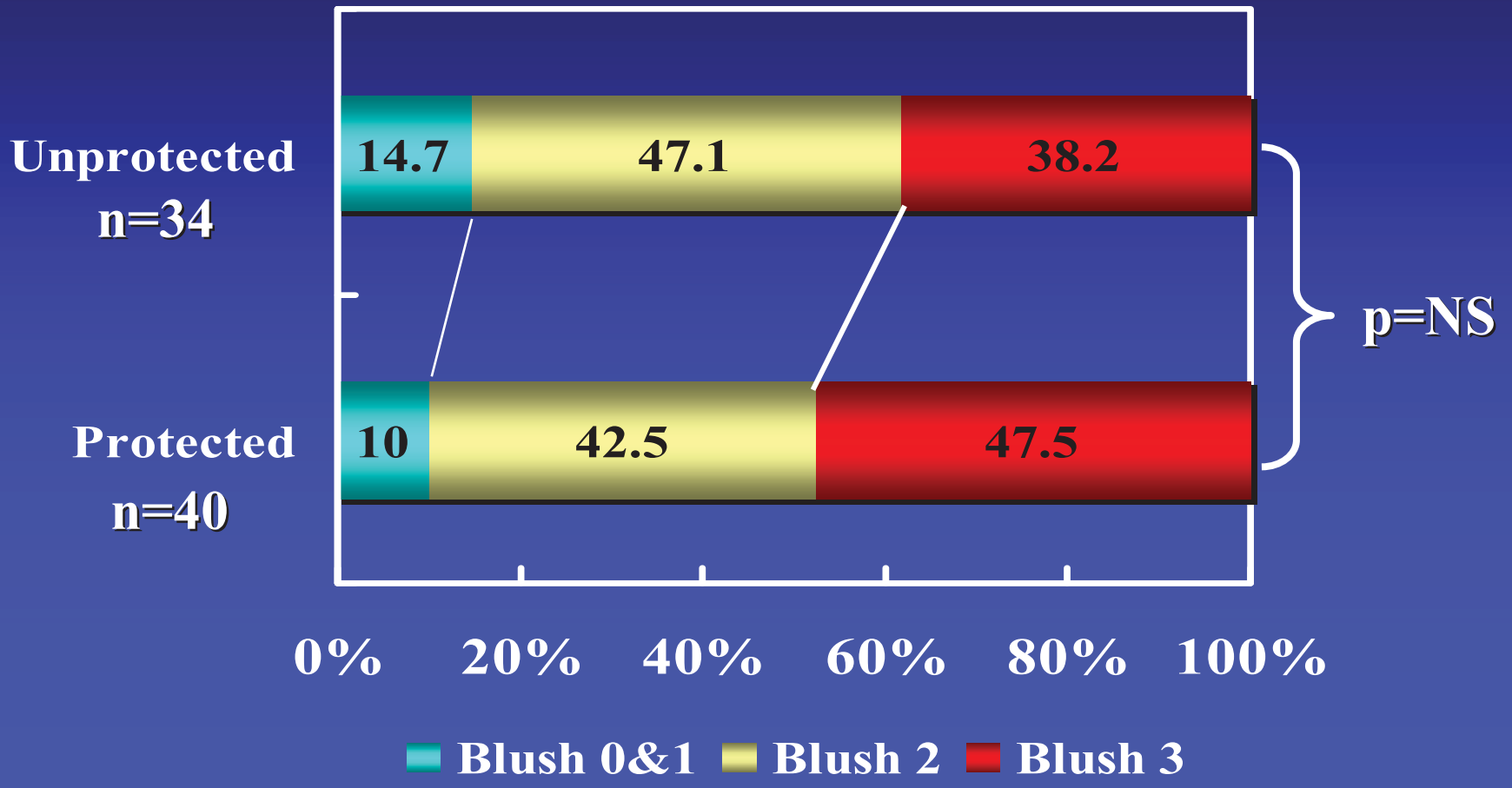
Angiographic Results

Blush Score at 6 month (preliminary data)



Angiographic Results

QCA at 6 month (preliminary data)

		Protected (N=173)	Unprotected (N=165)
Ref. Vessel Diam. (mm)		2.80	2.95
Lesion length (mm)		10.6±5.4	9.2 ±5.2
Diameter stenosis (%)	pre	87 ±18	89 ±16
	post	19 ±11	20 ±13
	1Mo	19 ±14	19 ±15
	6Mo	33 ±21	36 ±21
MLD (mm)	pre	0.32 ±0.49	0.27 ±0.42
	post	2.47 ±0.59	2.40 ±0.52
	1Mo	2.55 ±0.66	2.44 ±0.63
	6Mo	1.84 ±0.74	1.66 ±0.63
Binary restenosis (%) (n=88)		16.4	24.5

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Conclusions

- A preliminary interim analysis of the Japanese multicenter ASPARAGUS trial has been demonstrated
- The frequency of in-hospital MACE was similar among the protected and control groups, which may indicate that there was no detrimental influence associated with PercuSurge system
- A tendency to have higher incidence of Blush 3 has been observed in the group treated with distal protection device, especially in the cases with proximal RCA lesions

Myocardial Blush Scores

- Two studies have demonstrated that normal blush scores are achieved in only 19-28% of patients even though TIMI-3 flow was achieved in 77-89%
  - Reduced or absent blush correlated with persistent ST elevation, larger infarcts and higher mortality

	Myocardial Blush Score		
	0/1	2	3
Frequency Achieved			
Stone et al	30%	42%	28%
van't Hof et al	30%	51%	19%
Mortality			
Stone et al (1 Yr)	22%	13%	6%
van't Hof et al (1.9 Yrs)	23%	6%	3%