



**Effect of GuardWire® Temporary Occlusion and Aspiration System in Primary Stenting of Acute STEMI**  
**-Intracoronary Flow Study-**

*Seung-Jea Tahk MD., PhD.*  
*Ajou University Medical Center*  
*Suwon, Korea*

*On Behalf of Korean Randomized Multicenter Study Group*

**Defending the Microcirculation**  
**Distal Protection and Thrombectomy Devices**  
**Angioplasty Summit 2004**



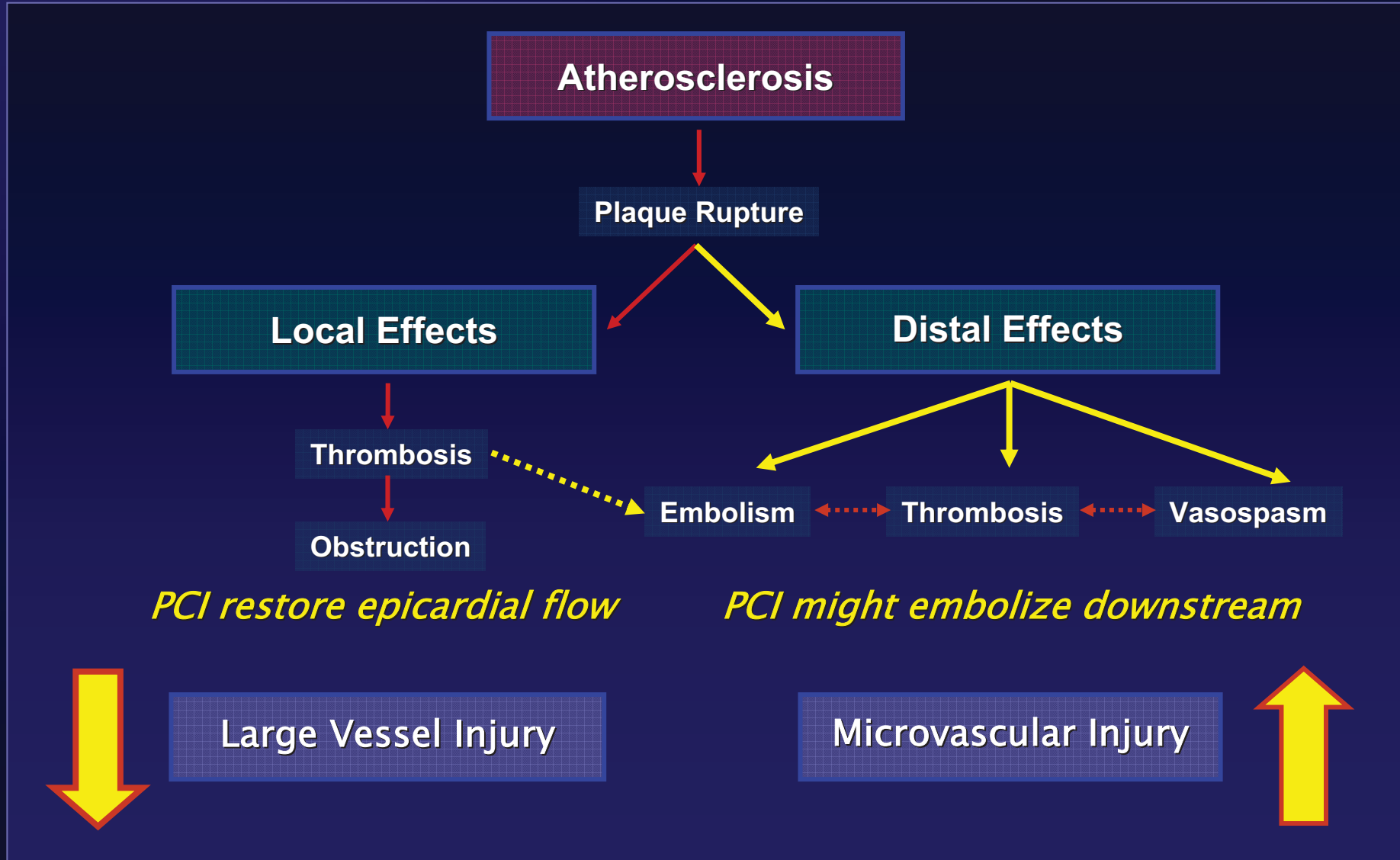
Tiempo

## Improving Mechanical Reperfusion in Acute STEMI

- Reperfuse more patients with primary stenting.
  - Stent implantation should be considered as the default reperfusion therapy.
  
- Reperfuse as fast as possible.
  - Faster is better!
  
- **Now, how to reperfuse better?**

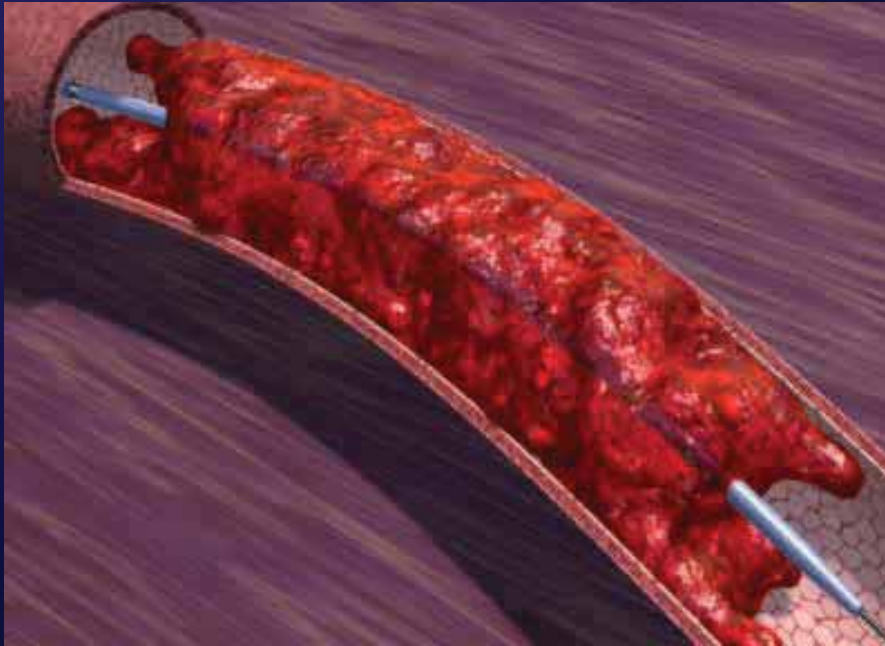


# Potential Effects of PCI in Acute Coronary Syndrome

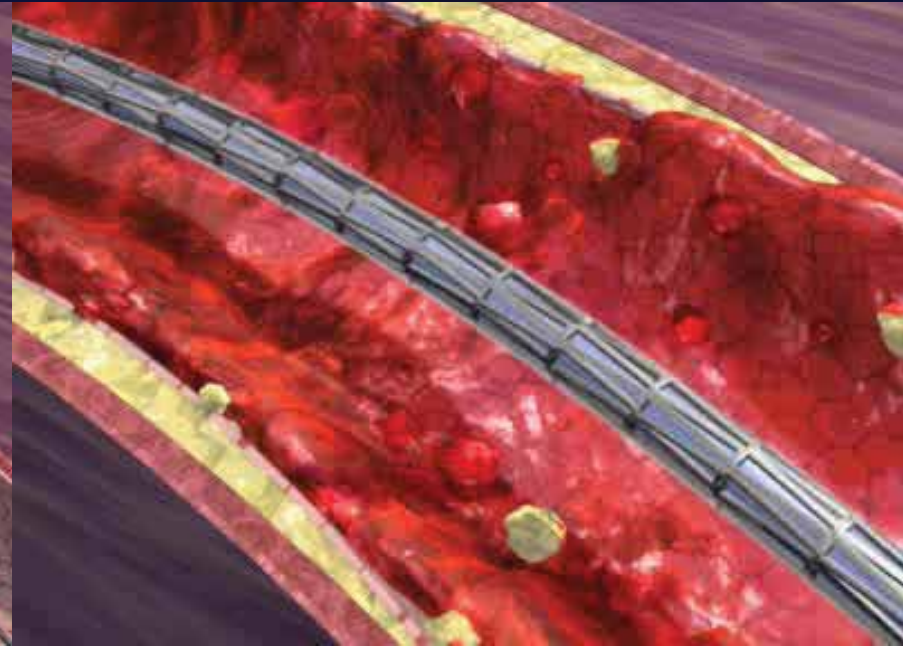




## Potential Effects of PCI in Acute Coronary Syndrome



Balloon in Thrombus



Stent in Thrombus "Cheese Grater Effect"

Intervention in thrombotic lesions might send thrombus and debris into the microvasculature, blocking flow downstream.

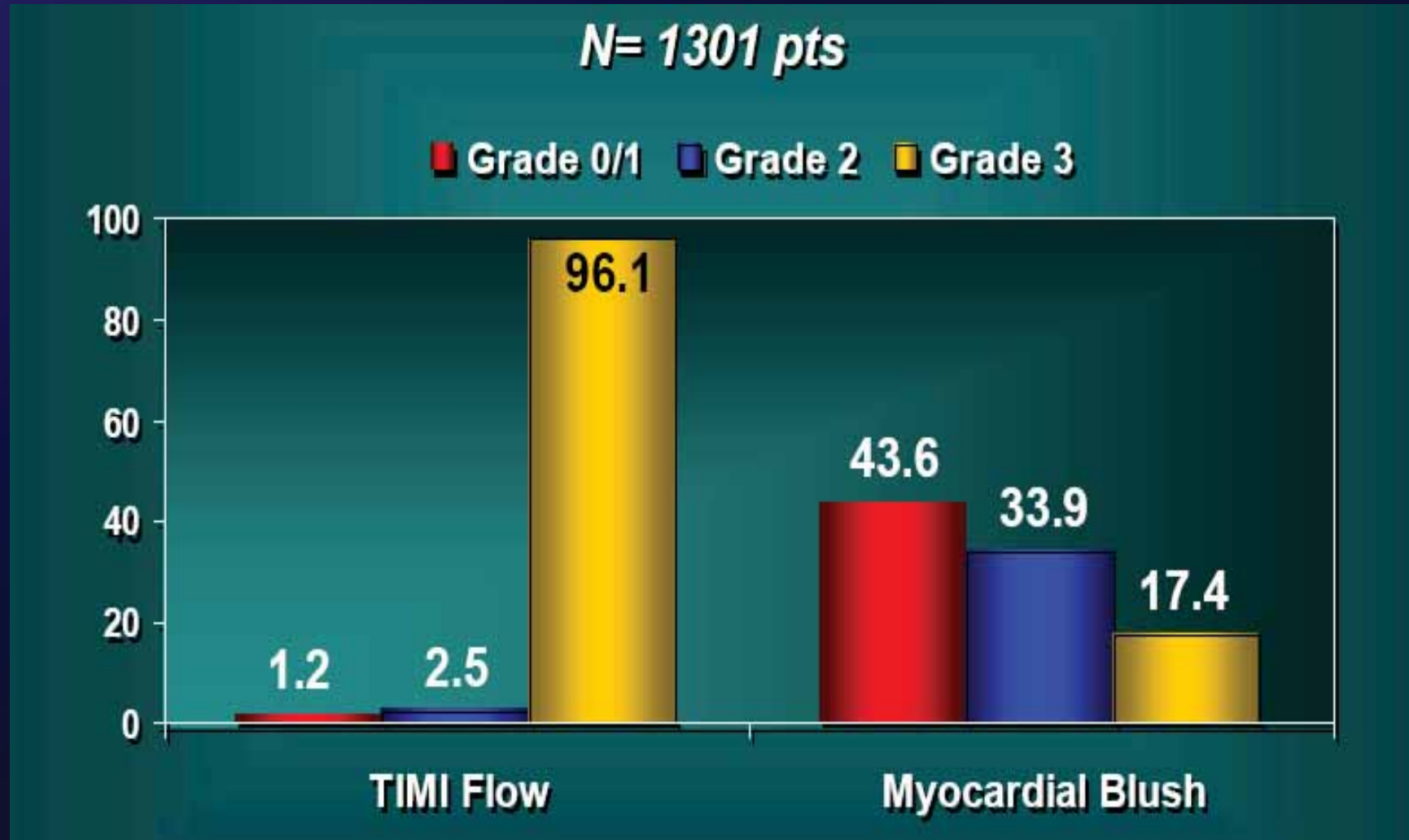
## Angiographic Distal Macroembolization during Primary PCI

- Incidence: 15.2%
- Predictor of more extensive myocardial damage and worse prognosis.

	Embolization	NO	p value
<b>TIMI 3 Flow (%)</b>	<b>70</b>	<b>90</b>	<b>0.01</b>
<b>Myocardial Blush (%)</b>			
0/1	68	17	0.01
2	32	55	0.05
3	0	28	0.05
<b>ST Segment Resolution &gt;50% (%)</b>	<b>64</b>	<b>90</b>	<b>0.001</b>
<b>LVEF at discharge (%)</b>	<b>42 ± 14</b>	<b>52 ± 9</b>	<b>0.005</b>
<b>5-year Clinical FU</b>			
<b>Mortality (%)</b>	<b>44</b>	<b>9</b>	<b>0.001</b>
<b>Death/Recurrent MI (%)</b>	<b>52</b>	<b>14</b>	<b>0.001</b>

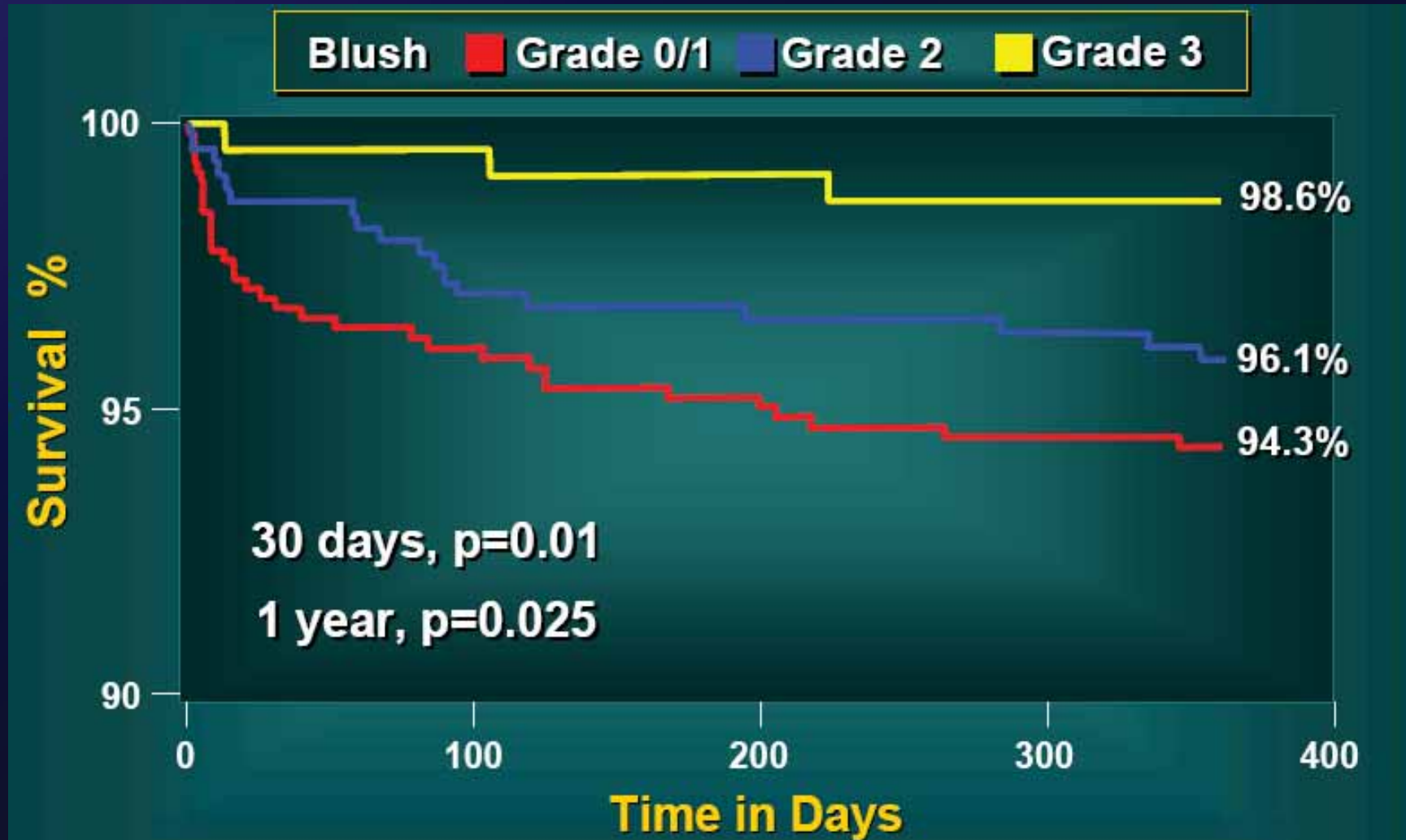
# CADILLAC

## Final TIMI Flow and Myocardial Blush Score

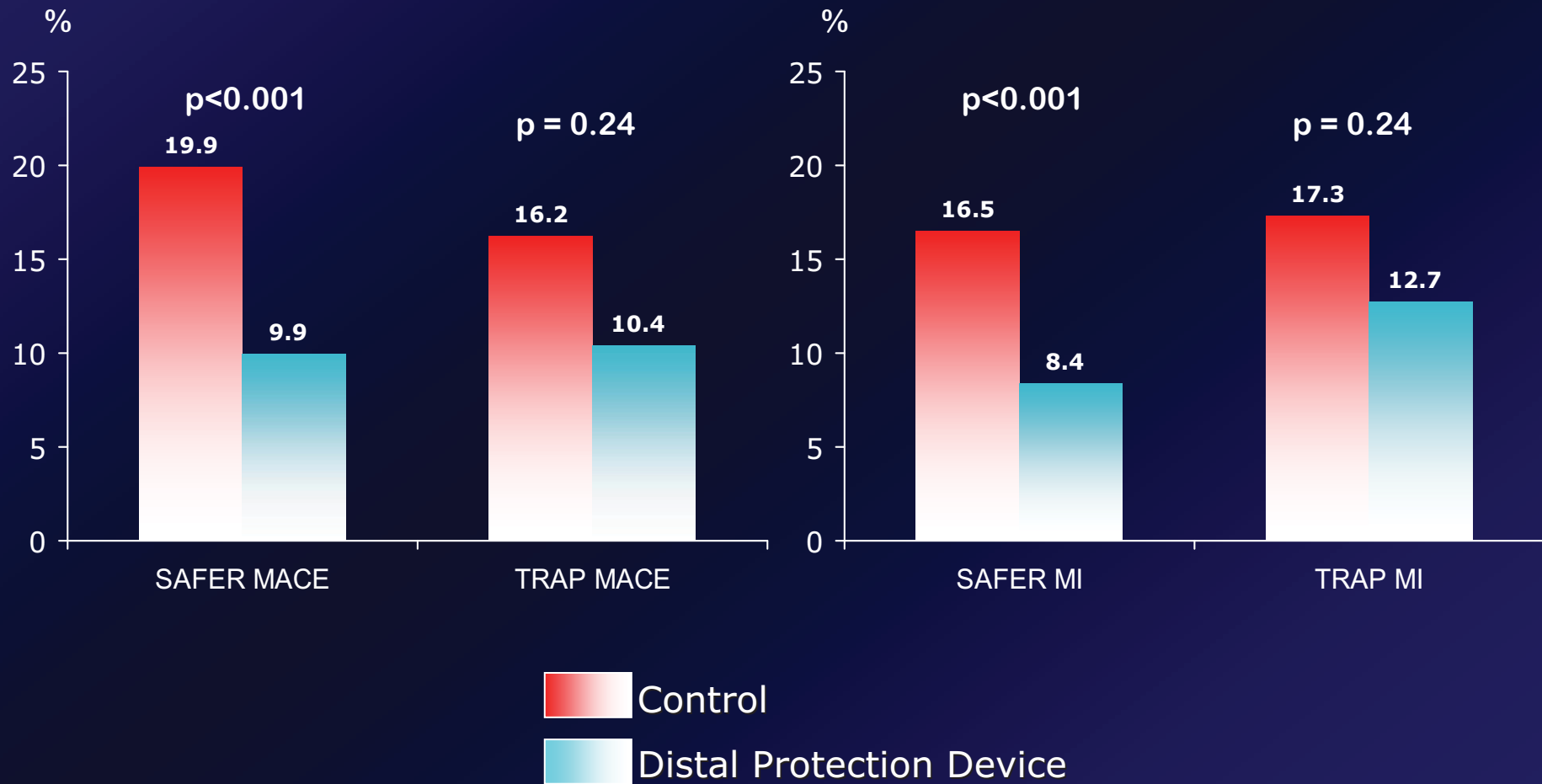


# CADILLAC

## Survival in Patients with Final TIMI 3 Flow



# SVG Angioplasty Effect of Distal Protection





## Interim Result of Korean Randomized Multicenter Study *Distal Protection during Primary Stenting in Acute STEMI*

- **Ajou University Medical Center \*** *SJ Tahk, MH Yoon, SY Choi*
- **Keimyung University Donsang Medical Center** *KB Kim, SH Hur*
- **Seungkyunkwan University Samsung Medical Center \*** *HC Geon*
- **Seoul National University Bundang Hospital** *IH Chae*
- **Seoul National University Hospital \*** *MM Lee, BK Ku*
- **YeungNam University Hospital** *YJ Kim, GR Hong*
- **Yonsei University Cardiovascular Center \*** *YS Jang*
- **Yonsei University Wonju Christian Hospital** *JH Yoon, SW Lee*

\* Doppler Center

## **Presenter Disclosure Information**

**Dr. Seung-Jea Tahk has the following relationships that might materially affect this presentation**

**Grant/Research Support: MEDTRONIC Korea**



## Study Hypothesis

- **Myocardial reperfusion after primary PCI in AMI is often suboptimal, as evidenced by persistent ST elevation, abnormal myocardial blush, unfavorable coronary flow pattern, which result in increased infarct size and mortality.**
- **Potentialiation of bulk emboli and additional microvascular injury during PCI is one of potential mechanism.**
- **Distal protection devices may be beneficial for the protection of microvascular integrity of myocardium.**

## Patients Enrollment

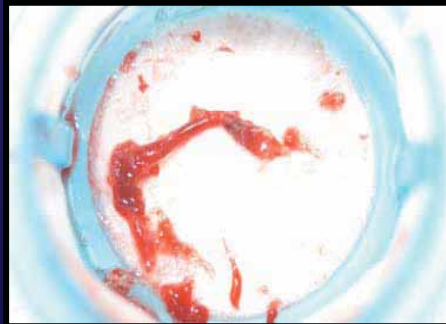
- **Prospective randomized multicenter trial**
  - **Primary stenting with distal protection vs. without protection**
- **Inclusion Criteria**
  - **Acute STEMI <12 hours from onset with persistent chest pain**
  - **Significant proximal stenosis (>70% in DS), eligible for stenting and flow study**
  - **Final diameter stenosis after baremetal stenting <30%**
- **Exclusion Criteria**
  - **Cardiogenic shock**
  - **Left main disease**
  - **Sustained atrial fibrillation, supraventricular/ventricular tachycardia or heart block requiring pacing.**

## Antithrombotic Regimen

- **Oral Antiplatelet Agents**
  - Aspirin 300mg at ER, 100mg indefinitely
  - Clopidogrel 600mg at ER, 75mg > 1 month
  
- **IV Heparinization**
  - During procedure: ACT>300
  
- **Use of GPIIb/IIIa inhibitors is strongly discouraged**



# Primary Stenting with Distal Protection

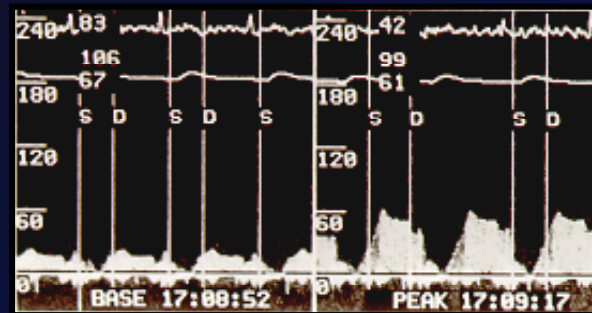


GuardWire® Temporary Occlusion and Aspiration System  
 (Medtronic AVE)  
 GuardWire Temporary Occlusion Catheter  
 Export® Aspiration Catheter



Doppler Guide Wire  
 FloWire™ (Endosnic)  
 FlowWire XT (JOMETRICS)  
 FlowMap® System

Intracoronary Adenosine 24-  
 48µg



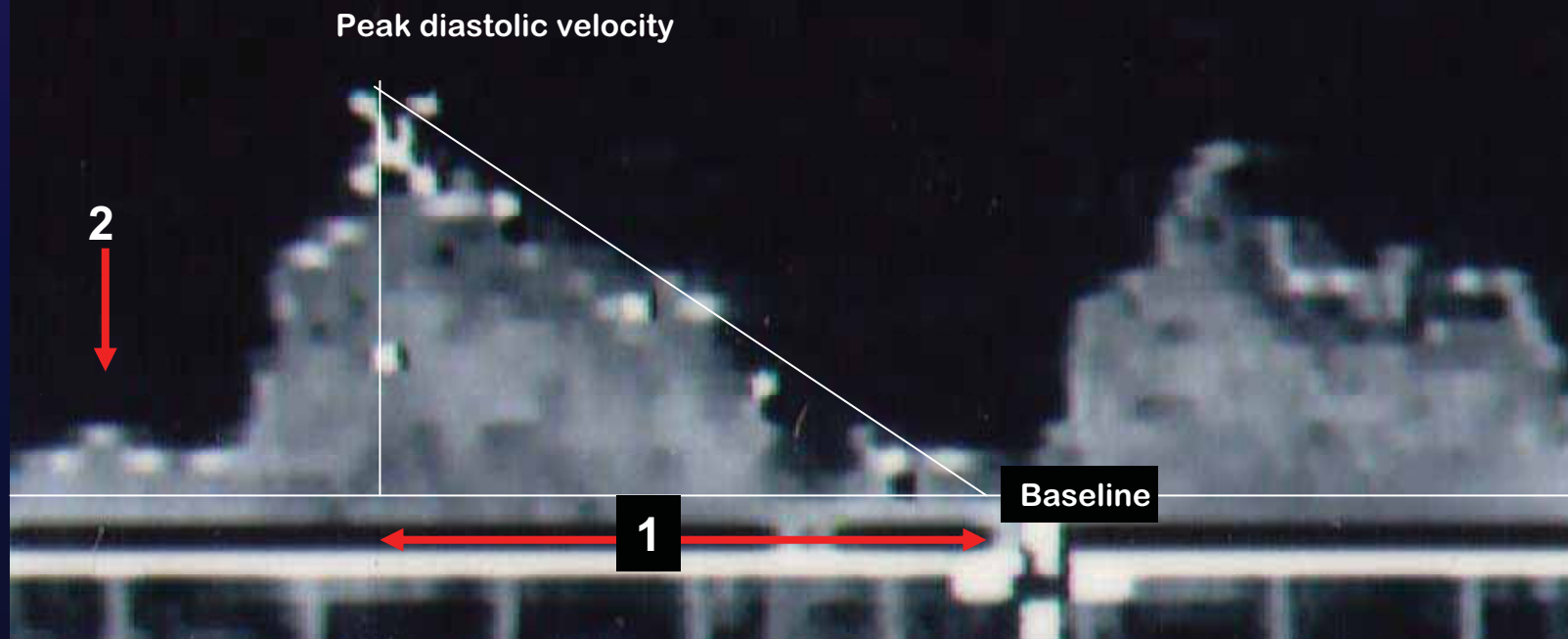
Thrombus aspiration was not permitted before stenting  
 Additional ballooning and stenting was permitted only with GuardWire protection

## Assessment of Myocardial Reperfusion

- **Coronary Angiography**
  - TIMI grade
  - TIMI myocardial perfusion grade
  
- **Coronary flow measurement**
  - Deceleration time of diastolic flow velocity
  - Basal and hyperemic coronary flow velocity
  - Microvascular resistance index
  - Coronary flow velocity reserve

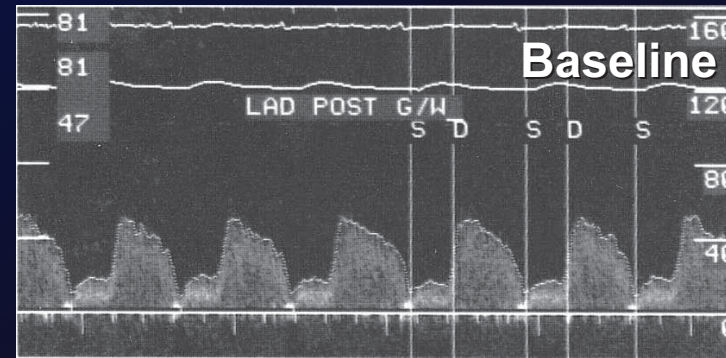
# Deceleration Time of Diastolic Flow Velocity

1. Deceleration Time of Diastolic Flow Velocity
2. Systolic Average Peak Velocity

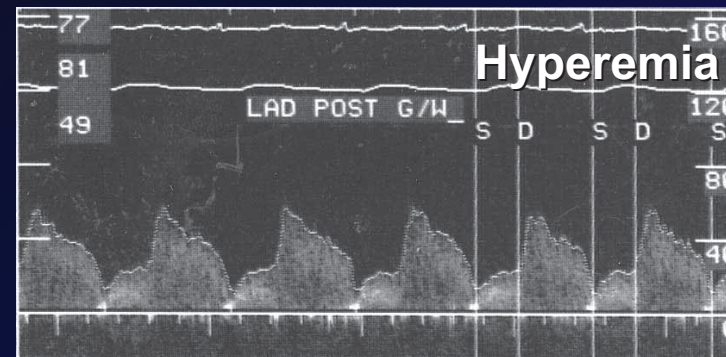


*T. Kawamoto et al. Circulation 1999*

# Flow Study: Anterior MI with distal protection device



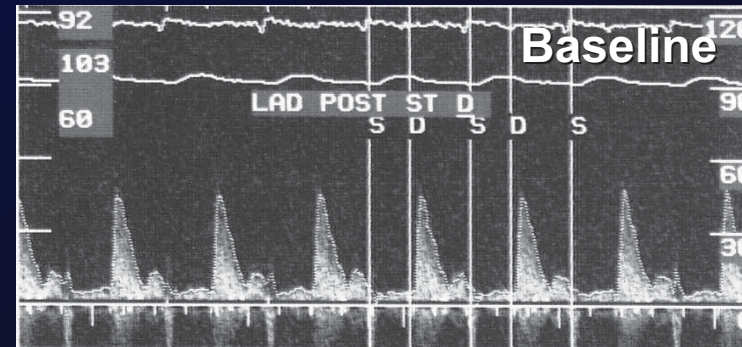
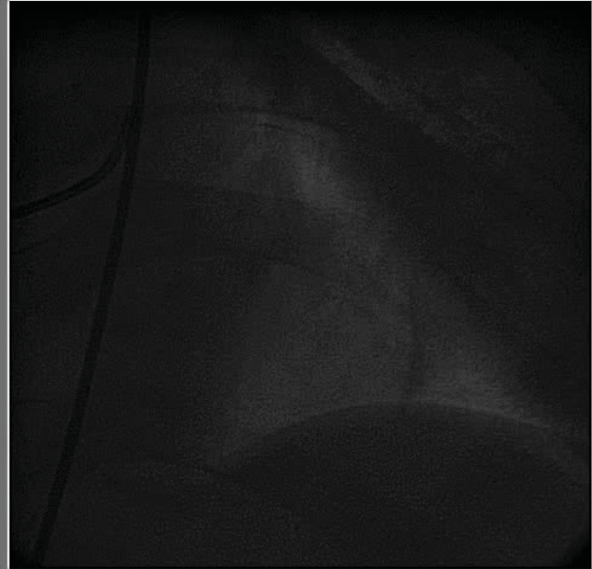
**APV 30 cm/s**  
**SAPV 17 cm/s**  
**DDT 712 ms**



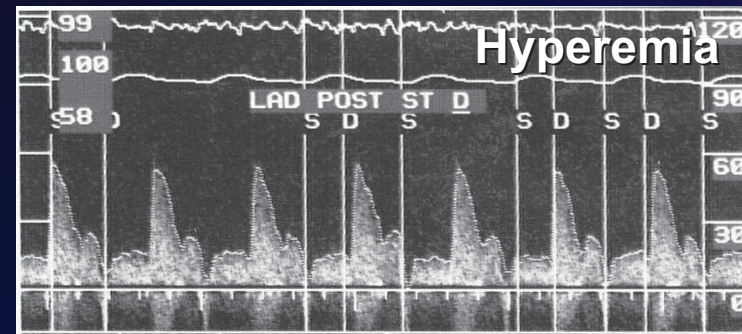
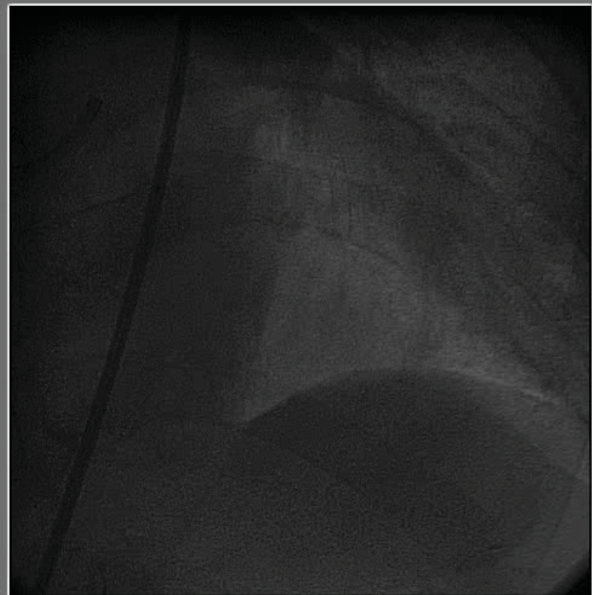
**APV 41 cm/s**      **CFR 1.37**  
**SAPV 18 cm/s**  
**DDT 764 msec**



# Flow Study: Anterior MI **without distal protection device**



**APV 12 cm/s**  
**SAPV 4.3 cm/s**  
**DDT 190 ms**



**APV 23 cm/s**      **CFR 1.92**  
**SAPV 13 cm/s**  
**DDT 254 msec**

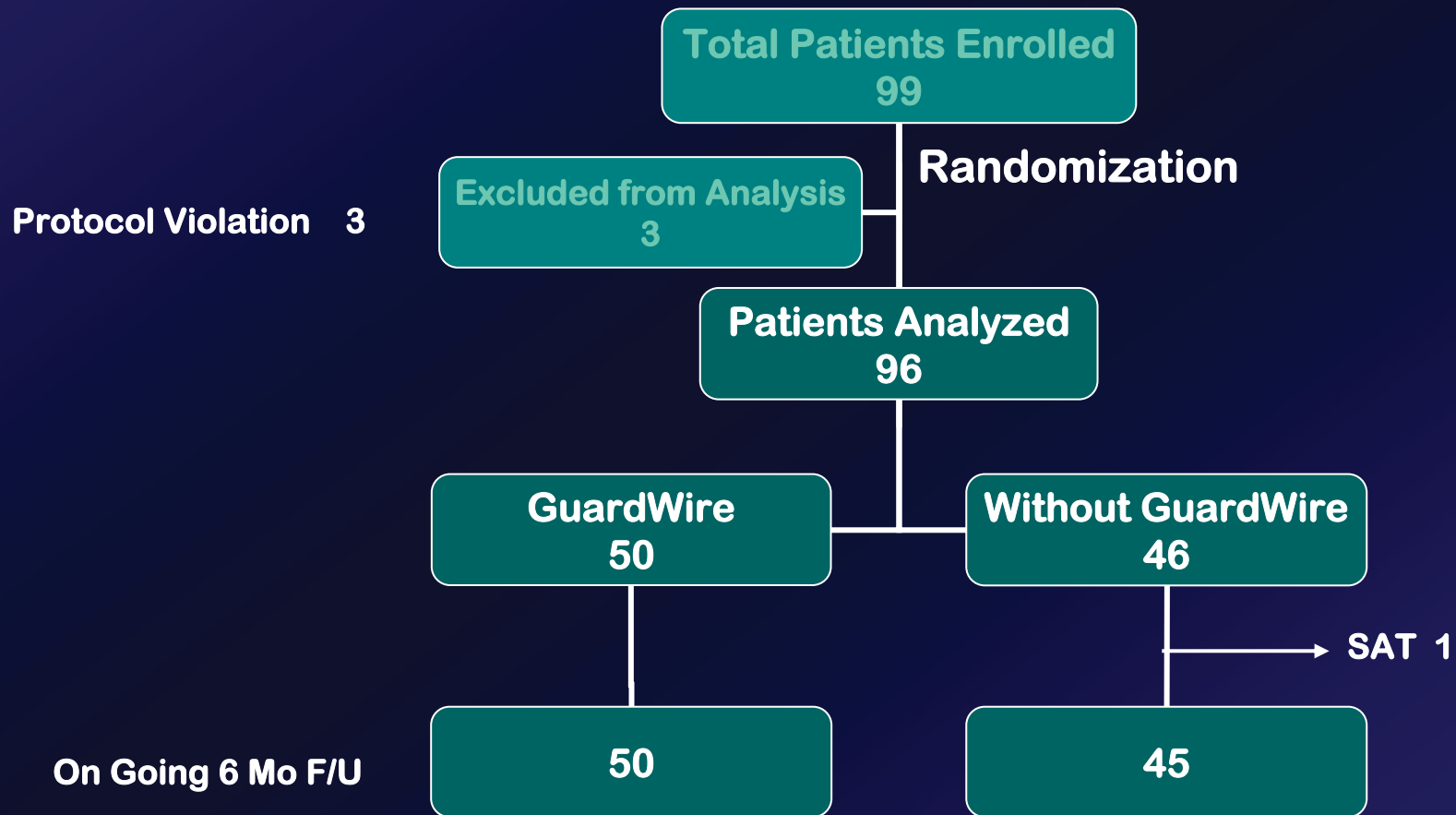


# Study Protocol

## *Data Analysis, Follow Up and End Points*

- Protocol review and angiographic and flow analysis in Core Lab.
- Follow Up
  - In-hospital
  - 1 month: Clinical (visit or telephone call)
  - 6 month: Clinical, echocardiographic, and angiographic follow-up
- Recurrence
  - Clinical Recurrence
  - Recurrence of typical angina
  - Any other evidence of recurrent myocardial ischemia
  - Angiographic restenosis: diameter stenosis > 50%
- End Point
  - MACE: Death, Nonfatal-MI, TLR
  - 6 months follow-up

# Patients Enrollment, Randomization and Follow Up (December 2003 – April 2004)



## Baseline Characteristics

	With GW (n = 50)	Without GW (n = 46)	p Value
Age (yrs)	55 ± 14	58 ± 15	0.948
Gender (Male, %)	41(82%)	32(70%)	0.263
Anterior MI (%)	26(54%)	27(60%)	0.484
<b>Risk Factor</b>			
Hypertension (%)	18(37%)	21(46%)	0.377
DM (%)	11(22%)	8(17%)	0.538
Smoking (%)	33(67%)	27(59%)	0.382
<b>Lipid Profile (mg/dL)</b>			
T. Cholesterol	185 ± 34	194 ± 39	0.380
Triglyceride	139 ± 101	135 ± 94	0.951
LDL-Cholesterol	114 ± 37	126 ± 37	0.756
HDL-Cholesterol	43 ± 11	41 ± 8	0.194
LVEF (%)	53 ± 10	48 ± 10	0.478
LVWMSI	1.41 ± 0.29	1.53 ± 0.32	0.351

## Procedural and Angiographic Findings

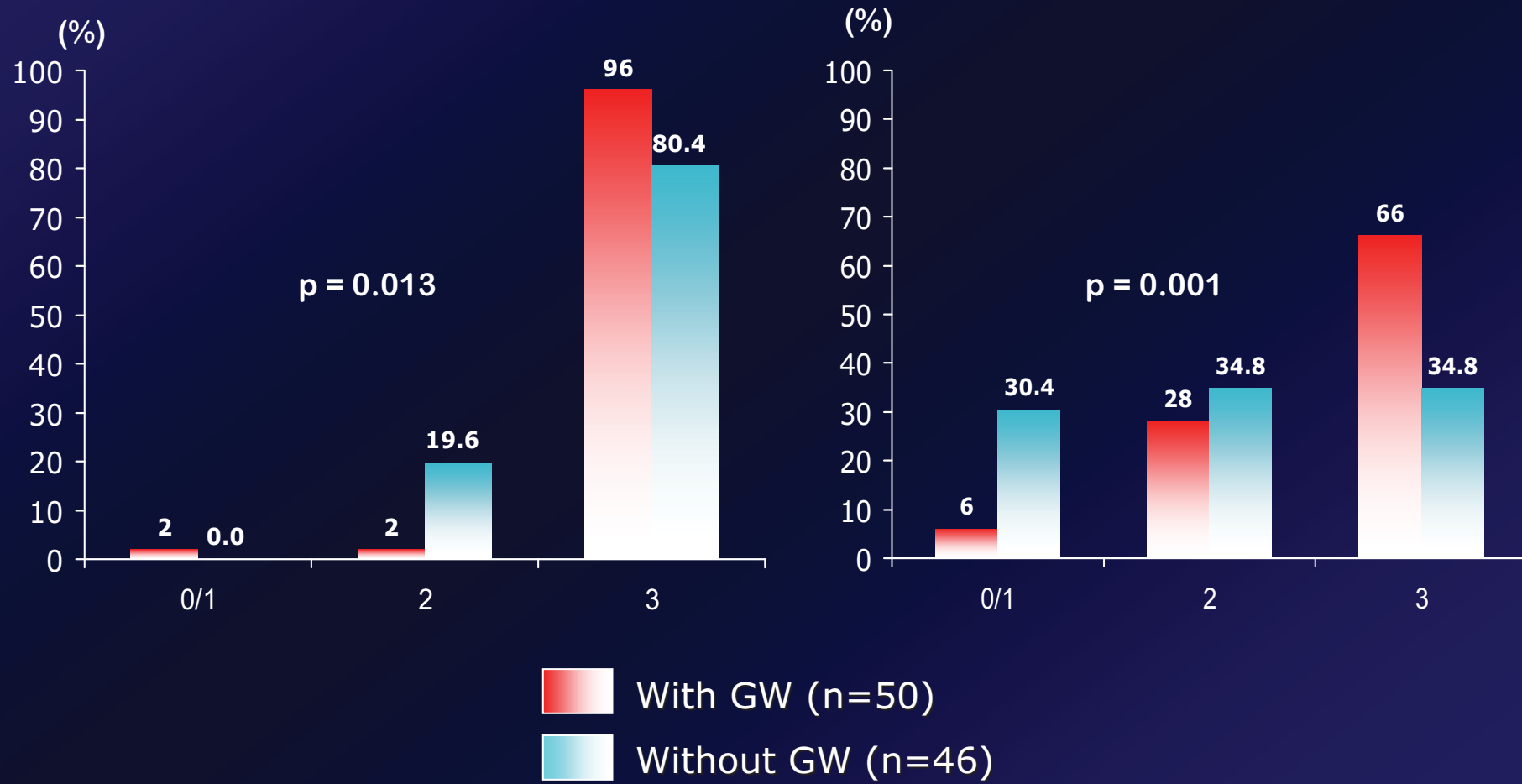
	With GW (n = 50)	Without GW (n = 46)	p Value
<b>Onset to PCI (min)</b>	<b>310 ± 145</b>	<b>315 ± 184</b>	<b>0.947</b>
<b>Pre-Stent</b>			
MLD (mm)	0.19 ± 0.28	0.20 ± 0.41	0.479
DS (%)	95 ± 8	94 ± 12	0.222
<b>Post-Stent</b>			
MLD (mm)	3.1 ± 0.4	3.0 ± 0.5	0.173
DS (%)	10 ± 7	12 ± 9	0.318
<b>Reference Diameter (mm)</b>	<b>3.4 ± 0.4</b>	<b>3.3 ± 0.5</b>	<b>0.099</b>
<b>IRA Studied</b>			<b>0.614</b>
LAD	26(54%)	27(60%)	
LCX	4(8%)	5(11%)	
RCA	19(38%)	13(29%)	

## Post Stent Angiographic TIMI Score and TMP Grades

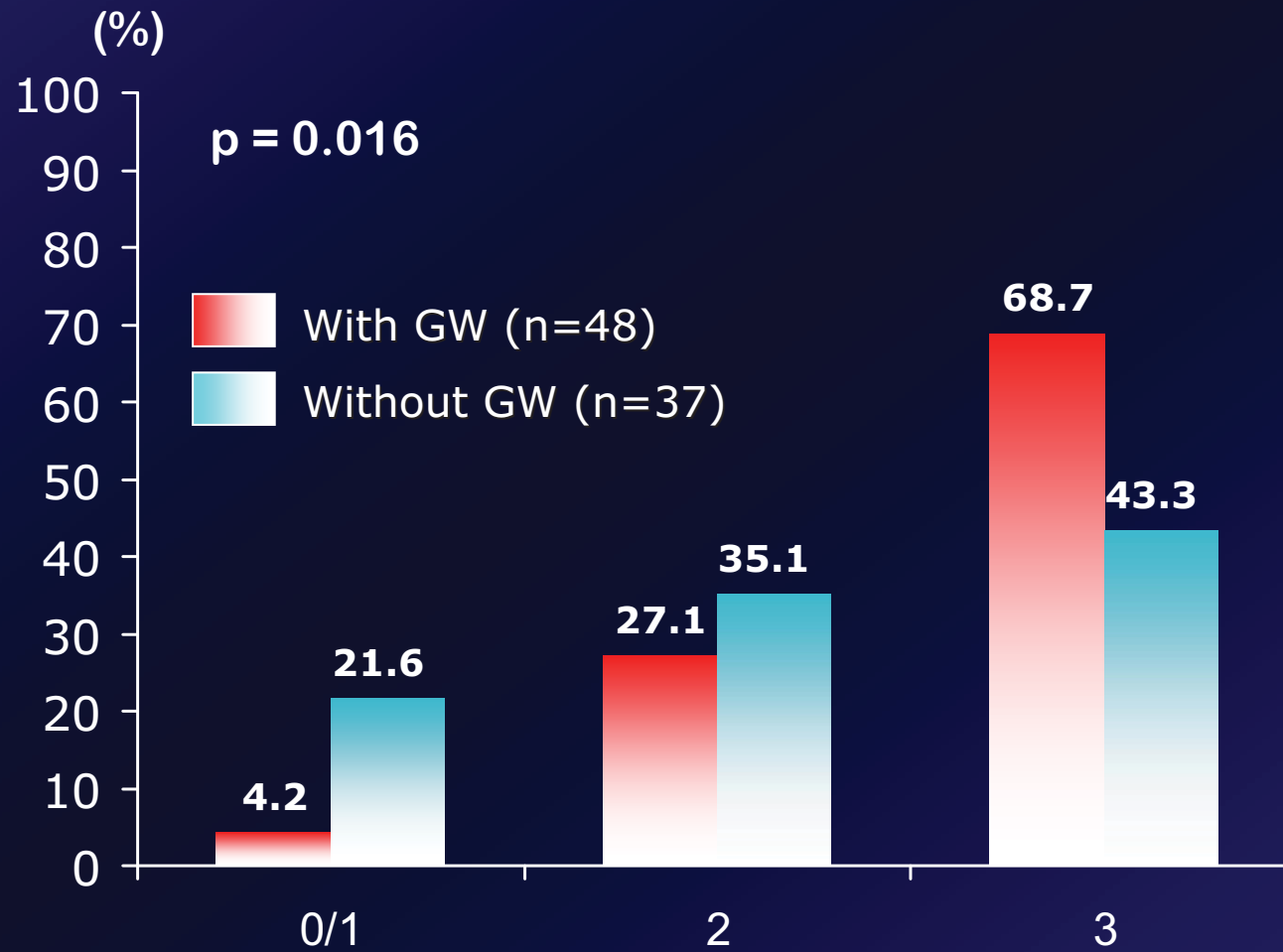
	With GW (n = 50)	Without GW (n = 46)	p Value
<b>TIMI Flow</b>			<b>0.013</b>
TIMI 0/1	1	0	
TIMI 2	1	9	
TIMI 3	48 (96.0%)	37 (80.4%)	
<b>TMP Grades</b>			<b>0.001</b>
TMP 0/1	3	14	
TMP 2	14	16	
TMP 3	33 (66.0%)	16 (34.8%)	



# Post Stent Angiographic TIMI Score and TMP Grade



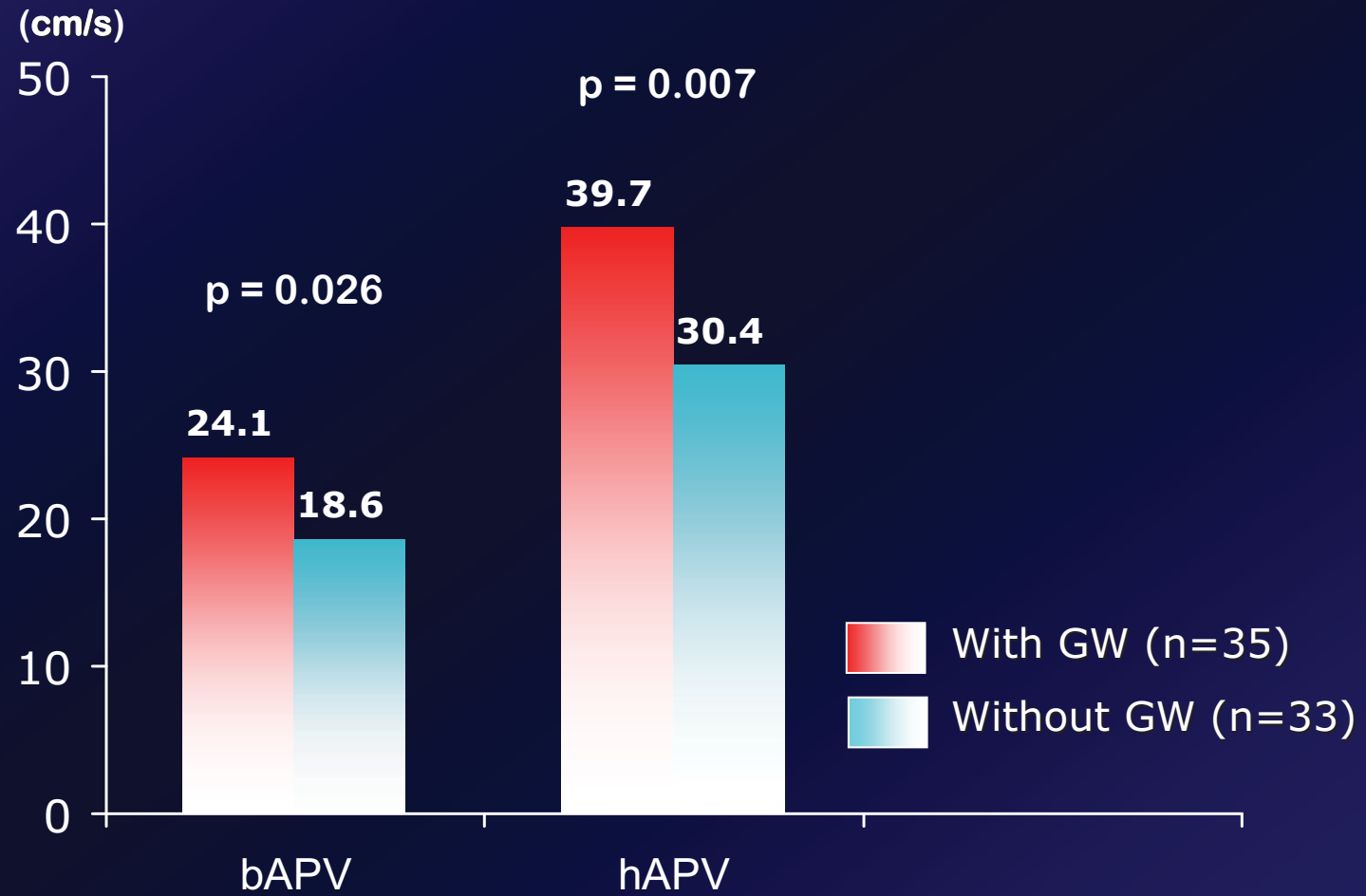
## Post Stent TMP Grade in Patients with TIMI 3 Flow



## Hemodynamic Findings and Coronary Flow Pattern

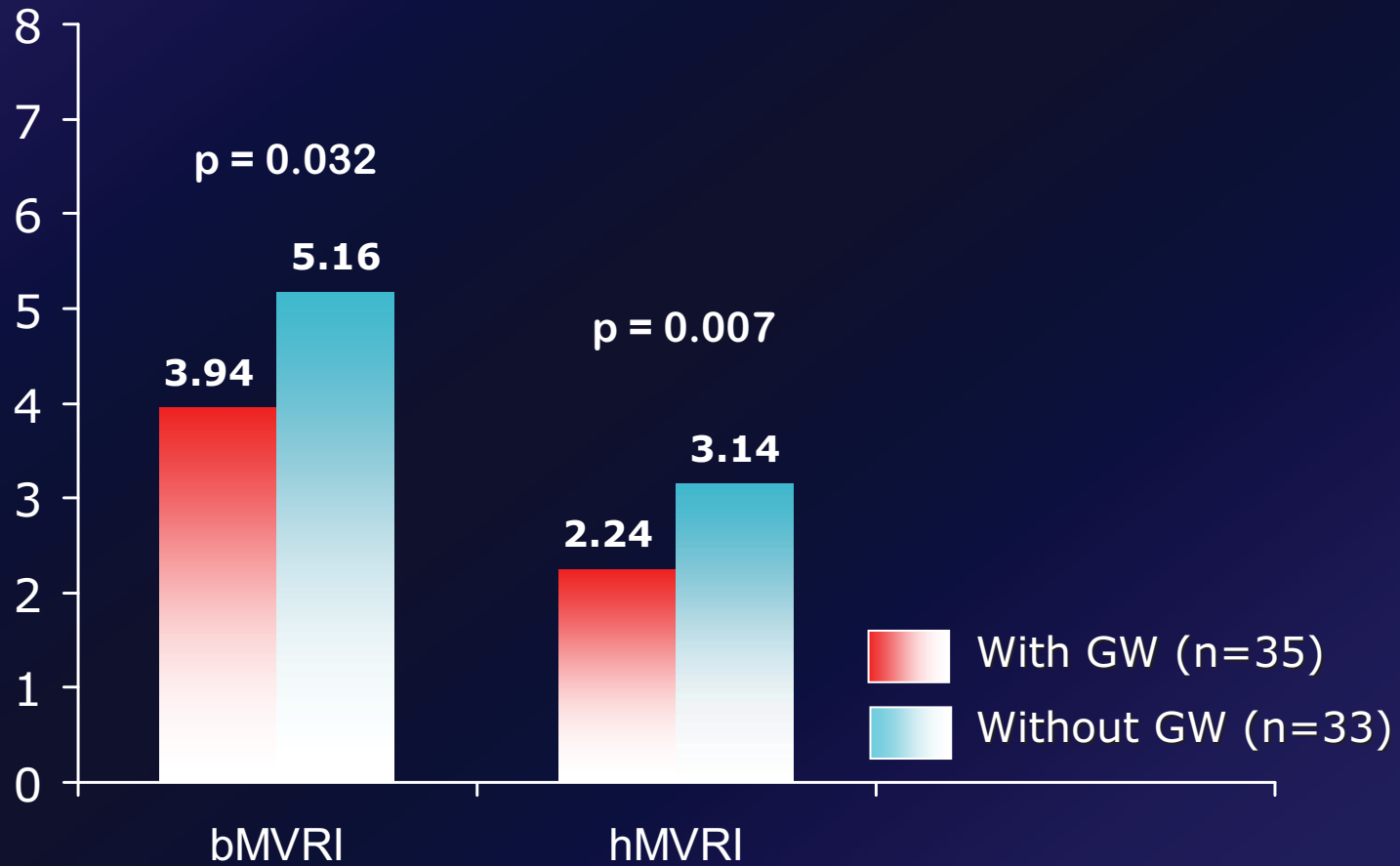
	With GW (n = 35)	Without GW (n = 33)	p Value
Heart Rate (/min)	78 ± 16	78 ± 17	0.859
Mean BP (mmHg)	76 ± 10	84 ± 19	0.040
bAPV (cm/s)	24.1 ± 11.4	18.6 ± 6.9	0.026
hAPV (cm/s)	39.7 ± 14.7	30.4 ± 10.8	0.007
CFR	1.76 ± 0.61	1.71 ± 0.55	0.752
bSAPV (cm/s)	15.1 ± 12.4	11.0 ± 4.6	0.112
hSAPV (cm/s)	28.3 ± 15.0	20.9 ± 9.1	0.029
bMVRI (mmHg•cm <sup>-1</sup> •s <sup>-1</sup> )	3.94 ± 2.12	5.16 ± 2.24	0.032
hMVRI (mmHg•cm <sup>-1</sup> •s <sup>-1</sup> )	2.24 ± 1.21	3.14 ± 1.36	0.007
bDDT (ms)	669 ± 261	519 ± 281	0.026
hDDT (ms)	750 ± 246	616 ± 268	0.035

## Coronary Blood Flow Velocity



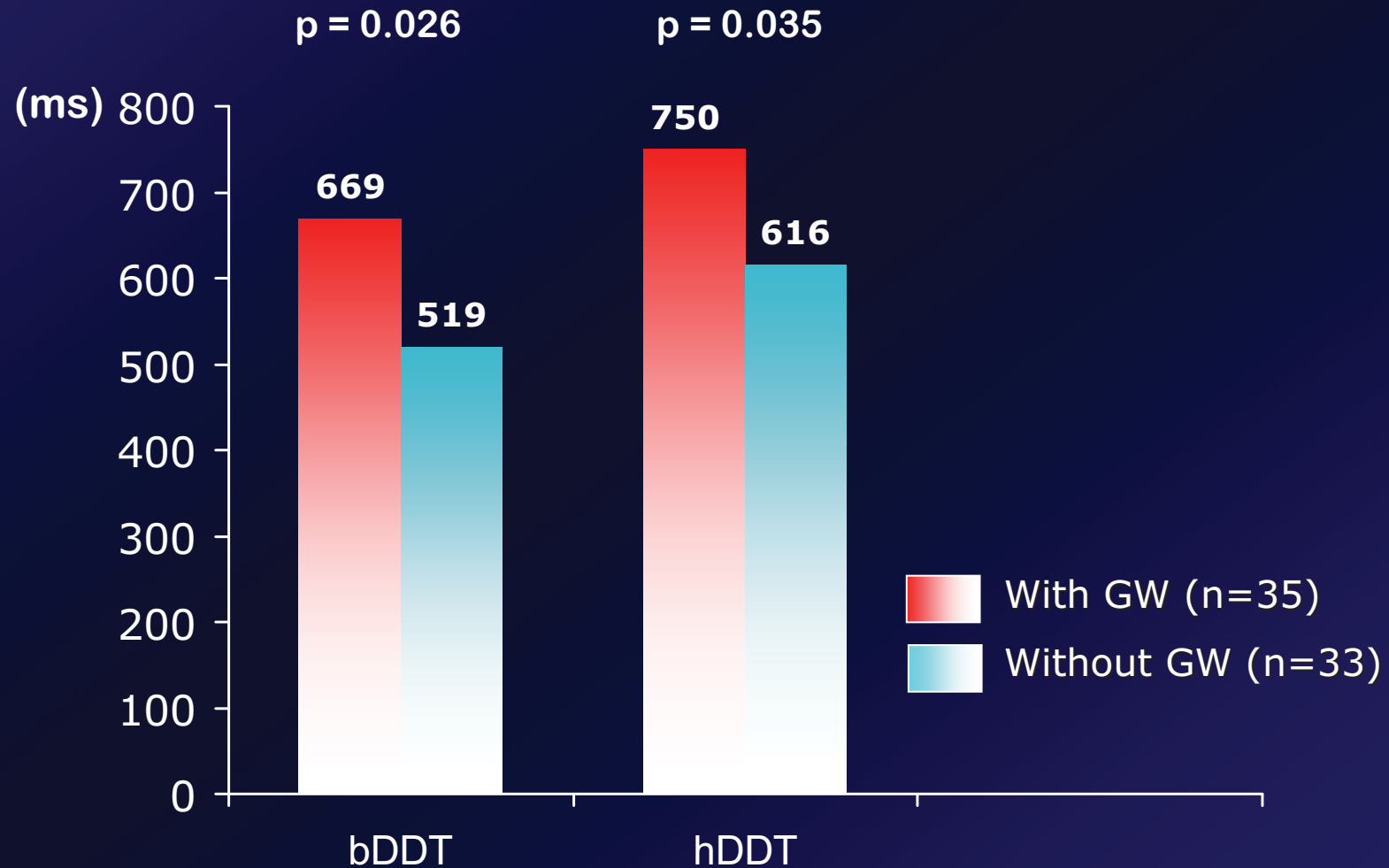
# Microvascular Resistance Index

(mmHg·cm<sup>-1</sup>·s<sup>-1</sup>)

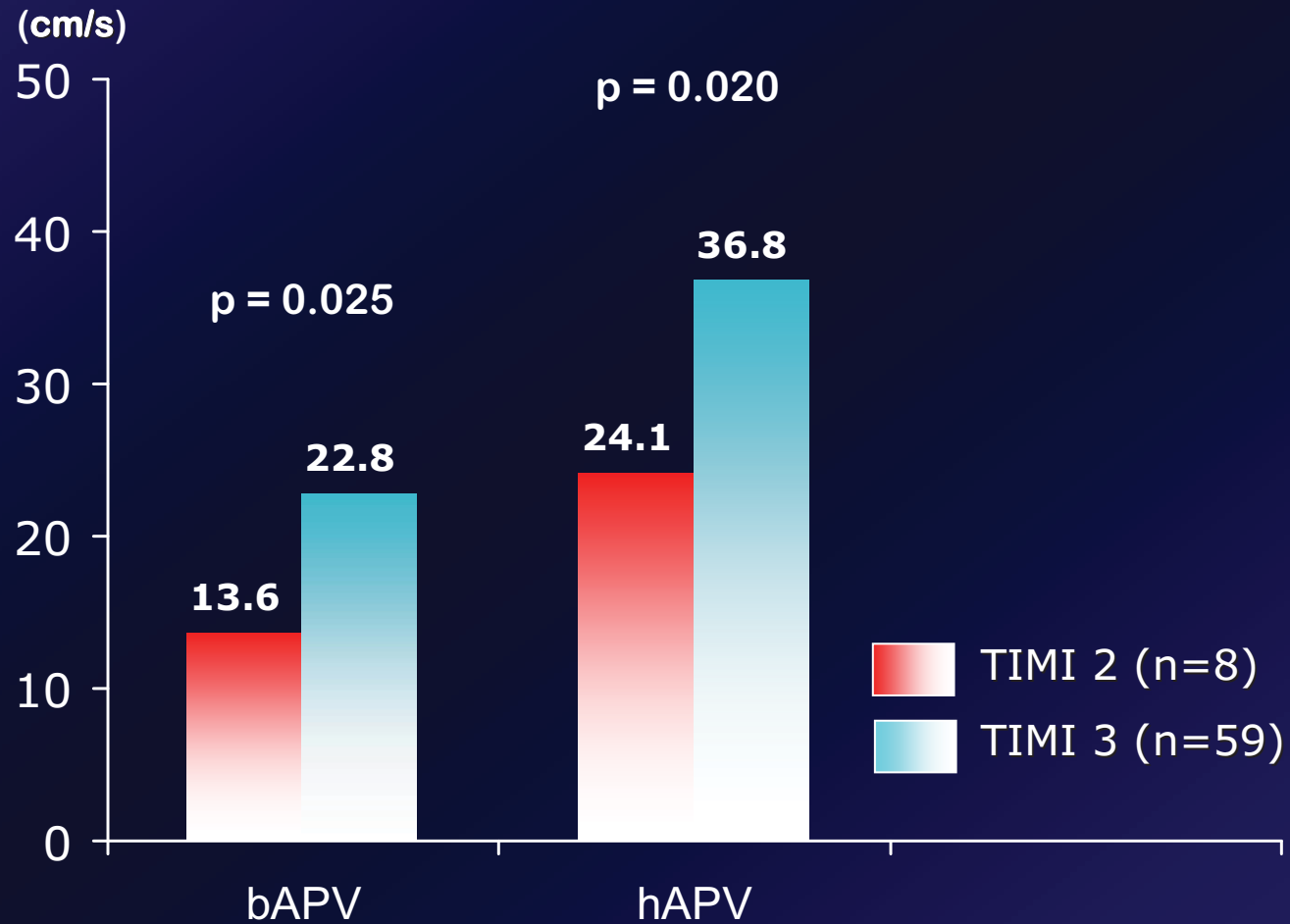




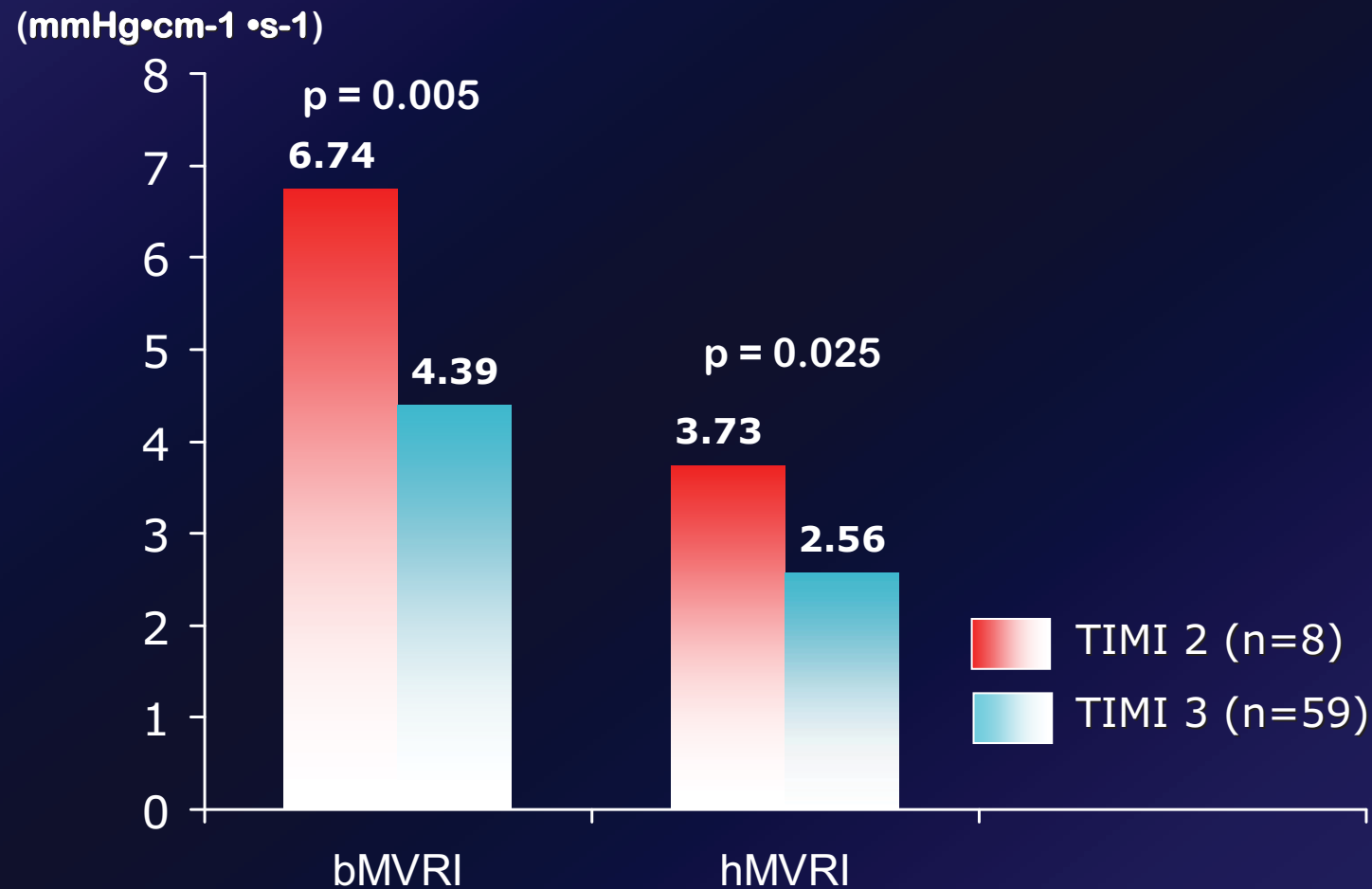
## Deceleration Time of Diastolic Flow Velocity



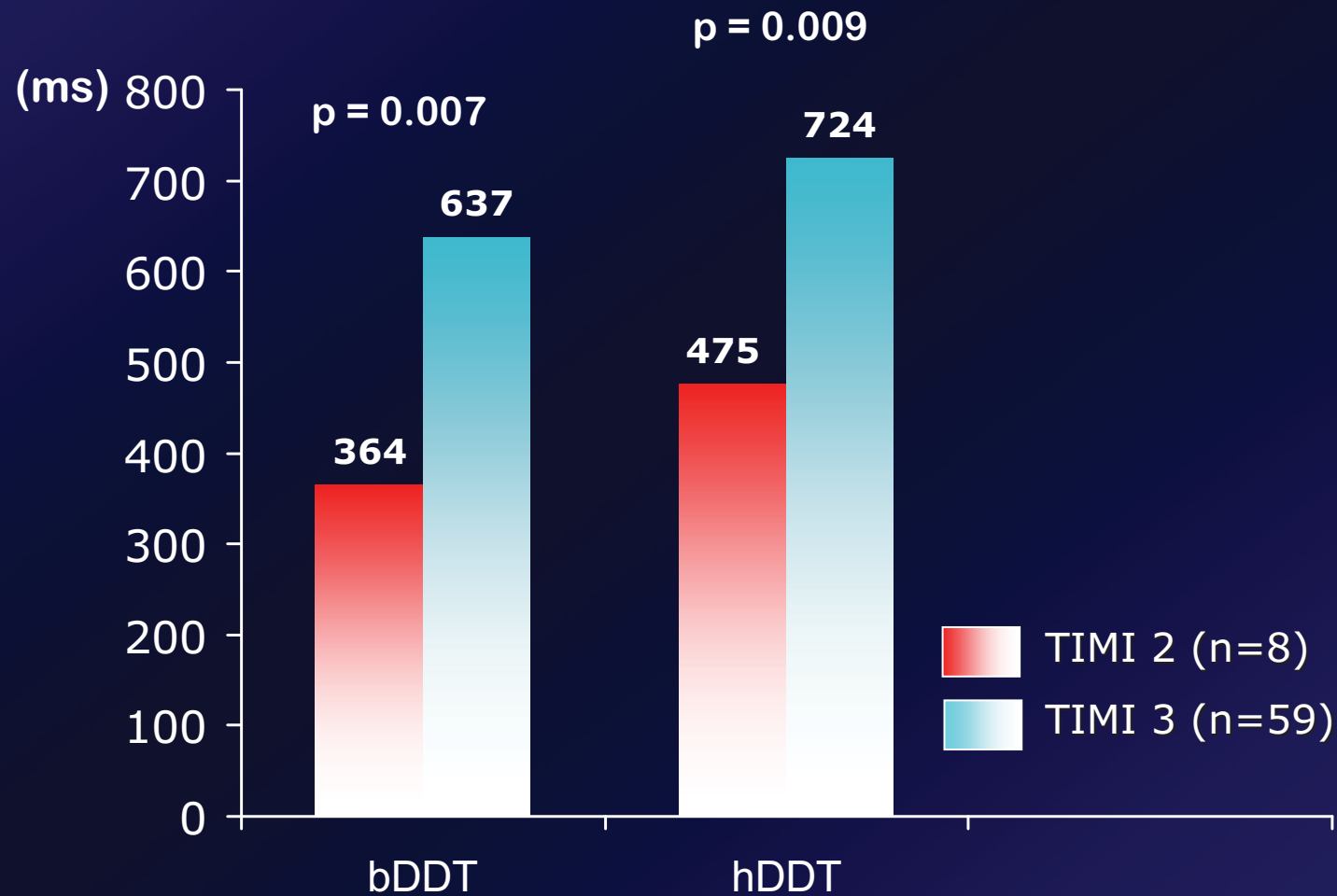
## Physiologic Significance of TIMI Flow Coronary Blood Flow Velocity



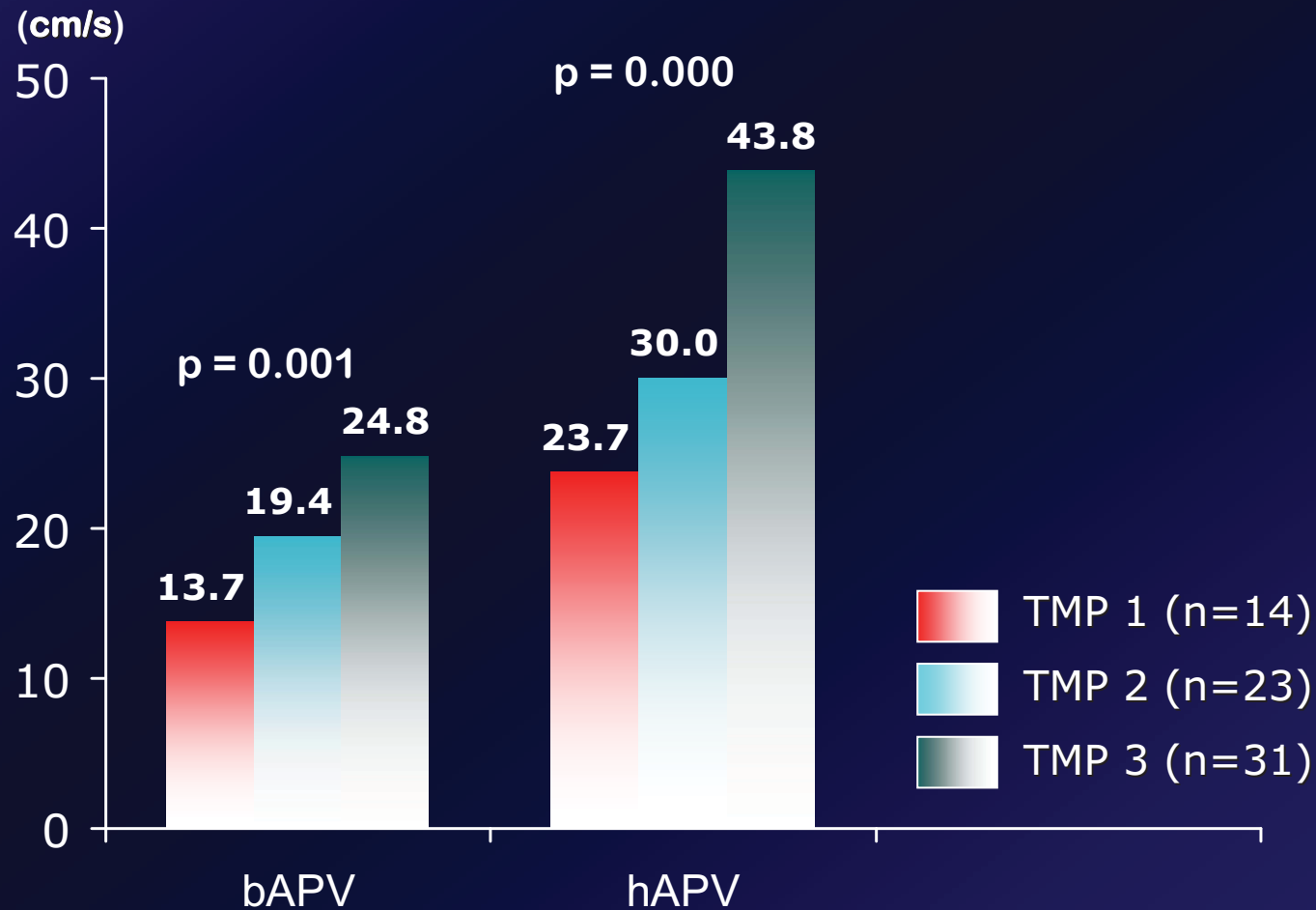
## Physiologic Significance of TIMI Flow Microvascular Resistance Index



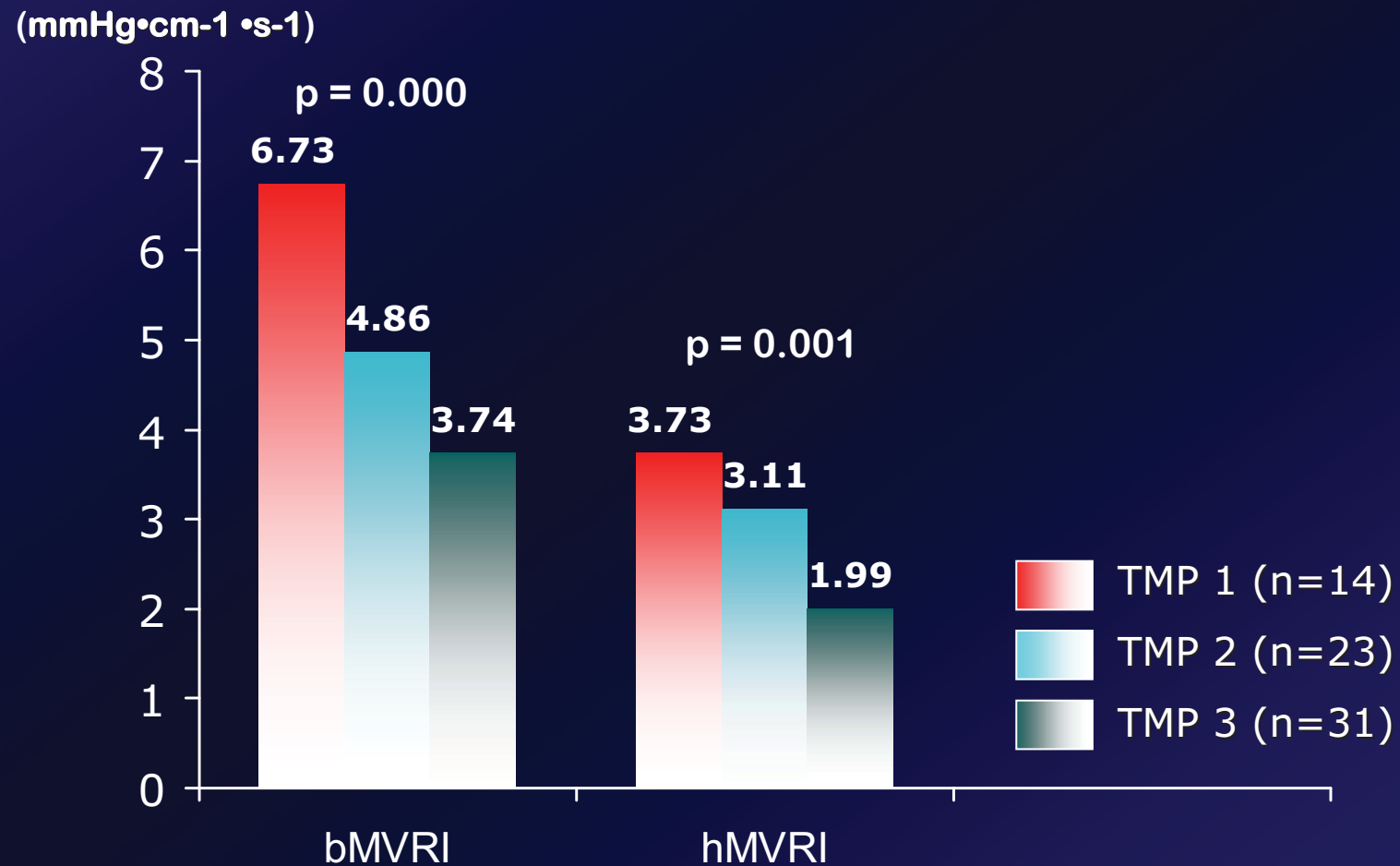
## Physiologic Significance of TIMI Flow Deceleration Time of Diastolic Flow Velocity



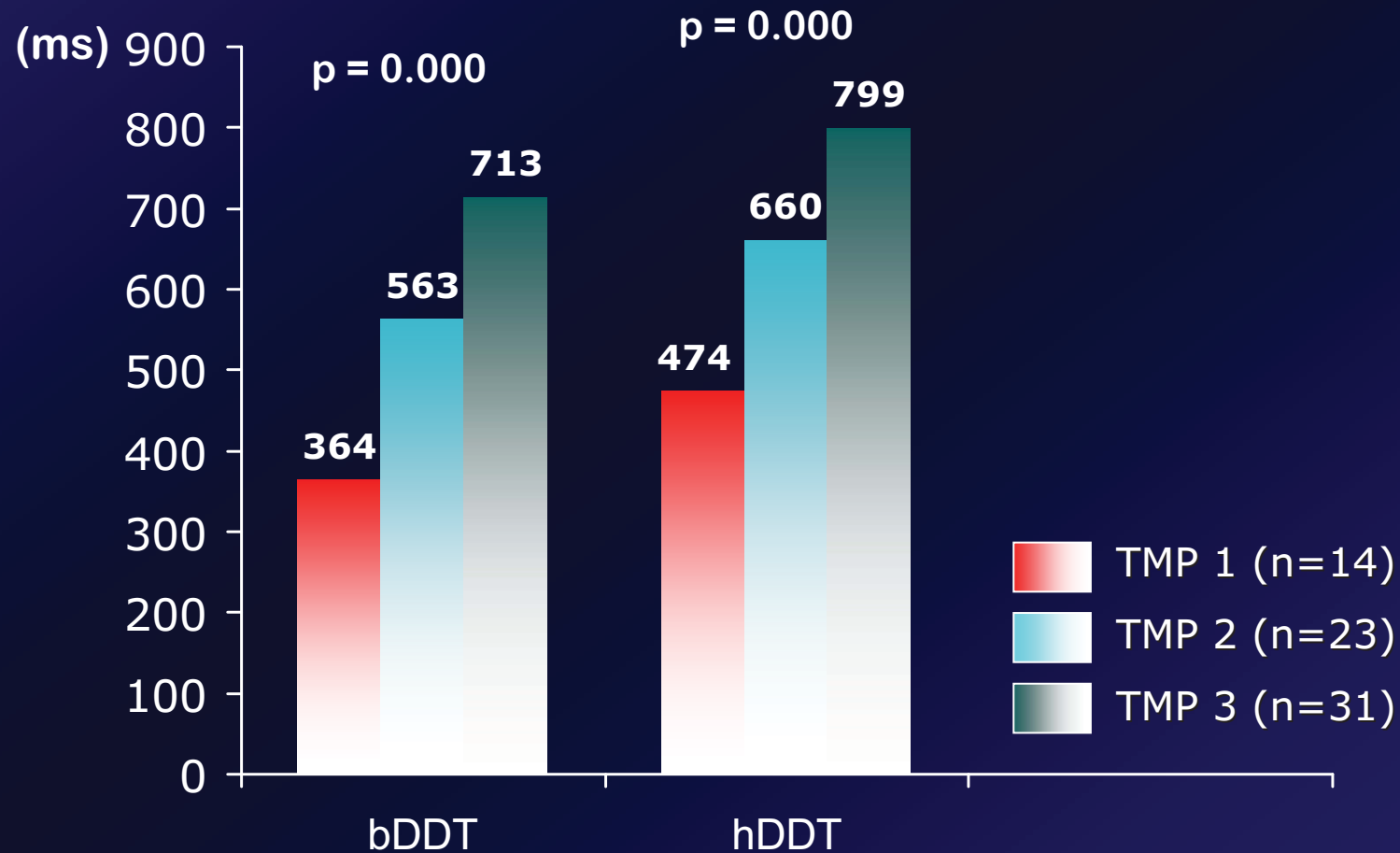
## Physiologic Significance of TIMI Myocardial Perfusion Grade Coronary Blood Flow Velocity



## Physiologic Significance of TIMI Myocardial Perfusion Grade Microvascular Resistance Index



## Physiologic Significance of TIMI Myocardial Perfusion Grade Deceleration Time of Diastolic Flow Velocity





## Conclusions

- In acute ST elevation myocardial infarction, patients who received primary stenting with distal protection showed significant favorable angiographic and intracoronary flow patterns as compared to patients without distal protection.
- This study suggested that distal protection device, GuardWire temporary occlusion and aspiration system, may effectively prevent distal embolization and protect microvascular integrity of myocardium during primary stenting.
- However, long-term pathophysiologic and clinical impact of distal embolization during primary stenting is still in question.