Durable Clinical Benefit Following Paclitaxel-Eluting Stent on the Outcome of Patients with Very Long Coronary Lesions
Multicenter Registry 2-Year Results

New Tokyo Circulation Research Group

New Tokyo Hospital

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Background

PCI for very long lesions represents.....

1. High incidence of complication
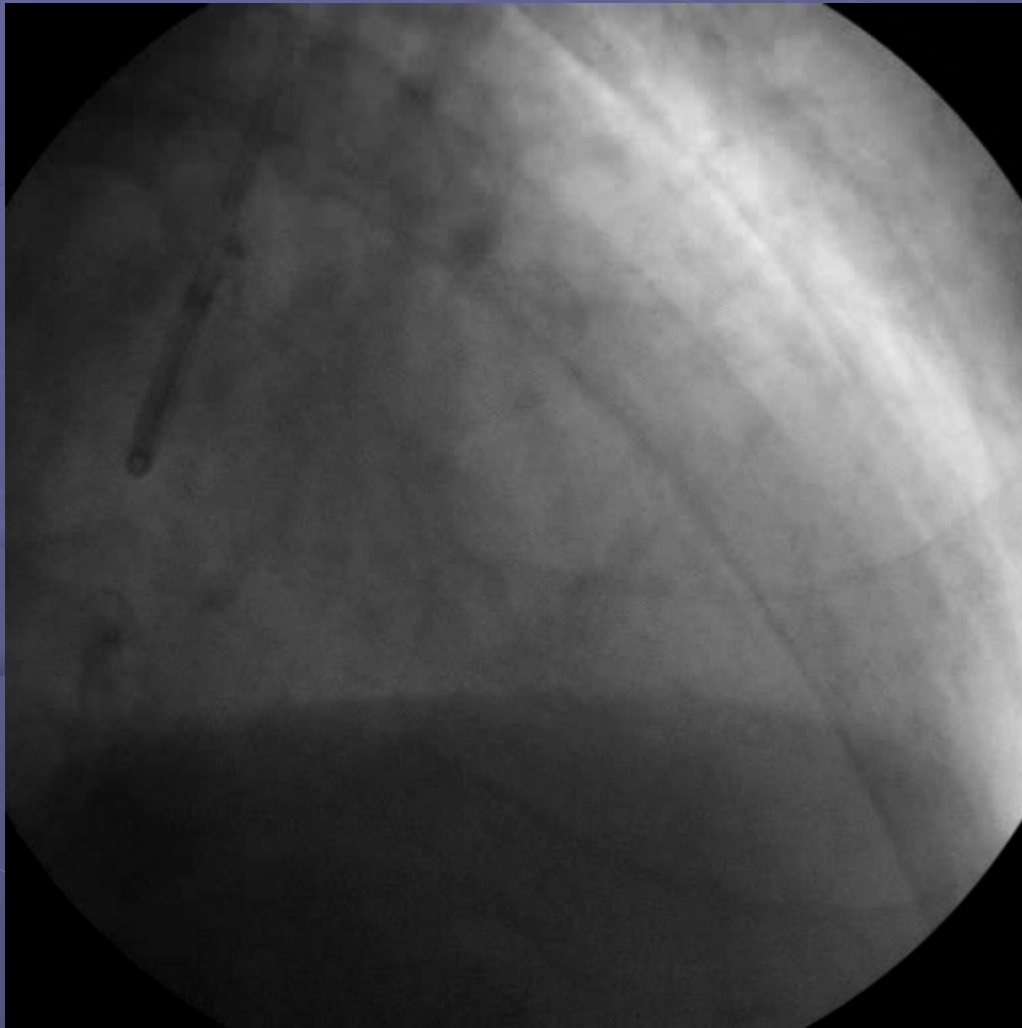
2. High incidence of restenosis

And more.....

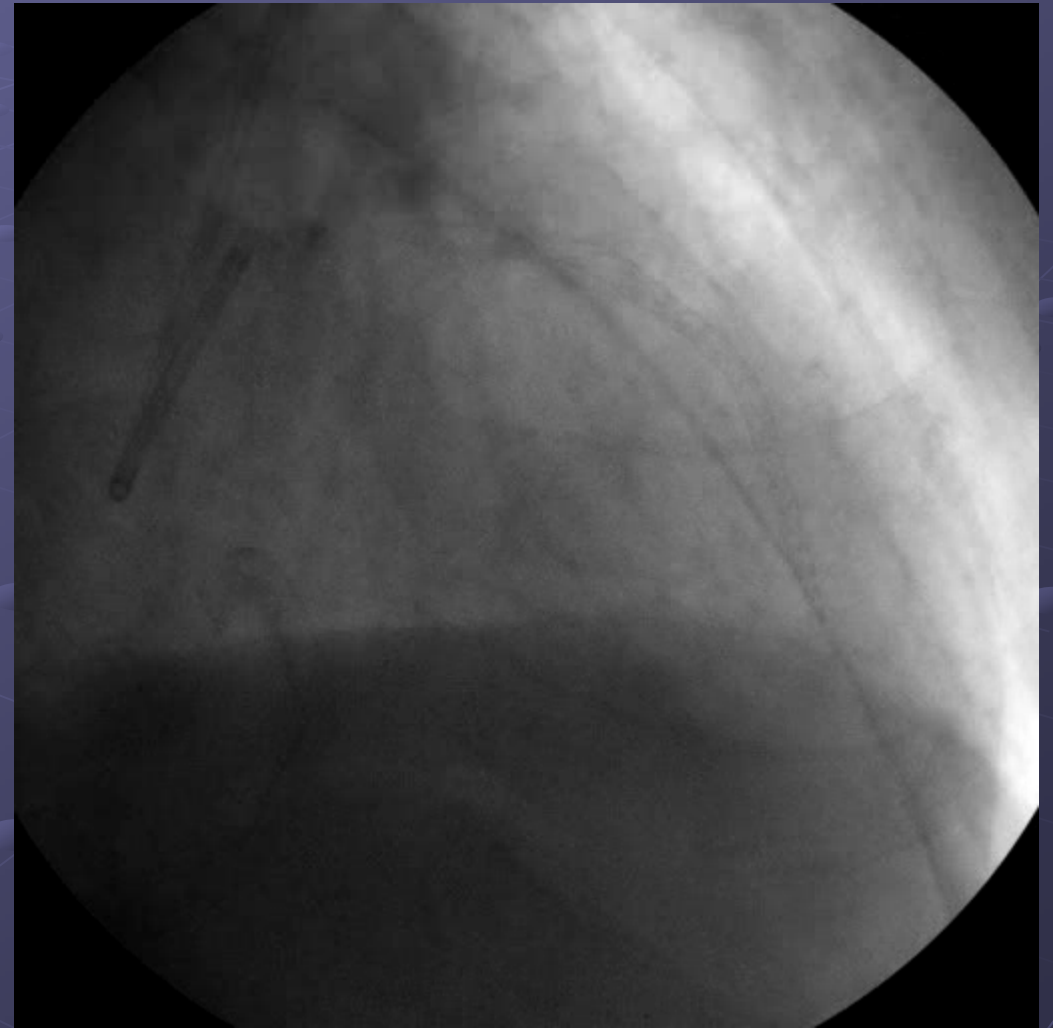1. Stent fracture

2. Stent thrombosis
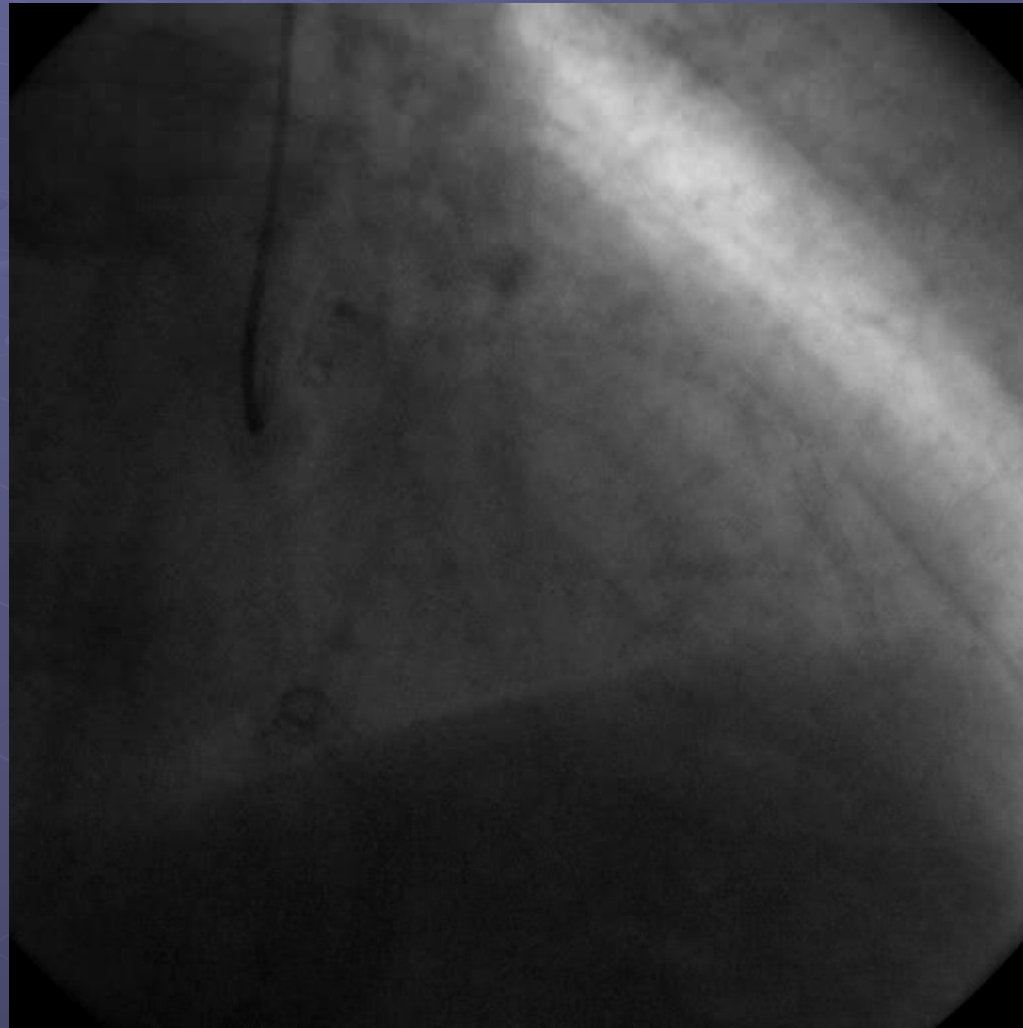
Case LAD diffuse lesion

Long Lesion

Pre

Post long TAXUS stenting

Case LAD diffuse lesion

Long Lesion

Follow up

Aim

To evaluate the safety, efficacy and durability of Paclitaxel-eluting stent (TAXUS) implantation for very long coronary lesions ($\geq$40mm).

To compare with a control group composed of patients with long coronary lesions treated with long bare metal stents in the same period.

Inclusion Criteria

- Patients symptomatic for chest pain or demonstrating inducible ischemia with angiographic evidence of ≥75% diameter stenosis of Very long coronary artery stenosis. (RD; 2.5-4.0 mm in diameter,≥40 mm lesion length)

- All consecutive patients who underwent successful PCI using Paclitaxel-eluting stent (PES) and Bare Metal Stent(BMS).

Exclusion Criteria

- Contraindication to antiplatelet agents

- In-stent restenosis

- Chronic total occlusions

- Acute myocardial infarction within 48 hrs

- Grafted lesion

Procedure Technique
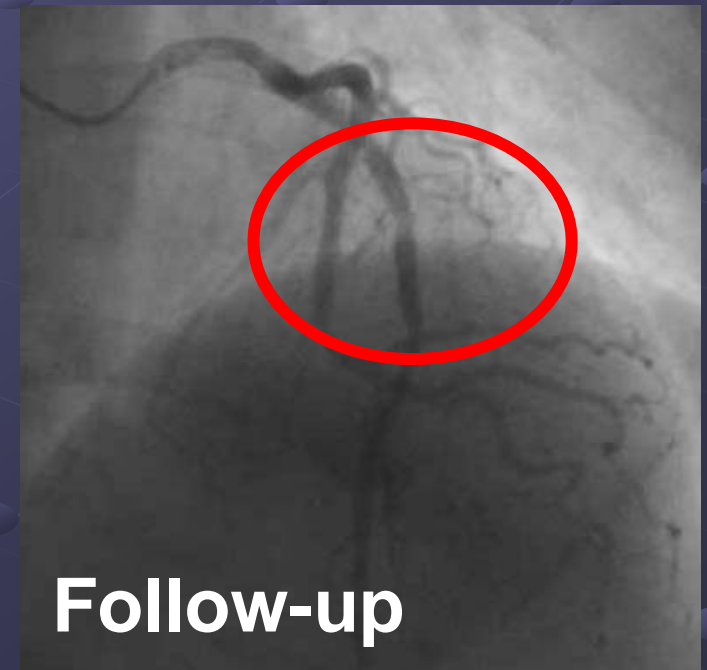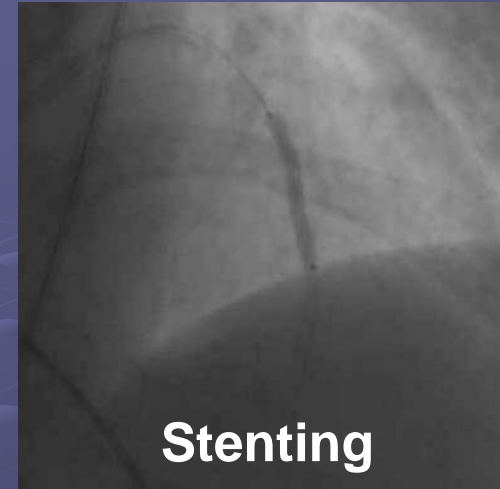
- Procedure strategy was mandated by the operator

  The use of adjunctive devices and
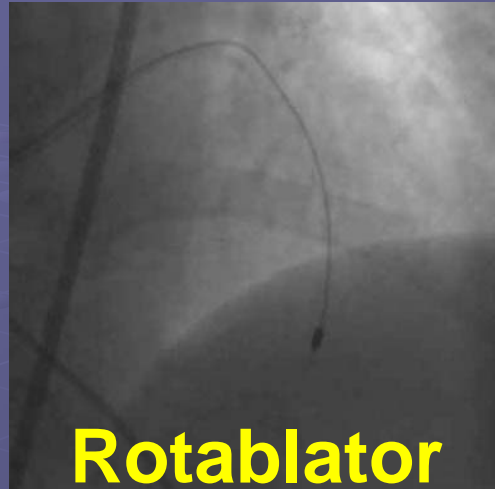 peri-procedual pharmacotherapy
  Type of stents(BMS), Type of stenting, Thrombectomy
  Glycoprotein IIb/IIIa inhibitor, IVUS

- Usage of IVUS was indispensable in case of calcified
  lesion, undilatable lesion, rotational atherectomy case.

- Vessel preparation was preceded by stenting.

Case LAD diffuse lesion

Long Lesion

Pre

Rotablator

Stenting

Post

Follow-up

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Case LAD diffuse lesion

Long Lesion

Pre

Just Stenting

Diffuse ISR

Post

Follow-up

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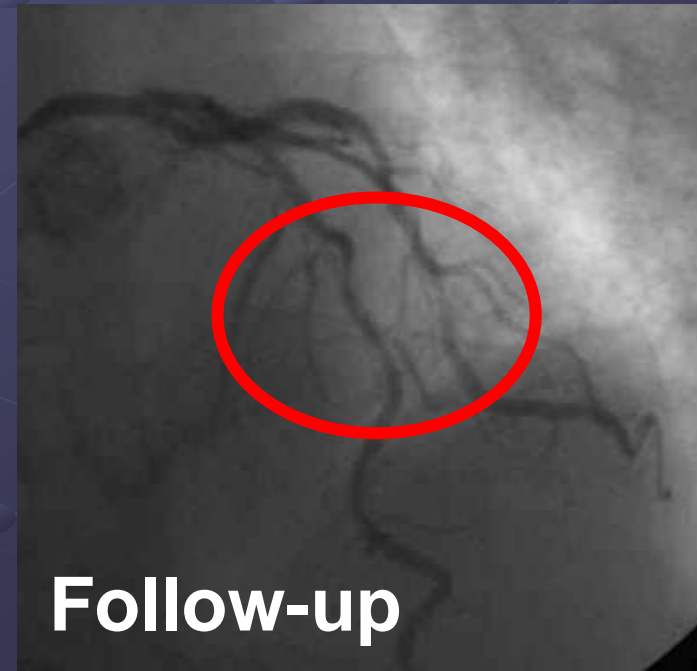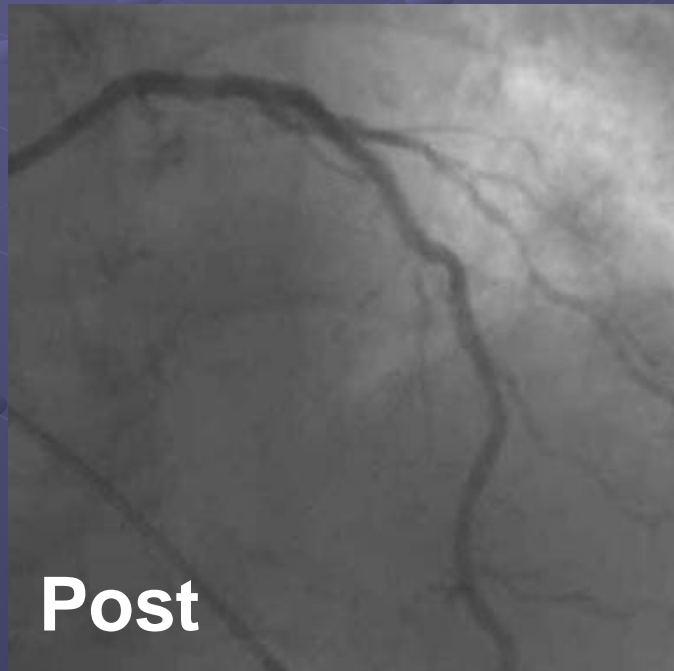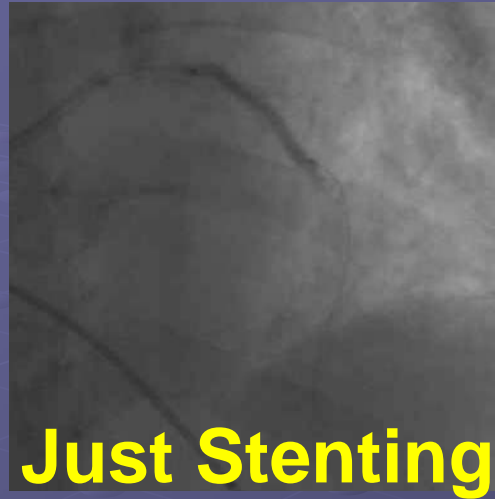
Case LAD diffuse calcified lesion

Long Lesion

Pre

Rotablator

Ballooning

Post stenting

Follow-up

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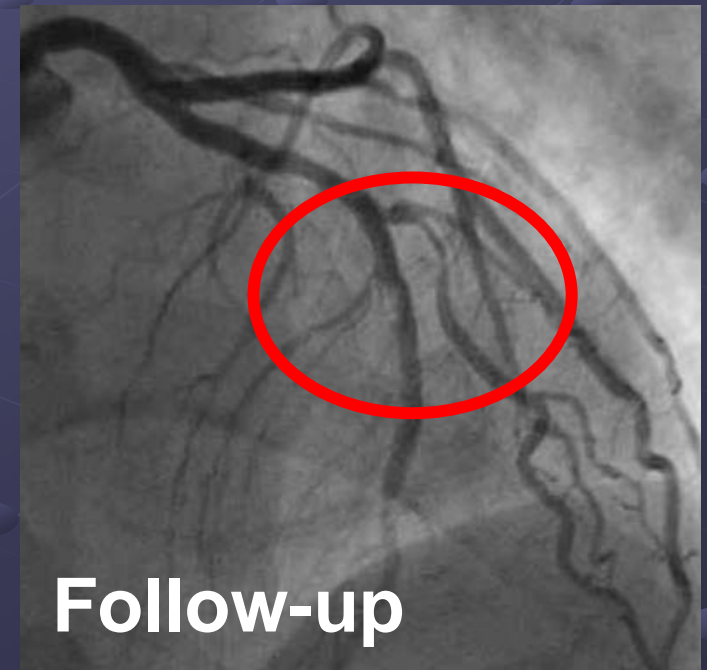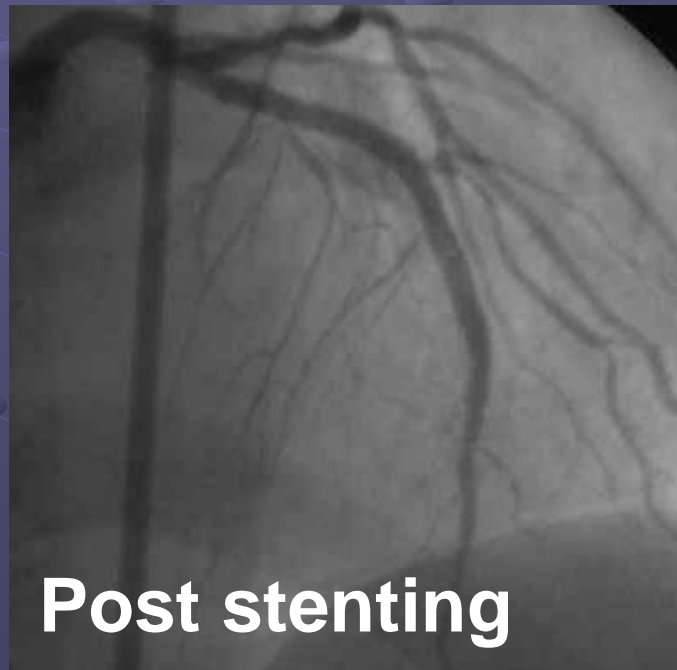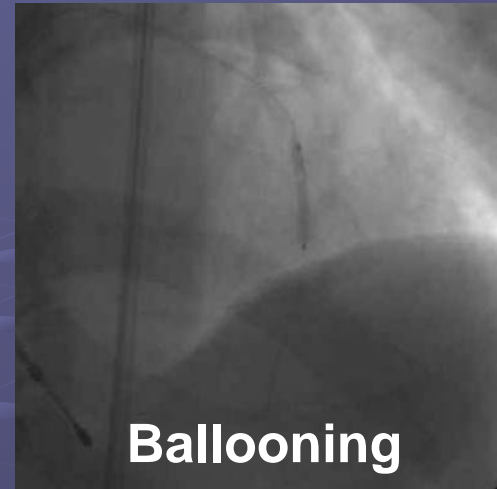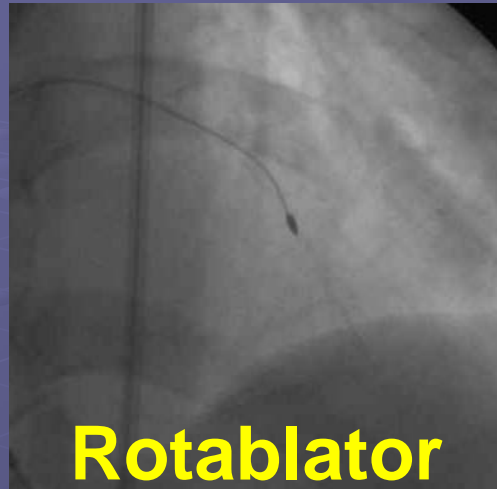
Antiplatelet Therapy

- After SES implantation……12 months long

  with   Aspirin   100 mg /day

                  Clopidogrel   75 mg /day

- After BMS implantation……1 month long

  with   Aspirin   100 mg /day

                  Ticlopidine   200 mg /day

Study End Points

Primary End Points

- 30 days MACE

- 12, 24 months MACE

Secondary End Points

- 12 , 24 months angiographic restenosis rate

- 12 , 24 months TLR

Definitions

Angiographic success: Recanalization of the artery with <50% residual diameter stenosis with restoration of TIMI 3 flow.

Clinical success: Angiographic success without in-hospital MACE

MACE: Death, QMI, CABG and Re-PCI

Target Lesion Revascuraization (TLR): Any surgical or re-PCI motivated by a significant narrowing within the stent or in the 5-mm distal or proximal peristent segment

Angiographic Analysis

All data were entered into the Asian multi-center DES-Very Long Lesion registry database at the New Tokyo Hospital. Quantitative coronary angiographic analysis was performed by a CMS quantitative analysis system (QCA-CMS, version 3.0, MEDIS, The Netherlands). Minimal lumen diameter, reference diameter, and percent diameter stenosis were measured before and after the procedure and at follow-up; the results from the single "worst" view were recorded.

Statistical Analysis

All data were entered into the Asian multi-center DES-Very long lesion registry database at the New Tokyo Hospital. Data are expressed as mean± SD unless otherwise indicated. For comparison of paired data, dependent t test analyses were used. For non-paired data, analyses were used to test differences in categorical variables.

-Multicenter Registry in Asia-

New Tokyo Hospital	🇯🇵	Sunao Nakamura M.D, Ph.D. (Japan)
Damansara Heart Center	🇲🇾	Tamil Selvan Muthusamy M.D. (Malaysia)
Konyang University Hospital	🇰🇷	Jang-Ho Bae M.D. (Korea)
Husada Hospital	🇮🇩	Yeo Hans Cahyadi M.D. (Indonesia)
Chest Disease Institute	🇹🇭	Sudaratana Tansuphaswadikul M.D. (Thailand)
Siriaj Hospital	🇹🇭	Damras Tresukosol M.D. (Thailand)
King Chulalongkorn Memorial Hospital	🇹🇭	Wasan Udayachalerm M.D. (Thailand)
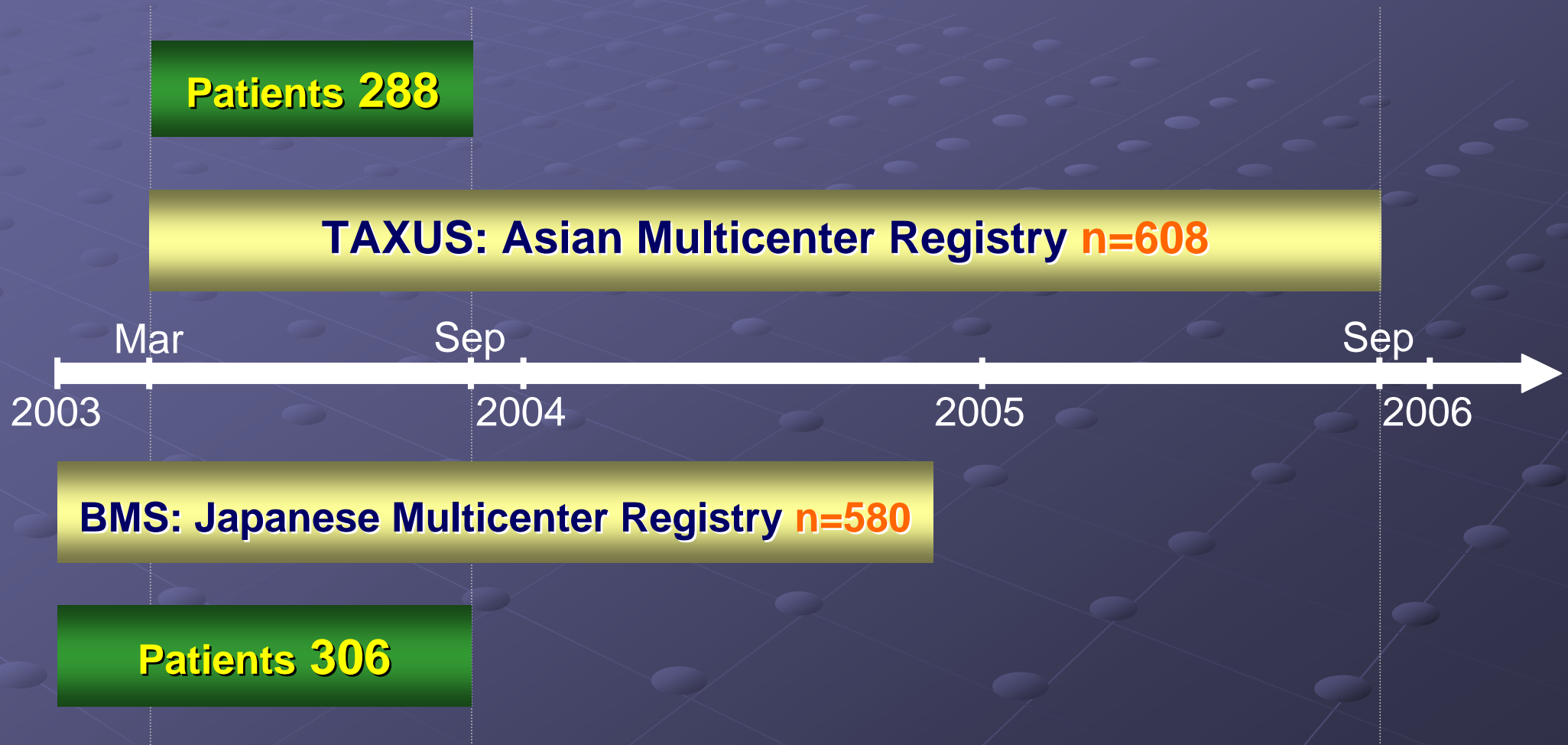
Interventional Procedure

Stenting Procedure

Following the adequate vessel preparation, coronary stents were implanted, adjunct high-pressure balloon inflation *(14 to 20 atm)* was added in all cases.

Bare Metal Stent

Express stent 6%
Terumo stent 21%
Medtronic 42%
Multi-Link 31%

Paclitaxel-Eluting Stent

TAXUS 100%
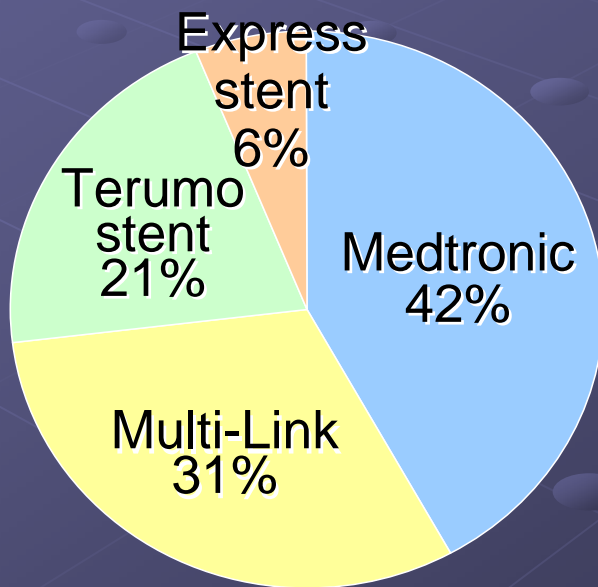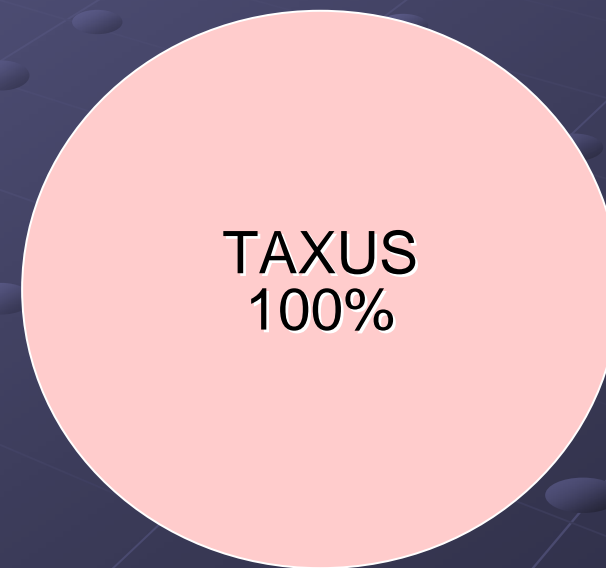
Baseline Characteristics

Long Lesion

	BMS	TAXUS	p
Patients (n)	306	288	-
Age (yrs)	67.8±10.5	70.8±10.5	NS
Male (%)	69.9	72.9	NS
Risk factors (%)			
Hypertension	51.0	62.5	NS
Hyperlipidemia	32.0	30.5	NS
Diabetes	33.0	34.3	NS
Smoking	52.3	59.0	NS
Previous MI (%)	13.4	10.4	NS
LVEF (%)	47.6	45.8	NS
Multi vessel disease(%)	70.6	78.1	NS

Data are presented as the wear value ±SD are number (%) of patients.
LVEF: left ventricular ejection fraction   MI: myocardial infarction

Lesion Characteristics

Long Lesion

	BMS	TAXUS	p
Patients / lesions (n)	306 / 379	288 / 322	-
Number of CAD (%)			
One	28.8	22.9	
Two	31.0	33.1	NS
Three	40.2	44.0	
Target vessel (%)			
LAD	51.2	52.8	
LCX	27.0	31.1	NS
RCA	21.8	16.1	
AHA / ACC lesion type (%)			
B_1	20.6	19.3	
B_2	35.1	38.9	NS
C	44.3	41.9	
Calcified lesion	42.0	60.2	<0.05

Data are presented as the number (%) of lesion.

Clinical Results (In-Hospital)

	BMS (n=306)	TAXUS (n=288)	p
Angiographic success (%)	98.0	97.2	NS
Clinical success (%)	98.0	97.9	NS
MACE at 30 days (%)	1.3	1.4	NS
ACO / SAT (%)	0.3	0.3	NS
Q-MI (%)	1.3	1.4	
Untreated dissection (%)	5.2	7.6	NS
No-flow (%)	1.3	1.0	NS
Slow-flow (%)	2.9	3.8	NS
Side branch occlusion (%)	3.9	4.9	NS

MACE: major adverse cardiac event (death, MI, CABG)
ACO: acute occlusion   SAT: sub acute thrombotic occlusion

Procedure Characteristics

	BMS	TAXUS	p
Patients / lesions	306 / 379	288 / 322	-
Balloon / artery ratio	1.06±0.14	0.92±0.14	NS
Maximum pressure (balloon)	12.4±6.5	12.5±7.8	NS
Stent / artery ratio (mean)	1.08±0.20	1.04±0.30	NS
Maximum pressure (stent)	16.8±7.0	20.8±10.2	<0.05
Stent / lesion length ratio	0.68+0.24	1.23±0.28	<0.05
Rotablator use (%)	25.5	10.1	<0.05
IVUS use (%)	47.0	11.1	<0.05
Number of the stents / lesion	1.4	2.6	<0.05

(n:mean)

Quantitative Coronary Angiographic Analysis = Baseline =

	BMS	TAXUS	p
Patients / lesions (n)	306 / 374	288 / 322	-
Ref. diameter (mm:proximal)	2.80±0.64	2.86±0.68	NS
Minimum lumen diameter (mm)			
Pre procedure	0.58±0.44	0.59±0.71	NS
Post procedure	2.36±0.65	2.29±0.63	NS
Lesion length (mm)	45.8±11.3	45.9±10.6	NS
Acute gain (mm)	1.90±0.60	1.70±0.79	NS
Stent length / Lesion length ratio	0.68±0.24	1.23±0.28	0.03

Quantitative Coronary Angiographic Analysis = Follow-Up =

	BMS	TAXUS One year	TAXUS Two year	p
Angiographic follow-up rate (%)	94.8	79.9	69.1	-
Reference diameter (mm)	2.82±0.66	2.83±0.69	2.82±0.70	NS
Minimum lumen diameter (mm)	1.55±0.66	1.95±0.60	1.90±0.70	0.03
Restenosis (%) (12 mo)	43.5	18.8	19.4	0.01
TLR (%) (12 mo)	32.0	14.9	15.6	0.01

TLR: target lesion revascularization.

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Two Year Clinical Follow-Up

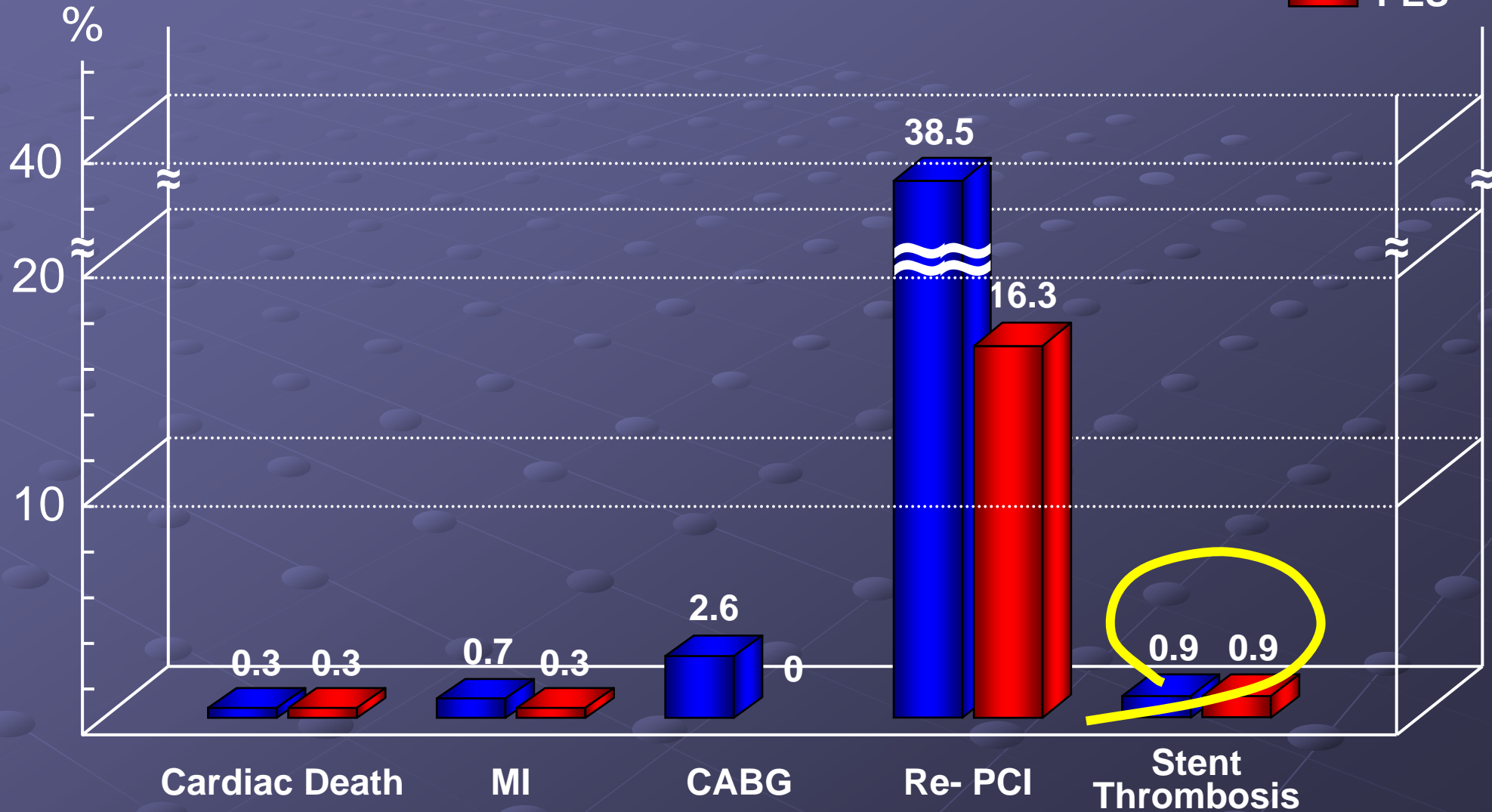|	BMS	TAXUS		p
		One year	Two year	
Patients / lesions	306	288	288	-
Death	0	0	0	-
Q-wave myocardial infarction	4 (1.3%)	4 (1.4%)	4 (1.4%)	NS
Repeat percutaneous intervention	120 (39.2%)	43* (14.9%)	45* (15.6%)	0.01
Coronary bypass surgery	4 (1.3%)	0 (0%)	0 (0%)	NS
Overall target lesion revascularization	124 (40.5%)	47* (16.3%)	49* (17.0%)	0.01
Any events	128 (41.8%)	47* (16.3%)	49* (17.0%)	0.01
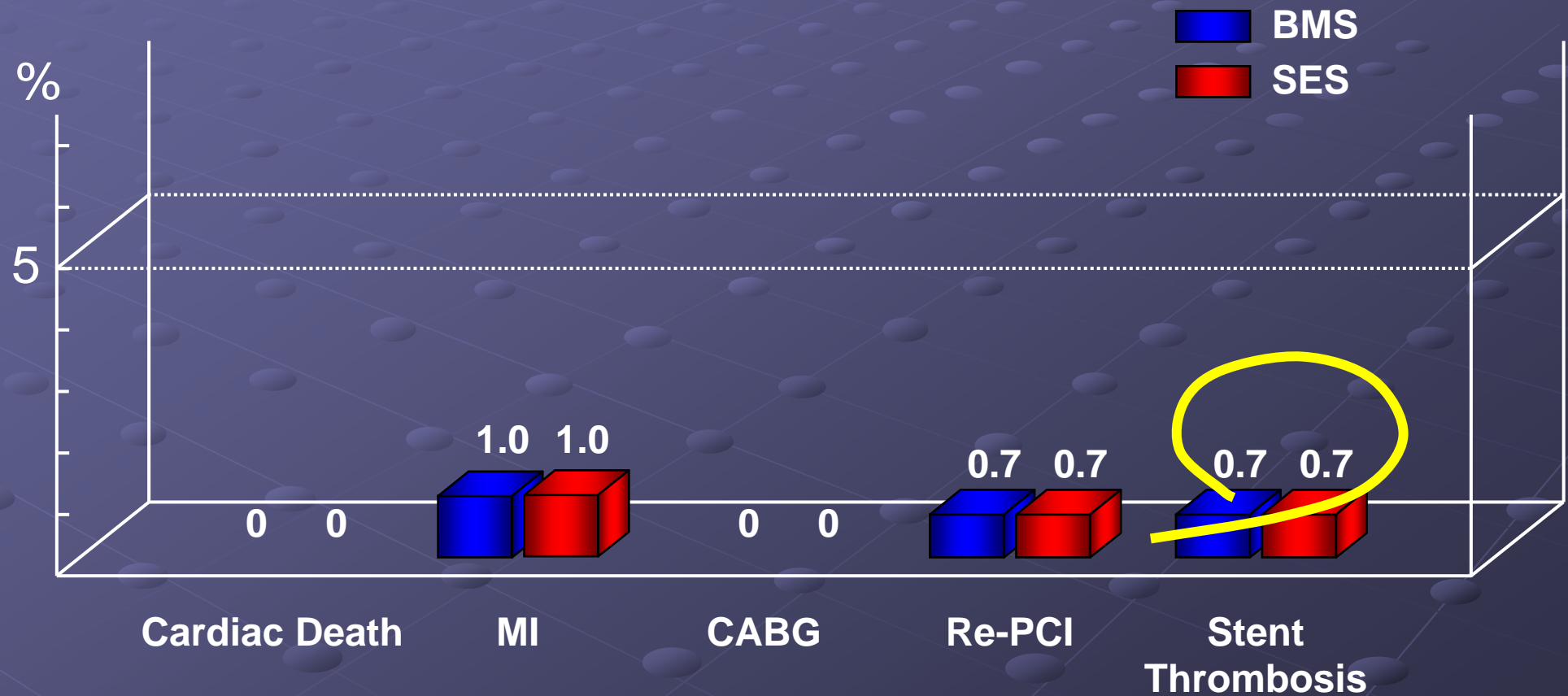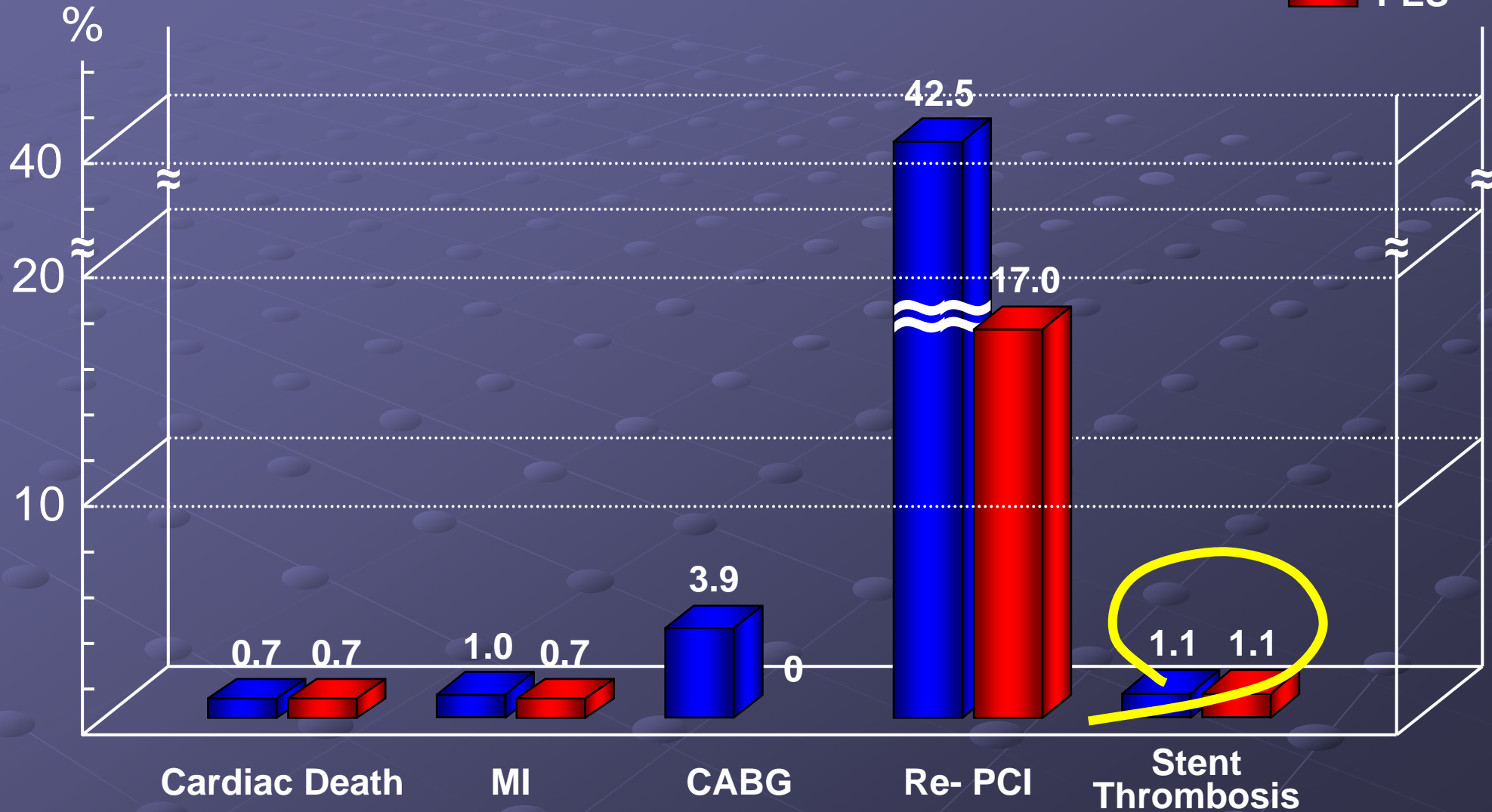
CYPHER™
Cordis, Johnson & Johnson
Sirolimus-Eluting Stent

TAXUS™
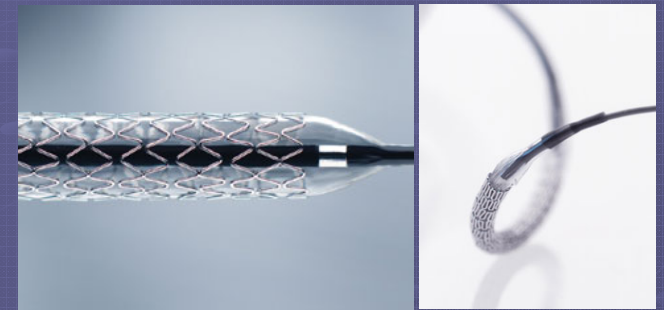**Boston Scientific**
Paclitaxel-Eluting Stent

ENDEAVOR™
Medtronic
Zotarolimus-Eluting Stent

JANUS™
SORIN BIOMEDICA
Tacrolimus-Eluting Carbostent

Genous™
OrbusNeich
EPC-Capture Stent

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Study Patients

> Patient cohort includes 922 patients with Very long lesion in our data-base, treated with Sirolimus-eluting stent (SES), Paclitaxel-eluting stent (PES), Zotarolimus-eluting stent (Endeavor: ZES), Tacrolimus-eluting stent (JANUS: TES) and EPC capture stent (ECS)

Asian-Multicenter DES-LMT Registry
Total 922 patients

	SES	PES	ZES	TES	ECS
Fin. 12 mo F/U	n=368	n=288	n=151	n=76	n=39
From	2002 March	2003 April	2005 May	2005 May	2006 March

Restenosis / TLR

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Stent Thrombosis: 1yr

SAT
LAST

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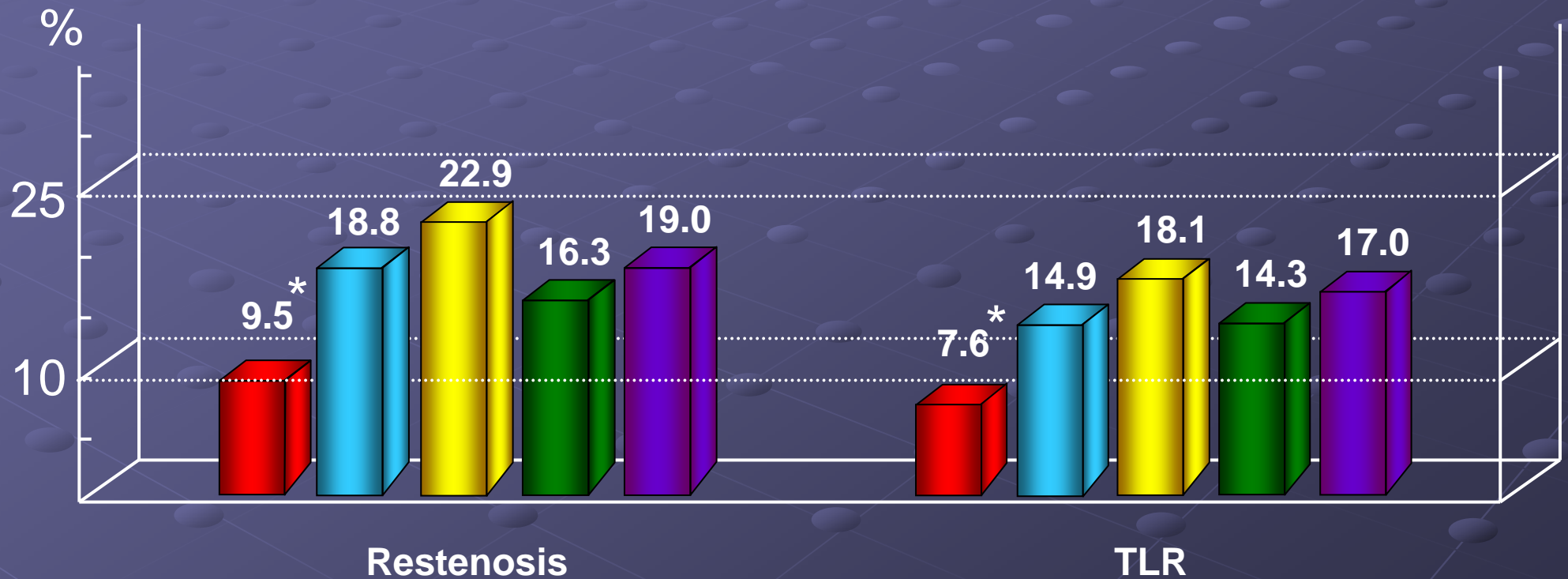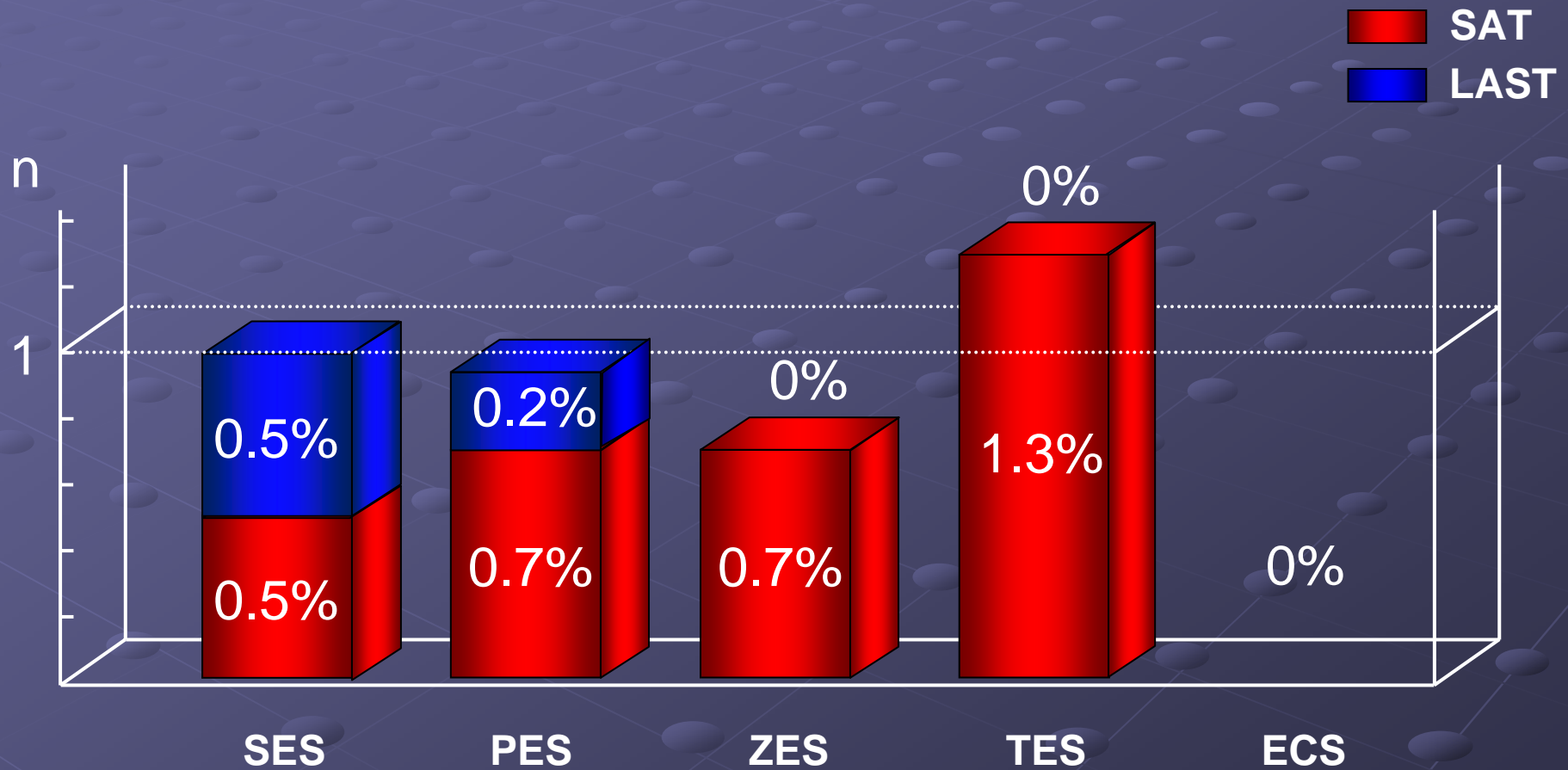
Multivariate Predictors of Thrombosis

	OR	95% CI	P
LVEF	0.89	0.80 – 0.98	0.02
Stent lengh	1.08	0.80 – 1.46	0.60
lesion length	1.00	0.67 – 1.50	0.99
Bifurcation stenting	1.40	0.16 – 12.23	0.76

Stent Thrombosis in J-Cypher Registry

ARC Definite / Probable

SAT 0.32%
LAST 0.30%

	30 Days	180 Days	365 Days
	0.32%	0.53%	0.62%
n of pts at risk	4903	4597	4240
5115			

Follow-up interval (Days)
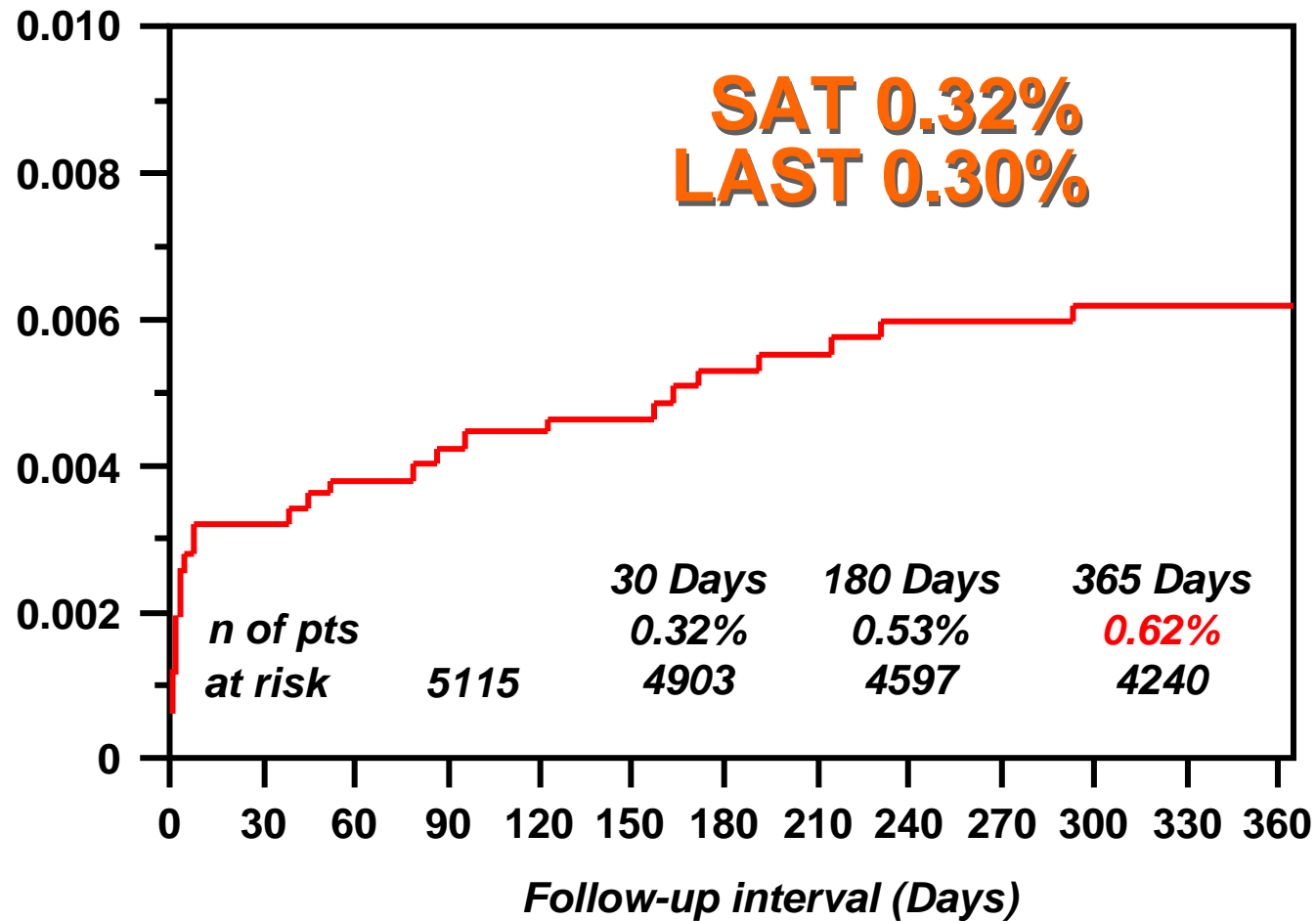
Stent Thrombosis in J-Cypher and Bern/Rotterdam study

Cumulative Incidence of Stent Thrombosis
Angiographic confirmation with clinical event

Bern / Rotterdam
Between 30 Days and 3 Years
Slope 0.6% / Year

j-CYPHER
Between 30 Days and 1 Years
Slope 0.2% / Year

2.9%
2.3%
1.7%
1.2%

0.27%   0.51%   0.63%

6,816	5,561	1,264	j-CYPHER N of pts at risk

Bern/Rotterdam

Days after stenting	0	9	30	365	720	1,095
Cumulative incidence(%)		1.1	1.2	1.7	2.3	2.9
Patients at risk(n)	8,146	7,162	7,002	5,339	2,641	971

Wenaweser P., ESC 2006 , Oral Presentation # 1012

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Conclusions

1. Long TAXUS stent implantation for very long lesions was safe and feasible.

2. Compared with BMS, long TAXUS stenting were associated with reduction of restenosis rate and target lesion revascularization and

   these clinical benefit is durable at least 2 years.