

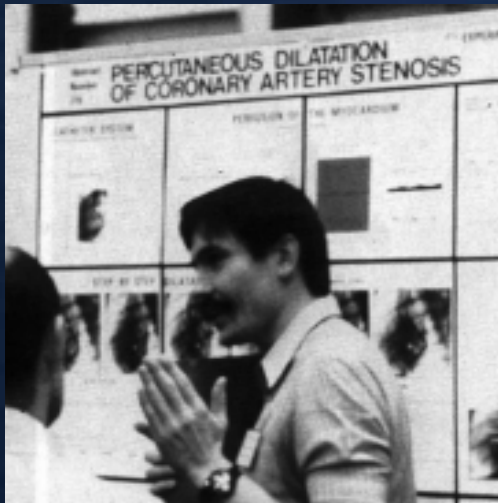
Drug-Eluting Stent for Multivessel Coronary Artery Disease : Impact on CABG

Hyeon-Cheol Gwon

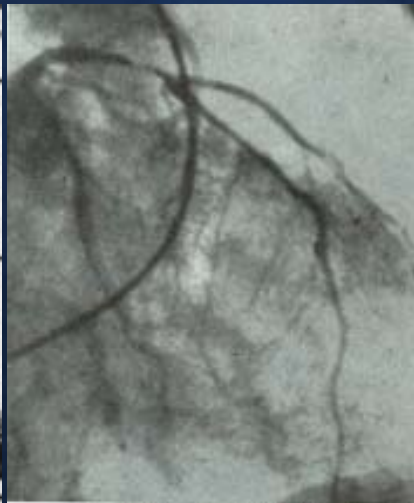
Cardiac and Vascular Center Samsung Medical Center
Sungkyunkwan University School of Medicine

First Human PTCA

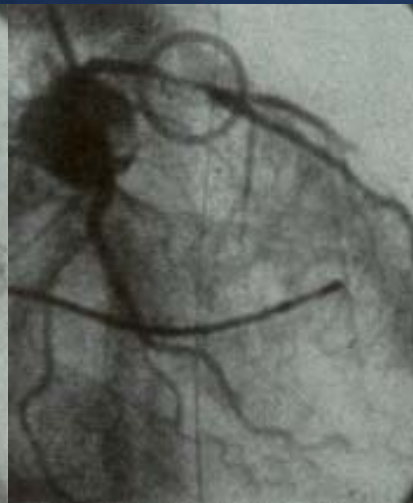
- 1977 Gruentzig
 - First human coronary balloon angioplasty (PTCA)



Gruentzig at AHA



Pre



Post



1-mo FU

PTCA vs. CABG

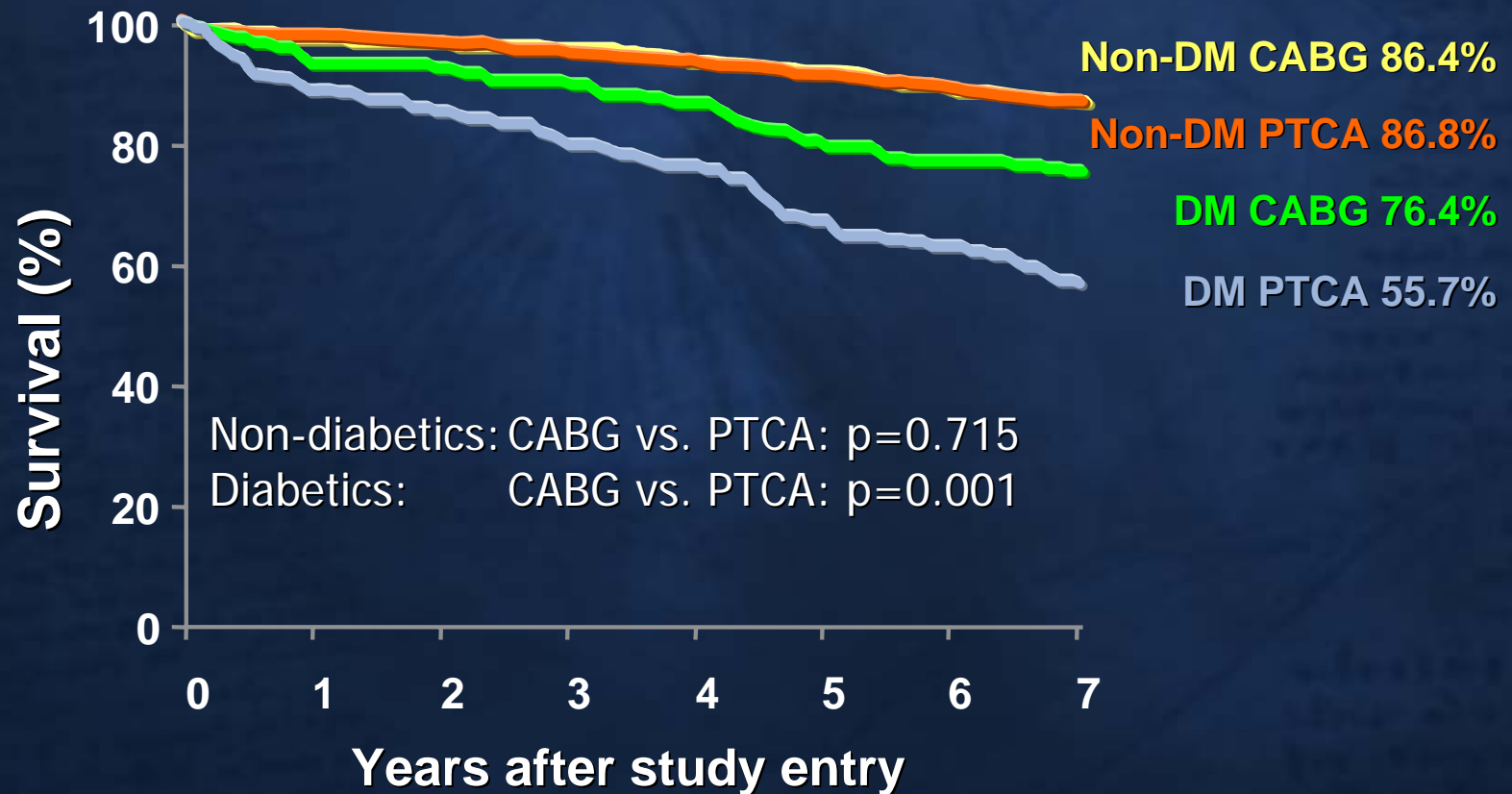
- Compare to CABG, PTCA is...

	Year	N	In-hospital		Late			
			<u>D</u>	<u>MI</u>	<u>D</u>	<u>MI</u>	<u>TLR</u>	<u>Angina</u>
RITA	1993	1011	ND	ND	ND	ND		
ERACI	1993	127	ND	ND	ND	ND		
EAST	1994	392	ND		ND	ND		
GABI	1994	359	ND		ND	ND		ND
CABRI	1995	1054	-	-	ND	ND		ND
BARI	1996	1829	ND			ND		ND

7-year mortality: PCI 19.1%, CABG 15.6%, p=0.043

BARI Trial

- Less mortality in CABG group over PTCA group in patients with treated diabetes



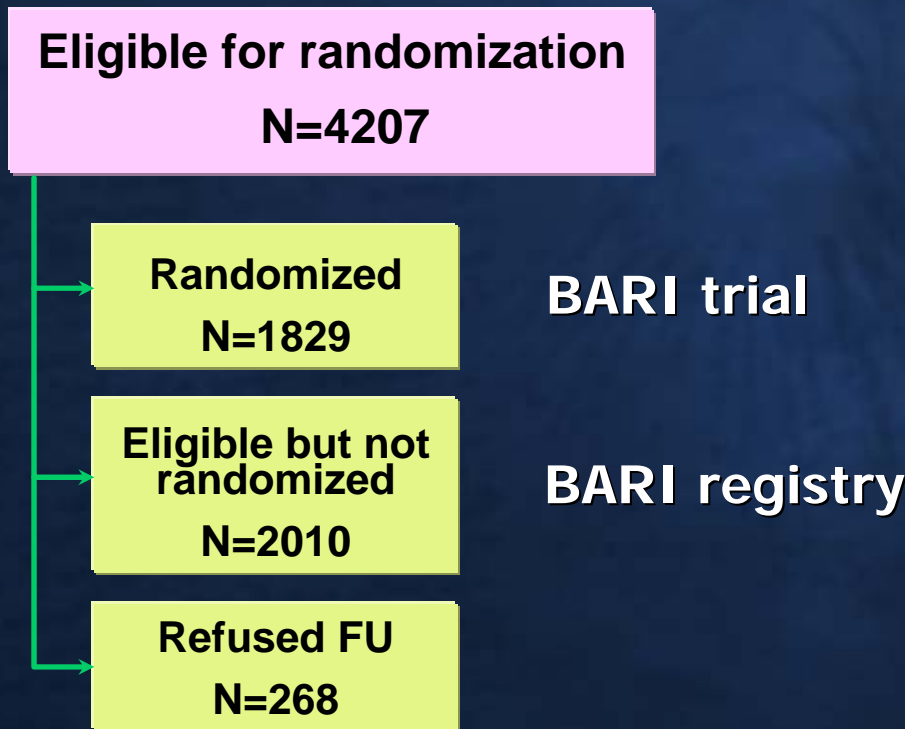
(BARI JACC 2000)

Criticism against BARI Trial

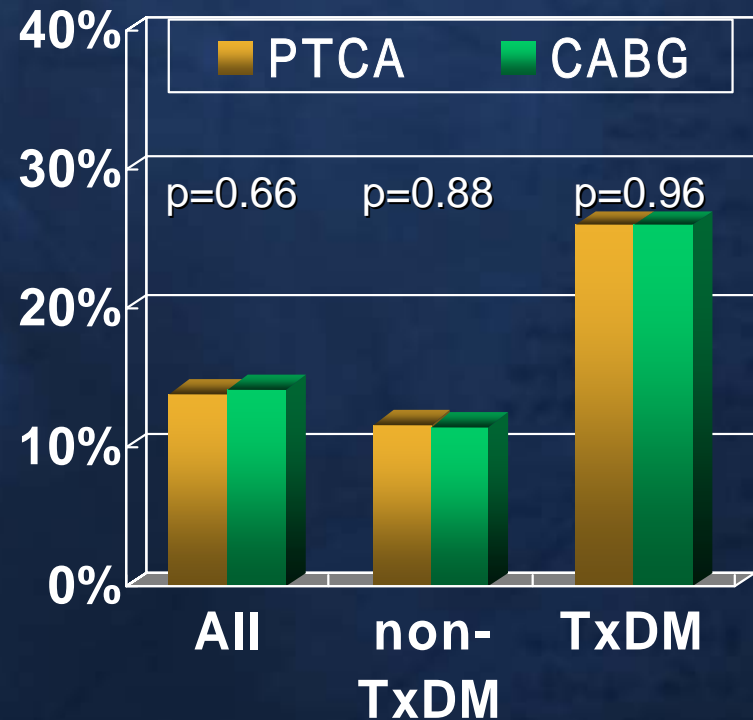
- Small number of diabetic patients (N=353)
- Diabetes was not a pre-specified subgroup for analysis
- Prior to stent era
- No GP IIb/IIIa inhibitors
- PCI was associated with incomplete revascularization compared to CABG

BARI Registry

Eligible but not randomized

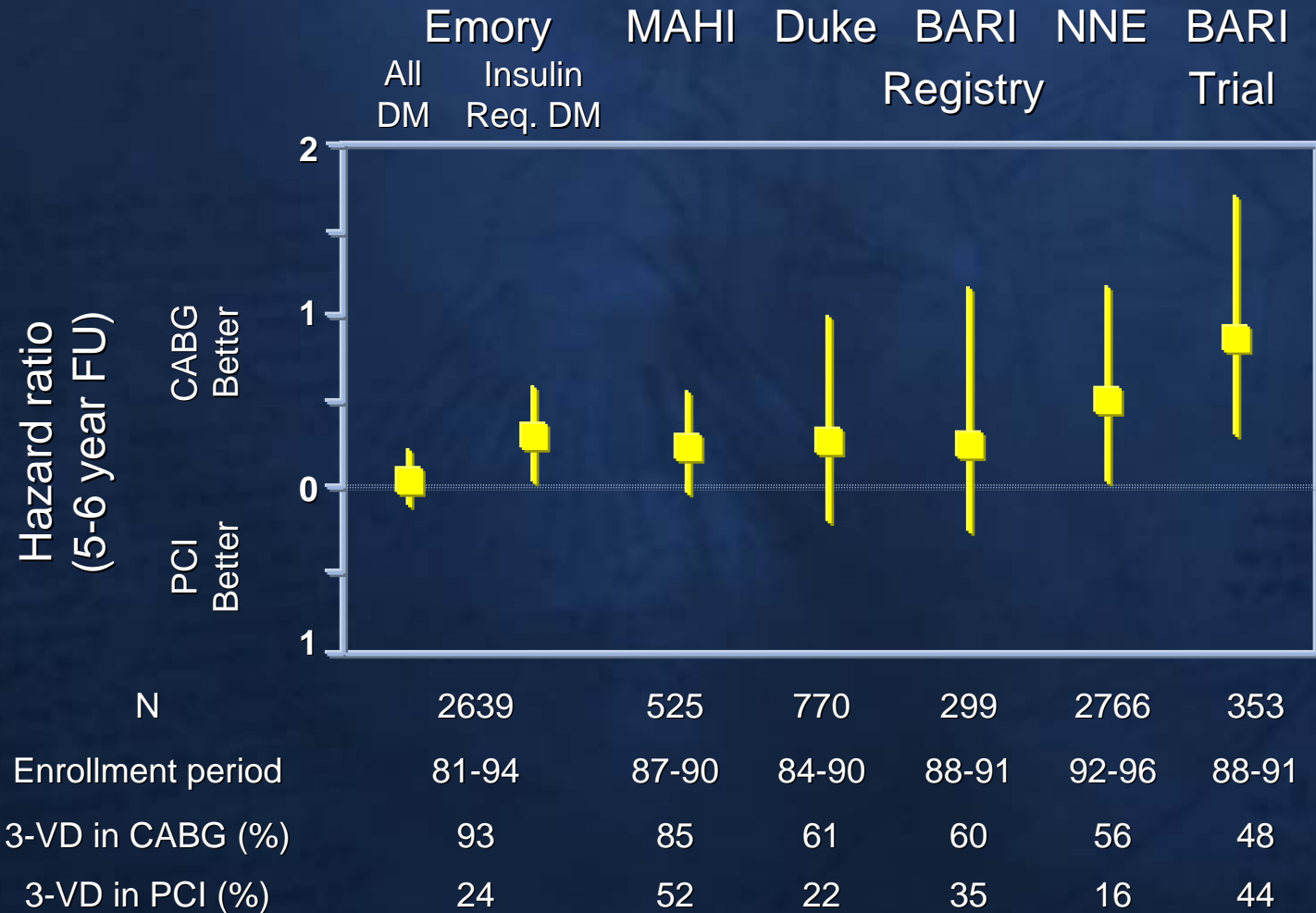


7-year mortality



(FEIT Circulation 2000)

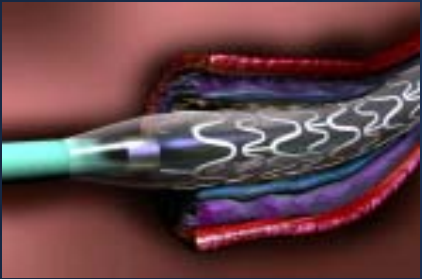
Survival in diabetics



PTCA vs. CABG

- Compared to CABG, PTCA is...
 - Similar death or MI
 - Higher risk for revascularization

RESTENOSIS!



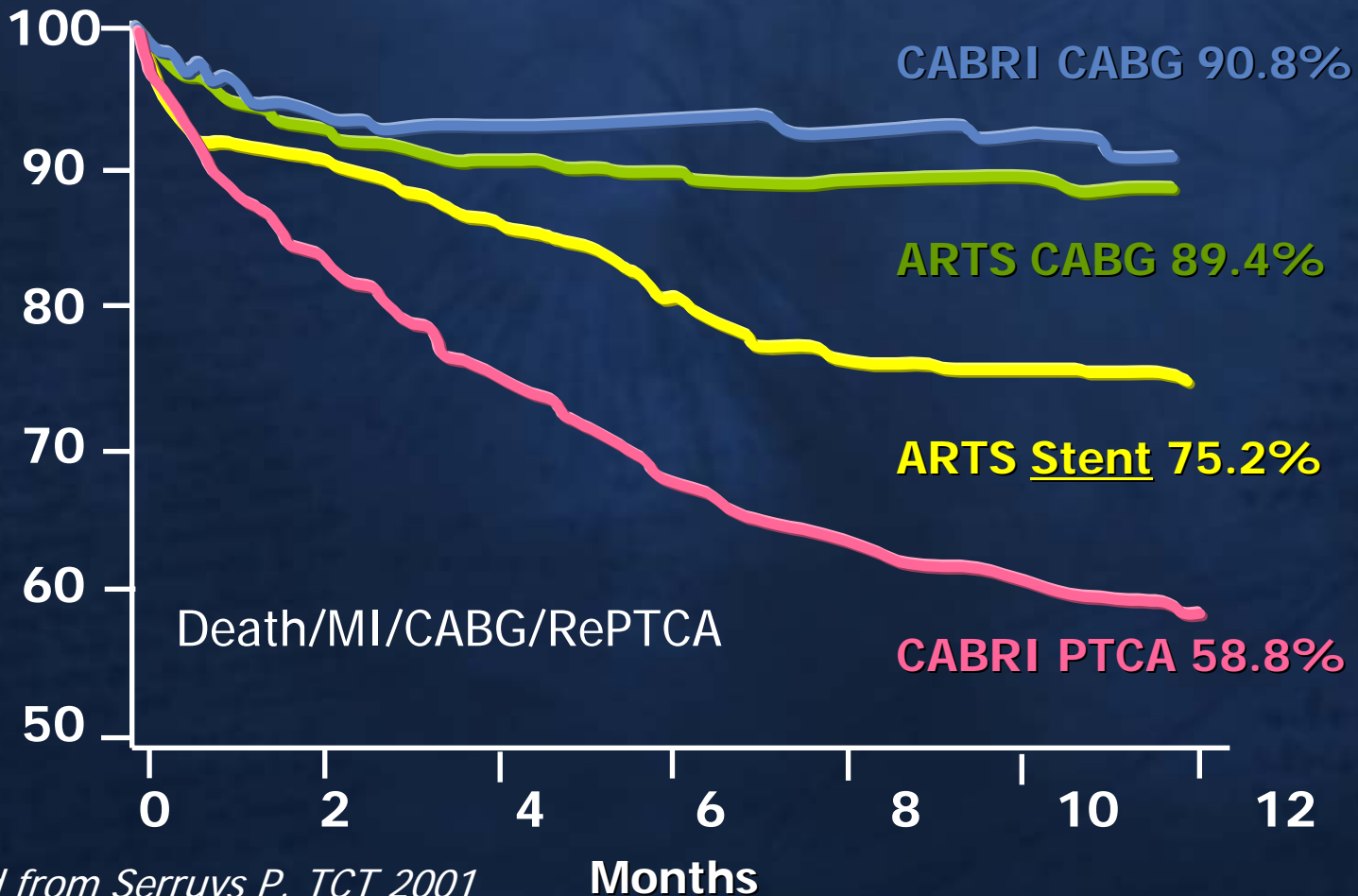
Stent vs. CABG

	Year	N	FU	<u>Death</u>		<u>MI</u>		<u>TVR</u>		
				<u>Stent</u>	<u>CABG</u>	<u>Stent</u>	<u>CABG</u>	<u>Stent</u>	<u>CABG</u>	
Kim et al.	2000	200	2Y	0	1	1	2	19	2	
ERACI-2*	2001	450	1Y	3.1	7.5	2.3	6.6	16.8	4.8	
SOS	2002	91	1Y	RESTENOSIS!				7	19	4
AWESOME [☞]	2001	454	3Y	20	21	-	-	-	-	
ARTS	1999	1200	1Y	MACE † : stent 9.5% vs. CABG 2.3%						

(*: mostly unstable angina, ☞: high risk patients, †: MACE = death, MI, rePCI, reCABG)

However, the gap is narrowing

Survival without MI or revascularization



Modified from Serruys P. TCT 2001

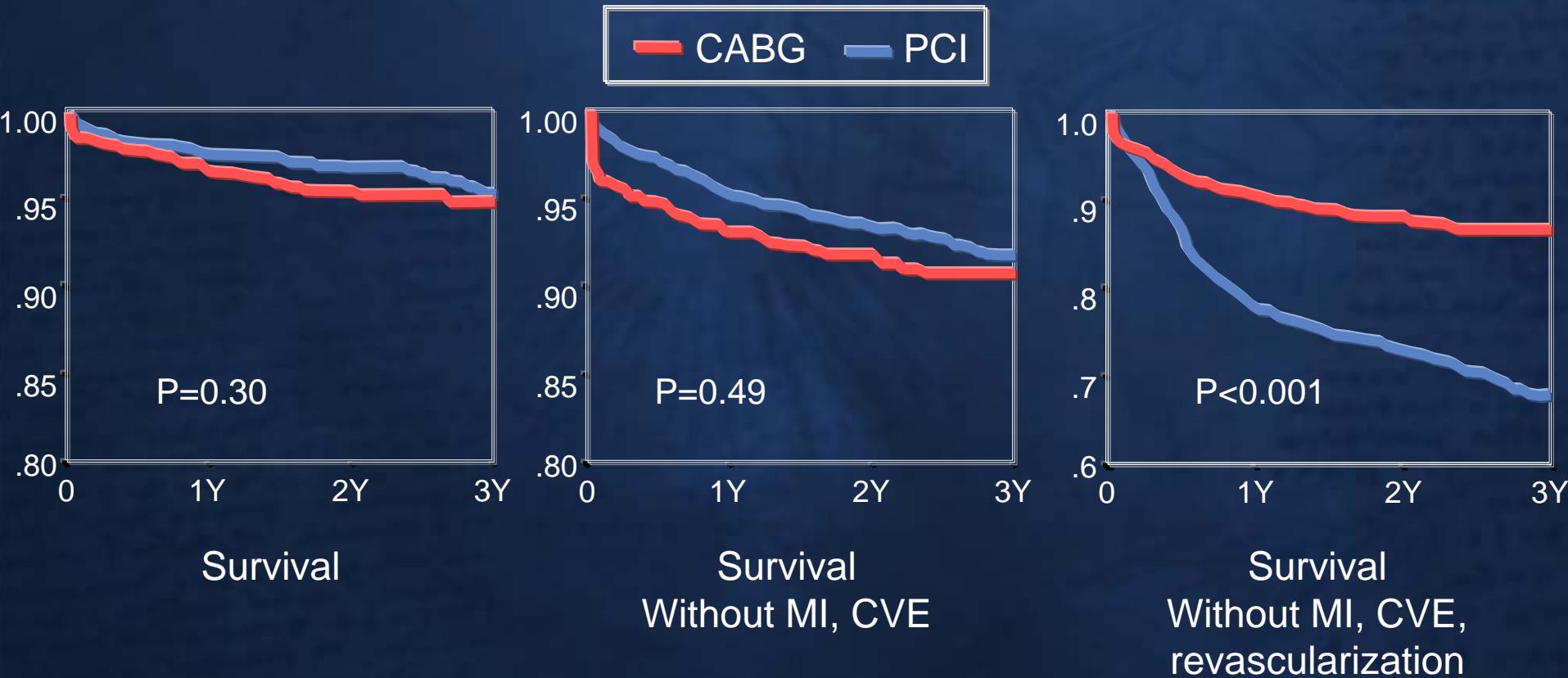
Korean Multicenter Revascularization Registry (KORR)

- Korea multi-center retrospective registry of PCI and CABG for multivessel disease
 - **Principal investigator** **Won Ro Lee**
 - Aju University Byung-il William Choi
 - Chon-Nam University Myung Ho Jeong
 - Dong-A University Moo Hyun Kim, Jong Soo Woo
 - Gachon Medical School Eak Kyun Shin
 - Korea University Young Moo Ro
 - Seoul National University Young-Bae Park, Ki-Bong Kim
 - Sunkyunkwan University Hyeon-Cheol Gwon, Young Tak Lee
 - Ulsan University Seung-Jung Park
 - Yonsei University Seung Yun Cho, Byung-Chul Chang

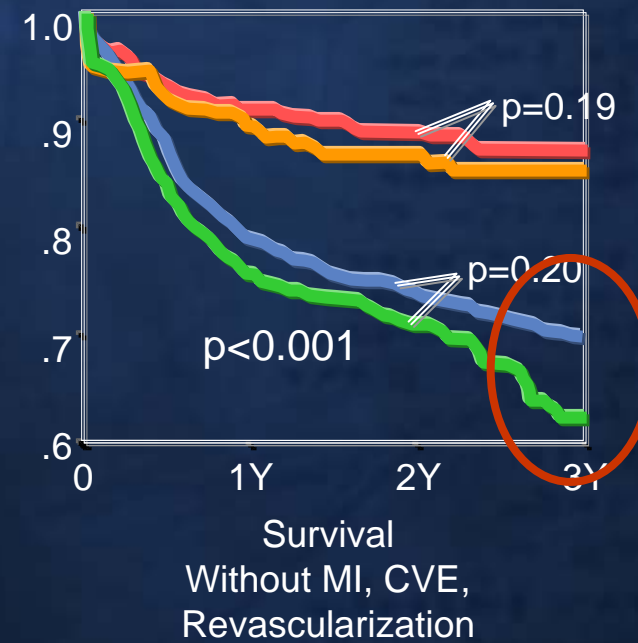
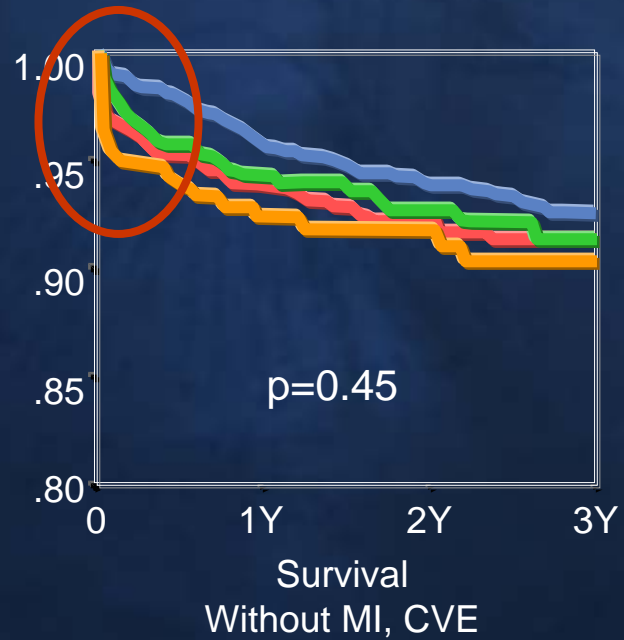
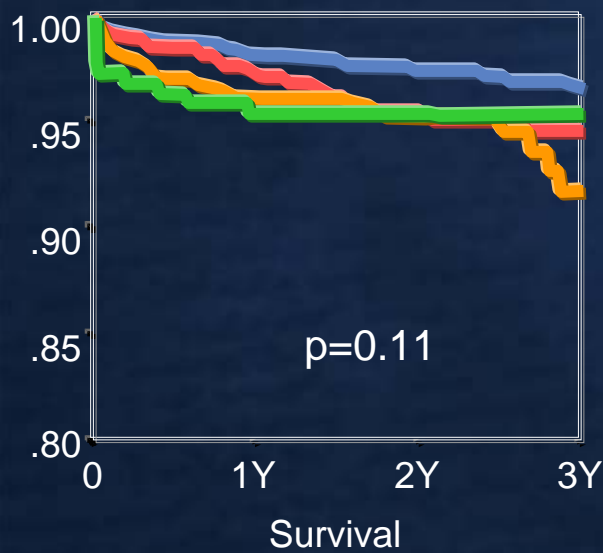
KORR: Subjects

- Inclusion criteria
 - Two- or three-vessel coronary artery disease who underwent elective PCI or CABG between January 1995 and December 2000
- Exclusion criteria
 - Cardiogenic shock
 - AMI indicated for primary PCI
 - AMI with VSD, MR, or myocardial free-wall rupture
 - Concomitant valve surgery
 - History of CABG
 - Significant left main disease
- Among 3,279 patients, 2,154 were selected after statistical adjustments for the disparities between two groups.
- Stent in 68.5% of PCI, one or more arterial graft in 92.1% of CABG

KORR: Results

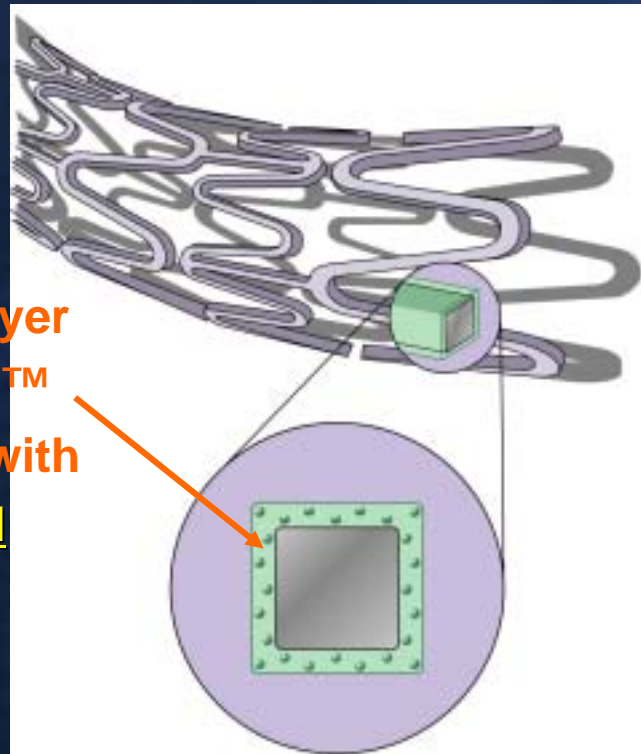


KORR: Results



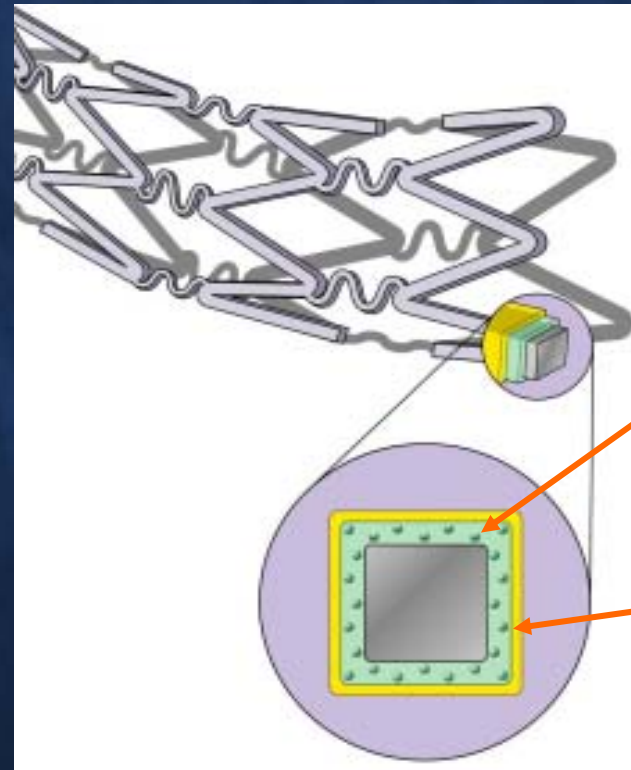
Drug-Eluting Stent

TAXUS™ Stent



Single Layer
Translute™
polymer with
Paclitaxel

Cypher™ Stent



PEVA with
Sirolimus

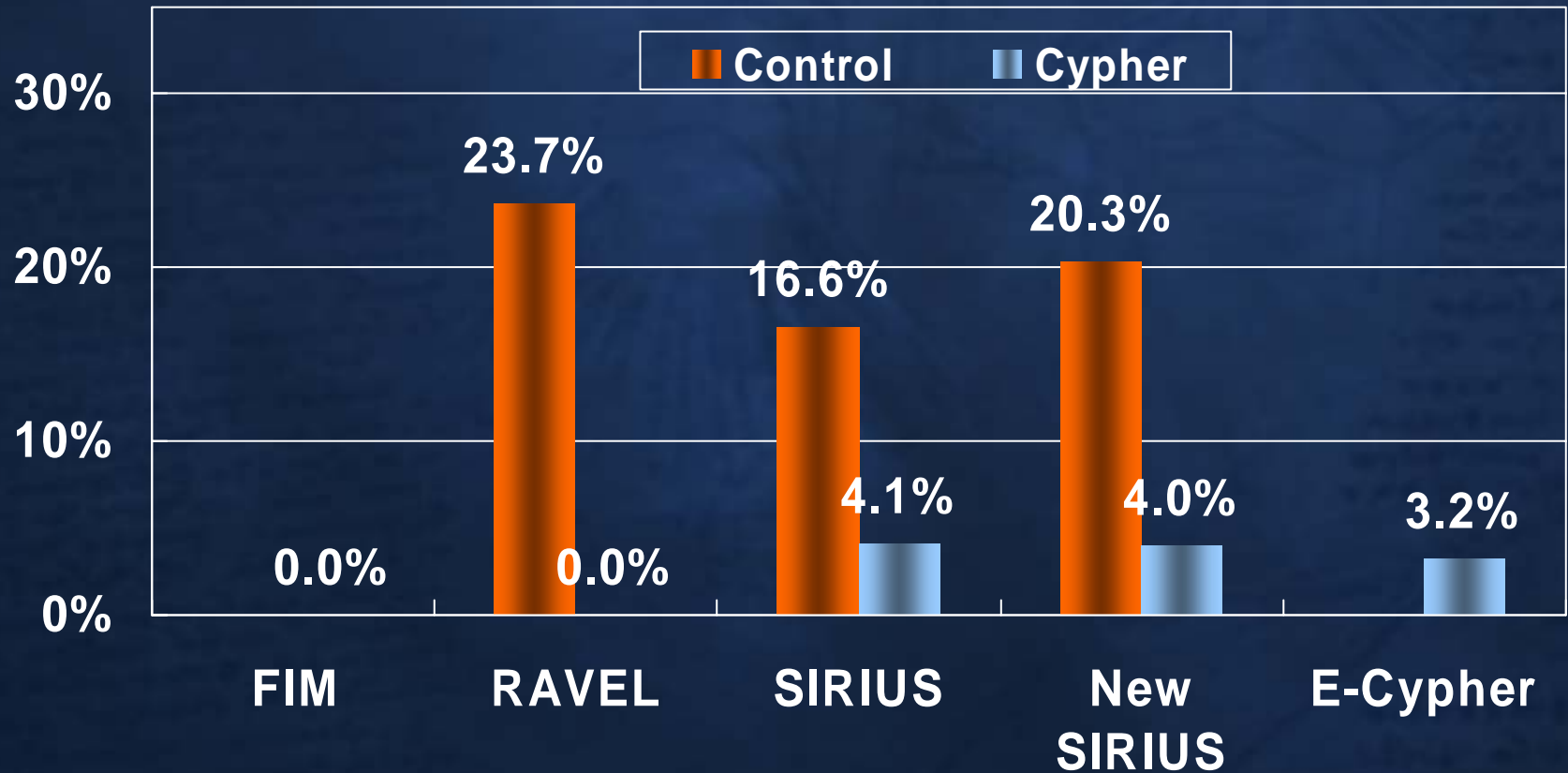
PBMA
Diffusion
Barrier

Cypher Studies

	N	Design	Indication
FIM	45	Registry	Stable angina, RD 3.0–3.5 mm, covered by 18 mm stent
RAVEL	238	RCT	Stable angina, RD 2.5–3.5 mm, covered by 18 mm stent
SIRIUS	1100	RCT	RD 2.5-3.5 mm Lesion length 15-30 mm
New SIRIUS	452	RCT	RD 2.5-3.5 mm Lesion length 15-30 mm
E-Cypher	5766	E-registry	Real world experience

Cypher: 9-mo TLR

(TLR: target lesion revascularization)

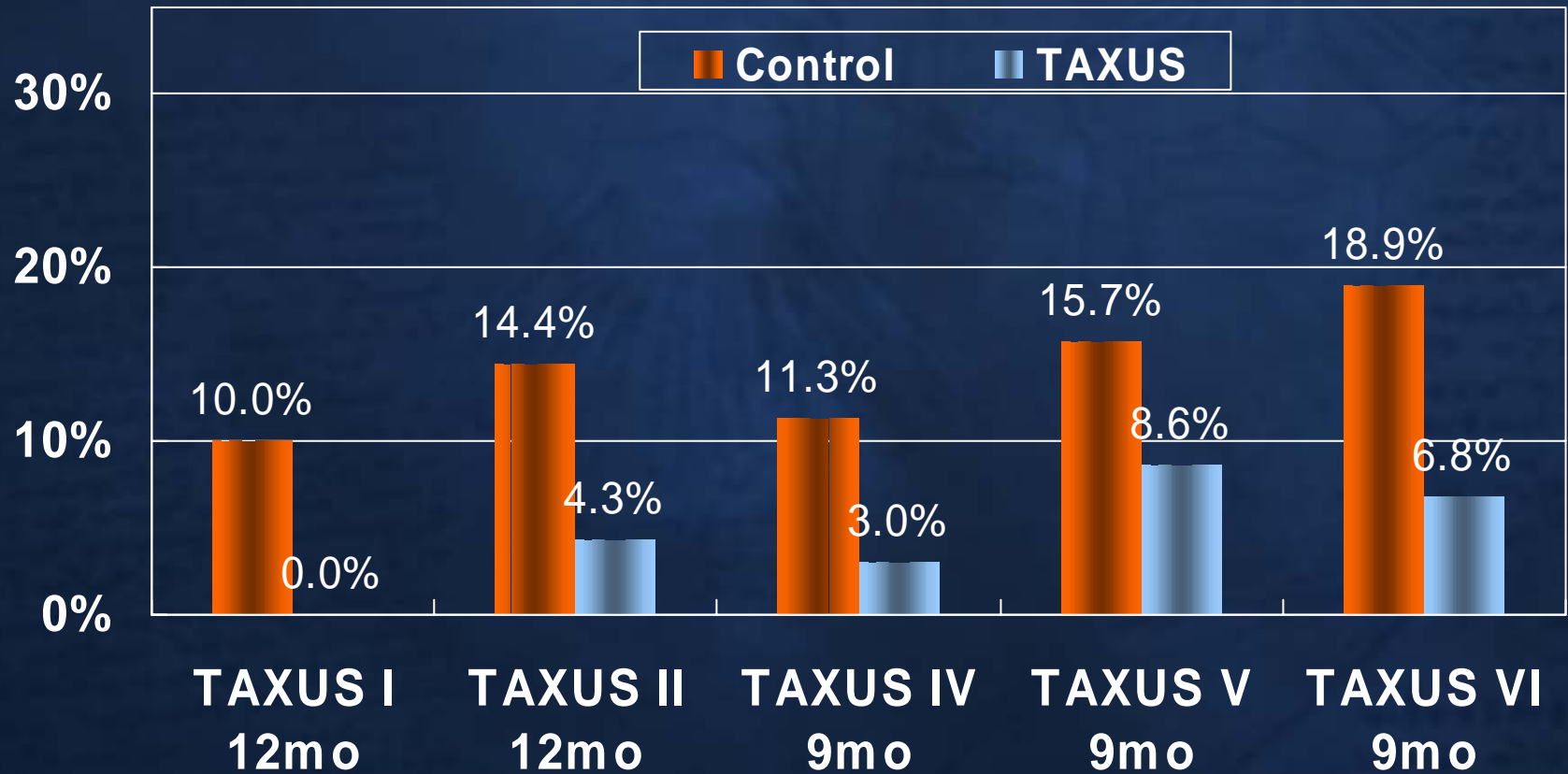


TAXUS Studies

	N	Design	RD (mm)	LL (mm)	Memo
TAXUS I	61	RCT	3.0-3.5	10-12	FIM, TAXUS NIRx
TAXUS II	536	RCT	3.0-3.5	10-12	TAXUS NIRx MR and SR
TAXUS IV	1326	RCT	2.5-3.5	10-28	Express TAXUS SR
TAXUS V	1156	RCT	2.25-4.0	10-46	TAXUS SR overlapping
TAXUS VI	448	RCT	2.5-3.75	18-40	TAXUS MR overlapping

TAXUS: TLR

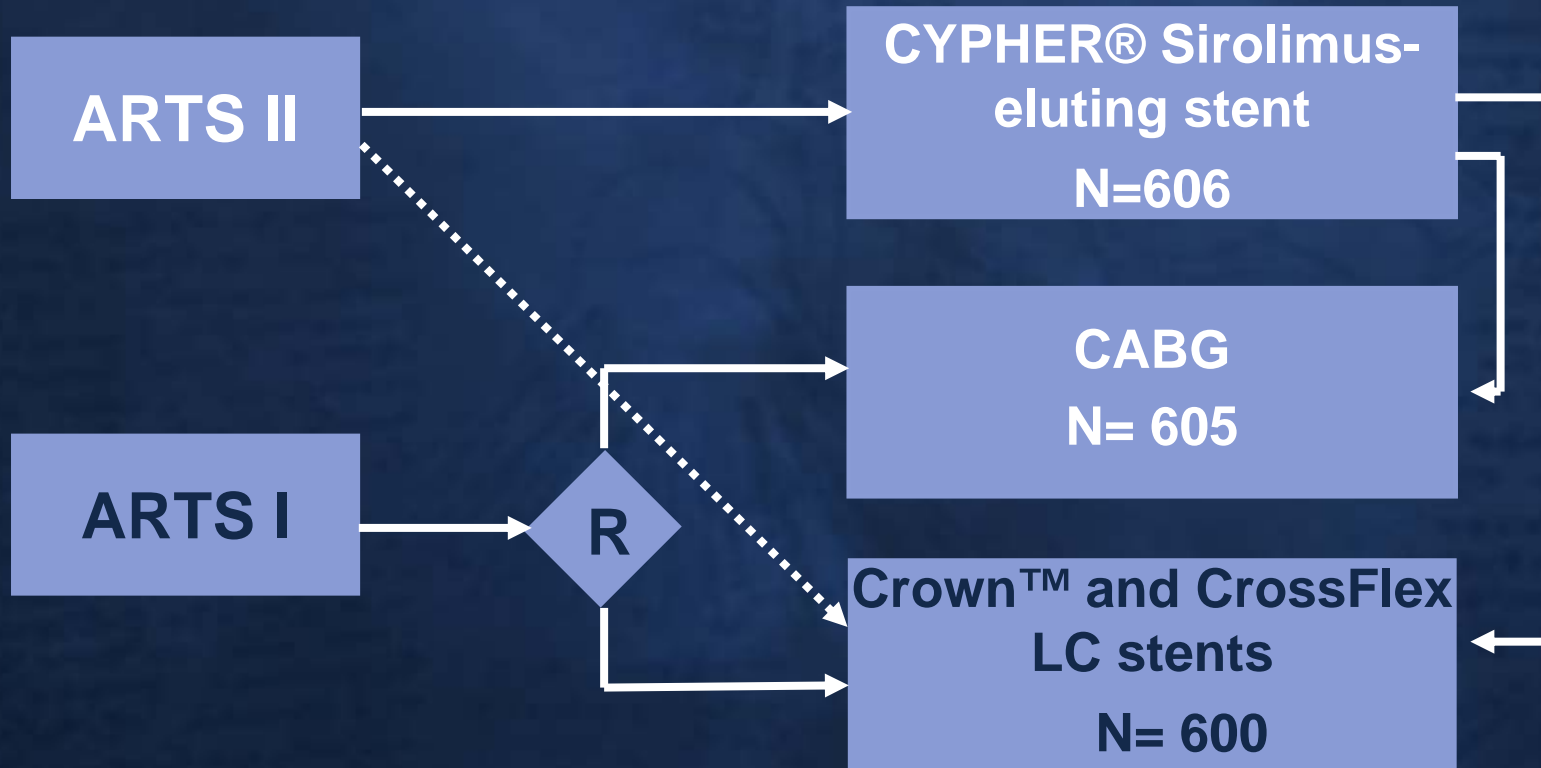
(TLR: target lesion revascularization)



(TLR: target lesion revascularization)

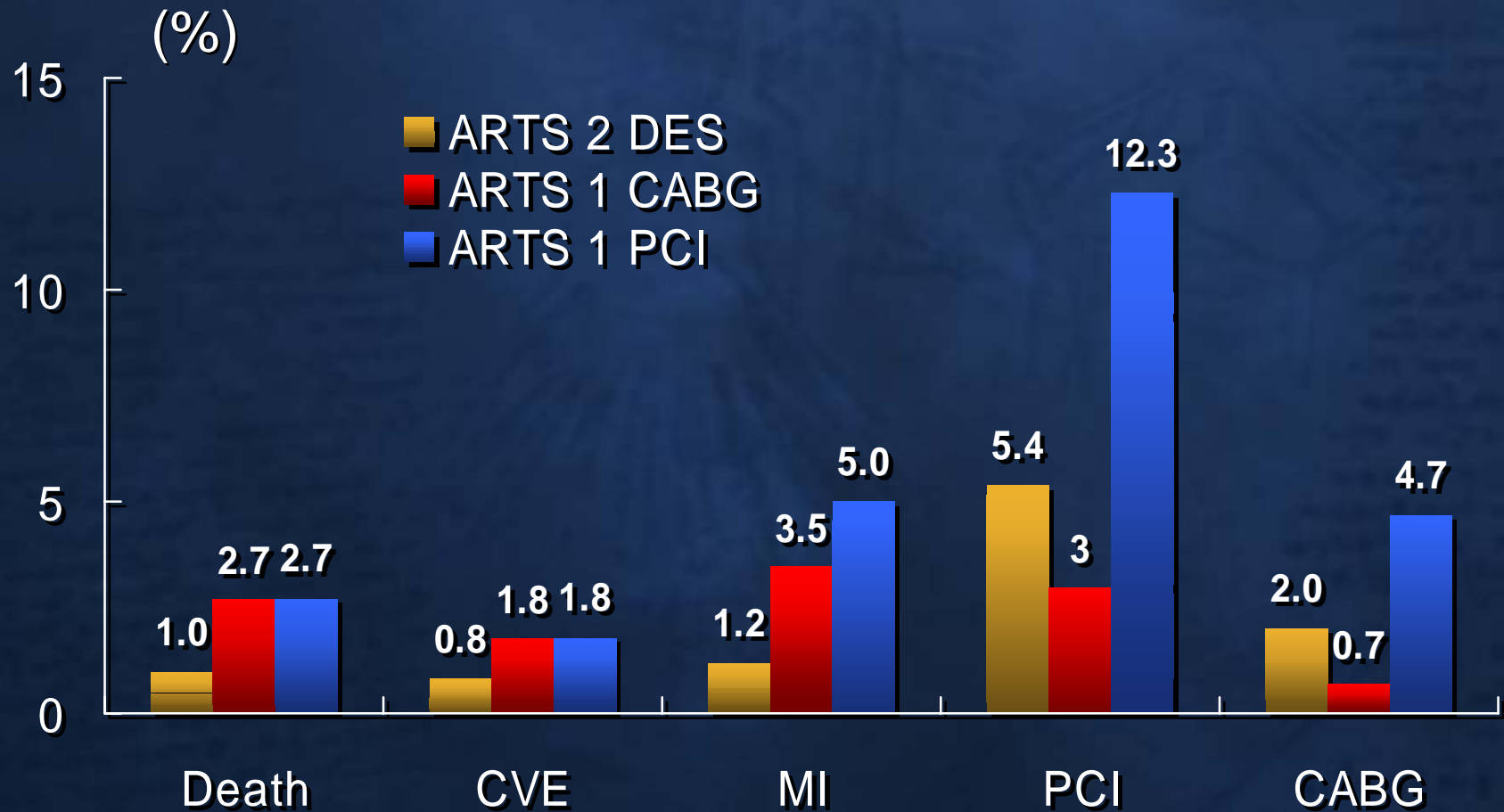
Multivessel Disease

ARTS II – Study design



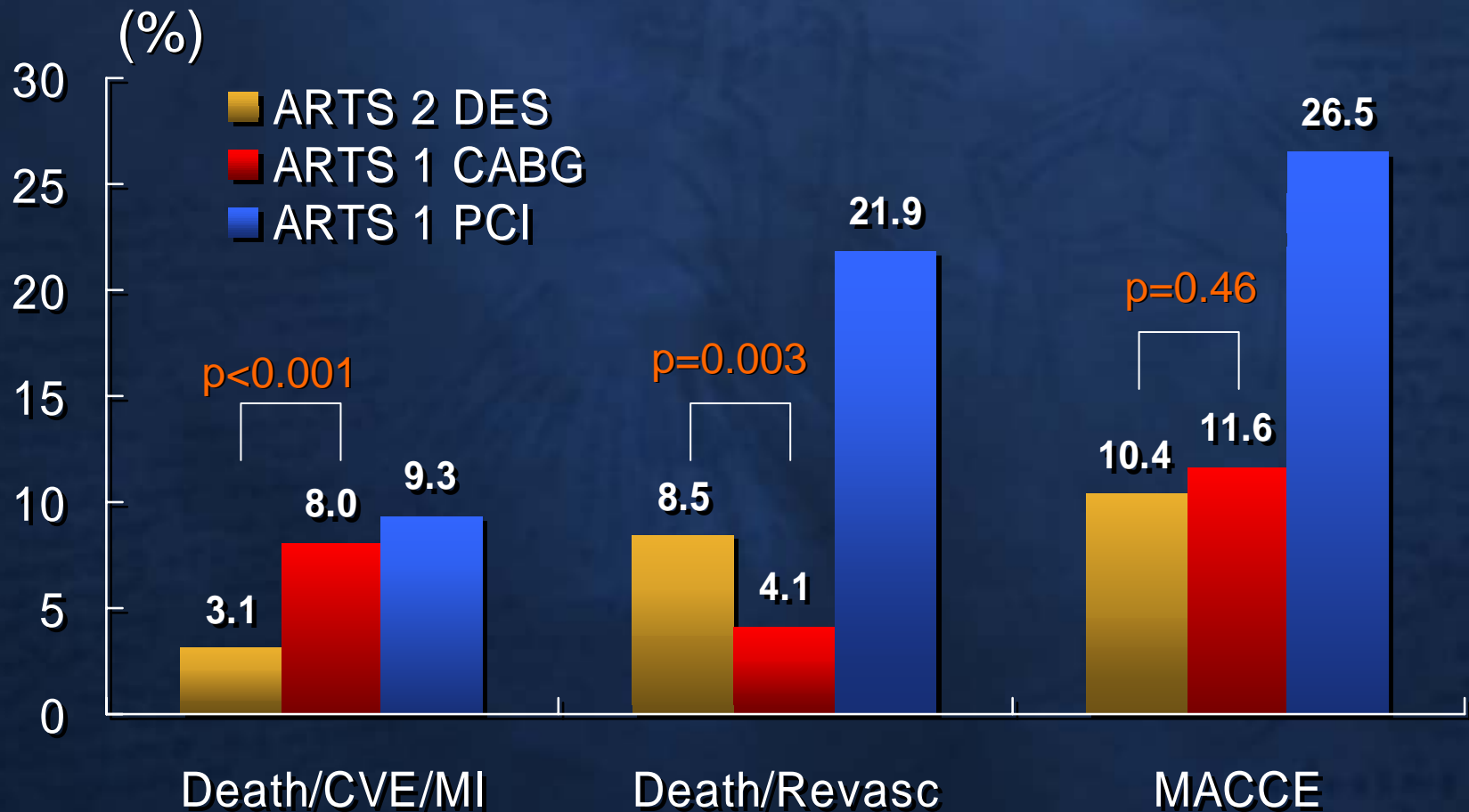
Primary endpoint: effectiveness of CYPHER® Sirolimus-eluting stent compared with CABG surgery as observed in ARTS I (measured as MACCE- free survival at 1 yr)

ARTS: 12-mo MACCE



Serruys: TCT Sept 2004

ARTS: 12-mo MACCE



Multicenter Randomized Studies

- SYNTAX
 - Left main or 3-vessel disease
 - TAXUS vs. CABG
- FREEDOM
 - Diabetic patients with multivessel disease
 - DES with ReoPro vs. CABG
- COMBAT
 - Left main disease with/without multi-vessel disease
 - Cypher vs. CABG

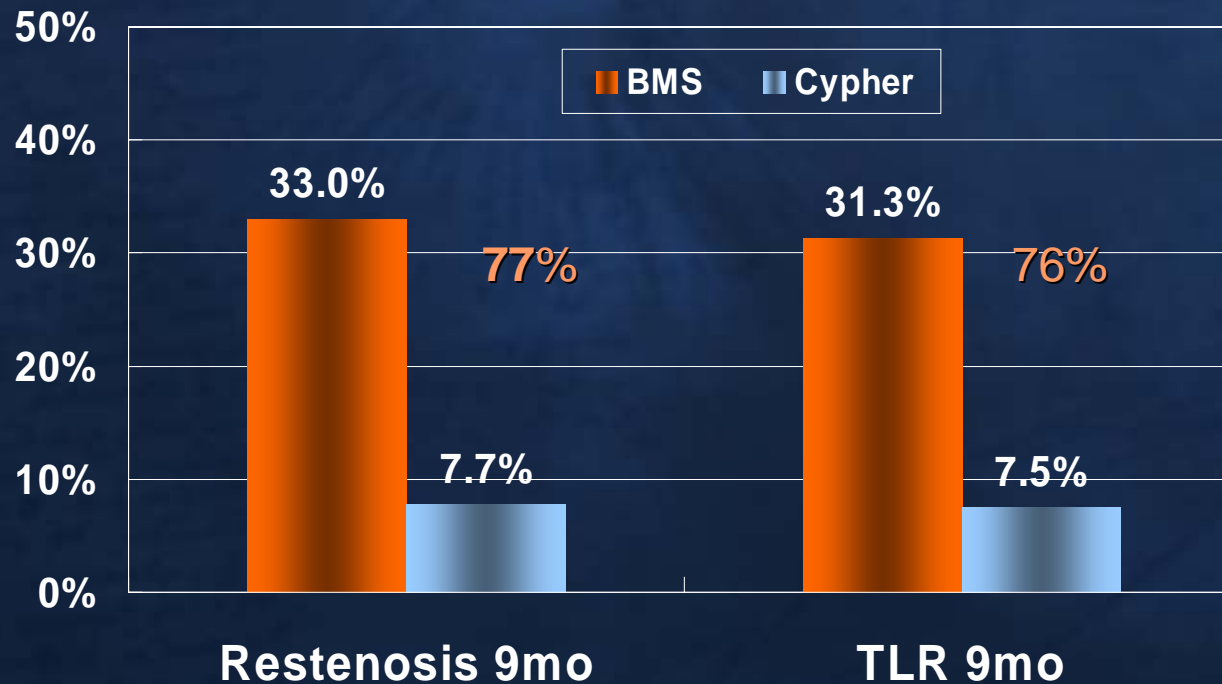
Complex Subsets

- Complex clinical subsets
 - Diabetes
 - Left ventricular dysfunction
- Complex lesion subsets
 - Diffuse disease
 - Left main disease
 - Instent restenosis
 - Bifurcation lesion
 - Chronic total occlusion

Diabetes

DIABETES: drug-eluting stent

- Randomized study: Cypher vs. BMS in diabetics
- N=160

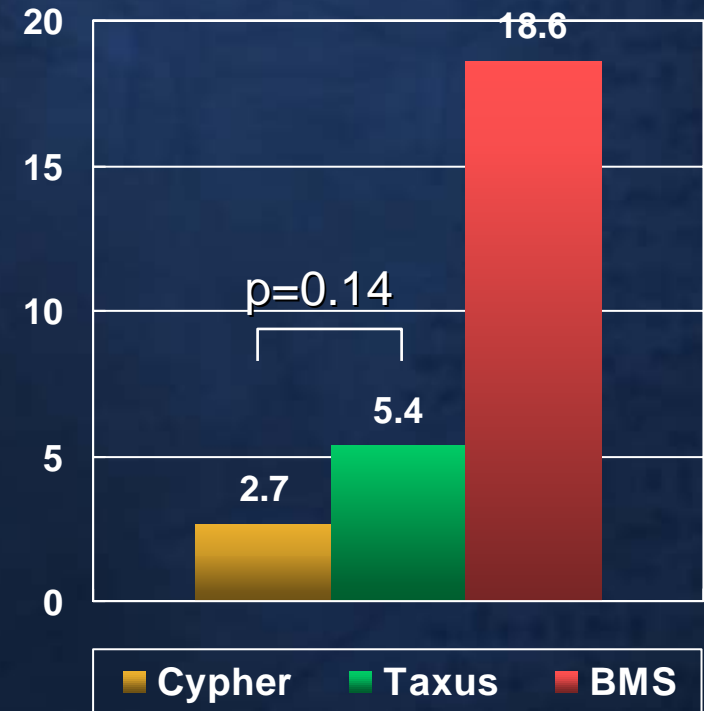


Diffuse disease

- Long DES (*Park SJ, Angioplasty Summit 2004*)

	Cypher	Taxus	BMS	p-value
N	337	194	201	
Ref. Diameter (mm)	2.8	2.9	3.1	<0.001
Lesion length (mm)	35.3	36.3	32.0	0.004
Stent length (mm)	42.8	43.1	36.0	<0.001
Late loss	0.27	0.78	1.35	0.001
Restenosis rate (%)	6.3	16.0	40.6	0.001

7-month TLR



Left Main Disease

- DES in left main disease (*Park SJ JACC 2005*)
 - Cypher stent in left main disease (N=131)
 - Including multi-vessel disease (58% of the patients)
 - 6-mo restenosis rate 3.8%

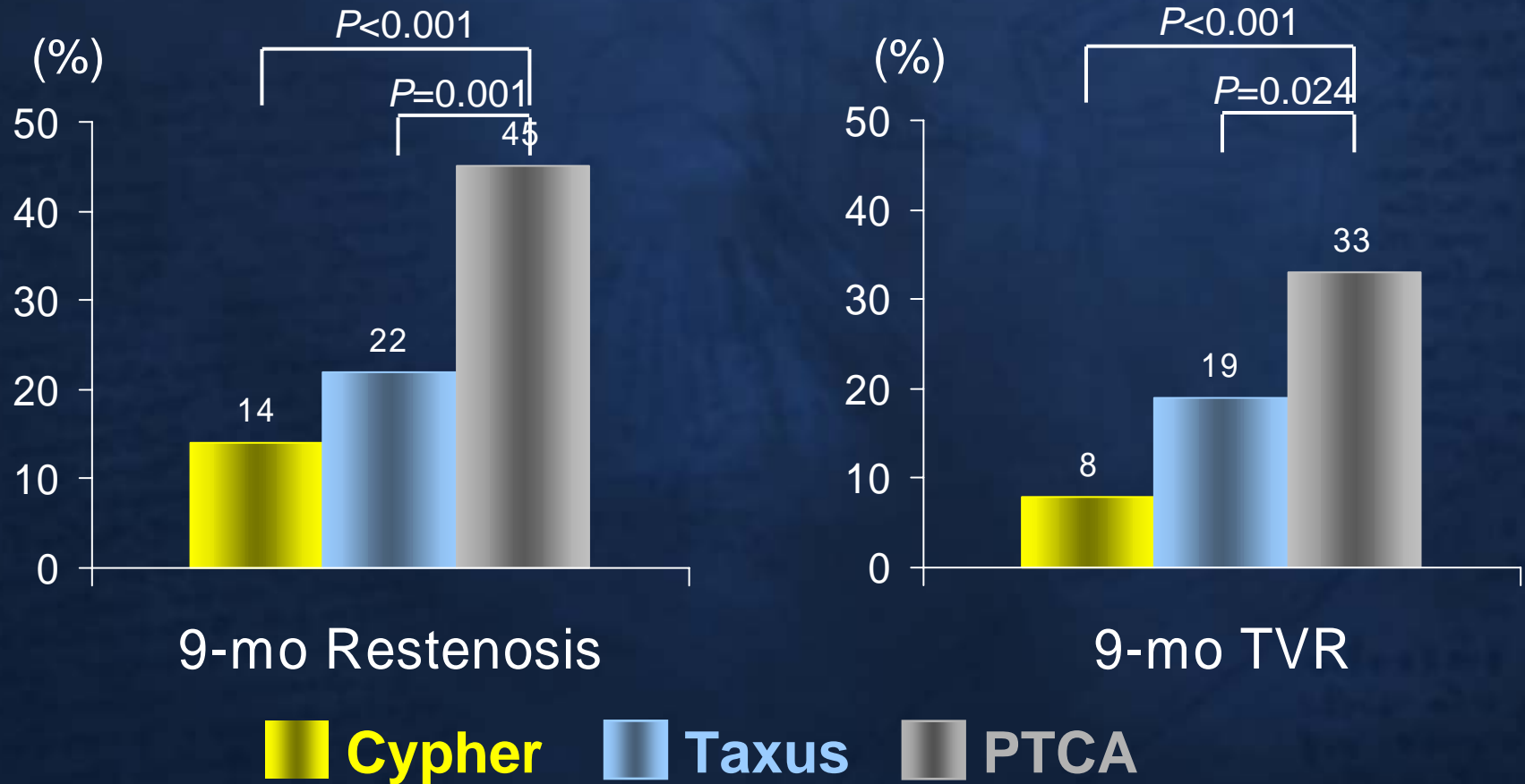
	In-hospital event	6-mo event
Death	0	0
QMI	0	0
NQMI	14(10.7%)	0
emCABG	0	0
RePCI	0	1(0.7%)*

(* due to edge restenosis)

Instant Restenosis

ISAR-DESIRE

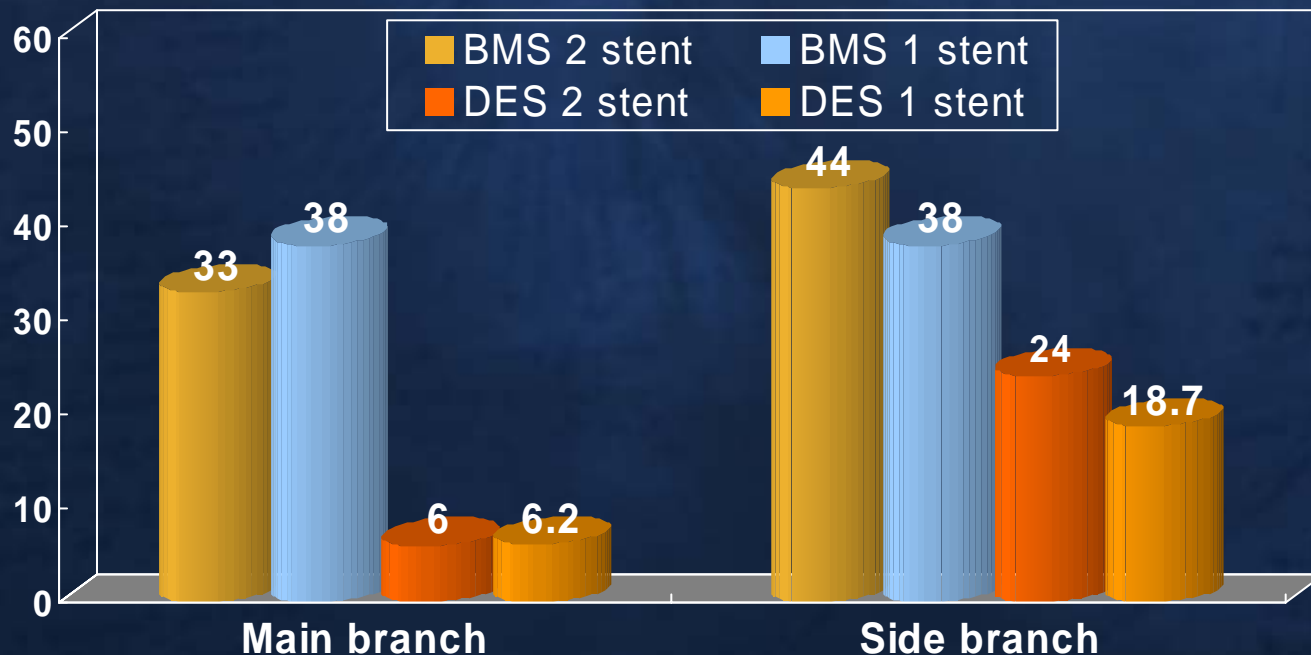
(Randomized study, N=100 in each group)



Bifurcation Lesion

- DES vs. BMS

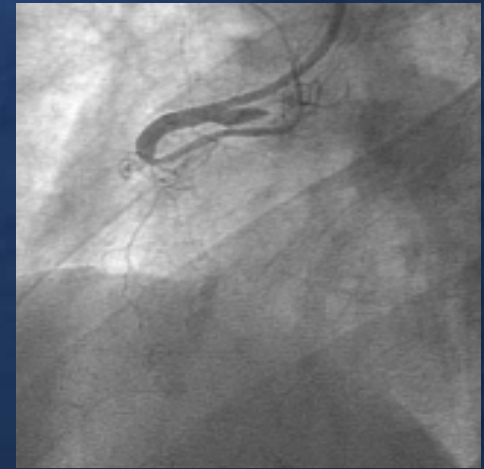
- BMS: 7 months restenosis (Yamashita JACC 2000;35:929-36)
- DES: 6 months restenosis (**SIRIUS Bifurcation study**)



Chronic Total Occlusion

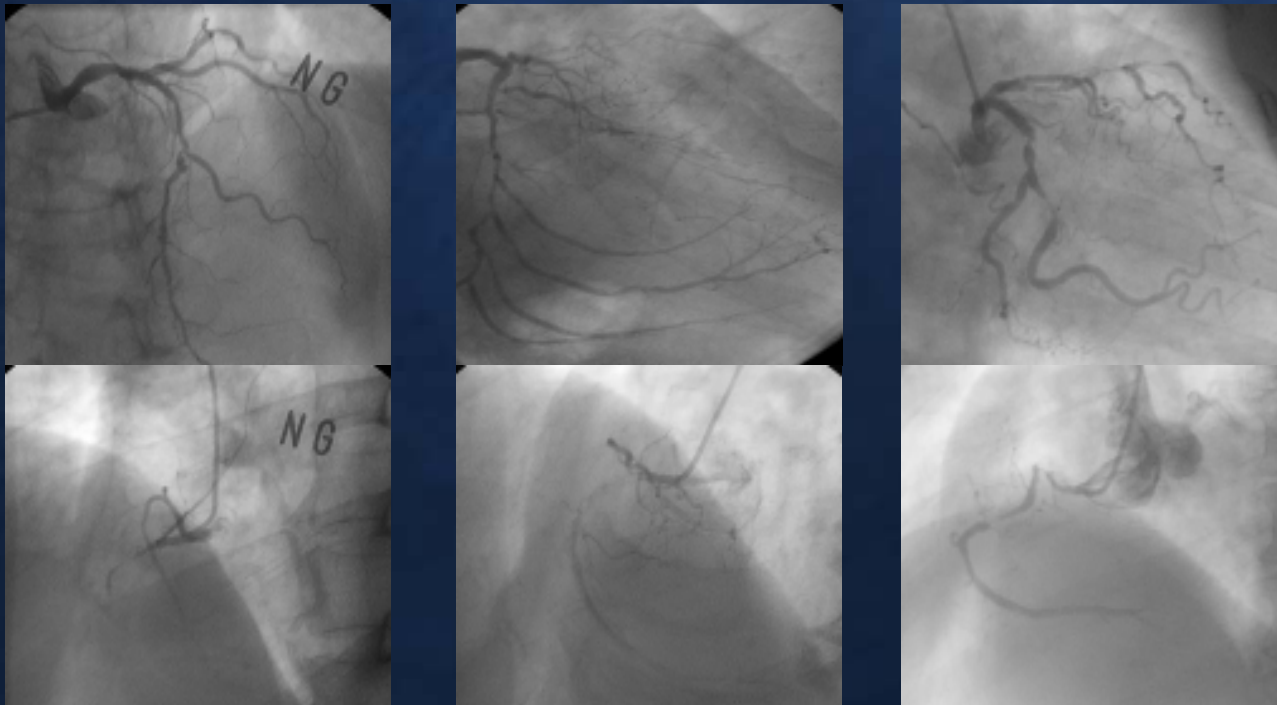
TRI: SMC Experience

- N=107
- Guiding catheter diameter
 - 5-French 47 patients
 - 6-French 60 patients
- One-day admission program: N=46 (43%)
- Cross-over to transfemoral approach: 1 (0.9%)
- **Procedural success: 90 (84%)**
- Complications
 - 1 minor hematoma



Still Yet to Know

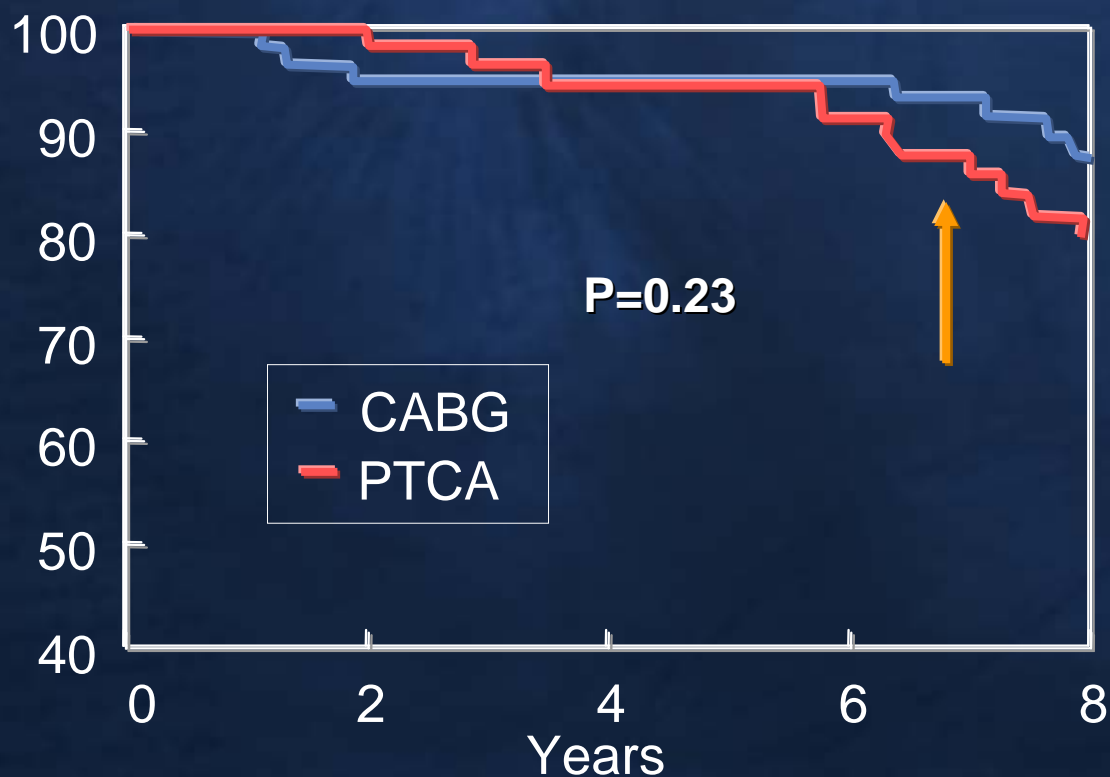
- Severe multi-vessel disease
E.g. Multiple bifurcations, CTOs, and diffuse lesions in diabetics
- Left ventricular dysfunction



Still Yet to Know

- Long-term result
 - Including non-culprit lesion progression

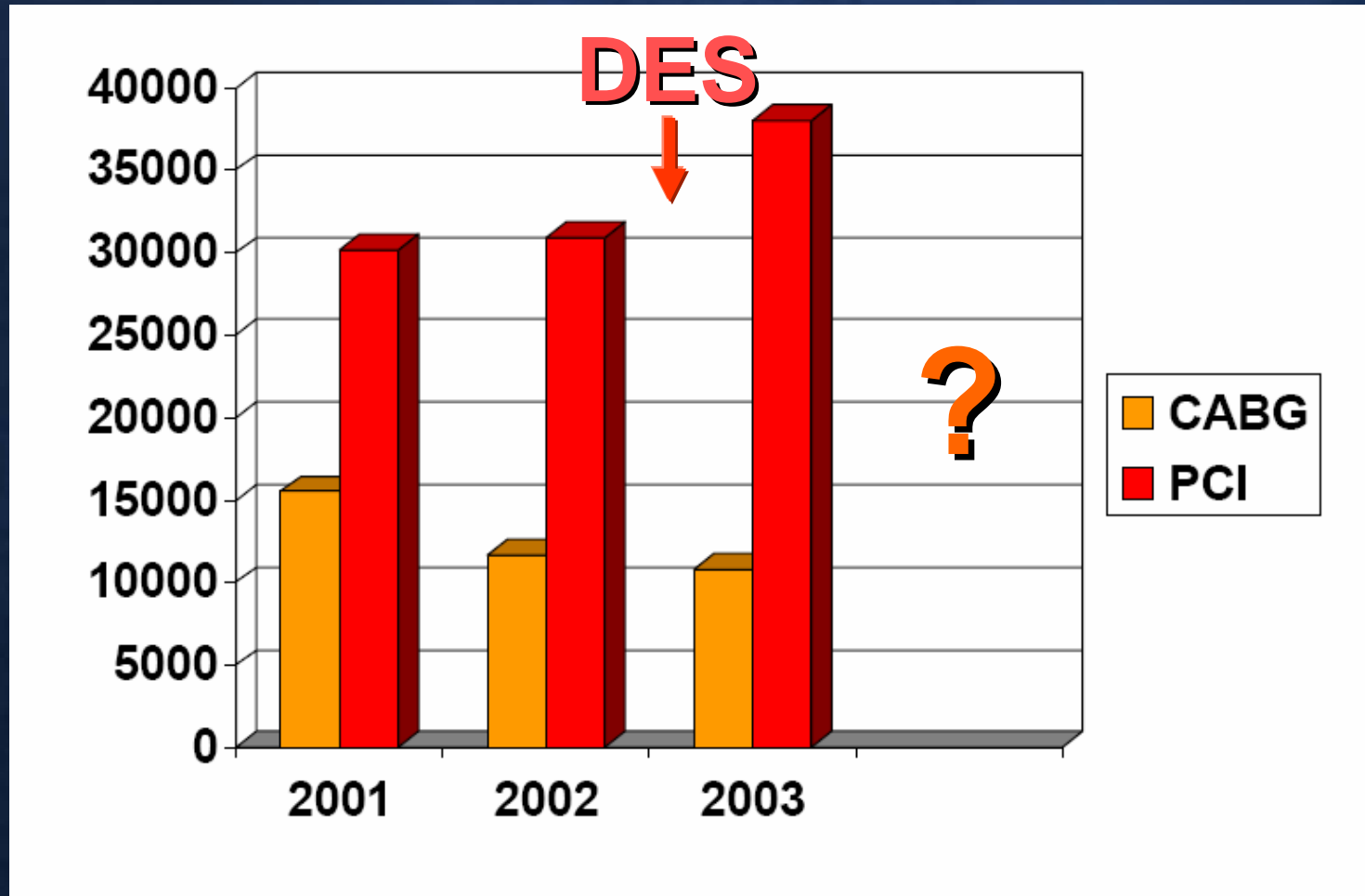
EAST trial: Survival in Diabetics



Drug-Eluting Stent Impact on CABG

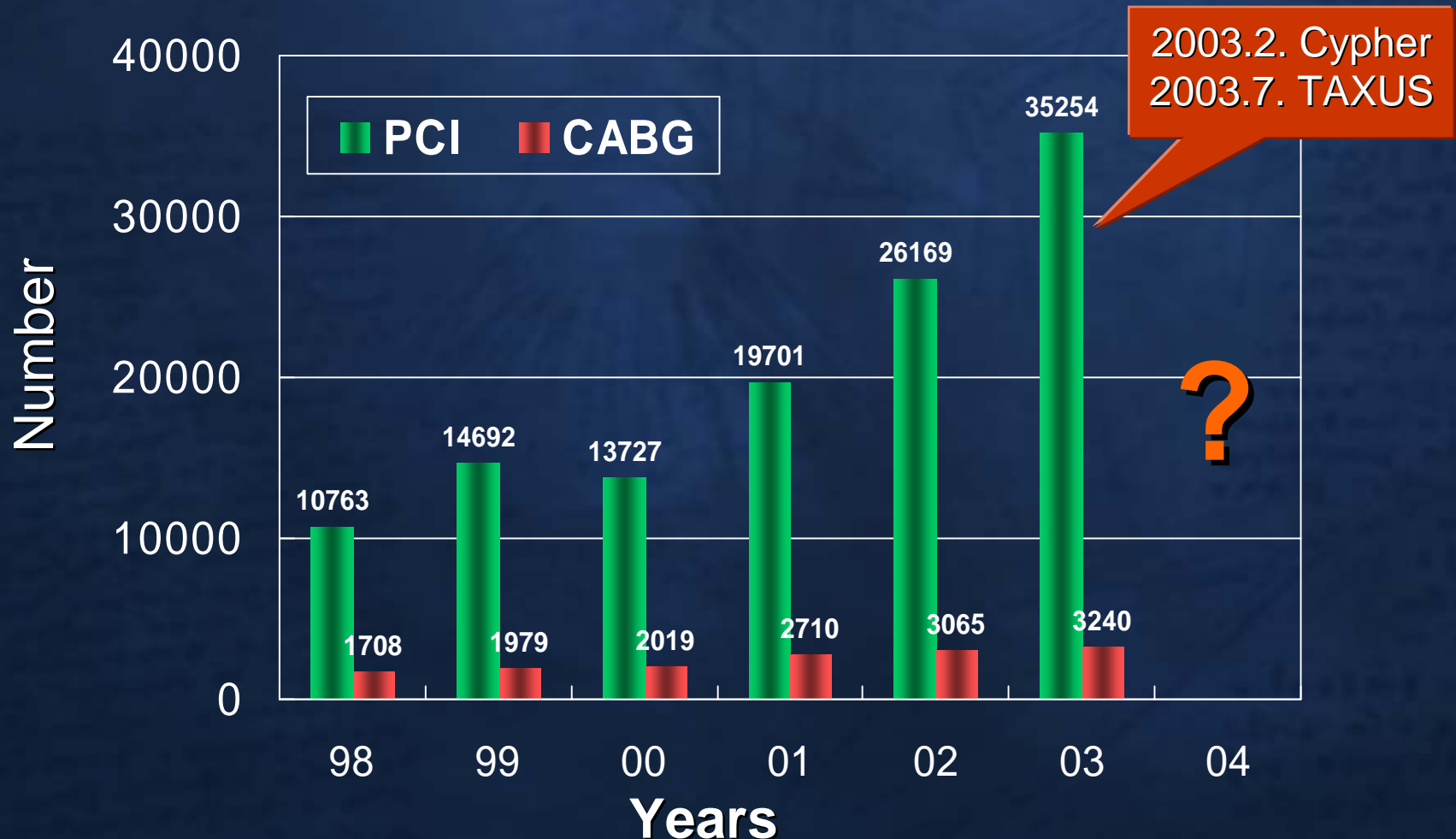


New York State CABG vs. PCI



Korea PCI vs. CABG

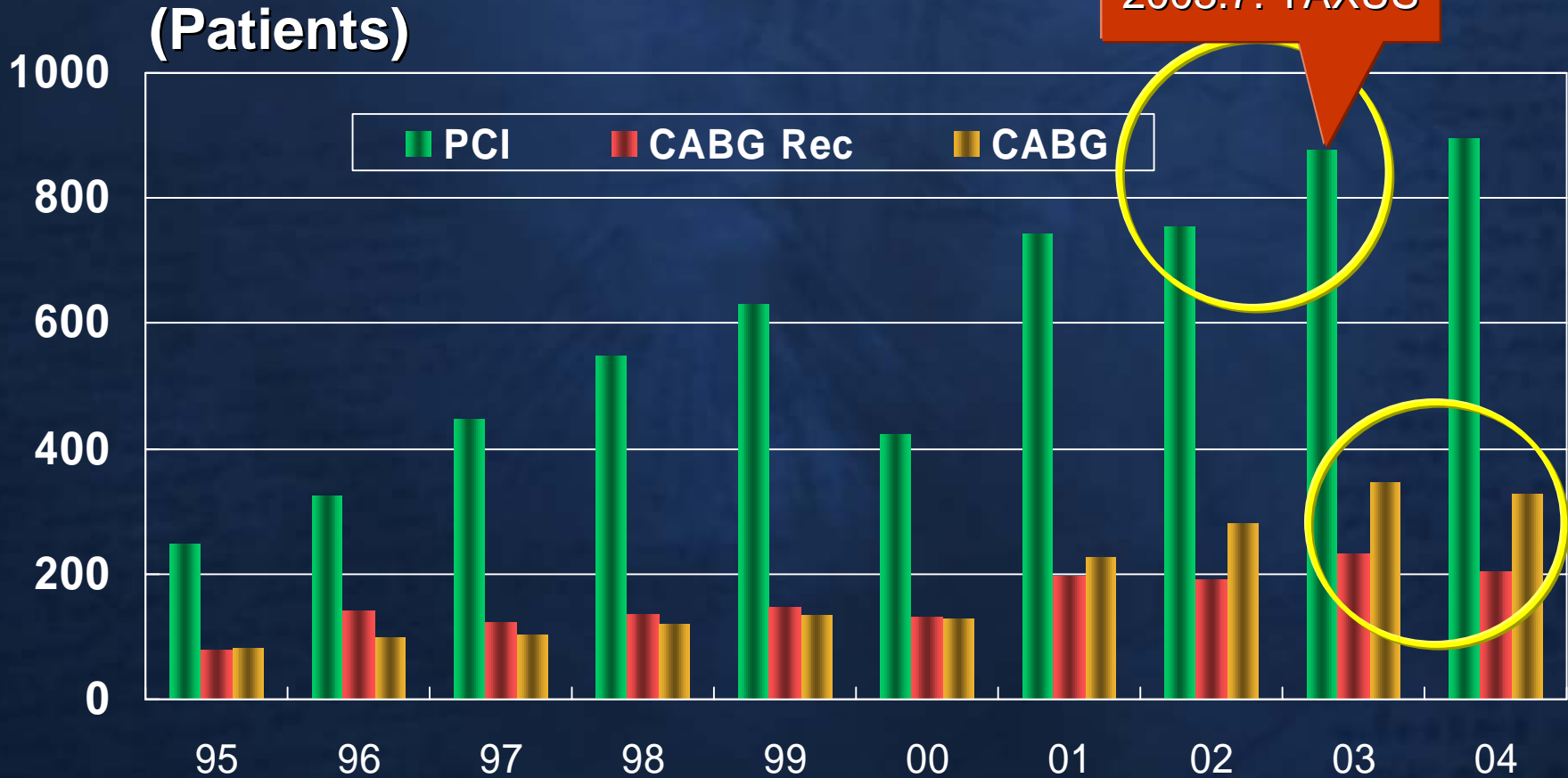
The Korea Heart Foundation



2003.2. Cypher
2003.7. TAXUS



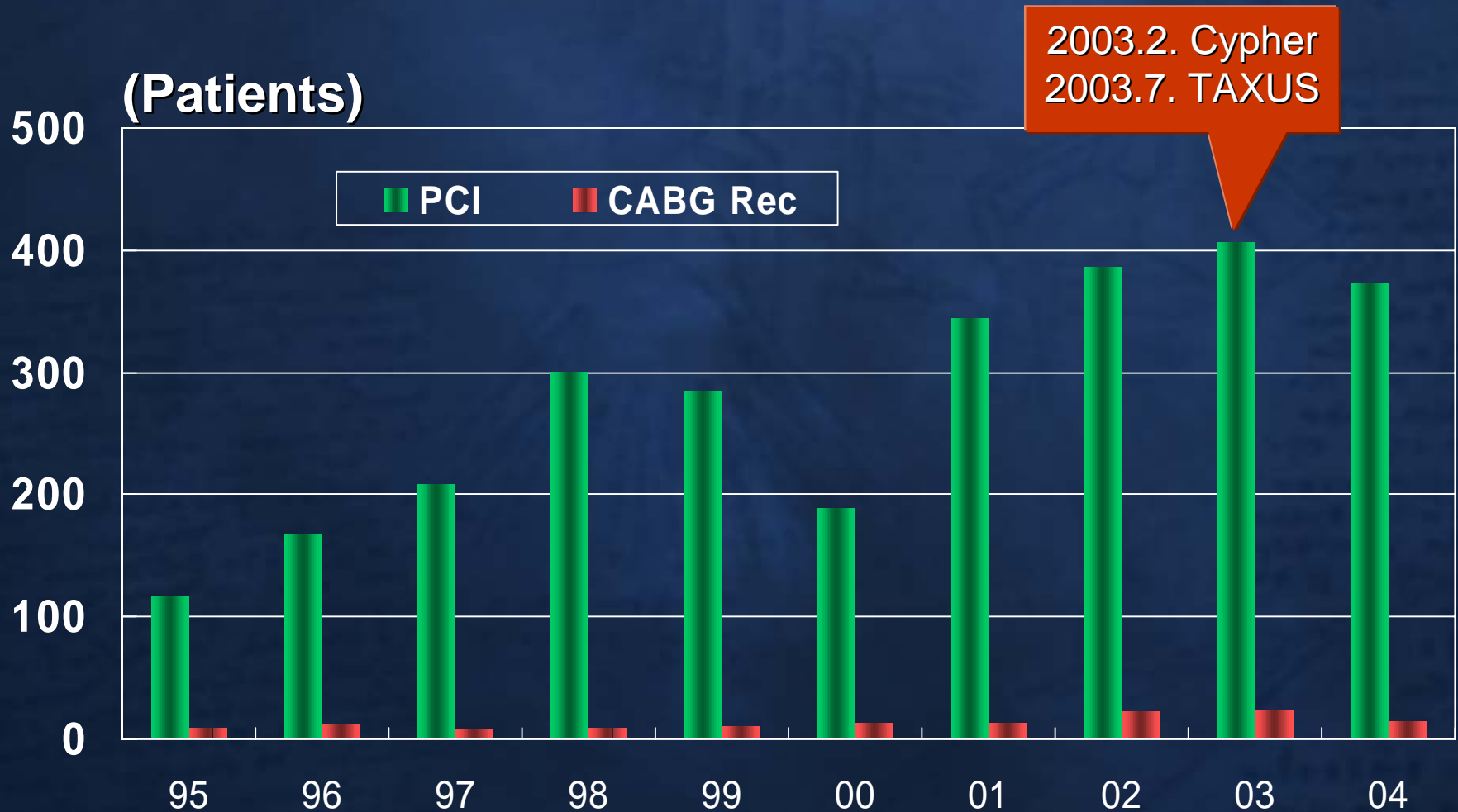
SMC Data



2003.2. Cypher
2003.7. TAXUS

(CABG Rec = recommended for CABG in SMC)

1-vessel disease

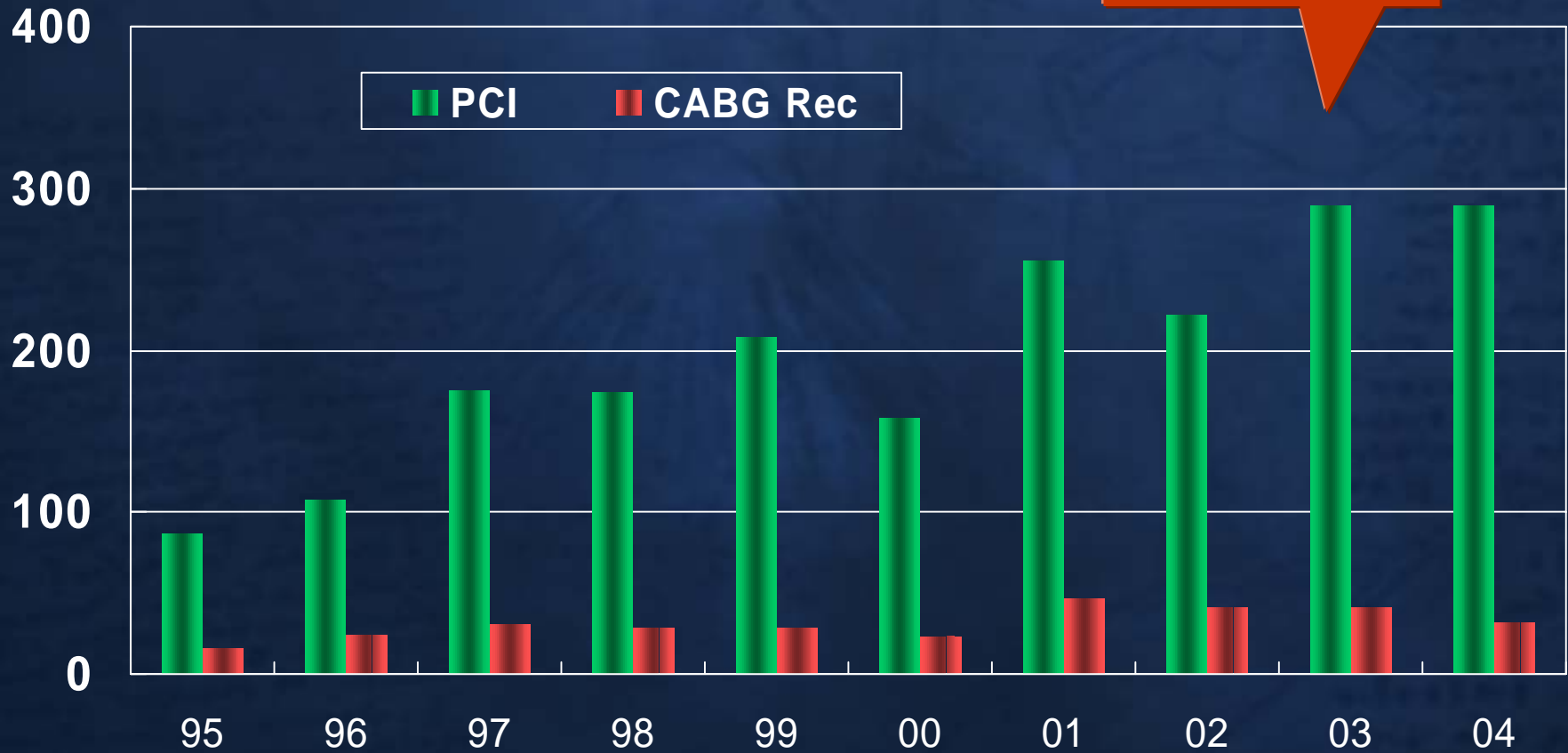


2003.2. Cypher
2003.7. TAXUS

2-vessel disease

2003.2. Cypher
2003.7. TAXUS

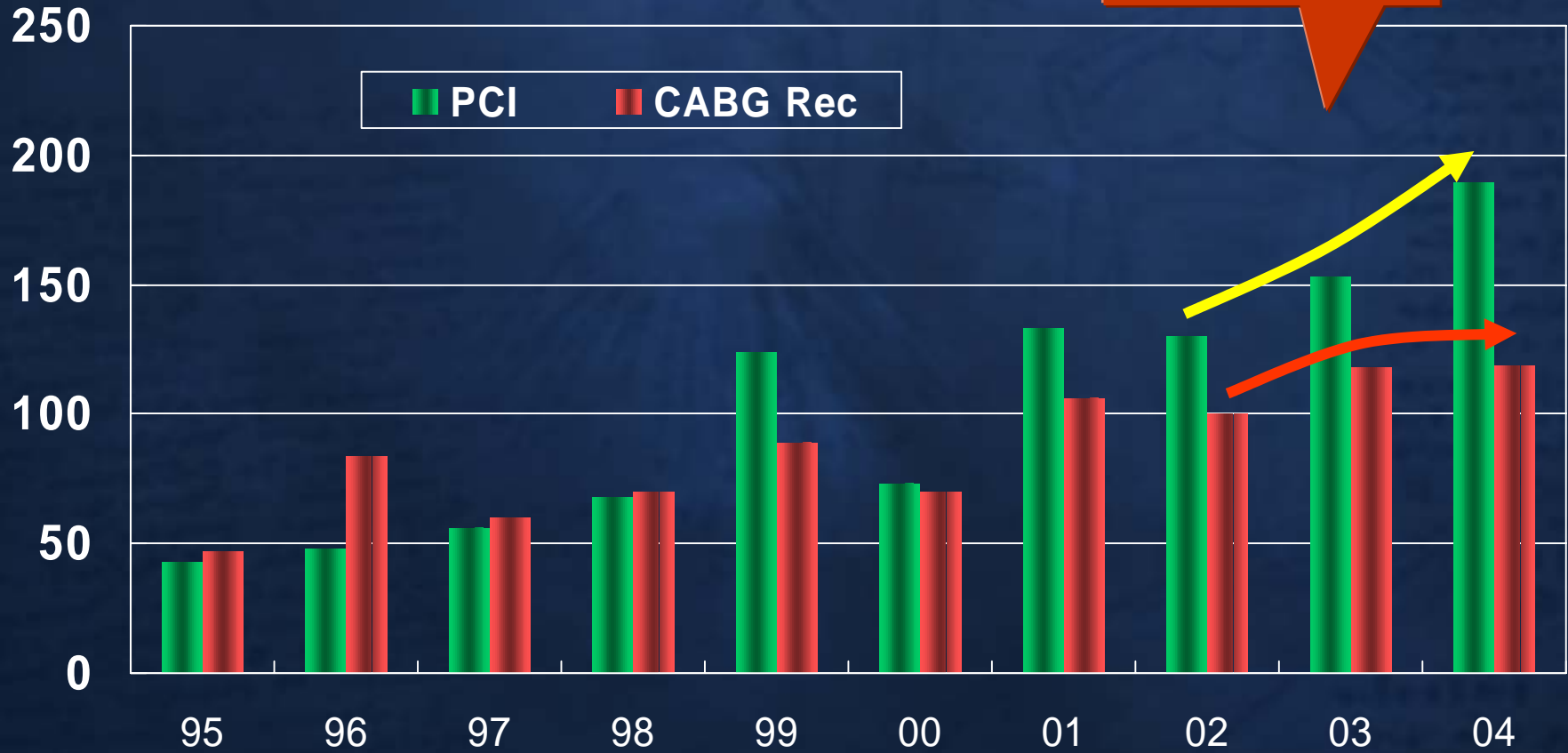
(Patients)



3-vessel disease

(Patients)

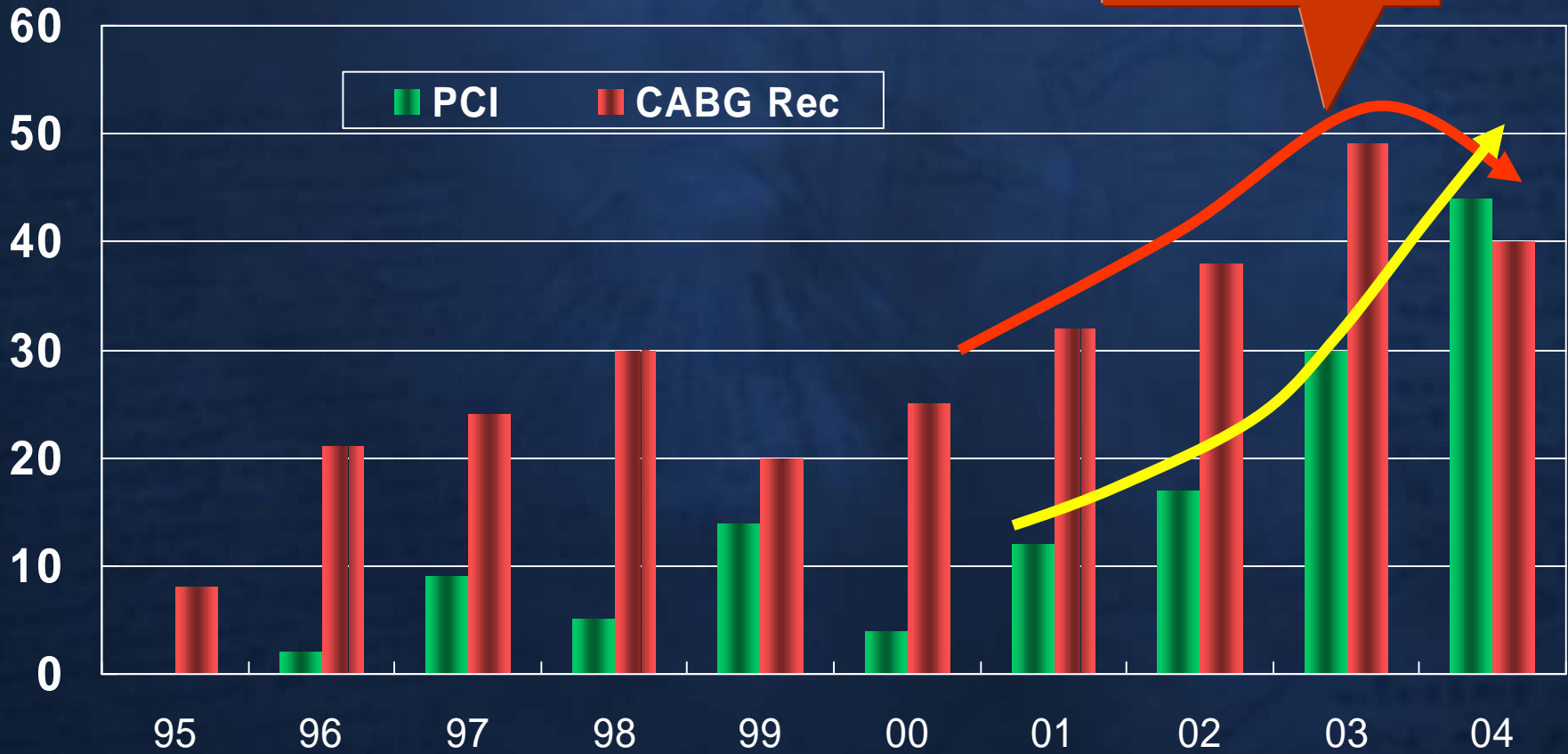
2003.2. Cypher
2003.7. TAXUS



Left main disease

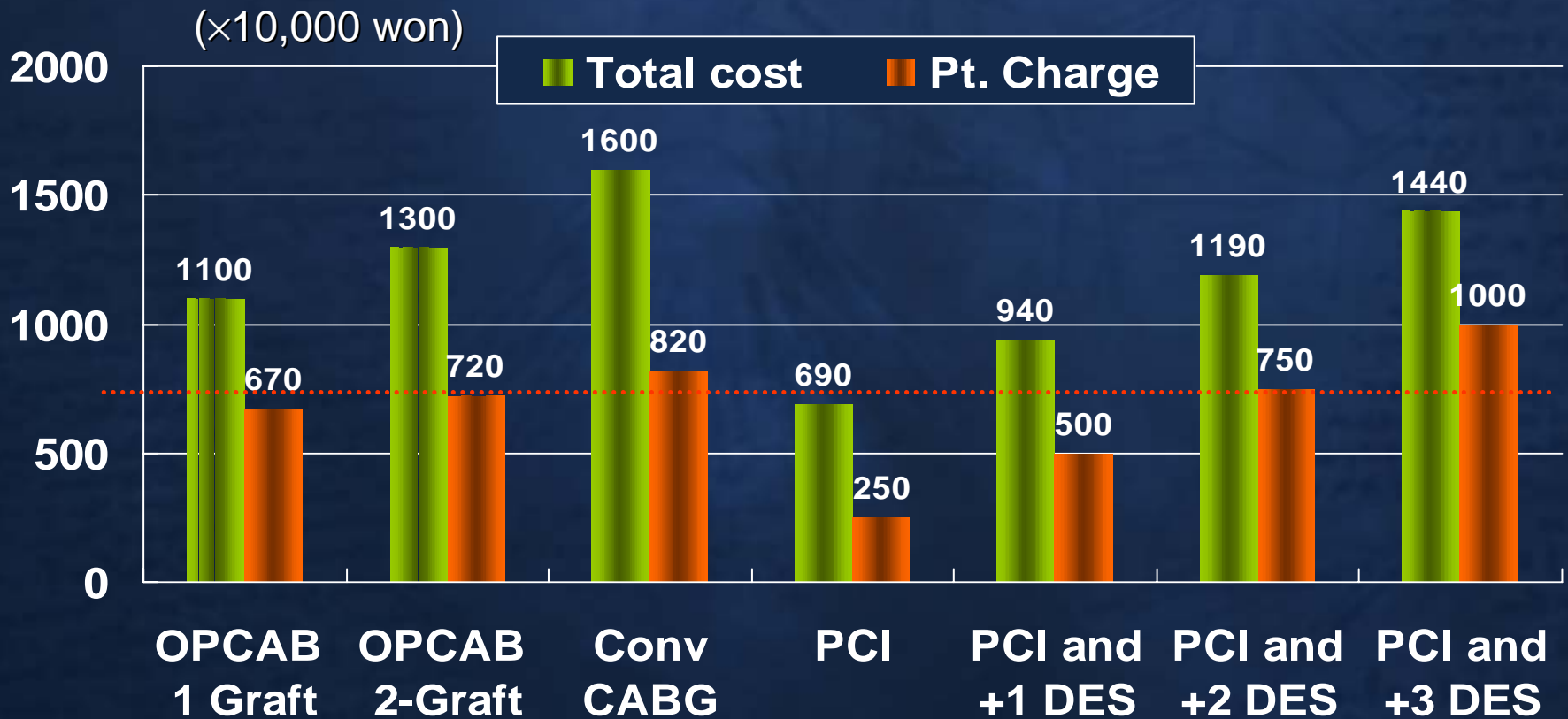
(Patients)

2003.2. Cypher
2003.7. TAXUS



Cost of PCI vs. CABG

(SMC data: Total cost during admission)



(+DES: additional DES not covered by insurance)

Which do you prefer?



CABG

- Pain
- Scar
- Stroke
- Bleeding
- Intubation
- Atrial fibrillation
- Cognitive decline
- Admission for a week



TRI with DES

- Local anesthesia
- Immediate ambulation
- Admission for 1-2 days
- Maybe equivalent MACE

What is the best way?

Combining medical Rx and revascularization

PCI

For any suitable anatomy



Risk reduction

- Glycemic control
- Lipid control
- BP control
- Weight control
- Exercise

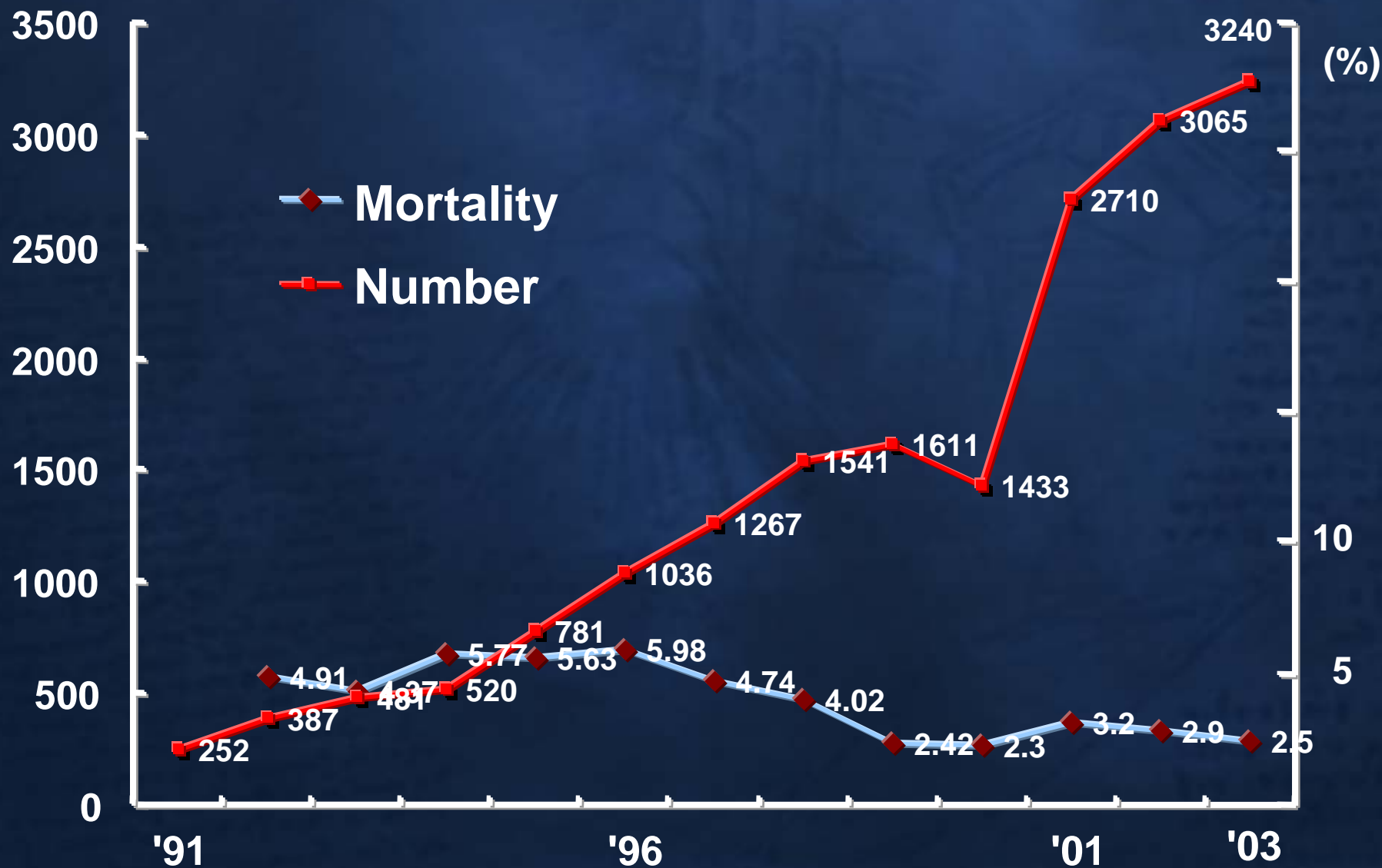
CABG

Unsuitable anatomy
For PCI

When PCI is

- Not possible (20% of CTO)
- Too time-consuming
- Too expensive

Annual Number of CABG in Korea



A friend in need is a friend indeed



TABLE Registry

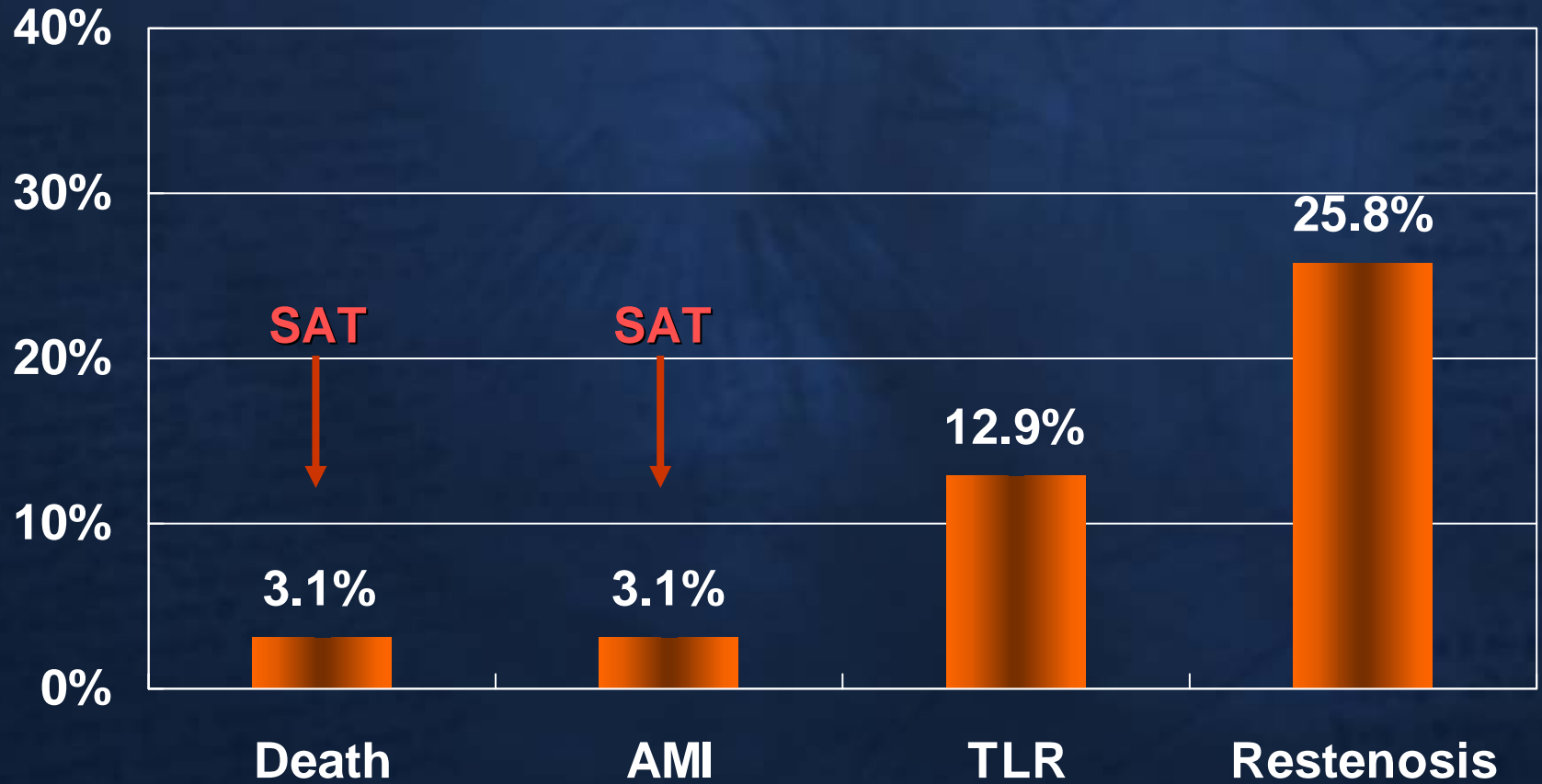
- QCA measurement

		RD (mm)	MLD (mm)	Length (mm)
Main	Pre	3.1 ± 0.6	0.9 ± 0.7	13.0 ± 6.9
Branch	Post	3.4 ± 0.7	2.7 ± 0.5	-
Side	Pre	2.7 ± 0.7	0.9 ± 0.5	8.9 ± 6.3
branch	Post	2.9 ± 0.7	2.5 ± 0.6	-

(RD: reference diameter, MLD: minimal luminal diameter)

TABLE Registry

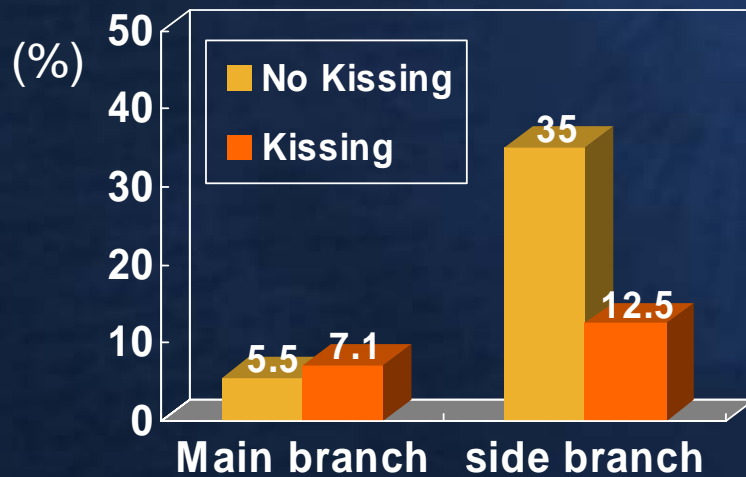
- 9-months FU (N=31)



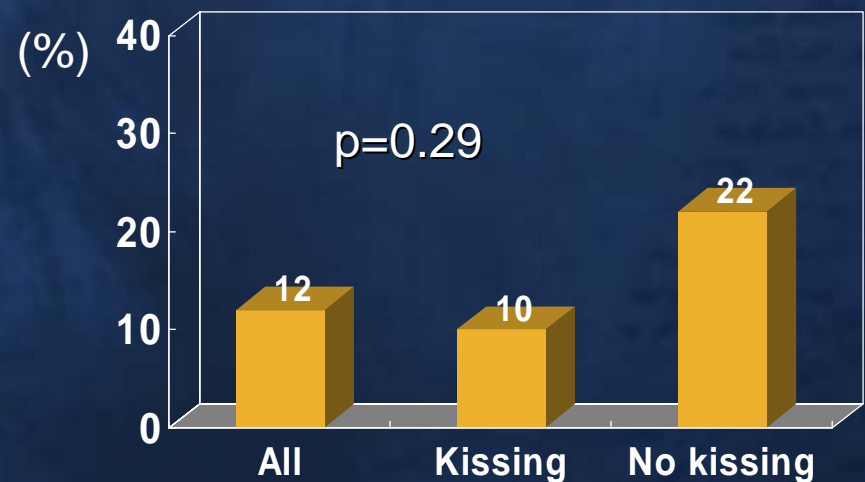
Crush Technique

- Kissing ballooning is crucial!

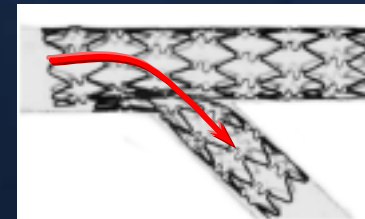
6-mo restenosis rate
(Milan, 2004 PCR)



6-mo TLR
(Lenox Hill, 2004 TCT)



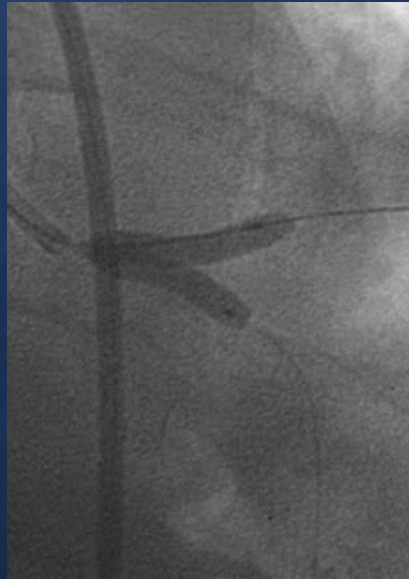
Problem: Technical difficulties of recrossing the 2 layers of stent strut into side branch



Kissing Stenting for Bifurcation



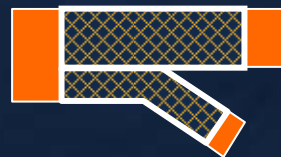
LM true bifurcation



2 TAXUS

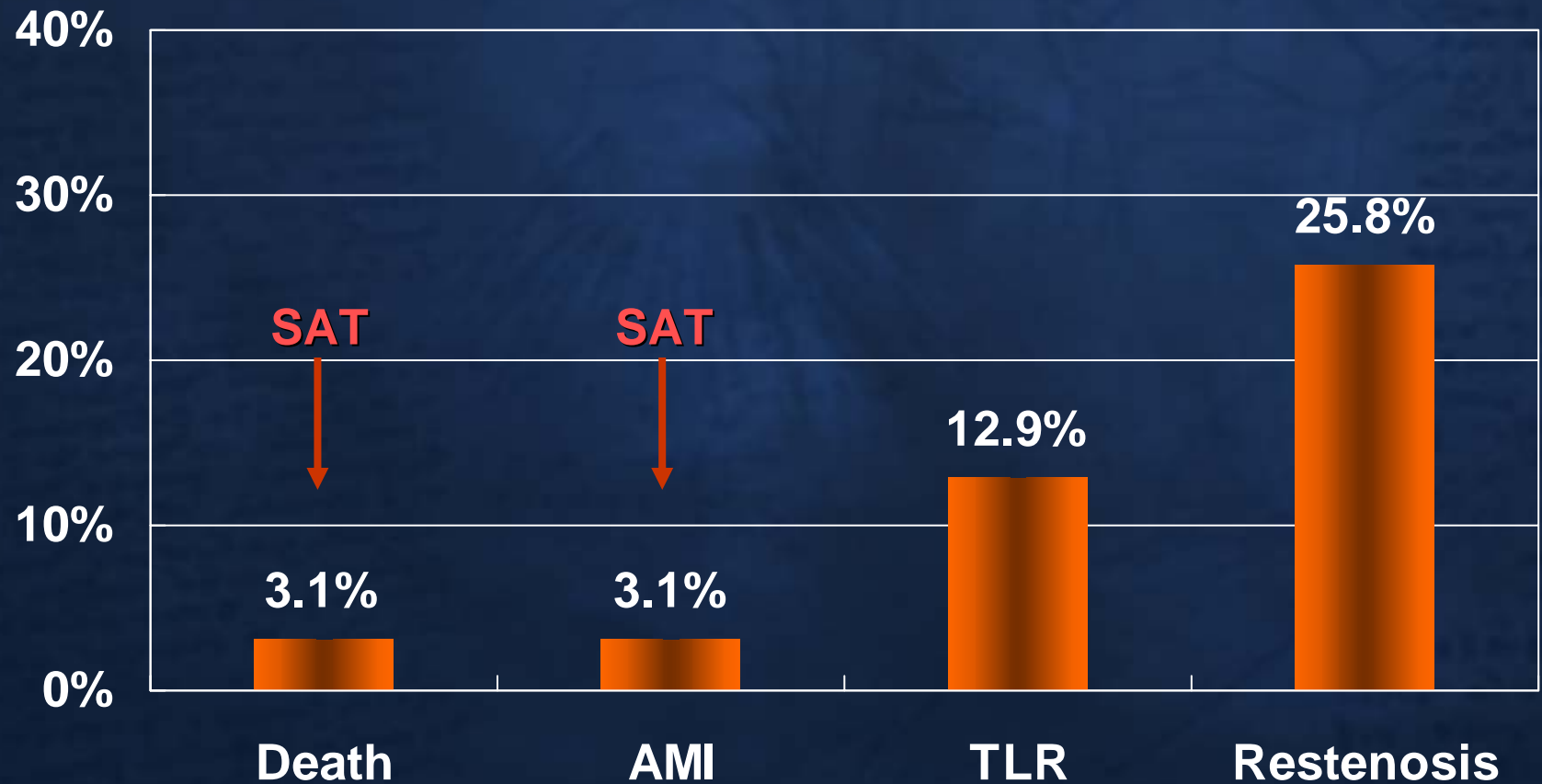


Final CAG

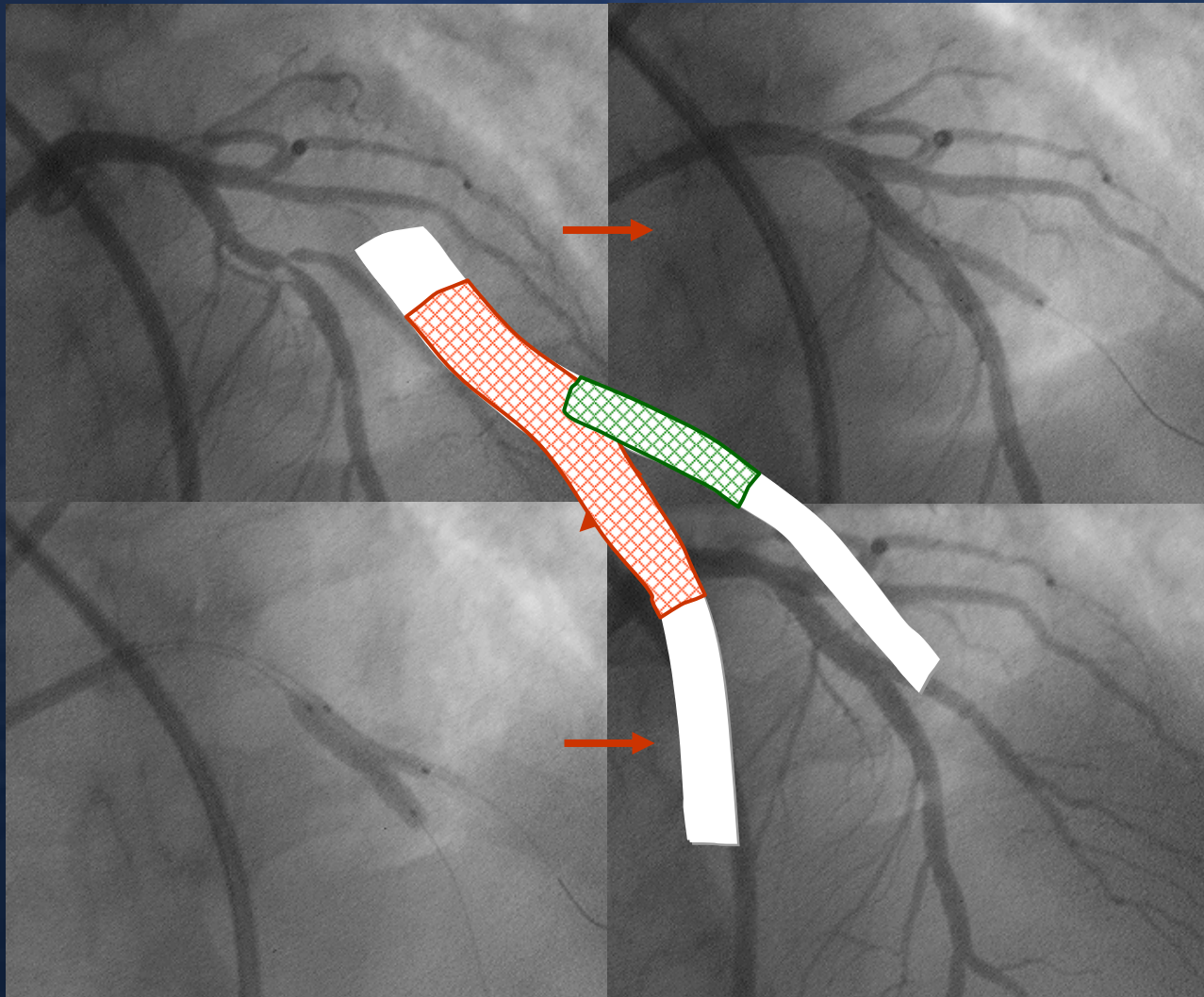


TAXUS Kissing Stent in Bifurcation

- 9-months FU (N=31)



Petit Internal Crush Technique



KORR: Results

