PCI for Chronic Total Occlusions

Chronic Total Occlusions

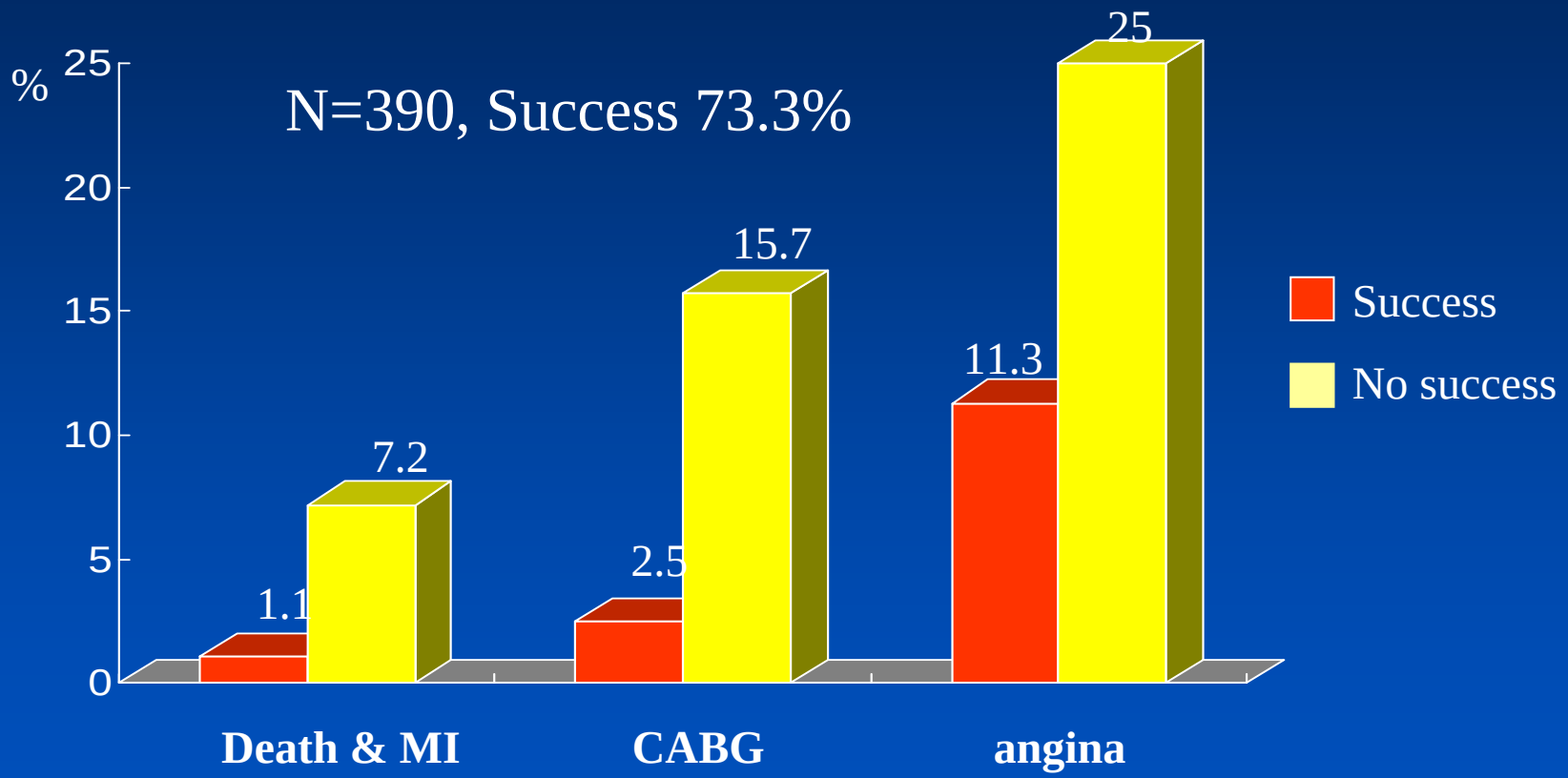
20-40% of patients with CAD

Why should we open ?

Rationale for CTO Revascularization

- Relief of symtomatic ischemia and angina
- Increase long-term survival
- Improve left ventricular function
- Reduced predisposition to arrhythmic events
- Improved tolerance of contralateral coronary occlusion

12-Month Clinical Outcome of PCI in CTO
TOAST-GISE



Olivari Z, et al. JACC 2003; 41:1672-1678

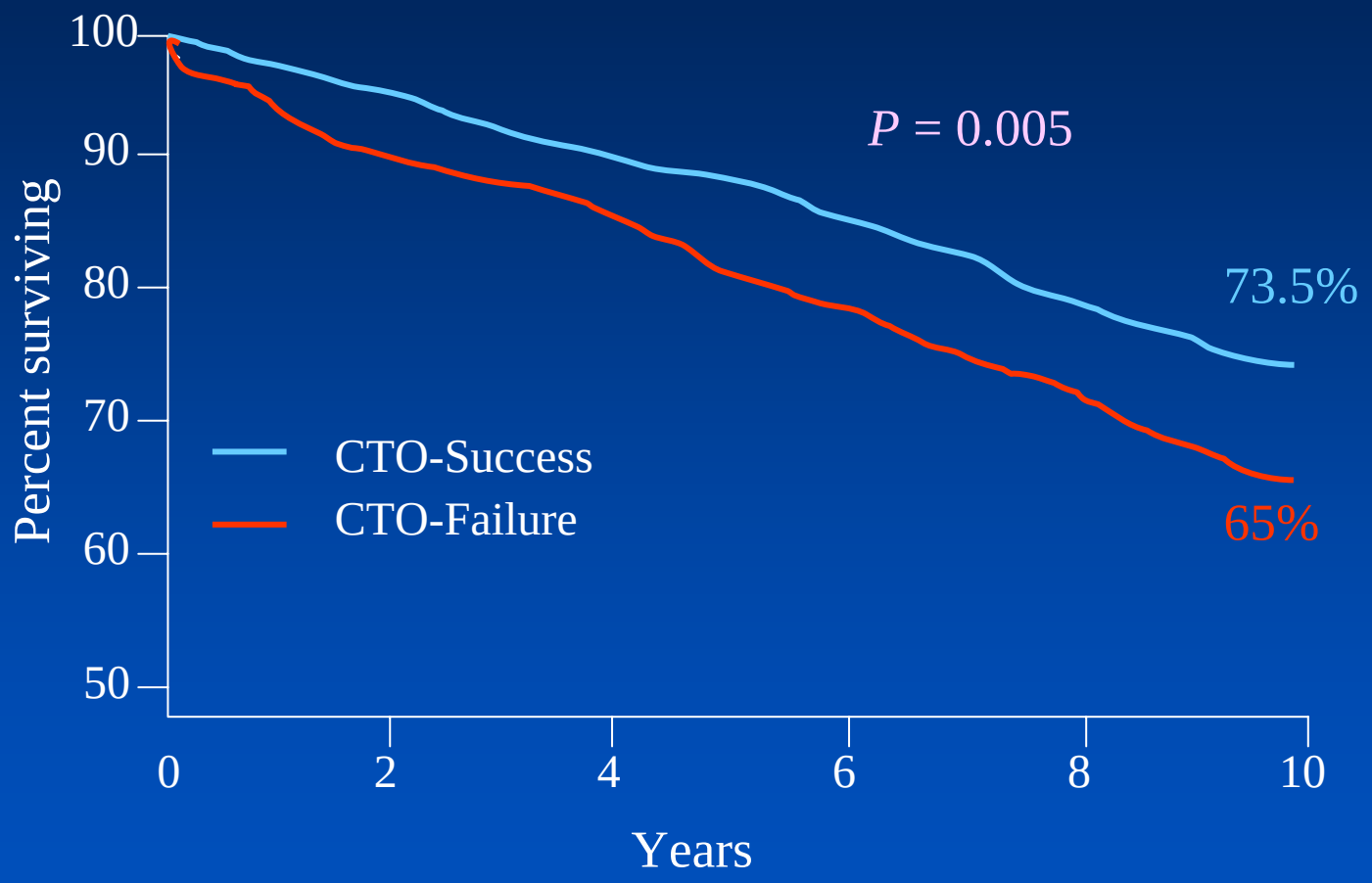
Long-term Survival
Success vs. Failure

Trial	Number of Patients(n)	Success (n)	Duration of follow-up(y)	Mortality(%) Success	Mortality(%) failure	*P* Value
British Columbia Cardiac Registry[1]	1458	1118(74.4%)	1	10.0	19.0	<0.001
Suero et al.[2]	2007	1491(76.7%)	10	26.6	35.0	0.001
TOAST-GISE[3]	369	286(77.5%)	6	1.1	3.6	0.13

[1] Kandzari, et al. TCT 2003
[2] Suero, et al. JACC 2001;38:409-414
[3] Olivari Z, et al. JACC 2003; 41:1672-1678

Reopening of CTO

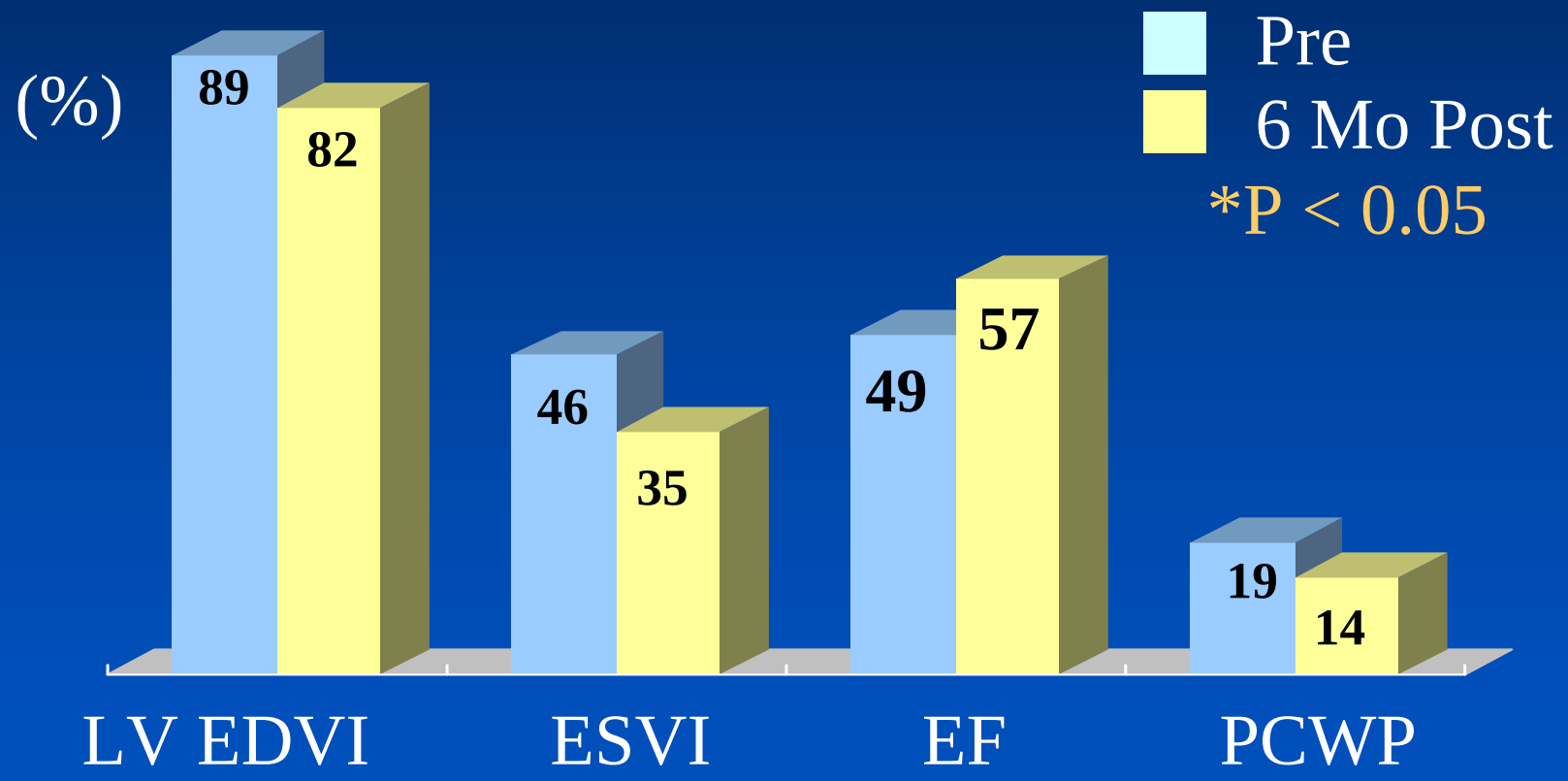
20 Years Experience



Suero, et al. JACC 2001;38:409-414

Effect on LV function

PCI in CTO improves LV function



Van Belle E, et al. AJC 1997;80:1150-1154

Issues in CTO Intervention

- Very dangerous
- Low procedural success
- High restenosis rate

Issues in CTO Intervention

- **Very dangerous**
- **Low procedural success**
- **High restenosis rate**

Possibility of High Complication

- Impairment of collateral flow

  - spasm, shearing off side-branches and collateral by dissection, distal embolization

- Retrograde dissection with branch occlusion Perforation

  - intra-wall balloon expansion, side-branch dilatation, damage of neochannels connecting vasa vasorum

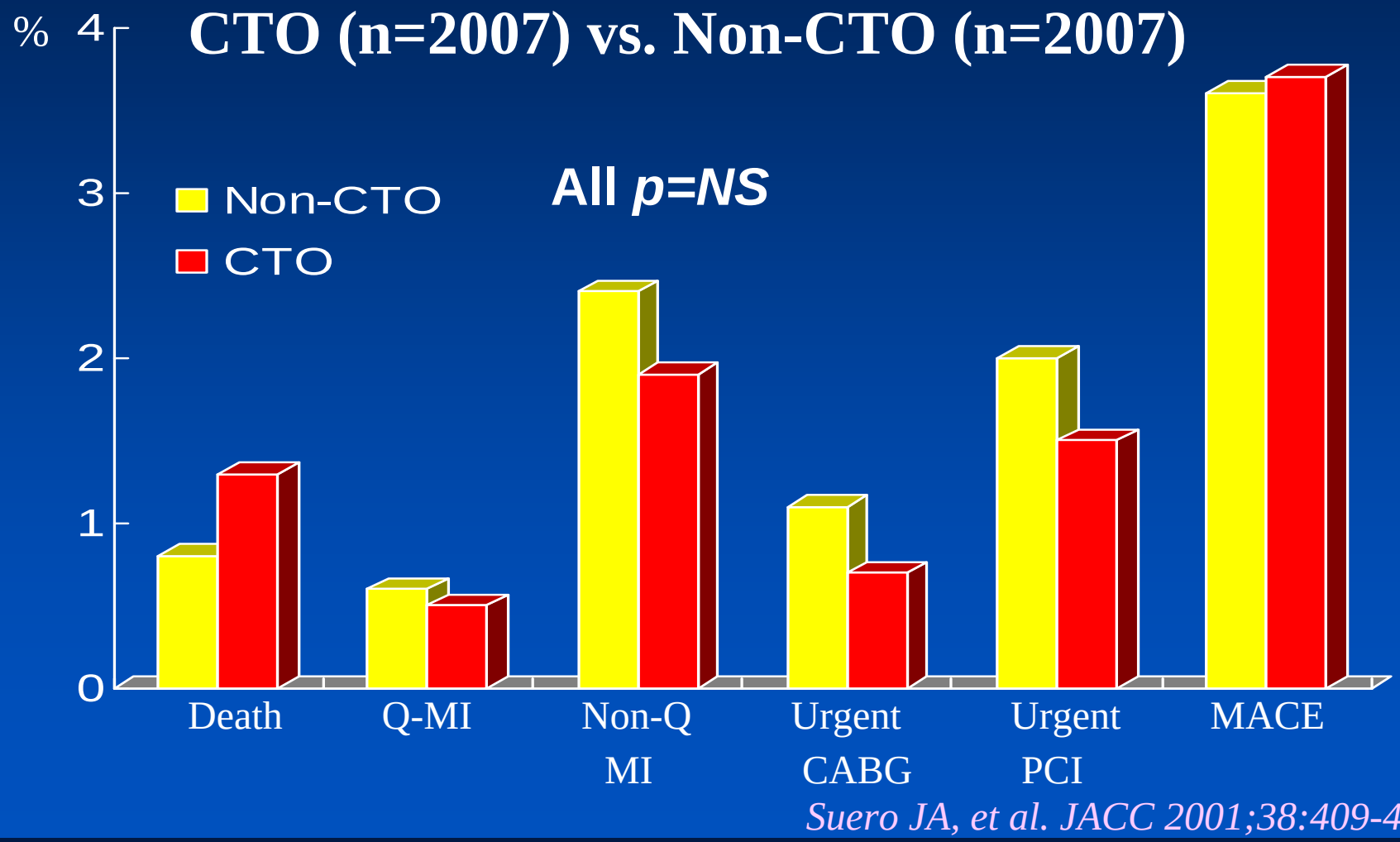
- Guidewire entrapment
- Subacute vessel reocclusion

  - 8% of total occlusion within 24hr Vs. 1.8% of non total occluson

- Extensive contrast use and fluoresence time

In-Hospital Major Complication

Not dangerous !



Suero JA, et al. JACC 2001;38:409-414

Issues in CTO Intervention

- Very dangerous
- Low procedural success
- High restenosis rate

Reasons for PCI failure in CTO

• Passage failure of guidewire	63%
• Long intimal dissection	24%
• Dye extravasation	11%
• Balloon did not cross or dilate	2%
• thrombus	1.2%

Kinoshita I, et al. JACC 1995;26:409-411

Predictors of Procedural Success

- Duration of occlusion
- Length of occluded lesion
- Presence of a non-tapered stump
- Origin of a side branch at occlusion site
- Vessel and lesion tortuosity and calcification
- Absence of antegrade flow
- Ostial occlusion
- Bridging collateral

Predictors of Procedural Success

Multivariate analysis from TOAST-GISE

Variables	Hazard Ratio	*P* value
Length ≥ 15 Vs. <8 mm	*3.9*	0.028
Length not measurable Vs. <8 mm	*3.8*	0.019
Moderate to severe calcification	*3.5*	0.023
Duration ≥ 180 days	*3.1*	0.013
Multivessel disease	*2.3*	0.009
Stump morphology not discernable	*2.2*	0.048

Olivari z, et al. JACC 2003;41:1672-1678

Procedural Success

Favorable


Tapered stump


Functional occlusion


Pre or post occlusion


Bridging collateral (-)

Unfavorable


Stump absent


Total occlusion

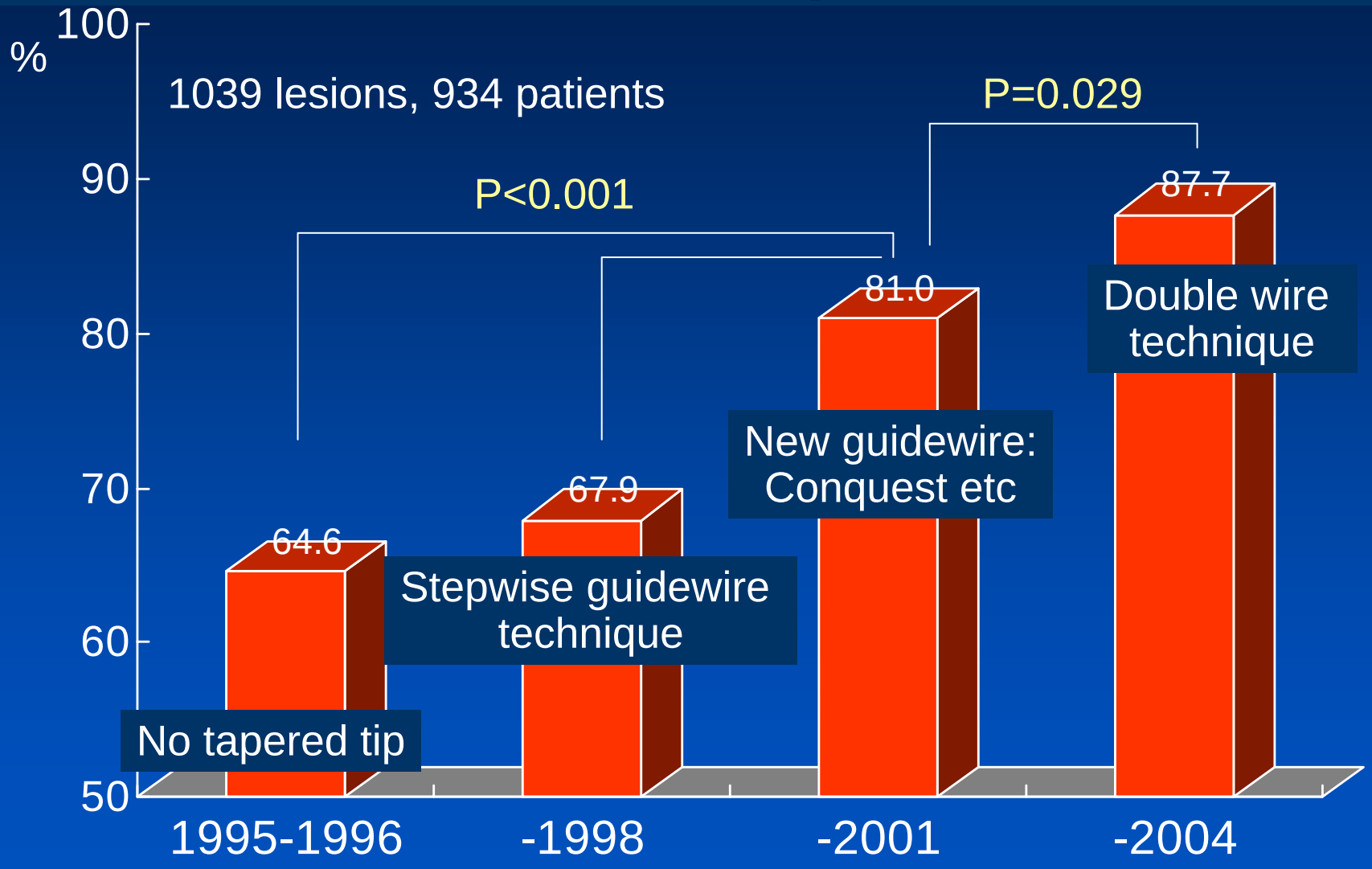

Side branch(+)


Bridging collateral (+)

How to improve procedural success ?

- Better guiding support
- Smart guidewire
- New device
- Technical advancement

Improved Success Rate
We can improve !

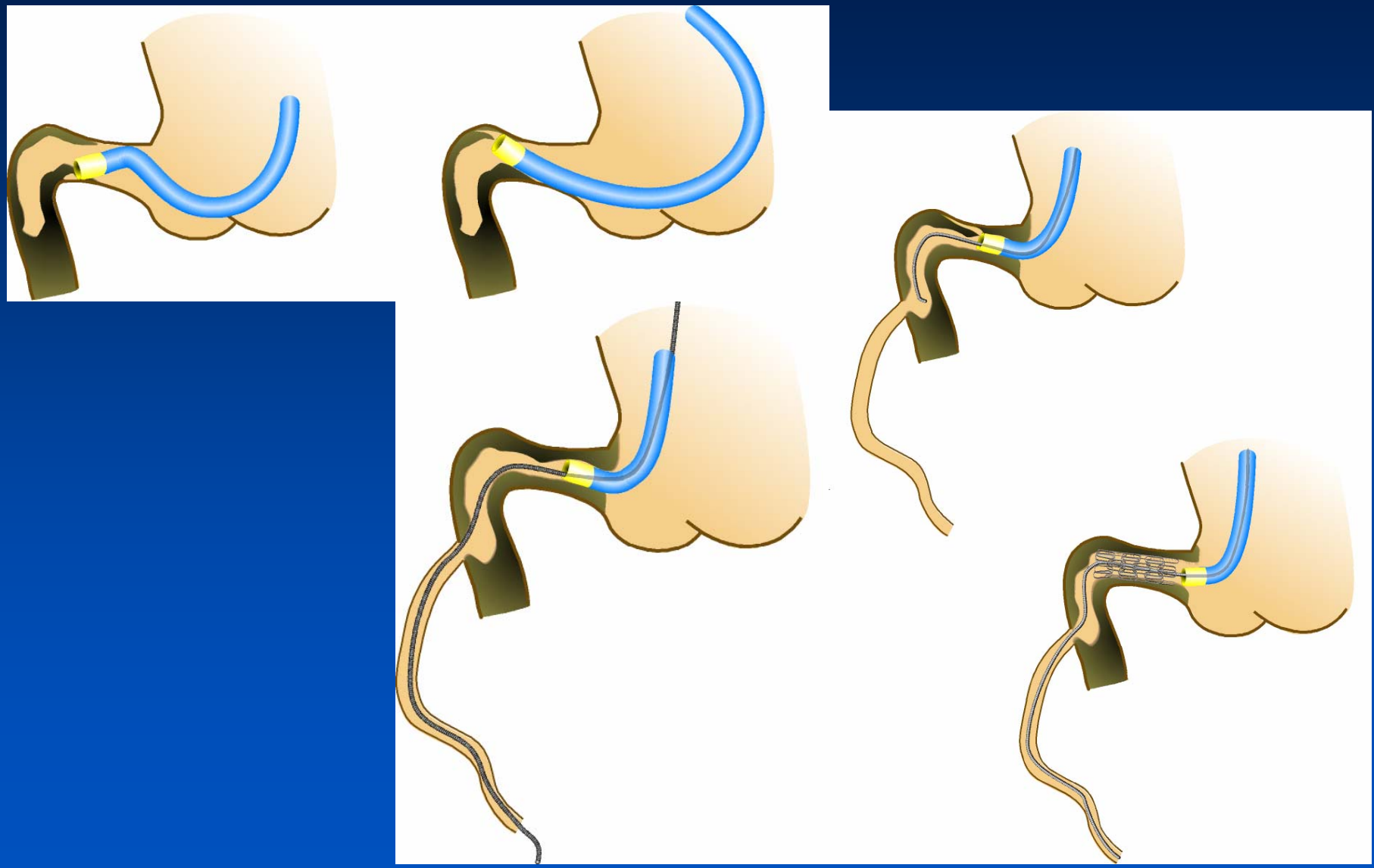


Hiroyuki tanaka, et al. ACC 2005

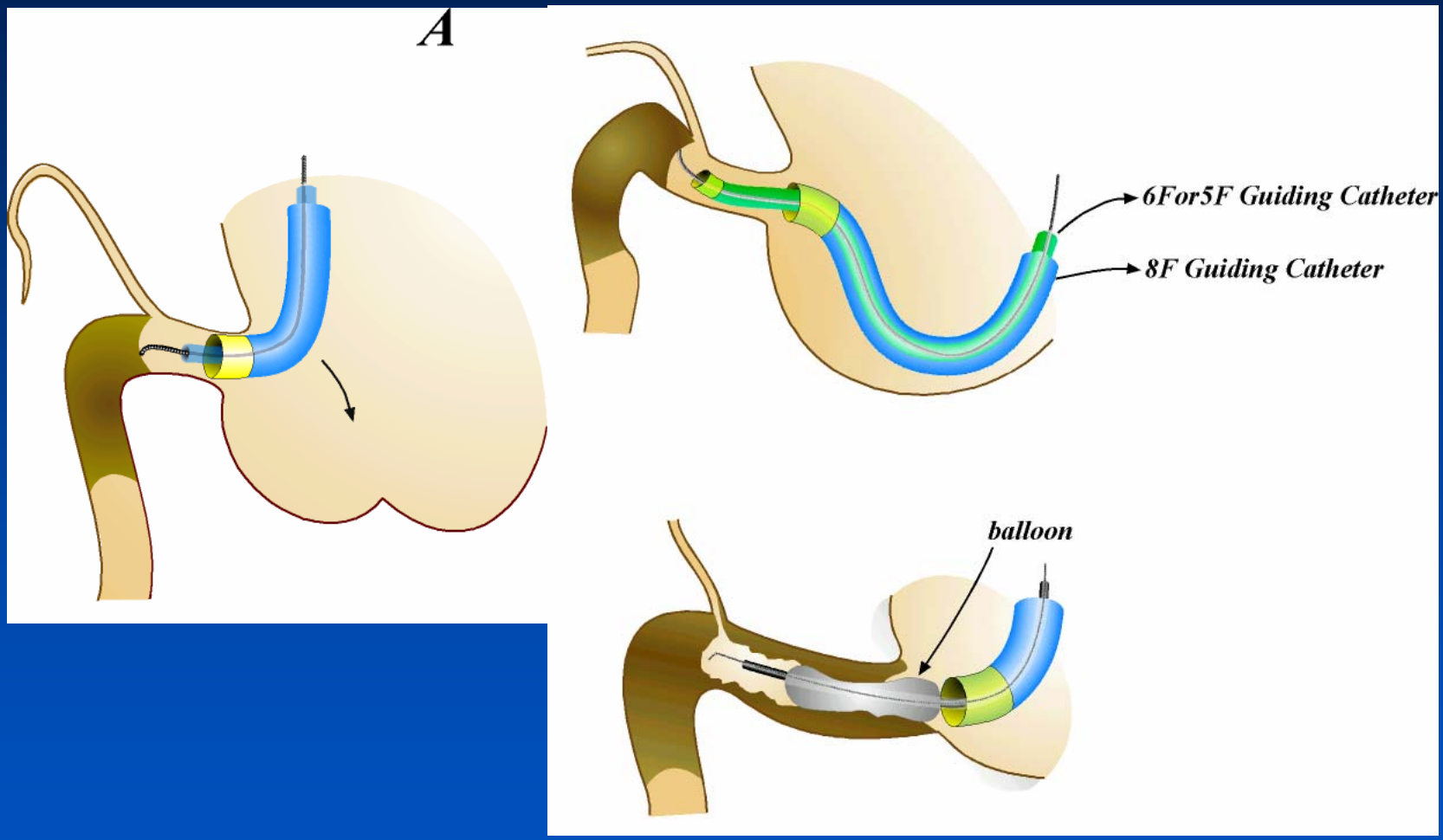
How to improve procedural success ?

- **Better guiding support**
- **Smart guidewire**
- **New device**
- **Technical advancement**

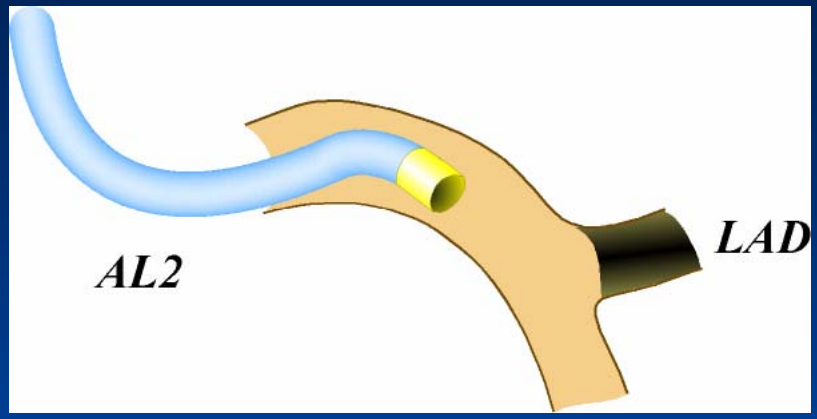
Guiding Catheter for RCA

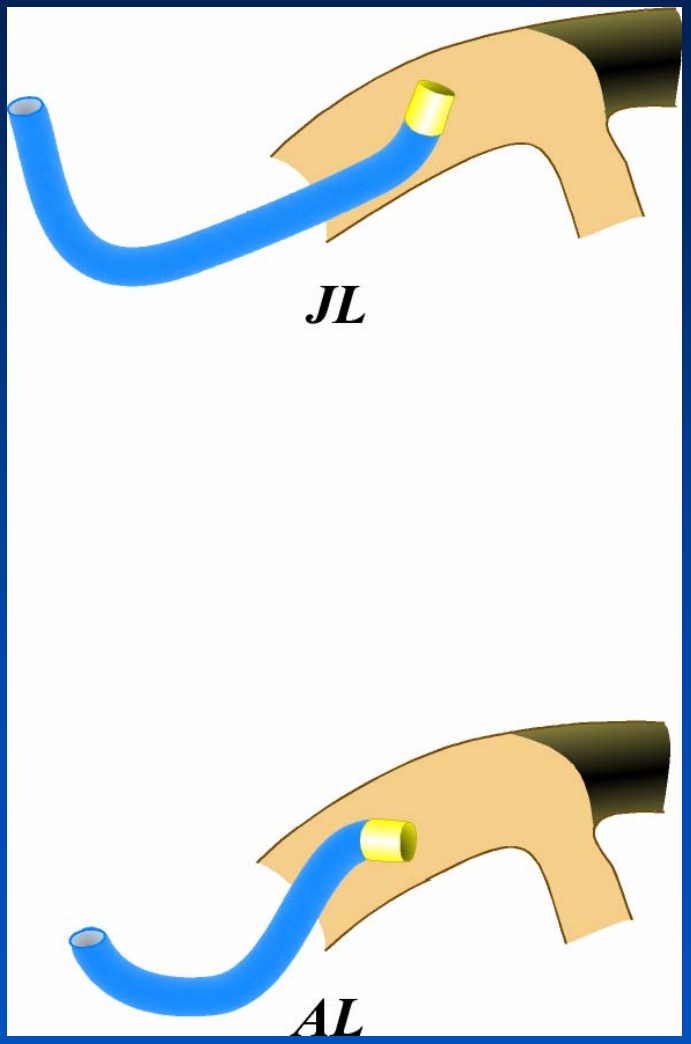


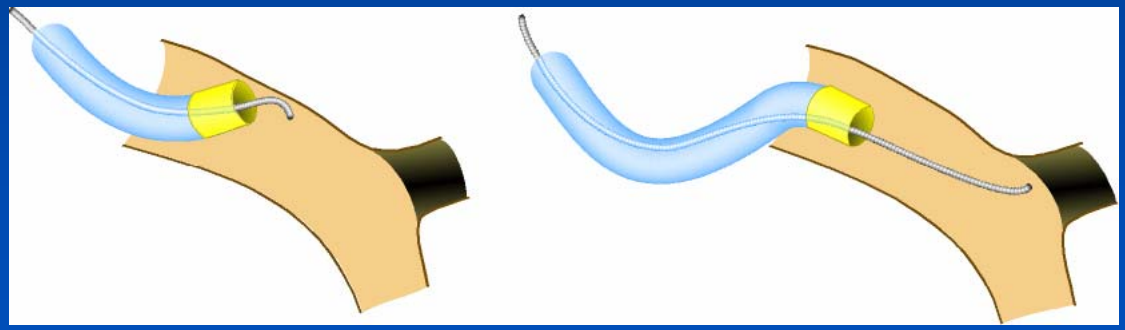
Two Guiding Catheter for RCA



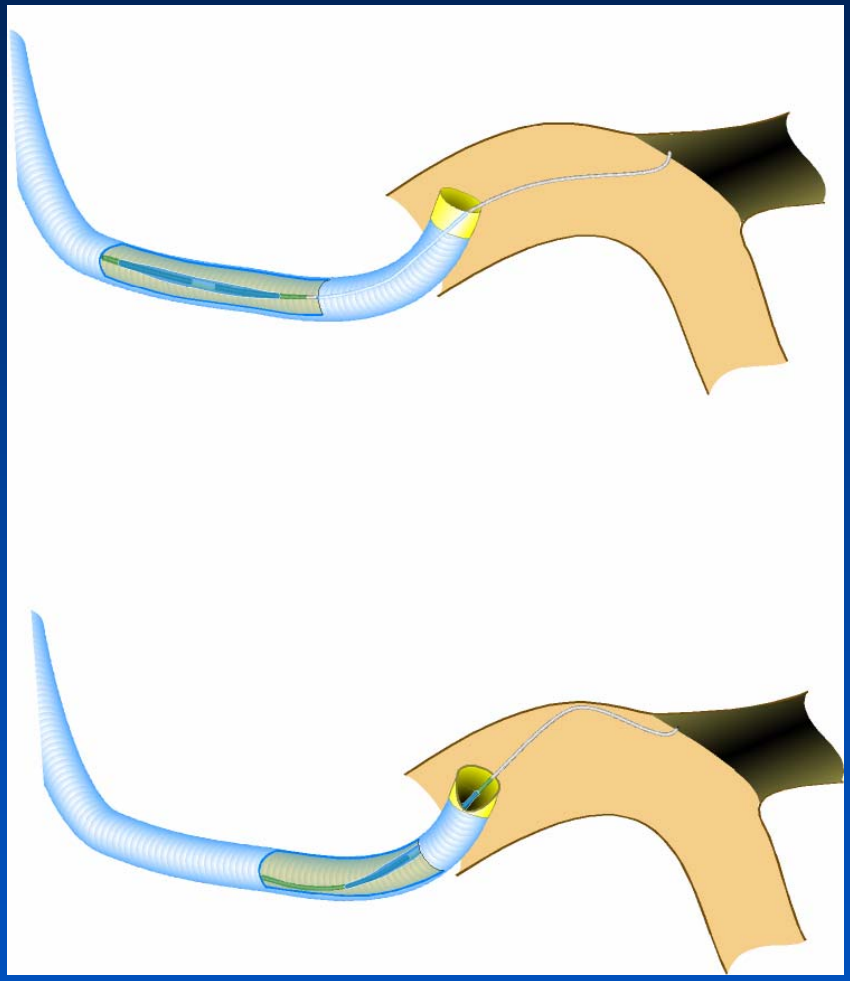
Guiding Catheter for LCA

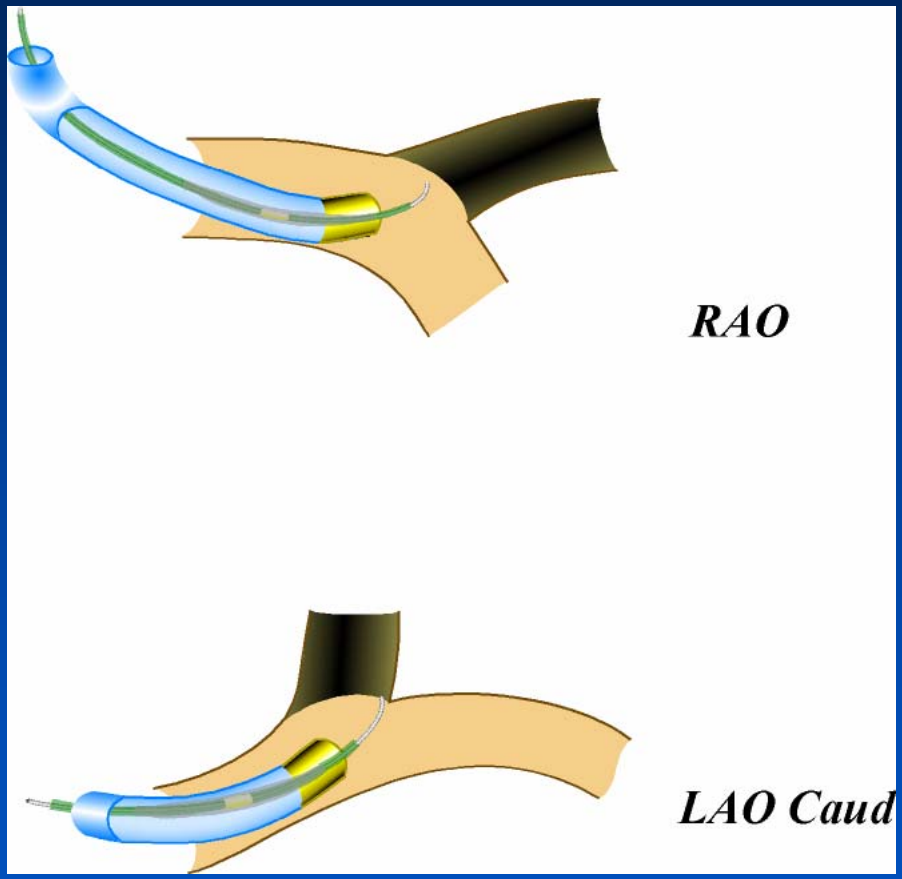






Position of Support Catheter





How to improve procedural success ?

- Better guiding support
- Smart guidewire
- New device
- Technical advancement

New Technologies for CTO

- **Dedicated guidewires**
  - Hydrophilic guidewire
  - Tapered-tip guidewire: Cross-IT, Conquest, Miracle
  - Guidewire manipulation by microchannel guidance
  - Re-entry technique
- **New devices**
  - FrontRunner™ Catheter
  - OCR SafeSteer™ System
  - Flow Cardia Crosser™ System
- **Biological approach**
  - Prolonged urokinase/tPA infusion
  - Collagenase plaque digestion

Ability to Cross CTO

Hydrophilic-coated Guidewire

	Conventional (n=46)	Crosswire (n=42)	*P*
1st GW success(%)	35	74	0.001
Crossover(%)	59	26	0.009
GW success after crossover(%)	37	0	<0.001
Total GW No.	1.7 ±0.6	1.3±0.5	<0.001
Procedure(min)	84±33	42±20	0.013

Lefevre et al, Am J Cardiol 2000;85:1144-7

Ability to Cross CTO

Tapered guidewire

- **Technical success: 76%**
- **Success rate in visible microchannel**
  - **incomplete micro-channel: 81%**
  - **micro-channels with distal filling: 100%**

Buettner HJ, et al. JACC 2002;39:30A

New CTO Wires for CTO Lesions

- **Miracle 12g** **is more controllable**

  to penetrate proximal cap,

  to advance in the tight CTO with bending,

  to puncture from pseudo to true lumen.

- **Conquest** **should be used**

  only when the appropriate direction can be seen

  to penetrate distal cap,

  to puncture from pseudo to true lumen.

- **Conquest should not be used**

  to seek the true lumen or advance for long distance.

Special Device for CTO recanalization

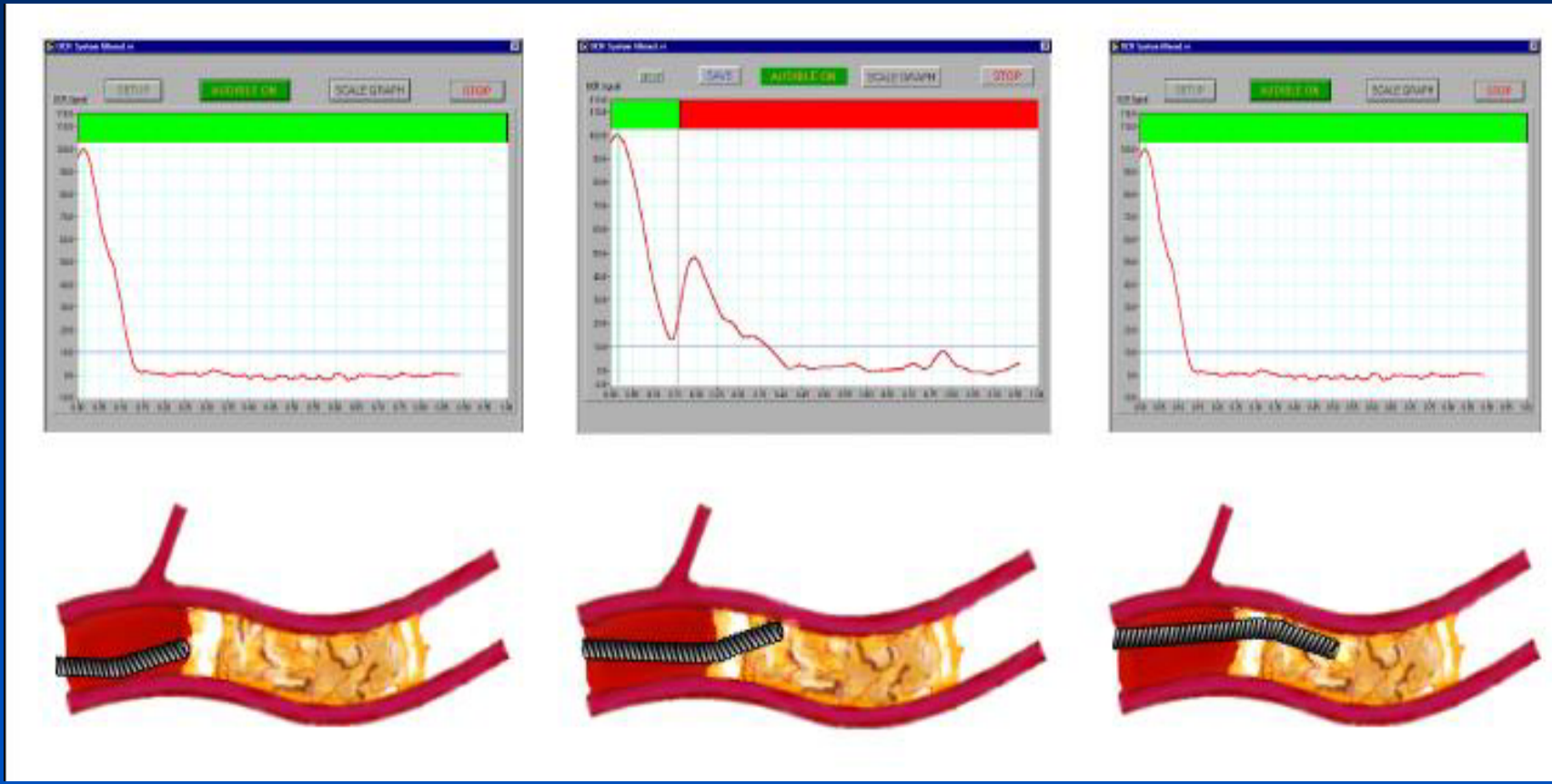
- Failed special device
  - Magum/Magnarail system
  - Kensey Catheter
  - ROTACS Low Speed Rotational Atherectomy Catheter
  - Excimer Laser Wire
- CTO device in current use
  - OCR SafeSteer™ System (Optical Coherence Reflectometry)
  - FrontRunner™ Catheter
  - Flow Cardia Crosser System

OCR SafeSteer System

- *Forward looking guidance system*, using OCR to determine tissue types *(plaque vs arterial wall)*.
- Designed to navigate through total occlusion.

OCR SafeSteer System

OCR Waveform Displays



GREAT Registry

116 Lesions 21 centers with CTO “failure to cross”
median occlusion duration: 22montths
Median lesion length: 25mm(>30mm long in 25%)

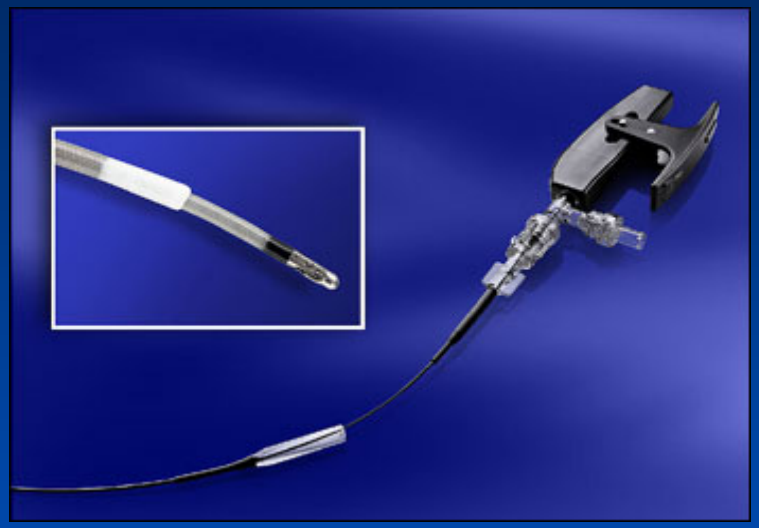
- **Device Success** **63(54.3%)**
- **Complication**

MACE	**8 (6.9%)**
-Non-Q MI	**5 (5.2%)**
Clinical perforation	**3 (2.6%)**
- Device related	**1 (0.9%)**

Baim DS et al. Am J Cardiol 2004;94:853-858

FrontRunner Catheter

Controlled Blunt Micro-Dissection



- Blunt controlled passage through occlusion
- Uses elastic properties of adventitia
  vs. inelastic fibrocalcific plaque

FrontRunner Catheter

Advantages

- Torqueable
- Guide support
- Directable/Steerable
- Hydrophilic coating
- Blunt tip to avoid perforation
- Avoids side branches

Disadvantages

- Difficult anatomy: tortuosity, small vessel, heavy calcium
- Expensive
- 8 Fr guiding for curved jaw
- Failure Modes

Clinical Outcomes of FrontRunner Catheter

- N =909
  - Pre-approval phase: 119 (using the largest device),
  - Post-approval phase: 197 (using a smaller, more flexibe catheter),
  - Current design: 593(using X-39 Frontrunner)
- Lesion length: >30mm in 21%
- Success rate
  - Pre-approval phase: 56%
  - Post-approval phase: 59%
  - Current design: 61%
- Perforation: 0.9%

Yang YM, et al. Catheter Cardiovasc Interv 2004;63:462

FrontRunner Catheter
Milan Experiences

50 pts with 50 CTO, Refractory to guidewire
Mean occlusion length 38.3 ± 22 mm

- Overall Device Success 50 % (25)
- Coronary perforation 17.3 % (9)
- Adverse events @ 30 days 15.7 % (8)

7 non-Q wave MI, 1 sudden death

Relatively high risk of perforation !

A Colombo et al, ACC 2004

The Crosser™ System

- *Generator*
  converts line power into high frequency current
- *Transducer*
  converts electric current into mechanical vibration
- *The Crosser catheter*

The Crosser™ System

Clinical Experiences

54 pts with 56 CTO, Refractory to guidewire
Mean occlusion length 27 mm (8~46 mm)

- Average time spent 2:43 min
- MACE (2 NQMI) 3.6 % (2/56)
- Clinical perforation 0 %

High frequency mechanical recanalization is a promising technology.

G. Sutsch et al, JIM 2004

How to improve procedural success ?

- Better guiding support
- Smart guidewire
- New device
- **Technical advancement**

Technical Advancement

Conventional Technique

- Bilateral angiography
- Over-the-wire catheter
- Collateral angiography
- Biplane angiographic equipment
- Stepwise guidewire exchange

Technical Advancement

New Technique

- Parallel wire technique
- Side branch technique
- Sub-intimal re-entry technique
- IVUS-guided recanalization technique
- Seesaw wiring technique
- etc

CONQUEST trial

Stepwise guidewire change

- Prospective Multicenter Registry in Japan
- Method: stepwise guidewire change

  - First step: intermediate GW

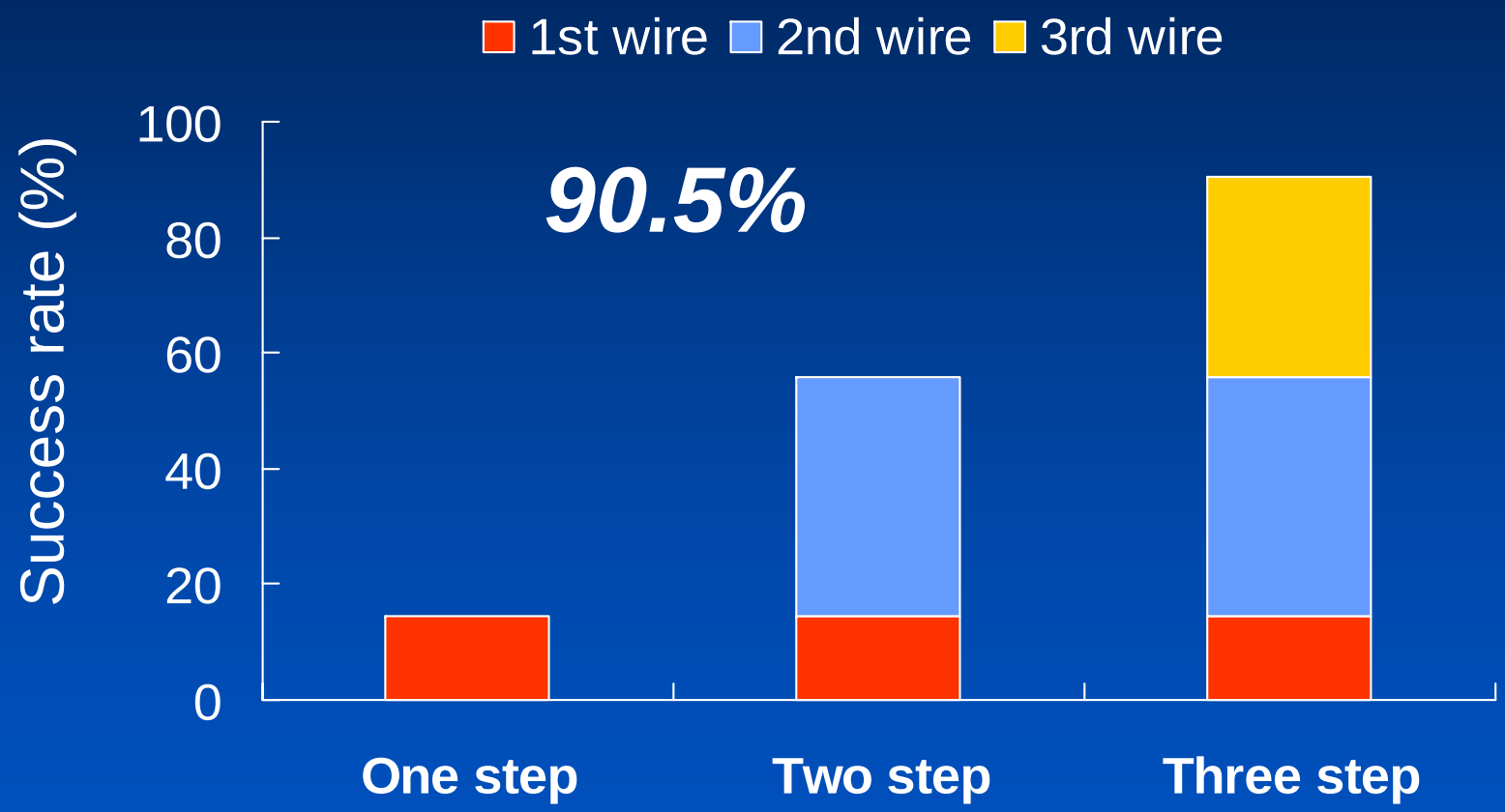
  - Second step: Conquest GW sereies

  - Third step: additional Conquest GW, Seesaw wire technique

T. Muramatsu, et al. TCT 2004

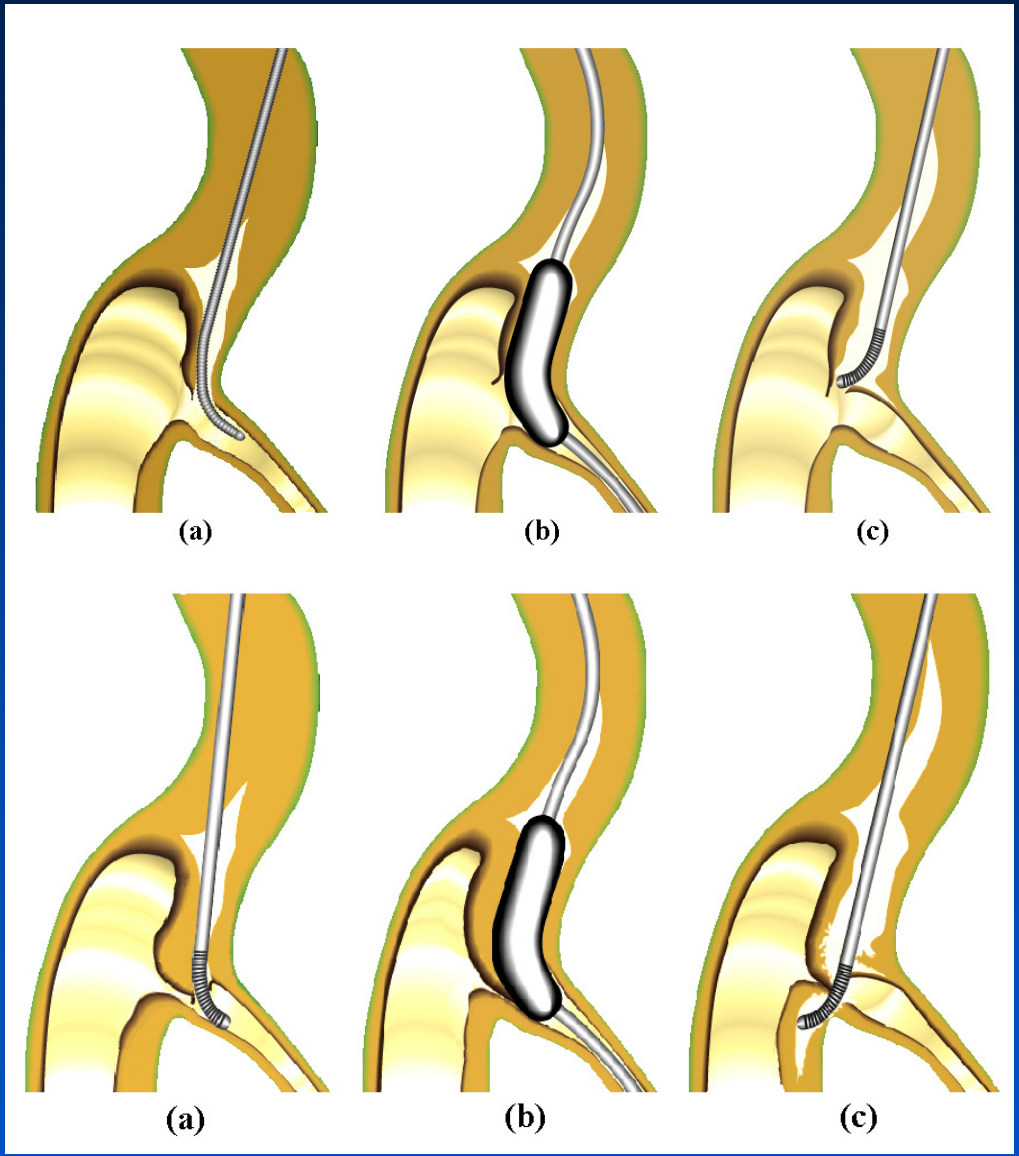
CONQUEST trial

110 patients, 116 CTO lesions

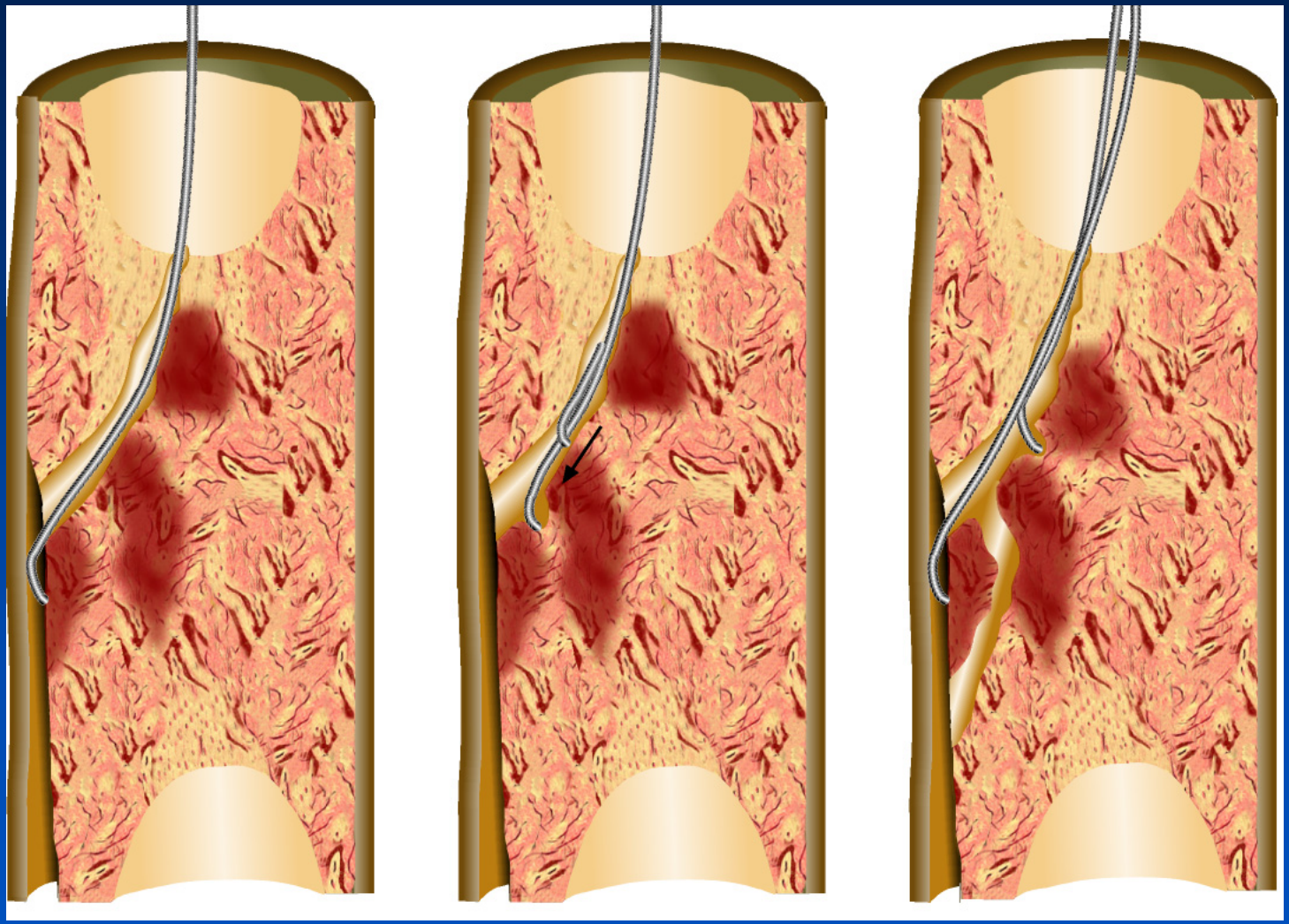


T. Muramatsu, et al. TCT 2004

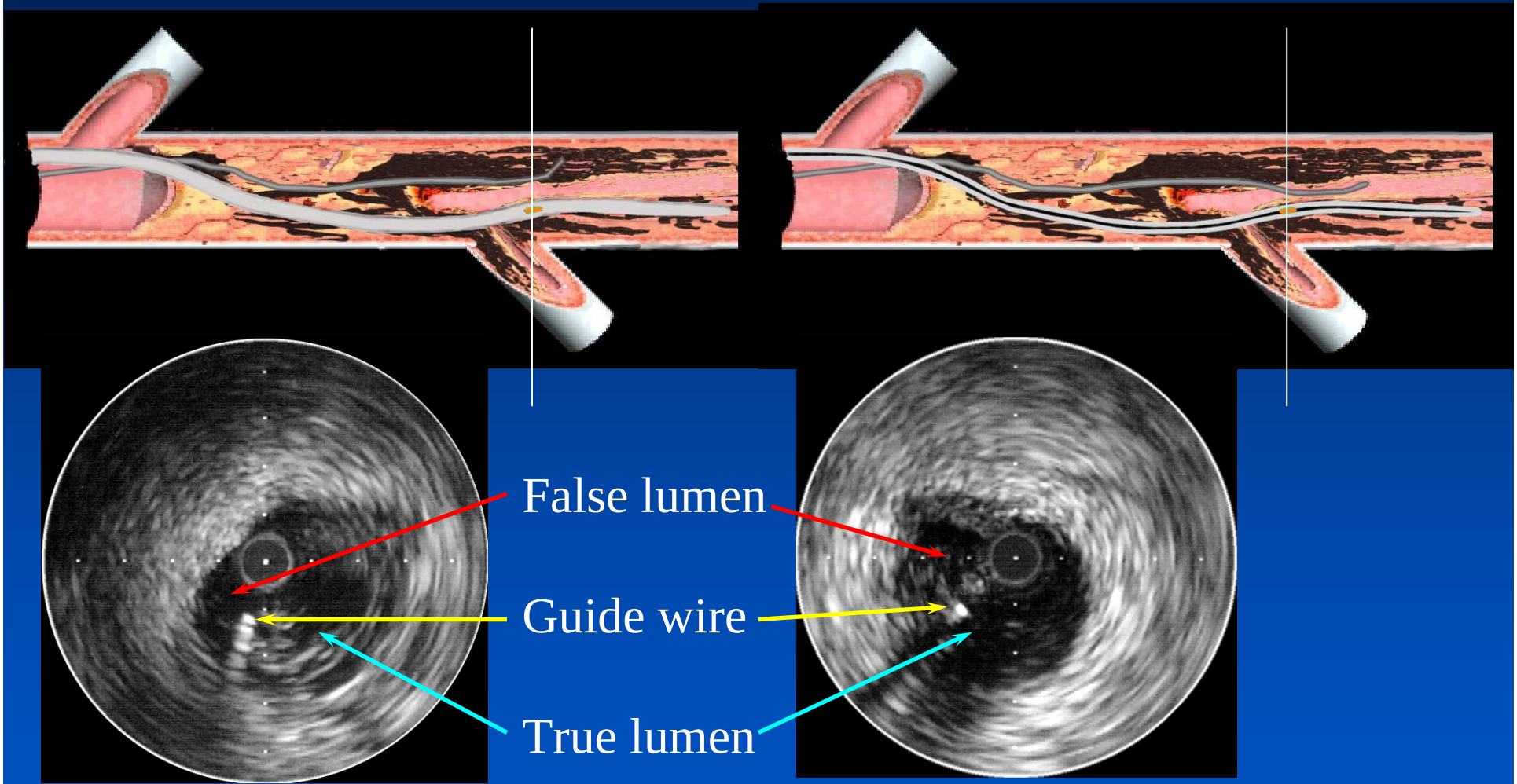
Side Branch Technique



Parallel Wire Technique



IVUS Guided Technique



Stop When…

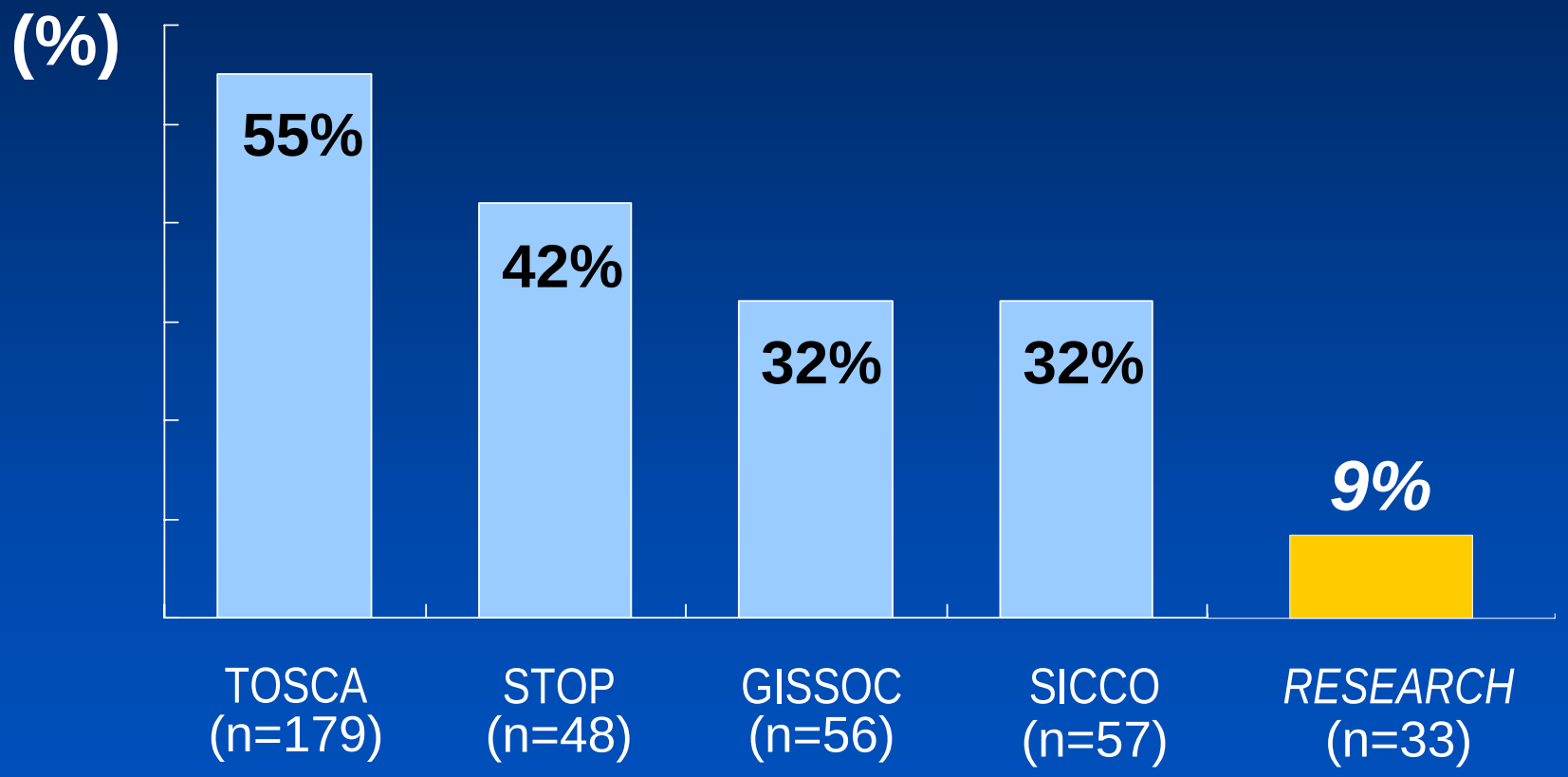
- Creation of a large false lumen, especially if adventitial staining is present
- Shearing off collateral resulting in loss of visualization of the distal flow
- Excessive patient or operator fatigue
- Excessive radiation exposure(e.g. 60 min of fluroscopy time)
- Excessive dye consumption

→ Second try at 6-8 weeks later

PCI with DES for Chronic Total Occlusions

RESEARCH Registry

6 Month Restenosis Rate



Serruys et al, JACC 2004;43:1594-8

Asian Registry with Cypher

	SES (n=60)	BMS (n=120)	*P* value
Late loss (mm)	0.08 ± 0.10	1.36 ± 0.88	0.001
Restenosis (%)	2	32	0.001
Reocclusion (%)	0	6	0.001
1 yr MACE, n(%)	2 (3)	50 (42)	0.001
Death (%)	0	0	NS
MI (%)	0	3 (3)	NS
Re-PCI (%)	2 (3)	44 (37)	0.001
CABG (%)	0	7 (6)	0.01

Nakamura et al. AJC 2005;95:161-166

German Study with Taxus

	Taxus (n=48)	BMS (n=48)	*P* value
Late loss (mm)	0.19 ± 0.62	1.21 ± 0.70	<0.001
Restenosis (%)	8.3	51.1	<0.001
Reocclusion (%)	2.1	23.4	0.003
1 yr MACE, n(%)	6 (12.5)	23 (47.9)	<0.001
Death (%)	2.1	4.2	NS
MI (%)	4.2	2.1	NS
Re-PCI (%)	6.3	31.9	<0.001
CABG (%)	0	12.8	NS

Werner et al. JACC 2004;44:2301-6

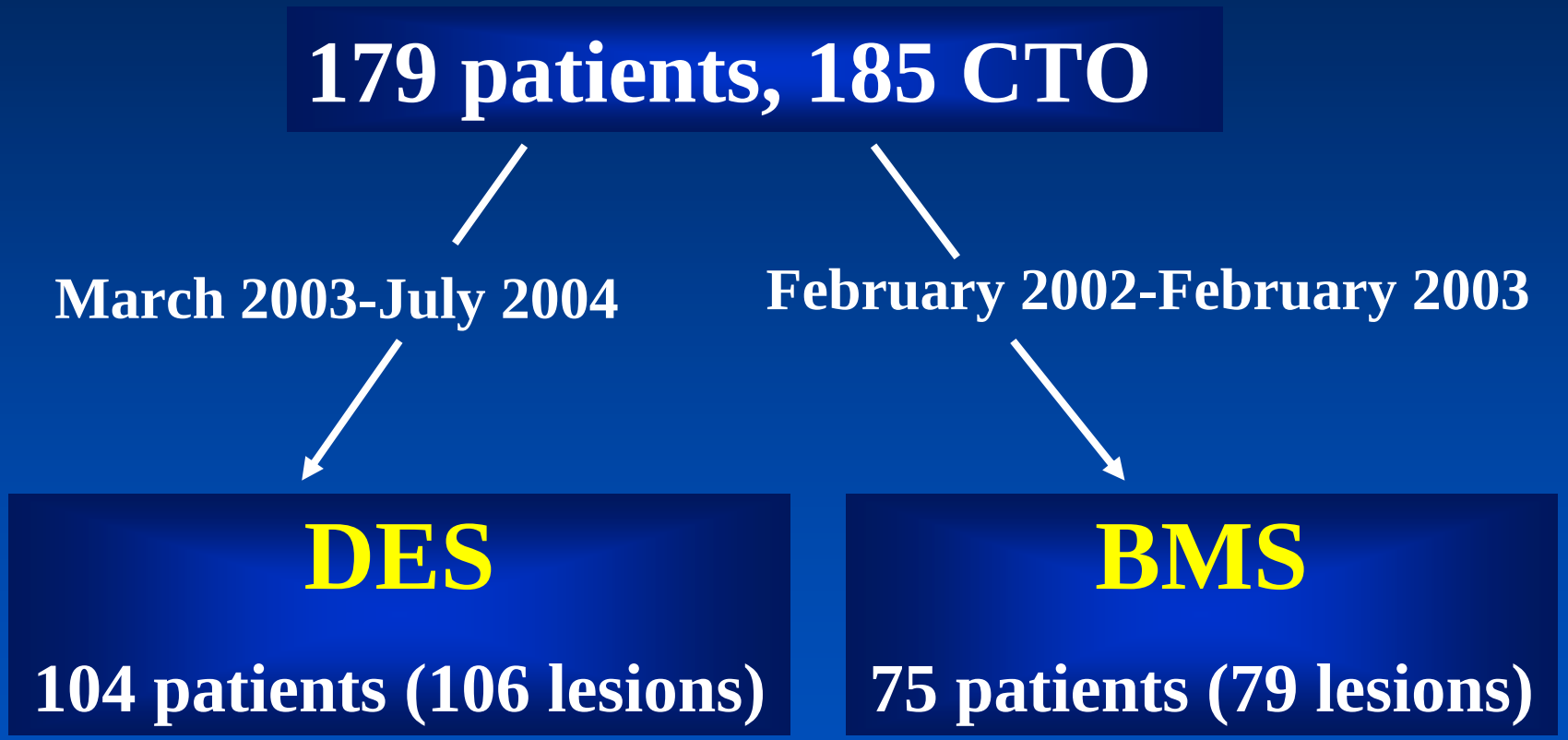
RECIPI study

Cypher vs. Taxus

	Cyper	Taxus	*p*
Patients number	142	85	-
Stent number	1.4 ± 0.7	1.4 ± 0.8	NS
Stent length (mm)	41 ± 19	38 ± 25	NS
In hospital Re-PCI, n(%)	1 (0.7)	1 (1.2)	NS
MACCE at 1 month, n(%)	5 (3.5)	1 (1.2)	NS
Death	1 (0.7)	0	NS
Non-Q MI	1 (0.7)	0	NS
TVR	3 (1.1)	1 (1.2)	NS
CABG	0	1(1.2)	NS

Giuesppe Sangiorgi et al. ACC 2005

CTO in AMC


179 patients, 185 CTO
March 2003-July 2004
February 2002-February 2003
DES
104 patients (106 lesions)
BMS
75 patients (79 lesions)

More Complex Lesion

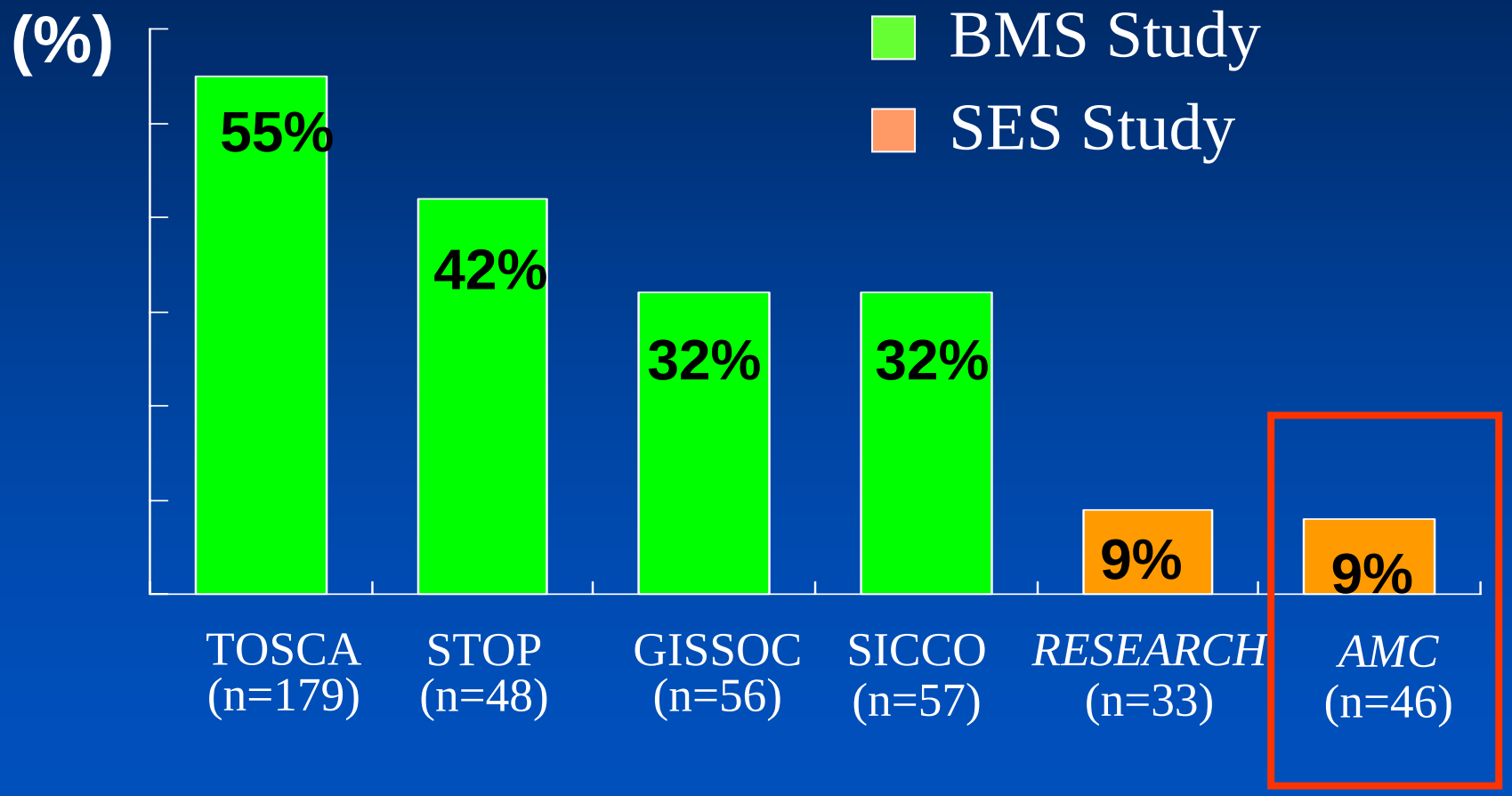
	DES (N=106)	BMS (N=79)	P value
Pre-stenting, mm			
Proximal RD	2.93 ± 0.50	3.11 ± 0.58	0.052
Lesion length	35.9 ± 19.5	25.8 ± 11.9	0.003
Post-stenting, mm			
Proximal RD	3.07 ± 0.49	3.29 ± 0.60	0.070
MLD	2.69 ± 0.45	2.89 ± 0.60	0.020
DS (%)	13.5 ± 13.4	12.5 ± 16.1	0.759
Acute gain	2.66 ± 0.45	2.82 ± 0.58	0.066

Restenosis Rate: 8.7%

Follow-up Results	DES (N=46)	BMS (N=54)	P value
Reference,mm	2.85 ± 0.57	3.12 ± 0.47	0.053
MLD, mm	2.37 ± 0.76	1.69 ± 0.88	<0.000
DS, %	11.8 ± 19.3	34.7 ± 22.7	<0.000
Late loss, mm	0.44 ± 0.64	1.13 ± 0.74	<0.000
Loss index	16.06 ± 23.66	40.29 ± 28.88	<0.000
Restenosis	4 (8.7)	16 (29.6)	0.009

Historical Comparison

6 Month Restenosis Rate



Serruys et al, ACC 2004

DES for CTO

- DES implantation is much more effective in reducing intimal growth and repeat intervention rate than BMS implantation for CTO lesions.
- However, the technical difficulties in re-crossing the occlusion keep the CTO lesion a challenging filed in interventional cardiology.

Issues in CTO Intervention

- **Very dangerous:**

  Not as expected

- **Low procedural success**

  Improved with new devices and techniques

- **High restenosis rate**

  No more in DES era