PCI for
Chronic Total Occlusion

Chronic Total Occlusions

20-40% of patients with CAD

Why should we open ?

Rationale for CTO Revascularization

- Long-term outcomes improvement
- LVEF improvement
- Electrical stability of myocardium
- Improved tolerance for future coronary events

Long-term Outcomes for CTO Revascularization

	Single vessel			Multivessel		
	CTO success (n = 261)	CTO failure (n = 99)	*P*	CTO success (n = 306)	CTO failure (n = 205)	*P*
Death (%)	97.3	99.0	0.3	92.5	86.3	0.02
Death or MI (%)	94.6	96.0	0.6	88.6	82.0	0.03
Death or CABG (%)	91.6	70.7	<0.001	86.9	61.5	<0.001
MACE (%)	72.0	47.5	<0.001	61.1	42.9	<0.001

Hoye A, et al, EHJ 2005;26:2630-6

Predictors for Long-Term Mortality

Mid-America Heart Institute, JACC 2001

Variables	HR	95% CI
Success	0.7	0.5-0.8
Age > 70	1.9	1.5-2.4
EF < 40%	2.1	1.7-2.7
2 vessel disease	1.5	1.1-2.2
3 vessel disease	1.9	1.4-2.7
Diabetes	1.4	1.1-1.8
Creatinine > 2.0mg/dl	2.2	1.3-3.9
Unstable angina	1.3	1.1-1.6

Predictors for Long-Term Mortality

British Columbia Cardiac Registries, TCT 2003

Variables	HR	95% CI
Success	0.4	0.3-0.6
Age (per 10)	1.3	1.1-1.6
EF < 50%	2.3	1.6-3.4
Multivessel disease	1.6	1.1-2.4
Diabetes	1.5	0.9-2.3
End stabe renal disease	2.8	1.4-5.7
Prior heart failure	1.7	1.1-2.8
Peripheral vascular disease	1.9	1.1-3.6
Chronic obstructive lung disease	1.6	1.1-2.7

Independent Predictors of Long-term Death and MACE

	HR	95% CI	P-value
Death			
Successful revascularization	0.58	0.34–0.98	0.04
Age	1.04	1.02–1.07	0.002
Diabetes mellitus	2.49	1.33–4.66	0.005
Multivessel disease	4.29	1.93–9.55	<0.001
MACE			
Successful revascularization	0.55	0.44–0.70	<0.001
Multivessel disease	1.43	1.14–1.79	0.002
Use of a stent	0.69	0.54–0.88	0.002

Hoye A, et al, EHJ 2005;26:2630-6.

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 or perforation**

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

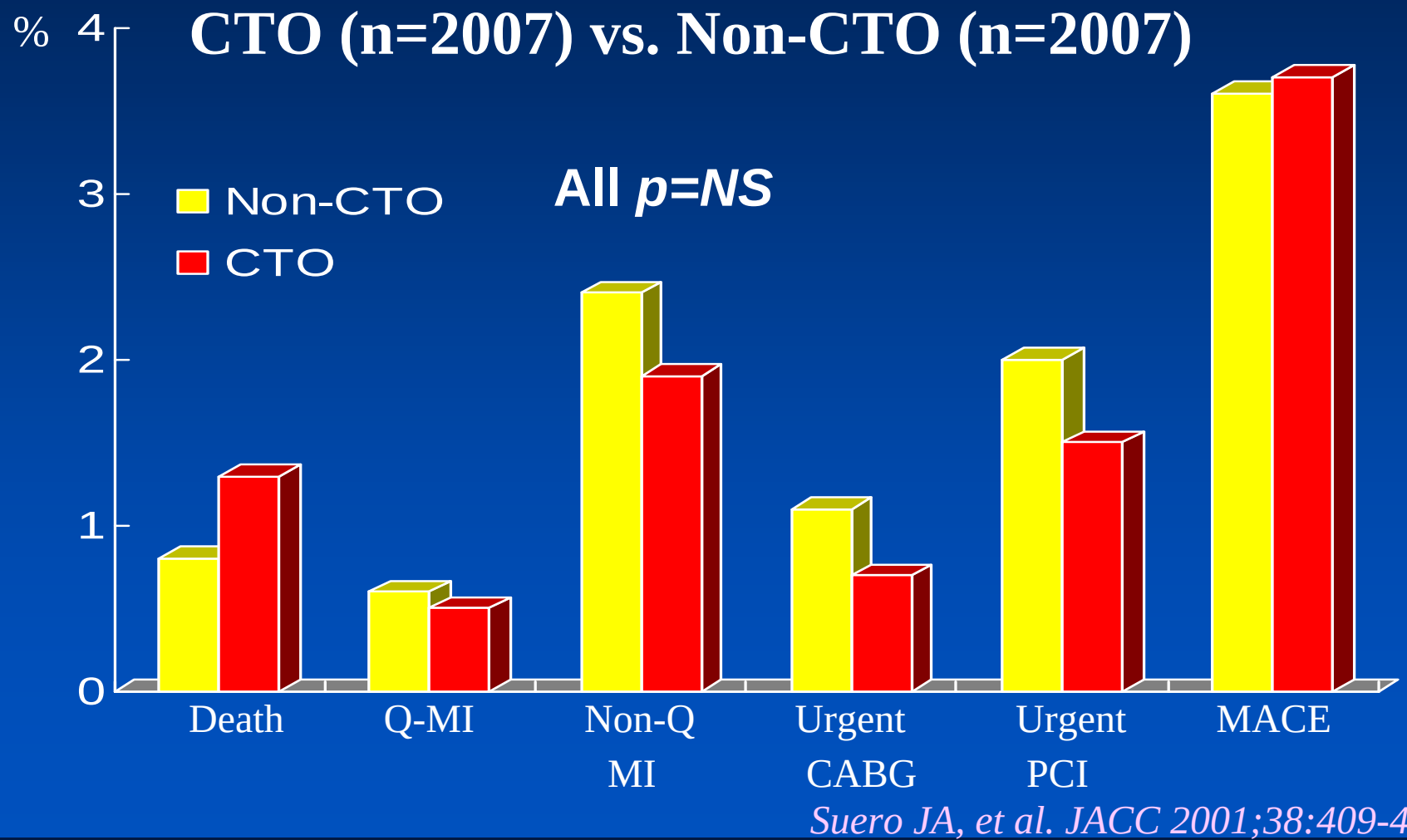
- **Guidewire entrapment**
- **Subacute vessel reocclusion**

  - 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

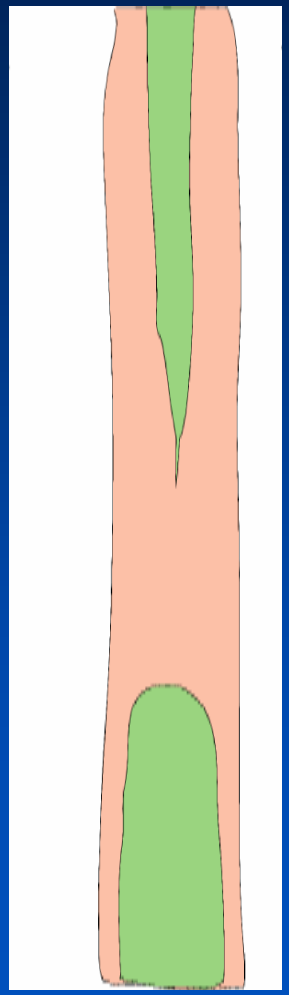
Olivari z, et al. JACC 2003;41:1672-1678

Predictors for Procedural Success

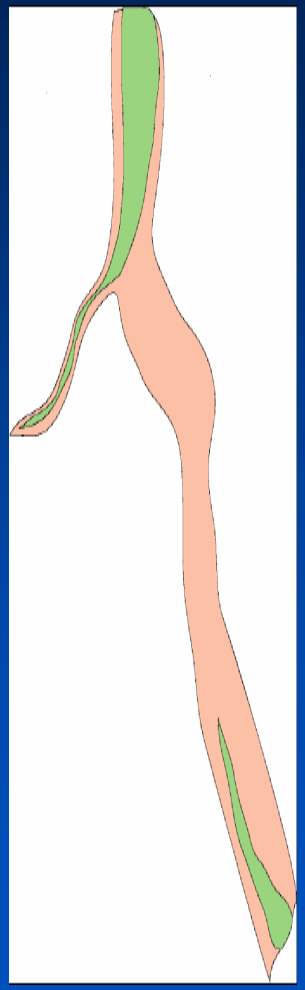
	N	OR	95% C.I.	P
Morphology				
Abrupt	187	1	-	-
Tapered	96	6.1	2.1-18.2	0.001
Angulation				
> 45	12	1	-	-
≤ 45	271	4.5	1.2-17.2	0.03
Missing segment				
≥ 15 mm	123	1	-	-
< 15 mm	160	34	1.6-7.0	0.001
Single Lesion				
Yes	134	1	-	-
No	149	2.2	1.1-4,4	0.03

Dong S, et al. J Interven Cardiol 2005;18:1-7

Easy vs. Hard CTO



- Straight vessel
- Stump present
- Short lesion
- Convex type
- No side branch

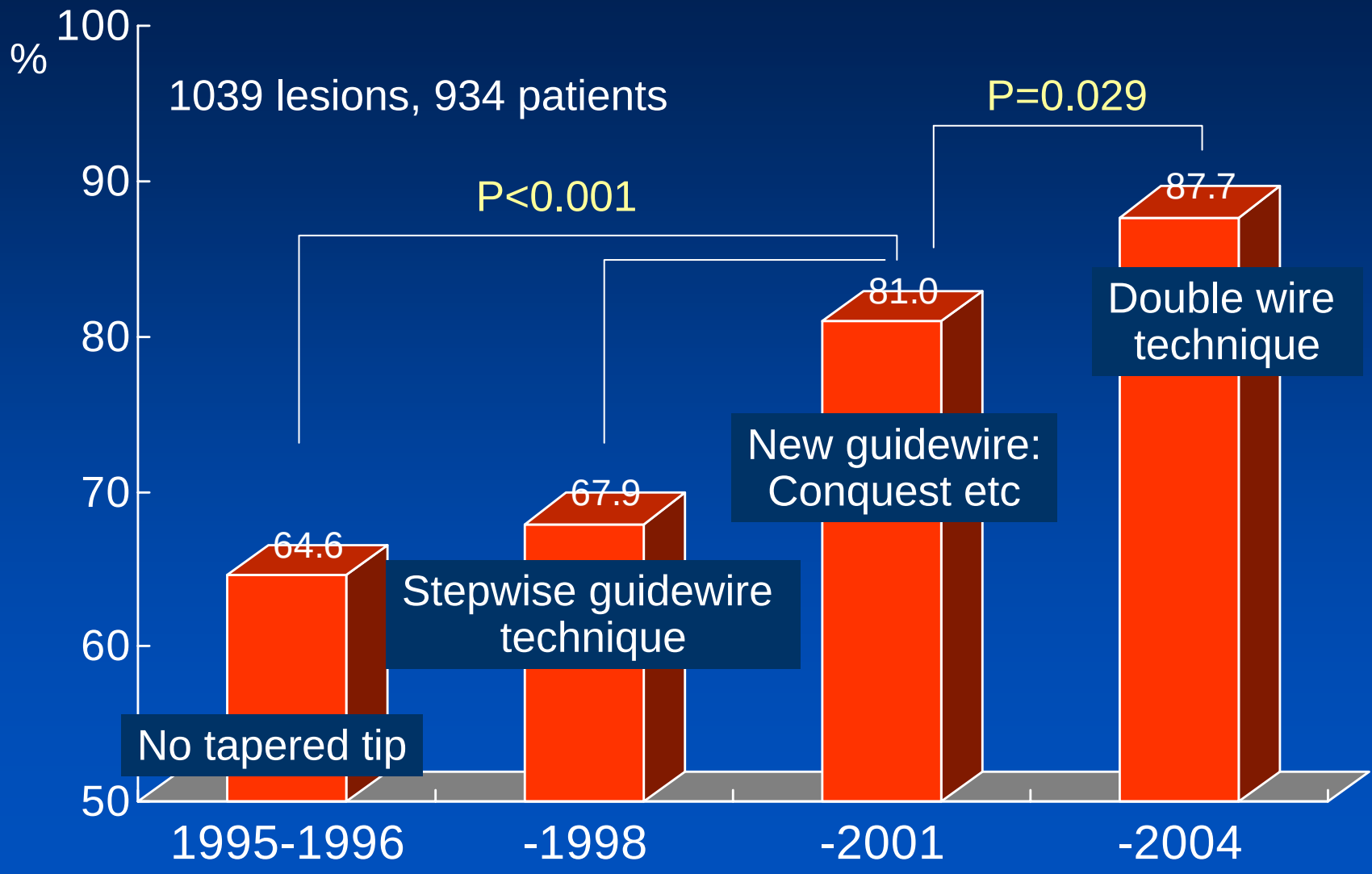


- Tortous vessel
- No stump
- Long lesion
- Tapered type
- Small side branch

How to improve procedural success ?

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

Improved Success Rate



Hiroyuki tanaka, et al. ACC 2005

How to improve procedural success ?

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

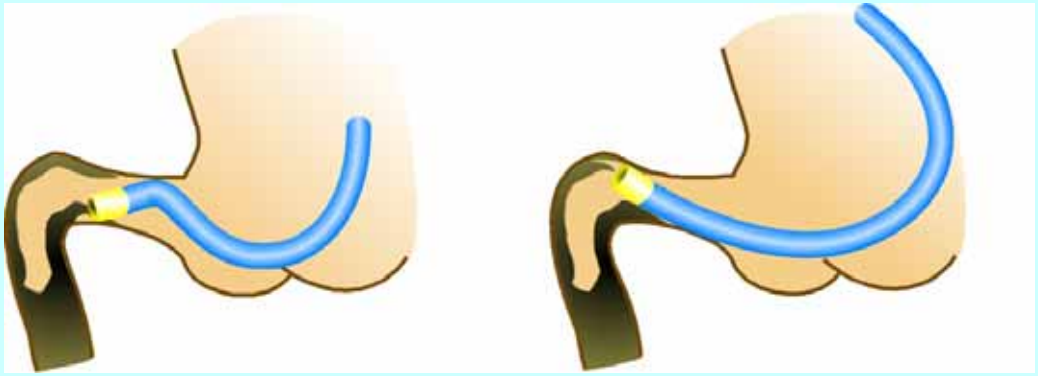
Guiding Catheter for CTO

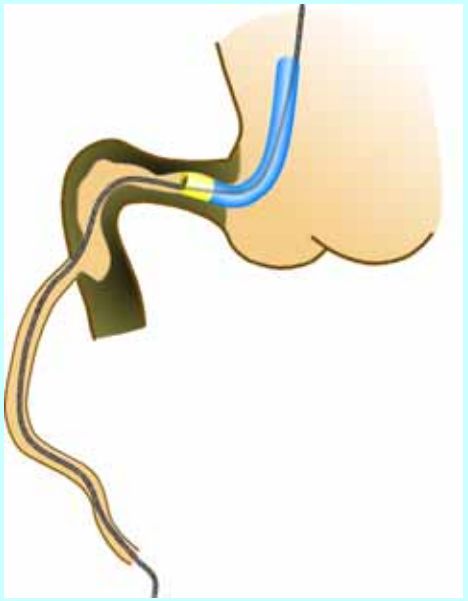
7F TFI with all Side Hole

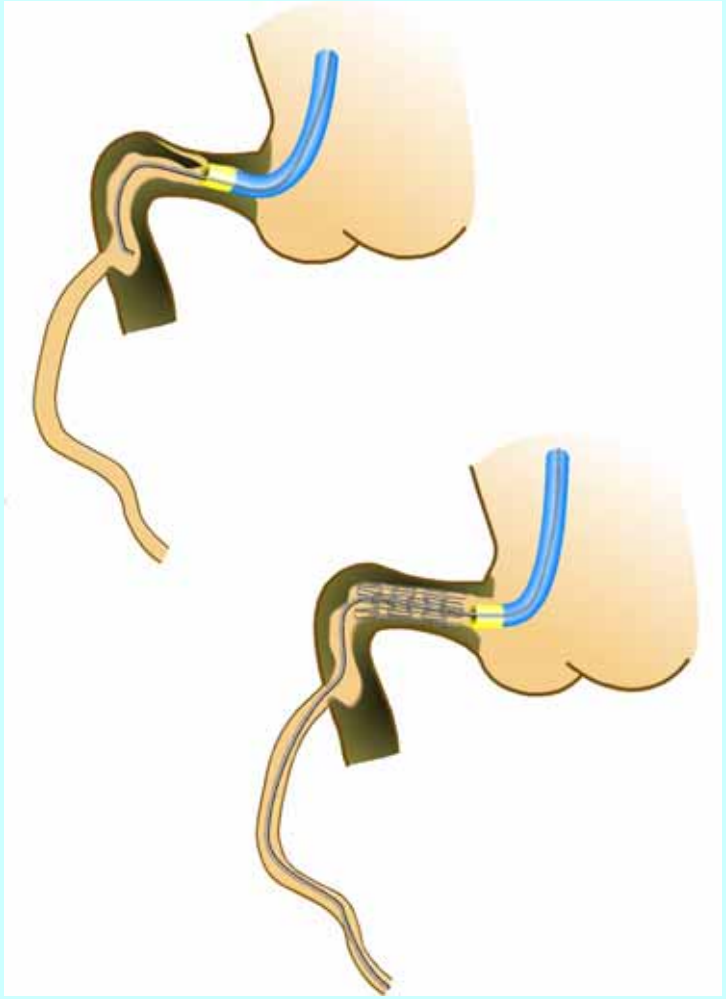
- **Left Coronary Artery**
  - **LAD: EBU 3.5, EBU 4.0**
  - **LCX: AL 1.0, 1.5**
- **Right Coronary Artery**
  - **AL 0.75, 1.0**

Strong Back up support

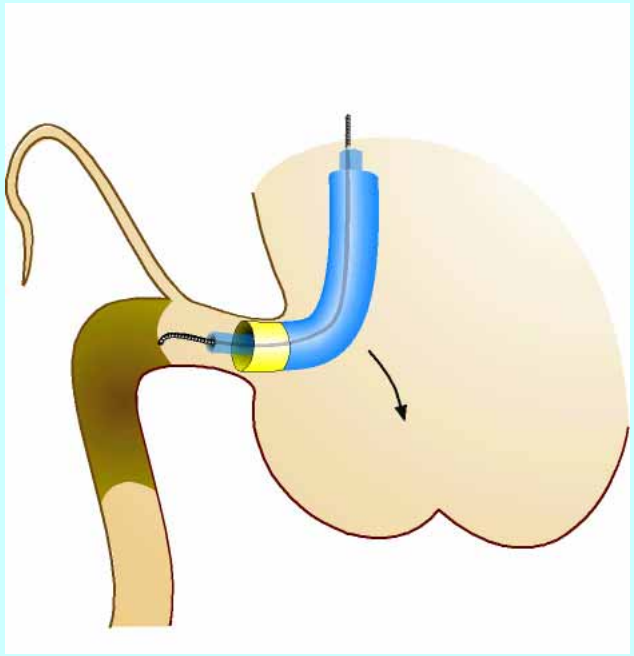
Guiding Catheter for RCA

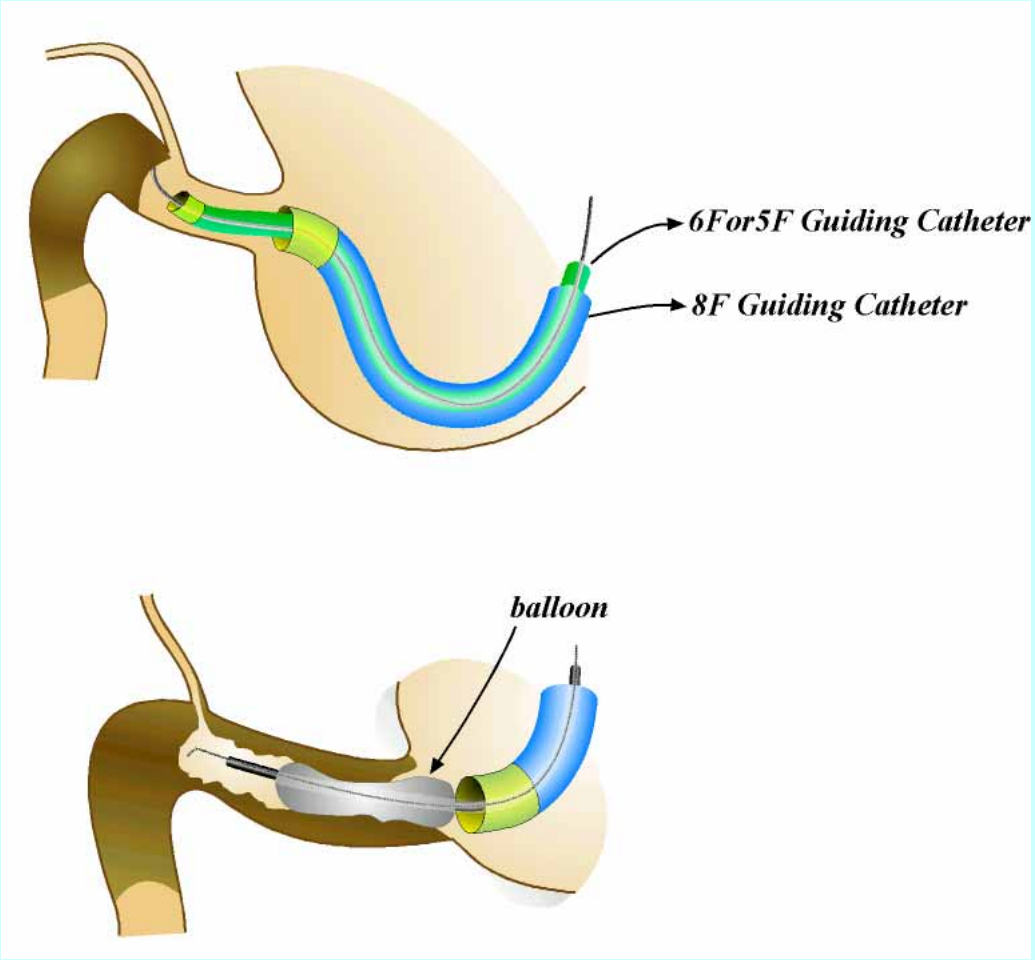




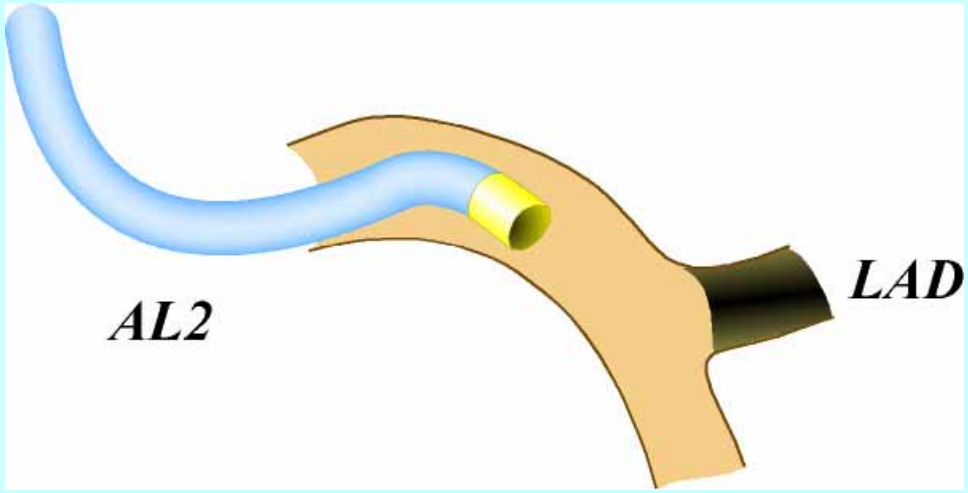


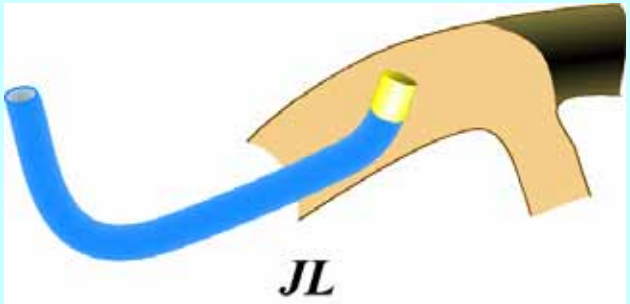
Two Guiding Catheter for RCA

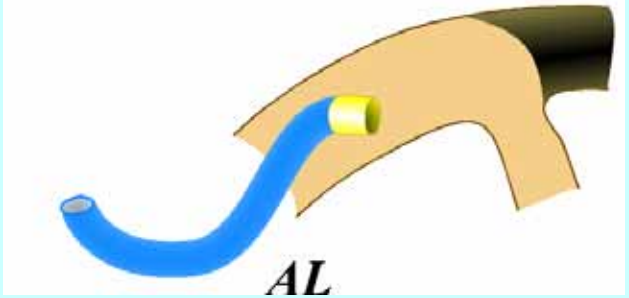




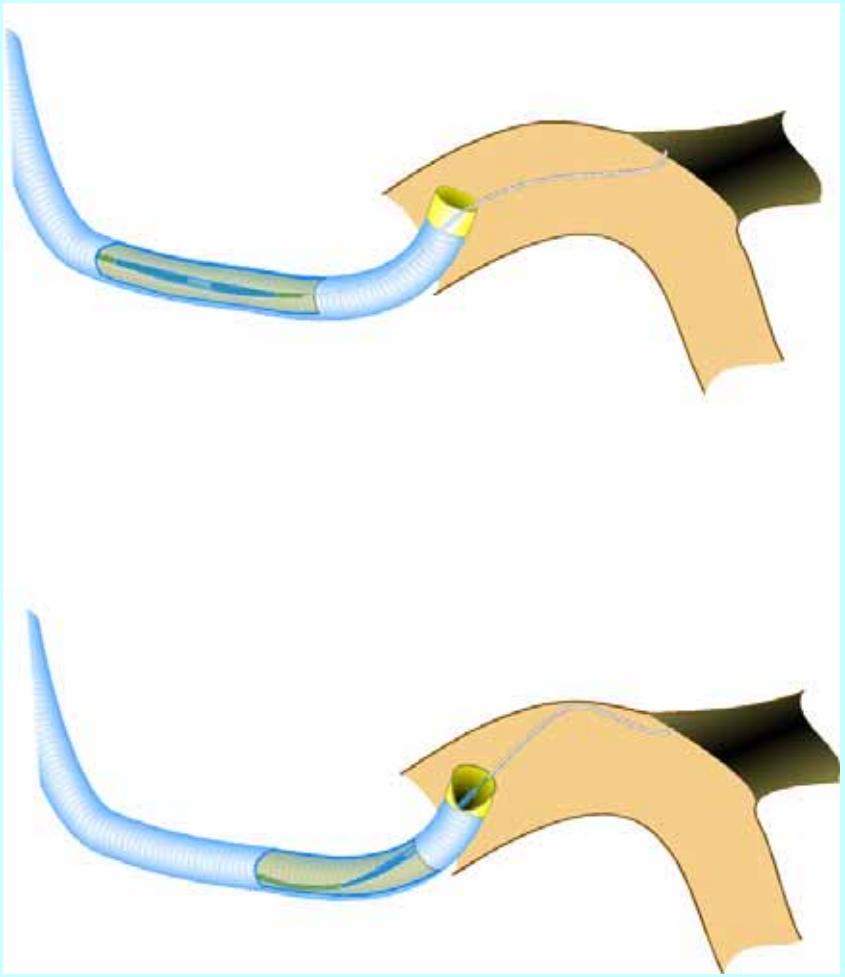
Guiding Catheter for LCA

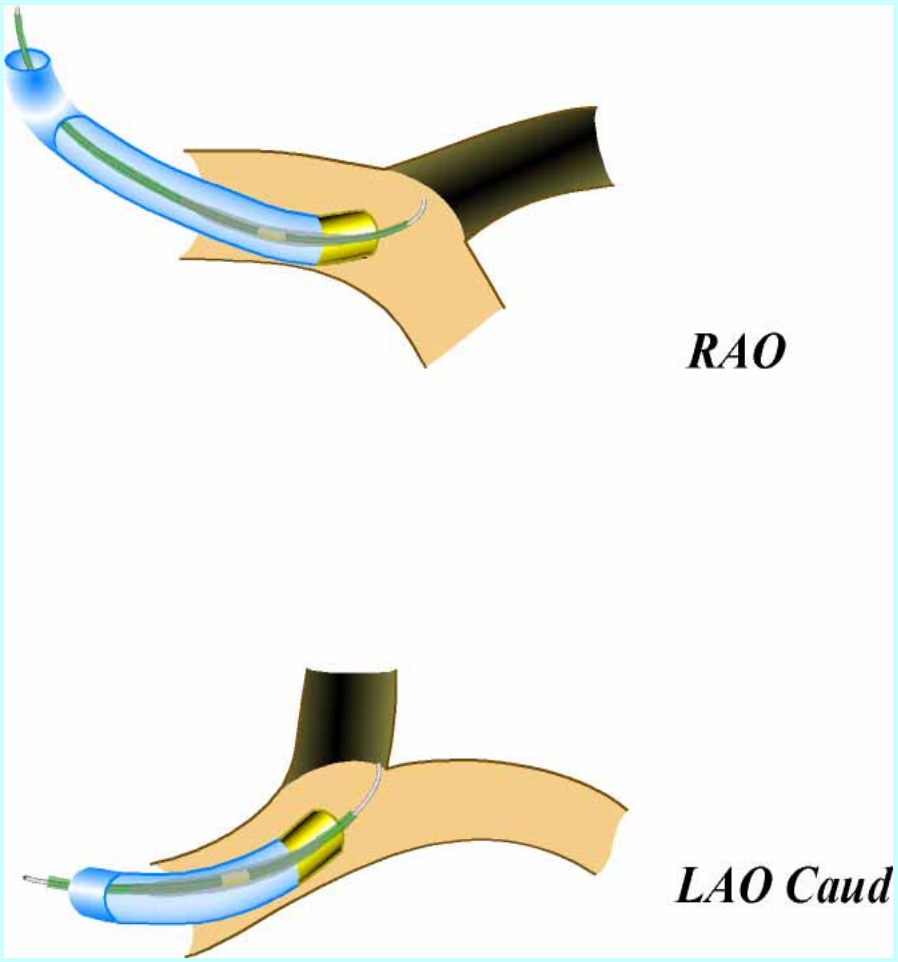






Position of Support Catheter





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

Guide Wire for CTO

- **Spring type**
  - **General use: Route, Rinato, TGV, ATW**
  - **Stiff type: Miracle, Conquest, TGV standard, Magic**
  - **Nitol type: Runthrough, BMW, Balance**
- **Plastic type**
  - **Choice PT, Whisper, Fielder**

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

Special Devices for CTO Recanalization

- Failed special device
  - Magum/Magnarail system
  - Kensey Catheter
  - ROTACS Low Speed Rotational Atherectomy Catheter
  - Excimer Laser Wire

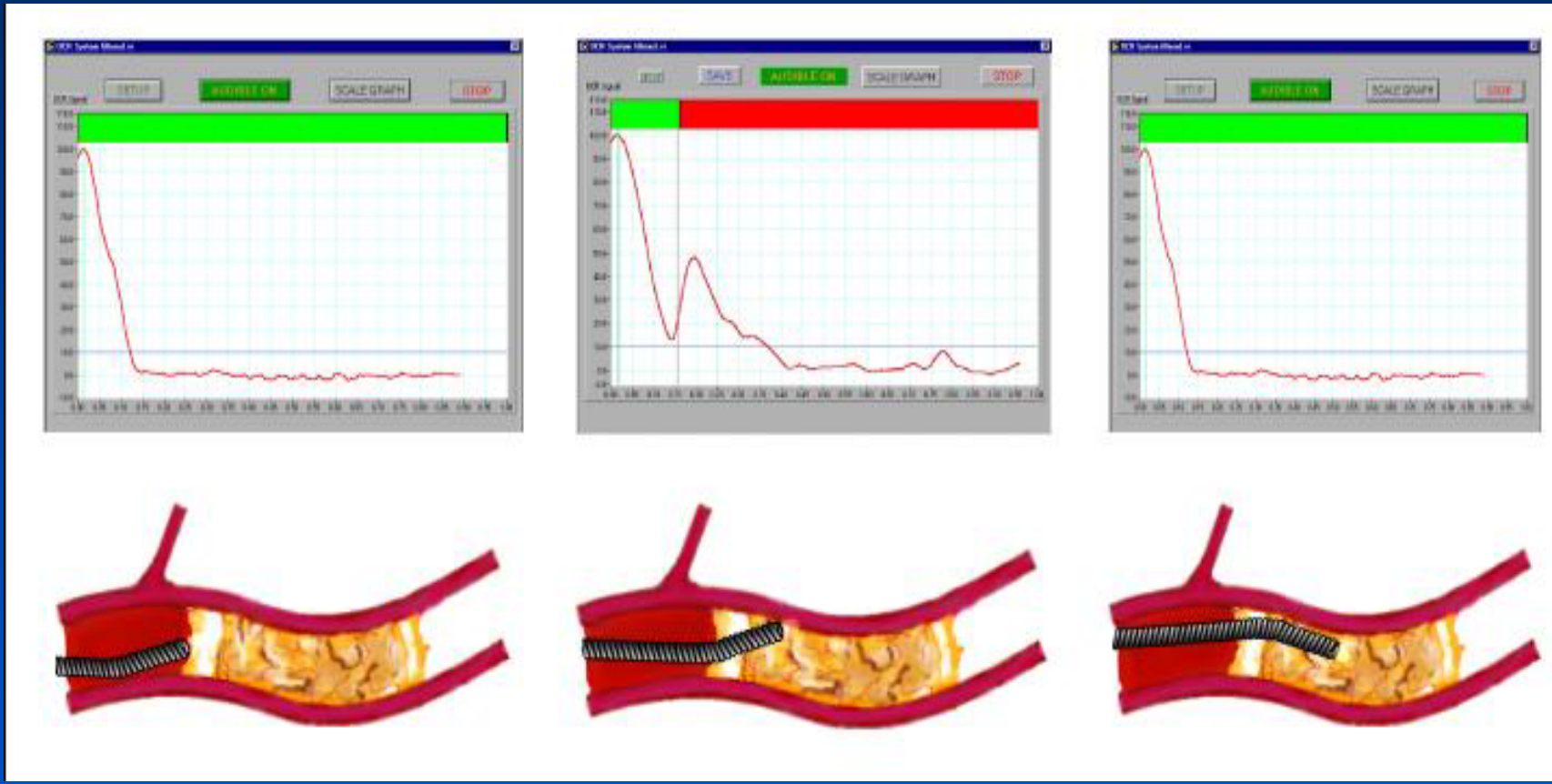
- CTO device in current use
  - OCR SafeSteer™ System
    (Optical Coherence Reflectometry)
  - FrontRunner™ Catheter
  - Flow Cardia Crosser System

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

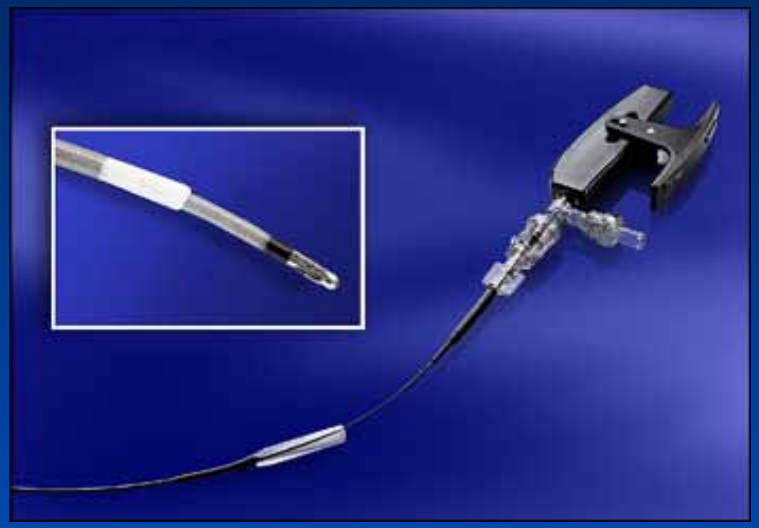
116 Lesions 21 centers with CTO “failure to cross”
median occlusion duration: 22montths
Median lesion length: 25mm(>30mm long in 25%)

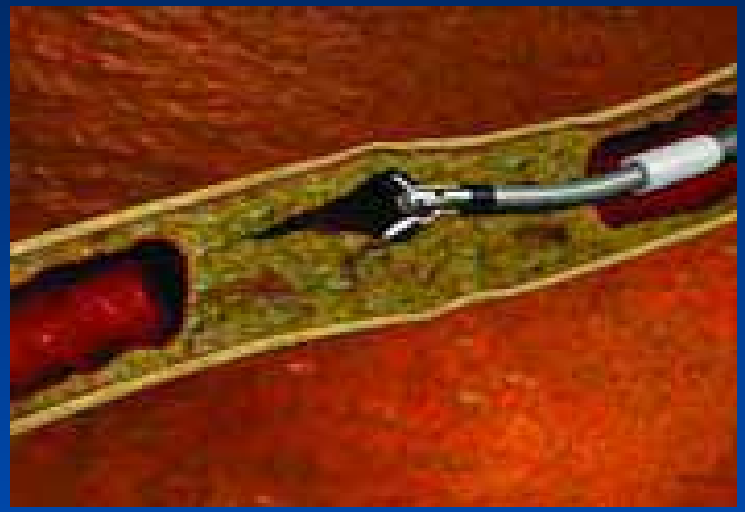
- Device Success 63(54.3%)
- Complication
  - MACE in hospital 8 (6.9%)
  - Non-Q MI 5 (5.2%)
  - Clinical perforation 3 (2.6%)
  - Device related 1 (0.9%)

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 Techniques

- Parallel wire technique
- Side branch technique
- Sub-intimal re-entry technique
- IVUS-guided recanalization technique
- Seesaw wiring technique
- Retrograde Wiring
- Micro-catheter
- Penetrating catheter

CONQUEST trial

Stepwise guidewire change

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

  - First step: intermediate GW

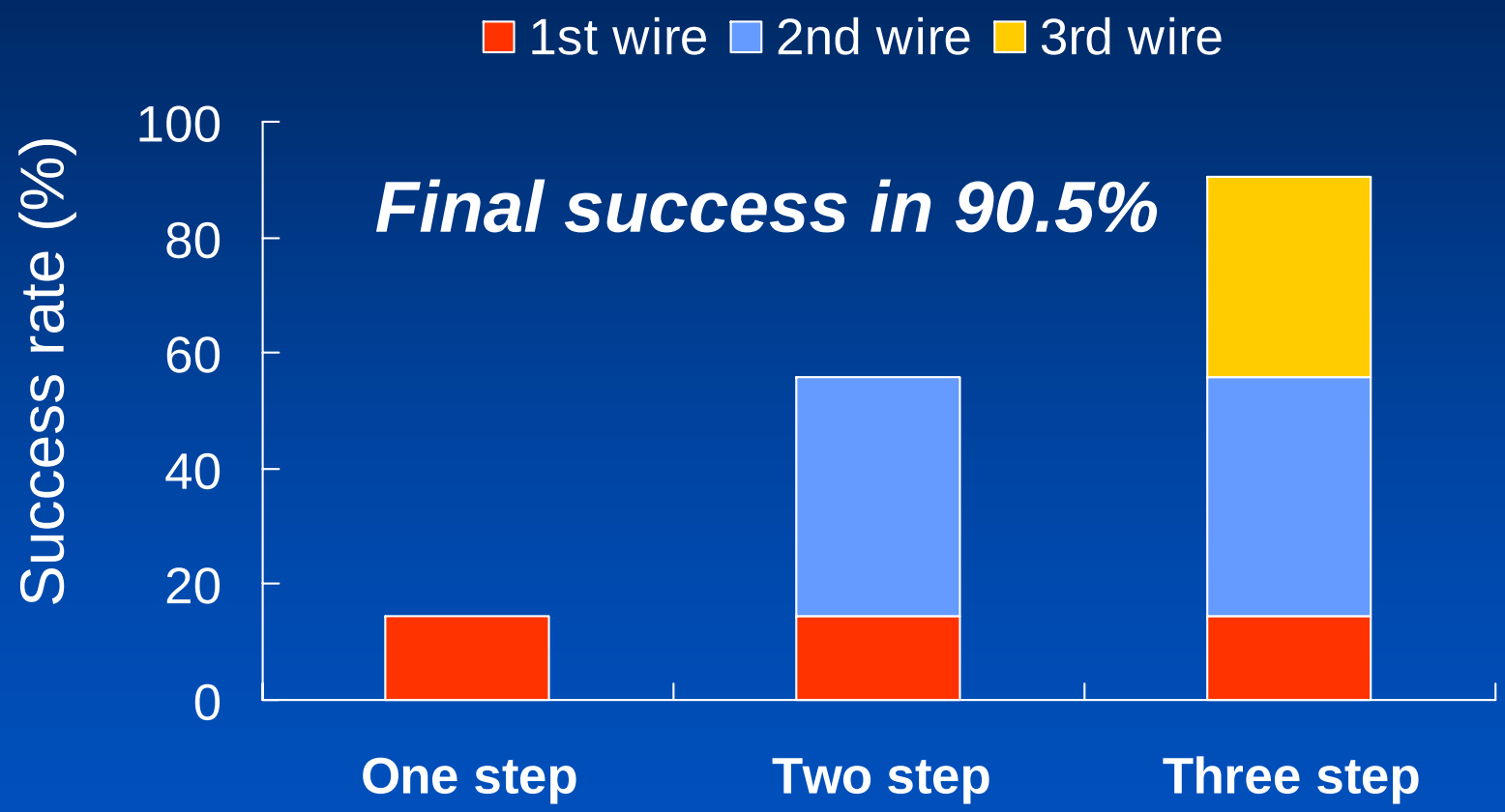
  - Second step: Conquest GW sereies

  - Third step: additional Conquest GW, Seesaw wire technique

T. Muramatsu, et al. TCT 2004

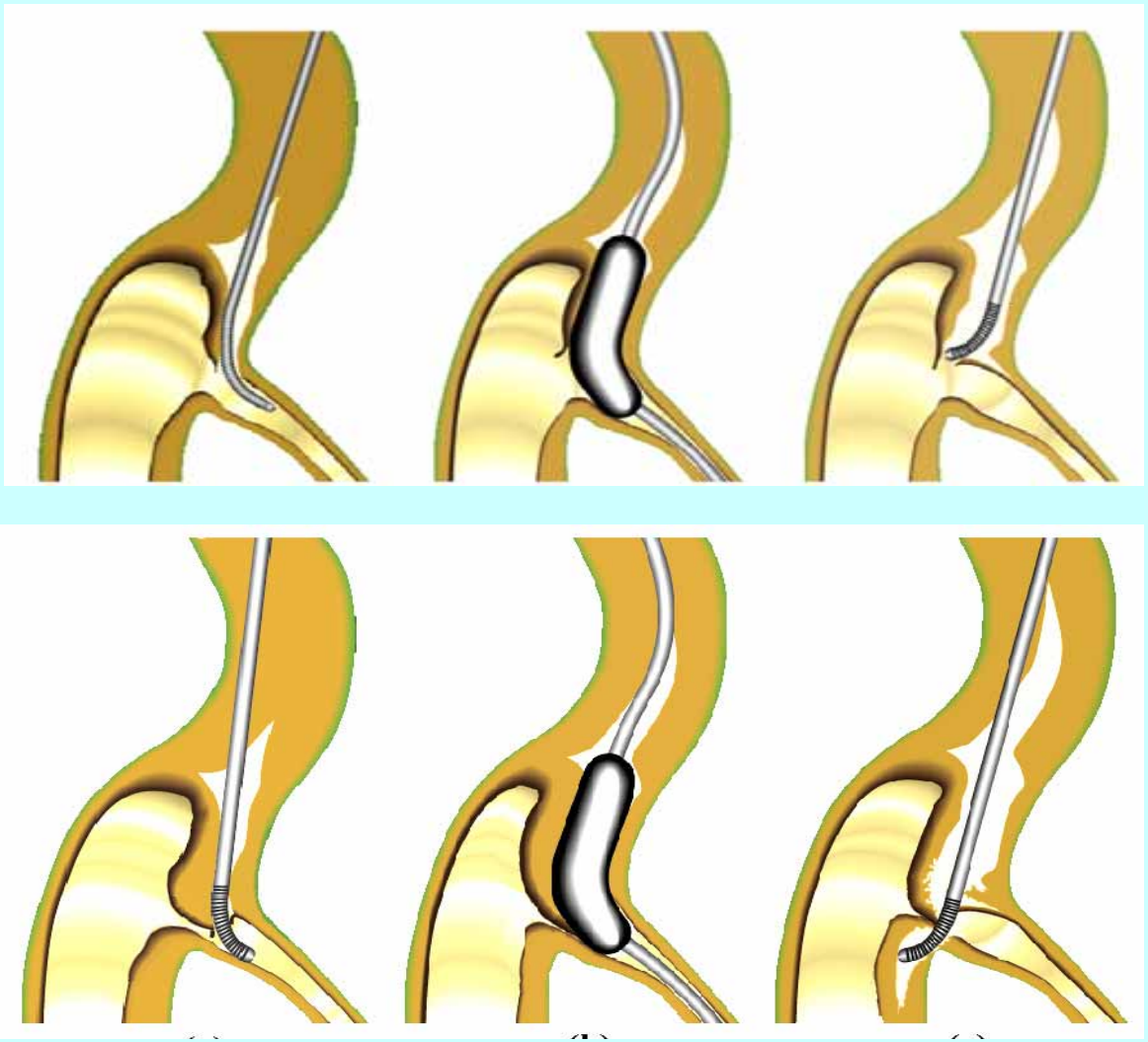
CONQUEST trial

110 patients, 116 CTO lesions

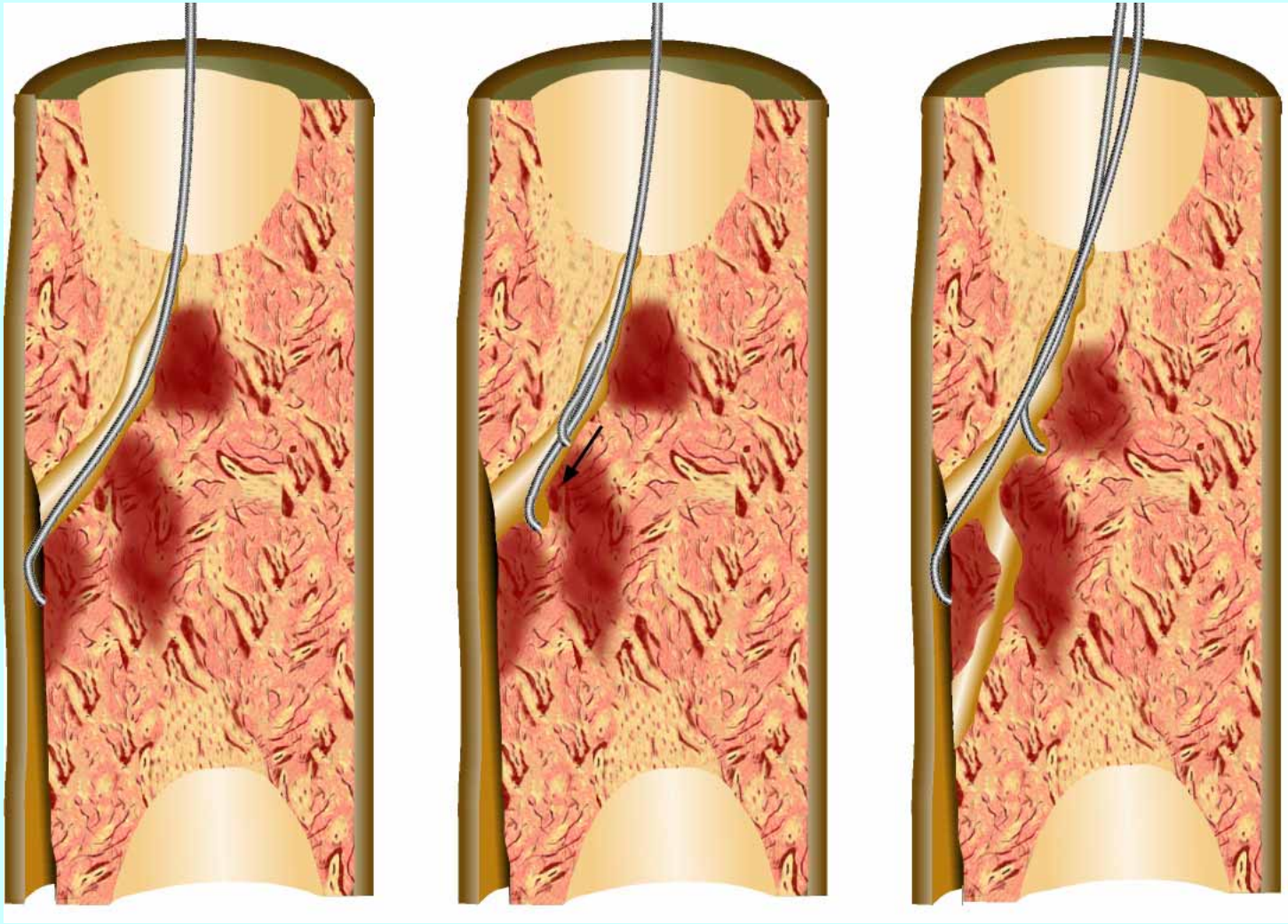


T. Muramatsu, et al. TCT 2004

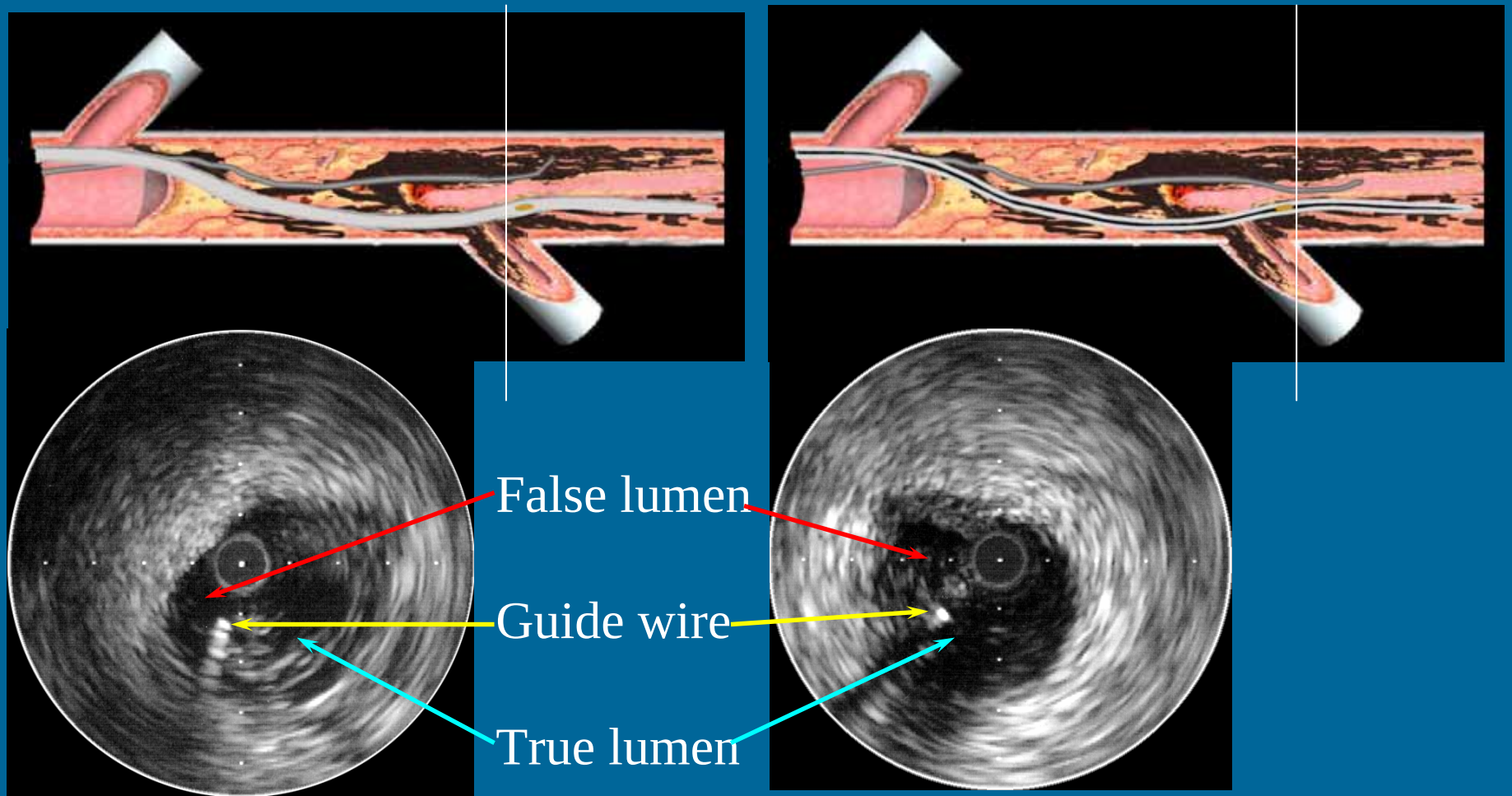
Side Branch Technique



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

Evolution of CTO Treatment

Guidewire	Tapered tip: CROSS IT, Conquest, Miracle Steerable guidewire Optical coherence reeflectometry
Ablation	Excimer laser Ultrasound Radiofrequency ablation
Mechanical	Blunt microdissection Fibrinolysis Demineralization, Collagenase
Re-entry	Percutaneous bypass
Post-crossing	Drug eluting stents Distal protection

Usefulness of Multi-slice CT For PCI of CTO

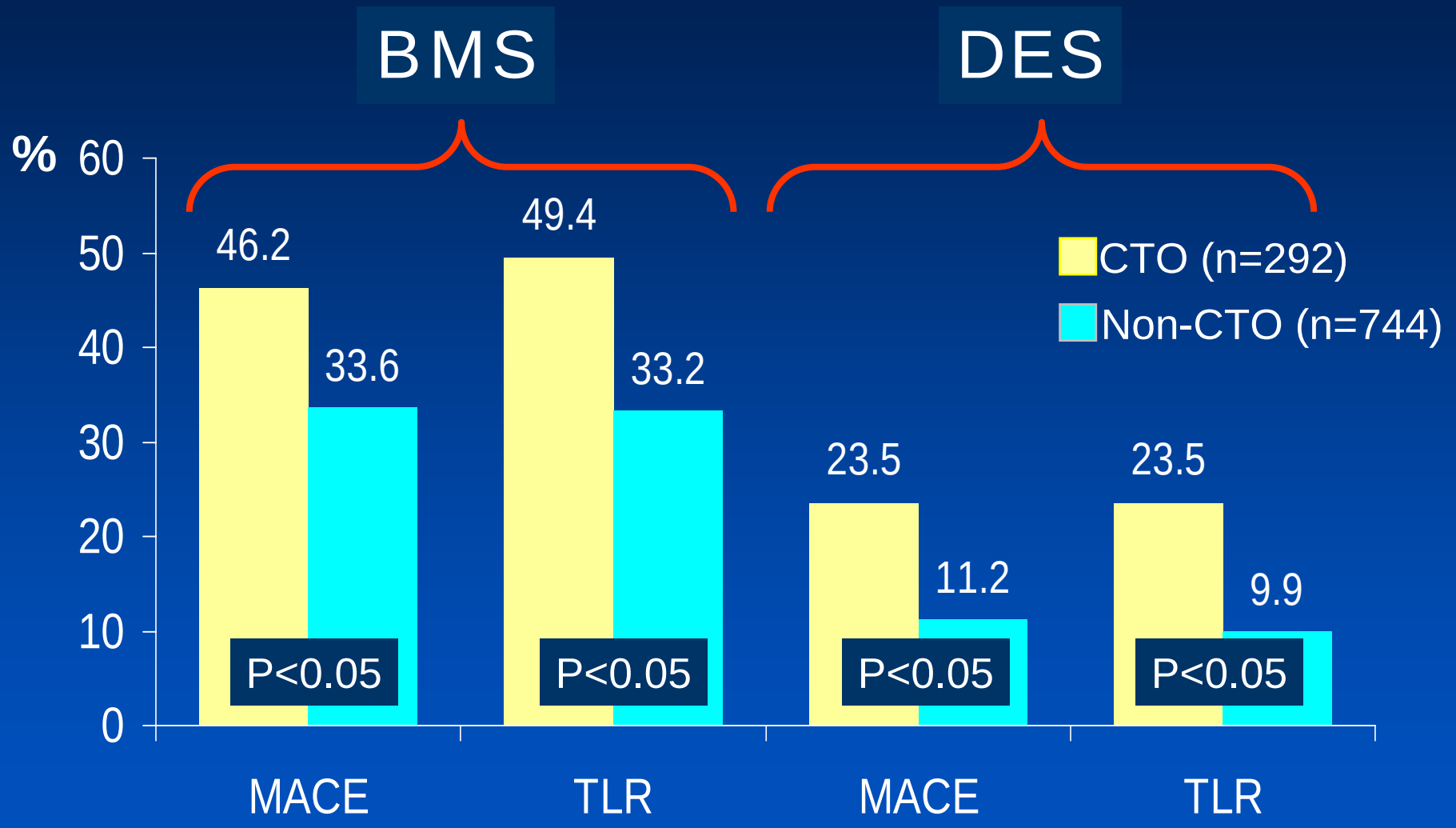
	With MSCT	Without MSCT
1st procedure successs	88.2 % (30/34)	69.2 % (19/26)
Final lesion success	94.1 % (32/34)	82.6 % (19/23)
Median fluoro time (mim)	32.4	49.6
Used contrast volume (ml)	258	287

Satoru Sumitsuji, et al. ACC 2006.

Results of PCI for CTO

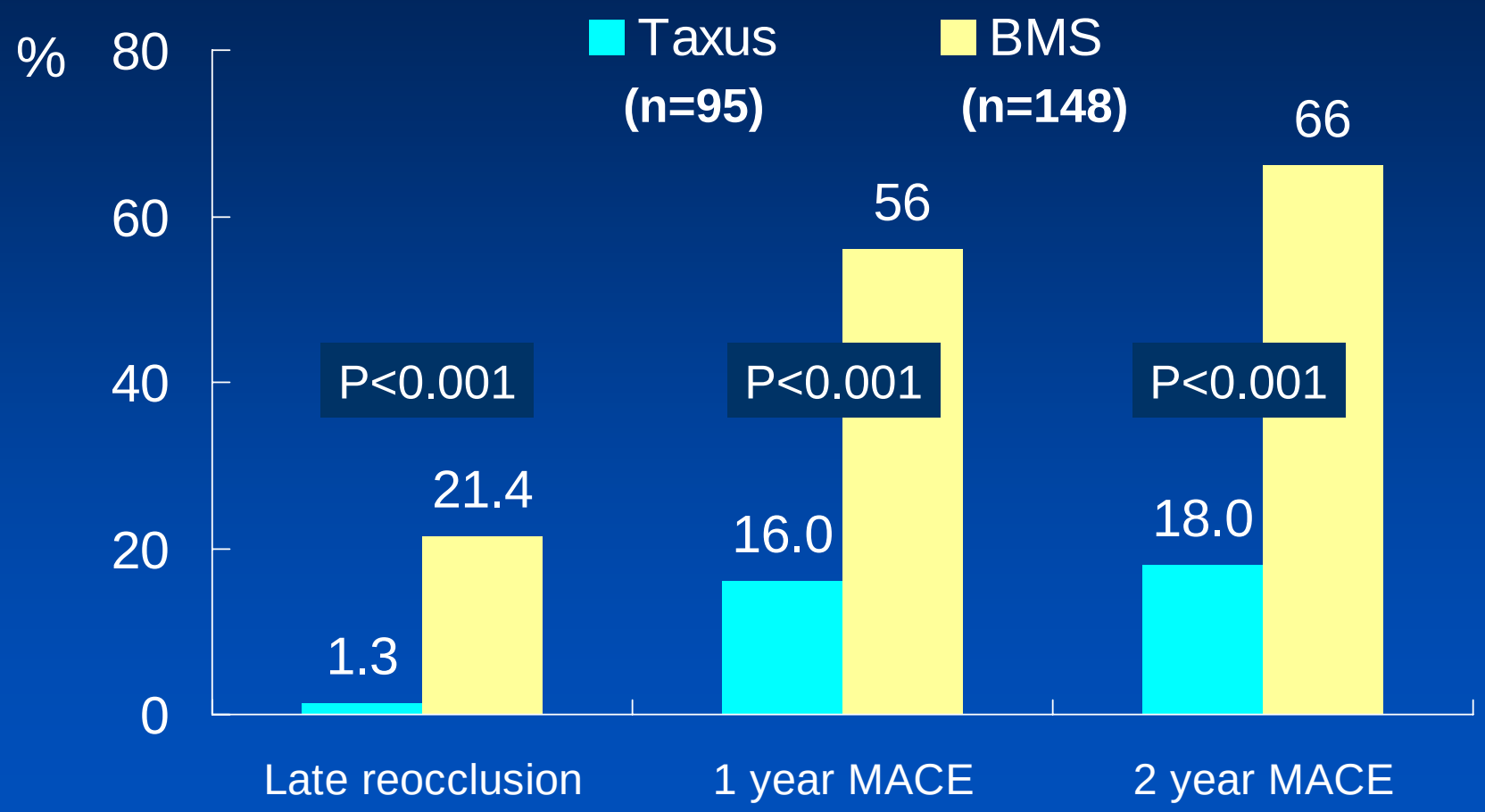
DES vs. BMS

CTO vs. Non-CTO from BMS to DES



Fujita et al. ACC 2006

Long-term Durability of DES for CTO

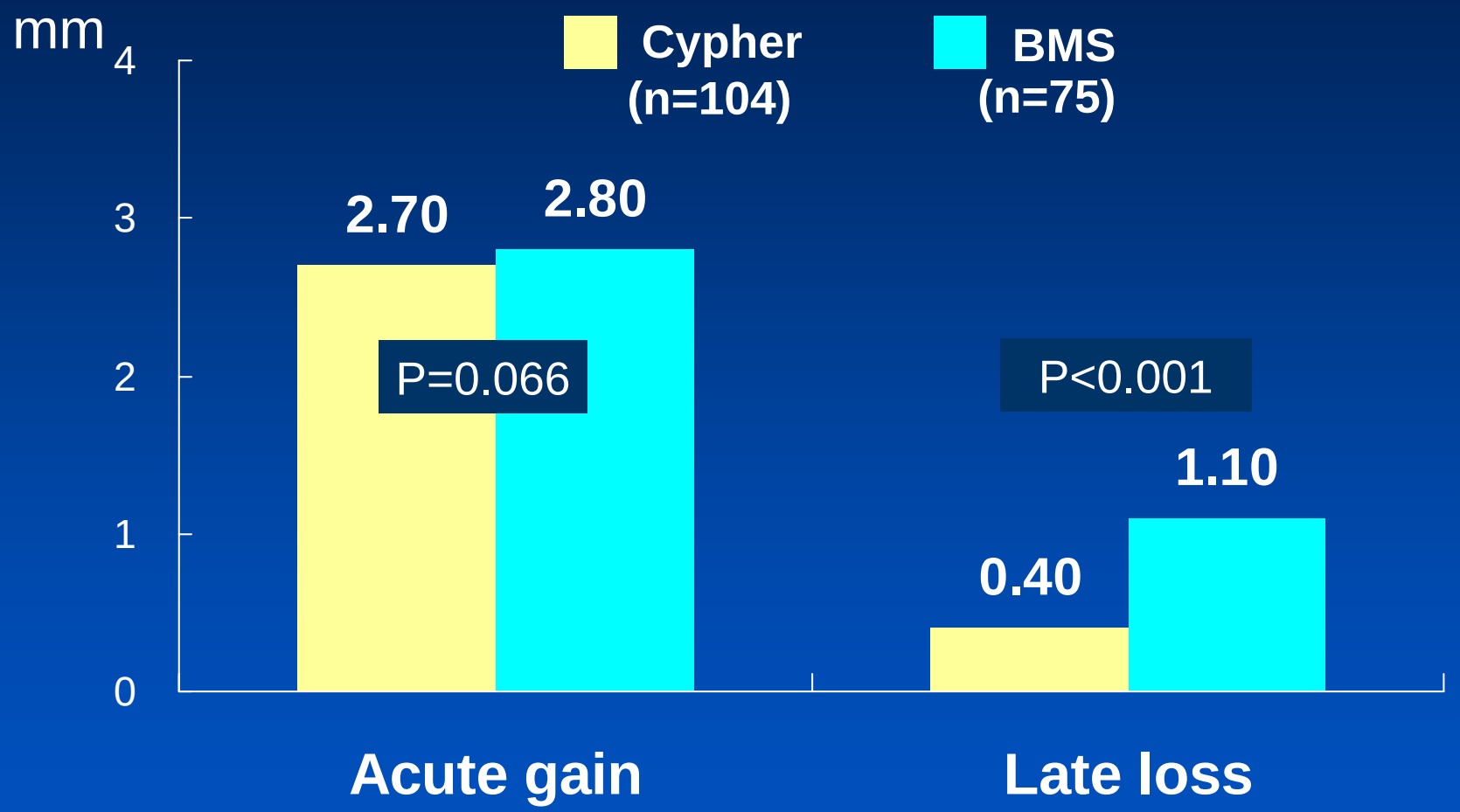


Werner et al. ACC 2006

AMC

Acute Gain & Late Loss

Cypher vs. BMS

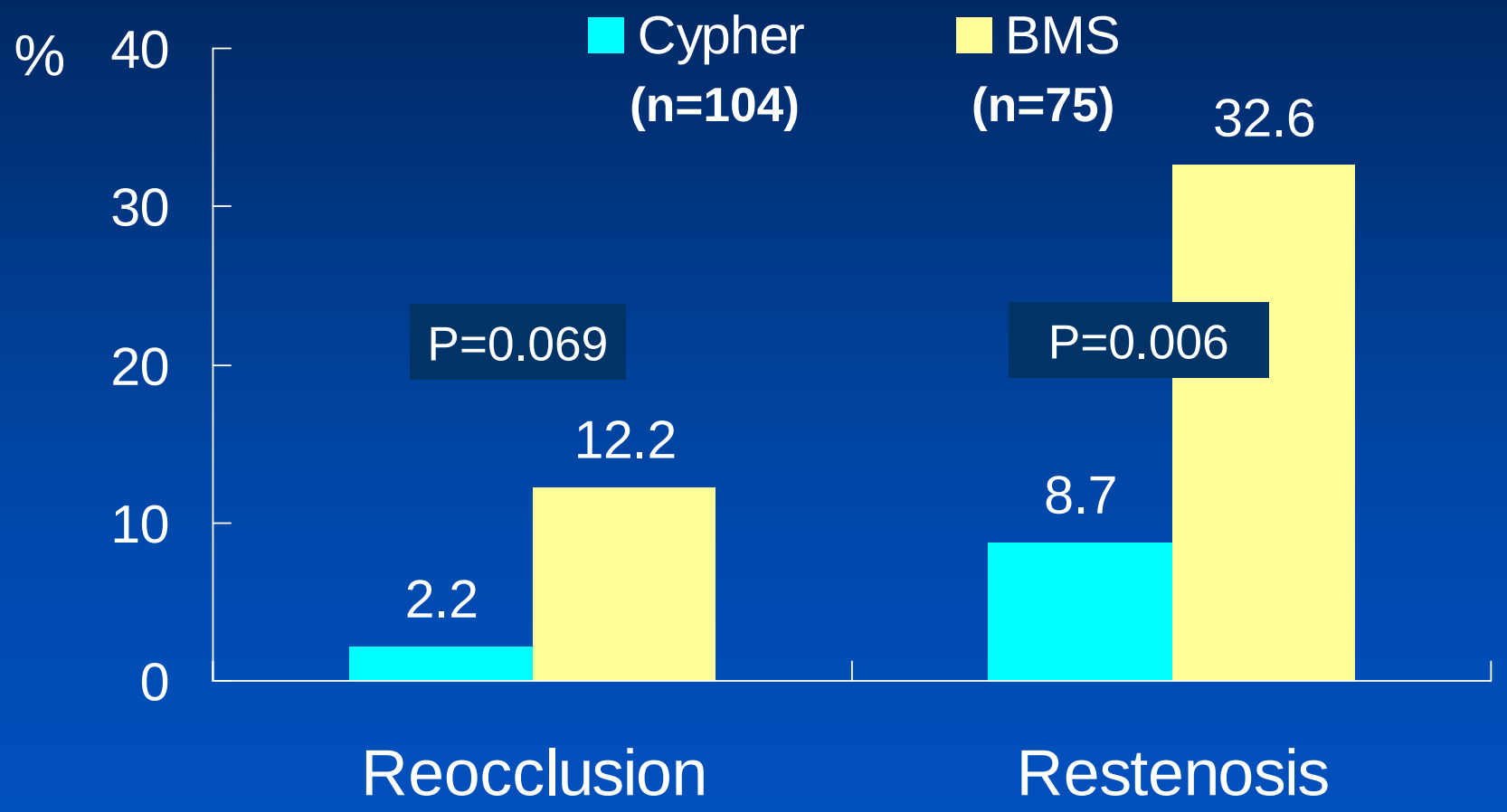


MK Kim et al. J Interv Cardiol 2006 (in print)

AMC

Chronic Total Occlusion

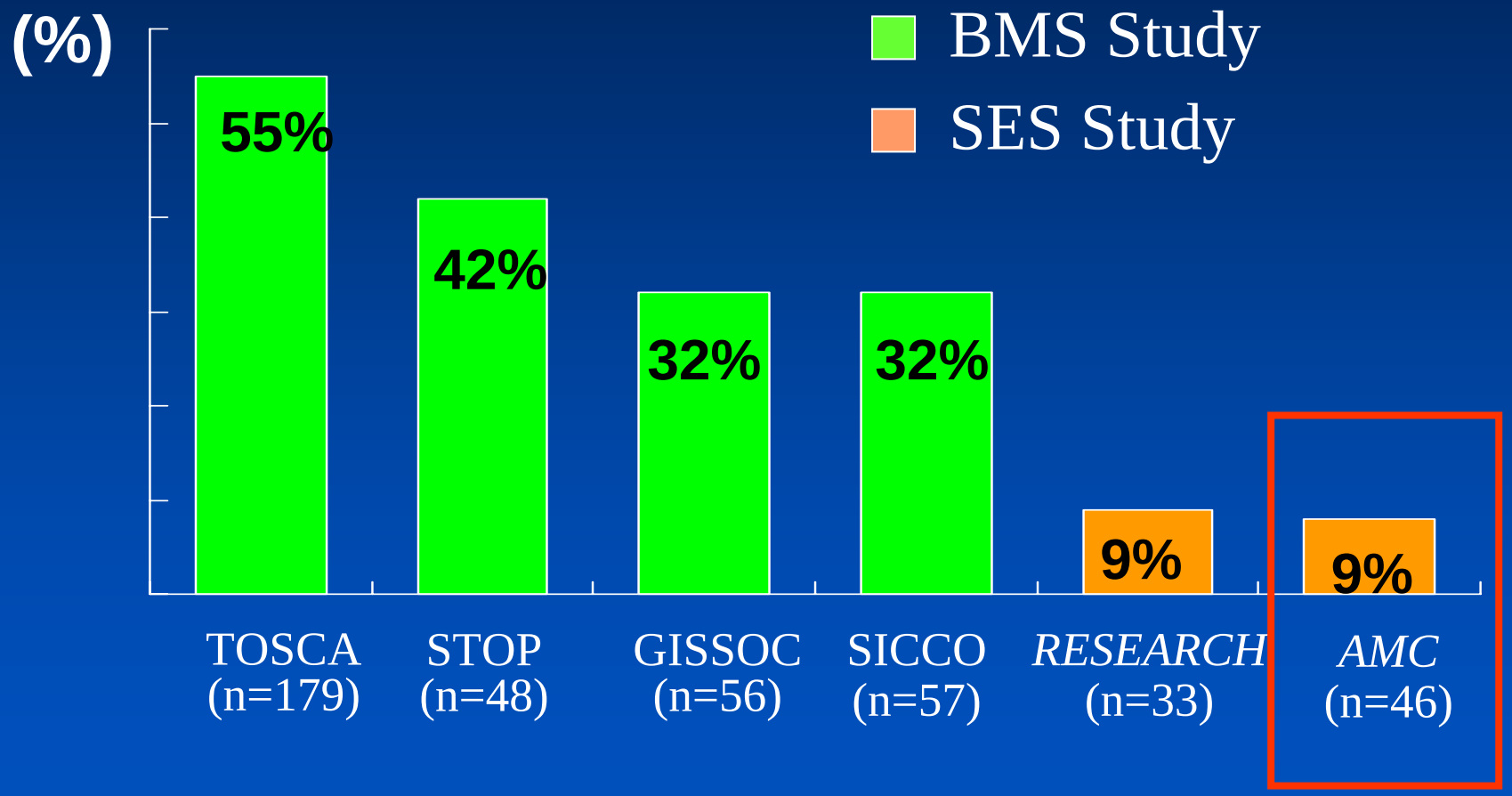
Cypher vs. BMS



MK Kim et al. J Interv Cardiol 2006 (in print)

Historical Comparison

6 Month Restenosis Rate



Serruys et al, ACC 2004

Results of PCI for CTO

DES Registry

CTO Representation in DES Trials

Trial	N	CTO (%)
ARRIVE	2,586	1.8
DIABETES	221	13.1
e-Cypher	14,316	2.9
WISDOM	903	7.0

Angiographic and Clinical Outcomes

DES in CTO treatment

Trial	Type	Lesion	Follow-up	Restenosis	TVR	MACE
Nakamura AJC 2005	SES	60	6 Mo	2%	3%	3%
Suarez de Lezo ACC 2003	SES	86	6 Mo	13%	6%	NA
Hoye JACC 2004	SES	56	6 Mo angio 1 Yr MACE	9.1%	3.6%	3.6%
SICTO EuroPCR 2004	SES	25	6M TVR	NA	8.0%	NA
Werner JACC 2004	PES	48	6 Mo angio 1 Yr MACE	8.3%	6.3%	12.5%

Results of PCI for CTO

Cypher vs. Taxus

Angiographic and Clinical Outcomes

Cypher vs. Taxus in CTO treatment

	Cypher (n=128)	Taxus (n=180)	P
Procedural success	100%	100%	NS
30 days MACE	0%	0%	NS
Reference diameter, mm	2.90±0.88	2.82±0.90	NS
MLD post, mm	2.80±0.80	2.73±0.81	NS
MLD 12 month, mm	2.73±0.80	2.63±0.77	NS
Restenosis 12 months	1.5%	1.7%	NS
TVR	2.3%	2.2%	NS
MACE 12 months	2.3%	2.2%	NS

Nakamura, et al, TCT 2004

Angiographic and Clinical Outcomes

Cypher vs. Taxus in CTO treatment

	Cypher (n=111)	Taxus (n=105)	P
Procedural success	100%	100%	NS
Reocclusion	6%	7.5%	1.0
Restenosis	24.3%	23.5%	0.84
Late loss, mm	0.47±1.12	0.68±1.35	0.36
TLR	14.4%	14.3%	1.0
TVR	17.1%	18.1%	0.86

Melzi, et al, ACC 2006

AMC

Chronic Total Occlusion
Cypher vs. Taxus

	Cypher (n=107)	Taxus (n=29)	P
Procedural success	100%	100%	NS
Lesion length, mm	36.5±20.3	28.0±15.6	0.23
Number of stents	1.8±0.8	1.7±0.9	0.51
Stent length, mm	48.6±24.4	45.0±25.4	0.48
Reference diameter, mm	2.9±0.5	3.1±0.4	0.15
MLD post-procedure, mm	2.7±0.4	2.9±0.3	0.007
MLD follow-up, mm	2.3±0.8	2.0±0.9	0.173

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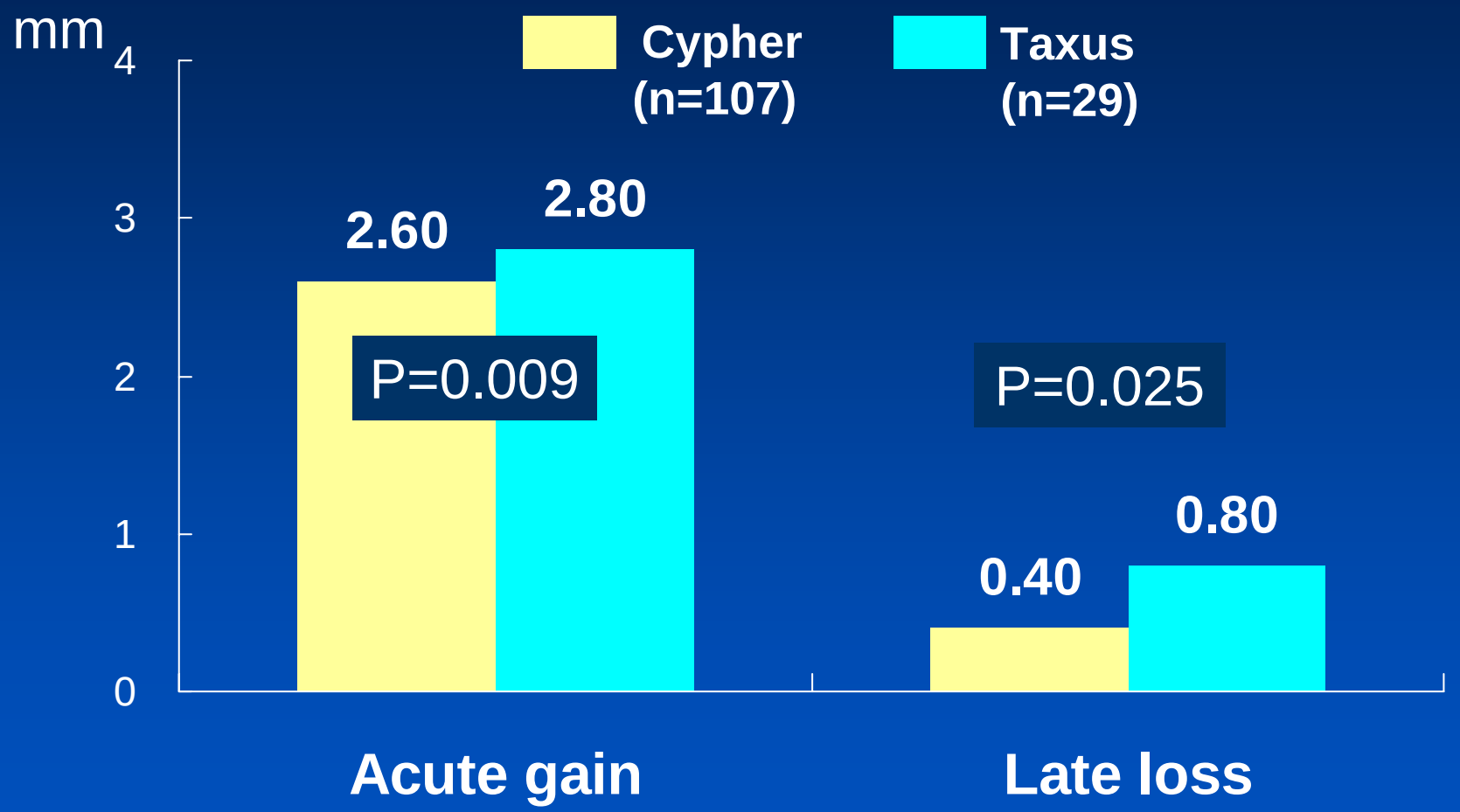
Acute Gain & Late Loss

Cypher vs. Taxus



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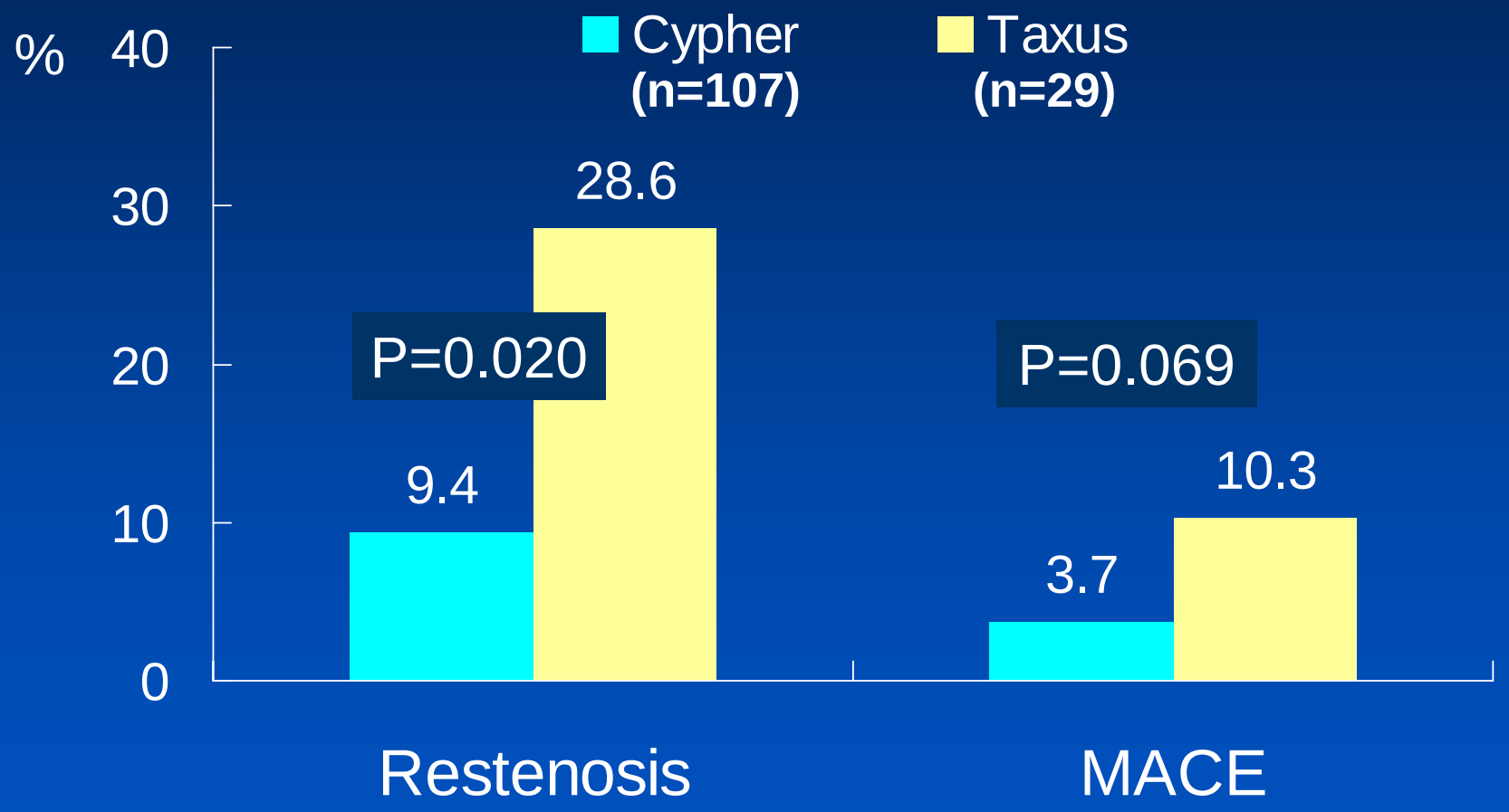
Chronic Total Occlusion

Cypher vs. Taxus



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