Summary from the Japanese Retrograde Summit Registry from 2009

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Retrograde Summit

- Society for the study of retrograde approach since 2009
- More than 25 Japanese centers involved
- Evaluation of retrograde approach from registry
- Prospective study regarding retrograde approach

Clinical Results of Retrograde Approach in Japan

Japanese Registry Data from Retrograde Summit
< Comparison between 2009-2011 >

Enrollment

January 2009 -

December 2011

Enrolling Centers: 28

Elective PCI cases
42,292

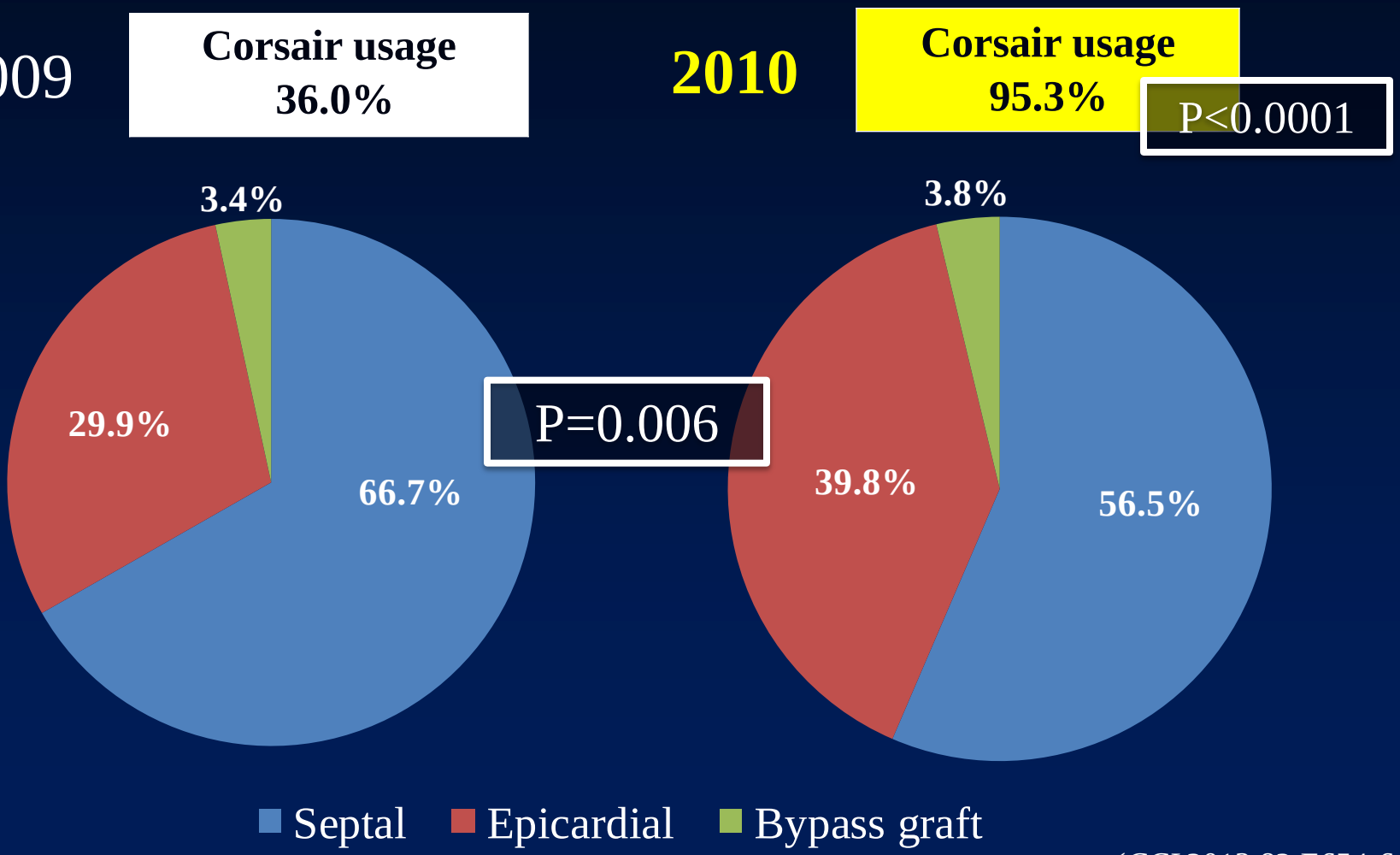
CTO cases
4.431 (10.5%)

Retrograde Approach cases
1.166 (26.3%)

JCR 2013

Collateral Crossing

Attempted Collateral Channel and Corsair usage



JCR 2013

(*CCI* 2013;82:E654-61)

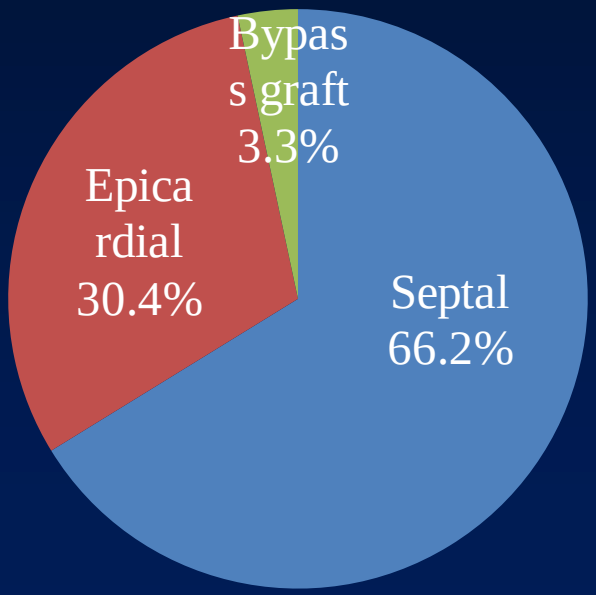
2011 data

Collateral Crossing

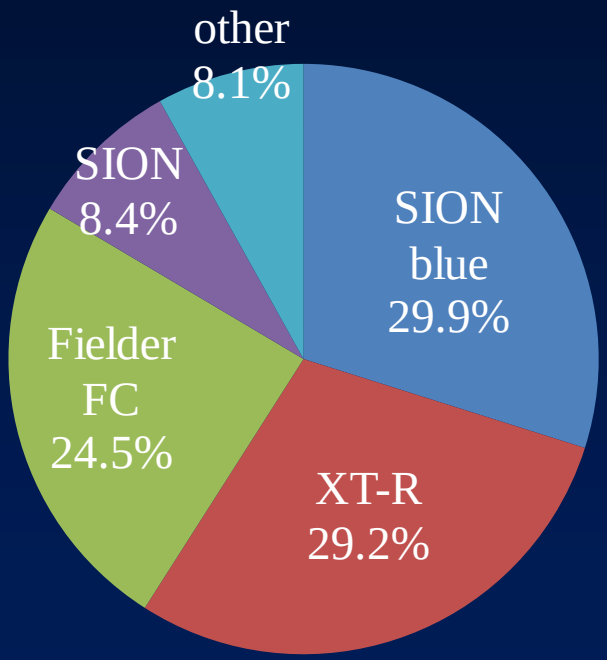
Successfully crossed in 300 (82.2%) cases

Retrograde Summit

Collateral Channel



Guide Wires



Number of GW : 1.9

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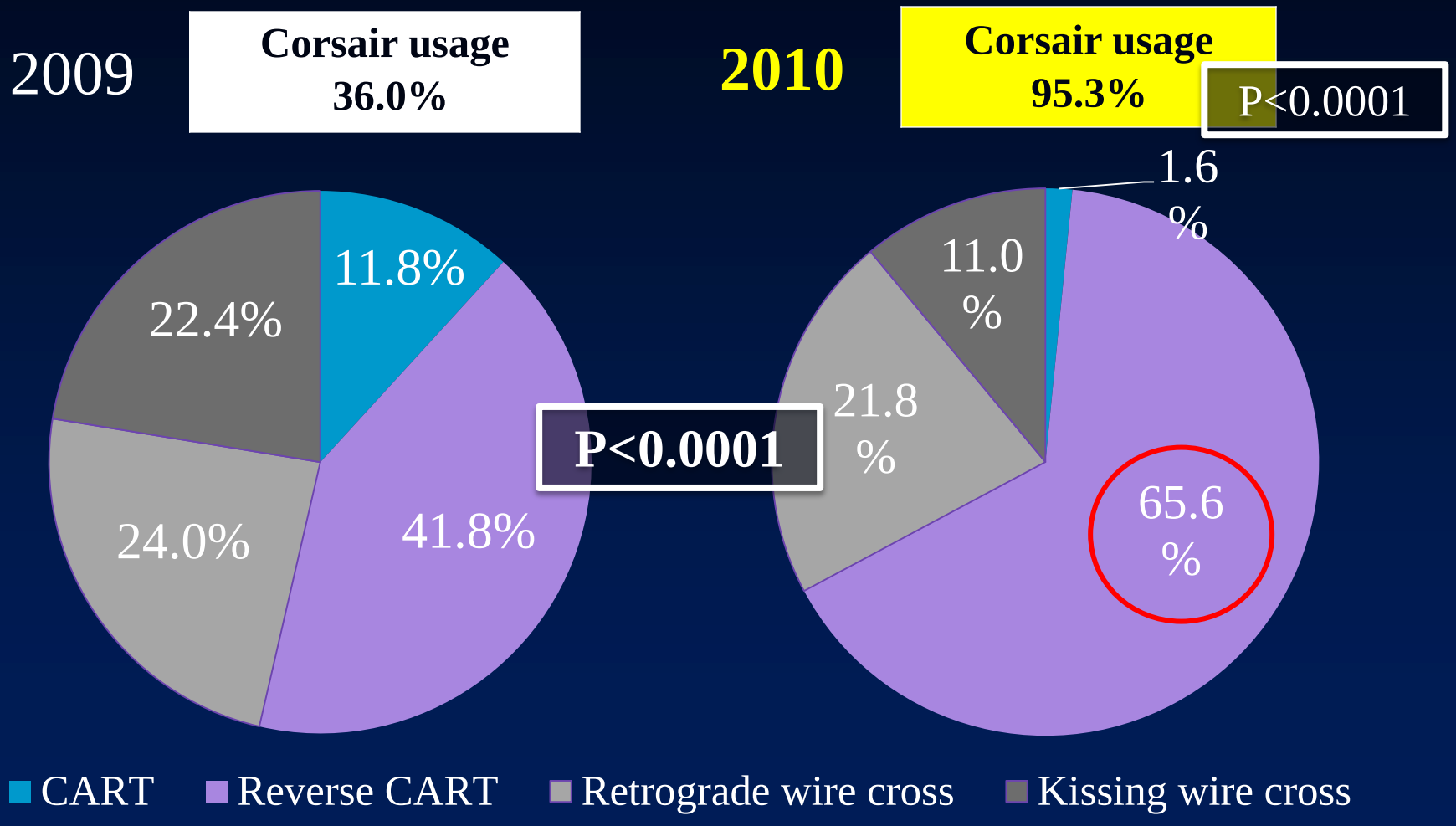
CTO Crossing

Successful Strategy



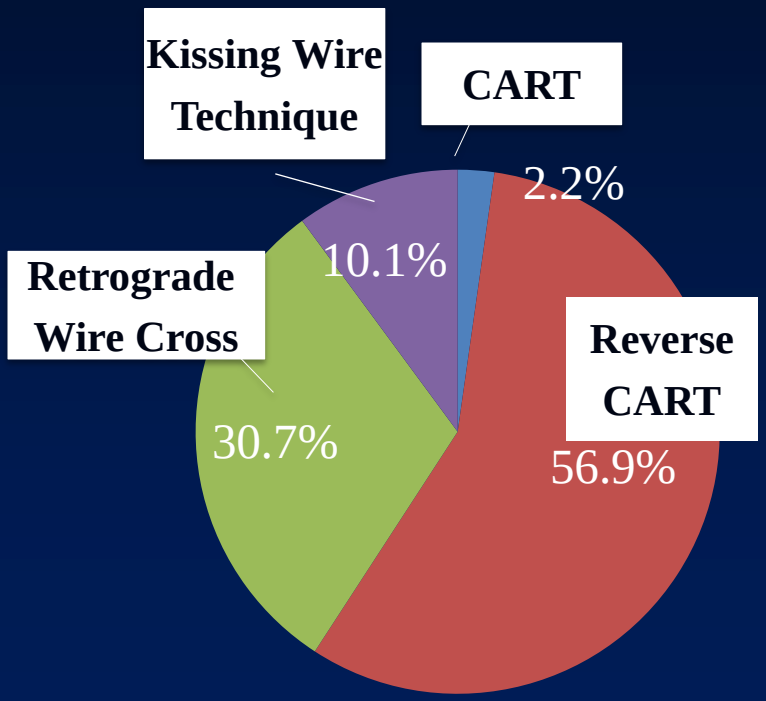
JCR 2013

(*CCI* 2013;82:E654-61)

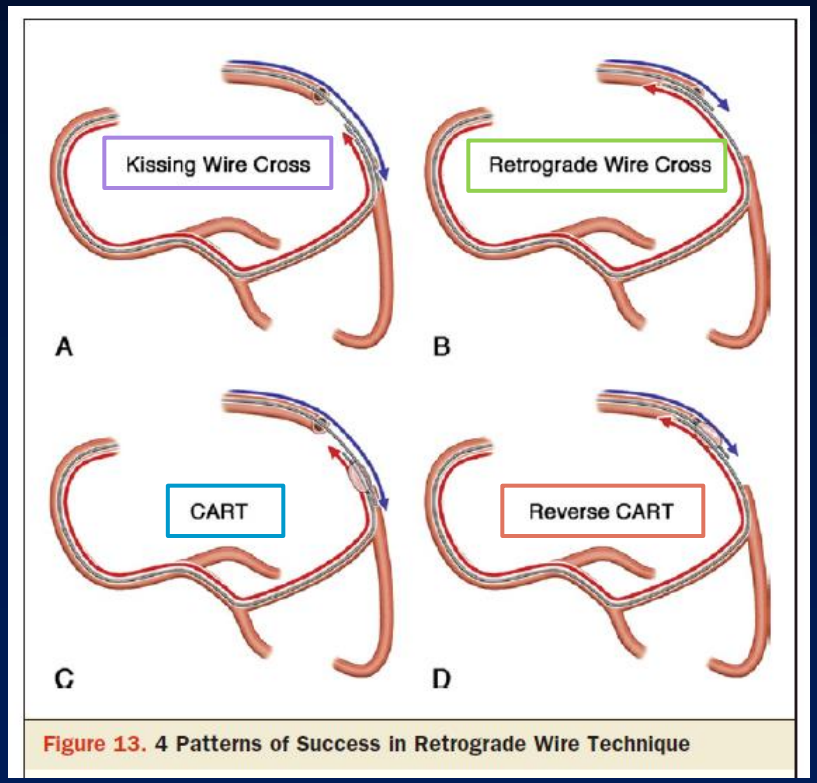
2011 data

CTO Crossing

Successful strategy



Patterns of Success in Retrograde Approach



JACC Cardiovasc Interv 2011

JCR 2013

2011 data

Clinical Results

Procedural outcome

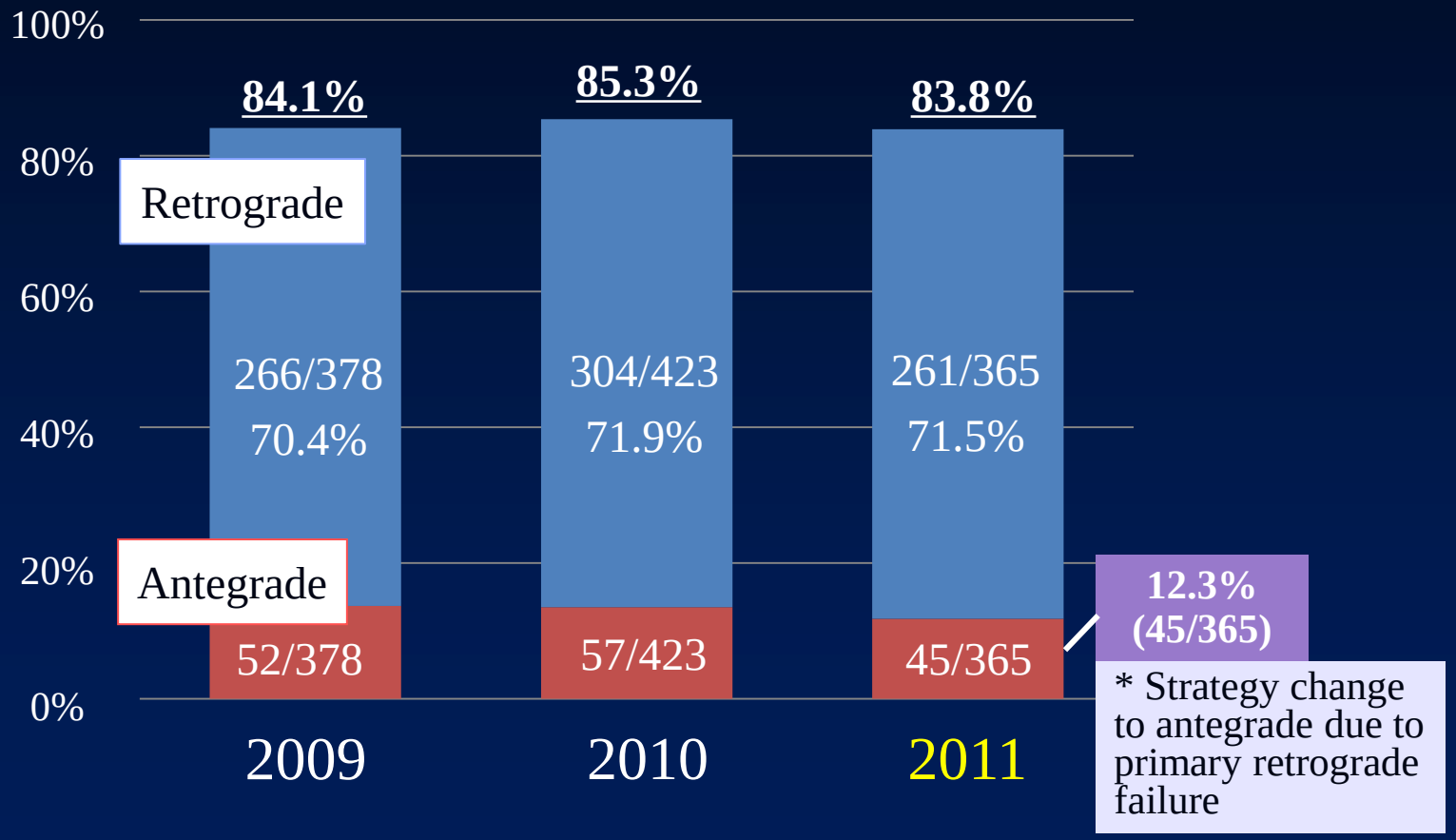
	2009 (378)	2010 (423)	2011 (365)
Contrast dose, ml	315.7±138.7	299.2±135.9	291.4±127.1
Procedure time, min	203.3±84.4	187.9±84.1	190.9±80.9
Fluoroscopic time, min	98.7±54.9	91.9±49.0	94.3±43.2
Air Kerma, mGy	-	6,564±5,169	6,593±4,569

JCR 2013

2011 data

Clinical Results

Procedure success (overall)

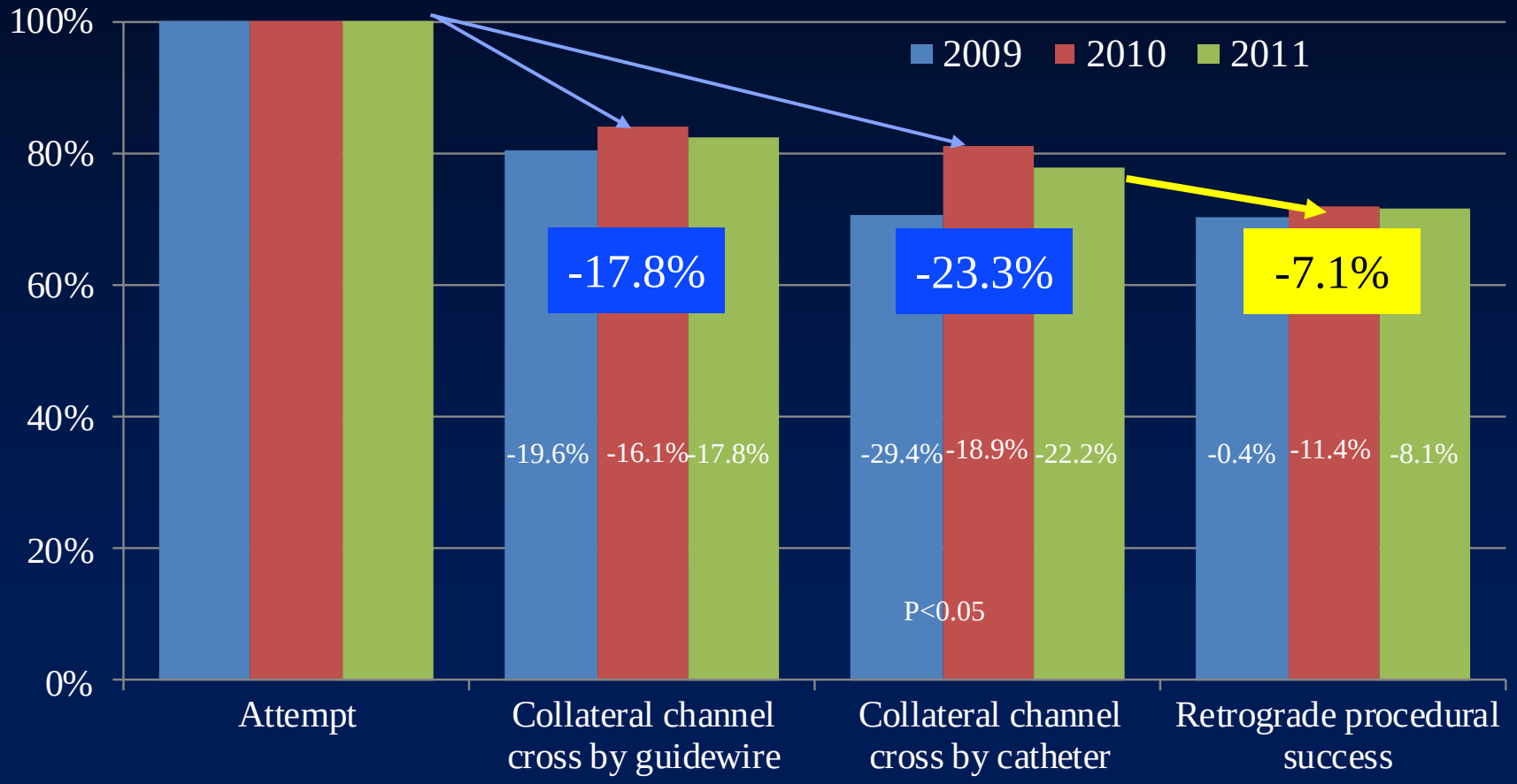


JCR 2013

2011 data

Clinical Results

Collateral crossing and retrograde success



JCR 2013

(*CCI* 2013;82:E654-61)

Multivariate Analysis

Independent predictors of retrograde success

	Odds ratio	95% CI	P
Use of Corsair	1.785	1.291-2.469	0.0005
Age ≥ 65 years old	0.607	0.441-0.837	0.0021
Calcification at CTO site	0.674	0.489-0.928	0.0149

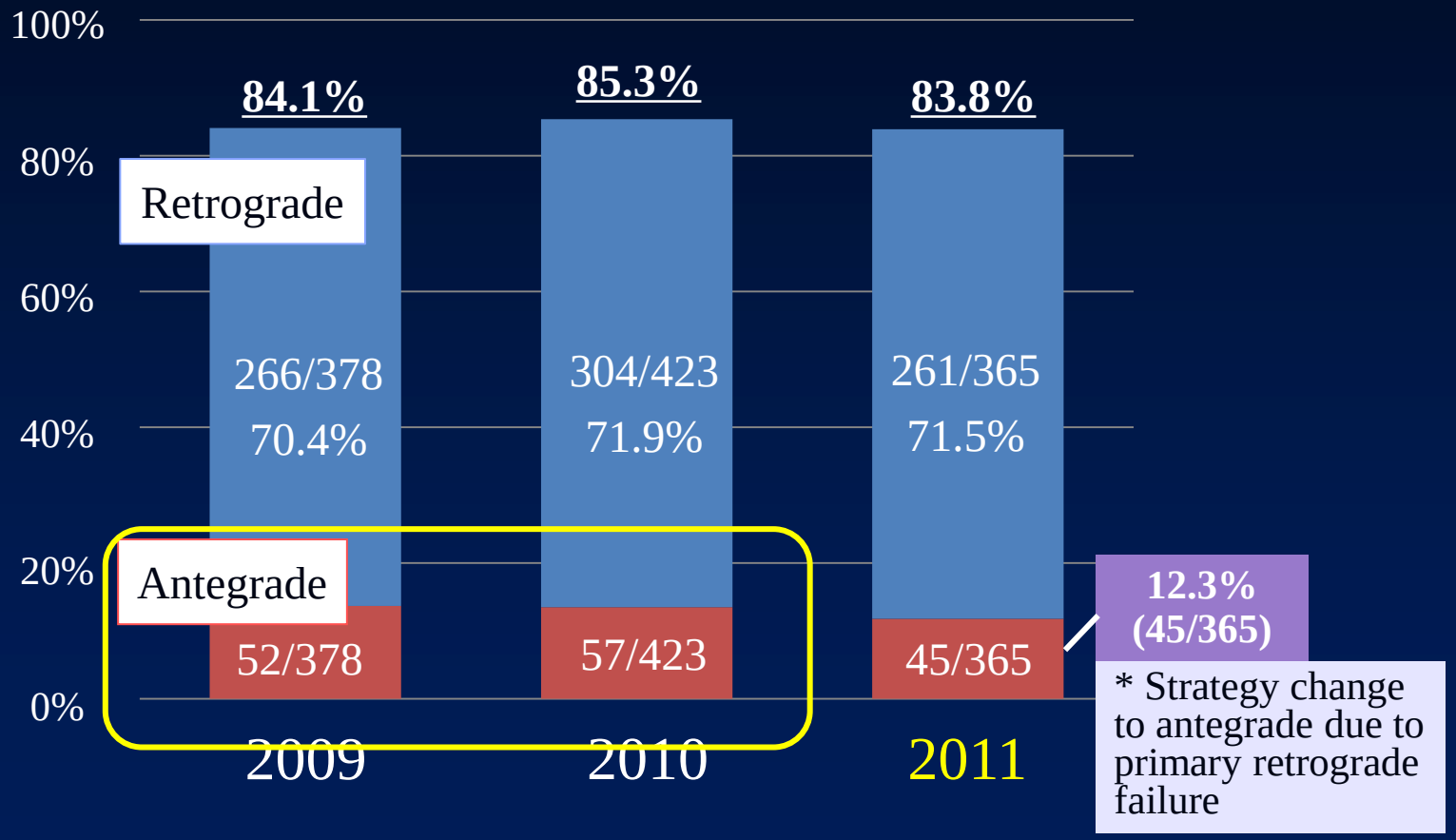
JCR 2013

(*CCI* 2013;82:E654-61)

2011 data

Clinical Results

Procedure success (overall)



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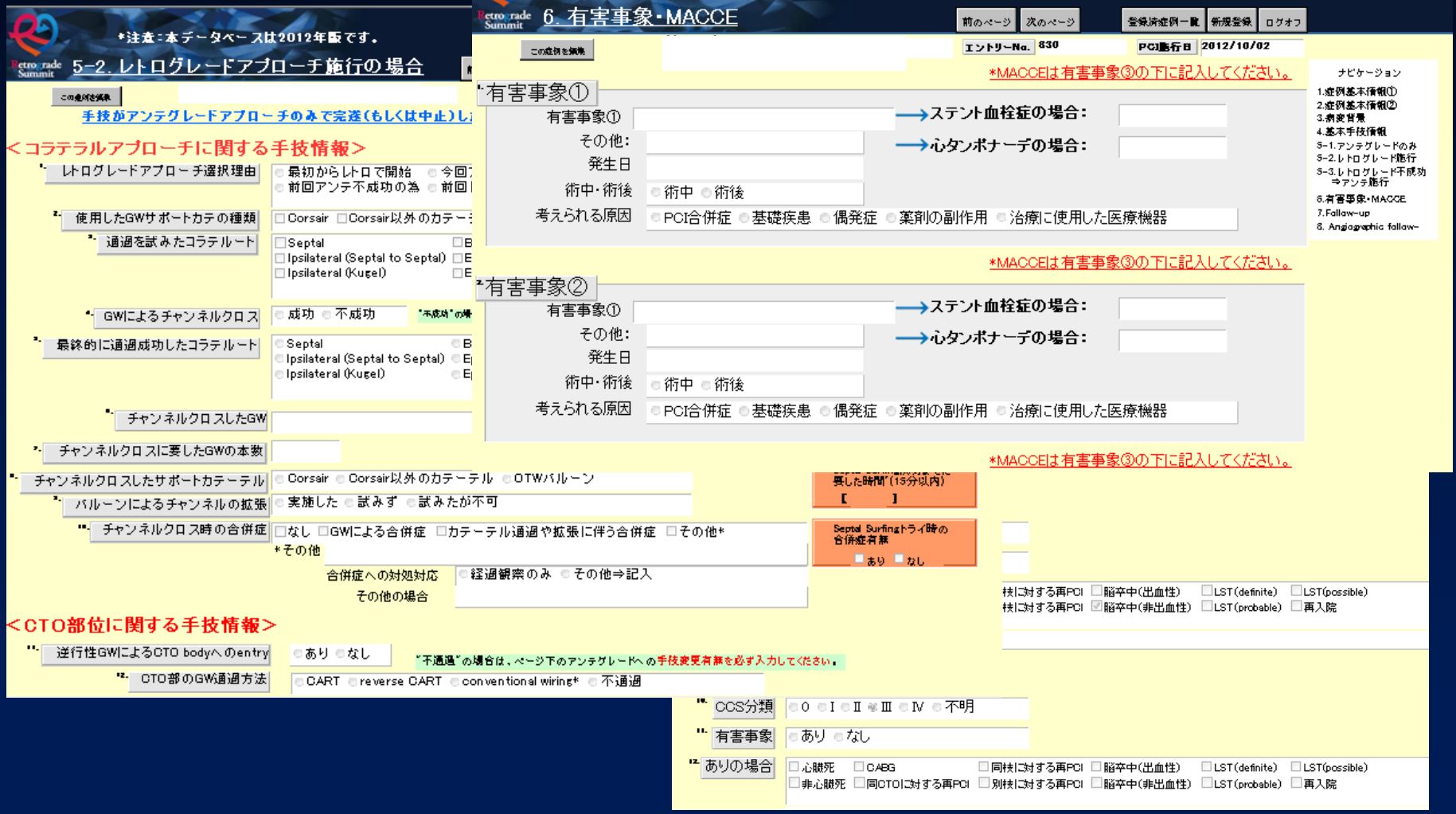
Antegrade Procedure Outcome after unsuccessful retrograde procedure

	2009	2010	P
Retrograde success	70.4% (266/378)	71.9% (304/423)	0.64
Switched to antegrade	78.6% (88/112)	75.6% (90/119)	0.60
Antegrade success	59.1% (52/88)	63.3% (57/90)	0.56

JCR 2013

(*CCI* 2013;82:E654-61)

WEB Registry started at 2012



JCR 2013

Enrollment

Retrograde Summit

Registered Hospitals (in order with entry number)

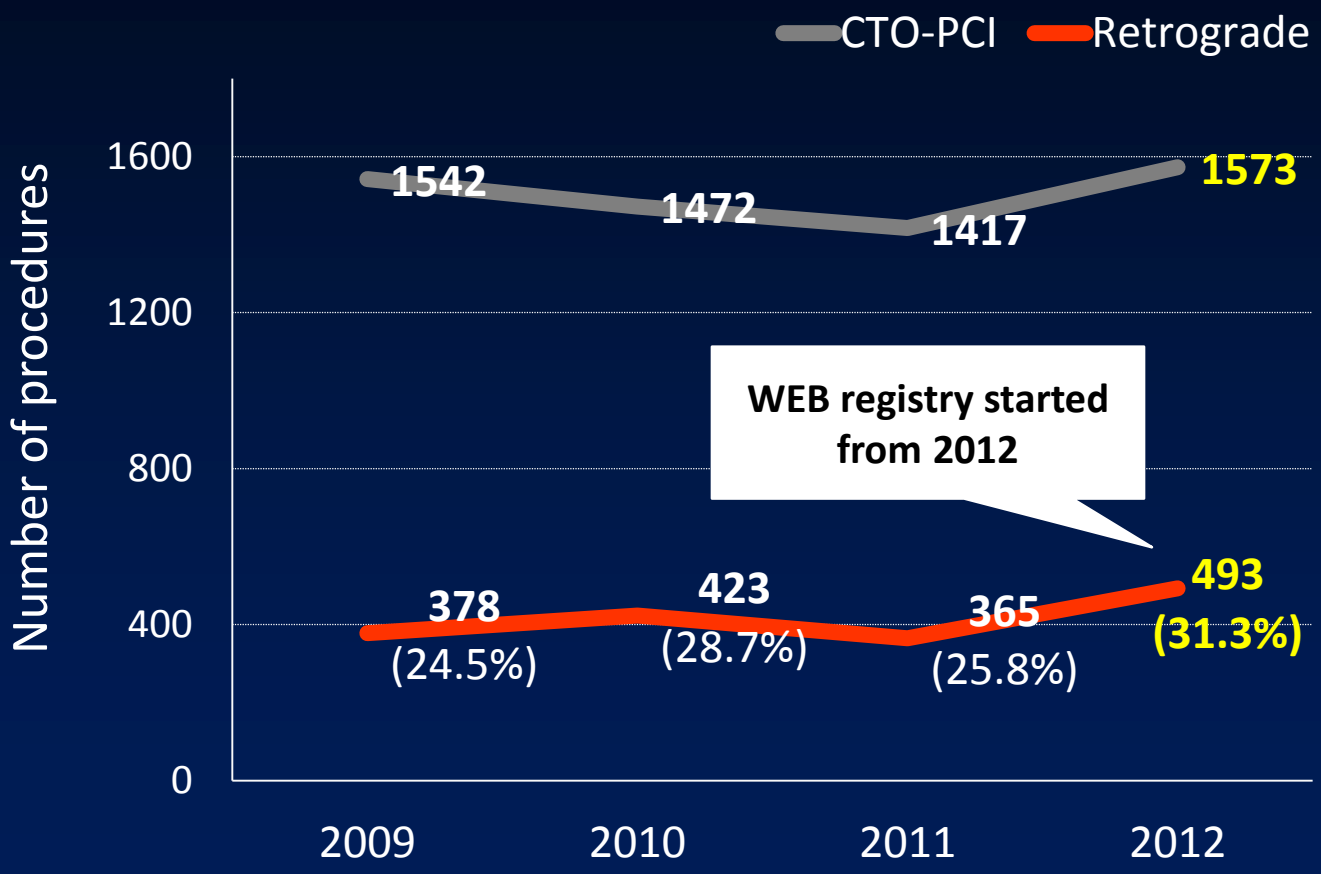
Sakurabashi Watanabe Hospital	106	Nagoya Daini Red Cross Hospital	27
Saiseikai Yokohamashi			26
Sapporo Cardio Vascul			26
Toyohashi Heart Cent			25
Saitama Cardiovascula			24
Takase Clinic			23
Saitama Sekishinkai H			22
The Cardiovascular Ins		tal	22
Seirei Hamamatsu Ge			21
Higashi Takarazuka Sa		itory Center	20
Shinkoga Hospital			18
Sanda City Hospital			16
Nagoya Heart Center			16
Edogawa Hospital			15
Hokkaido Social Insurance Hospital	41	NTT East Sapporo Hospital	13
Nagoya Tokushukai Hospital	41	Osaka Saiseikai Izuo Hospital	13
Shiga Medical Center for Adults	35	Tokushima Red Cross Hospital	13
Hoshi General Hospital	33	Iwate Prefectural Central Hospital	9
Kakogawa East City Hospital	30	Hokusetsu General Hospital	8
Kusatsu Heart Center	29	Toho University Omori Medical Center	3
Kushiro City General Hospital	29	Osaki Citizen Hospital	2
Hokko Memorial Hospital	28	Ohta Nishinouchi Hospital	1

Jan 2012 – Dec 2012

The number of registry : 1573

Registered Hospital : 44

Retrograde Summit registry data



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Registry Data

Jan - Dec 2012

	Total (1573)	Antegrade alone (1080)	Retrograde (493)	P value
Re-attempt cases	11.8%	6.8%	22.7%	<0.0001
- Previous attempt by Antegrade	79.3%	81.4%	78.0%	
- Previous attempt by Retrograde	15.1%	14.3%	15.6%	0.9226
- Detail of previous strategy : NA	5.6%	4.3%	6.4%	
Reason of previous failure				
- Failure to cross CTO by GW	87.7%	82.8%	90.4%	
- Failure to cross collateral by GW	1.2%	1.7%	1.0%	0.5236
- Delivery failure of treatment device	5.6%	8.6%	3.9%	
- NA	5.6%	6.9%	4.8%	

JCR 2013

Patient characteristics (1)

	Antegrade alone	Retrograde	P value
Age, yo	68.0±10.5	67.2±9.9	0.1353
Male	81.9%	84.6%	0.2015
Family history of CAD	17.3%	15.9%	0.5751
Previous MI	36.5%	44.9%	0.0019
Previous CABG	5.8%	14.3%	<0.0001
Previous PCI	57.3%	66.1%	0.0010
# of vessel disease - 1-vessel - 2-vessel - 3-vessel	 35.4% 39.9% 24.7%	 36.4% 34.7% 28.9%	0.0955
Hypertension	80.2%	79.8%	0.8648
Diabetes	41.7%	46.0%	0.1178
Hyperlipidemia	69.8%	70.6%	0.7298

JCR 2013

Patient characteristics (2)

	Antegrade alone	Retrograde	P value
Smoker	45.5%	53.2%	0.0066
Unstable angina	9.1%	7.3%	0.2427
CCS classification - 0 - I - II - III - IV	 30.3% 28.4% 31.5% 7.3% 2.5%	 32.5% 30.2% 30.2% 5.5% 1.7%	0.4768
NYHA classification - I - II - III - IV	 59.1% 28.7% 7.6% 4.7%	 57.1% 30.0% 7.3% 5.7%	0.9060
Pre Creatinine >2.5mg/dl	6.8%	7.9%	0.4062
LVEF <35%	8.8%	12.3%	0.0336

JCR 2013

Lesion characteristics (1)

	Antegrade alone	Retrograde	P value
Target vessel - RCA	39.7%	61.5%	<0.0001
- LAD	34.5%	26.4%	
- LCx	25.7%	11.6%	
- LMT	0.1%	0.6%	
Reference diameter	2.9±0.5mm	3.1±0.5mm	<0.0001
Occlusion length	22.9±15.3mm	33.1±21.3mm	<0.0001
ISR-CTO	17.5%	9.8%	<0.0001
Occlusion period ≥ 1 year	5.8%	14.7%	<0.0001
Occlusion period = NA	83.1%	75.2%	
Collateral filling grade			0.0044
- CC 0	10.7%	5.7%	
- CC 1	57.2%	54.7%	
- CC 2	32.1%	39.6%	

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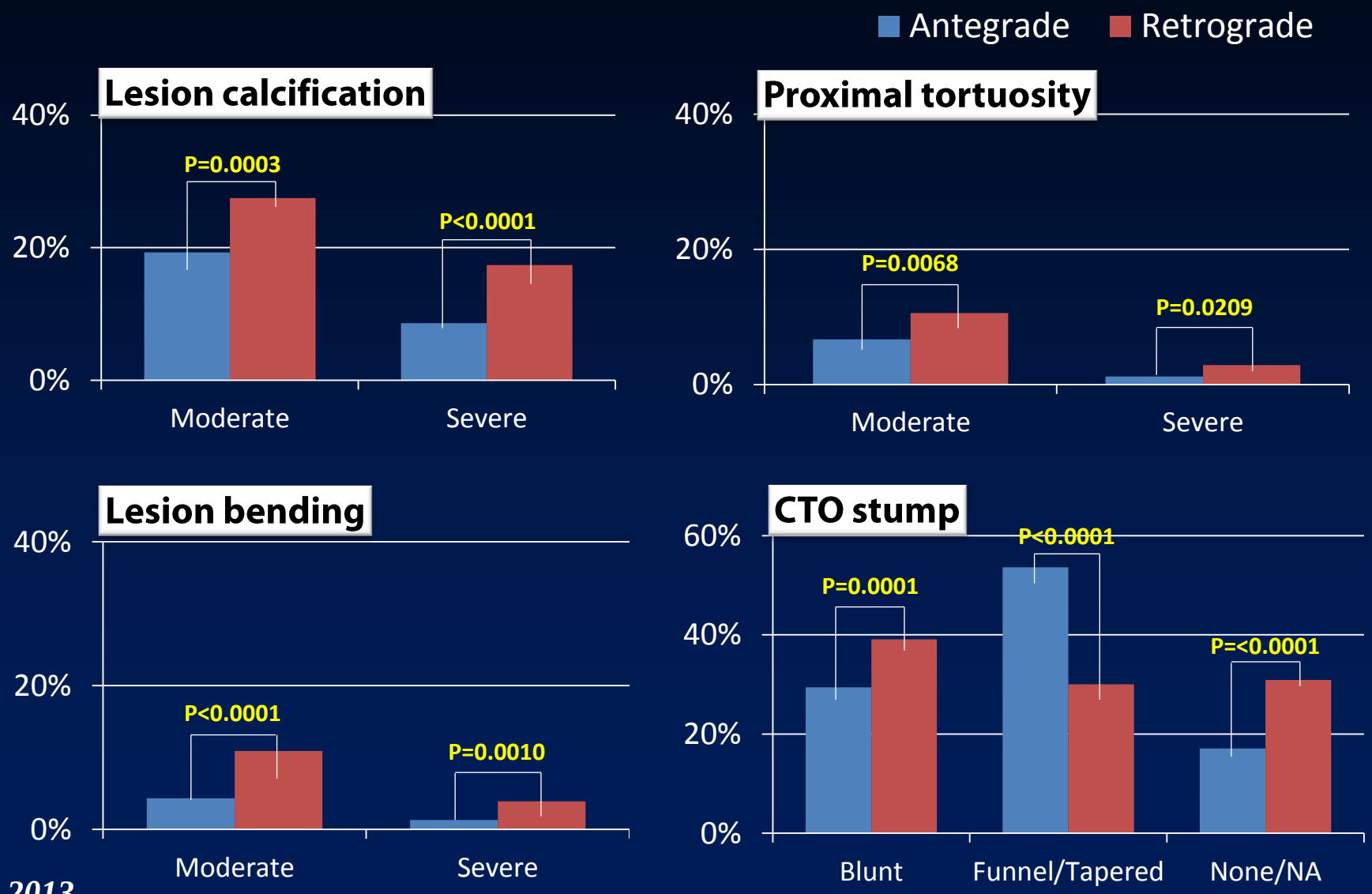
Lesion characteristics (2)

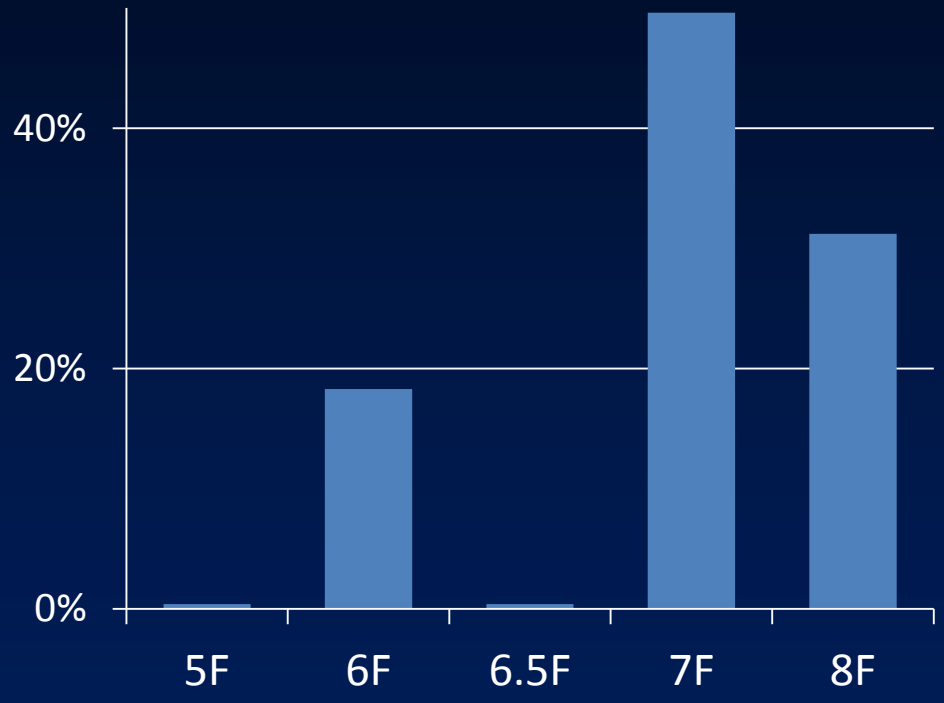


JCR 2013

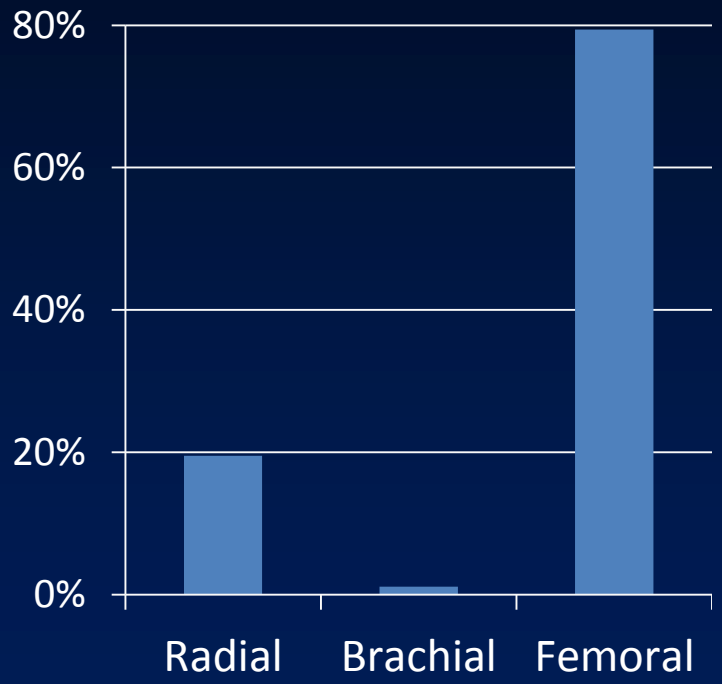
Approach : Antegrade alone

Retrograde Summit

Guiding catheter size



Puncture site

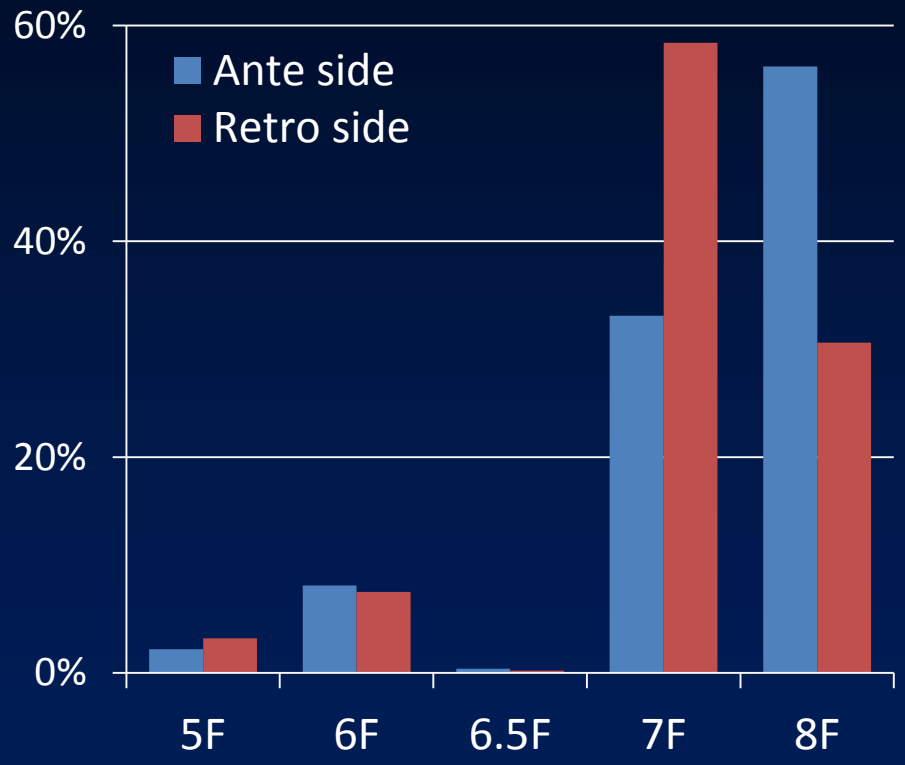


JCR 2013

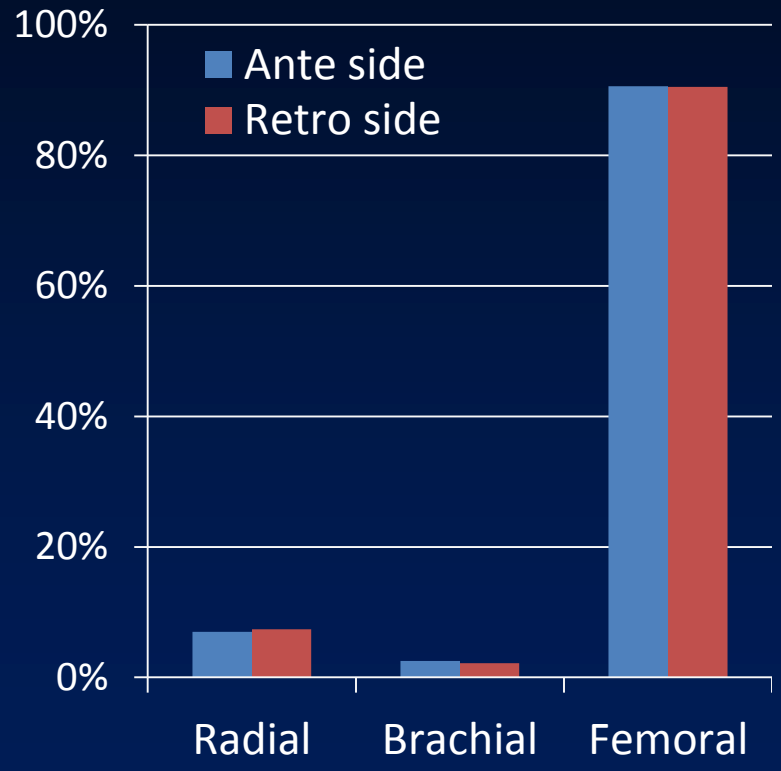
Approach : Retrograde

Retrograde Summit

Guiding catheter size



Puncture site

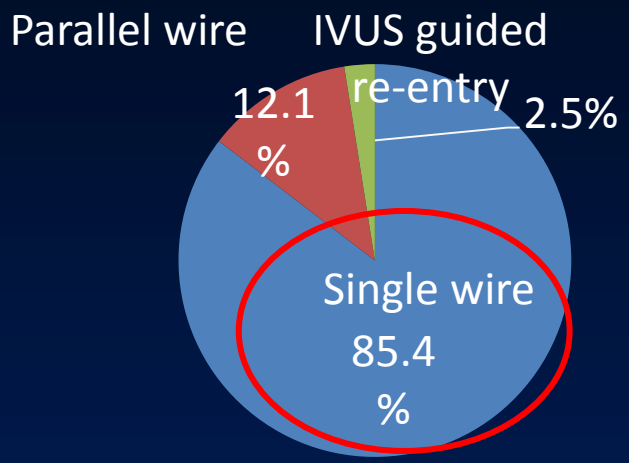


JCR 2013

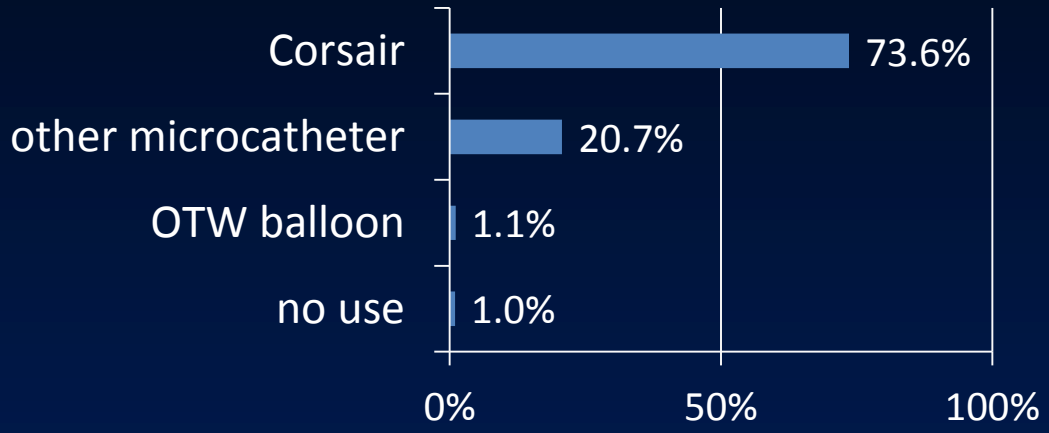
Antegrade alone (n= 1080)

Retrograde Summit

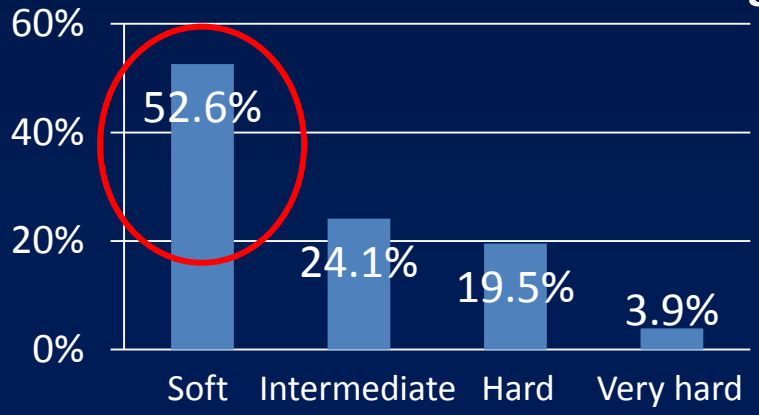
CTO crossing strategy



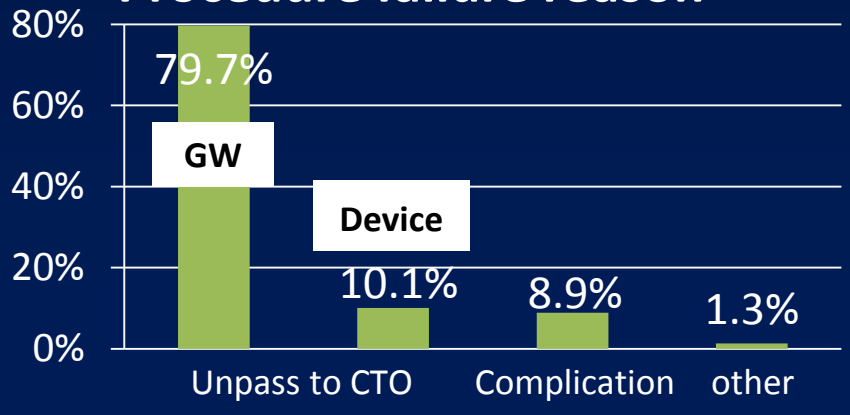
Used support catheter



Successful wire for CTO crossing



Procedure failure reason



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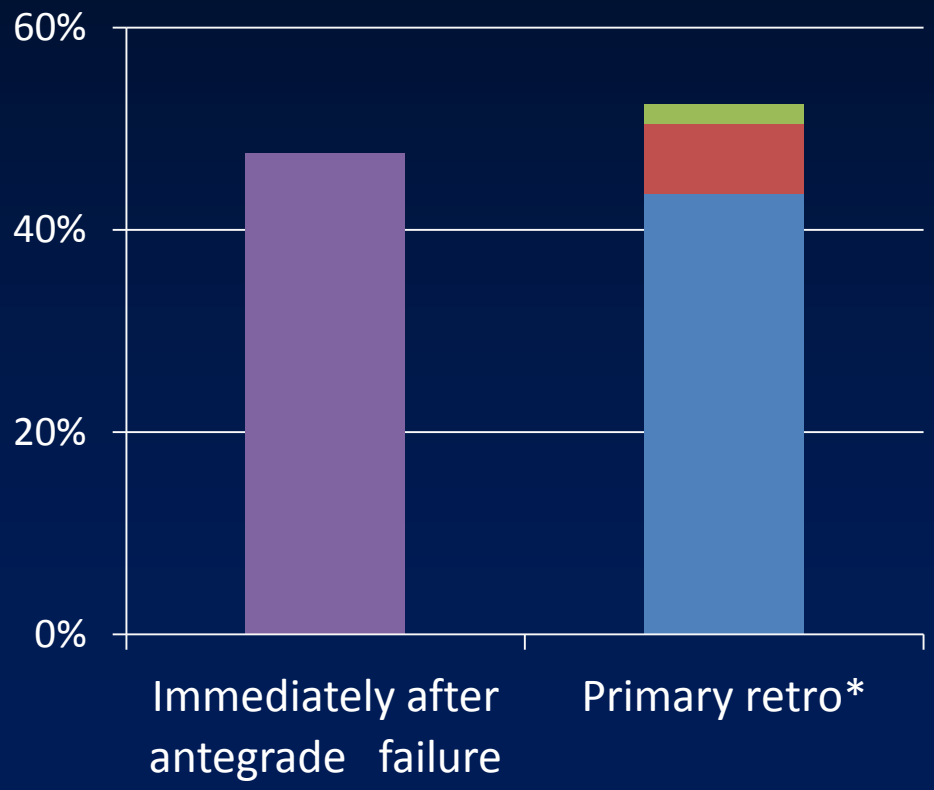
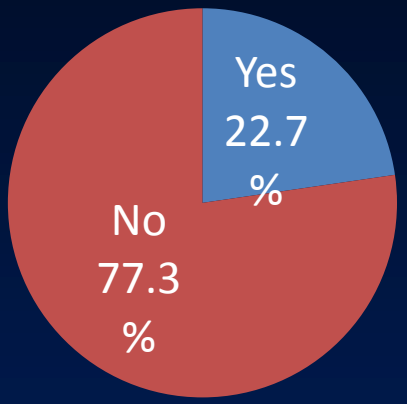
Retrograde (n=480*)

*13 data were excluded from detailed analysis due to short of data

Why or when retrograde was applied?



Re-attempt



*** Primary retro**

- Start with retrograde again after previous retorgrade failure
- Start with retrograde due to previous antegrade failure
- Start with retrograde approach

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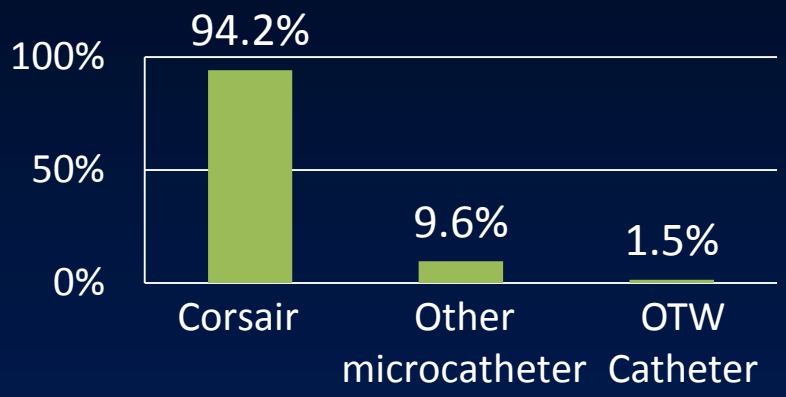
Retrograde: Collateral approach

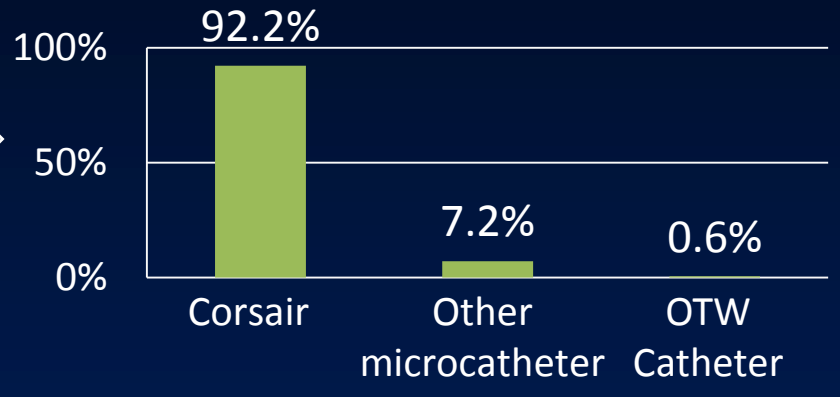
Retrograde Summit

Attempt

Catheter used for GW support
(multiple selection)

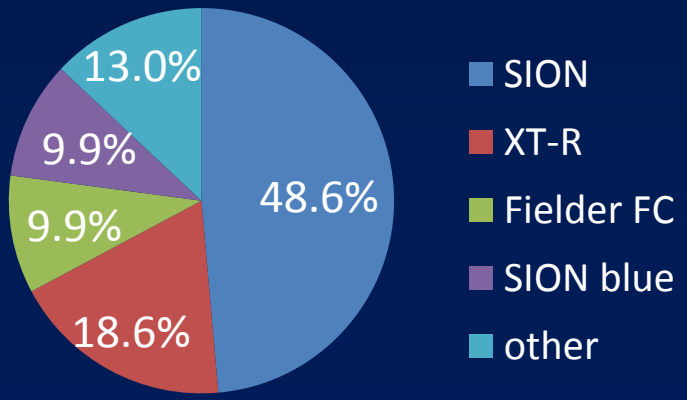


Successfully crossed catheter

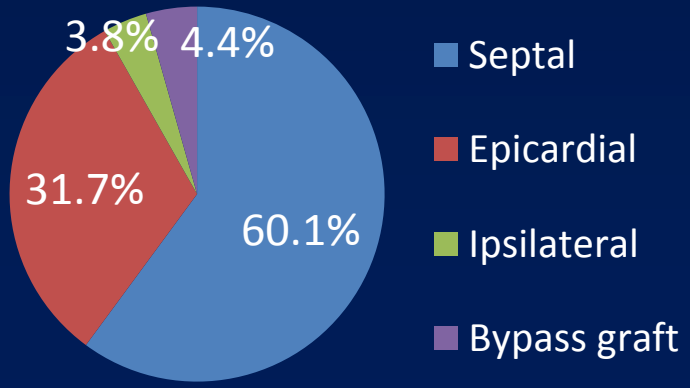


Collateral cross by GW , 77.1% (370/480)

No. of GW: 1.8



Succesful collateral route



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Retrograde: CTO Crossing

Successful strategy

Patterns of Success in Retrograde Approach

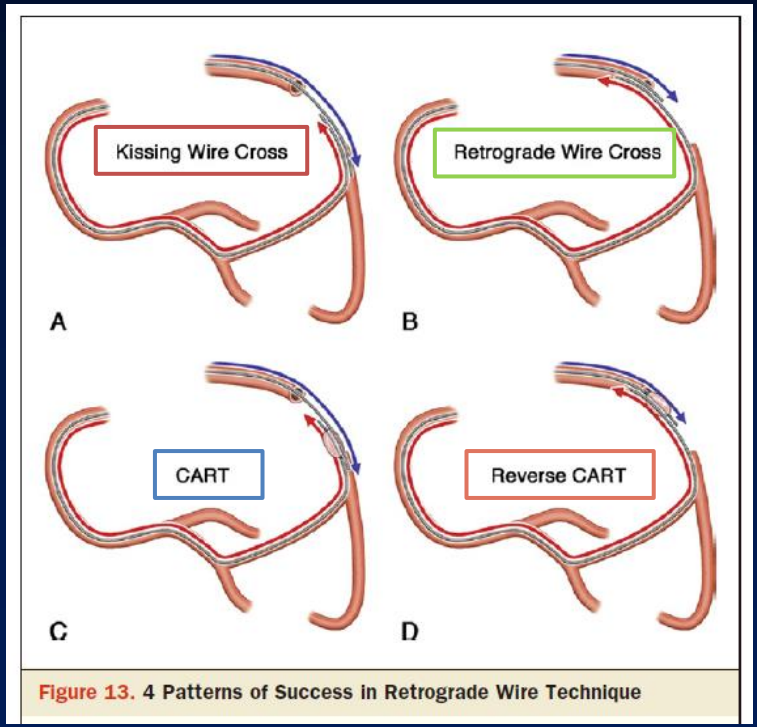
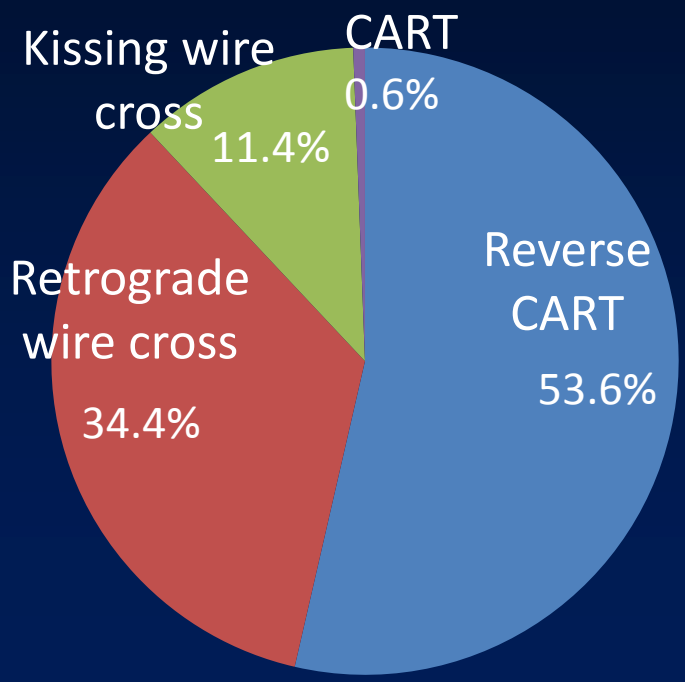


Figure 13. 4 Patterns of Success in Retrograde Wire Technique

JACC Cardiovasc Interv 2011

CTO cross by GW, 67.9% (326/480)



IVUS was used in 69% of Reverse CART

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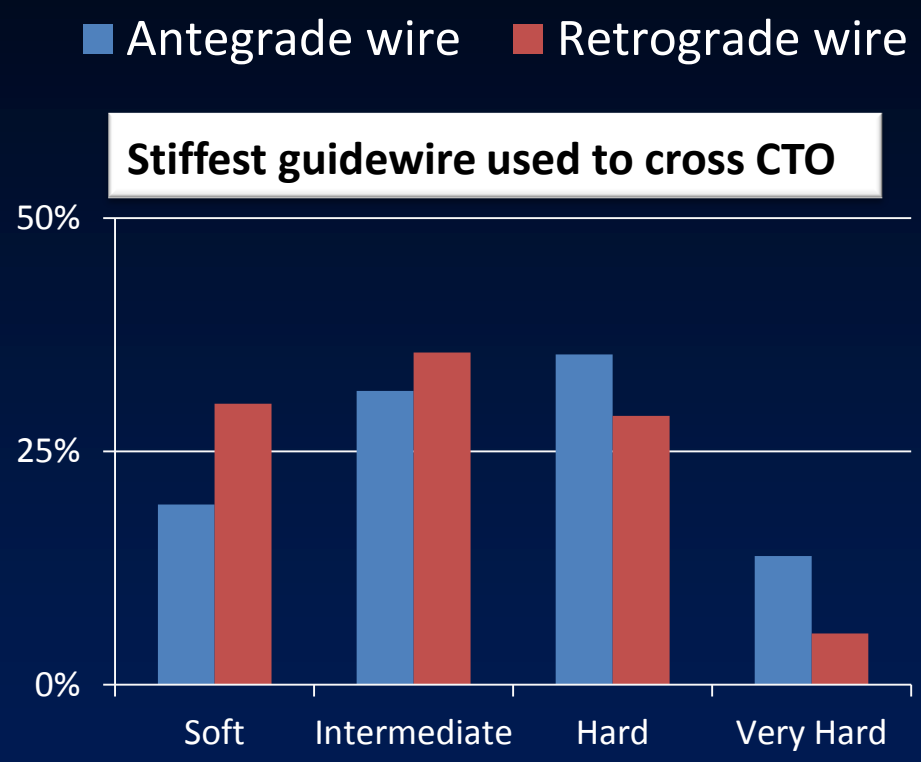
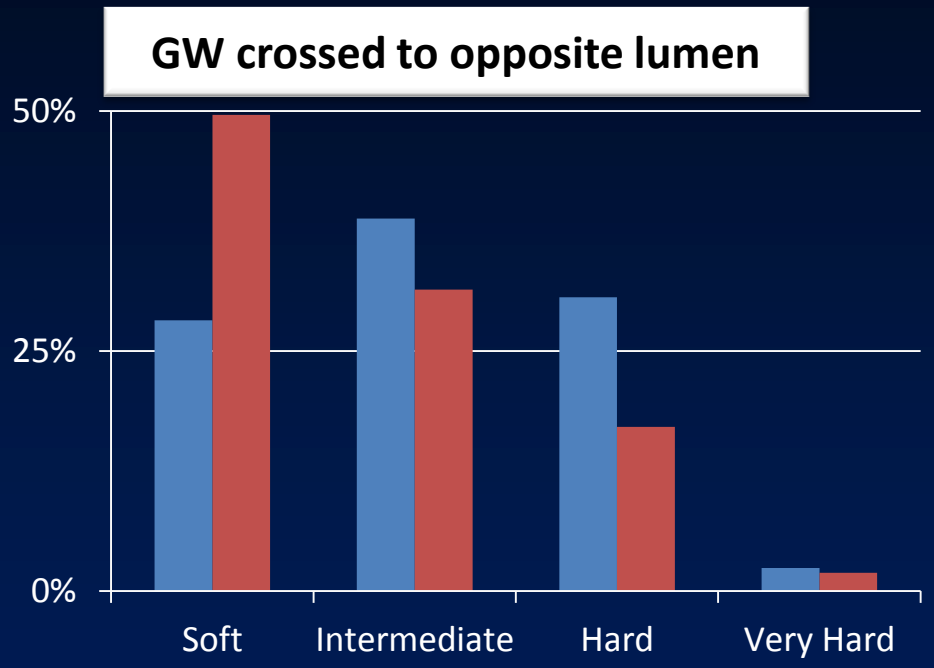
Retrograde: CTO Crossing





How to build antegrade system	
Externalization	89.3%
Antegrade parallel wire	7.3%
Rendez-vous	3.5%

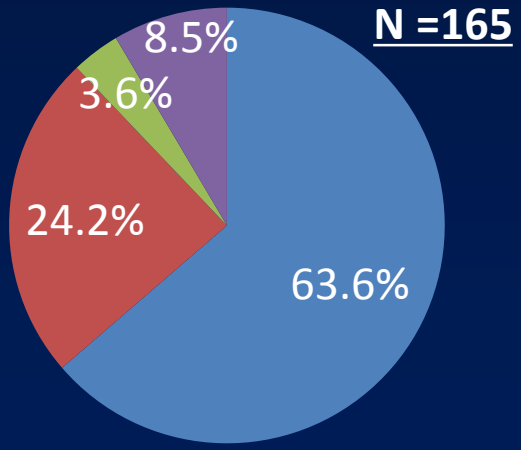
JCR 2013

Retrograde: Procedure outcome (1)

	N=480*
Retrograde procedure success	65.6% (315)

Reason of retrograde procedure failure

- Couldn't cross collateral channel
- Couldn't cross CTO by GW
- Couldn't cross CTO by any catheter
- Procedure discontinuation due to complication



JCR 2013

Retrograde: Procedure outcome (2)

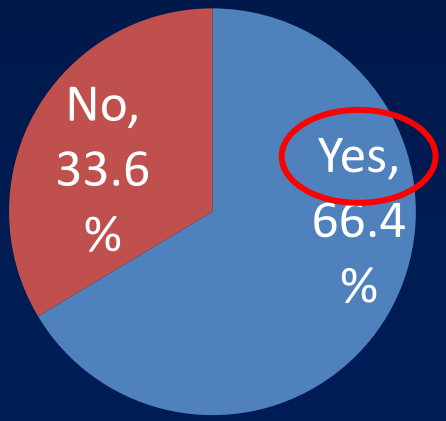
Retrograde Summit

Retrograde failure cases (n=165)

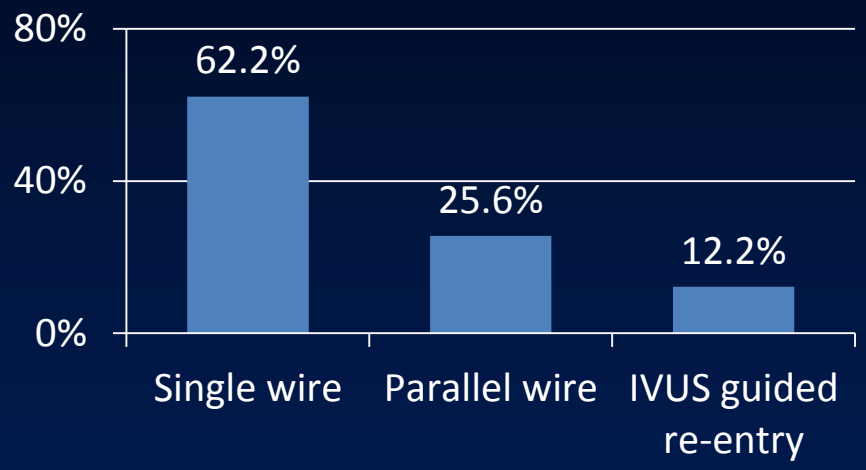
Switched to antegrade approach

75.8% (125/165)

Procedure success



Successful CTO crossing strategy



Failure reason	N=42
Couldn't cross CTO by guidewire	88.1% (37)
Couldn't cross CTO by any catheter	7.1% (3)
Procedure discontinuation due to complication	4.8% (2)

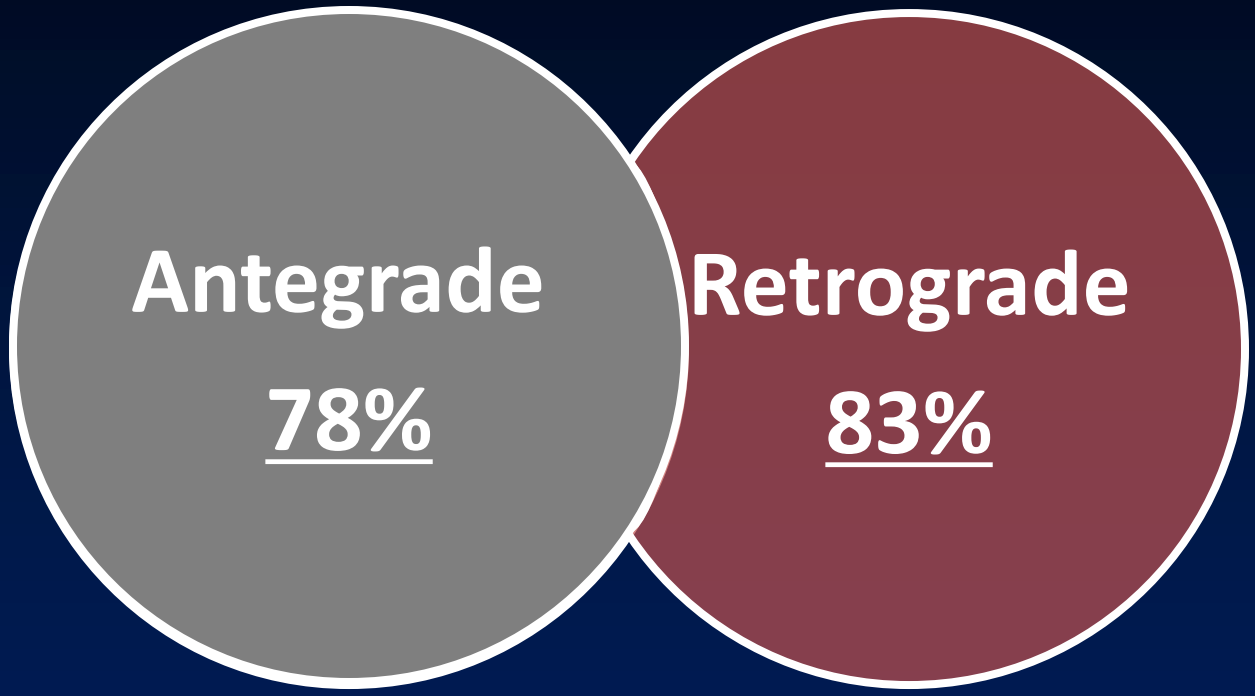
JCR 2013

Procedure outcome

	Total (1573)	Antegrade alone (1080)	Retrograde (493)	P value
Successful CTO crossing by GW	89.8%	92.1%	84.8%	<0.0001
Number of guidewire used for CTO approach	3.3±2.3	2.5±1.5	5.1±2.7	<0.0001
Number of micro/balloon catheter	2.9±2.2	2.5±1.7	3.9±2.7	<0.0001
Number of stent	1.7±1.2	1.5±0.9	2.2±1.5	<0.0001
Procedure success	**88.6%**	**91.1%**	**83.0%**	**<0.0001**
Procedure time, min	141.2±87.2	112.3±67.2	202.3±92.9	<0.0001
Contrast dose, ml	227.2±107.9	207.6±95.2	268.6±120.8	<0.0001
Fluoroscopy time, min	72.6±188.0	62.0±226.0	94.5±45.8	0.0034

JCR 2013

Procedure success for each strategy



・・・ Immediately after **antegrade failure** (n=228)

if these are counted as Antegrade group,

antegrade procedure success would fall to **78.1%** (1021/1308)

JCR 2013

MACCE

	Total (1573)	Antegrade alone (1080)	Retrograde (493)	P value
MACCE	**0.6% (10)**	**0.4% (4)**	**1.2% (6)**	**0.05**
- Cardiac death	0.2% (3)	0.3% (3)	0	
- Non cardiac death	0.1% (1)	0	0.2% (1)	
- MI	0.3% (4)	0	0.8% (4)	
- Stroke / non-bleeding	0.1% (2)	0.1% (1)	0.2% (1)	

JCR 2013

Adverse Events

	Total (1573)	Antegrade alone (1080)	Retrograde (480*)	P value
Adverse events	**1.5% (23)**	**0.8% (9)**	**2.9% (14)**	**0.0375**
- Stent thrombosis	0.2% (3”)	0.1% (1)	0.4% (2)	
- Cardiac tamponade	0.3% (5)	0.1% (1)	0.8% (4*)	
- Contrast induced nephropathy	0.1% (2)	0.1% (1)	0.2% (1)	
- Trouble at puncture site	0.4% (6)	0.3% (3)	0.6% (3)	
- Symptomatic cerebrovascular disease	0.1% (2)	0.1% (1)	0.2% (1)	
- Blood transfusion	0.1% (2)	0	0.4% (2*)	
- Other	0.2% (3)	0.2% (2)	0.2% (1)	

“ : 1 patient caused MI
* : same patients

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Other procedural complications

	Antegrade alone (1080)	Retrograde (480*)
- Coronary perforation	0.6% (6)	1.8% (9)
- Dissection	0.1% (1)	1.2% (6)
- Distal Embolization	0.1% (1)	0.4% (2)
- Side branch occlusion	0.1% (1)	0
- Hematoma	0	0.4% (2)
- GW fracture	0	0.4% (2)

JCR 2013

Retrograde approach relevant complications

Including minor events

	N=480*
Retrograde approach relevant	**12.1% (58)**
- Channel injury	11.3% (54)
➢ Additional treatment required	3.5% (17)
➢ Cardiac tamponade	0.6% (3)
- Donor artery trouble	0.2% (1)
- Other events	0.6% (3)

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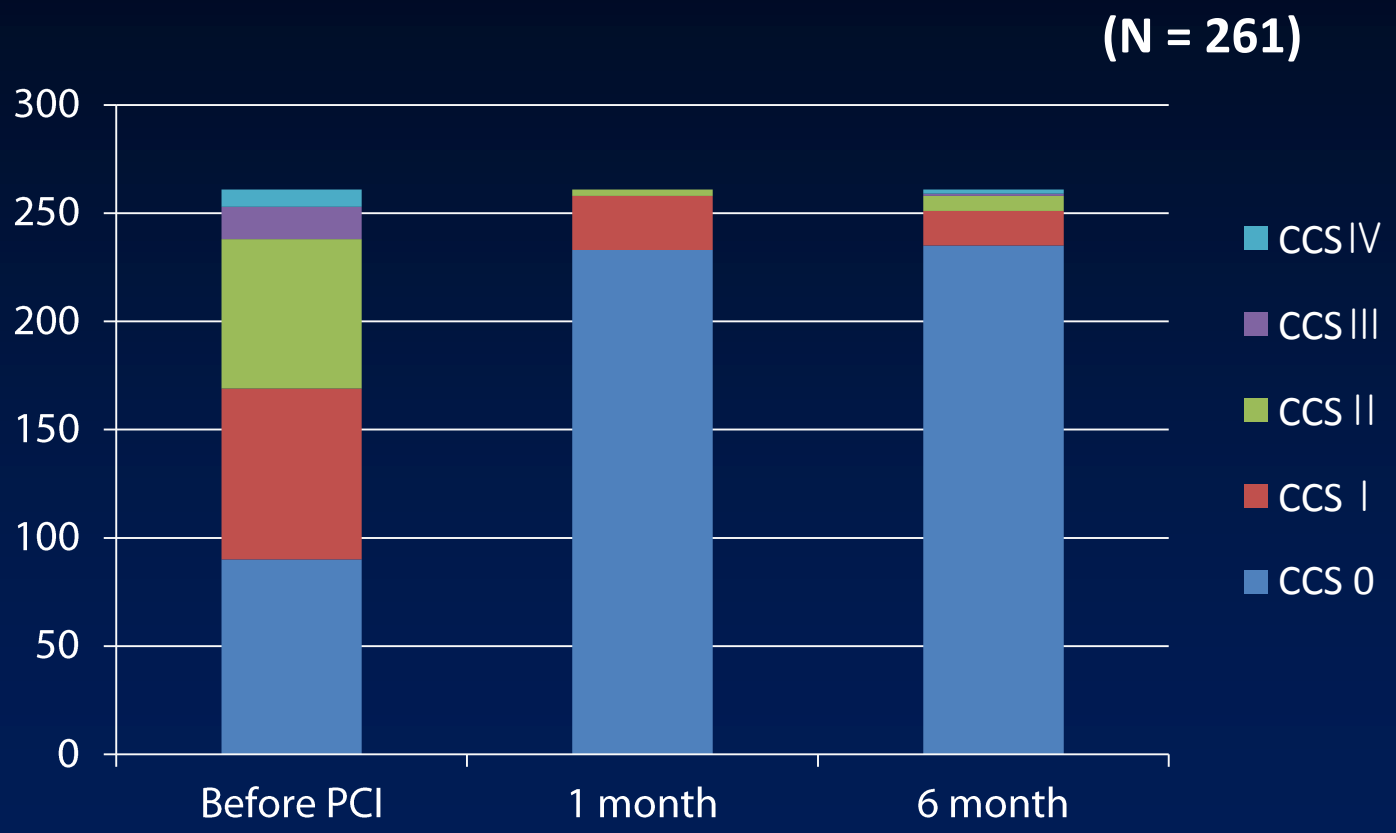
Follow- up:
Changes of CCS classification



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What we learned from this registry

- Corsair has standardized and facilitated retrograde approach, however overall success rate has not yet improved.
- Collateral channel crossing is the key for procedural success.
  - First, case selection. Second, good wire for channel crossing.
- Calcified occlusion still remains as a major obstacle even if we have retrograde approach.
- Outcomes of antegrade approach after retrograde approach must be unsatisfactory.

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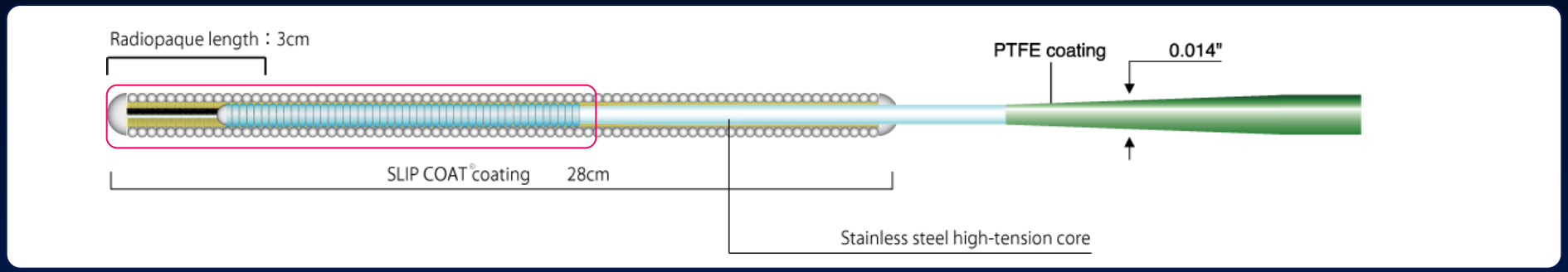
New Guide Wire for Collateral Channel Tracking

ASAHI SION, SION blue（*ASAHI Intecc*）



"Composite core" Double coil design

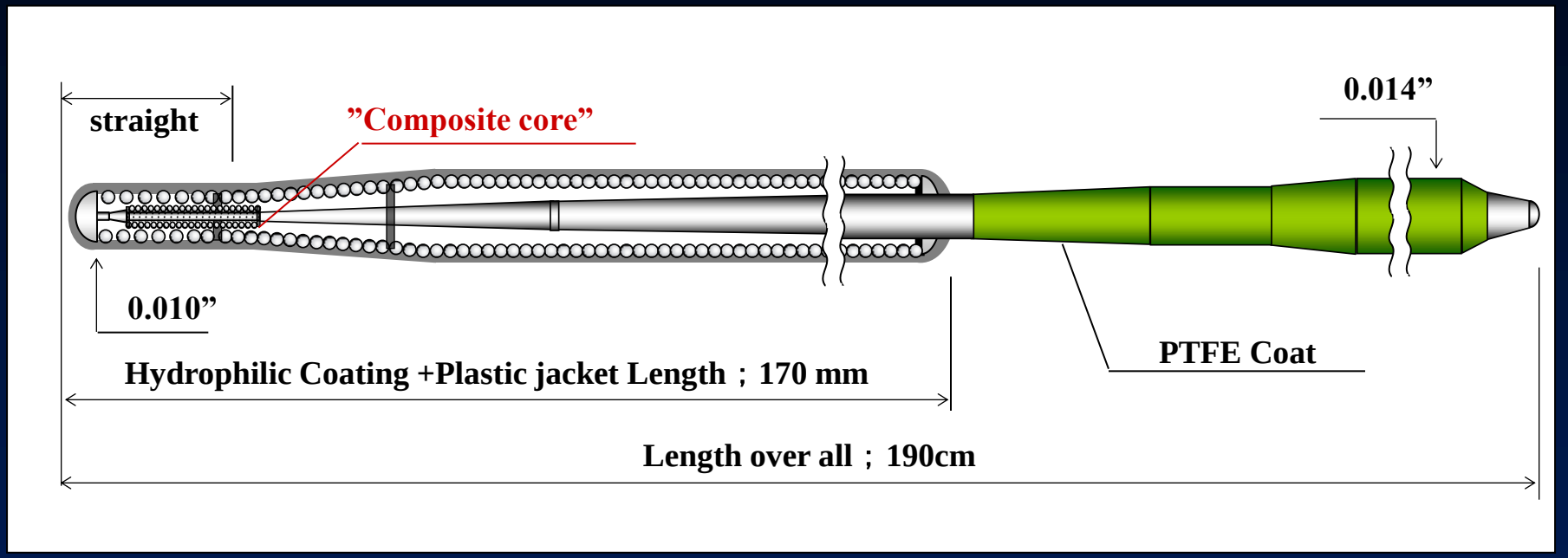
- Durable tip
- High torque response

- tip load ; SION 0.7g, SION blue 0.5g
- 0.014" diameter design
- 28cm Hydrophilic coating

JCR 2013

New X-treme XT-R <Revolution>

ASAHI intecc; Japan



- ✓ New Fielder XT with " composite core" design
- ✓ Durable & Flexible 0.010" tip – Tip load = 0.6gf
- ✓ High torque performance for retro/antegrade approach

What we learned from this registry

Retrograde Summit

- Corsair has standardized and facilitated retrograde approach, however overall success rate has not yet improved.
- Collateral channel crossing is the key for procedural success.
  - First, case selection. Second, good wire for channel crossing.
- Calcified occlusion still remains as a major obstacle even if we have retrograde approach.
  - Maybe RF energy in future. Already Bridge Point system.
- Outcomes of antegrade approach after retrograde approach must be unsatisfactory.

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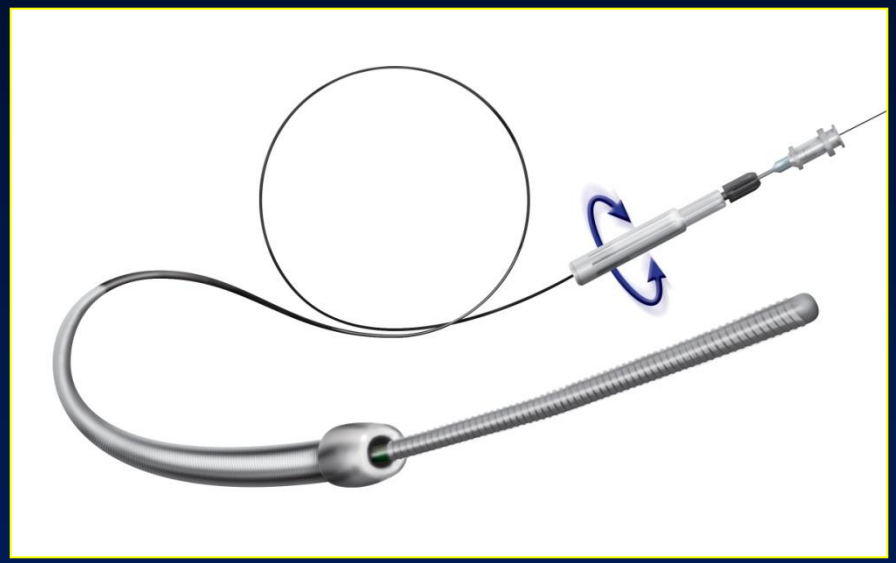
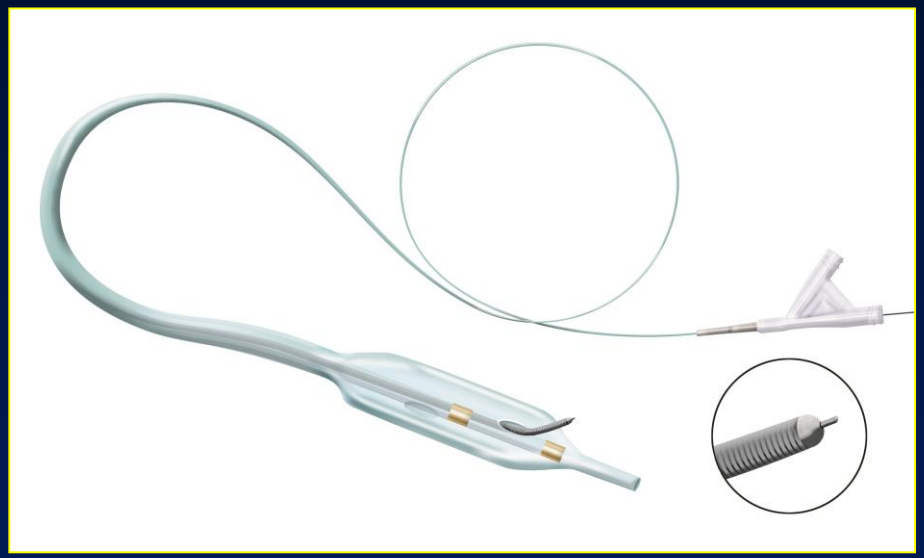
The BridgePoint System

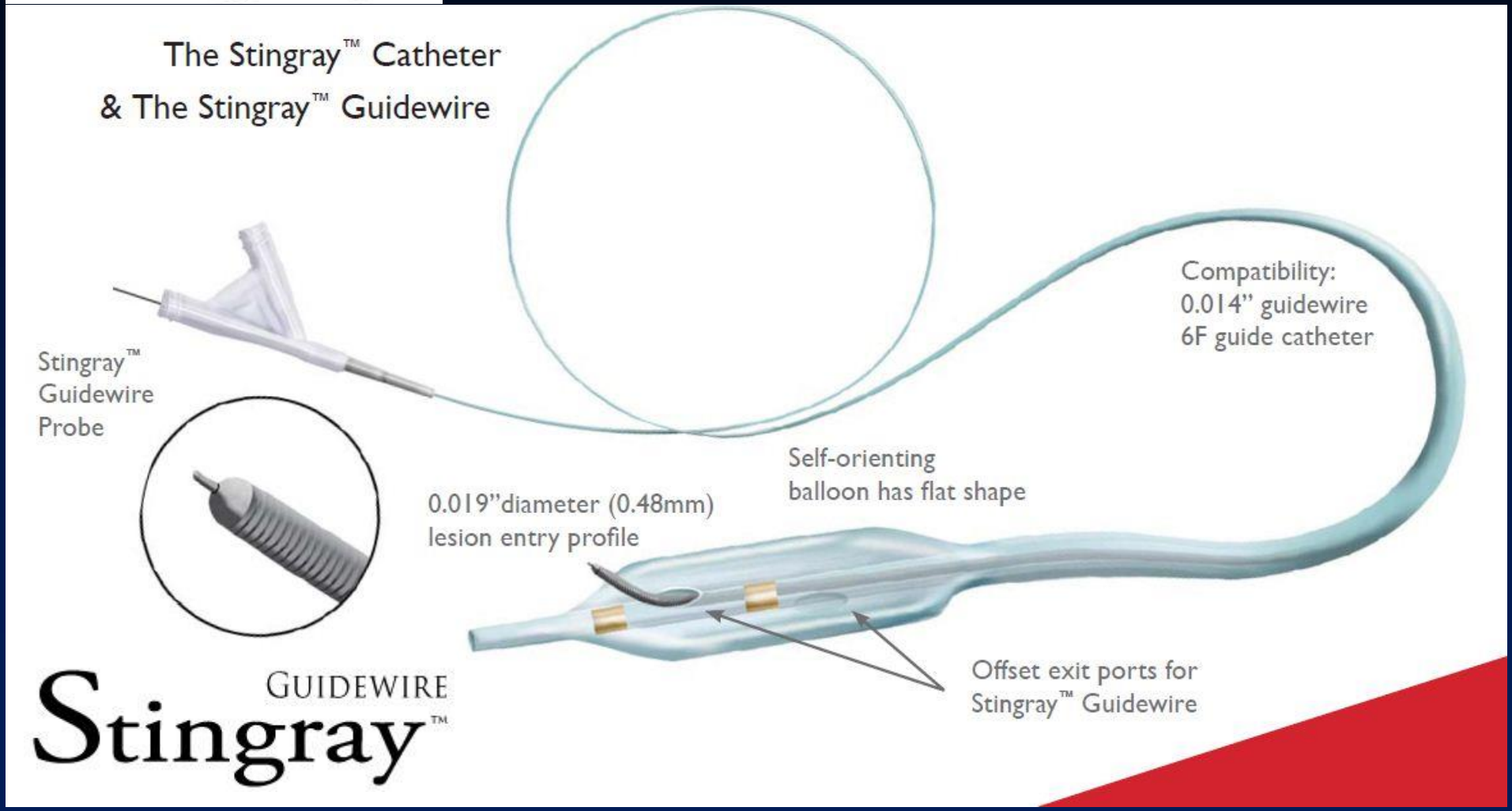
CrossBoss CTO Catheter



Stingray CTO Re-Entry System



Stingray™ Catheter



Stingray™ Guidewire

What we learned from this registry

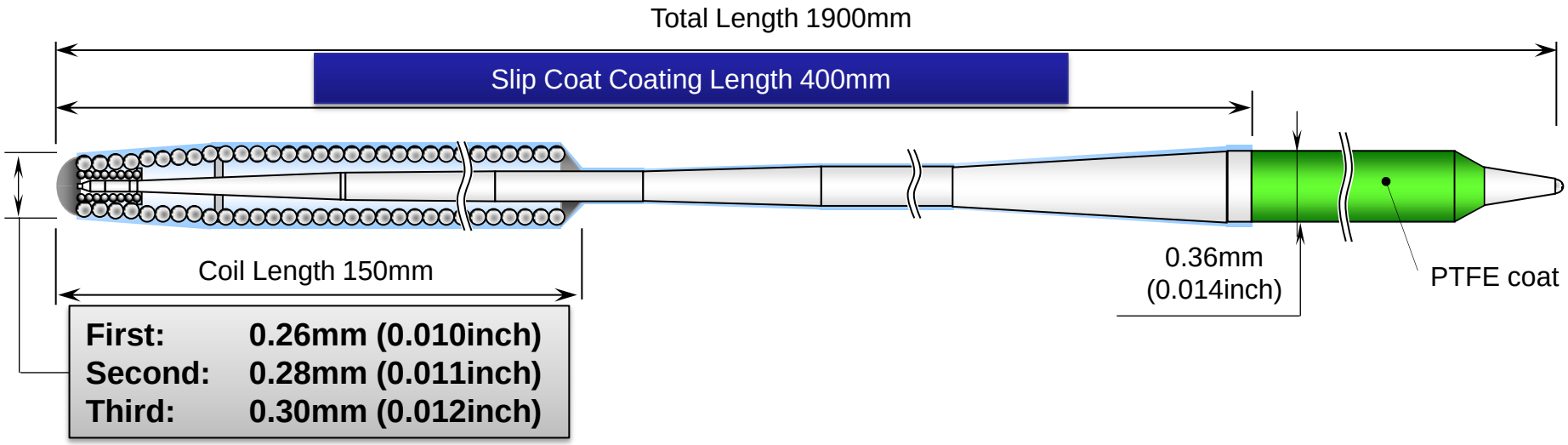
Retrograde Summit

- Corsair has standardized and facilitated retrograde approach, however overall success rate has not yet improved.
- Collateral channel crossing is the key for procedural success.
  - First, case selection. Second, good wire for channel crossing.
- Calcified occlusion still remains as a major obstacle even if we have retrograde approach.
  - Maybe RF energy in future. Already Bridge Point system.
- Outcomes of antegrade approach after retrograde approach must be unsatisfactory.
  - Antegrade manner must be improved by new wire technology.

JCR 2013

GAIA Basic structure

ASAHI intecc; Japan



First:	**0.26mm (0.010inch)**
Second:	**0.28mm (0.011inch)**
Third:	**0.30mm (0.012inch)**

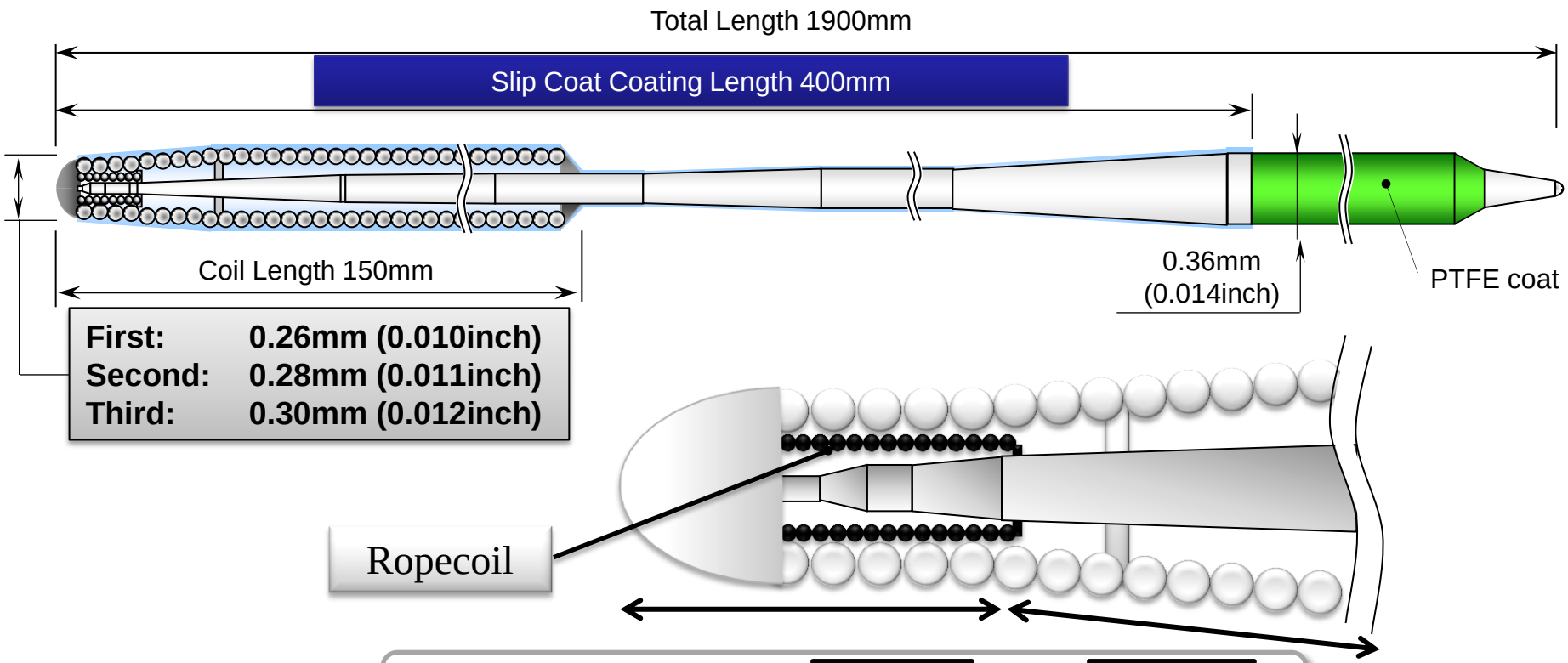
Various lineups for the different situation or lesion

ASAHI Gaia First	Diameter : 0.26mm (0.010”) - 0.36mm (0.014”) **Tip load : 1.7gf**
ASAHI Gaia Second	Diameter : 0.28mm (0.011”) - 0.36mm (0.014”) **Tip load : 3.5gf**
ASAHI Gaia Third	Diameter : 0.30mm (0.012”) - 0.36mm (0.014”) **Tip load : 4.5gf**

Long hydrophilic coating that enhance the smooth controllability in micro catheter.

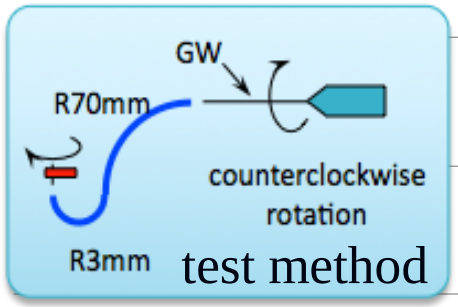
GAIA Basic structure

ASAHI intecc; Japan



	Straight	Tapered
ASAHI Gaia First	15mm	30mm
ASAHI Gaia Second	6mm	30mm
ASAHI Gaia Third	7mm	30mm

Difference in torque response



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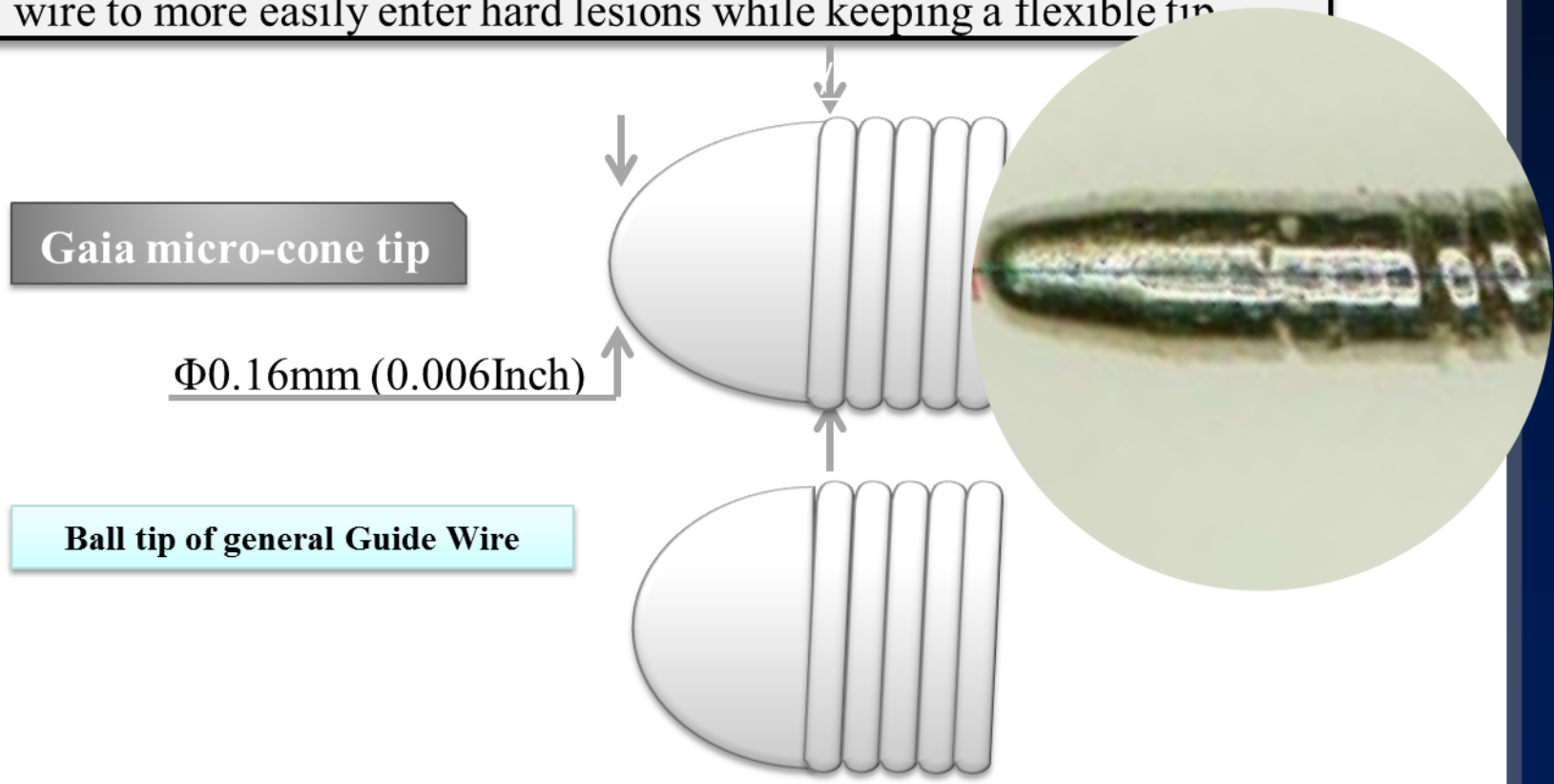
GAIA Tip structure ~ Micro cone tip

ASAHI intecc; Japan

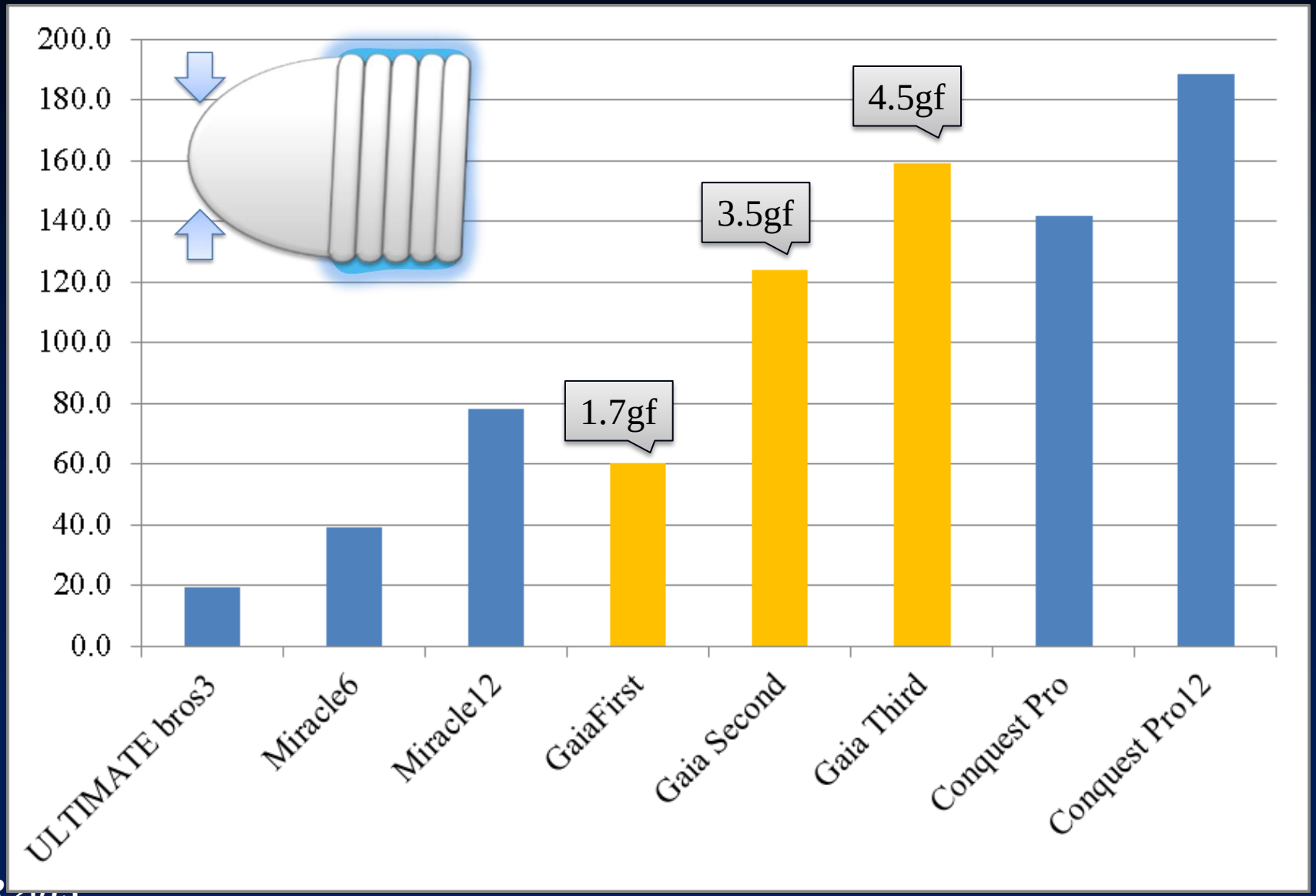
Retrograde Summit

Gaia micro-cone tip

Lower the ball tip's profile to provide better penetration, allowing the wire to more easily enter hard lesions while keeping a flexible tip

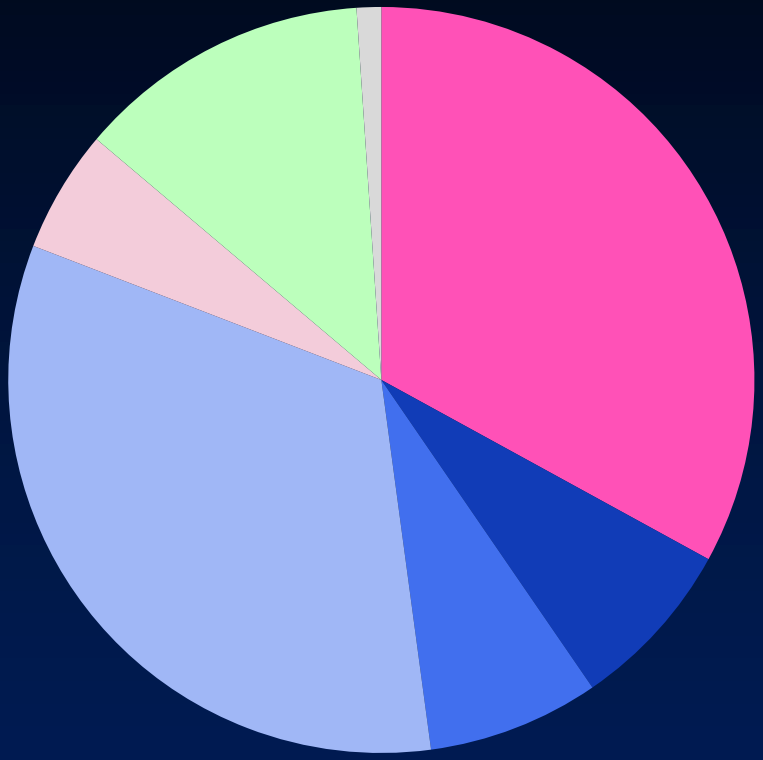


Modified penetration force

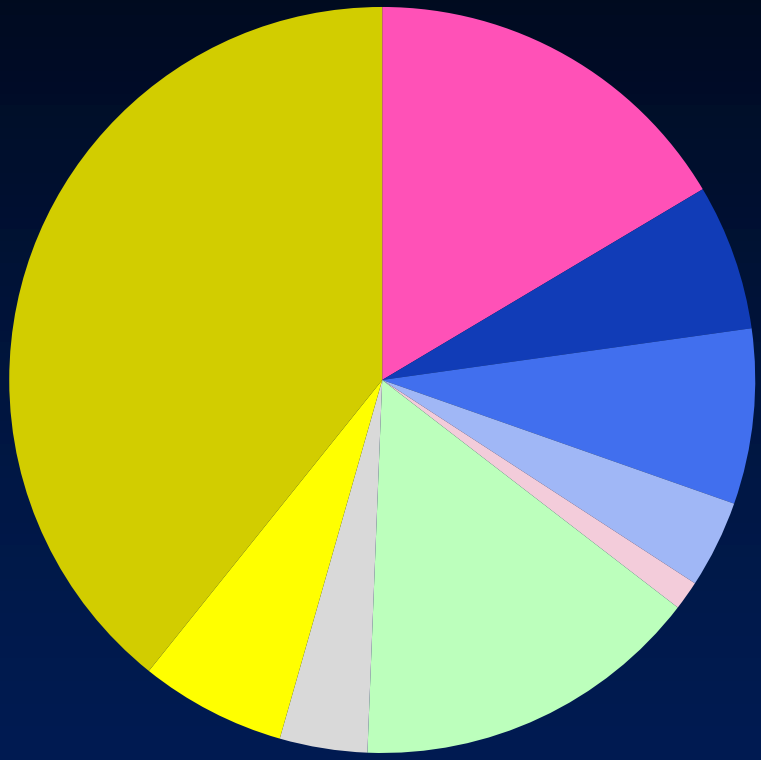


Wire used for CTO crossing

Before June 2012



After June 2012



Conquest family
Ultimate 3
others
Miracle 12
Pilot 200
GAIA 1st
Progress 120
XTA
GAIA 2nd

JCR 2013

Wire used for CTO crossing

in 2013

Conquest family

Ultimate 3

others

Miracle 12

Pilot 200

GAIA 1st

Progress 120

XTA

GAIA 2nd

JCR 2013

Retrograde approach procedural success will increase in association with case selection and development of dedicated devices.

However, long-term clinical outcomes comparing the various retrograde strategies including CART technique which carries the chance of subintimal tracking, to those of the antegrade approach, have yet to be adequately evaluated.

Retrograde Summit

J-PROCTOR

Subintimal Guidewire Tracking During Successful Percutaneous Therapy for Chronic Coronary Total Occlusions: Insights from an Intravascular Ultrasound Analysis

Kamran I. Muhammad,[1] MD, William L. Lombardi,[2] MD, Ryan Christofferson,[3] MD, and Patrick L. Whitlow,[1*] MD

Objectives: We sought to determine the frequency of subintimal guidewire tracking during successful percutaneous coronary intervention (PCI) for chronic coronary total occlusions (CTOs) and to better understand the procedural implications of this event. **Background:** Successful PCI for chronic CTO is associated with improved outcomes in patients with ischemia. While subintimal guidewire tracking resulting in failure to cross is recognized as the major mode of failure for CTO PCI, the implications of subintimal guidewire tracking during successful CTO PCI are unknown. **Methods:** Between March 2007 and October 2007, 26 consecutive patients, each with one de-novo CTO lesion successfully crossed with a guidewire were included in the analysis. Intravascular ultrasound (IVUS) was performed in each CTO vessel after guidewire crossing. Cases were classified as having definite subintimal wire tracking or no clear evidence of subintimal wire tracking based on analysis of IVUS images. **Results:** Subintimal wire tracking occurred in 45% of cases. In cases where subintimal wire tracking was present, a previous attempt at CTO PCI was more common (42% vs. 7%, $P \leq 0.05$). Subintimal wire tracking was also associated with significantly longer final mean stent length (71 vs. 50 mm), procedure time (122 vs. 69 min), fluoroscopy time (47 vs. 22 min), and contrast dose (300 vs. 199 mL, $P \leq 0.05$ for all). There was one perforation in the subintimal group which was successfully treated with stent placement. **Conclusions:** Subintimal wire tracking occurs frequently during successful PCI for CTO and is associated with increased lesion and procedural complexity.

- 26 CTO lesions successfully treated by a single operator
- 4 lesions by retrograde approach
- Subintimal tracking in 45% (12/26)
- Subintimal tracking was more common in reattempted case (45% vs. 7%), associated with longer stent length (71 vs. 50 mm), procedural time (122 vs. 69 min), fluoroscopy time (47 vs. 22 min), and contrast dose (300 vs. 199 mL).
- No long-term data available

(CCI 2012;79:43-48)

Retrograde Summit

J-PROCTOR

Intravascular Ultrasound Comparison of the Retrograde Versus Antegrade Approach to Percutaneous Intervention for Chronic Total Coronary Occlusions

Kenichi Tsujita, MD, PhD,* Akiko Maehara, MD,* Gary S. Mintz, MD,* Takashi Kubo, MD, PhD,* Hiroshi Doi, MD, PhD,* Alexandra J. Lansky, MD,* Gregg W. Stone, MD,* Jeffrey W. Moses, MD,* Martin B. Leon, MD,* Masahiko Ochiai, MD, PhD†

New York, New York; and Yokohama, Japan

Objectives We sought to evaluate the results of the antegrade versus retrograde chronic total occlusion (CTO) technique with intravascular ultrasound (IVUS) imaging.

Background The most common failure mode of CTO interventions remains the inability to successfully cross the occlusion with a guidewire. Recently, the retrograde approach through collateral channels has been introduced to cross complex CTOs.

Methods Between October 2002 and April 2008, IVUS was performed in 48 de novo CTO lesions after guidewire crossing ± pre-dilation with a 1.5- to 2.0-mm balloon. Twenty-three lesions were treated via the antegrade approach (Ante), and 25 lesions were treated via the retrograde approach (Retro).

Results Right coronary artery (RCA) CTOs were treated more frequently via the Retro technique. Although the CTO length was much longer in the Retro group (45 ± 26 mm vs. 18 ± 9 mm, $p < 0.0001$), at the end of the procedure Thrombolysis In Myocardial Infarction flow grade 3 was obtained in all patients. There were no significant differences between the 2 groups in minimum stent area and stent expansion. However, the incidence of the composite end point—subintimal wiring, angiographic extravasation, coronary hematoma, or IVUS-detected coronary perforation—was higher in the Retro group (68% vs. 30%, $p = 0.01$); and the guidewire was more often subintimal in the Retro group (40% vs. 9%, $p = 0.02$).

Conclusions The retrograde approach is a promising option for complex CTO segments, especially long RCA CTOs. Intravascular ultrasound can be a useful tool for the detection of procedure-related vessel damage and subintimal wire tracking. (J Am Coll Cardiol Intv 2009;2:846–54) © 2009 by the

- 48 CTO lesions successfully treated by a single operator
- 25 lesions by retrograde approach
- Subintimal tracking in more common in retrograde approach (40 vs. 9%)
- No long-term data available

(JACC Intv 2009;2:846-54)

Retrograde Summit

J-PROCTOR

Predictors of Reocclusion After Successful Drug-Eluting Stent–Supported Percutaneous Coronary Intervention of Chronic Total Occlusion

Renato Valenti, MD, Ruben Vergara, MD, Angela Migliorini, MD, Guido Parodi, MD, Nazario Carrabba, MD, Giampaolo Cerisano, MD, Emilio Vincenzo Dovellini, MD, David Antoniucci, MD

Florence, Italy

Objectives This study sought to assess the incidence of reocclusion and identification of predictors of angiographic failure after successful chronic total occlusion (CTO) drug-eluting stent–supported percutaneous coronary intervention (PCI).

Background Large registries have shown a survival benefit in patients with successful CTO PCI. Intuitively, sustained vessel patency may be considered as a main variable related to long-term survival. Very few data exist about the angiographic outcome after successful CTO PCI.

Methods The Florence CTO PCI registry started in 2003 and included consecutive patients treated with drug-eluting stents for at least 1 CTO (>3 months). The protocol treatment included routine 6- to 9-month angiographic follow-up. Clinical, angiographic, and procedural variables were included in the model of multivariable binary logistic regression analysis for the identification of the predictors of reocclusion.

Results From 2003 to 2010, 1,035 patients underwent PCI for at least 1 CTO. Of these, 802 (77%) had a successful PCI. The angiographic follow-up rate was 82%. Reocclusion rate was 7.5%, whereas binary restenosis (>50%) or reocclusion rate was 20%. Everolimus-eluting stents were associated with a significantly lower reocclusion rate than were other drug-eluting stents (3.0% vs. 10.1%; $p = 0.001$). A successful subintimal tracking and re-entry technique was associated with a 57% of reocclusion rate. By multivariable analysis, the subintimal tracking and re-entry technique (odds ratio [OR]: 29.5; $p < 0.001$) and everolimus-eluting stents (OR: 0.22; $p = 0.001$) were independently related to the risk of reocclusion.

Conclusions Successful CTO-PCI supported by everolimus-eluting stents is associated with a very high patency rate. Success-

- 802 CTO lesions successfully treated
- 1st generation DES in 66%, EES in 34%
- 34 lesions (4.2%) by STAR technique; EES in 16 lesions (47%)
- Angiographic follow-up in 616 (82%)
- Reocclusion in 7.5% (46/616); higher in 1st generation DES (10.1 vs. 3%), and in STAR technique (57% vs. 5.7%)
- Independent predictors of reocclusion were EES (OR: 0.22) and STAR technique (OR: 29.5)

(JACC 2013;61:545-50)

Our Questions
About the Subintimal Tracking

1. How often in the contemporary CTO-PCI?

2. Any effect of short subintimal tracking on long-term outcomes after DES?

J-PROCTOR REGISTRY

PROMUS STENT TREATMENT OF
CHRONIC TOTAL OCCLUSIONS
USING TWO DIFFERENT RECANALIZATION
TECHNIQUES IN JAPAN

Study Design

Flow Chart

CTO Cases

- ✓ **Primary Endpoint: 12 mo. TVR**
- ✓ **Secondary Endpoint: 12 mo. MACE and Fu QCA parameters**

PROMUS Stent Implantation

↓

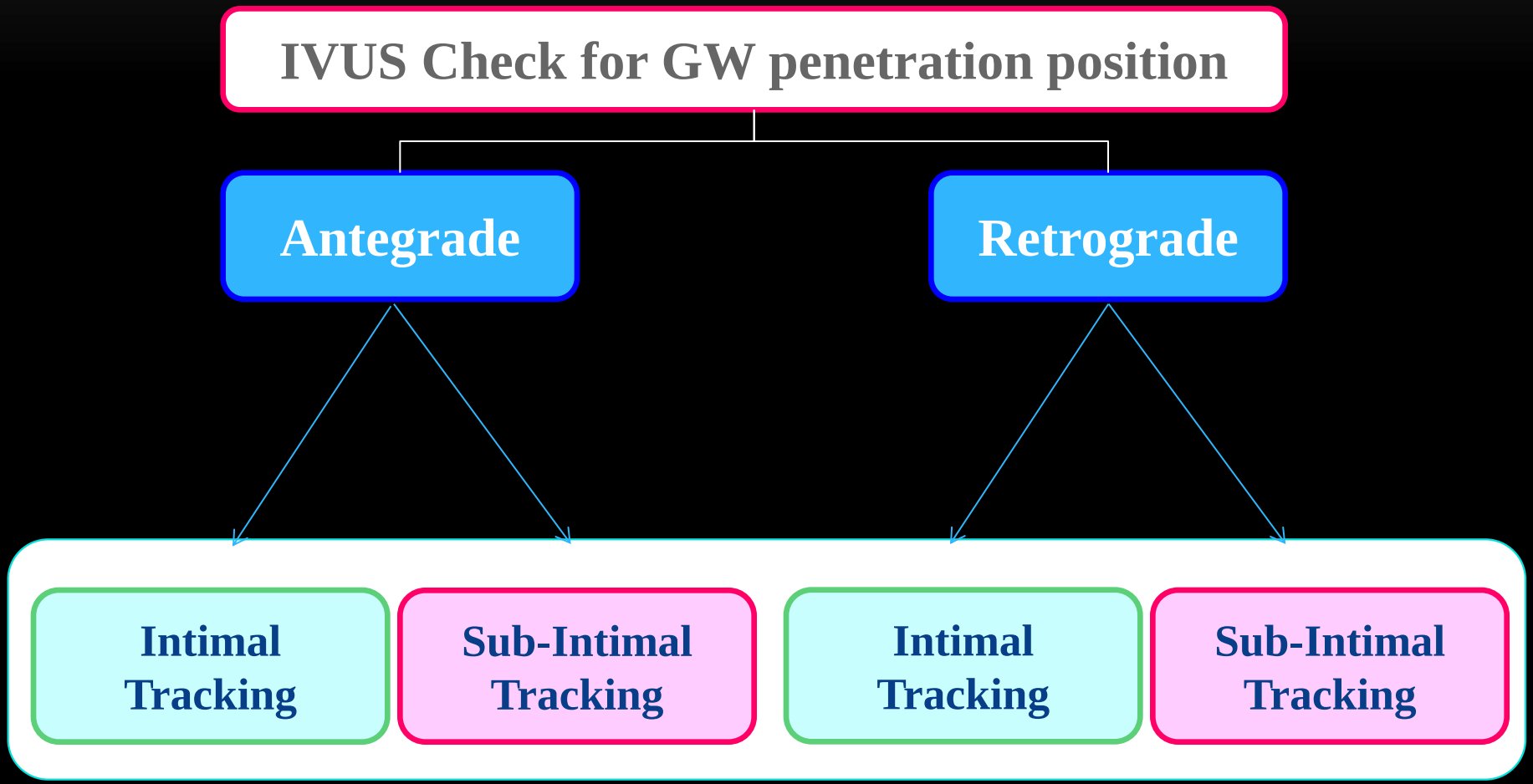
9 mo. Angiogram FU

↓

12 mo. Clinical FU

Study Design

Classification of GW penetration position



Study Design

Definition of GW positioning by IVUS

- Intimal Plaque Tracking

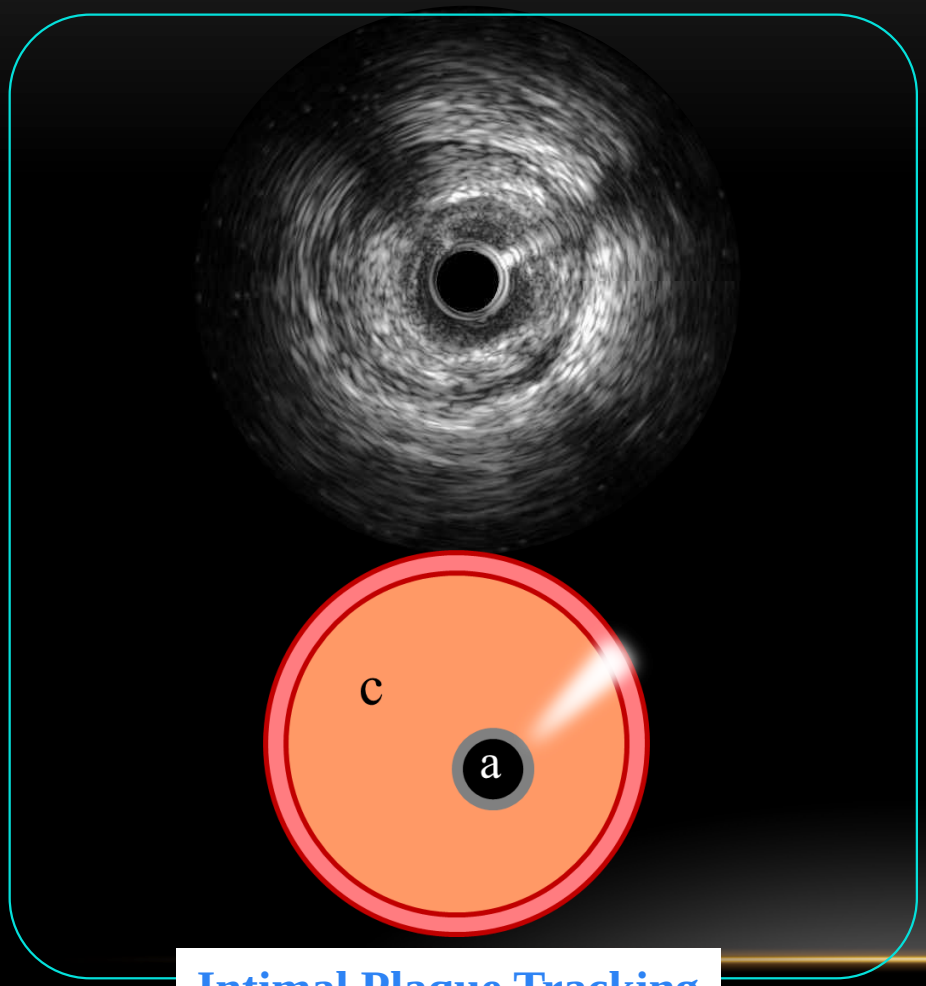
If the IVUS catheter was in the intimal plaque, yet surrounded by dissection with/without hematoma.

- Sub-Intimal Tracking

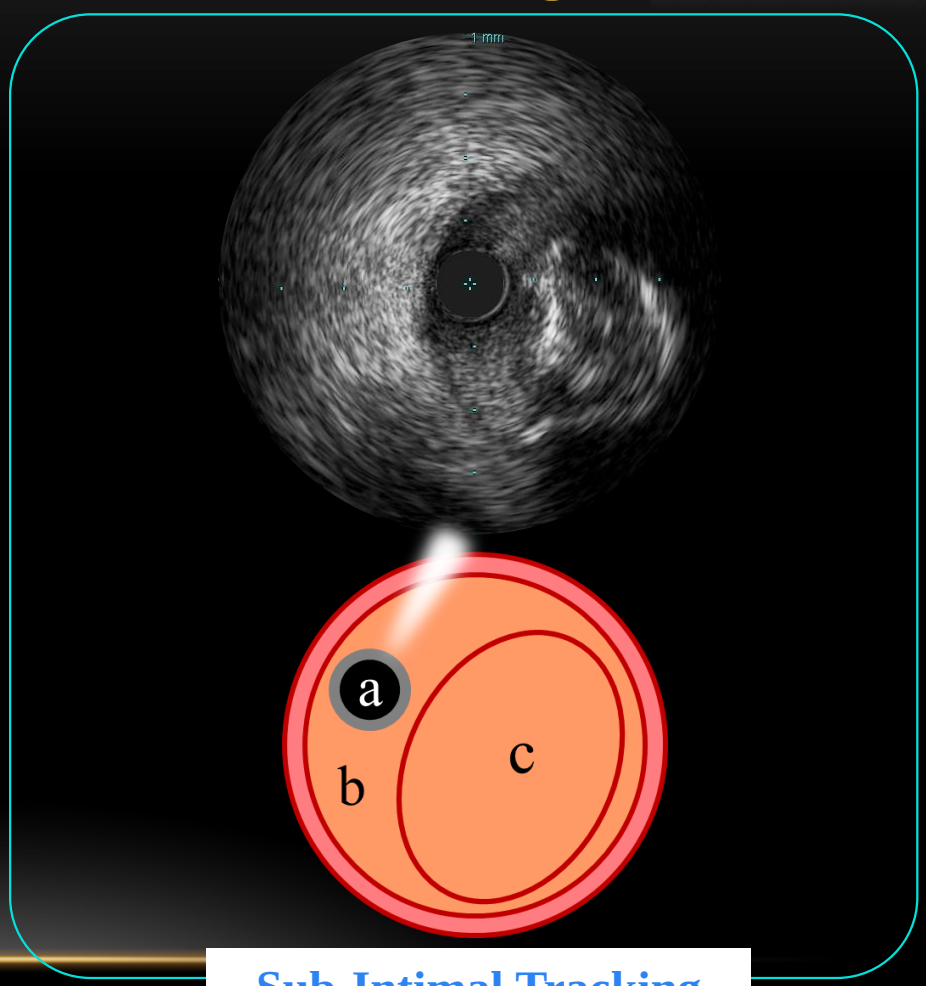
If the IVUS catheter was located in a dissection plane outside of intimal plaque but inside of EEM, even when it was localized.

IVUS Image

Intimal vs. Sub-Intimal Tracking



Intimal Plaque Tracking



Sub-Intimal Tracking

a = IVUS catheter , b = Sub-Intimal space, c = the Intimal Plaque

Study Organization

- Principal Investigator

  Etsuo Tsuchikane, MD, PhD (Toyohashi Heart Center)
- Clinical sites

  27 Hospitals in Japan
- Safety Committee

  Hiroshi Oota, MD (Itabashi-chuo Hospital)
- QCA and IVUS Core Laboratory;

  Cardiovascular Imaging Core Laboratory (CICL)
- Sponsor

  Retrograde Summit

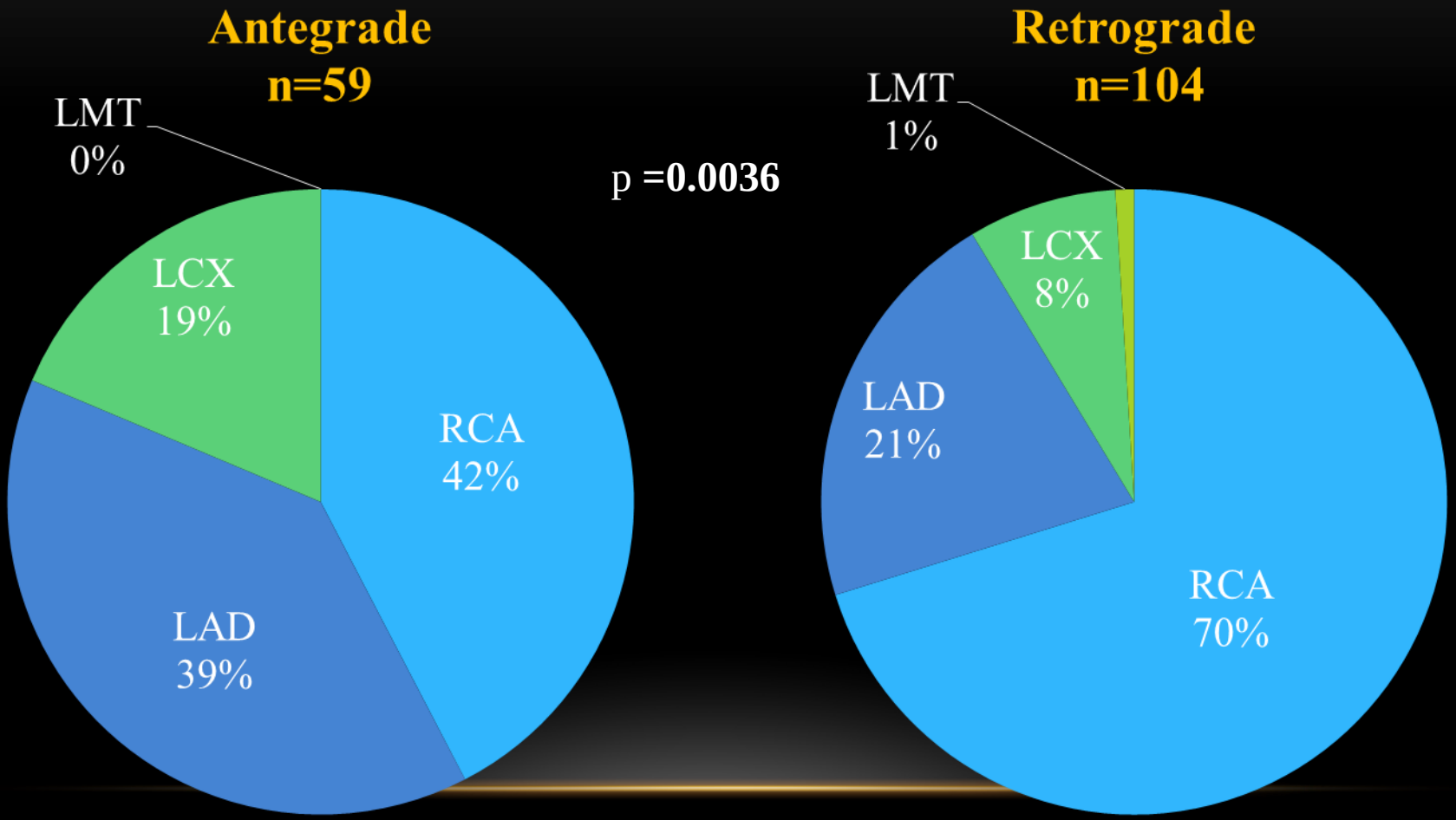
Baseline Patient Characteristics

	Ante 59	Retro 104	p value
Male	86.4%	89.4%	0.62
Age (years)	65.4 ±10.4	65.6 ±10.6	0.95
Previous MI	30.5%	44.2%	0.10
Previous CABG	6.8%	12.5%	0.30
Hypertension	64.4%	69.2%	0.60
Diabetes mellitus	37.3%	33.7%	0.73
Hyperlipidemia	62.7%	76.9%	0.07
Smoking	22.0%	13.5%	0.19
Average diseased vessel	1.9 ±0.8	1.8 ±0.8	0.70
Multi vessel disease	61.0%	56.7%	0.62

Lesion Characteristics

	Ante 59	Retro 104	p value
Calcification	67.8%	69.2%	0.86
Proximal tortuosity	33.9%	45.2%	0.19
Bending (>45)	3.4%	6.7%	0.49
Bifurcation	33.9%	29.8%	0.60
Occlusion length, mm	13.7±12.0	22.9±16.7	0.001
Reference diameter, mm	2.72±0.43	2.96±0.43	0.001
Reattempt	5.1%	27.9%	<0.0001
Bridge collateral	47.4%	45.5%	0.87

Target Vessel



PCI Procedure

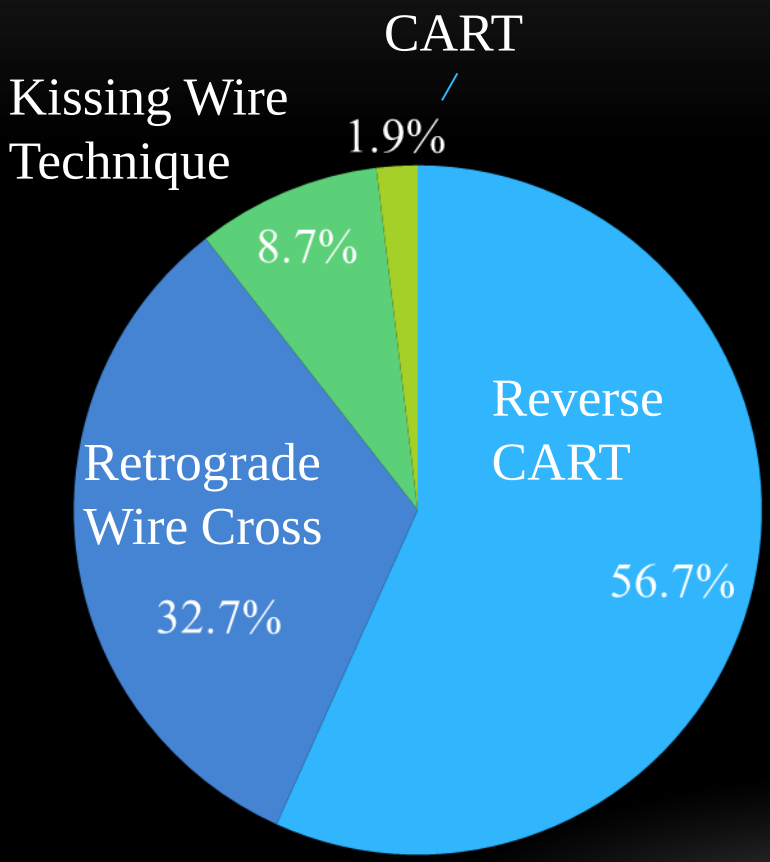
	Ante 59	Retro 104	p value
Number of GW	2.5±1.8	4.7±2.2	0.024
IVUS guided wiring	6.8%	60.6%	<0.0001
Number of stent	1.9±0.9	2.8±1.0	<0.0001
Maximum stent diameter, mm	3.00±0.39	3.13±0.39	0.035
Stent length, mm	41.2±20.6	59.6±23.5	<0.0001
Maximum stent pressure, atm	12.2±3.3	13.9±3.3	0.0020

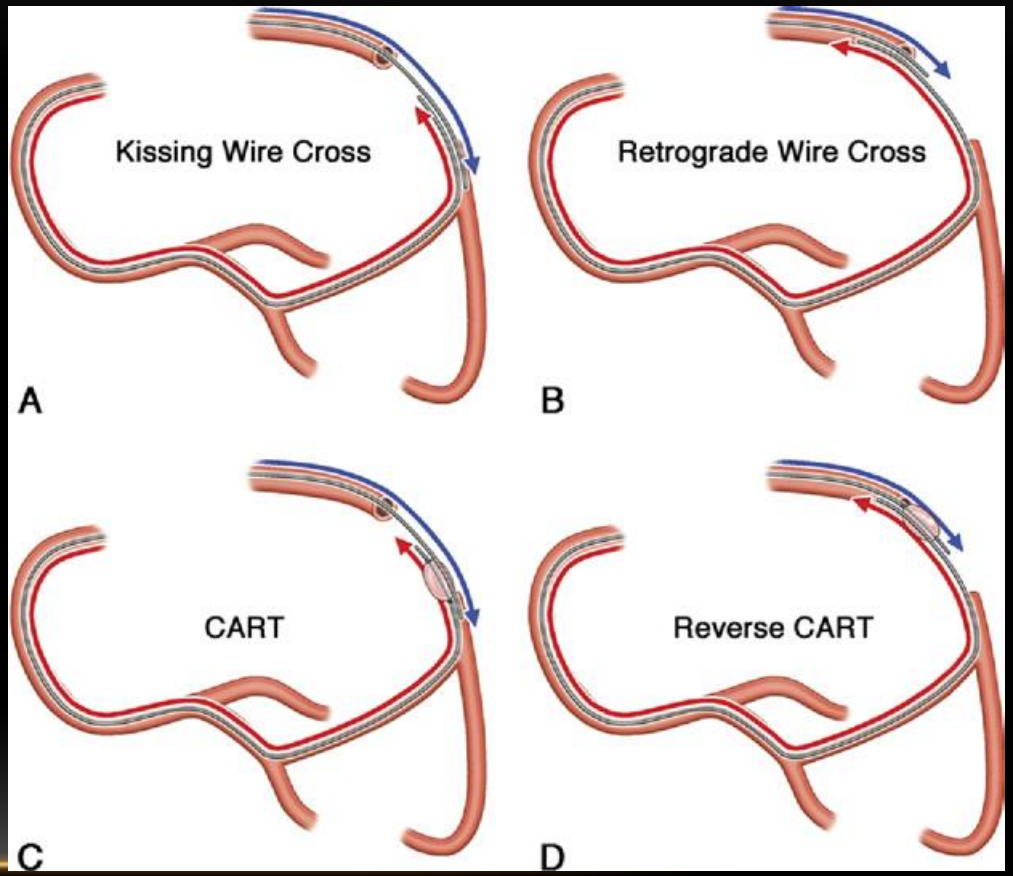
Procedure Results

	Ante 59	Retro 104	p value
Procedure time, min	105.2±60.1	187.7±81.9	<0.0001
Contrast dose, ml	226.8±111.0	291.6±133.8	0.0019
Fluoroscopic time, min	46.1±35.6	87.8±44.1	<0.0001
Procedure success	59 (100%)	104 (100%)	1.00
Procedure events	5.1% (3)	7.7% (8)	0.75
- GW perforation	5.1% (3)	5.8% (6)	1.00
- Channel injury	-	1.9% (2)	
- Donor artery trouble	-	0%	
In hospital MACE	0%	0%	1.00
Non Q wave MI	1 (1.7%)	2 (1.9%)	1.00

Retrograde Procedure

Patterns of Success



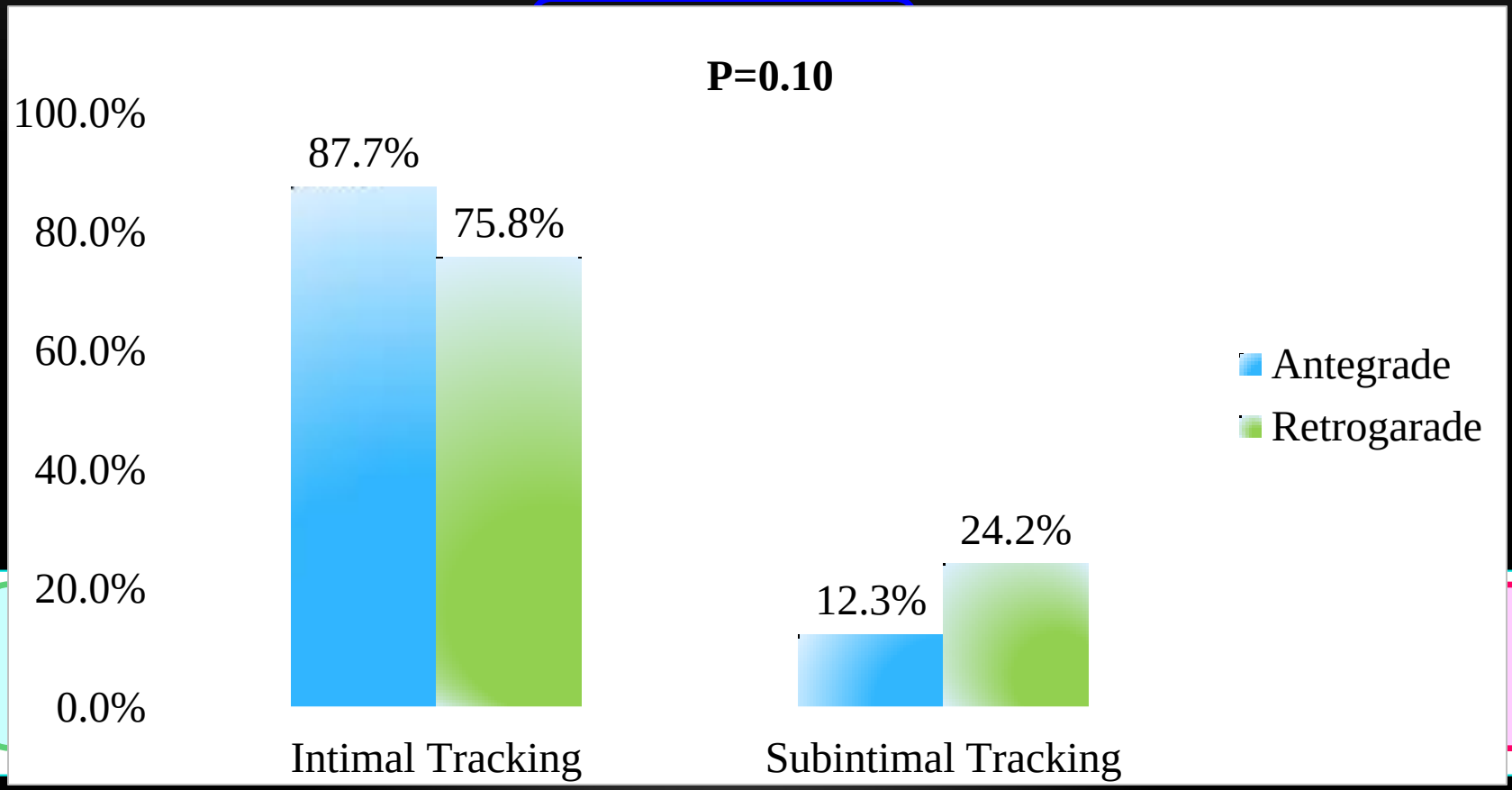


JACC. Cardiovasc Interv 2011;4:941-51

IVUS ANALYSIS RESULTS

Results

Acute IVUS classification



Lesion Characteristics by IVUS classification

	Intimal 125	Sub-Intimal 31	p value
Calcification	65.6%	83.9%	0.05
Proximal tortuosity	35.2%	54.8%	0.06
Bending (>45)	6.4%	3.2%	0.69
Bifurcation	34.4%	22.6%	0.28
Occlusion length, mm	18.5±14.8	23.9±20.5	0.14
Reference diameter, mm	2.82±0.43	3.02±0.44	0.020
Reattempt	16.8%	32.3%	0.08
Bridge collateral	40.0%	61.3%	0.044

Procedure Results by IVUS classification

	Intimal 125	Sub-Intimal 31	p value
Procedure time, min	155.9 ±85.7	171.7 ±84.4	0.36
Contrast dose, ml	264.4 ±120.6	282.0 ±170.7	0.51
Fluoroscopic time, min	69.7 ±45.2	85.3 ±47.3	0.10
Procedure events	5.6% (7)	9.7% (3)	0.42
- GW perforation	5.6% (7)	3.2% (1)	1.00
- Channel injury	0%	6.5% (2)	0.0385
- Donor artery trouble	0%	0%	
In hospital MACE	0%	0%	1.00
Non Q wave MI	1.6% (2)	3.2% (1)	0.49

12-MONTH FU
CLINICAL RESULTS

MACE at 12 months
Antegrade vs. Retrograde

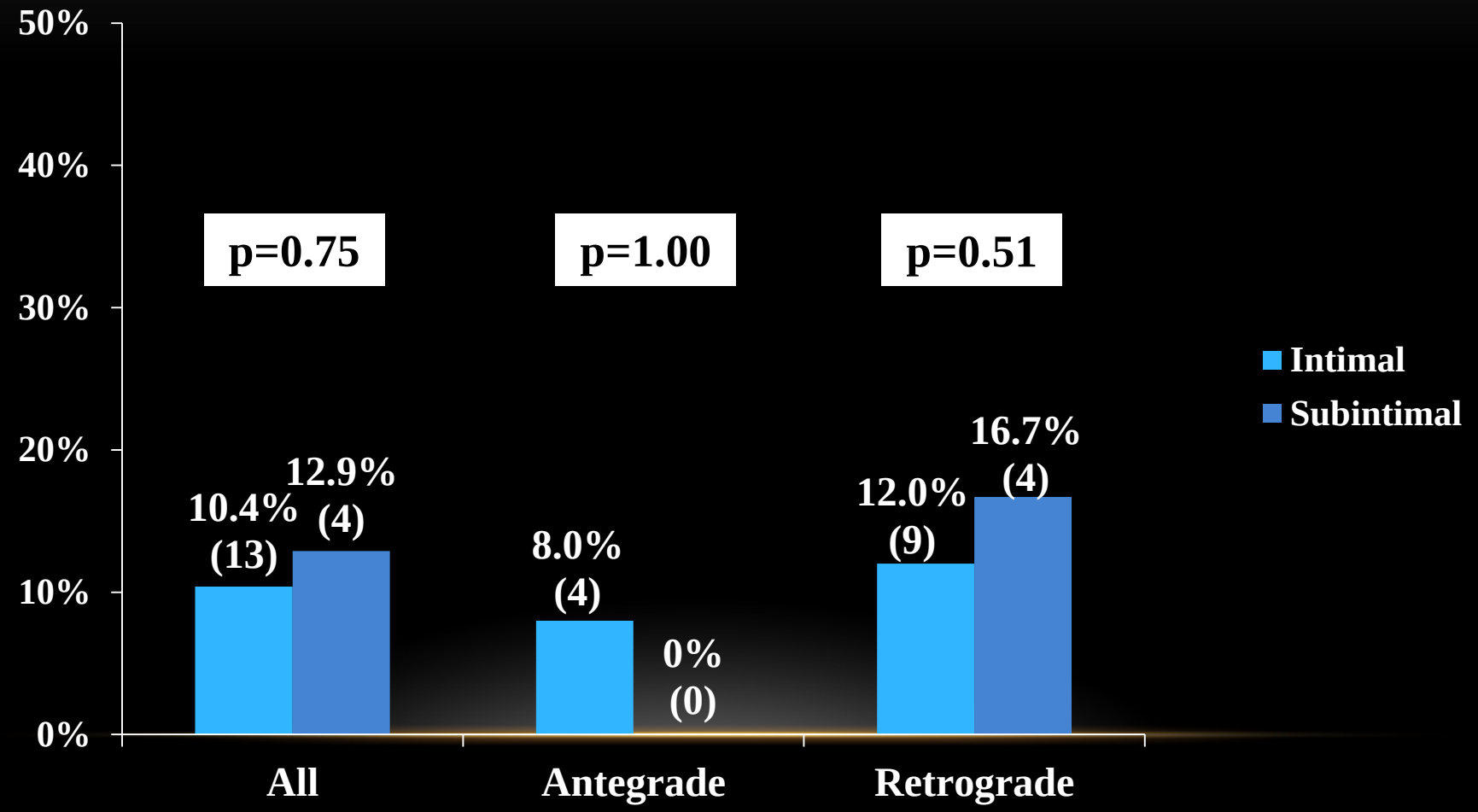
(Fu rate: 100%)

	Ante (59)	Retro (104)	p value
MACE	6.8% (4)	13.5 % (14)	0.30
TVR	6.8% (4)	12.5 % (13)	0.30
MI	0%	0%	
Cardiac death	0%	0%	
Non-Cardiac death	0%	1.0% (1*)	1.00
SAT/LT	0%	0%	

*Car Accident

TVR at 12 months

Antegrade (Intimal vs. Sub-intimal)
Retrograde (Intimal vs. Sub-intimal)



QCA RESULTS

Acute QCA Results
Intimal vs. Sub-Intimal

	Intimal (125)	Sub-Intimal (31)	p value
Pre Procedure			
RVD, mm	2.82±0.42	3.02±0.44	0.020
Occlusion Length, mm	18.5±14.8	23.9±20.5	0.14
Post Procedure(In stent)			
RVD, mm	3.09±0.48	3.17±0.44	0.38
MLD, mm	2.60±0.46	2.61±0.37	0.91
Stent Length, mm	50.5±23.8	60.5±23.0	0.040
Acute Gain, mm	2.6 ±0.5	2.6 ±0.4	0.91

9-month QCA Results
Intimal vs. Sub-Intimal

	Intimal (100)	Sub-Intimal (22)	p value
In Stent			
RVD, mm	3.00±0.46	2.95±0.41	0.87
MLD, mm	2.41±0.66	2.03±0.79	0.021
% DS, %	19.8±19.1	30.4±25.9	0.031
Late Loss, mm	0.21±0.52	0.57±0.93	0.016
Loss Index, %	7.8±22.6	19.7±30.3	0.038
Reocclusion	3.0% (3)	4.5% (1)	0.55
Aneurysm	1.0% (1)	9.1% (2)	0.08

Aneurysm (from QCA core lab) = an expansion of the lumen by at least 20% compared with the normal lumen dimensions in the treatment region (analysis segment) that extends with a wide or narrow mouth beyond the apparent normal contour

Acute QCA Results
Retrograde: Intimal vs. Sub-Intimal

	Intimal (75)	Sub-Intimal (24)	p value
Pre Procedure			
RVD, mm	2.89±0.41	3.08±0.43	0.06
Occlusion Length, mm	21.5±15.5	28.1±21.1	0.14
Post Procedure(In stent)			
RVD, mm	3.11±0.51	3.21±0.41	0.39
MLD, mm	2.60±0.48	2.63±0.41	0.74
Stent Length, mm	56.4±23.7	66.7±20.9	0.06
Acute Gain, mm	2.6±0.5	2.6±0.4	0.74

9-month QCA Results
Retrograde: Intimal vs. Sub-Intimal

	Intimal 77.3% (58)	Sub-Intimal 75.0% (18)	p value
In Stent			
RVD, mm	3.02±0.49	3.00±0.43	0.86
MLD, mm	2.32±0.73	1.92±0.83	0.05
% DS, %	23.2±20.3	34.8±26.7	0.05
Late Loss, mm	0.29±0.63	0.71±0.98	0.037
Loss Index, %	10.8±24.9	24.6±31.4	0.06
Reocclusion	3.4% (2)	5.6% (1)	0.56
Aneurysm	1.7% (1)	11.1% (2)	0.14

Aneurysm (from QCA core lab) = an expansion of the lumen by at least 20% compared with the normal lumen dimensions in the treatment region (analysis segment) that extends with a wide or narrow mouth beyond the apparent normal contour

Limitation

- Non randomized observational study
- Limited case number
- Relatively low rate of follow-up angiography (78.2%)
- Short follow-up period (1 year)

J-PROCTOR Summary

- According to IVUS analysis, Sub-intimal tracking tended to be higher in retrograde approach than antegrade.
- Lesion characteristics were more severe in Sub-intimal tracking group.
- No significant difference was observed in 1year TVR rate (primary endpoint) between Intimal and Sub-intimal tracking groups, in both antegrade and retrograde approach.
- Acute QCA analysis identified longer occlusion and stent lengths in the Sub-intimal tracking group.
- FU QCA analysis showed a higher late loss in the Sub-intimal group, but no difference in re-occlusion rate.

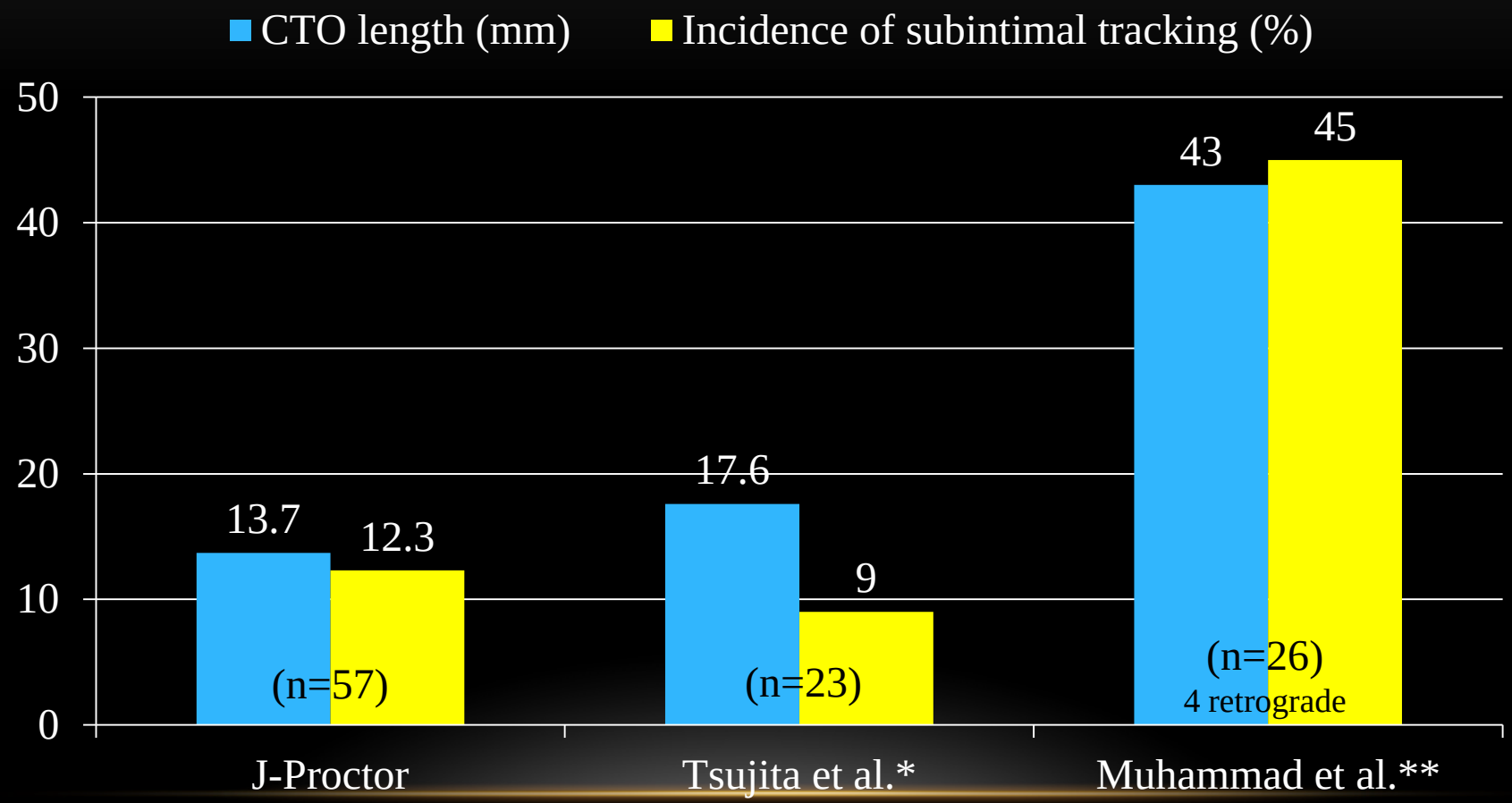
J-PROCTOR Conclusion

- No clinical negative impact by EES implantation after localized Sub-intimal tracking in either antegrade or retrograde manner at 1 year was demonstrated in this study.

Lessons from J-PROCTOR

1. Subintimal tracking is more predictable in the retrograde approach than the antegrade. But not so common even if reverse CART is commonly used (>50%).
2. Occlusion length may influence the incidence of subintimal tracking in both approaches.

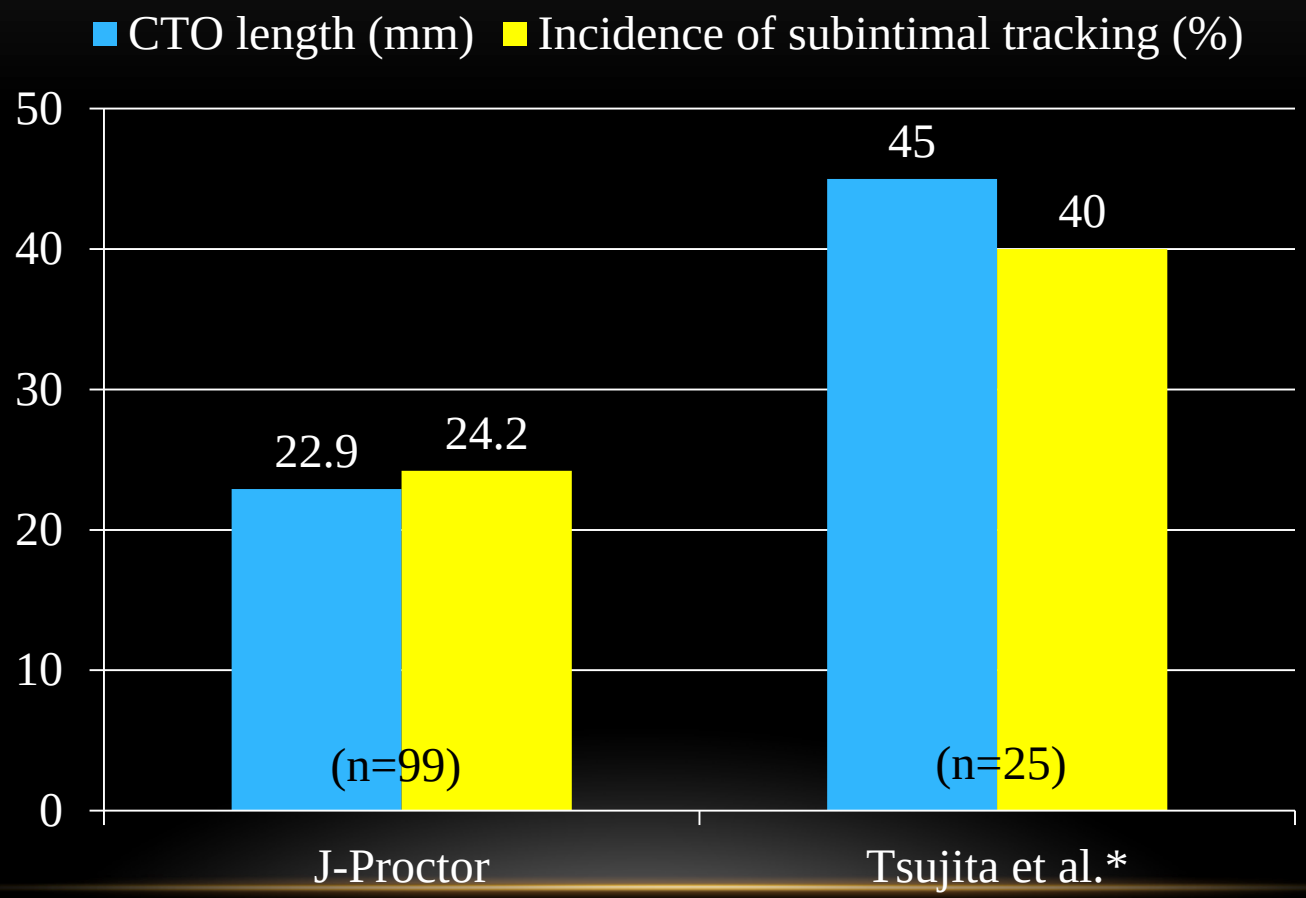
CTO length and Subintimal tracking
Antegrade approach



*(*JACC Intv 2009;2:846-54)*
*(**CCI 2012;79:43-48)*

CTO length and Subintimal tracking

Retrograde approach



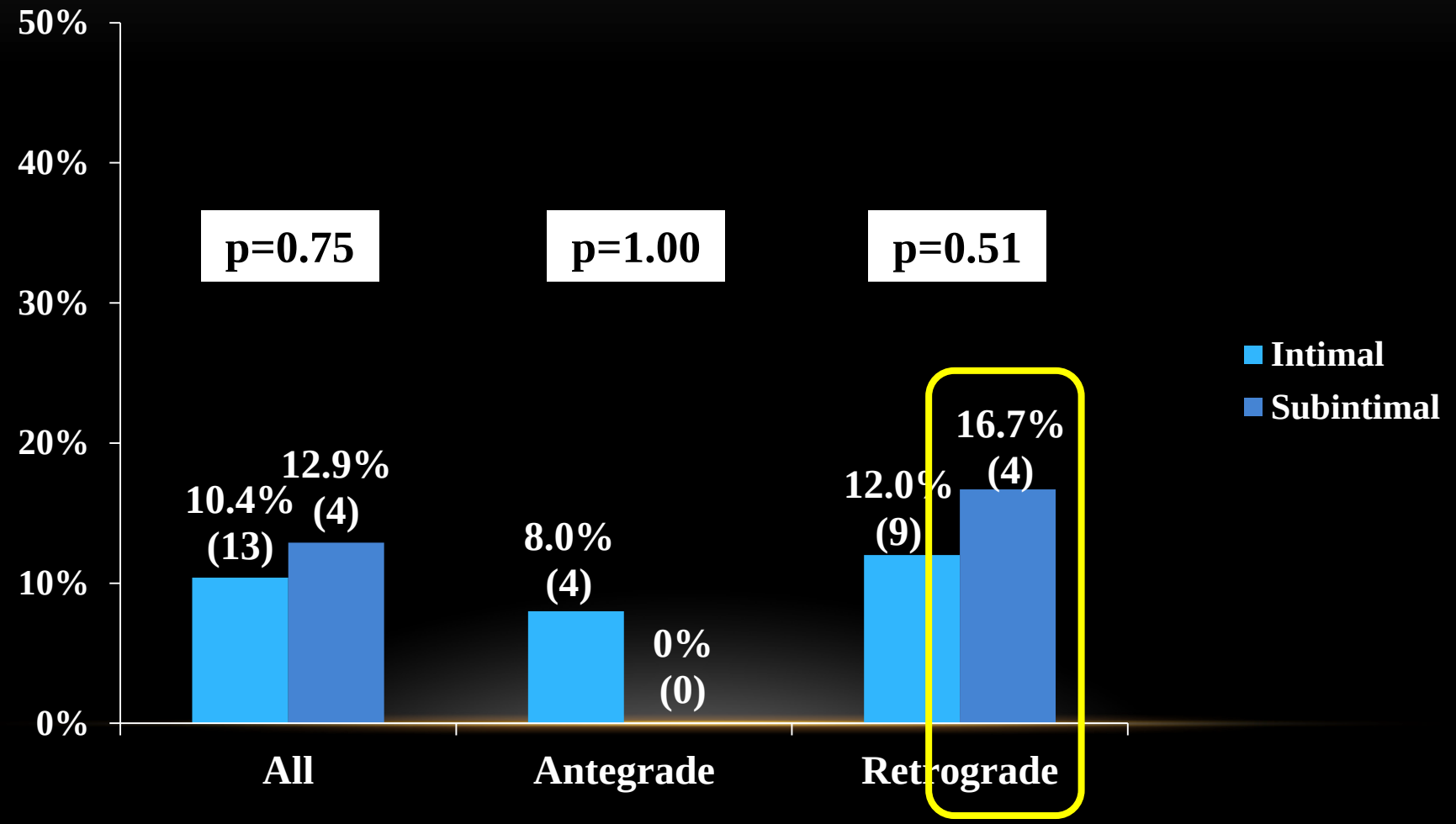
*(*JACC Intv 2009;2:846-54)*

Lessons from J-PROCTOR

1. Subintimal tracking is more predictable in the retrograde approach than the antegrade. But not so common even if reverse CART is commonly used (>50%).
2. Occlusion length may influence the incidence of subintimal tracking in both approaches.
3. Restenosis does not always occur in DES with subintimal dilatation.

TVR at 12 months

Antegrade (Intimal vs. Sub-intimal)
Retrograde (Intimal vs. Sub-intimal)



9-month QCA Results
Retrograde: Intimal vs. Sub-Intimal

	Intimal 77.3% (58)	Sub-Intimal 75.0% (18)	p value
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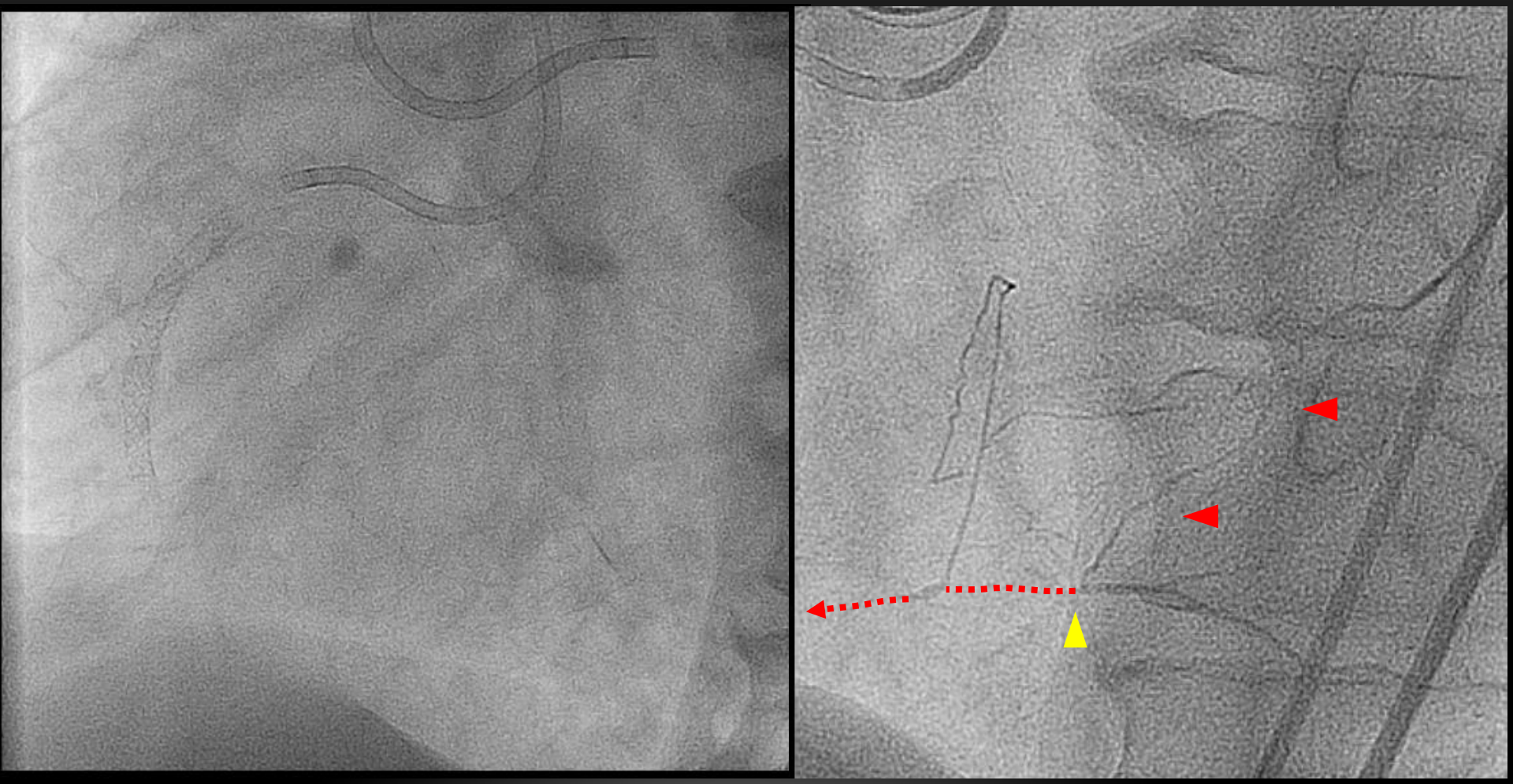
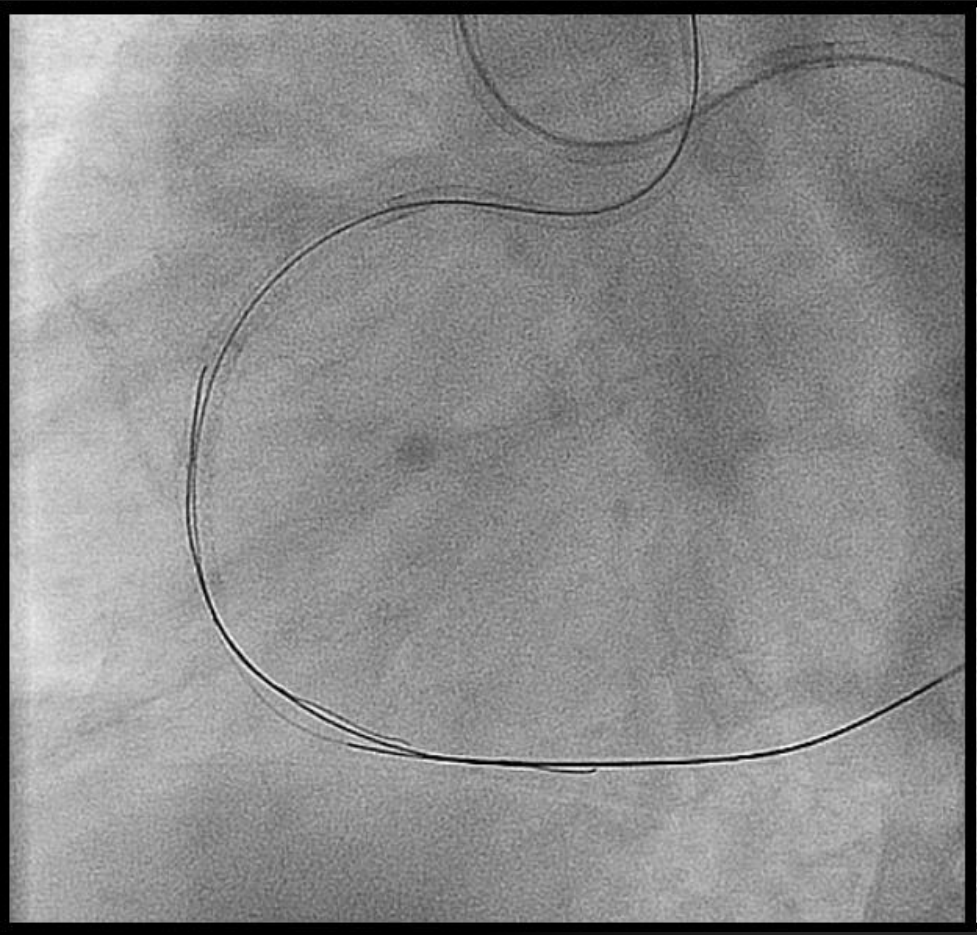
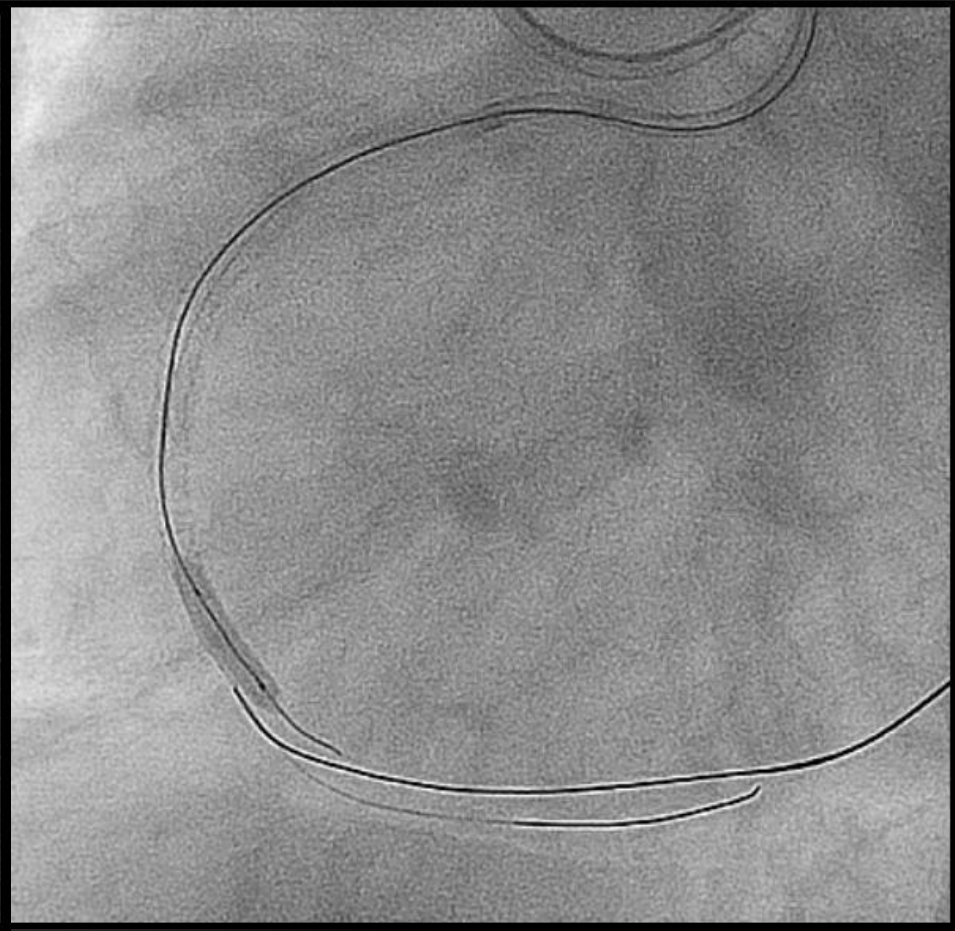
TVR Case in Retrograde Group #1



Epicardial channel

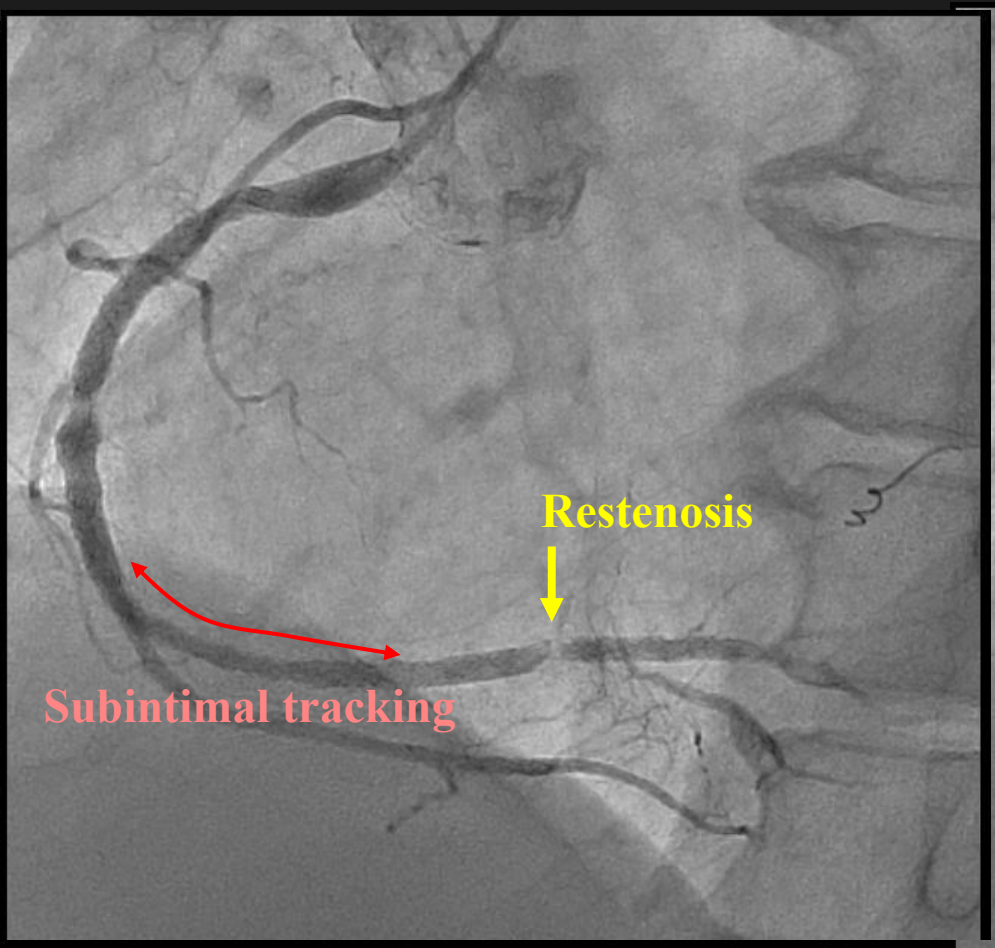
TVR Case in Retrograde Group #1

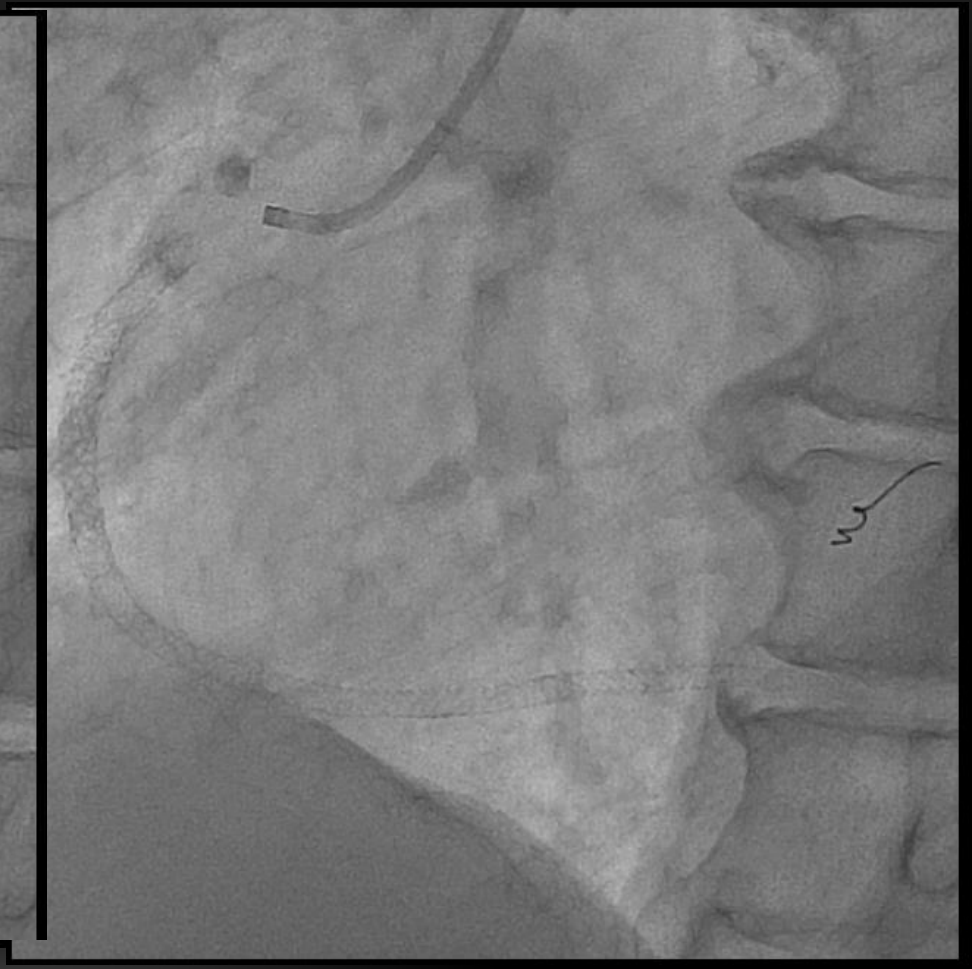




Reverse CART

TVR Case in Retrograde Group #1

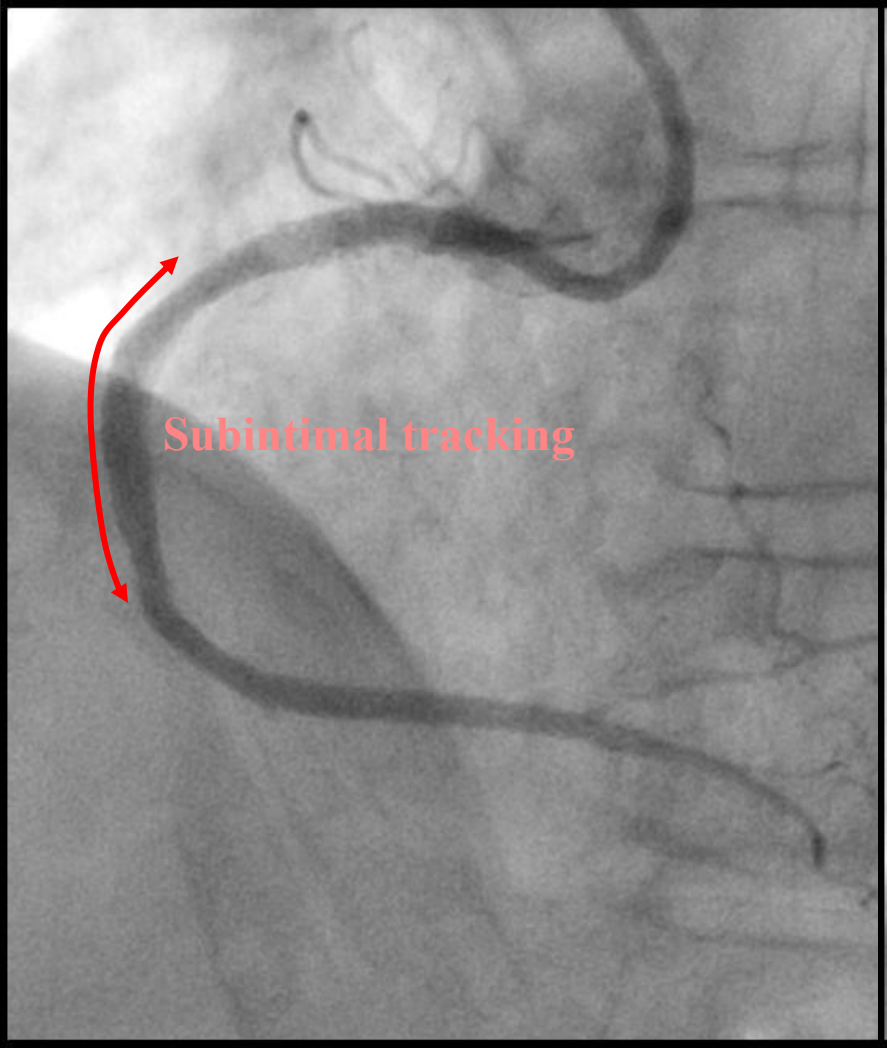


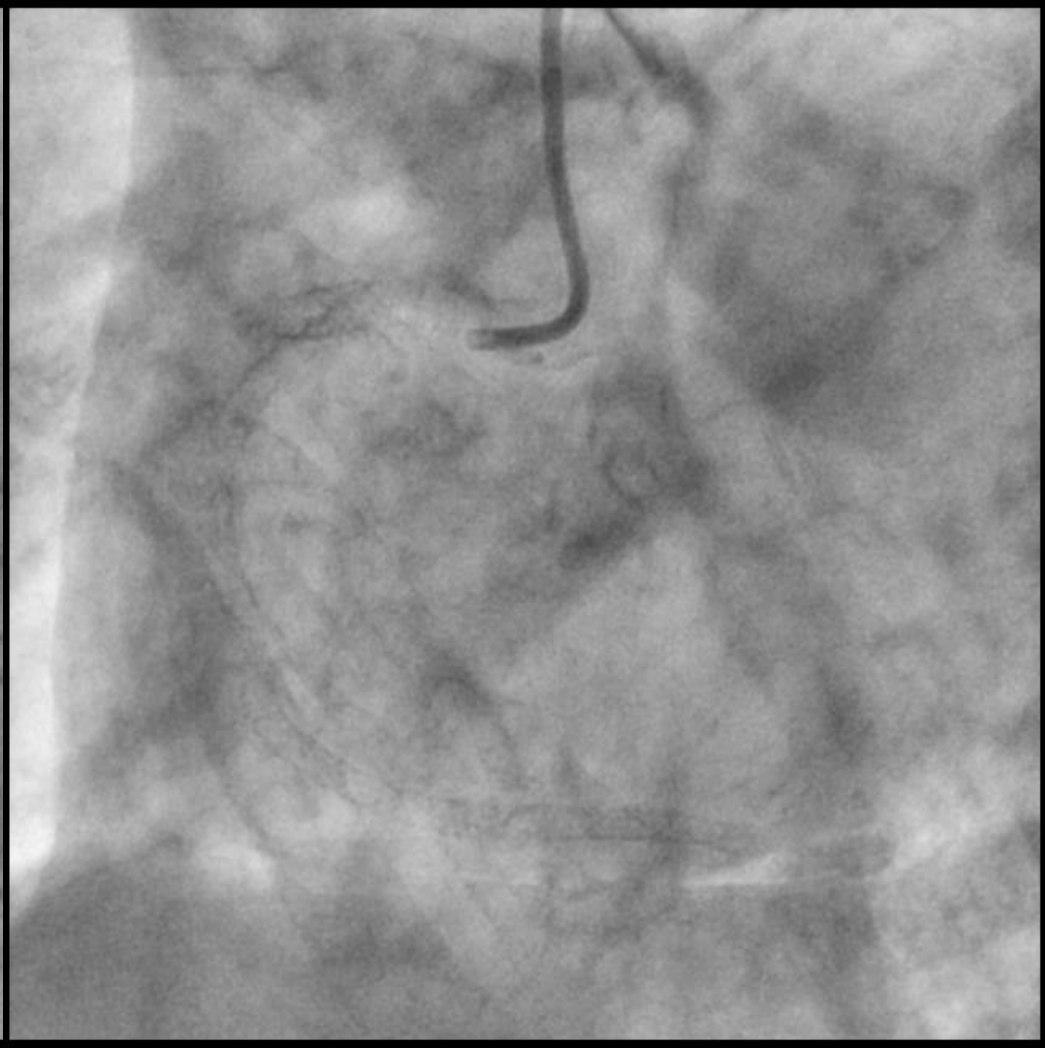


Final angiogram

9Mo Fu angiogram

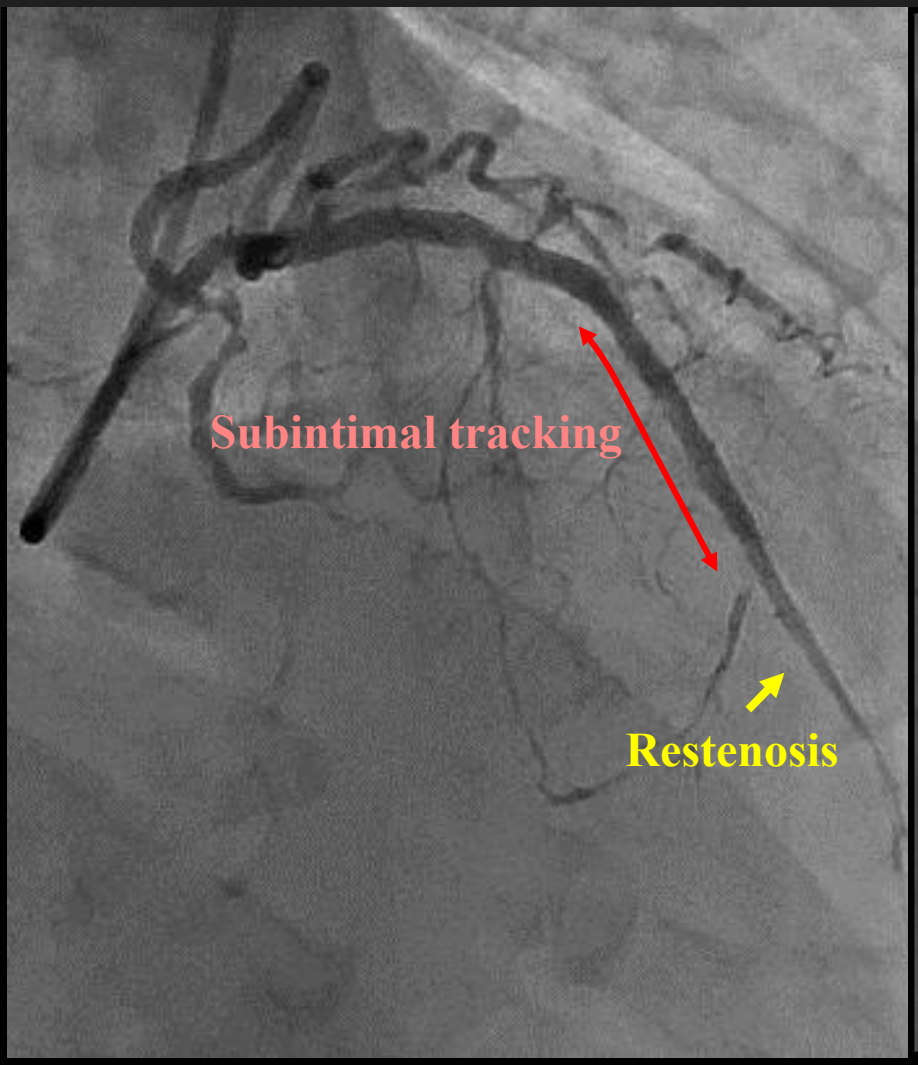
TVR Case in Retrograde Group #2

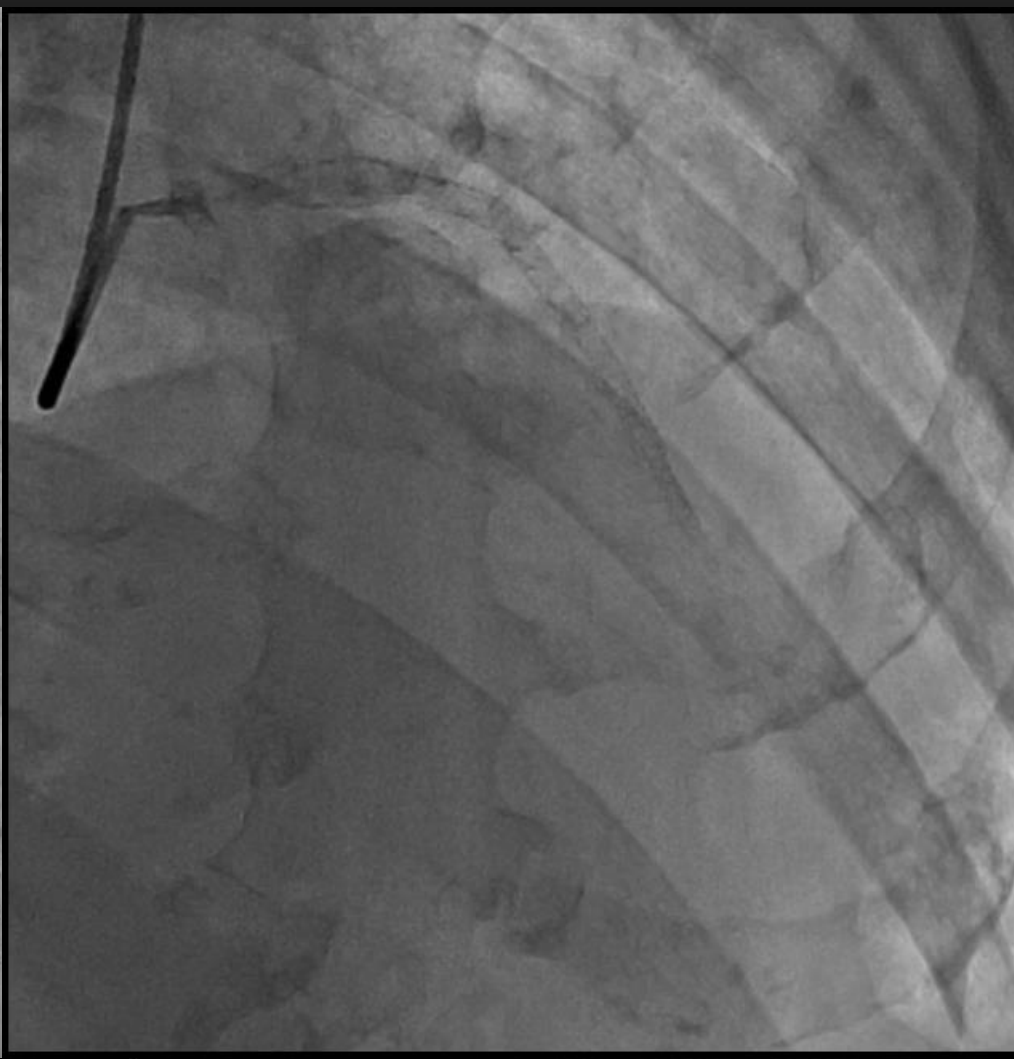




9Mo Fu angiogram

TVR Case in Retrograde Group #3





9Mo Fu angiogram

Lessons from J-PROCTOR

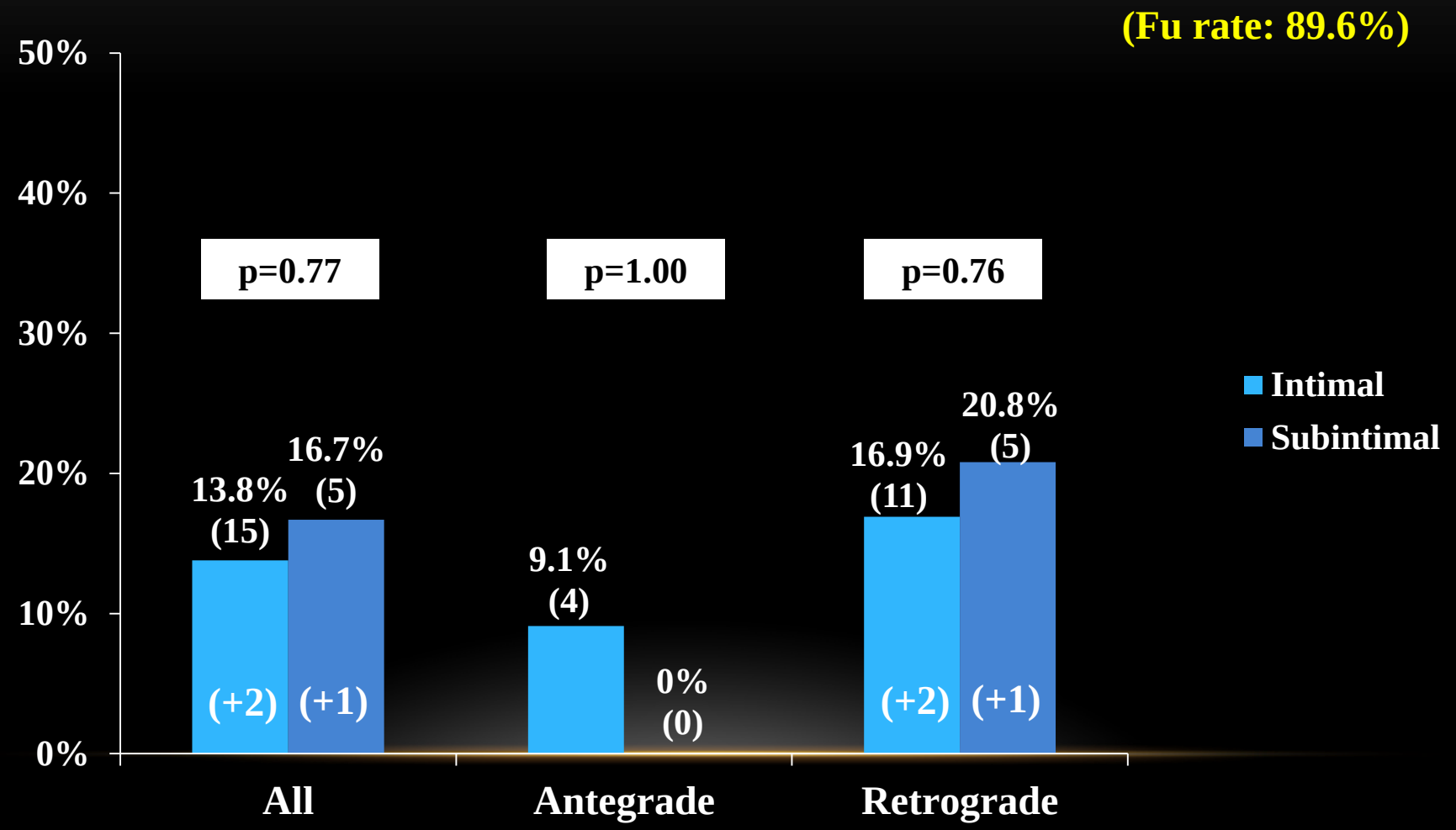
1. Subintimal tracking is more predictable in the retrograde approach than the antegrade. But not so common even if reverse CART is commonly used (>50%).
2. Occlusion length may influence the incidence of subintimal tracking in both approaches.
3. Restenosis does not always occur in DES with subintimal dilatation.
4. Short subintimal tracking and a final TIMI flow grade 3 with well preserved distal side branches may not worsen the vessel patency.
5. These suggestions warrants further evaluations.

Perspective

- We’re collecting 2 year follow-up clinical results.

TVR at 24 months

Antegrade (Intimal vs. Sub-intimal)
Retrograde (Intimal vs. Sub-intimal)



Perspective

- We’re collecting 2 year follow-up clinical results.

- We started a prospective registry through web of all CTO procedures in both antegrade and retrograde approach in 2012.
- Total 1573 cases were enrolled in 2012.

Retrograde Summit

J-PROCTOR

CTO Web Registry data: **1573**

- Success: **1411** / 1573
- ✓ EES: **901** / 1411 (Antegrade: 627, Retrograde: 274)
- ✓ Matched exclusion criteria: **182** (Antegrade:143, Retrograde:39)

Candidates for Clinical Analysis

Total: 719 (Antegrade: 484, Retrograde: 235)

Perspective

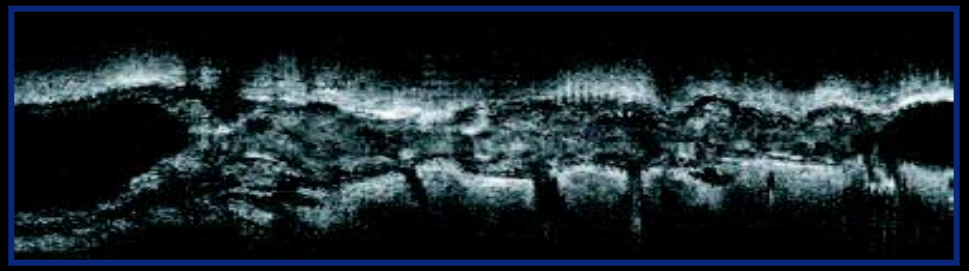
- We're collecting 2 year follow-up clinical results.

- We started a prospective registry through web of all CTO procedures in both antegrade and retrograde approach in 2012.
- Total 1573 cases were enrolled in 2012.
- Of those, eligible IVUS data and 1 year clinical follow-up results will be evaluated and presented in 2014 as J-PROCTOR 2.

Retrograde Summit

J-PROCTOR

15th CTO Club



June 20-21, 2014, *Nagoya*, Japan

www.cct.gr.jp/ctoclub