



# SUBINTIMAL VS. INTIMAL DRILLING DATA FROM J-PROCTOR REGISTRY

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# Background

Since the current retrograde approach for PCI in CTO was introduced in 2005, this approach has continued to increase PCI success rates in CTOs.

Despite the increased success rate, short and long term clinical outcomes comparing the various retrograde strategies, to those of the antegrade approach, have yet to be adequately evaluated.

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# Objective

To evaluate short and long term clinical outcomes comparing Intimal tracking group with Sub-intimal tracking group after successful revascularization of CTOs using antegrade or retrograde approach.

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# Definitions

## CTO

- A complete obstruction of a coronary artery with TIMI flow grade 0
- Estimated duration of occlusion of greater than 3 months

## Procedural Success

- Recanalization of target lesion with restoration of TIMI flow grade 3 and residual stenosis <50%

## MACE

- Cardiac Death, non-Q and Q-wave MI, Ischemia-driven target-vessel revascularization (TVR)
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# Study Design

## Inclusion & Exclusion Criteria

### □ Inclusion

- Age > 20
- Total coronary occlusion > 3 month
- Symptomatic or silent ischemia
- Suitable for 2.5-3.5 mm PROMUS stent implantation

### □ Exclusion

- ST elevation MI
  - Renal insufficiency (Scr  $\geq$  3.0mg/dl)
  - Hemodialysis
  - Saphenous vein graft lesion
  - In-Stent Restenosis lesion
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# Study Design

## Flow Chart

**CTO Cases**

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

Antegrade 50 : Retrograde 100

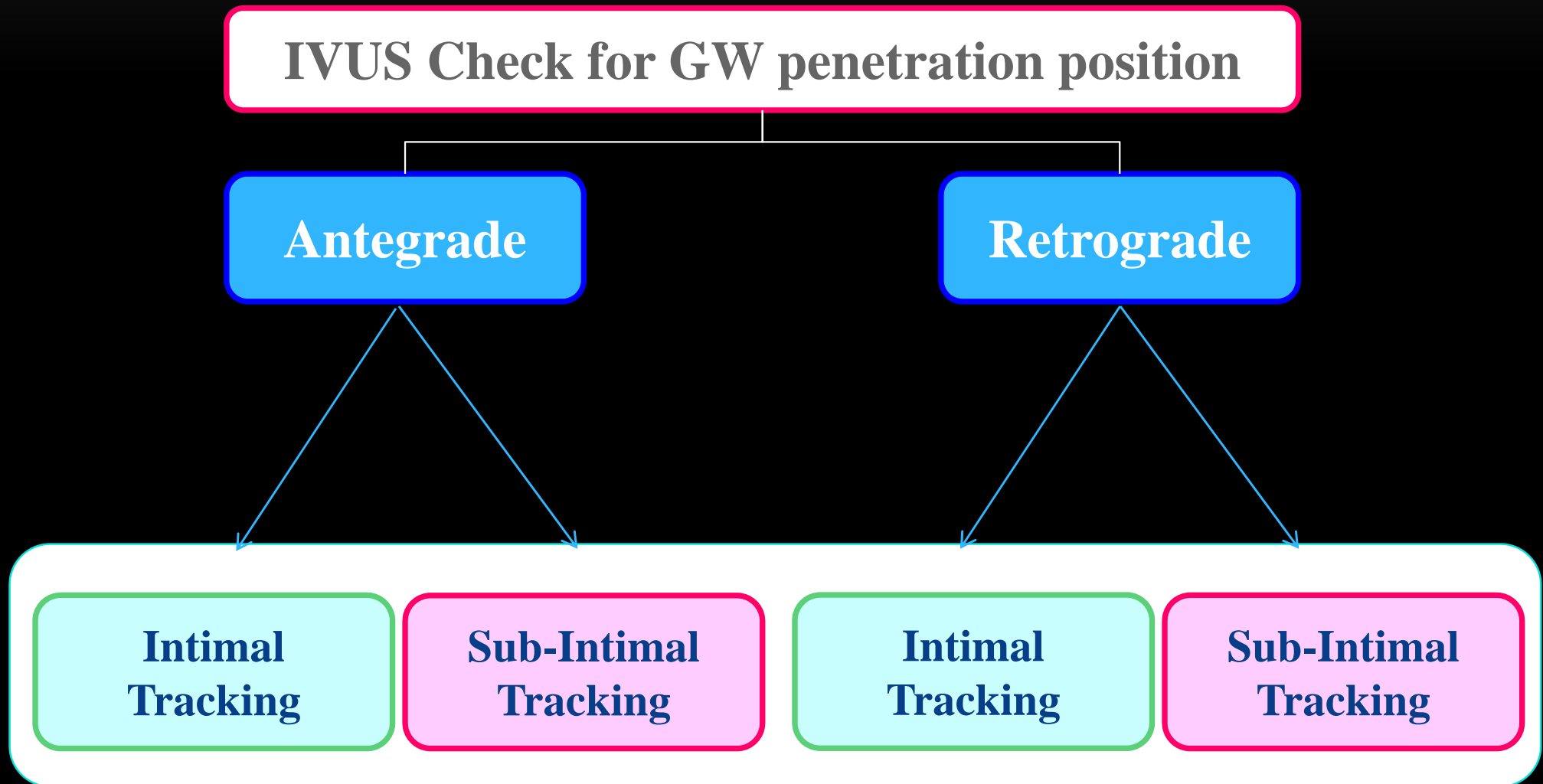
**PROMUS Stent Implantation**

**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

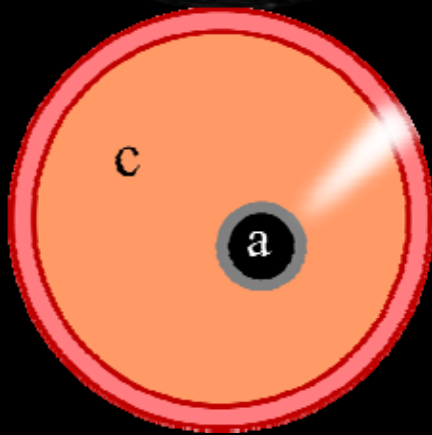
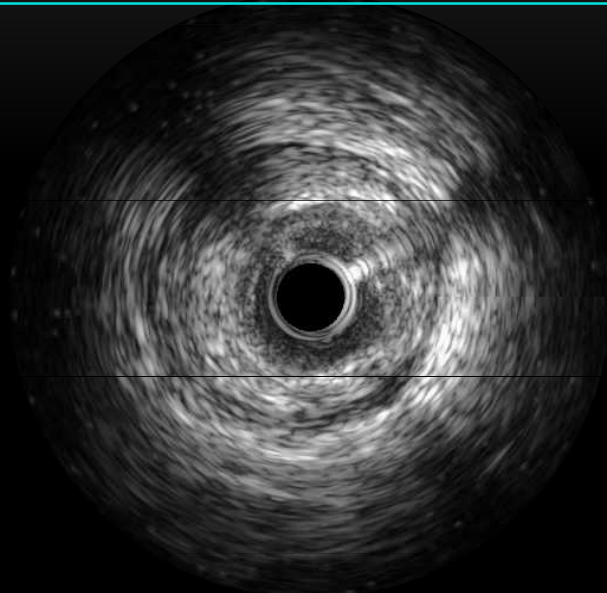
If the IVUS catheter was located in a dissection plane outside of intimal plaque but inside of EEM, even when it was localized.

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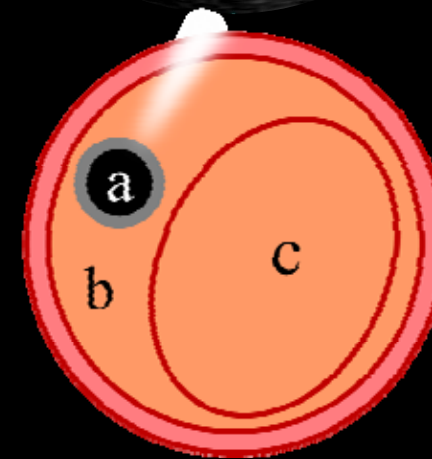
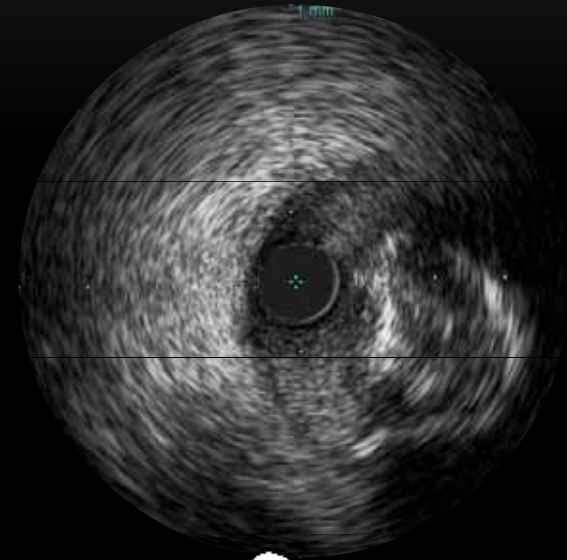


# IVUS Image

## 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
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# Study Investigators

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- Saiseikai Yokohama Tobu HP
  - Toyohashi Heart Center
  - The Cardiovascular Institute
  - Higashi Takarazuka Satoh HP
  - Sapporo Cardio Vascular Clinic
  - Showa University Northern Yokohama HP
  - Shinkoga HP
  - Tokorozawa Heart Center
  - Nagoya Heart Center
  - Tokushima Red Cross HP
  - Yotsuba Circulation Clinic
  - Hokko Memorial HP
  - Hokkaido Social Insurance HP
  - Toho University Medical Center Omori HP
  - Showa University HP
  - Kusatsu Heart Center
  - Rinku General Medical Center
  - Izumisano Municipal HP
  - Hamada Medical Center
  - Sayama Hospital
  - Shiga Medical Center for Adults
  - Nozaki Tokushukai HP
  - Nagoya Tokushukai General HP
  - Iwate Prefectural Central HP
  - Edogawa HP
  - Kokura Memorial HP
  - Hoshi General HP
  - Iwaki Kyoritsu General HP

# Baseline Patient Characteristics

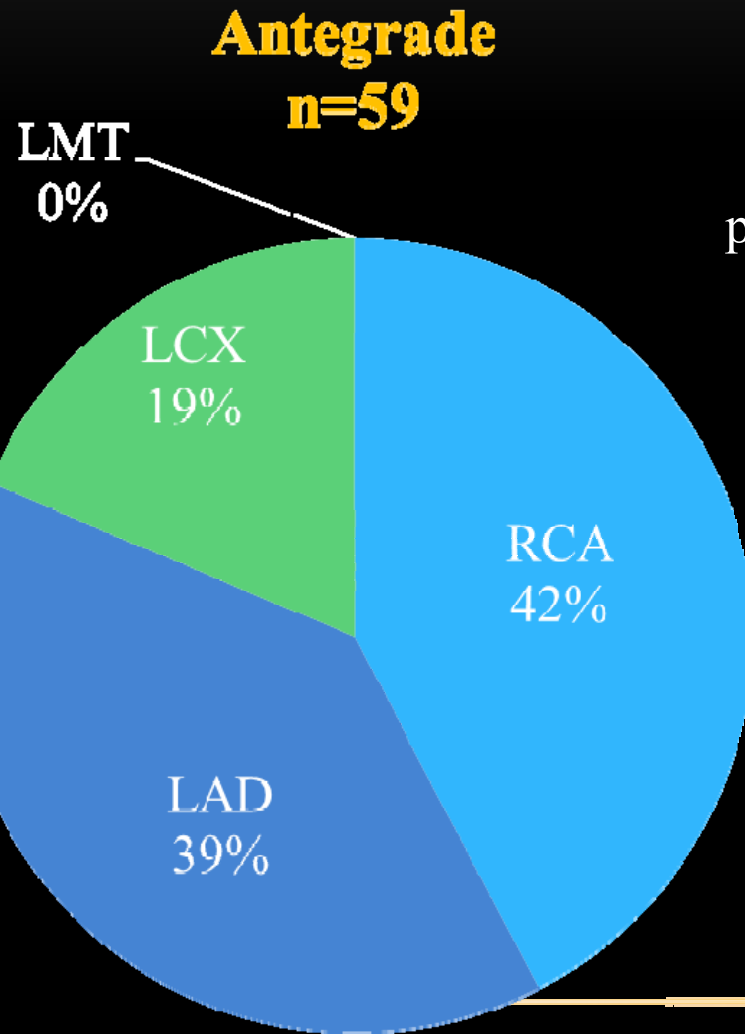
	Ante 59	Retro 104	p value
Male	86.4%	89.4%	0.62
Age (years)	65.4 ± 10.4	65.6 ± 10.6	0.95
Previous MI	30.5%	44.2%	0.10
Previous CABG	6.8%	12.5%	0.30
Previous PCI	35.6%	73.1%	<.0001
Hypertension	64.4%	69.2%	0.60
Diabetes mellitus	37.3%	33.7%	0.73
Hyperlipidemia	62.7%	76.9%	0.07
Smoking	22.0%	13.5%	0.19
Average diseased vessel	1.9 ± 0.8	1.8 ± 0.8	0.70
Multi vessel disease	61.0%	56.7%	0.62

# Lesion Characteristics

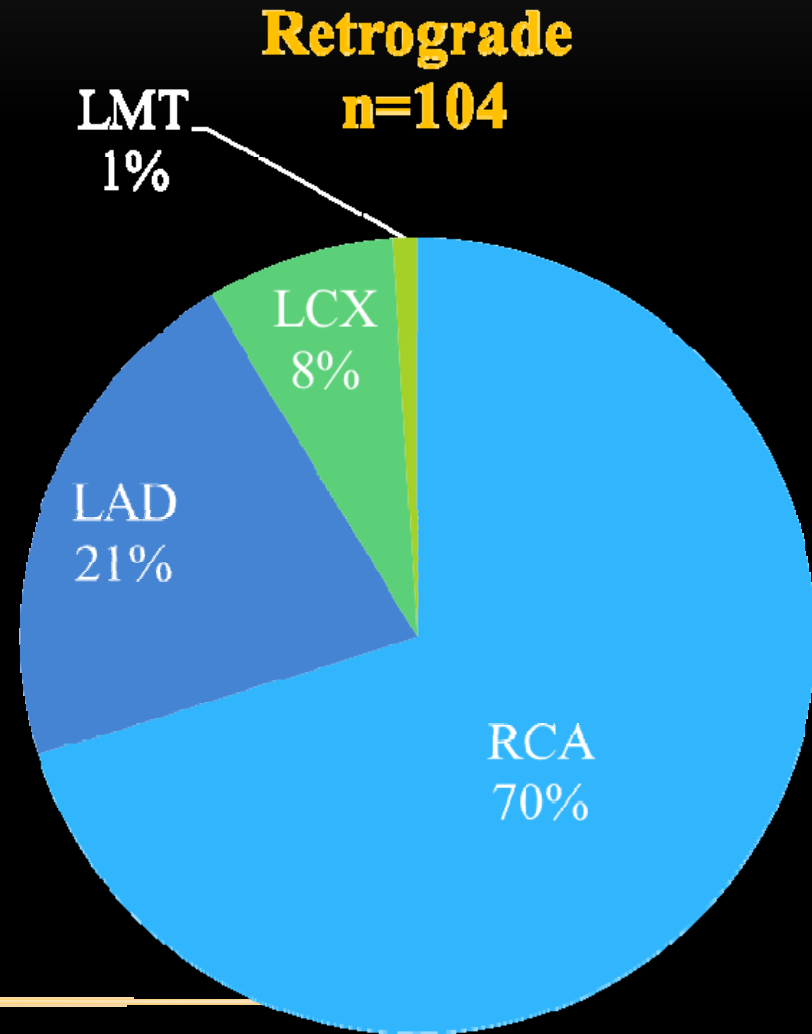
	Ante 59	Retro 104	p value
Calcification	67.8%	69.2%	0.86
Proximal tortuosity	33.9%	45.2%	0.19
Bending (>45)	3.4%	6.7%	0.49
Bifurcation	33.9%	29.8%	0.60
Occlusion length			
>20mm	52.5%	88.5%	<.0001
Reference diameter			
<3.0mm	42.4%	29.8%	0.12
2 <sup>nd</sup> attempt CTO PCI	5.1%	27.9%	0.0004
Bridge collateral	47.4%	45.5%	0.87



# Target Vessel



p = 0.0036



# 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
Stent diameter, mm	2.9 ± 0.4	3.0 ± 0.4	0.12
Stent length, mm	41.2 ± 20.6	59.6 ± 23.5	<0.0001
Maximum stent pressure	12.2 ± 3.3	13.9 ± 3.3	0.002

# Procedure Results

	Ante 59	Retro 104	p value
Procedure time, min	105.2 ± 60.1	187.7 ± 81.9	<.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	<.0001
Procedure events	5.1% (3)	7.7% (8)	0.7475
- GW perforation	5.1% (3)	5.8% (6)	1.00
- Channel injury	-	1.9%(2)	
- Donor artery trouble	-	0%	

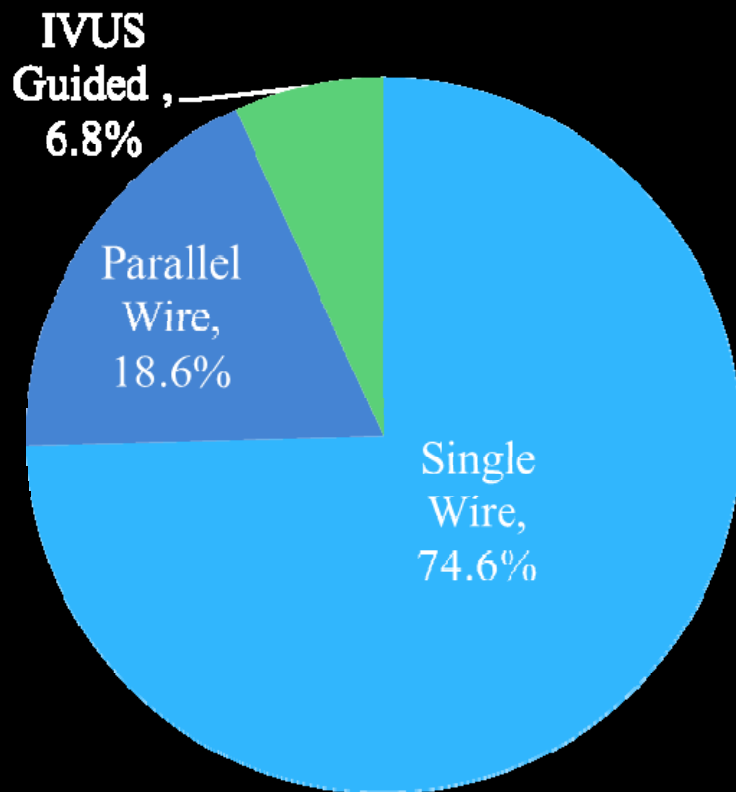


PROCEDURE  
ANTEGRADE & RETROGRADE

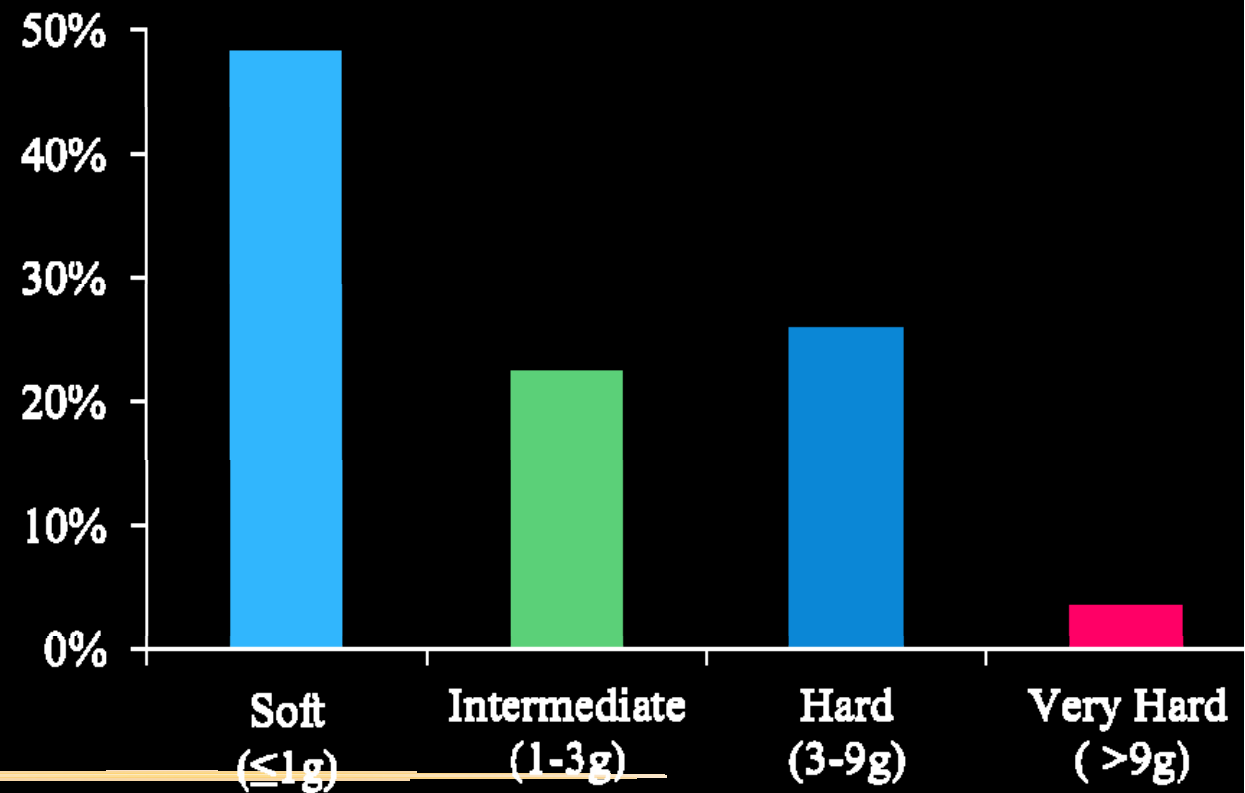
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# Antegrade Procedure GW technique and selection

## Antegrade GW technique



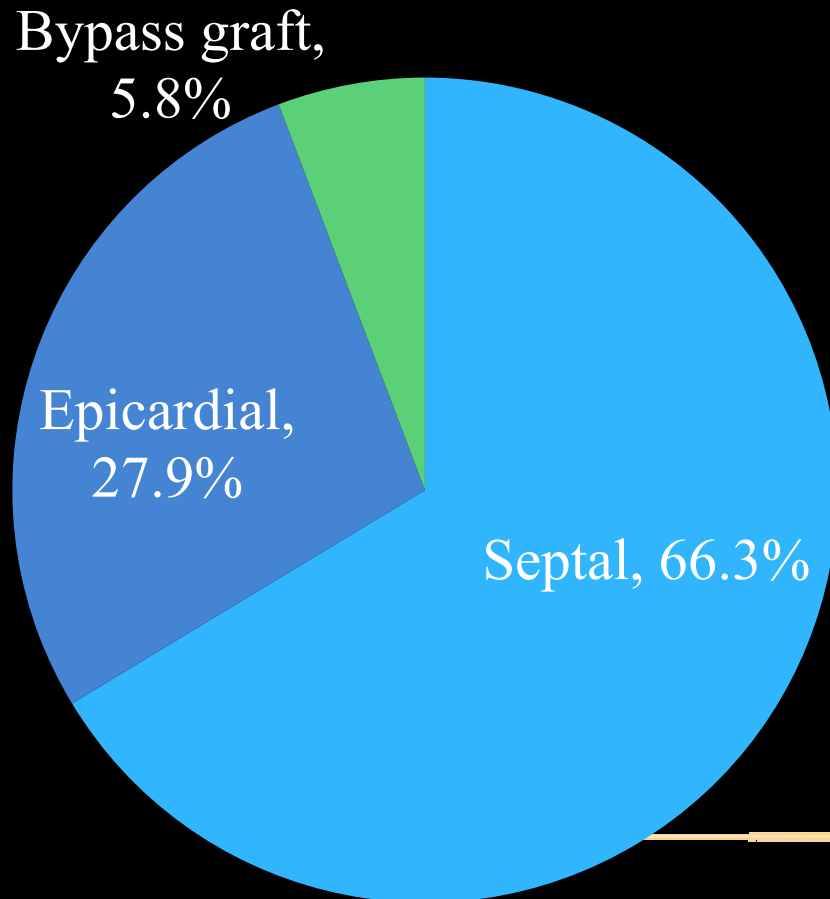
## Crossing GW CTO lesion



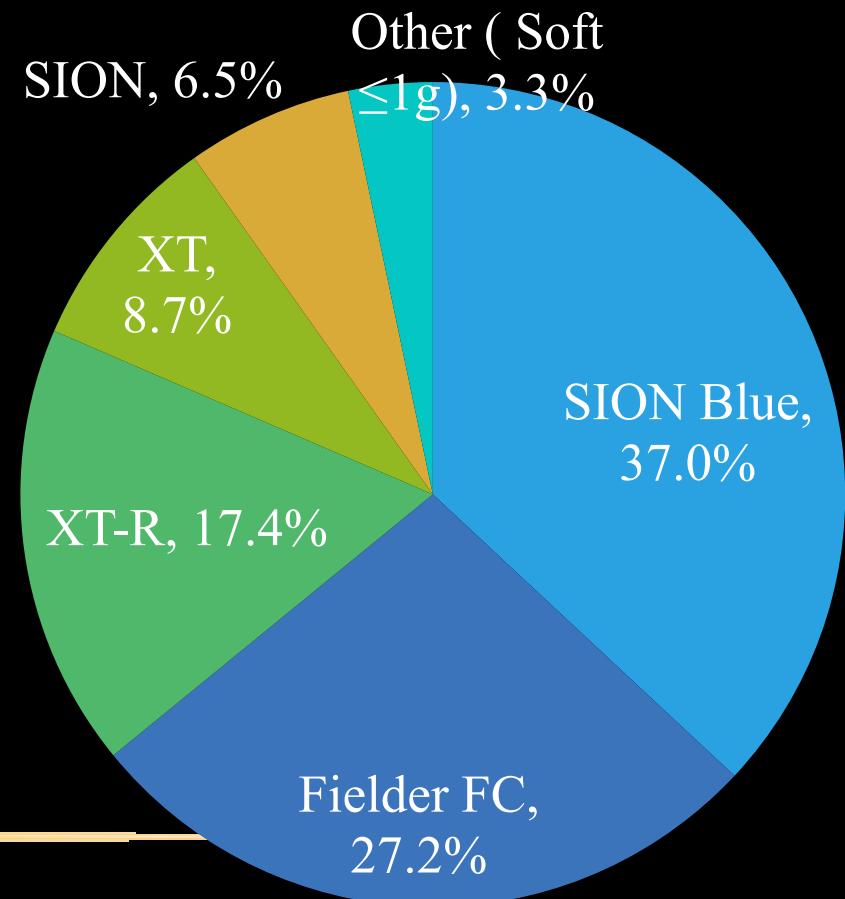
# Retrograde Procedure

## Collateral Crossing

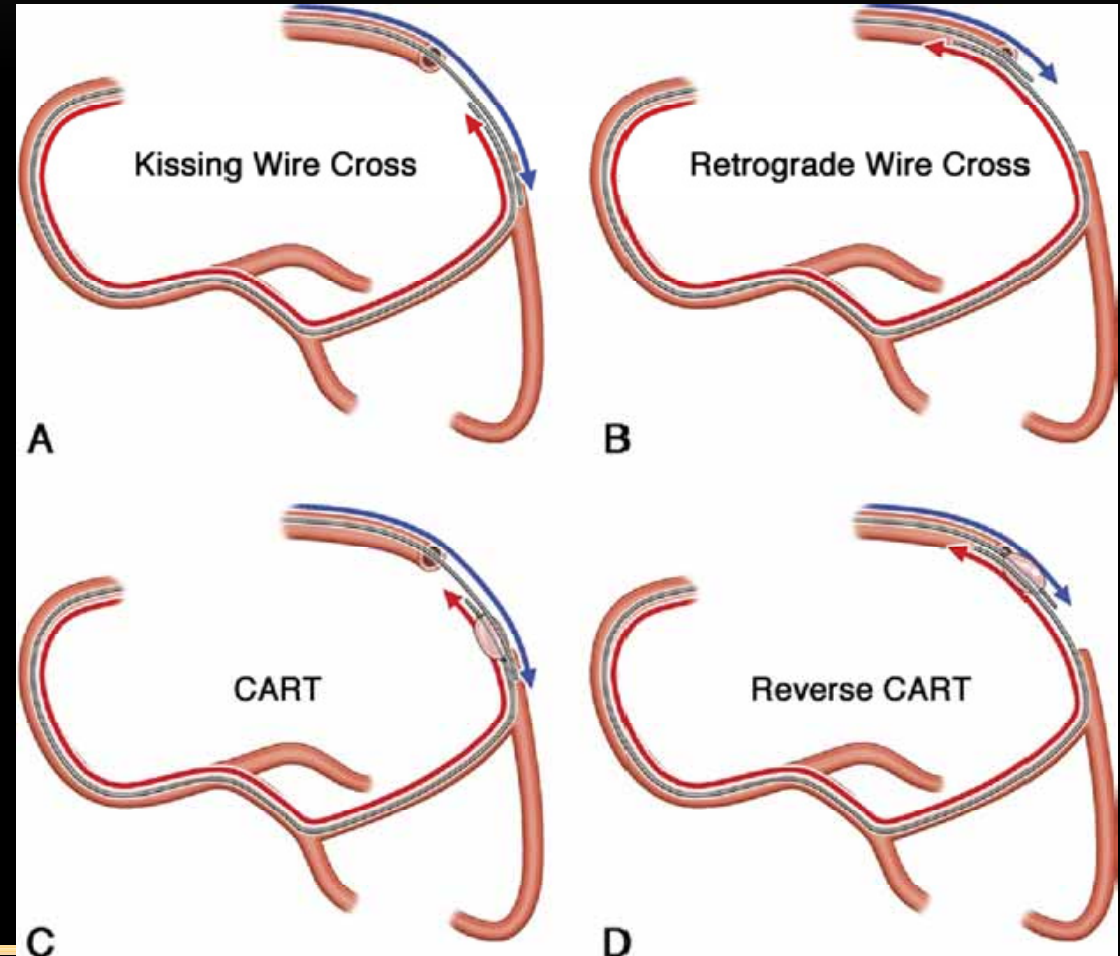
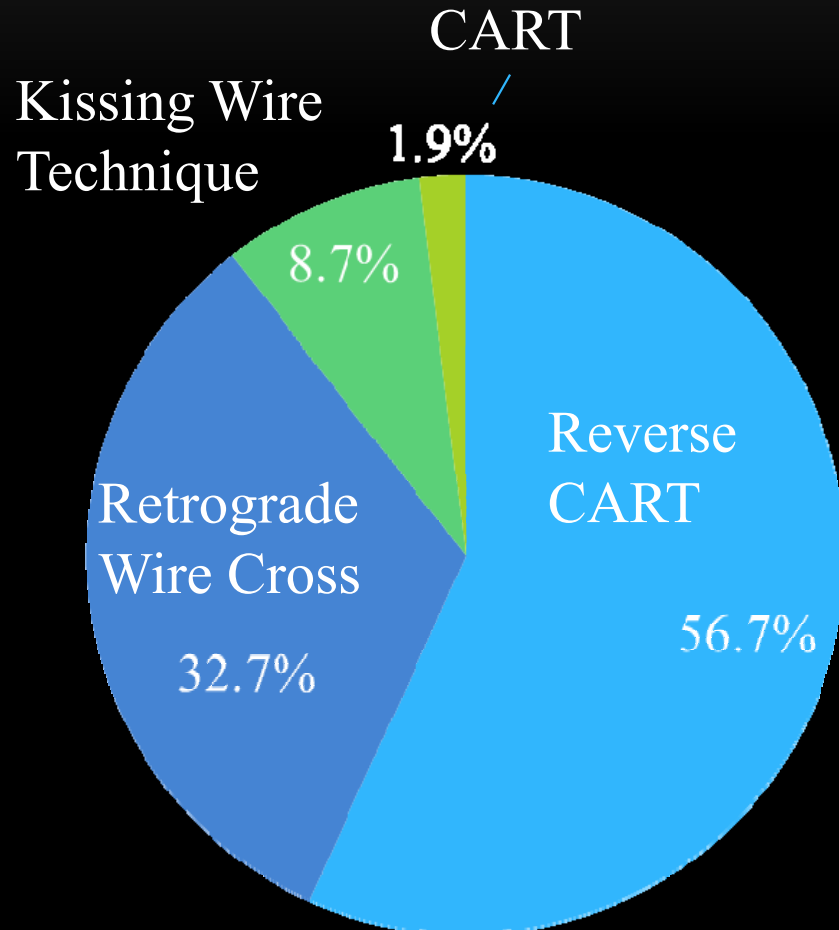
### Collateral Channel



### Crossing GW



# Retrograde Procedure Patterns of Success

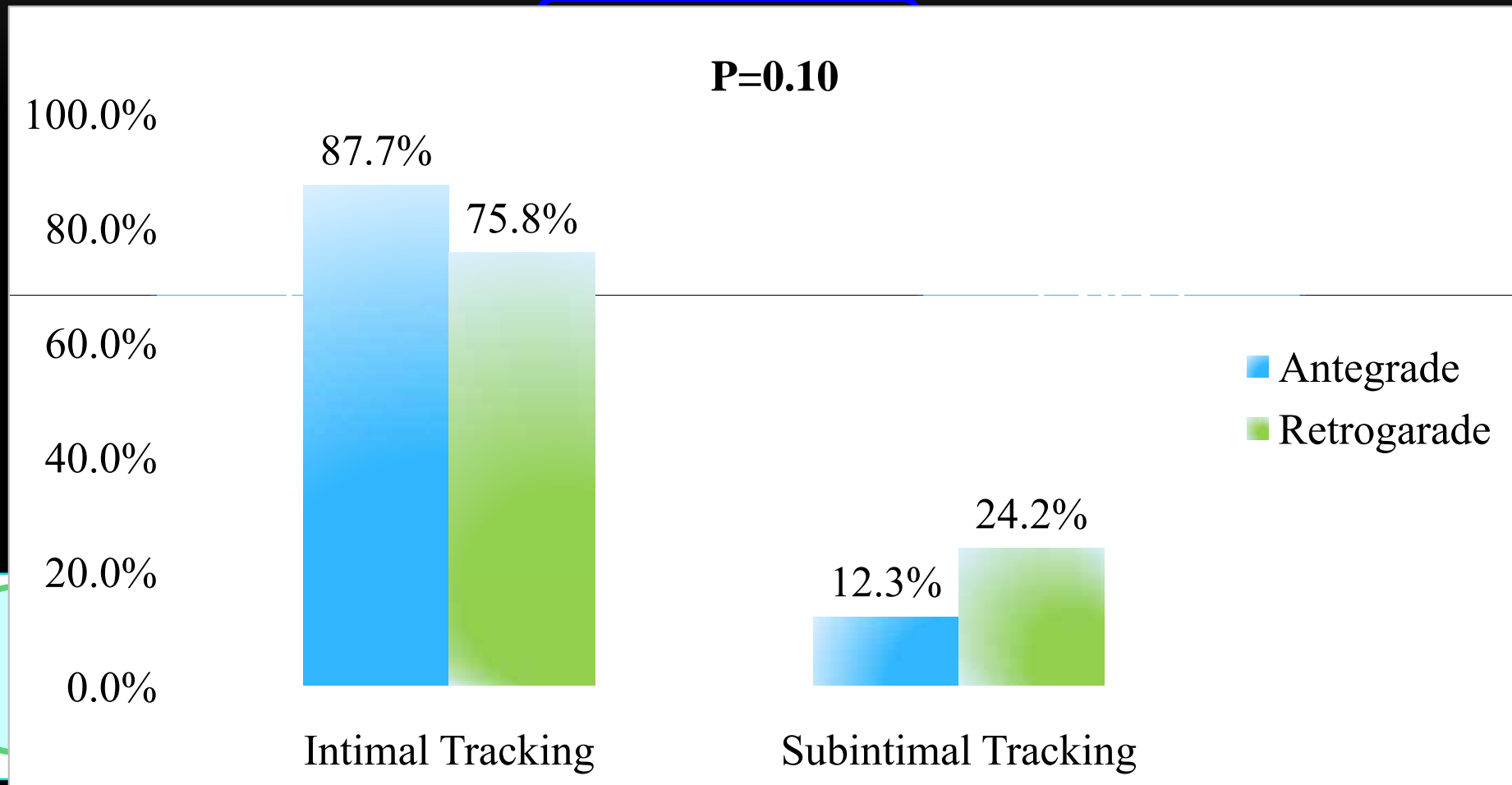


# IVUS ANALYSIS RESULTS

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# 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			
>20mm	72.0%	83.9%	0.25
Reference diameter			
<3.0mm	35.2%	29.0%	0.67
2 <sup>nd</sup> attempt CTO PCI	16.8%	32.3%	0.08
Bridge collateral	40.8%	61.3%	0.0456

# 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%	



# 12-MONTH FU CLINICAL RESULTS

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# MACE at 12 months

## Antegrade vs. Retrograde



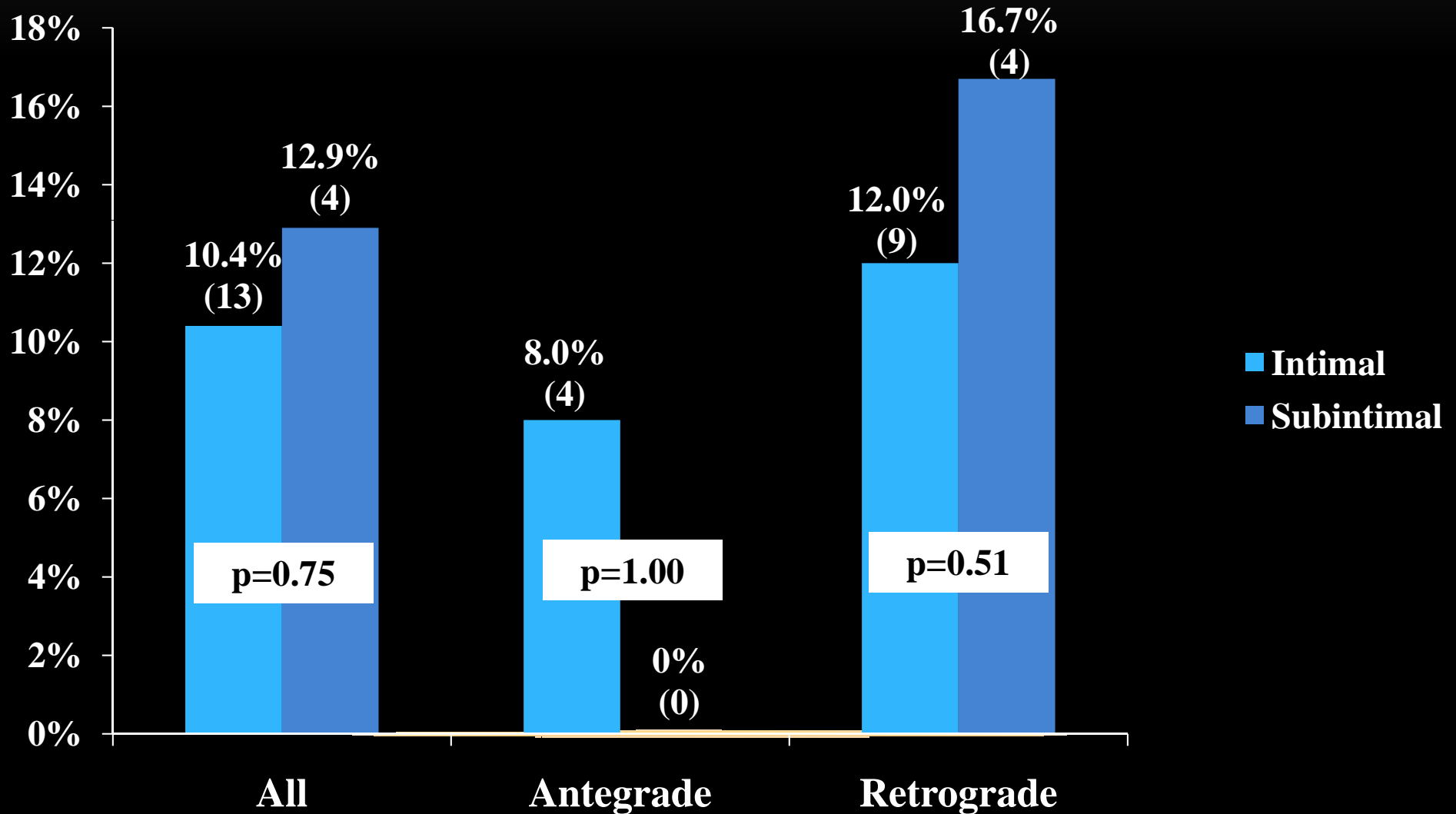
(Fu rate: 100%)

	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)	0 % (0)	
Cardiac death	0 % (0)	0 % (0)	
Non-Cardiac death	0 % (0)	1.0 %(*1)	1.00
SAT/LT	0 % (0)	0 % (0)	

\*Car Accident

# TVR at 12 months

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



# QCA RESULTS

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# Acute QCA Results

## Intimal vs. Sub-Intimal

	Intimal (125)	Sub-Intimal (31)	p value
<b><i>Pre Procedure</i></b>			
RVD, mm	2.8 ± 0.4	3.0 ± 0.4	0.02
Occlusion Length, mm	18.5 ± 14.8	23.9 ± 20.5	0.14
<b><i>Post Procedure( In stent)</i></b>			
RVD, mm	3.1 ± 0.5	3.2 ± 0.4	0.38
MLD, mm	2.6 ± 0.5	2.6 ± 0.4	0.91
Stent Length, mm	50.5 ± 23.8	60.5 ± 23.0	0.04
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
<i>In Stent</i>			
RVD, mm	3.0 ± 0.5	3.0 ± 0.4	0.87
MLD, mm	2.4 ± 0.7	2.0 ± 0.8	0.02
% DS, %	19.8 ± 19.1	30.4 ± 25.9	0.03
Late Loss, mm	0.2 ± 0.5	0.6 ± 0.9	0.02
Loss Index, %	7.8 ± 22.6	19.7 ± 30.3	0.04
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
<b><i>Pre Procedure</i></b>			
RVD, mm	2.9 ± 0.4	3.1 ± 0.4	0.06
Occlusion Length, mm	21.5 ± 15.5	28.1 ± 21.1	0.14
<b><i>Post Procedure( In stent)</i></b>			
RVD, mm	3.1 ± 0.5	3.2 ± 0.4	0.39
MLD, mm	2.6 ± 0.5	2.6 ± 0.4	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
<b><i>In Stent</i></b>			
RVD, mm	3.0 ± 0.5	3.0 ± 0.4	0.86
MLD, mm	2.3 ± 0.7	1.9 ± 0.8	0.05
% DS, %	23.2 ± 20.3	34.8 ± 26.7	0.05
Late Loss, mm	0.3 ± 0.5	0.6 ± 0.8	0.04
Loss Index, %	10.8 ± 24.9	24.6 ± 31.4	0.06
Reocclusion	2.7% (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



# Multivariate analysis

TVR Predictor	Odds Ratio	95% CI	P-value
Post Procedure RVD, mm	0.227	0.995-1.039	0.0179

Subintimal Predictor	Odds Ratio	95% CI	P-value
Previous PCI	2.904	1.151-7.328	0.02
Bridge collateral	2.415	1.061-5.497	0.0356

# Limitation

- Non randomized observational study
  - Limited case number
  - Relatively low rate of follow-up angiography (78.2%)
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# Summary

- Lesion length was significantly longer and reattempted case rate was higher for retrograde approach than antegrade.
- According to IVUS analysis results, Sub-intimal tracking tended to be higher in retrograde approach than antegrade.
- Sub-intimal tracking group lesion characteristics were more severe.
- No significant difference was observed in MACE rate at 12 months between Intimal tracking and Sub-intimal tracking, in both antegrade and retrograde approach arms.
- Acute QCA analysis identified longer occlusion and stent lengths in the sub-intimal group.
- FU QCA analysis showed higher late loss in the Sub-intimal group, but no difference in re-occlusion rate.

## Conclusion

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