IVUS-guided CTO intervention

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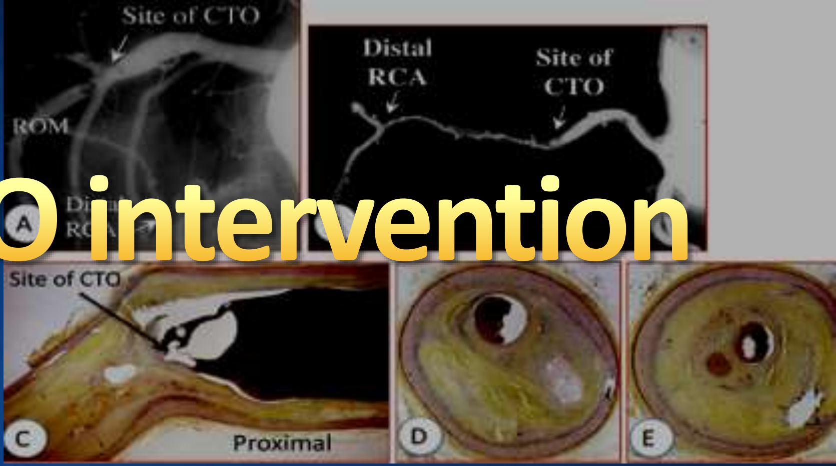
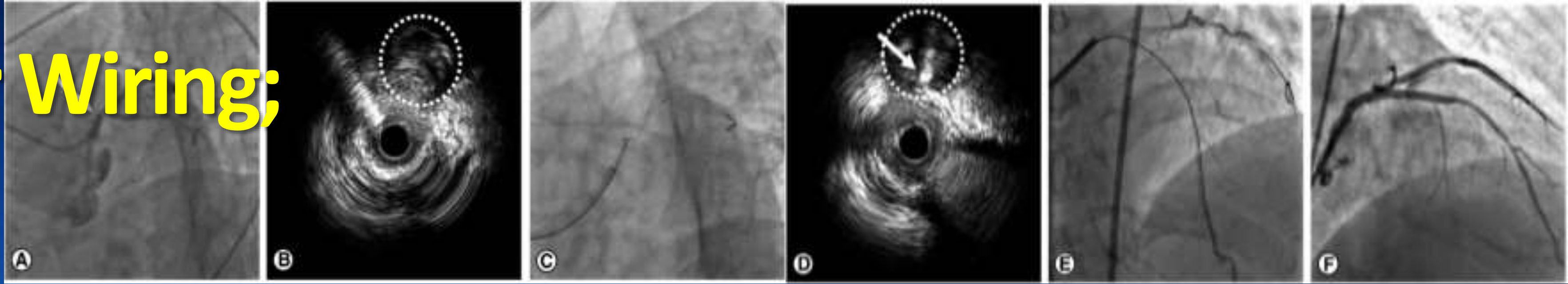
Role of IVUS for CTO intervention



- For wire-crossing
- Pre-stenting use
- Post-stenting use

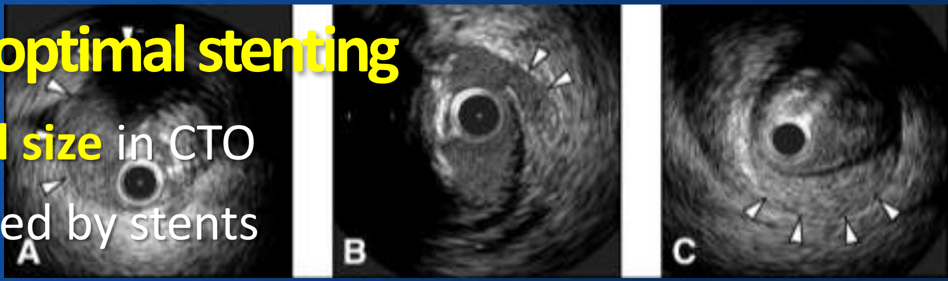
For Wiring;



- For the stumpless CTO lesions, IVUS guidance has been reported to lead a higher success rate.
  1) useful in revealing the entry point of occlusion.
  2) useful in repositioning a guidewire in the event of inadvertent sub-intimal passage.

Park et al. Int J Cardiol 2009

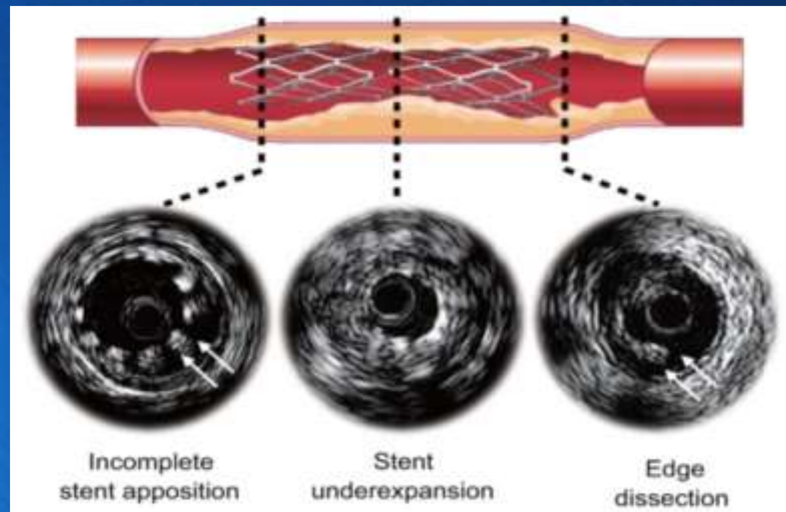
Pre-stenting; information for optimal stenting



- Accurate information regarding **vessel size** in CTO
- Determination of **lesion length**, covered by stents
- Evaluation of the **characteristics of plaques**
- Evaluation of the **complications of CTO intervention** such as dissection, hematoma, or vessel rupture
- Exact determination of the **location of guidewire**; true or false ?

Post-stenting;

IVUS for the optimal stenting

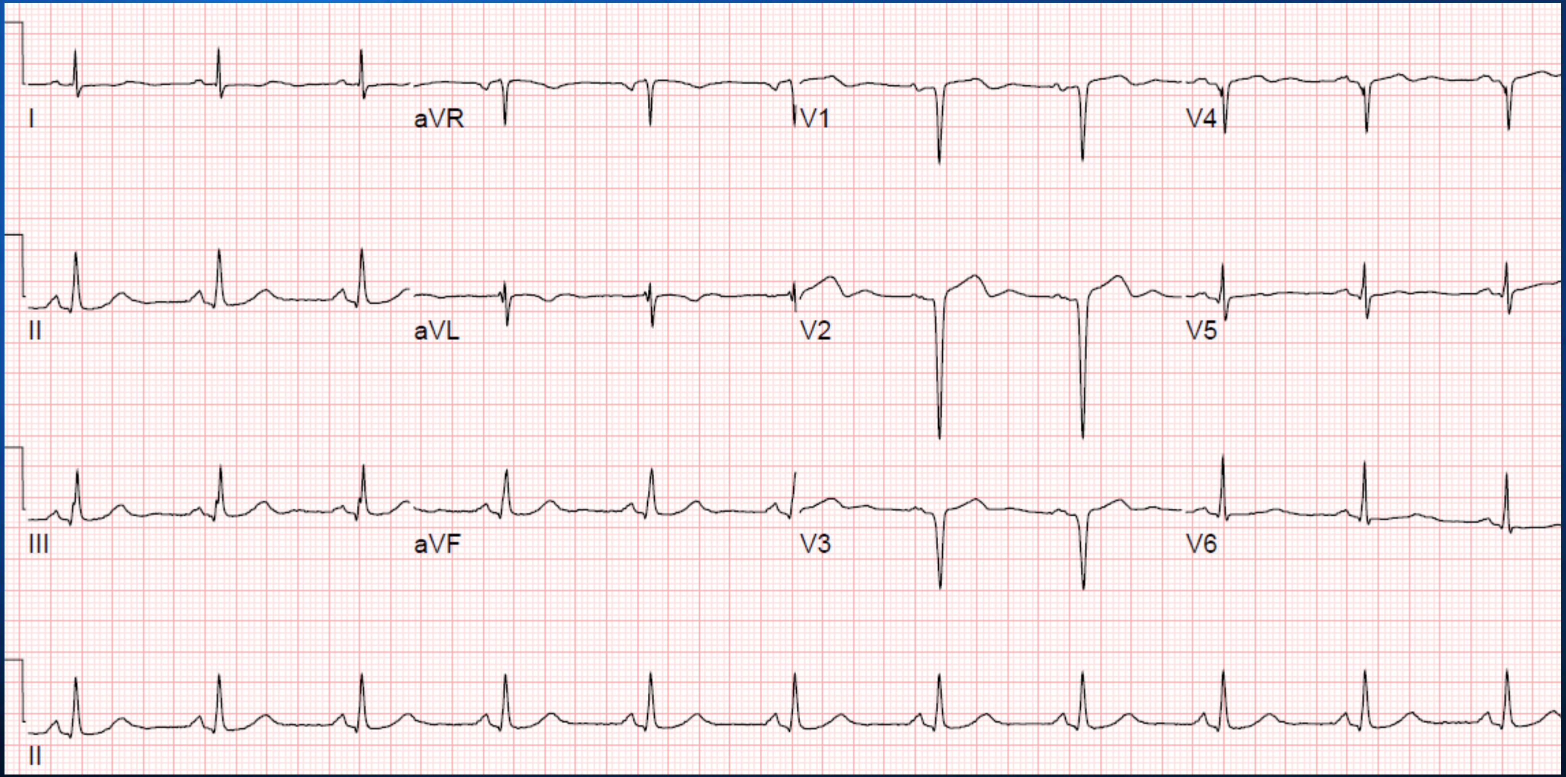


Yoon & Hur. KJIM 2012

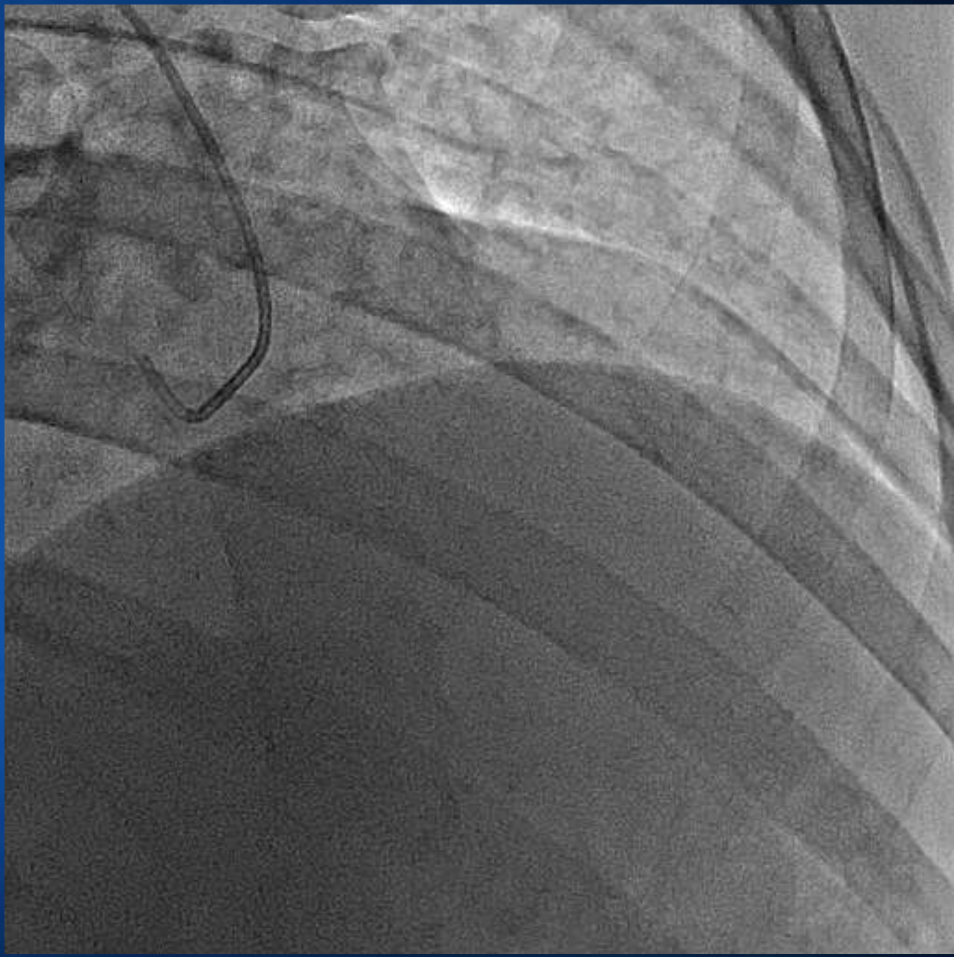
- Evaluation of the **optimal expansion** of stents
  - ✓ Prevention of stent underexpansion
  - ✓ Improvement of stent eccentricity
- Evaluation of the reference segment, especially **CTO distal segment**
- Evaluation of the **mechanical problems of stents** in CTO lesions

Case. F/52

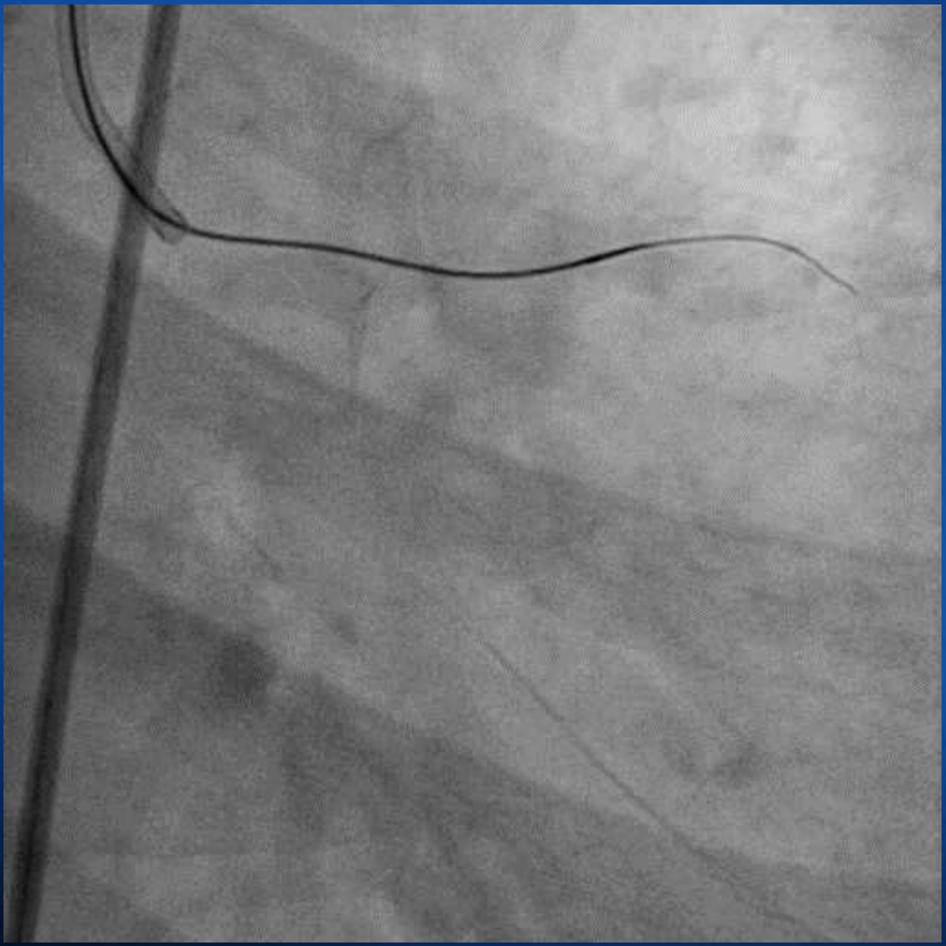
- CC: chest pain
- Risk factor: DM (10yrs, Insulin), HTN (10yrs)
- Echo : EF=44%, RWMA at LAD territory (hypokinesia without thinning)

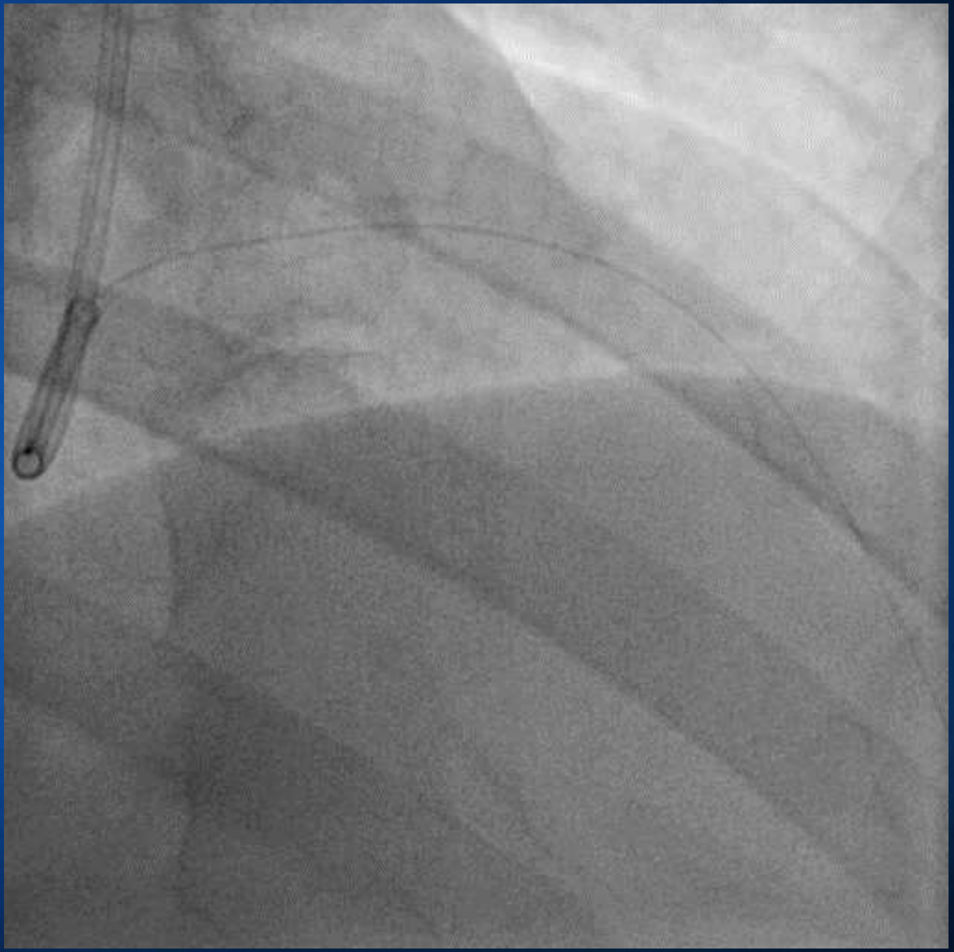


Diagnostic c-angio; LAD CTO

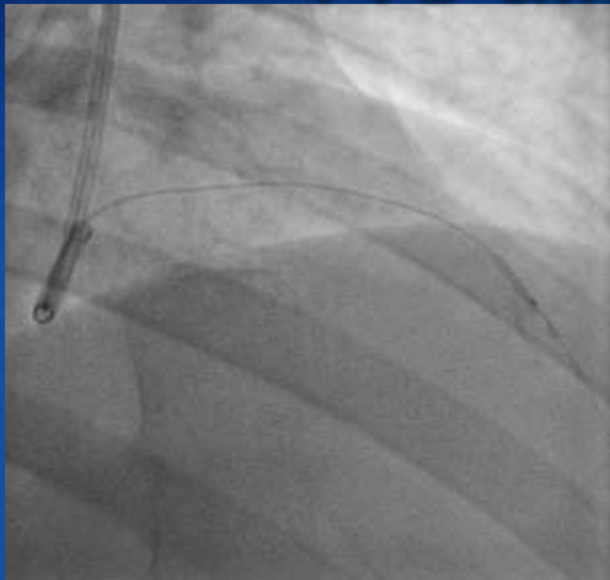


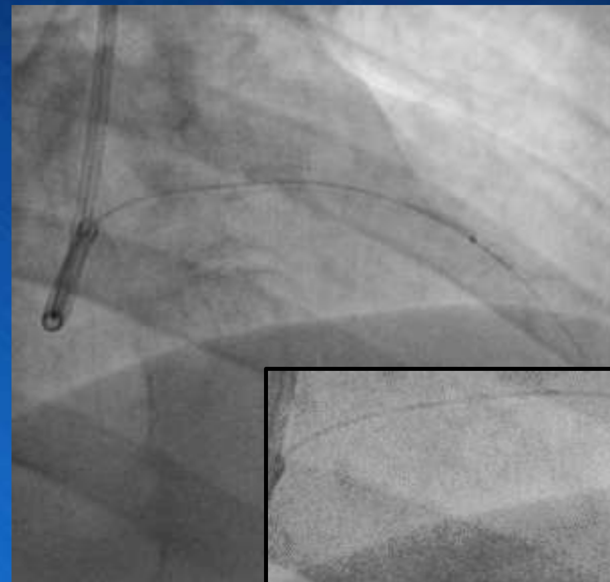
Successful guidewire-crossing by antegrade approach

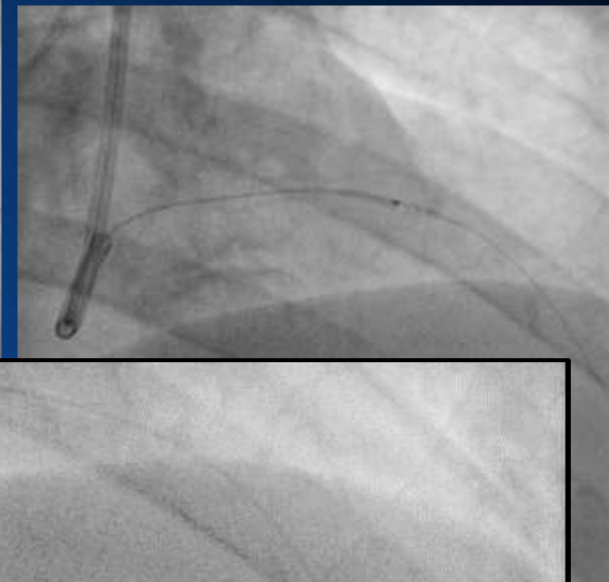


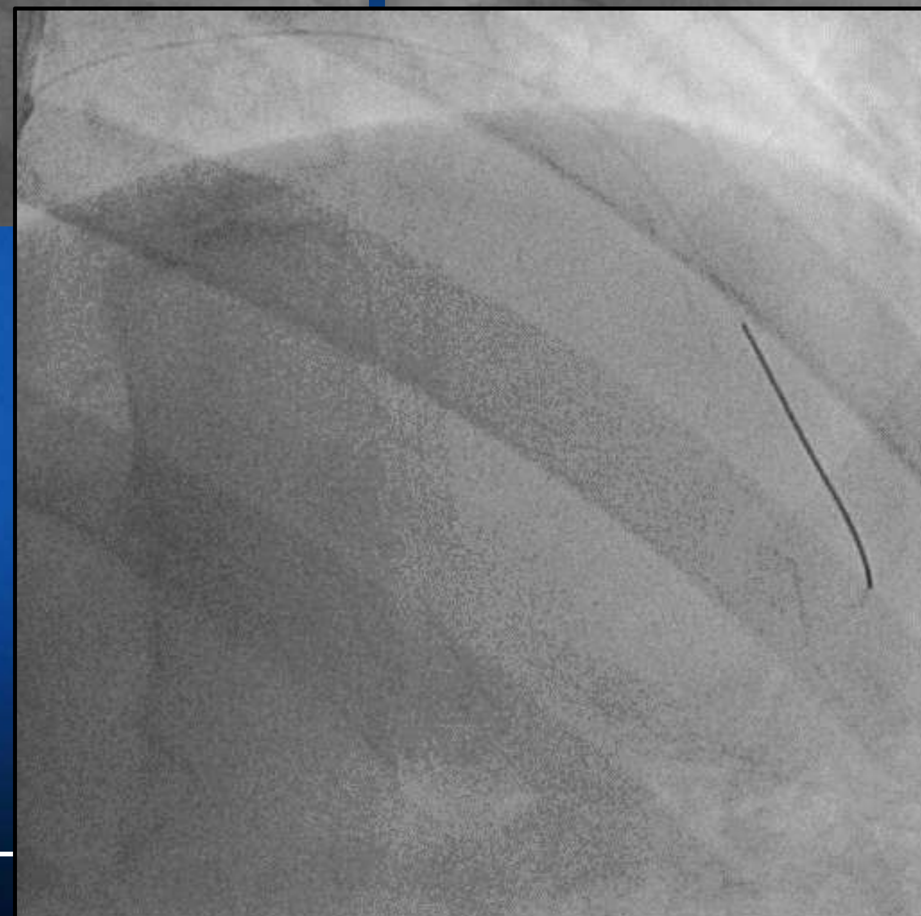


Pre-dilation from distal to mid-LAD

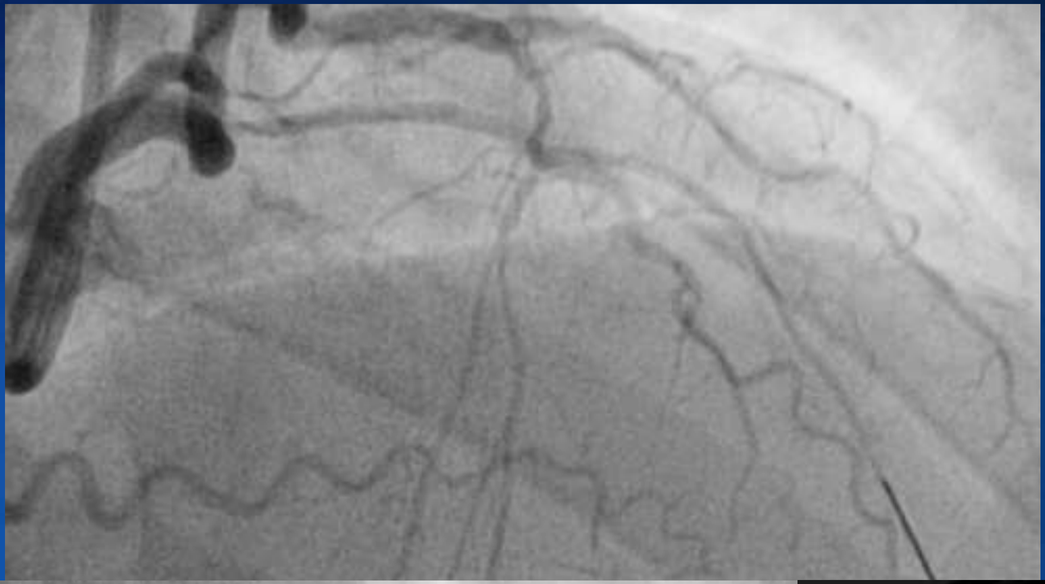




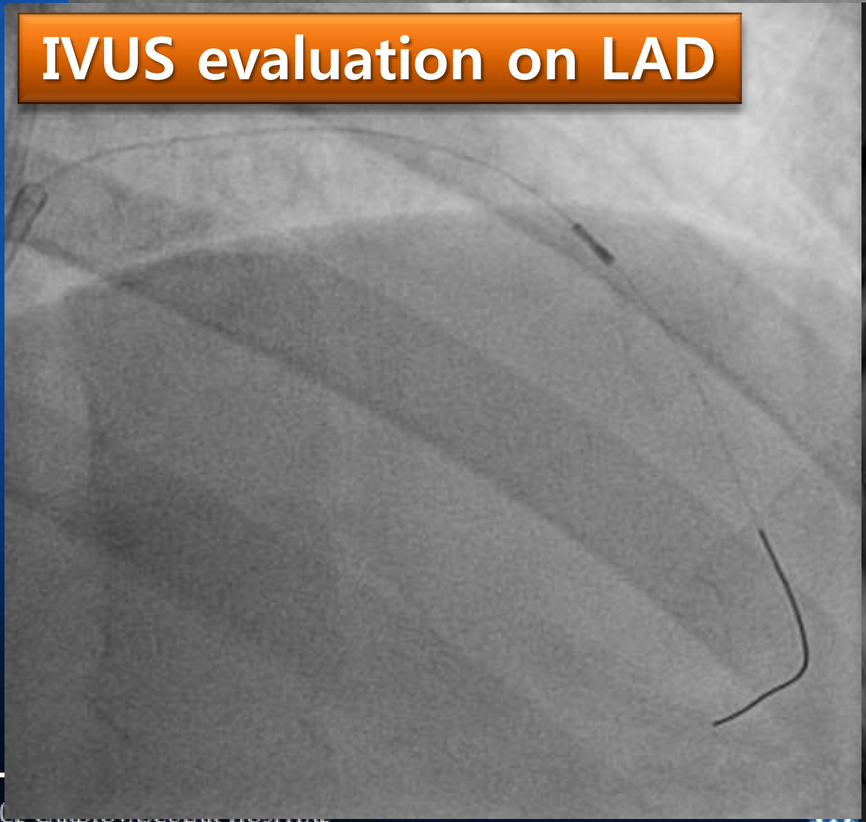


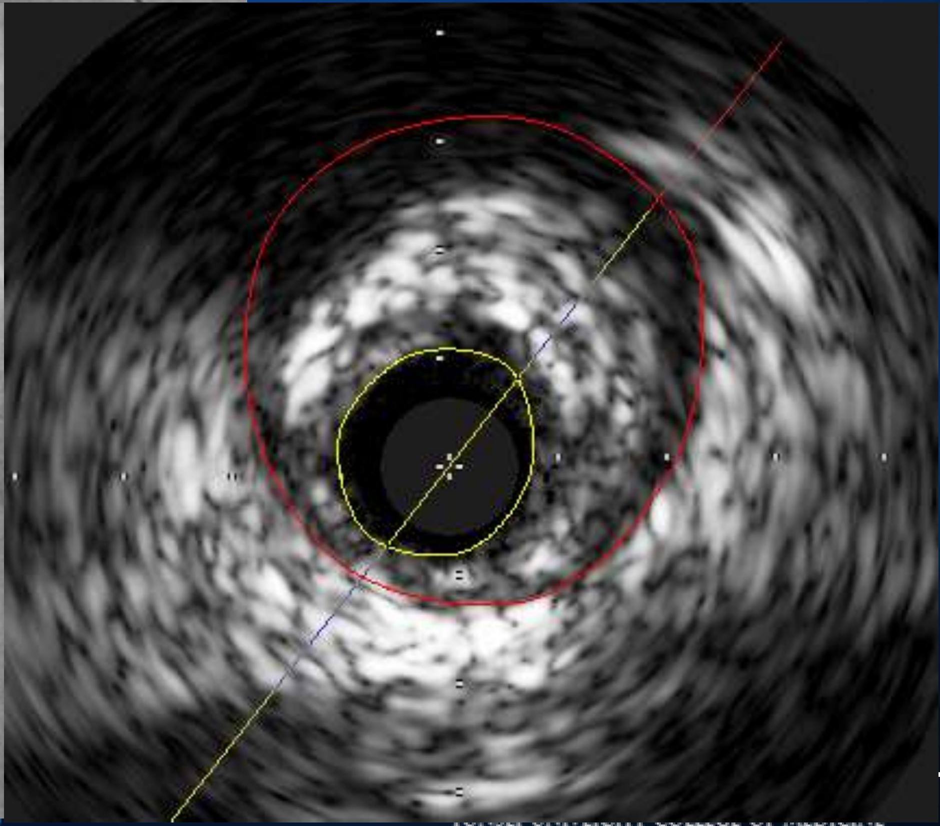


- *Diffusely narrowing LAD from proximal to distal, TIMI=2*

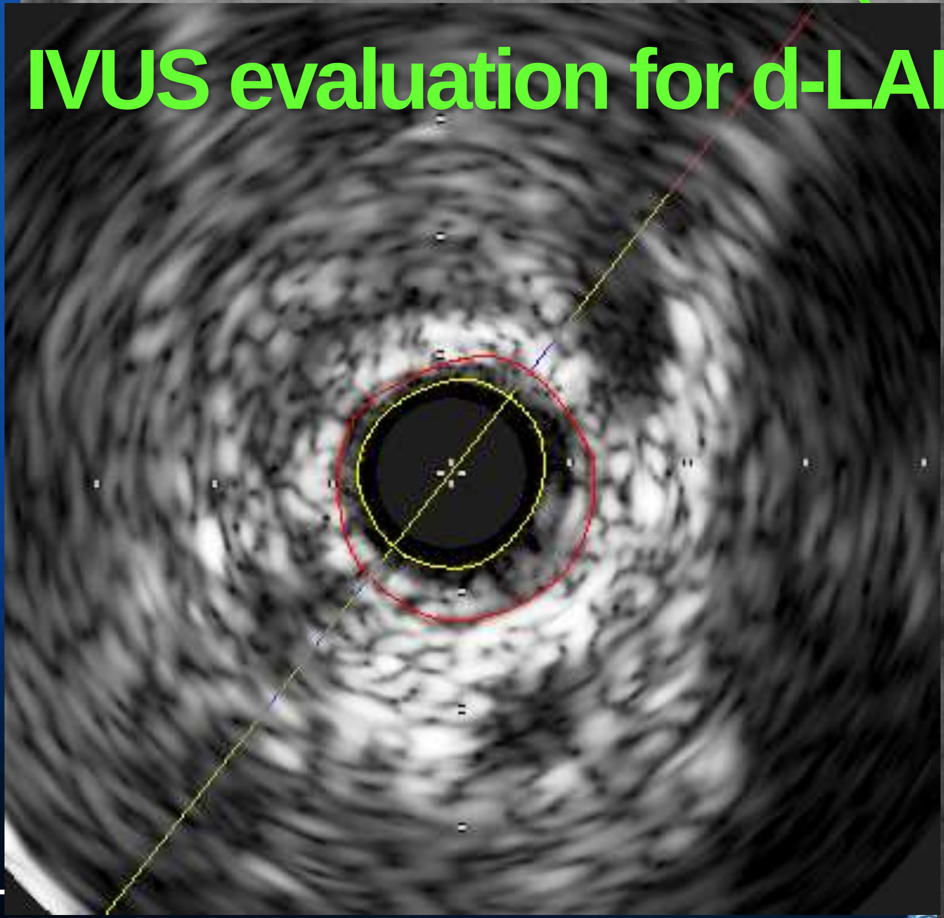


IVUS evaluation on LAD

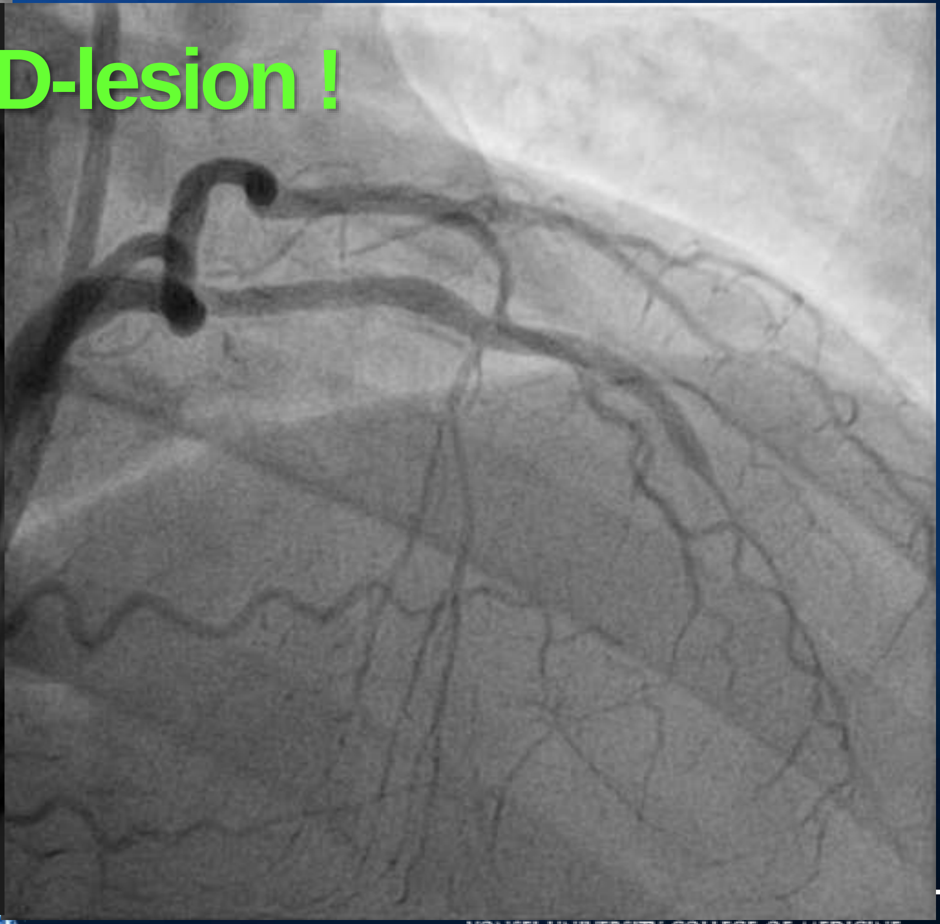




Two Resolute Integrity (2.75 x 26 & 2.5 x 30 mm) implantation on the m-LAD-lesion

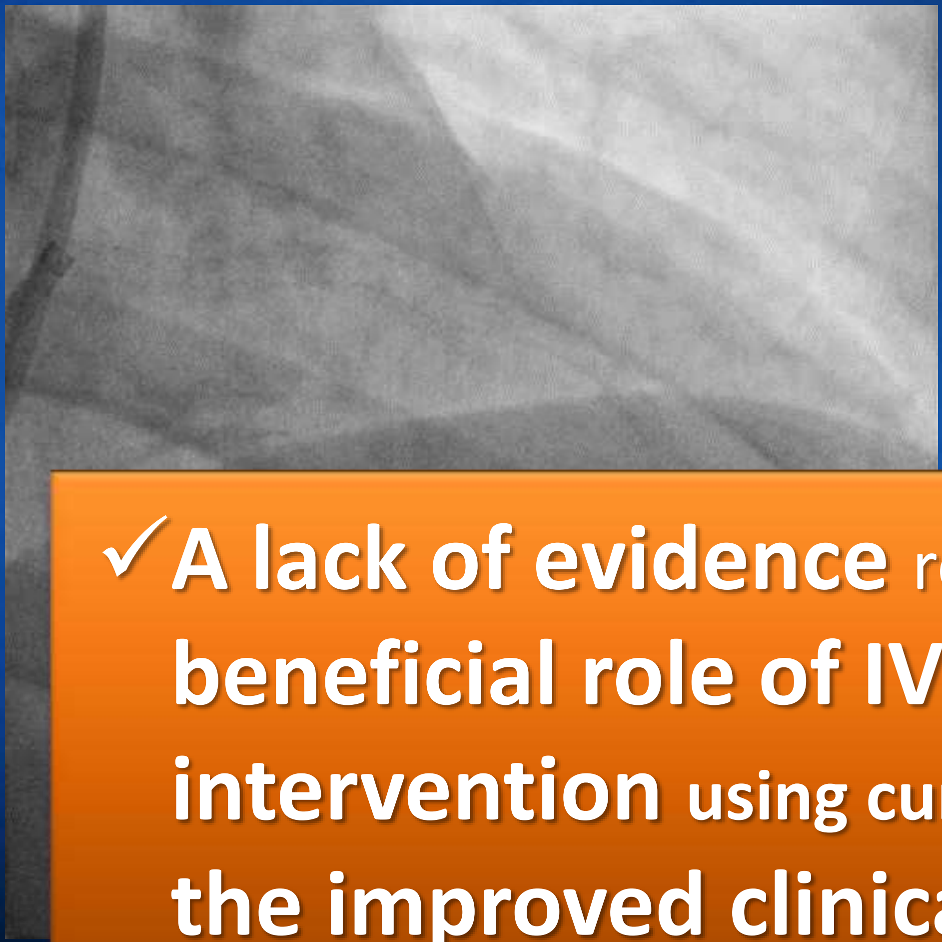


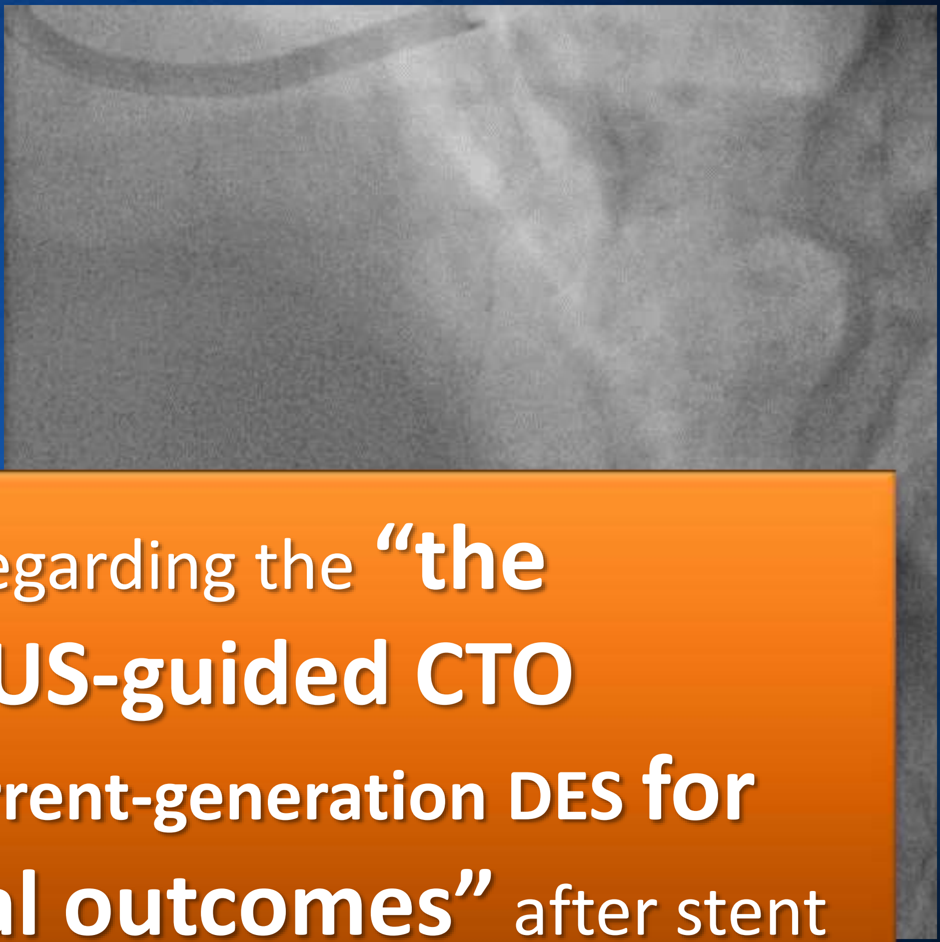
IVUS evaluation for d-LAD-lesion !



Finished the procedure without stenting or ballooning …

Final angiography





✓ **A lack of evidence** regarding the **"the beneficial role of IVUS-guided CTO intervention** using current-generation DES **for the improved clinical outcomes"** after stent implantation.

Usefulness of Intravascular Ultrasound Guidance in Percutaneous Coronary Intervention With Second-Generation Drug-Eluting Stents for Chronic Total Occlusions (from the Multicenter Korean-Chronic Total Occlusion Registry)

CrossMark

Study at a glance

K-CTO Registry (N=2568)

Failed: n=523

Success
n=2045

First-generation DES: n=1128
First- and second-generation DES: n=68
No information: n=315

Final Analysis n=534
Zotarolimus-eluting stents: n=344 / Everolimus-eluting stents: n=190

IVUS-guided CTO PCI
n=206 (39%)

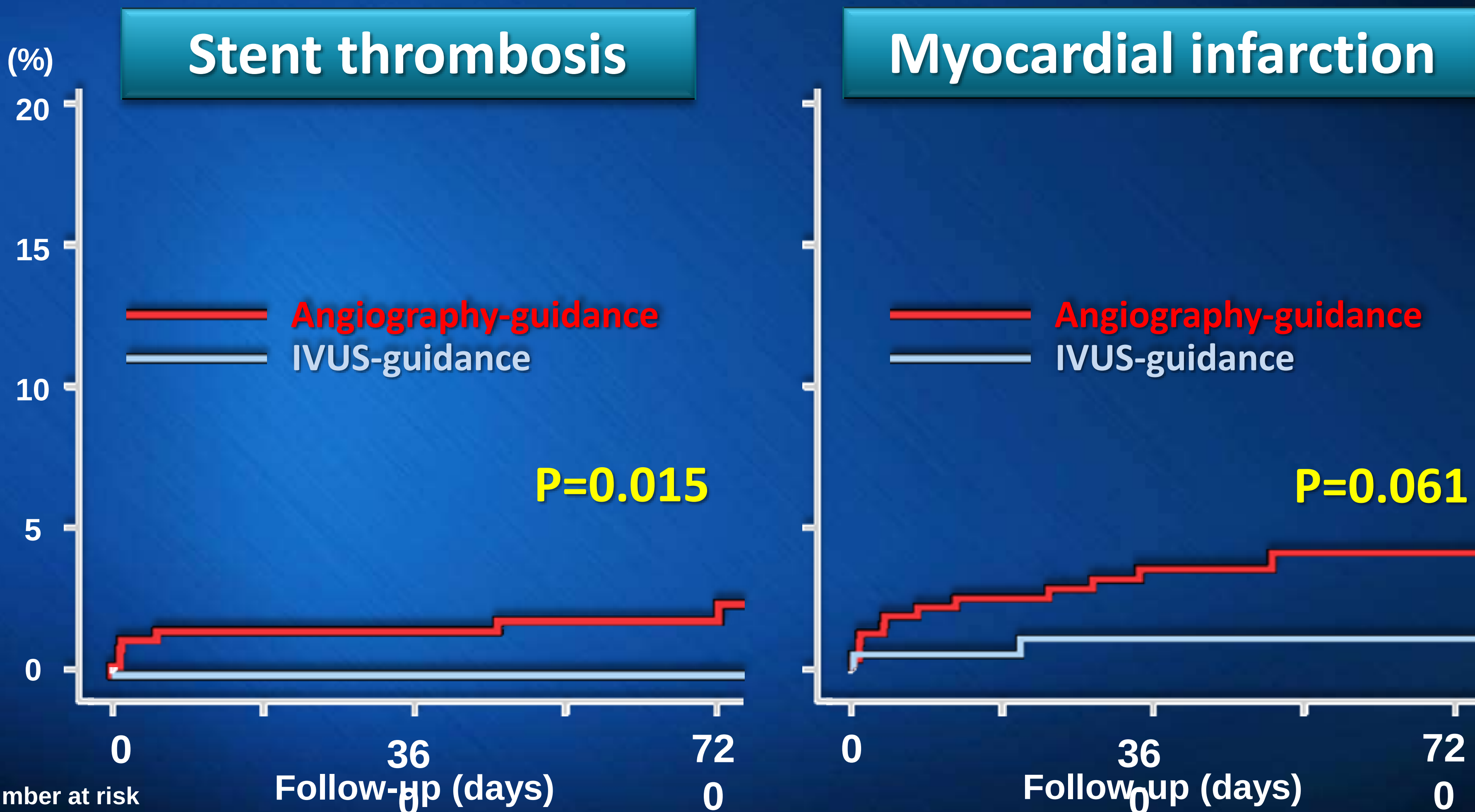
Angiography-guided CTO PCI
n=328 (61%)

- **Primary endpoint;** ***Definite or probable ST after propensity-score matching***

Hong SJ & Kim BK, et al. Am J Cardiol 2014;114:534-40.

IVUS-guidance vs. Angiography- guidance

in 201 propensity score-matched pairs



Number at risk						
Angio	201	180	112	201	180	110
IVUS	201	170	116	201	170	115

Limitation

- **Non-randomized, retrospective study**

✓ ***Based on these registry data,***
we performed randomized CTO trial.

Randomized CTO-IVUS study

Coronary Interventions

Clinical Impact of Intravascular Ultrasound–Guided Chronic Total Occlusion Intervention With Zotarolimus-Eluting Versus Biolimus-Eluting Stent Implantation

Randomized Study

Byeong-Keuk Kim, MD; Dong-Ho Shin, MD; Myeong-Ki Hong, MD; Hun Sik Park, MD; Seung-Woon Rha, MD; Gary S. Mintz, MD; Jung-Sun Kim, MD; Je Sang Kim, MD; Seung-Jin Lee, MD; Hee-Yeol Kim, MD; Bum-Kee Hong, MD; Woong-Chol Kang, MD; Jin-Ho Choi, MD; Yangsoo Jang, MD; for the CTO-IVUS Study Investigators*

Background—There have been no randomized studies comparing intravascular ultrasound (IVUS)–guided versus conventional angiography–guided chronic total occlusion (CTO) intervention using new-generation drug-eluting stent Therefore, we conducted a prospective, randomized, multicenter trial designed to test the hypothesis that IVUS-guided CTO intervention is superior to angiography-guided intervention.

Methods and Results—After successful guidewire crossing, 402 patients with CTOs were randomized to the IVUS-guided group (n=201) or the angiography-guided group (n=201) and secondarily randomized to Resolute zotarolimus-eluting stents or Nobori biolimus-eluting stents. The primary and secondary end points were cardiac death and a major adverse cardiac event defined as the composite of cardiac death, myocardial infarction, or target-vessel revascularization, respectively. After 12-month follow-up, the rate of cardiac death was not significantly different between the IVUS-guided group (0%) and the angiography-guided group (1.0%; *P* by log-rank test=0.16). However, major adverse cardiac event rates were significantly lower in the IVUS-guided group than that in the angiography-guided group (2.6% versus 7.1%; *P*=0.035; hazard ratio, 0.35; 95% confidence interval, 0.13–0.97). Occurrence of the composite of cardiac death or myocardial infarction was significantly lower in the IVUS-guided group (0%) than in the angiography-guided group (2.0%; *P*=0.045). The rates of target-vessel revascularization were not significantly different between the 2 groups. In the comparison between Resolute zotarolimus-eluting stent and Nobori biolimus-eluting stent, major adverse cardiac event rates were not significantly different (4.0% versus 5.7%; *P*=0.45).

Conclusions—Although IVUS-guided CTO intervention did not significantly reduce cardiac mortality, this randomized study demonstrated that IVUS-guided CTO intervention might improve 12-month major adverse cardiac event rate after new-generation drug-eluting stent implantation when compared with conventional angiography-guided CTO intervention.

Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01563952.

(*Circ Cardiovasc Interv*. 2015;8:e002592. DOI: 10.1161/CIRCINTERVENTIONS.115.002592.)

Randomized CTO-IVUS study

Objective

To test the hypothesis …

“IVUS-guided CTO intervention is superior to conventional angiography-guided CTO intervention”

Randomized CTO-IVUS study

A prospective, multi-center (20 centers in Korea), randomized trial

Total 467 patients with CTO were initially screened

Primary endpoint; **Composite of Cardiac death, MI, ST, & TVR at 12 months**

✓ Exclusion
- Wiring failure ; 61 patients
- Refusal of study enrollment ; 4 patients

A total of 402 patients were finally enrolled after successful guidewire-crossing

1:1 randomization

IVUS-guided group (n=201)

Angiography-guided group (n=201)

1:1 *randomization*
R-ZES vs. N-BES

Clinical follow-up for 12 months

Recommendation in the IVUS-guided group: 1) MSA ≥distal reference LA; 2) SA at CTO segment ≥5 mm^2 as far as vessel area permits; and 3) complete stent apposition.

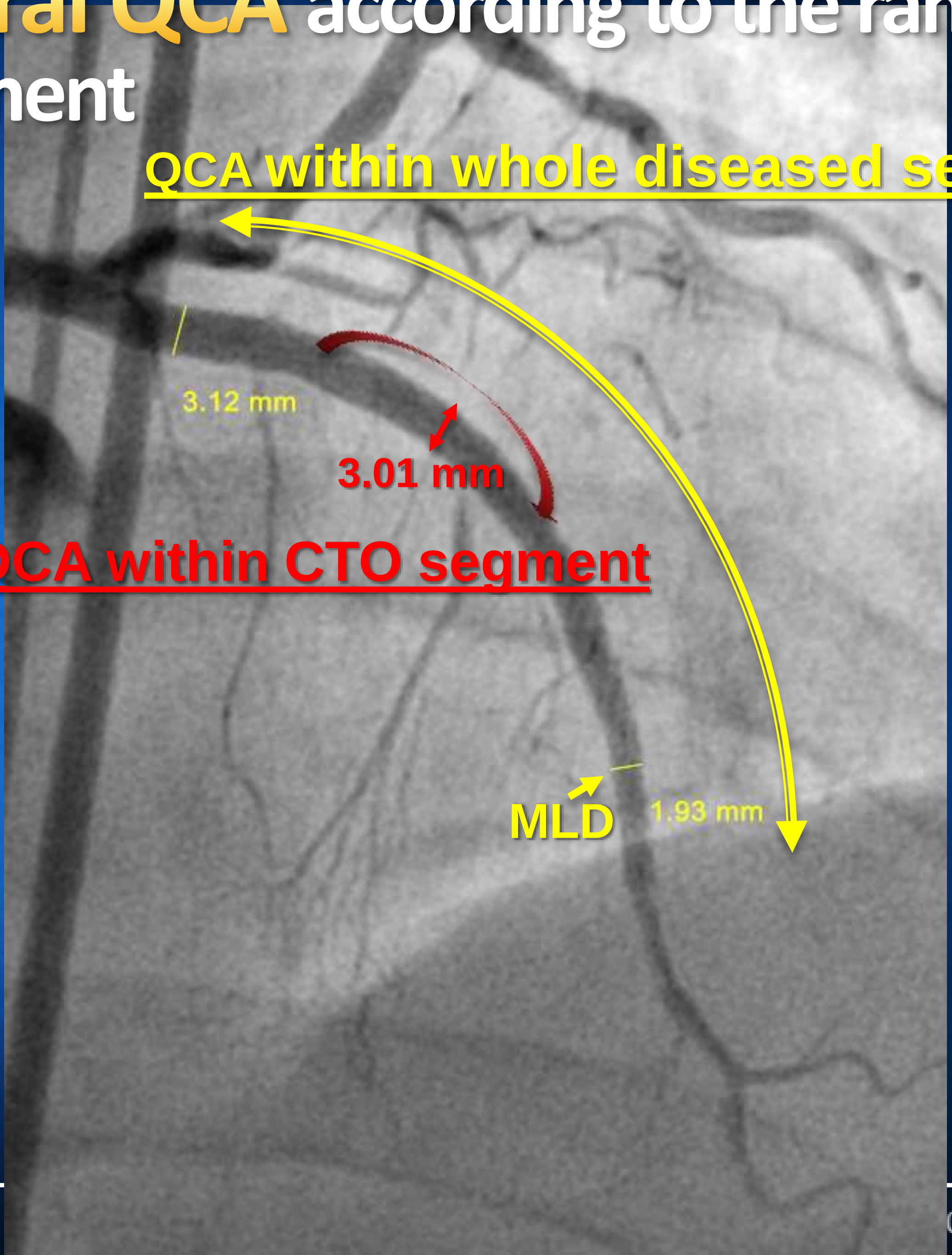
Procedural summary for CTO intervention

	IVUS-guided (n=201)	Angiography-guided (n=201)	p Value
Procedure success	199 (99.0%)	197 (98.0%)	0.411
Femoral artery access	149 (74.1%)	145 (72.1%)	0.653
Contralateral angiogram	101 (50.2%)	92 (45.8%)	0.369
Retrograde approach	14 (7.0%)	19 (9.5%)	0.364
Total number of stents, n	1.7 ± 0.8	1.6 ± 0.7	0.198
Mean stent diameter, mm	2.91 ± 0.52	2.85 ± 0.41	0.228
Total stented length, mm	43.6 ± 18.7	41.5 ± 17.6	0.245
High-pressure post-stent dilation	103 (51.2%)	83 (41.3%)	0.045
Maximum post-stent balloon pressure, atm	14.6 ± 3.7	13.8 ± 3.8	0.040
Total procedure time, min	95 ± 50	88 ± 47	0.167
Total fluoroscopic time, min	41 ± 26	37 ± 24	0.155
Total contrast volume used, mL	299 ± 128	295 ± 123	0.728

Quantitative & qualitative angiographic analyses

	IVUS-guided (n=201)	Angiography-guided (n=201)	p Value
Length of CTO, mm	26.8 ± 17.3	26.4 ± 17.6	0.860
Total lesion length, mm	36.3 ± 17.1	35.5 ± 17.0	0.615
Pre-procedural Reference vessel diameter, mm	2.69 ± 0.44	2.64 ± 0.55	0.346
Post-procedure			
Reference vessel diameter, mm	2.92 ± 0.39	2.86 ± 0.45	0.144
Minimum luminal diameter, mm	2.64 ± 0.35	2.56 ± 0.41	0.025
Percent diameter stenosis, %	9.0 ± 9.8	10.2 ± 10.9	0.272
Stent edge dissection	18 (9.0%)	27 (13.4%)	0.155

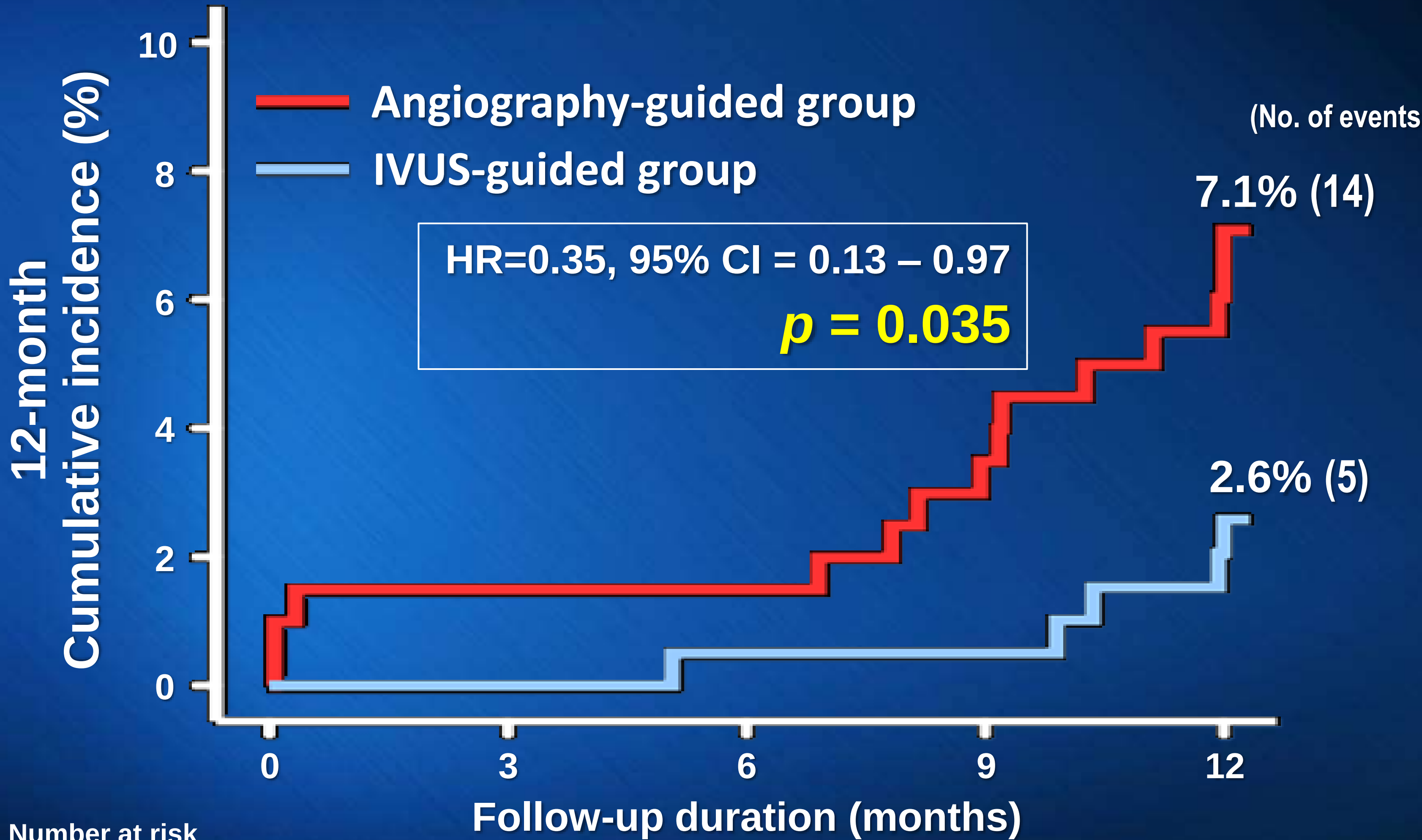
Post-procedural QCA according to the range of diseases segment



QCA at CTO segments

	IVUS-guided (n=201)	Angiography-guided (n=201)	p Value
Pre-procedure			
Reference vessel diameter, mm	2.69 ± 0.44	2.64 ± 0.55	0.346
Post-procedure			
Whole diseased segments			
Reference vessel diameter, mm	2.92 ± 0.39	2.86 ± 0.45	0.144
Minimum luminal diameter, mm	2.64 ± 0.35	2.56 ± 0.41	0.025
Percent diameter stenosis, %	9.0 ± 9.8	10.2 ± 10.9	0.272
CTO segments			
Minimum luminal diameter, mm	2.81 ± 0.37	2.69 ± 0.42	0.004
Percent diameter stenosis, %	3.3 ± 10.9	5.3 ± 12.5	0.095

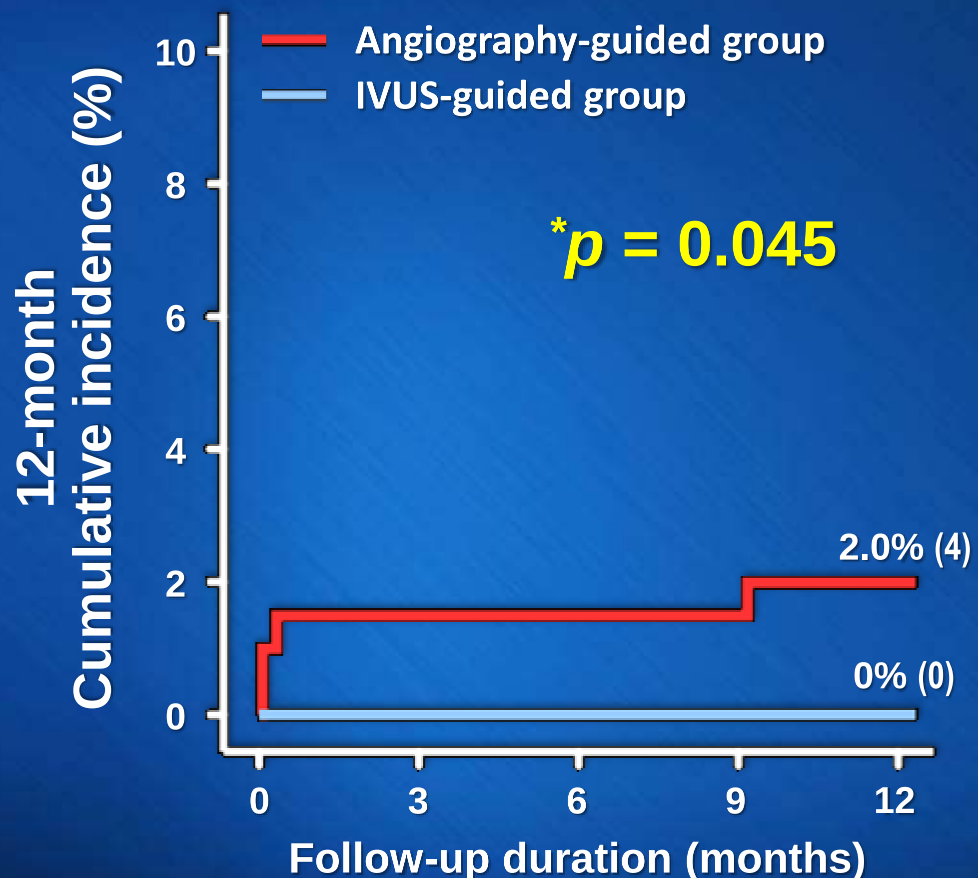
Primary endpoint (Cardiac death, MI, ST, or TVR)

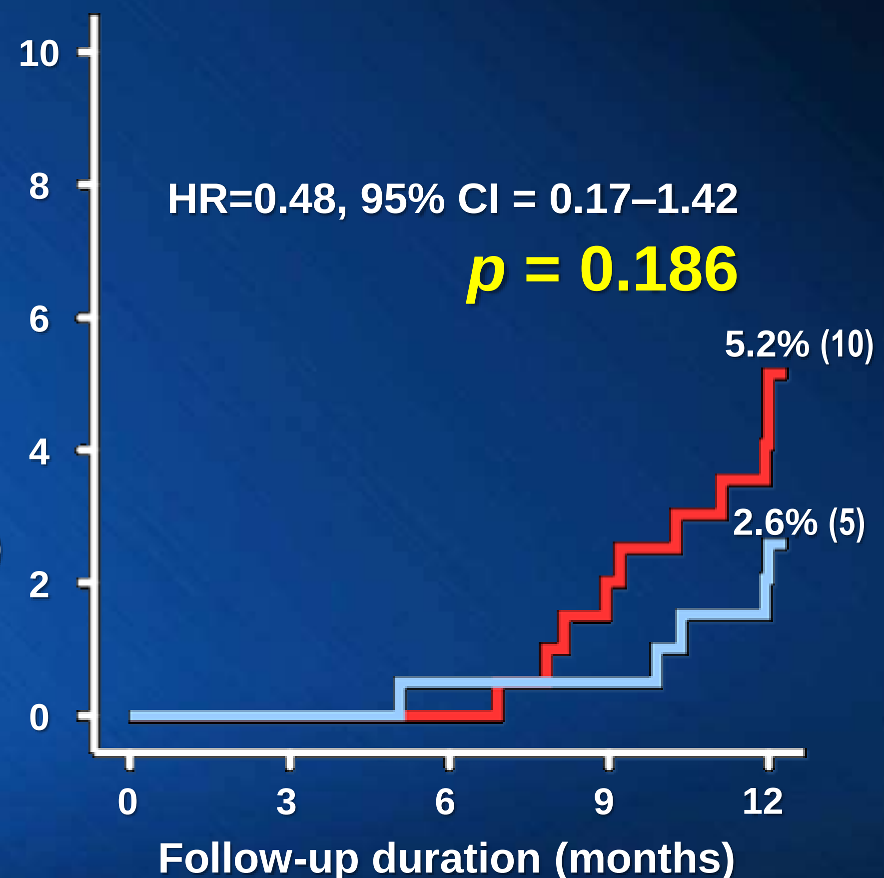


Number at risk

Angiography-guided	201	198	179
IVUS-guided	201	198	186

Cardiac death or MI	TVR

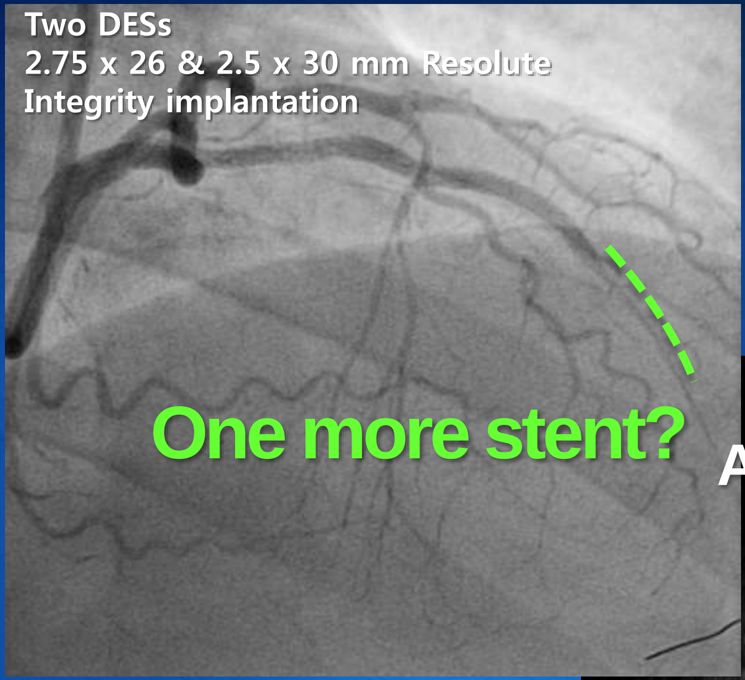




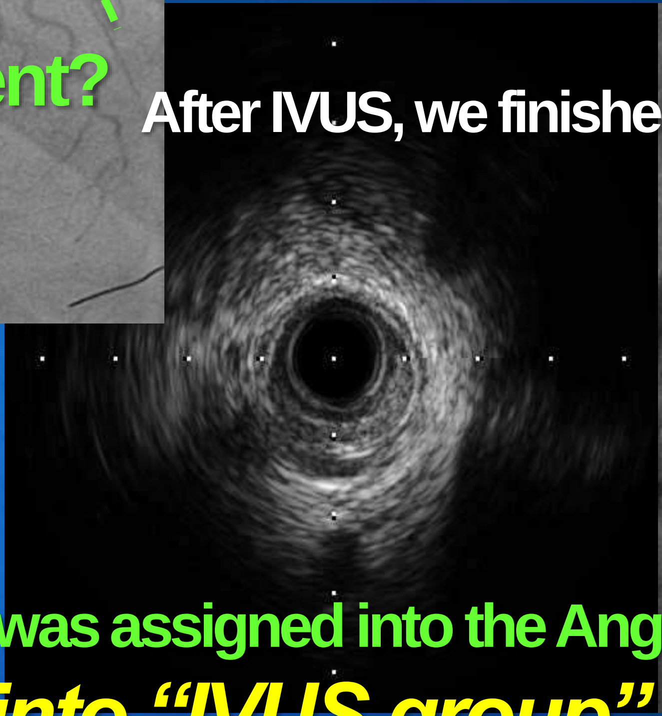
Number at risk

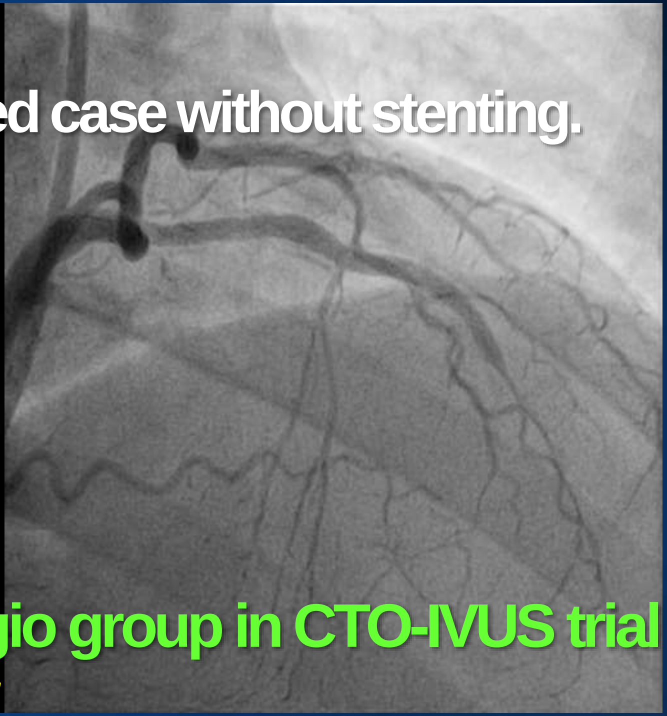
Angiography-guided	201	198	187	201	199	180
IVUS-guided	201	199	190	201	198	186

*Not calculable HR or CI because of no occurrence of the event



One more stent?





After IVUS, we finished case without stenting.

This case (No-275478) was assigned into the Angio group in CTO-IVUS trial

→Cross-over into "IVUS group"

for the safety concerns by operator's discretion

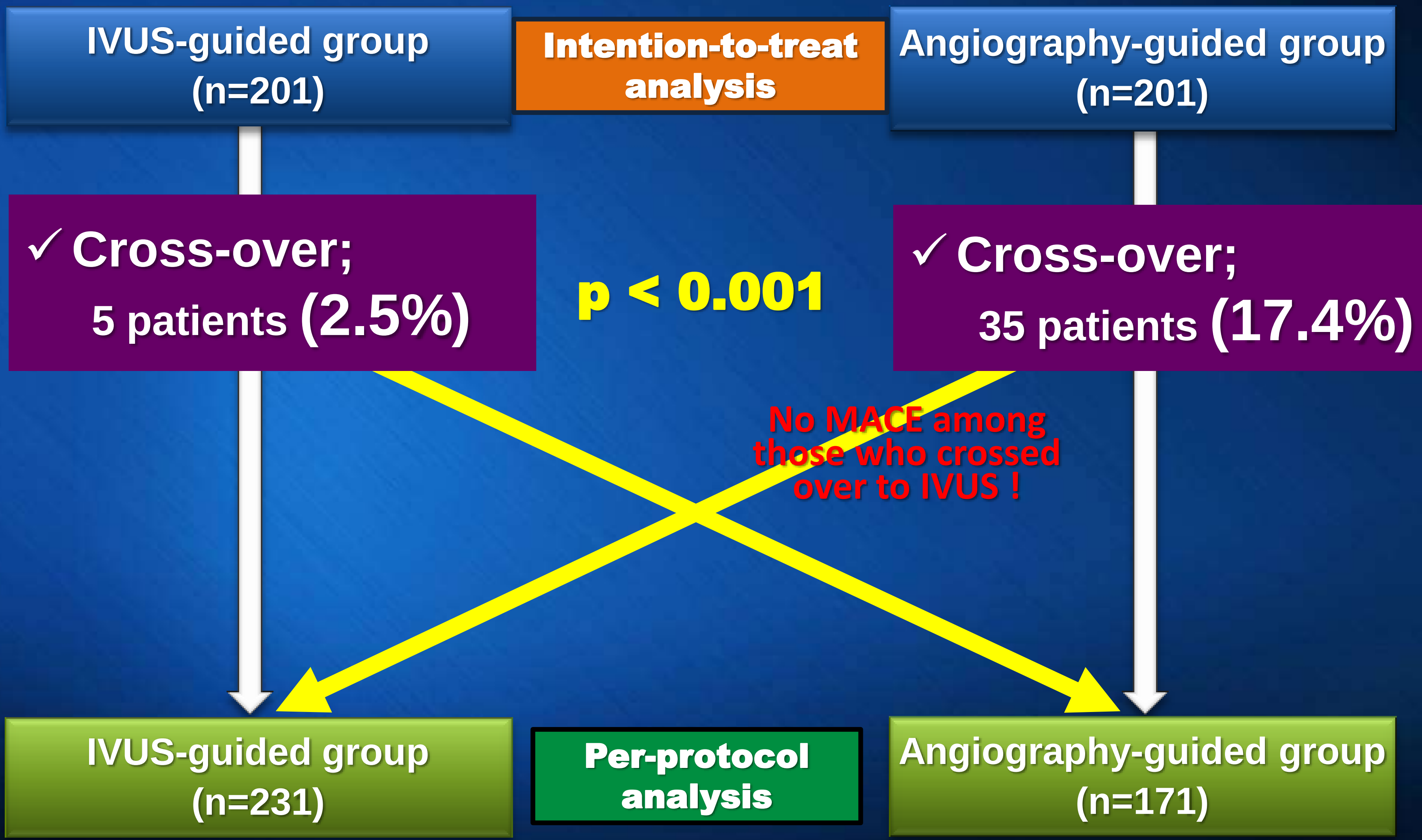
"Cross-over" in CTO-IVUS trial

... raise the concerns regarding protocol-violation.

- IVUS use in the inevitable cases had to be allowed for the safety concerns (... cross-over into IVUS guidance).

→ These might reflect the **"True incidence of inevitable use of IVUS during CTO intervention"** in the real world practice.

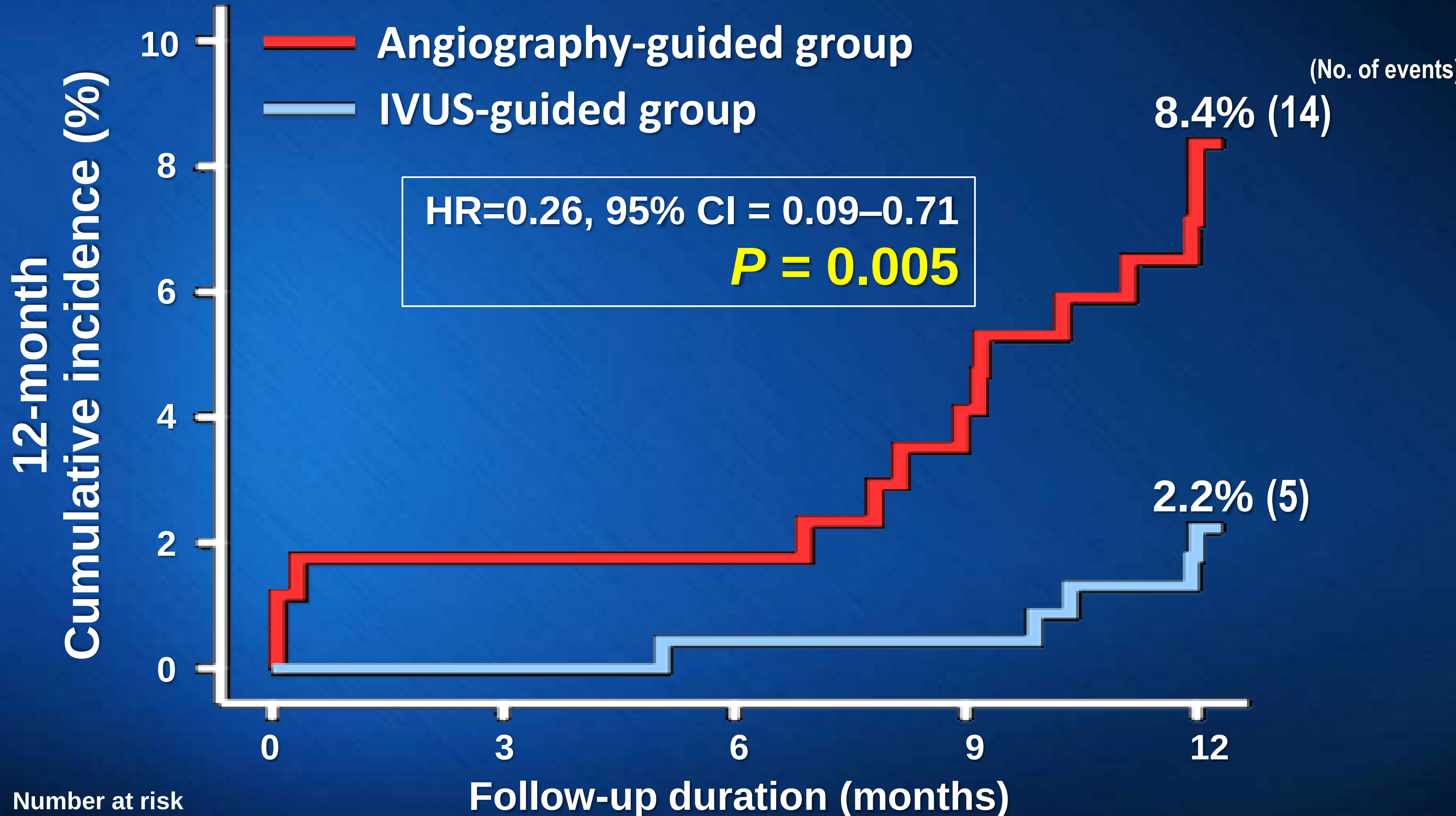
Cross-over rate in CTO-IVUS trial



Primary endpoint (Cardiac death, MI, TVR)

Per-protocol Analysis

Angio-group (7.1%) vs. IVUS-group (2.6%); *P*=0.035 on ITT

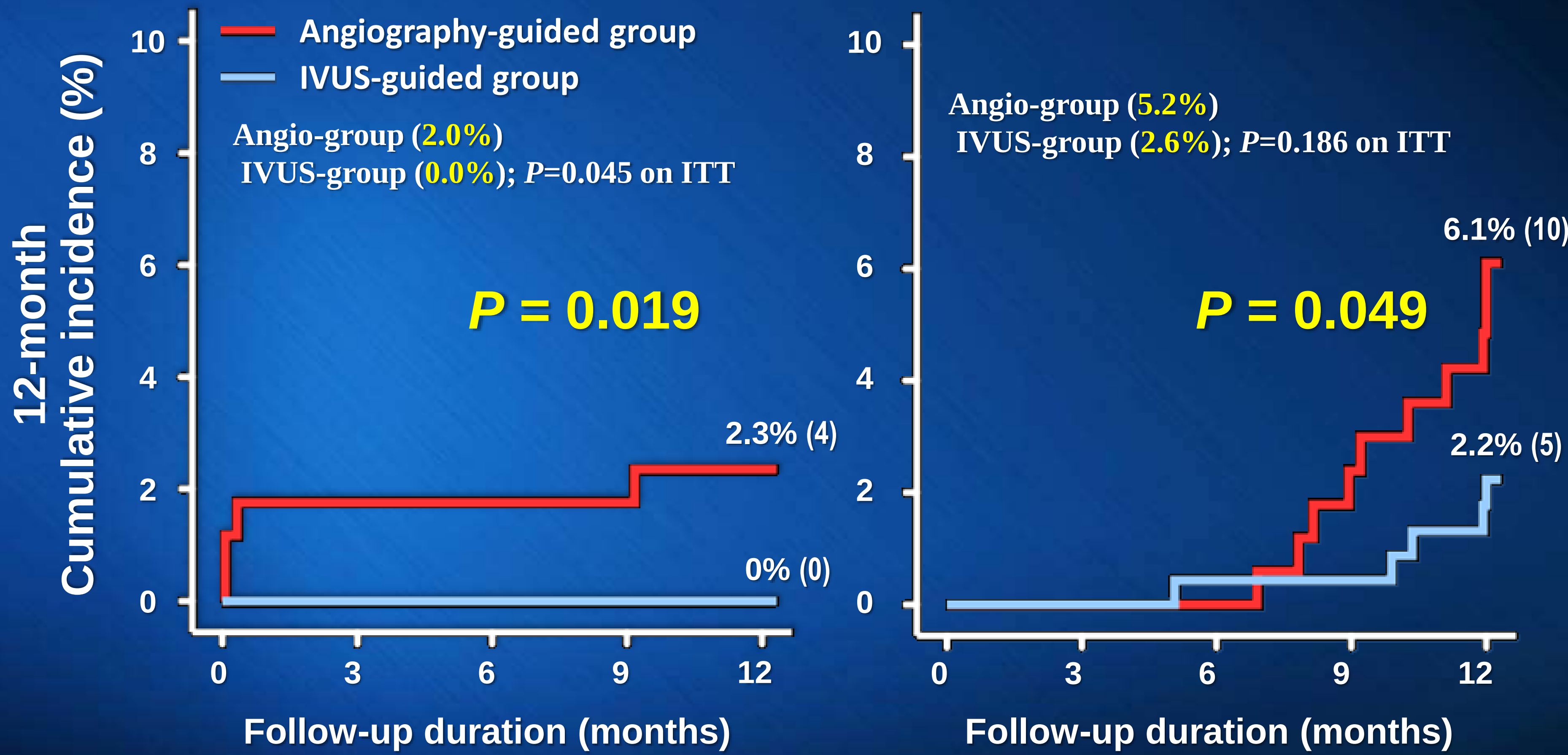


Number at risk	0	6	12
Angiography-guide	171	167	151
IVUS-guide	231	229	214

Per-protocol Analysis

Cardiac death or MI

TVR



Number at risk

Angiography-guide	171	167	159	171	168	152
IVUS-guide	231	230	218	231	229	214

Take-home message - I

- Besides the higher success by IVUS guidance for CTO intervention, **Our registry data and randomized study confirmed that IVUS-guided CTO intervention could improve clinical outcomes after 2nd-generation DES.**

Take-home message -II

- **Potential advantages of IVUS-guided CTO intervention;**
  - ✓ Prevention of stent underexpansion and optimal expansion (higher use of high-pressure dilation and larger post-procedural MLD)
  - ✓ Detection of procedure-complication and determination of further management (dissection or hematoma …)

  → causing **"optimal stenting"**

- **Use of IVUS might be necessarily needed for the next safe proceeding procedures and the improvement of clinical outcomes after stent implantation.**

Thank you for your attention

Save the Data 2016 CTO Seoul Camp

2016. 3. 11 (Fri) ~ 2016. 3. 12 (Sat)