Clinical Impact of IVUS use for CTO Intervention

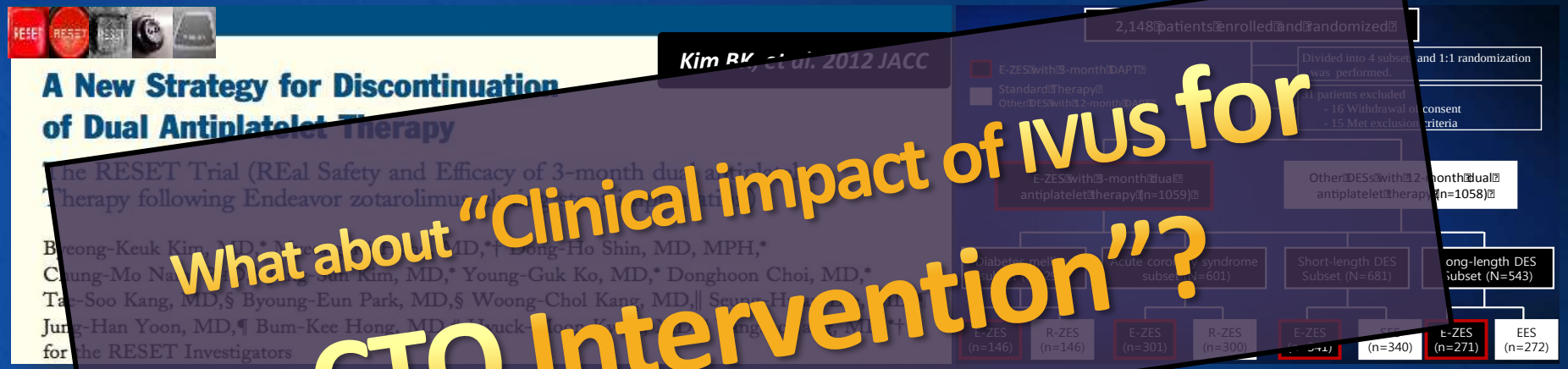
Byeong-Keuk Kim, MD, PhD

Division of Cardiology, Severance Cardiovascular Hospital
Yonsei University College of Medicine, Seoul, Korea

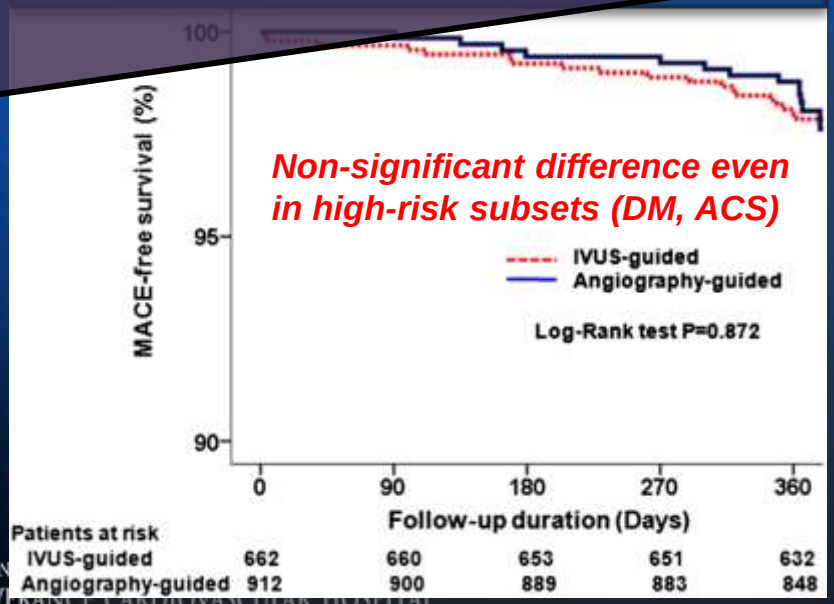
Q; IVUS, could improve clinical outcomes?

- Controversy still exists according to the lesion complexity.

What about "Clinical impact of IVUS for CTO Intervention"?

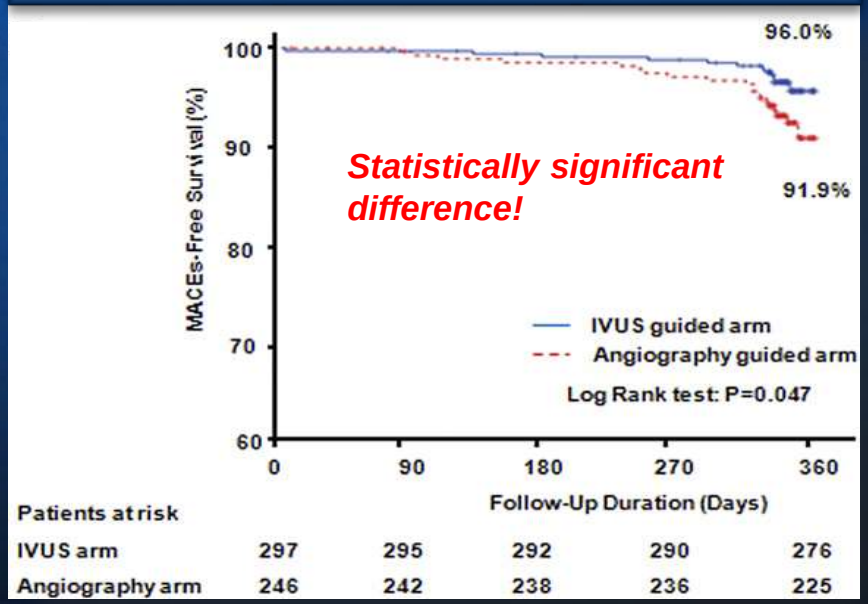


Sub-group analysis; Short-lesion registry study



Am J Cardiol 2013

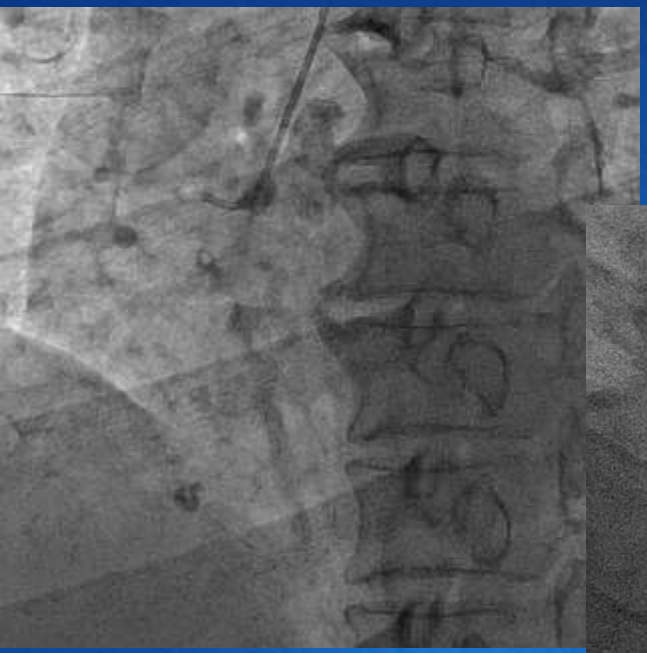
Sub-group analysis; Long-lesion random study

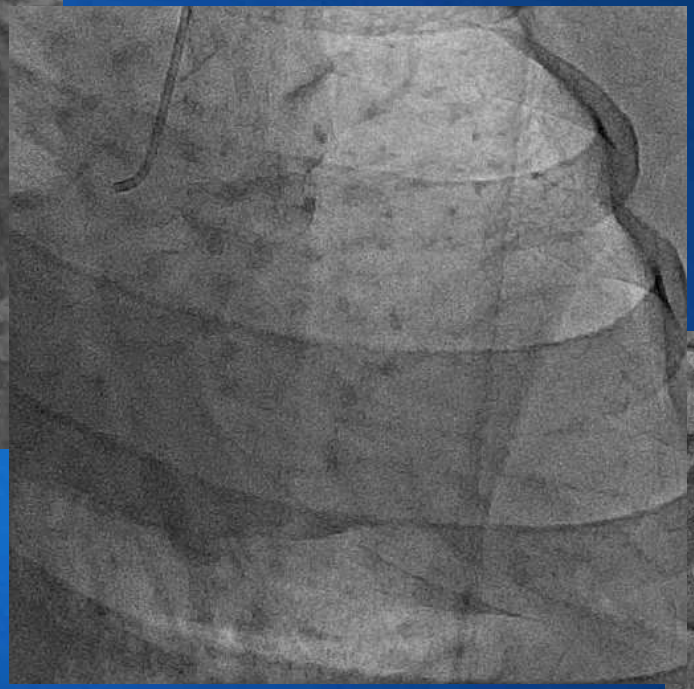


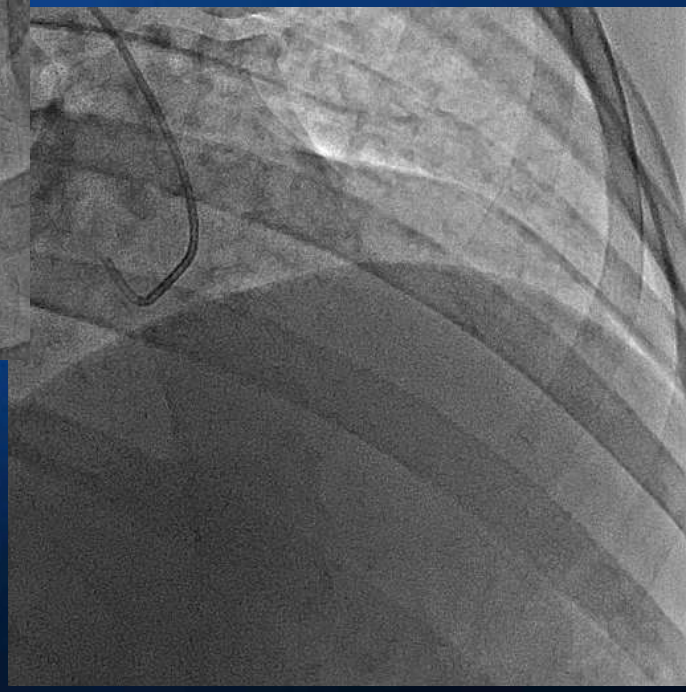
JACC Cardiovasc Interv 2013

Case. F/49, LAD CTO

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



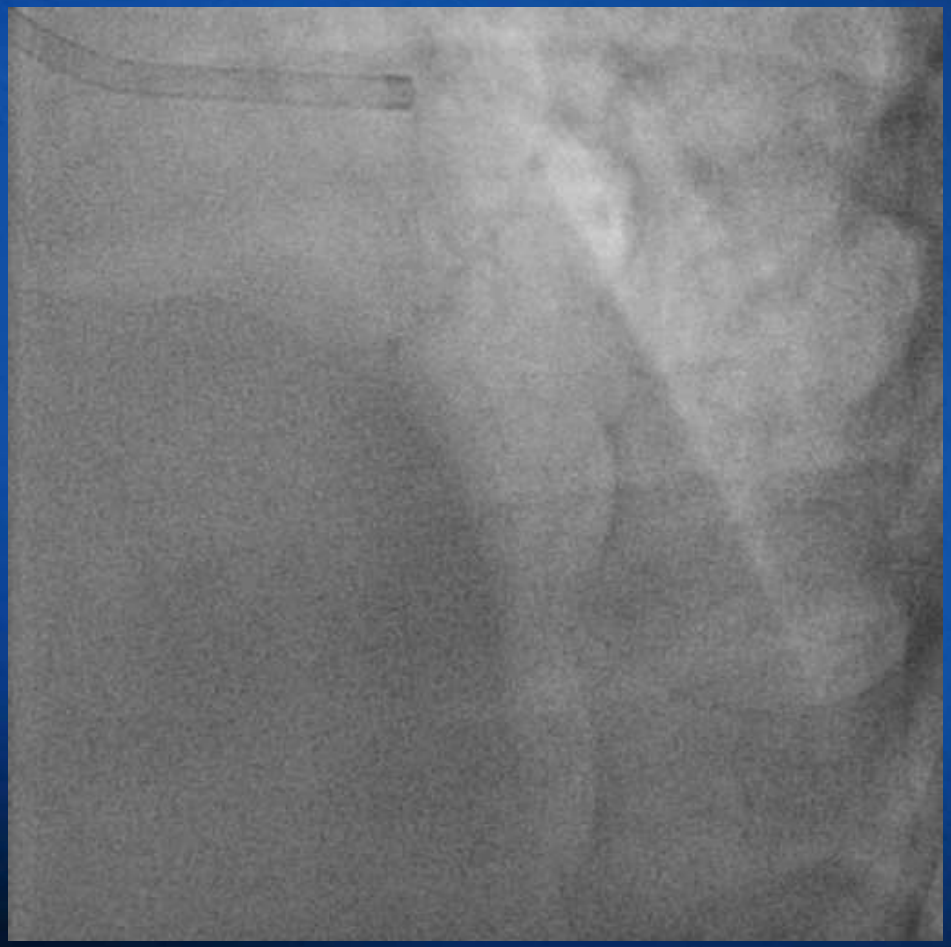


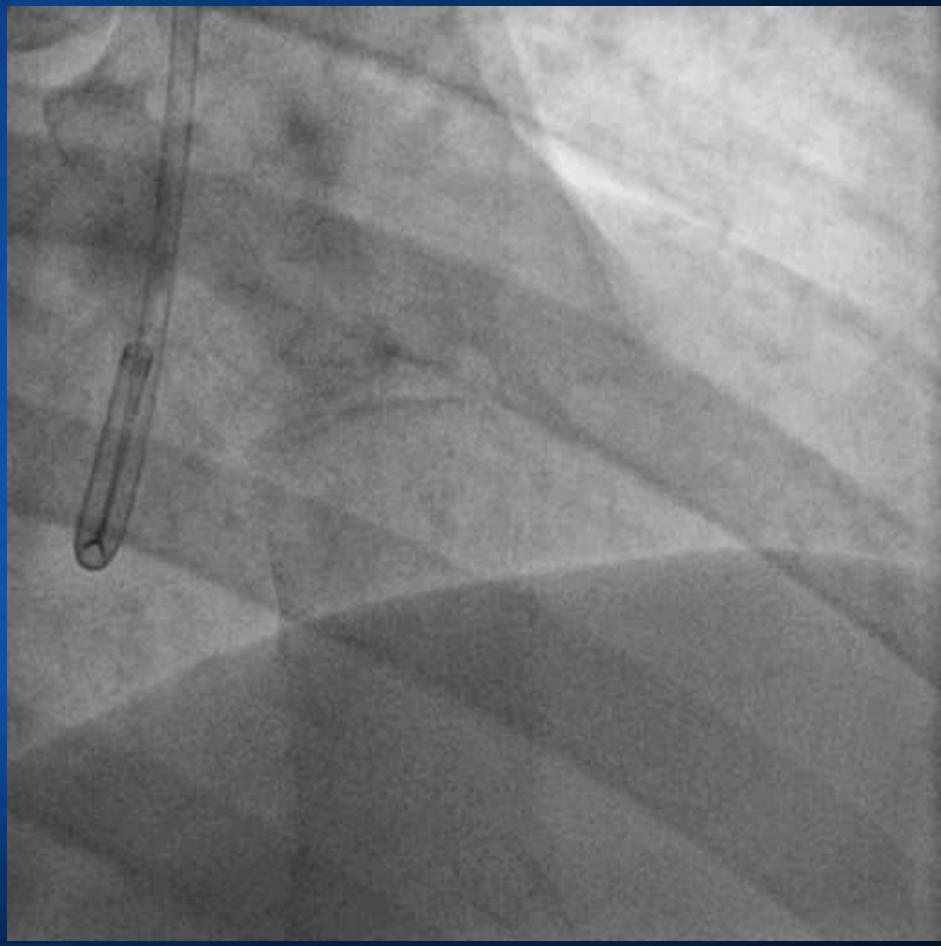


- 1VD
- LAD CTO, collateral flow from LCx

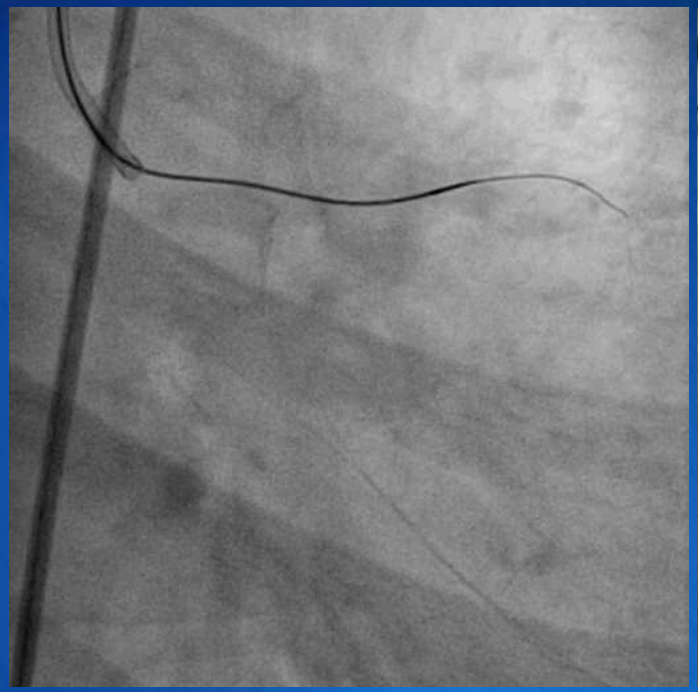
LAD CTO

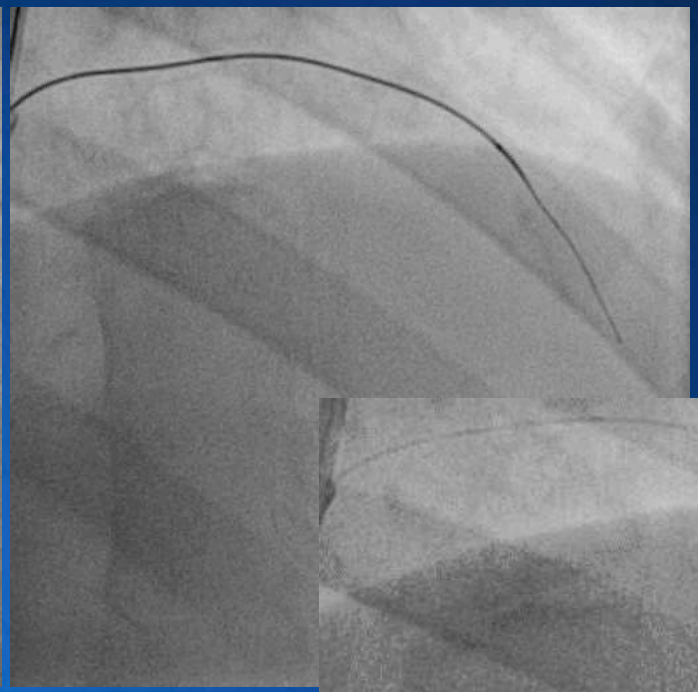
- Anterograde approach using femoral access
- 8Fr XB G/C

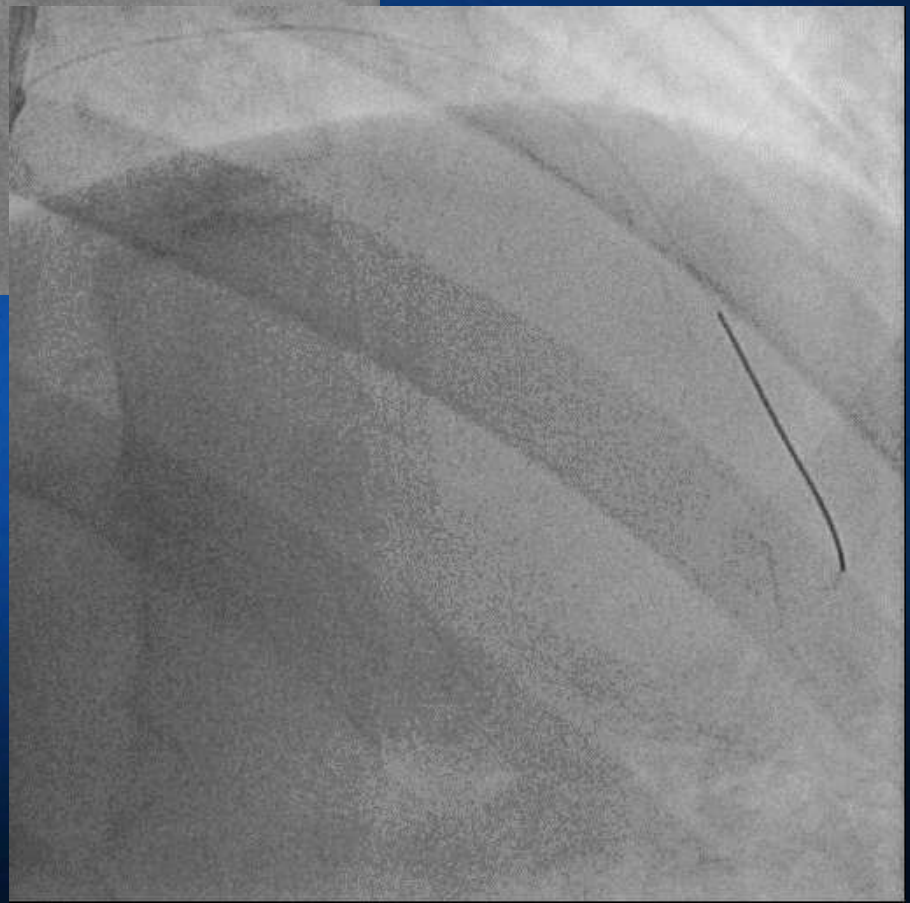




LAD CTO

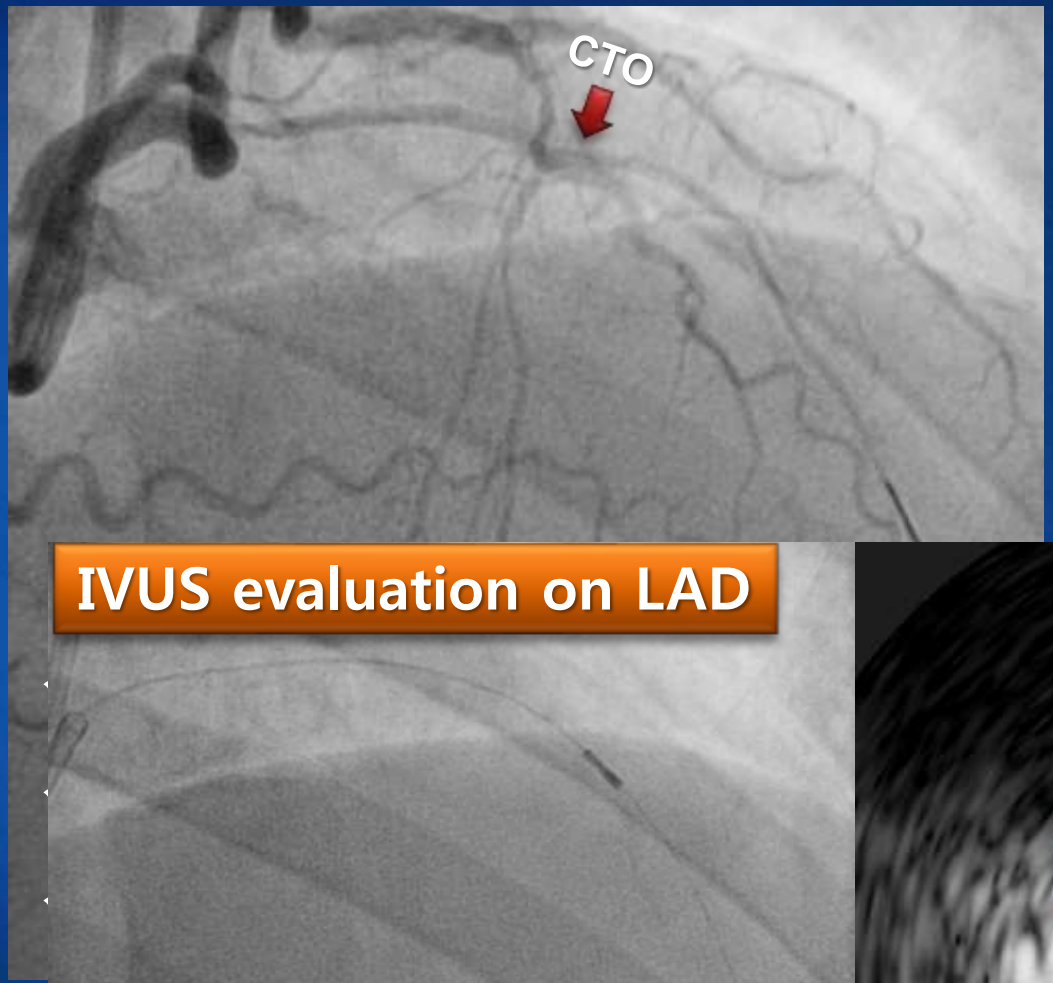




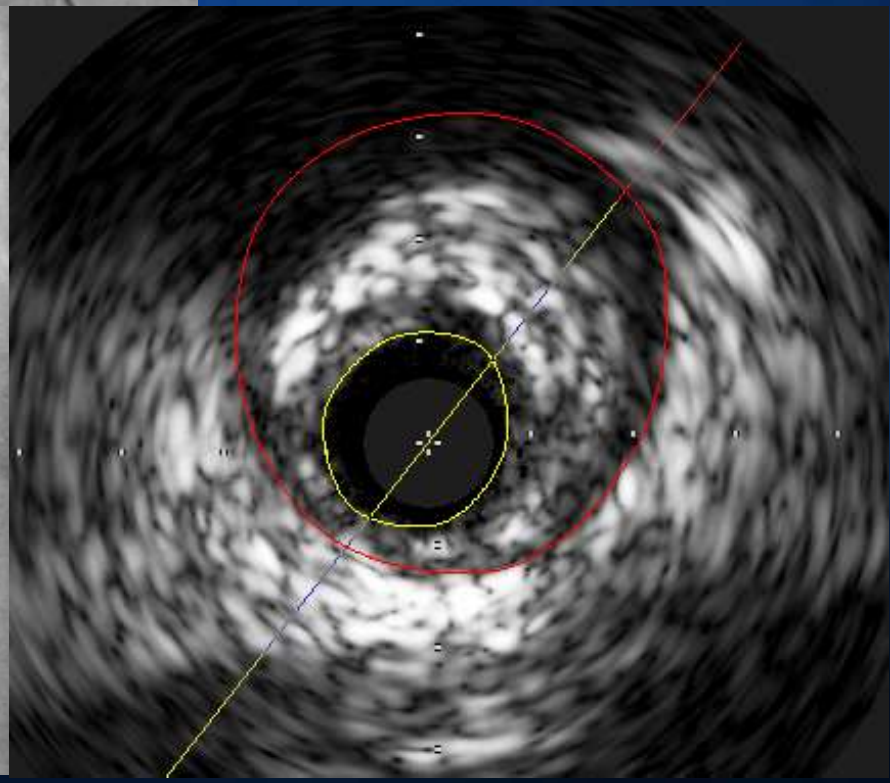


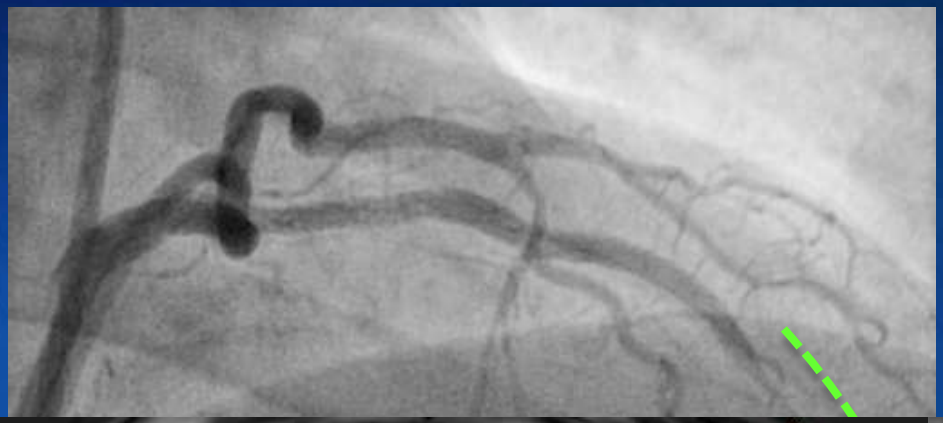
- ✓ Corsair, Sion blue → XT-A
- ✓ Successful guidewire-crossing and pre-dilation → diffusely narrowing LAD

Angiogram after pre-dilation

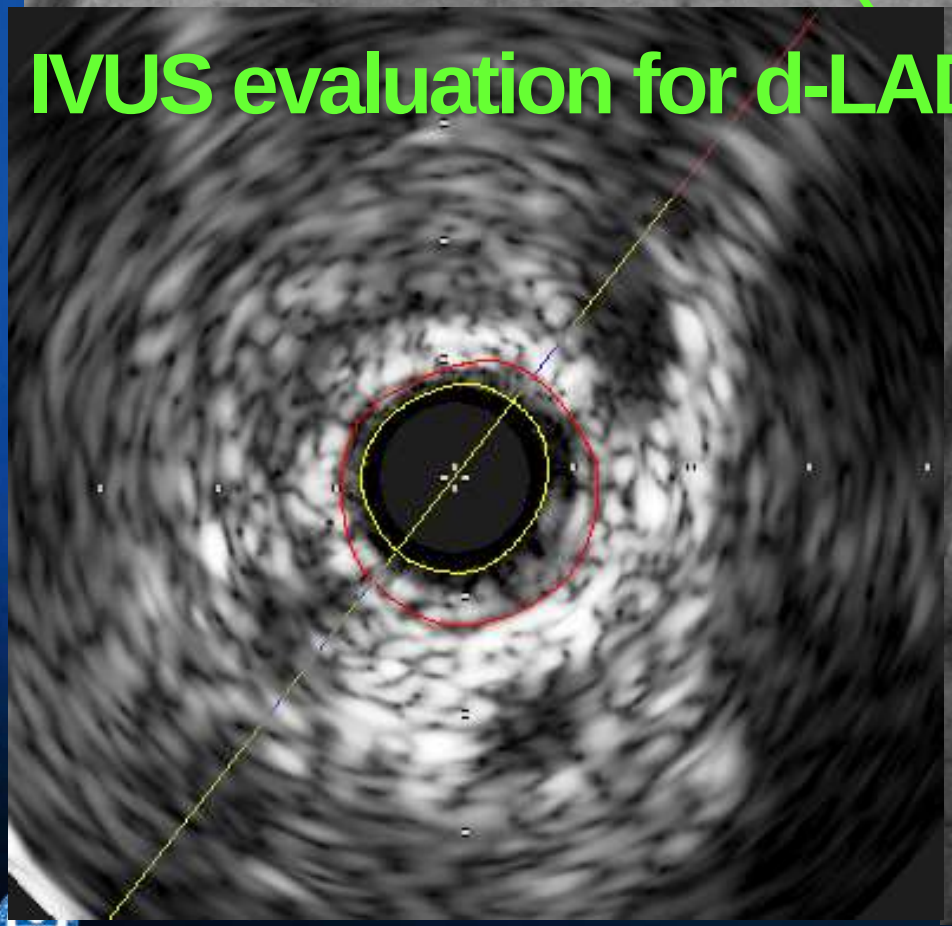


IVUS evaluation on LAD

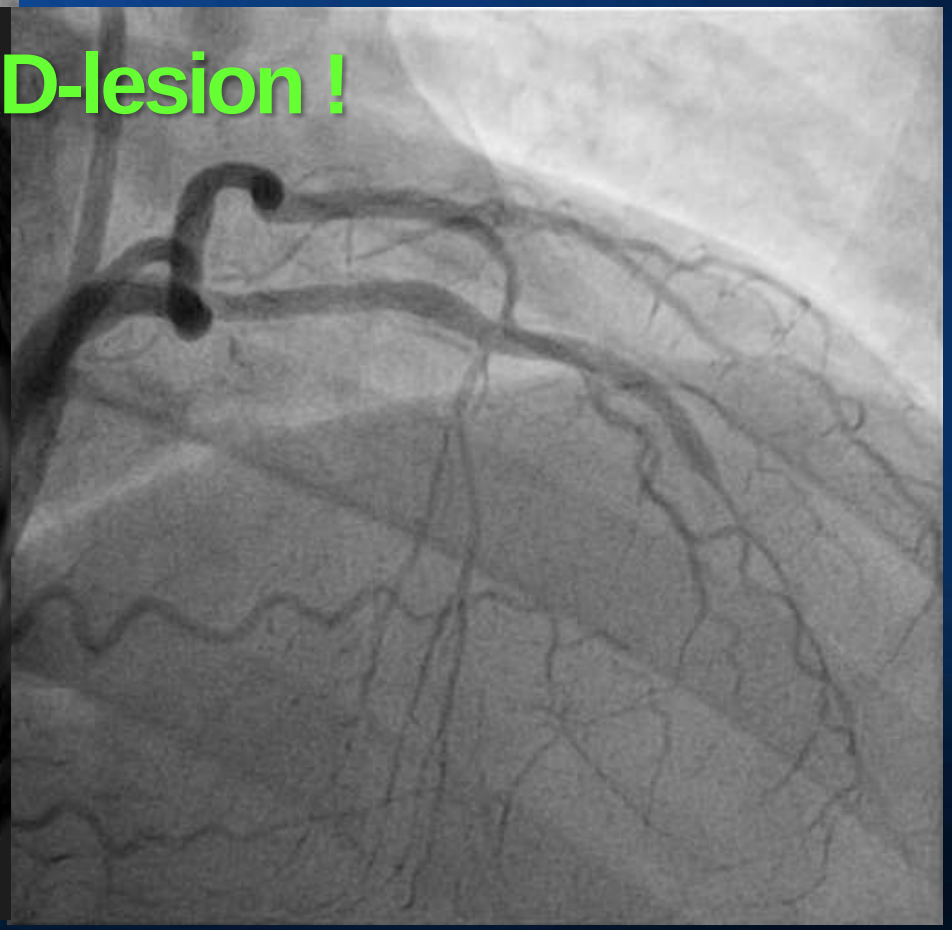




Two Resolute Integrity (2.75 x 26 & 2.5 x 30 mm) implantation on the m-LAD-lesion

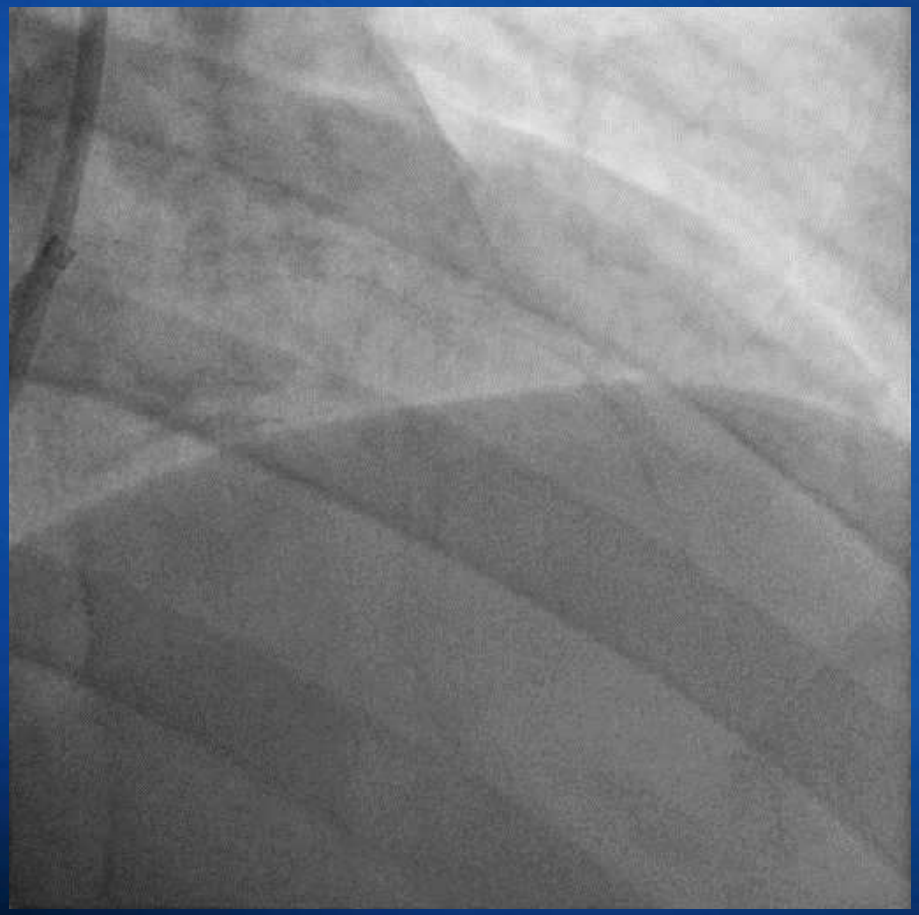


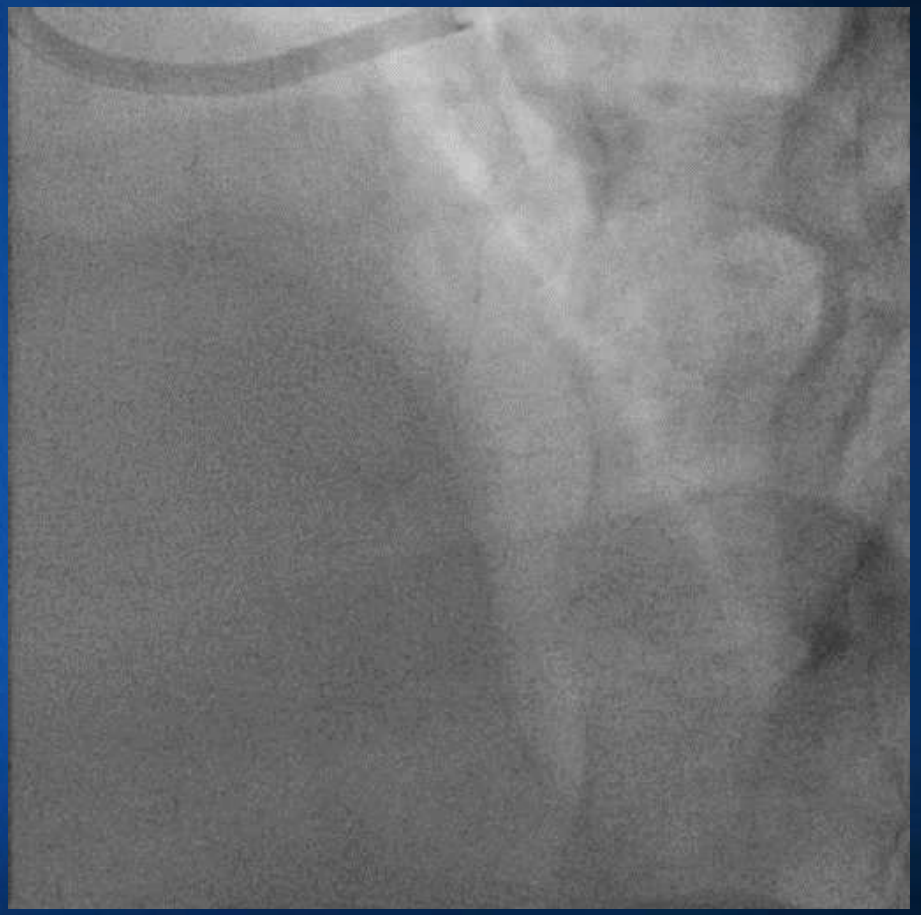
IVUS evaluation for d-LAD-lesion !



Finished the procedure without stenting or ballooning …

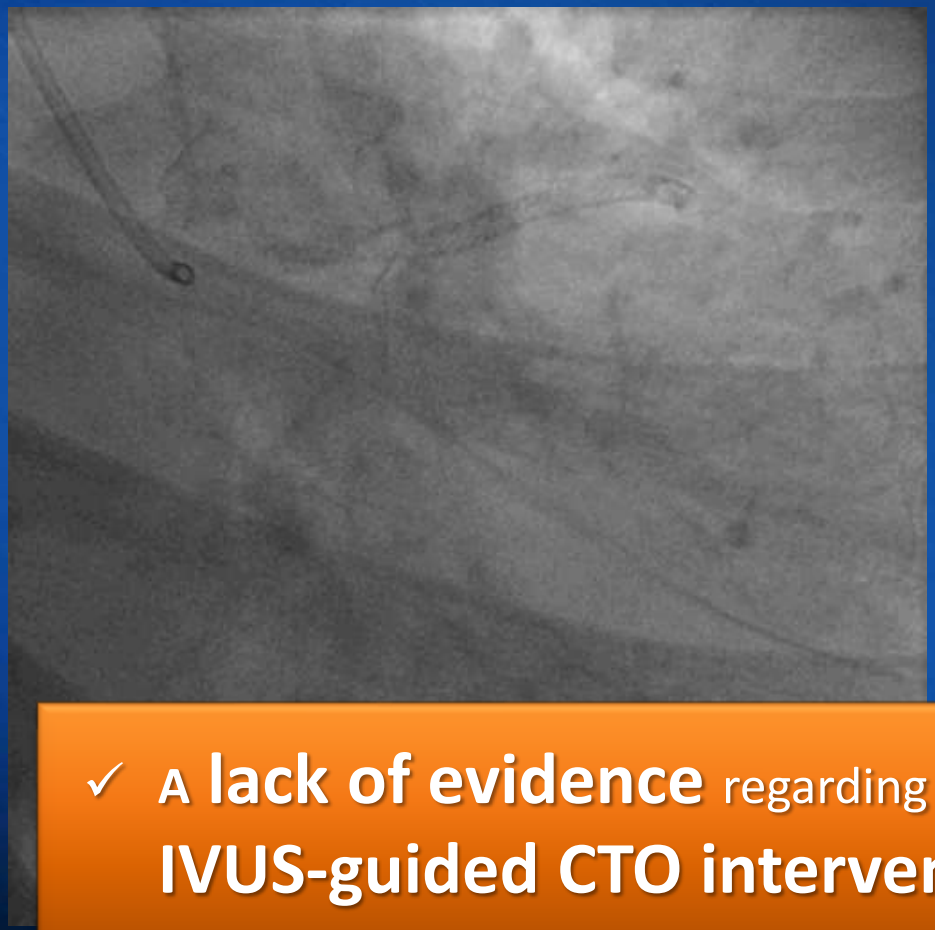
Final angiography

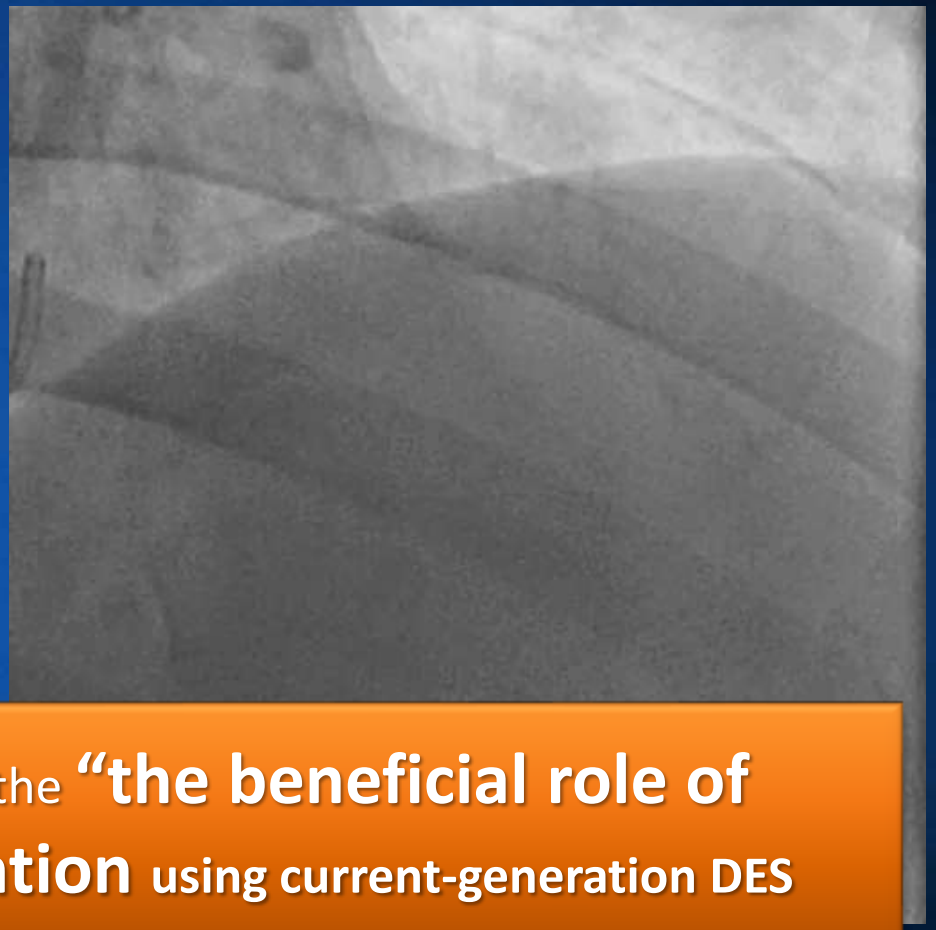




1-year follow-up; no events …

Follow-up CAG





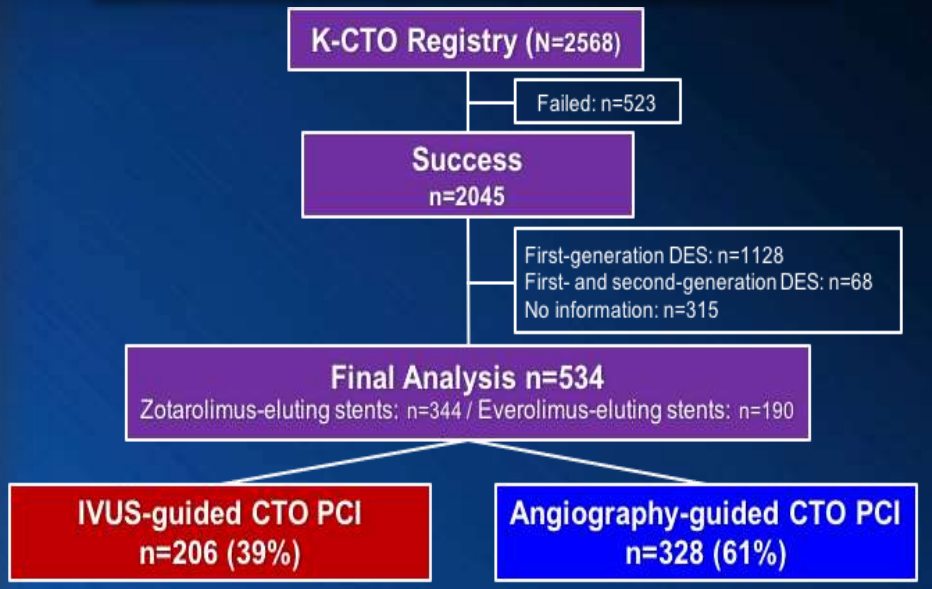
- ✓ A **lack of evidence** regarding the **"the beneficial role of IVUS-guided CTO intervention using current-generation DES for the improved clinical outcomes"** after stent implantation.

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)

Sung-Jin Hong, MD[a], Byeong-Keuk Kim, MD[a], Dong-Ho Shin, MD[a], Jung-Sun Kim, MD[a], Myeong-Ki Hong, MD[a,b], Hyeon-Cheol Gwon, MD[c], Hyo-Soo Kim, MD[d], Cheol Woong Yu, MD[e], Hun Sik Park, MD[f], In-Ho Chae, MD[g], Seung-Woon Rha, MD[h], Seung-Hwan Lee, MD[i], Moo-Hyun Kim, MD[j], Seung-Ho Hur, MD[k], and Yangsoo Jang, PhD, MD[a,b,*], for the K-CTO Registry

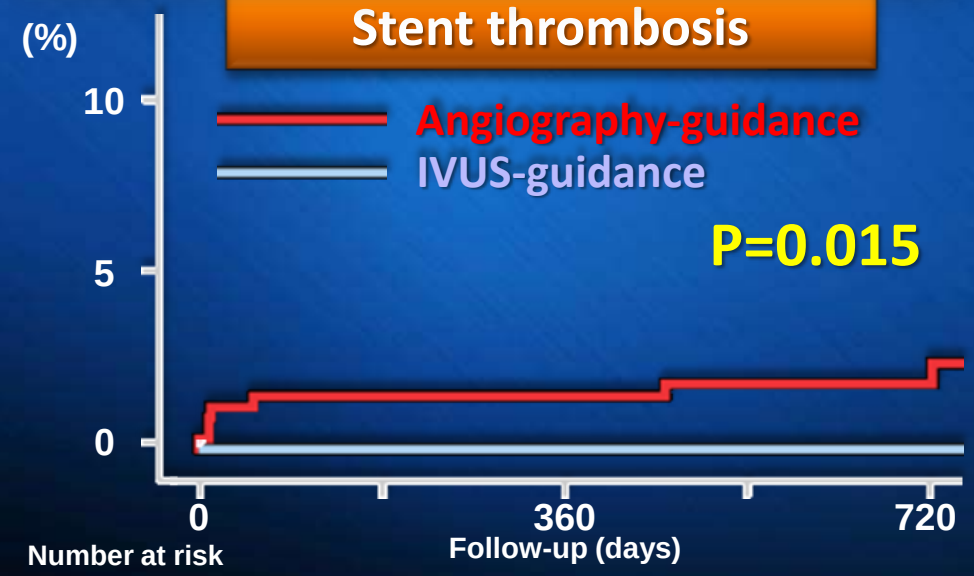
Despite the usefulness of intravascular ultrasound (IVUS) in percutaneous coronary intervention (PCI), the impact of IVUS guidance on clinical outcomes, particularly for chronic total occlusion (CTO) intervention, has rarely been studied. We sought to investigate the clinical usefulness of IVUS-guided CTO intervention with second-generation drug-eluting stent implantation. From 2007 to 2009, a total of 2,568 patients were enrolled in the Korean-CTO registry and 534 patients with successful implantation of second-generation drug-eluting stents were analyzed. IVUS-guided PCI was performed on 206 patients (39%). Clinical outcomes at 2 years were compared between the IVUS-guidance group and the angiography-guidance group in 201 propensity score–matched pairs. The primary end point was the occurrence of definite or probable stent thrombosis. Clinical characteristics were similar between both groups after matching. At 2 years, the IVUS-guidance group showed significantly less stent thrombosis than the angiography-guidance group (0% vs 3.0%, p = 0.014) and a lesser trend toward myocardial infarction (1.0% vs 4.0%, p = 0.058). Target lesion revascularization (TLR) and major adverse cardiovascular event rates were similar. However, a significant interaction was observed between the use of IVUS and lesion length for predicting the TLR (p = 0.037), suggesting usefulness of IVUS in long-lesion (≥3 cm) relative to short-lesion CTO. In conclusion, although IVUS-guided CTO PCI was not associated with a reduction in overall major adverse cardiovascular events, IVUS guidance appears to be associated with a reduction of stent thrombosis and myocardial infarction compared with angiography-guided CTO PCI. Additionally, TLR occurred less frequently in the IVUS-guidance group, especially for long lesions. (Am J Cardiol 2014;114:534–540)

K-CTO registry study

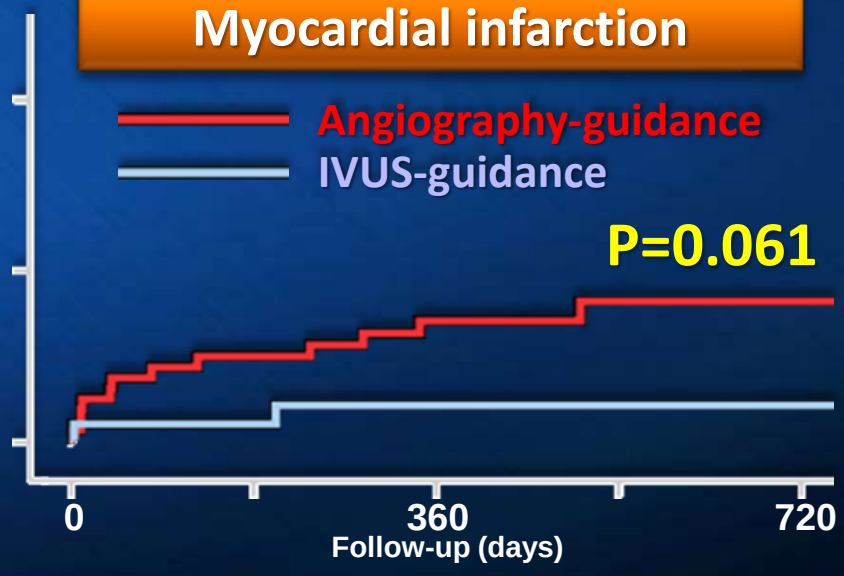


- Primary endpoint; *Definite or probable ST after propensity-score matching*

Stent thrombosis



Myocardial infarction



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

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.

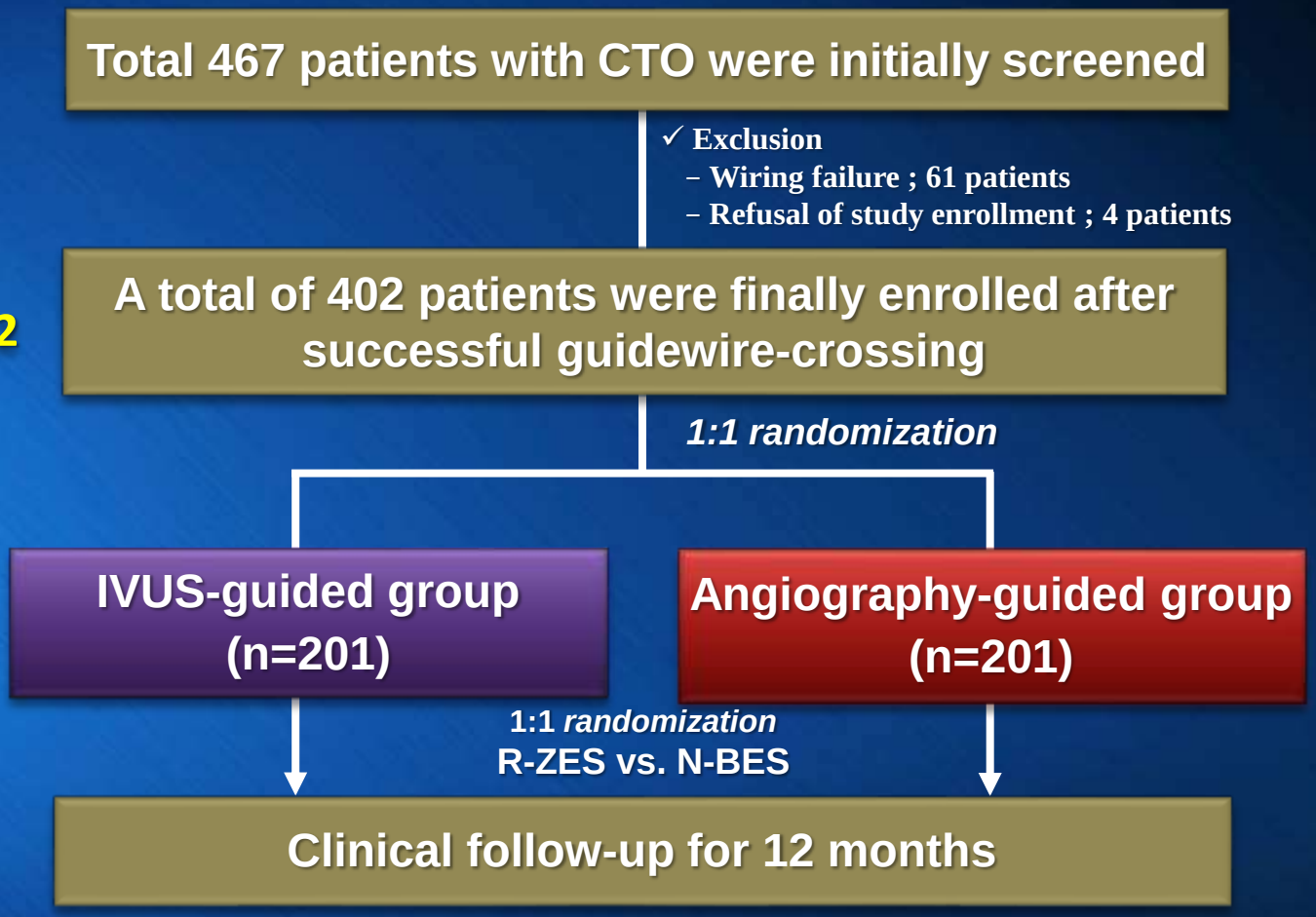
Clinical Trial Registration—URL: http://www.clinicaltrials.gov. Unique identifier: NCT01563952.

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

Randomized CTO-IVUS study

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

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

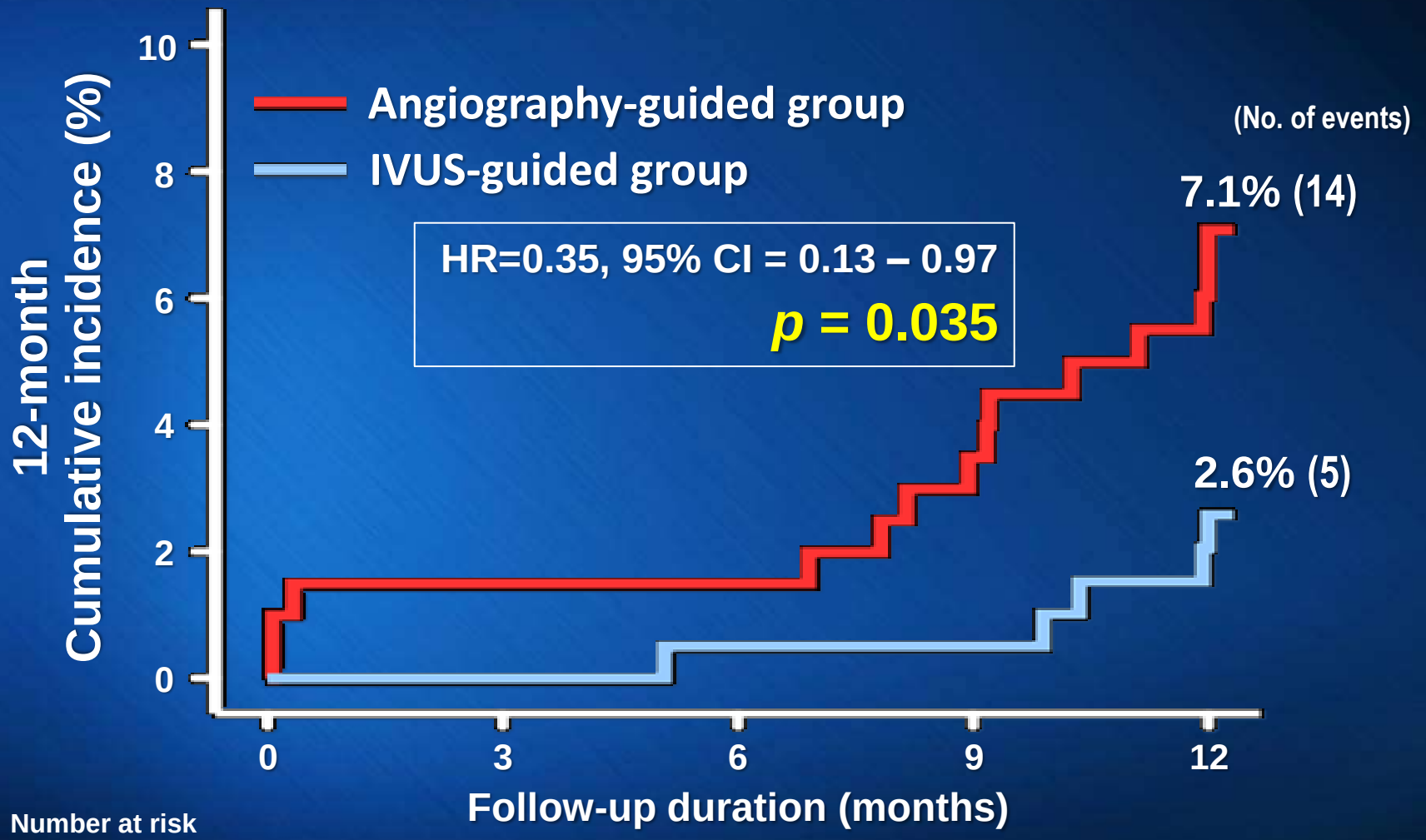


Recommendation in the IVUS-guided group: 1) MSA ≥distal reference LA; 2) SA at CTO segment ≥5 mm^2 as far as vessel area permits; and 3) complete stent apposition.

Procedural summary & QCA

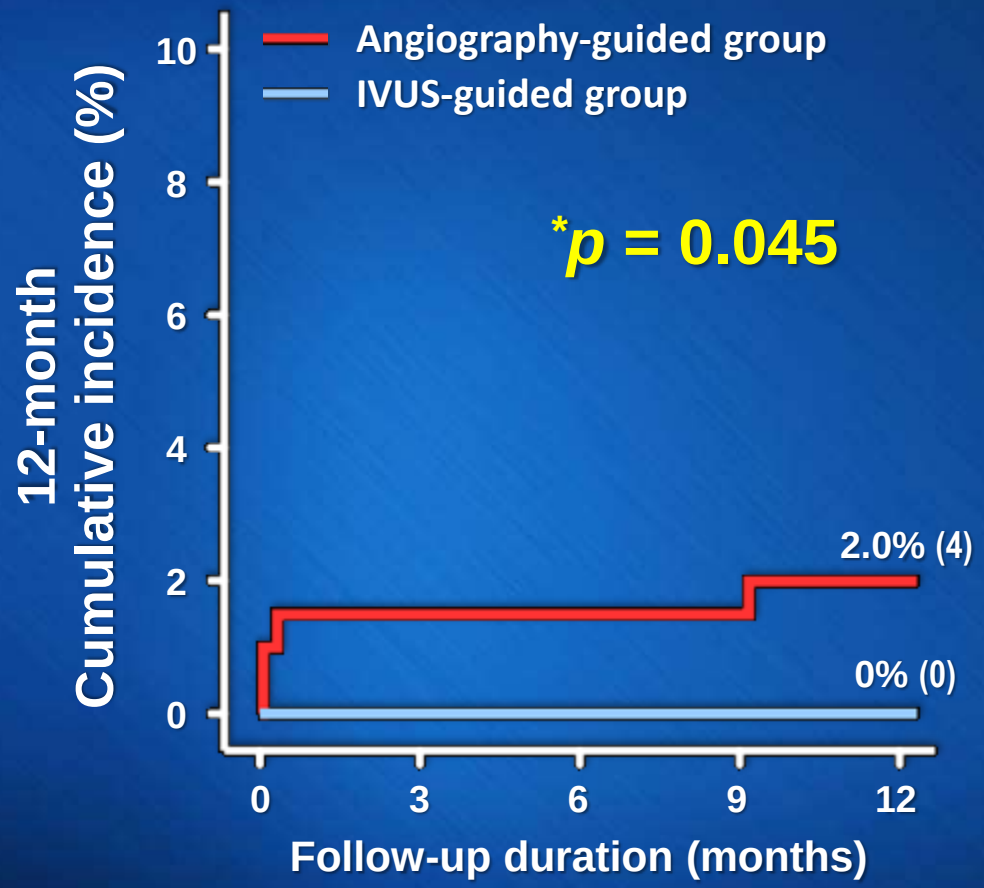
	IVUS-guided (n=201)	Angiography-guided (n=201)	p Value
Procedure success	199 (99.0%)	197 (98.0%)	0.411
Total number of stents, n	1.7 ± 0.8	1.6 ± 0.7	0.198
Mean stent diameter, mm	2.91 ± 0.52	2.85 ± 0.41	0.228
Total stented length, mm	43.6 ± 18.7	41.5 ± 17.6	0.245
High-pressure post-stent dilation	103 (51.2%)	83 (41.3%)	0.045
Maximum post-stent balloon pressure, atm	14.6 ± 3.7	13.8 ± 3.8	0.040
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
Stent edge dissection	18 (9.0%)	27 (13.4%)	0.155

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

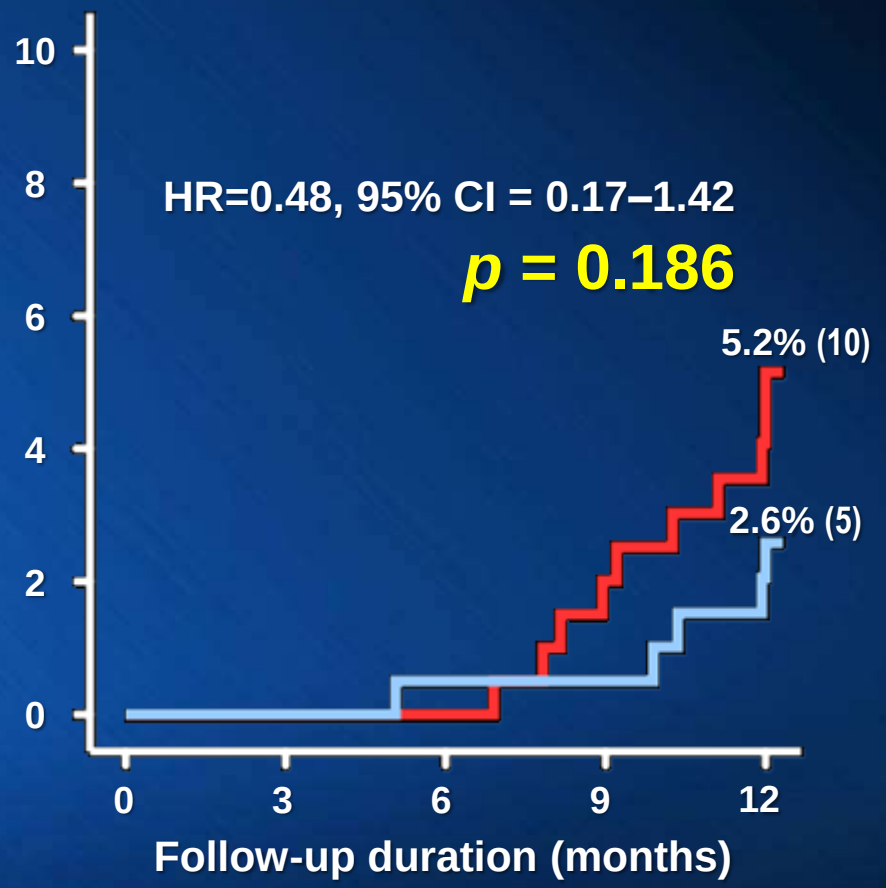


Number at risk			
Angiography-guided	201	198	179
IVUS-guided	201	198	186

Cardiac death or MI



TVR

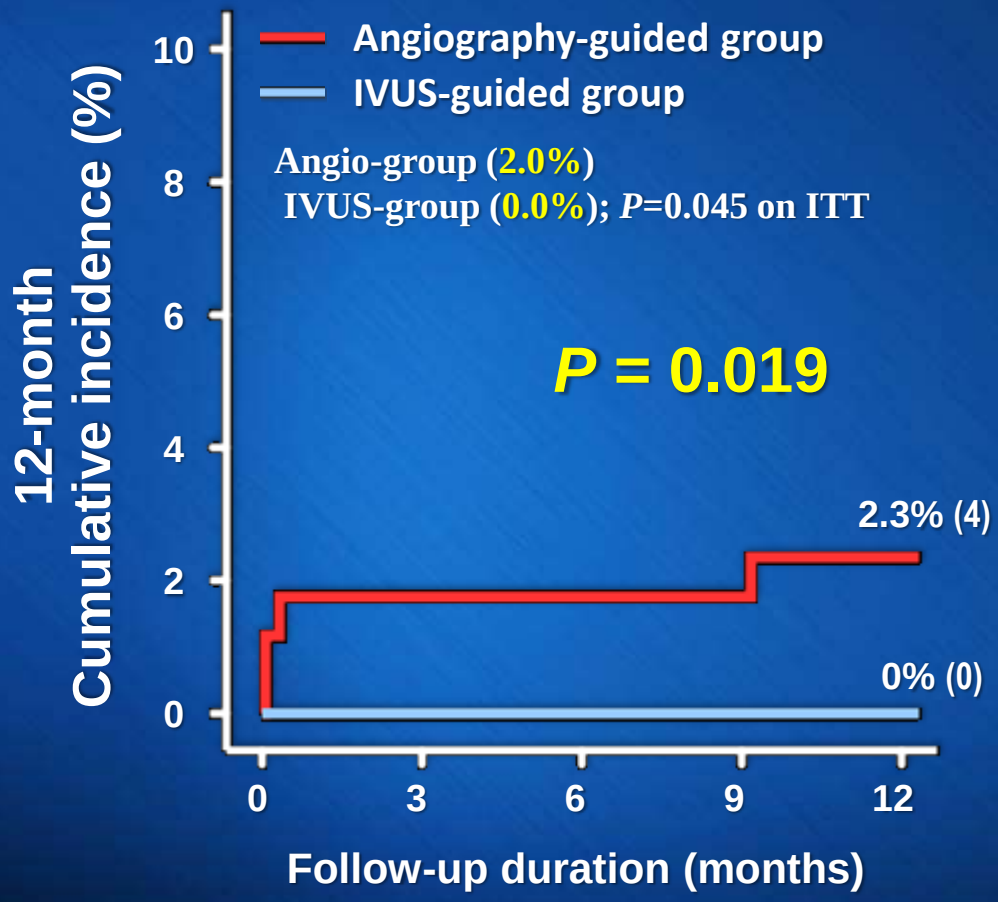


Number at risk						
Angiography-guided	201	198	187	201	199	180
IVUS-guided	201	199	190	201	198	186

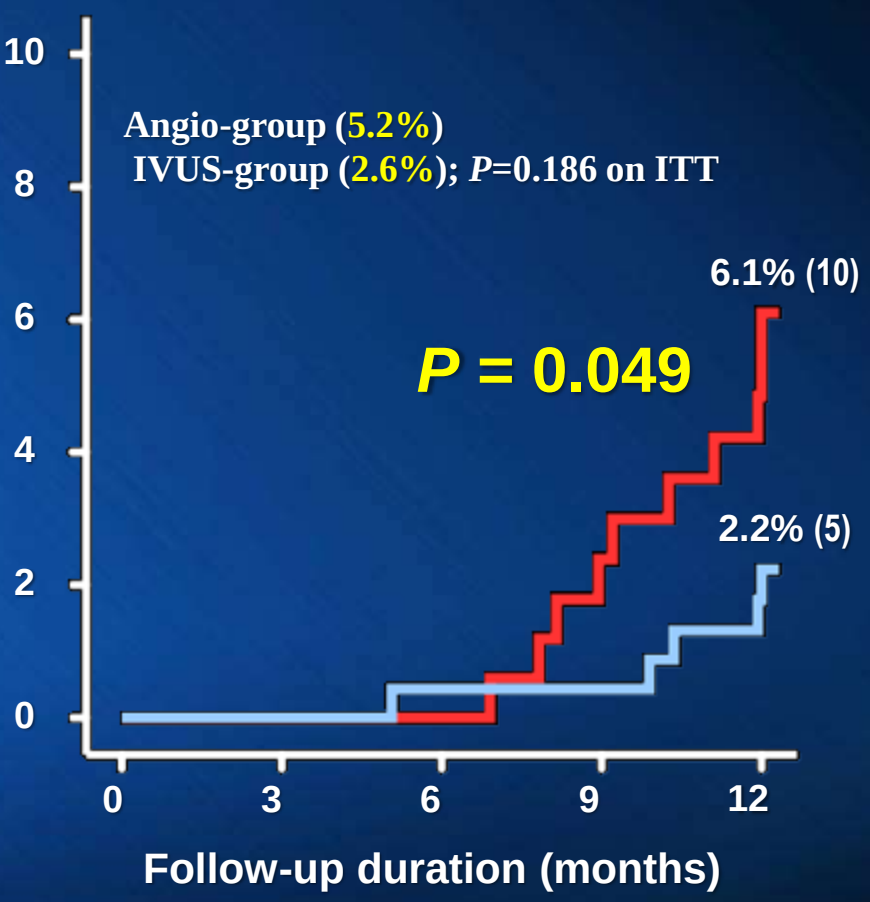
*Not calculable HR or CI because of no occurrence of the event

Per-protocol Analysis

Cardiac death or MI

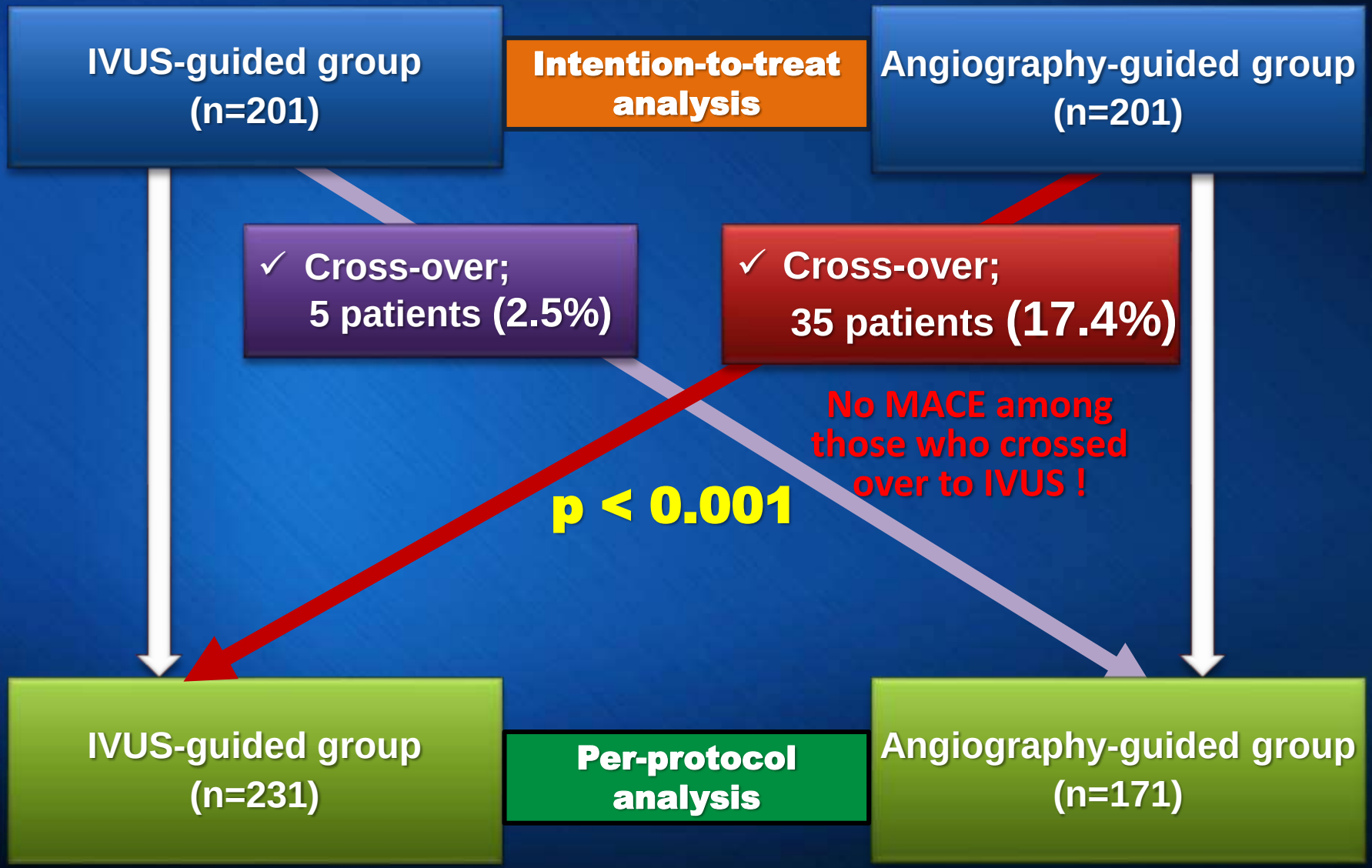


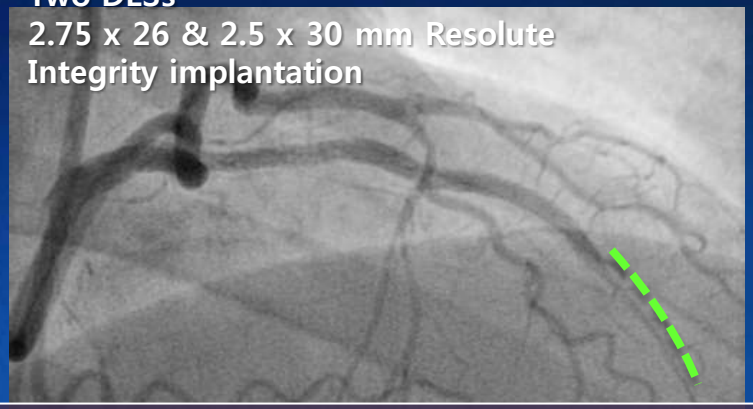
TVR



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

Study-at-a-glance





"Cross-over" in CTO-IVUS trial

- … raise the concerns regarding protocol-violation.
- IVUS use (Cross-over into IVUS guidance) in the inevitable cases had to be allowed for the safety concerns.

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

for the safety concerns by operator's discretion

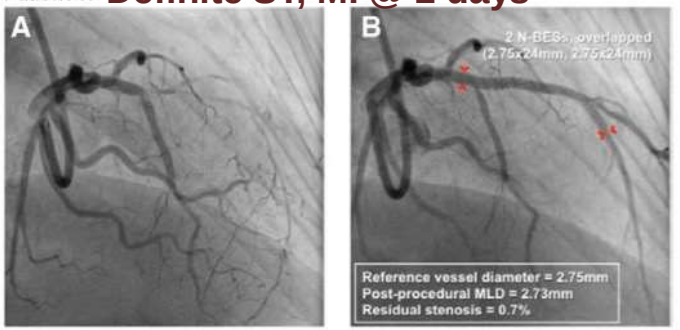
Fatal events ?

Table 3. Comparison of the Clinical Outcomes Between the IVUS-Guided Gr

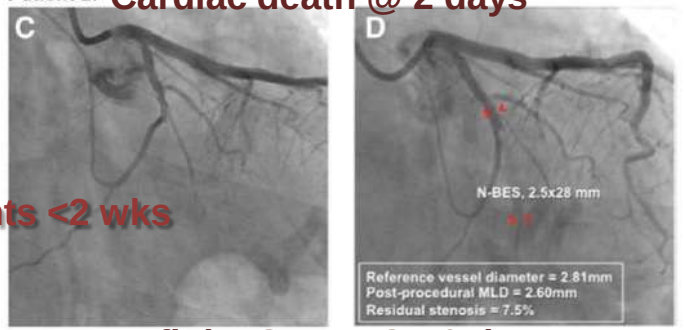
	IVUS-Guided Group (n=201)	Angiography-Guided (n=201)
Composite events		
MACE	5 (2.6)	14 (7.1)
Cardiac death or MI	0 (0.0)	4 (2.0)
Other components		
Death		
All	2 (1.0)	3 (1.5)
Cardiac	0 (0.0)	2 (1.0)
MI	0 (0.0%)	2 (1.0)
Stent thrombosis	0 (0.0)	3 (1.5)
Early	0	3
Late	0	0
Definite	0	2
Probable	0	1

3 patients; In-hospital or events <2 wks

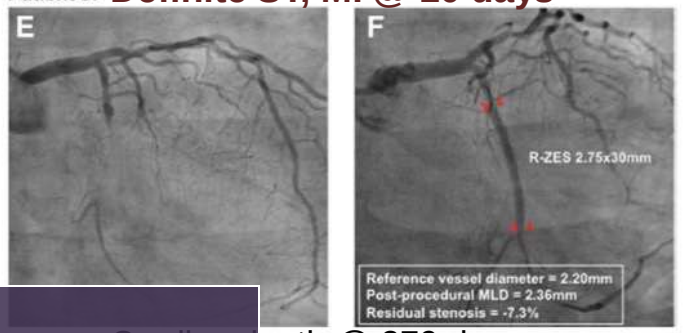
Patient 1. **Definite ST, MI @ 2 days**



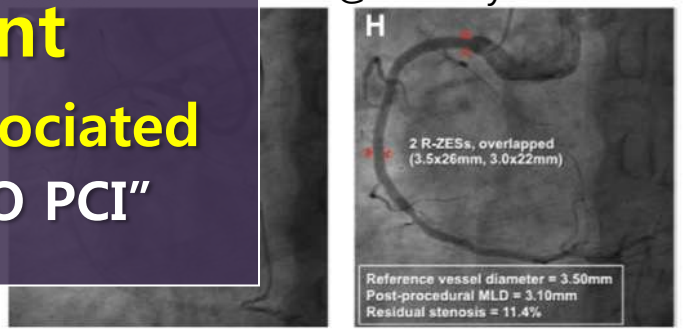
Patient 2. **Cardiac death @ 2 days**



Patient 3. **Definite ST, MI @ 10 days**



Patient 4. Cardiac death @ 279 days



→ Suggesting that "**IVUS could prevent early mechanical problems associated with fatal early-period events after CTO PCI**"

Take-home message

- **Our registry data and randomized study confirmed that IVUS-guided CTO intervention could improve clinical outcomes after 2nd-generation DES.**

- **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" & "solving mechanical problems"**

→ **… finally resultant short- & long-term safety**

Thank you for your attention