Optical Coherence Tomography-Guided or Intravascular Ultrasound-Guided PCI for In-Stent Restenosis Lesions in the OCTIVUS Trial

Kyeong-won Seo, MD

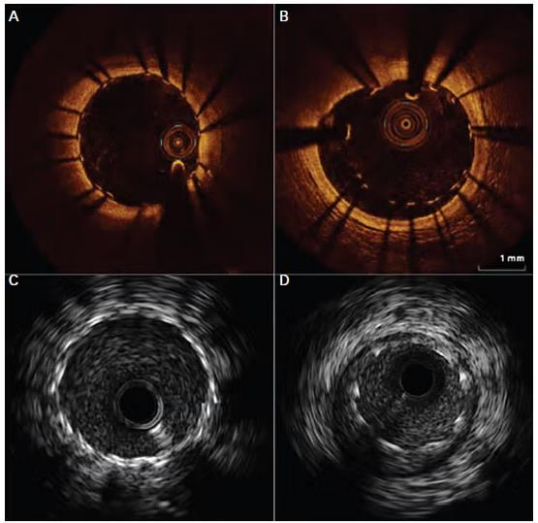
Asan Medical Center,
Ulsan University College of Medicine,
Seoul, Korea.

Disclosure

- I, Kyeongwon Seo DO NOT have any financial relationships to disclose.

Background

- Intracoronary imaging
  - Crucial role in PCI
  - Treatment of complex coronary lesions



Background

Recommendations for Use of Intravascular Imaging Referenced studies that support the recommendations are summarized in Online Data Supplement 25.		
COR	**LOE**	**Recommendations**
2a	**B-R**	1. In patients undergoing coronary stent implantation, IVUS can be useful for procedural guidance, particularly in cases of left main or complex coronary artery stenting, to reduce ischemic events.[1-10]
2a	**B-R**	2. In patients undergoing coronary stent implantation, OCT is a reasonable alternative to IVUS for procedural guidance, except in ostial left main disease.[11-13]
2a	**C-LD**	3. In patients with stent failure, IVUS or OCT is reasonable to determine the mechanism of stent failure.[14-17]

Assessment of procedural risks and post-procedural outcomes		
In patients with complex CAD in whom revascularization is being considered, it is recommended to assess procedural risks and post-procedural outcomes to guide shared clinical decision-making.	**I**	**C**
Calculation of the STS score is recommended to estimate in-hospital morbidity and 30-day mortality after CABG.[777,862–864]	**I**	**B**
In patients with multivessel obstructive CAD, calculation of the SYNTAX score is recommended to assess the anatomical complexity of disease.[786,865]	**I**	**B**
Intracoronary imaging guidance by IVUS or OCT is recommended when performing PCI on anatomically complex lesions, in particular left main stem, true bifurcations, and long lesions.[866,337,810,840,841]	**I**	**A**

1. ACC/AHA/SCAI guideline, 2021 / 2. ESC guideline 2024

RENOVATE-COMPLEX-PCI[1]	ULTIMATE[2]	IVUS-XPL[3]	ILUMIEN IV[4]	OCTOBER[5]
IVUS or OCT vs. Angiography	IVUS vs. Angiography		OCT vs. Angiography	OCT vs. Angiography
Complex lesion	De novo	Long lesion > 28mm	DM or Complex lesion	Complex bifurcation
1,639	1,448	1.400	2,487	1,201
TVF	TVF	TVF	TLF	MACE
1 yrs	1 yrs	1 yrs	2 yrs	2 yrs
ICI 7.7% Angio 12.3% HR 0.64, P=0.008	**IVUS 2.9%** Angio 5.4% HR 0.53, P = 0.019	**IVUS 2.9%** Angio 5.8% HR 0.48, P=0.007	OCT 7.4% Angio 8.2% HR 0.90, P=0.45	**OCT 10.1%** Angio 14.1% HR 0.7, P=0.035

1 J.M.Lee et al. NEJM. 2023 May 4 / 2 Junjie Zhang et al. JACC. 2018 Dec 18 / 3 Sung-Jin Hong et al. JAMA. 2015 Nov 10 / 4 Ziad A. Ali et al. JACC. 2024 JULY 23 / 5 N.R.Holm et al. NEJM. 2023 Oct 19

Background

Optical Coherence Tomography versus Intravascular Ultrasound Guided Percutaneous Coronary Intervention

OCTIVUS Trial

Patients with CAD undergoing PCI (N=2,000)

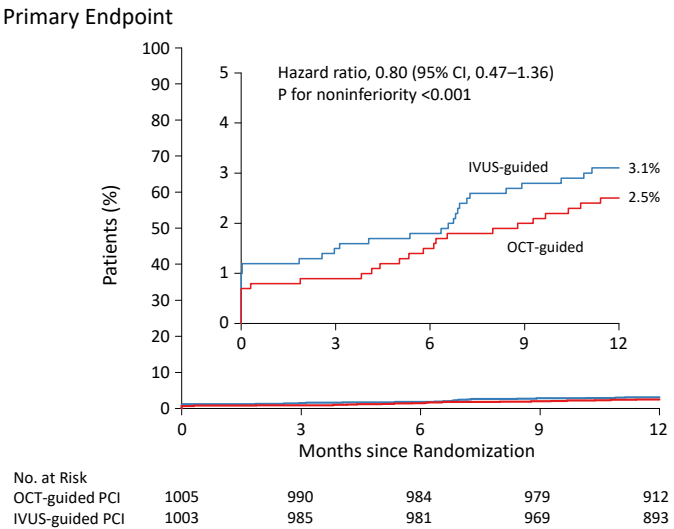
R

OCT-guided PCI (N=1,000)

IVUS-guided PCI (N=1,000)

Primary Endpoint: Target Vessel Failure at 1 year
(Composite of cardiac death, target-vessel MI and ischemia-driven TVR)

Clinical follow-up at 1, 6, 12 months, then 3 and 5 years

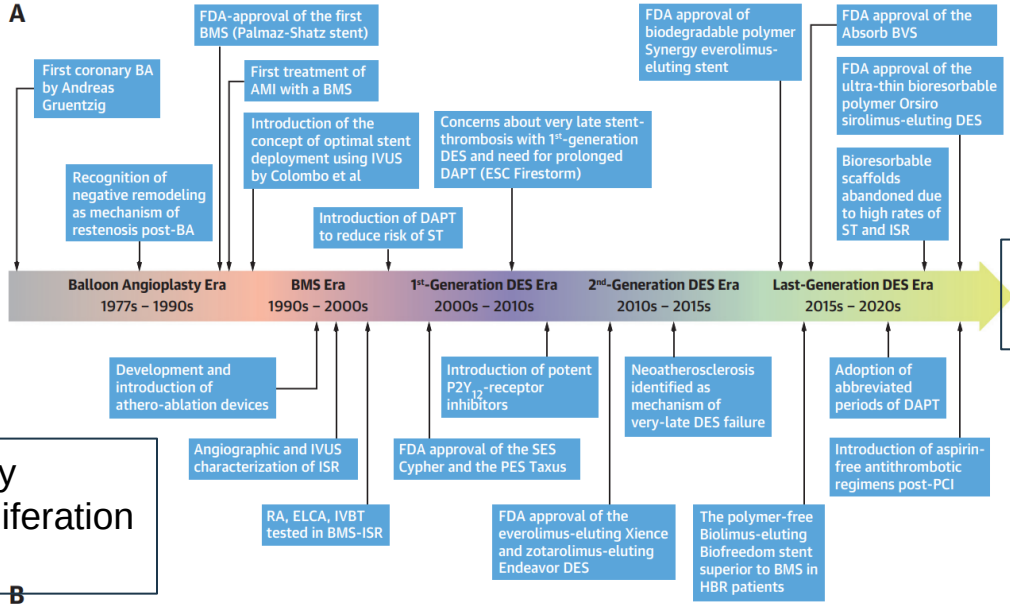


Kang DY et al. Am Heart J. 2020 Oct;228:72-80.

Background

abrupt vessel closure
coronary dissection
vessel recoil

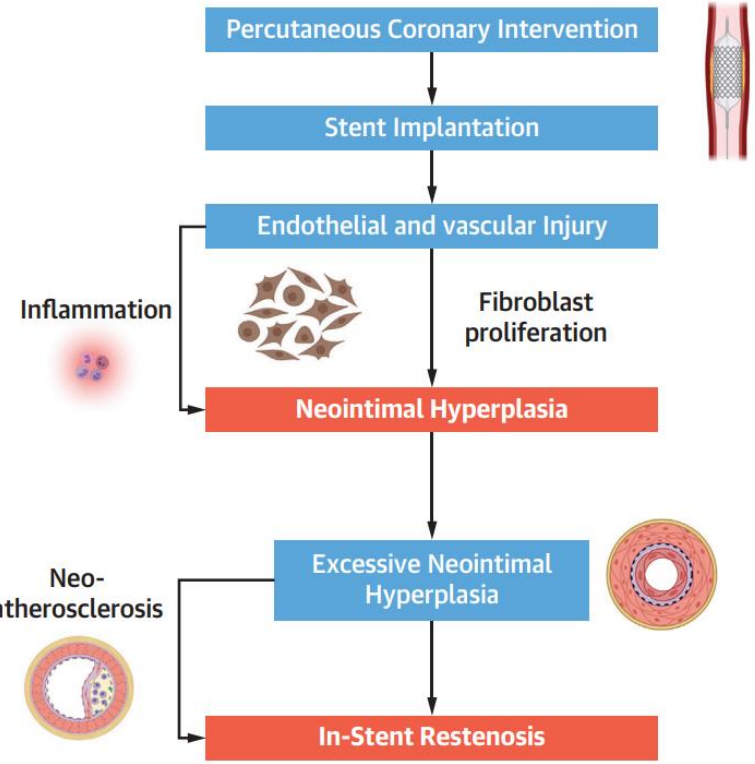
vascular injury
fibroblast proliferation
NIH



Favor long-term thrombotic safety profiles

Gennaro Giustino et al. JACC 2022 Jul, 80

Background



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Background

- Pathologic mechanisms of ISR are heterogeneous

- Anatomical factors
  - Vessel size
  - Smaller post procedural MLA
  - Severe calcification

- Clinical factors
  - DM, CKD, Older age, female sex, obesity, prev. PCI or CABG

- Stent-related factors
  - Type, drug distribution, drug type, strut thickness

- procedural factors
  - Stent underexpansion, malapposition, gap

Background

- Management of ISR is challenging because of its **heterogenous mechanisms** and the relatively high rate of recurrence

- **Intracoronary imaging modalities** (IVUS or OCT) are essential tools to characterize the mechanisms and substrate of ISR

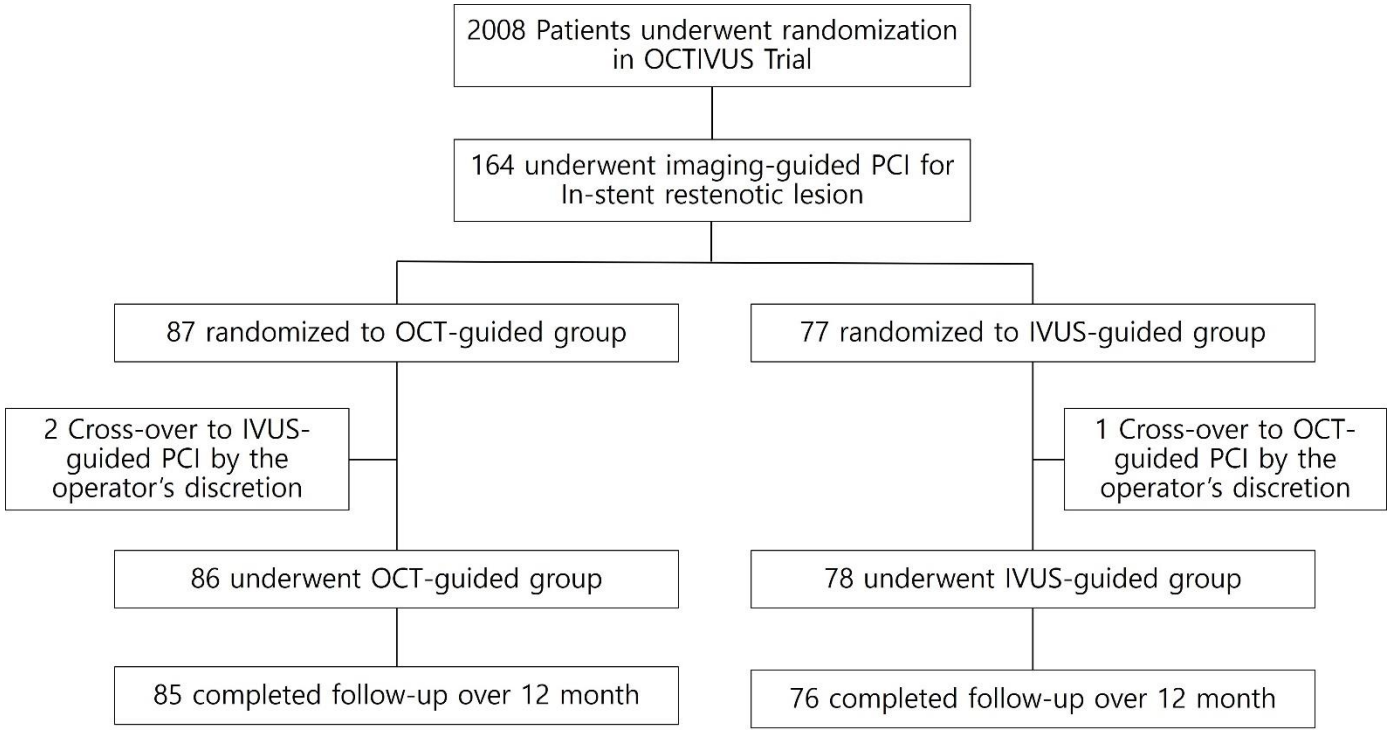
Object

- Comparative data on the efficacy and safety of OCT vs. IVUS in the treatment of ISR are limited.

- **OCT** vs. **IVUS** in **ISR** lesion

OCTIVUS trial

Subgroup analysis of ISR



Median follow-up period : 1.7 years

Methods

- Primary endpoint
  - Target-vessel failure : cardiac death, target-vessel MI, TVR

- Secondary endpoints
  - Target-lesion failure
  - Death
  - Target-vessel MI, any MI
  - Stent thrombosis
  - Stroke
  - CIN

Methods

- Not stratified by ISR at randomization
- Adjusted using inverse-probability-of-treatment weighting (IPTW)

Baseline characteristics

Characteristics	OCT (n=86)	IVUS (n=78)	*P* Value
Age	68.5±9.1	66.9±8.6	0.2581
Female sex	22 (25.6)	17 (21.8)	0.5695
Body-mass index	25.1±2.9	25.1±3.1	0.9086
Diabetes	33 (38.4)	35 (44.9)	0.3988
Insulin treatment	8 (9.3)	5 (6.4)	0.4936
Hypertension	56 (65.1)	54 (69.2)	0.5755
Hyperlipidemia	81 (94.2)	77 (98.7)	0.2135
Current smoker	16 (18.6)	12 (15.4)	0.5842
Family history of premature CAD	7 (8.1)	4 (5.1)	0.4414
Previous myocardial infarction	21 (24.4)	16 (20.5)	0.5501
Previous PCI	85 (98.8)	77 (98.7)	1.0000
Previous CABG	4 (4.7)	5 (6.4)	0.7374
Previous stroke	5 (5.8)	5 (6.4)	1.0000

Baseline characteristics

Characteristics	OCT (n=86)	IVUS (n=78)	*P* Value
Congestive heart failure	2 (2.3)	1 (1.3)	1.0000
Chronic pulmonary disease	3 (3.5)	2 (2.6)	1.0000
Peripheral vascular disease	2 (2.3)	3 (3.8)	0.6694
Atrial fibrillation	1 (1.2)	1 (1.3)	1.0000
End-stage renal disease on dialysis	3 (3.5)	4 (5.1)	0.7095
LVEF (%)	59.0±8.4	59.0±7.9	0.9922
LVEF ≤50%	10/66 (15.2)	12/62 (19.4)	0.5287
Clinical indication for index PCI			0.2047
Silent ischemia	6 (7.0)	1 (1.3)	
Chronic coronary syndrome	58 (67.4)	54 (69.2)	
Acute coronary syndrome	22 (25.6)	23 (29.5)	
Clinical indication for index PCI			0.2870
Silent ischemia	6 (7.0)	1 (1.3)	
Chronic coronary syndrome	58 (67.4)	54 (69.2)	
Unstable angina	12 (14.0)	15 (19.2)	
NSTEMI	10 (11.6)	8 (10.3)	

Anatomical or Lesion characteristics

Characteristics	OCT (n=86)	IVUS (n=78)	*P* Value
Treated complex coronary lesions			
Left main disease	14 (16.3)	19 (24.4)	0.1974
Any bifurcation disease	44 (51.2)	40 (51.3)	0.9878
Ostial lesion	6 (7.0)	6 (7.7)	0.8605
Chronic total occlusion	13 (15.1)	10 (12.8)	0.6724
Severely calcified lesion	4 (4.7)	5 (6.4)	0.7374
Diffuse long coronary lesions	42 (48.8)	37 (47.4)	0.8577
Multivessel PCI at index procedure	65 (75.6)	57 (73.1)	0.7136
Mean SYNTAX score	16.5±8.7	18.3±8.8	0.2083

Procedural characteristics

Characteristics	OCT (n=86)	IVUS (n=78)	*P* Value
PCI modality			0.9842
Use of drug-eluting stent	55 (64.0)	50 (64.1)	
Used of drug-coated balloon	31 (36.0)	28 (35.9)	
Total amount of contrast dye used — mL	249.4±128.1	208.1±104.1	0.0256
Total PCI time — min	52.7±25.0	64.0±33.4	0.0162
Procedural success			
Angiography-based	83 (96.5)	75 (96.2)	1.0000
Imaging-based	25 (29.4)	26 (35.1)	0.4406
Procedural complications requiring active intervention			
Any	1 (1.2)	4 (5.1)	0.1921
IVUS or OCT procedure-related complications	0 (0.0)	0 (0.0)	

Previous stent characteristics

Characteristics	OCT (n=95)	IVUS (n=98)	*P* Value
Previous stent type – n (%)			0.6
BMS	9 (12.0)	9 (12.0)	
Early generation DES	18 (24.0)	28 (26.0)	
Current generation DES	49 (64.0)	43 (59.0)	
BVS	0 (0.0)	2 (2.7)	
Unknown	19	25	
Previous stent size	3.1 ± 0.5	3.2 ± 0.4	0.6
Previous stent length	32.6 ± 23.3	35.4 ± 21.6	
Recurrent ISR	28 (32.0)	26(28.0)	0.6

Clinical outcomes (Crude)

Characteristics	OCT (n=86)	IVUS (n=78)	HR (95% CI)	*P* Value
Primary end point				
Target-vessel failure	9 (10.5)	23 (29.5)	0.34 (0.16-0.74)	0.0066
Secondary end points				
Target-lesion failure	9 (10.5)	23 (29.5)	0.34 (0.16-0.74)	0.0066
Death				
From any causes	1 (1.2)	2 (2.6)	0.60 (0.05-6.86)	0.6846
From cardiac causes	0 (0.0)	1 (1.3)	NE	-
Target-vessel MI	1 (1.2)	7 (9.0)	0.13 (0.02-1.06)	0.0572
Any MI	1 (1.2)	2 (2.6)	0.45 (0.04-5.00)	0.5185
Stent thrombosis	0 (0.0)	2 (2.6)	NE	-
Stroke	2 (2.3)	2 (2.6)	0.92 (0.13-6.56)	0.9366
Any revascularization	12 (14.0)	20 (25.6)	0.54 (0.26-1.11)	0.0929
Target-lesion revascularization	8 (9.3)	19 (24.4)	0.36 (0.16-0.83)	0.0165
Target-vessel revascularization	8 (9.3)	19 (24.4)	0.36 (0.16-0.83)	0.0165
Bleeding event (BARC type 3-5)	0 (0.0)	4 (5.1)	NE	-
CIN	2 (2.3)	3 (3.8)	0.60 (0.10-3.52)	0.5759

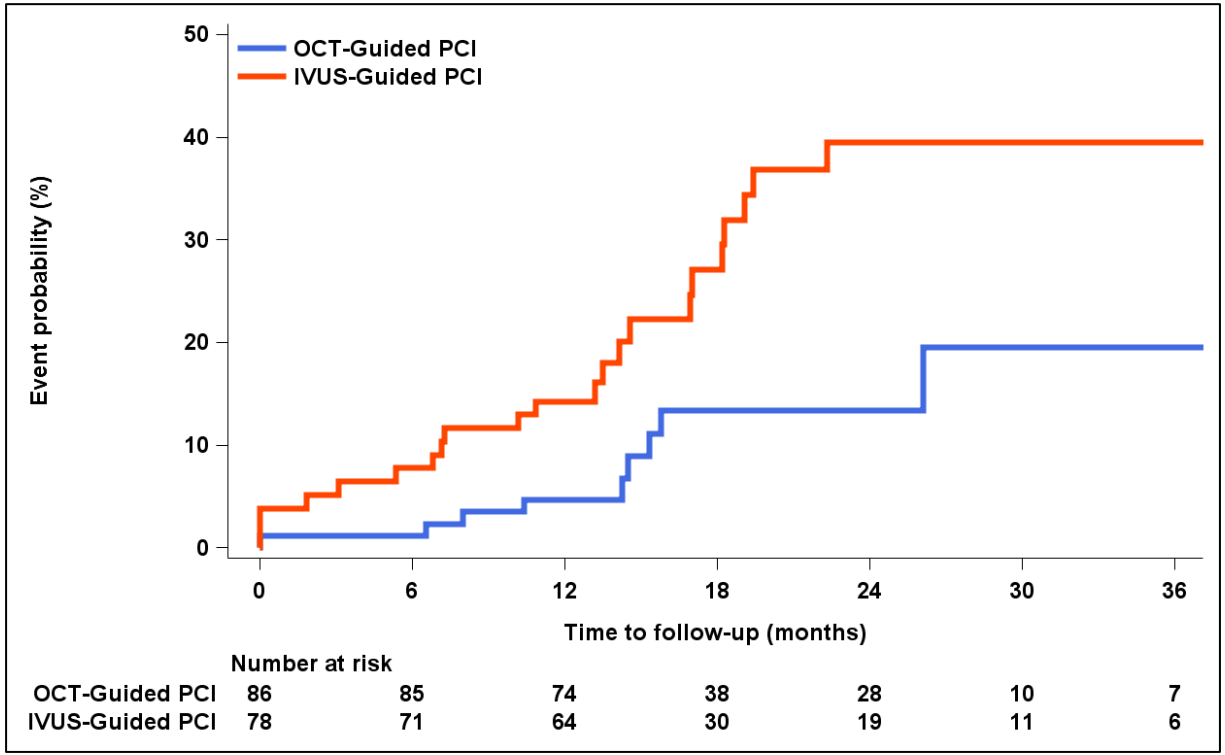
Clinical outcomes (IPTW)

Characteristics	OCT (n=86)	IVUS (n=78)	HR (95% CI)	*P* Value
Primary end point				
Target-vessel failure	16 (9.6)	47 (29.0)	0.31 (0.14-0.69)	0.0039
Secondary end points				
Target-lesion failure	16 (9.6)	47 (29.0)	0.31 (0.14-0.69)	0.0039
Death				
From any causes	2 (1.0)	4 (2.5)	0.51 (0.04-5.94)	0.5914
From cardiac causes	0 (0.0)	2 (1.3)	NE	-
Target-vessel MI	2 (1.2)	16 (10.1)	0.11 (0.01-0.94)	0.0434
Any MI	2 (1.2)	4 (2.6)	0.44 (0.04-4.73)	0.495
Stent thrombosis	0 (0.0)	4 (2.6)	NE	-
Stroke	4 (2.4)	4 (2.3)	1.06 (0.15-7.71)	0.9540
Any revascularization	21 (12.7)	38 (23.3)	0.52 (0.25-1.10)	0.0867
Target-lesion revascularization	14 (8.5)	36 (22.2)	0.35 (0.15-0.83)	0.0171
Target-vessel revascularization	14 (8.5)	36 (22.2)	0.35 (0.15-0.83)	0.0171
Bleeding event (BARC type 3-5)	0 (0.0)	8 (4.8)	NE	-
CIN	5 (2.9)	6 (3.6)	0.81 (0.13-4.92)	0.8155

* Adjustment using IPTW, variables are Age, BMI, hypertension, DM, prior MI, prior PCI

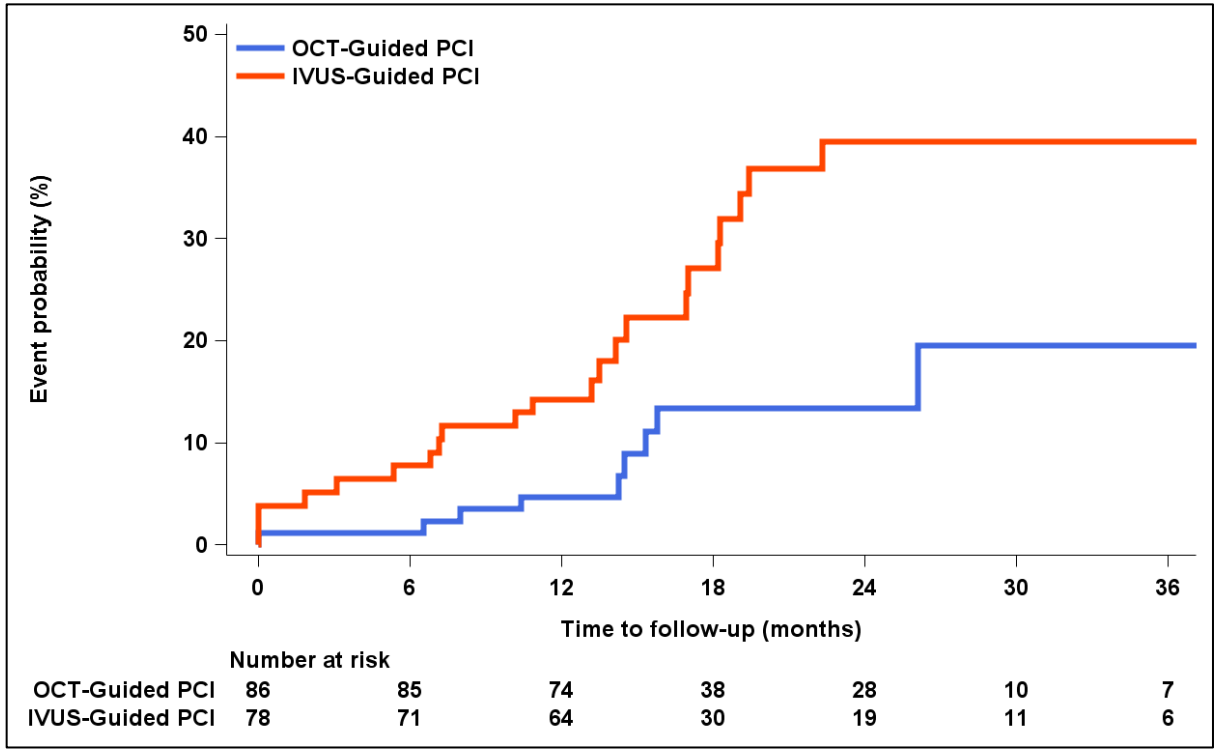
Kaplan-Meier Curve

Primary outcome; TVF



Kaplan-Meier Curve

After IPTW



Discussions

- Treatment of ISR lesion requires detailed evaluation of stent struts, lumen area and neointimal patterns

- Given **Higher resolution**, ability to delineate the composition of different plaque morphologies, OCT is superior to IVUS in assessing stent failure
  - identify stent underexpansion or malapposition
  - accurately detect thrombus
  - categorize the composition of the neointima or neoatherosclerosis

- Identifying the etiology of ISR has important implications for optimizing treatment and improving outcomes.

Summarize

- Despite the continuous advancement of DES technology, ISR remains a persistent clinical issue
- Because the mechanisms underlying ISR are heterogeneous, treatment should be tailored according to the specific characteristics of each lesion
- intracoronary imaging (ICI) plays a critical role in identifying the underlying pathology of ISR.
- In our study, OCT-guided PCI demonstrated superior clinical outcomes compared to IVUS-guided PCI
- Given Higher resolution, ability to delineate the composition of different plaque morphologies, OCT is superior to IVUS in assessing stent failure

Conclusion

- In ISR lesions**, OCT-guided PCI showed a significant reduction** in the primary-composite event of death from cardiac causes, target-vessel–related MI, or target-vessel revascularization as compared with IVUS-guided PCI

Thank you for your attention