Would I Still Use OCT in Bifurcation PCI After Illumien IV and Why?

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Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Affiliation/Financial Relationship	Company
Grant/Research Support (*Institutional)*	NIH/NHLBI, Abbott, Philips, Boston Scientific, Abiomed, Opsens, Acist Medical, Medtronic Cardiovascular Systems Inc
Consulting Fees/Honoraria	Amgen, Astra Zeneca, Boston Scientific
Equity	Shockwave Medical

Qualifying High-risk Criteria

High-risk Patient

- Medication-treated diabetes mellitus

High-risk Lesion

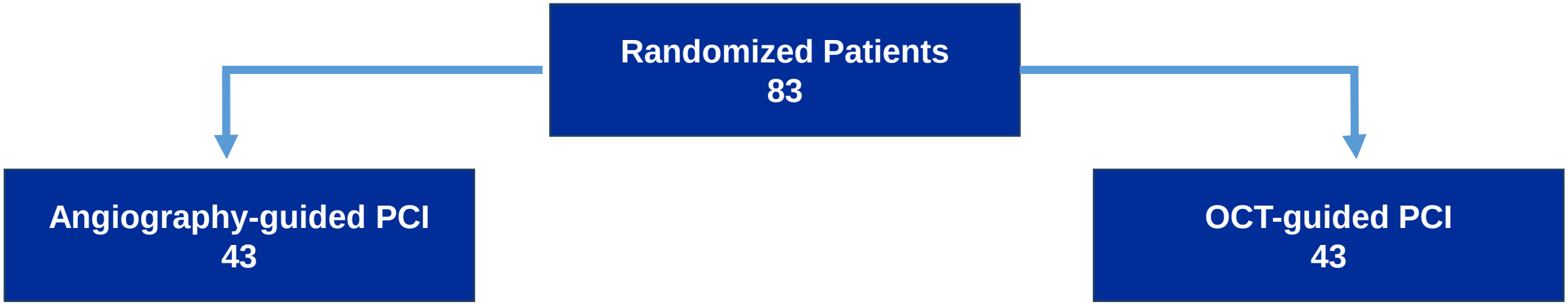
- NSTEMI
- STEMI >24 hours from symptom onset
- Long or multiple lesions (planned total stent length ≥28 mm)
- Diffuse or multi-focal in-stent restenosis
- Angiographic severe calcification
- Chronic total occlusion
- Bifurcation, planned to be treated with 2 stents

EuroIntervention. 2021 Jan 20;16(13):1092-1099.

Qualifying Characteristics

	OCT (n=1231)	Angio (n=1250)	Difference [95% CI]
Medication-treated diabetes mellitus	40.4%	39.8%	0.5% (-3.3, 4.4)
Long or multiple lesions	69.3%	65.9%	3.4% (-0.3, 7.0)
NSTEMI	24.5%	23.8%	0.6% (-2.8, 4.0)
Angiographic severe calcification	11.4%	11.7%	-0.3% (-2.8, 2.2)
In-stent restenosis (ISR)	10.6%	11.0%	-0.5% (-2.9, 2.0)
Chronic total occlusion (CTO)	7.6%	6.3%	1.3% (-0.7, 3.3)
STEMI (>24 hours from onset)	5.4%	5.6%	-0.2% (-2.1, 1.6)
Bifurcation with 2 planned stents	3.2%	3.4%	-0.2% (-1.6, 1.3)

ILUMIEN IV – 2-Stent Bifurcation



- Per Protocol only main branch OCT was required for final assessment

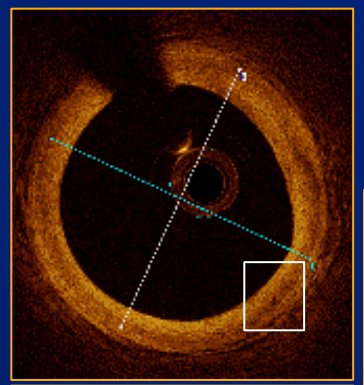
OCT Stent Sizing Algorithm

Pre-PCI OCT

Measure the EEL at both proximal and distal reference segments, if possible.[2]

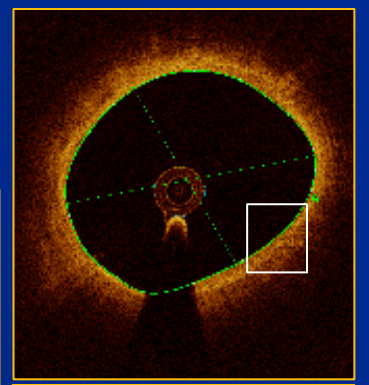
Can the EEL be identified at the distal reference segment to allow vessel diameter measurement?[3]

Yes



Stent diameter decided by OCT measurement of mean EEL to EEL diameter rounded down to nearest stent size[4]

No



Stent diameter decided by OCT measurement of mean lumen diameter rounded up to nearest stent size[4]

Stent length determined by OCT automation adjusted for Xience DES[5]

OCT Stent Optimization Algorithm

Target MSA (in both proximal and distal **segments** of the stent relative to the closest reference segment)

- Acceptable, ≥ 90%
- Unacceptable, <90%

Angiographic co-registration guided stent implantation

Angiographic success?
- ≤0% diameter stenosis

No → Post-dilation based on **Pre-PCI OCT EEL**
- ≥18atm with NC balloon in underexpanded segment

Post-PCI OCT

Target MSA criteria achieved?

No → Post-dilation based on **Post-PCI OCT EEL**
- ≥18atm with NC balloon in underexpanded segment

Reference segments free of major dissection with MLA ≥ 4.5mm^2 ?

No → Place additional DES
- Unless anatomically prohibitive

(i.e diffuse disease, tapering vessel)

Other reason for additional PCI?

Yes → Operator directed optimization

Final OCT imaging

Baseline Characteristics

	Angio (n=43)	OCT (n=40)
Age, years	62.4 ± 9.1	65.6 ± 8.4
Male	86%	88%
Hypertension	63%	70%
Dyslipidemia	65%	60%
Diabetes mellitus	32%	27%
Current smoker	23%	22%
Serum creatinine, mg/dl	0.91 ± 0.18	0.92 ± 0.18
Silent ischemia	9.0%	5.0%
Stable angina	28%	38%
Acute coronary syndrome	34%	23%

Procedural Characteristics

	Angio (n=43)	OCT (n=40)
Stent length, mm	63.0 ± 32.4	59.8 ± 18.4
Maximal stent diameter, mm	3.2 ± 0.4	3.3 ± 0.4
Post-dilatation, n	94%	100%
Post-dilatation balloons used, n	3.3 ± 2.1	3.8 ± 2.5
Maximum device size, mm	3.5 ± 0.4	3.9 ± 0.6
Maximum inflation pressure, atm	17.8 ±2.9	20.2 ± 2.7
Procedure duration, min	79.3 ± 35.6	122.7 ± 53.6
Fluoroscopy duration, min	24.2 ± 10.8	37.5 ± 17.4
Radiation dose, Gy	2.0 ± 1.3	2.8 ± 1.8
Contrast volume, mL	238.2 ± 94.1	302.3 ± 101.4

Primary Imaging Endpoint

Post-PCI MSA by OCT (mm^2)

Angio L=43	OCT L=40	Difference
5.3 ± 1.6	5.7 ± 1.6	0.4

Stent Expansion Endpoints

	Angio (L=43)	OCT (L=40)
Min stent expansion, %	75.5 ± 14.5	76.2 ± 14.8
Mean stent expansion, %	106.6 ± 14.7	110.6 ± 17.3
Stent expansion		
- Acceptable (≥90%)	24%	48%

Post-procedure OCT Findings

	Angio (L=43)	OCT (L=40)
Dissection, any	37%	38%
Major	6.5%	2.5%
Minor	15%	25%

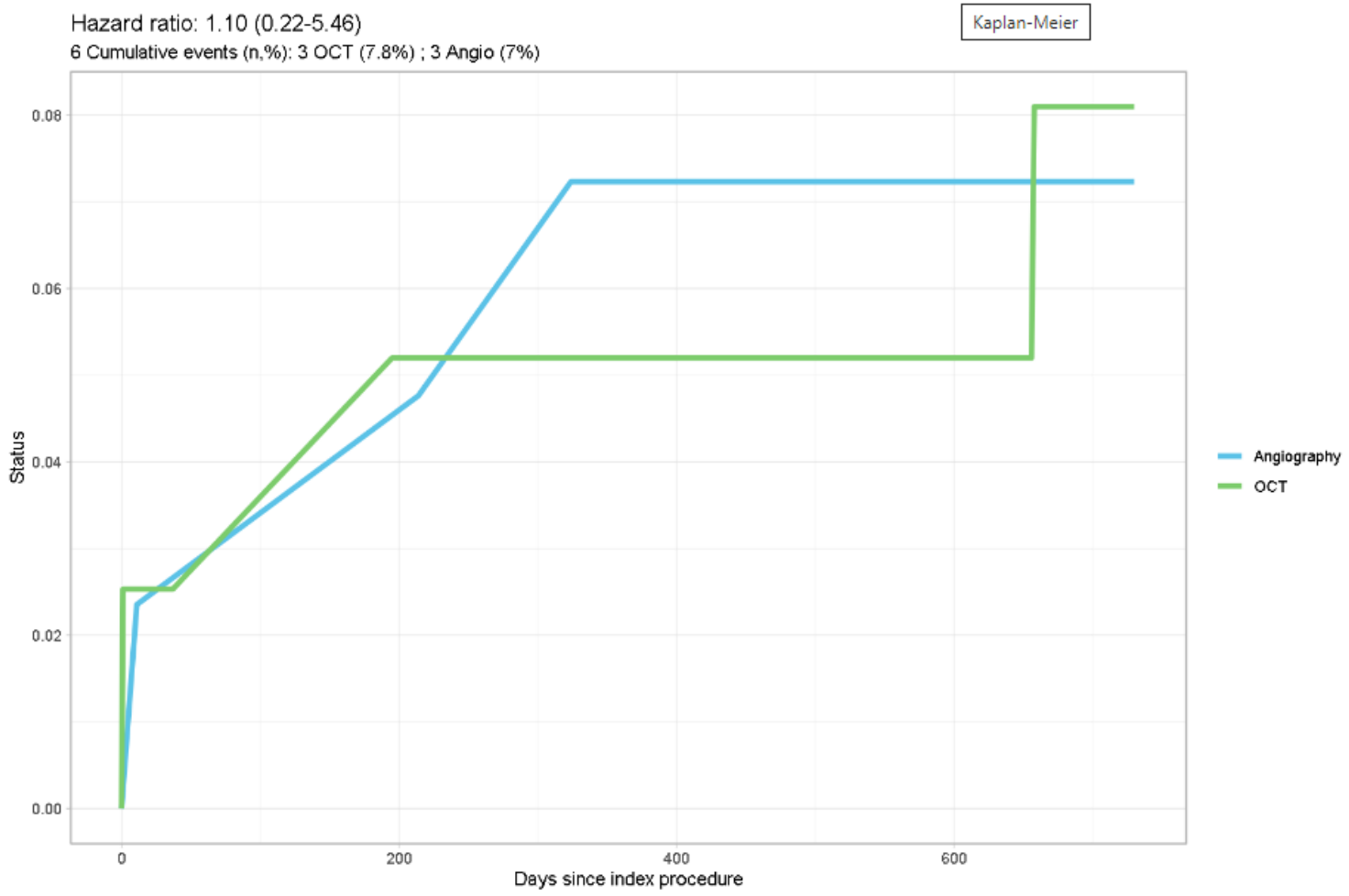
	Angio (L=43)	OCT (L=40)
Malapposition, any	74%	70%
Major	33%	23%
Minor	41%	48%

Post-procedure OCT Findings

	Angio (L=43)	OCT (L=40)
Tissue Protrusion, any	50%	43%
Major		
Minor	50%	43%

	Angio (L=43)	OCT (L=40)
Reference Segment Disease, any	13%	11%
Focal	9%	9%
Diffuse	4%	3%

Target Vessel Failure

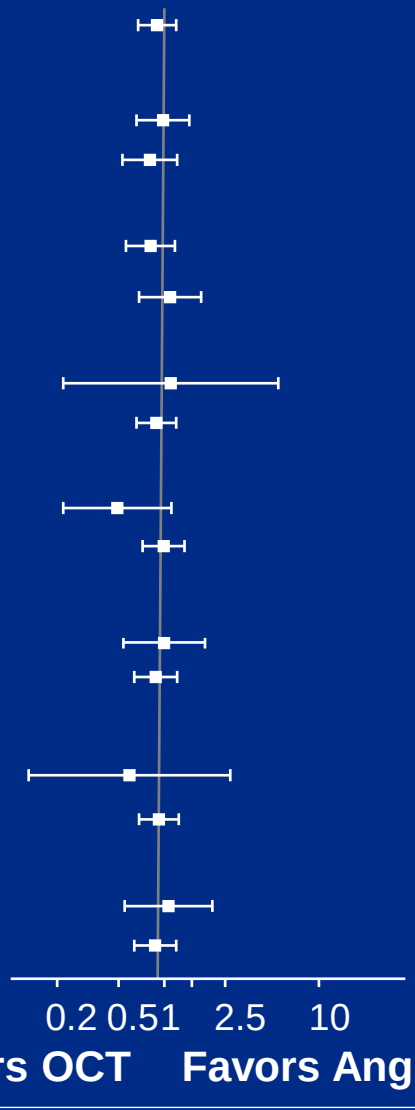


2-Year Clinical Outcomes

	Angio (n=43)	OCT (n=40)	Hazard Ratio (95% CI)
Target Vessel Failure	7.0%	7.8%	1.10 (0.22, 5.46)
-Cardiac	0%	0%	-
-TV-MI	0%	2.5%	-
-Periprocedural MI	0%	2.5%	-
- ID-TVR	7.0%	7.8%	1.08 (0.22, 5.35)
- Stent Thrombosis	0%	0%	-

Sub-group Analysis

Subgroup	OCT	Angiography	Hazard Ratio [95% CI]
All Subjects (n=2487)	7.4%	8.2%	0.90 [0.67, 1.19]
Medication-treated diabetes			
Medication-treated Diabetes (n=995)	10.1%	10.1%	0.98 [0.66, 1.46]
Others (n=1486)	5.6%	7.0%	0.80 [0.53, 1.22]
Total stent length ≥28mm			
≥28mm (n=1677)	6.4%	7.9%	0.81 [0.56, 1.16]
<28mm (n=804)	9.7%	8.7%	1.09 [0.68, 1.73]
Two-stent bifurcation			
Yes (n=83)	7.8%	7.0%	1.10 [0.22, 5.46]
No (n=2398)	7.4%	8.2%	0.89 [0.66, 1.19]
Severe calcification			
Yes (n=286)	6.6%	12.7%	0.50 [0.22, 1.11]
No (n=2195)	7.5%	7.6%	0.98 [0.72, 1.34]
NSTEMI/ STEMI >24h			
Yes (n=735)	5.9%	5.9%	1.00 [0.54, 1.82]
No (n=1746)	8.1%	9.1%	0.87 [0.63, 1.21]
CTO			
Yes (n=173)	3.3%	5.4%	0.60 [0.13, 2.69]
No (n=2308)	7.8%	8.4%	0.92 [0.68, 1.23]
Diffuse or multi-focal ISR			
Yes (n=268)	15.2%	13.5%	1.06 [0.55, 2.05]
No (n=2213)	6.5%	7.5%	0.86 [0.63, 1.19]



- In keeping with EBC recommendations, 2-stent bifurcation PCI was uncommon in ILUMIEN IV
- OCT-guidance resulted in a larger MSA than angiography guidance, with greater procedural success
- OCT-guidance led to fewer major dissections and major malapposition
- The 2-year rates of TVF were not different between OCT-guided and angiography-guided PCI

OCTOBER

OCT Optimised Bifurcation Event Reduction

Aarhus University Hospital
SKEJBY

REGION MIDTJYLLAND

OCT Protocol – Timing principles

1

Before stent implantation

Evaluation of predilatation

Planning of the procedure

2

After rewiring

Wire control

Stent optimization

3

Final evaluation

OCT treatment goals

Holm NR et al. Rational and design of the European randomized Optical Coherence Tomography Optimized Bifurcation Event Reduction Trial (OCTOBER), Am Heart J 2018

OCT Protocol – Four treatment goals

Optimal lesion coverage

No residual edge disease or untreated lesions

No stent malapposion

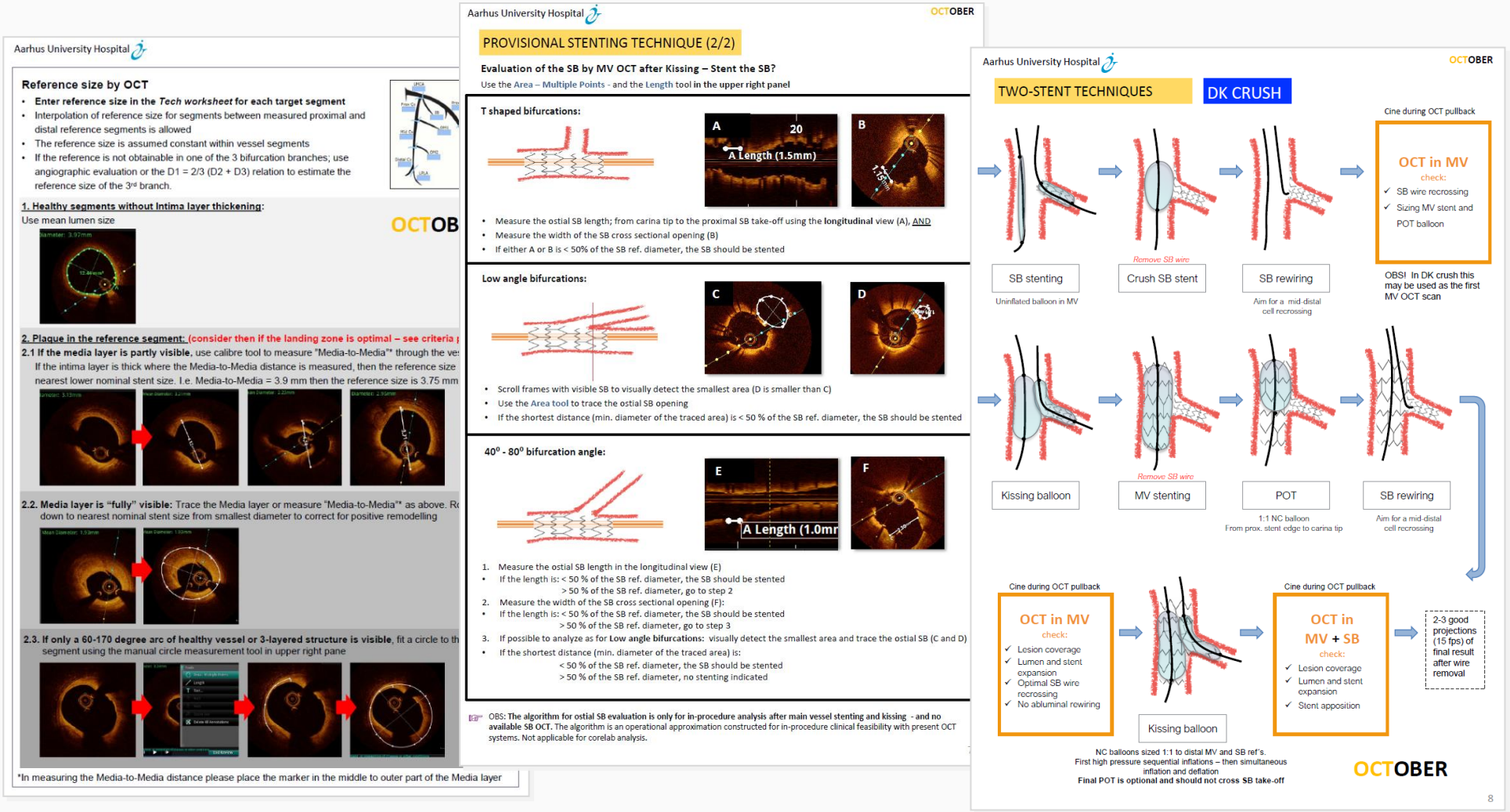
Optimal stent expansion

Stent diameter ≥ 90% of the corresponding segment´s reference diameter

No unintended crushed or distorted stent segments

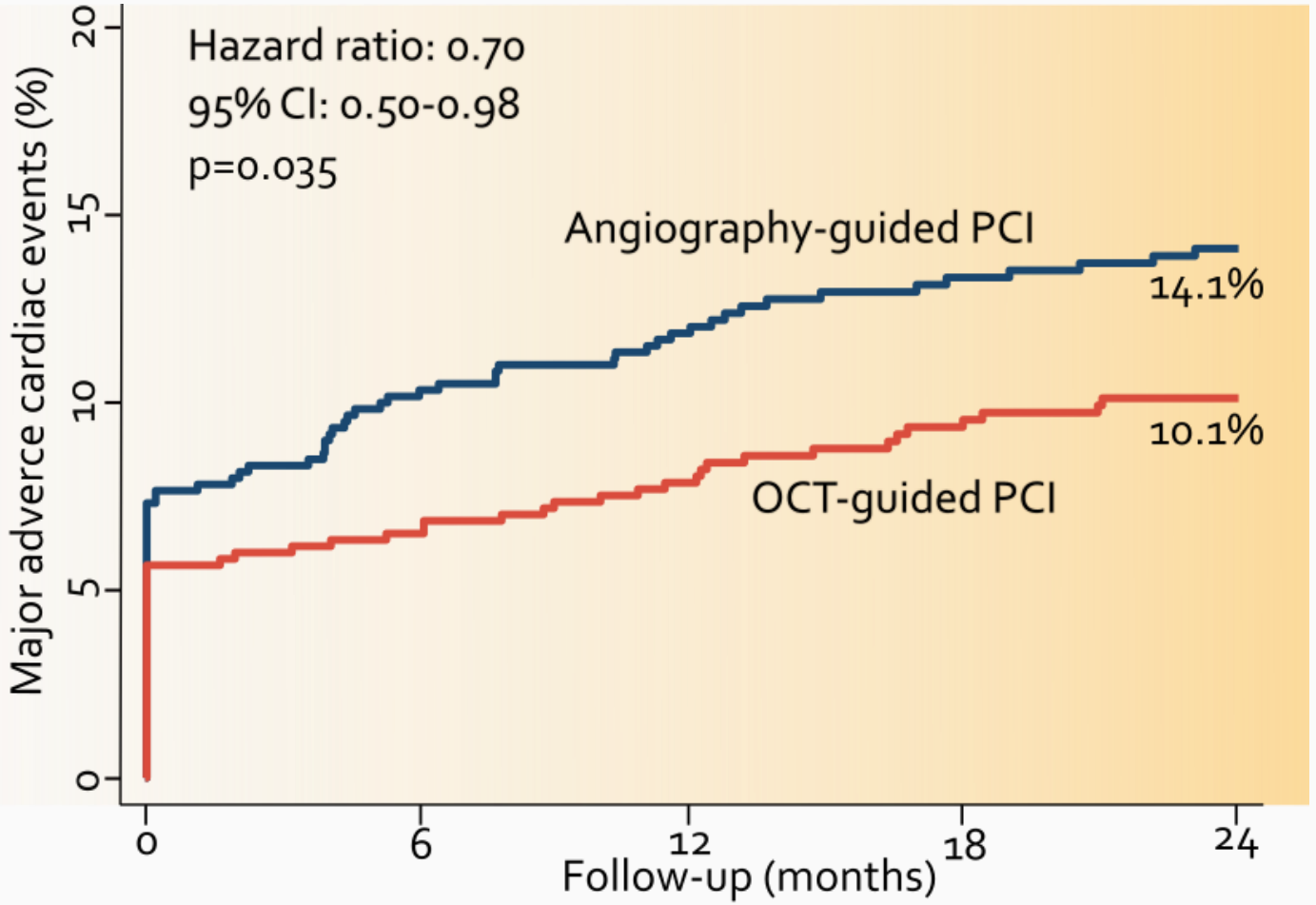
Holm NR et al. Rational and design of the European randomized Optical Coherence Tomography Optimized Bifurcation Event Reduction Trial (OCTOBER), Am Heart J 2018

OCT-guiding protocol



Holm NR et al. Rational and design of the European randomized Optical Coherence Tomography Optimized Bifurcation Event Reduction Trial (OCTOBER), Am Heart J 2018

Primary endpoint - MACE

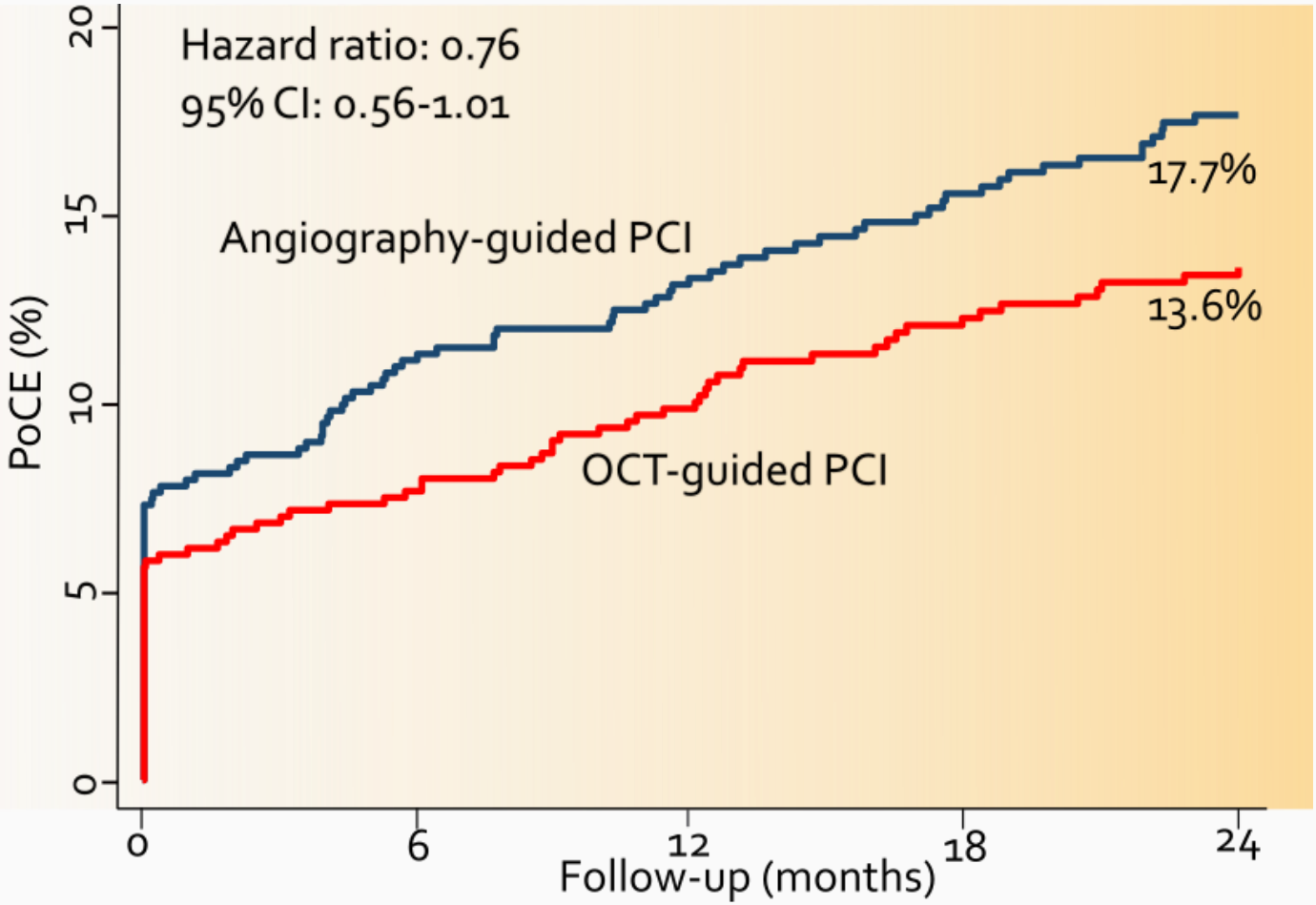


No. At Risk:					
OCT-guided PCI	600	553	537	472	439
Angiography-guided PCI	601	534	509	452	408

MACE: cardiac death, target lesion myocardial infarction, ischemia-driven target lesion revascularization

Kaplan Meier estimates
Comparison by unadjusted Cox analysis
Confirmed by adusted Cox analysis

Patient-oriented Composite Endpoint (PoCE)



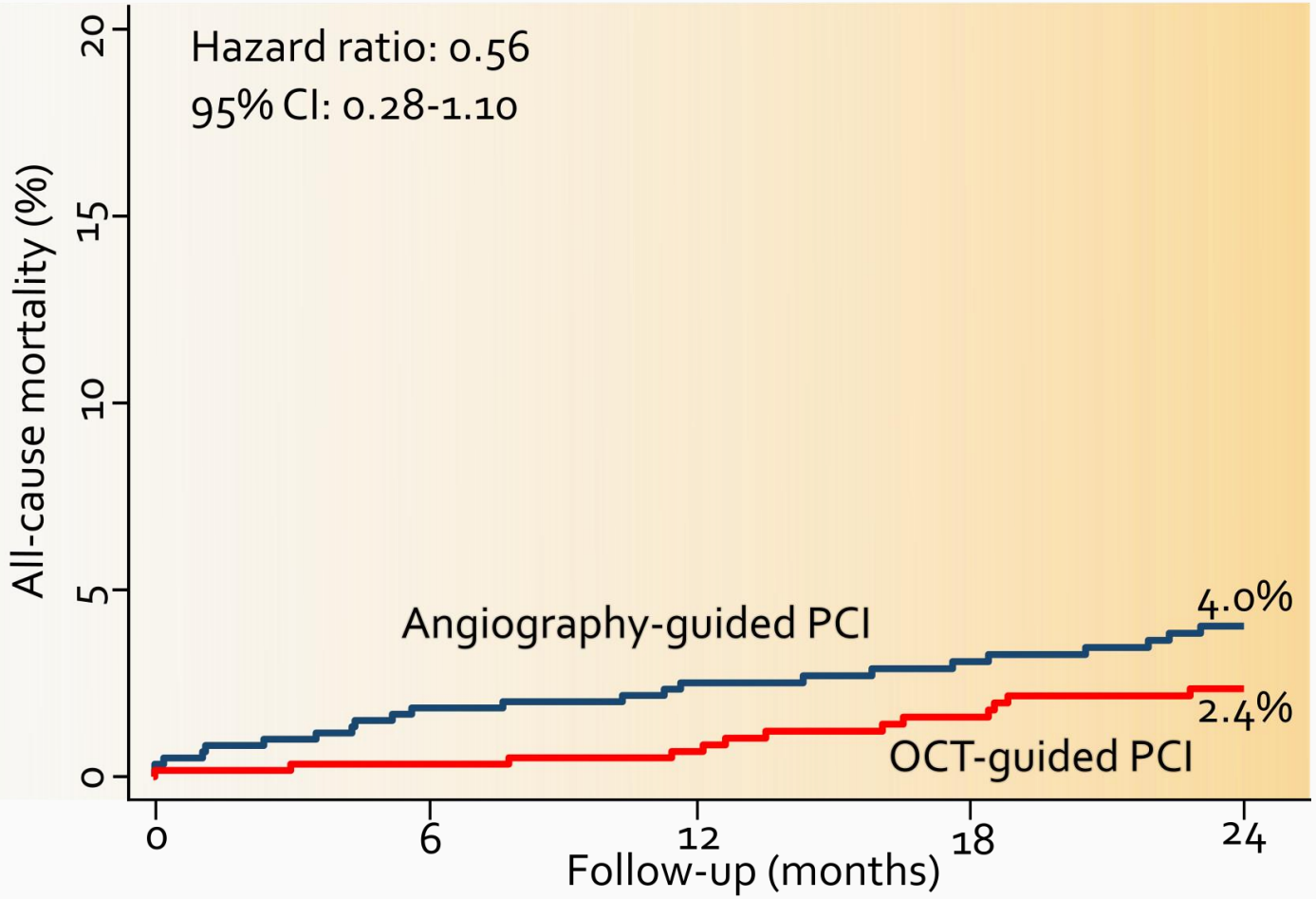
No. At Risk:					
OCT-guided PCI	600	547	527	460	427
Angiography-guided PCI	601	530	504	445	397

PoCE : All-cause mortality, Any myocardial infarction, any repeat revascularization

Kaplan Meier estimates

Secondary endpoint. Not powered

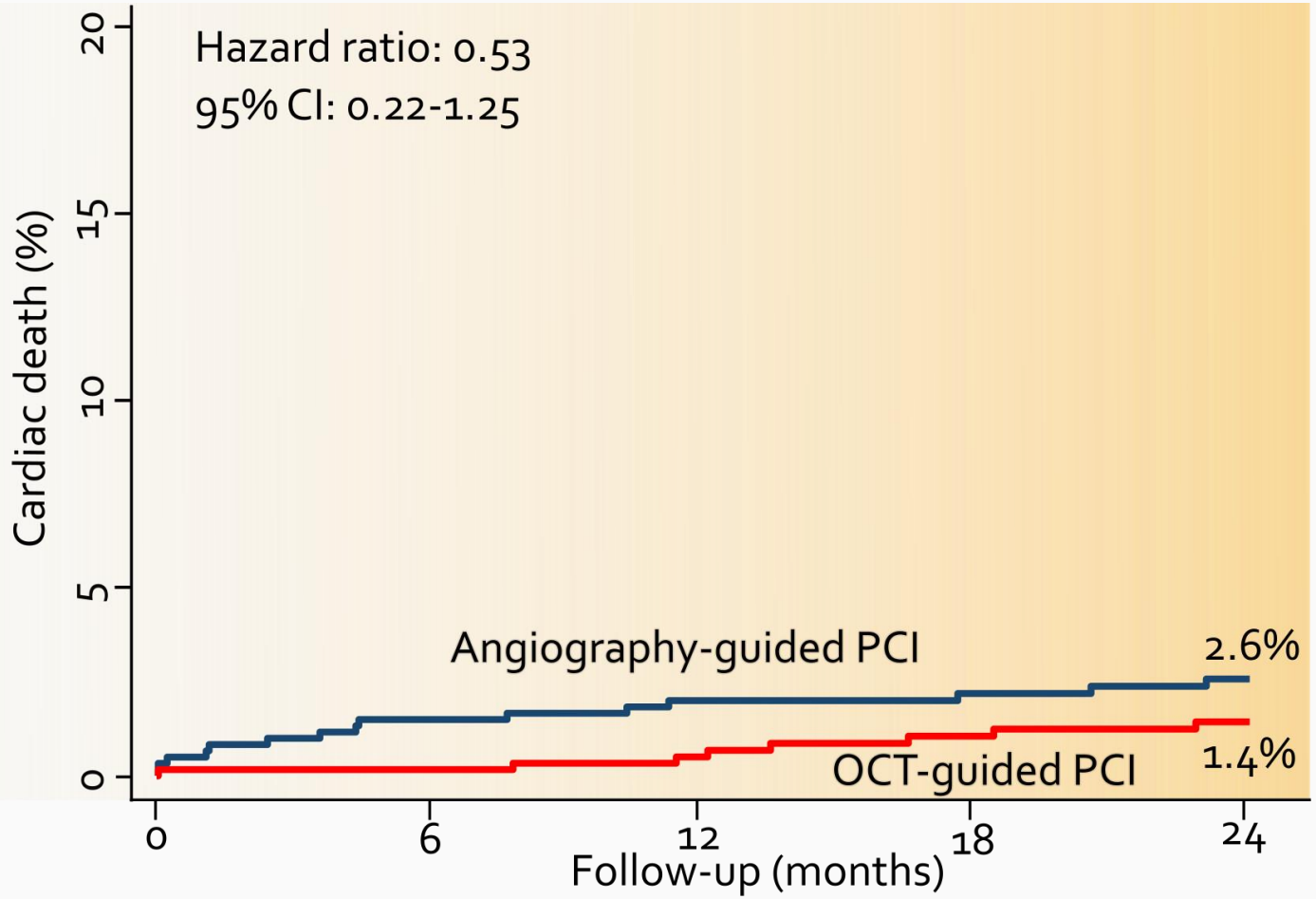
All-cause mortality



No. At Risk:					
OCT-guided PCI	600	591	581	519	483
Angiography-guided PCI	601	586	567	511	465

Kaplan Meier estimates
Secondary endpoint. Not powered

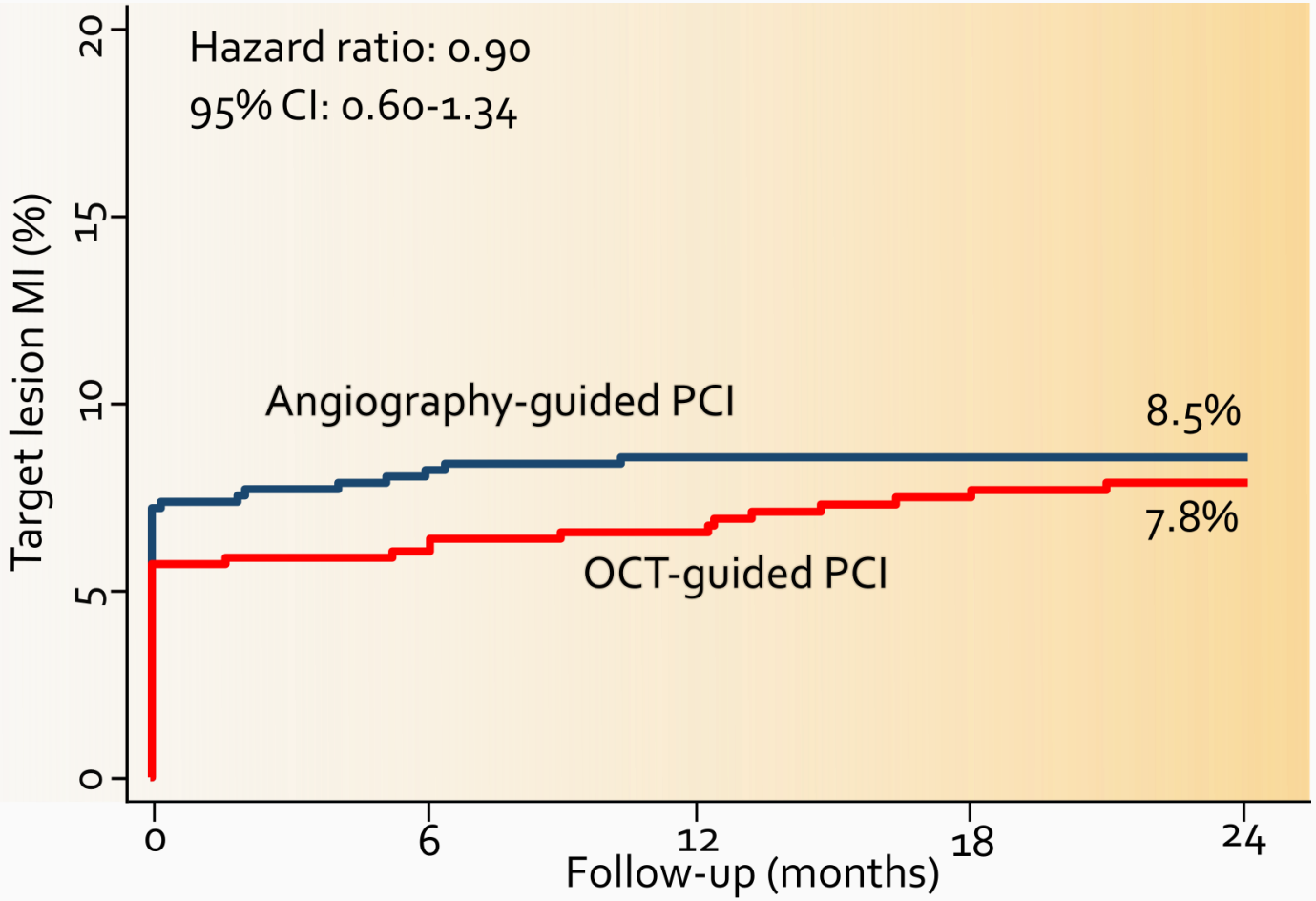
Cardiac death



No. At Risk:					
OCT-guided PCI	600	591	581	519	483
Angiography-guided PCI	601	586	567	511	465

Kaplan Meier estimates
Secondary endpoint. Not powered

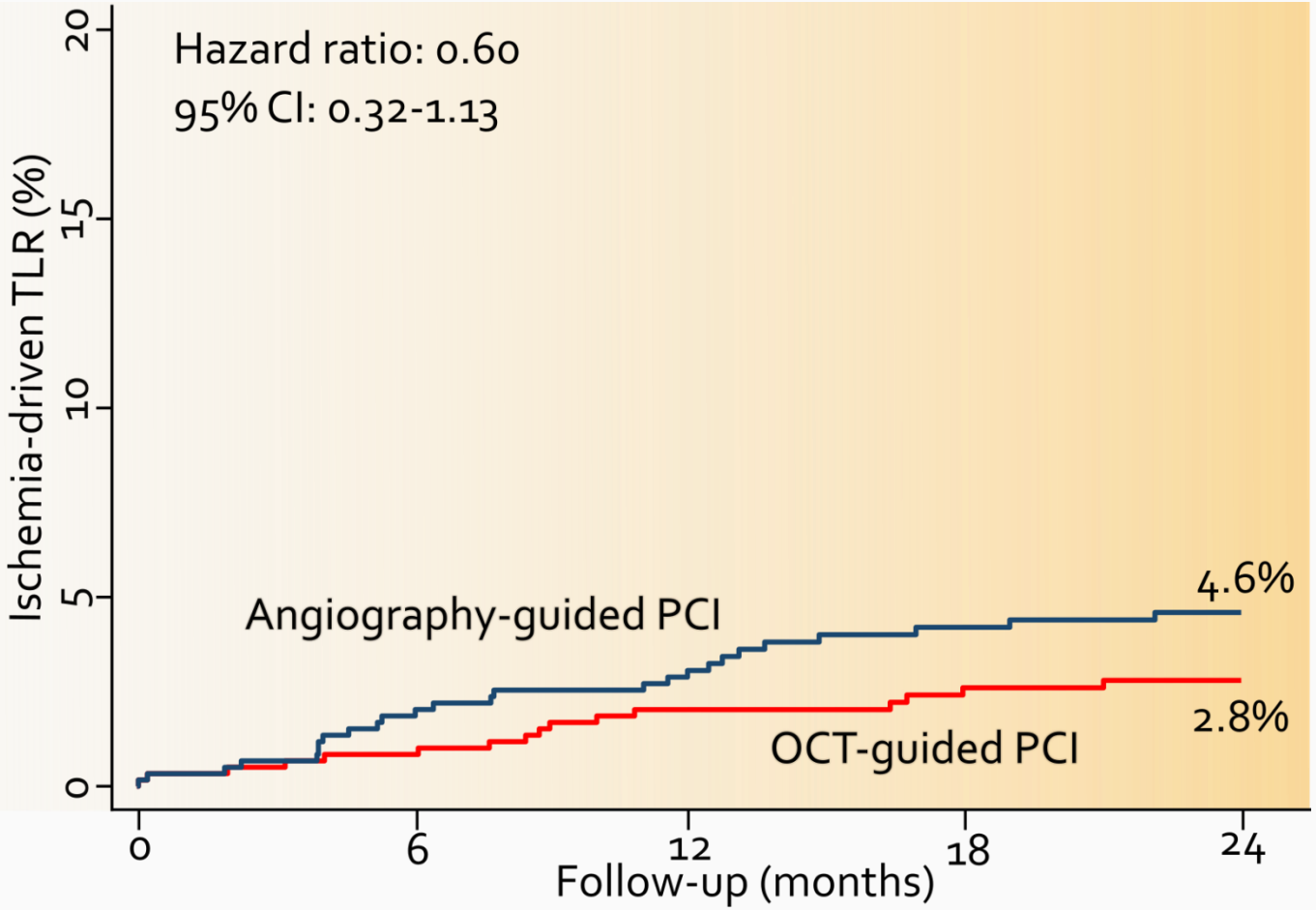
Target-lesion myocardial infarction



No. At Risk:					
OCT-guided PCI	600	556	543	479	446
Angiography-guided PCI	601	541	519	468	426

Kaplan Meier estimates
Secondary endpoint. Not powered

Ischemia-driven target lesion revascularization

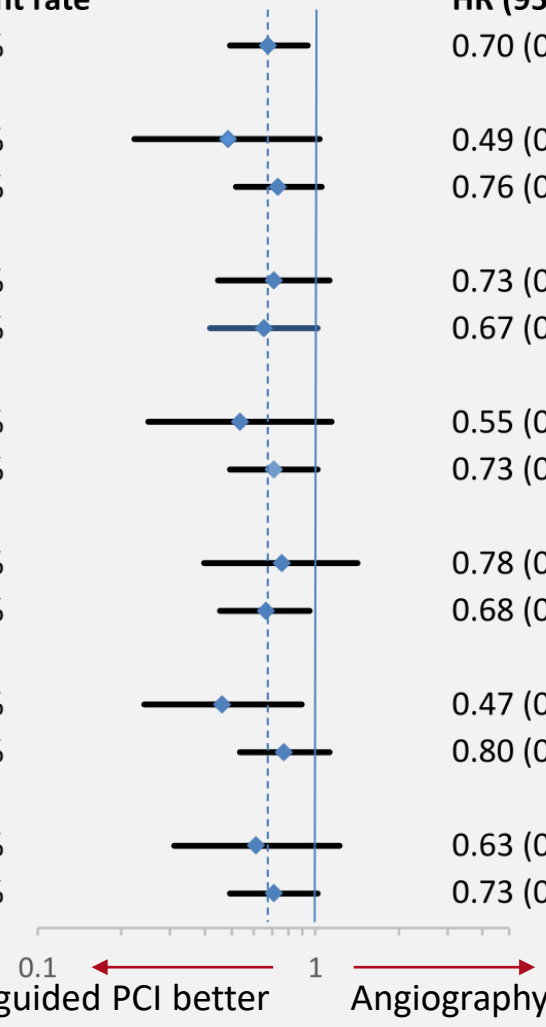


No. At Risk:					
OCT-guided PCI	600	586	569	505	469
Angiography-guided PCI	601	575	551	490	442

Kaplan Meier estimates
Secondary endpoint. Not powered

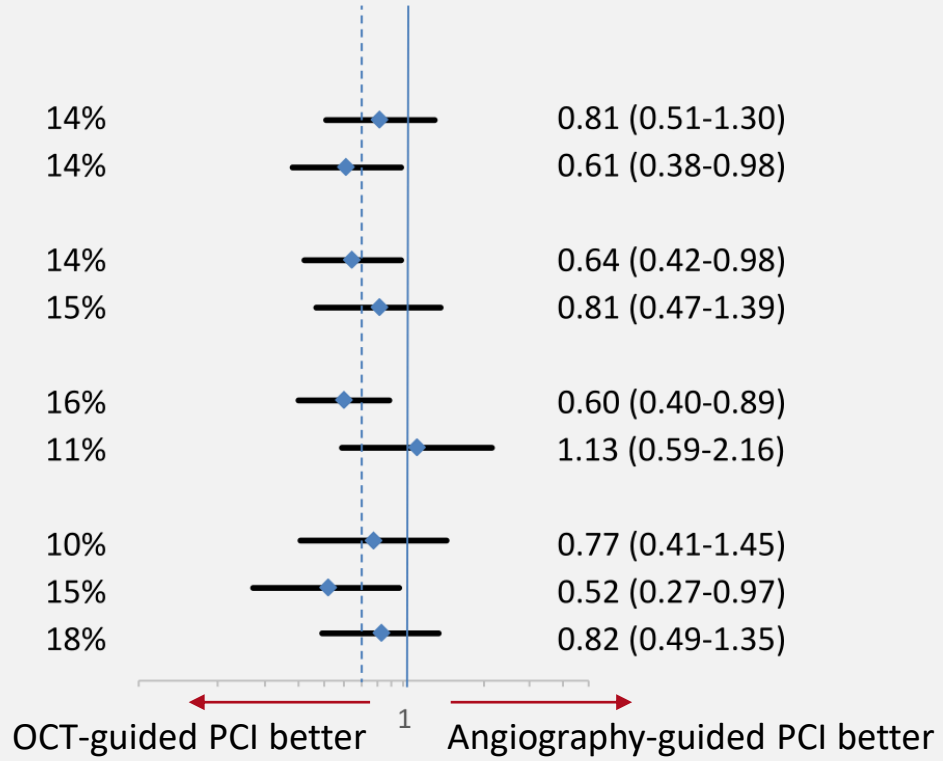
Subgroup analyses 1/2

	Event rate	Event rate	HR (95% CI)
All patients	10%	14%	0.70 (0.50-0.98)
Gender			
Female	8%	15%	0.49 (0.22-1.08)
Male	11%	14%	0.76 (0.53-1.10)
Age			
< 65 year	12%	16%	0.73 (0.45-1.18)
≥ 65 year	9%	13%	0.67 (0.42-1.07)
Diabetes			
Yes	10%	17%	0.55 (0.25-1.20)
No	10%	14%	0.73 (0.5-1.06)
Left main as study bifurcation			
Yes	14%	19%	0.78 (0.40-1.51)
No	9%	13%	0.68 (0.46-1.00)
Stent technique			
One-stent	6%	12%	0.47 (0.24-0.93)
Two-stent	13%	15%	0.80 (0.55-1.18)
Multi vessel			
Yes	12%	18%	0.63 (0.31-1.28)
No	10%	13%	0.73 (0.50-1.07)



Subgroup analyses 2/2

	Event rate	Event rate	HR (95% CI)
Acute coronary syndrome or staged PCI from recent AMI			
Yes	12%	14%	0.81 (0.51-1.30)
No	9%	14%	0.61 (0.38-0.98)
Calcified lesion			
None to minor	9%	14%	0.64 (0.42-0.98)
Moderate or severe	13%	15%	0.81 (0.47-1.39)
SB lesion length > 5mm by QCA			
Yes	10%	16%	0.60 (0.40-0.89)
No	12%	11%	1.13 (0.59-2.16)
SYNTAX Score			
< 17	8%	10%	0.77 (0.41-1.45)
17-21	8%	15%	0.52 (0.27-0.97)
> 21	14%	18%	0.82 (0.49-1.35)



2-Year Clinical Outcomes

- Bifurcation PCI in ILUMIEN IV was a very small sub-group, from which definitive value of OCT cannot be determined.

- OCT-guidance in the dedicated OCTOBER study showed a marked advantage over angiography-guidance.

- The totality of data supports an OCT-guided strategy.