L'OCT, un outil incontournable de l'angioplastie en 2023

L'importance des données cliniques en 2023

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PU-PH CHU Besançon

DÉCLARATION DE LIENS D'INTÉRÊT POTENTIELS

Intervenant : Nicolas MENEVEAU CHU Besançon

☑ Je déclare les liens d'intérêt potentiels suivants :

Consultant:

Abbott, Alliance BMS/Pfizer, Bayer, Edwards Lifesciences, Sanofi Regeneron, Terumo

Honoraria:

AstraZeneca

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Avant 2023

Beaucoup d'études observationnelles, peu d'essais randomisés (… et pas d'endpoints cliniques)

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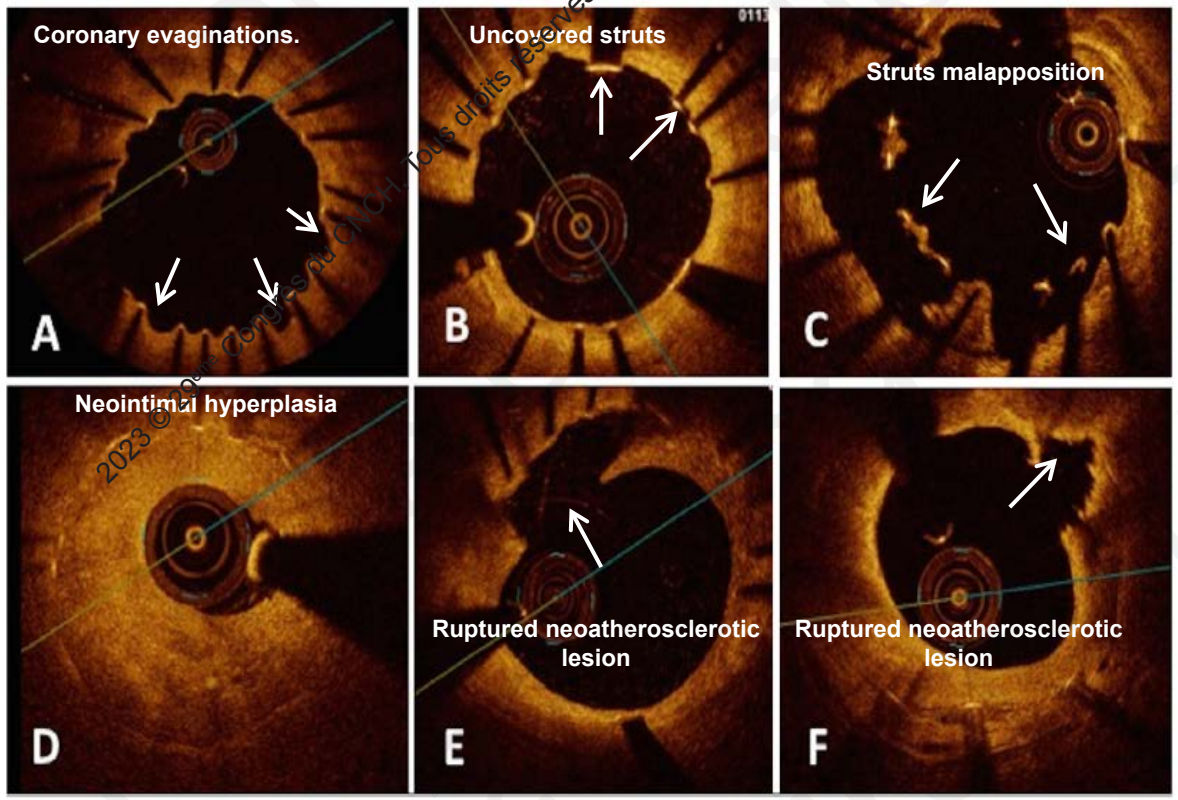
L'OCT dans les thromboses de stent

PESTO french registry

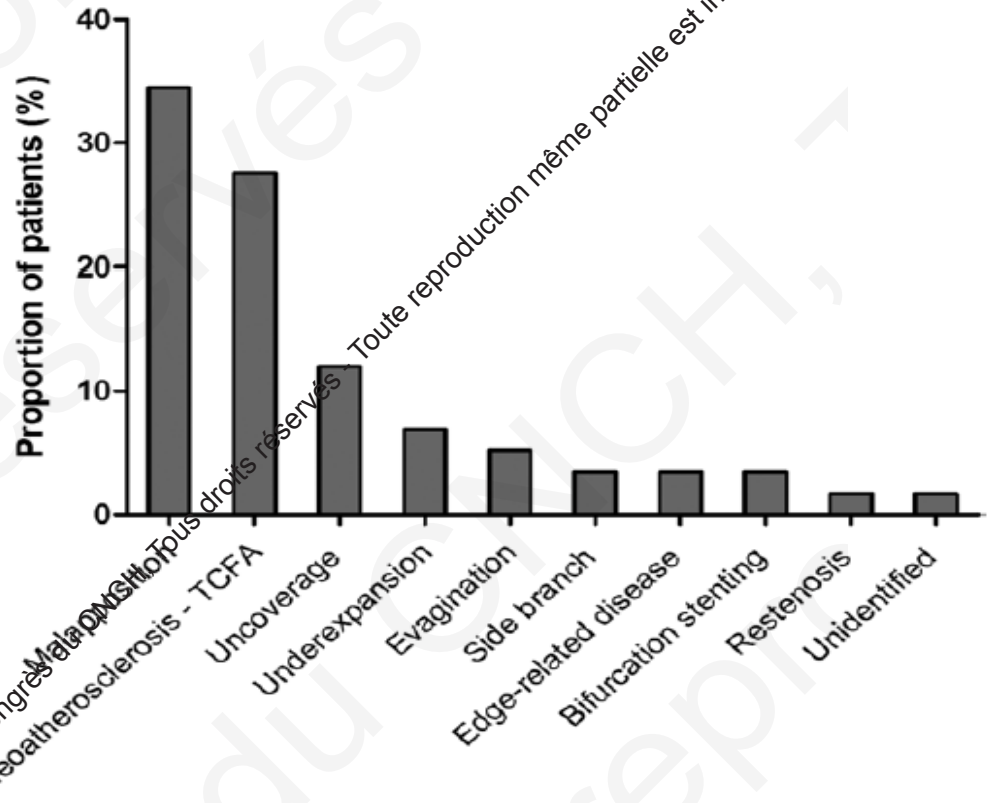
OCT imaging identified an underlying abnormality in 95% of cases



Souteyrand G et al. Eur Heart J. 2016;37:1208-16.
Amabile N et al. Int J Cardiol 2017;227:161–165.

European registry

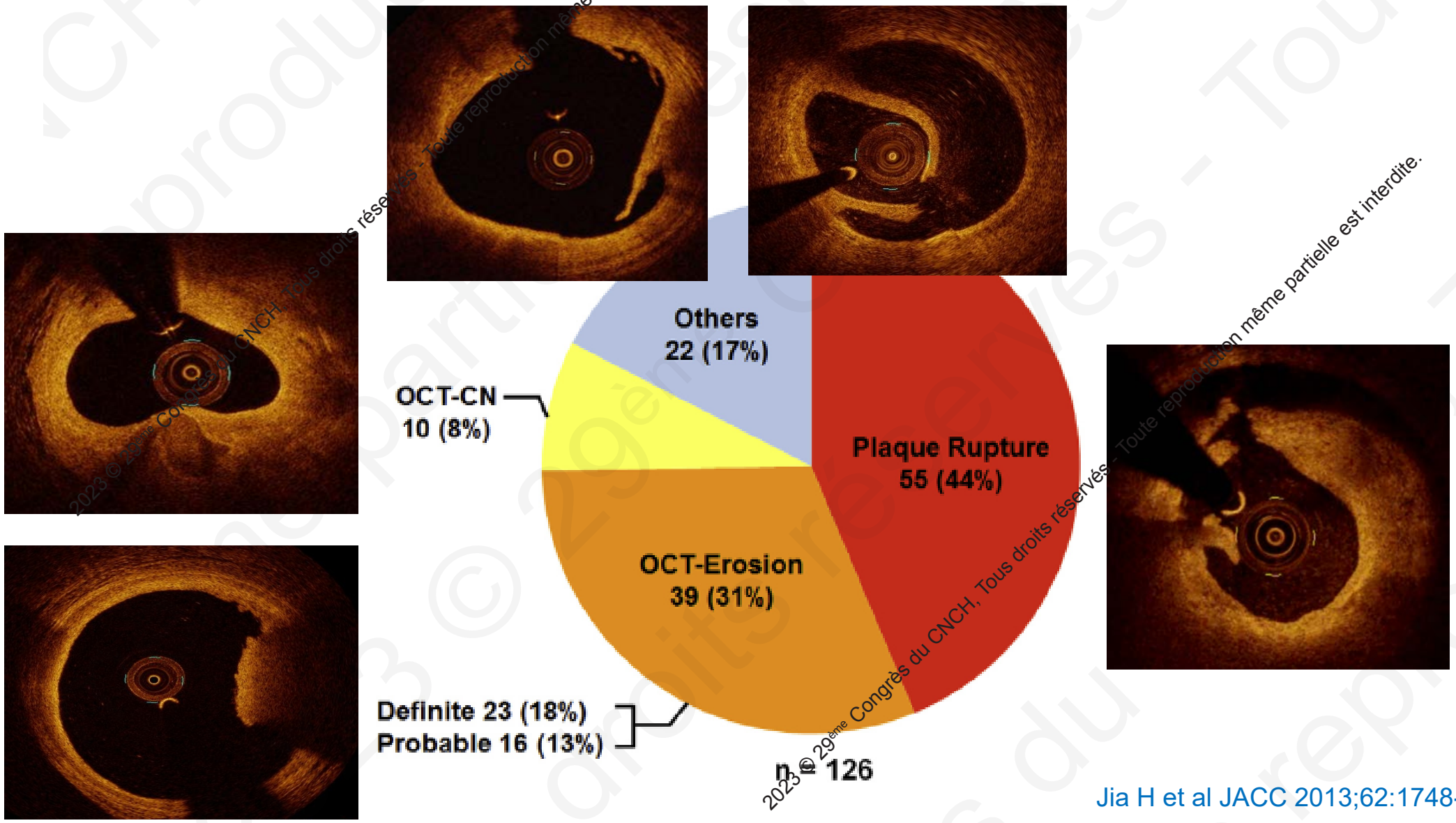
Leading causes of very late stent thrombosis



Taniwaki M et al. Circulation 2016;133:650-660.

OCT et SCA :

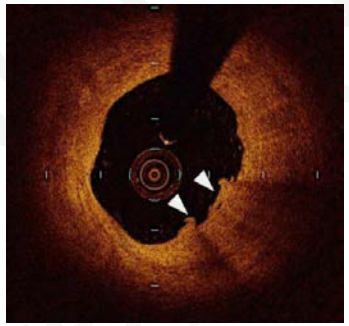
analyser la lésion responsable et le mécanisme du SCA



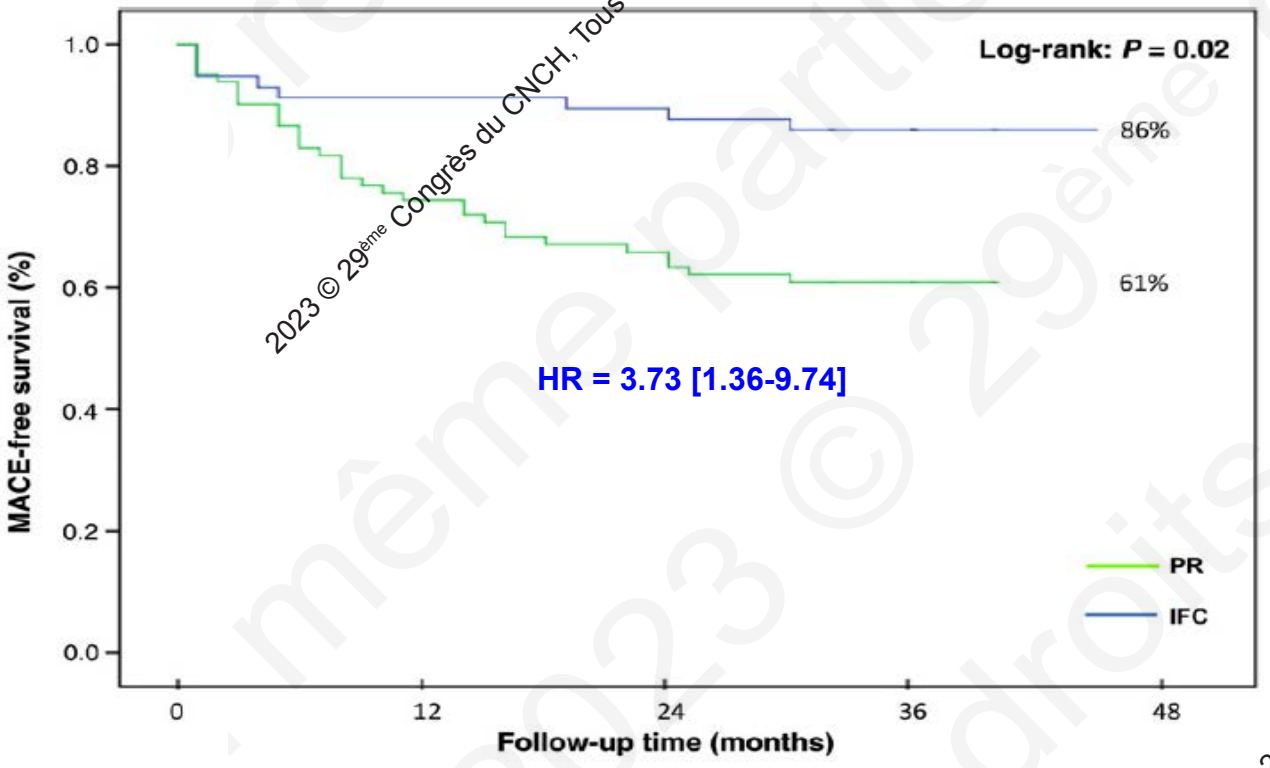
Jia H et al JACC 2013;62:1748-58.

Rupture de plaque vs érosion : un impact pronostique différent

et un traitement différent ?



VS



Niccoli G et al. Eur Heart J 2015.

Effective anti-thrombotic therapy without stenting: intravascular optical coherence tomography-based management in plaque erosion (the EROSION study)

Haibo Jia[1†], Jiannan Dai[2†], Jingbo Hou[1†], Lei Xing[1], Lijia Ma[1], Huimin Liu[1], Maoen Xu[1], Yuan Yao[1], Sining Hu[1], Erika Yamamoto[2], Hang Lee[3], Shaosong Zhang[1], Bo Yu[1]*, and Ik-Kyung Jang[2]*

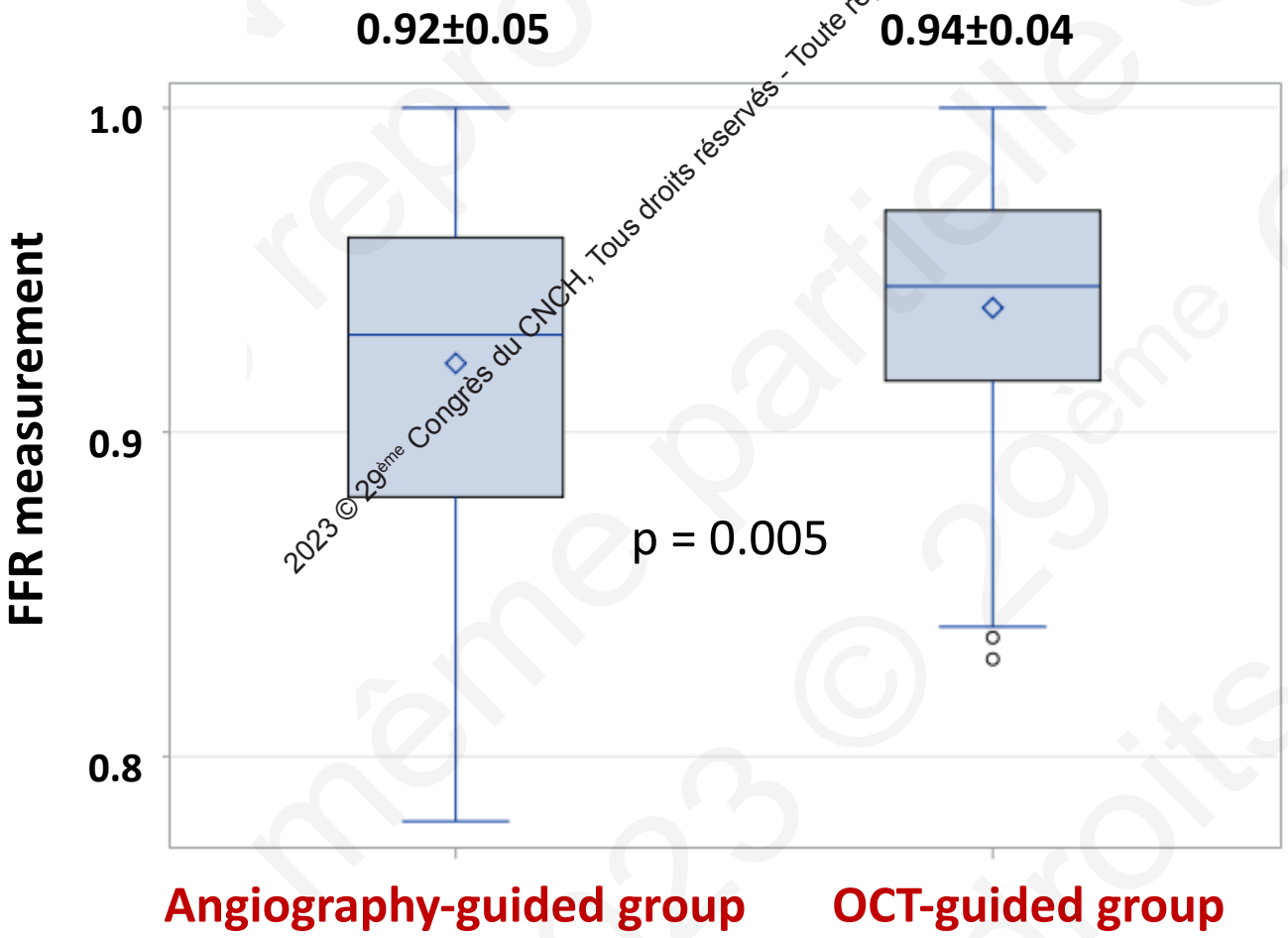
Conclusion :

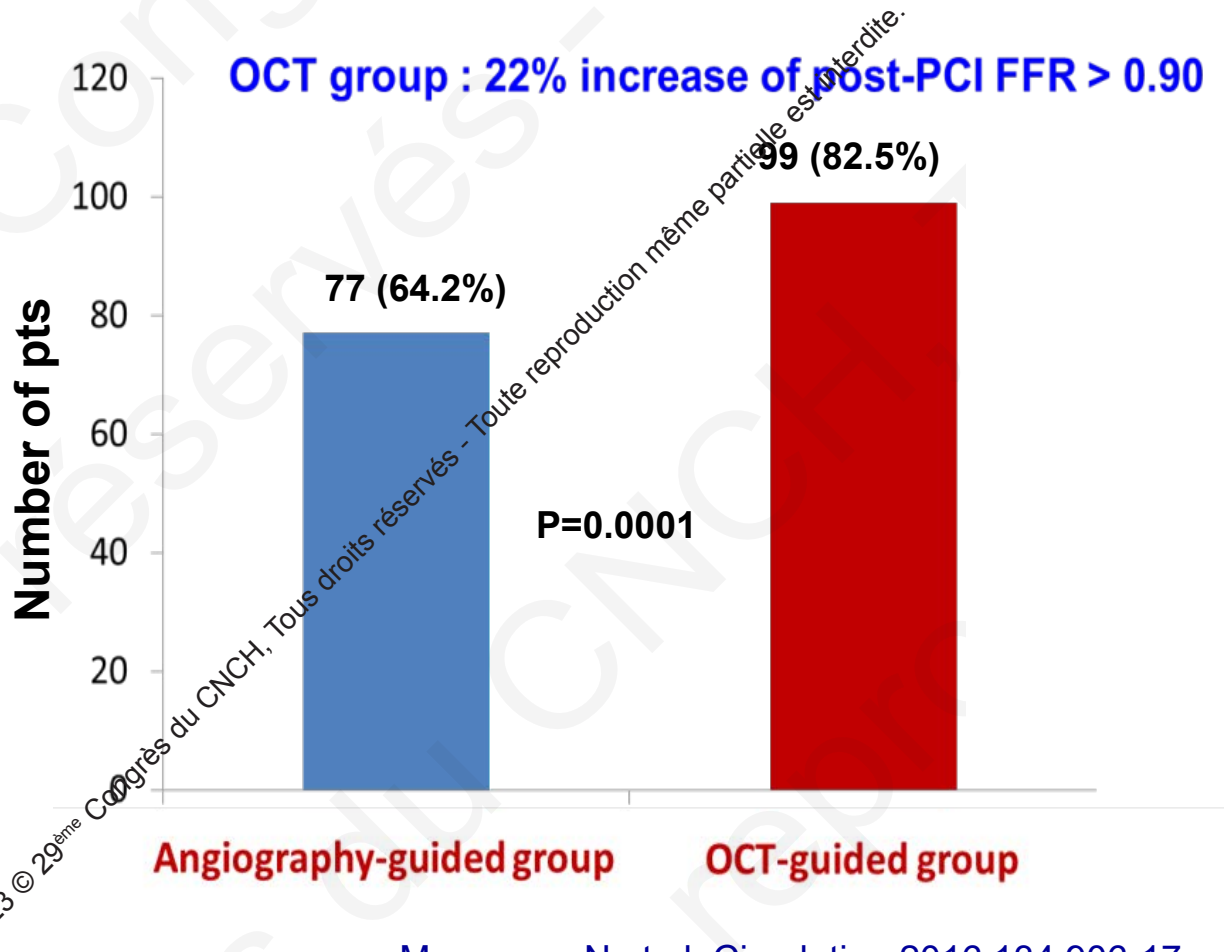
For patients with ACS caused by plaque erosion, conservative treatment with anti-thrombotic therapy without stenting may be an option.

Jia H et al. Eur Heart J 2017;38:792–800.

RCT : DOCTORS trial :

OCT-guided PCI : higher post-PCI FFR in ACS pts





Meneveau N et al. Circulation 2016;134:906-17.

RCT : ILUMIEN III trial :

OCT-guided PCI : greater stent expansion & reduced malapposition and dissection

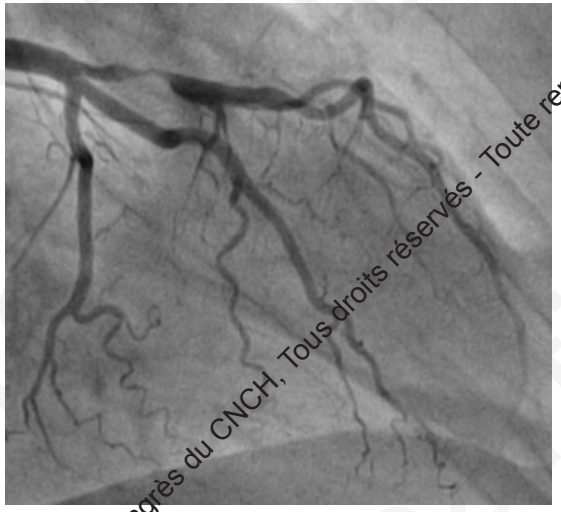
	OCT (n=140)	IVUS (n=135)	Angiography (n=140)	OCT *vs* IVUS p value	OCT *vs* angiography p value
Minimum stent area (mm²)	5·79 (4·54–7·34)	5·89 (4·67–7·80)	5·49 (4·39–6·59)	0·42	0·12
Minimum stent expansion (%)	87·6% (16·6)	86·5% (15·9)	82·9% (12·9)	0·77	0·02
Mean stent expansion (%)	105·8% (97·8–119·8)	106·3% (96·7–116·6)	101·4% (91·9–110·2)	0·63	0·001
Acute procedural success					
Optimal (≥95%)	36 (26%)	32/130 (25%)	23/136 (17%)	0·84	0·07
Acceptable (90 to <95%)	22 (16%)	16/130 (12%)	5/136 (4%)	0·42	0·0008
Unacceptable (<90%)	82 (59%)	82/130 (63%)	108/136 (79%)	0·45	0·0002
Intrastent flow area (mm²)	5·54 (4·34–7·05)	5·71 (4·59–7·58)	5·42 (4·25–6·36)	0·56	0·32
Total flow area (mm²)	5·68 (4·59–7·30)	5·87 (4·76–7·59)	5·52 (4·42–6·63)	0·72	0·27
Any dissection	39 (28%)	53/134 (40%)	61 (44%)	0·04	0·006
Major	19 (14%)	35/134 (26%)	26 (19%)	0·009	0·25
Minor	20 (14%)	18/134 (13%)	35 (25%)	0·84	0·02
Intimal	16 (11%)	11/134 (8%)	21 (15%)	0·37	0·38
Medial	27 (19%)	45/134 (34%)	40 (29%)	0·007	0·07
Adventitial	1 (1%)	0/134	0	1	1
Any malapposition	58 (41%)	52 (39%)	83 (59%)	0·62	0·003
Major	15 (11%)	28 (21%)	44 (31%)	0·02	<0·0001
Minor	43 (31%)	24 (18%)	39 (28%)	0·01	0·60
Any plaque or thrombus protrusion	94 (67%)	100 (74%)	95 (68%)	0·21	0·90
Major	27 (19%)	27 (20%)	25 (18%)	0·88	0·76
Minor	67 (48%)	73 (54%)	70 (50%)	0·30	0·72
Reference segment disease	44 (31%)	45 (33%)	39 (28%)	0·74	0·51

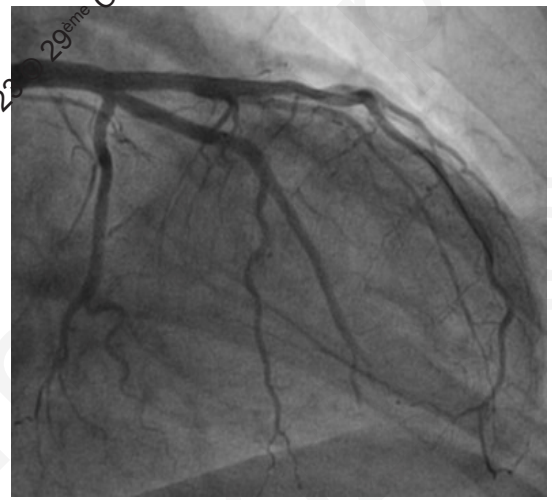
Data are median (IQR), mean (SD), n (%), or n/N (%). OCT=optical tomography. IVUS=intravascular ultrasound.

Ali ZA et al. Lancet 2016; 388: 2618–28,

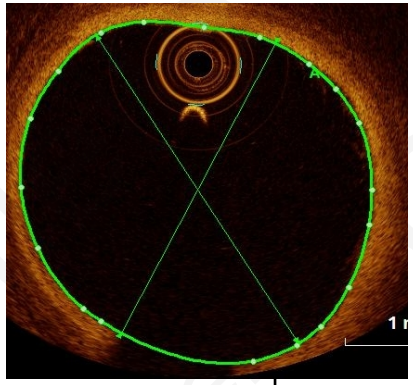
Critères d'optimisation de l'angioplastie en OCT

Déploiement optimal du stent (> 80% du diamètre de la lumière de référence)

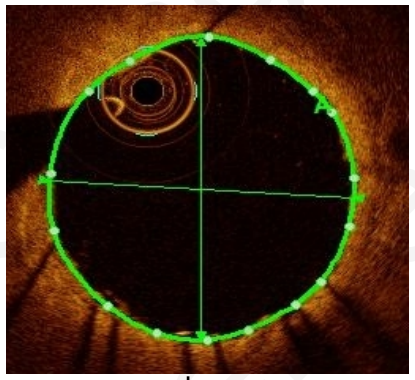




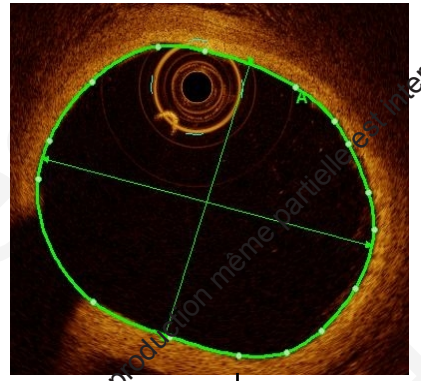
Distal reference
Area : 11.83 mm²



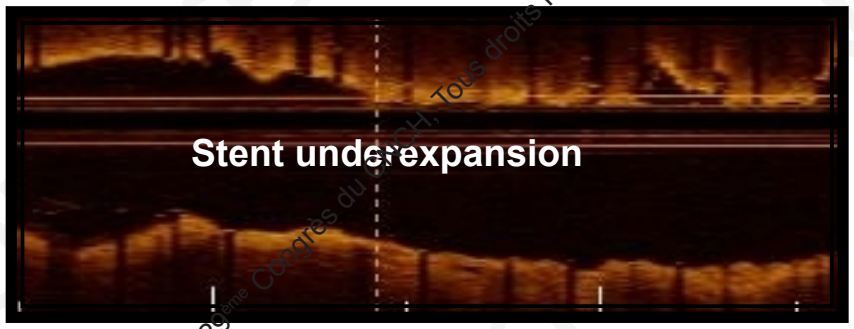
Minimal lumen area
Area : 7.06 mm²



Proximal reference
Area : 8.23 mm²

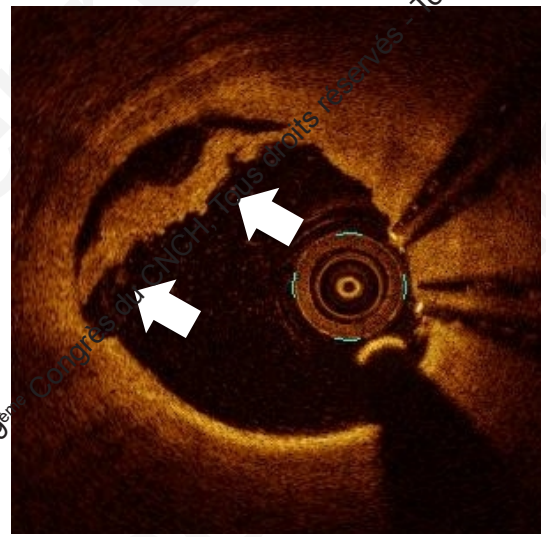


Stent expansion : 70.3%



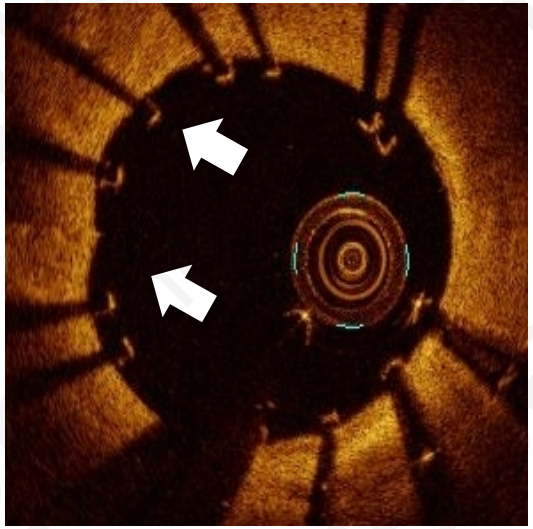
Critères d'optimisation de l'angioplastie en OCT

Dissection de bord



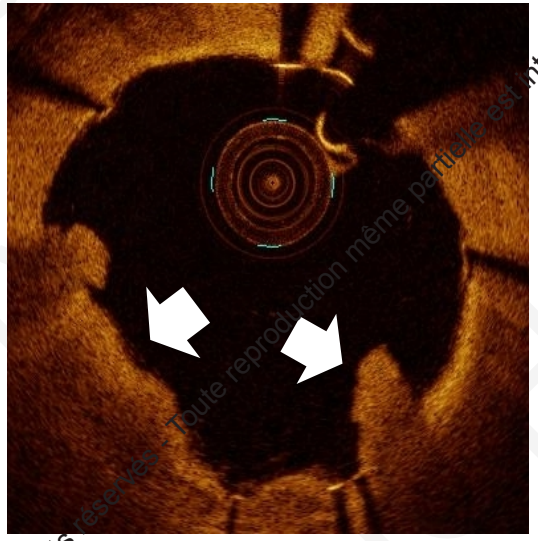
Dissection significative si s'étend sur > 60° et sur > 2 mm de longueur

Stent malapposition



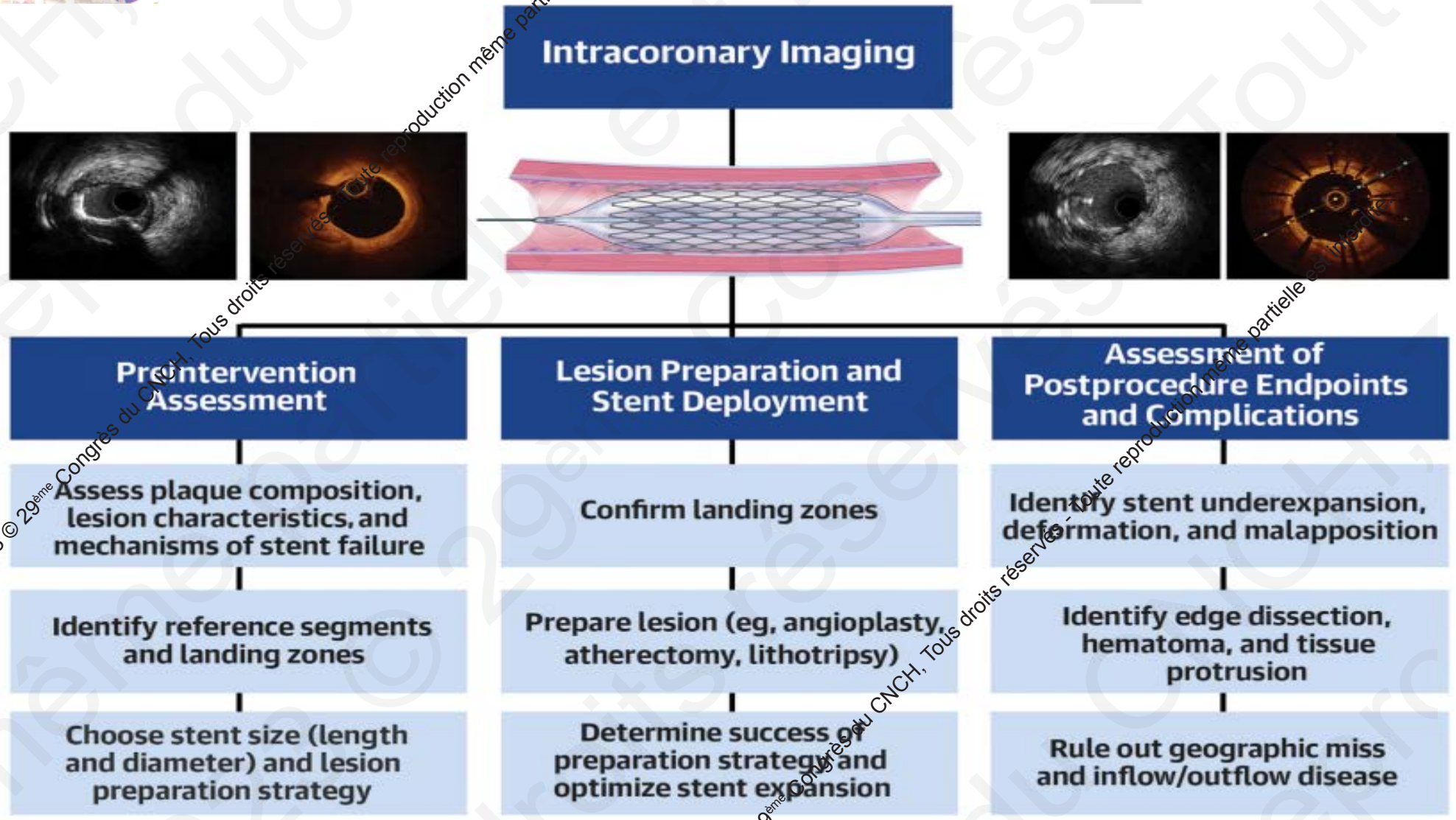
Malapposition significative des mailles du stent si la distance strut-paroi est > 0,4 mm sur > 1 mm de longueur

Protrusion de tissu



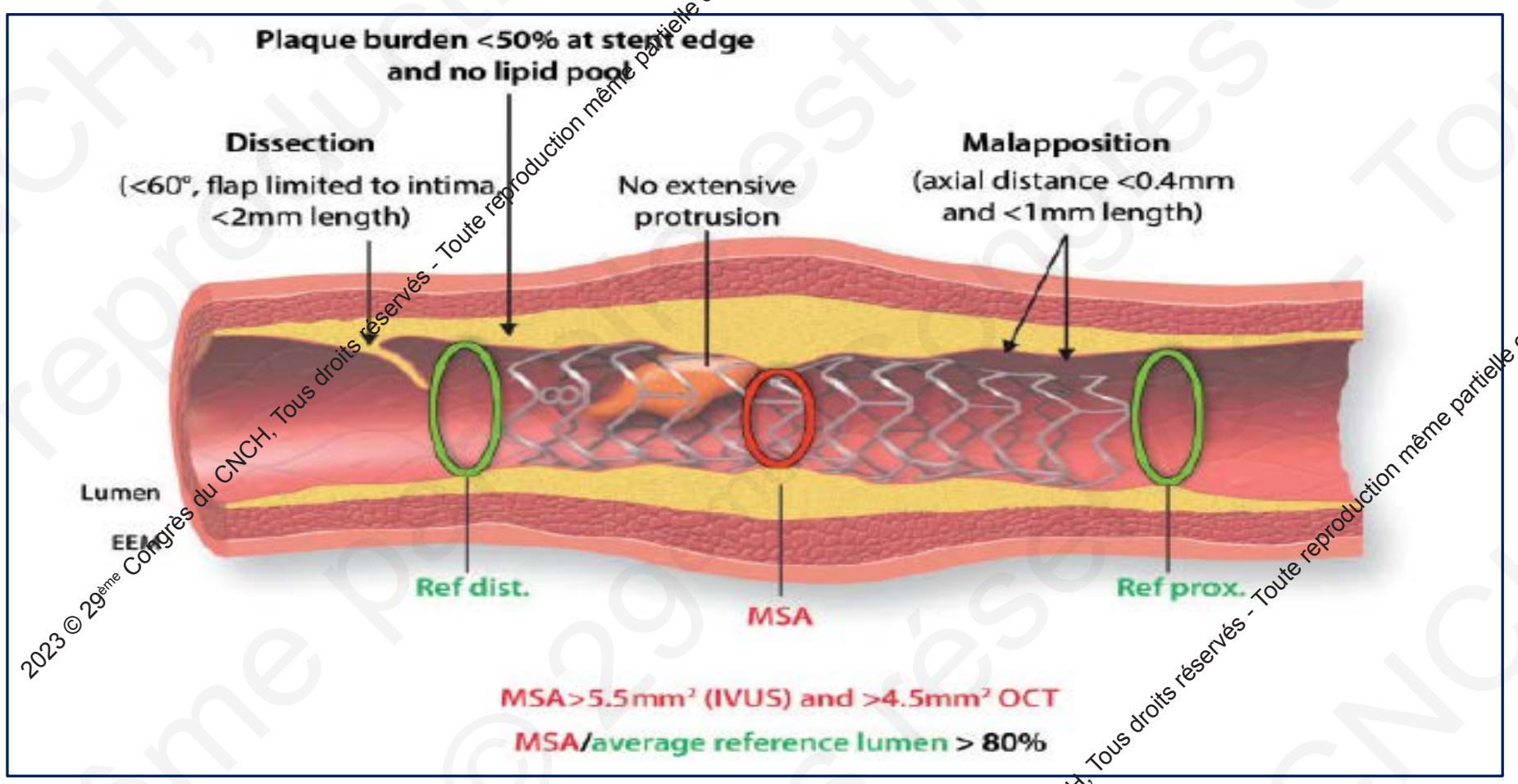
Pas de valeur seuil déterminée. Valeur pronostique sujette à caution (données discordantes)

Background



Truesdell AG, et al. J Am Coll Cardiol. 2023;81(6):590–605. (on behalf of the ACC Interventional Council)

OCT and PCI optimisation



- Déploiement optimal du stent (> 80% du diamètre de la lumière de référence)
- Couverture optimale de la lésion (éviter une zone d'atterrissage dans une plaque lipidique)
- Correction des malappositions significatives
- Corrections des dissections de bord étendues
- Eviter les protrusions tissulaires intrastent extensives (±)

Expert Consensus Document of the EAPCI. Eur Heart J 2018;39:3281–330.

2023

Des essais randomisés avec endpoints cliniques

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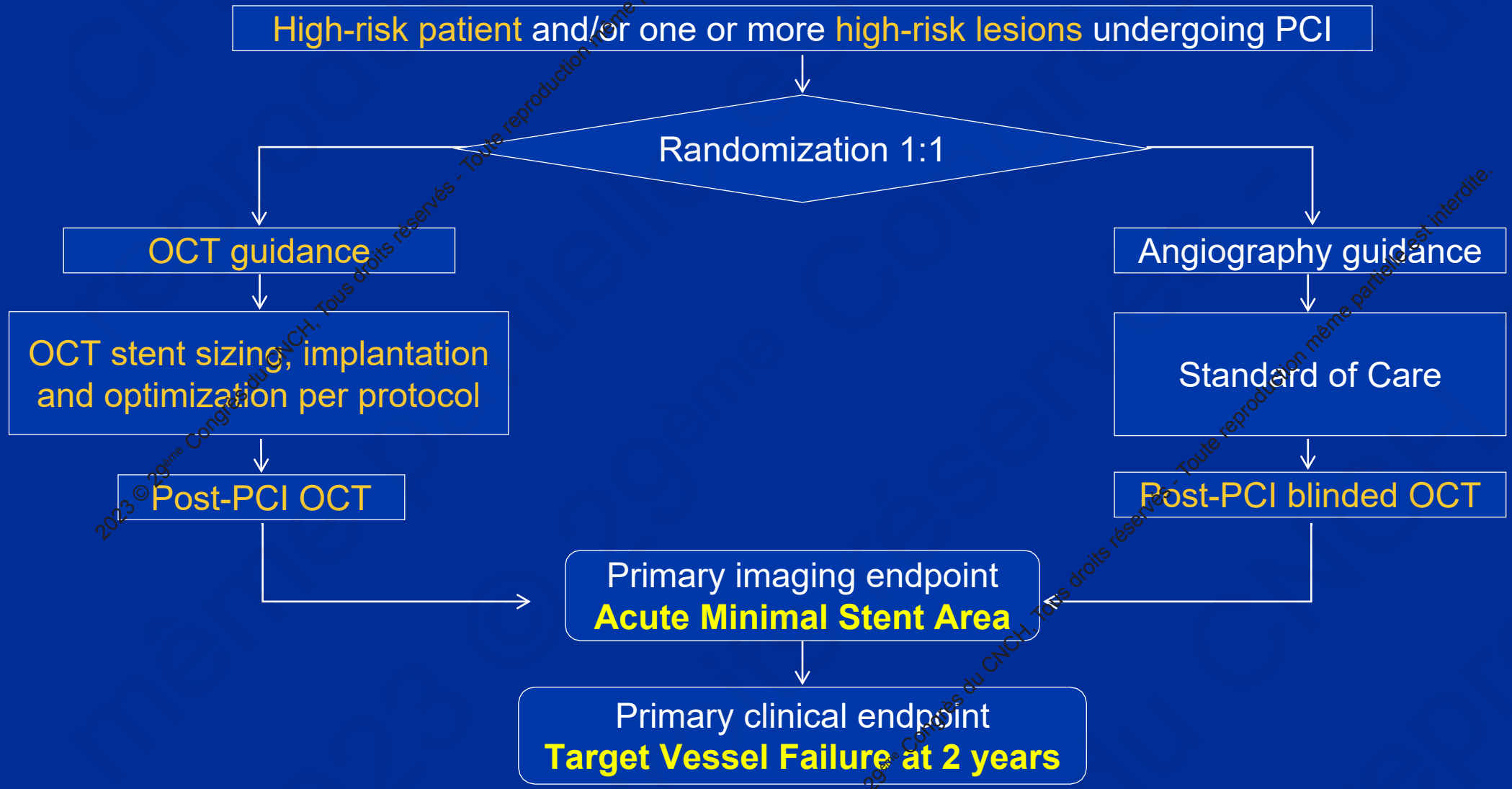
ILUMIEN IV : Study Flow



ClinicalTrials.gov #NCT03507777

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

Primary Imaging Endpoint

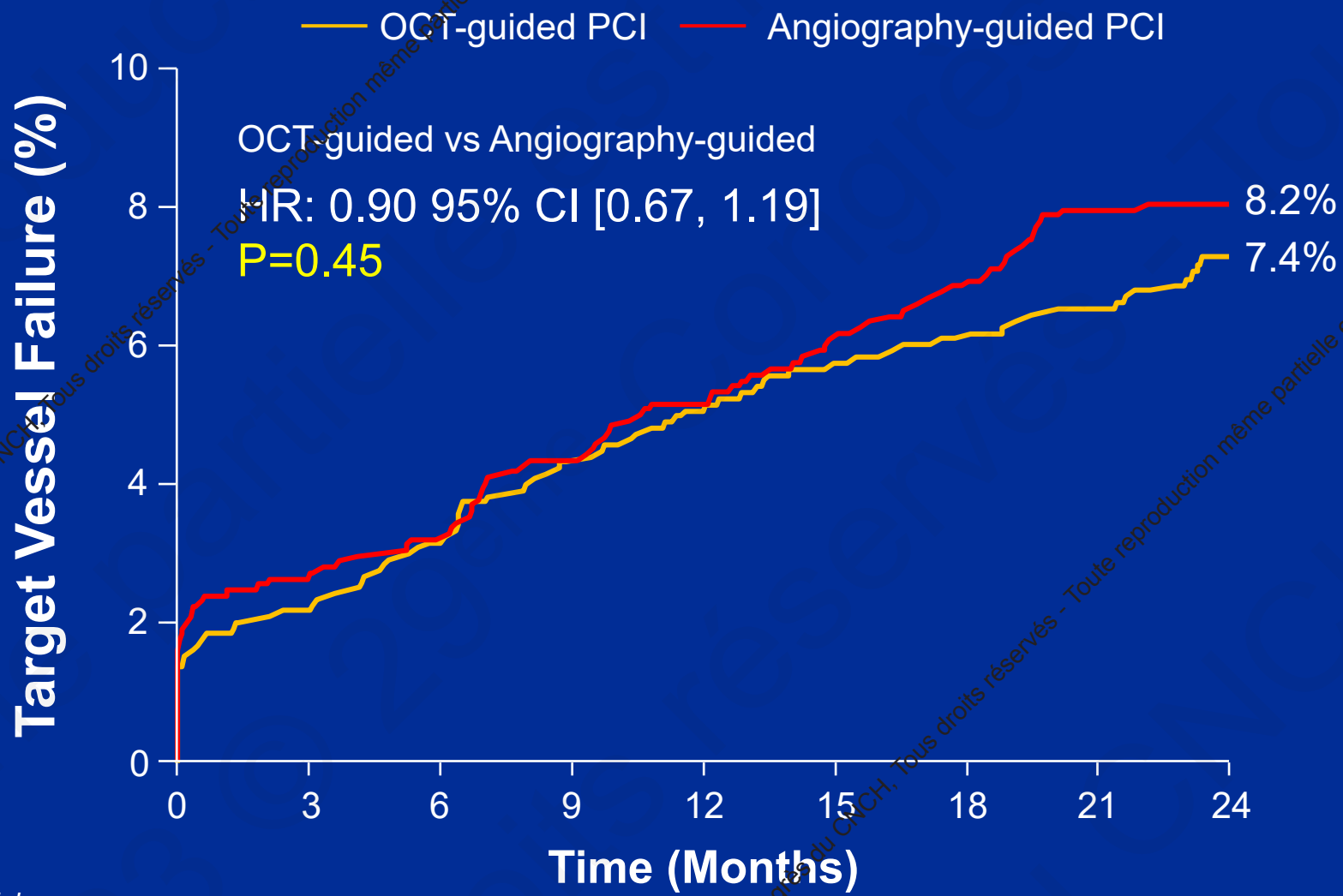
Final post-PCI MSA by OCT (mm^2)

OCT L=1222	Angio L=1328	Difference [95% CI]	P-Value
5.72 ± 2.04	5.36 ± 1.87	0.36 (0.21, 0.51)	<0.001

… and significant reduction in :

- stent underexpansion,
- struts malapposition,
- edge dissection,
- tissue protrusion

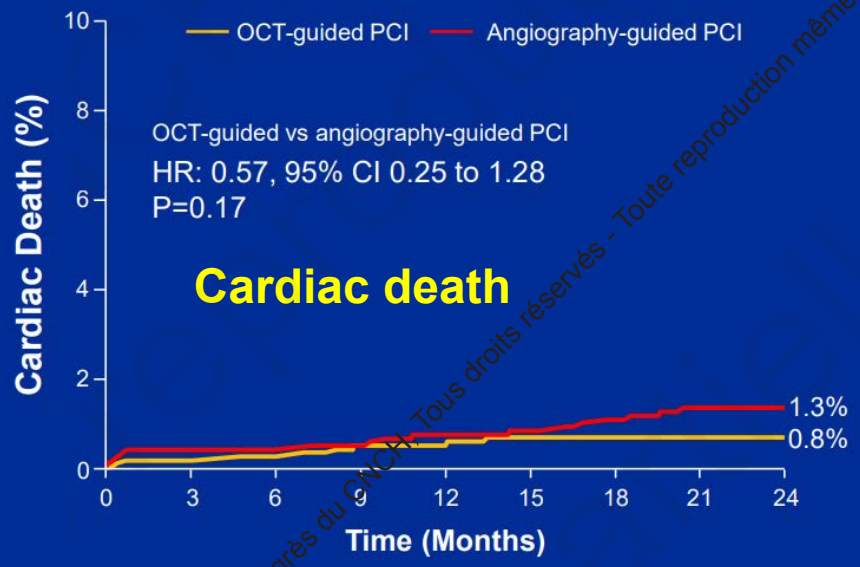
Primary Clinical Endpoint – Target Vessel Failure

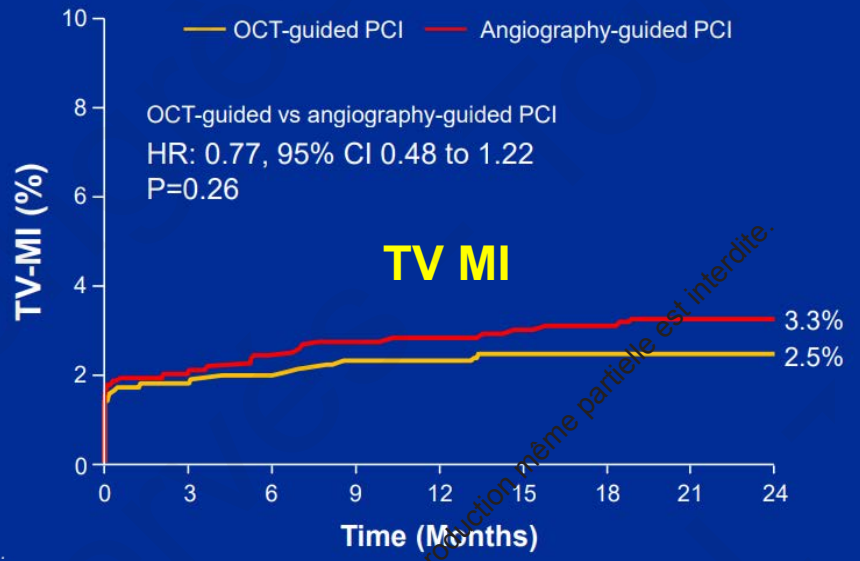


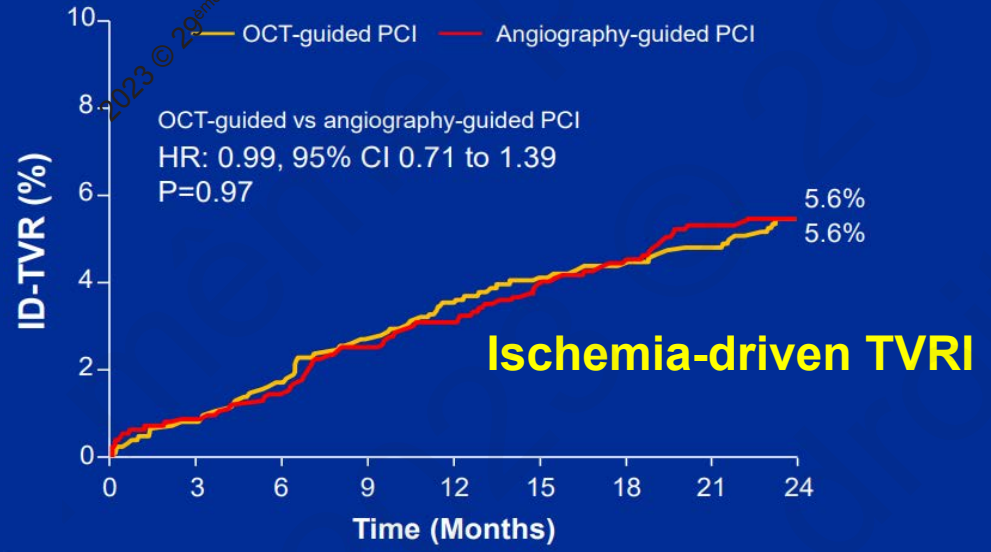
Number at risk:

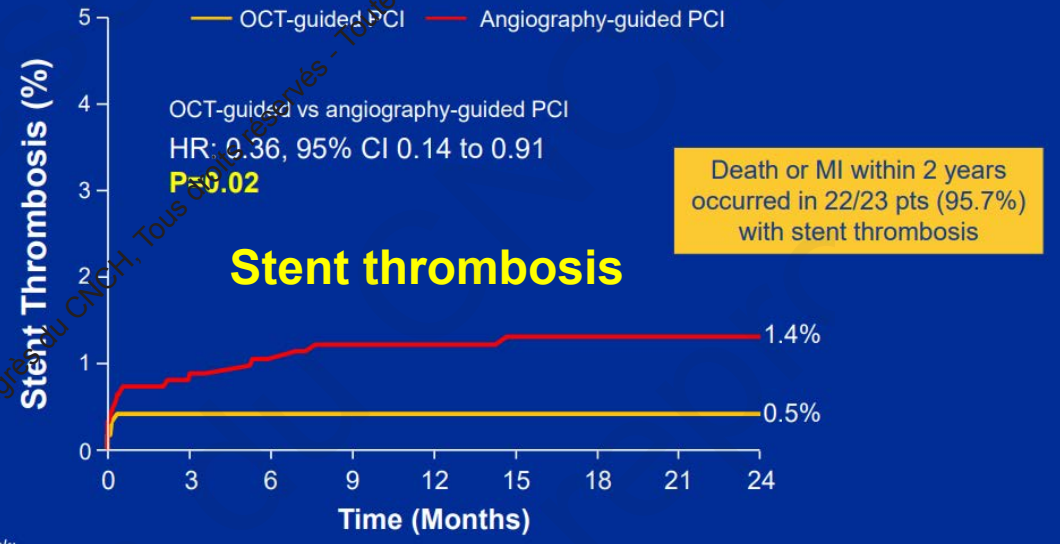
OCT-guided	1233	1187	1174	1157	1127	1096	1085	1077	560
Angiography-guided	1254	1195	1184	1168	1143	1108	1092	1070	573

Secondary Clinical Endpoints

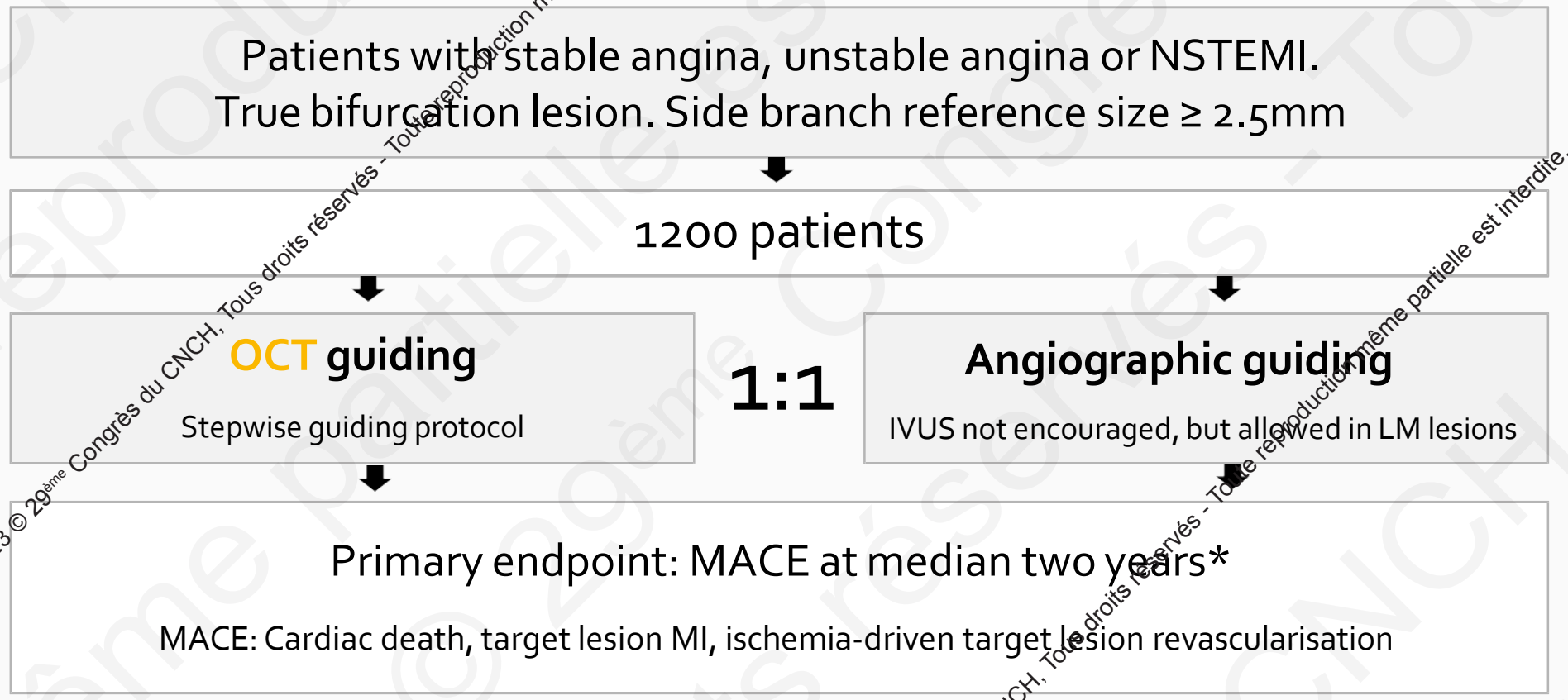








OCTOBER Trial overview



* At least one year of follow-up

Follow-up: 1 month, 1 year, annually through 5 years. All-cause mortality at 10 years

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

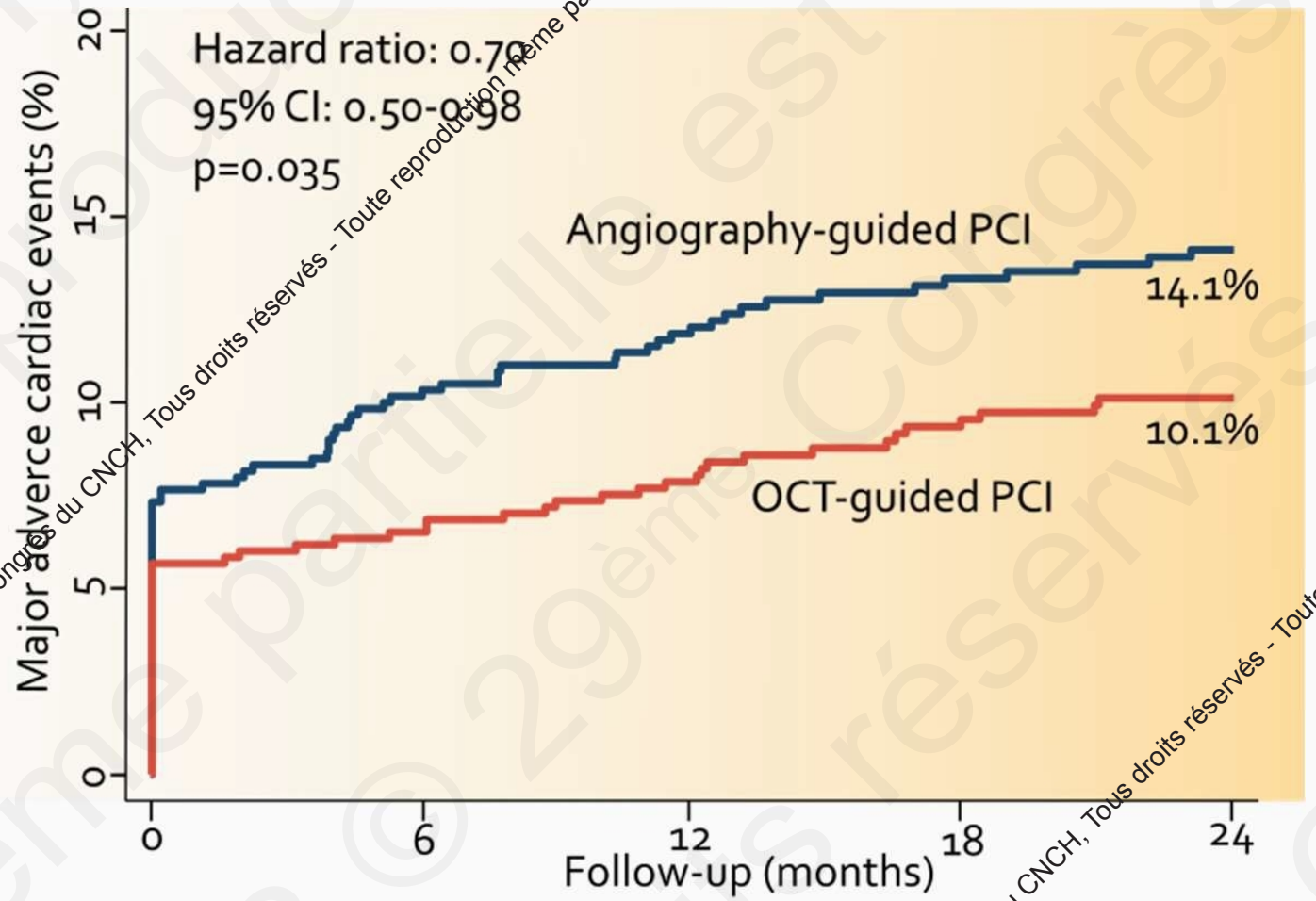
Optimal stent expansion

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

No unintended crushed or distorted stent segments

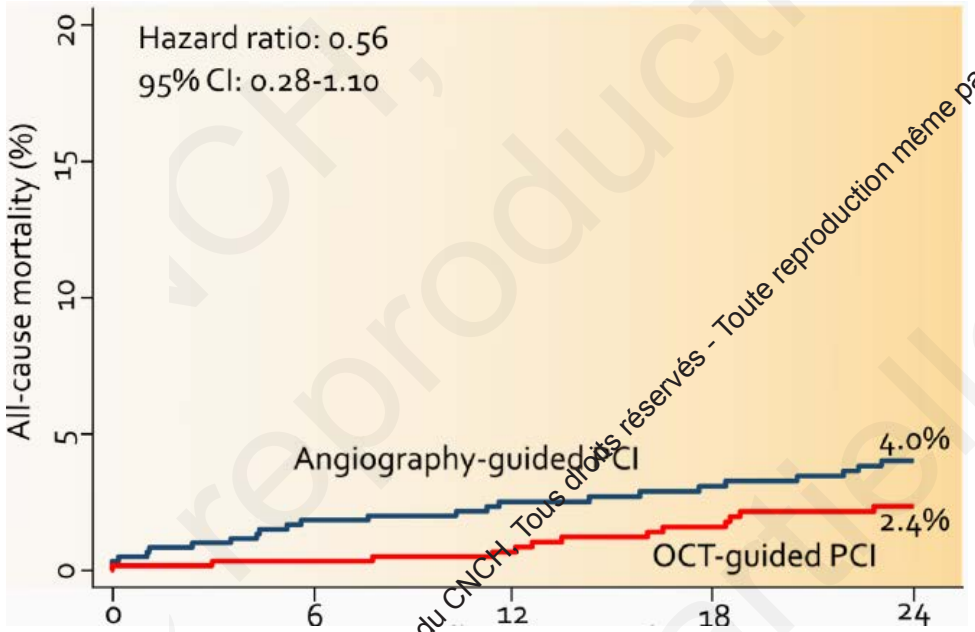
Holm NR et al. Rational and design of the European randomized Optical Coherence Tomography Optimized Bifurcation Event Reduction Trial (OCTOBER), Am Heart J 2018

Primary endpoint - MACE

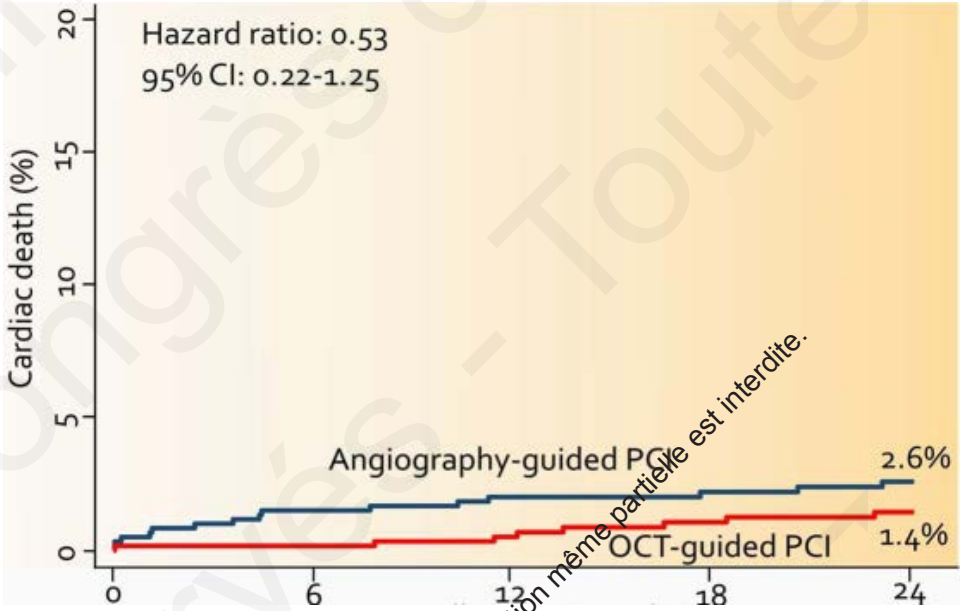


MACE: cardiac death, target lesion myocardial infarction, ischemia-driven target lesion revascularization

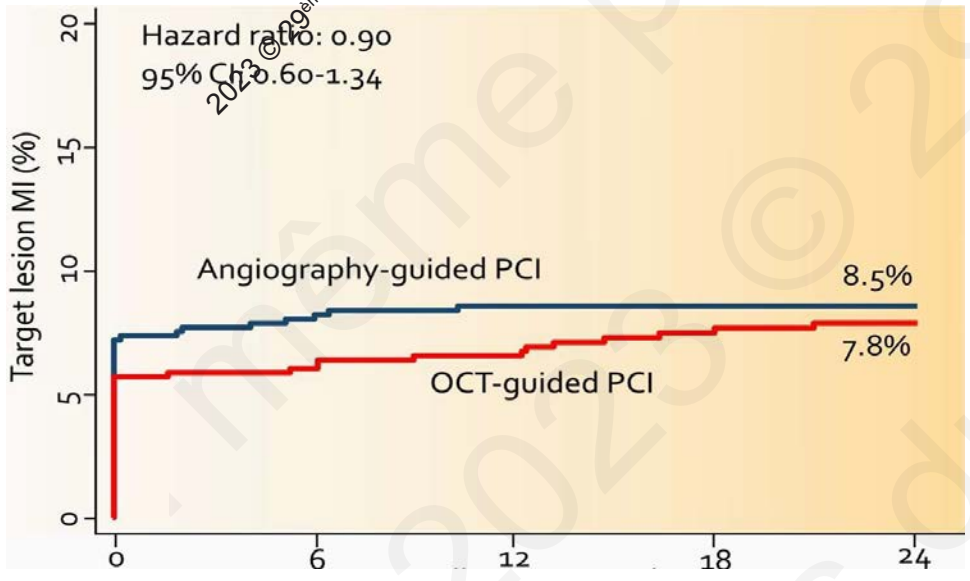
Mortality



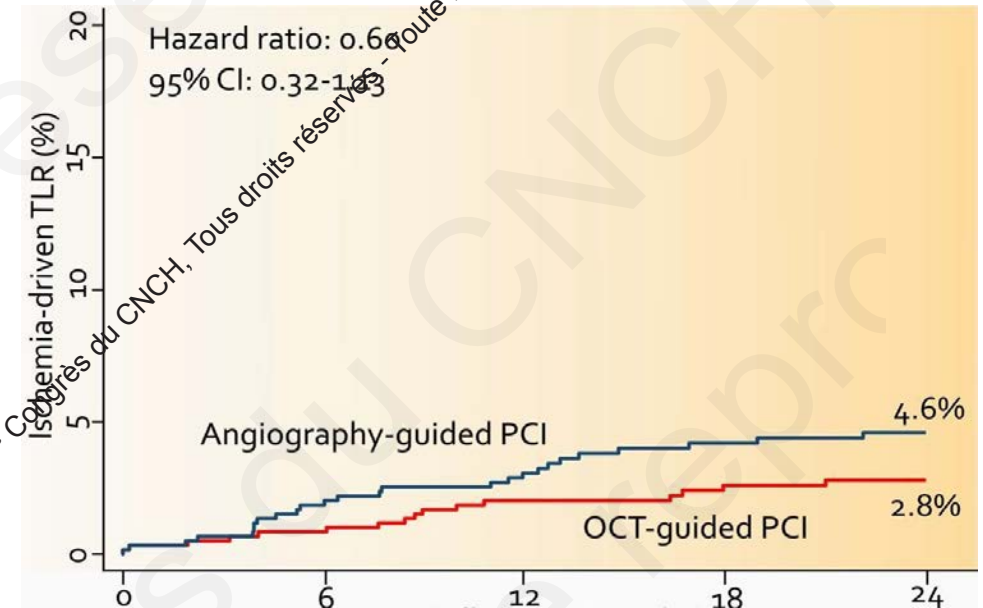
Cardiac death



Target-lesion MI



Ischemia-driven TLR



Conclusion

- **OCT en 2023** : données issues d'essais randomisés confirmant l'intérêt de l'OCT pour optimiser l'angioplastie des pts/lésions à haut risque
- **Bénéfices observés :**
  - **anatomiques : optimisation du résultat de l'angioplastie :**

- améliore : MSA, couverture de la lésion et déploiement du stent

- réduit : malapposition, dissection, thrombose de stent, protrusion tissulaire

  - **cliniques :**

- réduit le taux d'évts CV, en particulier dans les lésions de bifurcations

En attendant 2024

RCT des équipes françaises

- Etude CALYPSO (Lésions Ca++; N. Amabile)
- Etude DOCTORS LM (Tronc Commun; N. Meneveau)

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