

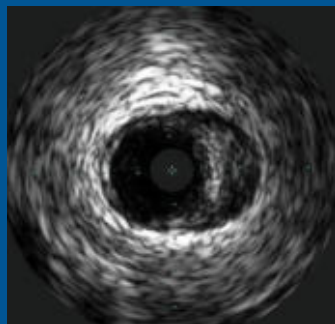


PALAIS DU PHARO
• MARSEILLE •

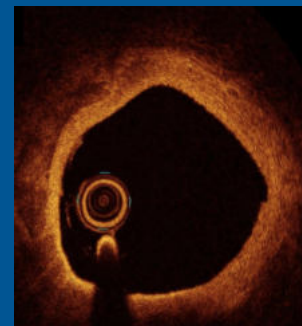
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JANVIER 2024

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Apport de l'imagerie endocoronaire: études 2023



Guillaume CAYLA
CHU de Nimes



G Cayla has received research grants/consultant fees/lectures fees from Amgen, AstraZeneca, Abbott, Bayer, Biotronik, Bristol-Myers Squibb, Edwards Microport, Medtronic, Pfizer, Sanofi-Aventis

2023: l'année de l'imagerie endocoronaire (guided PCI)

ESC 2023

ACC 2023

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Intravascular Imaging–Guided or Angiography–Guided Complex PCI

J.M. Lee, K.H. Choi, Y.B. Song, J.-Y. Lee, S.-j. Lee, S.Y. Lee, S.M. Kim, K.H. Yun, J.Y. Cho, C.J. Kim, H.-S. Ahn, C.-W. Nam, H.-j. Yoon, Y.H. Park, W.S. Lee, J.-O. Jeong, P.S. Song, J.-H. Doh, S.-H. Jo, C.-H. Yoon, M.G. Kang, J.-S. Koh, K.Y. Lee, Y.-H. Lim, Y.-H. Cho, J.-M. Cho, W.J. Jang, K.-j. Chun, D. Hong, T.K. Park, J.H. Yang, S.-H. Choi, H.-C. Gwon, and J.-Y. Hahn, for the RENOVATE-COMPLEX-PCI Investigators*

RENOVATE-COMPLEX-PCI



ORIGINAL ARTICLE

Optical Coherence Tomography–Guided versus Angiography–Guided PCI

Ziad A. Ali, M.D., D.Phil., Ulf Landmesser, M.D., Akiko Maehara, M.D., Mitsuaki Matsuura, B.S., Richard A. Shlofmitz, M.D., Giulio Guagliumi, M.D., Matthew J. Price, M.D., Jonathan M. Hill, M.D., Takashi Akasaka, M.D., Francesco Prati, M.D., Hiram G. Bezerra, M.D., William Wijns, M.D., Ph.D., David Leistner, M.D., Paolo Canova, M.D., Fernando Alfonso, M.D., Franco Fabbicchi, M.D., Ozgen Dogan, M.D., Robert J. McGreevy, Ph.D., Robert W. McNutt, Ph.D., Hong Nie, Ph.D., Jana Buccola, M.S., Nick E.J. West, M.D., and Gregg W. Stone, M.D., for the ILLUMEN IV Investigators*



ILLUMEN IV (18 pays)

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

OCT or Angiography Guidance for PCI in Complex Bifurcation Lesions

N.R. Holm, L.N. Andreassen, O. Neghabat, P. Laanmets, I. Kumsars, J. Bennett, N.T. Olsen, J. Odenstedt, P. Hoffmann, J. Dens, S. Chowdhary, P. O'Kane, S.-H. Böglow Rasmussen, M. Heigert, O. Havndrup, J.P. Van Kuijk, S. Biscaglia, L.J.H. Mogensen, L. Henareh, F. Burzotta, C. H. Eek, D. Mylotte, M.S. Llinas, L. Koltowski, P. Knaapen, S. Calic, N. Witt, I. Santos-Pardo, S. Watkins, J. Lenborg, A.T. Kristensen, L.O. Jensen, F. Calais, J. Cockburn, A. McNeice, O.A. Kajander, T. Heestermans, S. Kische, A. Eftekhari, J.C. Spratt, and E.H. Christiansen, for the OCTOBER Trial Group*



OCTOBER (13 pays)

Circulation

ORIGINAL RESEARCH ARTICLE

Optical Coherence Tomography–Guided or Intravascular Ultrasound–Guided Percutaneous Coronary Intervention: The OCTIVUS Randomized Clinical Trial

Di-Yoon Kang¹, MD, Jung-Min Ahn², MD, Sung-Chul Yoon, PhD, Seung-Ho Hur, MD, Yan-Kyeong Cho, MD, Chae-Hyun Lee, MD, Seon-Jun Hong³, MD, Susan Lee⁴, MD, Sang-Wook Kwon⁵, MD, Hoyoun Wren⁶, MD, Jun-Hyuk Oh⁷, MD, Jeong Cheon Cho⁸, MD, Young-Joon Hong, MD, Yong-Hoon Yoon⁹, MD, Hoyun Kim, MD, Yeonwoo Cho¹⁰, MD, Jinho Lee¹¹, MD, Young Won Yoon, MD, Soo-jaeng Kim, MD, Jang-Ho Bae¹², MD, Duk-Woo Park¹³, MD, Seung-Jung Park¹⁴, MD, for the OCTIVUS Investigators

OCTIVUS



+ Meta-analyse

ORIGINAL ARTICLE

Intravascular Imaging–Guided or Angiography–Guided Complex PCI

J.M. Lee, K.H. Choi, Y.B. Song, J.-Y. Lee, S.-j. Lee, S.Y. Lee, S.M. Kim, K.H. Yun,
J.Y. Cho, C.J. Kim, H.-S. Ahn, C.-W. Nam, H.-j. Yoon, Y.H. Park, W.S. Lee,
J.-O. Jeong, P.S. Song, J.-H. Doh, S.-H. Jo, C.-H. Yoon, M.G. Kang, J.-S. Koh,
K.Y. Lee, Y.-H. Lim, Y.-H. Cho, J.-M. Cho, W.J. Jang, K.-j. Chun, D. Hong,
T.K. Park, J.H. Yang, S.-H. Choi, H.-C. Gwon, and J.-Y. Hahn,
for the RENOVATE-COMPLEX-PCI Investigators*





RENOVATE-COMPLEX-PCI Trial (NCT03381872)

1,620 Patients with Complex Coronary Artery Lesions Undergoing PCI

* Definition of Complex Coronary Artery Lesions

- ① True bifurcation (Median 1,1,1/1,0,1/0,1,1) with side branch ≥ 2.5 mm
- ② Chronic total occlusion (≥ 3 months) as target lesion
- ③ PCI for unprotected left main disease
- ④ Implanted stent length ≥ 38 mm

- ⑤ Multivessel PCI (≥ 2 vessels treated at one PCI session)
- ⑥ Multiple stent needed (≥ 3 more stent per patient)
- ⑦ In-stent restenosis lesion as target lesion
- ⑧ Severely calcified lesion (encircling calcium in angiography)
- ⑨ Ostial lesion in LAD, LCX, and RCA

Randomization (2:1) for Treatment Strategy of Target Lesions
(Stratified by acute coronary syndrome and participating centers)

 **Imaging-Guided Strategy**

N = 1,080

Angiography-Guided Strategy 

N = 540

All patients were followed until 1 year after last patient enrollment.

Primary endpoint = TVF (cardiac death + TVR-MI + CD-TVR)

Critères d'inclusion



1. Patients (≥ 19 years) with coronary artery disease requiring PCI
2. Patients with a **complex coronary artery lesion** defined as:
 - True bifurcation lesion (Medina 1,1,1/1,0,1/0,1,1) with side branch ≥ 2.5 mm
 - Chronic total occlusion (≥ 3 months) as target lesion
 - Unprotected LM disease PCI (LM ostium, body, distal LM bifurcation including non-true bifurcation)
 - Long coronary lesions (implanted stent ≥ 38 mm in length)
 - Multi-vessel PCI (≥ 2 vessels treated at one PCI session)
 - Multiple stents needed (≥ 3 more stent per patient)
 - In-stent restenosis lesion as target lesion
 - Severely calcified lesion (encircling calcium in angiography)
 - Ostial coronary lesion (LAD, LCX, RCA)

Intervention: imagerie endocoronaire



Choix entre IVUS vs OCT laissé à la discrétion de l'investigateur

Séquence imagerie libre mais **run post implantation obligatoire**

Imagerie de **référence du site**

Sizing du stent

Longueur/diamètre du stent

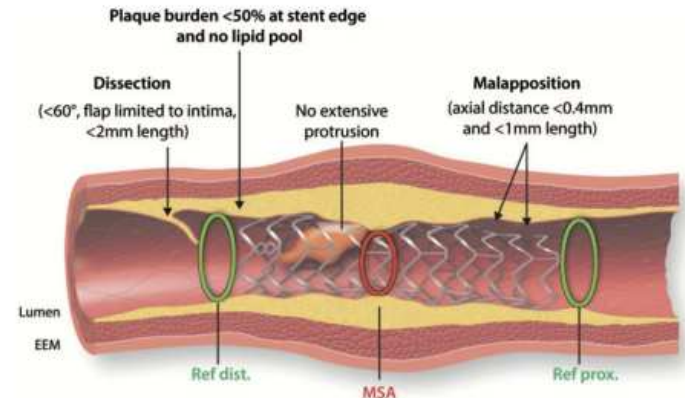
Optimisation du stent

Expansion du stent

Apposition du stent

Dissection de bord

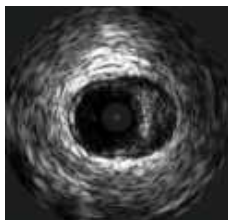
Procédure supplémentaire (ballon/stent)



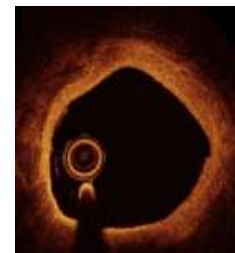
MSA > 5.5mm² (IVUS) and > 4.5mm² OCT

MSA/average reference lumen > 80%

Imagerie : protocole



	IVUS	OCT
Reference Sites	Largest size vessel lumen Plaque burden <50% At least 5 mm apart from target lesion	Most normal looking segment No lipid-containing plaque At least 5 mm apart from target lesion
Stent Sizing	By mean EEM diameter of proximal and distal reference segment	By mean EEM diameter at distal reference segment (rounded down to the nearest 0.25 mm). By mean Lumen diameter at distal reference segment (rounded up to the nearest 0.25 mm).
Stent Length	By measuring the distance from the distal to the proximal reference site.	
Stent Optimization		
• Stent Expansion	Visually assess that the residual angiographic diameter stenosis is <10% "AND" <ul style="list-style-type: none"> • Non-left main coronary artery lesions: MSA > 80% of the average reference lumen area "OR" a MSA of >5.5 mm² by IVUS and >4.5 mm² by OCT. • Left main coronary artery lesions: MSA of >7 mm² for a distal left main coronary artery stenosis and >8 mm² for a proximal left main coronary artery stenosis by IVUS. 	
• Stent Apposition	No major malapposition (defined as an acute malapposition of ≥0.4 mm with longitudinal extension >1 mm) of the stent over its entire length against the vessel wall.	
• Edge Dissection	No major edge dissection in the proximal or distal reference segments, defined as a location that is 5 mm from the edge of the stent, extends to the medial layer with potential to provoke flow disturbances (defined as ≥60° of the circumference of the vessel at site of dissection and/or ≥3 mm in length of the dissection flap)	
Additional Procedure	If any of above findings are identified, additional procedural intervention, including additional post-dilatation of the stent or additional stent implantation is recommended.	



Baseline Clinical Characteristics



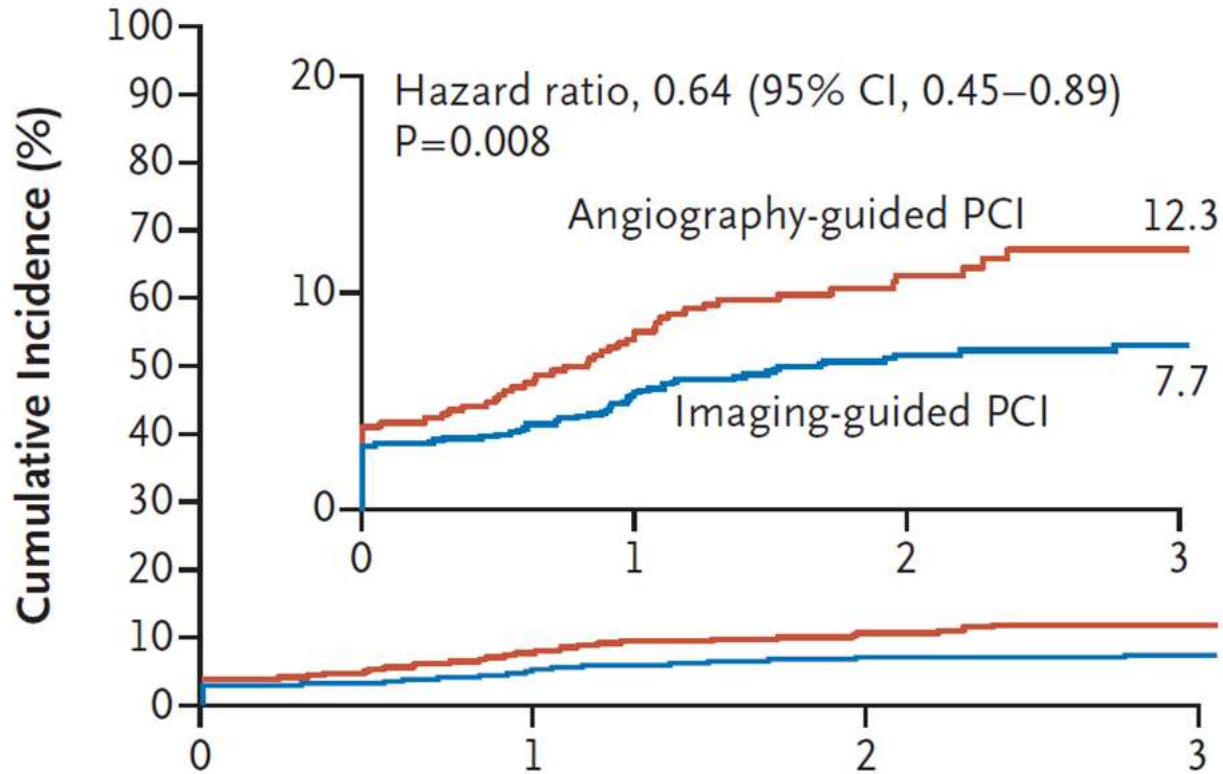
Characteristics	Total (N=1639)	Imaging-guided PCI (N=1092)	Angio-guided PCI (N=547)
Age – yr	65.6±10.2	65.3±10.3	66.0±10.0
Male – n (%)	1300 (79.3)	869 (79.6)	431 (78.8)
Initial presentation – no. (%)			
Stable ischemic heart disease	807 (49.2)	532 (48.7)	275 (50.3)
Acute coronary syndrome	832 (50.8)	560 (51.3)	272 (49.7)
Unstable angina	534 (32.6)	361 (33.1)	173 (31.6)
Acute myocardial infarction	298 (18.2)	199 (18.2)	99 (18.1)
Non-ST-segment elevation myocardial infarction	258 (15.7)	171 (15.7)	87 (15.9)
ST-segment elevation myocardial infarction	40 (2.4)	28 (2.6)	12 (2.2)
Medical history – no. (%)			
Hypertension	1005 (61.3)	682 (62.5)	323 (59.0)
Diabetes mellitus	617 (37.6)	394 (36.1)	223 (40.8)
Dyslipidemia	840 (51.3)	560 (51.3)	280 (51.2)
Current smoking	307 (18.7)	212 (19.4)	95 (17.4)
Chronic renal insufficiency	296 (18.1)	203 (18.6)	93 (17.0)
Previous PCI	395 (24.1)	268 (24.5)	127 (23.2)
Previous myocardial infarction	117 (7.1)	75 (6.9)	42 (7.7)
LV ejection fraction – (%)	58.7±11.6	58.4±11.9	59.3±11.0

Baseline Clinical Characteristics

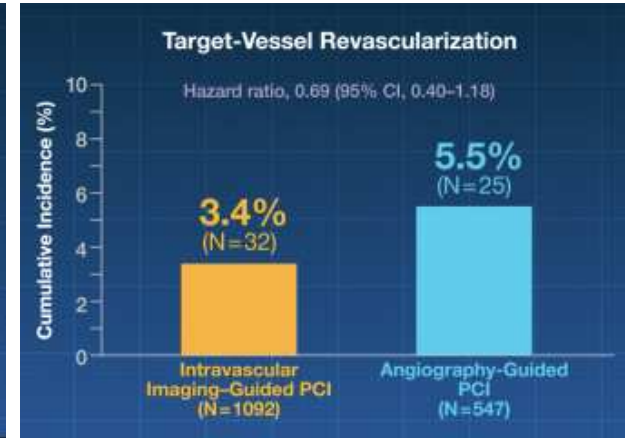
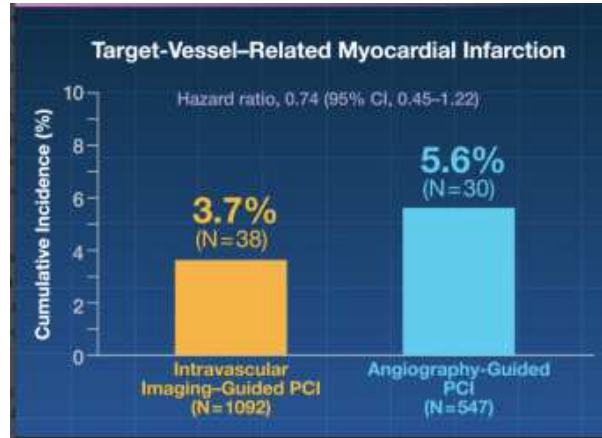
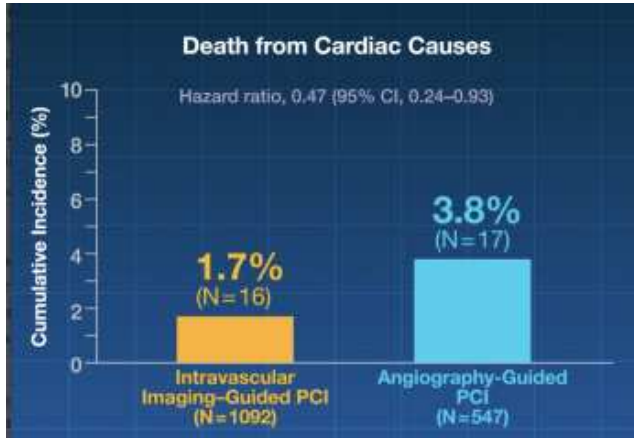


Characteristics	Total (N=1639)	Imaging-guided PCI (N=1092)	Angio-guided PCI (N=547)
Complex coronary lesions – no. (%)			
True bifurcation lesion with side branch ≥ 2.5 mm	359 (21.9)	233 (21.3)	126 (23.0)
Chronic total occlusion (≥ 3 months)	319 (19.5)	220 (20.1)	99 (18.1)
Unprotected left main coronary artery disease	192 (11.7)	138 (12.6)	54 (9.9)
Long coronary lesion (implanted stent ≥ 38 mm in length)	898 (54.8)	617 (56.5)	281 (51.4)
Multivessel PCI (≥ 2 vessels treated at one PCI session)	622 (37.9)	409 (37.5)	213 (38.9)
Multiple stents (≥ 3 more stent per patient)	305 (18.6)	208 (19.0)	97 (17.7)
In-stent restenosis	236 (14.4)	158 (14.5)	78 (14.3)
Severely calcified (encircling calcium in angiography)	231 (14.1)	157 (14.4)	74 (13.5)
Ostial coronary lesion (LAD, LCX, RCA)	251 (15.3)	182 (16.7)	69 (12.6)
Number of vessels with disease – no. (%)			
1-vessel disease	526 (32.1)	342 (31.3)	184 (33.6)
2-vessel disease	621 (37.9)	420 (38.5)	201 (36.7)
3-vessel disease	492 (30.0)	330 (30.2)	162 (29.6)
Procedural characteristics			
Total no. of target lesions treated	1.5 \pm 0.7	1.5 \pm 0.7	1.5 \pm 0.7
Intravascular imaging devices used – no./total no. (%) †	1091/1639 (66.6)	1078/1092 (98.7)	13/547 (2.4)
Intravascular ultrasound	813/1091 (74.5)	800/1078 (74.2)	13/13 (100.0)
Optical coherence tomography	278/1091 (25.5)	278/1078 (25.8)	0/13 (0.0)
Volume of contrast media used – ml	207.3 \pm 116.5	214.2 \pm 118.5	193.7 \pm 111.3

Primary endpoint: Target lesion failure



Critères individuels



Discussion



Procédures en ouvert

Post-dilatation plus fréquente dans le groupe imaging (60% vs 45%)

Critères déploiement optimal stent (critères préspecifiés)
obtenus uniquement dans **45,4% des cas dans le groupe imagerie endocoronaire**

Un seul pays et un centre = majorité des inclusions
(expérience groupe contrôle importante)

RENOVATE COMPLEXE PCI Conclusion:

L'imagerie intracoronaire (3/4 IVUS) pour guider l'angioplastie complexe réduit le critère composite décès cardiovasculaire, TV MI, CD Target vessel revascularisation @2 ans en comparaison à l'angiographie seule.



ILUMIEN IV: OPTIMAL PCI



+ Asie/Inde



n=2487, 60% ACS, 40%DM

Procédure OCT: + longueur stent, post dilatation, diamètre>, temps, contraste

Critère principal imagerie: **MSA : + 0.36 mm² dans le groupe OCT**

Critère principal clinique: **TVF : pas de différence (7.4 vs 8.2%, p=0.45)**

Critère « safety »: **moins de thrombose de stent dans le groupe OCT (0.5% vs 1.4%, p=0.02)**

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

ILUMIEN IV: conclusion commentaires

Dans l'angioplastie avec critères « haut risque » clinique (DM) ou angiographique

L'utilisation de l'OCT a permis :

une **amélioration du MSA (en ligne avec les études précédentes)**

sans traduction sur les critères cliniques à deux ans.

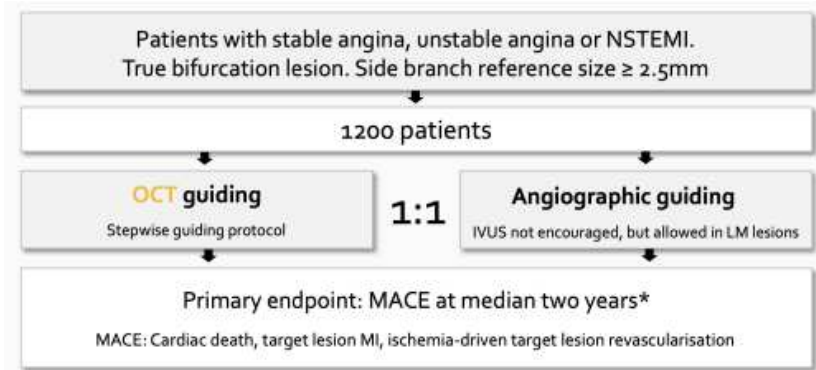
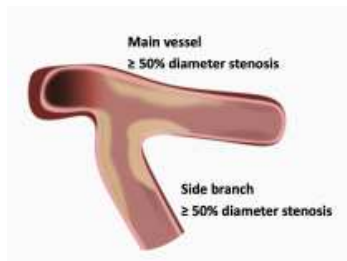
Avec des éléments positifs sur la sécurité (thrombose de stent)

Raisons de l'absence de différence critère clinique:

Impact du COVID (recrutement), niveau de risque de la population sélectionnée



OCTOBER

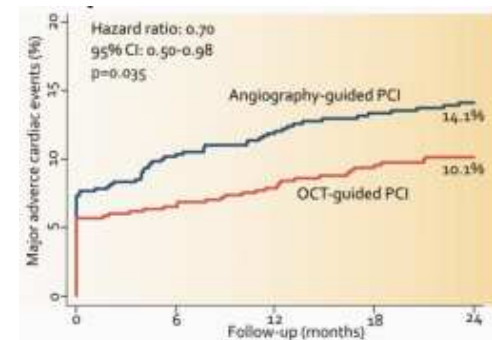


OCTOBER

n= 1201, 45% ACS , 65% 2 stent technique, NSTEMI 13%, DM 17%

OCT: Stent plus long (+6mm), plus de ballons utilisés (+1), ballons plus larges (+0.2)

OCT: > Contraste (+100 ml), Temps procédure (+18 m), Scopie (+5 min)



Reduction significative des MACE dans le groupe OCT-guided (MACE = Death, TL-MI, ID-TRV)

OCTOBER: conclusion/commentaires

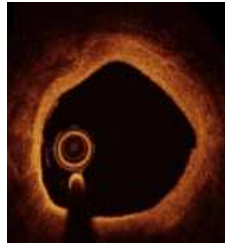


Plus **large étude** sur l'intérêt de l'OCT dans **l'angioplastie de la bifurcation**

Supériorité OCT/ Angiographie sur MACE @ 2 ans

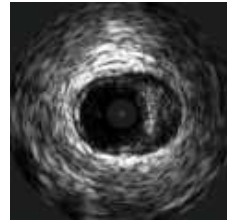
Résultats consistants sur les critères individuels et les sous groupes

OCTIVUS



OCT

VS



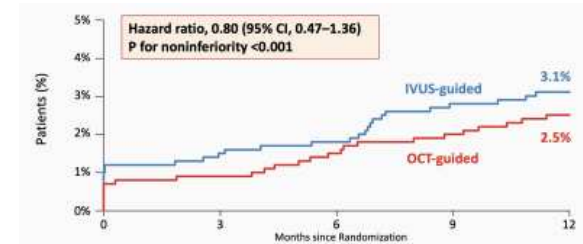
IVUS

Guided PCI

n=2000 PCI (non sélectionnée), 40% SCA

Analyse en non-infériorité (TVF estimé à 8% à 1 an en IVUS , marge NI 3.1%)

OCT-guided non-inferieure à l'IVUS-guided sur TVF (décès, TL-MI, ID-TR)



OCTIVUS: conclusion commentaires

OCT non-inferieure à l'IVUS dans une population peu sélectionnée

Taux d'événements plus bas qu'attendu

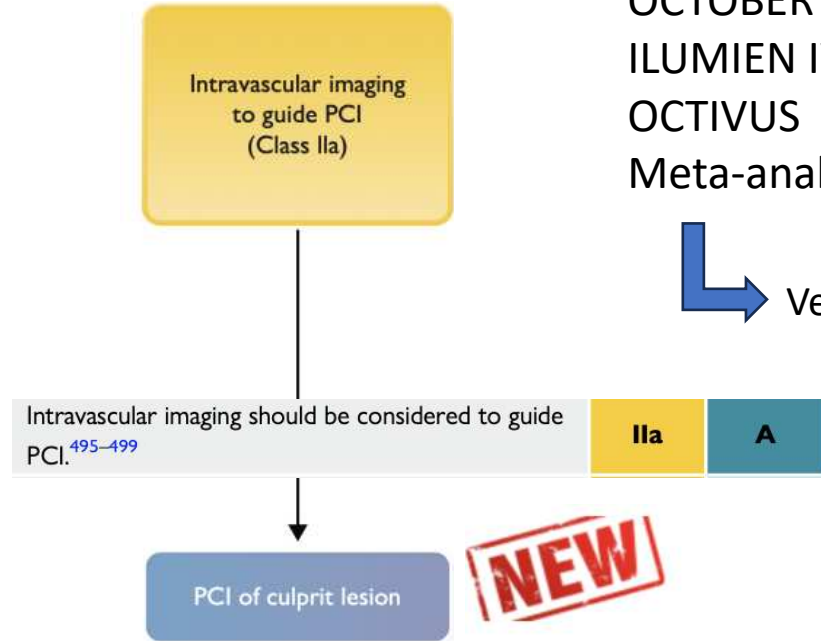
Plus de produit de contraste (+40 ml) dans le groupe OCT sans augmentation des néphropathies aux PDC

Analyse en sous groupe OCTIVUS COMPLEX PCI (JACC 2024) : même résultat

2023 ACS Guidelines: Intravascular Imaging

	IVUS	OCT
To guide left main revascularisation	IIa B	N/A
To optimize stent implantation	IIa B	IIa B
To detect reasons for restenosis	IIa C	IIa C

Neumann FJ., et al. EuroIntervention. 2019;14:1435-1534



OCTOBER
ILUMIEN IV
OCTIVUS
Meta-analyse

↳ Vers un classe I-A?

2018 ESC/EACTS Guidelines Revascularisation

2023 ACS Guidelines

2024 ACC Guidelines

Les limites à la généralisation de l'imagerie

Données cliniques suffisantes



Recommandations



Opérateurs: convictions et formations



Coût et remboursement



Conclusion

Les études 2023 sur l'imagerie (IVUS et OCT) pour guider l'angioplastie sont en faveur d'un **bénéfice clinique** en particulier **dans les lésions complexes**

Vont contribuer à la poursuite du changement de ma pratique

L'utilisation de l'imagerie en France **reste marginale** (8679 /an soit 4% des ATC), en dessous de la médiane des pays européens.

La problématique du remboursement de l'imagerie (et de la FFR) va continuer à être au premier plan



15-20% ATC



4% ATC