Les lésions calcifiées

Les techniques à l'épreuve

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APPAC
1 au 3 juin 2022

LES OUTILS pour lesions calcifiée

Ballon Non Compliant à tres haut

Imagerie endocoronaire

Cutting balloon

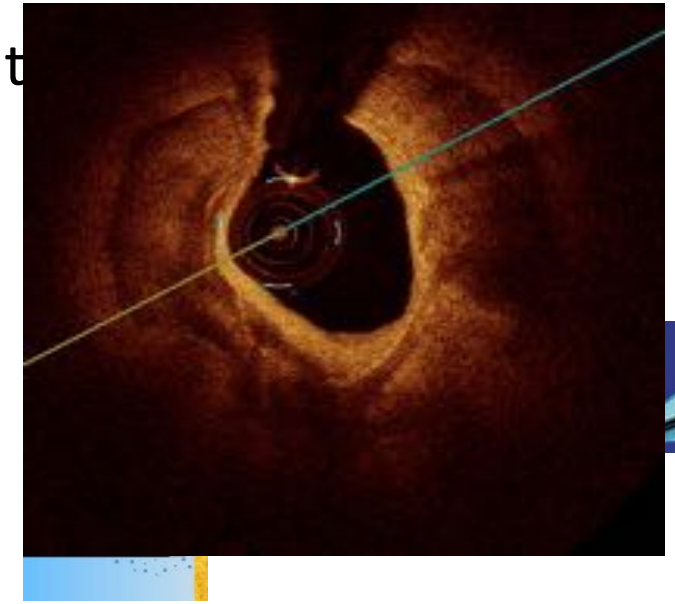
Scoring device

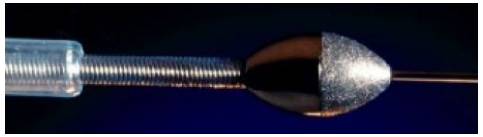
Laser

Rotational atherectomy

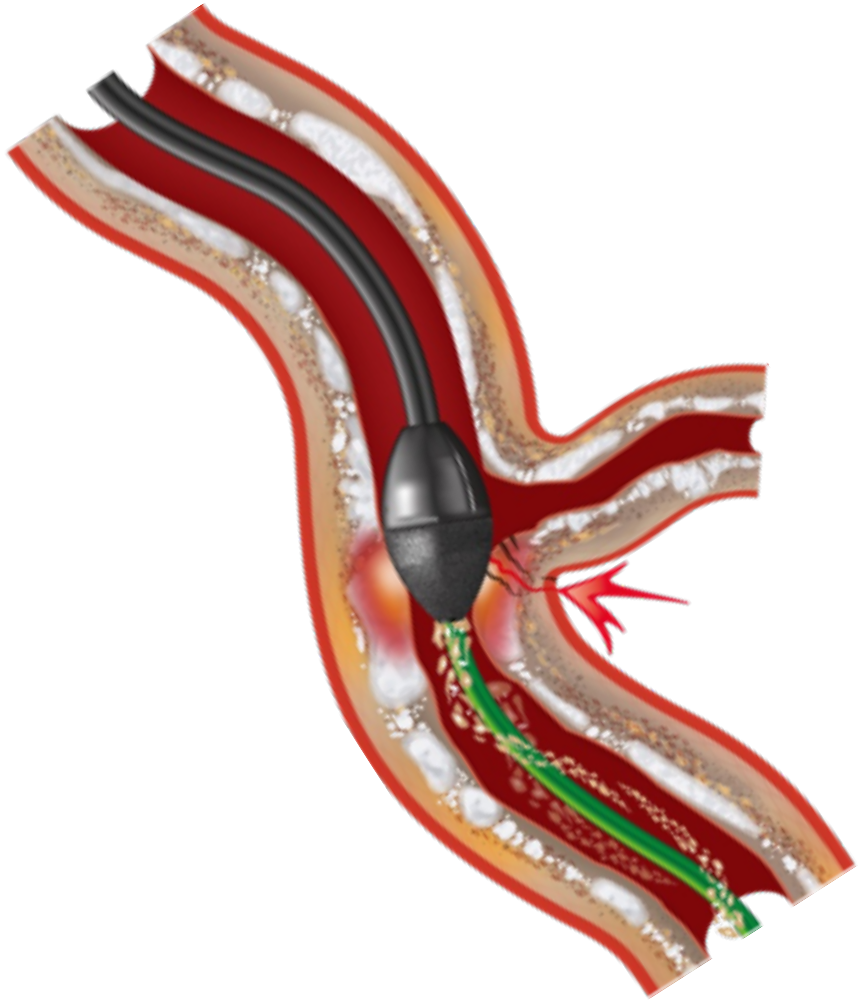
Shockwave™ intravascular lithotripsy

Orbital atherectomy

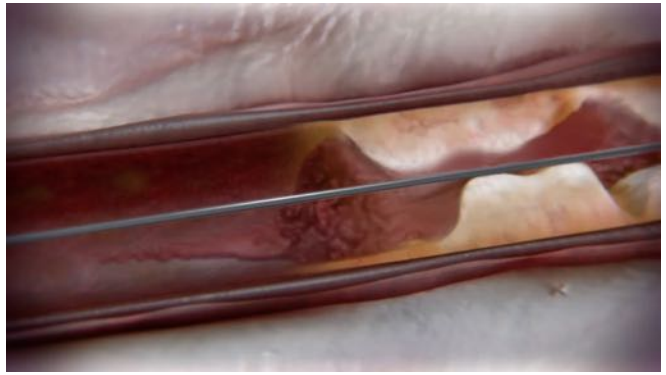


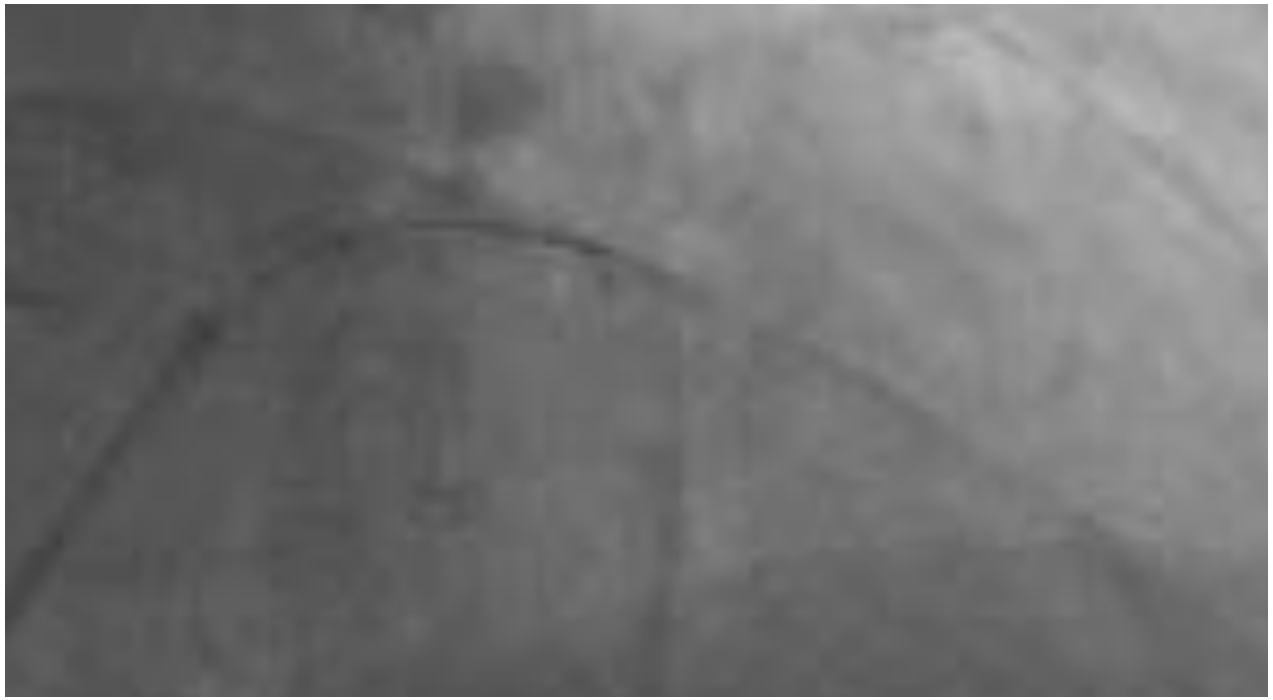


L'atherectomie rotative (RA)



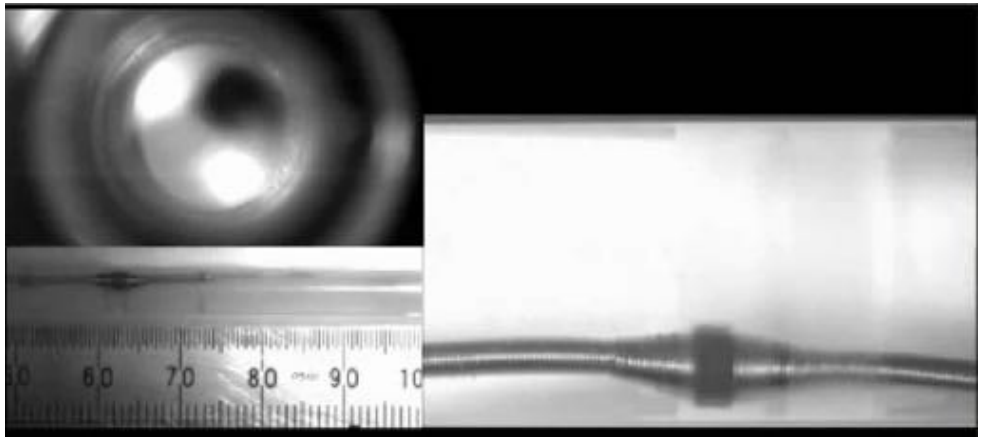
L'atherectomie orbitale (OA)

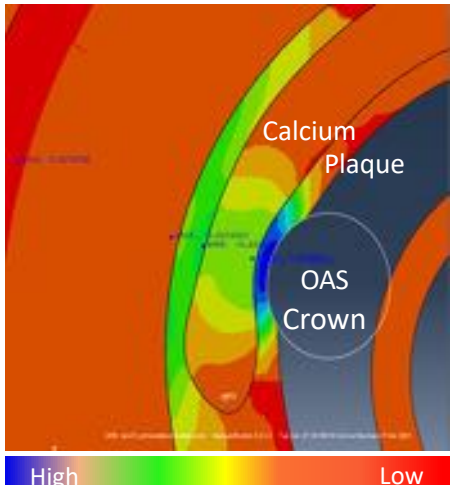


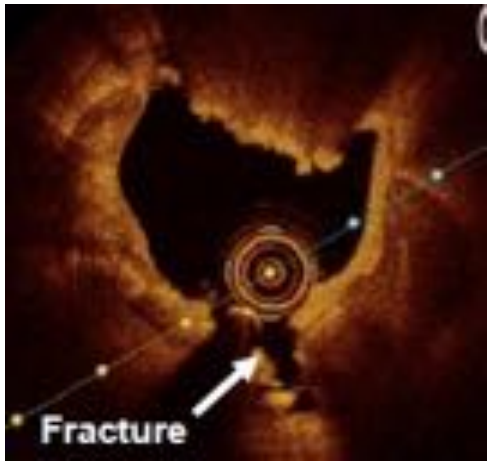


Courtesy of J. Monsegu

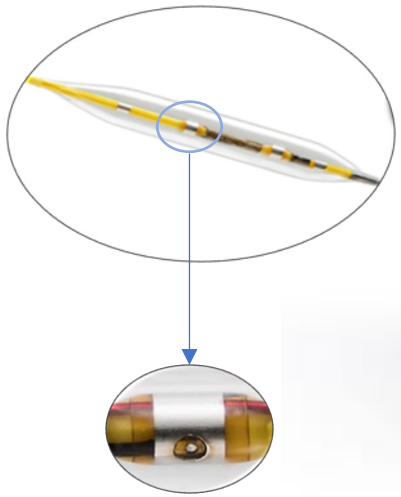
L'atherectomie orbitale (OA)





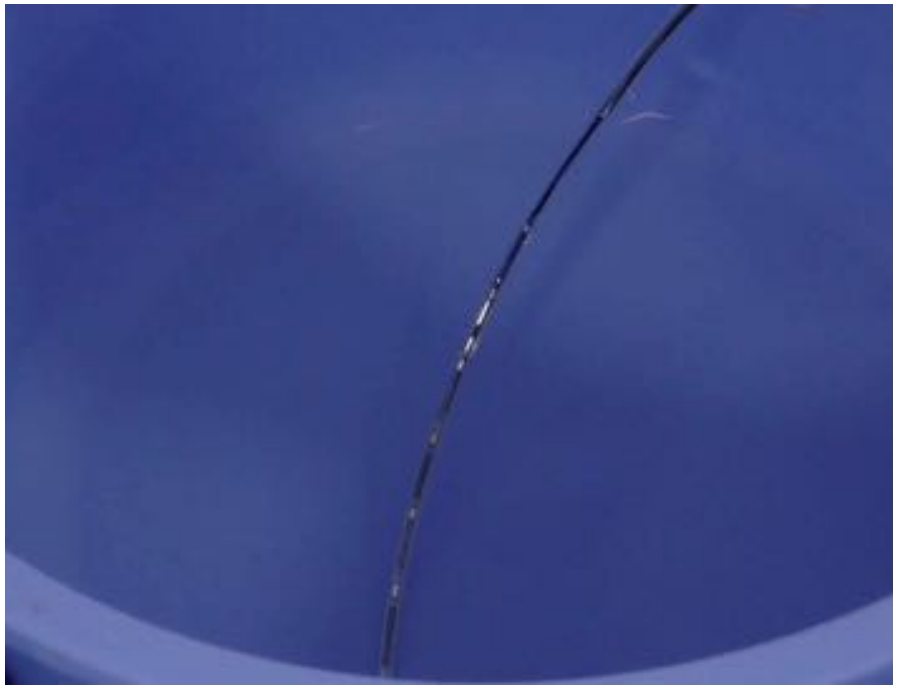


Lithotripsie intracoronaire (IVL)



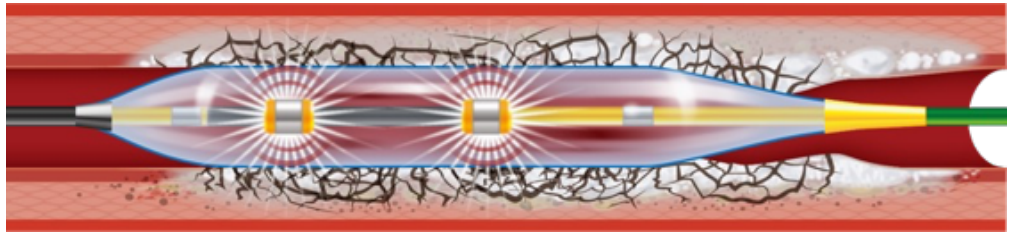
Emetteur
Pulse 1/s – Max 80 pulses

Générateur
Rechargeable / secteur



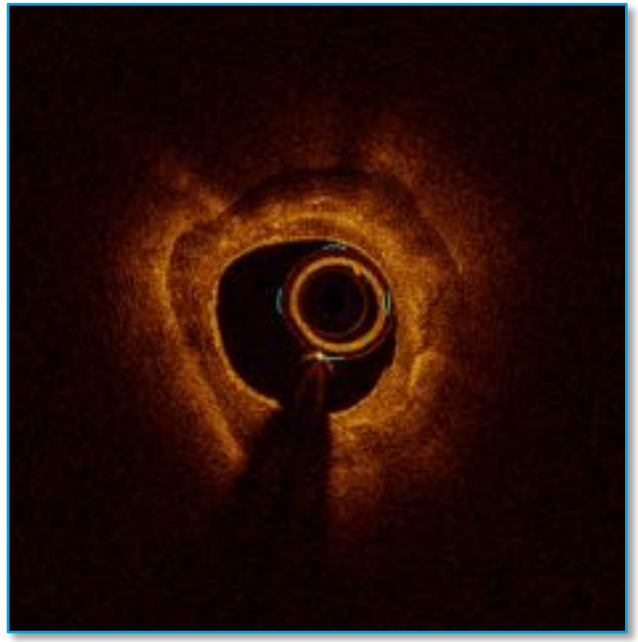
Cathéter
Usage unique

Connecteur
Plug magnétique



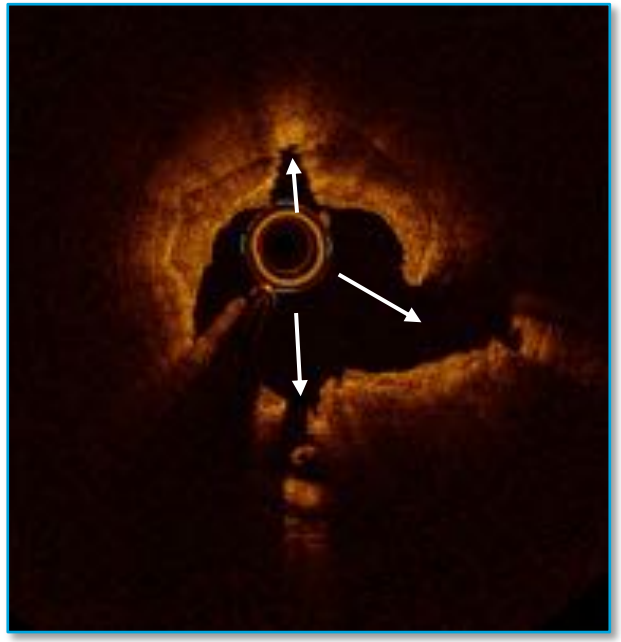
Lithotripsie intracoronaire (IVL)

Pre-procedure



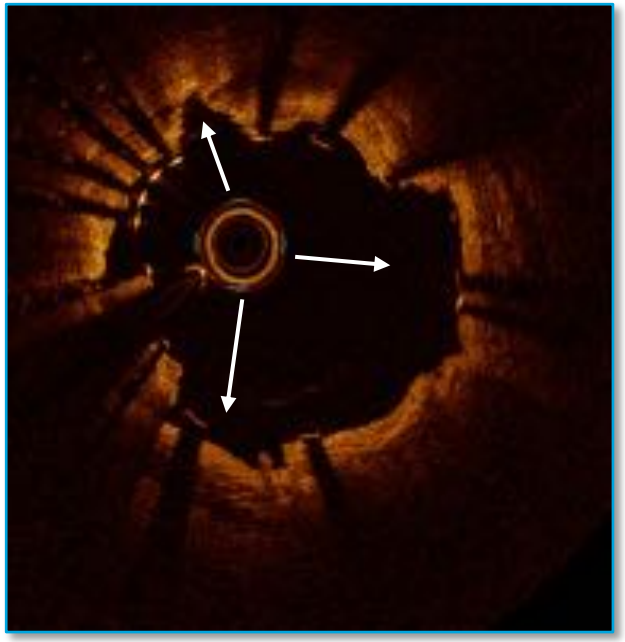
Lumen Area: 1.69 mm^2

Post-IVL



Lumen Area: 4.58 mm^2

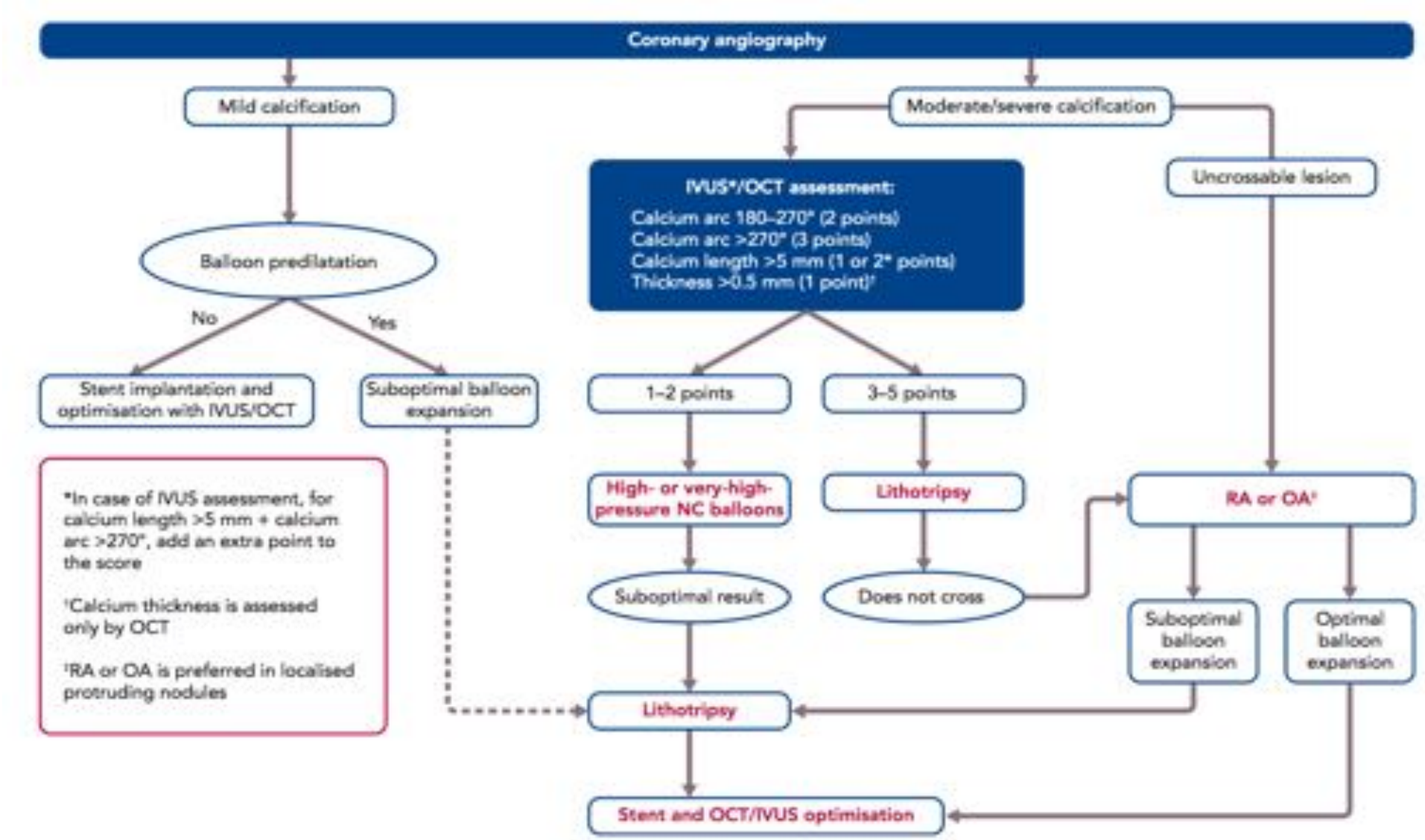
Post-stent



Lumen Area: 9.51 mm^2

Stent Area: 8.01 mm^2

Integration des outils dans le cath-lab



IVUS = intravascular ultrasound; NC, non-compliant; OA = orbital atherectomy; OCT = optical coherence tomography; RA = rotational atherectomy

Courtesy of Carlo Di Maria

A l’épreuve du TEMPS

Evolution vers le ROTAPRO

1989

Ann Cardiol Angeiol (Paris). 1989 Sep 30;38(7 Pt 2):505-8.

[Coronary atherectomy using a Rotablator].

[Article in French]

Fournier JL[1]

Author information

Abstract

A system or rotary atherectomy (Rotablator) was evaluated on coronary stenoses in Man. This device consists of catheter presenting an abrasive olive-shaped knob at one end, and sliding over a central metallic guide, rotating at more than 150,000 tpm. This drill liquifies the atheroma in small microparticles able to cross the microcirculation. The atherectomy surface is perfectly smooth and the risk of thrombosis is minimum. The atherectomy technique is quite simple, similar to PTCA, the balloon being replaced by a drill with a diameter ranging from 1.25 to 2 mm. 48 stenoses in 45 patients were treated with this technique. Twice, the Rotablator's guide was unable to cross the stenosis. In other cases, the stenosis was decreased, in an average, by 75 p. cent (SD 24%) to 43 p. cent (SD 20%) (p less than 0.001). The segment treated is characterized by smooth, linear edges without parietal minithrombi. Complications are most unusual (no deaths, no extended infarction, no emergency bypass related an early reobstruction). The coronary artery may react to the passage of the Rotablator by a spasm; this coronary spasm disappears (sometimes in a few hours) under nitrates derivatives perfusion. The middle term results are very encouraging; in fact, in 19 patients who underwent a control coronary angiography 3 months later, 3 (15%) presented a stenosis. In conclusion, rotary angioplasty is an easy, effective and harmless technique. The exact percentage of re-stenosis remains to be specified in larger series.

Rotawire Drive

Unsurpassed Torque Transmission

Able to navigate calcified lesions with 1:1 torque through tortuous anatomy, providing access for ROTAPRO™

Improved Core Wire Durability

Improved kink resistance and wear resistance compared to the legacy Rotawire

Highly Visible Safety Tip

014 platinum coil to provide visibility and added safety during Rotational atherectomy

ASAHI Core Wire Technology

One-piece stainless steal core wire transmits torque for predictable steering

Both wires 330cm total length

Both wires 0.009” body with 0.014” Spring Tip Diameter

Rotawire Drive

L'atherectomie rotative (RA)

HAS

Libellé de l'acte	2014	2015	2016	2017	2018
DDFF001 - Athérectomie intraluminale d'artère coronaire par méthode rotatoire [rotationnelle], par voie artérielle transcutanée	2 338	2 507	2 930	3 242	3 465

Au total, la population cible du système d'athérectomie rotationnelle ROTAPRO est de l'ordre de 3 000 patients par an avec une augmentation constante de 5 à 7% par an.

FRANCE PCI

Total Examens réalisés	Tous les centres	%
Angioplasties (ad-hoc)	29445	*68.24%*
Angioplasties seules	13704	*31.76%*
Total	**43149**	

indication avec angor	2014	2015	2016	2017	2018	2019	2020	2021	Total
Angor stable	1,8 %	3,3 %	2,7 %	3,0 %	2,4 %	2,4 %	2,2 %	2,2 %	**2,4 %**
Angor instable	1,4 %	1,8 %	1,8 %	1,5 %	1,1 %	1,7 %	1,2 %	1,0 %	**1,4 %**
NSTEMI	1,2 %	1,5 %	1,3 %	0,9 %	0,6 %	1,2 %	1,4 %	1,5 %	**1,3 %**
STEMI	0,3 %	0,2 %	0,2 %	0,6 %	0,2 %	0,2 %	0,3 %	0,2 %	**0,3 %**
Total	**1,3 %**	**2,1 %**	**1,8 %**	**2,0 %**	**1,5 %**	**1,6 %**	**1,6 %**	**1,6 %**	**1,7 %**

1.7% (n=715)

A l’épreuve de la SCIENCE :

A l’épreuve de la SCIENCE : Atherectomie rotative

RA : Etude ROTAXUS

	Athérectomie rotationnelle + TAXUS	TAXUS	
9 mois	**n=113**	**n=114**	
Décès toutes causes	5,0%	5,8%	
Infarctus du myocarde	6,7%	5,8%	
Revascularisation du vaisseau cible	16,7%	18,3%	
Revascularisation de la lésion cible	11,7%	12,5%	
MACE	24,2%	28,3%	
Thrombose de stent	1 cas	0	
2 ans	**n=109**	**n=108**	
Décès toutes causes	8,3%	7,4%	p = 1
Infarctus du myocarde	8,3	6,5%	p = 0,8
Revascularisation du vaisseau cible	19,3%	22,2%	p = 0,62
Revascularisation de la lésion cible	13,8%	16,7%	p = 0,58
MACE	29,4%	34,3%	p = 0,47

De Waha S et al. *Catheter Cardiovasc Inter*v. 2016

RA : Euro4C Registry

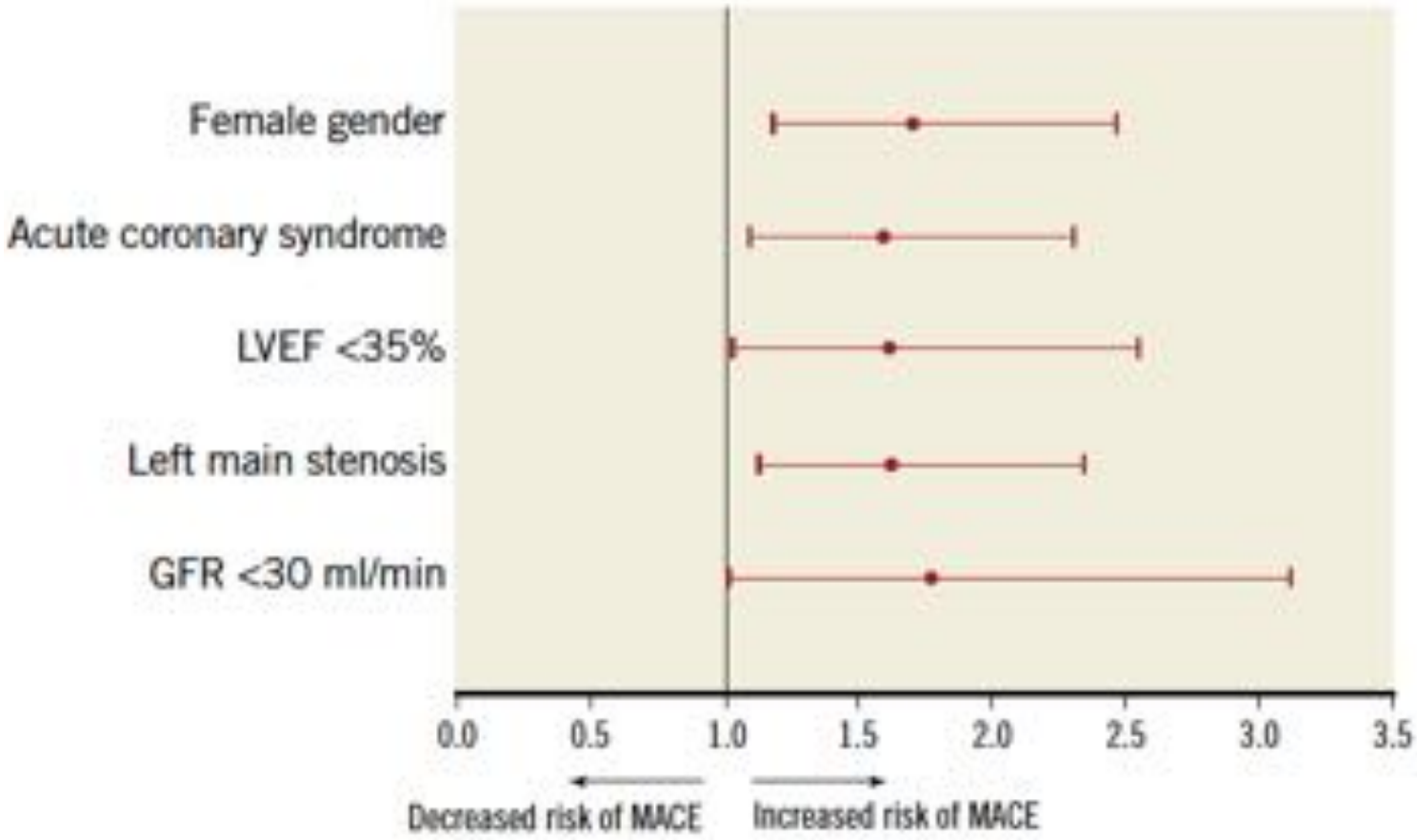
In-hospital outcomes	N	(%)
Clinical success	885/963	91.9
MACE	45/966	4.7
Death	15/965	1.6
Myocardial infarction	28/965	2.7
Stroke or TIA	3/965	0.3
Perforation	16/965	1.7
Dissection	38/965	3.9
Low flow/no flow	12/965	1.2
Emergency CABG	0/965	0.0
Tamponade	5/965	0.5
Bleeding, BARC ≥3	12/966	1.2

Outcomes	1-year outcomes		
	N	(%)	Incidence rate (for 100 person-years)**
MACE*	127/966	13.2	15.9 (13.4-18.9)
All-cause death	94/966	9.7	11.1 (9.1-13.6)
Cardiovascular death	55/966	5.7	6.5 (5.0-8.5)
Myocardial infarction	45/966	4.7	5.6 (4.1-7.4)
Target lesion revascularisation	23/966	2.4	2.8 (1.8-4.1)
Stroke	8/966	0.8	1.0 (0.5-1.9)
CABG	5/966	0.5	0.6 (0.2-1.4)
Target vessel revascularisation ***	33/966	3.4	4.0 (2.8-5.6)
Bleeding (BARC ≥3)	29/966	3.0	3.4 (2.3-4.9)

Bouisset et al. Eurointerevention 2020

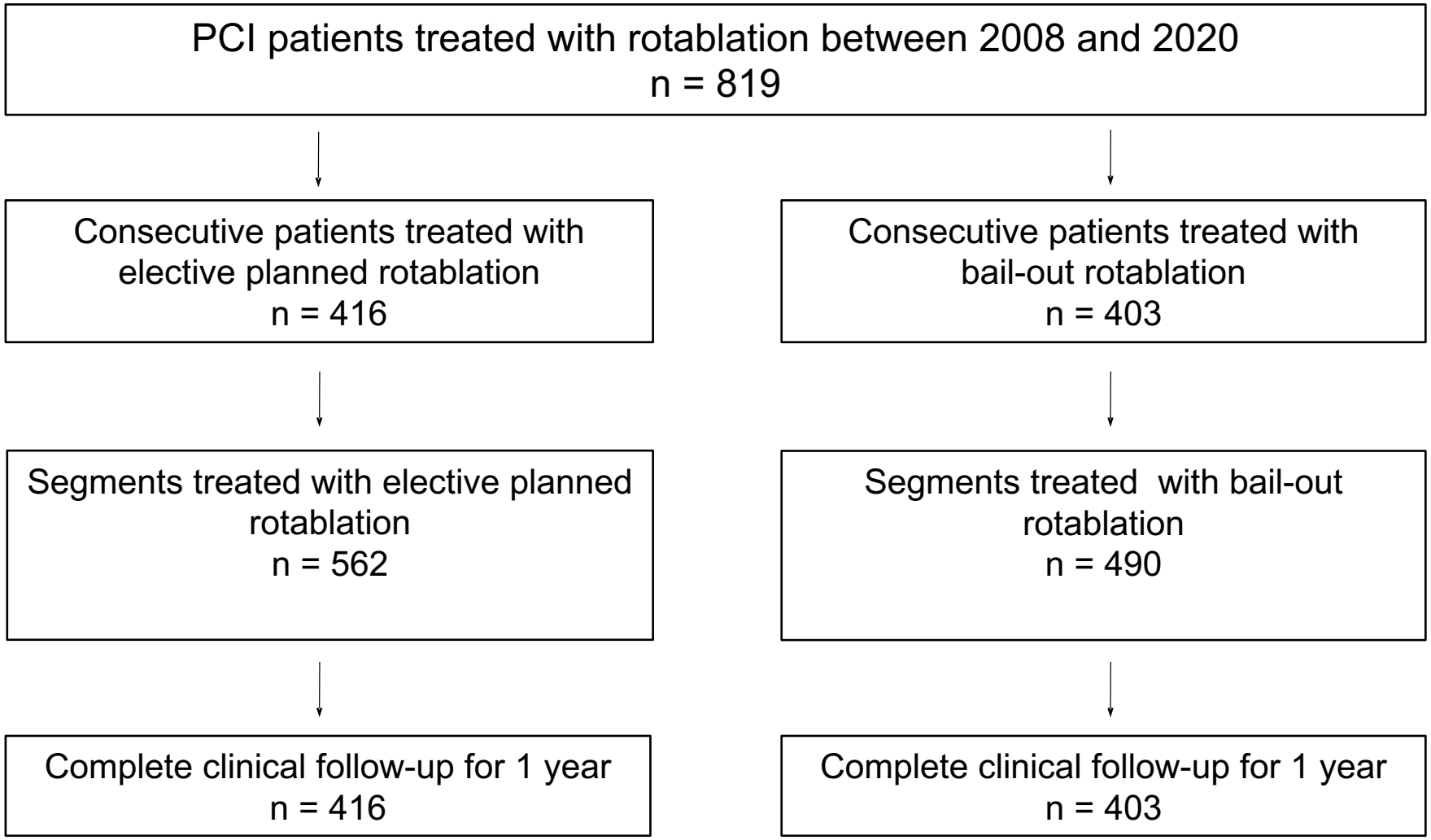
RA : Euro4C Registry

12-month MACE independent risk factors



Bouisset et al. Eurointerevention 2020

RA : Bad Krozingen Registry



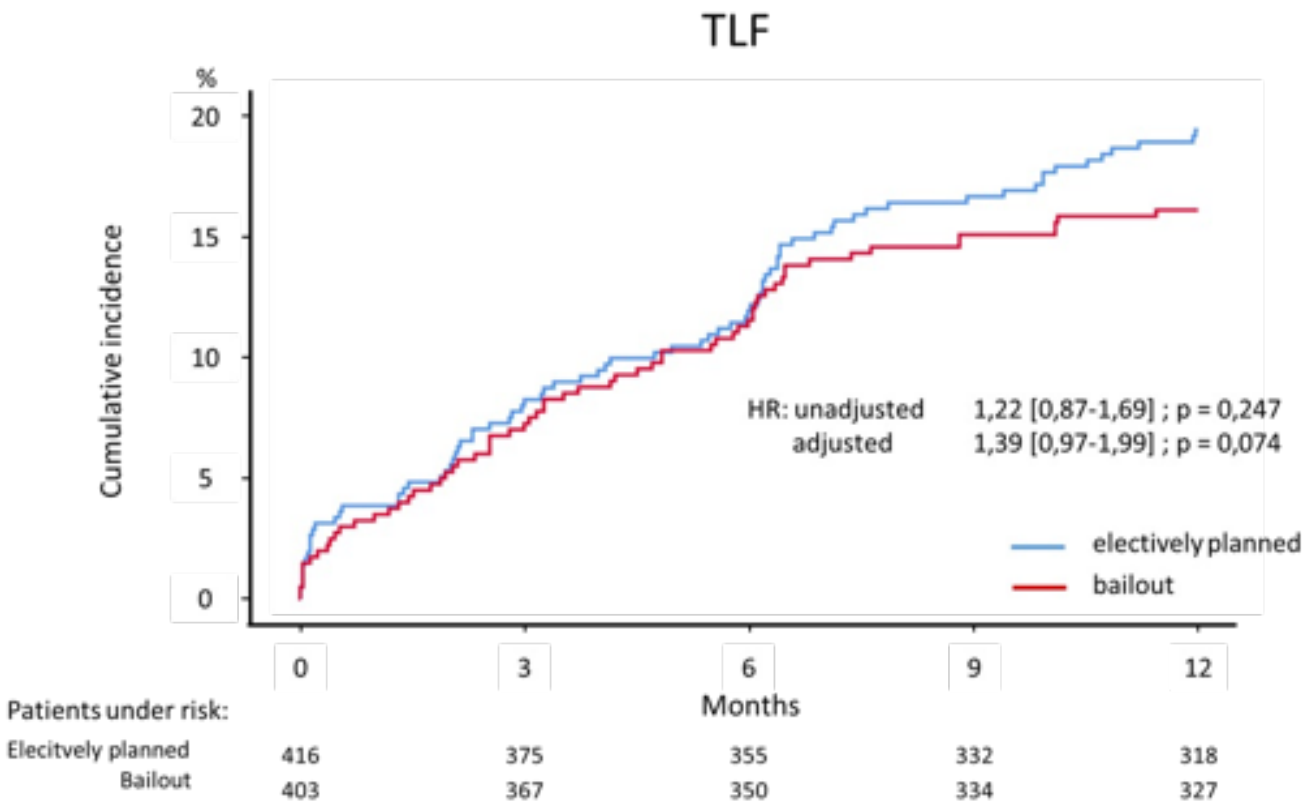
Courtesy of M. FERENC - EuroPCR 2022

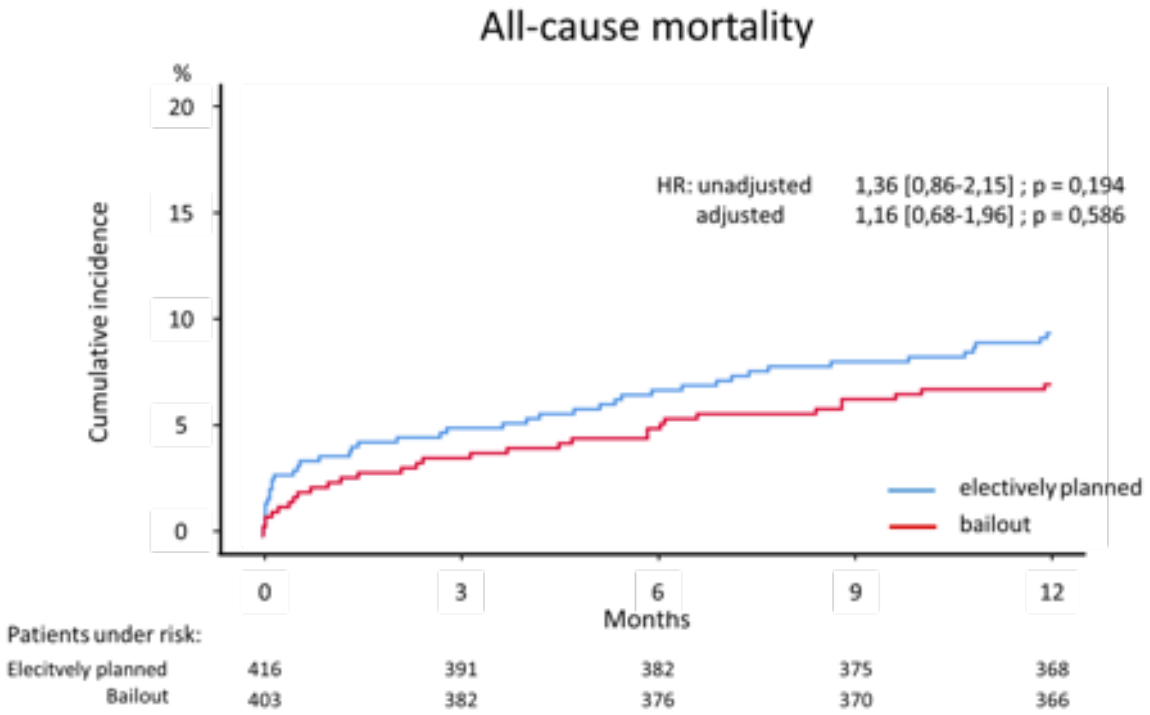
RA : Bad Krozingen Registry

	Planned Rotablation	**„Bail-out“ Rotablation**	**p**
	Segments n = 562	Segments n = 490	
Age (years)	**74,2 ± 8,8**	**71,3 ± 9,0**	**0,0001**
Male sex [n (%)]	450 (80,1%)	388 (79,2%)	0,759
BMI (kg/m^2)	**27,5 (± 4,4)**	**28,2 (± 4,2)**	**0,022**
Hypertention [n (%)]	523 (93,1%)	455 (92,9%)	0,904
Diabetes mellitus [n (%)]	**194 (34,5%)**	**214 (43,7%)**	**0,003**
Smoker [n (%)]	47 (8,4 %)	49 (10,0%)	0,391
Positive family history [n (%)]	168 (29,9%)	152 (31,0%)	0,737
Cholesterol (mg/dl)	158 (± 41)	163 (± 43)	0,075
LDL cholesterol (mg/dl)	95 (± 38)	97 (± 36)	0,585
Creatinines (mg/dl) pre Intervention	1,3 (± 1,0)	1,2 (± 0,9)	0,244
Creatinines (mg/dl) 24h post Intervention	1,3 (± 0,8)	1,3 (± 0,89)	0,287
Hemoglobin (g/dl)	13,3 (± 1,8)	13,5 (± 1,8)	0,231

Courtesy of M. FERENC - EuroPCR 2022

RA : Bad Krozingen Registry





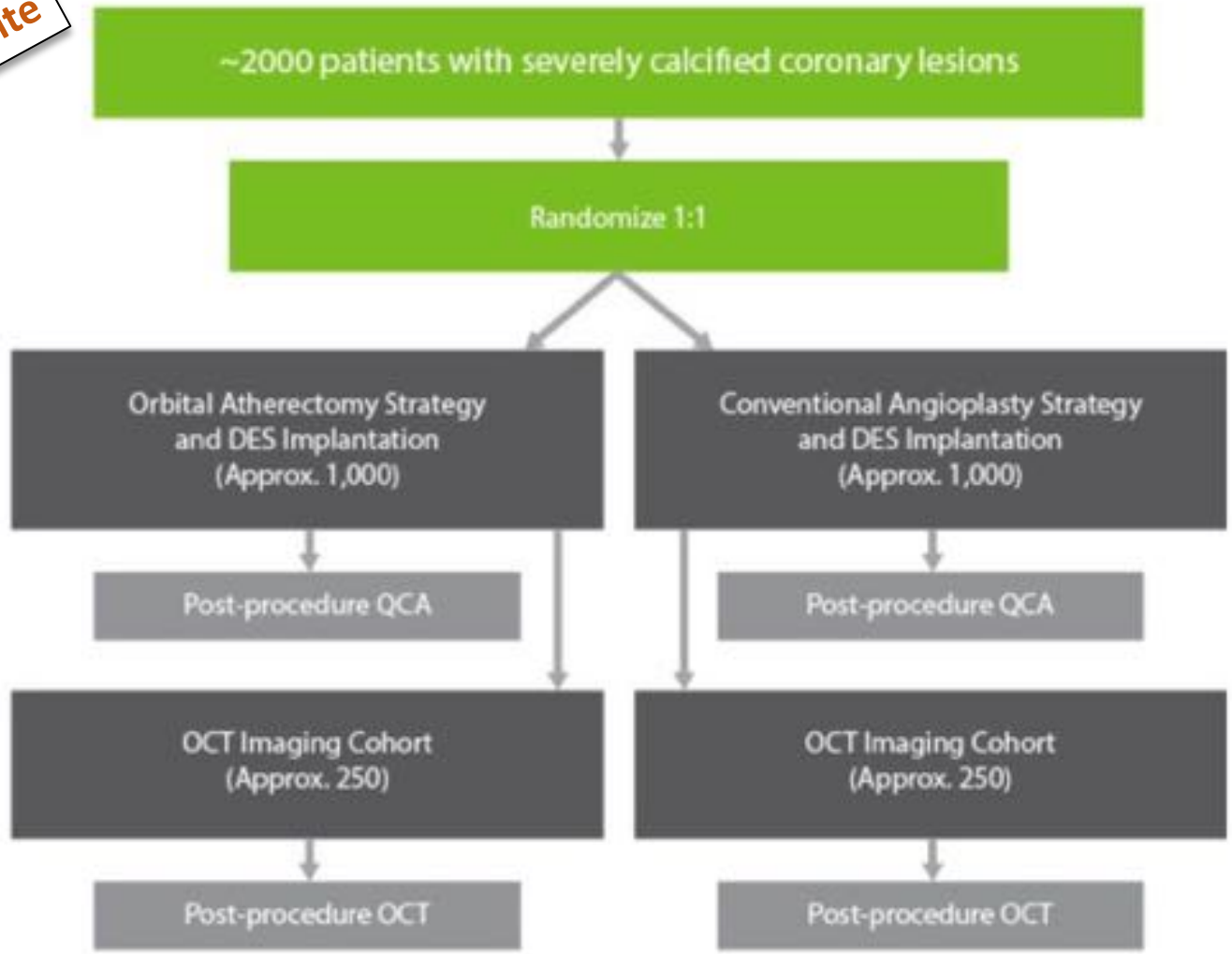
Courtesy of M. FERENC - EuroPCR 2022

A l’épreuve de la SCIENCE : Atherectomie orbitale

OA : Etude ECLIPSE

ECLIPSE Clinical Study

150 US Site



Co-Primary Endpoints

* MLA Stent / OCT lors de l'implantation

* Target vessel failure (TVF) à 12 mois :
Décès d'origine cardiaque,
Revascularisation du vaisseaux cible (Myocardial infarction ou ischemia driven)

A l’épreuve de la SCIENCE : Lithotripsie intravasculaire

IVL : Disrupt CAD Programm

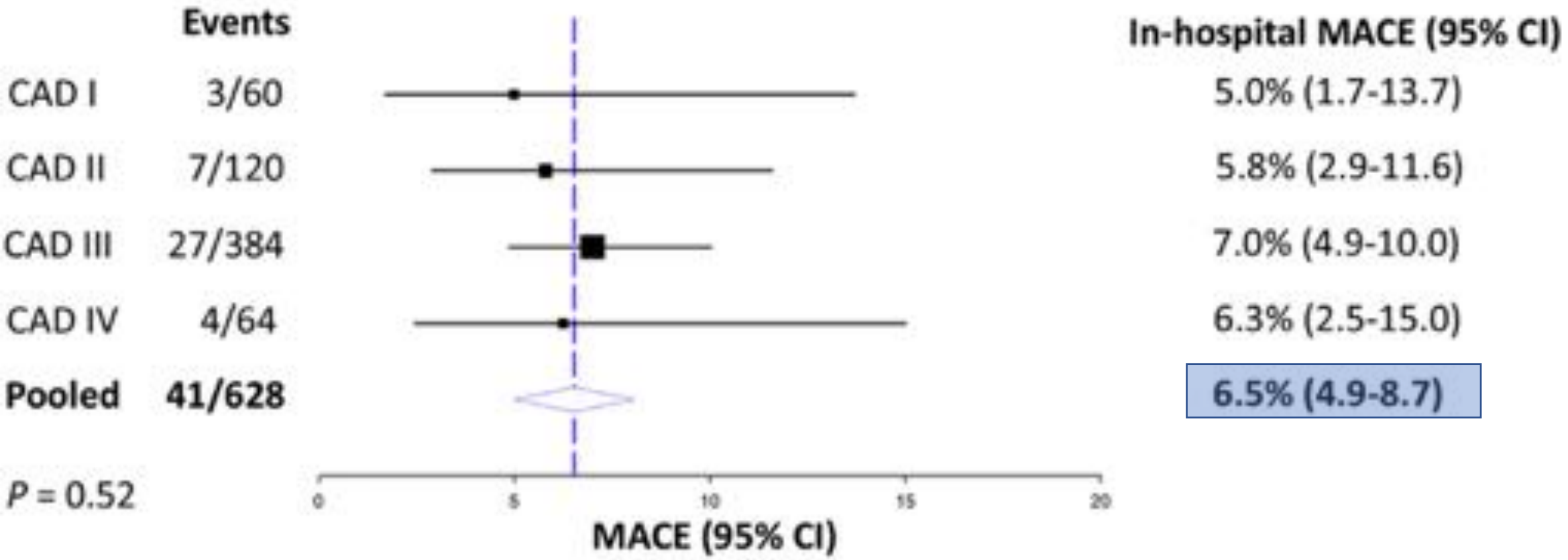
	Disrupt CAD I	Disrupt CAD II	Disrupt CAD III	Disrupt CAD IV
Status	Enrollment completed	Enrollment completed	Enrollment completed	Enrollment completed
Study design	Single arm, safety & feasibility	Single arm, post-market, safety & effectiveness	Single arm, IDE, safety & effectiveness	Single arm, pre-market safety & effectiveness
# of patients	60	120	384	64
# of sites	7	15	47	8
Regions	AU, EU	EU	US, EU	Japan
Published	Circulation 2019	Circ Interv 2019	JACC 2020	Circulation Journal 2020

IVL : Disrupt Pool Analysis

Intravascular Lithotripsy for Treatment of Calcified Coronary Lesions

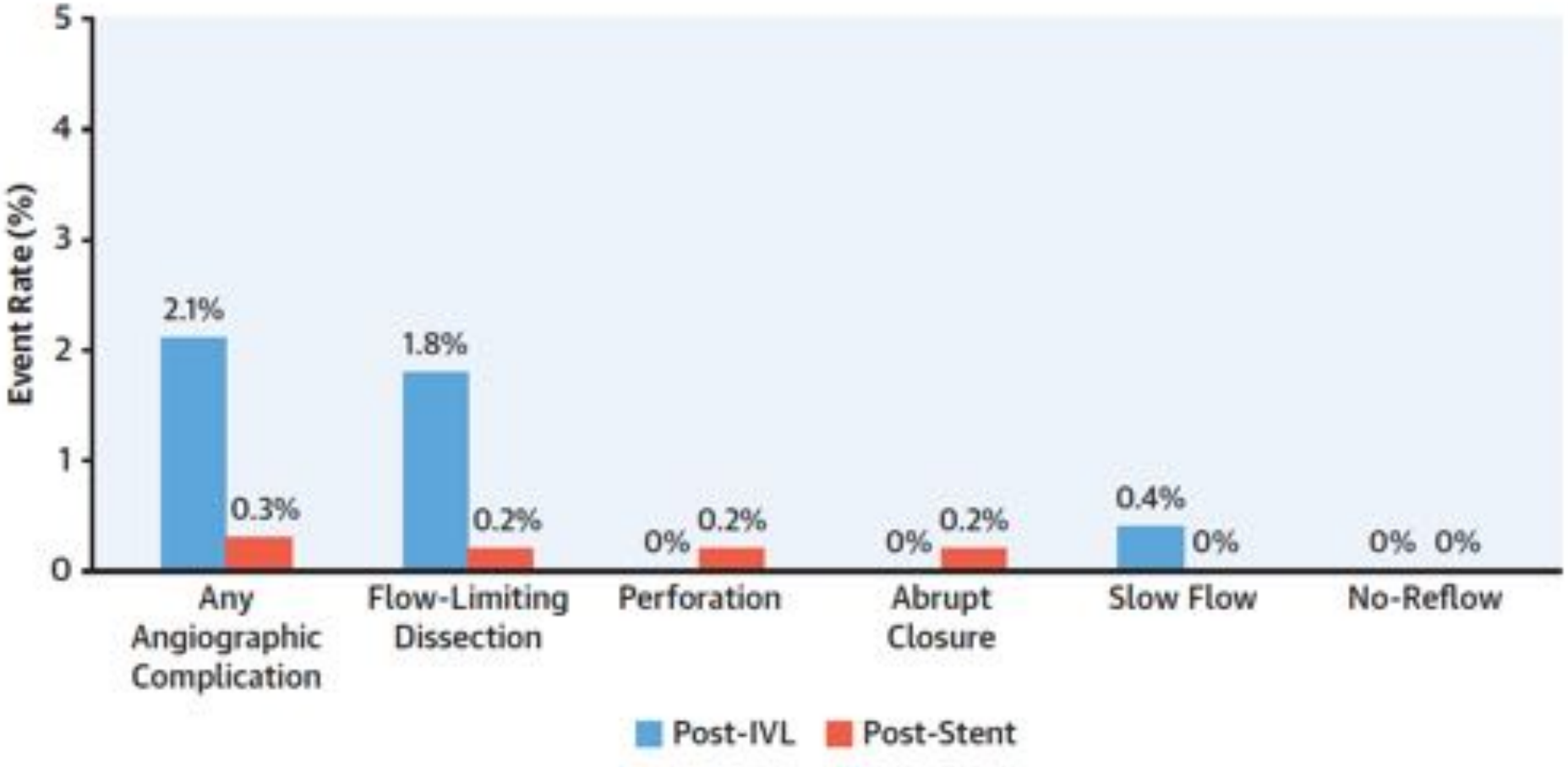
Patient-Level Pooled Analysis of the Disrupt CAD Studies

N = 628



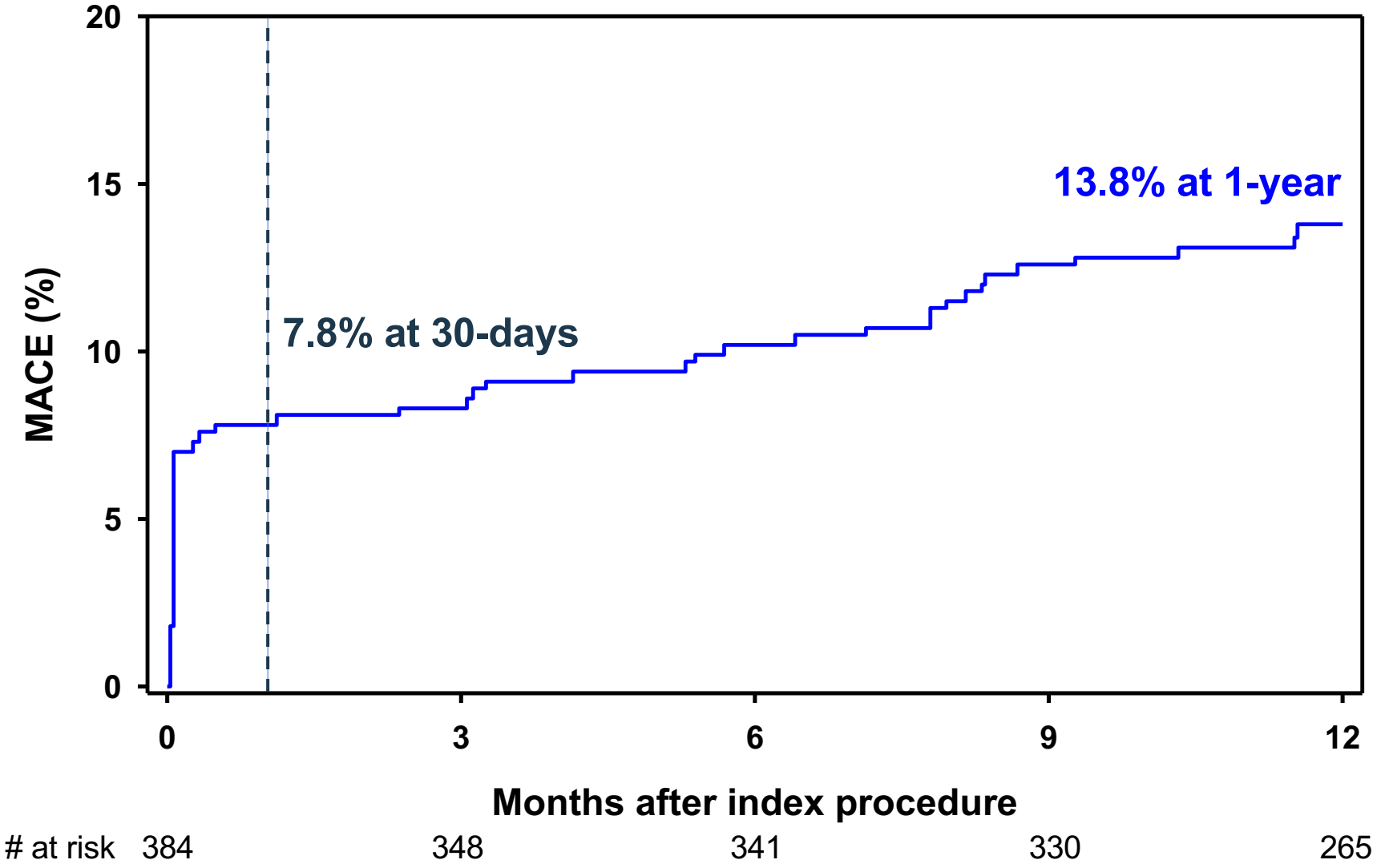
Kereiakes D et al. *JACC Inter* 2021

IVL : Disrupt Pool Analysis



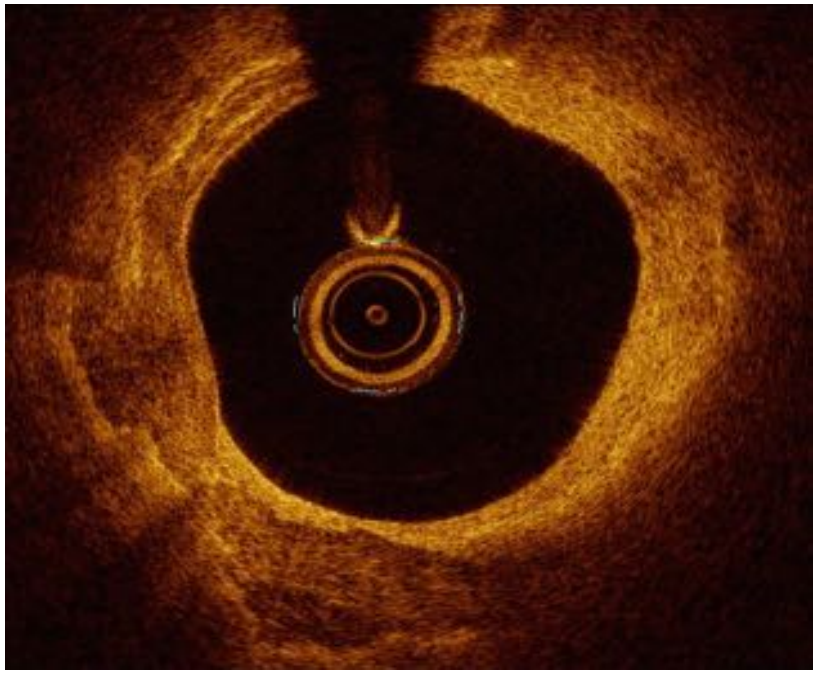
Kereiakes D et al. *JACC Inter* 2021

IVL : 12 month CAD III Follow up

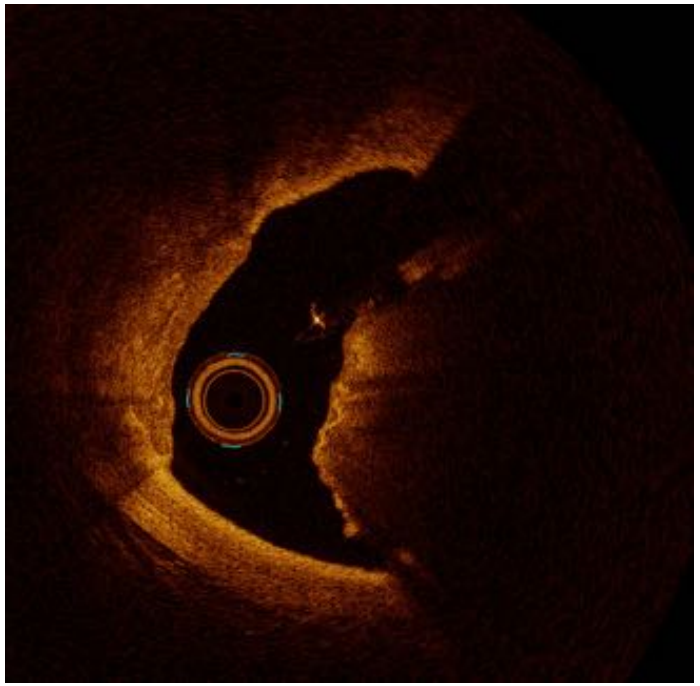


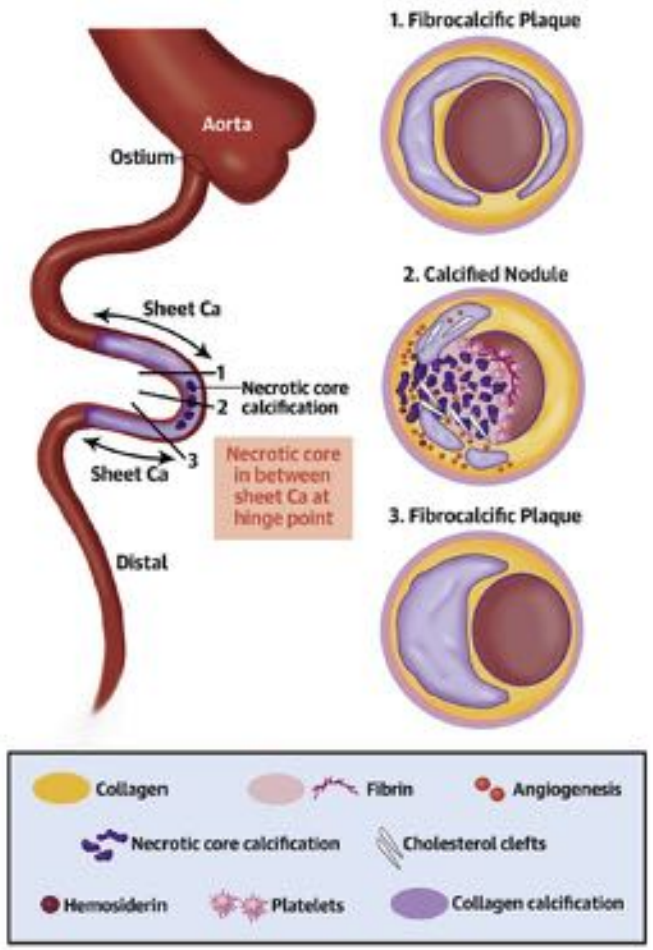
IVL: Calcium pattern

Lesions with Eccentric Calcium
(Calcium Angle < 180°)



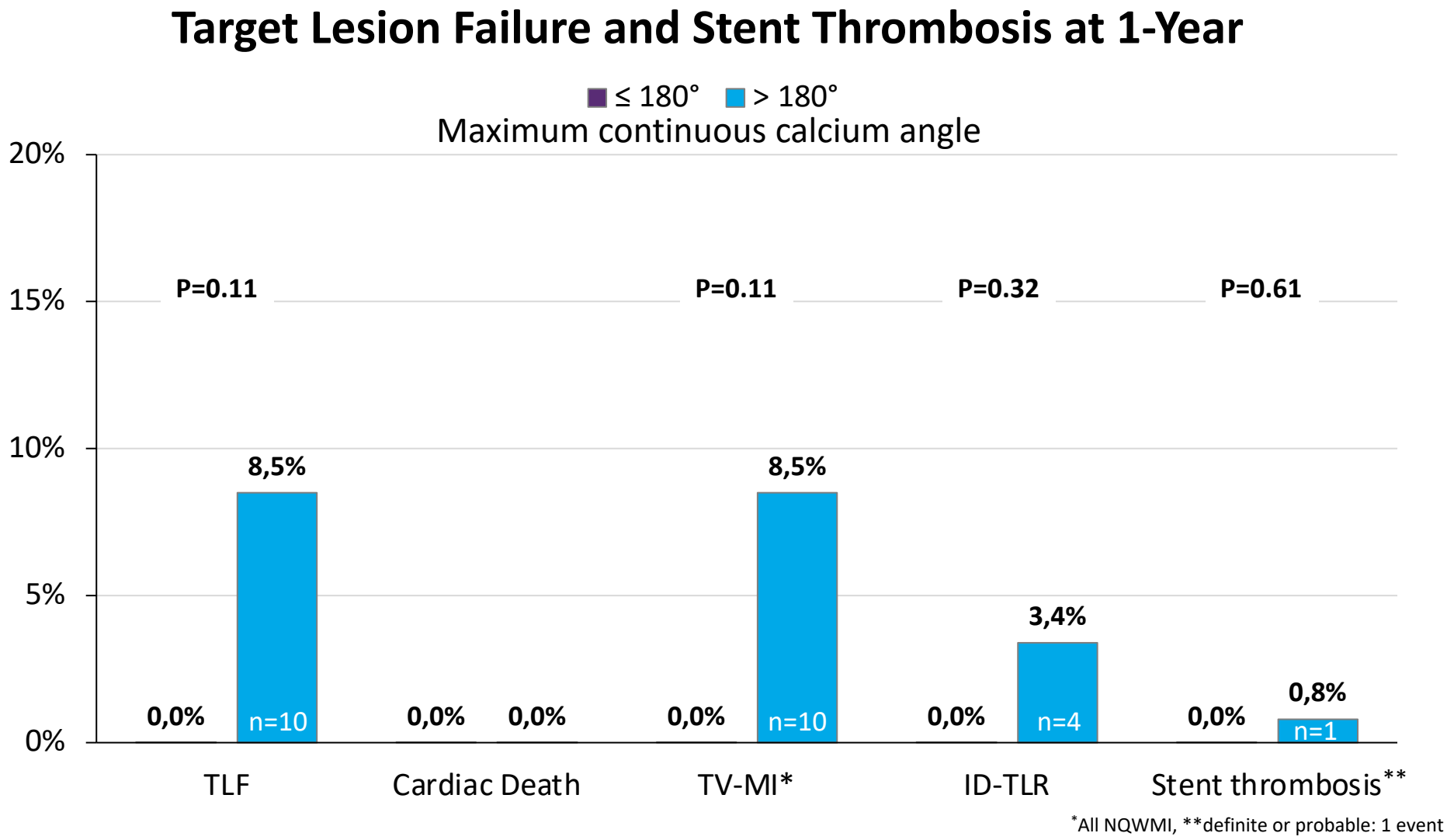
Lesions with calcified nodule





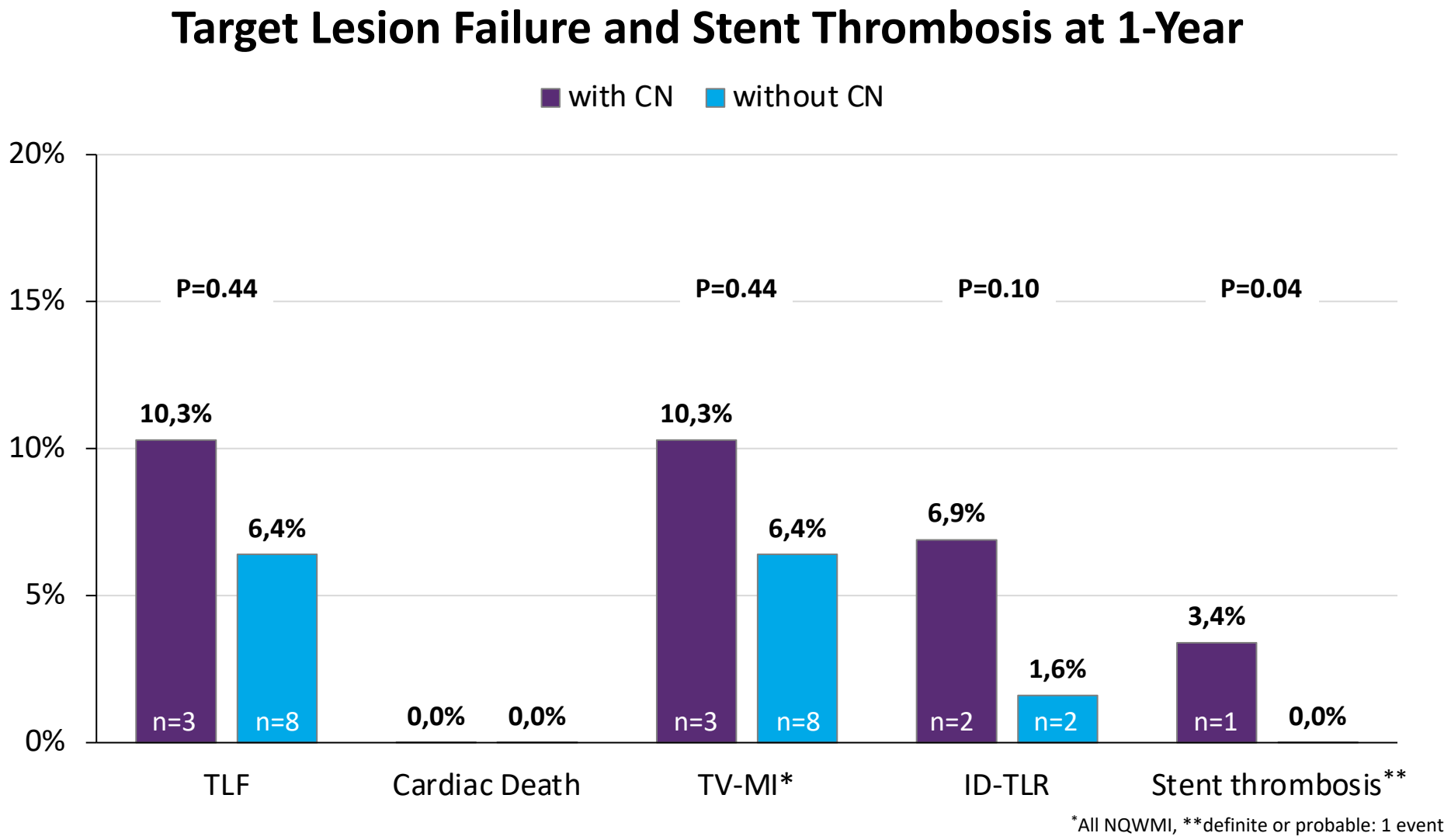
Torii, S. et al. J Am Coll Cardiol. 2021;77(13):1599-611
Lee, T. et al. J Am Coll Cardiol. 2017;10:883-91.

IVL: Eccentric lesion



*All NQWMI, **definite or probable: 1 event

IVL: Calcium Nodule



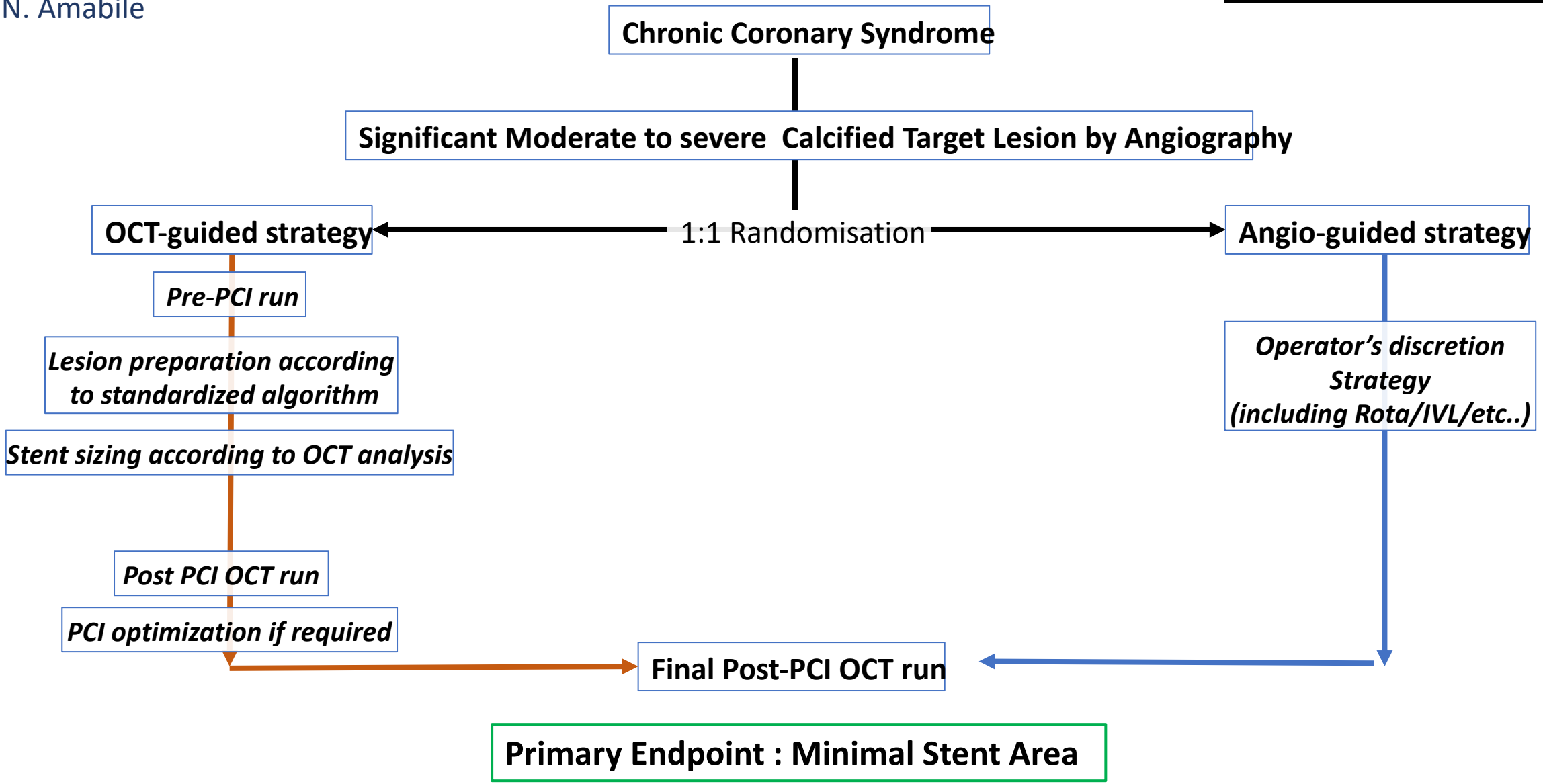
*All NQWMI, **definite or probable: 1 event

A l’épreuve de la PRATIQUE

A l'épreuve de la stratégie

CALIPSO

16 centres Francais
PI : N. Amabile



A l'épreuves des registres

SOCIETE FRANCAISE DE CARDIOLOGIE

REGISTRE NATIONAL
FRANCE LILI
LIthopLastie Intracoronaire

Critère composite *Target Vessel Failure (TVF)* à 1 an :

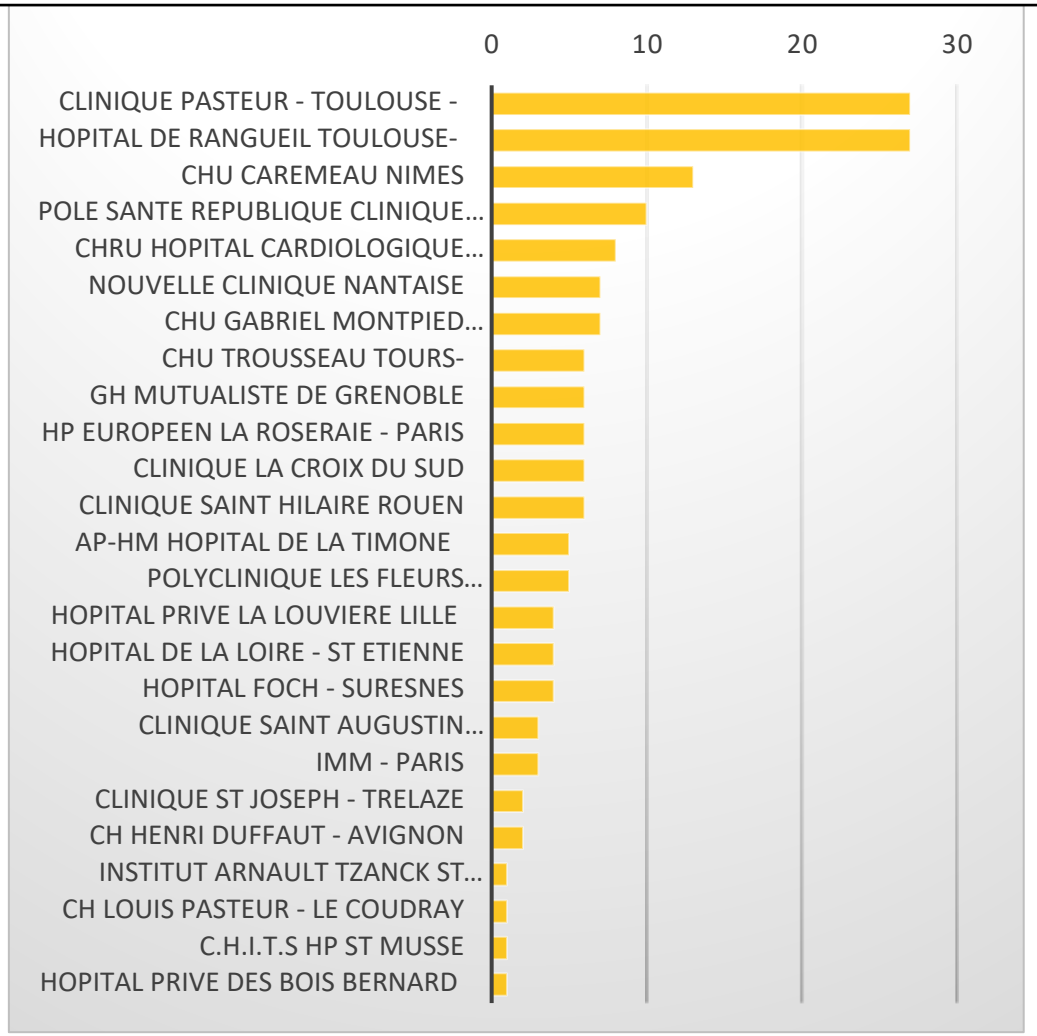
* Décès d'origine cardiaque

* Infarctus du myocarde selon la 4eme définition universelle de l'infarctus du myocarde (sauf si l'infarctus est clairement attribuable à un vaisseau non cible)

* Revascularisation du vaisseau cible (TVR)

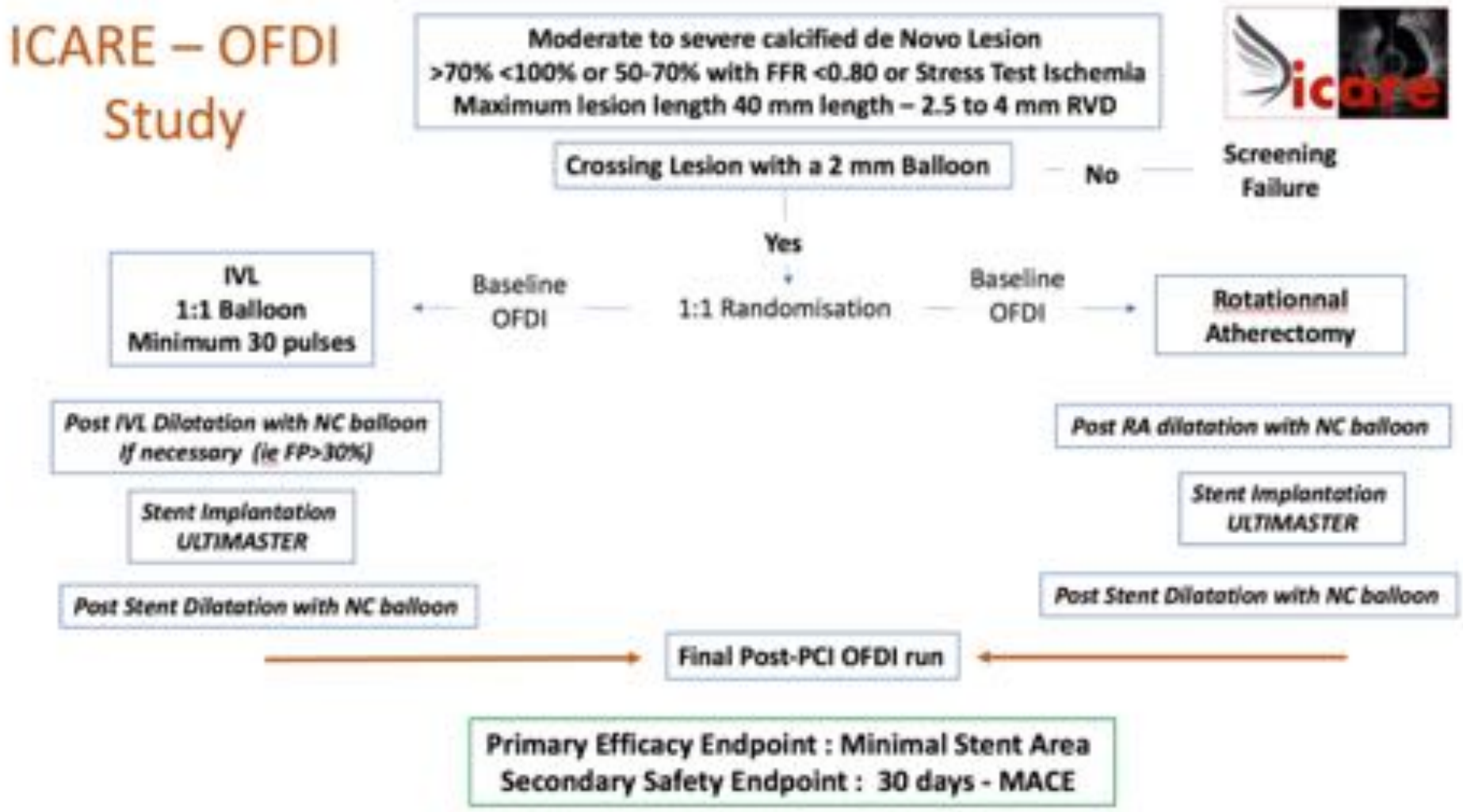
Etat des lieux des inclusions au 31/05/2022

165 patients ont été inclus dans le registre par **25** centres



A l'épreuve des indications communes

19 centres Francais
PI : P.Motreff



Conclusions

"My calcified lesion tool box " is rich …

Riche de DEVICE

Riche de SCIENCE

Riche de RECHERCHE