

Dealing with calcified and complex lesions: High-pressure balloons, what else!

– What have we learned from the VICTORY Trial and others?

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

<u>Nature of Financial Relationship</u>	<u>Ineligible Company</u>
Grant/ Research Support	Abbott Vascular, Cordis, Boston Scientific, OM Pharma, and SIS Medical.
Consultant Fees/ Honoraria	Abbott Vascular, Abiomed/ J&J MedTech, Acrostak, Amgen, Astra Zeneca, Bayer, Biosensors, Boston Scientific, Cordis, Daichii, MedAlliance, Novartis, NovoNordisk, OM Pharma, Sanofi, SIS Medical und Vifor.

PCI in calcified lesions: What we want !

– Healthy patients, goods outcomes, keep the hospital admin happy ;-)



Safe and healthy patients



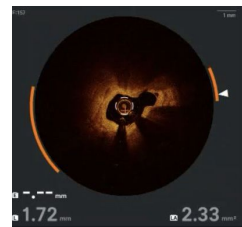
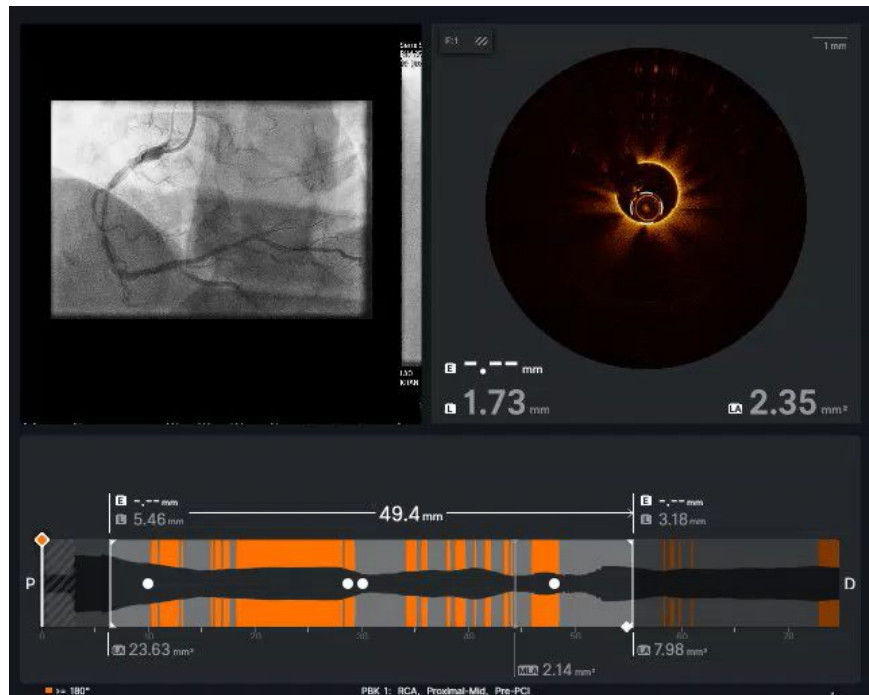
Good (PCI) outcomes



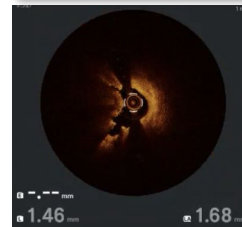
Healthy finances ;-)

How would you treat this patient?

– Heavily calcified lesions remain a challenge



Eccentric calcium



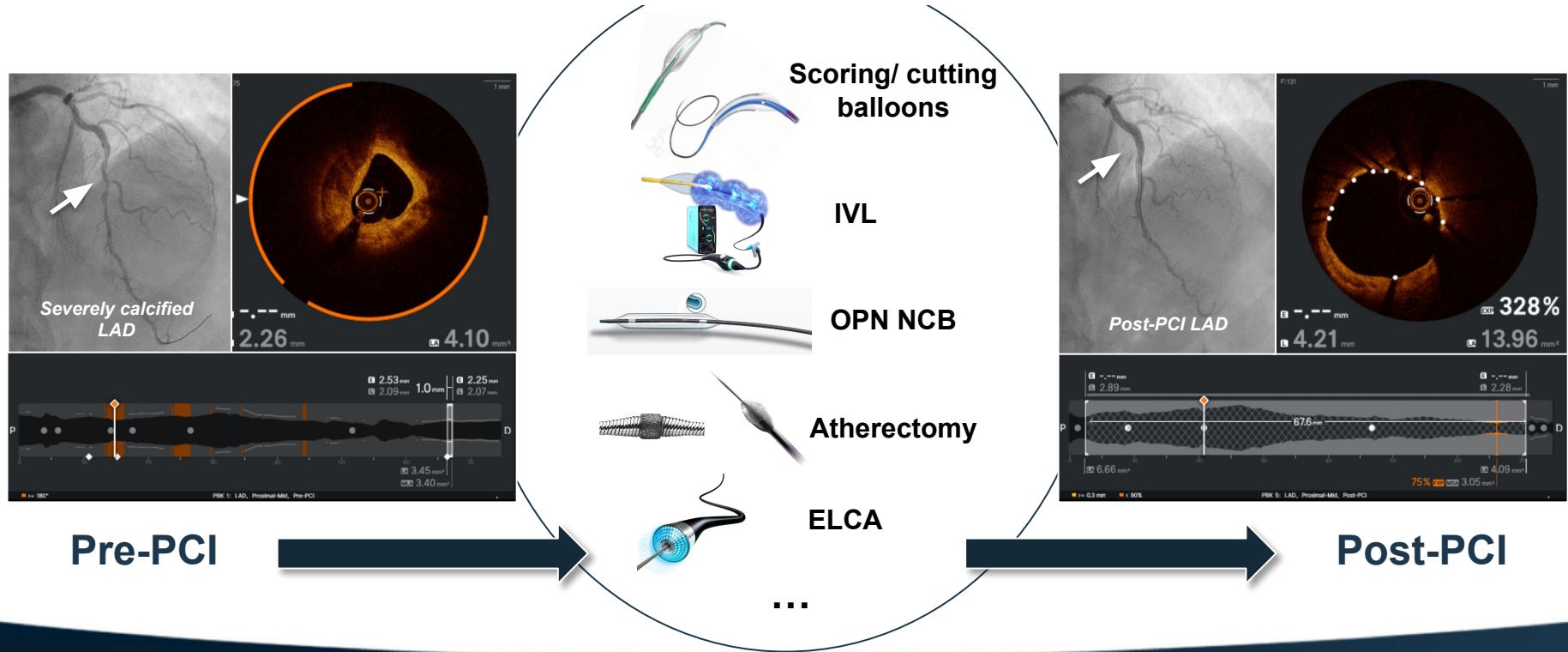
Nodular calcium



Deep and circular calcium

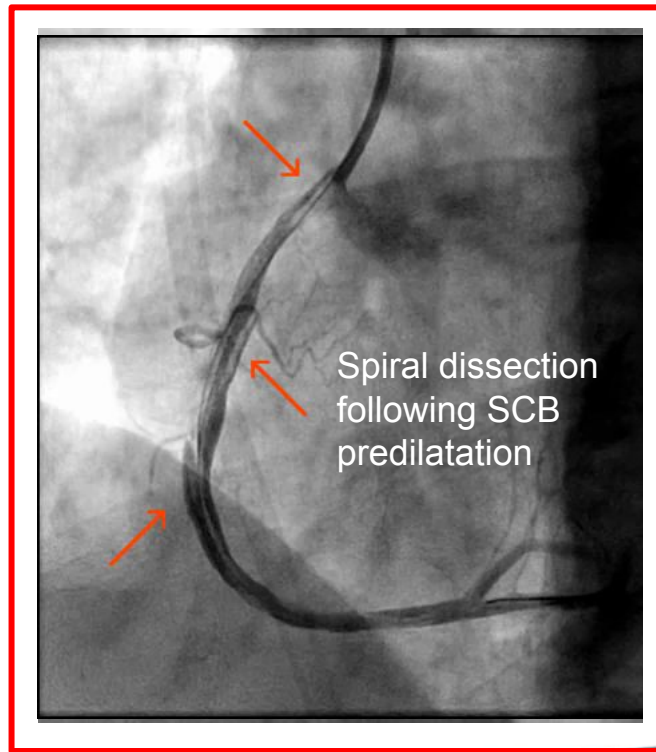
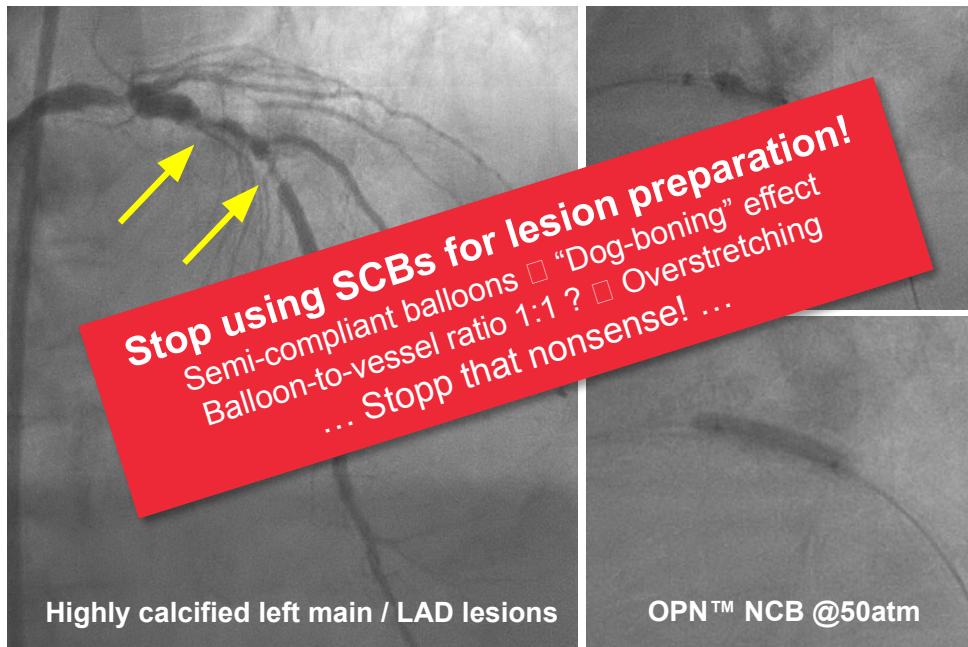
Q : How to pre-treat calcified lesions best?

– Which PCI devices should we use in this case?



Rethinking Lesion Preparation

– Why we prefer the OPN NCB over regular balloons in PCI



Why do we need to rethink our PCI approach?

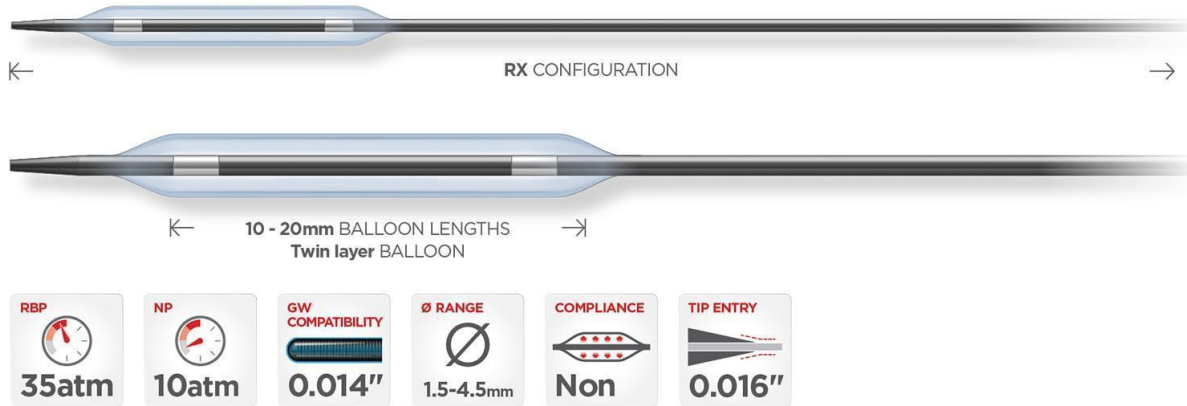
– Little guidance, too many tools and bad outcomes...

- **Calcified lesions:** High event rates and little randomized data
- ECLIPSE trial suggested a NC balloons safer than orbital atherectomy
- FDA approval trials for IVL were single arm and had NO control group

The OPN NCB

–The Swiss Army Knife of Your Cath Lab Toolbox

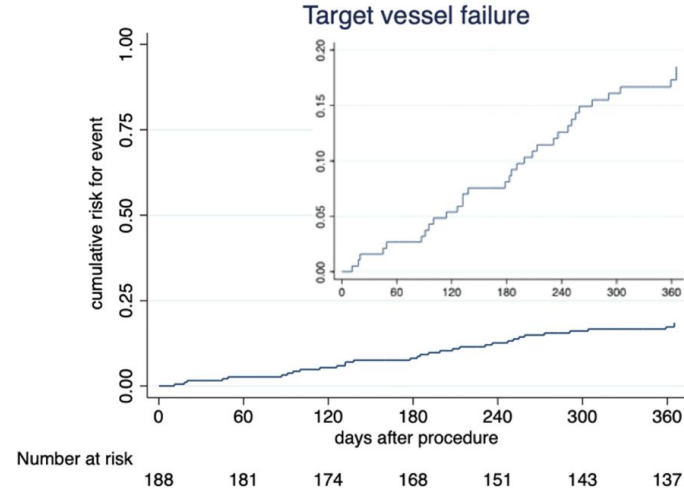
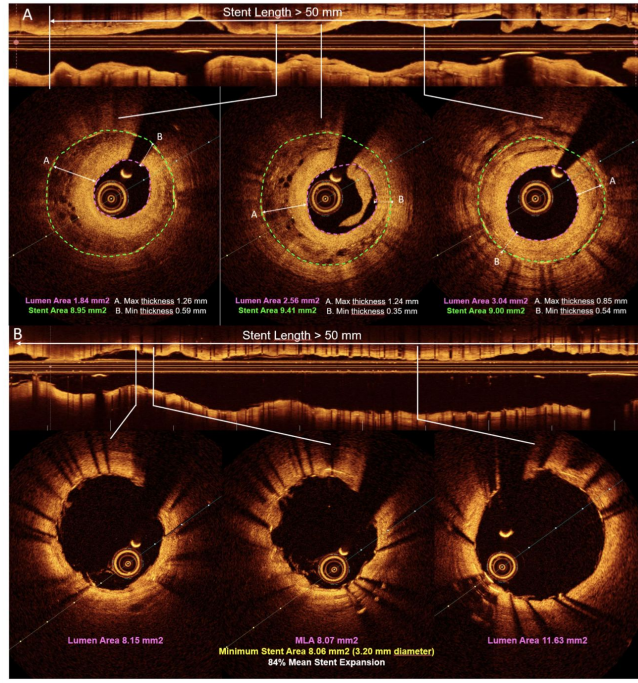
SIS Medical OPN NC



OPN NCB is double walled balloon that can go to 35 atm

OPN NCB for ISR management

– It stands out as an essential device for ISR lesions!



- 208 ISR lesions, moderately to heavily calcified (89 %)
- Low-rate of complications:
 - 0.96 % perforation
 - 4 % major dissections
 - 1.9 % no-reflow and 0.5 % acute vessel closure
- At 1-year FU, MACE in 19.7 %; 15.4 % patients had TVF; MI in 5.9 % of all patients.

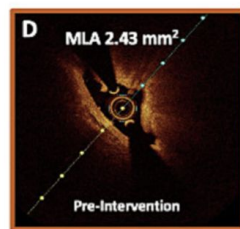
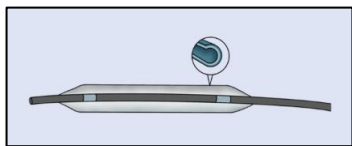
Plaque Modification with OPN NCB

Distribution of the luminal area gain following PCI with OPN NCB for plaque modification.

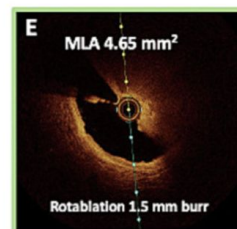
HamiLu Registry (n=50)

- EXP $\geq 80\%$ was achieved in 80% cases
- Mean **final EXP** of $85.7 \pm 8.9\%$
- CF were documented in 98% cases
- **Complications:** 1 flow limiting dissections; No perforations; No ST.

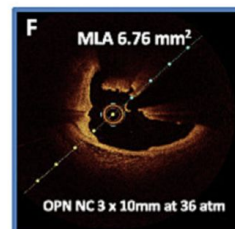
OPN NCB



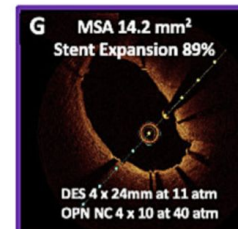
Initial



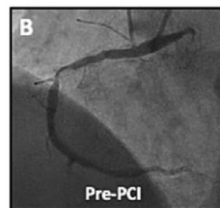
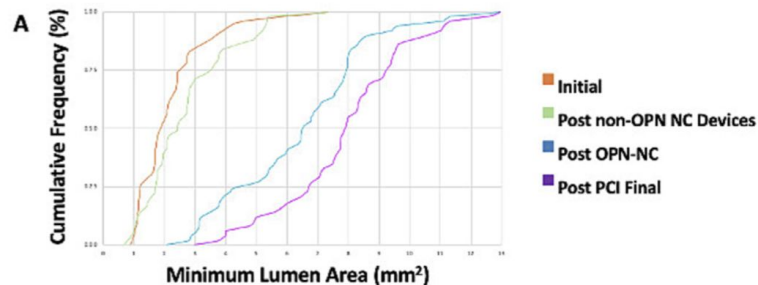
Post non-OPN NC Devices



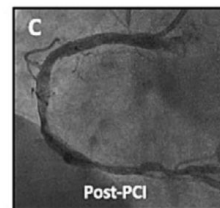
Post OPN-NC



Post PCI Final



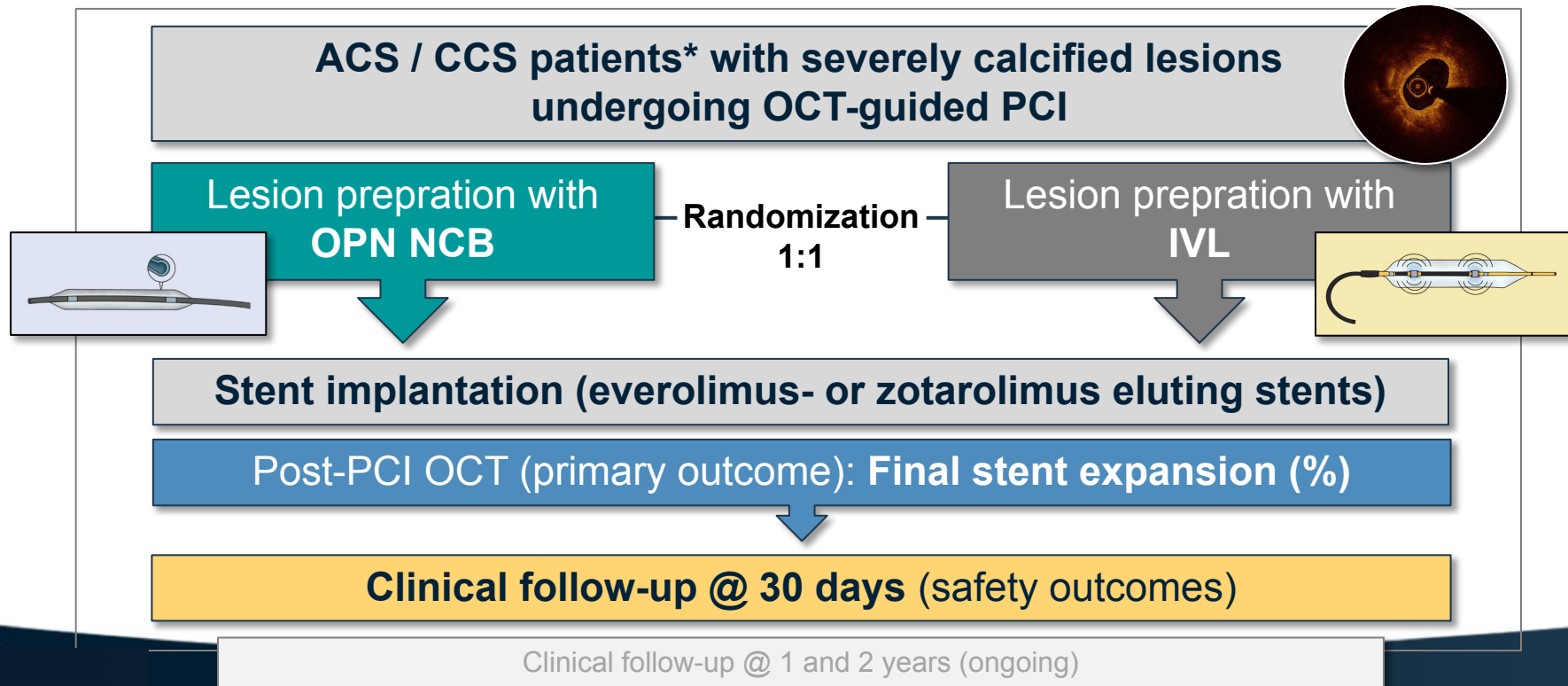
Pre-PCI



Post-PCI

Study Design

Prospective, randomized trial (3 centers), blinded outcome assessment (PROBE design)



* STEMI & cardiogenic shock patients were excluded

VICTORY : Key Eligibility Criteria

– We included severely calcified lesions!

Clinical inclusion criteria:

- Age ≥ 18 years and eligible to consent
- Acute or chronic coronary artery disease with ischemia related symptoms (e.g. angina) and/or evidence of myocardial ischemia (e.g. FFR/ iFR, CMR, SPECT or PET-CT)

Angiographic inclusion criteria:

- **Single de novo target lesion stenosis** of protected LMCA, or LAD, RCA or LCX (or of their branches) with*: (I) Stenosis of $\geq 70\%$; and (II) Stenosis $\geq 50\%$ and $< 70\%$ (visually assessed) with evidence of ischemia

AND AT LEAST ONE OF THE FOLLOWING CRITERIA:

- Evidence of **calcification at the lesion site by angiography (Grade 3)**, with fluoroscopic radio-opacities noted without cardiac motion prior to contrast injection involving both sides of the arterial wall
- AND/ OR by **OCT**, with presence of **$\geq 270^\circ$ calcium**
- AND/ OR Prior attempt at PCI & **inability to expand balloon** in target lesion

Main clinical and angiographic exclusion criteria:

- Acute STEMI or cardiogenic shock related to an AMI
- Renal failure with an eGFR $< 30 \text{ ml/min } 1.73 \text{ m}^2$
- Life expectancy of less than 1 year
- Anatomy where the device or OCT catheter are unlikely to be delivered due to tortuosity or other characteristics
- Target lesion is in a coronary artery bypass graft
- Flow limiting target vessel thrombus (evident on angiography or OCT)

Angiographic and OCT inclusion criteria:



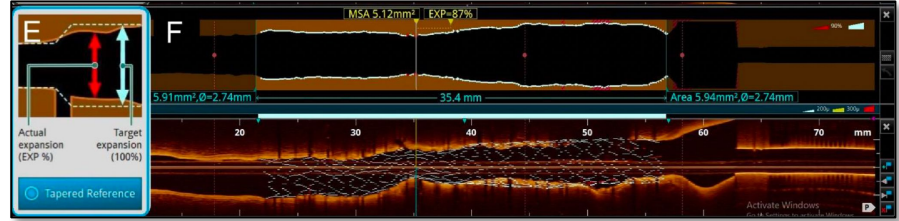
Suggested by the



Annotation: Only one lesion and vessel per randomized patient may be treated according to protocol and considered for the purpose of this study. The lesion considered for the study must represent the most calcified one.

Primary outcome – Stent expansion (SE, %)

***Final stent expansion
(SE) in percentage (%)***



Stent expansion (SE, %) assessed by automatic calculation of expansion based on an interpolation of the vessel size, considering OCT-detected side branches (tapered reference mode) using Abbott Vascular Imaging Software.¹

Stent expansion (%) represents a validated and reliably assessable OCT parameter; It is associated with adverse outcomes following stent implantation.²

¹ Ali et al. Intracoronary optical coherence tomography: state of the art and future directions. *EuroIntervention*. 2021;17(2):e105-e123

² Lee et al. Stent expansion evaluated by optical coherence tomography and subsequent outcomes. *Sci Rep*. 2023 Mar 7;13:3781

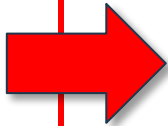
Core Lab Findings : Angiography & OCT

	OPN NCB (n=139)	IVL (n=139)
Angiographic findings:		
Target lesion SYNTAX Score	8.0 (5.0)	8.0 (5.0)
Angiographic severity of calcification (%)		
Moderate	40 (28.8)	35 (25.2)
Severe	83 (59.7)	86 (61.9)
Bifurcation lesion (%)	56 (40.3)	52 (37.4)
OCT findings:		
Reference vessel diameter – mean (mm)	3.53 (0.91)	3.51 (0.72)
Mean lumen diameter (mm)	1.57 (0.49)	1.56 (0.52)
Minimal lumen area (mm ²)	2.00 (1.28)	1.93 (1.28)
Lesion length (mm)	32.9 (15.8)	31.0 (16.6)
Eccentric calcium (%)	60 (43.5)	63 (45.9)
Nodular calcium (%)	38 (27.5)	34 (24.8)
Length of stented segment (mm)	46.3 (23.8)	45.8 (24.3)

Procedural Characteristics

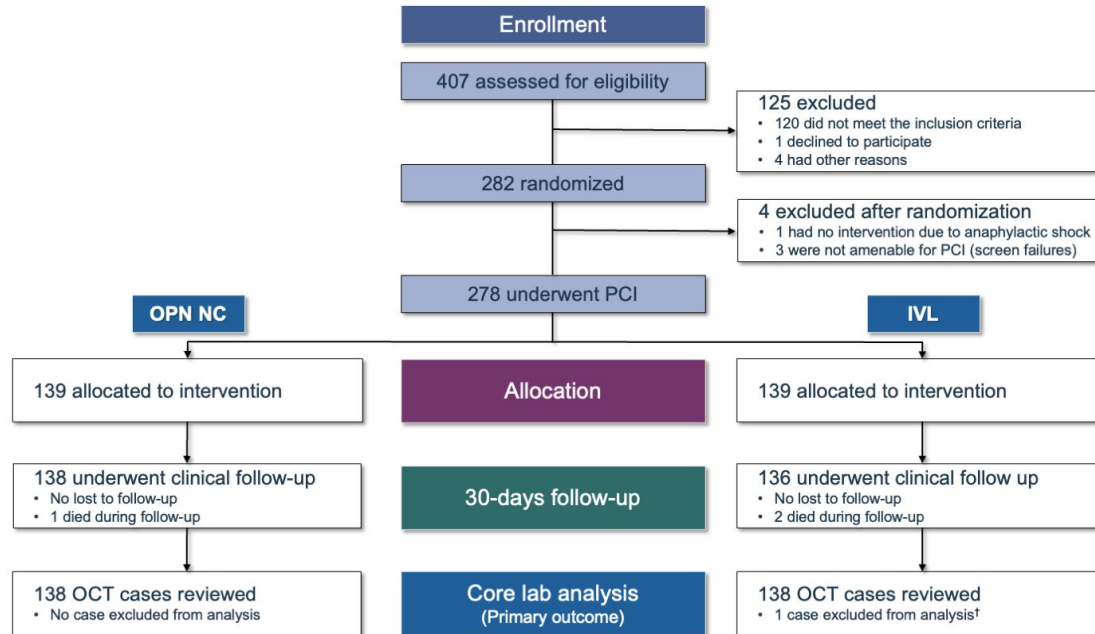
– VICTORY involved complex PCI procedures

	OPN NCB (n=139)	IVL (n=139)	
Radial access (%)	118 (85.5)	116 (83.4)	
Procedure time (min)	70 (36)	79 (31)	* p-value = 0.061
Contrast dose (mL)	284 (146)	294 (125)	
Radiation time (min)	22.4 (14.3)	24.7 (16.0)	
SCB prior to study device (%)	19 (13.7)	32 (23.0)	* p-value 0.044
NCB prior to study device (%)	33 (23.74)	56 (40.29)	* p-value 0.003
Scoring/cutting balloon (%)	1 (0.72)	0 (0)	
Rotational atherectomy (%)	22 (15.83)	17 (12.23)	
Study devices : OPN NCB vs. IVL group			
Number of devices used (n, %)			
1	91 (65.9)	133 (95.7)	} * p-value <0.001
2	46 (33.3)	6 (4.3)	
3	1 (0.72)	0 (0)	
Number of devices used [mean, (SD)]	1.35 (0.49)	1.04 (0.20)	
Max. diameter (mm)	3.0 (0.5)	3.5 (0.5)	
Max. pressure (atm)	40.0 (4.0)	6.0 (2.0)	



Procedural Characteristics

– VICTORY involved complex PCI procedures



Intern

Primary Outcome : Stent Expansion (%)

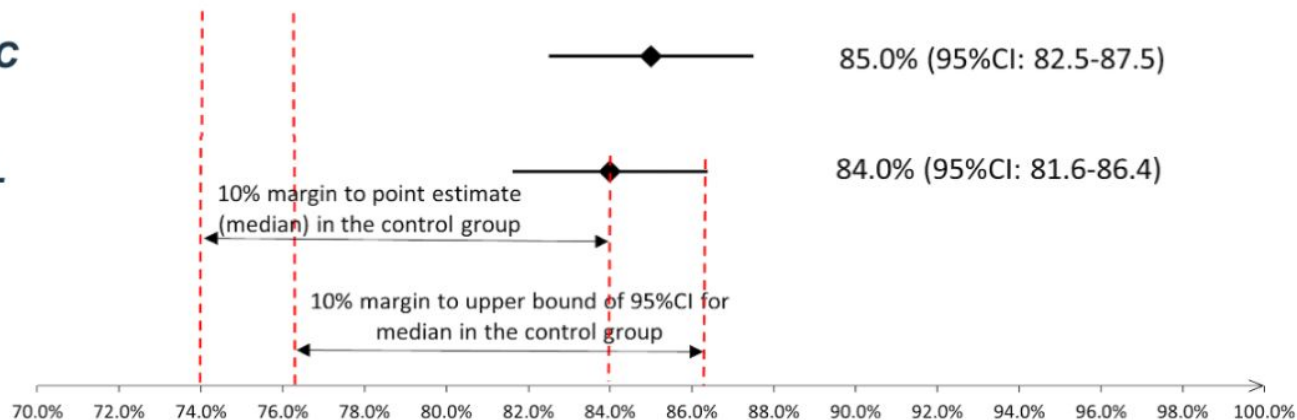
– OPN NCB is non-inferior to IVL

*Final stent expansion
(%, medians [95%CI])*

p for non-inferiority <0.0001

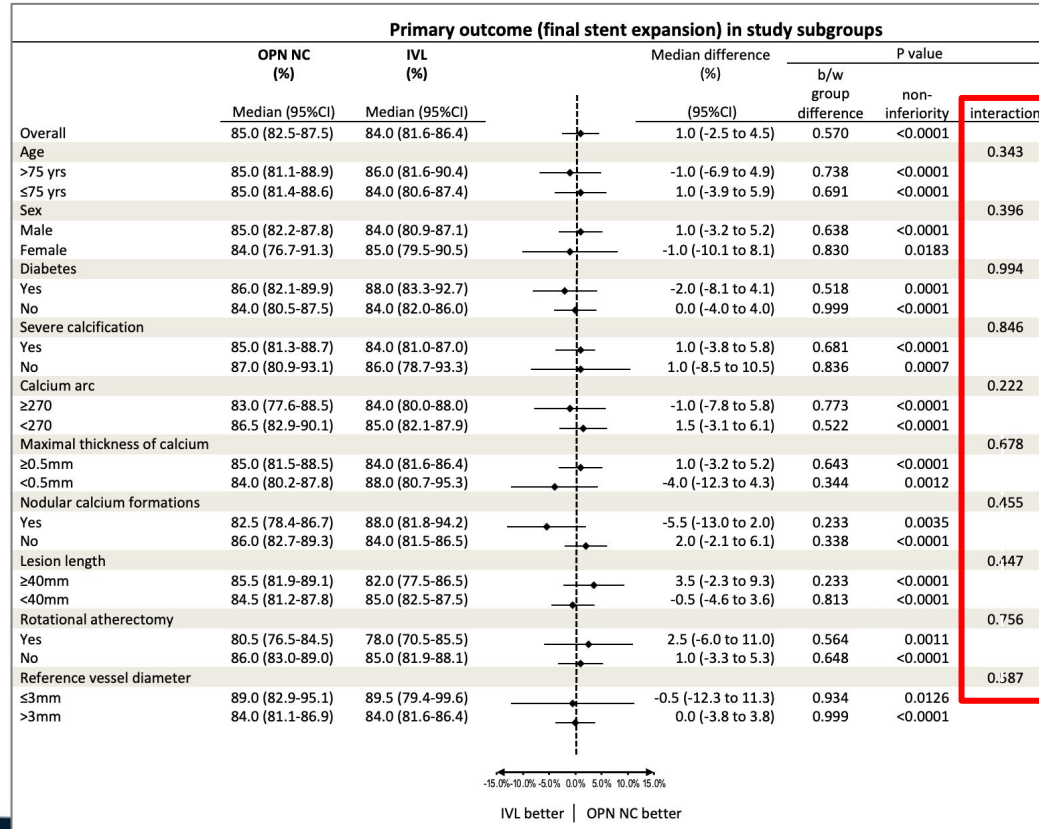
OPN NC

IVL



In calcified lesions, PCI with SH-NCB demonstrated non-inferiority to IVL for the primary outcome.

Subgroup Analyses for Primary Outcome



The subgroup analyses consistent

* p-values for superiority presented.

Safety Outcomes



	OPN NCB (n=139)	IVL (n=139)	p-value
Persistent side-branch occlusion (%)	2 (1.44)	1 (0.72)	0.571
Dissections (%)			
Mild	6 (4.3)	1 (0.7)	0.081
Flow limiting	2 (1.4)	1 (0.7)	
Coronary perforations (%)			
Ellis I	0 (0)	2 (1.45)	0.592
Ellis II	2 (1.44)	1 (0.72)	
Ellis III	0 (0)	1 (0.72)	
Ellis III cavity spilling	0 (0)	1 (0.72)	
Cardiac tamponade (%)	0 (0)	0 (0)	NA
No-reflow phenomenon (%)	1 (0.72)	1 (0.72)	0.999
Periinterventional VF/ VT (%)	0 (0)	1 (0.72)	0.999
Major bleeding (BARC 3) (%)	0 (0)	1 (0.72)	0.999



Secondary Outcomes

	OPN NCB (n=139)	IVL (n=139)	95%CI	p-value
Acute procedural success (%) *	137 (98.6)	135 (97.1)	1.015 (0.800-1.287)	0.903
Procedural success (%) †	127 (92.03)	118 (86.13)	0.579 (0.276-1.2170)	0.149
Strategy success (%) ‡	137 (98.6)	137 (98.6)	1.000 (0.789-1.267)	0.999
Final stent expansion ≥80% (%)	94 (68.1)	94 (68.6)	0.993 (0.746-1.321)	0.960
Final stent expansion ≥90% (%)	50 (36.2)	47 (34.3)	0.978 (0.729-1.312)	0.881
Minimum stent area (mm ²)	6.3±2.2	6.5±2.0		0.310
Target vessel failure (%) (Composite: CV death or TVR or MI)	6 (4.3)	5 (3.6)	1.200 (0.366-3.932)	0.763
Target vessel failure or stent expansion <80%	47 (33.8)	48 (34.8)	0.972 (0.650-1.453)	0.890

Use of OPN NCB, compared to IVL, resulted in similar rates of procedural and strategy success.

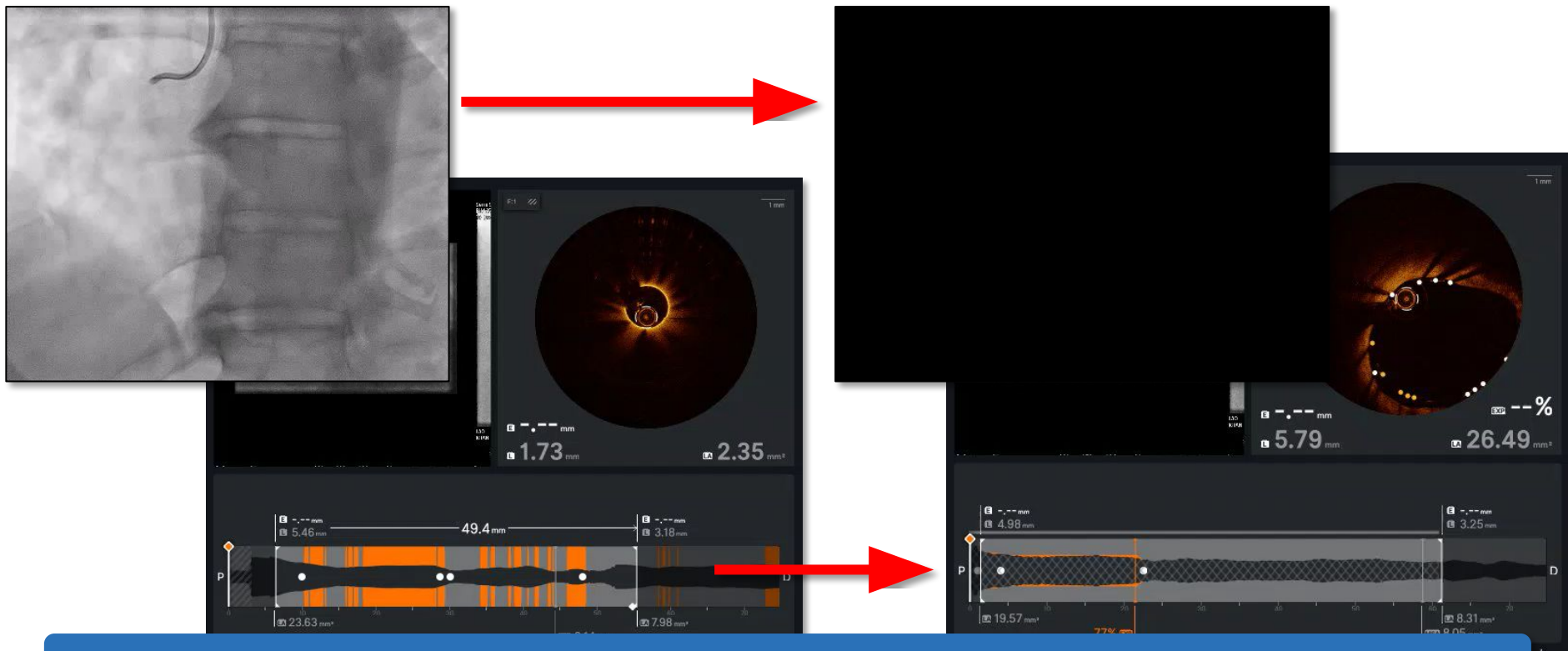
* Definition: Residual stenosis <30%, no flow-limiting dissection and/or no-reflow.

† Procedural success = Angiographic success without any MACE up to 30 days after index PCI.

‡ Strategy success = No crossover to the non-assigned device or PCI related problems.

A regular **VICTORY Case** : A simple angina case

– 62y/o male with CP – Calcified 3-V-CAD



Management : OPN NCB 3.0mm @40atm □ 2x zotarolimus-eluting stents 3.5x34mm (@14atm) □ Post-dil (NCB 4.0mm)

Key for success of VICTORY : Methods

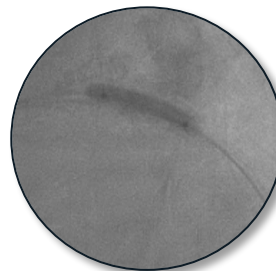
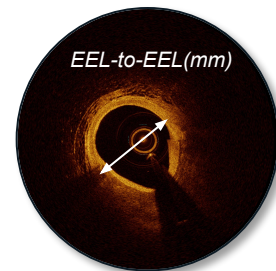
– Selection of OPN NCB and IVL devices

- Optimal device sizing was protocol-defined.

- **OPN NCB sizing:** For lesion preparation, we recommended using an OPN NCB, which was (at least) 0.5mm smaller than the actual vessel diameter (EEL-to-EEL determined by OCT measurements).

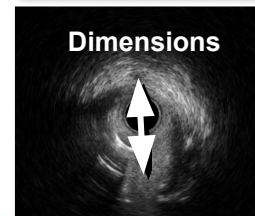
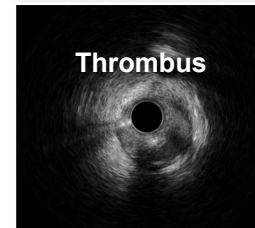
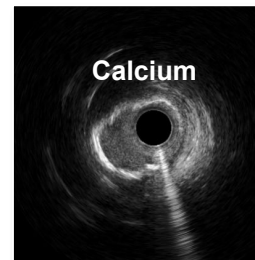
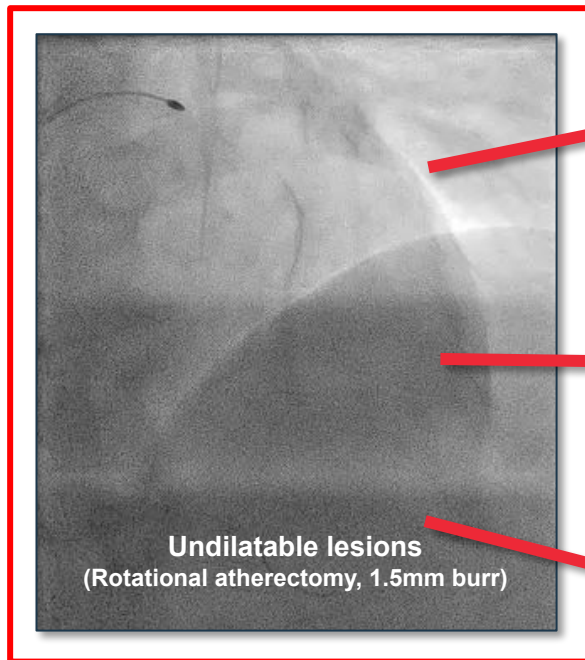
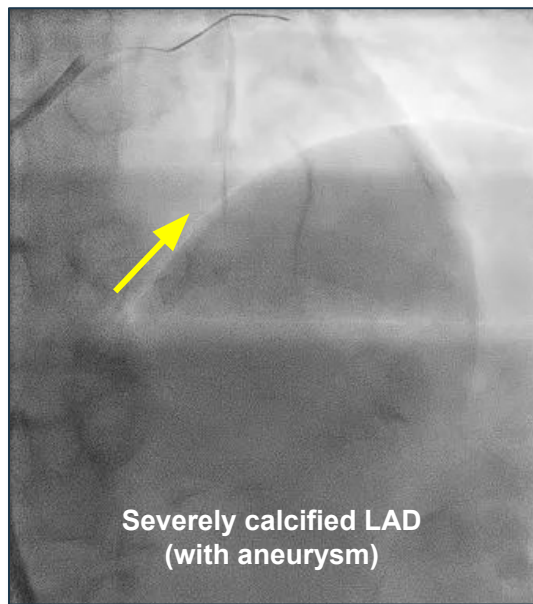
- **IVL device sizing:** A ratio of the IVL balloon to RVD, with a ratio of ~1 defined as appropriate balloon sizing. Oversizing and overinflating (above RBP) of the IVL balloon was discouraged.

Device-sizing based on OCT



The “VICTORY approach” applies only to OCT-guided PCI?!

— Yet an IVUS case demonstrating the opposite, highlighting its broader relevance!



EEL-to-EEL <3mm

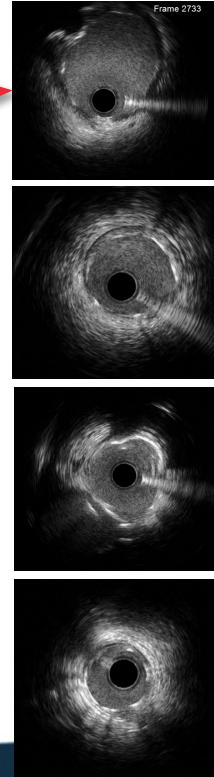
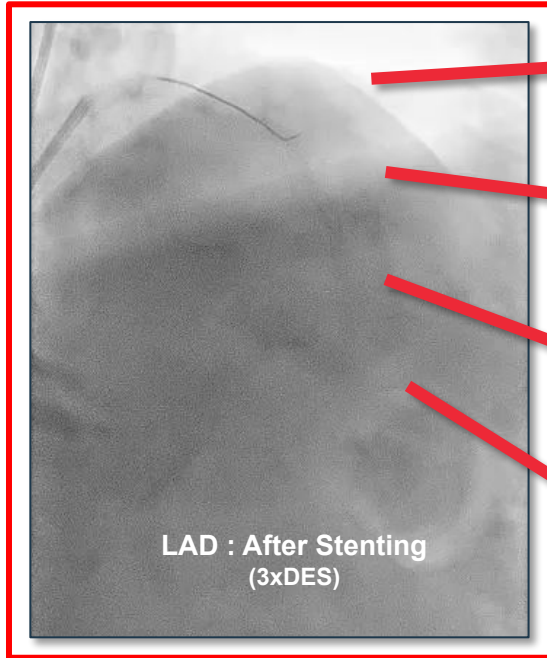
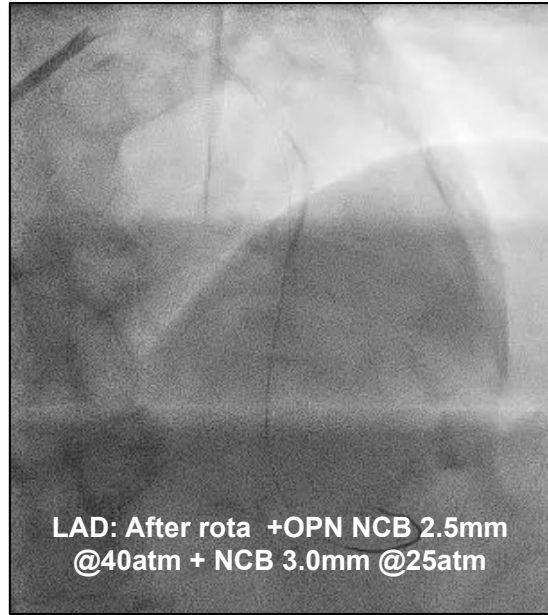
IVUS after rotablation

□ Assess & plan

Case vignette: 88 y/o lady with debilitating angina

A complex PCI case simplified by rota + OPN NC

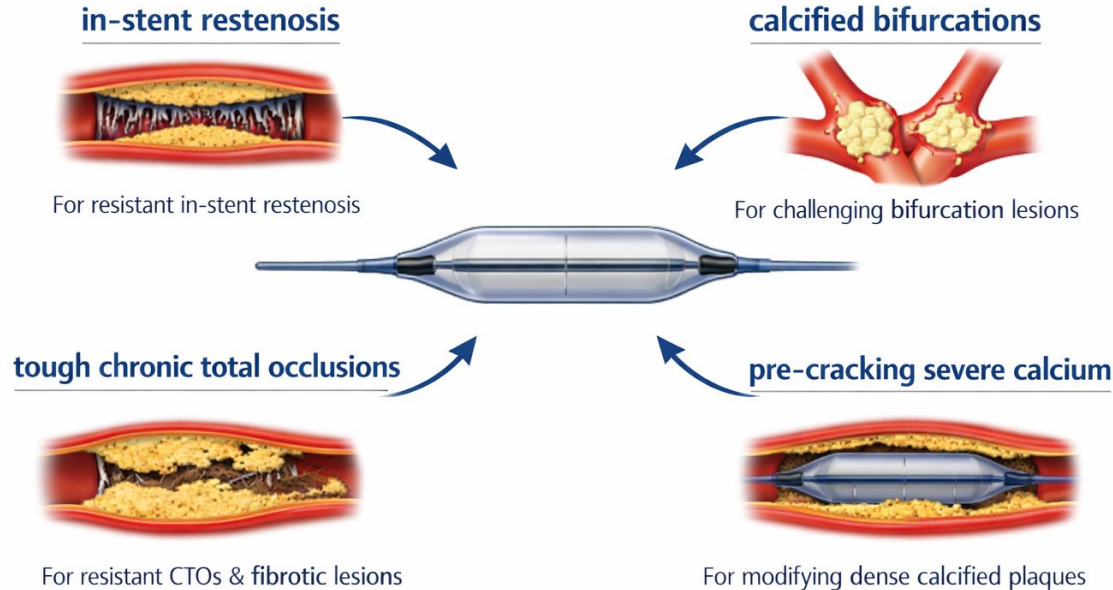
– This cases was done in <60'



Case vignette: 88 y/o chest pain free for >6 months

Integrating the OPN NCB into daily practice

— Far from a niche device — it's broadly applicable!



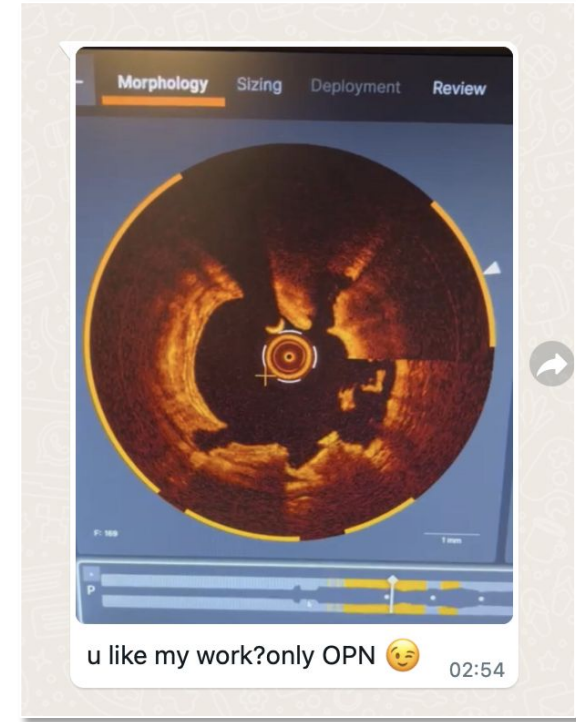
In our practice, the OPN NCB is not just a primary tool for calcium management — it has become the ideal non-compliant balloon, seamlessly complementing modified balloons, atherectomy devices and IVL.

Dealing with calcified and complex lesions: High-pressure balloons, what else!

– Take-Home Messages

In severely calcified coronary lesions, the following applies:

- **OPN NCB is non-inferior to IVL in terms of stent expansion**
- VICTORY indicates that adequately sized OPN NCBs @ high-pressure are safe to use
- The OPN NCB is a reasonable lower cost and easy to use device for management of complex lesions



PCI in calcified lesions: What we want !

– Healthy patients, goods outcomes, keep the hospital admin happy ;-)



Safe and healthy patients



Good (PCI) outcomes



Healthy finances ;-)

Thank you very much for your attention!



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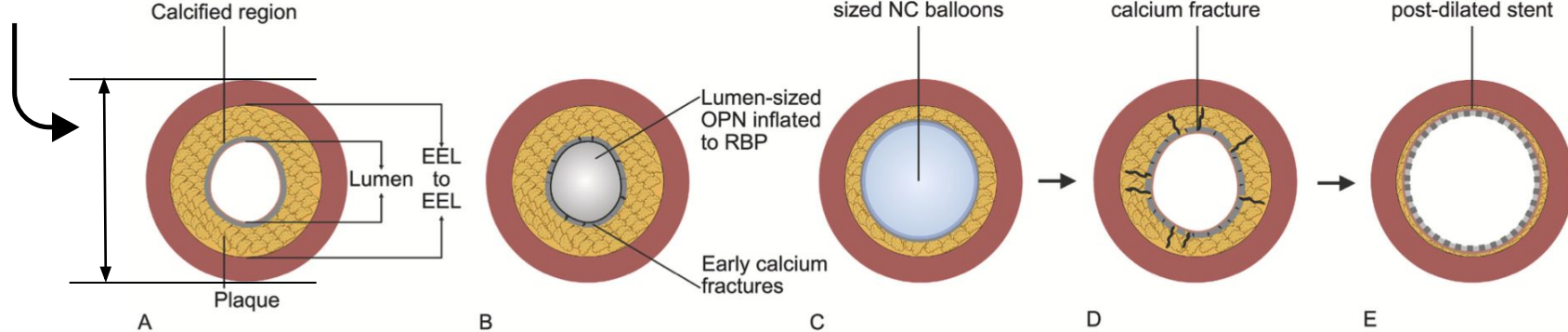
VICTORY
TRIAL

NCT05346068

OPN NCB for small, calcified and/ or CTO lesions

– Pre-crack the plaque technique' using OPN NCB

Small and calcified vessel
($<2.5\text{mm}$)



PRE-CRACK THE PLAQUE
TECHNIQUE USING OPN

The uniform, highly non-compliant inflation profile of the OPN NCB not only targets fibrocalcific tissue effectively but also reduces the risk of flow-limiting dissections — a key advantage in small vessels.