A Randomized, Multicenter, Non-Inferiority Comparison of Intravascular Lithotripsy and Super-High-Pressure Non-Compliant Balloons for Treatment of Calcified and Refractory Coronary Lesions

– The VICTORY Trial

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ClinicalTrials.gov: NCT05346068

Disclosure of Relevant Financial Relationships

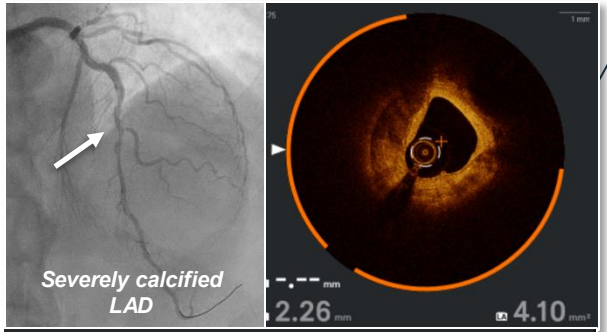
Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

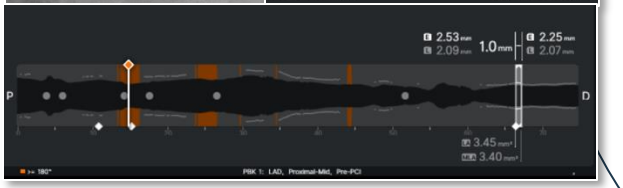
Nature of Financial Relationship	Ineligible Company
Grant/ Research Support	Abbott Vascular, Cordis, Boston Scientific, OM Pharma, and SIS Medical.
Consultant Fees/ Honoraria	Abbott Vascular, Abiomed/ J&J MedTech, Amgen, Astra Zeneca, Bayer, Biosensors, Boston Scientific, Cordis, Daichii, MedAlliance,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

All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

Q : How to pre-treat calcified lesions best?

– Which PCI devices should we use in this case?





Pre-PCI

Scoring/ cutting balloons

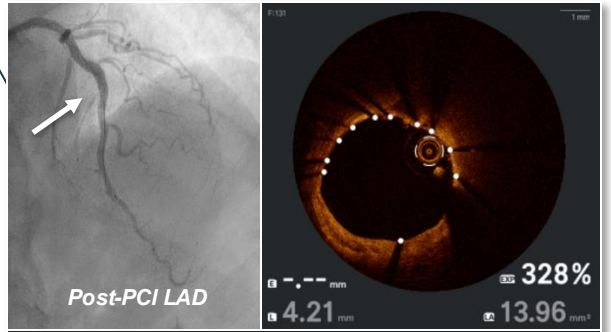
IVL

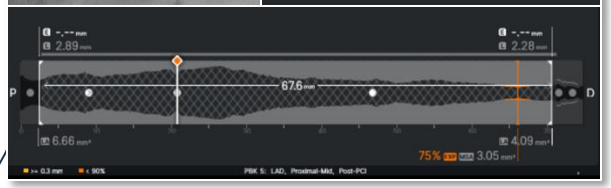
OPN NCB

Atherectomy

ELCA

...





Post-PCI

Background : PCI in Calcified Coronary Lesions

- 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
- Randomized trials are needed with IVL and OPN NC balloon to guide treatment

Kirtane et al. The Lancet 2025 Vol. 405 Issue 10486 Pages 1240-1251
Hill et al.; J Am Coll Cardiol 2020 Vol. 76 Issue 22 Pages 2635-2646

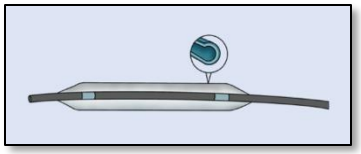
Plaque Modification with OPN NCB

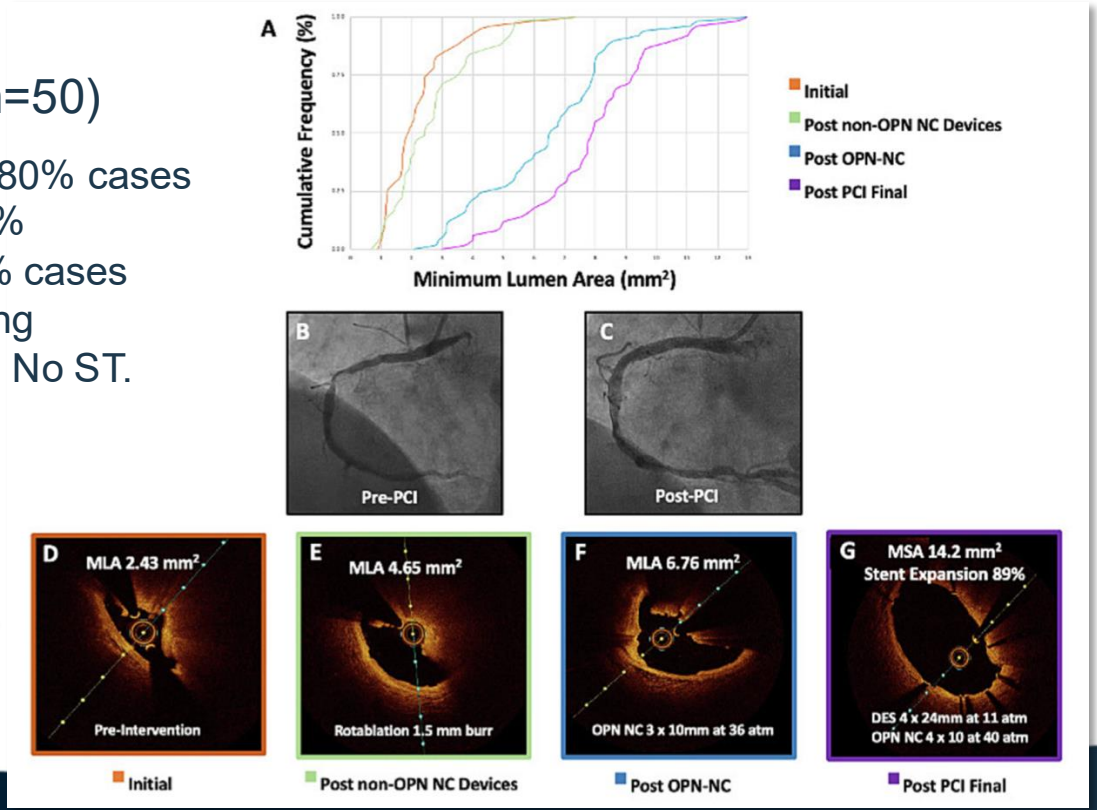
Distribution of the luminal area gain following PCI with OPN NCB for plaque modification.

HamiLu Registry (n=50)

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

OPN NCB





Pinilla-Echeverri et al. Cardiovascular Revascularization Medicine 52 (2023) 49–58

Objectives of the VICTORY Trial

- To assess whether lesion preparation using the super high-pressure ***OPN NCB*** is *non-inferior* to a strategy involving ***IVL***, in terms of the completeness of **final stent expansion (SE)**, measured as a percentage (%) by OCT in patients with heavily calcified coronary lesions.

- To **assess the safety** of a strategy of using ***OPN NCB*** compared to ***IVL*** for treatment of heavily calcified lesions, which are treated with drug eluting stents.

Sample Size Considerations

- Assuming a ***non-inferiority margin of 10% of stent expansion***, a standard deviation (SD) of 25% for both arms and a loss to follow-up or immeasurable stent expansion rate of 5%, we estimated that with **280 patients** – 140 patients to each study arm, the study will have a **90% power** to demonstrate the non-inferiority of the OPN™ NCB compared to the Shockwave™ IVL balloon catheter with a one-sided alpha of 0.025.
- Based on the participating sites track record for PCI trials, we were convinced that this number was feasible in reasonable time *(First patient enrolled 12/2022 → Last patient 08/2025).*

Key Eligibility Criteria

Clinical inclusion criteria:

- *Age ≥18 years and consentable*
- *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 ≥70%; and* ***(II)*** *Stenosis ≥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* ***≥270°calcium***
- *AND/ OR Prior attempt at PCI &* ***inability to expand balloon*** *in target lesion*

Suggested by the FDA

Main clinical and angiographic exclusion criteria:

- *Acute STEMI or cardiogenic shock related to an AMI*
- *Renal failure with an eGFR <30ml/min1.73m^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:

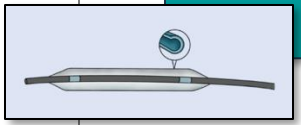
Annotation: Only one lesion and vessel per randomized patient may be treated according to protocol and considered for the purpose of this study. The lesion considered for the study must represent the most calcified one.

Study Design

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

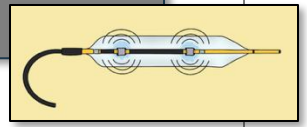
ACS / CCS patients* with severely calcified lesions undergoing OCT-guided PCI

Lesion prepration with **OPN NCB**



Randomization 1:1

Lesion prepration with **IVL**



Stent implantation (everolimus- or zotarolimus eluting stents)

Post-PCI OCT (primary outcome): **Final stent expansion (%)**

Clinical follow-up @ 30 days (safety outcomes)

Clinical follow-up @ 1 and 2 years (ongoing)

** STEMI & cardiogenic shock patients were excluded*

Measurements and procedures

- Patients presenting with chronic or acute coronary artery disease and requiring PCI to a very calcified coronary artery lesion will either be **randomized** to preparation of that corresponding lesion using the control device (**Shockwave IVL** balloon catheter) or the study device (the **super high-pressure NC PCI Balloon** (OPN NCB)).

- The treatment of the calcified coronary lesion was guided by use of intravascular imaging (optical coherence tomography, OCT).

- **Enrolled patients undergo follow-up at 30 days, 1 year and 2 years.**

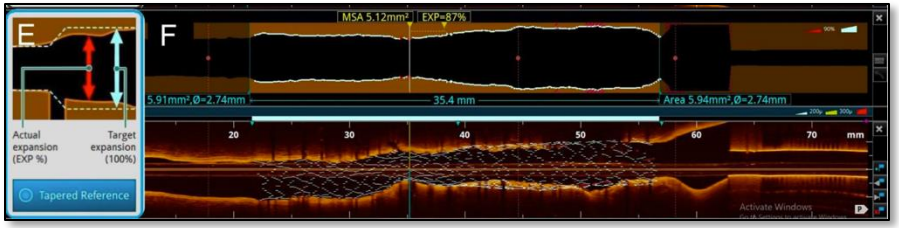
Methods

– Selection of OPN NCB and IVL devices

- **Optimal device sizing was specified in the study protocol Device**:
  - Both devices were used according to IFU
  - **OPN NCB device 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. Also oversizing and overinflating (above RBP) of the Shockwave™ IVL balloon was discouraged.
  - If **post-dilatation** at very high pressure was required (e.g. to correct stent underexpansion), we also encourage to use NCBs, which were 0.5mm smaller than the actual vessel diameter or assess the vessel diameter using OCT.

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 implantion.[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

Secondary and Safety Outcomes

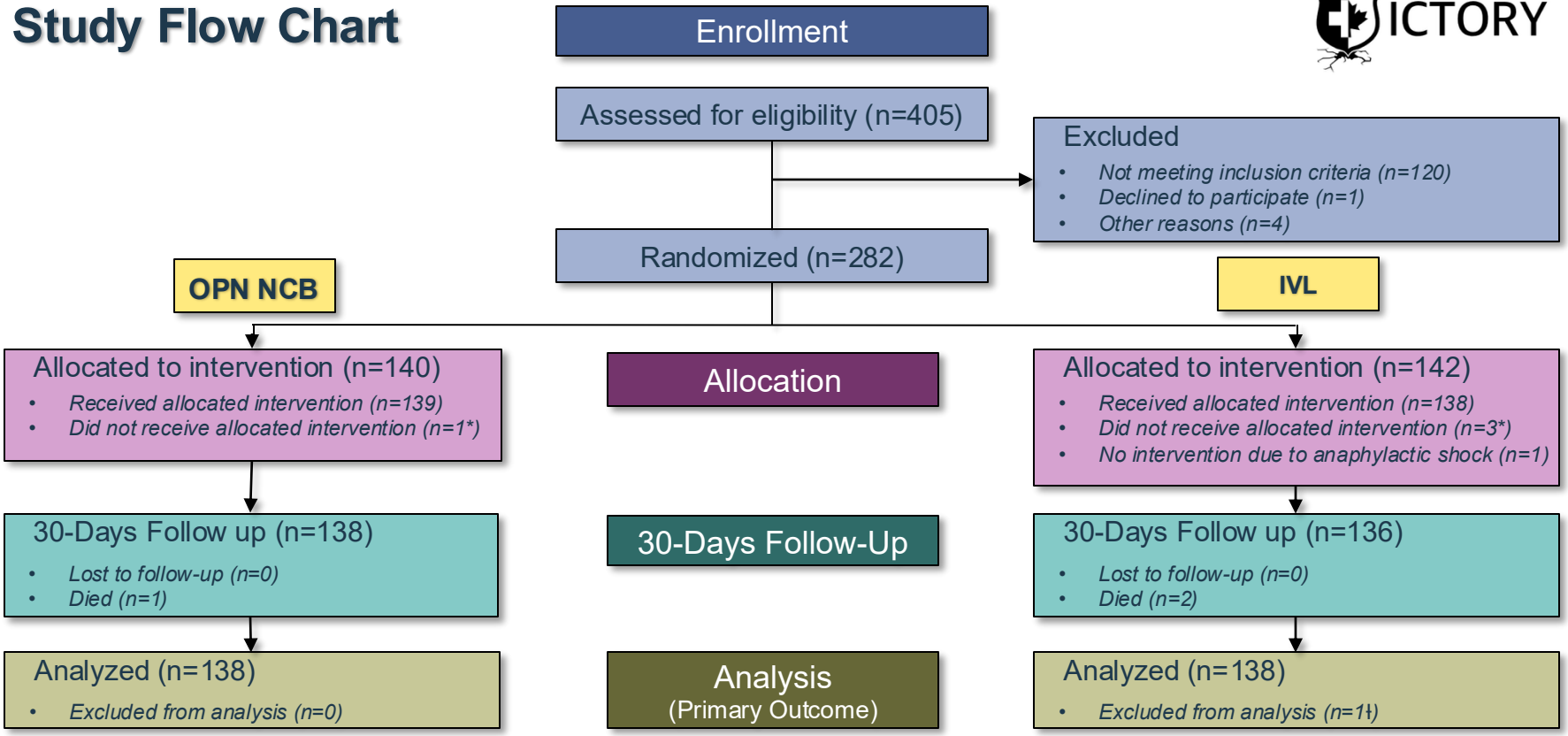
- **Secondary outcomes:**
  - Acceptable stent expansion (>80%) assessed by OCT
  - Optimal stent expansion (>90%) assessed by OCT
  - **Procedural success**, defined as the achievement of angiographic success (residual stenosis of <30%, no flow-limiting dissection and/or no no-reflo w) without any **major adverse cardiac events (MACE)**, which is defined as cardiac death, target vessel related myocardial infarction, TIA/ stroke and repeat revascularization (PCI or CABG) up to 30 days.
  - **Strategy success**, defined as procedural success using the assigned study device and stent, without requirement for lesion preparation with further devices (i.e. cross-over to the non-assigned study devices or cutting/ scoring balloons).
  - **Target vessel failure or stent expansion <80%**
  - **Target vessel failure:** cardiac death, target vessel MI or target vessel revascularization.

- **Safety outcomes:**
  - Coronary perforations (Ellis grade III and/or cavity spilling)
  - Periprocedural ventricular tachycardia/ fibrillation (VT/ VF)
  - Persistent periprocedural vessel occlusion/ MI (Periprocedural MI)
  - Contrast-induced nephropathy (CIN)
  - Major bleeding (BARC 3-5)

Other Outcomes

- **All of the following outcomes will be assessed at 30 days, 1 year and 2 years:**
  - MACE
  - Target vessel revascularization (TVR)
  - Target lesion revascularization (TLR)
  - Hospitalization due to cardiac origin
  - New MI (NSTEMI/STEMI)
  - Stent thrombosis (ST)
  - TIA or stroke
  - Cardiovascular death
  - All-cause death

Study Flow Chart



* Technical problems
† OCT run was accidentally destroyed

Clinical Characteristics

– The usual characteristics of a complex PCI cohort

	OPN NCB *(n=139)*	IVL *(n=139)*
Age (years)	70.6±8.6	71.6±8.2
Females (%)	25 (18.0)	17 (12.2)
Symptomatic chronic coronary syndrome (%)	81 (59.6)	74 (54.4)
Planned staged PCI after MI (%)	32 (23.5)	37 (27.2)
Diabetes (%)	42 (30.7)	33 (23.9)
Previous MI (%)	53 (39.3)	56 (40.6)
Previous PCI (%)	81 (58.3) *	59 (42.4) *
Previous CABG (%)	10 (7.2)	7 (6.1)
Heart failure (%)	19 (13.9)	20 (14.6)
Target vessel : Proximal LAD (%)	56 (40.3)	57 (41.0)

** p-value =0.008*

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 (n, %)	19 (13.7)	32 (23.0)	* p-value 0.044
NCB prior to study device (n, %)	33 (23.74)	56 (40.29)	* p-value 0.003
Scoring/cutting balloon (n, %)	1 (0.72)	0 (0)	
Rotational atherectomy (n, %)	22 (15.83)	17 (12.23)	
Study devices : OPN NCB vs. IVL group			
Number of devices used (n)			
1	91 (65.94)	133 (95.68)	
2	46 (33.33)	6 (4.32)	
3	1 (0.72)	0	
Number of devices used [mean, (SD)]	1.35 (0.49)	1.04 (0.20)	* p-value <0.001
Max. diameter (atm)	3.0 (0.5)	3.5 (0.5)	
Max. pressure (atm)	40.0 (4.0)	6.0 (2.0)	

Core Lab Findings : Angiography & OCT

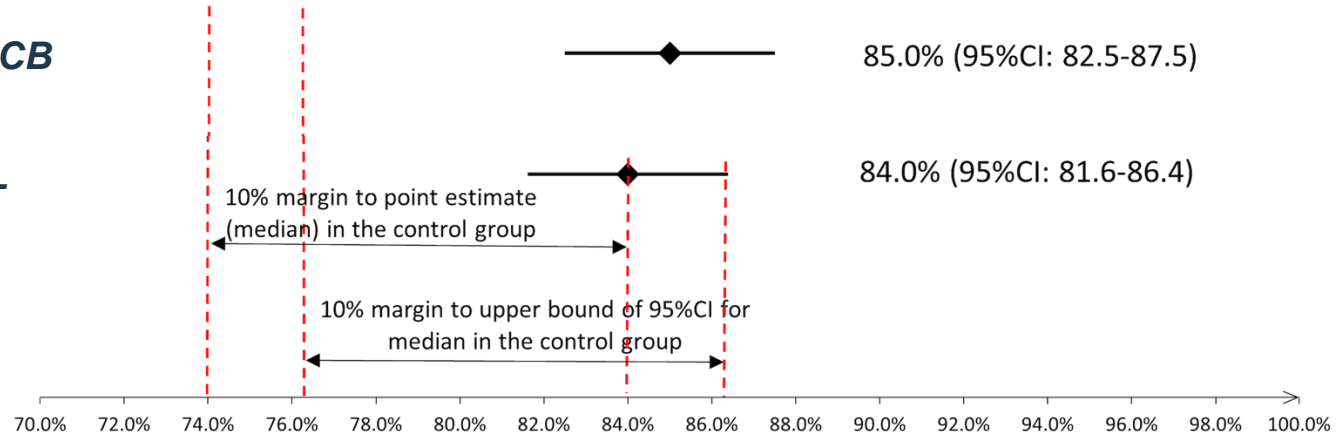
	OPN NCB (n=139)	IVL (n=139)
Angiographic findings:		
Target lesion SYNTAX Score	8.0±5.0	8.0±5.0
Angiographic severity of calcification (n, %)		
Moderate	40 (28.8)	35 (25.2)
Severe	83 (59.7)	86 (61.9)
Reference diameter (mm)	2.5±0.7	2.4±0.8
Bifurcation lesion (n, %)	56 (40.3)	52 (37.4)
OCT findings:		
Reference vessel diameter – mean (mm)	3.57±0.64	3.57±0.60
Mean lumen diameter (mm)	1.59±0.35	1.58±0.36
Minimal lumen area (mm2)	2.13±0.9	2.14±0.9
Lesion length (mm)	33.5±12.5	32.6±13.5
Eccentric calcium, n (%)	60 (43.5)	63 (45.9)
Nodular calcium, n (%)	38 (27.5)	34 (24.8)
Length of stented segment (mm)	46.7±15.7	46.1±15.1

Primary Outcome : Stent Expansion (%)

OPN NCB is non-inferior to IVL

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

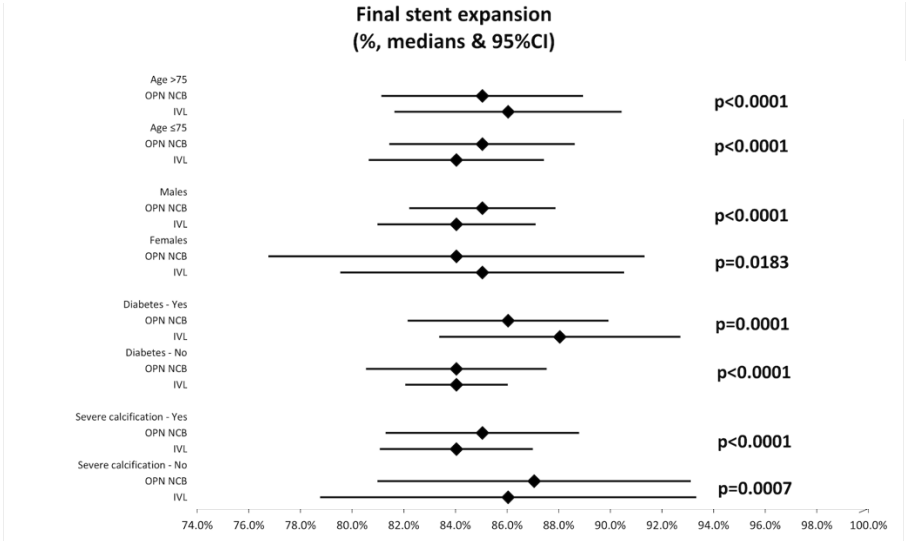
p non-inferiority <0.0001

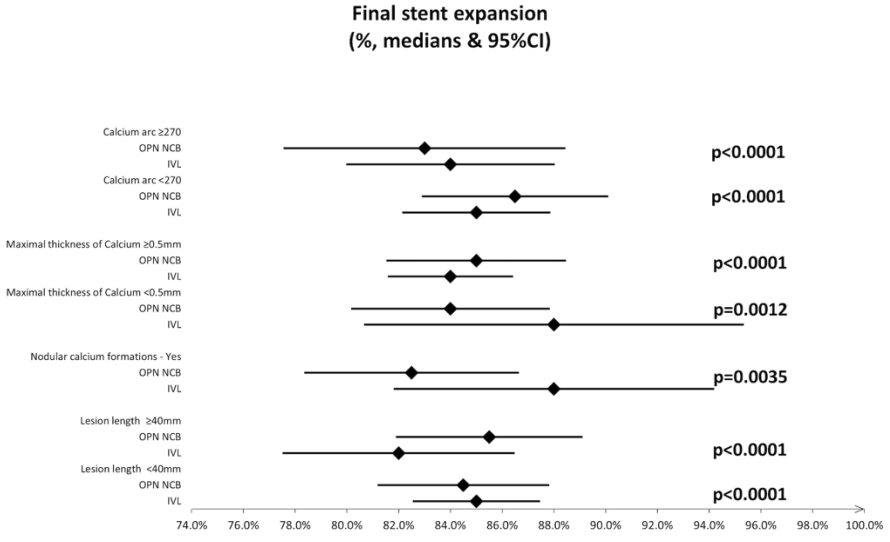


But OPN NCB was not superior to IVL for the primary outcome.

(Difference in medians: 1.0 (95%CI -2.45 to 4.45), p for superiority 0.570)

Subgroup Analyses for Primary Outcome





The subgroup analyses consistently indicated non-inferiority of the OPN NCB compared to IVL in heavily calcified lesions.

Secondary Outcomes

	OPN NCB (n=139)	IVL (n=139)	95%CI	p-value
Acute procedural success (n, %) *	137 (98.6)	135 (97.1)	1.015 (0.800-1.287)	0.903
Procedural success (n, %)	127 (92.03)	118 (86.13)	0.579 (0.276-1.2170	0.149
Strategy success (n, %)	137 (98.6)	137 (98.6)	1.000 (0.789-1.267)	0.999
Final stent Expansion ≥80% (n, %)	94 (68.1)	94 (68.6)	0.993 (0.746-1.321)	0.960
Final stent Expansion ≥90% (n, %)	50 (36.2)	47 (34.3)	0.978 (0.729-1.312)	0.881
Minimum Stent Area (mm2)	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*

Safety Outcomes

	OPN NCB (n=139)	IVL (n=139)	p-value
Dissections, n (%)			
Mild	6 (4.3)	1 (0.7)	0.139
Flow limiting	2 (1.4)	1 (0.7)	
Coronary perforations (n, %)			
Ellis I	0 (0.0)	2 (1.5)	0.999
Ellis II	2 (1.4)	1 (0.7)	
Ellis III	0 (0.0)	1 (0.7)	
Ellis III cavity spilling	0 (0.0)	1 (0.7)	
Side-branch occlusion (n, %)	1 (0.7)	1 (0.7)	0.999

Outcomes @ 30 days

	OPN NCB (n=139)	IVL (n=139)	95%CI	p-value
New MI (n, %)	3 (2.2)	5 (3.6)	0.600 (0.143-2.511)	0.484
Periprocedural MI (n, %)	40 (28.8)	46 (33.1)	0.870 (0.569-1.328)	0.518
Target vessel MI (TV-MI) (n, %)	0 (0.0)	3 (2.2)	*NA*	0.121
Target vessel revascularization (TVR) (n, %)	2 (1.5)	3 (2.2)	0.667 (0.111-3.990)	0.657
Target lesion revascularization (TLR) (n, %)	2 (6.7)	1 (3.4)	1.867 (0.169-20.586)	0.610
CABG surgery (n, %)	0 (0.0)	2 (1.5)	*NA*	0.245
CV Death (n, %)	2 (1.4)	2 (1.4)	1.000 (0.141-7.099)	0.999
All-cause death (n, %)	2 (1.4)	3 (2.2)	0.667 (0.111-3.990)	0.657

Limitations

- Trial not powered for clinical outcomes
- 1° outcomes (stent expansion by OCT) → Surrogate parameter
- VICTORY involved only experienced IVL and OPN NCB users
- OPN NCB and IVL sized according to OCT measurement

Conclusions

- **In severely calcified coronary lesions**, the following applies:
  - ***OCT-guided PCI involving lesion preparation with OPN NCB is non-inferior to IVL*** in terms of stent expansion.
  - VICTORY indicates that OPN NCB and IVL have a similar safety profile.
  - *The OPN NCB is a reasonable lower cost alternative to IVL which may be faster to use*

Thank you very much for your attention!

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