HIGH TECH MARSEILLE

28-30 JANVIER 2026

MARSEILLE
PALAIS DU PHARO

# Quel ballon pour les lésions calcifiées?

## Etudes SHORT-CUT & VICTORY

G.SOUTEYRAND

# CONFLITS D'INTÉRÊTS

**Consultant**

**Medtronic, Abbott, Terumo, B Braun, Edwards**

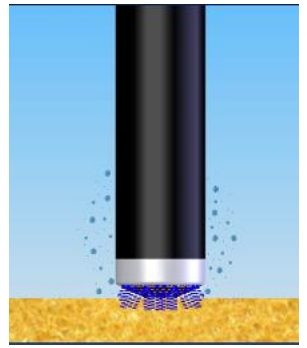
# Lésions calcifiées

## Arsenal thérapeutique ++

**Ballons non compliants**

**Ballons très haute pression OPN**

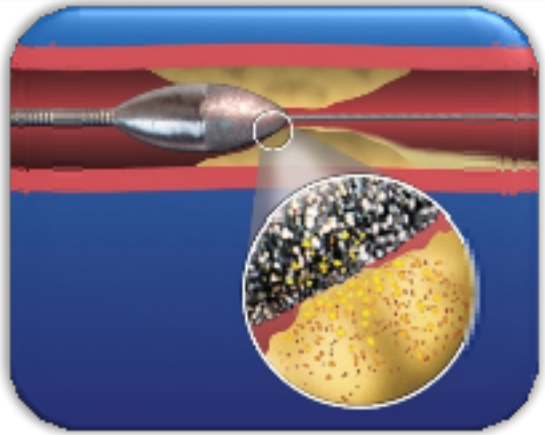

**Laser**



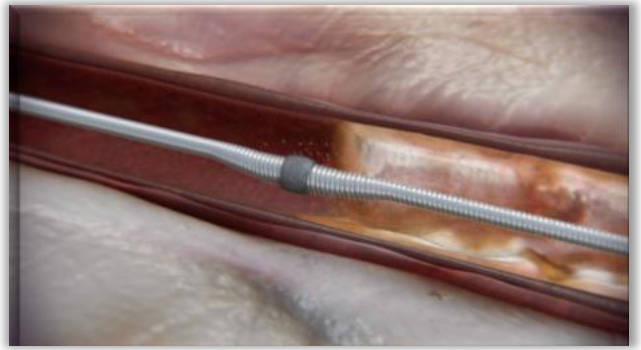
**Scoring ballon**

**Cutting ballon**

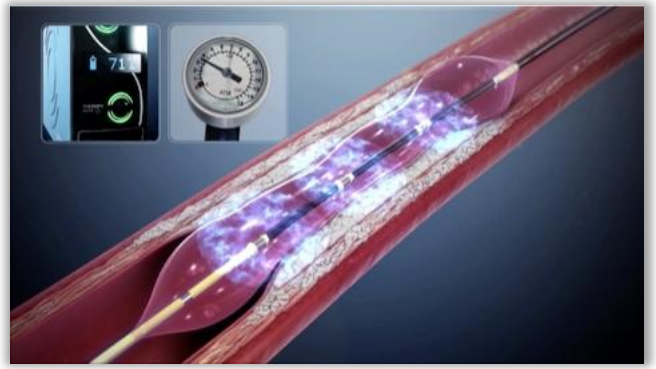
**Athérectomie rotationnelle**



**Athérectomie orbitale**



**Lithotripsie intravasculaire**



# Avant ces études

ESC European Society of Cardiology
European Heart Journal (2023) 44, 4340–4356
https://doi.org/10.1093/eurheartj/ehad342
FASTTRACK CLINICAL RESEARCH
Interventional cardiology

**Management strategies for heavily calcified coronary stenoses: an EAPCI clinical consensus statement in collaboration with the EURO4C-PCR group**

UNCROSSABLE

SUPERFICIAL CALCIUM

UNDILATABLE

DEEP CALCIUM

Rotational Atherectomy/Orbital Atherectomy

Laser

Intravascular Lithotripsy

C/S Balloon

SHP Balloon

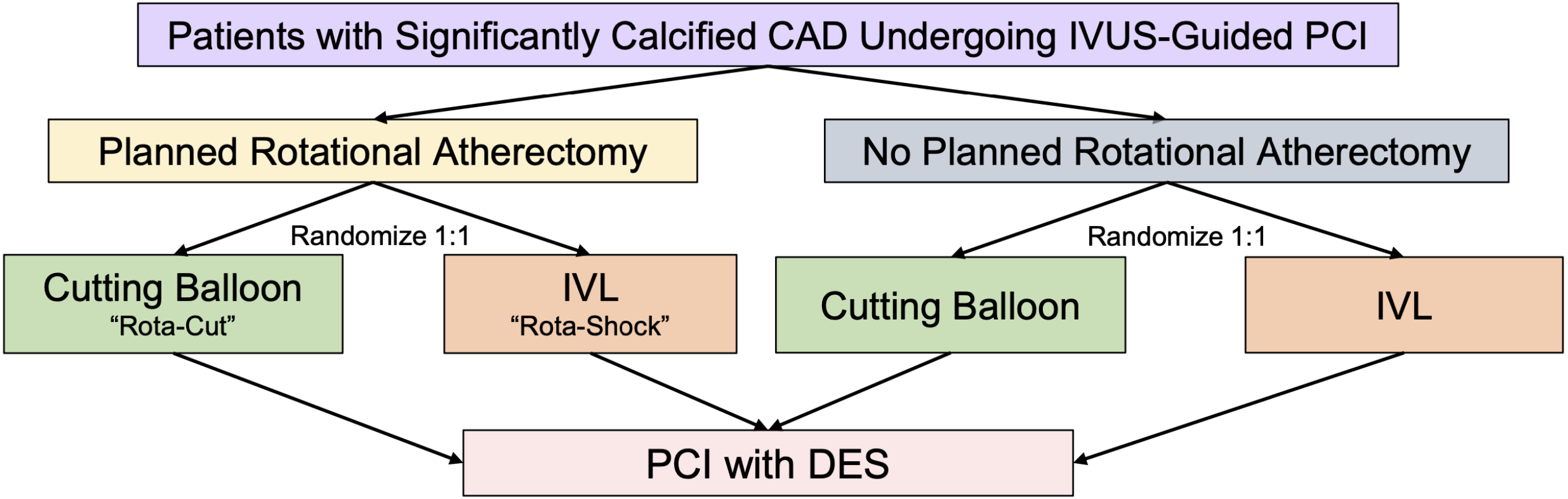
NC Balloon

*Barbato E. Eur Heart J. 2023*

# Etude Short-CUT

## Design de l'étude

The ShortCUT Trial:
Shockwave Lithotripsy Compared to Cutting Balloon Treatment in Calcified Coronary Artery Disease
Suzanne J. Baron MD MSc
Massachusetts General Hospital, Boston MA
Baim Institute for Clinical Research, Boston MA




**Primary Endpoint**: Post-procedural minimal stent area (MSA) at site of maximal $Ca^{++}$
*(IVUS Core Lab Adjudicated)*

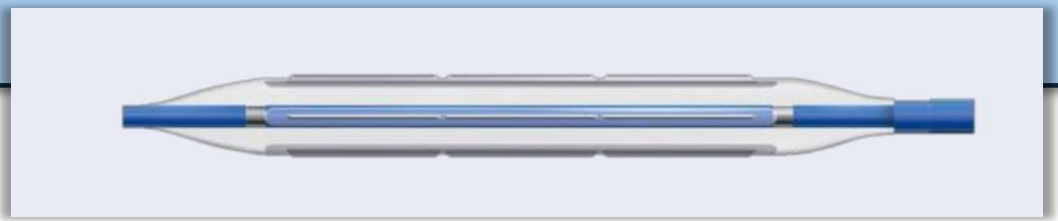
# Etude Short-CUT

## Groupe Litothripsie

Taille 1/1 par rapport ⌀ artère
Nombre pulses à discrétion opérateur

## Groupe Cutting ballon

Taille ballon 0.5mm plus petit que référence artère
Pression inflation haute : 16-20 atm



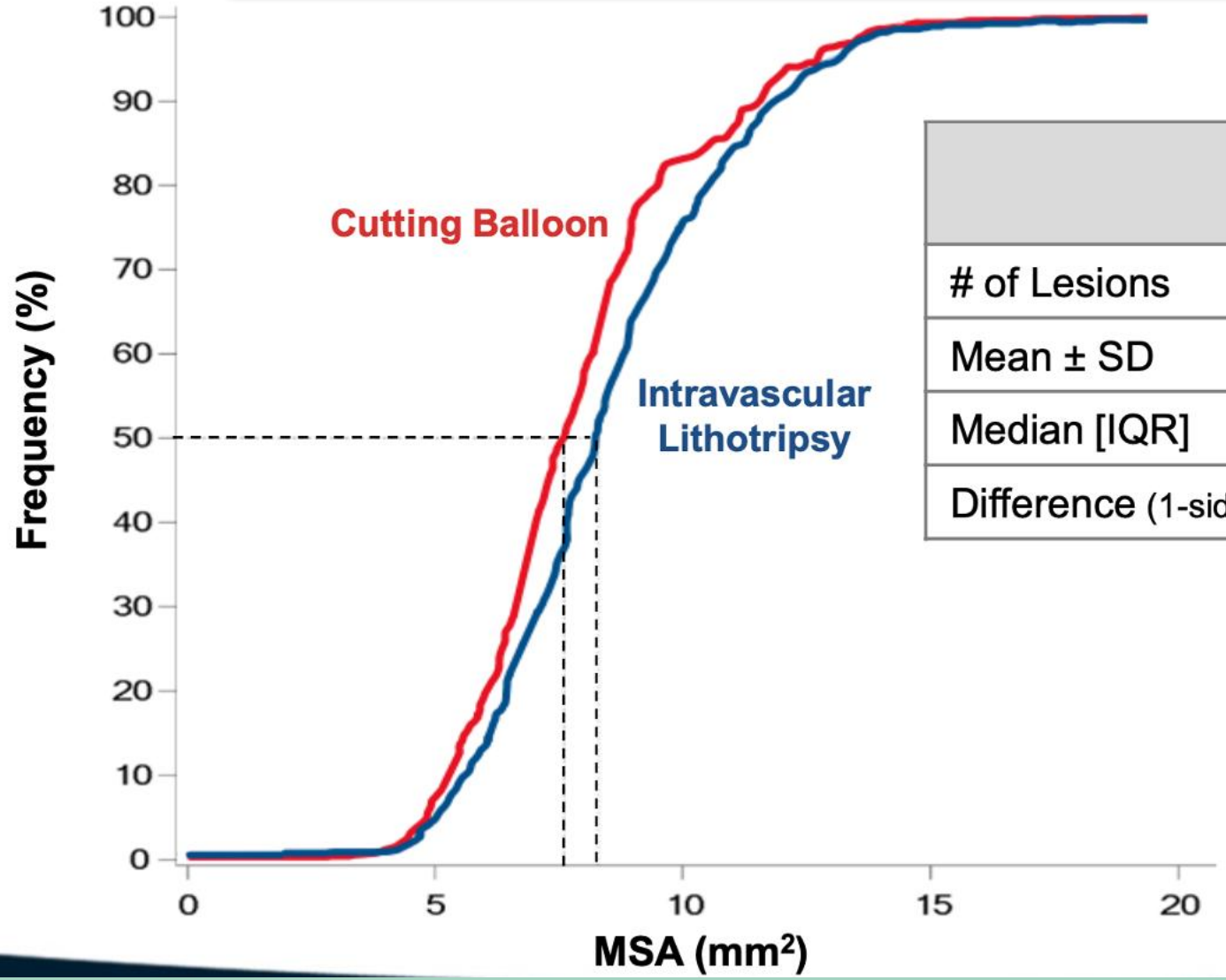
## IVUS haute définition

Recommandé avant la randomisation
Nécessaire après randomisation & fin procédure

| Caractéristiques Population | Intravascular Lithotripsy N = 207 Subjects | Cutting Balloon N = 206 Subjects |
|---|---|---|
| Age (yrs) | 72.1 ± 9.3 | 72.2 ± 9.5 |
| Male Sex | 75.8% | 74.3% |
| Diabetes Mellitus | 44.1% | 46.1% |
| Renal Insufficiency | 25.7% | 24.4% |
| On Dialysis | 5.9% | 5.9% |
| Prior PCI | 44.1% | 51.0% |
| Prior CABG | 14.9% | 18.6% |
| LVEF (%) | 53.3 ± 11.5 | 54.6 ± 10.9 |
| Indication for PCI | | |
| Stable Angina | 85.5% | 82.0% |
| Unstable Angina | 6.8% | 8.3% |
| NSTEMI | 7.7% | 9.7% |

# Etude Short-CUT

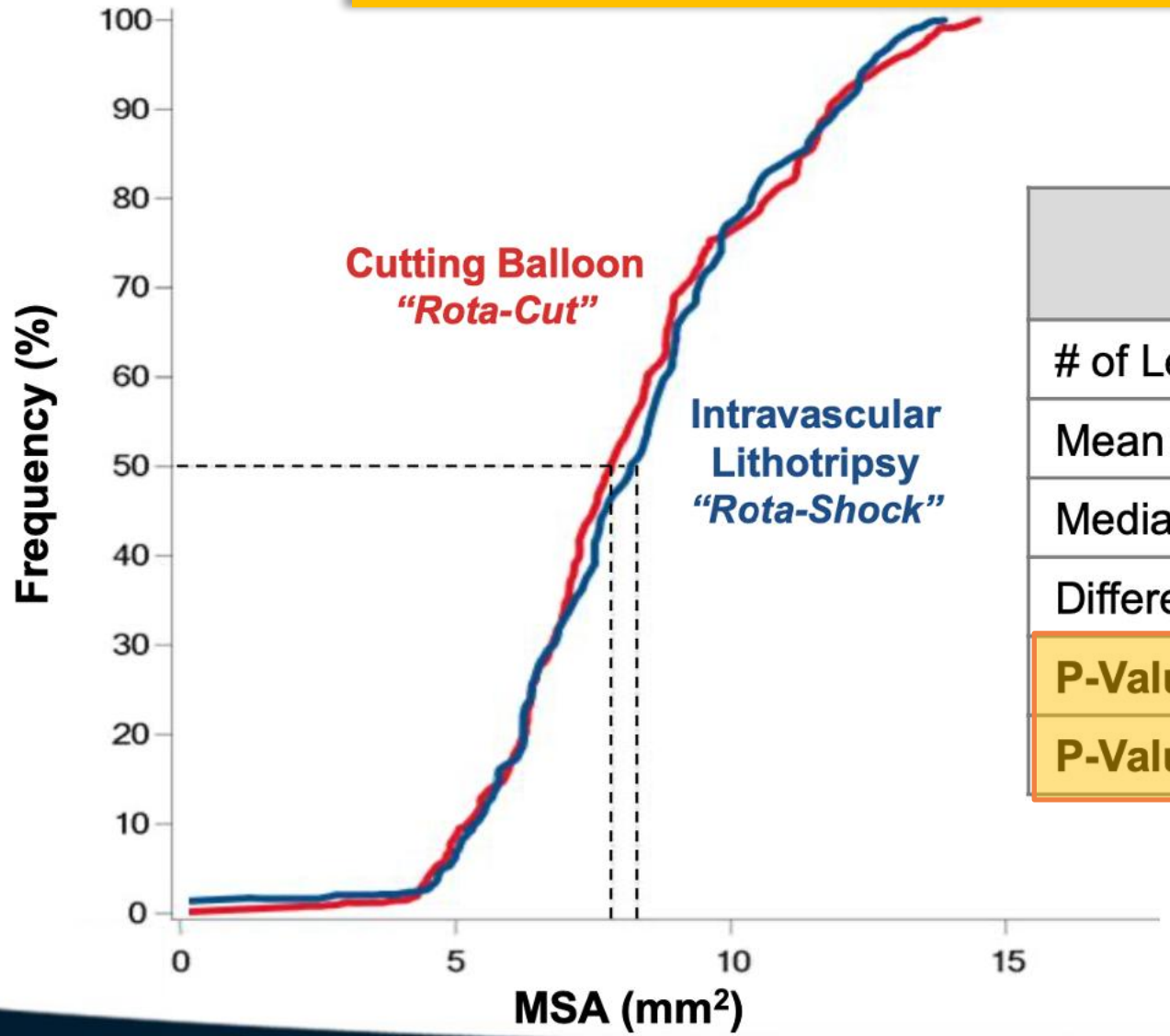
## Post procédure MSA sur site Max de calcifications




| | Intravascular Lithotripsy | Cutting Balloon |
|---|---|---|
| # of Lesions | 218 | 212 |
| Mean ± SD | 8.6 ± 2.5 | 8.0 ± 2.4 |
| Median [IQR] | 8.3 [6.7,9.9] | 7.6 [6.4,9.0] |
| Difference (1-sided 97.5% CI) | 0.6 (∞, 1.1) mm² | |

# Etude Short-CUT

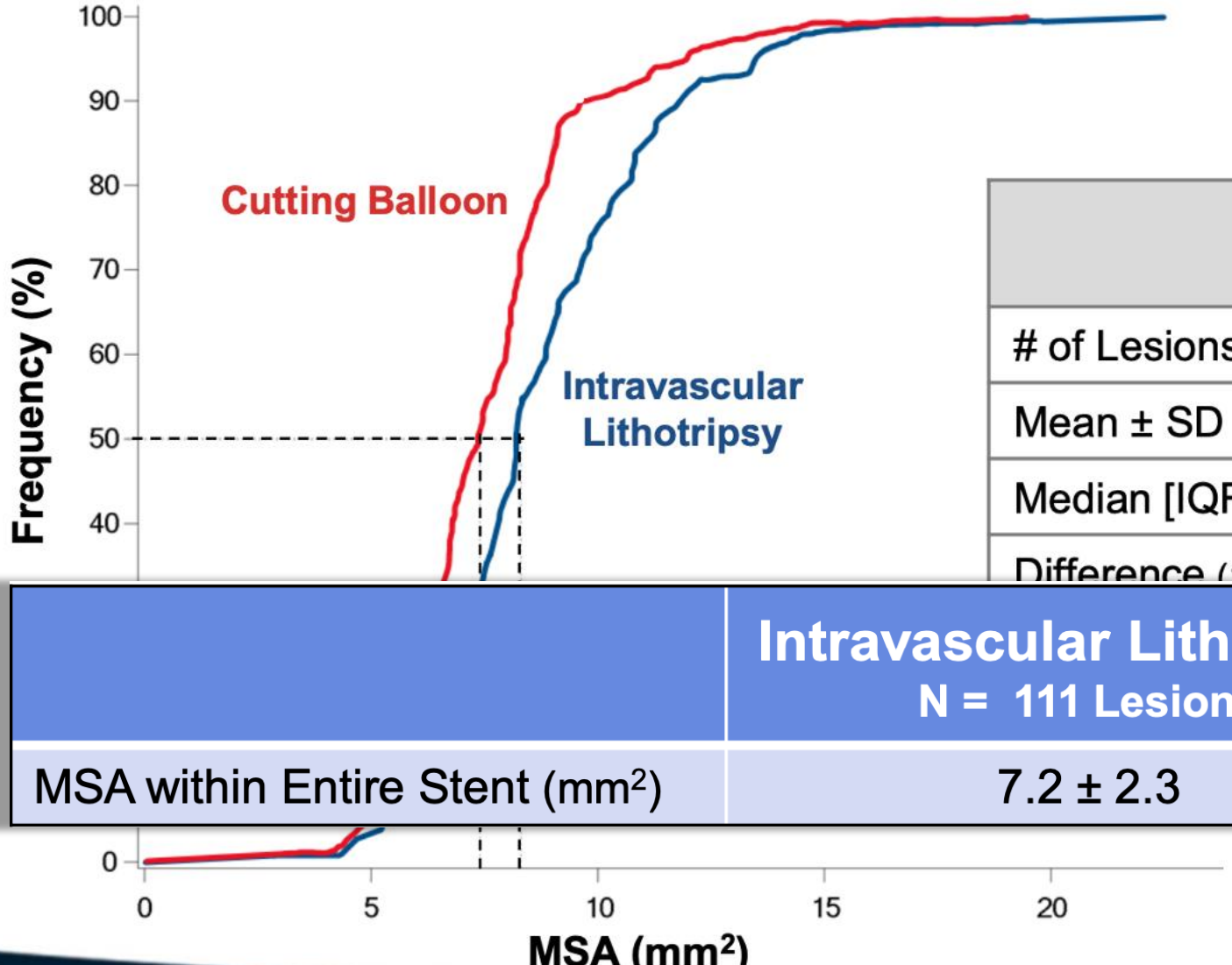
## Cohorte Athérectomie




| | Intravascular Lithotripsy | Cutting Balloon |
|---|---|---|
| # of Lesions | 107 | 107 |
| Mean ± SD | 8.4 ± 2.3 | 8.3 ± 2.5 |
| Median [IQR] | 8.3 [6.5,9.9] | 7.9 [6.4,9.8] |
| Difference (1-sided 97.5% CI) | 0.1 (∞, 0.8) mm² | |
| **P-Value (Non-Inferiority)*** | **< 0.001** | |
| **P-Value (Superiority)** | **0.622** | |

# Etude Short-CUT

## Cohorte non Athérectomie




| | Intravascular Lithotripsy | Cutting Balloon |
|---|---|---|
| # of Lesions | 111 | 105 |
| Mean ± SD | 8.8 ± 2.7 | 7.7 ± 2.3 |
| Median [IQR] | 8.3 [7.2,10.0] | 7.4 [6.3,8.5] |
| Difference (1-sided 97.5% CI) | 1.1 (∞, 1.8) mm² | |

| | Intravascular Lithotripsy N = 111 Lesions | Cutting Balloon N = 105 Lesions | P-Value |
|---|---|---|---|
| MSA within Entire Stent (mm²) | 7.2 ± 2.3 | 6.5 ± 2.2 | 0.03 |

# Etude Short-CUT

## Résultats cliniques

| | Intravascular Lithotripsy N = 207 Subjects | Cutting Balloon N = 206 Subjects | P-Value |
|---|---|---|---|
| Complication associated with Randomized Device | | | 0.34 |
| Dissection | 0.9% | 2.7% | |
| Perforation | 0.0% | 0.5% | |
| Abrupt Closure | 0.0% | 0.0% | |
| Balloon Rupture | 3.1% | 2.3% | |
| Intraprocedural Adverse Events * | 1.0% | 1.0% | 1.00 |
| Strategy Success ** | 89.7% | 89.2% | 0.88 |
| In-Hospital MACCE | 1.0% | 1.0% | 1.00 |
| 30-Day MACCE | 2.9% | 2.9% | 1.00 |

# Etude VICTORY

## Critères d'inclusion

**Sténose mono tronculaire sur SCA ou angor chronique**

**Lésion calcifiée angiographiquement**

**Et/ou OCT avec arc calcaire >270°**

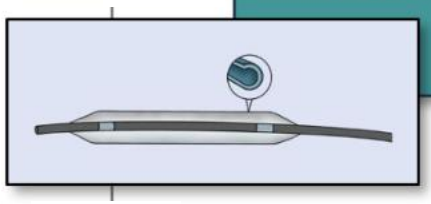
**Et/ou ballon d'angioplastie non ouvert**

# Etude VICTORY

## 3 centres, Etude prospective

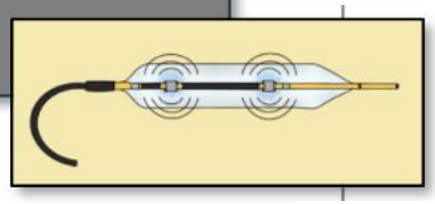
**ACS / CCS patients* with severely calcified lesions undergoing OCT-guided PCI**

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)

**Suivi clinique à 1 & 2 ans**

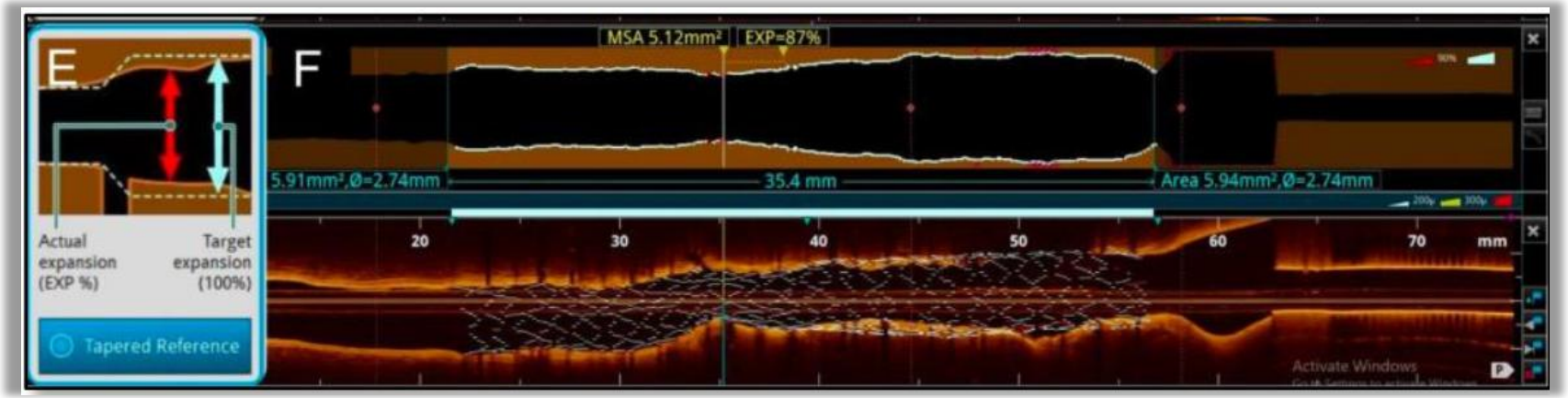
HIGHTECH

# Etude VICTORY

## Methode

- **Critère primaire**

Expansion finale du stent en %




- **Critère secondaire**

Expansion optimale, acceptable

Succès de procédure, de stratégie

Complications

HIGHTECH

# Etude VICTORY

## Population

### 282 patients randomisés

| | 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) |

# Analyse lésions

| | 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) |

# Charactéristiques procédure

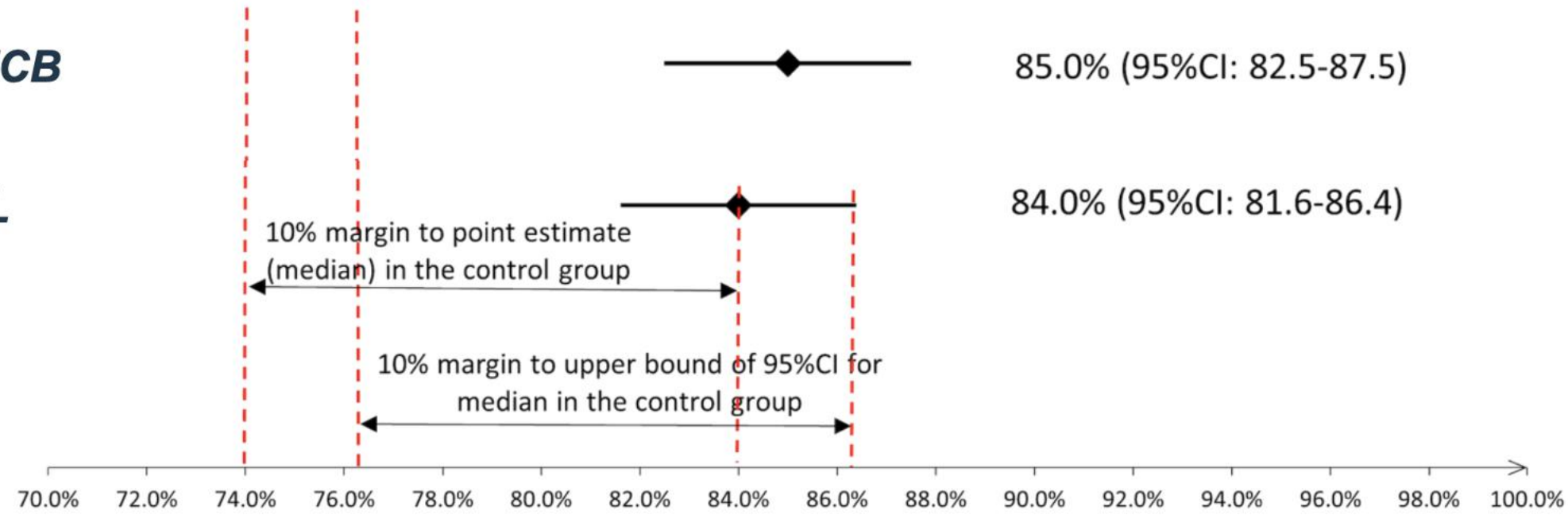
| | | OPN NCB (n=139) | IVL (n=139) | |
|---|---|---|---|---|
| Radial access (%) | | 118 (85.5) | 116 (83.4) | |
| Procedure time (min) | | 70 (36) | 79 (31) | * p-value = 0.061 |
| Contrast dose (mL) | | 284 (146) | 294 (125) | |
| Radiation time (min) | | 22.4 (14.3) | 24.7 (16.0) | |
| SCB prior 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 (atm) | | 3.0 (0.5) | 3.5 (0.5) | |
| Max. pressure (atm) | | 40.0 (4.0) | 6.0 (2.0) | |

# Etude VICTORY

## Critère d'analyse

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

***p for non-inferiority <0.0001***

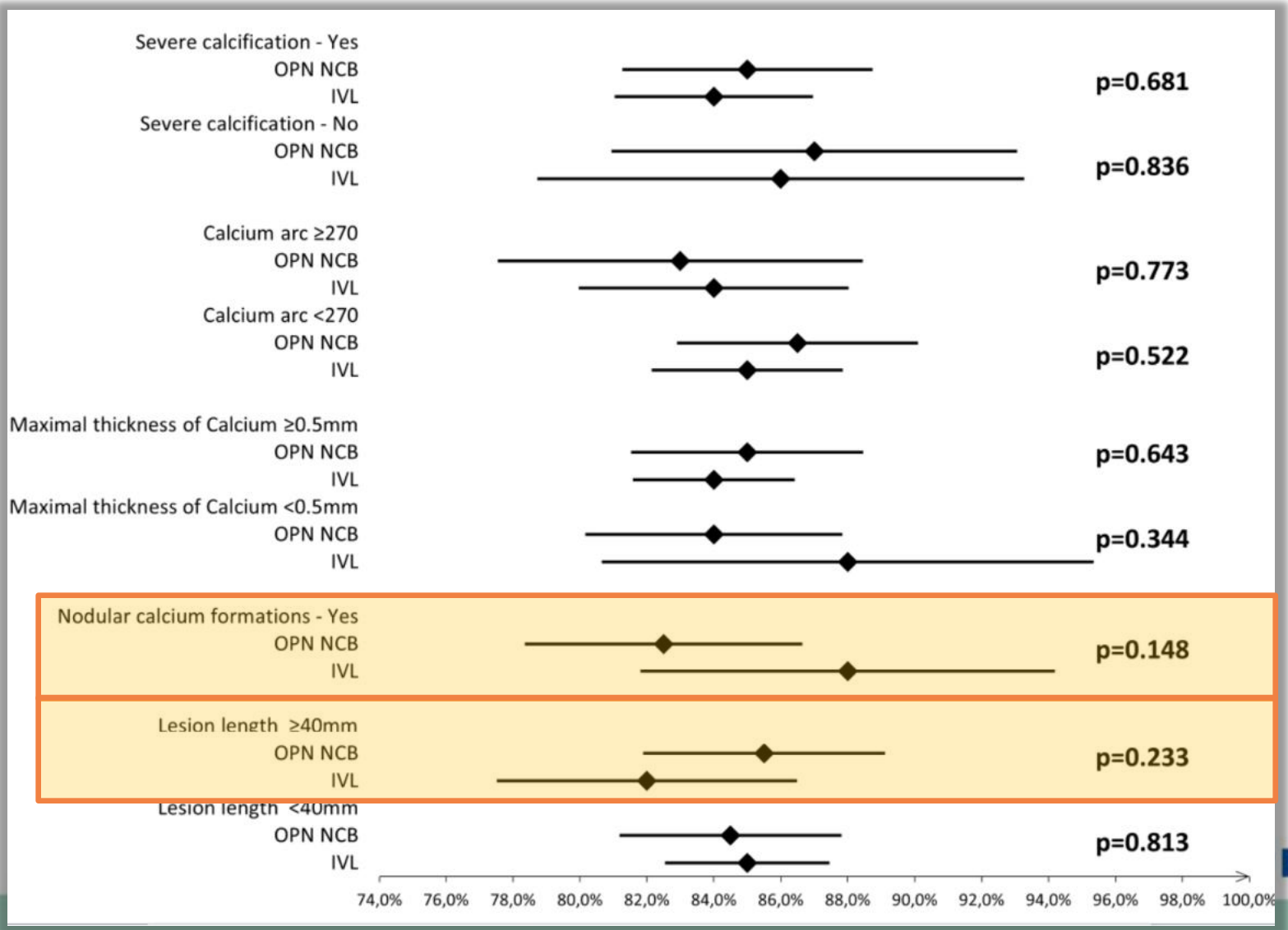



OPN NCB did **not** demonstrate superiority over IVL for the primary outcome.
*(Difference in medians: 1.0 (95%CI -2.45 to 4.45), p for superiority 0.570)*

# Etude VICTORY

## Analyse de sous-groupes

**Expansion finale en %**



# Critères sécurité

| | 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* |

# Etude VICTORY

| Suivi clinique | OPN NCB (n=139) | IVL (n=139) | 95%CI | p-value |
|---|---|---|---|---|
| New MI (%) | 3 (2.2) | 5 (3.6) | 0.600 (0.143-2.511) | 0.484 |
| Periprocedural MI (%) * | 40 (28.8) | 46 (33.1) | 0.870 (0.569-1.328) | 0.518 |
| Target vessel MI (TV-MI) (%) | 0 (0.0) | 3 (2.2) | *NA* | 0.121 |
| Target vessel revascularization (TVR) (%) | 2 (1.5) | 3 (2.2) | 0.667 (0.111-3.990) | 0.657 |
| Target lesion revascularization (TLR) (%) | 2 (6.7) | 1 (3.4) | 1.867 (0.169-20.586) | 0.610 |
| Stent thrombosis (%) | 0 (0.0) | 1 (0.74) | NA | 0.498 |
| MACE (%) † | 4 (2.90) | 11 (8.03) | 0.361 (0.114-1.134) | 0.081 |
| CABG surgery (%) | 0 (0.0) | 2 (1.5) | *NA* | 0.245 |
| CV Death (%) | 2 (1.4) | 2 (1.4) | 1.000 (0.141-7.099) | 0.999 |
| All-cause death (%) | 2 (1.4) | 3 (2.2) | 0.667 (0.111-3.990) | 0.657 |

# Change ma pratique?

## Conclusions

| UNCROSSABLE | SUPERFICIAL CALCIUM | UNDILATABLE | DEEP CALCIUM |
|---|---|---|---|

- Rotational Atherectomy/Orbital Atherectomy
- Laser
- Intravascular Lithotripsy
- C/S Balloon
- OPN
- NC Balloon

# Conclusions

**Imagerie endoconaire importante**

**Données sécurisantes pour utilisation OPN sur lésions natives de gros calibre**

**Très peu de complications**

**Associer outils ++**

**Ballons coupants & rotablator**

**Manque données clinique à long terme**

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