# Insights into Rota, Super High-Pressure Balloon, and Optimal Device Choices in Severe Calcified Lesions

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# Disclosure

- **Speaker: Dr. Kambis Mashayekhi**

☑ I have the following potential conflicts of interest to declare:

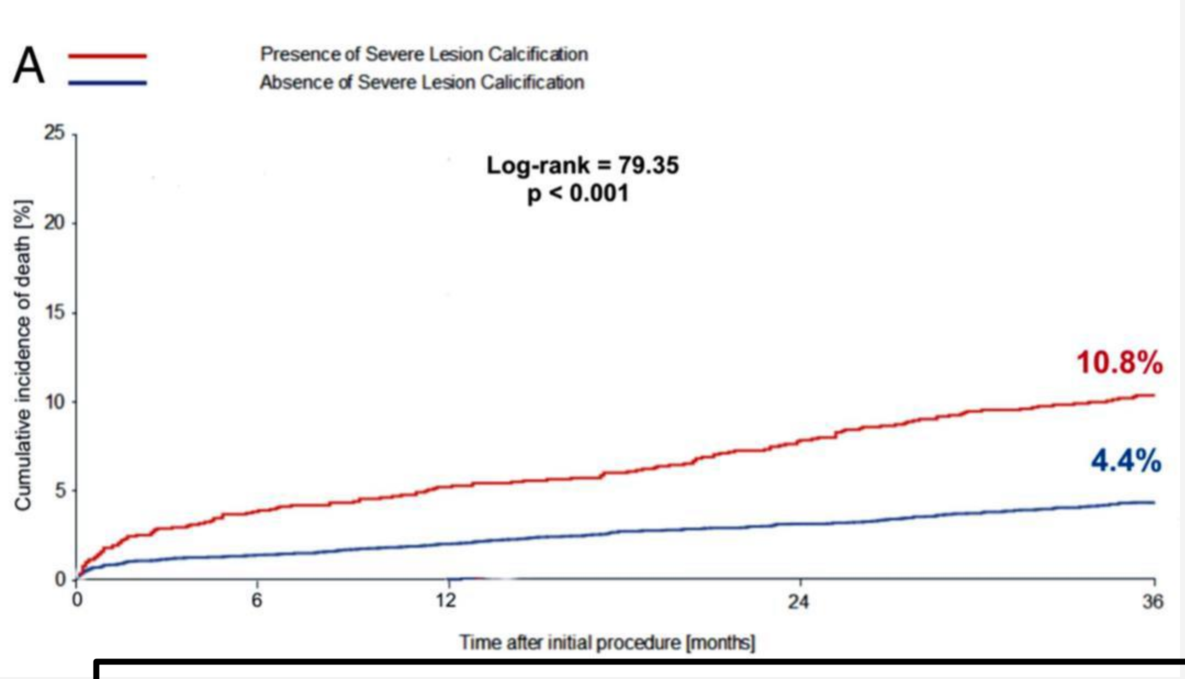
- **Personal: None**

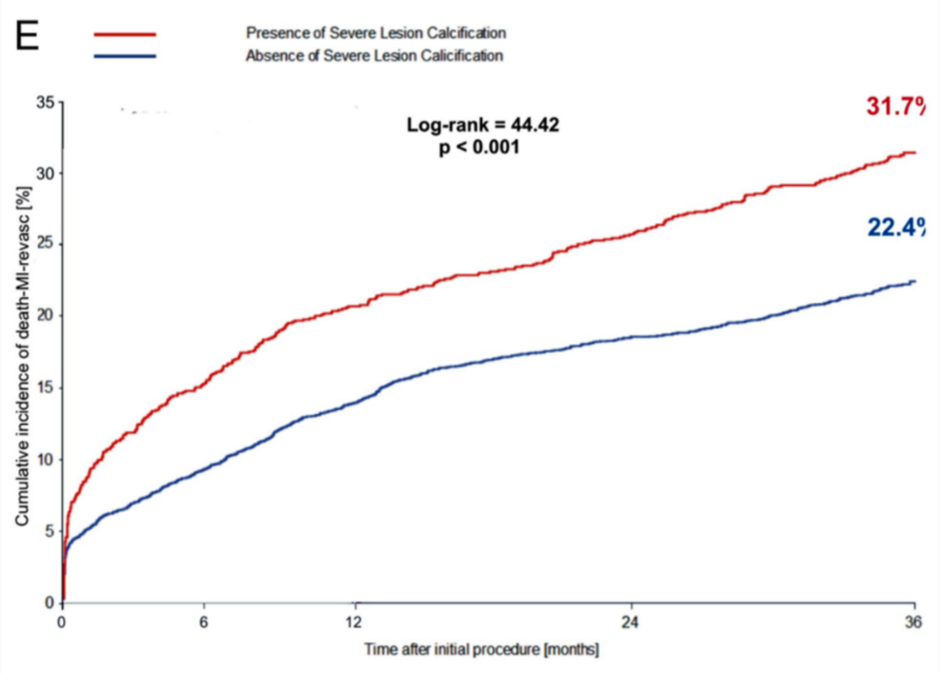
- **Institutional:**

**Speaker honoraria, consultancy fees, and research grants from Abbott, Abiomed, Asahi Intecc, Astra Zeneca, Biotronik, Boston, Cardinal Health, Daiichi-Sankyo, Medtronic, Philips Healthcare Shockwave, SIS, Teleflex, Terumo.**

# Background

## Prognostic implications of calcific CAD




- pooled analysis of 6,296 patients enrolled in 7 randomized clinical trials
- severe coronary calcification in 20% of patients with significantly elevated MACE rates

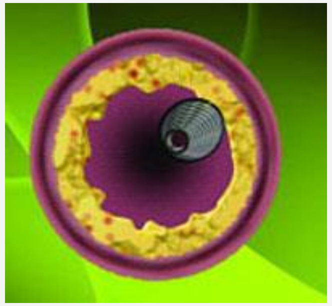
Bourantas C. et al., Heart 2014

# Background

## Lesion preparation strategies for calcific CAD

### Ablative techniques

Rotational atherectomy



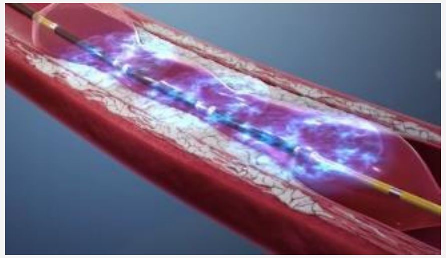
Orbital atherectomy

**modification/ablation of the plaque composition to promote stent-expansion**

### Balloon-based techniques

Super high-pressure balloon

Cutting-/Scoring balloon

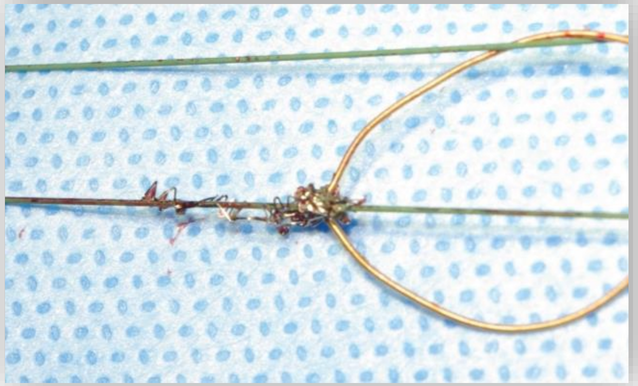


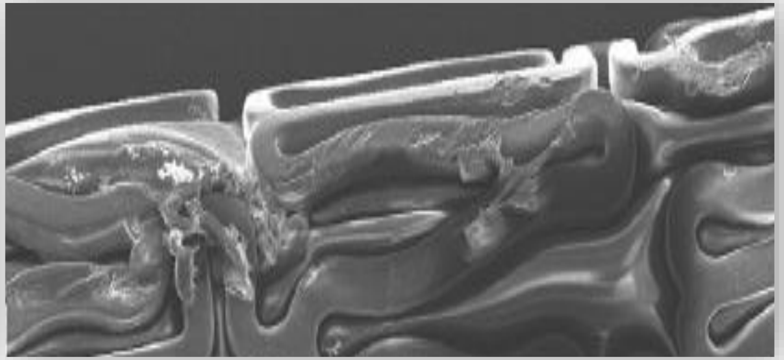
Intravascular lithotripsy

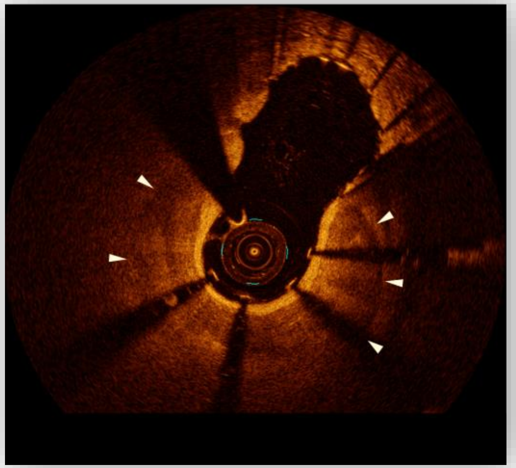
**cracking of the calcium component to increase plaque elasticity and allow stent-expansion**

De Maria et al. JACC Int. 2019

# Why prepare a calcified lesion?







1. To allow successful stent delivery
2. To allow adequate stent expansion
3. To prevent stent thrombosis and restenosis

# Primary use of Rotablation for debulking

## European expert consensus on rotational atherectomy

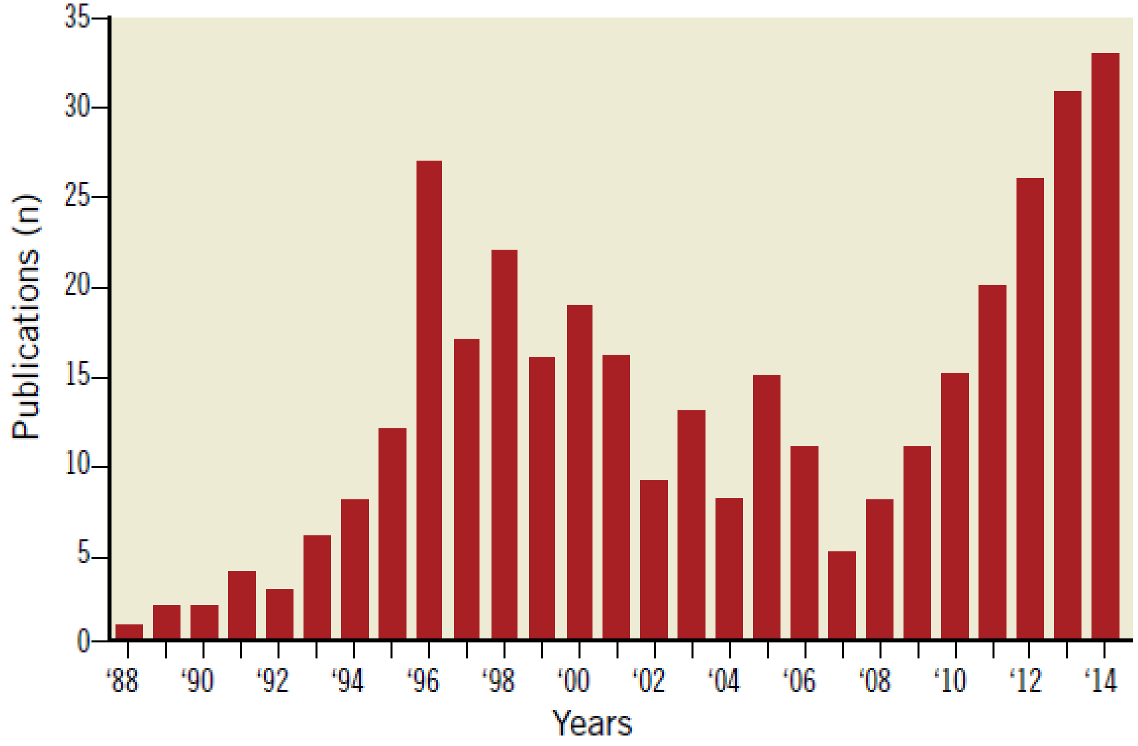



**Figure 1.** *Number of publications over the years on coronary rotational atherectomy (source Pubmed).*

**Table 1. Rate of rotational atherectomy as function of total PCI numbers in some EU countries (source Boston Scientific).**

| Country | Rate (%) |
|---|---|
| United Kingdom | 3.1 |
| France | 2.9 |
| Spain | 2.3 |
| Austria | 1.8 |
| Portugal | 1.5 |
| The Netherlands | 1.4 |
| Italy | 1.3 |
| Belgium | 1.3 |
| Switzerland | 1.1 |
| Germany | 0.8 |



Barbato E, *EuroIntervention*. 2015;11(1):30-36.

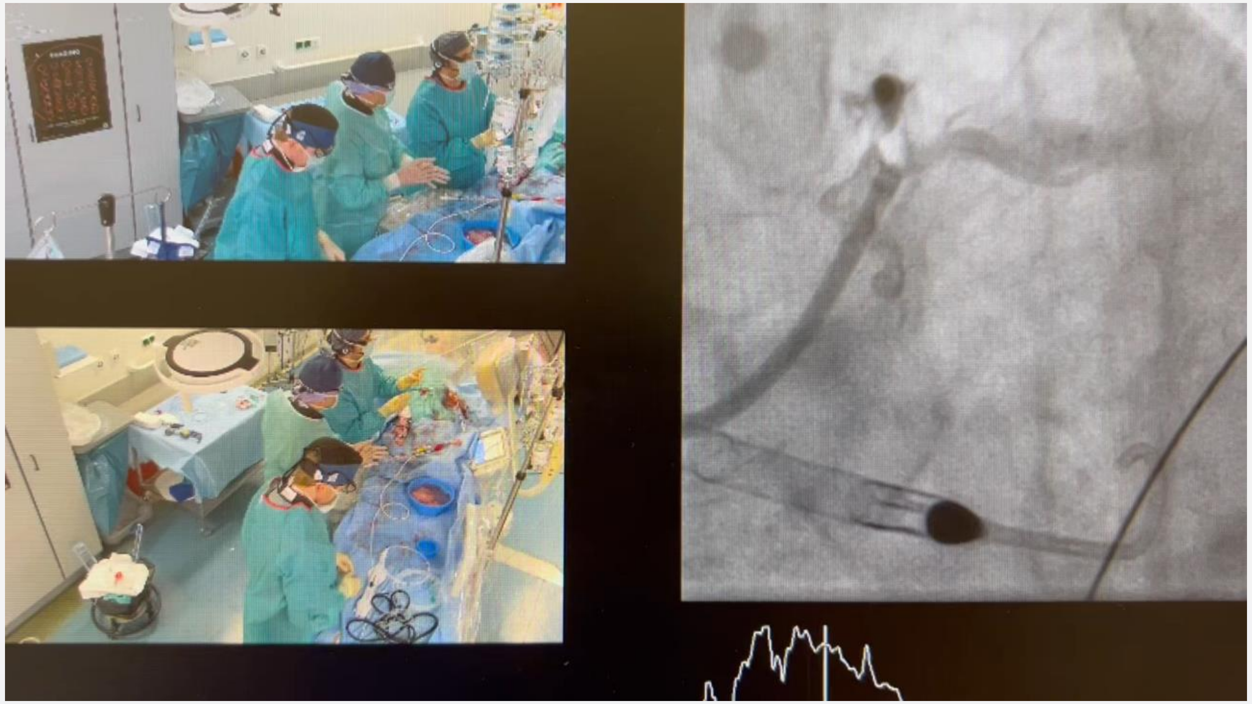
# Primary use of Rotablation for debulking

Rota Registry Bad Krozingen:16317 PCIs, 597 Rotablations (3,6%)

| | 2015 | 2016 | 2017 | 2018 | 2019 |
|---|---|---|---|---|---|
| % of Rota in PCI | **1,60%** | **1,97%** | **3,27%** | **4.71%** | **6,92%** |
| Numbers of Rota | 56 | 66 | 105 | 113 | 11 |
| Numbers of RotaPro | 0 | 0 | 0 | 30 | 216 |
| Burr Size used | | | | | |
| 1,25mm | 30,3% | 30,3% | 31,4% | 25,0% | 8,3% |
| 1,5mm | 46,4% | 24,2% | 32,6% | 45,8% | 49,7% |
| 1,75mm | 10,7% | 27,2% | 29,2% | 25,0% | 34,7% |
| 2,0mm | 12,5% | 18,2% | 6,7% | 4,2% | 6,2% |

# Newer plaque modification possibilities

*Rotablation / Shockwave / Super-High-Pressure*



# Feasibility and outcome of the Rotapro system in treating severely calcified coronary lesions: The Rotapro study

| | Total number (n=597) | Rotapro (n=246) | Rota (n=351) | P value |
|---|---|---|---|---|
| **Primary endpoint % (n)** | | | | |
| **In-hospital MACCE** | **(29) 4.9%** | **(9) 3.7%** | **(20) 5.7%** | **0.254** |
| **Mortality** | **(15) 2.5%** | **(6) 2.4%** | **(9) 2.6%** | **0.923** |
| MI Type 4a | (4) 0.7% | (17) 0.4% | (3) 0.9% | 0.647 |
| TVR | (20) 3.4% | (7) 2.9% | (13) 3.7% | 0.566 |
| Stroke | (17) 0.2% | (0) 0.0% | (17) 0.3% | 1.000 |
| **Secondary procedural endpoints % (n)** | | | | |
| Technical success | (589) 98.7% | (244) 99.2% | (345) 98.3% | 0.385 |
| Procedural Success | (568) 93.8% | (237) 95.5% | (331) 92.6% | 0.318 |
| Procedural time (min) | 88 [62 – 132] | 82.5 [57 – 119] | 96 [67 -146.5] | 0.0003* |
| Fluoroscopy time (min) | 34 [23 – 56] | 30 [21 – 50] | 38 [25 - 63.5] | 0.0001* |
| Contrast volume used (ml) | 250 [180 – 350] | 210 [160 -300] | 290 [150 - 380] | 0.0001* |
| Dose Area Product (cGy*cm2) | 8011 [4758 – 14062] | 6129.5 [3563 – 9939] | 9827 [6098 – 16402] | 0.0001* |
| **Major Complications % (n)** | | | | |
| Pericadiocentesis | (8) 1.3% | (2) 0.8% | (6) 1.7% | 0.348 |
| Vascular access complication | (13) 2.1% | (8) 3.45% | (5) 1.46% | 0.206 |

Ayoub M, …Mashayekhi K.Cardiol J. 2021 Oct 21.

# Patients with/without rotablation in the Bad Krozingen CTO DATABASE: 2789 patients with CTO PCI in stable Angina during 5 years (2015-2019)

| | CTO with Rotablation | CTO without Rotablation | |
|---|---|---|---|
| Total number of patients (%) | 193 (6.9%) | 2596 (93.1%) | 2789 (Patients) |
| Rota | 106 (55%) | | |
| RotaPro | 87 (45%) | | |
| History of CABG | 60 (33.5%) | 417 (16.7%) | <0.0001 |
| Procedural time in min. | 127 [94-186] | 81 [51-126] | <0.0001 |
| Fluoroscopy time in min. | 54 [35-80] | 35 [20-60] | <0.0001 |
| Contrast volume in cc | 310 [200-400] | 260 [190-390] | 0.0032 |
| Radiation dose in mGy | 1339 [806-2353] | 1762 [1231-2555] | 0.24 |
| Tamponade | 6 (3.1%) | 13 (0.5%) | <0.0001 |
| In-hospital MI SCAI | 24 (12.5%) | 142 (5.6%) | <0.0001 |
| In-hospital MI 4a | 3 (1.6%) | 47 (1.8%) | 0.80 |
| In-hospital MACCE | 8 (4.2%) | 72 (2.8%) | 0.27 |
| 3-year MACCE | 45 (23.3%) | 554 (21.3%) | 0.52 |



Ayoub… Mashayekhi, *J Clin Med*. 2023;12(10):3510

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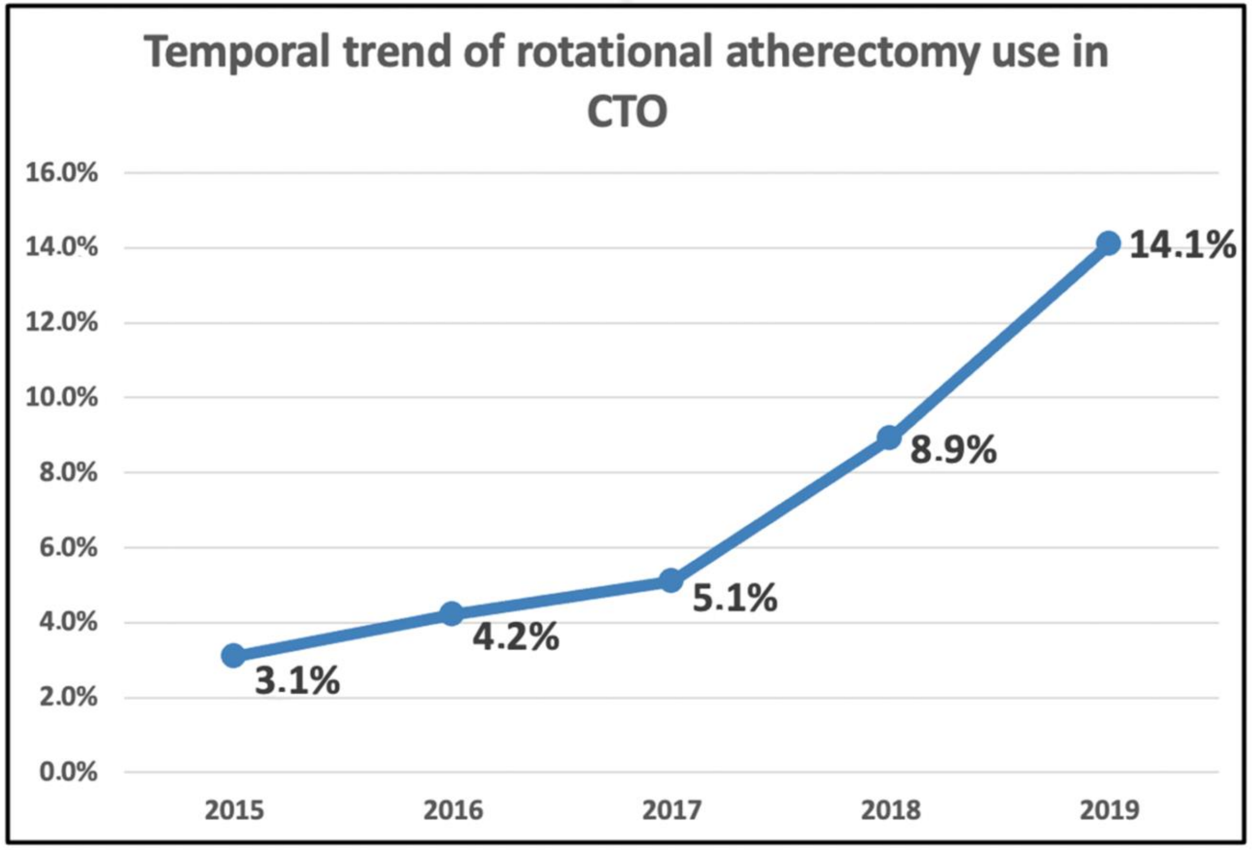
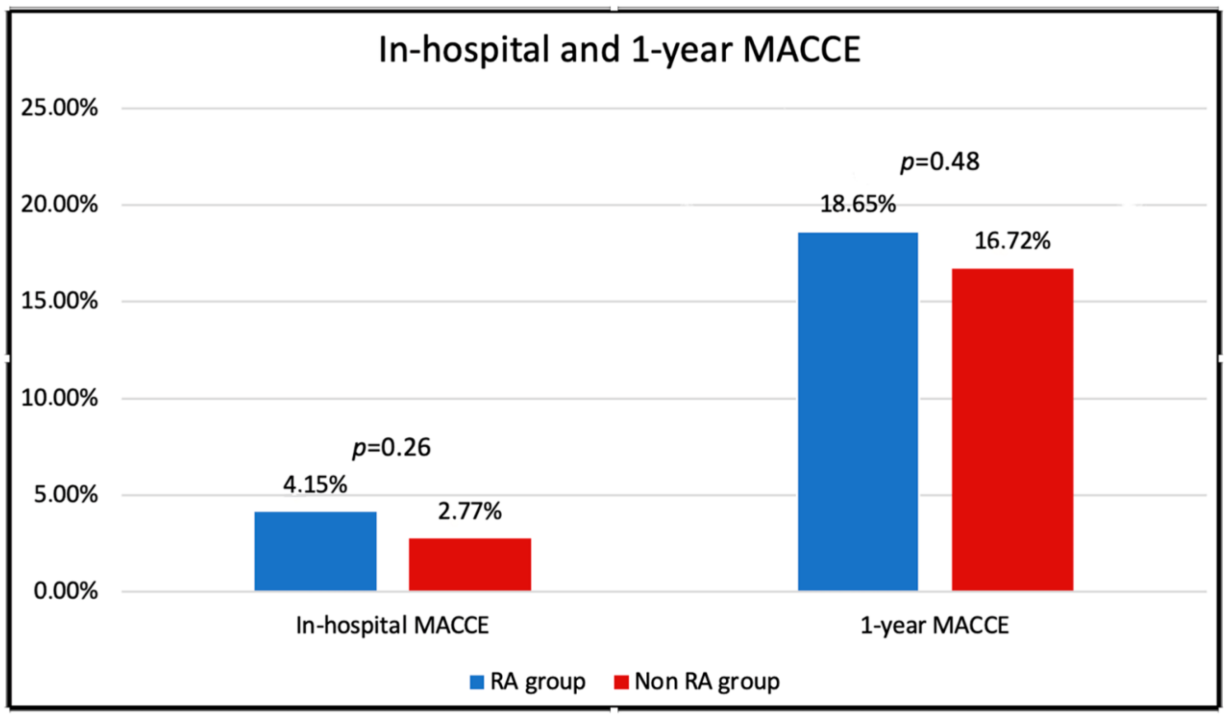



Ayoub… Mashayekhi, *J Clin Med*. 2023;12(10):3510

# Sex-Based Differences in Rotational Atherectomy and Long-Term Clinical Outcomes

**Table 3.** Clinical outcomes.

| Clinical Outcomes | All Patients (*n* = 597) | Women (*n* = 121) | Men (*n* = 476) | *p* Value |
|---|---|---|---|---|
| In-hospital MACCEs | 20 (3.3%) | 7 (5.8%) | 13 (2.7%) | 0.095 |
| In-hospital Mortality | 15 (2.5%) | 5 (4.1%) | 10 (2.1%) | 0.202 |
| In-hospital MI | [illegible] | [illegible] | [illegible] | [illegible] |
| In-hospital TVR | [illegible] | [illegible] | [illegible] | [illegible] |
| In-hospital Stroke | [illegible] | [illegible] | [illegible] | [illegible] |
| In-hospital TLR | [illegible] | [illegible] | [illegible] | [illegible] |
| Perforation | [illegible] | [illegible] | [illegible] | [illegible] |
| Pericardiocentesis | [illegible] | [illegible] | [illegible] | [illegible] |
| Bleeding | [illegible] | [illegible] | [illegible] | [illegible] |
| eGFR max. post-Rota | 68.6 ± 21 | 63.9 ± 21 | 70.6 ± 22 | 0.002 |
| 1-year MACCEs | 130 (21.8%) | 24 (19.8%) | 106 (22.3%) | 0.562 |
| 3-year MACCEs | 155 (25.96%) | 32 (26.45%) | 123 (25.84%) | 0.018 |

eGFR = estimated glomerular filtration rate, MACCEs = major adverse cardiac and cerebrovascular events, MI = myocardial infarction, TLR = target lesion revascularization, TVR = target vessel revascularization.

**Table 4.** Univariate and multivariate predictors of 3-year MACCEs in total cohort assessed by Cox regression analysis.

| a: Cox Regression Analysis for Predictors of MACCEs | | | | | | |
|---|---|---|---|---|---|---|
| | Univariate Analysis | | | Multivariate Analysis | | |
| | HR | 95% CI | *p* Value | HR | 95% CI | *p* Value |
| [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | 0.76 |
| [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | 0.80 |
| [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | <0.001 |
| [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | 0.92 |
| [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | [illegible] | 0.44 |

| [illegible] | | | | ...nalysis | | |
|---|---|---|---|---|---|---|
| | HR | 95% CI | *p* Value | HR | 95% CI | *p* Value |
| Age (change per year) | 1.06 | 1.03–1.10 | <0.001 | 1.04 | 1.01–1.07 | 0.03 |
| Gender (female) | 1.82 | 1.07–3.10 | 0.03 | 1.42 | 0.79–2.56 | 0.24 |
| ACS | 5.10 | 3.11–8.37 | <0.001 | 2.33 | 1.58–3.43 | <0.001 |
| Diabetes mellitus | 1.27 | 0.76–2.14 | 0.37 | 1.22 | 0.73–2.22 | 0.47 |
| History of CABG | 1.06 | 0.61–1.85 | 0.84 | 1.27 | 0.8–1.67 | 0.40 |

**After adjustment, the female sex has not been confirmed to be an independent risk factor for the rate of MACCEs after RA PCI.**

Ayoub,…..Mashayekhi. *J Clin Med*. 2023;12(15):5044

# Safety and Long-Term Outcomes of Rotablation in Patients with Reduced (<50%) Left Ventricular Ejection Fraction (rEF)

## The Rota-REF Study

**Table 4.** Study endpoints, procedural results, and major complications in patients with rEF stratified for PCI and RA-PCI.

| | LVEF < 50% | | | |
|---|---|---|---|---|
| | **Total Number (*n* = 4941)** | **PCI (*n* = 4744)** | **Rota (*n* = 197)** | ***p*-Value** |
| Primary endpoint % (*n*) | | | | |
| Procedural Success | 93.10% (4600) | 93.1% (4418) | 92.4% (182) | 0.687 |
| Technical success | 96.1% (4748) | 96% (4555) | 98% (193) | 0.482 |
| In-hospital MACCE | 4% (200) | 3.9% (185) | 7.6% (15) | 0.009 * |
| Mortality | 2.5% (125) | 2.4% (116) | 4.6% (9) | 0.062 |
| MI SCAI | 16.07% (785) | 15.38% (751) | 17.26% (34) | 0.548 |
| TVR | 3.4% (167) | 3.3% (156) | 5.6% (11) | 0.080 |
| Stroke | 0.26% (13) | 0.25% (12) | 0.5% (1) | 0.411 |
| TLR | 3.2% (160) | 3.1% (149) | 5.6% (11) | 0.057 |
| 1-year MACCE | 18.84% (931) | 18.74% (889) | 21.32% (42) | 0.364 |
| 3-year MACCE | 26.6% (1314) | 26.6% (1262) | 26.4% (52) | 0.949 |
| No flow (TIMI 0) | 0.5% (26) | 0.5% (24) | 1% (2) | 0.27 |
| Slow flow (TIMI 1 or 2) | 4.9% (244) | 5% (239) | 2.5% (5) | 0.11 |

**Table 4.** Study endpoints, procedural results, and major complications in patients with rEF stratified for PCI and RA-PCI.

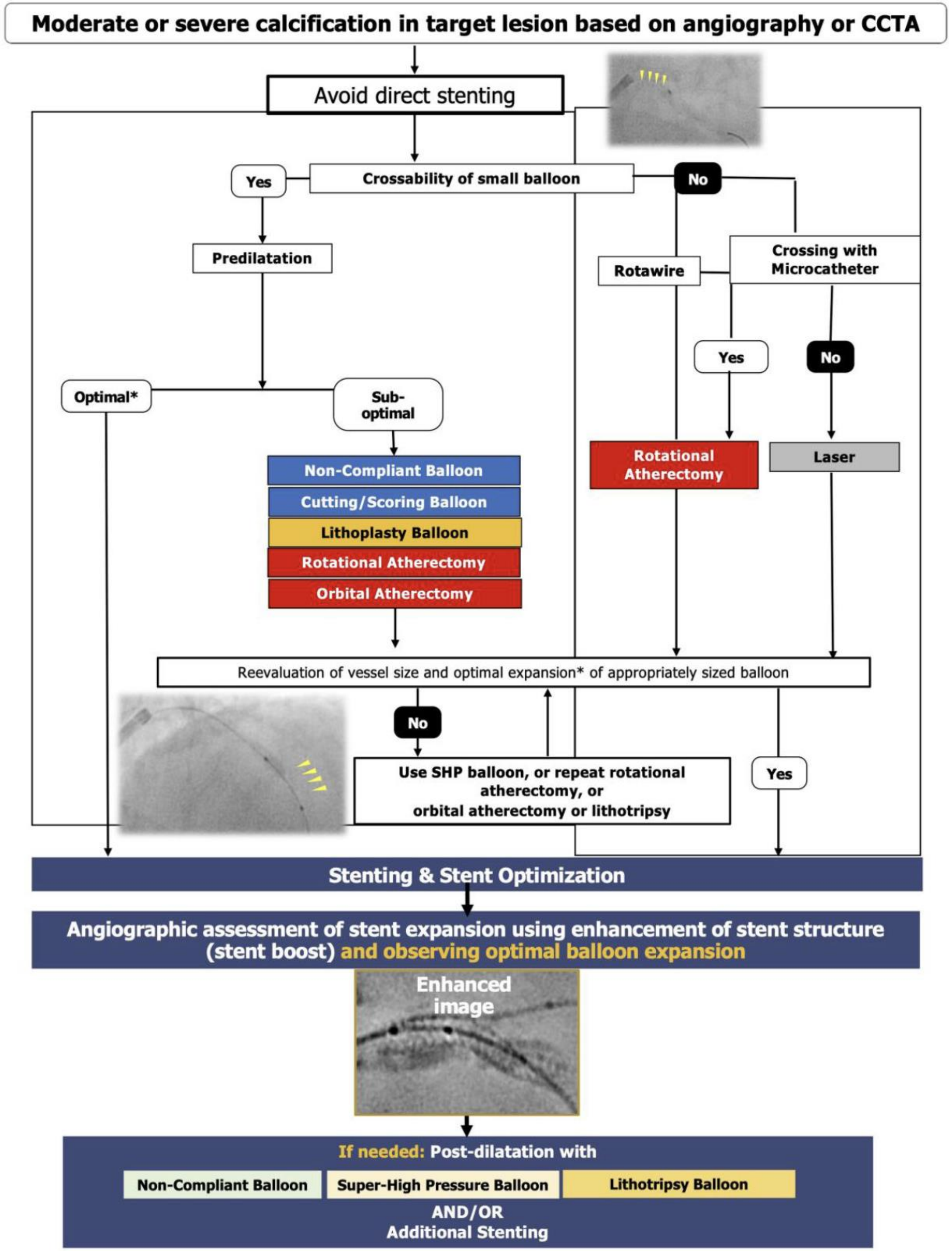
| | LVEF < 50% | | | |
|---|---|---|---|---|
| | **Total Number (*n* = 4941)** | **PCI (*n* = 4744)** | **Rota (*n* = 197)** | ***p*-Value** |
| Secondary procedural endpoints % (*n*) | | | | |
| Procedural time (min) | 44 (26–75) | 42 (26–72) | 100 (70–136.5) | 0.0001 * |
| Fluoroscopy time (min) | 16 (10–29) | 16 (9.5–28) | 39 (27–62.5) | 0.0001 * |
| Contrast volume used (mL) | 197.5 (150–270) | 190 (150–260) | 250 (182.5–345) | 0.0001 * |
| Dose Area Product (cGy · cm$^2$) | 5991 (3635–9863) | 5884.5 (3492–9669) | 9137 (5516–15,921) | 0.0001 * |
| Major Complications % (*n*) | | | | |
| Pericardiocentesis | 0.28% (14) | 0.23% (11) | 1.5% (3) | 0.0008 * |
| Vascular access complication | 1.74% (63) | 1.69% (60) | 3.75% (3) | 0.1608 |

Ayoub,… Mashayekhi, The Rota-REF Study. *J Clin Med*. 2023;12(17):5640.

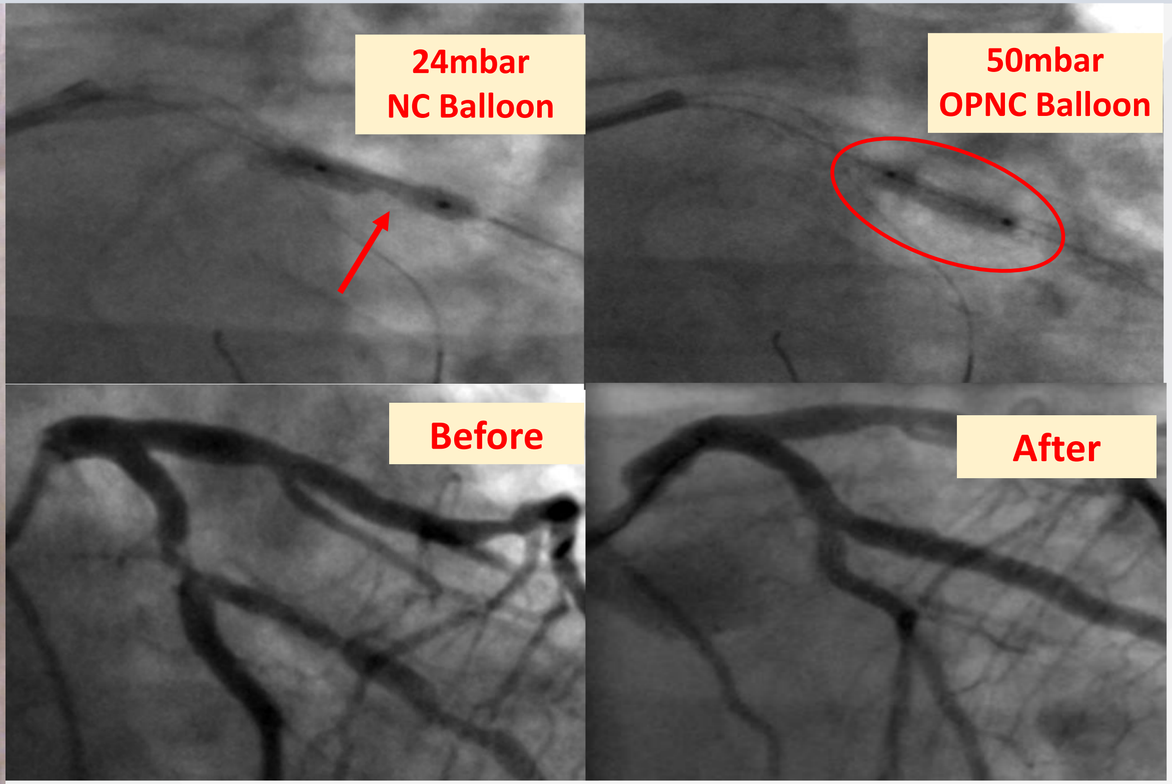
ESC European Society of Cardiology
European Heart Journal (2023) 00, 1–17
https://doi.org/10.1093/eurheartj/ehad342
FASTTRACK CLINICAL RESEARCH
*Interventional cardiology*

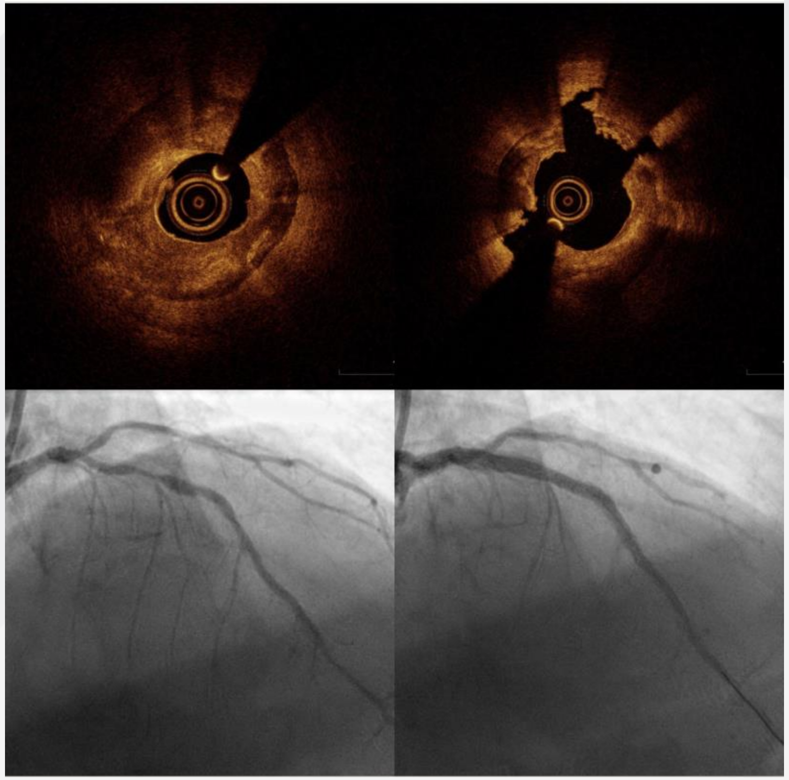
# Management strategies for heavily calcified coronary stenoses: an EAPCI clinical consensus statement in collaboration with the EURO4C-PCR group

**Emanuele Barbato [1]*, Emanuele Gallinoro [2], Mohamed Abdel-Wahab [3], Daniele Andreini [2,4], Didier Carrié [5], Carlo Di Mario [6], Dariusz Dudek[7], Javier Escaned [8], Jean Fajadet[9], Giulio Guagliumi[10], Jonathan Hill[11], Margaret McEntegart[12,13], Kambis Mashayekhi[14], Nikolasos Mezilis[15], Yoshinobu Onuma[16,17], Krzyszstof Reczuch[18], Richard Shlofmitz [19], Giulio Stefanini[20], Giuseppe Tarantini [21], Gabor G. Toth[22], Beatriz Vaquerizo [23], William Wijns[24], and Flavio L. Ribichini[25]**



# Ultra-High-Pressure Balloon OPN NC (SIS Medical)

| SIS MEDICAL 40atm Inflation Device | SIS MEDICAL 55atm Inflation Device |
|---|---|
| For standard and high pressure PTCA up to 40 atm | For super high pressure PTCA up to 55 atm |

# OPN NC – Clinical Evidence

2010

- ***The OPN NC can result in successful expansion of lesions and stents in which other standard noncompliant balloons have failed.***
  Raja Y., Routledge H. and Doshi S. A Noncompliant, High Pressure Balloon to Manage Undilatable Coronary Lesions. Catheterization and Cardiovascular Interventions 75:1067–1073 (2010).

2015

- ***Our group recently reported the safety and efficacy of OPN balloons for treatment with DES of highly resistant coronary lesions nonresponsive to conventional NC balloon inflation. Postdilatation with high pressure NC OPN balloon did not cause any BVS strut disruption.***
  Fabris E., Caiazzo G., Kilic I., Serdoz R., Secco G., Sinagra G., Lee R., Foin N. and Di Mario C. Is High Pressure Postdilation Safe in Bioresorbable Vascular Scaffolds? Optical Coherence Tomography Observations after noncompliant Balloons Inflated at More than 24 Atmospheres. Catheterization and Cardiovascular Interventions (2015).
- ***The OPN NC high pressure balloon is a plain rapid exchange PTCA catheter which can be easily used in case of the failure of conventional balloons, providing a safe and easy alternative strategy in case of failure of conventional NC balloon dilatation.***
  Secco G., Ghione M., Mattesini A., Dall'Ara G., Ghilencea L., Kilickesmez K., De Luca G., Fattori R., Parisi R., Marino P., Lupi A., Foin N. and Di Mario C. Very high pressure dilatation for undilatable coronary lesions: indications and results with a new dedicated balloon. EuroIntervention (2015).
- ***BVS are the future of coronary intervention but have to be implanted properly. Therefore, good pre- and post-dilatation using highly non-compliant balloons such as the OPN NC is necessary in order to achieve maximal luminal area and good scaffold expansion as well as to avoid scaffold thrombosis.***
  Cuculi F. Lesion preparation for bioresorbable scaffolds (and DES). (2015).

2016

- ***Noncompliant high-pressure balloon, (the OPN NC balloon) may still be considered preliminary to DES implantation in case of undilatable ISR lesions due to unexpanded stents or severe calcified intra stent neoatherosclerosis.***
  Moscarella E., Ielasi A., Cortese B. and Varricchio A. Coronary In-stent restenosis: Where are we Now? Ann Vasc Med Res 3(2): 1033 (2016).
- ***Good pre- and post-dilatation needs to be performed in order to achieve maximal scaffold expansion and full apposition. After aggressive post-dilatation with a OPN NC balloon at 35atm, a much better expansion of the scaffold can be observed.***
  Jamshidi P., Nyffenegger T., Sabti Z., Buset E., Toggweiler S., Kobza R. and Cuculi F. A novel approach to treat in-stent restenosis: 6- and 12-month results using the everolimus-eluting bioresorbable vascular scaffold. EuroIntervention; 11:1479-1486 (2016).

# OPN NC – Clinical Evidence

2017

- ***The OPN NC is a very interesting alternative to the classical noncompliant balloons, minimizing the risk of a restenosis or thrombosis. The double balloon technology ensures a uniform expansion of the balloon without dog-boning effect and therefore reduces the risk of vessel wall damage.***
  Karsenty, B. Lésion résistante. Place du ballon à très hautes pressions OPN NC. CathLab, No 39, 10-11 (2017).

2019

- ***The unique possibility offered by the OPN super high-pressure dedicated balloon provides an effective, easy and safety strategy for treatment of resistant coronary lesions non-responsive to conventional NC balloon dilatation.***
  Secco G., Buettner A., Parisi R., Pistis G., Vercellino M., Audo A., Chen J., Castriota F., Garbo R., Marino P., Di Mario C. Clinical Experience with Very High Pressure Dilatation for Resistant Coronary Lesions. Catheterization and Cardiovascular Interventions.

2020

- ***Proof that the OPN NC is safe and superior to all other devices used for the treatment for calcified lesions.***
  OPreNBiS Study. Optimal Lesion Preparation With Non-compliant Balloons Before Implantation of Bioresorbable Scaffolds
  Randomized study. Finalized and submitted for publications.

- ***A prospective randomized controlled trial of Super High-Pressure NC PTCA Balloon (OPN NC) versus Scoring PTCA Balloon (NSE Alpha) in severely calcified coronary lesions. The aim of the study is to show superiority in terms of effectiveness and outcome of the OPN NC vs. Scoring Balloons.***
  ISAR Calc. all patients enrolled; Published.

In prog.

- ***Effectiveness and safety of the OPN NC in calcified and highly calcified lesions.***
  OPeNIndia registry. Post market surveillance registry; up to 1,000 patients. Start in Q1/2019; expected finalization by the end of 2020.

Planned

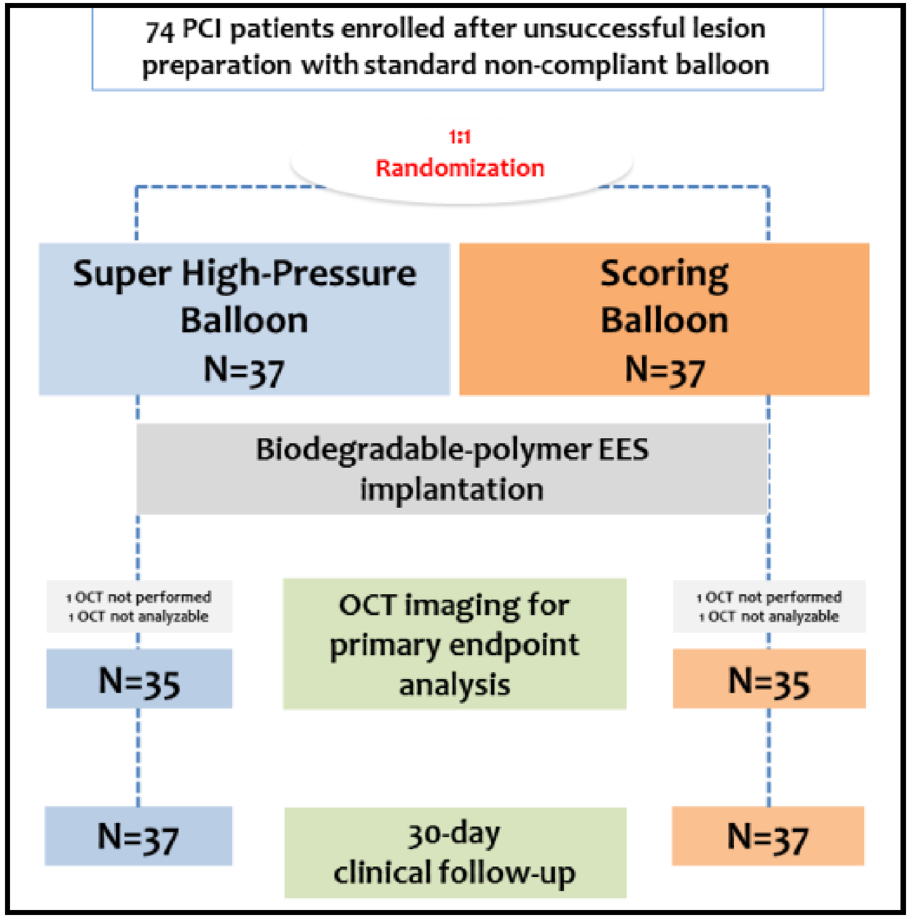
- ***In stent restenosis treatment by use of OPN NC.***
  ISAR-INSPIRE study: waiting for ethical vote

# The ISAR-CALC randomized trial

## Study flow

### Inclusion criteria

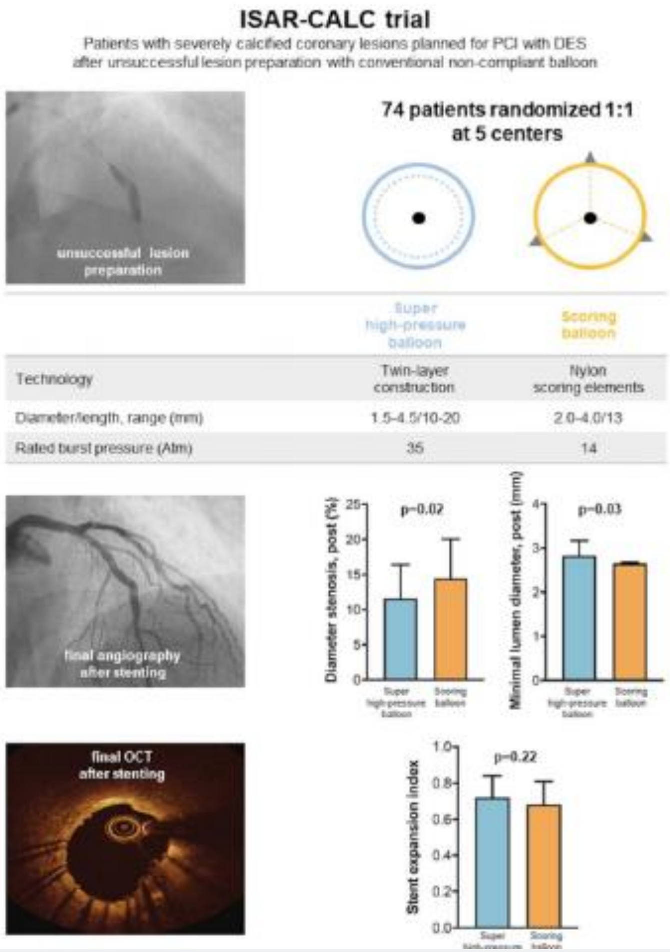
- Age above 18 years and consentable
- Persistent angina despite optimal medical therapy and/or evidence of inducible ischemia
- Angiographically-proven coronary artery disease
- **De-novo lesion** in a native coronary artery
- Target reference vessel diameter between 2.25 and 4.00 mm by visual estimation
- **Severe calcification** of the target lesion as determined by visual estimation at angiography
- **Unsuccessful lesion preparation with standard non-compliant balloon** (<30% reduction of baseline diameter stenosis at maximal pressure)
- Written informed consent




### Exclusion criteria

- Myocardial infarction (within 1 week)
- Target lesion is located in a coronary artery bypass graft
- Target lesion is an in-stent restenosis
- Target lesion is aorto-ostial
- Target vessel thrombus
- Limited long-term prognosis due to other conditions

# The ISAR-CALC randomized trial




## Conclusions

- High strategy success rates with ballon-based techniques
- Super high-pressure balloon versus scoring balloon led to comparable stent expansion as assessed with OCT imaging
- Trend towards improved angiographic performance with super high-pressure balloon (increased final MLD and reduced residual stenosis)
- Relevant rates of peri-procedural complications and adverse clinical events up to 30 days reflect the procedural complexity

Rheude et al. EuroIntervention 2020

# Use of Super High Pressure Balloon in Complex Percutaneous Coronary Interventions

## Results of an Expert Registry 2015 - 2020

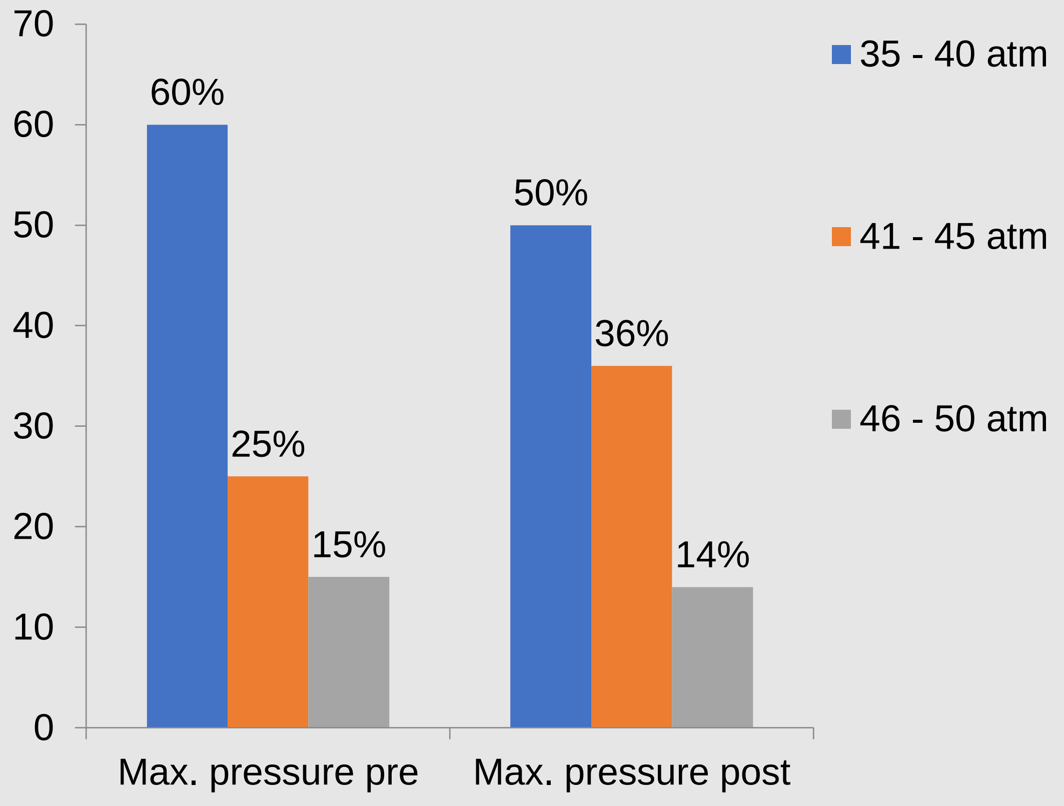
| Variable | Overall (n=15.812) | Total number | OPN (n=529) | Total number | NC (n=15.283) | P value |
|---|---|---|---|---|---|---|
| Technical Success | 99.6% | 551 | 99.3% | 15220 | 87.2% | 0.255 |
| Procedural Success | 97.7% | 517 | 97.7% | 14924 | 86.2% | 0.904 |
| Procedural Time (min) | 40 (24, 68) | | 65 (41, 106) | | 40 (24, 66) | <0.0001* |
| Fluoroscopy Time (min) | 15 (9, 25) | | 25 (15, 43) | | 15 (9, 25) | <0.0001* |
| Contrast Volume (mL) | 190 (150, 250) | | 220 (160, 300) | | 190 (150, 250) | <0.0001* |
| Dose Area Product (cGy*cm2) | 5317 (3144, 8823) | | 7400 (4101, 13287) | | 5284 (3125, 8688) | <0.0001* |
| MACE (4th Univ. Def. MI) | 1.9% | 8 | 1.5% | 299 | 2.0% | 0.467 |
| Death | 1.2% | 4 | 0.8% | 181 | 1.2% | 0.534 |
| Stroke | 0.1% | 0 | 0.0% | 19 | 0.1% | 1.000 |
| Acute MI (4th Univ. Def.) | 0.3% | 1 | 0.2% | 39 | 0.3% | 1.000 |
| TLR | 1.7% | 7 | 1.3% | 262 | 1.7% | 0.494 |
| TVR | 1.8% | 8 | 1.5% | 280 | 1.8% | 0.589 |
| Pericardial Tamponade Requiring Treatment | 0.3% | 0 | 0.0% | 44 | 0.3% | 0.405 |
| Vascular Access Complication | 1.5% | 7 | 2.3% | 171 | 1.5% | 0.253 |
| Bleeding | 2.4% | 14 | 2.8% | 351 | 2.4% | 0.539 |
| Perforation | 0.9% | 9 | 1.7% | 123 | 0.8% | 0.026* |
| 30-day MACE | 1.0% | 13 | 2.5% | 150 | 1.0% | 0.001* |
| 1-year MACE | 11.9% | 109 | 20.6% | 1771 | 11.6% | <0.0001* |

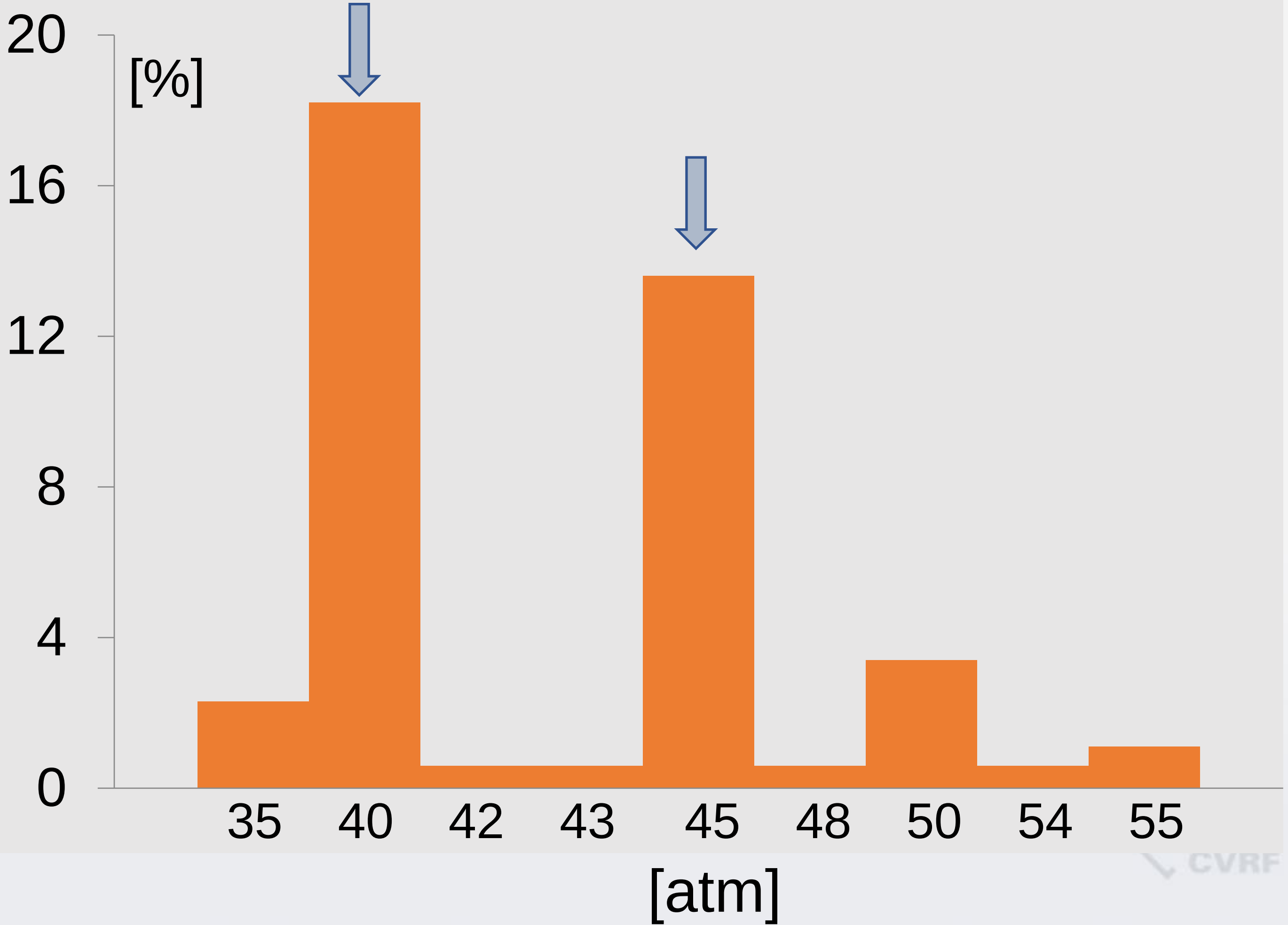


Mashayekhi, unpublished data 2024

# Results of an Expert Registry

*Distribution of maximum OPN NC balloon pressures*



# Conclusion

- Ablative and balloon-based techniques are commonly used for plaque modification of calcified lesions
- The utilization of atherectomy techniques is continuously increasing
- Rotablation is a safe and effective technique, resulting in an effective debulking of calcified plaque
- Balloon-based techniques are effective for cracking deep calcified plaques
- Clinical data of super-high-pressure balloon angioplasty demonstrating efficiency and safety
- Finally, all plaque modification tools are complementary and necessary in the armamentarium of every complex PCI operator