COPS

Cutting balloon to Optimize Predilatation for Stenting

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On behalf of Antonio Colombo and the COPS investigators

Background (i)

- Coronary artery calcifications (CAC) represent a challenge to percutaneous coronary interventions (PCI) by limiting stent expansion and increasing the probability of stent failure at follow-up.

- In the modern era, a number of calcium modification techniques have been introduced with variable success with the aim to improve acute and long-term outcomes of PCI.

Background (ii)

- The Wolverine cutting balloon (CB) is non compliant, rapid-exchange balloon with three or four microblade mounted on its surface that facilitate calcium cracking

- The actual recommendation for the usage of CB suggest inflations at nominal pressures.

- Data comparing CB inflated at high pressure instead of nominal pressure in coronary calcifications are lacking

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COPS trial

Cutting balloon to **O**ptimize **P**redilatation for **S**tenting

Prospective, randomized, multicenter open-label trial which enrolled 100 patients with significant calcified lesions evaluated at IVUS

Randomization 1:1

Cutting balloon	**Non-compliant Balloon**
n=50	n=50

Study Participants

- **Study PI**: Antonio Mangieri, Roberto Nerla
- **Senior study PI**: Antonio Colombo

- **Humanitas Rozzano:** PI: Benrhard Reimers; Co PI: Damiano Regazzoli, Gabriele Gasparini
- **MCH Cotignola**: Co PI: Fausto Castriota, Francesco Giannini
- **Clinical Mediterranea Napoli:** PI: Carlo Briguori, Co PI: Andrea Bezzecheri, Fulvio Casale

- **Statistical Analysis:** Pier Pasquale Leone, Montefiore Hospital
- **Corelab Analysis:** Arif Khokhar, Hammersmith Hospital

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Key inclusion criteria

- Severe de novo calcified coronary lesions
- A reference vessel diameter between 2.5 and 4.0 mm and deemed suitable for PCI
- **An arch of calcium at baseline IVUS of at least 100 degrees**

Key exclusion criteria

- In stent restenosis
- Safenous vein graft lesions
- STEMI
- Comorbidities which preclude the achievement of one-year follow-up

Endpoints

Primary Endpoint :

Minimal stent area (MSA) at calcium site

Secondary Endpoints :

1) **Eccentricity index** : $(LD_{max} - LD_{min}) / LD_{max}$
2) **MSA**
3) **Device failure**: unsuccessful device delivery and/or inflation resulting in inadequate lesion preparation and/or damage of the vessel as consequence of device usage.
4) **Vessel perforation**, rate of major adverse cardiovascular events (**MACE**) and target lesion revascularization (**TLR**) at one-year follow-up.

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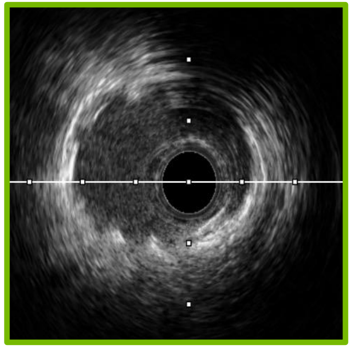
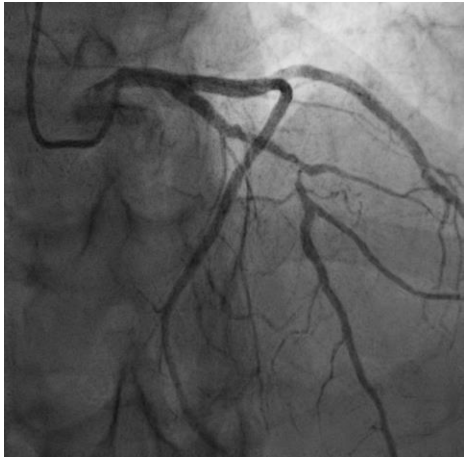
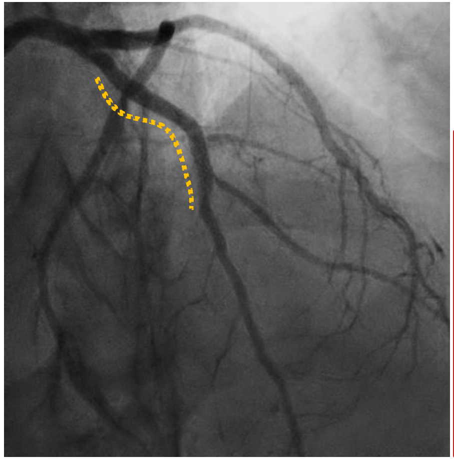
Endpoints

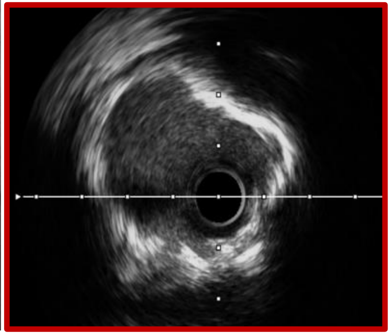
Overall stent MSA: 7.2 mm²

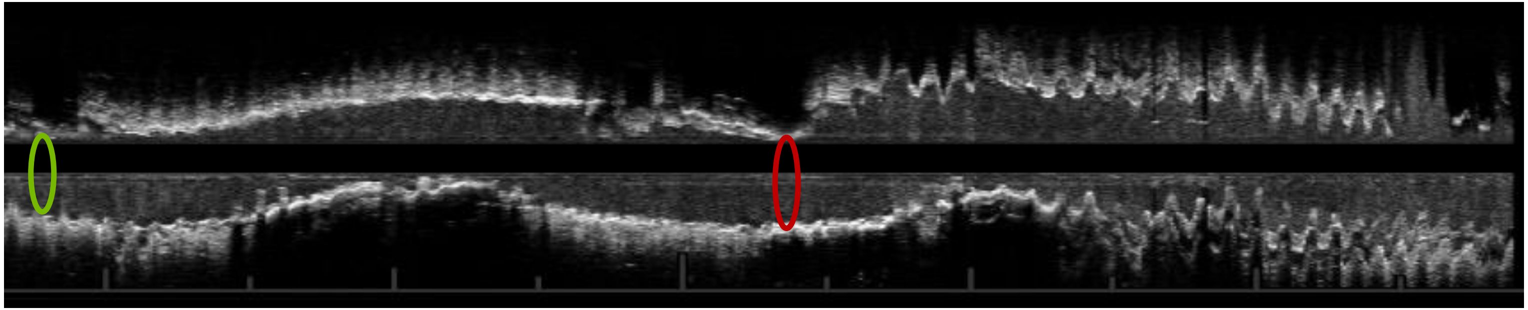






MSA at calcium site: 8.3 mm²





Methods

- **Assumptions:** we hypothesize a mean and standard deviation of MSA at calcium site of 5.0 ± 1.5 mm for the high-pressure CB lesion preparation vs. 4.0 ± 1.5 mm 2 for the NCB, a sample size of 36 patients per group was calculated to meet the primary endpoint requirements with a power of 80% and a two-sided alpha level of 0.05
- The **sample size** proposed was 50 patients in each group to further increase the power and account for possible protocol deviations.
- IVUS evaluation was performed by an independent corelab
- A downsizing of 0.5 mm compared to the media-to-media diameter on IVUS was recommended when CB was inflated at high pressures

The COPS trial was supported by an institutional grant by Boston Scientific, who had no responsibility for study management, data collection and monitoring

Study Flow Chart

September 2019-June 2021
100 patients enrolled

n=13 patients excluded for major protocol deviations

n=6 in the CB group
n=7 un the NCB group

n=87 patients included in the final analysis

Per protocol analysis

n=44 patients treated with cutting balloon

n=43 patients treated with non-compliant balloon

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Results

	Overall	CB (n=44)	NCB (n=43)	P value
Age	71±7.6	70.8±6.7	72.5±4.3	0.35
Female sex	16 (18.3)	11 (25)	5 (11.6)	0.166
Hypertension	70 (82.3)	31(73.8)	39 (90.7)	0.051
Diabetes	29 (34.5)	16 (39.2)	13 (30.2)	0.491
Hypercholesterolemia	63 (73.2)	30 (71.4)	33 (75)	0.809
Prior MACE	4 (4.71)	2 (4.8)	2 (4.5)	0.874
Chronic renal failure	9 (10.4)	6 (14.2)	3 (6.8)	0.258
Previous PCI	22 (25.8)	11 (26.2)	11 (25.5)	0.49
Previous CABG	10 (11.6)	4 (9.5)	6 (13.6)	0.739
LVEF (%)	54±5.6	55±8.8	53±3.9	0.343
UA/NSTEMI	5 (5.9)	4 (10.0)	(2.2)	0.187

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Results

	Overall	CB (n=44)	NCB (n=43)	P value
Type of lesion				0.484
Type B1	25 (28.7)	14 (32.5)	11 (25)	
Type B2/C	62 (71.2)	29 (67.4)	33 (75)	
Calcium distribution				0.482
Mixed Calcium	34 (40)	15 (34.8)	19 (45.2)	
Deep Calcium	25 (29.4)	15 (34.8)	10 (23.8)	
Superficial Calcium	26 (30.5)	13 (30.2)	13 (30.9)	
Arch of calcium (degrees)	266±84	274±84	258±85	0.373
Calcium length (mm)	12±6.6	11.9±7.3	12.5±6	0.667
Lesion length (mm)	24.3±9.7	23.5±9.6	25.1±9.8	0.442
Minimal lumen area (mm^2)	3.2±0.9	3.4±1.1	3±0.7	0.02
QCA evaluation				
Reference vessel diameter (mm)	3.4±0.4	3.51±0.3	3.39±0.4	0.112
Percentage of stenosis (%)	81.2±8.1	79.4±7.6	82.7±8.3	0.97

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Results

	Overall	CB (n=44)	NCB (n=43)	P value
Pre dilatation atmospheres	18.6±4.7	18.3±5	19±4.5	0.463
Number of stent implanted	1.3±0.4	1.3±0.5	1.2±0.4	0.314
Total Stent Length (mm)	32.9±12	31.6±12	34.2±12	0.837
Stent Diameter (mm)	3.3±0.4	3.4±0.3	3.3±0.4	0.737
Post dilatation	67 (77)	33 (75)	34 (79)	0.885
Diameter of the balloon for post dilatation	3.5±0.5	3.6±0.6	3.5±0.4	0.497
Balloon to artery ratio	0.89±0.2	0.86±0.1	0.92±0.2	0.057
Post dilatation atmospheres	20.9±0.6	20±5.2	21.7±5.4	0.201

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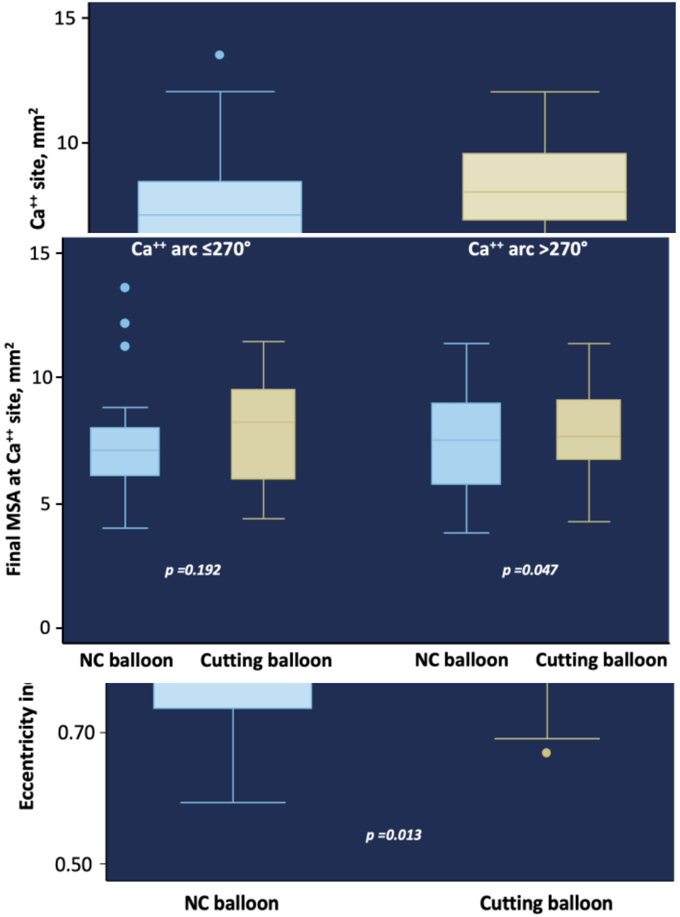
Results

	CB (n=44)	NCB (n=43)	P value
Final MSA (mm^2)	7.1±1.7	6.5±2.1	0.116
Minimal Stent Diameter	2.7±0.4	2.5±0.4	0.064
Maximal Stent Diameter	3.2±0.4	3.1±0.4	0.189
Final MSA at calcium site	8.1±2	7.3±2.1	0.035
Minimal stent diameter at calcium site	2.9±0.7	2.7±0.4	0.016
Maximal stent diameter at calcium site	3.5±0.5	3.3±0.4	0.132
Eccentricity index at calcium site	0.84±0.7	0.8±0.8	0.013

Benefit of cutting balloon are evident in lesions with > 270º of calcium



Results

	Overall	CB (n=44)	NCB (n=43)	P value
Device failure	3 (3.4)	3 (6.8)	0 (0)	0.517
Additional use of rotational atherectomy	1 (1.1)	1 (2.2)	0 (0)	0.79
Ellis type 1 vessel rupture	2 (2.2)	2 (4.4)	0 (0)	0.189
Implantation of a covered stent	1 (1.1)	1 (2.2)	0 (0)	0.65
Final TIMI flow >3	87 (100)	44 (100)	43 (100)	0.854
One year Follow-up				
Deaths	3 (3.4)	1 (1.1)	2 (4.6)	0.342
Cardiac deaths	1 (1.1)	0 (0)	1 (2.3)	0.887
Stroke	0 (0)	0 (0)	0 (0)	0.91
MI	0 (0)	0 (0)	0 (0)	0.96
TLR	3 (3.4)	1 (1.1)	2 (4.6)	0.49

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Limitations

- The study was performed in calcified lesions in which device crossability can be hampered. To perform baseline IVUS run, operators could pre dilatate the lesion with undersized balloons to facilitate the delivery of devices. This adjunctive maneuver could have biased the baseline IVUS findings.
- The open-label nature of the study could have potentially created some bias in the treatment methodology. In particular some operators were not confident in using the CB at high pressure and this could have had a potential influence on the study results.
- Potentially interesting variables such as fluoroscopy time, amount of contrast and some other complications such as periprocedural myocardial infarction were not reported in the database, thus potentially limiting the information about procedural complexity.

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Conclusions

- Treatment of calcified lesions with high pressure CB results in a larger MSA and more symmetric stent expansion at the level of the calcified segment compared to NCB.
- The use of CB compared to standard NCB angioplasty appears to be feasible even when inflated at high pressure
- The benefit of lesion preparation with CB is more pronouced in presence of severe calcifications
- Larger studies should investigate the use of CB in different type of lesions (fibrotic lesions, bifurcations, mild-moderate calcifications?)