

Optimizing PCI Specialty Balloon Use

Top tips for when and how to use drug-coated balloons, super-high-pressure balloons, and cutting and scoring balloons in percutaneous coronary intervention.

With Pier Pasquale Leone, MD, MSc; Antonio Colombo, MD; Matteo Maurina, MD; Valeria Paradies, MD; Ottavia Cozzi, MD; Antonio Mangieri, MD; Gabriele Gasparini, MD; and Damiano Regazzoli, MD

Drug-Coated Balloons

By Pier Pasquale Leone, MD, MSc, and Antonio Colombo, MD

The ability to deliver effective antiproliferative drug to the coronary vessel wall via drug-coated balloon (DCB) angioplasty without any remaining permanent foreign body is appealing in multiple scenarios within the percutaneous coronary intervention (PCI) panorama, and an appropriate strategy should regularly be implemented to maximize efficacy.¹

WHEN CAN DCB BE USED?

The evidence for DCB PCI is well established for in-stent restenosis (ISR) and de novo small vessel disease (often defined as ≤ 2.75 mm).² A promising level of observational data has been accruing for long lesions irrespective of vessel size, with the aim to avoid full-metal jacket, particularly for the left anterior descending artery. Data from randomized controlled trials are also underway (NCT04893291, NCT04859985).^{3,4}

Additional indications emerging from the need to simplify treatment of increasingly complex and diffuse disease and from deeper acknowledgment of the relevance of vessel remodeling are bifurcation lesions and chronic total occlusions (CTOs). Appealing clinical indications for DCB are (1) high bleeding risk, given the possibility for a short dual antiplatelet therapy course; (2) diabetes mellitus, often associated with diffuse disease and given the increased risk of ISR; and (3) acute coronary syndrome, where proper vessel size might not be obvious (Figure 1).

HOW SHOULD DCB BE USED?

From a procedural point of view, our hypothesis is that DCB angioplasty prevents restenosis without the need to implant a drug-eluting stent (DES), if an adequate and stable lumen is obtained after lesion preparation. We hereby provide details on lesion preparation, result assessment, DCB angioplasty and, if planned or required, stenting.

Lesion Preparation

Optimal lesion preparation is key. This is particularly true in a DCB approach because the entire angioplasty is performed upon lesion preparation and the DCB serves the sole purpose of 360° delivery of an antiproliferative drug to the vessel wall. The goal is to achieve atherosclerotic plaque and intimal dissection without propagation onto media and adventitia.

We opt to routinely predilate crossable lesions via prolonged noncompliant (NC) balloon inflations with a 1:1 balloon-to-artery diameter ratio by angiography. The aim is full balloon expansion in two orthogonal fluoroscopic views.⁵ If recoil ensues, we support crossover to angioplasty with repeated, prolonged inflations at nominal pressure with specialty balloons such as scoring and cutting balloons. Conversely, if insufficient balloon expansion is observed due to heavy calcification, NC and specialty balloon inflation should be considered even at high pressure.⁶ A scoring or cutting balloon with a 1:1 balloon-to-artery diameter ratio on angiography can be first inflated repeatedly to nominal

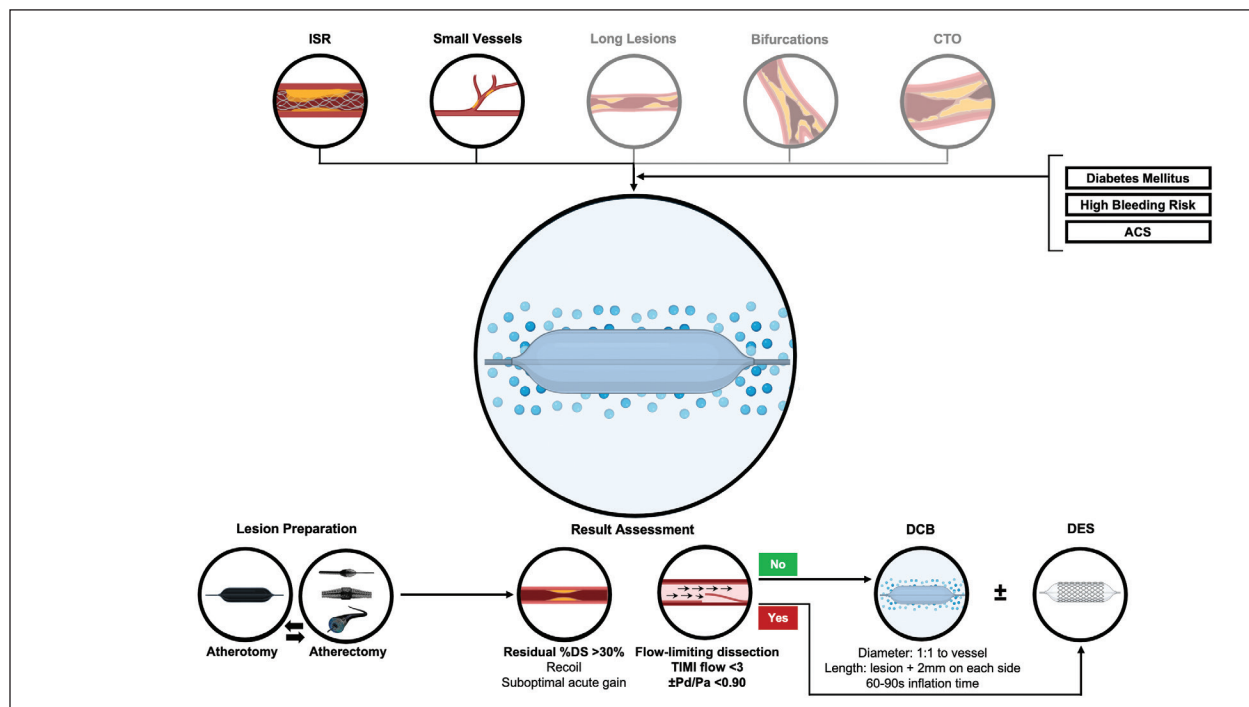


Figure 1. At the top, current and emerging (in opaque) indications for DCB PCI are highlighted. Clinical factors supporting the use of this approach are reported within the boxes on the right. At the bottom, a systematic approach to DCB PCI including lesion preparation, result assessment, and DCB angioplasty and/or stenting is suggested. Additional factors evaluated during result assessment include symptoms, electrocardiographic ischemic alterations, persistent contrast hang-up, and progressive luminal narrowing. ACS, acute coronary syndrome; DS, diameter stenosis; TIMI, thrombolysis in myocardial infarction.

pressure, favoring prolonged inflation to promote scoring/cutting plane shift. If high-pressure inflation is considered for nondilatable segments, one should consider NC, scoring, or cutting balloon undersizing by 0.5 mm on angiography or 1 mm on intravascular imaging (media-to-media).

Scoring or cutting balloon angioplasty should be preferred in the case of ISR. When adopted, NC balloons can be slightly upsized with respect to the previously implanted stent's diameter, especially if underexpansion is the underlying mechanism of stent failure.⁷ Gradual inflation of a super NC balloon (at up to 35 atm) or intravascular lithotripsy should follow in resistant cases. Atherectomy should be considered in device-uncrossable lesions and when proof of sufficiently severe calcification is available from angiography or intravascular imaging. It remains to be established whether early crossover to specialty balloons or atherectomy yields fewer and more benign dissections than high-pressure NC balloon inflation.

Result Assessment

Systematic evaluation of an adequate result includes assessment for significant recoil or inadequate acute lumen gain (ie, > 30% residual diameter stenosis). In addition, stability of the result is supported by absence of chest

pain, ischemic changes on electrocardiography, persistent contrast hang-up, progressive luminal narrowing, flow-limiting dissection, and thrombolysis in myocardial infarction flow < 3. In this situation, stent implantation may not be necessary (Figure 2).

When in doubt, we suggest using a pressure wire to evaluate the residual gradient across the dissected segment and recognize a threatening dissection (Pd/Pa [distal coronary/aortic pressure ratio] < 0.90) (Figure 1).⁸

Of note, wire withdrawal may help assess tortuous vessels by allowing the vessel to return to its proper shape. Rather than using intravascular imaging to guide assessment of dissection, we suggest using it to assess (1) plaque and calcium burden in complex lesions, (2) lumen gain in specific scenarios (such as ISR), and (3) vessel size in diffuse disease. Intravascular ultrasound is routinely preferred to avoid the rheolytic insult related to the high flow and volume injections needed for optical coherence tomography.

DCB Angioplasty

DCB angioplasty with a 1:1 balloon-to-artery diameter ratio and a length ≥ 2 mm longer than the predilated segment at either end should be planned. Uneventful delivery of the last used (and often bulkiest) balloon can be used as

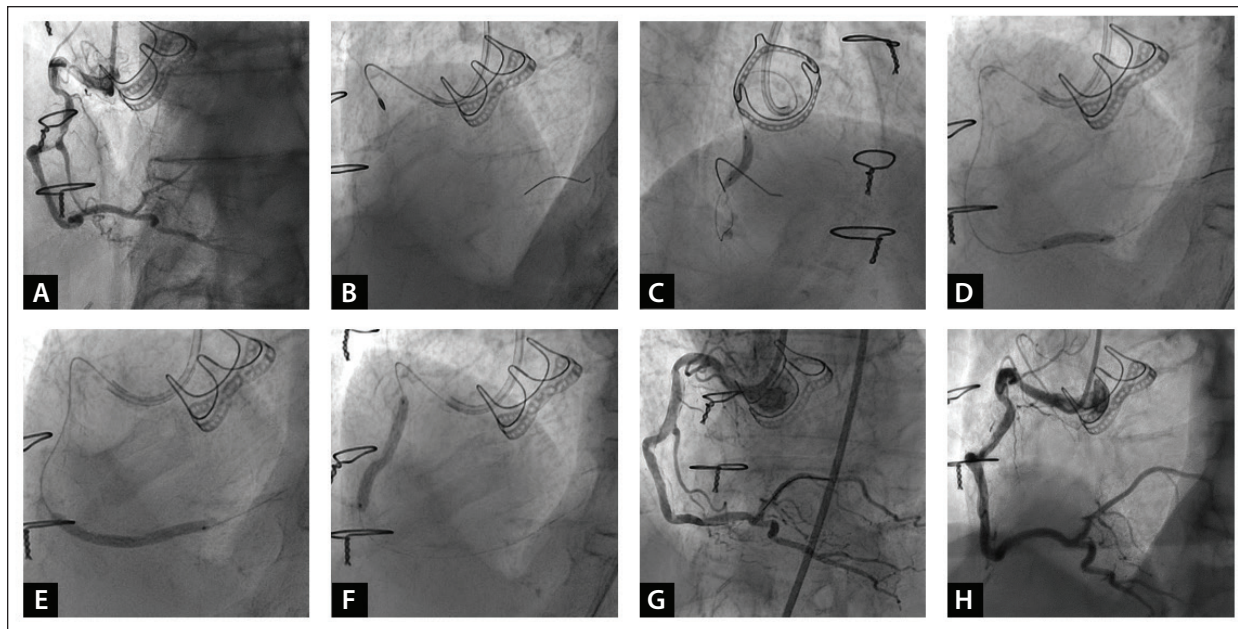


Figure 2. DCB angioplasty in a tortuous right coronary artery. Calcific lesions at the midproximal and distal segments of a tortuous diffusely diseased right coronary artery (A). Lesion preparation included rotational atherectomy with a 1.5-mm burr at the midproximal segment (B) and high-pressure, 3.5-mm NC balloon angioplasty along the vessel (C, D). Angioplasty with two sirolimus-coated 3.5- X 30-mm DCBs followed (E, F). Final angiography showed an adequate and stable result, with non-flow-limiting dissections at both segments (G). Spontaneous dissection healing and preserved lumen gain were evident at 1-month follow-up angiography (H).

proxy of sufficient support for DCB delivery. DCB delivery to the target lesion is time sensitive and should be performed in a pristine manner. Once positioned, it should be inflated to nominal pressure for 60 to 90 seconds to ensure adequate drug delivery (Figure 1). There is no evidence to support repeated inflation to optimize drug delivery or whether lesion modification with specialty balloons such as scoring or cutting balloon might improve diffusion of antiproliferative agents. Result assessment should follow similarly to that occurring after lesion preparation. Although no signs of inadequate or unstable result should be expected after the low-pressure DCB inflation, PCI may proceed with additional lesion preparation and DCB angioplasty or stent implantation according to case specifics.

Stenting

Stenting should be considered in the presence of inadequate or unstable result, with the goal of covering the entire dissection if present (ie, bailout stenting). It has been reported that 5% to 15% of patients with de novo disease require bailout stenting.^{4,8} On the other hand, an up-front, hybrid strategy of stenting in the proximal segment and DCB angioplasty distally can be considered when treating a long lesion.

Specific Scenarios

The following scenarios may require specific nuances:

Bifurcation. DCBs allow simplification of the procedure, as most of the angioplasty can often be performed sequentially. A DCB can be integrated for side branch angioplasty in a provisional stenting strategy,⁹ which is of particular interest when treating the ostial left circumflex in distal left main bifurcation lesions. Additionally, a DCB-only strategy can be considered after adequate lesion preparation. Scoring or cutting balloon angioplasty should be preferred for ostial side branch lesions. Although sequential DCB delivery and inflation are then usually adequate (generally with the side branch first), kissing DCB inflation could be planned to avoid carina shift in specific cases.

CTO. For CTOs, an up-front hybrid strategy including stenting the occluded segment and DCB angioplasty of the distal (often diffuse) disease and negatively remodeled vessel can be pursued.

Thrombotic lesion. Operators may consider thrombus aspiration before DCB implementation in the presence of a thrombotic lesion. Nonetheless, we discourage following this approach in lesions with high residual thrombotic burden.

CONCLUSION

Altogether, in the current panorama of PCI, a systematic approach with considerate implementation of DCB angioplasty will not jeopardize patient safety, and it might further optimize the efficacy of PCI.

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Super-High-Pressure Balloons

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The OPN NC balloon (SIS Medical AG) is a super-high-pressure, NC, rapid-exchange balloon specifically designed to treat highly calcified and/or nondilatable lesions.

OPN NC has 0.016- and 0.028-inch tip entry and crossing profiles, respectively, that can be inflated up to very high pressures (Figure 1). The reported pressure burst of the OPN NC is 35 atm, but the balloon maintains a linear compliance curve to > 40 atm.¹

This device can withstand high inflation pressures due to its dual-layer construction. Its design not only permits the application of very high pressures but also distributes forces between the layers, minimizing the risk of hydraulic vessel perforation in the event of intracoronary balloon rupture.

OPN NC balloons are compatible with all 0.014-inch coronary guidewires. They are produced in a wide range of diameters (from 1.5 to 4.5 mm) and three lengths (10, 15, and 20 mm).

RATIONALE

In addition to lesion preparation for de novo calcific and nondilatable lesions, OPN NC balloons are useful for treat-

ing ISR. The high-pressure strong predilatation compresses the neointima before new DES implantation or DCB PCI. In selected cases of restenosis, OPN NC balloons may replace cutting and scoring balloons as they are associated with low rates of dissections and perforations.^{1,2}

Due to their NC profile and high outer radial force, OPN NC balloons are used for stent postdilatation and/or to correct malapposition and underexpansion. Finally, their technical characteristics render them particularly suitable in cases requiring pre- or postdilatation over two overlapped layers of DES.

TIPS AND TRICKS

Due to the twin-layer design, OPN NC balloons are bulkier compared to standard semicompliant or NC balloons, resulting in lower deliverability. Thus, it is recommended to advance them on extra support wires, such as Grand Slam (Asahi Intecc USA, Inc.).³

When performing predilatation (especially in cases of ISR), it is recommended to downsize the OPN NC balloon diameter by 0.5 mm compared to the reference vessel diameter. On the other hand, postdilatation should be per-

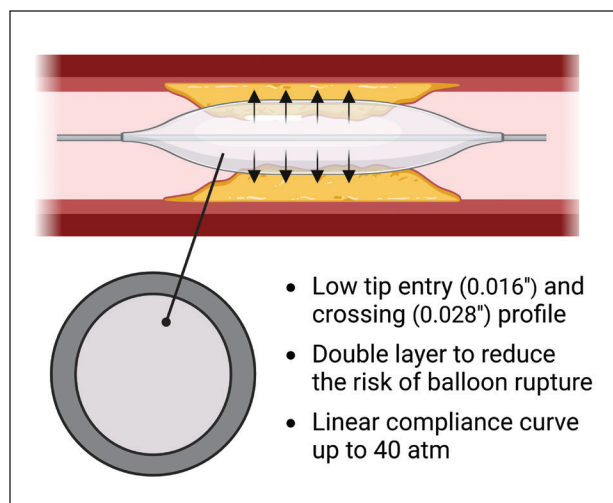


Figure 1. Technical characteristics of OPN NC balloons.

formed by selecting an OPN NC balloon with a diameter matching the reference vessel diameter at a 1:1 ratio.

It is recommended to slowly inflate the OPN NC balloon (5 atm for every 10-15 sec) for adequate balloon expansion and luminal gain. A sudden pressure drop can be observed when the lesion is cracked. OPN NC balloons should be used with the dedicated SIS Medical inflators, which have a working limit of 55 atm.

It is important to take into consideration that very high pressures (> 25-30 atm) may cause the hypotube of the OPN NC balloon to collapse over the guidewire, especially in the case of multiple inflations. As a consequence, the guidewire may come out “en bloc” when withdrawing the balloon, with possible negative consequences in case of vessel dissection (or other complications) or complex wiring. Wires with long hydrophilic coating (eg, Sion Blue, Asahi Intecc USA, Inc.) stick more easily on OPN NC balloons. The Sion Blue ES is better in this regard due to its

shorter spring coil, but is not optimal. The ideal guidewire has a short spring coil segment with a hydrophobic coating, such as the Grand Slam or the Miracle family of guidewires (Asahi Intecc USA, Inc.).³ Alternatively, one may consider securing the target vessel with a buddy wire.

CONCLUSION

The OPN NC balloon represents a significant advancement in interventional cardiology, offering a versatile solution for highly calcified and nondilatable lesions. With its dual-layer construction and remarkable resistance to high pressures, it shows promise as a valuable tool in select cases, with low rates of dissections and perforations. Continued device refinements and wider adoption will be crucial to enhancing its efficacy and expanding its applicability in managing complex coronary lesions.

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Cutting and Scoring Balloons

By Ottavia Cozzi, MD; Antonio Mangieri, MD; Gabriele Gasparini, MD; and Damiano Regazzoli, MD

Cutting and scoring balloons have protrusive elements on the surface for modifying atherosclerotic plaque. These protruding elements (microsurgical blades for cutting balloons or nitinol or silicone wires for scoring balloons) anchor to the vessel surface, allowing uniform pressure to be

distributed on a smaller surface compared to standard balloons. Commercially available cutting and scoring balloons differ regarding composition, number and shape of the protruding elements, the balloon crossing profile and compliance, and the design and coating of the distal body.

TIP 1: KNOW YOUR DEVICES

Modified balloon performance depends on different characteristics, including crossability, deliverability, compliance, and radial force.

The crossing profile is a function of the greatest diameter, usually at the level of the balloon. The protruding elements of cutting and scoring balloons create friction and reduce lesion crossability. The Wolverine cutting balloon (Boston Scientific Corporation) has a lower profile than the previous version (Flexotome, Boston Scientific Corporation). This was achieved by thinning the pad of the blade and adding a lubricious coating on the distal segment.

Deliverability depends on the balloon lesion entry profile (usually a tapered tip), pushability, and trackability. These characteristics result from a complex interaction between the design of the balloon (optimal crimping and reduced balloon thickness increase trackability), scoring elements, stiffening wire (shape and length past the rapid-exchange port), shape of the inflation lumen (a straight inflation lumen gives greater pushability), and stiffness of the metallic hypotube.

Balloon compliance, which refers to balloon diameter expansion as a function of pressure, varies among different cutting and scoring balloons, and as such, the operator should be aware of specific device compliance charts. Modified balloons are generally mounted on a relatively compliant balloon, which increases its diameter according to the pressure of inflation.

The protruding element shapes translate into different frictional properties. The triangle-shaped stainless steel microblades with cutting balloons have a better penetration depth compared to nitinol or silicone wires.¹ Besides lacking sharpness, the scoring wire of some scoring balloons are fixed just at the end of the balloon. This reduces their anchoring properties and may hamper precise focal transmission of pressure to the vessel if the wire turns around during the inflation.

TIP 2: DETERMINE YOUR STRATEGY

Balloon predilatation is often performed before cutting balloons to facilitate device delivery and potentially perform intravascular imaging in the tightest lesions. Adequate support should be granted when using either cutting and scoring balloons, and this comprises access route selection, use of a supportive guiding catheter (Amplatz left for the right coronary artery, extra-backup for the left), and a low threshold for techniques and devices to increase support, such as a buddy wire, a guiding catheter extension, or an anchoring technique.

Two different strategies have been described for cutting balloons (Figure 1) and are, arguably, applicable also for scoring balloons. The first is nominal pressure inflation of a cutting balloon sized in a 1:1 ratio to the vessel; the balloon apposes to the vessel and uses the cutting action of the blades on the wall, rather than relying on high balloon pressure for plaque modification. The second is high-pressure inflation with an undersized cutting balloon (0.5 mm less than the media-to-media diameter). This combines the action of the scoring element and microblades and the high inflation pressure exerted on a delimited surface for achieving plaque modification.² Undersizing is suggested to mitigate potential complications of balloon diameter increase at high pressure as a result of balloon semicompliance.

There is an absence of data from manufacturers regarding cutting balloon inflation at high atmospheres. According to manufacturer's instructions for use, an inflation pressure with cutting balloon should not exceed 12 atm. Although a certain degree of balloon distortion must be considered, in our view the microblades may limit expansion and compliance of the balloon at high pressure. No exceeding risk of complications (ie, flow-limiting dissections, perforations) was reported with this strategy in previous studies.^{3,4} A potential drawback may be deformation of the rapid-exchange port, which could

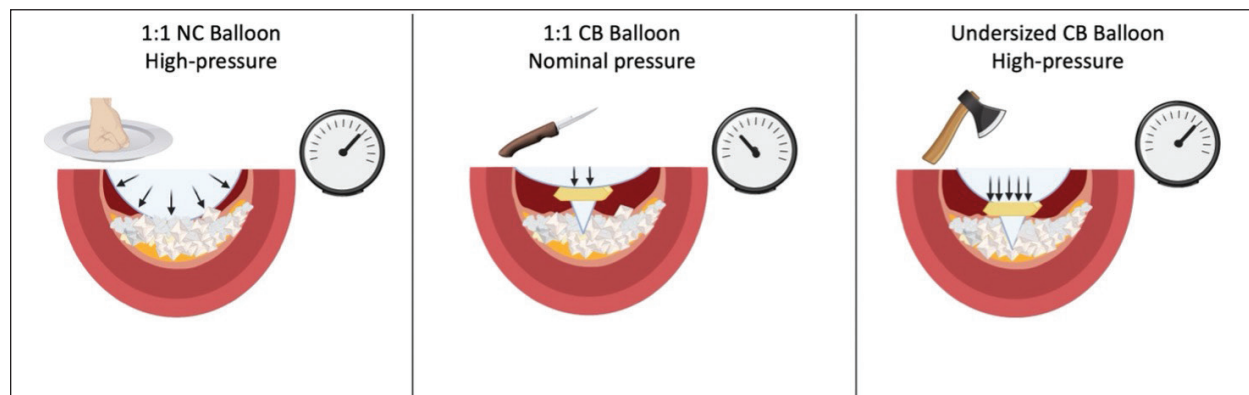


Figure 1. Effects of NC and cutting balloon (CB) inflated at nominal or high pressure on calcified plaque.

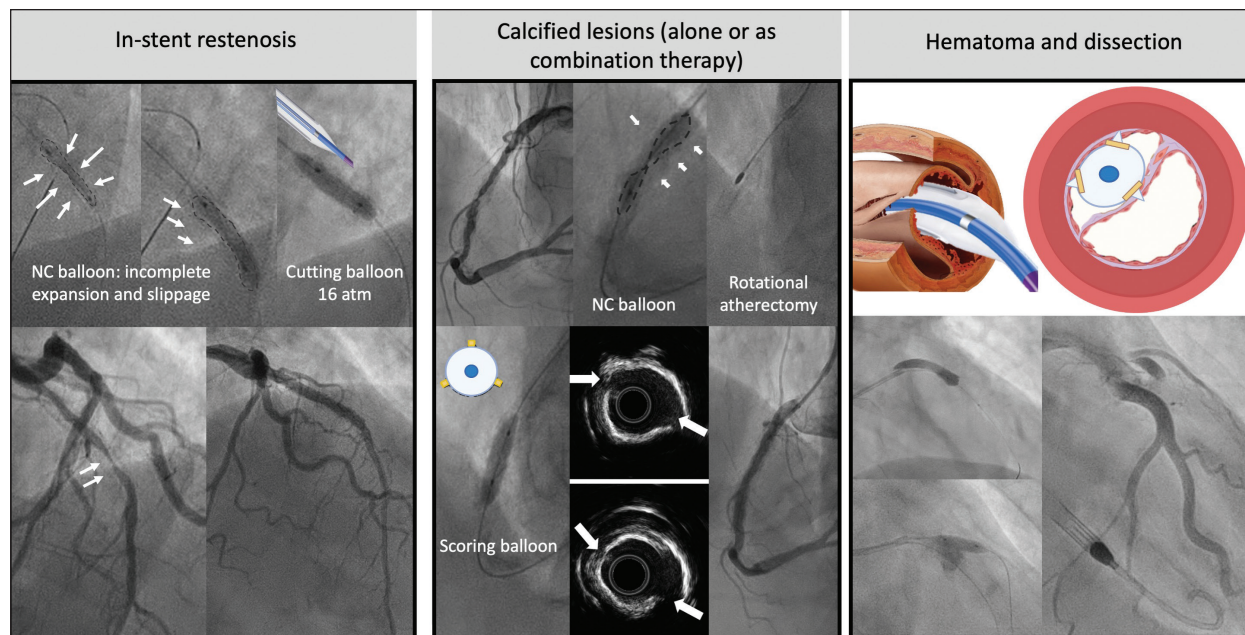


Figure 2. Severe ISR, successfully treated with cutting balloon inflation after failed NC balloon angioplasty (A). Combined use of rotational atherectomy and scoring balloon after failed NC balloon dilatation in a severely calcified lesion (B). Flow-limiting dissection of the left main artery, treated with multiple cutting balloon dilatation, resulting in flow restoration of the circumflex artery (C).

result in wire retraction when the balloon is pulled back, making a second wire advisable.

Our suggestion is a step-by-step inflation approach comprising prolonged inflations at progressively higher atmospheres followed by fluoroscopic or intravascular imaging evaluation to check full balloon expansion or proper lesion preparation. This approach exploits “plaque fatigue” while avoiding exceedingly aggressive dilatations.

Previous evidence suggests the effectiveness of lesion preparation with modified balloons before angioplasty using DCB. Drug transfer and tissue retention may be enhanced by the microinjury to the vessel wall achieved with cutting or scoring balloons. In this setting, gently dilatation of a modified balloon at nominal pressure can result in effective acute lumen gain, while allowing controlled plaque modification and microinjuries to increase drug tissue penetration.^{5,6}

TIP 3: KNOW WHERE TO USE THE BALLOONS

Fibrotic and Ostial Lesions

Substantial plaque modification in noncalcified fibrotic lesions is generally not achieved with conventional balloon angioplasty. Elastic recoil and balloon slippage are frequent. Microincisions created by cutting and scoring balloons minimize elastic recoil, thus allowing more even expansion of the vessel. Lesions located at the ostium

of epicardial vessels have high concentrations of elastic fibers and calcium, leading to elastic recoil and reduced vessel distensibility. As such, cutting and scoring balloons may be particularly advantageous here.

ISR

Cutting and scoring balloons should be sized 1:1 or upsized to 0.25 mm compared to the previously implanted stent size for ISR. Potential advantages include: (1) cutting balloon microblades can incise restenotic plaques up to the metallic stent cage and extrude the neointimal hyperplasia throughout the stent struts; (2) the hyperplastic tissue is rubbery and has a slippery surface; while conventional balloons tend to move forward or backward during inflation (Figure 2A), balloon anchoring is increased with scoring elements, thus reducing the risk of dissections at the stent margin; and (3) the incisions may favor intravascular diffusion of antiproliferative agents delivered by DCBs.⁵

Calcified Lesions

For calcified lesions, cutting and scoring balloons can be used alone or combined with atherectomy. Concentric, focal, and superficial lesions as well as those with relatively thin calcified plaques are more likely to respond well to cutting and scoring balloons. In the COPS trial, calcified lesion preparation with high-

pressure cutting balloon led to higher minimal stent area compared to NC balloons ($8.1 \pm 2 \text{ mm}^2$ vs $7.3 \pm 2.1 \text{ mm}^2$). The benefit of the cutting balloon was more evident among patients with $> 270^\circ$ arc of calcium.³ In previous bench tests, the maximum principal stress on the vessel wall was obtained when the microblades were in front of the thinnest part of the calcification. If adequate expansion was not achieved, a second dilation might be successful after rotating the balloon.² The main issues are balloon catheter stiffness (thus limiting its movements through tortuous and angulated lesions) and suboptimal balloon profile. Combined lesion preparation with rotational atherectomy and cutting balloon may overcome this challenges (Figure 2B). The strategy proved safe in previous studies, but benefits in terms of acute luminal gain appeared inconsistent.^{4,7}

Coronary Dissections and Intramural Hematoma

The goal of cutting and scoring balloons in spontaneous and iatrogenic flow-limiting coronary dissection and intramural hematoma is to create multiple fenestrations between the true and false lumen (Figure 2C).⁸ This favors adequate distal flow recovery and should prevent abrupt vessel closure, while avoiding intramural hematoma propagation (milking). The approach can be useful in cases where the operator is unwilling to stent (eg, small vessel dissections, uncertainty about the correct wire positioning in the true lumen, concerns about adequate coverage of the intramural hematoma for its whole length).

CUTTING OR SCORING BALLOONS?

Few head-to-head comparisons of scoring versus cutting balloons are available, but the following considerations may guide the operator's choice between the devices:

- Device crossability and trackability was previously better with scoring balloons compared to cutting balloons. This may be questionable today, as new-generation cutting balloons have been developed to have an improved profile.⁹
- In calcified lesions, the greater penetration depth with cutting balloon microblades may grant better plaque modification compared to scoring balloons.
- More evidence is currently available for scoring balloons compared to cutting balloons for treatment of ISR. ■

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