

Management of Balloon Undilatable CTOs

An appraisal of the available and potential device and technique options and treatment algorithms used to manage balloon undilatable lesions.

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Balloon undilatable lesions are defined as resistant lesions that cannot be expanded despite multiple high-pressure balloon inflations. Balloon undilatable lesions are often also balloon uncrossable (ie, cannot be crossed with a balloon after successful guidewire crossing) lesions. Balloon undilatable and balloon uncrossable lesions are usually heavily calcified. Approximately 12% of chronic total occlusions (CTOs) are balloon undilatable,¹ and 8% to 11% are balloon uncrossable.^{2,3} Following a systematic and algorithmic approach can facilitate management of these complex lesions (Figure 1).

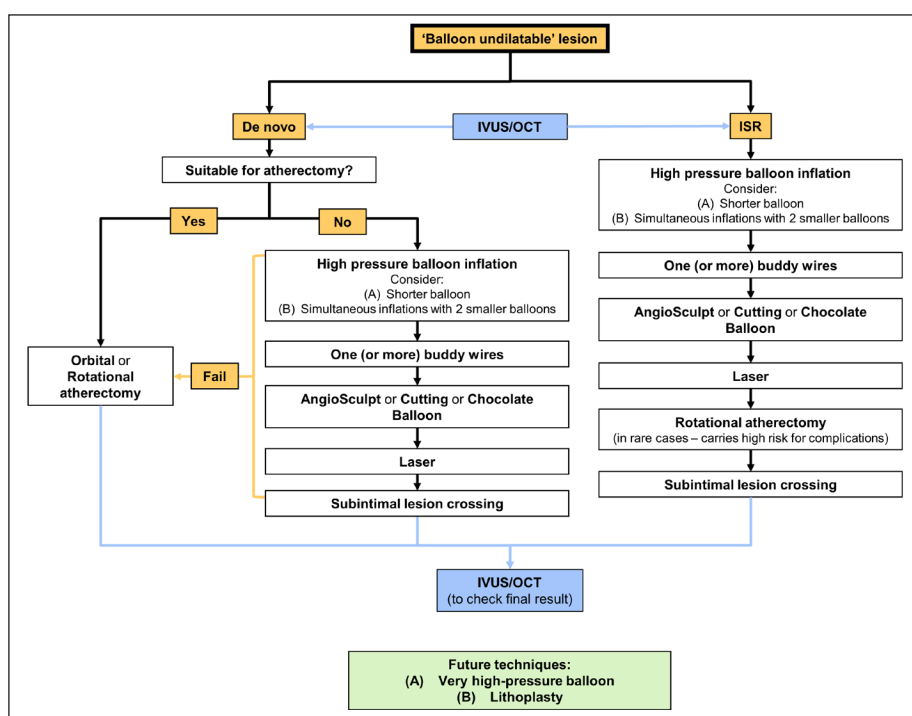


Figure 1. Proposed algorithm for treating balloon undilatable coronary lesions. ISR, in-stent restenosis; IVUS, intravascular ultrasound; optical coherence tomography (OCT).

AN ALGORITHM FOR TREATING BALLOON UNDILATABLE LESIONS

The key initial consideration for how to treat a balloon undilatable lesion is whether it is within a stent because this carries important implications about subsequent treatment, as orbital atherectomy is contraindicated in in-stent lesions and rotational atherectomy should be performed only as a last resort due to a high risk for complications. Conversely, laser atherectomy with simultaneous

contrast injection is an appealing treatment option for in-stent lesions, but it is infrequently used in de novo lesions because it can lead to dissections or perforations.

When treating balloon undilatable de novo lesions, orbital or rotational atherectomy may offer the best likelihood for optimal lesion expansion. Exceptions include very small or extremely tortuous coronary arteries, in which atherectomy may carry increased risk for complications.

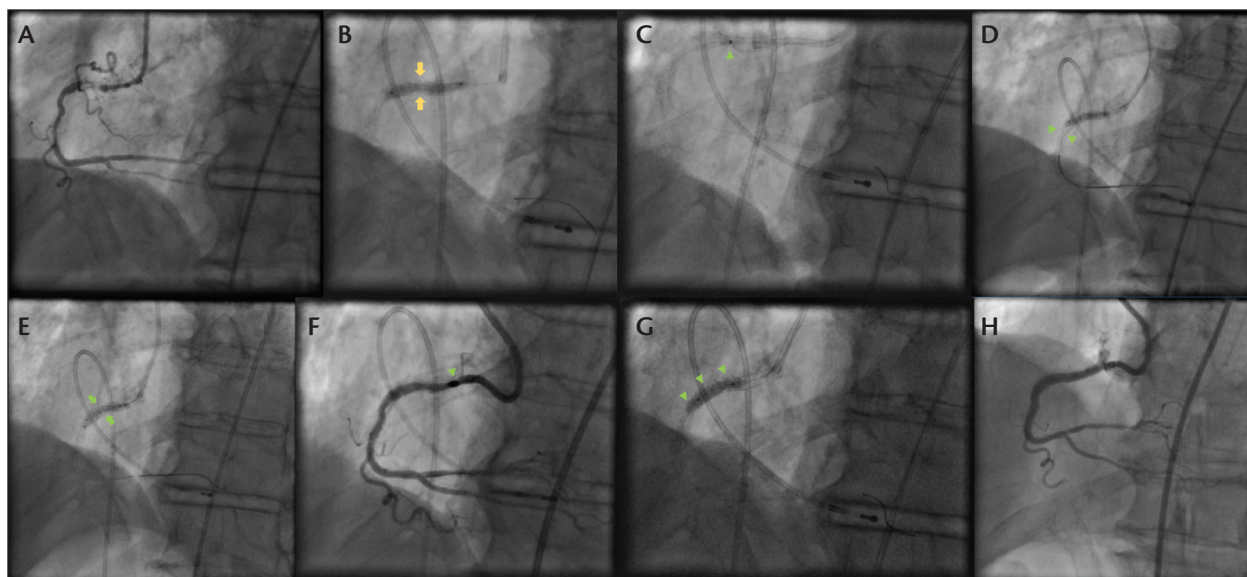


Figure 2. Clinical case representing the challenges of balloon undilatable CTO treatment requiring multiple aggressive methods to achieve successful recanalization. Proximal right coronary artery CTO within a previously implanted stent (A). The CTO was successfully crossed with wire escalation, but the lesion remained underexpanded (yellow arrows) despite balloon multiple high-pressure balloon inflations (diameters of 2.5/3.5 mm) (B). Laser coronary atherectomy (green arrowhead) with contrast injection also failed to properly expand the lesion (C). The buddy wire technique was also ineffective (green arrowheads) (D). Two simultaneous balloon inflations (green arrows) also failed to expand the lesion (E). Multiple runs of in-stent rotablation were performed with upsizing the burr size up to 2.15 mm (green arrowhead) (F). Finally, use of an AngioSculpt scoring balloon facilitated lesion dilation and stenting of the lesion (G). Final angiographic result (H).

The role of intravascular imaging in the treatment of balloon undilatable lesions cannot be overemphasized. Intravascular imaging can help both identify challenges with lesion expansion before treatment and also ensure that an optimal (or at least adequate) result has been achieved after treatment. It is not uncommon, especially for heavily calcified lesions, to appear to expand well during balloon inflations but show a small minimum lumen area when evaluated on intravascular imaging. Heavy circumferential calcification favors early use of coronary atherectomy, whereas less calcified lesions may be initially approached with balloon angioplasty.

CURRENT TECHNIQUES AND TREATMENT OPTIONS

High-Pressure Balloon Inflation

The simplest treatment of balloon undilatable lesions is high-pressure balloon inflation. Noncompliant balloons sized 1:1 or undersized by 0.5 mm should be used, and compliant balloons should be avoided. High pressures of up to 26 to 28 atm are often used with long inflation times (30 seconds to 2–3 minutes

depending on the patient's tolerance of ischemia). The main risk with high-pressure balloon inflation is balloon rupture that can cause vessel perforation. Balloon rupture should be suspected if there is sudden loss of pressure during inflation. The balloon should be deflated immediately and suction applied to minimize the risk of vessel perforation. The ruptured balloon should promptly be removed, followed by aspiration of the guide catheter (to remove any potential air emboli) and coronary angiography to determine whether vessel perforation has occurred. Balloon preparation should be meticulous to minimize the risk for air embolization in case of rupture. Occasionally, two smaller balloons can be used simultaneously, sized according to the Finet law (effective balloon diameter = 0.678 multiplied by balloon one diameter [mm] plus balloon two diameter [mm]) (Figure 2). In case of smaller vessel diameter (< 2 mm), smaller-diameter dedicated balloons (Sapphire Pro II 1-mm coronary dilation catheter, OrbisNeich) (Figure 3A) are available for performing simultaneous inflations. Shorter balloons can facilitate lesion dilation by concentrating the force to the undilatable segment.

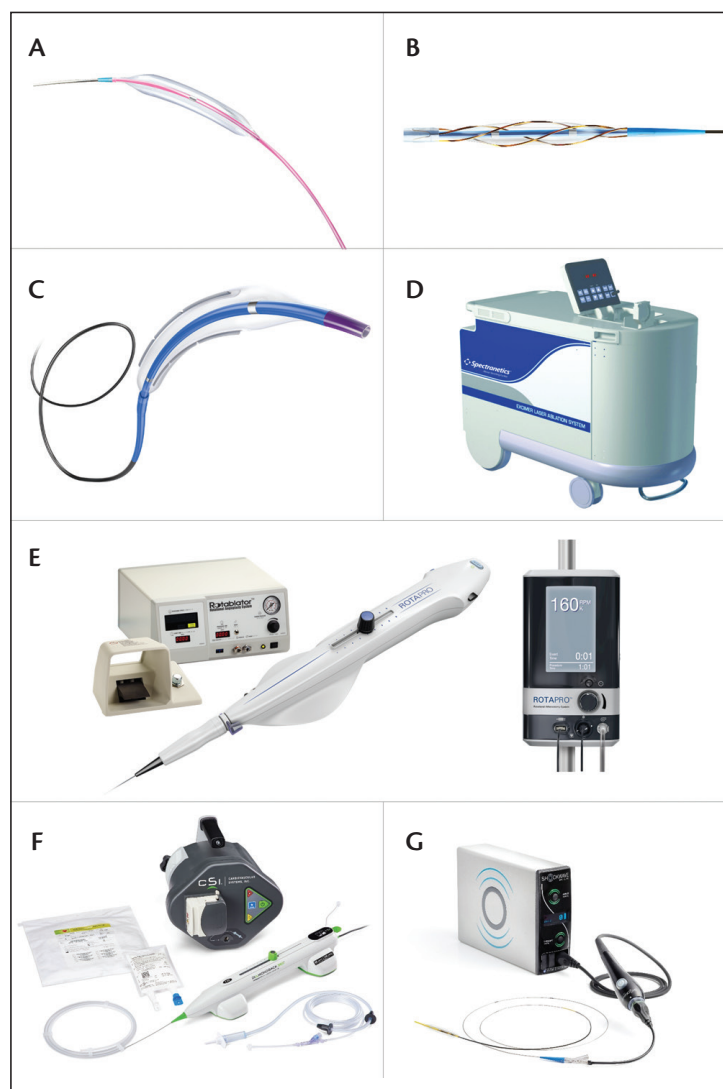


Figure 3. Specific devices for treating undilatable CTOs: Sapphire II Pro coronary dilation catheter (A); AngioSculpt scoring balloon catheter (B); Wolverine cutting balloon dilation device (C); CVX-300 excimer laser ablation system (D); Rotablator rotational atherectomy system (E); Diamondback 360 coronary orbital atherectomy system (F); Lithoplasty system (G). Images are reproduced with permission from OrbusNeich; Spectranetics, a Philips company; Boston Scientific Corporation; Cardiovascular Systems, Inc.; and Shockwave Medical, Inc.

Buddy Wires

Insertion of one (or more) buddy wires may improve the efficacy of high-pressure balloon inflations by causing focused wire cutting of the arterial vessel wall.⁴⁻⁶

Scoring, Cutting, or Nitinol-Framed PTA Balloons

A scoring balloon with nitinol wires wrapped around the balloon (AngioSculpt scoring balloon catheter,

Spectranetics, a Philips company) (Figure 3B), or a cutting balloon with parallel cutting blades (Wolverine cutting balloon dilation device, Boston Scientific Corporation) (Figure 3C) can be used to modify the balloon undilatable lesion.⁷ The Chocolate percutaneous transluminal angioplasty (PTA) balloon catheter (Medtronic) has a nitinol-constraining structure forming pillows of the balloon to dilate and intersegment grooves for plaque release, minimizing the risk of dissection or any traumatic plaque damage. Despite the nitinol structure, the Chocolate balloon facilitates atraumatic plaque modification without any cutting or scoring effect. However, all three balloons may be challenging to deliver due to a high profile and lack of flexibility. Delivery may be facilitated by use of various support techniques, such as distal⁸ or side branch anchoring,⁹ one or two guide extension catheters (mother-daughter or mother-daughter-granddaughter technique¹⁰) or simply upsizing the guide catheter if the wire position can be preserved or regained.

Laser Atherectomy

In case of failure to expand an already deployed stent, laser atherectomy is the preferred technique (CVX-300 excimer laser ablation system, Spectranetics, a Philips company) (Figure 3D). Laser atherectomy can be used over any standard 0.014-inch guidewire, unlike orbital and rotational atherectomy that require use of specialized guidewires. The 0.9-mm laser catheter is usually operated at the highest settings, including pulse repetition at 80 Hz and fluency at 80 mJ/mm². Laser atherectomy with simultaneous contrast injection can cause microcavitation and can be very powerful in modifying the vessel's architecture; however, this should only be performed within previously deployed stents,¹¹ as it can lead to vessel dissection or perforation.^{12,13}

Rotational or Orbital Atherectomy

Rotational¹⁴ and orbital¹⁵ atherectomy (Rotablator rotational atherectomy system, Boston Scientific Corporation; Diamondback 360 coronary orbital atherectomy system, Cardiovascular Systems, Inc.) (Figure 3E and 3F) can be very effective in modifying a balloon undilatable lesion but require use of specialized thin guidewires. Usually, the workhorse guidewire that was used to cross the lesion is exchanged for the

atherectomy guidewire using a microcatheter and the trapping technique with a Trapper exchange device (Boston Scientific Corporation) or a TrapLiner guide extension (Teleflex). Use of aminophylline or a temporary pacemaker may be needed in patients undergoing atherectomy of right coronary artery lesions or dominant circumflex lesions.

Subintimal Techniques

If all else fails, subintimal lesion modification may be attempted. Subintimal crossing of the undilatable lesion is performed, usually using a knuckled guidewire, as is routinely done in CTO interventions, followed by inflation of a balloon in the subintimal space, effectively “crushing” the balloon undilatable lesion. Such approaches require expertise in dissection and re-entry techniques and should be performed with caution due to the risk of perforation. Maintaining distal guidewire position is critical to maintain vessel patency in case of subintimal hematoma formation.

FUTURE TECHNIQUES

Two technologies are currently available in Europe to facilitate treatment of balloon undilatable lesions and will likely soon become available in the United States.

First, the OPN NC High-Pressure PTCA balloon (SIS Medical AG) is a very-high-pressure balloon that can be inflated up to 40 atm with low risk of rupture.¹⁶ Initial experience with the very-high-pressure balloon showed promising results of high efficiency in fully dilating undilatable lesions (91 lesions; 92.3% success rate) resulting in larger lumen gain, lower minimal lumen diameter, and residual stenosis compared to cases with use of regular noncompliant balloon, without any perforations or 30-day major complications.

Second, the Lithoplasty system (Shockwave Medical, Inc.) (Figure 3G) uses ultrasound shockwaves to overcome extreme lesion resistance.¹⁷ The first pilot study of 31 percutaneous coronary interventions (PCIs) using lithoplasty for heavily calcified coronary artery lesions showed effective intraplaque calcium fracture that was controlled and analyzed by optical coherence tomographic imaging.¹⁸ Procedure-related perforation, no-reflow, or acute vessel closure were not reported; however, in 13% (n = 4) of all cases, type B dissection occurred that required stent coverage but no additional treatment.¹⁹

TIPS AND TRICKS

Predilation should be performed with 1:1 sized balloons because the use of smaller balloons may fail to

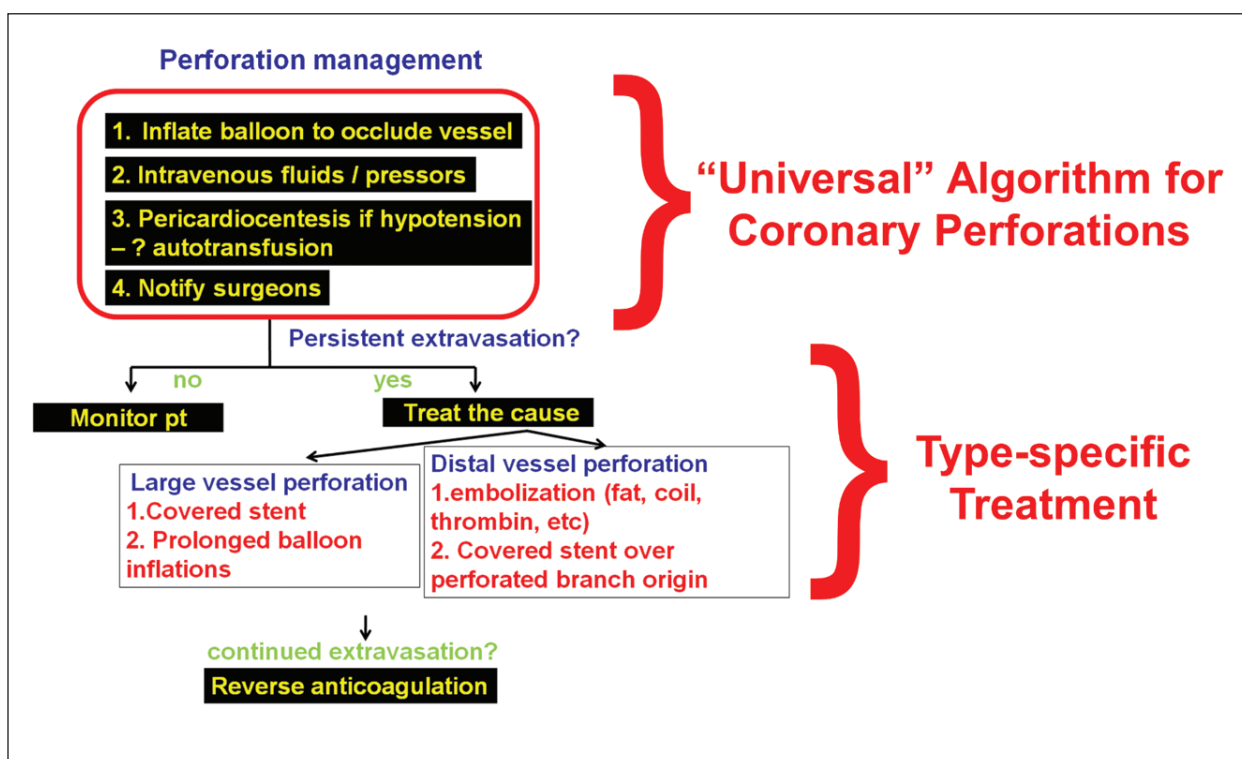


Figure 4. General algorithm for perforation treatment. Reproduced with permission from Brilakis E. Manual of Coronary Chronic Total Occlusion Interventions: a Step-by-Step Approach. 2nd ed. Elsevier Academic Press; 2018.

reveal poor lesion expansion, leading to stent implantation that makes treatment of balloon undilatable lesions much more challenging (because atherectomy should be avoided inside stents, making laser the preferred treatment strategy).

Treatment of balloon undilatable lesions can cause complications, such as coronary perforation and tamponade, hence equipment to treat perforations (eg, covered stents and coils) should be readily available when treating such lesions. Coronary perforation should also be approached in an algorithmic fashion (Figure 4),²⁰ with the first step being immediate balloon inflation to minimize bleeding into the pericardium.

Given the relatively high rate of perforation and pericardial tamponade in PCIs with undilatable lesions (12% and 6%, respectively),¹ standby echocardiography in the cath lab should be considered to facilitate treatment in case of perforation.

SUMMARY

Balloon undilatable lesions can be challenging to treat but are also likely to be increasingly encountered given the increasing complexity of PCIs. Careful planning and implementation of a stepwise, algorithmic approach can help optimize outcomes in this challenging lesion subgroup. ■

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