

Recoil, Dissection, and Restenosis in Below-the-Knee Arteries After Standard Balloon Angioplasty

Tools and techniques for addressing current challenges in the treatment of peripheral artery disease.

By Michael Lichtenberg, MD

The latest Global Burden of Disease Study report shows that the total number of people with peripheral artery disease (PAD) has increased globally from 1990 to 2019.¹ Chronic limb-threatening ischemia (CLTI) is the most severe manifestation of PAD, defined by critical hemodynamic status responsible for ischemic rest pain, nonhealing chronic ulceration (> 2 weeks of duration), or foot gangrene.² CLTI is commonly encountered in the tibio pedal vessels located below the knee (BTK), where surgical or endovascular treatments can be particularly challenging.

In BTK vessel recanalization, dissection is a severe problem after endovascular therapy, with an incidence varying from 5.9% to 30.7% (8 times more dissections detected on intravascular ultrasound vs angiography).³⁻⁵

One approach to treat post-balloon angioplasty dissection is to compress the separated intima using a slightly oversized balloon at low pressures with long inflation duration (≥ 3 minutes). Data show that severe dissections (type C or higher) in femoropopliteal (FP) lesions were observed less frequently after prolonged balloon dilation (> 3-minute inflation group: 22.7% vs 50.9%; $P < .001$),⁶ and also immediate improvements in angioplasty in infrainguinal lesions were seen with 3-minute balloon inflation versus a short dilation strategy.⁷ Furthermore, long versus short balloons may also affect the occurrence of dissections in the FP segment.⁸ It has been shown that severe vessel dissection patterns (type C or higher) were fewer and shorter when using a long balloon after balloon angioplasty.⁷

CUTTING, SCORING, AND MINIMAL TRAUMA BALLOONS

Given the challenges, dissections likely require additional treatment approaches, as they have been associated with reduced patient health outcomes. Long lesions with limited calcification and small diameter are more prone to dissection, and specialty balloons may limit the rates of dissection and bailout stenting.^{8,9} There are three categories of specialty balloons that can be used: cutting balloons, scoring balloons, and minimal trauma balloons. Cutting balloons include very sharp metal blades at their surface for cutting the atherosclerotic plaque at a specific location. Scoring balloons have wires or polymer running over them, which significantly increase the pressure at specific points associated with precise rupture of the plaque—these have shown success in above-the-knee lesions, but further studies are needed to confirm the results obtained in small studies. Minimal trauma balloons can be encased in a nitinol cage, creating a series of grooves and pillows that limit the propagation of dissection into the vessel wall (eg, Chocolate PTA balloon, Medtronic). In this last case, the cage enables the balloon to dilate in a controlled manner, reducing overinflation and torsion that can promote dissection (Figure 1).⁹

DISSECTION, RECOIL, AND RESIDUAL STENOSIS

Dissection and residual stenosis occur acutely after balloon angioplasty.⁶ As such, vessel preparation can optimize endovascular therapy, particularly when planning to use a drug-coated balloon (DCB).¹⁰ With that in mind, the goal of vessel preparation is to remove

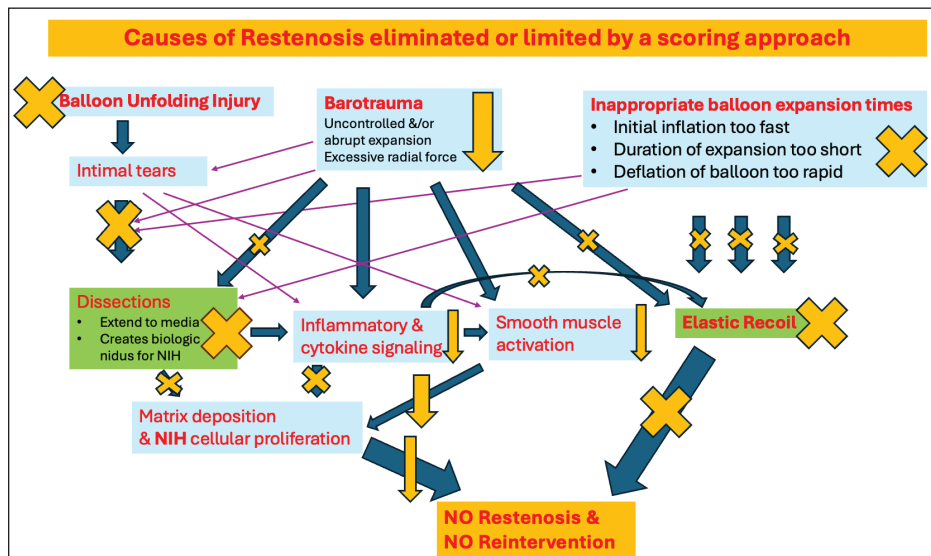


Figure 1. Scoring approach prevents restenosis. NIH, neointimal hyperplasia.

blocks for local drug delivery, avoiding drug loss on the way to the lesion, ensuring that a 1:1-sized DCB does not dissect the vessel, maximizing DCB expansion and vessel contact. Most operators use an aggressive lesion preparation strategy in an effort to “leave nothing behind” to create a functional lumen with the least amount of injury to the arterial wall. Currently, there’s an arsenal of tools to address these needs, including an increasing array of guidewires and support catheters, atherectomy, and intravascular lithotripsy (IVL).¹⁰ In simple lesions, atherectomy vessel preparation techniques are occasionally used as standalone definitive techniques, but they are usually followed by the use of more advanced therapies such as DCBs.¹⁰ Each device has important applications in the treatment of complex lesions, and the decision to use a given device should be based on the perceived complexity of the lesion, the presence and extent of calcium, and the final goals of the therapy.

Of course, the choice of vessel preparation depends on the type of lesion.⁹ As such, the presence of heavily eccentric calcification requires vessel lumen debulking using atherectomy or IVL devices.⁹ For example, in a severely calcified BTK lesion, where even the crossing support catheter and a small-size balloon are unable to traverse the lesion, the atherectomy device can prove invaluable.^{11,12} A recent single-center, non–industry-sponsored study showed that rotational atherectomy–assisted balloon angioplasty (BTK-RA) in CLTI BTK patients had significantly higher primary patency rates, target lesion revascularization, and lower in-hospital stay compared to the plain old balloon angioplasty

(POBA) group.¹³ Significant differences were found in minor amputation rates between the two groups ($P < .001$), while the respective limb salvage rates were similar in both groups.¹³ This study showed that the use of BTK-RA for the treatment of BTK lesions in patients with CLTI adds clinical advantages compared to POBA alone. In relation to IVL devices, a subgroup analysis of the Disrupt PAD III trial demonstrated a 99% success rate for achieving residual stenosis of $< 50\%$, with an average residual stenosis of $23.3\% \pm 12.5\%$ and no flow-limiting

dissections requiring adjunctive therapy in the IVL group compared to standard of care.¹⁴ This subanalysis of the PAD III observational study represents the largest IVL treatment of heavily calcified BTK lesions in a “real-world” patient cohort, and current ongoing studies will soon better define the role of IVL in BTK PAD.¹⁴

RECOIL MANAGEMENT

During balloon angioplasty, the elastic and muscle fibers undergo stretching. As such, if the force exerted by the balloon exceeds the vessel wall elasticity, plastic deformation occurs, and the artery will therefore not return to its former size.^{15,16} Furthermore, infrapopliteal arteries are commonly severely calcified, with calcium being unequally distributed among the arterial wall layers, altering the elastic properties of the artery.^{3,4,17,18} Also, because the tibial and pedal arteries are usually chronically occluded and underfilled, a challenge in the revascularization procedure is vessel size assessment and balloon undersizing, given that in different types of arteries, the degree of recoil was found to be directly related to the balloon-to-artery ratio.¹⁸⁻²⁰ It is now known that early recoil is highly prevalent in CLTI patients, with an incidence up to 97%, and that within 15 minutes after angioplasty alone, early elastic recoil can result in a mean lumen diameter decrease of 29%.²¹

Repeat angioplasty in cases of initial recoil should ideally be with a larger balloon for an extended duration of time.⁷ In addition, the use of serration angioplasty in infrapopliteal PAD seems to produce substantially less arterial recoil versus POBA and an adequate lumen

gain.^{22,23} The idea with a serration balloon is to dissipate the energy from the inflating balloon through the creation of channels that allow more predictability and control of the lumen expansion. A multicenter, sequential comparative study included patients with de novo or restenotic lesions of infrapopliteal arteries up to 22 cm in length and showed that arterial recoil (> 10%) occurred in fewer patients (25% of serration-treated lesions vs 64% in POBA-treated lesions; $P = .02$).²³ Moreover, after serration angioplasty, clinically relevant recoil (> 30%) was present in only 10% of the patients compared to 53% in POBA-treated group ($P = .01$).²²

FUTURE DIRECTIONS

There are also new concepts for reducing recoil, such as intra-arterial administration of iloprost, a prostacyclin mimetic, after balloon angioplasty of BTK vessels in CLTI, but more data are needed to corroborate this finding.²⁴ A novel retrievable scaffold therapy delivered via Spur peripheral retrievable scaffold system (Reflow Medical) showed that out of the 38 patients treated, recoil of tibial vessels was present in only 42.5% of the vessels, with 86.7% of vessels (26/30) patent at 6-month follow-up—although no significant difference in patency was found between lesions with recoil and lesions without recoil at 6 months (81.8% vs 89.5%).²⁵ This new retrievable scaffold therapy was also combined with sirolimus-coated balloon angioplasty to treat infrapopliteal artery lesions, showing negligible acute vessel recoil in 26% of the patients.²⁶ Both studies showed promise to reduce vessel recoil using a new interventional concept, such as using a temporary retrievable scaffold that can change vessel compliance and potentially allow the direct release of antiproliferative drugs to the lesion itself, which has proven challenging in the absence of a stent platform that facilitates vessel wall transfer. Just like with dissection and residual stenosis, research in vessel recoil after balloon angioplasty is urgently needed. We still don't understand the pathophysiology of phenotypic modulation of smooth muscle cells (SMCs) in CLTI patients, and identifying the genes associated with various SMC subphenotypes offers a potential for therapeutically targeting SMC phenotypic switching after angioplasty.

At this point, the need to integrate modern technologies into clinical routine seems mandatory to gain more favorable outcomes in these severely diseased patients and reduce the morbidity and mortality that ensues (Figure 1). ■

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