The Importance of Vessel Preparation

Properly preparing lesions before use of drug-eluting technologies has become a crucial step of the treatment algorithm.

BY RALF LANGHOFF, MD

Vessel preparation has gained importance as a crucial component of endovascular procedures. With the development of the leave-nothing-behind strategy, vessel preparation has been a key focus. For some interventions, dedicated pretreatment of the lesion is mandatory. Plaque modification is important when it comes to local drug delivery to the lesion via either balloon or stent. Adequate lesion pretreatment enhances the drug penetration into the vessel wall, which promotes and increases the antirestenotic properties.

In severely calcified arteries, the benefit of drug-coated balloons (DCBs) is less distinct due to the mechanical barrier in the arterial wall. This challenge can be overcome by dedicated vessel preparation such as atherectomy or scoring/cutting balloon angioplasty.[1,2] Additionally, the mechanism of vessel preparation affects the procedural success rate and long-term outcomes.[3,4] Consequently, vessel preparation has shifted from a trend to a consistent element of treatment algorithms.

FACILITATING VESSEL PREPARATION

Vessel preparation minimizes the risk of dissections, maximizes the luminal gain, and prepares the vessel bed for stents, vascular mimetic implants, and/or local drug delivery. Vessel preparation should be considered regardless of whether the lesion is stenotic or occlusive and is especially crucial if calcium is present.[5]

Today, vessel preparation consists of undersized balloon predilatation, angioplasty with scoring or cutting balloons, or atherectomy. Scoring or cutting balloons may be considered in calcified or very fibrotic lesions. The rationale behind this technology is that the entire force is focused on a wire or blade edge mounted on the balloon. This setup leads to a controlled plaque incision or a controlled dissection with less barotrauma to the entire lesion. Scoring or cutting balloons may be the first consideration in bifurcation and ostial lesions with the intention to minimize an expected plaque shift.

Every balloon angioplasty will create a certain extent of vessel injury. Larger dissections should be prevented, but microdissections will occur after any balloon-based intervention. There is a lack of scientific data on how to perform a standardized balloon angioplasty. Performance varies between medical specialties, vessel localizations, personal experience, and even the day of the week—balloon inflation times are presumably longer on Mondays compared to a Friday afternoon.

Zorger et al[6] investigated the influence of 30-second inflations compared to 180-second inflations and demonstrated that all procedural success endpoints (eg, bailout stenting, incidence of major dissections, and need for further intervention) were in favor of the long inflation time (Table 1).

The significance of a dissection after infrainguinal balloon angioplasty remains an active area of debate. There is no dedicated measuring tool to accurately define where and when a stent-based approach is preferred in infrainguinal arteries. Color-coded duplex ultrasound, intravascular

TABLE 1. OUTCOMES OF LONG VERSUS SHORT BALLOON INFLATION TIME

	Inflation time (s) 30 (n = 37)	Inflation time (s) 180 (n = 37)	*P* value
Major dissections (grade 3–4)	16	5	.010
Minor or no dissections (grade 1–2)	21	32	.010
Further interventions	20	9	.017
Stents	4	1	
Prolonged dilation	16	8	
Residual stenosis (> 30%)	12	5	N/A

Reprinted with permission from Zorger N, Manke C, Lenhart M, et al. Peripheral arterial balloon angioplasty: effect of short versus long balloon inflation times on the morphologic results. J Vasc Interv Radiol. 2002;13:355-359.

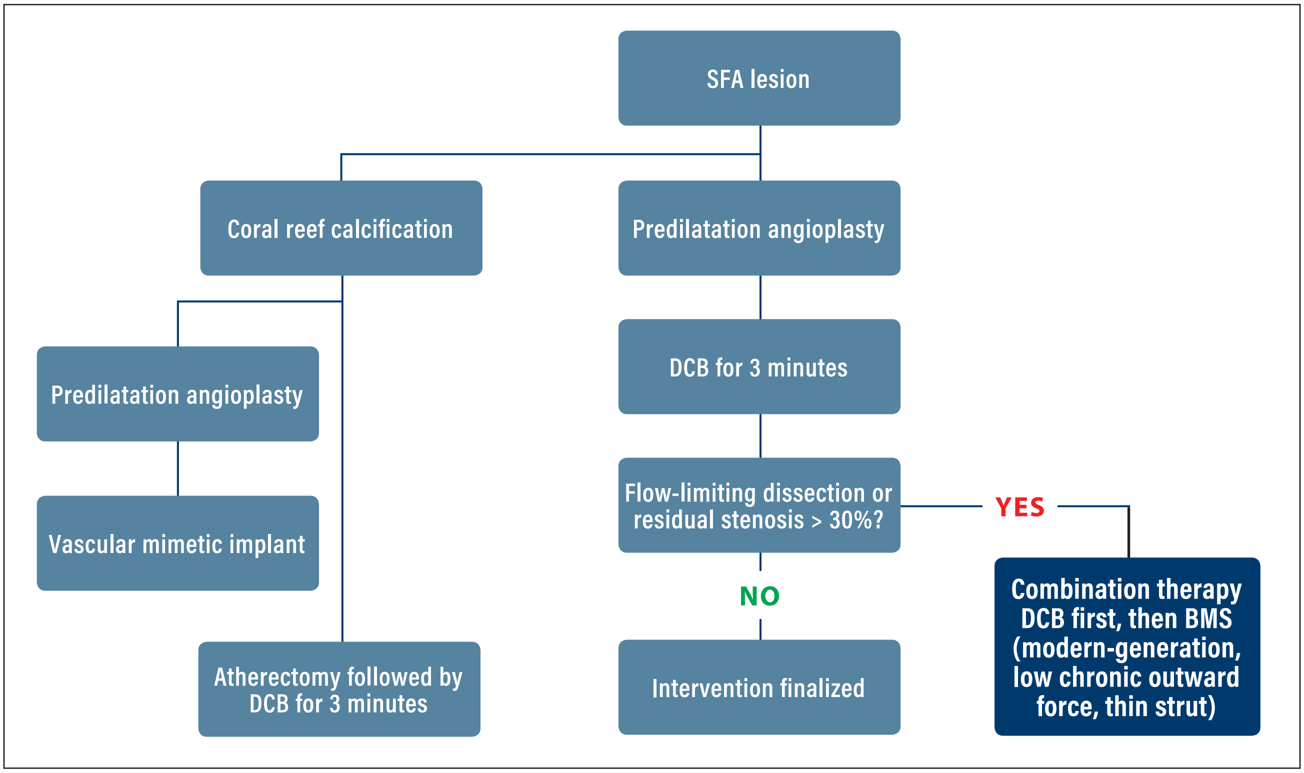

Figure 1. Treatment algorithm for SFA lesions. BMS, bare-metal stent.

ultrasound, optical coherence tomography, and fractional flow reserve measurements via pressure wire could add valuable guidance to the stenting approach.

Recently, Fujihara et al demonstrated in a registry[7] that an increase in the severity of superficial femoral artery (SFA) dissections is negatively correlated to primary patency and the rate of freedom from target lesion revascularization. In various current treatment algorithms, vessel preparation outcome predicts the ongoing pathway (Figure 1).

The absence of flow-limiting dissections after a crucial vessel preparation and the absence of significant vessel calcification justifies a DCB-only approach. If flow-limiting dissections occur, a stent-based intervention is needed, either with or without additional DCB treatment.[8,9]

The role of drug-eluting stents (DESs) in this algorithm remains a matter of debate, and regional reimbursement influences their scope of application. In Germany, for example, DESs are not well reimbursed. Consequently, the market share for DESs in Germany is low despite good supporting data. DESs are effective and have shown sustainable results in SFA trials compared to bare-metal stents.[10,11]

In coral reef calcified arteries, directional atherectomy (DA) can prepare the vessel bed for DCB treatment. Reducing the barrier within the vessel wall to boost drug uptake can lead to safe and durable therapy. Robust data to prove this concept are still pending. The ongoing REALITY trial (NCT02850107) may provide more detailed results but is still randomizing patients.

The DEFINITIVE AR trial[1] was a pivotal feasibility trial to investigate combination therapy (DA and DCB) compared to a DCB-only approach and find if the results of either therapy could be improved by combining them. The trial also identified patient subgroups where the combination of DA and DCBs could be more beneficial than in others. Results suggest that in longer and more calcified lesions, there is a trend of superiority of combining DA and DCBs. Patency was improved compared to using DCBs alone, especially in patients who underwent effective DA vessel preparation. Effectiveness was defined by < 30% residual stenosis after DA but before DCB use, presumably because the vessel preparation led to enhanced drug effectiveness and improved flow patterns as the endoluminal gain was optimized.

Calcium is the biggest challenge to a successful outcome. Although several different attempts to score the amount and distribution of calcium have been established, none is entirely accepted. The Peripheral Arterial Calcium Scoring System (PACSS score) (Table 2) is probably the most widely used.[12] Sophisticated techniques to prepare the vessel (eg, the so-called *pierce technique*) have been used. A

TABLE 2. PROPOSED PERIPHERAL ARTERIAL CALCIUM SCORING SYSTEM (PACSS)[12] (KRISHNA J. ROCHA-SINGH ET AL)
Proposed fluoroscopy/DSA-based Peripheral Arterial Calcification Scoring Systems (PACSS): Intimal and medial vessel wall calcification at the target lesion site as assessed by high-intensity fluoroscopy and digital subtraction angiography (DSA) assessed in the anteroposterior projection.
Grade 0: No visible calcium at the target lesion site
Grade 1: Unilateral calcification < 5 cm: (a) intimal calcification, (b) medial calcification, (c) mixed type
Grade 2: Unilateral calcification ≥ 5 cm: (a) intimal calcification, (b) medial calcification, (c) mixed type
Grade 3: Bilateral calcification < 5 cm: (a) intimal calcification, (b) medial calcification, (c) mixed type
Grade 4: Bilateral calcification ≥ 5 cm: (a) intimal calcification, (b) medial calcification, (c) mixed type
Reprinted from Rocha-Singh KJ, Zeller T, Jaff MR. Peripheral arterial calcification: prevalence, mechanism, detection, and clinical implications. Catheterization Cardiovasc Interv. 2014;83:E212–E220.

Japanese group used direct needle puncture of intra-arterial calcified plaques after successful wire passage to enable balloon delivery.[13]

Most recently, a report on the pave-and-crack technique as an aggressive but efficient way of vessel preparation showed sustained 12-month data on severely calcified SFA lesions (mostly PACSS grade 4 patients). To prepare the vessel before implanting a biomimetic implant (Supera stent, Abbott Vascular) safely, the implantation of a stent graft was necessary. Intensive angioplasty with high-pressure balloons under injection of local anesthesia into the arterial wall was then possible without fearing a vascular rupture.[14] The interventionalist ensures a nominal deployment of the Supera stent to its intended diameter via extensive vessel preparation.

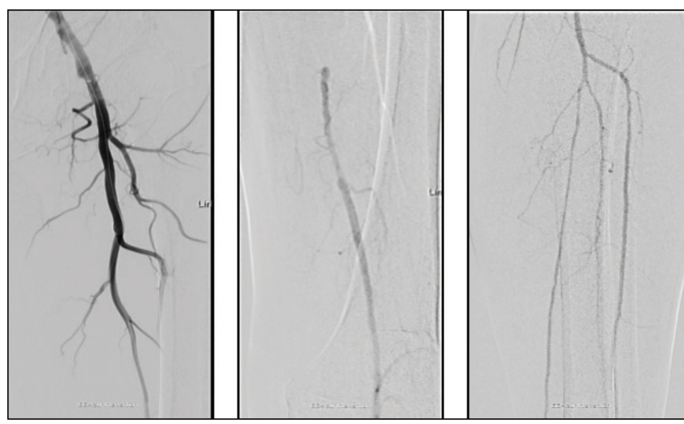

Figure 2. A 69-year-old woman presented with a long SFA occlusion.

CLINICAL CASE

A 69-year-old woman possessing all atherosclerotic risk factors (hypertension, hypercholesterolemia, diabetes, current smoker) presented with severe claudication in her left leg due to a long (29 cm) TASC D SFA occlusion (Figure 2) with moderate calcification in the distal Hunter's canal. To achieve a good wire passage into the chronically occluded SFA, a small stump of the SFA was visualized in an oblique view and helped to find the arterial ostium.

We began with a crossover approach, but due to a failed reentry into the true lumen, we switched to a retrograde access. Under fluoroscopic guidance, we punctured the distal SFA (Figure 3). After successful retrograde lesion crossing and externalization of the retrograde wire, we performed a predilatation of the entire lesion with an undersized 4-mm Passeo-18 balloon (Biotronik; 3-minute inflation time with nominal pressure). We then followed with three 6- X 120-mm Passeo-18 Lux DCBs (Biotronik) to apply paclitaxel to the lesion site (Figure 4).We could not identify any severe dissection on angiography and consequently left the lesion unstented.

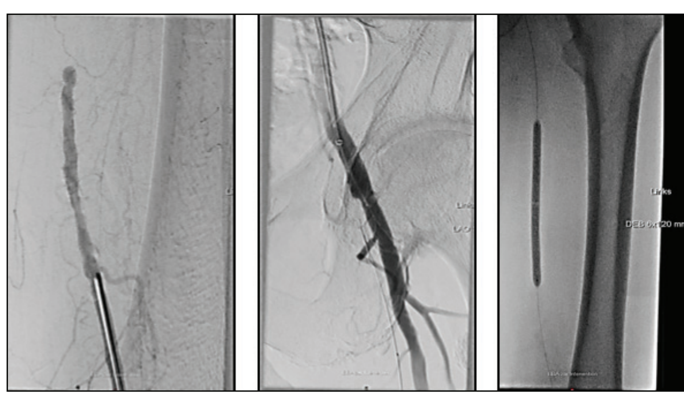

Figure 3. Retrograde access and DCB angioplasty.

Careful vessel preparation was performed after successful wire passage. This procedure led to an encouraging technical success, which motivated us to leave the lesion without any mechanical implant.

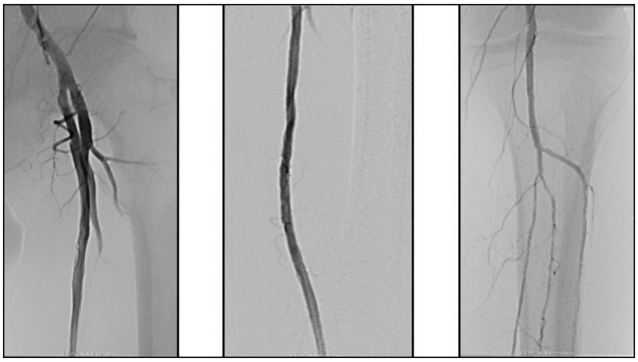

Figure 4. Final result after vessel preparation and DCB.

Treatment Workflow:

- Crossover approach with a 6-F, 45-cm Fortress sheath (Biotronik)
- 0.035-inch NaviCross support catheter (Terumo Interventional Systems)
- 0.035-inch, 260-cm, stiff, angled GlideWire (Terumo Interventional Systems)
- Retrograde access by direct puncture of the distal SFA/P1 segment with 18-gauge needle (Cook Medical)
- 0.018-inch, 260-cm angled GlideWire Advantage (Terumo Interventional Systems)
- Sheathless approach with a 90-cm, 0.018-inch CXI support catheter (Cook Medical)
- Externalization of the retrograde wire
- Stepwise predilatation with a 4- X 200-mm Passeo-18 balloon
- Stepwise angioplasty with three 6- X 120-mm Passeo-18 Lux DCBs without geographical miss

CONCLUSION

Vessel preparation has progressed from fiction to fact. It has become an integral part of current endovascular procedures and treatment algorithms with the goals of maximizing the lumen, preparing the vessel bed for definitive treatment, and minimizing the risk of dissections and peripheral emboli. ■

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