ROUNDTABLE DISCUSSION

Perspectives on BTK Vessel Prep

BTK versus ATK algorithms, vessel prep decision-making and device selection, impressions on the BTK vessel prep data landscape, and the impact of reimbursement on therapy selection.

Michel Bosiers, MD
Senior Consultant
Inselspital Bern
Bern, Switzerland
michel.bosiers@insel.ch

John H. Rundback, MD
Managing Partner
Advanced Interventional & Vascular Services LLP
Teaneck, New Jersey
john.rundback@americanendovascular.com

Sabine Steiner, MD
Division of Angiology
Department of Internal Medicine, Neurology and Dermatology
University Hospital Leipzig
Leipzig, Germany
sabine.steiner@yahoo.com

Daniel A.F. van den Heuvel, MD
St. Antonius Ziekenhuis
Nieuwegein, the Netherlands
d.van.den.heuvel@antoniusziekenhuis.nl

What is your algorithm for deciding whether vessel preparation is needed in a below-the-knee (BTK) case? Specifically, what imaging do you use and when? If you determine vessel prep is appropriate for a case, how do you decide which modality is ideal? How does your BTK algorithm differ from above the knee, if at all?

Dr. Bosiers: In short, plain old balloon angioplasty (POBA) of simple lesions is still my favorite approach, with the use of a drug-eluting stent (DES) if necessary. For long, complex BTK lesions, there is consensus that using percutaneous transluminal angioplasty (PTA) alone is not sufficient because of a high risk of elastic recoil and/or dissection and especially because of the high calcium burden we see in our patients with chronic limb-threatening ischemia (CLTI).

Because CT and MRI are not ideal to show the extent of BTK disease, I base my decision on using vessel prep on results of fluoroscopy (calcium burden, yes/no; how much) and angiography itself. Intravascular ultrasound (IVUS) can provide more accurate information; however, it is not reimbursed everywhere.

If the artery is heavily calcified and I can pass the lesion with a low-profile balloon, I would go for intravascular lithotripsy (IVL, Shockwave Medical), which uses pulsatile sonic pressure waves to create microfractures in the intimal and medial artery calcification (MAC). If I cannot pass with a balloon, I use orbital atherectomy (Diamondback 360, Cardiovascular Systems, Inc.).

If the history of BTK disease is rather short (such as in patients with a sudden worsening of their wound and now occluded artery), then I would consider an atherectomy device with an aspiration function to treat the underlying pathology and extract thrombus material (eg, Jetstream, Boston Scientific Corporation).

For a long, noncalcified chronic total occlusion (CTO), I would first go for prolonged PTA and use atherectomy devices such as Phoenix (Philips) or Jetstream if the vessel doesn't open after prolonged PTA. In these cases, it is important to perform angiography after 10 to 15 minutes to evaluate for elastic recoil. When elastic recoil occurs after prolonged PTA, a DES or a drug-eluting bioresorbable scaffold can be implanted.

My treatment algorithm differs from above the knee (ATK) in the use of drug-coated balloons (DCBs). I see a clear benefit of antiproliferative technology in the femoropopliteal region, where restenosis occurs because of intimal hyperplasia. I am using DCBs in all ATK lesions, regardless of the vessel prep technique used (POBA, IVL, or atherectomy). In BTK, I think the major reason for (acute) restenosis is recoil.

Dr. Rundback: Although we generally believe in vessel preparation as part of a BTK "optimized angioplasty" strategy, we rely on both angiography and IVUS to make specific case-by-case determinations regarding the modalities and methods. The recanalization plane and plaque morphology are critical factors in this decision-making. This analysis can be quite granular; for instance, predominantly luminal calcification would be treated differently than mostly medial patterns of calcification, and the presence of thrombus in lesions is approached differently than soft plaque alone. Every case is personalized.

Dr. Steiner: Similar to ATK lesions, lesion crossing is a prerequisite for all subsequent steps of BTK lesion preparation, and the difficulties that may be encountered during crossing will inform whether lesion preparation is needed and about the technique that may be required. In BTK disease, we usually face long CTOs involving distal disease and often poor runoff, especially in patients with long-standing diabetes and advanced chronic kidney disease. In the case of heavily calcified lesions, the advancement of low-profile balloons can be difficult, even after establishing a pull-through wire. In this situation, the use of most lesion preparation techniques is difficult due to limited pushability and crossability.

I rely primarily on angiographic imaging to assess the lesion and determine the extent of calcification. Because there is no reimbursement, I only use IVUS in selected cases with specific questions. Compared to ATK lesions, lesion preparation with atherectomy devices is not performed as frequently in BTK lesions. Directional atherectomy can be an excellent option for proximal, relatively short lesions. As IVL is currently not reimbursed in Germany, we are using the device primarily within the ongoing BTK randomized controlled trial (RCT). For longer calcified lesions, the use of orbital/rotational as well laser atherectomy can be helpful to optimize lumen gain. For isolated, highly calcified spots resistant to PTA, I would think about using a GoBack catheter (Upstream Peripheral Technologies) for lesion modification using a "picking technique." Optimal lumen gain has become a cornerstone of endovascular BTK procedures, as it is associated with improved patency. This can also be supported with the use of specialty balloons (cutting/scoring/focal force devices), which we therefore use on a regular basis to improve immediate angioplasty results.

Dr. van den Heuvel: I think that every case needs some form of vessel prep. I do not rely on preprocedural imaging (CTA or MRA) to decide which vessel prep modality is required. For this, I primarily rely on procedural imaging, which in addition to angiography also includes extravascular ultrasound (EVUS) and calcium assessment with single shot/still images. Although not as sensitive as IVUS, EVUS helps me size balloons and stents. I do have access to IVUS in my clinic, but considering the extra costs, I only use it for problem solving. A simple, single-shot image of the lesion provides important information about the amount and pattern of vessel wall calcification.

Of note, when I say every lesion needs some form of vessel prep, I do not mean that every lesion is treated with a specialty device. I consider stepwise dilatation with noncompliant, high-pressure balloons of increasing size as vessel prep, and this is my standard approach. Therefore, my algorithm is as follows: In the absence of calcium and assuming I am dealing with a chronic de novo lesion, I start with an undersized, noncompliant, high-pressure balloon to see how the vessel reacts to dilatation. Ultimately, I dilate the vessel to its reference diameter, so I do not oversize. My approach in ATK and BTK revascularization in this respect is the same. If the result is satisfying, I use a paclitaxel DCB in the superficial femoral artery, and in the BTK vessels, I only use DCBs in cases of late restenotic disease because of neointimal hyperplasia. If predilatation shows recoil or dissections, I first try prolonged (5-10 minutes) noncompliant, high-pressure ballooning with minimal oversizing. If this doesn't solve the problem, I perform spot stenting with DESs in case of focal recoil and DES or Tacks (Philips) when I must repair persistent flow-limiting dissections.

My approach in ATK and BTK disease is different when vessel wall calcifications are present. I think it is important to make a distinction between typical MAC, intimal calcifications, or a combination of these. In pure MAC, I again perform dilatation with increasing-size noncompliant, high-pressure balloons. In my experience, this can be done a bit more aggressively with larger balloons versus when there is no calcification. Often, this results in good luminal gain without dissections. Recoil can be a problem, and when this happens, I perform a prolonged dilatation with a noncompliant, high-pressure balloon as when there is no calcium. Alternatively, when recoil is severe, I use IVL. If there are also eccentric intimal calcifications, a simple angioplasty will very likely not result in an adequate acute luminal gain. Therefore, my BTK approach is different from ATK when I'm dealing with eccentric or combined calcification patterns. Here, I make a distinction between short and long lesions. In long lesions, POBA with a gradual increase in balloon size as a form of vessel prep is my preferred treatment. I do not have access to dedicated vessel prep devices such as the Temporary Spur stent system (Reflow Medical) or Serranator balloon (Cagent Vascular). However, the concepts are appealing to me because they break the ring of MAC, enabling low-pressure dilatation with less risk of dissections and better acute luminal gain. I do have access to scoring balloons, but in my experience, these balloons do not seem to make a big difference compared to my standard strategy of progressive dilatation. In short lesions

with eccentric calcifications, I use orbital atherectomy or IVL, followed by low-pressure standard balloon angioplasty. I also use this approach in focal calcified lesions in the popliteal artery.

What is the main reason to use BTK vessel prep—improvement of acute outcome (dissection and recoil reduction), improvement of long-term results, both, or other reasons?

Dr. Steiner: We know from IVUS studies that the luminal gain after atherectomy is mainly due to the removal of calcium, and this is an important reason for the use of lesion preparation in BTK disease, as it may also improve long-term patency. Previous studies also advocated for atherectomy for BTK lesions to minimize acute dissection and the need for bailout stents. Thus, modifying calcified plaques and preparing vessels before standard angioplasty may improve acute outcomes, reduce the risk of periprocedural complications, and achieve sustained patency over time.

Dr. Rundback: Vessel preparation BTK is an integral part of our strategy of "optimized angioplasty," consisting of intraluminal crossing when possible (early retrograde access); IVUS; the actual "prep" (predominantly with atherectomy); slow, incremental, "real-sized," prolonged balloon inflations with long, low-compliance balloons (using IVUS reference artery diameters); and then optimization with focal-force PTA, prolonged PTA, and dissection repair tools or scaffolds as needed. The vessel prep allows subsequent uniform balloon expansion and therefore reduces or "focalizes" dissections, allowing easier definitive management. The optimized angioplasty strategy overall reduces recoil, restenosis, and reintervention.

Dr. van den Heuvel: The answer is both. Of course, when treating stenotic or occlusive disease, you want the acute result to be optimal. This means good acute luminal gain, no elastic recoil, and no dissections. I do believe that the acute outcome will be better with the use of vessel prep devices. The question is whether these often-expensive vessel prep devices can be justified. When I have a patient with a small wound requiring only several weeks of vessel patency to heal, I probably will not use vessel prep devices. An exception is a focal lesion, for instance in the proximal anterior tibial artery, with high recoil and where I don't want to use a stent. In case of larger wounds or planned transmetatarsal amputations, I'm more focused on optimizing long-term patency. Here, I'm more likely to use vessel prep devices during the index procedure but still use the algorithm I explained previously. If recoil or restenosis is detected during duplex ultrasound follow-up and the wound is not yet healed, I'll order the patient back and perform a repeat intervention. Chances are high that I will then use a vessel prep device to improve patency given that the primary strategy was insufficient. We know that vessel prep devices increase luminal gain and thereby improve the acute results of a revascularization. They do so because these devices change vessel wall compliance and facilitate subsequent low-pressure ballooning, avoiding dissections. In addition to this mechanism, which improves the acute outcome, it might be that the drug uptake (paclitaxel or limus) is also improved through plaque modification, potentially translating into better long-term results. Currently, we do not have strong evidence to support this, but it is a plausible theory that needs further investigation.

Dr. Bosiers: The main reason is the improvement of the acute outcome by not having dissections and/or elastic recoil in these moderate/severe calcified arteries. I also want to avoid stenting, because we know that fractures and compression can occur, and even passing through it during a follow-up procedure can cause crimping, compression, or deformation of the stent. Unfortunately, there are no long-term data available.

Does your preprocedural plan for a primary therapy influence your decision as to how you approach vessel prep in the case?

Dr. Rundback: Although preprocedural planning can decrease table time and increase patient safety, vessel preparation is performed on a case-by-case basis. Once a lesion or lesions are crossed, diagnostic angiography and IVUS are utilized to evaluate a multitude of factors, including the length of the lesion(s) to be treated, intraluminal versus subintimal positioning, plaque morphology/consistency, and thrombus burden. All of these factors play a role in choosing the right vessel preparation strategy for each individual patient to optimize patient results.

Dr. van den Heuvel: To some extent. In BTK, my primary therapy is always POBA with bailout stenting on indication with no specific vessel prep. As I said, in restenotic/reocclusive disease, my approach is a little bit different. In these cases, I'll try even harder to get the optimal acute and long-term result. The form of vessel prep used is based on the previous digital subtraction angiogram and follow-up duplex findings. I use atherectomy (orbital, rotational, or laser) and IVL to improve the results.

Dr. Bosiers: Luckily, we have a lot of devices on the shelf, so I can adapt my strategy along the way if necessary. Going into a BTK case, you have to expect the unexpected and be prepared for everything.

Dr. Steiner: To date, standard balloon angioplasty, preferably using a more aggressive balloon sizing and higher inflation pressure to ensure optimal lumen gain by cracking recalcitrant calcification, is still the main treatment modality for BTK lesions. In contrast to femoropopliteal lesions, the use of drug-coated technologies is typically not considered as primary therapy for BTK lesions because there are limited positive data for the use of DCBs and the cost is not reimbursed. Balloon-expandable DES can be used for relatively short proximal BTK lesions in case of severe dissections. Thus, the decision to use vessel prep is typically made after baseline angiographic imaging and wire crossing to achieve optimal acute and long-term outcomes in appropriate lesions.

What is your impression of the data landscape for BTK vessel prep? Which trials and data guide your decision-making, and where do you see conflicting evidence? Where would you most like to see more data regarding vessel prep utility?

Dr. Rundback: The level of evidence supporting BTK vessel prep is highly variable. For specialty balloons, only small noncomparative studies have been performed, so there is substantial uncertainty regarding clinical benefit. Atherectomy also largely relies on data from single-arm trials or registries (with some small exceptions such as CALCIUM 360), although studies such as the COMPLIANCE 360° and LIBERTY 360 trials for orbital atherectomy and the PATHFINDER I registry for laser atherectomy do provide more robust science regarding safety and efficacy of these devices. However, what is most impactful is data regarding propensity score–adjusted long-term outcomes in Medicare beneficiaries, reporting improved limb salvage, and lower overall costs using a BTK atherectomy strategy.[1] These are crucial data and a springboard to other needed comparative data looking at treatment strategies with and without vessel preparation, as well as across vessel preparation platforms.

Dr. Bosiers: It is important to see high-quality, long-term data comparing a certain technique to POBA in real-world lesions and then analyze the cost-effectiveness. These data are lacking. We have data for all kinds of devices, from specialty balloons to atherectomy devices to laser, but these are usually in a small number of patients, used in simple lesions, or poor data quality. Here, there is still a lot of room for improvement. The recent findings of the BEST-CLI trial, where there was quite a lot of endovascular failure, have shown us that suboptimal treatment strategies are still being performed. The majority of patients in the endovascular group were treated with POBA (52.7%), and this could have led to the high reintervention rate of > 40% (perhaps because of recoil/dissection?) within 30 days.[2]

For short lesions, there is still room for PTA with the use of DES for recoil or dissection.[3] I am looking forward to bioresorbable drug-eluting scaffolds for these or even more complex lesions.

Dr. van den Heuvel: More and more published studies are presenting data about and discussing the different types of vessel prep. As far as I know, there are no comparative trials between the different forms of vessel prep and only a handful of studies comparing vessel prep devices with POBA. There is a severe lack of evidence regarding vessel preparation. A recently published systematic review and meta-analysis by Nugteren and colleagues compared different vessel prep techniques in combination with POBA or DCB to POBA or DCB alone.[4] Conclusions of this analysis were that the studies were very heterogeneous, the quality of the studies was only moderate to poor, and no additional value of the standard use of vessel prep techniques could be shown. However, this analysis did suggest a benefit of scoring balloons and mechanical atherectomy at 12 months with respect to limb salvage rates. Disrupt BTK II is an ongoing, prospective, single-arm study investigating the long-term durability of IVL in CLTI patients. I find this study very interesting because the Disrupt PAD III RCT showed improved outcomes with the use of IVL compared to POBA alone. It would be great if these results could be translated into the BTK segment in patients with CLTI. In addition, the data from the subgroup analysis of the LIBERTY 360 registry show promising results of orbital atherectomy, with low rates of major amputations at 3 years. More randomized data on orbital atherectomy or, in fact, any atherectomy or vessel prep in the CLTI population would be valuable.

Dr. Steiner: In general, data from clinical trials of endovascular BTK procedures are limited, and BTK vessel prep is no exception. Clinical research, particularly in the field of BTK, is hampered by numerous factors, such as the wide heterogeneity of patients, lesions, and local expertise, as well as the limited availability and reimbursement of various technologies. There are several promising clinical trials supporting the use of specific vessel prep devices, but more comparative research on the added value of these technologies is clearly needed. Importantly, longer follow-up is mandatory in order to assess potential long-term benefits of these often costly devices over standard angioplasty. Given the difficulties associated with RCTs in BTK disease, high-quality, multicenter, prospective registries with core lab adjudication of angiograms could be a valuable alternative to gain more insight into which

specific lesion subsets could benefit most from additional vessel prep.

The impact of practice settings and reimbursement on vessel prep use has recently been explored, with particular focus on the use of atherectomy in settings having favorable reimbursements (whether by region or clinic type). How can and should practices ensure they are selecting the optimal therapy for each patient and limiting the sway of bias toward optimal reimbursements?

Dr. Bosiers: First, we should choose the best strategy for our patients based on type of lesion and patient characteristics. Hospitals are businesses, and the cost-effectiveness of certain treatments definitely plays a role. Moreover, you can't have every device on your shelf, so you have to choose two to three devices to treat a plethora of lesions. Second, generating better data, I believe we can improve the reimbursement system and help find the best vessel prep tool for a certain type of lesion. In my opinion, there is no specific tool that can be used to treat every type of lesion. There is still a long way to go unfortunately.

Dr. Steiner: As an interventional community, we must strike a balance between adequate use of these often extremely helpful devices and avoidance of potentially harmful overuse in the interest of favorable reimbursement. Personal experience as an operator and clinical judgment will continue to play an important role in the choice of BTK vessel prep, as no large RCTs will be available in the near future. High standard of care can be ensured through thorough case discussions in a dedicated interventional team, in addition to routine reviews of the appropriateness of device selection and utilization in peripheral vascular procedures.

Dr. van den Heuvel: Regardless of practice setting or region, a treating physician should always put the patients' interest ahead of anything else. There should not be a financial incentive to use atherectomy devices or any other device for that matter. We want to offer our patients the best possible care, and at the same time, we must also make sure that reimbursements are enough to sustain the business model of our practices. Here lies the challenge and the risk of a bias toward optimal reimbursements. The use of certain devices or therapies should be evidence based. I believe that RCTs are still the most important source of data to help us to select the right therapy for each patient. However, I also believe that these data are not always applicable in our daily practice. Medical devices might perform differently in an uncontrolled real-world setting. So, how can and should practitioners ensure they are selecting the optimal therapy for each patient and limiting the sway of bias toward optimal reimbursements? For this, I think that health care providers should work together with our societies to develop clear objective performance goals (OPGs). What these goals are and which data (RCTs and/or real-world data) are used to set these goals is another question, but in the end, each practice should live up to these OPGs. This requires oversight and benchmarking of practices by government health care authorities. I think that feedback from health care authorities on the OPGs could help increase practices' efficiency and productivity while keeping the revenues at an acceptable level. A possible win-win situation for everyone.

Dr. Rundback: There is an unfortunate reality in the current health care climate that reimbursement plays a role in determining which therapies are available or offered to patients. Reimbursement considerations may either limit access (ie, hospital inpatient services) or result in overutilization (ie, office-based lab/ambulatory surgical center settings) of atherectomy technologies. Fortunately, the evidence for atherectomy has continued to mount, and devices have continued to evolve to create better alignment between practice and reimbursement. However, in my opinion, the need to make cost decisions during patient care is a serious problem and a problem that was created by irrational administrative and insurance policies that force physician and hospital care patterns to support solvency. Payment systems should ultimately focus on the work done, and all devices should be paid for as a pass-through (neither increasing or decreasing physician or facility bottom line) so that care is based on best practices alone and without consideration for device costs. We need fewer special interests affecting reimbursement and more thoughtful and collaborative payment structures. ■

1. Mustapha JA, Katzen BT, Neville RF, et al. Propensity score–adjusted comparison of long-term outcomes among revascularization strategies for critical limb ischemia. Circ Cardiovasc Interv. 2019;12:e008097. doi: 10.1161/CIRCINTERVENTIONS.119.008097
2. Farber A, Menard M, Conte M, et al. Surgery or endovascular therapy for chronic limb-threatening ischemia. N Engl J Med. 2022;387:2305–2316. doi: 10.1056/NEJMoa2207899
3. Katsanos K, Kitrou P, Spiliopoulos S, et al. Comparative effectiveness of plain balloon angioplasty, bare metal stents, drug-coated balloons, and drug-eluting stents for the treatment of infrapopliteal artery disease: systematic review and Bayesian network meta-analysis of randomized controlled trials. J Endovasc Ther. 2016;23:851-863. doi: 10.1177/1526602816671740
4. Nugteren MJ, Welling RHA, Bakker OJ, et al. Vessel preparation in infrapopliteal arterial disease: a systematic review and meta-analysis. J Endovasc Ther. Published online September 4, 2022. doi: 10.1177/15266028221120752

Disclosures
Dr. Bosiers: None.
Dr. Rundback: Paid consultant to AngioDynamics and Cardiovascular Systems, Inc./Abbott.
Dr. Steiner: Consultant to Boston Scientific and Cook Medical; receives research funding from C.R. Bard.
Dr. van den Heuvel: None.