Vessel Preparation in Lower Extremity Revascularization: Closing the Evidence Gap

A practical review of available vessel preparation strategies, patient and lesion selection, contraindications, treatment sequencing, and the evidence needed to guide future practice.

By Natasha Hasemaki, MD; Yassine Haddad, MD; and Konstantinos Stavroulakis, MD

Vessel preparation has become a routine component of lower extremity revascularization, particularly in the presence of calcification, heavy plaque burden, thrombus, or elastic recoil that may compromise drug delivery or optimal stent expansion. Although the term "vessel preparation" has been adopted in clinical guidelines, there remains a significant gap not only in the available evidence but also in its definition. Consequently, until recently, there was no universally accepted framework defining its objectives, indications, procedural strategies, or measures of success.

The most important development of the past year may be conceptual rather than technologic. An international Delphi consensus established a practical definition of vessel preparation.[1] This framework moves the field away from subjective or industry-driven interpretations of vessel preparation toward a standardized, evidence-based approach. By providing a clear definition, objectives, and procedural principles, it establishes vessel preparation as the first structured step of peripheral endovascular intervention rather than a device-specific concept or marketing term. At the same time, contemporary evidence has reinforced an important distinction between procedural success and durable clinical benefit.[2,3]

DEFINITION AND AIMS OF VESSEL PREPARATION

The Delphi consensus defines vessel preparation as "the initial step of an endovascular intervention aimed at facilitating subsequent treatment by modifying lesion characteristics."[1] Furthermore, it identifies six principal goals: (1) achieving luminal gain and adequate vessel expansion; (2) modifying vessel compliance; (3) reducing plaque and calcification burden; (4) optimizing drug delivery; (5) minimizing procedural risks; and (6) improving procedural efficiency. Ultimately, vessel preparation seeks to optimize the performance and durability of the definitive treatment. Importantly, vessel preparation strategies and definitive treatment modalities should both be tailored to the target vascular bed and the specific lesion characteristics, as these vary considerably across different clinical settings.

DEVICE SELECTION AND DEFINITIVE TREATMENT

Plain old balloon angioplasty (POBA) remains the most widely used vessel preparation strategy in contemporary practice; however, most experts participating in the Delphi consensus reported routine use of adjunctive vessel preparation technologies, including various atherectomy devices, intravascular lithotripsy (IVL), and specialty balloons. There was strong consensus that vessel preparation should be routinely considered in the femoropopliteal segment, whereas participants identified a substantial unmet need for dedicated vessel preparation technologies in both aortoiliac and below-the-knee (BTK) disease. IVL emerged as the preferred modality for heavily calcified aortoiliac and femoropopliteal lesions, although no consensus was reached regarding the device selection in BTK interventions. Considerable heterogeneity was also observed in the management of in-stent restenosis and stent occlusions, with agreement limited to thromboaspiration for iliac stent occlusions and rotational atherectomy for femoropopliteal scaffolds. Notably, no

consensus could be achieved regarding the optimal vessel preparation strategy for long lesions (≥ 20 cm) or chronic heavily calcified total occlusions of similar length, highlighting important evidence gaps and the need for future comparative studies. With respect to definitive treatment following vessel preparation, covered stents were the preferred option for aortoiliac lesions, drug-coated balloons (DCBs) for femoropopliteal disease, and POBA for BTK interventions.

CONTRAINDICATIONS

There are no universal contraindications to vessel preparation, as the term encompasses a broad range of technologies with distinct mechanisms of action. Instead, contraindications are generally device-specific and depend on lesion morphology and patient characteristics. The strongest consensus from the Delphi process was that directional and rotational atherectomy should not be performed in a subintimal plane. Significant thrombus is not an absolute contraindication to vessel preparation but should generally be managed with thrombus-directed therapy before plaque modification is undertaken.

Additional procedural considerations include severe vessel tortuosity or angulation, small vessel diameter, involvement of critical side branches, poor distal runoff, inability to safely deliver the device, and lack of an adequate bailout strategy for complications such as perforation or distal embolization. Patient-related factors, including frailty, limited life expectancy, renal impairment, elevated bleeding risk, and poor tolerance of prolonged procedures, should also be incorporated into decision-making, as the risks of an extensive vessel preparation strategy may outweigh its anticipated clinical benefit.

BARRIERS

The two most consistently identified barriers are device cost and insufficient randomized evidence. A central evidence barrier is the disconnect between procedural and patient-centered outcomes. A network meta-analysis found that atherectomy or IVL before DCB angioplasty reduced bailout stenting but did not improve 1-year target lesion revascularization, major amputation, or mortality.[2] An updated meta-analysis of randomized trials similarly reported less bailout stenting and flow-limiting dissection with atherectomy, without a significant clinical advantage at 12 months.[3] Whether these procedural gains translate into better long-term clinical outcomes remains uncertain.

Beyond the cost of individual devices, the economic burden of vessel preparation encompasses longer procedure times, additional device exchanges, embolic protection, increased radiation exposure, and frequently higher contrast volumes, all of which influence the overall value of care. Ultimately, reimbursement alone cannot justify widespread adoption in the absence of proven clinical benefit.

UNMET NEEDS AND THE ROAD AHEAD

Although the Delphi consensus provides the first standardized definition of vessel preparation, it also highlights the substantial heterogeneity in the routine use of vessel preparation technologies across contemporary practice. This variation is driven not only by differences in device availability but also by the limited clinical evidence supporting individual modalities and the heterogeneity of local reimbursement policies. Notably, experts agreed that there remains a significant unmet need for dedicated vessel preparation technologies for aortoiliac and BTK disease. As a result, POBA continues to serve as both the principal vessel preparation strategy and the definitive treatment modality for infrapopliteal disease. This observation is consistent with the findings of the BASIL-2 trial, in which adjunctive vessel preparation technologies were permitted but rarely adopted, with POBA remaining the predominant treatment strategy.[4]

In contrast, vessel preparation has become an integral component of femoropopliteal interventions, particularly in the presence of severe calcification, neointimal hyperplasia, or thrombotic lesions. However, it is important to recognize that most contemporary vessel preparation devices were originally developed for the superficial femoral and popliteal arteries. Consequently, their design characteristics and supporting evidence cannot necessarily be extrapolated to other vascular territories, which differ substantially in vessel size, biomechanics, lesion morphology, and therapeutic objectives. This underscores the need for vascular bed–specific technologies and dedicated clinical evidence rather than assuming that a single vessel preparation strategy is applicable across the entire peripheral arterial tree.

The most important unresolved question is whether vessel preparation translates into meaningful improvements in patient outcomes rather than merely optimizing procedural or angiographic results. Future randomized trials should be adequately powered to detect differences in clinically relevant endpoints, including clinically driven target lesion revascularization, major amputation, amputation-free survival, wound healing, functional status, walking performance, and health-related quality of life. These outcomes should be evaluated separately in patients with intermittent claudication and chronic limb-threatening ischemia, with sufficiently long follow-up

to determine whether immediate procedural benefits result in durable clinical advantages.

Important evidence gaps also exist around the definitive treatment that follows preparation. Most studies have evaluated preparation before DCB angioplasty and have treated bailout stenting as an adverse procedural endpoint; comparatively little evidence addresses preparation for planned stent implantation. The limited platform-specific literature is concentrated around the interwoven scaffolds, including studies emphasizing sufficient predilation in heavily calcified femoropopliteal disease.[5] Prospective studies should define vessel preparation endpoints for conventional nitinol, interwoven, drug-eluting, and covered stents and determine whether calcium modification or plaque debulking improves stent expansion, patency, and freedom from reintervention.

The drug platform is another source of uncertainty. Most randomized vessel preparation evidence has been generated with paclitaxel-coated balloons, and those results cannot automatically be extrapolated to limus-coated technologies.[2] Early sirolimus-eluting balloon studies are encouraging, but the evidence remains limited, and the relationships among lesion modification, drug transfer, and clinical benefit are not yet defined.[6] Dedicated studies should compare preparation strategies for paclitaxel- and limus-based devices. Technology development should continue to prioritize lower-profile systems, longer treatment lengths, improved crossing capability, and safer tools for aortoiliac and crural disease.

CONCLUSION

Vessel preparation is evolving from a collection of adjunctive devices into a lesion-specific clinical strategy. Current evidence supports meaningful procedural benefits in selected patients, but durable patient-level superiority remains incompletely proven. The best approach is to identify what is preventing an optimal result, select the most appropriate preparation strategy, avoid unnecessary escalation, and judge success by its effect on the definitive treatment and, ultimately, the patient. ■

1. Saratzis A, Patrone L, Secemsky EA, et al. Use of vessel preparation in endovascular peripheral arterial disease (PAD) interventions: a global qualitative analysis. J Endovasc Ther. Published online February 19, 2026. doi: 10.1177/15266028261424732
2. Yiu J, Tippireddy R, Biasi L, et al. Systematic review and network meta-analysis of vessel preparation techniques with plain balloon angioplasty, atherectomy, or intravascular lithotripsy before application of a drug coated balloon to treat atherosclerotic femoropopliteal disease. Eur J Vasc Endovasc Surg. 2025;69:118–129. doi: 10.1016/j.ejvs.2024.08.002
3. Ho JQJ, Udayasiri S, Stewart M, et al. Paving the way: a systematic review and meta-analysis of randomized controlled trials of atherectomy as vessel preparation prior to balloon angioplasty in peripheral arterial disease. Cardiovasc Intervent Radiol. Published online July 13, 2026. doi: 10.1007/s00270-026-04527-y
4. Bradbury AW, Moakes CA, Popplewell M, et al; BASIL-2 Investigators. A vein bypass first versus a best endovascular treatment first revascularisation strategy for patients with chronic limb threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal revascularisation procedure to restore limb perfusion (BASIL-2): an open-label, randomised, multicentre, phase 3 trial. Lancet. 2023;401:1798–1809. doi: 10.1016/S0140-6736(23)00462-2
5. Fujihara M, Takahara M, Iida O, et al. Endovascular therapy with interwoven nitinol stent placement after predilation for heavily calcified femoropopliteal artery disease: results of the BURDOCK study. J Vasc Interv Radiol. 2023;34:1929–1937. doi: 10.1016/j.jvir.2023.07.023
6. Soga Y, Iida O, Saito S, et al. 3-year results following femoropopliteal lesion treatment with a novel sirolimus-eluting balloon. JACC Cardiovasc Interv. 2025;18:2629–2637. doi: 10.1016/j.jcin.2025.08.041

Natasha Hasemaki, MD
Department of Vascular Surgery
University Hospital LMU Munich
Munich, Germany
Disclosures: None.

Yassine Haddad, MD
Department of Vascular Surgery
University Hospital LMU Munich
Munich, Germany
Vascular and Endovascular Surgery Unit
Mathias Spital Rheine
Rheine, Germany
Disclosures: None.

Konstantinos Stavroulakis, MD
Department of Vascular Surgery
University Hospital LMU Munich
Munich, Germany
Vascular and Endovascular Surgery Unit
Mathias Spital Rheine, Germany
Rheine, Germany
Disclosures: Consultant to Boston Scientific Corporation, Philips, and BD Interventional; receives scientific grants from Shockwave Medical, Boston Scientific Corporation, Philips, and Medtronic; receives honoraria from Boston Scientific Corporation, Shockwave Medical, BD Interventional, Medtronic, Abbott, Philips, Biotronik, and Bentley.