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Roundtable Discussion on the Current State of Atherectomy for Lower Extremity Arterial Disease

Jeffrey Carr, MD
Interventional Cardiology
CHRISTUS Health-Heart and Vascular Institute
Tyler, Texas
jeffcarr@me.com

Ralf Langhoff, MD
Head of Department, Angiology
Sankt Gertrauden-Krankenhaus GmbH
Charité-Humboldt University
Berlin, Germany
ralf.langhoff@sankt-gertrauden.de

Eric A. Secemsky, MD, MSc
Director of Vascular Intervention
Beth Israel Deaconess Medical Center
Associate Professor, Harvard Medical School
Boston, Massachusetts
esecemsk@bidmc.harvard.edu

Medtronic may not have product that is indicated for all of the treatments discussed broadly across atherectomy in this piece.

Peripheral artery disease (PAD) is progressive and chronic, and preserving future treatment options is critical. Atherectomy is an important endovascular tool that can reduce plaque burden and decrease the need for permanent scaffolds.[1,2] However, atherectomy use has been under scrutiny lately, questioning whether there are sufficient clinical data to support the use of this technology. To address this concern, a steering committee (Drs. Jeffrey Carr, Ralf Langhoff, and Eric Secemsky) led a systematic literature review (SLR) and meta-analysis of atherectomy publications through 2024. They presented the interim analysis results at VIVA 2024.[3,4] The following are excerpts from a conversation with the steering committee.

In your opinion, what is the greatest potential benefit of atherectomy for lower extremity endovascular interventions?

Dr. Secemsky: Although there remains substantial variability in use of atherectomy devices, there are some key subgroups where atherectomy use is most consistent. For my practice, long, heavily calcified lesions in the femoropopliteal segment benefit from plaque and vessel compliance modification to improve ultimate vessel size, avoid routine stenting (eg, full metal jackets), and potentially improve drug delivery. In particular, balloon-uncrossable and unyielding lesions require more aggressive preparation to facilitate delivery of definitive treatments (ie, drug-coated balloons [DCBs] and stents). Although lithotripsy has made a significant impact on vessel preparation in the periphery, this device fails to account for uncrossable lesions and those that do not respond to therapy.

Furthermore, in-stent restenosis is a common lesion subset where most practitioners and societies endorse atherectomy. Mechanisms of stent failure can be numerous, including stent underexpansion, neointimal hyperplasia, or neoatherosclerosis. Some atherectomy devices can help address poorly expanded stents, whereas others can facilitate decreasing the burden of tissue growth within the stent, restoring a sizable lumen and facilitating drug delivery.

Dr. Carr: We need durable interventional solutions for below-the-knee (BTK) disease, a significant contributor to chronic limb-threatening ischemia (CLTI). Due to the diffuse nature of BTK disease and small vessel sizes of these arteries, luminal gain is imperative, regardless of what the definitive therapy may be (standalone scaffolds or DCBs). Achieving luminal gain in a manner that minimizes deep wall injury and vessel barotrauma can be achieved by atherectomy. At a minimum, effective atherectomy can mitigate the need for very long or overlapping BTK scaffolds. We often hear "leave nothing behind" for infrainguinal interventions, but it is even more prescient in BTK arteries. We still don't know if and how antirestenotic drug delivery is optimized by atherectomy, but there are mechanistic arguments and growing evidence.[5] The greatest potential benefit of atherectomy is in achieving successful primary revascularization with a low rate of restenosis and target lesion revascularization.

Dr. Langhoff: Atherectomy offers treatment options for a broad spectrum of indications to treat various lesion pathologies, primarily in the femoropopliteal arteries. Atherectomy often comes into consideration when deciding how to treat calcified lesions, which is an absolutely proper choice in the treatment algorithm. Atherectomy is also a perfect tool to treat noncalcified, fibrotic or restenotic lesions, independent of lesion length. When training beginners on atherectomy use, and especially directional atherectomy, it is better to start with noncalcified lesions to get familiar with the devices

and safely remove the disease in a stepwise, controlled way. To remove eccentric, long, severely calcified plaques, more advanced skills and experience may be needed compared to "standard" lesions. The risk of stenting is almost zero if you respect certain rules. Efficient removal of plaque and stenotic tissue is a driver for better outcomes, as we have seen in trials (eg, DEFINITIVE AR). Atherectomy is a very effective vessel preparation prior to local drug delivery. Today, we treat all femoropopliteal lesions with drug delivery devices (preferably with DCB) in the absence of residual stenosis and dissection, and atherectomy seems a perfect tool to facilitate this.

In your practice, what obstacles do you commonly face in using atherectomy?

Dr. Carr: Many centers in the United States have limited choices of atherectomy devices due to contracting, product selection committees, and limits on space. I am fortunate to have multiple atherectomy modalities, such as directional, laser, and orbital atherectomy, available in my cath lab. My approach is to analyze the morphology of the plaque in target lesions (including with intravascular ultrasound as needed), then choose the best atherectomy device that will optimize lumen gain throughout the diseased segments. Even as an experienced operator (> 30 years of experience), a perceived and sometimes real obstacle is that atherectomy requires extra time in the case to optimize outcomes, especially for long, complex lesions. In general practice, assessing these tradeoffs of time versus outcome occurs in many cases. In my practice, I always try to prioritize outcomes.

There has been misinformation about economic incentives for atherectomy use that is tied with perception of overutilization. This has centered on conflating global fees paid to office-based labs and ambulatory surgical centers and comparing just the professional fees paid in hospital settings. This negative information coupled with alleged claims that there is a paucity of data to support atherectomy use has led to increased scrutiny by payers. Some commercial payers have recently responded by requiring prior authorization before atherectomy procedures can be done. Reimbursement or other access to care issues remain a challenge in many locations.

Dr. Secemsky: At our center, atherectomy is selectively used during peripheral intervention. As such, there are some barriers regarding operator knowledge, comfort, and experience with atherectomy devices. When atherectomy is used too infrequently, there can be confusion about appropriate setup and technique, as well as discomfort troubleshooting any device issues. In addition, we often use devices that require specific wires, which creates an extra level of challenges swapping out wires and employing embolic protection. Lastly, our staff often feels atherectomy setup is cumbersome, particularly for devices with large capital equipment, adding time delays and dissatisfaction with procedures.

Dr. Langhoff: In terms of obstacles, they are not related to the patient, devices, or technique for our center but more to the reimbursement system in Germany. The required length of hospital stays to get the full reimbursement based on the diagnosis-related group system is quite stringent (ie, the patient must stay 2 nights in the hospital). If the patient has no severe comorbidities or did not face any complications to justify a prolonged stay, atherectomy is not affordable. Consequently, this important vessel preparation technology, which significantly reduces dissections and partially removes the disease prior to antirestenotic therapy, is rarely used in claudicants. We use distal protection devices in all our atherectomy procedures, which is an additional cost driver and makes the decision to perform atherectomy even more crucial.

What is most needed to support the use of atherectomy in appropriate patients?

Dr. Langhoff: Once physicians understand the correct use of the device in combination with a supportive sheath and proper protection device, complications are rare. Training workshops in hospitals that treat diseased patients enables physicians to become familiar with potential risks and benefits. It is an ideal way to share tips and tricks, and there are many to share. Device prep is important and must be taught; however, beginners might experience trouble when treating in highly complex lesions too early in the learning curve, which may lead to frustration or handling mistakes when using the tools.

Dr. Carr: There is a lot of practice pattern variability in how atherectomy is applied, partly due to the inherent mechanisms of action for the various devices but also training and medical decision-making factors. Moreover, there is heterogeneity in disease manifestations. Appropriate diagnostic and therapeutic imaging and plaque characterization should be encouraged. We need to refine treatment algorithms based on best data at the lesion level in conjunction with long-term outcomes studies. Real-world lesions are not as well studied in investigational device exemption studies and randomized controlled trials, especially for CLTI. How do we extrapolate the data from these studies to real-world lesions such as very long, multisegmented lesions with heterogeneous disease and poor distal outflow?

It takes operator patience to remove plaque and maximize lumen gain without inducing vessel wall trauma (dissections, perforations, deep wall injuries, etc) in what I would call "careful atherectomy." Learning more about optimal plaque removal based on the lesion location and morphology is still needed.

It is healthy to have a scientific debate about efficacy and durability of all our interventions, but for all the criticisms, the real stories and data of limb salvage and lifestyle improvement

through reducing or resolving chronic pain and improving ambulation are vastly underreported and underrecognized. Physicians and patients on the front lines know this, but there is an issue of underutilization that can be devastating as well. Unnecessary amputations, geographic and ethnic disparities in lower extremity vascular care, and an undersupplied and undertrained interventional workforce are the main challenges we face. Unfortunately, most of our media highlights the rare operator outliers, oftentimes with inaccuracies, one-sidedness, and prejudice. Highlighting success stories when atherectomy has been appropriately applied will hopefully help this disparity in care.

Dr. Secemsky: One of the most frequent critiques of atherectomy is the lack of evidence. Although large-scale, prospective, outcome-driven trials are lacking, there is a surprising wealth of observational and small trial data supporting atherectomy safety and efficacy. Nonetheless, more data are always welcome and can facilitate continued growth, support reimbursement, and advance guidelines for these devices. We also need greater evaluation on the appropriate use of these devices. Although practices vary greatly, more standardized approaches of which devices should be used and in which lesion subsets will help drive more consistent and predictable use across operators and sites of service. Lastly, quality benchmarks that track safety of these devices can supplement other prospective studies in supporting these devices.

What was the purpose of the atherectomy SLR, and what do the data presented at VIVA mean to you?

Dr. Carr: Recently, there has been a lot of negative attention on atherectomy in the United States in the media, during podium presentations, and in opinions expressed in journal publications. In fact, concerns for overutilization have been tied to the perception that there is a paucity of data to support atherectomy use. So, we set out to discover: What is the totality of reported data for atherectomy? What is the level of rigor for the published evidence? Understanding that there is a diversity of devices and applications, what are the outcomes of atherectomy? I was quite surprised by the number of publications and evidence available.

Rather than discounting the role of atherectomy, we should continue to better study and define its optimal role in an ever-changing landscape of lower extremity revascularization. Following this literature review, we now have more confidence that there is a wealth of published atherectomy data, and it continues to grow.

Dr. Secemsky: The atherectomy SLR was designed to address sentiments that there was a disproportionate dearth of evidence supporting atherectomy compared to alternative devices. Although prior meta-analyses had been conducted, many of these focused on specific lesion subsets, study designs, and specific devices and didn't fully capture the evidence base. As such, this SLR was undertaken to summarize the safety and effectiveness of atherectomy. Overall, we found a large body of evidence supporting atherectomy devices that spans many decades. The analysis identified > 300 original research articles reporting outcomes on atherectomy for endovascular treatment of occlusive or stenotic PAD. The highest levels of evidence were represented, including meta-analyses; randomized trials; and prospective, multicenter, observational studies. The data demonstrated meta-analyzed rates of outcomes that meet thresholds observed in external clinical trials for other devices. Overall safety was well preserved. Findings were consistent across randomized trials and observational studies. Overall, these findings show that the size of the body of evidence that exists for atherectomy is actually greater than that for many other commercially available devices and confirms the safety of the treatment.

Dr. Langhoff: In a lot of discussions and workshops, we face the fact that the endovascular community is very critical of atherectomy, because most people believe that this method still is experimental and lacking evidence. In contrast, vascular surgeons in particular show a great interest and see the great potential of the currently available devices to treat a lot of pathologies, which may be because cutting or removing tissue is primarily a surgical technique.

Showing that there is a large body of evidence present, based on this SLR, offers confidence and stimulates the discussion on this treatment modality. Physicians become curious to try and gain experience with the device if they see, for example, a 25-cm-long stenotic and diseased superficial femoral artery lesion is "cleaned up" and perfectly patent after directional atherectomy and DCB without a scaffold at the end. The same is true for ostial lesions.

What are the future needs, and what can industry do to support atherectomy use in your practice?

Dr. Langhoff: Although everybody understands that vessel preparation is important, there is no clear guidance for when to apply which treatment. Data to investigate a proper algorithm for vessel preparation would be great, and maybe industry can cooperate on this topic.

It makes sense to offer workshops and cath lab experience to motivated users to share experience and become familiar with all treatment steps, from correct choice of sheath to removal of the filter device.

Dr. Carr: We need to: (1) Understand the evolving roles and limitations of plaque modification (such as intravascular lithotripsy and specialty balloons) versus plaque removal (atherectomy) in the context of drug delivery solutions. Does atherectomy improve drug delivery for DCBs, drug-eluting stents, and bioabsorbable devices and impact outcomes? (2) Provide appropri-

ate training of new and less experienced operators to optimize applications of the different atherectomy modalities. (3) Evaluate cost-effectiveness of atherectomy in the context of outcomes to better assist in value decision-making. (4) Sponsor prospective trials to answer more specific questions regarding atherectomy use and its accretive value to our procedures. (5) Encourage physician participation in clinical registries to answer questions with real-world patients and data, which will help develop alternative treatment pathways, support evidence-based guidelines updates, inform patient-reported outcomes, and consider the socioeconomic impact of atherectomy-based treatments.

Dr. Secemsky: Industry are important partners in device innovation and data generation, particularly in the postmarket setting. Unfortunately, in the United States, it is very challenging to get funding for multicenter studies, including registries and prospective trials, and investigators, societies, and even regulators look to industry to help support continued evidence generation. The future for atherectomy is both continued device innovation but also the commitment to continue supporting the study of atherectomy, whether through registries, trials, or other mechanisms. Private-public partnerships are key and have been successful in the past, helping eliminate some of the perceived biases associated with industry-supported efforts, but also maintaining a responsible relationship between committed parties. ■

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Disclosures

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