WHAT WOULD YOU DO?

Multiple Lower Limb Occlusions and Vascular Anomaly

MODERATOR: LAWRENCE A. GARCIA, MD

PANELISTS: GEORGE L. ADAMS, MD, MHS, MBA, FACC, FSCAI; MIGUEL MONTERO-BAKER, MD; AND SRINI TUMMALA, MD

CASE PRESENTATION

A 45-year-old man with a history of hypertension, hyperlipoproteinemia, diabetes mellitus, coronary artery disease treated with coronary artery bypass grafting/valve replacement, and ulceration/gangrene of the left fifth digit that required toe amputation now presents for further evaluation of gangrene to the fourth digit.

Noninvasive vascular imaging studies demonstrate a flat pulse volume recording at the foot and an ankle-brachial index of 0.55 (Figure 1). Baseline angiography with CO_2 and contrast is performed and demonstrates occlusion of the superficial femoral artery (SFA) and at the trifurcation of the popliteal artery. The anterior tibial (AT) artery appears patent to the ankle. Contrast angiography then confirms an anomaly from the popliteal artery to the dorsalis pedis (DP) with occlusions of the posterior tibial (PT) artery and popliteal/AT (Figures 2 and 3).

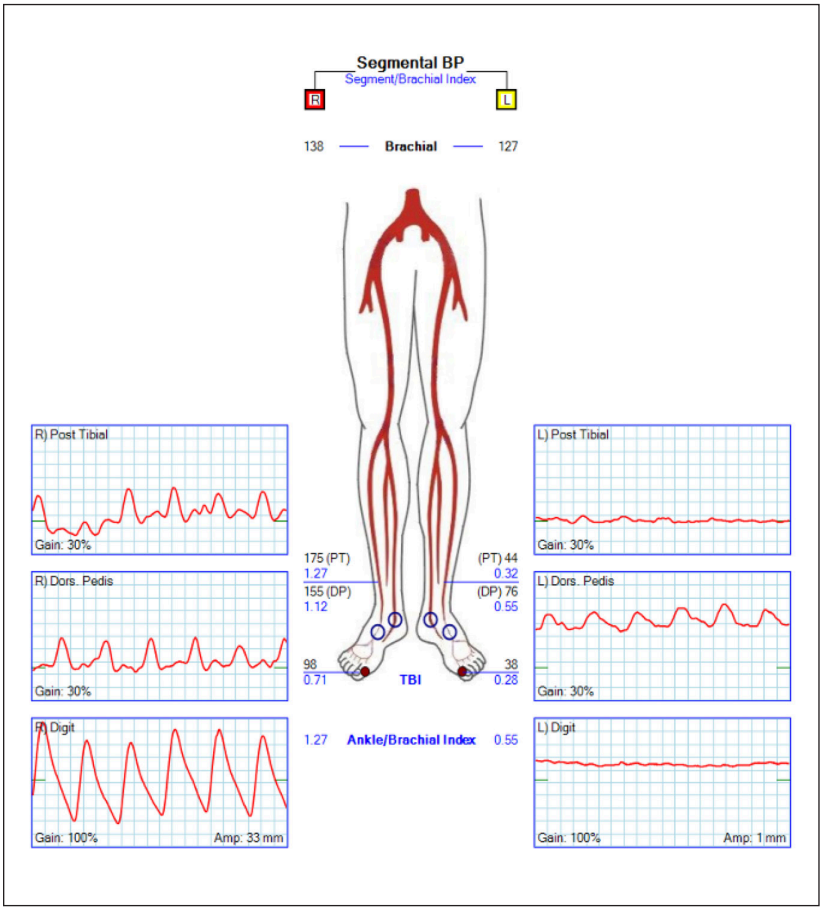

Figure 1. Pulse volume recording panels revealing flat waves for the below-knee vascularity. The PT, although with phasicity, is attenuated and broad based, consistent with an abnormal signal. In totality, this suggests poor inflow and partial flow.

What approach would you take in this patient?

Dr. Adams: Posterior circulation is the main focus given

the wound location. Angiography demonstrates multilevel disease, and therefore, both the SFA and tibial vessels should be treated. Below the knee, I would focus on the PT first and then the peroneal. The peroneal provides direct inline flow to the DP, which can provide dual blood supply to the wound through the pedal loop. I would begin with contralateral retrograde access and attempt to cross the SFA and tibioperoneal (TP) trunk occlusions in an antegrade fashion. If unable, I would access the PT artery and proceed with retrograde lesion crossing, with externalization of wire, and then treat from an antegrade approach.

Dr. Montero-Baker: I would advocate to better risk-stratify patient on the front end. I would seek to better understand the patient's frailty status, renal function (guessing it is somewhat altered, as there are images of CO_2 angiography), presence of an adequate autologous venous conduit (especially in the setting of previous coronary artery bypass grafting) and WIfI (Wound, Ischemia, and foot Infection) classification. My closest guess regarding WIfI stage by the provided description is W1 or W2, I3, and fI0. There's no specific mention of the infection, so I'll suppose a grade 0, but this is unlikely in the setting of a failed primary amputation.

With the above information, an endovascular-first approach would likely still be considered. This patient clearly has a risk of major limb amputation and would benefit from revascularization with aggressive wound care management. Based on noninvasive vascular labs, I would have been very comfortable performing this case by means of an ipsilateral antegrade common femoral artery (CFA) approach and possibly ipsilateral retrograde

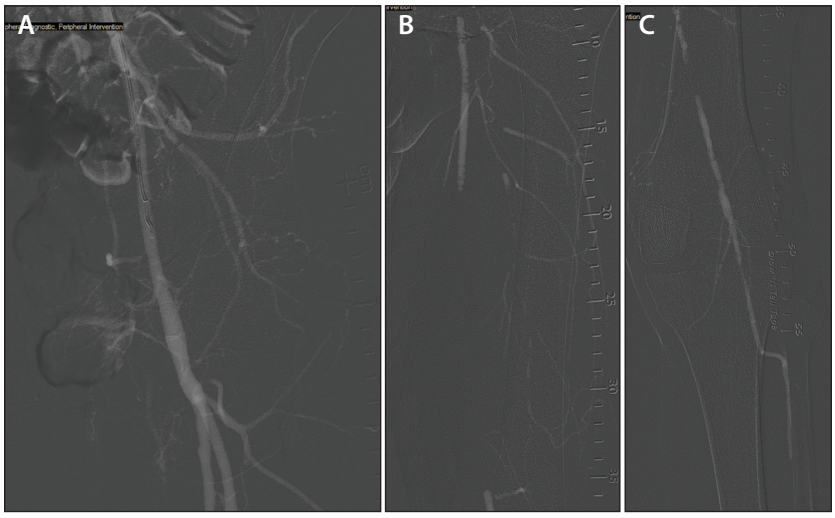

Figure 2. Baseline CO_2 angiogram of the CFA (A), SFA (B), and trifurcation (C).

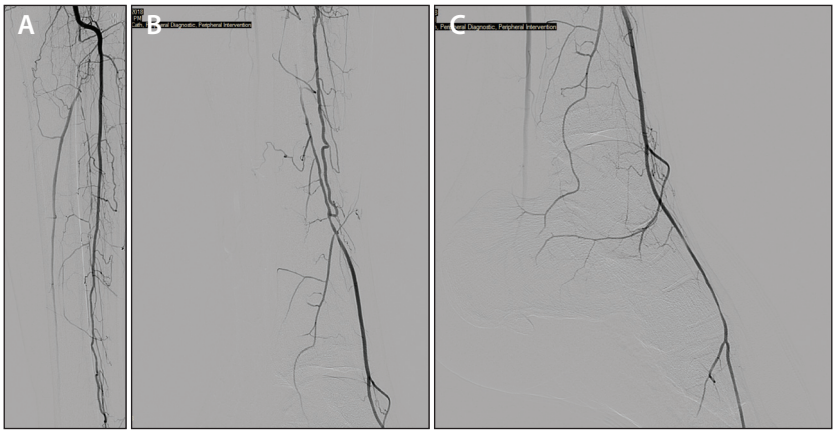

Figure 3. Baseline outflow angiogram of the trifurcation (A), peroneal/DP anomaly (B), and DP and PT arteries (C).

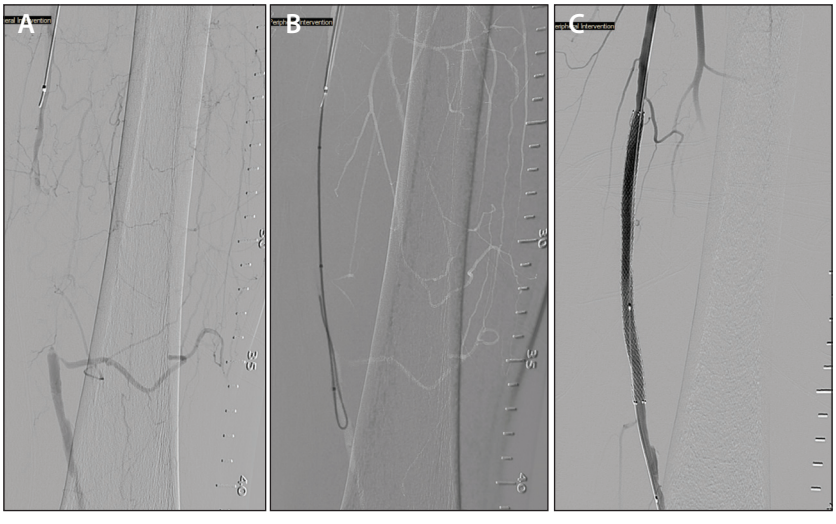

Figure 4. SFA CTO preintervention (A). Wire crossing "knuckle technique" (B). Final angiogram (C).

DP access. A primary bidirectional approach in such extensive anatomy would lead to a safer and faster intervention.

Dr. Tummala: Given this patient's comorbidities, I would opt for an endovascular-first approach. The history, exam findings, and noninvasive testing results suggest that this patient has at least two-level disease. For patients with critical limb ischemia, one must think about the access options that may be needed. As we all know, the most common access options include retrograde from the contralateral groin using a crossover technique, ipsilateral antegrade access, and/or pedal access. Prior to any intervention, my protocol is to obtain a full noninvasive study from the groins to the toes. This allows me to assess for inflow disease, which will help guide my approach.

If I don't have any noninvasive imaging or the testing is focused on the below-the-knee arteries, as in this case, then I will assess the left CFA waveform in the preprocedure area or in the angiosuite. If it's triphasic, then I know there is no hemodynamically significant left-sided inflow disease. I would also assess the left deep femoral artery and proximal SFA in a similar fashion. Assuming these are all normal, then I would feel comfortable using an ipsilateral antegrade approach. If they are not, then a retrograde approach from the contralateral leg is my preference.

In my experience, the antegrade approach gives more pushability, torqueability, a shorter distance to travel for disease below the knee and below the ankle, and the ergonomics are good when fixing either leg in terms of radiation exposure and so on. I typically access the CFA or proximal SFA and place a 6-F sheath as distal as possible in a normal segment of the SFA. This optimizes imaging and allows the use of two guidewire/catheter/balloon systems if needed. The case then proceeds as usual with anticoagulation and the usual guidewires, balloons, stents, and atherectomy as needed.

CASE CONTINUED

We proceed with endovascular therapy. We choose a crossover technique with a 6-F sheath to the contralateral SFA. We then cross the chronic total occlusion (CTO) at the SFA/popliteal artery using a "knuckle technique" (Figure 4). After confirming the nature of the popliteal artery anomaly, for the infrapopliteal CTOs, we first cross the PT into the foot with a V-18 ControlWire guidewire (Boston Scientific Corporation) without difficulty. Then, at the popliteal/AT, we cross similarly with the V-18 ControlWire guidewire into the foot and arch (Figure 5), and a 7- X 120-mm drug-eluting stent (DES; Zilver PTX, Cook Medical) is placed.

The PT is dilated twice with a 4- X 60-mm percutaneous transluminal angioplasty (PTA) balloon, with return of flow to the foot. We then dilate the popliteal artery and AT with a 2- X 220-mm PTA balloon distally and a 4- X 60-mm PTA balloon proximally, with the final residual of 0% in each vessel and flow to the foot (Figure 6).

Did the AT need revascularization?

Dr. Montero-Baker: I'm not quite convinced. It's always tricky to form a solid interventional plan based on the still images provided for this case. That said, this is a Kawarada type IIa arch (arch dependence off the DP artery). This would definitely be my target vessel path. My hesitation to decide on the AT is that there could be an anatomic variant in this patient in which the DP is primarily fed by the

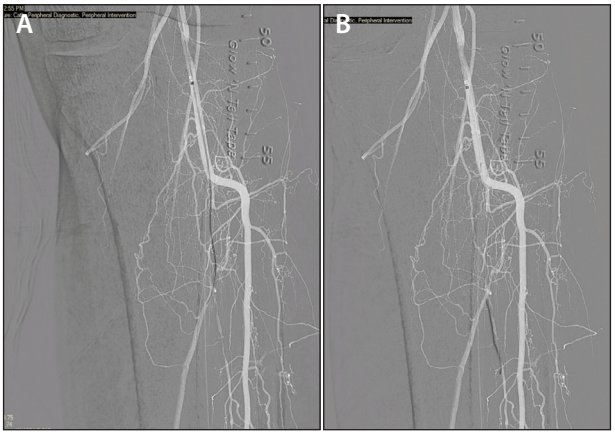

Figure 5. Infrapopliteal intervention: PT recanalization (A) and popliteal artery/AT recanalization (B).

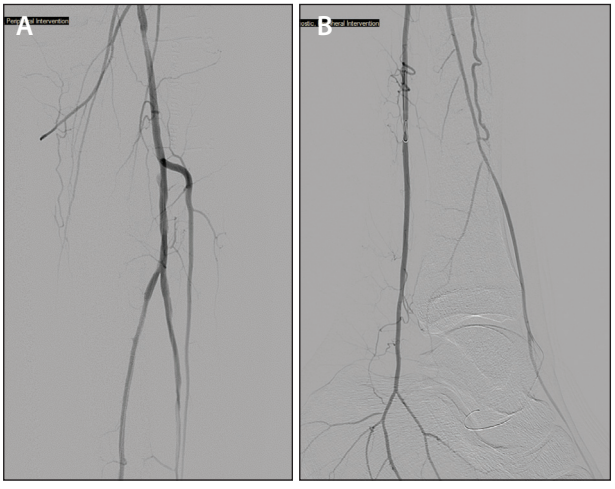

Figure 6. Final outflow in the trifurcation (A) and PT/DP outflow (B).

peroneal artery (or its anterior perforating artery to be more specific).

Dr. Tummala: In this case, the patient has gangrene in the left fourth digit and a nonhealing fifth toe amputation. Therefore, obtaining inline flow to the DP and PT will optimize flow to the fourth and fifth digits via the pedal-plantar loop. Typically, this means opening up the AT and PT to supply the foot. In this patient, the AT artery ends several centimeters above the ankle joint and is not continuous with the DP, so revascularizing it is not needed. Given that the peroneal artery is continuous with the DP, I would revascularize the TP trunk, peroneal artery, and PT, as this will optimize flow to the foot.

Dr. Adams: Knowing that the wounds were located on the fourth and fifth toes, my first priority would be focusing on the posterior circulation. Therefore, optimizing flow to the PT would by my first consideration. Upon discovery of the anomaly, I would have most likely treated the peroneal before the AT, as the peroneal provides flow to the DP. The initial angiogram of the AT shows collaterals to the DP.

For the SFA intervention, was stenting necessary and would you use a DES?

Dr. Adams: Stenting would not be my first-line treatment. I would prefer predilatation followed by drug-coated balloon (DCB) (ie, a leave-nothing-behind strategy). If there was the presence of recoil or dissection, I would then consider a DES. The location of the lesion being above the adductor canal and the absence of calcium also make a DES a good option.

Dr. Tummala: When possible, my algorithm is always to leave nothing behind in the femoropopliteal artery segment. However, there are several treatment options given this patient's scenario and the angiographic findings. When treating this patient, one must take many factors into account, such as the difficulty in crossing the CTO, as well as the length, location (relative to the knee joint and infrapopliteal vessels), and degree of calcification of the CTO in the arterial segment being treated.

In terms of nonstenting options, I believe that most would agree that PTA alone would not provide a durable long-term result. In terms of atherectomy, DEFINITIVE LE showed reasonable results as a standalone therapy.[1] Studies such as REAL PTX and DRASTICO have shown that DCBs with bailout stenting have similar safety and effectiveness as DESs at 12 months in the femoropopliteal segment.[2,3] A DCB would be a good option in this case and we know that DESs do better than DCBs after the first year; therefore, placement of a DES in this situation is another good option.

Given the recent FDA warning regarding paclitaxel, many operators are currently unwilling or unable to use DCBs or DESs in this anatomy. In this situation, options include nitinol stents such as the Supera (Abbott Vascular), Lifestent (BD Interventional), Innova (Boston Scientific Corporation), or stent grafts such as the Viabahn (Gore & Associates), among others, in the femoropopliteal segment.

Dr. Montero-Baker: This is a long occlusion in a patient with high risk of restenosis. I believe antirestenosis-acting devices are a must in this scenario (something that would have been discussed with the patient in the front end, as per the FDA's latest letter regarding this particular issue). I don't personally commit to using a scaffold in all patients based solely on anatomy. My decision matures during the case. How easy was the crossing? Is there a chance we have chronic and acute findings? Did I accomplish intraluminal or subadventitial crossing? What does the intravascular ultrasound show? And regardless of the answers of the previous questions, I'll start with a long scoring balloon, which I tend to very slowly bring up to nominal pressure. Attention to detail in vessel preparation leads to the best long-term results. If I get a good angiographic/intravascular ultrasound response, then I'll err on the side of avoiding a scaffold. If the technical response to the initial angioplasty is not acceptable, I'll resort to a combination of DCB with vasculomimetic spot stenting or DESs.

Was simple PTA the best option for the PT and popliteal artery? Would DES implantation be an option in these locations?

Dr. Adams: PTA is the best option for these lesions. The only other treatment addition I would consider would be a DCB, unless significant dissection was noted, thus warranting use of a scaffold. For the lesion locations, a coronary DES would be the only option due to the diameter restrictions. Although there has been benefit shown for coronary DES in infrapopliteal lesions, I would not choose this as front-line therapy without the presence of significant dissection or recoil after angioplasty.

Dr. Tummala: I think PTA was the best option here given the location and the postangioplasty result. Soon, another option will be DCB for the infrapopliteal

vessels, as it has shown promising results in this territory. In general, my protocol is vessel prep with orbital atherectomy and prolonged PTA. At least one study by Dr. Baumann and his group in Switzerland has shown that approximately 29% of the lumen is lost within 15 minutes after tibial angioplasty.[4] Therefore, accurate balloon sizing for the tibial vessels is very important, as patency rates can be affected. That is why I size all my tibial vessels using either extra- or intravascular ultrasound to obtain an accurate measurement prior to angioplasty. Although there are some data for DES use in the proximal tibial arteries, I only use them in cases of bailout, such as a flow-limiting dissection.

Dr. Montero-Baker: Frankly, I would have not gone after the PT artery, because it has an incomplete arch and the wound per description is not very complicated. Good podiatric reintervention once the flow to the forefoot would have been reestablished would likely lead to wound healing and remission of chronic limb-threatening ischemia. In general terms, long-segment below-the knee interventions in my hands translates to long plain old balloons or long DCBs, depending on the scenario.

For both the SFA and infrapopliteal interventions, would atherectomy with a DCB be an option?

Dr. Tummala: As I previously stated, I do believe that atherectomy followed by DCB is a good option in this case, with stenting only for bailout. This has been shown to achieve good 12-month patency.

Dr. Montero-Baker: From the technical standpoint, most atherectomy devices are not approved to be used in the subadventitial space, so this would preclude use in this particular case, in which I personally feel this would have been highly likely. That said, if one could prove luminal crossing (ie, confirming by intravascular ultrasound), then this could be a fair combination. This combination therapy (debulking and DCB) has proven to have a positive signal in small registries, but data-driven validation should be pursued.

Dr. Adams: Atherectomy is a possible treatment option, but I would place a filter distally, considering that the CTOs may contain soft plaque. I would follow atherectomy with a DCB.

CASE CONCLUSION

Follow-up confirmed wound improvement with stable gangrene and toe loss. However, infection recurred to the left foot 12 months later. The patient did not present for follow-up to undergo repeat angiography and underwent a below-the-knee amputation.

This patient was lost to follow-up to the interventional team and subsequently underwent amputation. What measures do you have in place to help ensure that patients are seen if they are not local, and what policies do you have in place (if any) if they develop complications or issues related to the intervention?

Dr. Adams: All my patients are currently required to follow up 4 to 6 weeks postintervention, either with myself or their referring provider. If a patient is referred, that physician is briefed on procedural outcomes and the discharge plan. If a patient presents with wounds, he or she will be admitted overnight with a consult from wound care prior to discharge, as well as weekly wound care visits to monitor healing or the need for additional revascularization. If the patient is not able to locally maintain weekly wound care visits, wound care providers are contacted within a closer geographic radius to ensure that all wounds are closely monitored to prevent escalation. We are currently investigating telemedicine communication to optimize follow-up.

Dr. Tummala: I see all my patients who have undergone intervention at 1, 3, 6, 9, and 12 months and then every 6 months after the first year. I obtain noninvasive testing at 1 month and then every 6 months postintervention. Some of our patients travel a long distance to see me for limb salvage, and it is difficult for them to return for a variety of reasons, including transportation, time off from work, and cost. For this subgroup of patients, I will see them via teleconsult or have them follow-up with their referring doctor who will obtain the noninvasive testing necessary to ensure good surveillance postintervention. If the patient develops a complication or needs additional intervention, then we have them come back to the office immediately. Unfortunately, regardless of how diligent my team is in contacting patients, some will still be lost to follow-up due to patient noncompliance.

Dr. Montero-Baker: Hardest question thus far of this exercise! I struggle with this every day; I think we all do. One of the most effective tools we've developed to avoid losing patients to follow-up at the Division of Vascular and Endovascular Surgery at Baylor College of Medicine is STEP (Save the Extremity Program). This is a multidisciplinary team developed to prevent major

amputations. On a daily basis, our clinic offers a vascular noninvasive laboratory, wound care specialists, vascular surgeons, podiatric surgeons, and infectious disease physicians. All patients must undergo a standardized workup that includes baseline evaluation of their wounds (documentation with photography), status of vascular health, and vascular/podiatric assessments. Many patients have normal vasculature, in which case the podiatric/wound care team will take charge and determine the plan of care. In cases where the vascular component is critical, the vascular group will lead the initial steps. Coordination and communication are essential, not only between the health care providers, but also with the patients and their support network. Patient navigators are readily available to answer care questions by phone or electronically. We insist on having patients relay their issues and constantly try to maintain direct lines of communication. It's less frequent that you'll lose patients to follow-up when you have a "one-stop shop," avoiding the fragmentation of care.

With how perfect this last paragraph may make the program sound, we still face so many challenges: competitive health care systems attempting to break the established relationship, patients' inability to determine where they should be taken in the setting of emergent care, limited involvement of our team due to prohibitive insurance plans, poor insurance plans with prohibitive copays, poor support networks, inadequate access to transportation, inability to control wound care due to geographic constraints, broken communication systems with referral health care providers, and overall poor patient adherence/engagement.

A nationwide systematic overhaul is desperately needed to attempt to control these variables. "All-in-one" care models should therefore be developed. I firmly believe that the more we can take the care to the patient, the better adherence will be. Home health care agencies could play a very important role in this. They should be expected to be more complex and involved. They should work under the surveillance of multidisciplinary centers of excellence and reimbursement should be driven at all levels by quality-of-care metrics and clinical results. ■

1. McKinsey JF, Zeller T, Rocha-Singh KJ, et al. Lower extremity revascularization using directional atherectomy: 12-month prospective results of the DEFINITIVE LE study. JACC Cardiovasc Interv. 2014;7:923-933.
2. Bausback Y, Wittig T, Schmidt A, et al. Drug-eluting stent versus drug-coated balloon revascularization in patients with femoropopliteal arterial disease. J Am Coll Cardiol. 2019;73:667-679.
3. Liistro F, Angioli P, Porto I, et al. Drug-eluting balloon versus drug-eluting stent for complex femoropopliteal arterial lesions: the DRASTICO study. J Am Coll Cardiol. 2019;74:205-215.
4. Baumann F, Fust J, Engelberger RP, et al. Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia. J Endovasc Ther. 2014;21:44-51.

Lawrence A. Garcia, MD
Section of Interventional Cardiology and Peripheral Interventions
St. Elizabeth's Medical Center
Boston, Massachusetts
lawrence.garcia@steward.org
Disclosures: Advisory panel and research funding from Abbott, Medtronic, Boston Scientific Corporation; equity in CV Ingenuity, Essential Medical, Inc., Syntervention, Inc., Tissue Gen, Transit Medical, Primacea, Inc., Orchestra BioMed, Inc.; founder of Innovation Vascular Partners Consulting, LLC.

George L. Adams, MD, MHS, MBA, FACC, FSCAI
Interventional Cardiology
UNC REX Healthcare
Director Cardiovascular and Peripheral Vascular Research
North Carolina Heart and Vascular Research
Raleigh, North Carolina
george.adams@unchealth.unc.edu
Disclosures: Research and consultant for Cook Medical, Boston Scientific Corporation, Abbott Vascular, Gore & Associates, Philips, and Cardiovascular Systems, Inc.

Miguel Montero-Baker, MD
Associate Clinical Chief of Vascular Surgery
Associate Professor
Michael DeBakey Department of Surgery
Baylor College of Medicine
Houston, Texas
mmontero@bcm.edu
Disclosures: Education/training for Abbott, Bard, Boston Scientific Corporation, Cook Medical, and Philips; advisory board for Abbott, Medtronic, and Bard; research from Bard, Shockwave Medical, Mercator, Boston Scientific Corporation, Euphrates Medical, and Limflo; ownership in Thermopeutics and Profusa.

Srini Tummala, MD
Director of Limb Preservation
Department of Vascular & Interventional Radiology
University of Miami Health System
Miami, Florida
drsrinitummala@gmail.com; @SriniTummala
Disclosures: Course faculty for Abbott; consultant, speaker, and course faculty for BD/Bard Peripheral Vascular; consultant to Boston Scientific Corporation.