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A discussion on lesion access techniques, lowering amputation rates, and device development for below-the-knee interventions.

What are some unique lesion access techniques that you have employed that may be useful to our readers?

In advanced limb salvage procedures, the common femoral artery antegrade stick is the preferred primary access site for the delivery of our peripheral interventional equipment and devices. For tibial lesions that do not have visualized takeoff from the parent vessel, we have adopted the technique of antegrade/retrograde approach via the pedal arch and/or the anterior communicating artery. We are also accessing tibial lesions via direct tibial stick using a 5-F micropuncture kit dilator for initial diagnostic angiography and lesion crossing.

Is a drug-eluting stent–first approach to below-the-knee (BTK) intervention becoming a reality for treating critical limb ischemia? How do you determine your initial approach?

In the majority of limb salvage procedures, drug-eluting stent placement in BTK interventions should not be the first attempted method of treatment in critical limb ischemia. Initially, it is best to avoid stenting of proximal tibials to prevent jailing of other hibernating vessels. Also, there is an unpredictable flow velocity after intervention in the tibial vessels. When there is decreased flow velocity secondary to outflow obstruction, there is a significant increased risk for in-stent thrombosis. On the other hand, once all tibial vessels are defined and stenting of a tibial artery is required to maintain patency, drug-eluting stents are a viable option.

I have developed scoring classification and mapping systems to determine the initial method of treatment for BTK/below-the-ankle lesions. My mapping system is very precise and specific to which tibial vessel is treated first. With the mapping system, I can pinpoint exactly which one of the major tibial vessels is the culprit vessel and/or which branch of the tibial vessel is contributing to the tissue loss or nonhealing ulcer. I have seen cases with two-vessel runoff to the foot where the patient still has a painful nonhealing ulcer. I believe that it is not the number of tibial vessels open to the foot that is the answer for amputation prevention or wound healing. The answer is simply to provide tibial vessel runoff with direct flow to the ischemic BTK or below-the-ankle nonhealing ulcer site.

Tell us about the new standard for amputation at your institution.

We have implemented an amputation prevention program at Metro Health Hospital (Wyoming, MI). All referred patients who are scheduled for amputation are seen within 24 hours of referral. If there is no contraindication, patients will then undergo peripheral angiography with planned intervention within 48 hours. We have found that early revascularization has led to limb preservation in more than 95% of our patients who were previously scheduled for amputation.

Referring physicians are just becoming aware of the new technology and interventional techniques that are available to help this population. Over the past year, we started to receive more and more patients that were already scheduled for amputation or patients that were told that they did not have any other option. I strongly believe that many patients scheduled for amputations can still have their limbs preserved.

What are the key aspects of building and maintaining a successful multidisciplinary peripheral vascular disease (PVD) program?

An important key to building a successful PVD program is partnering with and educating our referring physicians, which include primary care providers and podiatrists. We have implemented a program in which peripheral interventionists travel to physicians' offices, educate them on PVD screening, and share with them the latest available treatment options. After our initial visit, we maintain communication with referring physicians and provide them with patient outcomes after the procedure. Furthermore, to educate the public on PVD, we have also scheduled outreach community screening programs.

Our PVD program includes collaboration among interventional radiology, cardiology, vascular surgery, and our wound healing center to evaluate the best available treatment for each patient. To ensure the success of our PVD program at Metro Health Hospital, we are continuously collecting data and monitoring our outcomes. We are currently performing multiple internal retrospective PVD studies.

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Most recently, we participated in the CALCIUM 360° trial, and we are also currently involved in additional ongoing trials.

Newer devices are allowing for higher rates of limb salvage, but what is still needed to continue to improve patient outcomes?

Limb salvage outcomes can be improved by following these steps. First, we need to educate and train physicians on the use of new interventional devices in conjunction with education on the pathophysiology of tibial pedal disease. Second, we need to continue providing patient education on risk factor modification including smoking cessation, diet, and exercise. As care providers, we must be involved directly with our patients to help them understand their disease, its urgency, and the need for change of risk factors. Finally, we need more randomized, prospective, comparative research trials to evaluate and determine the best therapeutic options.

What percentage of your patients return for secondary BTK interventions? Are you able to revascularize the reoccluded vessels, or does the likelihood of amputation increase with each intervention?

We are in the process of analyzing these data. Anecdotally, we are not seeing an increased risk for amputation with secondary BTK interventions. In fact, we are seeing a decrease in the number of amputations in this population, as well. The decrease in the amputation rate is due to our ability to provide two-vessel runoff in the primary intervention.

What devices are you currently developing that you are most excited about?

I am cofounder of TDJAM Medical Technologies, LLC with Dr. Tony Das. One of the most exciting devices that we are currently developing is a chronic total occlusion device. This device has the ability to be used anywhere in the peripheral vascular tree. It is unique in that it can center itself and precisely enter a chronic total occlusion cap. This is a device that can be used after failure of other crossing devices including failed wire catheter technique, which is the most commonly used technique when operators advance a wire to the chronic total occlusion. A second device currently under development is a peripheral vascular interventional sheath that allows perfusion of the distal vessels while treating the target vessel. The sheath can also easily traverse vessels with severe tortuosity and deliver devices to the target lesions.

We are working on many other new devices at TDJAM LLC. All of our innovative devices are developed to address an unmet need. Our hope is that future innovations will continue to lead us to eliminating amputations due to peripheral vascular disease. ■