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CLI Care in the COVID-19 Era: An Evolving Landscape

An expert panel offers their insights and strategies for providing CLI care while navigating the COVID-19 pandemic.

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We are all aware of the unprecedented challenge that the global COVID-19 pandemic has provided for our communities, our patients, and health care providers. We face a rapidly evolving situation. My co-moderator, Dr. Ehrin Armstrong, and I are grateful to glean insights from our assembled panel of key clinicians who offer their perspectives on how to best optimize care for chronic limb-threatening ischemia (CLTI) under our current shared circumstance. We hope you find this discussion informative. We are all in this together.

– Dr. Andrew Holden

Dr. Armstrong: In Colorado, the concentration of COVID-19 patients was centered initially in ski resorts and then quickly spread to the Denver area. John, you are in the epicenter of the pandemic in the United States. How has COVID-19 impacted CLTI treatment in your area?

Dr. Rundback: Our hospitals in New Jersey have been dramatically impacted by COVID-19. Because of a need to preserve resources, elective procedures are not being performed. In addition, because the hospitals we work in are "in the news," patients don't want to go to them for fear of exposure to the novel coronavirus. We are medically managing all patients with claudication and borderline ischemic pain and delaying consults until the pandemic lessens. However, all patients are called either for formal telemedicine evaluation or, at the very least, to triage the severity of disease and determine if an in-person evaluation can wait. For borderline cases, we call the patients weekly to make sure they are stable.

Dr. Armstrong: Thanks, John for your interesting observations and strategies. Jay, how have you been managing CLTI patients in Florida?

Dr. Mathews: The COVID-19 pandemic has had many impacts, both seen and unforeseen, within our community. As expected, elective endovascular procedures have been halted, but we have also seen a significant decline in urgent/emergent procedures. This could reflect an understandable unwillingness on the part of patients who continue to self-isolate at home to come in for treatments, including those with CLTI. We have also seen impacts on the supply chain side of performing interventions. Vendors who would make sure that we had adequate inventory are no longer around to ensure that their product portfolio is available. It is challenging to be in the middle of a complex CLTI case and request a routine device only to find out it is unavailable.

Dr. Armstrong: That sounds challenging, Jay. Bryan, how has the pandemic affected your community?

Dr. Fisher: In middle Tennessee, this global pandemic has exacerbated the impact of CLTI. Unfortunately, many patients were already presenting late, with modifiable risk factors not being controlled. Although the existing economic and social disparities have increased the gap, the rate-limiting step in most cases is the patient's lack of desire to have procedures done in the hospital due to a perceived increased risk of getting the virus and potentially dying from it.

Dr. Armstrong: Thanks, Bryan. Scott, what unique challenges are you facing in Arizona?

Dr. Brannan: Our mission population is Native American critical limb ischemia (CLI) patients. The COVID-19 pandemic has hit the Navajo Reservation particularly hard, with approximately 1,200 cases and more than 40 deaths as of Spring 2020. The case fatality rate for the Navajo Nation has been 10 times higher than the rest of the United States. For other tribes, tribal members are often reluctant to leave the reservation because the incidence of infection on their reservations (Apache and Pima) are much lower. This is a microcosm of what we are seeing in the larger population in general. Many patients are more afraid of COVID-19 than they are of CLI.

Dr. Armstrong: Thank you, Scott. We know COVID-19 is a global problem. Michael, what is the situation for CLTI patients in Germany?

Dr. Lichtenberg: This pandemic has had a significant impact on our daily routine within our vascular center. As in other centers, many elective patients cancelled their appointments and procedure dates because of the virus. The main reason cited was the fear of high infection risk within a clinic environment. Many patients also assumed that all hospitals were occupied by patients with COVID-19, with no capacity for other indications. As many other specialized vascular centers

in the area faced a total shutdown, we experienced an overflow of CLTI patients from areas outside of our normal referral pathways. As a consequence, we had to adapt and increase our working time within the labs to cope with this challenge.

Dr. Holden: Thanks, Michael. All of you report that patients are cancelling procedures and staying home. Ted, what are your thoughts on how to stay in contact with your patients?

Dr. Gifford: What is evident, now more than ever, is the importance of building a framework for clear and effective communication with our patients so that we can stay up to date should their clinical condition change while they are awaiting revascularization. Many of our patients are reliant on their regular surveillance visits, visiting nurses for wound care, and prompt specialty consultation for urgent referrals. As we deal with the COVID-19 crisis, we have to find a way to make sure that our patients know that we are thinking about them and that we are making plans to address their needs as soon as it is safe to do so. Telehealth via video conferencing has played a major role in maintaining that connection with the patients in our practice.

For patients with peripheral artery disease but without CLTI, we are reaching out through local news outlets to promote awareness and offer guidance about maintaining vascular health. We want to encourage our patients with claudication who are isolated at home to stay active and to try to go for daily walks. We also recognize the effect this crisis may have on our patients' efforts at smoking cessation and similarly are trying to support their efforts to stay tobacco-free.

Dr. Holden: Good insight for us all, Ted. Michael, you have some additional thoughts?

Dr. Lichtenberg: Yes, thank you. The most important mistake from the beginning of the crisis was not to educate patients on the importance of self-care for their chronic cardiovascular diseases and, if indicated, to immediately contact their vascular specialists. In Germany, the German Angiology Society recently started a media campaign, "Don't let the virus be responsible for your amputation." We hope that this campaign will help prevent a limb-threatening crisis from taking place at the same time as the pandemic.

Dr. Holden: That's a very interesting initiative. At Auckland Hospital here in New Zealand, we also limited our treatment indications to acute limb ischemia, rest pain, and tissue loss and used telephone calls as well as video conferencing to communicate with patients. Another important question we face is which patients are still being treated during this crisis?

Dr. Mathews: I currently serve as the Cath Lab Director for Manatee Memorial Hospital. Together with colleagues from other disciplines, we drafted our policy regarding procedures to be performed during the COVID-19 pandemic. We have allowed CLTI (Rutherford class 4–6) and, of course, our acute limb cases. Some colleagues at other centers in Florida have been forced to limit cases to Rutherford class 6 patients, which we thought was too extreme. Of course, our policies are subject to change depending on availability of personal protective equipment (PPE), which remain in short supply.

Dr. Gifford: For the most part, we have limited our treatment to patients who come to the hospital with acute limb ischemia or who present urgently to the emergency department (ED) with severe CLTI. If a patient comes into the ED with severe digital or forefoot gangrene or if the patency of their bypass is in imminent danger, we have continued to offer them interventions. Throughout this time of uncertainty, we have advised patients and their families that we may reach a point where resources are so precious that the only procedures being performed are truly life-threatening.

Dr. Lichtenberg: We are dealing with significantly sicker patients including severe CLI infection and no-option situations. We have never faced such a high number of CLI-associated sepsis patients needing intensive care unit support. Many of these emergency patients demonstrated poorly controlled diabetes in the weeks preceding their arrival and showed signs of severe dehydration.

Dr. Armstrong: Thanks for those commentaries. The current policy to triage patients and reserve treatment for those most at risk means some patients are not receiving treatment, at least in the short term. What are the most important implications of these patients not receiving treatment?

Dr. Rundback: CLI is non-elective. We have had two patients with CLI who refused revascularization and wound care for fear of COVID-19 and ended up with gas gangrene and major amputation. There are 300 to 500 amputations each day in the United States, and management by dedicated vascular specialists and CLI teams can lower this by 60% to 80%. We need to urge primary care physicians, podiatrists, as well as high-risk patients that ischemic rest pain and nonhealing lower extremity wounds require urgent and immediate attention.

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Dr. Mathews: I am concerned for many of these patients who have been deferred or "denied" treatment. Many of these patients who have a lower Rutherford class will later present with a far more severe status, which could have been avoided. These are patients who are not exercising and may have limited mobility.

Dr. Fisher: One obvious implication is not identifying patients with CLTI. Based on the literature, we know that patients with mild claudication are at very low risk for limb loss and the increased risk at Rutherford class 3 isn't staggering. However, patients with rest pain and/or wounds are at high risk. The implications of minor and major amputations are potentially devastating. Compound this with a global pandemic and resultant economic hardships and you have the dire and unfortunate circumstances that many of our patients go on to endure.

Dr. Brannan: Over time, cases will get harder to treat. Patency rates decrease. The absence of treatment can lead to amputation. The difference in terms of procedural outcome durability between a 90% stenosis versus a 1-month-old chronic total occlusion is astronomical. By delaying treatment for severe Rutherford class 3 disease, we are producing difficult to treat and rapidly reoccluding Rutherford class 4 disease.

Dr. Armstrong: Given the challenging situation, how can CLTI care and outcomes be optimized?

Dr. Rundback: We remain diligent in our outpatient practice, performing extensive distal tibial and pedal arch interventions, digital artery interventions, rendezvous procedures, multivessel revascularization, and distal deep venous arterialization, when needed. Our need for emergency transfer to a hospital has been and remains almost nonexistent. To assure this, we use some unique strategies. We address occluded segments before working on stenotic segments to establish more overall foot flow and avoid unplanned occlusions and clinical worsening. We call this strategy "protected intervention." We also believe in targeted and multivessel interventions whenever feasible to allow the greatest chance for clinical resolution and lower the chance for acute decompensation. Wherever procedures are performed, we are cognizant that we must avoid hospital admission for these patients at this time. We are also using more low-molecular-weight heparin at discharge; again, this is with the goal of preventing acute thrombosis. The recent VOYAGER data have also impacted our decision to prescribe more rivaroxaban and aspirin than we did before.

Dr. Gifford: If you're going to perform a procedure on an urgent or emergent patient, ideally favor something that may help the patient recover faster. In our practice, we have looked to some of the sister hospitals in our network if we need to do a short endovascular procedure as opposed to bringing the patient through our main tertiary center. Similarly, if you have access to an outpatient-based lab, that may be a better option to avoid potential COVID-19 exposure for both patients and health care workers. We want to avoid, whenever possible, a discharge to a nursing home after revascularization. Given the negative effect of COVID-19 on nursing home residents around the country, if an endovascular therapy may offer a shorter postoperative recovery for our patients, now is the time to favor that approach.

Dr. Lichtenberg: I suggest to be as effective as possible with revascularization treatment strategies to avoid prolonged hospitalization. Our mandate is not only to revascularize but also to take care of long-term patency. My personal strategy is to use an aggressive lesion debulking strategy especially in calcified long lesions followed by prolonged drug-coated balloon (DCB) angioplasty to avoid dissection and recoil.

Dr. Fisher: Each intervention has its own inherent risks. For this reason, we must place a greater emphasis on identifying patients at risk and work aggressively to control their modifiable risk factors. This starts with smoking cessation and includes addressing hypertension and hyperlipidemia and controlling blood glucose levels to ensure adequate wound healing in patients with tissue loss.

Dr. Holden: Thank you all for those perspectives. All of you have emphasized the importance of optimizing acute results in CLTI intervention, particularly during this pandemic. We are seeing some new treatment options, including the recently FDA-approved Tack Endovascular System® for a below-the-knee (BTK) application. So finally, which tools do you currently rely on to treat CLTI?

Dr. Fisher: The tools and options available for treating CLTI are exciting and continue to evolve. Drug-coated technology has been a game changer; however, enthusiasm has been somewhat tempered for now due to a concern of increased mortality risk. There is a strong argument that the benefit of vessel patency and perfusion to an ischemic tissue bed outweighs the, albeit very small, risk of death. The application of drug-eluting self-expanding stents BTK also has the potential to

address acute and chronic remodeling. Off-label balloon-expandable coronary drug-eluting stents have also been successfully applied in the proximal tibials where recoil can be addressed without a significant risk of crushing due to external forces. Finally, low-profile scaffolding BTK is one of the most exciting new modalities aimed at addressing dissection that can be clearly seen with intravascular ultrasound (IVUS). I am excited to see the new technology that continues to evolve in the space and look forward to applications below the ankle that represent the final frontier in the treatment of complex CLTI.

Dr. Rundback: The tools are the same as before, with the exception that new enrollment in our cell-based therapy trials is currently suspended. We continue to use the same devices we did before the pandemic, including laser atherectomy, orbital atherectomy, percutaneous transluminal angioplasty, DCBs, Supera peripheral stents (Abbott), and Tack® implants (Intact Vascular, Inc.) for dissection repair. Additionally, we use IVUS guidance for vessel sizing and endpoint evaluation, small-vessel microcatheters and balloons, and specialty wires as appropriate and individualized within our algorithm for each patient.

Dr. Brannan: Low-risk transportation to and from the procedures with PPE for both the driver and passenger has been crucial. Also, the Tack device for multifocal dissections helps reduce the number of visits required to fully treat CLTI and decrease frequency of reinterventions.

Dr. Mathews: Our toolbox for above-the-knee (ATK) disease is vast, but our BTK options remain limited. For ATK disease, I tend to do a lot of atherectomy, plaque scoring, and DCB therapy, with focal scaffolding using the Tack Endovascular System® (Intact Vascular, Inc.) for dissection or drug-eluting stents for areas with severe recoil. IVUS is very helpful in guiding this algorithm.

For BTK disease, I also use a lot of atherectomy and angioplasty. IVUS is an even more important tool for BTK CLTI patients. Chronic undersizing is a common problem in BTK interventions, which may impact outcomes. We also continue to enroll in several BTK technology trials despite the COVID-19 pandemic, as these include the CLTI population.

I look forward to BTK scaffolding options such as the recently approved Tack system for BTK arteries, which showed impressive results in the TOBA II BTK study. Despite the constraints of operating during a pandemic, I welcome any new technologies that can optimize outcomes and make treating CLTI patients even better.

Dr. Armstrong: We thank you all for taking time to discuss this important topic with us. Dr. Holden and I hope the readers have found this as interesting and educational as we have. ■