PANEL DISCUSSION

CLTI: What's Your PLAN?

Perspectives on chronic limb-threatening disease management approaches, including classification systems, communication gaps, and the role of the PLAN (patient risk, limb severity, anatomic complexity) concept.

With Tony Das, MD, FACC; Kumar Madassery, MD, FSIR; and Leigh Ann O'Banion, MD

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What current classification systems are you using for chronic limb-threatening ischemia (CLTI), and why?

Dr. Das: The simplest and oldest system with the most familiarity to vascular and nonvascular internal medicine clinicians is the Rutherford classification system. We use this in clinical trials and to document the indications for vascular interventions. However, the wound, ischemia, and foot infection (WIfI) classification system is more widely used in the vascular community and especially when collaborating with various specialties, including wound care, podiatry, interventional cardiology, and vascular surgery team members, in a multidisciplinary program. I tend to use GLASS (Global Limb Anatomic Staging System) the least in CLTI patients. However, GLASS does consider wound presence, severity of ischemia, foot infection, and presence of tissue loss or gangrene as well.

Dr. Madassery: In order to effectively stratify patients, communicate with colleagues efficiently, and track and monitor outcomes for internal and external review/studies, classifications are necessary. They also help us effectively communicate patient status, reasoning for considering treatment, and monitoring of disease progression/outcomes. For CLTI, I use the Rutherford and WIfI systems. Currently, these two are the best tools we have to (1) classify patients with CLTI into a category and degree of disease and (2) incorporate outcomes-related data for staging, treatment, and expectation management. Other more specific subcategory classifications are sometimes used for education, such as the medial arterial calcification score.

Dr. O'Banion: In 2019, Conte et al published the Global Vascular Guidelines (GVG) on management of CLTI, not only setting the stage for optimal comprehensive classification of patients with CLTI but also stressing the multidisciplinary nature and patient-centered approach to this unique population.[1] Classification systems have existed in medicine for decades, and this was a much-needed shift for physicians treating CLTI to adopt a systematic approach to our patients using the WIfI, GLASS, and Society for Vascular Surgery Vascular Quality Initiative (SVS VQI) risk calculators, all of which aid in education and decision-making.

Are there particular components of classification that you find more important than others?

Dr. Madassery: I think many of us CLTI operators have realized that we still have not come up with a perfect system of classification; however, by combining the current systems and adding additional decision tree ideas—such as target artery pathway (TAP), angiographosome, woundosome, and GLASS—we may have a better approach to nonsubjective endpoints. Yet, this is still not a complete system for all of us to be in unison.

What matters to me is a way to easily stratify all major factors in a CLTI patient—namely, related comorbidities, functional status (like the Eastern Cooperative Oncology Group [ECOG] status in cancer), level of disease, outflow vasculature pattern/anatomy, and viable options. This seems well established for cancer patients, but despite CLTI having often worse mortality rates than most cancers, we have not accomplished similar systems.

Dr. O'Banion: I believe all three components of the GVG have their own unique role in approaching CLTI patients. The SVS VQI risk calculator allows to quickly evaluate a patient's risk, particularly in those with advanced CLTI where time to revascularization is critical. GLASS now replaces the aged TransAtlantic Inter-Society Consensus classification and gives us an improved classification system to identify the TAP to provide optimal flow to the foot.

However, the most important classification in my mind is WIfI. CLTI patients are most often of a socioeconomically disadvantaged, health-illiterate background. This leaves them vulnerable and often ignorant to the complexities of their disease. Although many patients may not understand risk percentages and the nuances of revascularization, by utilizing WIfI and the visual color graphs, all can understand that "green is good" and "red is bad." Having visual tools to aid in patient-centered decision-making is key, and WIfI allows this while also providing high-level scientific-based prognostic data individualized to each patient.

Dr. Das: The most important part of classification systems is the ability to document and follow wound size, depth, and tissue loss over time, and this is best performed with the WIfI classification. Second to this is the ischemia component that considers ankle pressure, toe pressure, and presence of noncompressible vessels, which are important for detailing clarity of describing a wound.

How do these classification systems streamline your management of patients with CLTI?

Dr. O'Banion: There is ample evidence-based medicine to suggest that reduction in care variation improves outcomes. Consistent use of the GVG in a systematic approach certainly accomplishes this. Just as in cancer patients, we can risk stratify and stage our CLTI patients in a globally accepted language so that there is consistency among all disciplines involved in care for the patient. Using these classifications also creates a template for discussion with patients to optimize their understanding of the disease and decrease the anxiety around being faced with a limb-threatening disease process.

Dr. Madassery: In my planning/management for a CLTI patient, I currently use the Rutherford and WIfI systems along with my decision tree based on anatomy, functional status, high-level risk factors, and available options. The problem is the streamlining of these four components, based on my anecdotal experience and various multidisciplinary and "multi-friend" discussions.

Dr. Das: They allow the various stakeholders to communicate in a language that establishes the process for interdisciplinary referral. Plainly, it identifies when a patient is healing and when a patient is deteriorating in smaller increments than the Rutherford or other less specific systems.

Do you think any treatment options are missed with current classification systems?

Dr. Das: The more specific a wound and the arterial disease morphology—including disease severity, occlusion length, presence of collaterals, and tissue loss—the more revascularization options can be considered. For example, presence of distal tibial or arch vessels that can be accessed with micropuncture techniques for retrograde tibial interventions are missed as options when less detail-oriented classifications like Rutherford and WIfI are used as opposed to GLASS. Now with deep vein arterialization (DVA), the presence of patent tibial

vessels becomes less indicative of successful treatment, and the current classification systems may not have proper parameters to consider this procedure for "no-option" patients.

Dr. Madassery: We have not yet figured out how to incorporate specific wound care options, novel approaches such as DVA and spinal cord stimulation, and a patient's existing detailed vascular anatomy with relevant treatment options. It will likely be very difficult to encompass all of these issues in a single system, but it may be beneficial to explore this.

Dr. O'Banion: As technology emerges, we are faced with a full and ever-growing CLTI toolbox. It is imperative to successfully pushing the limits of revascularization that we do more work to understand the role DVA plays in the "no-option patient" and how to accurately and consistently identify these patients using these classification systems. Another major tool yet to have a permanent place in these classifications is pedal acceleration time (PAT). I truly believe this tool will be at the forefront of perfusion measurement, particularly in patients with heavily calcified vessels and prior minor amputations. Incorporating PAT into the ischemia subset of WIfI will be a critical next step in refining the staging system.

Are there any communication gaps between your team and others in the multidisciplinary network you work within, from diagnosis and referral through treatment and ultimately follow-up?

Dr. Das: Communication gaps are often due to patient follow-up not being frequent enough. The CLTI patient can have minor tissue loss rapidly progress to major tissue loss within days. If the patient cannot visualize their wound or feel the wound, such as in diabetic foot ulcers or debilitated patients, the urgency of repeat revascularization can miss the window of opportunity for limb preservation.

Dr. O'Banion: CLTI is a lifelong diagnosis requiring long-term multidisciplinary follow-up. In similar scenarios in medicine, such as cancer, patients are afforded nurse navigators and an entire health system dedicated to ensuring they understand their disease and treatment plan and have access to follow-up. Hospital systems are behind in validating that need and supporting similar programs for patients with advanced vascular disease. Additionally, we need to continue to refine patient-facing materials that will allow improved understanding, as eliminating health illiteracy surrounding peripheral artery disease and CLTI will be critical to optimizing patient outcomes. We are heading in the right direction, but we have a lot of work to do!

Dr. Madassery: I think the hardest aspect is coordinating care among team members, especially if your patient was referred to you from outside your practice/institution. Even within the same institution, having a truly collaborative team without exclusivity is not the norm. We need everyone to understand the same CLTI language, be open to discussions, and be able to quickly discuss matters, rather than the prolonged processes it often takes to have consensus/discussions. For those of us in venous thromboembolism, we have well-established pulmonary embolism response teams, and from the moment of diagnosis, we can make a joint multidisciplinary discussion within a few minutes. Clearly, this is not the same for CLTI, but we need to understand and utilize these, as well as tumor board models, into limb preservation.

Patient navigators and nursing teams are crucial in these tumor board-style models, which often take on second- and third-opinion cases relatively expeditiously. I think this can and should happen in CLTI. We need patient-centered collaborative limb preservation boards that regularly make quality improvements and interactive treatment plans.

Effective communication of patient status needs to be universalized, even outside of vascular specialists, to ensure that all secondary factors for a patient can be addressed and monitored.

Finally, what is your PLAN (patient risk, limb severity, anatomic complexity) when managing patients with CLTI?

Dr. O'Banion: In any patient with CLTI, there are several critical goals that go beyond successful anatomic revascularization: relief of pain in patients with ischemic rest pain, successful long-term healing of foot wounds while simultaneously preserving functional limb, and, last but not least, accomplishing all this while minimizing cardiovascular events in these high-risk patients. It is also important to keep in mind that not all patients are candidates for revascularization. One must have a mindful, systematic, and consistent approach and carefully consider each patient individually, as no two cases are alike. With PLAN, this can be quickly and easily accomplished. Additionally, I cannot stress enough the critical nature of multidisciplinary care in CLTI. When pushing the limits of limb salvage, it may be my personal bias, but I truly believe a team "toe-and-flow" approach is key to success.

First and foremost, any patient presenting with CLTI should undergo staging with WIfI, just as we would stage

anyone presenting with cancer. This allows for standardized communication of disease severity across the disciplines caring for the patient. Wound classification, degree of ischemia, and presence of infection can all be assessed and documented on the first visit; this sets the stage for case planning and establishes a baseline for which all future visits can be measured against. As mentioned before, WIfI also allows ease of patient communication with color-coded graphics that provide a patient-facing tool to improve understanding of CLTI.

Patient risk is key to informed decision-making. The SVS VQI risk calculator allows me to identify frail patients or those with higher cardiovascular risk who should be favored for an endovascular-first approach. This also gives an objective measurement to discuss with patients when deciding which approach is most appropriate.

Finally, a comprehensive understanding of the anatomic complexity of disease is key to developing a plan for optimal revascularization. With use of the GLASS staging system, one is now able to define a TAP that best allows for pulsatile inflow to the foot, which these patients require given their advanced disease state. I believe that availability of a vein conduit also falls into this category, as presence of a suitable autologous vein is a major factor when deciding on an open- or endovascular-first approach.

The GVG revolutionized how we approach CLTI and aided in providing a standardized approach to developing a PLAN for successful limb salvage in our patients. As surgeons and scientists, we must continue to refine, add to, and develop these guidelines to aid in optimizing the patient experience and improving outcomes.

Dr. Das: My plan usually starts with assessing wound severity and feasibility of the anatomy for revascularization, using a combination of physical examination of the wound, arterial duplex and CTA of the anatomy, and digital subtraction angiography, which allows for a more complete assessment of accessible distal tibial vessels and the completeness, or lack thereof, of the pedal arch. Once I have these issues assessed properly, we can give the patient a multidisciplinary recommendation for wound healing or amputation prevention.

Dr. Madassery: I think the PLAN model developed by the GVG has merit and can help some of these concerns raised above, and we need more understanding of true risk estimation tools. This is honestly hard to employ with so many varying practice patterns, operator experience, availability of advanced tools and techniques, difference in wound care services and access, and even geographic variations.

I try to stratify patients based on presenting primary symptoms (wound vs pain), assess vascular status, determine the patient care stakeholders (other physicians, family, etc), and then come up with a plan, depending on whether patient has already had diagnostic imaging. Many of my patients are second or third opinions or go directly for DVA evaluation; however, there is still a large volume of primary CLTI patients. Each patient must be assessed wholly, and their overall ECOG-type status has relevance. As a wound care practitioner, I evaluate the wound myself when feasible to get a better idea of potential options and expectations. I like to talk to those helping manage the wounds when possible and get a mutual understanding, which helps with outreach/education.

Based on noninvasive imaging, Rutherford and WIfI classification, and wound care status, I then plan for angiography and revascularization if appropriate, with or without vein mapping depending on their factors. I try to go for DVA after I feel I've exhausted an arterial revascularization attempt. If the patient is nonambulatory, I have a lengthy discussion with the patient and family that aggressive revascularizations may not be in their best interest, and this is often hard for them to hear. However, this discussion is necessary. Finally, I try to address their CLTI comorbidities by evaluating their diabetes, smoking, protein deficits, medical therapy, and possible infection (chronic) statuses and reach out to colleagues to work on these issues together. I often find that many of their risk factors are not optimized, which can be difficult in this patient population but often is as important as a good revascularization.

This takes considerable time for each patient, but we have to continue to find efficient systems to encompass all relevant issues for patients with CLTI so we can more easily deliver the care these complex patients require. ■

1. Conte MS, Bradbury AW, Kolh P, et al; GVG Writing Group. Global vascular guidelines on the management of chronic limb-threatening ischemia. J Vasc Surg. 2019;69:3S-125S.e40. Published correction appears in J Vasc Surg. 2019;70:662. doi: 10.1016/j.jvs.2019.02.016

Disclosures
Dr. Das: Consultant to REVA Medical, Cordis, and Boston Scientific Corporation.
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